

***Special Project Waiver Application:***  
**Field Transfusion Paramedic**

Version 2: Updated 5/24/23



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**Goal:**

To make LTOWB available to patients in the field within 30 minutes from point of injury.

This project will fill a gap in prehospital trauma care and will enhance STP 4.5 which at this time is limited to bleeding control, large bore IV access, permissive hypotension, the administration of Tranexamic Acid, and rapid transport to definitive care. During transport the continued loss of blood results in hemodynamic instability and ischemia to critical organs resulting in the lethal triad of acidosis, coagulopathy, and hypothermia. Maintaining perfusion with crystalloids does little to curb morbidity and mortality. This gap can be filled with the addition of low-titer group O whole blood (LTOWB) in the field.

This will affect a population of patients within 20 cities and towns in the Norfolk County Region south of Boston along the route 95 and 128 corridor. Authorization will be limited to a select group of paramedics to promote a higher level of experience and skill retention. Initial training will involve up to 14 paramedics in 2 communities who will respond as a shared resource to participating cities and towns.

This joint project will involve affiliate medical directors: Michael Valkanas, MD, Norwood Hospital and Dan Muse MD, Brockton hospital along with Assistant Professor of surgery Crisanto Torres, MD, MPH, Boston Medical center, Trauma Surgery and Critical care with support from Boston Medical Center's Blood Bank.

The purpose of this project is to deliver lifesaving trauma care within 30 minutes of point of injury. This has already become the standard of care within the trauma bay and forward reaching EMS systems around the country. The ultimate goal is to decrease morbidity, mortality and the need for massive transfusions during in patient care. We intend to introduce to Massachusetts the first advancement in life saving prehospital trauma care since the inception of paramedics in the 1970s.

**Background/Nature of the project:**

Trauma is the leading cause of death in ages 45 and younger in the United States-yet up to 20% of trauma deaths are potentially survivable.<sup>1</sup> Despite advances in trauma care, hemorrhage remains the leading cause of preventable death for trauma patients. Aside from surgical intervention, these deaths are best mitigated through early hemorrhage control with tourniquets, hemostatic dressings, and aggressive approach to damage control resuscitation.<sup>2</sup> The treatment of hemorrhagic shock through resuscitative efforts remains a mainstay of care until definitive management is obtained.<sup>3</sup> Due to the time sensitive nature, ideal treatment and resuscitation would entail the use of a blood product

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<sup>1</sup> Christa A. L. Arefieva, MS, MSIV. "The Use of Low Titer Group O Whole Blood in Emergency Medicine." EM Resident. <https://emresident/article/group-o-whole-blood>.

<sup>2</sup> Christa A. L. Arefieva, MS, MSIV. "The Use of Low Titer Group O Whole Blood in Emergency Medicine." EM Resident. <https://emresident/article/group-o-whole-blood>.

<sup>3</sup> Braverman, Maxwell. "Prehospital Whole Blood Reduces Early Mortality In Patients With Hemorrhagic Shock." Transfusion: Supplemental Article (March 2021): S16

containing all the essential components closest to the time of injury, where prevention or reversal of the devastating downstream consequences of shock and coagulopathy occurs.<sup>4</sup>

Originally, crystalloid was believed to improve outcomes in hemorrhaging patients, recent evidence has pointed toward worse outcomes for patients who receive crystalloid in addition to blood transfusions. In a recent secondary analysis of the prehospital air medical plasma trial, crystalloid volume was associated with increased mortality in patients receiving blood transfusion. The significant reduction in early crystalloid volume in patients undergoing prehospital transfusion further supports the use of prehospital whole blood.<sup>5</sup> Standard trauma resuscitation includes the use of balanced fluids and massive transfusion protocols utilizing packed red blood cells, fresh frozen plasma, and platelets in a 1:1:1 ratio to mimic the composition of whole blood. However, this can result in an unbalanced approach leading to the lethal triad of iatrogenic coagulopathy, acidosis and hypothermia. In 2014 the committee on tactical combat casualty care recommended Fresh Whole Blood as the preferred resuscitative product for damage control resuscitation in hemorrhagic shock. The Association for the Advancement of Blood and Biotherapies (AABB) now recommends the emergency release and use of Low Titer Group O Whole Blood in the setting of life-threatening hemorrhagic shock because of its advantages.<sup>6</sup>

During the 2021 AABB Annual meeting Dr. Mark Yazer, MD, from the University of Pittsburgh, Pa., focused on the timing of treatment in major bleeding, demonstrating that pre-hospital (i.e.: ambulance, helicopter) blood transfusion can save lives...He further emphasized the benefits of whole blood transfusion-specifically, low titer group O whole blood (LTOWB)-in both adult and pediatric patients with major bleeding. He presented data from multiple observational studies showing that whole blood is associated with better survival rates than component therapy. He characterized the benefits of LTOWB from recent studies and a national trauma data base, as follows:

- Lower mortality rates
- Shorter length of stay in the hospital
- Fewer complications (i.e.: Kidney injury, DVT, PE)
- More rapid availability of the units

He also shared a study just published in the October issue of Annals of Surgery showing reduced time to base deficit correction in injured children when whole blood was transfused instead of blood components.<sup>7</sup> Whole blood...with the proposed advantages also allows for a lower volume of transfusion and ease of administration when compared to component therapy.<sup>8</sup>

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<sup>4</sup> <https://clinicaltrials.gov/ct2/show/NCT03477006>

<sup>5</sup> Braverman, Maxwell. "Prehospital Whole Blood Reduces Early Mortality In Patients With Hemorrhagic Shock." Transfusion: Supplemental Article (March 2021): S20

<sup>6</sup> Christa A. L. Arefieva, MS, MSIV. "The Use of Low Titer Group O Whole Blood in Emergency Medicine." EM Resident. <https://emresident/article/group-o-whole-blood>: 2

<sup>7</sup> <https://www.aabb.org/news-resources/news/article/2021/10/19/managing-major-bleeding>

<sup>8</sup> Braverman, Maxwell. "Prehospital Whole Blood Reduces Early Mortality In Patients With Hemorrhagic Shock." Transfusion: Supplemental Article (March 2021): S20

## Review of Local Literature

**Author: Crisanto M. Torres, MD, MPH**

The adoption of whole blood as the initial transfusion product among U.S. civilian trauma centers has gradually increased, replacing conventional component transfusion as the initial transfusion product among 40 to 70 adult civilian trauma centers across the U.S.<sup>1,2</sup> As more trauma centers began to emphasize the practice of whole blood, uncertainties remained about patient outcomes due to the lack of consistent evidence. Given this knowledge gap, Hanna et al. conducted a nationwide retrospective analysis comparing whole blood as an adjunct to component therapy with component therapy only in trauma patients from 2015 to 2016. The authors found a reduction in 24-hour mortality (OR, 0.78; 95%CI, 0.59–0.89; P = .01) and hospital mortality (OR, 0.88; 95%CI, 0.81–0.90; P = .01) associated with whole blood.<sup>3</sup> More recently, Torres et al. performed a survival analysis to evaluate whole blood and survival association in trauma patients with severe bleeding. The study has garnered international attention after its publication in JAMA Surgery improved survival in trauma patients presenting with severe hemorrhage, with a survival benefit found early after whole blood transfusion. A survival curve demonstrated separation within 5 hours of E.D. presentation. Whole blood as an adjunct to component based-MTP compared to component-based-MTP alone was associated with improved survival at 24 hours, demonstrating a 37% lower risk of mortality (hazard ratio, 0.63; 95%CI, 0.41-0.96; P = .03). Similarly, the survival benefit associated with WB-MTP remained consistent at 30 days (H.R., 0.53; 95%CI, 0.31-0.93; P = .02).<sup>4</sup> Consistent results were found by a prospective multicentered study conducted by Hazelton et al. that compared whole blood transfusion with MTP and without whole blood, showing that whole blood transfusion was associated with a 48% reduction in-hospital mortality.<sup>5</sup> The safety of whole blood has also been evaluated. In all the studies mentioned above, secondary outcomes that included complications were assessed. All studies showed no increased complications associated with whole blood transfusion. Additionally, a study performed by Williams et al. showed that low-titer group O whole blood has similar evidence of laboratory hemolysis, similar transfusion reaction rates, and is associated with a reduction in post-ED transfusions and an increased likelihood of survival compared to those receiving only red blood cell and or plasma.<sup>6</sup> Additionally, preliminary results from a nationwide analysis found the risk of death increased by 20% for every 10-minute delay in WB administration (HR 1.20; 95% CI, 1.12-1.28; P < 0.001 ). The findings from these studies are clinically important as it concludes an essential first step in prioritizing the selection of early whole blood transfusion for trauma patients with severe hemorrhage.

### Reference:

1. Hashmi ZG, Chehab M, Nathens AB, et al. Whole truths but half the blood: Addressing the gap between the evidence and practice of pre-hospital and in-hospital blood product use for trauma resuscitation. *Transfusion (Philadelphia, Pa.)*. 2021;61(S1):S348-S353. <https://onlinelibrary.wiley.com/doi/abs/10.1111/trf.16515>. doi: 10.1111/trf.16515.
2. Yazer MH, Spinella PC, Anto V, Dunbar NM. Survey of group A plasma and low-titer group O whole blood use in trauma resuscitation at adult civilian level 1 trauma centers in the U.S. *Transfusion (Philadelphia, Pa.)*. 2021;61(6):1757-1763. <https://onlinelibrary.wiley.com/doi/abs/10.1111/trf.16394>. doi: 10.1111/trf.16394.

3. Hanna K, Bible L, Chehab M, et al. Nationwide analysis of whole blood hemostatic resuscitation in civilian trauma. *The journal of trauma and acute care surgery*. 2020;89(2):329-335. <https://www.ncbi.nlm.nih.gov/pubmed/32744830>. doi: 10.1097/TA.0000000000002753.
4. Torres CM, Kent A, Scantling D, Joseph B, Haut ER, Sakran JV. Association of whole blood with survival among patients presenting with severe hemorrhage in U.S. and canadian adult civilian trauma centers. *JAMA surgery*. 2023. <http://dx.doi.org/10.1001/jamasurg.2022.6978>. doi: 10.1001/jamasurg.2022.6978.
5. Hazelton J, Ssentongo A, Oh J, et al. Whole blood vs component therapy for transfusion in trauma patients: A prospective multicenter study. . :1.
6. Williams J, Merutka N, Meyer D, et al. Safety profile and impact of low-titer group O whole blood for emergency use in trauma. *The journal of trauma and acute care surgery*. 2020;88(1):87-93. <https://www.ncbi.nlm.nih.gov/pubmed/31464874>. doi: 10.1097/TA.0000000000002498.

**Sample of EMS programs in other states with the same or comparable projects, if available, including a description of the duration of the program and a summary of the results**

**San Antonio Fire Department:** In 2018 San Antonio fire department collaborating with the South Texas Blood and Tissue Center and became the first service in nation to deploy whole blood in the field. Shortly after instituting transfusion protocols paramedics successfully infused a unit of whole blood to a patient who had rolled his car over and was in severe shock. They were able to resuscitate the victim and transport him to a level one trauma center. He survived and became the first patient to receive blood in the field. In San Antonio and Bexar County it takes 28.8 minutes, on average, from 9-1-1 EMS call to get a trauma alert patient requiring a massive transfusion to definitive care at a trauma hospital. Research shows if a patient is going to die from a gunshot wound to the chest or blunt injury, they are going to die in less than 30 minutes and mortality in traumatic torso injury occurs long before the golden hour. According to these numbers, the critically ill San Antonian suffering from a blunt or penetrating injury would die during transport to the ER or as they were being wheeled through the hospital doors. For this reason, they believe treating the patient's hemorrhagic shock at point of injury, with whole blood, may be as important to patient outcome as surgical treatment. In response, the San Antonio fire department began a program to initiate the transfusion of LTOWB in the field in 2018. Early initiation of transfusion is backed by data from the American College of Surgeon and trauma best practice and a study from Journal of trauma and acute care which found that Delays in MT protocol activation and delays in initial cooler arrival were associated with prolonged time to achieve hemostasis and an increase in mortality. Independent of products ratios, every minute from time of MT protocol activation to time of initial cooler arrival increases odds of mortality by 5%. This underscores the importance of initiating transfusion of whole blood to exsanguinating patients within 30 minutes of injury and doing all that can be done to avoid the delays that may occur in the trauma bay.

- "San Antonio Fire Department Whole Blood Program Reaches Milestone: The department has now administered 1,000 units of life-giving whole blood since its inception in Sept. 2018." Firehouse. Sept. 14, 2022
- [https://journals.lww.com/jtrauma/Abstract/2017/07000/Every\\_minute\\_counts\\_\\_\\_Time\\_to\\_delivery\\_of\\_initial.4.aspx](https://journals.lww.com/jtrauma/Abstract/2017/07000/Every_minute_counts___Time_to_delivery_of_initial.4.aspx)

**King County Medic One:** In May 2021 King County Medic One began carrying Whole Blood and transfusion equipment. Specialty trained paramedics deliver blood to a 600 square mile area south of Seattle Washington. The pilot program allows for the delivery of blood to trauma victims at the point of injury.

