



Instructions for Use

StatSpin CritSpin Digital Reader Model Number S120

For *In Vitro* Diagnostic Use

This manual is intended for

CSD2 Digital Reader -with tube adapter for 75mm tubes, and with a universal power supply.

Printed in U.S.A.

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Instructions for Use**StatSpin CritSpin Digital Reader Model Number S120**

PN 55-003823-001CC (September 2018)

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Rx Only

Original Instructions

Revision History

55-003823-001 CC, 09/2018

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

55-003823-001 CB, 03/2018

- Converted the CritSpin Digital Reader Operations Manual to a Beckman Coulter Instructions for Use (IFU) Manual, and made general clarification to the IFU
- Added: Revision History, Safety Notice, Symbols and Definitions table, Alerts for Warning, Caution, Important, Note, and Tip explanations, and Warning and Cautions
- Updated: Logo, Manufacturer address, and Limited Warranty statement
- Deleted: EC Rep

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

Warning indicates a potentially hazardous situation which, if not avoided, could cause death or serious injury. Warning can indicate the possibility of erroneous data that could cause an incorrect diagnosis.



Caution

Caution indicates a potentially hazardous situation which, if not avoided, 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

Important indicates important information to follow.



Note

Note indicates notable information to follow.



Tip

Tip indicates information to consider.

Warning 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.

Safety Notice

Warning and Cautions



Warning

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 Material Safety Data Sheets) for specific hazard information.



Warning

If the equipment is used in a manner not specified by Beckman Coulter, the protection provided by the equipment may be impaired.



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

Electromagnetic Wave and Noise

The system generates, uses, and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference between the system and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- This equipment complies with the emission and immunity requirements described in this part of the EN/IEC 61326 -1
- As to emission, this system has been designed and tested to CISPR 11 Class A, so in a domestic environment, it may cause radio interference, in which case, you may need to take measure to mitigate the interference.
- It is recommended to evaluate the electromagnetic environment prior to operations of the system.
- Do not use this system in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). As they can interfere with the proper operation.

- Do not use mobile or cordless telephones and transceivers in the same room as the system.
- Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the system.

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 CritSpin Symbols Glossary





Symbol	Description
	<p>Consult instructions for use</p> <p>Indicates the need for the user to consult the instructions for use.</p> <p><i>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</i></p>
	<p>Caution</p> <p>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.</p> <p><i>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</i></p>
	<p>Direct current</p> <p>To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5031</i></p>
	<p>Manufacturer</p> <p>Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</p> <p><i>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</i></p> <p>Supplemental Product-Specific Manufacturer Information</p> <p>This symbol identifies who the legal manufacturer of the product is.</p>

Table 1 CritSpin Symbols Glossary (Continued)





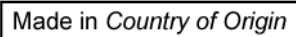



Symbol	Description
	<p>Date of Manufacture</p> <p>To indicate the date when the medical device was manufactured.</p> <p><i>ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.3</i></p>
	<p>In vitro diagnostic medical device</p> <p>Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.</p> <p><i>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</i></p>
	<p>Catalogue Number</p> <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</p> <p><i>ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.4</i></p>
	<p>Serial number</p> <p>Indicates the manufacturer's serial number so that a specific medical device can be identified.</p> <p><i>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</i></p>
	<p>Country of Origin Symbol</p> <p>This symbol indicates the country that the product was manufactured.</p>
	<p>Polarity of d.c. power connector</p> <p>To identify the positive and negative connections (the polarity) of a d.c. power supply, or the positive and negative connections on a piece of equipment to which a d.c. power supply may be connected.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5926</i></p>

Table 1 CritSpin Symbols Glossary (Continued)

Symbol	Description
	<p>Warning; Biological hazard</p> <p>To warn of a biological hazard.</p> <p><i>IEC 60878. Graphical Symbols for electrical equipment in medical practices. #7010-W009</i></p> <p>Supplemental Product-Specific Manufacturer Information</p> <p>This label indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard.</p> <p>This label indicates the use of biohazardous materials in the area. Use caution when working with possible infectious samples.</p> <p>Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.</p>
<p>Info for USA only: California Proposition 65</p> 	<p>California Proposition 65</p> <p>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.</p>

Contents

	Revision History , iii
	Safety Notice , v
CHAPTER 1:	System Overview , 1-1
	Intended Use , 1-1
	Description , 1-1
CHAPTER 2:	Operating Instructions , 2-1
	Operation , 2-1
	Read Spun Hematocrit Tubes inside Rotor , 2-1
	Use 75 mm Adapter , 2-3
	Readout Setting , 2-3
	Cleaning , 2-4
	Troubleshooting and Maintenance , 2-4
APPENDIX A:	Specifications , A-1
	Specifications , A-1
	Accessories List , A-1
APPENDIX B:	References , B-1
	References , B-1

Contents

CHAPTER 1

System Overview

Intended Use

The StatSpin CritSpin Digital Reader assists the operator in measuring spun hematocrits from the StatSpin Centrifuges. A tube adapter is also provided to measure spun hematocrits in 75 mm tubes from other hematocrit centrifuges.

