



CellSolutions® F50

Operator's Manual



CE
IVD

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PREFACE

Information about this Manual

This manual provides information on the installation, operation and maintenance of the CellSolutions F50 Processor and its software.

Throughout the manual the following three notices are used to highlight important information:

WARNING: INDICATES THE POSSIBILITY OF SEVERE PERSONAL INJURY OR LOSS OF LIFE IF INSTRUCTIONS ARE NOT FOLLOWED.

Caution: Indicates the possibility of severe equipment damage if instructions are not followed.

Note: Indicates useful information.

General Information

This device is intended for the preparation of thin-layer cell presentations on microscope slides for subsequent staining and evaluation. All users of the device should be appropriately trained on the uses of the device and understand the overall slide preparation and screening process.

WARRANTY INFORMATION

The F50 has a one-year warranty from the date of sale. For technical support or repair information contact your designated local representative or CellSolutions LLC.

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1.0 INTRODUCTION

1.1 Intended Use

The F50 automates certain steps in the process of preparing a microscope slide with a thin layer of cells for microscopic visual evaluation. The unit takes as input, preserved cell samples that have already been fixed. The system then outputs optimized samples onto microscope slides that are ready for staining and viewing by laboratory professionals trained in screening and interpreting cytology preparations.

Each laboratory is responsible for validating the instrument settings for Vacuum Time (VCTIME), Vacuum Pressure 1 (VCPRE1), Vacuum Pressure 2 (VCPRE2), Transfer Hold (TRANSHOLD), and Transfer Power (TRANSPOWE) to ensure optimal cell presentation. In addition, it is recommended each end user utilize a staining procedure that has been optimized for proper visualization of the cellular characteristics of the sample for adequate diagnosis.

1.2 Requirements

The device is designed to use the specific reagents and consumable materials identified in this manual (i.e. reagents, filters, slides). Use of other reagents and materials may damage the device and cause incorrect results as well as render the warranty invalid.

The samples should be collected by experienced professionals. CellSolutions recommends preservation of samples using the BestPrep® General Cytology Preservative Vial (C-101 or CF-101), CellSolutions Blue Preservative (CB-102), and/or CellSolutions Red Lytic Preservative (CR-102).

1.3 Hazards and Warnings

1.3.1 Chemical Hazards

The fluids processed by the device are biological samples that may contain infectious material.

**WARNING: SPECIMENS MAY CONTAIN INFECTIOUS MATERIAL.
WEAR PROTECTIVE CLOTHING AND AVOID CONTACT WITH
SPECIMEN.**

**WARNING: IF A SPILL OCCURS, CLEAN THE AFFECTED AREA
USING APPROPRIATE CLEANING MATERIAL FOR THE TYPE OF
SPILL. POTENTIAL BIOHAZARD CLEAN UP MAY REQUIRE THE USE
OF A TOWEL LIGHTLY DAMPENED WITH A 10% BLEACH
SOLUTION.**

1.3.2 Mechanical Hazards

The F-50 processor is controlled by software in communication with sensors and motors. The device is designed with a cover to protect the components, and to protect the operator from accidental harm due to exposure to moving parts while in operation.

1.3.3 Electrical Hazards

The F50 processor is designed to plug into an alternating current power supply. It operates on 100 to 240 volts and 50 to 60 Hz. Routine electrical precautions should be observed, such as unplugging the device before cleaning, and avoid spills while in use.

2.0 SPECIFICATIONS AND INSTALLATION

2.1 Equipment Specifications

The F50 processor is a liquid based cytology preparation system. A separate centrifuge and vortex mixer that is not provided with the system is recommended and may be required depending upon laboratory procedures. The centrifuge and vortex mixer listed below are suggested units, however, others may be used as long as they can achieve the required G-forces and mixing requirements of the process. The physical dimensions and specifications for each unit are as follows:

2.1.1 F50 Processor

Dimensions: Width: 390 mm (15 inches)
 Depth: 270 mm (11 inches)
 Height: 210 mm (8.5 inches)

Power: Input: 120-240VAC, 50-60Hz
 Output: DC12v, 4A

(Note: Operation at 100VAC to 240VAC is acceptable.)

Weight: 11 kg (24 lbs)

Operating Temperature: 5°C to 35°C (41° to 95°F)

Relative Humidity: 30 to 80% RH, non-condensing

Throughput: 45-60 slides per hour

2.1.2 Centrifuge

A centrifuge is required when concentrating large volume specimens or when processing non-gyn specimens. The following centrifuge is suggested as being one that is compatible with the F50 processor system:

Manufacturer: Drucker

Model: 755 VES with six-bucket rotor (horizontal spinning)

Dimensions: Width: 380 mm (15 inches)
 Depth: 430 mm (17 inches)
 Height: 230 mm (9 inches)

Power: Configuration 1: 120VAC, 60 Hz, 1 amp
 Configuration 2: 240VAC, 50 Hz, 0.5 amps

Weight: 17 kg (37 lbs)

Capacity: Six 50mL tubes (6 position rotor)

2.1.3 Vortex Mixer

A vortex mixer is required but not provided.