- <https://blog.bloodworksnw.org/transfusions-in-the-field-part-1-dr-michael-sayre-harborview-medical-center-s3-e32/>

**Austin-Treavis County Emergency Medical Services (ATCEMS)** and the local blood bank began a program in December 2021 with two response vehicles equipped with whole blood. This enabled trained paramedics to administer low titer o+ blood to patients who are losing blood due to traumatic or medical emergency on scene or on the way to the hospital. The blood is carried in specialized coolers inside ATCEMS units. These coolers maintain as FDA mandated temperature between one and six degrees Celsius. Dr. Jason Pickett, Chief Deputy Medical Director and Heidi Abraham, Deputy Medical Director, for the city of Austin, reported that in the first six months of operations they noted after just one unit of blood a rapid reversal of shock in the field which translated to increased long term survival rates while reducing the amount of blood a patient has to receive by half, conserving the community resource.

- <https://www.austintexas.gov/news/life-saving-program-provides-pre-hospital-blood-transfusions-multiple-patients>

**New Orleans EMS:** Developed traumatic shock guidelines as part of their regional prehospital protocols. New Orleans EMS trauma blood administration guideline allows for the administration of whole blood, packed red blood cells (PRBCs), leukocyte-reduced red blood cells (LRBCs), or plasma, based on the availability of supply. Medics selected for the program are experienced senior paramedics who receive extra training in the handling of blood products and prehospital blood administration. New Orleans's "blood medics" solely manage the blood administration, and a second paramedic addresses other patient issues such as vital signs, airway, and IV access and can assist the blood medic as needed. New Orleans Data has shown preadministration systolic blood pressure (SBP) averaged just over 70 mmHg, with an average SBP on arrival of 116 mmHg after 2 units of blood. During the first 3 months of the program, all patients who had not experienced traumatic arrest on scene survived, 40% went directly to the operating room, and only 1 required a massive blood transfusion.

- Meg Marino, MD, FAAP, and Tom Dransfield, EMT-P. "THE HIDDEN DANGERS OF SHOCK IN TRAUMA: NEW ORLEANS EMS TRAUMA BLOOD DELIVERY PROGRAM."

**Caldwell County EMS:** In January 2022, through a partnership with the University of North Carolina Health Blue Ridge, Caldwell County EMS began carrying LTOWB on supervisor vehicles. EMS staff received training on how and when to administer blood. To ensure no blood is wasted, the temperature is constantly monitored using coolers donated by UNC Health Blue Ridge and is changed out with the hospital every 21 days. In addition, UNC has partnered with 2 other counties, Burke and McDowell to provide blood products to their departments.

- <https://www.caldwellcountync.org/CivicAlerts.aspx?AID=46>



**Current list of Prehospital EMS agencies using LTWOB in the field.**

Virginia Beach EMS & Tidewater EMS in Virginia,

New Orleans EMS in Louisiana,

UPMC Pittsburgh EMS in PA,

North Carolina- UNC Health Blue Ridge with Burke County EMS, McDowell County EMS and Caldwell County EMS, Henderson County Emergency Medical Services (HCEMS) in collaboration with Pardee UNC Health Care, Jackson County EMS North Carolina, Wilkes County Emergency Medical Services, Cape Fear Valley Health EMS & Onslow County EMS,

COLLETON COUNTY, S.C.– Colleton County Fire-Rescue,

Northeast Georgia Medical Center and Region 2 Regional Trauma Advisory Committee (RTAC) with Dawson County Fire and Emergency Services, Jackson County Emergency Services, Habersham County EMS and White County EMS,

Oklahoma City Fire Department,

Lincoln County EMS in New Mexico, and

Seattle Fire Department & King County EMS in WA.

Palm Beach County Florida,

Maryland State Troopers

**Comprehensive List of agencies in Texas that work in conjunction with STRAC:**

1. Acadian Ambulance Service
2. Allegiance EMS
3. Bandera County EMS
4. Bexar County ESD 2
5. Bexar County ESD 7
6. Bulverde Spring Branch EMS
7. Canyon Lake EMS
8. Converse EMS
9. Gonzales County ESD 1 EMS
10. Karnes County EMS, Kennedy
11. La Salle County EMS
12. New Braunfels EMS
13. San Antonio Fire Department EMS
14. Schertz EMS
15. Seguin EMS
16. UT Health San Antonio EMS Fellows
17. Wilson County ESD 2
18. Wilson County ESD 3

**Plan for QA/QI:**

There will be 100% QA of all responses not dependent on the initiation of a transfusion. The PCRs will be reviewed by the affiliate medical directors as well as Dr. Torres, MD, MPH, Boston Medical center, associate professor and participating trauma service representative and the appointed Blood Bank representative. Cases will be discussed monthly with authorized paramedics and individually within one week after all transfusions. Any deviation from protocol or unintended outcome will be reported immediately to the medical director.

**Daily:**

Verify constant temperature control of the refrigerator.

- This will be through constant Wi-Fi monitoring
  - directly to the blood bank at Boston Medical Center and
  - ems coordinator(s) of designated transfusion service(Canton FD).

Daily checks of the units themselves.

- Check for changes in temp-a-dots,
- Observe for color changes, clots, or air in the bags.

**Weekly:**

- Verify:
- all units are accounted for
  - if units were transfused verify
    - Documentation
    - Patient
    - When
  - expiration dates
  - units are switched out before expiration date.
    - Enables blood to be used elsewhere

**Quality improvement:**

This is a limited project with a limited scope. Quality improvement will be on going and involve all participants. All facets of this program will be closely monitored and assessed. Improvements will be made based on experience and need for changes and updates.

**Guidelines and Evaluation:**

All responses will be closely monitored and follow up will be obtained focusing on patient outcomes, mortality, need for massive transfusions in hospital and any complications associated with the transfusion.

Equipment such as refrigeration units and temperature dots will be closely monitored and continually evaluated to ensure blood products can be safely stored and delivered in the prehospital setting.

Blood products are a limited resource and a valued therapy. In this regard, the ability of individual communities to utilize this as a shared resource will be closely monitored and evaluated.

**Factors that would mandate the withdrawal of the special project:**

Noted harm to patients.

The inability to deliver whole blood to exsanguinating patients within 30 minutes of point of injury.

Uncorrectable equipment failures resulting in waste of blood product.

Inability to trace units to final disposition

**. QA/QI process will mirror recommendations from DPH.**

**Standardization of care is based on the protocols developed in conjunction with other national services currently operating LTWOB programs. 100% follow-up of all field transfusion cases to evaluate outcomes and procedures followed by EMS.**

**As stated in QA/QI plan, 100% of scene-call cases will be reviewed by the SPW team with immediate post case review by CFD EMS coordinator and Dr Valkanas. Crews will notify EMS supervisory team after all transfusion calls and any cases that were unable to be responded to efficiently.**

**Outreach program will ensure follow-up with participating services to obtain feedback and inform the QA/QI process.**

**SPW team's AHMD's will identify cases that could have benefitted from the LTWOB program and conduct M&M rounds on specific cases to foster system development and program awareness.**

**Field Transfusion Operator:  
The Next Step in the Care of the Hemorrhaging Patient**

1. **Introduction** 0.5 hours
  - a. Summary of Scientific Literature
    - i. Emphasis on Stabilization of the hemorrhaging patient
    - ii. Need for Point of Injury care
    - iii. Use of cold stored low titer O negative blood
      1. Review Component Therapy Options
      2. Advantage of Whole Blood Therapy in the prehospital environment
  
2. **Prehospital Principles of Resuscitation and Transfusion** 1.0 hours
  - a. Airway Control
  - b. Rapid Recognition of Life-Threatening Hemorrhagic Shock
  - c. Hemorrhage Control with Mechanical Hemorrhagic Adjuncts
    - i. Pressure Dressings
    - ii. Combat Gauze/Wound Packing
    - iii. Tourniquet
    - iv. Pelvic Stabilization
  - d. Prevent Hypothermia
    - i. Rapid Transport
      1. Permissive Hypotension
      2. Avoid Crystalloid Resuscitation
      3. Large Bore IV
      4. Tranexamic Acid if Less than 3 hours form POI
    - ii. Definitive Care Point of Entry
  
3. **Criteria for Transfusion** 1.0 hours
  - a. Signs and Symptoms of Hemorrhagic Shock
    - i. Assessment of Blood Consumption (ABC) Score
      1. Non-Laboratory based predictor of the need for transfusion
        - a. Penetrating Mechanism
        - b. Positive Focused Assessment sonography for Trauma (FAST)
        - c. Systolic Blood Pressure less than 90 mmHg
        - d. Heart Rate Greater Than 120 beats per minute
        - e. Score two or greater
      2. Predicts the need for massive transfusion
        - a. % sensitivity
        - b. 85% specificity
    - ii. Indication for transfusion in the presence of severe traumatic injury
      1. Control external bleeding before or simultaneously

2. Systolic Blood Pressure < 100 or absence of radial pulse
3. Heart Rate > 100
4. Any above the knee amputation or double/triple/quadruple amputation
  - a. Regardless of Vital Sign Indication
  - b. Only indication not requiring vital sign parameter
5. Traumatic Injuries most likely to benefit from transfusion
  - a. Penetrating Injuries
    - i. Thoracic
    - ii. Abdomen
    - iii. Junctional
      1. Axilla
      2. Inguinal
      3. Cervical
  - b. Pelvic Fractures
  - c. Multiple Injuries
  - d. Proximal Amputations
    - i. Above the knee or elbow
    - ii. Complete or partial loss of the limb
      1. Severely Mangled
      2. Not completely Severed
6. Traumatic Arrest
  - a. Exsanguination with signs of life upon initial assessment of EMS
  - b. Transfusion supersedes compressions

- b. Limit Wastage of Blood Components
  - i. Use of transfusion triggers
  - ii. Aggressive Hemorrhage Control Efforts

#### 4. Procedure

1.0 hours

- a. An average unit of whole blood contains 500-600ml of product
- b. Clinical Indications of Hemorrhagic Shock
  - i. Hypotension SBP < 100
  - ii. Tachycardia > 100 BPM
  - iii. Respirations: Rapid/Shallow
  - iv. Pulse: Ineffective (weak and thready)
  - v. Mental Status: Decreased (Excluding head Injury)
  - vi. Skin Color Pale/Cyanotic
  - vii. Continued Bleeding from non-compressive wound
- c. Transfusion Procedures
  - i. Maintain Universal Precautions
  - ii. Gather Essential Items
    1. Blood Pressure cuff/Cardiac Monitor
    2. Blood Warmer Device
    3. Pressure Bag

4. "Y" type filtered blood administration set
5. Blood Product to transfuse (LTONWB)
6. Dedicated IV access
  - a. For use only for blood Product
  - b. IO/LB IV (18G or greater)
  - c. 0.9% KVO

iii. Pre-Transfusion

1. Verify Blood Label
  - a. Unit #
  - b. Type of product
  - c. Expiration Date
  - d. Temperature Indicator (Red = Not Acceptable)
  - e. Inspect blood product for gas, discoloration, clots, foreign objects, or sediment
  - f. Inspect plastic bag for evidence of cracks or leakage
2. Close all clamps on "Y" Tubing
3. Attach line to fluid warming cartridge and fluid warmer extension line
  - a. Check warming device is functioning correctly
4. Insert 1 spike into NS bag and hang
  - a. Prime "Y" section only
  - b. Close clamp
5. Insert second spike into blood product and hang
  - a. Open clamp
  - b. Run the length of the tubing
6. Attach Line to IV/IO Site
  - a. Verify good flow before initiating transfusion
7. Ensure all clamps are closed
8. Document pretransfusion Vital signs

iv. Transfusion

1. Open main line clamp for blood product to begin infusion
  - a. Ensure clamp to NS remains closed
  - b. Under no circumstances will other medications or IVF be introduced through transfusion line
    - i. Hemolysis
    - ii. Clotting
2. Transfuse within 4 hours of removal from storage container, unused:
  - a. Return to GSMC or
  - b. Transport with patient
3. Pressure infuser set to 300 mmHg
4. Monitor VSS every 5 min per MA Statewide treatment protocol
5. Post transfusion open NS line to deliver residual blood product
6. If second unit required; close NS clamp

7. Spike second unit first using above verification method
  - a. Open blood product and main line clamps to begin 2<sup>nd</sup> infusion
8. Monitor patient and vital signs closely
  - a. Goal SBP > 100
  - b. Goal Pulse < 100
  - c. Goal MAP: 70-80 mmHg
- d. Documentation
  - i. Pre-transfusion
    1. Unit number
    2. Type of blood product (LTOWB)
    3. Expiration Date
    4. Vital Signs
  - ii. Post-Transfusion
    1. Vital Signs
    2. Date/Time started/completed
    3. Note if interrupted and reason for interruption
    4. Patient identification

5. **Transfusion Reaction** 0.5 hours

6. **Storage, Transportation, and Monitoring of Blood Products** 1.0 hours

- a. SAFE-T-VUE Temperature indicator
  - i. Adheres directly to blood bags during transport
  - ii. Changes color white to red when the 10 degree C indication temperature has been reached or exceeded
    1. Nonreversible
    2. Indicates that a high temperature has existed
      - a. Remains red even if temp returns to normal
      - b. As long as white can be stored for future use
  - iii. Prepare indicator by refrigerating for a minimum of 24 hours at 1-6 C.
  - iv. Remove blood product and Safe-T Vue Indicator at the same time and place on a clean dry surface
    1. Use a cold packet on the surface below the product
    2. Remove excess moisture from the blood product bag
  - v. Hold Safe-T-Vue against the blood product with finger tips and peel the remove label to expose the adhesive.
    1. Only handle around the edge of the indicator

7. **Quality Control** 1.0 hours

**8. Practical**

- a. Product storage/handling 0.25
- b. Trauma/shock assessment 0.25
- c. Transfusion decision making 0.25
- d. Transfusion Procedure 0.25
- e. Documentation 0.25

9. **Testing/Evaluation** 1.0

**10. Clinical**

Upon completion of the didactic portion of the course, prospective transfusion paramedics will be scheduled for a clinical rotation with our partner transfusion services to ensure that participants will obtain proficiency with the transfusion of whole blood



**Protocol:**  
**Transfusion: Low Titer Type O Whole Blood (LTOWB)**

**Trauma:** Patients with blunt or penetrating Trauma with ongoing or suspected ongoing, major hemorrhage based on their presenting injury or diagnosis, and with clinical signs of shock should be administered whole blood.

