HOLOGIC®

Cellient® Automated Cell Block System

Operator's Manual

cellient®
AUTOMATED
CELL BLOCK SYSTEM

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Operator's Manual

HOLOGIC®

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Tel: 1-800-442-9892
1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

EC REP
Hologic Ltd.
Heron House
Oaks Business Park
Crewe Road, Wythenshawe
Manchester, M23 9HZ, UK
Tel: +44 (0)161 946 2206

Australian Sponsor:
Hologic (Australia) Pty Ltd
Suite 402, Level 4
2 Lyon Park Road
Macquarie Park NSW 2113
Australia
Tel: 02 9888 8000

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1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW AND FUNCTION OF THE CELLIENT® SYSTEM

The Cellient® Automated Cell Block System rapidly creates a paraffin embedded cell block by means of a controlled vacuum to deposit a layer of cells on a filter and infiltrate those cells with reagents and paraffin. The technique processes and embeds the sample in a much shorter time than traditional manual techniques, yet employs the same scientific methodology for the generation and histological analysis of embedded tissue samples.

The Cellient System semi-automated process offers these advantages:

- Consistent preparation
- Much shorter processing time to embed a sample into a block
- Excellent structural detail and preservation of nucleic acid integrity

The System consists of the Cellient Processor, which processes the sample; the cassette/filter assembly, which captures the sample and guides the infusion of reagents and paraffin; and the Finishing Station, which is used to embed the cell block in paraffin in preparation for cutting and slide preparation.

The instrument processes one sample at a time. It supports two modes of sample loading:

- Cellular material is automatically transferred from a ThinPrep® PreservCyt Solution vial into the cassette/filter assembly
- Tissue fragments are manually placed into the cassette/filter assembly prior to processing and augmented by aspiration of additional cellular material from the ThinPrep PreservCyt Solution vial

The instrument then processes the sample, dispensing stain (optional), dehydrating reagent, clearing reagent and finally infusing paraffin.

It is operated via a touch-screen graphic user interface. The interface is available in several languages, via a user preference.

A History Log records all cell block processing events, up to a total of 5,000 records. If the processor encounters any conditions that cause an error, the errors are recorded in an Event Log, up to a total of 10,000 records. Both of these logs

may be viewed on the user interface, and they may be downloaded via a USB port.

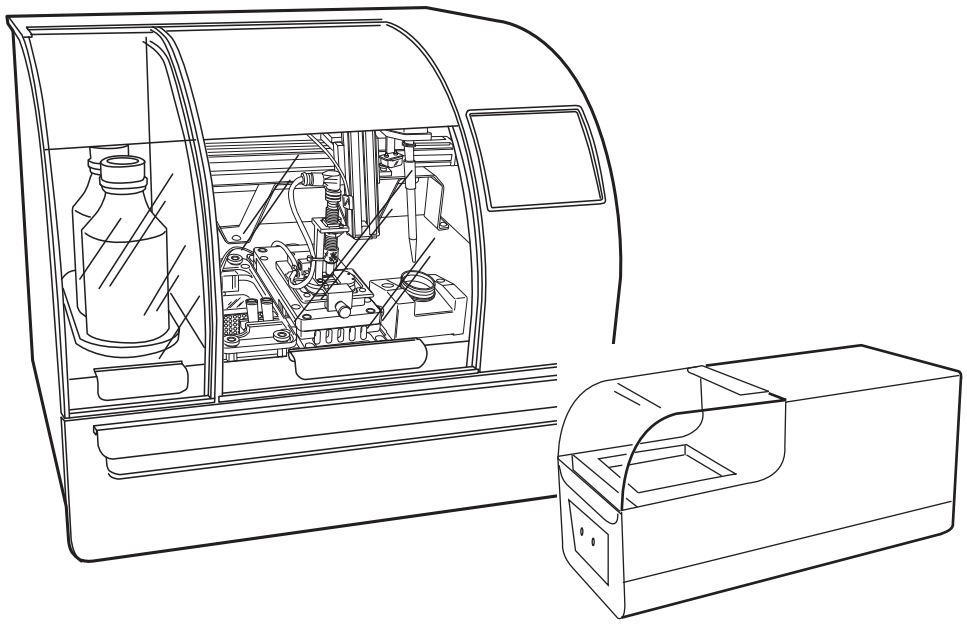


Figure 1-1 Cellient Automated Cell Block Processor and Finishing Station

SECTION B SPECIMEN PREPARATION

Procedures for the handling of cytology samples prior to preparation of paraffin embedded cell blocks differ greatly and are subject to many factors including:

- the method of specimen collection
- type of specimen
- amount of specimen
- fixative used

Specimens for routine cytology will generally arrive in the lab either fresh or in CytoLyt® Solution. For optimal results it is recommended that red blood cells, mucus and non-cellular debris are cleared prior to processing on the Cellient® Automated Cell Block system. Prepare samples according to Hologic's ThinPrep® 2000 Non-Gynecologic sample processing protocols or standard laboratory procedures [1].

Cytologic samples preserved in any fixative other than CytoLyt or PreservCyt® Solution should be washed in CytoLyt Solution and placed in a ThinPrep® vial containing PreservCyt Solution prior to processing on the Cellient® Automated Cell Block System.

Do NOT use formalin on the Cellient Processor.

Samples that will be made into a cell block on the Cellient® System should have all residual material saved from the routine cytology process. Quantity of sample will vary. Use the following table as a guideline.

Table 1.1: Sample Quantity

Centrifuge Tube Quantity	PreservCyt® Solution Vial Quantity	Process
Centrifuge tube empty	Vial with residual sample	Run vial on the Cellient System
Tube with cell pellet	Vial empty	Put a maximum of 10 drops (approximately ¼ ml) of cell pellet into a vial containing 20 ml of PreservCyt Solution and allow to stand for a minimum of 15 minutes prior to processing to allow the PreservCyt Solution to render the sample non-infectious
Tube with cell pellet	Vial with residual sample	Put a maximum of 10 drops (approximately ¼ ml) of cell pellet into a vial containing 20 ml of PreservCyt Solution. Top off vial with PreservCyt Solution if needed and allow to stand for a minimum of 15 minutes prior to processing to allow the PreservCyt Solution to render the sample non-infectious
Tube empty	Vial empty	Sample insufficient for cell block

CAUTION:

Cytology samples should utilize the Cellient System's Auto Sample Dispense process.

Tissue fragments and core specimens (maximum 14 gauge* needle) should be processed via the Cellient System's Manual Sample Dispense process.
* 14 g biopsy needle has an interior diameter of approximately 1.6 mm.

1 Hologic *ThinPrep® 2000 Processor Operator's Manual*. P/N MAN-01408-001.
see also:
Hologic *Non-Gyn Operations Sheet - Mucoid Specimens.* P/N 85488-001.
Hologic *Non-Gyn Operations Sheet - Fine Needle Aspirates.* P/N 85489-001.
Hologic *Non-Gyn Operations Sheet - Body Fluids.* P/N 85490-001.

Note: Previous processing of specimens in PreservCyt Solution may have reduced the volume of the vial below the minimum required as indicated by the frosted line on the side of the vial. Additional PreservCyt Solution must be added to the vial for a minimum of 20 ml.

Notes on using the Manual Dispense Mode:

- A PreservCyt Solution vial containing a minimum of 20 ml of solution must be loaded in the vial holder.
- Use standard histology lab techniques for handling tissue samples.
- Fragments and core samples received in formalin should be transferred directly into the sample loading well, using forceps or a pipette.
- When using a bulb pipette, care should be taken to minimize the amount of formalin transferred to the sample loading well.
- **Limit manually pipetted fluid to 5 ml or less.** The waste chamber has a capacity of 60 - 65 ml of waste fluid. (This waste is then emptied to the waste collection tank before the next cell block is processed.) Manual dispense mode uses 55 ml of fluid to process a block, plus the amount of fluid pipetted in by the operator. Use caution to keep the amount of pipetted fluid under 5 ml.

CAUTION: Limit the amount of fluid manually pipetted into the cassette to 5 ml or less. More may cause the waste chamber to overfill and damage the Cellient Processor.

Specimen Handling and Stability

The Cellient System cell blocks are stored, transported and handled the same as conventional cytologic cell blocks. Please refer to your laboratory guidelines for specimen handling.

SECTION C MATERIALS REQUIRED

Materials Provided

- Cellient®Processor
- Cassette and Filter Assemblies
- Pipette tips
- Embedding mold

Materials Required but not Provided

- Isopropyl alcohol, 99.8% (a.k.a. isopropanol or 2-propanol), various manufacturers
- Xylenes, 98.5% minimum (xylene isomers and ethyl benzene), various manufacturers

CAUTION: Do not substitute dehydrating, clearing, staining or paraffin agents other than those specified.

Note: The performance of the instrument using recycled alcohol, recycled xylene or xylene substitute has not been evaluated.

- PROTOCOL Eosin Y Intensified stain, #23-314-630 or -631 Fisher Scientific
- Paraplast-Xtra® paraffin wax, #503002, McCormick Scientific (direct or through various distributors)

Optional Items

- USB drive (optional, for downloading History and Error logs)
- USB Barcode Scanner (optional) (cable length has to be less than 3 meters)

SECTION D

CELLIENT SYSTEM TECHNICAL SPECIFICATIONS

Overview of Components

Refer to Figure 1-2 to Figure 1-10 for information regarding components and specifications.

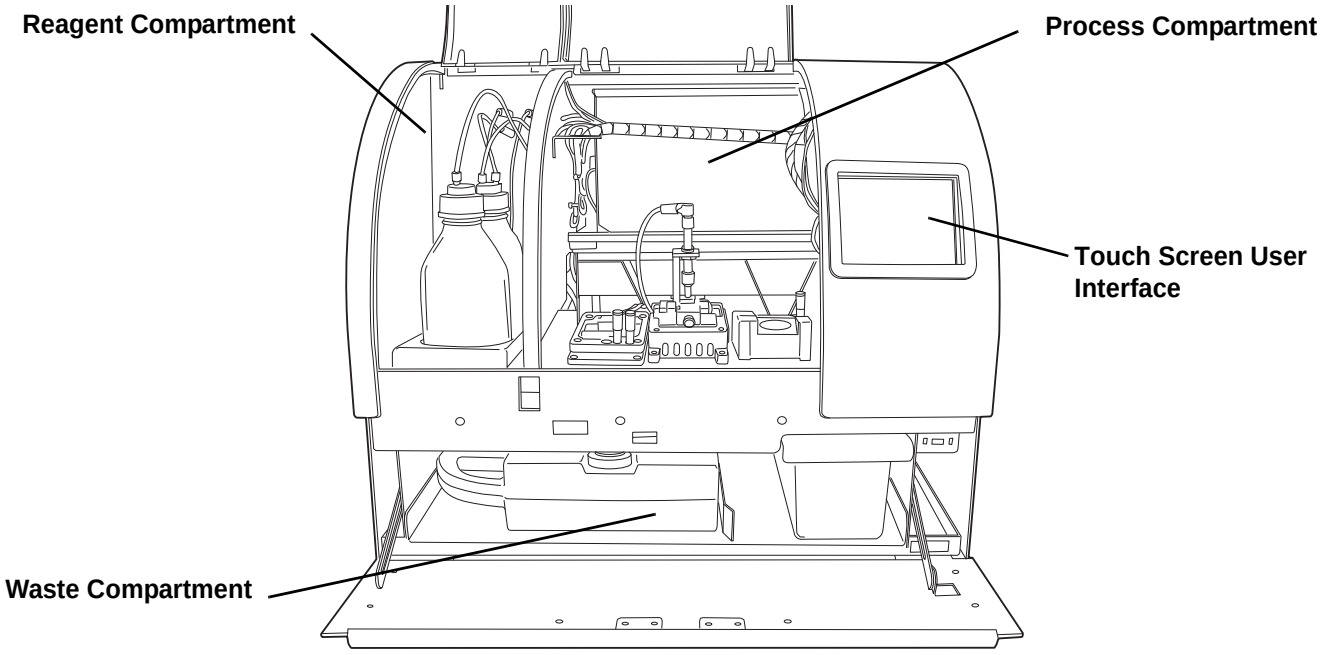


Figure 1-2 Cellient Processor Components

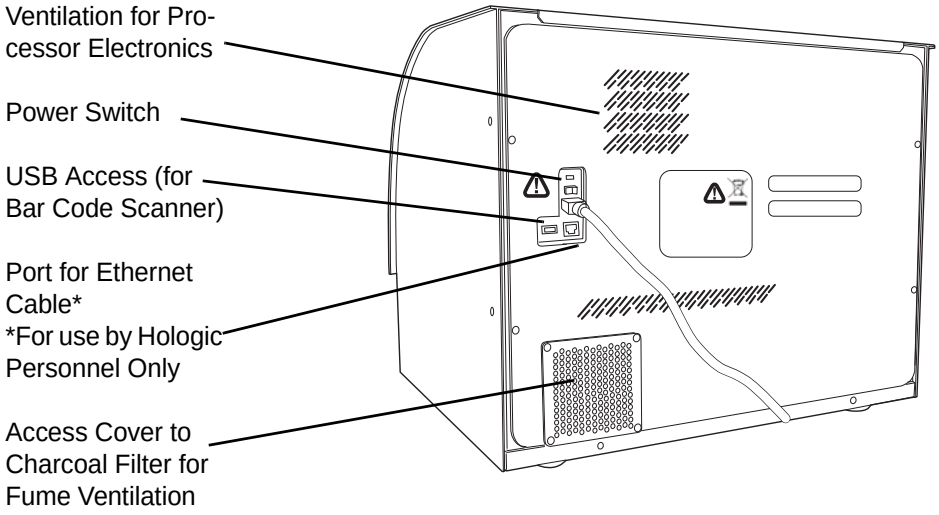


Figure 1-3 Cellient Processor - Rear

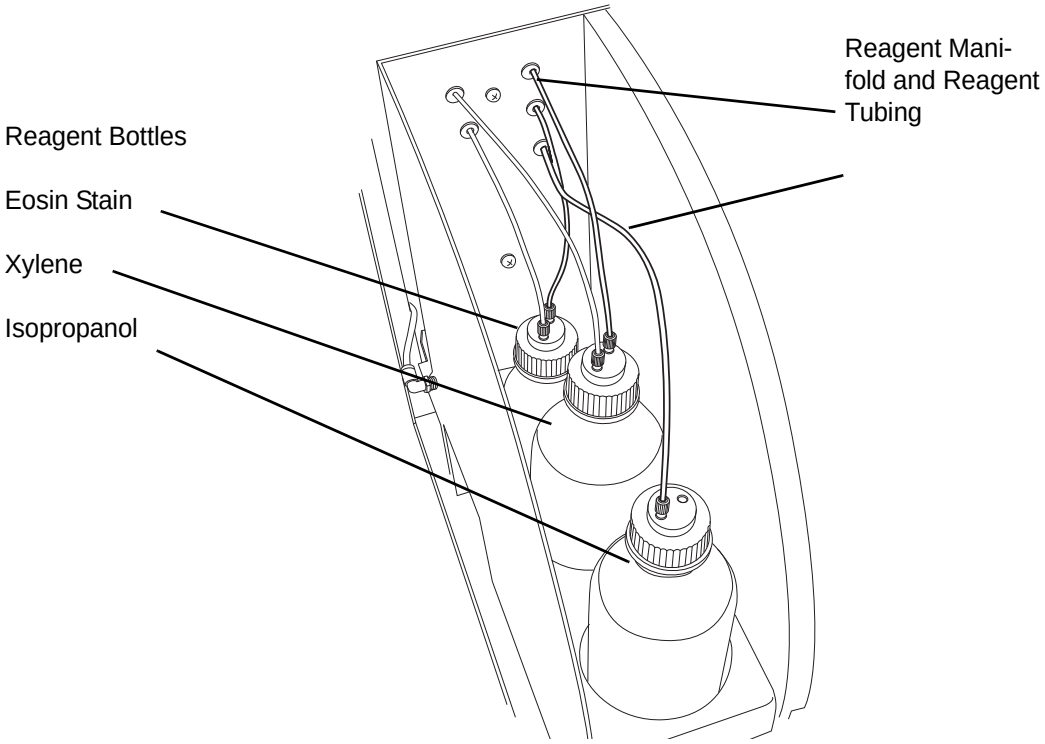


Figure 1-4 Reagent Compartment

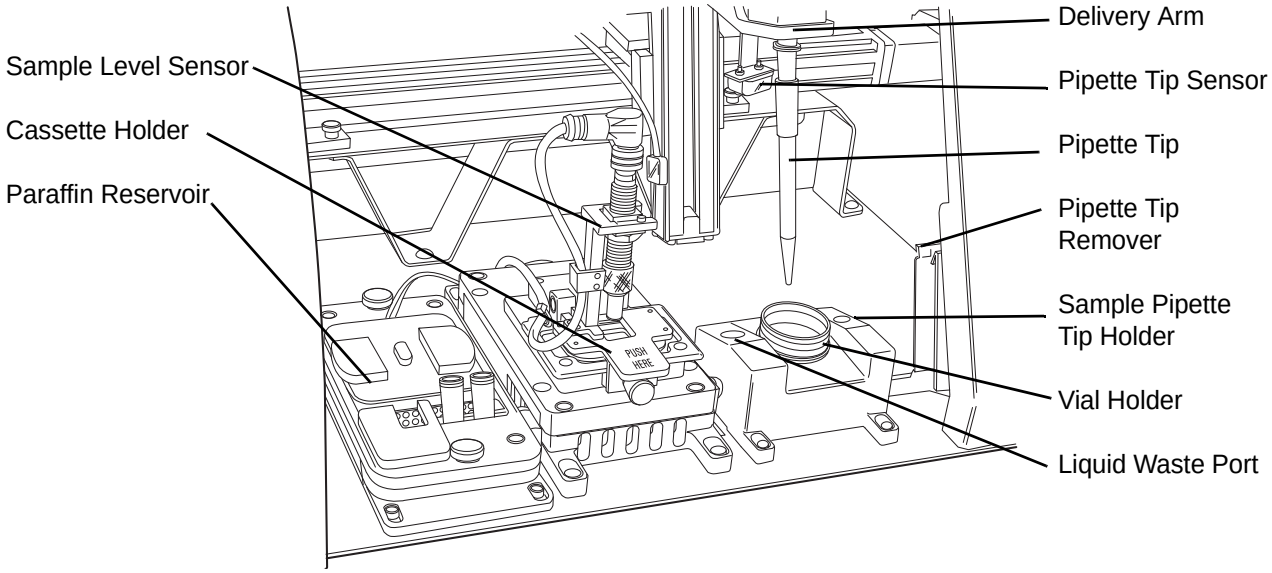


Figure 1-5 Process Compartment Components

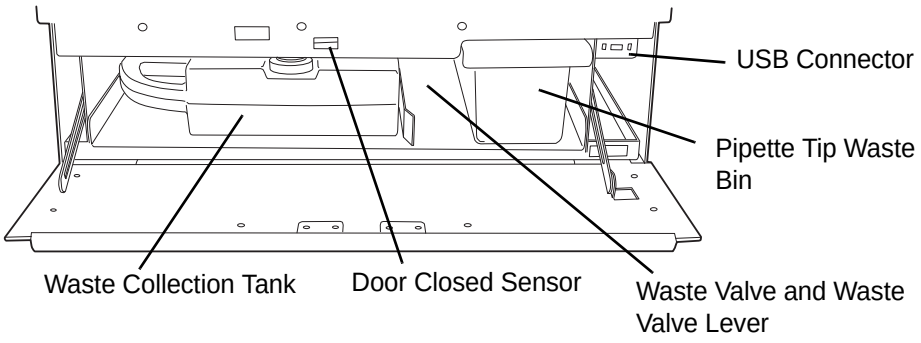
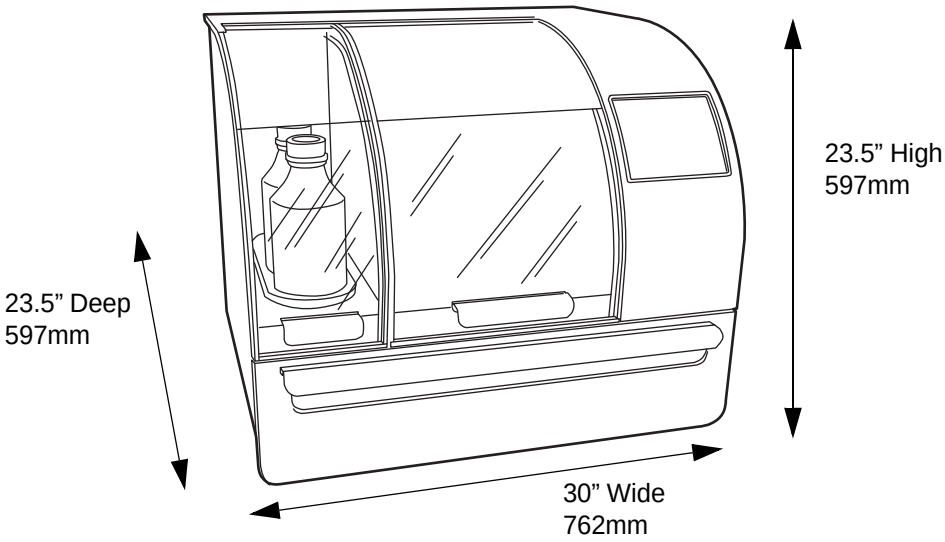


