



QuickScan Touch *plus* Visible Scanning Densitometer



Operator's Manual
Catalog Numbers 1640, 1646, and 1647

QuickScan Touch *plus*
Visible Scanning Densitometer

Operator's Manual

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.**

QuickScan Touch *plus* Program License Agreement

This copy of the QuickScan Touch *plus* 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 diskette 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 diskette 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 diskette returned to the address below during the 6-month period.

2. THIS IS THE ONLY WARRANTY MADE BY HELENA COVERING THE QuickScan Touch *plus* 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, Corp., 1530 Lindbergh Drive, Beaumont, TX USA. 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

Section 1 - Instrument Use and Function.....1-1

Section 2 - Principles of Operation.....2-1

Section 3 - Precautions and Limitations3-1

Section 4 – Hazards.....4-1

Section 5 – Installation.....5-1

Section 6 - User Setup.....6-1

Section 7 - Operating Instructions.....7-1

Section 8 - Test Functions and Quality Control.....8-1

Section 9 - Performance Specifications9-1

Section 10 - Maintenance, Troubleshooting, and Warranty10-1

Section 11 - Symbology11-1

Section 12 - Communication Specifications.....12-1

Section 13 - V8 interface (optional).....13-1

Section 14 - Myeloma Module (optional).....14-1

Section 15 - SPIFE Nexus (optional).....15-1

Section 16 INDEX.....16-1

List of Figures

Figure 1-1 QuickScan Touch <i>plus</i> System.....	1-2
Figure 2-1 Functional Units of the QuickScan Touch <i>plus</i> Block Diagram.....	2-3
Figure 2-2 Visible Scan Optics.....	2-3
Figure 2-3 Multi-user with Server.....	2-4
Figure 5-1 Back view of computer	5-6
Figure 6-1 Main Menu.....	6-29
Figure 6-2 Sign-In Menu.....	6-29
Figure 6-3 Setup, Add Demographic	6-30
Figure 6-4 Setup, Composite Identifier.....	6-31
Figure 6-5 Setup, Tests.....	6-32
Figure 6-6 Tests, Test Types	6-33
Figure 6-7 Tests, Gel Properties	6-34
Figure 6-8 Tests, Scan Settings	6-35
Figure 6-9 Tests, Scan Locations, IFE.....	6-36
Figure 6-10 Tests, Scan Locations, SPE	6-37
Figure 6-11 Tests, Setup, Fractions/ Ratios/Ranges	6-38
Figure 6-12 Tests, Patient Demographics	6-39
Figure 6-13 Setup, Worklist.....	6-40
Figure 6-14 Edit Worklist Template.....	6-41
Figure 6-15 Setup, Comments.....	6-42
Figure 6-16 Comments with Auto Interpretation	6-43
Figure 6-17 Setup, Reports.....	6-44
Figure 6-18 List Report	6-45
Figure 6-19 Levey-Jennings Report.....	6-46

Figure 6-20 Standard Report	6-47
Figure 6-21 Setup, Import/Export.....	6-48
Figure 6-22 Setup, Sample Handler	6-49
Figure 6-23 Setup, Quality Control	6-50
Figure 6-24 Setup, Users and Passwords	6-51
Figure 6-25 Setup, SQL Server Connection	6-52
Figure 6-26 Setup, SPIFE Touch	6-53
Figure 6-27 Setup, Language	6-54
Figure 7-1 Main Menu.....	7-44
Figure 7-2 New Worklist.....	7-44
Figure 7-3 Label Worklist.....	7-45
Figure 7-4 Add Patient ID.....	7-45
Figure 7-5 Add Patient to Import List	7-46
Figure 7-6 Import Patient Info	7-46
Figure 13-1 Main menu with V8 icon.....	13-5
Figure 13-2 Connecting the QST to the V8.....	13-6
Figure 13-3 V8 Test Setup	13-6
Figure 13-4 Import V8 Scans	13-7
Figure 14-1 Main Menu.....	14-13
Figure 14-2 Users and Passwords.....	14-13
Figure 14-3 Open Worklist in the Review folder	14-14
Figure 14-4 Review folder.....	14-14
Figure 14-5 Open Worklist in the Re-Edit folder	14-15
Figure 14-6 Re-Edit folder.....	14-15
Figure 14-7 Open Worklist in the Accept folder.....	14-16

Figure 14-8 Accept folder	14-16
Figure 14-9 Message Flags.....	14-17
Figure 14-10 Sending Scans to Review.....	14-17
Figure 14-11 Adding a Pathologist	14-18
Figure 14-12 Scan Lifecycle	14-18
Figure 14-13 Consult Dialog window.....	14-19
Figure 14-14 Send Mail	14-19
Figure 14-15 Open Worklist in the CONFER folder	14-20
Figure 14-16 CONFER folder	14-20
Figure 15-1 SPIFE Nexus	15-3

List of Tables

Table 5-1 Inventory.....	5-1
Table 5-2 System Requirements	5-2
Table 10-1 Troubleshooting	10-2

Section 1 - Instrument Use and Function

Helena's **QuickScan Touch *plus*** (Figure 1-1) is a visible scanning densitometer used to scan electrophoretic gels, quantitate data, and display and print results. The QuickScan Touch *plus* is intended for in-vitro diagnostic use only, in a laboratory or similar environment.

Visible sample gels are placed in the QuickScan Touch *plus* and scanned. Results for a number of different tests can then be viewed on the monitor and printed in a report. A built-in computer directs all operations of the system.

Varieties of test types are preprogrammed in the QuickScan Touch *plus*. Presently, these tests are Serum and Urine Proteins using acid blue stain, Serum Proteins using Ponceau S stain, Acid and Alkaline Hemoglobins, Alkaline Phosphatase, Cholesterol Profile, CK - Creatine Kinase, LD - Lactic Dehydrogenase, IFE - Immunofixation, and Lipoproteins. Parameters for up to 100 tests can be stored in the unit.

Stored results can be retrieved in seconds. Full editing features are provided so that fractions may be selected, baselines adjusted, comments added to the file, etc. Up to 100 copies of a test report can be printed.

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

Performance Characteristics

Interpretation of Results

Bibliography



Figure 1-1 QuickScan Touch *plus* System

Section 2 - Principles of Operation

The QuickScan Touch *plus* program contains factory preset default values for scanning parameters. These values can be changed, permanently or temporarily. Refer to section six for programming instructions. If default parameters are altered, they can be reinstalled as needed.

The functional units of the QuickScan Touch *plus* are shown in Figure 2-1.

2.1. Transmittance Densitometry

The visible mode optics configuration is shown in Figure 2-2. 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.

2.2. References

Control samples should 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.

2.3. Configuration

The QST is deployed in multiple configurations to meet end-user needs. This section discusses the differences in these deployment scenarios. In all scenarios, the QST application is the main end-user interaction method.

In one scenario, data is collected by the QST from a single instrument connected to the same computer that is used by a Technician and a Clinician, also using the QST program. The MSD is provided by the facility. This will be called the **Single-User-System-Facility-Database** Deployment Model.

In a second scenario, multiple pieces of laboratory instrumentation may be spread throughout the facility. The QST software running on a computer attached to each laboratory instrument is responsible for obtaining the data from the device. Multiple clinicians may use the QST software, running on a computer in their offices, to review the data. The MSD, provided by the facility, is on a separate computer managed by the facility. This will be called the **Multi-User-System-Facility-Database** Deployment Model (Figure 2-3).

2.4. 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. The user makes selections from information on the Color Display using the keyboard or mouse or the touchscreen if available. Access to the setup can be limited by use of a password.

Patient files can be duplicated and stored at the user's option. The backup

information can be restored to the memory should this become necessary.

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 printout is requested by the user, the printer produces a copy of the scan data and other user-entered information. Deviations in the results from reference ranges are indicated as high (+) or low (-) on the printout. All the data for each scan can be automatically stored on the hard drive or network location. The user can also "export" data through a serial output port to an external computer and data can be emailed.

QuickScan Touch *plus* is completely preprogrammed and is ready for use as is for the more common applications. However, scan parameters can be altered if so desired. All user input is through the mouse, keyboard, or the touchscreen if used. In normal use, the operator selects the type of test, enters patient demographics, places the gel in the scanner and starts or stops the automatic sequence of operations.

The computer runs a self-test at power on to detect error conditions or potential problems. If an error is detected, the computer responds by displaying an error message (Section 10.2).

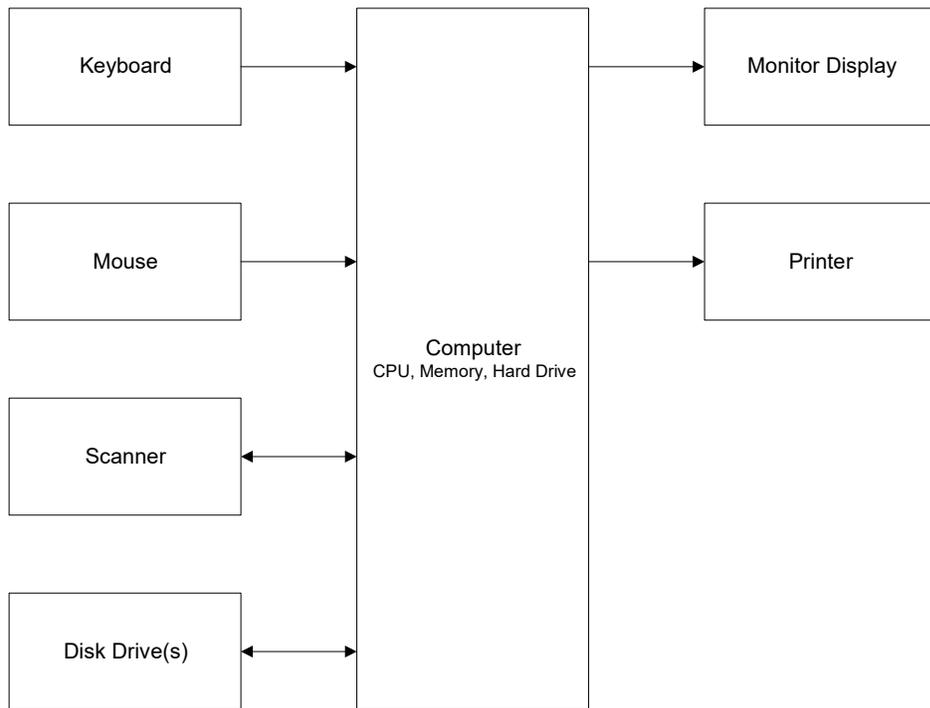


Figure 2-1 Functional Units of the QuickScan Touch *plus* Block Diagram

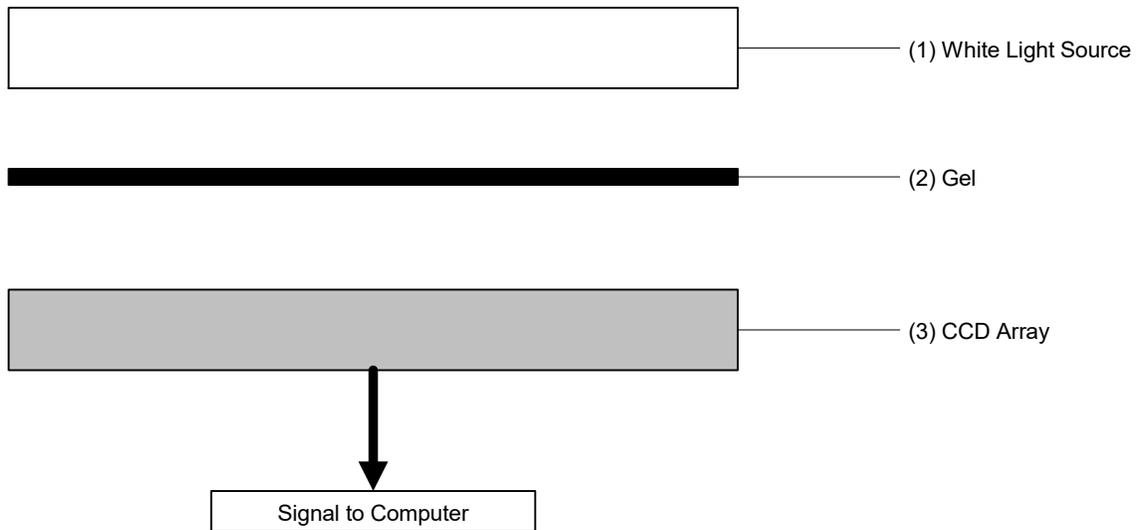


Figure 2-2 Visible Scan Optics

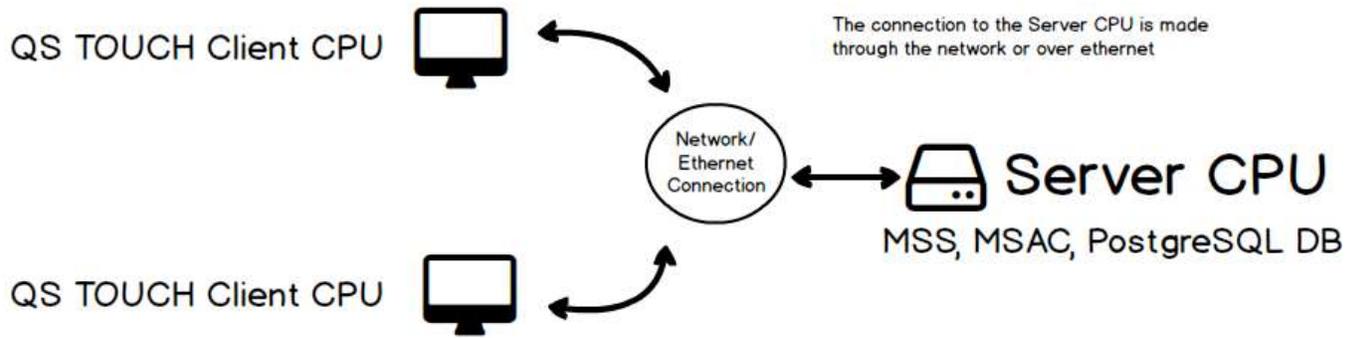


Figure 2-3 Multi-user with Server

Section 3 - Precautions and Limitations

3.1. For emergency shutdown, turn off the instrument using the computer power switch or disconnect the main power cord from the wall outlet.

