These checklists are a composite of bullet points from (1) regulations, (2) guidance documents, and (3) apheresis device manufacturer directions/specifications that have been a useful reference to the minimum requirements that should be contained in apheresis submissions. The checklists are living documents that undergo regular revision as the source materials change. They do not constitute current or future review policy. Note that the device manufacturer directions/specifications are also subject to change at any time and the latest versions from the manufacturer should always be consulted.

Components of the checklist:

Apheresis RBC Review Checklist: General represents bullet points from "Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods", February 2001.
Leukocyte Reduction Review Checklist: General represents bullet points from "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products", May 29, 1996.
Platelet Pheresis Review Checklist: General represents bullet points from "Revised Guideline for the Collection of Platelets, Pheresis", October 7, 1988.
Infrequent Plasma Donors Checklist: General represents bullet points from "Revision of FDA Memoradum of August 27, 1982: Requirements for Infrequent Plasma Donors", May 10, 1995.
SOPs and Labeling: represents bullet points for required documents to submit QC sheets: represents regulatory requirements for records and documentation

As of the date of the document, each device manufacturers directions/specifications for:

Baxter ALYX
Haemonetics MCS Plus LN 8150
Haemonetics MCS Plus LN 9000
Trima Version 5.1 (should also apply to version 4 and above except where noted)
Amicus (Baxter)

Version: July 2006

Apheresis RBC Review Checklist: General

"Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods, February 2001".	
Quantitative method of Hct or Hgb determination	
RBC loss: • 1 RBC including platelets and/or plasma deferred for 8 weeks o if 1 RBC **only**, may donate platelets or plasma by apheresis within 8 weeks if extracorporeal RBC loss is < 100 mL • 2 RBC deferred for 16 weeks • During incomplete procedure If < 200 mL, no deferral o If 2nd loss of < 100 mL in subsequent 8 weeks (total < 300 mL in 8 weeks), defer for 8 weeks from 2nd donation o If total RBC loss in 8 weeks ≥ 300 mL, defer for 16 weeks from last RBC loss • If ≥ 200 mL but < 300 mL, defer for 8 weeks • If ≥ 300 mL defer for 16 weeks	
Validation criteria: *actual validation and data not required in submission* • 100 consecutive units from all devices; single and double 95% compliance to pass or repeat • Expected/target values per manufacturer compared to actual • Other criteria per SOP (*see AABB below*)	
Monthly QC: • 50 total per site; at least one single • 95% compliance or validation repeated • Expected/target values per manufacturer compared to actual (*may be done on each donation rather than as part of QC*) • Other criteria per SOP (*see AABB* below)	
Informed consent: • Description of procedure • Donation frequency • Description of foreseeable risks: complications at venipuncture site; tingling or tremor due to anticoagulant, nausea, vomiting, light-headedness, fainting, dyspnea, dizziness, pallor, feeling of warmth, chills, excessive tiredness, or convulsions due to change in blood volume • Opportunity to refuse procedure; voluntary and consent may be withdrawn at any time • Right to ask questions • Statement that long term effect of lymphocyte reduction is unclear • Donor has reviewed information regarding spread of AIDS and should not donate if at risk	
Previously approved manipulation of products NOT requiring SOPs or data • Irradiation (*refer to BPB checklist*) • Freezing and/or deglycerolization (*refer to BPB checklist*) • Leukocyte reduction by filtration (*refer to BPB checklist*)	
AABB Standards for validation and QC: • Mean Hgb of ≥ 60g or 180 mL per unit AND • 95% Hgb > 50g or 150 mL per unit	
Concurrent plasma: There is no QC required for plasma. However, evidence of monitoring volume per the manufacturers specifications is required.	

Version: July 2006

Leukocyte Reduction Review Checklist: General

"Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products", May 29, 1996	
Use of validated or cleared device (Flow cytometry, Nageotte, Imagn)	
Criteria: • < 5.0 x 10e6 WBC per container (*plateletphereisis device claims are **per collection**)* • ≥ 85% recovery • Platelets Pheresis (doubles and triples): When the collection rWBC count is ≥ 5.0 x 10e6, the device has failed to LR and a failure investigation should be initiated. Counting each of the "baby" bags and labeling as LR if the rWBC count < 5.0 x 10e6 is appropriate providing a failure investigation of the collection is completed.	
Validation criteria: *guidance does not address validation nor require it be submitted with application*	
QC: • 1% of collections for each product type, selected at random; if less than 400 per month, then 4 of each product type • 100% compliance for labeling; *we accept 95% compliance for testing* • Units should not be re-filtered (*Trima allows-filtering of platelets flagged as > 5.0 x 10e6)*)	
SOPs to include: • Name of device manufacturer • Additional QC per manufacturer o Including method of investigation of QC failures • Time period when LF is performed (consistent with manufacturers directions) • Description of STCD use *(not needed)* • Handling of units that do not meet criteria for labeling of LR	

