

CritSpin Hematocrit Centrifuge

Operator's Manual

StatSpin[®]

Operator's Manual
CritSpin Microhematocrit Centrifuge
Model Number M961

FOR *IN VITRO* DIAGNOSTIC USE

Product Number

CS12 - CritSpin (for 100-240 VAC, 50/60 Hz)
CS22 – CritSpin with Digital Reader (for 100-240VAC, 50/60 Hz)

StatSpin is a registered trademark of StatSpin, Inc., a Subsidiary of IRIS International, Inc.

Copyright 2004

Printed in U.S.A.

Table of Contents

| | |
|---|-----------|
| How to use this manual | ii |
| Section 1 | 1 |
| Unpacking and Installation..... | 1 |
| Inspect Packaging | 1 |
| Verify Contents | 1 |
| Install System | 1 |
| Connect Power | 1 |
| Section 2 | 2 |
| System Overview | 2 |
| Principle and Intended Use..... | 2 |
| Symbols and Definitions | 2 |
| Error Indicators | 3 |
| Accessories | 3 |
| Section 3 | 4 |
| Operating Instructions..... | 4 |
| Opening and Closing the Cover..... | 4 |
| Installing the Rotor..... | 4 |
| Spinning the Sample..... | 5 |
| Section 4 | 6 |
| Maintenance | 6 |
| Overview..... | 6 |
| Cleaning..... | 6 |
| Checking the Rotor Speed..... | 6 |
| Replacing the O-Ring | 6 |
| Service..... | 7 |
| Troubleshooting..... | 7 |
| Section 5 | 8 |
| Determination of Packed Red Cell Volume (Microhematocrit) | 8 |
| Procedure for packed red cell volume (microhematocrit)..... | 8 |
| Quality Control | 8 |
| Normal Values | 9 |
| Illustrations..... | 10 |
| Appendix | 11 |
| Appendix A - Specifications | 11 |
| References | 12 |
| StatSpin Warranty..... | 13 |
| Limitation of Liability | 13 |



How to use this manual

This manual along with information contained on product labels and in package inserts should provide you with all the information you need to operate and maintain the CritSpin.

Notes appear in italics to highlight information. When the information requires special attention, a caution symbol appears next to the italicized text.



Please pay close attention to the instructions that accompany the notes and symbols as well as the standard laboratory practices outlined by your facility and local regulatory agencies. The table below lists all the CAUTIONS/WARNINGS for the CritSpin.

| | |
|---|---|
|  | <p>WARNING - North American Installation: Only use the power supply included with the unit. Use of other power supplies or transformers will damage the CritSpin electronics and void the warranty.</p> |
| | <p>WARNING - Outside of North America: Do Not Use the Line Cord Supplied. Use power cord for at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.</p> |
| | <p>CAUTION - The cover interlock bypass is designed for emergency use only. If the equipment is not used properly, safety may be impaired.</p> |
| | <p>CAUTION – Do not leave any rotor on the rotor-holder when the StatSpin is not in use for an extended period of time. Doing so may compress the O-Ring and decrease its ability to hold the rotor.</p> |
| | <p>CAUTION – Failure to properly install the rotor may result in damage to the centrifuge and will void the warranty.</p> |
| | <p>CAUTION – If rotor is left in place 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.</p> |
| | <p>IMPORTANT- The rotor (RH12) has a finite lifespan that is dependant on usage. Cracks or swelling that develop indicate the rotor should be replaced immediately.</p> |
| | <p>CAUTION – Unplug the CritSpin from the wall outlet before performing maintenance.</p> |
| | <p>WARNING – Do not expose CritSpin and its rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.</p> |
| | <p>CAUTION – DO NOT spray the bowl or outer surfaces with detergent or bleach. Excess liquid will harm the electronics and subsequent problems may not be covered under warranty.</p> |
|  | <p>CAUTION - Universal Precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent. (See references)</p> |

Please use the system as intended. Improper use of the CritSpin Centrifuge and/or its accessories may cause damage to the system, inaccurate results, or potentially nullify warranties.