3.2. Do not attempt to move or operate the instrument until the entire Operator's Manual, and the manuals provided with the scanner, monitor and printer, have been read and understood.

3.3. Keep the scanner lid closed. Do not place objects on the glass surface other than items to be scanned.

3.4. Always keep all glass surfaces in the scanner clean and dust free, or results may be compromised.

3.5. The instrument should be kept dust free if possible. No harsh cleansers, acids or bases should be used either inside or out. Do not immerse the unit. ALWAYS UNPLUG THE MAIN POWER CORD BEFORE CLEANING.

3.6. Should an instrument be contaminated by blood or blood derivatives, 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 alcohol, which is corrosive to metal surfaces.

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

3.8. Do not expose the instrument to drafts or operate the instrument in direct sunlight. Do not operate the instrument at temperatures below 59°F (15°C) or above 80.6°F (27°C), and do not allow prolonged exposure to high humidity.

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

3.10. Use standard precautions when handling the flash drive.

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

3.12. Although the QuickScan Touch *plus* is factory programmed for some procedures, you may alter scanning parameters if desired. If scanning problems occur, return to default parameters.

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

3.14. Use only gels and other media compatible with this system.

Section 4 - Hazards

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

4.2. Do not move the scanner until it is prepared for moving. See the scanner owner's guide for instructions on moving the scanner. Failure to do so may result in damage to the scanner.

4.3. 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.

4.4. 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's components.

4.5. Do not lubricate the instrument.

Section 5 - Installation

WARNING: Read sections three, Precautions and Limitations, and four, Hazards, before attempting to move, install, or operate the instrument.

5.1. Unpacking and Inspection

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

Carefully unpack the instrument's components and remove them from the shipping cartons. If possible, the packing material should be removed undamaged to facilitate repacking the instrument if it becomes necessary.

Remove the plastic wrappings from the components. If scissors are used to cut the plastic or binding tape, take care not to scratch the components.

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

1640 QuickScan Touch *plus*:

- 1 QuickScan Touch *plus* Software flash drive
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 QuickScan Touch *plus* Operator's Manual
- 1 QuickScan Touch *plus* Installation Instructions
- 1 QuickScan Touch *plus* Field Installation Form
- 1 QuickScan Touch *plus* Computer
 - 1 Mouse
 - 1 Keyboard with interface cable
 - 1 Power Cord
- 1 QuickScan Touch *plus* Scanner
 - 1 Transparency Lid
 - 1 USB Cable
 - 1 Power Cord
 - 1 Owner's Guide
- 1 Mouse Pad

- 2 USB Cables

1646 QuickScan Touch *plus*, Export Version I:

- 1 QuickScan Touch *plus* Software flash drive
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 USB Hardlock Key
- 1 QuickScan Touch *plus* Operator's Manual
- 1 QuickScan Touch *plus* Installation Instructions
- 1 Mouse Pad
- 2 USB Cables
- 1 Scanner Bed Template

1647 QuickScan Touch *plus*, Export Version II:

- 1 QuickScan Touch *plus* Software flash drive
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 USB Hardlock Key
- 1 QuickScan Touch *plus* Operator's Manual
- 1 QuickScan Touch *plus* Installation Instructions
- 1 QuickScan Touch *plus* Field Installation Form
- 1 QuickScan Touch *plus* Scanner
 - 1 Transparency Lid
 - 1 USB Cable
 - 1 Power Cord
 - 1 Owner's Guide
- 1 Mouse Pad
- 2 USB Cables

1672 Monitor, Flat Screen:

- 1 color Flat screen monitor
 - 1 Interface Cable
 - 1 Power cord

1695 Monitor, Flat Screen Touch

- 1 Color Flat Screen Monitor
 - 1 Interface Cable
 - 1 USB Cable
 - 1 Power Cord
- 1 Owner's Guide

1694 Printer, Laser:

- 1 Color Inkjet Printer
- 1 Magenta Toner Cartridge
- 1 Cyan Toner Cartridge
- 1 Yellow Toner Cartridge
- 1 Black Toner Cartridge
- 1 Power Cord

Table 5-2 System Requirements

- Computer - IBM compatible PC, 8 GB of RAM, 10 USB ports, 2 Ethernet ports, I7 processor, minimum 1TB hard drive space, Microsoft® Windows® 10 operating systems (if network and/or internet connections will be used, the use of the latest security patch and service pack is recommended), and optional CD/RW drive.
- Scanner - Perfection V700/750 or V800/850.
- Printer - any printer supported by Windows.
- Monitor - any monitor supported by Windows.

5.2. Select Instrument Location

1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and large temperature fluctuations. Ambient temperature should be from 59° - 80.6°F (15° - 27°C).
2. Select an area with enough space to place the instrument's components.
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 electromagnetic interference, such as a centrifuge, x-ray machine, etc.

5.3. Component Interface and Power Connections

1. Check each component to make sure that each has the same power rating (110 to 120 VAC or 220 to 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.

5.3.1. Computer

1. Record the computer's serial number located on the back of the computer for use later.
2. On the white Helena label containing a handwritten system serial number, located on the computer, write your Helena customer number.
3. Place the computer in the center of the area designated for the instrument. Keep in mind you will need access to the back of the computer to interface it with the other components.
4. Plug the female end of the computer's power cord into the back of the computer.

5.3.2. Printer

1. Record the printer's serial number located on the back of the printer for use later.
2. Place the printer relative to the computer.

3. Plug the provided Key into the bottom USB port on the back of the computer as shown in Figure 5-1.
4. Plug the printer interface cable into the back of the printer (Figure 5-1).
5. Plug the other end of the printer interface cable into one of the two USB ports on the back of the computer as shown in (Figure 5-1).
6. Plug the female end of the printer's power cord into the back of the printer.

For information on installing and removing toner or ink cartridges and on loading printer paper, see the printer owner's guide.

Note: For the V700/750 scanner, only use the scanner driver provided in the Helena software kit (8PF68010) and **not** the Epson driver that is included in the scanner box.

Note: For the V800/V850 scanner, use the Epson scanner driver.

5.3.3. Scanner

1. Record the scanner's serial number located on the back of the scanner for use later.
2. On the white Helena labels containing a handwritten system serial number, one located on the scanner and one on the transparency lid, write your Helena customer number.
3. Attach the transparency lid to the scanner per the instructions included in the scanner owner's guide.
4. Place the scanner relative to the computer.
5. Connect the USB cable to the scanner. Connect the other end of the USB cable to the top USB port on the back of the computer as shown in (Figure 5-1).

Unlock the scanner per the instructions included in the scanner owner's guide.

6. If needed, plug the female end of the scanner's power cord into the back of the scanner.

5.3.4. Monitor

1. Record the monitor's serial number located on the back of the monitor for use later.
2. Place the monitor relative to the computer.
3. Plug the female end of the monitor's power cord into the back of the monitor.
4. If needed, plug the monitor's interface cable into the matching receptacle on the back of the monitor.
5. Plug the monitor's interface cable into the matching receptacle on the back of the computer. Hand tighten the thumbscrews.

5.3.5. Keyboard

1. Place the keyboard relative to the computer.
2. Plug the keyboard cable into the matching connector on the back of the computer.

5.3.6. Mouse

1. Place the mouse relative to the computer.
2. Plug the mouse cable into the receptacle on the back of the computer.

5.3.7. Power Connections

Once each component is interfaced and has its power cord, plug each power cord into a grounded wall outlet of the proper voltage and frequency. This information can be found on the serial number plates located on the back of the instrument's

components. Do not turn the power on at this time.

5.4. Installation

5.4.1. Components

Helena Service will set up the QuickScan Touch *plus* using the Installation Instructions included with the inventory. Once installed, the QuickScan Touch *plus* icon will be displayed on the computer.

5.4.2. Computer

Double-click the QuickScan Touch *plus* icon. The Sign In screen is displayed. Using the dropdown arrow, select the *QSTAdmin* user. This is the default user will full permissions. Enter the password Adm1n.

If the main menu appears on the monitor, the system is operating correctly. If an error message appears instead, refer to section 10.2, Troubleshooting.

5.5. Helpful Hints

5.5.1. Mouse

The mouse may be used to make selections and indicate where information is to be entered. Move the white arrow, or a symbol resembling a black Roman numeral one, 1, around the screen to the desired selection or location by moving the mouse over the mouse pad. With the white arrow over the desired area, click the button located on the left of the mouse. Clicking this button twice is required to select some options. In this manual, any statement to “click” or “double click” an area refers to these instructions. Any instruction to “select” something can be completed using the mouse.

5.5.2. Keyboard

The keyboard is used to enter information and in some areas to make selections. Any word displayed on the screen containing an underlined letter, for example Setup, can be accessed by simultaneously pressing the Alt key and the underlined letter key. In this manual, any keys listed with hyphens between them, for example, Alt-S, need to be pressed simultaneously. On most screens, you can also access an area by pressing the Tab key until the desired area is indicated. The up, down, left, and right arrow keys can be used in areas where information is entered either to scroll through the areas available to enter information or to position your cursor within an indicated area.

5.5.3. Displays and Manual

In understanding this manual, keep the following things in mind:

“Click” or “double click” - refers to the instructions given in section 5.5.1.

“Field” - is the area into which information is entered.

“Cursor” - refers to the location entered information will be placed and is most often indicated by a white arrow or a symbol resembling a black Roman numeral one, 1.

“Drop down menu” or “drop down list” - refers to a list of options available for your selection. A field has a drop down menu or list when the right side of the field has a square containing an arrow. You can access the drop down menu/list by clicking on the arrow or the field.

“Highlight” or “highlighted” - refers to the information currently selected and is displayed as white text with a blue background.

“Slide” or “slide bar” - refers to when the display allows you to use either your mouse or your arrow keys to move an indicator bar in order to define the desired setting or access additional fields.

In this manual, *Italic text* refers to the display and **bold text** refers to keyboard keys.

Note: *With the “touch screen” monitor in conjunction with the QuickScan Touch plus software, the operator may “touch” or “tap” the icons shown on the screen instead of using a mouse. Tapping text blocks (where information needs to be added) will bring up an onscreen keyboard that can be used in place of a normal keyboard. Refer to the monitor’s specific operator’s manual for more details. Hotkeys should not be enabled or used on the touch screen itself, only on the physical keyboard. Refer to section 10.1.3, page 10-2 for information on cleaning and maintenance of the touchscreen.*

5.6. Verification of Functionality

After reading and understanding the Operator’s Manual, complete the applicable section of the Field Installation Verification Form QuickScan Touch *plus* as the following steps are performed:

1. Record on the verification form the serial numbers of each component recorded in section 5.3.

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

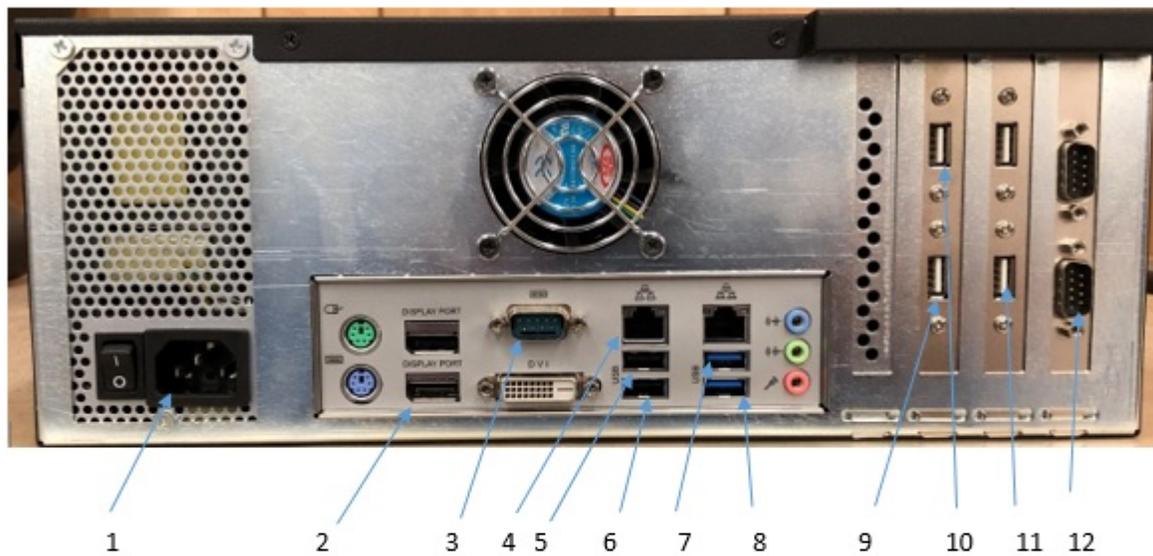
Enter the QC values; see section 6.8. Perform a calibration QC; see section 8-1. Print out the QC results and include the printout with the Verification Form.

Return the Verification Form as instructed on the form.

