Instructions for Use

CytoFuge 2 Cytocentrifuge System Model Number M801-22

This manual is intended for

CF02 - CytoFuge 2 for 100 to 240 VAC, 50/60 Hz





Instructions for Use

CytoFuge 2 Cytocentrifuge System Model Number M801-22

PN 55-003074-001FB (September 2016)

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Original Instructions

Revision History

55-003074-001 FB, 9/16

- Converted the CytoFuge 2 Cytocentrifuge System Operator's Manual to a Beckman Coulter Instructions for Use (IFU)
- Made general clarifications to the IFU
- Update the Logo
- Deleted "In Vitro Diagnostics", and IVD symbol
- 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

55-003074-001FB iii

Revision History

İV 55-003074-001FB

Safety Notice

Beckman Coulter provides product service and support to the StatSpin product line. 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, if not avoided, could 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, 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 indicates important information to follow.



Note indicates notable information to follow.



Tip indicates information to consider.

55-003074-001FB V

Safety Notice

Warnings and Cautions

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.



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



Only use the external power supply (Beckman Coulter Part Number X01-003553-001) included with the unit. Use of other power supplies or transformers will damage the CytoFuge 2 electronics and void the warranty.



Outside of North America: Do not use the external supplied line cord. Use an approved power cord with at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector that is suitable for the external power outlet of the country of intended use.

MARNING

Do not operate the CytoFuge 2 or its rotor below the minimum operating temperature (10°C).

NARNING

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; discontinue use until repairs have been performed.



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

WARNING

Do not expose CytoFuge 2 and its rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones, strong oxidizing agents, or environmental influences, including natural ultra-violet radiation.

Vİ 55-003074-001FB



Only reset the cycle counter after the drive assembly is replaced.



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

WARNING

Always operate the system with all shields and doors 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 Material Safety Data Sheets) for specific hazard information.



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

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.



Never operate the CytoFuge 2 without the rotor properly mounted. Failure to install and secure the rotor correctly can damage the centrifuge.

55-003074-001FB **Vİ**İ

Safety Notice

Warnings and Cautions



CAUTION

Be careful when replacing the rotor. Confirm that the two locator pins are in the corresponding holes in the rotor. Do not over tighten the Rotor Hold-Down Nut (3-lobed). Make certain it is replaced with the flat surface facing up.



CAUTION

The Cytofuge 2 is designed to use only the model CFRT-2 rotor. The use of any other rotor may result in a hazard.



CAUTION

Never use any tool to tighten either the rotor hold-down nut (3-lobed) or the cover nut.



CAUTION

Addition of excess amounts of liquid (overfilling) to Cell or Filter Concentrator causes the fluid to spin out during centrifugation.



CAUTION

Never operate the CytoFuge 2 without the rotor cover in position.



CAUTION

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



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. 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.



CAUTION

Follow universal precautions on all specimens, even if a specimen is not known to contain an infectious agent (See References.)

VIII 55-003074-001FB



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.



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



Maintain a 30 cm (12 inch) clearance free of obstructions around the equipment during operation.

Please use the system as intended. Improper use of the CytoFuge 2 can cause damage to the system, inaccurate results, or potentially nullify warranties.

The CytoFuge 2 and its associated components and reagents are covered under U.S. Patent Nos. 5, 480,484 & 5,679,154.

Recycling Label

This label is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this label indicates that:

- 1. the device was put on the European Market after August 13, 2005 and
- 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 local Beckman Coulter office for details on the take-back program that facilitates the correct collection, treatment, recovery, recycling and safe disposal of these products.

For the Japan Market:

This system is considered an industrial waste, subject to special controls for infectious waste. Prior to disposal of the system, refer to the "Waste Disposal and Public Cleaning Law" for compliance procedures.

