ThinPrep® 5000
Sample Transfer System

Operator's Manual

HOLOGIC®

ThinPrep® 5000
SAMPLE TRANSFER SYSTEM

Operator's Manual

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HOLOGIC®

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1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW AND FUNCTION OF THE THINPREP® 5000 SAMPLE TRANSFER SYSTEM

The ThinPrep® 5000 Sample Transfer System automatically transfers a liquid sample from a ThinPrep Solution vial directly into a 96-well deep-well micro-titer plate. The sample transfer amount is selectable between 0.5 and 2.0 mL in 0.1-mL increments. Vials are loaded into the instrument via a carousel which holds up to 48 vials. To fully fill a 96-well plate, two carousels of vials are needed. The system will pause and alert the operator when a carousel has been completed. The system will also pause any time it encounters an empty position in the carousel. The operator determines whether to end processing or replenish and continue. When all 96 wells have been filled, the operator is alerted that the batch is complete. The instrument can process up to two deep-well plates at a time. The system will also allow two samples to be transferred from a vial to two separate 96-well plates if multiple tests are to be run out of the vial. Drawing maximum volume, 2 mL, it takes approximately two hours to transfer 96 samples.

Each sample vial is affixed with a barcode label prior to being loaded into the carousel and loaded into the instrument. Each deep-well plate bears a barcode, which is read when the plate is loaded into the instrument. Chain of custody is ensured by mapping each vial's barcode label as it is processed to the specific well on the specific plate to which the sample is being transferred. This information can be printed on an optional external printer, or saved to a USB key.

The system checks that the deep-well plate is empty before beginning a batch. It checks positions 1 (A1) and 49 (A7) to determine that they are empty. If a half plate has already been run and the system identifies this plate ID in the database, only position 49 will be checked before beginning.

The system senses the liquid level of the vial contents before attempting to aspirate sample. If the system senses that the level is low but not insufficient, it will tilt the vial to ensure a complete draw of sample. If the volume is not enough to draw the volume selected by the operator, the vial will be recapped and returned to the carousel. The plate report will call out which well position was not filled. The graphical plate map on the user interface will also indicate an unprocessed position.

There is a liquid level detection bypass option that can be enabled at the time of installation or during a service visit. This allows the system to process all vials, regardless of fill level.

Note: This option is not recommended if the transferred samples will be used for nucleic acid amplification technologies.

A 1000 µL, sterile, filtered pipette tip is used to aspirate a sample from a vial and then to dispense into a well of the plate. The operator selects how many mLs of sample are to be transferred into the wells of the deep-well plate. (The fill volume selections are determined at the time the instrument is

installed.) The sample will be aspirated and dispensed in one or two passes, depending on the selected volume. The pipette tip is discarded into a waste bin.

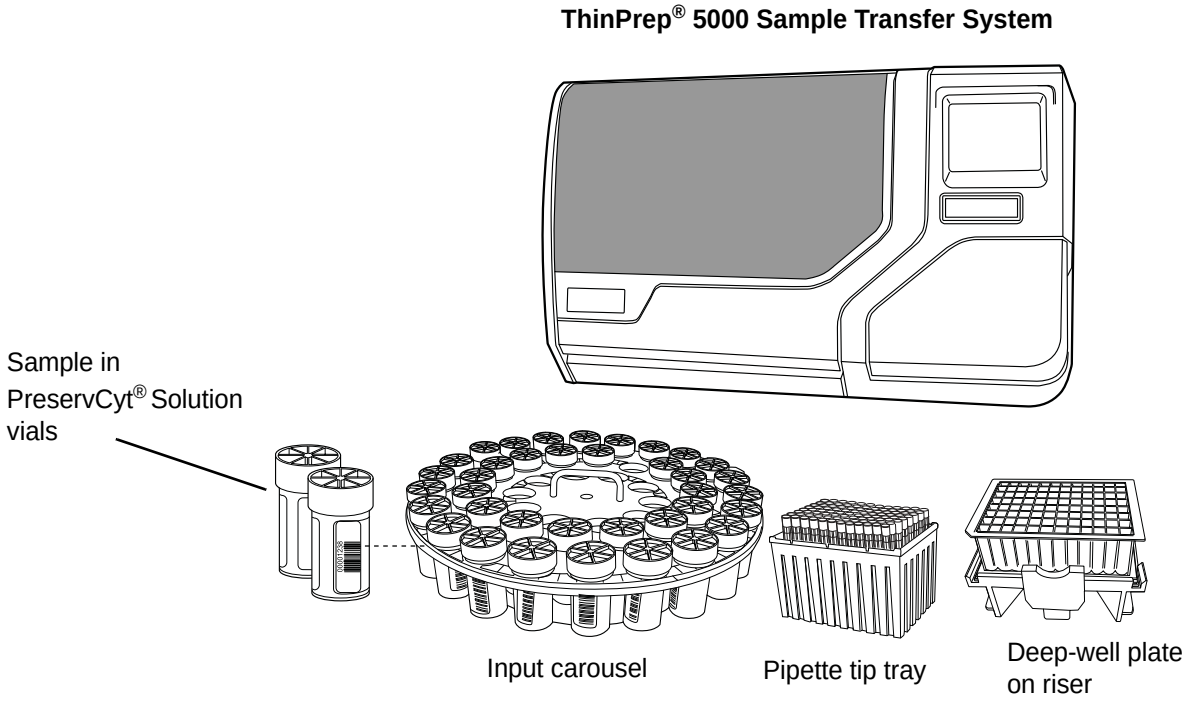


Figure 1-1 A ThinPrep 5000 Sample Transfer System

Key system components include the ThinPrep® 5000 Sample Transfer System, barcoded ThinPrep solution sample vials, input carousel for loading the vials, trays of micropipette tips, barcoded 96-well deep-well micro-titer plates and risers for those plates.

The system is operated via a touch screen graphic user interface. The interface provides operational interaction with the system, some administrative functions (such as user preferences or system settings) and graphical status indicators of system operation and readiness.

At the conclusion of a batch, a report is generated. The plate report indicates the success or failure of sample processing, system information and the sample ID number/deep-well plate position map. This can be viewed via the user interface, saved to a USB key or printed if an optional printer is installed. The system can produce plate maps for 24, 48 or 96 vials.

A usage history and a system error history are retained in system memory and can be accessed by the operator the same as a plate report. These history files may be viewed on screen, saved to a USB key or printed via optional printer.

Overview of Processing

For routine sample processing, the system proceeds in this fashion once the batch is started:

- Check the deep-well plate ID(s)
- Move the deep-well plate to determine that positions 1 and 49 are empty
- Pick up a vial
- Read the vial barcode
- Tighten the vial cap then disperse the vial contents
- Uncap the vial
- Sense the vial volume level
- Pick and sense the presence of a pipette tip
- Introduce the pipette tip to the vial and aspirate sample
- Dispense sample into the deep-well plate
- Dispose of the pipette tip
- Recap the vial
- Return the vial to the carousel

Materials Provided

The following items are included when the ThinPrep 5000 Sample Transfer System is delivered for installation.

(These items may vary according to your order.)

- ThinPrep 5000 Sample Transfer System
- ThinPrep 5000 Sample Transfer System Operator's Manual
- Power cord
- Carousel (2)
- Riser for deep-well plate (2)
- USB flash drive
- Drip catcher for the evaporation cover
- Uninterruptible Power Supply 1500VA
- Pipette tips (3 boxes)
- Deep-well plates (3)
- PreservCyt® Solution vials (1 tray of 50 vials)

Note: Use the pipette tips and deep-well plates supplied by Hologic. Do not substitute consumables. Refer to Chapter 8, Ordering Information.

SECTION B

TECHNICAL SPECIFICATIONS

Overview of Components

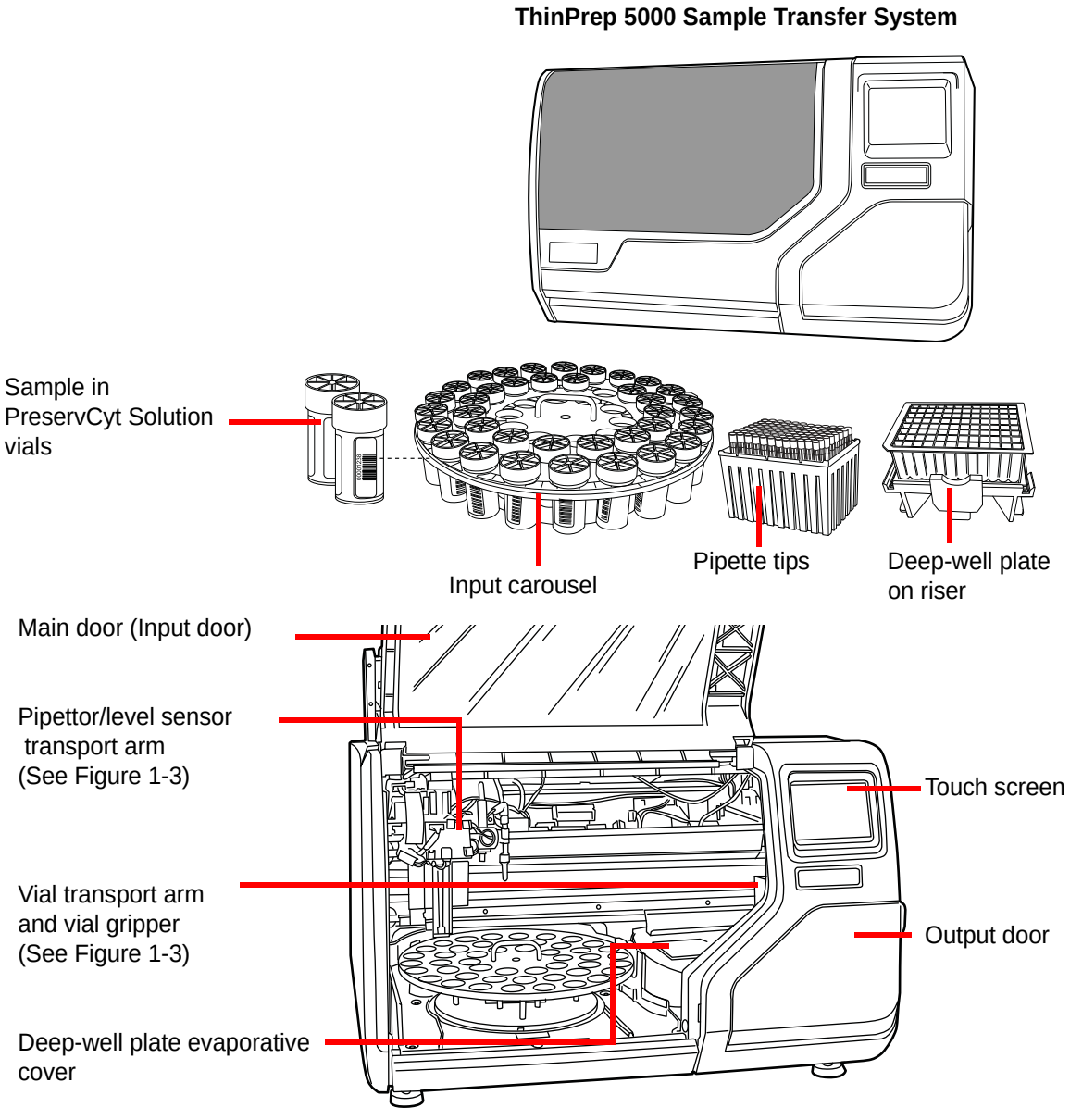


Figure 1-2 Overview of Components

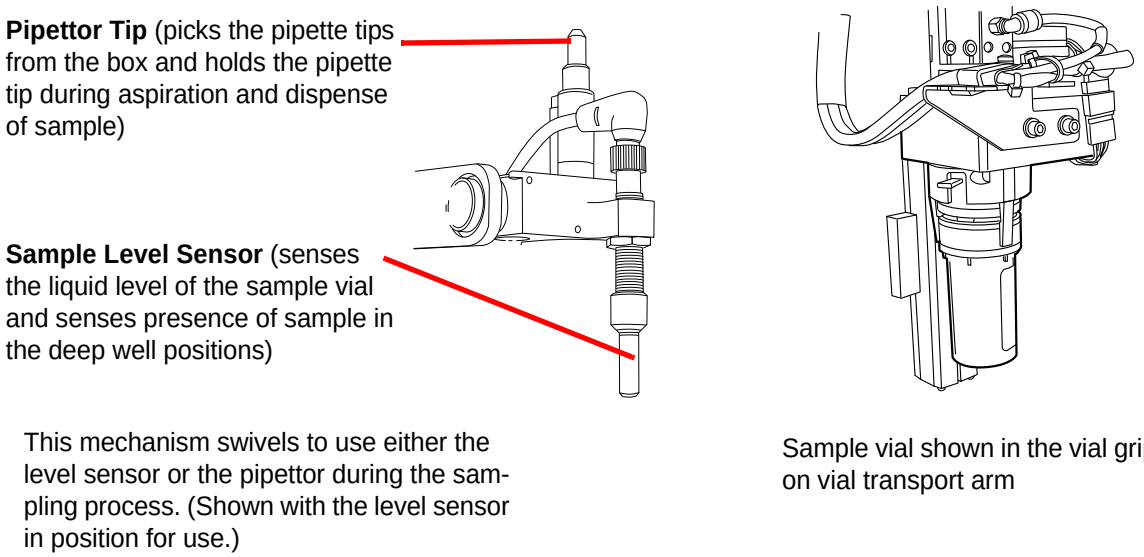


Figure 1-3 Liquid Level Sensor and Pipettor Tip and Sample Vial Gripper

Dimensions and Weight (Approximate)

ThinPrep 5000 Sample Transfer System: 22 inches (56 cm) high x 34 inches (86 cm) wide x 26 inches (66 cm) deep

185 lbs/84 kg

Clearances

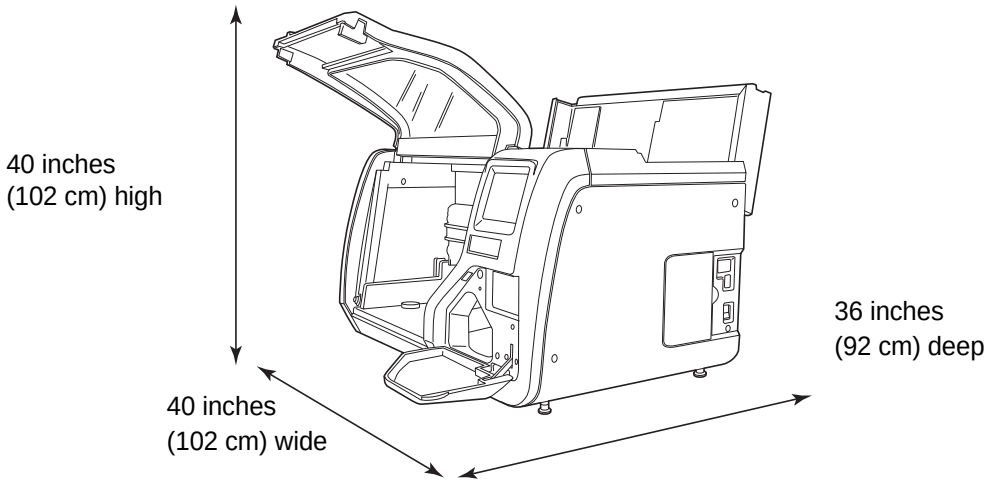


Figure 1-4 ThinPrep 5000 Sample Transfer System Clearances Shown with Top Service Lid Open

Environmental

Operating Temperature

16–32°C

60–90°F

Operating Humidity

20%–80% RH, non-condensing

Non-operating Temperature

-28°C–50°C

-20°F–122°F

Non-operating Humidity

15%–95% RH, non-condensing

Power

Electrical Voltage and Frequency/Power

100-240V, ~4A, 50-60Hz

Fusing

Two 15A/250V 3 AB SLO-BLO

Connections to External Circuits

The external connections on the ThinPrep 5000 Sample Transfer System are PELV (Protected Extra Low Voltage) as defined by IEC 61140. Outputs of other devices connected to the instrument should also be PELV or SELV (Separated Extra Low Voltage). Only devices approved for safety by an appropriate agency should be connected to the ThinPrep 5000 Sample Transfer System.

Safety, EMI and EMC Standards

The ThinPrep 5000 Sample Transfer 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 model/rating label, located on the rear of the instrument, to see the safety certification markings (see Figure 1-6). This equipment meets the IEC 61010-2-101 particular safety requirements for IVD equipment.

This equipment meets the emission and immunity requirements of IEC 61326-2-6. This equipment has been tested and found to comply to CISPR 11 Class A emission limits.

In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the equipment. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded RF sources), as these may interfere with the proper operation.

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

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

This Class A digital apparatus complies with Canadian ICES-003.
Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

Specimen Processing

The rate of cross-contamination was measured using a fluorescent stain for the detection of DNA. Cross-contamination rates for both manual and automated sample transfer were statistically equivalent.

SECTION C INTERNAL QUALITY CONTROL

Power On Self-Test

When the ThinPrep 5000 Sample Transfer System is powered on (refer to page 2.3), the system goes through a self-diagnostic test. The electrical, mechanical and software/communications subsystems are tested to confirm that each performs properly. The operator is alerted to malfunctions by a message on the touch screen interface and by audible sound (if enabled).

SECTION D THINPREP 5000 SAMPLE TRANSFER SYSTEM HAZARDS

The ThinPrep 5000 Sample Transfer System 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 instrument.

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.

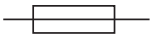
A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data or invalidate a procedure, although personal injury is unlikely.

A ***Note*** provides useful information within the context of the instructions being provided.

Symbols Used on the Instrument

The following symbols are used on this instrument:

Attention, refer to accompanying documents



Fuse

Waste Electrical and Electronic Equipment.

Do not dispose in municipal waste.

Contact Hologic for disposal of the instrument.

In Vitro Diagnostic equipment

Power Switch On

Power Switch Off

Manufacturer

Authorized Representative - Europe

Conforms to EC directives

Figure 1-5 Symbols

Location of Labels on the Instrument

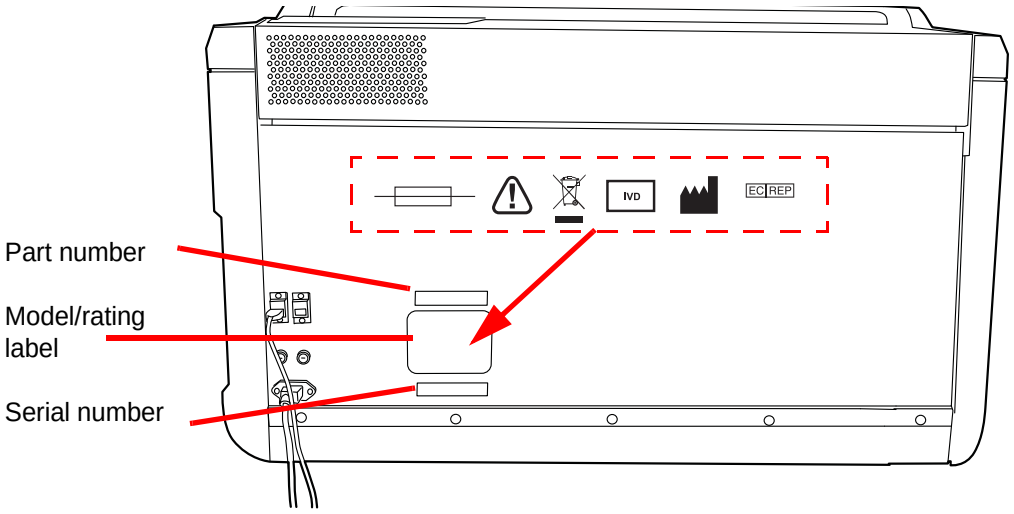


Figure 1-6 Rear of the ThinPrep 5000 Sample Transfer System

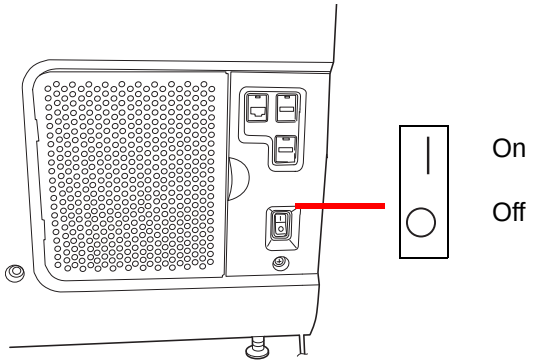


Figure 1-7 Right Side of Sample Transfer System

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. Disconnection from the power source is by removal of the power cord.

WARNING

Flammable Liquids

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

CAUTION

Use Universal Precautions

Wear protective clothing in accordance with Universal precautions when operating the instrument.

SECTION E DISPOSAL

Disposal of Consumable Items

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.
- **Used Pipette tips**. Dispose of in your laboratory waste.
- **Deep-well plates**. If PreservCyt Solution is present, pour off into hazardous waste. Dispose of the plate in laboratory waste.
- **Absorbent Pads** for deep-well plate evaporation cover. Dispose of as regular waste. (If dripping wet, dispose of as hazardous waste.)

Disposal of the Device

Do not dispose in municipal waste.

Please contact Hologic Technical Support.

Material Safety Data Sheet

PreservCyt® Solution:

The Material Safety Data Sheet (MSDS) for this solution may be requested from Hologic Technical Support, or found on-line at www.hologicmsds.com.

2. Installation

Chapter Two

Installation

WARNING: Service Installation Only

SECTION A GENERAL

The ThinPrep® 5000 Sample Transfer System must be installed by personnel who have completed Hologic service training for the processor. When installation is complete, the operator(s) are trained, 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 Chapter 7, Service Information.)

Leave the instrument in the packing cartons for Hologic service installation.

Store the instrument in a suitable environment until installation (cool, dry, vibration-free area).

SECTION C PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

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

Location

Locate the ThinPrep 5000 Sample Transfer System near (within 3 meters) a 3-wire grounded power outlet that is free of voltage fluctuations and power surges. The processor will be connected to a UPS (uninterruptible power supply), which will be plugged into the electrical outlet. Refer to Figure 1-4 to ensure that there is sufficient clearance around the instrument. If the instrument will be configured with a printer, further space and a power outlet will be required.

