CellSolutions 120

Operator's Manual

CE
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PREFACE

Information About This Manual

This manual provides information on the installation, operation and maintenance of the CellSolutions 120 System 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 have an understanding of the overall slide preparation and screening process.

WARRANTY INFORMATION

The CellSolutions 120 has a one-year warranty from the date of sale. For technical support or repair information contact your designated local representative or CellSolutions.

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1.0 INTRODUCTION

1.1 Intended Use

The CellSolutions 120 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 concentrated by centrifugation. The system then outputs optimized samples of approximately the same cellularity onto microscope slides that are ready for staining.

1.2 Requirements

The device is designed to use the specific reagents and consumable materials identified in this manual (i.e. reagents, disposable tubes, automated pipette tips, labels). 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 using an acceptable cervical sampling device that allows detachment or thorough rinsing of the brush or spatula head in the preservative vials. The vials used for collection are BestPrep® General Cytology Preservative Vials (C-101-500).

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

1.3.2 Mechanical Hazards

The CellSolutions 120 is controlled by a computer in communication with sensors and motors that when properly operated should prevent any accidental harm to the operator. The operator should take reasonable care not to interfere with moving parts of the system while in operation.

1.3.3 Electrical Hazards

The CellSolutions 120 has 2 items that are separately plugged into an alternating current supply. The 2 items are a computer and the CellSolutions 120 Processing Platform. Each item operates on 100 to 240 volts and 50 to 60 Hz. Usual electrical precautions should be observed.

2.0 SPECIFICATIONS AND INSTALLATION

2.1 Equipment Specifications

The system comes with a CellSolutions 120 processing platform, and a computer. A separate centrifuge and vortex mixer that is not provided with the system is needed to perform the overall process. 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 CellSolutions 120:

Dimensions: Width: 1630 mm (64 inches)
Depth: 740 mm (29 inches)
Height: 770 mm (30 inches)

Power: Configuration 1: 120VAC, 60Hz

- CellSolutions 120 platform – 8 amps
- Computer – 0.5 amps

Configuration 2: 240VAC, 50Hz

- CellSolutions 120 platform – 4 amps
- Computer – 0.5 amp

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

Weight: 114 kg (250 lbs)

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

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

Throughput: 100 slides per hour (may vary based on sample size)

Barcode: DataMatrix, QR Code, (Other formats available – Contact Authorized Representative)

Remote Access: Remote Troubleshooting Support (Contact Authorized Representative for availability)

Computer: System runs on a computer supplied with machine (Windows 10, i7 or better processor, SSD hard drive, 16GB RAM or more)

2.1.2 Centrifuge:

A centrifuge is required but not provided. The following centrifuge is suggested as being one that is compatible with the CellSolutions 120 system:

Manufacturer: Drucker

Model: Horizon 24 Flex with six-bucket rotor

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: 24 tubes (6 position rotor with a 4-tube rack in each position)

2.1.3 Vortexer:

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

In addition to the bench top space required to hold the CellSolutions 120 platform, space is also needed for the computer and for handling tubes, racks, and slides.

Recommended Bench Space for CellSolutions 120:
Width: 2440 mm (96 inches)
Depth: 840 mm (33 inches)
Height: Approximately 1000 mm (39 inches)

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.

It is very important that in addition to the physical dimensions of the CS-120, 50-80 mm (2 -4 inches) between the unit and the wall is required, and 150 mm (6 inches) above the unit is required for ventilation and maintenance.

2.3 Installation and Setup

The CellSolutions 120 should be placed on a sturdy and 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.

Once the unit is in its final place on the table, the 4 machine feet should be adjusted to level the machine. The feet should be adjusted until the bubble in the level attached to the deck is centered. All 4 feet must be adjusted so they are touching the table and the unit does not tilt back and forth on two feet.

Note: It is critical that the machine be completely level so that the cell suspension deposited on the slide does not run off the slide or pool toward one side of the deposit area. If the solution pools to one side, that side will have a higher cell concentration than the rest of the slide.
Note: Any time the machine is moved, the level should be re-checked and adjusted if necessary.

The inlet tubing to the GluCyte pump and Dilution pump should be placed in bottles. The container for dilution fluid should be filled with a 50% ethanol solution.

The priming container should be place in machine near the pipette tip rack.

During operation, the unit ejects used pipette tips to the right rear of the unit into the metal storage container. This container should be inspected and emptied several times a day if necessary.

2.4 Powering the Unit

The CellSolutions 120 processing platform and the computer have separate power cords. Each of these components can be powered with 100 to 240 VAC and 50 to 60 Hz. Check that the available power is correct before plugging the components into the wall socket.

The computer is connected to the processing platform with a USB cable. The cable should be connected between the machine and computer. There are 5 additional USB cables for Cameras and the slide printer. All these should also be connected between the USB panel on the right side of the machine and the computer.

After all the connections noted above are made, the computer should be started first and then processing platform can be turned on. Once the computer is booted up and the unit is powered on, the CellSolutions 120 software can be started by double clicking the icon on the computer desktop.

2.5 Aligning Unit for Operation

After shipping or moving the CellSolutions 120 the mechanical alignment of the system may have slightly changed. Contact CellSolutions for adjustments to alignment if needed.

The unit has an initialization file that specifies motor alignment values (i.e. location of tip rack or sample tubes) and calibration information. If the System Checks indicate that adjustments are needed to the initialization file, trained maintenance personnel should be contacted.

2.6 Transport, Storage, Disposal

Prior to removing the unit from service for decommissioning, storage or transport, the unit must be cleaned/decontaminated. This is done by wiping all external surface 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.

The system should have fluids purged from the pump and tubing prior to removing unit from service. This can be accomplished by removing the pump inlet tube from the containers and using the Prime Fluid Lines option in the Utilities Menu (see section 6.5) to pump liquids out of the pump and tubing. At least 5 ml of air should be pumped through the system.

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 uses 2 different fluids:

- 50% ethanol solution
- GluCyte™ Cell Adherent: Part Number: GC 100

The amount of diluent used varies per sample with typical amounts between 100ul to 1000ul per sample. The amount of GluCyte™ used is between 100 and 200ul per sample depending upon cell pellet volume.

3.2 Re-usable Materials

The sample trays provided with the machine hold up to 12 centrifuge racks/buckets. Each rack/bucket contains 4 samples so the tray can hold 48 sample tubes. There is also space for the 48 secondary tubes that are used during processing.

3.3 Consumable Materials

The device uses one of each of the items below for each sample. These items are either supplied in the Kit GCK 500-A that includes GluCyte™, or purchased separately where mandated.

- BestPrep® General Cytology Preservative Kits (No. C-101-500) This item is not supplied in the Kit GCK 500-A but is needed for the procedure. Please order this item separately using Catalog No. C-101-500.
- Glass Slides (No. GCK D4) Supplied in Kit GCK 500-A
- Disposable Centrifuge Tubes: (No. GCK D1) Supplied in Kit GCK 500-A
- Disposable Tubes: 13x75mm, 5ml, round bottom tubes (No. 55.475) Supplied in Kit GCK 500-A
- Automated Pipette Tips: (No. GCK D3) Supplied in Kit GCK 500-A (One Pipette Tip is used for each sample plus one additional Pipette Tip is used at the beginning of each run.)

The system also uses a specialized ribbon for printing on the glass slides. One roll of ribbon will print approximately 5000 slides. The ribbon is not supplied as part of the Kit and should be purchased separately using Catalog No. GCK D7.

4.0 OPERATION OVERVIEW

The objective of the CellSolutions 120 is to produce barcoded slides that are ready to be stained. The slides prepared will have a thin layer of cells adhering in a defined area of the slide. The cell deposition area has a controlled cellularity (number of cells per square millimeter) that is readily suitable for evaluation either manually, using a microscope or a suitable microscopic imaging system.

The operation can be broken down into the steps listed below.

4.1 Specimen Identification

A camera is used to identify barcode labels on the side of each sample tube. The barcodes on adjacent tubes are excluded from the active view of camera, so there is no mistake regarding sample identification

4.2 Slide Presentation and Barcoding

The system feeds microscope slides from the bottom of a stack of slides onto a processing platform. After the barcode on the tube is read a matching barcode is printed onto the microscope slide. The unit is capable of processing four samples at a time, so making all 4 slides is a requirement before the next work phase.
If any primary tube barcodes cannot be identified, the tube will be skipped, and a slide will not be printed. There will be an empty spot in the Stainer Rack when a slide is not printed.

4.3 Specimen Volume Detection

To achieve a relatively consistent cellularity on the final slide, the device must first get an approximation of how many cells there are in the original specimen tube. The device uses an air pressure sensor in the pipetting system that can detect when a pipette tip contacts a liquid level surface. Once the elevation of the pelletized sample inside the tube is found, the unit can determine the volume of the pellet.

4.4 Specimen Dilution

The machine dilutes the sample in two different tubes (primary and secondary tubes) and with two different fluids (diluent and GluCyte™) to achieve desired cellular concentration prior to dispensing to the microscope slide. The amount of dilution is based on the number of cells in the original sample. The system uses the volume of the pellet to approximate the number of cells.

Each sample is diluted differently based on the number of cells in that sample. Normally, the cell pellet is first diluted with 50% ethanol and then the diluted sample is further diluted by mixing with GluCyte™. If there is an extremely small sample, the first dilution step is skipped and the sample is just diluted with GluCyte™.

4.5 Specimen Mixing and Transfer

The device uses a disposable pipette tip and a pipette pump to both mix and transfer samples. The mixing is done by aspirating and dispensing the fluid multiple times to ensure the cell suspension is a homogeneous mixture within the diluent or GluCyte™.

4.6 Specimen Application to Slide

The device aspirates a specific volume of the mixed cell and GluCyte™ suspension and transfers it to the slide. Once the solution is dispensed to the slide it is inscribed into a defined pattern by bringing the pipette tip near the surface and spreading it into a rectangular pattern. The robot arm ejects the pipette tips into a collection container after the cell mixture is inscribed on the slide.

4.7 Loading Slide into Staining Rack

The rack used to collect slides after the sample has been applied is a 20-position rack that can be used in an automated or manual staining system. The device pushes a slide into the rack as the processing is completed. Each of the 20 positions in the slide rack corresponds to a specific location in the 48-position tube rack. After all the tubes in the tube rack have been processed and the slides have been loaded into the slide rack, the slide rack rotates to the drying station and an empty rack rotates to the load position in preparation for the next rack of tubes.

The device can handle 10 staining racks at a time. Each staining rack has a capacity of 20 slides. During the daily work process, these racks must also be checked and emptied regularly, of course, taking into account the drying time.

