ESH Touch

(Automatic Sample Handler for Electrophoresis)

Operator's Manual

Catalog Number 1380: 100 - 240 Vac

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(Automatic Sample Handler for Electrophoresis)

Operator's Manual

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Section 1 - Instrument Use and Function

Helena's ESH Touch (Figure 1-1) is a sample handling system that transfers samples from test tubes into sample cups and sample trays for Helena Laboratories SPIFE 3000 instruments. It also performs specified dilutions for IFE.

The ESH Touch contains preprogrammed test parameters for provision of the correct amount of specimen to be run for SPIFE Lipoproteins. Cholesterol Profile, Serum Protein SPE and SPIFE Split Beta SPE tests as well as five different combinations of dilutions for each of the SPIFE IFE tests. In addition, the instrument can be user programed to change the amount of sample in the sample cups or provide unique dilution ratios for specific patients for the IFE test.

The ESH Touch is intended for in-vitro diagnostic use only, and is for use in a laboratory or similar environment. This is for indoor use only.

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
    Expected results
    References
    Evaluation of the Bands
    Interpretation of Results
    Bibliography

Figure 1-1 ESH Touch

Section 2 - Principles of Operation

The functional units of the ESH Touch are shown in Figure 2-1. Operation is controlled by a microprocessor and its programmed memory and a touchscreen.

The Sample Handler contains a sample arm assembly (controlling sample delivery and transport), two independent motor control modules (controlling movement of the sample arm), a bar code reader, and 4 USB ports. Two RS232 outputs are provided for data transfer to and from a Laboratory Information System (LIS) and/or a Helena Electrophoresis system.

Software updates are provided via a jump drive.

Using the touchscreen, the user may select the type of test, enter a dilution scheme, start or stop the automatic sequence of operations, wash the applicator and pump tubing, select test parameters, and change displayed menus. Patient data, control values, and other data are manually entered into the associated electrophoresis instrument worklist by the instrument's touchscreen, or automatically entered by reading a bar code and using the LIS interface.

When automatic operation is started, the instrument will indicate the test for which the specimen is to be loaded. It will also require the correct specimen tray for that sample to be loaded into position. The ESH Touch will identify the samples by reading a bar code label (if used) on the sample tube and will either send that bar code directly to the QuickScan Touch or receive information for those bar codes from and LIS and send that information to a QuickScan 2000. It will make the appropriate dilutions for the various Immunofixation lanes and transfer a predetermined amount of sample from sample tubes to the sample tray.

The computer runs a self-test at power on to detect error conditions or potential problems. If an error is detected, the computer responds by displaying an error message.
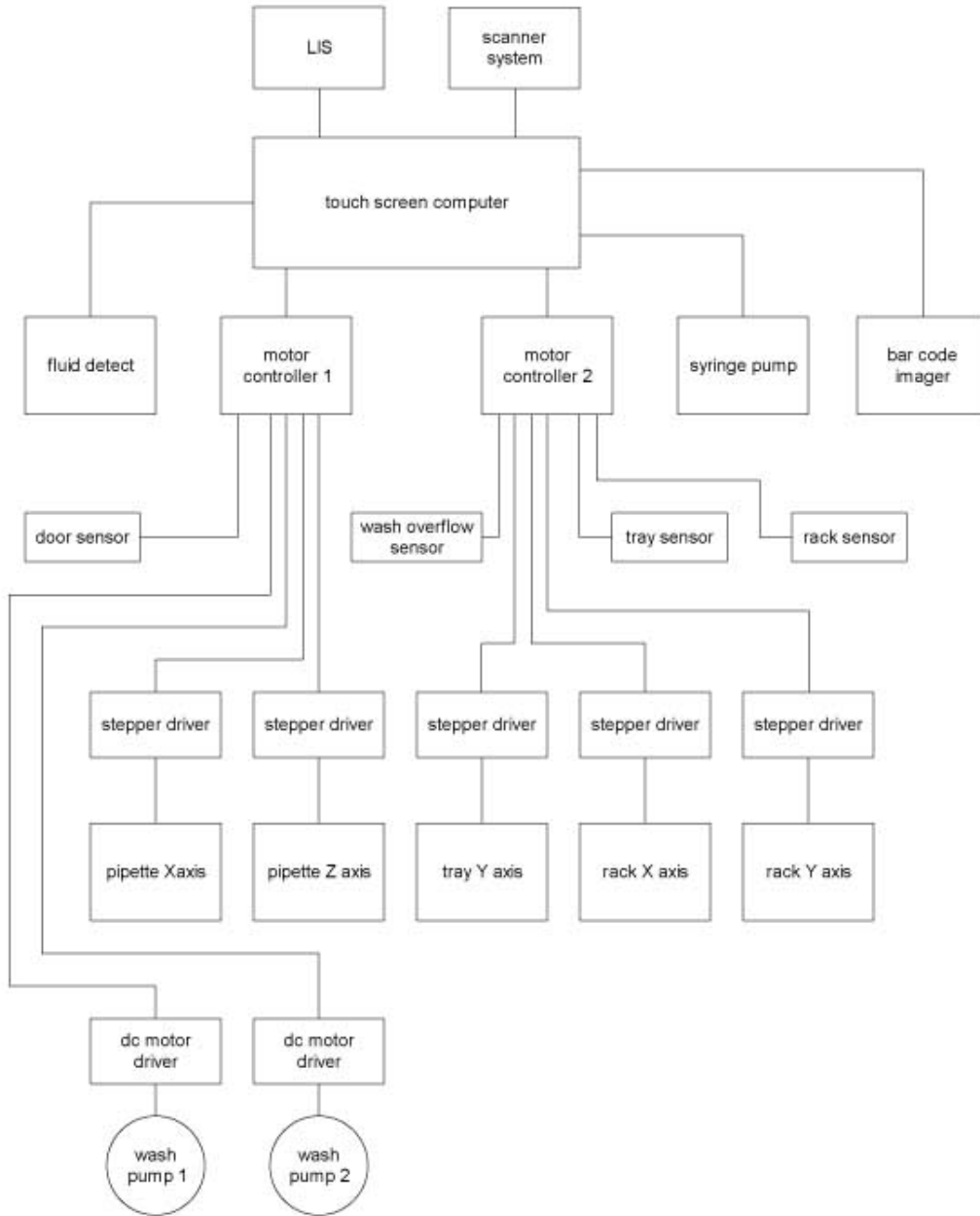
Figure 2-1 Block Diagram

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 diluent preparation and handling and other information.

3.3. Provide adequate room at the sides and back of the instrument for good air circulation.

3.4. 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 may contain alcohol and alcohol is a corrosive 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.**

3.5. 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.

3.6. Use only diluent made specifically for use with the Helena procedure in use.

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

3.8. For emergency shutdown, disconnect the ESH Touch power cord.

3.9. Keep hands and clothing away from the applicator arm when in operation.

3.10. Do not expose the sample trays to temperatures above 158° F (70° C), or severe warping of the trays may result, making them unusable.

3.11. Installation is to be performed by the operator.

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

3.13. Instructions for the "responsible body*" (*Under IEC 61010-2-101:2002 -- the person(s) responsible for the use and maintenance of equipment and for ensuring that operators are adequately trained for eliminating and reducing hazards involved in removal from use, transportation, or disposal.)

3.14. Action(s) to be taken in case of malfunction: See Section 3.8 and 10.2.

3.15. Requirements for handling biohazards: Due to potential biohazard risk from human based components (blood, CSF [Cerebrospinal Fluid], urine, plasma, blood cells, ect.), guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other protective equipment as warranted for safe handling and disposal of test tubes, reagents, applicators, or other items containing or contaminated by biohazards and use, transportation and disposal of this device. For information on minimizing biohazard risk, see to Section 3.4.

3.16. Storage and transport environmental requirements (see Section 9 for more detail):
Operating Temperature range: 15° – 27°C
Storage and shipping temperatures: -9.4° – 60°C

3.17. The Helena Agent shall provide a power cord or adapter of the proper configuration for the country in which the instrument is to be installed. The power cord or adapter will comply with IEC 60227, IEC 60245, or be certified as rated for the power specified in Section 9 of this manual.

3.18 Insure all waste is disposed of in accordance with local, state, and federal regulations.

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

4.3. 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. **Do not operate any instrument with the cover removed.**

4.4. Do not attempt to operate the instrument without plugging the power cord into an easily accessible, grounded AC wall outlet of the proper voltage and frequency. This information is contained on the serial number plate located on the back of the instrument.

4.5. Caution: Do not place fingers under the sample probe when the instrument is in use.

4.6. Do not lubricate the instrument.

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

4.8. Follow safe handling and disposal procedures for diluent used with this instrument.

4.9. In case of power loss or brown out (low voltage) during operation, clean the sample tray as described in Section 7 and repeat the run.

4.10. **WARNING:** External equipment (barcode reader, computer, etc.) that is connected to the instrument must have no live parts that are accessible.

Section 5 - Installation Instructions

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. 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 ESH Touch , Cat No. 1380
3 Lengths of Tubing
1 Screwdriver
1 Diluent Bottle and Cap
1 DI water Bottle and Cap
1 Saline Bottle and Cap
1 Waste Bottle and Cap
2 Fuses
1 Power Cord (See Note)
1 Probe Cleaning Wire, 8JM20111
1 Operator's Manual
1 Installation Report
10 Tube Racks, Cat No. 1382

1 flash drive with ESH Touch software
1 Nut Driver for probe removal
1 Plumbing Kit
1 Maintenance Table

*Note: Power Cord provided in Accessory is for use in North America **ONLY**. For all other locations, a Power Cord will be provided per Section 3.17.*

Table 5-2 Accessories

Touch Series Barcode Scanner, Cat No. 1381
ESH Touch Replacement Tube Racks, Cat No. 1382
ESH Touch Rack Carrier, Cat No. 1384
ESH Touch Probe, Cat No. 1385
ESH Touch tubing for Probe, Cat. No. 1386
Weigh boat, Part No. 81040045
Stylus, Part No. 9S791009

5.2. Installation

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

1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and large temperature fluctuations. Ambient temperature should be between 59° to 81° F (15° to 27° C).

2. Place the unit on a level, flat surface (Figure 5-1).

3. If interfacing to an LIS, plug the LIS interface cable into the receptacle on the back panel marked *LIS* (Figure 5-2). If interfacing with a Quickscan system, plug the scanner interface cable into the receptacle on the back panel marked *Scanner*. If using a barcode reader, plug into one of the four USB ports below.

4. Plug the power cord into the receptacle provided at the back of the instrument above the round fuses. Plug the other end into a grounded wall outlet of the proper voltage and frequency. Because the power cord is the mains disconnect

device, the wall outlet used should be easily accessible. This information can be found on the serial number plate located on the back of the instrument (Figure 5-2).

5. 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.

6. The instrument has two black pumps located on the left side of the instrument (Figure 5-3). Each pump is connected to a check valve by a short length of tubing. The pump on the left (Figure 5-3) is connected to the DI Wash bottle and the syringe. The pump on the right is connected to the internal wash station and the saline bottle. The pumps may be shipped without their pump heads installed.

7. If so, the pump heads are reinstalled by aligning the hole in the bottom of the pump head with the appropriate post protruding from the pumps (Detailed directions and photos can be found in Section 10.3.6, Tubing/Pump replacement).

8. Install the syringe pump head to the post located farthest back and left (Figure 5-3).

9. Install the wash pump head to the post located farthest forward and right (Figure 5-3). With the pump heads installed, remove the caps from each of the pump tubing elements to the fittings on the instrument (Figure 5-3).

NOTE: Do not remove the check valves; if they are removed, they must be replaced in the same orientation, or water/saline will not be drawn into the

instrument. Saline solution may damage the instrument.

10. Fill the DI water bottle with deionized water and the Saline bottle with saline solution. Place each bottle next to the instrument or on the floor on the left side (Figure 5-4).

11. Connect the DI water bottle to the fitting on the instrument labeled DI WATER RESERVOIR (Figure 5-3).

12. Connect the Saline bottle to the fitting on the instrument labeled SALINE RESERVOIR (Figure 5-3). Confirm tubes are connected to the correct bottle, as reversing the order will cause the instrument to malfunction.

13. Attach the piece of large diameter tubing (1/4" I.D) to the Hazardous Waste outlet located on the lower left side of the instrument (Figure 5-4). Trim the large diameter tubing as short as is practical to connect to the Waste Bottle Lid. Run the end of the tubing to the bottle lid.

14. All bottles connected to the instrument must be vented to the atmosphere. The waste bottle must be placed **below** the instrument

CAUTION: Never put the waste bottle above the outlet. The waste tubing should always go to a waste drain bottle or an unrestricted waste drain.

15. If desired, the waste can empty directly into a drain or waste collection system, in accordance with the law and regulations of the local authority per Section 3.18, by using a length of hose from the waste connection to the drain or waste system.

16. If using a drain other than the provided waste bottle, plug the waste shorting plug into the side of the instrument into the waste overflow connector and insure there are no entrapment loops in the hose.
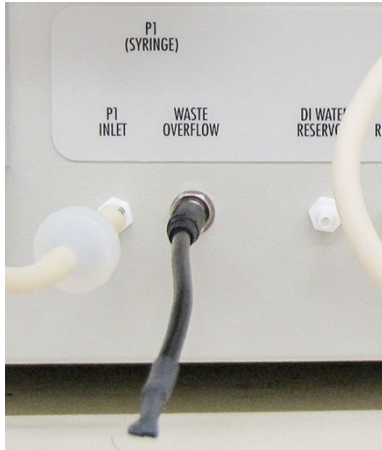
17. Turn on the power. The instrument performs a brief self-test, the displays should briefly show the following menu. If an error message appears instead, refer to the Section 10, Troubleshooting.

