SPIFE® Touch

Gel Electrophoresis and Processing

Operator's Manual

Catalog Number 1068, 120 Vac
Catalog Number 1069, 240 Vac

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Section 1 - Instrument Use and Function

Helena Laboratories' SPIFE Touch (Figure 1-1) is used for automatic sample application, electrophoresis, automatic reagent application and spreading, staining, fixing, destaining, and drying of SPIFE agarose gels. It will completely process the gel for viewing or for quantitation of results on a densitometer. SPIFE Touch is to be used only with Helena Laboratories SPIFE gels. SPIFE Touch is intended for in-vitro diagnostic use only, and is for use in a laboratory or similar environment. This instrument is for indoor use only.

SPIFE Touch contains preprogrammed parameters for SPIFE Serum Protein, Serum or Urine IFE, CSF IgG IEF, Acid Hemoglobin, Alkaline Hemoglobin, Alkaline Phosphatase, Cholesterol Profile, and Split Beta SPE. The parameters for each these tests may be customized, if desired.

The SPIFE Touch automates or eliminates the technique-dependent steps of conventional electrophoresis. Samples are automatically applied to the gel, then electrophoresed. When appropriate, reagents are automatically spread on the gel and incubated.

Gels are moved to a gel holder and lowered into the staining chamber, where they are washed, stained, destained, fixed, and dried automatically. The processed gels can then be scanned with a densitometer and the results printed on a report form.

Refer to the procedure supplied with the reagents for information on the following areas:

Summary
Principle
Reagents
Instruments
Specimen Collection and Handling
Reagent Preparation
Sample Application
Test Procedure
Performance Characteristics
Stability of End Product
Reference Values
Evaluation of the Bands
Interpretation of Results
Bibliography

Figure 1-1 SPIFE Touch

Section 2 - Principles of Operation

The relationship of the functional units of the SPIFE Touch are shown in Figures 2-1 and 2-2. The SPIFE Touch is divided into two distinct parts; the applicator/incubation and separator side on the right and the stainer side on the left. Operation is controlled by a microprocessor and its memory and by a touchscreen.

The applicator consists of a rack which holds disposable blade applicators, a motor to move the blades to the sample and to the gel, a reagent dump bar, and a motor to move the bar. The electrophoresis side contains a power supply, electrodes, constant voltage output for electrophoresis, and an electrophoresis chamber with heating and cooling systems. The stainer side contains a heater/dryer blower, a gel chamber, gel carrier switch, fluid level detectors, temperature sensor, fluid valve, and fluid pump.

The microprocessor directs instrument operations and the touchscreen allows the operator to respond to the prompts and messages. During a typical operation, the operator loads the sample, selects the type of test, and can start or stop the automatic sequence of operations using the touchscreen. Any time a prompt appears which requires a user action, an alarm will sound until the user presses the indicated key.

Sample is manually loaded into sample wells and the operator positions the wells and the gel. The applicator then automatically picks up sample and applies it to the gel.

For electrophoresis and incubation, the gel is manually placed in the electrophoresis chamber. The electrodes are positioned, the door is closed, and the touchscreen will prompt the user when the next action is required. Electrophoresis takes place at the programmed parameters when high voltage is applied across the electrodes and gel. If required by the test, incubation and pre-drying are accomplished by controlling and monitoring the temperature of the electrophoresis chamber.

If required by the test, the reagent is automatically applied and spread.

When prompted, the operator removes the electrodes, then the gel blocks. The electrodes are then replaced, the plate is dried, and the gel is ready to be placed in the stainer chamber.

The microcomputer directs the fluid valve to open one of the fluid lines and turns on the fluid pump to fill the stainer chamber with the appropriate solution. A level detector signals the microcomputer when to stop the filling operation, and the pump is turned off. The operation is timed. When the time reaches zero, the microcomputer directs the fluid valve to open another line and turns the pump on again. The pump empties the solution through a fluid drain.

This sequence of events is repeated for each necessary solution in the staining, fixing, and destaining procedures. If agitation is required, the fluid pump moves solution in and out of the stainer chamber.

The microcomputer then signals the heaters in the staining chamber to heat the chamber to drying temperature. An air fan blows heated air through the chamber. Temperature is controlled by a sensor. When drying time reaches zero, the microcomputer turns off the heaters and an alarm notifies the operator that the procedure is complete.

The computer initializes at power on and runs a self-test to detect error conditions or potential problems. If an error is detected, the computer responds by

displaying an error message (see section 10.2, Troubleshooting).

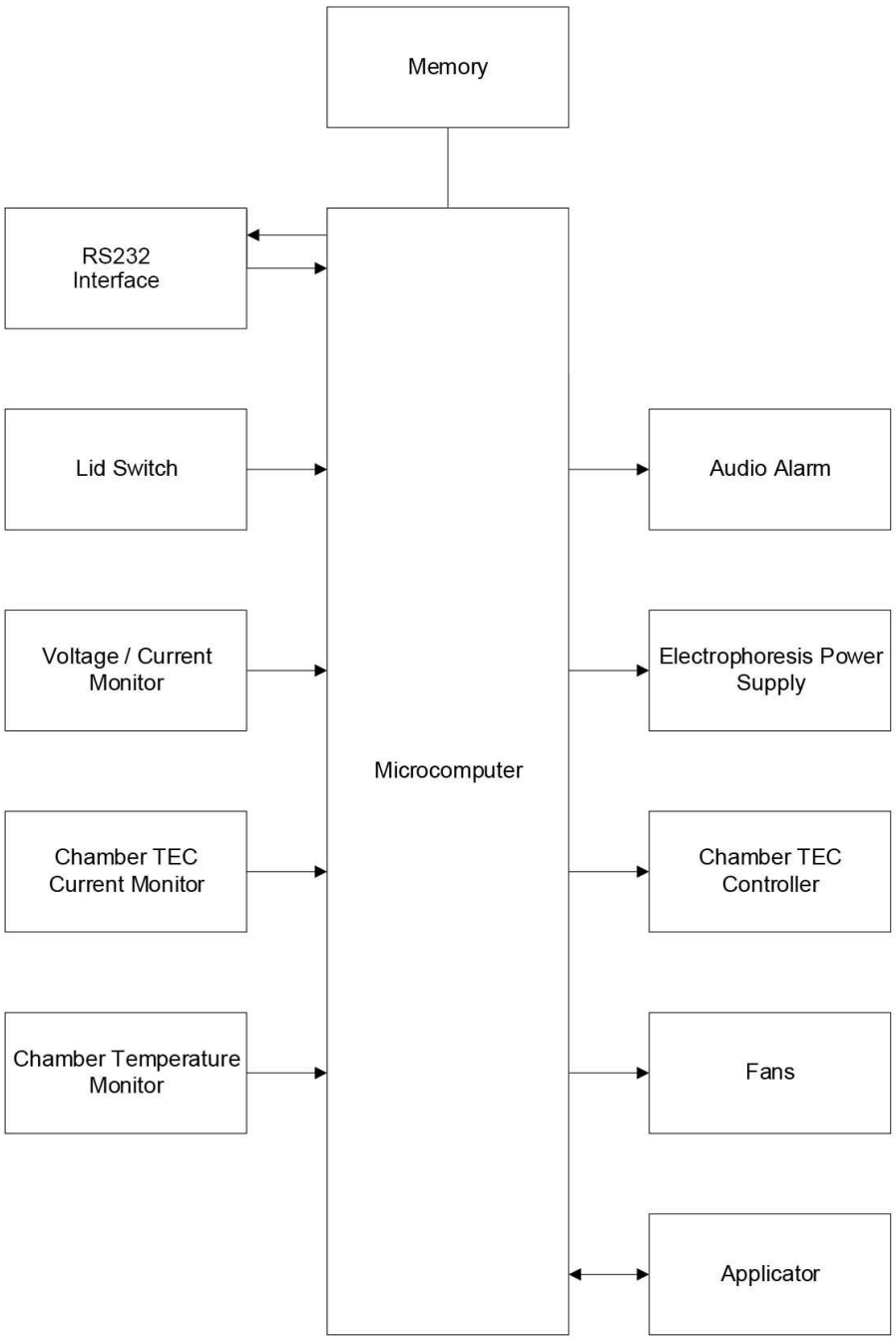


Figure 2-1 Signal Flow Diagram, Electrophoresis Side

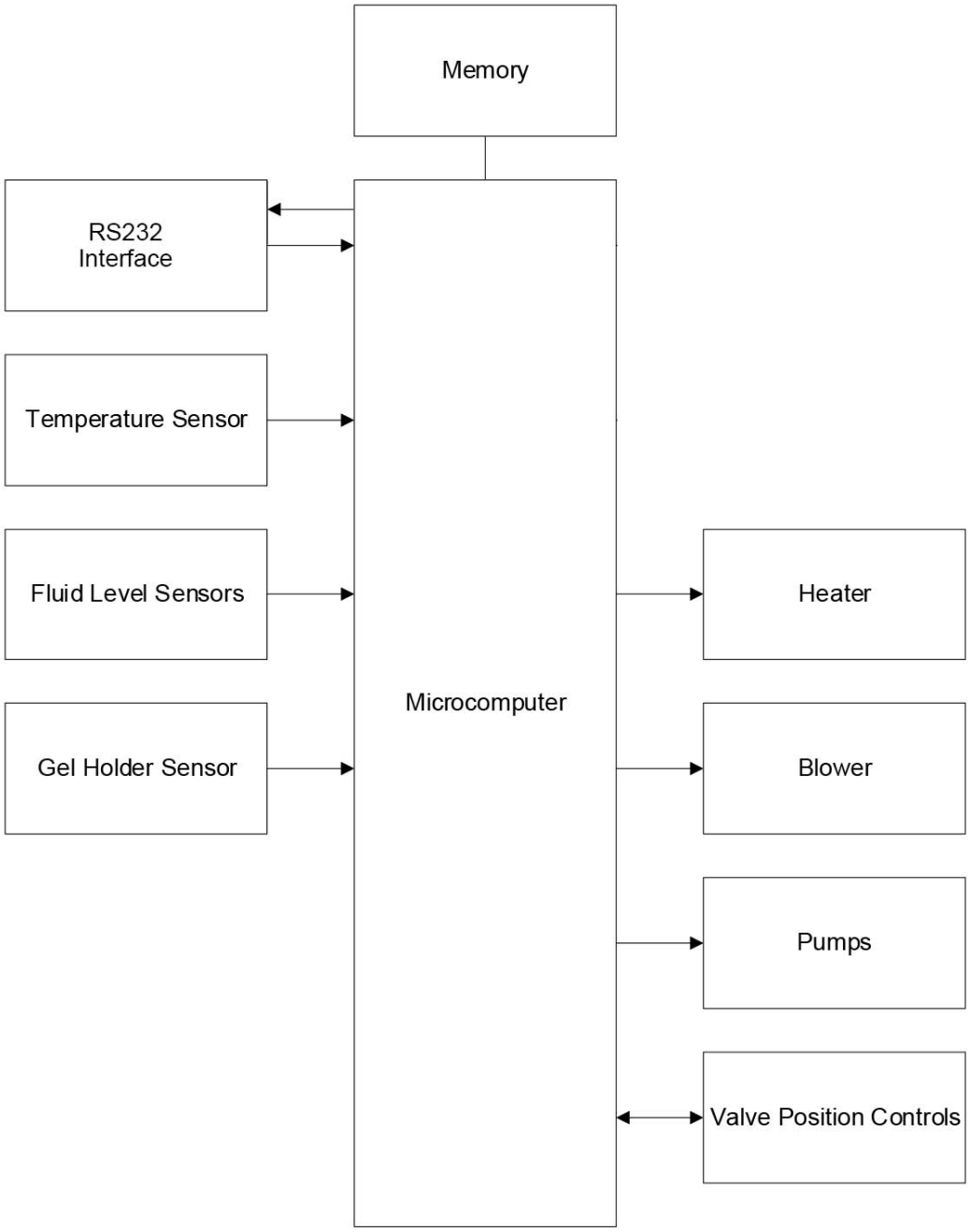


Figure 2-2 Signal Flow Diagram, Stainer Side

Section 3 - Precautions and Limitations

3.1. The entire operator's manual should be read and understood before attempting instrument operation.

3.2. Refer to the procedure supplied with the gels and reagents for proper gel orientation, reagent preparation, specimen collection and handling, and other information.

3.3. Use only reagents and gels made specifically for use with SPIFE instruments. Refer to the procedures supplied with the reagents for precautions and limitations specific to the reagents.

3.4. Do not expose the instrument to drafts or to direct sunlight. Do not operate at temperatures above 81°F (27°C) or below 59°F (15°C), or allow prolonged exposure to high humidity.

3.5. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, x-ray machine, etc.

3.6. Provide adequate room on all sides of the instrument for good air circulation.

3.7. Do not block air vents or intakes.

3.8. To prevent damage to the SPIFE Touch, never place objects on the top of the instrument. Keep the gel holder installed in the stainer at all times.

3.9. This instrument should not be connected to any other devices or instruments in any way not described in this manual.

3.10. Do not expose the sample tray to temperatures above 158°F (70°C), or severe warping of the tray may result, making the tray unsuitable for use.

3.11. Installation should not be attempted unless a representative of Helena Laboratories or of its subsidiaries or distributors is present, or, unless verbal or written permission to proceed has been given by Helena Laboratories, its subsidiaries or distributors.

3.12. The instrument should not be moved once the Helena Laboratories approved representative has installed the instrument. For ALL moves, the instrument's shipping bracket, used to lock the applicator sled in place, must be installed. Improper handling of the applicator sled could result in the instrument needing realignment, which can only be completed by a Helena Laboratories representative.

3.13. This instrument meets the leakage current specifications of directive EN 61010-1. To meet standards more stringent than this, we recommend either grounding the instrument to station ground via the ground lug provided on the back of the instrument, or the purchase of an isolation transformer. Specifications for this transformer are given in section nine.

3.14. For emergency shutdown, disconnect the SPIFE Touch power cord.

3.15. All tubing must be securely connected to fittings to prevent leaks.

3.16. Before starting electrophoresis verify the following. The sample gels are oriented correctly. The sample cups are installed correctly and are fully seated in the sample tray. The applicator blades are properly seated and installed in the slots indicated in the procedure supplied with the reagents. The reagent bottle is installed correctly and fully seated in the dump bar, if applicable.

3.17. Due to high heat, do not touch the surfaces of the electrophoresis chamber immediately after pre-drying.

3.18. Should an instrument be contaminated by blood or blood derivative, spray any contaminated surface with a commercial virucidal and germicidal agent. Observe where the specimens are used inside the instrument and confine cleaning to that area. Wipe up the residue. These

materials contain corrosives and are harmful to metal surfaces.

No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. **ALWAYS UNPLUG THE MAIN POWER CORD BEFORE CLEANING.**

Section 4 - Hazards

4.1. If the instrument is used in a manner not specified by this manual, the protection provided by equipment design may be impaired.

4.2. This device contains very high voltages which can be extremely dangerous. Safeguards are built into the instrument to prevent user contact with high voltage; however, **ALWAYS TURN OFF THE POWER, DISCONNECT THE MAIN POWER CORDS, AND USE EXTREME CARE** when attempting disassembly for cleaning, repair, or adjustments.

4.3. Shock hazard. Never touch the cables at the rear of the SPIFE Touch during operation. When the electrophoresis chamber lid is open, power to the chamber is cut off. However, never touch the electrophoresis chamber during electrophoresis**.**

4.4. Electrical supply voltage specifications are not to exceed +/- 10% of the nominal supply voltage.

4.5. Do not attempt to operate the instrument without plugging the power cords into a grounded wall outlet of the proper voltage and frequency. This information is contained on the serial number plate located on the back of the instrument.

