

StatSpin Cytofuge®

COMPACT CYTOCENTRIFUGE SYSTEM

2



...Fast, Simple,
Economical

...Prepares Monolayer
Cell Presentations

...For a complete range
of body fluids

StatSpin®

Productivity Tools

THE RAPID, SIMPLE AND ECONOMICAL WAY TO PREPARE

StatSpin CytoFuge® 2 PERSONAL CYTOCENTRIFUGE SYSTEM

The StatSpin CytoFuge® 2 is a low-cost personal cytocentrifuge. It has simple understandable controls and new snap-seal Filter Concentrators that make operation easy. Samples are processed quickly, silently and conveniently on any bench or in a safety cabinet. Results are consistent: easy to scan monolayer cell presentations of excellent morphologic detail.

StatSpin CytoFuge® 2 is ideal for a complete range of body fluids:

- Pleural Fluids
- Sputum
- Urine
- Synovial Fluids
- Pericardial Fluids
- Fine Needle Aspirates
- Bronchial Washings
- Peritoneal Fluids
- Cerebrospinal Fluids

The CytoFuge® 2 is:

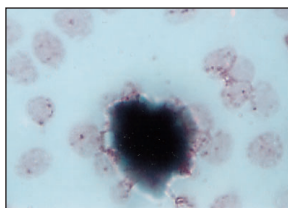
- Compact and Quiet – fits in small area or safety hood
- Reduces exposure to biohazards with covered rotor and chamber gaskets
- Optimal control acceleration and braking
- Cover Interlock System prevents operation with cover open
- Patented rotor design eliminates trunnion carriers or bulky clamps
- Accurate and Repeatable – speed and cycle time controls accommodate a range of applications



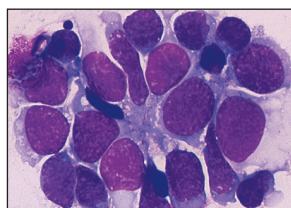
Compact low profile design can be used in a biological safety cabinet. No need to carry the rotor back and forth to the centrifuge as with competitive equipment.

QUALITY MONOLAYER CELL PRESENTATIONS

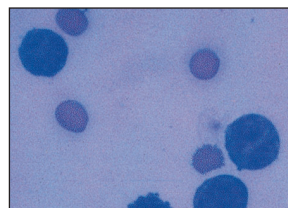
Diagnostic Tool for...Cytology, Hematology, Microbiology and Research



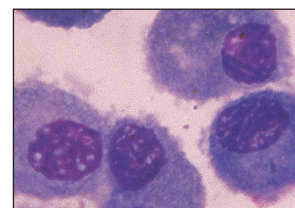
Cerebrospinal Fluid



Retinal Cells

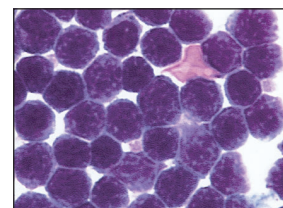
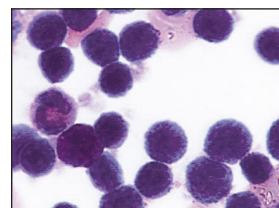
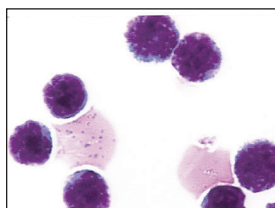


Bone Marrow



Bronchial Aspirate

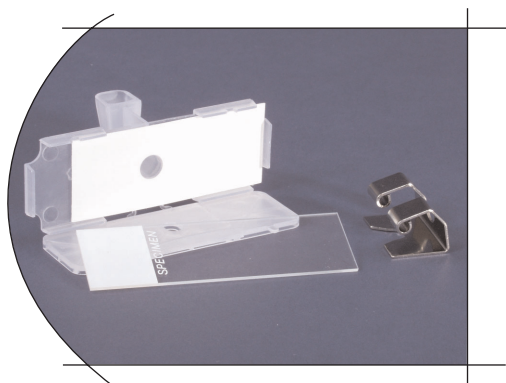
The CytoFuge 2 offers a choice of filter or gasket-seal concentrator formats. The system handles samples from routine body fluid preps to research methods involving application of multiple cell concentrations or controls on the same slide. A broad range of selectable speed and run times enables precise replication of most procedures developed on other cytocentrifuge equipment.



