Instructions for Use

StatSpin MP Centrifuge Model Number M901

For *In Vitro* Diagnostic Use

This manual is intended for

SSMP StatSpin MP for 100 to 240 VAC, 50/60 Hz (Included: RT12 and RH12 rotors)

55-001806-001HD
December 2021

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

BECKMAN COULTER

Instructions for Use
StatSpin MP Centrifuge Model Number M901
PN 55-001806-001HD (December 2021)

Trademarks

Find us on the World Wide Web at:
www.beckmancoulter.com

Rx Only

Original Instructions

Revision History 55-001806-001

HD (December, 2021)

- Deleted: Lipemia Clearing with LipoClear section
- Updated the following:

  Copyright page
  Symbols and Definitions
  Safety Notices Warning and Cautions throughout
  Accessories
  Cycle Selection
  Illustrations
  Installing the System
  Installing the Rotor
  Instructions for Use
  Limited Warranty and Disclaimer
  Preparation of Urine Sediment for Microscopic Examination
  Procedure for Packed Red Cell Volume (Microhematocrit)
  RT12 Tube Rotor
  RH12 Microhematocrit Rotor
  Specifications
  Quality Control

HC (September, 2018)

- Moved: Symbol/Regulatory Mark and a link to the website in the California Proposition 65 statement

HB, (March, 2018)

- Added: Symbols and Definitions table
- Updated: Manufacturer address, Warning and Cautions, Limited Warranty statement, Opening and Closing the Cover, Installing a Shield, and Instructions for Use
- Deleted: CE, and EC Rep

HA (September, 2016)

- Converted the MP Multipurpose Centrifuge Operator's Manual to a Beckman Coulter Instructions for Use (IFU)
- Made general clarifications of the IFU
- Updated Logo

- Added warning and caution statements, and updated existing warning and caution statements
- Added the Recycling Label information
- Updated specifications, symbol tables, error codes, troubleshooting and maintenance sections
- Updated Limited Warranty statement

Safety Notice

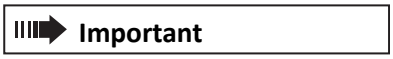
Read all product manuals and consult with Beckman Coulter-trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the manufacturer's recommendations. If you have any questions:

- Visit http://www.beckmancoulter.com.
- US customers: Contact Beckman Coulter Customer Support at 1-800-854-3633.
- International customers: Contact your local distributor.

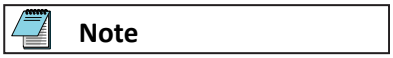
Alerts for Warning, Caution, Important, Note, and Tip

Warning indicates a potentially hazardous situation which can cause death or serious injury. Warning can indicate the possibility of erroneous data that could cause an incorrect diagnosis.

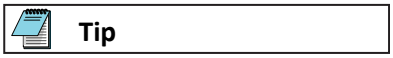
Caution indicates a potentially hazardous situation which can cause minor or moderate injury. Caution can also alert against unsafe practices, or indicate the possibility of erroneous data that could cause an incorrect diagnosis.



Important indicates important information to follow.



Note indicates notable information to follow.



Tip indicates information to consider.

Warnings and Cautions

Pay close attention to the instructions that accompany the notes and symbols and the standard laboratory procedures outlined by your facility and local regulatory agencies.

Warning

Always operate the system with all shields (when used with RT12 rotor) and cover in position and secured to avoid injury.

Perform system operations with caution.

Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats.

Wash hands thoroughly after contact with sample media and all maintenance activities.

Observe all laboratory policies and procedures related to the handling of biohazardous materials.

Refer to the applicable sources (such as Safety Data Sheets) for specific hazard information.

Warning

Do not expose the rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones, or strong oxidizing agents, or environmental influences, including natural ultra-violet radiation. Doing so will subject the rotor to corrosion or weakening of the construction.

Warning

Do not operate the centrifuge below the minimum operating temperature. See Specifications.

Warning

Handle and dispose of sharp fragments according to the World Health Organization's Laboratory Biosafety Manual and relevant local and national regulations.

Warning

Safety protection may be impaired if equipment is used in a manner not specified by the manufacturer.

Warning

Inspect the instrument for cracks or any physical damage to housing, cover, and rotor upon the receipt of the unit. Damage can cause unsafe operation; if damage or cracks are found, discontinue use until repairs have been performed.

Warning

Only reset the cycle counter after conducting the recommended inspections and service. Resetting the cycle counter without performing the recommended inspections and service reduces the reliability and safety of the instrument.

Warning

Only use the external power supply (Beckman Coulter Part Number X01-003553-001) included with the unit. Use of any other external power supply can cause damage to the unit and will void the warranty.

Warning

Outside of North America: do not use the power cord supplied. Use power cord for at least 1.0 Amp with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.

Warning

Picking up or moving the centrifuge during operation can cause injury to the operator and/or damage to the centrifuge.

