SPIFE Nexus

Automated Electrophoresis

Operator's Manual

Catalog Number 1650

SPIFE Nexus

Automated Electrophoresis System

Operator's Manual

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┌─────────────────────────────────────────────┐
│                  WARNING!                     │
│   DO NOT ATTEMPT TO MOVE, INSTALL, OR         │
│   OPERATE THIS INSTRUMENT BEFORE              │
│   READING AND UNDERSTANDING THE               │
│   CONTENTS OF THIS MANUAL, PARTICULARLY       │
│   THE PRECAUTIONS, LIMITATIONS AND            │
│   HAZARDS IN SECTIONS THREE AND FOUR.         │
└─────────────────────────────────────────────┘
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4. Use of this program constitutes acceptance of the terms and conditions of this agreement.

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Section 1 - Instrument Use and Function

Helena's **SPIFE Nexus** (Figure 1-1) is an automated electrophoresis system with a built-in Sample Handler, as well as Sample Applicator), destain/wash vat area, Stain/Reagent Dispenser and Spreader, and Antisera Applicator. Once the sample tubes are loaded, the instrument automatically loads samples from test tubes to sample cups, applies samples from sample cups to associated gels, electrophoreses at a programmable voltage, applies antisera, stain, destains, blots, and scans each finished gel. Once the gel is finished and scanned, it slides out of the front of the instrument. The touch screen facilitates entering or changing procedure parameters and operation of the instrument.

The SPIFE Nexus contains preprogrammed parameters for Split Beta Serum Protein Electrophoresis, Serum Immunofixation, Urine Proteins, and Urine Immunofixation; however, the end user may alter the parameters for these tests, if desired, and create unlimited new test procedures. In the future, additional test procedures will become available from Helena Laboratories.

Stored results can be retrieved in seconds and full editing features are provided with the QuickScan Touch *plus* software program so fractions may be selected, comments added to the file, etc.

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

- Summary
- Principle
- Reagents
- Instruments
- Specimen Collection and Handling
- Step-by-Step Method

- Evaluation of the Bands
- Stability of End Product
- Results
- Expected Values
- Reagent Preparation
- Sample Application
- Test Procedure
- Performance Characteristics
- Expected Results
- References
- Reference Values
- Interpretation of Results
- Bibliography

Figure 1-1 SPIFE Nexus System

Section 2 - Principles of Operation

The functional units of the SPIFE Nexus are shown in Figure 2-1. Operation is controlled by a computer and microcontrollers.

Software updates are provided via portable USB storage media.

2.1. Principles of Operation – User Interface

The SPIFE Nexus is powered on by pressing the round silver button on the front of the instrument. Holding this button down for 20 seconds will cause a hard reboot of the instrument.

The button on left-hand side is an emergency breaker. If the instrument draws more than 15 Amps, it will shut off the instrument. This should be used for EMERGENCY only. Using this button on a regular basis will cause computer errors.

The computer runs a self-test at power initialization to detect error conditions or potential problems.

On the touch screen, the user can open the software by double tapping the SPIFE Nexus icon on the screen or by double clicking the mouse.

The user may select the test types, start or stop the automatic sequence of operations, prime the Sample Handler and Pump Tubing, select test parameters, and change displayed menus.

On the right-hand side of the instrument, there are four USB ports, one serial port, one LIS port, one network port, one AC outlet, one display outlet, six fluid ports as well as a waste full sensor interconnector.

Once a run has begun, the SPIFE Nexus will scan the barcodes on the following items and will alert the user if one of these items is incorrect or missing for the current run: Sample Tray, Gel Cassette, Platen

Cover (with correct Electrode insert), Applicator Blade Template, Reagent Chiller, as well as the Blotter Holder.

2.2. Principles of Operation – Sample Handler System

The Sampler Handler portion of the SPIFE Nexus consists of the Tube Transport area, Sample Tray Platform, and Electrophoresis Platform.

The test tube racks are loaded into the Tube Transport area in the front of the instrument. The door folds down and the user can load up to ten racks ensuring the recessed notch on the back of the test tube rack has the metal bar slid into it. The instrument will identify the samples by reading a barcode on the sample tube and will send that information to the SPIFE Nexus software. Once all the samples in the rack have been processed, it will be shifted to the left. To prevent jams, a sensor on the far left-hand side will alert the instrument if the area is full.

The pipette pulls the sample from the test tube and aliquots the required volume into the Disposable Sample Cups that have been loaded within the reusable sample tray and placed onto the Sample Tray Platform. The pipette will also make the appropriate dilutions for the various Immunofixation lanes and then transfer a predetermined amount of sample from the dilution well into the sample appropriate sample cups.

Once all the samples have been transferred to the Sample Tray, the instrument will pick up the Applicator Holder and position it over the Sample Tray. Once the Applicator Holder is in position, the instrument will lower and immerse the applicator blades into the sample cups. After that, the Applicator Holder will move over and apply the samples onto the gel that is located on

the electrophoresis platen. Once the samples have been applied, the motor driven claw will place the Applicator Holder back into the Consumables Tray.

2.3. Principles of Operation – Electrophoresis and Staining

The relationship of the functional units of the SPIFE Nexus are shown in Figure 2-1. Operation is controlled by the main controller, slave microprocessors, their hardware interfaces, and user selections of control parameters displayed on the monitor and selected using the keyboard, mouse, or touch screen.

The Electrophoresis Station consists of a programmable temperature controlled platen. A microprocessor controls the electrophoresis voltage supply and monitors the status of the electrophoresis voltage, current, as well as platen temperature.

From this station, the following actions may be carried out: electrophoresis, staining, antisera/fixative application, as well as blotting, and drying. The type of test that is being run dictates which actions will occur here and in what order.

For electrophoresis, the instrument positions the Platen Cover with the appropriate Electrode Insert in contact with the gel surface and applies the preprogrammed temperature and voltage ranges for the desired amount of time.

Once electrophoresis has occurred, the instrument removes the Platen Cover and replaces it in its storage area.

For IFE plates, there is storage for Antisera and Fixative located within the onboard Reagent Storage area. The Reagent Chiller consists of the onboard storage area and a motor driven pipette, which applies the antisera to the gel. After antisera has been applied to the gel and the selected absorption time has elapsed, the gel will be blotted with a disposable blotter. The Blotter Holder, which has a disposable adhesive blotter on the bottom, is stored in the Consumables Tray. The motor driven claw will pick up the Blotter Holder and place the loaded Blotter Holder onto the top of the gel to remove excess antisera from the gel surface.

Pre-drying is accomplished by utilizing the electrophoresis platform set to heating mode.

Stain is applied by using the Stain/Reagent Dispenser and a borosilicate glass Reagent Roller. The Stain/Reagent Dispenser moves over the gel and pours a small amount of stain onto the gel surface. Once the stain has been applied, a roller rolls back and forth over the gel, evenly dispersing the liquid.

At this stage, the gel is moved to the Wash/Destain Station. A vertical vat is filled with either Wash or Destain that can be circulated bottom to top or top to bottom. After this step, the vat is emptied.

The master microprocessor then signals the heater in the Drying Chamber to heat the chamber to drying temperature. The Dryer Station consists of a vertical forced air dryer with programmable temperature settings and air temperature monitoring. The gel is placed into the dryer and a Dryer Platen Cover is placed on top of the dryer opening.

Once the gel has completed all program-selected operations, the gel is transferred into the scanner. The gel is scanned and then pushed out of the front of the instrument signaling to the user that the gel has been completed.

2.3.1. QuickScan Touch *plus*

Finished gels images are viewed in the QuickScan Touch *plus* software. Using this software, scans can be edited if so desired.

All user input is through the touchscreen, mouse, or keyboard. For more information on how to edit a scan, reference the QuickScan Touch *plus* Operator's Manual.

2.3.2. Instrument Shutdown

Note: *Before shutting down the instrument, ensure **any** USB drives have been removed from the right-hand side of the instrument.*
Failure to do this will cause the instrument to not power down properly and it will still be drawing power. Additionally, when the user attempts to press the silver power button on the front of the instrument, it will not power back on.

To properly shut down the instrument, click the X in the upper right-hand corner to close out the SPIFE Nexus software. The computer and main instrument can be turned off by selecting the Windows logo in the lower left-hand side of the monitor. Select *Power* then *Shut down.*
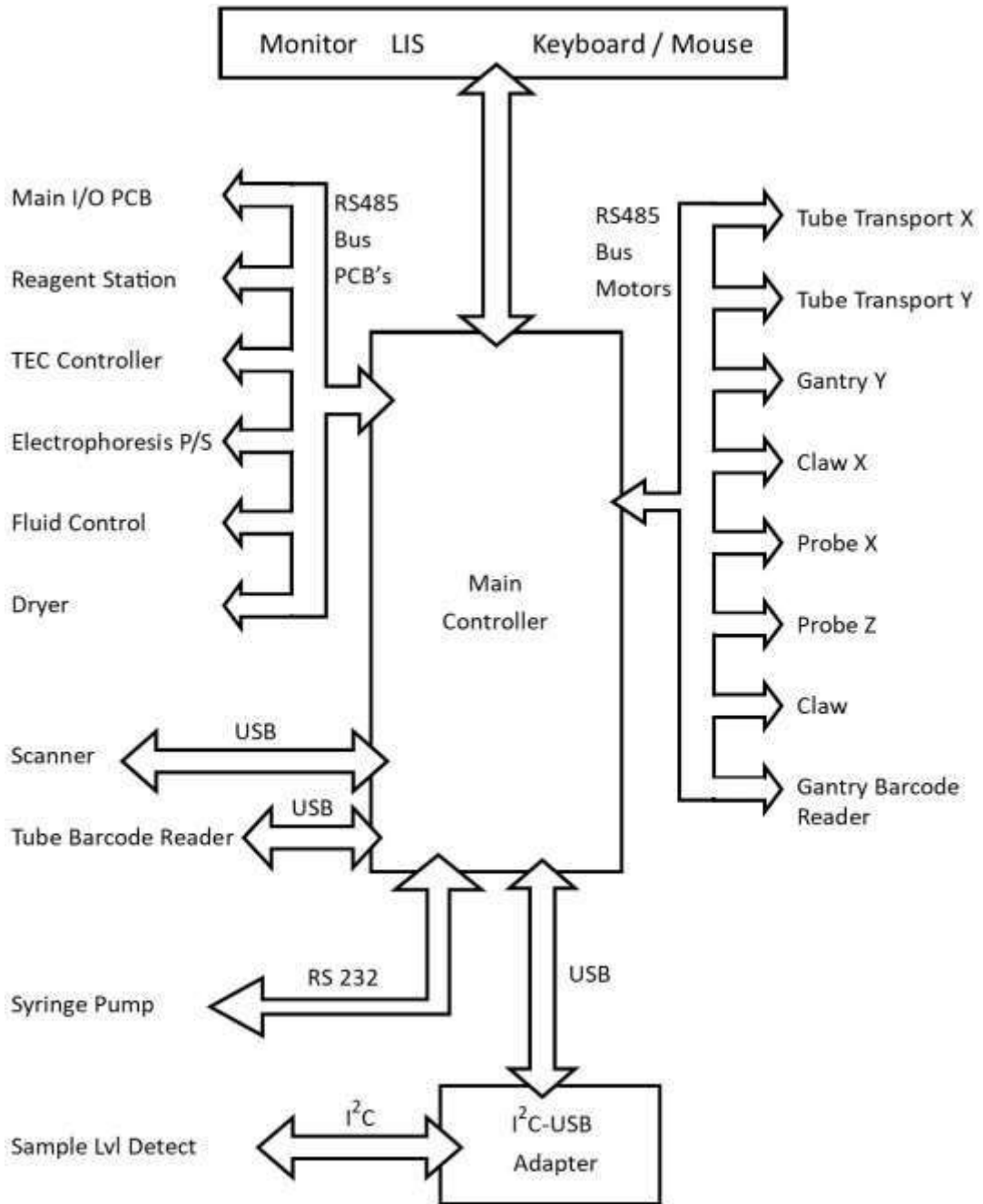
Figure 2-1 Flow diagram

Section 3 - Precautions and Limitations

3.1. For emergency shutdown, turn off the instrument using the main power switch on the left-hand side of the instrument or disconnect the main power cord from the wall outlet.

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

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

3.4. Use only hardware and software accessories made specifically for the instrument.

3.5. Storage and transport environmental requirements:
Storage and shipping temperatures: 5° - 40°C (41°- 104°F).
Relative Humidity: 10 -80%, non-condensing.

3.6. Do not expose the instrument to drafts or operate the instrument in direct sunlight. Do not operate the instrument at temperatures below 15°C (59°F) or above 27°C (80.6°F).

3.7. Provide adequate room (2" minimum [5 cm]) at the sides and back of the instrument for good air circulation.

3.8. Do not attempt to operate the instrument until the entire Operator's Manual, and the manuals provided with the scanner, monitor and printer, have been read and understood. Section 11 contains all the warning symbols that may be found throughout the manual and on the instrument.

3.9. Do not place any objects inside the scanning slot other than items to be scanned.

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

3.11. Do not expose the Gel Cassette to temperatures above 70°C (158°F), or severe warping of the Cassette may result, making it unsuitable for use.

3.12. The instrument should not be moved once the Helena Laboratories approved representative has installed the instrument. If the instrument must be moved, it should be recalibrated and checked before use.

3.13. This instrument meets the leakage current specifications of directive EN 61010-1.

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

3.15. Due to high heat, do not touch the areas including the Pre-Dry and Dryer stations.

3.16. The instrument should be kept dust free if possible. Harsh cleansers, acids or bases should never be used either on the inside or outside of the instrument. See Section 10.9.3 for more detail. **NOTE: Always unplug the main power cord before cleaning.**

3.17. 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.

Harsh cleansers, acids or bases should never be used either on the inside or outside of the instrument. See Section 10.9.3

for more detail. **NOTE: Always unplug the main power cord before cleaning.**

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

3.19. Do not block air vents and intakes. They are located on the front and rear of the instrument.

3.20. Keep hands and clothing away from the motor driven arm when in operation.

3.21. 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.

3.22. 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.)

3.23. Requirements for handling biohazards: Due to potential biohazard risk from human blood, 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 and use, transportation and disposal of this device.

3.24. The Helena Laboratories representative/distributor 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.

3.25. For disposal, send this instrument to a proper recycling center in accordance with applicable federal, state, and local requirements.

3.26. Although the SPIFE Nexus is factory programmed for some procedures, the operator may alter scanning parameters if desired. If scanning problems occur, return to default parameters.

3.27. Gel Cassettes are fragile and will break if dropped.

3.28. Do not include additional software programs on the SPIFE Nexus without first consulting Helena Laboratories Service personnel.

3.29. To prevent software failure, properly eject any storage devices before removing them from USB ports.

3.30. It is recommended that the user refrain from changing display settings (font, size, color, resolution, etc.) while operating the SPIFE Nexus in order to prevent software failure.

3.31. Operators should follow all instructions within the manual regarding priming the instrument and monitoring fluid levels. Failure to perform these maintenances and monitor fluid levels could result in possible carryover by contamination from one sample to another.

3.32. If a severe fluid/reagent spill should occur, possibly leaking into the instrument, call Helena Laboratories Service department before attempting use.

3.33. Lift the instrument manually or with multiple people, as it weighs approximately 113.4 kg (250 pounds).

3.34. On the right-hand side of the instrument, the display power port is to only be used for the power cord that is connected to the computer monitor (display).

3.35. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. All procedures in- volving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generating of droplets of these substances. Blood specimens or other potentially infectious materials shall be placed in a container that prevents leak- age during collection, handling, processing, storage, transport, or shipping.

Equipment that may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the user can demonstrate that decontamination of such equipment or portions of such equipment are not feasible. Gloves shall be worn when it can be reasonably anticipated that the user may have contact with blood or other potentially infectious materials, as well as touching contaminated surfaces. Other personal protective equipment (eye protection, gowns, etc.) shall be worn, as appropriate.

All equipment, environmental, and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

Warning labels (with **"Biohazard"** symbol) are affixed to containers of regulated waste and other components of the instrument likely to be contaminated with potentially infectious materials.

3.36 The instrument main door uses an interlock to control access to the inside of the instrument as a means to prevent access to hazards presented by operation of the instrument. If the interlock fails permitting access to the instrument during operation, cease using the instrument and call Helena Laboratories Service department before attempting use.

Section 4 - Hazards

Section 11 contains all the warning symbols that may be found throughout the manual and on the instrument. If the instrument is used in a manner not specified by this manual, the protection provided by equipment design may be impaired.

4.1. Many safety features have been built into the instrument. Do not attempt to defeat or bypass any of these safety features.

4.2. These devices contain high voltages, which can be extremely dangerous. Turn off the system power, disconnect the main power cord and use extreme care when attempting disassembly for cleaning, repair or adjustments. Do not operate any instrument with the cover off unless instructed to do so by a qualified service technician directly representing Helena Laboratories, its subsidiaries, or its distributors.

4.3. Do not attempt to operate the instrument unless the power cords are plugged into grounded wall outlets of the proper voltage and frequency. This information is contained on the serial number plate located on the back of the instrument.

4.4. Do not lubricate the instrument.

4.5. Do not place fingers near any moving parts when the instrument is in use.

4.6. Requirements for handling biohazards: Due to potential biohazard risk from human based components, 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 personal protective equipment as warranted for safe handling and disposal of test tubes, reagents, applicators, or other items containing or contaminated by biohazards.

4.7. Use only diluents and reagents specified by the Helena Laboratories 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 diluents and reagents used with this instrument.

4.9. In case of power loss during operation, the instrument will reset and the sample run will need to be restarted.

4.10. Shock hazard. Never touch the cables at the rear of the unit during operation.

4.11. Do not touch the Dryer Station area. Surfaces can reach temperatures of approximately 65°C (149°F).

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

4.13. Do not use poisonous or injurious gases near or in the instrument.

Section 5 - Installation

Installation is to be performed by qualified Helena personnel. The customer will be required to verify that a functional instrument has been installed to completion.

WARNING: Read Section 3 (Precautions and Limitations) & Section 4 (Hazards) before attempting to move or turn on the instrument.

WARNING: Do not attempt to lift instrument manually.

Note: The SPIFE Nexus is an "Overvoltage Category II, Appliance Class I – Protective Earth Connected" device under EN 61010-1 and is for use in a laboratory or similar environment.

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 Nexus

1 SPIFE Nexus Container Kit

> 3 2½ gallon bottles (Wash, DI Water, and Saline)
>
> 2 2 gallon Waste containers
>
> 1 13 liter Destain jerrican
>
> 3 Wash Cap Assemblies with tubing
>
> 1 Destain Cap Assembly with tubing
>
> 1 Waste Vat Cap Assembly with tubing and shorting plug
>
> 6 Pigtail Tubing Ports
>
> DI Tubing Assembly
>
> Tubing

5 SPIFE Nexus Applicator Blade Weights, Cat. No. 2572

1 SPIFE Nexus Applicator Holder

1 Line Cord, Shielded, 20 AWG

1 Line Cord, Jumper Cordset C13, 10 AMP

1 Level

1 SPIFE Nexus Blotter Holder

1 SPIFE Nexus Platen Cover

1 SPIFE Nexus Dryer Chamber Cover

1 Dilution Bottle with cap

1 Stylus

1 Tube Racks package (10/pkg)

1 SPIFE Nexus Applicator Blade Templates (set of 8), Cat. No. 2570

1 SPIFE Nexus Antisera Spreader Tips (10/pkg), Cat. No.2574

1 SPIFE Nexus Carbon Electrode Insert, Cat. No.2576

2 SPIFE Nexus Cassettes, Cat. No. 2580

2 SPIFE Nexus Reagent Roller, Cat. No. 2583

1 SPIFE Gel Block Remover, Cat. No. 1115

1 SPIFE Maintenance Swabs, 5/pkg, Cat. No. 1113

1 SPIFE Nexus Contact Sheets, 5/pkg, Cat. No. 2584

1 SPIFE Nexus Consumables Tray

1 SPIFE Nexus Blotter Guide

1 Installation Report

1 Installation Flash Drive, SPIFE Nexus software

1 SPIFE Nexus Operator's Manual

1 QuickScan Touch *plus* Operator's Manual

1 Customer Maintenance Form

1 Tray, Spill Vat

Available Supplies

Cat #   Product Description

2582 SPIFE Nexus Ready Run Kit (contains Consumables Tray, Reagent Roller, Applicator Holder, Blotter Holder, Blade Weights, and Applicator Guide Template set)

2575 SPIFE Nexus Disposable Stain Cups (100/pkg)

2570 SPIFE Nexus Applicator Blade Templates (set of 8)

2572 SPIFE Nexus Applicator Blade Weights (5/pkg)

2574 SPIFE Nexus Antisera Spreader Tips (10/pkg)

2576 SPIFE Nexus Carbon Electrode Insert

2583 SPIFE Nexus Reagent Roller

2584 SPIFE Nexus Contact Sheets (5/pkg)

2420 SPIFE Nexus Split Beta SPE-60 Kit (600 tests)

2421 SPIFE Nexus Split Beta SPE-40 Kit (400 tests)

2422 SPIFE Nexus Split Beta SPE-20 Kit (200 tests)

2408 SPIFE Nexus IFE-15 Kit (10 gels, consumables, antisera)

2409 SPIFE Nexus IFE-9 Kit (10 gels, consumables, antisera)

2401 SPIFE Nexus IFE-6 Kit (10 gels, consumables, antisera)

3360 SPIFE Disposable Sample Cups, Deep Well

3362 SPIFE IFE-15 Disposable Cup Tray

3363 SPIFE-IFE-9/15 Disposable Cups

3368 SPIFE-IFE-3/6 Disposable Cups

3370 SPIFE 20, 40, 60 Disposable Cup Tray

3377 SPIFE-IFE-3/6 Disposable Cup Tray

3378 SPIFE-IFE-9 Cup Tray

1696 Pos. ID Barcode Labels for Touch and SPIFE Nexus Systems (1000/pkg)

9173 Service Manual for SPIFE Nexus

1184 Extended Warranty

1185 Consolidated Service for SPIFE Nexus

2580 SPIFE Nexus Cassette

1694 Color Printer, Laser

1422 Black and White Printer, Laser

5.2. Unpacking and Inspection

5.2.1. 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. The waste vat must be placed below the instrument.
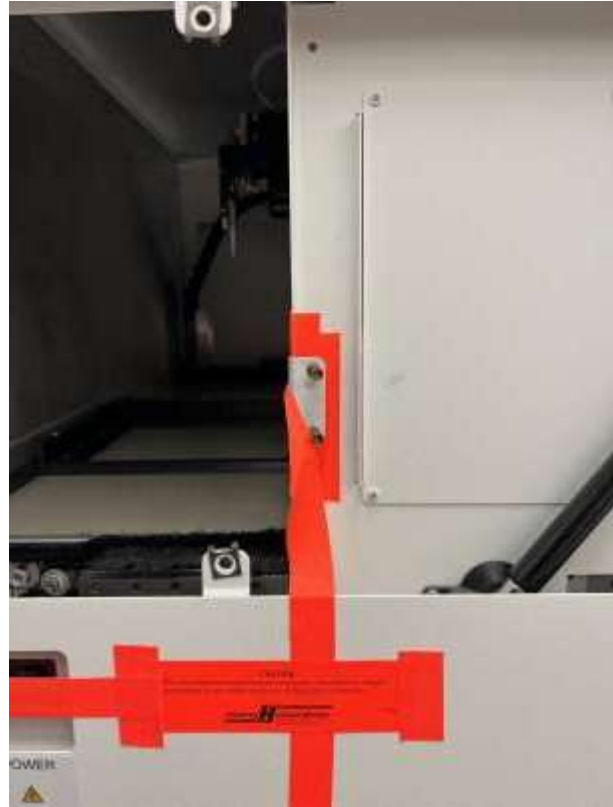
4. Refer to *Section 9: Performance Specifications* for instrument dimensions and weight

NOTE: At least 2" (5.1 cm) of clearance are necessary for all sides of instrument to prevent overheating.

Ambient temperature should be from 15°-27°C (59°-80.6°F).

5.2.2. Removing Shipping Bracket and Leveling Instrument

1. There will be shipping brackets.
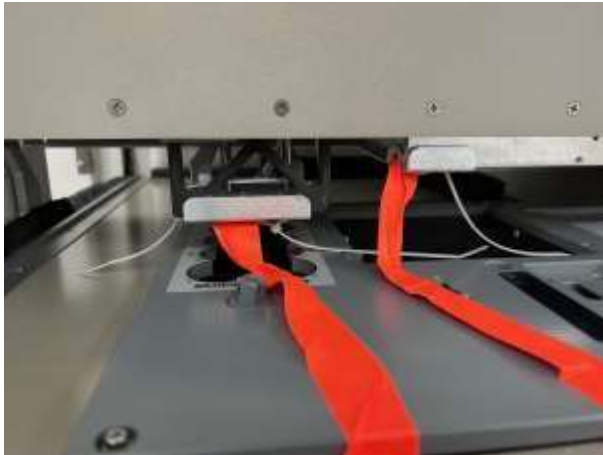
2. Unscrew the brackets.

3. Place a 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.

NOTE: Only use containers and fittings supplied with the instrument. Do not connect the instrument to pressurized supplies. Use only tubing, fittings and containers rated for a minimum of 16.5 PSI.

2. Attach the six pigtails to the ports on the right hand side of the instrument.

3. From the length of tubing provided, cut appropriate lengths for each of the five containers. The tubing should be long enough to reach the bottle but not so long so there are kinks or excessive amounts draped across the floor.

4. Attach the length of tubing to the cap that will be used on the Saline vat. Fill vat with saline. Attach the tubing from the Saline vat to Port 1. Ports are located on the right side of the instrument (see Figure 5-3).

5. Attach the length of tubing to the cap that will be used on the Destain vat. Fill with Destain. Attach the tubing from the Saline vat to Port 2.

6. Attach the length of tubing to the cap that will be used on the Wash vat. Fill with Wash. Attach the Tubing Assembly from the Wash vat to Port 3.

7. Attach the DI Tubing Assembly to the cap that will be used on the DI Water vat. Fill with DI water. Attach the Tubing Assembly from the DI Water vat to Port 4.

8. For the Overflow Wash line, attach the length of tubing to the cap that will be used on the Waste vat. Attach the tubing to Port 5. This catches any overflow from the Wash cycles and channels it into the Waste vat.

9. Attach the length of tubing to the cap that will be used on the Waste vat. Attach the tubing from the Waste vat to Port 6.

Note: Port 6 can only be used for waste.

10. If using the Waste vat, connect other end of the sensor into the receptacle located at the rear of the instrument, labeled "Waste Flow Sensor Interconnector".

11. The tubing from port 6 may be run to a sink for waste disposal, 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 "Waste Flow Sensor Interconnector". The waste tubing should always remain unrestricted between the instrument and waste drain or vat.

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

13. Install the Spill Tray as shown in Figure 5-6.

5.2.4. Power Cord and Parts Handling

1.   Confirm that the main power switch is off and plug the SPIFE Nexus power cord into the outlet provided on the left side of the instrument (Figure 5-4).

NOTE: Keep area around mains inlet and power switch clear and readily accessible for emergency disconnection of equipment.

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 Nexus meets the leakage current specifications of directive EN 61010-1. To meet standards more stringent than this, we recommend the purchase of an isolation transformer. Specifications for this transformer are given in Section Nine.

4.   The barcode reader, an optional acces- sory, is used for positive patient ID and plugs into the outlet provided on the right side of the instrument Figure 5-3.

5.   Turn on the Main power switch on the left hand side of the instrument. Power on the instrument by pressing the large silver but- ton on the front bottom of the instrument.

Note: Ensure the digital audio input option is selected by using the silver dial on the right side of the monitor. This will allow sounds to be heard through the DisplayPort connection.

The SPIFE Nexus software is ready to operate once the desired test(s) and the worklist(s) have been created. Setup instructions are in Section 6 - User Setup.

Figure 5-1 Front view of the SPIFE Nexus
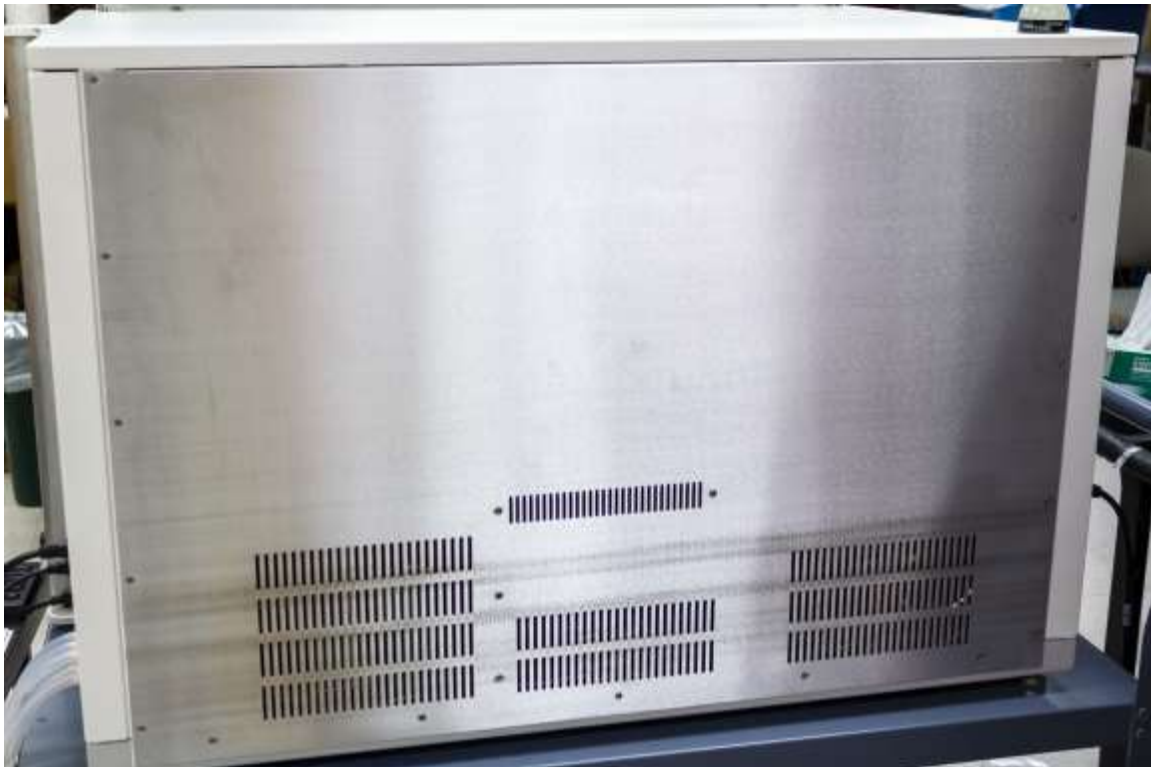
Figure 5-2 Back view of the SPIFE Nexus

Figure 5-3 Right side view of the SPIFE Nexus

1	USB Ports	Monitor, Mouse/Keyboard, optional Barcode Reader, Data Drives
2	Serial Port	Not Used or Functional
3	Network Port	Ethernet port for system networking
4	LIS Port	RS-232 serial port for interfacing to a Laboratory Information System (LIS).
5	Fluid Ports	These ports are used to connect the tubing to the vat containers. 1 – Saline 2 – Destain 3 – Wash Vat 4 – DI Water 5 – Overflow Wash 6 – Waste
6	Display Power	AC outlet for connected Display/Monitor, IEC 60320-1 C13
7	Display Port	Display/Monitor interface port
8	Waste Full Sensor Interconnector	Input from Waste Container to detect a full Waste Vat

Figure 5-4 Left side view of the SPIFE Nexus

Figure 5-5 Hose placement

Figure 5-6 Spill Tray Placement

Section 6 - User Setup

This section will describe the step-by-step process in creating tests containing multiple samples that may also require dilution schemes for specific immunoglobulins.

1. Turn the power on for the instrument by pressing the large silver button on the front of the instrument.

2. The Microsoft® Windows® program opens and displays the SPIFE Nexus icon.

3. Upon first use, a serial number must be entered. Right click and select, *Run as Administrator*.

4. The User Account Control will display prompting the user for an administrator name and password. After the password has been entered, the software will prompt the user for the serial number.

5. Once the serial number has been entered, this screen will not show again.

Note: *If the SPIFE Nexus is being used with the QuickScan Touch plus software and users were created, the logon prompt will be displayed. If QuickScan Touch plus will not be used in conjunction with the SPIFE Nexus, a User's icon will be included on the menu bar as well as the SPIFE Nexus Setup window. See Section 6.5 for more details.*

6. Once the software has initialized and the user has logged in, it will display a prompt to the operator stating, "*Priming is recommended at the beginning of each day as well as after refilling DI Water or Saline. Would you like to Prime?*" with *Yes* and *No* buttons.

　　a. Select *Yes* to prime the instrument.

　　b. Select *No* to proceed to the main menu.

7. The main menu will be displayed. There are six icons displayed on the menu bar:

Start, Stop, Prime, Unlock Door, Setup, Maint, and *About* (Figure 6-1).

8. Select *Setup*.

9. The *SPIFE Nexus Setup* window opens and displays three tabs: *Tests, Instrument*, and *Language.* There are also *OK* and *Cancel* buttons (Figure 6-2).

6.1. Tests

1. The *Tests* window displays all the current tests as well as options to *Edit, Add, Delete, Print, Export*, and *Import (*Figure 6-2)*.*

2. *Edit* - To edit an existing test, highlight the needed test and select *Edit.* The *Edit Test* window appears and contains the test name and its current parameters (Figure 6-3). See Sections 6.1.1 through 6.1.5 for instructions on using this window. Note that once a test has been edited and saved, the **new test will overwrite the original test.**

3. *Add* - To add a new test, select *Add* and the *Add Test* window (Figure 6-4) displays with blank fields (see Sections 6.1.1 through 6.1.5 for further detail).

4. *Delete* - To delete an existing test, highlight the needed test and select *Delete.* A *Confirm Delete* prompt displays:

　　a. Select *Yes* to delete the test.

　　b. Select *No* to retain the test.

Note: *Custom deleted tests cannot be restored after deleting. They can only be recreated using default settings and then altering the parameters back to the custom settings.*

5. *Print* – select to print the highlighted test's settings.

6. *Export* – select to export the highlighted test to another location.

　　a. The *Export Test* window will appear.

b. Select the location to save the test and click *Save*.

c. The window will close automatically and return to the *Tests* window.

7. *Import* - select to import a test from another location.

a. The *Import Test* window will appear.

b. Select the location where the test is located and select *Open*.

c. The window will close automatically and return to the *Tests* window.

8. Once all the tests have been set up and/or altered as desired:

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

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

i. 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*.

6.1.1. Test Type and Test Name

1. *Test Type* – On the *SPIFE Nexus Add Test* window, use the drop down list to select the appropriate test type. If editing, this step may be skipped. (Figure 6-5).

2. *Test Name* - Prior to naming the test, or altering specific parameters, click on the *Default Settings* button at the upper right of the screen. The appropriate default settings for the test type, and test type selected will automatically be displayed as the test name. The test name may be entered/altered as needed; however, each test setup must have a unique test name. The complete test name will automatically

include the name entered here, the maximum number of samples setup for this test as well as the stain type.
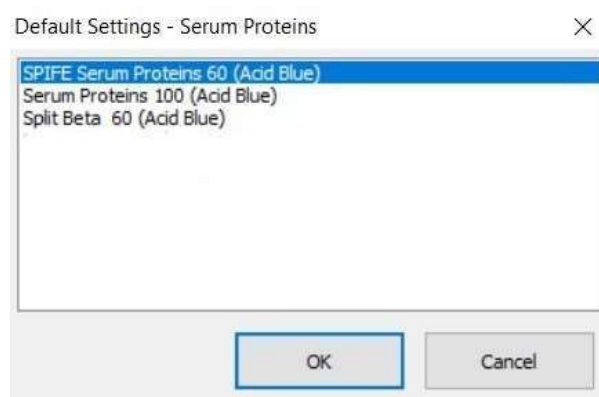
3. On the same screen, below *Test Type* and *Test Name*, there are three tabs; *Sample Loading* (Section 6.1.2), *Gel Preparation* (Section 6.1.3), and *Scan* (Section 6.1.4). Each of these contains menus for setting up test-specific parameters and processes.

Note: When naming a test, in order for the gel to be scanned in QuickScan Touch plus, the test name must be the same in both the SPIFE Nexus software as well as the QuickScan Touch software. The test name is <u>case-sensitive</u>.

6.1.2. Sample Loading

The following parameters may be altered as needed. Note that only parameters specific to the test type selected are available for modification. For example, dilutions are not a default setting for Serum Proteins.

1. When *Tests* is selected in the *Setup* menu, and the *Add (*or *Edit) Test* menu is opened, the *Sample Loading* tab is selected first by default.

a. *Sample Load Enabled* – enable to have the sample tray loaded with onboard samples pulled from the onboard test tube racks.

b. *Tray* – use the dropdown arrow to select the necessary sample tray.

c. Volumes – from this section, the volumes may be individually customized for each row.

d. Row – use the dropdown arrow to select the desired row.

e. *Required Volume (µL)* – the minimum volume required to be in the sample cup for the test to occur.

f. *Dispense Volume (µL)* – the volume dispensed into the sample tray before leaving the required volume behind.

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

h. *Primary Wash Cycles* – the number of washes between sample tubes.

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

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

k. *Samples Per Gel* – the number of samples per gel that will be processed.

l. *Lanes Per Sample* – the number of lanes per sample.

m. *Dilution Mix Cycles* – select the number of times to have the system aspirate and dispense the dilution mix. This feature is only available for Immunofixation Electrophoresis (IFE) tests.

n. *Cover gel while loading sample* – select *Yes* for the platen cover to be placed over the gel while the sample tray is being loaded to prevent the gel from drying out.

o. *Dilutions* – Dilutions are available only with Immunofixation Electrophoresis (IFE) tests.

i. Dilutions may be individually set for each sample (or for the entire row by clicking on the header and highlighting the column) and each specificity. Available dilutions are Neat; 1 in 2; 1 in 3; 1 in 4; 1 in 5; 1 in 6; 1 in 7; 1 in 8; 1 in 10; 1 in 12; 1 in 14; 1 in 16; 1 in 18, and 1 in 20 (Figure 6-6).