5.7. Programming Setup

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

Figure 5-1 Back view of computer



1. Power cord
2. DisplayPort for Monitor
3. LIS (Com1)
4. V8 Ethernet
5. Mouse/Keyboard USB
6. V8 Dongle
7. Hard Lock Key
8. Scanner USB
9. Printer USB
10. Monitor USB
11. Barcode Reader
12. ESH TOUCH (Com2)

Section 6 - User Setup

WARNING: *Patient Overlays may be assigned automatically in Test Setup, in Pre-Scan Setup, or at the level of the scan. Patient overlays may also be manually selected and pasted. Patient Overlays are labeled with patient identification, demographics, and results. It is recommended that patient identification be reviewed on each overlay.*

Note: *For information on the optional Myeloma Module software, see Section 14.*

Note: *For information on the optional V8 Interface, see Section 13.*

1. Turn the power on for the instrument and computer.
2. The Microsoft® Windows® program opens and displays the QuickScan Touch *plus* icon. Double-click the icon.
 - a. If the system detects no setup errors, the Sign In window appears. (Figure 6-2).
 - b. If an error message appears, refer to the message, and perform the actions suggested in the message.
3. For further assistance, or if the error recurs, record the message and call Helena Laboratories for further assistance. Also see Table 10-2.
4. 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).
5. Enter the appropriate *User name* and *Password* and select *Sign In*. The *Remember Me* option may be enabled to save the last user that logged into the software.

Note: *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.

6. *User Setup* is accessed by selecting *Edit* on the 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, Sample Handler, Quality Control, Users and Passwords, and SQL Database Server* (Figure 6-3).

Note: *If optional Myeloma Module software and V8 Interface are enabled, additional choices will be available. These are: V8 CE System, User Message Flags, and Pathologists. See Chapters 13 and 14 for more information.*

The options listed in *QuickScan Touch plus 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. *Sample Handler*: Allows the user to set connection parameters for the Electrophoresis Sample Handler (ESH). (See Section 6.7)

h. *Quality Control*: Allows the user to set up and track the NDDC information. (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)

j. *SQL Database Server*: Allows the user to test the server connection. (See Section 6.10).

h. *SPIFE Touch*: Allows to user to add SPIFE Touch serial numbers as well as set a default serial number. (See Section 6.11)

i. *Language*: Allows the user to select a language. (See Section 6.12)

6.1. Patient Demographics

The demographic labels common to all tests are set up 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 set up as part of each individual test.

1. From the main menu, select *Edit* and then *User Setup*.

2. From the *QuickScan Touch plus Setup* window, select *Patient Demographics* (Figure 6-3). This window displays all the

current demographic labels as well as 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 a medical record number. *PATIENT NAME IS NOT A UNIQUE IDENTIFIER*.

6.1.1. Edit Demographics

1. *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. Note that the ASTM field numbers may be reassigned to field names as desired to accommodate the needs of the user's information system.

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

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

6.1.2. Add Demographics

1. *Add* - To add a patient demographic, select *Add*. The *Add Demographic* window opens.

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 ASTM field numbers may be reassigned to field names as desired to accommodate the needs of the user's 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 is displayed. Select *Yes* to continue or *No* to return to the *Edit Demographic* window.

2. *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.

3. *Move Up* – moves a demographic label up in the list of demographics. Select the demographic label to be moved and then select *Move Up*.

4. *Move Down* – moves a demographic label down in the list of demographics. Select the demographic label to be moved and then select *Move Down*.

5. *Key Identifier* – is any Patient Demographic that is unique to each patient, such as the patient's ID number. It will be the first column in the worklist. The Key Identifier should be the first demographic entered.

Note: Once a key identifier has been selected, it should not be changed as this can cause retrieval problems.

Once all the demographics have been set up as desired:

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

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

i. If changes were made, a *Confirm Cancel* prompt is displayed.

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

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

6.1.3 Composite Identifier

An alternative to the Patient Identifier is the Composite Identifier (Figure 6-4). The Composite Identifier consists of multiple demographics that have been combined into a single identifier.

Patient Information - Worklist 03/17/2021 16:35:09 SB Patient Test 000479925365				
	Composite Identifier	Patient Identifier	Patient Name	Birthdate
1	Jaxon Riley11/26/2012M	100	Jaxon Riley	11/26/2012
2	Tori Anderson10/09/2002F	101	Tori Anderson	10/09/2002
3	Jason Finn01/15/1916M	102	Jason Finn	01/15/1916
4	Siobhan Amott07/15/1970F	103	Siobhan Amott	07/15/1970
5	Bob Jones02/15/1970M	104	Bob Jones	02/15/1970
6				

Note: The Composite Identifier is created from the Patient Demographics that have

been included. For example, in Figure 6-4, the Composite Identifier can be created with any combination of the included demographics. .

1. Select *Enable Composite Identifier*.
2. The user is prompted with a Confirmation dialog box, “*Enabling Composite Identifier will disable Primary Key Identifier which may affect the pairing of scans in Myeloma Software. Are you sure you want to continue?*” with *Yes* and *No* buttons.
3. Select *Yes*.
4. The *Setup* button is no longer greyed out. The *Primary Key Identifier* box is now grey.
5. Click the *Setup* button.
6. The *Select Source Demographics* box is displayed. *Patient Name, Birthdate, Patient Sex, Patient Race, and Total* are listed on the left hand side. There are two arrows to move demographics from one side of the box to the other as well as *OK* and *Cancel* buttons. The *Move Up* and *Move Down* buttons are grey since no demographics have been selected to create the Composite Identifier.
 - a. *Right Arrow* – select to add demographics to be combined to create the Composite Identifier.
 - b. *Left Arrow* – select to remove demographics from being combined to create the Composite Identifier.
 - c. *Move Up* – select the move the highlighted demographic up in the list.
 - d. *Move Down* – select the move the highlighted demographic down in the list.
 - e. *OK* – to save all the changes made and exit, select *OK*.

f. *Cancel* – to exit 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, select *Edit* and then *User Setup*.

2. From the *QuickScan Touch plus Setup* window, select *Tests*. The window displays the existing tests. (Figure 6-5).

3. *Edit* - To edit an existing test, highlight the needed test and select *Edit*. The *Edit Test* window appears containing the test name and its current parameters. See sections 6.2.1 through 6.2.6 for instructions on using this window.

Note: *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 displays. (See section 6.2.1 for further detail.)

Note: *The Edit Test and Add Test windows use the same window for entering information concerning test setup.*

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

a. Select *Yes* to delete the test.

b. Select *No* to retain the test.

6. *Print* – The *Print Settings* window appears allowing the user to select the

desired printer, print range, and number of copies.

7. *Export* – A named test with settings may be exported to a file for use in another QuickScan Touch *plus* system. Select *Export* to export the test settings. Select a file name and source in which to save the test. The test will be saved as a Test Export File (.xtf) and can only be opened in the QuickScan Touch *plus* software. Note that the gel image and Scan Location in Test Setup is not exported with the test settings.

8. *Import* – Select to import test setting from another file or location. Select the folder and file name and click on *Open*. Select the desired test file. The test file will be a Test Export File (.xtf) and can only be opened in the QuickScan Touch *plus* software.

9. Once the test has been set up and/or altered as desired:

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

b. *Cancel* - to exit 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*.

6.2.1. Test Type and Test Name

1. *Test Type* – On the *Add Test* window, use the dropdown list to select the appropriate test type (Figure 6-5). Then, the user may choose to enter custom

settings or click the *Default Settings* button to choose from a list of available default test settings for that test type (Figure 6-6).

Note: do not name the test until after clicking on the *Default Settings* button as the *Default Settings* button will clear the test name.

2. *Test Name* - may be entered/alterd as needed. The test name will automatically include the maximum number of samples and the stain type the test is setup to use *plus* the name entered in this field. Each test setup must have a unique *Test Name*. Note that for Cholesterol Profiles to have access to the Auto Edit and Report Total LDL features, the test name must include "Chol". Additionally, for Serum Proteins to have access to the Restricted Bands feature in the edit mode, the test name must include either "Proteins" or "SPE".

3. On the same screen there are five additional tabs; *Gel Properties*, *Scan Settings*, *Scan Locations*, *Fractions/Ratios/Ranges*, and *Patient Demographics*. Each tab contains menus for setting up test-specific parameters.

6.2.2. Gel Properties

1. Select the *Gel Properties* tab (Figure 6-7) and the following information will be as follows:

a. *Scan Lanes per Row* –may be from 1 to 20.

b. *Scan Lanes per Sample* – may be from 1 to 6.

c. *Rows per Gel* – may be from 1 to 5.

d. *Stain Type* – includes *Acid Blue*, *Acid Violet*, *Amido Black*, *Fat Red 7B*, and *Ponceau S*, and should only need customizing when entering a

user-defined test. The stain type selected should match the color of the pattern scanned. Note that for Titan Gel Serum Protein gels, for better correlation with other Helena densitometers, select *Acid Blue* stain instead of *Amido Black*.

6.2.3. Scan Settings

Select the *Scan Settings* tab (Figure 6-8) and the following information will be as follows:

1. *Resolution* – Choose from 200, 400, 600, 800, or 1200 dpi. A resolution of 200 dpi is recommended for routine use and for clinical use. An increase in dpi will not be visually apparent on a standard high resolution monitor without greatly enlarging the gel image. Gel images scanned in higher dpi require greater storage, and a large number of high resolution gels in the worklist folder may result in slowing of the system.

2. *Sequence* - can be altered by entering the sample positions needed, separating the position numbers with a comma and/or designating a set of positions with a hyphen. For example 3, 5, 8-12, 15, 20.

3. *Aperture Size* - may be from 1 to 12, see Section 9.6 for the measurement that corresponds to each aperture setting.

4. *Smooth* - Do not select unless procedure recommends otherwise; the graph will not be smoothed. With *Smooth* selected, set the *Smoothing Level* to a value from 1 to 10, with 1 being minimal smoothing and 10 being maximum smoothing. Smoothing will affect the results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing **could affect** small monoclonals.

5. *Auto Interpretation* - enables automatic interpretation of the scan results and

requires user-defined interpretations be setup.

6. *Auto Edit* -  only available for tests with "Chol" in the test name. Note that if not selected in setup, Auto Edit is available for selection in the Edit mode. As an aid to scanning, the auto edit program applies curvilinear analysis to the scans and marks the fractions appropriately. Only the fractions present will have fraction labels displayed or printed. The auto edited pattern may be modified by inserting a fraction mark but doing so loses the label identity so that all fractions labels will be used in order. **With Auto Edit in use, scans should be reviewed and can be edited, as needed.**

a. *Auto Edit Settings* - select  and the *Auto Edit Settings* window displays and allows for selection of the following.

i. *Force Lp(a) Fraction* - selection of this feature provides for automatic marking of an Lp(a) fraction, based on the position of the Lp(a) in the Reference. In order to keep Lp(a) values on the report, the software marks automatically this small amount of Lp(a) based on an amount indicated by the Lp(a) area on the reference.

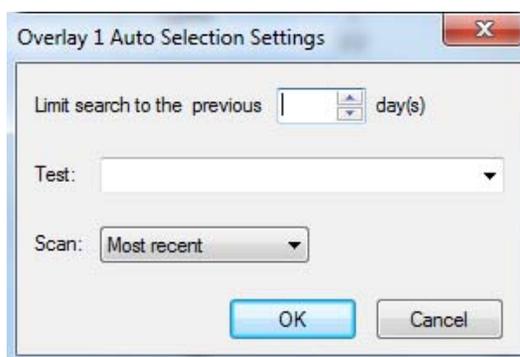
Note: *This feature is based on the absolute position of the Lp(a) on the reference. An appropriately labeled and marked reference scan must be on the worklist. These scans must always be reviewed because faulty fraction marking can compromise not only Lp(a) values but also HDL quantitation.*

7. *Report Total LDL* - is only available when "Chol" is in the *Test Name*. Select this feature for the results to include the Total LDL value of Lp(a) *plus* LDL.

8. *Report Total non-HDL* – Is the Total cholesterol minus whatever the value of HDL is.

9. *Patient Overlay 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. Select *Overlay 1 Auto Selection Settings* and choose from the following:

- a. *Limit search to the previous days* – search from any number of previous days.
- b. *Test* - select from any available test.
- c. *Scan* – choose from *Most recent*, *Next most recent*, *Prior oldest*, and *Oldest*.



10. *Patient Overlay 2* - select to have a second patient's scan, shown in blue, overlaid on the current scan. Select *Overlay 2 Auto Selection Settings* and choose from the following:

- a. *Limit search to the previous days* – search from any number of previous days
- b. *Test* - select from any available test.
- c. *Scan* – choose from *Most recent*, *Next most recent*, *Prior oldest*, and *Oldest*.



11. *Image Contrast* - is set, using a slide bar, in a range of *-10.0 Lighter* to *10.0 Darker*, in 0.2 increments. The setting affects only the appearance of the scan image when displayed and printed and does not affect the quantitation.

12. *Gain*

a. *Gain Mode:*

i. *Auto* - the maximum fraction amplitude is set to 100% of the graph height with the rest of the fraction heights proportional to it. Note that Serum Proteins are usually scanned in auto gain.

ii. *Manual* - the fraction amplitude is proportional to concentration and is the gain of choice for light patterns such as urines. This option is selected because an auto-scanned sample that is light will show many fractions. With Manual gain selected, Auto Scale is accessible in the Edit mode for use if a specific pattern over ranges because that pattern is not light. Patterns of varying intensity are usually scanned in Manual gain, for example, Urine Proteins and CK Isoenzymes.