A standard laboratory vortex mixer with comparable specifications to the unit noted below is acceptable.

Manufacturer: Thermolyne

Model: Maxi Mix II, No. M37615

Dimensions: Width: 130 mm (5 inches)
Depth: 200 mm (8 inches)
Height: 150 mm (6 inches)

Weight: 3 kg (6 lbs)

2.2 Recommended Installation Space

Recommended Bench Space for F series Processor:

Width: 1200 mm (48 inches)
Depth: 750 mm (30 inches)
Height: Not Critical.

Recommended Bench Space for centrifuge, vortex mixer, and handling:

Width: 1200 mm (48 inches)
Depth: 750 mm (30 inches)
Height: Not critical.

The above dimensions are recommended values. Each installation site's space will vary based on space constraints and usage volumes.

2.3 Installation and Setup

The F50 processor should be placed on a stable table that does not tilt or flex.

The unit can be placed with the back toward a wall so long as there is at least 50 mm (2 inches) of space between the unit's back and the wall. This space provides ventilation for unit cooling.

The tubing from the waste pump should be placed in a reservoir bottle or container. The waste bottle should be placed below the height of the processor or on the floor directly. The container should be emptied after each day of use.

A waste disposal container is recommended to discard used filters.

2.4 Power the Unit

Check that the available power is correct before plugging the components into the wall socket.

The power supply can be plugged into the processor.

Although not part of the system, it is recommended that a surge protector be used between the wall socket and the power cord of the processor.

2.5 Transport, Storage, Disposal

Prior to removing the unit from service for decommissioning, storage or transport, the unit must be cleaned/decontaminated.

To decontaminate the internal system, load an unused filter onto the unit and pour 10mL of a 10% bleach solution into the filter and cycle the system. Repeat this step. Flush the system by pouring 10mL of deionized (DI) water the filter and cycle the system. Repeat this step.

The system should have fluids purged from the pump and tubing prior to removing unit from service. At least 5 ml of air should be pumped through the system. Waste container should be emptied and washed with a 10% bleach solution followed by DI water.

To decontaminate the external surfaces, disconnect the power cord and wipe all external surfaces of the unit that may have come in contact with biological samples. The surfaces should be wiped with a towel that is lightly dampened with a 10% bleach solution. Do not spray cleaning solution directly on the unit. A second wash should be done with a damp cloth containing water to remove bleach residue.

If the equipment is to be permanently removed at the end of its service life cycle, it should be handled as Waste Electrical and Electronic Equipment (WEEE). The equipment, including accessories, does not belong in your regular waste. For disposal of the equipment in the European Economic Area (EEA) or other areas with specified WEEE regulations, contact your CellSolutions Representative for disposal guidance or dispose of in accordance with your local regulations. The unit must first be cleaned and decontaminated as noted above.

3.0 MATERIAL REQUIREMENTS

3.1 Reagents

The device is designed to process samples preserved in the following types of preservative solutions:

- BestPrep® General Cytology Preservative (C-101)
- CellSolutions F50 General Cytology Preservative (CF-101)
- CellSolutions Blue Preservative (CB-102)
- CellSolutions Red Lytic General Cytology Preservative (CR-102)

3.2 Single Use Materials

F50 filters, preservative fluids, and slides are for single use only. Washing or reusing will have negative impacts on the filter, specimen quality, and patient care through possible cross contamination and/or degradation.

3.3 Consumable Materials

The following items are purchased separately from CellSolutions as needed depending upon usage and sample type.

- BestPrep® General Cytology Preservative Kits (C-101-500; C-101-200; C-101L; C-101G)
- CellSolutions F50 General Cytology Preservative Kits (CF-101-500; CF-101-200; CF-101L; CF-101G)
- CellSolutions Filter Kit (CS-400F)
- CellSolutions Blue Preservative (CB-102-25; CB-102L, CB-102G)
- CellSolutions Red Lytic General Cytology Preservative (CR-102L; CR-102G)

4.0 Operating Procedures

4.1 Principles of Operation

The F-series cytology processor is based upon a patented dual filter technology that provides a vacuum to process clinical samples such as urines, fine needle aspirates, etc. CellSolutions® cytology reagent line can be used for a variety of clinical sample types, i.e. FNA, urines, buccal etc. This line of cytology reagents consists of a preservative which will lyse red blood cells.

Clinical samples containing large volumes of blood or mucus may require pre-treatment before running on the F-series processor to avoid clogging the filter. The filter will allow fluids to travel through the filter while trapping cells onto the filter which can then be transferred onto a charged slide for cellular adherence.

The processor works by vacuum to pull fluids through the filter. The time and suction pressure can be adjusted based upon the viscosity/type of the sample to be processed. This is depicted in Figure 4-1. The processor can also apply a variety of pressure on the filter as it is pressed against the slide to transfer cells from the filter. The four parameters can be modified while in the MODE setting prior to pressing start. The processor will store all previous settings.