4.8 Specimen Drying

After the specimen is applied to the slide, the slide must remain in a horizontal orientation until the solution is dry. This drying time is greatly influenced by the ambient conditions. In order to allow drying to proceed in a reasonable time frame, the device blows air over the slides while they are in the drying station.

5.0 SAMPLE PREPARATION

5.1 Sample Collection

Using approved detachable cell sampling brushes or a combination of detachable endocervical brushes and detachable spatulas, the samples are collected following the manufacturers' recommendations for the specific devices. The detached portion of the sampling devices with the collected cells is placed into the BestPrep® General Cytology Preservative Vials. The cap is then screwed onto the vial until firmly sealed so as to prevent any leakage.

5.2 Sample Identification and Tracking

Each lab may have different protocols for sample identification. The following is provided as one method of sample handling through the CellSolutions 120 process. (If a different method is used, the lab should ensure at a minimum the slide produced by the CellSolutions 120 unit can be positively traced back to the original sample.)

5.2.1 Assign the original sample identifying information to a tracking number that will be used throughout the process. This tracking number appears on a set of 3 identical barcode labels that are pre-printed or are printed on demand.
5.2.2 Place one of the three barcode labels with the tracking number on the patient requisition form.
5.2.3 Place another of the three barcode labels on the original sample container.
5.2.4 Place the remaining barcode on the primary centrifuge tube into which the sample will be transferred.

NOTE: It is the responsibility of the lab to ensure the sample tracking method used is in accordance with all applicable standards.

5.3 Sample Transfer

- Verify the tracking number on the original sample vial matches the number on the disposable centrifuge tube into which the sample will be transferred.
- Vortex the vial for 5 to 10 seconds to thoroughly mix and free cells from the collection device.
- Open the original container and pour the sample into the primary tube while ensuring the collection device is not transferred to the primary tube.

5.4 Centrifugation

The sample should be centrifuged under the following conditions to create an intact pellet of cells in the bottom of the tube.:

- G-force = 800 X G
- Time = 10 minutes

The recommended centrifuge for the CellSolutions process is the Drucker Horizon 24 Flex with a six-bucket rotor. The settings on this centrifuge to achieve proper results are:

- Speed: 2150 rpm
- Time: 10 minutes

If a different centrifuge is used, consult the applicable documentation to determine the settings required to achieve a G-force of 800.

5.5 Decanting

Samples can either be decanted from the primary tubes individually or in groups of four while in the centrifuge racks. The method used is subject to an individual lab's needs and requirements. One of the following methods should be used to decant the samples into a suitable disposal basin or container approved for accepting biological samples.

Note: Proper decanting is very important. The unit measures the volume in the tube after decanting to get an approximation of the cell pellet size. If extra fluid is left on the pellet after decanting, the unit may over-estimate the size of the cell pellet.

5.5.1 Decanting individual tubes

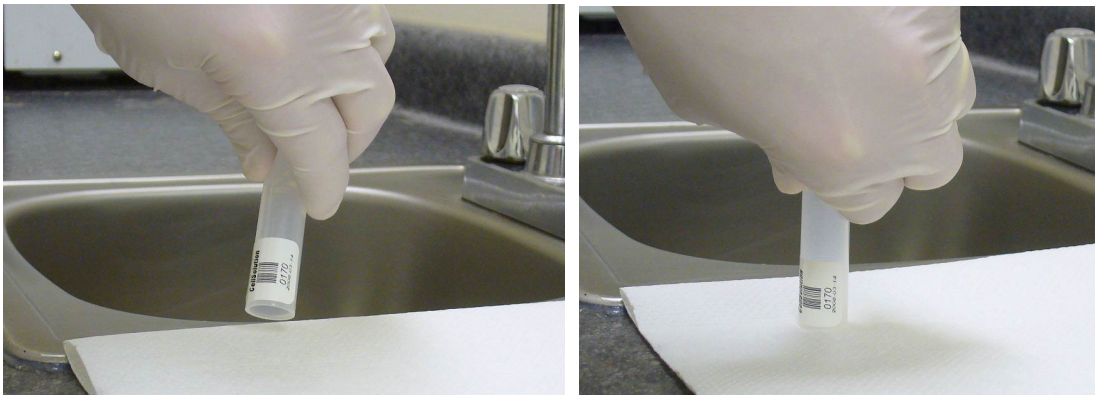
a. Invert the tube in one quick smooth motion to an angle of approximately 80 degrees so that the fluid drains down one side of the tube.

(a) (b)

Figure 5-1

b. Hold the tube at approximately 80 degrees for approximately 5 seconds.

c. While holding the tube in this inverted orientation move it to a location where it can be blotted onto a paper towel. The blotting is used to wick away the fluid that collects on the rim of the tube.



(a) (b)

Figure 5-2

Note: The tube should not be turned upright after pouring into the basin and before blotting. Turning upright would allow drops of fluid on the rim to go back down into the tube. The level detection system of the device relies on proper decanting and removal of as much fluid from the pellet as possible.

d. Once the tube is in contact with the paper towel, the tube can be completely inverted to a vertical position so the entire rim of the tube is contacting the paper towel. Hold the tube in this position for about 2 seconds so the paper towel absorbs the initial fluid collected around the tube rim.

e. While keeping the tube inverted, move the tube to a clean, unused part of the paper towel and allow the tube to remain inverted on the towel for between 60 to 120 seconds.

f. Blot the tube by slightly lifting the tube, moving it to a clean, unused section of the paper towel and then momentarily touching the entire rim of the tube to the towel. Blot multiple times until no fluid appears on the towel.

Note: When blotting, the tube should be lightly touched to the towel. Do not tap the tube as that could cause the cell pellet to dislodge.

g. After blotting, the tube can be turned upright.

h. The process can be repeated for subsequent tubes while ensuring that tubes are blotted in areas of the paper towel that have not been previously used.

5.5.2 Decanting tubes in racks

a. With tubes in the centrifuge rack, grasp the rack and tubes in such a way so your thumb and index finger are holding all four tubes while the rack is being held by your remaining fingers (see figure below). The index finger and thumb should separate tubes into groups of two as shown below so the tubes do not contact each other.

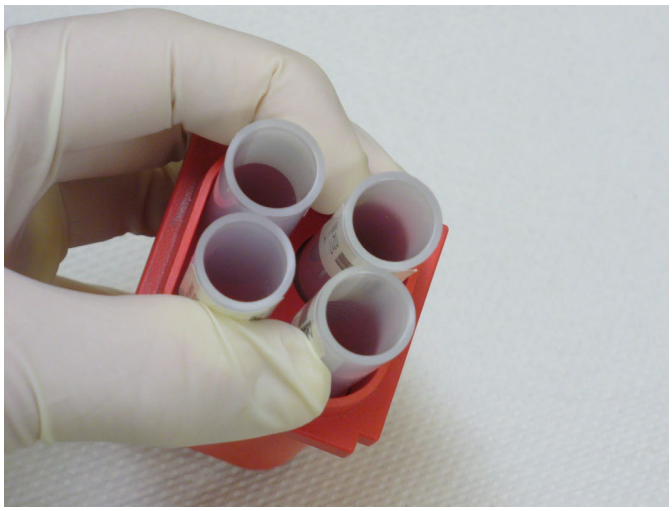


Figure 5-3

b. In one quick smooth motion invert the four tubes to an approximate angle of 80 degrees over a basin so that the separated tubes are above each other (see figure below).

Note: Inverting the tubes quickly allows the tubes to be inverted before the fluid reaches the rims of the tubes and holding the tubes at approximately 80 degrees as shown allows the fluid to drain down one side of the tube and out the rim of the tube without contacting adjacent tubes.

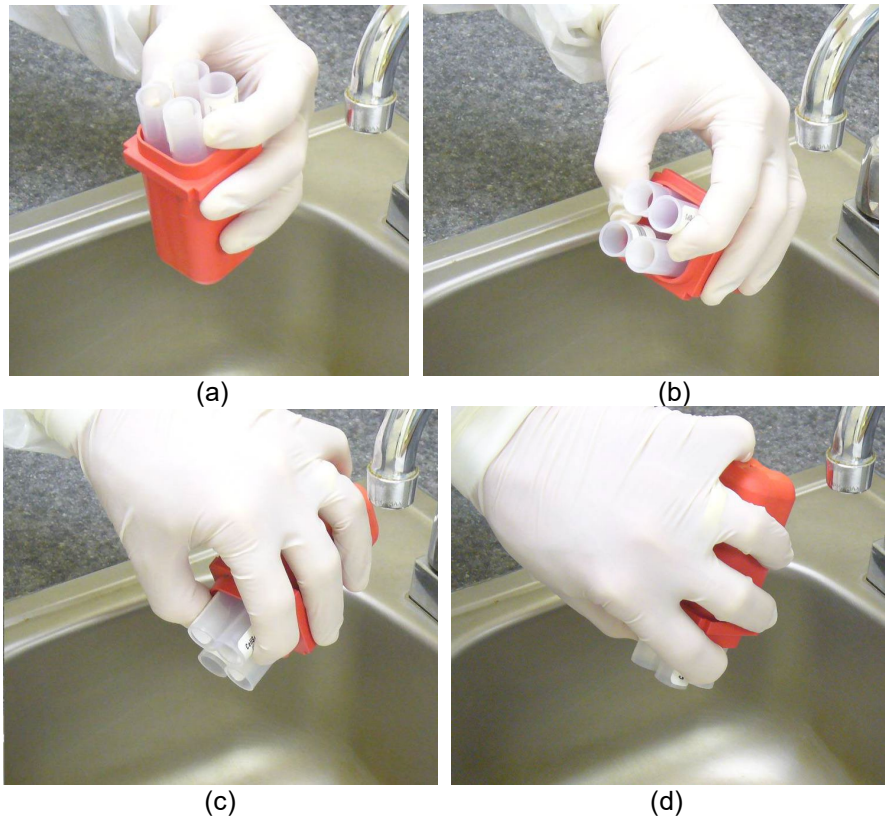


Figure 5-4

c. Hold the tube inverted at the 80-degree angle for about 5 seconds.

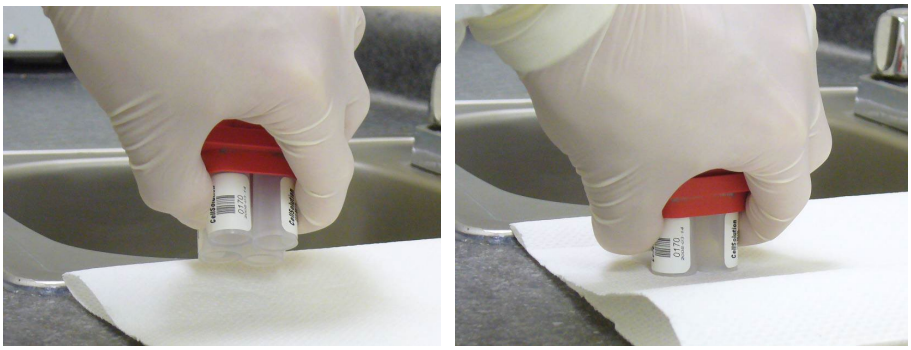
d. While holding the tubes in this inverted orientation move them to a location where they can be blotted onto a paper towel. The blotting is used to wick away the fluid that collects on the rim of the tube.