Figure 1-6 Waste Compartment

Dimensions



Approximate Weight: 140 lbs (63.5 kg)

Figure 1-7 Cellient Processor Dimensions

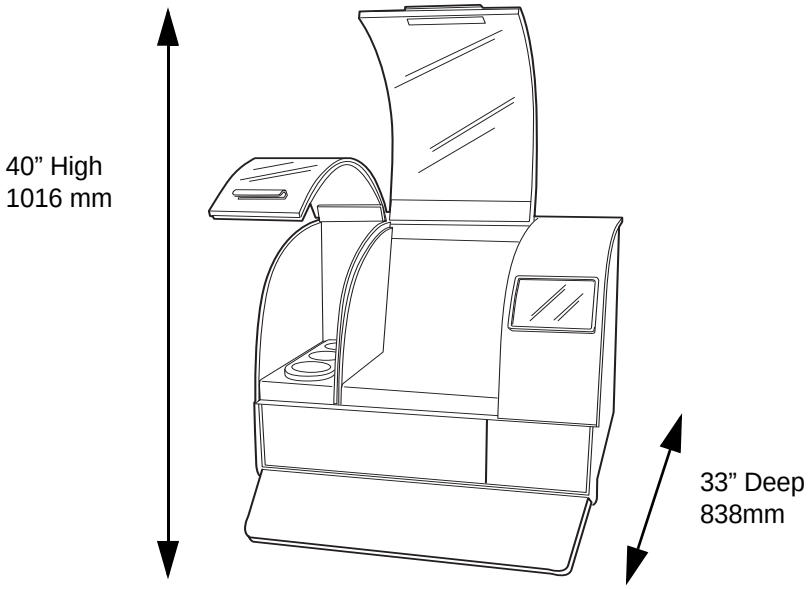


Figure 1-8 Recommended Clearances

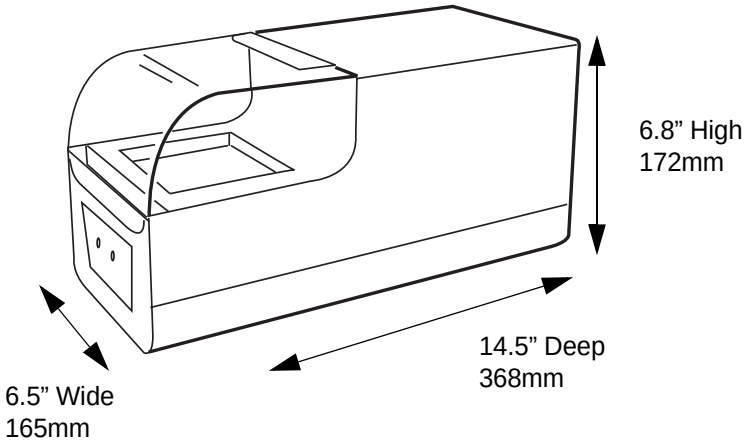


Figure 1-9 Finishing Station

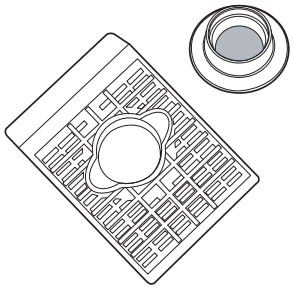


Figure 1-10 Cassette/Filter Assembly

Environmental

Operating Temperature Range: (the Cellient processor is plugged in and turned on)

16°C to 32°C

Non-Operating Temperature Range: (the processor is plugged in but not turned on)

-28°C to 50°C

Operating Humidity Range:

20 to 80% relative humidity, non-condensing

Non-Operating Humidity Range:

15 to 95% relative humidity, non-condensing

Pollution Degree II, in accordance with IEC 60664.

Category II. The Cellient Automated Cell Block System is for indoor use only in an office or a clean laboratory environment.

Altitude: 0 meters (sea level) to 2000 meters

Atmospheric Pressure: 1100 millibar to 500 millibar

Power

Voltage:

100 - 240 Volts alternating current
Mains supply voltage not to exceed ±10% of the nominal voltage

Frequency:

47 to 63 Hz

Power:

Processor: Less than 350W
Finishing Station: Less than 150W

Fusing:

Processor: Two T6.3AL, 250V, 5 x 20 mm, glass, time delay, low break capacity

Finishing Station: Two T3.15AL 250V 5x20 mm, glass, time delay, low break capacity

Connections to External Circuits

The external connections on the Cellient Processor are PELV (Protected Extra Low Voltage) as defined by IEC 61140. Outputs of other devices connected to the Cellient Processor should also be PELV or SELV (Separated Extra Low Voltage). Only devices approved for safety by an appropriate agency should be connected to the Cellient Processor.

Dimensions and Weight (Approximate)

Cellient Processor
23.5″ (597mm) H x 30″ (762mm) W x 23.5″ (597mm) D
140 lbs (63.5 kg)

Finishing Station
6.8″ (173mm) H x 6.5″ (165mm) W x 14.5″ (368mm) D
13.75 lbs (6.23 kg)

Cellient System Standards

The Cellient Automated Cell Block System has been tested and certified by a U.S. nationally recognized testing Laboratory (NRTL) to comply with current Safety, Electro-Magnetic Interference (EMI) and Electro-Magnetic Compatibility (EMC) standards. Refer to the product label, located on the rear of the processor or finishing station, to see the safety certification markings.

This product is *in vitro diagnostic* (IVD) medical equipment.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional radio frequency sources), as these may interfere with the proper operation.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This Class A digital apparatus complies with Canadian ICES-003.

SECTION E INTERNAL QUALITY CONTROL

Power On Self Test (POST)

When the Cellient processor is powered on (refer to Power On the Cellient Processor page 2.8), the processor goes through a self-diagnostic test. Electrical, mechanical and software systems are tested to confirm each functions properly. The operator is alerted to any malfunction via a message on the user interface.

If the system does not function, or there are persistent errors, contact Hologic Technical Support. (Refer to Service Information, Chapter 6.)

SECTION F CELLIENT PROCESSOR HAZARDS

The Cellient processor is intended to be operated in the manner specified in this manual. Be sure to review and understand the information listed below in order to avoid harm to operators and/or damage to the processor.

If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

Warnings, Cautions and Notes

The terms WARNING, CAUTION and Note have specific meanings in this manual.

- A **WARNING** advises against certain actions or situations that could result in personal injury or death.
- A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data or invalidate a procedure, although personal injury is unlikely.
- A ***Note*** provides useful information within the context of the instructions being provided.

Symbols Used on the Processor

The following symbols are used on this processor:

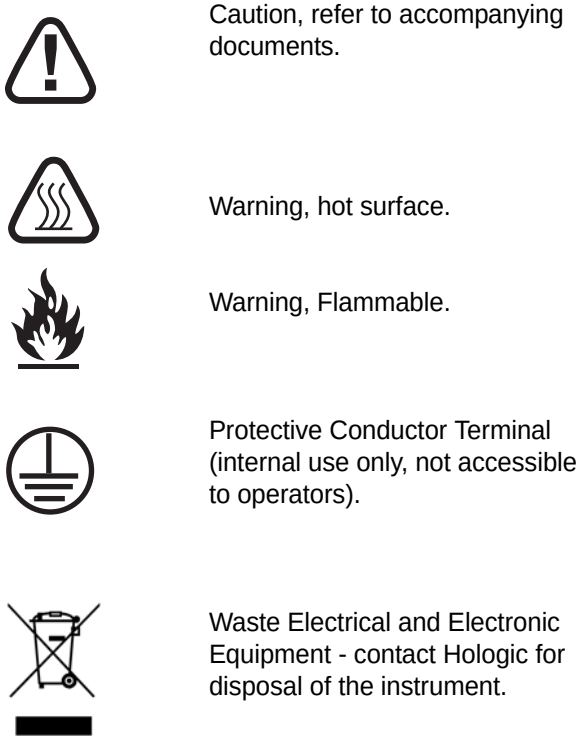


Figure 1-11 Symbols used on the processor

The Cellient processor has symbols placed on it specifically to advise the operator to refer to the Operator's Manual. (Refer to Figure 1-12.) Be sure to review and understand the warnings listed below in order to avoid damage

to the processor and any harm to operators. One or more of the warnings may be pertinent to the area marked.

The model/rating label and the serial number label are also located on the Cellient processor.

Location of Labels on the Processor

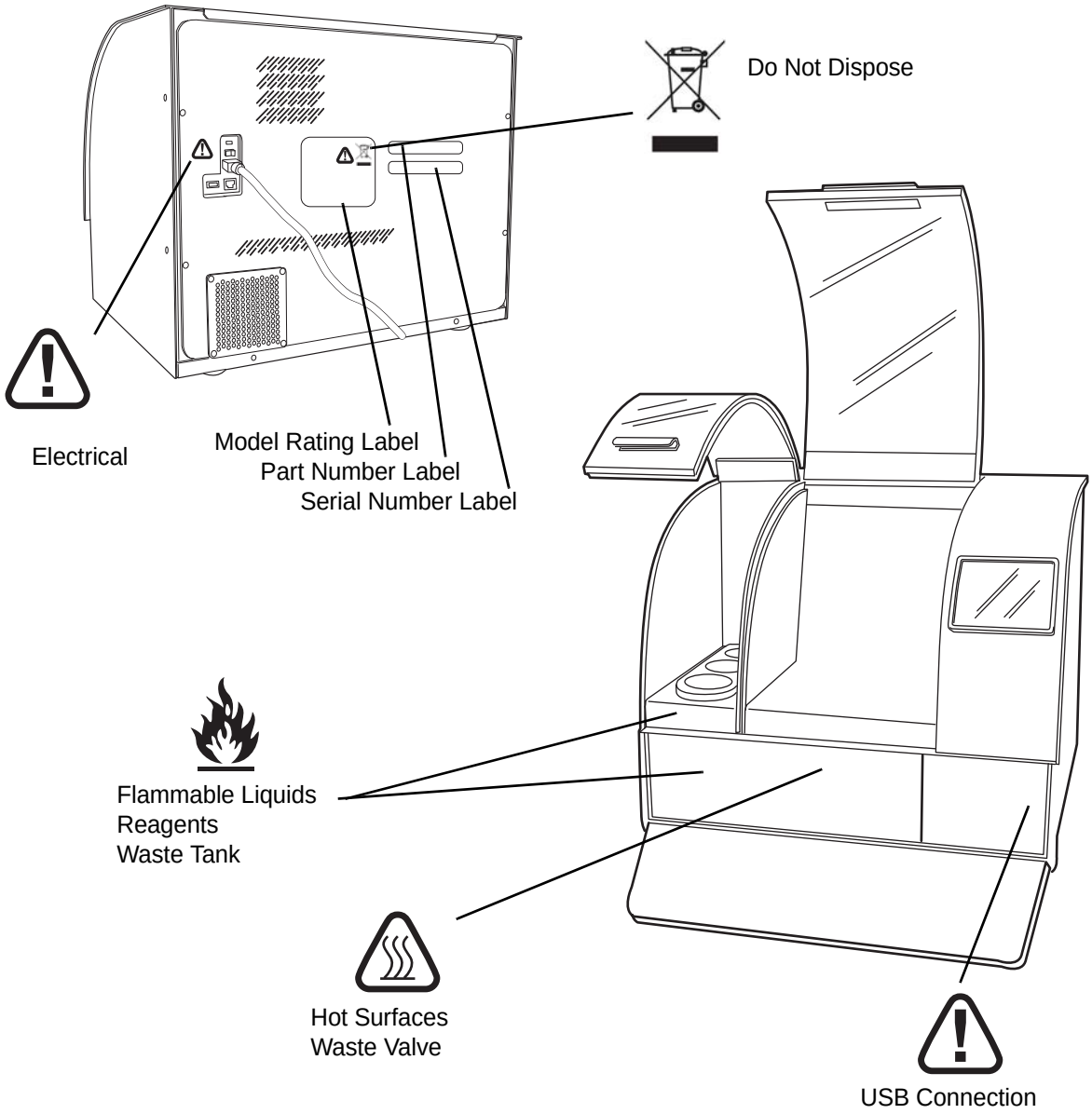


Figure 1-12 Label Locations

Warnings Used in this Manual:

WARNING **Service Installation Only**

This system is to be installed by trained Hologic® personnel only.

WARNING **Moving Parts**

The processor contains moving parts. Keep hands, hair, loose clothing, jewelry, etc., clear. Do not operate with the doors open.

WARNING **Grounded Outlet**

To ensure safe operation of the equipment, use a three-wire grounded outlet.

WARNING **Poisonous Substances**

Follow the manufacturer's recommendations for reagent handling and cleanup of spills. Refer to manufacturer's MSDS for more information. Wear protective laboratory gear.

WARNING **Flammable Liquids**

Flammable liquids. Keep away from fire, heat, sparks and flame.

WARNING **Hot Surfaces / Hot Paraffin**

The equipment contains hot surfaces. Melted paraffin will be hot. Use extreme caution when handling items near these surfaces. Allow hot surfaces and hot paraffin to cool before handling.

WARNING **Instrument Fusing**

For continued protection against fire, replace only with fuses of the specified type and current rating. Refer to the Maintenance chapter for instructions on replacing user accessible fuses. Refer to Ordering Information for fuse specification and ordering.

WARNING **Cold Surface**

Adhere to manufacturer's recommendations for proper use of freeze spray.

SECTION G

DISPOSAL

Disposal of Consumables

Pipette tips - may be disposed of in your laboratory refuse.

CAUTION:
All disposables are for single use only and should not be reused.

PreservCyt® Solution - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

CytoLyt® Solution - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

Alcohol - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

Xylene - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

CAUTION:
For proper handling, storage and disposal of each chemical, refer to the recommendations on the Manufacturer's Material Data Safety Sheet (MSDS).

Eosin - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

Used cassette - may be disposed of in your laboratory refuse.

Used cassette filter assembly - may be disposed of in your laboratory refuse.

Pre-filled plastic wax transfer mold - may be disposed of in your laboratory refuse.

Used paraffin - cool to solidify, then dispose of in your laboratory refuse.

Contents of waste tank - follow local, state, provincial and federal or county guidelines. Dispose of all solvents as hazardous waste.

Charcoal Filter assembly - dispose of in your laboratory refuse.

As with all laboratory procedures, universal precautions should be followed.

Disposal of the Instrument

Disposal of Waste Electrical and Electronic Equipment (WEEE)

Hologic is dedicated to meeting country specific requirements associated with the environmentally sound treatment of our products. Our objective is to reduce the waste arising from our electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE equipment to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment.

Your Responsibility

As a Hologic customer, you are responsible for ensuring that devices marked with the symbol shown below are not placed into the municipal waste system

unless authorized to do so by the authorities in your area. Please contact Hologic (see below) prior to disposing any electrical equipment provided by Hologic.

Symbol Used on the Instrument

Do not dispose in municipal waste.

Contact Hologic (see below) for information regarding proper dispo

Reclamation

Hologic will provide for the collection and proper reclamation of electrical devices we provide to our customers. Hologic strives to reuse Hologic devices, subassemblies, and components whenever possible. When reuse is not appropriate, Hologic will ensure the waste material is properly disposed of.

Manufacturer/Corporate Headquarters 	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752 USA Tel: 1-800-442-9892 1-508-263-2900 Fax: 1-508-229-2795 web:www.hologic.com
Authorized Representative - Europe EC REP	Hologic Ltd. Heron House, Oaks Business Park Wythenshawe, Manchester, M23 9HZ United Kingdom Tel: +44 (0)161 946 2206

Material Safety Data Sheet

CytoLyt® Solution; PreservCyt® Solution:

The Material Safety Data Sheet (MSDS) for these solutions may be requested from Hologic Technical Support at 1-888-898-2357 (USA and Canada).

2. Installation

Chapter Two

Installation

WARNING
Installation by Hologic Personnel Only

SECTION A GENERAL

The Cellient® Automated Cell Block System must be installed by Hologic personnel. When installation is complete, Hologic personnel will train the operator(s), using the Operator's Manual as the training guide.

SECTION B ACTION UPON DELIVERY

Remove and read the *Operating Instructions Prior to Installation* sheet attached to the packing carton.

Inspect the packing cartons for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Service Information, Chapter 6.)

Leave the equipment in the packing cartons for Hologic installation.

Store the equipment in a suitable environment until installation (cool, dry, area).

SECTION C PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

A pre-installation site assessment is performed by Hologic Personnel. Be sure to have prepared any and all site configuration requirements as instructed.

Location And Configuration

Room for the Cellient processor should be made on a flat, sturdy surface that can support the 140 lbs (63.5 kg) the processor weighs. Do not place in close proximity to external vibrations.

Allowing for clearances, the following space is required for the equipment: 41" (104 cm) H x 30" (76 cm) W x 33" (84cm) D.

The Cellient processor comes with a charcoal filter for fume ventilation. If your laboratory will use an alternative ventilation method, this will be arranged for at the time of the pre-installation site assessment. Additional room for clearances may be indicated.

There should be adequate space for the Finishing Station. It does not need to be situated next to the Cellient processor. Ensure that it has proper clearances: 12″ (30.5 cm) H x 6.5″ (16.5cm) W x 14.5″ (37 cm) D.

CAUTION
Route connections carefully to avoid pinching the cables. To avoid tripping over, or disconnecting cabling, do not place cabling near foot traffic.

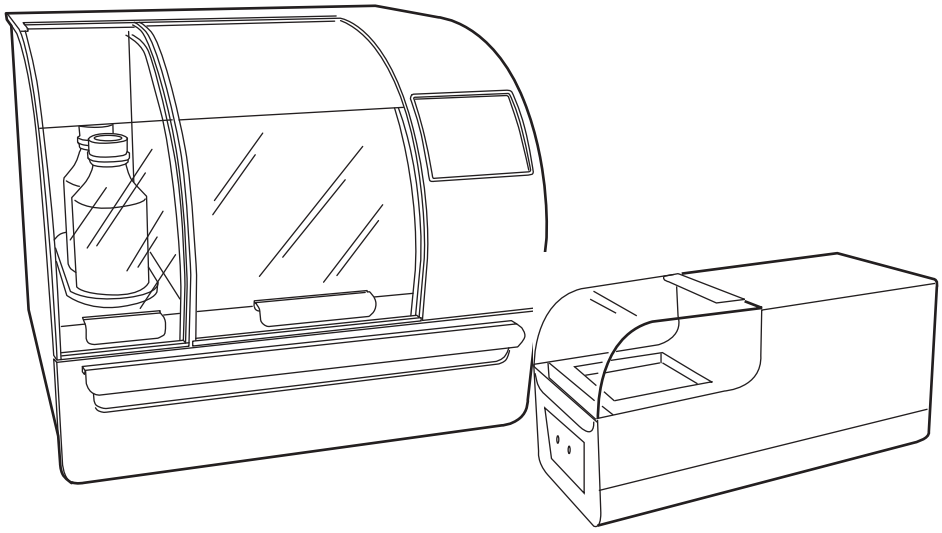


Figure 2-1 A Typical Cellient Processor and Finishing Station

SECTION D MOVING THE CELLIENT® PROCESSOR

CAUTION:
The processor weighs 140 lbs (63.5 kg) and should always be moved by at least two people.

The Cellient processor is a precision instrument and should be handled with care. Prior to relocating the equipment, unload any item(s) which may spill or break: reagents, pipette tips, sample vial. Run a waste cycle (page 4.11) and remove and cap the waste collection tank (page 4.6). The paraffin reservoir may be emptied - see Maintenance, Chapter 4.

If it must be moved, it should be grasped and lifted by bottom of the housing. Do not lift it by the doors or door handles.

If the Cellient processor is to be shipped to a new location, please contact Hologic Technical Support. (Refer to Service Information, Chapter 6.)

SECTION E

INSTALL THE CONSUMABLES

As with all laboratory procedures, universal precautions should be followed.

WARNING
Poisonous Substances
Flammable Liquids

Refer to manufacturers' MSDS for more information

Reagent Bottles

Before installing the reagents on the processor, fill each bottle with the reagent indicated below.

Note: If you are replenishing reagents, refer to the instructions on page 4.10.

- Isopropyl alcohol, 99.8% (a.k.a. isopropanol or 2-propanol), various manufacturers, 900 ml maximum - do not overfill
- Xylenes, 98.5% minimum (xylene isomers and ethyl benzene), various manufacturers, 900 ml maximum - do not overfill

  Note: The performance of the instrument using recycled xylene or xylene substitute has not been evaluated.

CAUTION:
Do not substitute dehydrating, clearing, staining or paraffin agents other than those specified.

