![Helena Laboratories logo]

SPIFE 4000

Automated Electrophoresis

Operator's Manual

Catalog Number 1620, 110 VAC

Catalog Number 1621, 220 VAC

Catalog Number 1622, 100 VAC

SPIFE 4000

Automated Electrophoresis

Operator's Manual

<div style="border:1px solid black">

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.

</div>

SPIFE 4000 Program License Agreement

This copy of the SPIFE 4000 program is sold on the condition that the purchaser agrees to the terms of this license agreement. If not, the purchaser should return the unopened disk package to Helena Laboratories to obtain a refund. Retention of the product will constitute acceptance of this license.

1. Helena Laboratories Corp. (Helena) warrants to the ORIGINAL PURCHASER ONLY (Purchaser) that the disk on which the computer program is contained shall be free of defects in materials and workmanship under normal use for 6 months from the date of purchase. Helena will repair or, at its option, replace any defective disk returned to the address below during the 6-month period.

2. THIS IS THE ONLY WARRANTY MADE BY HELENA COVERING THE SPIFE 4000 PROGRAM. THE COMPUTER PROGRAM AND THE ENCLOSED INSTRUCTIONAL MATERIALS ARE SOLD "AS IS," WITHOUT ANY WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO: ANY WARRANTY OF PERFORMANCE, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. PURCHASER ASSUMES ALL RISKS AS TO THE PERFORMANCE AND RESULTS OF THE PROGRAM. IN NO EVENT WILL HELENA OR ITS SUPPLIERS BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR OTHER DAMAGES, INCLUDING BUT NOT LIMITED TO ANY DAMAGES ARISING FROM USE OR MISUSE OF THE PROGRAM.

3. This computer program is for the use of purchaser only, and only on the computer system specified. No part of the program may be reproduced, nor may any part of the program be utilized in or transferred to any information storage and retrieval system of electronic or mechanical medium without prior written permission of Helena. Purchaser may make up to two back-up copies of the program for Purchaser's personal use only, and should forward any questions concerning reproduction or transfer of the program, and requests for permission to do so, to Helena Laboratories, P.O. Box 752, Beaumont, TX 77704-0752. Any noncompliance with this paragraph will result in termination of this license, and may also result in legal liability under U.S. copyright laws.

4. Use of this program constitutes acceptance of the terms and conditions of this agreement.

List of Sections

List of Figures

List of Tables

Section 1 - Instrument Use and Function

Helena's **SPIFE 4000** (Figure 1-1) is a fully automated instrument that loads sample into sample trays and onto SPIFE agarose gels; electrophoreses, stains, fixes, destains, and dries SPIFE agarose gels; and is a visible scanning densitometer used to scan electrophoretic gels, quantitate data, and display and print results. The SPIFE 4000 is intended for *in-vitro* diagnostic use only, in a laboratory or similar environment.

SPIFE 4000 eliminates the technique-dependent steps of conventional electrophoresis. The cassette containing the gel is moved from the Sample Handler section to the Electrophoresis station, where electrophoresis is performed. After this, the cassette is then moved to the Antisera station where, if so indicated by the test parameters, antisera application is performed. Next, the cassette is moved to the Pre-dry station where drying occurs. The cassette is then moved to the Wash station where, if so indicated by the test parameters, washing is performed followed by the Stain, Destain, and Final Dry stations. Afterwards, the cassette is moved to the Scanner station, scanned, and deposited in the Cassette Pick-up Assembly. Scan data is then transferred to the User Interface.

SPIFE 4000 contains preprogrammed parameters for Serum Proteins, Serum Immunofixation, Urine Proteins, Urine Immunofixation, Acid Hemoglobin, and Alkaline Hemoglobin; 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.

A built-in computer directs all operations of the system. It will include a read/write CD drive, internal hard drive, monitor, printer, mouse, keyboard, and a minimum of 2 USB ports.

Stored results can be retrieved in seconds and full editing features are provided so fractions may be selected, comments added to the file, etc.

Refer to the procedure supplied with the gels 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
- Stability of End Product
- Expected Results
- References
- Reference Values
- Evaluation of the Bands
- Interpretation of Results
- Bibliography

Figure 1-1 SPIFE 4000 System

Section 2 - Principles of Operation

2.1. Principles of Operation – User Interface

The computer runs a self-test at power initialization to detect error conditions or potential problems. If an error is detected, the computer responds by displaying an error message (See Section 10). Correct the error prior to responding to the message.

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. In addition, more than 1 type of test can be run in a single run, eliminating the need for multiple runs. The extra tests may even be added after the run has begun.

2.2. Principles of Operation - Sample Handler

Operation is controlled by a microprocessor and user selections of information on the Display using the keyboard or mouse.

The Sample Handler contains a sample arm assembly (controlling sample delivery and transport), three independent motor control modules (controlling movement of the sample arm), a bar code reader, and a mechanism for apply sample to a gel. The Sample Handler contains four removable carousels, each of which holds 28 sample tubes. Carousels can be continuously removed and replaced. Once the unit has started, the Sample Handler follows the following sequence of events.

The operator loads the required disposable sample trays, applicator blades, and pre-blotted gels into the cassettes. Up to 10 disposable sample trays, 20 applicator blades, and 10 gels can be loaded at a time. Sample trays, blades, and gels can

be continuously replaced. If an IFE procedure has been selected, the tris buffer must be supplied to the fluid supply port labeled "TBS WASH." Test tubes are loaded onto the carousels, bar codes facing outward, and each carousel is loaded onto a turntable peg. The instrument confirms the proper sample tray has been loaded. If it is correct, the sample tray is moved into position. The turntable is rotated to identify which carousel(s) have been loaded and after identifying them, moves to position number one. After aspirating the sample, it dispenses it into the tray and performs all the necessary dilutions.

After elevating the blade tray and selecting 2 applicator blades, the unit will move the sample tray into position for the applicator immersion and the cassette into position for application to occur. After the applicator blades have been immersed in the sample wells for the preprogrammed time period, it will raise and slide into position above the gel. The blades will then be lowered to the apply position and the elevator will be raised so that the blades contact the gel and transfer the sample to the gel. Upon completion of a preprogrammed exposure time, the unit will lower the elevator to remove the applicators off the gel surface. It will then reposition the gel cassette to the electrophoresis section of the instrument and return when the cassette has been moved from the elevator floor. Finally, the sample handler will push the used sample tray into a pick up hopper and dispose of the applicators into a waste container tray.

2.3. Principles of Operation – Electrophoresis and Stainer

The relationship of the functional units of the electrophoresis and stainer of the SPIFE 4000 are shown in Figure 2-1. Operation is controlled by a master micro-

processor, a slave microprocessor, their hardware interfaces, and user selections of control parameters displayed on the monitor and selected using the keyboard or mouse.

The applicator consists of the applicator pickup assembly, the disposable applicator blade tray, cassette elevator, and waste areas for sample trays and used blades. For electrophoresis, the system uses two electrodes built into the cassette and makes electrical contact via a flat spring on the unit. Additionally, there is onboard Antisera. Fixative and blotter storage is provided for IFE gels. Antisera fluid and blotters for 10 cassettes may be stored in the Antisera block. The Wash/Stain/Dry section is based on a vertical concept with the vats having fluid level sensors and the Dryer using a forced air drying system.

During a typical run, the operator loads sample tubes, selects the needed tests and the number of corresponding samples per test, and can start or stop the automatic sequence of operations using the user interface.

For electrophoresis, 3 hoses deliver deionized water to the chamber floor while the cassette is moved by the robotic claw into the electrophoresis chamber and raised slightly to facilitate contact with the Mylar. The preprogrammed temperature and voltage ranges for electrophoresis are applied for the desired amount of time.

After IFE application and selected absorption time, each gel will automatically be blotted with comb and flat blotters. Pre-drying is accomplished by controlling and monitoring the temperature of a resistive heated plate at the next station.

For washing, staining, and destaining, the unit uses a vertical concept with valves, pumps, and a fluid detection level to alert the instrument when the vat is full. When the predetermined time has elapsed, the vats empty the solutions through a tube to the waste container which also has level detection to prevent overflow. If agitation is required, the carriage lifts the cassettes containing the gels up and down slightly.

The Master microprocessor then signals the heaters in the staining chamber to heat the chamber to drying temperature. A forced air dryer blows heated air through the chamber while the temperature is controlled by a sensor. When the drying time has elapsed, the microcomputer turns off the dryer and the gel is sent to be scanned.

All operations are under the two microprocessors control. The cassette, which carries the electrophoresis gel, has four features that accept a robotic claw to facilitate moving it from station to station. The same robotic claw can be used to detect if a cassette move malfunction has occurred or if a cassette has been removed.

The cassette will initially be transferred from the Sample Handler section of the instrument into the Gel Processor section by means of an elevator apparatus.

The Electrophoresis station consists of a programmable temperature controlled platen, microprocessor controlled electrophoresis voltage supply and status monitoring of the electrophoresis voltage, current and platen temperature.

The Antisera station consists of a motor driven pipette, which applies the antisera to the gel, and a motor driven apparatus to place comb and flat blotters on the gel for the removal of excess antisera and then to dispose of the blotters.

The Pre-dry station consists of a programmable temperature controlled platen

and status monitoring of the platen temperature.

The Wash station consists of a valve and a pump that are required for filling and emptying the Wash vat.

The Stain station consists of valves and pumps that are required to select the correct stain type and fill and empty the Stain vat. At the end of staining, the used stain is returned to the supply source.

The Destain station consists of a valve and a pump to fill and empty the Destain vat.

The Final dry station consists of a programmable temperature forced air dryer and status monitoring of the air temperature.

Once the gel has completed all program selected operations, the cassette is transferred into the Scanner station and the User Interface is signaled that a gel is ready for scanning.

Since each station operates independently of the others, it is possible for all stations to be occupied and in process at the same time.

2.4. Principles of Operation - Densitometer

The SPIFE 4000 program contains factory preset default values for scanning parameters. These values can be changed, permanently or temporarily. Refer to Section 6 for programming instructions. If default parameters are altered, they can be reinstalled as needed.

The functional units of the SPIFE 4000 densitometer are shown in Figure 2-3.

2.4.1. Transmittance Densitometry

The visible mode optics configuration is shown in Figure 2-3. A lamp (1) provides white light which passes through the samples on the electrophoretic gel (2). The entire gel is scanned in one pass.

The amount of light passing through the sample is an inverse logarithmic function of sample density. For example, if the sample density is doubled, the transmitted light is reduced by a factor of ten.

The transmitted light falls on a CCD array (3), generating current in proportion to the amount of light hitting the sensors. This signal is stored in memory, and used by the computer to calculate the area under the curve for the various signal peaks, representing sample densities on the pattern.

The aperture size, selected by the user, mathematically determines the area of the scanned pattern used in calculations. If the aperture is too small, resolution will be high, but noisy or jagged patterns may result. If the aperture is too large, a smooth curve results, but resolution may be too low.

2.4.2. References

Control samples can be designated as Reference samples when the operator is using the Reference Overlay feature. This feature allows the program to overlay the Reference pattern over the sample pattern on the display or report, if desired.

2.4.3. Other Aspects of Operation

The computer directs all system operation according to the information contained in the memory and in response to commands from the user and the instrument. The user makes selections from information on the monitor using the keyboard or mouse. Access to setup can be limited by use of a password.

Patient files can be duplicated and stored at the user's convenience. The backup information can be restored to the memory should this become necessary. Excessive data slows the computer, so periodic archiving of data is recommended.

The computer uses the sensor signal level to calculate fraction data for each pattern. An analog graph of the data is produced, which the user can edit as desired. The peak areas are expressed as percentages, with integration counts included, if desired. When the total quantity in the sample is known, the quantity in each fraction can be determined.

When the results are displayed on the monitor, the user can elect to edit the pattern at that time, or later. If a hardcopy is required by the user, a custom report can be created of the scan data and other information. Deviations in the results from reference ranges are indicated as high (+) or low (-) on the printout. All the data for each scan will be automatically stored on the hard disk. The user can also "export" data through a USB port, CD burner, or the data can be exported to a laboratory information system.

The SPIFE 4000 instrument is completely pre-programmed and ready for use for the more common applications; however, scan parameters can be altered if so desired. All user input is through the mouse or keyboard. In normal use, the operator selects the type of test, enters patient demographics, and the unit automatically places the gel in the scanner and starts the sequence of operations.
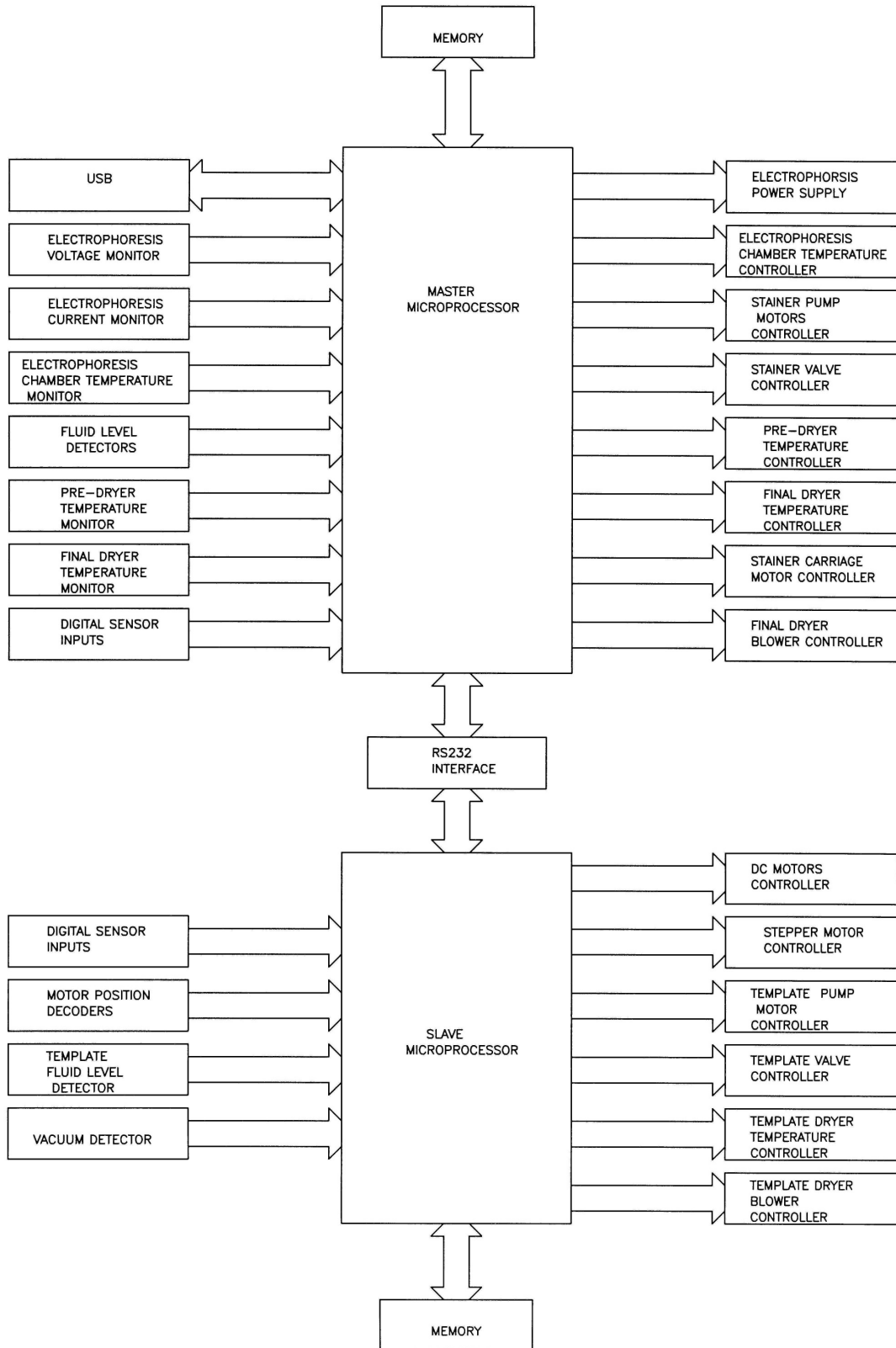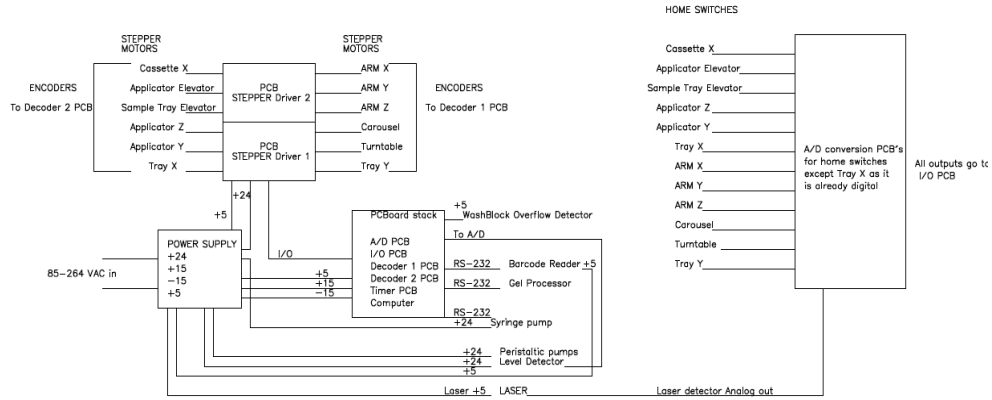
Figure 2-1 Signal Flow Diagram, Gel Processor

Figure 2-2 Signal Flow Diagram, Sample Handler

(1) White Light Source

(2) Gel

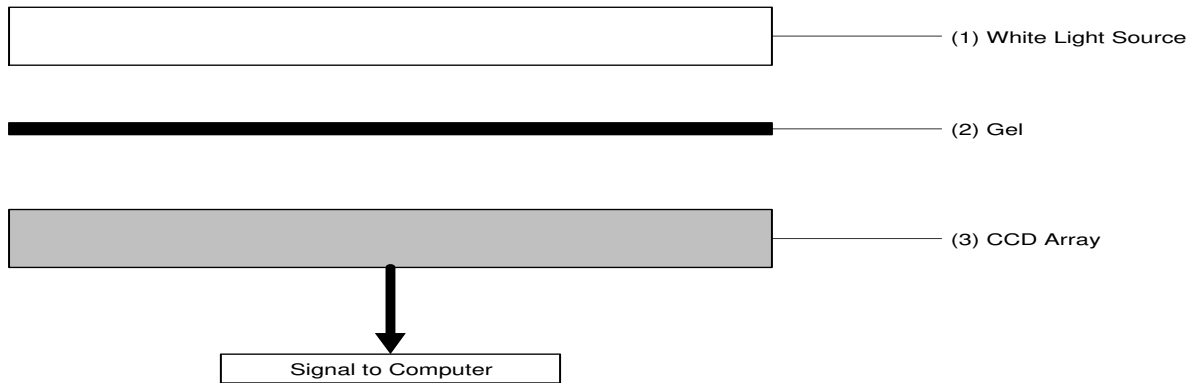(3) CCD Array

Signal to Computer

Figure 2-3 Visible Scan Optics

Section 3 - Precautions and Limitations

3.1. For emergency shutdown, turn off the instrument using the main power switch on the back 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 SPIFE 4000. 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 under the scanning surface 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 cassette to temperatures above 70°C (158°F), or severe warping of the tray may result, making the tray 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. To meet standards more stringent than this, we recommend either grounding the instrument to station ground via the ground screw provided on the back left side of the cart frame of the instrument, or the purchase of an isolation transformer. Specifications for this transformer are given in Section 9.

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

3.15. Due to high heat, do not touch the area 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. **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. **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 right side, rear, and the bottom of the instrument.

3.20. Keep hands and clothing away from the applicator 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 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 4000 is factory programmed for some procedures, you may alter scanning parameters if desired. If scanning problems occur, return to default parameters.

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

3.28. Do not operate any additional software not provided by anyone but Helena while running the SPIFE 4000 software.

3.29. To prevent software failure, make sure to 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 4000 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. Do not overfill the stain container. Overfilling the stain container can cause high pressure leakage during recirculation. Do not fill the stain container while the Stain Vat is filled, or else the Stain supply bottler will overflow when the Stain is

returned to the supply bottle at the end of the programmed Staining time.

3.33. Do not attempt to lift the instrument manually, as it weighs approximately 159 kg (350 pounds).

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 blood borne pathogens. All procedures involving 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. Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

Equipment which 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 is not feasible. Gloves shall be worn when it can be reasonably anticipated that the user may have hand contact with blood, other potentially infectious materials, and when handling or touching contaminated items or surfaces. Other personal protective equipment (eye protection, gowns, etc.) shall be worn, as appropriate.

All equipment and 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.

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 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 all samples will be lost.

4.10. WARNING: The applicator sensor on this instrument is equipped with a CLASS II LASER. Its output is <1 milliwatt; however, permanent eye damage could occur if it is stared into. The laser is not visible with safety covers in place. Appropriate labeling identifies where the risk of laser exposure could occur if the preventative measures are tampered with.

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

4.12. Do not touch the Pre-Dryer or the Final Dry areas. Surfaces can reach temperatures of approximately 65°C (149°F).

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

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 4000 is a "Category II" 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. Inventory all items (refer to the packing lists for a complete list of materials). If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

Table 5-1 Inventory

Crate
    1 SPIFE 4000
Pallet
    1 Computer (w/ CAT #1620 **only**)
    1 Printer (w/ CAT #1620 **only**)
    1 Monitor (w/ CAT #1620 **only**)
    Box of containers
- 2 Waste containers (5 gallon)
- 1 Destain Container (5 gallon)
- 1 TBS wash container (2 ½ gallon)
- 1 DI water wash container (2 ½ gallon)
- 1 Saline wash container (2 ½ gallon)
- 2 Stain bottles (2 liter)
- 1 DI water (surfactant) jar w/ modified cap
- 2 Wash caps (for 2 ½ gallon containers)
- 2 Reduction/ Extension hoses

Pallet size box
- 1 Fluids table bottom
- 1 Fluids table top
- 1 Fiberglass tray

- 1 Hose harness assembly
- 1 Box of 10 cassettes
- 1 Box software/ operator's manual
    - 1 Operator's Manual
    - 1 Operating Software CD
    - 1 Mouse pad
- 1 Box of accessories
    - 1 Linecord (w/ CAT #1620 **only**)
    - 1 Serial cable 9 pin
    - 1 USB cable
    - 1 Jumper linecord
    - 1 Dilution bottle
    - 1 Cleaning wire
    - 1 Screwdriver 4-way
    - 1 Gel block remover
    - 3 Contact sheets for electrophoresis chamber
    - 2 spare fuses 15 AMP (w/CAT# 1620)
    - 2 spare fuses 7 AMP (w/CAT# 1621)
    - 2 Spare fuses 3 AMP
- 1 Box of parts removed for shipping
    - 1 Weight Platen
    - 1 Disposables Tray Assembly
    - 1 Cassette Pickup
    - 4 Carousels (numbered 1-4)
    - 4 Carousel Base Bearings
    - 1 Gel Staging Lid
    - 1 Mouse Pad Shelf
    - 1 Top cover assembly

5.2. System Requirements

Computer - IBM compatible PC, minimum 2.4 GHz, minimum 2 GB of RAM, minimum 1 rs232 Port or adapter, minimum two USB ports, Microsoft® Windows® 7 operating system (If network and/or internet connections will be used, the use of the latest security patch and service pack is recommended), and CD/RW drive.

Printer - any printer supported by Windows®.

Monitor - any monitor supported by Windows®.

5.3. Instrument Location & Environmental Operating Conditions

Refer to *Section 9: Performance Specifications* for instrument dimensions and weight.

1. Select an environment free of drafts, direct sunlight, dust, and large temperature fluctuations. To protect the SPIFE 4000 from rust, a low humidity environment is optimal where condensation on the instrument doesn't occur.

NOTE: At least 2" (3.1 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).

2. Select an area with enough space to place the instrument's components.

NOTE: At least 10" (25 cm) of clearance are necessary on the left side of the instrument to ensure adequate accessibility to disconnect the device from power, if necessary.

3. Select a location close to the needed wall outlets.

Grounded wall outlets must be of the proper voltage and frequency as described on the serial plates located on the back of the instrument's components.

The wall outlets 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, if the operator experiences difficulty in operation, it may be necessary to install an isolation transformer. Transformer specifications are available from Helena Laboratories.

4. Do not select a location that places the instrument near a strong source of elec-tromagnetic interference, such as a centrifuge, x-ray machine, etc.

5.4. Power Cord & Parts Handling

1. Confirm that the main power switch is off and plug the SPIFE 4000 power cord into the outlet provided on the back of the instrument.

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.

NOTE: 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 4000 meets the leakage current specifications of directive EN 61010-1.

To meet standards more stringent than this, we recommend either grounding the instrument to station ground via the ground screw provided on the back left side of the cart frame of the instrument, or the purchase of an isolation transformer. Specifications for this transformer are given in Section 9.

3. Turn the main power on.

4. Turn the computer and monitor on.

5. Click on the SPIFE 4000 icon and open the program.

6. Once the User Interface issues the command to initialize, the Gel Processor section will drain all stainer tanks to the Waste container and drive all motor controlled mechanisms to their initial state.

7. If an error occurs, the fault will be transmitted to the User Interface to be displayed.

5.5. Component Interface and Power Connections

1. Check each component to make sure that each has the same power rating (100-120 VAC or 200-240 VAC). This information is located on the back of each component.

2. Check to ensure that the power switches are off on the instrument's components.

3. When inserting interface cables into connectors, make sure that they are firmly seated.

5.5.1. Components

1. Computer

2. Printer

3. Monitor

4. Keyboard

5. Mouse

5.6. Verification of Functionality

After reading and understanding the Operator's Manual, complete the applicable sections of the **SPIFE 4000 Field Installation Verification Form** as the following steps are performed:

1. Record on the verification form the serial numbers of each component listed in Section 5.5.

2. Record the software version and serial number. Refer to Section 7.8.1 for instructions on obtaining the software information.

3. Refer to Section 8.3 to perform a calibration Quality Control check. Printout the results and include the printout with the Verification Form.

4. Return the Verification Form as instructed on the form.

5.7. Programming Setup

The SPIFE 4000 software is ready to operate once the desired test(s) and the worklist(s) are setup. Setup instructions are in Section 6 - User Setup.

Note: *If more than 1 SPIFE 4000 is to be used, label all respective parts and accessory to prevent confusion between the two systems.*

Figure 5-1 Front view of the SPIFE 4000
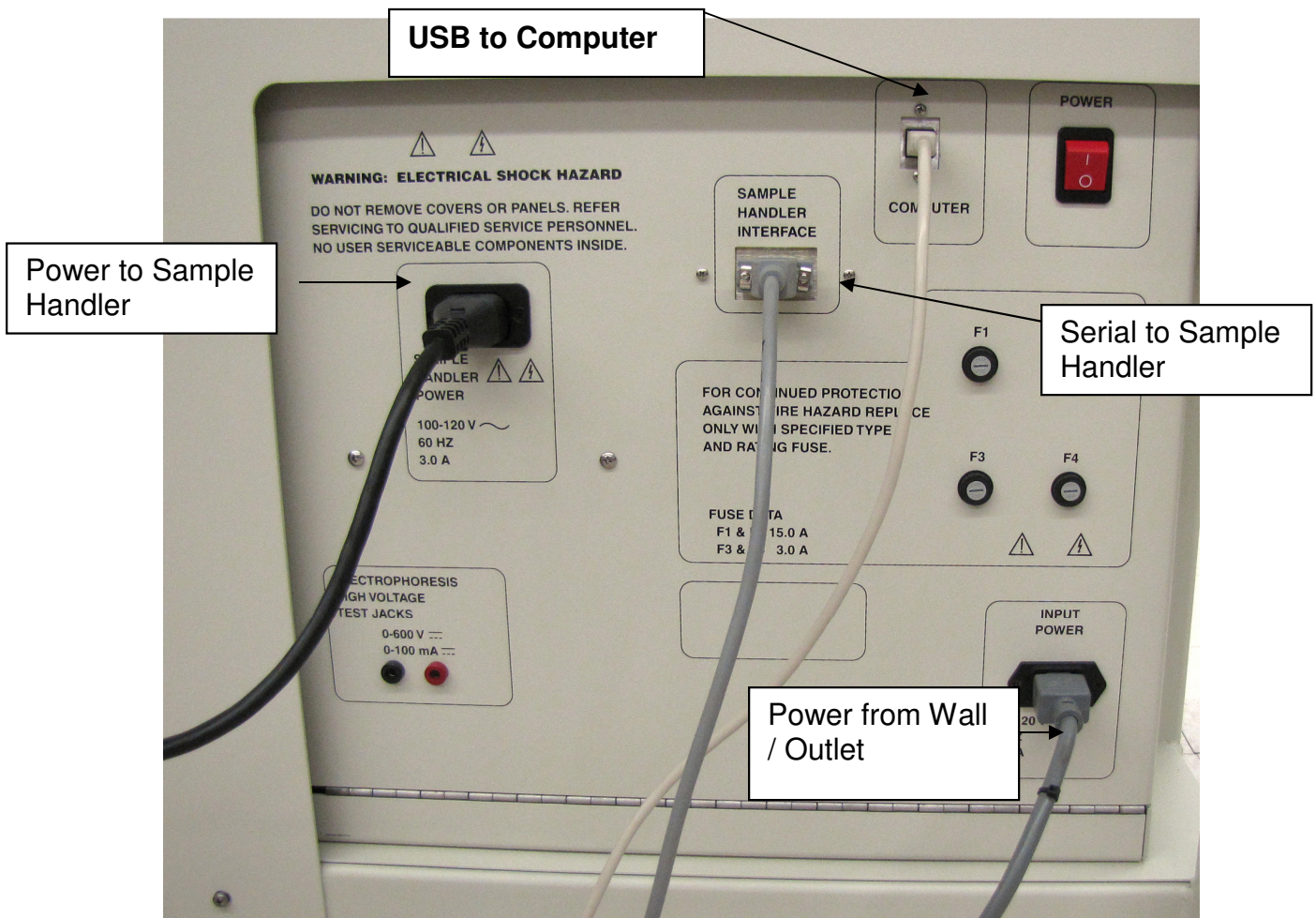
Figure 5-2 Back view of the SPIFE 4000 (gel processor)

Serial to Gel Processor

Connect free end to open port on Waste

Power from Gel Processor
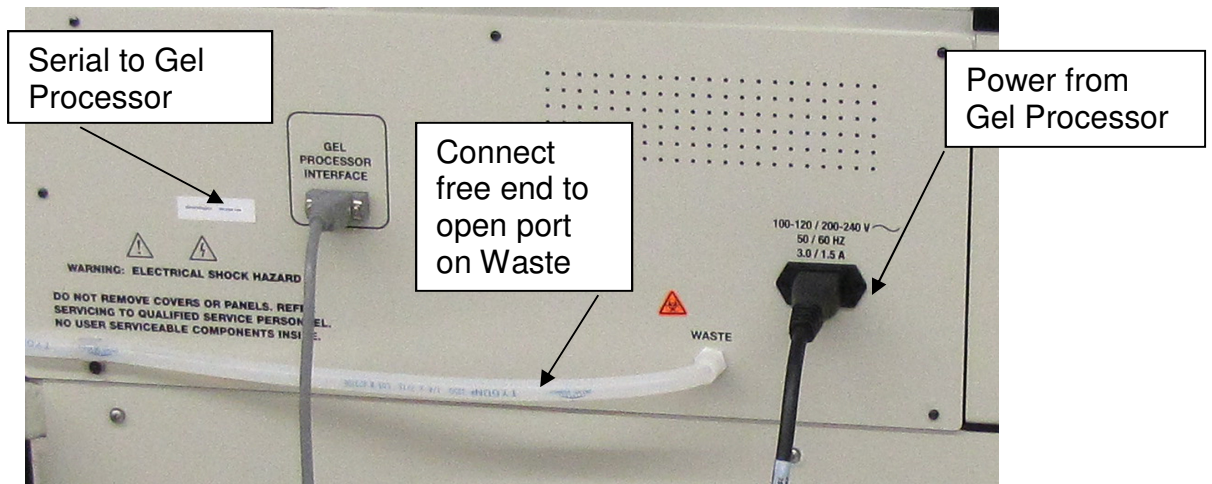
Figure 5-3 Back view of the SPIFE 4000 (sample handler)

USB to Printer

Mouse
Keyboard
Monitor

USB to Gel Processor

Figure 5-4 Back view of the computer

Figure 5-5 Back view of the SPIFE 4000, lower right side of gel processor

Section 6 - User Setup

1. Turn the power on for the instrument and computer.

2. The Microsoft® Windows® program opens and displays the SPIFE 4000 icon. Select the icon.

   a. If the system detects no setup errors, the log on window appears.

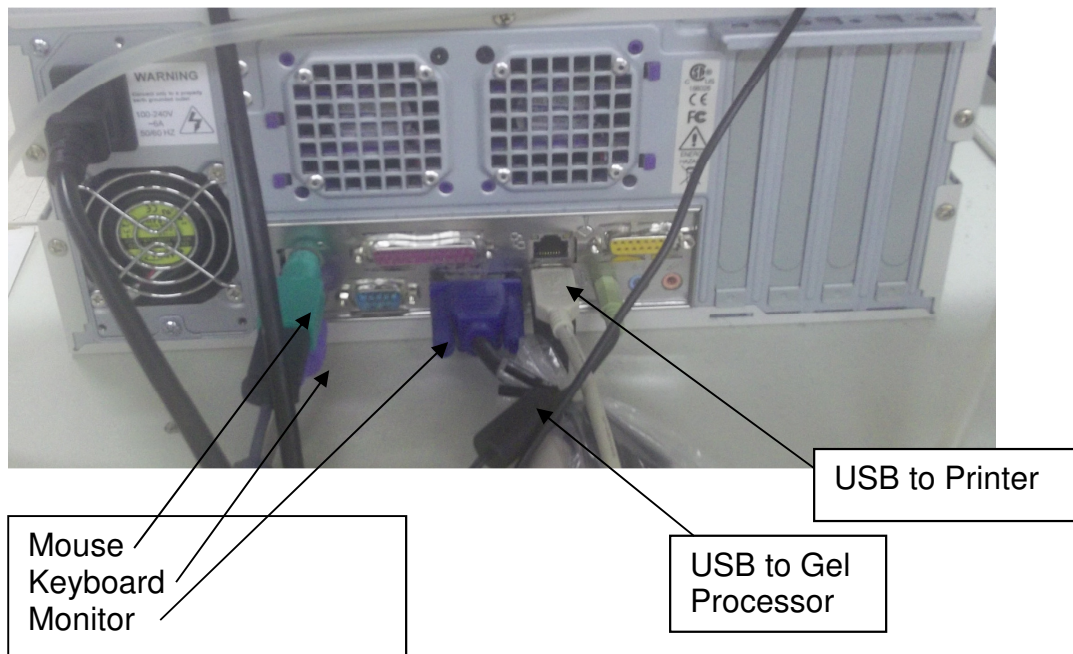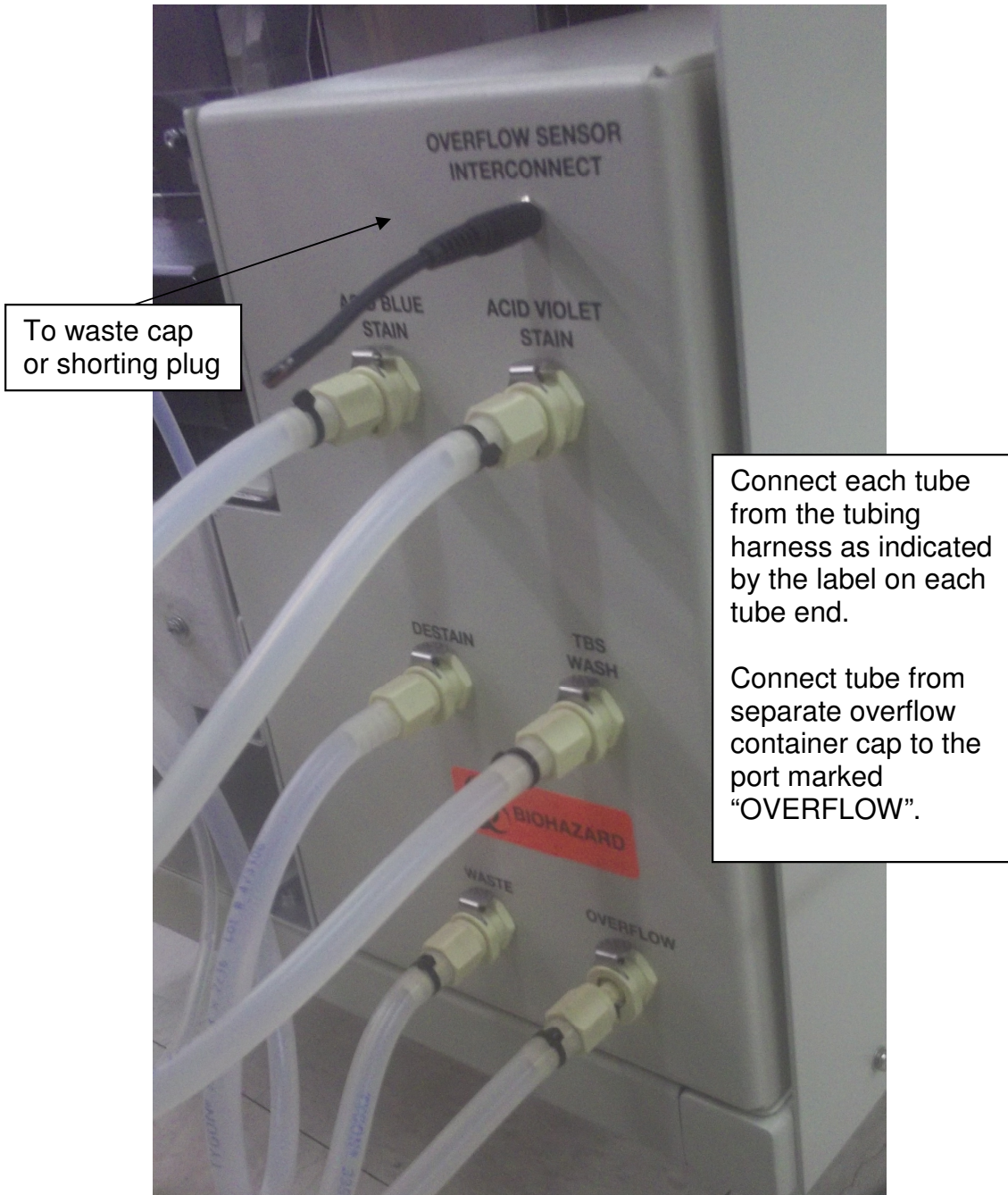   b. If an error message appears, refer to the message, and perform the actions suggested in the message. For further assistance, or if the error recurs, record the message and call Helena Laboratories for further assistance. Also see Table 10-2.

3. Note that access to the software can be controlled by setting up individual user names and passwords each with specific software access (see Section 6.9).

   a. Enter the appropriate *User name* and *Password* and select *Log On*. Note that User Names and Passwords are case sensitive. If no security levels have been added, the window will still appear and any name may be typed in without the use of a password.

4. *User Setup* is accessed by selecting *Edit* on the main menu (Figure 6-1) and, from the drop down menu, selecting *User Setup*. Note that *Setup* will not be accessible if the user name in use does not have permission to change the setup. When *User Setup* is selected, a menu appears with the following choices: *Patient Demographics, Tests, Worklists, Comments / Interpretations, Reports, Import / Export, Quality Control, Message Options,* and *Users and Passwords* (Figure 6-2).