Adults Age 15 and over

- SBP  $\leq$  70 mmHg or
- SBP  $\leq$  90 mmHg and heart rate  $\geq$  110 or
- Altered Mental status due to hemorrhage and/or absent radial pulse or
- Clinical signs of hemorrhagic shock or
- Traumatic Arrest Witnessed by EMS

**Dosage:** **Adult**

1 Unit (500ml), May repeat x 1 if patient still meets indications

**Procedure:**

- Establish 1 and when possible 2 or more large bore IVs. Humeral IO can be considered if a peripheral cannot be obtained.
- Prime blood tubing and disposable blood warmer unit with normal saline (do not use ringers or D5W). Spike 1 unit of LTOWB to “y” connector on primed blood tubing and disposable blood warmer.
- Using blood warmer, administer LTOWB at wide open rate with a pressure bag.
- Once blood bag is completely empty, begin normal saline to flush line (maximum 250ml) and recheck vital signs.
- Administer 1 Gm Calcium Gluconate For every 1-2 units of whole blood transfused.
- **If not already administered, and criteria met as outlined in SWTP 6.5**, infuse 15mg/kg to max dose of 1 Gram of Tranexamic Acid.

**Contraindications:** Whole Blood is incompatible with LR and Dextrose solutions  
Patient refusal of blood transfusion for religious, social, or cultural reasons

**Considerations:** When possible, verbal consent for transfusion will be obtained from patient prior to initiation. In most cases, due to the nature of trauma, transfusion will be initiated based on implied consent in the emergent setting.

**Side Effects:** Urticaria (1 to 3%)  
Chills and fever (1%)

**Considerations:** To Avoid waste, cooling box should not be opened until need conformed, Keep second unit in the box. Return LTOWB to blood bank on a regular basis.

# ALS Interfacility Transfer Protocols A2

## Part E3 Blood and / or Blood-Product Administration

- Infusion/bloodbank documentation must be transported with the patient.
- Paramedics will not initiate a blood product infusion.
- At least one additional IV line should be in place.
- Paramedic will not administer any medications through an IV line which is being used to infuse blood or a blood product.
- Ensure the blood and / or blood products are infusing at the prescribed rate.
- Monitor and record the patient's vital signs every 5 – 10 minutes.
- If any signs and symptoms of transfusion reaction, proceed immediately to the TRANSFUSION REACTION PROTOCOL (Part D2 )**
- When the transfusion has finished:
  - ✓ Record transfusion end-time and post-infusion vital signs.
  - ✓ Disconnect infusion set tubing from primary line.
  - ✓ Flush primary line with normal saline only.
  - ✓ Place any used supplies into a clean biohazard marked container or bag.
  - ✓ Deliver all empty transfusion bags and tubing to the receiving facility with the patient.

# ALS Interfacility Transfer Protocols

## A2 Part D2- Blood Transfusion Reaction

### Symptoms of a Transfusion Reaction

#### Acute Hemolytic Reaction

Fever, hypotension, flushing, wheezing, dark and / or red colored urine, oozing from IV sites, joint pain, back pain, chest tightness

#### Nonhemolytic Febrile Reaction

Fever, chills, rigors, vomiting, hypotension

#### Allergic Reaction

Urticaria, hives (usually without fever or hypotension)

#### Anaphylactic Reaction

Dyspnea, wheezing, anxiety, hypotension, bronchospasm, abdominal cramps, vomiting, diarrhea

#### Volume Overload

Dyspnea, hypoxia, rales, tachycardia, jugular vein distention

#### Transfusion-Related Acute Lung Injury ("TRALI")

Dyspnea, hypoxia, rales (usually without fever or signs of pulmonary edema)

- STOP** the infusion if any of the above symptoms are discovered!
- Start infusion of normal saline
- Contact **MEDICAL CONTROL**
- Treat hypotension and anaphylactic reaction with standing orders (established pre-hospital protocols)
- If minor allergic reaction (urticaria / wheezing) administer **diphenhydramine**, 50 mg IV
- If SpO2 is below 90% or patient experiences wheezing / rales, administer high-flow supplemental oxygen and consider positive pressure ventilation. If significant signs of volume overload, consider **furosemide**, 40 mg IV.
- Notify issuing hospital's blood bank of any suspected reaction.



# Prehospital Blood Product Transfusion Record

Patient Name:	Transporting Agency Run / Case #:	Receiving Facility Medical Record #:
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Product Unit Number (Affix sticker below, or write unit number)	Product Type (Check One)	Transfusion Date & Start Time	Transfusion Complete* (Check One)	Transfusion Reaction** (Check One)	Transporting Medic Initials
1. Affix Sticker Here or Write Unit #	LTOWB		<input type="checkbox"/> Yes <input type="checkbox"/> Ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Affix Sticker Here or Write Unit #	LTOWB		<input type="checkbox"/> Yes <input type="checkbox"/> Ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Affix Sticker Here or Write Unit #	LTOWB		<input type="checkbox"/> Yes <input type="checkbox"/> Ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Affix Sticker Here or Write Unit #	LTOWB		<input type="checkbox"/> Yes <input type="checkbox"/> Ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Name of Transfusing Agency:		Receiving Facility:		Type of Call:	
		BMC Tufts MA Gen Other:		Childrens BIDMC	
Medic Unit #:		Comments:			

\*If blood product transfusion is ongoing at time of patient transfer to hospital, document "Ongoing."

\*\*Document actions taken in 'Comments' Section at the time of patient drop-off at receiving hospital.

**Mandatory Blood Product & Blood Form Tracking:**

- Transporting crew keep **White Copy**; give the yellow and pink copies AND the blood bag to the Emergency/Trauma Team.
- Emergency Department keep **Yellow Copy**; give the **Pink Copy** AND the blood bag to the Blood Bank/Transfusion Services.

Blood Bag & Form given to: \_\_\_\_\_

PRINTED NAME

SIGNATURE

**Actions to take for suspected transfusion reaction:**

- ✓ **STOP TRANSFUSION**
- ✓ Disconnect tubing from infusion site; flush site with normal saline
- ✓ Keep line open with normal saline
- ✓ Re-initiate new transfusion if deemed clinically essential
- ✓ Document actions taken in 'Comments' section

Transporting Crew: Please send a copy to **Canton FD** via text image to **508-843-3591**, or email [lreardon@town.canton.ma.us](mailto:lreardon@town.canton.ma.us), or FAX: **(781) 821-5390**

## **Notification of the Transfusion Paramedic Unit for intercept**

As a regional resource available through the regional Mutual Aid Agreement, the Transfusion Paramedic Unit will be placed on the running cards at the relevant regional dispatch centers for emergent dispatch in large scale incidents such as building collapse/mass casualty by and specific request for mutual aid response and specialty intercept.

### **Procedure:**

Requesting service can contact: Norfolk County Control/Bristol County Control/Plymouth County Control via radio or directly by phone.

Request: Canton Fire Department's Whole Blood Transfusion Unit

At that time the CFD Whole Blood Unit to be dispatched either directly to the scene if relevant, or to a predesignated and established access point similar to established LZ's used for aeromedical intercept.

Transfusion medic will intercept with the requesting service and board their ambulance with all relevant equipment. To minimize scene delays the Transfusion Paramedic will evaluate the PT for eligibility and if appropriate, initiate the transfusion while enroute to the predesignated trauma center.

### **Communications:**

Whole Blood Transfusion Unit will either request a common fireground channel for communications with requesting service or may opt to switch over to requesting services primary communications channel to establish intercept plan and ETA if necessary.

- SPW team will work with the Fire Chief's Association to establish intercept locations in area communities and sections of major roadways.

## Quality Plan

This document overviews the basic concepts embodied in the *Boston Medical Center* Transfusion Service Quality Plan. The policies that support these statements can be found in the remaining section of this manual and other Blood Bank Manuals.

### GENERAL OVERVIEW

The *Boston Medical Center* Transfusion Service Quality Plan is modeled after the American Association of Blood Banks' *Quality Program* and *Quality Systems Essentials*, and the FDA *Guideline for Quality Assurance of Blood Establishments*. The AABB and FDA use a systems approach to the quality program that emphasized detection and prevention of errors that could compromise blood safety or patient outcome. This quality program uses self-assessment to determine where areas of less-than-optimal performance exist. Continuous improvement techniques are then applied to prevent future errors. This approach is more timely and effective than peer inspection alone.

### QUALITY SYSTEM ESSENTIAL (QSE): Organization

A quality system is an initiative of the entire Boston Medical Center (BMC) Transfusion Service, which includes the transfusion service, stem cell processing lab and tissue dispensary. The blood bank is part of the Department of Pathology and Laboratory Medicine. In the transfusion service, the medical director, supervisor, assistant supervisor and staff all support and participate in quality system activities. The goal is to integrate error prevention into daily activities to maximize the benefits of transfusion medicine to our patients.

See attached organization chart for the organizational relationships of the BMC Blood Bank and Transfusion Service. The hospital Transfusion Committee represents a vital link between the blood bank and the users of the blood bank. The Transfusion Committee reports quarterly to the Medical Dental Staff of the hospital and at least annually to Medical Executive Committee.

The medical director has the ultimate responsibility and authority for all medical and technical policies and procedures that affect lab personnel and test performance, and for the consultative and support services that relate to the care and safety of patients. The medical director is the quality representative, and will delegate responsibilities as necessary. The supervisor is responsible for technical oversight and coordination of all aspects of the department in order to achieve quality objectives. Management reviews will be conducted on a periodic basis to assess compliance with the quality plan. All policies, processes and procedures shall ensure that BMC meets the requirements of AABB, CAP, FDA, Joint Commission, Mass Public Health and other regulatory agencies.

The medical director is a liaison between the blood bank and clinicians involved in the vein-to-vein transfusion process, beginning with the sample collection for compatibility testing, ordering the right component for the appropriate indication at the right time, the informed consent process, and blood administration issues. Blood warmers are serviced and maintained through Biomedical Engineering.

## **QSE: Personnel**

The BMC transfusion service training program is an integrated and continuous process. It combines the facets of job qualifications, orientation, job task training and assessment, competence assessment and remedial training, continuing education and proficiency testing in a comprehensive documented system for each employee.

Details are found in **SOP I 004: Training and competency assessment/new employee orientation checklist.**

1. Job descriptions and employee qualification
  - Job descriptions are written and maintained for each position.
  - To be considered for hire, candidates must meet the qualification (education and/or experience as stated in the job description.)
  - The candidate must provide documentation of education, training and experience.
2. Orientation
  - New employees are provided orientation to the organization, department and specific job for which they are hired.
3. Training
  - Training is provided as required per job description expectations and includes training related to specific job requirements, safety, computer, personal development, quality and other skills as needed.
  - Staff development is provided to meet individual needs, regulatory and accreditation requirements, and the changing needs of the facility.
  - Training is considered completed when the individual demonstrates sufficient knowledge and skills for the job task.
  - Retraining is initiated when indicated.
  - Documentation of training and initial competence are maintained.
4. Assessment of competence
  - Staff competence is initially determined during job task training.
  - Ongoing competence is determined at 6 months and at least annually thereafter.
5. Continuing education
  - Continuing education by various means available is encouraged.
  - Documentation of continuing education is maintained.
6. Performance appraisal.
  - A documented performance review based on job accountabilities, objection

measures and predefined standards are completed annually for each employee.

7. Trainer qualifications

- Selected individuals who meet qualifications may function as trainers in this facility.

## **QSE: Equipment Calibration and Preventive Maintenance**

Calibration, preventive maintenance and quality control procedures are part of a comprehensive quality control program for all transfusion service equipment and reagents. Schedules for each aspect of calibration, routine preventive maintenance and reagent/equipment quality control are maintained and followed. All results are documented and reviewed. See **QC Manual**.

1. Selection

- New equipment specifications are determined prior to selection. Such specification will meet all applicable regulatory requirements, i.e. FDA approval.
- The specifications are shared with suppliers, where appropriate.
- The supplier's ability to meet the specifications and other criteria are considered in the selection process, where appropriate.

2. Installation

- Installation is performed by a documented plan.
- The supplier may take an active role in the installation process.
- The equipment is properly installed and tested as part of the validation protocol.

3. Calibration

- All measurement devices, new or repaired, used in critical processes are calibrated according to procedures written in accordance with manufacturer's recommendations, regulatory requirements and accreditation standards.
- Complete documentation of equipment identity, location, results of scheduled calibrations, actions taken and disposition of the equipment is maintained.

4. Preventative maintenance

- Preventative maintenance schedules are determined by manufacturer's recommendations, regulatory requirements, accreditation standards and internal requirements.
- Documentation of maintenance includes findings, actions, and follow-up.

5. Defective equipment

- Defective equipment is identified, controlled and repaired or replaced.



## QSE: Supplier Issues

Supplier qualification is the transfusion service's strategy to provide assurance that the supplier's ongoing operations will result in consistently acceptable products and services. BMC Transfusion Service periodically reviews contracts for supplies and services. BMC also maintains a system to inspect and document receipt, storage and use of all incoming reagents and materials and to capture any recurrent problems.

