

StatSpin MP

**Operator's Manual for
Multi-Purpose Centrifuge**

Operator's Manual
for
StatSpin*[®] *MP
Multi-Purpose Centrifuge
Model Number M900

For in vitro diagnostic use

Product Numbers

SSMP, SSMP-10 and SSMP-22

Covered under one or more of the following US patents:

StatSpin and accessories:	#4,846,974
	#4,981,585
FlagTag Labels:	#4,884,827
StatSampler Tubes:	#5,257,984

Other patents applied for.

StatSpin, LipoClear, StatSampler, SafeCrit and FlagTag are registered trademarks of StatSpin Inc.

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TABLE OF CONTENTS

1.	INTRODUCTION & INTENDED APPLICATIONS	
1.1	Introduction	1
1.2	Intended Applications	1
	- Preparation of Plasma/Serum from blood	1
	Venous Blood	1
	Capillary Blood Collectors	1
	- Lipemia clearing with LipoClear®	2
	- Urine Sedimentation	3
	- Microhematocrits	3
2.	UNPACKING & INSTALLATION	
2.1	Check for damage	4
2.2	Check for complete packaging	4
2.3	Installing the StatSpin MP	5
2.4	Power connection	5
3.	SAFETY FEATURES & PRECAUTIONS	
3.1	Symbols and definitions	6
3.2	Interlock mechanism	6
3.3	Manual latch	6
3.4	Opening & closing the cover	7
3.5	Precautions	7
3.6	Hazards	7
4.	WORKING WITH STATSPIN	
4.1	Instructions for use	8
4.2	Description of rotors	9
4.3	Appropriate use of rotors	9
5.	CONTROLS & INDICATORS	
5.1	Controls	
	- "Urine / 45 seconds"	10
	- "Hct / 120 seconds"	10
	- Tube Rotors / 30 seconds"	10
	- "PlasmaRotors / 30 seconds"	10
	- "LipoClear / 95 seconds"	10
	- "Coag Plasma / 120 seconds"	10
	- "stop / open" button	10
	- "power" indicator	10

5.	CONTROLS & INDICATORS (cont.)	
5.2	Indicators (audible)	
	System Function Codes	11
	System Malfunction Codes	11
6.	MAINTENANCE	
6.1	Cleaning	12
6.2	Replacing an O-Ring	13
6.3	Checking the rotor speed	13
7.	SPECIFICATIONS	14
8.	SERVICE	15
9.	PREPARATION OF URINE SEDIMENT FOR MICROSCOPIC EXAMINATION	
9.1	Procedure	16
10.	DETERMINATION OF PACKED RED-CELL VOLUME or MICROHEMATOCRIT (Hct)	
10.1	Procedure	17
10.2	Quality control	19
10.3	Normal values	19
10.4	Illustrations	20
11.	PREPARATION OF BLOOD FOR COAGULATION TESTING	
11.1	Procedure	21
12.	REFERENCES	22



UNIVERSAL PRECAUTIONS

Universal Precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent. Universal Precautions have been stated by Center for Disease Control in 1987 and updated in 1988 and are reprinted in National Committee for Clinical Laboratory Standards proposed guidelines, "Protection of Laboratory Workers From Instrument Biohazards".

(see references)

1. INTRODUCTION & INTENDED APPLICATIONS

1.1 Introduction

The StatSpin is a small, quiet, high-speed centrifuge. It employs a unique, proprietary drive and suspension system which results in nearly vibration-free operation. Light-weight, low-mass rotors achieve both top speed and full braking in a few seconds. The StatSpin instrument is designed to meet international safety standards.

1.2 Intended Applications

PREPARATION OF PLASMA/SERUM FROM WHOLE BLOOD

A. Venous Blood

PlasmaRotor® (RD01) consumable provides a means for the rapid separation of plasma from anticoagulated whole blood. To prepare plasma for chemistry testing use the "*PlasmaRotor / 30 seconds*" cycle. To prepare platelet-poor-plasma for coagulation testing use the "*Coag Plasma / 120 seconds*" cycle.

Note: Do not spin a Tube Rotor on the PlasmaRotor cycle. It will not reach operating speed and will "time out" and an audible signal will sound. (see section 6.2)

B. StatSpin Capillary Blood Collectors

StatSpin Inc. offers a complete line of sample collection products to improve both the ease of sample collection and the quality of the sample. All collectors are spun in their respective rotors on the "*Tube Rotors / 30 Seconds*" cycle.

