Current Status: *Scheduled* **PolicyStat ID:** *10757351*

Origination: *1/13/2022*
Effective: *1/13/2022*
Last Approved: *12/14/2021*
Last Revised: *12/14/2021*
Next Review: *12/14/2023*
Document Contact: *Brooke Klapatch: Medical Technologist*
Area: *Laboratory-Blood Bank*
Key Words:
Applicability: *Royal Oak*

Transporting Blood Components in a Biofridge® - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of the document is to provide the Blood Bank staff with policies that apply to the transport of blood components in the BioFridge®.

II. SCOPE:

The BioFridge® is used to transport red blood cells (RBCs) and thawed plasma (FFP)/liquid plasma when a patient is undergoing a transplant.

III. DEFINITIONS:

A. **BioFridge®:** The BioFridge® is a portable medical refrigerator that has the capacity to store a massive pack of blood products. It operates as both a refrigerator and a cooler, depending on whether it is plugged into an electrical outlet.

IV. GENERAL INFORMATION:

A. The BioFridge® is intended to provide a massive pack of blood products for transplants only. There should never be any other ratio of blood products given in the BioFridge®. If a different quantity was requested by OR, clarification should be given to the requestor that only a massive pack is allotted in the BioFridge®. For information on the Massive Transfusion Protocol (MTP), refer to the Transfusion Medicine policy, *Providing Blood Components for Massive Transfusion*.

B. Transported RBCs and FFP/liquid plasma shall be placed in a qualified container (BioFridge®) having sufficient refrigeration capacity to cool the blood components continuously in a temperature range of 1 – 10 °C until the unit is returned to the Blood Bank.

C. The BioFridge® shall be qualified and the process validated for the appropriate transport temperature.

D. All required preventative maintenance of the BioFridge® will be conducted by Beaumont Facilities Management.

E. The BioFridge® power cord should always remain attached to the unit and should be plugged into an electrical outlet whenever possible to limit the reliance on the internal power supply.

V. SPECIFIC POLICIES:

A. Appropriate Coolants / Packing the Biofridge®

1. Unlike standard and massive transfusion coolers, the BioFridge® does not use wet ice as the coolant. The BioFridge® consists of an internal power source.
2. A National Institute of Standards and Technology (NIST) traceable data logger is placed in the BioFridge® before dispense so that the temperature of the BioFridge® may be monitored.
3. The BioFridge® has been validated to maintain the temperature of blood components for the length of time indicated in the table below.

Type of Cooler	Maximum # Blood Components	Transport Temperature	Validated Length of Time
BioFridge®	6 units of RBCs and 6 units of FFP/liquid plasma	1 – 10°C	16 hours

The BioFridge® must be used to transport blood components for a single patient only. Additional coolers may be used in addition to the BioFridge® in order to ensure blood components are always available for the patient.

B. Blood Products Dispensed in the BioFridge® Must be Returned in the BioFridge®

Returned blood products that were dispensed in the BioFridge® must be returned in the same BioFridge® in which they were dispensed. If a blood product is returned to the Blood Bank but is not in the BioFridge®, refer to the *Discard or Quarantine of Blood Products* section of this document.

C. Tracking of the BioFridge®

1. The Blood Bank should be able to track the BioFridge®, and the location to where the BioFridge® is issued should be determined. For example, when the BioFridge® is dispensed to the operating room, the OR number is documented on the pink copy of the crossmatch tag, and the BioFridge® name should be documented on the pink copy of the crossmatch tag. The pink copy is then placed in the slot of the hanging tray with the timer corresponding to the BioFridge® located at Triage.
2. The BioFridge® should not be transported with a patient as the patient is transported to a new location in the hospital.

D. Determination of Whether a Product Returned in the BioFridge® is Acceptable for Reissue

1. The BioFridge® should be returned within the acceptable, validated length of time, as indicated in the table above, regardless if it was plugged in or not while outside the Blood Bank.
2. The temperature of each RBC and FFP/liquid plasma unit should be taken with the infrared thermometer. The BioFridge® has an external temperature display to indicate the current device temperature. In addition, a NIST traceable data logger will be started and placed within the BioFridge® to continuously monitor the temperature of the storage device. This data logger will be connected to a computer and the

temperature points will be downloaded using the MaxiThermal computer program. The temperature of each product, external temperature display, and the temperature points of the data logger must be within the acceptable transport temperature range of 1 - 10°C.