1. Supplier qualification
  - BMC has defined the characteristics or functional requirements for critical materials, blood and blood components, products or services. These requirements include FDA licensure or 510K approvals, where applicable.
  - BMC has assessed both the ability of our suppliers to meet our requirements and their actual performance.
2. Contract review
  - Agreements to obtain blood and components, products and services are reviewed to ensure that each party's expectations are defined and agreed to and that any changes are appropriately recorded and communicated.
3. Receipt, inspection and testing of incoming supplies
  - There is a process for receiving, inspecting and testing (where required) incoming critical materials, blood and components, and products.
  - Criteria have been established for accepting critical materials, blood and components, and products.
  - Critical materials, blood components and products not meeting acceptance criteria are quarantined.
  - There is a process to ensure tracking and storage of critical materials, blood components and products prior to use.
  - Relevant procedures are **SOP I 019: Receipt and processing of materials, reagents and supplies**, and **TS019 Processing of blood received from other facilities**.

## QSE: Process Control

The essence of process control is to take as much variation as possible out of the process so that predictable outcomes are assured. In a controlled operation, little chance for error exists because processes and procedures are reliable and consistent. BMC uses many control measures with in process control.

1. Development and use of standard operative procedures
  - Written procedures for operation tasks. **SOP I 007: Development of procedures (SOP for SOP)**.

2. Change Control
  - All changes follow an established process and are documented, evaluated, and approved. **SOP I 022: Change Control.**
3. Blood Bank computers and software
  - User acceptance activities and validation are performed for new or revised software, as well as new hardware.
4. Process validation for new or changed processes or procedures
  - Validation activities include equipment installation and documentation that the process works as intended before actual use.
  - Revalidation is performed when process changes occur that could affect the outcome of a process.
  - Written validation protocols are used for all validations.
  - Retrospective validation is performed for well-established processes using historical data, when appropriate.
  - Validation results are reviewed and approved prior to process implementation.
  - Results of all validation activities are documented. **SOP I 020: Validation Process.**
5. Continuous monitoring and control of production processes.
6. Use of labels and the labeling process.
  - A process is maintained for all activities related to labeling blood components, beginning with the selection or design of a label and finishing with its' placement on the blood component. ISBT 128 is required for blood products.
  - Blood component labels are selected based upon criteria specified in regulatory requirements and accreditation standards. Upon receipt, labels are logged in and inspected prior to use.
  - Labels printed in house are validated and proofed against the current version master copy (when applicable) prior to use. ISBT 128 labels are generated by Hematrax® label software.
  - A process is maintained to ensure that recurrent label problems are detected, evaluated, and remedied when necessary.
  - A master set of labels is maintained. See **SOP II 006: Label Control.**
7. Proficiency testing
  - Proficiency testing measures and compares BMC testing systems with the outcome of testing performed by other laboratory peers.
  - BMC participates in proficiency testing programs available for all analytes.
  - The PT program includes designation of testing personnel, frequency of challenges, routine review, and corrective action. See **SOP I 005: Proficiency testing program.**
8. Quality Control (QC)

- Established schedules for QC of equipment, reagents and blood components are maintained and followed. See **QC Manual** for specific policies/procedures.
9. Process and product specifications
- Specifications are determined from regulations and accreditation standards (AABB, FDA, Joint Commission, FACT and others) and are incorporated into their respective procedures.
10. Non-conforming blood and blood components
- The means to identify and handle these are incorporated into their respective procedures.
11. Final inspection and testing
- Criteria have been developed for the release of finished blood or blood components, products or services.
  - **TS 011: Issue of red blood cells and components to patient floors.**
  - **SOP II 012: Issue of red blood cells to the operating rooms.**
  - **SOP II 018: Viral Donor Testing and Release of Product into Inventory.**
12. Handling, storage, distribution and transport
- Storage requirements for in-process and finished blood components are maintained and followed. **COMP 016: Storage temperatures and dating periods.**
  - Packing requirements for transportation have been developed:
  - **SOP II 012: Issue of red blood cells to the operating room.**
  - **COMP 015: Transport of blood to other facilities.**
  - **SCELL 012: Stem Cell Shipping**
  - There are methods to trace any blood component or product distributed, issued or returned.
  - There is a process to investigate (where applicable) and dispose of returned blood and component and products. **SOP II 013: Reissue of blood products from patient floors.**
13. Monitoring the outcomes of transfusion
- **TS 020: Investigation of all suspected transfusion reactions.**
  - Assessing the appropriateness of transfusion utilization through the activities of the Transfusion Committee.
  - Transfusion Data is collected to track total numbers of units transfused by component type. Transfusion Data and ALL transfusion reactions are reported monthly to the CDC's National Healthcare Safety Network (NHSN) Biovigilance Website as required by Massachusetts Department of Public Health.

## **QSE: Documents and Records**

The BMC Transfusion Service believes that documents and records are the heart of a quality system. The documentation system allows both internal and external assessors to track and trace processes, procedures and outcomes to determine if there were deviations or errors that could compromise safe patient transfusion. The transfusion service maintains procedures for how to write operational procedures and for how to organize and manage those procedures. The record keeping system allows for appropriate and timely reviews where needed and proper storage and protection of all documents and records. See **SOP I 018: Records and Data Management**.

### 1. Document control

- The Boston Medical Center Transfusion Service maintains:
- A structure to link its policies, processes and procedure.
- A process to ensure uniformity of standard operating procedures and forms.
- A process to:
  - Review and approve new documents that include QA and management.
  - Annual review of existing documents.
  - Control of document versions and effective dates.
  - Review and approve document changes that include QA and management.
  - Control document distribution and obsolete documents.
  - Archive and protect obsolete documents.

### 2. Generating, reviewing, retaining and retrieving records.

- Formats and content of records are defined in respective SOPs.
- Records are generated according to instructions in related SOPs.
- Regulatory requirements and accreditation standards are used to determine what records are reviewed and the review schedule.
- Records are retained according to regulatory requirements, accreditation standards, and internal specification.
- Records are stored in a manner that maintains their integrity and facilitates their retrieval.

## **QSE: Deviations, Nonconformances, and Adverse Events**

The Boston Medical Center Transfusion Service maintains a system to define, detect, report, analyze, classify, act on and follow-up incidents, errors and accidents. The error management process also allows for timely notification of the FDA CBER in required cases. Because error management is essential to process control and process improvement, BMC provides an atmosphere of encouragement in reporting errors. See **SOP I 015: Management of Incidents/Errors and Accidents**.

### 1. Reporting, classifying, analyzing

- BMC maintains a mechanism to document and investigate events that have the potential to affect the quality and safety of blood, blood components, products and services. It is particularly important to characterize pre-analytic (specimen collection) and post-analytic (blood administration) variables, because

communication with the staff outside the blood bank is key to improving these areas.

2. Corrective and preventative action
  - Action is taken to eliminate the root cause of existing problems in order to prevent recurrence. Where appropriate, the hospital Quality Improvement department will serve as liaison between the blood bank and users of the blood bank to address critical issues.
  - Corrective actions are monitored for effectiveness.
3. Tracking and trending
  - A log of events is maintained to ensure that the steps in resolving a problem are taken.
  - Trend analysis of incidents, errors and accidents is performed to aid in prioritizing process improvement efforts.
4. Management review and impact
  - Event reports are submitted to management for review and approval of corrective action.
5. Regulatory agency notification
  - A system exists to determine whether an error/event is reportable to the FDA.
  - There is a procedure for reporting errors to the FDA. See **SOP I 021: Biological Product Deviation Reporting**.
  - Adverse events involving medical devices are reported to the FDA.
6. Failure to meet specified requirements
  - There is a process to identify, separate, and document blood components and critical material failures at the time of
    - Incoming inspection
    - Inventory handling
    - Distribution or issue

## **QSE: Internal and external assessments**

The Boston Medical Center Transfusion Service uses the AABB *Quality Program* to identify critical control points and key elements for transfusion service systems. Wherever possible, monitoring is made part of the daily work routine so that all employees participate in the quality system. Reports are made on a scheduled basis. Follow-up action is taken as needed.

1. External assessments
  - BMC participates in external assessment conducted by the FDA, CMA and Massachusetts State DPH, where required.
  - BMC participates in the voluntary external assessments required of the Joint Commission, CAP, AABB and FACT accreditation programs.

- A process is maintained to conduct, report, and follow-up on external inspections, assessments or investigations.
2. Operation self-assessment
    - BMC has identified its applicable operations systems. They are:
      - Blood component preparation
      - Blood and blood component labeling
      - Storage, transportation and expiration
      - Compatibility testing and component selection
      - Blood transfusion and RhIG administration
      - Complications of transfusion and tissue implantation
      - Blood bank and transfusion service records
      - Tissue tracking
      - Processing of autologous hematopoietic progenitor cells (HPCs)
      - Storage of blood components, tissue products and HPCs
    - Procedures are in place for Transfusion Service personnel to capture data on quality indicators for operational systems.
    - BMC maintains a system of planned and documented internal audits to improve quality that:
      - Ensures operational systems meet regulations and standards.
      - Determines the effectiveness of the quality system.
      - Provides a basis for quality improvement.
  3. Periodic reporting
    - Individuals with quality assurance responsibilities compile results of self-assessments of operational systems in summary reports.
    - Formal reports detailing the finding, results, and any identified problems are prepared and communicated to all Transfusion Service staff the Department of Laboratory Medicine Leadership team, and the hospital's Transfusion Committee.
  4. Tracking and trending
    - Results of current assessments are compared to previous results.
    - Trend analysis is performed to aid in prioritizing process improvement efforts.
  5. Follow-up
    - Follow-up is performed to determine the effectiveness of any changes or corrective action.
  6. Management involvement
    - Summary and formal reports are submitted to Department of Laboratory Medicine Leadership team for review and comment. See Departmental Policy **AD DP 09: Quality Planning and Management Program.**

## **QSE: Process Improvement**

The Boston Medical Center Transfusion Service believes that the effort and cost of well-designed processes and procedures is less than the cost of correcting errors at a later time. When internal or external assessments demonstrate that a process is not providing the expected quality outcome, continuous improvement techniques are applied. Employees are trained in the organization's continuous improvement process and use these techniques when internal problems have been identified. Follow-up monitoring assures that the corrective action continues to be effective.

1. The following activities serve as a source of ideas for process improvement:
  - External assessment report findings (FDA, Joint Commission, AABB, CAP, FACT)
  - The findings from quality indicators of operating systems and internal quality audits
  - Reports of customer complaints
  - Analysis of incident, error, accident reports
  - Review of any selected process to determine if the process can be made more efficient and effective
  
2. BMC uses an approach to problem resolution that includes:
  - Identification, prioritization and selection of problems to be resolved
  - Use of data collection and data analysis tools
  - Implementation of process changes, where appropriate
  - Evaluation of applied solutions for effectiveness in solving the problem
  
3. Statistical tools to analyze numeric data are used when appropriate.

### **QSE: Facilities and Safety**

The Boston Medical Center Transfusion Service provides safe and adequate environmental conditions in the workplace as part of the laboratory's overall environmental safety plan.

1. As part of the hospital's mandated environmental control program, procedures are maintained and training is provided and documented for:
  - Emergency preparedness
  - Chemical hygiene ("right to know")
  - Blood borne pathogens
  - General safety
  
2. Apheresis activities, such as stem cell collection and therapeutic apheresis are conducted in Dialysis unit (Menino basement), outpatient chemo clinic (Moakley 3) and inpatient units.

### **Attachments**

See SOP I 008 Appendix A for current Organizational Chart - Transfusion Medicine



EXCEPTIONAL CARE. WITHOUT EXCEPTION.

***Blood Bank & Transfusion Medicine  
Transfusion Service Manual TS 020***

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## **Investigation of Suspected Transfusion Reactions**

### **1.0 Purpose**

- 1.1 To explain the blood bank workup of a suspected transfusion reaction.

### **2.0 Scope**

- 2.1 Suspected transfusion reactions of any blood components reported to the blood bank.
- 2.2 All reported transfusion reactions are evaluated utilizing standardized NHSN criteria.
- 2.3 Transfusion-transmitted disease (such as hepatitis) is covered under “Recall and Lookback policy”.
- 2.4 Suspected delayed hemolytic or serologic transfusion reactions, either reported to the blood bank or suspected by the blood bank.

### **3.0 Specimen**

- 3.1 EDTA samples (2 pink tops are requested), and urine sample if applicable, from patient.
- 3.2 Blood bag of the unit implicated in suspected reaction.

### **4.0 Equipment and Materials**

- 4.1. As required for direct antiglobulin test
- 4.2. As required for ABO/Rh testing
- 4.3. As required for blood culture

### **5.0 Calibration**

- 5.1 This section is not applicable for this procedure.

### **6.0 Quality Control**

- 6.1 This section is not applicable for this procedure.

### **7.0 Procedure**

- 7.1 House Officers or Nursing personnel should print out a “Transfusion Reaction Investigation” form from Epic and submit form with patient samples and blood bag. If



hemoglobinemia, hematuria or hemolysis is mentioned on the form, notify the medical director immediately.

- 7.2 Test **TRXN** is ordered through Epic to download into Sunquest, if not, order using **Order Entry**. Label all specimens, including urine, with the lab labels. Note the Accession number on the Transfusion Reaction form.
- 7.3 Consult with the Medical Director in the case of a suspected delayed hemolytic or serologic transfusion reaction. Blood Bank staff may initiate a test **TRXN** in the event of a suspected delayed reaction.