The CritSpin Centrifuge, and its associated components are covered under one or more of the following US patents nos.: 4,846,974 & 4,981,585 & 5,566,919

Unpacking and Installation

Inspect Packaging

The CritSpin and its accessories are delivered in one carton. If the centrifuge or accessories have suffered any damage in transport, please inform your carrier immediately.

NOTE: Save shipping carton and components to simplify return should service be required.

Verify Contents

The CS12 & CS22 package contains:

One CritSpin Centrifuge (Model No. M961)

One Hematocrit Rotor (Product No. RH12)

One Universal Switching Power Supply
(StatSpin Product No. 01-3553-001, APS Product No. AD-740U-1240)

One grounded line cord (for North American use only)

One Operator's Manual

One Sample Pack containing various consumable products

The CS22 package also contains:

One CSD1 Digital Reader with power cable connector (refer to CSD1 operator's manual)

Install System

1. Place the CritSpin on a level surface suitable for laboratory instrumentation.
2. Maintain a 300mm clearance boundary around the centrifuge for ventilation and safety.
3. Position the CritSpin away from direct sunlight and sources of heat or cold.
(See Appendix A for specifications.)

Connect Power

Plug the power supply into a grounded outlet supplying the voltage and frequency indicated on the power supply. When power is connected, the Power On LED will illuminate and the cover lock will release.



WARNING - North American Installation: Only use the power supply included with the unit. Use of other power supplies or transformers will damage the CritSpin electronics and void the warranty.



WARNING - Outside of North America: Do Not Use the Line Cord Supplied. Use power cord for at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.

Note: Please refer to the CSD1 Digital Reader Operator's Manual for installation instructions.

Section 2














System Overview

Principle and Intended Use

IVD For *in vitro* diagnostic use for determining packed red cell volume (PCV) or hematocrits (Hct).


The CritSpin is a microprocessor controlled, high-speed bench top centrifuge designed to rapidly spin micro capillary tubes for packed cell determination. The preset cycle is for 120 seconds.

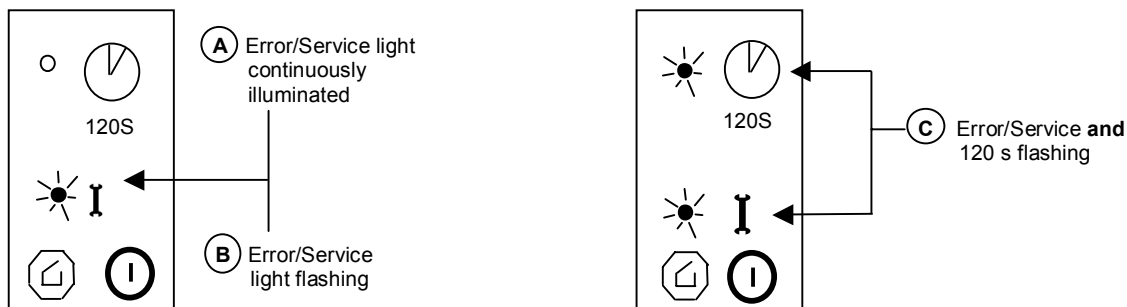
Symbols and Definitions

| | | |
|---|------------------------------------|--|
|  | Start button | The <i>start</i> button initiates the pre-timed cycle. NOTE: The CritSpin does not have an on/off switch and is normally left plugged in and “on”. |
|  | Stop/open button | The <i>stop/open</i> button interrupts the cycle and stops the centrifugation. This button may also be used to release the cover. |
|  | Time | Time indicator (120 s) |
|  | Error/Service indicator | The red LED identified, as <i>error/service</i> is illuminated continuously or flashing when service is required. |
|  | Power input | DC Power Input: 24V DC Plug-in |
|  | Product/Reference Number | Indicates the StatSpin product/catalog number |
|  | Caution | Statement of caution/warning, read instruction carefully |
|  | Temperature limitation | Indicates storage requirements range |
|  | For <i>in vitro</i> diagnostic use | Clarifies for use as <i>in vitro</i> diagnostic only |
|  | Non sterile | Indicates non-sterile product |
|  | Serial Number | Indicates instrument serial number code |
|  | Biological Risk | Universal precautions should be followed on all specimens |
|  | Consult Instructions | Consult instruction manual or insert sheet for further explanation |

Error Indicators

Error codes for the CritSpin are specified by the *Error/Service* LED flashing or continuously illuminated.