- PROTOCOL Eosin Y Intensified stain, #23-314-630 or -631 Fisher Scientific, 200 ml maximum - do not overfill

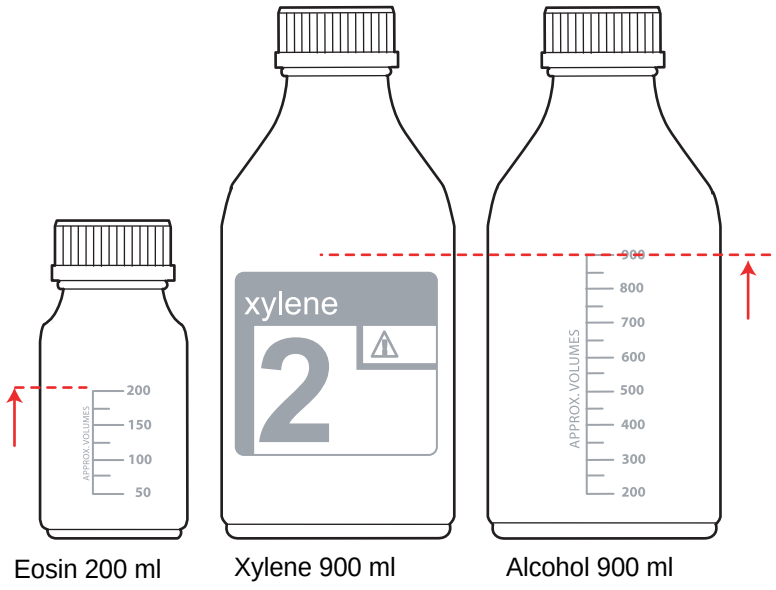


Figure 2-2 Maximum Reagent Bottle Fill Volumes

1 Isopropanol (blue label, blue tubing to the manifold)

2 Xylene (green label, green tubing to the manifold)

3 Eosin stain (red label, red tubing to the manifold)

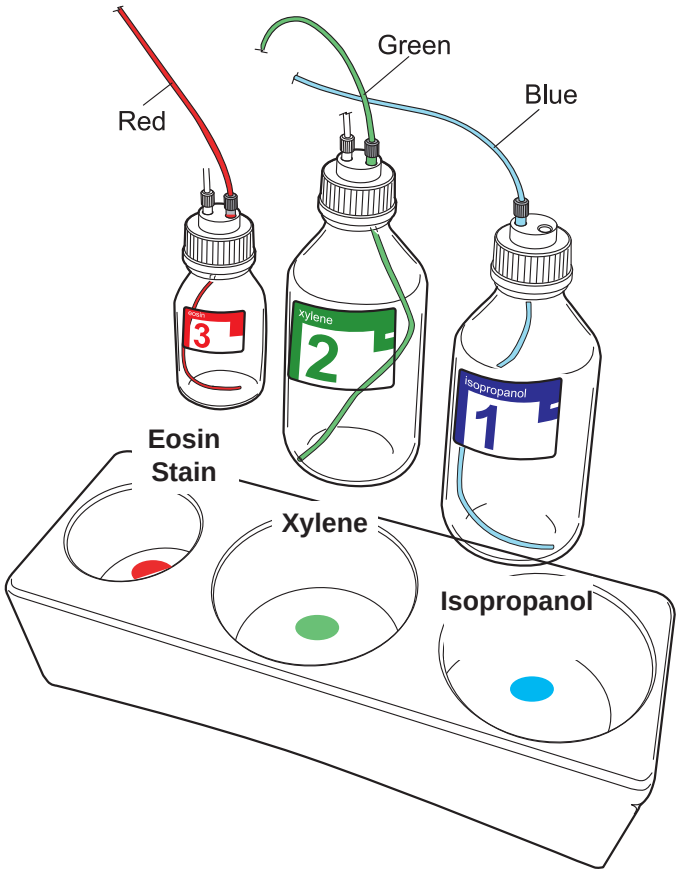


Figure 2-3 Reagent Bottles

Each bottle label, its tubing and corresponding well on the reagent tray are color coded. The tubing that passes through the bottle cap should not be disconnected from the cap. To open the bottle, unscrew the blue cap from the bottle.

The xylene (2) and eosin stain (3) bottles are pressurized. The colored tube is the reagent, the white tube is for the air. The isopropanol (1) bottle is not pressurized and only has the reagent supply tubing in the cap. See Figure 2-3.

Note: The eosin stain bottle must be present even if stain is not used. The processor monitors the pressurized bottles and will not process a cell block if the pressure system is open.

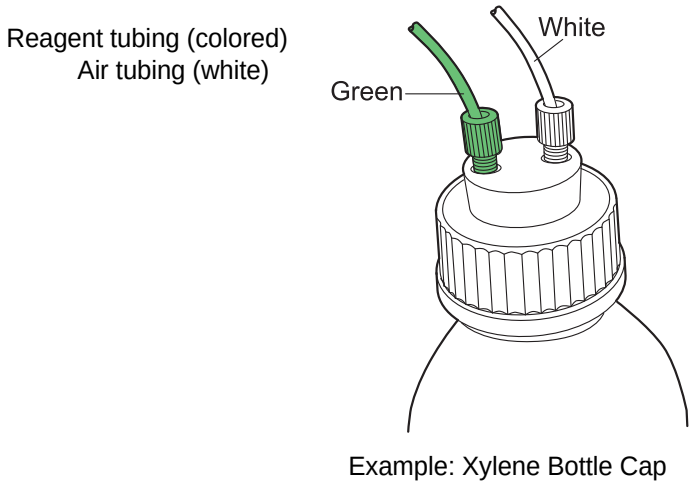


Figure 2-4 Reagent Bottle Cap

Place the reagent bottle in its reagent tray well.

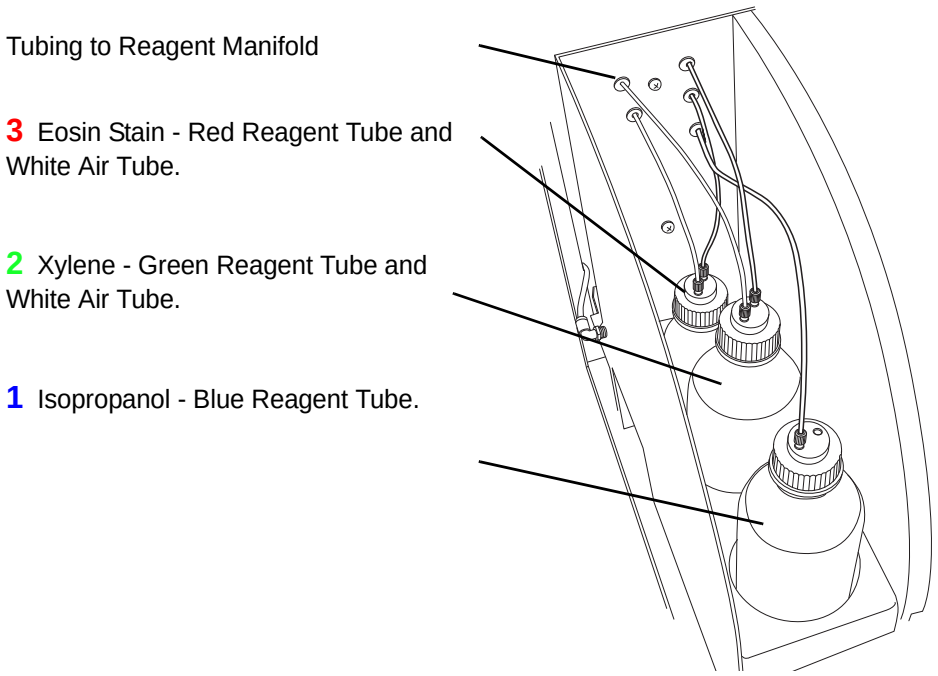


Figure 2-5 Reagent Bottles and Manifold Connectors

Note: The tubing lengths are factory cut to fit exactly between the bottle location and the manifold connector. If the tubing does not reach, check that the bottle is in the correct bottle well.

Paraffin Reservoir

WARNING
Hot Surfaces
Hot Paraffin

- Paraplast X-Tra® paraffin

The paraffin reservoir is installed and ready to be filled with wax. At first start up, use about 5.5 oz (156 g) of paraffin and allow adequate time for it to completely melt. It will melt faster if a little is added at a time.

Paraffin may be added as needed at any time, but never overfill the reservoir. If the paraffin level is too low, the operator will be notified with a displayed message: "Paraffin reservoir is low or temperature is not correct".

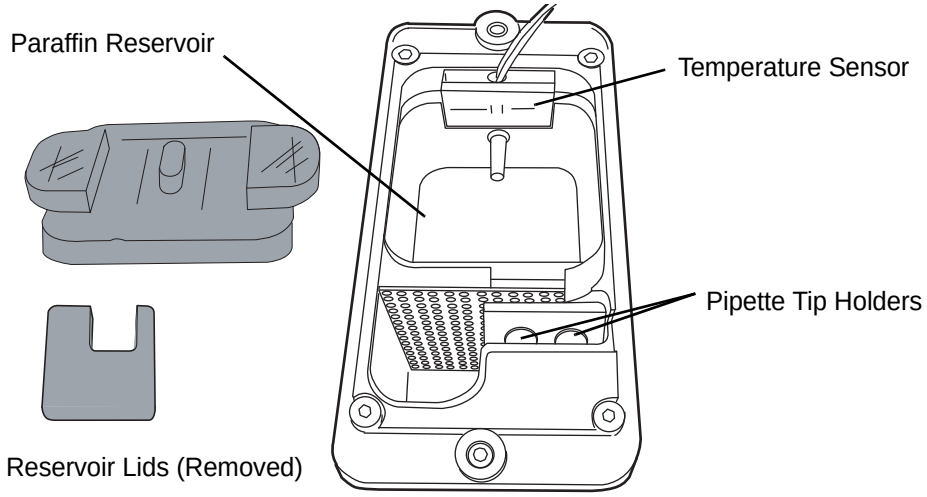
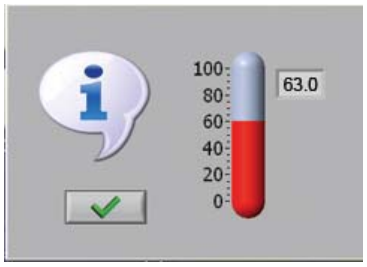


Figure 2-6 Paraffin Reservoir

The paraffin reservoir temperature is always monitored when the processor is turned on. To view the temperature, touch the Maintenance tab and touch the Information icon. The paraffin temperature is displayed (°C).

Maintenance Tab

Information Icon



Paraffin Reservoir Temperature.

Refer to page 4.8 for cleaning out the reservoir, if needed.

Location of USB port

A USB (universal serial bus) port is located inside the waste compartment door, on the right. This is where you temporarily connect the USB key, for downloading the History and Event logs. Refer to Figure 2-7 for location.

Refer to page 3.17 for instructions on how to download logs.

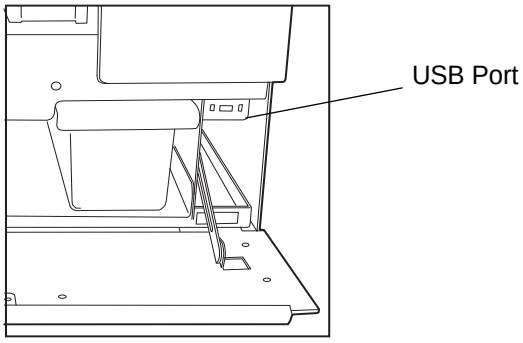


Figure 2-7 USB Port for Downloading Logs

SECTION F

INSTALL USB BAR CODE SCANNER (OPTIONAL)

If a bar code scanner will be used for input of specimen accession numbers, connect it to the USB port at the rear of the processor, shown in Figure 2-8.

The scanner must connect via USB connection and support Bar Code 128 symbology. USB cable length must be less than 3 meters. (Refer to the manufacturer's documentation that comes with the device.)

See page 3.4 for accession number requirements.

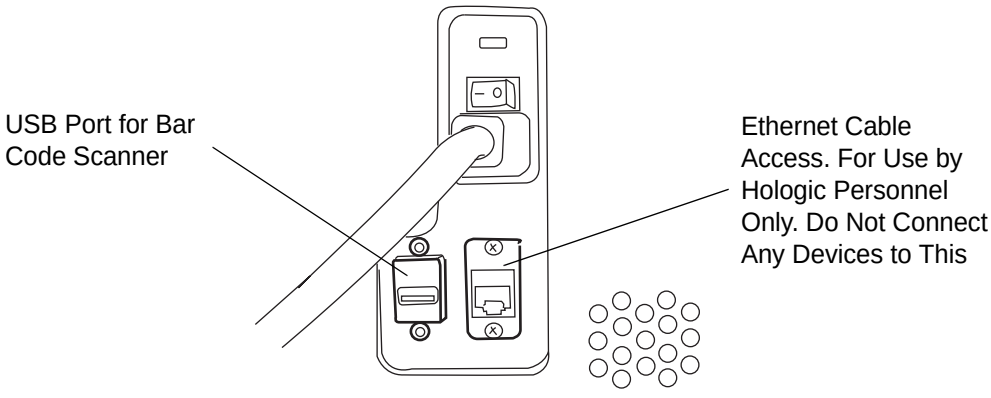


Figure 2-8 USB Port for Bar Code Scanner

SECTION G

POWER ON THE CELLIENT® PROCESSOR

WARNING
Grounded Outlet

Do not power on or operate if equipment has been damaged.

The Cellient processor power On/Off switch is located at the rear of the machine. Confirm that it is in the Off position and plug the receptacle end of the power cord into the socket. Plug the other end of the power cord into a wall outlet. To ensure safe operation of the processor, a three wire grounded outlet must be used. (Refer to Figure 2-9.)

Close the doors.

Power on the Cellient processor by pressing the rocker switch on the rear of the processor to On.

Note: Disconnection from power supply source is by removal of the power cord.

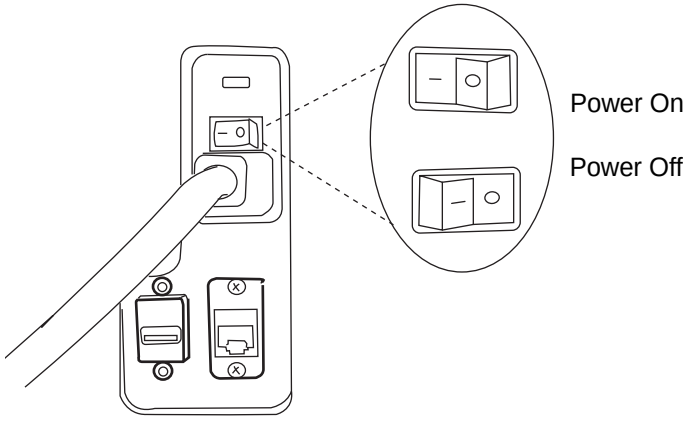


Figure 2-9 Power On/Off Switch

WARNING
Moving Parts

Allow the processor to initialize. The processor is ready for operation when the main processing screen is displayed (Figure 2-10).

Figure 2-10 Cellient Processing Screen Display

SECTION H

SELECT LANGUAGE

Touch the User Preferences tab. 

Touch the pull down field of the language box to view the list of languages.

Figure 2-11 Select Language

Touch the desired language. All displayed messages will be in the selected language.

SECTION I

SET DATE AND TIME

Touch the Maintenance tab.  Touch the Time and Date icon.

Time and Date Icon

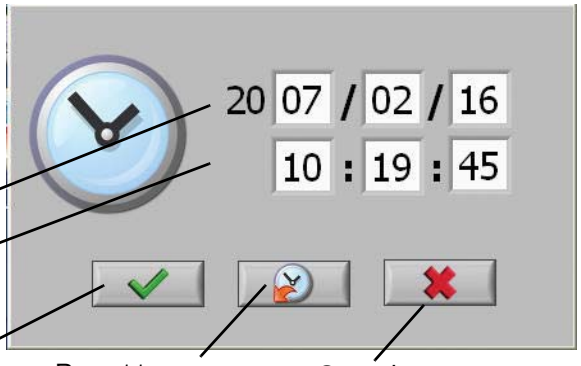


Figure 2-12 Set Time and Date

To change any setting, touch the field displayed for that item. For example, to change the month, touch the field for month and select the desired month number (see Figure 2-13).

Touch the field to set the month. Touch the desired setting.

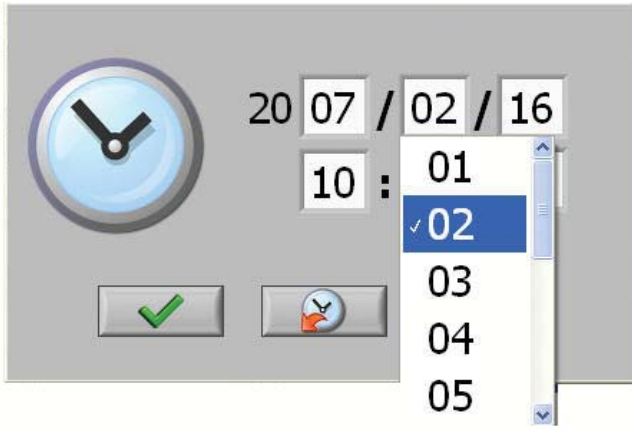


Figure 2-13 Set Month

Touch and select all of the fields that are to be set. Press the OK button to save changes. To cancel, press the cancel button. The system will revert to the previously saved settings and exit to the Maintenance screen.

SECTION J HOW TO POWER OFF THE CELLIENT PROCESSOR

The Cellient processor is intended to remain powered on, even when idle. To turn it off, as desired, be sure to remove any sample that may be on the processor, either in the cassette holder or in the vial holder.

1. Touch the Maintenance tab icon.

2. Press the Application Quit button.

A confirm shut down, yes/no dialogue box appears. Click on yes.

Wait for the application to turn off and the processor to shut down.

3. Turn the rocker switch on the rear of the processor to Off.

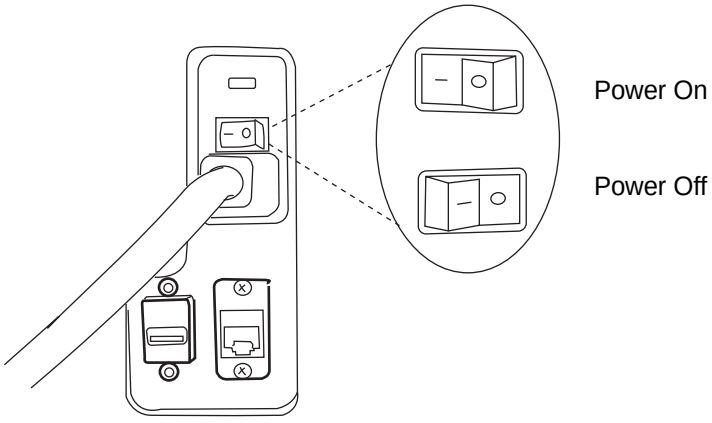


Figure 2-14 Power Switch

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3. Operation

Chapter Three

Operation

SECTION A

OVERVIEW - PROCESSING A CELL BLOCK

The Cellient® Automated Cell Block System automatically embeds cell samples in a paraffin block.

The Finishing Station applies a final layer of paraffin, to aid in microtome sectioning of the sample.

Process Flow

A cell block is processed in the following sequence of events:

- User preferences selected:
  Accession ID On / Off
  Sample Dispense Auto/Manual
  Eosin Stain On / Off
- Load consumables and sample vial
- Pretest
- Sample dispense (system pause for manual sample dispense mode)
- Stain dispense (if selected On)
- Apply dehydration agent
- Apply clearing agent
- Heats
- Paraffin infusion
- Cools, hardens (audible beep when complete)
- Finishing Station - embedding

SECTION B

MATERIALS REQUIRED PRIOR TO OPERATION

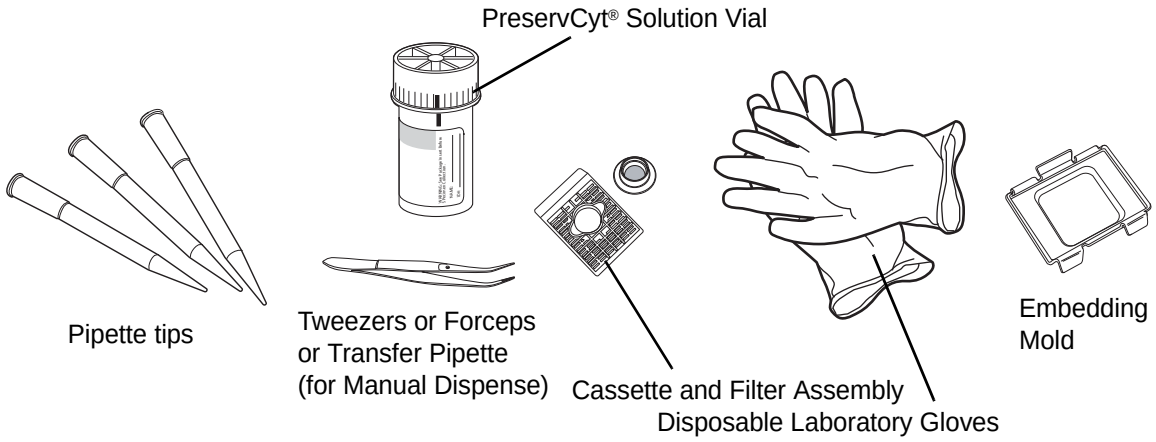


Figure 3-1 Materials Required for Operation

The **PreservCyt® Solution with sample** is a plastic vial that contains an alcohol-based preservative solution that preserves non-gynecologic cells for up to three weeks at room temperature.