After processing, the slide should either be spray fixed or stored in 95% ethanol until they are stained and coverslipped. The processor and reagents should only be used by a trained and qualified laboratory technologist.

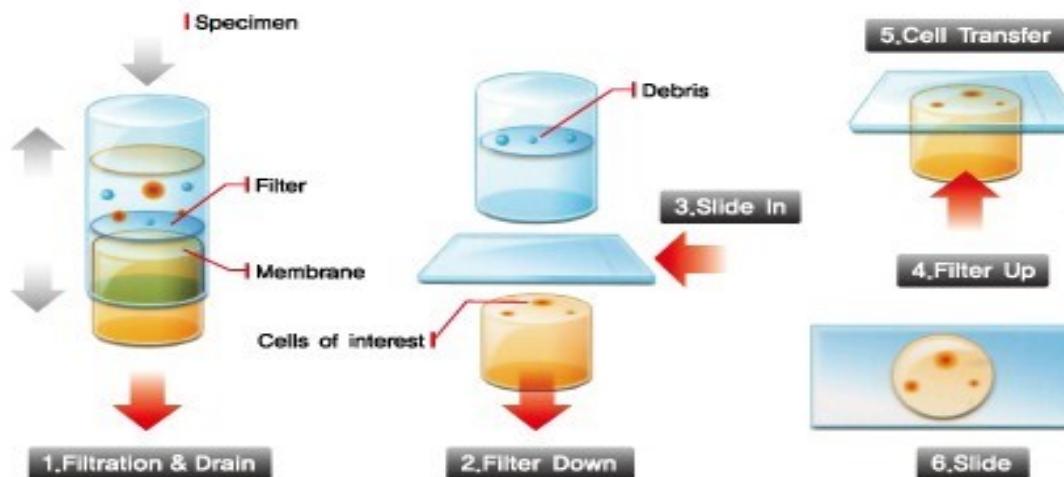


Figure 4-1

4.2 User Interface

Figure 4-2 shows the CellSolutions F50 main interface window that is displayed upon startup.

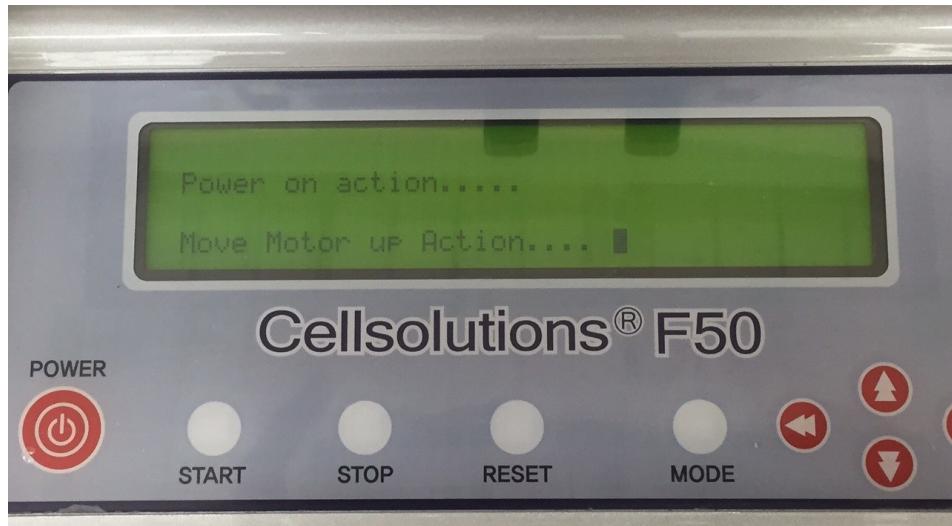


Figure 4-2

This screen is the starting point for the process and also provides the status of the process while samples are being run. The functionality of each button is covered in the following discussion of machine operation.

4.3 System Keypad

The processor operates with a series of simple keypad strokes.

