PRINCIPLES OF DONOR PLATELET APHERESIS

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European Society For Hemapheresis Congress

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What is an Apheresis Donation?

- Apheresis involves the use of machines to selectively collect a blood component (red cells, platelets, white cells or plasma).
- A specific blood component is selected and is automatically separated by the machine (most commonly platelets or plasma).
- The components that are not required are returned to the donor.
- The advantage of an apheresis donation is that relatively large amounts of the component can be selectively collected.

What are Platelets?

- Platelets are colorless, irregularly shaped bodies found in blood.
- The primary role of platelets is to prevent bleeding in injured blood vessel walls by forming an aggregate at the site of injury.
- Platelets can also participate in blood coagulation, inflammation and wound healing.

Who can Donate Blood

Age:	**17th – 71st birthday (regular donor)** **17th – 61st birthday (first time donor)**
Weight:	**At least 50 kg (110 lbs)**
Hemoglobin:	**Must meet requirements**
Frequency of Donation:	**Minimum interval between donations is 56 days**
Health:	**In good health and feeling well.**
Screening:	**At time of donation, a number of questions are asked to determine donor eligibility, e.g.:**

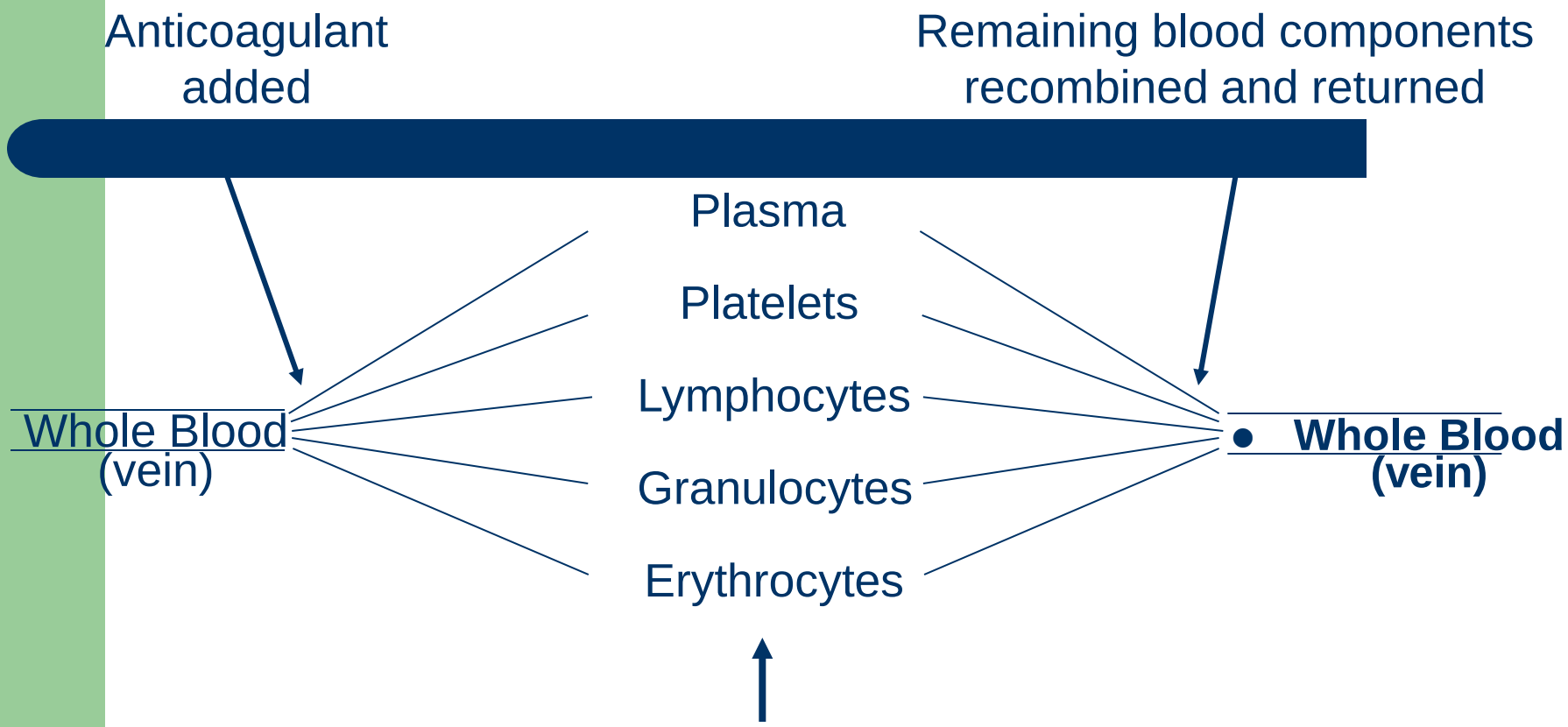
If donor has had a	*Donor must wait before donating for…*
• ***Dentist visit:***	***3 days after visit***
• ***Cold, flu or sore throat:***	***Full recovery***
• ***Ear/ body piercing or tattooing:***	***6 months***

Why are Single Donor Apheresis Products Requested?

Platelets:

- To prevent alloimmunization (e.g., bone marrow transplantation).
- For refractory patients, HLA/platelet antigen matched for patients with specific HLA/platelet antibodies.
- For directed donations, e.g., mother to baby for neonatal thrombocytopenia (NTP).