Other criteria consistent with manufacturers directions:
• Trima, Amicus, Spectra LRS Turbo 7.0 plateletpheresis: do not use filtration so residual WBC count QC is required; evidence of 85% component recovery is not.
• ALXY RBCs and Haemonetics MCS+ 9000 plateletpheresis with LN994CF filter are auto-filtered: residual WBC count is required, evidence of 85% component recovery is displayed by the device software
• Any other manufacturers post-filtration specifications are required to be included in an SOP; they may or may not be part of QC:
  o Haemonetics MCS Plus LN 8150: mean RBCs ≥ 153 mL
  o Trima: may include a minimum RBC volume 160 mL	

Trima upgrades from 4.0 to 5.0, 5.01 and 5.1 affect plateletpheresis only; both improved count and leukocyte reduction. *Other components may be approved without review of data.*	
AABB standards for QC and validation: • Mean Hgb of ≥ 51g or 153 mL per unit AND • 95% Hgb > 42.5g or 128 mL per unit	

Residual WBC limit of 5.0 x 10e6 is: Per **collection** for plateletpheresis (see above exception for labeling) Per **unit** for RBCs (including double RBCs)	

Version: July 2006

Platelet Pheresis Review Checklist: General

"Revised Guideline for the Collection of Platelets, Pheresis", October 7, 1988	
Donation criteria • 48 hrs between donations; 2 per 7 days; 24 per year maximum • Total volume per donation limited to 500 mL; 600 mL if 175 lbs • RBC loss o Donation of 1 unit of WB or 450 mL RBC loss during pheresis deferred for 8 weeks o Maximum per year should not exceed RBC loss allowed for whole blood collection	
Donor criteria • Platelet count pre-donation, minimum 150,000; may use pre count or post count from previous donation *(always question automatic use of default)*	
Misc • Physician available within 15 minute • Written procedure for managing cardiopulmonary adverse events • Personnel should have specialized training and periodic refresher • Equipment standardized and calibrated on a regular basis • Sterility testing during validation • Plt cnt/volume/pH QC may be done at time of issue • Component processing • Routine (daily) o Plt cnt on all collections o Separated plasma should be observed for hemolysis o Hct on products with visibly apparent RBCs; if more than 2 mL, sample should be attached for compatibility testing • Monthly QC o 4 collections per machine type, per product type, per site *Note: this does not need to include both bags of a double or all three bags of a triple* o 75% meet absolute plt cnt of 3.0×10^{11} o 100% meet pH of ≥ 6.0 o At expiration of time of issue	
Informed consent • Description of procedure • Description of foreseeable risks o Side effects of procedure o Hazards of solutions/drugs given • Opportunity to refuse procedure; voluntary and consent may be withdrawn at any time • Right to ask questions • Long term effect of lymphocyte reduction is unclear • Donor has reviewed AIDS information and should not donate if at risk *(may be in regular donor history questionnaire)*	

Version: July 2006

Infrequent Plasma Donors Checklist: General

"Revision of FDA Memoradum of August 27, 1982: Requirements for Infrequent Plasma Donors", May 10, 1995	
Donation every 28 days (or less)	
Plasmapheresis donor recommendations o Minimum wt of 110 lbs o Maximum allowable plasma volume per year excluding anticoagulant is 12.0 L if ≤ 175 lbs; 14.4 L if > 175 lbs o Maximum allowable plasma volume per collection (collection volume includes anticoagulant) Weight / Vol/wt / Collection vol/Wt 10 – 149 lbs / 625 mL/640 g / 690 mL/705g 150 - 174 lbs / 750 mL/770g / 825 mL/845g 175 lbs and up / 800 mL/820g / 880 mL/900g o Not participating in other blood or plasma collection programs, or not donating more often than every 4 weeks	
Plateletpheresis donor recommendations o No more than every 48 hours; 2 in 7 days; 24 per year o Total volume per procedure should not exceed 500 mL; 600 mL if > 175 lbs o Maximum volume per year is 12.0 L; 14.4 L if > 175 lbs	

SOPs and Labeling

If not previously approved for a particular component(s) the submission should contain:	
SOPs: *Reference in SOPs to "follow the Operator's Manual" is acceptable if a plan for change control (i.e OM revisions, vendor letters, notification to customers) is provided or summarized.*	
Validation: • Any SOP(s) specifically related to validation • Validation summary that includes: o A description o Responsibilities including review o Sample size o Performance criteria o Summary of results o Description of training including the trainer, program, requirements for passing; competency assessment o Summary of failure investigations	
Device specific SOPs	
List of process related approved SOPs (handling adverse events, QC, SCTD)	
Donor qualifications and deferral • Donor history questions (*see BPB checklist*) • Plasma loss • RBC loss that includes o Testing samples collected o Incomplete procedure	
Sample preparation [21 CFR 211.160(b)(2,3)	
Arm prep (*refer to BPB checklist*)	
QC including: • Random or representative selection • Time limits for testing [21 CFR 211.111] • Description of testing [21 CFR 211.165(c)] • Acceptance/rejection criteria [21CFR 211.165(d)] • Disposition of unsuitable units [21 CFR 211.165(f)]	
Device maintenance	
Handling of adverse events	
Failure investigation [21 CFR 211.186(b)(7)] including: • Criteria for initiation	
Product specifications (i.e. volume, concentration limits) including: • Disposition of out of spec units [21 CFR 211.165(f)]	
Informed consent	
Labels (*refer to BPB checklist*) including: • "Apheresis" needs to be indicated on labels in product name or attributes	
Circular of Information, which should comply with guidance document	