Warning

Electromagnetic Compatibility

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE

ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- **Evaluate the electromagnetic environment before installation and operation of this device.**
- **Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.**
- **Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.**
- **This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.**

Caution

Disconnect the power cord of the external power supply from the electrical outlet before performing maintenance or inspection.

Caution

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

Caution

Do not operate the centrifuge without a shield in place when using an RT12 rotor.

Caution

Do not spray cleaning solutions directly onto the centrifuge bowl or housing. Overspray can reach the motor bearings or internal circuitry, causing harm to the electronics and could also cause corrosion or weakening of the construction of the protective casing.

Before using any cleaning or decontamination methods other than those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment. Cleaning and decontamination

may be necessary as a safeguard before laboratory centrifuges, rotors, and any accessories are maintained, repaired, or transferred.

Caution

Do not use glass tubes of any kind in the RT12 rotor.

Caution

Do not use the shield with the RH12 Microhematocrit rotor.

Caution

During operation maintain a 30 cm (12 inch) clearance around the centrifuge. The clearance must be free from obstruction and away from the edge of the surface that the centrifuge is on. The appliance coupler on the external power supply is considered the power source disconnect device, ensure that it is accessible after installation.

Caution

If rotor is left in position between runs, be certain to completely seat the bottom of the rotor on the holder before spinning another sample. Failure to correctly seat the rotor each time can cause the rotor to become loose during centrifugation.

Caution

Follow Universal Precautions with all biological specimens, regardless of whether the specimen is known to contain an infectious agent. (See References)

Caution

Inspect rotor on a routine basis. Rotor lifespan depends on usage. Inspect rotor for cracks and replace the rotor immediately when any crack or visible wear occurs.

Caution

Never operate the centrifuge without the rotor properly mounted. Failure to install and secure the rotor correctly can damage the centrifuge.

Caution

Position the RT12 rotor in the centrifuge first, then install the shield.

Caution

Running the centrifuge repeatedly with an unbalanced load condition can cause excessive vibrations and premature equipment failure.

Caution

The cover interlock bypass is for emergency use only. Disconnect the power cord of the external power supply from the electrical outlet and ensure the rotor has come to a complete stop before using the interlock bypass. If the equipment is not used correctly, safety can be impaired.

Caution

The instructions prohibit use of the specified materials within the centrifuge

- **flammable or explosive materials.**
- **materials which could react chemically with sufficient vigor to cause a hazard.**

Caution

The RT12 and RH12 rotors have a finite lifespan that is dependent on usage. The RT12 and the shield should be replaced after approximately 3600 cycles, which is equivalent to 18 months of service running an average of 10 cycles per day. The RH12 rotor should be replaced after approximately 2600 cycles, which is equivalent to 12 months of service running an average of 10 cycles per day. Rotors should be inspected routinely and replaced immediately when any crack or visible wear occurs.

Caution

The centrifuge is designed to use only the RT12 and RH12 rotors. The use of any other rotor may result in a hazard.

Caution

The RT12 rotor must be balanced before operation. If only one sample is being processed, a second sample can serve as the balance tube, or use a similar tube filled with water as a balance.

Important

This device is intended for indoor use only.

Please use the instrument as intended. Improper use may cause damage to the instrument, inaccurate results, or potentially nullify warranties.

Symbols and Definitions

Table 1 MP Symbols Glossary

Symbol	Description
	**Warning; Biological hazard** This symbol indicates a warning of a biological hazard. *ISO 7010. Graphical Symbols - Safety colors and safety signs. #W009* **Supplemental Product-Specific Manufacturer Information** This symbol indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard. This symbol indicates the use of biohazardous materials in the area. Use caution when working with possible infectious samples. Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.
	**Consult instructions for use** This symbol indicates the need for the user to consult the instructions for use. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.3*
	**Caution** This symbol indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.4*

Table 1 MP Symbols Glossary (Continued)

Symbol	Description
	**Warning; Crushing of hands** This symbol indicates a warning of a closing motion of mechanical parts of equipment. *ISO 7010. Graphical Symbols for electrical equipment in medical practices. #W024* **Supplemental Product-Specific Manufacturer Information** Use caution to avoid injury to hands when close to equipment with moving mechanical parts.
	**Moving Parts Symbol** This symbol indicates that there are moving parts in the area. Only operate the system when all covers are in position and use caution to reduce the risk of personal injury. While the system is operating, do not touch the moving parts of the system. Do not insert fingers or hands into any system opening.
	**cNRTLus Certification Mark** This symbol indicates recognition by a Nationally Recognized Testing Laboratory (NRTL) that the system has met the relevant product safety standards for the United States and Canada. *OSHA, CEC*
	**RCM Symbol** This symbol indicates compliance with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.