18. After the self-test, a Status menu will appear alerting the user "test not selected"

19. Prior to use, the instrument must be primed. See Section 10.1.1 for instructions.

Syringe

Wash
Station

Figure 5-1 Instrument Setup

LIS Interface

Power Cord

Figure 5-2 Back Panel

Figure 5-3 Pumps and Tubing

Waste Tubing

DI Water and Saline Bottles

Hazardous Waste Bottle

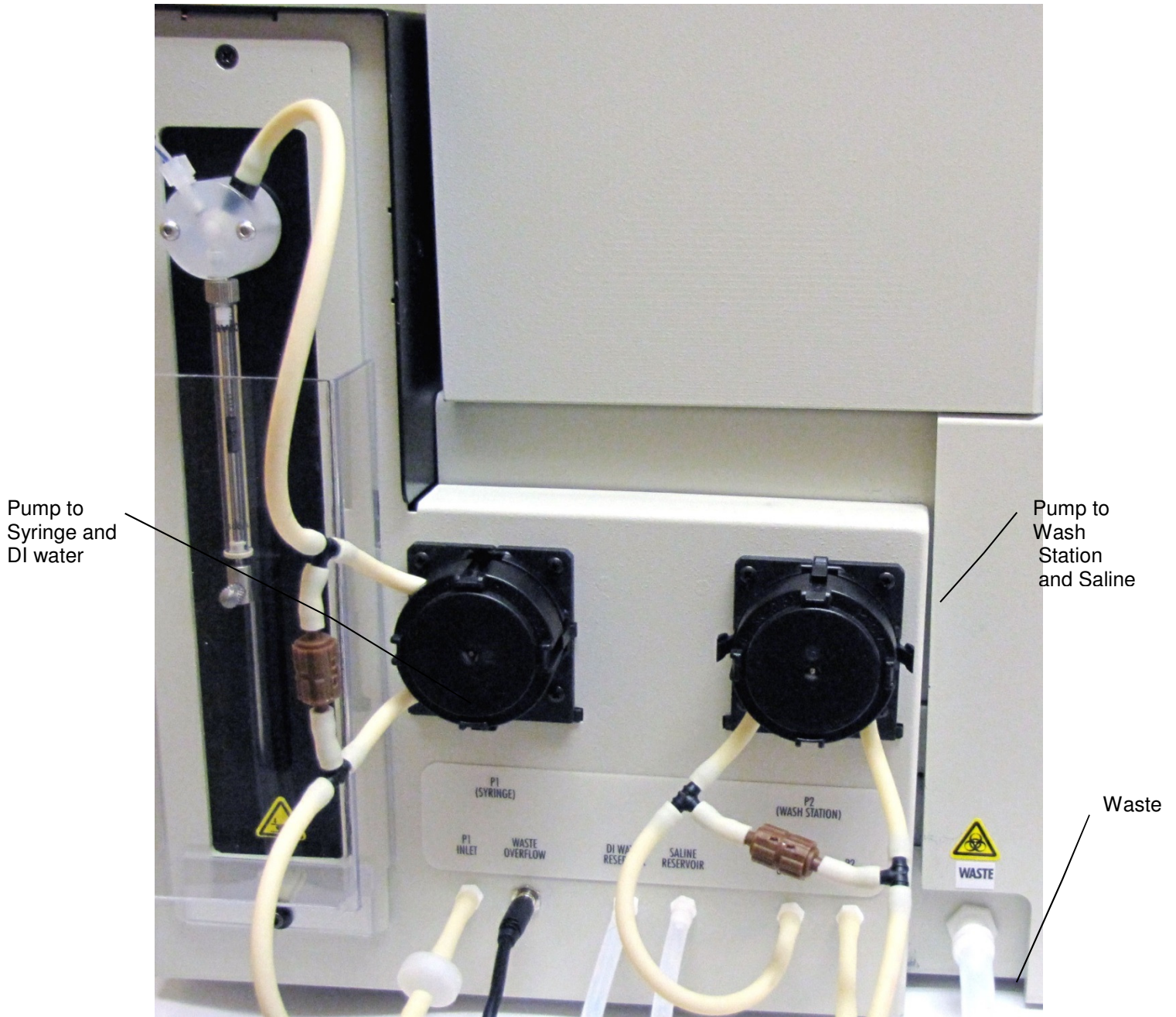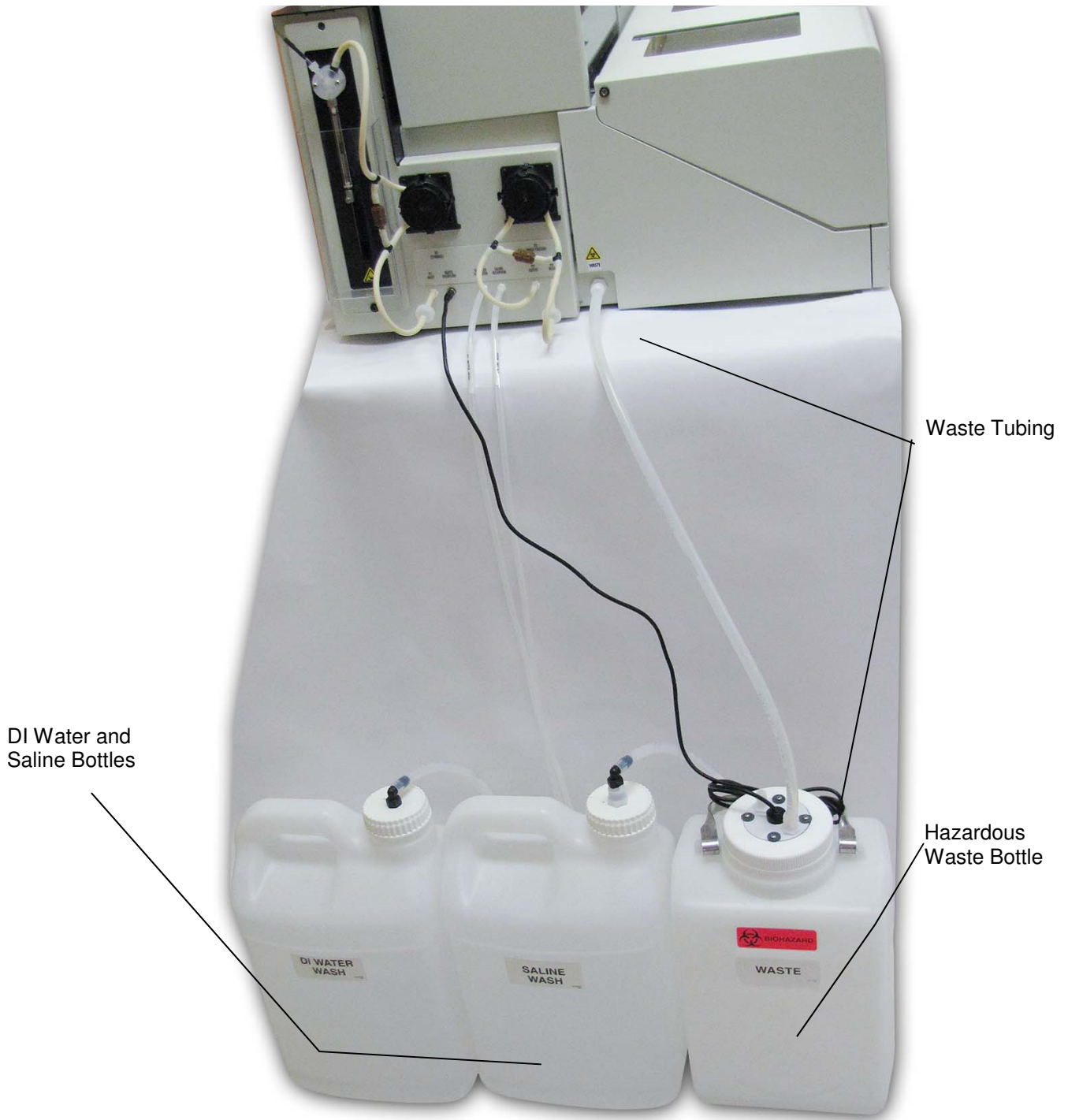**Figure 5-4 DI Water, Saline, and Hazardous Waste Bottles**

Figure 5-5 Test tube rack

Section 6 - Controls and Displays

This section describes the step-by-step process in setting up dilution schemes for multiple samples and/or individual dilutions for specific immunoglobulins for each sample.

Figure 6-1 is the main menu for the ESH Touch. Shown on the main menu are buttons for *Start*, *Test*, *Dilutions*, *Maintenance*, *Setup*, *About*, and *Shut Down*.

To enter values on the screen, tap the touchscreen inside the text field to bring up an onscreen keyboard.

6.1. Setup

The *Setup* screen includes buttons to alter the preferences for *Sound*, *Interface*, *Test*, *Tray,* and *Password.* From these screens, the user can set display preferences, create and edit tests, and set a password to protect these settings. Using the touchscreen, select the desired component to update.

6.1.1. Sound

The master volume is the overall volume level for the instrument. The alarm volume setting is only for errors occurring during the run (Figure 6-2).

1. *Master Volume* – can be adjusted using the slider bar from 0 to 100.

2. *Sound audible when displaying error messages* – check box to have an audible sound for error messages.

3. *Alarm Volume* – can be adjusted using the slider bar from 0 to 100.

4. *OK* – to save all the changes made and return to the main menu, select *OK*.

5. *Cancel* – to exit and return to the main menu without saving any changes made, select *Cancel.*

a. If changes were made, a *Confirm Cancel* prompt will be displayed.

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.1.2. Interface

Interface and Communication settings are set here, including creating communication logs and patient demographic fields (Figure 6-3).

Note: Interface settings should match the instrument being interfaced. Check requirements of the destination scanner before proceeding.

6.1.2.1. Interface Settings

1. *Scanner* – Use dropdown menu to select the scanner the samples will be run on (*QuickScan 2000*, *QuickScan Touch*, or *None*).

2. *Host computer connected* – check to enable.

3. *Positive Sample Identification* – check to enable.

4. *For no barcode, ID = < NO BAR CODE >* – enable to have this displayed if a barcode is not found.

5. *For no tube, ID = < NO TUBE >* – enable to have this displayed if a test tube is not found.

6. *Field Count* – used to set the number of available patient demographic fields.

Note: Field Count is only enabled when using a QuickScan 2000 not using an ASTM protocol.

6.1.2.2. Communication Settings

Use the dropdown menus to select the following specifications. If using a

QuickScan Touch, these options will be fixed and greyed out as set parameters.

1. *Baud Rate* – select from *1200*, *2400*, *4800*, *9600,* or *14400*. The default is *9600*.

2. *Data Bits* – select from *7* or *8*. The default is *8*.

3. *Stop Bits* – select from *1* or *2*. The default is *1*.

4. *Parity* – select from *None*, *Odd*, or *Even*. The default is *None*.

5. *Protocol* – select from *None*, *XON-XOFF*, or *ASTM*. The default is *ASTM*.

6. *Create scanner communication log* – click to enable. This is the communication log between the ESH Touch and any QuickScan that has been used.

7. *Create host communication log* – click to enable. This is the communication log between the ESH Touch and any LIS that has been used.

Note: *The scanner and host communication logs are normally* ***not*** *enabled (not checked). They only should be enabled when troubleshooting of the instrument is needed.*

6.1.2.3. OK and Cancel

1. *OK* – to save all the changes made and return to the main menu, select *OK*.

2. *Cancel* – to exit and return to the main menu without saving any changes made, select *Cancel.*

a. If changes were made, a *Confirm Cancel* prompt will be displayed.

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.1.3. Tests

This window displays the current ESH Touch tests. From this screen, tests can added, edited, and deleted. From the *Setup* screen (Figure 6-4), select the *Test* button.

6.1.3.1. Edit Tests

1. The ESH Touch is loaded with the following default tests:

a. *SPIFE SPE/Split Beta SPE 60*

b. *SPIFE Split Beta SPE 100*

c. *SPIFE Cholesterol Profile*

d. *SPIFE IFE 3*

e. *SPIFE IFE 6*

f. *SPIFE IFE 9*

g. *SPIFE IFE 15*

h. *SPIFE Acid Hemoglobin*

i. *SPIFE Alkaline Hemoglobin*

j. *SPIFE Lipoprotein*

2. To edit an existing test, select the desired test from the test list and tap *Edit.* The *Test Setup* window appears on the *Properties* tab. (Figure 6-5)

3. From this window, values may be entered for the following items:

a. *Test Name* – The test name may be entered / altered as needed.

b. *Immunofixation* – this option is only available with an Immunofixation Electrophoresis (IFE) test selected. Click to enable.

c. *Tray* – select the appropriate tray from the dropdown menu.

d. *Sample Volume (μL)* – the volume of sample that will be distributed into the tray well.

e. *Primary Wash Time (sec)* – the time of the wash between sample tubes.

f. *Primary Wash Cycles* – the time of the wash between sample tubes.

g. *Secondary Wash Time (sec)* – the time of the wash between dilutions of the same sample. This feature is greyed out when tests other than IFE are selected.

h. *Secondary Wash Cycles* – the time of the wash between dilutions of the same sample. This feature is greyed out when tests other than IFE are selected.

i. *Lanes per Sample* – the number of lanes that will be run on a gel for each sample.

Note: *If the user wishes to use default settings from a specific test, tapping the default button will bring up the preloaded tests and its respective parameters. Select one and the parameters will auto load into the new test.*

4. From the *Dilutions* tab (Figure 6-6), dilution schemes may be set for individual samples. Choose from *Neat*, *1:2*, *1:3*, *1:4*, *1:5*, *1:6*, *1:7*, *1:8*, *1:10*, *1:12*, *1:14*, *1:16*, *1:18*, and *1:20*.

Note: *Dilutions will be greyed out and not available for trays that do not have dilution wells.*

a. To select an individual cell, touch that cell to edit the dilution.

b. To select an entire row, touch the sample number to edit all the dilutions in the row.

c. To select an entire column, touch the column label to edit all the dilutions in the column.

5. *OK* – to save all the changes made and return to the main menu, select *OK*.

6. *Cancel* – to exit and return to the main menu without saving any changes made, select *Cancel.*

a. If changes were made, a *Confirm Cancel* prompt will be displayed.

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.1.3.2. Add Test

1. To add a new test, select *Add* and the *Test Setup* window appears on the *Properties* tab (Figure 6-5) with empty text fields. From this window, values may be entered for the following items:

a. *Test Name* – The test name may be entered / altered as needed.

b. *Immunofixation* – this option is only available with an Immunofixation Electrophoresis (IFE) test selected. Click to enable.

c. *Tray* – select the appropriate tray from the dropdown menu.

d. *Sample Volume (µL)* – the volume of sample that will be distributed into the tray well.

e. *Primary Wash Time (sec)* – the time of the wash between sample tubes.

f. *Primary Wash Cycles* – the number of times (if more than one) the syringe will cycle up and down with a saline wash between samples.

g. *Secondary Wash Time (sec)* – the time of the wash between dilutions of the same sample. This feature is greyed out when tests other than IFE are selected.

h. *Secondary Wash Cycles* – the number of times (if more than one) the syringe will cycle up and down with a

saline wash between dilutions of the same sample. This feature is greyed out when tests other than IFE are selected.

i. *Lanes per Sample* – the number of lanes that will be run on a gel for each sample.

Note: If the user wishes to use default settings from a specific test, tapping the default button will bring up the preloaded tests and its respective parameters. Select one and the parameters will auto load into the new test.

2. From the *Dilutions* tab (Figure 6-6), dilution schemes may be set for individual samples. Choose from *Neat, 1:2*, *1:3*, *1:4*, *1:5*, *1:6*, *1:7*, *1:8*, *1:10*, *1:12*, *1:14*, *1:16*, *1:18*, and *1:20*. This feature is greyed out when tests other than IFE are selected.

a. To select an individual cell, touch that cell to edit the dilution.

b. To select an entire row, touch the sample number to edit all the dilutions in the row.

c. To select an entire column, touch the column label to edit all the dilutions in the column.

3. *OK* – to save all the changes made and return to the main menu, select *OK*.

4. *Cancel* – to exit and return to the main menu without saving any changes made, select *Cancel.*

a. If changes were made, a *Confirm Cancel* prompt will be displayed.

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.1.3.3. Delete

1. To delete an existing test, select the desired test from the test list and tap *Delete*.

2. A *Delete Confirm* window appears and asks, "Are you sure you want to delete this test?"

3. To confirm delete, tap *Yes*. To cancel, tap *No*.

6.1.4. Tray

The Tray screen allows the user to select which tray will be used and edit its settings. All compatible Helena Laboratories trays are listed on the default list. Refer to Figures 6-7 through 6-10. The user may Add, Edit, or Delete Tray Settings.

*Note: Helena Laboratories **strongly** recommends **not** making changes to tray parameters.*

6.1.4.1. Add

1. To add a tray, select *Add*. The *Tray Setup* window opens.

2. See Sections 6.1.4.4, *Tray Setup*, for instructions on changing tray specifics.

6.1.4.2. Edit

1. To edit an existing tray, select the tray to be altered and then select *Edit.* The *Tray Setup* window opens.

2. The existing list of trays include:

a. *Hemoglobin 20 Disposable 3370*

b. *IFE 3 Disposable 3377*

c. *IFE 6 Disposable 3377*

d. *IFE 9 Disposable 3378*

e. *IFE 15 Disposable 3362*

f. *Lipoprotein 80 3364*

g. *SPE 60 Disposable 3370*

h. *SPE 100 Disposable 3366*

3. See Sections 6.1.4.4.1 – 6.1.4.4.4 for instructions on changing tray specifics

Note: Cholesterol can use SPE 100 3366 while SPE 60 3370 is for hemoglobins.

6.1.4.3. Delete

1. To delete a tray, select the tray to be deleted and then select *Delete*.

2. A *Confirm Delete* prompt displays:

a. Select *Yes* to delete the tray.

b. Select *No* to retain the tray.

6.1.4.4. Tray Setup

If adding a test, select the appropriate tray designed for the test. Refer to the customer procedure for all the related parameters associated with the test. Plasma samples may require additional wash times.

Note: If the user wishes to use default settings from a specific test, tapping the default button will bring up the preloaded tests and its respective parameters. Select one and the parameters will auto load into the new test.

6.1.4.4.1. Properties

1. The followings parameters may be set here:

a. *Tray Name*

b. *Tray Type Code*

c. *Rows per Tray*

d. *Wells per Row*

e. *Dilution Wells present*

f. *Dilution Well Volume*

Note: If adding a test, select the appropriate tray for that test.

6.1.4.4.2. X Settings

1. The *Well X Offset (mm from left pin)* may be set here for the following:

a. *Sample Wells*

b. *Dilution Wells*

2. The values may be typed or changed using the *+* and *–* buttons or the onscreen keypad. Use the scroll bar to see all wells.

6.1.4.4.3. Y Settings

1. The *Well Y Offset (mm from left pin)* may be set here for the following:

a. *Sample Wells*

b. *Dilution Wells*

2. The values may be typed or changed using the *+* and *–* buttons or the onscreen keypad. Use the scroll bar to see all.

6.1.4.4.4. Z Settings

1. The *Z Offset (mm above platform)* may be set here for the following:

a. *Sample Wells – Aspirate*

b. *Sample Wells – Dispense*

c. *Dilution Wells – Aspirate*

d. *Dilution Wells – Dispense*

2. The values may be typed or changed using the *+* and *–* buttons or the onscreen keypad. Use the scroll bar to see all wells.

6.1.4.5. OK and Cancel

1. *OK* - to save all the changes made to setup and exit setup, select *OK*.

2. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel*.

a. If changes were made, a *Confirm Cancel* prompt displays.

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.1.5. Password

A password may be set to protect the Setup parameters (Figure 6-11).