Note: The tube should <u>not</u> be turned upright after pouring into the basin and before blotting. Turning upright may allow drops of fluid on the rim to either go back down into the tube or potentially onto an adjacent tube. The level detection system of the device relies on proper decanting and removal of as much fluid from the pellet as possible.

e. Allow the lower two tubes to contact the paper towel first. Then tilt the rack so the tubes are vertical and the rims of all the tubes are contacting the

paper towel. Hold the tubes in this position for about 2 seconds so the paper towel absorbs the initial fluid collected around the tube rim.

f. While keeping the tubes inverted, move the tubes to a clean, unused part of the paper towel and allow the tubes to remain inverted on the towel for between 60 to 120 seconds.



(a) (b)

Figure 5-5

g. Blot the tubes by slightly lifting the tubes, moving them to a clean, unused section of the paper towel and then momentarily touching the rims of each tube to the towel. Ensure the rims of all 4 tubes contact the towel. Blot multiple times until no fluid appears on the towel.

Note: When blotting, the tubes should be lightly touched to the towel. Do not tap the tubes as that could cause the cell pellet to dislodge.

h. After blotting, turn the tubes upright.

i. The process can be repeated for subsequent tubes while ensuring that tubes are blotted in areas of the paper towel that have not been previously used.

5.6 Vortexing

The samples should be vortexed to break up the cell pellet after decanting. Each individual tube can be vortexed or the 4 tubes in one centrifuge rack can be vortexed together. Adequate mixing can be obtained by holding the rack or individual tube on the vortexer for 4 to 6 seconds then lifting it off the vortexer for one second. This brief on-off vortex sequence should be repeated two additional times.

Note: If vortexing in the rack, the tubes should be squeezed tight against the sides of the rack so that the vortexer's vibrations are adequately transferred through the rack to the tubes. This can be done by tightly holding the tubes and racks as described above for decanting.

Figure 5-6

6.0 OPERATING PROCEDURE

The CS120 is designed to allow continuous operation. New samples and consumables can be loaded as needed while the system is processing previously loaded samples. This means that a run could consist of a single sample or it could be over a thousand of samples. Once a run on the CS120 is started, it remains ready to accept new samples until the operator terminates the run. This continuous operation means the operator will need to monitor the system consumable levels to ensure the CS120 has the necessary consumables to complete sample processing.

6.1 Software Operator Interface

The following screen shot shows the CellSolutions 120 main interface window that is displayed upon startup.

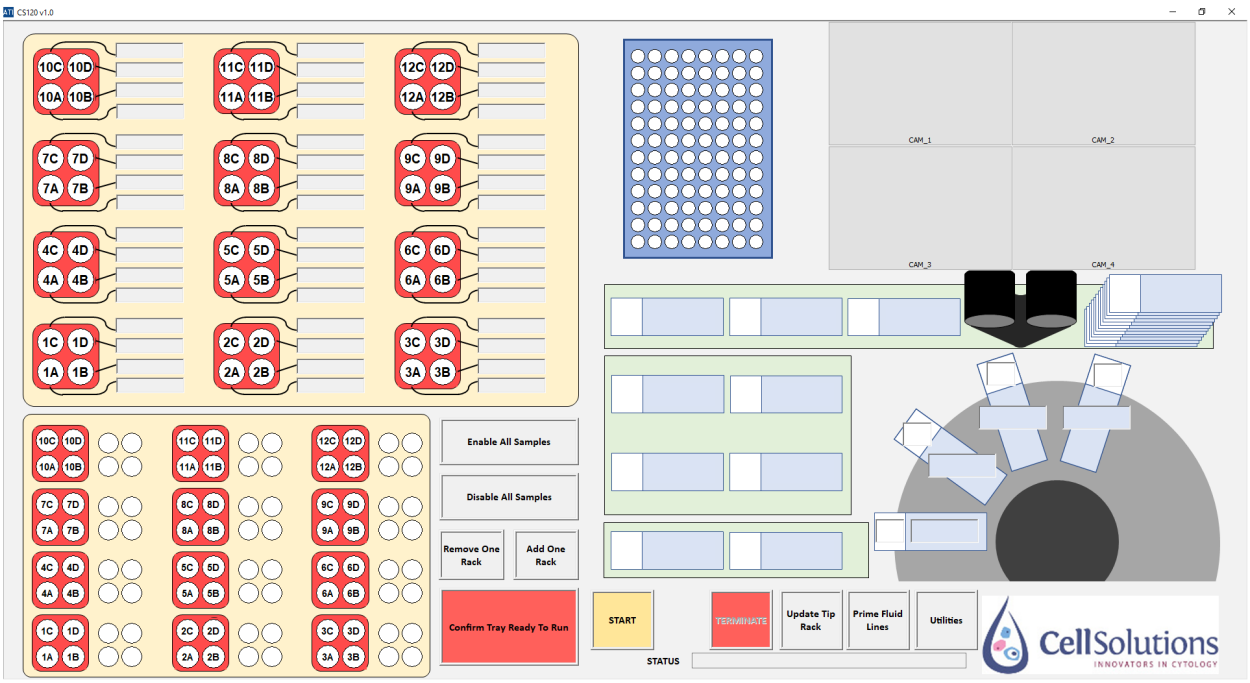


Figure 6-1

This screen is the starting point for the process and also provides the status of the process while samples are being run.

6.2 Preparing System for a Run

Before starting a run of samples, the operator should load or check status of all the items the machine uses during the process. Operator should load or check the following:

6.2.1 Empty Used Pipette Tip Container

The Used Pipette Tip Container is on the right side of the machine. Slide the container out of unit and empty the used pipette tips into an appropriate bio-hazard container.

Figure 6-2

6.2.2 Load Fluid Bottles

The unit uses two fluids in the process. One of the fluids is GluCyte™ and the other is a Ethanol Solution Diluent. The operator should verify that the GluCyte™ being used has not expired. The bottles should be loaded as shown:

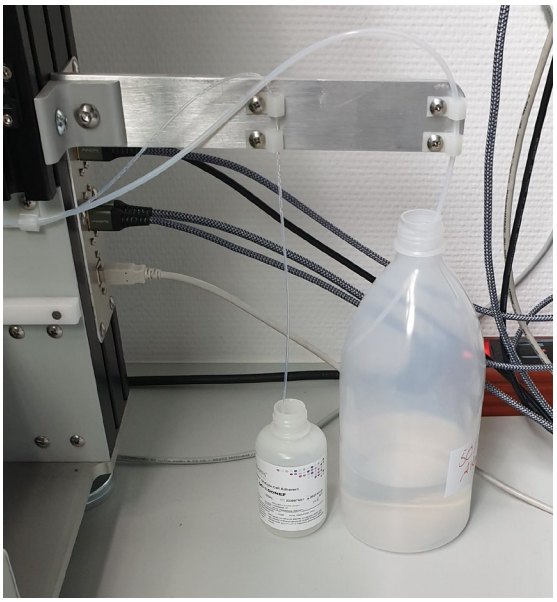


Figure 6-3

The GluCyte™ and diluent containers should be checked to ensure there is adequate fluid for operation.

6.2.3 Tip Rack and Used Tip Collection Check

The pipette tips come in a rack of 96 tips. The cover of the tip rack should be removed from the rack and the rack should be loaded as shown with the cover hinges to the right.

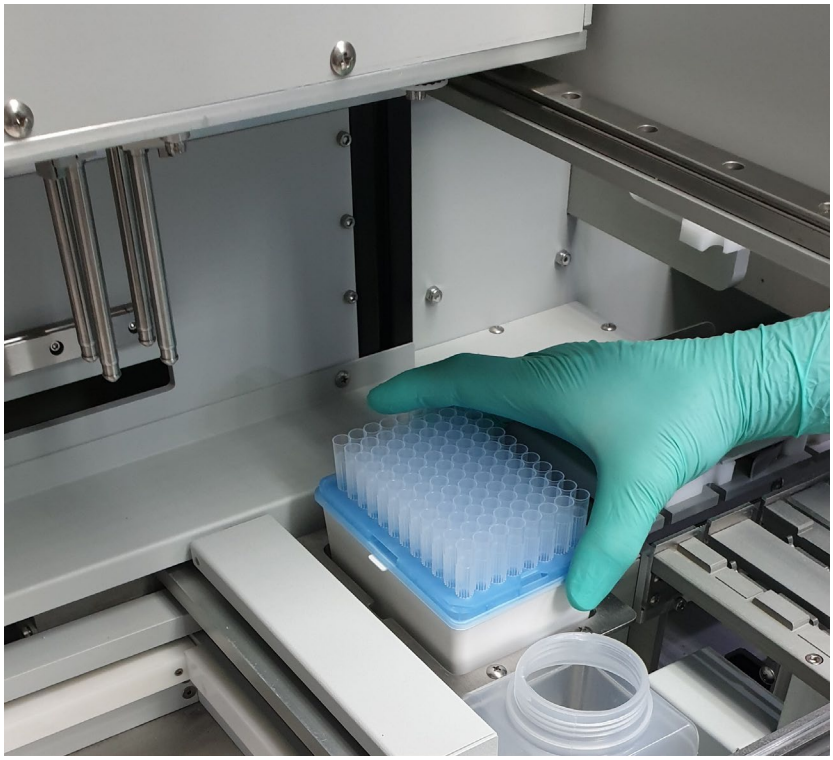


Figure 6-4

If there were tips left in the rack from a previous run, the status is maintained while the unit is turned off. When system is re-started it will display the tip configuration from the last run.

The operator should verify the physical status of the tip rack matches the status the device has displayed in the window. If needed the operator should press the Tip Rack Update button to change the tips displayed on the operator interface. The Tip Update window allows groups of 4 tips to be added or removed and allows all 96 tips to be added or removed.

NOTE: The unit does not pick up 4 tips that are adjacent to each other because the distance between tips is too small to allow a 4 to be picked up at one time. The unit picks up 4 tips with one tip position gap. The system uses a pickup sequence that allows it to use all 96 tips during a run. Pressing the Add or Remove Tips buttons shows the sequence of pickup.

6.2.4 Microscope Slides Loaded

Microscope slides should be loaded on the slide platform with the frosted area of the slide facing up and toward the left.