Error/Service = 



- A** Error/Service light will continuously illuminate when the centrifuge has achieved a total cycle count of 18,000, which is the useful life of the drive system. Drive mechanism needs replacing. Contact an authorized service center.
- B** Error/Service light will flash when one of the following conditions occur:
1. System Error – Restart the centrifuge.
 2. Motor Failure – Drive mechanism requires replacement.
 3. Rotor Improperly Seated – Re-install rotor.
- C** Error/Service and 120 s lights will flash when the cover is open during spin.

Accessories

| Product No. | Description |
|-------------|--|
| RH12 | Hematocrit rotor, 12-position |
| HR4C | Circular Hematocrit Reader |
| HR05 | Card-style Hematocrit Reader |
| HT9H-10 | Hematocrit Tubes, 40mm, glass, heparin |
| HT9U-10 | Hematocrit Tubes, 40mm, glass, untreated |
| HP8U-10 | Hematocrit Tubes, 40mm, plastic, heparin |
| HP8U-10 | Hematocrit Tubes, 40mm, plastic, untreated |
| HS24-10 | Clay Sealant Pad |
| CSD1 | Digital Reader (included with CS22 Product Number) |

Section 3

Operating Instructions

Opening and Closing the Cover

The centrifuge's electrically operated cover interlock mechanism prevents operation until the cover is completely closed and latched, and prevents the cover from being opened while the rotor is turning. When the cover is completely closed and locked an operating cycle can be initiated.

The centrifuge is also equipped with a manually operated latch that holds the cover down after spinning is complete. The interlock is automatically released at the end of the operating cycle or by pushing the *stop/open* button. Squeeze the black latch pieces together to open cover.

Cover Interlock By-pass

The electronically operated cover interlock mechanism can be released manually by inserting the straightened end of a large paper clip or similar object into the small hole in the center of the front membrane panel. Manually push the lock lever inward about one inch (25mm) to release the interlock mechanism if the stop/open button does not release the cover.



CAUTION - The cover interlock bypass is designed for emergency use only. If the equipment is not used properly, safety may be compromised.

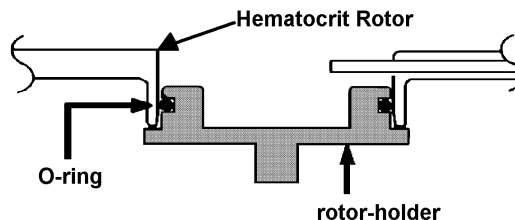
Installing the Rotor

The CritSpin is shipped with the rotor contained in accessory box.



CAUTION - The rotor (RH12) has a finite lifespan that is dependant on usage. Replace rotor after 18,000 cycles or approximately 800 hours of operation. Cracks or swelling are signs of fatigue, replace immediately.

1. Remove the rotor from accessory box.
2. Install rotor by pressing rotor firmly in a downward motion onto the rotor-holder of the CritSpin. The rotor bottom fits over a rubber O-Ring on the rotor-holder. The Figure below 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.
3. If the 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.



CAUTION - Do not leave the rotor on the rotor-holder when the StatSpin is not in use for an extended period of time. Doing so may compress the O-Ring and decrease its ability to hold the rotor.



CAUTION - Failure to properly install the rotor may result in damage to the centrifuge and will void the warranty.



CAUTION – If rotor is left in place 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.

Spinning the Sample

Loading



CAUTION - Never operate the CritSpin without the rotor in place.

1. Ensure the appropriate tubes are placed in the rotor (See accessories).
2. One to 12 tubes may be placed in the rotor for spinning.
3. Close and latch the centrifuge cover.
4. Press *start* button.