1. To enable, tap the box next to *Require a password to access Setup.*

2. Type the desired password.

3. *OK* - to save all the changes made to setup and exit setup, select *OK.*

4. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel.*

a. If changes were made, a *Confirm Cancel* prompt displays:

1) To exit without saving changes, select *Yes.*

2) To save changes, select *No* in response to the prompt and then select *OK.*

6.2. About

Tapping the *About* button displays all the current information for the ESH Touch instrument, including the software version and Helena Laboratories contact information (Figure 6-12).
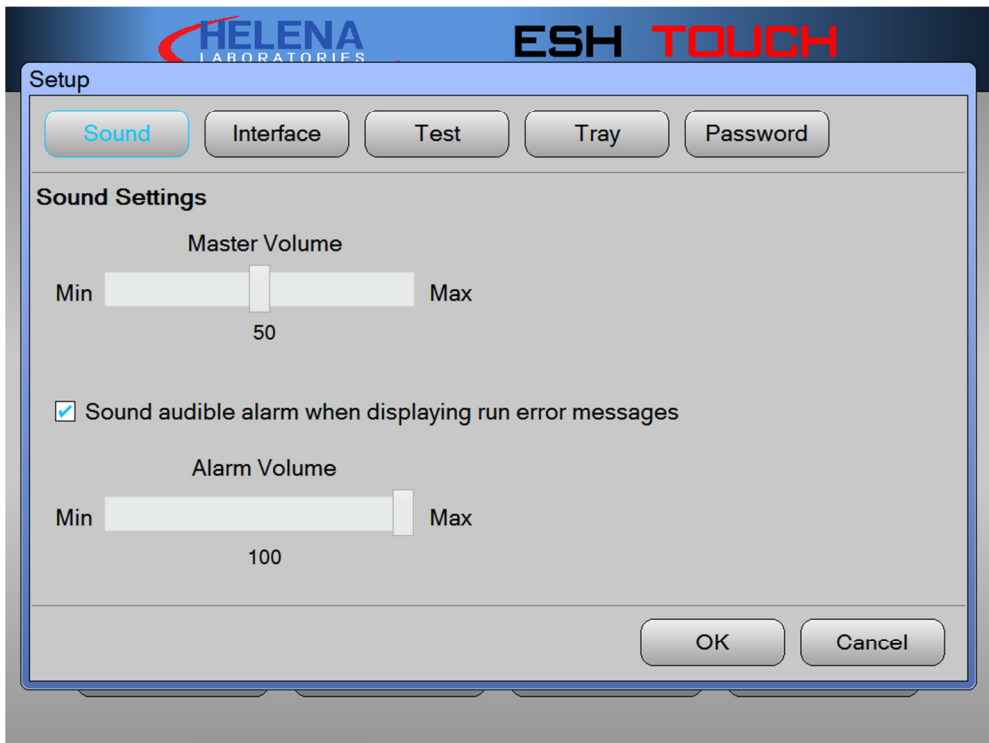
Figure 6-1 Main Menu
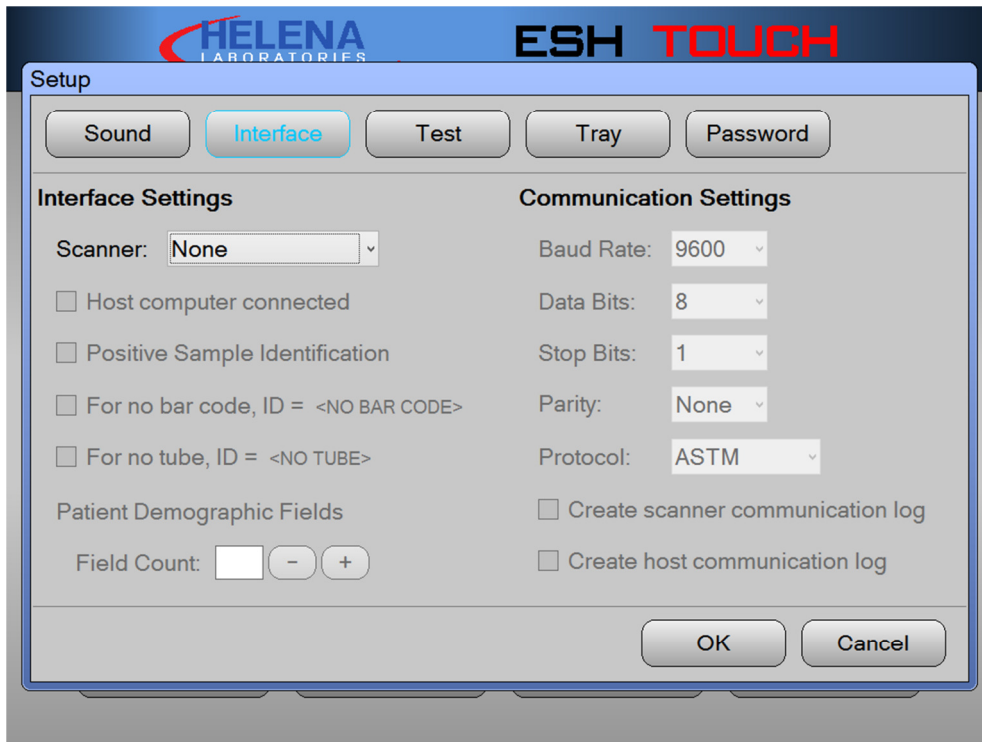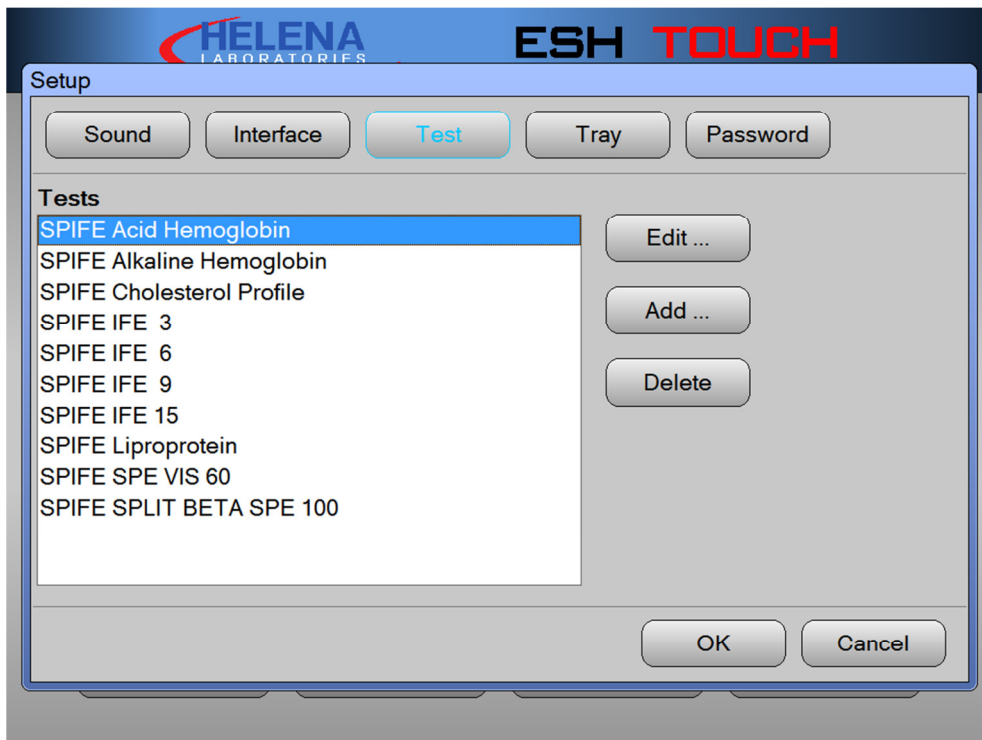

Figure 6-2 Setup menu

Figure 6-3 Setup menu
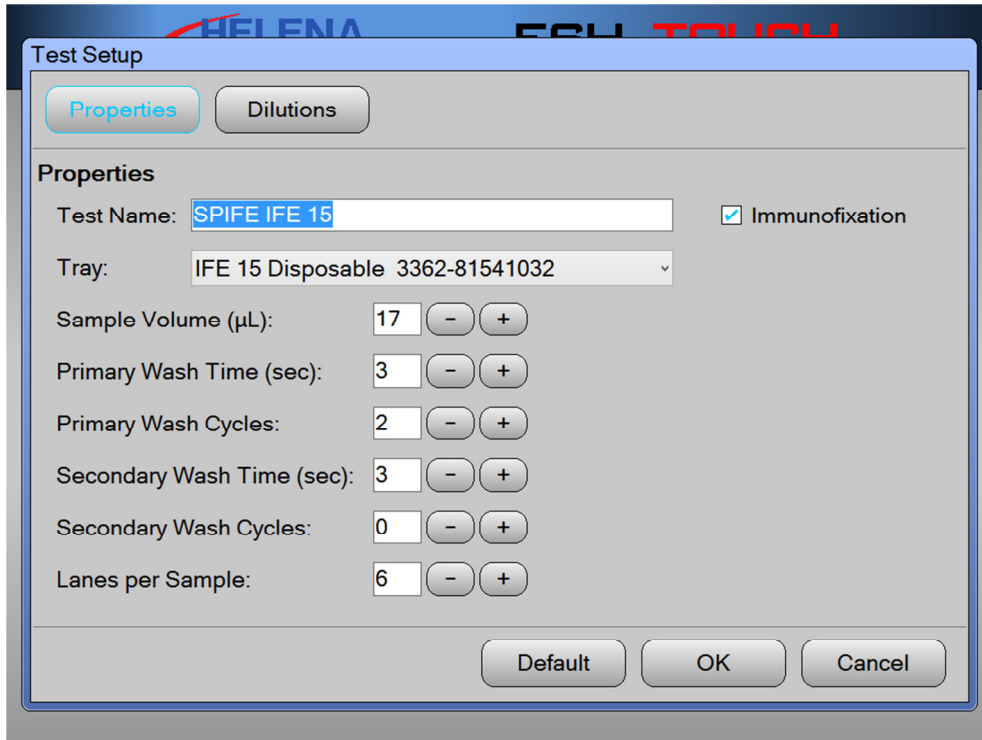

Figure 6-4 Setup menu

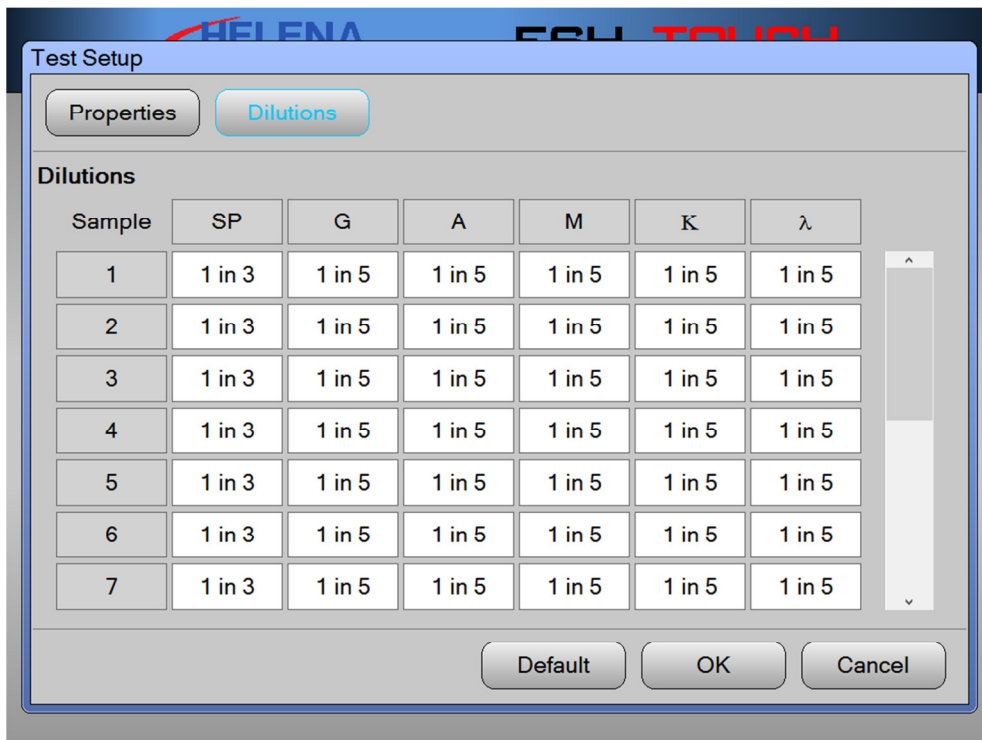**Figure 6-5 Test Setup Properties**
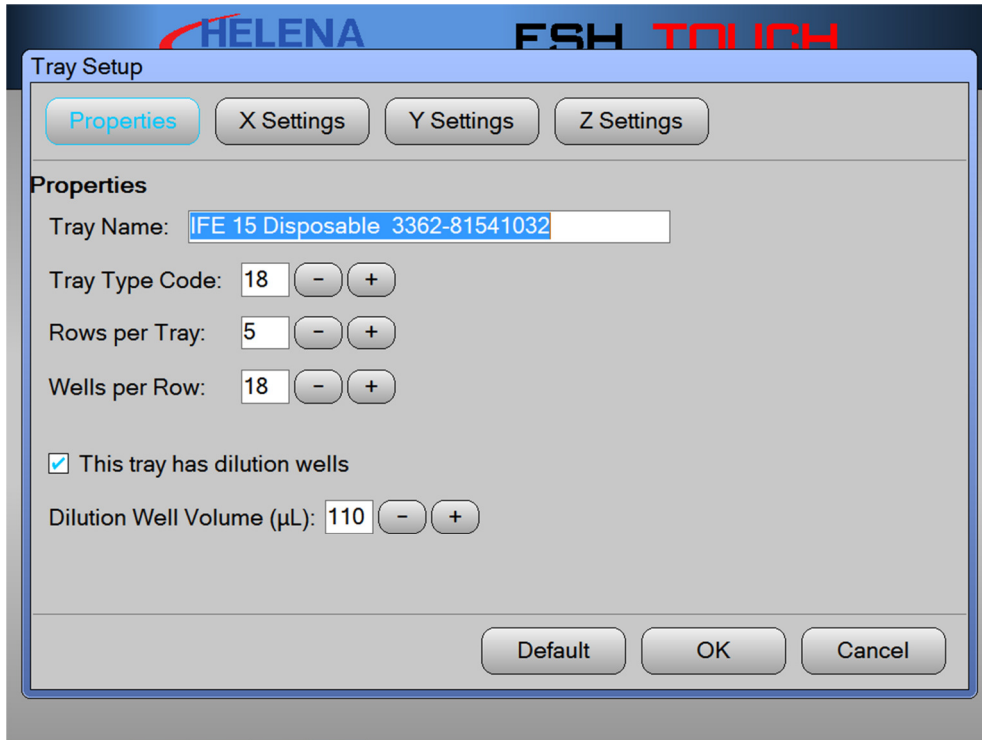