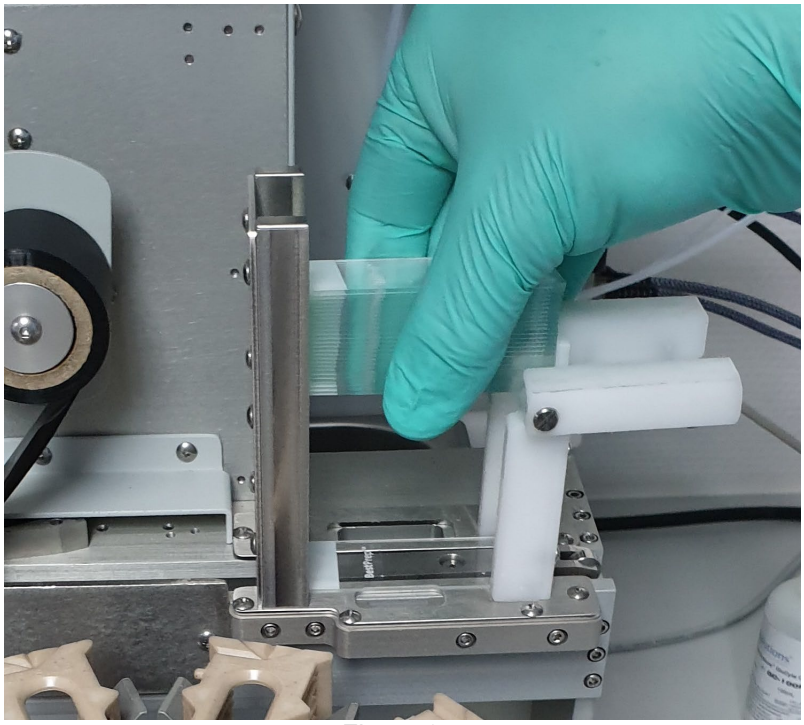


Figure 6-5

6.2.5 Staining Rack Loaded

An empty staining rack should be placed in the processing location of the rotary table. The rack needs to be fully seated in the holder with the bottom of the tray contacting the rotary table disk. A second empty rack can be placed in the left position in preparation for the next set of samples.

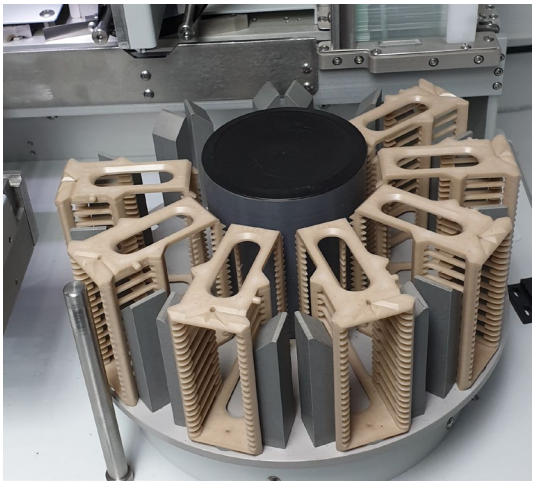


Figure 6-6

6.2.6 Printer Ribbon Loaded

The ribbon in the slide printing mechanism should be checked to make sure it does not have wrinkles and is properly fed past the print head.

See Appendix C for information on loading printer ribbon.

6.2.7 Empty the Fluid Priming Container

The system primes fluid into a small container that is located in front of the pipette tip rack. The container should be emptied if needed.

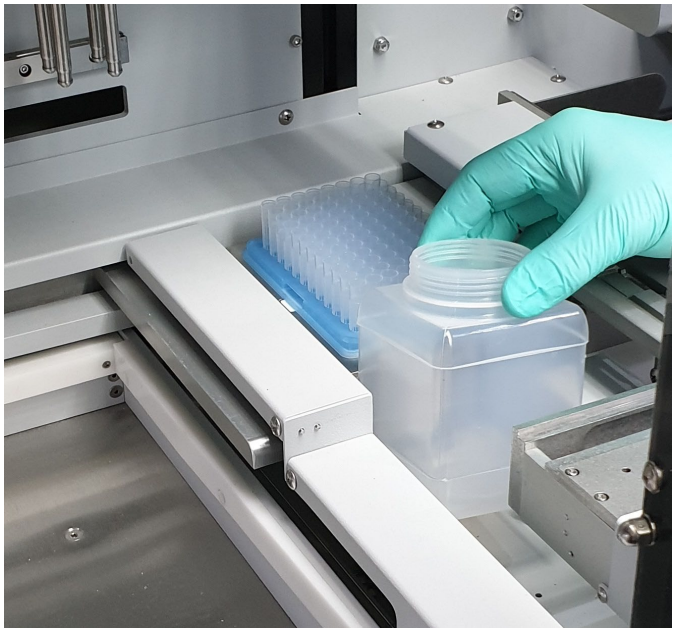


Figure 6-7

6.2.8 Load Sample Tray

The sample tray loaded with racks (up to 12), primary tubes (up to 48 and loaded in the racks) and secondary tubes (up to 48) should be placed on the tray infeed.

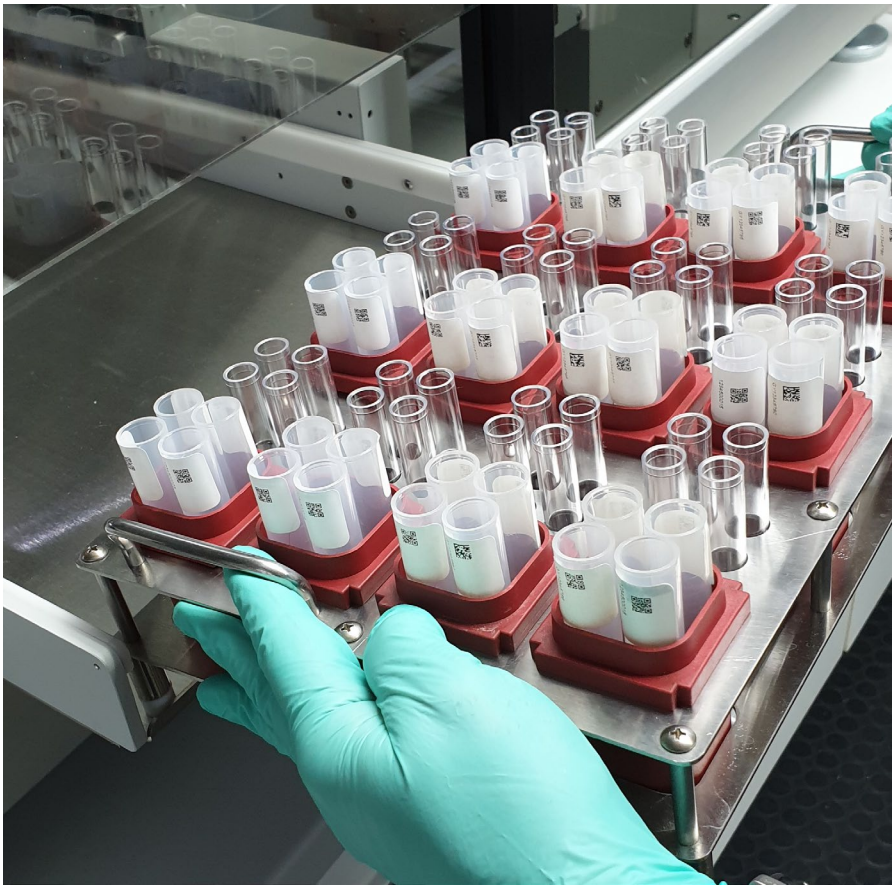


Figure 6-8

All 4 feet of the tray should be on the tray infeed platform.

Figure 6-9

The barcode labels on the primary tubes in the A and C positions should be pointing to the left. Labels on the tubes in the B and D position should be pointing to the right. (Refer to the operator interface image for the A, B, C and D positions.) The following image show proper orientation of the tubes:

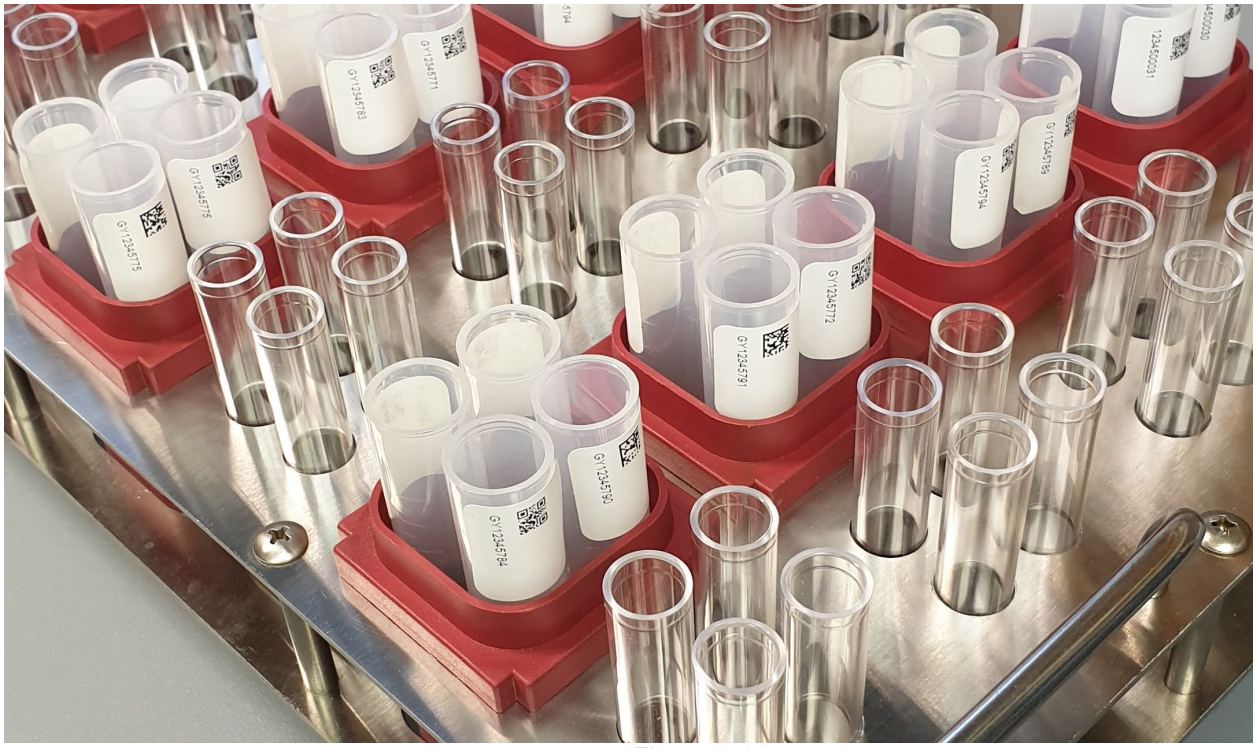


Figure 6-10

The system always starts with the tubes in the front-left corner of the tray. The operator interface shows the order in which the samples are processed.

