

Apheresis Licensing Workshop

Gambro BCT-Specific Information

Presentation Outline

- Gambro BCT support material and intended use
- Revised FDA License Checklist (Trima[®] system and Trima Accel[®] system)
- Summary of Trima-specific requirements and best practices
- Comments regarding 7-Day Platelets
- Information regarding product labeling
- Helpful web resources / contact information

Documents to Support Licensing

- *Trima Accel[®] Automated Blood Collection System Operator's Manual*
- *Trima Accel[®] Automated Blood Collection System Administrator's Guide*
- Customer letters
- Platelet bag storage recommendations
- 7-day platelet literature

All documents state Gambro BCT manufacturer recommendations

All documents are available at www.gambrobct.com

Documents to Support Implementation

- Additional literature is designed to help customers plan and execute a successful implementation
 - Training Checklist
 - Quick Reference Guide
 - Example SOPs / Validation Plans
- Additional literature is *not* intended to introduce additional requirements

Documents to Support Implementation

- Gambro BCT Guides
 - RBC Process Control Guidelines
 - Leukoreduction RBC Process Control Guidelines
 - Guide for Platelet and Plasma Collections
- These documents are currently under revision, and provide:
 - Description of how to take product samples
 - Example SOPs
 - Formulas and conversion factors used to calculate product content

Revisions to License Checklist

- Trima-specific section:
 - Page 17: Revised product combination listing
 - Page 17: RBC loss section
 - Version 5: Removed volume loss for “Platelet only”
 - Page 18: LR RBC section:
 - Removed statement requiring the Trima RBC to be “stored at 4°C for > 8 hours” prior to leukoreduction
 - Page 18: Concurrent Plasma section
 - Clarified: 600 mL max plasma volume = bag specification

Revisions to License Checklist

- **Trima-specific section:**
 - Page 18: RBC section
 - TBV > 4500 mL applies only to dRBC collections
 - Page 18: Donor Profile: RBC section
 - Removed RBC loss statement
- **Leukocytes Reduction Review Checklist: General**
 - Page 2: Other criteria consistent with manufacturer's directions:
 - Removed the statement that "Trima: may include a minimum RBC volume of 160 mL"

Gambro BCT

Platelet Storage Recommendations

Storage Parameter	Recommended Ranges
Volume per bag	100 to 400 mL
Platelet concentration	1.0 to 2.1 x 10 ⁶ / μL
Maximum total platelets per bag	≤ 5.1 x 10 ¹¹ platelets
Temperature	22 ± 2°C

Summary of Gambro BCT Device Specifications

- Plasma storage bag
 - Maximum collect volume/bag: 1000 mL
 - Maximum volume frozen/bag: 600 mL
- Collection specific
 - Maximum volume removed per collection:
up to 15% donor TBV

Summary of Trima Accel Device Specifications

- Trima donation requirements (donor-specific)
 - Same as for routine WB donors
 - dRBC donors must have TBV > 4500 mL
- Trima Accel rWBC (leukoreduction) claim
 - < 5×10^6 WBC per collection
- Trima Software Upgrade Matrix


Validation

- Plasma and platelet volumes collected
 - $\pm 10\%$ display volume
- RBC product volume collected
 - RBC product volume + 100 mL AS3 within $\pm 10\%$ display volume + 100 mL AS3
- Example validation plan

Best Practice: Obtaining Donor Pre-Hematocrit

Ideal	Same day venous test result
Good alternative	Same day finger stick test

Best Practice: Obtaining Donor Pre-Platelet Count

Ideal	Same-day venous sample: value entered at or near start of procedure	5% variance
Good Alternative  Least Desirable	Average of last 3 venous pre-counts	8 to 15% variance
	Pre-count from last donation	No data
	Machine default or calculated average mean	30% variance

7-Day Platelets

- Limited to Gambro BCT and Fenwal apheresis platelet products
- Both registered and licensed facilities may apply
- Prior FDA approval required for each facility
 - Request an exception or approval to use an alternate procedure (i.e., store platelets 7 days)
 - Use PAS process to make request

Product Labels

- Refer to
 - AABB & ICCBBA websites
 - Gambro BCT website
 - For codabar to ISBT product code crosswalk for Trima products
 - PASSPORT study
 - For 7-day platelet product code list

Helpful Resources

www.gambrobct.com

www.passportstudy.com

www.iccbba.org

www.aabb.org

www.fda.gov/cber

Contact Information

Gambro BCT
24 Hour Customer Support Center

1-877-339-4228
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