6.1.3. Gel Preparation

The Gel Preparation tab allows the user to customize the different operations for the gel, such as Sample Application or Electrophoresis Time creating a unique testing process.

6.1.3.1. Stain Type

Stain Type – Using the dropdown menu, select from the following stain types: *Acid Blue, Acid Violet, Amido Black, Fat Red 7B, Fetal Tek,* or *Ponceau S*.

6.1.3.2. Gel Preparation Processes

From this section, gel processes can be added or deleted and then reordered depending on the necessary requirements.

1. *Add* – select to add a new process to the test chronologically. The *Add Gel Preparation Process* window will appear with the processes detailed in 6.1.3.2.1 through 6.1.3.2.11 (Figure 6-7).

2. *Insert* – select to add a new process at a selected place. The *Insert Gel Preparation Process* window will appear with the processes detailed in 6.1.3.2.1 through 6.1.3.2.11 (Figure 6-8).

3. *Delete* – To delete an existing process, highlight the unneeded process and select *Delete*. A *Confirm Delete* prompt displays:

a. Select *Yes* to delete the process.

b. Select *No* to delete the process.

4. *Move Up* – select to move the highlighted process up in the list.

5. *Move Down* – select to move the highlighted process down in the list

6.1.3.2.1. Applicator Load

Enter the parameters to configure how a sample tray will be loaded with samples removed from the onboard test tubes.

1. *Applicator Load Enabled* – select *Yes* to have the instrument automatically load the sample tray or *No* to add a manually preloaded sample tray.

2. *Applicator Load Time (mm:ss)* – the length of time the blade remains immersed in the sample.

3. *Applicator Load Speed (mm/ss)* – the speed at which the blade is removed from the sample (measured in millimeters per second).

4. *Application Load Offset (mm from center)* – set to center the blades over the sample wells. Selecting a positive number will move the blades toward the front of the machine, while selecting a negative number moves the blades toward the back of the instrument. The default value is 0.

6.1.3.2.2. Sample Application

Enter the parameters to configure how sample will be applied to the gel.

1. *Sample Application Enabled* – select *Yes* to have sample applied to the gel or *No* if sample application is not necessary.

2. *Apply Time (mm:ss)* – the length of time the blades remain in the gel.

3. *Absorption Time (mm:ss)* – the length of time the gel is allowed to sit after sample has been applied.

4. *Application Offset (mm from center)* – set to center the blades over the gel. Selecting a positive number will move the blades toward the front of the machine, while selecting a negative number moves the blades toward the back of the instrument. The default value is 0.

6.1.3.2.3. Electrophoresis

Enter the parameters to configure how electrophoresis will occur.

1. *Electrophoresis Enabled* – select *Yes* to enable electrophoresis or *No* to disable this process.

2. *Operating Mode* – select from *Constant Voltage, Constant Current,* or *Constant Power.*

Note: *Currently, only Constant Voltage is available for use.*

3. *Voltage (volts)* – set the required voltage to be applied during electrophoresis.

4. *Temperature (°C)* – set the platen temperature to be maintained during electrophoresis.

5. *Time (hh:mm:ss)* – set the length of time for electrophoresis to occur.

6. *Safety Limits* - Set the performance limits for the test using the arrows to make the required selection. If the instrument should fall outside these limits, the run will be aborted.

a. *Minimum Voltage (volts) – the minimum voltage allowed for the test to continue.*

b. *Maximum Voltage (volts) – the maximum voltage allowed for the test to continue.*

c. *Minimum Current (mA) – the minimum current allowed for the test to continue.*

d. *Maximum Current (mA)* – the maximum current allowed for the test to continue.

e. *Minimum Temperature (°C)* – the minimum temperature allowed for the test to continue.

f. *Maximum Temperature (°C)* – the maximum temperature allowed for the test to continue

6.1.3.2.4. Fixative /Antiserum Application

Enter the parameters to configure how fixative will be applied onto the gel.

1. Fixative / Antiserum Application Enabled – select *Yes* to have reagent applied to the gel or *No* to bypass this process.

2. *Absorption Time (mm:ss)* – the length of time the gel is allowed to rest after reagent is applied.

3. *Lane 1 Position (mm from calibration point)* – the offset point (from left to right) from the calibration point.

4. Row 1 Start (mm from calibration point) – the starting point (from back to front) of the lane where the antiserum application begins.

5. *Row 1 End (mm from calibration point)* – the ending point (from back to front) of the lane where the antiserum application ends.

6. *Lane to Lane Spacing (mm)* – the center lines spacing between the lanes.

7. *Row to Row spacing (mm)* – the distance between rows, measured from center line to center line.

8. Application Position Check –

a. Select from the following dropdown menu options:

i. *Row 1 Lane 1 Start*

ii. *Row 1 Lane 1 End*

iii. *Last   Lane*

iv. *Last Row End*

b. *Move To* – click to move to the selected application position to verify correct position.

c. *Home* – click to return the pipette to the Home position.

d. Apply Settings – select to view more

6.1.3.2.5. Reagent / Stain Application

Enter the parameters to configure how reagent will be applied to the gel.

1. *Reagent / Stain Application Enabled* – select *Yes* to have the stain reagent dispenser apply stain to the gel or *No* for no stain application.

2. *Spread Cycles* – select the number of times to have the roller spread stain across the gel. A full spread cycle involves rolling from the top gel block to the bottom and back.

3. *Half Spread Cycle* – select *Yes* to have the roller finish in the middle of the gel or *No* to have the roller continue to the top gel block.

4. *Temperature (°C)* – set platen temperature to be maintained during stain application.

5. *Absorption Time (hh:mm:ss)* – the length of time the gel is allowed to rest after stain is applied.

6. *Pour Position (mm from cal point)* – the position where the stain is poured onto the gel.

7. *Spread Start (mm from cal. point)* – the position where the roller begins to spread the stain.

8. *Spread Length (mm)* – the total distance the roller will travel to spread the stain across the gel.

9. *End of Roll Pause (sec)* – enter the number of seconds for the roller to pause after stopping.

6.1.3.2.6. Pre-Dry / Incubate

Enter the parameters to configure how the gel will be pre-dryed.

1. Incubate / Pre-Dry Enabled – select *Yes* to Pre-dry the plate or *No* if it is not necessary.

2. *Temperature (°C)* – set the platen temperature to be maintained during the Pre-Dry process.

3. *Time (hh:mm:ss)* – set the length of time for Pre-Dry to occur.

6.1.3.2.7. Wash / Destain

Enter the parameters to configure the wash cycles. For the SPIFE Nexus, there is one vat, but multiple wash processes can be set up by selecting the process type below in Step 1.

1. Process type – choose from *DI Water Wash, Buffer Wash,* or *Destain.*

2. *Wash / Destain Enabled* – *Yes* to include a Wash/Destain step or *No* to not include any wash or destain cycles.

3. *Recirculate* – select from the dropdown menu:

a. *No Recirculate* – the vat is filled only and then drained, allowing the fluid to remain motionless.

b. *Recirculate Bottom to Top* – the fluid is kept moving by pumping it from the top of the vat to the bottom; causing the fluid in the vat to travel from the bottom to the top

c. *Recirculate Top to Bottom* – the fluid is kept moving by pumping it from the bottom of the vat to the top; causing the fluid in the vat to travel from the top to the bottom.

4. *Recirculation Speed* – use dropdown menu to set speed from 1 to 10.

5. *Time (hh:mm:ss)* – set the length of time for the Wash / Destain process.

6. *Pulse Cycles* – use the up and down arrows to select the number of pulse cycles to include. A pulse cycle is when the Nexus switches the direction of the fluid in the vat and creates a "pulse".

7. *Pulse Time(sec)* – enter the number of seconds for the Nexus to "pulse" the fluid.

6.1.3.2.8. Dry

Enter the parameters to configure how the plate will be dried.

1. *Dry Enabled* – select *Yes* to move the plate to the dryer chamber or *No* to not dry the plate.

2. *Temperature (°C)* – set the dryer chamber temperature to be maintained during the Dry process.

3. *Time (hh:mm:ss)* – set the length of time for the Dry process.

6.1.3.2.9. Blot

Enter the parameters to configure blotting the gel.

1. *Blot Enabled* – select *Yes* to have the gel blotted or *No* for no blotting.

2. *Temperature (°C)* – set platen temperature to be maintained during blotting.

3. *Time (hh:mm:ss)* – set the required length of time for the gel to be blotted.

6.1.3.2.10. Manual Process

This has been incorporated to give the user the freedom for assay development. Enter the parameters to configure the process.

1. *Manual Process Enabled* – select *Yes* to include a manual process in the test or *No* for no manual process to be included.

2. *Process Name* – add a descriptive name for the process.

3. *Start Message* – the message that will be displayed when it is time for the manual process to occur.

4. *Time (hh:mm:ss)* – the length of time the manual process is allotted. This time begins after the user clicks or taps *OK* in the start message to alert the Nexus the process has been started.

5. *End Message* – the message that will be displayed when the manual process has ended. To proceed, the user closes out whatever they were doing, shuts the machine door, and clicks *OK* to proceed to the next step of automation.

6.1.4. Scan

Select *Yes* to enable plate scanning or *No* for the plate to not be scanned (Figure 6-9).

6.1.5. Pre-Start Checklist

A checklist, specific to the test selected, can be displayed before the test starts to help the user ensure all the necessary supplies have been collected and placed onto the instrument (Figure 6-10).

1. *Show Pre-Start Checklist* – select *Yes* to have the Pre-Start Checklist display before the test begins or *No* to skip it. For example, a serum protein run could include the following:

- DI water reservoir full
- Stain loaded into the stain reagent dispenser
- Stain roller loaded onto the stain reagent dispenser
- Serum protein applicator with blades loaded
- Blade template placed on applicator

- Blade weights placed
- Consumables Tray pushed into place
- Bottom part of cassette placed on electrophoresis platen
- DI Water added to platen
- Gel removed from clamshell and blotted
- Gel placed on platen over DI Water and aligned on pins
- Top portion of cassette holder placed on top of the bottom portion, locking in place magnetically
- Sample cups are placed into sample tray
- Sample tray is placed on the sample tray platform, aligned with pins
- Sample tubes loaded into tube transport area

6.1.6. Instrument Setup

From this tab, the required consumables for the test are listed. Default settings will auto populate these fields (Figure 6-11).

1. *Cassette* – select from the following:

   a. *C01: Standard Cassette*

   b. *C02: Quick Gel Cassette*

2. *Applicator Template* – select from the following:

   a. *A01: IFE 3, 6, 9 / CK / SPE / Split Beta (60)*

   b. *A02: LD / Alkaline Phosphatase*

   c. *A03: Acid HB / SPE HiRes (20) / QG Alk HB / QG Cholesterol / QG Lipo*

   d. *A04: IFE (15) / Split Beta-100 / Cholesterol*

   e. *A05: Lipoprotein*

f. *A06: QG (CK, IFE, LD, SPE, Split Beta, Acid HB)*

g. *A07: A1AT*

h. *A08*: *Alkaline HB*

3. *Reagent Applique* – select from the following:

a. *R01: Antisera Storage*

4. *Electrophoresis Plate* – select from the following:

a. *E01: Standard 2 Carbon Electrodes*

b. *E02: Standard 1 Carbon, 1 Stainless electrode*

c. *E03: Quick Gel*

5. *Blotter Holder* – select from the following:

a. *B01: Standard Blotter*

b. *B02: Quick Gel Blotter*

6.1.7. OK and Cancel

1. OK - to save all the changes made and return to the Setup menu, select *OK.*

2. Cancel - to exit setup without saving any changes made, select *Cancel.*

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

i. To exit without saving changes, select *Yes.*

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

6.2. Instrument

This tab allows the user to customize error and status messages (Figure 6-12).

1. *Sample ID for no tube* – the text to be displayed if no tube is detected.

2. *Sample ID for no bar code* – the text to be displayed if no sample ID is detected

3. *Platen idle temperature (°C)* – the idle temperature of the electrophoresis platen.

4. *Reagent Chiller* – select *On* to initiate the reagent chiller or *Off* to disable the reagent chiller.

5. *Interior Lights* – select *On* to turn on the Interior Lights or *Off* to disable the Interior Lights.

6. *Status Indicator Lights* – customize which warning lights to enable and be shown on the status light.

a. *Show Red on Error* – select *Yes* to show red for a critical error or *No* for no light to be displayed.

b. *Show Yellow on Warning* – select *Yes* to show yellow for a warning message or *No* for no light to be displayed.

c. *Show Blue on Attention Required* – select *Yes* to display blue when a material or item is required or *No* for no light to be displayed.

d. *Show Green when Running* – select *Yes* to display green for when the status is satisfactory or *No* for no light to be displayed.

e. *Flash Green on Test Completion* – select *Yes* to flash green for when the current run has been completed or *No* for no light to be flashed.

7. *Alarm Volume* – use the slide bar and select from 0 to 100 for the alarm volume.

6.3. Language

All available languages are displayed. At this time, only English is available (Figure 6-13).

6.4. Unlock Door

A safety interlock feature automatically locks the main instrument door when it is off as well as when the door has been shut.

Select to unlock the main door of the instrument.

6.5. About

The *About* icon displays all the current information for the SPIFE Nexus instrument, including the software version and Helena Laboratories contact information (Figure 6-14).

6.6. Users

In the event the SPIFE Nexus will not be used with Helena's QuickScan Touch *plus* software, users and passwords may still be created. If this is the case, the display will have a slightly different look to it (Figure 6-15).

After double clicking the SPIFE Nexus icon on the desktop, the instrument will display the SPIFE Nexus Sign In window. Log into the software using the default username 'Administrator' and the password 'Adm1n'.

SPIFE Nexus Sign In

User Name: Administrator

Password:

☐ Keep me signed in until I sign out.

Sign In   Exit Program

Located on the Main Menu bar is the *Users* icon. Selecting it will display which user is currently logged into the system.

SPIFE Nexus User   ✕

User 'Administrator' is signed in.

Sign Out   Close

Selecting *Sign Out* will sign out the current user and display the *Sign In* window again.

Selecting *Close* will close the dialog box and return to the Main Menu.

6.6.1. User setup

1. From the Main Menu, select *Setup*.

2. The *SPIFE Nexus Setup* window opens and displays four tabs: *Tests*, *Sample trays*, *Instrument*, *Language,* and *Users.* There are also *OK* and *Cancel* buttons.

3. Select the *Users* tab (Figure 6-16). The Users tab is displayed as well as options to *Edit, Add, Delete*, and *Print*. Any current users will be listed.

4. *Edit* - To edit an existing user, highlight the needed user and select *Edit*. The *Edit User* window appears and contains the test name and its current parameters (Figure 6-17).

    a. *User Name* – enter the desired user name.

    b. *Password* – enter the desired password.

    c. *This user has permission to* – select each of the following which will apply to the current user

        i. *Change Setup*

        ii. *Change Calibration*

        iii. *Clear Log Files*

        iv. *Setup Users*

5. *Add* - To add a new user, select *Add* and the *Add User* window (Figure 6-18) displays with blank fields.

    a. *User Name* – enter the desired user name.

    b. *Password* – enter the desired password.

c. *This user has permission to* – select each of the following which will apply to the current user.

      i. *Change Setup*

      ii. *Change Calibration*

      iii. *Clear Log Files*

      iv. *Setup Users*

6. *Delete* - To delete an existing user, high-light the needed user and select *Delete*. A *Confirm Delete* prompt displays:

    a. Select *Yes* to delete the user.

    b. Select *No* to retain the user.

7. *Print* – select to print the highlighted user name and information.

8. When the editing is completed:

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

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

      i. 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.*
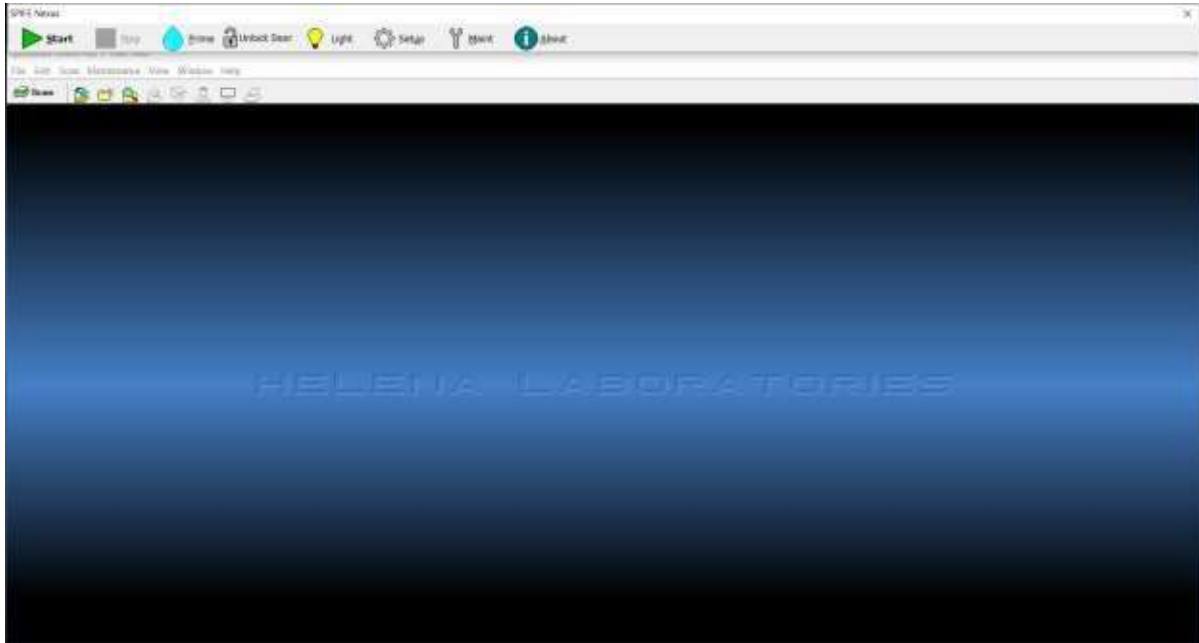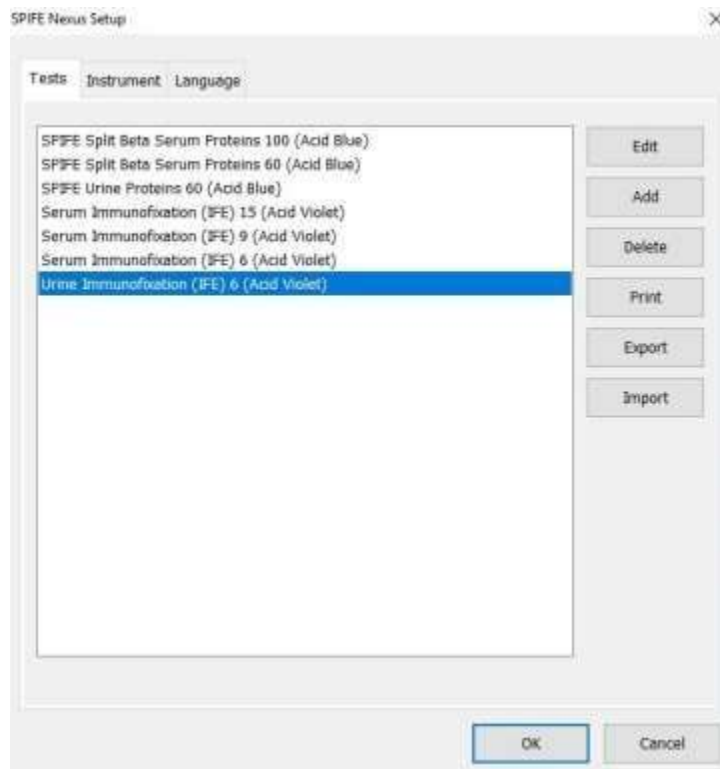
Figure 6-1 Main Menu
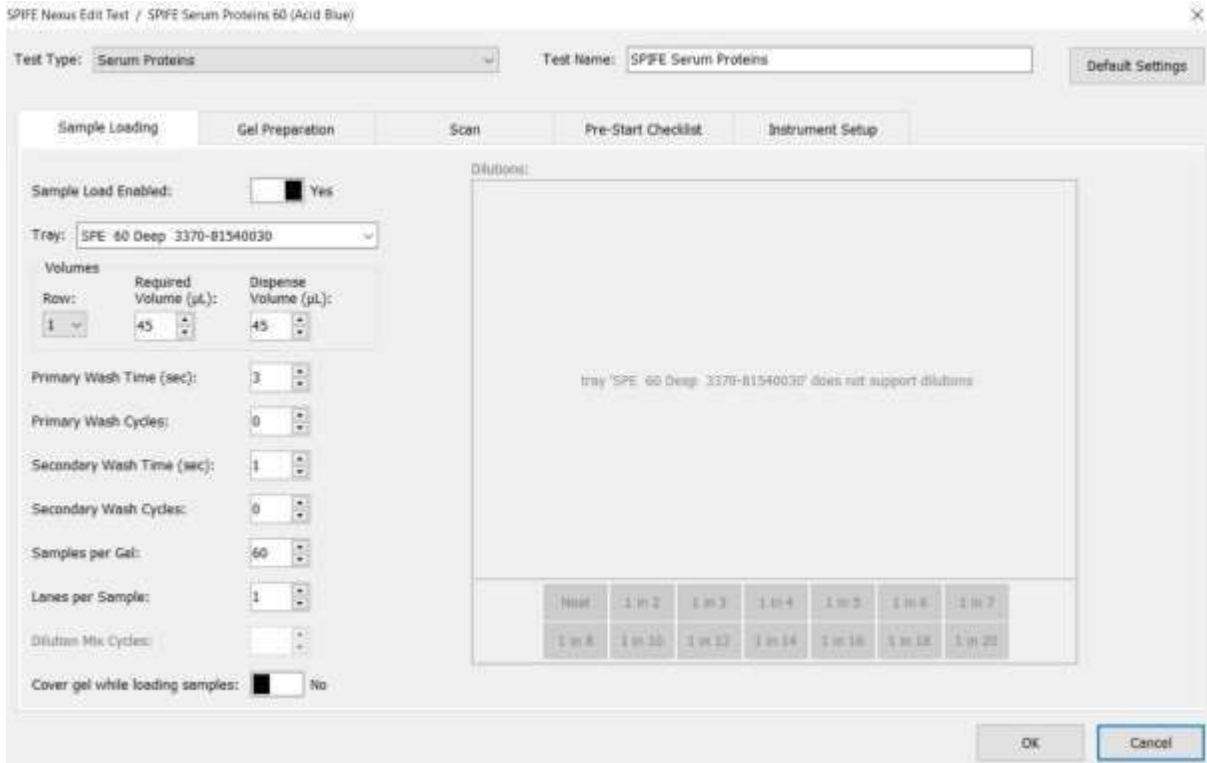

Figure 6-2 SPIFE Nexus Setup, Tests

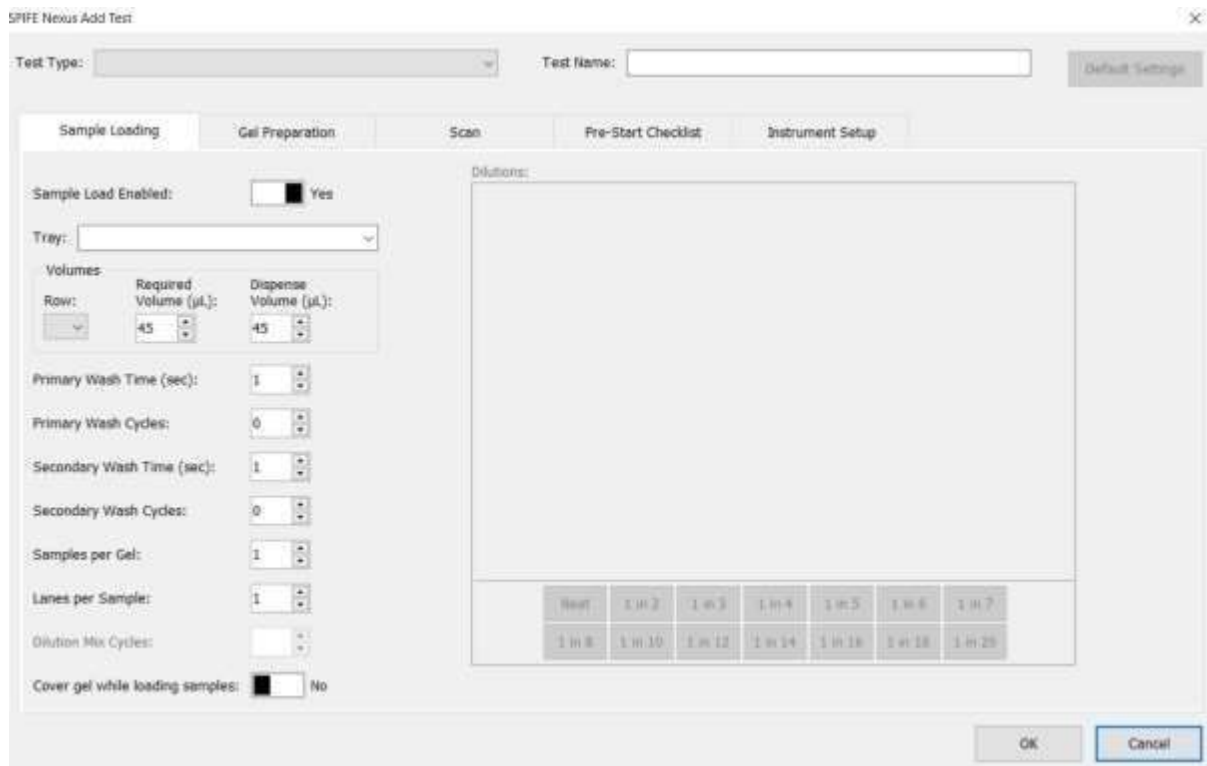**Figure 6-3 SPIFE Nexus Setup, Edit Test**

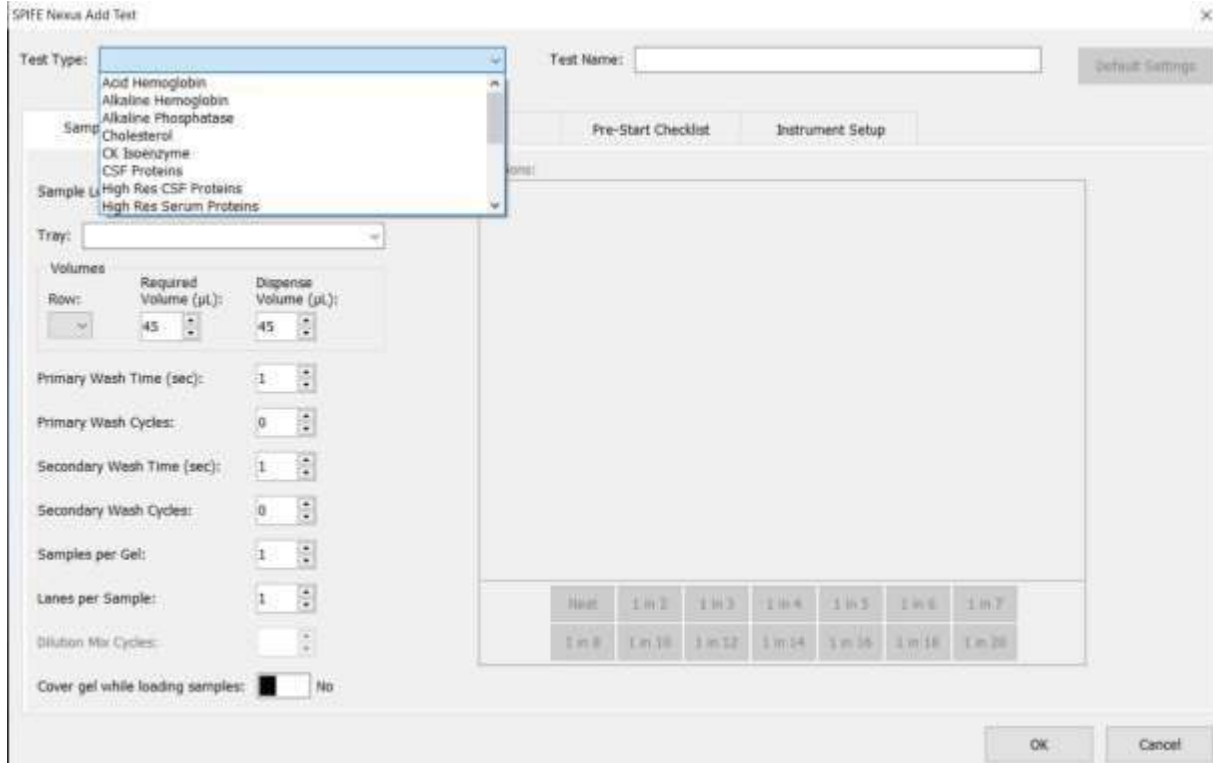

Figure 6-4 SPIFE Nexus Setup, Add Test

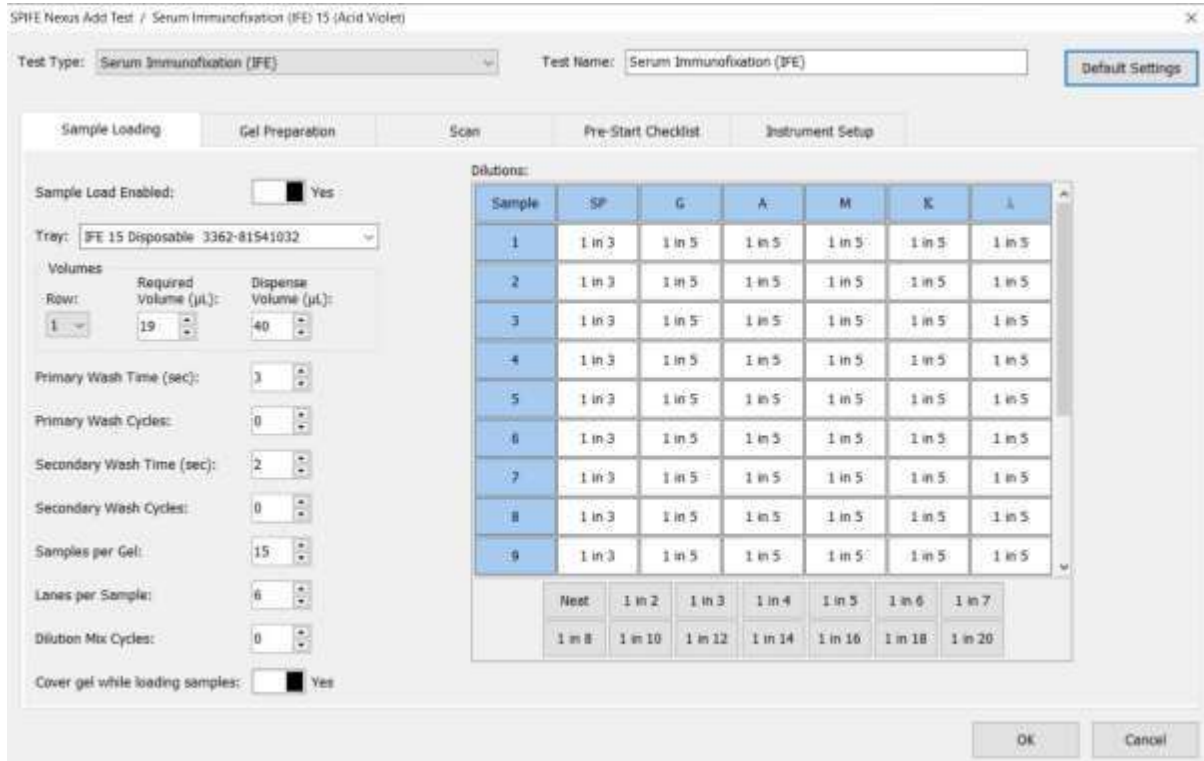**Figure 6-5 Add window with dropdown menu**

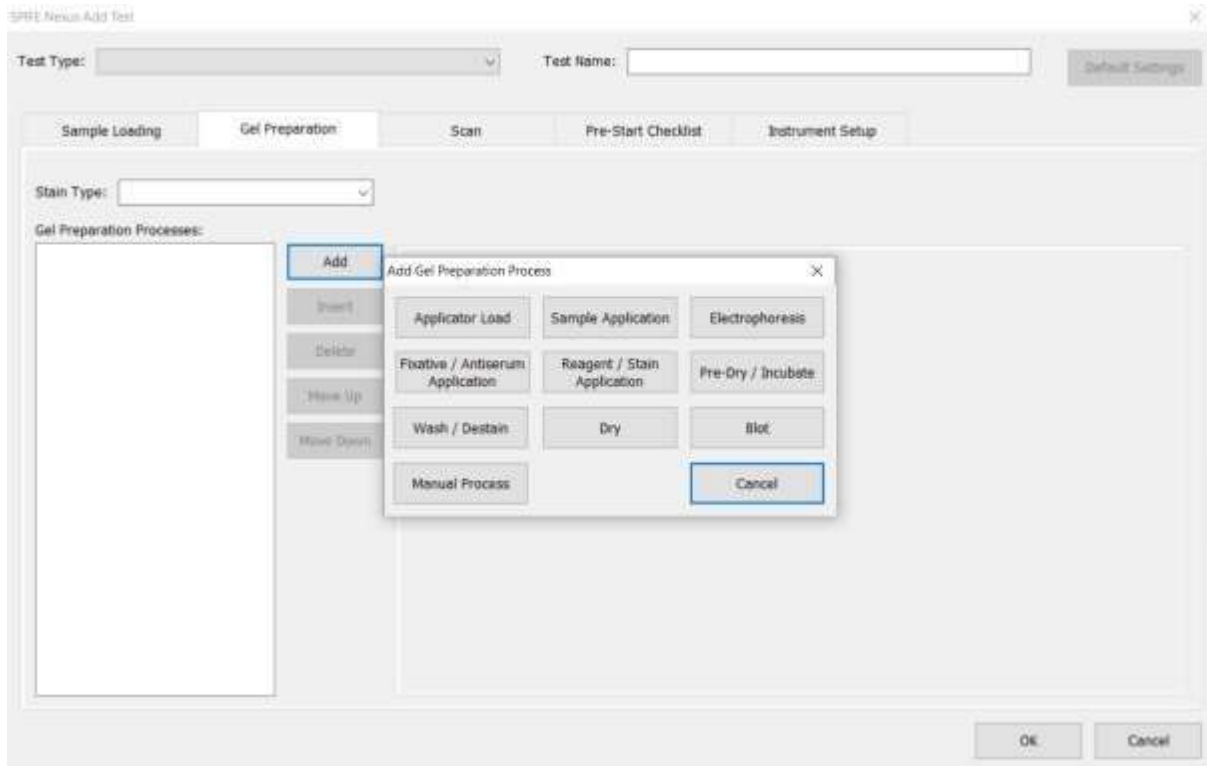**Figure 6-6 Add window, IFE**

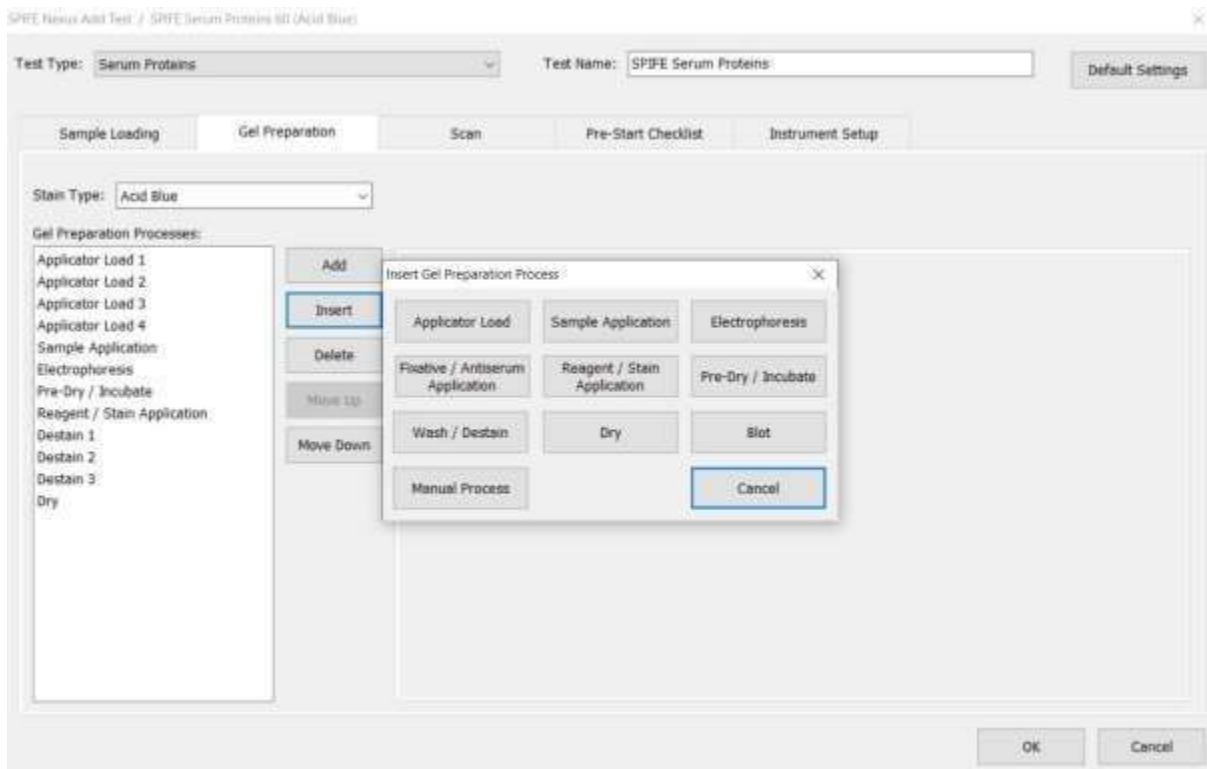**Figure 6-7 Add Process Option Block**
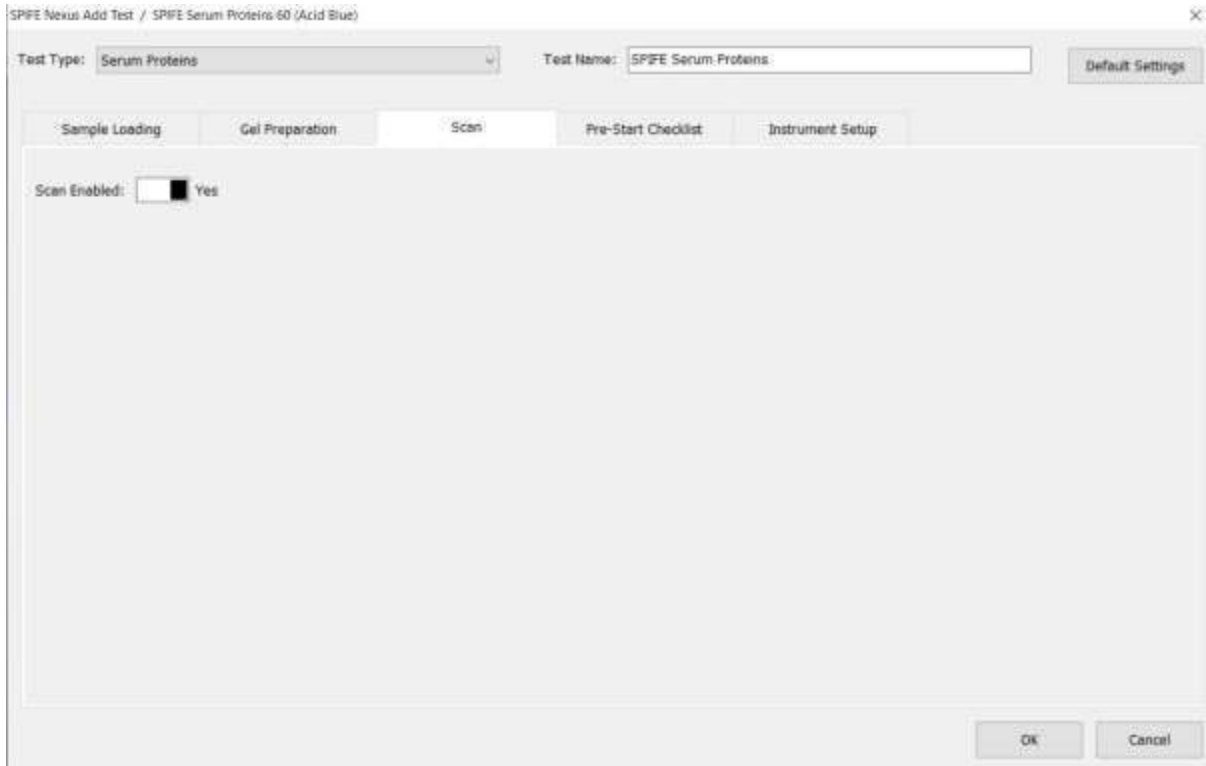