Requesting a new CP:
• New SOPs
• New labels
• List of process related approved SOPs/labels
• Implementation plan including
  o Summary of validation
  o Summary of failure investigations
  o Description of training
  o Description of how standardized will be ensured
• Location of main site (and any other known affected sites)	

New facility under an approved CP: • Location of new site • Description of implementation • 2 months of quality control data	

QC Sheets

To include: • Facility [21 CFR 211.194(a)(1)] • Device manufacturer and type [21 CFR 211.194(a)(2)] • Blood Unit Number [21 CFR 606.140(c)] • Date of collection [21 CFR 211.194(a)(1)] • Date of testing [21 CFR 211.194 (a)(7); 600.12(a); 606.160 (a)(1)] • Appropriate collection types (single, double, triple, autologous if applicable) • Interpretation of results [21 CFR 211.194(a)(6); 606.160 (a)(1); 606.160 (a)(2)(i)] • Interpretation of month • Yield [21 CFR 211.103; 211.186(b)(7)] • Acceptable criteria [21 CFR 211.165(d)] • Initials [21 CFR 211.194 (a)(7); 600.12(a); 606.160 (a)(1)] • Evidence of review [21 CFR 211.194(a)(8; 211.103)] • Records of calculations [21 CFR 211.194 (a)(5)]	

Baxter ALYX

Cleared for: 2 LR RBC (ACD-A/AS-1) LR RBC (ACD-A/AS-1) and plasma	
Product specifications: • Pre-LR actual RBC volume ± 10% of target RBC volume • Residual WBC < 5.0 x 10e6 • % recovery displayed	
If Hct by centrifugation, should be spun for 5" (for product Hct)	
Informed consent also should include: • Possible adverse events including: allergic symptoms (skin redness, itching, hives); chills (infusion of RT saline or donor blood) • Hypocalcemia (infusion of citrated anticoagulants) resulting in unusual taste or smell, tingling around mouth or fingers, muscle discomfort, twitching or spasms • Improper operating conditions can cause complications such as blood loss, hemolysis, air embolism, blood clotting.	
Product profile: • Volume differences between bags > 10 mL should be corrected • Early termination of LR may result in inadequate AS-1 delivery and should be evaluated by Medical Director • Extended LF may result in display message that residual WBC and RBC content should be checked	
Calculation of blood volume in containers (container tare wts included in kit instructions; negligible volume of anticoagulant included) • Total plasma in plasma container (mL): o [Total container wt (g) – Container tare wt (g)]/ 1.03 g/mL • Total product volume: Red cells and plasma in red cell container (mL): o [Total container wt (g) – Container tare wt (g)]/ 1.08 g/mL • Red cell content of red cell container = above value x 85% • Whole blood in In-process container (mL): o [Total container wt (g) – Container tare wt (g)]/ 1.05 g/mL • Red cell content of In-process container = value above x donor Hct • Total volume of red cell storage container (mL): weigh each container separately and: [Total container wt (g) – Container tare wt (g)]/ 1.06 g/mL • Product Hgb = [Total product volume (mL) x sample Hgb (g/dL)]/100 mL	
Donor profile: national stds for donor Wt and Hct AND A) 2 LR RBC • Allogeneic male: o Ht ≥ 5'1"; predonation Hgb or Hct ≥ 13.3 g/dL or ≥ 40% o Maximum total RBC target volume: • 130-149 lbs: 360 mL • 150-174 lbs: 400 mL • ≥ 175 lbs: 420 mL • Allogeneic female: o Ht ≥ 5'5"; predonation Hgb or Hct ≥ 13.3 g/dL or ≥ 40% o Maximum total RBC target volume: • 150-174 lbs: 360 mL • ≥ 175 lbs: 400 mL	

B) LR RBC and plasma (Allogeneic male or female) o predonation Hgb ≥ 12.5 and ≤ 18.3 g/dl ,or Hct ≥ 38% and ≤ 55% • 110-129 lbs: max. RBC target vol. 200ml; max. plasma 450ml • 130-174 lbs: Max. RBC target vol. 200ml; max. plasma 550ml o predonation Hgb ≥ 12.5 and ≤ 16.6 g/dl ,or Hct ≥ 38% and ≤ 50% • ≥ 175 lbs: maxi. RBC target vol. 200ml; max. plasma 650ml o predonation Hgb ≥ 16.7 and ≤ 18.3g/dl ,or Hct ≥ 51% and ≤ 55% • ≥ 175 lbs: maxi. RBC target vol. 200ml; max. plasma 550ml	
RBC loss (plasma loss) • RBC loss from samples included in total product collected (use of sample pouch) • If procedure discontinued early: 110 mL (including 15 mL in tubing) o Donor RBC loss due to kit volume = Hct x 110 mL o Donor plasma loss due to kit volume = 110 mL – donor RBC loss • If blood has not entered separation chamber: ≤ 60 mL (use above)	
Maintenance: • Daily: machine must be OFF at least once in 24 hrs to perform self-checks o Power cycle instrument o Perform scale checks (500 gm and 1000 gm weights): ± 3 gms o Wipe centrifuge compartment • Monthly o Inspect/clean fan filters o Clean pump block gasket o Clean optical sensors o Inspect centrifuge gasket • As needed o Clean touch screen o Clean instrument housing	