55-003074-001FB iX

Safety Notice

Recycling Label

X 55-003074-001FB

Contents

Revision History, iii

Safety Notice, v

CHAPTER 1: Installation , 1-1

Inspecting the Packaging, 1-1
Confirming the Contents, 1-1
Installing the System, 1-1
Connecting the Power, 1-2

CHAPTER 2: System Overview, 2-1

Intended Use, 2-1

Symbols and Definitions, 2-1

Audible Indicators, 2-2

Cell and Filter Concentrators, 2-3

CHAPTER 3: Sample Requirements and Preparation, 3-1

Overview, 3-1

Sample Volumes, 3-1
Pre-concentration, 3-1

Dilution, 3-2

CHAPTER 4: Operating Instructions, 4-1

Quick Start Instructions, 4-1

Detailed Instructions, 4-1

Access the Rotor, 4-2 Remove the Rotor, 4-2 Replace the Rotor, 4-3

Add Sample to the Cell and Filter Concentrator, 4-3

Spin the Sample, 4-4

CHAPTER 5: Maintenance, 5-1

Overview, 5-1 Cleaning, 5-1

Inspecting the Rotor Speed, 5-1

Troubleshooting, 5-2

Service, 5-2

APPENDIX A: Specifications, A-1

Specifications, A-1

APPENDIX B: References, B-1

References, B-1

55-003074-001FB Xi

Contents

Xİİ 55-003074-001FB

Inspecting the Packaging

The CytoFuge 2 and its accessories are delivered in one carton. If the centrifuge or accessories have suffered any damage in transport, inform your carrier immediately.



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

Confirming the Contents

The package contains:

- One CytoFuge 2 cytocentrifuge (Model No. M801-22)
- 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 Accessory Carton
- One Warranty Card Complete the warranty registration as directed

The accessory carton includes:

Table 1.1 Accessory Carton

Item	Product Number	
3-well Cell Concentrators and 3-well gaskets, package of 4 each	CC03	
1-well Cell Concentrators and 1-well gaskets, package of 4 each	CC01	
Stainless Steel Clips for Cell Concentrators, package of 8 each	CLIP	
Backing Plates for Cell Concentrators, package of 4 each	BP01	
Filter Concentrators, 2 bags of 4 each	FF01	
Stainless Steel Clips for Filter Concentrators, package of 4 each	FFCL	

Installing the System

To install the system:

1 Place the CytoFuge 2 on a level surface suitable for laboratory instrumentation.

55-003074-001FB 1-1

Installation

Connecting the Power



Maintain a 30 cm (12 inch) clearance free of obstructions around the equipment during operation.

2 Position the CytoFuge 2 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 supply of the external power cord into a grounded outlet supplying the voltage and frequency indicated on the power supply. When power is connected, two beeps sound, and the cover lock releases. To turn the system off completely, disconnect the power located at the rear of the analyzer.



WARNING

Only use the external power supply (Beckman Coulter Part Number X01-003553-001) included with the unit. Use of other power supplies or transformers will damage the CytoFuge 2 electronics and void the warranty.



WARNING

Outside of North America: Do not use the external supplied line cord. Use an approved power cord with at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector that is suitable for the external power outlet of the country of intended use.

1-2 55-003074-001FB

System Overview

Intended Use

The CytoFuge 2 is a microprocessor -controlled cell preparation system that uses centrifugal force to deposit cells onto microscope slides. Samples are centrifuged in reusable or disposable gasket-sealed chambers (Cell Concentrators), or in disposable chambers (Filter Concentrators) that include a filter material to absorb and capture suspension fluid during cytocentrifugation.

A four-position rotor with transparent cover is supplied as standard equipment. The system is designed to be operated on a laboratory bench or, if potentially biohazardous material is processed, in a biological safety cabinet. A cover interlock system prevents operation until the centrifuge cover is securely latched, and prevents access to spinning parts until the rotor has come to a complete stop. Speeds from 600 rpm to 4400 rpm and cycle times from 2 minutes to 30 minutes can be selected. Automatic acceleration rate control and dynamic braking are included to protect delicate samples.

Symbols and Definitions

Table 2.1 CytoFuge 2 Symbols and Definitions

Symbol	Name	Definition		
•	Start button	The Start button initiates the pre-timed cycle at a fixed speed.		
	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.		
•	Power indicator	The Green LED, identified as power, is illuminated when the CytoFuge 2 is connected to a power source.		
	Release cover	Located below the Stop or Open button on the instrument front panel.		
	Time selector	Available time settings: 2, 4, 6, 8, 10, and 30 minutes.		
C	Speed Selector	Available speed settings: 600, 700, 850, 1,000, 1,300, 1,600, 2,200, and 4,400 rpm.		
24V ==== 1.7 A	Power input	DC Power Input: 24-V DC Plug-in.		
REF	Product or Reference Number	Indicates the StatSpin product or catalog number.		