StatSampler® Collection System. Combines the best features of other collectors:

1. Ease of filling using a capillary tube;
2. Smaller sample volume (100 or 200 uL);
3. Immediate anticoagulation in the capillary tube;
4. Rapid processing in a microcentrifuge tube;
5. Isolation of cells with a barrier gel (for plasma or serum).

StatSampler Tubes are centrifuged in the RT12 Tube Rotor (included with the StatSpin MP).

Summary: StatSpin Capillary Blood Collectors

Product Name	Volume(µL)		Additive	Product Number
	fill	max yield		
StatSampler	100	whole blood	EDTA	SS1E
"	200	whole blood	EDTA	SS2E
"	200	100+ plasma	Heparin(w/ gel)	SS2H
"	200	100+ serum	None (w/ gel)	SS2U
"	200	100+ plasma	EDTA (w/ gel)	SS2X

LIPEMIA CLEARING WITH LipoClear®

StatSpin MP can be used to centrifuge samples treated with LipoClear (LC10, LC40, LC15). LipoClear is a non-toxic, noncarcinogenic, lipemic sample clearing reagent, prefilled in microcentrifuge tubes. The kit is available for 0.5mL and 1.5mL sample sizes(see table below). After sample is added, mixed and allowed to stand for 5 minutes, the tubes are spun on the “*LipoClear / 95 Seconds*” cycle in the RT12 Tube Rotor. See LipoClear Product Insert Sheet for details.

Product No.	Sample Size	Packaged As
LC10	0.5 mL	10 tubes / pack
LC40	0.5 mL	40 tubes / pack
LC15	1.5 mL	40 tubes / pack

URINE SEDIMENTATION

StatSpin MP quickly prepares urine sediment for microscopic examination. This is accomplished with the precalibrated urine tubes (Product Number TU15). These urine tubes are spun on the “*Urine / 45 Seconds*” cycle in the RT12 Tube Rotor. The preparation of urine sediment for microscopic examination is more completely described on page 16.

MICROHEMATOCRIT

The StatSpin MP spins micro-capillary tubes for determining packed red cell volume (PVC) or hematocrits (Hct). Four types are available:

Hematocrit Tubes

<u>Type</u>	<i>Product Number</i>	<i>Treatment</i>	<i>Application</i>
<u>Glass</u>	HT9H	Heparinized	For finger-stick samples
	HT9U	Untreated	For anticoagulated samples
<u>Plastic</u>	HP8H	Heparinized	For finger-stick samples
	HP8U	Untreated	For anticoagulated samples

These tubes are easy to fill and require less than 20uL of blood. The tubes are spun on the “*Hct / 120 seconds*” cycle in the RH12 Rotor.

2. UNPACKING & INSTALLATION

2.1 Check for damage sustained during transport

The StatSpin MP and its accessories are delivered in one carton.

If the apparatus or the accessories have suffered any damage in transport, please inform your carrier immediately.

Save the shipping carton with all of its components in the event that the instrument needs to be returned for service.

Please complete and return the Warranty Card.

2.2 Check for complete packaging

The package contains:

- One StatSpin MP
- One wall transformer with cord or switching power supply
- One Operator's Manual with warranty card and extra O-rings
- One accessory carton

The accessory carton consists of:

- One Tube Rotor (RT12)
- One Hematocrit Rotor (RH12), with circular reader HR4C
- Samples of various consumable products - see packing list

2.3 Installing the StatSpin Centrifuge

Place the StatSpin MP on any surface acceptable for laboratory instrumentation. Position the StatSpin MP away from direct sunlight and sources of heat and cold. Mark a 300mm clearance boundary around the centrifuge to allow adequate ventilation and safety.

The room temperature should be between 15°C and 32°C. When the centrifuge is cold, especially at a temperature below 10°C, the noise level will rise.

2.4 Power connection

The power supply should be plugged into a grounded outlet with the voltage indicated on the label on the back of the transformer. The frequency (Hz) can be either 50 or 60 cycles. When power is connected 3 “beeps” will sound and the cover lock (see section 3.2 “Internal Lock”) will be released and the instrument will be ready for use. To turn centrifuge off completely, disconnect power plug-in located at rear of the instrument.



IMPORTANT: If the voltages do not match, do not connect the StatSpin to the power source.