2 INSTALLATION

During operation the ThinPrep 5000 Sample Transfer System is sensitive to vibrations. It should be placed on a flat, sturdy surface that can support the 185 lbs (84 kg) that it weighs. It should be placed away from any vibrating equipment.

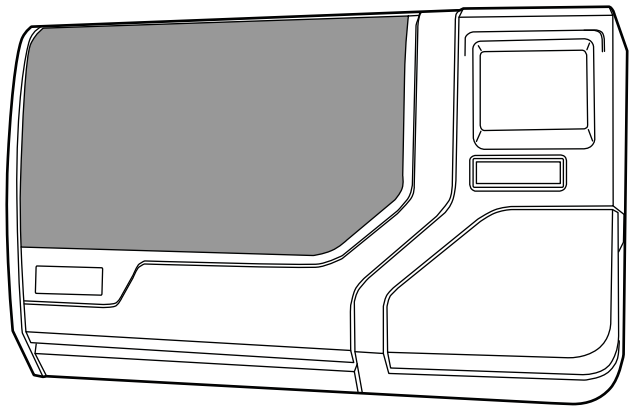


Figure 2-1 A Typical ThinPrep 5000 Sample Transfer System

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

SECTION D MOVING THE THINPREP 5000 SAMPLE TRANSFER SYSTEM

CAUTION: The processor weighs 185 lbs (84 kg) and should always be moved by at least two people.

The ThinPrep 5000 Sample Transfer System is a precision instrument and should be handled with care. Prior to relocating the equipment, unload any items which may spill or break: carousel, sample vials, deep-well plates, pipette tip trays.

If the instrument must be moved, it should be grasped and lifted by the bottom of the housing. There are two contoured hand hold areas along the right and left undersides of the processor housing especially for lifting the instrument.

If the ThinPrep 5000 Sample Transfer System is to be shipped to a new location, please contact Hologic Technical Support. (Refer to Chapter 7, Service Information.)

SECTION E STORAGE AND HANDLING POST INSTALLATION

The ThinPrep 5000 Sample Transfer System may be stored where it is installed. Be sure to clean and maintain the instrument as described in the Maintenance chapter of this manual.

SECTION F CONNECT POWER TO THE SYSTEM

All power cords must be plugged into a grounded outlet. Disconnection from the power supply source is by removal of the power cord.

Make sure the power switch is off. Then insert the power cord into the receptacle on the rear of the instrument (Figure 2-2). The instrument comes with a UPS (uninterruptible power supply). The instrument's power cord is plugged into the UPS. Plug the UPS power cord into a grounded outlet.

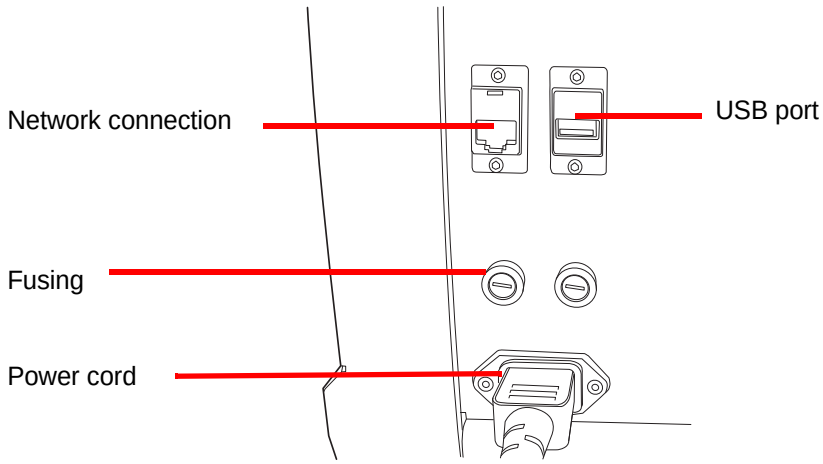


Figure 2-2 Rear of ThinPrep 5000 Sample Transfer System

SECTION G TURN ON THE THINPREP 5000 SAMPLE TRANSFER SYSTEM

CAUTION: Do not power on the processor while a USB key is in any of the USB ports. See Figure 2-2 and Figure 2-3 for USB port locations.

Both doors must be closed prior to turning on the instrument.

Press the rocker switch located on the lower right side of the instrument to the on position. See Figure 2-3.

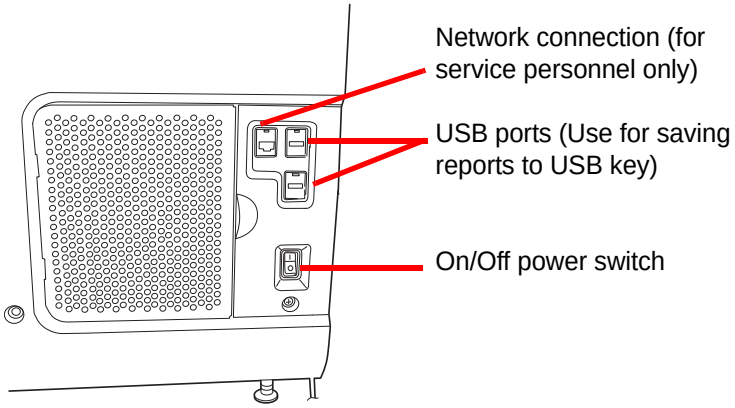


Figure 2-3 Power Switch

The user interface will display the ThinPrep 5000 Sample Transfer System logo while the system starts up and the main screen will appear when the instrument is ready for use. The mechanisms will move and then position for access. The doors will unlock.

Note: The ThinPrep 5000 Sample Transfer System is intended to be left on. For shutdown or extended shutdown, see page 2.5.

Figure 2-4 Startup Splash Screen

SECTION H

ESTABLISH USER OPTIONS

At the time the instrument is installed, or during a service visit, the fill volumes for each deep-well plate can be selected. Also, the option to bypass vial fluid level detection can be enabled. These options are only accessible via the Service interface.

Deep-well Plate Fill Volumes

Each deep-well plate has three volumes that can be selected (they do not have to match.) The volumes are 0.5 mL to 2.0 mL in increments of 0.1 mL.

Vial Fluid Level Detection

The sample vial fluid level sensing can be turned off, if desired. The system will process all vials regardless of their fluid level.

Note: The operator must visually check the deep-well plates after processing, to determine if any wells are empty or partially filled.

- There is no indication on the user interface that this mode is active
- The graphic process display will not indicate empty or partially filled wells (with a red circle)
- The plate report will not indicate empty or partially filled wells
- Systems configured this way will never generate an Insufficient Fluid error (6250)

SECTION I

TURN OFF THE THINPREP 5000 SAMPLE TRANSFER SYSTEM

Normal Shutdown

CAUTION: Never turn off power to the instrument without first quitting the application via the user interface.

If the instrument is to be turned off, it must be in an idle state. If a batch is in progress, either let it finish, or stop the batch. To shut down, touch the Admin Options tab on the user interface and press the **Shutdown** button.

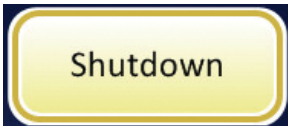


Figure 2-5 Shutdown Button

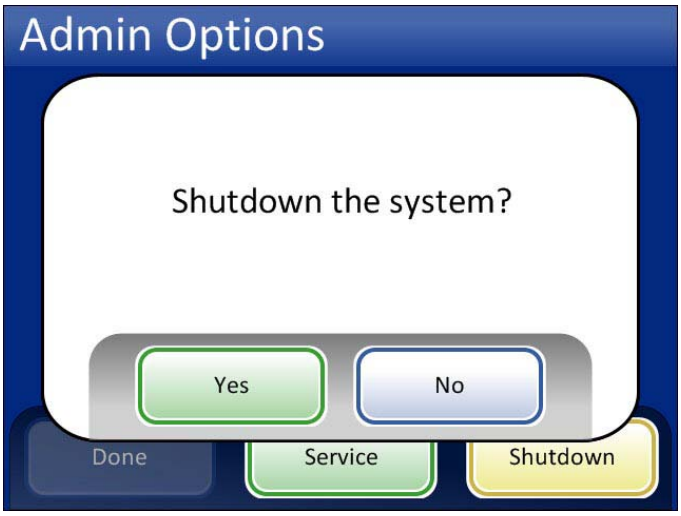


Figure 2-6 Shutdown Confirmation

A confirmation box will be displayed on the touch screen. Press the **Yes** button to proceed with system shutdown.

Press the **No** button to cancel shutdown and return to the Admin Options screen.

The instrument checks all USB ports and if it detects that any USB devices are present, a message will prompt the user to remove them. Remove any devices and press the **OK** button to continue.

Figure 2-7 Remove USB Drives Message

Wait until the touch screen interface goes blank. Then turn off the power switch located on the right side of the instrument.

Extended Shutdown

If the instrument is to be shut down for an extended amount of time, or be taken out of service, remove any items that may be on board and close all doors. Follow the instructions for Normal Shutdown. Completely remove power to the instrument by unplugging the power cord from the wall outlet.

INSTALLATION

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3. User Interface

3. User Interface

Chapter Three

User Interface

This chapter provides detailed information on the user interface screens and how to use them to operate, troubleshoot and maintain the ThinPrep® 5000 Sample Transfer System.

The main screen after the system turns on will display as shown below (one plate loaded):

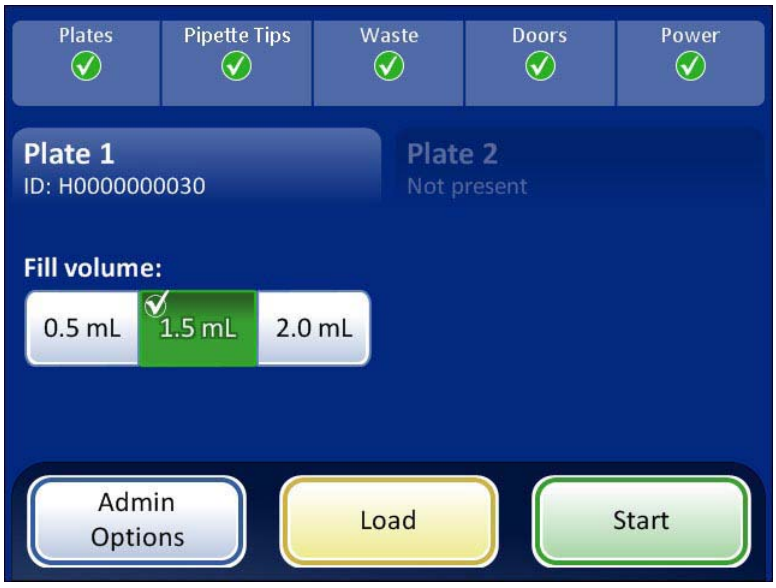


Figure 3-1 Main Screen

SECTION A ADMIN OPTIONS

The administrative options allows the user access to:

- system settings
- system reports and logs
- a lock screen button for cleaning
- a means of scheduling a delayed batch start
- system shutdown

To display the Admin Options screen, press the **Admin Option** button on the main screen.

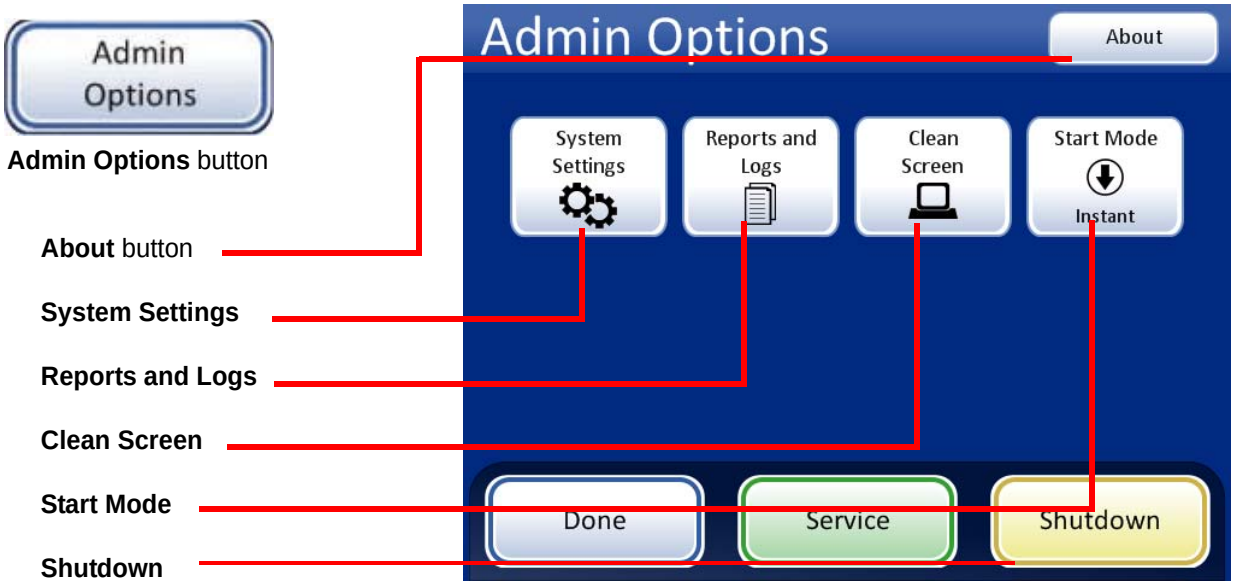


Figure 3-2 Administrative Options Screen

About Button

Pressing the **About** button will display the system information of copyright, software version and instrument serial number.

Figure 3-3 About Button

System Settings

System Settings button from the Admin Options screen

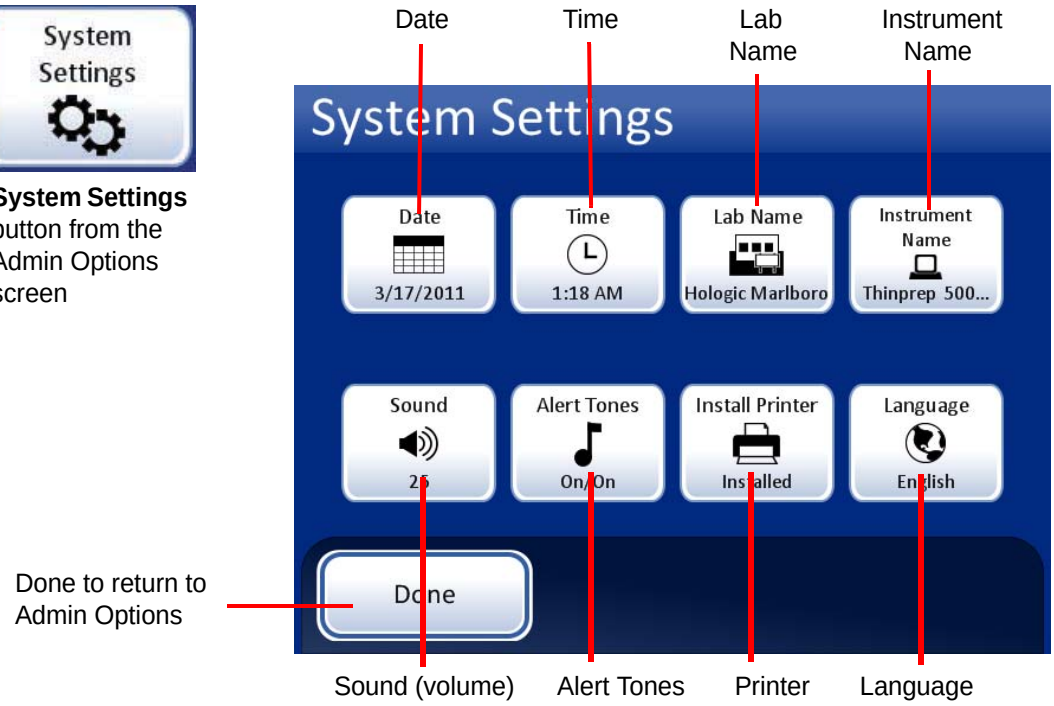


Figure 3-4 System Settings Screen

Date

Date button (shows current setting)

Figure 3-5 Date Button and Edit Date Screen

To change the date (month, day, year) touch the up / down button for that field until the desired value is displayed. Press the **Save Changes** button to return to the System Settings screen.

Time

Time button (shows current setting)

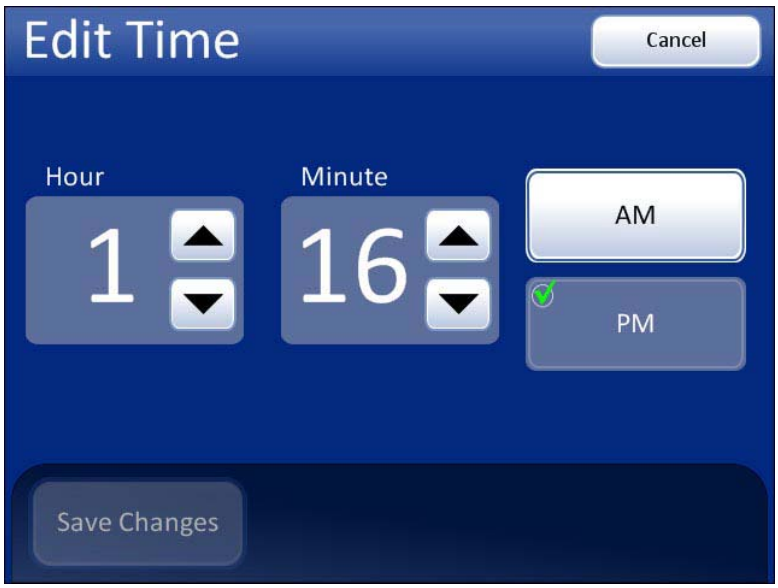
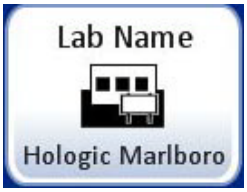


Figure 3-6 Time Button and Edit Time Screen

To change the time (hour, minute, meridian), touch the up / down button for that field until the desired value is displayed. For the meridian, press the AM or PM button, as appropriate. Press the **Save Changes** button to save and return to the System Settings screen.

Lab Name



(Shows current setting)

Figure 3-7 Lab Name Button

To enter or edit a name for the facility at which the ThinPrep® 5000 Sample Transfer System is located, press the **Lab Name** button. Press the letter buttons to enter a name, up to 20 characters. To create a capital letter, press the **Shift** button and then press the letter. With the next letter, the system reverts to lower case. Use the **Space** button for a space and the **Delete** button to remove entered letters.

Press the **abc/123** button to display an alternate keyboard to enter numbers and symbols. Switch between keyboards as often as desired before saving changes.

Alphabet Keyboard Display

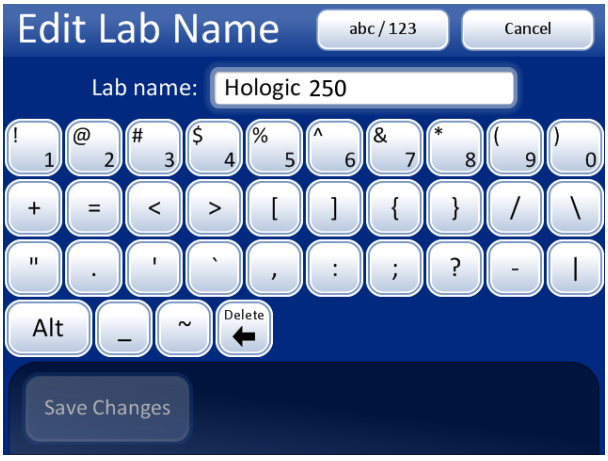
Shift for a capital letter

Delete to remove entries

abc/123 to display numeric keys

Cancel to return to System Settings screen (Reverts to previous entry if any)

Save Changes to save the entry and return to System Settings screen



Numeric and Symbols Keyboard Display

Type in numbers or symbols; use **Alt** key for top row symbols

Delete to remove entries

abc/123 to display keyboard

Cancel to return to System Settings screen (Reverts to previous entry if any)

Save Changes to save the entry and return to System Settings screen

Figure 3-8 Edit Lab Name Keyboard Screens

Instrument Name

(Shows current setting)

Figure 3-9 Instrument Name Button

To enter or edit a name for the instrument, press the **Instrument Name** button. Press the letter buttons to enter a name, up to 20 characters. To create a capital letter, press the **Shift** button and then press the letter. With the next letter, the system reverts to lower case. Use the **Space** button for a space and the **Delete** button to remove entered letters.

Press the **abc/123** button to display an alternate keyboard to enter numbers and symbols. Switch between keyboards as often as desired before saving changes.

Press the **Save Changes** button to save and return to the System Settings screen.

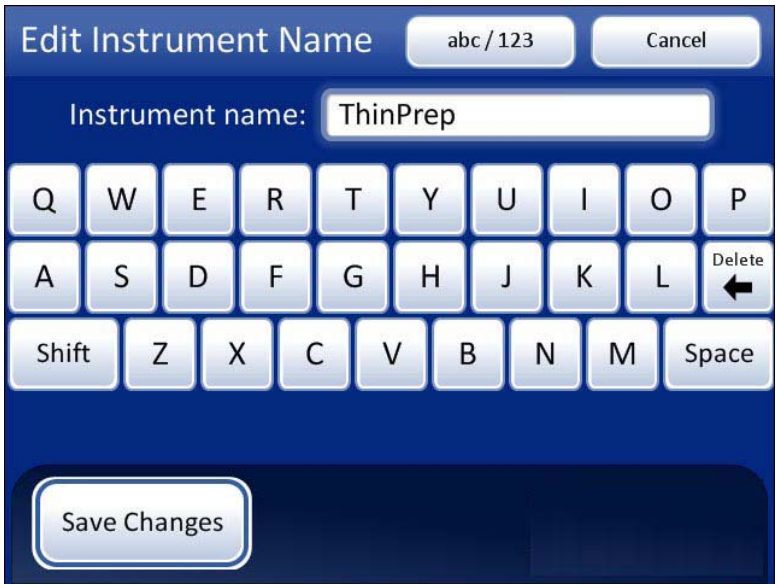


Figure 3-10 Edit Instrument Name Screen

Sound

(Shows current setting)

Figure 3-11 Sound Button

Audible alert tones can be set to signal batch completion and error condition. The volume of the audible alert tones may be increased or decreased using the Sound setting.

Done. Save setting adjustment and return to System Settings screen

Preview. Press this button to hear the sound at the current volume. The button becomes a **Stop** button, which is pressed to cease the volume test.