Table 1 MP Symbols Glossary (Continued)

Symbol	Description
	**Recycling Symbol** This symbol is required by the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. This symbol indicates that: 1. The device was put on the European Market after August 13, 2005. 2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or your local Beckman Coulter Representative for more information on the take-back program that facilitates the correct collection, treatment, recovery, recycling, and safe disposal of these products. *EU Directive 2002-96-EC: waste electrical and electronic equipment (WEEE)* For the Japan market: This system is considered an industrial waste, subject to special controls for infectious waste. Before disposal of the system, refer to the *Waste Disposal and Public Cleaning Law* for compliance procedures.
	**RoHS Caution Symbol** This symbol indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture. These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 *Marking for Control of Pollution Caused by Electronic Information Products* requirements.
	**"OFF" (power)** This symbol indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5008* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the off position.

Table 1 MP Symbols Glossary (Continued)

Symbol	Description
	"ON" (power) This symbol indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5007* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the on position.
	**Alternating current** This symbol indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5032*
	**Direct current** This symbol indicates on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5031*
	**Date of Manufacture** This symbol indicates the date when the medical device was manufactured. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.3*
	**Manufacturer** This symbol indicates the medical device manufacturer. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.1* **Supplemental Product-Specific Manufacturer Information** This symbol indicates who the legal manufacturer of the product is.

Table 1 MP Symbols Glossary (Continued)

Symbol	Description
REF	**Catalogue Number** This symbol indicates the manufacturer's catalogue number so that the medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.6*
SN	**Serial number** This symbol indicates the manufacturer's serial number so that a specific medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.7*
Made in *Country of Origin*	**Country of Origin Symbol** This symbol indicates the country that the product was manufactured in.
	**Polarity of d.c. power connector** This symbol indicates the positive and negative connections (the polarity) of a direct current power supply, or the positive and negative connections on a piece of equipment to which a direct current power supply may be connected. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5926*
	**California Proposition 65** This symbol indicates that this product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm. For more information go to https://www.P65Warnings.ca.gov.
LOT	**Batch Code** Indicates product lot number.
IVD	**In vitro diagnostic medical device** This symbol indicates a medical device that is intended to be used as an in vitro diagnostic medical device. *ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.5.1*

Table 1 MP Symbols Glossary (Continued)

Symbol	Description
	**Do Not Reuse** Indicates product is single use only.
	**Use By Date** Indicates product expiration date.
	**Contents** Indicates product contents.
	**Temperature limitation** Indicates storage requirements limit.
	**Start button** The **Start** button initiates a pre-timed cycle at a fixed speed. **Note** The StatSpin MP has no on-off switch, and therefore is normally left plugged in and “on”.
	**Stop or Open button** The **Stop** or **Open** button interrupts the cycle and stops the centrifugation. This button can also be used to release the cover.
	**Cycle Selector button** The **Cycle Selector** button allows for selection of the cycle.
	**Error or Service Indicator** The red LED, identified as Error or Service, is illuminated continuously or flashing when service is required.

Contents

Contents

CHAPTER 1

Installation

Inspecting the Packaging

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

Note

Save shipping carton and components to simplify return if service is required.

Confirming the Contents

Product No. SSMP, (supplied with two rotors, RT12 and RH12)

Each package contains:

- One External Power Supply (Beckman Coulter Part No. X01-003553-001)
- One grounded line cord (for North American use only)
- One Instructions for Use
- One Sample Pack containing various consumable products
- One Warranty Registration Card – Complete the warranty registration as directed

Installing the System

To install the system:

1 Place the StatSpin MP on a level surface suitable for laboratory instrumentation.

Caution

During operation maintain a 30 cm (12 inch) clearance around the centrifuge. The clearance must be free from obstruction and away from the edge of the surface that the centrifuge is on. The appliance coupler on the external power supply is considered the power source disconnect device, ensure that it is accessible after installation.

2 Position the StatSpin MP away from direct sunlight and sources of heat or cold.
For the acceptable range of operating temperature and humidity, refer to Specifications

Connecting the Power

Plug the power cord of the external power supply into a grounded outlet supplying the voltage and frequency indicated on the power supply. When power is connected, the Urine

setting LED illuminates, two beeps sound, and the cover lock releases. To turn the system off completely, disconnect the power located at the rear of the unit.

Warning

Only use the external power supply (Beckman Coulter Part Number X01-003553-001) included with the unit. Use of any other external power supply can cause damage to the unit and will void the warranty.

Warning

Outside of North America: do not use the power cord supplied. Use power cord for at least 1.0 Amp with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.

CHAPTER 2

System Overview

Intended Use

For in vitro diagnostic use for rapid separation of whole blood, preparing urine sediment for microscopic analysis and centrifuging microhematocrit tubes for packed cell volume determination.

Product Description

The StatSpin MP 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. This instrument is designed to meet international safety standards.