StatSpin Product No.	Description	MFG	Model
01-3553-001	AC Power Adapter	APS	AD-740U-1240
01-3436-001	Centrifuge Power Supply	AULT	SW105
01-2535-001	AC Transformer (Only for use with model M900-12)	StatSpin	21-1402-02

This StatSpin MP will give you very quiet, nearly vibration-free operation. To do this it utilizes a unique drive and motor suspension system. Please plug in and allow an hour or more to come to room temperature before running. After installation leave it plugged in unless it will not be used for a long period of time.

3. SAFETY FEATURES & PRECAUTIONS

3.1 Symbols and definitions



Caution: To reduce risk of injury - do not operate with an unbalanced load.

Caution: Inspect rotors for fatigue.

Caution: Incorrect tubes may damage rotor.



Caution: To reduce risk of shock, do not disassemble. Refer servicing to qualified service personnel. There are no user serviceable parts.

3.2 Interlock Mechanism

The StatSpin Centrifuge incorporates an electrically operated lock mechanism which:

1. Prevents the centrifuge from being operated unless the cover is completely closed and latched.
2. Prevents the cover from being opened while the centrifuge is in operation.

3.3 Manual latch

StatSpin Centrifuge is also equipped with a manually operated external latch which continues to hold the cover down after spinning is complete and the interlock mechanism has released.

3.4 Opening & closing the cover

1. When the cover is completely closed it is locked shut and an operating cycle can be selected. It can only be released if the “stop / open” button is pushed.
2. The cover is released at the end of the operating cycle or it can be released by pushing the “stop / open” button. The cover can then be opened by squeezing the black pieces of the latch together and lifting (see illustrations below).



The cover of the StatSpin is usually left down, but not latched. In the event of a power failure while a sample is being processed, the automatic lock can be released manually.

This is done by inserting the straightened end of a large paperclip or similar object into the small hole between the two buttons, in the front of the latch cover (facing the instrument) and manually pushing the lock lever inward.



IMPORTANT: Do not attempt to defeat the safety features of your StatSpin Centrifuge. Improper use of the equipment may impair the protection provided by the unit.

3.5 Precautions

The StatSpin MP is designed to prepare blood samples for diagnostic testing. Accordingly, use of the StatSpin MP places a responsibility upon administrative personnel to insure adequate training of operators in the safe and effective use of the centrifuge.

3.6 Hazards

The StatSpin MP is not explosion-proof and should not be used in a potentially explosive atmosphere.

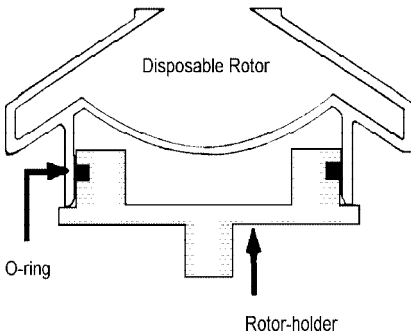
4. WORKING WITH STATSPIN MP

4.1 Instructions for use (general operation)

The StatSpin MP is normally left plugged-in and “on”. There is no “on-off” switch.

1. Lift the cover of the instrument and install a rotor. Press rotors firmly in a downward motion onto the rotor-holder of the StatSpin MP.

Inserting the rotor



All rotor bottoms fit over a rubber O-ring on the rotor-holder. The Figure on the left shows a rotor, (cross-section) in place on the rotor-holder. As the rotor turns, the O-ring is moved outward by centrifugal force enhancing the frictional coupling between the rotor-holder and the rotor.

Do not leave any rotor on the rotor-holder when the StatSpin is not in use for a long time. Doing so may compress the O-ring and decrease its ability to hold rotors.

IMPORTANT: If a rotor is left in place and only the tubes are exchanged between runs, be certain to “bottom” the rotor on the rotor-holder before spinning another sample. Failure to properly “seat” the rotor each time may result in the rotor becoming loose during centrifugation.

2. Close and latch the cover.
3. Choose the desired cycle by turning the knob so the indicator aligns with the desired cycle (e.g. “*LipoClear / 95 Seconds*”, “*Urine / 45 Seconds*”, or “*Hct / 120 Seconds*” etc.) Press “start” button. (See section 5.0, “CONTROLS and INDICATORS”)

IMPORTANT: For specific procedures (e.g. urine sedimentation, hematocrits and coagulation preparation) see pages 16-21 in this manual.