5. The options listed in *User Setup* are described in brief below.

   a. *Patient Demographics*: Allows the user to set up demographic labels for all tests (see Section 6.1).

   b. *Tests:* Allows the user to set up new tests, edit existing tests, or delete tests (see Section 6.2).

   c. *Worklists:* A worklist defines the operation to be performed, and the disposition of the data. A user may simply use the default worklist template, or create a unique worklist design designated for use with a specific test. Under this menu, the user can set up a new worklist template for a specific test, or edit an existing worklist template. That worklist template worklist will always be used for the designated test, although some parameters may later be altered per scan (see Section 6.3).

   d. *Comments/Interpretations:* Allow the user to create and edit a menu of comments for each test. The user may also set up criteria by which data can be interpreted and commented upon automatically (see Section 6.4).

   e. *Reports:* Allows the user to define the contents and appearance of patient reports (see Section 6.5).

   f. *Import/Export:* Allows the user to set up parameters for importing and exporting data (see Section 6.6).

   g. *Quality Control*: Allows the user to set up and track the NDDC information (see Section 6.7).

   h. *Message Options* (see Section 6.8).

   i. *Users and Passwords:* Allows the user to add new users, and define levels of operation by user (see Section 6.9).

6.1. Patient Demographics

Determine the demographics that all of the displays and reports, regardless of test, will need to contain. Those demographic labels common to all tests are setup here in *Patient Demographics*.

Demographics that will vary based on the type of test (for example, *Total* is a demographic often best designated as a test specific demographic) are setup as part of each individual test. Test specific demographics will be created in test set up (see Section 6.2.4).

1. From the Main Menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *SPIFE 4000 Setup* window (Figure 6-2), *Patient Demographics* is displayed. This window displays all the currently setup demographic labels, options to *Edit, Add, Delete, Move Up, Move Down*, and *Print.* There is also a box in which to designate the *Key Identifier.*

Note: *For the Key Identifier, select a unique identifier such as an accession number or medical record number. PATIENT NAME IS NOT A UNIQUE IDENTIFIER.*

3. *Edit* - To edit an existing demographic, select the demographic label to be altered and then select *Edit.* The *Edit Demographic* window opens.

   a. *Label* - enter or select from the drop down list the desired label. Some common labels include: *Patient Name, Patient ID, Birthdate, Sex, Date Drawn, Time Drawn*, and *Tech ID*.

   b. *ASTM Field Number: Field Name* - use the drop down list of ASTM demographics to assign the applicable ASTM demographic.

   c. *OK* – select to accept and saves the changes made to the demographic.

   d. *Cancel* – select to reject and delete the changes made. A *Confirm Cancel* prompt display. Select *Yes* to continue or *No* to return the *Edit Demographic* window.

4. *Add* - To add a patient demographic, select *Add.* The *Add Demographic* window opens(Figure 6-3).

   a. *Label* - enter or select from the drop down list the desired label.

   b. *ASTM Field Number: Field Name* - use the drop down list of ASTM demographics to assign the applicable ASTM demographic.

   c. *OK* – select to accept the changes made to the demographic.

   d. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt display. Select *Yes* to continue or *No* to return the *Edit Demographic* window.

5. *Delete* - To delete a demographic, select the demographic *Label* to be deleted and then select *Delete.*

   a. A *Confirm Delete* prompt displays:

      i. Select *Yes* to delete the demographic.

      ii. Select *No* to retain the demographic.

6. *Move Up* - To have a demographic label display sooner in the list of demographics, select the demographic *Label* to be moved and then select *Move Up.*

7. *Move Down* - To have a demographic label display later in the list of demographics, select the demographic *Label* to be moved and then select *Move Down.*

8. *Key Identifier* – Any Patient Demographic that is unique to each patient, such as the patient's name or patient's ID number. It will be the first column in the worklist. Once a key identifier has been selected it should not be changed as this can cause retrieval problems. The Key Identifier should be the first demographic entered.

9. Once all the demographics have been setup 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*.

6.2. Tests

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *SPIFE 4000 Setup* window (Figure 6-2), select *Tests.* The window displays the existing tests (Figure 6-4).

Note: All scanning is done automatically except for Alkaline Hemoglobins, where start and end scanning is set manually. For more detail, see Section 7.2.

3. *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. See Sections 6.2.1 through 6.2.4 for instructions on using this window. Note that once a test has been edited and saved, the **new test will overwrite the original test.**

4. *Add* - To add a new test, select *Add* and the *Add Test* window (Figure 6-5) displays (see Section 6.2.1 for further detail.)

5. *Delete* - To delete an existing test, highlight the needed test (Figure 6-4) and select *Delete*. A *Confirm Delete* prompt displays:

   a. Select *Yes* to delete the test.

   b. Select *No* to retain the test.

6. 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*.

   c. *Default Settings* – will restore all manufacturers original test settings to the selected test.

6.2.1. Test Type and Test Name

1. *Test Type* – On the *Add Test* window, use the drop down list to select the appropriate test type (Figure 6-6).

For a test to have access to the Restricted Bands feature, the test type must list "protein" in the test name.

2. *Test Name* - Prior to naming the test, or altering specific parameters, click on the *Default Settings* button at the bottom 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 and the stain type setup for this test.

3. On the same screen, under *Test Type*, and *Test Name*, there are three tabs, *Gel Preparation* (Section 6.2.2), *Fractions/Ratios/Ranges* (Section 6.2.3), and *Patient Demographics* (Section 6.2.4) each of which contains menus for setting up test-specific parameters.

6.2.2. Gel Preparation

6.2.2.1. Processes

1. When *Test* is selected under Setup, and the Add Test menu is opened, the *Gel Preparation* tab is selected first by default. *Processes* is highlighted on the left-hand side of the menu (Figure 6-5). The *Processes* menu displays the options listed below.

- a. Sample Preparation
- b. *Sample Application*
- c. *Electrophoresis*
- d. *Fixative Application*
- e. *Pre-Dry*
- f. *Wash*
- g. *Stain*
- h. *Destain*
- i. *Dry*
- j. *Scan*

2. For each box checked, that process will be available for that test.

3. On the right hand side of the display, a menu is available for every item selected. Processes not checked will not appear on the left hand side of the menu.

4. When the process on the right hand menu is highlighted, a new display opens on the right side, where details specific to that process may be modified.

6.2.2.2. Pre-Start Checklist

The pre-start check list is displayed on the screen. The user must check off each item in the list before they can start the run. The pre-start check list is optional, and can be turned off by the operator in the test setup, by clicking on the box at the top of the screen. Also, the checklist itself can be changed by the operator in the test setup. To modify the checklist, click inside the text screen and edit as needed. Items can be added or deleted from the list, or the wording can be changed by the operator (this is per test). Below are the default checklists.

Serum Proteins:
- Sample tubes loaded in carousels and
  carousels loaded in the instrument
- Serum Protein applicator blades loaded
- Serum Protein sample trays loaded
- Serum Protein gels loaded
- DI water (surfactant) loaded
- Acid Blue stain loaded
- Destain loaded

IFE:
- Sample tubes loaded in carousels and
  carousels loaded in the instrument
- IFE applicator blades loaded
- IFE sample trays loaded
- IFE gels loaded
- Diluent loaded
- DI water (surfactant) loaded
- Flat blotters loaded
- Comb blotters loaded
- Antisera and fixative loaded
- Antisera template in place
- Acid Violet stain loaded
- Destain loaded
- TBS Wash loaded

6.2.2.3. Sample Preparation

The following parameters may be altered as needed. Note that only parameters specific to the test type selected are available for modification. Dilutions for Serum Proteins may not be automatically prepared by the SPIFE 4000K Sample Handler (Figure 6-7).

1. *Volume (µL)*

2. *Primary Wash Time (mm:ss)*

3. *Primary Wash Cycles*

4. *Secondary Wash Time (mm:ss)*

5. *Secondary Wash Cycles*

6. *Samples Per Gel*

7. *Applications Per Sample*

8. *Dilutions*

   a. *Dilutions* are available only with Immunofixation Electrophoresis (IFE) Test Type selected.

9. *Edit Dilution*

   a. Dilutions may be individually set for each sample 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; and 1 in 14 (Figure 6-7).

6.2.2.4. Sample Application

1. *Applicator Load Time (mm:ss)*

2. *Applicator Load Speed*

3. *Application Rows*

4. *Row 1 Location (mm from gel edge)*

5. *Apply Time (mm:ss)*

6. *Apply Cycles*

7. *Absorption Time (mm:ss)*

8. *Inter-Ger Start Delay (mm:ss)*

6.2.2.5. Electrophoresis

1. *Voltage (Volts):*

2. *Minimum Current Limit (mA)*

3. *Maximum Current Limit (mA)*

4. *Temperature (°C)*

   Time (hh:mm:ss)

6.2.2.6. Fixative Application

1. *Absorption (hh:mm:ss)*

2. *Blot Time – Comb Blotter (hh:mm:ss)*

3. *Blot Time – Flat Blotter (hh:mm:ss)*

6.2.2.7. Pre-Dry

1. *Temperature (°C)*

2. *Time (hh:mm:ss)*

6.2.2.8. Wash

1. *Cycles*

2. *Time (hh:mm:ss)*

6.2.2.9. Stain

1. *Stain Type*

2. *Absorption Time (hh:mm:ss)*

6.2.2.10. Destain

1. *Cycles*

2. *Time (hh:mm:ss)*

3. *Agitate Destain*

6.2.2.11. Dry

1. *Temperature (°C)*

2. *Time (hh:mm:ss)*

6.2.2.12. Scan

The following options are available on the *Scan* menu (See Figure 6-8):

1. *Sequence*

2. *Aperture Size*

3. *Smooth*

Smoothing is not recommended for the clinical laboratory, as the results can be affected.

    a. *Smoothing Level (1-10)*

4. *Auto Interpretation:* Check this box to either enable or disable *Auto Interpretation* for this specific test. Parameters for *Auto Interpretation* must be set up separately for each test under *Comments and Interpretations* (refer to Section 6.4 for further information.) **If *Auto Interpretation* is used, care must be taken to individually review EVERY scan.**

5. *Patient Overlay 1*

Criteria may be set up for each test to automatically search prior scans to be used for one or two *Patient Overlays*. An option exists to either automatically apply the scans that meet criteria as patient overlays, or manually apply the overlays.

    a. *Selection Method: Manual* or *Auto*

    b. *Auto Settings*

        i. *Limit search to previous X day(s) (1-365)*

        ii. *Test Type: Patient Overlays* must be searched for by a specific test type or name.)

        iii. *Scan: (Recent, Next most recent, Prior oldest, Oldest.)*

        iv. *Ok*

        v. *Cancel*

6. *Patient Overlay 2*

    a. *Selection Method: Manual* or *Auto*

    b. *Auto Settings*

        i. *Limit search to previous X day(s) (1-365)*

        ii. *Test Type: (Patient Overlays* must be searched for by a specific test type or name.)

        iii. *Scan: (Recent, Next most recent, Prior oldest, Oldest.)*

        iv. *Ok*

        v. *Cancel*

7. *Image Contrast*

    a. *Lighter* to *Darker*

8. *Gain*

    a. *Gain Mode: Auto or Manual*

In *Auto Gain*, the maximum amplitude of the largest fraction is automatically set at 100% of the graph, with the rest of the height in proportion. If samples are scanned in *Auto Gain*, they may not be viewed in manual gain without rescanning.

    b. *Manual Gain: Min 0* to *Max 10*

In *Manual Gain*, the fraction amplitude is proportional to concentration. *Manual Gain* is the gain of choice for light fractions such as urine proteins. Gain may be adjusted to the desired amplitude in increments of 0.1.

Note: *If Manual Gain is selected, the Auto Scale feature can be applied later to individual scans, in order to view them as if scanned in Auto Gain mode.*

9. *Fraction Detection*

    a. *Sensitivity: Min 0 to Max 10*

Fraction Detection Sensitivity sets the sensitivity of the instrument to detect positive or negative changes in the slope of the scan for determining when to demarcate fractions. A sensitivity of zero will turn off the automation fraction detection, and thus there will be no fractions on the scan.

    b. *Forced Fractions: No, Float, or Fixed*

Forced Fractions are not recommended for the clinical laboratory. *No* is recommended.

    i. Select *No* to select fractions based only on pattern slope changes.

    ii. Select *Float* for fraction marks based on the pattern slope only if they occur within a window around the *Reference* fraction marks. If no fraction marks appear in the window, a mark is forced at the *Reference* fraction mark location. If *Float* is selected, a *Reference Overlay* is needed.

    iii. Select *Fixed* to use the same fraction locations as a previously scanned reference on the same gel. If fix is selected, a *Reference Overlay* is needed.

  c. *Combine Split Beta Fraction*

  d. *Save Gel Image*

    i. Enable *Save Gel Image* to save an image of the gel as part of the worklist. After the gel has been scanned and saved, the image may be viewed, printed, or saved to a file.

6.2.3. Fractions / Ratios / Ranges

1. *Unit of Measure* (Figure 6-9)

  a. *Fractions* - can contain up to 10 characters. Fractions may be any unit, except percent. For example, units may be g/L, g/mL, U/L, U/dL, etc.

  b. *Total* - is only available with Immunofixation Electrophoresis (IFE) Test Type selected. This feature gives the use the option of using a different unit of measurement for immunoglobulins. It may be any unit for proteins except percent. For example, immunoglobulin levels may be measured as g/L, g/mL or other units. This field can contain up to 10 characters.

  c. *Decimal Places* - select the desired number of decimal places for numeric results. Options are *0*, *1*, or *2.*

2. *Restricted Bands*

  a. *Label* - enter a label, of up to 12 characters (for example M-Spike or M-Protein) for use when a restricted band is marked.

  b. *Marking Method* – select from *Sliced*, *Skimmed* or *Sliced or Skimmed*. It is recommended that the user enabled only one method per test.

  c. *Automatically locate restricted band delimiters* – check to enable this function.

3. *Label* – enter a label for each of the following as needed:

  a. *Ratio 1* and *2*

  b. *Total*

  c. *Fraction 1, 2, 3, 4, 5, 6, 7, 8, 9,* and *10*

4. *Ratio Assignment 1* and *2* – for each of the following, indicate the ratio assignments as *Numerator*, *Denominator*, or leave the space blank, to indicate it is neither. Each may be part of one, two or no ratios.

  a. *Total*

  b. *Fraction 1, 2, 3, 4, 5, 6, 7, 8, 9,* and *10*

5. *Range Set A, B, C, D, E, F, G, H,* and *I* – are the nine available reference ranges. When using control ranges, the patient reference range is usually placed in range A, because this is the default range. If a patient's demographic data do not meet the specific criteria for another range set, then Range set A is automatically used for that patient.

  a. *Edit Range Set*

i. *Type - Patient*, *Normal Control*, *Abnormal Control*. Range set A is the default reference range, and unless otherwise specified, range set A will be applied to all samples. Normal patient reference ranges should be entered in range set A. Note that Normal and Abnormal Control can only be used once per set of reference ranges. To apply control ranges to a sample, the sample must be designated Normal or Abnormal as appropriate.

ii. *Sex / Age Characteristics* - only available with *Patient* selected.

1) *Sex* - may contain only one character and is often used as the index for selection of range. For example, use M, for male, or F, for female. The corresponding letter must be entered as sex when filling in patient demographics on the patient information window or range A will be selected. If the range is age specific, put no letter in the sex field. Other letters may be used in the gender field to identify other range sets (for example, a third level of control might be identified as "D" in the gender field.)

2) *Age Low* and *Age High* - may be used for an age range. Place the lower limit, from 0 to 125, in the *Age Low* field and then select either *Year(s)*, *Month(s)*, or *Day(s)* from the drop down list in the field to the right. Place the upper limit, from 0 to 125, in the *Age High* field and select either *Year(s)*, *Month(s)*, or *Day(s)* from the drop down list in the field to the right.

3) *Clear* – select to clear all entries made for Sex/Age Characteristics.

iii. *OK*

iv. *Cancel*

b. *Ratio 1* and *2*

i. *Edit Ratio Range*

1) *Low Limit* and *High Limit* – enter the low and high limits.

2) *Clear Range* – select to clear the limits.

3) *OK*

4) *Cancel*

c. *Total*

i. *Edit Total Range*

1) *Low Limit* and *High Limit* – enter the low and high limits.

2) *Clear Range* – select to clear the limits.

3) *OK*

4) *Cancel*

d. *Fraction 1, 2, 3, 4, 5, 6, 7, 8, 9,* and *10*

i. *Percent Range*

1) *Edit Fraction Range*

a) *Low Limit* and *High Limit* – enter the low and high limits.

b) *Clear Range* – select to clear the limits.

c) *OK*

d) *Cancel*

ii. *Units Range* – The default *Unit of Measure in* the box labeled *Fractions* is gm/dl. When a different *Unit of Measure* is entered then the column labeled *Units* is renamed with the new Unit of Measure.

1) *Edit Fraction Range*

a) *Low Limit* and *High Limit* – enter the low and high limits.

b) *Clear Range* – select to clear the limits.

c) *OK*

d) *Cancel*

6.2.4. Demographics, Test Specific

Demographics entered under the demographics tab in test setup are specific only to the specific test currently opened. While entering these test specific demographics, a list appears of the demographics previously entered under Patient Demographics from the Main Menu. One can also create and label new demographic fields (Figure 6-10).

1. *Edit* - To edit an existing demographic, select the demographic *Label* to be altered and then select *Edit (only test specific demographics can be edited here).* The *Edit Demographic* window opens, displaying all the fields entered from the Main Menu (Figure 6-10):

   a. *Label* - enter or select from the drop down list the desired label. Some common labels include: Patient Name, Patient ID, Birthdate, Sex, Date Drawn, and Time Drawn.

   b. *ASTM Field Number: Field Name* - use the drop down list of ASTM demographics to assign the applicable ASTM demographic. Please note that the ASTM fields are not permanently labeled. If a laboratory system uses a different ASTM field name for a given ASTM field number, the ASTM number should be consistent between systems. The demographic label may be customized in the SPIFE 4000 software to match any field name in the laboratory information system.

   c. *OK* – select to accept the changes made to the demographic.

   d. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt will display. Select *Yes* to continue or *No* to return the *Edit Demographic* window.

2. *Add* - To add a patient demographic, specific to this test, select *Add.* The *Add Demographic* window will open.

   a. *Label* - enter or select from the drop down list the desired label.

   b. *ASTM Field Number: Field Name* - use the drop down list of ASTM demographics to assign the applicable ASTM demographic. Note that the Field name is not a permanent assignment and the label may be customized.

   c. *OK* – select to accept the changes made to the demographic.

   d. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt will display. Select *Yes* to continue or *No* to return the *Edit Demographic* window.

3. *Delete* - To delete a test specific demographic, select the demographic *Label* to be deleted and then select *Delete.*

   a. A *Confirm Delete* prompt displays:

      i. Select *Yes* to delete the demographic.

      ii. Select *No* to retain the demographic.

4. *Move Up* - To have a demographic label display sooner in the list of demographics, select the desired label to be moved and then select *Move Up.*

5. *Move Down* - To have a demographic label display later in the list of demographics, select the desired label to be moved and then select *Move Down.*

6.3. Worklists

The worklist template setup defines the operation to be performed and the disposition of the data. A worklist template is a guideline to setup in which to specify the appearance of the worklist, display settings, print settings and scan setting. For every gel scanned a new worklist is built

using the worklist template. For every gel scanned/new worklist that is built, the display, print, and export settings may also be temporarily modified.

Multiple customized worklist templates may built. Custom worklist templates may also be automatically applied. If a test and a worklist template share the same (case sensitive) name, then that worklist template will be used as the default worklist for that test. The worklist template must also include the word "scan" following the name of the test.

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *SPIFE 4000 Setup* window (Figure 6-2), select *Worklists.* The window displays where worklists will be stored and allows access to the currently setup worklist templates (Figure 6-11).

3. *Folder where worklists will be stored* - To designate where worklists will be stored, select the *Search for folder* icon located to the right in the *Folder where worklists will be stored* cell. Use the drop down menu to select the desired location.

4. *Edit* - To edit an existing worklist template, highlight the needed worklist template and select *Edit*. See Sections 6.3.1 through 6.3.4 for instructions on using this window.

5. *Add* - To add a worklist template, select *Add*. See Sections 6.3.1 through 6.3.4 for instructions on using this window.

6. *Delete* - To delete an existing worklist template, highlight the needed worklist and select *Delete*. A *Confirm Delete* prompt displays:

   a. Select *Yes* to delete the worklist template.

   b. Select *No* to retain the worklist template.

7. Once all the worklist templates have been setup 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*.

6.3.1. Template Name

1. *Template Name* – Enter (or alter) the desired worklist template name (Figure 6-12). For a worklist template to be used as the default template for a specific test, the template name must be exactly the same as the test name, followed by the word "scan." For example, a test might be named "Special Serum Proteins," and the worklist template would then be "Special Serum Proteins Scan." Otherwise the default worklist template will be used.

2. *Template Appearance* – The layout and appearance of the template may be customized. Components may be resized by positioning the cursor over the bottom right hand corner of the component and dragging the cursor in and out. Components may be relocated by placing the cursor over the upper left corner and dragging the cross hatch cursor to the desired position. Components may not overlap. Take care not to position components off the visible screen or they will not appear on the display.

6.3.2. Display Settings

1. *Display Settings* - Select and the *Display Settings* window (Figure 6-13) appears.

2. *Automatically display after scanning*– Select to have the worklist display once a scan is complete.

3. *Overlays* - if not already selected, select *Overlays* to access the options available:

    a. *Overlay Unedited* - select to have the unedited pattern, shown in green, overlaid on the sample pattern. This feature allows the user to see the cumulative effect of any editing.

    b. *Overlay Reference* - select to have the reference pattern, shown in yellow, overlaid on the sample pattern. If selected, a sample will need to be labeled *Reference* for each gel (Section 7.3.1.7) and will need to be listed prior to any sample for which it will be the overlay. The sample may be labeled *Reference* before or after the run. This feature is a useful tool to aid in marking fractions on a sample that is not well delineated.

    c. *Overlay Patient 1* - select to have a patient's scan, shown in pink, overlaid on the current scan. An IFE image may be selected as one or both patient overlays; the image will be shown as an overlay thumbnail.

    d. *Overlay Patient 2* - select to have a second patient's scan, shown in blue, overlaid on the current scan.

    e. *Show Overlay Thumbnails* – select to show thumbnails of overlays.

        i. Up to two overlay thumbnails may be displayed

        ii. IFE images may be displayed as Overlay Thumbnails.

4. *Results* - select to access the options available:

    a. *Display Percent* – select to include the percent in the display.

    b. *Display Units* – select to include the units in the display. If in use, a total demographic is required.

    c. *Display Integrals* – select to include the integrals in the display. If in use, samples must be scanned in manual gain. These integrals are arbitrary amounts used in rough comparison of amounts of material and are altered as soon as the gain is altered.

    d. *IFE*

        i. Display units – select to include the units in the display. If in use, a total demographic is required.

5. *Ranges* – select to access the options available.

    a. *Display Percent Range*

    b. *Display Units Range*

    c. *Display Ratio Range*

    d. *Flag Percent Out*

    e. *Flag Units Out*

    f. *Flag Ratio Out*

    g. *IFE*

        i. *Display Units Range*

        ii. *Flag Units Out*

6.3.3. Export Settings

1. *Export Settings* - Select and the *Export Settings* window (Figure 6-14) appears.

2. *Automatically export after scanning.* – select to have the worklist export once a scan is complete.

3. *Destination* - select one of the following:

a. *Host Computer* - once selected the following options are available (and are explained below)*: Patient Information*, *Graphics*, *Results*, *Ranges*, and *Comments*.

b. *File* - once selected the following options are available (and are explained below): File Information, Patient Information, and Results.

4. *Patient Information* – is available with all three of the *Destination* options. Select one of the following:

a. *Don't Export*

b. *Export Key Identifier Only*

c. *Export All Patient Information*

5. *Image and Graph* – select to export *Image*, *Graph*, or both. This function is only available when *Host Computer* is selected.

a. *Export Image*

b. *Export Graph*

6. *Results* - select as needed.

a. *Export Percent* – select to export percent.

b. *Export Units* - requires that a total demographic exist.

c. *Export Integrals* - requires that samples are scanned in manual gain. These integrals are arbitrary amounts used in rough comparison of amounts of material and are altered as soon as the gain is altered.

7. *Ranges* – select which ranges to export and what to flag out.

a. *Export Percent Range*

b. *Export Units Range*

c. *Export Ratio Range*

d. *Flag Percent Out*

e. *Flag Units Out*

f. *Flag Ratio Out*

8. *Comments* – select to have comments exported.

a. *Export Comments*

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

10. *Cancel* - to exit 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.*

6.3.4. Print Settings

1. *Automatically print after scanning.* – select to have the worklist print once a scan is complete (Figure 6-15).

2. *Report* - if not already selected, select *Report* to access the options available:

a. *Report* - from the drop down list select one of the reports. The list consists of all the currently setup reports (Section 6.5.1).

b. *Number of Copies* - select number of copies to be printed at once.

3. *Patient Information* - Select one of the following:

a. *Print Key Identifier Only* – select to have only the demographic classified as *Key* printed.

b. *Print All Patient Information* - select to have all the demographics printed.

4. *Overlays* - Note that if a color printer is not used, the reports may be difficult to read, including the Overlay(s). Select as needed:

a. *Overlay Unedited* - select to have the unedited pattern overlaid on the edited pattern.

b. *Overlay Reference* - select to have the reference pattern overlaid on the sample pattern. If selected, a sample will need to be labeled *Reference* for each gel scanned (Section 7.3.1.7).

c. *Overlay Patient 1* - select to have a patient's scan overlaid on the current scan.

d. *Overlay Patient 2* - select to have a second patient's scan overlaid on the current scan.

e. *Print Overlay Thumbnails*

5. *Results* - Select as needed:

a. *Print Percent* – select to print percent.

b. *Print Units* - requires that a total demographic exist.

c. *Print Integrals* -Integrals are unitless values that represent the area under the graph curve and are dependent upon the gain used when scanning.

d. *IFE*

i. *Print Units* - allows printing immunological totals as part of the IFE report.

6. *Ranges* - The options accessible depend on which selections are made in *Results*, and/or on selections made within *Ranges.* Select as needed:

a. *Print Percent Range*

b. *Print Units Range*

c. *Print Ratio Range*

d. *Flag Percent Out*

e. *Flag Units Out*

f. *Flag Ratio Out*

g. *IFE*

i. *Print Units Range*

ii. *Flag Units Out*

7. *Levey-Jennings Graph* - Select either:

a. *Plot Percent* - select to plot using the setup Reference Range Percent Range.

b. *Plot Units* - select to plot using the setup Reference Range Units Range.

Note: *To print a Levey-Jennings chart, the user must specify whether Units or percent is to be charted, and **must also** choose the Level-Jennings report type under Report settings.*

8. *Ok* - to save all the changes made and exit, select *OK*.

9. *Cancel* - to exit 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.*

6.3.5. OK and Cancel

1. *OK* - To accept the additions/changes made to the worklist and return to the *User Setup* window, select *OK.*

2. *Cancel* - to exit to the *User Setup* window 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.*

6.4. Comment / Interpretation Settings

Note: When creating parameters in User Setup for Auto Interpretation and comments associated with those parameters, a single test must be designated. The Auto Interpretation and any associated comments will not be accessible from a scan of a different test, unless the operator returns to Comments/Interpretations in User Setup and changes the test designation.

Note: If creating stored comments as well as Auto Interpretation comments ensure the comments do not contain the same wording/text. Similar wording will cause the stored comment not to be applied correctly.

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *SPIFE 4000 Setup* window (Figure 6-2), select *Comments / Interpretation.* The right side of the window allows access to the currently setup comments and interpretations.

3. *Folder where comments and interpretations will be stored* – Indicate the desired folder location by using the *Search for folder* icon and choosing from the drop down menu or typing the location using the keyboard.

4. *Edit* - To edit an existing comment and interpretation, highlight the needed comment and select *Edit* and the *Edit Comment and Interpretation* window displays. See the instructions for the *Add Comment and Interpretation* window to use this window.

5. *Add* - To add a comment and interpretation, select *Add* and the *Add Comment and Interpretation* window (Figure 6-16) displays.

    a. *Label* - enter or edit the label for the comment. The label can contain unlimited

characters. The label is not displayed or printed as part of the test results, but is used by the operator to identify the saved comments.

    b. *Text* - use the keyboard to enter or edit the comment which can contain an unlimited amount of characters.

    c. *Auto Interpretation* (Figure 6-17) - select to designate the comment as an Auto Interpretation. Note that the test for which the auto interpretation is to be used must be setup to use reference ranges of units and/or percent, and must have auto interpretation selected for use. With *Auto Interpretation* selected, the following is accessible:

        i. *Test* - using the drop down list, select a test. The contents of the list are based on the currently setup tests.

        ii. *Interpret Based on* - select either Percent or Units.

        iii. The Fraction Labels setup for the *Test* selected display horizontally across the window to allow for their use as interpretation criteria. For each of the labels, select one of the following:

            1) *Not a Factor*

            2) *Absent (< 0.0) A* - enter the desired absent threshold of from 0.0 to 99.9.

            3) *Decreased*

            4) *Normal to Decreased*

            5) *Normal*

            6) *Normal to Elevated*

            7) *Elevated*

        iv. *Pattern Characteristic* - an optional text description of the appearance of the scan. For example if the valley between the Alpha 2 fraction and the Beta fraction was missing, the pattern characteristic might be "Alpha 2/Beta bridge."

Interpretations can be retrieved by pattern characteristic. Only pattern characteristics for interpretations with a test designation the same as the scan test will be listed as available for the scan.

d. *OK* – select to accept the changes made to the comment or interpretation.

e. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt display. Select *Yes* to continue or *No* to return the *Add Comment and Interpretation* window.

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

a. Select *Yes* to delete the comment and interpretation.

b. Select *No* to retain the comment and interpretation.

7. Once all the comments and interpretations have been setup 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*.

Note: If using Pattern Characteristics, check all fractions and total protein as "Not a Factor" when creating the comment. The Pattern Characteristic will not be applied if it doesn't conform to the comment. For example, if Total Protein is

checked as "Normal" and the scan doesn't have a normal total protein, the original applied comment will be "toggled off" but the pattern characteristic will not be applied.

6.5. Report Settings

6.5.1. Reports

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *User Setup* window (Figure 6-2), select *Reports.* The right side of the *User Setup* window allows access to the existing reports, any other currently setup reports (Figure 6-18).

3. From this window, select one of the following actions:

a. To create a new report, select *Add*. The *Add Report* window displays.

b. To alter a previously setup report, highlight the needed report and select *Edit*. The *Edit Report* window opens and the report is ready for editing.

c. To copy a currently setup report, highlight the needed report and select *Copy.* The report is copied and added to the end of the report list. The new report may then be opened and edited if desired.

d. To delete a report, highlight the needed report and select *Delete*. A *Confirm Delete* prompt displays:

i. Select *Yes* to delete the report.

ii. Select *No* to retain the report.

6.5.1.1. Report Type

1. *Standard Report* - Standard report will be used as a default if no other report type is selected (see Figure 6-21). The Standard report contains a title, patient demographics, scan identifier, image of the sample, graph of the scan, overlay information, results, and comments.

2. *List report* – The List report contains a title, and a list of all patients, demographics, and results. Statistics are printed at the bottom of the list report. Integer results are not included.

3. *Profile Report* – A profile report can be used to print more than one result. The default profile report includes a title, scan identifier, demographics, image of the sample, graph, and results. At the bottom of the report are a second graph, second set of results, and comments. The graph and results are both assigned to scan 1 by default and to Overlay 1 by default, such that a scan with an overlay may be printed with a full image of the overlay scan, as well as the results from the overlaid scan.

4. *Levey-Jennings* – The Levey-Jennings report contains a title and a chart. The Levey-Jennings Chart prints the control performance and time of run for each control run. The limits of the chart are selected from the reference range entered under test setup. Separate charts will be printed for each control. The chart may be printed in either units or percent range but separate ranges must be done for each (Figure 7-11). To create a Levey-Jennings Chart:

    a. Under *File*, select *Find.*

    b. Search for *Normal* or *Abnorma*l, as the demographic under the desired test.

    c. All controls (Normal or Abnormal) must be labeled in the same manner in order to be located using the *Find* feature.

    d. Create a new worklist using the desired control.

    e. Select Print. Select Print Settings. Under Report type, Select *Levey-Jennings* chart. Under Levey-Jennings, select either units or percent. Under Print options select All, or select the desired scans.

    f. Please note that a Levey Jennings chart will be printed for control results that are all designated as controls, and are all from the same test, even if they are included under the same Levey-Jennings worklist. If the test settings have been altered, or control ranges modified, then only results from the test during one, unaltered time frame may be included on a single chart.

6.5.1.2. Report Name

1. *Report Name* - Enter the desired name. This name is only used for quick identification of the report and is not printed on the report; however, all reports must have a name.

6.5.1.3. Paper Size and Orientation

1. *Size* - Select from the four available paper sizes. Note that if the report currently contains components and the *Size* is altered, some or part of the components may not be accessible in this window and will not print out.

2. *Orientation* - Set the paper orientation to either *Portrait* or *Landscape.* Note that if the report currently contains components and the *Orientation* is altered, some or part of the components may not be accessible in this window and will not printout.

Note: *There are four default report types which may be edited, or copied and used as a template to customize a new report; Standard Report, List Report, Profile Report, and Levey-Jennings report. Editing the default report is not recommended, as there is no backup to restore default settings. To modify a default report, it is recommended to first create a copy, then edit the copy.*

6.5.1.4. Add

1. *Add* – Click on the location within the report the selected component should appear (Figure 6-19).

2. Right click to access the drop down menu of components available to add and select one. Note that each component appears with a gray frame around it. The top left corner is used to move the component location around the report. The bottom right corner is used to resize the width and/or height of the component. When the mouse cursor is moved over these corners its appearance will change and the frame will change to dotted lines to indicate that the component can be moved or resized. Press and hold the left mouse button down while moving the mouse to move or resize the component.

3. The components available through *Add* are as follows (Figure 6-19):

a. *Scan Identifier* - includes the name of the test, the sample number, and the date and time the sample was scanned.

b. *Patient Info* - includes the demographic labels and entered patient information. Note that the Print Settings selected will determine if all or only the Key demographic print (Section 7.2.4).

c. *Image* - select to include an image of the scan.

d. *Graph* - select to include an image of graph.

e. *Overlay Info* - select to include a legend of any overlays included. The legend only prints if the Print Settings specify (Section 7.2.3.2).

f. *Results* - results will display in the format selected earlier in Section 6.

g. *Comments* - once the position for this component is selected, right click on the box and select *Settings*. The *Com-ments 1 Presentation Settings* window displays. Only the header name can be entered at this point, but the appearance of the comment can still be altered. Once entered, select *Ok* and the comment is placed on the report. The comment may need to be resized for all the text to display and/or for the text to wrap as desired.

h. *Text* - once the position for this component is selected, right click on the box and select *Settings*. The *Text 1 Presentation Settings* window displays. Use this window to enter the desired text. Once entered, select *Ok* and the text component is placed on the report. The text component may need to be resized for all the text to display and/or for the text to wrap as desired.

i. *List* - once the position for this component is selected, right click on the box and select *Settings*. The *List 1 Presentation Settings* window displays (Figure 6-20). Click to *Print Statistics* and change the font and color of the report elements. Once entered, select *Ok* and the component is placed on the report.

j. *Chart* – select this to include the Levey-Jennings report.

6.5.1.5. Settings

1. Position the mouse cursor over the specific component, right click and select *Settings.* Depending on the component selected, the window displays different formatting parameters. For information on moving and/or resizing a component, see Section 6.5.1.4. Sections 6.5.1.5.1 through 6.5.1.5.10 detail the specific items that may be altered (Figure 6-21).

2. Once all the components have been setup 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.*

6.5.1.5.1. Scan Identifier

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple Scan Identifier components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment* – To assign this component to a patient overlay scan, set this to 1 for patient overlay 1 or 2 for patient overlay 2. The scan identifier for the specified overlay will be printed.

3. *Font Settings*

a. *Name* – use the drop down list to select the desired font name.

b. *Size* - use the drop down list to select the desired font size.

c. *Effects* - select *Bold*, *Italic* and/or *Underline* as needed.

4. *Color* - Use the pop up list to select the desired color.

6.5.1.5.2. Patient Info

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create reports that include more than one scan from the same worklist, include multiple Patient info components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment* – All elements from a single patient scan have a default overlay assignment of zero. To assign a scan component associated with a patient overlay scan, set the overlay assignment to 1 for patient overlay 1 or 2 for patient overlay 2. The patient information for the specified overlay will be printed. For example, to include the comments, results, or image strip from patient overlay 1, add a comment, results, or image component with a scan assignment of zero, and an overlay assignment of 1.

3. *Components* - Highlight the component needing modification and then use *Color* and/or *Font Settings* to modify.

a. *Label*

b. *Demographic*

4. *Font Settings*

a. *Name* – use the drop down list to select the desired font name.

b. *Size* - use the drop down list to select the desired font size.

c. *Effects* - select Bold, Italic and/or Underline as needed.

5. *Color* - Use the pop up list to select the desired color.

6.5.1.5.3. Image

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple image components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment* – To assign this component to a patient overlay scan, set this to 1 for patient overlay 1 or 2 for *patient overlay* 2. The image for the specified overlay will be printed.

3. *Border* - Select to place a border around the component.

4. *Border Width* - Select from 3 different widths to border the image.

6.5.1.5.4. Graph

1. *Scan Assignment* – For single scan reports, this should be set to 1. To create multi-scan reports, include multiple graph components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment – To assign this component to a patient overlay scan, set this to 1 for patient overlay 1 or 2 for patient overlay 2. The graph for the specified overlay will be printed.*

3. *Options*

    a. *Border* - select to place a border around the component.

    b. *Border Width* - select from 3 different widths to border the image.

    c. *Vertical Tick Marks* - select to include a scale positioned vertically on the component.

4. *Components* - Highlight the component needing modification and then use *Color* to modify (Figure 6-21).

    a. *Graph Outline*

    b. *Graph Fill*

    c. *Unedited Overlay*

    d. *Reference Overlay*

    e. *Patient Overlay 1*

    f. *Patient Overlay 2*

    g. *Fraction Delimiter*

    h. *Restricted Band Delimiter*

5. *Color* - Use the pop up list to select the desired color.

6.5.1.5.5. Overlay Info

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple Overlay Info components and set the first to 1, the second to 2, etc.

2. *Components* – Highlight the component needing modification and then use *Color* and/or *Font Settings* to modify.

    a. *Header*

    b. *Thumbnail Label*

    c. *Graph Outline*

    d. *Graph Fill*

    e. *Fraction Delimiter*

    f. *Restricted Band Delimiter*

3. *Font Settings*

    a. *Name* – use the drop down list to select the desired font name.

    b. *Size* - use the drop down list to select the desired font size.

    c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

4. *Color* - Use the pop up list to select the desired color.

6.5.1.5.6. Results

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple Results components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment* – To assign this component to a patient overlay scan, set this to 1 for *patient overlay* 1 or 2 for *patient overlay* 2. The results for the specified overlay will be printed.

3. *Components* – Highlight the component needing modification and then use *Color* and/or *Font Settings* to modify.

    a. *Header*

    b. *Label*

    c. *Results In*

    d. *Results Out*

    e. *Range*

4. *Font Settings*

    a. *Name* – use the drop down list to select the desired font name.

    b. *Size* - use the drop down list to select the desired font size.

    c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

5. *Color* - Use the pop up list to select the desired color.

6.5.1.5.7. Comments

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple Comments components and set the first to 1, the second to 2, etc.

2. *Overlay Assignment* – To assign this component to a patient overlay scan, set this to 1 for *patient overlay* 1 or 2 for *patient overlay* 2. The comments for the specified overlay will be printed.

3. *Header* – Select to have a header displayed. If enabled, the header text can be entered in the edit box to the right.