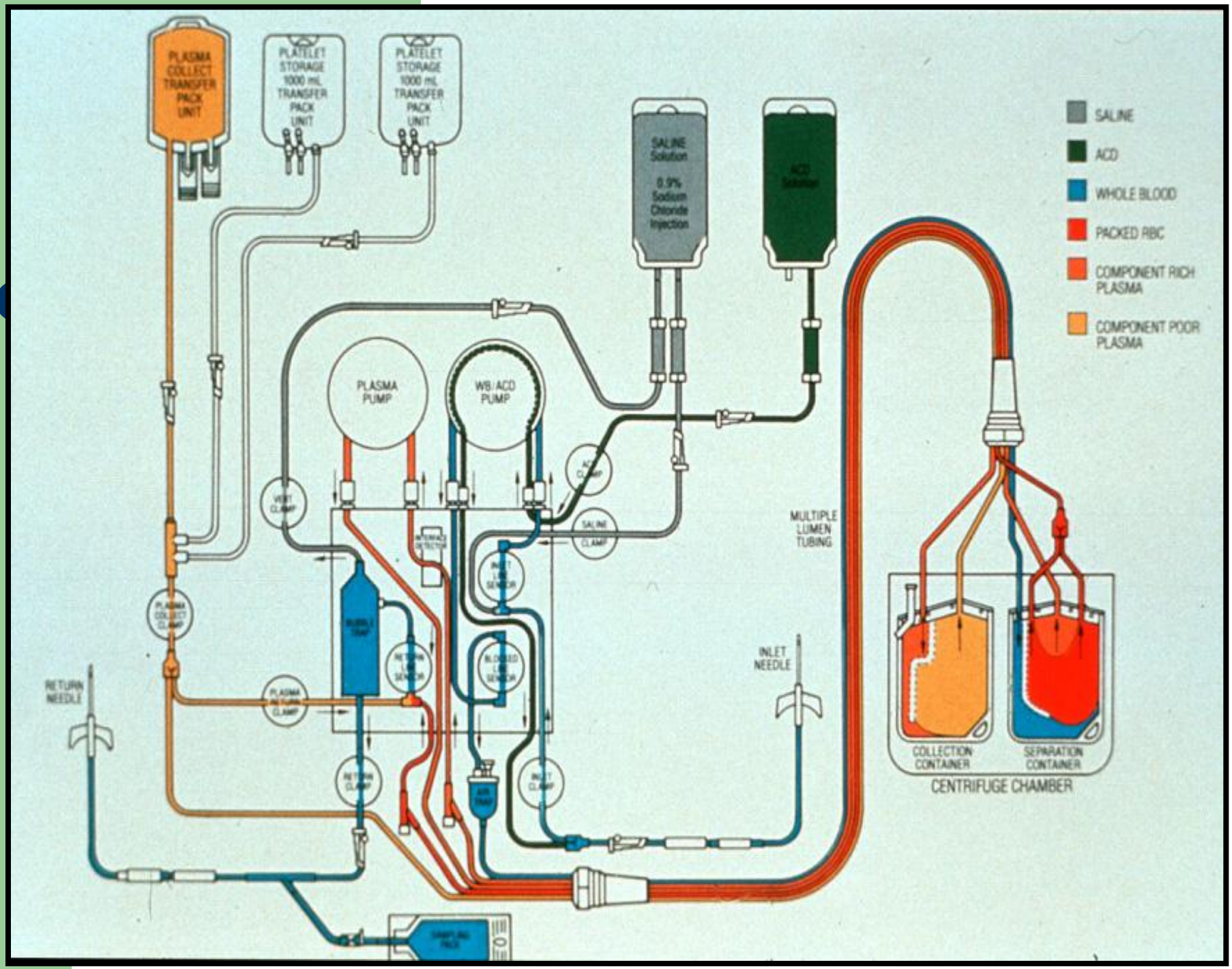
Principles of apheresis



Blood components separated by centifugation and selectively removed

APHERESIS PROCEDURES - GENERAL

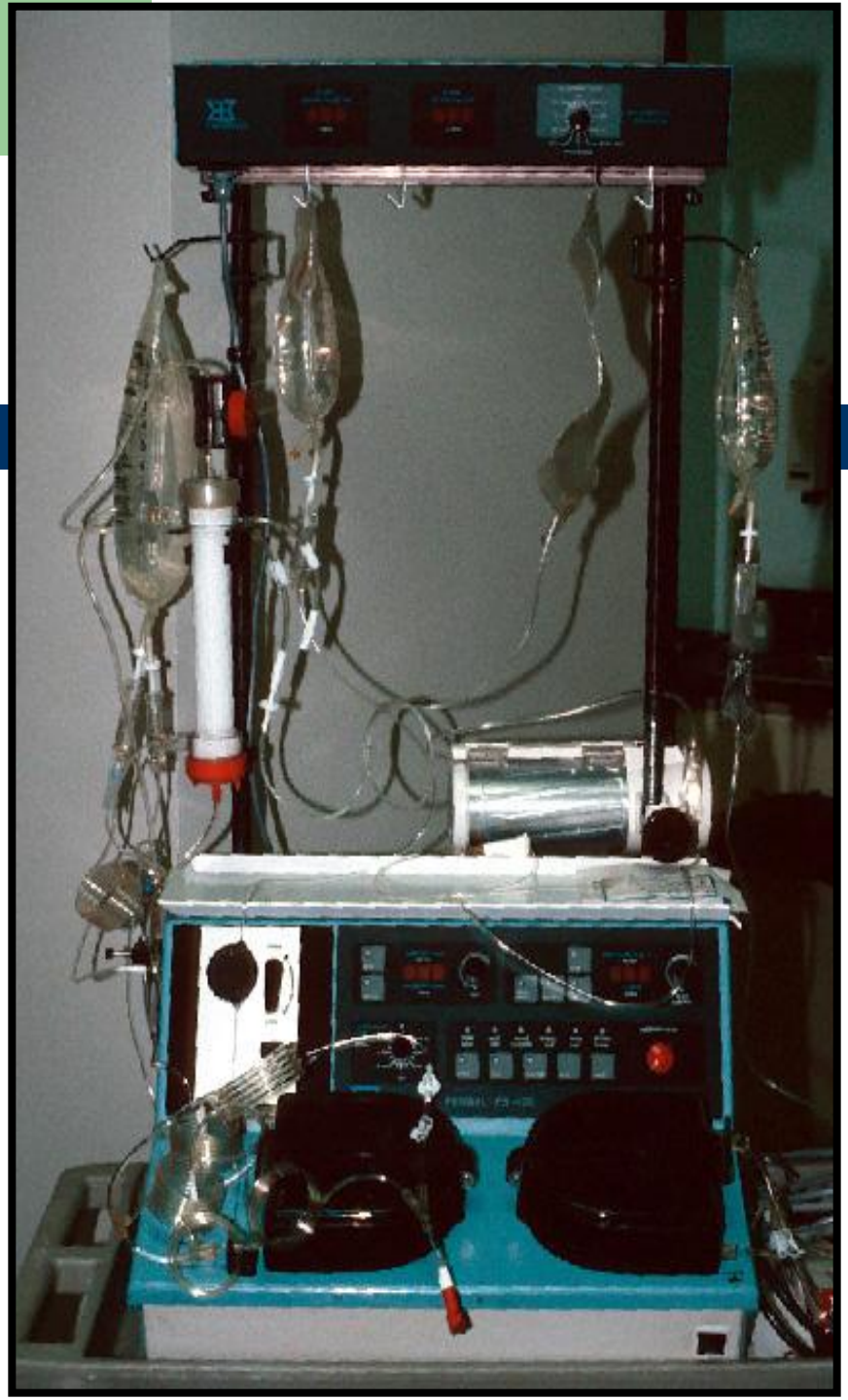
- Used for treatment or blood component donation
- Allows blood separation at bedside
- < 15% of blood volume in extracorporeal circuit
- Sterile, single use tubing and separation kit
- Anticoagulant must be added - usually citrate (ACD)


PLASMA COLLECT TRANSFER PACK UNIT
PLATELET STORAGE 1000 mL TRANSFER PACK UNIT
PLATELET STORAGE 1000 mL TRANSFER PACK UNIT
SALINE Solution 0.9% Sodium Chloride Injection
ACD Solution
SALINE
ACD
WHOLE BLOOD
PACKED RBC
COMPONENT RICH PLASMA
COMPONENT POOR PLASMA
PLASMA PUMP
WB/ACD PUMP
MULTIPLE LUMEN TUBING
INLET NEEDLE
RETURN NEEDLE
COLLECTION CONTAINER
SEPARATION CONTAINER
CENTRIFUGE CHAMBER

Apheresis Methods

- Filtration
- Plasma only
- Europe and Japan
- Specialized U.S. procedures
- Smaller equipment, smaller extracorporeal volume
- Centrifugation
- Most versatile
- Any cell or plasma can be removed
- Popular in U.S.
- Larger equipment and larger extracorporeal volume


COBE Spectra




Chloride
-3
-4
-5
-6
-7
-8
-9

APHERESIS TECHNOLOGY (centrifugal)

- Continuous flow
- One or two access points
- Continuous blood separation
- Intermittent flow
- One access needed
- Blood separation in cycles
- Slightly longer processing time
- Slightly larger extracorporeal volume

DONOR APHERESIS

APHERESIS DONOR COLLECTIONS

- Platelets
- Plasma
- Granulocytes
- Red blood cells
- Lymphocytes
- Peripheral blood stem cells

Donor Apheresis

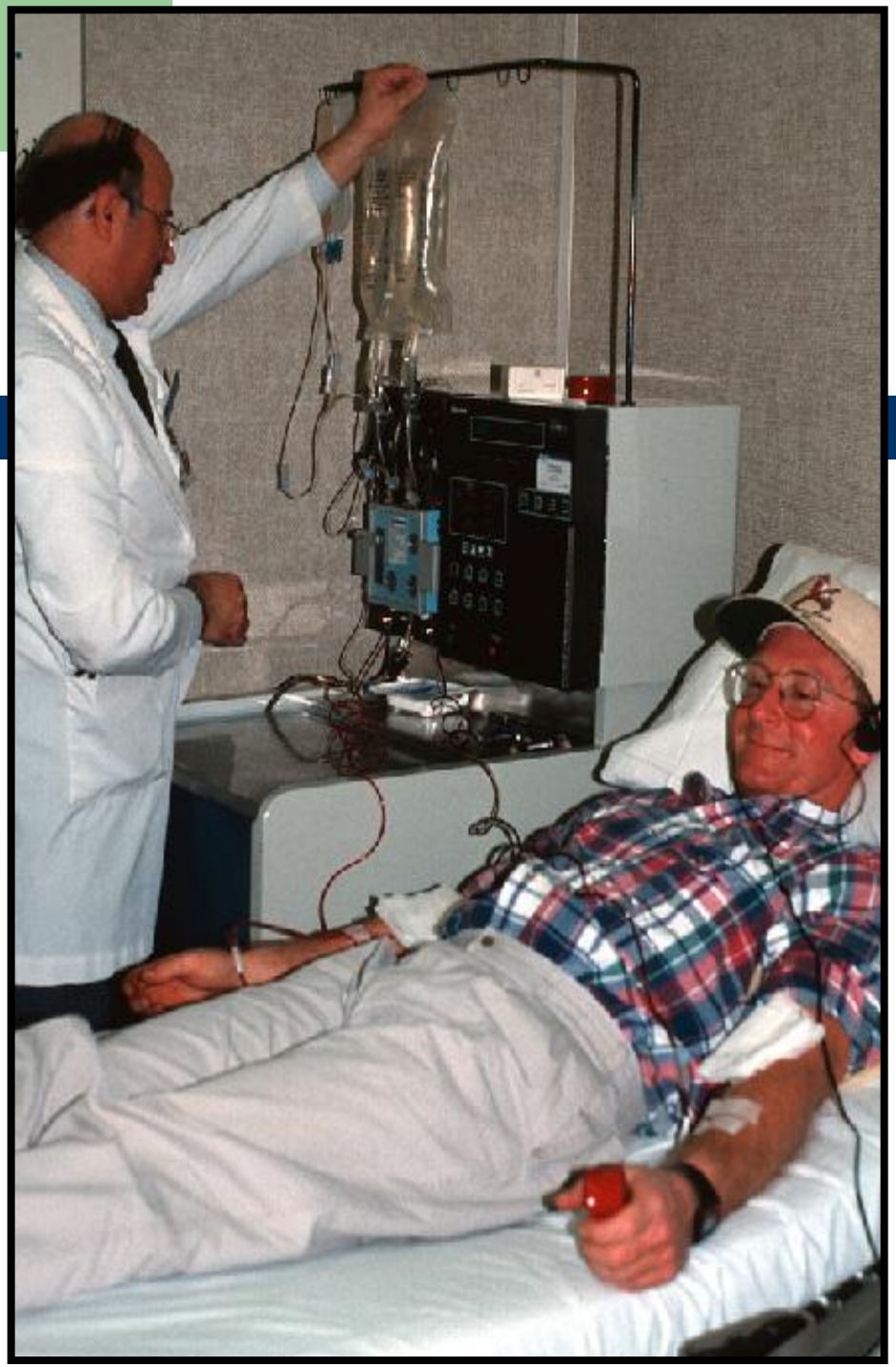
- Advantages
- Select only component(s) needed
- Return rest of blood
- No need for component separation in lab
- More frequent donation allowed (some)
- Disadvantages
- Expense/equipment/training
- Citrate exposure