4.6. **Do not operate with the cover removed.** Do not place fingers under the applicators.

4.7. Do not lubricate any parts of the instrument not specified by Helena Laboratories.

4.8. Do not touch the gel chamber anywhere except where directed by the labeling. The inner surfaces of the gel chamber reach temperatures of 60° to 70°C and can cause burns.

4.9. Use only the reagents specified by the Helena procedure in use. Damage to the instrument may result from introducing some types of solutions into the instrument.

4.10. Follow safe handling and disposal procedures for reagents used with this instrument.

4.11. Keep flammable liquids and flammable vapors away from the instrument at all times.

Section 5 - Controls and Displays

WARNING: Read Section Three (Precautions and Limitations) and Section Four (Hazards) before attempting installation or operation

5.1. Unpacking and Inspection

1. Check all shipping containers for signs of damage. If damage is found, immediately notify the shipping carrier.

2. Carefully unpack the instrument and accessories and remove them from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.

CAUTION: The instrument and its components are heavy. Use a minimum of two people to lift the instrument. Lift only from the bottom surface of the instrument. Use approved lifting techniques when moving the instrument.

3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife are used to cut the plastic or binding tape, take care not to scratch the instrument.

4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.

5. Inventory all items. If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

Table 5-1 Inventory

1 SPIFE Touch
5 Reagent Vats
1 Waste Vat
3 Stain Cap Assemblies with Tubing
1 Waste Vat Cap Assembly with Level Sensor, Shorting Plug, Elbow Fitting, and Tubing
1 Destain Cap Assemblies with Tubing
1 Wash Cap Assemblies with Tubing
3 Applicator Weights
1 Screwdriver
1 Level
8 Fuses, Assorted
1 Power Cord
1 SPIFE Gel Block Remover, Cat. No. 1115
1 Replacement Electrodes for REP 3 and SPIFE, 2/pkg, Cat. No. 3709
1 SPIFE Maintenance Swabs, 5/pkg, Cat. No. 1113
1 REP/SPIFE Contact Sheets, Cat. No. 1361
1 Tips for IFE-6/3 Multi-Channel Pipette, 72/pkg, Cat. No. 3402
1 Reagent Spreaders for SPIFE Touch and REP 3, 2/pkg, Cat No. 3706
1 Installation Report
1 Operator's Manual
1 Maintenance Table

Available Supplies

Cat #	Product Description
1111	SPIFE QuickGel Electrode, 2/pkg
1346	Pos ID Barcode Reader & Cabling
1666	Pos ID Barcode Labels 1000/pkg
3357	SPIFE QuickGel Dispo Stainless Steel Electrode, 3/pkg
3358	SPIFE QuickGel Holder, 1/pkg
3359	SPIFE QuickGel Chamber Alignment Guide (usage instructions included in the procedures supplied with the applicable reagents)

3360 SPIFE Dispo Sample Cups - Deep Well

3364 SPIFE 2000/Touch 20-80 Dispo Cup Tray

3366 SPIFE 2000/Touch 20-100 Dispo Cup Tray

3369 SPIFE Dispo Sample Cups - Shallow Well, 100/pkg

3370 SPIFE 2000/Touch 20, 40, 60 Dispo Cup Tray

3388 SPIFE Disposable Stainless Steel Electrodes, 3/pkg

5.2. Unpacking and Inspection

NOTE: The SPIFE Touch is a "Category II" device under EN 61010-1 and is for use in a laboratory or similar environment.

5.2.1. Selecting Instrument Location

1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and large temperature fluctuations. Ambient temperature should be between 59° to 80°F (15° to 27°C).

2. Locate the instrument on a level, flat surface, near an easily accessible wall outlet.

3. The location needs to be large enough to allow proper air circulation around the instrument and provide space to place the vats Figure 5-7). All reagent vats connected to the instrument must be vented to the atmosphere, and must be placed on the same surface as the instrument for the stainer chamber to operate. The waste vat must be placed below the instrument.

5.2.2. Removing Shipping Bracket & Leveling Instrument

1. Unscrew the thumbscrew securing the shipping bracket located in the electrophoresis chamber Figure 5-1. Remove the bracket and thumbscrew. Store the bracket and thumbscrew for future use (Figure 5-4 and 5-5).

2. Place the provided bubble level in the center of the electrophoresis chamber and adjust the two feet on the lower right side to level the chamber floor. The floor should be level both from side-to-side and front-to-back.

5.2.3. Connecting Vats & Instrument

1. Only remove the port cap when installing the tubing to that port.

2. Attach the two lengths of 3' tubing to their vat caps. Attach the vat caps to the Wash vat and the Destain vat. Route the tubing from the vat caps through each vat's handle. This supports the tubing, preventing it from crimping at the vat cap. Attach the tubing from the Wash vat to port 1 and the tubing from the Destain vat to port 2. (Ports are located on the left side of the instrument, see Figure 5-7.

3. Attach the two lengths of the 2' tubing, included with the two like sized vat caps, to ports 3 and 5, located on the left side of the instrument Figure 5-7. Attach each of the other ends of these tubes to their vat cap. Place the vat cap attached to port 3 to a Stain vat and the vat cap attached to port 5 to the other Stain vat.

4. Attach one length of 2' tubing to port 7, located on the left side of the instrument Figure 5-7. Attach the other end of this tubing to the vat cap. Fill the Maintenance Wash vat with deionized water. Attach the vat cap to the Maintenance Wash vat.

5. Attach the length of 4' tubing to port 4, located on the left side of the instrument Figure 5-7. Note that port 4 can only be used for waste.

6. Attach the 1 1/2" end of the of the 6' tube plus elbow fitting plus 1 1/2" tube assembly to the catch pan port located

under the right rear of the instrument, as viewed from the back. Confirm that the flow of fluid is not restricted either by the orientation of the elbow fitting or because the 6' piece of tubing raises above the level of the catch pan.

7. If using the Waste vat for waste collection, attach the other ends of the tubes from port 4 and the catch pan port to the barbed fittings on the Waste vat cap. Put the Waste vat cap securely on the Waste vat. Check the length of the tubing to insure that no loops form below the Waste vat cap Figure 5-6, adjust tube length as needed.

8. If using the Waste vat, connect the level sensor to the top of the Waste vat cap. Plug the other end into the receptacle located at the rear of the instrument, labeled "OVERFLOW SENSOR INTERCONNECT".

9. The tubing from port 4 and the catch pan port may be run to a sink for waste dispose, instead of the Waste vat. When using a sink, use the Shorting Plug instead of the level sensor. Plug the Shorting Plug into the receptacle located at the rear of the instrument, labeled "OVERFLOW SENSOR INTERCONNECT".

NOTE: The waste tubing should always remain unrestricted between the instrument and waste drain or vat.

10. Check that any ports on the instrument not used are left capped. Insure that all tubing is securely connected to fittings to prevent leaks.

5.2.4. Power Cord & Parts Handling

1. Confirm that the main power switch is off and plug the SPIFE Touch power cord into the outlet provided on the back of the instrument Figure 5-8.

2. Plug the power cord into a grounded wall outlet of the proper voltage and frequency. These specifications can be found on the serial number plate located on the back of the instrument.

3. The wall outlet should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument's circuitry contains filters to reduce the effect of line voltage fluctuations; however, they should still be avoided. If the operator experiences difficulty, it may be necessary to install an isolation transformer.

NOTE: A detachable power cord used with this instrument must have been selected by an agent of Helena Laboratories that is an approved type suitable for application and acceptance by local registry authorities in the country which it is used, based on the serial tag specifications for voltage and current.

NOTE: The SPIFE Touch meets the leakage current specifications of directive EN 61010-1. To meet standards more stringent than this, we recommend either grounding the instrument to station ground via the ground lug provided on the back of the instrument, or the purchase of an isolation transformer. Specifications for this transformer are given in section nine.

4. Remove electrodes from chamber before turning instrument ON to avoid damage to the sled.

5. The barcode reader, an optional accessory, is used for positive patient ID and plugs into the outlet provided on the back of the instrument Figure 5-8.

6. Prime the stainer pump using the following steps: With the power off, pour approximately 100mL of tap water into the stainer chamber, from the top. Wait a few

minutes, allowing time for the fluid to back-fill the pump tubing and wet the pump.

7. Turn the main power switch on. The instrument empties the chamber and initializes and performs a brief self-test. Once complete, the displays should show the initial boot up sequence to set the language. If an error message appears instead, refer to the section on Trouble-shooting, 10.2.