Operating Controls

Table 2 MP Operating Controls

	**Start button** The **Start** button initiates a pre-timed cycle at a fixed speed. **Note** The StatSpin MP has no on-off switch, and therefore is normally left plugged in and “on”.
	**Stop or Open button** The **Stop** or **Open** button interrupts the cycle and stops the centrifugation. This button can also be used to release the cover.
	**Cycle Selector button** The **Cycle Selector** button allows for selection of the cycle.
	**Error or Service Indicator** The red LED, identified as Error or Service, is illuminated continuously or flashing when service is required.

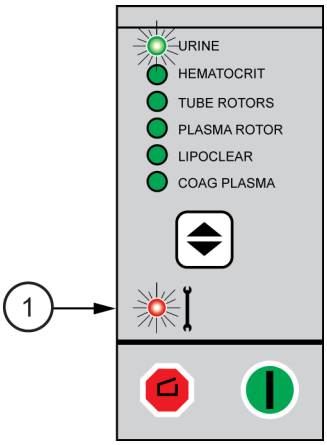
Note

Buttons should be depressed with finger tips only. Never press buttons with a sharp object such as a pen, screwdriver, centrifuge insert, fingernail, etc. The buttons are membrane switches designed to be activated by finger actuation. Use with any hard, sharp object can cause damage to the tactile layer of the button, rendering the button unstable and prone to premature failure.

Error Indicators

The combination of the Error or Service indicator and the cycle LEDs on the front panel specify the error code.

Figure 1 Rotor failed to reach rpm within 30 s



1. Error or Service indicator flashing or continuous

Figure 2 Cover opened or cycle changed during operation

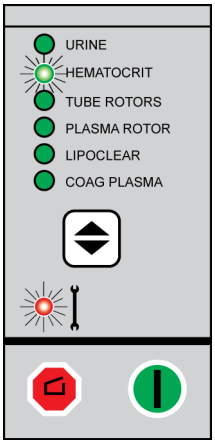
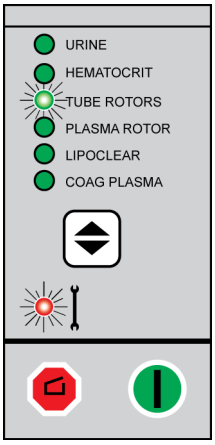


Figure 3 Insufficient power to maintain rpm



The system beeps continuously if one of the following conditions are present:

- Centrifuge is over operating temperature
- Short circuit of the motor drives, fan, or solenoid
- Reduction in the availability of electrical power
- Short-term power failures

To stop the beeps, press the **Stop** button

Error or Service indicator continuously illuminates when the centrifuge has achieved a total run time of 150 hours, which is the useful life of the drive system. Drive mechanism needs replacing. Contact Beckman Coulter Customer Support.

Accessories

Table 3 Accessories

Product No.	Description	Cycle Required
RT12-KIT	2 x 1.5 mL Fixed Angle Rotor with shield	Urine, Tube
TU15-10	1.5 mL Pre-calibrated Urine Tube (10 bags of 50)	Urine
RH12	12 Position microhematocrit rotor with circular reader (HR4C)	Hematocrit
HP8H-10	SafeCrit Capillary Tube (40 mm, Sodium Heparin), 100% plastic microhematocrit tubes for the RH12 rotor. (10 vials of 100)	Hematocrit
HP8U-10	SafeCrit Capillary Tube (40 mm, Untreated), 100% plastic microhematocrit tubes for the RH12 rotor. (10 vials of 100)	Hematocrit
HT9H-10	Glass Capillary tube (40 mm Ammonium Heparin), Glass microhematocrit tubes for RH12 rotor. (10 vials of 100)	Hematocrit

Table 3 Accessories (Continued)

Product No.	Description	Cycle Required
HT9U-10	Glass Capillary tube (40 mm Untreated), Glass microhematocrit tubes for RH12 rotor. (10 vials of 100)	Hematocrit
HS24-10	Sealant Pad for Capillary tubes (10 pads)	N/A
HR05	Hematocrit Reader, Card style for 40 mm hematocrit tubes	N/A
HR4C	Hematocrit Reader, Circular designed to be used in conjunction with the RH12 rotor	N/A
00-Ring	Replacement O-Rings for rotor holder (5 bags of 3)	N/A

CHAPTER 3

Operating Instructions

Opening and Closing the Cover

To close the cover, firmly apply pressure on the cover directly above the latch until the gasket compresses completely and the latch engages with the cover. The 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 has 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** or **Open** button. Squeeze the black latch pieces together to open cover.

Cover Interlock By-pass

⚠ Caution

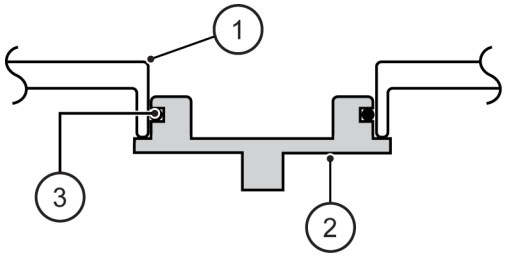
The cover interlock bypass is for emergency use only. Disconnect the power cord of the external power supply from the electrical outlet and ensure the rotor has come to a complete stop before using the interlock bypass. If the equipment is not used correctly, safety can be impaired.