Pleural Fluid (Multiple concentrations of cells on the same slide using three-well Cell Concentrators)

Disposable Filter Concentrators

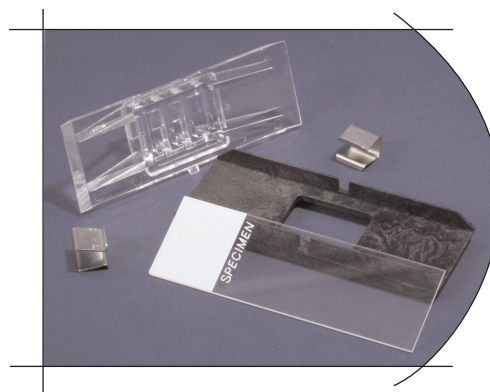
Save time and improve results by eliminating the need to clean and sterilize reusable sample chambers. The device includes a unique hinged backing plate and an integral filter card which absorbs fluid at a controlled rate during the spin cycle. Cells are gently concentrated in a monolayer onto a 7 mm diameter area on the slide with minimal cell loss to the filter.



- Sample volume range – 50 to 400 μL
- Self-rocking feature prevents premature absorption by the filter – improves cell recovery.
- Stainless steel clip eliminates bulky trunnion carriers, provides consistent results.

Reusable/Disposable Cell Concentrators

Available in 1 and 3-well formats, these silicone gasket-sealed devices are made of transparent plastic; they are competitively priced for disposable use. Autoclavable versions are also offered.



- Sample Volume Range
 - 1-well Cell Concentrator 300 to 800 μL
 - 3-well Cell Concentrator 50 to 200 μL
- 3-well Concentrator permits application of different samples, different concentrations or controls on the same slide.
- Reuse capability reduces operating costs.
- Autoclavable version

StatSpin Cytofuge[®] 2



Specifications:

Safety Features	• Cover interlock system • Leak-resistant rotor with transparent lid • Low voltage drive system (24 V) • Designed to meet requirements of IEC-1010-2-020
Rotor Capacity	• One to four slides
Speeds (Forces)	• 600 rpm (20 xg) 1300 rpm (93 xg) • 700 rpm (27 xg) 1600 rpm (140 xg) • 850 rpm (40 xg) 2200 rpm (265 xg) • 1000 rpm (55 xg) 4400 rpm (1060 xg)
Operating Times	• 2, 4, 6, 8, 10 and 30 minutes
Power	• 100 to 240 VAC, $\pm 10\%$, 50 or 60 Hz
Dimensions (H x W x D)	• 15.2 cm x 16.8 cm x 21.8 cm (5.3 in. x 6.6 in. x 8.6 in.)
Weight	• 2.5 kg (5.5lbs)

Ordering Information - Filter Concentrators

FF01	CytoFuge Filter Concentrators 48/box
FFCL	Replacement Filter Clips 4/bag
FFR1	Reusable Filter Concentrators 20 plastic concentrators and 200 filter cards

Product

CF02	CytoFuge 2 Cytocentrifuge for 100-240 V, 50/60 Hz. Includes universal power supply, 4-place rotor with lid and start-up supply of accessories.
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Cell Concentrators

CC01	1-well with gaskets 10/box
CC03	3-well with gaskets 10/box
CCR1	Autoclavable 1-well with gaskets 10/box
CCR3	Autoclavable 3-well with gaskets 10/box

Accessories

CLIP	Replacement Stainless Steel Clips 10/bag
BP01	Replacement Backing Plates 10/bag

Replacement Silicone Gaskets

GK01	1-well 100/bag
GK03	3-well 100/bag

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***CytoFuge*[®] 2 Cytocentrifuge System**

Operator's Manual

***StatSpin*[®]**

Operator's Manual
***CytoFuge*[®] 2 Cytocentrifuge System**

Model Number M801-22

FOR *IN VITRO* DIAGNOSTIC USE

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

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How to use this manual

This manual along with information contained on product labels and in package inserts should provide you with all the information you need to operate and maintain the CytoFuge® 2.