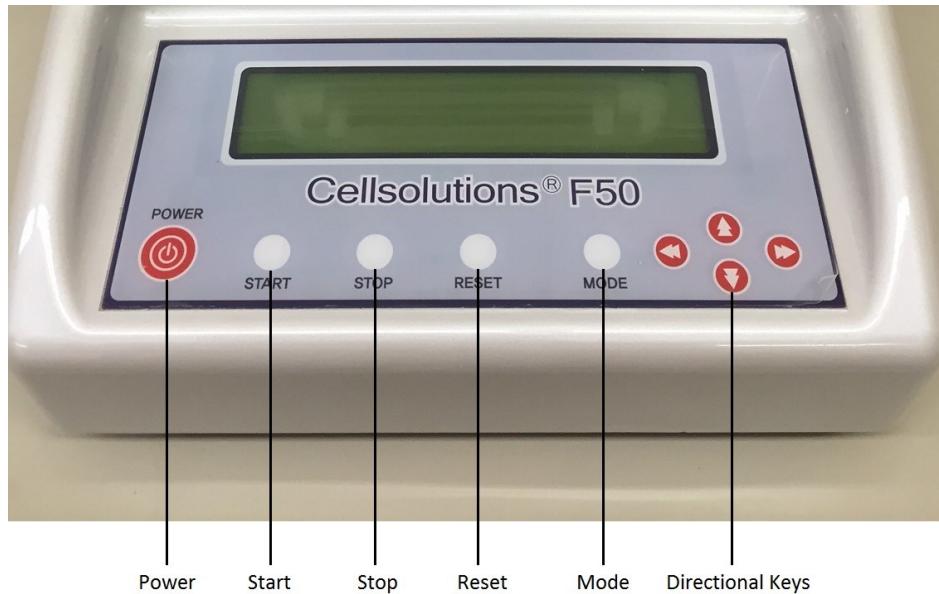


Figure 4-3

4.3.1 Power

Pressing the **POWER** button allows the system to initialize all the motors in the system.

4.3.2 Start

After the slide is placed into the slide holder and the sample has been transferred to the filter, the **START** button should be pressed to initiate processing.

4.3.3 Stop

To stop a run in progress, press the **STOP** button to halt the run. As an example, if the slide was not inserted into the slide holder, the **STOP** button should be pressed to halt the run while the slide can be inserted. Press the **START** button to resume processing.

It is important to remember that any excessive delay during this stop may result in a less than optimal cell presentation.

4.3.4 Reset

The **RESET** button is used for instrument initialization after an unexpected loss of power.

4.3.5 Mode

This button allows the operator to select which mode they wish to run. If the lab is running a variety of samples, different specimen types can be configured by a MODE number. i.e. MODE 1, FNA, MODE 2 Urines, etc. The processor will store all MODE settings until the operator chooses to modify them.

MODE 7- Manual is for equipment operation test measuring mode to be used by Field Service.

4.3.6 Direction Keys

Up and down and left to right movements are controlled by these keys.

The **LEFT** to **RIGHT** keys allows the user to select from five (5) setting that can be modified to the user's preference. These five settings are **vacuum time**, **vacuum pressure 1**, **vacuum pressure 2**, **filter contact time** and **filter contact pressure**.

The **UP** and **DOWN** keys allow the operator to adjust to a specific setting. Vacuum time which is the length of time the vacuum runs can be set from 0 to 60 seconds. Vacuum pressure is the strength that the vacuum pulls and can be set from 0 to 99. Filter contact time is the length of time the filter is held against the slide to allow for cell transfer and can be set from 0 to 20 seconds. The last parameter is slide contact pressure. This is the force used to press the filter onto the slide and can be set from 0 to 99.

4.4 System Initialization

Pressing the **POWER** button allows the system to initialize all the motors in the system.



Figure 4-4

4.5 Operating Modes

There are six (6) different operating modes that change the way the system operates. The modes are displayed as Mode 1 – Mode 6. By using the direction keys, the operator can select which mode to use. For example, Mode 1 can be setup to process FNA's. Mode 2 can be selected for urines, etc.

The processor will allow the establishment of six different operating parameters. These can be established based upon specimen type and optimized by the laboratory.

	Vacuum Time (VCTIME)	Vacuum Pressure1 (VCPRE1)	Vacuum Pressure2 (VCPRE2)	Transfer Hold (TRANSHOLD)	Transfer Power (TRANSPOWE)
Mode 1					
Mode 2					
Mode 3					
Mode 4					
Mode 5					
Mode 6					

The settings for Vacuum Time, Vacuum Pressure 1, Vacuum Pressure 2, Transfer Hold, and Transfer Power can be made once the MODE is selected.

The system will use the stored modes for each new run of samples. The operator can set their own operating parameters for each of the MODES.

5.0 Procedure for Gynecologic Sample Preparation

- 1) The sample vial is evaluated for turbidity and given a score of *Low*, *Medium* or *High*.

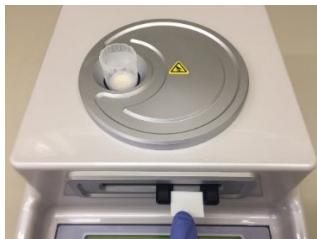
L=Low

M=Medium

H=High



- 2) Turn the filter clockwise to lock into place, and insert the slide facing downward.



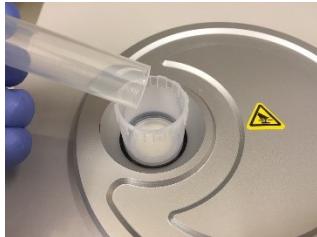
- 3) The sample vial should be vortexed, and the corresponding amount of sample for each turbidity level should be transferred to a conical tube.



Turbidity-Based Transfer Volumes
Low = 6.0mL
Medium = 4.0mL
High = 2.0mL

*High Turbidity samples should have volume increased to a minimum of 3.5mL with BestPrep® General Cytology Preservative. This dilution and mixing allow for more even distribution of cells. If this step is not performed, the cell deposit may be too dense in areas.

- 4) Vortex the sample tube and transfer to the filter.