In case of power failure or malfunction, 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 (25 mm) to release the interlock mechanism if the **Stop** or **Open** button does not release the cover.

Installing the Rotor

1. Remove the rotor from accessory box.
2. Install rotor by pressing rotor firmly in a downward motion onto the rotor-holder of the StatSpin MP. The rotor bottom fits over a rubber O-Ring on the rotor-holder. The figure shows a rotor (cross-section) in position on the rotor-holder. As the rotor turns, the O-Ring moves outward by centrifugal force, enhancing the frictional coupling between the rotor-holder and the rotor.

Figure 4 Install the Rotor



1. Rotor
2. Rotor-holder
3. O-Ring

Caution

Position the RT12 rotor in the centrifuge first, then install the shield.

Caution

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

Caution

Never operate the centrifuge without the rotor properly mounted. Failure to install and secure the rotor correctly can damage the centrifuge.

Caution

If rotor is left in position between runs, be certain to completely seat the bottom of the rotor on the holder before spinning another sample. Failure to correctly seat the rotor each time can cause the rotor to become loose during centrifugation.

Caution

The RT12 rotor must be balanced before operation. If only one sample is being processed, a second sample can serve as the balance tube, or use a similar tube filled with water as a balance.

Description of Rotors

RT12 Tube Rotor

A 2-place rotor designed to accommodate a variety of sample collection tubes for blood and urine separation, in addition to a variety of standard 1.5 mL and 2.0 mL centrifuge tubes

with a maximum diameter of 10.9 mm. These tubes should be supported by the collar of the rotor.

Caution

Do not use glass tubes of any kind in the RT12 rotor.

Caution

Do not operate the centrifuge without a shield in place when using an RT12 rotor.

The following tubes are approved for use with the RT12 rotor:

- Prepared Microtubes: TP1H, TP1U, TP5G and CH03
- Precalibrated Urine Tube: TU15-10
- Standard 1.5 - 2.0 mL microcentrifuge tube (e.g. Eppendorf)

Installing a Shield

A shield should always be used with the RT12 rotor and should be replaced when the rotor is replaced. Push down on the shield until it is fully seated.

RH12 Microhematocrit Rotor

A 12-place covered rotor used to centrifuge StatSpin capillary tubes for microhematocrit testing. Maximum tube size is 1.7 mm O.D. x 42 mm L. It is recommended that rubber cushions provided with the rotor be replaced twice a year or whenever a tube breaks in the rotor.

The following tubes are approved for use in the rotor:

- Glass capillary tubes: HT9H, HT9U
- SafeCrit plastic capillary tubes: HP8H, HP8U

Caution

Inspect rotor on a routine basis. Rotor lifespan depends on usage. Inspect rotor for cracks and replace the rotor immediately when any crack or visible wear occurs.

Caution

Do not use the shield with the RH12 Microhematocrit rotor.

Caution

The RT12 and RH12 rotors have a finite lifespan that is dependent on usage. The RT12 and the shield should be replaced after approximately 3600 cycles, which is equivalent to 18 months of service running an average of 10 cycles per day. The RH12 rotor should be replaced after approximately 2600 cycles, which is equivalent to 12 months of service running an average of 10 cycles per day. Rotors should be inspected routinely and replaced immediately when any crack or visible wear occurs.

Consult the insert sheets provided with these rotors for instructions for use. To purchase additional rotors not supplied with your StatSpin centrifuge, contact your local distributor and increase the versatility of your centrifuge.

Cycle Selection

Select spin time settings to achieve optimum results for specific applications. The following are general guidelines:

Table 4 StatSpin MP Cycle Settings

Setting	RPM/RCF	Time	Rotor
Urine	9,800/3,900	45 seconds	RT12
Hematocrit	16,000/13,700	120 seconds	RH12
Tube Rotor	15,800/12,000	30 seconds	RT12

Note

The Plasma Rotor, LipoClear, and Coag Plasma cycles are no longer supported by Beckman Coulter. The associated accessories needed to run the cycles are obsolete and not available.

Instructions for Use

1. Lift cover and install rotor. When using RT12 rotor, confirm that the shield is installed.
2. To close the cover, firmly apply pressure on the cover directly above the latch until the gasket compresses completely and the latch engages with the cover.
3. Select desired cycle by selecting the **Cycle Selector** button until the correct LED is illuminated.
4. Press the **Start** button.

5 When the cycle is complete, the rotor decelerates to a complete stop in 10 seconds and the latch interlock automatically unlocks.