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



Please pay close attention to the instructions that accompany the notes and symbols as well as the standard laboratory practices outlined by your facility and local regulatory agencies. The table below lists all the CAUTIONS/WARNINGS for the CytoFuge 2.

	WARNING - North American Installation: Only use the power supply 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 Line Cord Supplied. Use power cord for at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.
	CAUTION - The cover interlock bypass is designed for emergency use only. If the equipment is not used properly, safety may be impaired.
	CAUTION - Be careful when replacing the rotor. Make sure the two locator pins are in the corresponding holes in the rotor. Do not over tighten the hold-down nut. Make certain it is replaced with the flat surface facing up
	CAUTION - NEVER use any tool to tighten either the rotor nut or the cover nut
	CAUTION - Addition of excess amounts of liquid (overfilling) to Cell or Filter Concentrator will result in the fluid being "spun out" during centrifugation
	CAUTION - NEVER operate the CytoFuge 2 without the rotor cover in place.
	CAUTION - Unplug the CytoFuge 2 from the wall outlet before performing maintenance.
	WARNING – DO NOT expose CytoFuge 2 and its rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.
	CAUTION - DO NOT spray the bowl or outer surfaces with detergent or bleach. Excess liquid will harm the electronics and subsequent problems may not be covered under warranty.
	CAUTION - Universal Precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent. (See references)

Please use the system and reagents as intended. Improper use of the CytoFuge 2 Cytocentrifuge System or its reagents may cause damage to the system, inaccurate results, or potentially nullify warranties.

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

Unpacking and Installation

Inspect Packaging

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

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

Verify Contents

The package contains:

One CytoFuge 2 cytocentrifuge (Model No. M801-22)

One Universal Switching Power Supply
(Product No. 01-3553-001, APS Model No. AD-744-1240)

One grounded line cord (for North American use only)

One Operator's Manual

One Accessory Carton

The Accessory Carton consists of:

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

Install System

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

Connect Power

Plug the power supply into a grounded outlet supplying the voltage and frequency indicated on the power supply. When power is connected, two "beeps" will sound and the cover lock will release. To turn unit off completely, disconnect power located at the rear of the instrument.



WARNING - North American Installation: Only use the power supply 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 Line Cord Supplied. Use power cord for at least 1.0 Amp or more with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used.

Section 2

System Overview

Principle and Intended Use

IVD

For in vitro diagnostic use in concentrating cells onto a microscope slide.

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 may be selected. Automatic acceleration rate control and dynamic braking are included to protect delicate samples.

Symbols and Definitions

	Start button	The <i>start</i> button initiates a pre-timed cycle at the speed selected. NOTE: The <i>CytoFuge 2</i> does not have an on/off switch and is normally left plugged in and “on”.
	Stop/open button	The <i>stop/open</i> button interrupts the cycle and stops the centrifugation. This button may also be used to release the cover.
	Power indicator	The green LED identified as <i>power</i> is illuminated when the <i>CytoFuge 2</i> is connected to a power source.
	Release cover	Located below <i>stop/open</i> button on instrument front panel
	Time selector	Available time settings: 2, 4, 6, 8, 10, and 30 minutes
	Speed selector	Available speed settings: 600, 700, 850, 1000, 1300, 1600, 2200, and 4400 rpm
	Power input	DC Power Input: 24V DC Plug-in

Symbols and Definitions (cont.)