Haemonetics MCS Plus LN 8150

• Cleared for RBC and Plasma(using the LN 822 AS-3 Set); Double RBC (LR and non-LR); CP2D/AS-3 (using the LN 832 AS-3 Set or the LN 832F AS-3 Set)	
Product specifications: • Single and double RBCs (non-LR): total RBC volume is ± 15% of target • Double RBCs with LR filter: mean ≥ 153 mL; 180 mL • 180 mL per bag is default • **LN832F aborted procedures**. If a second draw cycle begins and is subsequently aborted for any reason, 200 ml of AS-3 will be transferred to the reservoir bag. ***If the second draw cycle is aborted prior to the point that a second viable unit is likely, a manual transfer of 100 ml AS-3 may be performed after AS-3 insert "to the reservoir bag."*** It is recommended that quality control be performed to assure that all RBC product criteria are met. If the venipuncture has displayed problems in the first cycle such as continuous poor flow and/or high pressure return problems, it is suggested that the procedure be aborted before the end of the first return cycle. This will result in the device transferring the 100 ml of AS-3, for a single unit of RBC. ***This unit may be transferred to a final RBC storage bag and labeled as an unlicensed apheresis-RBC product. It may be leukocyte reduced with sterile connection to an appropriate single unit leukoreduction filter, again as an unlicensed product.*** It is recommended that quality control be performed to assure that all RBC product criteria are met.	
Product profile: • Storage at RT: filter within 8 hrs of venipuncture; 10- 25 minutes • Storage at 1-6C: filtration within 72 hrs of venipuncture; 20 – 35 minutes • Products that fail LR specs should be evaluated for residual WBC and % recovery • > 85% recovery of RBC mass	
Sampling and calculations: • Sample must be collected from (distal portion of) RBC bag tubing • Stripping, mixing, sampling and measurement should as soon as possible following each other <u>Non-LF RBC:</u> • Product weight = total product weight – empty bag • Total volume (ml) = product wt(g)/1.058 (SG of 1.06 may be used) • Absolute red cell volume: (Sample Hct/100) x product volume <u>LF RBC:</u> For prefiltration sampling procedure, use filtration harness which includes filter and RBC bags; for postfiltration use empty RBC bag o Product weight = total product weight – empty bag o Total volume (ml) = product wt(g)/1.058 (or 1.06) Absolute red cell volume: (Sample Hct/100) x product volume	
Donor profile: all WB criteria **AND**	

RBCs

- Allogeneic male:

	Pre Hct	Hgb	Max RBC target
110–120 lbs:	38-41%	12.5-13.9 mg/dl	185 ml
	42%+	14.0 mg/dl	190 ml
130-149 lbs:	38-41%	12.5-13.9 mg/dl	190 ml
	42%+	14.0 mg/dl	195 ml
150-174 lbs:	38-41%	12.5-13.9 mg/dl	200 ml
	42%+	14.0 mg/dl	210 ml
175 lbs +	38-41%	12.5-13.9 mg/dl	210 ml
	42%+	14.0 mg/dl	210 ml

- Allogeneic female

110–120 lbs:	38-41%	12.5-13.9 mg/dl	180 ml
	42%+	14.0 mg/dl	180 ml
130-149 lbs:	38-41%	12.5-13.9 mg/dl	185 ml
	42%+	14.0 mg/dl	190 ml
150-174 lbs:	38-41%	12.5-13.9 mg/dl	190 ml
	42%+	14.0 mg/dl	195 ml
175 lbs +	38-41%	12.5-13.9 mg/dl	200 ml
	42%+	14.0 mg/dl	210 ml

- Autologous male:

110-129 lbs:	34-37%	11.3-12.4 mg/dl	170ml
	38-41%	12.5-13.9mg/dl	185ml
	42%+	$\geq$ 14.0 mg/dl	190ml
130-149 lbs:	34-37%	11.3-12.4 mg/dl	180ml
	38-41%	12.5-13.9 mg/dl	190ml
	42%+	$\geq$ 14.0 mg/dl	195ml
150-174 lbs:	34-37%	11.3-12.4 mg/dl	190ml
	38-41%	12.5-13.9 mg/dl	200ml
	42%	$\geq$ 14.0 mg/dl	210ml
175 lbs +	34-37%	11.3-12.4 mg/dl	200ml
	38-41%	12.5-13.9 mg/dl	210ml
	42%+	$\geq$ 14.0 mg/dl	210ml

- Autologous female:

110-129 lbs:	34-37%	11.3-12.4 mg/dl	160ml
	38-41%	12.5-13.9mg/dl	180ml
	42%+	$\geq$ 14.0 mg/dl	180ml
130-149 lbs:	34-37%	11.3-12.4 mg/dl	170ml
	38-41%	12.5-13.9 mg/dl	185ml
	42%+	$\geq$ 14.0 mg/dl	190ml
150-174 lbs:	34-37%	11.3-12.4 mg/dl	180ml
	38-41%	12.5-13.9 mg/dl	190ml
	42%	$\geq$ 14.0 mg/dl	195ml
175 lbs +	34-37%	11.3-12.4 mg/dl	190ml
	38-41%	12.5-13.9 mg/dl	200ml
	42%+	$\geq$ 14.0 mg/dl	210ml

Plasma

	Pre Hct	Hgb	Min	Max plasma target vol
• Allogeneic male:				
o 110–120 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	450 ml
	42%+	14.0 mg/dl	320	
o 130-149 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	500 ml
	42%+	14.0 mg/dl	320	
o 150-174 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	550 ml
	42%+	14.0 mg/dl	320	
o 175 lbs +	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	550 ml
	42%+	14.0 mg/dl	320	
• Allogeneic female:				
o 110–120 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	450 ml
	42%+	14.0 mg/dl	320	
o 130-149 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	450 ml
	42%+	14.0 mg/dl	320	
o 150-174 lbs:	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	500 ml
	42%+	14.0 mg/dl	320	
o 175 lbs +	34-37%	11.3-12.4 mg/dl	400	
	38-41%	12.5-13.9 mg/dl	360	550 ml
	42%+	14.0 mg/dl	320	

Double RBCs, non-LF

- Allogeneic male: Ht ≥ 5'1"

	pre Hct	pre Hgb	max RBC target vol
o 130-149 lbs	≥40-<41%	≥13.3-13.6 mg/dl	360 ml
	≥41-<42%	≥13.7-13.9 mg/dl	370 ml
	≥42%	≥14.0 mg/dl	380 ml
o 150-174 lbs	≥40-<41%	≥13.3-13.6 mg/dl	400 ml
	≥41-<42%	≥13.7-13.9 mg/dl	410 ml
	≥42%	≥14.0 mg/dl	420 ml
o 175 lbs +	≥40-<41%	≥13.3-13.6 mg/dl	
	≥41-<42%	≥13.7-13.9 mg/dl	420 ml
	≥42%	≥14.0 mg/dl	

- Allogeneic female: Ht ≥ 5'5"

o 150-174 lbs	≥40-<41%	≥13.3-13.6 mg/dl	360 ml
	≥41-<42%	≥13.7-13.9 mg/dl	370 ml
	≥42%	≥14.0 mg/dl	380 ml
o 175 lbs +	≥40-<41%	≥13.3-13.6 mg/dl	400 ml
	≥41-<42%	≥13.7-13.9 mg/dl	410 ml
	≥42%	≥14.0 mg/dl	420 ml

- Autologous male:

o 130-149 lbs:	36-39%	12.0-13.2 mg/dl	320ml
	40%+	≥ 13.3 mg/dl	360ml
o 150-174 lbs:	36-39%	12.0-13.2 mg/dl	360ml
	40%+	≥ 13.3 mg/dl	400ml
o 175 lbs +	36-39%	12.0-13.2 mg/dl	400ml
	40%+	≥ 13.3 mg/dl	420ml

- Autologous female:

o 130-149 lbs:	36-39%	12.0-13.2 mg/dl	280ml
	40%+	≥ 13.3 mg/dl	320ml
o 150-174 lbs:	36-39%	12.0-13.2 mg/dl	320ml
	40%+	≥ 13.3 mg/dl	360ml
o 175 lbs +	36-39%	12.0-13.2 mg/dl	360ml
	40%+	≥ 13.3 mg/dl	400ml

Double RBCs, LF

- Allogeneic male: Ht ≥ 5'1"

	pre Hct	pre Hgb	max RBC target vol
o 130-149 lbs	≥40%	≥13.3 mg/dl	
o 150-174 lbs	≥40	≥13.3 mg/dl	360 ml
o 175 lbs +	≥40	≥13.3 mg/dl	

- Allogeneic female: Ht ≥ 5'5"

o 150-174 lbs	≥40	≥13.3 mg/dl	360 ml
o 175 lbs +	≥40	≥13.3 mg/dl	

- Autologous male:

o 130-149 lbs:	36-39%	12.0-13.2 mg/dl	320ml
	40%+	≥ 13.3 mg/dl	360ml
o 150-174 lbs:	36-39%	12.0-13.2 mg/dl	360ml
	40%+	≥ 13.3 mg/dl	400ml
o 175 lbs +	36-39%	12.0-13.2 mg/dl	400ml
	40%+	≥ 13.3 mg/dl	420ml

- Autologous female:

o 130-149 lbs:	36-39%	12.0-13.2 mg/dl	280ml
	40%+	≥ 13.3 mg/dl	320ml
o 150-174 lbs:	36-39%	12.0-13.2 mg/dl	320ml
	40%+	≥ 13.3 mg/dl	360ml
o 175 lbs +	36-39%	12.0-13.2 mg/dl	360ml
	40%+	≥ 13.3 mg/dl	400ml