**NOTE: A positive workup in the absence of positive results pre-transfusions (DAT, Antibody screen/ID, incompatible crossmatch) indicating a delayed hemolytic transfusion reaction is a Critical Alert Value and must be called to the patient's health care provider. Document this call as a comment in the TRXN test, including name of health care provider, credentials, phone # and time.**

- 7.3.1 Suspect a delayed reaction when a new antibody is identified in a recently transfused patient (up to 3 months post transfusion).
- 7.3.2 Plasma may be hemolyzed, but typically, delayed reactions are extra-vascular, with clear plasma.
- 7.3.3 A drop in hematocrit post transfusion with no other explanation may be the only sign of a delayed reaction.
- 7.3.4 A positive DAT post transfusion must be investigated as a potential delayed serologic reaction. Perform an eluate as per **TS007 Elution Techniques**.
- 7.3.5 A pre-transfusion specimen may not be available for suspected delayed reactions. Result all pre-tests in the TRXN battery as Not Done.
- 7.3.6 Add tests to the TRXN battery as appropriate: LGXM, Eluate, etc.
- 7.4 Centrifuge one sample immediately. While sample is spinning, verify records (see below). Visually check the plasma for hemolysis. Locate the pre-transfusion sample (if applicable) and compare the post plasma color with the pre plasma color. If hemolysis is noted in the post sample but not in the pre sample, notify medical director immediately.
- 7.5 Verify records.
  - 7.5.1 Check the group and type on the blood bag and the patient's transfusion record (unit tag).
  - 7.5.2 Examine the bag for clots, color, gas, etc.

- 7.5.3 Check the unit tag carefully. Make sure that the intended recipient was the actual recipient.
- 7.5.4 Check the patient's name, hospital number, unit number, blood group, negative for antigens as necessary (i.e. Kell neg if patient has anti-Kell), expiration date in the laboratory computer system.
- 7.5.5 Complete the Clerical Check test in Sunquest in the TRXN battery.
- 7.5.6 If the bag has not been returned, attempt to have it returned. If unavailable, complete a clerical check with what is available, noting that the bag was discarded.
- 7.5.7 If any information does not agree, notify Medical Director immediately.
  
- 7.6 Perform ABO/Rh on the post sample. Compare and verify blood type with pre-transfusion computer records. Record results on patient worksheet and Sunquest. If any information does not agree, notify Medical Director immediately.
  
- 7.7 If the only symptom noted is "hives", no more workup is necessary. Otherwise, proceed to perform direct antiglobulin test.
  
- 7.8 Direct Antiglobulin Test.
  - 7.8.1 Pre-sample (occasionally for platelet and FFP transfusions a recent pre-sample is unavailable). Perform poly-specific, anti-IgG and anti-complement.
  - 7.8.2 Post sample. Perform poly-specific, anti-IgG, and anti-complement.
  - 7.8.3 Record results in Sunquest, and on patient worksheet.
  
- 7.9 Urinalysis
  - 7.9.1 Send urine sample if received to hematology for urinalysis and microscopy. Order test **URC**. Label the urine with this accession number, send to Hematology Lab for analysis. Note the accession number on the reaction form.
  
- 7.10 Additional serologic testing
  - 7.10.1 Continue on to *pre* ABO/Rh rechecks, antibody screening, and crossmatches if:
    - clerical check does not agree, OR
    - post DAT is positive and pre DAT is negative, OR
    - serum is pink in the post sample, OR
    - the symptoms noted include hemoglobinemia, hematuria or hemolysis.
  
- 7.11 Bacteriologic testing

NOTE- If Yersinia is suspected, contact microbiology for current culturing instructions.

- 7.11.1 If temperature increase is more than 3°F and the post reaction temperature is greater than 101°F, or as requested, perform bacteriologic culture per SOP TS 021 "Blood culture of banked blood and blood components".

- 7.11.2 In function RE, create a new patient. Medical Record Number and patient name:
- BBK- (computer assigns next number)
  - BBK,donor number

7.11.3 Test code **BC** for blood culture.

7.11.4 Label blood culture bottles with computer labels; note the accession number on the reaction form.

7.11.5 Enter if blood culture was done under TRXN test battery in Blood Culture Required field. Enter YES if done and Not Done if not required. See Section 9.0 Reporting Results.

7.12 Notify medical director or designee, who will give preliminary interpretation and recommendations. Document in the laboratory computer system using MD Interpretation codes.

7.13 Place component bag in “reaction drawer” in the refrigerator, to be kept for at least one week.

## 8.0 Calculation/Interpretation

8.1 Preliminary interpretation of reaction investigation will be done by medical director or designee, and communicated to nursing unit via computer system.

8.2 Final interpretation will be performed by medical director or designee when all test results become available.

8.3 After final sign off by medical director or designee, paperwork will be given to supervisory staff who verify all charges are entered, tests resulted, and recommendations entered for each work up. See section 10.8.

## 9.0 Reporting Results

### 9.1 Blood Order Processing

9.1.1 Enter Medical Record number

9.1.2 Select appropriate accession number.

9.1.3 Enter results using result codes in the next few charts. Remember before any code is entered type “;” semicolon

Test	Result
ABO/Rh.	Use blood type codes.
	BTNT (no samples submitted.)
Unit Number	Free text the suspect unit number. “;W#####” If multiple units are suspect, multiple unit #s can be entered.

Blood Culture Required	If done enter YES (Yes) If not done enter n or ND (Not Done)
Clerical Check	Use the following coded keys:
	Correct Clerical Check (CCOR)
	Incorrect Clerical Check. (CINC)
	Free text “; <b>DONOR BAG NOT RETURNED</b> ” if applicable.
Pre-Transfusion Specimen Appearance	;appearance codes. (see below) n = Not Done (no sample)
Post-Transfusion Specimen Appearance	;appearance codes. n = Not Done (no sample)
Pre-Transfusion DAT	<b>N</b> = Negative n = Not Done (no sample) <b>P</b> = Positive
Post-Transfusion DAT	<b>N</b> = Negative n = Not Done (no sample) <b>P</b> = Positive
MD Interpretation	Use “; <b>MD Interpretation</b> ” codes
BB Problem	Use “; <b>MD Interpretation</b> ” codes (same as above)

<b>Appearance Codes</b>	
<b>YEL</b>	Yellow
<b>DY</b>	Dark Yellow
<b>PY</b>	Pale Yellow
<b>SLH</b>	Slight Hemolysis
<b>MODH</b>	Moderate Hemolysis
<b>MKDH</b>	Marked Hemolysis
<b>GHEM</b>	Gross Hemolysis
<b>BRWN</b>	Brown

**NOTE: MD Interpretation codes are for the RXIN test within TRXN. RXIN is limited to the following codes ONLY. If a code does not work, verify entry and notify Supervisory staff for guidance.**

<b>MD Interpretation Codes</b>	
<b>TAD</b>	Transfusion associated dyspnea
<b>FNHTR</b>	Febrile non-hemolytic transfusion reaction. Consider premedication with antipyretics.
<b>DSTR</b>	Delayed serologic transfusion reaction
<b>TAGVHD</b>	Transfusion-associated graft vs. host disease
<b>PTPP</b>	Post transfusion purpura
<b>TTI</b>	Transfusion-transmitted infection

<b>UNKW</b>	Unknown/Other
<b>SUT</b>	Symptoms unrelated to transfusion.
<b>TACO</b>	Transfusion associated circulatory overload
<b>TRALI</b>	Transfusion-related acute lung injury
<b>ALLRX</b>	Allergic reaction. Consider premedication with antihistamine.
<b>HYPRX</b>	Hypotensive transfusion reaction
<b>AHRX</b>	Acute hemolytic transfusion reaction
<b>DHRXN</b>	Delayed hemolytic reaction
<b>CLINN</b>	See clinical note for additional details and recommendations.
<b>RTMD</b>	REVIEWED BY Reggie Thomasson, MD

9.2 File results. MD Interpretations added at the BB Patient Problem Info prompt will automatically be added to the patient's BAD file. (To order this test, add “,” comma in Add Spec. Test;)

9.3 Editing results.

- 9.3.1 Select test to be modified
- 9.3.2 Enter new result or TAB to 2<sup>nd</sup> line to add additional information.
- 9.3.3 Hit TAB
- 9.3.4 You will get a QA Warning of “Specimen test result modification
- 9.3.5 Acknowledge it with a check in the box and then hit OK
- 9.3.6 Save. You will now have to override the QA Failure.

## 10.0 Procedure Notes

- 10.1 Time is of the essence in the investigation of a suspected reaction. The goal is to obtain a preliminary interpretation by the medical director or designee within one hour of the blood bank being notified of a suspected reaction (assuming appropriate completion of form and submission of samples by the clinical service).
- 10.2 Preliminary interpretation should be performed prior to another blood component being issued to the same patient. Exception is the patient in the operating room with other components in a cooler. Communication between the blood bank staff and the clinical service is critical.
- 10.3 Acute intravascular hemolytic reactions require good communication between the blood bank physician and the clinical service to ensure appropriate patient management (such as hydration and diuresis).
- 10.4 If TRALI is suspected by the clinical team, notify medical director who will work in concert with treating physicians to investigate. Medical director or designee will also notify collecting facility in order to facilitate evaluation of the donor. The proposed

etiology is likely due to donor (occasionally recipient) antibodies directed towards white blood cells (WBC) as well as other WBC activating agents within the transfused component. This can lead to hypoxemia, respiratory failure, hypotension, fever, and bilateral pulmonary edema evidenced by the presence of infiltrates on chest x-ray. Hemolysis and cardiogenic pulmonary edema must be ruled out. The collecting facility has policies to help reduce the risk of TRALI and routinely provides information on those mitigation strategies.

- 10.5 Some transfusion reaction workups such as for TRALI (transfusion-related acute lung injury) involve the blood supplier; in these cases, final interpretation may take more time.
- 10.6 **In the event of suspected transfusion related death, notify the Medical Director, supervisor and or designee immediately!!!** The Medical Director will conduct an investigation to determine if the transfusion was directly responsible for the death. If transfusion related death confirmed:
  - 10.5.1 The Medical Director is responsible for notifying the FDA and the Chief Pathologist.
  - 10.5.2 The supervisor is responsible for notifying the Laboratory Manager and Risk Manager / Quality Assurance.
    - 10.5.2.1 The Risk Manager will be responsible for notification to the following Agencies:
      - 10.5.2.1.1 Massachusetts Department of Public Health
      - 10.5.2.1.2 Joint Commission
- 10.7 A transfusion-related fatality must be reported to the FDA immediately by telephone, fax, or e-mail; followed by a written report within 7 days. Contact information is as follows:
  - e-mail: [fatalities2@cber.fda.gov](mailto:fatalities2@cber.fda.gov)
  - telephone: 800-835-4709
  - Address:  
Office of Compliance and Biologics Quality/CBER  
Attn: Consumer Safety Officer  
10903 New Hampshire Ave  
WO71-7240  
Silver Springs, MD 20993-0002
- 10.8 In the event that the product is deemed to be at fault (i.e. bacterial contamination suspected or confirmed) or if more information about the unit is needed, (i.e. TRALI workups) the Medical Director or supervisor will notify the collecting facility.
- 10.9 Supervisory staff will ensure, all testing has been resulted, MD sign off code has been entered, See clinical note for additional details and recommendations appended and

additional recommendations and restrictions are entered. For all washed cell recommendations, the code WASHR will be entered in the BAD file.

10.10 Transfusion reaction statistics are presented to Transfusion Committee quarterly.

10.11 Transfusion reaction statistics are reported to Massachusetts Department of Public Health using CDC National Hemovigilance Surveillance Network case definition criteria.

## **11.0 Limitations of Procedure**

11.1 The workup of a delayed transfusion reaction may be different since the component bag is generally not available. Consult medical director for guidance.

## **12.0 References**

12.1 *AABB Standards*, American Association of Blood Banks, current edition.

12.2 *AABB Technical Manual*, current edition.

12.3 Final guidance for industry. Notifying FDA of fatalities related to blood collection or transfusion. FDA/CBER, September 2003.

## **13.0 Definitions**

13.1 This section is not applicable for this procedure.

## **14.0 Records**

14.1 All reaction workups and interpretations are documented in laboratory computer system and SCM and Logician clinical charts.

14.2 Paper transfusion reaction investigation forms are kept indefinitely in the Blood Bank logbook.

## **15.0 Attachment Appendices**

15.1 Appendix A: Transfusion Reaction investigation form.

15.2 Appendix B: Patient Worksheet

## **Management of Incident, Errors and Accidents**

### **1.0 Purpose**

- 1.1 The **Management of Incidents/Errors and Accidents** procedure outlines the proper method for the documenting, reporting, investigation and corrective action of occurrences within the Transfusion Service

### **2.0 Scope**

- 2.1 The Transfusion Service is designed to assure accurate reporting of test results and/or dispensing of products to a patient. When procedures are followed appropriately, the multiple check system should discover any problems/mistakes prior to reporting the test results or dispensing products. When the multiple check system identifies a possible occurrence, this procedure shall be initiated.
- 2.2 Because accurate and timely occurrence reporting is an important aspect of error management and process improvement, all occurrences are to be reported and investigated.
- 2.3 This procedure applies to errors or accidents that may affect product quality. In the transfusion service, this includes (but is not limited to):
  - 2.3.1 Incorrect identification of samples used in Transfusion Service testing (pre-analytic error)
  - 2.3.2 Errors in Transfusion Service testing; appropriate test(s) not performed (analytic)
  - 2.3.3 Administering the wrong unit for transfusion (post-analytic)
  - 2.3.4 Non-conformances or errors in stem cell processing

### **3.0 Specimen**

- 3.1 This section does not apply to this procedure.