CAUTION
All disposables are for single use only and should not be reused.

The **cassette** is a plastic container that, when placed (with the filter assembly) in the processor, will collect the cellular material of the processed cell block.

The sample **filter assembly** is a disposable filter assembly that is placed in the cassette prior to cell block processing. It is discarded when the cell block is removed from the processor.

Forceps, tweezers or transfer pipette are used to place the sample into the sample cassette when loading the processor for manual dispense mode.

Note: Must be cleaned between samples.

Pipette tips are used for application of sample material, reagents and paraffin, during the cell block process. The processor automatically places the tips in a waste bin, for the operator to discard later.

Note: Pipette tips used on the Cellient processor are pre-cleaned before being shipped. This is to reduce scratching artifacts when cutting the cell blocks. Keep the pipette tips sealed in their plastic bag until use.

Disposable laboratory gloves - As with all laboratory procedures, universal precautions should be followed.

The **embedding mold** is a tray filled with paraffin. The cell block is embedded in the paraffin in preparation for sectioning.

CAUTION
Do not substitute dehydrating, clearing, staining or paraffin agents other than those listed above.

Reagents: the following reagents are required to be loaded in the processor prior to processing a sample:

- Isopropyl alcohol, 99.8% (a.k.a. isopropanol or 2-propanol), various manufacturers, 900 ml maximum - do not overfill
- Xylenes, 98.5% minimum (xylene isomers and ethyl benzene), various manufacturers, 900 ml maximum - do not overfill

  Note: The performance of the instrument using recycled alcohol, recycled xylene or xylene substitute has not been evaluated.
- PROTOCOL Eosin Y Intensified stain, #23-314-630 or -631 Fisher Scientific, 200 ml maximum - do not overfill

Paraffin: Paraplast X-tra® paraffin must be present and molten in the paraffin reservoir.

SECTION C PREPARING THE CASSETTE AND FILTER ASSEMBLY FOR PROCESSING

Prior to processing a cell block, fit the cassette and filter assembly together. Note that there is a sample loading side and a vacuum side to each piece. See Figure 3-2 and Figure 3-3.

Note: If you are using a cassette printer, print the cassettes before fitting the filter assembly on.

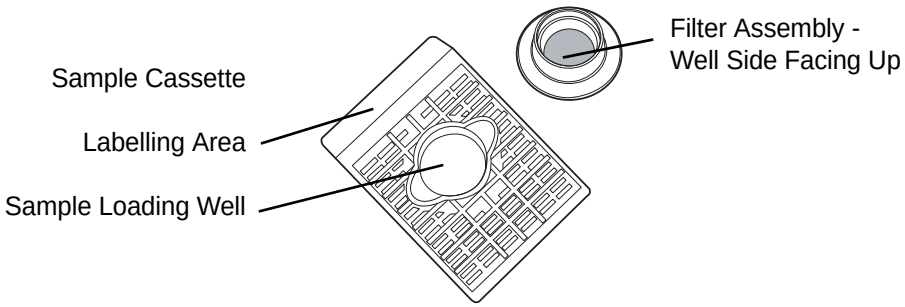


Figure 3-2 Cassette and Filter Assembly - Sample Loading Side

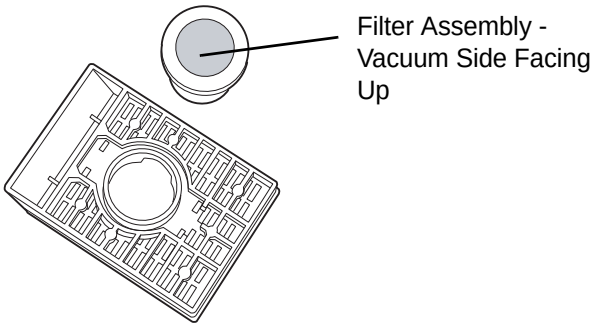


Figure 3-3 Cassette and Filter Assembly - Vacuum Side

Press the filter assembly firmly into the vacuum side of the cassette. Make sure it is flat against the cassette body (not cocked or uneven). See Figure 3-4.

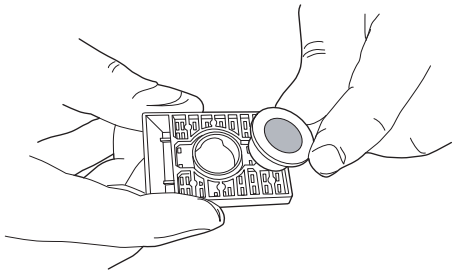


Figure 3-4 Press Filter Assembly Onto Cassette - Vacuum Side

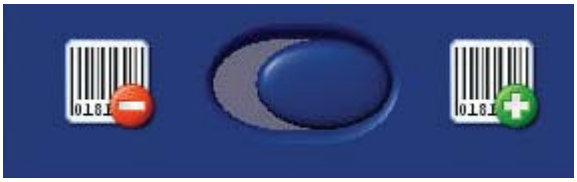
SECTION D

PROCESSING STEPS

Accession ID

Before beginning to process a cell block, select **User Preferences** - Select Accession ID On/Off. (This may already be set up during equipment installation. It can be changed before any sample is processed.)

User Preferences Tab



Select Accession ID

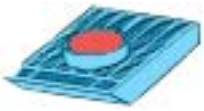
Off ⇦ ⇨ On

Select Accession ID ON  if you plan to enter an accession ID for the sample, either manually typing it in, or using a barcode scanner.

Select Accession ID OFF if you do not wish to enter an ID number into the cell block history log.

Manual/Auto Sample Dispense

From the main processing screen, select whether the sample dispense will be manual or automated.



Processing Screen Tab

Select Manual or Auto Sample Dispense

Manual ⇦ ⇨ Auto

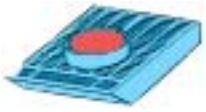
Figure 3-5 Select Manual or Auto Dispense Mode

Automated means that the sample will be aspirated directly from the PreservCyt Solution vial by the processor during cell block processing.

Manual (or partially automated) means that the pellet or sample fragments will be loaded into the cassette holder by the Operator. Further sample will then be automatically aspirated from the PreservCyt Solution vial during cell block processing.

Be sure to read and understand "Notes on using the Manual Dispense Mode:" on page 1.4.

Eosin Stain On/Off



Processing Screen Tab

Select Eosin Stain

Off ⇦ ⇨ On

Figure 3-6 Select Eosin Stain On or Off Mode

Prior to processing a cell block, the user may choose to have Eosin stain dispensed into the sample or not. Move the selection button to the right to select Eosin stain On. Move the selection button to the left to select Eosin stain Off.

Load Consumables and Sample Vial

Open the process compartment door and load one sample pipette tip, two paraffin pipette tips, the PreservCyt® Solution vial and a cassette and filter assembly. Refer to the following figures.

A PreservCyt Solution vial must be loaded for both the automated and manual dispense modes.

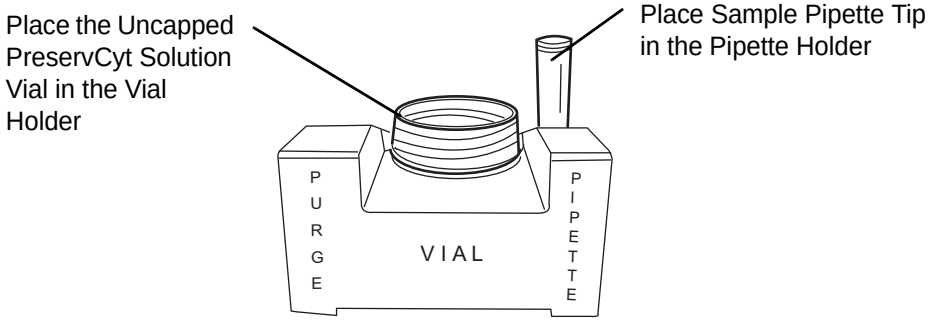
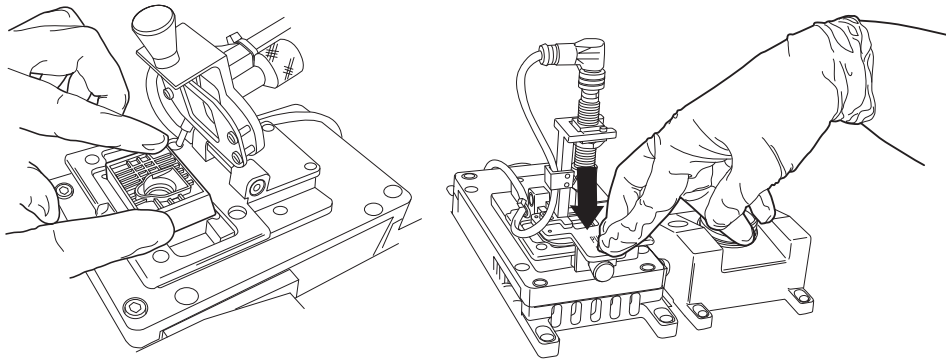


Figure 3-7 Load Sample Vial and Sample Pipette Tip

Note: The capped PreservCyt Solution vial should be gently inverted, swirled or agitated and then uncapped prior to loading into the vial holder. This will help keep sample well dispersed in the solution.

CAUTION:
Only load the cassette into the cassette holder just before processing.
Leaving the cassette in the holder longer than 10 minutes may cause it to deform and result in a poor cell block.



Load the Cassette/Filter Assembly into the Cassette Holder. Load the Assembly with the Filter Side Down.

Securely Latch the Cassette Holder by Pressing Straight down.

Figure 3-8 Load the Cassette/Filter Assembly into the Cassette Holder

The amber light at the top of the sample level sensor is on when the cassette holder is in the closed position and a cassette is in place. It is off when a cassette is absent in the holder or if the holder is open. If the light is red, the sensor might be clogged or obstructed. See Clean Sample Level Sensor on page 4.7.

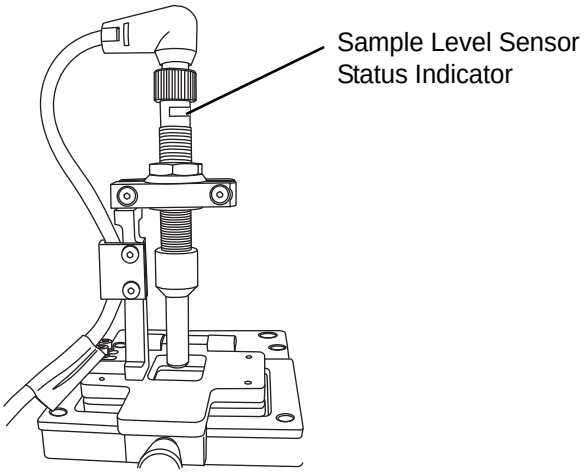


Figure 3-9 Sample Level Sensor (Closed Position)

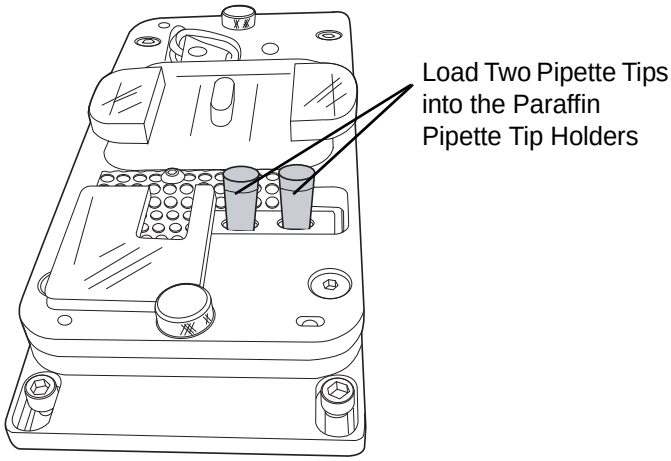


Figure 3-10 Load Paraffin Pipette Tips at Paraffin Reservoir

Begin: Press the Process Button

Close the all the doors and press the Process button. 

If **Accession ID** is selected as On, a keyboard will be displayed, for entry of an accession number. See Figure 3-11.

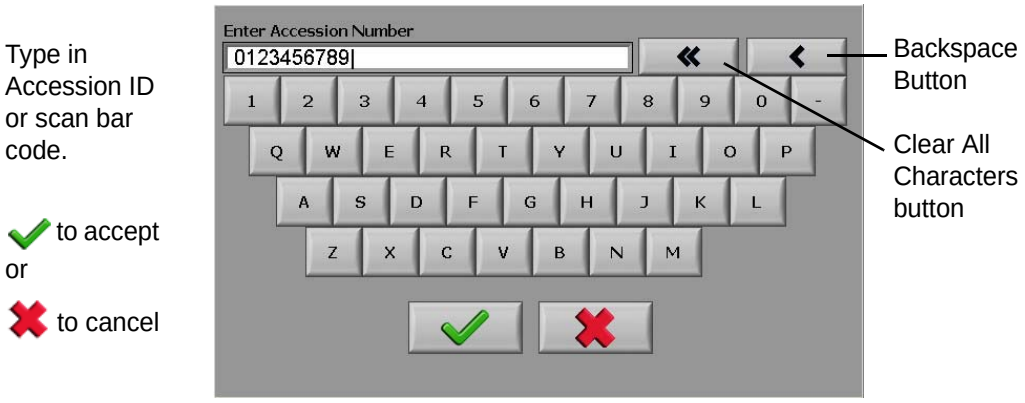


Figure 3-11 Accession ID Entry Display

An ID number may be entered manually by touching the correct letters and numbers on the display, or a barcode scanner may be used.

If a bar code scanner is used, scan the accession ID now.

Note: The bar code scanner is another manufacturer's product. Please refer to the documents that came with it for specifications, operation, safety and maintenance.

The accession ID may be 0 to 32 characters long, alpha-numeric. Bar Code 128 symbology will be accepted if a scanner is being used.

The accession number is stored in the history log with any other information the processor may record about that cell block. (Refer to page 3.17, history log.)

After an accession number has been entered, press the OK button to proceed.

To cancel the Accession ID screen press the cancel button to return to the Main screen display.

A message prompt displays: "Please load consumables: tips, cassette and sample vial".

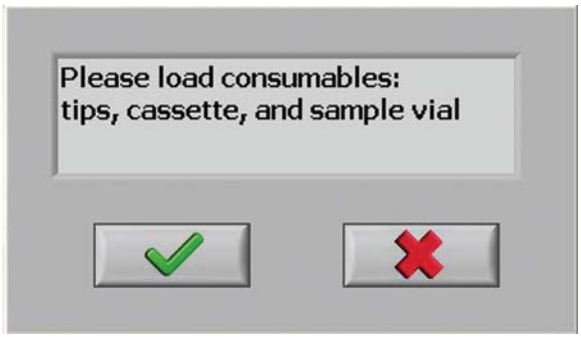


Figure 3-12 Load Consumables Message

If these items are already loaded, press the OK button ✔ to proceed. The doors will lock.

If these items are not loaded, open the doors and load items into the process compartment.

Pretest

After pressing the Process button, the processor will perform a pretest of the system.

- It will scan for the presence of sample and paraffin pipette tips and a sample vial.

WARNING
Moving Parts

- It will monitor that there are sufficient quantities of isopropanol, xylene and eosin to process a cell block.
- Checks of the main system functions are made.
- A waste cycle will run, to empty the waste chamber.

If all the components are present, the processor will begin processing, starting with an initialization step.

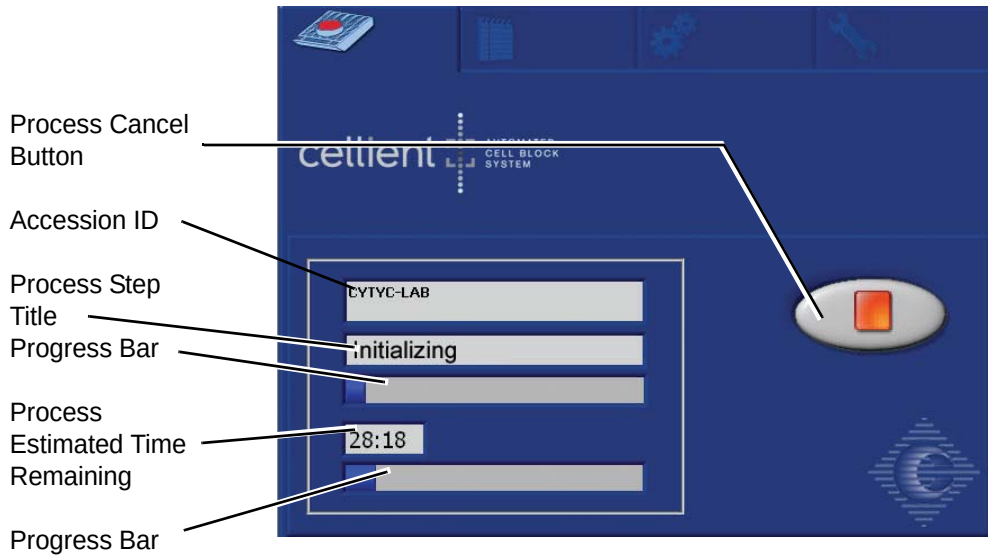


Figure 3-13 Processing Screen

Dispense Sample

Manual Sample Dispense Mode

If Manual Dispense mode has been selected, the processor will pause and unlock the doors. A message "Manually load selected sample into cassette well, then replace the vial into the holder and click the OK button" is displayed. See Figure 3-14.

Figure 3-14 Load Sample Manually Message

This prompts the operator to place the pellet or tissue fragments into the well of the cassette assembly and place the PreservCyt Solution vial into the vial holder. The cassette holder may be opened while placing the sample fragments in the cassette well. Once the sample fragments are placed in the cassette well, re-close the holder and press the OK button ✔ to proceed. The doors will lock

and the processor will draw any further sample required directly from the PreservCyt Solution vial, as described in Auto Sample Dispense Mode, below.

Note: Tissue sample size should be less than 1.6 mm in diameter or 14g ID.

Auto Sample Dispense Mode

If Auto Dispense is selected, the processor will automatically aspirate a specific amount of sample from the PreservCyt Solution vial without any operator assistance.

The pipetted sample is dispensed into the cassette well. A gentle vacuum is applied. More sample is dispensed and suctioned, as needed, until a target flow of fluid through the filter is reached (meaning the filter is adequately loaded with specimen sample for a cell block).

The process step title will read “Loading Sample”.

Figure 3-15 Loading Sample

Dispense Stain (optional)

If Eosin Stain On is selected, it is dispensed, following Sample Dispense. 0.25 ml of stain is dispensed into the cassette well.

The process step title will read “Adding Stain”.

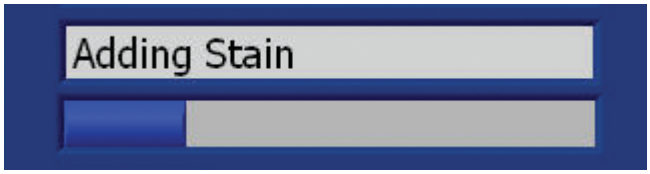


Figure 3-16 Adding Stain

Apply Dehydration Agent (Alcohol)

Isopropanol dehydrating agent is dispensed into the cassette. The sample is exposed to the reagent for a precise amount of time and then vacuum is applied to remove it from the cell block in process. The specific amount of isopropanol dehydrating agent dispensed and the amount of time the sample is exposed to

the reagent depends on whether Manual Sample Dispense or Auto Sample Dispense is selected.

The process step title will read “Processing in alcohol”.

Figure 3-17

Apply Clearing Agent (Xylene)

Xylene clearing agent is dispensed into the cassette. The sample is exposed to the reagent for a precise amount of time and then vacuum is applied to remove it from the cell block in process. The specific amount of xylene dehydrating agent dispensed and the amount of time the sample is exposed to the reagent depends on whether Manual Sample Dispense or Auto Sample Dispense is selected.

The process step title will read “Processing in xylene”.

Figure 3-18

Paraffin Infusion

The sample is heated to the system high temperature set point. Melted paraffin is dispensed onto the sample and vacuum is gently applied to draw paraffin through the cell block and fill the cassette well.

The sample is then cooled to the system low temperature set point. The cell block hardens for 10 minutes at the cooled temperature; the door locks disengage and the cell block may be removed from the processor.

Figure 3-19

At the end of the cooling time, the processor will give an audible beep, to indicate that the cell block processing has completed.

Remove Cell Block from the Processor

Remove the cassette from the cassette holder. The operator must acknowledge the cell block has been removed by touching the OK button.

Note: Remove the cassette first and then press the OK button.

Figure 3-20 Remove Completed Block

CAUTION: *Once the cassette is removed from the processor, IMMEDIATELY remove the filter.* See the next section for the procedure.

SECTION E

REMOVE THE FILTER ASSEMBLY FROM THE CELL BLOCK

WARNING: Cold Surface. Adhere to manufacturer's recommendations for proper use of freeze spray.

After processing a cell block, the filter assembly must be removed. To aid the release of the filter assembly from the cassette, chill the cell block:

- Use freeze spray on the metal disk of the filter assembly (Figure 3-21). Place the cassette filter side up on a clean, flat surface. Hold the freeze spray nozzle 2 - 5 cm from the metal disk of the filter assembly and spray for 3 - 5 seconds.