Table 1: CritSpin Cycle Setting:

| Setting | Speed | Time |
|--|------------------------|-------------|
| 120 s Intended to provide pre-timed cycle to spin packed cell volumes in microhematocrit tubes. | 16,000 rpm (13,700 xg) | 120 seconds |

NOTE: The CritSpin has no “on-off” switch, and therefore is normally left plugged in and “on”.

Unloading

1. Upon completion of the cycle, the rotor decelerates to a complete stop in 10 seconds and the latch interlock automatically unlocks.
2. Squeeze the black latch pieces together to open cover.
3. Carefully remove Rotor and/or tubes for reading.

Note: Please refer to the CSD1 Digital Reader Operator’s Manual for operating instructions.

Section 4

Maintenance

Overview

StatSpin recommends that instrument operators perform periodic inspections and preventative maintenance on all StatSpin instruments. Contact StatSpin's customer service department or distributor if, at any time, the instrument is not functioning properly.



CAUTION - *Unplug the CritSpin from the wall outlet before performing maintenance.*

WARNING - *Do not expose CritSpin and its rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.*

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.

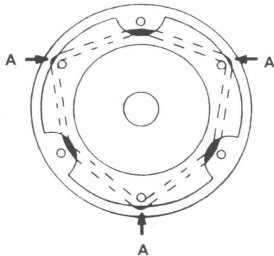


CAUTION - *DO NOT spray the bowl or outer surfaces with detergent or bleach. Excess liquid will harm the electronics and subsequent problems may not be covered under warranty.*

Checking the Rotor Speed

The rated speeds can be checked with a photoelectric tachometer available from many sources. If the CritSpin fails to achieve operating speed 16,000 rpm (± 250 rpm) contact your distributor or StatSpin Customer Service department.

Replacing the 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 which the O-Ring touches the rotor are indicated by the letter "A". Extra O-Rings have been included.

Service

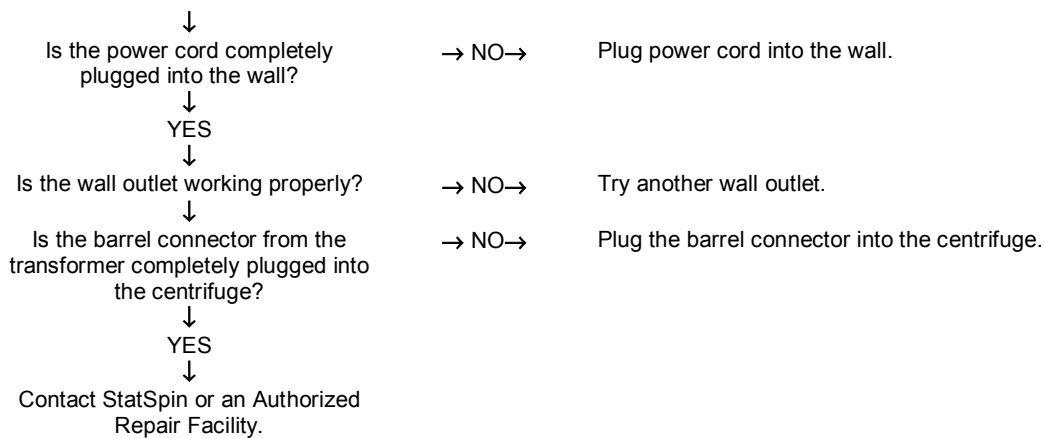
Refer all service to qualified service personnel. Reference the StatSpin Warranty for further instruction. Be sure to complete and return the warranty card as directed.

Decontamination before returning for service

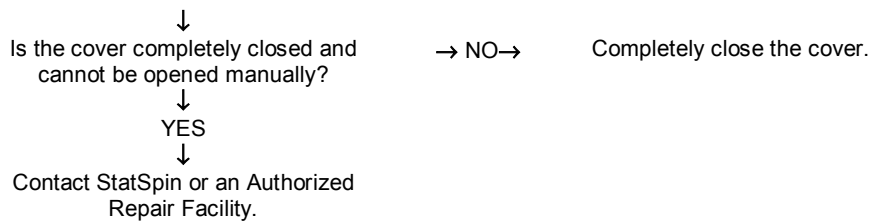
Any instrument or accessory containing accumulated blood and/or other biological or chemical deposits must be cleaned prior to shipment to the manufacturer/dealer for service. This decontamination is required by Federal Law (Title 48 and 49 of the Federal Regulations) and in accordance with the Environmental Protection Agency's Regulations for Biohazard Waste Management. StatSpin personnel cannot perform this decontamination.