4. *Word Wrap* – Select to have text wrap the width of the box.

5. Font Settings

    a. *Name* – use the drop down list to select the desired font name.

    b. *Size* - use the drop down list to select the desired font size.

    c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

6. *Color* - Use the pop up list to select the desired color.

6.5.1.5.8. Text

1. *Border* - Select to place a border around the component.

2. *Border Width* - Select from 3 different widths to border the image.

3. *Color* - Use the pop up list to select the desired.

4. *Font Settings*

    a. *Name* – use the drop down list to select the desired font name.

    b. *Size* - use the drop down list to select the desired font size.

    c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

5. *Justify* - Select the text and choose from left, right, or center justify.

6. *Cut* – Highlight the text and choose to cut the selected text.

7. *Copy* - Highlight the text and choose to copy the selected text.

8. *Paste* - Select the appropriate location for the text and choose to paste.

9. *Undo* – Select the arrow to undo the last change.

6.5.1.5.9. List

1. *Print Statistics* – click to include statistics.

2. *Components* - Highlight the component needing modification and then use *Color* and/or *Font Settings* to modify (Figure 6-20).

    a. *Test Name*

    b. *Header*

c. *Label*

d. *Result In*

e. *Result Out*

3. *Font Settings*

a. *Name* – use the drop down list to select the desired font name.

b. *Size* - use the drop down list to select the desired font size.

c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

4. *Color* - Use the pop up list to select the desired color of the selected component.

5. *Background Color* – Use to change the background color of the selected component.

6.5.1.5.10. Chart

1. *Components* – Highlight the component needing modification and then use *Color* and/or *Font Settings* to modify.

a. *Header*

b. *Fraction / Units*

c. *Range*

d. *Date Scanned*

e. *Times Scanned*

f. *Results In*

g. *Results Out*

2. *Font Settings*

a. *Name* – use the drop down list to select the desired font name.

b. *Size* - use the drop down list to select the desired font size.

c. *Style* - select *Bold*, *Italic* and/or *Underline* as needed.

3. *Color* - Use the pop up list to select the desired color.

4. *Background Color* – Use the pop up list to change the color of the background.

6.6. Import / Export

6.6.1. Import / Export

For additional information, see Section 12 - Communication Specifications.

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *User Setup* window (Figure 6-2), select *Import / Export.*

6.6.1.1. Setup

1. Select *Enable Host Computer Communication* if the instrument is to be interfaced to a host computer. If the instrument is not interfaced to a host computer, it is recommended that this option be unchecked to improve performance of the software. If enabled, the *Setup Host Computer Interface* options (Figure 6-22) will display.

2. *Port* - Select *COM1* or *COM2*

3. *Baud Rate* – Select *1200, 2400, 4800, 9600, 14400,* or *19200*

4. *Data Bits* - Select *7* or *8*

5. *Stop Bits* – Select *1* or *2*

6. *Parity* - Select *none, odd,* or *even*

7. *Protocol* – Select *none, XON-XOFF*, or *ASTM*

8. *Create Communication Log* – When enabled, a record is kept of all communication. The log is accessible from the main menu; see Section 7.6.4. This option should only be enabled for troubleshooting purposes and should not be left enabled during normal instrument operation.

9. *Print* – click to print the *Setup* choices.

6.7. Quality Control

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *User Setup* window (Figure 6-2), select *Quality Control*.

3. The *Quality Control* window displays (Figure 6-23). Setup as the following describes:

4. Entering the *Neutral Density Densitometer Control* (*NDDC*) information:

    a. *Identifying Number* – enter an identifying number to save the scan to.

    b. *Neutral Density Densitometer Control (NDDC)* - enter the information contained on the card supplied with the Neutral Density Densitometer Control (NDDC) as follows on the Quality Control Screen.

    c. *QC History* - set the *Maximum number of QC scans to keep.*

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

    e. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel.* A *Confirm Cancel* prompt displays appears. Select *Yes* to continue and exit the *User Setup* window without saving changes or *No* to return to the *Quality Control* window.

6.8. Message Options

1. From the main menu (Figure 6-1), select *Edit,* and then *User Setup.*

2. From the *SPIFE 4000 Setup* window (Figure 6-2) select *Message Options* (Figure 6-24).

3. *Sound audible alarm when displaying alert messages?* - click to enable and adjust volume from a minimum of 0 to a maximum of 100.

4. *Sound audible alarm when displaying error messages?* - click to enable and adjust volume from a minimum of 0 to a maximum of 100.

5. *Alert user when a carousel needs to be replaced* -click to enable.

6. *Print* -click to print *Message Options* choices.

Note: During a run of more than 112 samples (28 samples per carousel); the carousels will need to be changed in order to continue the run without delay. If positive patient identification is not in use, then the carousels MUST be replaced or samples could be misidentified.

6.9. Users and Passwords

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*.

2. From the *SPIFE 4000 Setup* window (Figure 6-2), select *Users and Passwords.*

3. *Edit* – To edit an existing user, highlight the needed user and select *Edit* and the *Edit User* window displays. See the instructions for the *Add User* window to use this window.

4. *Delete* - To delete an existing user, highlight 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.

5. *Add* - To add a user, select *Add* and the *Add User* window (Figure 6-25) displays.

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

    b. *Password* – enter the desired password.

NOTE: Passwords are case-sensitive.

    c. *This user has rights to* – select each of the following which apply to the user being setup:

        i. *Edit patient information*

ii. *Edit scans*

iii. *Export*

iv. *Print*

v. *Delete scans*

vi. *Change worklist settings*

vii. *Change setup*

viii. *Setup users* (this option is only available if *Change Setup* has been selected.)

ix. *Change calibration*

d. *OK* - select to accept the changes made to the user.

e. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt will display. Select *Yes* to continue or *No* to return the *Add User* window.

6. *Edit* – To edit an existing user, highlight the needed user and select *Edit* and the *Edit User* window displays. See the instructions for the *Add User* window to use this window.

7. Once all the users have been setup 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*.
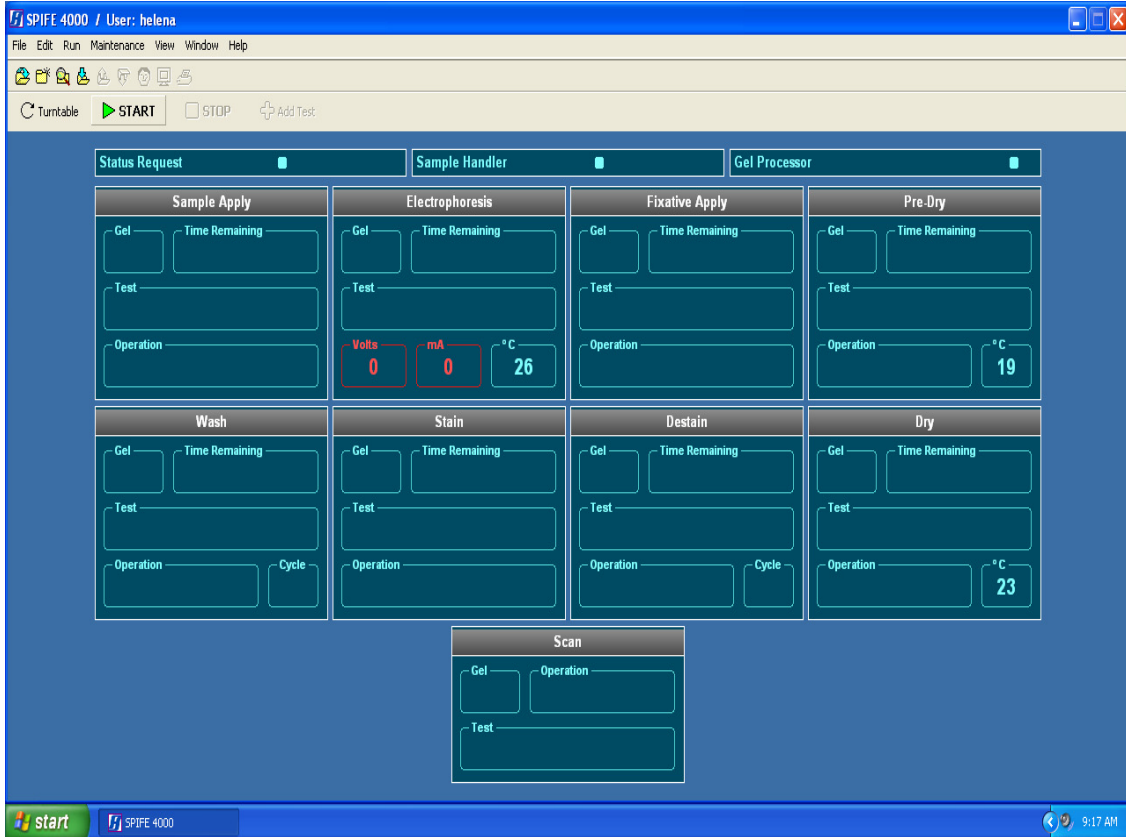
Figure 6-1 Main Menu
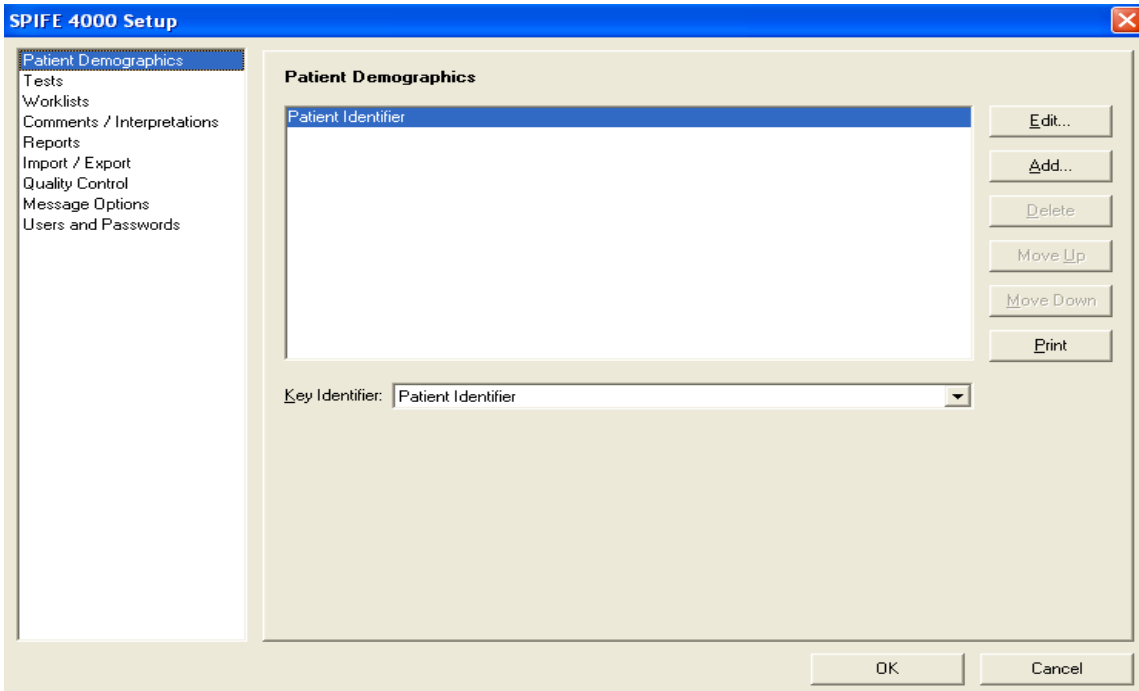
Figure 6-2 User Setup, Patient Demographics
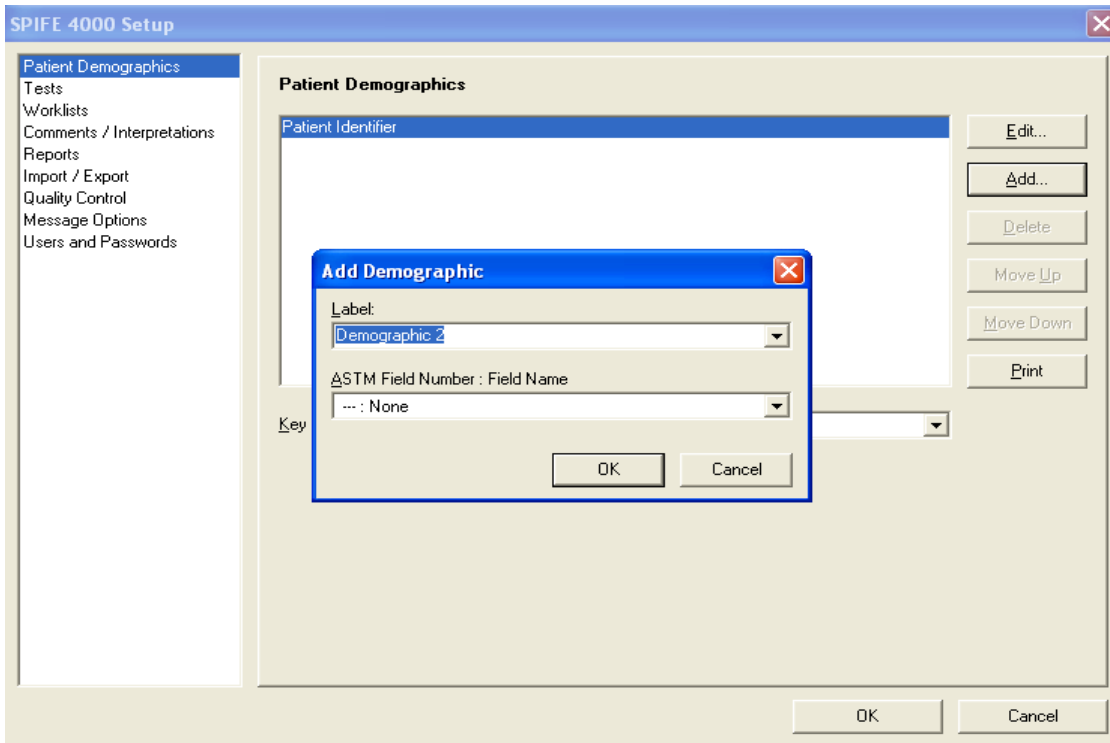
Figure 6-3 Add Demographics
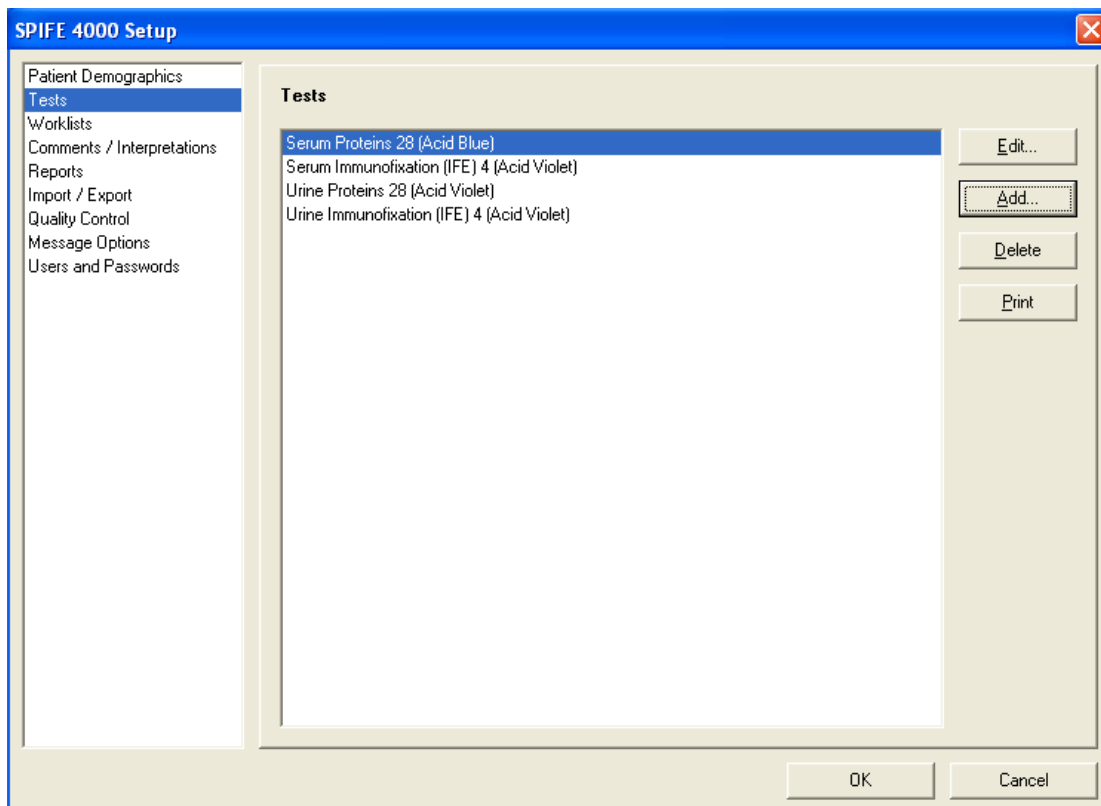
Figure 6-4 User Setup, Tests
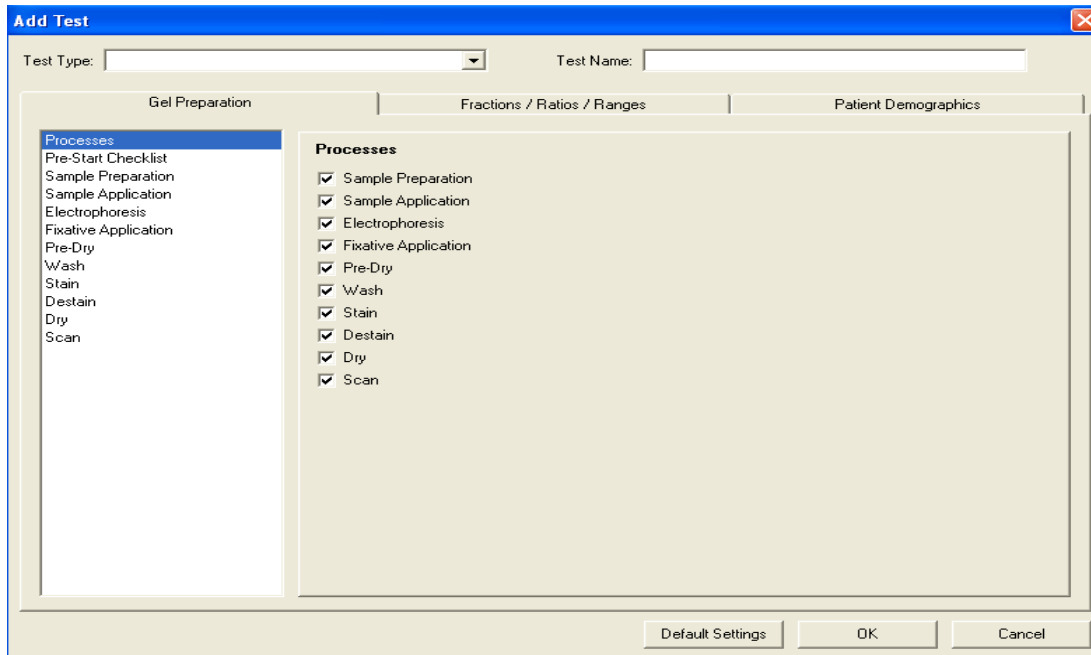
Figure 6-5 Setup Test, Add Test
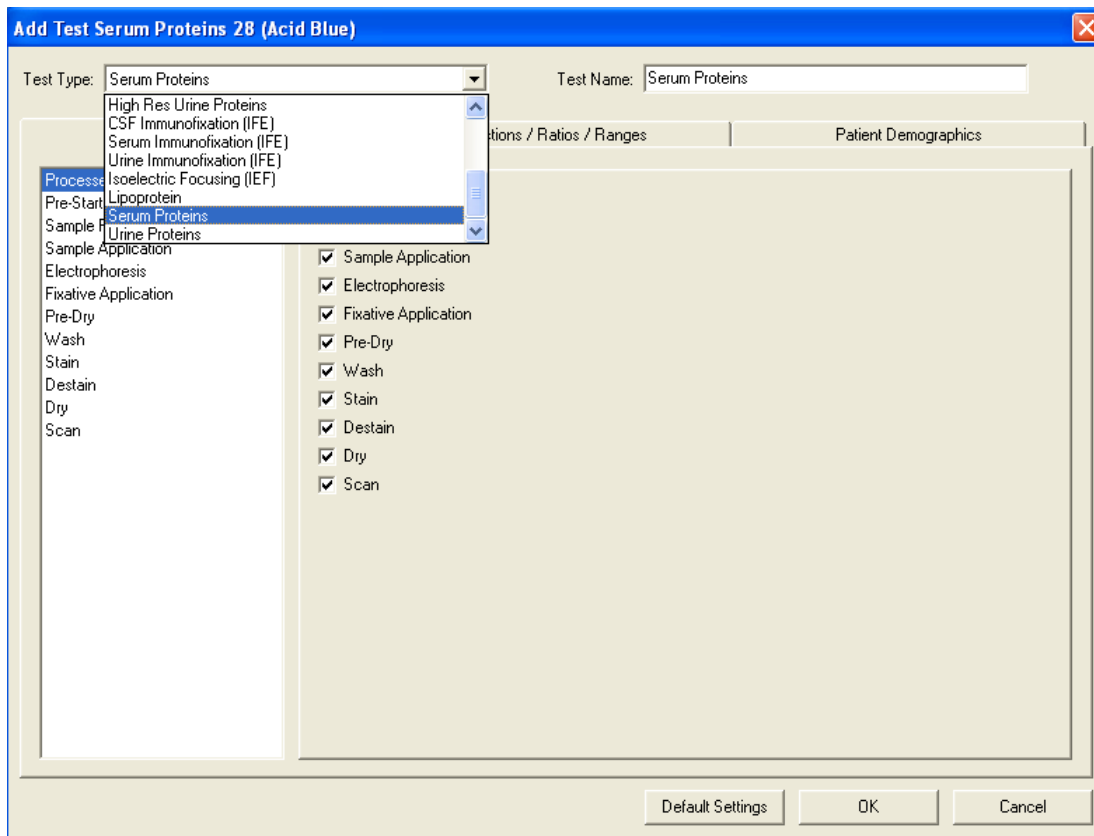
Figure 6-6 Setup Test, Test Type
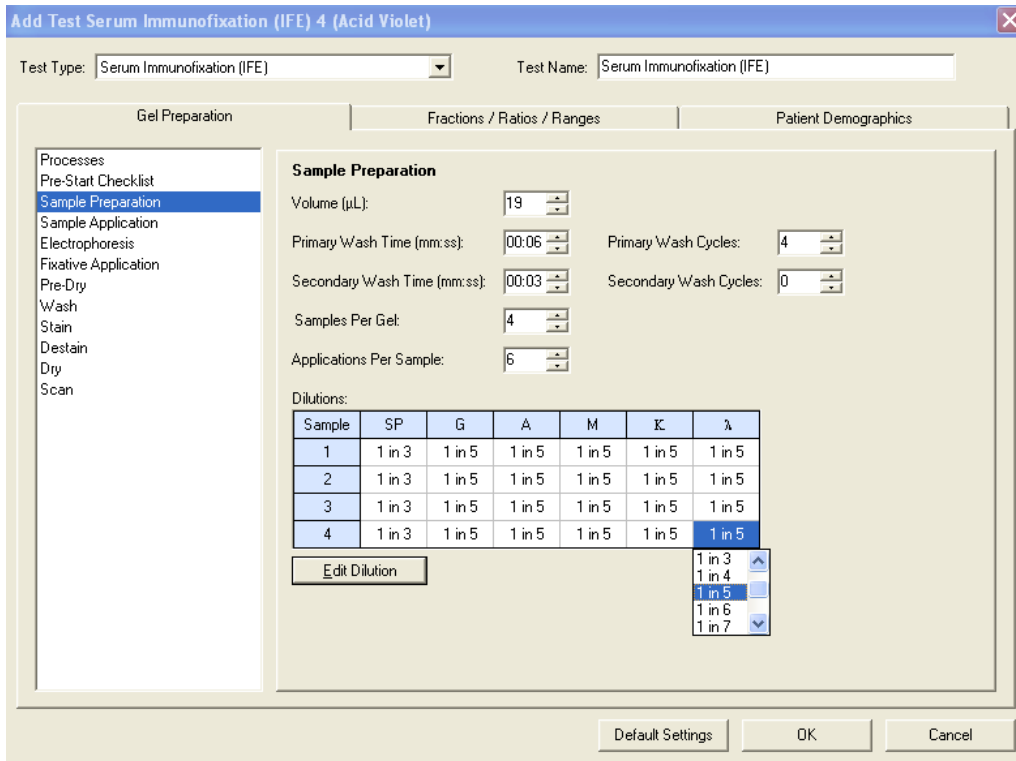
Figure 6-7 Add Test, Gel Preparation, Sample Preparation
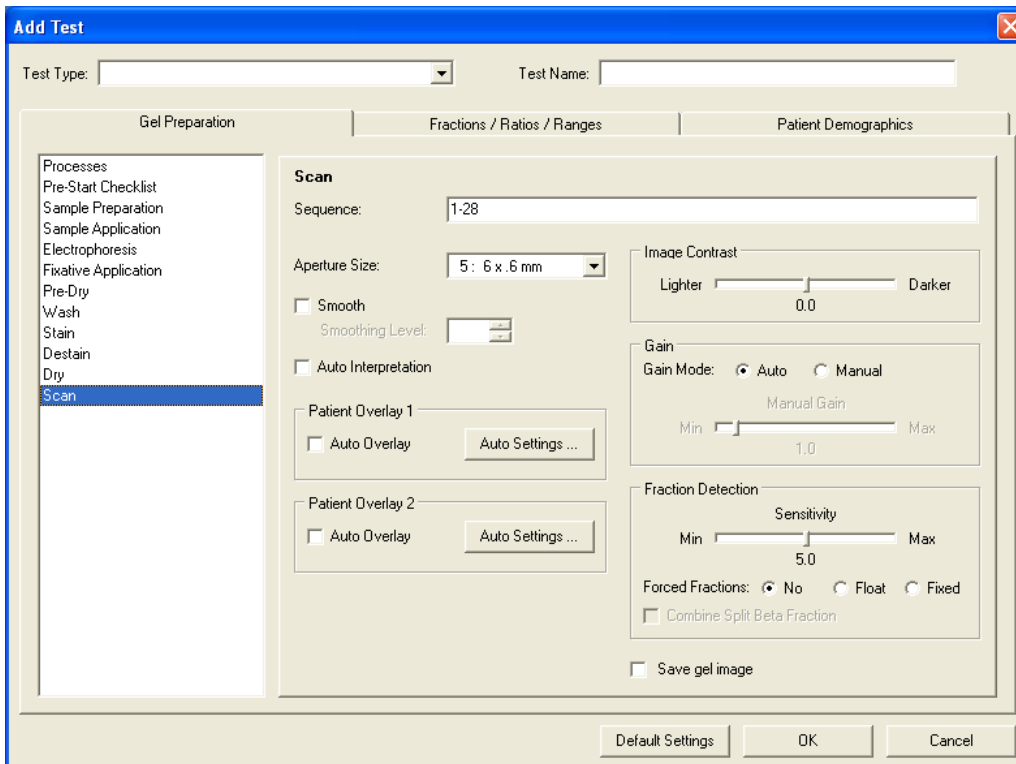
Figure 6-8 Add Test, Gel Preparation, Scan

Figure 6-9 Add Test, Fractions / Ratios / Ranges

Figure 6-10 User Setup, Test Specific Demographics
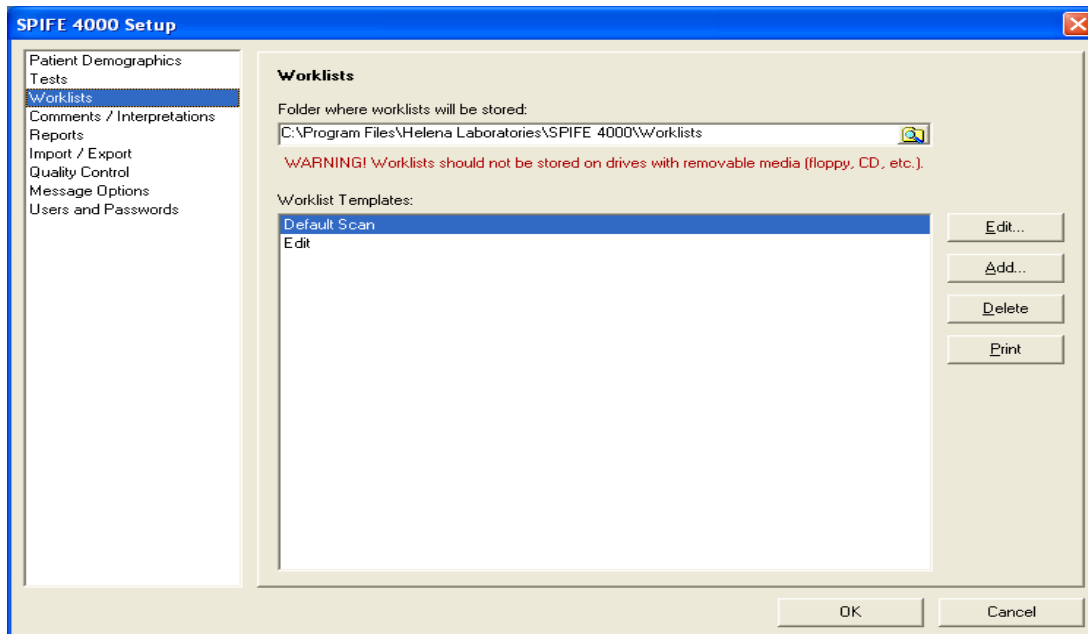
Figure 6-11 User Setup, Worklists
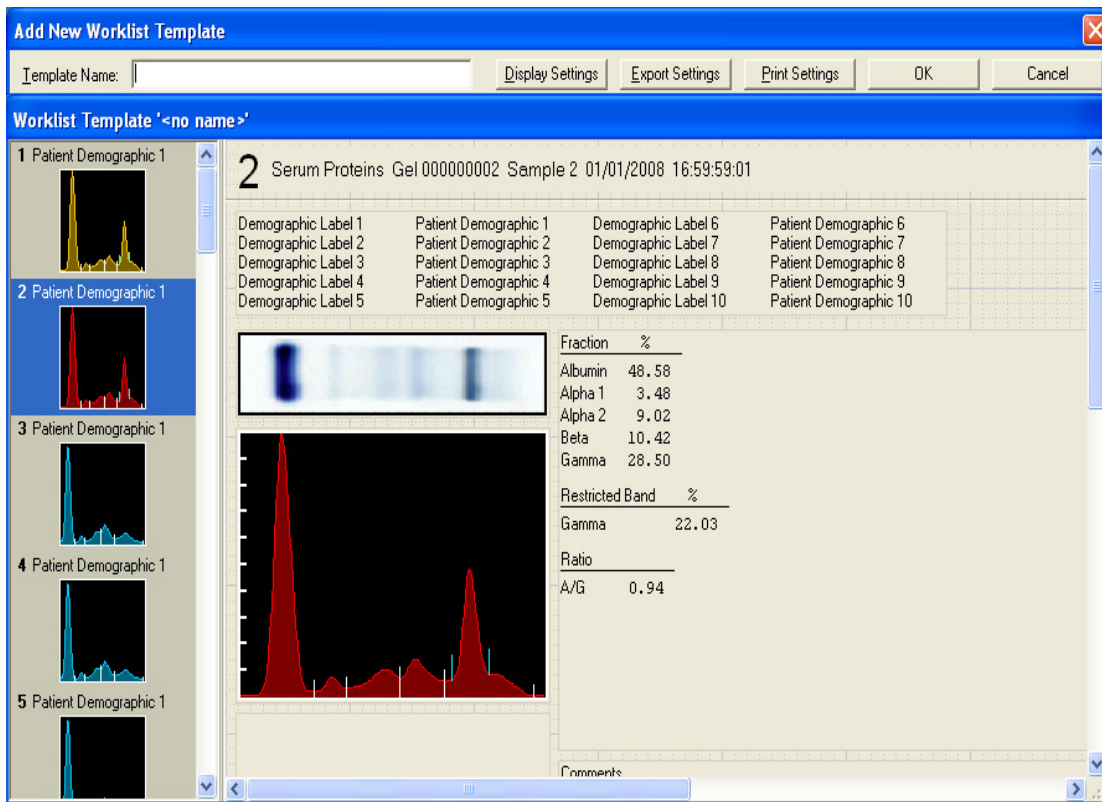
Figure 6-12 Setup Worklists, Template Name
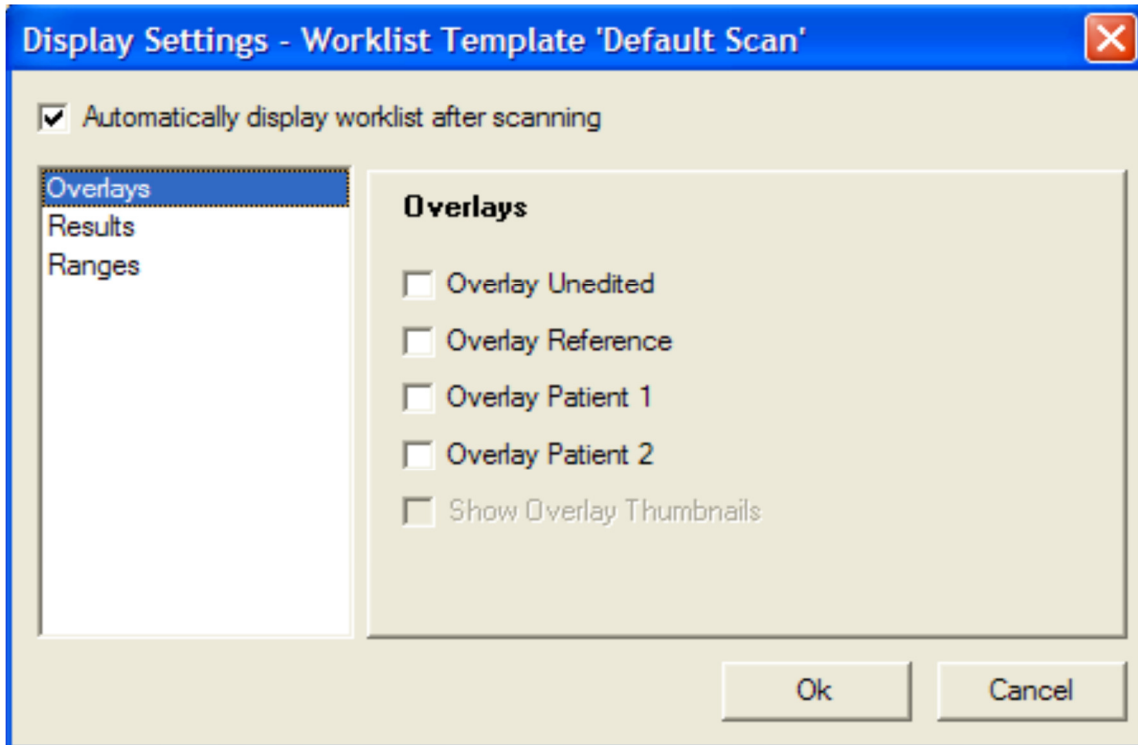
Figure 6-13 Display Settings
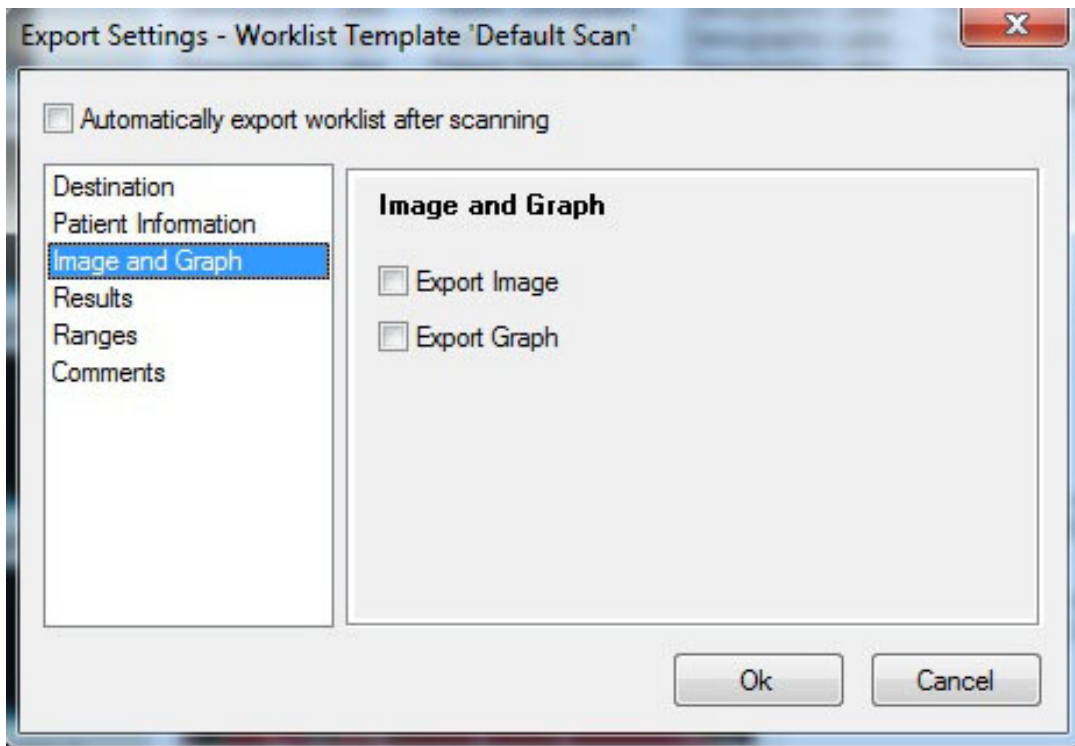
Figure 6-14 Export Settings
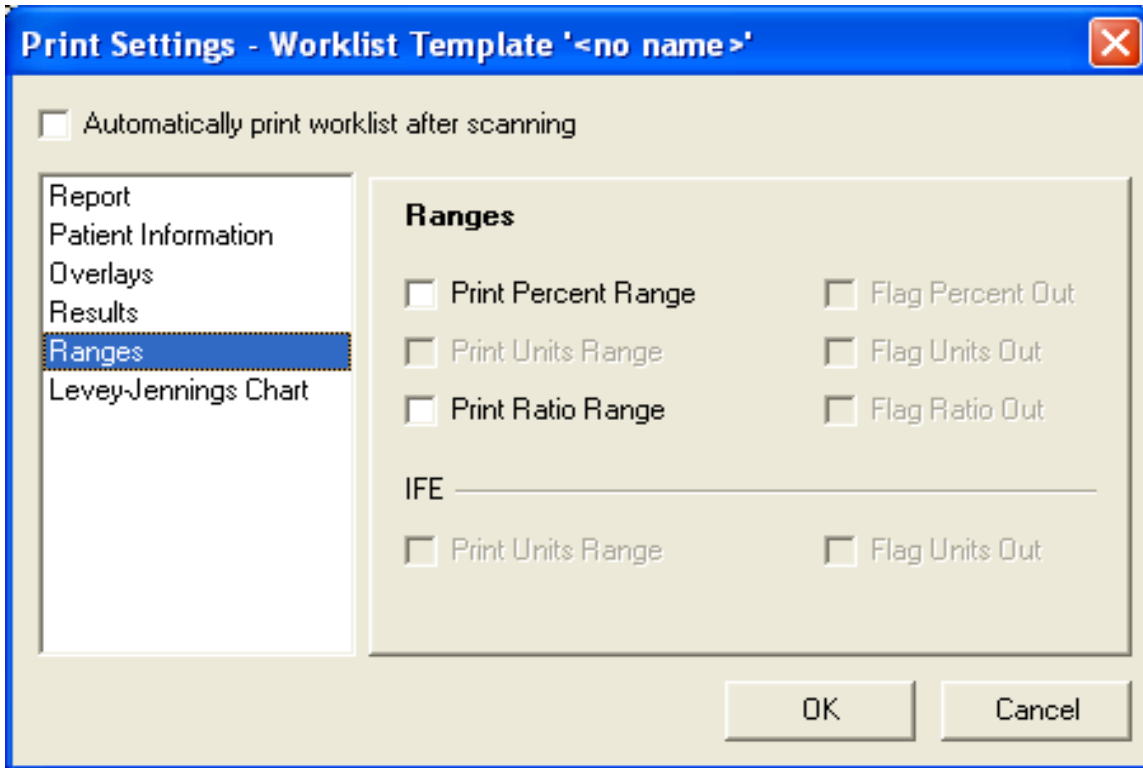
Figure 6-15 Print Settings
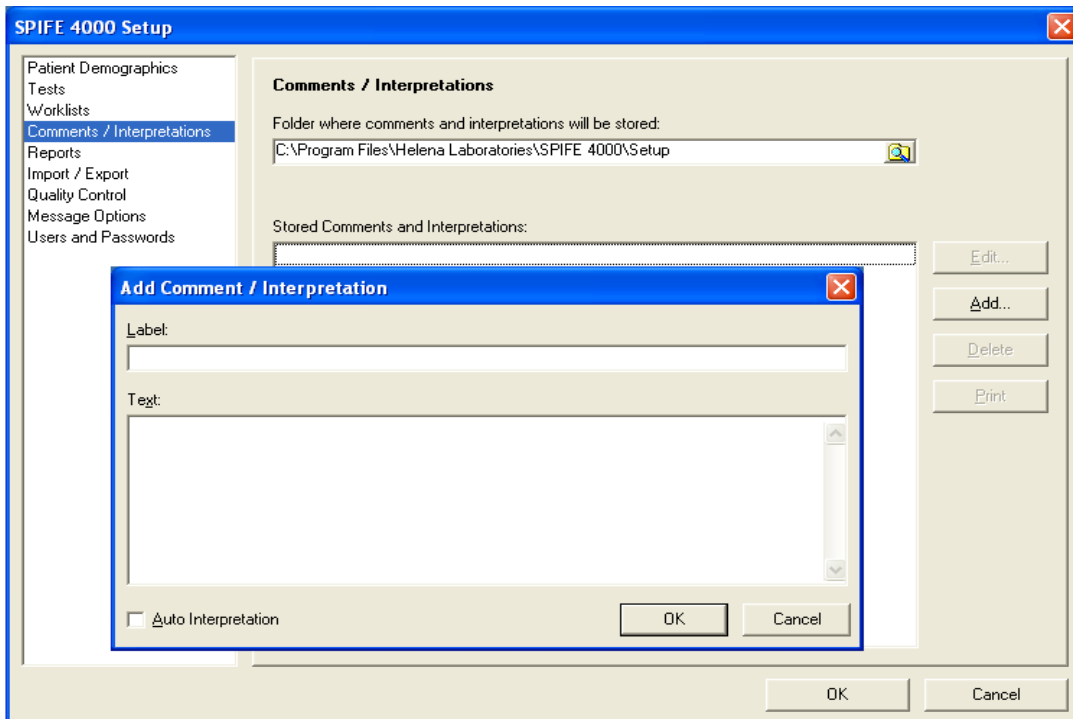
Figure 6-16 Comments / Interpretation, Add / Edit Comments