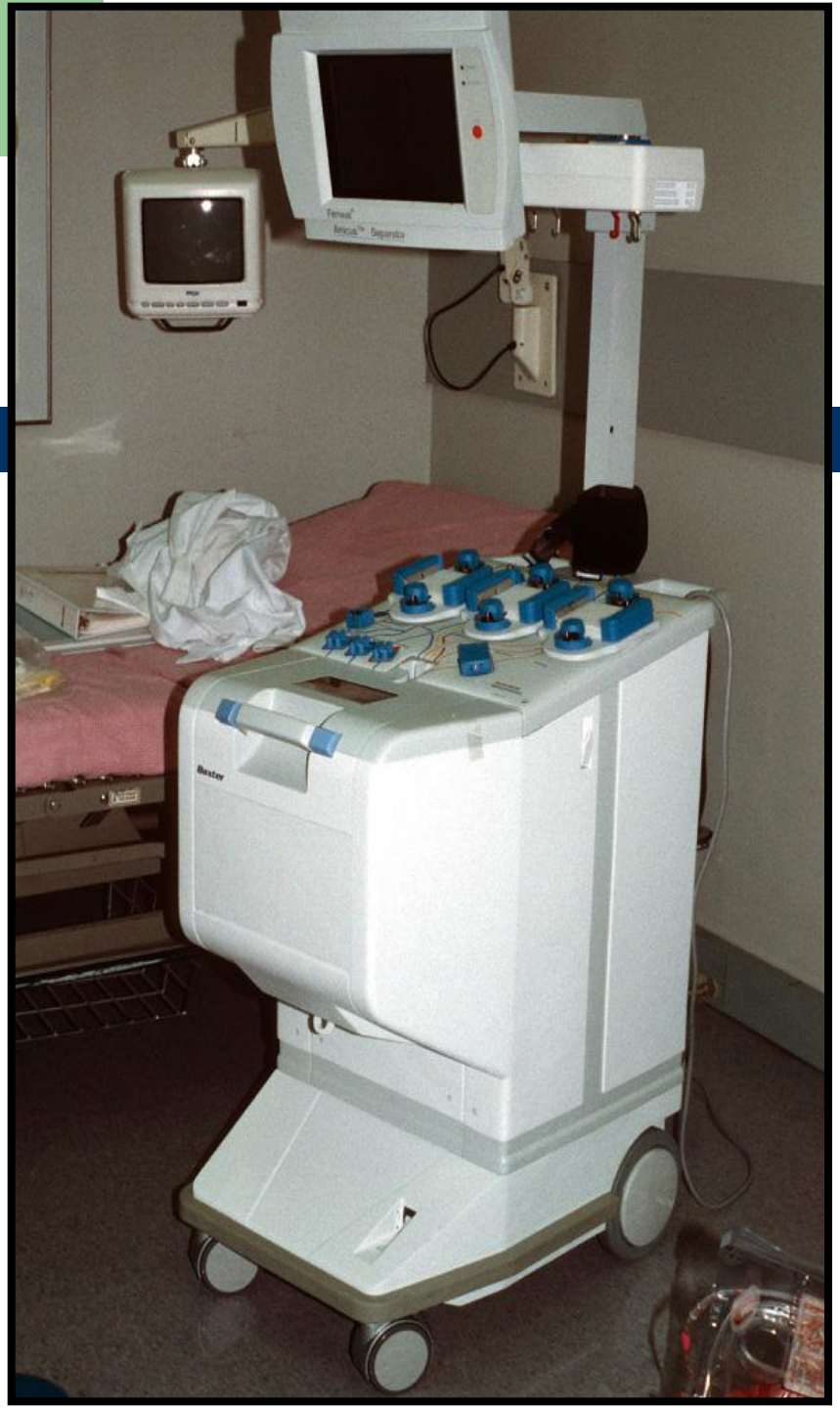
Donor Apheresis

- Probable trend in future
- May totally replace whole blood donation
- Can customize collection:
- -Individual donor preferences
- -Blood type of donor
- -Inventory needs of blood center

DONOR APHERESIS EQUIPMENT - U.S., 2002

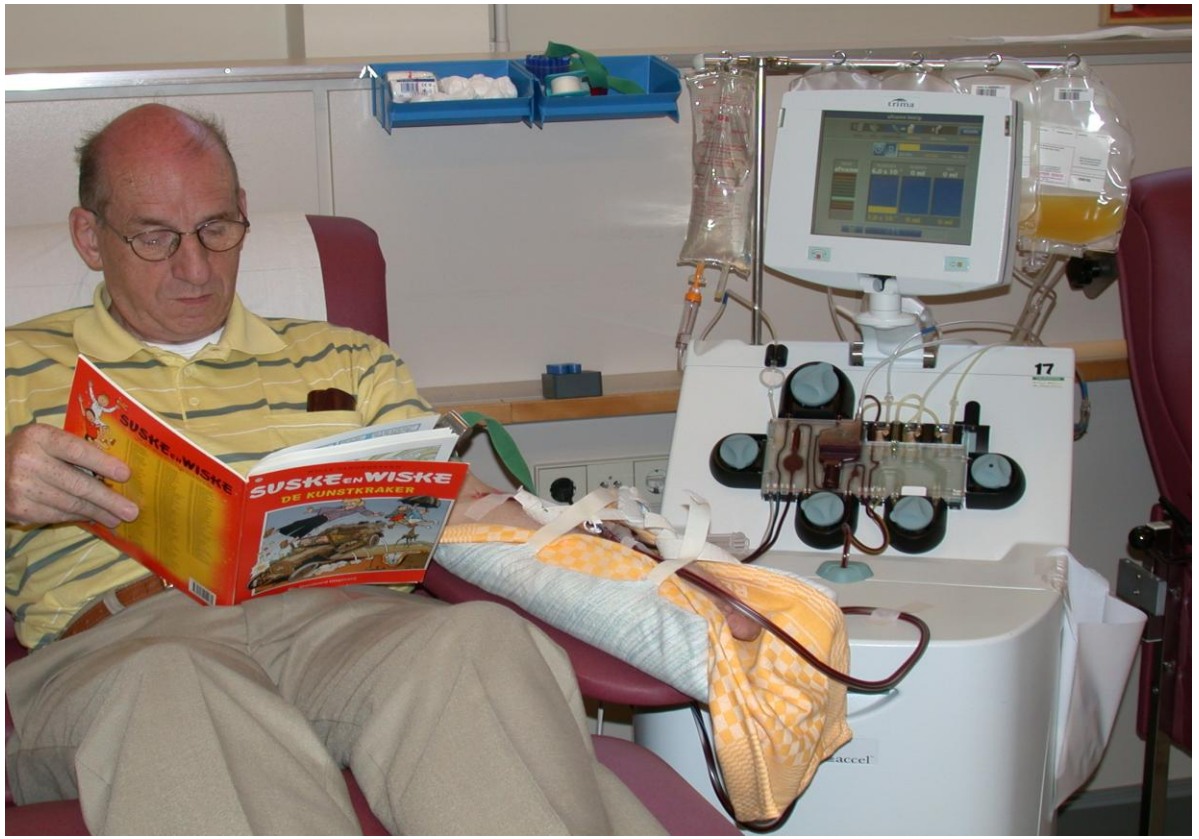
- Continuous Flow
- Baxter/Fenwal CS-3000 Plus, Amicus
- Gambro/Cobe Spectra, Trima
- Intermittent Flow
- Haemonetics LN-8150 MCS, LN-9000 MCS