For *in vitro* diagnostic use.

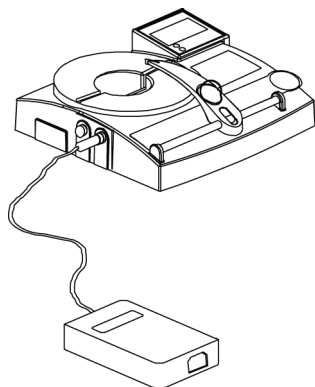
Description

The CritSpin Digital Reader operates from the switching power supply (PN X01-003553-001) provided with the digital reader. Plug the power supply into the digital reader (Digital Reader (PN CSD2).)

Important

Use only the AC Power Adapter supplied with the digital reader. Use of another power supply will damage the Reader and void the warranty.

Figure 1.1



Reader Configuration Product No.: CSD2

System Overview
Description

CHAPTER 2

Operating Instructions

Operation

To use this digital reader, hematocrit tubes are filled with blood, sealed and centrifuged in the RH12 hematocrit rotor. The procedure and step-by-step drawings for filling hematocrit tubes can be found in your centrifuge Instructions for Use manual. Normal values are located in your Instructions for Use manual, read the manual before performing a hematocrit. Follow laboratory procedures when performing any procedure on body fluids. When tubes are centrifuged, the hematocrit rotor is removed from the centrifuge and placed into the digital reader.

Read Spun Hematocrit Tubes inside Rotor

The digital reader has a tilt bar on the underside. Use the tilt bar to provide a tilted position from which to read tubes. You can use either position for reading.

- 1 Install the rotor in the digital reader:
 - a. Move the pointer all the way to the right.



Tip

To move the pointer, gently press it down to allow a smooth gliding motion.

- b. Place the rotor in the center of the digital reader.
- 2 Turn the rotor so that the first tube to be read is at the 3-o'clock position.
- 3 To initiate the first reading, press **Set**.
The LED next to the label **Move pointer to bottom of cells. Set "0"** flashes.

Figure 2.1 Press and Set Buttons



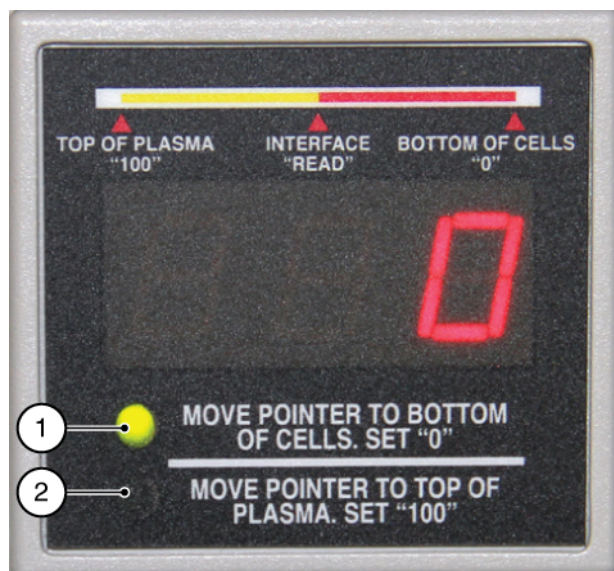
Operating Instructions

Read Spun Hematocrit Tubes inside Rotor

1. Press button

2. Set button

Figure 2.2 LEDs that Flash



1. LED that flashes for step 3.

2. LED that flashes for step 4.

-
- 4** Move the pointer to the bottom of the red blood cells (top of the clay). Then press **Set**. The system displays 0 in the digital display.

The LED next to the label **Move pointer to top of plasma. Set "100"** flashes.

-
- 5** Move the pointer to the top of the plasma (plasma and air interface). Then press **Set**. The system displays 100 in the digital display.

The digital display becomes active, and numbers change as you move the pointer.

-
- 6** Move the pointer slowly to the plasma and red cell interface, and then press **Press**.



Note

To avoid false readings, do not press the membrane on either side of the gliding pointer arm.

-
- 7** Read the digital display, and record the number.

-
- 8** Turn the rotor for the next tube to be read, and press **Set** to initiate the next reading.