Figure 5-1 SPIFE Touch Controls and Displays

Figure 5-2 Power On/Off Switch, Right Side

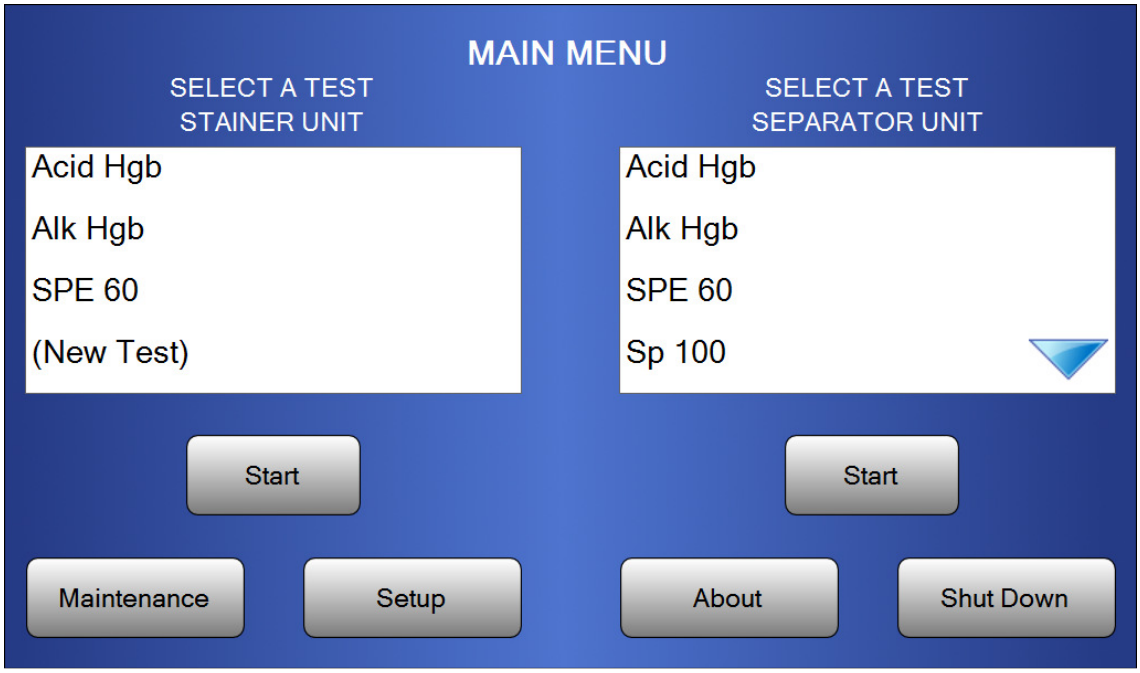


Figure 5-3 SPIFE Touch Menus

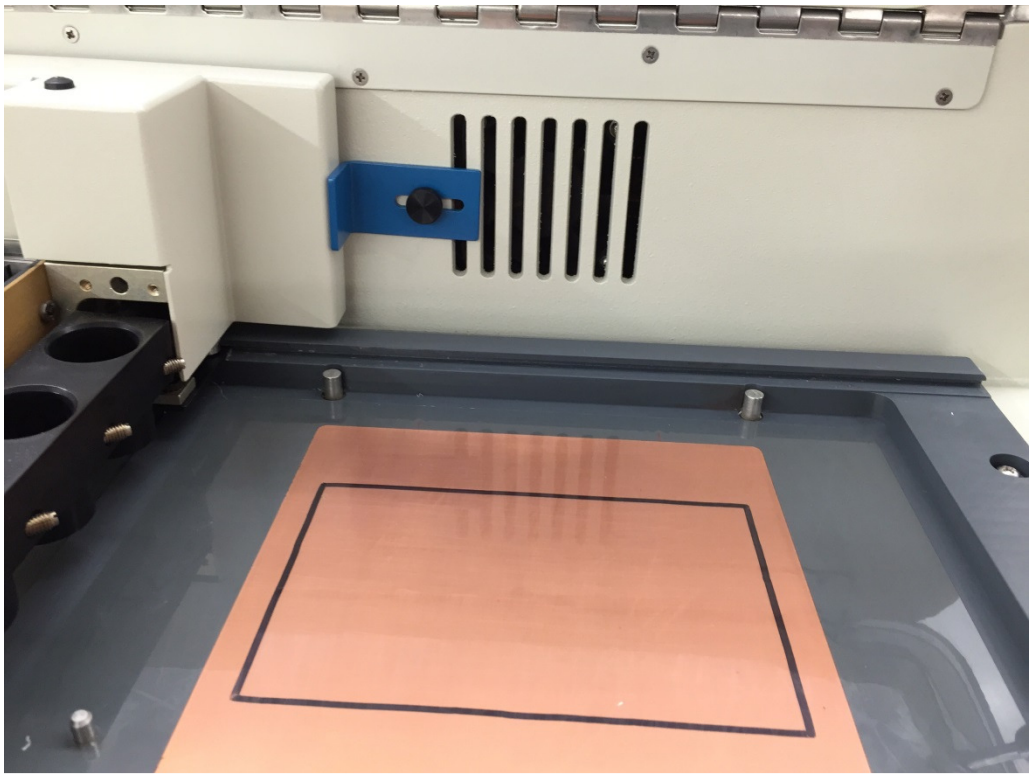


Figure 5-4 Shipping Bracket Installed

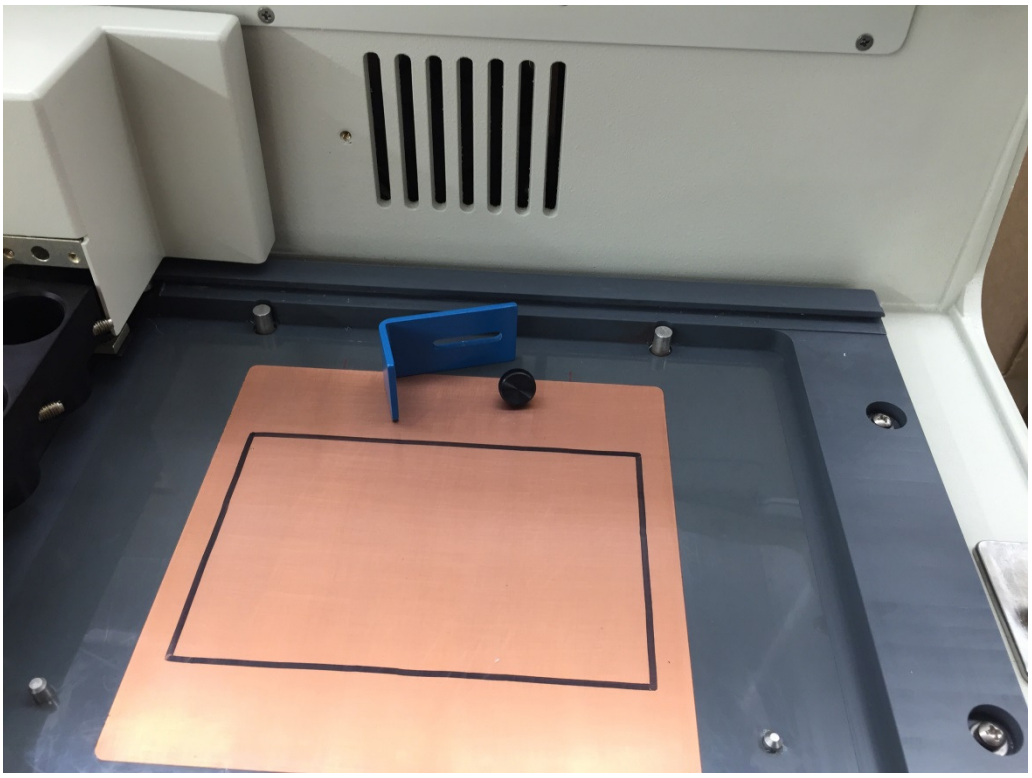


Figure 5-5 Shipping Bracket Removed

Figure 5-6 SPIFE Touch Installation

Figure 5-7 Ports and Tubing, Left Side

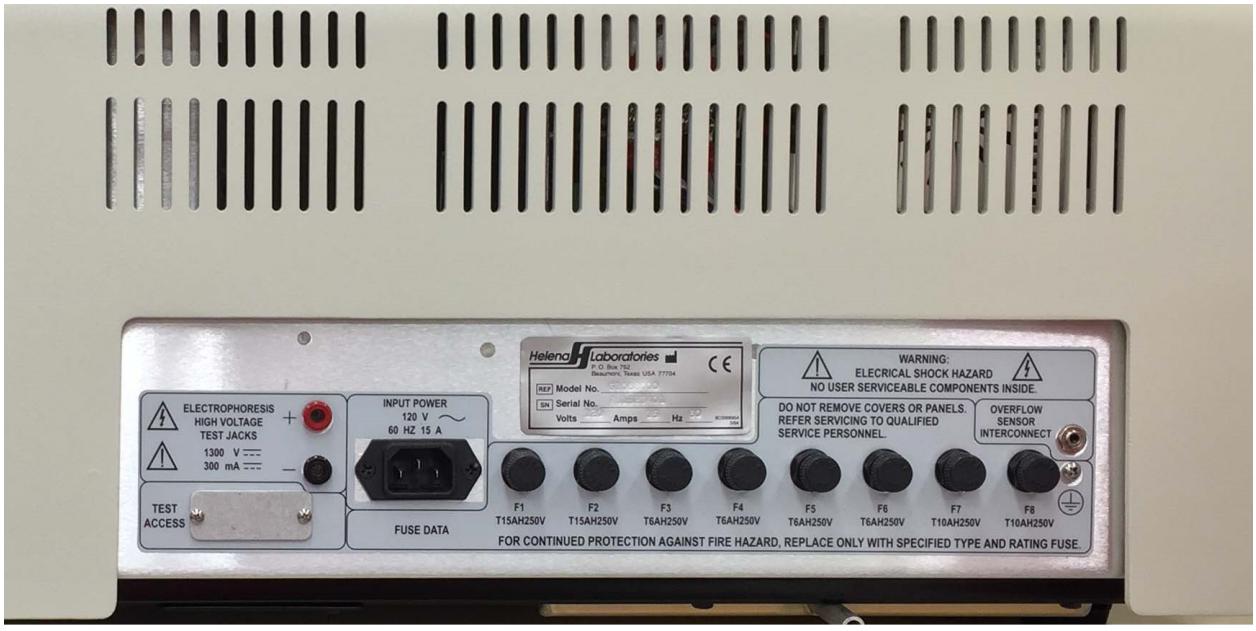


Figure 5-8 Connection for Barcode Reader, Power Cord, Catch Pan Port, and Overflow Sensor (or Shorting Plug), Back

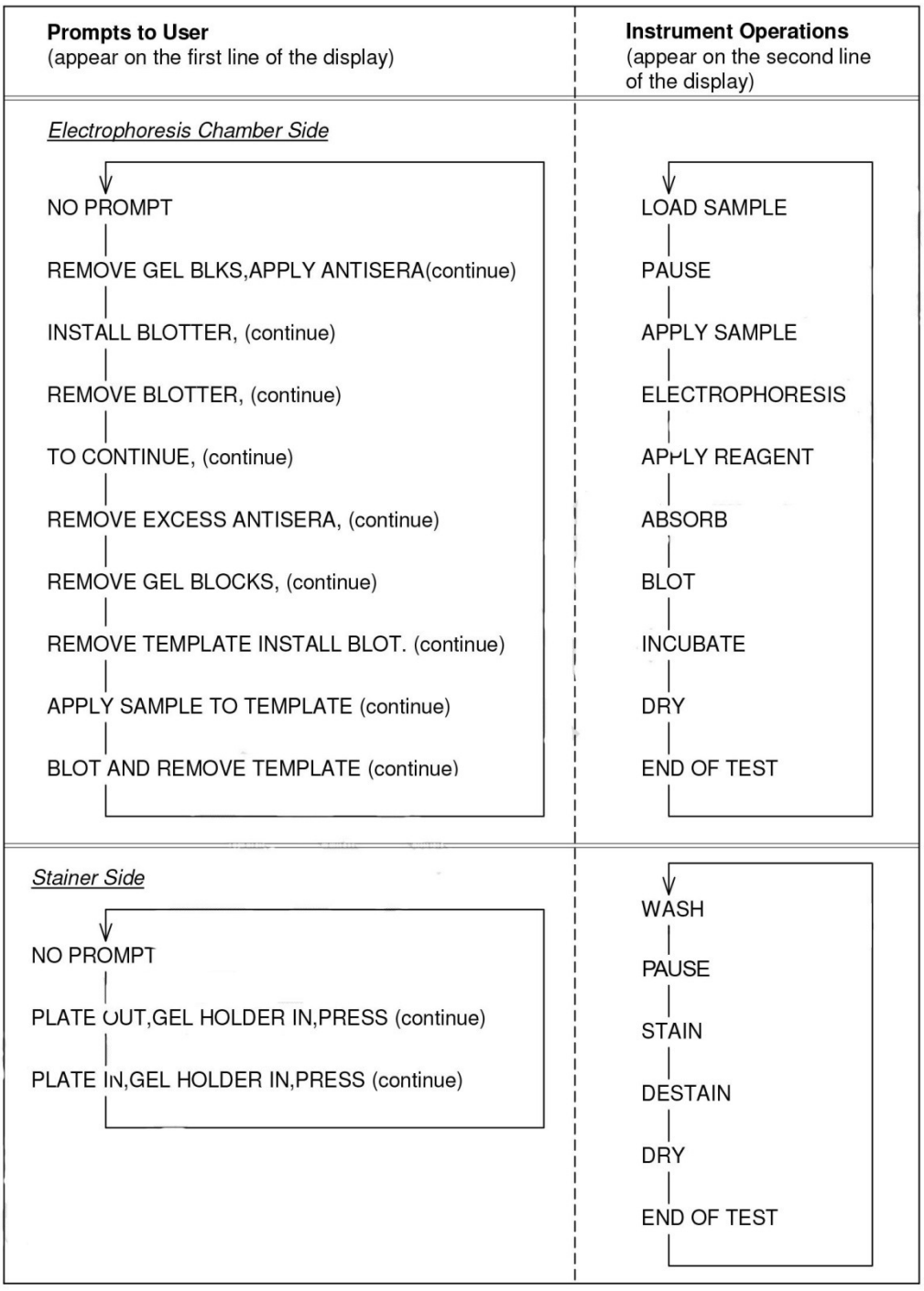


Figure 5-9 SPIFE Touch Flow

Section 6 - Installation Instructions

6.1. Initial Setup

Upon first use, a serial number must be entered. Once the serial number has been entered, this screen will not show again.

6.1.1. Language

Note: *Multiple languages will be included in a later release of the SPIFE Touch software.*

6.1.2. Password

An optional password may also be established to protect settings. Once established, an operator without a password can view the settings but cannot change them. A password may always be added at a later time from the Maintenance menu.

1. The password pop-up dialog box displays, "*Do you want to password protect settings?*"

2. If a password is needed, press *YES*.

a. The instrument displays a dialog box with a numeric keypad and text boxes for the password to be entered.

b. For alpha characters, press the *ABC* button.

c. Enter the new password then re-enter the password below for verification. Use the Backspace key (*Bksp*) to erase the previous digit or *Esc* to cancel.

d. If the passwords don't match, the instrument will display, "*Passwords Do Not Match Retry*".

i. Press *YES* to retry.

ii. Press *NO* to cancel and return to the Main Menu.

e. Press *Enter* when finished.

3. If a password is not needed, press *NO*.

6.1.3. Select Test

From this menu, the user can build a custom test menu and set the order the tests will be displayed on the screen. The default tests are shown on the left side of the screen. Use the up (▲) and down (▼) arrows to navigate through the complete list (Figure 6-1).

1. *Add* – Highlight the desired test on the left side of the screen and press *Add*. The test will be added to the right side of the screen.

2. *Remove* – Highlight the test on the right side of the screen that needs to be removed and press *Remove*. The test will be removed from the new list.

3. *Move Up* – Select the test in the new menu on the right hand side of the screen and press *Move Up*. The test will be moved up 1 position.

4. *Move Down* - Select the test in the new menu on the right hand side of the screen and press *Move Down*. The test will be moved down 1 position.

5. Pressing *Cancel* will clear all test additions on the right side of the screen. If a language and password have been selected, they will remain active.

6. Once all tests have been added, press the *OK* button to go to the Main Menu.

6.2. Test Setup

Test parameters can be altered for both the Stainer and Separation units of the SPIFE Touch. This allows the user to add and edit tests, or create new tests.

6.2.1. Add a Test

This section describes how to add an existing preloaded test from either the Stainer Unit or the Separator Unit.

1. On the Main Menu, press the scroll button until *(New Test)* is shown on either the Stainer Unit or the Separator Unit. Press the *(New Test)* button.

2. The Add or Create Test window appears and asks, "*Do you want to ADD a test from the list or CREATE a new test?"* (Figure 6-2)

3. Press the *Add* button.

4. All default tests will be shown on the left hand side of the screen in the Available Tests column. Use the up (▲) and down (▼) arrows to navigate through the complete list.

5. *Add* – Highlight the desired test on the left side of the screen and press *Add*. The test will be added to the right side of the screen.

6. *Remove* – Highlight the test on the right side of the screen in the Selected Tests column that needs to be removed and press *Remove*. The test will be removed from the list.

7. *Move Up* – Select the test in the new menu on the right hand side of the screen and press *Move Up*. The test will be moved up 1 position.

8. *Move Down* - Select the test in the new menu on the right hand side of the screen and press *Move Down*. The test will be moved down 1 position.

9. Pressing *Cancel* will clear all test additions on the right side of the screen. If a language and password have been selected, they will remain active.

10. Once all tests have been added, press the *OK* button to go to the Main Menu.

6.2.2. Create a Test

This section describes how to create a new test for either the Stainer Unit or the Separator Unit.

1. On the Main Menu, press the scroll button until *(New Test)* is shown on either the Stainer Unit or the Separator Unit. Press the *(New Test)* button.

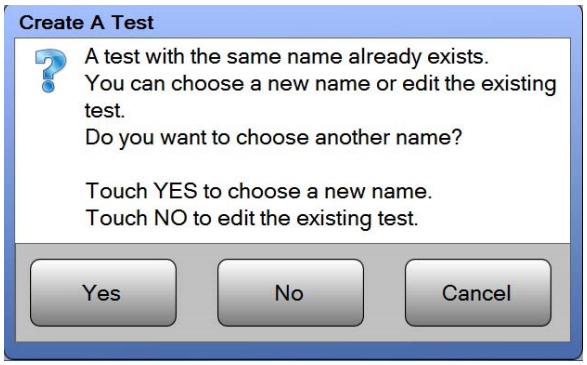
2. The Add or Create Test window appears and asks, "*Do you want to ADD a test from the list or CREATE a new test?"*

3. Press the CREATE button.

4. The CREATE A TEST window appears and asks for a test name (Figure 6-3).

5. Touch inside the text box and the on-screen keyboard appears. Type the name of the test and close the text keyboard. Tap *Next* to continue or Cancel to return to the previous screen without saving changes.

6. If a test name is typed that is already in use, the SPIFE Touch will alert the user with a message.



7. The TEST SETUP screen appears (for the unit chosen) with the newly created test name displayed on the screen. Operations are listed on the left (for a new test, it will only have END listed). (Figures 6-4 and 6-5)

8. To add/create and edit operations, see Section 6.2.3.

9. Press *Back* to cancel all changes and *Done* to save test setup.

Note: *The test name can also be changed by pressing the Rename Test button during the editing process*.

6.2.3. Edit a Test

This section describes how to edit a new or existing test from either the Stainer Unit or the Separator Unit.

1. From the Main Menu, select a test from either the Stainer Unit test list or Separation Unit test list by tapping the test name. If necessary, use the scroll bar to view the entire list. Press the SETUP key.

2. If a password has been enabled, the user will be prompted for it at this point.

3. The Setup menu appears with the test's current settings. The steps available to edit are Instrument Operations, Prompts, and Test Parameters.

6.2.3.1. Instrument Operations

These are operations carried out by the SPIFE Touch itself, such as Load Sample or Apply Sample. The user may edit a step, add a new step, or delete steps.

1. Press the *Add* button to add an instrument operation. A Select Operations pop-up menu appears with the following choices:

a. Separator side: *Load sample, Pause, Apply Sample, Electrophoresis, Apply Reagent, Absorb, Blot, Incubate*, or *Dry*.

b. Stainer side: *Wash, Pause, Stain, Destain, or Dry*.

c. Tap the desired operation and press *OK*. Press Cancel to return to the *Test Setup* screen without saving changes.

2. To edit the parameters for the instrument operation, highlight the operation on the screen. To the right, the parameter buttons are shown. To edit, tap the button. See Section 6.2.3.3 for all available options.

3. To remove an instrument operation, touch the operation in question, then press *Remove.* The operation will be deleted from the Test Setup.

4. To move an instrument operation up or down in the sequence of events, use the Move Up ▲ or Move Down ▼ buttons.

5. To add Positive Patient ID (*PPI*), tap the toggle button to the *Enabled* or *Disabled* setting.

6. To exit this menu, without saving changes, press the *Back* button.

6.2.3.2. Prompts

Prompts are operations carried out by the user, such as *Remove Gel Blocks* or *Install Blotter*. The user may add a new prompt step or choose to have no prompt at the specified locations.

1. To edit or add, press the prompt button. A pop-up menu appears with the following choices:

a. Separator Unit:

i. *None*

ii. *Remove Gel Blocks, Apply Antisera*

iii. *Install Blotter, Remove Blotter*

iv. *To Continue, Remove Excess Antisera*

v. *Remove Gel Blocks*

vi. *Remove Template Install Blot*

vii. *Apply Sample to Template*

viii. *Blot and Remove Template*

ix. *Install Applicator Blades*

x. *Install Chamber Cover*

b. Stainer Unit:

i. *None*

ii. *Plate Out – Gel Holder In*

iii. *Plate in – Gel Holder In*

2. The user makes a choice by tapping the screen and presses *OK* to make the change and return to the Setup menu.

3. Pressing *Cancel* closes the popup menu and returns the operator to the Set-up screen with no changes being made.

6.2.3.3. Test Parameters

Test Parameters are the specific settings used in the test, such as time, temperature or voltage.

1. For numerical parameters, such as *Time* or *Temperature*, tap the parameter on the screen that needs to be changed. An onscreen numeric keypad will appear.

2. The user can use the numeric keypad to change the values for each parameter. Type the numeric value and then press *Enter*. The new value appears in the field.