NOTE: The system always starts with tubes in rack number 1 (front-left). If running fewer than 48 samples (12 racks with 4 tubes each), the racks must be loaded in the sequence as shown on operator interface.

Figure 6-11

NOTE: The system always processes in groups of 4. Each tube rack should be loaded with 4 samples if possible. If 1, 2, or 3 tubes are loaded in a rack, the system will stop when it processes that rack and prompt the user to acknowledge that a tube is not present in the rack.

After a tray of samples is loaded, the system needs to be informed of the samples that are ready to run. Use the buttons in the lower left of the operator interface to update the system graphic so it matches the number of racks loaded in the tray. The following shows an example of 7 racks loaded.

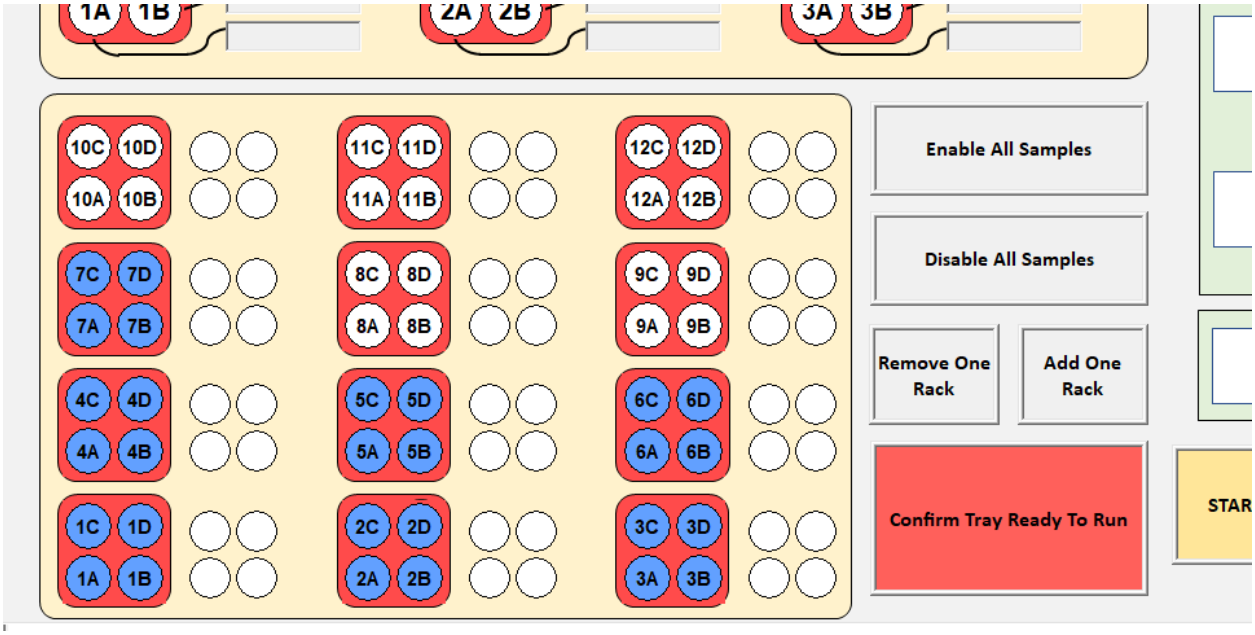


Figure 6-12

Press the Confirm button after using the Add or Remove buttons to make the graphic match the actual loaded configuration of the tray. The following image show how the interface looks when 7 racks have been confirmed as ready to run.

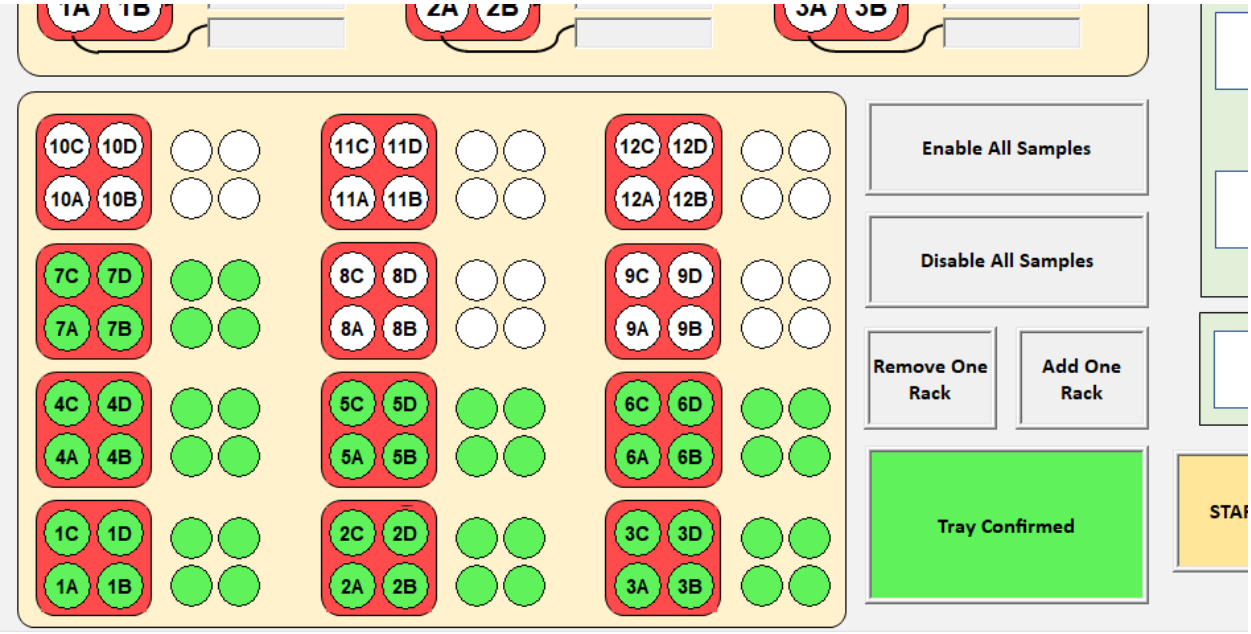


Figure 6-13

6.3 Starting a Run

Pressing the Start Button allows the system to initialize all the motors in the system. During this process all the motors will drive to “Home” positions. After Homing, the unit will perform several moves to verify that each motor is communicating and operating correctly.

After homing the system will move to a position where the GluCyte™ and Diluent pumps can be primed over the waste fluid container. A window will open that allows the operator to prime each pump. While priming, the operator should visually observe that the fluids are dispensed, and no air is present in the tubing.

After priming is complete, the system will begin processing samples.

6.4 Processing Samples

6.4.1 Normal Operation

After the Startup Checklist is completed and operator’s PIN is entered, the unit will run the samples without any further operator input unless one of the following conditions is encountered:

- The Pause or Terminate button is pressed.
- The pipette tip rack is empty.
- The microscope slide stack is empty.
- A staining rack is not loaded.
- The barcode label is not read on the tubes or slides (The system has an option that allows a tube which has an unreadable barcode to be skipped. When this option is enabled, a skipped tube will be highlighted in red on the screen and a note will be added to the data file indicating the sample was not processed.)
- There is a warning or error alert. Refer to the Troubleshooting section of this manual for information about errors and warnings.

The unit operates with multiple sub-systems. Each sub-systems run in parallel until they require a “hand-shake” with the other sub-systems. The sub-systems are:

Tube Handling Sub-System
This sub-system pulls sample tray into the processing area and discharges trays. It also controls reading of tube barcodes and dispensing fluids into the tubes.

Pipetting Sub-System
This sub-system mixes and transfers fluid from the tubes to the microscope slides using pipette tips.

Slide Printing Sub-System
This sub-system pulls slides from the slide reservoir and prints barcodes on the slides slide.

Slide Shifting Sub-System
This sub-system removes slides from the print station and shifts them onto a platform where the sample is pipetted onto the slides. It also shifts slide from the platform to the slide loading station.

Slide Loading Sub-System
This sub-system pushes slides into the staining racks.

6.4.2 Dry Time Information

The slides should not be removed from the system until they are dry to ensure the specimen remains in the deposit area. It takes approximately 30 minutes for the slides to dry. Before removing a rack of slides, the operator should perform a visual check to ensure the specimen deposit is dry.

The system uses a fan that blows air across the slide to speed the drying of the specimen solution on the microscope slide. The dry time is affected by the ambient temperature and humidity. The drying time is normally 30 minutes; however, under certain conditions it can take longer than 30 minutes to dry.

When running the system continuously, it takes about 10 to 12 minutes to fill a staining rack with 20 slides. A rack will rotate from one position to the next about every 10 minutes. This means that under normal conditions the third rack after the loading station will have had 30 minutes of dry time. The operator can typically remove racks in the fourth stating after the slide loading station.

NOTE: If the operator removes the rack before the slides are dry, they should take steps to ensure the slides dry in a horizontal position. Note that without the air blowing across the slides, this drying will take an extended period of time.

6.4.3 Pause Button

While the device is running the Pause button can be pressed at any time to pause system motion. All of the specimen information and system status is retained so that the device is ready to run. Some system motions may continue briefly after pressing the Pause button. This is done so the device comes to a controlled pause location and is ready for restart.

Caution: After pressing Pause, the operator should wait for all motion to stop before accessing the device.

When the device is paused, the Pause button changes to a Continue button. When the operator is ready to allow processing to proceed, the Continue button should be pressed. The system may do some initialization of a few motors and will then automatically start processing samples from where it left off.

While paused, the Utilities button on the main screen becomes active. See section below for details on functions available under Utilities.

6.4.4 Terminate Button

The TERMINATE button should be used only when the run is to be terminated or must be immediately stopped due to some uncontrolled condition. The PAUSE button should be used under most conditions when the operator needs to interrupt operation.

The TERMINATE button causes all motion to immediately stop. This may leave motors in uncontrolled locations. A window will be displayed asking the operator if he/she wants to terminate the run or allow processing to continue. If the system is restarted after the TERMINATE button is pressed, the operator must ensure the samples are properly transferred to the slide without causing any cross-contamination between samples.

If the run is terminated all remaining samples will not be completed. The operator would need to ensure samples that were not complete are removed and processed in a new run.

CAUTION: If a run is terminated with a pipette tip on the probe, the operator must manually remove the pipette tip. The tip should be removed by placing a paper towel under the tip while pulling the tip off the probe. The towel must be placed to catch any fluid that may be in the tip. The tip should be discarded in a biohazard container.