Figure 3-12 Sound Screen

Press the **-1** button repeatedly to decrease the volume. Press the **+1** button repeatedly to increase the volume (0 to 31). Test it by pressing the **Preview** button to hear the sound. It will repeat until the **Stop** button is pressed. Continue to adjust and preview the sound volume until it is satisfactory. Press the **Done** button to save the setting and return to the System Settings screen.

Alert Tones

Figure 3-13 Alert Tones Button

Alert tones are audible alarms that sound upon batch completion or during an error condition. Three sounds are offered for each. Select a tone or select the option to turn off any audible alarm for each condition.

Note: The volume of the tones is adjusted by the Sound screen. See the previous section.

Having differentiated tones makes it easier to know if the instrument has completed a batch or needs attention. In a setting that might have multiple machines, the different tones can help identify them.

Alert tones for batch completion.

Alert tones for an error condition.

Turn the option On and then select a tone. Press the sound icon to hear the tone.

Figure 3-14 Alert Tones Screen for Batch Completion and Error Condition

When a batch completes, the alert tone will sound once.

When an error condition occurs, the alert tone will sound and then repeat every few seconds. The error message window will have a **Silence Alarm** button that can be pressed to turn the alarm off. (Figure 3-15.)

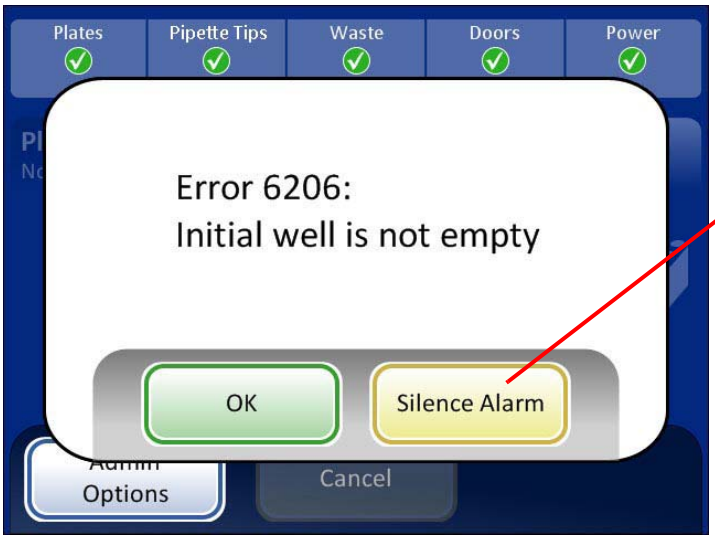


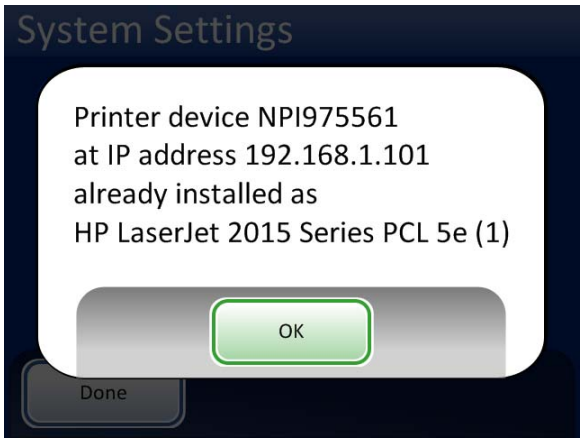
Figure 3-15 Silence Alarm Button

Install Printer

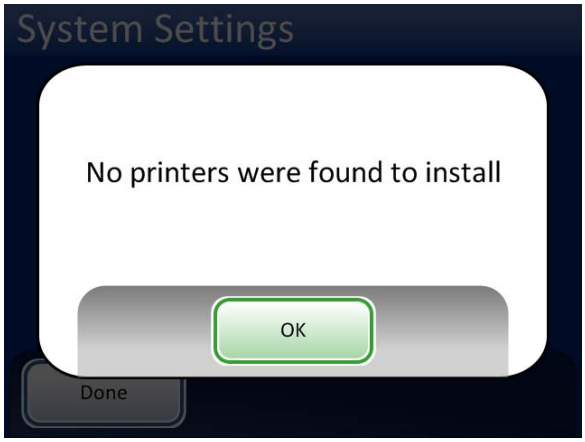
Shows current setting

Figure 3-16 Install Printer Button

If a network printer is installed as part of your system, this function will search the network for its presence and connect to it at the time of setup. If a printer is not installed, or unavailable to the system, a message will display that a printer could not be found.



Printer installed message



Printer not installed message

Figure 3-17 Install Printer Messages

Language

Current setting is shown

Figure 3-18 Language Button

Press the **Language** button to select the language that is displayed on the user interface and on the reports.

Figure 3-19 Select Localization Screen

Select a locale for the language. This will apply customary time and date format for that region to the language.

Press the **Save Changes** button to immediately apply the selected language and locale to the system.

Reports and Logs

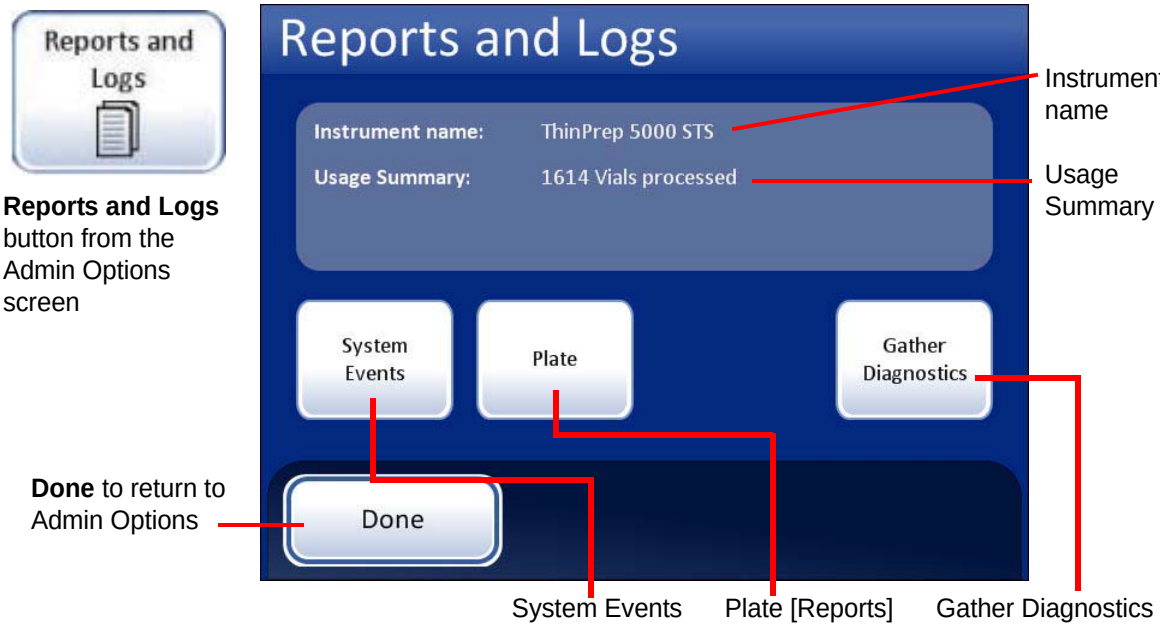


Figure 3-20 Reports and Logs Screen

The Reports and Logs interface present system information in three forms:

- Usage Summary (see Figure 3-20), which tallies how many vials the system has processed to date.
- System Events - a log of all system events from oldest to most recent. The system retains the error history for three years, then begins to purge the oldest records as new ones are logged.
- Plate Reports - displays a plate report of every deep-well plate that has been entered into the system database.

System Events

Figure 3-21 System Events Button

The System Events report displays all of the system error conditions encountered during sample vial processing. A System Event is an error condition that the instrument is not capable of recovering from without user intervention.

Note: This does not include sample preparation errors that do not interfere with the operation of the instrument.

The database retains the log of errors for three years and then purges entries older than that.

Figure 3-22 System Events Report Screen

Event Codes Button

The **Event Codes** button, found on the System Events screen and the Plate Reports screen leads to a list of system event codes. It is helpful to have the explanation of the event code while looking at system events or plate reports.

Note: Only the events that have been encountered by the system will be displayed.

The **Event Codes** button is available to the operator during plate processing. By touching the image of the plate on the touch screen, the Plate Report window will appear and the Event Codes button can be pressed.

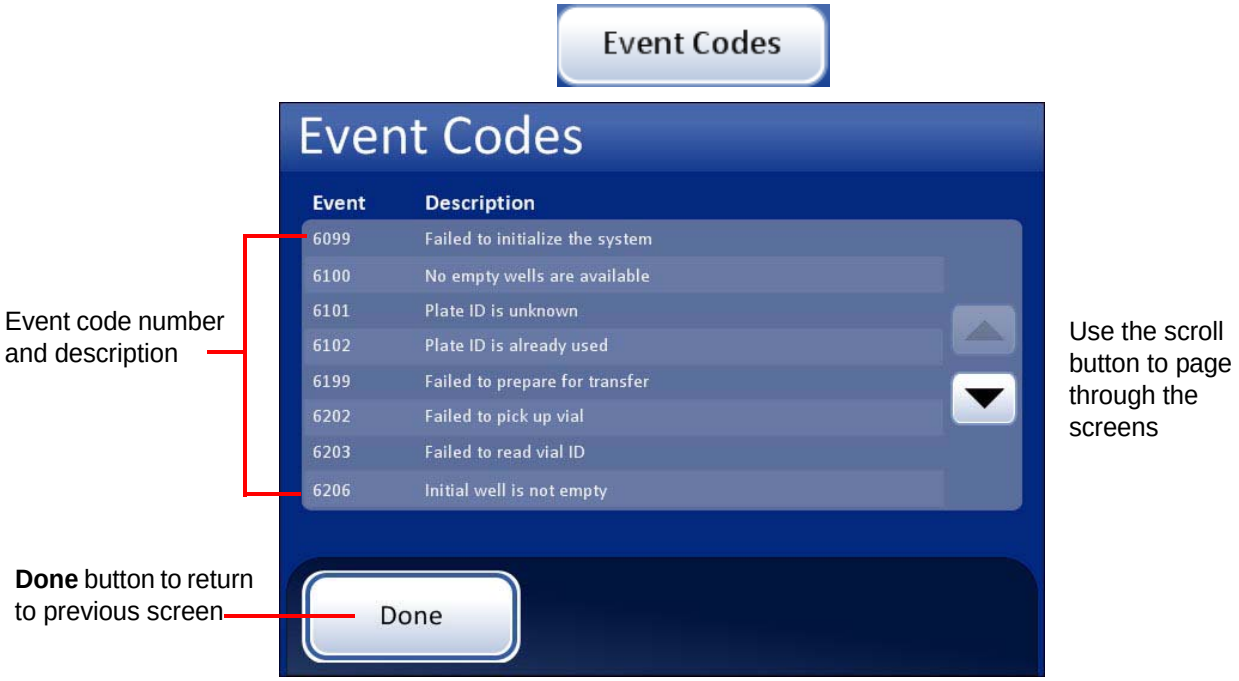


Figure 3-23 Event Codes Screen

Plate Report

Figure 3-24 Plate Report Button

The plate report function keeps a plate report of every deep-well plate that has entered the system database. The system stores plate reports up to 18 weeks, then purges files older than that. Press the

Plate button to see a list of all plates in the database - each plate becomes known when its barcode is successfully read when the plate is initially loaded into the instrument.

Figure 3-25 List of Deep-well Plates in the Database

Each plate's unique ID is read when it is loaded into the system and date/time stamped. A plate listed with a green check mark indicates the plate is currently loaded. The list of plate reports may be sorted by touching **Plate ID** or **Time** at the top of the list. Touch the field a second time to reverse the sort order.

Press a plate ID to open the plate report. (See Figure 3-26.)

Figure 3-26 Plate Report Screen

Plate ID - the barcode on the deep-well plate is the ID. This is read when the plate is loaded into the instrument.

Plate Status - displays the state of the deep-well plate:

- OK
- Not processed
- Canceled (batch canceled by operator)
- 6204 - or whatever event ID is associated with the batch halting, if the batch did not finish

Plate Summary - tally of how many samples were transferred and how many errors were encountered.

Plate Events - unsuccessful transfer from the vial to the deep-well plate. The status column will have an event code that can be referred to by pressing the **Event Codes** button in the upper right of the screen. (Or see Chapter 6, Troubleshooting.) Usually it is a sample-related error, such as vial cap too tight, insufficient vial fluid, duplicate vial barcode, etc.

_DNP this extension on the ID indicates "Did Not Process." Sample was not transferred from the vial.

_QNS this extension on the ID indicates "Quantity Not Sufficient." There was not enough sample in the vial to result in a successful transfer.

Note: Visually check the fill level of the associated deep well positions for these samples. Manually pipette from the vial to fill the well, if necessary.

Transferred Samples - lists the barcoded vial IDs that were successfully transferred to the deep well.

Assign Vial ID - for unsuccessfully transferred samples, as listed in the Plate Event section, enter a sample ID. This is necessary to complete the plate map associated with the deep-well plate positions. Refer to "ASSIGN VIAL ID" on page 4.18.

Export - Exports the plate report to a USB drive if a USB key is in one of the ports.

CAUTION: Be sure to perform Assign Vial ID steps **prior** to exporting, because the plate report cannot be edited once it has been saved for external use.

Print - if the instrument is configured with a printer, the plate report can be printed.

Done - closes the plate report and returns to the Plate Report screen.

Gather Diagnostics

Figure 3-27 Gather Diagnostics Button

Gather diagnostics is a function intended for instrument troubleshooting by Hologic Technical Support. It gathers and zips the error history log and other instrument operating information.

Put a USB device into one of the USB ports and press the **Gather Diagnostics** button.

Figure 3-28 Gather Diagnostics Screen

The instrument operating information will be gathered into a folder on the USB key titled STS Logs. The folder will have two zip files. These can be e-mailed to Hologic Technical Support.

Clean Screen

The touch screen can be locked for cleaning purposes. The screen will be rendered inactive for 20 seconds. To lock the screen, press the **Clean Screen** button.

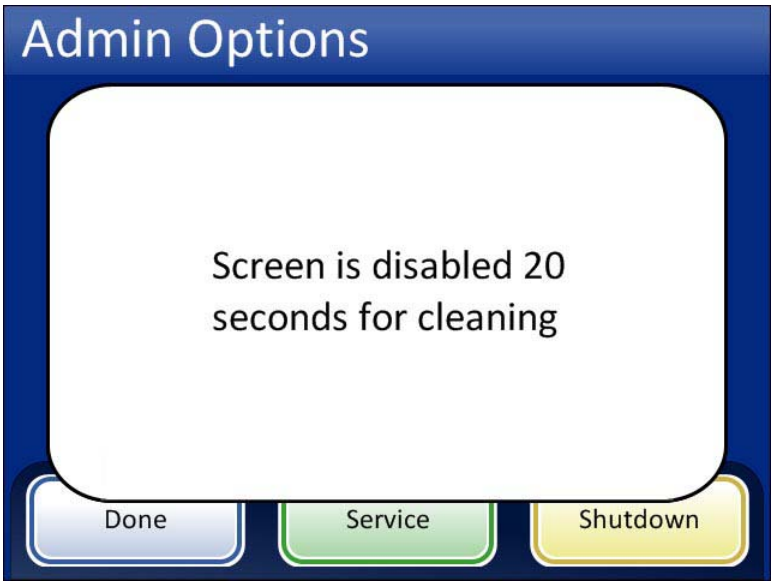


Figure 3-29 Screen Disabled Message

A message appears that the screen is disabled. The touch screen may be gently cleaned with soap and water and a damp cloth.

Start Mode

Figure 3-30 Start Mode Button

The system provides the ability to specify a delayed batch start time and date in the future. This feature is detailed in section “DELAYED START MODE” on page 4.13.

SECTION B

MAIN SCREEN, INSTRUMENT IDLE

When the ThinPrep 5000 Sample Transfer System is powered on and ready for use, the main screen will be displayed.

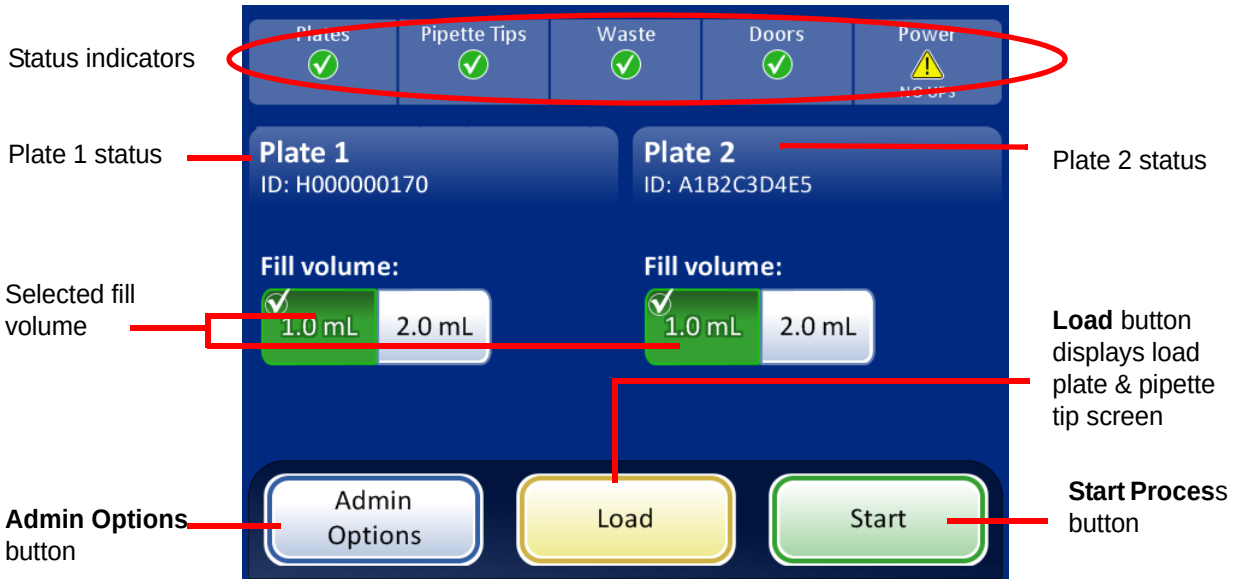


Figure 3-31 Main Screen

Status Indicators

The status indicators are located at the top of the main screen display.

Touch the status indicator on the screen for a brief pop-up explanation of what the status means. A table of the status indicators is shown below.

Table 3.1: Status Indicators

PLATES	PIPETTE TIPS	WASTE	DOORS	POWER
Status OK, ready to process	Status OK, ready to process	Status OK, ready to process	Status OK, ready to process	Status OK, ready to process
Plate not detected. Insert deep-well plate or make sure it is in position	No pipette tips have been detected after 3 tries. Check that a pipette tip tray is available	The pipette tip waste bin is full, undetected or absent. Insert an empty bin and close the door.	One or both doors are open. Close doors.	The system is running on battery power (UPS). If a batch is in process, it will finish the sample and pause the batch.
				The UPS is not detected or battery is low in power.

Plates - The system monitors whether a deep-well plate is present or not. If a plate is present, the icon is a check mark. If a plate is not present, the icon is an 'X'.

Pipette Tips - The system monitors whether a tray of pipette tips is present. If a tray is present, the icon is a check mark. If a tray is not present, the icon is an 'X'.

Doors - The main door and the output door must be closed in order to run the instrument. If both doors are closed, the icon is a check mark. If either door is open the icon is an 'X'.

Waste - The system monitors if the pipette tip waste bin is present. If it is present, the icon is a check mark. If the waste bin is not present the icon is an 'X'.

At initial startup or the beginning of a new batch, the Waste icon will be an 'X'. Always check for used pipette tips and discard any that are present.

Power - the system monitors that there is power to run the processor. If power is available the icon is a check mark. If the system is relying on the UPS for power, the icon is an 'X'.

CAUTION: If the system is relying on the UPS battery power (such as a power outage), there is a limited time in which there will be sufficient power to safely run the system. (Approximately

30 minutes.) The instrument should be shut down. If a batch is in process, interrupt it and elect to end the batch. (Refer to Figure 4-21.) When the mechanisms have put all consumables away and the main screen displays, shut down the system according to the directions in section "TURN OFF THE THINPREP 5000 SAMPLE TRANSFER SYSTEM" on page 2.5.

WARNING: Never disconnect the UPS wall plug when the instrument is running on battery power. The instrument needs to remain connected to ground through the UPS.

Plates 1 and 2 Status

The status of the deep-well plate positions is always monitored. The status of a plate at any time may be:

- Not Present
- Present but ID Unknown (could not read barcode)
- Present, ID Known (and displayed on the plate graphic on the User Interface)
- Present, ID known, 'x' left (number of wells still to be filled)
- Present, processed and therefore unavailable for further use

At the time the instrument is powered on or when a plate is loaded, the system will check the barcode ID. If the barcode cannot be read, the plate is considered invalid and not used for processing.

If the barcode is read, the system will check the internal database to see if the plate has previously been processed. The plate ID and data is retained in memory for 18 weeks.

If the plate was previously used for a full batch, it is considered invalid and not used for further processing. If the plate was partially filled, the remaining wells are considered available for sample transfer.

If the plate was not previously used, it is considered empty and available for output for a full batch.

Fill Volumes

The sample well fill volume is selectable between 0.5 and 2.0 mL in 0.1 mL increments. Up to three volumes can be set at install (or during a service visit) for amounts that will be most frequently used. The fill volumes do not have to match between plate 1 and 2. Depending on your instrument configuration, the fill volume selectors may be different than shown in this manual. Examples are shown below.

Two pre-selected fill volumes with each plate the same

Three pre-selected fill volumes with differing amounts per plate

Figure 3-32 Examples of Fill Volumes

4. Operation

Chapter Four

Operation

SECTION A

INTRODUCTION

Normal instrument operation consists of loading supplies, starting the batch and unloading the prepared deep-well plate(s) and processed sample vials when the batch is complete. A plate report is generated at the completion of each deep-well plate. The report indicates the success or failure of processing each vial, as well as any errors encountered. The report may be viewed on the user interface, or the report may be saved as a file to a USB key. A hard copy may be printed out if the system is configured with an optional printer.