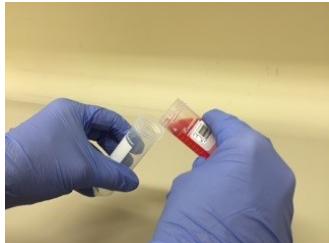
- 5) Process the sample with the following recommended GYN Mode settings:
VCTIME=4 VCPRE1=40 VCPRE2=40 TRANSHOLD=2 TRANSPOWE=2

- 6) After processing, the slide should be immediately removed and placed into a fixative or spray-fixed. The filter should be discarded in the appropriate waste container.

6.0 Procedure for Non-Gynecologic Sample Preparation

Note: For optimal cytology presentation, use C-101 (BestPrep® General Cytology Preservative) for processing non-gynecological specimens on the CellSolutions™ F50 instrument.

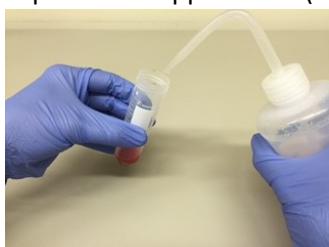
- 1) Transfer an appropriate volume of sample to a 50mL conical centrifuge tube.



- 2) Centrifuge specimen(s) at 800g for 10 minutes. Consult centrifuge manufacturer's manual for appropriate RPM.
- 3) Decant supernatant leaving the cell pellet. A small amount of fluid may be left to assist in step 5. Mucoid clumps can be decanted into the original specimen container if desired.



- 4) (Optional) Treat bloody specimens with 30mL of CellSolutions Red Lytic (CR-102) and vortex. Let specimen sit for a minimum of 15 minutes. Repeat steps 2 and 3. Excessively bloody or mucoid specimens may need additional Red Lytic treatments to break apart mucus or improve supernatant appearance (maximum 2-3 treatments).



- 5) Vortex the sample to re-suspend the cell pellet.



- 6) Using a transfer pipette, transfer an adequate amount of sample (6 drops recommended) to a 10mL vial of BestPrep® General Cytology Preservative (C-101). Follow the processing notes listed below. Allow all specimens to fix for at least 15 minutes.



- 7) Insert the filter and turn clockwise to lock into place. Insert the slide with the frosted area (sample identifier) facing downward.



- 8) **Vortex the sample vial and transfer 5mL of specimen to the filter.** Cap the vial and retain the remaining sample.



- 9) Process the sample with the following recommended Non-GYN Mode settings:
VCTIME=4 VCPRE1=40 VCPRE2=40 TRANSHOLD=2 TRANSPW=2

- 10) After processing, the slide should be immediately removed and placed into a fixative or spray-fixed. The filter should be discarded in the appropriate waste container.

7.0 Processing Samples

7.1 Normal Operation

After pressing the **POWER** key, the instrument will enter the Standby mode. To begin a run, Use the **UP** and **DOWN** arrow to select from MODE 1 to MODE 6. Press the **MODE** button to select the appropriate settings based upon specimen type.



Figure 7-1

7.2 MODE Setting

To change a setting for a specific sample type, the setting should be changed within the MODE established for that specific sample. The Vacuum Time (VCTIME), Vacuum Pressure 1(VCPRE1), Vacuum Pressure 2 (VCPRE2), Transfer Hold (TRANSHOLD), & Transfer Power (TRANSPOWE) can be adjusted from this menu. Use the arrows to select and increase or decrease a setting.

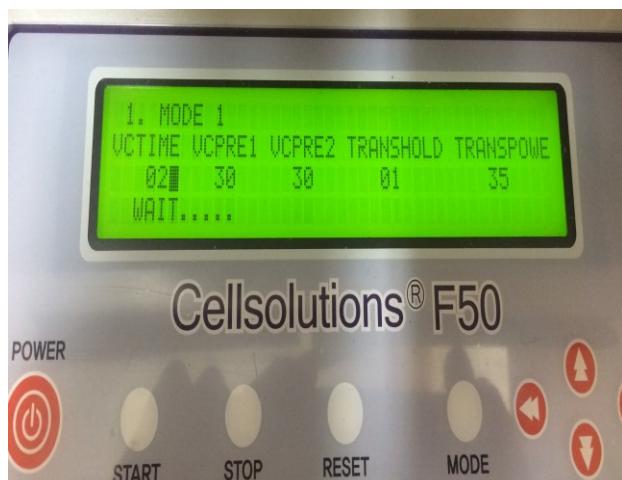


Figure 7-2

The following parameters are recommended to be stored in Mode 4, for performing the daily waste line flush. It is necessary to flush fluids from the line each day the sample processing occurs. See section 8.1 for Waste Line Flush Procedure.

VCTIME=10 VCPRE1=80 VCPRE2=80 TRANSHOLD=2 TRANSPOWE=2

7.3 Insert Filter

Place the filter into the filter slot and rotate clockwise (to the right). The grooves on the filter need to line-up with the grooves in the filter slot.