OR

- Place in a -20°C freezer for 5 minutes

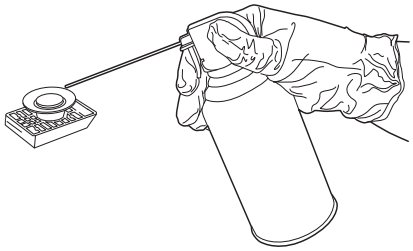
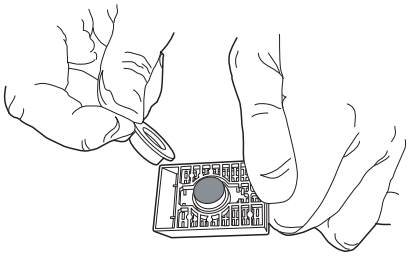


Figure 3-21 Use Freeze Spray to Chill the Cell Block

To remove the filter, very gently pull the filter assembly off the cassette. The filter will lift off of the cell block. Discard the filter assembly. See Figure 3-22.



Lift Off Filter and Discard

Figure 3-22 Remove Filter Assembly From Cell Block

Let the cassette stand at room temperature for at least 60 seconds before placing it into the embedding mold on the Finishing Station.

SECTION F

EMBED CELL BLOCK IN PARAFFIN

The Finishing Station embeds the cell block in paraffin. Turn on the Finishing Station if it is not on already.

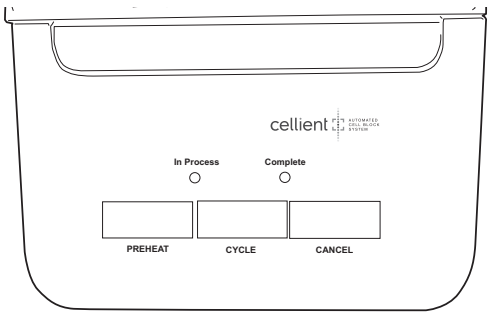


Figure 3-23 Finishing Station Control Panel

Make sure the embedding mold is clean.

Note: Use of an embedding mold release solution is not required, but it may be applied if the laboratory prefers to use it. If a release agent is used, make sure the embedding mold is allowed to dry thoroughly before use.

Note: Embedding molds that are not used immediately should be kept covered or otherwise dust-free until they are used. This reduces the likelihood of debris appearing in the finished cell block.

CAUTION:
Use the Hologic-supplied stainless steel embedding molds.

Remove the paraffin square from the clear plastic transport mold, by peeling off the protective seal and gently popping it out of the mold.

Place the paraffin into the embedding mold.

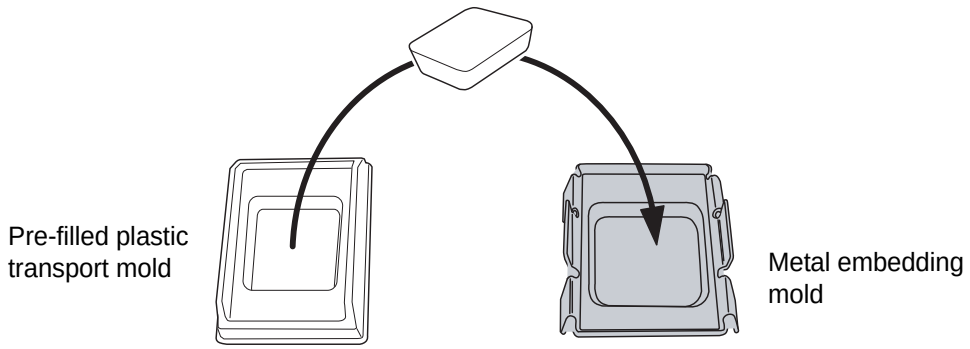


Figure 3-24 Place Paraffin in Embedding Mold

Place the metal embedding mold on the Finishing Station plate and press the Preheat button, to begin melting the paraffin. The door must be closed (it will latch during heating). When the unit has heated the paraffin sufficiently to melt it and bring it to the correct temperature for finishing the cell block, the unit will beep and the door will unlatch. This will take approximately 7 minutes.

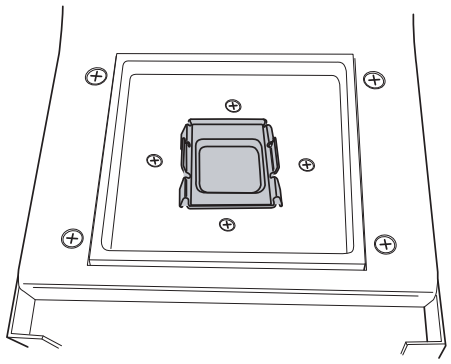


Figure 3-25 Melt Paraffin on Finishing Station Process Plate

Confirm that the paraffin is completely melted. Let it continue to melt, if needed. The In Process and Complete LEDs blink alternately. Introduce the cassette to the embedding mold by fitting one end into the mold and gently lowering the cassette until it is fully inserted into the mold. (Avoid creating air bubbles between the paraffin and the sample.)

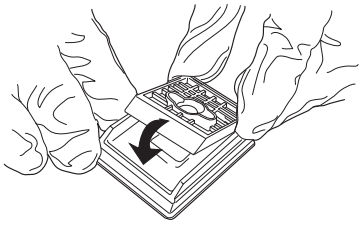


Figure 3-26 Place Cassette in Embedding Mold

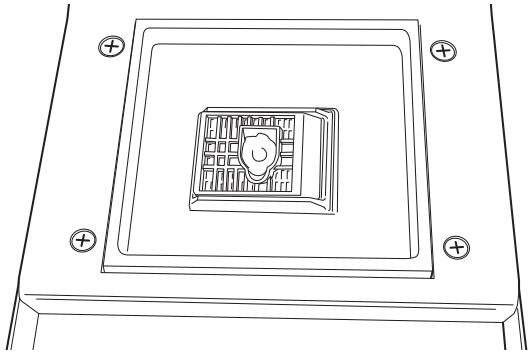


Figure 3-27 Embedding Mold on Finishing Station

Close the door. Press the Cycle button and let the embedding cycle run. (The door will latch.) At the end of the cycle, there is a 10 second long beep, the door unlatches and the Complete LED flashes.

Gently remove the cassette from the embedding mold.

Note: At the end of an embedding cycle, the process plate remains cold and the unit continues to beep every 10 minutes up to 1 hour or until Preheat or Cancel is pressed. (After 1 hour the process plate returns to ambient temp.)

- If another block is ready for embedding, add another paraffin plug into an embedding mold, place it on the process plate, close the door and press the Preheat button to begin heating the plate.
- If another block will be ready for embedding soon but not immediately, press the Cancel button to let the plate return to ambient temperature.

Refer to Chapter 8, Finishing Station for further information regarding the Finishing Station.

SECTION G

HISTORY LOG - VIEW AND DOWNLOAD

The Cellient System keeps a history log of each cell block that is run on the processor - even those that are begun and then not finished, due to error or operator cancel. The most recent 5,000 events are retained and the display allows the user to view and scroll through the list of events.

Touch the Logs Screen icon to view the History log. 

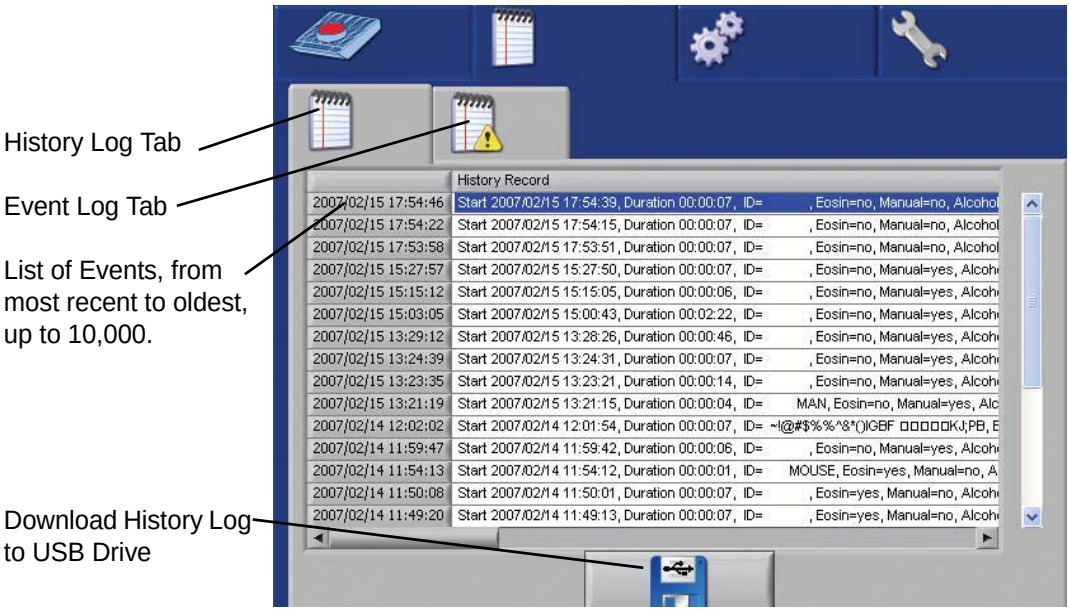


Figure 3-28 History Log Display

The History log captures the following properties of a cell block process:

- Time & Date
- Start time
- Duration
- Accession ID (if used)
- Eosin On or Off
- Manual or Auto dispense mode
- Volume of isopropanol loaded

- Volume of xylene loaded
- Paraffin infusion time
- Total volume of sample loaded
- Any errors encountered

To download the history log, attach a USB drive to the port located next to the pipette tip waste bin (see Figure 1-6) and press the Download USB icon. The file is written to the drive with a title of: "Processor name Date Time - History.csv". For instance, "HologicLab200612081020-History.csv". CSV stands for comma separated value.

The file can be renamed once it has been downloaded.

SECTION H EVENT LOG - VIEW AND DOWNLOAD

The Cellient® System logs the last 10,000 error events encountered, beginning with the most recent. This display allows the user to view and scroll through the list of events.

Note: The event log is in English only.

Touch the Event Log icon to view the Event log. 

The event log captures the following properties:

- Error event number and description (4-5xxx)
- Info - block status, processor status (4-8xxx)
- Note - Field Service note (4-0000)

To download the event log, attach a USB drive to the port located next to the pipette tip waste bin (see Figure 1-6) and press the Download USB icon. The file is written to the drive with a title of: "Processor name Date Time - Event.csv". For instance, "HologicLab200612081020-Event.csv". CSV stands for comma separated value.

The file can be renamed once it has been downloaded.

4. Maintenance

Chapter Four

Maintenance

SECTION A OVERVIEW

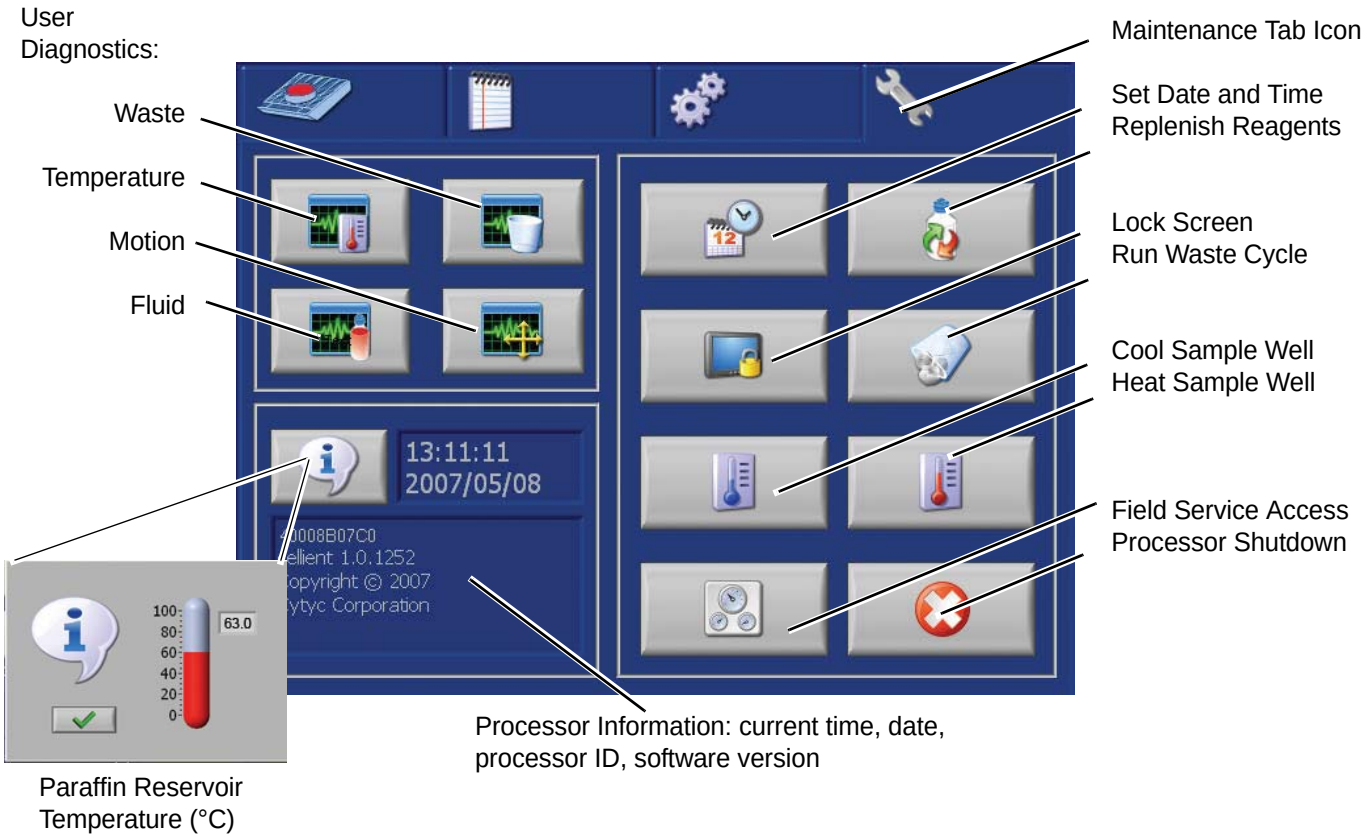


Figure 4-1 The Maintenance Screen

This chapter contains routine maintenance procedures for the Cellient Processor and describes other processor functions that are accessed from the Maintenance screen.

Routine Maintenance

Daily	Paraffin Temperature
	Empty pipette tip waste bin
	Wipe spills
	Check reagent solution volumes (25 ml minimum of Eosin, 100 ml of isopropanol and xylene)
	Clean sample well of residual paraffin
Weekly	Empty the waste collection tank (or sooner if indicated by the processor)
	Clean metal embedding molds
	Clean sample level sensor
Yearly	Change charcoal filter (if it is being used)
As Needed	General cleaning
	Replenish reagents
	Run waste cycle
	Change paraffin in the reservoir (clean reservoir before replenishing with wax)

Other Maintenance Screen Functions

- Set Time and Date
- Heat Sample Well
- Cool Sample Well
- Field Service Access
- User Diagnostics
- View Paraffin Reservoir Temperature
- Processor Shutdown

Cellient® Processor

Routine Maintenance for the month of: _____

	Daily					Weekly			Yearly	As Needed			
DATE	Paraffin Temp.	Empty pipette tip waste bin	Wipe spills	Check reagent solution volumes	Clean sample well of paraffin	Empty waste collec-tion tank	Clean metal embed-ding molds	Clean sample level sensor	Change charcoal filter (if one is used)	General cleaning	Replen-ish reagents	Run waste cycle	Change paraffin in the reservoir
	page 4.1	page 4.4	page 4.9	page 4.10	page 4.4	page 4.6	page 4.12	page 4.7	page 4.8	page 4.9	page 4.10	page 4.11	page 4.8
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SECTION B EMPTY PIPETTE TIP WASTE BIN

Check the pipette tip waste bin daily. Empty the bin before it gets too full - no more than 10 blocks (30 discarded tips) maximum. A full waste bin can block movement of the delivery arm.

Pipette tips may be disposed of in your laboratory refuse. The waste bin may be cleaned out with soap and water. Hot water may help loosen any residual paraffin.

Note: Lining the bottom of the bin with a paper towel will help prevent build up of residual paraffin in the bin. This can reduce the likelihood of delivery arm movement errors.

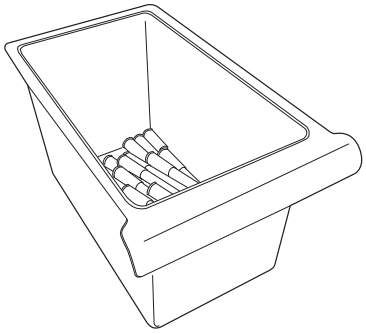


Figure 4-2 Pipette Tip Waste Bin

SECTION C CLEAN SAMPLE WELL OF RESIDUAL PARAFFIN

Paraffin may build up around the bottom of the cassette holder area. Clean the paraffin off regularly to ensure cassettes don't stick to the well, or sit unevenly in the well. The Heat Sample Well button will heat the well to the system high temperature set point. Then any paraffin build up may be wiped off with a Kimwipe® or a lint-free cloth.

Touch the heat button to activate.

The following message will be displayed:

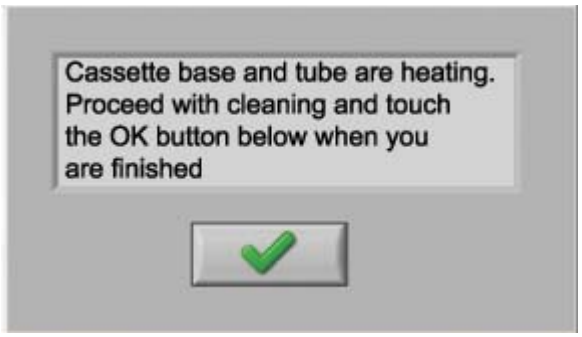


Figure 4-3 Heat Sample Well Message

CAUTION:
Hot surface

Clean the interior of the sample well. See Figure 4-4. Use caution, as the surfaces of the cassette base and tube are hot.

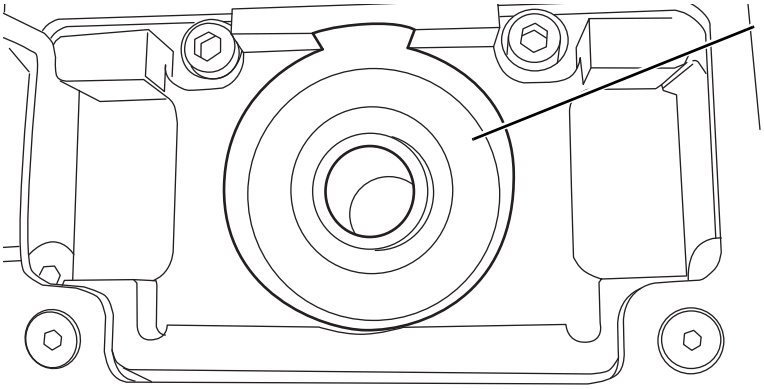


Figure 4-4 Clean Sample Well

SECTION D

EMPTY THE WASTE COLLECTION TANK

The waste collection tank, located in the waste compartment, has a volume of 4 liters and the user is alerted when the tank is two-thirds full. It must be emptied when the Waste Tank Full alert icon appears on the main display. Figure 4-5.

Figure 4-5 Waste Tank Full Alert

The processor will not run any more cell blocks until the tank has been emptied.

WARNING
Poisonous Substances
Flammable Liquids

Refer to manufacturers' MSDS for more information

Open the waste compartment door. The lower end of the waste chamber fits into the neck of the waste tank opening. Turn the lever on the waste chamber outward, to release contact with the waste tank. See Figure 4-6.

Carefully remove the waste collection tank. Screw the lid onto the container to prevent any spills.

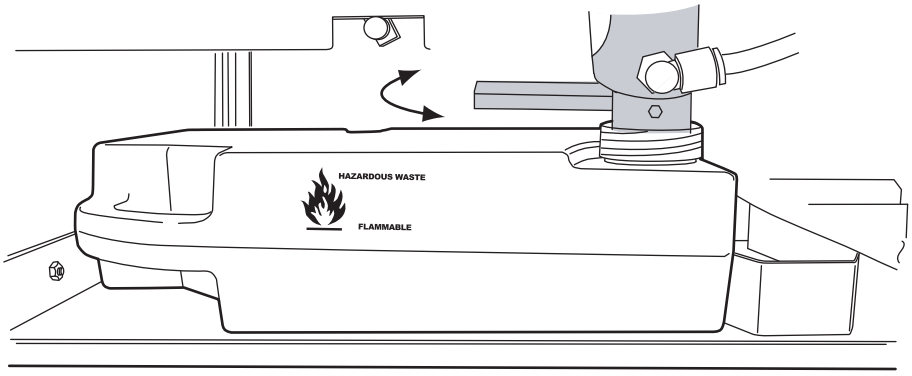


Figure 4-6 Remove/Replace Waste Collection Tank

Dispose of the contents of the waste collection tank according to local, state, provincial and federal or county guidelines.