1) *Manual Gain* - is set in a range of *0.0 Min* to *10.0 Max*, in 0.1 increments. Set using the slide bar accessible only when Manual is selected. Adjust the slide bar as needed to achieve the desired amplitude with the highest peak at

the desired level when scanned. Start at a manual gain of five and increase or decrease gain as needed. Note that Manual Gain should be selected for Urine gels in order to minimize noise

13. Fraction Detection

a. *Sensitivity* - sets the "sensitivity" of the instrument to +/- slope changes when detecting fractions. Set, using the slide bar, within a range of *0.0 Min* to *10.0 Max*, in 0.1 increments. A sensitivity of zero turns off the auto fraction selector thus causing no fraction marks on the scan. Start at a sensitivity of four and increase or decrease as needed.

b. *Forced Fractions* - scanning using the *Float* or *Fixed* option is based on the assumption that the scan distance is the same for all rows. Any pattern may be named Reference to serve as a fraction mark guide. If using *Float* or *Fixed*, it is recommended that a representative sample of each row be identified as "Reference".

i. *No* - select to pick fractions based only on pattern slope change.

ii. *Float* - select 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 selected, a sample will need to be labeled Reference for each gel and will need to be scanned prior to any sample for which it will be the overlay. If *Float* is selected, then to more clearly see the impact on the scan, set the Worklist to Overlay Reference on the Display and/or Print Settings. An example of a use for the float feature is to force 5

fractions on a Urine Protein when a Serum is used as the Reference.

iii. *Fixed* - select to use the same fraction locations as those of a previously scanned Reference. If selected, a sample will need to be labeled Reference for each gel and will need to be scanned prior to any sample for which it will be the overlay. The Fixed fractions feature is useful when the software would not normally insert marks where the operator desires. If Fixed is selected, then to more clearly see the impact on the scan, set the Worklist to Overlay Reference on the Display and/or Print Settings. This feature requires there be no pattern shift between the reference and the patterns. For this reason, either No or Float is usually the preferred choice.

iv. *Combine Split Beta Fraction* – select to combine the split beta fraction.

14. *Save gel image* – check to save the gel image with the worklist.

15. *Do pre-scan setup* – check to include a pre-scan setup before the plate is scanned.

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

17. Once the test has been set up and/or altered as desired:

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

b. *Cancel* - to exit 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*.

6.2.4. Scan Locations

To set up the scan begin and end positions and the sample to sample step over positions, proceed as follows.

1. Open the scanner lid.
2. Position the gel on the scanner: If scanning a Helena gel with a round and an obround hole, place the round hole over the right pin on the scanner and the obround hole over the left pin. If scanning a gel with no holes, place the gel so that the first sample is on the right, back corner of the scanner with the samples oriented left to right. If needed the gel may be taped down to the scanner bed to make it lie flat.
3. Close the lid.
4. Select *Update Image*. The scanner scans the gel and the message "Scanning in Progress" displays until an image of the gel displays (Figures 6-9 and 6-10). For each row of the 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.
5. For each row, use the mouse to move the green lines to the front of the pattern to set the scan begin and the red lines to the other end of the pattern to set the scan end. These lines should never overlap. The control assay sheet (for whichever test is being used) can be used to determine which side of the scan the start scan line should be set.
6. For each row, use the mouse to set the sample step over by placing the blue lines

on the center of the samples located on the left of the window (the first sample) and placing the purple lines on the center of the samples located on the right of the window (the last sample). This operation defines the distance 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. Therefore, it is recommended that a sample is always in the last sample position of each row.

7. The QuickScan Touch *plus* software will use the position of these lines to automatically calculate the space between each sample. This calculation is used to automatically setup the scanner so that all future scans of the same type test gel will use this as a preset scan begin, end and sample step over.

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

Once the test has been set up and/or altered as desired:

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

6.2.5. Fractions / Ratios / Ranges

1. *Unit of Measure* (Figure 6-11)

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 user 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 Paraprotein) for use when a restricted band is marked.

Scan Locations	Fractions / Ratios / Ranges	Patient Demographics
Restricted Bands:		
Label:	<input type="text" value="Paraprotein"/>	
Marking Method:	<input type="text" value="Sliced or Skimmed"/>	
<input checked="" type="checkbox"/> Automatically locate restricted band delimiters		

b. *Marking Method* – using the dropdown menu, select from *Sliced*, *Skimmed*, and *Sliced or Skimmed*.

c. *Automatically located restricted band delimiters* – enable to have the software automatically locate the restricted band delimiters.

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 does 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*. Note that Normal and Abnormal Control can only be used once per set of reference ranges. And if used, then a 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.

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 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*

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

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

3) *OK*

4) *Cancel*

ii. *Units Range* – The default *Unit of Measure* in the box labeled *Fractions* is g/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*

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

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

a) *OK*

b) *Cancel*

6.2.6. Patient Demographics

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 6-12).

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.

- 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.
 - c. *OK* – select to accept the changes made to the demographic.
 - d. *Cancel* – select to reject the changes made.
 - i. A *Confirm Cancel* prompt display.
 - 1) Select *Yes* to continue or
 - 2) *No* to return the *Edit Demographic* window.
2. *Add* - To add a patient demographic, specific to this test, select *Add*. The *Add Demographic* window opens.
- 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.
 - i. A *Confirm Cancel* prompt display.
 - 1) Select *Yes* to continue or
 - 2) *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. The physical layout of a worklist, Display, Print, and Export Settings may be modified and a template created, much in the same way a report is created. 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. A specific worklist template may also be selected and applied any time a new worklist is created by the user.

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

2. From the *QuickScan Touch plus Setup* window, select *Worklists* (Figure 6-13). The window displays where worklists will be stored and allows access to the currently setup worklist templates.

Note: *It is NOT recommended to alter the default setup files, however it is recommended to backup all User Settings to the computer hard drive, and also to an external device.*

3. *There are two templates present, the Default Scan, (Figure 6-12) and Edit.* Note that any edits to the *Default Scan*

Template will be applied to every new worklist created.

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. *Naming and assigning* - To assign a worklist template to a specific test, the template must share the name of the test, followed by the word "Scan." The full name of the test must be included within the template name, and must be spelled correctly. If there are multiple templates that share the test name, the first template will be applied automatically. Any template may be manually applied if specifically designated by the user by using the *New Worklist function*.

7. *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.

8. *Print* – To print the existing worklist. From *Printer Settings* window select the needed printer properties, print range, and number of copies.

9. *Export* – Allows the user to export a worklist template. Click on *Export*, name the template file, and designate the folder. The file will be saved as an Worklist Template Export .XWF)

10. *Import* - Allows the user to import a worklist template. Click on *Import*, name the template file, and designate the folder.

The file will be saved as an Worklist Template Import .XWF.

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 is displayed.

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

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

Note: *The following sections include direction of adding or editing scans. The Edit screen can be displayed by clicking the Edit button on the Worklist menu. The Edit Worklist Template is displayed with the following options.*

6.3.1. Template Name

1. *Template Name* – Enter (or edit) the desired worklist template name (Figure 6-14). 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.

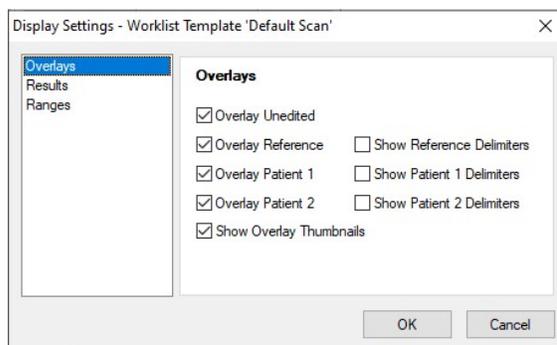
6.3.2. Display Settings

1. Select the *Display Settings* button.

WARNING: *Patient Overlays may be assigned automatically in Test Setup, in Pre-Scan Setup, or at the level of the*

scan. Patient overlays may also be manually selected and pasted. Patient Overlays are labeled with patient identification, demographics, and results. It is recommended that patient identification be reviewed on each overlay.

1. **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 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.

f. **Show Reference Delimiters**

g. **Show Patient 1 Delimiters**

h. **Show Patient 2 Delimiters**

2. **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** – for IFE only

i. **Display units** – for IFE only. Select to include the units in the display.

3. **Ranges** – the options available depend on selections made in **Results**. Select as needed.

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** – for IFE only

i. **Display Units Range**

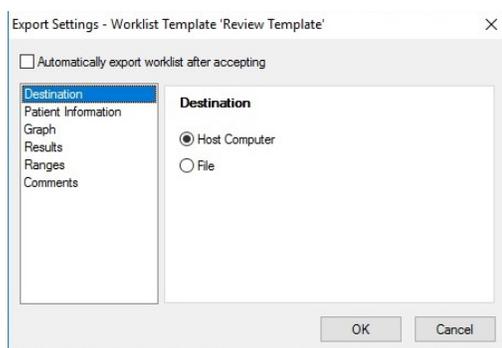
ii. *Flag Units Out***6.3.3. Export Settings**

Select the *Export Settings* icon. If the host computer option is to be used, ensure it is enabled in *Import / Export*, Section 6.6.

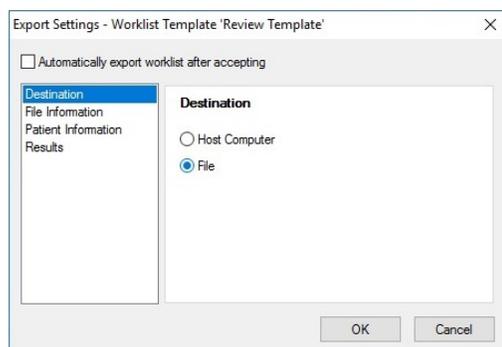
1. *Automatically export after accepting* – select to have the worklist export once a scan is complete.

2. *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*.



3. *File Information* –

a. *Save in* – click the icon on the right of the text box to select a location.

b. *File name* – enter a file name of characters.

c. *Include Column Headers* – select to include.

d. *Delimiter* – choose from *Tab*, *Space*, *Comma*, *Semicolon*, or *Other*.

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

a. *Don't Export*

b. *Export Key Identifier Only*

c. *Export All Patient Information*

5. *Graph* – only available with the *Host Computer* option.

a. *Export Graph* – click to include 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.

5. *Ranges* – select as needed.

a. *Export Percent Range*

b. *Export Units Range*

c. *Export Ratio Range*

d. *Flag Percent Out*

e. *Flag Units Out*

f. *Flag Ratio Out*

6. *Export Comments* – click to include comments.

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

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

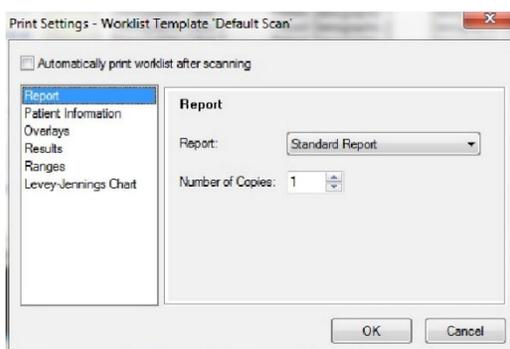
a. If changes were made, a *Confirm Cancel* prompt displays.

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.



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 in use, including the *Overlay(s)* on the

reports may make the reports difficult to read. 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.

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

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

e. *Print Overlay Thumbnails* - select to have overlay thumbnails included on the printout of patient's scan.

f. *Print References Delimiters* - select to have reference delimiters included on the printout of patient's scan.

g. *Print Patient 1 Delimiters* - select to have Patient 1 delimiters included on the printout of patient's scan.

h. *Print Patient 2 Delimiters* - select to have Patient 2 delimiters included on the printout of patient's scan.

Note: Up to two overlay thumbnails and an IFE image can be printed as *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 unit-less 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.

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. Worklist Appearance

The appearance may be altered for certain components on the worklist, such as altering the background color of the graph. Right clicking on the component will open

the settings window with all the applicable options.

6.3.6. 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

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.*

1. From the main menu, select *Edit* and then *User Setup*.

2. From the *QuickScan Touch plus Setup* window, select *Comments / Interpretation* (Figure 6-15). The right side of the window allows access to the currently setup comments and interpretations.

3. *Edit* - To edit an existing comment and interpretation, highlight the needed comment and select *Edit* and the *Edit Comment / Interpretation* window displays.

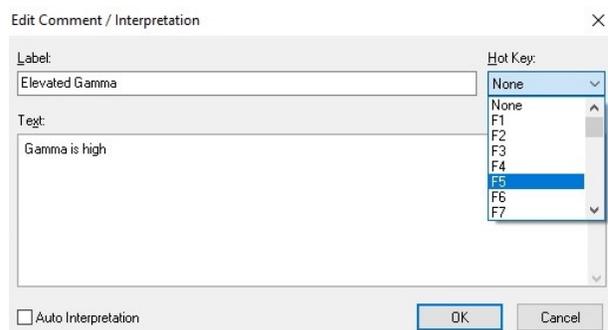
Note: See the instructions for the Add Comment and Interpretation window to use this window.