55-003074-001FB 2-1

 Table 2.1
 CytoFuge 2 Symbols and Definitions (Continued)

Symbol	Name	Definition		
<u> </u>	Caution	Statement of caution or warning. Read instructions carefully.		
1	Temperature limitation	Indicates storage requirements limit.		
②	Do not reuse	Indicates product is single use only.		
EC REP EC Representative		European Community Authorized Representative.		
NON STERILE	Non-sterile	Indicates non-sterile product.		
LOT	Batch Code	Indicates product lot number.		
SN	Serial Number	Indicates instrument serial number.		
	Use by	Indicates product expiration date.		
i	Consult Instructions	Consult instruction manual or insert sheet for further explanation.		
c B us	NRTL Certification	Show conformity to the safety regulations for the United States and Canada.		
CE	CE Marking	Show conformity to the applicable European Union Directives.		

Audible Indicators

 Table 2.2
 Normal Function Codes

Sound	Meaning
2 medium beeps	Sounds on power up; instrument ready.
3 short beeps	Cycle completed per specified operating parameters.
Chirp	Start or stop command recognized by the microprocessor.

Table 2.3 Malfunction Codes

Error Indicator	Error
1 long beep followed by: 2 short beeps	Lid opened during operation.

2-2 55-003074-001FB

 Table 2.3
 Malfunction Codes (Continued)

Error Indicator	Error
1 long beep followed by: 1 short beep	Rotor failed to reach selected rpm within allotted time
1 long beep followed by: 4 short beeps	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.

Cell and Filter Concentrators

Various concentration options are available for use with the CytoFuge 2. For more information, refer to the package inserts for the Filter Concentrators (both reusable and disposable) and the Cell Concentrators (both reusable and disposable).

55-003074-001FB 2-3

System Overview

Cell and Filter Concentrators

2-4 55-003074-001FB

Sample Requirements and Preparation

Overview

The approximate cell concentration of the specimen should be established before slide preparation on the CytoFuge 2. Samples containing higher than optimal cell concentration produces slides with cells too closely packed or overlapping. Samples containing too low a cell concentration yields slides where cells are difficult to find, count, or examine. The following is a general guideline for sample concentration based on an average cell diameter of $10~\mu m$:

Table 3.1 Sample Concentration

Sample Concentration	Recommendation	
500 - 1500 cells/μL ¹	Use optimum sample volume	
Less than 500 cells/μL	Pre-concentrate sample	
More than 1500 cells/μL	Dilute sample	



Follow universal precautions on all specimens, even if a specimen is not known to contain an infectious agent (See References.)

Sample Volumes

Use the following guidelines for sample volumes in each of the CytoFuge 2 concentrators:

	Maximum Volume Range	Optimum Volume Range
Filter Concentrator	50 to 300 μL	100 to 300 μL
One-well Cell Concentrator	300 to 1,600 μL	400 to 800 μL
Three-well Cell Concentrator	50 to 400 μL	100 to 200 μL

Pre-concentration

For best results, samples low in cellular content should be pre-concentrated. For example, if the original sample contains about 100 cells/ μ L, a 10x pre-concentration provides the 1,000 cells/ μ L, which is recommended for the CytoFuge 2.

- **1** Aliquot 10 mL of sample to a conical polypropylene centrifuge tube.
- **2** Spin the sample at 1000 to 1500 xg for 10 to 15 minutes in a conventional centrifuge.
- **3** Decant 9 mL of cell-free supernatant.

55-003074-001FB 3-1

¹ In samples known for low cell populations (e.g. CSF), 50 to 100 cell/μL produces acceptable results.

Sample Requirements and Preparation

Dilution

- 4 Mix the cell pellet and remaining supernatant by vortexing or agitation of the tube.
- **5** Aliquot appropriate volume of the concentrated sample to CytoFuge concentrators.

Dilution

For best results, dilute samples with extremely high cell density. For most applications, buffered saline or standard tissue culture media (for example Geys balanced salt solution), both with a drop or two of bovine serum albumin (BSA), which promotes cell adhesion to the microscope slide, can be used as a diluent.

3-2 55-003074-001FB

Operating Instructions

Quick Start Instructions

Details regarding each instruction can be found in the following sections.



NOTE

The CytoFuge 2 has no on-off switch, and therefore is normally left plugged in and on.

- **1** Assemble the number and type of concentrators required.
- **2** Install the concentrators in the rotor in a balanced arrangement.
- **3** Load the concentrators with sample. (Empty concentrators can be used for balance.)
- **4** Screw on the rotor lid.
- **5** Close and latch cover.
- **6** Select **time** and **speed**.
- **7** Press start.