Figure 6-8 Insert Gel Prep Process
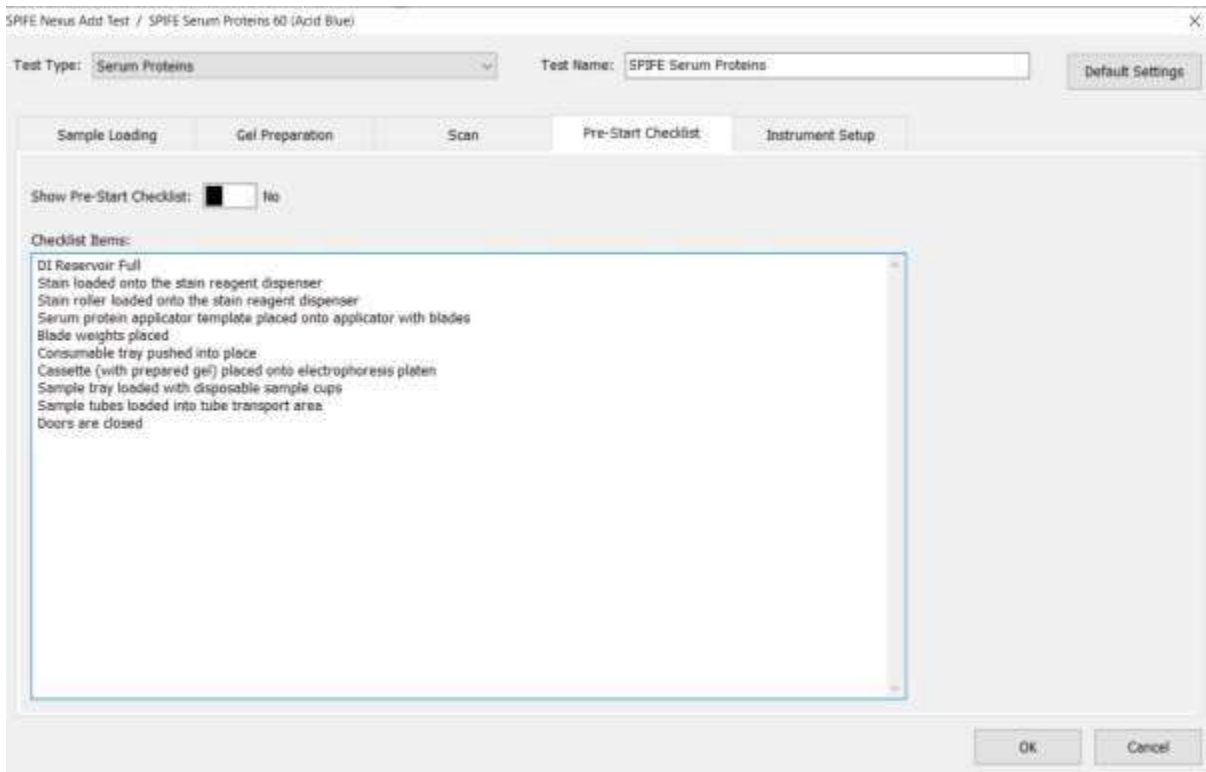
Figure 6-9 Scan

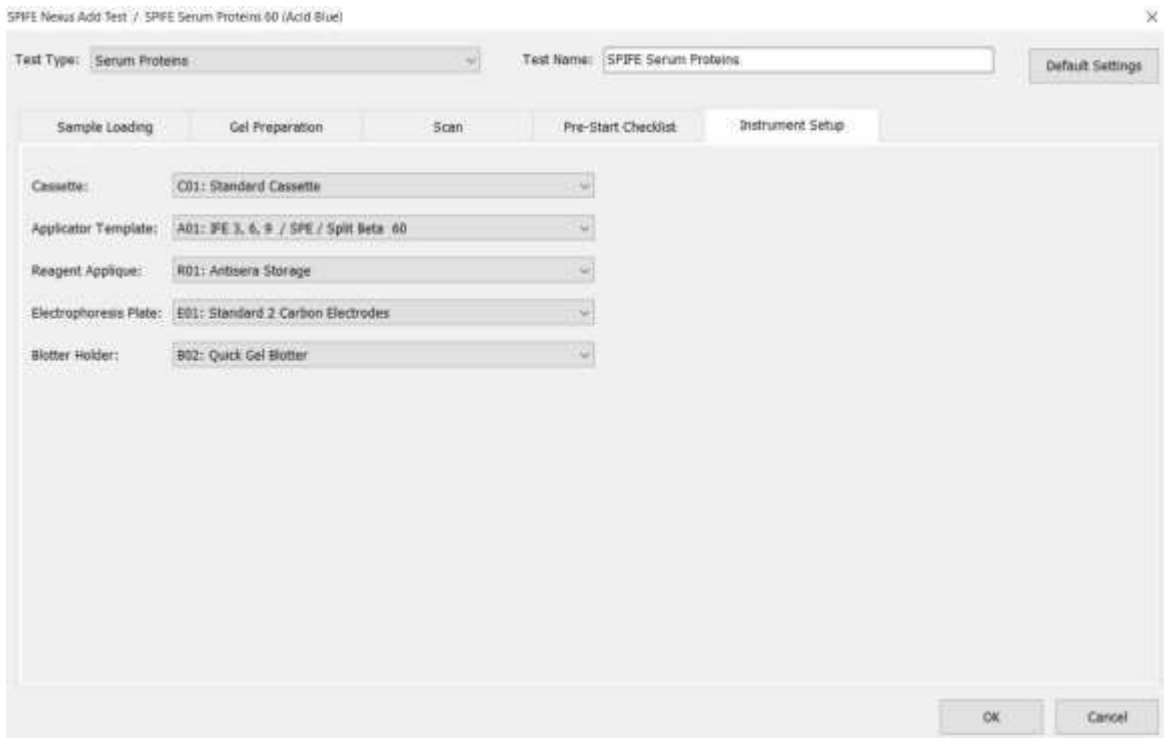

Figure 6-10 Pre-Start Checklist
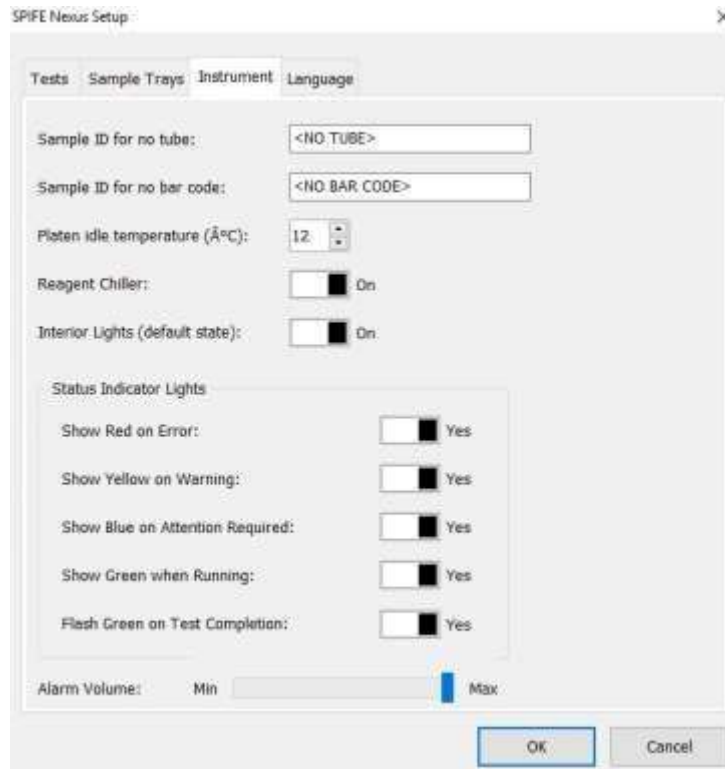
Figure 6-11 Instrument Setup
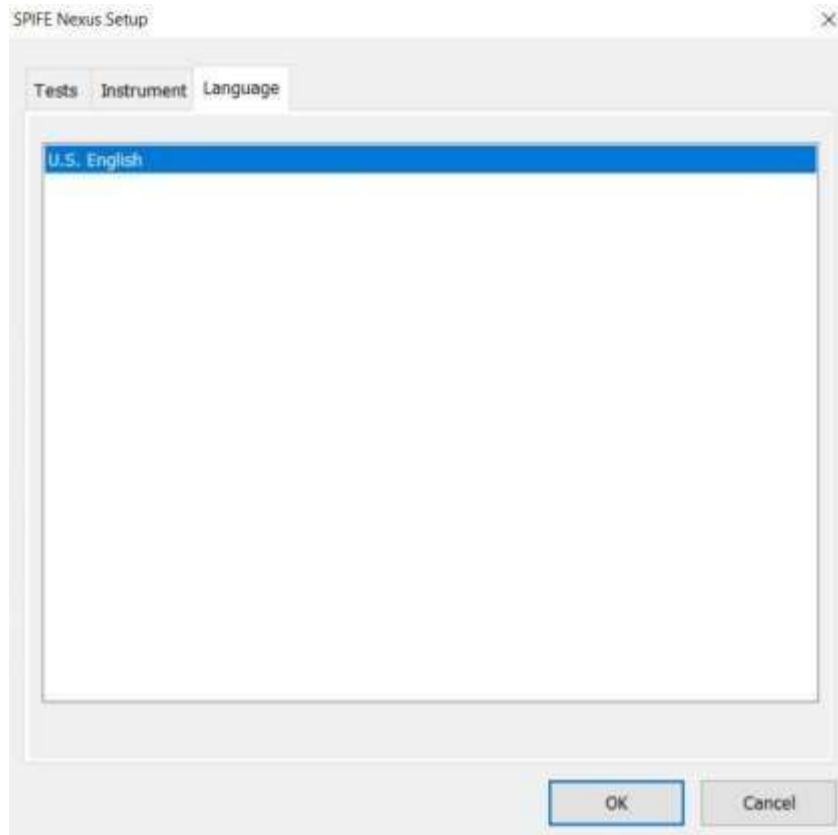

Figure 6-12 Instrument

Figure 6-13 Language
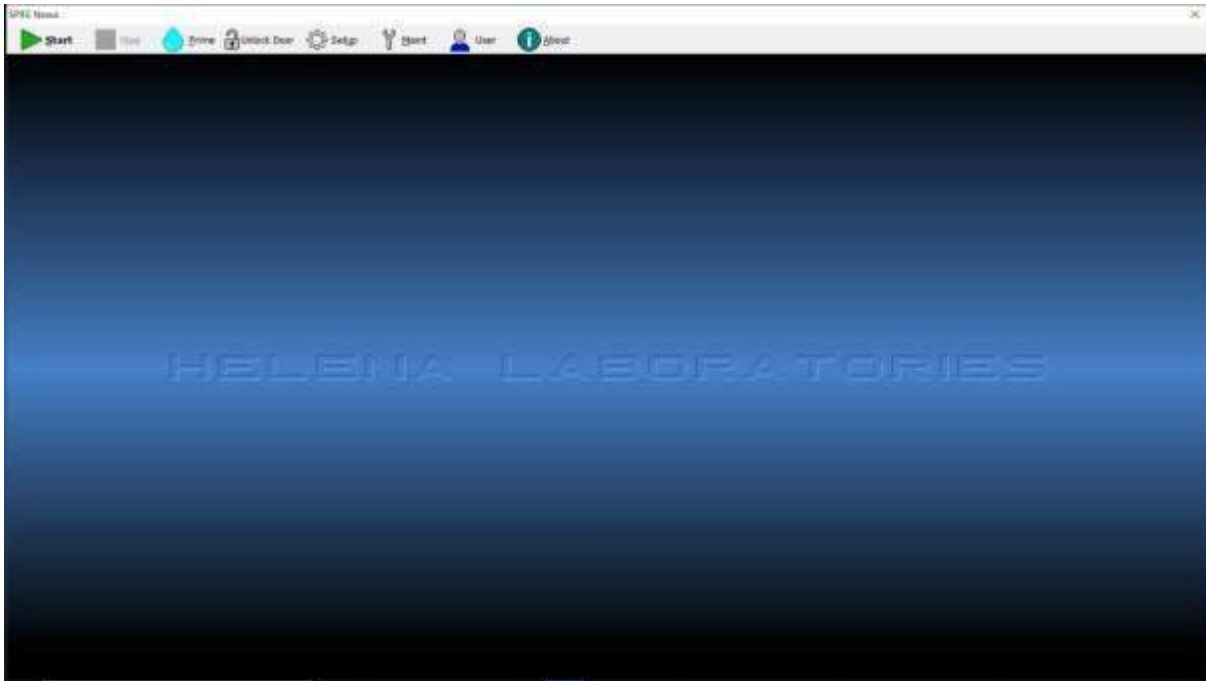

Figure 6-14 About

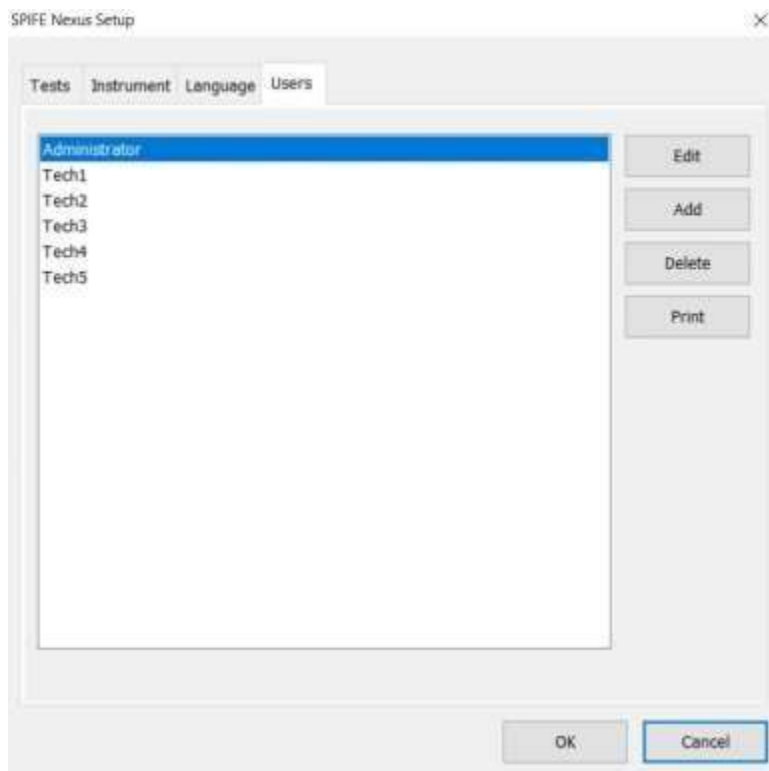**Figure 6-15 Main Menu with Users Icon**
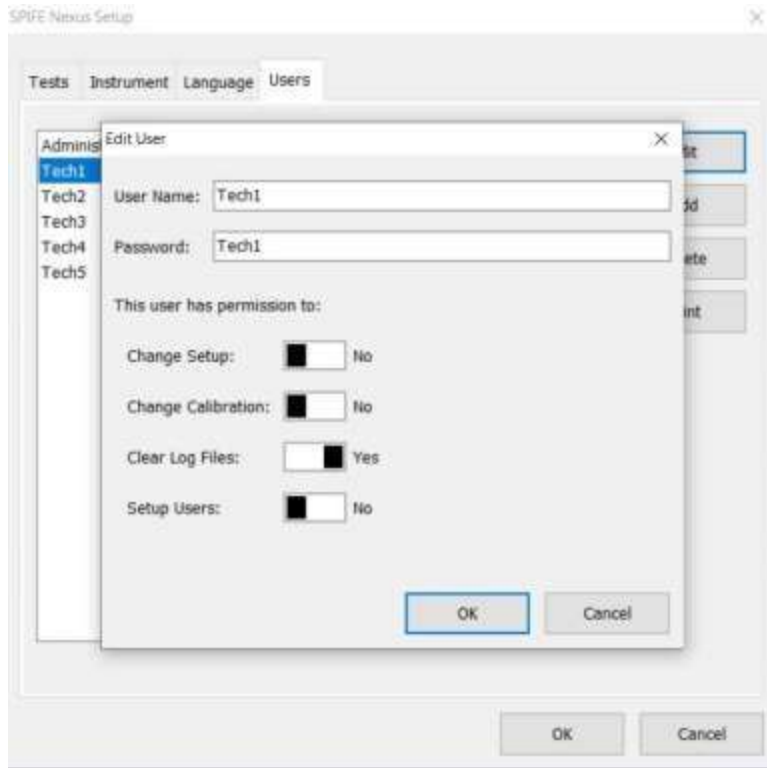

Figure 6-16 Users
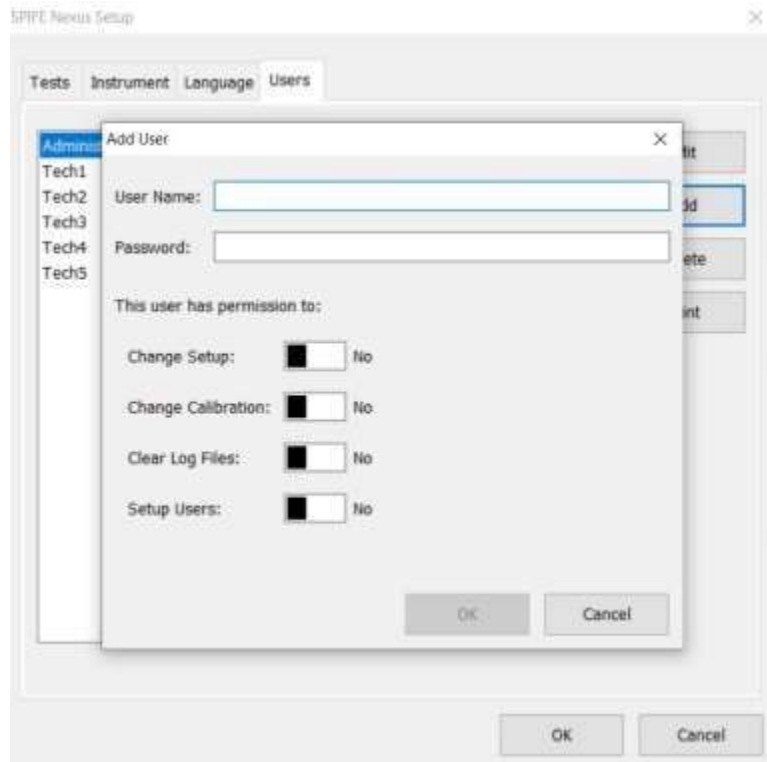
Figure 6-17 Edit Users

Figure 6-18 Add Users

Section 7 - Operating Instructions

CAUTION: Do not attempt to operate this instrument until after manual has been read. This includes Section 4, which incorporates safe biohazard practices.

If the system has not been set up, go through Section 6 before proceeding. Proceeding without completing test and instrument setup may result in difficulty in completing the instructions contained in this section. This section is a broad overview of a typical run. The later sections will be test oriented and describe in detail how to execute a run of that test type.

When the power is off, a safety interlock feature locks the main instrument door. To access the inside of the instrument, it must be turned on first.

To power on the instrument, first switch on the main power on the left hand side of the instrument. Once the large silver button on the front of the instrument begins to glow red, press it to turn on the instrument. The Microsoft® Windows® program will open and displays the SPIFE Nexus icon.

*Note: Do not power **off** the instrument using the side switch on the left hand side. This is for emergency shut off only.*

Double click the SPIFE Nexus icon and the QuickScan Touch *plus Sign In* window will appear.

Enter the default User name of 'Administrator' and a default password of 'Adm1n' if another username and password have not already been created in the QuickScan Touch *plus* software.

Note: If QuickScan Touch plus will not be used in conjunction with the SPIFE Nexus, a separate option will be available to set up users and passwords. See Section 6.6 for further detail.

If the main menu (Figure 7-1) appears on the monitor, the system is operating correctly. If an error message appears, or the instrument does not perform as described in this manual, refer to the message, and perform the actions required in the message. For further assistance, or if the error recurs, record the message and call Helena Laboratories (Section 10.2 - Troubleshooting).

Note: Once the software has initialized and the user has logged in, it will display a prompt to the operator stating, "Priming is recommended at the beginning of each day as well as after refilling DI Water or Saline. Would you like to Prime?" with Yes and No buttons.

If the instrument will not be in use for an extended period of time (one or more shifts), the computer should be turned off.

Exit the SPIFE Nexus software by clicking the X in the upper right hand corner. Once the Nexus software is closed, power off the computer by selecting the *Windows* icon in the bottom left hand corner, then selecting the *Power* icon, then the *Shut down* icon.

If the instrument is in continuous use, exit the SPIFE Nexus software and reboot the computer on a daily basis.

Once a run is started, a black circle will be displayed in the middle of the screen with the name of the test being executed as well as the estimated time remaining.

A green circle will track clockwise around the outer edge of the black circle in relation with the *Estimated Time Remaining*.

Displayed below the *Estimated Time Remaining* is the *Current Process*. This displays the process that is actively occurring. A blue circle will track clockwise in relation with the progress of the current process. Below it, the *Time Remaining* for it is displayed as well as the current action of the instrument and/or temperature.

A *Stop* button is at the bottom of the black circle. If *Stop* is selected, the instrument will prompt the user with, "*All processing for gel 1 will be stopped. Are you sure you want to stop gel 1?*" as well as *Yes* and *No* buttons. Selecting *No* will cancel the Stop action and the instrument will continue to process the gel. Selecting *Yes* will stop the run immediately.

7.1. Overall Preparation for Instrument Operation

Note: The following sections will provide detailed steps for preparing the different types of tests. This section is more of a broad overview for preparing the instrument for a run.

1. If the TBS Wash, or Destain run low during a run, an error message will prompt the user to add more and the instrument will pause all operations. The instrument will remain paused until the operator prompts continue. **Be sure to correct the error before responding to the message**.

Note: Ensure that there are no air bubbles in the tubing lines.

2. Port 6 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.

3. The system will detect an incorrect sample tray type as well as an incorrect applicator blade template by scanning the barcodes on both of them and alerting the user with an error message.

4. When using bar codes, position the test tubes in the test tube rack so that the bar code label is positioned facing out of the vertical slot of the test tube rack (Figure 7-12). Ensure that the entire bar code label is visible in the vertical slot and the tube is straight up and down**.**

5. Each test tube rack holds ten tubes and the SPIFE Nexus can hold up to 10 racks at a time for a maximum load of 100 samples. Position 1 is the back left corner. The instrument 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.

6. Load the samples in the test tube rack in the same order as listed on the corresponding QuickScan Touch *plus*'s worklist, **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.

Note: Ensure 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 7-11)

7. Low Sample volume: If there is insufficient sample volume (less than 500 µl) for a urine Immunofixation test, 20 µl of sample may be pipetted by hand into the sample cups. The sample cups would then be placed into the instrument, and the urine IFE test programmed as usual with the exception of **not** checking the sample preparation option.

8. Operators must follow all instructions within the manual regarding priming the instrument, monitoring fluid levels, and cleaning. Failure to perform these maintenance procedures and monitor fluid levels could result in possible carryover by contamination from one sample to another or compromised results.

Note: Before starting any test, remove any unnecessary pieces from the Consumables Tray.

7.1.1. Running a Split Beta Plate

1. If the SPIFE Nexus software is not already open, double click on the desktop icon and log in.

2. Verify levels of waste, DI water, saline, wash, and destain are sufficient to process the plate.

3. Place the tube racks into the tube transport area and close the door.

Note: Do not open lower door while sampling of the patient tubes is occurring. Failure to do so may result in a software error and a possible loss of patient barcodes.

4. Remove the Consumables Tray from the SPIFE Nexus and use it to collect the following items for the run.

    a. Gel

    b. Stain

    c. Applicator Blade(s)

    d. Reagent Roller

    e. Disposable Stain Cups

    f. Blade Weights

    g. Blade Template

    h. Gel Cassette

    i. Sample Tray

    j. Disposable Sample cups

    k. IFU associated with test

    l. Rep Prep

5. Verify the IFU matches with all the following steps. If it deviates, defer to the IFU.

6. Place the three stain cups in the stain reagent dispenser and pipet 700µl of SPIFE Nexus Blue stain into each of the cups.

7. Place the roller on the Stain / Reagent dispenser.

8. Place the Applicator Blade Template over the top of the Blade Holder with the barcode to the left hand side.

9. Place the Applicator Blades into the designated slots of the Applicator assembly. The grooves on the sides of the blades should face the back of the instrument and be fully seated.

10. Place an Applicator Blade weight on top of each Applicator Blade. When placing the weight on the blade, position the weight with the thick side to the front.

11. Replace Consumables Tray ensuring the tray is firmly pushed into the correct position.

12. Place the bottom part of the magnetic two-piece Gel Cassette onto the electrophoresis platen.

13. Slide the Disposable Sample Cups into the sample tray, ensuring they are fully inserted into the tray.

14. Place the sample tray onto the SPIFE Nexus sample tray platform. Align the holes in the tray with the pins on the instrument.

15. Open the outer gel package. Open the inner clamshell, remove plastic film covering gel surface and place a blotter on top of the gel surface. Gently blot the gel per the directions detailed in the associated IFU. Dispose of the blotter afterwards.

16. Using a dropper, place approximately 2 ml of Rep Prep across the left side of the electrophoresis platen.

17. Place the left edge of the gel over the Rep Prep aligning the round hole on the upper pin of the cassette. Gently lay the gel down on the Rep Prep, starting from the left and ending on the right side fitting the obround hole over the lower pin. Make sure no bubbles remain under the gel.

18. Place a Positive ID barcode label (Cat. No. 1696) on the upper right hand side of the gel (Figure 7-9). Select the barcode that starts with a "G".

19. Place the top portion of the cassette holder on top of the gel with the 2D barcode in the upper right hand corner. It should snap together magnetically.

20. Close the main lid of the instrument.

21. Select the START icon on the touchscreen. The *SPIFE Nexus Run* window appears (Figure 7-2).

7.1.1.1. SPIFE Nexus Run window

1. *Test* - Using the dropdown menu, select the preprogrammed test to be run. The default Run Processes associated with the selected test will be displayed.

2. *Tray* - The sample tray associated with the selected test will be displayed. Dilutions will not be available since they are associated with Immunofixation.

3. *Run Processes* – Run processes can be enabled or disabled before running by selecting *Yes* or *No*, thus altering the previously created test for the current run.

4. **Verify** preset *Run Processes* reflect the same information listed in the IFU. If the default settings for the test are different than the IFU instructions, the test may be edited using the directions detailed in Section 6, Test Setup.

Note: Tests may be edited in the Setup menu. See Section 6 for more detail.

   a. *Sample Load*

   b. *Applicator Load 1*

   c. *Applicator Load 2*

   d. *Applicator Load 3*

   e. *Applicator Load 4*

   f. *Sample Application*

   g. *Electrophoresis*

   h. *Reagent / Stain Application*

   i. *Destain 1*

   j. *Dry 1*

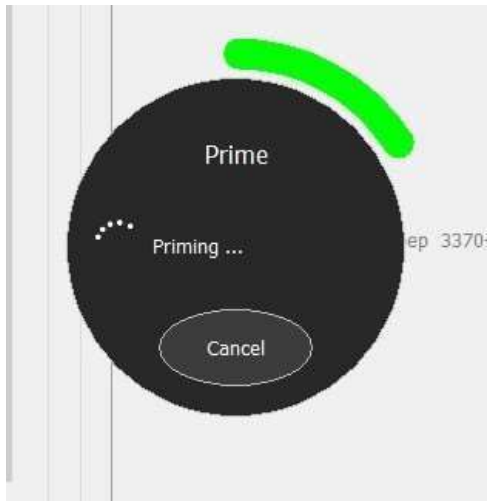   k. *Destain 2*

   l. *Dry 2*

   m. *Scan*

5. *Unlock Door* – select to unlock the main door.

6. *Prime* – Select to prime the sample handling system as well as the sample delivery system. This should be done on a daily basis.

   a. A prompt alerts the user "Prime, moving to wash……". A *Cancel* button is also displayed which will immediately stop the operation.

b. Next it will alert the user, "Priming…".

c. Next it will alert the user, "Priming completed…".

d. Next it will alert the user, "Moving pipette…".

e. Once complete, the window will close and return to the *SPIFE Nexus Run* window.

7. *Start Run* – select to start the run.

8. *Rescan* – select to rescan the plate.

9. *Cancel* – select to cancel the run and return to the Main Menu.

10. If the Pre-Start Checklist was enabled, the *Pre-Start Checklist* will be displayed as well as *Continue* and *Cancel* buttons.

11. Once all the items in the list have been checked off, the *Continue* button will be available to select. Pressing this will initiate the run sequence.

12. Selecting *Cancel* will return the user to the *SPIFE Nexus Run* window.

13. Dispose of all used consumables, such as Applicator Blades and Sample Cups.

7.1.2. Running an IFE Plate

Note: *The IFE test includes a NaOH Pipette Wash after antisera application to remove any residual fluid from the pipette. Reference the IFU for more information.*

1. If the SPIFE Nexus software is not already open, double click on the desktop icon and log in.

2. Verify levels of waste, DI water, saline, wash, and destain are sufficient to process the plate.

3. Place the tube racks into the tube transport area and close the door.

4. Remove the Consumables Tray from the SPIFE Nexus and use it to collect the following items for the run.

    a. Gel

    b. Stain

    c. Protein Fixative

    d. Antisera

    e. Antisera tip

    f. Applicator Blade(s)

    g. Reagent Roller

    h. Disposable Stain Cups

    i. Blade Weights

    j. Blotter

    k. Blotter Holder

    l. SPIFE Nexus Blotter D

    m. Blade Template

    n. Gel Cassette

    o. Diluent bottle

    p. Sample Tray

    q. Disposable Sample cups

    r. IFU associated with test

    s. Rep Prep

5. Verify the IFU matches with all the following steps. If it deviates, defer to the IFU.

6. Place the two stain cups in the stain reagent dispenser and pipet 400µl of acid violet stain into each of the cups.

7. Place the roller on the stain reagent dispenser.

8. Place the Antisera and Protein Fixative into the appropriately labeled wells of the Antisera Station.

9. Fill the diluent bottle with 0.85% saline and place it into the designated well in the Reagent Chiller. Be sure to fully seat the diluent bottle, as the pipette may be damaged by contact with the sides of the bottle.

10. Verify the Antisera Spreader Tip is installed.

11. Place the blade template over the top of the blade holder with the barcode to the left hand side.

12. Place the Applicator Blades into the designated slots of the Applicator assembly. The grooves on the sides of the blades should face the back of the instrument and be fully seated.

13. Place an Applicator Blade weight on top of each Applicator blade. When placing the weight on the blade, position the weight with the thick side to the front.

14. Place a disposable blotter onto the Blotter Holder and seat it in its correct location. When applying the disposable blotter onto the Blotter Holder, it is best to wear gloves to avoid contamination.

    a. Flip the Blotter Holder upside down, so the white bottom is upright.

    b. Place the black Blotter Application Guide on the Blotter Holder. This will ensure the blotter is affixed in the correct position.

    c. Peel the two adhesive strips off the disposable blotter and place it gently on the bottom of the Blotter Holder.

15. Replace Consumables Tray ensuring Blotter Holder is in the correct position.

16. Slide the Disposable Sample Cups into the Sample Tray, ensuring they are fully inserted into the tray.

17. Place the sample tray onto the SPIFE Nexus sample tray platform. Align the holes in the tray with the pins on the instrument.

18. Place the bottom part of the magnetic two-piece cassette holder onto the electrophoresis platen. The barcode should be in the upper right hand corner.

19. Open the outer gel package. Open the inner clamshell, remove plastic film covering gel surface and place a blotter on top of the gel surface. Gently blot the gel per the directions detailed in the associated IFU. Dispose of the blotter afterwards.

20. Using a dropper, place approximately 2 ml of REP Prep across the left side of the electrophoresis platen.

21. Place the left edge of the gel over the Rep Prep aligning the round hole on the upper pin of the cassette. Gently lay the gel down on the Rep Prep, starting from the left and ending on the right side fitting the obround hole over the lower pin. Make sure no bubbles remain under the gel.

22. Place a Positive ID barcode label (Cat. No. 1696) on the upper right hand side of the gel (Figure 7-9). Select the barcode that starts with a "G".

23. Place the top portion of the cassette holder on top of the gel with the 2D barcode in the upper right hand corner. It should snap together magnetically.

24. Close the main lid of the instrument.

25. Select the START icon on the touchscreen. The *SPIFE Nexus Run* window appears (Figure 7-4).

7.1.2.1. SPIFE Nexus Run window

1. *Test* - Using the dropdown menu, select the preprogrammed test to be run. The default Run Processes associated with the selected will be displayed.

2. *Tray* - The tray associated with the selected test will be displayed.

3. Dilutions - Dilutions may be individually set for each sample (or for the entire row by clicking on the header and highlighting the column) and each specificity. Available dilutions are Neat; 1 in 2; 1 in 3; 1 in 4; 1 in 5; 1 in 6; 1 in 7; 1 in 8; 1 in 10; 1 in 12; 1 in 14; 1 in 16; 1 in 18, and 1 in 20 (Figure 7-4).

4. *Run Processes* – Run processes can be enabled or disabled before running by selecting *Yes* or *No*, thus altering the previously created test for the current run.

5. **Verify** preset *Run Processes* reflect the same information listed in the IFU. If the default settings for the test are different than the IFU instructions, the test may be edited using the directions detailed in Section 6, Test Setup.

Note: *Tests may be edited in the Setup menu. See Section 6 for more detail.*

    a. *Sample Load*

    b. *Applicator Load 1*

    c. *Applicator Load 2*

    d. *Applicator Load 3*

    e. *Applicator Load 4*

    f. *Sample Application*

    g. *Electrophoresis*

    h. *Fixative / Antisera Application*

    i. *Pre-Dry / Incubate 1*

    j. *Blot*

    k. *Pre-Dry / Incubate 2*

    l. *Buffer Wash*

    m. *Reagent / Stain Application*

    n. *Destain 1*

    o. *Dry 1*

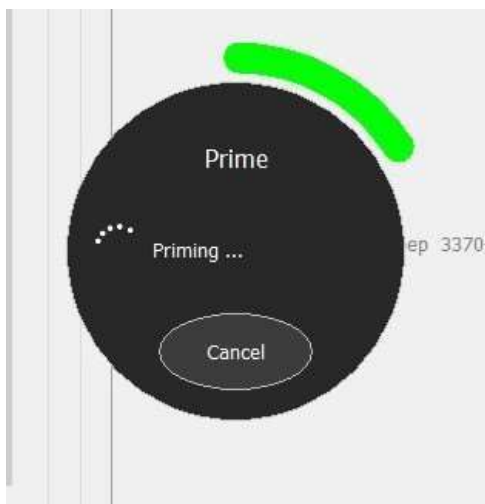   p. *Destain 2*

    q. *Dry 2*

    r. *Scan*

6. *Unlock Door* – select to unlock the main door.