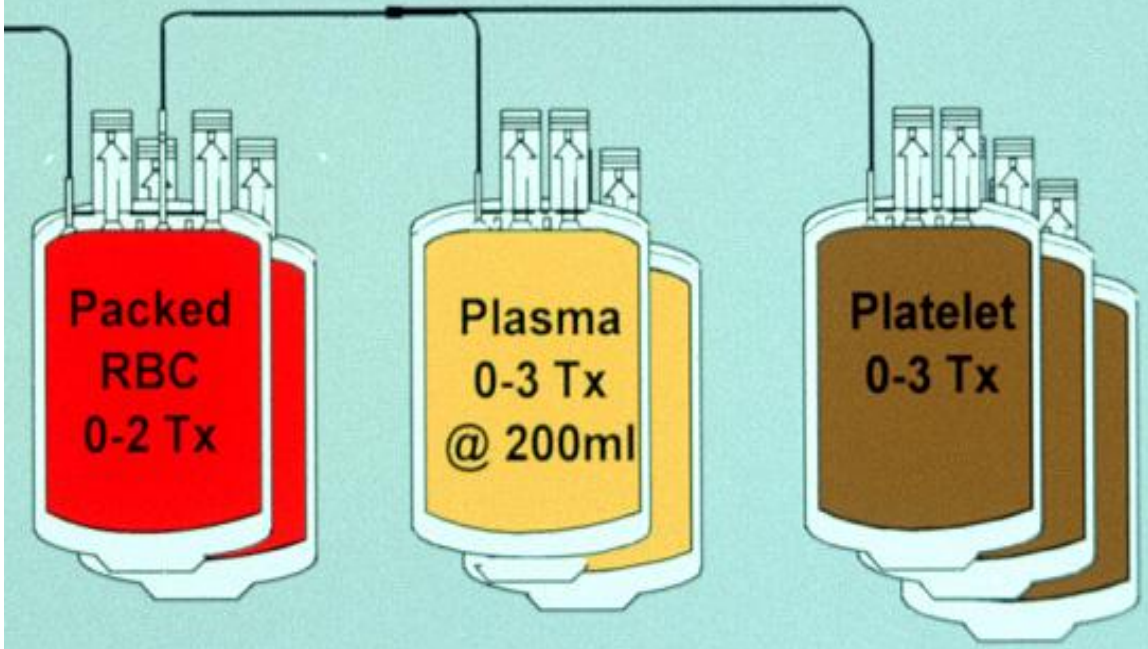

HAEMONETICS
MCS
MCS

TRIMA Accel



Automated Blood Component Collection System

2 - 3 Transfusions



COMPLICATIONS - DONOR APHERESIS

- Common
- Citrate toxicity
- Hematoma or infiltration
- Rare
- Allergy (citrate, plasticizer)
- Cellulitis
- Thrombosis
- Change in volume status

CITRATE

- Chelates calcium
- Metabolized in liver, kidney and skeletal muscle
- Cleared quickly from circulation
- Administered as ACD

SIGNS/SYMPTOMS OF CITRATE TOXICITY

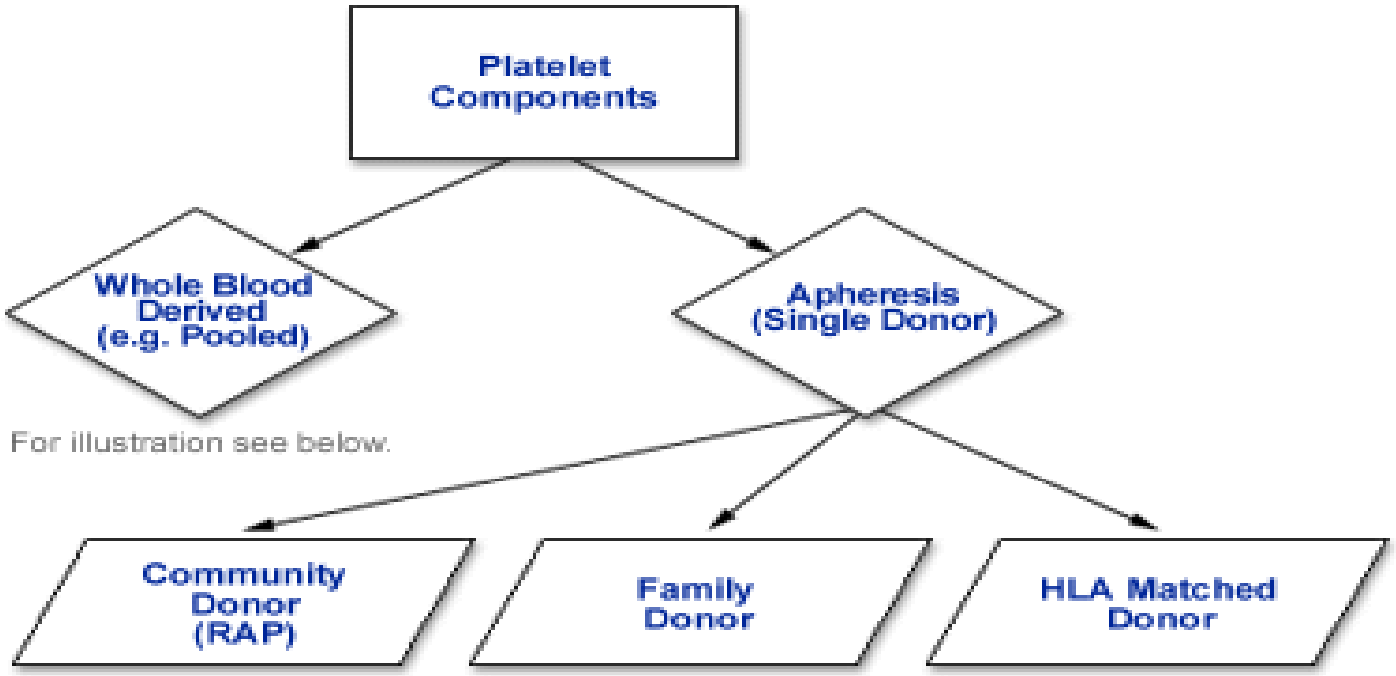
- Tingling/numbness around nose and mouth "circumoral parasthesias"
- More extensive tingling
- Muscle cramping
- Vibration in chest
- Nausea
- Tetany
- Chvostek's sign