When placing the waste tank into the processor, be sure that the waste chamber outlet is positioned into the neck of the waste tank opening. Turn the lever of the waste valve inward, to engage with the waste tank.

Note: When the waste collection tank is not present in the waste compartment, an alert icon will appear on the main processing screen:

Figure 4-7 Waste Tank Missing Icon

The processor will not process a cell block until the waste tank is present. Place the waste tank into the processor if it is not loaded. If the waste tank is loaded, gently pull it out and put it back in again, to ensure that it has contacted the sensor at the rear of the waste compartment.

Make sure the waste valve lever is engaged.

SECTION E CLEAN SAMPLE LEVEL SENSOR

The lower end of the sample level sensor should be cleaned regularly. Be careful not to clog the nozzle in attempting to clean it.

Important:

Do not use wipes or swabs that will leave any shredded material inside the sensor.

CAUTION: Do not insert further than the length of the swab head.

Open the cassette holder and tilt it back to expose the bottom part of sample level sensor. Moisten a kimwipe or lint free cloth with alcohol and wipe the outside surface of the level sensor.

Moisten a lint-free swab or a kimwipe twisted into a swab with alcohol and gently insert it into the opening of the level sensor with a twisting motion to clean the inside of the lower part of the sensor. DO NOT insert further than the length of the swab head.

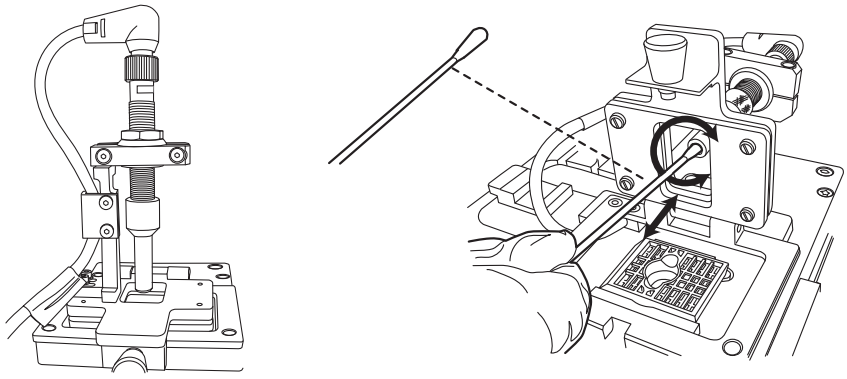


Figure 4-8 Clean the Sample Level Sensor

Allow the alcohol to dry thoroughly (5-10 minutes) before using the Cellient Processor.

SECTION F CLEAN OUT PARAFFIN RESERVOIR

WARNING:
Hot Surfaces
Hot Paraffin

The reservoir may be cleaned out as needed. It should be cleaned out prior to replenishing with new paraffin, to remove any debris that might be present. The paraffin can be suctioned out while still melted, using a large syringe or transfer pipette. Place the paraffin in a receptacle that will be thrown out. Allow the discarded paraffin to solidify and then dispose of in your laboratory refuse.

The reservoir may be cleaned out with xylene, if desired.

SECTION G CHANGE CHARCOAL FILTER

If the Cellient Processor is not connected to a fume hood and the charcoal filter is being used to filter exhaust fumes from the interior of the processor, the filter can be removed and replaced on a yearly basis. Be sure to have a replacement filter available before removing the old one.

The filter is accessed from the rear of the processor (refer to Figure 1-3).

1. Unscrew the thumbscrews that hold the access cover in place. Set it aside. (Refer to Figure 4-9.)

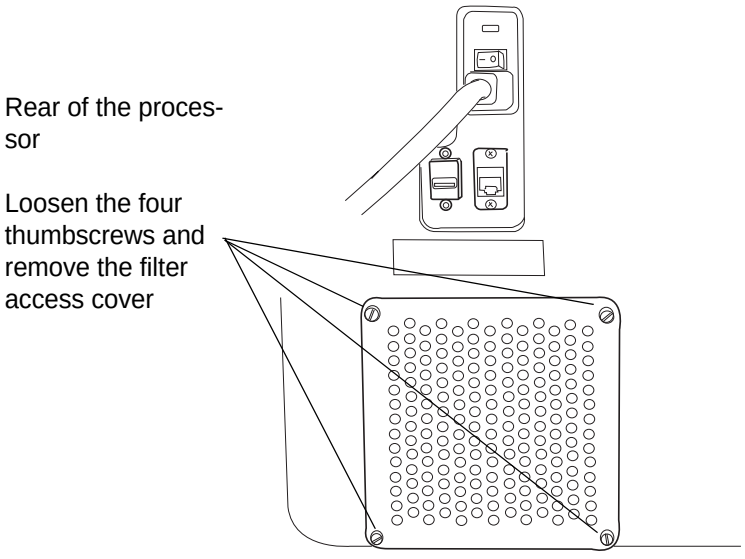


Figure 4-9 Remove the Filter Access Cover

2. Pull the charcoal filter out of the processor. Note that the top of the filter has a label, with arrows indicating the direction of the air flow through the unit. The arrows point outward, toward the rear of the processor. (Refer to Figure 4-10).

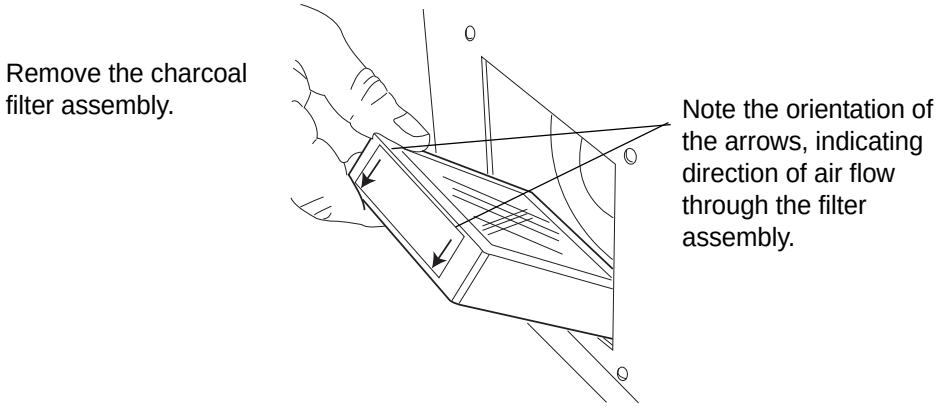


Figure 4-10 Remove the Charcoal Filter

3. Place the new charcoal filter into the processor. Orient it so that the arrows indicating air flow point outward, toward the rear of the processor.
4. Replace the access cover and tighten the thumbscrews, finger tight.

The old charcoal filter may be disposed of in your laboratory refuse.

SECTION H

GENERAL CLEANING

The exterior of the Cellient® Processor may be wiped down as needed with a lint-free wipe dampened with water. DO NOT use xylene on the processor doors, the material is not xylene resistant.

Touch Screen User Interface

The touch screen display can be locked for cleaning purposes. The screen will be rendered inactive for 60 seconds. To lock the screen, touch the icon for the Maintenance screen and press the Lock Screen button, shown below.

Maintenance Tab Icon

Lock Screen Button

Figure 4-11 Lock Screen Button

As soon the Lock Screen button has been pressed, the user interface is inactive for 60 seconds. During that time, the touch screen may be gently cleaned with soap and water and a damp cloth. A display shows the seconds remaining until the interface is interactive again.

Interior

The interior may be cleaned as needed with soap and water.

WARNING
Hot surfaces
Hot Paraffin

Caution the area around the paraffin reservoir, the cassette holder and near the liquid waste chamber may be hot. Allow the cassette holder and waste chamber to cool adequately before cleaning that area.

SECTION I

REPLENISH REAGENTS

WARNING
Poisonous Substances
Flammable Liquids

If the volume of the isopropanol or xylene gets below 100 ml, or the eosin gets below 25 ml, an alert icon will appear on the main processing display:

Figure 4-12 Reagent Low Icons

One or more of the icons may be displayed at once. The processor will not process a cell block until the low reagent condition has been addressed.

Press the Maintenance Tab icon and then touch the Change Reagents button. This will allow the processor to disable the pressure on the xylene and eosin reagent bottles.

Maintenance Tab Icon

Change Reagents Button

Figure 4-13 Change Reagent Buttons

When the button has been touched, a message will appear, instructing you to "Remove, refill and replace the reagents. Press OK when you are done and the bottles are reconnected."

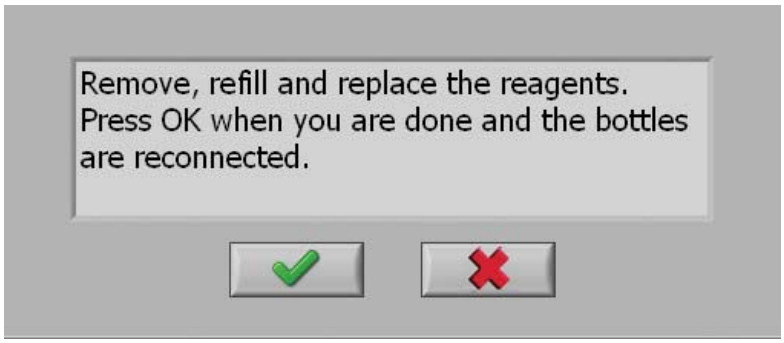


Figure 4-14 Replenish Reagents

Open the reagent compartment door and unscrew the cap of the bottle of reagent that needs replenishment. Refill the reagent bottle and place it back in the compartment well. Screw the cap on securely. Refer to Chapter 2, Section E for locations and descriptions of the reagent bottles.

Close the doors and press the OK button. ✔ The processor will prime the lines and repressurize the xylene and eosin bottles, as needed.

Note: To reduce the chance of causing an over pressure error, do not overfill the bottles beyond the max volume of 900 ml for xylene and 200 ml for eosin. Do not fill beyond the top graduation mark on the bottle.

SECTION J RUN WASTE CYCLE

The processor automatically runs a waste evacuation cycle at the start of every cell block, however a waste cycle can also be run when desired. It heats the waste chamber and valve for a couple of minutes and then opens the waste valve to allow any waste to transfer into the waste collection tank.

Run a waste cycle before removing and emptying the waste collection tank. (See Section D for emptying the waste collection tank.)

Note: If the Waste Collection Tank Full icon appears, you cannot run a waste cycle. The tank must be less than full.

To run a waste cycle, press the Run Waste Cycle button, shown below.

Figure 4-15 Run Waste Cycle Button

A progress bar and a count down display show the cycle time elapsing. It takes approximately two and a half minutes to complete.

Note:

SECTION K CLEAN METAL EMBEDDING MOLDS

As needed, clean the embedding molds:

- Soak in xylene
- Run through laboratory dishwasher
- Let dry

Note: Use of an embedding mold release solution is not required, but it may be applied if the laboratory prefers to use it. If a release agent is used, make sure the embedding mold is allowed to dry thoroughly before use.

SECTION L SET TIME AND DATE

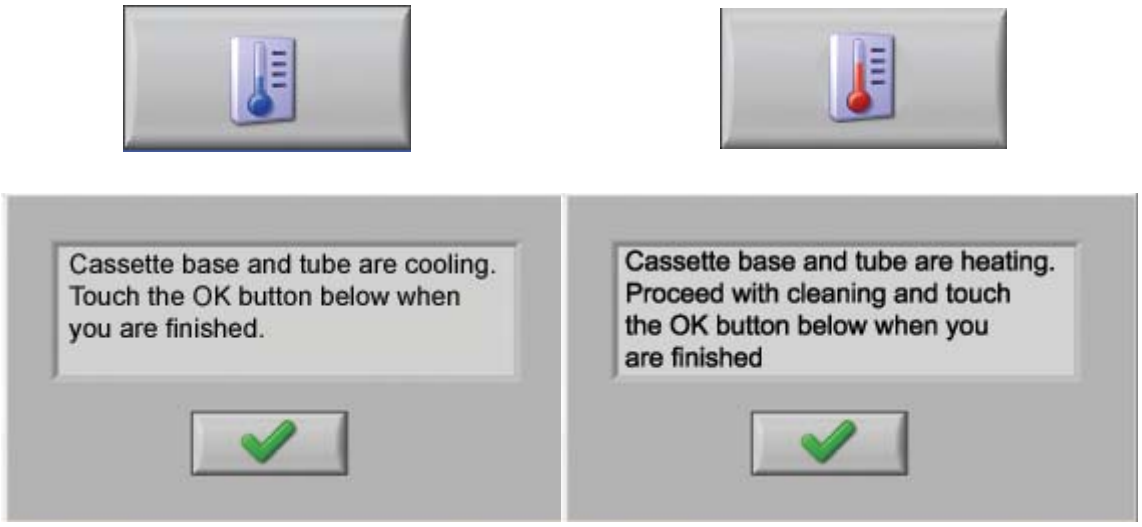
The time and date is set from the Maintenance screen. This is described in "SET TIME AND DATE" on page 4.12.

SECTION M HEAT/COOL SAMPLE WELL

The sample well can be heated or cooled independently of processing a cell block. Examples of this use are routine cleaning of the sample well of residual paraffin (see page 4.4) or repairing broken blocks (see "TROUBLESHOOTING CELL BLOCKS" on page 5.9.

To heat or cool the sample well, touch the appropriate button on the Maintenance screen. A message will display that the unit is cooling or heating.

Note: It cools to a cold set point or heats to a hot set point, and then maintains the temperature until the OK ✔ button is touched. It then returns to room temperature.



Cool Sample Well Button and Message

Heat Sample Well Button and Message

Figure 4-16 Cool and Heat Sample Well Buttons

SECTION N

FIELD SERVICE ACCESS

Figure 4-17 Field Service Access Button

The Field Service Access allows service engineers access to modules in the software used for service and repair of the Cellient processor. This is password protected and is not for general use.

SECTION O

USER DIAGNOSTICS

The four diagnostic buttons exercise the main subsystems: temperature, fluid, waste and motion control.

When run, each diagnostic operation tests the function of the subsystem it represents. The result of the test is displayed on the user interface as either pass or fail. If a test fails, a short description of the error encountered is displayed.

The result of a diagnostic test is written to the Event log.

It is not necessary to run the diagnostic tests unless you experience a persistent error, or if you are asked to do so by Hologic Technical Support.

Temperature Diagnostic

The temperature diagnostic heats the sample well to the hot set point and then cools it to the cool set point, checking that it reaches the desired values within a specified time period. After the diagnostic completes the sample well is allowed to return to ambient temperature and the processor returns to idle mode.

Press the temperature diagnostic button to begin.

Figure 4-18 Temperature Diagnostic Button

A check screen prompts for you to proceed or cancel.

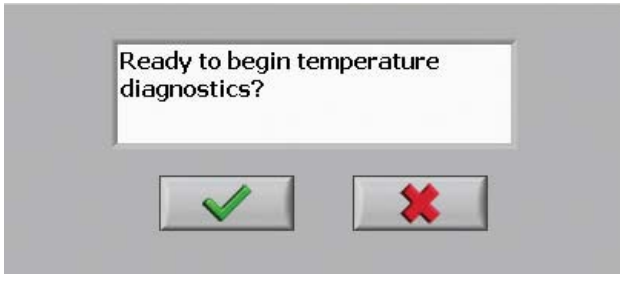


Figure 4-19 Begin Temperature Diagnostic Message

The test heats and then cools the sample well, then returns to ambient temperature. A graph of the temperature is displayed.

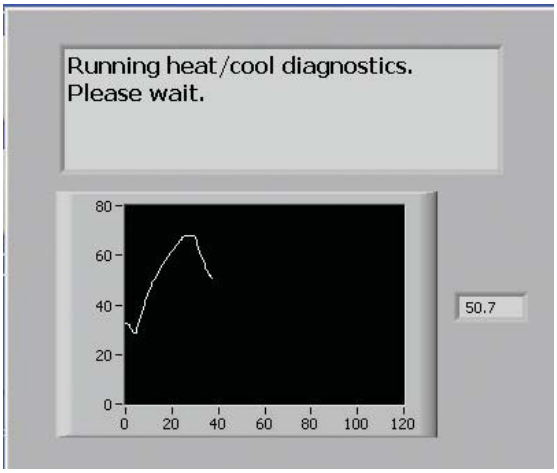


Figure 4-20 Temperature Diagnostic Display

When the test has completed, the Pass/Fail result is displayed.

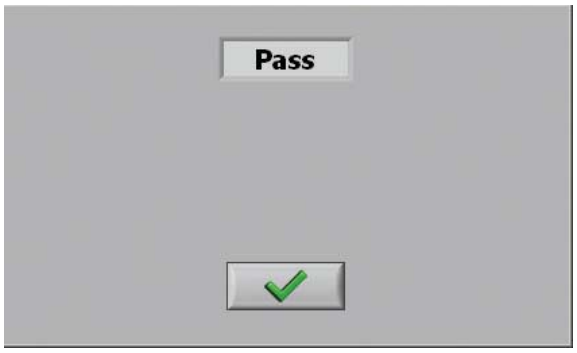


Figure 4-21 Temperature Diagnostic Pass Result

Press the OK button to return to the Maintenance screen.

If the temperature diagnostic should fail, contact Hologic Technical Support.

Waste Diagnostic

The waste diagnostic runs the waste evacuation cycle. The waste chamber and valve are heated to the system high temperature set point. Then the waste valve is opened for 10 seconds and then closed. The heat turns off and the processor returns to idle mode.

Before running the diagnostic, check to make sure the waste collection tank is present and is not full. The waste diagnostic will not run if the waste collection tank is not present or is full.

Figure 4-22 Waste Diagnostic Button

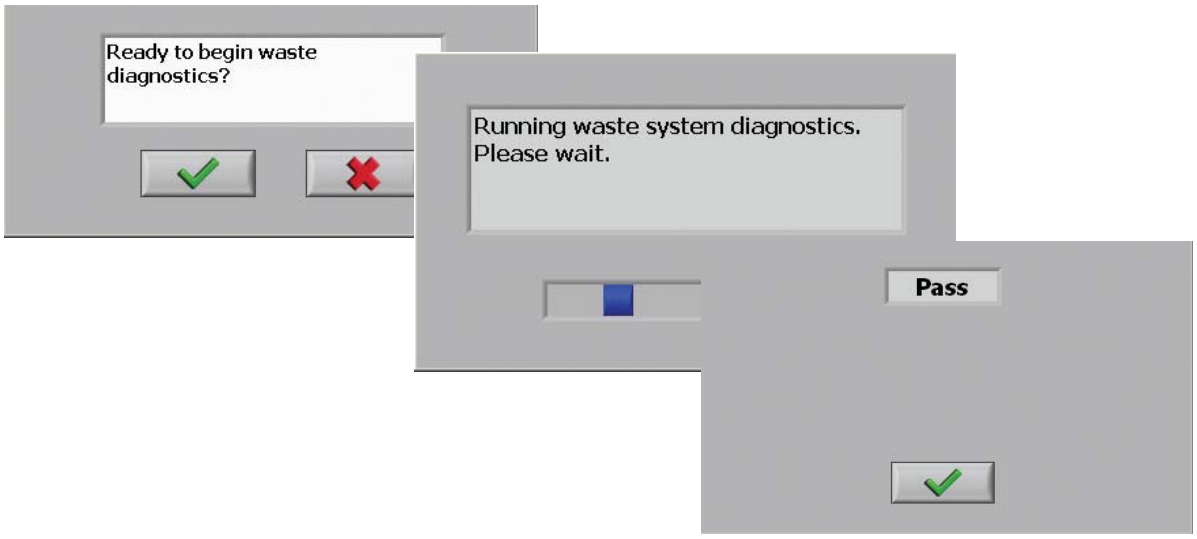


Figure 4-23 Waste Diagnostic Messages

When the test has completed, press the OK button to return to the Maintenance screen.

If the waste diagnostic should fail, contact Hologic Technical Support.

Fluid Diagnostic

The fluid diagnostic tests the reagent dispensing capability of the processor. You are prompted to load a cassette/filter assembly and a sample pipette tip. The processor then dispenses and draws down a small quantity each of isopropanol, eosin and xylene. It monitors the volume dispensed and how quickly it is pulled through the filter.

CAUTION:
Do not reuse this cassette and filter assembly on a patient sample after running the diagnostic. Single use only.

Before running the diagnostic, check to make sure the waste collection tank is present and is not full.