7. *Prime* – Select to prime the sample handling system as well as the sample delivery system. This should be done on a daily basis.

    a. A prompt alerts the user "Prime, moving to wash……". A *Cancel* button is also displayed which will immediately stop the operation.
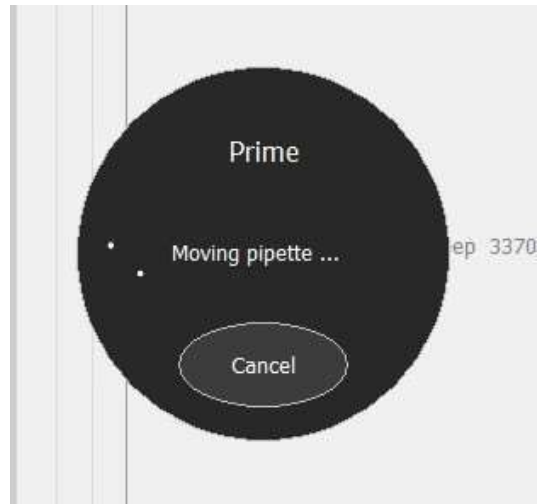
b. Next it will alert the user, "Priming…"

c. Next it will alert the user, "Priming completed…"

d. Next it will alert the user, "Moving pipette…".

e. Once complete, the window will close and return to the *SPIFE Nexus Run* window.

8. *Start Run* – select to start the run.

9. *Rescan* – select to rescan the plate.

10. *Cancel* – Select to cancel the run and return to the Main Menu.

11. If the Pre-Start Checklist was enabled, the *Pre-Start Checklist* will be displayed as well as *Continue* and *Cancel* buttons.

12. Once all the items in the list have been checked off, the *Continue* button will be available to select. Pressing this will initiate the run sequence.

13. Selecting *Cancel* will return the user to the *SPIFE Nexus Run* window.

14. Dispose of all used consumables, such as Applicator Blades and Sample Cups.

7.1.3. Running a Urine Proteins Plate

1. If the SPIFE Nexus software is not already open, double click on the desktop icon and log in.

2. Verify levels of waste, DI water, saline, wash, and destain are sufficient to process the plate.

3. Place the tube racks into the tube transport area and close the door.

4. Remove the consumables tray from the SPIFE Nexus and use it to collect the following items for the run.

    a. Gel

    b. Stain

    c. Applicator Blade(s)

    d. Reagent Roller

    e. Disposable Stain Cups

    f. Blade Weights

    g. Blade Template

    h. Gel Cassette

    i. Sample Tray

    j. Disposable Sample cups

    k. IFU associated with test

    l. Rep Prep

5. Verify the IFU matches with all the following steps. If it deviates, defer to the IFU.

6. Place the three stain cups in the stain reagent dispenser and pipet 700µl of SPIFE Nexus Blue stain into each of the cups.

7. Place the roller on the Stain / Reagent dispenser.

8. Place the Applicator Blade Template over the top of the Blade Holder with the barcode to the left hand side.

9. Place the Applicator Blades into the designated slots of the Applicator assembly. The grooves on the sides of the blades should face the back of the instrument and be fully seated.

10. Place an Applicator Blade weight on top of each Applicator Blade. When placing the weight on the blade, position the weight with the thick side to the front.

11. Replace Consumables Tray ensuring the tray is firmly pushed into the correct position.

12. Place the bottom part of the magnetic two-piece Gel Cassette onto the electrophoresis platen.

13. Slide the Disposable Sample Cups into the Sample Tray, ensuring they are fully inserted into the tray.

14. Place the sample tray onto the SPIFE Nexus sample tray platform. Align the holes in the tray with the pins on the instrument.

15. Open the outer gel package. Open the inner clamshell, remove plastic film covering the gel surface, and place a blotter on top of the gel surface. Gently blot the gel per the directions detailed in the associated IFU. Dispose of the blotter afterwards.

16. Using a dropper, place approximately 2 ml of Rep Prep across the left side of the electrophoresis platen.

17. Place the left edge of the gel over the Rep Prep aligning the round hole on the upper pin of the cassette. Gently lay the gel down on the Rep Prep, starting from the left and ending on the right side fitting the obround hole over the lower pin. Make sure no bubbles remain under the gel.

18. Place a Positive ID barcode label (Cat. No. 1696) on the upper right hand side of the gel (Figure 7-9). Select the barcode that starts with a "G".

19. Place the top portion of the cassette holder on top of the gel with the 2D barcode on the upper right hand side. It should snap together magnetically.

20. Close the main lid of the instrument.

21. Select the START icon on the touchscreen. The *SPIFE Nexus Run* window appears (Figure 7-2).

7.1.3.1. SPIFE Nexus Run window

1. *Test* - Using the dropdown menu, select the preprogrammed test to be run. The default Run Processes associated with the selected test will be displayed.

2. *Tray* - The sample tray associated with the selected test will be displayed. Dilutions will not be available since they are associated with Immunofixation.

3. *Run Processes* – Run processes can be enabled or disabled before running by selecting *Yes* or *No*, thus altering the previously created test for the current run.

4. **Verify** preset *Run Processes* reflect the same information listed in the IFU. If the default settings for the test are different than the IFU instructions, the test may be edited using the directions detailed in Section 6, Test Setup.

Note: Tests may be edited in the Setup menu. See Section 6 for more detail.

    a. *Sample Load*

    b. *Applicator Load 1*

    c. *Sample Application 1*

    d. *Applicator Load 2*

    e. *Sample Application 2*

    f. *Applicator Load 3*

    g. *Sample Application 3*

    h. *Electrophoresis*

    i. *Pre-Dry / Incubate*

    j. *Reagent / Stain Application*

    k. *Destain 1*

    l. *Dry 1*

    m. *Destain 2*
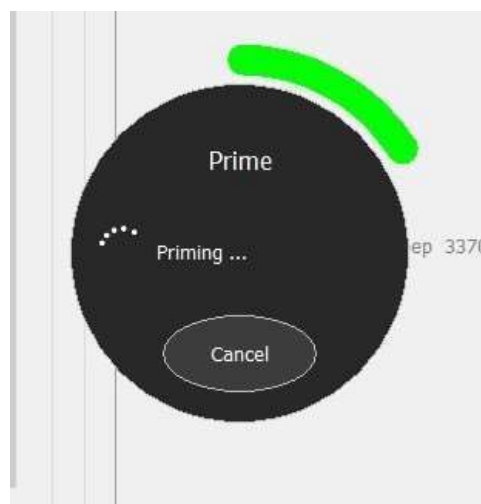
    n. *Dry 2*

    o. *Scan*

5. *Unlock Door* – select to unlock the main door.

6. *Prime* – select to prime the sample handling system as well as the sample delivery system. This should be done on a daily basis.

    a. A prompt alerts the user "Prime, moving to wash……". A *Cancel* button is also displayed which will immediately stop the operation.
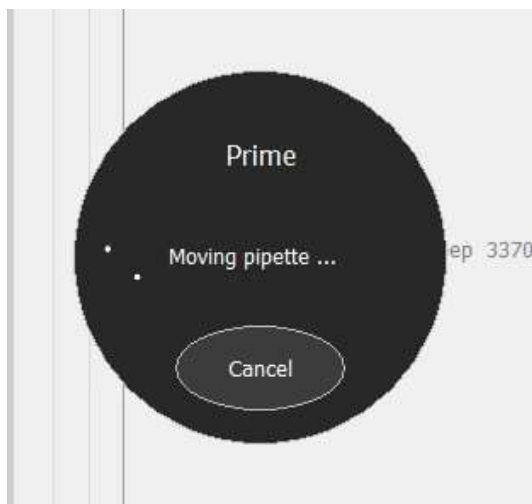

    b. Next it will alert the user, "Priming…"

c. Next it will alert the user, "Priming completed…"

d. Next it will alert the user, "Moving pipette…".

e. Once complete, the window will close and return to the *SPIFE Nexus Run* window.

7. *Start Run* – select to start the run.

8. *Rescan* – select to rescan the plate.

9. *Cancel* – select to cancel the run and return to the Main Menu.

10. If the Pre-Start Checklist was enabled, the *Pre-Start Checklist* will be displayed as well as *Continue* and *Cancel* buttons.

11. Once all the items in the list have been checked off, the *Continue* button will be

available to select. Pressing this will initiate the run sequence.

12. Selecting *Cancel* will return the user to the *SPIFE Nexus Run* window.

13. Dispose of all used consumables, such as Applicator Blades and Sample Cups.

7.1.4. Running a Urine IFE Plate

Note: *The IFE test includes a NaOH Pipette Wash after antisera application to remove any residual fluid from the pipette. Reference the IFU for more information.*

1. If the SPIFE Nexus software is not already open, double click on the desktop icon and log in.

2. Verify levels of waste, DI water, saline, wash, and destain are sufficient to process the plate.

3. Place the tube racks into the tube transport area and close the door.

4. Remove the Consumables Tray from the SPIFE Nexus and use it to collect the following items for the run.

    a. Gel

    b. Stain

    c. Protein Fixative

    d. Antisera

    e. Antisera tip

    f. Applicator Blade(s)

    g. Reagent Roller

    h. Disposable Stain Cups

    i. Blade Weights

    j. Blotter

    k. Blotter Holder

    l. SPIFE Nexus Blotter D

    m. Blade Template

    n. Gel Cassette

    o. Diluent bottle

p. Sample Tray

q. Disposable Sample cups

r. IFU associated with test

s. Rep Prep

5. Verify the IFU matches with all the following steps. If it deviates, defer to the IFU.

6. Place the two stain cups in the stain reagent dispenser and pipet 400µl of acid violet stain into each of the cups.

7. Place the roller on the stain reagent dispenser.

8. Place the Antisera and Protein Fixative into the appropriately labeled wells of the Antisera Station.

9. Fill the diluent bottle with 0.85% saline and place it into the designated well in the Reagent Chiller. Be sure to fully seat the diluent bottle, as the pipette may be damaged by contact with the sides of the bottle.

10. Verify the Antisera Spreader Tip is installed.

11. Place the blade template over the top of the blade holder with the barcode to the left hand side.

12. Place the Applicator Blades into the designated slots of the Applicator assembly. The grooves on the sides of the blades should face the back of the instrument and be fully seated.

13. Place an Applicator Blade weight on top of each Applicator blade. When placing the weight on the blade, position the weight with the thick side to the front.

14. Place a disposable blotter onto the Blotter Holder and seat it in its correct location. When applying the disposable blotter onto the Blotter Holder, it is best to wear gloves to avoid contamination.

a. Flip the Blotter Holder upside down, so the white bottom is upright.

b. Place the black Blotter Application Guide on the Blotter Holder. This will ensure the blotter is affixed in the correct position.

c. Peel the two adhesive strips off the disposable blotter and place it gently on the bottom of the Blotter Holder.

15. Replace Consumables Tray ensuring Blotter Holder is in the correct position.

16. Slide the Disposable Sample Cups into the Sample Tray, ensuring they are fully inserted into the tray.

17. Place the sample tray onto the SPIFE Nexus sample tray platform. Align the holes in the tray with the pins on the instrument.

18. Place the bottom part of the magnetic two-piece cassette holder onto the electrophoresis platen. The barcode should be in the upper right hand corner.

19. Open the outer gel package. Open the inner clamshell, remove plastic film covering gel surface and place a blotter on top of the gel surface. Gently blot the gel per the directions detailed in the associated IFU. Dispose of the blotter afterwards.

20. Using a dropper, place approximately 2 ml of REP Prep across the left side of the electrophoresis platen.

21. Place the left edge of the gel over the Rep Prep aligning the round hole on the upper pin of the cassette. Gently lay the gel down on the Rep Prep, starting from the left and ending on the right side fitting the obround hole over the lower pin. Make sure no bubbles remain under the gel.

22. Place a Positive ID barcode label (Cat. No. 1696) on the upper right hand side of the gel (Figure 7-9). Select the barcode that starts with a "G".

23. Place the top portion of the cassette holder on top of the gel with the 2D barcode in the upper right hand corner. It should snap together magnetically.

24. Close the main lid of the instrument.

25. Select the START icon on the touchscreen. The *SPIFE Nexus Run* window appears (Figure 7-5).

7.1.4.1. SPIFE Nexus Run window

1. *Test* - Using the dropdown menu, select the preprogrammed test to be run. The default Run Processes associated with the selected will be displayed.

2. *Tray* - The tray associated with the selected test will be displayed.

3. Dilutions - Dilutions may be individually set for each sample (or for the entire row by clicking on the header and highlighting the column) and each specificity. Available dilutions are Neat; 1 in 2; 1 in 3; 1 in 4; 1 in 5; 1 in 6; 1 in 7; 1 in 8; 1 in 10; 1 in 12; 1 in 14; 1 in 16; 1 in 18, and 1 in 20 (Figure 7- 4).

4. *Run Processes* – Run processes can be enabled or disabled before running by selecting *Yes* or *No*, thus altering the previously created test for the current run.

5. **Verify** preset *Run Processes* reflect the same information listed in the IFU. If the default settings for the test are different than the IFU instructions, the test may be edited using the directions detailed in Section 6, Test Setup.

Note: *Tests may be edited in the Setup menu. See Section 6 for more detail.*

    a. *Sample Load*

    b. *Applicator Load 1*

    c. *Applicator Load 2*

    d. *Applicator Load 3*

    e. *Applicator Load 4*

    f. *Sample Application*

    g. *Electrophoresis*

    h. *Fixative / Antisera Application*

    i. *Pre-Dry / Incubate 1*

    j. *Blot*

    k. *Pre-Dry / Incubate 2*

    l. *Buffer Wash*

    m. *Reagent / Stain Application*

    n. *Destain 1*

    o. *Dry 1*

    p. *Destain 2*
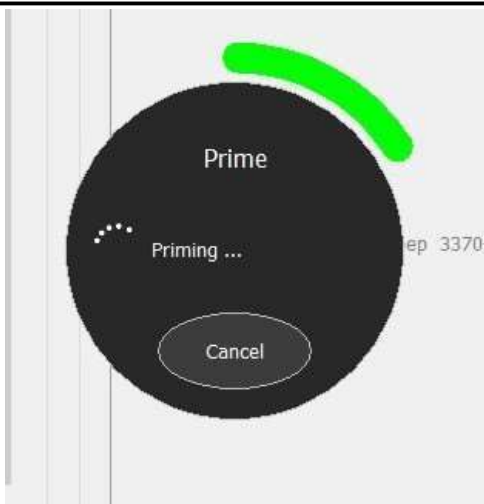
    q. *Dry 2*

    r. *Scan*

6. *Unlock Door* – select to unlock the main door.

7. *Prime* – Select to prime the sample handling system as well as the sample delivery system. This should be done on a daily basis.

    a. A prompt alerts the user "Prime, moving to wash……". A *Cancel* button is also displayed which will immediately stop the operation.
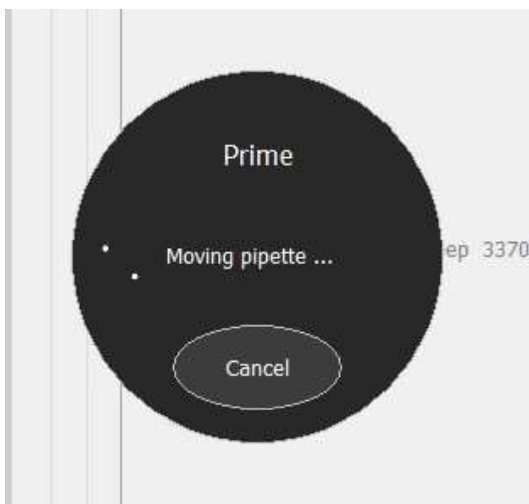

    b. Next it will alert the user, "Priming…"

c. Next it will alert the user, "Priming completed…"

d. Next it will alert the user, "Moving pipette…".

e. Once complete, the window will close and return to the *SPIFE Nexus Run* window.

8. *Start Run* – select to start the run.

9. *Rescan* – select to rescan the plate.

10. *Cancel* – Select to cancel the run and return to the Main Menu.

11. If the Pre-Start Checklist was enabled, the *Pre-Start Checklist* will be displayed as well as *Continue* and *Cancel* buttons.

12. Once all the items in the list have been checked off, the *Continue* button will be available to select. Pressing this will initiate the run sequence.

13. Selecting *Cancel* will return the user to the *SPIFE Nexus Run* window.

14. Dispose of all used consumables, such as Applicator Blades and Sample Cups.

7.1.5. Running an Acid Hemoglobin Plate

Note: This will be available in a future release (Figure 7-6).

7.2. Results

Once the gel has been completely processed by the instrument, the cassette containing the dried plate will slide out of the instrument on the right hand side of the front panel where it can be removed by the user.

The worklist will automatically be displayed on the screen in the QuickScan Touch plus software for review and editing. For more information on its entirety of available features, consult the QuickScan Touch *plus* Operator's Manual.

Dispose of any consumables such as Sample Cups, Sample Cups, Applicator Blades, and blotters as biohazardous waste. Refer to Section 10 for the maintenance required after every test.

7.3. Rescanning and Scanning Gels

All scanning, including Rescan, is handled through the SPIFE Nexus software and not the QuickScan Touch *plus* software.

7.3.1. Rescan

Note: Any open worklists must be closed before a rescan can occur.

Note: Rescans may only be performed on gels that have a Positive Patient ID tag affixed to the gel.

1. Place the cassette containing the gel onto the electrophoresis platen.

2. Click the *Start* icon.

3. Select *Rescan.*

4. The SPIFE Nexus claw will pick up the cassette and place it into the scanning slot.

5. If a Positive Patient ID tag has been detected, after it has been placed in the slot, the QuickScan Touch plus software will prompt the user and ask if this is a rescan.

    a. Select *Yes* if the plate needs to be rescanned.

    b. Select *No* if rescanning is *not* desired.

6. The QuickScan Touch *plus* software opens the original worklist and rescans the plate into it.

7. If a Positive Patient ID tag cannot be detected, after it has been placed in the slot, the QuickScan Touch *plus* software will alert the user the gel barcode scan failed and will display a text box allowing the user to enter the information.

    a. Enter the Positive Patient ID Gel Id number and click *Yes.*

    b. Select No if no Gel Id number is available. The QuickScan Touch *plus* cannot rescan the plate without a Gel Id tag as a reference to find the original worklist.

8. The QuickScan Touch *plus* software opens the original worklist and rescans the plate into it.

7.4. About

1. Select the *About* and a window will display containing the current software version and system serial number, as well as the software version numbers of the software for each of the instrument components.

2. The system serial number should be the same as the handwritten serial number on the Helena labels located on the computer, scanner, and transparency lid.

3. *OK* - select to exit the window.

7.5. Timeout

The Nexus software has a timer feature. After one hour and forty-five minutes of software inactivity, a small timer will appear with an *Abort Shutdown* button. Clicking the *Abort Shutdown* button will prevent the software from being closed out.

7.6. Exit

To exit the SPIFE Nexus software, from the main menu (Figure 7-1), select the **X** at the top right of the main menu. This will shut down the software as well as the instrument.
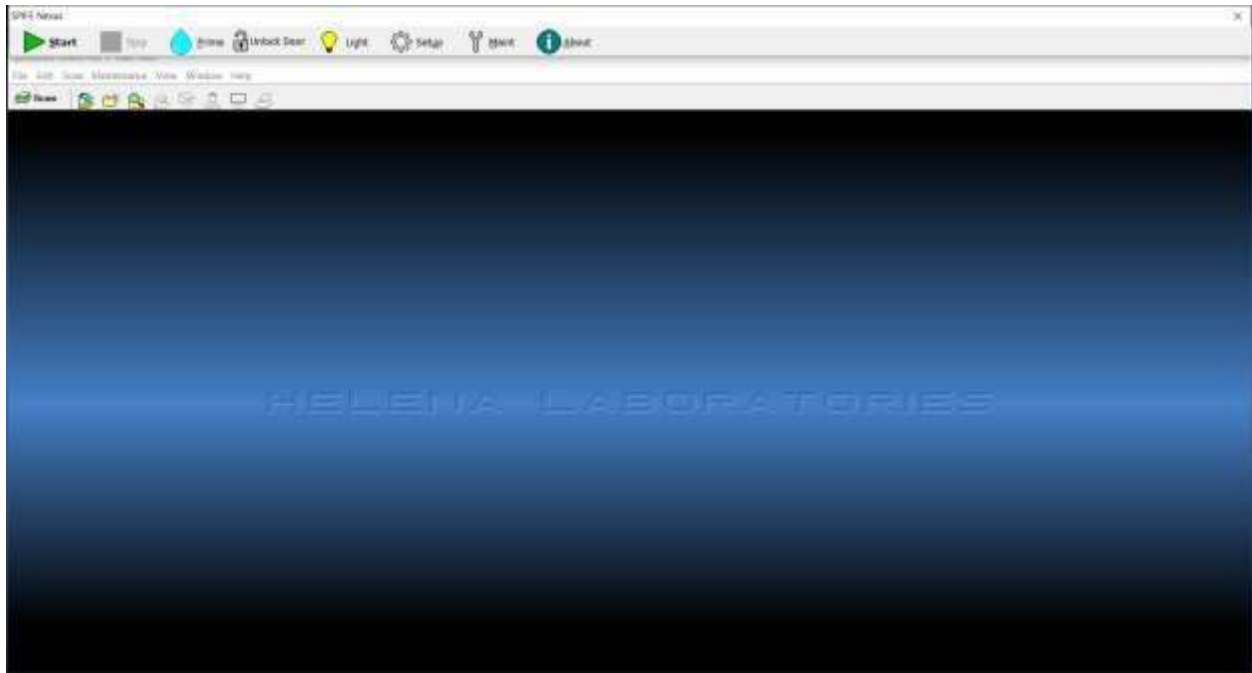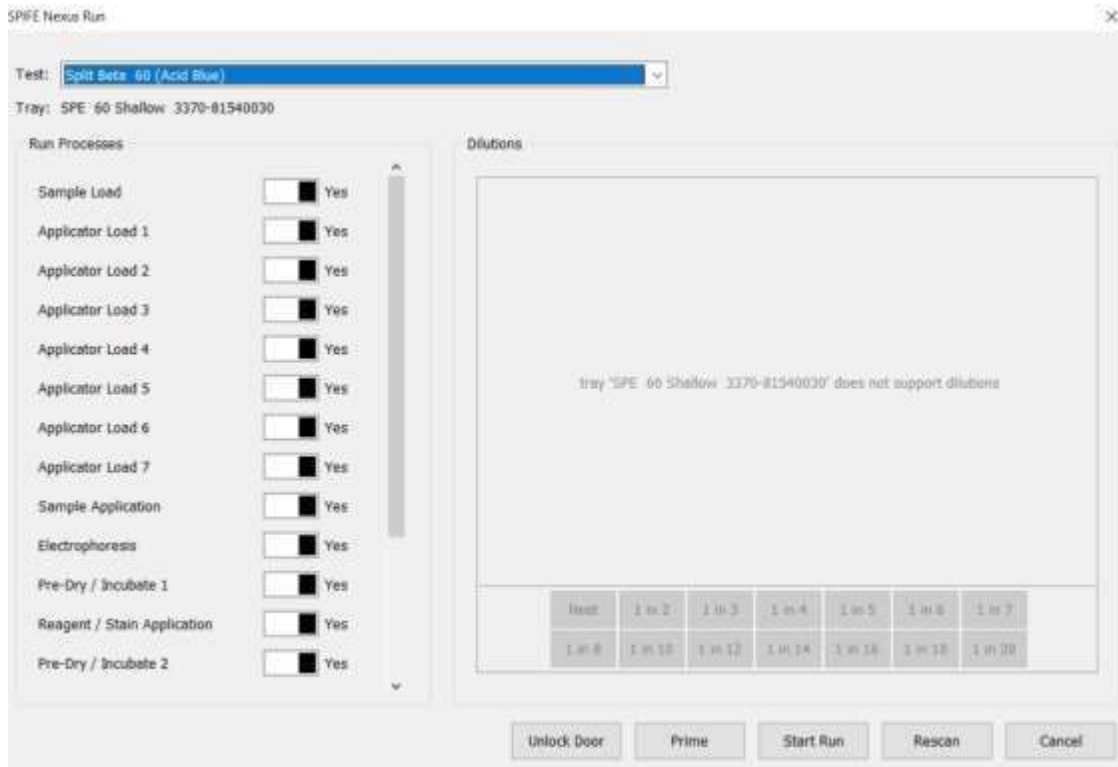
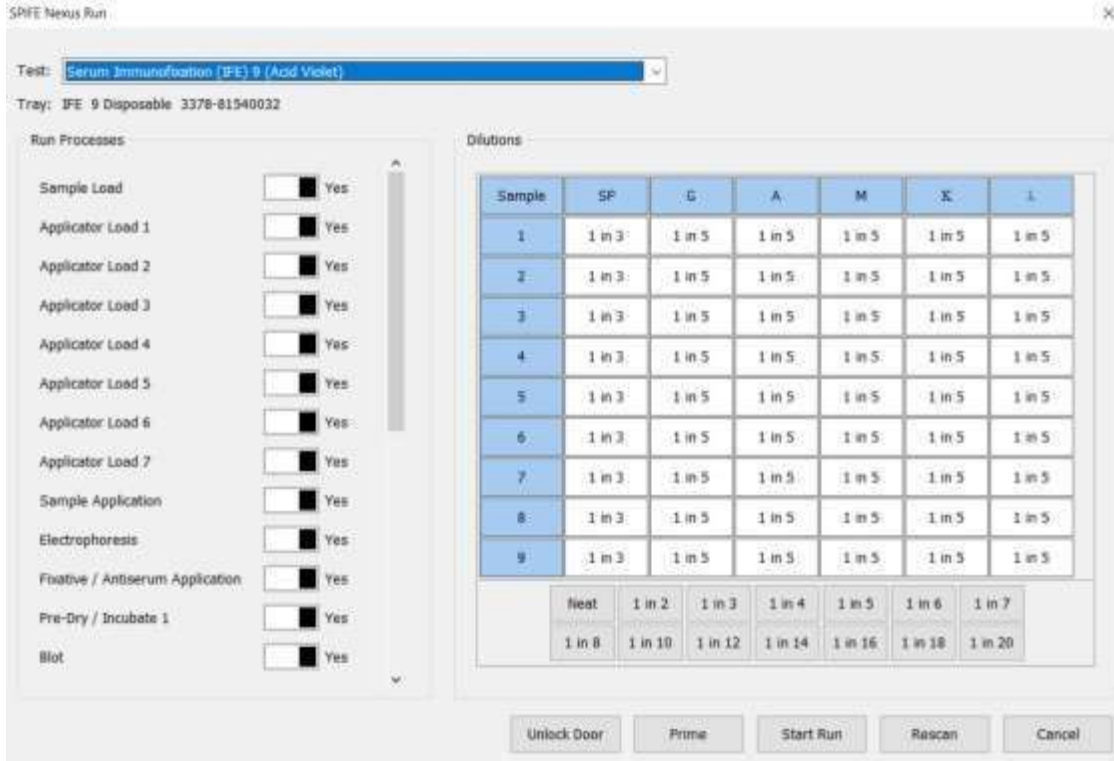**Figure 7-1 Main Menu**

Figure 7-2 Run Screen, Split Beta

SPIFE Nexus Run   ✕

Test: Serum Immunofixation (IFE) 9 (Acid Violet)   ▼

Tray: IFE 9 Disposable 3378-81540032

Run Processes

Process		Value
Sample Load	▮	Yes
Applicator Load 1	▮	Yes
Applicator Load 2	▮	Yes
Applicator Load 3	▮	Yes
Applicator Load 4	▮	Yes
Applicator Load 5	▮	Yes
Applicator Load 6	▮	Yes
Applicator Load 7	▮	Yes
Sample Application	▮	Yes
Electrophoresis	▮	Yes
Fixative / Antiserum Application	▮	Yes
Pre-Dry / Incubate 1	▮	Yes
Blot	▮	Yes

Dilutions

Sample	SP	G	A	M	K	λ
1	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
2	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
3	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
4	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
5	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
6	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
7	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
8	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5
9	1 in 3	1 in 5	1 in 5	1 in 5	1 in 5	1 in 5

Neat	1 in 2	1 in 3	1 in 4	1 in 5	1 in 6	1 in 7
1 in 8	1 in 10	1 in 12	1 in 14	1 in 16	1 in 18	1 in 20

[Unlock Door]   [Prime]   [Start Run]   [Rescan]   [Cancel]

Figure 7-3 Run Screen, IFE

SPIFE Nexus Run   ✕

Test: SPIFE Urine Proteins 60 (Acid Blue)   ▼

Tray: SPE 60 Deep 3370-81540030

Run Processes

Process		Value
Sample Load	▮	Yes
Applicator Load 1	▮	Yes
Sample Application 1	▮	Yes
Applicator Load 2	▮	Yes
Sample Application 2	▮	Yes
Applicator Load 3	▮	Yes
Sample Application 3	▮	Yes
Electrophoresis	▮	Yes
Pre-Dry / Incubate	▮	Yes
Reagent / Stain Application	▮	Yes
Destain 1	▮	Yes
Dry 1	▮	Yes
Destain 2	▮	Yes

Dilutions

tray 'SPE 60 Deep 3370-81540030' does not support dilutions

Neat	1 in 2	1 in 3	1 in 4	1 in 5	1 in 6	1 in 7
1 in 8	1 in 10	1 in 12	1 in 14	1 in 16	1 in 18	1 in 20

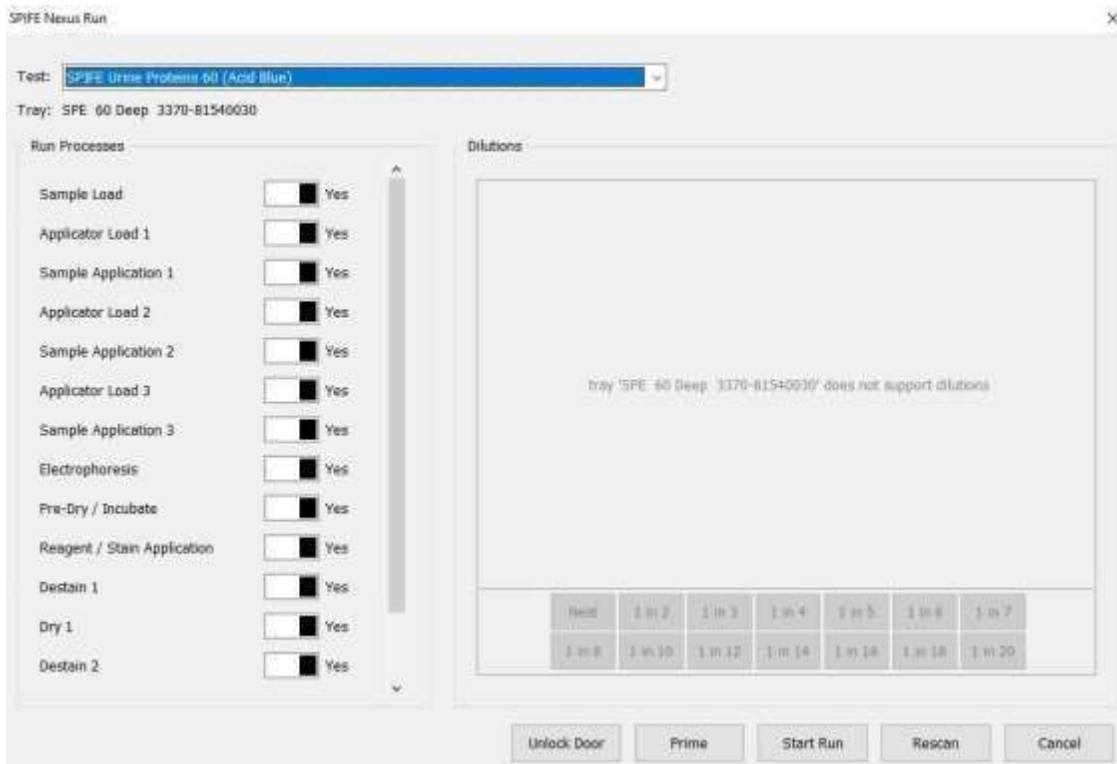[Unlock Door]   [Prime]   [Start Run]   [Rescan]   [Cancel]

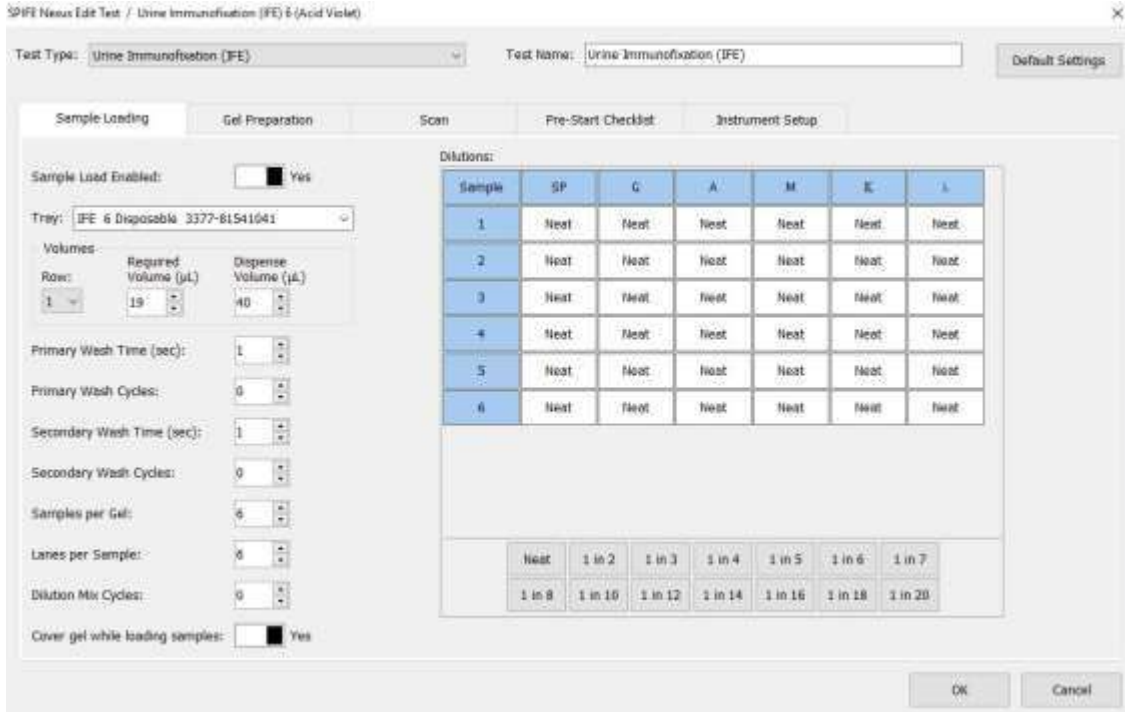**Figure 7-4 Run Screen, Urine Proteins**

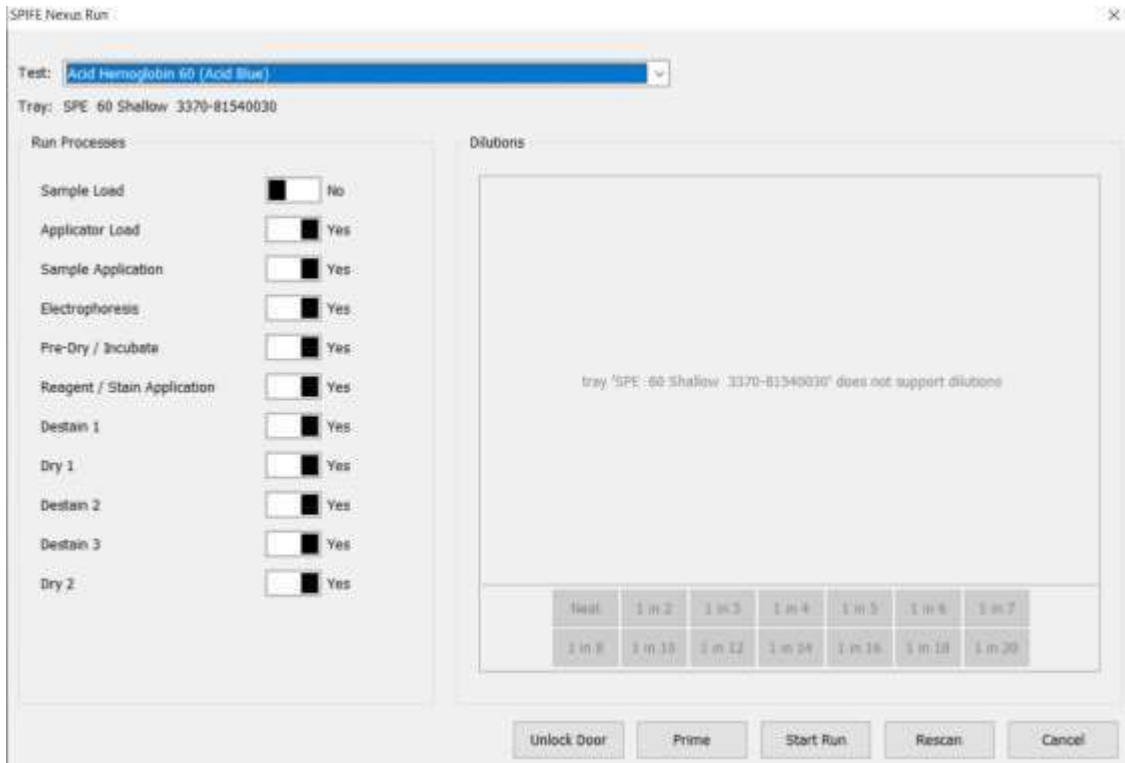**Figure 7-5 Run Screen, Urine IFE**

Figure 7-6 Run Screen, Acid Hemoglobin (future)