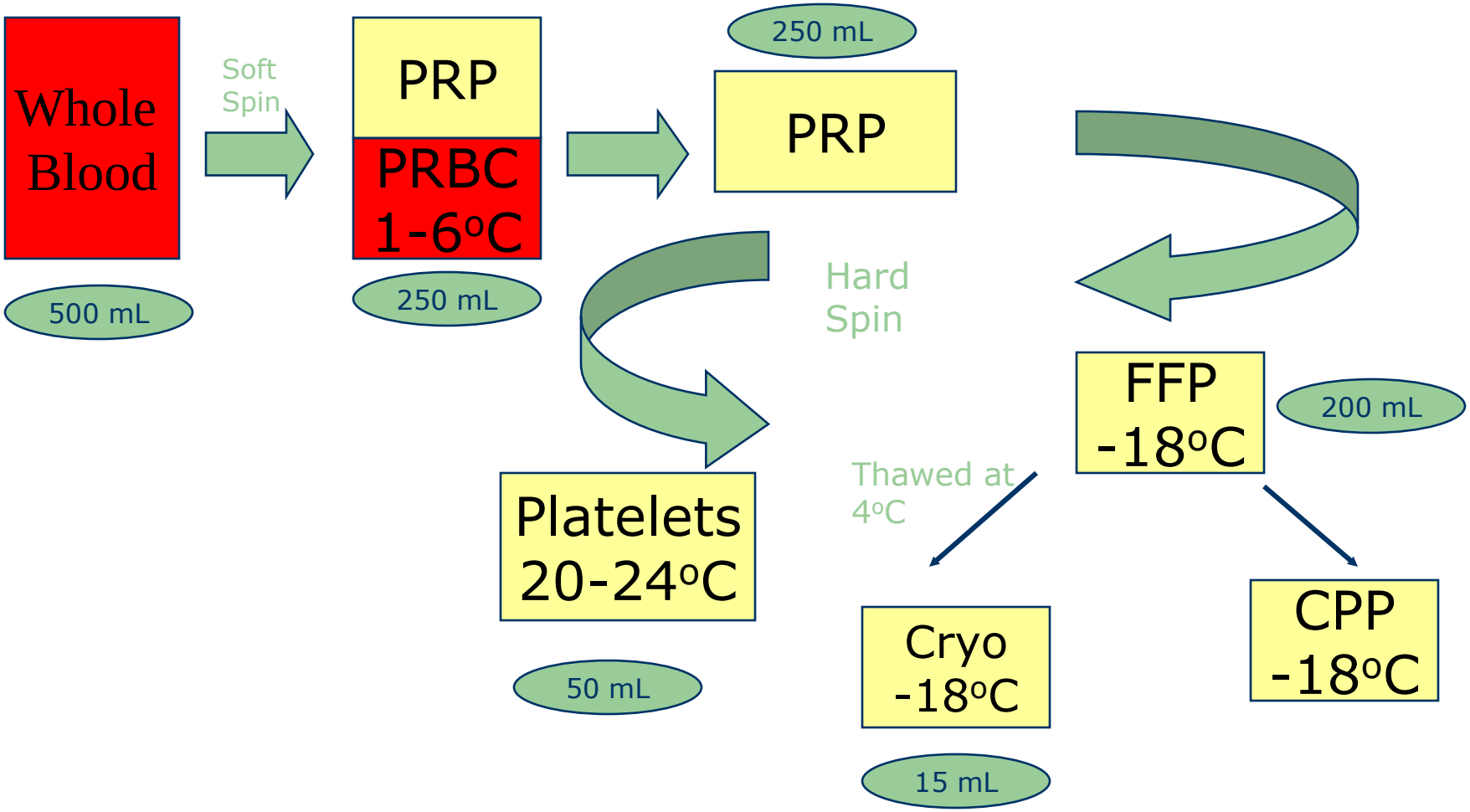
TREATMENT - CITRATE TOXICITY

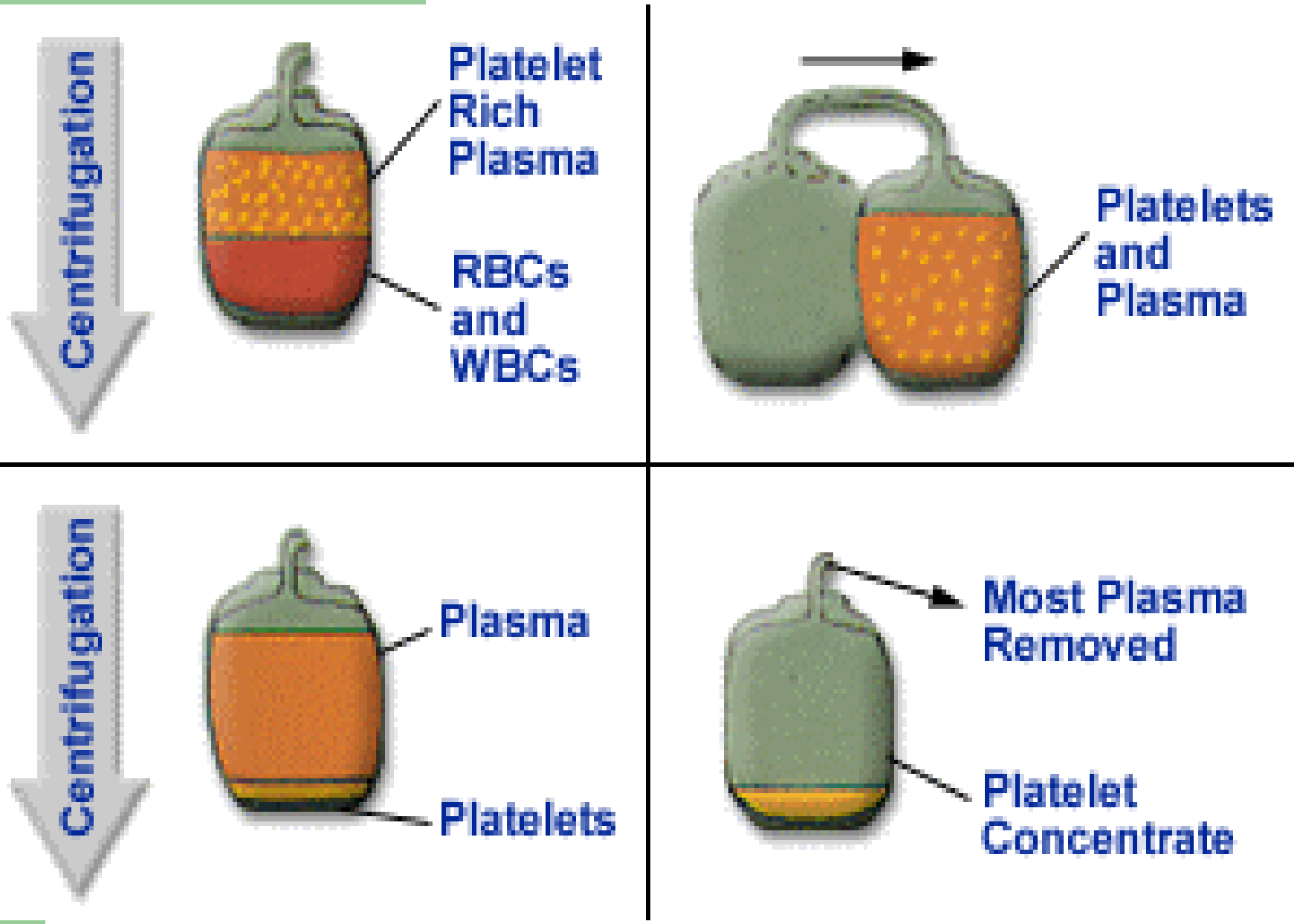
- Mild cases:
- Tums
  - Milk
  - Slow procedure
  - Decrease ratio of anticoagulant to blood
- No bleeding tendency
- Much anticoagulant removed in platelet collection
- Severe cases -- IV calcium replacement

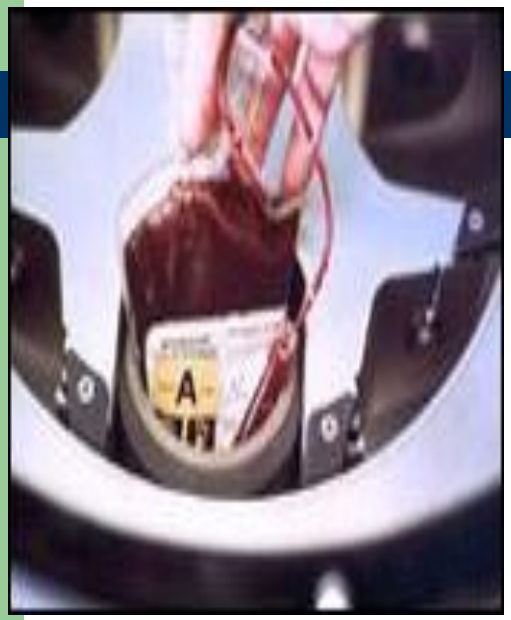
PLATELET APHERESIS

Available Platelet Preparations




Whole Blood
500 mL
Soft Spin
PRP
PRBC 1-6°C
250 mL
250 mL
PRP
Hard Spin
Platelets 20-24°C
50 mL
FFP -18°C
200 mL
Thawed at 4°C
Cryo -18°C
15 mL
CPP -18°C


Centrifugation
Platelet Rich Plasma
RBCs and WBCs
Platelets and Plasma
Centrifugation
Plasma
Platelets
Most Plasma Removed
Platelet Concentrate


A

DONOR ELIGIBILITY - PLATELET APHERESIS

- No whole blood donation for 8 weeks
- No platelet donation for 48 hours
- No aspirin in last 36 hours
- Platelet count >150,000/ul
- No more than 2 times per week
- No more than 24 donations in one year