Troubleshooting

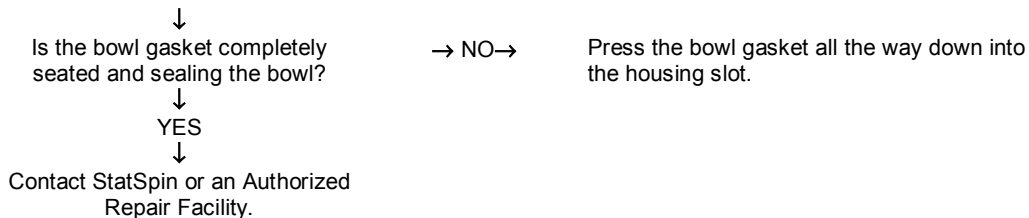
No Power Light



Centrifuge Will Not Spin/Shuts Off Prematurely



Centrifuge will not open at end of cycle



Section 5

Determination of Packed Red Cell Volume (Microhematocrit)

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

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 with the color-coded band. (See Figures, page 10)
3. Fill to the color-coded band. Remove from sample and tilt the banded end downward until the blood moves half-way between the band and the end of the tube.
4. Hold the tube in a horizontal position and push the **dry** (banded) end of the tube fully into the vertically held sealing compound. Twist and remove.
5. Using a laboratory tissue wipe off any blood that is forced from the other end.
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.
9. After the rotor stops, remove the rotor. To read hematocrit, place the rotor into the middle of the illuminated, digital reader. Follow directions printed on the reader.
10. Spun tubes inside the Hematocrit rotor can also be read with the circular reader, HR4C as well as removed from the rotor and read with the card-style reader, HR05.

Quality Control

1. The Quality Control procedures established for your laboratory should be followed.
2. To verify the adequacy of cell packing, on a daily basis, 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.

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

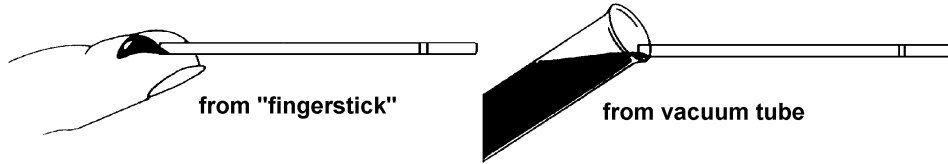
| Gender | Mean % | Range (2 s.d.) |
|---------|--------|----------------|
| Males | 47 | 40 - 54 |
| Females | 42 | 37 - 47 |

Animals

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

Illustrations

Filling Capillary Micro-Hct Tube

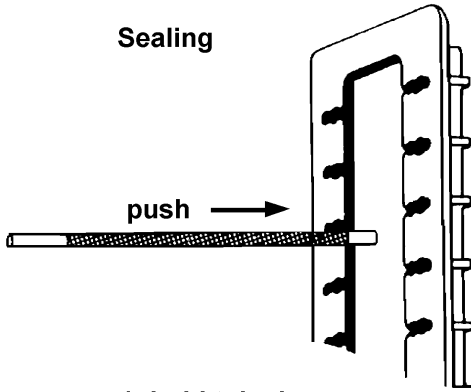
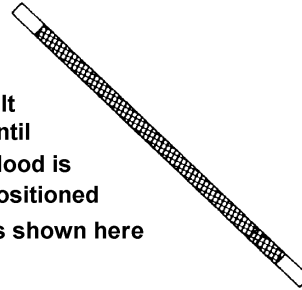