Figure 6-17 Comments/ Auto Interpretation
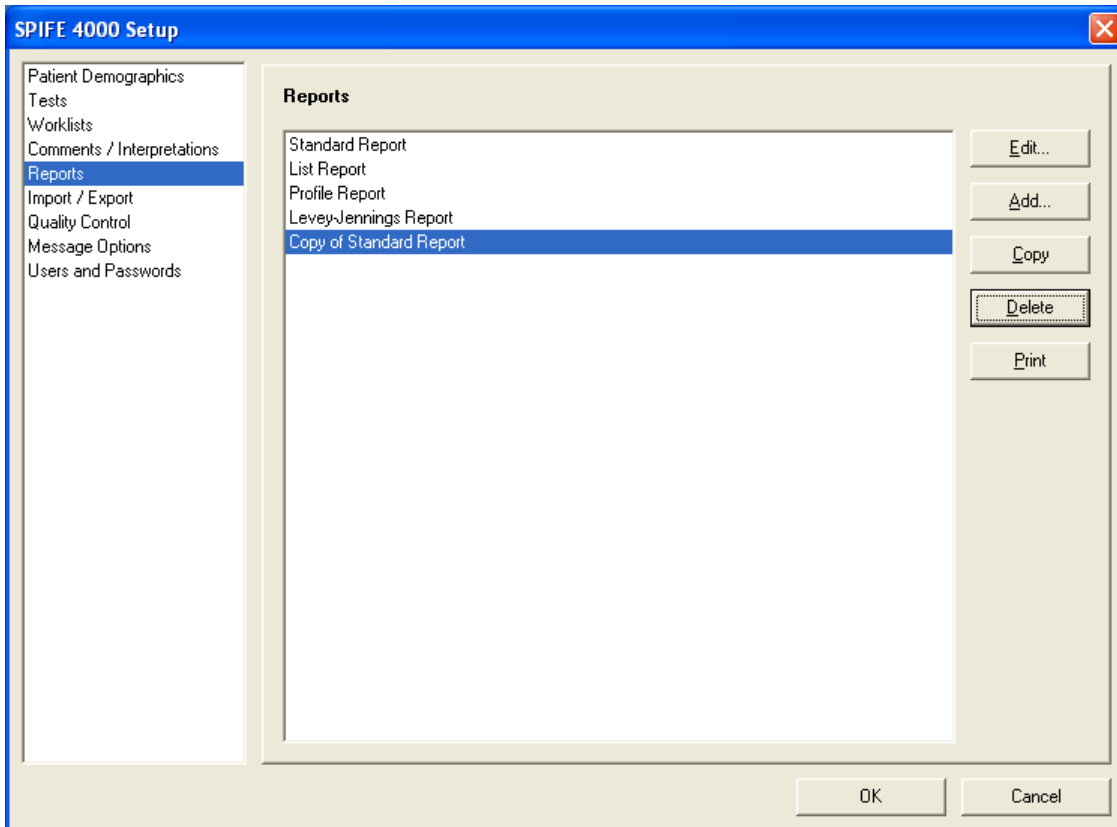
Figure 6-18 Add Report
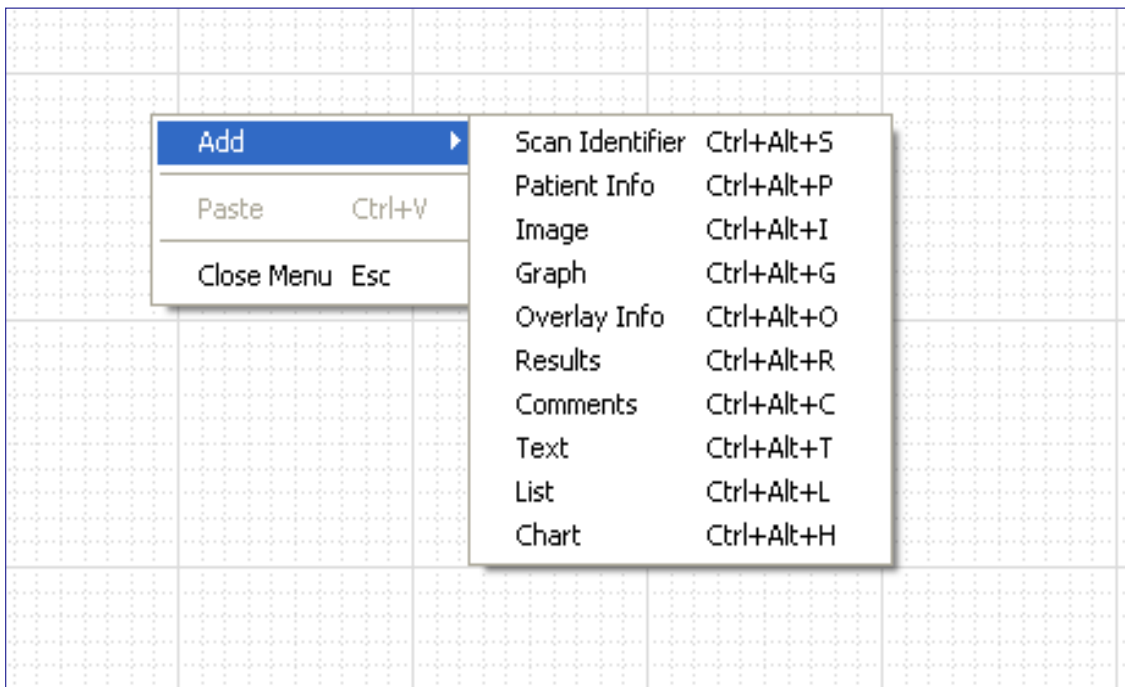
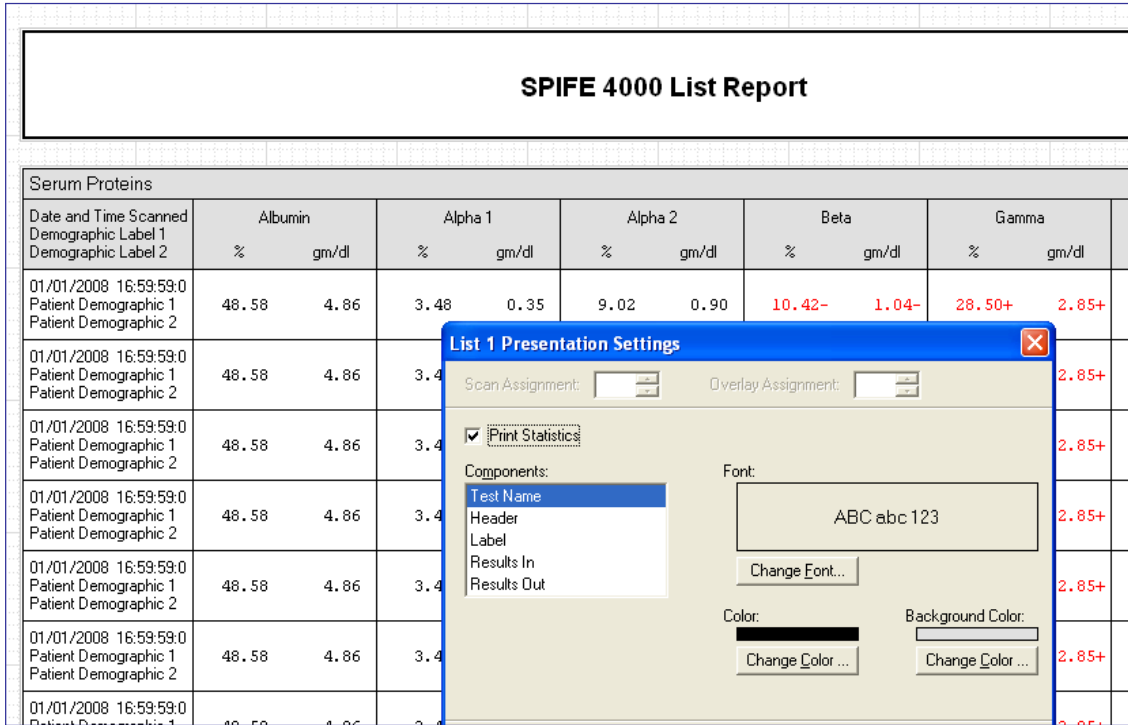**Figure 6-19 Setup Report, Add Components**

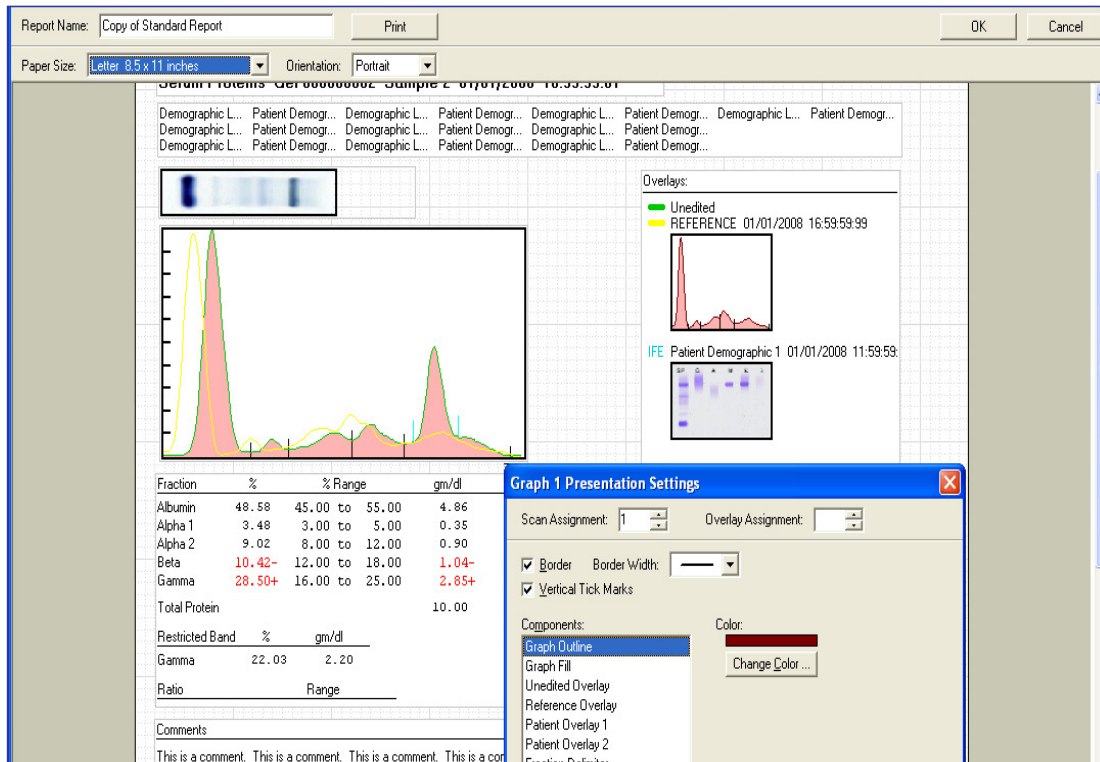**Figure 6-20 Setup Report, List Report, Settings**
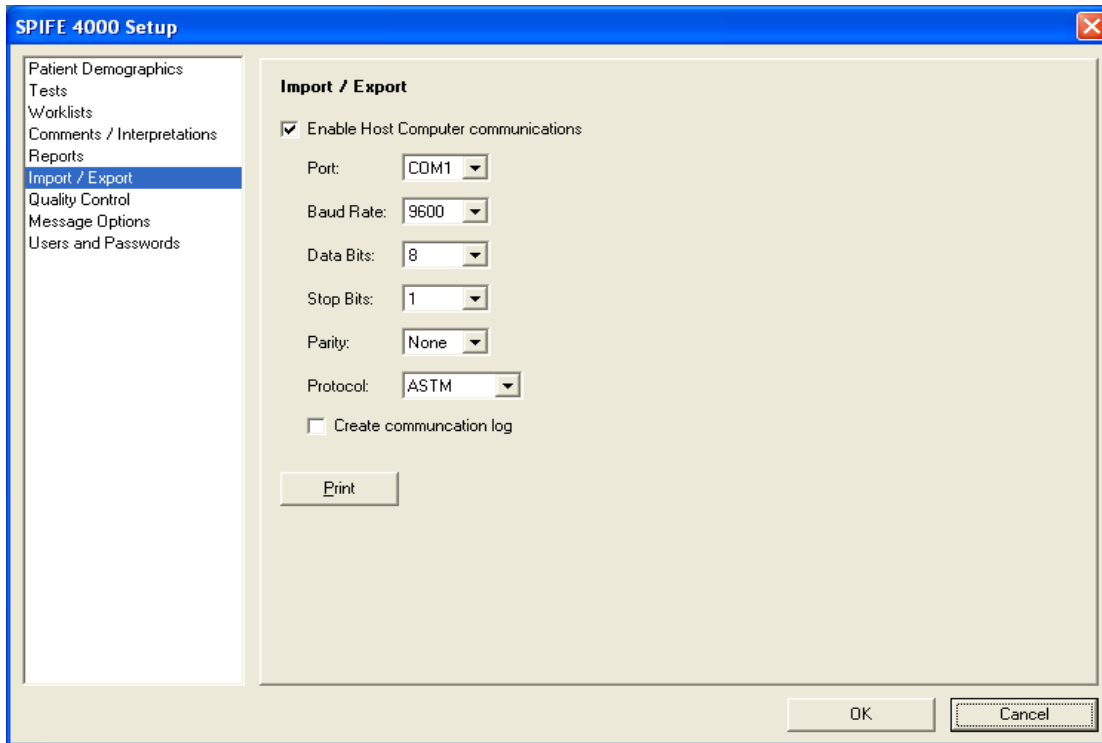

Figure 6-21 Setup Report, Settings

Figure 6-22 User Setup Import/ Export
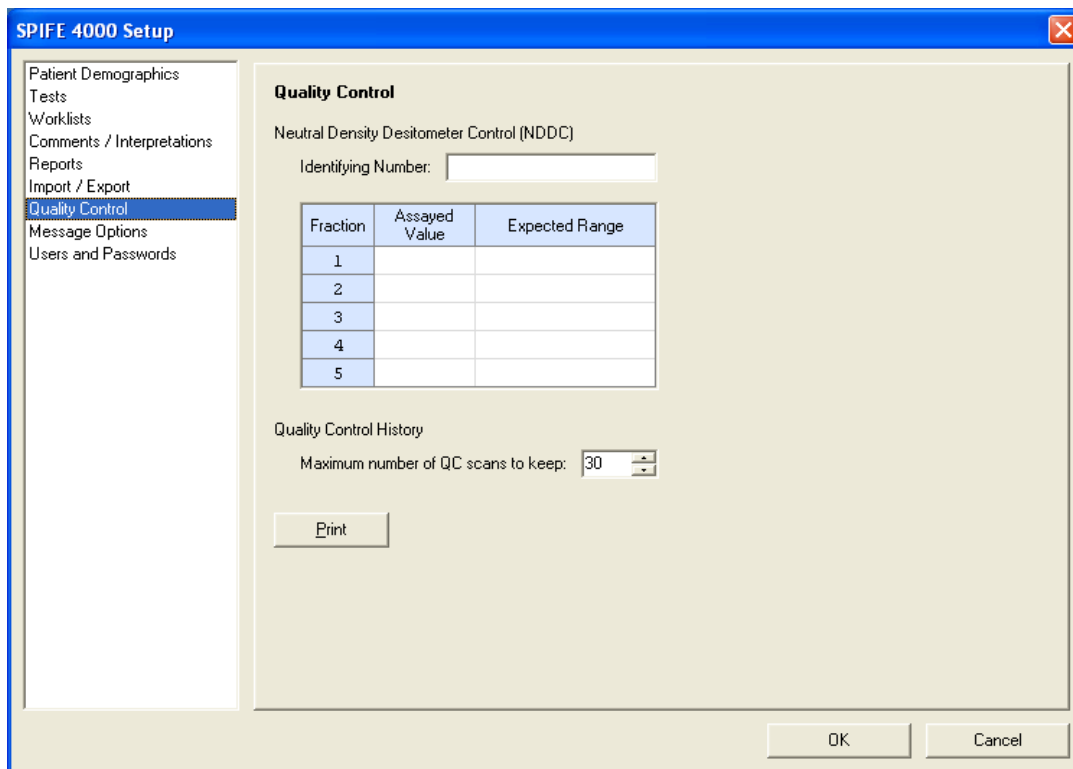

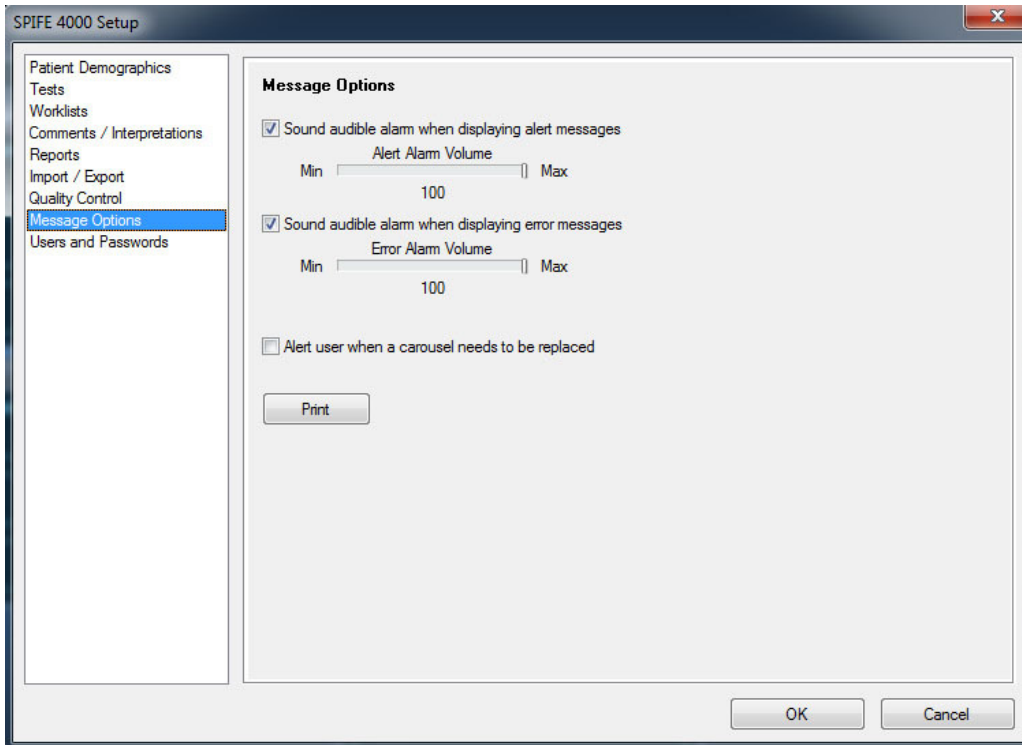**Figure 6-23 User Setup, Quality Control**

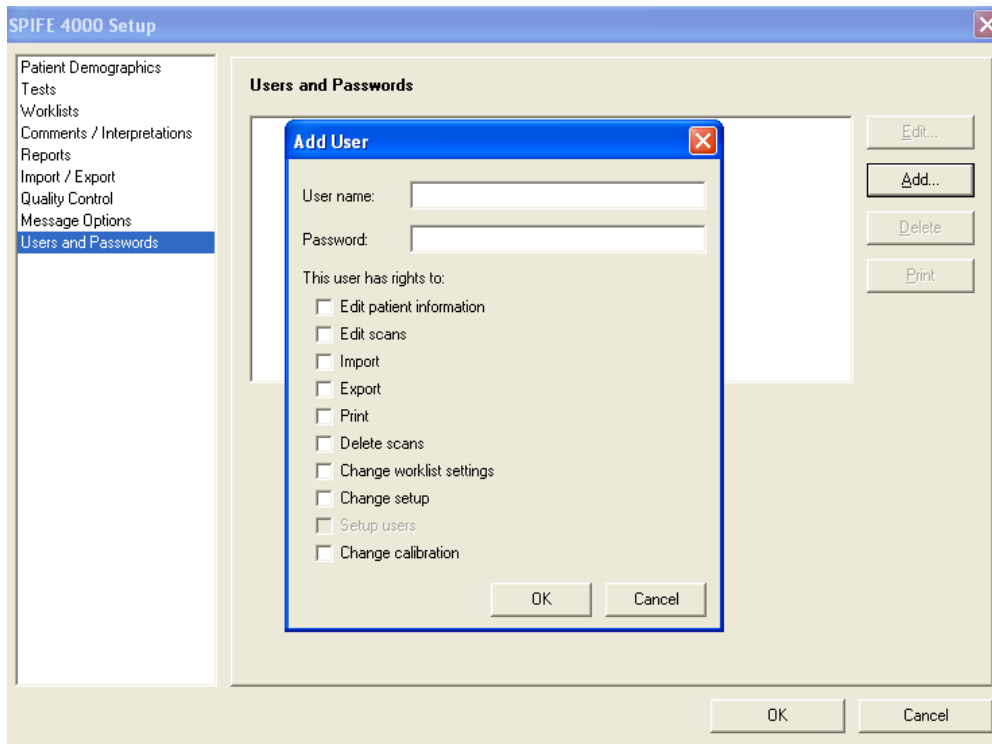**Figure 6-24 Users and Passwords, Message Options**

Figure 6-25 Users and Passwords, Add User

Section 7 - Operating Instructions

CAUTION: Do not attempt to operate this instrument until you have read and understood this manual. This includes Section 4 which incorporates safe biohazard practices.

If the system has not been setup, go through Section 6 before proceeding. Proceeding without completing test and instrument setup may result in difficulty completing the instructions contained in this section. This section is a general overview of how to process samples, and may vary from test to test depending on its respective programmed parameters.

If the system is turned off, turn the power on for the instrument and computer. The power switch for the instrument is located on the back of the left-hand bottom side (when facing the instrument). The Microsoft® Windows® program will open and displays the SPIFE 4000 icon. Select the icon.

Take care to select the icon only once. Opening multiple copies may corrupt files.

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).

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 4000 software, and then shut down the computer.

If the instrument is in continuous use, exit the SPIFE 4000 software and reboot the computer on a daily basis.

7.1. Preparation

7.1.1. Instrument Preparation

1. Stack the appropriate number of disposable sample trays (one per gel) into the Sample Tray Holder. The trays are keyed to only slide into the holder in the correct fashion.

Note: If running more than one type of test, ensure the proper number of each type of tray (one per gel) has been added. The first tray in the sequence will start from the bottom of the stack.

2. The system will detect incorrect tray types and alert the user with an error message. The Sample Tray Holder will hold up to 10 trays at a time, and may be replenished without interrupting the run.

3. Remove the Applicator Tray from the instrument. Place the appropriate number of Applicator Blades needed into the tray starting from the back (farthest from the handle) and adding forward with the Mylar facing the front of the instrument.

Note: If additional tests are added to a run after sample application has been completed for the last gel in the run, applicator blades will need to be added in the empty starting slots prior to adding the new test or an error message will occur.

4. The second set of blades should begin at the white notch in the middle of the tray and, again, be added forward. Take care to insert the correct blade, as the system cannot detect which type of blade is inserted. Use of the incorrect blade may result in no sample application. If the incorrect blade is used, no sample will be applied. Replace the applicator tray when finished. If running more than one type of test, ensure the proper number of each type of applicator blade has been added in the proper sequence. The applicator blade tray can hold up to 20 blades for pro-

cessing 10 gels at a time, and may be replenished during a run when indicated by the instrument.

5. Fill the diluent bottle with 0.85% saline and place it into the designated well in the sample handler. Be sure to fully seat the diluent bottle, as the needle may be damaged by contact with the sides of the bottle.

6. Fill the deionized water, destain, and Tris-Buffered Saline bottles.

7. Add the appropriate stain to the stain bottle. The stain should be replaced after processing 10 gels to avoid contamination. If running more than one type of test, add both stains. Failure to replace stain after every 10 tests may result in compromised gel quality.

WARNING: Do not overfill the stain container. Overfilling the stain container can cause high pressure leakage during recirculation.

WARNING: NEVER REPLACE STAIN DURING INSTRUMENT OPERATION.

8. If the stain, 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**.

9. If a run is stopped to replace any disposables (gels, blades, blotter, fluids, etc.) a message will be displayed on each subsequent scan indicating a delay in the processing occurred. The message will be either "< 1 minute", "> 1 minute" or "> 5 minutes" depending upon the length of the delay. If gels are paused long enough (> 5 minutes) in steps where the results may be affected, then the machine will either truncate or abort the run, in order to avoid producing compromised results. Having

additional supplies and fluids on hand is recommended.

10. Empty waste container after every 10 gels. When the waste container is full, the instrument will pause all operations and display an error message. The waste container must be emptied within 5 minutes or the run will be truncated.

WARNING: When changing the waste container during operation, open the gel processor door as a precaution to avoid possible waste spillage.

11. Place the Protein Fixative and antisera vials into the appropriately labeled wells of the Antisera Tray. Fill the largest well with deionized water. Place the lid on the tray and insert one pipette tip into each hole in the lid. **Antisera pipette tips should be changed with each new antisera vial**. Carefully place the antisera station into the instrument.

12. Add the appropriate number of flat blotters and comb blotters to their bins.

13. Fill the D.I. water (surfactant) jar with deionized water.

14. Add the gel loaded cassettes to the humidor and place the sealing cover on the top (refer to procedure included with gels on preparation techniques before adding gels to the instrument). Close the humidor lid to prevent desiccation. If running more than one type of test, ensure the proper number of each type of gel has been added with the gel needed first on the bottom of the stack. The humidor holds up to 10 gels at once. A Serum Protein gel, and a Urine Protein gel can each accommodate 28 specimens; an IFE gel can accommodate 4 specimens with 6 lanes each.

Note: The system cannot differentiate between the gel types and the incorrect gel will yield incorrect results.

Note: *When the user has more than four plates in a run, the user will have to replace the carousels during gel application to prevent a delay that could compromise the results*.

15. The sample handler will alert the user as each carousel rotates into a position where it may be removed. At that time the user may:

- Remove and replace the carousel and hit OK at which point, the instrument recognizes the carousel has been switched and will sample from that carousel without throwing an error.
- Select OK without replacing the carousel. The sample handler will assume the carousel has been replaced. **If the user selects OK, which will override the error message, and the user fails to replace the carousel, misidentification of samples could occur**.
- If the carousel isn't replaced and OK is not hit, when the position returns to be sampled an error will appear alerting the user the samples have already been run. The user then has the option to replace the carousel and select Retry, Finish or Stop.

Note: *The user must address and correct any errors before responding to the message to avoid potential misidentification or gel compromise.*

16. Load patient test tubes into the carousel counter-clockwise at the space numbered 1. Position the test tubes in the carousel so the entire bar code label is visible in the vertical slot. Failure to load correctly can result in the bar code not being read. Each carousel holds up to 28 samples.

17. Low Sample volume:

a. The user may program the test for a smaller number of samples, and then pipette by hand the "missing" samples at the end of the plate. For example, if there are 4 samples of low volume, the use may program in a test of 24 samples, and then pipette in sample number 25-28 by hand. The patient information would then be typed into the instrument after the run.

b. 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.

18. Place the loaded carousel(s) onto the turntable. If the turntable needs to be rotated to load more carousels, select *Run* and *Rotate turntable*. This will rotate the turntable ninety degrees. It can also be accomplished by using the *Rotate* shortcut key on the menu bar (the turntable icon). The first carousel of samples should be placed in the home position. (The home position is immediately prior to the sampler position, which is accessible in the front of the instrument.)

7.1.2. Instrument Operation

1. Refer to Section 6 of the Operator's Manual for detailed instructions on setup.

2. The main menu (Figure 7-1), will be displayed. The instrument status can be added or removed from the background by selecting *View* and *Instrument status*.

NOTE: 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.

3. Prime the sample handler by selecting *Maintenance*, then *Prime*, then *Sample Delivery system* (Figure 7-4). While priming, be sure to visually confirm water flow surrounding the needle. The sample delivery system should be primed after each run to minimize contamination

Note: Ensure that there are no air bubbles in the tubing lines. Also, ensure that there are no excessive air bubbles within the water flow surrounding the needle when priming the sample delivery system.

4. Prime the surfactant delivery system by placing a maintenance blotter (Cat. 2307) loaded cassette into the humidor. Then, select *Maintenance*, then *Prime*, then *Surfactant delivery system*. Once the cassette stalls on the third platen (Pre-dry station), the user will be prompted to remove the cassette from the instrument. After doing so, check the maintenance blotter for evenly applied moisture. If no moisture is present, or is not evenly applied, check the D.I. water (surfactant) jar for fluid. Troubleshooting may be necessary if the instrument will not prime properly after adding fluid.

Note: Ensure that there are no air bubbles in the tubing lines when priming the surfactant delivery system.

Note: Tubes within D.I. water (surfactant) jar must be submerged in fluid to properly prime.

5. To add the desired test(s) from the menu bar select *Run* then *Start* or click the *Start* shortcut button (the eleventh icon) on the menu bar. The *Start Run* window appears.

Note: When the user has more than four plates in a run, the user will have to replace

the carousels during gel application to prevent a delay that could compromise the results.

6. The sample handler will alert the user as each carousel rotates into a position where it may be removed. At that time the user may:

- Remove and replace the carousel and hit OK at which point**,** the instrument recognizes the carousel has been switched and will sample from that carousel without throwing an error.
- Select OK without replacing the carousel. The sample handler will assume the carousel has been replaced**. If the user selects OK, which will override the error message, and the user fails to replace the carousel, misidentification of samples could occur**.
- If the carousel isn't replaced and OK is not hit, when the position returns to be sampled an error will appear alerting the user the samples have already been run. The user then has the option to replace the carousel and select Retry, Finish or Stop.

Note: The user must address and correct any errors before responding to the message to avoid potential misidentification or gel compromise.

7. The user must address and correct any error before responding to the message to avoid potential misidentification or gel compromise.

8. Select the first test by selecting *Add Test*. The *Add Test* window appears with a drop down menu of all existing tests. After selecting the test, choose either *Enter the total number of samples to be run* or *the*

total number of gels to be run and enter the number.

Note: If a test is added after a previous run is in process and there is still a gel in the humidor, then the blades may be added in front of the existing blades.

If the last gel has dropped from the humidor, then the sample handler's memory has cleared and new blades must be placed into the applicator blade holder starting at the back.

9. Run options can be altered by selecting the *Options* button. The *Run Options* window appears with the name of the test in the top bar (Figure 7-2).

    a. *Processes* – check or uncheck to alter the gel preparation steps.

        i. *Sample Preparation*

        ii. *Sample Application*

        iii. *Electrophoresis*

        iv. *Fixative Application*

        v. *Pre-Dry*

        vi. *Wash*

        vii. *Stain*

        viii. *Destain*

        ix. *Dry*

        x. *Scan*

    b. *Dilutions* - using the drop down menu or the *Edit Dilution* button, dilutions can be altered. The preprogrammed list includes 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, and 1 in 14 (Figure 7-3).

    c. Clicking Cancel exits without saving changes made.

Preparation Notes

Preparing a	1 part Sample
1 in 4 dilution	+ 3 parts Diluent
	= 4 Parts total
Serum Proteins	up to 28 samples can be accommodated on the gel
IFE	up to 4 samples can be accommodated on the gel with up to 6 specificities

10. After the test or tests to be run have been selected, press *Continue to* start the run or *Cancel* to abort the run. If the run needs to be terminated, the *Stop* button can be clicked and all processes will stop. As a safety feature, if the *Stop* button is clicked at any time, the run will stop immediately without asking for confirmation. Any cassettes in transit will need to be removed manually. This can also be accomplished by selecting *Run* and then *Stop*.

11. If the run needs to be ended, but not immediately, select *Run* and then *Finish*. All cassettes that are in process will be finished.

12. The instrument will load and apply samples, electrophorese, immunofix, wash, stain, destain, dry and scan the gels. The computer screen displays the progress of the cassettes through the various stations.

13. After the gels have been scanned, they will be dropped into the cassette receptacle.

14. Remove the cassettes from the Cassette Pick-Up Assembly. If storing the gels, remove and discard the two gel blocks. If not, discard the used gels. Discard blotters, applicator blades, sample trays, and blotter combs as biohazard waste.

15. Cassettes should be washed and dried after each use with deionized water. The Antisera template should be washed

after a day's run or every 20 plates. Anti-sera pipettes should be changed with each new Antisera vial.

7.2. Results

Warning: Do not cut, delete, or reorder the sequence of scans from any work-list. Do not rescan a plate with a different scan sequence. Removing scans from a worklist or reordering the sequence could potentially cause problems with archiving scans, or with the application of patient overlays. To avoid exporting undesirable scans, export scans individually from that worklist.

When running an *Alkaline Hemoglobin* gel, after the instrument scans the gel, the *Adjust Scan Location* window opens and waits for the user to set the scan lines.

For each gel there is a green scan begin line, a red scan end line, a blue line to indicate the first sample position on the row, and a purple line to indicate the last sample position on the row.

Use the mouse to move the green line to the front of the pattern to set the scan begin and the red line to the other end of the pattern to set the scan end. These lines should never overlap.

Place the blue line on the center of the sample located on the left of the win-dow (the   first   sample lane, even if a sample wasn't run in it) and place the purple line on the center of the sample located on the right of the window (the first sample lane, even if a sample wasn't run in it). This operation defines the dis-tance from one sample to the next. The purple line must be centered in the last sample position regardless of the number of samples in the row.

7.2.1. Saving and Exporting Scan(s)

1. All results are automatically saved to the predetermined location.

2. To export to another location, from the Main Menu (Figure 7-1), either select the *Open Worklist* shortcut button (the first icon) on the menu bar or select *File*, then *Open*. The *Open Worklist* dialog box appears (Figure 7-6).

3. Select a currently open worklist, or use the various search boxes. The search can be modified by using the following parame-ters:

    a. *Look in*

    b. *Label*

    c. *Test*

    d. *Gel Identifier*

    e. *Date*

4. After selecting the desired worklist, select *Open*. The worklist opens display-ing all the scans. To export the scans, click the *Export Worklist* shortcut button (the fourth icon) or select *File* then *Export*. The *Export Scans* dialog box appears.

5. Choose individual scans using the keyboard and/or mouse or click *Select All* to export all scans in the worklist.

6. Click *Export Settings*. The *Export Set-tings* dialog box appears allowing the user to choose their exporting destination and how the scans will be exported.

    a. *Destination*

       i. *Host Computer* – select to export to the current location.

       ii. *File* – select to export to a differ-ent file folder location.

    b. *File Destination* – this is only availa-ble when *File* is selected.

i. *Save in* – select specific file to export to.

ii. *File Name* – a different file name can be added.

iii. *Include Column headers* – check to include column header.

iv. *Delimiter* – choose from tab, space, comma, semicolon, or other. If using other, a specific symbol can be added in the space.

c. *Patient Information* – select one

i. *Don't Export*

ii. *Export Key Identifier Only*

iii. *Export all Patient Information*

d. *Image and Graph*

i. *Export Image*

ii. *Export Graph*

e. *Results* – select one or all

i. *Export Percent*

ii. *Export Units*

iii. *Export Integrals*

f. *Ranges* - select one or all

i. *Export Percent Range*

ii. *Export Units Range*

iii. *Export Ratio Range*

iv. *Flag Percent Out*

v. *Flag Units Out*

vi. *Flag Ratio Out*

g. *Comments*

i. *Export comments*

h. *OK* - Clicking *OK* saves all the changes made and exits. *OK* does not automatically export the scans; *Export* must be clicked separately on the next screen.

i. *Cancel* - Clicking *Cancel* exits without saving changes made.

7. After choosing the desired location for the files to be exported, click *Export* to export the files.

8. *Cancel* - Clicking *Cancel* exits without saving changes made.

7.2.2. Archiving Scans

1. Open or select the worklist (Section 7.2.1) containing the scans to be archived. From the main menu (Figure 7-1), select *File* and *Archive.* The *Archive Worklist* window will appear (Figure 7-8).

2. After selecting the desired worklist(s), choose the location where the files will be archived using the drop down menu in the *Save to* box. The user also has the option of deleting the files after archiving by checking the *Delete worklist after archiving* option.

3. Select *Archive* to save worklists or *Cancel* to cancel the action without archiving worklists.

7.2.3. Printing Scans

1. Open or select the worklist (section 7.2.1) containing the scans to be printed. From the main menu (Figure 7-1), either select *File* and *Print Scans* or select the *Print Scans* icon (the ninth icon).