RBCs remaining in disposable set = 5-10 ml absolute RBCs

Maintenance:

- Daily: machine must be shut down once in 24 hrs to allow for self-checks
  - Weigher to be checked daily using a certified weight: Acceptable range (displayed volume) = ± 1% or 495 – 505g (500g); 990 – 1010 g (1000g); 1485 – 1515 (1500g) – Per Haemonetics (e-mail from John Sokolowski) dated March 24, 2005 the 500g, 1000g, and 1500g weights are mentioned as reference weights since they are common in laboratories but as long as a weight is certified any certified weight is acceptable.
  - Clean SPM/DPM
- Daily or and with spill:
  - Exterior surfaces and control panel
- Monthly and with spill clean:
  - Centrifuge well and cover
  - Pumps
  - Bowl optics and line sensor
  - Air detectors
  - Monthly:
  - Air filters/filter screen
  - Inspect O-rings and apply grease
- Per local regulations with spill and after major voltage surge
  - Current leakage
- Annually ± 45 days: PM by manufacturer

Haemonetics MCS Plus LN 9000

Cleared for Single and Double Platelets; Single Platelets with Plasma; LR Platelets LR with in-line filters: CPP filter (LN 994CF); Single only, CLX (LN 994F)	
Product specifications: • Singles stored in ~ 200 – 300 mL of plasma; doubles 350 – 450 mL of plasma • LR: o CPP LN 994CF (pre-storage): Single < 1.0×10^6 in 99%; < 5.0×10^6 in 95%; Double < 1.0×10^6 in 97.8% o CLX LN 994F (up to 1 hr post collection): < 5.0×10^6 in 95% o During LR, if RBC spillover occurs, manual intervention of the process or volume processed is > 5000 mL, residual WBC count should be done o Reverse flow of filtered platelet back through filter; should be discarded • Platelets o CPP bag: 5.0×10^{11} per bag; 2600×10^6 platelets per ml o CLX bag: 3.5×10^{11}per bag o Double Platelets: if plt cnt exceeds bag limitations, an additional bag should be attached with a SCD	
Product profile: Platelets • LN 994CF: immediate post-collection filtration; % recovery calculated by device. Platelets held in reservoir bag and filter is located between reservoir and storage bags. *Per Sue Finneran, Regulatory Affairs Manager for Haemonetics during the last cycle while the donor is still attached to the machine the storage bags are lowered below the level of the reservoir bag and the product is allowed to begin filtration through the in-line filter.* In addition with this set - CF = Continuous Filtration and continuous filtration does not require or permit a determination of whether or not there has been more than a 15% platelet loss during the leukoreduction process. Stated another way, the 85% platelet recovery standard is not applicable to leukocyte reduction by continuous filtration. (As cleared by DH under BK970034) • LN 994F: filtration up to 1 hr post collection Plasma: 500 mL donors under 175 lbs; 600 mL donors ≥ 175 lbs	
Sampling and calculations: Platelets • Pre-procedure: if from injection port, 3-5 mL must be discarded • Use scale to ensure equal volume split between platelet bags • *Refer to Apheresis Procedures document for exact sampling procedures* • Product volume (mL) for platelets and plasma: [total product wt – empty bag]/1.026	
Donor profile: all WB criteria **AND**	
• Program donor sex, Wt, Ht , Hct (Hgb x 3 may be used) and pre-donation platelet count • Predonation count may be historical, an average, or default (250,000) • Total Blood Product Volume calculation by chart • ECV estimate from table o Does not include samples o Residual blood in set is ~ 55 mL of which ~45 mL is plasma o Max volume of RBCs in LN 994 is 190 mL	
Maintenance: • Daily: Clean SPM/DPM	

• Monthly:
  o Inspect L gasket and apply silicone grease (vacuum centrifuge only; not mechanical)
  o Clean disposable ID window
  o Clean air detectors
  o Clean line sensor
• Monthly and with spill clean:
  o Optic bowl lens
  o Pumps
  o Exterior surface and user panel
• Quarterly: Air filters
• Per local regulations with spill and after major voltage surge
  o Current leakage
• Annually: PM by manufacturer ± 30 days	

Trima Version 5.1
(should also apply to version 4 except where noted)