PLATELET COUNT-PLATELET APHERESIS

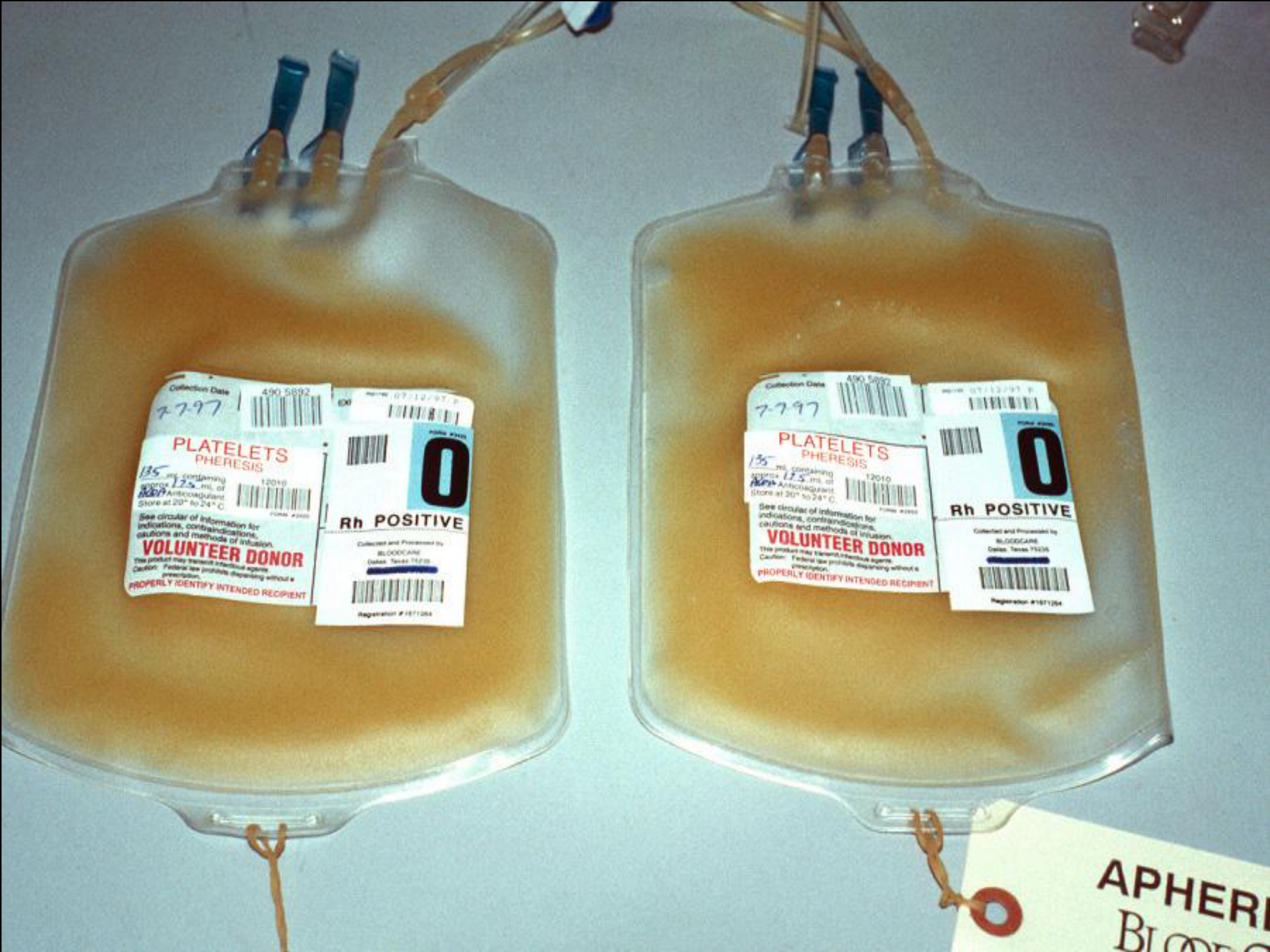
- Platelet count drops 25-35% after procedure
- Rarely below 90,000
- No bleeding complications
- Recovers in several days

APHERESIS QUALITY CONTROL

- Platelets:
  - ≥3.0 x 10" platelets per collection (90%)
  - pH ≥ 6.2 at 5 days (90%)
  - May check at issue if none available at 5 days
  - Test at least 4 per month:
    - Site, manufacturer, split vs single
- Granulocytes:
  - ≥1.0 x 10^{10} WBCs per collection (75%)

SPLIT APHERESIS PLATELETS

- Donor with high platelet count
- Slightly longer procedure
- Yields bag of equal to or greater than 6.5 x 10" platelets
- Split immediately into two or three "doses"


PLATELETS
PHERESIS
VOLUNTEER DONOR
PROPERLY IDENTIFY INTENDED RECIPIENT
O
Rh POSITIVE
PLATELETS
PHERESIS
VOLUNTEER DONOR
PROPERLY IDENTIFY INTENDED RECIPIENT
O
Rh POSITIVE
APHER

PLATELET UNIT COUNTING

- QC for count and pH (4 per month)
- Also must count every bag
- Not required to label bag with count
- Low count bags must be so labeled

LEUKOREDUCTION AND PLATELET APHERESIS

- Gambro/Cobe - LRS system for Spectra and Trima
- Fenwal - Amicus with elutriation
- Haemonetics - Filter in MCS kit

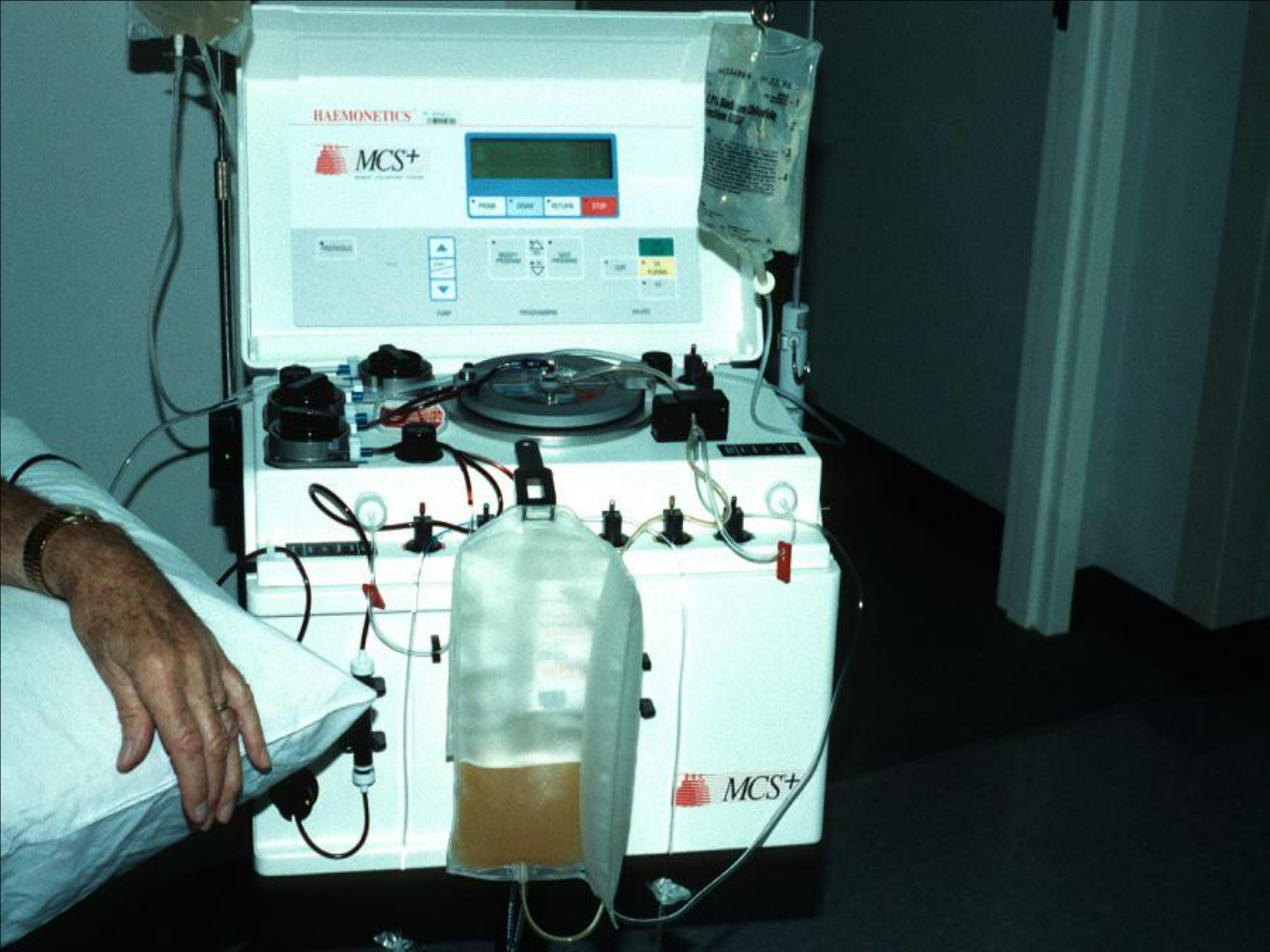

fusion

ADVANTAGES – LEUKOREDUCTION IN APHERESIS

- Leukoreduction prior to storage
- No filter failure
- No loss of cells in filter
- Possible cost advantage