2. The *Print Scans* window (Figure 7-9) displays listing all the scans within the worklist in use. The list of scans contains the test name, the sample number, the date and time scanned, the key demographic, and a colored square. The color of the square represents the following: Blue indicates the scan has the proper number of fractions and all the fractions are within range values. Red indicates the scan has not been reviewed. Yellow indicates the scan has been viewed in the edit mode; however, still does not have

the proper number of fractions and/or one or more fraction is out of range. This window also has the additional options of *Select All*, *Print Settings, Printer Setup, Print*, and *Cancel.*

7.2.3.1. Select Scans to Print

1. To select all of the scans listed, select *Select All.*

2. To select a specific scan listed, click on the desired scan to highlight it. To make additional selections, simultaneously press the **Ctrl** key on the keyboard and click on the desired scan. Repeat, as needed, to highlight all the desired scans.

7.2.3.2. Print Settings

From the *Print Scans* window, select *Print Settings* to alter the contents of the report from the currently setup parameters. From *Print Settings* window (Figure 7-10), as needed, customize the following print related settings:

7.2.3.2.1. Report

1. *Report* - from the drop down list, select one of the reports shown. The list consists of all the currently setup reports (section 6.5.1).

2. *Number of Copies* – select the number of copies needed.

7.2.3.2.2. Patient Information

Select either *Print Key Identifier Only* or Print *All Patient Information*.

7.2.3.2.3. Overlays

1. Select one or all of the below overlays to add to the printed report:

    a. *Overlay Unedited*

    b. *Overlay Reference*

    c. *Overlay Patient 1*

    d. *Overlay Patient 2*

    e. *Print Overlay Thumbnails*

7.2.3.2.4. Results

1. Select one or all of the below options to add to the printed report:

    a. *Print Percent*

    b. *Print Units*

    c. *Print Integral*

    d. *For IFE*:

        i. Print Units

7.2.3.2.5. Ranges

1. Select one or all of the below options to add to the printed report:

    a. *Print Percent Range*

    b. *Print Units Range*

    c. *Print Ratio Range*

    d. *Flag Percent Out*

    e. *Flag Units Out*

    f. *Flag Ratio Out*

    g. *For IFE*

        i. *Print Units Range*

        ii. *Flag Units Out*

7.2.3.2.6. Levey-Jennings

The settings for this may be found in section 6.5.1.1, Report Type (Figure 7-11).

2. Choose to *Plot Percent* or *Plot Units.*

7.2.3.2.7. Ok and Cancel

1. *Ok* - select to exit the window and save the selections made.

2. *Cancel* - select to exit the window without saving any selections.

Note: *OK* saves the print settings, but does not print the scan. *Print* must then be selected to print the scan.

7.2.3.3. Printer Setup

1. *Name* - from the drop down list select the appropriate printer.

2. Note that if the instrument is connected to a phone line, a report can be faxed by selecting *Fax* from the drop down list, if available, making the remaining selections on this window, then, once *Print* is selected on the *Print Scans* window, following the prompts.

3. Press *OK* to retain the *Printer Setup* properties or *Cancel* to discard the changes.

7.2.3.4. Print and Cancel

1. *Print* - with all the desired scans selected, select to print the highlighted scans. Caution: Due to memory limitations, do not initiate additional print jobs until the first print job is entirely complete.

2. *Cancel* - select to exit without printing.

7.2.4. Clearing Scan(s)

1. With a worklist open, to clear the worklist contents, from the main menu either select *File* then *Clear* or select the *Clear the Worklist* icon (the fifth icon).

2. The *Confirm Clear* box will appear to alert the user that the worklist is about to be cleared.

3. To return to the worklist without clearing the contents, select *No.*

4. To clear the contents and return to the empty worklist, select *Yes.*

7.2.5. Exit

To exit the SPIFE 4000 software, from the main menu (Figure 7-1) either select *File* and then *Exit* or select the **X** at the top

right of the main menu. Note that any worklists open when the software is exited will be open when the software is reopened.

7.3. Editing

7.3.1. Patient Info/Edit Patient Info

1. Open or select a scan worklist (Section 7.2.1). To enter patient demographic information, from the main menu either select *Edit* then *Patient Info,* or select the *Edit Patient Info* icon (the sixth icon). If manually entering patient information for a gel that has not yet been run, before the Patient Information window will be displayed, a prompt will appear. The user must select the test and specify the gel assignment number. The gel assignment number will determine which gel in the next run the worklist will be assigned to. The gel will be assigned only if there is a test entered for in that position that matches the test specified in the worklist. To change a gel assignment, right click on the patient information screen and select the top menu item *Change Gel Assignment.* Duplicate gel assignments cannot be created.

2. The *Patient Information* window (Figure 7-12) displays. The window contains a table for entering patient demographic information.

3. The titles of each column in the table are the demographic labels assigned in setup (Section 6.1). These include any test specific demographics (Section 6.2.4) applicable to the test attributed to the worklist in use. The first column is always the demographic designated as the Key identifier.

   a. The column width may be adjusted. Place the cursor on the line separating the column to be adjusted and the next column. Click and hold the left button on the

mouse while moving the mouse left or right as needed to resize the column. When the desired width is reached, release the button. Use caution not to resize a column so narrowly that it is not visible or appears to be removed.

4. The titles of each row in the table are *1* through the total number of samples the test attributed to the worklist in use specifies (for example, 1-28 in a default serum proteins test.)

5. Most often, the first sample is used as the Reference sample. Confirm the cursor is in the row one, column one field, and right click to select *Reference* (Section 7.3.1.1). *Reference* will appear in the location indicated by the cursor. When designated as the reference, the control can then be used for forced fractions or as a reference overlay. Samples scanned following the reference may be displayed and/or printed with the reference overlay. One may use any sample as a reference overlay, by adding the term "Reference" to the Key Identifier demographic. More than one sample may be labeled as "Reference." Each scan will use the nearest previous scan labeled "Reference" for its reference overlay. For example, if sample 1 and 6 are labeled "Reference", then sample 2 will apply an overlay from 1, sample 5 from 1, sample 7 from 6. The sample may also be labeled by manually typing in the word "Reference." The sample may be labeled Reference either before or after the run.

6. With row *1* most likely the Reference, enter patient information beginning in the first field of row *2.* Each cell of information may contain up to 20 characters, more may be entered however only the first 20 characters will be used. Enter the patient information in the row that corresponds to the patient sample on the gel and in the column that corresponds with the demographic label assigned to the column.

Patient information can also be entered by scanning the barcode for the patient sample.

7. To move through a row entering information, either use the mouse, or press **Tab** after each entry and **Enter** at the end of the row. The **arrow** keys move the cursor up, down, left and right within the patient information window. For large moves, use the mouse and/or the **Page Up** and **Page Down** keys. Errors can be typed over to correct them. Repeat until all patient information is entered.

8. Before entering patient information into a worklist already containing patient information and/or scans, the worklist or patient information should be cleared (Section 7.2.4).

7.3.1.1. Patient Identification

1. Place the cursor in the next cell to be changed. The information can be typed in or by right clicking the mouse; the user can use the following options.

2. *Demographics*

a. *Find* – select to search by identifier. This can be narrowed by checking the *Match by whole words* and/or *Match case* options.

b. *Find Again* – after using the *Find* option, this can be selected to identify the identifier in the entire sample list.

c. *Cut* – select to have the sample information in the cell removed and made available for placement in another cell.

d. *Copy* - have the sample information in the cell made available for duplication in another cell.

e. *Paste*- select to have the sample information that has been cut or copied entered into the new cell.

f. *Delete* - select to have the sample information in the cell deleted.

g. *Select* – select to highlight all text in the indicated cell.

h. *Paste to the following patients*- select to have the indicated demographic entered into all the fields under the indicated field.

i. *Increment and paste to the following patients* - select to have the indicated numeric demographic entered into all the fields under the indicated field increased by one in each field. For example if the indicated field contains the number 123, the next would be 124, then 125, and so on.

j. *Reference* – select to designate a sample as a *Reference* sample.

k. *Normal Control* - select to designate the *Normal* control.

l. *Abnormal Control*- select to designate the *Abnormal* control.

m. *Today's Date* - select to enter today's date in the indicated field.

n. *Yesterday's Date* - select to enter yesterday's date in the indicated field.

3. *Patient*

a. *Cut* - select to have the sample information in the cell removed and made available for placement in another cell.

b. *Copy* - have the sample information in the cell made available for duplication in another cell.

c. *Paste* – select to have the sample information that has been cut or copied entered into the new cell.

d. *Delete* – select to have one patient deleted.

e. *Import* – select to import one patient's information.

4. *All Patients*

a. *Import* – select to import the entire worklist.

b. *Print* – select to have the worklist printed.

c. *Delete* - select to have all patient information deleted.

5. *Undo and Close* – select *Undo* to undo the last change or *Close* to close the Patient Identification box.

7.3.1.2. Editing Scans

1. Open or select a scan worklist (Section 7.2.1). The display settings may be changed to alter the appearance of the display by clicking on the *Display Settings* icon (the seventh icon).

2. The window includes the scan and any demographics, fractions, and comments associated with the scan. To move between the scans in the worklist, use the arrow keys located on the keyboard or the mouse (Figure 7-13) or click on the scan thumbnail.

3. The cursor on the scan is represented as a white cross hair and is controlled with the mouse. To move the cursor, place the white arrow on the cross hair, press and hold the button on the left side of the mouse. Move the mouse, which moves the arrow and cross hair, to the desired location and release the button on the mouse.

4. Right click on the image of the scan to access the editing menu (Figure 7-14). The following options appear:

i. *Undo*

ii. *Delimit Bands*

iii. *Delete Area*

iv. *Baseline Correction*

v. *Comments*

vi. *Appearance*

vii. *Auto Edit*

viii. *Auto Interpretation*

ix. *Restore*

5. Once an edit function is performed, the last function can be undone by right clicking on the scan and selecting *Undo*. To undo all actions, right click and select *Restore*. See Section 7.3.1.11 for additional information.

6. Once all the editing is complete on the scan, select another scan to edit or select the **X** at the top right of the window to exit and return to the main menu.

7. The following section details the options provided to edit the scans by right clicking the mouse.

7.3.1.3. Delimit Bands

1. *Delimit Bands* provides access to *Fractions* and *Restricted Bands*.

2. *Fractions*

    a. *Insert Fraction* - Although the SPIFE 4000 program will automatically place fraction marks where the software detects a change in the slope of the scan, the user MUST review and edit every scan. Delimit scans is only available when the total number of fractions is less than ten. To indicate a fraction, place the cursor on the appropriate location on the scan and select the Insert icon (icon with the plus sign), or right click then mouse-highlight Delimit Bands and select Insert Fraction. The user may also use the hot-key Ctrl+Ins. A fraction delimiter appears on the graph at that point and the fraction data is automatically recalculated and causes a change in values.

    b. *Delete Fraction* - Delete is only available when at least one fraction is present. To delete a fraction mark, place the cursor near the fraction mark to be removed and select the delete icon (icon with the negative sign), or right click the mouse select Delimit Bands- Delete Fraction. The user may also use the hot-key: Ctrl+Del. The closest fraction mark is deleted and the fraction data is automatically recalculated when editing causes a change in values.

3. *Restricted Bands* - is only available when testing proteins.
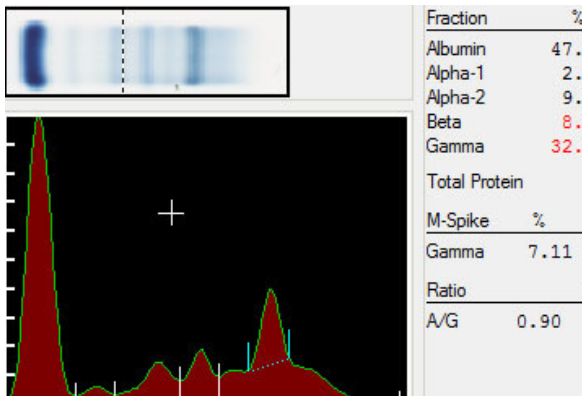
    a. *Mark Restricted Bands*

        i. The Restricted bands features - are only available when the name of the test in use contains "Proteins" or "SPE". There are now two marking methods available in the SPIFE 4000 software, Sliced, and Skimmed. Up to three restricted bands in total may be marked. Traditionally, restricted bands/ M-proteins have been marked using the "Sliced" method, as seen below.

        ii. The Sliced marking method will include in the measurement all protein between the two marks, from the peak of the scan to the baseline, which most likely includes some element of normal baseline protein. To indicate a band, touch the screen or place the cursor on the appropriate location on the scan and select Mark sliced restricted band icon. The user may also right click the mouse, select Delimit Bands- Mark Sliced Restricted Band, or use the hot-keys: Ctrl+M for Sliced.
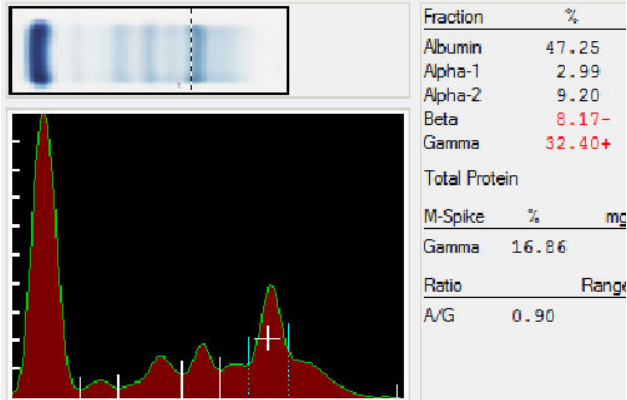
b. *Mark Skimmed Restricted Band* **-** The Skimmed method includes only the portion of the marked protein that is above what is estimated to be above the predicted normal tracing of the scan. Thus any protein would appear to have been obscured by a normal background in not included in the total M-protein measurement. To indicate a band, touch the screen or place the cursor on the appropriate location on the scan and select

Mark skimmed restricted band icon User may also right click the mouse, select Delimit Bands- Mark Skimmed Restricted Band, or use the hot-keys: Ctrl+Alt+M for skimmed.

c. *Unmark* - Touch the screen or place the cursor between the band marks needing deletion and select *Unmark* .

d. *Auto Locate Restricted Band Delimiters* - By default, the SPIFE 4000 software will mark a restricted band correctly using

the sliced or skimmed method, based on the point on the scan tracing where the spike begins to deviate from the predicted baseline curve. The Auto Locate Restricted Band Delimiter feature is enabled by default in Test Setup, and may be disabled in Test Setup. The operator also has the option to disable or enable the Auto Locate Restricted Band Delimiter feature at the level of an individual scan. Right click on the scan, select Delimit Fractions, and then place a check next to Auto Locate Restricted Band Delimiter to enable the feature, or remove the check to disable the feature and mark manually. Once the selection is made, the option will remain enabled or disabled for that worklist until the operator alters it for another scan. The operator may enable or disable the feature as many times as desired on any given worklist.

e. *Reposition Delimiter* - To adjust the position of a delimiter, touch or click on the 17th icon then touch or use the cursor to click and drag one of the delimiters to the desired location.

i. With very small bands, the automatic marking feature may not be able to recognize the band.

Note: *It is extremely important the total M–protein measurement method is CONSISTENT over time. EVERY OPERATOR MUST MARK RESTRICTED BANDS USING THE SAME TECHNIQUE, AND EVERY PATIENT'S RESULTS MUST BE REPORTED USING THE SAME TECHNIQUE IN WHICH THEY WERE PREVIOUSLY REPORTED. Treatment of many conditions is based on the change in M-protein, thus any change in measurement technique may produce what appears to be an artificial change, and has to potential to affect treatment. It is HIGHLY RECOMMENDED to discuss*

changes in marking methods with pathologists and treating clinicians.

Note: **When marking restricted bands (i.e. monoclonal gammopathies), the user should mark the scan from left to right.**

f. *Unmark Restricted Bands* – is only available if at least one restricted band has been identified. Place the cursor between the band marks needing deletion, right click and select *Delimit Bands*, then *Unmark Restricted Bands.*

7.3.1.4. Delete Area

1. *Delete Area* - allows for removing areas of the scan.

2. *Mark* - Place the cursor (Section 7.3.1.2) on one side of the area needing deletion. Right click and select *Delete Area*, then *Mark*.

3. *Unmark -* Once *Mark* is used, *Unmark* is accessible. Select if the location marked is incorrect.

4. *Apply -* Once *Mark* is used, *Apply* becomes accessible. Place the cursor on the other side of the area needing deletion and then right click, selecting *Delete Area*, then *Apply*. The area between and above the marks is deleted.

5. Repeat as needed.

7.3.1.5. Baseline Correction

1. *Baseline Correction* is used if the baseline needs to be moved or if the pattern has a non-linear baseline due to irregularities in background intensity.

2. *Mark* - Place the cursor (Section 7.3.1.2) on the desired location of the new baseline. Right click and select *Baseline Correction*, then *Mark.* A straight, horizontal line is then placed at the specified location indicating the new baseline.

3. *Unmark -* Once *Mark* is used, *Unmark* becomes available. Select *Unmark* to remove the line indicating the new baseline.

4. To create a non-linear baseline, place the cursor on another location and again select *Mark*. The line indicating the new baseline is drawn between the marked locations. Repeat until the baseline is indicated as desired. Non-linear baseline correction is not recommended for clinical use.

5. *Apply* - With the baseline marked as desired, right click and select *Baseline Correction*, then *Apply.* The pattern is readjusted so the baseline is a straight line and the numeric data reflects the change.

7.3.1.6. Comments

1. *Comments* – allows for new comments to be added to the scan using the keyboard or existing comments to be edited. Saved comments previously set up in Section 6.4 can also be added using *Available comments* (Figure 7-15).

2. To add an *Available Comment*, right click and select *Comments*, then *Open*. This window lists all the currently setup comments under *Available Comments.* The highlighted comment's contents are shown to the right of the list.

3. To select a comment, highlight the desired comment and choose *Select.* Repeat as needed to include all comments. When finished, choose *Open* then *OK.*

4. A comment may also be typed in manually to the space provided.

7.3.1.7. Overlays

Overlays (Figure 7-16) allows for overlaying *Unedited*, *Reference* and/or *Patient* scans.

7.3.1.7.1. Unedited

1. *Unedited* - Once an editing function, which alters the pattern's appearance, is performed, *Unedited* is available. Select *Unedited* and the original, unedited scan, appearing in green, is shown over the edited scan, appearing in red.

7.3.1.7.2. Reference

1. *Reference* - Select *Reference* to overlay a previously scanned reference pattern on the scan. This makes a comparison of the patient to a reference very easy. If selected, a sample will need to be labeled *Reference* for each gel scanned, see Section 7.3.1. The *Reference* appears in yellow over the sample, which is in red.

7.3.1.7.3. Patient

1. *Patient 1 or 2* - Select *Patient* 1 and/or *Patient* 2 to overlay a saved patient pattern. The pattern can be from the same patient or a different patient. *Patient 1* appears in pink while *Patient 2* appears in blue.

2. Patient overlays may be selected automatically or manually.

   a. To automatically apply a patient overlay, click on the *Auto Select* button. Designate a date range between 1 and 365 days and select a test. If that patient has had a scan meeting the specified criteria, then the scan will be overlaid.

   b. To manually apply a patient overlay, open the worklist that contains the scan to be overlaid. Scroll over the thumbnail image of the desired scan and right click on the scan. Copy the scan. Return to the scan being edited and scroll over the

thumbnail image. A menu will appear with an option to *Paste*, and then to *Paste to Worklist*, *Paste to Overlay 1*, and *Paste to Overlay 2.* Select the appropriate overlay. The overlay may be of the same patient or a different patient.

3. Using the same procedure, IFE images may be applied as overlays and will appear as thumbnail images.

4. After adding all the desired overlays, click *OK*.

5. Auto Overlay: To update the overlays for a scan (for instance, if the if the overlay criteria are "Most Recent," and there have been gels scanned subsequent to the open worklist, Auto Overlay will display the later scan.)

7.3.1.8. Appearance

1. *Appearance* allows access to options that alter the appearance of the scans without altering the results.

2. *Auto Scale* - is only accessible when the pattern has been scanned in manual gain. When Auto Scale is selected, the pattern is adjusted to full scale as if it had been scanned in auto gain.

3. *Smooth* - select and the *Smooth* window will display. Select the desired *Smooth* setting of *1* through *10.* Select *Ok* and the *Edit Scan(s)* window will display with the scan smoothed as indicated. Select *Cancel* to exit without smoothing. Note that smoothing, in most cases, is not recommended. Smoothing may affect results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing could affect small monoclonals.

4. *Zoom* - use the slide bar to enlarge or reduce the pattern from *1x* to *10x*, in increments of 0.1. The final magnification is shown in red in the right bottom corner of the pattern.

5. *Image Contrast* - the default setting is selected during *Test* setup (Section 6.2.2) and can be altered, using the slide bar, to adjust from *Lighter* to *Darker*. The setting affects only the displayed image of the scan and does not affect the results.

7.3.1.9. Auto Edit

This feature will be available for future tests.

7.3.1.10. Auto Interpretation

1. *Auto Interpretation* - select to enable auto interpretation of scan results based on user-defined interpretations (Section 6.4).

2. *Pattern Characteristics* – is only available if *Auto Interpretation* is enabled. Select and the *Pattern Characteristic* window displays. The window contains *None* and the pattern characteristics setup for the test in use. Only pattern characteristic which fit the auto interpretation criteria set up in test setup may be applied (Section 6.4).

    a. Select the desired pattern characteristic and select *OK.*

    b. To exit without making a selection, select *Cancel.*

    c. If there is a comment with the same Auto Interpretation criteria as the Pattern Characteristic, and the Pattern Characteristic is applied, only the comment associated with the Pattern Characteristic will be automatically displayed.

7.3.1.11. Restore and Undo

1. *Restore* - select to return the pattern to its appearance prior to all editing. Editing may then need to be repeated. Restore may not be accessible if the user is currently in the process of marking a band; the mark must be applied or removed before Restore may be selected.

2. *Undo* - select to return the pattern to its appearance prior to the last editing function performed.

7.3.2. Editing IFE Scans

For IFE scans, the *Scan* window (Figure 7-17) contains an indicator bar over the scan to aid in viewing. To move the indicated bar up or down, use the mouse to place the white arrow on the indicator bar. Press and hold the button on the left side of the mouse. Move the mouse, which moves the indicator bar, to the desired location, and then release the button. Right click the mouse to see the following options (Figure 7-18).

7.3.2.1. Image Contrast

1. *Image Contrast* - allows the setting defined in setup to be altered. Appearance affects only the displayed image of the scan and does not affect the results.

    a. Using the slide bar, set from *Lighter* to *Darker*, as needed.

    b. To reset to the setup settings, select *Reset.*

    c. Negative Image: To view the image in negative contrast, select the negative contrast icon at the top of the screen, or right click on the scan, and select Negative Image.

7.3.2.2. Immunoglobulin Totals

1. The window contains labels and the units of measure (for up to ten totals), all selected during test setup (Section 6.2.3). If total protein has not been added as a demographic or as a test specific demographic, then an entry space for total protein will also appear here.

    a. Enter the totals, as needed, using the keyboard. Each total may be from 0.0 to 999999.0 total protein Immunoglobulin concentrations.

b. To remove all the displayed totals, select *Clear* and *Yes* in response to the prompt.

c. Once the totals are added as needed, select *Ok.*

d. To exit without entering or altering the totals, select *Cancel.* If any alterations were made, an *Alert* prompt will display. To exit without applying the changes, select *Yes.* To return the *Immunoglobulin Totals* window, select *No.*

2. Immunototals may also be added after scanning has occurred by right clicking on the scan and then selecting Immuno Totals. They must be entered individually for each scan.

Note: Immunoglobulin Totals and Ranges may not be displayed as a default option.   Select Display Options and Display Results and Ranges if Totals and Ranges do not appear.

7.3.2.3. Comments

This window functions the same as *Comments* on non-IFE edit windows. For information see Section 7.3.1.6.

7.3.3. User Setup

See Section 6.

7.4. Positive Sample Identification

WARNING: On runs of more than four plates when positive patient ID is not in use, failure to replace the carousels could result in misidentification of samples.

The sample handler will alert the user as each carousel rotates into a position where it may be removed. At that time the user must either remove and replace carousels as alerted, or be available to replace carousels before the fourth carousel has completed sampling. Failure to replace carousels in a timely manner will result in delays that may compromise results.

The user must address and correct any error before responding to the message to avoid potential misidentification or gel compromise.

7.4.1. Initial Scanning

The bar code on the sample tube is used to uniquely identify the patient. This identifier will be used as the key identifier if the instrument is not connected to a host computer (LIS) or if connected will be used to query the LIS in order to retrieve patient information. This bar coded identifier and the patient information will be tied to the gel by the gel number which is based on the order in which the gel proceeds through the instrument. At the time of scanning, a bar code printed on the gel will be read and stored in the worklist and in each scan record in the worklist. This will tie the worklist and the scans to that specific gel.

7.4.2. Rescanning

When a gel is to be rescanned, the bar code on the gel will be read and the worklist that contains the gel identifier will be opened and the rescanned scans will replace the original scans in that worklist (See Section 7.5).

7.4.3. Manual Entry of Patient Information

The user has the ability to manually enter patient information in case the patient information could not be downloaded from the host computer. Manually entered patient information will be displayed and printed in italics to indicate the loss of positive sample identification for that patient.

7.5. Rescan

7.5.1. Rescanning

1. Place the cassette containing the gel on the scanning platform. The cassette hangers should be facing the right hand side for the gel to be properly read.

2. From the *Main Menu*, select *Run* and then *Rescan*.

3. The bar code is read and identified. Then, the corresponding worklist is accessed.

4. When a gel is scanned, the window displays "Scanning in Progress."

5. Once scanned, the cassette will drop into the cassette receptacle.

6. The window then displays the rescan. The previous scan is replaced with the rescan.

7. Rescanning may not be performed while a run is in process.

7.6. View

7.6.1. Gel Image

If Save Gel Image was enabled in Test Setup, the user may view, print, or save an image of the completed gel.

1. Select *View* and *Gel Image* to display the image of gel.

2. Right click on the image of the gel. A menu will appear with the options to print or save the image.

3. The image may be saved to a file.

7.6.2. Display Options

This window allows for the display parameters for the indicated worklist to be temporarily altered. See Section 6.3.2 and Figure 6-8 for a complete description.

7.6.3. Instrument Status

Select *View* and *Instrument Status* to show the status of all the current conditions of the instrument. This can be hidden by unchecking the option.

7.6.4. Communication Log

1. Select *View* and *Communication Log.* The *Communication Log* window will display.

2. *Print* - select to print the displayed communication log.

3. *Clear* - select to delete the displayed communication log.

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

7.6.5. Error Log

1. Select *View* and *Error Log.* The *Error Log* window will display.

2. *Print* - select to print the displayed trace log.

3. *Clear* - select to delete the displayed trace log.

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

7.6.6. Memory Status

1. Select *View* and *Memory Status.* The *Memory Status* window will display.

2. The window will display the percent or byte information for *Memory Used*, *Total Physical Memory*, *Available Physical Memory*, *Total Virtual Memory*, and *Available Virtual Memory.*

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

7.7. Windows

7.7.1. Close All

With multiple worklists open, to close all the worklists at once, select *Windows* and *Close All*.

7.7.2. List of Open Worklists

With multiple worklists open, to select a worklist for use, select *Windows* and click on the desired worklist.   Note that the numbers on the left attributed to each worklist represent the order in which the worklists were open.