The Filled Capillary Tube



Color-coded band

Tilt until blood is positioned as shown here



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

after filling



after positioning

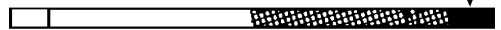


after sealing



sealant

after spinning



top of plasma

top of red cells

bottom of red cells

Appendix

Appendix A - Specifications

| | |
|--------------------------|--|
| Product No. | CS12 (supplied with RH12 Rotor) |
| | CS22 (supplied with RH12 Rotor and CSD1 Digital Reader) |
| Model No. | M961 |
| Speed | 16,000 rpm \pm 250 |
| Force | 13,700 xg |
| Cycle | 120 s: 120 seconds |
| Acceleration Time | Approximately 6 seconds |
| Deceleration Time | Approximately 10 seconds |
| Electrical | 24 Volts, DC, 1.7 amp. Includes switching power supply for 100-240 VAC, 50/60 Hz |
| Dimensions | Height 6"/ 15.2 cm |
| | Width 6.8"/ 17.3 cm |
| | Depth 8.6"/ 21.8 cm |
| | Weight 5 lbs/ 2.3 kg |
| Environmental | 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 over-voltages according to installation category II |
| | Pollution degree 2 |
| Product No. | CSD1 |
| | Refer to the CSD1 Operator's Manual for specifications |

References

1. NCCLS. "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Second Edition." NCCLS document M29-A2 [ISBN 1-56238-453-8]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
2. CDC. Recommendations for prevention of HIV transmission in health care settings. MMWR (Suppl. No. 2S):2S-18S, 1987.
3. CDC. Updated: US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis. Appendix A and B. MMWR 50 (RR-11): 1-42, June 29, 2001.
4. NCCLS. "Procedure for Determining Packed Cell Volume by Microhematocrit Method. Approved Standard-Third Edition." NCCLS document H7-A3 [ISBN 1-56238-413-9]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne Pennsylvania 19087-1898 USA, 2000.
5. NCCLS. "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Fourth Edition." NCCLS document H3-A4 [ISBN 1-56238-350-7]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne Pennsylvania 19087-1898 USA, 1998.
6. NCCLS. "Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard-Fourth Edition" NCCLS document H4-A4 [ISBN 1-56238-382-5]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne Pennsylvania 19087-1898, 1999.



A Subsidiary of IRIS International, Inc
Norwood, MA 02062 USA
Phone: 800-782-8774
or 781-551-0100
Fax: 781-551-0036
www.statspin.com

StatSpin Warranty

StatSpin, Inc., a Subsidiary of IRIS International, Inc. warrants that the instruments shall be free from defects in material and/or workmanship, under normal use and service, for the period expiring twelve (12) months from the date of installation, provided the purchaser has completed and forwarded to StatSpin the Warranty Registration Card. StatSpin will, at its discretion repair or replace any unit covered under this warranty returned to StatSpin with shipping costs prepaid. Repaired or replaced instruments supplied under this warranty carry only the remaining portion of the original warranty and repairs shall not interrupt or prolong this warranty. For warranty terms and conditions outside the United States, contact your Authorized StatSpin Distributor.

No warranty extended by StatSpin shall apply to any instrument that has been damaged due to misuse, negligence, accident, or damage resulting from unauthorized repairs, alterations, or improper installation.

StatSpin makes no warranty other than the one set forth herein. This warranty is given expressly in lieu of all other warranties, expressed or implied. The purchaser agrees that there is no warranty of merchantability or of fitness for any intended purpose and that there are no other remedies or warranties, expressed or implied, which extend beyond the description on the face of the agreement. No agent or employee of StatSpin is authorized to extend any other warranty or assume for StatSpin any liability except as set forth above. This warranty is only applicable to the original purchaser.

Limitation of Liability

StatSpin shall not be liable for any loss of use, revenue or anticipated profits, or for any consequential or incidental damages resulting from the sale or use of the products. The purchaser shall be deemed liable for any and all claims, losses, or damages incurred by the use or misuse of the StatSpin instrument by the purchaser, its employees or others, following receipt of the instrument or other items.