3. Use the *Bksp* button to correct mistakes and erase the previous digit.

4. Use the *Esc* button to return to the Set-up menu with no changes being retained.

5. For non-numerical values, the choices can be selected by toggling the button.

6. The following parameters may be changed on the Separator side.

a. *Load Sample*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*
   iv. *Speed (1-6)*

b. *Pause*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*

c. *Apply Sample*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*
   iv. *Speed (1-6)*
   v. *Location (1* or *2)*

d. *Electrophoresis*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*
   iv. *Voltage*
   v. *mA*

e. *Apply Reagent*
   i. *Prompt*
   ii. *Temperature*
   iii. *Cycles*

f. *Absorb*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*

g. *Blot*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*

h. *Incubate*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*

i. *Dry*
   i. *Prompt*
   ii. *Time*
   iii. *Temperature*

7. The following parameters may be changed for the Stainer side.

Note: *The choices for Fill, Drain are as follows:* ***1)*** *Fill, Drain,* ***2)*** *Fill, Don't Drain,* ***3)*** *Don't Fill, Don't Drain, and* ***4)*** *Don't Fill, Drain*

a. *Wash*

i. *Prompt*

ii. *Time*

iii. *Recirculation (Off, On, Reverse)*

iv. *Valve*

v. *Fill, Drain*

b. *Pause*

i. Prompt

ii. Time

c. *Stain*

i. *Prompt*

ii. *Time*

iii. *Recirculation (Off, On, Reverse)*

iv. *Valve*

v. *Fill, Drain*

d. *Destain*

i. *Prompt*

ii. *Time*

iii. Recirculation (*Off, On, Reverse)*

iv. *Valve*

v. *Fill, Drain*

e. *Dry*

i. *Prompt*

ii. *Time*

iii. *Temperature*

8. Tapping the Done button will take the user back to the Main Menu.

6.3. User Preferences

The SPIFE Touch also has advanced settings available to the user in the Maintenance Menu. To access this menu, in succession, press the bottom right of the touchscreen, then the bottom left, and then the Setup button. Select the USERS button.

The *Maintenance Menu* will then display on the screen. The settings to choose from are: *Adjust Alarm Volume, Adjust Purge Time, Update Software, Backup Settings, Reset Default Settings, Reset Custom Settings, Set Password, Set Date Time, Download Log, and Language*.

6.3.1. Adjust Alarm Volume

1. Press the *Adjust Alarm Volume* button to display the *Adjust Alarm Volume Menu* (Figure 6-7).

2. Use the up (▲) and down (▼) buttons to adjust the *Separator Volume* and the *Stainer Volume*. Press the *Test* button to hear the volume level.

3. Press *Store* to retain any volume changes and *Back* to return to the Maintenance menu.

6.3.2. Adjust Purge Time

1. Press the *Adjust Purge Time* button (Figure 6-8).

2. Use the up (▲) and down (▼) buttons to adjust the purge time.

3. Press *Set* to retain any changes and *Back* to return to the *Maintenance Menu*.

6.3.3. Update Software

Note: *This icon will only be visible in the Maintenance menu if a proper USB thumb drive has been inserted with all three update files present.*

1. Insert the jump drive.

2. Press the Maintenance button. Press the *Update Software* button (Figure 6-9).

3. There are three components that will be updated; two instrument and a UI. A progress bar will appear alerting the user of the component.

4. After the UI component is updated, a dialog box will appear and alert the user that the instrument will need to reboot.

6.3.4. Backup Settings

1. Press the *Backup Settings* button (Figure 6-9).

2. From the Backup Setting Menu, *"Select the Test(s) you want to back up / Then press Backup"*.

3. Select the desired test(s) and insert a flash drive).

4. The tests will be backed up. Press the *Back* to return to the *Maintenance Menu.*

6.3.5. Reset Default Settings

1. Press the *Reset Default Settings* button (Figure 6-11).

2. The screen displays, "*Select the Test(s) you want to update, Then press Update*".

3. The screen displays, *"Are you sure you want to replace the current settings with the default settings for the selected test(s)?"*

4. Select *Yes* to reset the default settings or *No* to cancel.

5. Press *Back* to return to the *Maintenance Menu.*

6.3.6. Reset Custom Settings

1. Press the *Reset Custom Settings* button (Figure 6-12).

2. The *Reset Custom Settings* dialog box appears and displays, "*USB Drive not detected. Insert drive and retry. Please press OK*".

3. Insert the jump drive and press *OK*.

4. Press *Back* to return to the *Maintenance Menu.*

6.3.7. Set password

1. Press the *Set Password* button (Figure 6-13).

2. The SPIFE Touch will ask the user "*Do you want to password protect settings?*" If so, press *Yes*. If not, press *No* to return to the *Maintenance Menu*.

3. Using the on screen keypad, enter the desired password and then re-enter it to confirm.

4. Press the *OK* button to return to the *Maintenance Menu*.

6.3.8. Set Date Time

1. Press the *Set Date Time* button (Figure 6-14).

2. The *Set System Date Time* screen appears.

3. Using the up and down arrows, set the *Year, Month, Date, Hour*, and *Minute*. A *24 Hour* option is also available.

4. Press *Set* to retain the new date and time and *Back* to return to the *Maintenance Menu*.

6.3.9. Downloa d Logs

1. Insert a jump drive and press the *Download Logs* button (Figure 6-15).

2. Press *Back* to return to the *Maintenance Menu.*

6.3.10. Language

1. Press the *Language* button (Figure 6-16).

2. The possible languages options will be displayed. Select the desired language by pressing the onscreen button.

3. The SPIFE Touch will display, *"Are you sure you want to set the system to *desired language*?"*

4. Press *Yes* to accept and *No* to cancel.

5. The language will be changed. Press *Back* to return to the *Maintenance Menu.*

6.3.11. Return to Main Menu

1. Press the *Main Menu* button to return to the Main Menu.

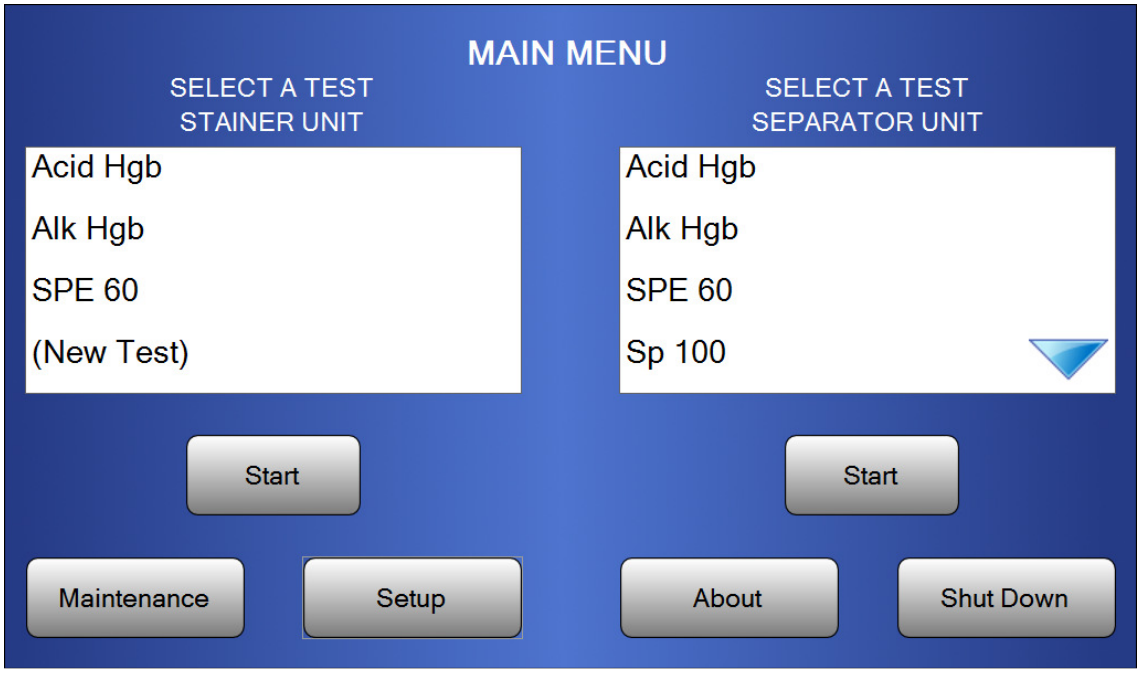


Figure 6-1 Select Test

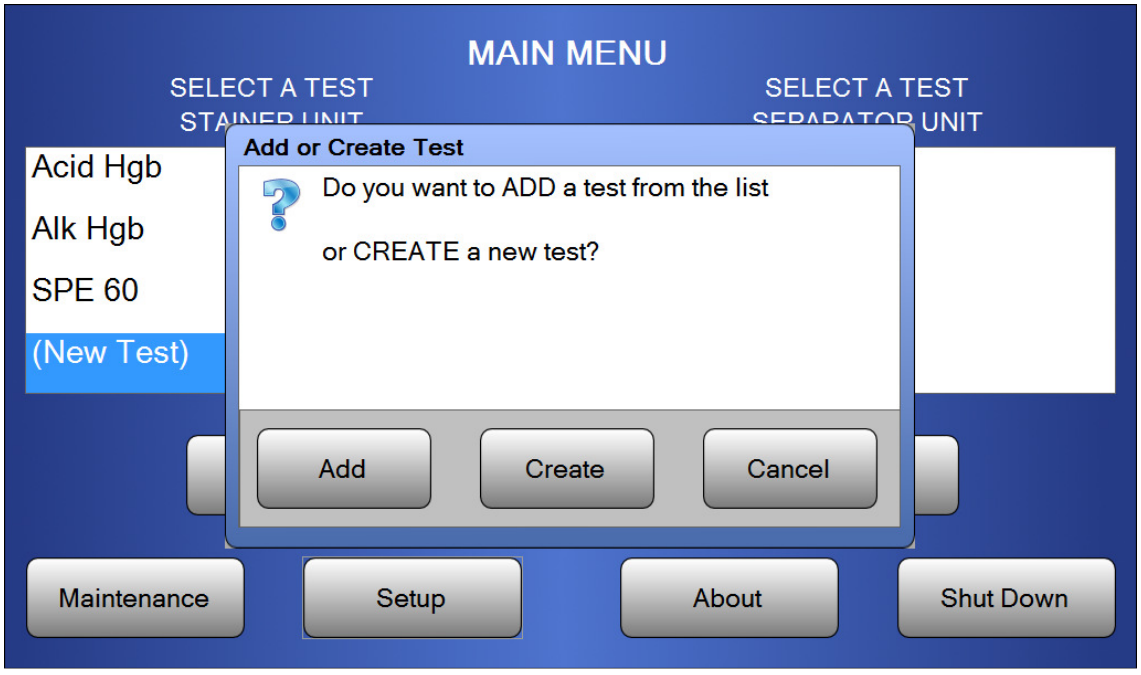


Figure 6-2 Add or Create a Test

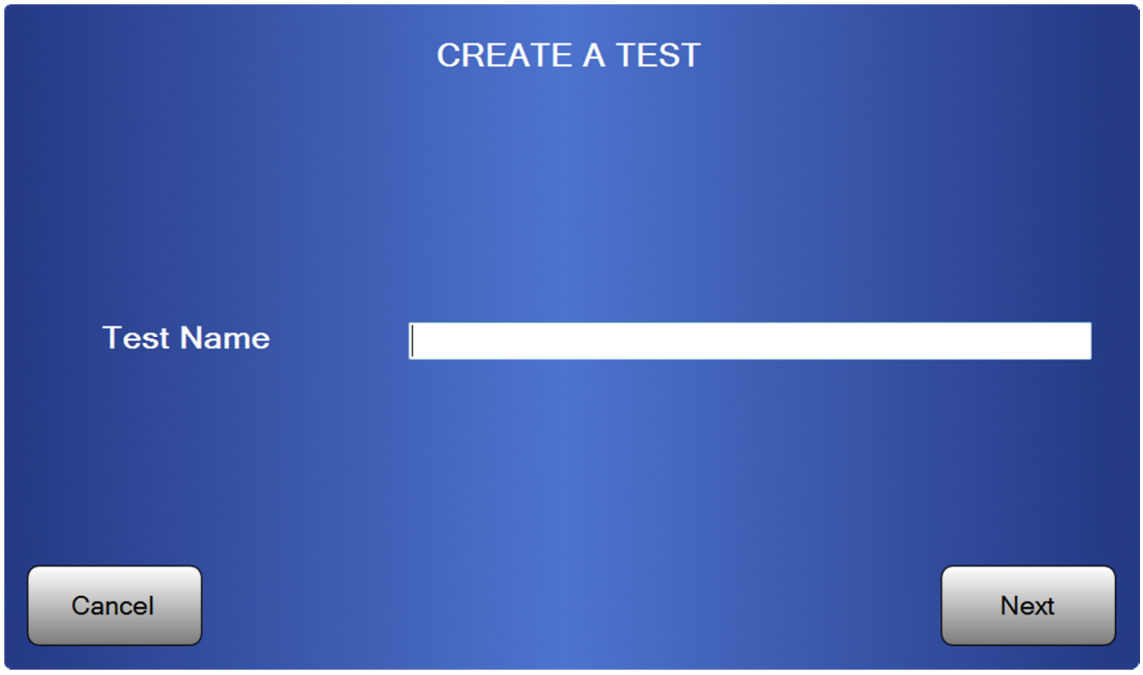


Figure 6-3 Create a Test (Name)

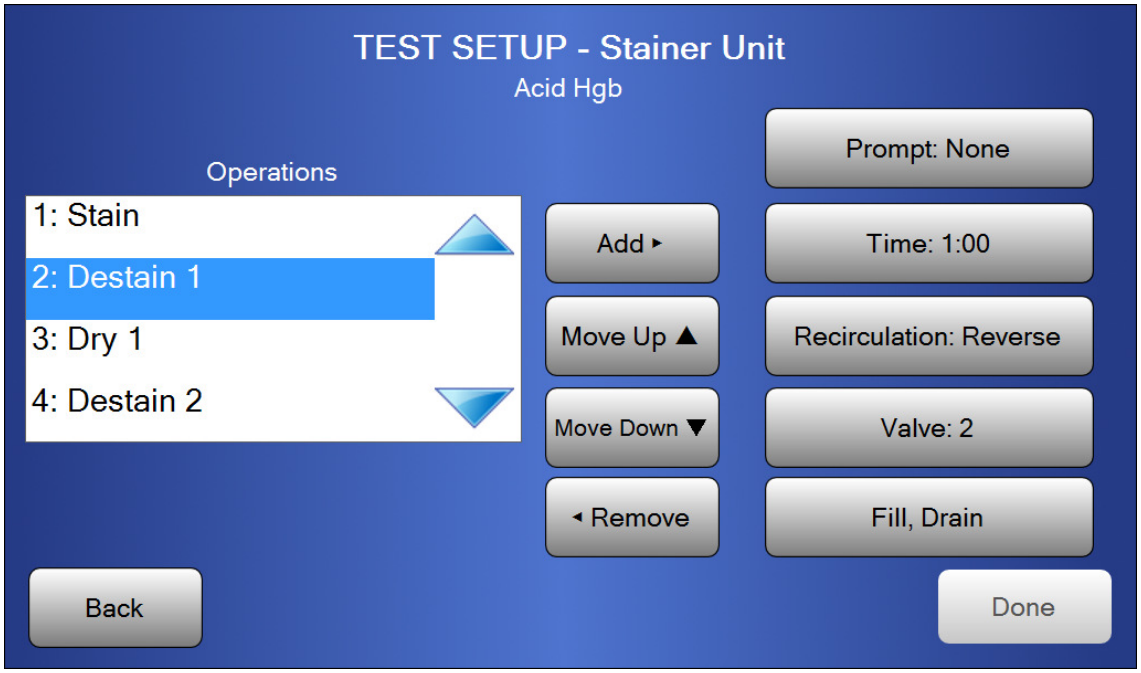


Figure 6-4 Create a Test (Stainer)