3. All units must be visually inspected upon return to the Blood Bank in a cooler. Refer to the Transfusion Medicine policy, *Visual Inspection of Blood Products*.
4. The technologist returning the BioFridge® must verify that the blood products have been returned within the validated 16 hour period.
    a. The technologist returning the cooler must determine whether each of the products in the cooler is acceptable for reissue. This determination includes the following:
    b. Assessment of the length of time that the BioFridge® was outside of the Blood Bank;
    c. Assessment of the blood product and BioFridge® temperatures;
    d. The visual inspection;
    e. Verification that the product was not entered;
    f. And for RBCs, verification that an integral segment remains attached.
5. For additional information, refer to the Transfusion Medicine policy, *Return of Blood Products* in the *Determination of Whether a Blood Product is Acceptable for Reissue* section of the document. Blood products should be placed in quarantine or discarded, as appropriate, if any of these conditions have not been met.
6. Upon return of the BioFridge® to the Blood Bank, the crossmatch tag should be removed, and the corresponding pink copy of the crossmatch tag should be documented with the following information:
    a. The temperature of the unit, including the decimal point (as taken with the thermometer).
    b. The temperature of the BioFridge®, taken off of the external display of the BioFridge®
    c. The determination of whether the product is “OK to reissue.” Circle the applicable “Y” (YES) or “N” (NO).
    d. The reason that the blood product was returned.
    e. The returning technologist’s initials.
    f. The date and time the blood product was returned to the Blood Bank (time stamp).

E. Determining Whether the BioFridge® is Suitable for Subsequent Dispensing Once it has Been Returned

When the BioFridge® is returned to the Blood Bank, it is the responsibility of a technologist to evaluate the condition and battery life of the BioFridge® to determine whether or not it can be reissued. If the voltage displayed on the power supply capacity status volt meter is 12.1V or higher, then it is acceptable to use the BioFridge® immediately for subsequent dispensing. If the displayed voltage is below 12.1V, then it is likely that the BioFridge® has not been plugged in and should be charged prior to subsequent dispensing.

F. Discard or Quarantine of Blood Products

1. Any blood product that is not suitable for transfusion or that has an unsatisfactory visual appearance must be discarded. If a technologist has any concerns about whether a blood product is suitable for transfusion, then the blood product should be placed into quarantine.

2. For additional information, refer to the Transfusion Medicine policy, *Return of Blood Products* and the Transfusion Medicine policy, *Blood/Tissue Product Quarantine or Discard*.
3. If a blood product is dispensed in the BioFridge®, but returned outside of the BioFridge® or in a different cooler (but the product temperature is still acceptable), then proceed as follows:
    a. Quarantine the product if it is an antigen negative RBC (confirmed or preliminary negative).
    b. Discard the product if it is an RBC that is not antigen negative.
    c. Discard the product if it is an FFP/liquid plasma.

G. Downloading and Initializing the Data Logger

The data logger will be used in the BioFridge® following the same guidelines and setting as it is used for the helicopter cooler. Refer to the section *Data Logger Download* in the Transfusion Medicine policy, *Preparing and Dispensing Components for the Helicopter* for information on downloading and initializing the data logger. All downloaded data logger files from the BioFridge® will be saved in the BIOFRIDGE DATA LOGGER folder on the V:/ Drive instead of the HELICOPTER DATA LOGGER folders.