When the timed cycle is complete, the rotor stops; three beeps sound; and the interlock mechanism releases. The cover latch can then be squeezed to open.

- **8** Unscrew the rotor lid.
- **9** Remove the concentrators.
- **10** Aliquot fluid. (Cell Concentrators only)
- **11** Disassemble the concentrators.
- **12** Recover the slides for further processing.

Detailed Instructions

Opening and Closing the Cover

The electrically operated cover interlock mechanism prevents operation until the cover is completely closed and locked, and prevents the cover from being opened while the centrifuge is in operation. 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.

55-003074-001FB 4-1

Operating Instructions

Detailed Instructions

Cover Interlock By-pass



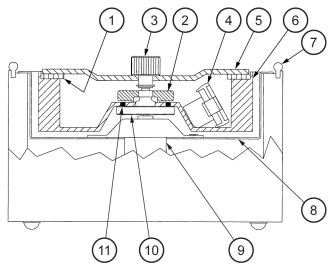
The cover interlock bypass is for emergency use only. Disconnect the power cord of the external power supply from the electrical outlet and ensure the rotor has come to a complete stop before using the interlock bypass. If the equipment is not used correctly, safety can be impaired.

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 between the two buttons in the front of the latch cover (facing the instrument). Manually push the lock lever inward about one inch (25mm) to release the interlock mechanism if the **Stop** or **Open** button does not release the cover.

Access the Rotor

Access the rotor cover by turning the cover nut counterclockwise while holding the rotor itself to prevent turning. The rotor has four positions, allowing two or four concentrators to be centrifuged.

Figure 4.1 Cross-section of the CytoFuge 2



- 1. Rotor Gasket
- 2. Rotor Hold-Down Nut (3-lobed)
- 3. Cover Nut
- 4. Cell Concentrator (shown in rest position)
- 5. Rotor Cover
- 6. Rotor

- 7. Bowl Gasket
- 8. CytoFuge Bowl
- 9. Motor
- 10. Rotor Mount
- 11. Rotor Indexing Pin

Remove the Rotor

1 Hold the rotor with one hand and remove the rotor cover.

4-2 55-003074-001FB

- **2** Remove the Rotor Hold-Down Nut (3-lobed) by turning it counterclockwise.
- **3** Lift the rotor straight out from the centrifuge bowl.

Replace the Rotor



Be careful when replacing the rotor. Confirm that the two locator pins are in the corresponding holes in the rotor. Do not over tighten the Rotor Hold-Down Nut (3-lobed). Make certain it is replaced with the flat surface facing up.



Never use any tool to tighten either the Rotor Hold-Down Nut (3-lobed) or the cover nut.

- **1** Place the rotor on the two rotor indexing pins, aligning the corresponding holes.
- **2** Tighten the rotor hold-down nut by turning it clockwise.
- **3** Replace the rotor cover.

Add Sample to the Cell and Filter Concentrator

Place assembled Cell and Filter Concentrators in the CytoFuge 2 rotor before loading sample. Process the specimen as quickly as possible following sample addition to prevent cells from settling.

Slowly add sample to the bottom of the funnel. Avoid getting droplets onto the walls of the funnel. Avoid exposing the filter material or the microscope slide to sample during the loading process. Do not overfill the device.



In a properly loaded Concentrator, while in the "rest" position, the fluid does not contact the slide. During the first few rotations the Concentrators tilt to a vertical orientation, (noted by an audible click) bringing the fluid in contact with the microscope slide. The Concentrators remain upright until rotation has nearly stopped at which time they shift back to the rest position.



Addition of excess amounts of liquid (overfilling) to Cell or Filter Concentrator causes the fluid to spin out during centrifugation.

55-003074-001FB 4-3

Operating Instructions

Detailed Instructions

Spin the Sample



Never operate the CytoFuge 2 without the rotor cover in position.

- **1** Screw on the rotor cover.
- **2** Close and latch the centrifuge cover.
- **3** Select the **time** and **speed**.

CytoFuge 2 operating parameters generally depend upon the size and specific gravity of the cells to be concentrated onto the microscope slide. The operator should experiment with different settings to achieve optimum performance for specific applications. The following are general guidelines:

Table 4.1 CytoFuge 2 Speed and Time Settings

Application	Speed Range	Time Range	
Cytology	600 to 1000 rpm	2 to 4 minutes	
Hematology	1000 to 2200 rpm	4 to 8 minutes	
Microbiology	1600 to 4400 rpm	4 to 10 minutes	



NOTE

- For fragile cells, reduce speed.
- For wet preparations, reduce time.
- small particle (e.g. bacteria), increase speed and time.