Figure 7-7 Instrument, Front View
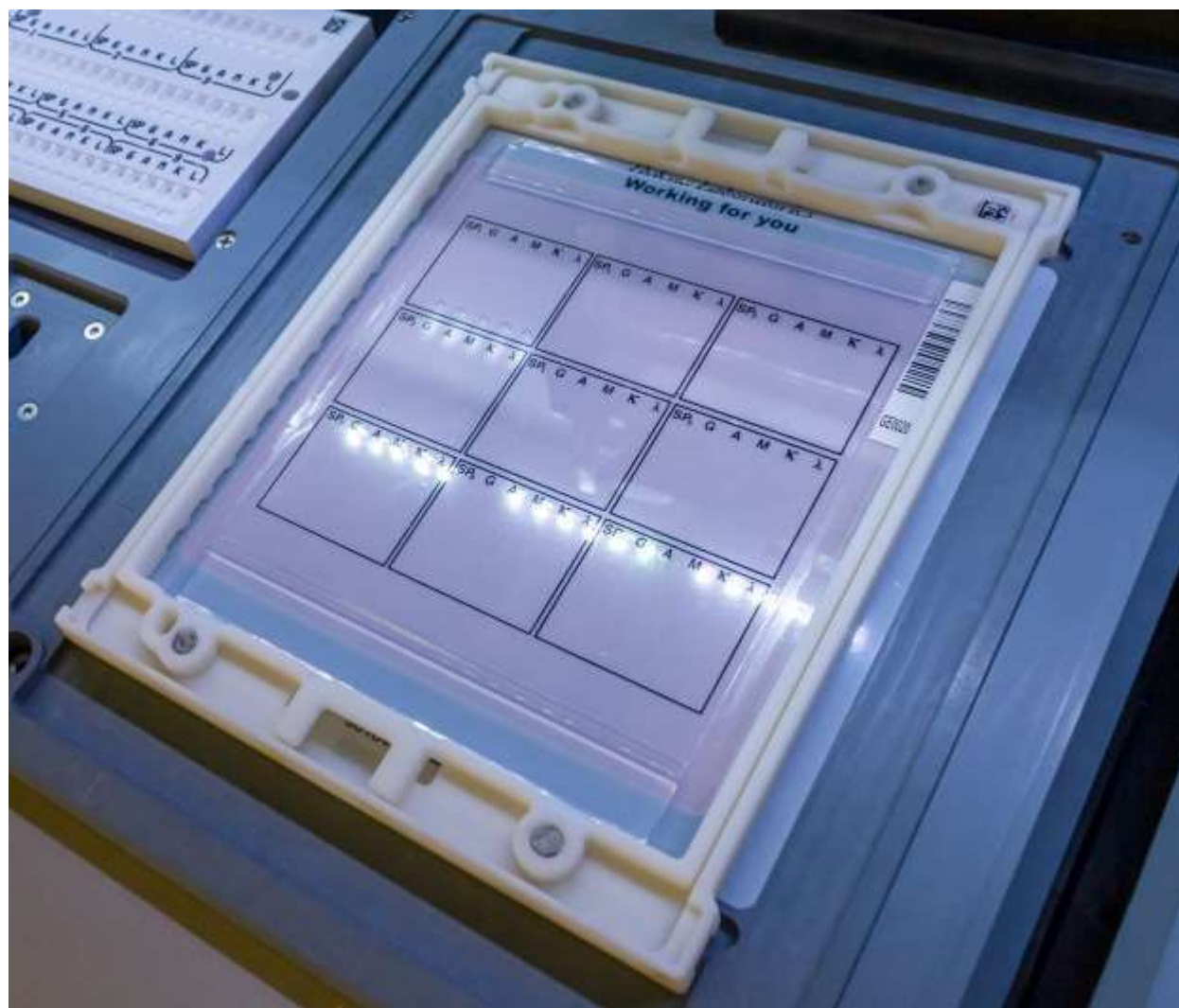
Figure 7-8 Reagent Chiller
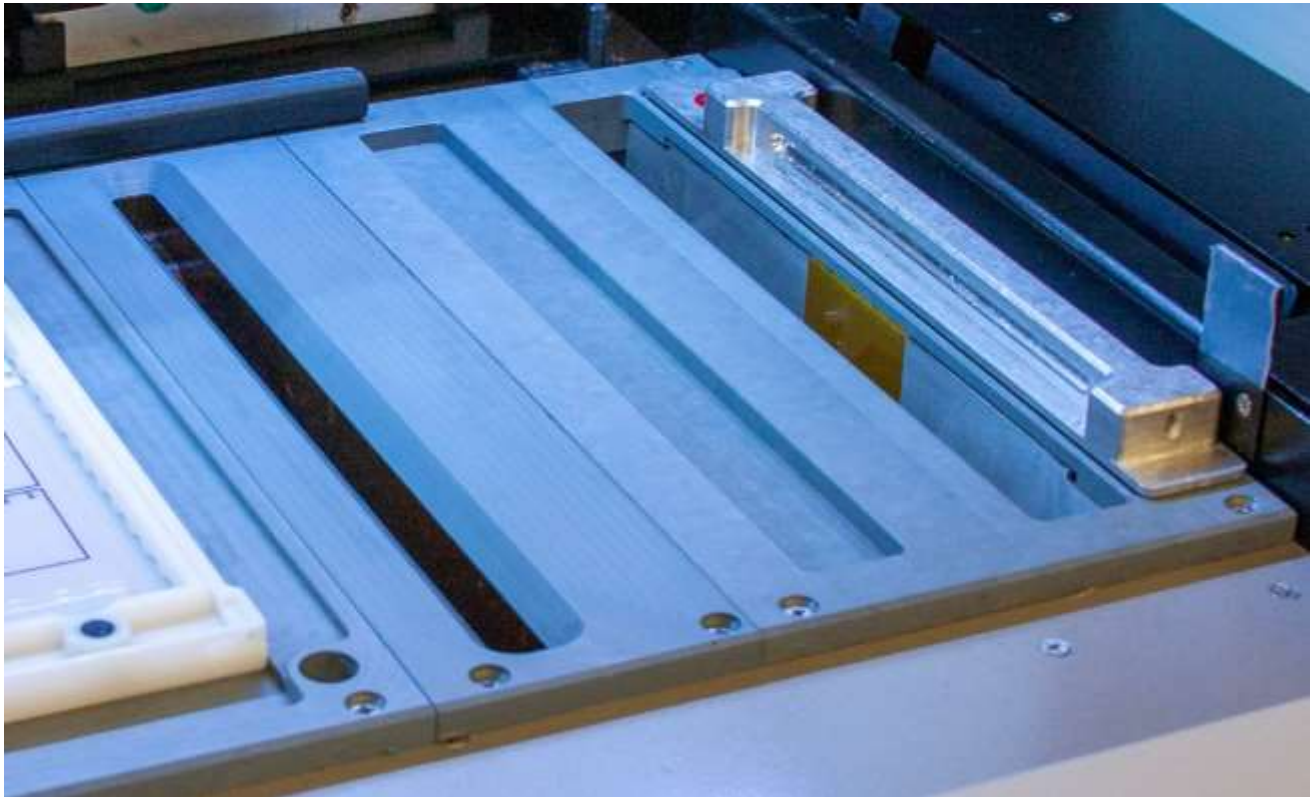
Figure 7-9 Electrophoresis Platen

Figure 7-10 Wash Vat and Dryer Chamber
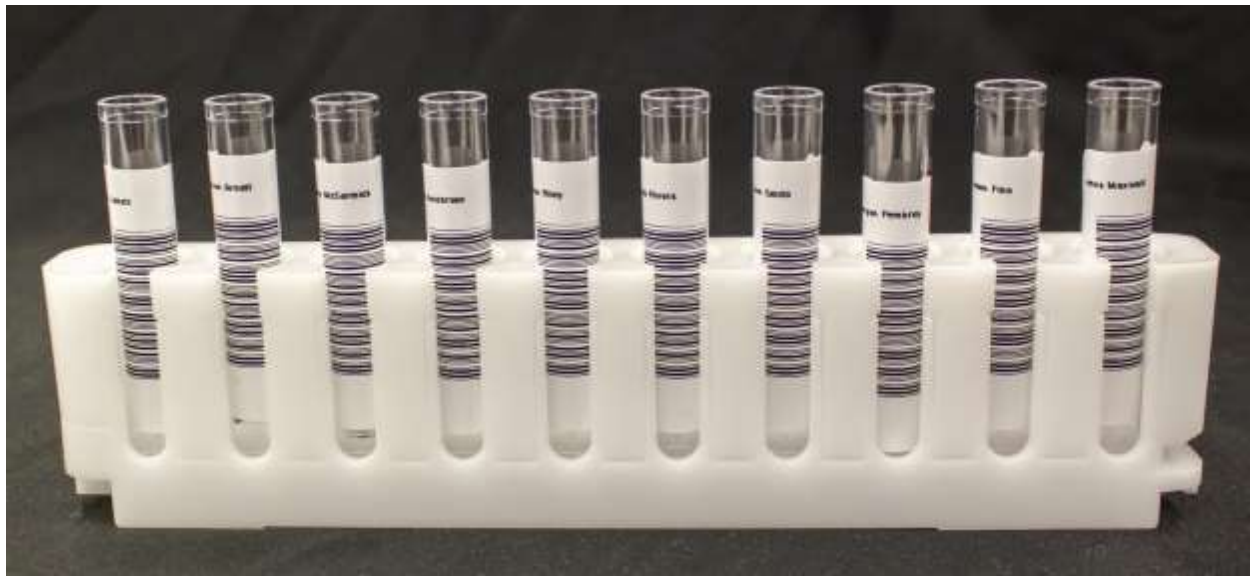
Figure 7-11 Tube Transport

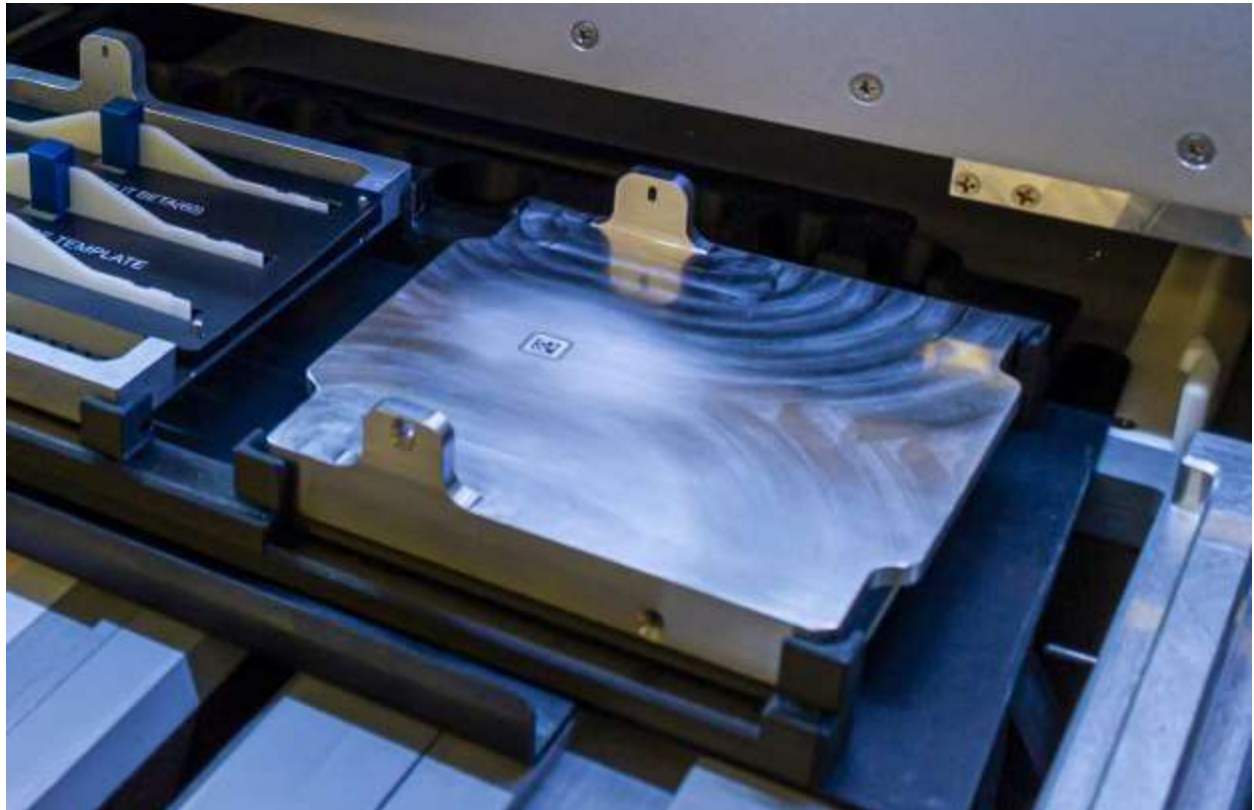**Figure 7-12 Barcode Placement**

Figure 7-13 Sample Tray (with Cups)

Figure 7-14 Placement of Blotter Holder in Consumables Tray

Figure 7-15 Applicator Holder with Applicator Blades, Applicator Blade Template, and Blade Weights
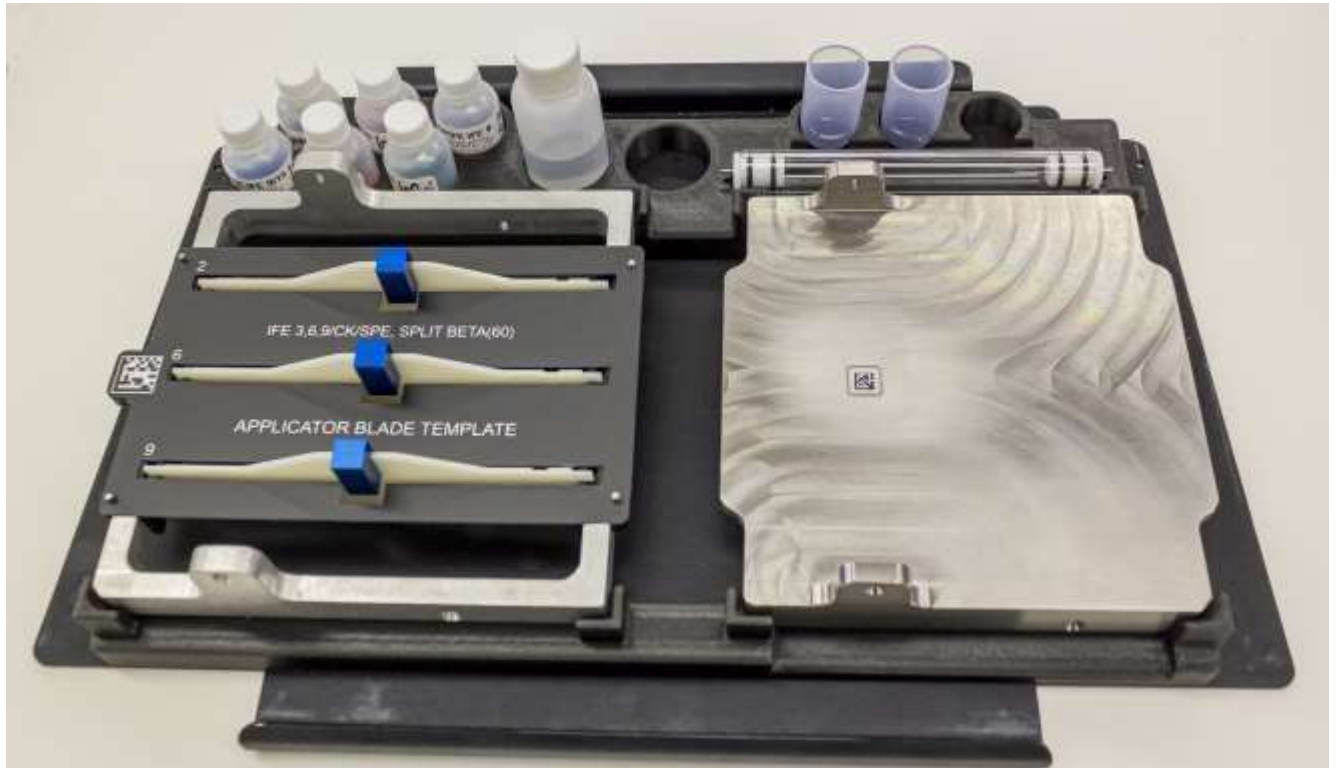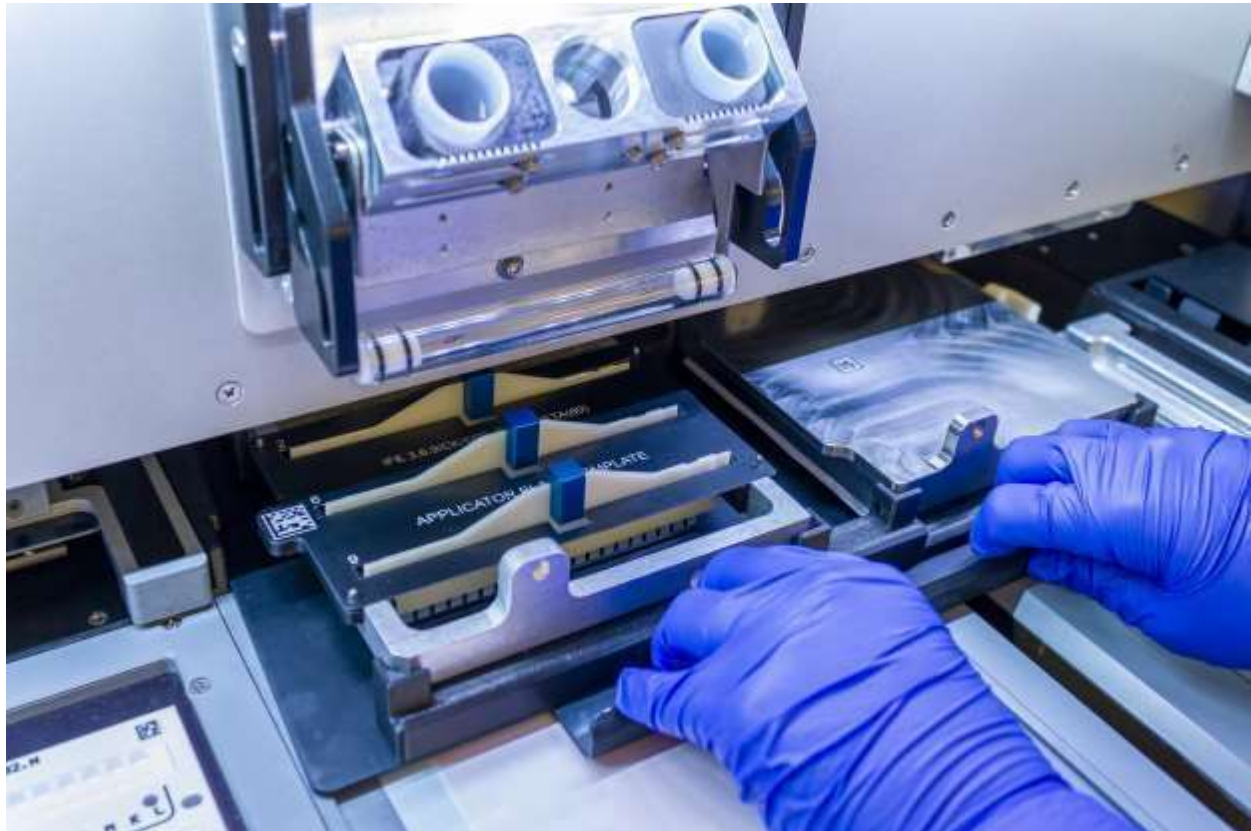
Figure 7-16 Consumables Tray
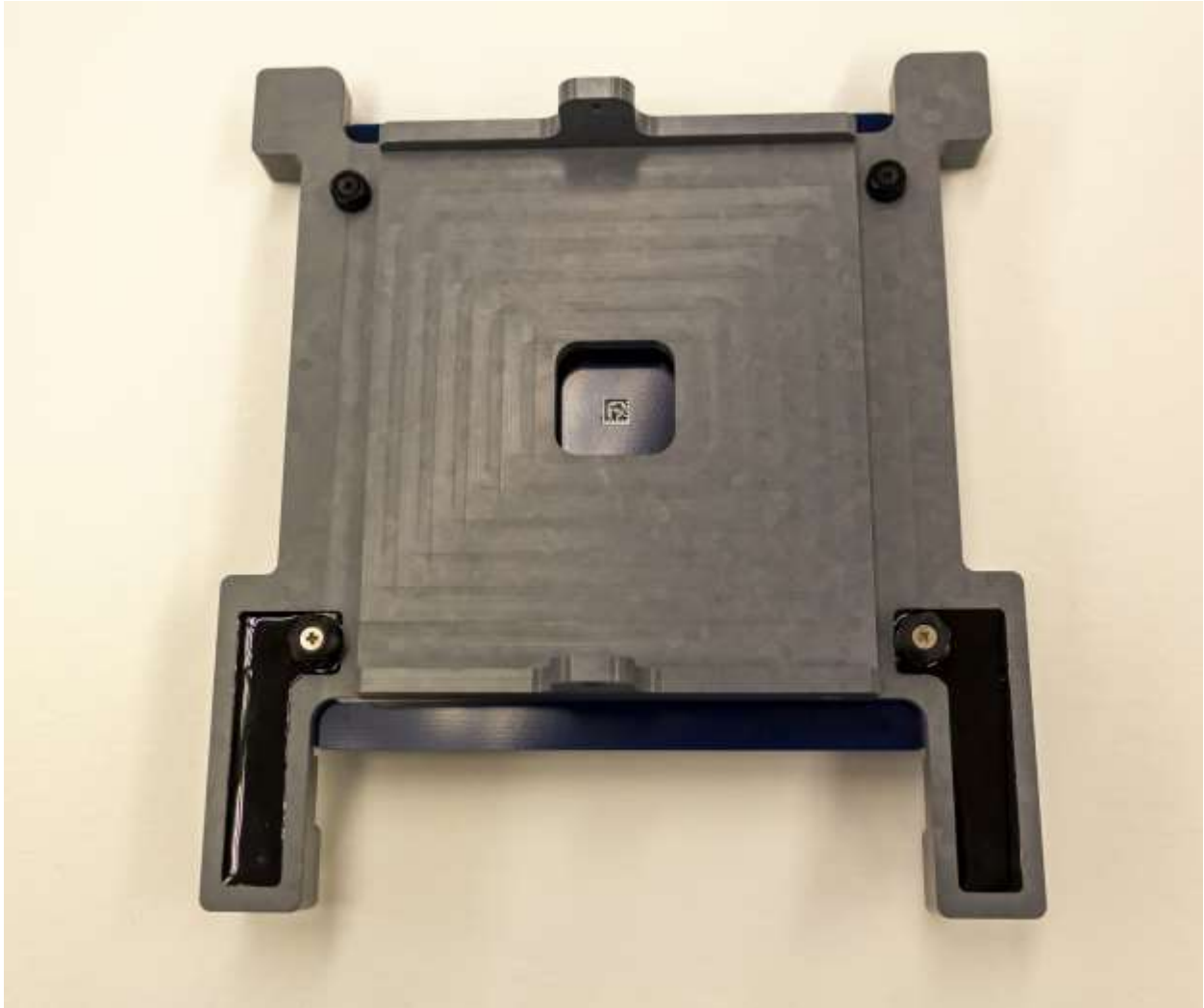
Figure 7-17 Sliding Consumables Tray into Place

Figure 7-18 Platen Cover with Electrode Insert
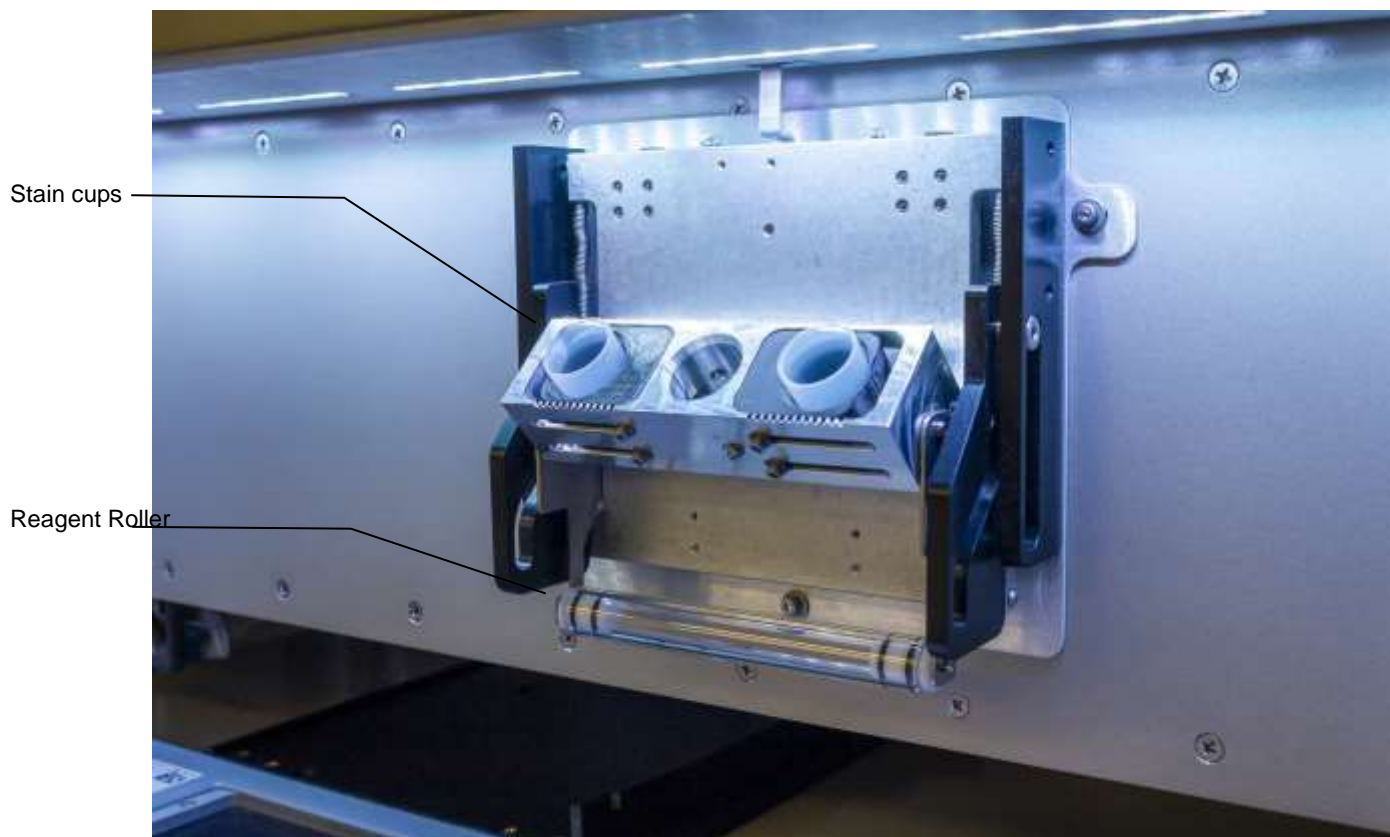
Stain cups

Reagent Roller

Figure 7-19 Stain / Reagent Dispenser Bar

Section 8 - Test Functions and Quality Control

8.1. Startup

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.

8.2. Quality Control

8.2.1. Controls

1. For quantitative gels, a normal control should be run in scan position 1 and/or abnormal control in the last position, with samples in between. The control data should be compared to the ranges printed on the assay sheet provided with the control.

2. 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.

3. It is recommended that each laboratory set up an effective quality control program based on licensing requirements.

8.3. Instrument Performance Check

8.3.1. Neutral Density Densitometer Control (NDDC)

Note: In order to run an NDDC check, the SPIFE Nexus must be used in conjunction with the QuickScan Touch plus software system.

1. The QC plate contains a Neutral Density Densitometer Control (NDDC) containing 5 bands of known quantitation, and a 10 Step Optical Density (OD) Step Tablet with an OD Range of .05 to 3.05 in .30 increments. Scan the QC plate at frequent, regular intervals.

#### 8.3.2. 10 Step Optical Density (OD) Step Tablet

1. The OD Step Tablet checks linearity and analog response of the visible light source and detector.

2. A list of the quantitative ranges for the NDDC bands should have been entered during QC setup.

3. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, either select *Maintenance* and then *Quality Control.* The *QC* window displays. A list of all saved QC scans is displayed, with the options to view, Print, Scan, Delete, and Cancel.

8.3.3. QC Main Menu

1. The History of all saved QC scans is available from the main QC menu. The availability of previous QC results is dependent upon selections made in setup The list of previous results includes the NDDC registration number and the date and time the QC was run.
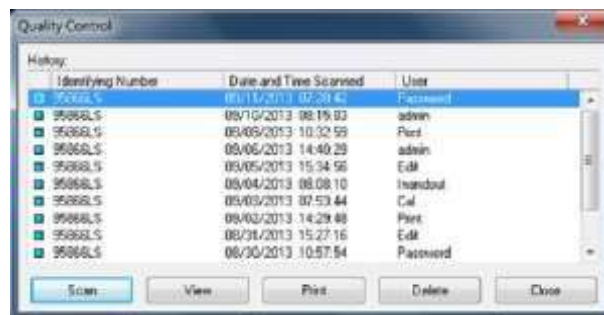
2. Highlight the desired QC and select from the following:

   a. *View* - A single scan may be selected from the list for view.
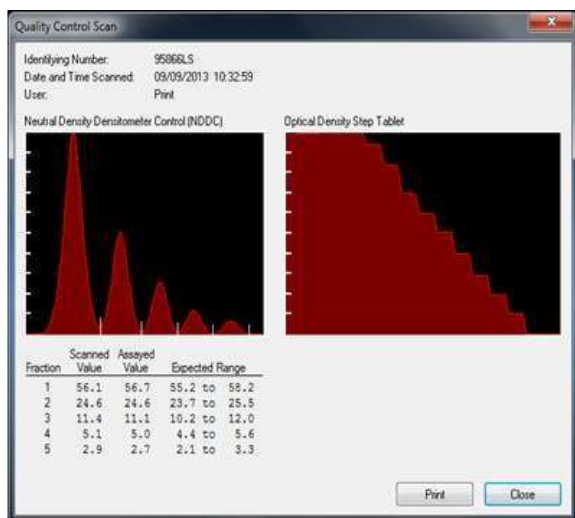
b. *Print* is available with a single QC scan/NDDC result displayed. Select and the *Print QC Results* window displays. As needed, select the appropriate *Printer* and *Number of Copies.* Select *Print* to print the scan. Select *Cancel* to exit without printing. It is recommended that a permanent record of the QC results be kept.

c. *Delete* **-** Delete to delete the indicated QC. Select *Delete* and *Alert* displays. Select *Yes* to exit and delete the selected QC scan, or *No* to exit without deleting the scan.

8.3.4. Scan

1. To run a new QC scan using the NDDC/OD Step Table, select *Scan*, click on *Maintenance*, then *QC*, then *Scan*. The message "*Place the QC Plate in the scanner, click 'OK' to continue*" displays.

2. The obround hole of the QC plate slides over the bottom left pin of the cassette. The round hole of the QC plate slides over the round pin of the cassette. Snap the two pieces of the cassette together and place it into the scanning slot of the SPIFE Nexus. The NDDC plate will not fill the entire cassette. It is smaller than a standard gel.

3. Select *OK* and "Scanning in Progress" displays.

4. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup. Out of range values are indicated by a *plus* or minus on the display and report.

5. The OD Step Tablet shows proper linearity when, on the QC printout, a straight line can be drawn which connects the vertical points from the bottom step through **at least six peaks.**

8.3.5. Unacceptable   results

If the results are not acceptable:

Optics alignment or instrument servicing may be required. Contact Helena Laboratories for assistance.

8.3.6. Print QC History Report

1. *Print* - From the main QC window, the Print function may be used to print a report containing all previously run QC. The report includes for each previously run QC the NDDC registration number, the date and time of the run, and each of the five NDDC fraction results.

2. The report also includes, for each of the five NDDC fractions, the mean, standard deviation, and coefficient of variation, determined from the results of each previously run QC. Select *Print*, the report prints and the display returns to the *QC History* window. Select *Cancel* to return to the window without printing.

8.3.7. Delete

1. From the *Quality Control* window, use the delete function to delete the indicated QC.

2. Select *Delete.*

3. A *Confirm Delete* prompt displays:

a. Select *Yes* to delete the selected QC scan.

b. Select *Yes to All* to delete the multiple selected QC scans.

4. Select *No* or *Cancel* to retain the QC scan and return to the *Quality Control* window.

8.3.8. Cancel

Cancel - select to exit the QC History window.

8.3.9. Exit

To exit the *QC* window, select the X located on the top right of the window.

Section 9 - Performance Specifications

FOR INDOOR USE ONLY

Media Types:
Agarose and cellulose acetate gels

Maximum Sample Size:
7.8 x 6 in. (12.7 x 12.7 cm)

Input Power:
100 to 120 VAC at 16 Amps Max / 240 VAC at 10 Amps Max

50/60 Hz

Max Mains Supply Voltage Fluctuation 10%

Appliance Class: I

Over voltage Category: II

Circuit Protection / Fuses:
Circuit Protection: 20 amp breaker

Display Power AC outlet Fuse:
T3.15AH250V

Line Cords: Line cords used must meet regulatory requirements of installation jurisdiction and have an insulation rating of 250VAC

Leakage Current:
< 3.5 mA. sinusoidal

Dimensions: Height x Width x Depth:

SPIFE Nexus Instrument:
29" (53.3 cm) x 41" (104.1 cm) x
31" (78.8 cm)
41" (104.1 cm) wide without the monitor pole
44" (111.8) wide with the monitor pole.

Computer, Monitor, and Keyboard:
23" (58.4 cm) H x 14" (35.6 cm) W x
16"(40.6 cm) D

Total Weight: ~ 250 lbs (113.4 kg)

Operating Environment:

Pollution Degree 2

15° to 27°C (59° to 80.6°F) 20% - 80% non-condensing relative humidity

Max Altitude 2000m

Storage / Shipping Environment:

5°C to 40°C at 10%-80% non-condensing relative humidity (41° to 104°F)

Complete specifications for the scanner, monitor and printer can be found in their respective owner's guides.

Operating System:
Microsoft® Windows® 10
*Windows is a registered trademark of Microsoft Inc.

Electrophoresis Timer Range: 1 sec. to 20 min. in 1-second increments @1100V and 150mA

Chamber:

Electrophoresis Temperature Range:
10°C to 32°C

Pre-Drying Temperature Range: 30° to 62°C

Final Drying Temperature Range: 30° to 65°C (86° to 149°F)

Pump System: 1 gear pump, 1 syringe pump, 2 peristaltic pumps

Test Tubes: 12-16 mm diameter, 75-100 mm height (Minimum sample volume 500uL)

Bar Codes:

Type	Character Density Minimum Bar Width	Ratio Thin to Thick	Max Characters Bar Width

Type	Character Density Minimum Bar Width	Ratio Thin to Thick	Max Characters Bar Width
Code 3 of 9 (Code 39) (alphanumeric)	0.0075	3:1	10
EAN	0.014	n/a	13
Codabar (numeric)	0.0098	n/a	10
UPC - 12 (numeric)	0.014	n/a	13
CODE 128 (alphanumeric)	0.0075	3:1	25

The size of the placement zone varies depending on the length of the tube. See CLSI's AUTO02-A2, Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard – Second Edition, December 2005 for more detailed information.
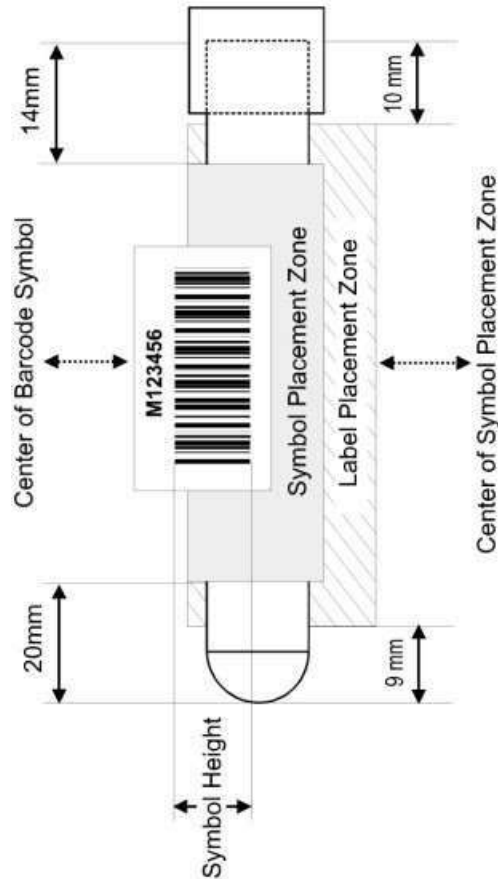
Test Tube Type	Minimum volume
13 X 75 round bottom	150 uL
16 X 100 mm round bottom	300 uL
13 mm conical bottom	75 uL
13 mm Serum separator tubes	Min. volume 500 uL above plug
16 mm Serum separator tubes	Min. volume 800 uL above plug

Section 10 - Maintenance, Troubleshooting and Warranty

This section describes routine operator maintenance procedures as well as detailed calibration instructions.

For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

Table 10-1 details the recommended preventative maintenance schedule for the Nexus.