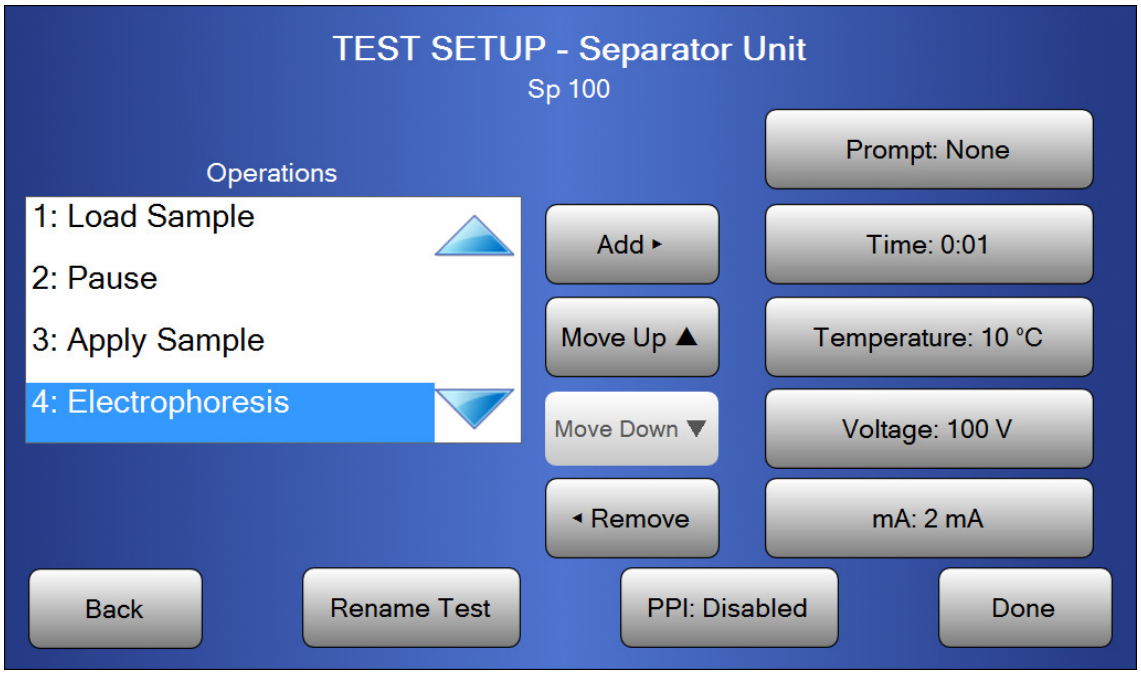


Figure 6-5 Create a Test (Separator)