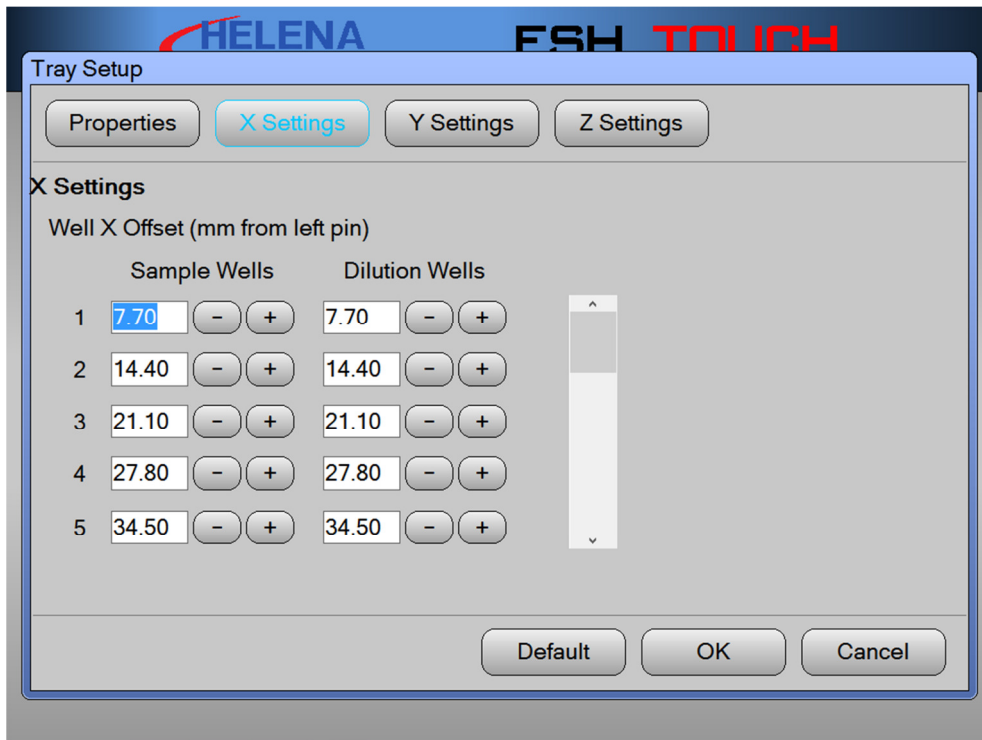**Figure 6-6 Test Setup Dilutions**

Figure 6-7 Tray Setup

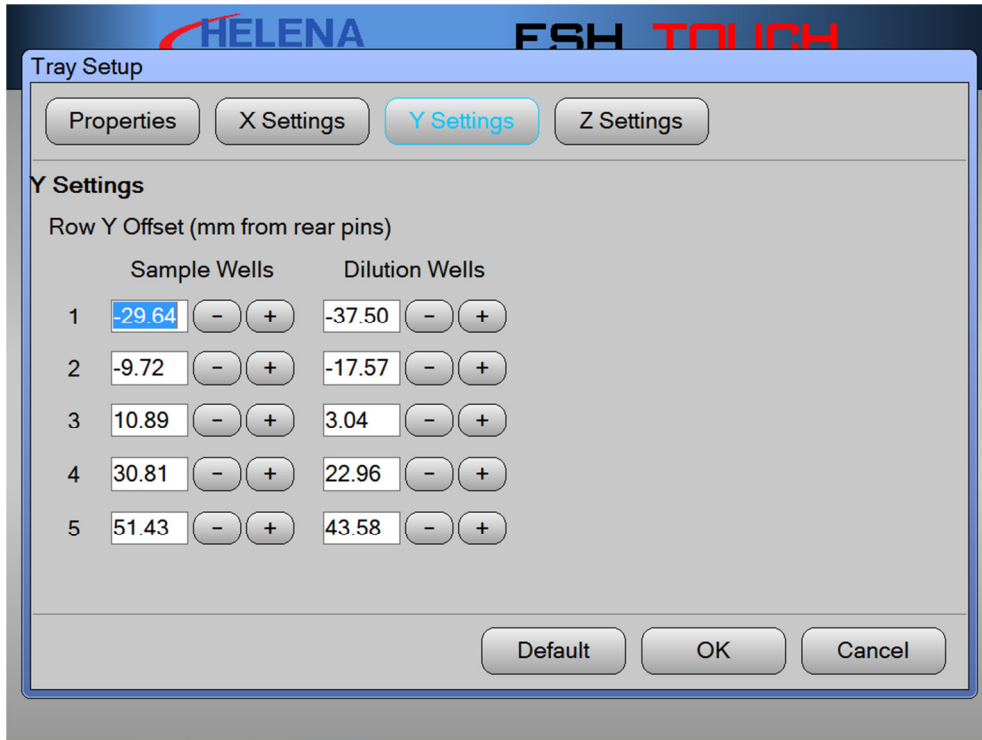**Figure 6-8 Tray Setup X Settings**

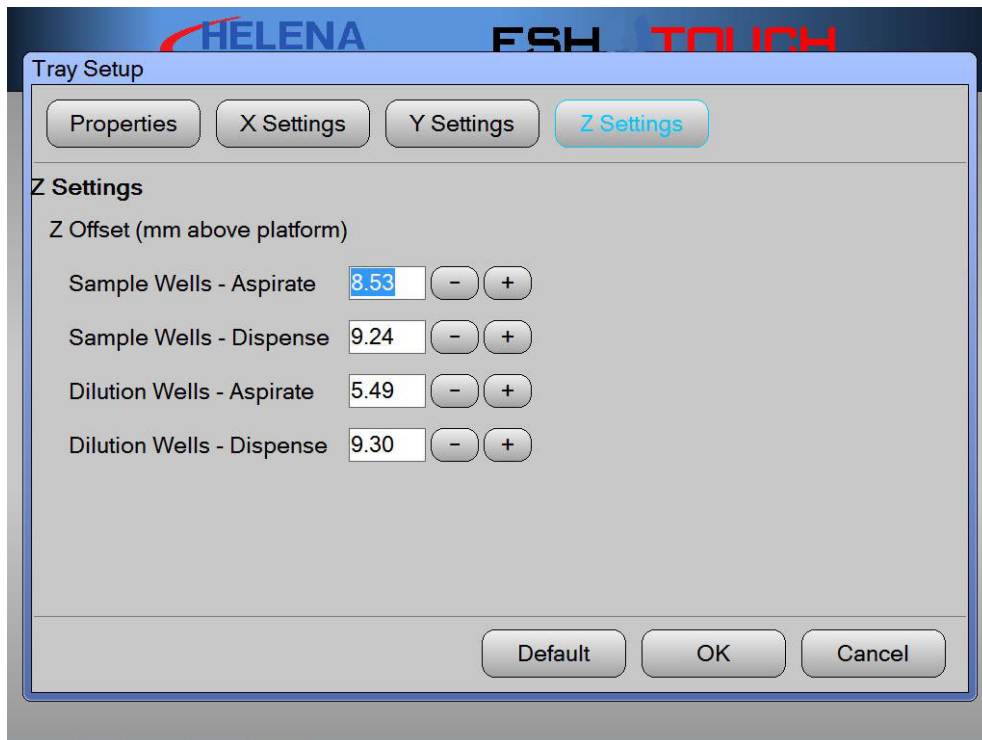**Figure 6-9 Tray Setup Y Settings**
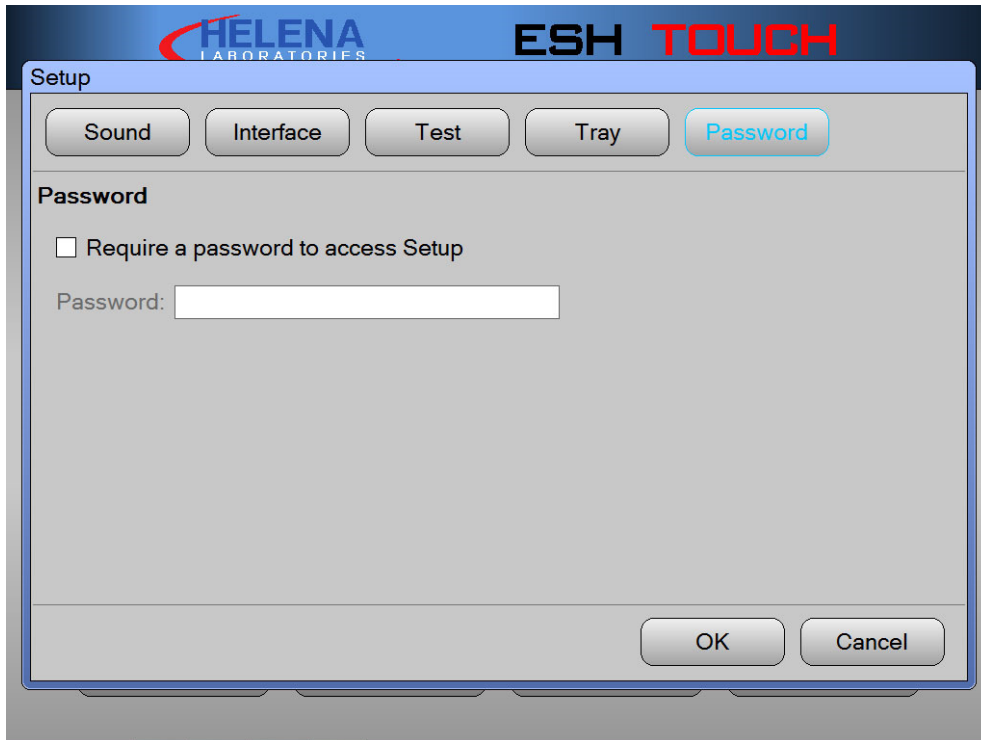

Figure 6-10 Tray Setup Z Settings

Figure 6-11 Password

Figure 6-12 About

Section 7 - Operating Instructions

CAUTION: Do not attempt to operate this instrument until you have read and understood this manual, particularly Section 3, Precautions and Limitations and Section 4, Hazards.

If the system has not been run previously, go through all of Section 5 before proceeding.

If the instrument does not perform as described in this manual, refer to Troubleshooting, Section 10 or contact Helena Laboratories.

7.1. Enter Patient Information

The sample handler may be instructed to read test tube bar codes and relay the information to whichever scanner it is attached. Patient ID barcodes can be either numeric or alphanumeric. After loading the samples per Section 7.2, the following options for patient identification available are:

1. When the ESH Touch is connected to a QuickScan Touch and programmed to communicate the bar codes on the tubes, they may be scanned by the bar code reader while in the sample rack. This information is sent to the QuickScan Touch which uses it to build the patient work list.

2. When the ESH Touch is connected to a QuickScan 2000 and an LIS, the ESH Touch uses the bar code to query the LIS and sends the obtained information to the QuickScan 2000.

3. If the ESH Touch is connected to a QuickScan 2000 and not to an LIS, the sample handler sends the data to the

QuickScan 2000 just as it does with the QuickScan Touch.

4. When the ESH Touch is not interfaced to transfer data, the operator may manually build the Worklist on the densitometer in the order in which the tubes will be presented to the ESH Touch.

Note: When using positive patient ID with the barcodes provided by Helena laboratories, the barcodes affixed to the sample trays may be scanned through the window above the sample tray. Opening the cover to scan samples will generate an on screen error.

Note: The ESH Touch Barcode software does not strip start/stop characters from bar codes that use start/stop characters, such as Codabar.

7.2. Preparation

1. Turn on the power switch, located on the right side of the instrument. A self-test takes place and *initializing…* is displayed:

2. When a main menu is appears, the instrument is ready for operation. No warm up time is necessary.

3. Fill the DI water and Saline bottles and empty the Hazardous Waste bottle.

4. Daily, prior to first use, prime the instrument. See Section 10.1.1 for instructions.

5. For instructions on specimen collection/handling, reagent preparation, and preparation of patient samples and controls, refer to the appropriate sections in the procedure supplied with the reagents.

6. Position the correct sample tray on the holder as shown in Figure 7-2. If the test procedure requires it, load the sample tray with sample cups.

7. If performing IFE tests, fill the Diluent Bottle with 0.85% Saline and place the bottle in the Diluent Bottle Holder. The holder is located between the wash station and the bar code reader (Figure 7-3).

NOTE: When using bar codes, position the test tubes in the test tube rack so that the bar code label is positioned facing out in the vertical slot on the circumference of the test tube rack (Figure 7-4). Ensure that the entire bar code label is visible in the vertical slot and the tube is straight up and down.

8. Each test tube rack holds ten tubes and the ESH Touch can hold up to 10 racks at a time for a maximum load of 100 samples. Position 1 is the back left corner. The ESH Touch starts at the left most test tube rack in the back. It then samples the entire rack and moves all the way to the back to start on the second rack.

Note: Do NOT use an empty serum separator tube in the test tube rack. Doing so will cause the needle to crash.

9. Load the samples in the test tube rack in the same order as listed on the densitometer's worklist (see Section 7.1), **beginning at position 1.** It is best to load consecutively without skipping positions. If a position is skipped in the test tube rack, the corresponding position on the worklist will be skipped. (See Section 6.1.2.1 concerning skipped positions).

Note: Insure the recessed notch on the back of the test tube rack has the black metal bar slid into it. This will prevent the racks from falling over or jamming the instrument (see Figure 7-4).

7.3. Select Test

1. If the test displayed on the Status display is not correct or no test is displayed, tap the *Test* button**.**

2. Select the desired test and tap OK.

3. The setup parameters for the current test may be verified before (if not password protected) by tapping the following buttons *Setup → Test → Edit → Properties.* If correct, tap *OK* to return to the main screen.

4. Tap the *Start* button.

5. The Status display will display the current operation (such as washing pipette, moving to diluent, e.g.) as well as the current sample tube number.

6. When a run is complete, an alarm will sound. Transfer the loaded sample tray to the appropriate electrophoresis instrument. Refer to the instrument's Operator's Manual and to the test procedure for further instructions.

7.4. To Abort Operation

Tap the *Stop* to abort operation at any time. When operation is interrupted for any reason, the instrument will perform a wash. Clean and dry the sample tray and replace it in the instrument. See Section 7.5 for these procedures.

7.5. End of Day Cleanup

1. When finished for the day, discard the disposable sample strips in a biohazard container.

2. Wipe the sample trays with a viridical wipe or with 10% bleach solution

3. If the sample trays are grossly contaminated, soak in a 10% bleach solution for approximately 15 minutes, rinse thoroughly with water, and then rinse in deionized water. Drain the tray and dry with compressed air or air dry.

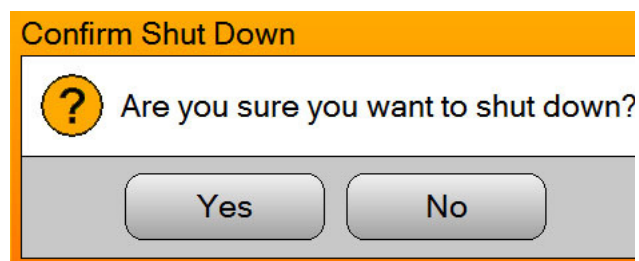4. Dispose of the sample tubes in a biohazard container.

5. From the Main menu, tap the Maintenance button. Tap the Wash / Prime button.

6. Once the wash is complete, the ESH Touch returns to the main menu.

7.6. Shut Down

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

2. A *Confirm Shut Down* dialog box displays, "*Are you sure you want to shut down?"*

3. Tap *Yes* to shut down the ESH Touch or *No* to Cancel.

4. Once the software has shut down, tap the power button on the right hand side to shut down the instrument.

7.7. Results

Once the ESH Touch has placed all the samples in the tray, the sample tray is transferred to the appropriate electrophoresis instrument so it may be processed by the predetermined test.

If an incorrect sample tray is loaded onto the ESH Touch, it will be rejected by the electrophoresis instrument.

7.8. Backup

See Section 10.1.2 for *Backup* instructions.

7.9. Restore

See Section 10.1.5 for *Restore* instructions.

7.10. Update Software

See Section 10.1.8 for *Update Software* instructions.

7.11. Examples of Add a Test Function

This section of the operator's manual gives examples of tests that can be run on the ESH Touch.

7.11.1. IFE Test Example

1. This is a typical example of the parameters included running the SPE IFE 15 test.

2. Properties

a. *Tray*: IFE 15 Disposable 3362-81541032

b. *Sample Volume (µL)*: 17

c. *Primary Wash Time (sec)*: 3

d. *Primary Wash Cycles*: 2

e. *Secondary Wash Time (sec)*: 3

f. *Secondary Wash Cycles*: 0

g. *Lanes Per Sample*: 6

3. Dilutions

a. SP: 1:3 dilution

b. G: 1:5 dilution

c. A: 1:5 dilution

d. M: 1:5 dilution

e. K: 1:5 dilution

f. λ: 1:5 dilution

7.11.2. SPE/Split Beta Example

1. This is a typical example of the parameters included running the SPIFE SPE/Split Beta SPE 60 test.

2. Properties

a. *Tray*: SPE 60 Disposable 3370-81540030

b. *Sample Volume (µL):* 45

c. *Primary Wash Time (sec):* 3

d. *Primary Wash Cycles:* 0

e. *Secondary Wash Time (sec):* if enabled by selecting *Immunofixation*, then 1

f. *Secondary Wash Cycles:* if enabled by selecting *Immunofixation*, then 1

g. *Lanes Per Sample:* 1

3. *Dilutions* – none

4. *Immunofixation* - when enabled, the secondary wash time and wash cycles are available.

7.11.3. Acid Hemoglobin Example

1. This is a typical example of the parameters included running the SPE IFE 15 test.

2. *Properties*

a. *Tray*: Hemoglobin 20 Disposable 3370-81540030

b. *Sample Volume (µL)*: 17

c. *Primary Wash Time (sec):* 3

d. *Primary Wash Cycles:* 0

e. *Secondary Wash Time (sec):* if enabled by selecting *Immunofixation*, then 1

f. *Secondary Wash Cycles:* if enabled by selecting *Immunofixation*, then 1

g. *Lanes Per Sample:* 1

3. *Dilutions* - none

4. *Immunofixation* - when enabled, the secondary wash time and wash cycles are available.
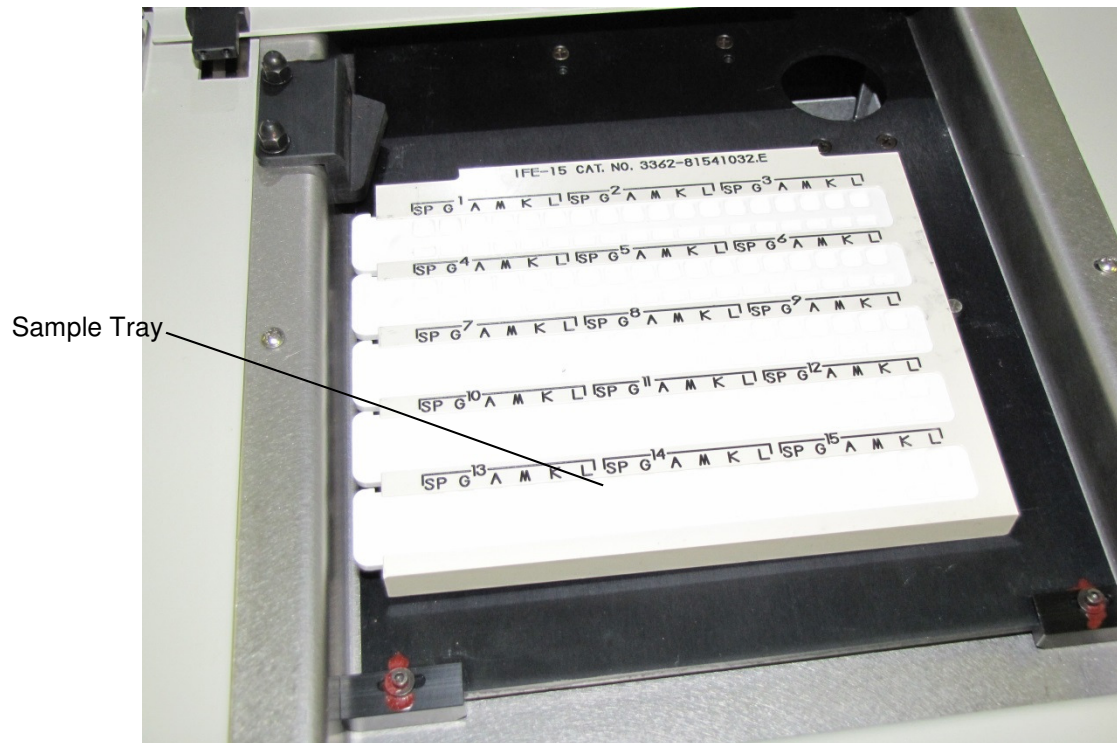
Figure 7-1 Parts of the Instrument

Figure 7-2 Position the Sample Tray on the Holder

Diluent
Bottle
in Holder

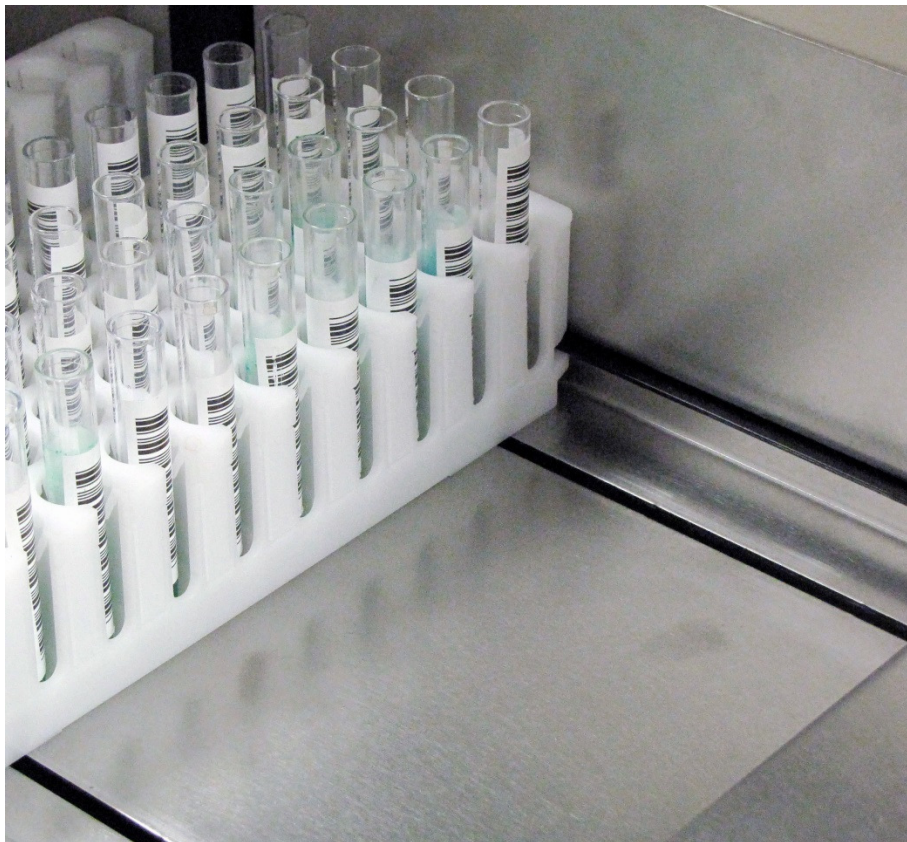**Figure 7-3 Diluent Bottle Holder and Wash Station**

Figure 7-4 Bar Codes Facing Out

Section 8 - Test Functions and Quality Control

The instrument automatically performs a self-test any time the power is turned on. Should an error message appear on the display, see Section 10, Troubleshooting.