4. *Add* - To add a comment and interpretation, select *Add* and the *Add Comment and Interpretation* window (Figure 6-15) 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. Keep in mind when assigning Labels, that when viewing the list of available comments, the list is presented alphabetically. Thus, it may be helpful to use this feature to group together comments that relate to the same tests, for example SPE Normal and SPE Polyclonal.

b. *Text* - use the keyboard to enter or edit the comment that can contain an unlimited amount of characters. Word wrap is not applied when printing a list of comments. For longer comments, press enter (carriage return) at the end of each sentence.

c. *Hotkey* – users can now link Function keys (F1-F12) to comments, which can be used while editing scans. Shift, Ctrl, and Alt keys are available to use in conjunction with the function keys for a greater number of comments to be mapped; however, F1 and F10 are not available due to Windows restrictions.



d. *Auto Interpretation* - select to designate the comment as an *Auto Interpretation*. (Figure 6-16) 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. Whatever value is set here, any value less than it will be viewed as a zero.

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.

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

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

5. *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.

6. *Print* – Select to print the comment. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

7. *Export* – Select to export the comment to another file location.

8. *Import* – Select to import the comment from another file location, including a flash drive, network, etc.

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

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

6.5. Reports

6.5.1. Reports Setup

1. From the main menu, select *Edit* and then *User Setup*.

2. From the *QuickScan Touch plus Setup* window, select *Reports* (Figure 6-17). The right side of the *QuickScan Touch plus Setup* window allows access to the existing reports, any other currently setup reports.

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

a. *Edit* -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.

It is recommended that when creating a new report, that the Default report is Copied then the Copy is edited and renamed. Once the Default report has been modified, the Default cannot be reset.

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

c. *Copy* - 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. *Delete* - 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.

e. *Print* – Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

f. *Export* – Select to export the report to another file location.

g. *Import* – Select to import the report from another file location.

Note: Use Sections 6.5.1.1 – 6.5.1.5 to either *Add* or *Edit* a report.

6.5.1.1. Report Name

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.

6.5.1.2. Paper Size

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 printout.

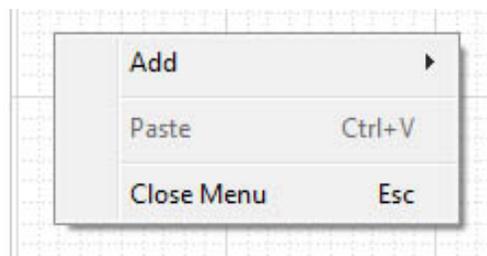
6.5.1.3. Orientation

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.

6.5.1.4. Add

1. *Add* – Click on the location within the report the selected component needs to appear.

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 it.



The components available through *Add* are as follows:

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 determine if all or only the Key demographic print.

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.

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 *Comments 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. 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.

k. *Bar code* – select this to include the bar code.

l. *Picture* – select this to include a picture from file.

m. *Line* – select to add a line.

n. *Box* – select to add a box.

Note: See Section 6.5.1.5 for a more detailed description of the available components and their features.

6.5.1.5. Settings

1. *Settings* - Position the mouse cursor over the component, right click and select *Settings*. Depending on the component selected, the window displays. For information on moving and/or resizing a component, see section 6.5.1.4.

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.

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

6.5.1.6. Patient Info

1. *Scan Assignment* - For single scan reports, this should be set to 1. To create multi-scan reports, include multiple Patient info 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 patient info 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. *Label* – Select to change font settings for the Demographic label (ie: Patient Name, Patient ID).

b. *Demographic* – Select to change the font settings for the actual demographic (John Smith, 123456)

c. *Font Settings* – use to select font.

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

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

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

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

6.5.1.7. 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.

6.5.1.8. 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.

4. *Components* - Highlight the component needing modification and then use *Color* to modify.

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*

i. *Color*

6.5.1.9. 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* - Select specific fonts and customize size and style.

- a. *Name*
- b. *Size*
- c. *Style*
- d. *Color*

6.5.1.10. 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* - Select specific fonts and customize size and style.

- a. *Name*
- b. *Size*
- c. *Style*
- d. *Color*

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

- a. *Header*
- b. *Comment*

6. *Font* - Select specific fonts and customize size and style.

- a. *Name*
- b. *Size*
- c. *Style*
- d. *Color*

6.5.1.11.1. Text

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

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

3. *Font* - Select specific fonts and customize size and style.

- a. *Name*
- b. *Size*
- c. *Style*

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

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.

6.5.1.12. List

1. Statistics are automatically included as part of a list report (Figure 6-20).

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

a. *Test Name*

b. *Header*

c. *Label*

d. *Result In*

e. *Result Out*

3. *Font* - Select specific fonts and customize size and style.

a. *Name*

b. *Size*

c. *Style*

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.

6.5.1.13. 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* – Select specific fonts and customize size and style.

a. *Name*

b. *Size*

c. *Style*

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.

6.5.1.14. Barcode

Note: *If using a barcode type with a checksum, verify that the checksum digits in the laboratory information system are scanned and interpreted in the same manner as the QuickScan Touch plus, and with any bar code scanner. Incorrect patient identification may occur if bar code numbers are not read in an identical manner.*

1. A barcode may be printed on a report.

2. *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.

3. *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

4. *Barcode Type* – select from one of the below.

a. *Code 39*

b. *Interleaved 2 of 5*

c. *Code 128*

d. *Codabar*

e. *UPC-A*

f. *UPC-E*

- g. *EAN-13*
 - h. *EAN-8*
5. *Include checksum in bar code* – Select to include on report.
 6. *Bar Code Prefix* - add prefix here.
 7. *Bar Code Suffix* – Add suffix here.
 8. *Bar Code Label Font*
 - 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.
 9. *Bar Code Label Color* - Use the pop up list to change the color of the bar code.

6.5.2. Picture

1. A picture or image (For example, a logo) may be added to a report form.)
2. Right click on the report and click *Add*. Select *Picture* from the drop down menu.
3. A blank square will appear on the report form. Right click on the square and click on *Settings*, to locate a folder in which the desired *.bmp picture file may be found. Click on *Open* to add the image.
4. Position and size may also be altered.

6.5.2.1. Line

1. *Line Style* – Use the dropdown menu to select from a variety of line styles.
2. *Line color* - Use the pop up list to change the color of the line.

6.6. Import / Export

6.6.1. Import / Export

For additional information, see Section 12 - Communication Specifications.

1. From the main menu, select *Edit* and then *User Setup*.
2. From the *QuickScan Touch plus Setup* window, select *Import / Export* (Figure 6-21).

6.6.1.1. Setup Host Computer

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 will not be grayed out.
 - a. *Port* - Select *COM1* or *COM2*.
 - b. *Baud Rate* – Select *1200*, *2400*, *4800*, *9600*, *14400*, or *19,200*.
 - c. *Data Bits*- Select *7* or *8*.
 - d. *Stop Bits* – Select *1* or *2*.
 - e. *Parity* - Select *none*, *odd*, or *even*.
 - f. *Protocol* – Select *XON-XOFF* or *ASTM*.
 - g. *Create Communication Log* – When enabled, a record is kept of all communication. The log is accessible from the main menu; see Section 7.7.2. This option should only be enabled for troubleshooting purpose and should not be left enabled during normal instrument operation.
 - h. *Print* – Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

6.7. Sample Handler

1. *Electrophoresis Sample Handler connected* – Select if a Helena

Electrophoresis Sample Handler is connected to the system (Figure 6-22)

2. Setup options – Port, Baud Rate, Data Bits, Stop Bits, Parity, and Protocol from Section 6.6.1.1.

3. *Positive Sample Identification* - select if the Helena Electrophoresis Sample Handler will be used for *Positive Sample Identification*. Both the QuickScan Touch *plus* and the Electrophoresis Sample Handler parameters must match.

4. *Create communication log* – When enabled, a record is kept of all communication. The log is accessible from the main menu. This option should only be enabled for troubleshooting purpose and should not be left enabled during normal instrument operation.

5. *Print* - Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

6. 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*.

6.8. Quality Control

1. From the main menu, select *Edit* and then *User Setup*.

2. From the *QuickScan Touch plus Setup* window, select *Quality Control* (Figure 6-23.). The *Quality Control* window displays. Setup as the following describes.

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

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

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. *Print* - Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

4. 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*.

5. QC history data files are stored in the folder 'C:\Program Data\Helena

Laboratories\QuickScan Touch Plus\QC'. To backup QC scans, locate the above folder and copy to a flash drive or network.

6.9. Users and Passwords

Note: *If multiple users have been created, it is best to completely close out of the software and reopen it when switching between users to insure all the correct permissions are in place.*

1. From the main menu, select *Edit* and then *User Setup*

2. From the *QuickScan Touch plus Setup* window, select *Users and Passwords* (Figure 6-24).

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

a. *User name* – enter the desired user name. It cannot contain spaces.

b. *Password* – enter the desired password. It cannot contain spaces.

NOTE: Passwords are case-sensitive.

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

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*

x. *Clear QuickScan Touch logs*

xi. *Clear system logs*

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

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

5. *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.

6. *Print* - Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies.

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 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: *The QuickScan Touch will automatically log out the user after an eight-hour session.*

6.10. SQL Database Server

1. From this screen, the user can view the status of the connection status of the server as well as its location (Figure 6-25).
2. If it is not connected, a series of dots will be displayed next to the word *Status*.
3. Clicking the *Test* button will restore the connection and *Connected* will be displayed.

6.11. SPIFE Touch

The QuickScan Touch *plus* can now track the SPIFE Touch instrument that was used to process the gel plate.

1. From the main menu, select *Edit* and then *User Setup*.
2. From the QuickScan Touch *plus Setup* window, select *SPIFE Touch* (Figure 6-26).
3. *Edit* – To edit an existing serial number, highlight the number and select *Edit* and the Edit window will display. Reference the next step (*Add*) on how to use this window.
4. *Add* - To add a new serial number, select *Add* and the *Add User* window (Figure 6-25) displays.
 - a. Enter (or edit) the serial number in the text box.
 - b. Select OK to accept the changes.
 - c. Select Cancel to reject the changes made. A Confirm Cancel prompt display. Select *Yes* to continue or *No* to return the SPIFE Touch window.
5. *Delete* - To delete an existing serial number, highlight the number and select *Delete*. A *Confirm Delete* prompt displays.
 - a. Select *Yes* to delete the user.
 - b. Select *No* to retain the user.

6. *Default Serial Number* – use the dropdown arrow to designate a default SPIFE Touch serial number.

6.12. Language

In the future, the QuickScan Touch *plus* will offer the user the opportunity to select additional languages for the software to use. Currently, only U.S. English is available (Figure 6-27).