4.1 Instructions for use (cont.)

4. When the timed cycle is complete, the rotor will stop spinning.
5. The interlock mechanism will release and the black cover latch can be squeezed to open the cover. (see illustrations section 3.3)

4.2 Description of rotors

PlasmaRotors (RD01) - are used to process larger amounts (usually 2 to 3 ml) of blood for chemistry or coagulation testing. Consult the insert sheet provided with these rotors for instructions on their use. StatSpin PlasmaRotors are self-balancing.

Tube Rotors (RT12, RM02) - A variety of Tube Rotors are available for use with your StatSpin. These accommodate a wide variety of blood collectors or other tubes.

IMPORTANT: Tube Rotors should be balanced. If only one sample is being processed, a second sample can serve as the balancing tube or a tube can be filled with water.

4.3 Appropriate use of rotors



IMPORTANT: Observe the following when using Tube Rotors. For any rotor use only the tubes which are specified for use with it.

Never use tubes which fit loosely in the rotor sleeves and rest on the bottom of the rotor. In Tube Rotors, RT12 or RM02, the tubes must be supported by a collar at the top of the tube.

Never centrifuge glass tubes of any type in two-place Tube Rotors.

IMPORTANT: StatSpin Rotors are designed to be very lightweight to provide very quiet operation, compact size, and rapid processing. **All such Rotors have a finite lifespan that is dependent upon usage. Rotors should be inspected for cracks and should be replaced immediately if any crack should appear.**

5. CONTROLS & INDICATORS

5.1 Controls

The cycles of the StatSpin MP are selected by turning the large knob. Spin times are indicated below the cycle's title. To initiate the cycle, install the appropriate rotor, close and latch the cover and press the "start" button on the front panel.

"Urine / 45 seconds"

- for use with the RT12 Tube Rotor and TU15 pre-calibrated urine tubes.

"Hct / 120 seconds"

- for use with the RH12 (& RH03) Hematocrit Rotors.

"Tube Rotors / 30 seconds"

- for use with RT12 and RM02 Tube Rotors with most capillary blood collectors.

"PlasmaRotors / 30 seconds"

- for use only with RD01 PlasmaRotor for separating up to 3mL of whole blood for chemistry testing.

"LipoClear / 95 seconds"

- for use with LipoClear, reagent prefilled tubes for clearing lipemic samples or HDL-Cholesterol precipitating tubes.

"Coag Plasma / 120 seconds"

- for use only with RD01 PlasmaRotor for separating up to 3mL of whole blood to prepare platelet-poor-plasma for coagulation testing.

"stop / open" button

- interrupts the cycle and stops the centrifugation. The "stop / open" button is rarely used as the cycles are automatically timed. It can be used to release an accidentally latched cover.

"power" indicator

- green LED, illuminated when the StatSpin is connected to a power source.

The StatSpin Centrifuge is not provided with an "on/off" switch. The centrifuge is normally left plugged in and "on". The cover is usually left down but not latched.

5.2 Indicators (audible)

System Function Codes

- Two medium beeps: instrument ready, heard upon power-up.
- Three short beeps: cycle completed per specified operating parameters.
- Chirp: start or stop command recognized by the microprocessor.

System Malfunction Codes

One long beep followed by:

- One short beep: rotor failed to reach rpm within thirty seconds.
- Two short beeps: cover opened or cycle changed during operation.
- Four short beeps: insufficient power to maintain rpm and/or use of incorrect rotor.
- Five short beeps: over current detector tripped.

6. MAINTENANCE

StatSpin has a Service Maintenance Program. Contact StatSpin's Customer Service Department for details (In USA, dial toll free: 800-782-8774, or Phone: 781-551-0100, Fax: 781-551-0036).

StatSpin recommends that instrument operators perform periodic inspections and preventative maintenance on all StatSpin instruments. This recommended protocol includes:

- 1.) Replace the O-Ring (see section 6.2). - the only user serviceable part.
- 2.) Contact the manufacturer's customer service department if, at any time, the instrument is not functioning properly. (e.g. dislodging rotors, not cycling at stated speed etc.)



IMPORTANT: Unplug the centrifuge before starting any maintenance work.

6.1



Cleaning

The outside surfaces and switch overlay panel can be cleaned with a water-dampened cloth and mild detergent.