User operations:

- Start
- Delayed start
- Interrupt
- Resume
- Cancel
- Assign vial ID
- Manually scan a vial ID
- Shut down

Typical batch processes:

- Load and run ½ of a 96-well plate with one carousel of 48 samples
- Load and run a complete 96-well plate with two carousels of 48 samples
- Load and run two ½ 96-well plates with one carousel of 48 samples
- Load and run two complete 96-well plates with two carousels of 48 samples

Plate map files and reports can be generated for batch sizes of 24, 48 and 96 samples.

4 OPERATION

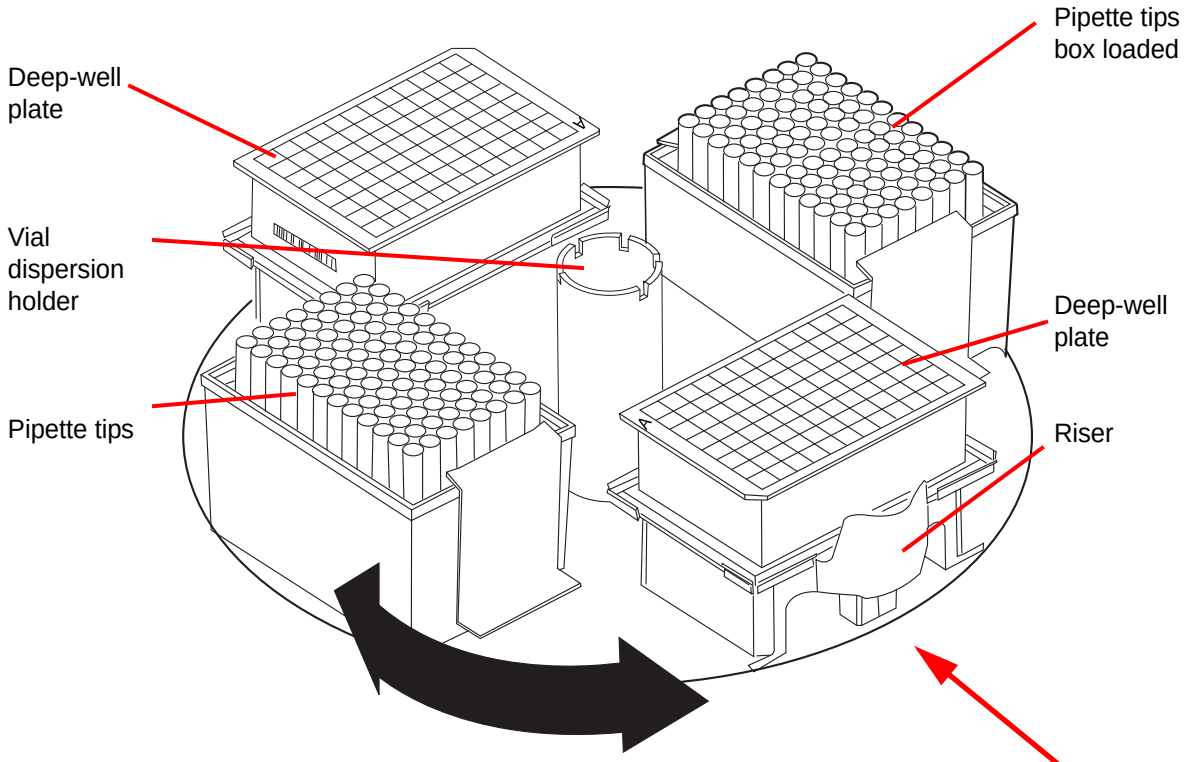


Figure 4-1 Output Carousel Diagram

SECTION B MATERIAL REQUIREMENTS

CAUTION: Use universal precautions. Wear protective clothing in accordance with universal precautions when operating the instrument.

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

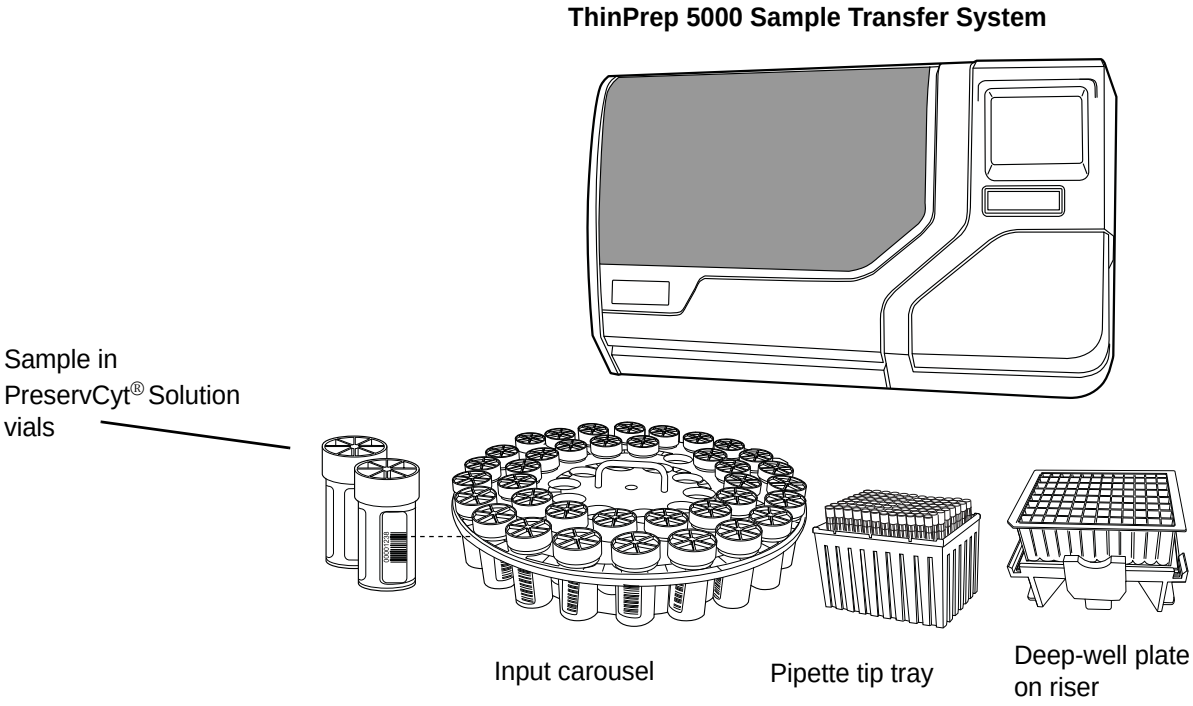


Figure 4-2 Required Materials

- ThinPrep® 5000 Sample Transfer System
- Sample in vials of PreservCyt® Solution
- Input carousel
- Pipette tips
- Deep-well plates
- Riser for deep-well plate

Important Operational Notes

- Wear protective clothing in accordance with Universal precautions when operating the instrument
- When loading vials into the carousel, always check that the caps are on tightly and that there are no obvious impediments to processing (vial packaging not completely removed, labels on the cap, foreign objects left in the vial).
- Keep pipette tip trays covered when not in use, to keep them dust-free
- To protect against loss of sample due to evaporation, do not leave deep well plates in the instrument once they have been filled.

SECTION C

LABELING THE SAMPLE VIALS AND DEEP WELL PLATE

Vial Barcode Label Format

The ThinPrep 5000 Sample Transfer System accepts vial barcodes formatted with

- Code 128 symbology
- Interleaved 2 of 5 symbology
- Code 39 symbology
- Code 93 symbology

Sample IDs may contain 5 to 14 alphanumeric characters (based on what each symbology supports). All ASCII 128 printable characters (decimal codes 32-126) are acceptable. Any barcode containing a non-supported character or too few or too many characters will cause an error.

Adhering Vial Labels

Place the vial barcode label **vertically** on the PreservCyt Solution label, using the edge for alignment, as shown in Figure 4-3. During application, avoid placing the barcode label over patient information, multiple labels, or on the torque features of the vial. Do not place labels on the vial cap or on the bottom of the vial. Sticking labels on incorrectly can cause a failure to read the barcode or a failure of the instrument removing the vial from the carousel.

A minimum of 2.5 mL of sample is required for successful transfer.

Additionally, check to make sure there is no foreign matter in the vial (such as a piece of sample collection device or other non-biologic debris).

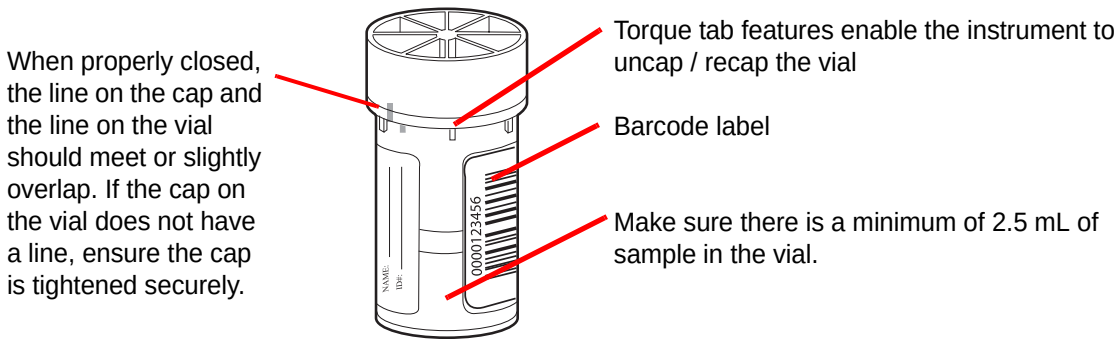


Figure 4-3 PreservCyt Solution Sample Vial

Deep-well Plate Barcode Labels

The ABgene deep-well plates have a barcode label on them. If the label cannot be read or must be replaced for some reason, be sure to use a 1-dimensional, code 128 barcode that the system can read. The barcode must be placed on the lower right side of the plate so that the barcode reader can scan it properly. Refer to Figure 4-6.

SECTION D

LOAD THE THINPREP 5000 SAMPLE TRANSFER SYSTEM

Load the Carousel into the Instrument

Load the carousel with prepared, barcoded sample vials. The vials do not need to be oriented in any way in the tray.

Note: If the instrument comes to an empty position on the carousel, the batch ends. Make sure there are exactly the number of samples loaded for the intended batch size and they are contiguous.

Load the carousel into the processor. Open the front door and slide the tray into the center of the processing area. It is properly in place when it stops against the rear wall.

The carousel does not have to be inserted with the number 1 position oriented in a particular way. When the instrument begins processing, it will automatically align the carousel to begin processing at position 1.

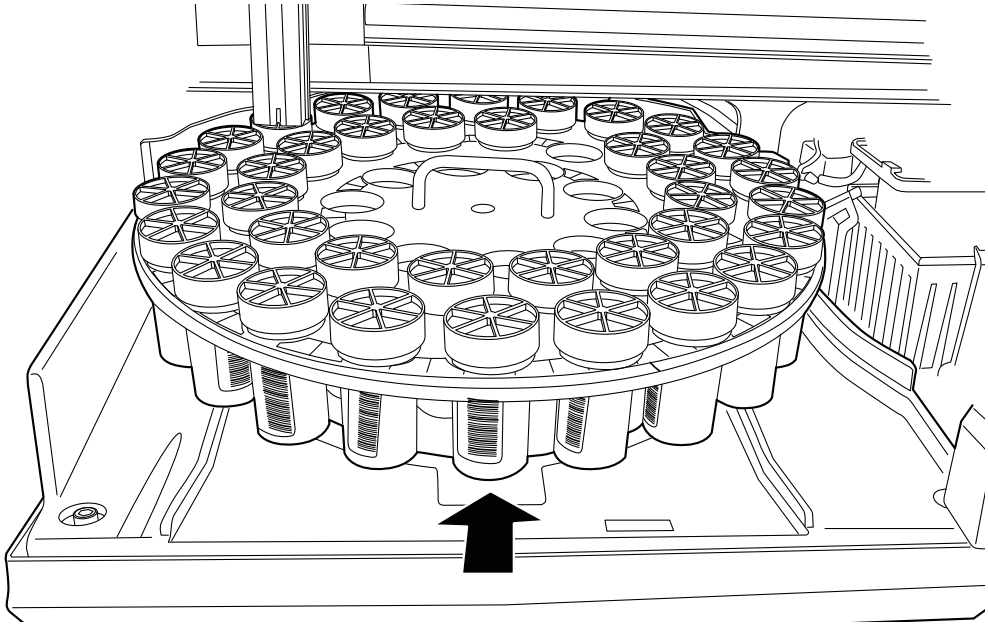


Figure 4-4 Load Carousel into the Instrument

Deep-well Plate

To load the output carousel, press the **Load** button and then press the Plate 1 or Plate 2 segment on the touch screen, to bring the corresponding plate position to the door.

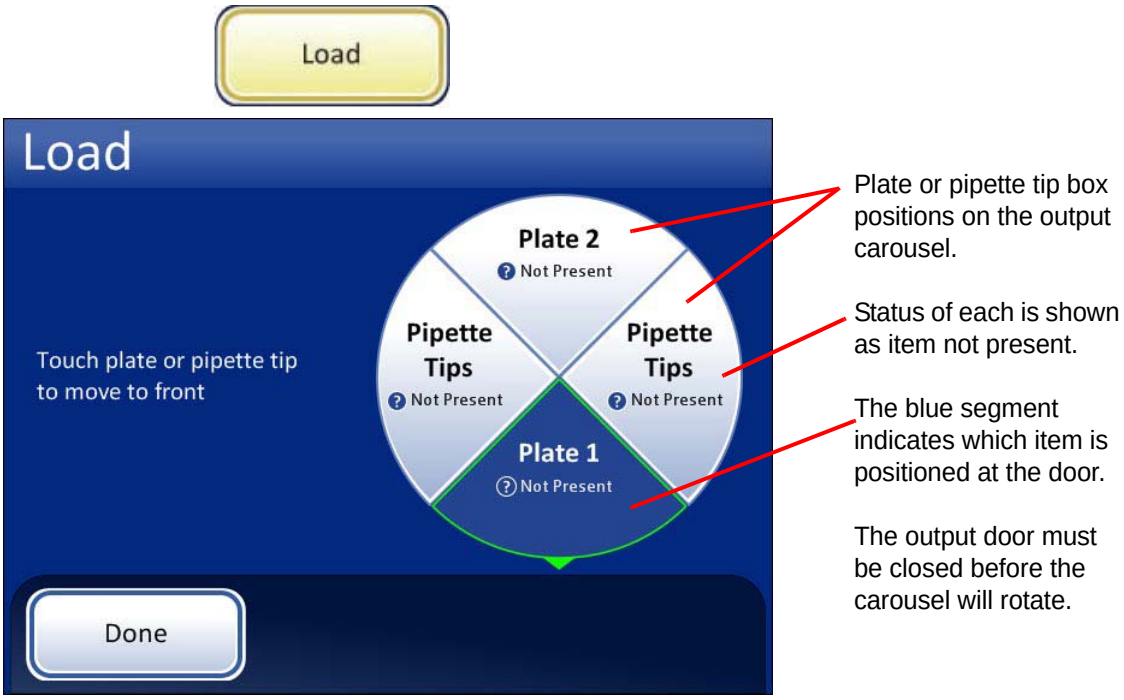


Figure 4-5 Bring Plate 1 Carousel Position to the Door for Loading

Place a deep-well plate on the riser. Make sure the barcode label is facing toward the right, so that the barcode reader can scan the plate ID. Make sure the plate is positioned so that the well position labeled A1 is at the back left. Open the output carousel door and load the plate and riser into the carousel.

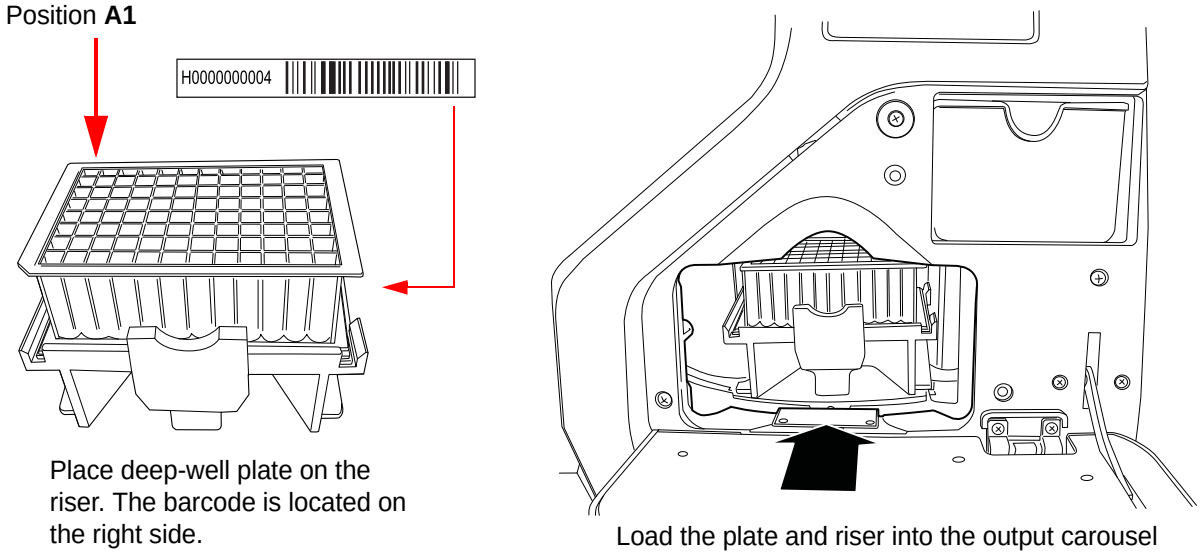


Figure 4-6 Load A Deep-well Plate

Close the output door. The instrument will read the barcode on the plate. The Load screen will update the display to indicate that the plate is present. The barcode number is displayed.

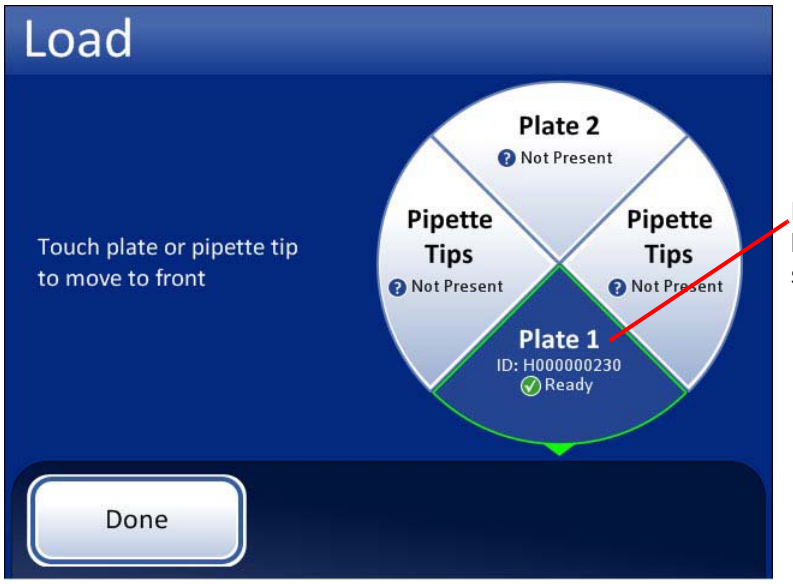


Figure 4-7 Deep-well Plate Loaded

To load a second plate, touch the **Plate 2** segment on the Load screen to bring that position of the output carousel to the door. Load the plate as described above.

Note: Only load a second plate if you intend to run two samples out of the same vial (one sample for plate 1 and one sample for plate 2). Otherwise, do not load plate 2.

Pipette Tip Box

Load boxes of pipette tips the same as loading deep well plates.

From the Load screen, touch either **Pipette tip** segments to move that position to the output door. (Either pipette tip position is acceptable.)

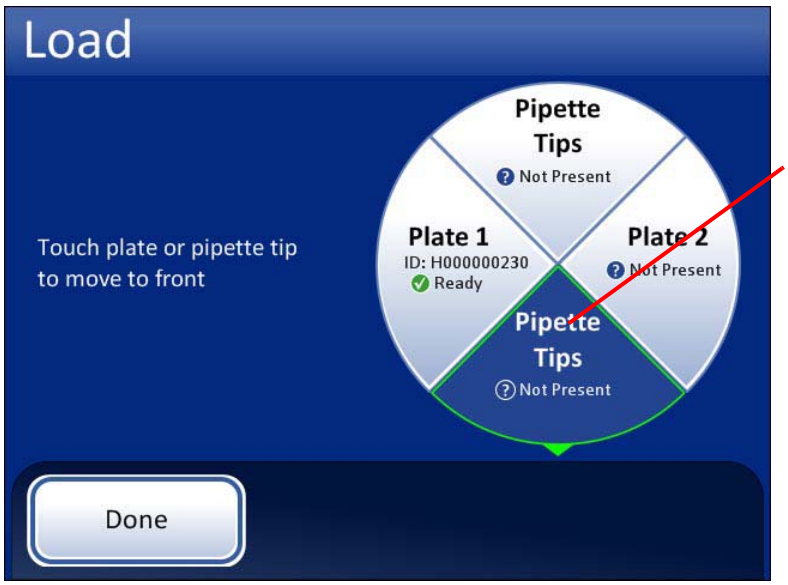
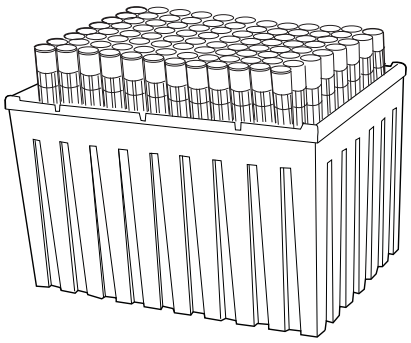


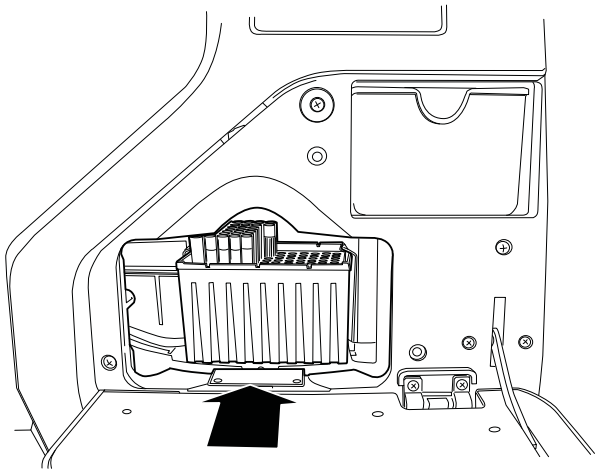
Figure 4-8 Bring a Pipette Tip Carousel Position to the Door for Loading

Open the output door. Load a box of pipette tips into the carousel. Full pipette tip boxes are not oriented in any particular way when loading into the instrument.