Section 9 - Performance Specifications

Electrophoresis Instruments:	SPIFE 3000
Densitometer Instruments:	QuickScan 2000, QuickScan Touch
Input Power:	Cat. No. 1380: 90 to 264 Vac, 47 to 63 Hz
Fuses:	F1, F2: 6.3A T/250V
Dimensions:	≤ 21 in. (53.3 cm) High ≤ 25.5 in. (64.8 cm) Wide ≤ 25 in. (63.5 cm) Deep
Weight:	≤ 100 lb. (45 kg)
Operating Environment:	15° to 27°C (59° to 81°F)
	Altitude 2000 m
	Humidity 20-80%, non-condensing
Storage / Shipping Temperature:	-9.4°C at uncontrolled humidity to
	60°C at 80% humidity (15° to 140°F)
Shipping Altitude:	4,267 meters (14,000 feet)
Pump System:	2 peristaltic pumps, 1 syringe pump
Computer System:	Internal computer, hard drive, 4 external USB ports, 2 external RS232 connections, touchscreen capable monitor

Test Tubes:

Test Tube Type	Minimum volume
13 X 75 round bottom	150 uL
16 X 100 mm round bottom	300 uL
13 mm conical bottom	75 uL
13 mm Serum separator tubes	min. vol 500 uL above plug
16 mm Serum separator tubes	min. volume 800 uL above plug

Electrophoresis Instrument and LIS Interfacing:

Programmable Baud Rate:	1200, 2400, 4800, 9600, 14400
Programmable Data Bits:	7, 8
Programmable Stop Bits:	1, 2
Programmable Parity:	None, Odd, Even
Programmable Protocol:	None, XON-XOFF, ASTM

Installation category II   Pollution degree 2

Section 10 - Maintenance, Troubleshooting, Warranty

This section describes routine operator maintenance procedures. For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

10.1. Maintenance Menu

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

Table 10-1 Preventative Maintenance Schedule

Daily (if used)
Wash/Prime ESH Touch
Clean Sample Trays
Weekly
Clean/10%Bleach DI Water and Saline Bottles
Monthly
10% Bleach ESH Touch
As Needed
Replace Tubing/Pump
Replace Fuses
Clean Probe Tip
Replace/Calibrate Probe
Backup Parameters
Replace Syringe Seal and O-ring

Select the *Maintenance* button on the *Main Menu* (see Figure 10-1). The *Maintenance* screen appears. Select from one of the following choices: *Wash/Prime, Backup, Host Com Log, Date And Time, Restore, Scanner Com Log, Test/Calibrate, Update Software,* and *Error Log.*

10.1.1. Wash / Prime

The ESH Touch will automatically wash (which flushes bubbles from the line) the instrument before each run. If the instrument has not been used in consecutive runs, this should be done before a run is started.

1. Every day, confirm the bottles are full of deionized water and saline, and the waste bottle is empty

2. The *Wash / Prime* function can be used to clear any air bubbles and flush the line.

3. Tap the *Wash / Prime* button. The screen displays "*moving pipette to wash station*".

4. While the line is being flushed, the time remaining will display on the screen in seconds.

5. Tap the *Cancel* button to cancel the operation.

10.1.2. Backup

The *Backup* function will back up the calibration settings and the current test list for the instrument. In the event of an issue, the instrument parameter may be restored from this.

1. Tap the *Backup* button.

2. The ESH Touch allows the user to backup information on either a predetermined internal location or flash drive.
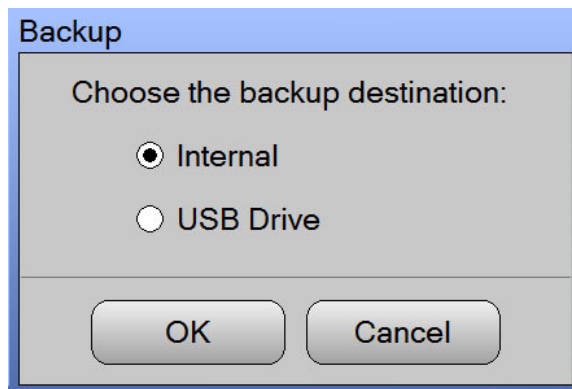
3. Select the desired location. If using a flash drive, insert the flash drive into one of the four USB ports and tap *OK*.

4. The information is now safely backed up. If using a flash drive, store it in a safe location.

10.1.3. Host Com Log

The *Host Com Log* is the communication log between the ESH Touch and any LIS that has been used. This is normally not enabled (see Section 6.1.2.2) and is used for troubleshooting purposes.

1. Tap the *Host Com Log* Button. The *Host Com Log* is displayed.

2. The user can either *Save* or *Clear* the log.

3. To save, tap the *Save* button. The ESH Touch will display a message to, "*Insert a USB drive into one of the USB ports. The file 'HostCommLog.txt' will be saved to the folder 'Helena Laboratories\ESH Touch\Files' on that drive. Tap 'OK' when ready.*"

a. Insert the flash drive and tap *OK*. The log will be saved as a text file on the flash drive.

4. To clear, tap the *Clear* button.

a. A *Confirm Clear* dialog box appears. Tap *Yes* to clear the log or *No* to return to the Main Menu.

10.1.4. Date and Time

1. Tap the *Date And Time* Button.

2. Enter the correct date and time and tap *Set*.

3. Tap *Close* when finished.

10.1.5. Restore

In the event of a severe instrument error, the last configuration of calibration settings and current test list can be restored from either an internal backup file or flash drive.

1. Tap the *Restore* button.

2. The ESH Touch allows the user to restore the information from either a predetermined internal location or a flash drive.

3. Select the desired location. If using a flash drive, insert the flash drive into one of the four USB ports and tap *OK*.

4. A *Confirm Overwrite* dialog box appears asking if the user wants to overwrite the current information.

5. Tap either *Yes*, *Yes to All*, *No*, or *Cancel*.

6. The instrument will show *Restore Complete* when the action is complete and prompt for the removal of the flash drive if one was used.

10.1.6. Scanner Com Log

The *Scanner Com Log* is the communication log between the ESH Touch and any QuickScan that has been used. This is normally not enabled (see Section 6.1.2.2) and is used for troubleshooting purposes.

1. Tap the *Scanner Com Log* Button. The *Scanner Com Log* is displayed.

2. The user can either *Save* or *Clear* the log.

3. To save, tap the *Save* button. The ESH Touch will display a message to, "*Insert a USB drive into one of the USB ports. The file 'ScannerCommLog.txt' will be saved to the folder 'Helena Laboratories\ESH Touch\Files' on that drive. Tap 'OK' when ready.*"

   a. Insert the flash drive and tap *OK*. The log will be saved as a text file on the flash drive.

4. To clear, tap the *Clear* button.

   a. A *Confirm Clear* dialog box appears. Tap *Yes* to clear the log or *No* to return to the Main Menu.

10.1.7. Test / **Calibrate**

To access the Maintenance and Calibration menus, tap the *Maintenance* button on the lower left side of the display. The following items may be calibrated from this menu.

A warning box appears when this menu is accessed. Improper calibration will result in damage to the instrument and Helena recommends **only** a qualified individual should change these parameters.

10.1.7.1. Pipette X

This screen is for calibration of the X axis for the pipette probe assembly. Choose from the following (Figure 10-2):

1. *Motor enabled* – unselecting this disables power to the Pipette X motor.

2. *Current Position* – current position of pipette probe in the X position.

3. *Home* – the preset leftmost limit position of travel for Pipette X.

4. *New Position* – enter the value of where Pipette X needs to go and select *Go To*.

5. *Calibrated Position*s:

   a. *Wash Station* – X calibration point where the probe is aligned with the wash station.

   b. *Sample Aspirate* – X calibration point where probe is aligned to aspirate sample from the test tube.

   c. *Diluent Aspirate* – X calibration point where probe is aligned to aspirate diluent.

   d. *Tray Pin* – X calibration point where the probe is aligned with the center of the sample tray pin.

10.1.7.2. Pipette Z

This screen is for calibration of the Z axis for the pipette probe assembly. Choose from the following (Figure 10-3):

1. *Motor enabled* – unselecting this disables power to the Pipette Z motor.

2. *Current Position* – current position of Pipette probe in the Z position.

3. *Home* – the preset uppermost limit position of travel for Pipette Z probe.

4. *New Position* – enter the value of where Pipette Z needs to go and select *Go To*.

5. *Calibrated Positions*:

   a. *Wash Station* – Z calibration point where the probe is inserted into the wash station.

   b. *Sample Aspirate* – Z calibration point where probe is at lowermost to aspirate sample from the test tube.

   c. *Diluent Aspirate* – Z calibration point where probe is lowermost to aspirate diluent from the diluent bottle.

   d. *Tray Platform* – Z calibration point where probe is at limit of travel to the top of the tray platform.

10.1.7.3. Tray Y

This screen is for calibration of the Y axis for the tray assembly. Choose from the following (Figure 10-4):

    1. *Current Position* – current position of tray in the Y position.

2. *Home* – the forward most limit of travel position for Tray Y.

3. *New Position* – enter the value of where Pipette Z needs to go and select *Go To.*

4. *Calibrated Positions*:

    a. *Tray Sensor* – the calibrated position for reading tray type barcodes.

    b. *Diluent Aspirate* – the calibrated position for the sample tray where the tray is aligned for diluent aspiration.

    c. *Pipette* – the calibrated sample tray Y position where the most left pin on the tray is aligned with the test probe.

10.1.7.4. Rack X

This screen is for the calibration of the tube transport assembly. Choose from the following (Figure 10-5):

    1. *Current Position* – current position of rack in the X position.

    2. *Home* – the preset right most limit of travel for tube transport

    3. *New Position* – enter the value of where Rack X needs to go and select *Go To.*

    4. *Calibrated Position*:

    a. *Rack Y Transfer* – the calibrated rack X position where rack is transferred to sample aspirate drive.

    b. *Rack Removal* – calibrated position for discharging the tube rack into the processed rack area.

    5. *Calibrated Movement:*

    a. *Rack Step* – the calibrated distance between racks.

10.1.7.5. Rack Y

Choose from the following (Figure 10-6):

    1. *Current Position* – current position of rack in the Y position.

2. *Home* – the rearmost limit of travel of the sample aspirate drive.

3. *New Position* – enter the value of where Rack Y needs to go and select *Go To.*

4. *Calibrated Position:*

    a. *Rack X Transfer* – forward calibrated position to transfer racks from the tube transport drive.

    b. *Sample Aspirate* – position to align the first test tube for sample aspiration.

5. *Calibrated Movement:*

    a. *Tube Step* – calibrated distance between tubes.

10.1.7.6. Syringe Pump

Choose from the following (Figure 10-7):

    1. *Current* – the current pump plunger and valve positions.

2. *New* – rotates valve between syringe and wash positions.

3. *Syringe Settings:*

    a. *Syringe Size* – choose from 50 µl, 100 µl, 250 µl, 500 µl, or 1000 µl.

    b. *Plunger steps per µl* – stoke travel of diluter to acquire or dispense 1 µl of fluid. Each syringe size has its own default.

4. *Volume Delivery Test* – test accuracy of system to deliver a set volume of fluid or sample.

    a. *Test Volume (µl)* – use +/- to set desired volume.

5. *Test* – tap to run volume delivery test.

10.1.7.7. Wash Pumps

This screen is for testing the functionality of the wash pumps. Choose from the following (Figure 10-8):

1. *Pipette Pump* – Select *Off* or *On.*

2. *Wash Block Pump* – Select *Off* or *On.*

3. *Pipette Wash Flow Sensor* – check to enable*.*

4. *Wash Block Flow Sensor* – check to enable.

10.1.7.8. Fluid Detect

This section is for testing the fluid detection system. Choose from the following (Figure 10-9).

1. *Current Value* – displays the current value.

2. *Minimum Value* – displays the lowest value recorded since entering menu or selecting *Clear Min / Max*.

3. *Clear Min / Max* – resets the values to 0.

4. *Maximum Value* – displays the highest value recorded since entering menu or selecting *Clear Min / Max*.

5. *Test Fluid Detect* – tests the function of the fluid detect system.

6. *Noise Level %* – signal percentage deviation compared to full scale.

10.1.7.9. Bar Code Imager

This screen tests the functionality of the bar code imager. Choose from the following (Figure 10-10):

The *Serial Number*, *Application Version*, *Monitor Version*, *MAC Address*, and *Date of Build* of the Bar Code Imager are displayed on this screen.

1. *Read Bar Code* – tests the function of the bar code reader.

10.1.7.10. Sensors

This allows the user to view the current state of the instruments switches and sensors. A green status light means the sensor is engaged while a grey square means it is disengaged. Choose from the following (Figure 10-11).

1. *Wash Overflow Sensors* – internal drain is clogged from wash (if green)

2. *Tray Bar Code Sensor* – optical switch for reading tray

3. *Rack Detect Sensor* – optical switch for detecting racks.

4. *Door Closed Sensor* – optical switch for detecting if door is open or not.

5. *Waste Full Sensor* – waste is full and needs to be emptied

10.1.7.11. Com Ports

This screen tests the RS232 communication ports. Choose from the following (Figure 10-12).

1. Select a port to test by tapping one of the following ports (either *Test scanner com port* or *Test host computer com port*).

2. Tap *Test Port*.

3. A dialog box appears and displays (if host was selected), "Connect a loop plug back to the host computer com port. Tap '*OK*' when ready."

4. Tap *OK*. The instrument will either display "*Port Tested OK*" or "*Failed*".

10.1.7.12. Cycle test

This screen is the interface for the cycling the instrument repeatedly to test functionality. Choose from the following (Figure 10-13).

1. Set the cycle count using the – and + buttons.

2. *View Log Files* – this displays errors incurred while the instrument is running.

3. Tap the *View Log Files* button and the *Log Files* window opens. The user has the option to either *Open* or *Cancel*.

4. Select the desired file by tapping it on the screen and then tapping *Open.*

5. The log file opens and the user has the option to either *Save* the file or *Close* the window.

6. To save, tap the *Save* button. The ESH Touch will display a message to, "*Insert a USB drive into one of the USB ports. The file* (**selected file name will show here**) *will be saved to the folder 'Helena Laboratories\ESH Touch\Files' on that drive. Tap 'OK' when ready*.

   a. Insert the flash drive and tap *OK*. The log will be saved as a text file on the flash drive.

7. Tap *Close* to close the window.

10.1.7.13. Password

A password may be set to protect the Calibration parameters (Figure 10-14).

   1. To enable, tap the box next to *Require a password to access Setup.*

2. Type the desired password.

Note: *If a password is lost or forgotten, contact Helena Laboratories and the Service group can reset the password.*

10.1.7.14. OK and Cancel

   1. *OK* - to save all the changes made to setup and exit setup, select *OK.*

2. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel.*

   a. If changes were made, a *Confirm Cancel* prompt displays:

   1) To exit without saving changes, select *Yes.*

   2) To save changes, select *No* in response to the prompt and then select *OK.*

10.1.8. Update Software

In the event the ESH Touch software needs to be updated, a flash drive is normally used.

   1. Tap the *Update Software* button.

2. The dialog box alerts the user to, *"Insert the USB drive that contains the software updates into one of the USB ports. Tap 'OK' when ready".*

3. Insert the USB drive and tap *OK*.

10.1.9. Error Log

The *Error Log* is the log of errors generated by the ESH Touch, including any errors that occur during cycling. Reviewing the log may help the user determine the difference between random and systematic errors.

   1. Tap the *Error Log* Button. The *Error Log* is displayed.

   2. The user can either *Save* or *Clear* the log.

   3. To save, tap the *Save* button. The ESH Touch will display a message to, "*Insert a USB drive into one of the USB ports. The file 'ErrorLog.txt' will be saved to the folder 'Helena Laboratories\ESH Touch\Files' on that drive. Tap 'OK' when ready*."

   a. Insert the flash drive and tap *OK*. The log will be saved as a text file on the flash drive.

   4. To clear, tap the *Clear* button.

   a. A *Confirm Clear* dialog box appears. Tap *Yes* to clear the log or *No* to return to the Main Menu.

10.1.10. Close

Tap *Close* to exit out of the Maintenance Screen.

10.2. Backup Reminder

Each time the instrument's interface parameters are altered and/or the probe is re-calibrated, the instrument's parameters should be backed up (Section 7.8).

10.3. Instrument Care

10.3.1. Cleaning Spills

TURN OFF THE POWER AND UNPLUG THE POWER CORD BEFORE PROCEEDING. 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 may contain alcohol and alcohol is a corrosive to metal surfaces.

Clean spills with a soft cloth or sponge. Do not use corrosive or abrasive cleansers. Dry the unit before plugging the power cord in.

10.3.2. Inspect/Clean Probe

The following refers to Figures 10-18, 10-19, and 10-20.

1. If sample adhesion/debris on the probe is suspected, it may be removed.

Note: The software must be turned off and instrument powered down before the probe cleaning occurs. Failure to do so will result in incorrect probe calibration.

Note: If the instrument has been used to process blood or blood derivatives, follow appropriate biohazard guidelines including the use of protective gloves and other personal protective equipment.

2. Remove the three screws which secure the pipette assembly cover and remove cover.

3. The tool needed is a 3/16" nut driver for a hex threaded standoff.

4. Remove the 2 hex threaded standoffs (male/ female) securing the probe (Figure 10-18).

5. Gently pull out and up to remove the probe (Figure 10-19).

Note: Take care not to bend the probe tip resting inside the black guide piece at the bottom.