The flow of this chapter will follow the SPIFE Nexus Maintenance window. After each of the windows have been detailed, the different instrument maintenance procedures will be listed**.**

From the Main Menu, select the *Maint* icon. The SPIFE Nexus Maintenance window appears displaying the following options: *Wash Pipette, Maintenance Wash, Test / Calibrate, View Logs, Backup, Restore*, and *Close* (Figure 10-1).

Table 10-1 Preventative Maintenance Schedule

After Every Test
- Clean Gel Cassettes
- Clean Reagent Roller
- Clean visible spills and excess stain
- Clean Blotter Holder

Daily, if used
- General Inspection of Instrument for cleanliness
- Prime fluid system daily
- Clean the Reagent/Sample Tray station
- Clean the Electrophoresis Cover
- Clean the Electrophoresis Platen and inspect the Contact Sheet for damage
- Clean the top of the Wash/Destain station
- Clean the top of the Dryer and Dryer Cover
- Inspect and clean the Antisera Spreader Tip. Replace if worn.
- If the Instrument will not be in use for a shift or more, exit the SPIFE Nexus software and power down the instrument
- If the instrument is in continuous use, exit the SPIFE Nexus software and reboot the instrument on a daily basis.

Weekly
- Clean/Bleach DI Water Bottle
- Clean/Bleach Saline Water Bottle
- Clean Sample Pipette Wash block

Monthly
- Bleach the instrument/System Flush
- Clean optical fluid sensors in the Wash Vat

As Needed
- Replace Contact Sheets
- Rinse/Replace Fluid Vats
- Replace Tubing/Pump
- Inspect Pipette
- Backup Parameters

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*Contact a Helena Service Representative for assistance with replacing and calibrating the sample handler pipette. **Incorrect pipette calibration may result in severe pipette damage.**

10.1. Wash Pipette

Select to wash the pipette system.

1. Click the *Wash Pipette* button.

   a. A prompt alerts the user "Wash, moving to wash……". A *Cancel* button is

also displayed which will immediately stop the operation.

b. Next it will alert the user, "Wash, washing pipette…".

c. Next it will alert the user, "Wash, washing completed…"

d. Next it will alert the user, "Wash, moving pipette…".


2. Once complete, the window will close and return to the SPIFE Nexus Main Menu.

10.2. Maintenance Wash

1. The Maintenance Wash is designed to flush the three different lines from the re-agent bottles into the vat in the instrument. Each different wash fills the vat with the chosen fluid, recirculates it, and then drains the fluid from the vat.

2. Click the *Maintenance Wash* button. The *Maintenance Wash* tab opens dis-playing the following options: *DI Water*

Wash, Destain Wash, Buffer Wash, and *Cancel* (Figure 10-2).
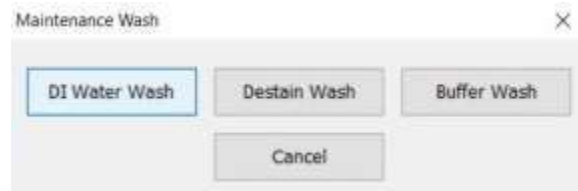
3. *DI Water Wash* – Select to perform a DI Water Wash of the vat and flush the DI Water line to the instrument.

   a. A prompt alerts the user "*Maintenance Wash, Filling vat with DI Water…*". A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.
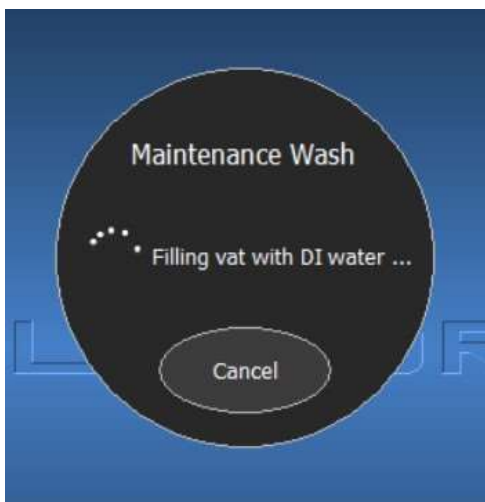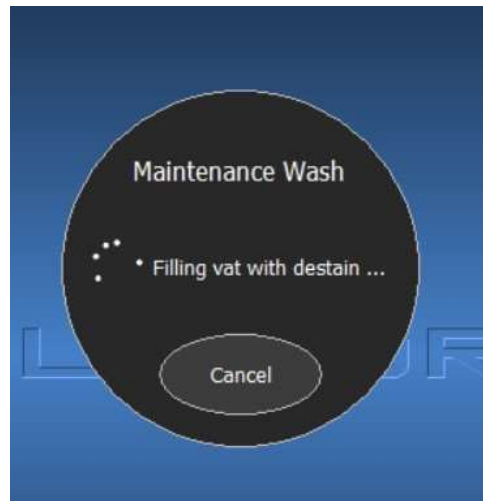

   b. Next, it will alert the user "*Draining vat…*".

   c. Once complete, the window will close and return to the main menu.

4. *Destain Wash* – Select to perform a Destain Wash of the vat and flush the Destain line to the instrument.

   a. A prompt alerts the user "*Maintenance Wash, Filling vat with destain…*". A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.
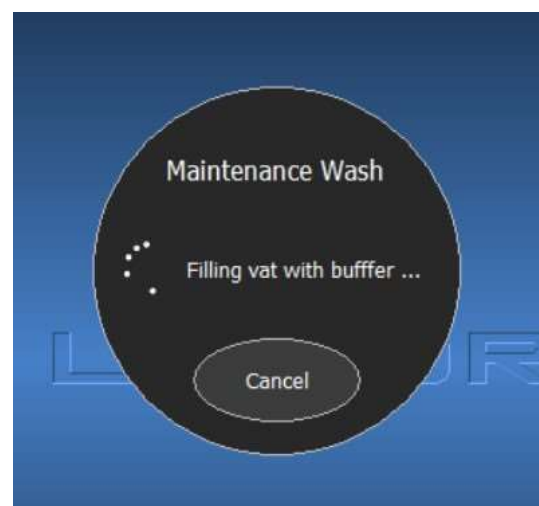

   b. Next, it will alert the user "*Draining vat…*"

   c. Once complete, the window will close and return to the main menu.

5. *Buffer Wash* – Select to perform a Buffer Wash of the vat and flush the Buffer Wash line to the instrument.

   a. A prompt alerts the user "*Maintenance Wash, Filling vat with buffer…*". A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.

   b. Next, it will alert the user "*Draining vat…*"

   c. Once complete, the window will close and return to the main menu.

6. *Cancel* – click to return to the SPIFE Nexus Main Menu.

10.3. Clean Platen Cover

1. From the SPIFE Nexus Maintenance window, select the *Clean Platen Cover* button to have the Platen Cover brought from its home position to the front of the instrument

2. Remove the Platen Cover, dampen a lint-free tissue with DI water and wash the surface of the electrophoresis chamber. Using a cotton-tipped applicator moistened with DI water, clean the surrounding trough (all four sides) and the entire under side of the lid.

3. Replace the Platen Cover and select OK on the onscreen prompt.

4. The SPIFE Nexus replaces the Platen Cover and closes the SPIFE Nexus Maintenance window.

10.4. Test / Calibrate

Click the *Test / Calibrate* button to open the *SPIFE Nexus Test and Calibrate* window (Figure 10-3).

10.4.1. Pipette

The screen allows the user to troubleshoot and calibrate the pipette. The X-axis motor controls the left and right movement of the pipette. The Y-axis motor controls the front and back movement of the pipette. The Z-axis motor controls the up and down movement of the pipette.

1. *X-Axis* – use the following options to move the X-axis motor.

   a. *Motor* – select *Enabled* to enable the pipette X-axis motor or *Disabled* if the user needs to move the pipette manually.

   b. *Current Position* – displays the current position of the X-axis motor.

c. *Home* – select to send the X-axis motor to the home position.

   d. *New Position* – set a new position for the X-axis motor then click the *Move To* button to move it to another location.

   e. *Reset Motor* – select to reset the pipette X-axis motor to clear a motor fault.

2. *Y Axis* – use the following options to move the Y-axis motor.

   a. *Motor* – select *Enabled* to enable the pipette Y-axis motor or *Disabled* if the user needs to move the pipette manually.

   b. *Current Position* – displays the current position of the Y-axis motor.

   c. *Home* – select to send the Y-axis motor to the home position.

   d. *New Position* – set a new position for the Y-axis motor then click the *Move To* button to move it to another location.

   e. *Reset Motor* – select to reset the pipette Y-axis motor to clear a motor fault.

3. *Z Axis* – use the following options to move the Z-axis motor.

   a. *Motor* – select *Enabled* to enable the pipette X-axis motor or *Disabled* if the user needs to move the pipette manually.

   b. *Current Position* – displays the current position of the Z-axis motor.

   c. *Home* – select to send the Z-axis motor to the home position.

   d. *New Position* – set a new position for the Z-axis motor then click the *Move To* button to move it to a new location.

   e. *Reset Motor* – select to reset the pipette Z-axis motor to clear a motor fault.

4. *Calibrate* – displays all of the calibration values for the pipette drive in order for the customer to fully calibrate the instrument after replacing the pipette.

a. *Calibrated positions* – from this section, the user can use the arrows (or click and type) to manually set the X, Y, and Z motors for the following positions: *Sample Aspirate*, *Tray Station*, *Reagent Storage*, *Spreader*, *Wash Station,* and *Platen*.

b. *Pipette* – select to operate the pipette move controls.

i. *Motors* – select *Enabled* to enable the pipette motors or *Disabled* if the user needs to move the pipette manually.

ii. *Move To* – once the new positions are determined, selecting *Move To* will move the motors to the positions.

iii. *Record Position* – select to record the current position of the pipette into the currently selected calibration value.

iv. *Move X To Home* – select to send the X-axis motor to its home position

v. *Move Y To Home* – select to send the Y-axis motor to its home position

vi. *Move Z To Home* – select to send the Z-axis motor to its home position.

c. *Jog Pipette* – select which direction to slightly move the pipette position.

i. *Backward* – select to jog the pipette backwards.

ii. *Left* – select to jog the pipette left.

iii. *Right* – select to jog the pipette right.

iv. *Forward* – select to jog the pipette forwards.

v. *Up* – select to jog the pipette up.

vi. *Down* – select to jog the pipette down.

vii. *Jog Speed* – select between *Low* and *High* depending on how far the pipette needs to travel.

5. *Move* – use to move the pipette to one of the below locations on the instrument.

a. *Move to Wash* – select to move the pipette to the wash station.

b. *Move To Aspirate* – select to move the pipette to the aspirate location.

c. *Move To Spreader Pickup* – select to move the pipette to the Antisera Spreader Tip pickup location.

d. *Move To Spreader Store* – select to move the pipette to the Antisera Spreader Tip store location.

e. *Move To Idle* – select to move the pipette to the idle position.

f. *Move To Reagent* – select to move the pipette to a specific reagent well.

i. From the *Well Number* dropdown menu, select a sample well from 1 to 10.

ii. Select *Move To* to move the pipette to the chosen reagent well number.

g. *Move To Tray Well* – select to move the pipette to a specific well in the tray selected.

i. *Tray* – From the dropdown menu, select a sample tray from the programmed tray templates.

ii. *Well* – using the dropdown arrow, select either *Sample* or *Dilution* (IFE).

1) *Sample* – select a sample well in the tray using the arrows.

2) *Dilution* – select a sample well in the tray using the arrows. This option is only available with Immunofixation tests

iii. *Move To* – after the well has been selected, click the *Move To* button to move to the new well.

6. *Home All* – select to move all the pipette motors to their home locations.

10.4.2. Tube Transport

The X-axis motor controls the left and right movement of the tube transport. The Y-axis motor controls the front and back movement of the tube transport. (Figure 10-4)

1. *X Axis* – use the following to move the X-axis motor.

a. *Current Position* – displays the current position of the tube transport X-axis.

b. *Home* – select to move the transport X-axis to its home location.

c. *New Position* – enter a new location, then select the *Move To* button to move the tube transport X-axis motor to its new location.

d. *Reset Motor* – select to reset the transport X-axis motor to clear a motor fault.

2. *Y Axis* – use the following to move the Y-axis motor.

a. *Current Position* – displays the current position of the tube transport Y-axis.

b. *Home* – select to move the transport Y-axis to its home location.

c. *New Position* – enter a new location, then click the *Move To* button to move the tube transport Y-axis motor to its new location.

d. *Reset Motor* – select to reset the transport Y-axis motor to clear a motor fault.

3. *Calibrate* – from this section, the user can use the arrows to manually set the X

motor for the *Last Rack Position* and *Rack Removal* and the Y position for the *X Axis Transfer* and *Sample Aspirate* positions.

a. *Calibrated Distances* – the current calibrated distances are displayed on the screen.

i. *Rack Sensor to Y Transfer* – the current calibrated distance a rack has to move past the rack sensor to be in position for the Y-Axis to pick it up.

ii. *Rack Step* – the current calibrated distance between the racks.

iii. *Tube Step* – the current calibrated distance between the tube positions in a rack.

b. *Tube Transport* – use to move the tube transport to a specific location.

i. *Move To* – select to move the tube transport to the selected calibrated position.

ii. *Record Position* – select to record the current position of the pipette into the currently selected calibration value.

iii. *Move X To Home* – select to move the X-axis motor to its home position.

iv. *Move Y To Home* – select to move the Y-axis motor to its home position.

v. *Move X to Y Transfer* – the position where the Y-axis picks up a rack to be pulled into the sampling position.

vi. *Step Rack +* – move forward to the next rack position.

vii. *Step Tube +* – move forward to the next tube position,

viii. *Step Rack -* – move backward to the previous rack position.

ix. *Step Tube -* – move backward to the previous tube position.

x. *Rack Detected* – This will be illuminated if a rack is detected.

xi. *Tube Detected* – This will be illuminated if a tube is detected

c. *Jog Tube Transport* – select which direction to slightly move the tube transport.

i. *Left* – select to jog the tube transport left.

ii. *Right* – select to jog the tube transport right.

iii. *Backward* – select to jog the tube transport backward.

iv. *Forward* – select to jog the tube transport forward.

v. *Jog Speed* – select between *Low* and *High* depending on how far the tube transport needs to travel.

4. *Move* – use to move the tube transport to one of the below locations on the instrument.

a. *Move to Aspirate* – select to move the tube transport to the aspirate position.

b. *Move To Removal* – select to move the tube transport to the removal location.

c. *Move To Idle* – select to move the tube transport to the idle location.

5. *Home All* – select to move all the transport motors to their home locations.

10.4.3. Claw

The X-axis motor controls the left and right movement of the claw. The Y-axis motor controls the front and back movement of the claw. The Z-axis controls the up and down movement of the claw. (Figure 10-5)

1. *X-Axis* – use the following to move the X-axis motor.

a. *Current Position* – displays the current position of the claw X-axis.

b. *Home* – select to move the claw X-axis to its home location.

c. *New Position* – enter a new location, then click the *Move To* button to move the claw X-axis motor to its new location.

d. *Reset Motor* – select to reset the claw X-axis motor to clear a motor fault.

2. *Y Axis* – use the following to move the Y-axis motor.

a. *Current Position* – displays the current position of the claw Y-axis.

b. *Home* – select to move the claw Y-axis to its home location.

c. *New Position* – enter a new location, then click the *Move To button* to move the claw Y-axis to its new location.

d. *Reset Motor* – select to reset the claw Y-axis motor to clear a motor fault.

3. *Z Axis* – use the following to move the Z-axis motor.

a. *Current Position* – displays the current position of the claw Z-axis.

b. *Home* – select to move the claw Z-axis to its home location.

c. *New Position* – enter a new location, then click the *Move To* button to move the claw Z-axis motor to its new location.

d. *Reset Motor* – select to reset the claw Z-axis motor to clear a motor fault.

4. *Claw* – use to move the claw to a new position.

a. *Current Position* – displays the current position of the claw.

b. *Home* – select to move the claw to its home location.

c. *New Position* – enter a new location, then click the *Move To* button to move the claw to its new location.

5. Calibrate – from this section, the user can use the arrows to manually set the X, Y, and Z-axis motors for the following positions using the arrows: *Applicator Storage, Applicator to Tray, Applicator to Platen, Cassette Platen Pickup, Cassette Platen Lay Down, Cassette Vertical Align Tab, Cassette to Wash / Destain, Cassette to Dryer, Cassette to Scanner, Platen Cover Storage, Platen Cover to Platen, Platen Cover Transport, Reagent Pour / Spread, Blotter Storage, Blotter to Platen, Dryer Cover Storage,* and *Dryer Cover to Dryer.*

Note: *Cassette Platen Lay Down* and *Platen Cover Transport* only have a Z value.

a. *Claw Engage Positions* – the current claw engage positions are displayed on the screen for the following.

      i. *Applicator*

      ii. *Cassette*

      iii. *Blotter*

      iv. *Platen Cover*

      v. *Dryer Cover*

b. *Claw* – use the following options to move the claw to a specific location.

      i. *Motors* – select *Enabled* to enable the claw motor or *Disabled* if the user needs to move the claw manually. This only applies to the X-axis and Y-axis. It cannot be moved manually along its Z-axis (up and down)

      ii. *Move To* – once the new positions are determined, selecting *Move To* will move the claw to the position.

      iii. *Record Position* – select to record the current position of the claw into the currently selected calibration value.

      iv. *Engage Claw* – select to move (and close) the claw to the engage position that is selected.

      v. *Record Engage Pos* – select to record the current position of the claw into the currently selected calibration value.

      vi. *Move X To Home* – select to send the X-axis motor to the home position.

      vii. *Move Y To Home* - select to send the Y-axis motor to the home position.

      viii. *Move Z To Home* – select to send the Z-axis motor to the home position.

      ix. *Disengage Claw* – select to move (and open) the claw to the disengage position that is selected.

c. *Jog Claw* – select which direction to slightly move the claw position.

      i. *Backward* – select to jog the claw backwards.

      ii. *Left* – select to jog the claw left.

      iii. *Right* - select to jog the claw right.

      iv. *Forward* – select to jog the claw forward.

      v. *Up* – select to jog the claw up.

      vi. *Down* – select to jog the claw down.

      vii. *Open* – select to open the claw.

      viii. *Close* – select to close the claw.

ix. *Jog Speed* – select between *Low* and *High* depending on how far the claw needs to travel.

6. *Move* – select from below to move the claw to a specific position on the instrument. To physically complete the step, ensure the item is correctly placed that will be moved.

a. *Cassette* – select from the following positions to move the Gel Cassette.

i. *Move To Platen Pickup*

ii. *Move To Wash*

iii. *Move To Stain*

iv. *Move To Dryer*

v. *Engage Cassette*

vi. *Disengage Cassette*

vii *Move To Stain Pour*

viii. *Move To Idle*

b. *Applicators* – select from the following positions to move the Applicator Holder.

i. *Move To Storage*

ii. *Move To Apply*

iii. *Extract From Tray*

iv. *Move To Apply*

v. *Engage Applicator*

vi. *Disengage Applicator*

c. *Blotter* – select from the following positions to move the Blotter Holder.

i. *Move To Storage*

ii. *Move To Blot*

iii. *Engage Blotter*

iv. *Disengage Blotter*

d. *Electrophoresis Cover* – select from the following position to move the Platen Cover.

i. *Move To Storage*

ii. *Move To Chamber*

iii. *Engage Cover*

iv. *Disengage Cover*

e. *Dryer Cover* – select from the following position to move the Dryer Cover.

i. *Move To Storage*

ii. *Move To Dryer*

iii. *Engage Cover*

iv. *Disengage Cover*

7. *Home All* – select to move all the claw motors to their home locations.

10.4.4. Syringe Pump

This allows the user to troubleshoot the syringe and plunger. (Figure 10-6)

1. *Firmware Version* – lists the main control firmware version

2. *Current Position Valve* – displays current position of the syringe pump valve.

3. *Current Position Plunger (µL)* – displays current position of the syringe plunger.

4. *New Position* – select either *syringe* or *wash* from the dropdown menu. Enter a new location, then click the *Move To* button to move it to its new location.

5. *Plunger steps per sec* – enter the plunger steps per second required.

6. *Syringe Settings* – displays the syringe settings.

a. *Syringe Size (µL)* – use the dropdown arrow to select the syringe size.

b. *Plunger steps per µL* – use the arrows to select the plunger steps per µL.

7. *Volume Test* – After placing a weigh boat in the sample tray area, enter the

volume using the up and down arrows. Click the *Test Volume* button to have the pipette remove the above volume of DI Water and aliquot it into the weigh boat so it may be weighed and verified.

8. *Reset* – click to reset to clear a syringe pump fault.

10.4.5. Fluid Detect

This section will display the output from the fluid sensor. Choose from the following (Figure 10-7).

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

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

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

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

5. *Initialize* – select to initialize the fluid detect.

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

7. *Conversion Time* – use the dropdown arrow to select the desired time in ms, then press *Set.*

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

10.4.6. Main Control

This screen allows the user to enable or disable LED alert lights and view the status of stations in the instrument. (Figure 10-8)

1. *Firmware Version* – lists the main control firmware version.

2. *Unlock Door* – click to unlock the door.

3. *Reset Scanner* – select to reset the scanner.

4. *Gantry LEDs* – select which gantry LEDs to illuminate when one of the below conditions occurs. Selecting *On* will have the light illuminate inside the main area of the instrument while selecting *Off* will disable this feature.

a. *Red LED* – red displays when a critical error is present.

b. *Green LED* – green displays when all is satisfactory.

c. *Blue LED* – blue displays when a material or item is required.

5. *Status LEDs* – select which status LEDs to illuminate when one of the below conditions occurs. Selecting *On* will have the LED status light located on the top of the instrument illuminate while selecting *Off* will disable this feature.

a. *Red LED* – red displays when a critical error is present.

b. *Green LED* – green displays when all is satisfactory.

c. *Blue LED* – blue displays when a material or item is required.

d. *Yellow LED* – yellow displays when a warning is present.

6. *Status* – displays the status with green being an active condition.

a. *Upper Door Open* – displays the upper door status.

b. *Lower Door Open* – displays the lower door status.

c. *Pipette Door Open* – displays the pipette door status. The pipette door is located above the power button on the left hand side of the instrument. It should only be accessed by Helena Laboratories Service personnel.

d. *Pump Door Open* – displays the pump door status.

e. *Back Door Open* – displays the back door open status.

f. *Rack Area Full* – displays the rack area full status

g. *Cassette In Scanner* – displays the Gel Cassette in scanner status.

h. *Cassette In Outlet* – displays the Gel Cassette in outlet status.

i. *Power Button Pressed* – displays the power button pressed status.

j. *USB 5 Volts* – displays the status of power from the main controller USB ports.

k. *Platen Cover Installed* – displays the Platen Cover status.

l. *Consumable Tray Installed* – displays the Consumables Tray status.

10.4.7. Fluid Control

This screen allows the user to enable or disable valves and pumps as well as view the status of different areas in the instrument (Figure 10-9).

1. *Firmware Version* – lists the fluid control firmware version.

2. *Valves* – select *Open* to open one of the below valves or *Closed* to close it.

     a. *Wash Valve*

     b. *Recirculate Valve*

     c. *Destain Valve*

     d. *Vat DI Water Valve*

     e. *Waste Valve*

     f. *Pipette DI Water Valve*

3. *Pumps* – select *On* to enable one of the below pumps or *Off* to disable it.

     a. *Vat Pump*

     b. *Waste Vac Pump*

     c. *DI Water Pump*

     d. *Saline Pump*

     e. *Pipette Vac Pump*

     f. *Overflow Pump*

4. *Vat Pump Settings* – select the direction and frequency.

     a. *Direction* – select either *CW* (clockwise) or *CCW* (counterclockwise).

     b. *PWM Frequency* – using the arrows, set the PVM Frequency.

     c. *PWM Duty Cycle* – using the arrows, set the PVM Duty Cycle.

     d. *Set PVM* – select to set the displayed PVM values.

5. *Status* – displays the status with green being an active condition.

     a. *Pump Door Open* – displays the pump door open status.

     b. *Cassette In Vat* – displays the Gel Cassette in vat status.

     c. *Vat Full* – displays the vat full status.

     d. *Waste Full* – displays if the waste full status.

     e. *Vat Overflow* – displays the vat overflow status.

     f. *Wash Overflow* – displays the wash overflow status.

     g. *No DI Water* – displays the No DI Water status.

     h. *No Saline* – displays the no saline status.

6. *Wash Functions* – select to open the *Wash Functions* dialog window.

     a. *Pipette Wash Block* – select On to enable the pipette wash block or *Off* to disable it.

b. *Wash Station* – select *On* to enable the Wash Station or *Off* to disable it.

c. *DI Water Pump* – select *On* to enable the DI Water Pump or *Off* to disable it.

d. *Move To Wash* – select to move the pipette to wash.

e. *Status* – displays the status with green being an active condition.

i. *No DI water* – displays the DI water status

ii. *No Saline* – displays the Saline status.

iii. *Wash Overflow* – displays the Wash Overflow status.

f. *Close* – click to close the *Wash Functions* window.

7. *Vat Functions* – select to open the *Vat Functions* dialog window

a. *Fill* – select to fill the vat.

i. *Fill Valve* – using the dropdown menu, select from *DI Water*, *Buffer*, or *Destain*.

ii. *Time Limit (sec)* – using the arrows, select a time limit in seconds.

iii. *Fill Vat* – select to fill the selected vat.

b. *Drain* – select to drain the vat.

i. *Drain Valve* – using the dropdown menu, select from *Waste*, *DI Water*, *Buffer*, or *Destain*.

ii. *Time Limit (sec)* – using the arrows, select a time limit in seconds.

iii. *Drain Vat* – select to drain the selected vat.

c. *Recirculate* – select to recirculate any fluid in the vat.

i. *Direction* – using the dropdown menu, select from *CW* (Clockwise) or *CCW* (Counterclockwise).

ii. *Time Limit (sec)* – using the arrows, select a time limit in seconds.

iii. *Recirculate* – select to start recirculation.

d. *Status* – displays the status with green being an active condition.

i. *Vat Full* – displays the vat full status.

ii. *Vat Overflow* – displays the vat overflow status.

e. *Stop* – select to stop all operations.

f. *Close* – select to close the *Vat Functions* dialog window.

10.4.8. Platen Temp Control

This screen allows the user to enable or disable platen power, set PVM values, set output levels, as well as view the status of different areas in the instrument (Figure 10-10).

1. *Firmware Version* – lists the platen temperature control firmware version.

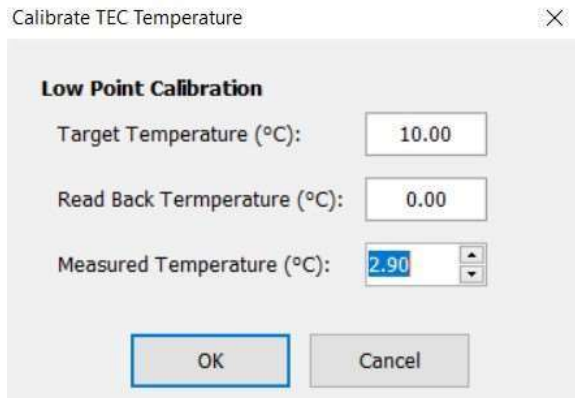2. *Platen TEC* – select to set platen thermoelectric cooler.

a. *Power* – select *On* to enable power to the electrophoresis platen or *Off* to disable power to the electrophoresis platen.

b. *Mode* – select *Heat* to raise the temperature or *Cool* to reduce platen temperature.

c. *Required Temperature (°C)* – use the arrows to set the required temperature.

d. *Set Temp* – after entering the new value, select to set the new temperature.

e. *Calibrate* – select to open the *Calibrate TEC Temperature* dialog window.

Calibrate TEC Temperature　　　　✕

Low Point Calibration

Target Temperature (°C):　　10.00

Read Back Termperature (°C):　　0.00

Measured Temperature (°C):　　2.90 ▲▼

OK　　　　Cancel

i. *Low Point Calibration* – use to set the low point calibration value.

1) *Target Temperature (°C)* – enter the target temperature.

2) *Read Back Temperature (°C)* – enter the read back temperature.

3) *Measured Temperature (°C)* – using the arrows, enter the measured temperature.

ii. *OK* – to save all changes and exit the *Calibrate TEC Temperature* dialog window, select *OK*.

iii. *Cancel* – to exit without saving any changes made, select *Cancel.*

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

i. To exit without saving changes, select *Yes.*

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

3. *Outputs* – outputs are the physical outputs on the PCB (printed circuit board) which can be used to test the PCB to determine if the output state is correct. The state can be set to either *Low* or *High* to aid in diagnosis.

a. *R89 (Fan Enable)*

b. *RC6 (Good LED)*

c. *RC7 (Error LED)*

d. *RF0 (Heat / Cool)*

e. *RF1 (Power Enable)*

f. *RA4 (PVM Enable)*

4. *PWM* – select to set pulse width modulation.

a. *Frequency (Hz)* – Using up and down arrows, select the desired frequency then click *Set PVM.*

5. *Status* – displays the status with green being an active condition.

a. *Platen Temperature (°C)* – displays the platen temperature.

b. *Air Temperature (°C)* – displays the air temperature.

c. *TEC Current (Amps)* – displays the TEC Current.

d. *Power Supply Voltage (Volts)* – displays the power supply voltage.

e. *Duty Cycle (%)* – displays the duty cycle.

f. *PID Output* – displays the PID output.

g. *Cassette on Platen* – displays the cassette on platen status.

h. *Door Open* – displays the door open status.

i. *Cover Installed* – displays the cover installed status.

j. *Thermostat Open* – displays the thermostat open status.

6. *PID Settings* – displays the proportional integral derivative settings.

a. *Kp* – displays the proportional gain setting.

b. *Ki* – displays the integral gain setting.

c. *Kd* – displays the derivative gain setting.

d. *Ei* – displays the maximum interval error.

e. *Max PID* – displays the maximum

proportional integral derivative setting.

10.4.9. Dryer Control

This screen allows the user to enable or disable the dryer power, set output levels, set PVM values, as well as view the status of different locations of the instrument (Figure 10-11).

1. *Firmware Version* – lists the dryer control firmware version.

2. *Dryer* – select to set dryer parameters.

a. *Power* – select *On* to enable power to the dryer or *Off* to disable power to the dryer.

b. *Required Temperature (°C)* – using the up and down arrows, enter the required temperature.

c. *Set Temp* – select to set the new temperature.

d. *Calibrate* – click to open the *Calibrate Dryer Temperature* dialog window.

i. *Low Point Calibration* – use to set the low point calibration value.

1) *Target Temperature (°C)* – enter the target temperature.

2) *Read Back Temperature (°C)* – enter the read back temperature.

3) *Measured Temperature (°C)* – using the arrows, enter the measured temperature.

ii. *OK* – to save all changes and exit the *Calibrate TEC Temperature* dialog window, select *OK*.

iii. *Cancel* – to exit without saving any changes made, select *Cancel.*

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

i. To exit without saving changes, select *Yes.*

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

3. *Outputs* – outputs are the physical outputs on the PCB (printed circuit board) which can be used to test the PCB to determine if the output state is correct. The state can be set to either *Low* or *High* to aid in diagnosis.

a. *R89 (Fan Enable)*

b. *RC6 (Good LED)*

c. *RC7 (Error LED)*

d. *RF1 (Power Enable)*

e. *RA4 (PVM Enable)*

4. *PVM* – select to set pulse width modulation.

a. *Frequency (Hz)* – Using up and down arrows, select the desired frequency then click *Set PVM.*

b. *Duty Cycle (%)* - Using up and down arrows, select the desired duty cycle then click *Set PVM.*

5. *Status* – displays the status with green being an active condition.

a. *Dryer Temperature (°C)* – displays the status of the dryer temperature.

b. *Air Temperature (°C)* – displays the status of the air temperature.

c. *Duty Cycle (%)* – displays the status of the duty cycle.

d. *Delta Temperature (°C)* – displays the status of the delta temperature.

e. *Cassette in Dryer* – displays the Gel Cassette in dryer status.

f. *Door Open* – displays the door status.

g. *Cover Installed* – displays the Dryer Cover installed status.

h. *220V Operation* – is illuminated when 220V operation is present.

10.4.10. Reagent Chiller Control

This screen allows the user to enable or disable the Reagent Chiller power, set output levels, set PVM values, as well as view the status of different locations of the instrument (Figure 10-12).

1. *Firmware Version* – lists the Reagent Chiller control firmware version.

2. *Reagent Chiller TEC* – select to set the Reagent Chiller thermoelectric chiller values.

a. *Power* – select *On* to enable power to the Reagent Chiller or *Off* disable the power.

b. *Calibrate* – click to open the *Calibrate Reagent Chiller Temperature* dialog window.

i. *Low Point Calibration* – use to set the low point calibration value.

1) *Target Temperature (°C)* – enter the target temperature.

2) *Read Back Temperature (°C)* – enter the read back temperature.

3) *Measured Temperature* (*°C*) – using the arrows, enter the measured temperature.

ii. *OK* – to save all changes and exit the *Calibrate TEC Temperature* dialog window, select *OK*.

iii. *Cancel* – to exit without saving any changes made, select *Cancel.*

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

i. To exit without saving changes, select *Yes.*

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

3. *Outputs* – outputs are the physical outputs on the PCB (printed circuit board) which can be used to test the PCB to determine if the output state is correct. The state can be set to either *Low* or *High* to aid in diagnosis.

a. *RB9 (Fan Enable)*

b. *RC6 (Good LED)*

c. *RC7 (Error LED)*

d. *RF0 (Power Enable)*

4. *Status* – displays the status with green being an active condition.

a. *Block Temperature (°C)* – displays the block temperature status.

b. *Air Temperature (°C)* – displays the air temperature status.

c. *Power Supply Voltage (Volts)* – displays the power supply voltage status.

d. *Pipette Spreader Tip Installed* – displays if the Pipette Spreader Tip is installed.

10.4.11. Electrophoresis Platen Power Supply

This screen allows the use to enable or disable the power, set output levels, set PVM values, as well as view the status of different locations of the instrument (Figure 10-13).

1. *Firmware Version* – lists the EP Power Supply firmware version.

2. *Power Supply* – select to set power values.

a. *Power* – toggle back and forth between *On* and *Off.*

b. *Operating Mode* – use the dropdown menu to select from *Constant Voltage, Constant Current*, or *Constant Power*.

c. *Required Voltage* – use the arrows to set the required voltage.

d. *Calibrate* – use the dropdown menu to select from *Voltage, Current*, or *Power.*

e. *Calibrate* – select to open the Calibrate Voltage dialog window.

i. *Low Point Calibration* – use to set the low point calibration value.

1) *Target Voltage (volts)* – enter the target voltage.

2) *Read Back Voltage (volts)* – enter the read back voltage.

3) *Measured Voltage* (volts*)* – using the arrows, enter the measured voltage.

ii. *OK* – to save all changes and exit the *Calibrate Voltage* dialog window, select *OK.*

iii. *Cancel* – to exit without saving any changes made, select *Cancel.*

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

i. To exit without saving changes, select *Yes.*

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

3. *Outputs* – outputs are the physical outputs on the PCB (printed circuit board) which can be used to test the PCB to determine if the output state is correct. The state can be set to either *Low* or *High* to aid in diagnosis.

a. *RC0 (Fan Enable)*

b. *RC1 (AC Enable)*

c. *RC2 (Supply Enable)*

d. *RC3 (Supply On LED)*

e. *RC4 (Error On LED)*

f. *RC4 (Error LED)*

g. *RA4 (PWM Enable)*

4. PVM – select to set pulse width modulation.

a. *Frequency (Hz)* – Using up and down arrows, select the desired frequency then click *Set PVM.*

b. *Duty Cycle (%)* - Using up and down arrows, select the desired duty cycle then click *Set PVM.*

5. *Status* – A green square indicates the following status is active.

a. *EP Voltage (volts)* – displays the current EP voltage status.

b. *EP Current (mA)* – displays the EP Current status.

c. *EP Power (watts)* – displays the EP Power status.

d. *Air Temperature (°C)* – displays the current air temperature.

e. *Door Open* – displays the door open status.

f. *220V Operation* – is illuminated when a 220V unit is in use.

10.4.12. Bar Code Imagers

This function can be used to verify barcodes on test tubes or on other consumable items such as sample trays (Figure 10-14).

1. *Tube Bar Code Imager* – images the test tube and displays the bar code.

a. *Move To* – select to move the imager to one of the following locations.

     i. *Tube Read*

     ii. *Next Tube*

     iii. *Rack Removal*

     iv. *Home*

b. *Read Bar Code* – click to read the barcode on the current test tube. If no barcode is present, a NOREAD will be displayed.

c. *Clear* – press to clear the barcode or text in the text box.

2. *Gantry Bar Code Imager* – images the consumable and displays the bar code.

a. *Move To* – select to move the imager to one of the following locations.

     i. *Blotter Holder*

     ii. *Applicator Template*

     iii. *Electrophoresis Plate*

     iv. *Reagent Applique*

     v. *Sample Tray*

     vi. *Cassette*

     vii. *Home*

b. *Read Bar Code* – click to read the barcode on the current test tube. If no barcode is present, a NOREAD will be displayed

c. *Clear* – press to clear the barcode or text in the text box.

10.4.13. OK and Cancel

1. *Unlock Door* – select to unlock the Main Door of the SPIFE Nexus.

2. *OK* – to save all the changes made to the *SPIFE Nexus Test and Calibrate* setup, select OK.

3. *Cancel* – to exit without saving any of the changes made to the different tabs, select *Cancel.*

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

     i. To exit without saving changes, select *Yes.*

     ii. To save changes select *No* in response to the prompt and then select *OK.*

10.5. View Logs

The View Logs option allows the user to search all the different types of logs generated by the SPIFE Nexus. After opening the necessary log file, it can be viewed, printed, or even deleted.