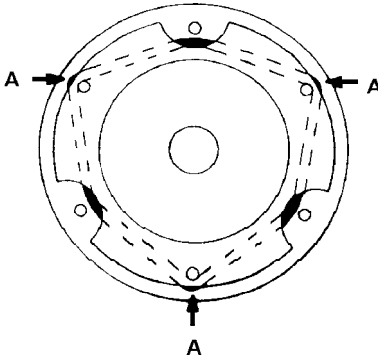
The inner surface or bowl, a powder-coated steel surface, can be cleaned with a mild detergent and disinfected if necessary by wiping with a cloth dampened with 70% alcohol or 10% bleach.



IMPORTANT: DO NOT SPRAY the bowl or outer surfaces with detergent or bleach. Excess liquid will harm the electronics and subsequent problems **will not** be covered under warranty.

Do not use abrasives or solvents. The clear cover is made of scratch-resistant polycarbonate and can be cleaned with mild detergent, glass or plastic cleaners on a soft cloth.

6.2 Replacing an O-ring



The Figure on the left illustrates the position of the rubber O-ring which is attached to the rotor-holder. Should it ever break a new one can be installed as shown, by weaving it behind and in front of the 6 pins on the rotor-holder.

The points at which the O-ring touches the rotor are indicated by the letter "A". Extra O-rings have been included with this manual.

6.3 Checking the rotor speed

The speed of the StatSpin Centrifuge should be checked by the user twice a year.¹¹ The speed cannot be adjusted by the user. The rated speeds ($\pm 5\%$) can be checked with a photoelectric tachometer available from many sources. If the StatSpin fails to achieve operating speed $\pm 5\%$, contact your distributor or StatSpin (800-782-8774) for service.

The timing of the StatSpin Centrifuge's cycles should be checked by the user twice a year. The time cannot be adjusted by the user. If the StatSpin Centrifuge fails to achieve specified times, contact your distributor or StatSpin (800-782-8774) for service.

7. SPECIFICATIONS

StatSpin MP Centrifuge:

Power requirements

Voltage:

SSMP-10	nominal 100 V~ (range 90 to 110)
SSMP	nominal 120 V~ (range 108 to 132)
SSMP-22	Range 90 to 240 V

Frequency: 50 or 60 Hz

Environmental

- Conditions:**
- Indoor use.
 - Altitude up to 2000m
 - Temperature 5°C to 40°C
 - Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.
 - Main supply voltage fluctuations not to exceed +/- 10% of the nominal voltage.
 - Transient overvoltages according to installation category II
 - Pollution degree 2

Timing: electronic, microprocessor controlled

6 fixed cycles of time and speed	(see table)
Maximum time to achieve operating speed	6 seconds
Maximum time to stop rotation	10 seconds

Operating Cycle	Rotor used	Speed* (rpm)	Maximum (rcf or "g")	Time* (seconds)
"Urine / 45 Seconds"	RT12	9,800	3,900	45
"Hct / 120 Seconds"	RH12			
	RH03	16,000	13,700	120
"Tube Rotors / 30 Seconds"	RT12			
	RM02	15,800	12,000	30
"PlasmaRotor / 30 Seconds"	RD01	20,000	11,200	30
"LipoClear / 95 Seconds"	RT12	15,800	12,000	95
"Plasma for Coag / 120 Seconds"	RD01	20,000	11,200	120

*Speeds and Times \pm 5%

8. SERVICE

With the exception of replacing the rotor-holder O-ring, there are no user-serviceable repairs. Refer to the Warranty for service instructions. Be sure to complete and return the Warranty as directed.

Decontamination - Any machine or accessory containing accumulated blood and/or other chemical deposits must be cleaned prior to shipment to the manufacturer/dealer for service. *This decontamination is required by Federal Law* (Title 48 and 49 of the Code of Federal Regulations) and in accordance with the E.P.A.'s Regulations for Biohazard Waste Management. This decontamination cannot be performed by StatSpin personnel.



Cleaning

The outside surfaces and switch overlay panel can be cleaned with a water-dampened cloth and mild detergent.

The inner surface or bowl, a powder-coated steel surface, can be cleaned with a mild detergent and disinfected if necessary by wiping with a cloth **dampened** with 70% alcohol or 10% bleach.