7.8. Help

7.8.1. About

1. Select *Help* and *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.

7.9. Results: Reference Procedures

For a complete discussion of results and their interpretation, refer to the following sections of the procedure supplied with the reagents: Instruments, Evaluation of Bands, Stability of End Product, Results, Expected Values, Performance Characteristics, and Interpretation of Results.
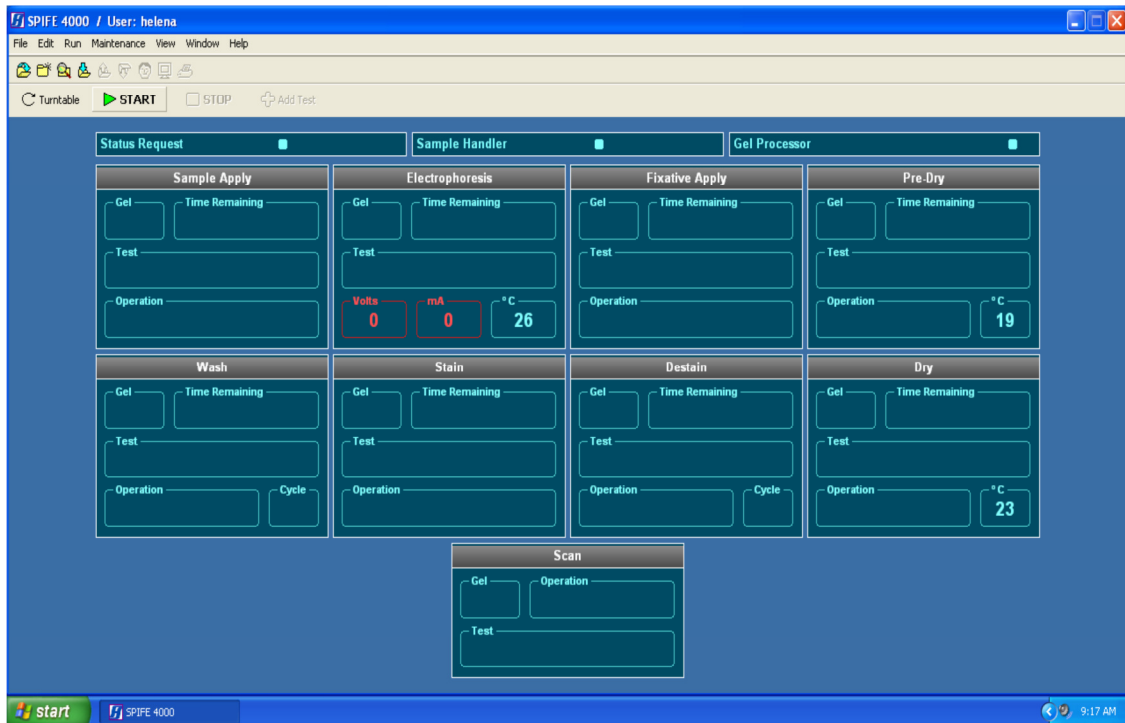
Figure 7-1 Main Menu
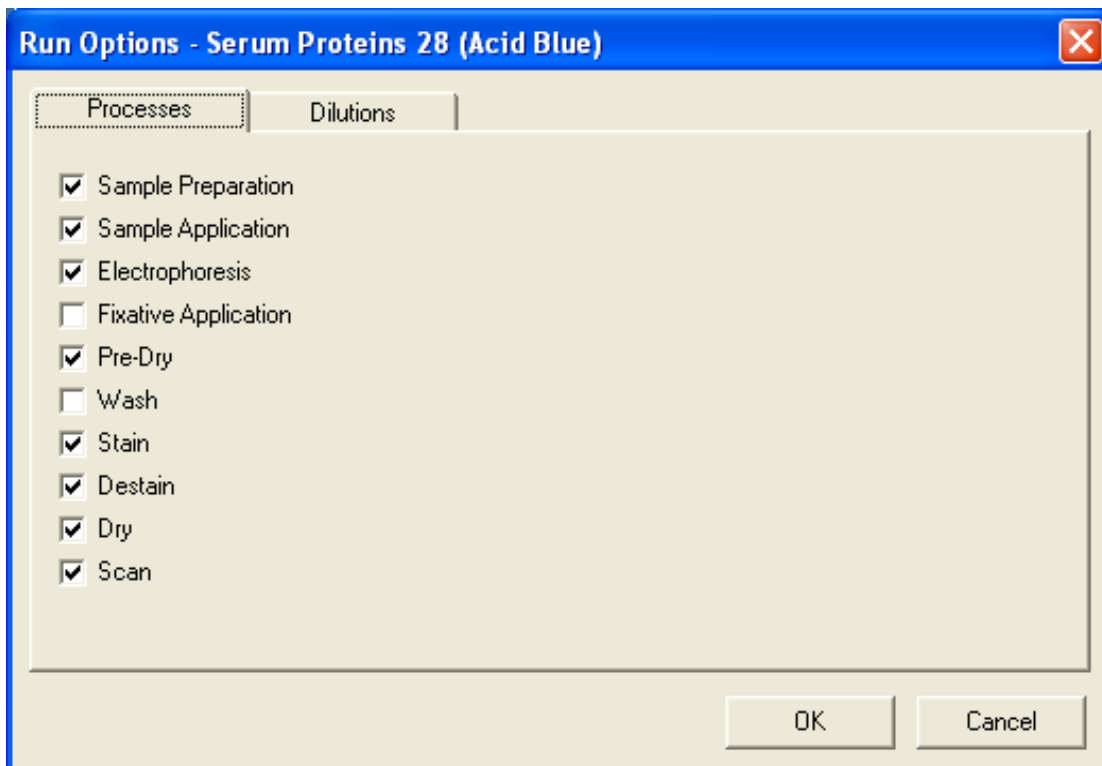
Figure 7-2 Run Options, Processes
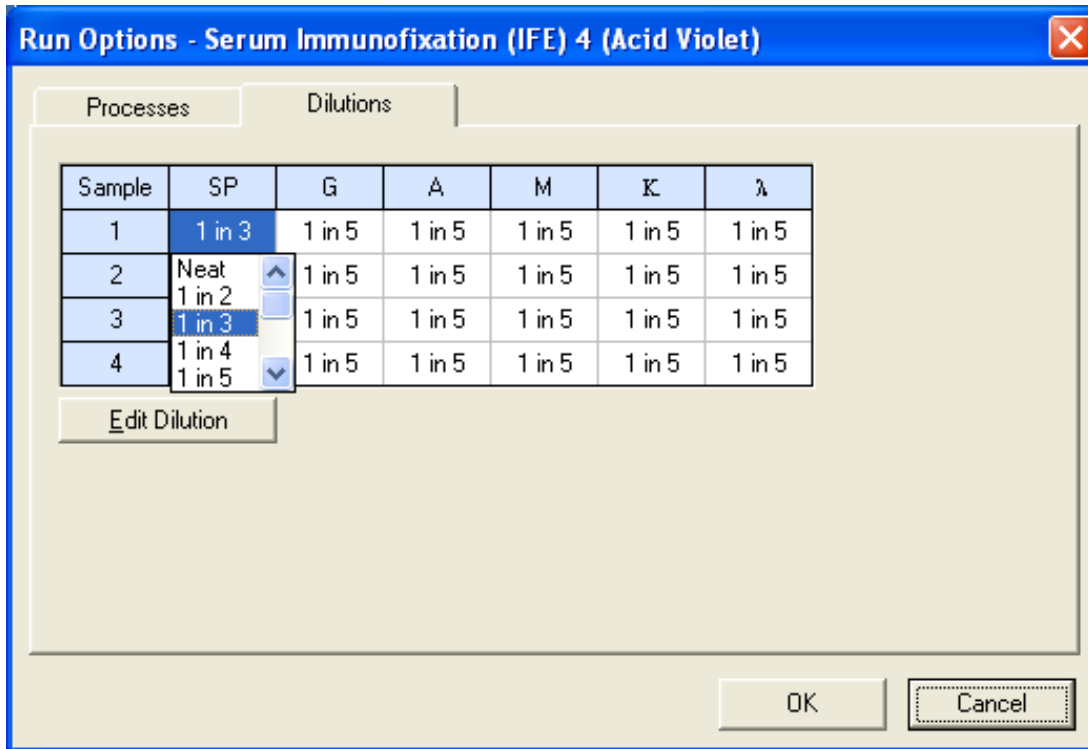
Figure 7-3 Run Options, IFE, Dilutions
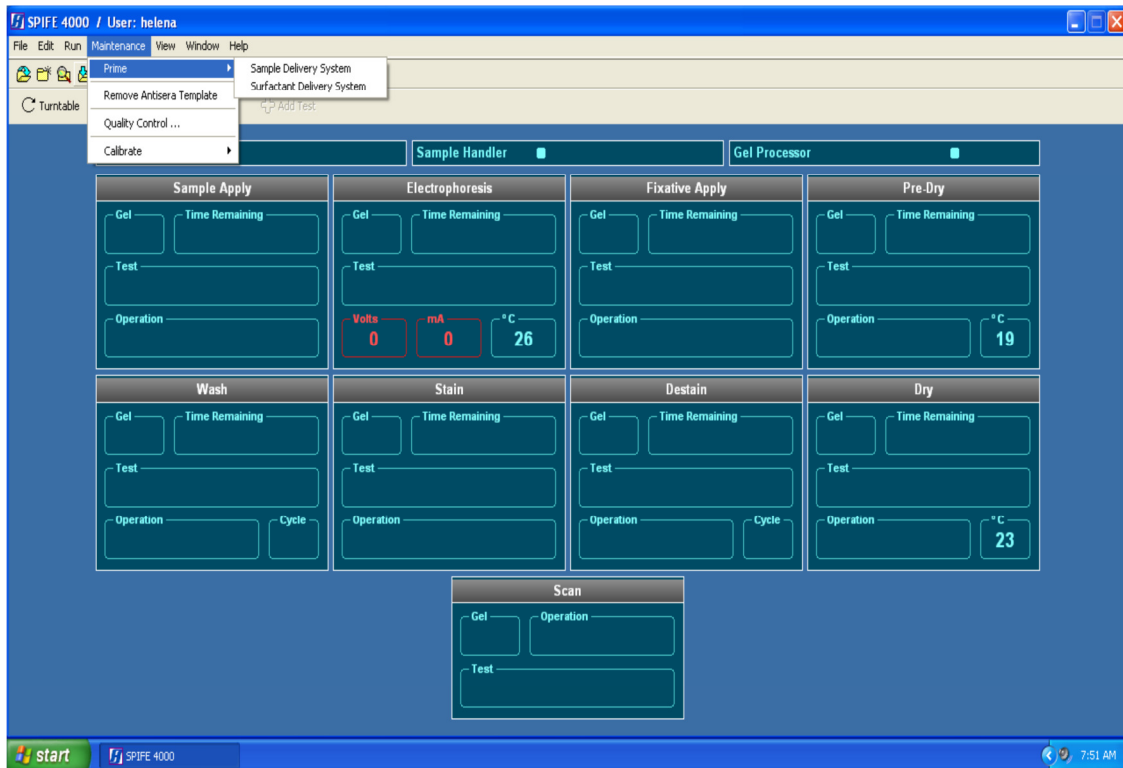
Figure 7-4 Maintenance Menu
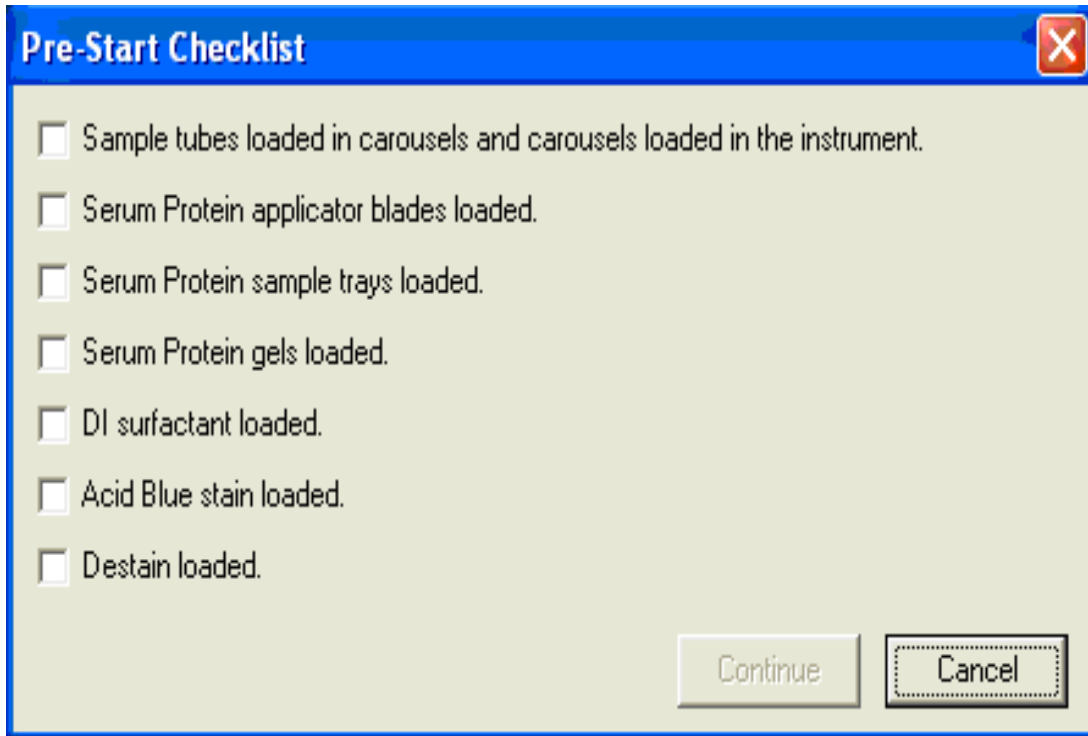
Figure 7-5 Pre-start checklist
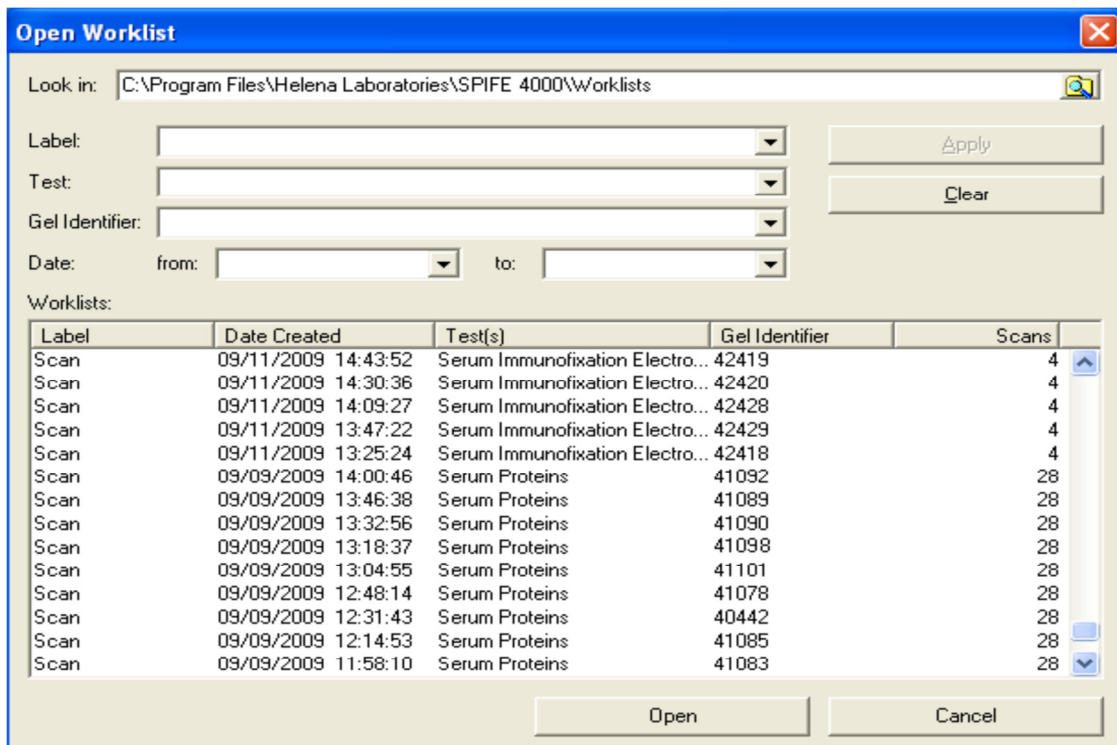
Figure 7-6 Open Worklist
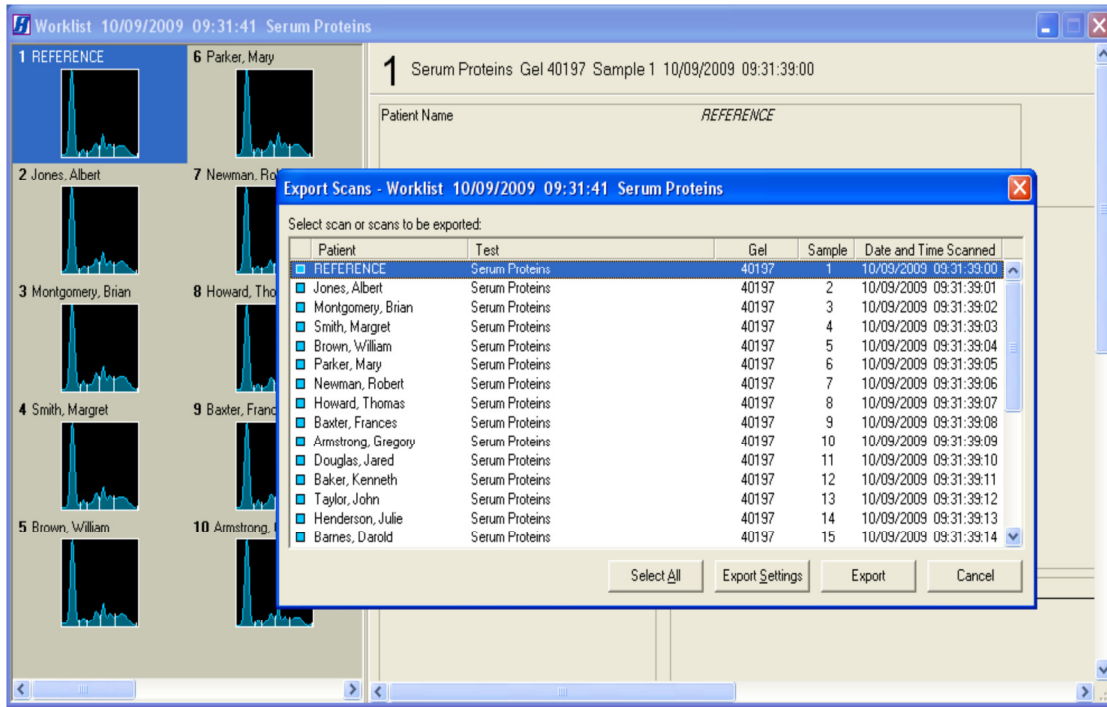
Figure 7-7 Export Scans
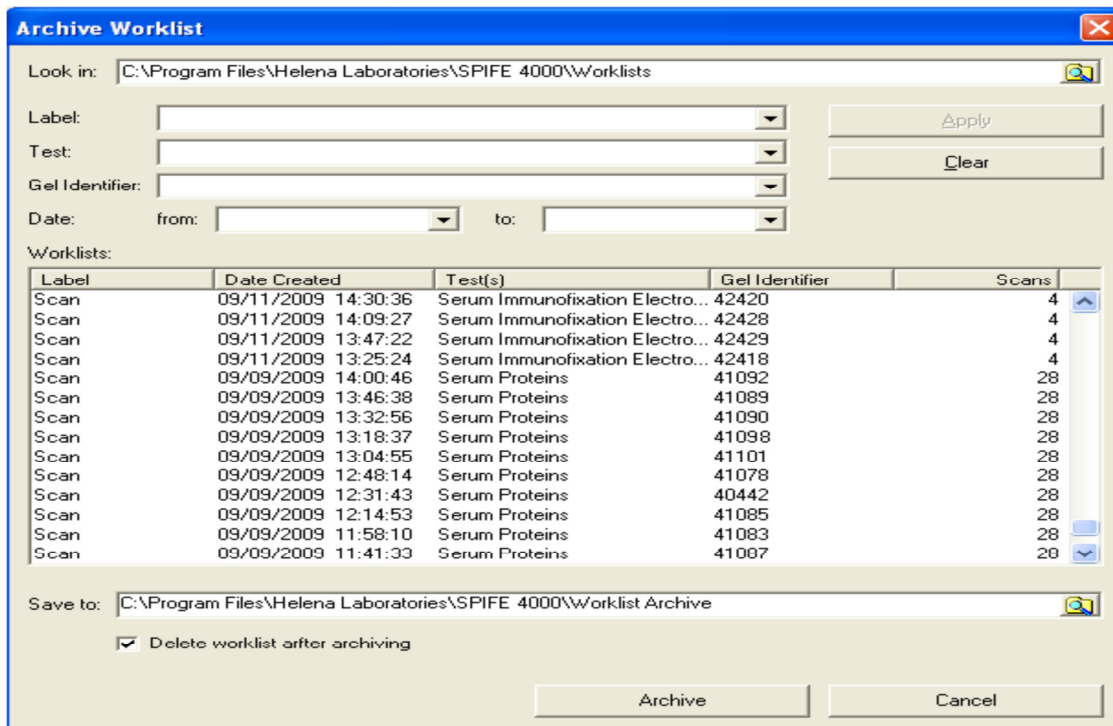
Figure 7-8 Archive Scans
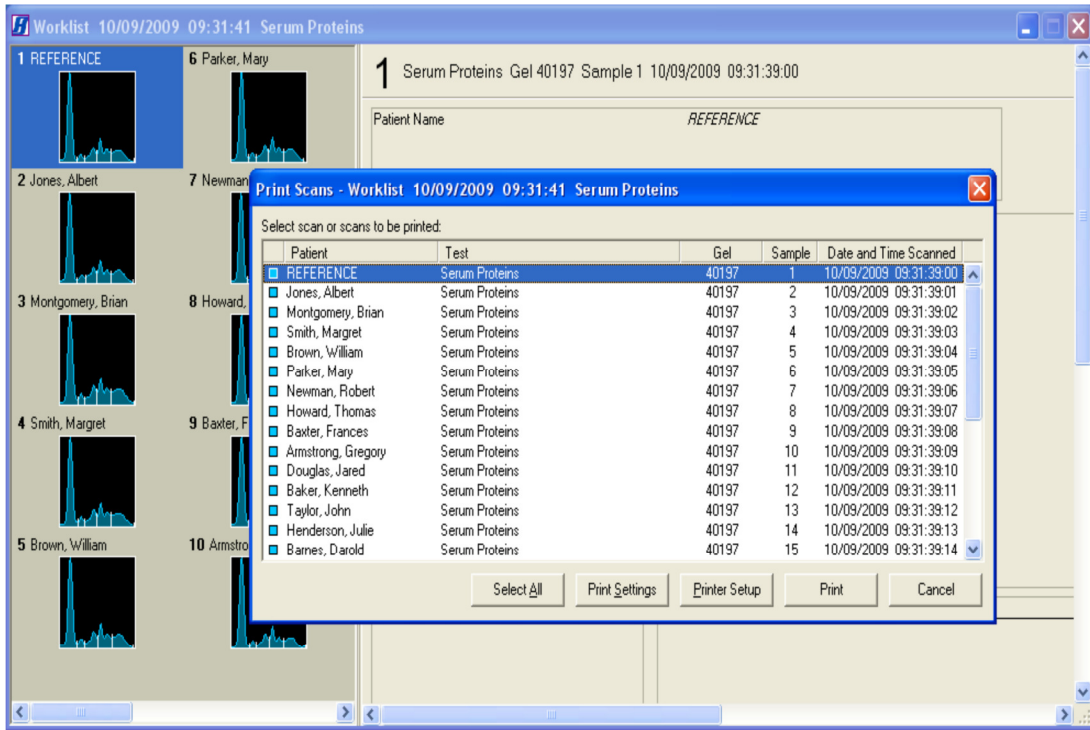
Figure 7-9 Print Scans
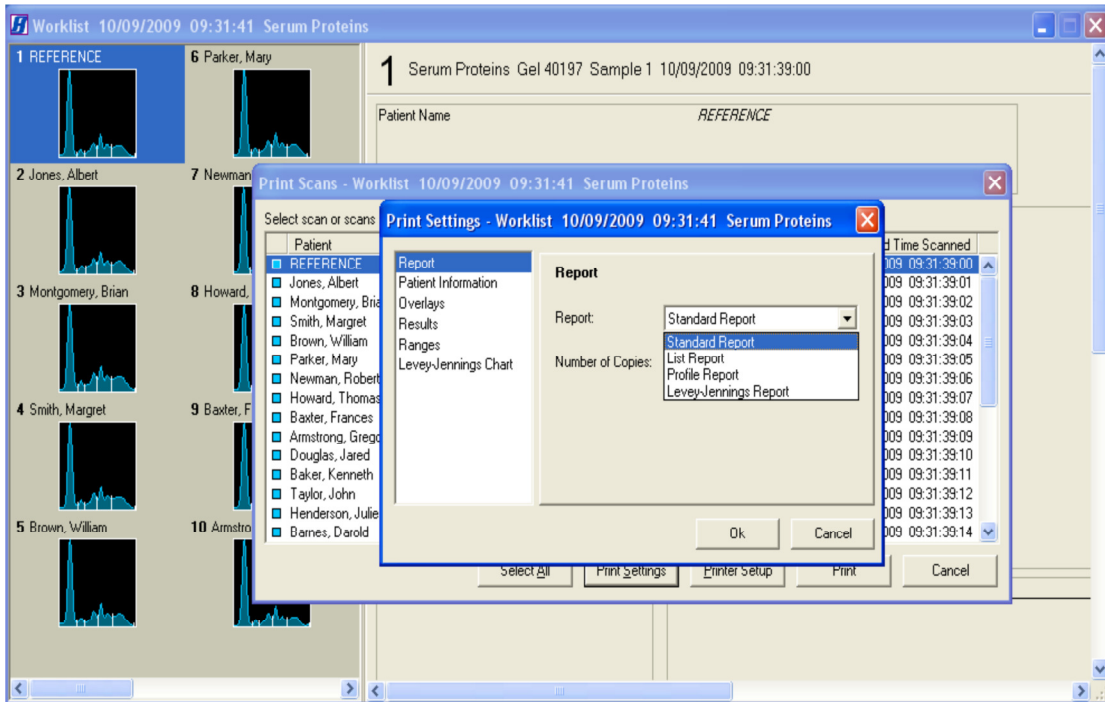
Figure 7-10 Print Scans, Print Settings
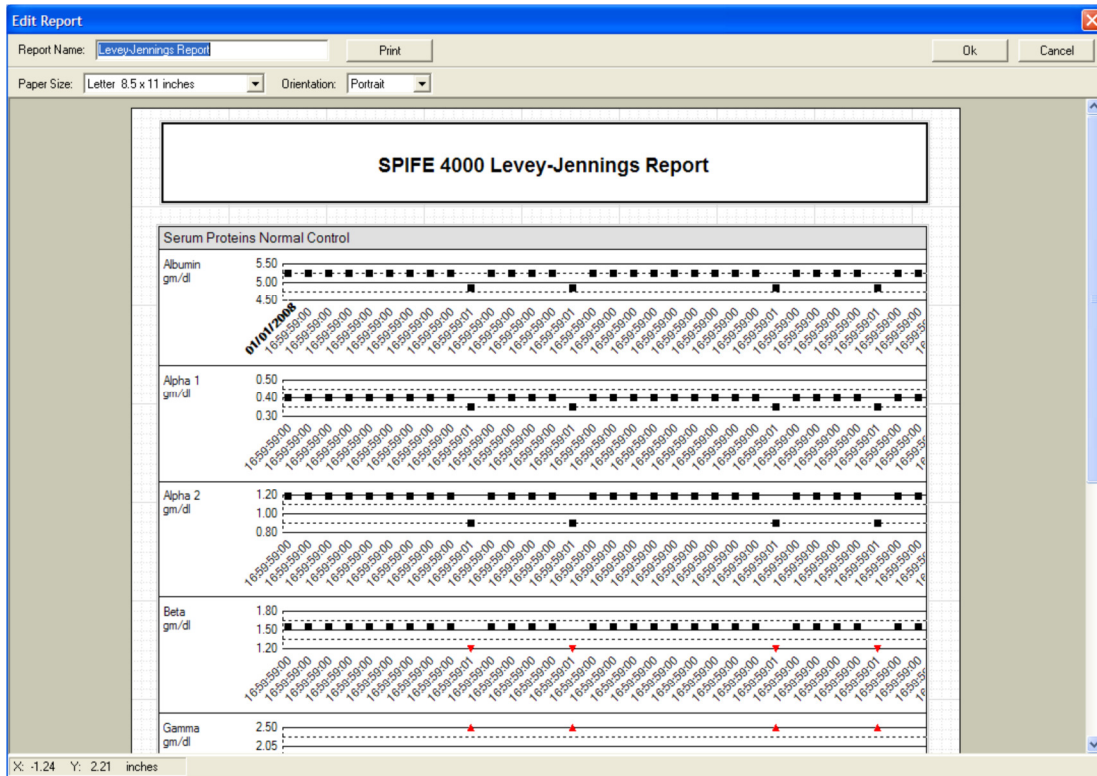
Figure 7-11 Levey-Jennings

Figure 7-12 Edit Scans, Patient Information
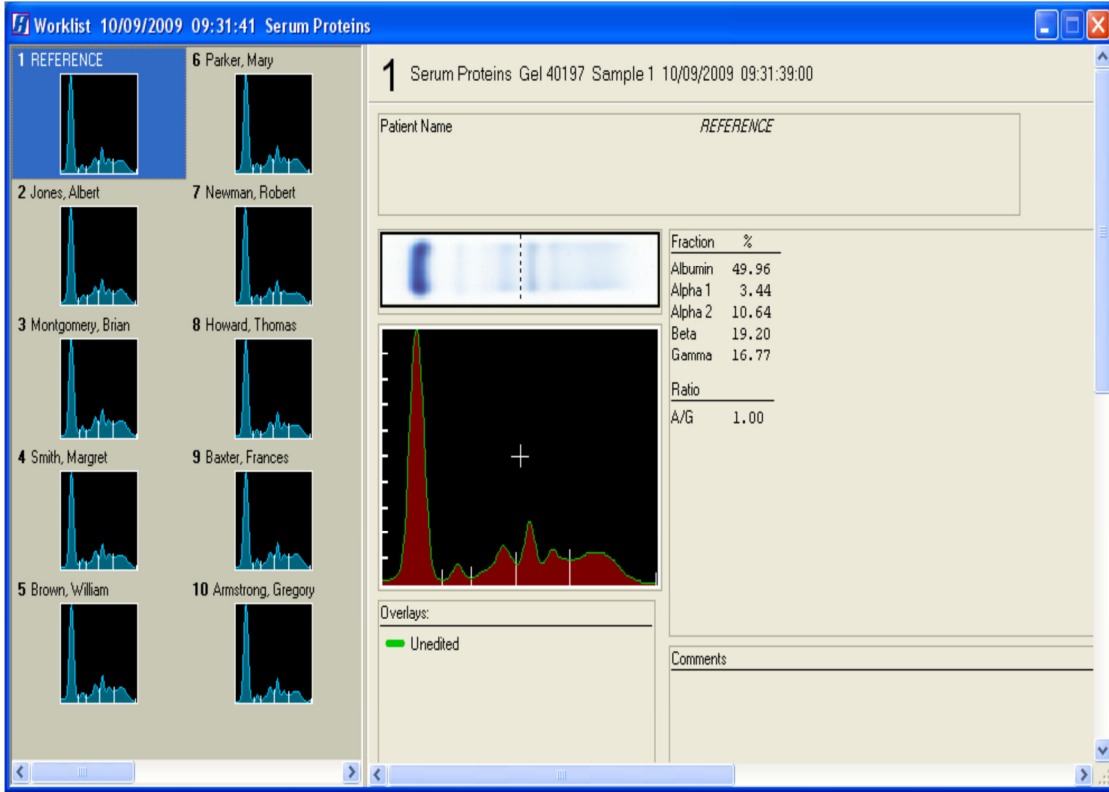
Figure 7-13 Editing Scans
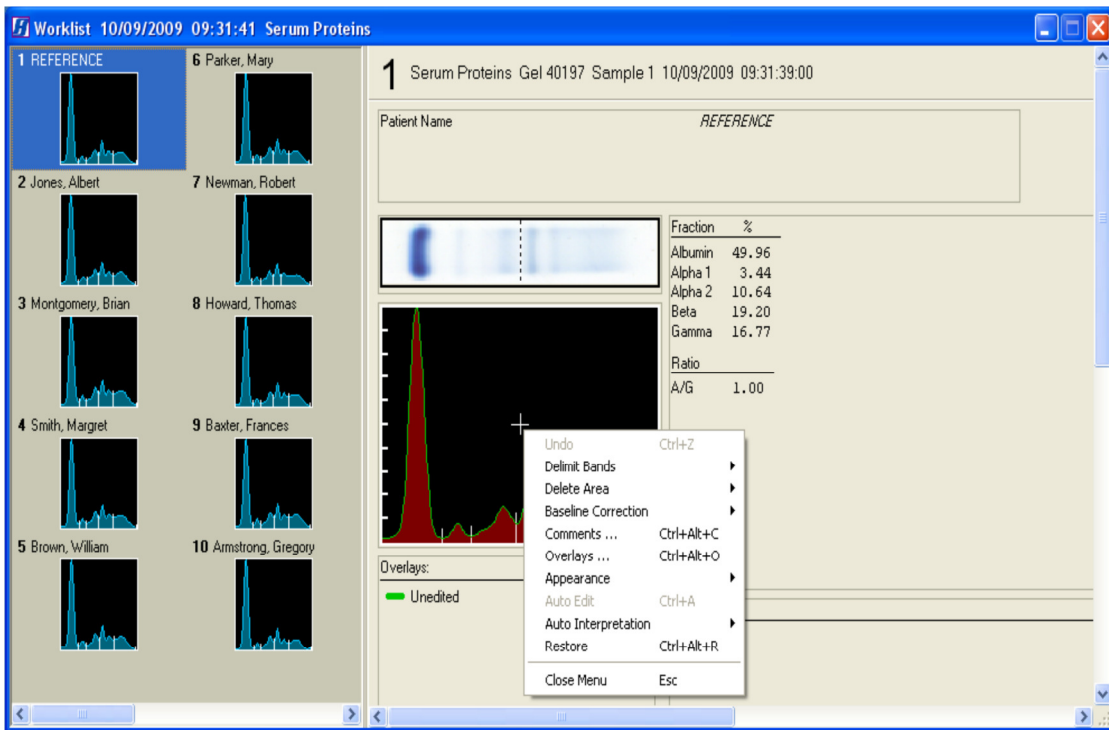
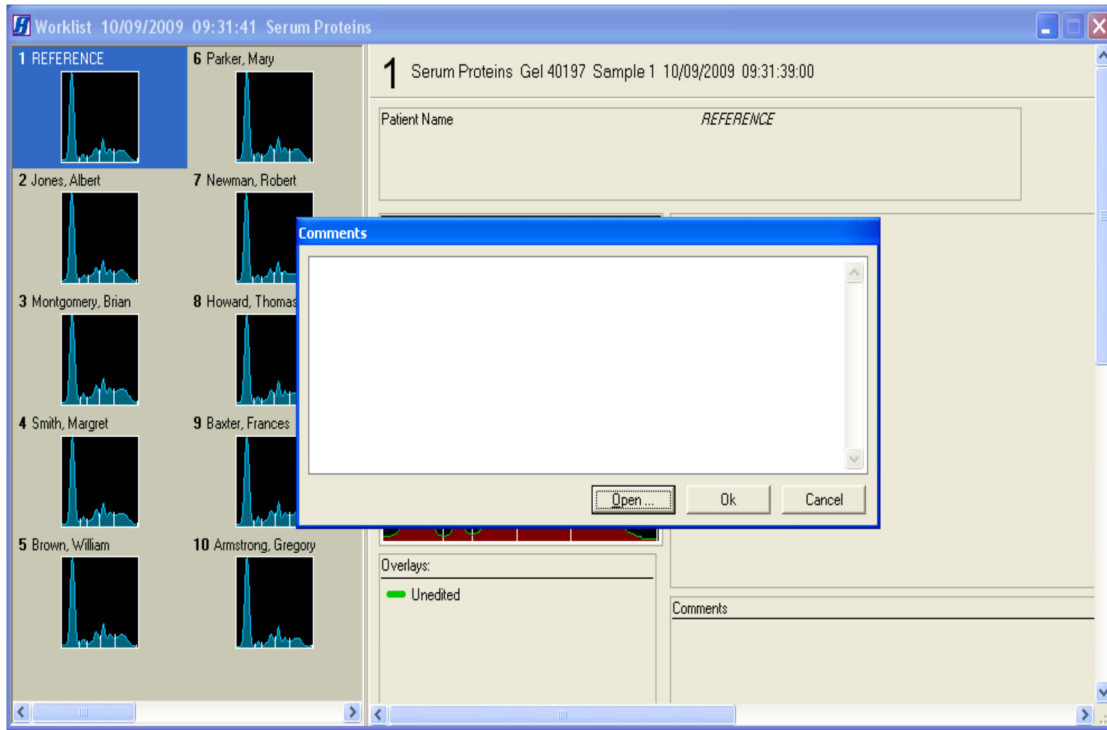**Figure 7-14 Editing Scans, Edit Commands**

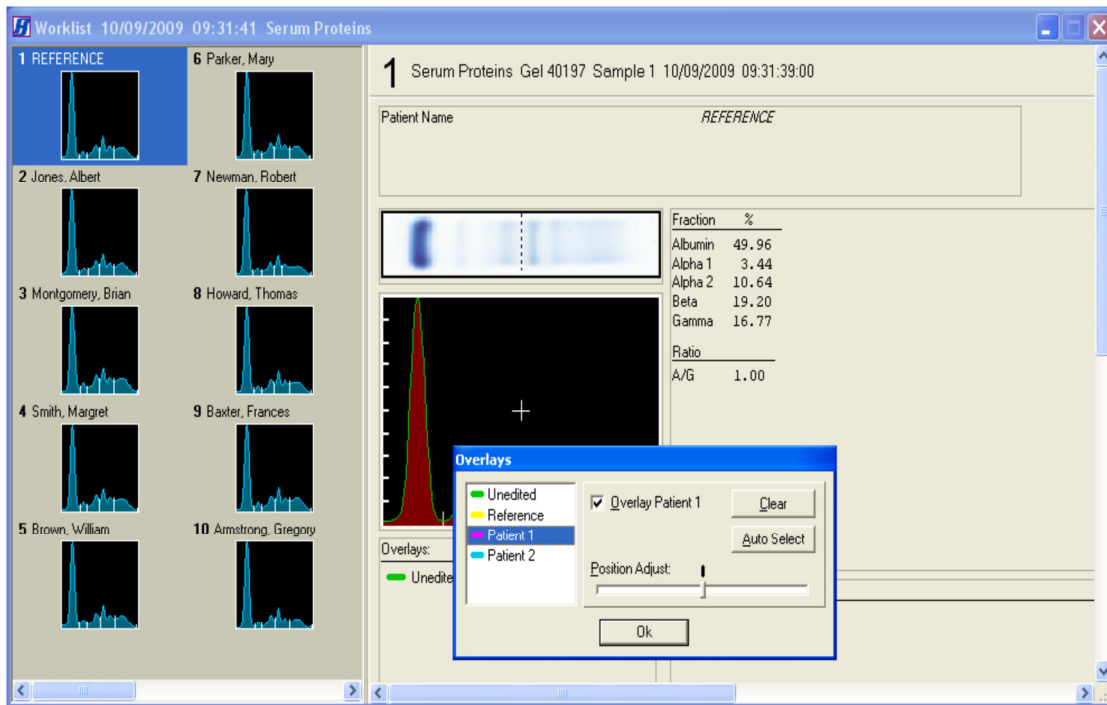**Figure 7-15 Editing Scans, Comments**

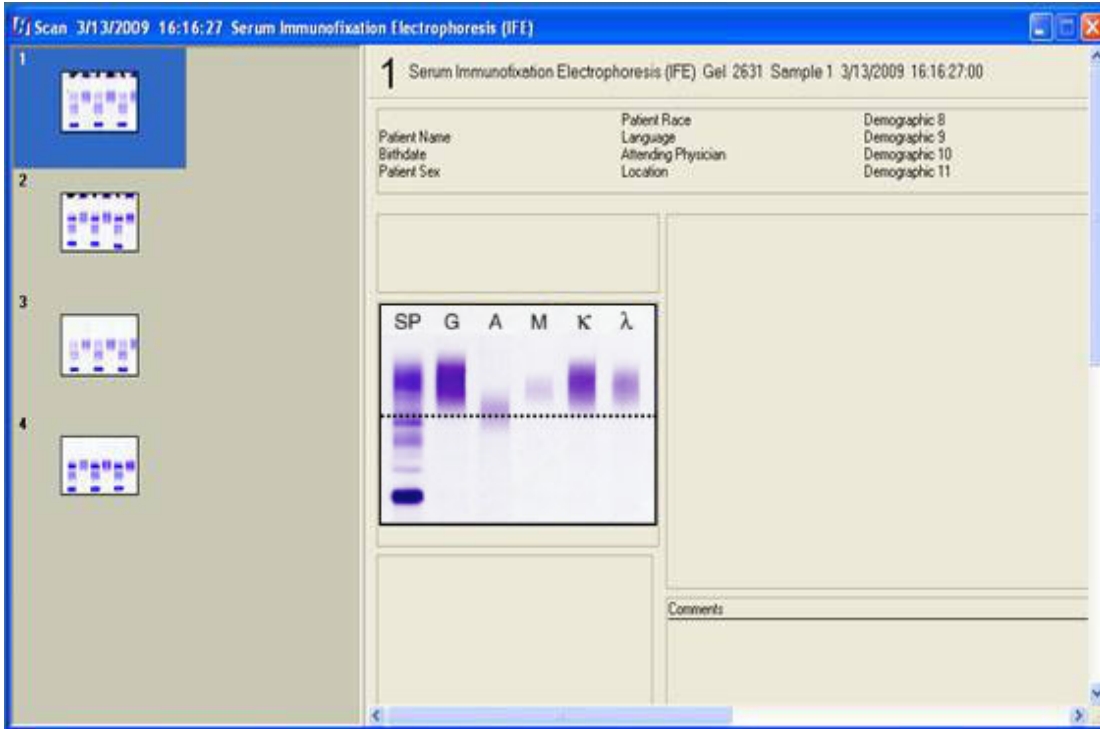**Figure 7-16 Editing Scans, Overlays**

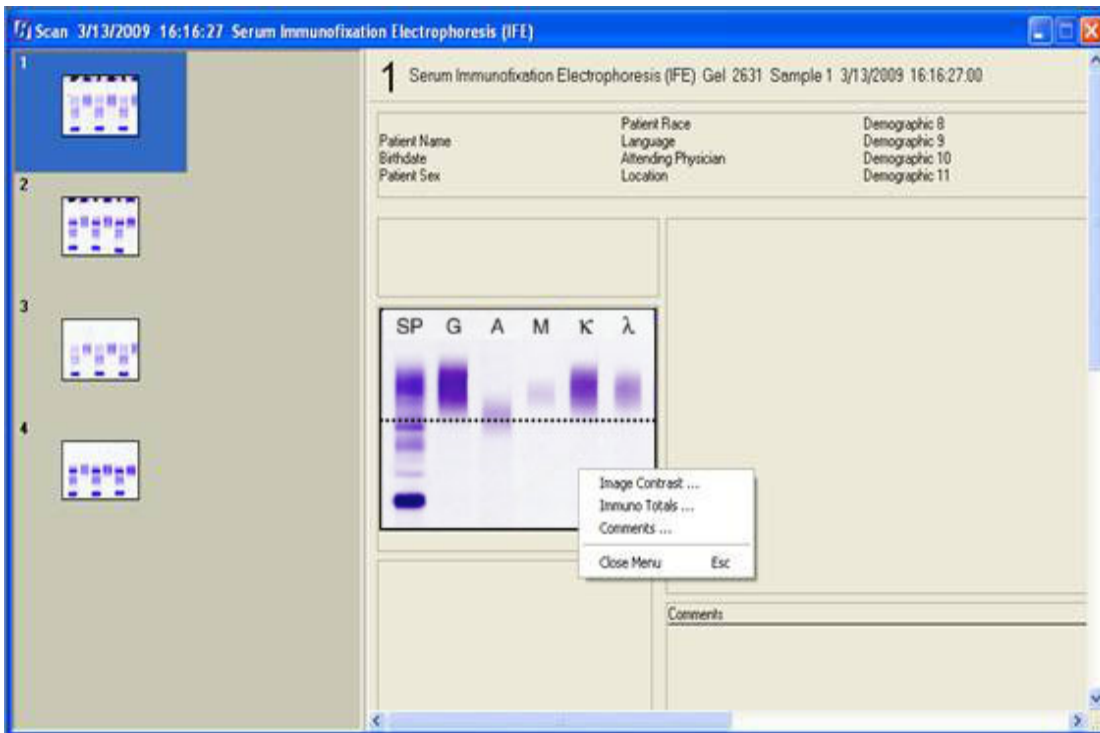**Figure 7-17 Editing IFE Scans**

Figure 7-18 Editing IFE Scans, Edit Commands
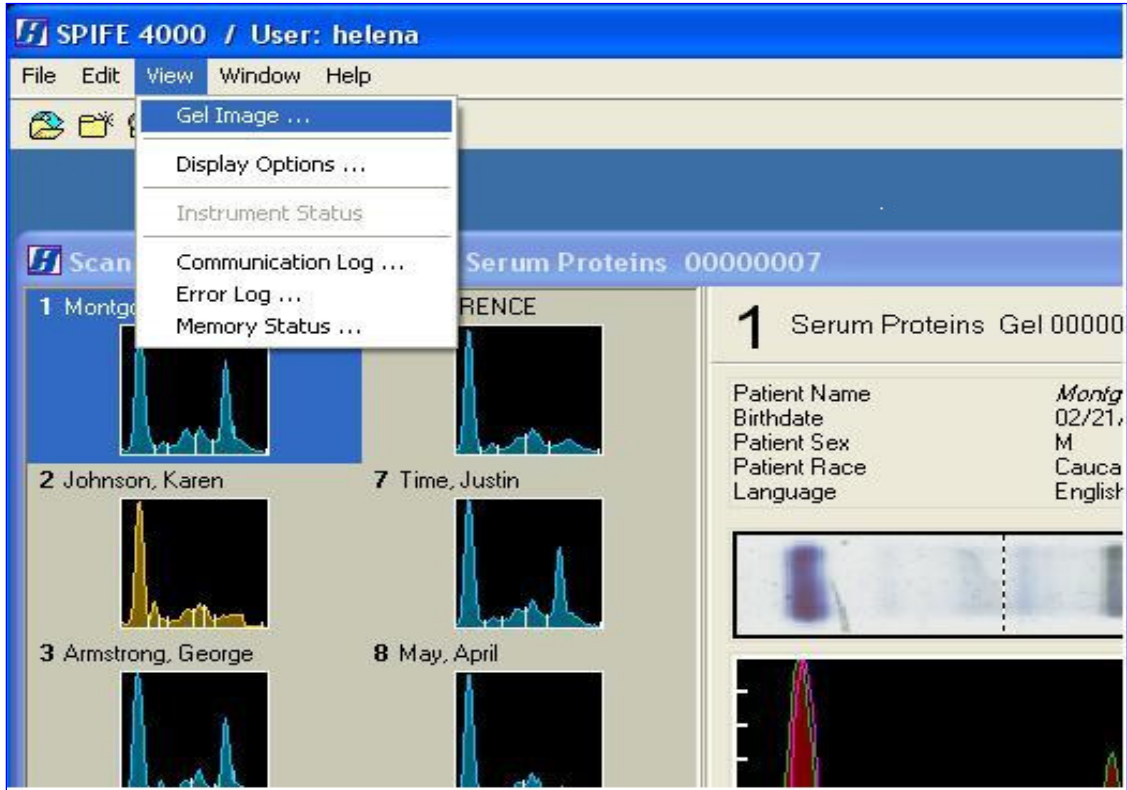
Figure 7-19 View Gel Image

Sample
Delivery
Area

Figure 7-20 Instrument, Front View

Antisera Station

Gel Humidor

Applicator Blade Tray

Carousel Area

Sample Tray Holder

Figure 7-21 Sample Handling Area

Flat Blotters

Comb Blotters
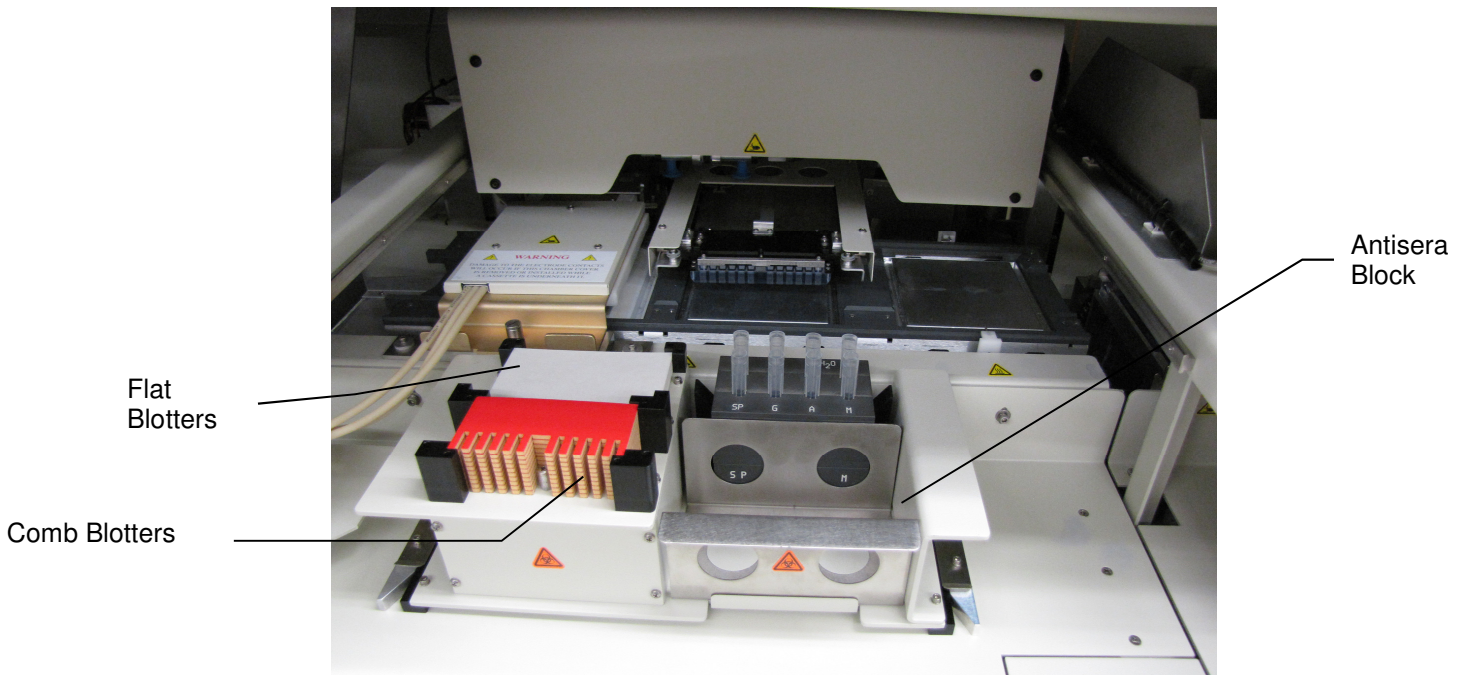
Antisera Block

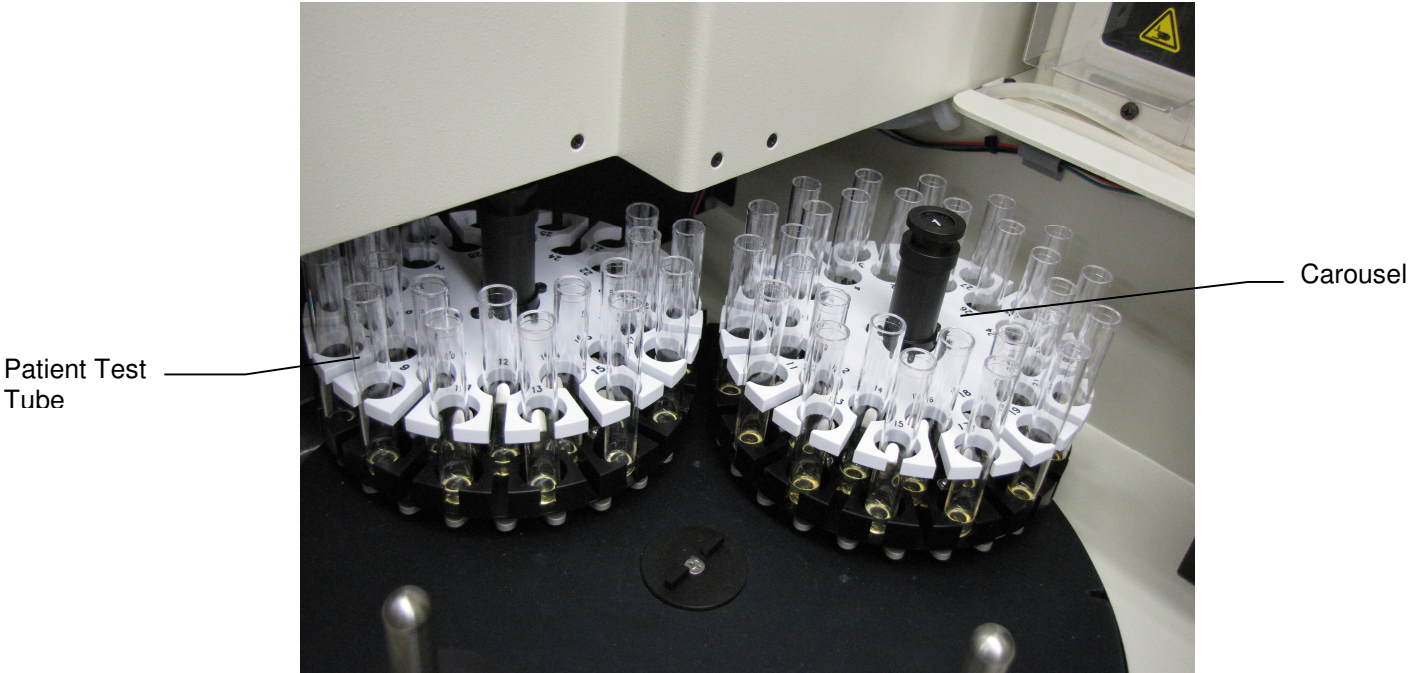**Figure 7-22 Antisera Station**

Figure 7-23 Carousels / Turntable

Section 8 - Test Functions and Quality Control

8.1. Tests

The instrument will not initialize until the User Interface initializes and commands the instrument to initialize. The instrument will then proceed to initialize all of its motor controlled mechanisms and control interfaces. Should an error occur during initialization the error identity will transmitted to the User Interface for display, see Table 10-2.