VI. EQUIPMENT AND SUPPLIES:

A. BioFridge® Model BFT-15 Portable Refrigerator Unit
B. Fischer Scientific Data Logger with USB Cradle
C. MaxiThermal computer program
D. Zip ties
E. Timers
F. Infrared thermometers (to take temperature of each returned component, stored in labeled drawers at Triage and near the irradiator)

VII. PROCEDURE:

A. Preparing the BioFridge® For Dispense

1. The BioFridge® should only be dispensed for transplants upon request. Follow the steps below when preparing and issuing the BioFridge®.
    a. Verify the BioFridge® was previously plugged in and the internal power supply has a sufficient charge. This charge is displayed on the side of the BioFridge®.
    b. If a data logger is not already zip tied to the metal basket within the BioFridge® compartment, obtain one from the walk in refrigerator and zip tie it to the compartment basket. It is not required to place the data logger in a biohazard bag.
    c. Verify the data logger has been properly initialized by confirming the display reads “27 Days” with a crescent moon displayed. Once verified, press the start button on the data logger until the data logger screen starts blinking REC.
    d. Verify all blood products are ready for dispense as described in the Transfusion Medicine policy, *Dispensing Blood Components*. Issue the blood products in the Blood Bank computer system. Indicate that the blood products are being issued in the BioFridge® during this step.

e. Gently place all RBC and FFP/liquid plasma blood products into the BioFridge® basket within the refrigerated compartment.

   i. All 12 blood products will fit into the compartment by loading the blood products in two rows with 6 units on the bottom and the other 6 units resting on top of them.

f. Close the clear compartment door followed by the main top lid of the compartment. Verify the top compartment lid is securely latched using the metal latch on the side of the BioFridge®.

g. If a platelet is being dispensed along with the BioFridge®, the platelet should not be placed within any of the BioFridge® compartments. The platelet should be placed in a separate biohazard bag and given to the employee that is transporting the blood products.

h. Start a triage timer for 14 hours. Keep the dispense form with the pink copies of the crossmatch tag in a slot on the hanging rack with the corresponding timer.

B. Return of the BioFridge® Back to the Blood Bank

1. The BioFridge® should be returned to the Blood Bank within 14 hours of dispense. Note that there is a label on the BioFridge® stating this policy. This policy applies even if the BioFridge® has been plugged into an electrical outlet while outside of the Blood Bank. Follow the steps below each time the BioFridge® is issued from the Blood Bank.
2. When the BioFridge® is issued, a triage timer should have been set for 14 hours. If the timer sounds indicating that 14 hours have elapsed since the BioFridge® was dispensed, call the patient's caregivers and notify them that the BioFridge® must be returned to the Blood Bank. Document this notification on the dispense form.
3. When the BioFridge® is returned to the Blood Bank, the BioFridge® and all blood components within must be evaluated. Refer to the *Determination of Whether a Product Returned in a Cooler is Acceptable for Reissue* section of this document.
   a. If the returned blood products are deemed acceptable for reissue, the blood products may be returned back into available status.
   b. If the returned blood products are not deemed acceptable for reissue, the blood products should be returned and placed into quarantine or discard status, as appropriate.
      i. Take the temperature of each returned blood product and document on the pink copy of the crossmatch tag.
      ii. Submit a variance report, quarantine or discard the returned blood products, and document on the *Communications and Daily Blood Bank Rounds Log*.
4. Attach the downloaded MaxiThermal printout with the data logger temperature points to the pink copies of the crossmatch tag and the dispense form.
   a. The Graph and Summary should always be printed. If the number of high or low alarms is greater than zero, the entire set of data points should be printed and attached as well.
5. Re-initialize the data logger and place it back into the BioFridge® so it is ready to dispense again.
   a. Refer to the Transfusion Medicine policy, *Preparing and Dispensing Components for the Helicopter* for information on initializing the data logger.
6. Verify the BioFridge® is plugged back into an electrical outlet in order to maintain a maximum charge on the internal power supply.

VIII. REFERENCES:

1. AABB, Standards for Blood Banks and Transfusion Services, current edition
2. AABB, Technical Manual, current edition
3. BioFridge™ Portable Medical Refrigerator Unit Instruction Manual. Revised December 1, 2017.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	12/14/2021
	Craig Fletcher: System Med Dir, Blood Bank	12/13/2021
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist	11/19/2021
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	11/19/2021
	Rebecca Thompson: Medical Technologist Lead	11/19/2021
	Brooke Klapatch: Medical Technologist	11/18/2021

Applicability

Royal Oak