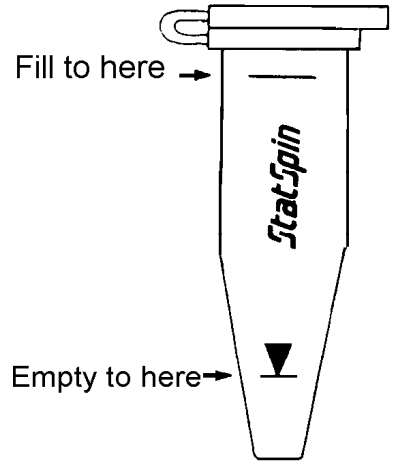
IMPORTANT: DO NOT SPRAY the bowl or outer surfaces with detergent or bleach. Excess liquid will harm the electronics and subsequent problems **will not** be covered under warranty

Do not use abrasives or solvents. The clear cover is made of scratch-resistant polycarbonate and can be cleaned with mild detergent, glass or plastic cleaners on a soft cloth.

9. PREPARATION OF URINE SEDIMENT FOR MICROSCOPIC EXAMINATION

9.1 Procedure

1. Add fresh urine to a Urine Tube (Part Number TU15) up to the top mark (representing 1.5 mL).
2. Cap the tube using the attached stopper and centrifuge in the Tube Rotor, RT12. Balance the rotor either with another sample or with a water filled tube. This balance does not have to be exact. Select the "Urine / 45 Seconds" cycle on your StatSpin MP.



3. When the cycle is complete (about 45 seconds) the cover is released. Remove the tube from the rotor, unstopper, and invert the tube. It will drain to the lower mark, the surface tension of the tube will retain 0.1 mL.
4. Recap the tube and resuspend the urine sediment at the bottom of the tube by holding the tube with the index finger and thumb and "flicking" the tube with the opposite hand.
5. After sediment has been resuspended apply one drop to a microscope slide, apply a cover slip to it, and read following the protocol used in your laboratory.

10. DETERMINATION OF PACKED RED-CELL VOLUME OR MICROHEMATOCRIT (H_{CT})

Both glass and plastic micro-capillary tubes are available. Product Number HT9H(glass) & HP8H(plastic) have been pretreated with heparin (may be color coded red) and should be used for capillary blood. They should be stored in a cool dry place. Product Number HT9U(glass) & HP8U(plastic) are untreated (may be color coded blue) and used for venipuncture (anticoagulated) samples.

For glass tubes only: if the vial of tubes is new, unscrew the top, remove and discard the foam cushion and reattach the top. Now a single tube at a time can be shaken from the vial through the small hole in the center of the cover.

10.1 Procedure for packed red-cell volume (microhematocrit)

- 1A. Capillary ("fingerstick") blood - prepare a skin site and lance. Use heparinized tubes, Product Number HT9H or HP8H.
or
- 1B. Venous blood - take well-mixed anticoagulated blood from a syringe or a vacuum blood collection tube. Use untreated tubes, Product Number HT9U or HP8U.
2. Hold the micro-capillary tube by the end (may have color-coded band). (See Figures, page 20)
3. Fill to within 5mm of the end of the tube. Remove from sample. Turn the capillary tube so the dry end is ready for accepting the sealing compound.
4. Hold the tube in a horizontal position and push the **dry** (may have color-coded band) end of the tube into the vertically held sealing compound. Twist first and remove.
5. Using a laboratory tissue wipe off any blood that is forced from the other end.

10.1 Procedure for packed red-cell volume (cont.)

6. Put the tube, sealed end towards the outer rim, in any of the twelve positions on the Hematocrit Rotor, RH12. This rotor need not be balanced. Screw cover in place.
7. Holding the rotor by the black “cover knob”, attach the rotor to the rotor-holder.

IMPORTANT: Always hold hematocrit rotor by the black knob on the rotor cover, when pressing it firmly in a downward motion onto the rotor-holder and when removing the rotor from the centrifuge. Pressing on the outer edges of the Hematocrit Rotor, RH12, may result in damage to the rotor.

8. Centrifuge the Hematocrit Rotor. Use "Hematocrit / 120 second" cycle.
9. After the rotor stops, remove the rotor. To read hematocrit values place the circular reader, HR4C, over the rotor cover and follow the directions on it:

“Position the reader so that the base of the red cells intersects the “0” (zero) line and the 100 percent line intersects the top of the plasma. Read the height of the red cell column directly from the scale. Interpolate between the markings to one percent.”

Note: An illuminating, magnifying hematocrit tube reader, Product Number HR6L, is available separately.