For the instrument to initialize or reinitialize correctly:

1. All safety shields must be closed.

2. All error messages should be addressed, in particular, the antisera tray should be installed, and the waste container must be emptied if needed.

3. The Applicator Magazine should be installed with the elevator door closed.

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

Refer to the appropriate owner's guide for tests of the monitor and printer.

8.2. Quality Control

On every gel, Helena Laboratories normal control should be run in scan position 1 and/or abnormal control in the last position, and samples in between. The control data should be compared to the ranges printed on the assay sheet provided with the control. Keep a permanent record of the results. Data may be maintained in a Levey-Jennings chart.

Each laboratory should establish its own reference ranges of expected values for the procedures in use. Refer to the electrophoresis procedure supplied with the reagents for further information.

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

8.3. Instrument Performance Check

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 0.05 to 3.05 in 0.30 increments. Scan the QC plate at frequent, regular intervals.

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

A list of the quantitative ranges for the NDDC bands should have been entered during QC setup, see Section 6.7. The quantitation for the five bands is compared to the entered data. Deviations in the results for the 5 bands are indicated high (+) or low (-) on the display and printout.

1. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, select *Maintenance* then *Quality Control.* The *Quality Control History* window displays (Figure 8-1). It contains all previous scans including the *Identifying Number*, *Date and Time Scanned,* and *User*. The availability of previous QC results is dependant upon selections made in setup (Section 6.7). An identifying colored box will be at the beginning of each line showing in range QC scans (blue) and out of range QC scans (red)

2. *Scan* - select to QC using the NDDC/OD Step Tablet. The message "*Place the cassette containing the QC Plate in the scanner and click 'OK' to continue*" will display.

　a. Place the QC plate onto the cassette by slipping it onto the pins. Take care to see that it is oriented correctly with the OD Step tablet next to the cassette arms. Place the cassette on the scanner.

　b. Select *OK.* A progress box will appear and display the status of the scan.

　c. The NDDC results and image are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup (Figure 8-2).

　d. An image of the OD Step Tablet will appear on the display (Figure 8-2). 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 7 steps. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup. Any out of range values will be highlighted in red and flagged with a "+" or "-" to denote if the value is over or under the *Expected Range.*

　e. *Print* - is available with a QC result displayed. Select and the *Printer Setup window* will display. As needed, select the appropriate *Printer* and *Number of Copies.* Select *Print* to print the QC results. Select *Close* to exit without printing. It is recommended that a permanent record of the QC results be kept.

3. *View* - select the desired previously run QC and click *View* to open it.

4. *Print* - use to print a report containing all previously run QC. For each previously run QC, the report includes the NDDC registration number, the date and time of the run, and each of the five NDDC fraction results. 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.

　a. *Delete* - use to delete the indicated QC. Select *Delete* and a *Confirm Delete* prompt displays. Select *Yes* to exit and delete the selected QC or *No* to exit without deleting QC.

　b. *Cancel* - select to exit the *QC History* window.

5. To exit the *Quality Control History* window, select the **X** located on the top right of the window.
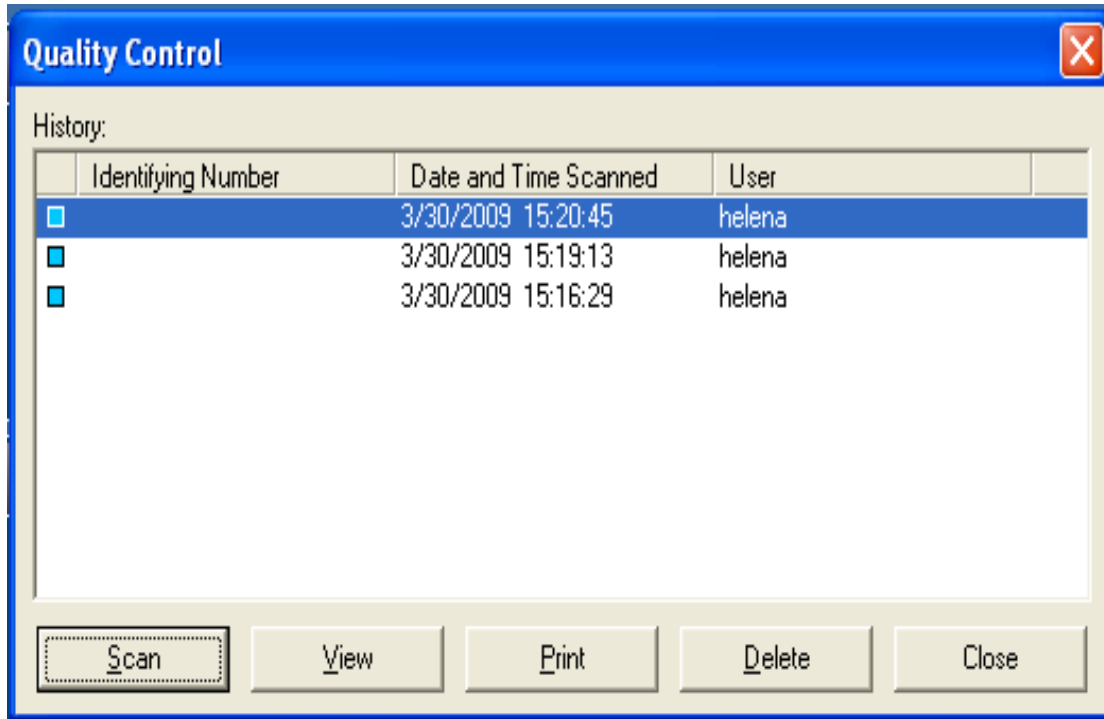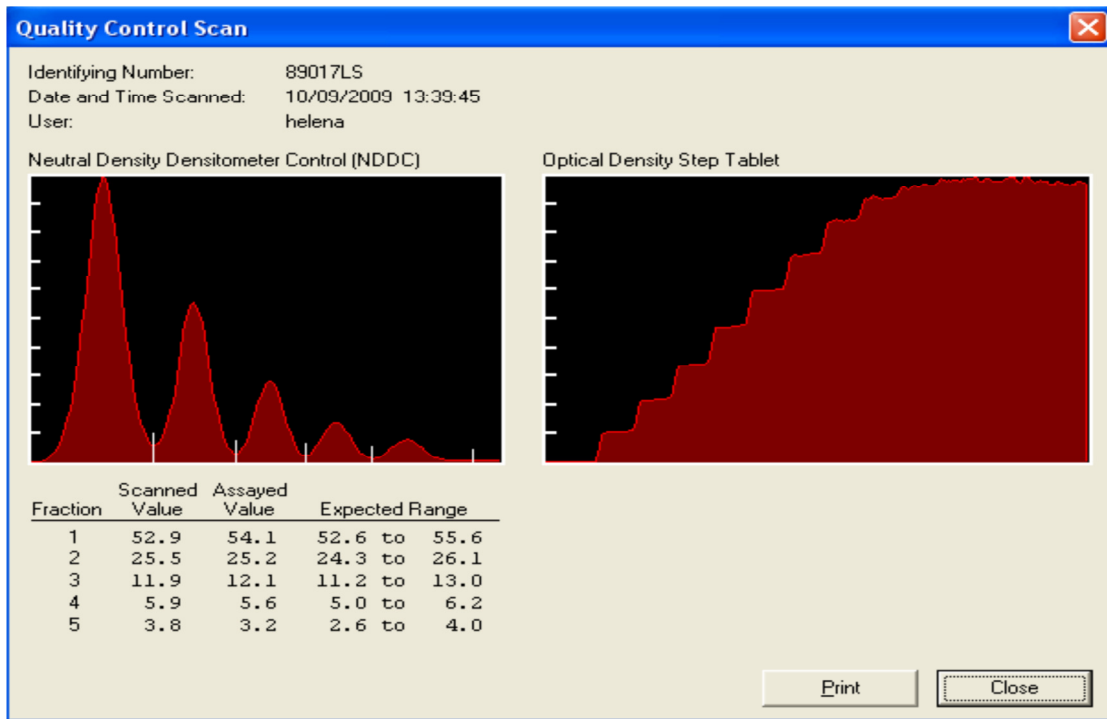
Figure 8-1 Quality Control History

Figure 8-2 NDDC/OD Step Tablet Image

Section 9 - Performance Specifications

Tests:
Serum Proteins and IFE

Media Types:
Agarose and cellulose acetate gels

Maximum Sample Size:
5 x 5 in. (12.7 x 12.7 cm)

Input Power:
120 VAC, 60 Hz, 1000 Watts
230 VAC, 50 Hz, 1000 Watts

Leakage Current:
< 3.5 mA. sinusoidal

Dimensions: Height x Width x Depth:

SPIFE 4000 Instrument & Fluids Table:
60 x 79 x 32 in. (152.4 x 200.7 x 81.3 cm)

Computer, Monitor, and Keyboard:
22 x 18 x 24 in. (55.9 x 45.7 x 61 cm)

Scanner:
≤ 8 x 13 x 22 in. (20.3 x 33 x 55.9 cm)

Printer:
10 x 14 x 14 in. (25.4 x 35.6 x 35.6 cm)

Total Weight: 350 lbs (158.8 kg)

Environment: 15° to 27°C (59° to 80.6°F)

Instrument Operating Environment:
  Ambient Temperature Range: 15° to 27°C (59° to 80.6°F)

Altitude tested up to 2000 meters

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

Densitometer Specifications

Scanning Parameters:
  Gain: Automatic or Manual
  Over range: > 100% of full scale

Optics Mode:
Visible Transmittance (white light)

Aperture Sizes (mm):
1   1 x .1
2   2 x .2
3   3 x .3
4   4 x .4
5   6 x .6
6   7 x .7
7   8 x .8
8   2.5 x .25
9   5 x .1
10   5 x .25
11   5 x .5
12   12 x 12

Scan Length:
Variable from 0.01 to 221.5 mm

Zeroing:
Automatic

Light Source:
Cold Cathode Fluorescent (white light)

Light Detectors:
CCD Array

Optical Density Linearity:
  0.05 to 2.3

Operating System:
Microsoft® Windows® 7
*Windows is a registered trademark of Microsoft Inc.

Electrophoresis Timer Range: 1 sec. to 90 min. in 1 second increments

Chamber Temperature Range: 10°C to 30°C

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

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

Fuses: F1, F2 15A/250V slow blow

Pump System: 2 peristaltic pumps, 1 syringe pump

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	Maximum Characters Bar Width
Code 3 of 9 (Code 39) (alphanumeric)	0.0075	3:1	10
Codabar (numeric)	0.0098	n/a	10
Interleaved 2 of 5 (numeric)	0.0075	3:1	20
UPC - 12 (numeric)	0.014	n/a	13
EAN, L reduced (numeric)	0.014	n/a	13
CODE 128 (alphanumeric)	0.0075	3:1	25
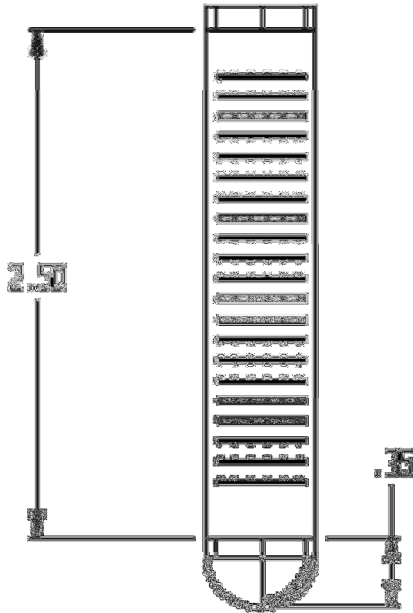
This drawing represents the proper placement of the bar-code label.

Electrophoresis Instrument and LIS Interfacing:

Ports: 3-wire RS232, no hardware hand-shaking

Programmable Baud Rate:	1200, 2400, 4800, 9600, 14400, 19200
Programmable Data Bits:	7, 8
Programmable Stop Bits:	1, 2
Programmable Parity:	None, Odd, Even
Programmable Proto-col:	None, XON-XOFF, ASTM

Section 10 - Maintenance, Troubleshooting, and Warranty

This section describes routine operator maintenance procedures.

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

10.1. Maintenance

WARNING: The SPIFE 4000 is factory lubricated. Do NOT lubricate the instrument.

Table 10-1 Preventative Maintenance Schedule

After Every Test
- Clean Cassettes and Electrodes.
- Check for leftover cassettes throughout the system.

Daily, if used
- General Inspection of Instrument for cleanliness.
- Power down the instrument prior to opening the Gel Processor Safety Shield.
- Clean the Antisera Template if IFE test were performed (after a day's run or every 20 plates).
- Gently clean comb and flat blotter suction cups with DI water.
- Remove the Electrophoresis Chamber Lid, and gently clean surface and sides of the platen.
- Examine the cassette electrodes for corrosion.
- Lift and clean the surface and sides of the Antisera, and Pre-Dry station platens.
- Pipette Tip Change (with new Antisera vial).
- Wipe the sides of the platens carefully.
- Clean Scanner Area.

- Wash/Prime Electrophoresis Sample Handler, before and after each use.
- Prime Electrophoresis Sample Handle daily if instrument is not in use.
- Prime Surfactant Delivery System.
- If the instrument will not be in use for a shift or more, exit the SPIFE 4000 software and power down the computer.
- If the instrument is in continuous use, exit the SPIFE 4000 software and reboot the computer on a daily basis.

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

- Archive and delete worklists for optimum function (or as necessary depending on operational volume)

Monthly
- Bleach Electrophoresis Sample Handler
- Clean Reagent Block
- Dynamic Coating Procedure

As Needed
- Inspect Waste Overflow Vat
- Fuse Replacement
- Replace Contact Sheets
- Clean Instrument
- Rinse/Replace Fluid Vats
- Replace Tubing/Pump
- Inspect/Clean Needle*
- Replace/Calibrate Needle*
- Backup Parameters

*Contact a Helena Service Representative for assistance with replacing and

calibrating the sample hander needle. **Incorrect needle calibration may result in severe needle damage.**

10.1.1. Clean Cassettes and Electrodes

Rinse the cassette in deionized water. Scrub the entire surface of both carbon electrodes with a brush. Dry with a lint-free tissue.

10.1.2. Perform Manual Maintenance of Antisera Template

NOTE: Be extremely careful when handling, cleaning, transporting, etc. the antisera template to prevent damage.

1. Remove the antisera template from the hangers very carefully.

2. Clean all surfaces with a mild detergent and a soft brush. Rinse with D.I. water and dry template with a paper towel.

3. DO NOT touch the gel contact surfaces.

4. Replace the template.

10.1.2.1. Dynamic Coating Procedure

Dynamic coating can prevent surface tension and fluid adhesion induced voids in the antisera lanes.

1. Clean all surfaces with a mild detergent and a soft brush. Rinse with D.I. water and thoroughly dry template with a paper towel.

2. Dip a cotton swab into the dynamic coating solution ringing tip along the neck of bottle.

3. Run the cotton swab along each IFE channel only on the underside of the template. Re-moisten the cotton swab after every 3 channels coated.

4. Allow to dry.

5. Repeat steps 2 and 3.

6. Before the channels are completely dry, run a dry cotton swab along each channel ensuring an even surface.

7. Replace the template.

10.1.3. Clean Electrophoresis, Antisera, and Pre-Dry station platens

1. Remove the Electrophoresis Chamber Lid, 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 (Figure 10-1).

2. When cleaning the lid, be sure to inspect the electrode contacts for carbonization.

NOTE: Be careful of pressure applied to the contacts – gently clean any necessary areas.

3. Take care to clean any residue from the electrode contact strips. Inspect the contact sheet for smoothness (i.e. no folds, bubbles, corruptions, etc.).

4. Using a second tissue, wipe dry all areas which were cleaned.

5. Wash and dry the Antisera station platen. Dampen a lint-free tissue with DI water and wash the surface of the Antisera station platen. Using a cotton-tipped applicator moistened with DI water, clean the surrounding trough.

6. Using a second tissue, wipe dry all areas which were cleaned.

Note: Ensure the Pre-dry station platen is not hot.

7. Dampen a lint-free tissue with DI water and wash the surface of the Pre-dry station platen. Using a cotton-tipped applicator moistened with DI water, clean the surrounding trough.

8. Using a second tissue, wipe dry all areas which were cleaned.

10.1.3.1. Clean Antisera Platen

1. Under the *Main Menu*, select *Maintenance*, then *Clean Antisera Plate*.

2. The instrument moves the antisera template to the rea and displays, "*The antisera platen may now be cleaned. When cleaning is complete, shut the safety door and click 'OK'.*"

10.1.3.2. Clean suction cups

1. Under the *Main Menu*, select *Maintenance*, then *Clean suction cups.*

2. The instrument displays, "*Remove the antisera tray from the instrument then click 'OK'.*"

3. Remove the antisera tray and press *OK*. The instrument brings the suction cups to the front and displays, "*The suction cups may now be cleaned. When cleaning is complete, shut the safety door and click 'OK'.*"

10.1.3.3. Clean Reagent Block

1. Scrub thoroughly, including holes, with detergent and water.

2. Dry and replace.

10.1.4. Clean Scanner Area

1. All surfaces of the scanner area should be checked for residue and/or debris.

2. Clean any residue or debris from the areas with a damp cloth and water.

3. Ensure that the glass slide, which covers the optical detector, is dry after cleaning by wiping with a lint free cloth.

10.1.5. Inspect/Clean Needle

1. After every run, inspect for sample adhering to the sides of the needle.

2. If this occurs, or if sample will not apply, clean the needle with an alcohol swab and allow the needle to dry.

3. Also, after every run, the sample delivery system should be primed to prevent saline buildup.

4. If required, the operator may run the needle cleaning wire (8JM20111) up through the end of the needle to clear any debris.

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

5. If the needle appears to be bent or is still blocked, refer to Section 10.1.17, Needle Replacement.

10.1.5.1. Clean Sample Pipettor

1. Under the *Main Menu*, select *Maintenance*, then *Clean Sample Pipettor.*

2. The instrument displays, "*The sample pipettor may now be cleaned. When cleaning is complete, shut the safety door and click 'OK'.*" After cleaning, press OK.

3. The instrument then displays, "*Flushing the pipettor. Verify that water is flowing from the pipettor, then click 'OK'.*" If water is flowing press, OK.

10.1.6. Wash/Prime Electrophoresis Sample Handler

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

2. Under the *Main Menu*, select *Maintenance*, then *Prime*, and then *Sample Delivery System*.

3. Water flow can be seen surrounding the needle. Bubbles may be seen initially. As the flow continues, any air bubbles should be flushed through the lines.

4. Repeat step 2 if needed to ensure the tubing is primed and there are no air bubbles in the lines.

10.1.7. Prime Surfactant Delivery System

1. Confirm that the DI Water (surfactant) jar is full of DI water. The ends of the tubing should be below the water, and the lid should be in place.

2. Insert a *Maintenance Blotter* into a cassette.

NOTE: It is important to insert the *Maintenance Blotter* correctly into the cassette to allow the cassette to move smoothly through the instrument.

The *Maintenance Blotter* should be inserted in the same manner as a gel, with the white blotting material entirely contained within the space inside the cassette. When viewed from the bottom or sides of the cassette, there should be no visible blotting material outside the edges of the cassette.

3. Under the *Main Menu*, select *Maintenance*, then *Prime*, then *Surfactant Delivery System*.

4. The instrument will display a prompt to insert the Maintenance Blotter into the humidor with the blotter side up and select OK.

5. Remove and inspect the blotter when it stops on the third platen. The blotter should be evenly moist.

10.1.8. Clean/Bleach DI Water Bottle
***Note:** This procedure should also be used for the Saline Water Bottles.*

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

2. Clean out the bottles 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. Under the *Main Menu*, select *Maintenance*, then *Prime*, and then *Sample Delivery System*. The wash operation will ensure that no bubbles are in the lines.

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

10.1.9. Clean Sample Needle Wash block

1. Clean detector contacts with D.I. water using a swab. This prevents a build up of salt deposit on the overflow detector contacts.

10.1.10. Bleach Electrophoresis Sample Handler

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

2. Remove the tubing from the bottles located on the right hand side of the instrument. Leave the ends of the tubing exposed to air.

3. Under the Main Menu, Select *Maintenance*, the *Prime*, and then *Sample Delivery System*. Repeat until there is no liquid coming through the tubes.

4. Place the ends of the tubing into the bleach solution.

5. Under the Main Menu, Select *Maintenance*, the *Prime*, and then *Sample Delivery System*. Repeat until approximately 60 mL of bleach solution has been pumped through the tubing and needle.

6. Under the Main Menu, Select *Maintenance*, the *Prime*, and then *Sample Delivery System*. Repeat until there is no liquid coming through the tubes.

7. Place the ends of the tubing into 200 mL of clean DI water.

8. Under the Main Menu, Select *Maintenance*, the Prime, and then *Sample Delivery System*. Repeat until all 200mL of the DI water has been pumped through the system.

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

9. Refill and replace the DI water bottle.

10. Insert the tubing onto the appropriate bottle ports.

10.1.11. Overflow Vat

1. Inspect the stain overflow vat. It should be emptied when it is half full.

2. The vat should be placed at ground level, as it drains by gravity. Connect the vat to the port marked "overflow valve" on the bottom right side of the instrument. Place the vat on its side with the cap upwards, as indicated by the label.

10.1.12. Fuse Replacement

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

2. Using the provided screwdriver, which matches the slot in the fuse holder, press inward and turn the fuse holder counter-clockwise to remove the fuse holder.

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

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

5. Repeat for the other fuses as necessary.

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

10.1.13. 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, re-

placement of the contact sheet is recommended.

Note: *Never remove the electrophoresis chamber lid while a cassette is located at the electrophoresis station as this will cause damage to the electrode contacts within the lid.*

1. Turn the power switch off and unplug the power cord. Remove the chamber lid.

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

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

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

5. 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.

6. Press the contact sheet to the chamber floor and rub outward.

7. Continue peeling the backing from the contact sheet, rubbing the contact sheet down with a side-to-side stroke. Avoid wrinkles and bubbles; the sheet may be peeled up slightly, taking care not to stretch it, and smoothed down again to create a flat surface. Rub all the edges

of the contact sheet, using clean gauze, to ensure that the adhesive sticks to the chamber floor.

8. 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.

9. Plug in the power cord and turn the power switch on.

10.1.14. Clean Instrument

1. Should the instrument be contaminated by blood or blood derivative, first **turn off the power and unplug the power cord**, then spray any contaminated surface with a commercial virucidal and germicidal agent. Wipe up the residue. These materials contain alcohol, 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.

10.1.15. Rinse / Replace Reagent Vat(s)

1. Prior to refilling reagent vats, rinse them with hot water and then with DI water. If mold develops in vats, replace vat, cap, and tubing (reagent vats – 2 liter 9B884011, 2½ gallon 9B84011, and 5 gallon 9C270001, saline/ DI wash

caps 8JM48042, hose harness with caps 8JM48041).

10.1.16. Replace Tubing/Pump(s)

1. Disconnect the tubing at the check valves and syringe pump.

2. Press the two levers on either side of each pump head and pull out, completely removing the pump assemblies.

3. Press down on the new assemblies until they snap in place.

4. Reattach the tubing at the check valves and syringe pump. Confirm tubes are connected to the correct bottle, as reversing the order will cause the instrument to malfunction.

10.1.17. Needle Replacement

Incorrect needle calibration may result in severe needle damage.

If possible, contact a Helena Service Representative for assistance with replacing and calibrating the sample hander needle.

The top safety cover will need to be removed to replace the needle. To remove the safety cover, extract the (2) screws at the back of the cover, while pulling the cover towards the front of the unit until the slots (in the bottom of the cover) release from the arm housing. The cover should be able to be lifted from the unit. To replace, reverse the procedure.

Note: The instrument should not be operated while the cover is removed to avoid any potential accidents.

There is a (4) way screwdriver in the accessory kit. The tools needed are a #1 Phillips Head Screwdriver and a 1/4" open-ended wrench.

1. Turn the instrument off.

2. Use the top of the needle assembly to lower the needle assembly. Lower the assembly until the nose block is accessible.

3. Using the Phillips head screwdriver, remove the screw located on the front of the nose block.

4. Using the flathead end of the (4) way, place the flat into the slot on the front of the "L"- shaped metal piece and twist. The "L" shaped piece will move to the left and can be more easily removed. Remove the "L" shaped metal piece located on the nose block by sliding the piece forward until it is free of the instrument.

5. The needle tubing is secured to the instrument by a plastic hose clamp. Remove the tubing from the clamp.

6. Enclosed with the replacement needle is a small piece of emory cloth. Obtain the cloth and cut it into two pieces.

7. Grasp the top of the needle assembly and, using a piece of the cloth, grasp the old needle. Pull down on the old needle unit it comes free of the assembly. If there is not enough clearance underneath the needle, pull the entire needle assembly up (the nose block would no longer be visible) and then pull the needle free of the nose block.

8. Feed the needle tubing through the assembly to allow slack in the needle's connection to the assembly.

9. Using the two pieces of emory cloth, grasp both the tubing, just above the needle, and the needle. Pull the needle free of the tubing.

10. Obtain the replacement needle, and using the two pieces of emory cloth,

grasp both the tubing, just above where the needle will be inserted, and the replacement needle. (Use caution not to slide the emory cloth over the surface of the replacement needle.)

11. The needle has a silver end and in approximately the center of this end is an indent. Insert the replacement needle into the tubing up to the indent.

12. With the needle inserted into the tubing, use the emory cloth to grasp the needle and push it up into the nose block. Do not bend the needle. When the needle is properly placed, only it is visible through the opening in the nose block visible from the side.

13. Replace the "L" shaped metal piece by sliding it into place on the front of the nose block. If excessive resistance is felt, the needle may not be far enough up into the nose block.

14. Replace the screw in the front of the nose block.

15. Re-clamp the needle tubing in the hose clamp on the top of the instrument.

16. Complete Section 10.1.17, Needle Calibration.

17. Replace the splash shield by slipping the bent ends of the plastic shield into the metal slots on either side of the front of the instrument and then replace the securing screw.

10.1.18. Needle Calibration

1. In the Sample Handler Calibration and Test menu, go to the Turntable section.

2. In the Turntable section press the *Home* box. After the Turntable rotates to home (if necessary), place the Carousel on the Turntable post toward the front.

3. Place a Test Tube with a barcode label centered on it in position #1 in a Carousel. Then in the Turntable New Position box type 4000 and press the *Move To* box. The Turntable will rotate 90° to place the Carousel into a position under the needle.

4. After that, in the Sample Handler Calibration and Test menu select Carousel. Press the *Home* box and the Carousel will rotate the Test Tube to the #1 position.

5. In the Sample Handler Calibration and Test table select the Pipettor X-Y-Z section in Sample Handler Calibration and Test menu. In the Current Position section, press the *Home* box. The Arm will zero out on all the home switches.

Caution: Damage can occur to the Needle in this section if the wrong sequence of commands is given prior to the Needle being calibrated.

There are two ways to calibrate the needle position in this section: manual and keyboard.

10.1.18.1. Manual Method

NOTE: In this method, the Arm Needle block will be moved manually to each of the (4) Calibrated locations. When manually moving the Arm Needle block, do not get overly aggressive when moving the block. There will be some resistance to movement, just proceed slowly.

1. Using the Linear Bearing, move the Needle over the Test Tube location and visibly position the X-Y position of the Needle over the Test Tube.

2. Using the Rack, slowly lower the Needle into the Test Tube – re-position the X-Y as needed to achieve the centerline.

3. When the Needle is centered, lower the needle down until the needle bottoms out in the Test Tube (maximum 2900 cts in the "Z" axis).

4. When the centerline and the bottom are achieved, go to the Current Position location.

5. The Current Positions of the Needle will be displayed. These X-Y-Z values from the Current Position boxes should be typed into the corresponding Sample Aspirate boxes. That concludes the Calibration of the Sample Aspirate location. In the Current Position section press the Home box and the Arm will return to home position.

6. The next position to be calibrated will be the Wash Station. Again, manually position the Needle over the Wash station center in the X-Y position.

7. Slowly move the Rack down and adjust the X-Y position as needed to center. Push down until the Needle tip goes approximately 1/4" below the surface of the Wash Station nozzle.

8. Again, note the Current Position section. The current positions will be displayed and those X-Y-Z values from the Current Position boxes should be typed into the corresponding Wash boxes in the Calibrated Position section.

9. The next position to be calibrated is the Diluent Aspirate position in the Calibrated Position section.

10. Press the Home box in the Current Position section and the Needle will re-zero to Home.

11. Place an empty Diluent Bottle in the holder to the left of the Wash Station with the lid off.

12. Gently move the needle in the X-Y position over the center of the bottle opening.

13. Slowly move the Needle down (and adjust the X-Y position as needed to center) until the Needle hits the bottom of the bottle. Back up a few steps and make note of the Current Position section.

14. Type the values in the Current Position X-Y-Z into the corresponding Diluent Aspirate boxes in the Calibrated Position section.

15. The last position to be calibrated will be the Sample Dispense in the Calibrated Position section.

16. In this calibration sequence, a sample tray needs to be left in the proper position. In the Sample Handler Calibration and Test table, go to the Tray Y section. Place an IFE Sample Tray in the tray hopper.

17. In the Calibrated Positions box at the Tray Stop location, select the *Move To* box. The belt will drive out to the position in the box. Check to see if the Sample Tray is touching the wall of the Sample Tray X chute. If so, go to the next Selection in the Calibration Table.

18. In the Sample Handler Calibration and Test table select the Tray X section and in the Calibrated Positions box go to Tray Load press the *Move To* box .The Sample Tray will move toward the toggle switch. Check to see if the Sample Tray stopped in a position where the toggle switch roller is centered in the notch of the Sample Tray. If the Sample Tray stopped at the correct position, the notch in the Sample Tray will be centered on the roller of the switch.

19. Leave the Sample Tray at its current location because it will be used to calibrate the sample dispense position of the Pipettor XYZ.

20. Position the Needle over the X-Y center location of the furthest left – most interior – shallow well of the Sample Tray (Figure 10.7).

21. Type the values in the Current Position X-Y into the corresponding white boxes of the Sample Dispense boxes in the Calibrated Position section.

22. Once the X and Y positions have been calibrated, move the needle assembly over a section of the top part of the sample tray. Move the needle Z axis down until the needle makes contact with the top edge of the sample tray. Make note of the Z cts in the current position box. This value should be typed into the Z calibration box of the sample dispense.

23. In the Current Position section, press the Home box and the Arm will re-zero itself. This completes the Manual Calibration of the Pipettor X-Y-Z.

24. After calibrating the X-Y-Z of the sample dispense, type in the X and Y positions in the new position box. Let the unit position the needle automatically. Ensure that the needle is at the correct position for dispense. If so hit home and allow the needle to return to home. If not, adjust as necessary. (Always come from the home position.)

25. Once calibration is complete, lift up the arm window and manually remove the sample tray.

10.1.18.2. Keyboard Method

Note: When Calibrating the X-Y-Z with this method, ALWAYS use the New Position boxes to move the Needle around.

1. ALWAYS leave the Z Axis location at 0 unless calibrating the Z axis.

2. When the instrument has not been calibrated, DO NOT assume that the values in the Calibrated Positions section are correct. They are default values.

3. DO NOT select any of the *Move To* boxes in the Calibrated Positions or fatal damage could occur to the Needle.

4. When calibrating the Z Axis, increment down in small amounts. When nearing the down location, it is recommended that the manual method is used to determine the max down position of the Z Axis.

Note: The sequence of calibration should be done in the same order as the Manual Method. The same rules apply for the Keyboard Method that applies to the Manual Method.

5. Use the New Position boxes to establish the X-Y position first and then the Z position. To get a rough position in the X-Y to start, type in the X-Y values from the Calibrated Positions section into the corresponding New Position boxes (Note: ALWAYS leave the Z Axis location at 0 unless you are calibrating the Z axis) and click the *Move To* box .

6. The Needle will move to that location and values can be added or subtracted for new positions.

7. After the X-Y-Z positions have been determined, enter those values in the corresponding boxes in the Calibrated Positions section.

10.1.19. Electrode Replacement

1. Using a small flathead screwdriver, loosen the screw securing the carbon electrode on the cassette. Take care *not to remove the screw completely,* given its small size (Figure 10-8).

2. Remove the old carbon electrode (Figure 10-9).

3. Place the new carbon electrode onto the peg and replace the screw.

10.1.20. Backup Parameters

1. Under 'Files' on the main menu, select 'Backup.' This gives the user the ability to backup both setup and calibration data.

2. The user is given the ability to specify a location (drive and/or folder) for the back-up data to be stored. The user must specify a location each time the system is backed up.

3. There is also a corresponding operation labeled 'Restore.' After selecting this operation, the user will need to specify which backup file the system will be restored to.

4. The user can manually backup or restore the system as often as necessary.

10.1.21. Electrophoresis High Voltage Jacks

The electrophoresis high voltage jacks located on the back of the instrument provide access to verify the voltage present in the electrophoresis chamber with a volt meter.