If the box has been *partially used*, make sure that the side with available tips is placed toward the **left** when loading. (Otherwise the instrument will not find a tip and after three tries, will end the batch.)



Box of pipette tips



Load the pipette tips into the carousel. Partially loaded boxes must have the tips toward the left.

Figure 4-9 Load Pipette Tips

Close the output door. The instrument senses that a box of pipette tips is present (Figure 4-10).

Note: The system assumes a newly loaded box of pipette tips is always full. The box does not have to be full, but the tips must be present along the left side of the box. If a tip is not detected after three tries, the batch halts.

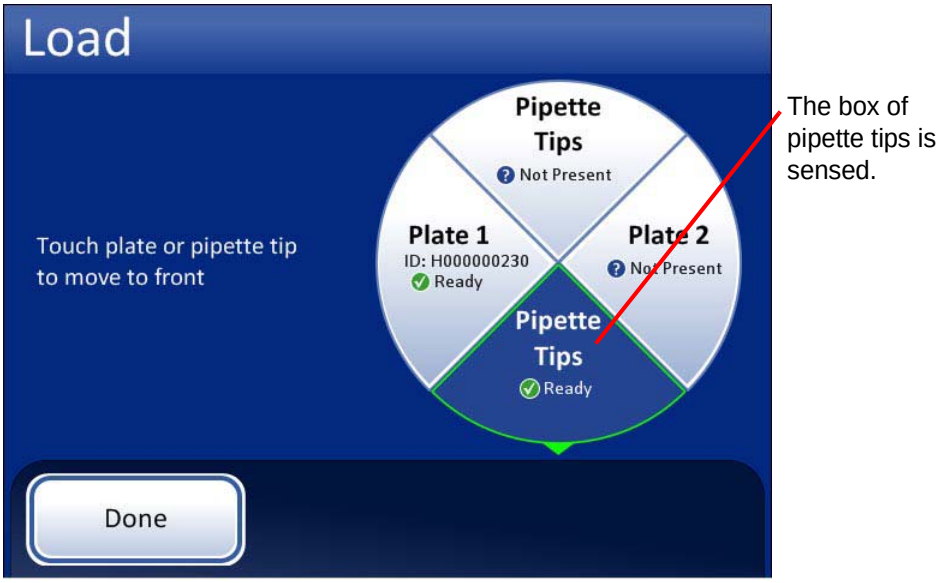


Figure 4-10 Pipette Tips Loaded

Touch the other **Pipette Tip** segment on the Load screen to load another box of pipette tips.

Pipette Tip Handling

- When loading a pipette tip box, the system detects its presence; the **Ready** status assumes the box is full.
- At the end of a batch, the system keeps count of remaining tips until the box is removed from the carousel.
- The system will interrupt a batch if no pipette tip is detected after three tries. The choices are to continue (operator replenishes tips) or end the batch.
- The system determines there are no more pipette tips (if it has been counting tips from a full box) and interrupts the batch. The choices are to continue (operator replenishes tips) or end the batch.
  Note: The system will continue to use tips from one box to the other box, if two boxes are loaded.
- If two plates are being filled in a batch (two samples taken out of one vial), a pipette tip is picked and used to fill a well on one plate and then the same tip is used again to fill the corresponding well on the other plate. It is then discarded.

Select Deep Well Fill Volume

When the plates and pipette tips have been loaded, a fill volume for the deep-well plate(s) must be selected. Depending on how your system is configured, there will be one, two or three fill volumes available for each plate. Select the desired fill volume by pressing the volume button on the touch screen. Examples are shown below, Figure 4-11.

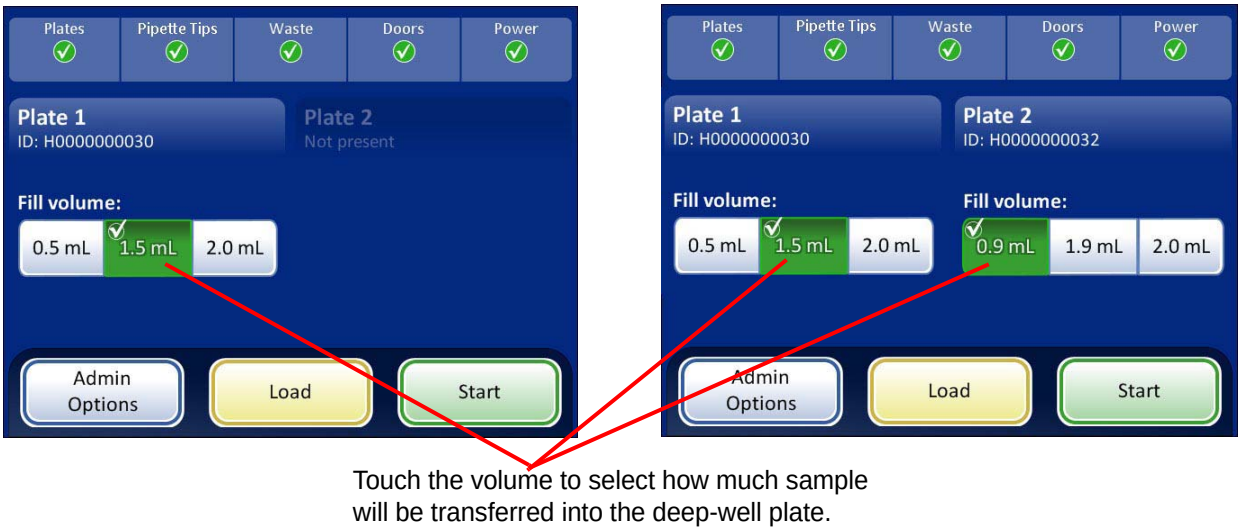


Figure 4-11 Select Fill Volume - Example with 1 and 2 Plates

Choices for the volume amounts are determined at installation of the ThinPrep 5000 Sample Transfer System. The volume range is between 0.5 mL and 2.0 mL, in 0.1 mL increments. The volumes for each plate may be different.

Note: Once set, fill volumes can only be changed with a service visit.

Empty Pipette Tip Waste Bin

When the system concludes a batch, the Waste indicator icon on the top of the screen changes to indicate that the pipette tip waste bin should be emptied (Figure 4-12). A new batch will not start until the waste bin has been removed, emptied and replaced.

Waste bin full indicator

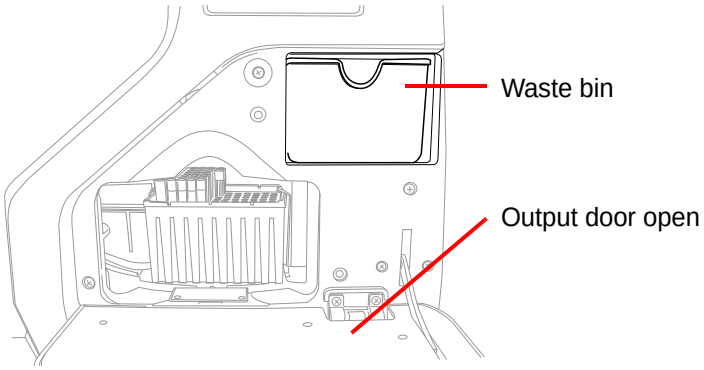


Figure 4-12 Pipette Tip Waste Bin

SECTION E

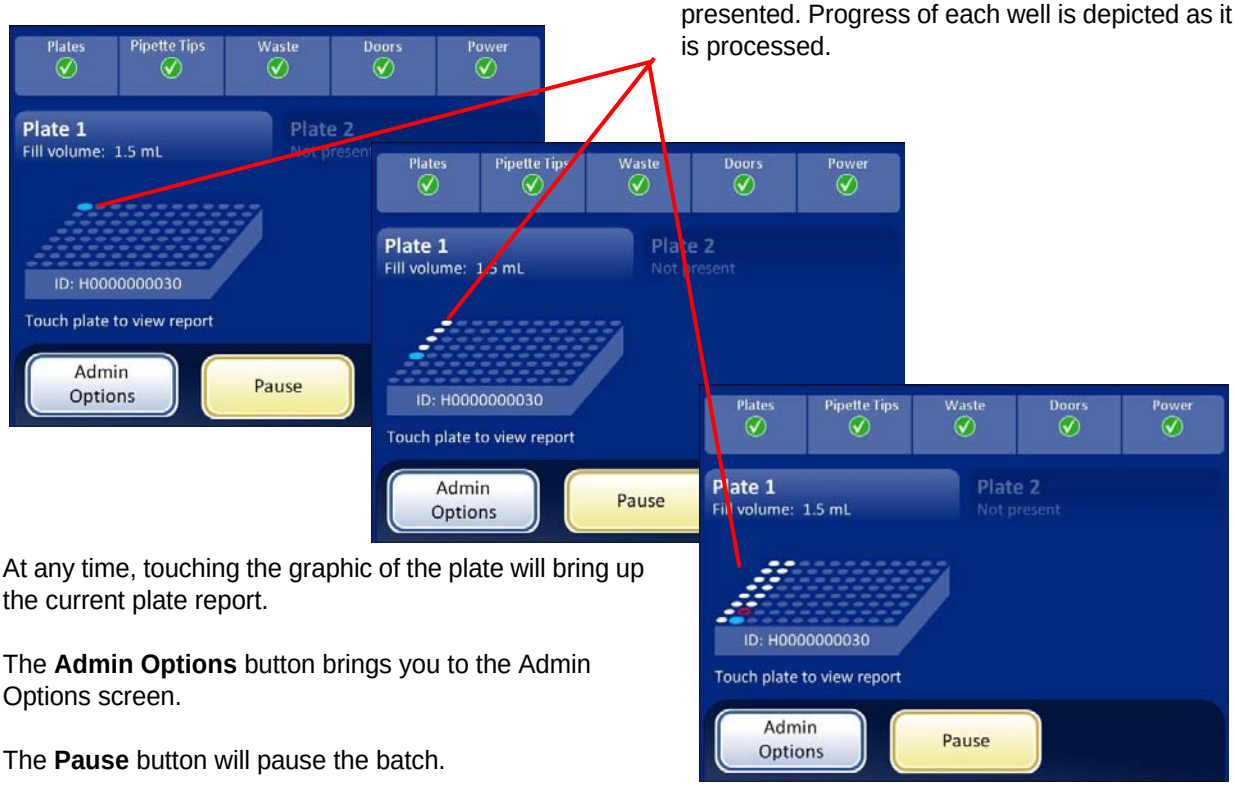
START A BATCH

When the input carousel has been loaded with labeled sample vials, and deep-well plate(s) and pipette tips are loaded, press the **Start** button (Figure 4-13) to begin.

Figure 4-13 Start Batch Button

Both doors will be heard to lock. The batch processing screen displays. See Figure 4-14.

During a batch, a graphic of the deep-well plate is presented. Progress of each well is depicted as it is processed.



At any time, touching the graphic of the plate will bring up the current plate report.

The **Admin Options** button brings you to the Admin Options screen.

The **Pause** button will pause the batch.

Figure 4-14 A Batch in Process

Each well is filled in order from position A1 to H6 (samples 1 to 48) for one carousel of samples and positions A7 to H12 (sample 49 to 96) for a second carousel. As the plate is filled, the progress is updated on the touch screen display. See Figure 4-15.

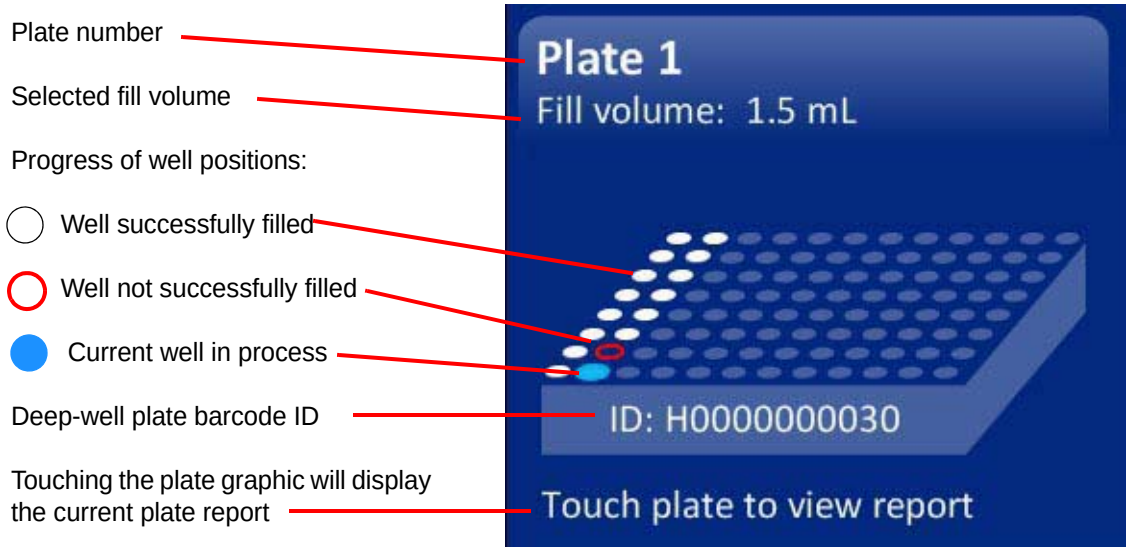


Figure 4-15 Plate Progress Indicators

View Plate Report During Processing

To view the plate report during processing, touch the image of the plate on the touch screen. The Plate Report screen will appear (Figure 4-16).

The **Event Codes** button is available to view the event code if a sample encountered an error

Assign Vial ID button is available, indicating an error had been encountered

Export button is not available until the plate is finished.

Figure 4-16 Plate Report During Processing

SECTION F

DELAYED START MODE

Set the Delayed Start Date and Time

The ThinPrep 5000 Sample Transfer System allows the operator to pre-set a delayed start date and time for a batch. The system will automatically begin processing a batch when it reaches the set time.

The system will allow a pre-set time and date up to 18 days ahead. Due to concerns about evaporation of samples already transferred into deep-well plates from a previous half batch, only new, empty plates should be pre-set for delayed start mode.

From the Admin Options screen, press the **Start Mode** button.

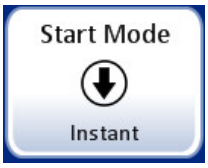
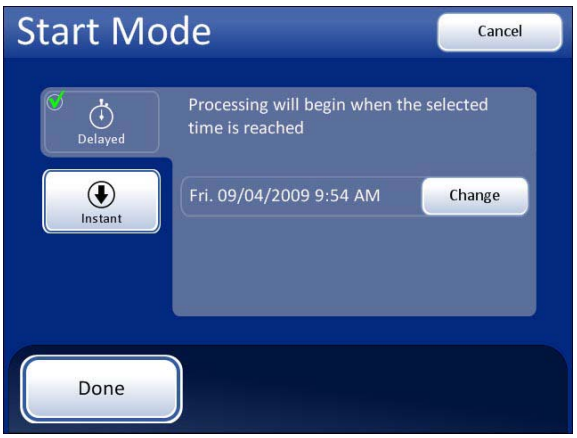


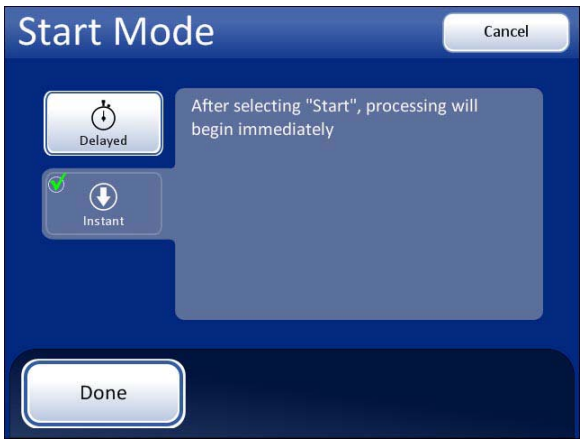
Figure 4-17 Start Mode Button



Delayed Start Mode selected.
Press the **Change** button to set date and time for automatic batch start.

Done button accepts changes and returns to Admin Options screen.

Cancel button cancels any changes and returns to Admin Options screen.



Instant Start mode selected. Batch processing will begin immediately upon pressing the main screen **Start** button.

Done button accepts changes and returns to the main screen.

Cancel button cancels any changes and returns to Admin Options screen.

Figure 4-18 Select Start Mode Screens

Select the **Delayed** mode. Press the **Change** button to set the date and time for the delayed start.

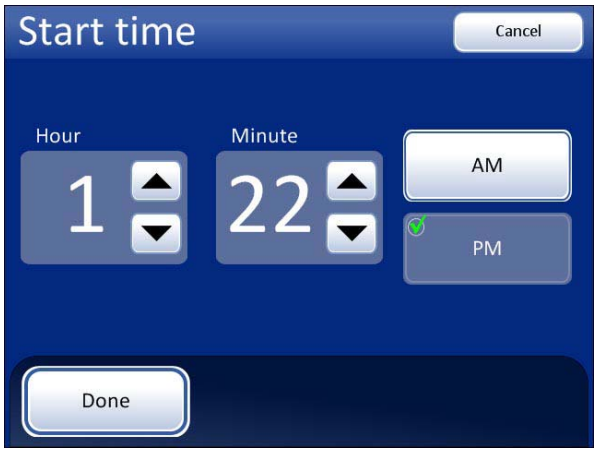
A Start Date screen (a calendar) will display. Press the date that the batch is to begin on. As soon as a date has been selected, a Start Time screen will display. Select the desired start time.

Press the **Done** button to accept the delayed time and date and return to the main screen.

Press the date of the delayed start.

Press the arrow buttons to change the month backward or forward.

Press the **Cancel** button to abandon changes and return to the Start Mode screen.



Use the up / down buttons to select the time (hours and minutes) for the batch to begin.

Select AM or PM for the meridian, if a 12-hour clock is used.

Done key accepts changes and returns to the Start Mode screen.

Figure 4-19 Select Delayed Start Date and Time

Make sure the instrument is loaded with prepared sample vials, deep-well plates and pipette tips. Close the doors. Select the fill volume for the deep-well plate(s). The instrument will begin processing when the selected date and time are reached.

How to Override a Delayed Start

If a delayed start has been set and a batch is to be processed on the instrument before then, press the **Start** button. A message is displayed on the touch screen that shows the programmed start time. (Figure 4-20.)

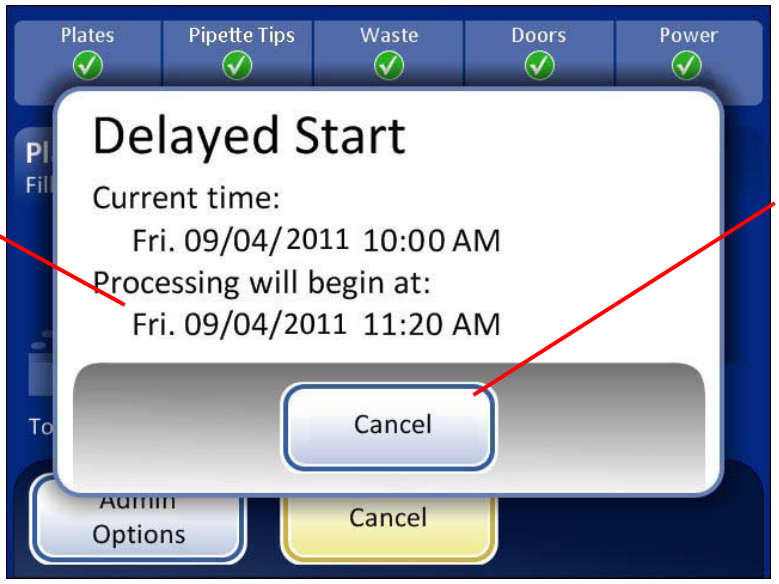


Figure 4-20 Delayed Start in Progress Message

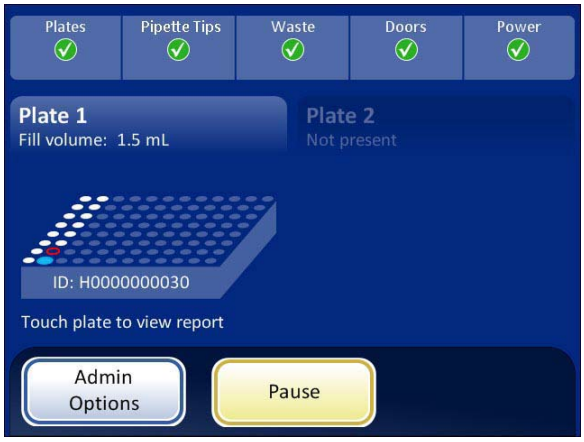
To cancel the scheduled batch start, press the **Cancel** button. The display will return to the main screen and the batch can be started.

If the scheduled batch has been canceled, the steps to schedule a delayed start time must be repeated.

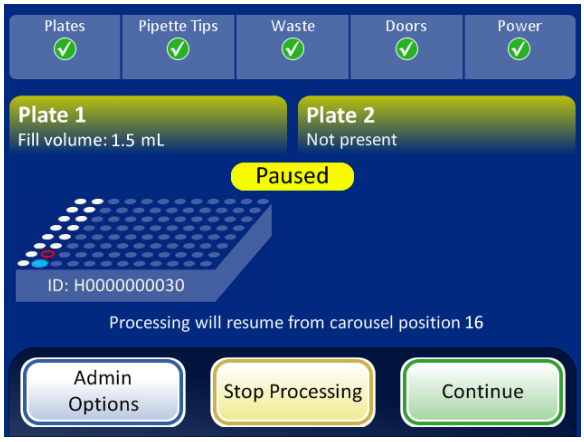
SECTION G PAUSE/CANCEL A BATCH

A batch may be paused while running and resumed immediately or sometime later.

To pause or interrupt a batch while processing, press the **Cancel** button. (Figure 4-21.) The instrument will finish the sample that is in process, recap the vial and return it to the carousel. The doors will unlock.



Press the **Pause** button to interrupt the batch in process. The doors unlock when the current vial has been returned to the carousel.