Cleared for: LR Single (SDP), Double (DPP)and Triple (TPP) Platelets SDP, DPP, TPP and LR Plasma SDP or DPP and RBC (ACD-A/AS-3) (**version 4.0**) and SDP, DPP, TPP and RBC (ACD-A/AS-3) (**version 5.0**) SDP or DPP, LR Plasma and RBC (ACD-A/AS-3) DRBC (ACD-A/AS-3); RBC (ACD-A/AS-3) and Plasma; RBC (ACD-A only); Plasma	
Platelet pheresis: retained plasma volume and RBC loss must be monitored/tracked per procedure.	
RBC loss (does not include samples): • Extracorporeal blood volume: o Version 4: 230 mL (~95 mL RBCs) o Version 5: 95 mL for Platelets only 182 mL (~ 100 mL RBCs) for RBC/Plasma 196 mL for LRS Platelet, RBC Plasma • Residual RBC volume should be monitored and tracked: o After rinseback: Version 4: 30 ml RBC 35 ml plasma Version 5: 30 mL for Platelets only 25 mL RBC, 40 mL plasma for RBC/Plasma 30 mL RBC, 33 mL plasma for LRS Platelets/RBC/Plasma o No rinseback: Version 4: 95 mL RBC, 112 mL plasma Version 5: 95 mL for Platelets only 91 mL RBC, 83 mL plasma for RBC/Plasma 85 mL RBC, 121 mL plasma for LRS Platelets/RBC/Plasma	
Product specifications	
Platelets: • Concentration: 1000 x 10^3/ul to 2100 x 10^3/ul • Maximum yield: $\leq$ 5.1 x 10^{11} per bag • Volume: 100 – 400 ml/bag • Daily qualification of platelets o WBC and platelet counts: within 48 hrs of donation; within 6 –24 hours of sample collection. o If not tested within 6 hours, rotate/mix continuously at 20-24 C. o Immediately before counting, mix for 15 minutes *Gambro 7-day platelet pheresis leukocyte reduced product requests should include the additional checklist for the variance.*	

	RBCs: • Donor volume limits must be set (using height, weight and gender): o Percent TBV: default is 15% (maximum) • RBC: Total product volume (TPV; which includes storage solution) = ± 10% of Total displayed volume (TDV) + 100 mL storage solution. Calculate range or use formula: o Lower limit: (displayed volume + additive solution) x 0.9 and o Upper limit: (displayed volume + additive solution) x 1.1 OR o [(TDV+100) – TPV)]/(TDV+100) x 100 • dRBC: RBC: Total product volume (TPV; which includes storage solution) = ± 10% of Total displayed volume (TDV) + 200 mL storage solution. *Alternate:* product volume of each unit (PV; which includes storage solution) = ± 10% of Total displayed volume (TDV)/2 + 100 mL storage solution. Calculate range or use formula: o Lower limit: (displayed volume + additive solution) x 0.9 and o Upper limit: (displayed volume + additive solution) x 1.1 • Maximum 600 ml (including storage solution) • The recommended RBC dose range [Red Cell Mass] for optimal storage per RBC bag [with 100 mL of AS-3] is 150 mL to 250mL (not required)	
	LR RBCs • < 5.0 x 10^6 residual WBCs • Retain 85% of RBCs post filtration o use Hct and volume to calculate RBC content or mass (% recovery = [post filtration volume x Hct]/[pre filtration volume x hct] x 100) OR o measure Hgb (% recovery = [post Hgb x volume]/[pre Hgb x volume] x 100) OR o use volume as a measure of filtration percent recovery (as submitted in 510k; % recovery = [post filtration volume/pre filtration volume] x 100) • Minimum of 160 ml RBC post filtration (*from draft LR guidance and may not be included)* • If filtered using TLR filter, must be at RT and within 8 hrs of end of run time o filtration occurs after addition of storage solution o filtration must be completed in 8 hrs • Cold Trima RBCs may be filtered with another dockable leukocyte reduction filter (stored at 4C for > 8 hrs per letter from Pall)	
	Concurrent plasma • Maximum plasma volume of 600 ml if to be frozen, 1000 ml if not frozen	
Donor profile: national standards for donor Wt and Hct **AND**:		
	RBCs: • Total Blood volume > 4500 ml • RBC loss not more than allowed for WB including residual volume from rinseback/lack of rinseback; RBC product volume; donor samples	
	Plasma: • Wt between: o 110 and 175 lbs: collect ≤ 15% of TBV/procedure and maximum ≤ 12.0L plasma per year o 175 lbs: collect ≤ 15% of TBV/procedure and maximum • ≤ 14.40 L plasma per year	

	Platelets: • Donor platelet count algorithm: pre-donation; average; pre-donation from previous donation; default (200,000) • Wt between: o 110 and 175 lbs: collect ≤ 15% of TBV/procedure and maximum ≤ 12.0L plasma per year o 175 lbs: collect ≤ 15% of TBV/procedure and maximum • ≤ 14.40 L plasma per year	
Maintenance: • The Safe Seal system (for sealing tubing) must be cleaned when contaminated. • Daily: Clean spills • Weekly and as necessary: Clean sensors and valves • Periodic: Clean pump housing and pump rotors Clean fluid leak detector • After a blood spill: Clean the centrifuge chamber Remove and clean the filter		
Refer to BPB "Apheresis Procedures" for manufacturer recommended validation and QC.		