10.2 Quality Control

1. The Quality Control procedures established for your laboratory should be followed.
2. To verify the adequacy of cell packing, select one or more tubes, (preferably with a hematocrit over 50), centrifuge and read. Spin these tubes a second time. The difference between the initial reading and the second reading should be 1 percent or less.

10.3 Normal Values

The following tables represent commonly accepted hematocrit values:

Children

Age	%
Birth	44 - 64
14 - 90 days	35 - 49
6 months - 1 year	30 - 40
4 - 10 years	31 - 43

Adults

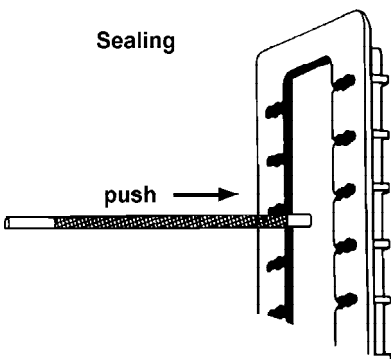
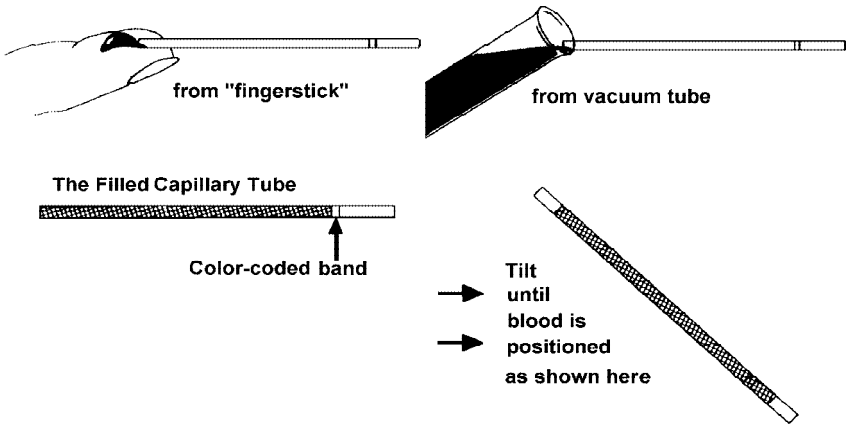
Gender	Mean %	Range (2 s.d.)
Males	47	40 - 54
Females	42	37 - 47

Animals

Species	%
Canine	37 - 55
Feline	24 - 45
Equine	32 - 52
Bovine	32 - 38
Porcine	32 - 50
Ovine	24 - 45

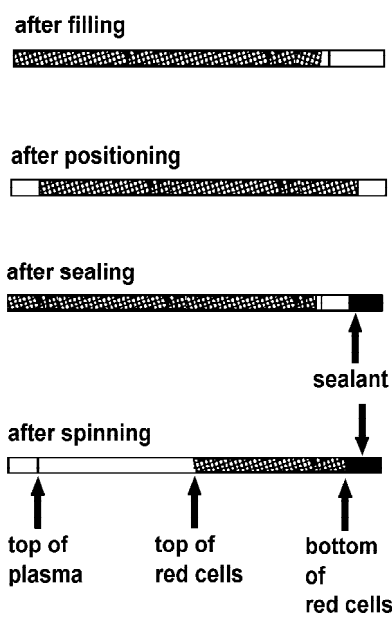
10.4 ILLUSTRATIONS

Filling Capillary Micro-Hct Tube



1. hold tube in a horizontal position
2. hold sealant in a vertical position
3. push tube until bottomed - twist and remove

Position of blood sample



11. PREPARATION OF BLOOD FOR COAGULATION TESTING

11.1 Procedure for preparing blood for coagulation testing

1. Collect the sample through venipuncture into a blue-topped citrated tube. Transport to the laboratory according to your laboratory's procedure. ⁷
2. Transfer from 2 to 3 mL of the citrated whole blood to a StatSpin PlasmaRotor, RD01.
3. Firmly press the Rotor onto the "rotor-holder" of the StatSpin.
4. Select the "*PlasmaRotor / 120 Seconds*" cycle on the StatSpin MP. Close and latch the cover and push the "*start*" button.
5. The StatSpin will automatically shut off after 120 seconds.
6. Remove the PlasmaRotor from the StatSpin and tilt gently to one side.
7. The plasma will drain to the side of the PlasmaRotor and can be extracted for testing in a coagulation analyzer. Use care in removing the plasma.

12. REFERENCES

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