1. Select the *View Logs* button. The *SPIFE Nexus View Log* window is displayed (Figure 10-16).

2. *Open Log* – select to open a log file from the *Log Files* folder.
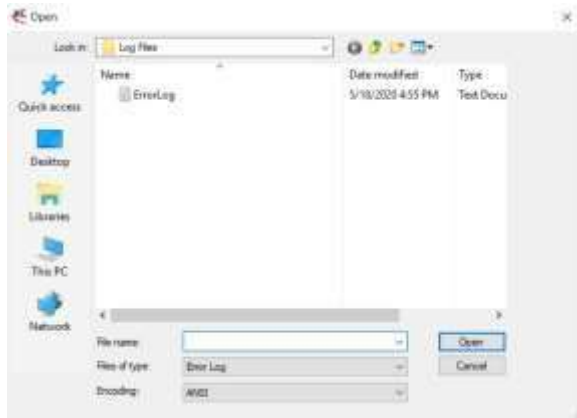
a. From Files of type dropdown menu, select from *Error Log, Startup Log, Run Log, Communication Log*, or *Rescan*.
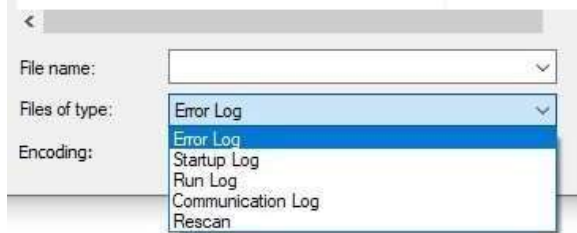
b. Once the type of file has been selected, all files of that category will be displayed.

c. Select the necessary file and click *Open*.

d. The file is now displayed in the *SPIFE Nexus View Log* window.

3. *Clear Log* – select to clear the log.

a. A *Confirm Clear* prompt displays.

i. Select *Yes* to clear the log and display a blank screen.

ii. Select *No* to keep the log and cancel the clear request.

4. *Close Log* – select to close the log and display a blank screen.

5. *Find* – select to find a word or phrase.

a. Click the *Find* button. The *Find* dialog box is displayed.

b. *Find what* – add a text or phase to search for

c. *Match whole words only* – select to match whole words and not partial ones.

d. *Match case* – select to make a case sensitive search.

e. *Find* – once all the options have been added, click to search the log and return to the *SPIFE Nexus View Log* window. Any results will be highlighted in blue.

f. *Cancel* – select to exit the window.

6. *Find Next* – once *Find* has been utilized, select *Find Next* to move to the next finding.

7. *Print* – select to print the log.

8. *Close* – select to close the window and return to the *SPIFE Nexus Maintenance* window.

10.6. Backup

1. Press the *Backup* button. The *Backup Setup and Calibration* window is displayed.
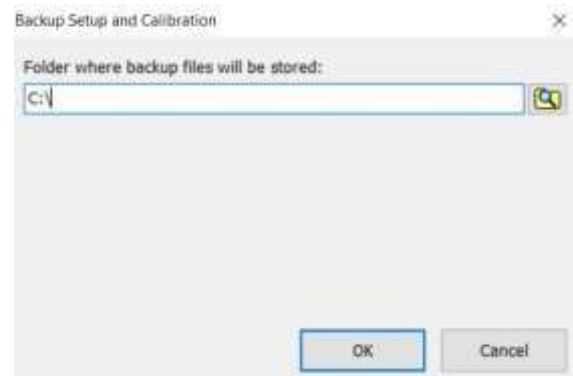
2. Select the folder to save the backup using the *Find Files* icon or by typing the file location in the test box.

3. Click *OK* to back up the files and return to the *SPIFE Nexus Maintenance* window.

4. Click *Cancel* to not back up anything and return to the SPIFE Nexus Maintenance window.

10.7. Restore

1. Press the *Restore* button. The *Restore Setup and Calibration* window is displayed.
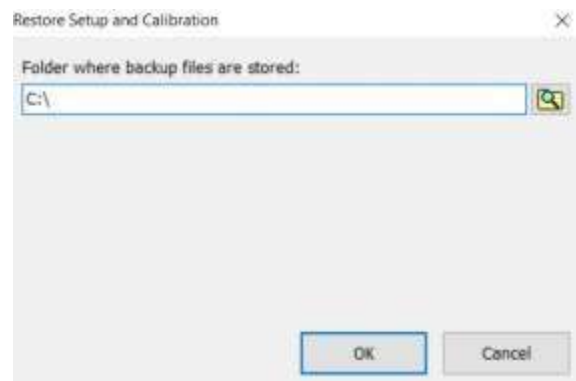
2. Select the folder where the files to be restored are located using the *Find Files* icon or by typing the file location in the test box.

3. Click OK to restore the files and return to the *SPIFE Nexus Maintenance* window.

4. Click *Cancel* to not restore any files and return to the *SPIFE Nexus Maintenance* window.

10.8. Close

Select *Close* to exit out of the *SPIFE Nexus Maintenance* menu.

10.9. Instrument Care

This section describes the physical maintenance procedures that need to be performed as part of the Calibration and Maintenance program.

Note*: If the instrument must be powered off for a maintenance procedure, open*

the main instrument door before turning off the power. When the power is off, a safety interlock feature locks the main instrument door.

After Each Test

10.9.1. Clean Cassettes

1. Separate the two pieces of the Gel Cassette and wash with soap and deionized water.

2. Rinse the pieces in deionized water and dry.

10.9.2. Clean Reagent Roller

1. Remove the Reagent Roller from the instrument.

2. Wipe clean with an isopropyl prep pad and allow to air dry.

10.9.3. Clean Visible Spills and General Instrument Cleaning

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

2. 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. Scrub the stained area of the instrument to remove any stain. Take care that excessive scrubbing does not remove the paint. Use the sponge side of the pad to wipe off excess cleanser. Dampen a paper towel and wipe off remaining residue.

10.9.4. Clean Blotter Holder

1. Remove the used SPIFE Nexus Blotter D from the Blotter Holder.

2. Wipe clean with an isopropyl prep pad and allow to dry.

10.9.5. Clean Electrophoresis Platen and Contact Sheet

1. 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.

2. Inspect the contact sheet. It should not be curling along the edges or show injury or gouged areas. If it does, see Section 10.9.17 on how to replace the contact sheet.

3. Should the chamber be contaminated by blood or blood derivative, first **power off the instrument** and then wipe the area down with Isopropyl prep pads or spray with a 70% isopropyl mix.

4. Wipe up any liquid reside to avoid corrosion. Dry the unit before plugging the power cord back in and powering the instrument back on.

Daily, if used

10.9.6. Prime Fluid System

1. The instrument should be primed on a daily basis, preferably at the beginning of a shift before any runs have been started.

2. From the Main Menu, select the *Prime* icon.

3. A prompt alerts the user "Prime, moving to wash…*".* A *Cancel* button is also displayed which will immediately stop the operation.

4. Next it will alert the user, "Priming…".
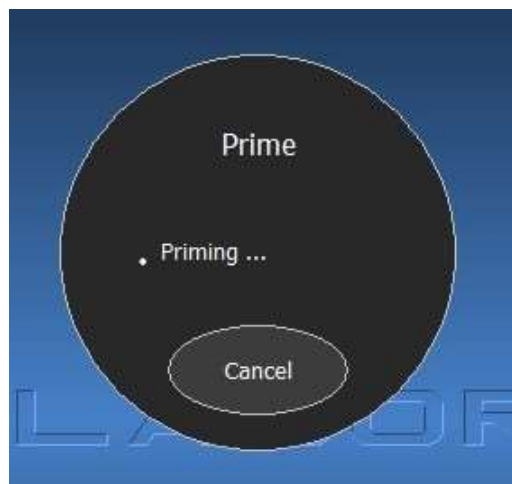
5. Next, it will alert the user, "Priming completed…"

6. Next it will alert the user, "Moving pipette…".

7. Once complete, the window will close and return to the SPIFE Nexus Main Menu.

10.9.7. Clean Reagent/Sample Tray Stations

1. Dampen a lint-free tissue with DI water and wash the surfaces of the Antisera and Sample Tray stations.

2. Using a second tissue, wipe dry all areas that were cleaned.

10.9.8. Clean Platen Cover

1. From the SPIFE Nexus Maintenance window, select the *Clean Platen Cover* button to have the Platen Cover brought from its home position to the front of the instrument.

2. Remove the Platen Cover. Dampen a lint-free tissue with DI water and wash the top surface of it. Flip the Platen Cover over and use a cotton-tipped applicator, moistened with DI water, and clean the surrounding trough (all four sides) and the entire under side of the lid.

3. Replace the Platen Cover and select OK.

4. The instrument replaces the Platen Cover to its home position.

10.9.9. Clean Wash/Destain Station

1. If extremely dirty, dampen a lint-free tissue with DI water and wash the surface of the Wash / Destain Station.

2. To finish, wipe the area down with Isopropyl prep pads or spray with a 70% isopropyl mix.

10.9.10. Clean Dryer and Dryer Cover

Note: Ensure the Dryer station is not hot.

1. If extremely dirty, dampen a lint-free tissue with DI water and wash the surface of the Dryer and Dryer Cover.

2. To finish, wipe the area down with Isopropyl prep pads or spray with a 70% isopropyl mix.

3. If necessary, wash the Dryer Cover with DI water.

4. Dry and replace the Dryer Cover in its home location.

10.9.11. Inspect and clean Antisera Spreader Tip

1. Using the spreader tip tool, remove the Antisera Spreader Tip from the well (Figure 10-17).

2. Wash the spreader tip with deionized water and dry.

3. Replace the spreader tip on the spreader tip tool, bracing it against a finger to prevent it from slipping off the end of the tool before reinserting it into the well.
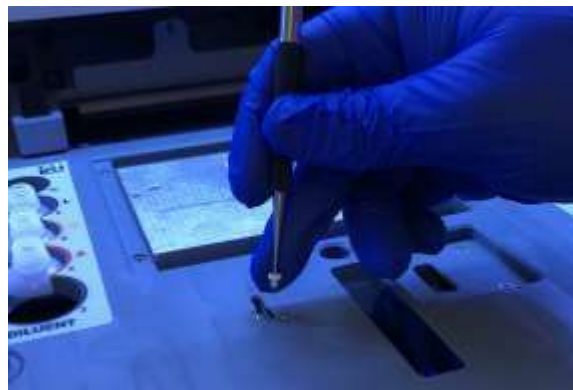
4. Replace monthly or when Antisera Spreader Tip appears discolored or misshapen.

Weekly

10.9.12. Clean/Bleach DI Water and Saline Bottles

Note: This procedure should also be used for the Saline, Buffer Wash, and Destain Bottles.

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

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

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

4. Refill and replace the DI water bottle.

5. Insert the tubing into the bottle and connect the DI water bottle port designated DI H_2O.

6. From the main menu, select *Prime*. The priming operation will ensure that no bubbles are in the lines.

10.9.13. Clean Sample Pipette Wash Block

1. Insert a long cotton tipped swab into the sample pipette area and clean away any debris.

2. Select the *Maint* icon then Wash Pipette to finish.

Monthly

10.9.14. Bleach entire instrument

Note: *It is <u>VERY</u> important to empty the waste container before starting to avoid potential chemical interaction.*

1. Once a month, prepare approximately 2L of a 10% bleach solution in a large glass flask or other bleach safe container.

2. Remove the tubing from the Saline, DI Water, Wash, and Destain bottles located on the right hand side of the instrument (tubes 1-4). Leave the ends of the tubing exposed to air.

3. Prime the machine (to remove DI and Saline from pipette lines).

4. From the main menu, select the *Maint*, then *Maintenance Wash*.
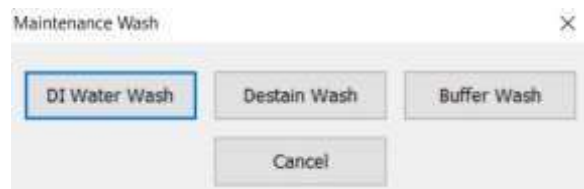
5. Select *DI Water Wash* to rid the vat lines of fluid. Repeat with Destain Wash and Buffer Wash until all fluid has been purged from the lines.

6. Place the ends of the tubing into the prepared bleach solution. Repeat steps 3 through 5 to pull bleach prepared solution through all lines.

7. Remove the ends of the tubing from the bleach solution.

8. Place the ends of tubes 1-4 into prepared DI water and repeat steps 3 through 5 to rinse lines.

Note: *It is important to thoroughly rinse the system with DI water after bleaching.*

Failure to do so could cause erroneous results.

9. Refill and replace the DI water bottle.

10. Insert the tubing onto the appropriate bottle ports.

10.9.15. Clean Optical Fluid Sensors

1. Open the main door and then turn off the instrument.

2. Using applicator HPN 8R200095, insert the applicator and swab the first sensor on the upper part of the right hand side towards the back of the vat.

3. Swab the other sensor located on the lower part of the right hand side towards the front of the vat.

10.9.16. Clean 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

10.9.17. Replace Contact Sheet

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 instance, replacement of the contact sheet is recommended.

1. From the Main Menu, select the *Maint* icon.

2. On the *SPIFE Nexus Maintenance* window, select the *Test / Calibrate* button. When prompted with a SPIFE Nexus warning concerning improper calibration, select *Yes.*

3. Select the *Platen Temp Control* tab.

4. Under *Platen TEC*, toggle the mode to *Heat.*

5. Set the *Required Temp* to 40°C. Select the *Set Temp* button.

6. Toggle the *Power* to *On.*

7. Wait until *Status Platen Temp* reaches 40°C.

8. Toggle the *Power* to *Off.*

9. Remove old contact sheet by slowly peeling it up, beginning at one of the corners.

10. Remove all remaining adhesive from the surface of the chamber floor using an adhesive remover pad.

11. Once all of the adhesive has been removed, clean the chamber floor with an alcohol pad.

12. Any corrosion needs to be smoothed off the chamber floor. Using a very fine scotchbrite pad, sand the grain in one direction of the chamber floor, smoothing any corrosion. Use caution not to alter the flatness of the chamber floor.

13. Clean any debris from the chamber with an alcohol pad and use compressed air along the seams of the chamber housing to ensure all liquid has been eliminated. It is important that the chamber floor be completely flat, smooth, and free of any material, liquid, or debris.

14. 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 one side.

15. Holding the contact sheet adhesive side down, align the sheet centered with equal distance on each side.

16. Press the exposed contact sheet to chamber floor. Continue peeling the backing from the contact sheet while rubbing the contact sheet down using 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 edges of the contact sheet using clean gauze to ensure the adhesive sticks to the chamber floor.

17. 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.

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.

10.9.18. Rinse / Replace Reagent Vats

If mold develops in the Destain/Buffer Wash Vat, rinse it with hot water and then with DI water. For replacement vat, cap, or tubing, reference the Section 5 Inventory Table.

10.9.19. Replace Tubing / Pump

1. Turn off the instrument. Using a #2 Philips Screwdriver, remove the protective diluter guard panel.

2. Disconnect the peristaltic pump head tubing from the elbow fittings.

3. Grasp the peristaltic pump head and rotate it counterclockwise to unlock the pump motor and remove the pump head.

4. If tubing needs to be replaced, replace the tubing.

5. Replace a new pump head onto the pump motor by turning it clockwise.

6. Reconnect the peristaltic pump head tubing to the elbow fittings.

7. Replace the protective diluter guard panel as well as the two screws.

10.9.20. Inspect Pipette

1. From the Main Menu, select the *Maint* icon.

2. From the *SPIFE Nexus Maintenance* window, select the *Test / Calibrate* button.

3. Select the *Fluid Control* tab.

4. Select the *Wash Functions* button.

5. Select *Move to Wash* to bring the pipette to the wash station.

6. Click *Close.*

7. Select the *Pipette* tab.

8. Select the *Calibrate* button.

9. Jog the pipette slightly up to view the tip.

10. Select the *Fluid Control* tab again and reopen the *Wash Functions* window.

11. Enable the *Wash Station* function.

12. Inspect the flow and verify fluid is discharging vertically and not sideways.

13. If the fluid flow is skewed, contact Helena Laboratories.

Note: *Incorrect pipette calibration may result in severe pipette damage. Contact Helena Service.*

10.9.21. Backup Parameters

1. See Section 10.6 for instructions on backup procedure.

10.9.22. Safe Start Instructions

In the event of a test ending prematurely, the SPIFE Nexus has a Safe Start window that will be displayed if the claw is currently holding an object. The jog buttons on the menu help the user maneuver the claw to a position where it can safely release the object without damaging itself or the instrument with au- tomated movement.

1. *Jog claw* – This allows the user to select which direction to slightly move the claw's position.

    a. *Backward* – select to jog the claw backwards.

    b. *Left* – select to jog the claw left.

    c. *Right* – select to jog the claw right.

    d. *Forward* – select to jog the claw forward.

    e. *Up* – select to jog the claw up.

    f. *Down* – select to move the claw down.

g. *Open* – select to open the claw, which will release anything the claw is holding.

SPIFE Nexus Initialize Error

The claw contains an object that must be removed before the claw can be intialized. Use the jog buttons below to position the claw to a location where the object can be safely dropped and then open the claw.

Jog Claw

Backward		Up
Left	Right	Down
Forward		Open

2. Use the jog buttons on the menu to guide the claw containing the object to a flat surface within the machine, preferably towards the front of the instrument.

3. Lower the object and ensure the height of the object will not prevent the gantry from passing over it. If the gantry hits the object, it can damage the instrument and possibly require recalibration.

4. When the object is in a safe position, click the *Open* button. The claw will open, and all motors will return to their home positions.

5. If this occurs during the execution of a run, the SPIFE Nexus will end the run at this point.

6. If this occurs during initialization before the run has begun, the SPIFE Nexus will continue initialization.

7. After the main door unlocks, the item which was released by the claw can be moved back to its storage location by the operator
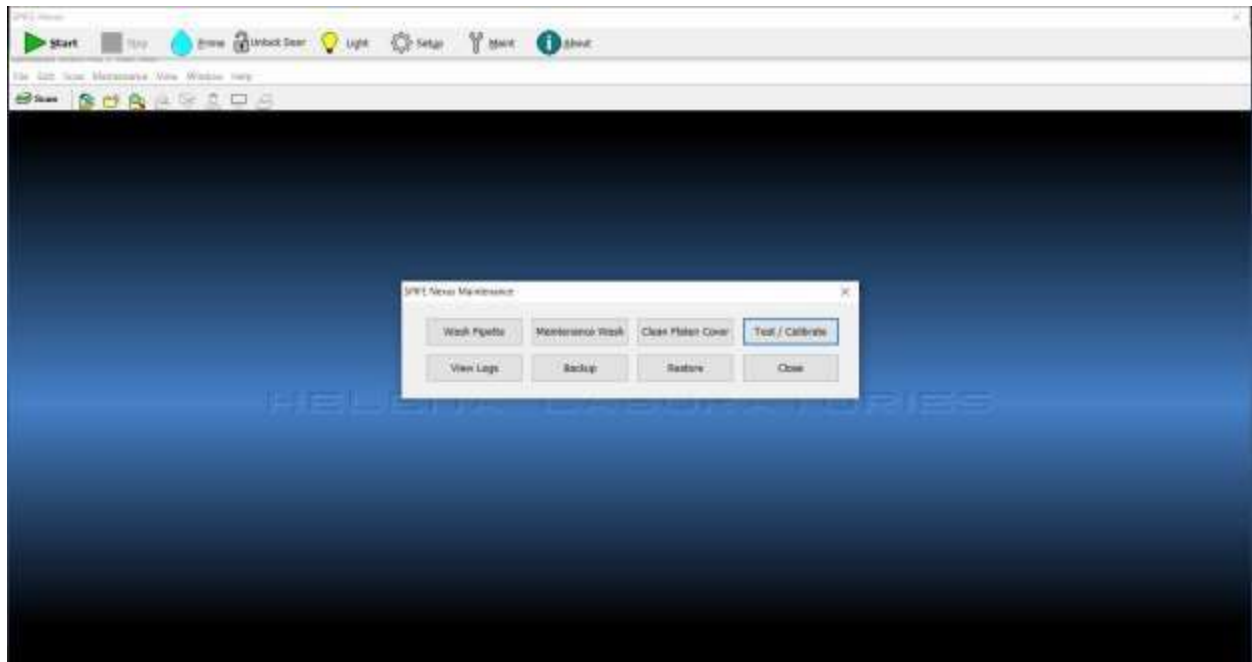
Figure 10-1 Nexus Maintenance
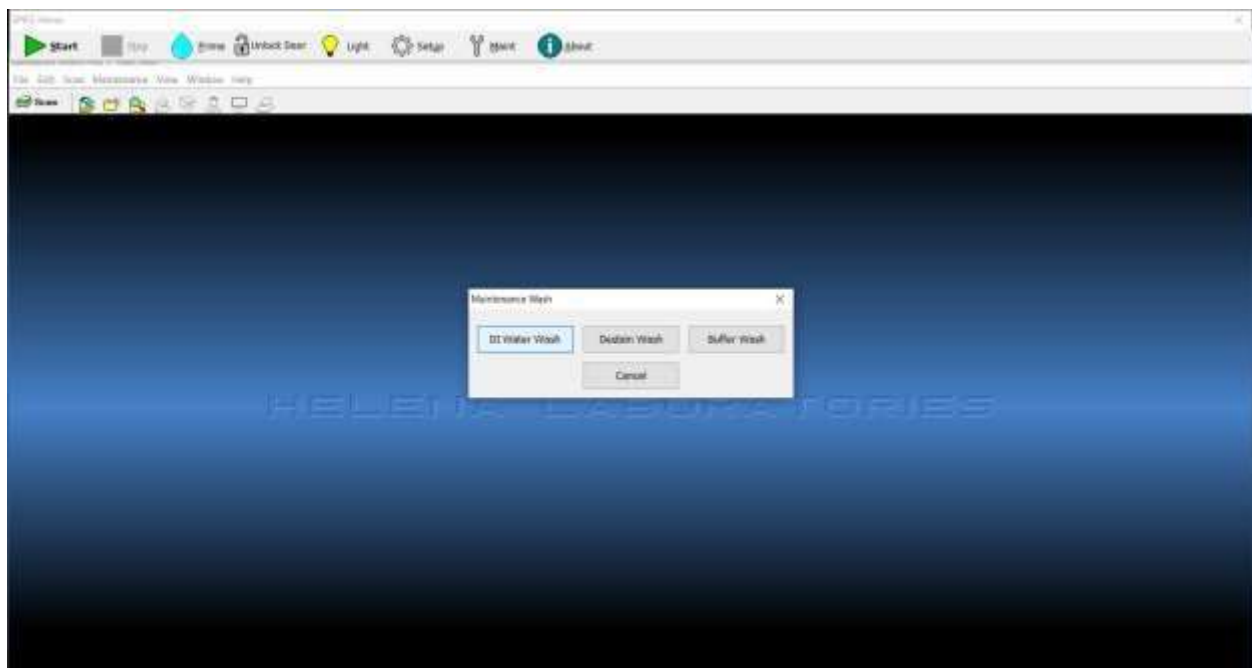
Figure 10-2 Maintenance Wash
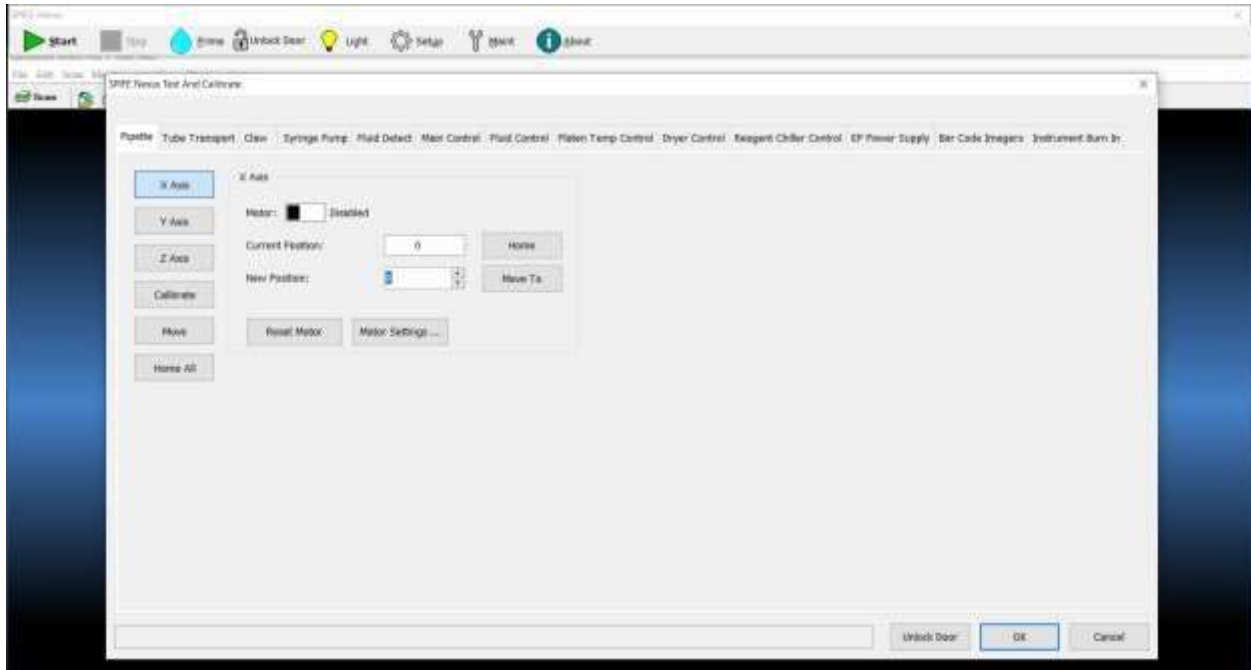
Figure 10-3 Pipette
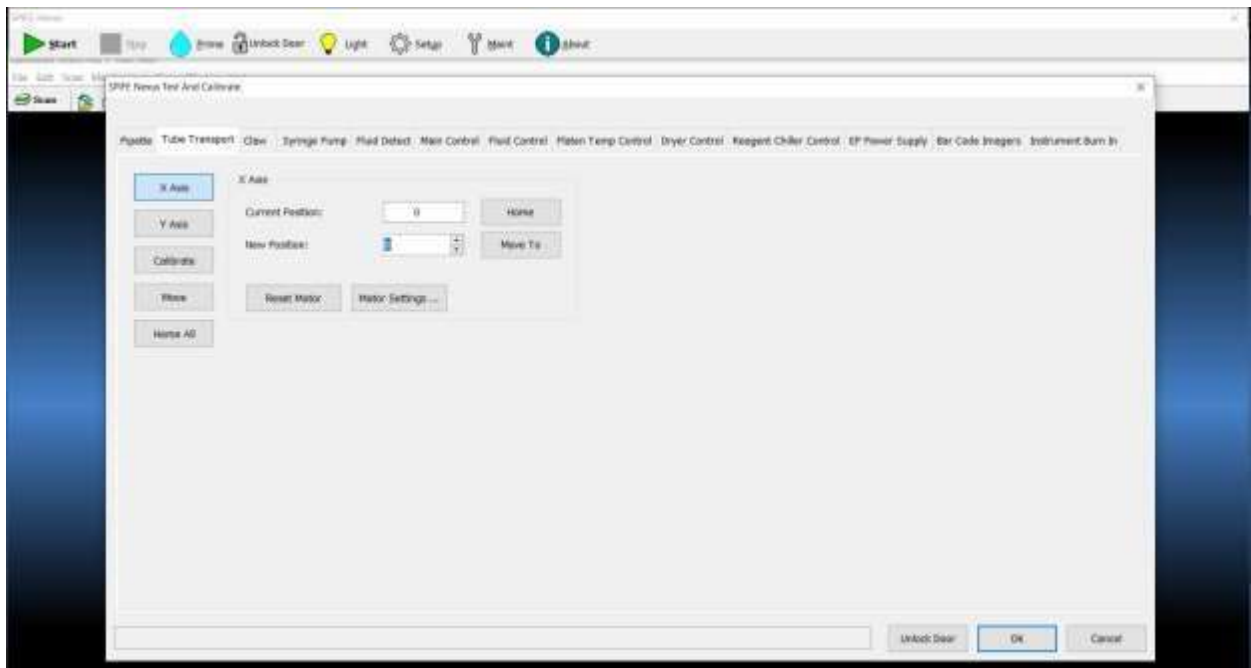
Figure 10-4 Tube Transport
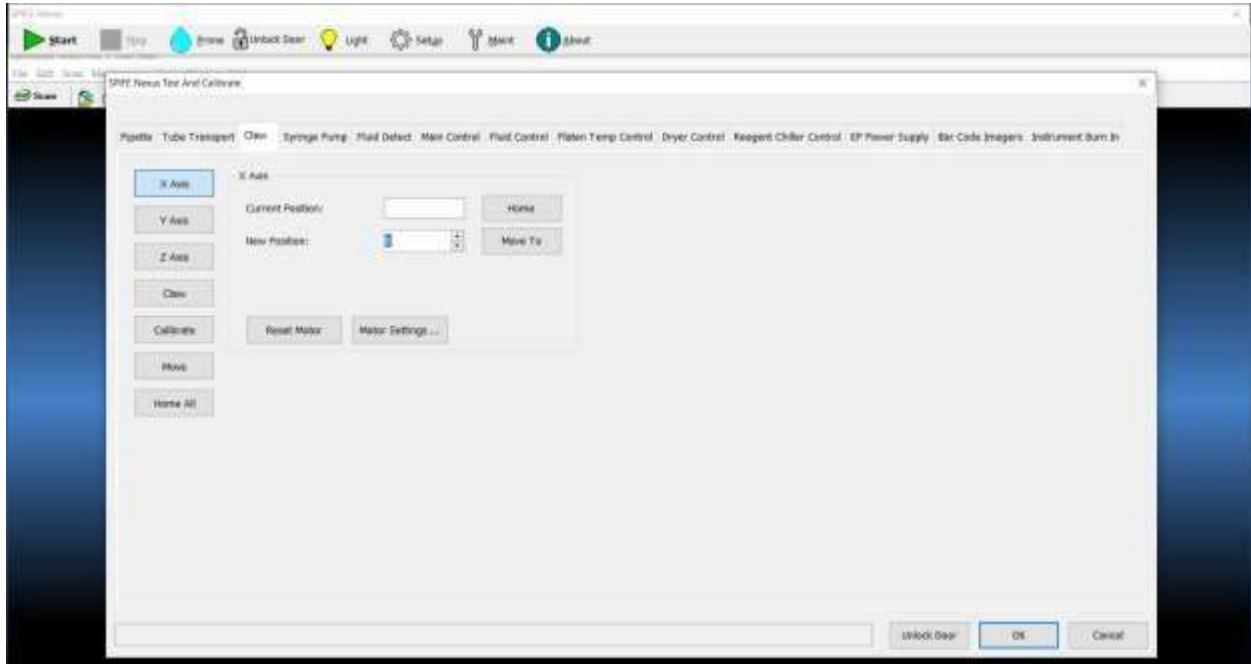
Figure 10-5 Claw
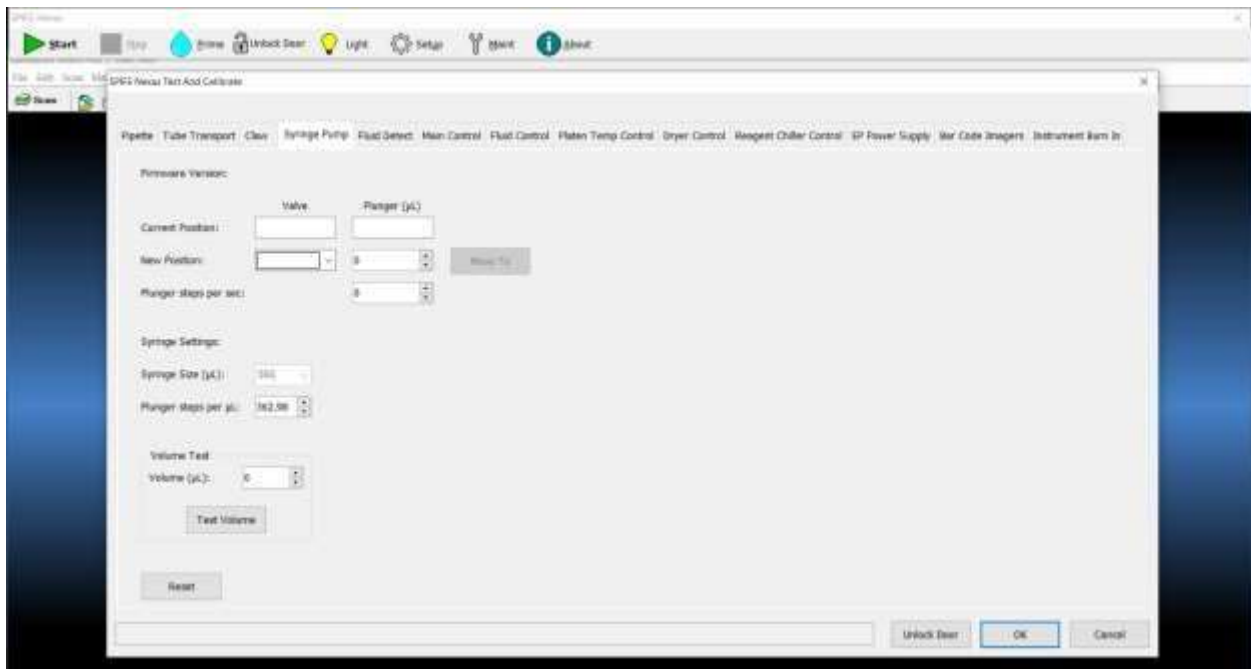
Figure 10-6 Syringe Pump
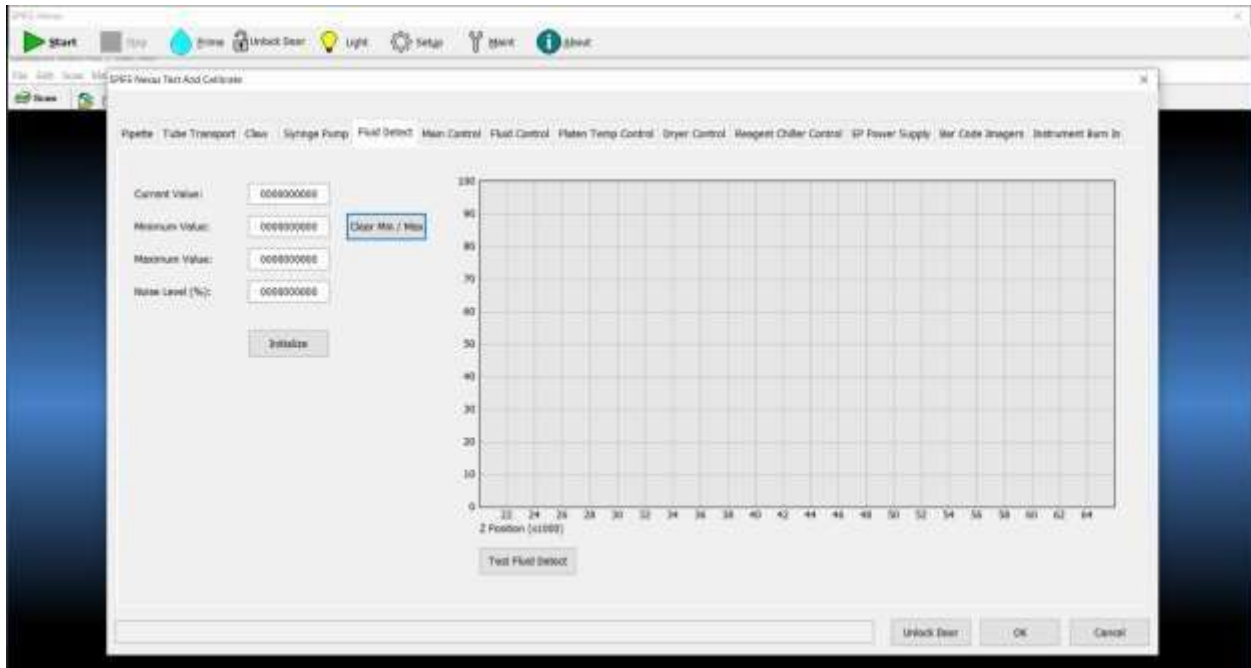
Figure 10-7 Fluid Detect
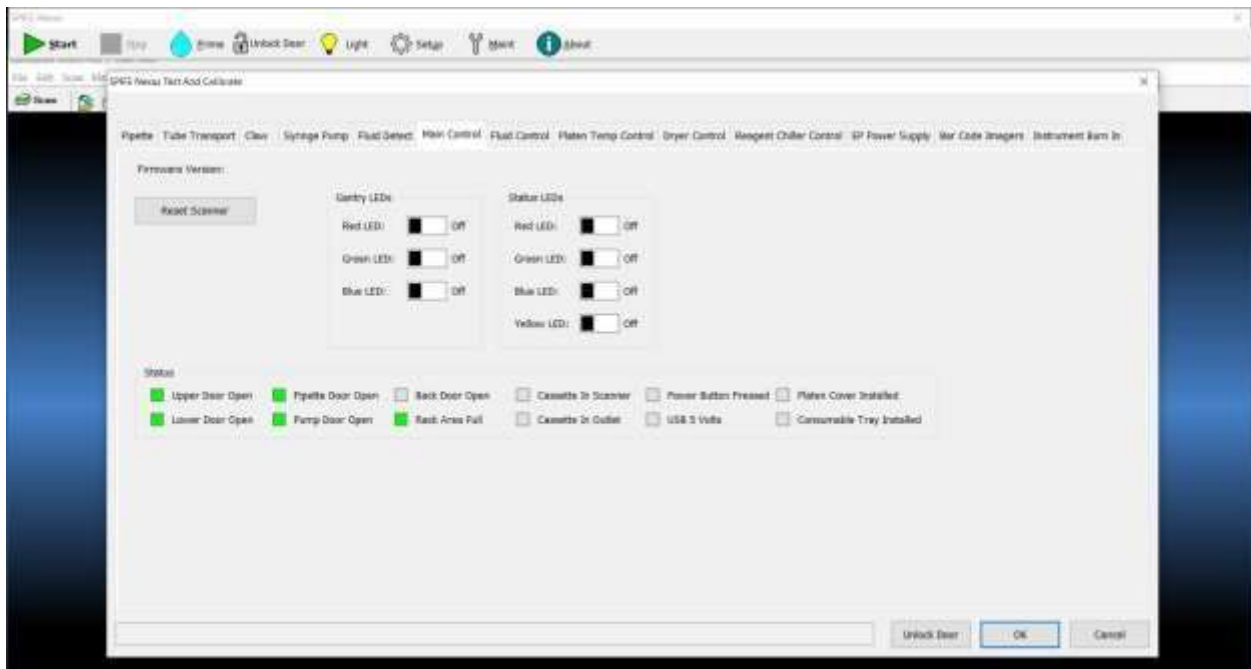
Figure 10-8 Main Control
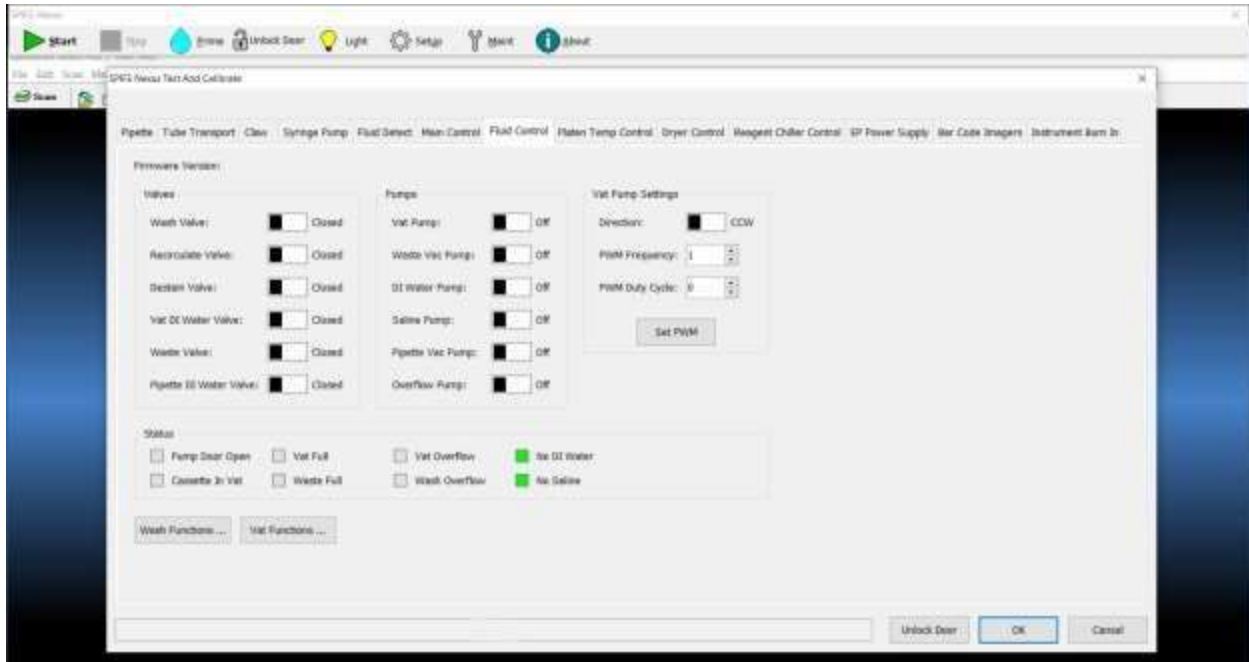
Figure 10-9 Fluid Control
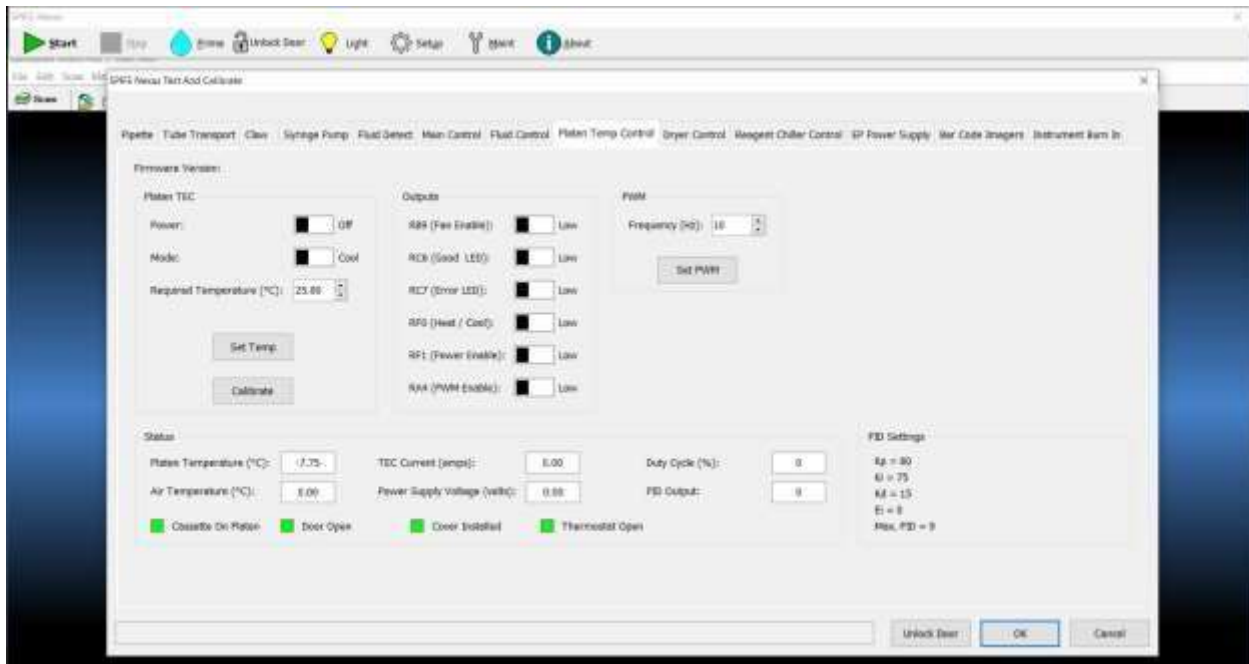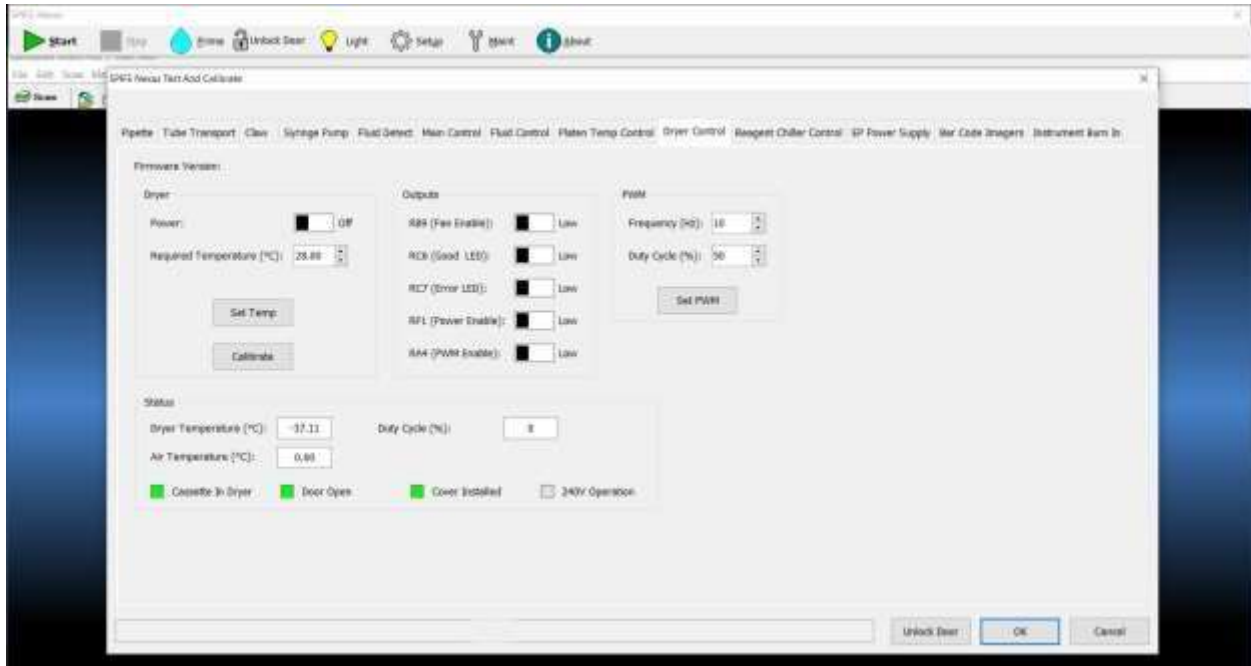