The batch is paused.

Figure 4-21 Pause a Batch

When the batch has paused, the doors unlock and the operator has access to the carousels. To resume processing press the **Continue** button. To stop the batch, press the **Stop Processing** button and the display returns to the main screen (Figure 4-22).

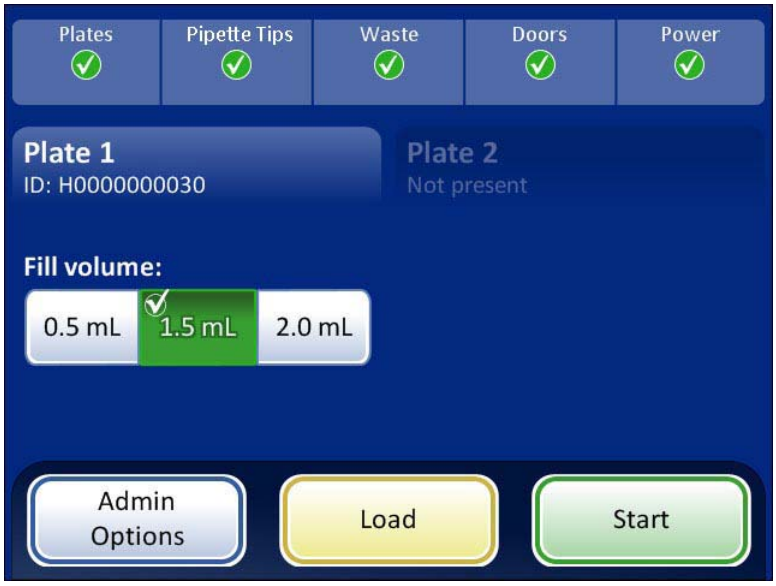


Figure 4-22 Main Screen

Note: While the batch is paused the deep-well plate may be removed and replaced without issue, but do not remove the pipette tip box or the system will lose count of how many tips remain in the box.

When a batch is paused it may be resumed, or the deep-well plate may be removed and continued at another time. As long as the system can find the plate ID in the database, the plate can continue being processed.

Note: The batch report associated with the deep-well plate ID resides in the database for 18 weeks.

Resume the Batch

To resume running the batch, press the **Continue** button.

The doors will lock and the batch will continue where it left off.

End the Batch

To terminate the batch, press the **Stop Processing** button and simply unload the deep-well plate.

SECTION H BATCH COMPLETE

When 48 samples have completed transfer, the system pauses and a message is displayed (Figure 4-23).

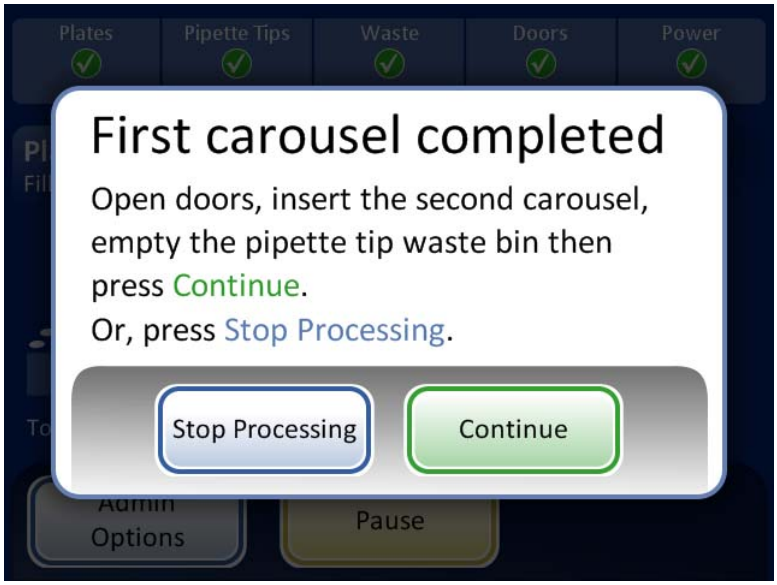


Figure 4-23 First Carousel Completed Message

Continue

To continue transferring sample into the remaining 48 wells of the deep-well plate, open the main door and replace the sample carousel with a new one.

Open the output door, pull out the pipette tip waste bin and discard the tips. Replace the bin.

Note: The system will continue to keep count of remaining pipette tips in the box **unless you remove the box or power cycle the instrument**. Then be sure to either replace the box with a full one, or load a partial box with tips in the left rows of the box. The system always assumes a box of pipette tips is full when it is loaded.

Close both doors. Press the **Continue** button when ready. The system will check that well A7 (#49) is empty and then resume transferring samples to the deep-well plate.

Stop Processing

To end the batch, press the **Stop Processing** button. The Plate Report window will display. Print it (if a printer is configured with your system), or export it or close the window.

CAUTION: If the **Assign Vial ID** button is active when the Plate Report window displays, the ID number(s) must be assigned before the report is exported. That is the *only* time the vial ID can be edited. Refer to the next section.

Unload the deep-well plate(s) from the instrument.

Visually check the deep-well plate(s) after processing to determine successful transfer of samples.

Cover the well plate per lab protocol to limit evaporation and contamination of the samples.

SECTION I ASSIGN VIAL ID

The system allows the operator to manually enter well position IDs for well positions that were not filled due to sample processing errors. This action is performed after a batch is complete but before the batch report is generated for external use (Export).

When a batch containing processing errors completes, the operator is prompted to manually fill the deep well and enter a sample ID for each position that was not filled. Each unsuccessful well position is identified at the beginning of the plate report. (See Figure 4-24.) Enter a sample ID via the touch screen keyboard or use the instrument vial barcode scanner.

- A sample with no ID indicates the barcode was missing or could not be read
- A sample ID with _QNS appended means “Quantity Not Sufficient.” The vial did not contain enough sample for the system to transfer
- A sample ID with _DNP appended means “Did Not Process.” There was a sample error that prevented the system from transferring sample (vial cap too tight, for example)

- Duplicate IDs are accepted – if you do not intend to have duplicate IDs, reconcile your ID records before continuing
- The plate cannot be edited after the batch report has been generated for external use (Export).

Assign Vial ID button is available to manually enter vial IDs for samples that were not processed successfully.

List of vials not processed - this example shows one "Quantity Not Sufficient," two "Did Not Process" and one failure to read the barcode.

CAUTION: Do not press **Export** button until all vial IDs have been assigned. They cannot be assigned after the plate report is generated for external use.

Figure 4-24 Plate Report with Assign Vial ID Button Available

Note: If a plate report has the **Assign Vial ID** button enabled when it appears, attend to that first before doing anything else. Once the plate report is generated, IDs cannot be entered.

Press the **Assign Vial ID** button to go to the Assign Vial ID screen.

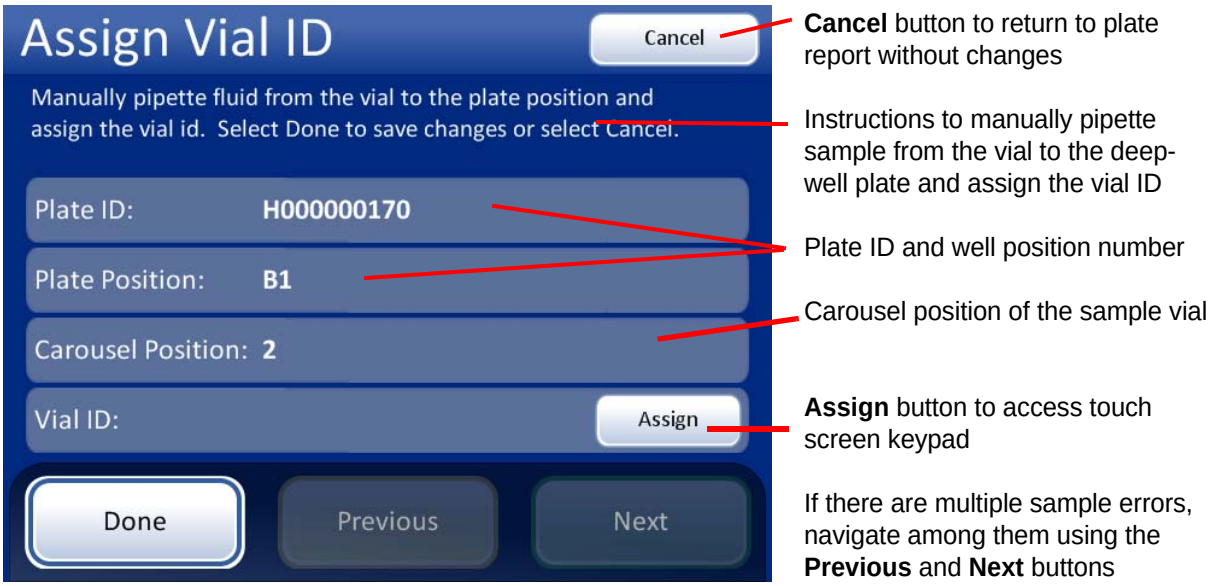


Figure 4-25 Assign Vial ID Screen

Press the **Assign** button to access the touch screen keypad.

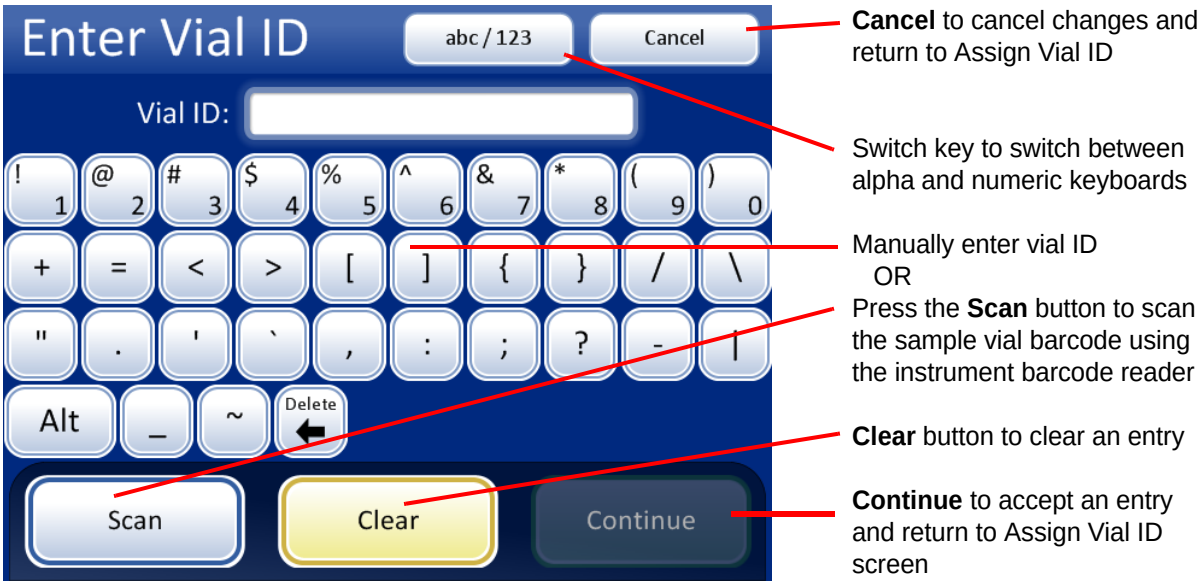


Figure 4-26 Manually Enter Vial ID

Enter a vial ID number (up to 14 characters) via the keyboard and press the **Continue** button.

Or the sample vial barcode can be scanned using the instrument barcode scanner:

1. Open the main door of the instrument and retrieve the vial to be scanned from the carousel.
2. Press the **Scan** button on the touch screen.
3. Hold the vial in front of the vial barcode scanner as shown in Figure 4-27.You have 30 seconds to position the vial so that the scanner reads it. If the barcode cannot be read, enter the ID using the keyboard interface.

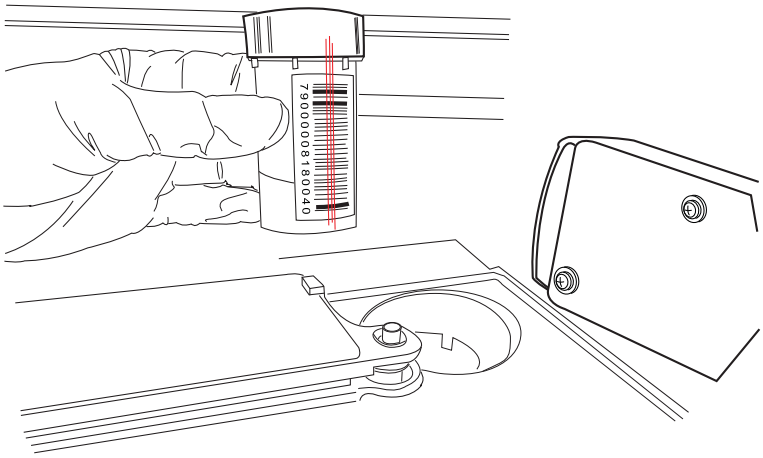


Figure 4-27 Scan a Sample ID Using the System Barcode Scanner

Figure 4-28 Vial ID Has Been Entered

When the deep well position has been filled and the vial ID assigned, press the **Done** button to return to the plate report.

The **Assign Vial ID** button is not available

No errors in the status bar

Done to go to main screen

Export to save file externally

Print to print the report if you have an optional printer

Figure 4-29 Plate Report After Assigning Vial ID(s)

SECTION J

EXPORT

CAUTION: Export finalizes the plate, locking it so that no further transfers may be made. If vial IDs need to be entered, they must be done prior to exporting the report.

Plate Reports

Refer to Figures 2-2 and 2-3 for USB port locations. Insert a USB drive into any of the three ports.

When the **Export** button is pressed, a confirmation message appears, warning that the plate will be finalized (Figure 4-30).

Figure 4-30 Plate Report Export Confirmation

If **Yes** is pressed to continue, the report that is open on the user interface is immediately saved to the USB device as an XML file. A confirmation message displays on the interface. See Figure 4-31.

Note: If the system detects that more than one USB port has a USB device inserted, a message via the user interface will prompt you which port to send the report to.

Figure 4-31 Report Has Been Exported Message

Once a plate has been finalized by exporting, it cannot be changed again (even if it was not completely processed). At the start of each batch, the system checks the status of the plate. If it has been exported, a warning message will appear. The plate may not be run again.

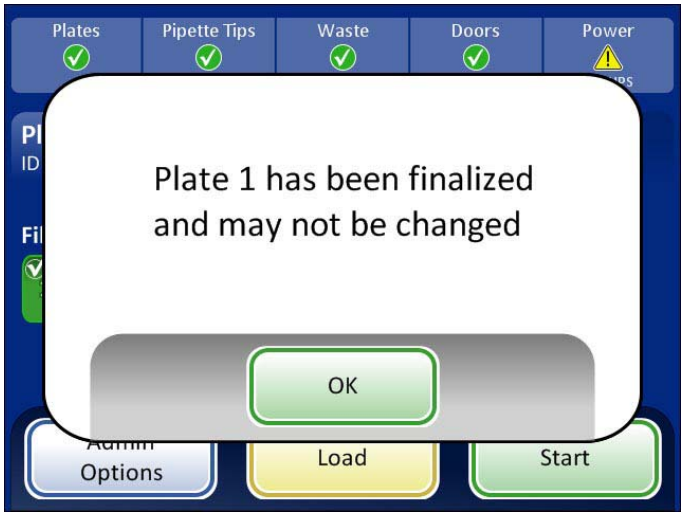


Figure 4-32 Plate Has Been Finalized Message

The system creates a folder titled "**STSReports"** on the USB device. Each report is written there. Reports are automatically named by the convention of "STSPlate-Plate ID-Lab Name-Instrument Name-Date Time stamp.XML". This is illustrated below. A style sheet file is also created (STSReports.xsl) so that the report will appear correctly on screen for viewing. It matches the format by which the plate report prints out if a printer is configured with your system (see Figure 4-41).

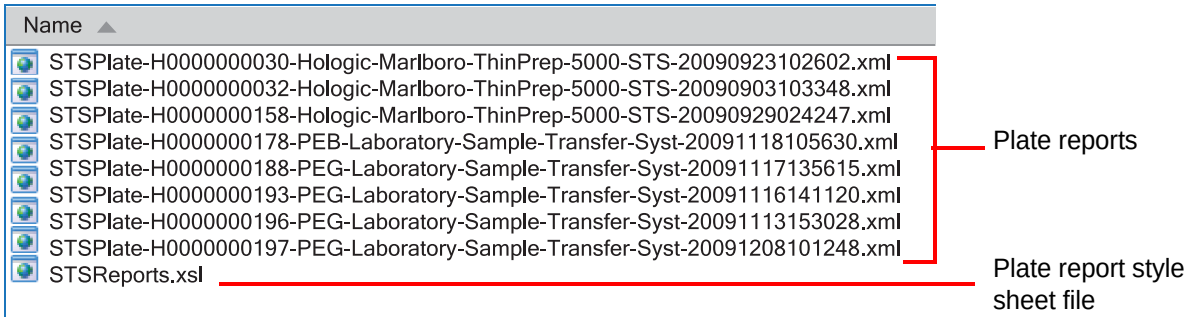


Figure 4-33 Example of Contents of an STSReports Folder

Plate Maps

Another folder titled "**PlateMaps**" is created on the USB device. A plate map is an electronic file of the sample ID of each well position on the deep-well plate. This can be used with any device that accepts this type of input.

The files are automatically named by the barcode number of the plate with a .csv (comma separated value) extension.

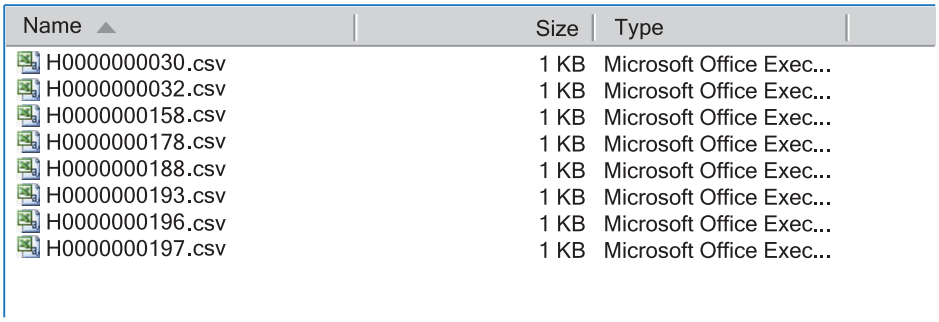


Figure 4-34 Example of Contents of a PlateMaps Folder

Using Plate Map Files with MicroSoft® Excel-based Programs

If a sample ID barcode has leading zeros (i.e., 0012345), when the plate map file from STS (in .csv format) is cut and pasted into an Excel-based file for molecular testing the leading zeros will be removed by Excel.

If the file is **Imported** into Excel (rather than Excel opening it automatically), the leading zeros of sample IDs will be preserved and the file can be used with any program using Excel.

1. Take the thumb drive containing the plate map file(s) and insert it into the computer being used for molecular testing.
2. Open a new Excel spreadsheet from the File menu.
3. Select Data/Import External Data/Import Data.... from the drop-down menus.

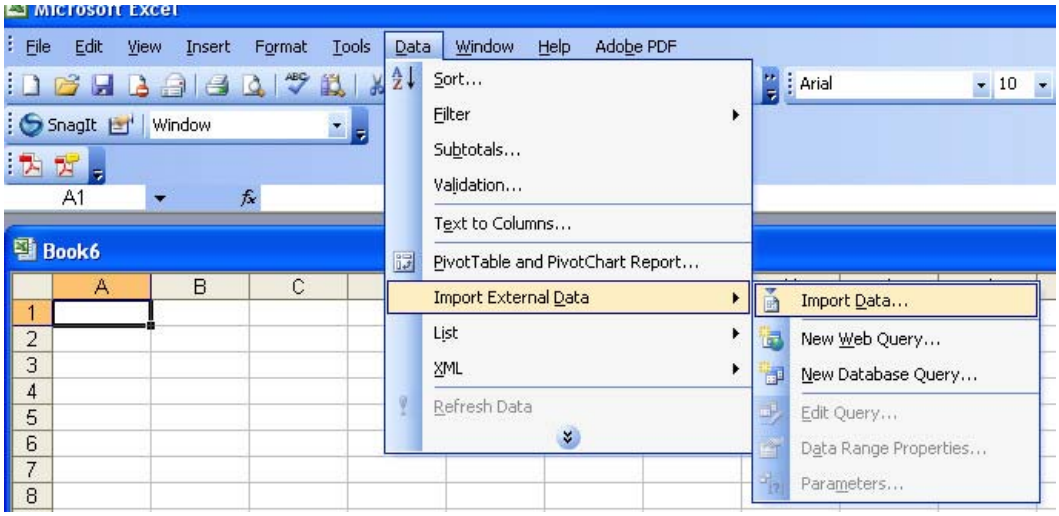


Figure 4-35 Select Import Data

Select a plate map by clicking on it (see Figure 4-36).

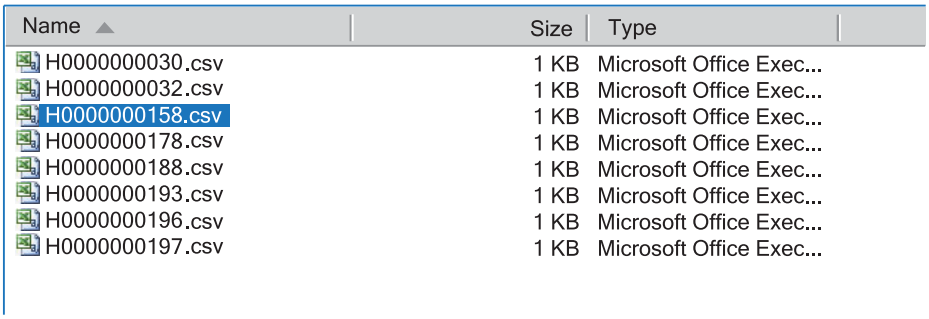


Figure 4-36 Select Plate Map

4. An Excel Import Wizard dialog box appears.

Make sure the Delimited file type is selected and then press the **Next** button.