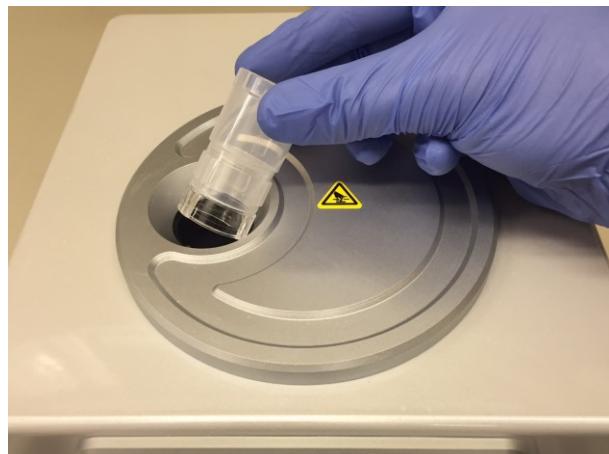


Figure 7-3



"Caution: Pinch Point. Moving parts keep hands and fingers clear."

7.4 Insert Slide

Label the slide to correspond to the sample to be processed. Place the slide into the slide receptacle frosted side DOWN. This is a charged slide so it is important to place the frosted side down to assure cell adherence.

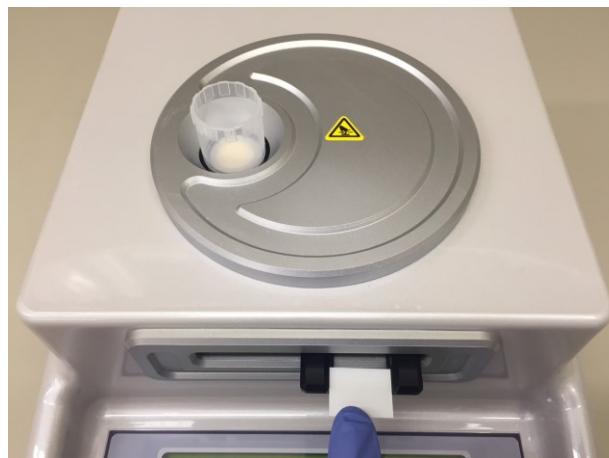


Figure 7-4

7.5 Add Sample

Vortex the sample for 20 seconds prior to pouring over the filter. Transfer the specimen to the filter. The transfer can be done by pouring or using a graduated transfer pipette. A minimum of 3.5mL of sample is required for optimum processing. Failure to use a minimum of 3.5mL will result in a less than optimal preparation. The laboratory should determine appropriate processing volumes.



Figure 7-5

7.6 Start Run

Press the **START** button to process the sample.

7.7 End Run

After processing is complete, the slide will reappear at the slide receptacle. Remove the slide and place in a 95% ethanol bath until ready to stain.

CAUTION: If the slide is broken or cracked, use caution when removing the glass to avoid cut or injury.

7.8 Filter Removal

After processing is complete, remove the used filter by turning it **COUNTERCLOCKWISE**. Lift up and remove from the filter and dispose of it in accordance with local regulations on biohazard waste disposal.

7.9 Additional Processing

With the F50 processor, one slide will be made for each sample. It is the laboratory's responsibility to determine how many slides are required for a given sample type.

When running more of the same sample type, simply replace the filter, insert a properly labeled slide and continue to run more specimens.

If you are changing specimen type, you may need to switch MODE to the specific parameters you have chosen for that specimen type.

7.10 Stop Button

If during operation you wish to perform an emergency stop during a run, simply press the STOP button and the processor will come to a stop.

Fix what issue has arisen, and press the RESET button to continue the run.

7.11 Run Completion and Cleaning

It is recommended the filter area be cleaned each day at the end of use. A single filter can be designated and reused for daily clean up by marking the filter.

Place the filter into the unit. Pour 10mL of deionized water into the filter and press 'START'. Repeat this cycle with an additional 10mL of deionized water. This filter can be reused until it shows sign of filter degradation.

Empty the waste container in accordance with local regulations.

7.12 System Shutdown

When you have completed all the runs, you can power down the processor. Press the MODE button to return the processor to the Standby mode. Press the POWER button. The move motor will move down and allow the slide receptacle to retract into the instrument. A message will appear saying **PUSH POWER KEY**.

8.0 MAINTENANCE

Proper maintenance is necessary for the unit to produce quality slides. The maintenance is separated into daily, weekly, monthly and annual maintenance tasks.

Completion of the maintenance tasks should be documented in a copy of CellSolutions F50 series Maintenance Log (See end of this section) or similar table. The person completing the maintenance should sign or initial the log.

The cleaner used to clean and disinfect surfaces should be a bleach solution (<5% and non-fragrant) or similar cleaner (i.e. 95% ETOH). The cleaning solution should be sprayed on a towel so it is lightly dampened.

Caution: Do not spray cleaning solution directly on the instrument. Sprayed liquids could damage the instrument. Clean surfaces only with a towel that has been sprayed or lightly dampened.