6 Squeeze the black latch pieces together to open cover.

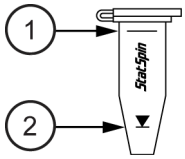
CHAPTER 4

Specimen Processing

Preparation of Urine Sediment for Microscopic Examination

The StatSpin MP quickly prepares urine sediment for microscopic examination. This preparation is accomplished with the pre-calibrated urine tubes. (Product Number TU15)

Figure 5 Calibrated Urine Tube



1. Fill to here
2. Empty to here

1	Add fresh urine to a urine tube (Product No. TU15). Fill to the top mark (representing 1.5 mL).
2	Cap the tube using the attached stopper and centrifuge in the Tube Rotor, RT12.
3	Balance the rotor either with another sample or with a water-filled tube.
4	Select the **Urine** setting.
5	Press the **Start** button.
6	When the cycle is complete, the cover releases. Remove the tube from the rotor and remove the stopper.
7	Invert the tube to drain fluid to the lower mark. (The surface tension retains 0.1 mL.)
8	Recap the tube and resuspend the 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.
9	After sediment has been resuspended, apply one drop to a microscope slide, apply a cover slip, and examine the slide. Follow the protocol used in your laboratory for urine microscopic examination.

Determination of Packed Red Cell Volume or Microhematocrit

Both glass and plastic micro-capillary tubes are available. Product Number HT9H(glass) and HP8H(plastic) have been pretreated with heparin and should be used for capillary

blood. Store the tubes in a cool dry place. Product Number HT9U(glass) and 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 then 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)

1 Capillary ("fingerstick") blood - prepare a skin site and lance. Use heparinized tubes, PN HT9H or HP8H.

or

Venous blood - take well-mixed anticoagulated blood from a syringe or a vacuum blood sample tube. Use untreated tubes, PN HT9U or HP8U.

2 Hold the micro-capillary tube by the end with the color-coded band. For more information, refer to Illustrations

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 12 positions on the Hematocrit Rotor, RH12. This rotor does not need to be balanced. Screw the cover in position.

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 the outer edges of the Hematocrit Rotor, RH12, can damage the rotor.

8 Select the **Hematocrit** setting.

9 Press the **Start** button.

10 After the rotor stops, remove the rotor. Spun tubes inside the rotor can also be read with the circular reader, HR4C or removed from the rotor and read with the card-style reader, HR05.

Quality Control

1 Follow the Quality Control procedures established for your laboratory.

2 To confirm the adequacy of cell packing, perform these steps daily:

a. Select one or more microhematocrit tubes (preferably with a hematocrit over 50%).

b. Centrifuge the microhematocrit tube and read.

c. Spin these microhematocrit tubes a second time.

Confirm that the difference between the initial reading and the second reading is 1% or less.

Normal Values

The following tables represent commonly accepted hematocrit values:

Table 5 Children

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

Table 6 Adults

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

Illustrations

Figure 6 Filling Capillary MicrohematocritTube from Finger-stick

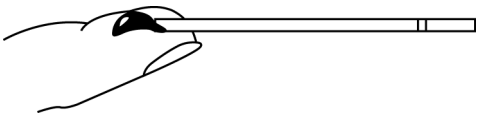


Figure 7 Filling Capillary Microhematocrit Tube from Vacuum Tube

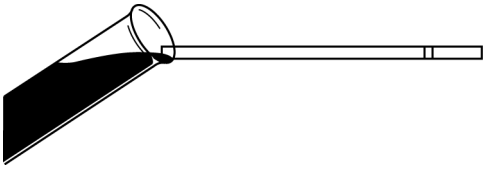
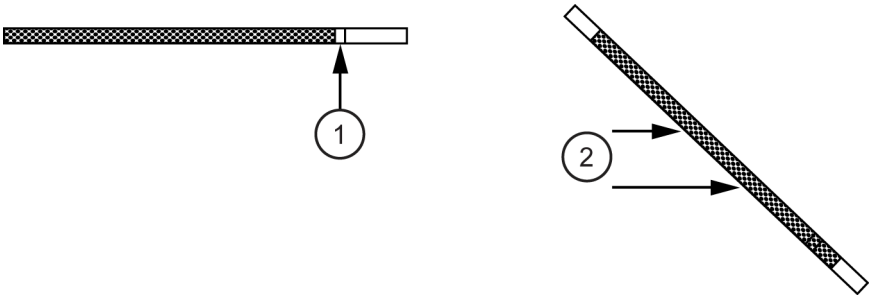
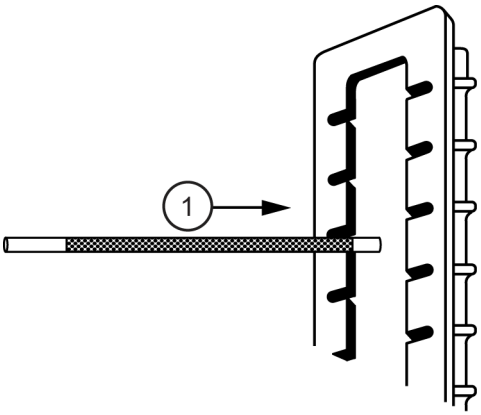