Figure 4-24 Fluid Diagnostic Button

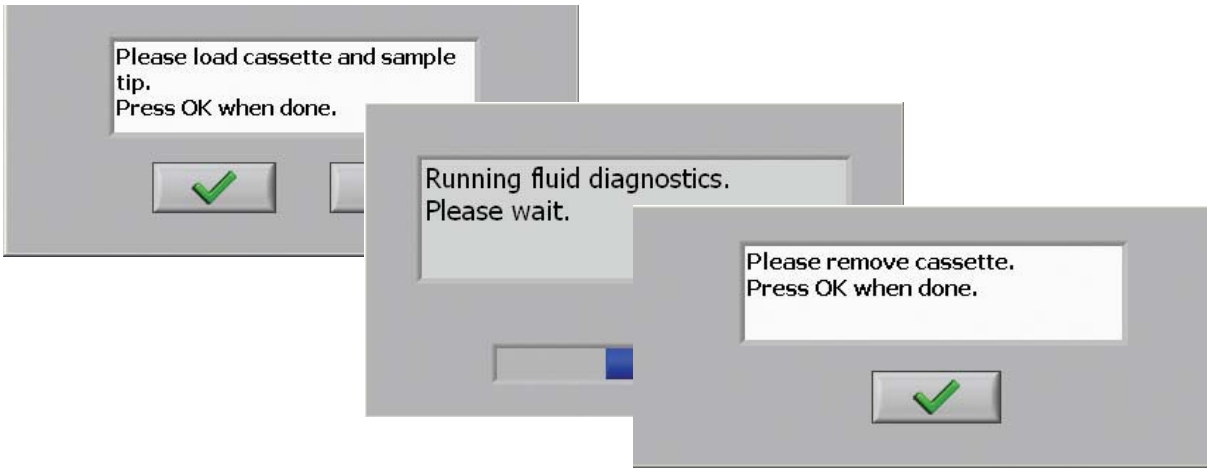


Figure 4-25 Fluid Diagnostic Messages

When the test has completed, press the OK button to return to the Maintenance screen. Remove the cassette from the cassette holder.

If the diagnostic has been run repeatedly, run a Waste Cycle to empty the waste chamber.

If the fluid diagnostic should fail, contact Hologic Technical Support.

Motion Diagnostic

The motion diagnostic tests the delivery arm range of movement and movement speed. It also checks that the syringe pump operates correctly.

Figure 4-26 Motion Diagnostic Button

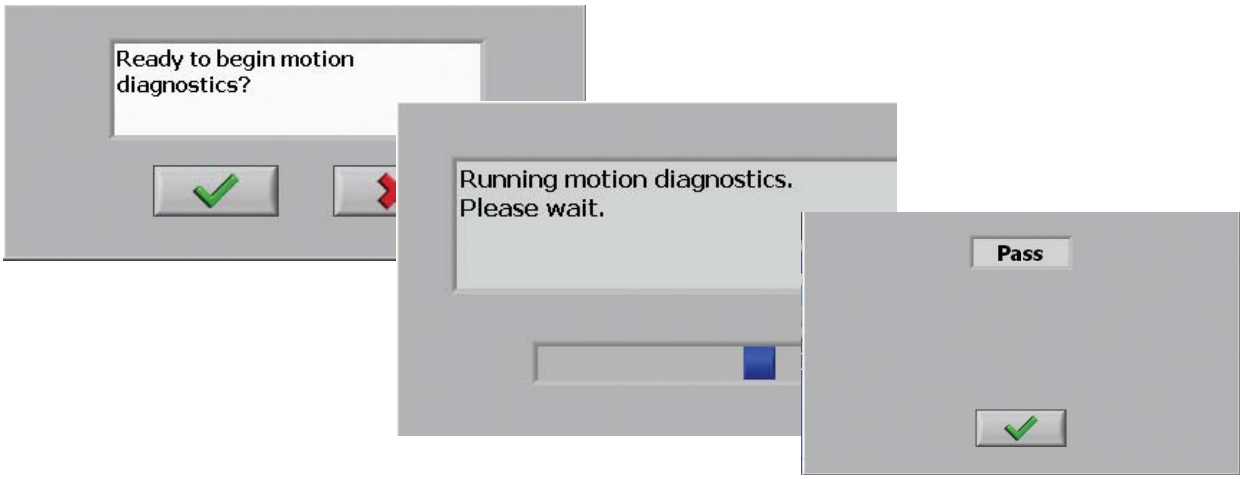


Figure 4-27 Motion Diagnostic Messages

When the test has completed, press the OK button to return to the Maintenance screen.

If the motion diagnostic should fail, contact Hologic Technical Support.

SECTION P SHUT DOWN THE PROCESSOR

CAUTION: Always shut down the processor via the User Interface. Do not turn off power to the equipment without first shutting down the application.

The Cellient processor is intended to be left on, but if it needs to be powered off, touch the Processor Shut Down button on the Maintenance screen. (See Figure 4-28.)

Figure 4-28 Processor Shut Down Button

A display prompting you to confirm shut down is displayed.

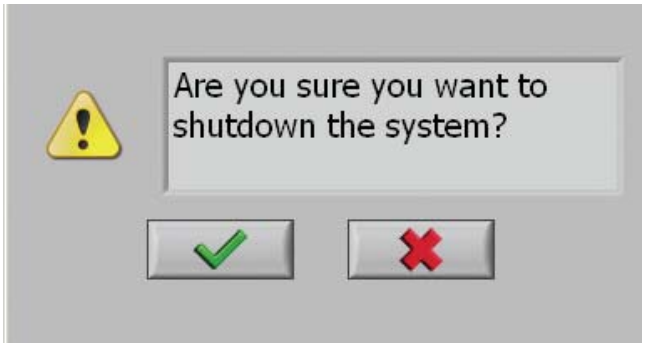


Figure 4-29 Processor Shut Down Query

To continue with shut down, press the OK button.

To cancel shut down, press the cancel button to return to the Maintenance screen.

If neither button is pressed, after 45 seconds the display returns to the Maintenance screen and the processor remains idle.

When the application has shut down, turn off the processor by pressing the rocker switch on the rear of the instrument to Off.

SECTION Q REPLACING THE USER-ACCESSIBLE FUSES

There are two user-accessible fuses located at the power switch module of the Cellient Processor (refer to Figure 1-3) and at the power switch module of the Finishing Station. If the fuses must be replaced, follow these steps:

WARNING
Instrument Fusing

Only replace with fuses of the specified type and current rating.

Refer to the Ordering Information for ordering fuses.

1. Turn off the instrument.
2. Remove the power cord from the wall outlet or power source.
3. Remove the power cord from the receptacle on the instrument.
4. Using a small #1 slotted screwdriver, carefully pry open the cover of the power entry module (Figure 4-30).

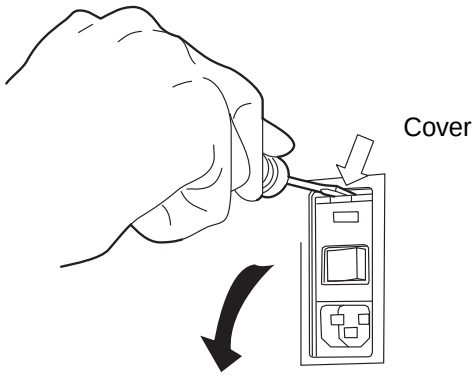


Figure 4-30 Remove Fuse Access Cover

5. Gently pull down the cover. It is hinged at the bottom end.
6. Insert the screwdriver under the fuse holder to pull it out.

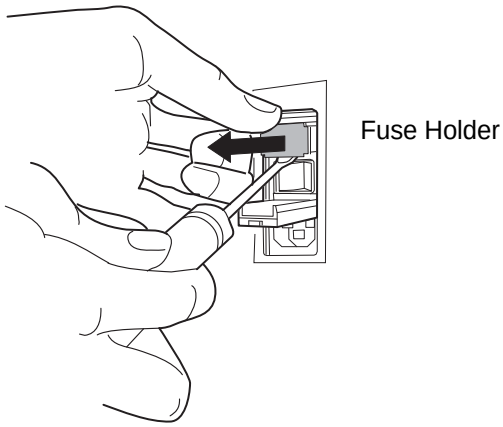


Figure 4-31 Remove the Fuse Holder

7. Remove the existing fuses and discard them.
8. Insert two new fuses into the fuse holder as shown.

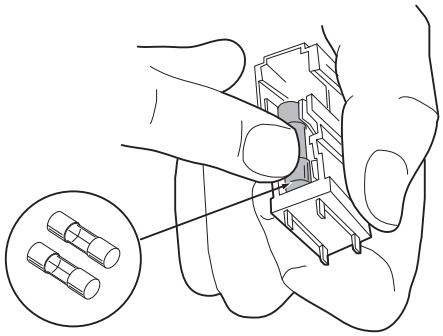


Figure 4-32 Install New Fuses

9. Insert the fuse holder back into the power entry module.
10. Close the access cover.

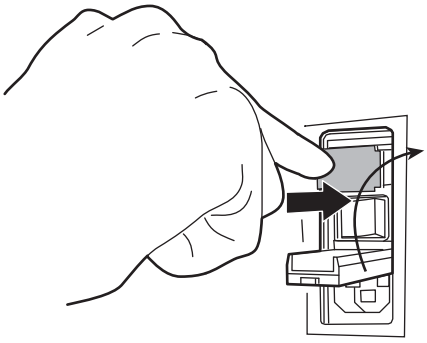


Figure 4-33 Install the Fuse Holder

11. Plug the power cord into the socket on the instrument.
12. Reattach the power cord to the wall outlet or power source.
13. Turn on the instrument.
14. If the instrument still fails to operate, contact Hologic Technical Support.

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5. Troubleshooting

Chapter Five

Troubleshooting

SECTION A OVERVIEW

If the Cellient® processor encounters an error condition prior to or during processing of a cell block, the process is halted and an alert message is displayed on the user interface. If an error condition is detected during pre-test, a cell block will not be made. If a cell block is in process, it is not completed. The processor will attempt to empty the sample well by applying vacuum, eject a pipette tip if one is loaded and return to an idle state. Note, some errors may prevent these actions. The Operator may need to manually remove the pipette tip or empty the sample well.

The error condition is logged in the History Log and the Event Log.

If the processor cannot operate, or an error persists, contact Hologic Technical Support.

SECTION B SENSOR ALERT ICONS

The processing screen displays certain icons to alert the operator to conditions that require user intervention. These conditions are monitored by the processor and the icons appear only when operator action is needed:

- Reagent low or not present
- Waste collection tank missing
- Waste collection tank full
- Processing compartment door open
- Waste compartment door open

Figure 5-1 Sensor Alert Icons

Table 5.1: Sensor Alert Icons

Icon	Sensor	Possible Cause/ Corrective Action
	Isopropanol reagent bottle	• The reagent bottle containing isopropanol has less than 100 ml and must be replenished before processing can continue. See page 4.10 for replenishing reagents. • The bottle is missing or not seated squarely in the reagent tray.
	Xylene reagent bottle	• The reagent bottle containing xylene has less than 100 ml and must be replenished before processing can continue. See page 4.10 for replenishing reagents. • The bottle is missing or not seated squarely in the reagent tray.
	Eosin reagent bottle	• The reagent bottle containing eosin has less than 25 ml and must be replenished before processing can continue. See page 4.10 for replenishing reagents. • The bottle is missing or not seated squarely in the reagent tray.
	Processing compartment door is open	The door to the processing compartment must be closed in order for the processor to run.
	Waste compartment door is open	The door to the waste compartment must be closed in order for the processor to run.
	Waste collection tank missing	The waste collection tank is missing. Replace the tank. Be sure to place it into the waste compartment so that it contacts the sensor at the back wall. Take care to align the tank opening with the waste valve.
	Waste collection tank full	The waste collection tank can contains 4 liters and alerts the user when it is 2/3 full. The processor will not run until the tank has been emptied. See page 4.6 for emptying the waste tank.

SECTION C

MAINTENANCE SCREEN DISPLAYS AT POWER UP

When the Cellient processor powers up, the Processing screen should be displayed. If the Maintenance screen is displayed, a component of the Power On Self Test (POST) has failed.

The Processing screen will not be accessible until the error has been resolved.

A message will be displayed in the information section of the screen. Normal operation is disabled. See Figure 5-2.

Figure 5-2 Power Up Error Message

- Visually inspect the processing compartment to see if there is any obvious obstruction to moving the delivery arm.
- Check to see that the waste collection tank is present in the waste compartment.
- Check that each well in the reagent compartment has a bottle present.
- Go to the Event Log and see what error number has been recorded for this event. Look up the error in the table in the next section and follow any suggested actions.

SECTION D

ERROR MESSAGES

Table 5.2: Error Messages

Error Number	Error Message	Possible Cause/Corrective Action
4-5000	User Stopped Processing.	The Stop button was pressed during processing. The processor halts the process. The cell block is not completed.
4-5001	Error picking up pipette tip or a tip was dropped during processing.	The pipette tip is missing or dropped. Check that tip(s) are loaded prior to processing. Only use pipette tips that come with the Cellient system cell block kit.
4-5002	Failed to lower fluid level in sample well. The filter is probably clogged. Please ensure that the sample was prepared correctly for Cellient processing.	Fluid flow through the sample well is too slow. Examine the sample filter for blockage. Examine the sample well for blockage. Run the Fluid Diagnostic.
4-5004	Target temperature not reached within a reasonable time.	The sample well is heating or cooling too slowly. Run the Temperature Diagnostic.
4-5005	Error communicating with motion controller.	System error moving the delivery arm. Run the Motion Diagnostic.
4-5006	Paraffin reservoir over-temperature.	Paraffin reservoir is too hot. Power off the processor and contact Hologic Support.
4-5007	Time-out operating waste valve motor.	Waste valve operation took too long. Run the Waste Diagnostic.
4-5008	Vacuum actuation time-out.	Vacuum took too long. Run the Fluid Diagnostic.
4-5009	The waste valve heater did not reach the correct temperature within the allowed time limit.	Heating the waste valve prior to evacuation took too long. Run the Waste Diagnostic.

Table 5.2: Error Messages

Error Number	Error Message	Possible Cause/Corrective Action
4-5010	A critical configuration file is missing or corrupted. Processing cannot be start. Service mode is available.	System error at start up. Contact Hologic Technical Support.
4-5011	Horizontal (X-axis) motion error - possible obstruction to the sample delivery arm.	System error moving delivery arm. Check for any obvious obstruction. Run the Motion Diagnostic.
4-5012	Vertical (Y-axis) motion error - possible obstruction to the sample delivery arm.	System error moving delivery arm. Check for any obvious obstruction. Run the Motion Diagnostic.
4-5013	One or more tips are not loaded.	Pre-test check did not find enough pipette tips. Load pipette tips.
4-5014	One or more reagents are low.	Pre-test check indicates one or more reagents are low. Replenish reagents as needed.
4-5015	Failed dispensing pre-test.	Pre-test check did not dispense the correct amount of alcohol. Visually inspect the reagent compartment. Check that the cassette holder is latched closed. Run the Fluid Diagnostic.
4-5016	Failed vacuum pre-test.	Pre-test check indicates vacuum failed. Check the cassette and see if the filter is blocked or clogged. Run the Fluid Diagnostic.
4-5017	Cassette not loaded or cassette latch open.	Examine the cassette holder and confirm that the cassette is loaded and the holder is latched closed. Make sure the sample level sensor is clean. Refer to page 4.7.
4-5018	The sample Vial is not loaded or empty.	Confirm that a PreservCyt® Solution vial containing solution is loaded and has fluid and is free of large fragments.

Table 5.2: Error Messages

Error Number	Error Message	Possible Cause/Corrective Action
4-5019	The xylene and eosin bottles are over-pressurized. Loosen then retighten the cap on either the xylene or eosin bottle. Make sure the bottles are not filled beyond the recommended maximum volume.	Loosen and retighten the caps of the xylene and eosin reagent bottles.
4-5020	Failed to lower paraffin level in sample well. The filter is probably clogged. Please ensure that the sample was prepared correctly for Cellient processing.	Paraffin could not be drawn through the sample. This may be due to a sample which has completely clogged the cassette filter or may be due to a failure of the vacuum or level sensing subsystems. Try diluting the sample to reduce the cellularity. Contact Hologic Technical Support
4-5021	Could not save log file to USB storage device - device not present - no space available - or device is write protected.	Check that a USB drive is connected to the processor and that it is not full or write-protected.
4-5022	Leak in pressurized reagent system - check stain and xylene bottle caps and connections.	The xylene and eosin reagent bottles are pressurized. Check that the caps are secure and that the tubing is connected to the manifold.
4-5023	Waste collection tank is not present.	Make sure the waste collection tank is present in the waste compartment.
4-5024	Waste collection tank is full.	Remove and empty the waste collection tank.
4-5025	Paraffin reservoir is low or temperature is not correct.	Check the paraffin level in the reservoir. Add more paraffin if necessary.
4-5026	Fluid spill or leak detected in base of system.	Liquid has been detected in the bottom of the processor. Check to see if a spill or leak has occurred.
4-5029	Doors were opened during processing when they were supposed to be locked.	Always operate the processor with the doors closed.

Table 5.2: Error Messages

Error Number	Error Message	Possible Cause/Corrective Action
4-5030	Failed diagnostic alcohol dispensing test.	Check that the alcohol bottle is present and contains at least 100 ml. Check that the cap is secure. Make sure a casette is in the holder. Contact Hologic Technical Support
4-5031	Failed diagnostic stain dispensing test.	Check that the stain bottle is present and contains at least 25 ml. Check that the cap is secure. Make sure a cassette is in the holder. Contact Hologic Technical Support
4-5032	Failed diagnostic Xylene dispensing test.	Check that the xylene bottle is present and contains at least 100 ml. Check that the cap is secure. Make sure a cassette is in the holder. Contact Hologic Technical Support
4-5033	Failed diagnostic vacuum or level sensor test.	Run the Waste Diagnostic. Check the cassette filter for blockage & replace. Re-run the Fluid Diagnostic. Contact Hologic Technical Support
4-5034	Cannot move to top Y limit sensor - either no Y motion or limit sensor failure or arm is outside limits.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support
4-5035	Cannot move to bottom Y limit sensor - either no Y motion or limit sensor failure.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support
4-5036	Cannot move to right X limit sensor - either no X motion or limit sensor failure or arm is outside limits.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support
4-5037	Cannot move to left X limit sensor - either no X motion or limit sensor failure.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support

Table 5.2: Error Messages

Error Number	Error Message	Possible Cause/Corrective Action
4-5040	X motion encoder reading does not match commanded position - encoder failure or X step size incorrect.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support
4-5041	Y motion encoder reading does not match commanded position - encoder failure or Y step size incorrect.	Check for any obvious obstruction of the delivery arm. Re-run Motion Diagnostic. Contact Hologic Technical Support
4-5042	Alcohol failed to dispense during processing. Please run the fluid diagnostics.	Check for any detached tubing to the alcohol. Run the Fluid Diagnostic.
4-5043	Xylene failed to dispense during processing. Please run the fluid diagnostics.	Check for any detached tubing to the xylene. Run the Fluid Diagnostic.

SECTION E

TROUBLESHOOTING CELL BLOCKS

Cassettes Not Seating Properly When Loaded

If the cassette does not sit evenly in the cassette holder, check that the well is free of residual paraffin build up. This should be cleaned daily. Refer to cleaning the sample well on page 4.4.

Fixing Broken or Cracked Cell Blocks

Breaks or fractures of blocks at the end of processing but before being embedded in paraffin may be due to:

- Not removing the filter assembly from the cassette within 30 seconds of spraying with freeze spray.
- Inadequate cooling/hardening of the block.
- Not enough paraffin in the block.

Check the following:

- Timely removal of the filter assembly from the cassette. Handle the blocks gently.
- A Temperature Diagnostic of the cassette well may be performed (refer to page 4.14).
- Paraffin in the cassette should be near the top of the well (within 2 mm).

Note: When removing the cell block from the processor, minor surface cracking on the face of the block may be noticed. The cracking can be caused by the cooling phase of the finishing cycle or by the rapid cooling by the freeze spray. This is considered harmless unless the integrity of the cell block is affected.

Cell Block Recovery (After Initial Paraffin Delivery)

If paraffin infusion of the cell block did not complete due to instrument error, the block may be completed on the Cellient Processor.

1. Return the cassette to the cassette holder, if it has been removed from the processor. Secure the cassette holder latch.
2. Select the Maintenance tab and press the Red Thermometer button to heat the sample well.

Maintenance Tab Icon

Heat Sample Well Button

3. Allow the paraffin to fully liquefy (observe that the molten wax is clear).
4. If necessary, add additional paraffin via pipette (should be within 2 mm of top of sample well).
   - Open the cassette holder latch.
   - Pipette more paraffin into the sample well.
   - Re-secure the cassette holder latch.
5. When the paraffin is molten, press the Blue Thermometer button to cool the cell block.

Cool Sample Well Button

6. Wait approximately 20 minutes to ensure solidification of the block.
7. Remove the cassette/filter assembly from the processor.
8. Apply freeze spray or place in -20 C freezer prior to separating the filter assembly.
9. Finish the cell block as usual.

Wax Column Separated from Cassette When Removing Filter Assembly

If the wax column comes away with the filter instead of remaining in the cassette when the filter is removed, follow this procedure to recover the cell block for finishing.

1. Reassemble the filter assembly containing the wax column to the original cassette.

Note: The cassette may or may not contain any wax.
Ensure that the original orientation of wax fragments is maintained.

2. Load the cassette/filter assembly into the Cellient® Processor cassette holder and securely latch the holder closed.
3. Select the Maintenance tab and press the Red Thermometer button to heat the sample well.

Maintenance Tab Icon

Heat Sample Well Button

4. Allow the paraffin to fully liquefy (observe that the molten wax is clear).
5. If necessary, add additional paraffin via pipette (should be within 2 mm of top of sample well).
   - Open the cassette holder latch.
   - Pipette more paraffin into the sample well.
   - Re-secure the cassette holder latch.
6. When the paraffin is molten, press the Blue Thermometer button to cool the cell block.