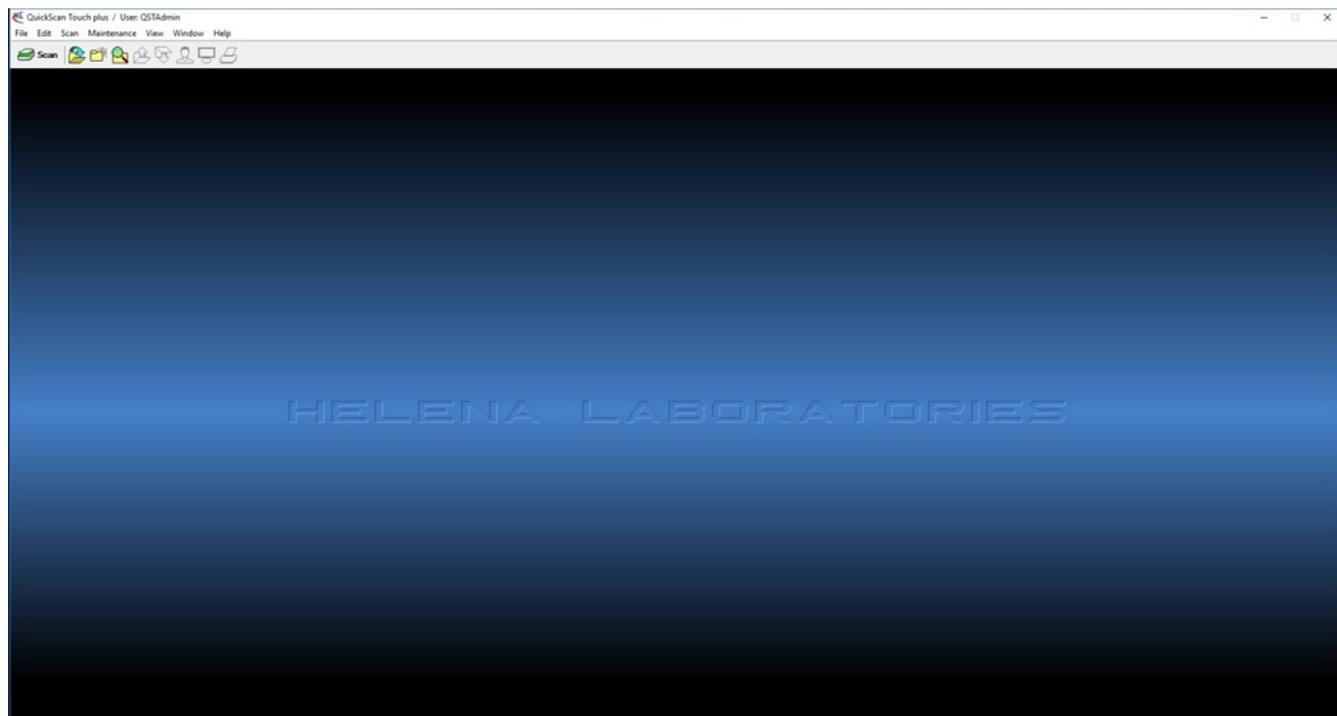


Figure 6-1 Main Menu

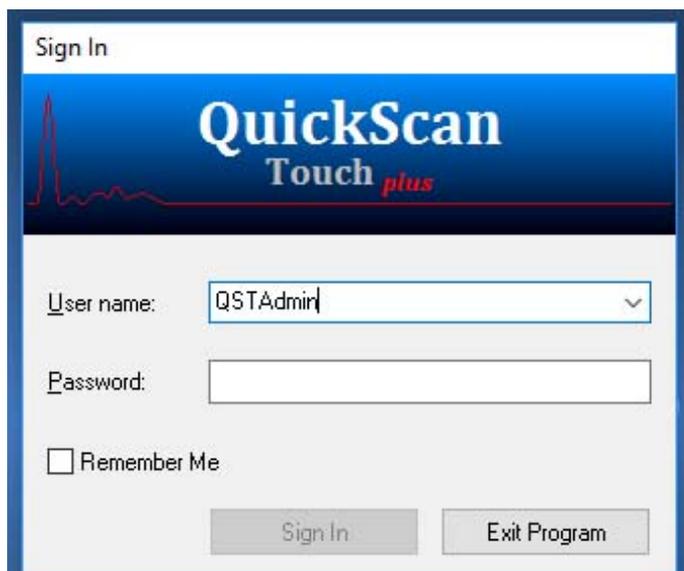


Figure 6-2 Sign-In Menu

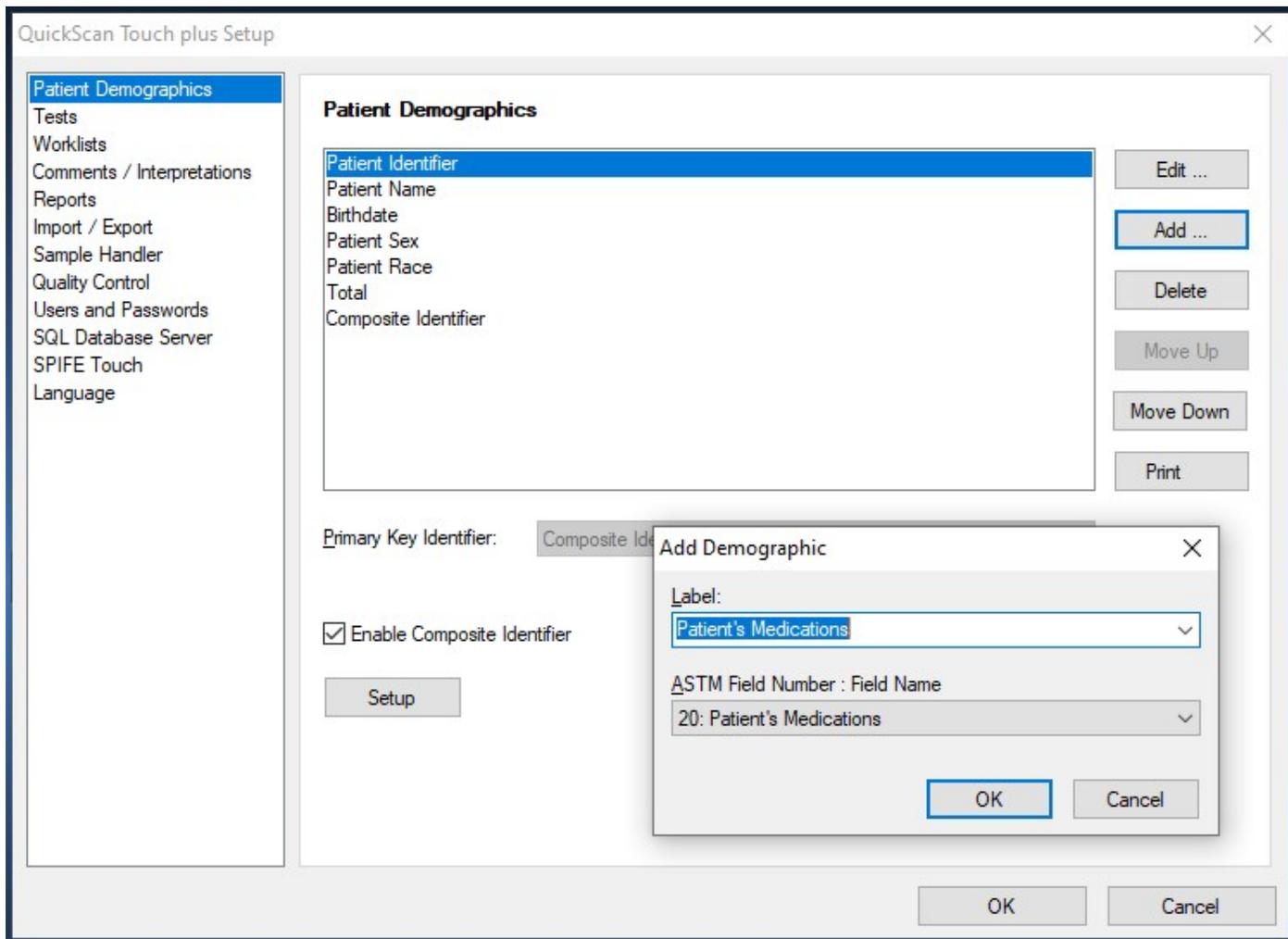


Figure 6-3 Setup, Add Demographic

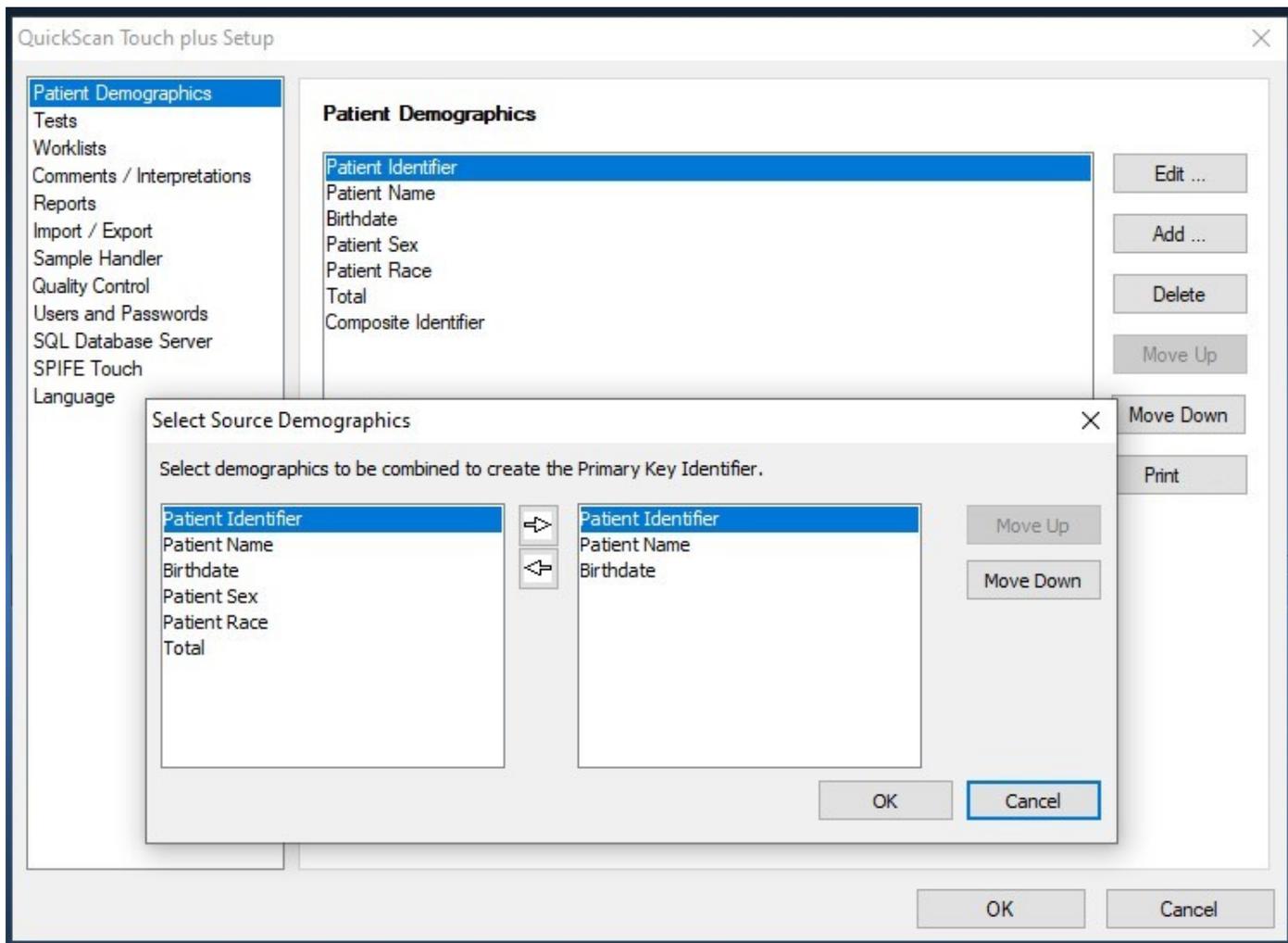


Figure 6-4 Setup, Composite Identifier

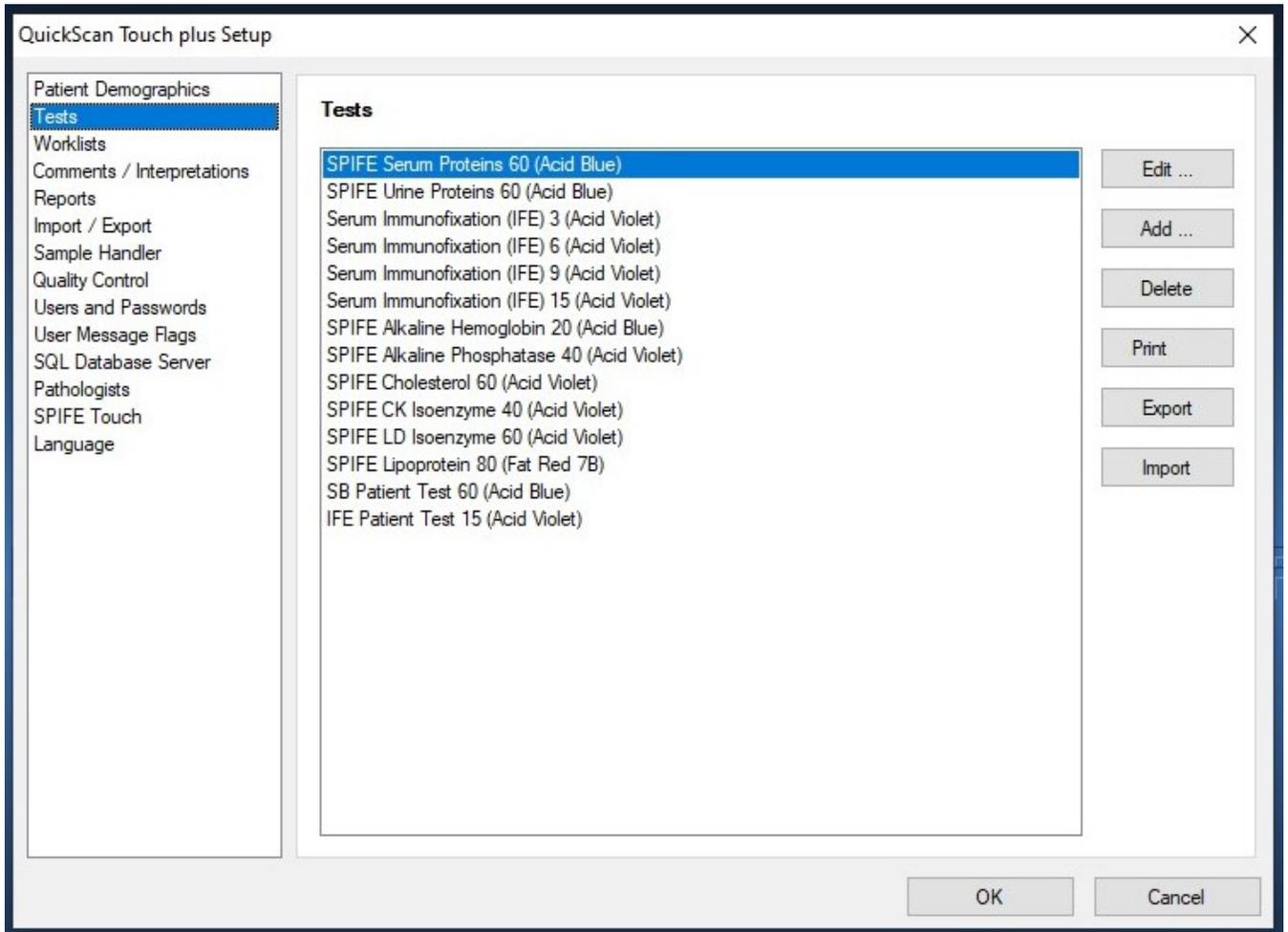


Figure 6-5 Setup, Tests

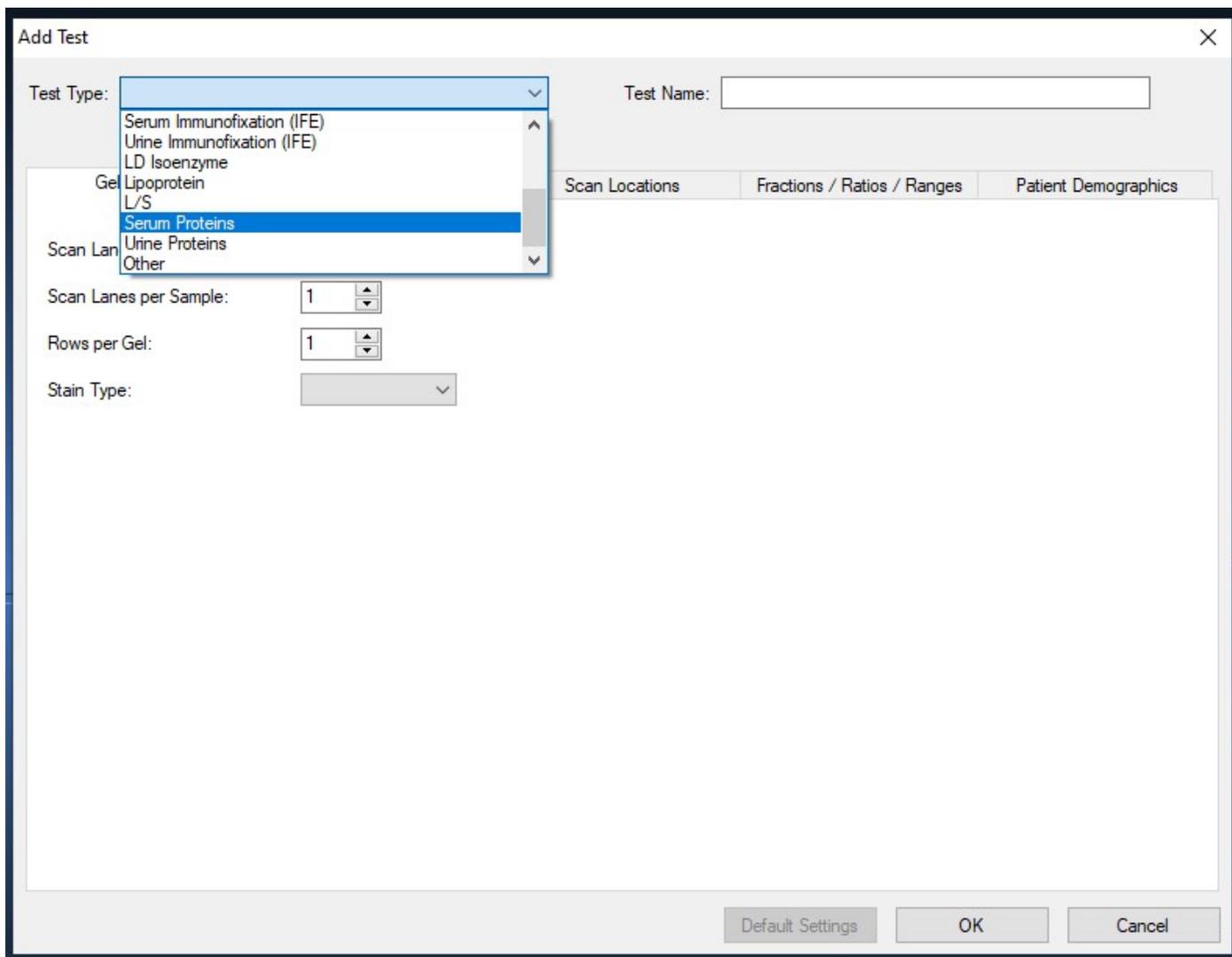


Figure 6-6 Tests, Test Types

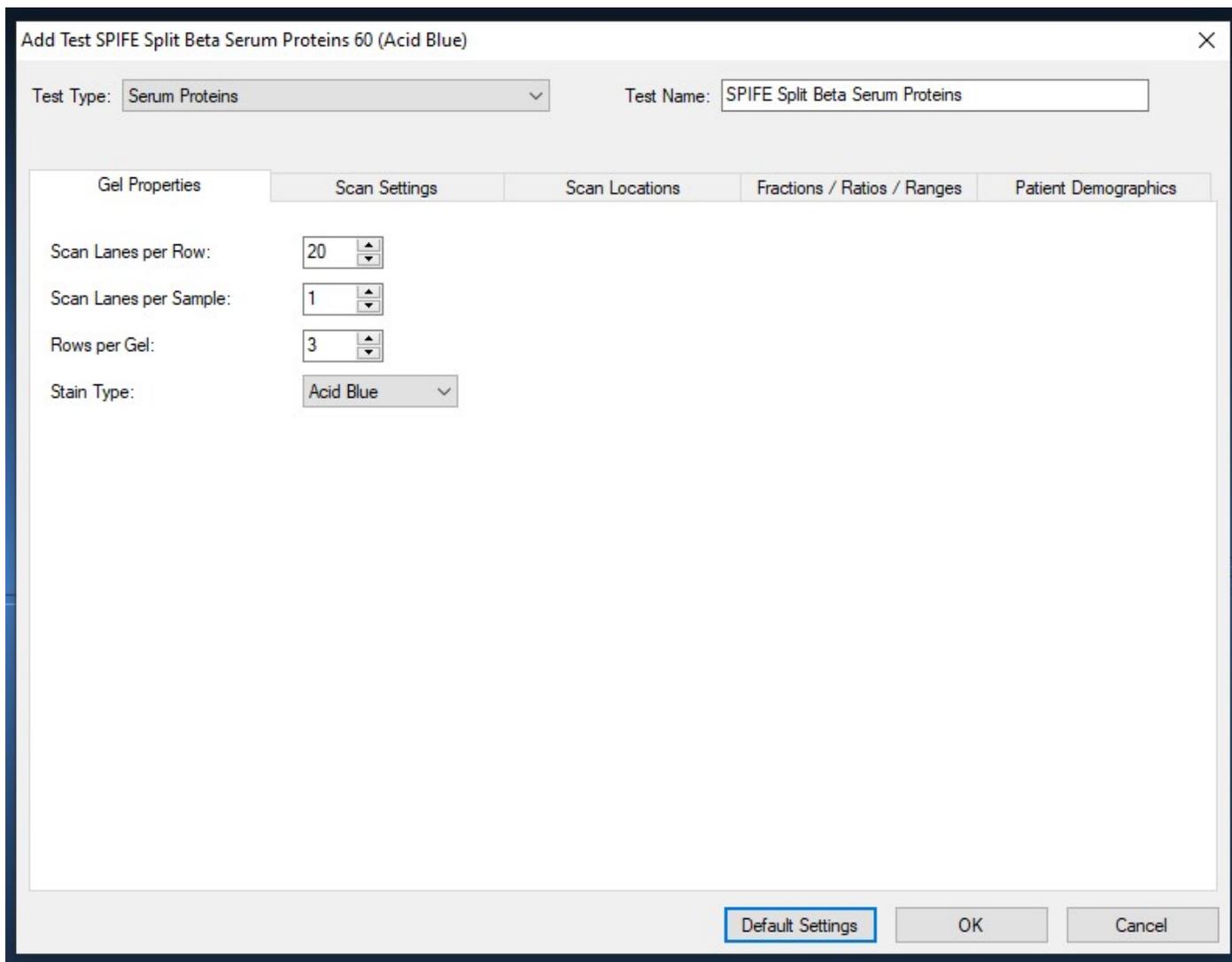


Figure 6-7 Tests, Gel Properties

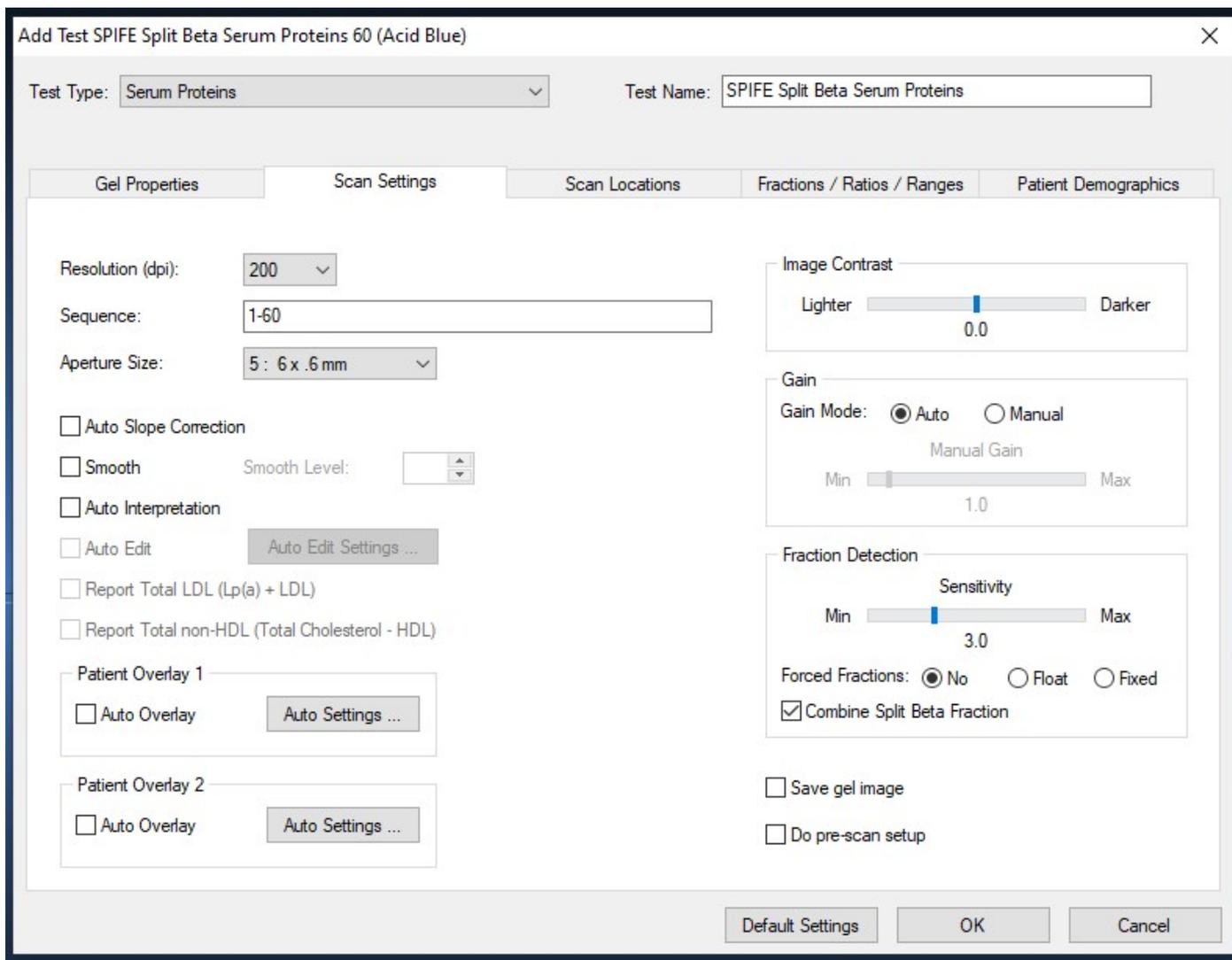