Figure 8 The Filled Capillary Tube



1. Color-coded band
2. Tilt until blood is positioned as shown

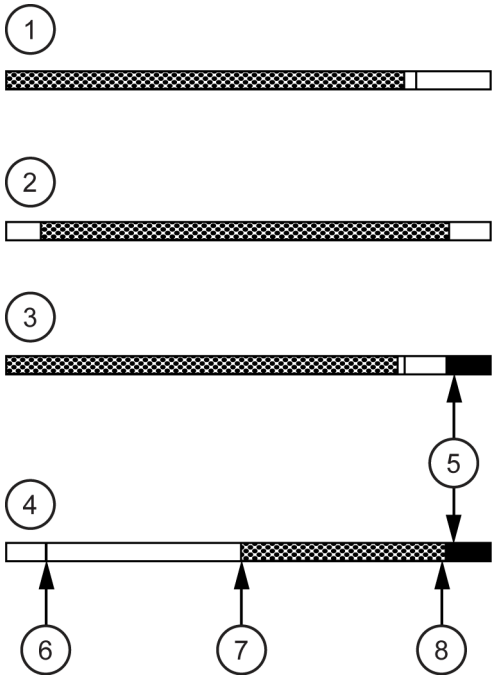
Figure 9 Sealing



1. Push

- hold tube in a horizontal position
- hold sealant in a vertical position
- push tube until bottomed - twist and remove

Figure 10 Position of Blood Sample



1. After Filling
2. After Positioning
3. After Sealing
4. After Spinning
5. Sealant
6. Top of plasma
7. Top of red cells
8. Bottom of red cells

CHAPTER 5

Maintenance

Overview

Beckman Coulter recommends that instrument operators perform periodic inspections and preventative maintenance on all devices. Contact Beckman Coulter at any time if the instrument is not functioning correctly.

Caution

Disconnect the power cord of the external power supply from the electrical outlet before performing maintenance or inspection.

Warning

Do not expose the rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones, or strong oxidizing agents, or environmental influences, including natural ultra-violet radiation. Doing so will subject the rotor to corrosion or weakening of the construction.

Cleaning

Clean the outside surfaces and the control panel with a water-dampened cloth and mild detergent. Clean the inner surface or bowl, with a mild detergent and if necessary, a disinfectant, wiping with an cloth dampened with 70% alcohol or 10% bleach solution.

Caution

Do not spray cleaning solutions directly onto the centrifuge bowl or housing. Overspray can reach the motor bearings or internal circuitry, causing harm to the electronics and could also cause corrosion or weakening of the construction of the protective casing.

Before using any cleaning or decontamination methods other than those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment. Cleaning and decontamination

may be necessary as a safeguard before laboratory centrifuges, rotors, and any accessories are maintained, repaired, or transferred.

Inspecting the Rotor Speed

The rated speeds can be inspected with a stroboscope or photoelectric tachometer. If the StatSpin MP fails to achieve operating speed (±5%) contact Beckman Coulter Customer Support.

Replacing the O-Ring

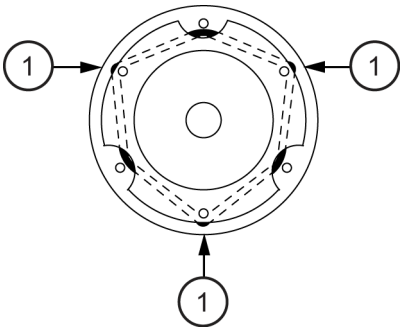
The figure illustrates the position of the rubber O-Ring which is attached to the rotor-holder.

If the rotor becomes difficult to install, apply a very small amount of silicone-type lubricant to the 3 points on the O-Ring gasket. The O-Ring should be inspected regularly and replaced when it appears “flattened” or worn. The O-Ring should be replaced as preventative maintenance at least once a year.

A new O-Ring 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 number 1 in the figure. Extra O-Rings have been included.

Figure 11 Position of the O-Ring



1. Positions where the O-Ring touches the rotor

Troubleshooting

No LED’s (lamps) are on		
Is the instrument completely plugged into the electrical outlet?	No ➔	Plug power cord of the external power supply into the electrical outlet.
Yes ⬇		

No LED's (lamps) are on		
Is the electrical outlet working correctly?	No ➔	Try another electrical outlet.
Yes ↓		
Is the barrel connector from the transformer completely plugged into the centrifuge?	No ➔	Plug the barrel connector of the external power supply into the centrifuge.
Yes ↓		
Contact Beckman Coulter Customer Support.		

Centrifuge Will Not Spin/Shuts Off Prematurely		
Is the cover completely closed and cannot be opened manually?	No ➔	Completely close the cover.
Yes ↓		
Contact Beckman Coulter Customer Support.		