6.4.5 Loading System During a Run

The system is capable of continuous operation with continuous dosing. It is the responsibility of the operator to continuously replace the prepared sample racks. These include a maximum of 48 samples (primary tubes) and 48 empty secondary tubes, of course the system works with fewer samples.
It is also the responsibility of the operator to check the amount of consumables, the saturation of the pipette tip container used and the amount of liquid when loading the sample rack! Replace and / or empty if necessary! The operator may also Pause the unit to replenish items before they are needed. To load items on the unit, the operator must first Pause the system.

CAUTION: Do not attempt to load the unit while it is running. Loading the unit while it is moving could cause a pinch hazard and if bumped out of position could cause sample cross-contamination.

While the system is Paused, the Utilities button becomes active to allow the user to access certain functions. See Utilities section below for more information.

6.4.6 Run Completion and System Unloading

At the completion of a run the unit will rotate the staining rack that was just loaded to the drying position. If there was a staining rack in the drying position from the previous run it will now be in the unload position. A window will then be displayed notifying the operator that the run is completed.

At that point the tube rack can be removed and the staining rack in the unload position can be removed. Note that the staining rack that was rotated to the slide drying position should not be removed from the system until the slides are dry.

CAUTION: Removing a Slide Staining Rack from the unit before the slides are dry could cause the sample deposit to dry improperly. This could result in the sample running outside the normal deposit area.

The window displayed at the completion of the run provides the operator with the option to initiate another run or to stop processing samples. If another run is initiated, the Startup Check List window will be displayed. If the Terminate button is pressed, the machine will need to re-home and initialize all motors before processing more samples.

6.5 System Utilities

The Utilities button on the main screen allows access to a Utilities menu while the system is not running. The Utilities menu allows the operator to test several functions of the machine including slide printing and barcode reading. This menu also allows maintenance personnel to test operation and to calibrate the system.

6.6 System Shutdown

When no more samples are to be processed the software can be shut down by clicking the red box in the upper right corner of the software window. The computer can be shut down normally and the CS120 processing platform can be powered down.

Daily maintenance outlined in Section 8 of this manual should be performed if the unit will not be operated for more than 8 hours.

7.0 MAINTENANCE

Proper maintenance is necessary for the unit to produce quality slides. The maintenance is broken down into daily, weekly and semi-annual maintenance tasks.

Completion of the maintenance tasks should be noted in a copy of CellSolutions 120 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 10% Bleach Solution or similar cleaner. The cleaning solution should be sprayed on a towel so it is lightly dampened.

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

7.1 Daily Maintenance

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

- ❑ The following items should be removed from the machine or emptied:
    - Remove all disposable centrifuge tubes (GCK D1)
    - Remove all disposable tubes (55.457)
    - Remove and dispose all used pipette tips (GCK D3) in an appropriate biological hazard waste container.
    - Clean any recognized spills with cleaning solution
- ❑ The GluCyte™ (GC 100) bottle and diluent bottle should be capped.

7.2 Weekly Maintenance

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

- ❑ Inspect the sample tube rack for signs of spills. If necessary, soak in cleaning solution or wash in commercial washer.
- ❑ Inspect surfaces of machine for signs of spills. Wipe any potentially contaminated locations with a cloth containing cleaning solution.

Note: A cloth lightly dampened with cleaning solution should be used. Do not use a bottle to spray machine or use cloth dampened to the point of dripping.

- ❑ Inspect diluent bottle for any evidence of contamination. Clean, if necessary, using the procedure in semi-annual maintenance section.
- ❑ Inspect tubing to the diluent bottle for any evidence of damage and replace if necessary.

- Use a lint free cloth to wipe off the bottom part of the fluid probe that gets pressed into the pipette tips.

- Use a lint free cloth to wipe off the sloped surface in front of the two microscope slide detection sensors on the slide lift platform.

- Wipe Tip Discharge Chute and the Used Tip Collection Container with a cloth dampened with cleaning solution.

7.3 Semi-Annual Maintenance

Perform the following maintenance after every 6 months of operation:

- Rinse out the diluent bottle with a 5% bleach solution. After bleach solution, rinse bottle at least 3 times with warm tap water. Then rinse once with DI water.

Note: Ensure the diluent bottle is thoroughly rinsed. Leaving bleach in the bottle could damage the pump.

- Inspect tubing and fittings for evidence of damage or leakage.
    - Inspect the tubing from the bottles to the fluid pump inlet for damage.
    - Inspect the inlet and outlet fittings to the fluid pump for evidence of leakage.
    - Inspect the fittings and tubing between the pipettor pump and fluid probe for signs of damage or leakage.
    - If damage or leakage is observed, contact Maintenance Support to report problem.

- Perform diluent pump calibration check as follows:

    - Press Utilities button on main screen then select System Checks.
    - Select Pump Calibration Check.
    - Follow screen prompts to pump 10 ml of fluid into a graduated tube.
    - Record volume actually dispensed.
    - Verify that actual volumes are within range of 9.5 ml and 10.5 ml.
    - If volumes are out of range, note actual volumes and contact Maintenance Support to have pumping volume calibration values adjusted.

- Perform pipettor calibration check as follows:

    - Press Utilities button on main screen then select System Checks.
    - Select Pipettor Calibration Check.
    - Follow the screen prompts to place a pipette tip on the fluid probe and then to aspirate and dispense fluid.
    - The container for aspirating fluid should be filled with water and can be manually held so the pipette tip is submerged between 5 and 15 mm below the fluid surface.
    - The fluid should be dispensed into a graduated tube with volume indication marks.
    - A total of at least 1000 microliters of water should be transferred from the water container to the graduated tube. Note that the menu

allows 250 microliters to be transferred in one aspirate/dispense sequence so 4 transfers will be necessary to achieve 1000 ul.
- The transferred volume should be between 950 ul and 1050 ul (+/- 5%).
- Note that larger volumes can be used for calibration. If larger calibration volumes are used, the acceptable range needs to be +/- 5% of the total.
- If volumes are out of range, note actual volumes and contact Maintenance Support to have the pipettor and tubing inspected.

- Perform fluid level detection check as follows:

  - Press Utilities button on main screen then select System Checks.
  - Select Fluid Level Detection Check.
  - Pour about 0.5 ml of water in a primary tube. When prompted, place the tube in position 20 of a sample rack and load the rack on the machine.
  - Firmly press a pipette tip on the fluid probe.
  - Press the Begin Test button to allow the system to detect the fluid level.
  - The pipette tip will travel down to the liquid surface and should stop about 1 mm below the fluid surface.
  - Visually verify the tip is between 0 and 2 mm below the fluid surface.
  - Press the Continue button to complete the test.
  - If the pipette tip is out of range, Contact Maintenance Support.

CellSolutions 120 Maintenance Log

Start of period:_____ **End of period:_____**

Weekly	Week 1 / /	Week 2 / /	Week 3 / /	Week 4 / /	Week 5 / /	Week 6 / /	Week 7 / /	Week 8 / /	Week 9 / /
Clean Sample Racks									
Inspect for Spills									
Inspect Diluent Bottle and Tubing									
Wipe Probes, Platform, and Chute									

Weekly	Week 10 / /	Week 11 / /	Week 12 / /	Week 13 / /	Week 14 / /	Week 15 / /	Week 16 / /	Week 17 / /	Week 18 / /
Clean Sample Racks									
Inspect for Spills									
Inspect Diluent Bottle and Tubing									
Wipe Probes, Platform, and Chute									

Weekly	Week 19 / /	Week 20 / /	Week 21 / /	Week 22 / /	Week 23 / /	Week 24 / /	Week 25 / /	Week 26 / /	
Clean Sample Racks									
Inspect for Spills									
Inspect Diluent Bottle and Tubing									
Wipe Probes, Platform, and Chute									

Semi-Annual	Date Performed (/ /)
Clean Diluent Bottle	
Inspect Fluid Tube Fittings	
Perform Diluent Pump Calibration Check	
Perform Pipetter Calibration Check	
Perform Fluid Level Detection Check	

8.0 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 unit detects many conditions that impact operation and automatically halts operation if operator intervention is required. The error message will be displayed with an Error Code in a window that pops up on top of the main operating window. This window may also provide information on the likely cause of the problem along with instructions on how to resolve the error.

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

Problem	Likely Cause(s)	Corrective Action
Cell deposit on slide is more dense on one side	Machine is not level causing higher liquid level on one side during drying	Adjust machine feet to level machine. Use bubble level on Slide Rack rotary table.
Cell Deposit is not dry after 30 to 40 minutes.	Fan is not functioning or is obstructed.	Check to determine if it is working correctly. Contact Maintenance if fan is not blowing air.
Cell Deposits are all tending to be too dense (High Cellularity)	Primary tubes are not properly vortexed.	Ensure tubes are vortexed per instructions
	Pressure sensor in pipette line is not functioning.	Call Maintenance.
	Insufficient diluent is being added.	• Diluent container is empty. Need to fill container and prime system. • Diluent tubing is clogged and needs to be flushed or replaced. • There is air in tubing. Need to prime the line.
	Insufficient GluCyte™ is being added.	• Perform calibration check on pump and call maintenance if out of calibration. • Check that tubing between pump and probe is tightly connected and lines are not pinched or damaged. Replace if necessary.
	Pipettors are not transferring correct volumes	• Perform calibration check and call maintenance if out of calibration. • Check that tubing is tightly connected and lines are not pinched or damaged. Replace if necessary.
	During dispense to slide the pipette tips are too high and are not allowing the required aspiration of some sample at end of pattern draw.	Observe if the tips are about 0.5mm above slide during pattern draw. If not, contact maintenance to have height calibration adjusted.

Problem	Likely Cause(s)	Corrective Action
Cell Deposits are tending to be too light (Low Cellularity)	Pressure sensor in pipette line is not functioning.	Contact Maintenance.
	System is not detecting pellet height correctly due to incorrect height calibration between pipette tip and sample tube	Contact Maintenance to have robot arm calibration values checked.
	Original sample had insufficient cells	Inspect samples before placing on machine to ensure there are visible cells in tube. Review decanting procedure to make sure cells are not being lost during decanting.
Cells wash off during staining	GluCyte™ was not added to disposable tube or insufficient GluCyte™ was added	• Check for clogged or pinched tubing from pump to probe • Perform calibration check procedure in Maintenance section.
	Incorrect fluid or out of date GluCyte™ was dispensed	• Ensure pump inlet line is placed in correct container. • Ensure GluCyte™ being used is within proper expiration date.
	Incorrect microscope slides are being used on the unit	• Use only slides provided with test kits.
Barcodes are frequently not being read on tube	Tubes are not orientated with barcodes facing to right side	• Refer to manual section 6 for proper placement of tubes in racks. • Ensure correct tubes and racks are being
	Barcode label orientation on tubes is not correct	The black bars of the barcode label must be orientated horizontally is using 1D Codes
	Robot arm location while reading barcode is not correct.	Contact Maintenance to have robot arm calibration values checked.
	Label placement on tube is not correct	Ensure labels are placed with the top edge about 1.5 mm from the top rim of the tube
	The lens on the camera is dirty	Use a soft lint free cloth to lightly wipe off the camera lens.