Figure 10-10 Platen Temp Control
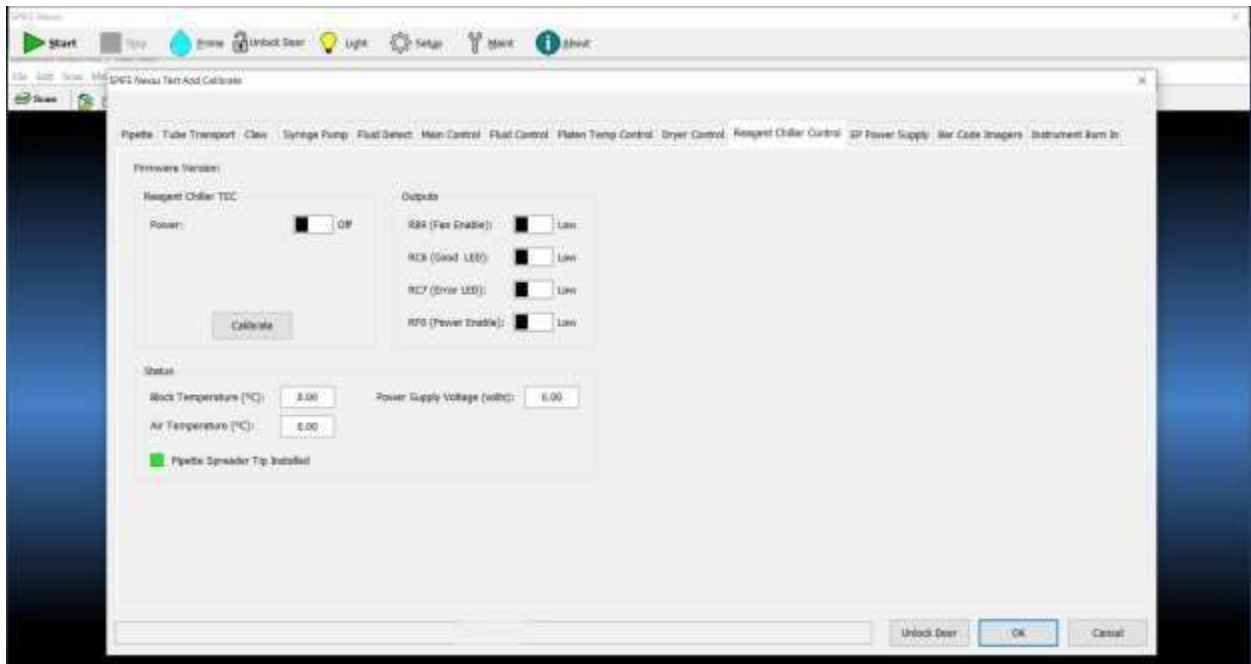
Figure 10-11 Dryer Control

Figure 10-12 Reagent Chiller Control
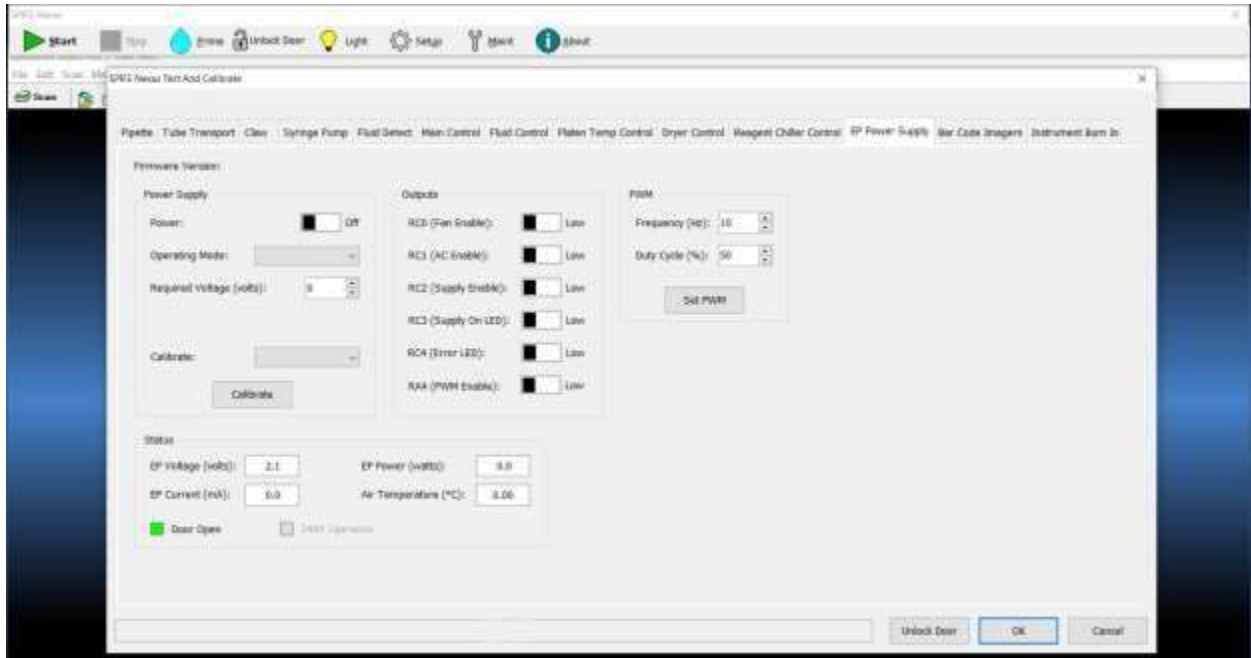
Figure 10-13 EP Power Supply
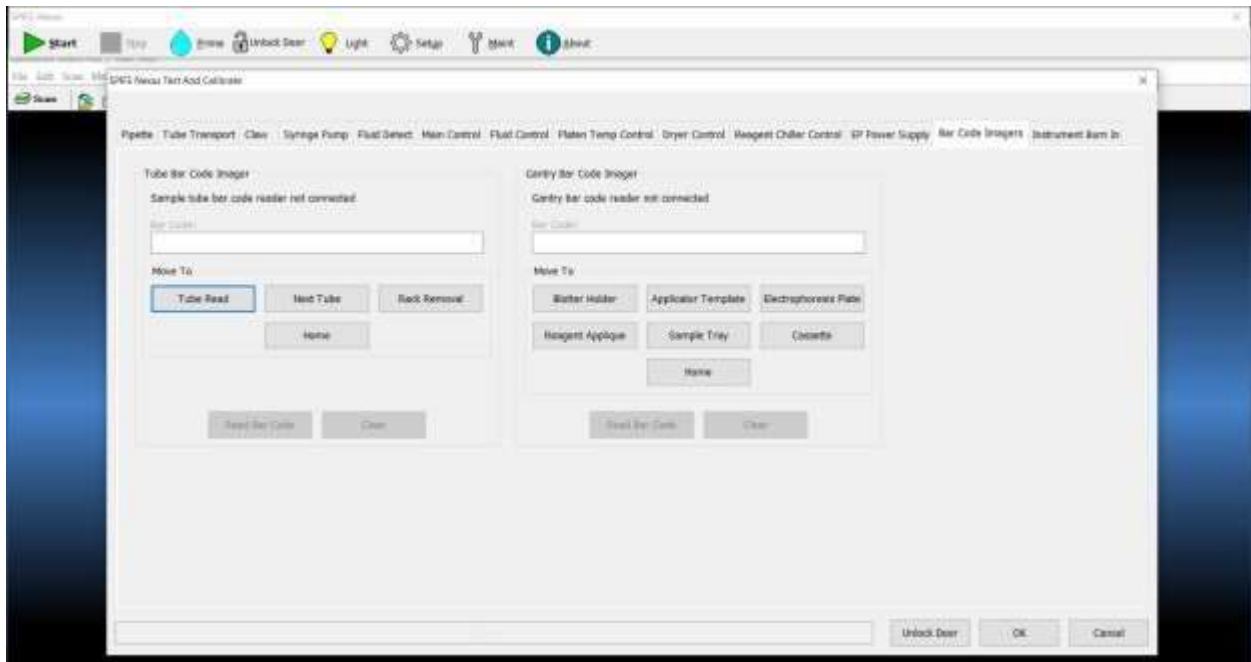
Figure 10-14 Bar Code Imagers
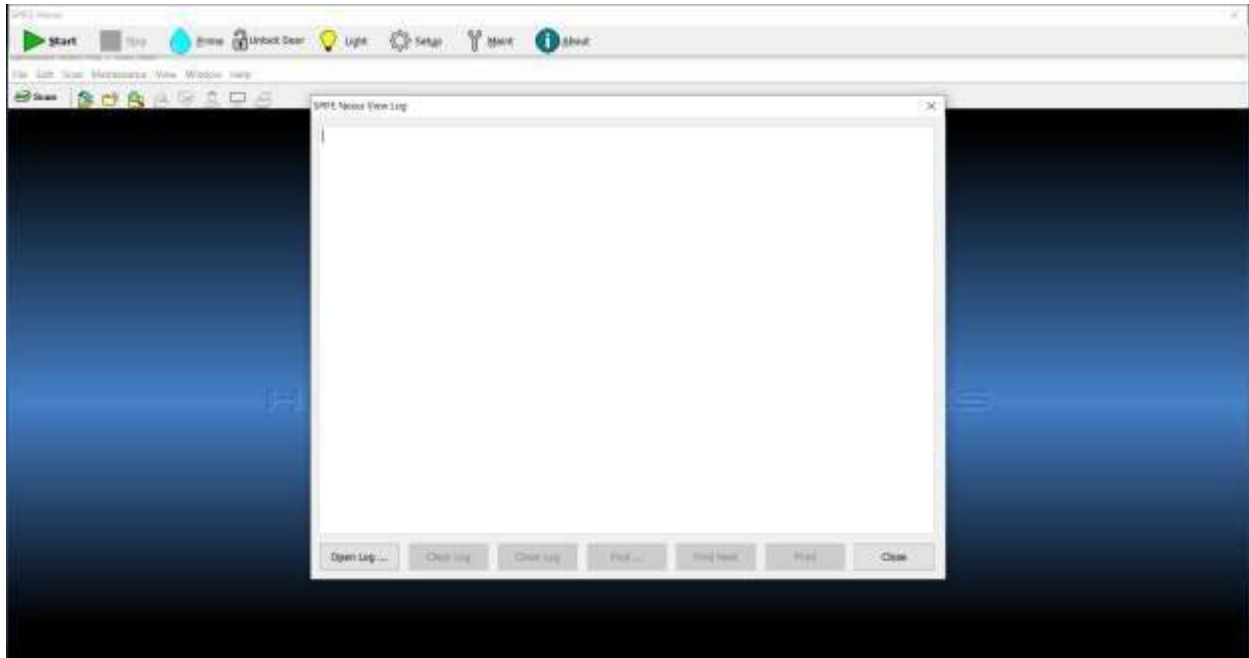
Figure 10-15 View Log
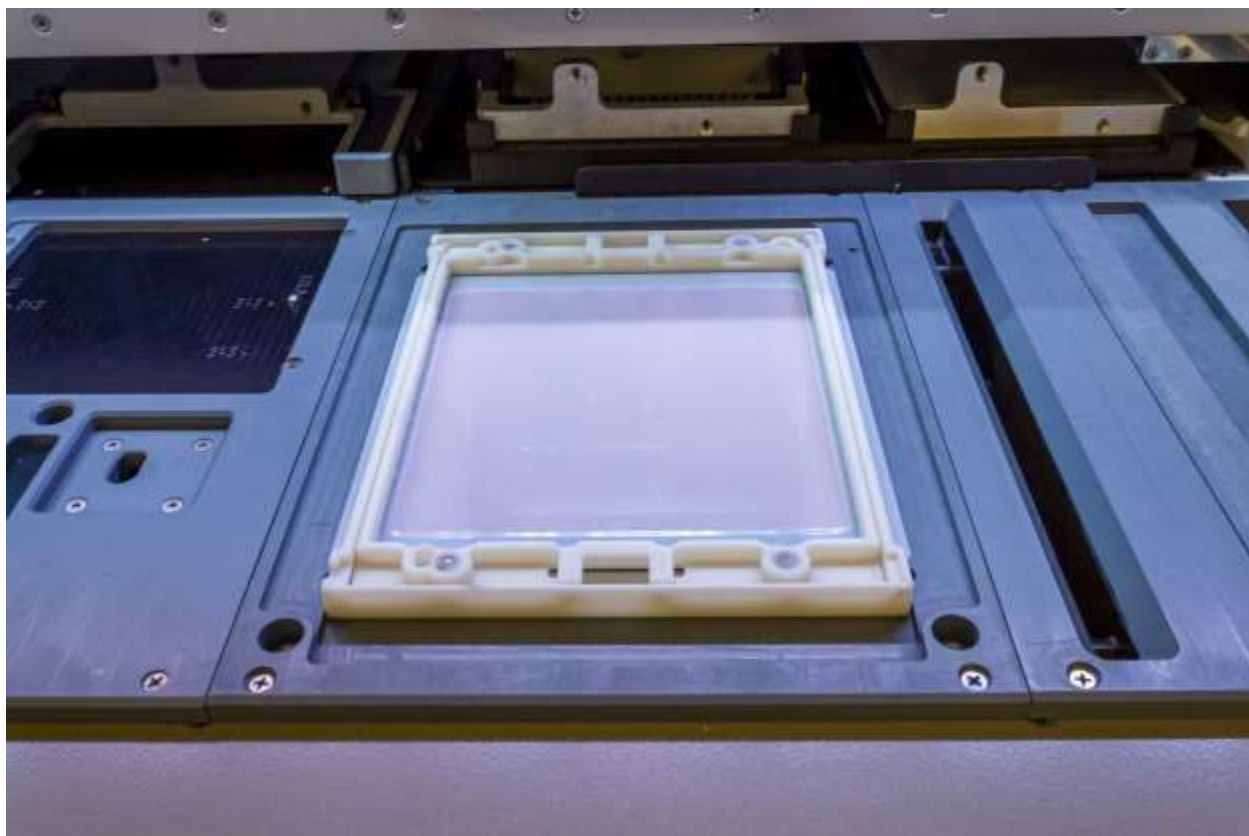
Figure 10-16 Inspect Contact Sheet
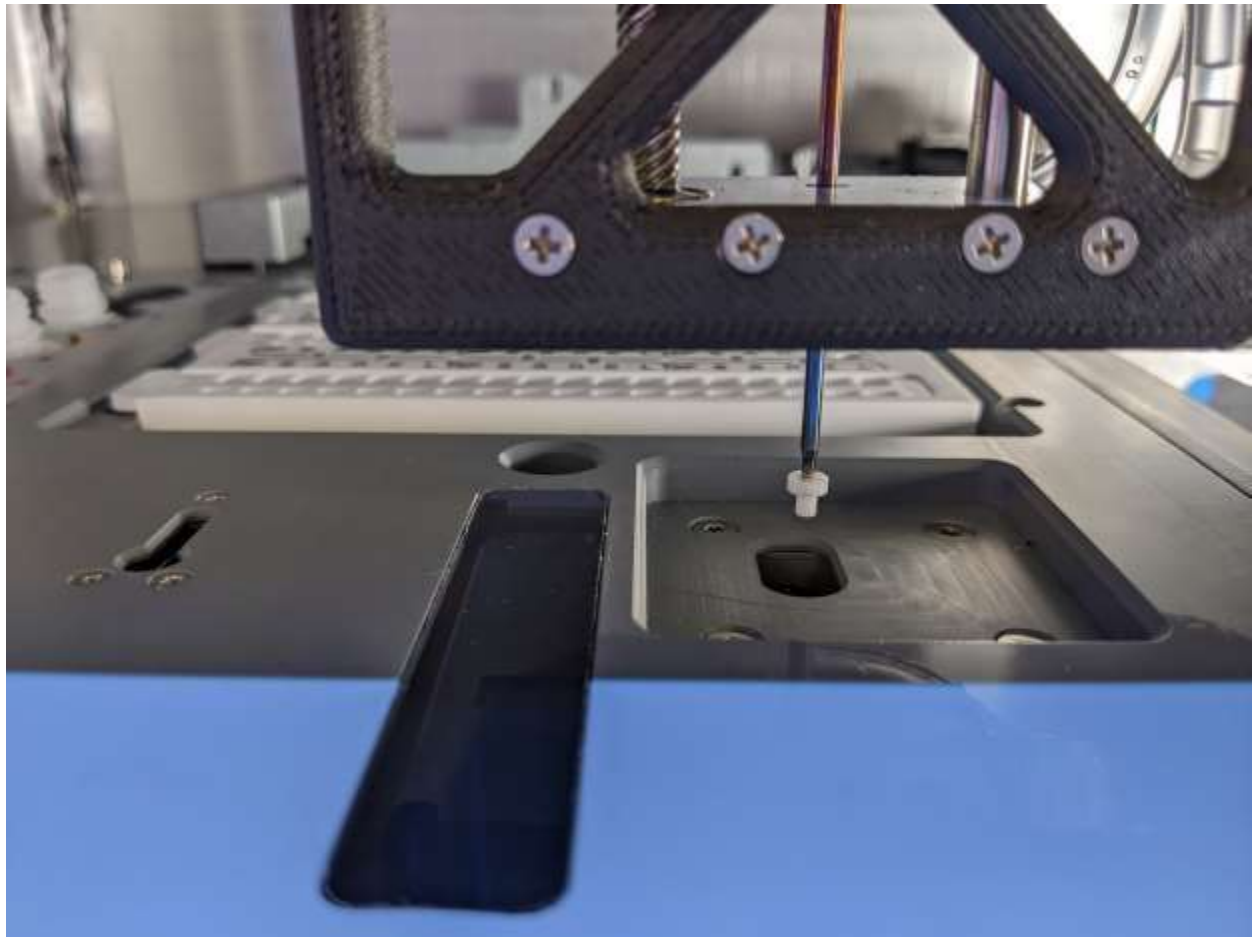
Figure 10-17 Antisera Spreader Tip

Month/Year: _____   Serial Number: _____

Table 10.1 SPIFE® Nexus Preventive Maintenance Schedule

After every test	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean Gel Cassette																															
Clean Reagent Roller																															
Clean Blotter Holder (if used)																															
Clean visible spills																															

Daily Items, If Used	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
General Inspection for Cleanliness																															
Prime Fluid System																															
Clean Reagent/Sample Tray Stations																															
Clean Platen Cover. Clean Electrophoresis Platen and inspect Contact Sheet																															
Clean Wash/Destain Station																															
Clean top of Dryer and Dryer Cover.																															
Inspect and Clean Antisera Spreader Tip (if used)																															

Note: Duplicate this page for maintenance copies. Initial each item as required. Refer to section ten, Maintenance, of the Operator's Manual for details. If uncertain about how to perform any step, please contact Helena Laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information. Page 1 of 2.

Month/Year: **Serial Number:**

Table 10.1 (cont.) SPIFE® Nexus Preventive Maintenance Schedule

Weekly Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean/Bleach DI Water Bottle																															
Clean/Bleach Saline Bottle																															
Clean Sample Pipette Wash Block																															
Monthly Items																															
Bleach entire instrument and tubing																															
Clean Optical Fluid Sensors																															
Clean Waste Vat Sensor																															
Replace Antisera Spreader Tip																															
As Needed																															
Replace Contact Sheet																															
Rinse/ Replace Fluid vat																															
Replace tubing/pump																															
Inspect pipette fluid flow																															
Backup parameters																															

Note: Duplicate this page for maintenance copies. Initial each item as required. Refer to section ten, Maintenance, of the Operator's Manual for details.

*If uncertain about how to perform any step, please contact Helena Laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information. Page 2 of 2.

Troubleshooting

When using the SPIFE Nexus software, error messages may appear. If corrective action is not obvious, call Helena Laboratories for assistance. For system problems, refer to the following table. If the recommended solutions should fail to solve a problem, call Helena Laboratories for assistance.

Table 10-2 Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
SPIFE Nexus screen disappears when user selects an item in the QuickScan Touch *plus* software.	When the QuickScan Touch *plus* software is being used, the SPIFE Nexus screen is hidden.	Select the top bar of the SPIFE Nexus window to bring it forward in front of the QuickScan Touch *plus* window.
No power to instrument	Power cord unplugged	Plug cord into proper wall outlet.
	Fuse blown	Call Helena Laboratories for assistance.
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.
No sample dispensing into sample tray	Empty DI water bottle	Refill DI Water bottle.
	Bent or clogged pipette	Inspect pipette then prime instrument (10.9.13)
	No sample in tube	Add sample to tube.
	Low sample volume	Minimum sample volume is 500µl. User may hand-pipette samples with low sample volume directly into cups if necessary (see 7.1).
	Air bubbles in DI water tubing	Prime instrument (see 10.9.6).
	Air bubbles, foam in sample	Examine sample tube.
	Sample tube not seated corrected	Examine sample tube.
	Tubing/Pump failure	Replace tubing/ pump head (see 10.9.19) and call Helena Laboratories for assistance.
	Test not programmed for correct number of samples.	Check test parameters (see 6.1).
No sample applied to plate	Incorrect applicator blade used	Check blades, check for application mark on plate.
	No sample in tube	Examine sample tube.

PROBLEM	POSSIBLE CAUSE	SOLUTION
		Also see "No sample dispensing into sample tray".
Sample in wrong well	Incorrect tube order or wrong test loaded	Verify tube order in racks and verify correct test has been selected.
Level detect failure	Saline in pipette	Peristaltic pump tubing reversed. Verify tubing is piped correctly.
Pipette wasn't washed Cross contamination	Tubing/Pump failure	Replace tubing/ pump head (see 10.9.19) and call Helena Laboratories for assistance.
Pipette stops before aspirating or doesn't pipette sample	Blockage of pipette Sensor failure	Replace tubing/ pump head (see 10.9.19) and call Helena Laboratories for assistance.
	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.
Failed to Initialize: Pipette X Pipette Z Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Failed to home: Pipette X Pipette Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Failed to get to target position: Pipette X Pipette Z Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Electrophoresis chamber not reaching programmed temperature	Fuse blown	Call Helena Laboratories for assistance.
	Electrical problem	Call Helena Laboratories for assistance.
	Restricted air flow	Remove obstructions and ensure

PROBLEM	POSSIBLE CAUSE	SOLUTION
Fan does not run		enough air space surrounds instrument.
	Electrical problem	Call Helena Laboratories for assistance.
Gel Cassette does not eject	Mechanical or Electrical problem	Push cassette out manually Call Helena Laboratories for assistance
Dryer too hot	Electrical problem	Call Helena Laboratories for assistance.
Vat level detector failures	Dirty stainer chamber	Use Maintenance Swab soaked in Destain solution to clean inside of stainer chamber, especially around level detector sensors.
	No fluid in chamber	Ensure that wash vat is correctly connected to the instrument and that the vat(s) contain fluid.
Reagent does not dump	No stain added to cups	Check for stain.
	Programming Problem	Check programming for the test against the IFU (see 6.1) and reenter, if parameters have been changed.
	Electrical Problem	Call Helena Laboratories for assistance.
Unable to communicate with the bar code imager	Connection Problem	Call Helena Laboratories for assistance.
"No diluent" error	Diluent needs to be refilled.	Add diluent and tap 'OK' to continue.
	Level detect failure.	Call Helena Laboratories for assistance.
Incorrect sample volume	Tubing/Pump failure	Replace pump head (see 10.9.19 and call Helena Laboratories).
	Bent or plugged pipette	Inspect pipette (see 10.9.20).
	Leaks in delivery system	Check for loose fittings or breaks in tubing line.
Pipette wasn't washed Cross contamination	Peristaltic pump failure	Prime instrument. Check peristaltic pumps.
Board communication Failure. Contact Helena Service	No response was detected from one of the following boards: Fluid Control, EP Power Supply, or Dryer	Call Helena Laboratories for assistance.

10.10. 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.

Warranty Duration

This warranty is provided to the original purchaser for six months from date of sale.

Section 11 - Symbology

The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable. To prevent the operator from gaining access to the machine while it is running, sensors and locks have been put in place. If access is gained, please contact Helena Laboratories Support.

⚡	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 – reference applicable section of Operator's Manual before proceeding.
⎓	Direct current
∿	Alternating current
⏦	Both direct and alternating current
⏚	Ground (earth) terminal
⏚	Protective conductor terminal (grounded conductors)
⏛	Equipotentiality (conductor with all parts at a single potential)
|	On (power switch)
○	Off (power switch)
📖	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, biohazard: this symbol applies where potential biohazards exist and universal precautions should be exercised. Note: An orange label is for domestic orders & a yellow is for foreign orders.
	Caution, crush hazard: Do not place fingers near any moving parts when the instrument is in use. Do not operate with the cover(s) removed.
	Caution, puncture hazard: Do not place fingers near any moving parts when the instrument is in use. Do not operate with the cover(s) removed.
	Attention, warning. Refer to the Operator's Manual for more information about this area of the instrument.

Section 12 - Index

ADDENDUM –A–

Dear SPIFE Nexus Customer,

We are constantly improving our products in an effort to give you the most effective instrument possible. A new software version will be released shortly, but we wanted to inform you of an improved procedure to maintain your SPIFE Nexus.

It was discovered that residue can accumulate on the bottom track of the SPIFE Nexus scanner. This can impede the movement of the cassette through the scanner and cause a "rainbow" effect on the resulting scans, or it can even cause a complete failure to scan if the cassette becomes stuck.   To combat this, it is recommended to complete the following procedure on a weekly basis.

Cleaning the scanner

1. Open the Main Door and then turn off the instrument.

2. After the power has been turned off, dampen a maintenance swab (Cat. No. 1113) with distilled water and insert it into the front scanner port.
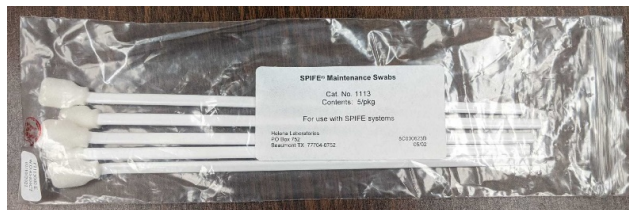
3. Swipe the swab back and forth along the bottom of the scanner. This will remove any buildup. Do not attempt to clean the sides of the scanner. If buildup exists further back into the scanner, the top scanner opening can be used to access the back of the scanning track. (The pictures below detail before and after cleaning).

4. Once cleaned, allow time for the distilled water to dry before powering the instrument back on for use.

ADDENDUM –B–

SPIFE Nexus PM Change

Dear SPIFE Nexus Customer,

Section 10.9.14 changes to as follows.

10.9.14. Bleach Wash/Destain system

Note: *It is important to empty the waste container before starting to avoid potential chemical interaction*.

1. Once a month, prepare approximately 2L of a 10% bleach solution in a bleach-safe container.

2. Remove the caps from the DI Water, Wash, and Destain bottles. Leave the caps attached to the tubing and connected to the fluid port of the instrument. Place the ends of the cap straws into the prepared bleach solution.

3. From the main menu, select the *Maint*, then *Maintenance Wash*.

4. Select *DI Water Wash.* The vat will fill, circulate, and purge. Repeat with *Destain Wash* and *Buffer Wash*.

5. Remove the cap straws from bleach solution and place into DI water bottle containing at least 2L of DI water.

6. Repeat steps 3 and 4 to rinse lines with DI water.

7. Remove the cap straws from the DI water and replace caps on appropriate bottles.

8. Empty the waste container of used bleach solution.

9. Repeat steps 3 and 4 to prime lines with appropriate fluids.

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

Month/Year: **Serial Number:**

Table 10.1 SPIFE® Nexus Preventive Maintenance Schedule

After every test	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean Reagent Roller 10.9.2																															
Clean visible spills 10.9.3																															
Clean Blotter Holder (if used) 10.3.4																															
Daily Items, If Used	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Prime fluid system 10.9.6																															
Clean Platen Cover electrodes 10.9.8																															
Clean top of Dryer & Dryer Cover 10.9.10																															
Clean Gel Cassette 10.9.1																															
General inspection for cleanliness																															
Inspect platen contact sheet 10.9.5.2																															
Weekly Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean bottom track of scanner (see Addendum)																															
Monthly Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Sanitize Wash/ Destain vat & tubing 10.9.14																															
Bleach fluid & waste containers 10.9.12																															
Replace Antisera Spreader Tip (call Service)																															
As Needed	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Backup parameters 10.9.21																															
Replace platen contact sheet 10.9.17																															
Sanitize pipette tubing (call Service)																															
Clean Reagent/ Sample Tray Stations 10.9.7																															
Clean optical fluid sensors 10.9.15-16																															
Clean bottom surface of Dryer (see Addendum)																															

Note: Duplicate this page for maintenance copies. Initial each item as required. Refer to section ten, Maintenance, of the Operator's Manual for details. If uncertain about how to perform any step, please contact Helena Laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information. D700011A, 06/23

IVD

SPIFE Nexus

Operator's Manual

Software Version 1.4.2.0

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

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