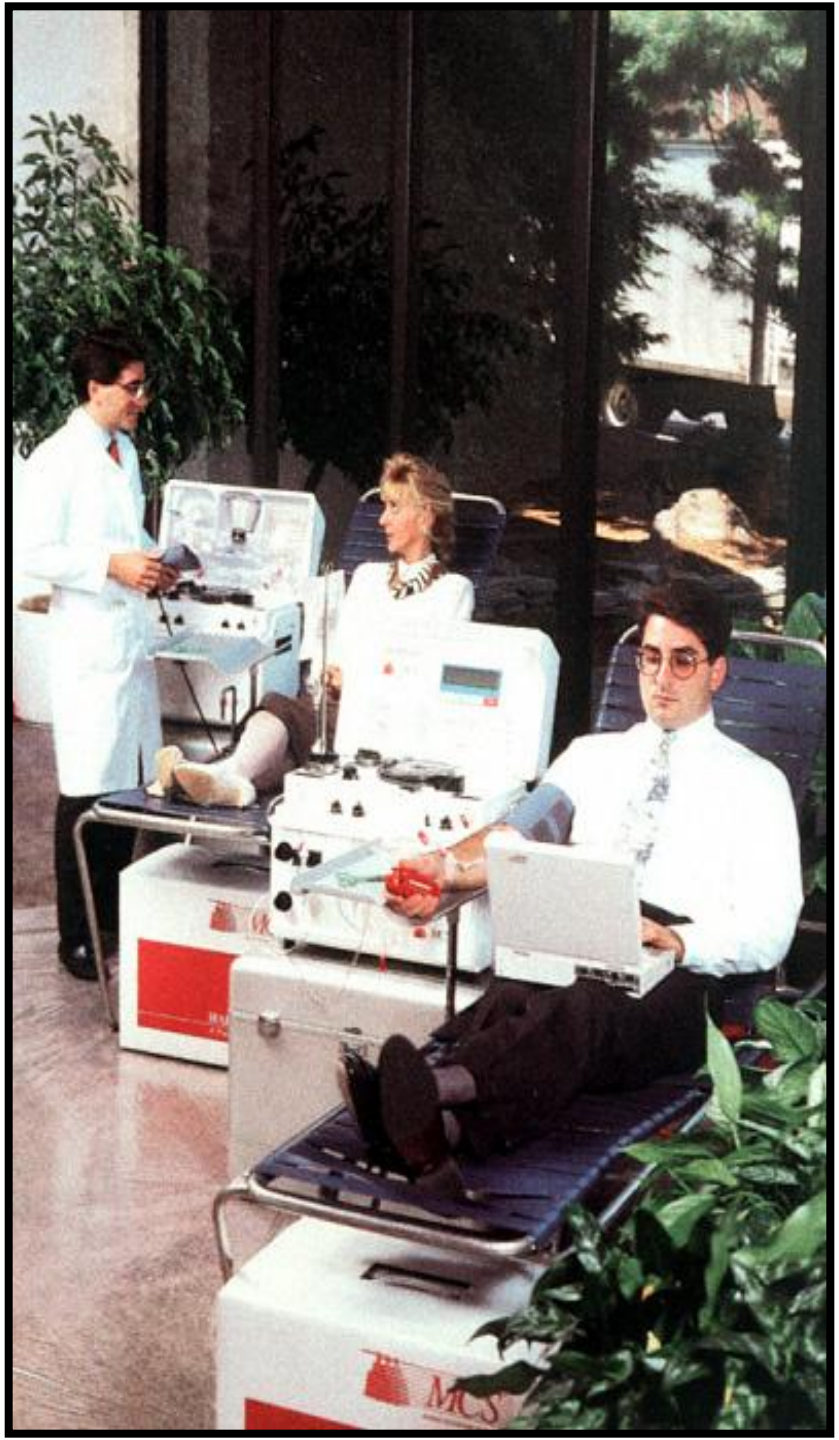
CONTAMINATION LEUKOCYTE LEVEL - QUALITY CONTROL

- WBCs < 5.0×10^9 routinely
- WBCs < 5.0×10^6 to be "leukoreduced"
- Europe and proposed U.S. 1.0×10^6
- Must count 4 per month per each site and technology (singles, doubles, and triples)


HAEMONETICS
MCS+
PRIME
DRAW
RETURN
STOP
MCS+

APHERESIS COMPONENTS WITH SAME NUMBER

- Double RBC collections
- Double platelet collections
- Aliquots of jumbo plasma


MCS

Centrifuge speed	4800 – 7000 rpm (varies with protocol)
Pump speed	0-150 ml/min (adjustable)

For detailed information describing intended use, warnings, precautions and contraindications, refer to the instructions provided for each device or contact Haemonetics Corporation.

TO YOUR APHERESIS PROGRAM.

HAEMONETICS®

Apheresis Procedure Length

- Red cells plus plasma -- 40 minutes
- Double red blood cells -- 45 minutes
- Platelets (single) -- 70 to 120 minutes
- Granulocytes -- 3 hours
- Peripheral blood stem cells -- 4 to 6+ hours

Platelets Pheresis

- Hemapheresis is used to harvest a therapeutic adult dose of platelets from one individual donor
- Contains > 3x 10^{11} platelets
- Equivalent of 6-8 units of platelets
- Leukocytes reduced