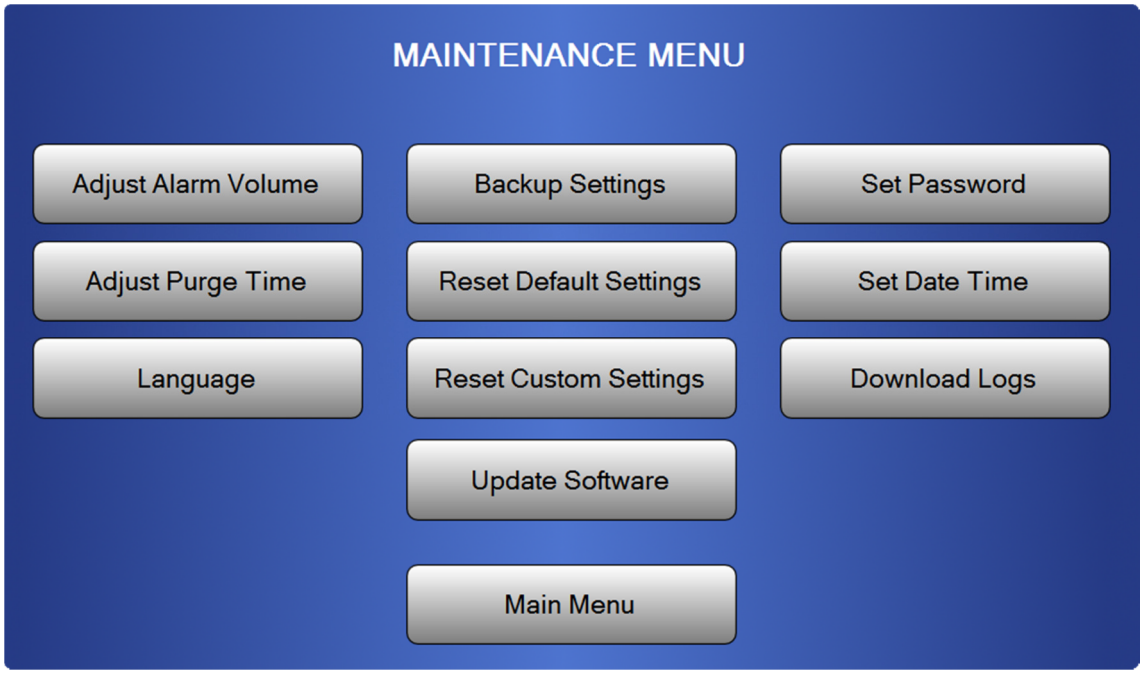


Figure 6-6 Maintenance Menu

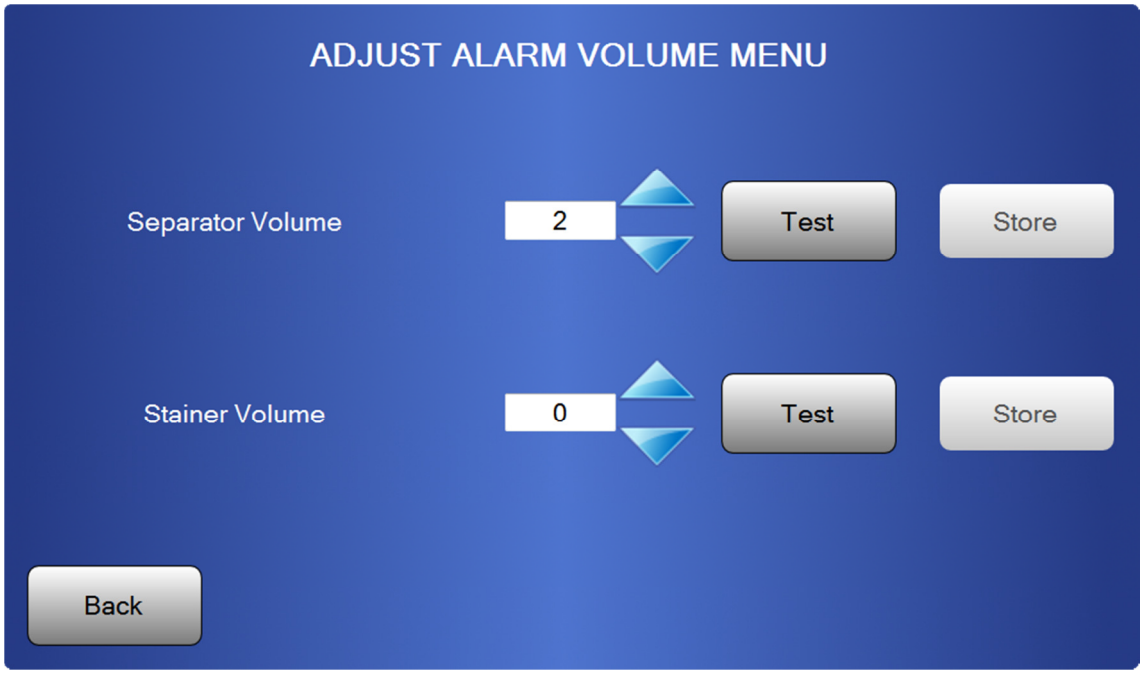


Figure 6-7 Adjust Alarm Volume

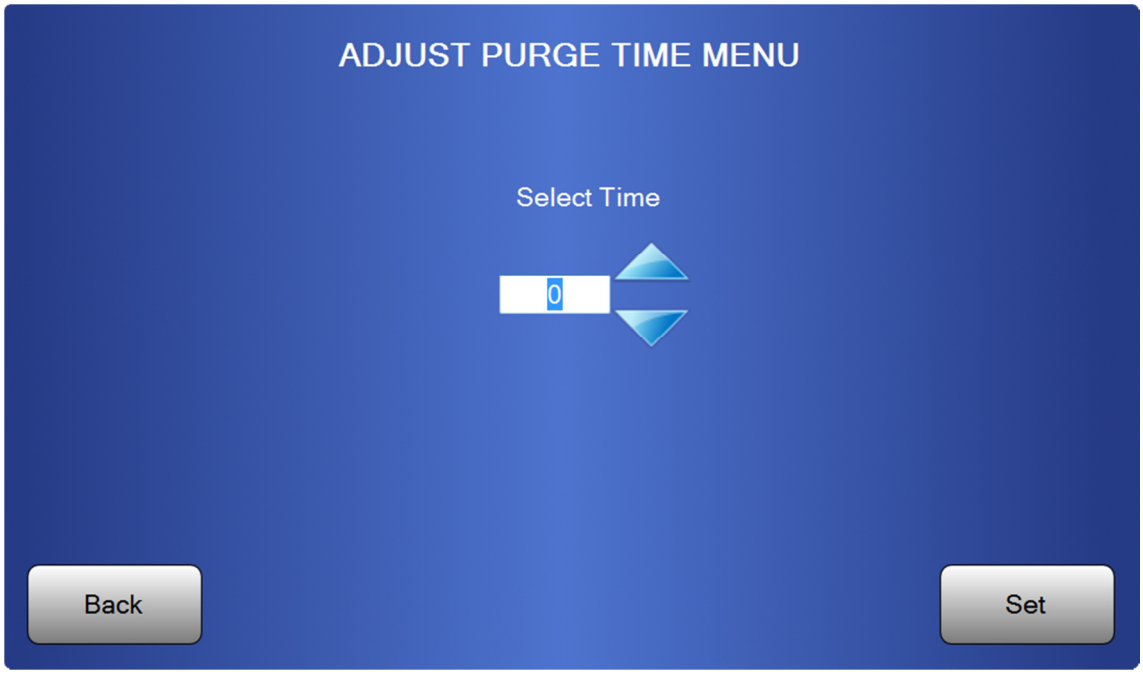


Figure 6-8 Adjust Purge Time

Figure 6-9 Update software

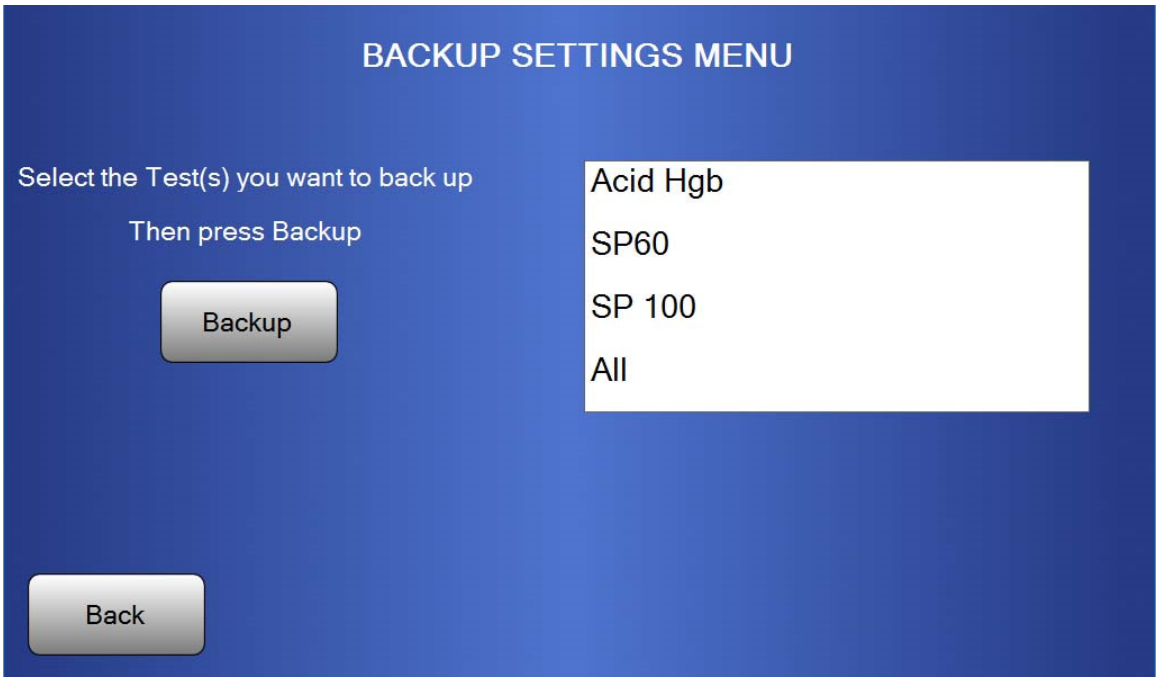


Figure 6-10 Backup Settings

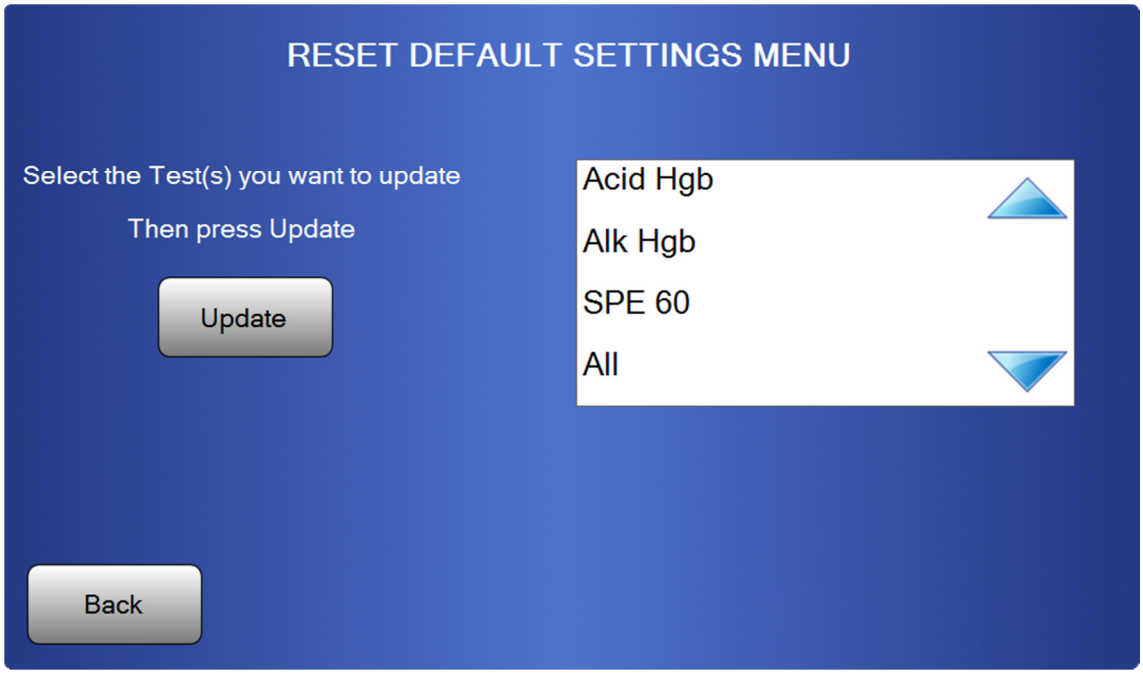


Figure 6-11 Reset Default Settings

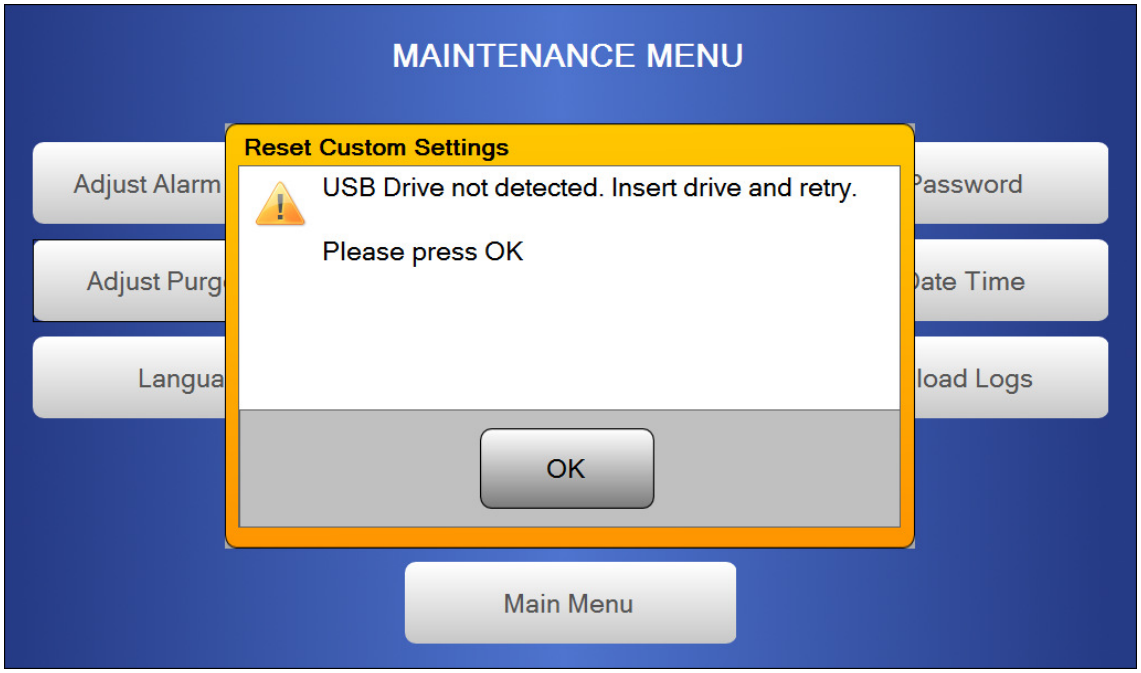


Figure 6-12 Reset Custom Settings

Figure 6-13 Set Password

Figure 6-14 Set Date Time

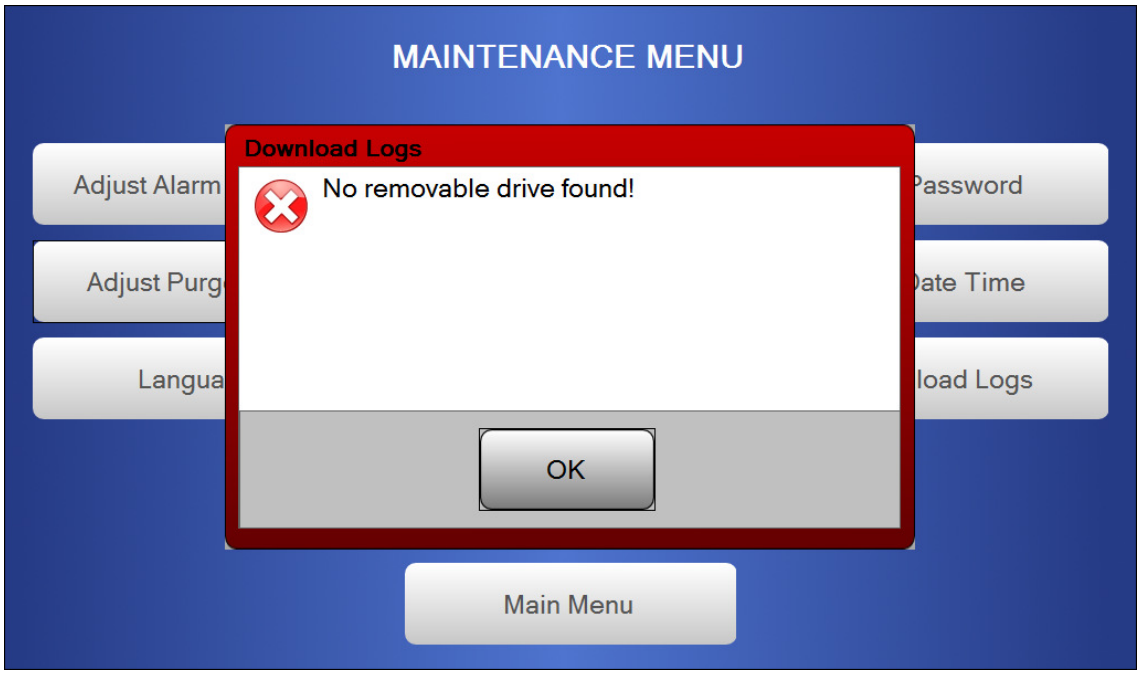


Figure 6-15 Download Logs

Figure 6-16 Language

Section 7 - Operating Instructions

7.1. Preparation

7.1.1. CAUTIONS

To prevent damage to the SPIFE Touch, never place objects on the top of the instrument.

Do not block air vents and intakes. They are located on the right side, rear, and the bottom of the instrument.

Keep flammable liquids and flammable vapors away from the instrument at all times.

Electrodes are fragile and will break if dropped. Do not allow the edges of the electrodes to touch the instrument housing.

Keep the gel holder installed in the stainer at all times.

7.1.2. Powering Up Instrument

1. **If SPIFE Touch has not been used for an extended period of time, the pump must be re-primed before the power is turned on.** If used recently, go to step 2.

a. With the power turned off, pour approximately 100 ml of tap water into the stainer chamber, from the top.

b. Wait a few minutes, allowing time for the fluid to back-fill the pump tubing and wet the pump. When the power is turned on in step 4, the SPIFE Touch will empty the chamber and prime the pump.

2. The Destain vat and the Maintenance Wash vat, should always contain fluid. The Stain vat, containing Acid Blue stain, and the Stain vat, containing Acid Violet stain, will contain fluid depending on the tests used. See the procedure supplied with the reagents. Any used vats need to be checked to verify their fluid levels, replenish as required. **To avoid splashing of stain, fill the stain vats only half full.**

3. Port 4 should be connected to the waste vat or drain. Check that the waste tubing is unrestricted. Check the waste vat and empty if necessary. The waste vat includes an overflow sensor, and a message will appear when the waste vat needs emptying during operation.

4. Turn on the power switch, located on the right side of the instrument. After initialization performs the self-test, the display shows the list of enabled tests and is ready for operation. No warm up time is necessary.

7.2. Positive Patient ID

1. Positive Patient ID can be enabled during the test editing process by toggling between *PPI: Disabled* and *PPI: Enabled* (see Figures 6-4 and 6-5).

7.3. Instrument Operation

7.3.1. Kit Supplied Procedures

For instructions on specimen collection and handling, reagent preparation, preparation of patient samples an d controls, handling of sample cups and tray (Figure 7-2), applicator blades), and gel and gel holder refer to the appropriate sections in the procedure supplied with the kits.

7.3.2. Start a Test

1. From the Main Menu, select the test to be run by touching the screen (Figure 7-4).

2. If editing is required before running, press *Setup* to make changes.

3. If no edits are needed, press *Start*.

7.3.3. Instrument Alarm

When a prompt is accompanied by an alarm, the alarm will stop when, on the

separator side, the lid is opened, and on the stainer side, if the gel holder is removed. With the alarm silenced, the prompt message can be resolved, which may be a step required at that time for the particular test or a problem which has occurred. After the prompt message is resolved, press the indicated key to proceed.

7.3.4. Start Test at Any Operation

1. To start a test at any operation during the test, press that operation when the Select Starting Operation Screen appears (Figure 7-5). To run the test in its entirety, press Start. The display shows the current operation and the instrument's status.

7.3.5. To Abort Operation

1. Press *Abort* at any time to abort the operation of the instrument.

2. If an error occurs, the instrument will give the user three options.

3. *Retry* – the instrument will retry the operation.

4. *Disable* – the instrument displays "*This will disable the instrument until service is called or the instrument is restarted. Are you sure you want to disable the instrument?"* with *Yes* and *No* buttons.

5. *Quit* – the instrument displays "*This will only stop the test and return the instrument to Standby. Are you sure you want to quit?"* with *Yes* and *No* buttons.

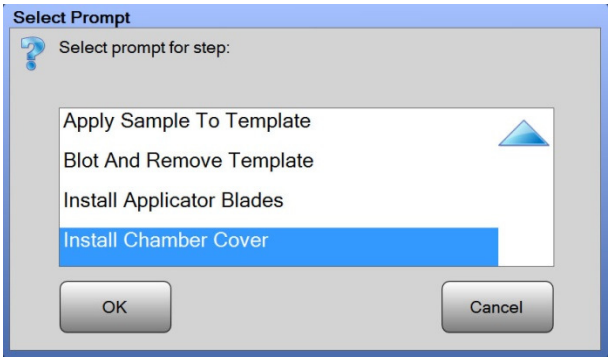
7.3.6. Separator Specific Information

1. If the chamber lid is opened at the beginning or during electrophoresis, the power to the chamber is cut off and a message displayed

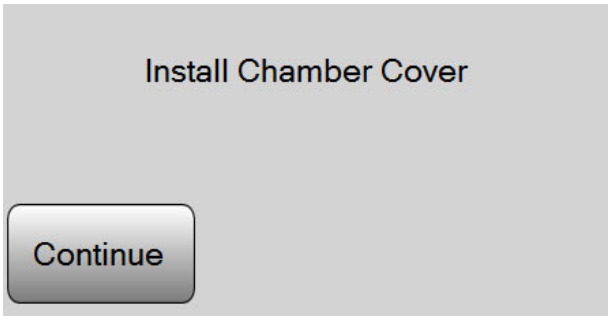
CAUTION: Shock hazard. Never touch the chamber during electrophoresis.

2. Once the lid is closed, the electrophoresis operation will continue.

3. If a chamber cover is required, the Install Chamber Cover prompt needs to be included.



4. When the cover needs to be placed, the instrument will alert the user.



7.3.7. Stainer Specific Information

1. If liquid is present in the chamber, when Start is pressed, the chamber will evacuate to port 4 for approximately 5 seconds, while the display states *DRAINING PUMP*. When complete, operation will continue based on the test selected.

2. To attach the gel to the gel holder, place the round hole in the mylar gel on the left pin of the holder, the obround hole in the mylar gel on the right pin of the holder, and the **center of the gel under the prongs on the holder** (Figure 7-3).

3. After the test is finished, remove the gel and replace the gel holder.

4. Once the next test to be run is selected, if it does not use a Stain and the previous

test did use a Stain, the instrument will automatically wash the Stainer chamber with deionized water for approximately seven minutes. The instrument will prompt to remove the gel plate from the gel holder (plate out), replace the gel holder (holder in) and begin the wash (press continue). Once the wash cycle is complete, the instrument will prompt to replace the gel plate and to reinsert the gel holder.

7.4. Results

Refer to the procedure supplied with the reagents for a complete discussion of results and their interpretation.

7.5. Cleanup

The sample cups, applicator blades, and reagent vials should be handled and disposed of as biohazards. See section 10.1, Maintenance, for information on cleaning the instrument and all reusable pieces. Cleaning is required at different times during the use of the instrument, after every test, daily, etc. and is specified in section 10.1.12.

7.6. Shut Down

1. To shut down the instrument, tap the Shut Down button on the screen.

2. A *Shut Down* dialog box displays, "*Are you sure you want to shut down the instrument? To turn off all power to the system you must turn off the power switch, AFTER pressing Yes below!*"

3. Pressing *Yes* will shut down the instrument. Pressing *No* will cancel the Shut Down request and return the display to the Main Menu.