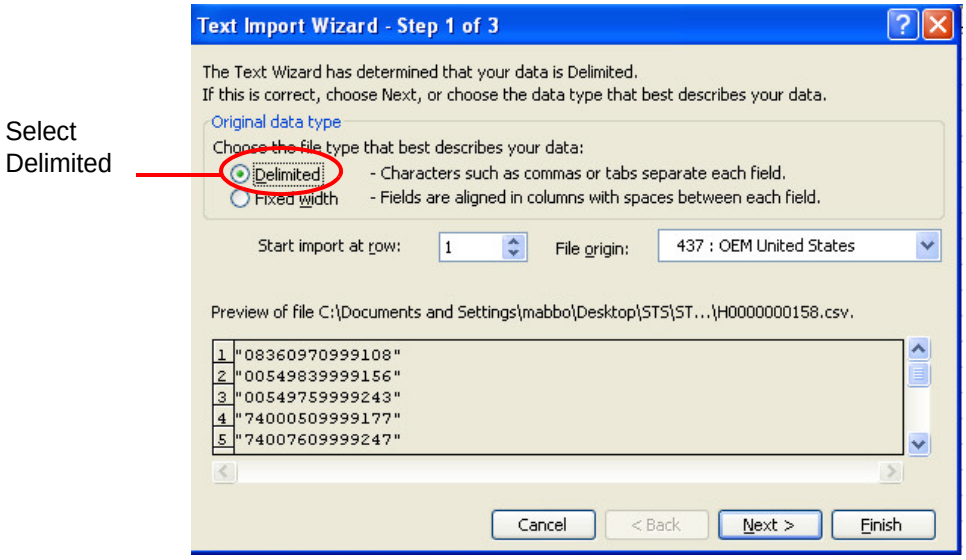


Figure 4-37 Select Delimited File Type

5. Excel wizard steps 2 and 3 require you to select the delimiter type (click on both Tab and Comma) and the data format (click on Text). See Figure 4-38.

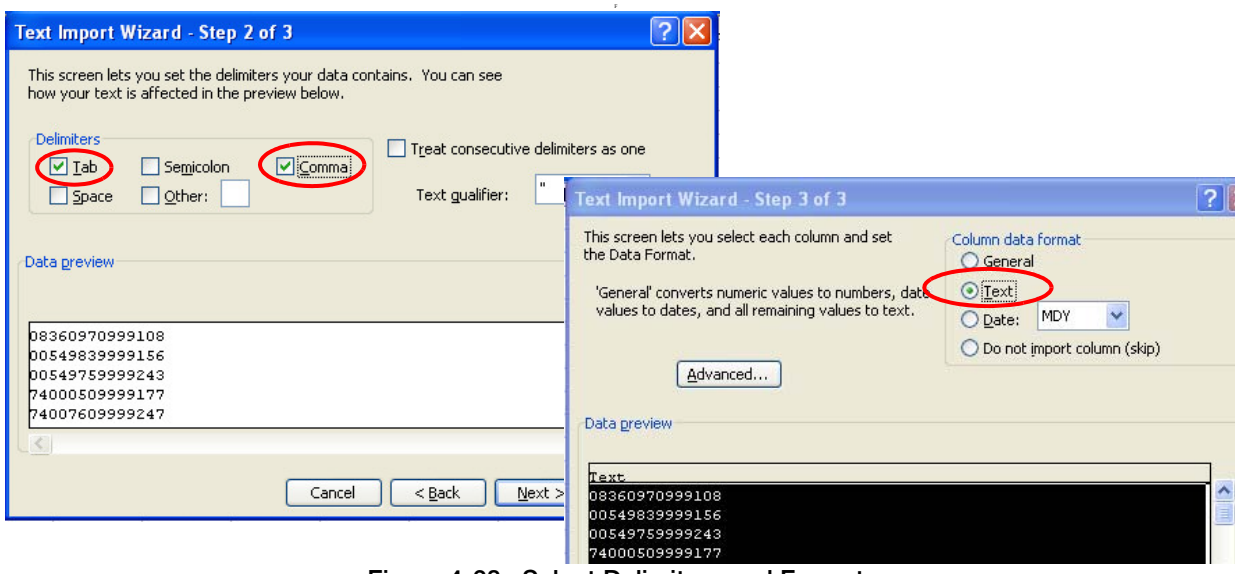


Figure 4-38 Select Delimiters and Format

6. The final step asks where to save the file. Because a worksheet has already been opened in step 2, just click **OK** (Figure 4-39).

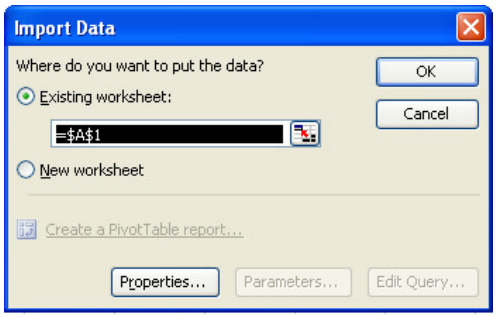


Figure 4-39 Import the Data into the Worksheet

7. The spreadsheet will appear with the sample IDs listed, including all characters.

	A	B
1	08360970999108	
2	00549839999156	
3	00549759999243	
4	74000509999177	
5	74000309999247	
6	74007609999252	
7	083761309999252	
8	740000259999128	
9	83668809999025	
10	83668799999070	
11	83668959999101	
12	00549909999161	
13	10019929999061	
14	83668559999255	
15	74007569999002	
16	08376140999012	
17	10019899999031	
18	10019969999160	
19	83668909999150	
20	10017629999210	
21	74000279999092	
22	80005709999017	
23	10019919999143	
24	10019829999654	

Figure 4-40 Imported csv File Complete

8. Select the IDs (clicking on the column header will select all at once) and from the menu bar select Edit/Copy.
9. Paste into the molecular testing application (all leading zero's will remain intact).

SECTION K

PRINT PLATE REPORT

If the system is configured with an optional printer, press the **Print** button to print the report as a hard copy. See Figure 4-41.

ThinPrep® STS Plate Report

Report time: 03/22/2011@ 10:15 AM
Lab: Hologic 250
Instrument: ThinPrep 5000 STS
Serial number: D002K09DP
Plate ID: H0000000032
Status: OK

Plate events

Vial ID	Date/Time	Vial Position	Plate Position	Status	Description
83668909999150_QNS	03/22/2011 8:04 AM	5	E1	6250	Insufficient fluid
79000781178110_DNP	03/22/2011 8:21 AM	22	F3	6251	Failed to uncap vial
83668669999249_DNP	03/22/2011 8:23 AM	24	H3	6253	Failed to read vial ID
83668929999074_QNS	03/22/2011 8:37 AM	38	F5	6250	Insufficient fluid
83806019999026_QNS	03/22/2011 8:38 AM	39	G5	6250	Insufficient fluid
08375890999233_DNP	03/22/2011 8:41 AM	42	B6	6252	Duplicate vial ID

Transferred samples

Vial ID	Date/Time	Vial Position	Plate Position	Status
83668809999025	03/22/2011 8:00 AM	1	A1	OK
79000151115002	03/22/2011 8:01 AM	2	B1	OK
08387390999138	03/22/2011 8:02 AM	3	C1	OK
83805969999060	03/22/2011 8:03 AM	4	D1	OK
10019939999083	03/22/2011 8:05 AM	6	F1	OK
10019979999206	03/22/2011 8:06 AM	7	G1	OK
83668729999235	03/22/2011 8:07 AM	8	H1	OK
74007569999002	03/22/2011 8:08 AM	9	A2	OK
79000351135022	03/22/2011 8:09 AM	10	B2	OK
79000661166233	03/22/2011 8:10 AM	11	C2	OK
83801329999238	03/22/2011 8:11 AM	12	D2	OK
10019959999018	03/22/2011 8:12 AM	13	E2	OK
10019919999143	03/22/2011 8:13 AM	14	F2	OK

Figure 4-41 Plate Report Printout

OPERATION

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5. Maintenance

Chapter Five

Maintenance

Routine maintenance as described in this manual may be performed by the operator without special tools. Repairs to the instrument and/or scheduled preventive maintenance should only be performed by trained Hologic personnel. Contact Technical Support as described in Chapter 7.

Table 5.1: Routine Maintenance

Every Batch	Empty waste bin at the start of each batch
Daily or more	Clean around carousel and dispersion area
Weekly or as desired	Wipe off level sensor and pipettor tip
As needed	Wipe off barcode reader sensors
	Clean touch screen
	Clean pipette tip waste bin
	Clean carousels and risers
	Change absorbent pad
	Remove and clean drip trays
	Replacing user accessible fuses

General Cleaning

Appropriate cleansers to be used on the ThinPrep® 5000 Sample Transfer System are

- deionized (DI) water
- 70% alcohol
- 10% bleach solution followed by a DI water and 70% alcohol wipe down

Do not use strong solvents on any of the painted or plastic surfaces.

Note: It is the laboratory's responsibility to determine the compatibility of the cleaning agent with the intended subsequent use of transferred sample.

5 MAINTENANCE

SECTION A

EMPTY WASTE BIN

Before running a batch, remove and empty the pipette tip waste bin. The status indicator for Waste will display a red 'x' with the caption "Waste Bin Full." See Figure 5-1. The batch will not start until the bin has been removed, emptied and replaced.

Open the Output carousel door as shown in Figure 5-1. Pull out the waste bin and discard the used pipette tips. Return the bin to the instrument and close the carousel door.

Status indicator on main screen

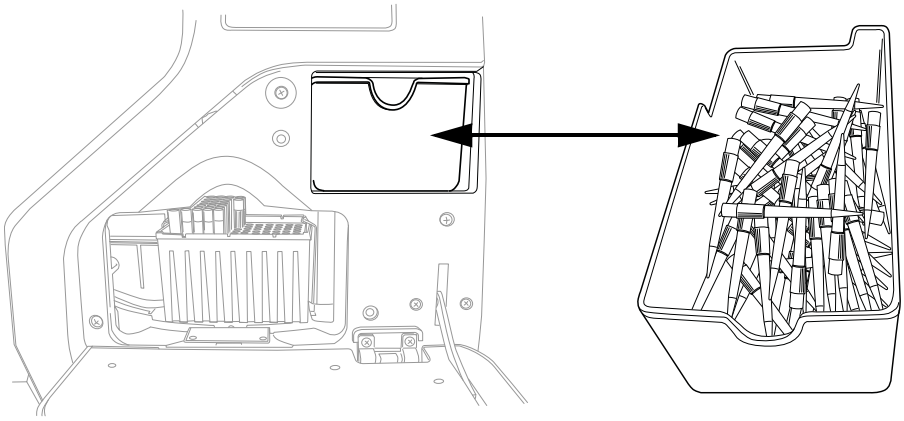


Figure 5-1 Waste Bin Status and Location

Cleaning the Waste Bin

As desired, clean the pipette tip waste bin with an appropriate cleanser such as soap and water, alcohol or a 10% bleach and water solution. Be sure to dry the bin before replacing it in the instrument.

SECTION B

CLEAN AROUND CAROUSEL AND DISPERSION AREAS

On a daily basis, or sooner if desired, remove the carousel and clean around the bottom of the processing area, using a 10% bleach and water solution followed by an alcohol wipe down. Do not dislodge the carousel sensor, but do keep the area around it clean and make sure nothing blocks it. See Figure 5-2.

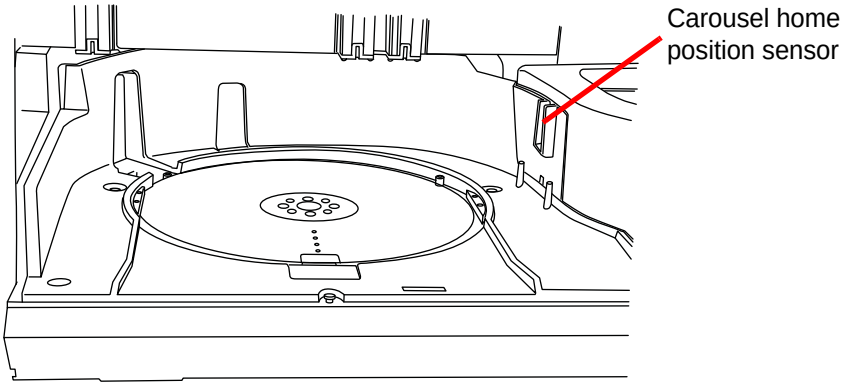


Figure 5-2 Carousel Area

Clean around and inside the dispersion well. The pipette tip stripper area can be wiped down as well. See Figure 5-3.

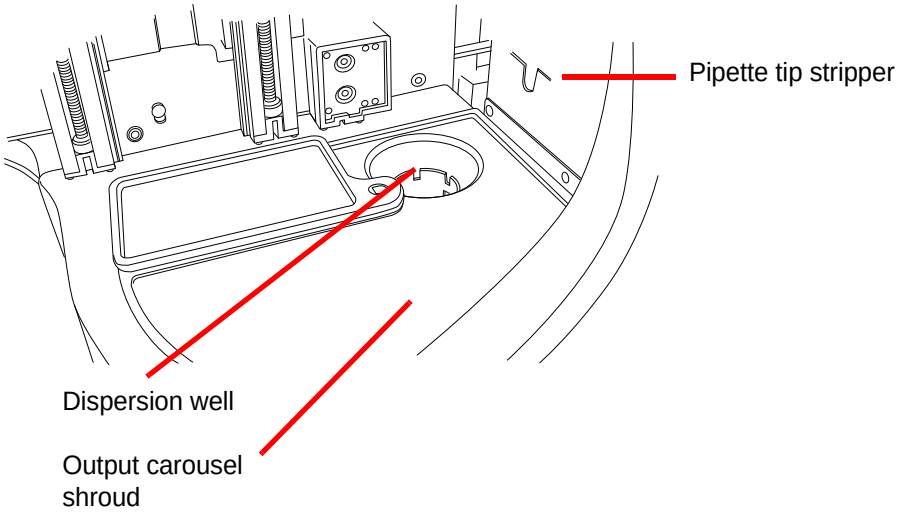


Figure 5-3 Clean Dispersion Well Area

SECTION C LEVEL SENSOR AND PIPETTOR TIP

On a weekly basis, or sooner if desired, wipe down the liquid level sensor and the pipettor tip with an appropriate cleanser such as 70% alcohol.

Note: Be sure the level sensor is completely dry before attempting to use the instrument.

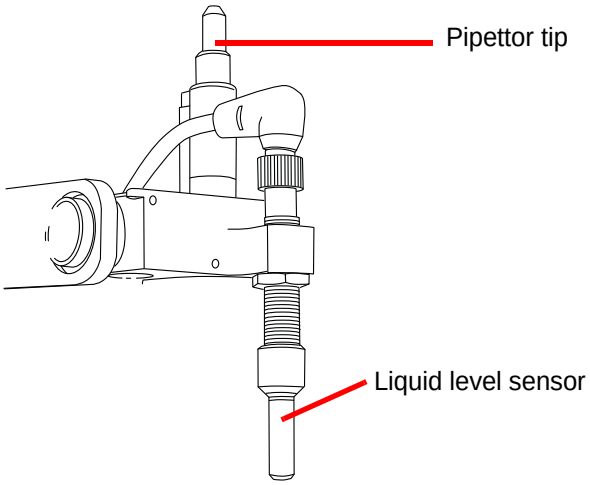


Figure 5-4 Level Sensor and Pipettor Tip

SECTION D CLEAN SENSORS

The lens of the vial barcode reader, the pipette tip sensor and the deep-well plate/pipette tip box presence sensor can be wiped down periodically. Use water or alcohol to clean the surface of the lenses.

Note: The deep-well plate barcode reader is not accessible by the operator. If the reader should need cleaning or service, contact Technical Support.

The sample vial barcode reader is just above the dispersion well, against the front wall of the instrument. The pipette tip sensor is next to it on the right. See Figure 5-5.

The sensor that detects the presence of deep-well plate or pipette tip box is inside the output carousel. Open the door and remove a pipette tip box or deep-well plate if one is present at the door. The sensor is to the right of the dispersion well. See Figure 5-5.

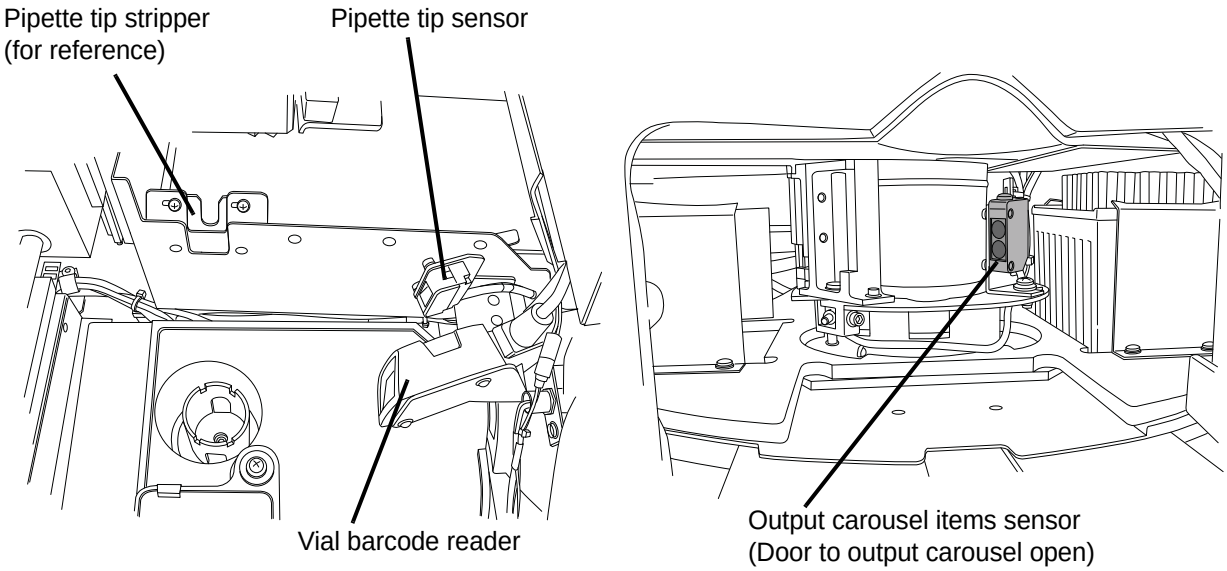


Figure 5-5 Location of Sensors

SECTION E TOUCH SCREEN

As needed, clean the user interface touch screen with soap and water and a lint free towel. From the Admin Options screen, press the **Clean Screen** button, Figure 5-6.

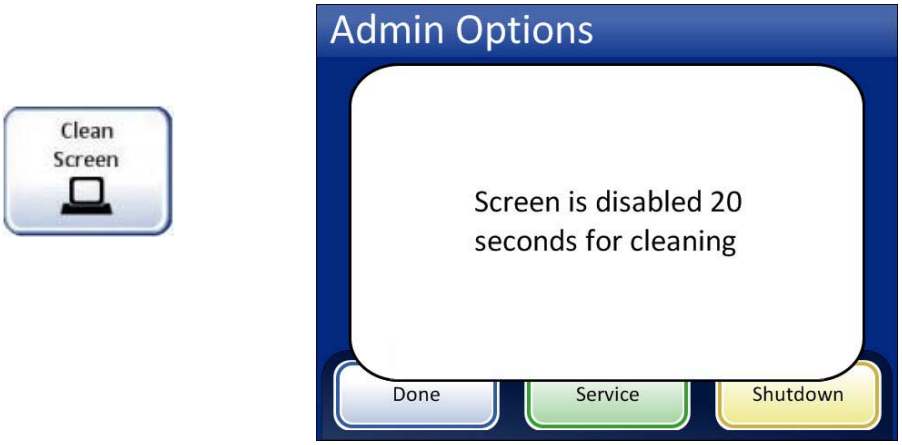


Figure 5-6 Clean the Touch Screen

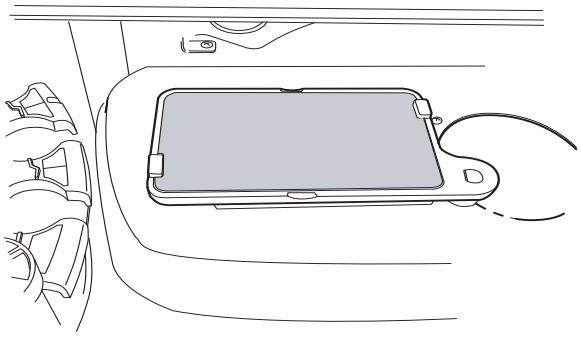
The system disables the touch screen for 20 seconds so that the screen may be cleaned without inadvertently activating buttons or having to power off the instrument.

SECTION F CAROUSELS AND RISERS

As needed, clean the sample vial carousel and deep-well risers by washing them with soap and water or wiping them with alcohol. Do not use strong detergent or solvent. Be sure to thoroughly dry the items before using them in the instrument.

SECTION G CHANGE ABSORBENT PAD

There is an absorbent pad on the evaporative cover that protects the deep-well plates and pipette tip boxes. See Figure 5-7. This pad is to absorb any drips that might fall from a pipette tip.



Evaporative cover with absorbent pad

Figure 5-7 Absorbent Pad

Replace the pad once a year, or as desired. The pad can be disposed of as regular waste, unless it is dripping wet, then dispose of as hazardous waste.

When the pad is replaced, notice that one side is rough and absorbent and one side is smooth and finished. The rough side should face outward to catch any drips.

Refer to Ordering Information for ordering pads.

SECTION H REMOVE AND CLEAN DRIP TRAYS

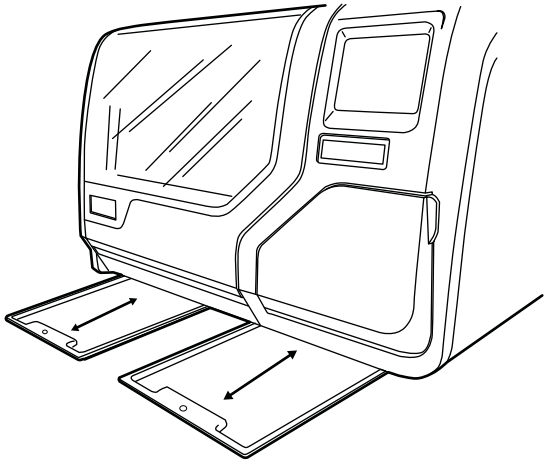


Figure 5-8 Drip Trays

Two plastic drip trays are located on the underside of the ThinPrep® 5000 Sample Transfer System. They slide all the way out for inspection and cleaning. If a tray is difficult to move initially, wiggle it side to side and it should release easily.