	Product/Reference Number	Indicates the StatSpin product/catalog number
	Caution	Statement of caution/warning, read instruction carefully
	Temperature limitation	Indicates storage requirements range
	Do not re-use	Indicates product is single use only
	EC Representative	European Community Authorized Representative
	For <i>in vitro</i> diagnostic use	Clarifies for use as <i>in vitro</i> diagnostic only
	Non sterile	Indicates non-sterile product
	Batch code	Indicates product lot number
	Serial Number	Indicates instrument serial number code
	Use by	Indicates product expiration date
	Consult Instructions	Consult instruction manual or insert sheet for further explanation

Audible Indicators

Normal Function Codes	
Sound	Meaning
2 medium beeps	Sounds on power up; instrument ready
3 short beeps	Cycle completed per specified operating parameters.
Chirp	<i>Start</i> or <i>stop</i> command recognized by the microprocessor.
Malfunction Codes	
1 long beep followed by: 1 short beep	Rotor failed to reach selected rpm within allotted time
1 long beep followed by: 2 short beeps	Lid opened during operation
1 long beep followed by: 3 short beeps	Internal temperature exceeded 60°C (unit can not be restarted until internal temperature drops below 52°C)
1 long beep followed by: 4 short beeps	Insufficient power to maintain rpm
1 long beep followed by: 5 short beeps	Over current detector tripped.

Cell and Filter Concentrators

A variety of concentration options are available for use with the CytoFuge 2. See the package inserts for the Filter Concentrators (both reusable and disposable) and the Cell Concentrators (both reusable and disposable) for detailed information.

Sample Requirements/Preparation

Overview

The approximate cell concentration of the specimen should be established prior to slide preparation on the CytoFuge 2. Samples containing higher than optimal cell concentration will produce slides with cells too closely packed or overlapping. Samples containing too low a cell concentration will yield 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 μm :

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

* In samples known for low cell populations (e.g. CSF), 50-100 cell/ μL will produce acceptable results.



CAUTION - *Universal Precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent. (See references)*

Sample volumes

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

	Max. Volume Range	Optimum Volume Range
Filter Concentrator	50 to 500 μL	100 to 400 μL
One-well Cell Concentrator	300 to 1600 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/ μL , a 10x pre-concentration will provide the 1,000 cells/ μL , which is recommended for the CytoFuge 2.

To pre-concentrate a sample,

1. Transfer 10 mL of sample to a conical polypropylene centrifuge tube.
2. Spin the sample at 1000-1500 xg for 10-15 minutes in a conventional centrifuge.
3. Decant 9 mL of cell-free supernatant.
4. Mix the cell pellet and remaining supernatant by vortexing or agitation of the tube.
5. Pipette 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 (e.g. Geys balanced salt solution), both with a drop or two of bovine serum albumin (BSA), which promotes cell adhesion to the microscope slide, may be used as a diluent.

Section 4

Operating Instructions

Quick Start Instructions

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

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 may 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 concentrators.
10. Aspirate fluid. (Cell Concentrators only)
11. Disassemble concentrators.
12. Recover slides for further processing.

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

Detailed Instructions

Opening and Closing the Cover

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

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

Cover Interlock By-pass

The electronically operated cover interlock mechanism can be released manually by inserting the straightened end of a large paper clip or similar object into the small hole 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/open button does not release the cover.



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

Access the Rotor

Access the rotor cover by turning the knurled knob ③ (cover nut) counterclockwise while holding the rotor itself to prevent turning. (See Figure 1.)