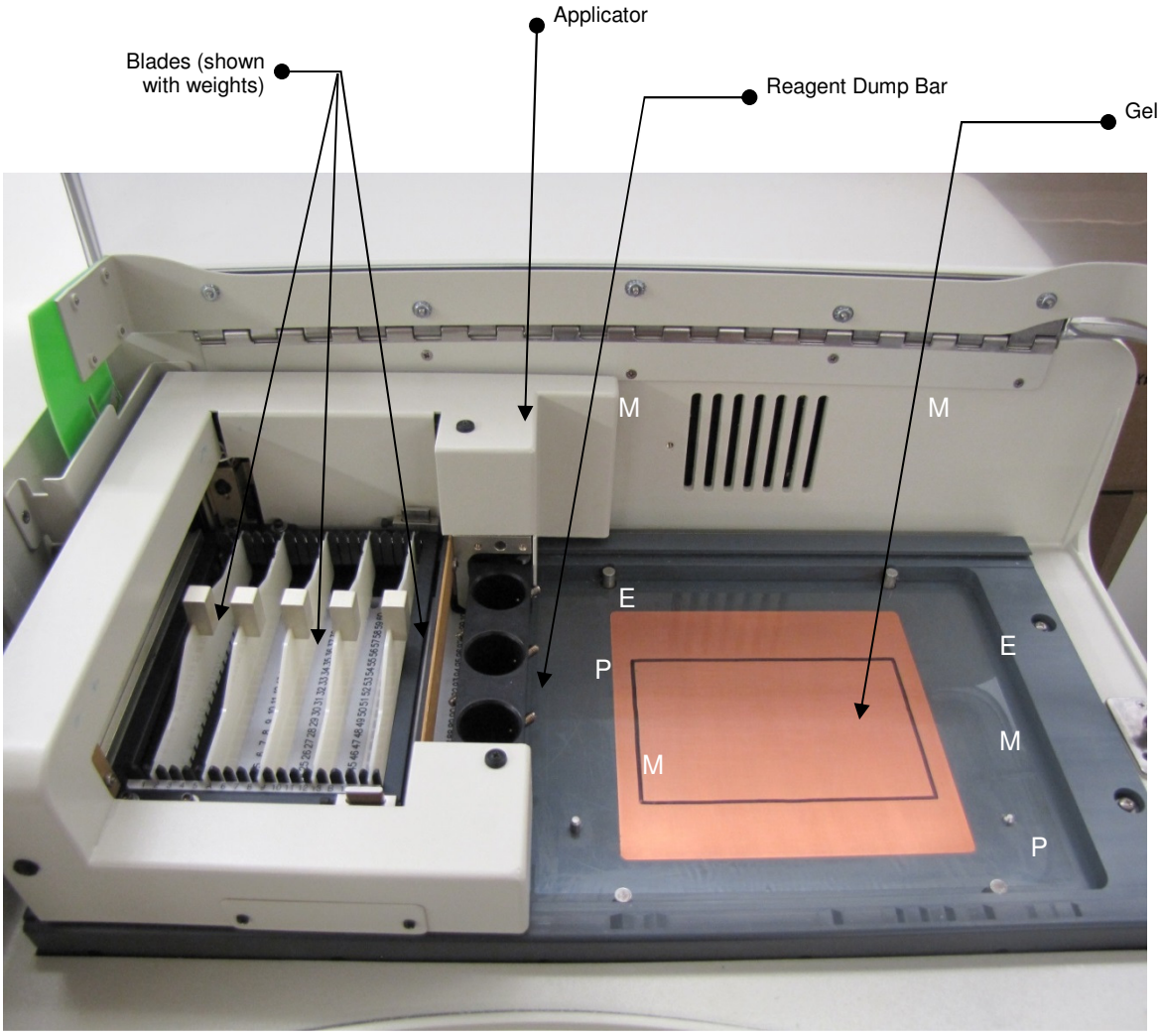


Figure 7-1 Blades in Applicator, Gel in Chamber

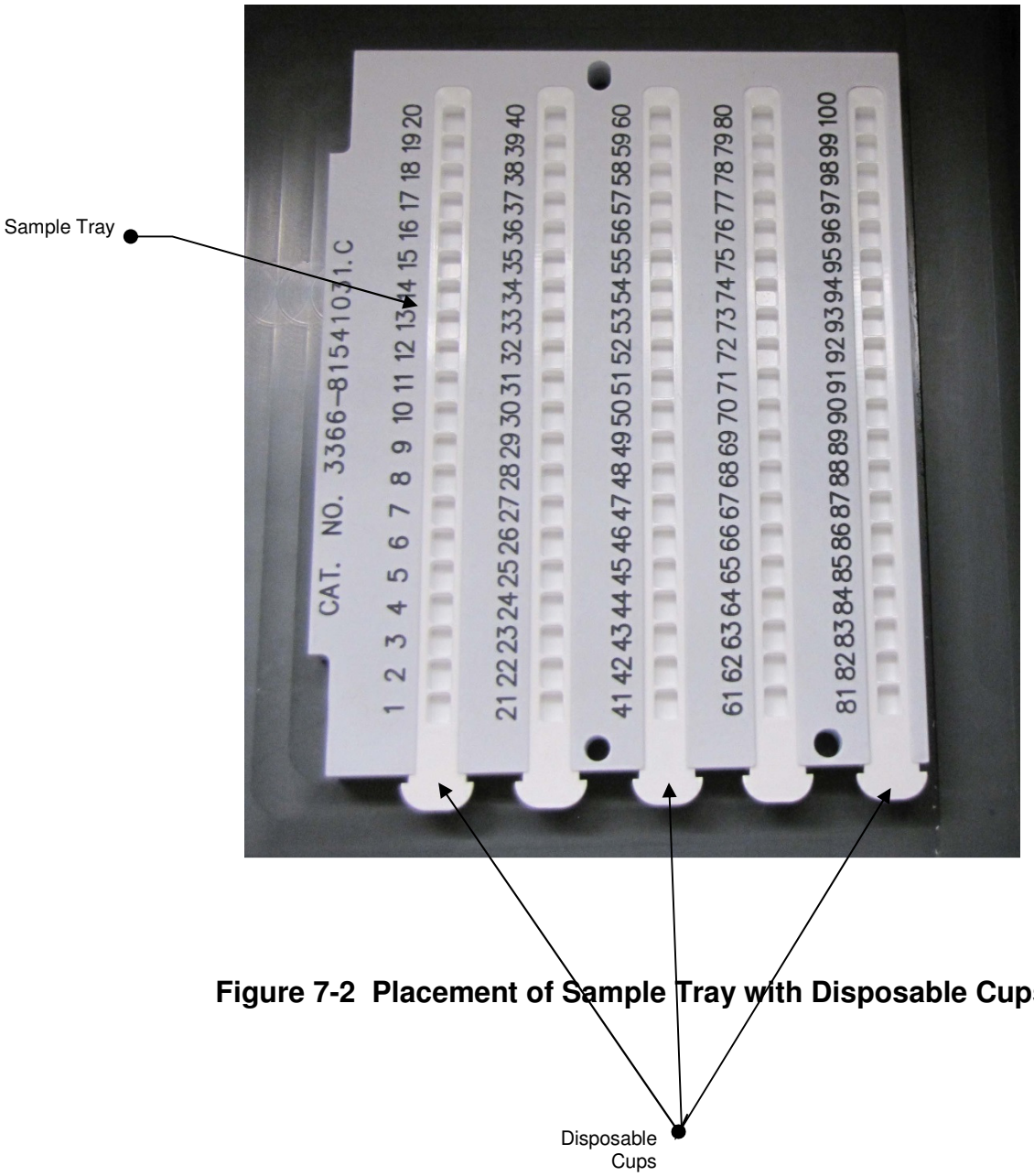


Figure 7-2 Placement of Sample Tray with Disposable Cups

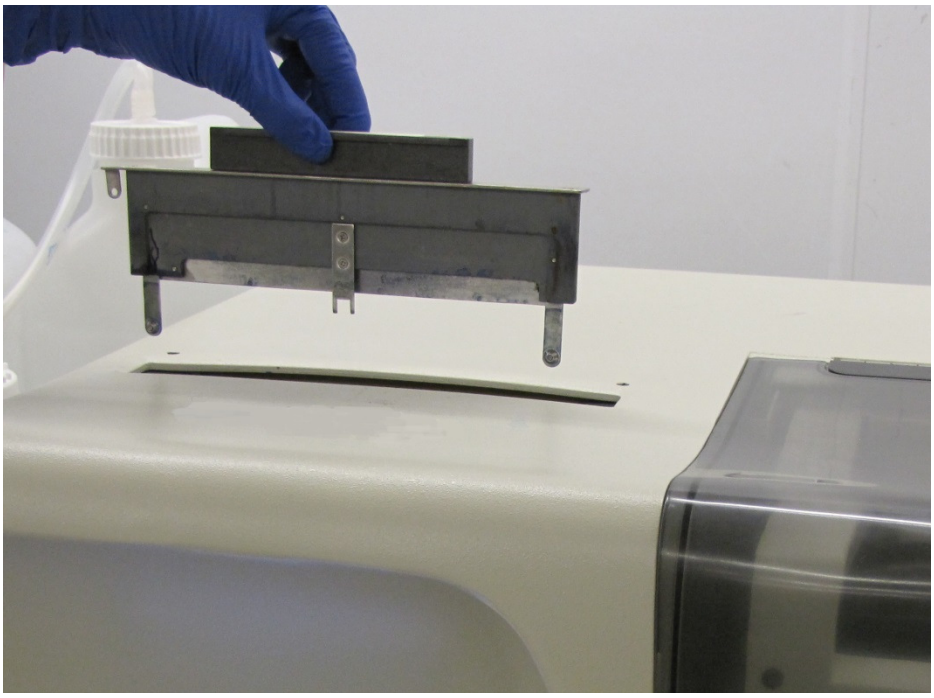


Figure 7-3 Gel and Gel Holder Above Stainer Chamber

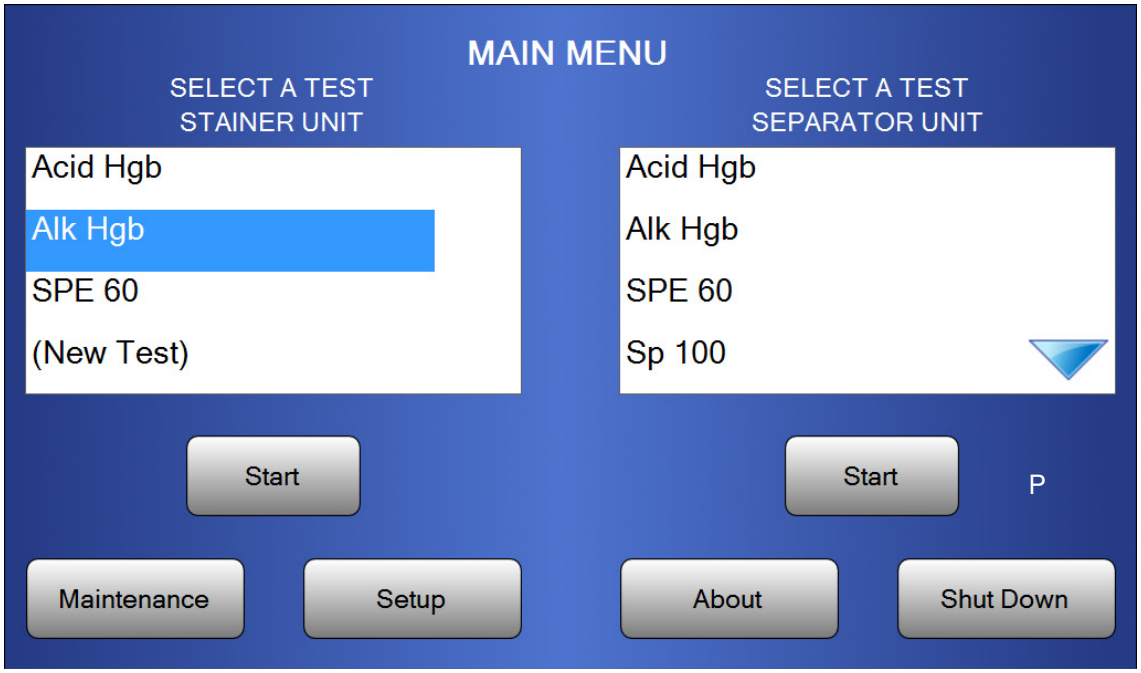


Figure 7-4 Select Test

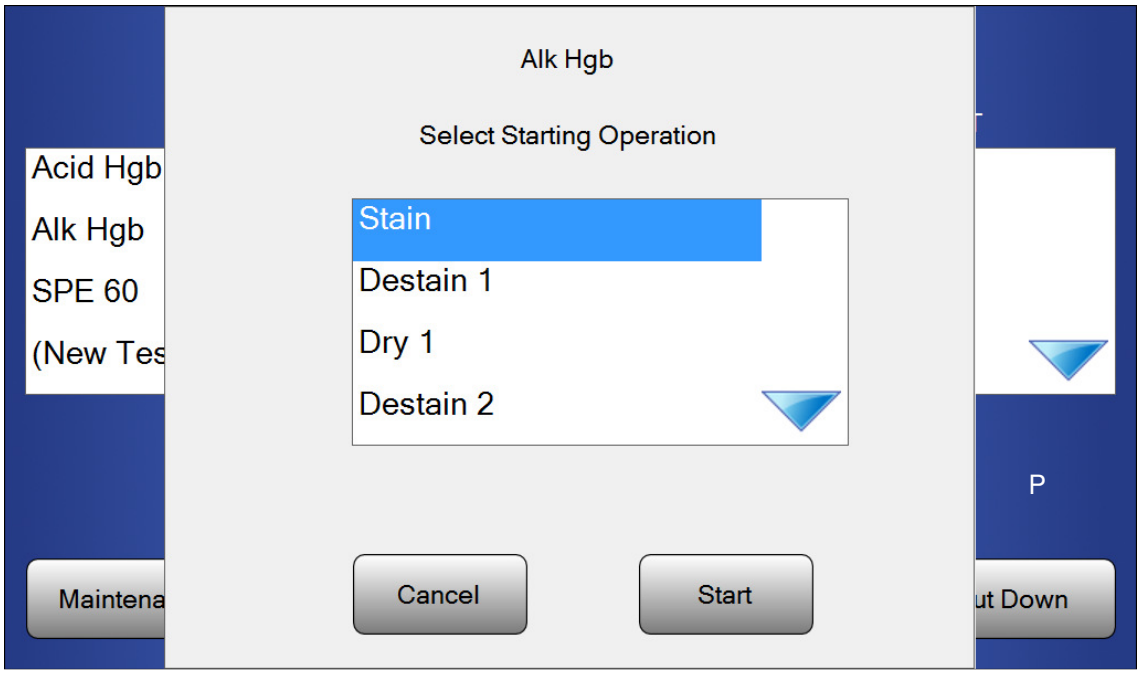


Figure 7-5 Select Test

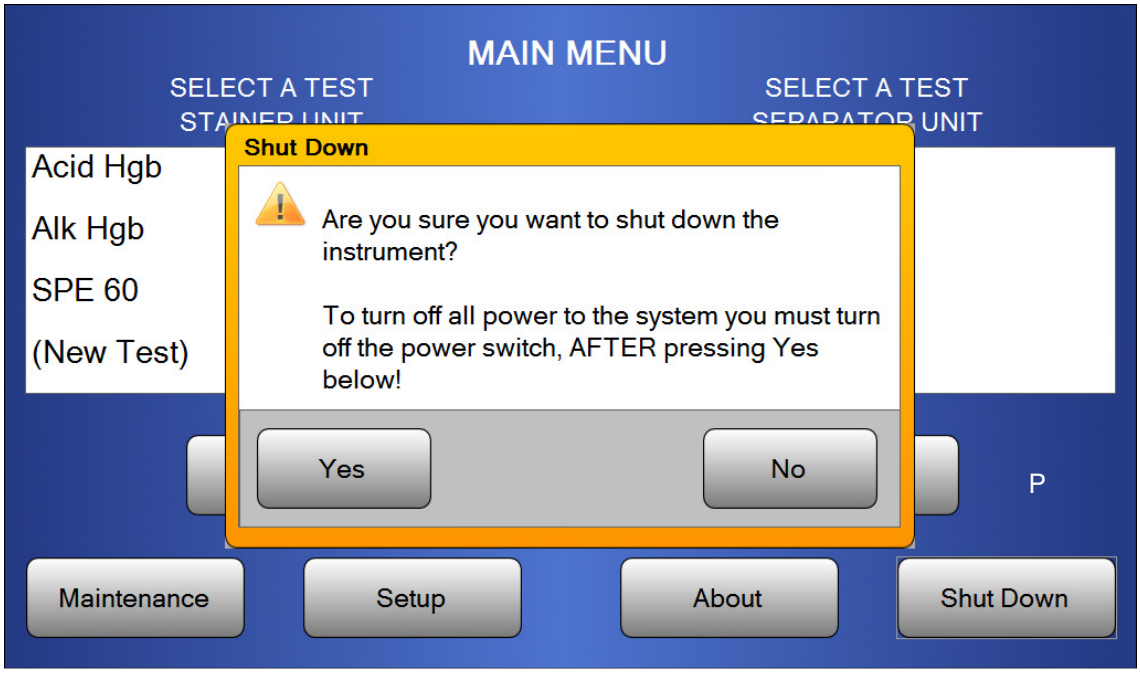


Figure 7-6 Shut Down

Section 8 - Test Functions and Quality Control

The instrument automatically initializes and performs a self-test any time the power is turned on or a test is aborted. Should an error message appear on the display, see section 10.2, Troubleshooting.

A control should be run on each electrophoresis gel. Control data should be compared to the assay ranges printed on the assay sheet provided with the control. The patient data should be compared to the normal range values for the procedure in use and to the laboratory normal range values. Each laboratory should establish its own normal range of expected values for the procedures in use. Refer to the procedure supplied with the reagents for further information.

Section 9 - Performance Specifications

Displays:

Touchscreen

Timer Range:

1 sec. to 99 min. 59 sec. in 1 second increments

Chamber Temperature Range:

10° to 62°C (50° to 144°F)

Stainer Drying Temperature Range:

30° to 90°C (86° to 194°F)

Input Power:

120 Vac Model Cat. No. 1068:
120 Vac, 50/60 Hz

240 Vac Model Cat. No. 1069:
240 Vac, 50/60 Hz

Fuses:

120 Vac Model Cat. No. 1068:
F1, F2: 15A/250V slo blo
F3, F4: 6A/250V slo blo
F5, F6: 6A/250V slo blo
F7, F8: 10A/250V slo blo

240 Vac Model Cat. No. 1069:
F1, F2: 8A T/250 V
F3, F4: 6.3A T/250 V
F5, F6: 6.3A T/250 V
F7, F8: 5A T/250 V

Dimensions:

61 cm (24 in.) High
99 cm (39 in.) Wide
76 cm (30 in.) Deep

Weight:

35 kg (78 lb.)