Wash them with soap and water. Allow them to dry thoroughly before returning them to the system.

SECTION I REPLACING THE USER ACCESSIBLE FUSES

WARNING: Instrument Fusing.

There are two user accessible fuses located on the rear of the instrument, just above the power cord module (Figure 5-9). If the instrument fails to operate, the fuses can be replaced as outlined below.

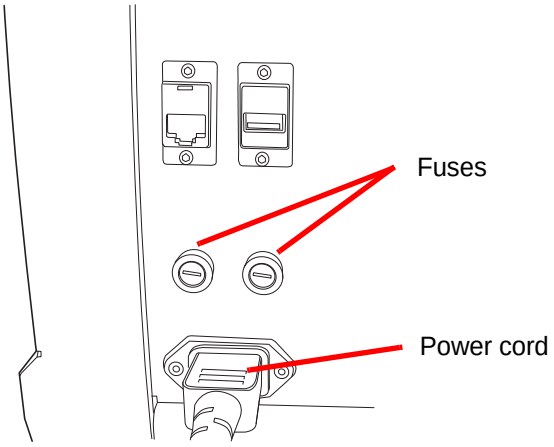


Figure 5-9 Location of User Accessible Fuses

1. Make sure the power switch is in the OFF position.
2. Remove the power cord from the receptacle on the instrument.
3. Using a small, flathead screwdriver, turn each fuse head clockwise 1/4 turn. The fuse, which is slightly recessed in the fuse holder when latched, will pop forward slightly when it has been turned far enough to be released from the catches.
4. Pull the fuses out of the receptacles. They may be discarded as regular waste.
5. Insert two new 15A/250V 3 AB SLO-BLO fuses (P/N 53247-015).

Note: Hold the fuse by the metal ends.

6. Using the flathead screwdriver, press each fuse cover into the receptacle while turning clockwise 1/4 turn. The fuse can be felt to engage with the catches and it will be slightly recessed into the fuse holder.
7. Reattach the power cord to the instrument.
8. Turn the instrument power switch ON.

If the instrument fails to operate, contact Hologic Technical Support.

ThinPrep® 5000 Sample Transfer System Maintenance

Maintenance Schedule for the Month/Year: Instrument

	Every Batch	Daily or more	Weekly	As Needed						
	Empty Waste Bin page 5.2	Clean Carousel, Dispersion Areas page 5.3	Wipe off Level Sensor and Pipettor page 5.4	Clean Barcode Reader Sensors page 5.4	Clean Touch Screen page 5.5	Clean Pipette Tip Waste Bin page 5.2	Clean Carousels and Risers page 5.6	Change Absorbent Pads page 5.6	Remove and Clean Drip Trays page 5.7	Change User Accessible Fuses page 5.7
1										
2										
3										
4										
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6. Troubleshooting

Chapter Six

Troubleshooting

SECTION A

GENERAL

There are four categories of error/status that the system can generate:

- Status Indicators
- Sample Processing Errors
- User Correctable/Batch Errors
- System Errors

SECTION B STATUS INDICATORS

Status Indicators

The status indicators are located at the top of the main screen display.

Touch the status indicator on the screen for a brief pop-up explanation of what the status means. A table of the status indicators is detailed in section “Status Indicators” on page 3.19.

SECTION C SAMPLE PROCESSING ERRORS

Sample processing errors pertain to individual samples and they occur when a sample vial is being processed. The system continues to operate without user intervention.

The error only appears on the batch report. It will not be recorded in the Error Log. If a deep well position was not filled, the **Assign Vial ID** button will be available on the Plate Report when it is first generated. Refer to “ASSIGN VIAL ID” on page 4.18.

When a sample processing error occurs:

- If a vial has been picked up, the system will return it to the input carousel.
- If a pipette tip has been picked up, it will be disposed of.

SECTION D USER CORRECTABLE / BATCH PROCESSING ERRORS

Batch processing errors are errors that the system is capable of recovering from with user intervention. The errors occur during the processing of a batch. When the system encounters a batch error condition, the batch halts and signals the error via a message on the user interface and by sounding the audible alarm, if it is enabled.

Typical batch errors:

- No pipette tips are available and must be replenished.
- The system has determined the deep-well plate is not empty and cannot be used.

SECTION E

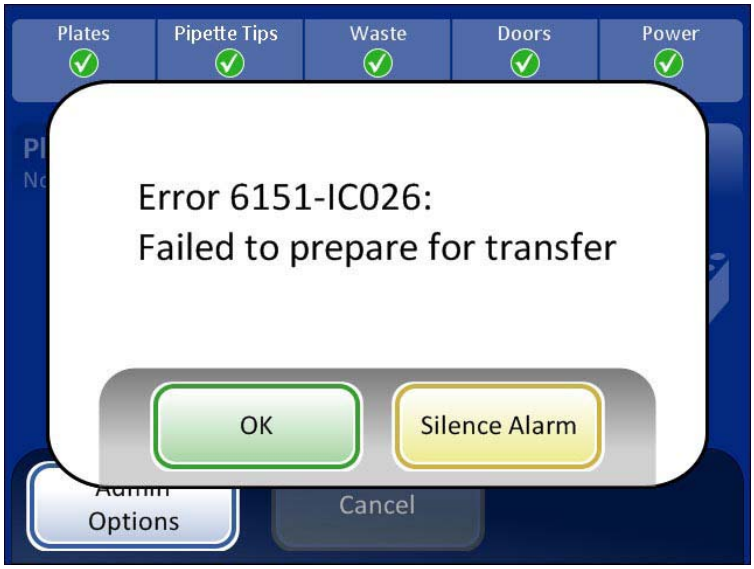
SYSTEM EVENTS

System events are errors that the ThinPrep 5000 Sample Transfer System is not capable of recovering from without user intervention. A system error is an error that will most likely require field service assistance. A user may choose or be instructed to restart the system. The error is reported to the error log.

Clearing a System Event

When a system event has been detected, the system will usually:

- Move mechanisms out of the way, release the input carousel lock, unlock the doors and return to an idle state.
- Display the error message and sound the audible alarm, if enabled (see Figure 6-1.) The system attempts to recover (a minute or less). See Figure 6-2 as an example.



The system encounters an error and attempts to recover.

If the audible alarm is enabled, it can be silenced.

Figure 6-1 System Detected an Error

If the system cannot recover, it attempts to move the mechanisms out of the way, turns off the transport arm motors so the operator can easily move the pipettor and vial transport arms and release the input carousel so that it can spin freely. The doors unlock for user access.

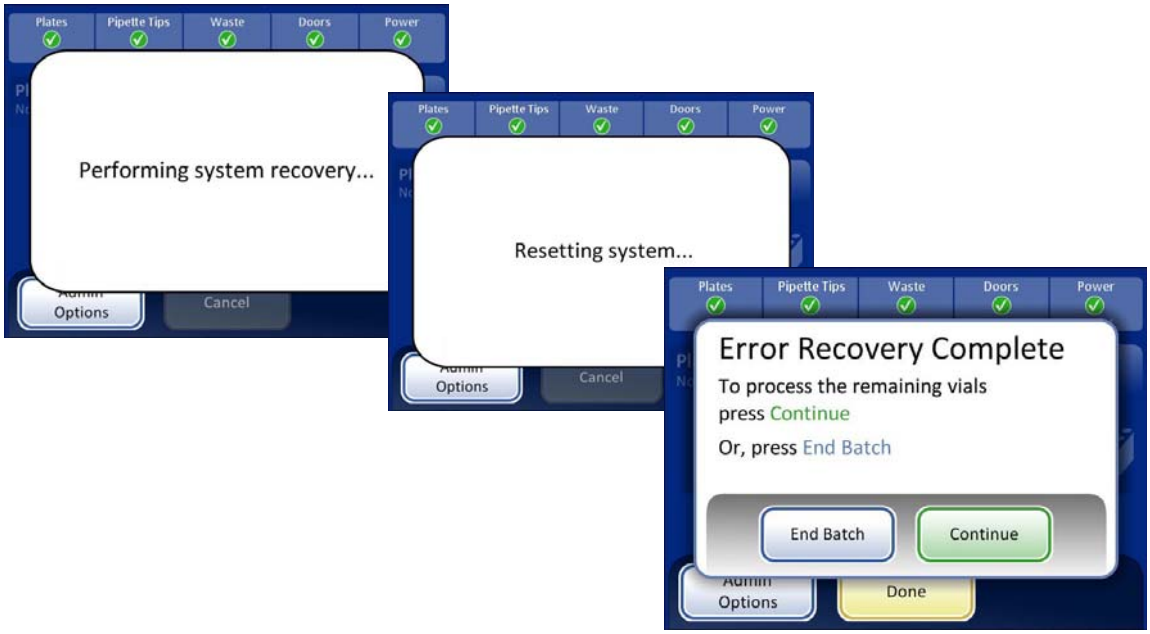


Figure 6-2 System Error - Example

Clear System

For some system errors, a message dialog may display instructing the operator to remove the vial cap from the gripper, or to drain fluid from a pipette tip. The display provides buttons that will release the holding pressure on the vial cap or to release fluid from the pipette tip, depending on the error. See Figure 6-3.

Figure 6-3 Clear System Screen

It may be difficult to view and reach the vial cap. Gently slide the vial transport arm to the middle of the processing area to access the cap. The pipettor transport arm may be moved in the same way.

Release Vial Cap

The vial gripper fingers remain closed in an error condition, so that a vial will not drop. Press the **Release Vial Cap** button to open the gripper and retrieve the vial. See Figure 6-4.

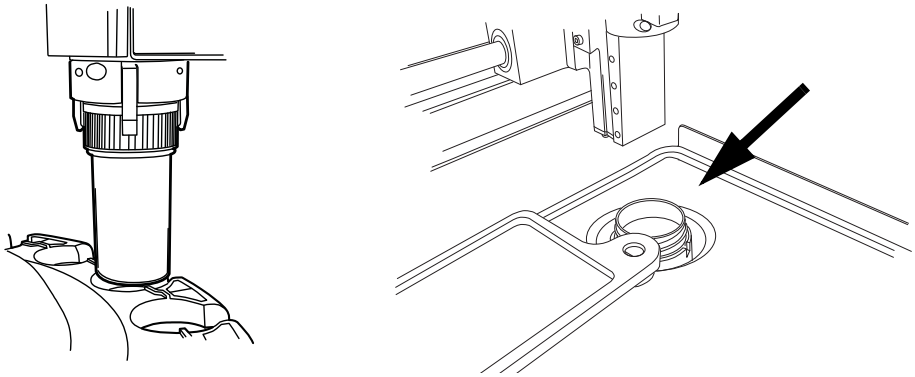


Figure 6-4 Release Vial, Check Dispersion Well

Note: Often just the vial cap is in the gripper. Carefully check the dispersion well and retrieve the vial, if necessary. Manually recap the vial. See Figure 6-4.

Remove Pipette Tip

If a pipette tip is to be pulled off of the pipettor, pull it off with a counterclockwise (tightening) twist. This will prevent loosening of the pipettor tip. See Figure 6-5.

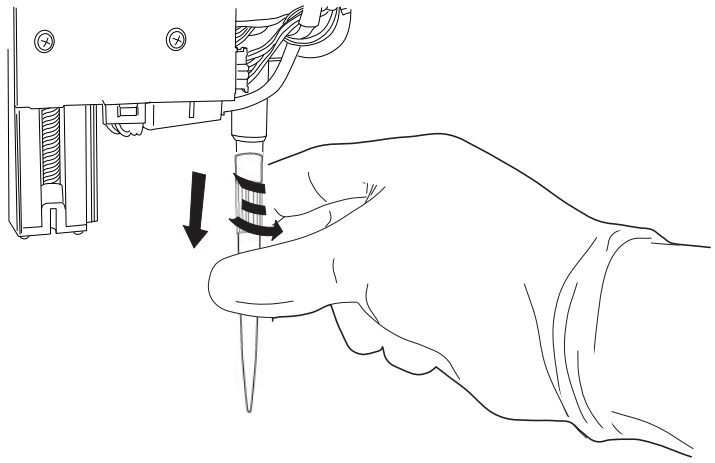


Figure 6-5 Remove Pipette Tip

Restricted Mode

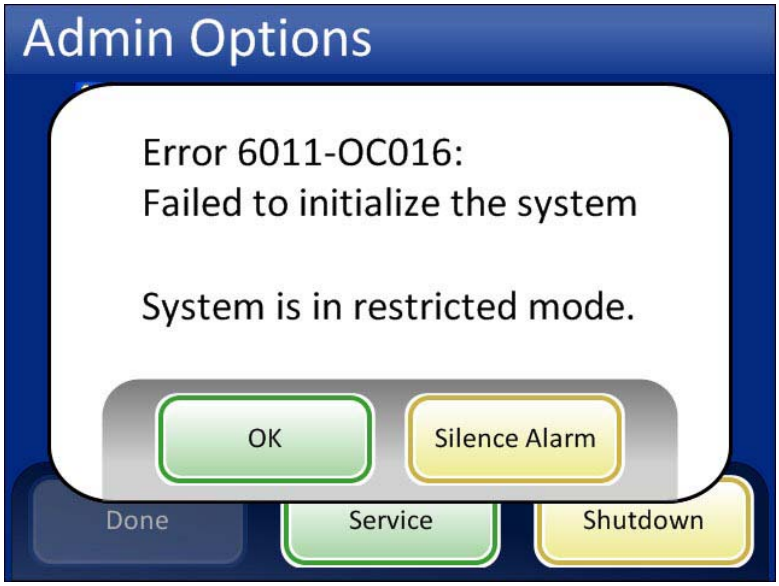


Figure 6-6 Restricted Mode Message

Some error conditions do not allow the system to process a batch and the operation transitions to a restricted mode. After acknowledging the error message, the user interface returns to the Admin Options screen. The **Reports** button is available, where you can review or download the Error History report (which will have captured the error code). The **Service** access button is available if the system cannot recover and requires a service visit. The **Shutdown** button is available, in order to restart the instrument, which usually clears a system error.

CAUTION: Do not restart the instrument with a USB key in any of the ports.

To recover from an error requiring shutdown, press the **Shutdown** button.

Wait for the computer to turn off (wait until the touch screen interface goes blank). Then turn off the power switch on the right side of the instrument. After a few seconds of the power being fully off, turn the processor on again and let it boot up. The main screen should be displayed when the system is ready to process.

If the restricted mode screen appears, contact Technical Support.

System Error Code

A system error has a two-part error code associated with it. The first four digits represent the error category and the following characters represent the status of the particular electromechanical device at the time the fault occurred. See Figure 6-7.

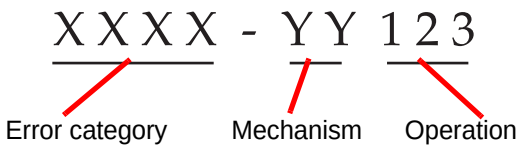


Figure 6-7 System Error Code

The error codes will be logged in the Error History report. The report displays the last 100 errors, but keeps up to 3 years' worth in the system database.

In most cases, the 'clear system' dialog box will display. Check that the mechanisms are clear and begin a new batch.

If an error is persistent, contact Technical Support.

SECTION F ERRORS

6000 - 6013

POST (power on self test) errors. These errors occur during instrument boot up and initialization. The user interface will be in restricted mode (see page 6.6). Attempt to restart the instrument. If the error persists, contact Technical Support.

6100 - No empty wells are available

The system checks the first well of a new deep-well plate or the 49th position of a second half of a plate prior to beginning the batch. If it detects liquid already in the well, the batch will not start. Confirm that the deep-well plates are empty before loading.

6101 - Failed to read plate ID

System error. The batch will not start if the barcode on the deep-well plate cannot be read. Confirm that the plate has a barcode on it and that it is legible. Refer to "Deep-well Plate Barcode Labels" on page 4.4.

6102 - Plate ID is already used

System error. The batch will not start. Use a different plate or replace the barcode on that plate.

6150 - Failed to home all mechanisms

System error. The system will recover and attempt to rehome all mechanisms.

6151 - Failed to load carousel

System error. System will recover and attempt to rehome.

6152 - Failed to move deep well plate

System error. System will recover and attempt to continue. Check that there is no obstruction of the output carousel.

6153 - Database error

System error. The system will revert to restricted mode (see page 6.6.) Restart the system.

6201 - Failed to move to position to pick up vial

System error. System will recover. The vial was not picked and the well was not filled.

6202 - Failed to pick up vial

System error. The vial was not picked up. The well was not filled.

6203 - Failure reading vial ID

The vial barcode could not be read. The system returns the vial to the input carousel. The well was not filled.

6204 - Failed to verify plates were ready

System error. The output carousel did not move to the correct position. The system will attempt to recover. Check that there is no obstruction of the output carousel.

6205 - Failure checking for vial in gripper

System error. The vial was not moved to the dispersion well. Operator assistance may be required to retrieve the vial and replace it in the input carousel.

6206 - Initial well is not empty

The system determined the initial well is not empty. The batch will not start.

6207 - Failure preparing vial for aspiration

System error. The system attempts to recover. Check that the vial can be picked (not too many labels or labels sticking to the carousel). Check that there is no obstruction of the output carousel.

6208 - Failure picking up pipette tip

System error. Unable to pick up a pipette. Check that the vial is not left in the dispersion well.

6209 - Failed to find a pipette tip

System error. Failed to detect a pipette tip after three tries. The vial is not processed and the well is not filled. Check that there are pipette tips in the box and that they are loaded correctly.

6210 - Failure transferring fluid

System error. Failed to transfer fluid from vial to well position. The pipette tip may need to be removed from the pipettor.

6211 - No more pipette tips

Batch processing error. The system is out of pipette tips.

6212, 6213, 6214 - Failure completing transfer

System error. System attempts to recover and put all mechanisms home. The operator may need to check that the vial is capped and returned to the input carousel. The pipette tip may need to be removed from the pipettor.

6215 - Database error

System error. The system reverts to restricted mode (see page 6.6). Restart the system.

6250 - Insufficient fluid

Sample processing error. Not enough fluid in the vial to process it. The vial is returned to the input carousel. The well is not filled.

6251 - Failed to uncap vial

Sample processing error. The vial could not be uncapped. The well is not filled. Check the condition of the vial.

6252 - Duplicate vial ID

Sample processing error. The vial has the same ID as another vial. The vial is not processed, the well is not filled.

6253 - Failed to read vial ID

Sample processing error. The barcode on the vial could not be read. The vial is returned to the input carousel and the well is not filled. Check to see if the barcode is present and legible.

6300 - Failure while completing carousel

System error. Occurs after all transfers are complete and the system is attempting to put mechanisms back. Check that there is no obstruction of either carousel.

6400 - Failed to move pipette tips or deep well plate to door

System error. Occurs when the operator is trying to move a plate or pipette tip box to the output door. Check that there is no obstruction of the output carousel.

6500, 6501, 6502 - Failure reading plate ID

Failure to read the deep-well plate ID. Check that there is no obstruction of the output carousel and that the plate has a barcode present.

6600 - Internal system error

Internal system error. The system reverts to restricted mode (see page 6.6). Restart the system.

6601 - Failed to release pipette tips or deep well plate

System error. The system will revert to restricted mode (see page 6.6). Restart the system.

6602 - Failed to drain fluid

System error. System reverts to restricted mode (see page 6.6). Restart the system.

6603 - Failed to release vial

System error. System reverts to restricted mode (see page 6.6). Restart the system.

6604 - Failed to scan the barcode

System error. The vial barcode could not be read. Manually enter ID (see page 4.20).

6700 - Batch cancelled

The operator cancelled the batch.

6701 - Could not perform error recovery

System error. After failing to automatically recover from an error, the system reverts to restricted mode. Restart the system.

6702 - System error

System error. The system attempts to recover.

6703 - Three consecutive errors of the same type

System error. The system attempts to recover.

6704 - System was shut down by UPS

The system was shut down because the charge available to the UPS went below 25%. Contact Technical Support.

6705 - System failed to home all mechanisms

System error. The system reverts to restricted mode. Check for any obstruction of moving parts. Restart the system.

6706 - Emergency stop

A door was opened when the system had it locked. The system reverts to restricted mode. Restart the system.

6800 - 6803 - Database error

System error. Occurs when the system is trying to read or write to the database. The system reverts to restricted mode. Restart the system. If the error persists, contact Technical Support.

7. Service Information

Chapter Seven

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 5:00 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 1-888-898-2357 option 1.

Orders can also be faxed to the attention of Customer Service at 608-663-7077.

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 ThinPrep® 5000 Sample Transfer System issues and related application issues, representatives from Technical Support are available by phone 8:30 a.m. to 5:00 p.m. CST Monday through Friday at 1-888-898-2357.

Service contracts can also be ordered through Technical Support.

Protocol for Returned Goods

For returns on warranty-covered ThinPrep 5000 Sample Transfer System accessory and consumable items, contact Technical Support.

SERVICE INFORMATION

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8. Ordering Information

8. Ordering Information

Chapter Eight

Ordering Information

Mailing Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752

Remittance Address

Hologic, Inc.

24506 Network Place

Chicago, IL 60673-1245

Business Hours

Hologic's business hours are 8:30 a.m. to 5:00 p.m. CST Monday through Friday, excluding holidays.

Customer Service

Product orders, which include standing orders, are placed through Customer Service by phone during business hours at 1-888-898-2357 option 1.

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Protocol for Returned Goods

For returns on warranty-covered ThinPrep 5000 Sample Transfer System accessory and consumable items, contact Technical Support.

8 Ordering Information

Table 8.1: Supply Items for the ThinPrep® 5000 Sample Transfer System

Item	Description	Order Number
Absorbent pad, evaporation cover	Absorbent pad	71921-001
Carousel, sample vial	48 vial input carousel	ASY-03441
Riser	Deep-well plate riser	ASY-03442
Pipette Tips, 1000 uL, Ret.	Pipette tips	LBS-00124
ABgene 2.2 mL deep-well plate	Deep-well plate, barcoded	LBS-00006
ThinPrep 5000 Sample Transfer System Operator's Manual	1 replacement manual	MAN-01479-001
15A/250V 3 AB SLO-BLO fuses	Replacement fuses	53247-015

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ThinPrep® 5000
SAMPLE TRANSFER SYSTEM

HOLOGIC®

Operator's Manual

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

MAN-01479-001 Rev. 007