Centrifuge Does not Open at the End of the Cycle
Follow Cover Interlock By-pass instructions in Chapter 3 to open the cover and retrieve samples, then contact Beckman Coulter Customer Support.

Service

Refer all service to qualified service personnel or Contact Beckman Coulter Customer Support at 1-800-854-3633.

Be sure to complete and return the warranty card as directed.

Decontamination before returning for service:

Any instrument or accessory containing accumulated blood or other biological or chemical deposits must be cleaned before shipment for service. This decontamination is required by Federal Law (Title 48 and 49 of the Federal Regulations) and according to the Environmental Protection Agency's Regulations for Biohazard Waste Management. Beckman Coulter cannot perform decontamination.

Limited Warranty and Disclaimer:

Subject to the below exceptions and conditions, Beckman Coulter warrants to the original purchaser that the Equipment will be free from substantial defects in material, under normal use and service, for the period expiring twelve (12) months and (ii) Services will be performed in a workmanlike manner. As exclusive and sole remedy for breach of the warranty, Beckman Coulter will, at its discretion, repair or replace any Equipment unit or

part covered under this warranty returned to Beckman Coulter or an authorized repair center. 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. No warranty extended hereby shall apply to any instrument that has been damaged due to misuse, negligence, accident, or damage resulting from unauthorized repairs, alterations, or improper installation.

THE WARRANTIES IN THIS SECTION ARE PROVIDED IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND ARE YOUR EXCLUSIVE REMEDIES RELATING TO PERFORMANCE OF THE PRODUCTS OR SERVICES. BECKMAN COULTER DISCLAIMS ALL OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY WARRANTY ABOUT THE MERCHANTABILITY OF THE PRODUCTS, INFRINGEMENT OR THEIR FITNESS FOR A PARTICULAR PURPOSE. IF ANY IMPLIED WARRANTIES APPLY AS A MATTER OF LAW, THEY ARE LIMITED IN DURATION TO THE LENGTH OF THE TERM OF THIS AGREEMENT.

Representations and warranties made by any representatives, salespersons or agents of Beckman Coulter, which are inconsistent or in conflict with or in addition to the terms of this Agreement, will not be binding upon Beckman Coulter unless reduced to writing and approved by an expressly authorized officer of Beckman Coulter.

Limitation of Liability:

BECKMAN COULTER'S TOTAL LIABILITY AND YOUR EXCLUSIVE REMEDY UNDER THIS AGREEMENT WILL BE LIMITED TO DIRECT MONEY DAMAGES NOT TO EXCEED THE AMOUNT PAID BY YOU UNDER THIS AGREEMENT DURING THE TWELVE MONTHS PRECEDING THE DATE THAT THE CLAIM FIRST ACCRUED. THIS LIABILITY LIMIT IS CUMULATIVE AND ALL DAMAGES PAID TO YOU UNDER THIS AGREEMENT WILL BE AGGREGATED IN CALCULATING THE SATISFACTION OF BECKMAN COULTER'S LIABILITY LIMIT. BECKMAN COULTER WILL NOT BE RESPONSIBLE FOR ANY DAMAGES THAT YOU MAY INCUR FROM DELAYED SHIPMENT OR PRODUCT SELECTION, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT, WARRANTY OR OTHERWISE. BECKMAN COULTER WILL HAVE NO LIABILITY TO YOU, OR ANY THIRD PARTIES FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PENAL LOSS OR DAMAGE OF ANY NATURE WHATSOEVER (INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR LOSS OF USE), EVEN IF BECKMAN COULTER WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND WHETHER OR NOT SUCH DAMAGES WERE FORESEEABLE.

APPENDIX A

Specifications

Specifications

Product Number	SSMP (supplied with 2 rotors, RT12 and RH12)
Model Number	M901
Cycles and Speeds	Urine 9,800 (3,900 x *g*), 45 seconds
	Hematocrit 16,000 (13,700 x *g*), 120 seconds
	Tube Rotor 15,800 (12,000 x *g*), 30 seconds
Acceleration Time	Approximately 6 seconds
Deceleration Time	Approximately 10 seconds
Electrical	24Vdc, 1.7A Includes switching power supply for 100 to 240 VAC, 50/60 Hz
Dimensions	Diameter: 6.6 in / 16.25 cm
	Height: 6.3 in / 13.2 cm
	Weight: 5.5 lbs / 2.5 kg
Environmental	Indoor use (IP20)
	Altitude up to 2000 m
	Operating temperature: 15°C to 32°C
	Storage temperature: 0°C to 60°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

APPENDIX B

References

References

1. CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition.* CLSI document M29-A3 [ISBN 1-56238-567-4]. CLSI, 940 West Valley Rd, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.
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.
7. NCCLS. *Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline - Third Edition.* NCCLS document H21-A3 [ISBN 1-56238-363-9]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne Pennsylvania 19087-1898 USA, 1998.

References

References

www.beckmancoulter.com