Operating Temperature:

15° to 27°C (59° to 81°F)

Humidity 20-80%, non-condensing

For Indoor Use Only

Shipping Temperature:

15° to 140°F (-9.4° to 60°C)

Humidity 0-80%

Altitude 4267 meters (14,000 feet)

For Indoor Use Only

Pollution degree 2

Installation category II

IVD rated

Optional Isolation Transformer Specifications:

Input Voltage: 120V (or 230V)
Output Voltage: 120V (or 230V)
Power Range: 2000 VA
Frequency: 60 Hz (or 50 Hz)
Isolation: 4000 VRMS
Leakage Current: Less than 500 µA
Voltage Tolerance: 3%

WARNING: *After transport or storage in humid conditions, the instrument could fail to meet all safety requirements for use. Instrument should be allowed to dry out for a* ***minimum*** *of 4 hours to restore it to normal condition before operation. The instrument cannot be assumed to meet all the safety requirements during the drying-out process*.

Section 10 - Maintenance, Troubleshooting, Warranty

10.1. Maintenance

This section describes routine operator maintenance procedures. The procedures included with the kits may also contain required maintenance. For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

WARNING: The SPIFE Touch is factory lubricated. Do NOT lubricate the instrument.

Table 10-1 Maintenance Schedule Summary

After Every Test
Clean Electrophoresis Chamber
Clean Electrodes
Clean Rigid Antisera Template
Clean Sample Base
Daily, If Used
Perform Maintenance Wash
Weekly
Clean Stainer Level Detectors
Monthly
Clean Waste Level Sensor
As Needed
Fuse Replacement
Replace Contact Sheet
Clean Gel Holder
Clean Antisera Tray
Clean Instrument
Rinse/Replace Reagent Vat(s)

After Every Test

10.1.1. Clean Electrophoresis Chamber

After every test, clean the electrophoresis chamber. First, ensure that the chamber floor is not hot, then dampen a lint-free tissue with deionized water and wash the surface of the electrophoresis chamber.

Should the chamber be contaminated by blood or blood derivative, first **turn off the power and unplug the power cord**, then spray any contaminated surface with a commercial virucidal and germicidal agent. Wipe up the residue. These materials contain alcohol and alcohol is a corrosive to metal surfaces. Dry the unit before plugging the power cord in.

10.1.2. Clean Electrodes

Remove and rinse the electrodes in deionized water. Dry with a lint-free tissue. Replace electrodes in the instrument.

10.1.3. Clean Rigid Antisera Template

After each test, clean the template with soap, water, and a soft brush. Rinse thoroughly with water. Dry the template thoroughly with lint-free tissues.

10.1.4. Clean Sample Base (Non-Disposable Type)

After use, soak the sample base in a 10% Bleach Wash for approximately 15 minutes, rinse thoroughly with water, then with deionized water. Drain water and dry the tray thoroughly with lint-free tissues.

Daily, If Used

10.1.5. Perform Maintenance Wash

At the end of the day, if used, ensure that the Maintenance Wash vat is filled with deionized water and is attached to port 7, then perform the maintenance wash procedure.

1. From the Select Tests menu on the Stainer Side, scroll down and select the Maintenance Wash program. Press Start.

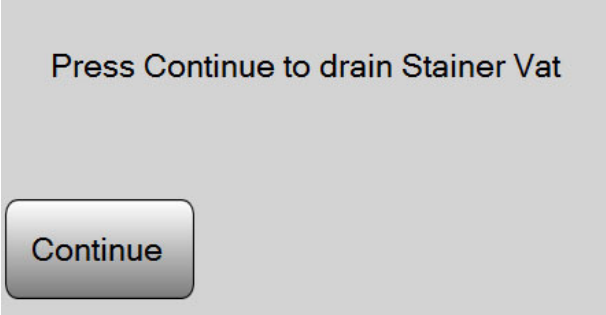
2. The Select Starting Operation window will appear with all the included steps.

3. Press the desired wash step or Start to run all steps.

As the final step in the wash, the liquid will not be drained from the chamber.

This system soak function is designed to enhance the cleaning of the system and to prevent sticking of the valve and pump. As a result, the user may leave the liquid in the chamber as necessary.

Before running a test, the instrument will prompt the user to drain the vat.



Weekly

10.1.6. Clean Stainer Level Detectors

Clean the stainer level detectors weekly, or any time a stainer level detector fails. Turn off the power and unplug the power cord. Remove the gel holder in order to access the chamber interior. Use a maintenance swab dipped in alcohol to clean the level detectors. When viewed from the front of the unit, the detectors are located on left side in the recessed areas of the stainer chamber near the top and bottom. When finished, plug in the power cord, turn the power on, and perform a Maintenance Wash (see section 10.1.5).

Monthly

10.1.7. Clean the Waste Level Sensor

1. Unscrew the waste vat cap and remove it from the waste vat.

2. Remove the two pieces of tubing from the vat cap.

3. Turn the vat cap over and hold the waste level detect sensor under running tap water, removing any residue.

4. Screw the waste vat cap back onto the waste vat and replace the two pieces of tubing.

As Needed

10.1.8. Fuse Replacement

1. Turn off the power and unplug the power cord.

2. Using the provided screwdriver, which matches the slot in the fuse holder, press inward and turn the fuse holder counterclockwise to remove the fuse holder (Figure 10-1).

3. Remove the blown fuse and replace it with one of the same type and rating.

4. Push the fuse holder in and turn clockwise, with the screwdriver, to reseat the fuse.

5. Repeat for the other fuses as necessary.

6. Plug in the power cord and turn on the power. If the fuse immediately blows again, call Helena Laboratories for assistance.

10.1.9. Replacing Contact Sheet (Electrophoresis Chamber Insulation)

The contact sheet, which insulates the electrophoresis chamber floor, may fatigue after extended use. An indication of this is a high voltage error during electrophoresis. Another indication is repeated distortion of an area of the electrophoresis gel, which can be related to a deformity in the underlying contact sheet. In either in-

stance, replacement of the contact sheet is recommended.

1. Heat the electrophoresis chamber using the *Dry 1* operation in the Serum Protein test. See section 7.3.4 for instructions on starting a test at any operation. Once the chamber is almost to temperature a timer displays. Allow the timer to count down two minutes and then stop the test.

2. Turn the power switch Off and unplug the power cord.

3. Remove the old contact sheet by slowly peeling it off, beginning from the right rear of the chamber floor.

4. Remove all remaining adhesive from the surface of the chamber floor using an Adhesive Remover Pad provided with the contact sheets. Once all the adhesive is removed, clean the chamber floor with methanol and a gauze.

5. Any corrosion should be smoothed off the chamber floor. Using the 600 grit emory cloth, provided with the contact sheets, and sanding with the grain of the chamber floor, smooth any corrosion. Use caution not to alter the flatness of the chamber floor. Clean any debris from the chamber floor with methanol and a gauze. It is important that the chamber floor be completely flat, smooth, and free of any material.

6. Plug in the power cord and turn the power switch On.

7. As in step one, heat the electrophoresis chamber; however, allow the timer to count down five minutes and then stop the test.

8. Turn the power switch Off and unplug the power cord. Allow the electrophoresis chamber to cool for approximately five minutes.

9. Obtain a new contact sheet from the package. For easier installation, peel back the contact sheet's backing about 1/4" to 1/2" along the side of the contact sheet with the two holes.

Note: *Contact sheets must stay in their container so that they will remain flat. If sheets roll up, leave them rolled up so that they will not come loose from the backing. Rolled sheets are more difficult to apply but may still be used as long as the backing has not separated from the sheet, allowing the adhesive to dry out.*

10. Holding the contact sheet adhesive side down, align the holes in the contact sheet over the pins located toward the front of the chamber floor. For the contact sheet to lay smoothly on the chamber floor, the contact sheet should not touch the sides of the pins. Press the contact sheet to the chamber floor, beginning between the pins, and rub outward.

11. Continue peeling the backing from the contact sheet, rubbing the contact sheet down with a side-to-side stroke. Avoid wrinkles and bubbles; the sheet may be peeled up slightly, taking care not to stretch it, and smoothed down again to create a flat surface. Rub all the edges of the contact sheet, using a clean gauze, to insure the adhesive sticks to the chamber floor.

12. When the entire sheet is in place, it should lay completely flat and smooth. If the contact sheet has been stretched, it may be difficult to smooth out the wrinkles. If this occurs, replace the contact sheet.

13. Plug in the power cord and turn the power switch ON.

10.1.10. Clean Gel Holder

Any time a residue is seen on the gels after staining and drying, clean the gel holder.

1. Remove the gel holder from the stainer chamber.

2. Wipe off all residue on the gel holder with a cloth soaked in Destain, rinse in deionized water, then dry with a lint-free tissue. For heavy accumulations, soak the gel holder in Destain until residue can be removed, then rinse in deionized water and dry.

3. Replace the gel holder in the stainer chamber.

10.1.11. Clean Antisera Tray

Clean the Antisera tray (if used) with soap, water, and a soft brush. Rinse thoroughly with water. Dry the tray thoroughly with lint-free tissues.

10.1.12. Clean Instrument

The SPIFE Touch has two main areas that must be cleaned differently. The first area is the clear polycarbonate lid, which can easily be damaged by improper cleaning. The rest of the instrument, with painted metal surfaces, can withstand a more vigorous cleaning.

10.1.12.1. Clear Polycarbonate Lid

The clear plastic lid should **only** be cleaned with a soft damp cloth (not a paper towel) and a mild soap, if necessary. Anything else will cause permanent damage to the plastic.

10.1.12.2. Main Instrument

Should the instrument be contaminated by blood or blood derivative, first **turn off the power and unplug the power cord**, then spray any contaminated surface with a commercial virucidal and germicidal agent. Wipe up the residue. These materials contain alcohol and alcohol is a corrosive to metal surfaces. Dry the unit before plugging the power cord in.

Should the instrument become stained, dampen a scrubbing pad with water. Apply a small amount of Dial® Antibacterial Soft Scrub® with Bleach Cleanser to the rough side of the pad. Firmly scrub stained area of the instrument. Use the sponge side of the pad to wipe off excess cleanser. Dampen a paper towel and wipe off remaining residue.

Cleaning spills in a timely manner will help prevent permanent staining.

10.1.13. Rinse/Replace Reagent Vat(s)

Prior to refilling reagent vats, rinse them with hot water and then with DI water. If mold develops in vats, replace vat, cap, and tubing (reagent vats - 2 liter 9B884011 and 2½ gallon 9B584011, stain cap with tubing 8JM54006, wash cap with tubing 8JM32027, 9C270013 13L destain container, and 8JM54149 destain cap).

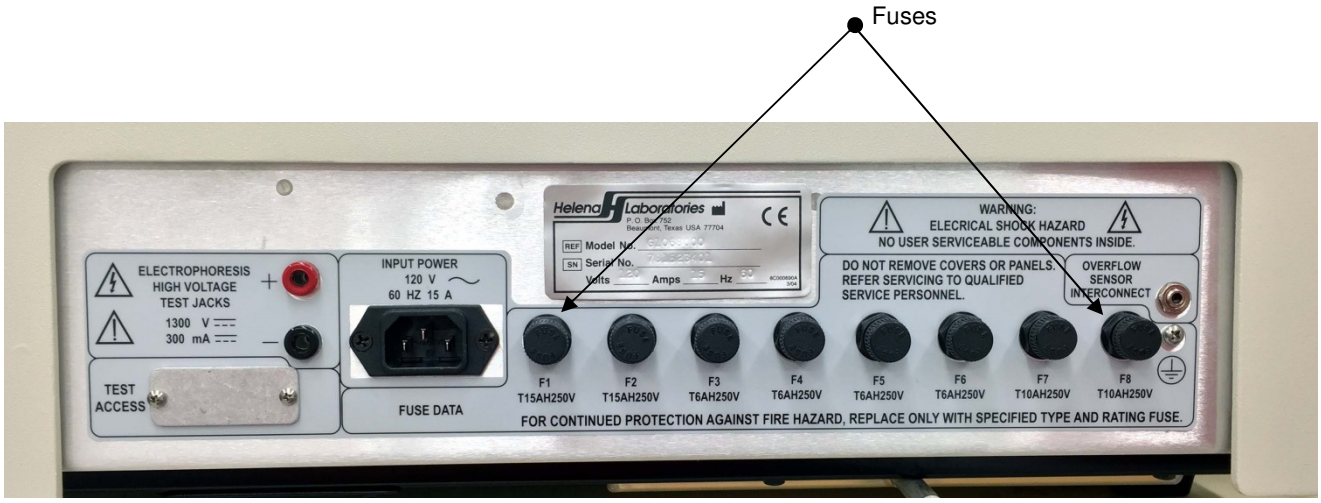


Figure 10-1 Fuses

10.2. Troubleshooting

If the recommended solutions should fail to solve a problem, call Helena Laboratories for assistance.

Table 10-2 Troubleshooting

Problem	Possible Cause	Solution
No power to instrument	Power cord unplugged	Plug cord into proper wall outlet.
	Fuse blown	Check fuses on back of unit. Replace, if required.
Error message is displayed	Error found during self-test or operation	Do as directed by the message. If message returns, call Helena Laboratories for assistance.
Electrophoresis chamber not reaching programmed temperature	Fuse blown	Check fuses on back of unit. Replace, if required.
	Electrical problem	Call Helena Laboratories.
Cycle will not start when press SELECT or START	Lid not closed	Close lid.
	Fuse blown	Check fuses on back of unit. Replace, if required.
	Broken electrode	Replace electrode or call Helena Laboratories.
	Electrical problem	Call Helena Laboratories.
No power to stainer chamber	Fuse blown	Check fuses on back of unit. Replace, if required.
	Electrical problem	Call Helena Laboratories.
Incubator or dryer too hot	Electrical problem	Call Helena Laboratories.
Fan does not run	Restricted air flow	Remove obstructions and check to be sure enough air space surrounds instrument.
	Electrical problem	Call Helena Laboratories.
Gel appears unacceptable	Programming problem	Check programming for the test against the record of programmed parameters (see 6.3) and reenter, if parameters have been changed.

	Other problem	If programming is OK, check reagent bottles and repeat test. If still unacceptable, call Helena Laboratories.
Stainer level detector failures	Dirty stainer chamber	Use Maintenance Swab dipped in Destain solution to clean inside of stainer chamber, especially around level detector probes.
	No fluid in chamber	Ensure that stain vat(s) are correctly connected to the instrument and that the vat(s) contain fluid.
Reagent does not dump	Programming Problem	Check programming for the test against the record of programmed parameters (see 6.3) and reenter, if parameters have been changed.
	Electrical Problem	Call Helena Laboratories.
Stainer chamber incorrectly filling/draining	Stainer Value/Pump Failure	Call Helena Laboratories.
Electrophoresis high voltage error	Fatigued Contact Sheet	Replace contact sheet (see 10.1.9).
Electrophoresis gel has repeated distortion in same area	Fatigued Contact Sheet	Replace contact sheet (see 10.1.9).

10.3. Warranty

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies.

In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose.

Section 11 - Symbology

NOTE: The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable.

	Caution, electric shock hazard, high voltages capable of causing personal injury - shut down the instrument and unplug the power cord before touching - do not operate with the cover(s) removed
	Caution, heat hazard - allow heated components to cool before handling
	Caution, general hazard - see Precautions and Hazards (Sections 3 and 4) of Operator's Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
	Frame or chassis terminal
	Equipotentiality (conductor with all parts at a single potential)
	On (power switch)
	Off (power switch)
	Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of IEC 536)

SPIFE® Touch

Operator's Manual

Software version 1.0

For additional information, call
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