Amicus

Cleared for: Single needle platelets with optional RBCs (ACD-A AS-1; require filtration for leukocyte reduction), plasma (platelets drawn concurrently do not need to be re-licensed Double needle platelets with optional plasma	
Plateletpheresis: WBCs should be counted if: • Performing manual product transfer • The platelet storage container clamps are not closed before removing the kit from the instrument (RBCs will enter storage container). • Greater number of RBCs than expected is seen (1 inch in diameter near entrance to collection chamber is normal) • Centrifuge spins down during procedure • Procedure is paused for > 135 second Defaults • Recommended pre-platelet count 250,000 • MPV 10.1 or greater (if actual value not entered) • Hct 42% • Weight 110 lbs • DN and SN yield adjuster: 1.00 • Single dose storage fluid (200 – 400 mL): recommend 285 mL • Double dose storage fluid (200 – 800 mL): recommend 570 mL • Double dose limit: suggest 5.0 Estimator will calculate the expected post-donation platelet count. This should be > 100,000/uL Weight scales: • Front scales: 0 to 1200 gms or 0 to 2500 gms: ± 1% or 2 gms whichever is greater • Rear scales: 0 to 3600 gms; ± 1% or 5 gms whichever is greater	
RBC loss: • Kits (excluding plasma container, WB and RBC containers) o Single needle: 209 mL o Double needle: 205 mL • Blood sampling pack contains 50 mL of whole blood • Product sampling pack contains 3-5 mL • RBC kit volumes o Single needle: 64 mL • If reinfusion incomplete: Max cycle volume x donor Hct + 64 mL o Double needle: 60 mL • Plasma kit volumes (excluding plasma container, WB and RBC containers: 145 mL for both single and double needle • RBC kit volume after re-infusion • 30 mL with single needle • 20 mL with double needle Manual re-infusion: operator must observe and monitor lines for presence of air and RBC loss must be calculated	
Adverse events • Lightheadness, fainting, vomiting, hyperventilation, hematoma formation, syncopal reactions due to hypovolemia • Allergic symptoms	

• Chills • Hypocalcemia (tingling); if severe, tetany, seizure, cardiac arrhythmia and death • Muscle discomfort, twitching or spasms • Unusual taste in mouth • With improper operating conditions: blood loss, hemolysis, air embolism, and blood clotting	
Product specifications During platelet and/or plasma collection: • The observance of more than ~ 6 inches of RBCs in the line from bottom right port of the right cassette to the centifuge pack OR • In the plasma • Requires discontinuation of the procedure and re-infusion AND • Should have a residual WBC count performed on the product.	
Platelets: • Total plasma volume processed: o < 175 lbs, maximum 600 mL o ≥ 175 lbs, maximum 700 mL • WB volume limit o Single Dose WB Volume Limit (for single platelet) should be set at 5400 mL (maximum 5500 mL) o Double Dose WB Volume Limit (for double platelets) should be set at 6900 mL (maximum 7000 mL) o Triple platelets maximum processed volume is 8000 mL (maximum 8000 mL) • Total plasma volume should be within 20 mL or ± 10%, whichever is greater, of target total plasma volume • Maximum platelet per container and minimum volumes (including ACD) to ensure a pH of ≥ 6.2 • 4.7×10^{11} maximum per bag • Software version 2.52 and above will alarm for conditions that may require that the product be counted for WBCs • Leukoreduced platelets: o < 5 x 10e6 99% of time with 99% confidence o < 1 x 10e6 98% of time with 97% confidence	
Concurrent Plasma • Volume collected based on medical judgment and in conformance with FDA requirements • Container weight: 30 gms for 600 mL bag; 35 gms for 800 mL bag	
Concurrent RBCs • Have ~ 85% hematocrit • Container weight: 32 gms; tubing 0.2 gms/inch • Absolute RBC volume: displayed or calculated o Volume = [RBC product wt (gms) – tare weight of RBC container (gms)]/density factor (1.077 g/mL) o Absolute RBC volume = volume x Hct of product (~85%) Expected is 190 – 210 mL	
Donor profile: national standards	

	Estimator should be used:
	• Donor pre-donation platelet count
	  o Recommended 100,000/uL post-donation estimated count
	  o In absence of pre-count, use 250,000
	• MPV
	• Hct
	  o Calculated Hct: After 10-15 minutes of processing, observe "Calculated Hct" parameter on screen
	  o Add 10% = approximate unanticoagulated WB Hct
	  o If different from current HCT value in Estimator by more the 4% points, enter new value
	  o Calculated Hct should not be used to determine donor eligibility
	• Wt
	• Ht (60 inches default)
	• Gender (female default)
	• Yield or WB to process
	• RBC volume (defaut is 0 ml)
	• Volume out per kg (est of maximum donor ECV) may recommend ≤ 10.5 mL/kg (AABB std)	

Sampling: Pre-collection sampling may be done using the Return line (single needle) or Inlet line (double needle) • If Interlink Injection site is used before before two hermetic seals are made on the line leading to the kit, the system is considered "opened" and the expiration time is 24 hrs. Platelet samples placed in pediatric 2 mL EDTA tubes need a dilution correction factor of 1.02		
Maintenance: • Routine: Clean touch screen Clean spills (lubrication of pump head is to be done by Baxter service personnel **ONLY**). • Weekly ± 2 days: Clean or checks air inlet filter Clean interface detector system Clean window and ramp • Biannual ± 30 days Replace gaskets • Annual ± 30 days PM and calibration be service rep		