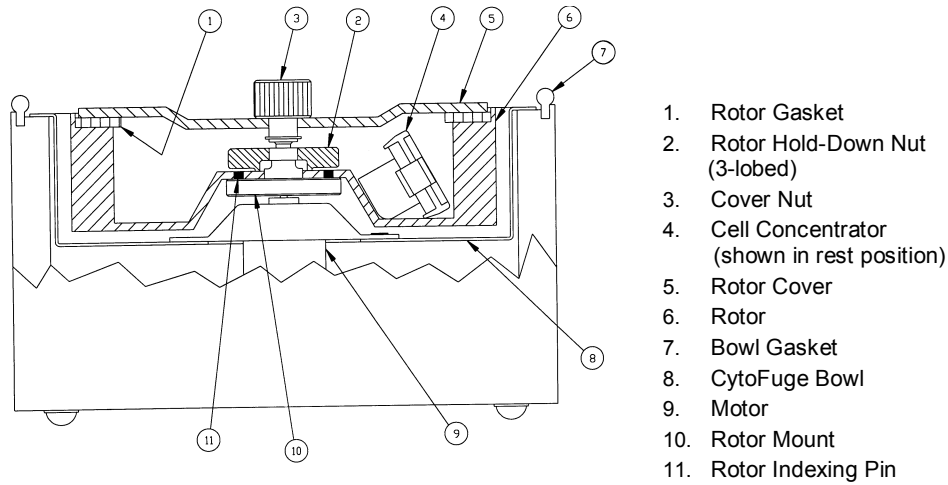


Figure 1. Cross section of the CytoFuge 2 showing the bowl and rotor with the names and locations of the parts. The rotor has four positions, allowing two or four concentrators to be centrifuged.

Remove the Rotor

1. Hold the rotor ⑥ with one hand and remove the rotor cover ⑤.
2. Remove the three-sided nut ② by turning it counterclockwise.
3. Lift the rotor ⑥ straight out from the centrifuge bowl.

Replace the Rotor

1. Place the rotor ⑥ on the two rotor indexing pins, aligning the corresponding holes.
2. Tighten the rotor hold-down nut ② by turning it clockwise.
3. Replace the rotor cover ⑤.



CAUTION - Be careful when replacing the rotor. Make sure the two locator pins are in the corresponding holes in the rotor. Do not over tighten the hold-down nut. Make certain it is replaced with the flat surface facing up.

CAUTION - NEVER use any tool to tighten either the rotor nut or the cover nut.

Add Sample to the Cell and Filter Concentrator

Place assembled Cell and Filter Concentrators in the CytoFuge 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.

NOTE: 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.



CAUTION - Addition of excess amounts of liquid (overfilling) to Cell or Filter Concentrator will result in the fluid being “spun out” during centrifugation.

Spin the Sample



CAUTION - Never operate the CytoFuge 2 without the rotor cover ⑤ in place.

1. Screw on the rotor cover⑤.
2. Close and latch the centrifuge cover.
3. Select the *time* and *speed* (See Table 1)
4. Press *start* button.

Table 1: CytoFuge 2 Speed and Time Settings. 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:

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

Section 5

Maintenance

Overview

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



CAUTION - Unplug the CytoFuge 2 from the wall outlet before performing maintenance.



WARNING - Do not expose CytoFuge 2 and its rotor to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.

Cleaning

Clean the outside surfaces and switch overlay 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 surfaces with a **dampened** cloth using 70% alcohol or 10% bleach solution.



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

Checking the Rotor Speed

The rated speeds ($\pm 5\%$) can be checked with a photoelectric tachometer available from many sources. If the CytoFuge 2 fails to achieve operating speed $\pm 5\%$ contact your distributor or StatSpin Customer Service department.

Service

There are no user-serviceable parts. Refer all service to qualified service personnel.

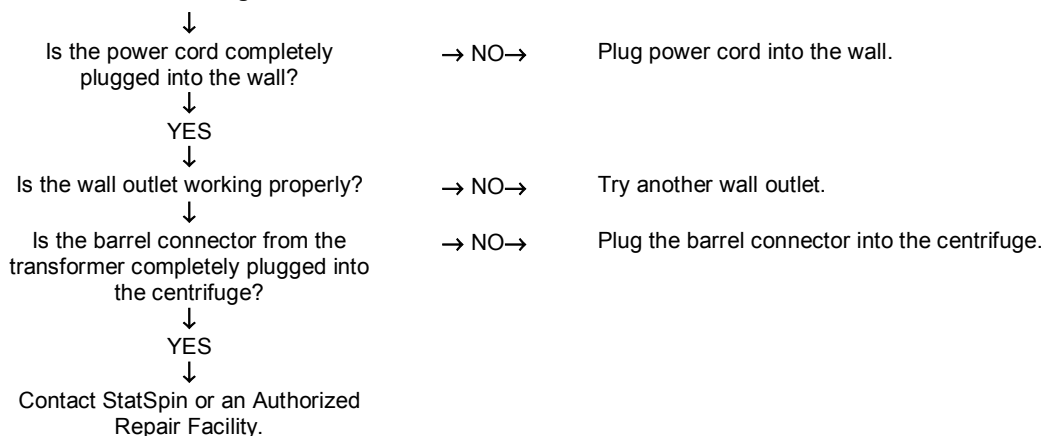
Reference the StatSpin Warranty for further instruction. Be sure to complete and return the warranty card as directed.