CAUTION: The SPIFE 4000 instrument contains high voltages, which can be extremely dangerous, inside the electrophoresis jacks.
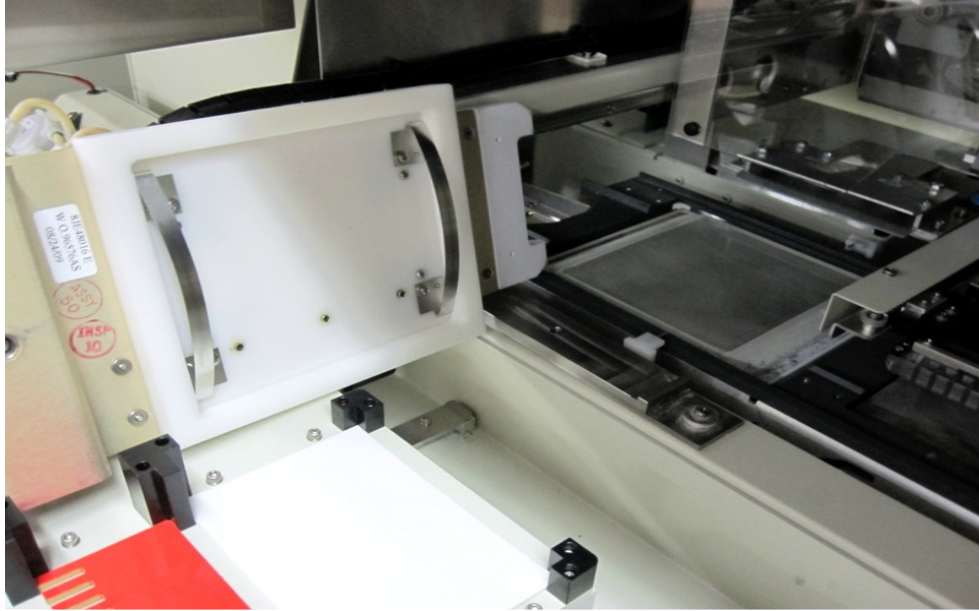
Figure 10-1 Electrophoresis Platen
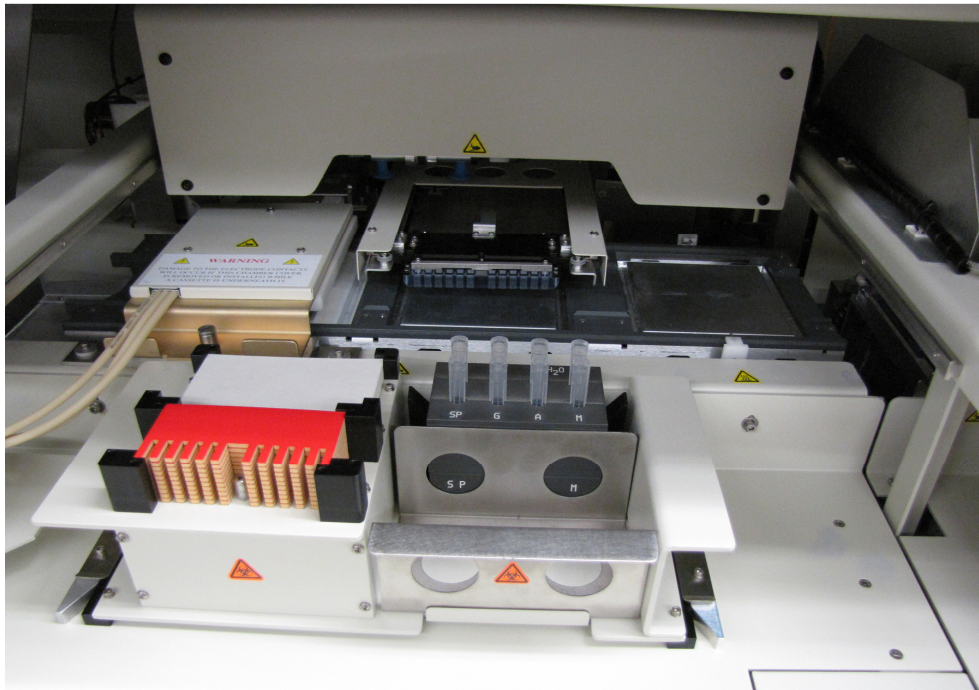
Figure 10-2 Antisera station
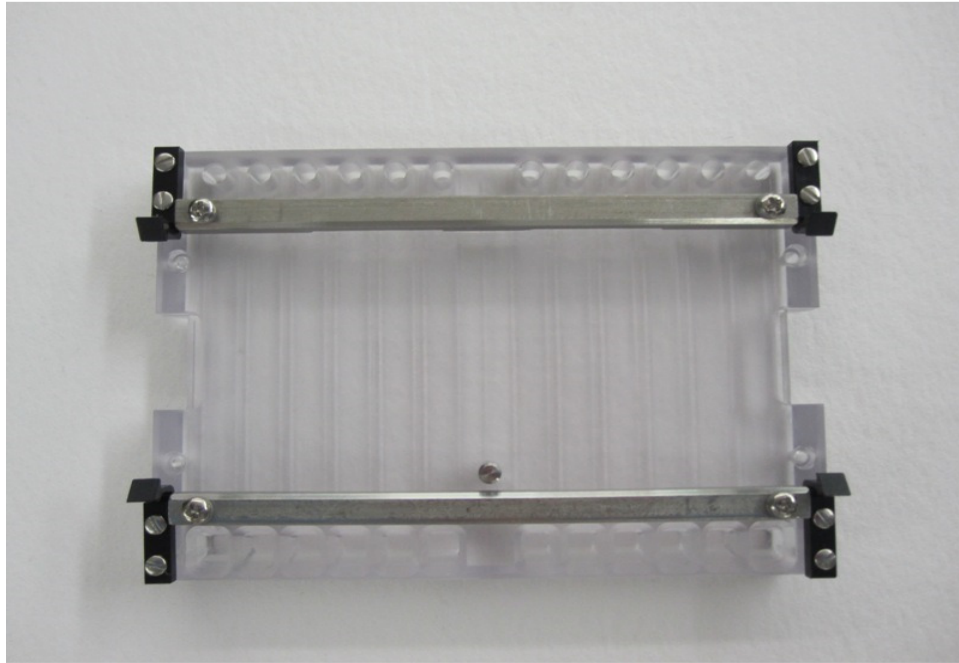
Figure 10-3 Antisera Template
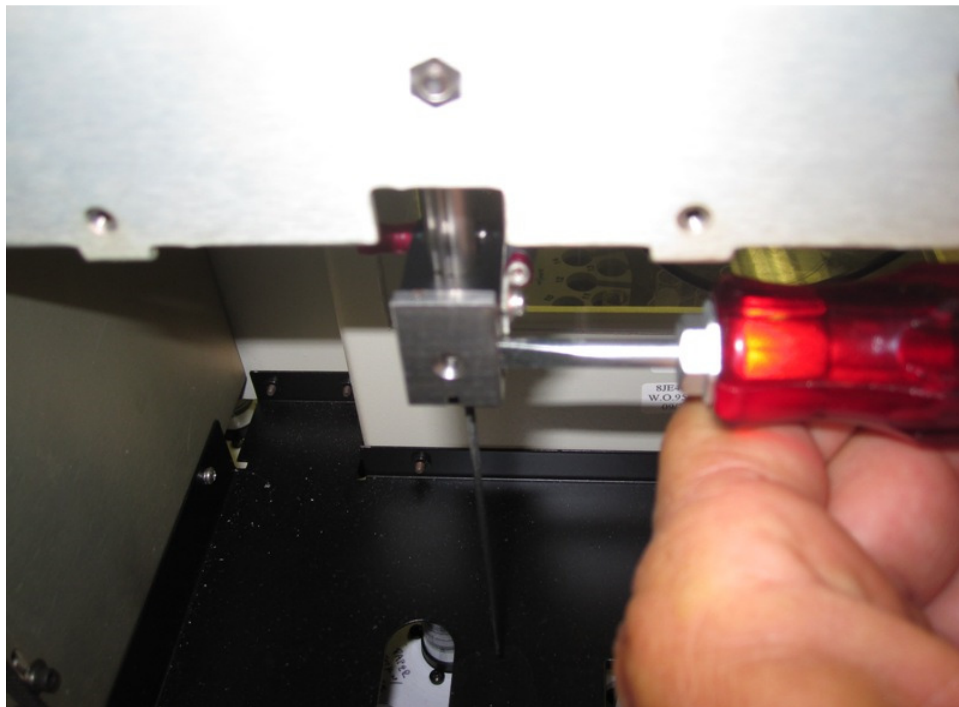
Figure 10-4 Remove Needle Cover
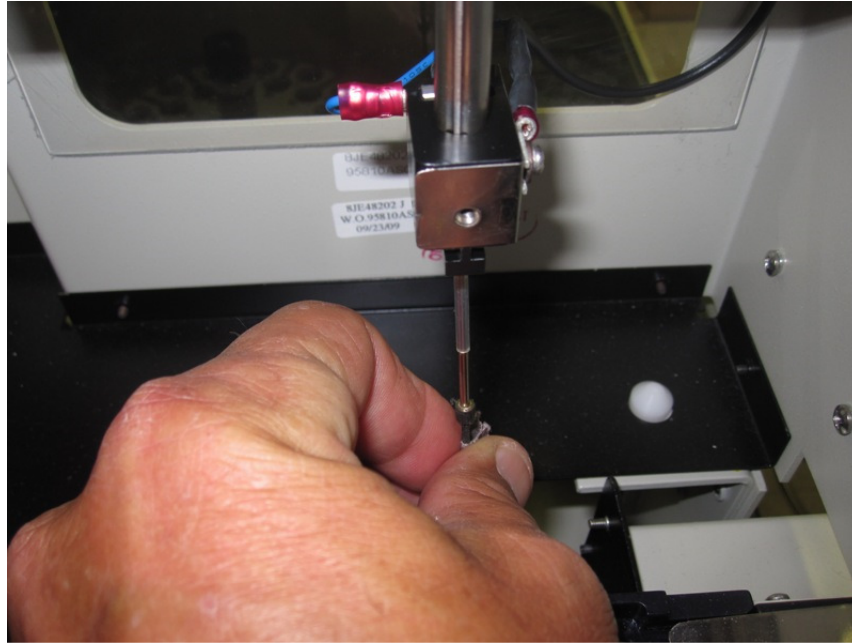
Figure 10-5 Remove Needle
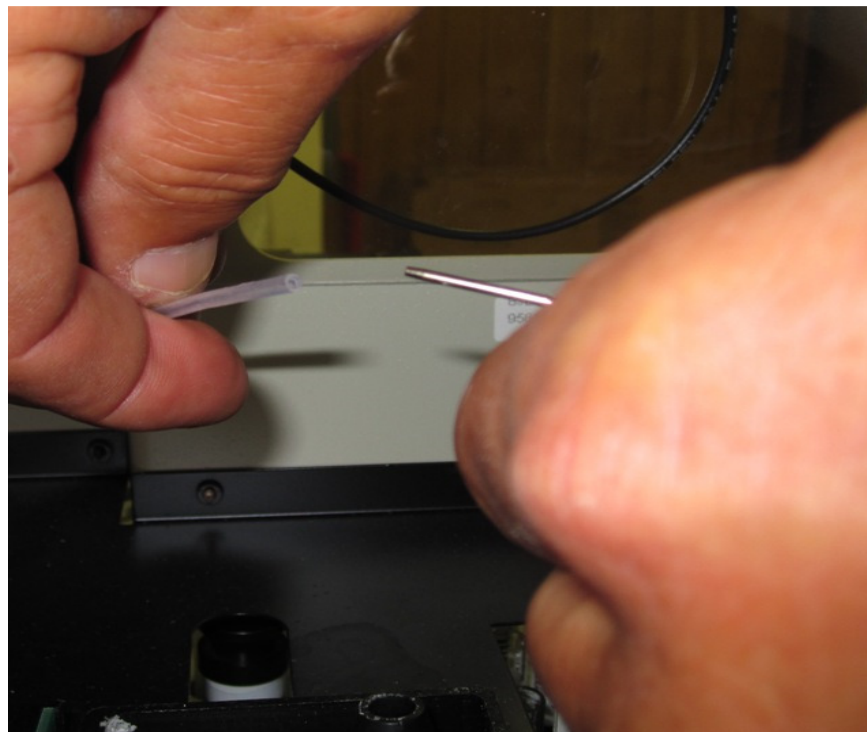
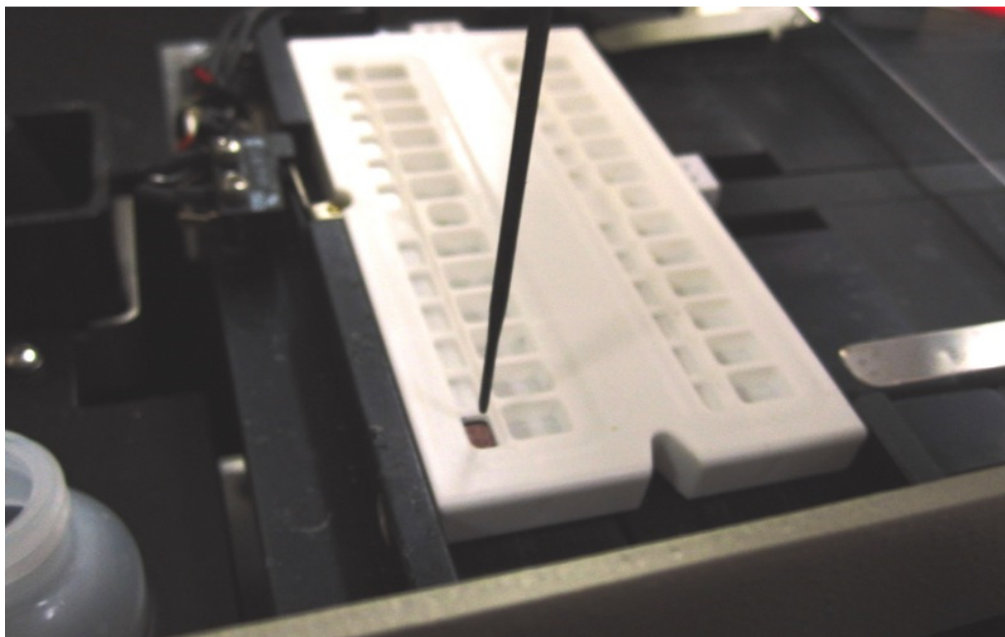

Figure 10-6 Replace Tubing

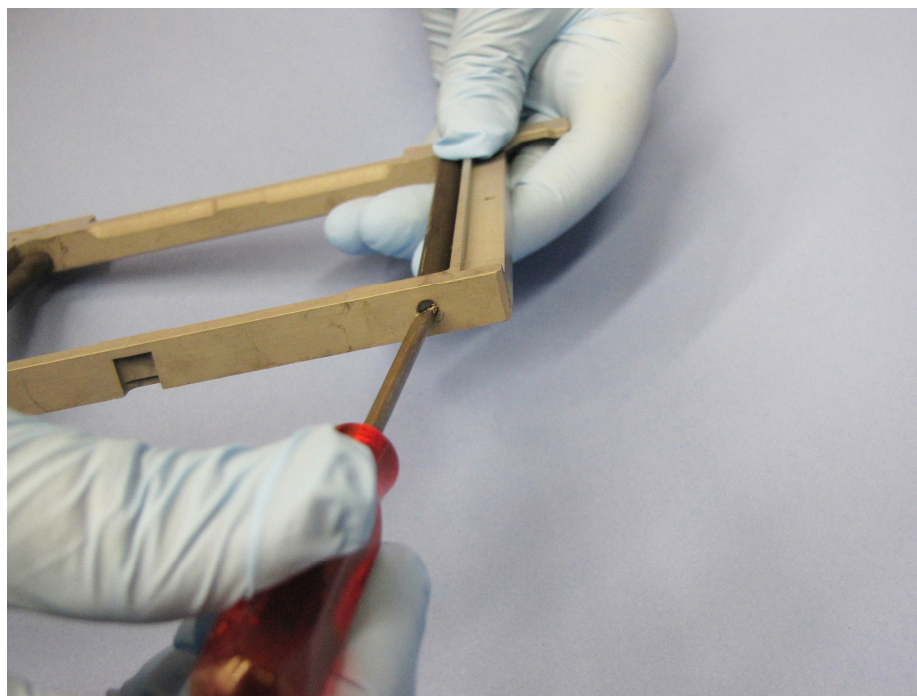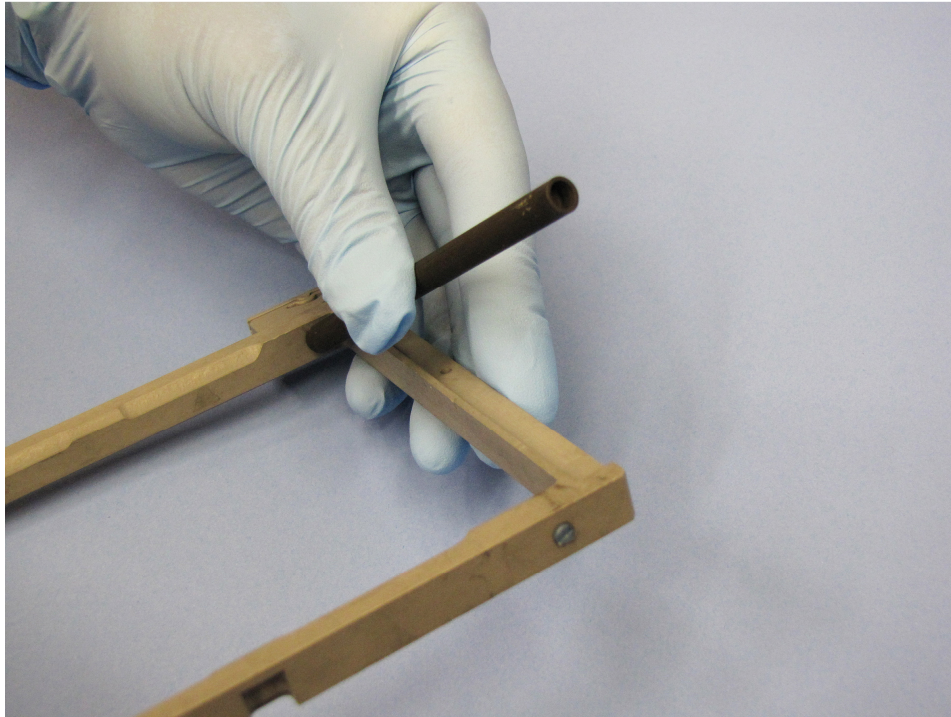**Figure 10-7 Sample Handler Needle Calibration Home Position**

Figure 10-8 Carbon Electrode Replacement, loosen screw

**Figure 10-9 Carbon Electrode Replacement, remove carbon electrode
(Do not remove screw)**

Month/Year: **Serial Number:**

Table 10.1 SPIFE® 4000 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 cassettes and electrodes																															
Check for cassettes throughout the system																															

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
Inspect for cleanliness																															
Clean Antisera Template if IFE tests done																															
Clean blotter suction cups with DI water																															
Change pipette tips																															
Clean surface and sides of Electrophoresis platen																															
Clean surface and sides of Antisera platen																															
Clean surface and sides of Pre-Dry platens																															
Examine cassette electrodes for corrosion																															
Clean Scanner area																															
Wash/ prime Electrophoresis Sample Handler before and after use. Prime daily if not in use.																															

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 you are uncertain about how to perform any step, please contact Helena Laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information. Page 1

Month/Year:　　　　**Serial Number:**

Table 10.1 SPIFE® 4000 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 Water Bottle																															
Clean sample needle wash block																															
Archive and Delete worklists																															
Monthly Items																															
Bleach sample delivery system																															
Dynamic coating of antisera template																															
As Needed																															
Inspect Waste Overflow Vat																															
Replace fuse(s)																															
Replace contact sheet																															
Clean instrument																															
Rinse/ Replace fluids vat(s)																															
Replace tubing/pump																															
Inspect/clean needle*																															
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 you are 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 4000 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. Also, refer to the component owner's guide for troubleshooting procedures.

Table 10-2 Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
Error message appears	Refer to the message	Perform actions in message; if recurs, record the message and call Helena Laboratories for assistance. Perform the action indicated by the message BEFORE clicking on message. **Do not click Retry without correcting the error.**
Power switch on, no power	Power cord not plugged in	Plug in power cord.
	Bad wall outlet	Use another outlet.
	Blown fuse	Replace fuse (See 10.1.11).
No display (dark screen)	Brightness turned down	Turn up brightness on display, see monitor owner's guide.
	Display power switch off	Turn on display power switch.
No presentation on display	Loose interface or power cable	Push cable connections in fully.
	Defective interface cable	Call Helena Laboratories.
No printout is produced	Did not select Print	Select Print, select a Printer, a Report, Number of copies, and OK (See 7.2.3).
	Loose interface cable	Push cable connections in fully.
	Paper installed improperly	Reinstall paper.
	Defective interface cable	Replace cable.
	Improper printer setup	Refer to printer owner's guide for settings.
	Printer off-line but printout requested	Leave printer on-line during operation.
Poor quality printout	Needs toner/ink	Replace toner/ink cartridge.
	Other problem	Refer to printer owner's guide.
No response to keystrokes or mouse movement	Mouse cable disconnected	Firmly insert keyboard or mouse plug into receptacle on back of computer.
	Cursor on active screen behind visible screen	Click Alt-Tab.

PROBLEM	POSSIBLE CAUSE	SOLUTION
	Undetermined cause	Press **Alt-Ctrl-Del** key to reset program. Select Processes first, and terminate the Scan.exe process, then Applications, and terminate the SPIFE 4000 application (unsaved data will be lost).
		Call Helena Laboratories.
Control and/or NDDC out of range	Scanner Issue	Clean scanner glass.
No sample dispensing into sample tray	Empty DI water bottle	Refill DI Water bottle.
	Clogged needle	Clean needle (Section 10.1.5).
	No sample in carousel	Load carousel (Section 7.1.1.10).
	Low sample volume	Minimum sample volume 500µl. User may hand-pipette smaller sample size into cups if necessary (See section 7.1.1.11).
	Air bubbles in DI water tubing	Prime instrument (Section 7.1.2).
	Air bubbles, foam in sample	Examine sample tube.
	Sample tube not seated corrected	Examine sample tube.
	Tubing/Pump failure	Replace tubing/ pump head (Section 10.1.13) and call Helena Laboratories.
	Test not programmed for full carousel of samples.	Check test parameters.
	Drain line clogged or excessive loop to waste chamber	Clean/replace tubing.
No sample applied to plate	Incorrect blade used	Check blades, check for application mark on plate.
	No sample in cup	Insufficient sample volume.
Needle wash overflow sensor triggered	Saline buildup	Rinse with DI water. Check drain lines for clogs or excessive loop to waste jug.
Plate does not proceed from elevator floor to electrophoresis chamber	Error message previously overridden	Ensure that all gel processor and scanner safety shields are closed, and that the waste jug is empty. Ensure that Antisera

PROBLEM	POSSIBLE CAUSE	SOLUTION
		Tray is in place.
Electrophoresis chamber not reaching programmed temperature	Fuse blown	Check fuses on back of unit. Replace, if required (Section 10.1.11).
Incubator or dryer too hot	Electrical problem	Call Helena Laboratories.
Fan does not run	Restricted air flow	Remove obstructions blocking vents and check to be sure enough air space surrounds instrument.
	Electrical problem	Call Helena Laboratories.
Stainer chamber incorrectly filling/draining	Stainer Value/Pump Failure	Call Helena Laboratories.
Stainer level detector failures	Electrical problem	Ensure that stain vat(s) are correctly connected to the instrument and that the vat(s) contain fluid.
Electrophoresis high voltage error	Fatigued Contact Sheet	Replace contact sheet (Section 10.1.10).
Electrophoresis gel has repeated distortion in same area	Fatigued Contact Sheet	Replace contact sheet (Section 10.1.10).
	Insufficient DI water in DI water (surfactant) jar	Refill DI water (surfactant) jar
	DI Water (surfactant) Pump failure	Replace DI water (surfactant) peristaltic pump and call Helena Laboratories (see Section 10.1.15).
Gel appears unacceptable	Programming problem	Check programming for the test against your record of programmed parameters and reenter, if parameters have been changed (see Section 6).
	Dry gels	Overblotting, left in humidor too long.

PROBLEM	POSSIBLE CAUSE	SOLUTION
	Uneven predry with resultant excess stain	Insufficient DI water in DI well of antisera block.
Gel appears unacceptable	Insufficient predry	Predry platen unable to rise sufficiently. Clean sides and moat of predry platen (see Section 10.1.3).
Gel appears unacceptable	Other	Check reagent bottles and repeat test. Ensure that stain has been changed within the last 10 gels. Ensure stain made with glacial acetic acid Replace destain. If still unacceptable, call Helena Laboratories.
Improper or no dilutions on IFE plate	Insufficient saline in diluent bottle.	Replace diluent.
Inappropriate staining or "leakage" on IFE plate.	Damaged or dirty template	Clean template thoroughly. Inspect template for damage (see Section 10.1.2).
Blotchy background stain on IFE	Tris buffer made up incorrectly, connected incorrectly.	Replace reagents, verify connections.
Scanner began scanning gel too early on plate	Scanner identified a mark on the gel as albumin	Inspect the gel for extraneous staining, debris, and rescan. If problem persists, call Helena Laboratories.
No fraction marks on patterns	Float or Fixed Fraction detection in use. Fraction sensitivity set to zero.	Under Scan in Test Setup, ensure that "No" is checked for Fixed or Float fraction.
Auto Interpretation comments not applied	Incorrect test selected	Check Comments in Setup.
Auto Interpretation comments not applied	Auto comment not enabled	Check Test Setup. Right Click on scan and select Auto comment.
Auto Interpretation comments not applied	Ranges not entered	Verify ranges present.
Unable to apply reference overlay	No scan labeled Reference.	Label a scan on the worklist "reference."

PROBLEM	POSSIBLE CAUSE	SOLUTION
	Reference Overlay not selected on Overlay option at scan, or under Display Options.	The scans following the reference scan may have reference overlays applied.
Unable to apply reference overlay	Scan has been rescanned	Rescan entire plate.
Patient Overlays not applied	Not enabled in test setup Incorrect test or date range identified in criteria Not in display or print options	Review test setup. Patient overlay may also be enabled at the level of the scan. Select Auto Overlay.
Most recent overlay not applied	Overlaid scan more recent than original scan	Select Auto Overlay.
Unable to view results or ranges	View option not selected	Check option to view under Display (see Sections 6.3.2, and 7.3.2.2).
Auto Interpretation comments not visible	Parameters not designated Not applied to correct test in test setup Not enabled Scan options in test setup Disabled under "Comments" on the scan	Check settings (see Sections 6.4, and 7.3.1.8).
Software lockup during a run	In the case of a software lock up during a run, if the instrument is continuing to process gels, do **not** attempt to reboot the system until after the gels have been processed. In this circumstance, it is possible that positive patient identity may be preserved if the system is not restarted until after the gels have been completed. After the run is over (or if the system is not processing gels), attempt to close out the software by clicking the **X** in the upper right hand corner. If this does not work, open the computer task manager and shut down the program. Reboot Windows and restart the SPIFE 4000 instrument.	
No response to keyboards or mouse movement	Inactive window displayed in front of active window	Press Alt-Tab.
Data does not export to the LIS	Instrument not connected to LIS or faulty connection	Verify connection to LIS.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Data does not export to the LIS	Communication settings incorrect	Verify that LIS communication settings match SPIFE 4000.
Data does not export to the LIS	Other	Contact local information technology services. Contact Helena Laboratories.
Data does not export to LIS	Incorrect Export destination selected	Review Export Settings.
Data does not export to LIS	Selected Export Settings, but not Export	Click Export.
Data does not import from the LIS	LIS not connected, faulty connection	Verify connection.
Data does not import from the LIS	LIS not connected, faulty connection	Verify connection.
Data does not import from the LIS	Communication settings don't match	Verify that communication settings in the SPIFE 4000 are identical to settings in the LIS.
Data does not import from the LIS	Bar code labels on tubes not read	View scan properties. If bar-code on sample was not read, the sample identifier will be blank. Type the bar code number into the key ID for that patient, and manually import the data.
Data does not import from the LIS	Incorrect label, typo in LIS	Verify data.
	Other	Contact local information technology services. Contact Helena Laboratories.

10.2. 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. In no event will Helena Laboratories be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement at the manufacturer's option.

All software and driver disks provided with this instrument must be retained and be accessible in the sleeves provided at the end of this manual for the warranty to be valid.

Warranty Duration

This warranty is provided to the original purchaser for six months from date of sale.

Warranty Exclusions

WARNING! Do not use the SPIFE 4000 for any purpose other than that described in this manual. Modification of the software or the use of the SPIFE 4000 computer to run other programs may affect the operation and reliability of the instrument. Helena Laboratories is not liable for any consequential damages should the customer choose to ignore this warning.

Section 11 - Symbology

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

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

	Manufacturer
	Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC
	Caution, 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, laser hazard: Avoid exposure. Do not stare into beam.
	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.

Section 12 - Communication Specifications

12.1. Interface Specifications

The SPIFE import/export interface conforms to the EIA standard RS-332C and is configured as a DTE (Data Terminal Equipment). Only RECEIVE DATA, TRANSMIT DATA and SIGNAL COMMON lines are used. The baud rate is user selectable at 1200, 2400, 4800, 9600 10400, 14400, 19200, or 28800 baud. The number of data bits may be set at 7 or 8 and the number of stop bits may be either 1 or 2. Parity may be set to none, even odd, mark, or space. Protocol options include no protocol, XON-XOFF flow control, or ASTM protocol. The SPIFE 4000 does not order the tests.

12.2. Mechanical Specifications

9 pin D-shell connector (male):

Pin	Description
1	receive line detect
2	receive data*
3	transmit data*
4	data terminal ready
5	signal common*
6	data set ready
7	request to send
8	clear to send
9	ring indicator

*only these lines are used by the SPIFE 4000 software.

12.3. Communications Protocol

The protocol used by the SPIFE software is user selectable (see Section 6.6). Listed below are the protocol options available.

12.3.1. <u>No Protocol</u>

Data is transmitted and received as ASCII text with no flow control or error checking/correction. This option is not recommended unless the SPIFE 4000 is to be connected to a terminal.

12.3.2. XON-XOFF Flow Control

Data is transmitted and received as ASCII text and XON/XOFF (ASCII codes 17 and 19) handshaking is used to control data flow. When importing, the SPIFE 4000 software will transmit an XOFF character when its communications buffer becomes three quarters full. Data transmission should stop at this point. The SPIFE 4000 software will process the data in the buffer and when it becomes half empty, an XON character will be transmitted and data transmission can resume. When exporting, the SPIFE 4000 will recognize an XOFF character and stop transmission until an XON character is received. There is no error checking or correction when using this protocol.

12.3.3. ASTM Protocol (E1381-95 & E1394-97)

This protocol provides procedures for link connection and release, delimiting and synchronism, sequence control, error detection and error correction. Data is transmitted and received as ASCII text and some restrictions are placed on which characters can be used in the data content. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, and <DC4>.

12.3.3.1. Transfer Phases

There are three distinct phases in transferring information between the SPIFE 4000 and the computer system. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases assure the actions of sender and receiver are coordinated. The three phases are Establishment, Transfer, and Terminate.

12.3.3.1.1. Establishment Phase

The Establishment phase determines the direction of information flow and prepares the receiver to accept information. The sender notifies the receiver that information is available. The receiver responds that it is prepared to receive before information is transmitted. A system which does not have information to send normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the <ENQ> character to the intended receiver. Upon receiving the <ENQ>, the receiver prepares to receive information. All other characters are ignored. It replies with the <ACK> character to signify it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

A receiver that cannot immediately receive information replies with the <NAK> character. Upon receiving the <NAK>, the sender must wait at least 10 seconds before transmitting another <ENQ>.

Should both systems simultaneously transmit an <ENQ>, the data link is in contention. The SPIFE 4000 has priority to transmit information when contention occurs. Contention is resolved as follows. Upon receiving a reply of <ENQ> to its transmitted <ENQ>, the computer system must stop trying to transmit, it must prepare to receive. When the next <ENQ> is received, it replies with an <ACK> or <NAK> depending on its readiness to receive.

12.3.3.1.2. Transfer Phase

During the transfer phase, the sender transmits information to the receiver. The transfer phase continues until all information has been sent.

Information is sent in frames, each frame contains a maximum of 247 characters (including frame overhead). Records or data that are longer than 240 characters are divided between two or more frames. A frame is one of two types, an intermediate frame or an end frame.

Intermediate frames terminate with the characters <ETB>, checksum, <CR> and <LF>. End frames terminate with the characters <ETX>, checksum, <CR> and <LF>. The frame structure is illustrated below:

Intermediate Frame:
 <STX> FN "data" <ETB> C1 C2 <CR> <LF>

End Frame:
 <STX> FN "data" <ETX> C1 C2 <CR> <LF>

Where:

<STX> - Start of text transmission character

FN - single digit frame number "0" to "7"

"data" - data content

C1 - first character of checksum

"0" - "9" & "A" - "F"

C2 - second character of checksum

"0" - "9" & "A" - "F"

<ETB> - end of transmission block character

<ETX> - end of text transmission character

<CR> - carriage return character

<LF> - line feed character

The frame number is an ASCII digit ranging from "0" to "7." The frame number begins at "1" with the first frame of the transfer phase. The frame number is incremented by one for each new frame transmitted. After "7," the frame number rolls over to "0."

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters which are sent after the <ETB> or <ETX> character. The checksum is computed by adding the binary values of the frame characters, keeping the least significant

eight bits of the result. The checksum is transmitted as ASCII hexadecimal.

The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the data is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

After the frame is sent, the sender stops transmitting until a reply is received. The receiver replies to each frame. A reply of <ACK> signifies the last frame was received successfully and the receiver is prepared to receive another frame.

A reply of <NAK> signifies the last frame was not received successfully; the receiver is prepared to receive the frame again. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected. A frame is not successfully received if any of the following occur:

- Any character errors are detected (parity error, framing error, etc.).

- The frame checksum does not match the checksum computed on the received frame.

- The frame number is not the same as the last accepted frame or one higher (modulo 8).

A frame may be retransmitted up to 6 times. If after 6 tries the frame has still not been successfully transmitted, the sender transmits an <EOT> and regards the data link to be in the neutral state.

A reply of <EOT> signifies the last frame was received successfully, the receiver is ready to receive another frame, but is a request to the sender to stop transmitting. The sender does not have to stop transmitting after receiving the request. If it continues to transmit, there is a possibility of overflowing the receiver's buffers. If the sender chooses to ignore the <EOT>, the receiver must retransmit the request.

12.3.3.1.3. Termination Phase

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all data has been sent.

The sender transmits the <EOT> character and then regards the data link to be in a neutral state. Upon receiving the <EOT>, the receiver also regards the data link to be in the neutral state.

12.3.3.1.4. Timeouts

The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

During the establishment phase, the sender sets a timer when transmitting the <ENQ>. If a reply of an <ACK>, <NAK> or <ENQ> is not received within 15 seconds, a timeout occurs and the sender regards the link to be in the neutral state.

During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an <ENQ> is not received within 20 seconds, a timeout occurs and the receiver regards the link to be in the neutral state.

During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts transmission by proceeding to the termination phase.

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards

the last incomplete record or set of data and regards the link to be in the neutral state.

12.4. Data Transfer Format

The SPIFE 4000 software in general adheres to the ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer System. The only exception is the format for transfer of patient information. Because the SPIFE 4000 software allows user designation of the demographic fields, and because the ASTM Standard defines the demographic fields and the order in which they will be transmitted, deviation from the standard can occur. However, the end user can define the SPIFE 4000 demographics to match those defined in the ASTM standard, if strict adherence to the standard is required.

12.4.1. General Information

Data is exchanged in records of different types. Each record is introduced by field number 1 identifying the record type, and terminated by a carriage return. There are 7 record types recognized by the SPIFE 4000: Header Record (H), Patient Record (P), Test Order Record (O), Result Record (R), Comment Record (C), Request Information Record (Q), and the Terminator Record (L).

NOTE: The record ID field is not case sensitive.

Records are related to each other in a definite hierarchy. At level zero is the Header record and Terminator record. At level one is the Patient record and the Request-Information record. At level two is the Test Order record. At level three is the Result record. Comment Records do not have an assigned level. A Comment record always relates to the immediately preceding Patient, Order, or Result record. Therefore if a Comment record were to follow a patient record (level 1), then the Comment record would be treated as a level 2 record.

A sequence of patient records, order records, or result records at one level is terminated by the appearance of a record type of the same or higher level. Thus, a sequence of results for one patient is terminated by the next patient record.

Each record is composed of fields which are position sensitive and variable in length. Each field is separated by a field delimiter (the vertical bar, "|"). The position sensitivity requires that when the contents of a field are null, its corresponding field delimiter must be included in the record to ensure that the *i'th* field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields; that is, if the tenth field was the last containing data, the record could terminate after the tenth field (with a carriage return) and therefore would contain only nine delimiters.

A system may transmit a null value for a field because (1) it does not know the value, (2) it knows the value is irrelevant to the receiving system, or (3) the value has not changed since the last transmission, or any combination thereof. Because the sending system can use null values to indicate no change, a null value does not overwrite existing data in the receiving system. The transmission of a double quote (ASCII 34) in a field tells the receiving system to replace any existing value with a null value.

Each field may be composed of sub-components. These sub-components are separated by a component delimiter (the caret, "^"). The component delimiter is used to separate data elements of fields of a hierarchical or qualifier nature.

12.4.1.1. Header Record

The header record must always be the first record in a transmission. When the SPIFE 4000 transmits a header record it will have the following format:

H|\^&||HELSP4000|Helena Laborato-ries^SPIFE 4000^*serial number*|P.O. Box 752 Beaumont^TX^77704-0752^USA|Toll Free: 800-231-5663 Local: 409-842-3714<CR>

HELSP4000 Password indicating the sending instrument is a Helena SPIFE 4000

> *serial number* – Serial number of the SPIFE 4000.

When the SPIFE 4000 receives a header record it only considers the first two charac-ters to be significant, all other characters up to the carriage return will be ignored. There-fore, the minimum characters the computer system needs to transmit for the header record would be:

> H|<CR>

12.4.1.2. Patient Record

When importing data using ASTM, demo-graphic data will be assigned to an ASTM field in demographic setup. The user may override this automatic assignment in Im-port/Export setup, (see Section 6.6.)

12.4.1.3. Order Record

The SPIFE 4000 will transmit an order record immediately preceding any result records for a patient as required in the ASTM specifica-tion. The format will be as follows:

O|1|*specimen identifier*|*instrument specimen identifier*|^^^*test name*<CR>

> *specimen identifier* – Number read from bar code on specimen tube.

> *instrument specimen identifier* – The gel identifier and sample position where this specimen was run.

> *test name* - Name of the test per-formed.

The SPIFE 4000 currently does not recognize test order records transmitted by the comput-er system.

12.4.1.4. Result Record

Each fraction and each ratio of a patient scan will be transmitted as a separate result rec-ord. If multiple results for each fraction are required, they will be transmitted in separate records. For example, if the percent and units values of a fraction are required, they will be transmitted in separate records.

A fraction result will be transmitted in the following format:

R|n|^^^*test name^fraction name^type*|*nnnn.nn*|*unit of measure*||*nnnn.nnnnnn.nn*|*f*||F||| *yyyymmddhhmmss*|*yyyymmddhhmmss*<CR>

A ratio result will be transmitted in the follow-ing format:

R|*n*|^^^*test name^ratio name*|*nnnn.nn*|||||F||| *yyyymmddhhmmss*|*yyyymmddhhmmss*<CR>

> *n* - Sequence number. For the first result record, the value will be 1, for the second, 2, ... etc.

> *test name* - Name of the test per-formed.

> *fraction name* - User defined fraction name.

> *ratio name* - User defined ratio name.

> *type* - Result type, will be one of the following: % (percent), U (units), or I (inte-grals).

> *nnnn.nn* - Fraction or ratio value.

> *unit of measure* - User defined unit of measure. If the result type is "I," this field will be null.

> *nnnn.nn-nnnn.nn* - User defined refer-ence range.

> *f* - Result abnormal flag. Will be one of the following: L (low), N (normal), or H (high).

> *yyyymmddhhmmss* - Date and time the test was started and completed. The date is transmitted with the year first, month second and day last.

The SPIFE 4000 does not recognize result records transmitted by the computer system.

12.4.1.5. Comment Record

The SPIFE 4000 will transmit comment records in the following format:

C|1|I|*comment text*<CR>

The SPIFE 4000 does not recognize comment records transmitted by the computer system.

12.4.1.6. Request Information Record

The SPIFE 4000 can transmit a request to import patient demographics. This request must be user initiated. The format will be as follows:

Q|1|patient ID||||||||||D<CR>

patient ID - A user entered value which the computer system will recognize as the identifier for a single patient or a group of patients.

The SPIFE 4000 does not recognize request information records transmitted by the computer system.

12.4.1.7. Terminator Record

The terminator record must be the last record in a transmission. When the SPIFE 4000 transmits a terminator record it will have the following format:

L|1|<CR>

When receiving a terminator record, the SPIFE 4000 only considers the first character significant, all other characters up to the carriage return will be ignored.

12.4.1.8. Importing External Data into the SPIFE 4000

To import external data, such as IFE Immunoglobulins or Total Proteins, a test order record and a result record for each external result needs to send immediately following the patient record for which the external data applies. See the example below:

08:32:48:15 |<-- STX>2P|1|||PAT296862|Patterson^Helen||20030121|F|black||||Alford^G.|9||4' 11"|129||||||20000000||176||||||||||5<CR><ETX>07<CR><LF>

08:32:48:29 |--> <ACK>

08:32:48:51 |<-- <STX>3O|1|001||^^^Serum Immunofixation (IFE)<CR><ETX>A6<CR><LF>

08:32:48:52 |--> <ACK>

08:32:48:74 |<-- <STX>4R|1|^^^Serum Immunofixation (IFE)^IgG^U|5|mg/dl<CR><ETX>29<CR><LF>

08:32:48:87 |--> <ACK>

08:32:49:10 |<-- <STX>5R|2|^^^Serum Immunofixation (IFE)^IgA^U|6|mg/dl<CR><ETX>26<CR><LF>

08:32:49:23 |--> <ACK>

08:32:49:46 |<-- <STX>6R|3|^^^Serum Immunofixation (IFE)^IgM^U|7|mg/dl<CR><ETX>35<CR><LF>

08:32:49:48 |--> <ACK>

The third field in the test order record contains the specimen ID, which is the identifying number sent in the query record. This ties the test order record and the following results records to the patient. In the above example the specimen ID is '001'. The test name in the order record and the result records must match exactly the test name in the QuickScan Touch. In the example above, the test name is 'Serum Immunofixation (IFE)'. The immunoglobulin name or fraction name in the result record must also match exactly the immunoglobulin name or fraction name in the SPIFE 4000. In the above example the immunoglobulin names are 'IgG', 'IgA' and 'IgM'. The 'U' following the immunoglobulin names is

required and indicates the values are unit values. The value for the immunoglobulin or fraction follows the name field. In the example above the value for IgG is 5, the value IgA is 6 and the value for IgM is 7. The unit of measure follows the values and should also match what is defined in the SPIFE 4000.

Section 13 - Index

$$C\hspace{-0.3em}\mathrm{E}$$

SPIFE 4000

Operator's Manual

Software Version 2.0

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

Helena Laboratories
P.O. Box 752
Beaumont, Texas 77704–0752
USA

EC REP

Helena Laboratories UK, Ltd
Queensway South
Team Valley Trading Estate
Gateshead
Tyne & Wear
United Kingdom
NE11 0SD