### **4.0 Equipment and Materials**

- 4.1 **Problem Log Form** (Appendix A)
- 4.2 **Mislabeled Specimen Form** (Appendix B)
- 4.3 **Occurrence Log** (Appendix C)

### **5.0 Calibration**



5.1 This section does not apply to this procedure.

## 6.0 Quality Control

6.1 This section does not apply to this procedure.

## 7.0 Procedure

### 7.1 Identify occurrence and perform IMMEDIATE action

7.1.1 Any staff person who discovers an occurrence **MUST** immediately take the necessary steps to stop an occurrence from continuing and to gain control of a situation. Examples include, but are not limited to:

7.1.1.1 If an incorrect product was issued

- Determine the location of the product and retrieve it if possible.
- Notify Medical Director or Designee if unit cannot be retrieved and patient safety Or care may be compromised.

7.2.1.2 Erroneous Test result have been filed:

- Notify the patient's physician or designee of the corrected result
- Change results in BOP
- Update BAD file if necessary.
- Fill out the Correction Report Form and document all fields.
- Notify Medical Director or Designee if erroneous results compromise patient safety or care.

7.1.1.2 Integrity, safety, potency

7.1.1.3 All occurrences are different but the person discovering any error is responsible for doing their best to bring the situation under control and preventing further harm.

7.1.2 Submit the **Problem Log Form** to the Transfusion Service Supervisor or designee within one (1) working day.

7.1.3 Minor mislabeled specimens (not full name, hospital number cut off, etc.) will be tracked using the **Mislabeled Specimen Form** (Appendix B). These samples are not acceptable for blood bank testing.

7.1.4 Major mislabeled specimens (wrong patient's information) will be tracked using the **Problem Log Form**. In the case that the Blood Bank discovers a major mislabeled specimen (blood type discrepancy), the Blood Bank will notify all other Laboratory sections which may have received blood samples at the same time.

### 7.2 Technologist documents the occurrence on the Problem Log

7.2.1 Fill out all patient information listed.

7.2.2 Describe incident in as much detail as possible.

7.2.3 Record immediate corrective action (i.e. unit recalled or quarantined)

7.2.4 If immediate Supervisory or Medical Director notification was required or performed, document who and when such notification was made.

7.2.5 Leave all problem logs on the supervisor's door. **All urgent matters must be communicated directly with supervisor or designee.**

7.3 Transfusion Service Supervisor or designee will investigate all occurrences as soon as possible.

- 7.3.1 Determine if the occurrence is an incident which involves the Transfusion Service in any way.
- 7.3.2 Determine the source of the occurrence: Transfusion Service, a department outside of the Laboratory or a product manufacturer or supplier.
- 7.3.3 Determine if all appropriate immediate corrective action was taken and if further action is required to solve the issue.
- 7.3.4 Determine if immediate preventive action is necessary to prevent further immediate occurrences.
- 7.3.5 If occurrence is deemed to have effected patient outcomes, notify Medical Director and Risk Management (Risk Management on call pager 7233).
- 7.3.6 Medical Director will notify patient's physician as appropriate.
- 7.3.7 The Transfusion Service supervisor or designee shall classify occurrence
  - 7.3.7.1 Determine the critical control point(s) or key element(s) where the occurrence happened within the system. There may be more than one.
  - 7.3.7.2 Classify occurrence as Minor, Intermediate, Major or Sentinel event. (See definitions in Section 13.0)
- 7.3.8 Determine if occurrence requires further review or follow up either internally or externally.
  - 7.3.8.1 For cases requiring no further follow up, document retraining/education, discussions, any corrective action and sign form to indicate case has been closed.
  - 7.3.8.2 For more serious instances, continue as described in sections 7.4 and 7.5.

7.4 When necessary the Transfusion Supervisory or Designee will Determine Root Cause

- 7.5.1 Determine whether the occurrence was systematic, behavior or knowledge related.
  - 7.4.1.1 Systematic: a number of one error type committed by many individuals.
  - 7.4.1.2 Behavior: a number of errors, or many error types, committed by one individual
  - 7.4.1.3 Knowledge: a number of one error type committed by one individual.
- 7.4.2 The Transfusion Service supervisor or designee shall employ a series of problem techniques to determine the most basic reason that a problem has occurred (root cause).

7.5 When necessary the Transfusion Service Supervisor or Designee will initiate the corrective action process.

- 7.5.1 Use the following guide to determine appropriate corrective action:

7.5.1.1 Systematic: The majority of problems will relate to specific processes and their procedures:

- Using information from the root cause analysis, modify the process to rectify the problem.
- Redraw the process overview.
- Revise the operating procedure as needed.
- Complete all required documentation.
- Revalidate the process.
- Retrain, if appropriate

7.5.1.2 Knowledge

- Retrain staff member(s) involved using the operating procedure and/or training guide and competence assessment tools.
- Document all training and outcomes.

7.5.1.3 Behavior

- Follow progressive disciplinary action per BMC policy
- Document all disciplinary action per BMC policy.

7.5.2 The Medical Director shall review, approve and sign off RCA and corrective action plans.

7.5.2.1 For Stem Cell Processing corrective actions will be reviewed, approved and signed off by the Processing Facility Director, Transfusion Service Medical Director or designee, and the Processing Facility Quality Manager.

7.5.3 As needed, review the effectiveness of the corrective action with the Laboratory Quality Assurance Officer, (or designee) and/or BMC's Risk Management Department.

7.5.4 Implement approved corrective action or modify as directed.

7.5.5 Record actions implemented or modified on the **Problem Log Form**.

7.6 Transfusion Service Supervisor or designee will report occurrence, as needed, as determined by its classification and involvement of the Transfusion Service.

7.7.1 Hospital Risk Reporting System (RL)

7.6.1.1 For instances that originated or occurred in a different department and are considered Sentinel, Major, or at the supervisors discretion, will be reported in the RL System

7.6.1.2 RL system will be followed up to determine response of department causing occurrence.

7.6.1.3 Transfusion Medicine will work with departments to ensure a change in process to prevent occurrences when appropriate.

7.6.2 Notify outside agencies

#### 7.6.2.1 FDA/CBER (if applicable)

- The FDA shall be notified of all transfusion related fatalities by telephone within one (1) working day, and by written correspondence within seven (7) days after the fatality.
- The Medical Director, Transfusion Service, shall submit a letter to the FDA wherein all applicable information is documented.
- Current notification address, numbers, and online submission information is found on the FDA website.
- Record FDA/CBER file number on problem log.
- Non-fatal reportable instances are filed as written in SOP I 021 **Biological Product Deviation Reporting**.

#### 7.6.2.2 AABB/CAP/FACT

- Determination is made in conjunction with supervisor, medical director, Risk, lab QA specialist, and Laboratory Medicine leadership if accrediting agencies must be notified.
- Transfusion Medicine supervisory staff will notify AABB
- Stem Cell Coordinator will notify FACT
- Laboratory Medicine leadership will notify CAP.

#### 7.6.2.3 If determined to be necessary, Risk Management Department will

- Send notifications to Joint Commission
- Send notifications to the State of Massachusetts
- Send notification to any supplier or manufacturer if occurrence involved an instrument or reagents

7.6.3 Other than the FDA/CBER as noted in 7.7.2.1, notify agencies as required the outcome of the error investigation and corrective action within thirty (30) days.

7.6.4 Ensure all agencies/systems contacted are noted on the Problem Log. Record any tracking numbers and attach copies of written correspondences. .

### 7.7 Supervisory staff or designee fill **Occurrence Log**

- 7.7.1 Assign each problem log a 6 digit ID#: 2 digit month, 2 digit year, 2 digit sequential #. (i.e. 092001 is the first recorded problem log of September 2020)
- 7.7.2 Record the area that occurrence occurred: Transfusion Service, Stem Cell, Tissue Dispensary.
- 7.7.3 Write a brief description of the occurrence.
- 7.7.4 Record the classification: Sentinel, Major, Intermediate, Minor
- 7.7.5 Record any RL or FDA/CBER file number.

### 7.8 On going monitoring, trending, and analysis

- 7.8.1 Occurrences are monitored, tracked and/or audited by the Transfusion Service supervisor and Medical Director to determine if the corrective action has been successfully implemented.
- 7.8.2 Time frames for follow up audits will be defined in the corrective action analysis.

7.8.3 Analysis of occurrences, results of corrective action and results of follow up monitoring are made part of the Transfusion Service's report to the Department of Laboratory Medicine and Quality Improvement/Risk management

7.8.4 The Transfusion Service supervisor and the Medical Director or designees shall evaluate and compare the root causes of Transfusion Service errors to determine tendencies, patterns or trends

7.9 Pre-analytic and post-analytic errors may need to be addressed by areas outside the Transfusion Service. Transfusion Medicine will assist when appropriate to help outside departments correct any issues or system failures.

## **8.0 Calculation/Interpretation**

8.1 This section does not apply to this procedure.

## **9.0 Reporting Results**

9.1 A summary of occurrence types, actions taken and findings from Follow up monitoring are made part of the internal assessment report as scheduled. Refer to SOP I 008 Quality Plan.

9.2 Analysis of occurrences, results of corrective actions and results of Follow up monitoring are made part of the Transfusion Service's report to the facility's quality assurance or risk management function.

## **10.0 Procedure Notes**

10.1 No additional procedure notes are required for this procedure.

## **11.0 Limitations of the Procedure**

11.1 This section does not apply to this procedure

## **12.0 References**

12.1 Quality Program. Bethesda, MD: American Association of Blood Banks, 1994

12.2 21 CFR 600.14 Finished units for distribution

12.3 21CFR 606.100 (c) Investigation of discrepancy

12.4 21 CFR 606.160 Records

12.5 210 CFR 606.170 (a) Records of adverse reactions

12.6 21 CFR 606.170 (b) Notifications of fatalities

12.7 FDA-CBER Memorandum: Responsibilities of blood establishments related to errors and accidents in the manufacture of blood and blood components. March 20, 1991.

13.14 System – Major operation or function within the facility.

13.15 Trend Analysis – The evaluation of concerns, occurrences, accidents or error root causes in order to identify tendencies, patterns or trends.

#### **14.0 Records**

14.1 All records are retained as defined in the SOP I 018 **Records and Data Management** policy.

#### **15.0 Attachment Appendices**

15.1 Appendix A: See SOP I 015 Appendix A for current version of **Problem Log Form**

15.2 Appendix B: See AD DP 007 Appendix A for current version of **Mislabeled Specimen Form**

15.3 Appendix C: Example of in use **Occurrence Report Master List**

15.4 Appendix D: Occurrence Log Definitions and Guidelines

## The QinFlow Warrior:

- Warm near-freezing blood/IV fluids at up to 200ml/min, vs. only 100-150ml/min of alternative solutions
- Warm up to 3.5 liters of near-freezing blood/IV fluids with a single charge, vs. 1-2 liters of alternative solutions
- Uniquely validated to handle intense and intermittent bolus flows (more below)

The Warrior is a 3-part system composed of a controller (or Base Unit), battery, and per-patient warmer (i.e. disposable unit). Several accessories are offered so as to optimize the offering to the specific operating environments, such as mount accessory and extension cable. **Assembly is simple and fail-safe and takes seconds to accomplish.** Blood/IV fluids will be warmed almost from the first drop, even at high resuscitation rates. An LCD display indicates to the user the incoming and outgoing blood/IV fluid temperature at all times. **The consumable's fluid path is aluminum-free, thus eliminating toxicity concerns associated with aluminum.** Instead, the consumable uses patented medical grade stainless steel warming technology. The efficiency of our technology ensures immediate warming. The systems measure the blood/IV fluids' temperature a few hundred times per second and automatically adjusts the heating to ensure 38°C ( $\pm 2^\circ\text{C}$ ) output. Thus, **the Warrior and the Warrior EXTREME handle intermittent bolus flows generated by push-pull resuscitation methods (e.g. hand pump, syringe or Lifeflow-like devices which are fairly common in trauma settings), exceptionally well.** The technology has been perfected over several thousand field utilizations.

## Practically Zero Maintenance

- **Service Cycles:** 5 years between service cycles.
- **No Calibration:** No need for periodic calibration.
- Defibrillation Proof Type BF Applied Part: Safe to be used jointly with a defibrillator.
- **Simple To Operate:** Fail safe assembly. Functions on gravity feed. Flow can be regulated with pressure bag or pump (300 mmHg).
- **Same Disposable Unit Fits All Protocols:** The same disposable unit can be used for blood and fluid products.
- **No Proprietary Tubing:** Does not require proprietary blood/IV fluids line. Fits all common IV tubings.
- There are no service requirements for the system other than charging the batteries routinely. Inspection is required every 5 years.
- There are no maintenance requirements other than inspection in 5 years and recharging battery according to the required intervals.
- Batteries will be routinely rotated into the unit and onto the charger to ensure that battery life is optimized and that a freshly charged battery is available for use at all times. The unit will be accompanied by a back-up battery for all transports to prevent failure due to expended battery.

- The hardware components of the transfusion system will be maintained in redundancy in that a second QinFlow warmer and spare batteries, Blood tubing, and disposable patient unit will be carried by the transfusion medic to ensure failsafe's are addressed.
- The Warrior warming unit must be cleaned after each use. Use of common disinfectant for cleaning the reusable parts is recommended by the manufacturer. Operators shall not submerge, sterilize or autoclave any components.
- Warming Units and their components will be tested daily in conjunction with inspection and data logging of the condition and temperatures of whole blood units in cold storage.