6. The probe tip can be cleaned while still attached to the tubing.

Caution: The probe tip has a very small diameter and probe wire can cause a potential needle stick injury. Take care to avoid puncturing the skin when inserting the wire.

7. Using the probe cleaning wire, 8JM20111, CAREFULLY insert the wire into the tip of the probe. Slide in and out several times to remove any debris or residue (Figure 10-21).

8. Seat probe back in position by dropping it down into the guide and pressing it into place.

9. Replace the 2 hex threaded standoff.

10. Replace the pipette assembly cover.

11. Turn the instrument back on by pressing the side power button.

10.3.3. Clean Sample Trays

1. Rinse sample trays thoroughly with water, and scrub with a soft brush if necessary.

2. Drain the tray and dry with compressed air.

3. Dispose of the sample tubes in a biohazard container.

10.3.4. Clean/Bleach Bottles

1. Once a week, empty the DI water bottle and the Saline bottle, located on the left side of the instrument.

2. Clean out the bottles with a 10% bleach solution to prevent bacterial or fungal contamination.

3. Rinse the bottles thoroughly with DI water to remove the bleach solution.

4. Refill and replace the DI water and Saline bottles.

5. Insert the tubing onto the fitting on top of the appropriate bottles. Connect the DI water bottle to the check valve connected to the tubing that leads to the Syringe. Connect the Saline bottle to the check valve that leads to the pump labeled "Saline" which then leads to the Wash Station (Figure 5-3).

Warning: Confirm tubes are connected to the correct bottle, as reversing the order will cause the instrument to malfunction.

6. From the *Maintenance* screen, tap the *Wash/Prime* button. The wash operation will ensure that no bubbles are in the line.

7. Repeat step 6 if needed to ensure the tubing is primed and there are no air bubbles in the lines.

10.3.5. Bleach ESH Touch

1. Once a month, prepare approximately 100 mL of a 10% sodium hypochlorite solution.

2. Remove the tubing from the bottles located on the left hand side of the instrument and place in bleach solution.

3. From the *Maintenance* screen, tap the *Wash/Prime* button. The wash operation will ensure that no bubbles are in the line.

4. Allow the solution to sit in the tubing for 15 minutes.

5. Remove the tubing from the bleach solution and rinse the outer surface of the tubing with DI water.

6. Insert the tubing into 200 mL of clean DI water.

7. From the *Maintenance* screen, tap the *Wash/Prime* button. Repeat until all 200 mL of DI water is pumped through the system.

Note: *It is important to thoroughly rinse the system with DI water after bleaching. Failure to do so could cause erroneous results.*

8. Refill and replace the DI water and Saline bottles.

9. Insert the tubing onto the appropriate bottles. Touch the bottom of the bottles: Connect the DI water bottle to the check valve connected to the tubing that leads to the Syringe. Connect the Saline bottle to the check valve that leads to the pump labeled "Saline" which then leads to the Wash Station (Figure 5-1). Confirm tubes are connected to the correct bottle, as reversing the order will cause the instrument to malfunction.

10. Repeat step 7 if needed to ensure the tubing is primed and there are no air bubbles in the lines.

10.3.6. Tubing/Pump Head Replacement

To replace either pump head (or tubing) the procedure is exactly the same except for the orientation of the black lever clips. For the *syringe* pump (on the left), the clips are oriented vertically in 12:00 and 6:00 positions with the check valve sitting to the left of the pump. For the *saline* pump (on the right), the clips are oriented horizontally at the 3:00 and 9:00 positions with the check valve resting under the pump head.

1. For the pump head being replaced (Saline or Syringe), disconnect the tubing from the black connectors (Figure 10-15).

2. To remove the pump head, depress the two levers (clips) on either side of the pump head and pull straight out, completely removing the pump head.

3. To install a new pump, place the pump at the appropriate location and press down until the pump snaps into place (Figure 10-16).

4. Replace the tubing into the connectors.

5. To replace only tubing, simply remove the old tubing and firmly seat the new tubing onto the connectors or check valves.

10.3.7. Fuse Replacement

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

2. Using a screwdriver, which matches the slot in the fuse holder, press inward and turn the fuse holder counterclockwise to remove the holder (Figure 10-17).

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

4. Push the fuse holder in and turn clockwise with a 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 blows again immediately, call Helena Laboratories for assistance.

10.3.8. Probe Replacement

The following refers to Figure 10-18 and Figure 10-19.

Note: *The software must be turned off and instrument powered down before the probe replacement occurs. Failure to do so will result in incorrect probe calibration.*

Note: *If the instrument has been used to process blood or blood derivatives, follow appropriate biohazard guidelines including the use of protective gloves and other personal protective equipment.*

1. Power down the software and turn the instrument off

2. Remove the three screws which secure the pipette assembly cover and remove cover.

3. The tool needed is a 3/16" nut driver for a hex threaded standoff.

4. Remove the 2 hex threaded standoffs (male and female) securing the probe (Figure 10-18).

5. Gently pull out and up to remove the probe (Figure 10-19).

Note: *Take care not to bend the probe tip resting inside the black guide piece at the bottom.*

6. If replacing the probe, remove the probe from the attached clear tubing.

7. If removed, replace the tubing by pressing the tubing end onto the probe

approximately ¼". Sandpaper may also to be used to grip tubing if necessary.

8. Seat probe back in position by dropping it down into the guide and pressing it into place.

9. Replace the 2 hex threaded standoff.

10. Replace the pipette assembly cover.

11. Turn the instrument back on by pressing the side power button.

12. Dispose of the old probe in a sharps container to avoid injury.

10.3.9. Replace Syringe Seal/O-Ring

The following refers to Figure 10-21.

1. Tap the *Maintenance* button on the touchscreen followed by the *Test/Calibrate* button.

2. Tap the *Syringe Pump* button.

3. On the *Syringe Pump* screen, set the *New* position at 100 and tap *Move To*.

4. This will drop the plunger down so it can be removed.

5. Remove plastic guard protecting the syringe.

6. Unscrew the cross knurled fastener at the bottom of the syringe.

7. Unscrew the knurled fastener at the top of the syringe under the valve head.

8. Gently pull the syringe down to remove it.

9. Using any type of pliers (such as needle nose), pull the white tip off of the syringe shaft. If the black o-ring does not come off with the tip, remove it also.

10. Slide the new o-ring and tip on the syringe shaft.

11. Reinstall the syringe and replace the fasteners.

12. Cancel out of the *Syringe Pump* screen.

Note: *Before the next test starts, the instrument will automatically reinitialize*

and re-home all components, including the syringe position.

10.4. Troubleshooting

If the recommended solutions in Table 10-2 should fail to solve a problem, call Helena Laboratories for assistance.

Table 10-2 Troubleshooting

Problem	Possible Cause	Solution
No power to instrument	Power cords unplugged	Plug cords into proper wall outlet.
	Blown fuse	Replace fuse.
Unable to communicate with the bar code imager	Connection Problem	Call Helena Laboratories Service
Communication Failure No transfer of data	Intermittent connector issue	Check for loose fittings or breaks in tubing line.
	Bad cable	Check cables. Replace if necessary
	Faulty Initial Setup	Verify interface settings in Section 6.1.2.
Level detect failure	Saline in needle	Peristaltic pump tubing reversed. Verify tubing is piped correctly.
Controls out	Incorrect test setup	Review setup with customer procedures and operator's manual.
Error found during self-test or operation	Computer error	Turn power off and on again. If the message returns, call Helena Laboratories.
Error – Instrument not calibrated	Corrupt or missing calibration file	Call Helena laboratories Service
No diluent	Diluent needs to be refilled.	Add diluent and tap 'OK' to continue.
Cycle will not start	Incorrect sample tray	Verify tray in use is appropriate for the selected test.
	Blown fuse	Check fuses on back of unit, replace if required.
	Electrical problem	Call Helena Laboratories.
No sample dispensing into sample tray	Empty DI water bottle	Refill DI Water bottle.
	Clogged probe	Clean probe (see Section 10.3.2).
	No sample in test tube rack	Load test tube rack (see Section 7.2).
	Air bubbles in DI water tubing	Prime instrument (see Section 10.1.1).
	Wrong sample well in strip	Review Customer Pro for needed materials

Problem	Possible Cause	Solution
	Tubing/Pump failure	Replace pump head (see Section 10.3.6 and call Helena Laboratories.)
	Bent probe	Replace probe if necessary (see Section 10.3.8)
Sample in wrong well	Tubing/Pump failure	Replace pump head (see Section 10.3.6 and call Helena Laboratories.)
	Bent or plugged probe	Inspect and replace probe if necessary (see Section 10.3.8)
	Leaks in delivery system	Check for loose fittings or breaks in tubing line.
Incorrect sample volume	Tubing/Pump failure	Replace pump head (see Section 10.3.6 and call Helena Laboratories.)
	Bent or plugged probe	Inspect and replace probe if necessary (see Section 10.3.8)
	Leaks in delivery system	Check for loose fittings or breaks in tubing line
Probe wasn't washed Cross contamination	Peristaltic pump failure	Clean/replace probe Check peristaltic pumps
Controls out	Tubing/Pump failure	Replace pump head (see Section 10.3.6 and call Helena Laboratories.)
	Bent or plugged probe	Inspect and replace probe if necessary (see Section 10.3.8)
	Leaks in delivery system	Check for loose fittings or breaks in tubing line.
Probe stops before aspirating or doesn't pipet sample	DI bottle and Saline bottle are reversed.	Verify saline bottle tubing is connected to the wash station and DI water tubing is connected to the syringe.
Wash block overflow	Wash not draining	Correct the problem preventing the wash block from draining and tap 'OK' to continue. Waste line has excessive length creating an entrapment loop and is not allowing waste to drain. Shorten tubing to remove loop.

Problem	Possible Cause	Solution
Failed to Initialize: Pipette X Pipette Z Tray Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service
Failed to home: Pipette X Pipette Tray Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service
Failed to get to target position: Pipette X Pipette Z Tray Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service
Syringe pump command overflow.	Communication problem with Syringe Pump	Turn off instrument and call Helena Laboratories Service
Syringe pump initialization failure	No syringe installed or mechanical failure.	Turn off instrument and call Helena Laboratories Service
Internal syringe pump error. Invalid syringe pump command. Invalid syringe pump command sequence Invalid syringe pump parameter	Communication problem with Syringe Pump	Turn off instrument and call Helena Laboratories Service
Syringe pump not initialized Syringe pump not responding Syringe pump plunger move not allowed Syringe pump plunger overload. Syringe pump valve overload	Communication problem with Syringe Pump Mechanical Failure	Turn off instrument and call Helena Laboratories Service