Barcodes are frequently not being read on slide		
	A bright external light is causing a glare on the slides	Point bright light away from area in which barcode scanner reads the slide labels.
Barcode on Slide is not Readable	Printer Ribbon is wrinkled or not properly installed.	See Appendix C for proper installation of Ribbon.
	Print head is dirty.	See Appendix C for instruction on cleaning print head.
	Print head is damaged.	See Appendix C for detailed instruction on diagnosing print issues.
GluCyte™ not dispensed in disposable tube	Bubbles in GluCyte™ Bottle affecting level detection reading	Do not shake or stir GluCyte™. This can cause large bubble on the liquid surface. Ensure there are no bubbles in bottle before placing on unit.

Appendix A

Glossary of Terms

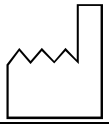
The following list provides definitions for terms used in this manual.

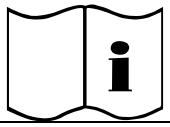
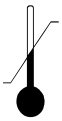
Term	Definition/Description
Automated Pipette Tip (disposable)	Plastic pipette that fits on a probe that is connected to pipetting pump. Used to aspirate and dispense fluids. One time use. (GCK D3, in Kit GCK 500-A)
Barcode Camera	Optical device for detecting code embedded in barcode symbol
Cellularity	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.
Disposable Centrifuge Tubes	15 ml conical centrifuge tubes used during processing of sample on unit (GCK D1, in Kit GCK 500-A)
Disposable Tubes	5 ml tubes used for mixing of sample with GluCyte™ (55.457, in Kit GCK 500 -A)
GluCyte™	Liquid reagent with polymer type structure that encapsulates cells into a membrane when dried. Refer to GluCyte™ Manual Method Instructions for Use and GluCyte™ MSDS for details on GluCyte™ reagent. (GC 100, in Kit GCK 500-A)
Gynecological	Refers to a sample collected from a female cervix. Abbreviated as GYN. Non-GYN sample are all other non-cervical samples.
Homing	Refers to the process used by motor to drive to a known sensor position in order to provide a reference position for all motions.
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
X-Axis	Refers to a direction of motion in the horizontal plane that is left to right
Y-Axis	Refers to a direction of motion in the horizontal plane that is front to back
Z-Axis	Refers to the vertical direction of motion

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
CE	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
EC REP	Authorized Representative in the European Community
	Caution, refer to accompanying documents. Used next to front indicator light showing operation attention is required.

Symbol	Definition/Description
IVD	In Vitro Diagnostic Medical Device
LOT	Batch Code (Lot Number)
SN	Serial Number
	Use by (Expiration Date)
	Refer to Operator's Manual for Instructions.
	Temperature Limitation. Refer to Section 2.1 for Temperature Limits.
	Pinch point label used on machine to warn operator to keep clear of moving parts to prevent injury.
	Protective electrical earth ground connection on machine
	Waste Electrical and Electronic Equipment

Appendix C

Microscope Slide Printer

The microscope slide printer uses a thermal transfer ribbon to print barcode and identification information on the frosted end of the microscope slide. A print head heats the ribbon as a microscope slide moves with the ribbon under the print head. The ink in the ribbon is transferred to the slide based on the heating pattern from the print head.

Installing Ribbon

1. The ribbon is installed on the Supply Spindle which is on the right side of the machine.

Figure C-1

2. The ribbon is passed under the Front Guide Rod, the Print Head, and the Back Guide Rod.

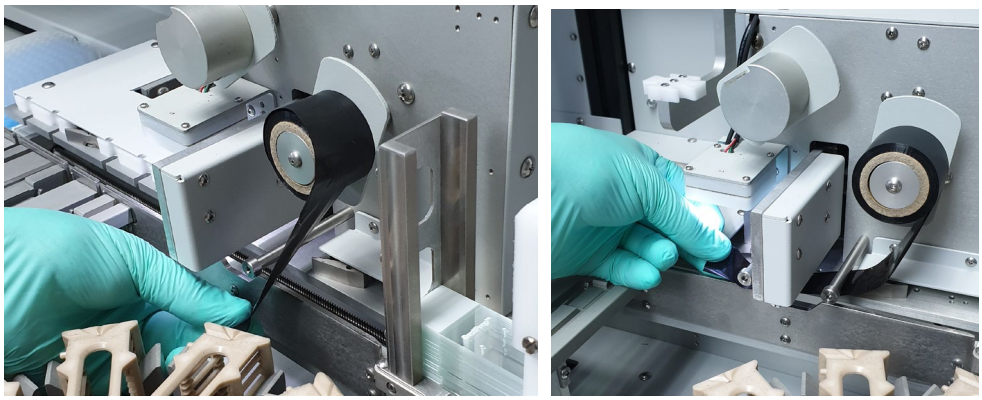


Figure C-2

3. The ribbon should be looped over the back Takeup Spindle as shown below.

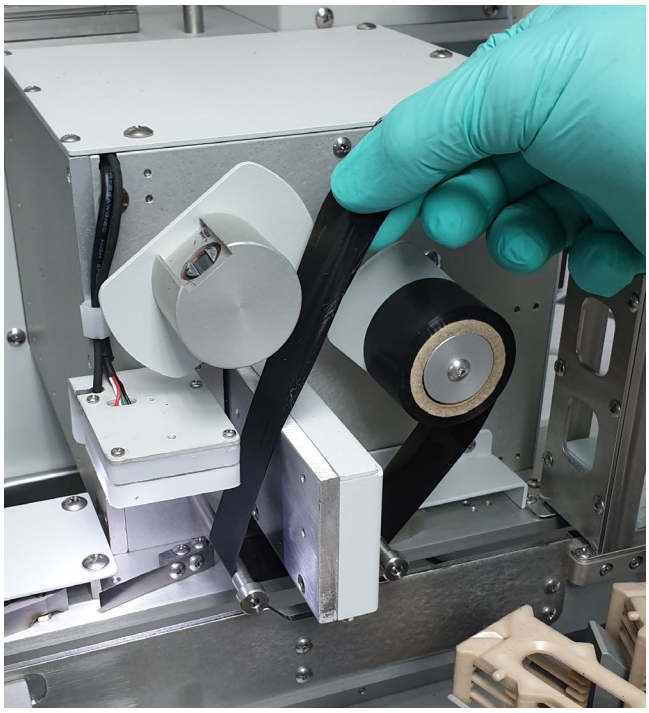


Figure C-3

4. The notch in the Takeup Spindle should be rotated to the top and the ribbon should lay smooth over the top of the spindle.

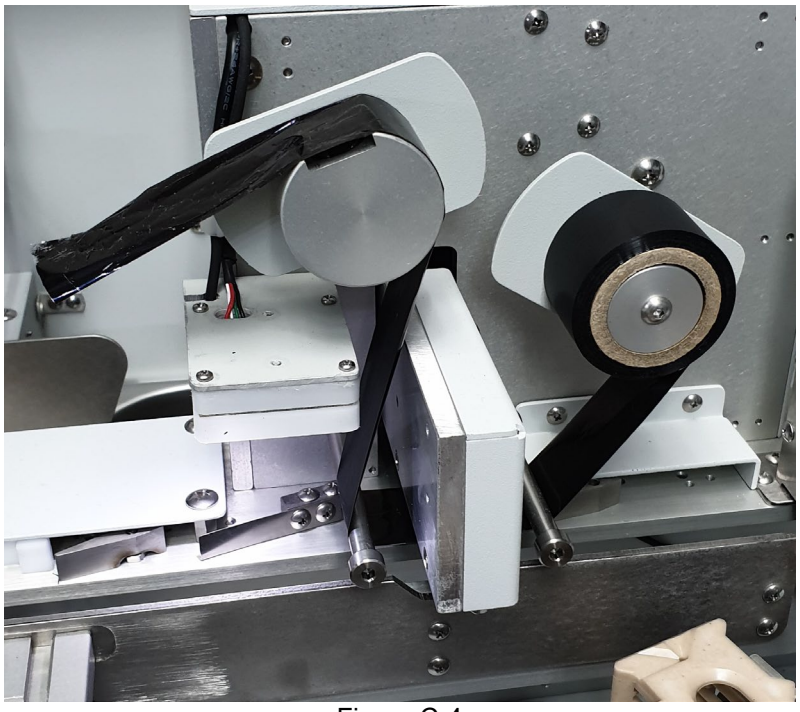


Figure C-4

5. The ribbon is held in place with a Spindle Flange that has a bar the fits in the notch on the Takeup Spindle. A magnet in the Takeup Spindle holds the Spindle Flange down and clamps on the ribbon.