Decontamination before returning for service

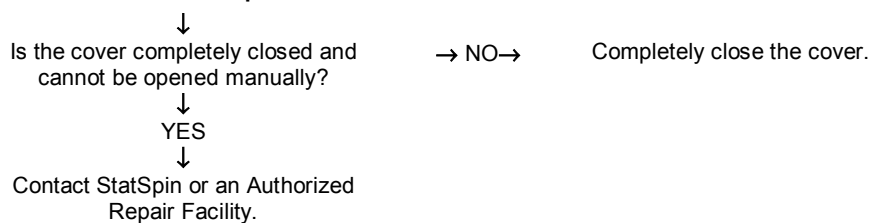
Any instrument or accessory containing accumulated blood and/or other biological or chemical deposits must be cleaned prior to shipment to the manufacturer/dealer for service. This decontamination is required by Federal Law (Title 48 and 49 of the Federal Regulations) and in accordance with the Environmental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

Troubleshooting

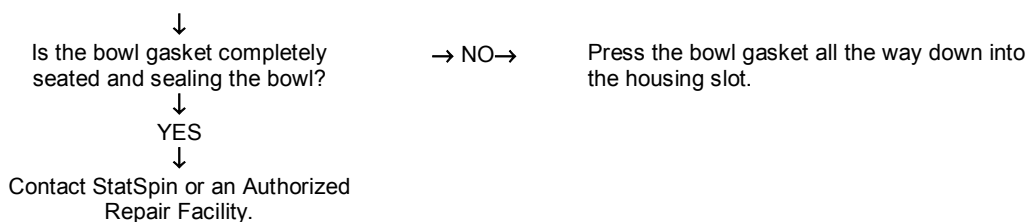
No Power Light



Unit Will Not Spin



Unit will not open at end of cycle



Appendix

Appendix A - Specifications

Product No.	CF02
Model No.	M801-22
Speeds and Forces	600 rpm / 20 xg
	700 rpm / 27 xg
	850 rpm / 40 xg
	1000 rpm / 55 xg
	1300 rpm / 93 xg
	1600 rpm / 140 xg
	2200 rpm / 265 xg
	4400 rpm / 1060 xg
Cycle times	2, 4, 6, 8, 10, and 30 minutes
Electrical	24 Volts, DC, 1.7 amp. Includes switching power supply for 100-240 VAC, 50/60 Hz
Dimensions	Diameter 6.8"/ 16.3 cm
	Height 5.3"/12.0 cm
	Weight 4.75 lbs/2.5 kg
Environmental	Indoor use
	Altitude up to 2000m
	Temperature 5°C to 40°C
	Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C
	Main supply voltage fluctuations not to exceed +/- 10% of the nominal voltage
	Transient over-voltages according to installation category II
	Pollution degree 2

References

1. NCCLS. "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Second Edition." NCCLS document M29-A2 [ISBN 1-56238-453-8]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
2. CDC. Recommendations for prevention of HIV transmission in health care settings. MMWR (Suppl. No. 2S):2S-18S, 1987.
3. CDC. Updated: US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis. Appendix A and B. MMWR 50 (RR-11): 1-42, June 29, 2001.

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Made in USA



StatSpin Warranty

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

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

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

Limitation of Liability

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

MODEL: M801-22