Figure 10-1 Maintenance Menu
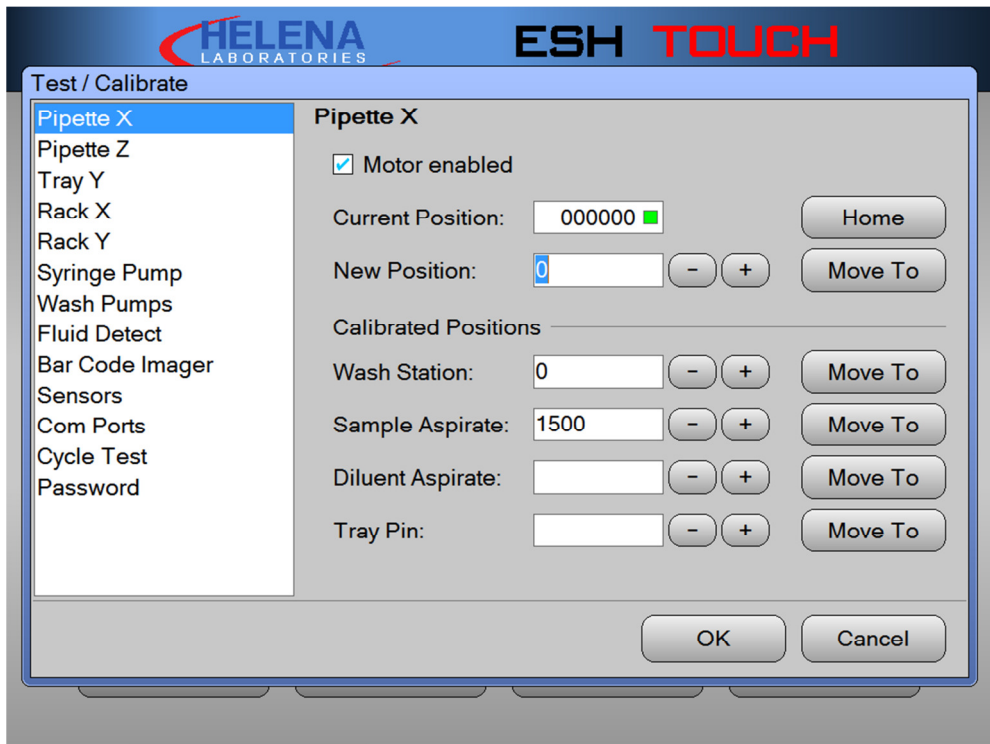
Figure 10-2 Pipette X
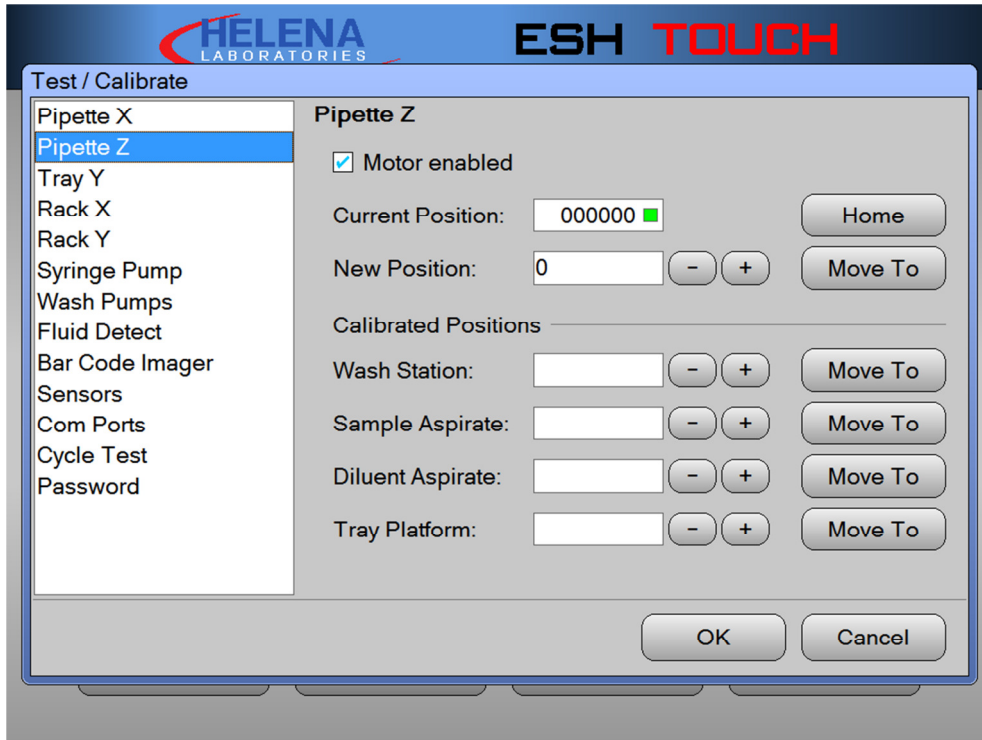
Figure 10-3 Pipette Z
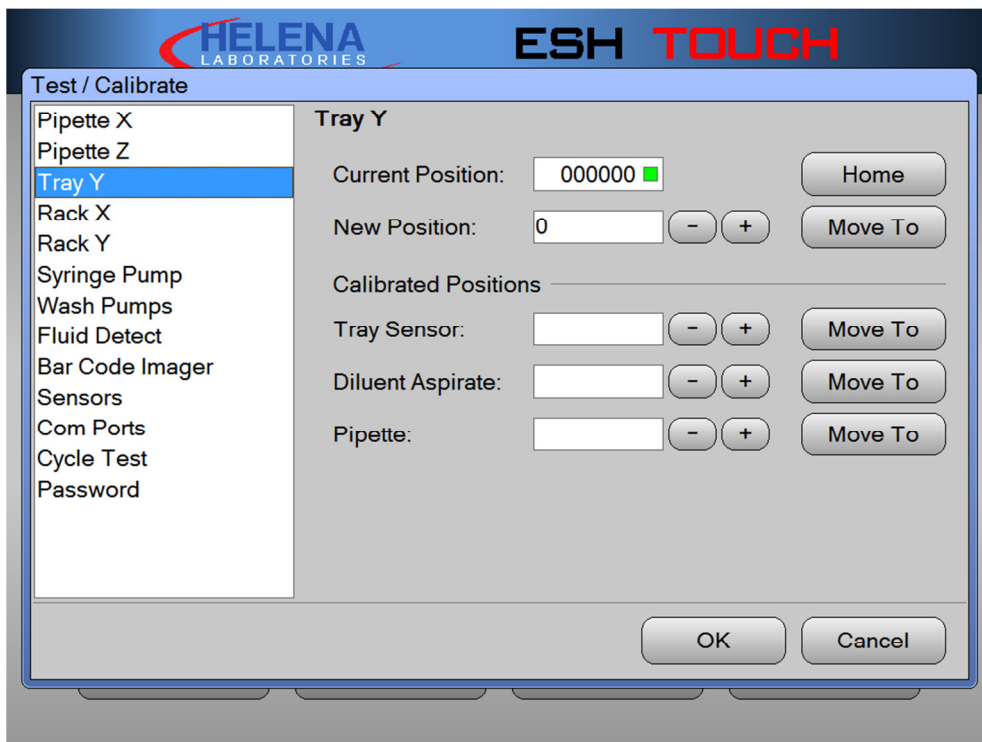
Figure 10-4 Tray Y
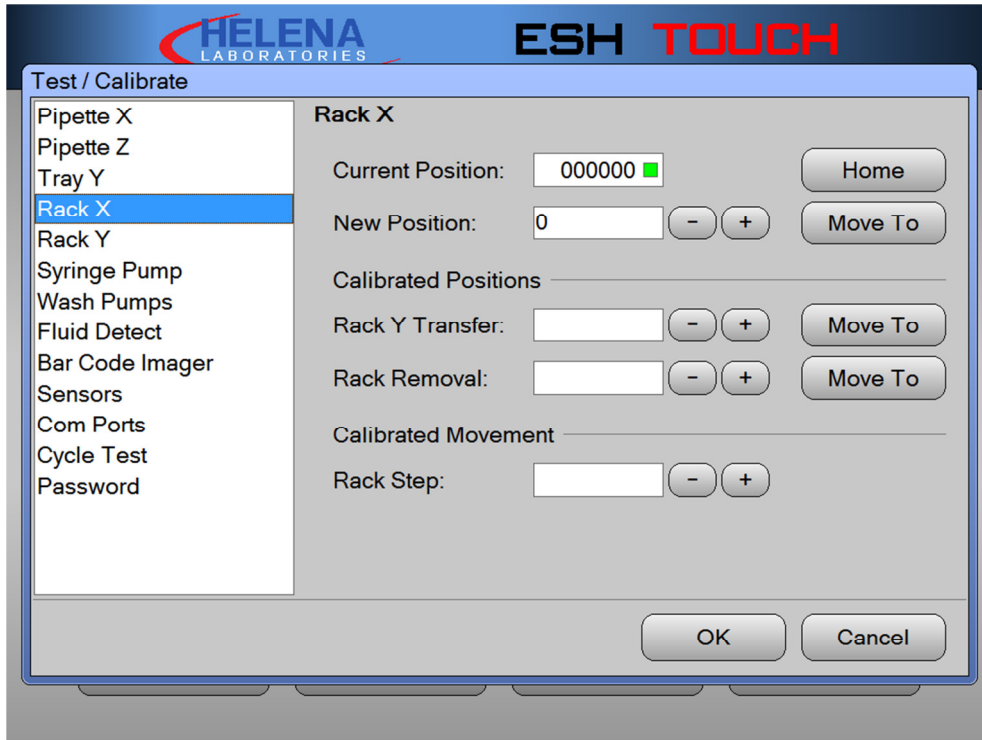
Figure 10-5 Rack X
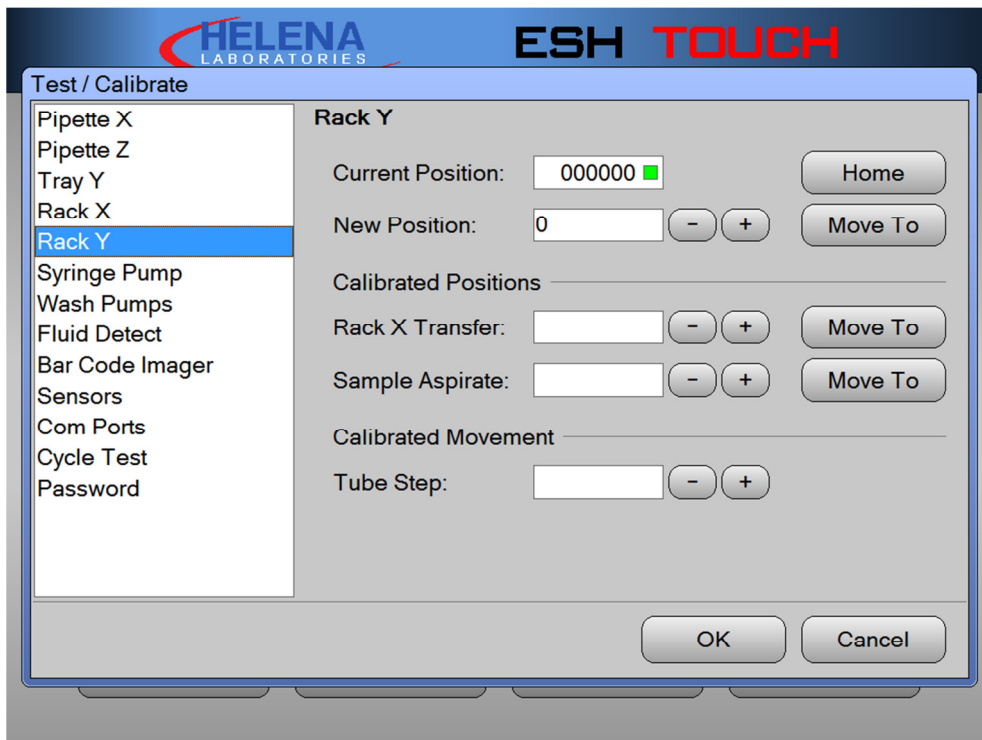
Figure 10-6 Rack Y
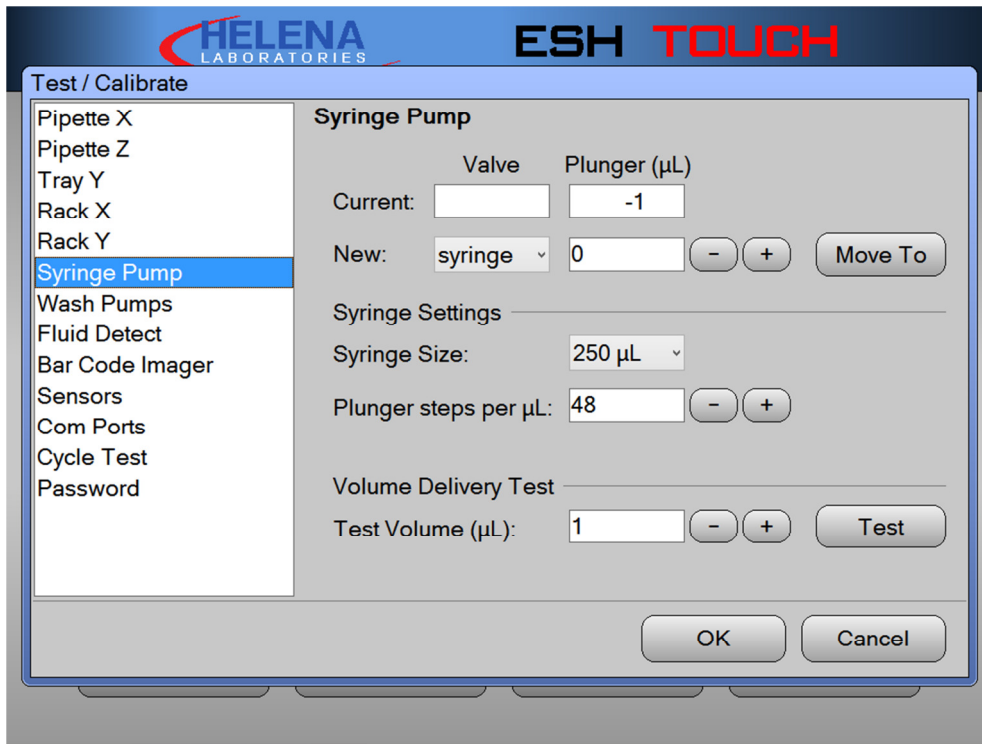
Figure 10-7 Syringe Pump
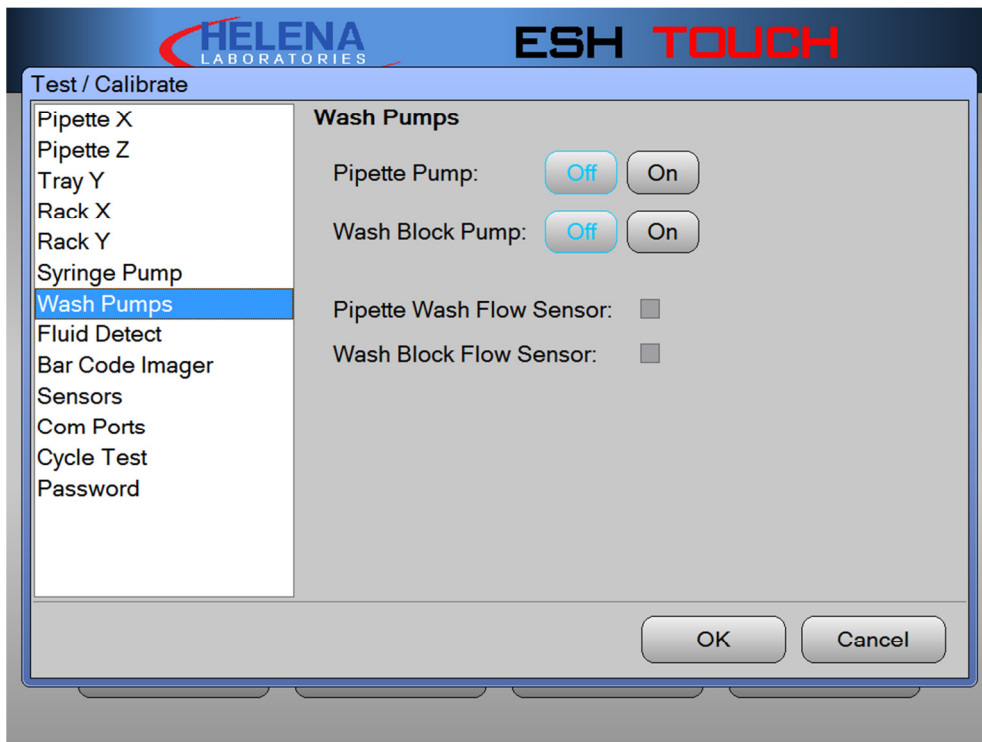
Figure 10-8 Wash Pump
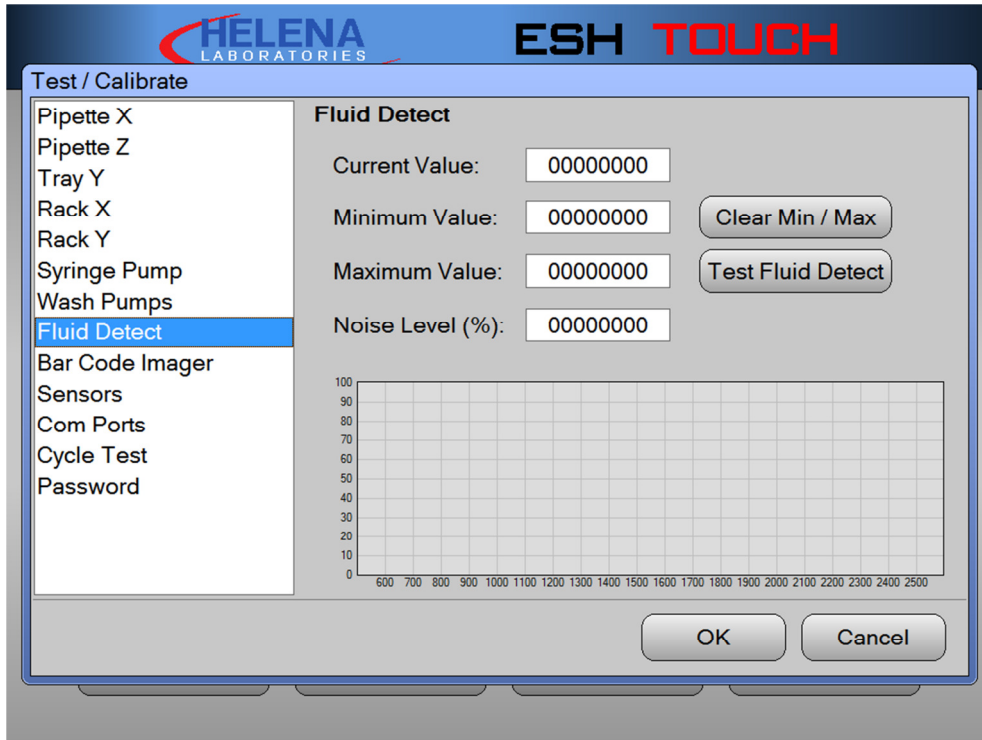
Figure 10-9 Fluid Detect
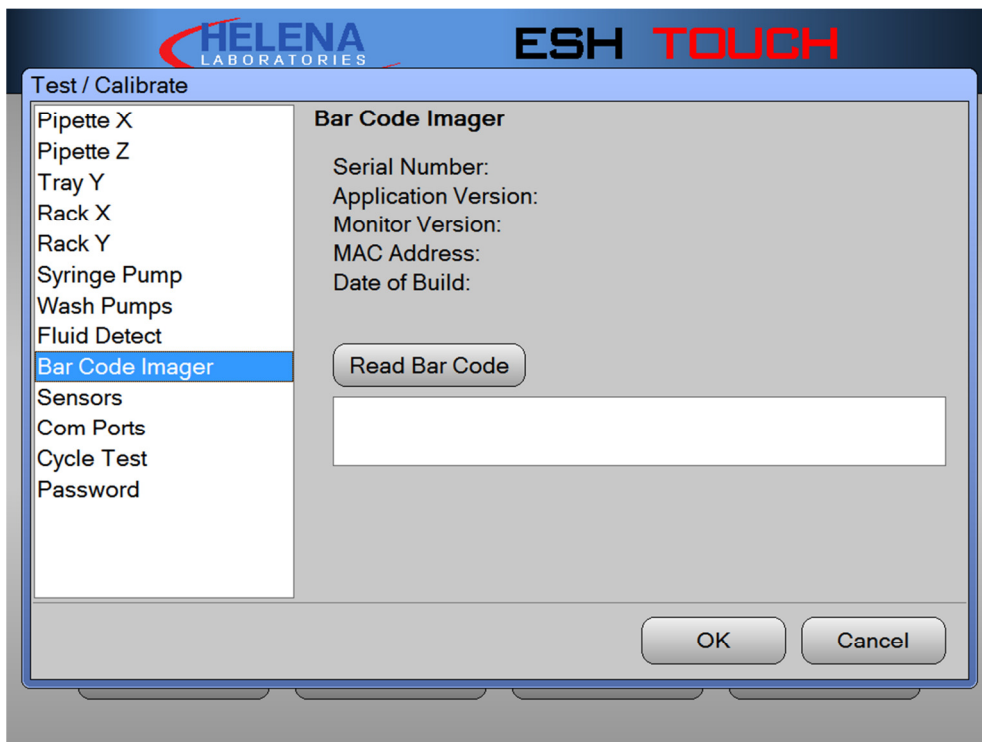
Figure 10-10 Bar Code Imager
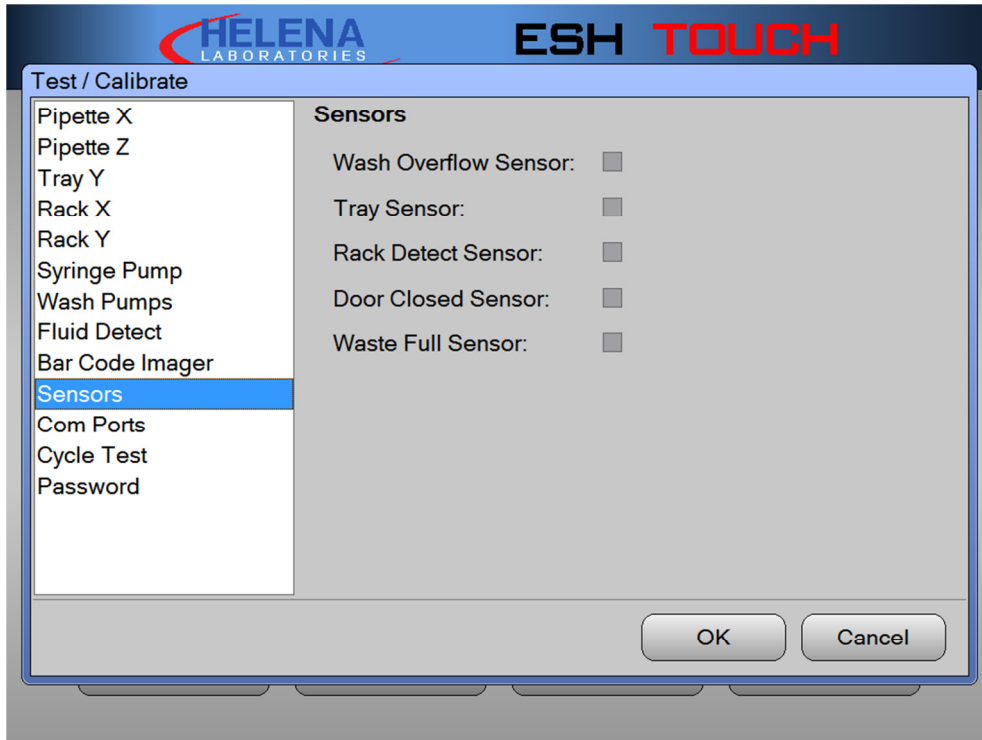
Figure 10-11 Sensors
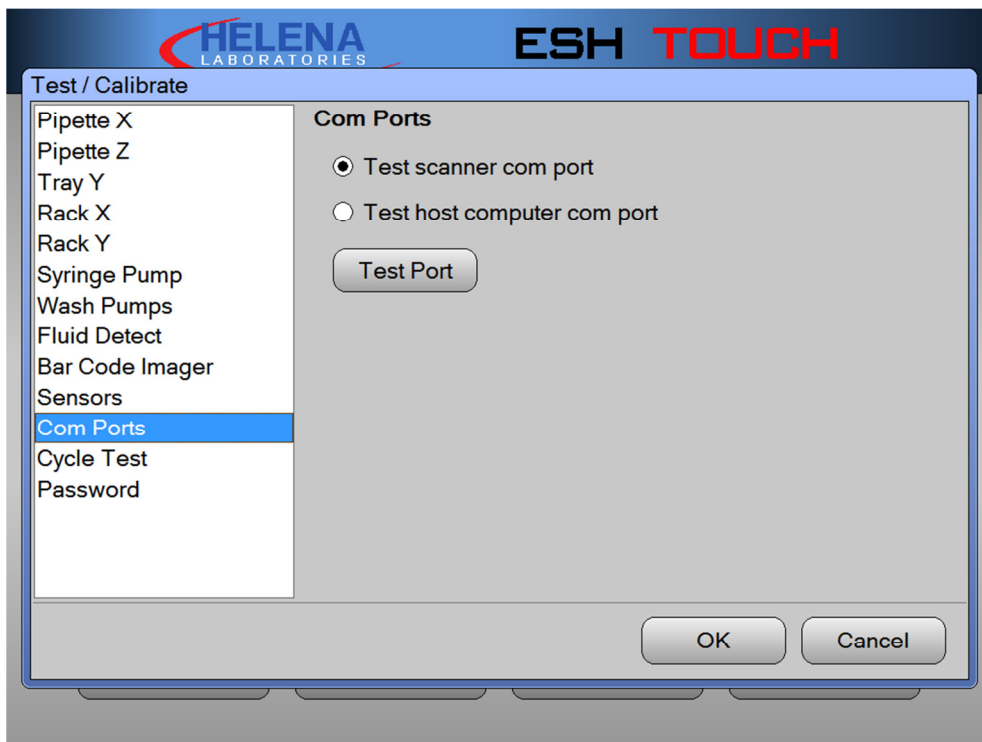
Figure 10-12 Com ports
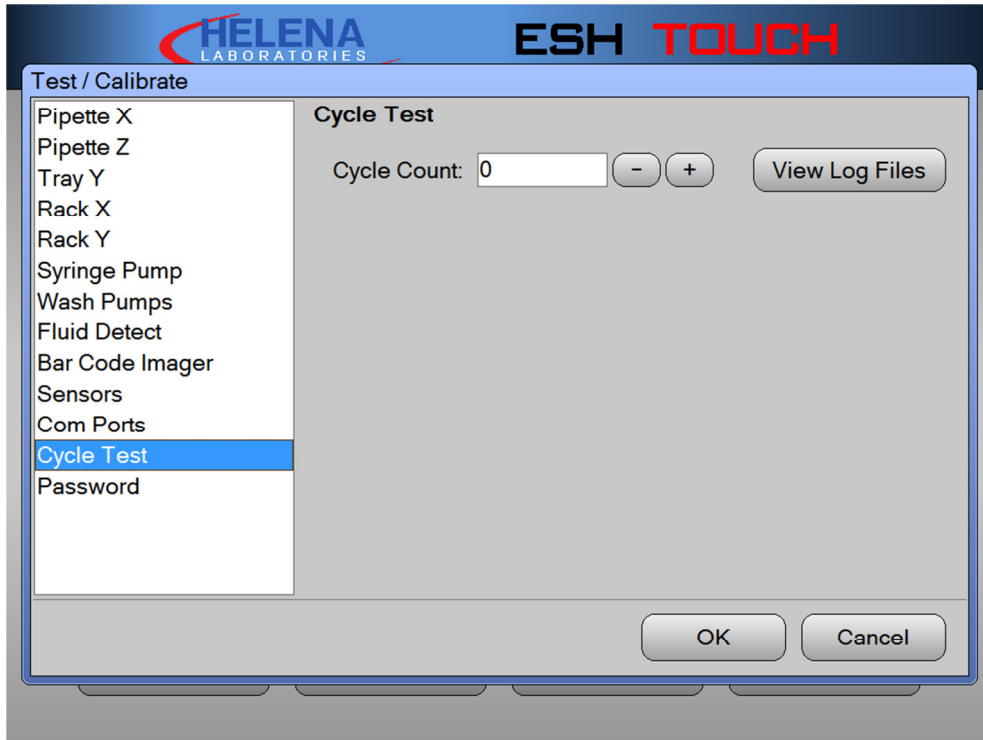
Figure 10-13 Cycle Test
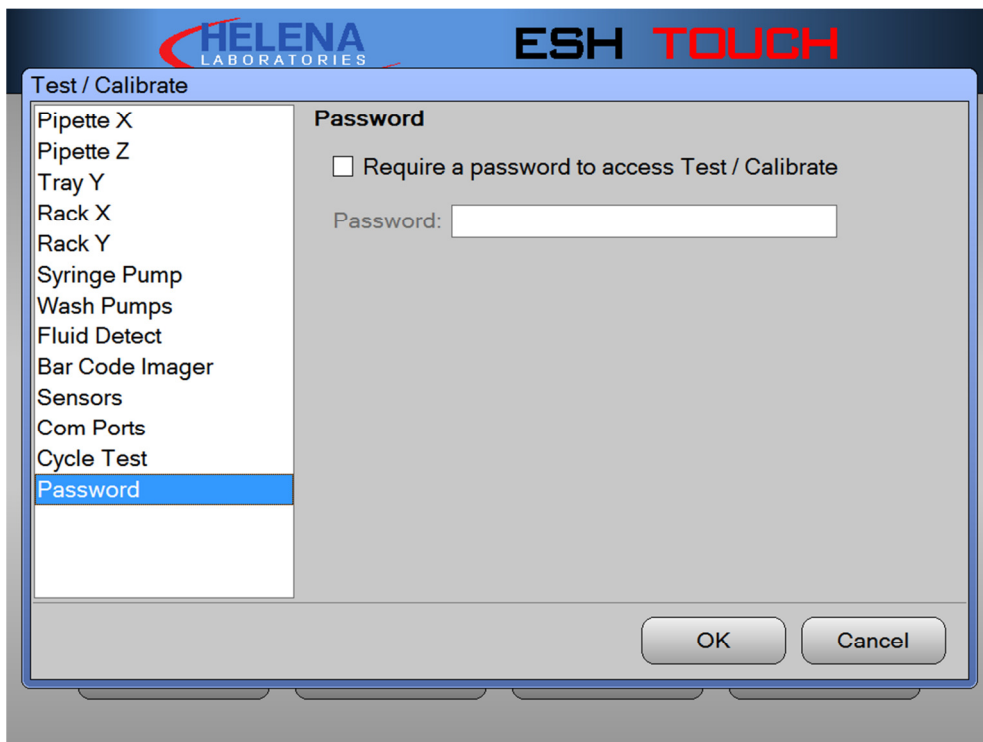
Figure 10-14 Password