Cool Sample Well Button

7. Wait approximately 20 minutes to ensure solidification of the block.
8. Remove the cassette/filter assembly from the processor.
9. Apply freeze spray or place in -20 C freezer prior to separating the filter assembly.
10. Finish the cell block as usual.

Cellient® Cell Block Fractures During Sectioning

To recover a Cellient cell block that fractures during sectioning, recover the cell block on the Finishing Station. (Refer also to "EMBED CELL BLOCK IN PARAFFIN" on page 3.14.)

1. Remove the protective seal from a transport mold from the Cellient Filter Cassette Kit. Gently pop out the paraffin square and place it into the metal embedding mold.
2. Place the metal embedding mold on the Finishing Station plate and press the Preheat button, to begin melting the paraffin.
3. Let the paraffin continue to heat until it is completely melted (observe that the molten wax is clear).
4. Introduce the cassette with the fractured block into the embedding mold by fitting one end into the mold and gently lowering the cassette until it is fully inserted into the mold. Avoid creating air bubbles between the paraffin and the sample.

Note: A small amount of paraffin will overflow the edge of the mold.

5. Close the Finishing Station door.
6. Press the Cycle button and let the embedding cycle run. The unit will beep when finished and the door will unlatch.
7. Gently remove the cassette from the embedding mold.

6. Service Information

Chapter Six

Service Information

Corporate Address

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA

Business Hours

Hologic's business hours are 8:30 a.m. to 5:30 p.m. EST Monday through Friday, excluding holidays.

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours at 1-800-442-9892 Option 5.

Orders can also be faxed to the attention of Customer Service at 1-800-409-7591.

Warranty

A copy of Hologic's limited warranty and other terms and conditions of sale may be obtained by contacting Customer Service at the numbers listed above.

Technical Support

For questions about Cellient® System issues and related application issues, representatives from Technical Support are available by phone 7:00 a.m. to 7:00 p.m. EST Monday through Friday at 1-800-442-9892 Option 6 (USA and Canada).

For Technical Support outside USA and Canada:

Asia	+852 3526 0718	Netherlands	0800 022 6782
Australia	+61 2 9888 8000	Norway	800 155 64
Austria	0800 291 919	Portugal	800 841 034
Belgium	0800 773 78	Spain	900 994 197
Denmark	8088 1378	South Africa	0800 980 731
Finland	0800 114 829	Sweden	020 797 943
France	0800 913 659	Switzerland	0800 298 921
Germany	0800 183 0227	UK	0800 032 3318
Ireland (Rep)	1 800 554 144	Rest of the world	0041.21.633.39.26
Italy	800 786 308	Intl Fax number	0041.21.633.39.10

Protocol for Returned Goods

For returns on warranty-covered Cellient System accessory and consumable items, contact Technical Support.

7. Ordering Information

7. Ordering Information

Chapter Seven

Ordering Information

Mailing Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752

Remittance Address

Hologic, Inc.

PO Box 3009

Boston, MA 02241-3009

Business Hours

Hologic's business hours are 8:30 a.m. to 5:30 p.m. EST Monday through Friday, excluding holidays.

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours at 1-800-442-9892 Option 5.

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Protocol for Returned Goods

For returns on warranty-covered Cellient System accessory and consumable items, contact Technical Support.

Table 7.1: Reordering Supply Items for the Cellient Processor

Item	Description	Quantity	Part Number
Cellientt® Filter Cassette Kit	50 cassettes 50 filter assemblies 50 embedding molds (includes bag of 150 pipette tips)	Kit, ea	71305-001
Cellient System Operator's Manual	Additional Operator's Manual	ea	MAN-02078-001
PreservCyt® Solution (non-Gyn application)	20 ml in 2 oz vial	50 vials/box	0234005
	946 ml in a 32 oz bottle	4 bottles/box	0234004
CytoLyt® Solution	946 ml in a 32 oz bottle	4 bottles/box	0236004
	30 ml in a 50 ml centrifuge tube	80 tubes/box	0236080
	30 ml in a 120 ml cup	50 cups/box	0236050
Fuse, 5x20 mm Time Delay, Glass, 6.3A for Cellient Processor	Replacement fuse	ea	50077-021
Fuse, 5x20 mm Time Delay, Glass, 3.15A for Finishing Station	Replacement fuse	ea	50077-018
Charcoal filter	Replacement charcoal filter	ea	51973-001

8. Finishing Station

8. Finishing Station

Chapter Eight

Finishing Station

SECTION A

OVERVIEW

The Finishing Station is used to embed the cell block in a final layer of paraffin before it is sectioned. The Finishing Station has a process plate that heats to a high temperature set point to melt the paraffin and cools to a low temperature set point to harden the block. The preheat switch heats the unit to high temperature to melt the paraffin. The cycle switch takes a cell block through a timed heat and cool cycle for embedding the sample.

CAUTION: Use the paraffin plugs that come with the Cellientt® Filter Cassette Kit. They are pre-filled with the same Paraplast X-tra® paraffin that is used on the Cellient processor.
If you mismatch waxes, poor bonding may occur and result in a cell block that cuts poorly or even breaks apart.

Note: Keep the paraffin plugs sealed in their transport molds until ready for use. This minimizes any debris getting into the finished cell block.

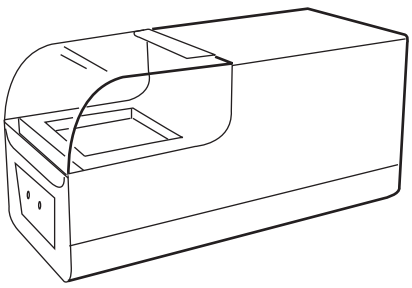

Figure 8-1 Finishing Station

One embedding mold will fit on the process plate at a time. The door should be closed when heating or cycling the unit.

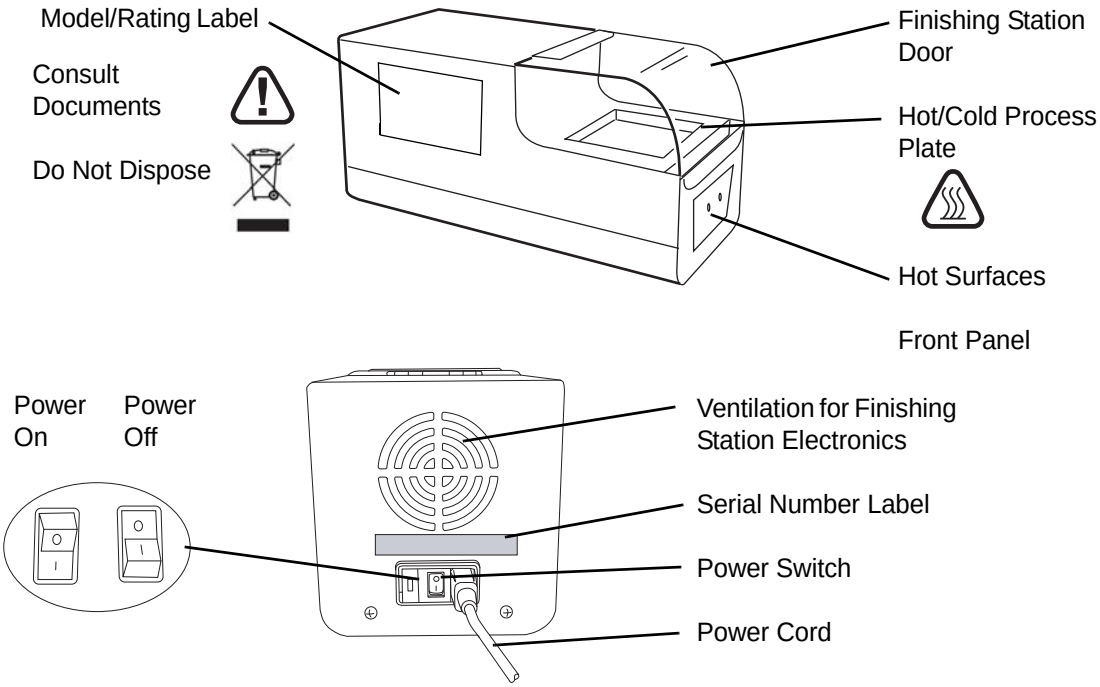

Figure 8-2 Finishing Station Components and Labels

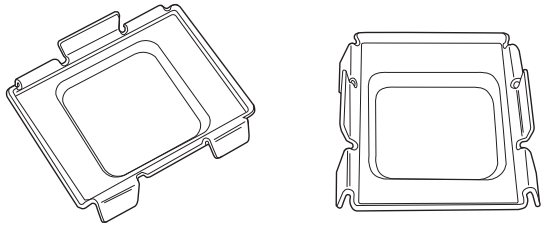

Figure 8-3 Embedding Molds

The Finishing Station is operated via the front panel. Three touch switches and two LED indicator lights control and display the operating states of the unit. See Figure 8-4.

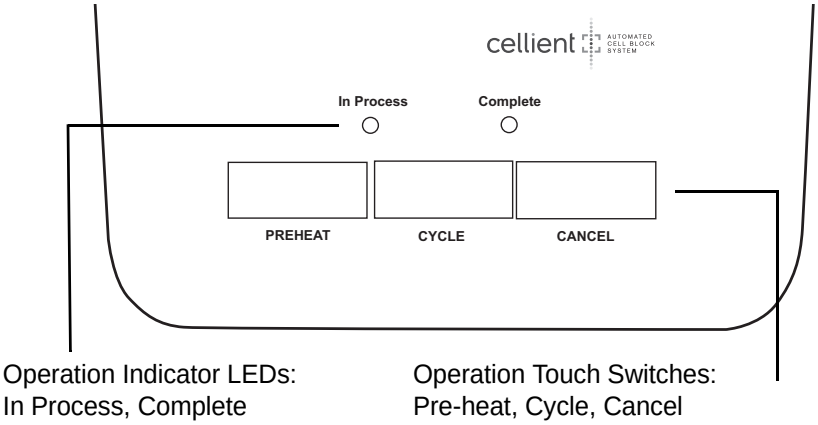

Figure 8-4 Finishing Station Front Panel

SECTION B

OPERATION

Refer to "EMBED CELL BLOCK IN PARAFFIN" on page 3.14 for steps to embed the cell block in paraffin.

Note: When a block has been completed and is removed from the cold process plate, remove it from the embedding mold right away. This will ensure a clean release of the paraffin from the mold.

Refer to Table 8.1, Finishing Station Operation Indicators, for a description of the touch switches and LEDs.

Table 8.1: Finishing Station Operation Indicators

Operator Action	LED	Audible Beep	Description
Power on unit	All LEDs flash	1 beep	Successful power up of the unit
Remove the paraffin plug from the transport mold and place in metal embedding mold. Place on the Finishing Station process plate and close the door.			
Press **Preheat** switch	The In Process LED flashes while unit heats	1 beep when temp reaches high temperature set point	In Process LED remains on when temperature has been reached. The door is latched closed while heating. The Process and Complete LEDs flash alternately while the Finishing Station idles at temperature.
Insert cell block cassette into the metal embedding mold. Close the door.			
Press **Cycle** switch	The In Process LED flashes while unit heats and cools		The door is latched during the Cycle.
		Beep 10 seconds when the cycle is complete	The door unlatches. The Complete LED flashes.
Remove the mold from the process plate and gently separate the cell block from the mold.			
			The process plate remains cold and the unit will continue to beep very 10 minutes up to 1 hour or until Preheat or Cancel is pressed. (After 1 hour the process plate returns to ambient temp.)
To continue to embed cell blocks, place another paraffin filled metal embedding mold on the process plate and press **Preheat**.			
At the conclusion of all embedding, press the **Cancel** switch to turn off the process controller. The unit returns to ambient temp. (Note: the unit is still powered ON.)			

SECTION C MAINTENANCE

Clean the Finishing Station of spills or paraffin build up on an as needed basis.

WARNING:
Hot Surfaces
Hot Paraffin

Paraffin on the Finishing Station process plate may be wiped off with a lint-free cloth or Kimwipe® while the wax is still melted. Use caution, as the surface of the process plate can be hot.

Turn off the Finishing Station and allow to cool before handling the device.

Use soap and water and a lint-free cloth to wipe down the surfaces of the Finishing Station. Paraffin build up on surfaces other than the process plate can be scrapped off.

SECTION D TROUBLESHOOTING

Cell Blocks Not Releasing From the Embedding Mold

WARNING:
Cold Surface. Adhere to manufacturer's recommendation for proper use of freeze spray

If the ambient temperature of the room is very high (32°C), the cell block may be too warm when it is removed from the Finishing Station. It may be difficult to remove from the embedding mold.

- Use freeze spray on the bottom of the embedding mold. Place the cell block face down on a clean, flat surface. Hold the freeze spray nozzle 2- 5 cm from the bottom of the embedding mold and spray for 3 - 5 seconds.

OR

- Place in a -20° freezer for 5 minutes.

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HOLOGIC®

Cellient®

Automated Cell Block System | Operator's Manual

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
1-800-442-9892
+1-508-263-2900
www.hologic.com

EC REP Hologic Ltd.
Heron House, Oaks Business Park
Crewe Road, Wythenshawe
Manchester, M23 9HZ, UK
+44 (0)161 946 2206

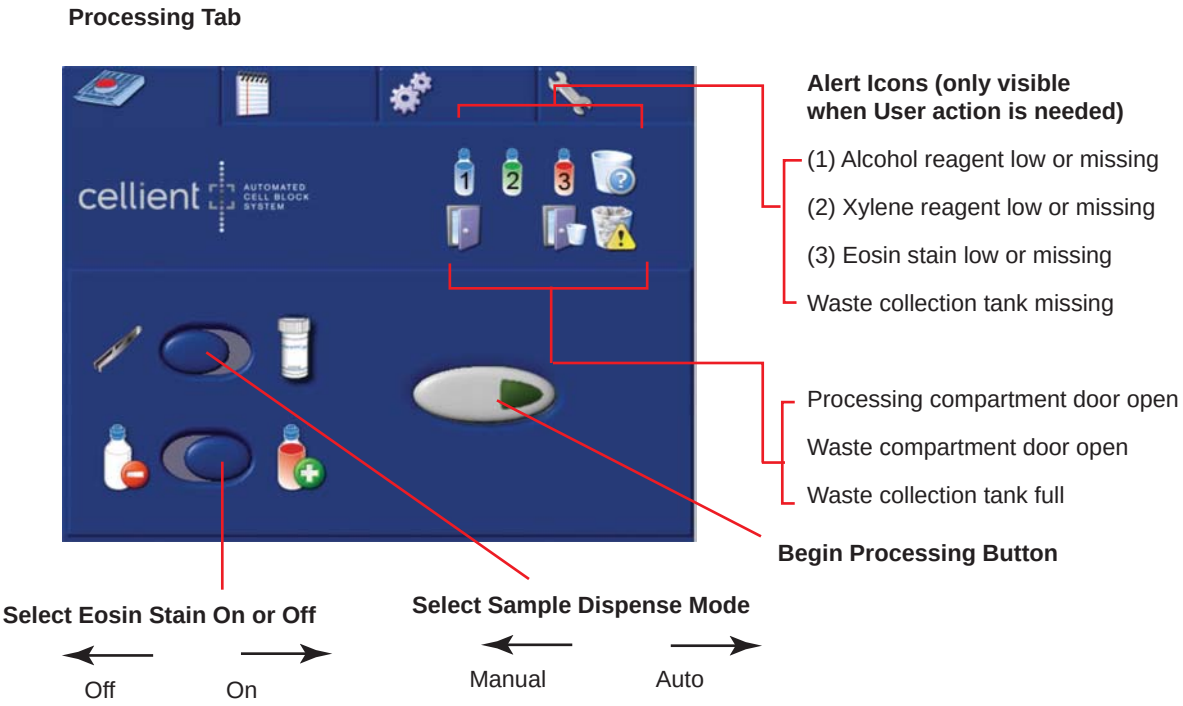
CE

MAN-02078-001 Rev. 003

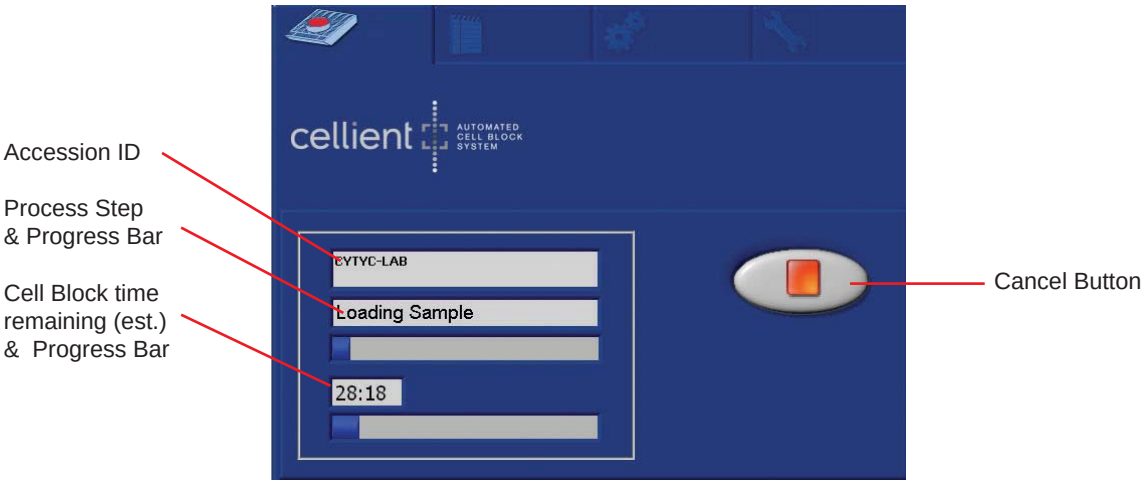
cellient®
AUTOMATED
CELL BLOCK SYSTEM

Quick Reference Guide

Processing Screen (Idle)



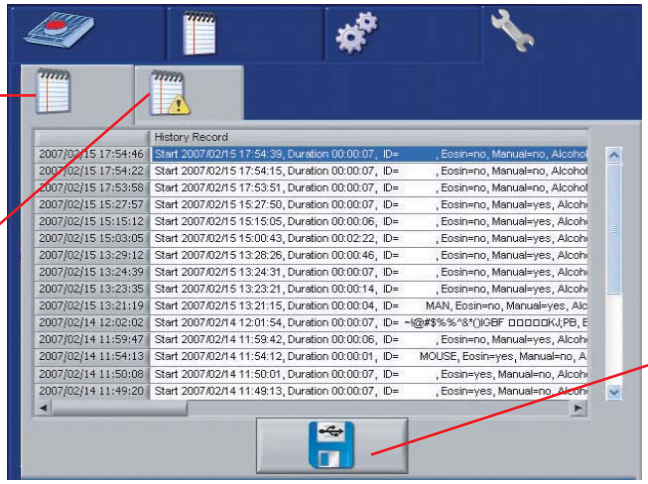
Processing Screen (Processing)



 Refer to the Cellient® System Operator's Manual for complete operating instructions AW-05574-001 Rev. 002

Logs Screen

Logs Tab



History Log Tab
Lists every cell block run; most recent up to 5,000

Event Log Tab
Logs every error encountered; most recent up to 10,000

Save Logs to USB Key
Saves log to USB

User Preferences Screen

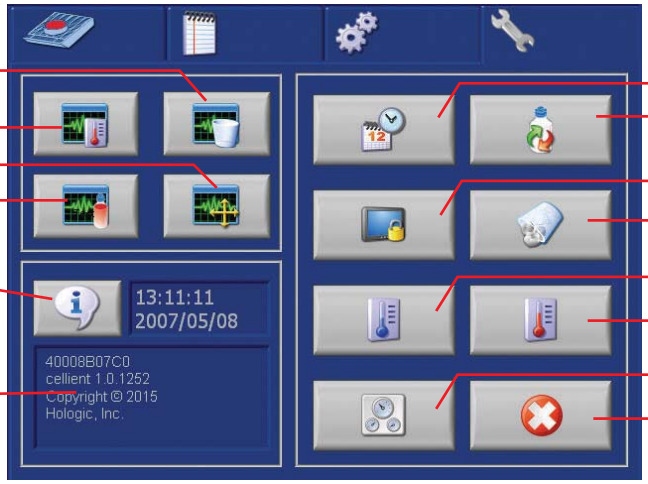
Preferences Tab

Accession ID On or Off
Off ← → On

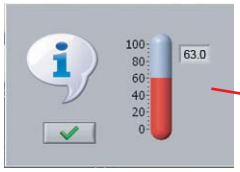
Select Language
English
Deutsch
Italiano
Español
Dansk
Nederlands
Français
Português
Svenska

Maintenance Screen

Maintenance Tab



User Diagnostics:
Waste
Temperature
Motion
Fluid



Paraffin Reservoir Temperature (°C)

About Box
(date, time, software version)

Set Time and Date
Change Reagent(s)
Lock Screen for Cleaning
Run Waste Cycle
Chill Sample Well
Heat Sample Well
Service Menu Access
SHUT DOWN SYSTEM