Flushing of the waste line requires a cleaning filter. Because the filter quickly becomes saturated and deteriorates with continued use, it is recommended to modify a single filter designated for cleaning/flushing the waste line. Use a knife or other device to separate the filter pad from the filter (Figure 8-1). Label the filter clearly (Figure 8-2) and keep separate from other filters.



Figure 8-1



Figure 8-2

8.1 Daily Maintenance

Daily maintenance should be performed after each day of operation or before shutting the instrument down for more than 8 hours.

- Perform Waste Line Flush Procedure
 1. Mark a filter for use in daily cleaning. The same filter can be used for 2 weeks
 2. Insert the Cleaning Filter (Do not insert slide)
 3. Pour in 10ml of de-ionized water
 4. Press Start
 5. Press the Mode Button
 6. Press the Down Arrow until Cleaning Mode (Mode 4) is selected
 7. Press the Mode Button
 8. Confirm the cleaning mode has recommended settings (See section 7.2)
VCTIME=10 VCPRE1=80 VCPRE2=80 TRANSHOLD=2 TRANSPWYE=2
 9. Press Start (fluid will be pushed from the Drain Lines)
 10. Repeat steps 3-9.
 11. Remove the Filter after the cycle is complete
 12. Press the Mode Button
 13. Press the Up Arrow to return to the desired sample processing mode (Mode 1)
 14. Press the Mode Button and the F50 is ready for use

- Use a lint free cloth to wipe off filter slot area
- Dispose of all used filters
- Waste container should be emptied. This may be less frequent depending upon volume. It is up to the laboratory to establish how often this will be performed.

8.2 Weekly Maintenance

After one week of operation or 40 hours of use, perform the following maintenance.

- Inspect/Empty waste container. Clean if necessary.
- Use a lint free cloth to wipe off the surface in front of the slide receptacle.

8.3 Monthly Maintenance

Perform the following maintenance monthly:

- Clean waste line
 1. Mark a filter for use in daily cleaning. The same filter can be used for 2 weeks
 2. Insert the Cleaning Filter (Do not insert slide)
 3. Pour 10ml of a 5% bleach solution (non-concentrate, non-fragrant) into the filter
 4. Press Start
 5. Press the Mode Button
 6. Press the Down Arrow until Cleaning Mode (Mode 4) is selected
 7. Press the Mode Button
 8. Confirm the cleaning mode has recommended settings (See section 7.2)
VCTIME=10 VCPRE1=80 VCPRE2=80 TRANSHOLD=2 TRANSPWE=2
 9. Press Start (fluid will be pushed from the Drain Lines)
 10. Perform two additional cycles of steps 3-9 using deionized water.
 11. Remove the Filter after the cycle is complete
 12. Press the Mode Button
 13. Press the Up Arrow to return to the desired sample processing mode (Mode 1)
 14. Press the Mode Button and the F50 is ready for use
- Clean waste container

Disconnect the waste container from the waste tubing (Figure 8-3). Empty any waste from the bottle. Be sure to follow local regulations. Add a 10% Bleach solution to the waste bottle. Allow the solution to sit in the bottle for approximately ten minutes. Rinse waste bottle with water. Re-attach waste tubing to waste bottle.



Figure 8-3

8.4 Annual Maintenance

Perform the following maintenance annually:

- Replace silicon washer

Remove the silicon washer from the filter slot (Figure 8-4). Insert a new silicon washer into the filter slot, ensuring that the filter is securely in place (Figure 8-5).

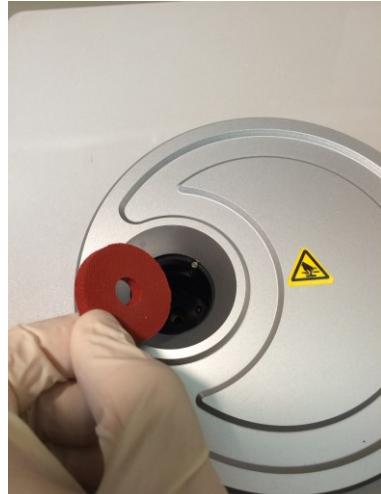


Figure 8-4



Figure 8-5

CellSolutions F50 Maintenance Log

Month & Year: _____

Daily Activities

Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Waste Line Flush																															
Clean Filter Slot																															
Dispose of used filters																															
Empty waste container*																															

Weekly Activities

Activity	Week 1 / /	Week 2 / /	Week 3 / /	Week 4 / /
Wipe down surface in front of slide receptacle				
Inspect/Empty Waste Bottle				

Monthly Activities

Activity	Date Performed (/ /)
Clean Waste Bottle	
Clean Waste Line with 5% bleach and two cycles of deionized water	

Annual Activities

Activity	Date Performed (/ /)
Replace Silicon Washer	

9.0 TROUBLESHOOTING

This section provides information on solving problems that may occur during operation. With this information the operator can resolve most problems. If the problem cannot be resolved by the operator, Maintenance Support should be contacted. If local Maintenance Support personnel cannot resolve the problem, CellSolutions Technical Support should be contacted.