DESCRIPTION PRODUCT INFO **SPECIFICATIONS** OPTIONAL ACCESSORIES REGULATORY STATUS

COMMERCIAL INFORMATION DISCLAIMERS REVIEWS (0)

## Specifications

### Warrior

### Warrior EXTREME

#### Performance

	Warrior	Warrior EXTREME
Max delivery rate, 4°C input	Up to 200 ml/min	Up to 200 ml/min
Max delivery rate, 20°C input	Up to 290 ml/min	Up to 290 ml/min
Battery capacity, 4°C input	Up to 3.5 liters	Up to 3.5 liters
Battery capacity, 20°C input	Up to 5 liters	Up to 5 liters

#### Physical Characteristics

	Warrior	Warrior EXTREME
Dimension (H x W x L)	23.2 x 15.6 x 7.8 cm / 9.13" x 6.14" x 3.07"	23.2 x 15.6 x 7.8 cm / 9.13" x 6.14" x 3.07"
Weight	1,720 g / 3.79 lb (Base Unit and batter)	1,720 g / 3.79 lb (Base Unit and batter)

#### Battery Characteristics

	Warrior	Warrior EXTREME
Battery Type	Rechargeable, Li ion, 21.6V, 4.6Ah, 99.36Wh	Rechargeable, Li ion, 21.6V, 4.6Ah, 99.36Wh
Battery Charging Input Voltage	Battery Charging Input Voltage: 100-240 VAC   50-60 Hz   Max 2.0 A   12/24V	Battery Charging Input Voltage: 100-240 VAC   50-60 Hz   Max 2.0 A   12/24V
Battery Life	Battery Life: Up to 400 full cycles or 3 years	Battery Life: Up to 400 full cycles or 3 years

#### Standards and Safe to Fly

(partial list)

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Certified for IEC 60601-1</li> <li>• Certified for IEC 60601-1-2:2014 (EMC standard 4th edition)</li> </ul> | <ul style="list-style-type: none"> <li>• Certified for IEC 60601-1</li> <li>• Certified for IEC 60601-1-2:2014 (EMC standard 4th edition)</li> </ul> |
|--|--|

- Certified for IEC 60601-1-11
- Certified for the applicable sections of RTCA / DO 160G
- Compliant with EN1789

- Certified for IEC 60601-1-12
- Certified for the applicable sections of RTCA / DO 160G
- Compliant with EN1789
- Compliant with MIL STD 461G RE102 & RS103

## Environmental Specifications

Storage Conditions	-20°C to 60°C (-4°F to 140°F) & 93% RH	-20°C to 60°C (-4°F to 140°F) & 93% RH
Operating Conditions	-5°C to 40°C (23°F to 104°F)	-5°C to 40°C (23°F to 104°F)
Transient operating conditions	-20°C to 50°C (-4°F to 122°F) & 90% RH (compliant)	-20°C to 50°C (-4°F to 122°F) & 90% RH (certified)
Atmospheric Pressure / Altitude	-549 to 1,060 hPa / -400 to 4,572 meter (1,312 to 15,000 ft)	-549 to 1,060 hPa / -400 to 4,572 meter (1,312 to 15,000 ft)
Ingress Protection (IP)	IP22	IP56

## RELATED PRODUCTS

# CREDO PROMED™ SERIES FOUR CONTAINER

REV122821



## Exceptionally Soft and Comfortable...

Designed specifically for the dynamic needs of first responders, the Credo ProMed™ product line currently consists of three different sized temperature- controlled portable medical transport bags that thermally protect the integrity of valuable medical supply payloads for 48 - 96 hours.

The outer bag is constructed of highly durable ballistic nylon fabric and the patented Thermal Insulation Chamber (TIC™) panels with phase change material and VIP components contained within, are qualified to consistently protect medical materials such as blood and platelets within 2-8°C.

These hand portable, highly durable and convenient to use soft-sided bags offer: Easy conditioning of the TIC™ system panels which makes the ProMed a simple, nimble, and consistently reliable option. Once the TIC™ system panels are staged and properly placed inside the Vacuum Insulated Panel (VIP) assembly, simply insert payload content and be on your way.

Rugged and sturdy supportive interior side panels, double-stitched seams, reinforced protective corners, durable buckle straps, comfortable padded shoulder strap and a water and soil resistant protective bottom panel. A sophisticated design with a clear view pocket for business essentials and a sturdy elastic back strap designed to slip effortlessly over telescoping handles enabling secure transport.

These containers will compliment the Quantum and LifeFlow to provide a complete blood delivery package.

## Features:

- Duration: Up to 72 hours
- Temperature: 2° to 8° C
- Volume: 2L - 8L
- Outer Container: Ballistic nylon fabric with durable web strapping and secure buckles
- Standard Color: Tan

## Dimensions:

- L 8 in. x W 9 in. x D 10 in.
- Weight: 7.64 lbs

Size   Unit	Item#	NSN#
2Units	35-0011	
4Units	35-0012	
8Units	35-0013	



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# Safe-T-Vue® 10

Non-reversible temperature indicators

## Refrigerator and Temporary Container Storage Solution

- For transport of red blood cells, whole blood, and plasma
- Indication temperature 10°C
- Allows for identification of nonheat-exposed blood products for storage and future reissue
- Promotes requirements of accountability during transport
- Accuracy of +/- 0.4°C

## Cost-effective Monitoring and Quality Control

Safe-T-Vue® 10 is a blood bag temperature monitor for use by health care providers to determine if blood or blood products have reached or exceeded the indication temperature to support compliance with blood handling requirements.

## Simple to Use — Proven to Improve Compliance

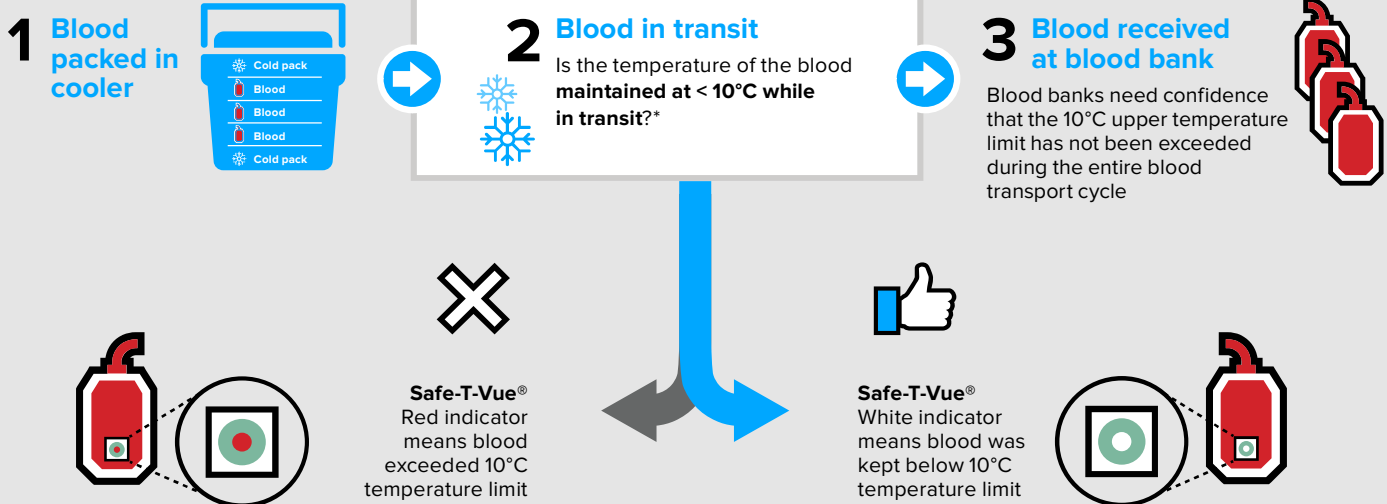
Safe-T-Vue 10 changes color from white to red when the blood has reached or exceeded 10°C. Because it is non-reversible, Safe-T-Vue will indicate that a high temperature excursion occurred, even if the blood product is recooled to below 10°C.

## Preserves Valuable Blood Supplies

As long as the indicator remains white, blood may be stored for future use.\* Safe-T-Vue indicators will constantly monitor the temperature of the blood product for the life of the unit and do not require removal on future re-issues.



**ZEBRA**  
CAPTURE  
YOUR EDGE



\* AABB standards for blood banks and transfusion services, and 21 CFR 600.15 Code of Federal Regulations for temperatures during shipment for biological products.



## Safe-T-Vue® 10

Non-reversible temperature indicators

### Cost-effective, reliable, and simple

Safe-T-Vue® 10 is applied directly to the blood bag or product to provide direct-contact temperature monitoring. Indication temperature 10°C

### Five simple steps

1. Remove the blood bag and Safe-T-Vue from the refrigerator
2. Remove label to expose adhesive
3. Attach Safe-T-Vue directly to blood bag
4. Peel foil back to expose RED and WHITE rounds
5. Fold the white round into the red round and press firmly together to activate

### Packaging

- Boxes of 50, part No. 7201-50
- Cases of 200 (4 boxes of 50 indicators each), part No. 7201-200

### Documentation

- Each box is stamped with lot number and expiration date
- All shipments contain QA documentation, also available for download on our website
- Editable validation procedures can be downloaded from our support page to allow for easy customization to your facility's validation procedures

 Video instruction on the website:  
[www.zebra.com/temppmonitoring](http://www.zebra.com/temppmonitoring)

Tap into the future of temperature monitoring at [www.zebra.com/temppmonitoring](http://www.zebra.com/temppmonitoring)

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## SINGLE-USE DATALOGGER IS THE ULTIMATE COLD-CHAIN PARTNER

Monitor materials every step of the way.

### TraceableOne™ USB Datalogger Thermometer

#### Monitor

Sensitive materials  
during transport

#### Ready to Use

Pre-programmed  
alarm parameters

#### Automatically

Download PDF  
Data Report

Download directly to PC—No Software to Install

**TRACEABLE®**  
**PRODUCTS**

# TraceableOne™ USB Datalogger Thermometer

## Features

- Logger generates PDF data report
- Supplied with Traceable® to NIST Certificate
- Download directly to PC—No software required

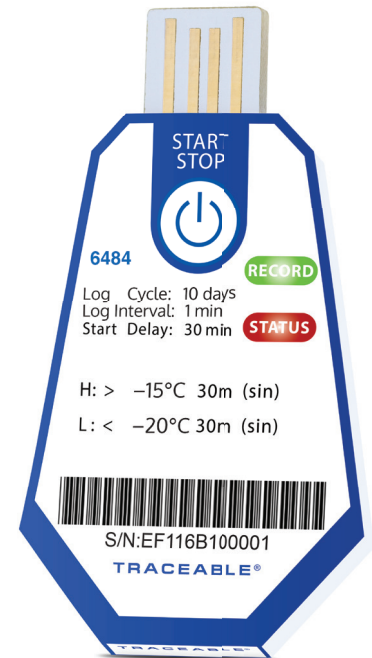
## Easy to Use

Right-out-of-the-box, use logger to track environmental conditions of reagents, clinical samples, vaccines, pharmaceuticals, and food items during transport. Press start to begin recording crucial temperature data, 30 minute time delay before logging begins.

Compact, single-use dataloggers fit anywhere—even inside a small cooler. No software or driver is required for set-up or download data. Flashing Red and Green LED indicate logger is recording data, stopped recording, and if an alarm has been triggered. Logging duration runs from either 10, 30, 60, or even 90 days. Logging Intervals update either every 1, 3, 6, or 10 minutes.

Temperature Range: -30.0 to 70.0°C (-22.0 to 158.0°F); resolution: 0.1°C; accuracy: ±0.5°C/±0.9°F (-20 to 40°C); ±1°C/±1.8°F otherwise. Pre-programmed alarm parameters for specific applications. Refrigerated transport alarm parameters: 2 to 8°C (35.6 to 46.4°F) Frozen transport alarm parameters: -20 to -15°C (-4 to 5°F). An alarm is triggered when temperatures are outside the optimal range for more than 5 minutes.

Cat. No. Qty 40/pk	Cat. No. Qty 10/pk	Logging Cycle (Days)	Logging Interval	Alarm Parameters (Low to High)
6471	6483	10	1 Minute	2 to 8°C (35.6 to 46.4°F)
6472	6484	10	1 Minute	-20 to -15°C (-4 to 5°F)
6474	6486	30	3 Minutes	2 to 8°C (35.6 to 46.4°F)
6475	6487	30	3 Minutes	-20 to -15°C (-4 to 5°F)
6477	6489	60	6 Minutes	2 to 8°C (35.6 to 46.4°F)
6478	6490	60	6 Minutes	-20 to -15°C (-4 to 5°F)
6480	6492	90	10 Minutes	2 to 8°C (35.6 to 46.4°F)
6481	6493	90	10 Minutes	-20 to -15°C (-4 to 5°F)



## Automatic PDF data report

Plug logger into any PC USB port and a PDF report is automatically generated containing data summary, graph, and user-initiated marks.

## Protective plastic pouch keeps logger dry

Water-resistant design (IP67) eliminates concerns when shipping materials with cold packs, ice, or in damp environments.

## Traceable to NIST for accuracy

Single-point, batch calibrated supplied with an individually-serial numbered Traceable® Certificate which assures accuracy from an ISO/IEC 17025:2005 (1750.01) calibration laboratory accredited by A2LA. It indicates traceability of measurements to the SI units through NIST or other recognized national measurement institutes (NMI) that are signatories to the CIPM Mutual Recognition Agreement.

CliniCool® Silver Series undercounter pharmacy/vaccine refrigerators are ideal for clinical labs, medical offices and pharmacies with a limited space and budget. These units offer superior temperature performance for safe storage of vaccines while meeting federal and state guidelines.