-
- 9** Continue until all tubes are read and recorded.
-

Use 75 mm Adapter

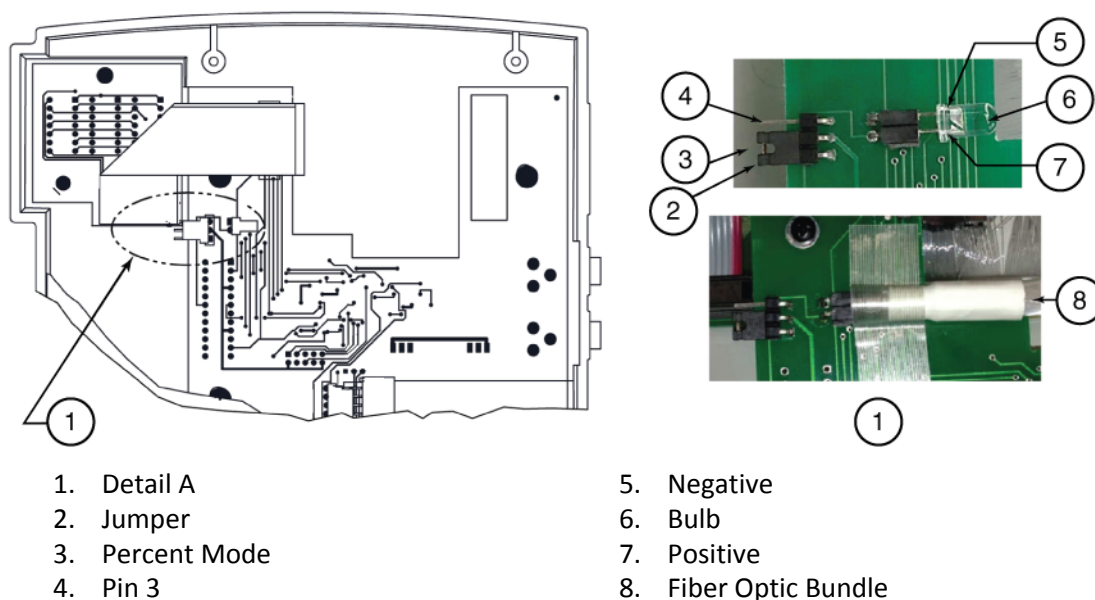
- 1 Move the pointer completely to the right. Place the tube adapter in the slot in the center of the digital reader.
- 2 Place the spun 75 mm hematocrit tube in tube adapter (clay on the right). Slide the hematocrit tube completely to the right. Follow steps 1 to 5 in the Read Spun Hematocrit Tubes inside Rotor to read the tube. Record the result.

Readout Setting

The digital display can be set to read either percent or decimal figures. When the digital reader is shipped, it is set in the percent mode. The mode can be changed from a percent to a decimal figure.

- 1 Remove the base plate on the underside of the digital reader by removing four Phillips screws. Set the base plate and screws aside.
- 2 Move the jumper (small black piece) from pins 1 + 2 to pins 2 + 3.

Figure 2.3



Cleaning

The instruction overlay on the digital reader has a protective coating. To clean the instrument, dampen an absorbent tissue with warm water and a mild detergent and wipe all surfaces.

Troubleshooting and Maintenance

The error indicator "flashing zero" indicates an error in the reading sequence. Repeat the reading. Select **Set** to reset and begin the reading process.

The light is the only user-serviceable part of the digital reader. To replace the light, remove the bottom plate by releasing the four screws on the underside. For more information, refer to [Readout Setting](#) figure. Gently dislodge the bulb by pulling out the bulb. Remove bulb and snap in new bulb. Replace the component to the original position.

The StatSpin CritSpin Digital Reader has no other user-serviceable parts. If a problem occurs, the operator must contact Beckman Coulter Customer support 1-800-854-3633. Disassembly of the unit voids the warranty.

APPENDIX A

Specifications

Specifications

Product No.	CSD2 (supplied with the digital reader)
Model No.	S120
Electrical	24 Volts DC, 1.7 amps. Power supplied by switching power supply for 100-240 VAC, 50/60 Hz.
Dimensions	Height: 2 3/8" 6.0 cm
	Width: 6 7/8" 17.5 cm
	Length: 6 3/8" 16.2 cm
	Weight: 1.25 lbs. 0.6 kg
Environmental	Indoor use
	Altitude up to 2000m
	Operating temperature: 15°C to 32°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

Accessories List

Table A.2 CritSpin Digital Reader Accessories

PN	Description
X01-003553-001	Power Supply
X01-003877-001	Light Bulb for Digital Reader
X00-002227-001	RH12-1 12-position Hematocrit Rotor

Plastic and glass tubes are available from your local dealer, or Contact Beckman Coulter Customer Support 1-800-854-3633.

Specifications
Accessories List

References

- 1 Clinical Laboratory Standards Institute. Proposed Guideline, *Protection of Laboratory Workers from Instrument Biohazards*, Document I 17-P, Vol. 11, No. 15, Appendix A, Pg. 61.
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