4 Press the **start** button.

4-4 55-003074-001FB

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.



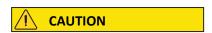
Disconnect the power cord of the external power supply from the electrical outlet before performing maintenance or inspection.



Do not expose CytoFuge 2 and its 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.

Cleaning

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



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. 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.

Inspecting the Rotor Speed

The rated speeds (±5%) can be inspected with a photoelectric tachometer available from many sources. Point the tachometer through the transparent cover at the reflective patch located near rotor center. If the CytoFuge 2 fails to achieve operating speed (+5%), contact Beckman Coulter Customer Support.

55-003074-001FB 5-1

Troubleshooting

Table 5.1 No Power Light

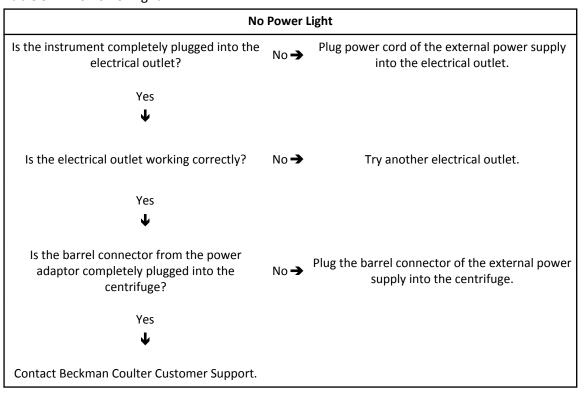


Table 5.2 Centrifuge Will Not Spin or Shuts Off

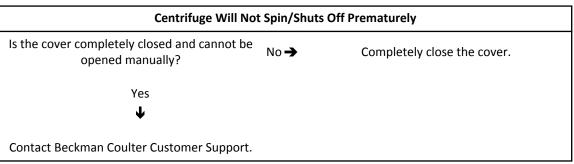


Table 5.3 Centrifuge Does not Open at the End of the Cycle

Centrifuge Does not Open at the End of the Cycle		
Follow Cover Interlock By-pass instructions in Chapter 4 to open the cover and retrieve samples, then contact Beckman Coulter Customer Support.		

Service

There are no user-serviceable parts. 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.

5-2 55-003074-001FB

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

Beckman Coulter 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. Subject to the limitations below, Beckman Coulter warrants that the centrifuge 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 manufacture. As exclusive and sole remedy for breach of the warranty, Beckman Coulter will, at its discretion, repair or replace any StatSpin unit or part covered under this warranty returned to Beckman Coulter or an authorized repair center. Repaired or replaced StatSpin 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 StatSpin instrument that has been damaged due to misuse, negligence, accident, or damage resulting from unauthorized repairs, alterations, or improper installation. No warranty is provided for the centrifuge other than the one expressly 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 warranty set forth herein. No person or entity has been authorized by Beckman Coulter to extend any other warranty or assume any liability except as set forth above. This warranty is only applicable to the original purchaser.

55-003074-001FB 5-3

Maintenance

Service

5-4 55-003074-001FB

Specifications

Product No.	CF02		
Model No.	M801-22		
Speeds and	600 rpm, 20 xg		
Forces	700 rpm, 27 xg		
	850 rpm, 40 xg		
	1,000 rpm, 55 xg		
	1,300 rpm, 93 xg		
	1,600 rpm, 140 xg		
	2,200 rpm, 265 xg		
	4,400 rpm, 1,060 xg		
Cycle Times	2, 4, 6, 8, 10, and 30 minutes		
Electrical	24Vdc, 1.7A Includes power supply for 100 to 240 VAC, 50/60 Hz		
Dimensions	Height 5.3 in. (13.5 cm)		
	Diameter 6.8 in. (17.3 cm)		
	Weight 4.75 lbs (2.2 kg)		
Environmental	Indoor use (IP20)		
	Altitude up to 2,000 m		
	Operating temperature range is 10°C - 40°C		
	Storage temperature is 0°C - 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		

55-003074-001FB A-1

Specifications

Specifications

A-2 55-003074-001FB

APPENDIX B References

References

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