Figure 6-8 Tests, Scan Settings

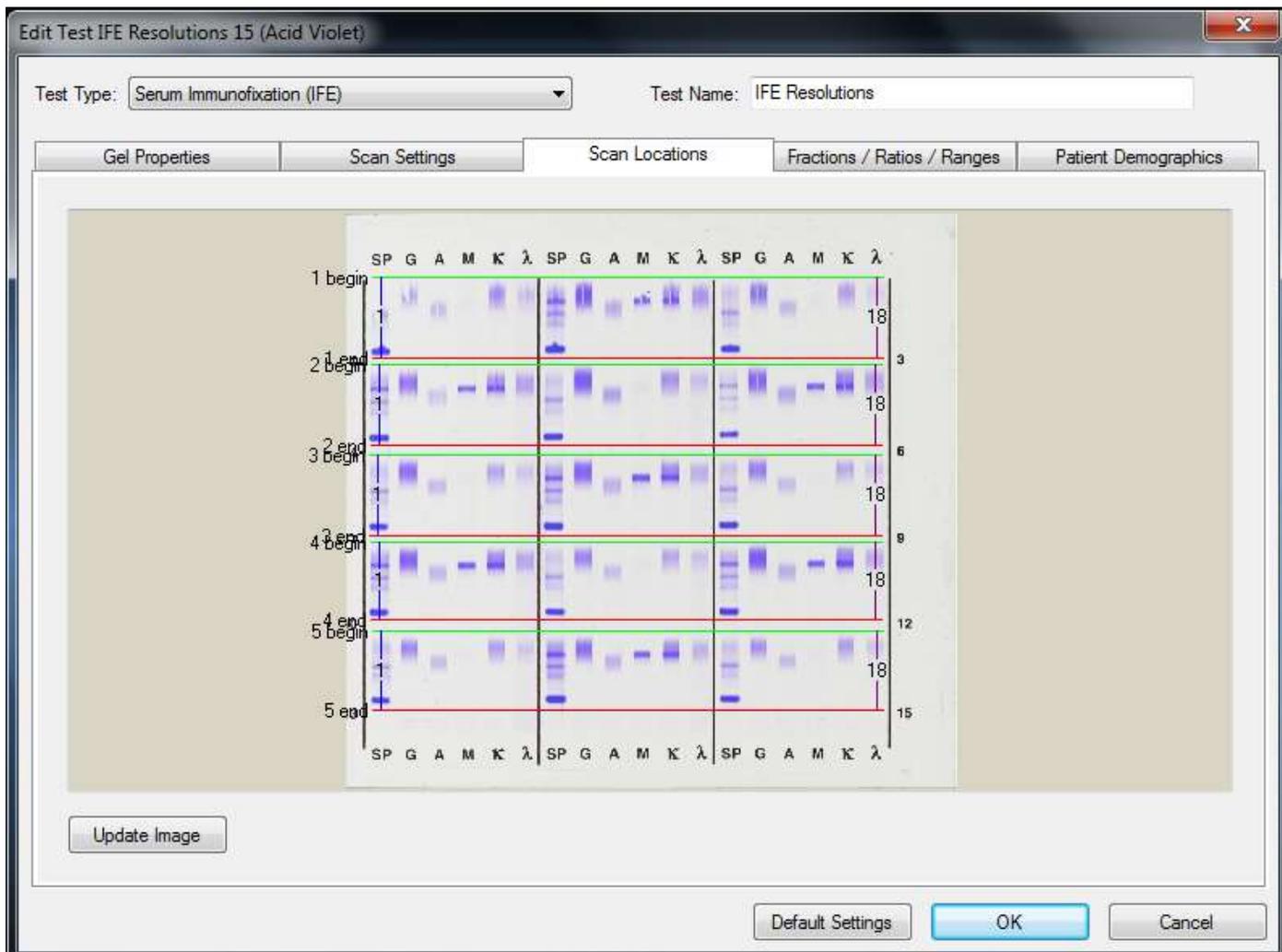


Figure 6-9 Tests, Scan Locations, IFE

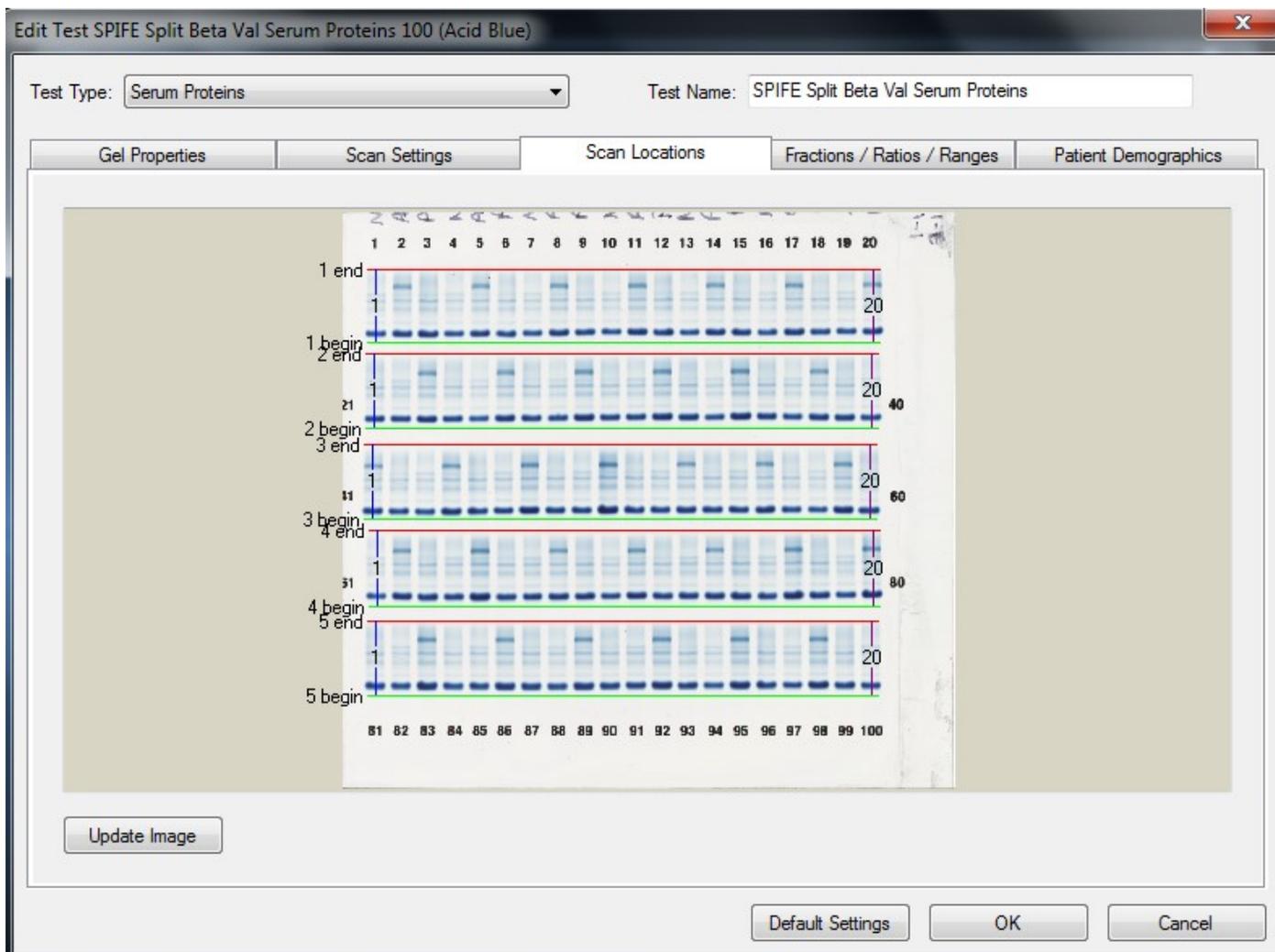


Figure 6-10 Tests, Scan Locations, SPE

Add Test SPIFE Split Beta Serum Proteins 60 (Acid Blue) ✕

Test Type: Serum Proteins Test Name: SPIFE Split Beta Serum Proteins

Gel Properties
Scan Settings
Scan Locations
Fractions / Ratios / Ranges
Patient Demographics

Units of Measure: Restricted Bands:

Fractions: Label:

Total: Marking Method: Sliced or Skimmed