If CellSolutions Technical Support is required, the operator should report any error codes or unusual conditions along with the result of any error recovery or adjustment performed. To facilitate quicker problem resolution, Technical Support personnel may also request to have the Operational Log and/or the Sample Data Files e-mailed.

The following table includes problems that may not detected by the instrument. The likely causes and corrective actions are provided for each of the problems.

9.1 "Beeping" noise is heard when the instrument's power is turned on.

More than 85% of the time, the causes for the beeping noise is due to the problem in the location of the sensor or the sensor being disconnected from the machine or from the controller. (**Figure 9-1**) Double check the sensor location and sensor cable by opening the instrument (**Figure 9-2**)

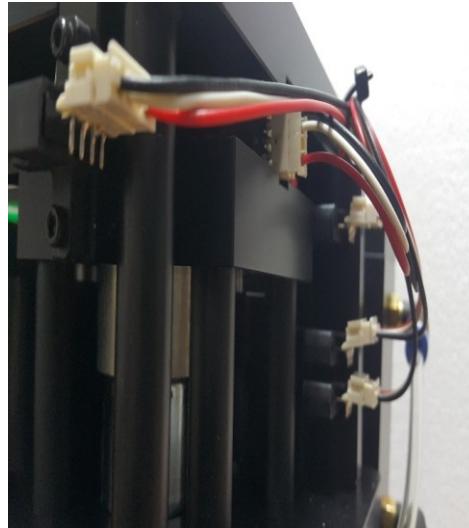


Figure 9-1



Figure 9-2

9.2 Vacuum operation isn't smooth and there's water diffusion on the slides.

9.2.1 At the settings input menu, try increasing the vacuum pressure. (**Figure 9-3**) At this moment, because there's a possibility that the cell might be squashed by the filter, find an appropriate level by balancing the transpower and vacuum pressure settings.



Figure 9-3

9.2.2 Open the instrument to check if the pump motor tank is maintaining a vacuum. (**Figure 9-4**)

9.2.3 Open the tank and see if water is collected within the tank. If so, replace the motor as there's a high possibility that the inside of the pump motor will be filled with water as well. (**Figure 9-5**)



Figure 9-4



Figure 9-5

9.3 Wastewater is not discharged through the waste hose.

Check to see if the waste hose is connected to the waste bottle. If there are no problems identified with the hose connection, utilize no-load operation and alcohol, to remove any foreign substances that might have been inside the hose.

9.4 Lower filter cap stuck in filter slot

If the upper cap of the filter is removed from the filter slot, and the lower cap remains inside the instrument, follow the instructions below:

9.4.1 Restart the instrument in its current state. (Figure 9-11)

- 9.4.2** When the lower cap descends as in the picture, insert the upper cap and turn it clockwise as shown in the picture. (Figure 9-12).



Figure 9-11



Figure 9-12

- 8.4.3** Once the instrument beeps to signal processing is complete, the re-assembled filter can be removed by turning in a counter-clockwise direction.

9.5 Power Loss

In case of a sudden power loss, check if the power adapter is connected with the equipment as shown in the picture. (Figures 9-13 & 9-14)



Figure 9-13



Figure 9-14

9.6 Suction pressure is weaker than normal

If suction pressure is weaker than normal perform the following checks:

- 9.6.1** Check if the filter is turned to the extreme right end. (**Figure 9-15**)

- 9.6.2** Check if the VAC value of the machine is correctly set.
- 9.6.3** When the waste hose is submerged under full reagent wastes in the waste container, normal suction pressure is reduced. Therefore, empty the waste container if this is observed.



Figure 9-15

Appendix A

Glossary of Terms

The following list provides definitions for terms used in this manual.

Term	Definition/Description
Cellularity	Density of cells on slide (number of cells per square mm)
Centrifuge	Device that uses centrifugal force to cause cells in a solution to collect and pack tightly at the bottom of the tube.
Decant	Pouring supernatant from a tube.
Pellet	Cells that have been packed tightly in the bottom of a tube following centrifugation.
Priming	Process of pumping fluid through tubing to purge air from tubing.
Vortex	Refers to a device that mixes or agitates solutions in test tubes or centrifuge racks

Appendix B

Glossary of Symbols

The following list provides definitions for symbols used in this manual and in conjunction with the device.

Symbol	Definition/Description
	European Conformity marking.
	Biohazards may be present. Good Laboratory practices should be followed.
	Hazardous Voltage. Contact may cause electrical shock or burn. Turn off and unplug power before servicing.
	Manufacturer
	Manufactured date
	Authorized Representative in the European Community
	Caution, refer to accompanying documents. Used next to front indicator light showing operation attention is required.
	Icon next to indicator light that shows unit is running.
	Icon next to power on indicator light.

	In Vitro Diagnostic Medical Device
	Batch Code (Lot Number)
	Serial Number
	Use by (Expiration Date)
	Refer to Operator's Manual for Instructions.
	Temperature Limitation. Refer to Section 2.1 for Temperature Limits.
	Protective electrical earth ground connection on machine
	Caution: Pinch Point. Moving parts below keep hands and fingers clear.