Figure C-5

6. Rotate the Takeup Spindle counter-clockwise to wind up the extra ribbon.

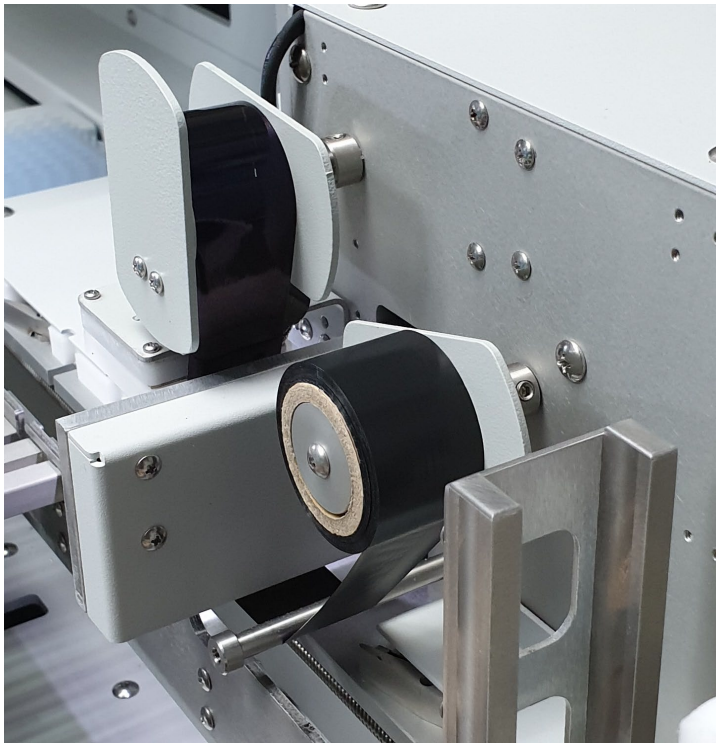


Figure C-6

7. Check to make sure the ribbon is not wrinkled and is smooth against the print head.

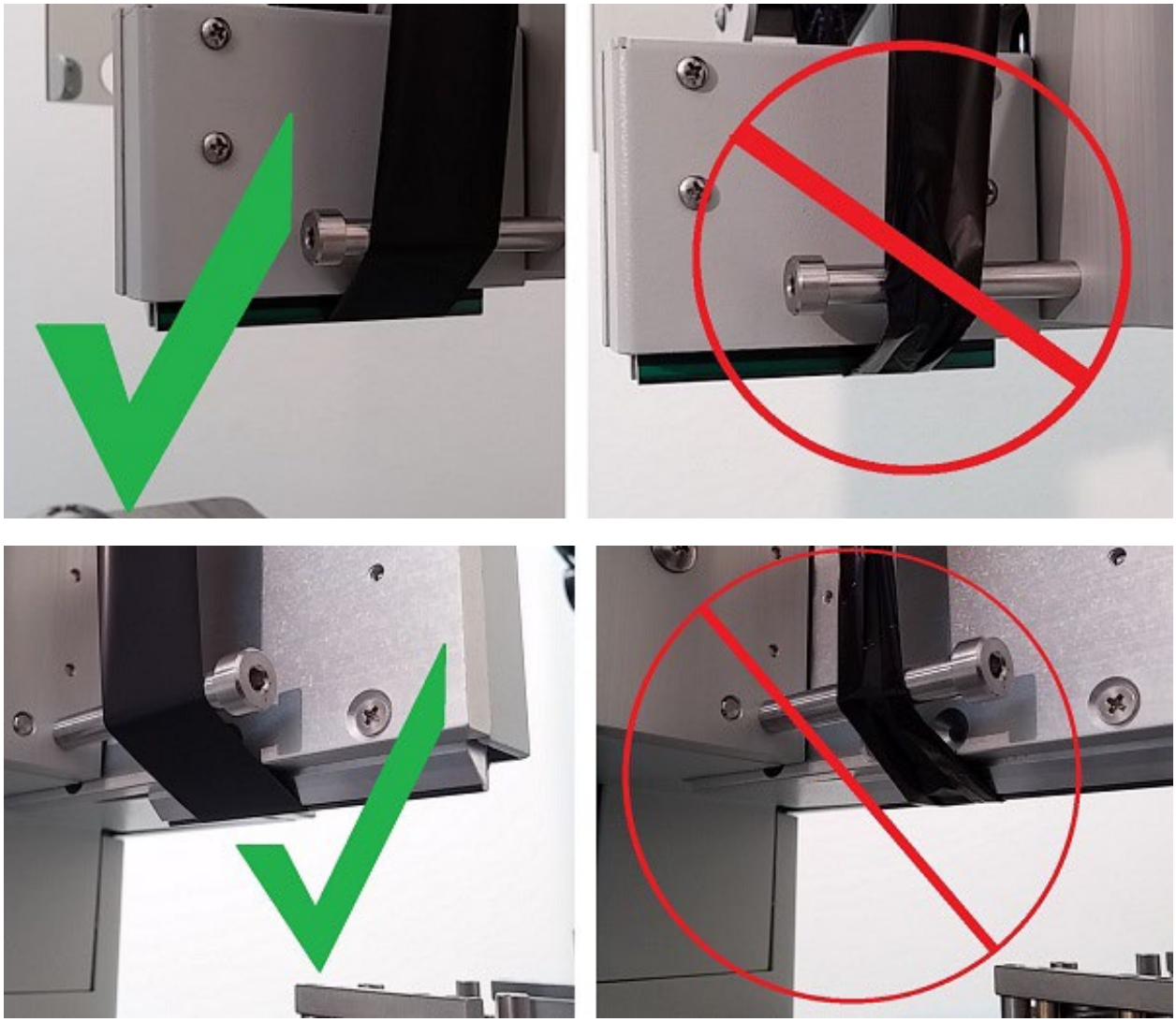


Figure C-7

8. With the ribbon installed the door can be close and the system is ready for running.

Removing Used Ribbon

1. To remove used ribbon, pull the Spindle Flange away from the Takeup Spindle. The Flange is held in place with a magnet so it just needs to be pulled out.

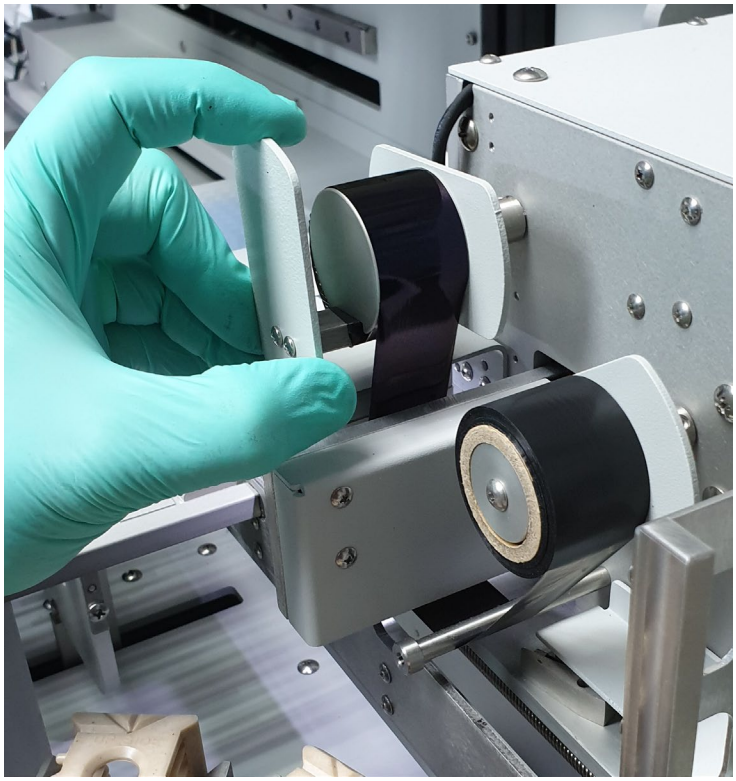


Figure C-8

2. Slide the used ribbon off the Takeup Spindle.

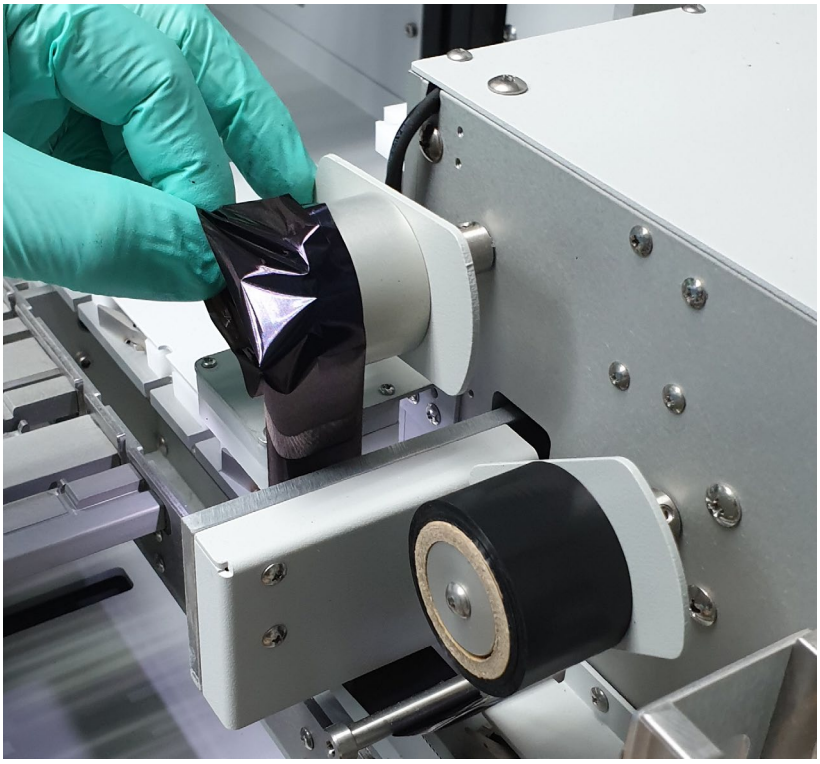


Figure C-9

Cleaning the Print Head

The print head is made of an extremely durable material and the ribbon is specially formulated so that under normal conditions the print head should rarely need cleaning.

One indication that the head may need to be cleaned is if there are unprinted areas on the slide. This could be caused by one or more of the heating elements on the print head being blocked with some type of debris. The debris could be the result of a dusty environment or could be caused if someone installed the ribbon in the system with the wrong side toward the print head.

1. To clean the print headfirst remove the ribbon. Then lightly dampen a lint-free wipe (i.e. Kim wipes) with Isopropyl Alcohol.

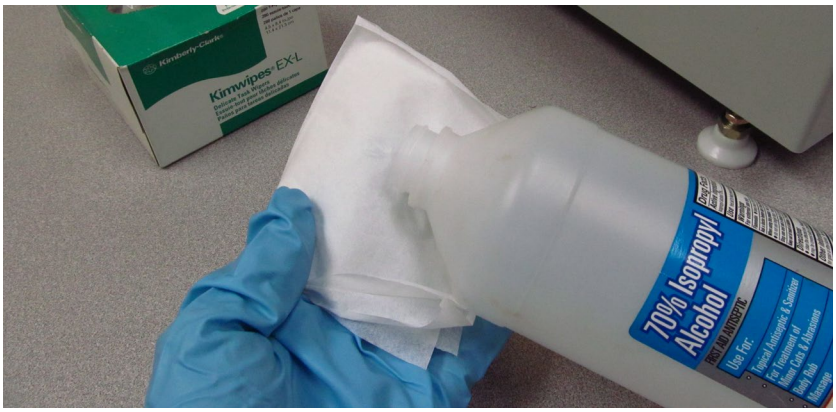


Figure C-10

2. Gently wipe the print head with the lint-free wipe.

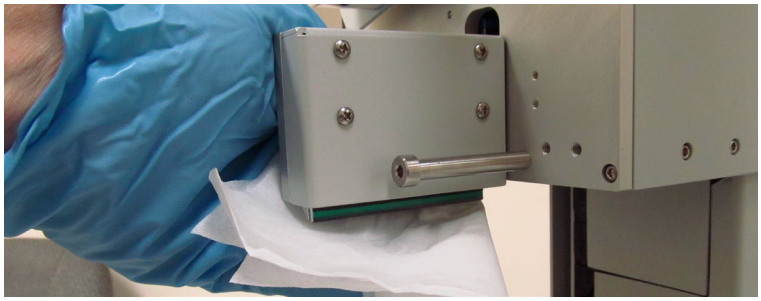


Figure C-11

3. Allow the print head to dry for at least 2 minutes then re-install the ribbon and use the software to print a test slide.

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