Figure 10-15   Tubing/Pump Replacement
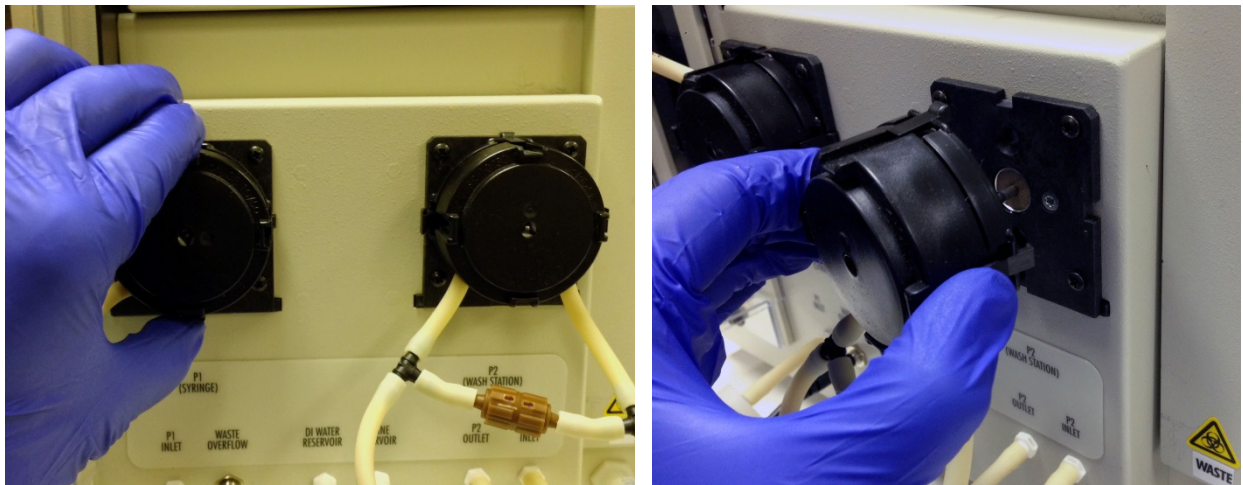
Figure 10-16 Tubing/Pump Replacement

Figure 10-17 Fuse Replacement
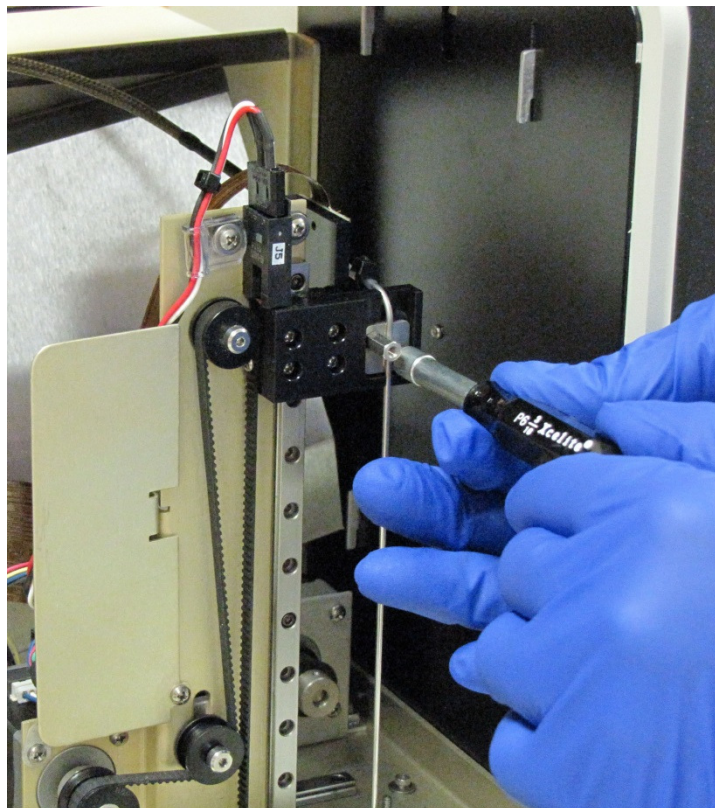
Figure 10-18 Probe Replacement/Cleaning
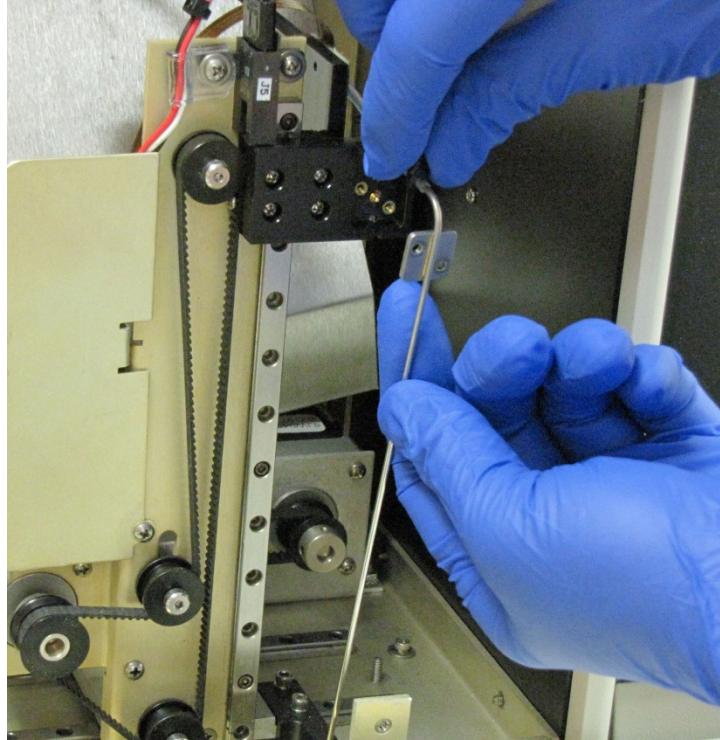
Figure 10-19 Probe Replacement
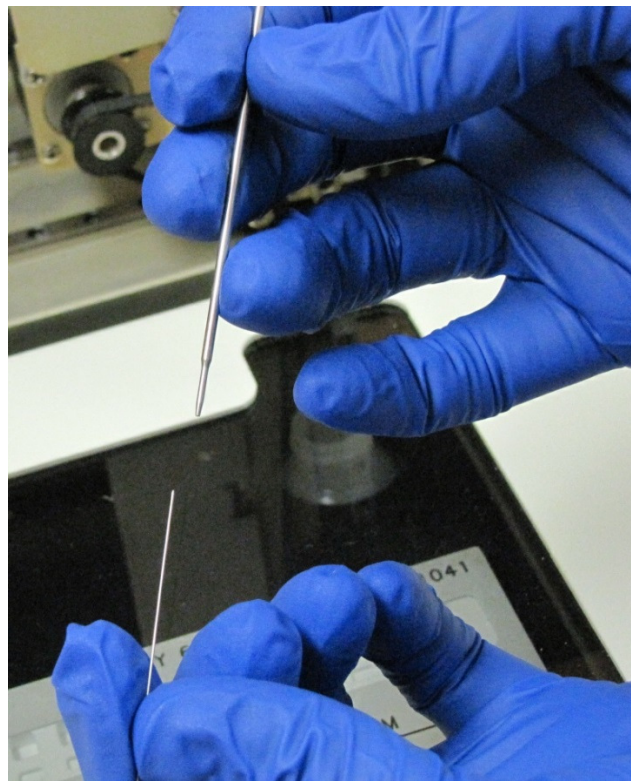
Figure 10-20 Probe Cleaning
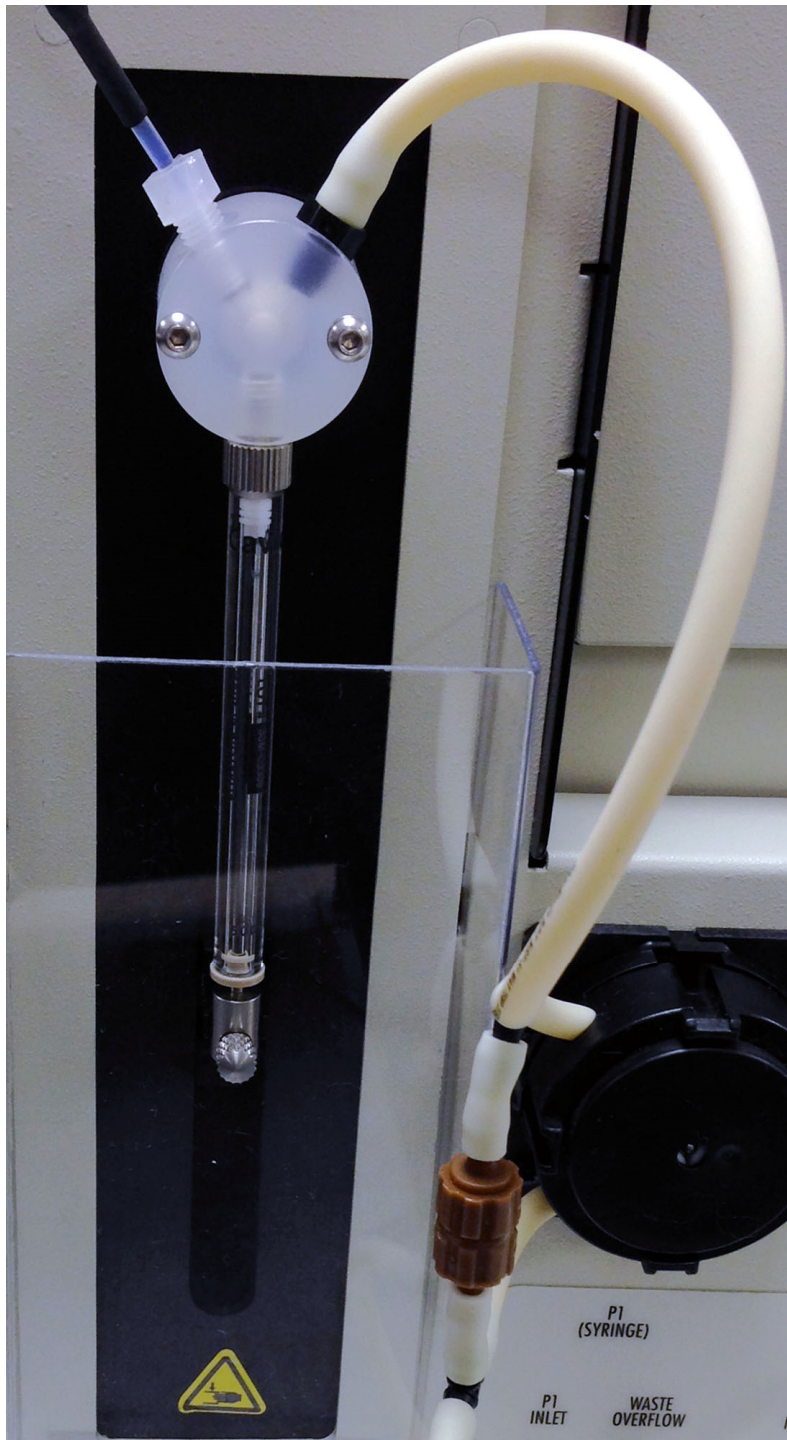
Figure 10-21 Syringe Seal / O-Ring Replacement

10.5. 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.

The software disk provided for use with this instrument must be retained and be accessible for the warranty to be valid.

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)
📖	Consult instructions
EC REP	European authorized representative
▰	Manufacturer

	Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC
	Caution, puncture hazard: When cleaning instrument or probe, handle carefully so not to puncture skin.
	Caution, biohazard: this symbol applies where potential biohazards exist and universal precautions should be exercised.
	Pinch Point Hazard: keep hands clear during operation.

CE

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ESH Touch

Software Version 1.0

Operator's Manual

For additional information, call Helena Laboratories at 800-231-5663, toll free.

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