### Standard Product Features:

- Cycle defrost
- Microprocessor temperature controller with battery back-up (batteries included)
- Adjustable operating temperature range: +36°F to +46°F (+2°C to +8°C)
- Digital temperature display
- Digital Data Logger (DDL) meets current CDC requirements for vaccine storage and monitoring. F/C switchable, has a 3-year certification of calibration, and (1) buffered probe in product simulated solution. Min/Max memory along with Alarm event handling. USB port for downloading stored data
- Audible and visual high and low temperature alarms, with battery back up
- Remote alarm contacts
- 2 probes; 1 in air 1 in glycol bottle
- Four adjustable shelves (two large, two small) with guard rail on back to prevent product from being pushed against the back wall
- Bottom footed shelf to allow air circulation
- Back wall evaporator cover
- Forced draft circulation
- Keyed door lock
- LED light
- Magnetic door gasket for positive seal
- Leveling legs
- Probe access port (3/8")
- Powder coat exterior
- High density urethane foam cabinet and door insulation
- HFC-free refrigerant (R600a), foam insulation and packaging
- Pharmacy refrigerator/freezer toolkit and temperature logs
- Pyxis®, Omnicell® and AcuDose RX® compatible
- Cord label stating: Warning! Do not unplug the appliance or break circuit. Expensive vaccine in storage.
- Warranty: 2 years parts and labor, plus an additional 3 years for compressor parts only

### Vaccine Compliant Features

All units tested and certified to maintain temperatures within refrigerated or frozen ranges required by the CDC

(1) Data Logger with 1 bottle probe, 3 years NIST Certified of Calibration

Vaccine Storage Power Cord Warning Label

Vaccine Toolkit



Hydrocarbon refrigerant used in all CliniCool Undercounter models



## Specifications and Ordering Information:

Model	LHP-2-UR-PH	LHP-2-URG-PH	LHP-3-UR-PH	LHP-3-URG-PH	LHP-3-URB-PH	LHP-5-UR-PH
Weight lbs	91	91	85	97	85	129
Overall Height in.	21 1/4*	21 1/4*	28 7/8*	28 7/8*	30 3/4*	32 1/8*
Overall Width in.	17 1/4*	17 1/4*	17 3/4*	17 3/4*	17 3/4*	23 3/4*
Overall Depth in.	19 1/4*	19 1/4*	19 1/2*	19 1/2*	22 3/4*	24*
Interior cu. ft.	1	1	2.5	2.5	2.5	5.2
Number of Shelves	2, adj	2 adj	4 adj	4 adj	4 adj	3 adj
Door Type	solid	glass	solid	glass	solid	solid
Defrost Type	cycle	cycle	cycle	cycle	cycle	cycle
Compressor Size	1/8 HP	1/8 HP	1/8 HP	1/8 HP	1/8 HP	1/6 HP
Plug (Receptacle)	5-15P	5-15P	5-15P	5-15P	5-15P	5-15P
Total Amp Draw	0.9	0.9	0.9	0.9	0.9	1.3
Voltage	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz

Model	LHP-5-URG-PH	LHP-5-URB-PH	LHP-5-URBPH-ADA	LHP-5-URBG-PH	LHP-5-URBGPH-ADA	LHP-5-URBSS-PH
Weight lbs	129	137	150	150	150	135
Overall Height in.	32 1/8*	33 3/8*	31 15/16*	33 3/8*	31 15/16*	33 3/8*
Overall Width in.	23 3/4*	23 3/4*	23 3/4*	23 3/4*	23 3/4*	23 3/4*
Overall Depth in.	24*	24 1/2*	24 1/2*	25 1/2*	25 1/2*	24 1/2*
Interior cu. ft.	5.2	4.6	4.6	4.6	4.6	4.5
Number of Shelves	3 adj	2 adj, 1 fixed	2 adj, 1 fixed	2 adj, 1 fixed	2 adj, 1 fixed	2 adj, 1 fixed
Door Type	glass	solid	solid	glass	glass	Solid SS
Defrost Type	cycle	cycle	cycle	cycle	cycle	cycle
Compressor Size	1/6 HP	1/8 HP	1/8 HP	1/8 HP	1/8 HP	1/8 HP
Plug (Receptacle)	5-15P	5-15P	5-15P	5-15P	5-15P	5-15P
Total Amp Draw	1.3	1.74	1.74	1.74	1.74	1.74
Voltage	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz	115V, 60Hz

Exterior dimensions do not include 4" clearance required for installation.  
Specifications subject to change without notice.



Receptacle Required



115V/1PH/ 60Hz  
NEMA-5-15P



**LABRepCo**  
An Employee-Owned Company

## Traceable® Memory-Loc™ USB Refrigerator/ Freezer Thermometers

Datalogging thermometer that can be used in 21 CFR 11 environments

- Meets current CDC requirements and additional recommendations for vaccine storage and monitoring
- Use in 21 CFR 11 environments, raw data is locked and may not be cleared/changed on base unit
- Data-logging thermometer with fixed one minute logging interval
- Stores up to 10 unique alarm events
- Capable of storing over 1 million temperature observations
- Hassle-free retrieval of data - unit can remain in use while downloading and analyzing data
- Status indicators - Low battery, low memory, USB data transfer and active alarm state
- Supplied: stand, Velcro®, magnetic strips, wall mount, Traceable® Certificate, batteries



Cat. No.	Range	Resolution	Accuracy	Probe
LABC3-6440	-50 to 70°C	0.01°	±0.25°C	Memory-Loc™ USB Therm, 1 bottle
LABC3-6441	-50 to 70°C	0.01°	±0.25°C	Memory-Loc™ USB Therm, 2 bottles

### Specifications:

- Range: -58.00 to 158.00°F (-50.00 to 70.00°C)
- Resolution: 0.01°
- Accuracy: ±0.25°C
- Size: 2-3/4 x 4-1/4 x 3/4-inch
- Weight: 5 ounces

### Hi/Lo Alarms and Time/Date Stamps

Alarm tracking feature stores in memory each alarm event detailing when the alarm state occurred, as well as when the unit returned back to within range. Alarm state indicators include visual LEDs, audio alerts, and flashing LCD segments. Data for up to 10 different alarm events can be retrieved with the most current event viewable on the display.

### USB data transferring

All new feature allows recorded data (CSV file) to be transferred from thermometer to PC (or Mac?) using a USB flash drive (not included). No software is needed for computer interface. Each thermometer has a unique ID allowing multiple units to be used in the same location. Raw data on unit cannot be overwritten or modified. Indicator light will appear when 95% of memory is full.

### Data-Logging Features

Can be used in environments requiring 21 CFR 11 compliance. Thermometer logs 2 years of observations with a 1 minute logging interval. Device will stop recording when storage is full and will not overwrite recorded data. Data is unable to be deleted from memory once stored. Use supplied A/C adaptor for primary source of power. Batteries are intended as back-up power source.

### Highly accurate and reliable

High-accuracy thermometer has a temperature range of -58 to 158°F (-50 to 70°C) and resolution of 0.01 and maintains an accuracy of ±0.25°C across the entire temperature range. Ideal for monitoring temperatures in refrigerators, freezers, water baths, heating blocks, and incubators.

### Bottle probe features

Bottle probes are sealed in a miniature bottle (1 x 2-1/2 inches) filled with nontoxic glycol. Solution is GRAS (generally recognized as safe) by the FDA (Food and Drug Administration). Eliminates concerns about incidental contact with food or drinking water. Temperature-buffered bottle sensor eliminates rapid changes when refrigerator door is opened. Ideal for use in monitoring storage conditions for vaccines or other important samples. Meets all current CDC requirements and recommendations for temperature monitoring of vaccine storage as part of the Vaccines for Children program.

### Traceable to NIST for accuracy

An individually-numbered Traceable® Certificate is provided which assures accuracy from an ISO/IEC 17025 calibration laboratory accredited by A2LA. It indicates traceability to standards provided by NIST (National Institute of Standards and Technology). High-impact, chemical-resistant ABS plastic case is: 2-3/4 x 4-1/4 x 3/4 inches. Weight is 5 ounces. Supplied: A/C adaptor, stand, Velcro®, magnetic strips, wall mount, Traceable® Certificate, and back-up batteries. Replacement battery Cat. No. 1111.

### Traceable® Memory-Loc™ Datalogging Thermometers (patents pending)

Cat. No.:	Probe:
LABC3-6440	(2.5 x 1-inch) bottle, 1 each
LABC3-6441	(2.5 x 1-inch) bottle, 2 each

**Traceable to NIST for accuracy:** To assure accuracy, all Traceable® Thermometers are provided with an individually serial-numbered Traceable® Certificate is provided from our ISO/IEC 17025 calibration laboratory accredited by A2LA. It indicates traceability to standards provided by NIST (National Institute of Standards and Technology).

**These are the areas that the Medical Control Committee would like clarified;**

- 1) Removal of the transfusion of blood products to medical patients from the proposed protocol.  
– No real literature supporting pre-hospital blood use for medical patients. Without supporting literature and established risks and benefits of transfusing medical patients this part of the proposed protocol should be omitted. Additionally, some medical bleeds are due to undiagnosed underlying coagulopathies, or hematologic malignancies. Transfusing these patients prior to obtaining lab work makes work up and diagnosis of these conditions impossible due to the presence of exogenous blood. ~ We removed the medical portion during this phase of the application process
- 2) Include clarification on the use and maintenance of blood warmers by the participating services \_ see attached data sheet on QinFlow Warrior series warmers
- 3) Inclusion of a procedure for reporting to DPH’s hemovigilance program, especially as some locations in the proposed service area have Rhode Island Hospital trauma point of entry. - This could make hemovigilance reporting difficult as two states would be involved. Procedure should include how Rhode Island is involved in the process. – team plans to operate as a transfusion service with procedures mirroring the procedures by BMC Blood Bank where appropriate and following the requirements and recommendations of DPH.
- 4) Clarification on how information is collected should patients receiving transfused units not go to BMC due to the location of the incident and hospital diversion status. – A copy of the transfusion record will be left with the receiving facility’s emergency room staff and/or the transfusion service. The Transporting crew will obtain the medical record number for the patient and deliver a copy of the transfusion record and patient care report to the Blood Bank Director at BMC electronically, or physically during replenishment.
- 5) Inclusion of a procedure to transfer a unit of blood between two separate pre-hospital entities.  
– Patient evaluated by ground unit and transfusion begun then determined the patient will be flown. – Mirroring local hospital procedures, Prehospital Blood Product Transfusion Record will be documented and handed off to BMF crew along with relevant patient demographics and clinical findings. Transfusion crew will document the volume of LTWOB transfused prior to transfer of care and will follow up with BMF to obtain copies of patient care reports and specific data on the time of completion of the transfusion and any potential issues or problems encountered during transfer, including transfusion reactions. In the case of transferring care of Patient’s who have completed a field transfusion; the transfusion paramedics will ensure that the expended blood bag, a copy of the transfusion record, and any other relevant data accompanies the patient during hand-off to BMF crew.
- 6) Utilize Boston MedFlight and UMass Life Flight’s existing transfusion administration protocols that have an established age limit of 15 y/o and up are eligible for this treatment. - Not enough research and data to support a protocol with no lower age limit until there is more information about safety and potential complications in this vulnerable population. Following

MedFlight's and LifeFlight's protocols would bring the SPW protocol in line with what is already being done in other agencies in the Commonwealth. – Pediatric portion of protocol removed

7) Clearer explanation of QA/QI process – what is being reviewed, data collected, outcomes data, respiratory failure, hemolysis, more blood at receiving facility, who did the response team not get to and how do you identify? What are the plans for follow-up with services and facilities? This program would probably involve BMC, RI Hospital, South Shore Hospital, and BWH as receiving facilities. Follow-up outcomes data and process needs to be evaluated to ensure a standardization of care. QA/QI process will mirror recommendations from DPH. Standardization of care is based on the protocols developed in conjunction with other national services currently operating LTWOB programs. 100% follow-up of all field transfusion cases to evaluate outcomes and procedures followed by EMS. As stated in QA/QI plan, 100% of scene-call cases will be reviewed by the SPW team with immediate post case review by CFD EMS coordinator and Dr Valkanas. Crews will notify EMS supervisory team after all transfusion calls and any cases that were unable to be responded to efficiently. Outreach program will ensure follow-up with participating services to obtain feedback and inform the QA/QI process. SPW team's AHMD's will identify cases that could have benefitted from the LTWOB program and conduct M&M rounds on specific cases to foster system development and program awareness.

8) Clearer explanation of the license process/oversight of the blood in lieu of the information provided by Medflight – regulatory process mirror that is successful (mirror BMF) present a road map of regulatory process and approvals that will be required. Contact with DPH has been initiated and we are awaiting guidance from them regarding the program. Additionally, Boston Med Flight was contacted to obtain guidance on the approval process. We plan to follow the regulatory process that DPH implements so that we can successfully navigate the regulatory process and implement our LTWOB pilot program.

9) Protocol for activating the resource ~ see above activation plan: The Transfusion Paramedic Unit will be placed on the running cards at the relevant regional dispatch centers for emergent dispatch in large scale incidents such as building collapse/mass casualty by and request. Requesting service can contact Norfolk County Control/Bristol County Control/Plymouth County Control and call for Canton's Whole Blood Unit to be dispatched either directly to the scene if relevant, or to a predesignated and established access point similar to established LZ's used for aeromedical intercept. SPW team will work with the Fire Chief's Association to establish intercept locations in area communities and sections of major roadways.