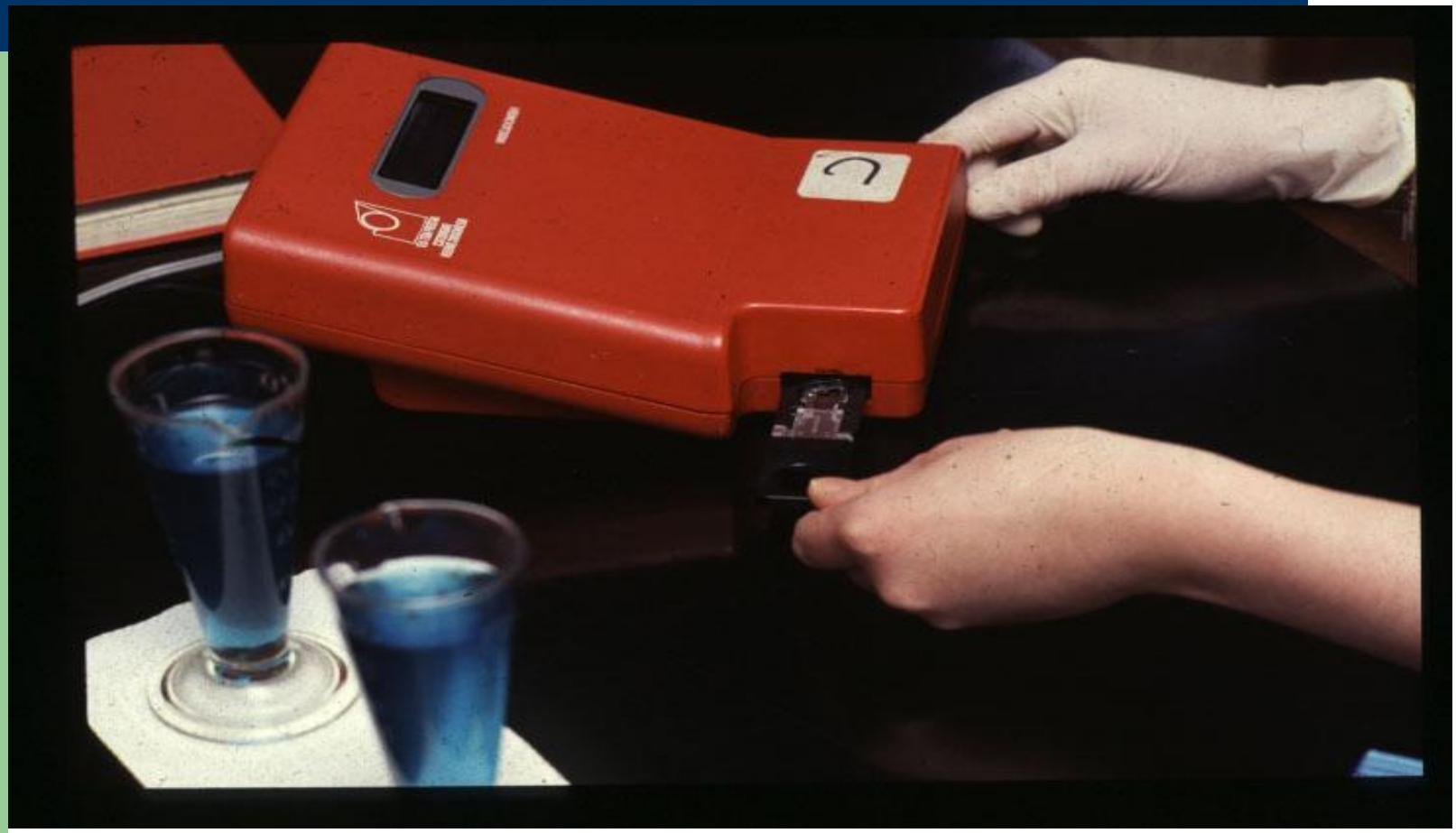
PLATELET PACKS: SINGLE DONOR

- Indications
  - Thrombocytopenia (<50,000/microL)
  - Cancer patients having chemo. or radiation (<20,000)
  - DIC (<50,000)
  - Massive transfusion (<50,000)
- If patient becomes refractory to plts (has plt Abs), will need to give single donor packs (plateletpheresis units)
  - determine 1 hr post transfusion plt increment (see p. 347)
  - if less than 50% of expected two times, pt. considered refractory
- ABO/Rh compatible

PLATELET PACKS: SINGLE DONOR

- Processing - requires special equipment to perform apheresis procedure
- At least 3 X 10^{11} plts in 300 mL
- Storage at RT with constant agitation for 5 days
- Indications - same as for random donor packs but patient has been shown to be refractory
- Expected net gain - 30,000 to 60,000/microL
- ABO/Rh compatible; may also type to determine HLA compatibility

Haemoglobin Testing



Bacterial Detection of Platelet Products

- AABB requirement since 3/04
- Two commercial systems detecting
  - CO_2 generation
  - O_2 consumption
- Swirling or pH

Documentation
Maintenance
Calibration
Labeling
of Platelet

DOCUMENTATION

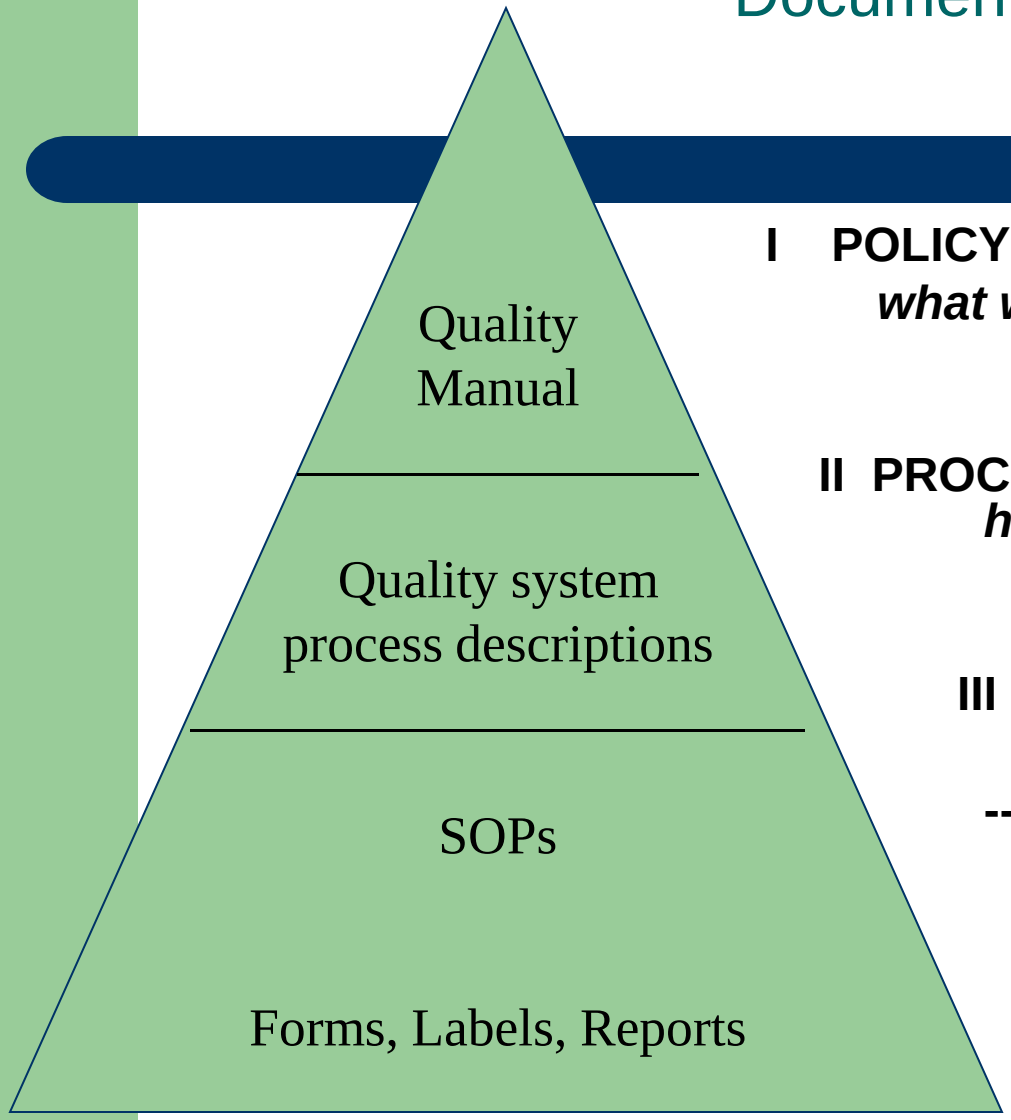
Documents

- **approved information that describes the organisation's quality system policies, processes and procedures**
- **mostly SOPs eg. PLT preparation**

Records

- **capturing process/ procedure data on forms eg. PLT log**

Quality System Documentation Heirarchy



I POLICY DOCUMENTS
what will be done

II PROCESS DESCRIPTION DOCUMENTS
how it happens

III PROCEDURE DOCUMENTS
how to do it

IV RECORDS ***what was done***

Documentation

Component preparation

General rules remain

Blood collection

- **type of bags**

- **Time**

- collection time

- bet’ collection and separation

- time of storage

Separation

- centrifuge

- centrifugation time and speed

Platelet concentrate (RDP) Quality Control

Facility Name
Date _____

Centrifuge #	*Donor #*	*Expiration date*	*Volume 40-60 ml*	*pH > 6.2*	*Platelet count*	*Total plts per unit >5.5 x10^{10}*	*Results Acceptable? Yes/No*	*Date tested*	*Tech*

Total % units meeting requirements

pH __ (100%) Volume __ (100%) Plt count __ (>75%)

Comments _____

Reviewed by _____ Date _____

SOP/ version date

MAINTENANCE

Equipment maintenance

- **Documentation of installation**
- **Installation validation**
- **Preventive maintenance - AMC**
- **Regular calibration, and after repairs**
- **Performance monitoring**

RECORDS OF EQUIPMENT MAINTENANCE

- ***Instrument serial #*** _____
- ***Model no.*** _____
- ***Date of purchase*** _____
- ***Name of supplier*** _____
- ***Maintenance visit schedule*** _____
- ***Dates of breakdown / repairs*** _____

Signature _____

CALIBRATION

Establishment of accuracy over operating range by appropriate reference material/ calibrators

All calibrated equipment

label with

- **date of last calibration and signature**
- **date of next calibration**

CALIBRATION

PERFORMANCE CHECKS

To verify that instrument in specified range of accuracy and precision

REFERENCE STANDARDS

Measurement standards

- **Certificate of assigned values**

Traceable to national standard of measurement

- **Precalibrated certified stds.**
- **Internal working std.**

RECORDS OF CALIBRATION

- ***Instrument serial #*** _____
- ***Date of calibration*** _____
- ***Due date of next calibration*** _____
- ***Details of adjustment/repairs*** _____
- ***Results of calibration*** _____

  before/after repairs _____
- ***Statement of compliance*** _____

Signature _____

LABELING

Critical material in document management system

- **Must conform to regulatory requirements**
- **Quality supervisors must review/ approve before use**
- **Specific and controlled- size, type, wording**
- **Bar coded labels**

  ISBT 128 : information, wording, location stdzed

  enhances efficacy, accuracy & safety
- **Master set, careful when change out of old stock**
- **Special labeling e.g. irradiated or LD product**

THANK YOU