Decimal Places: 1 Automatically locate restricted band delimiters

	Label	Ratio Assignment		Range Set A :	Range Set B :	
		1	2			
Ratio					Range	
1	A/G					
2						
					Units Range	
Total	Protein					
Fraction				Percent Range	Units Range	Percent Range
1	Albumin	Numerator				
2	Alpha-1	Denominator				
3	Alpha-2	Denominator				
4	Beta	Denominator				
5	Gamma	Denominator				

Figure 6-11 Tests, Setup, Fractions/ Ratios/Ranges

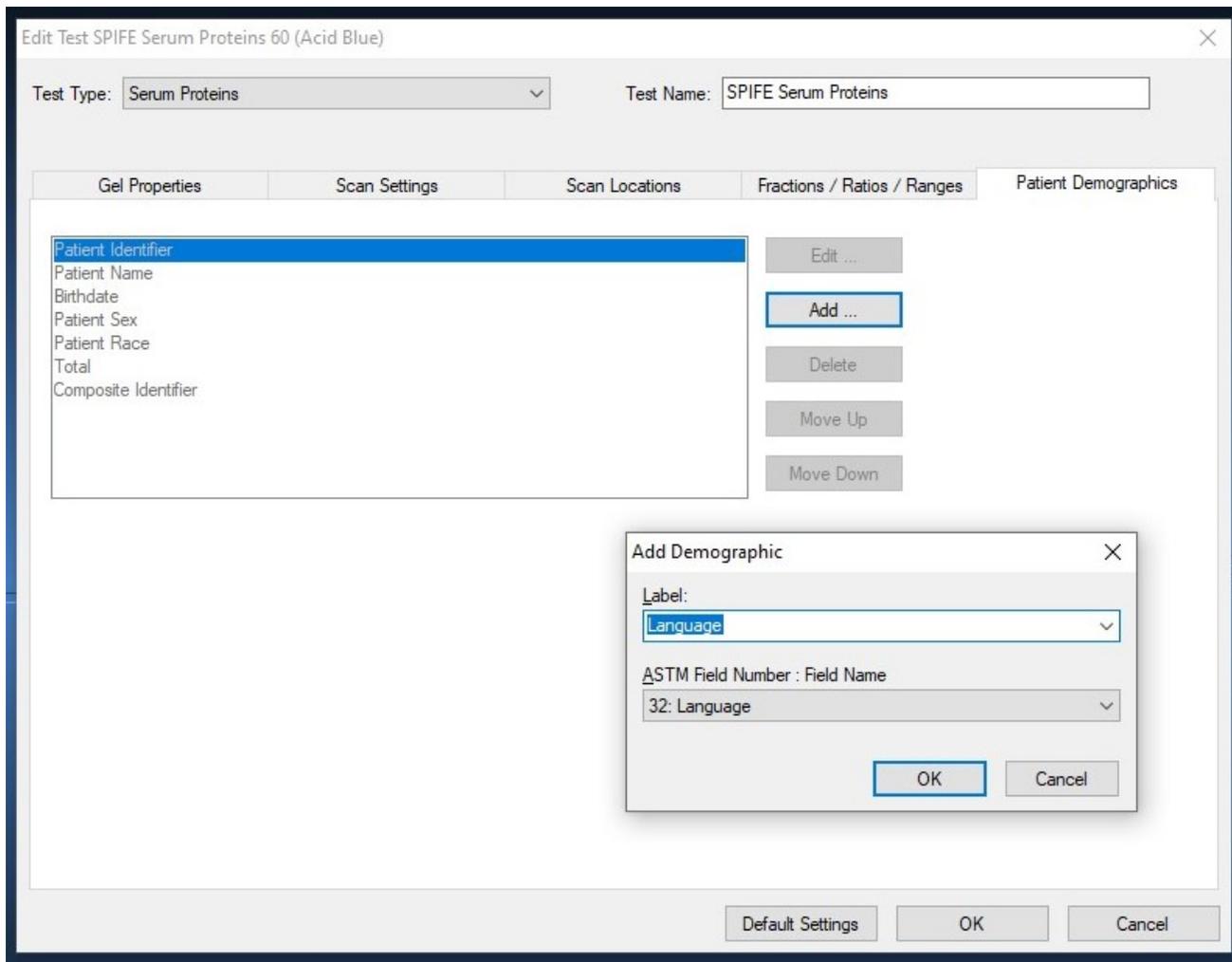


Figure 6-12 Tests, Patient Demographics

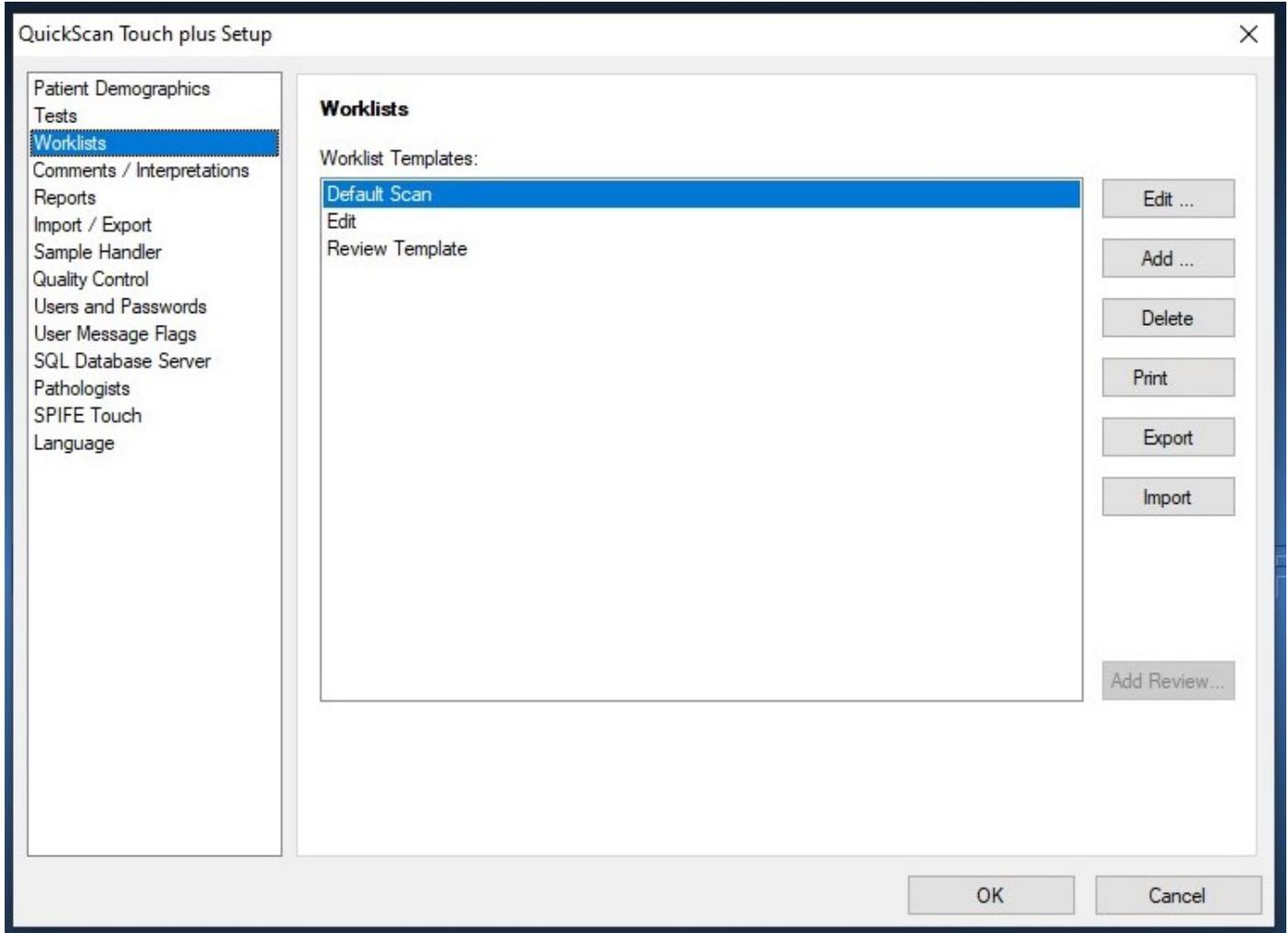


Figure 6-13 Setup, Worklist

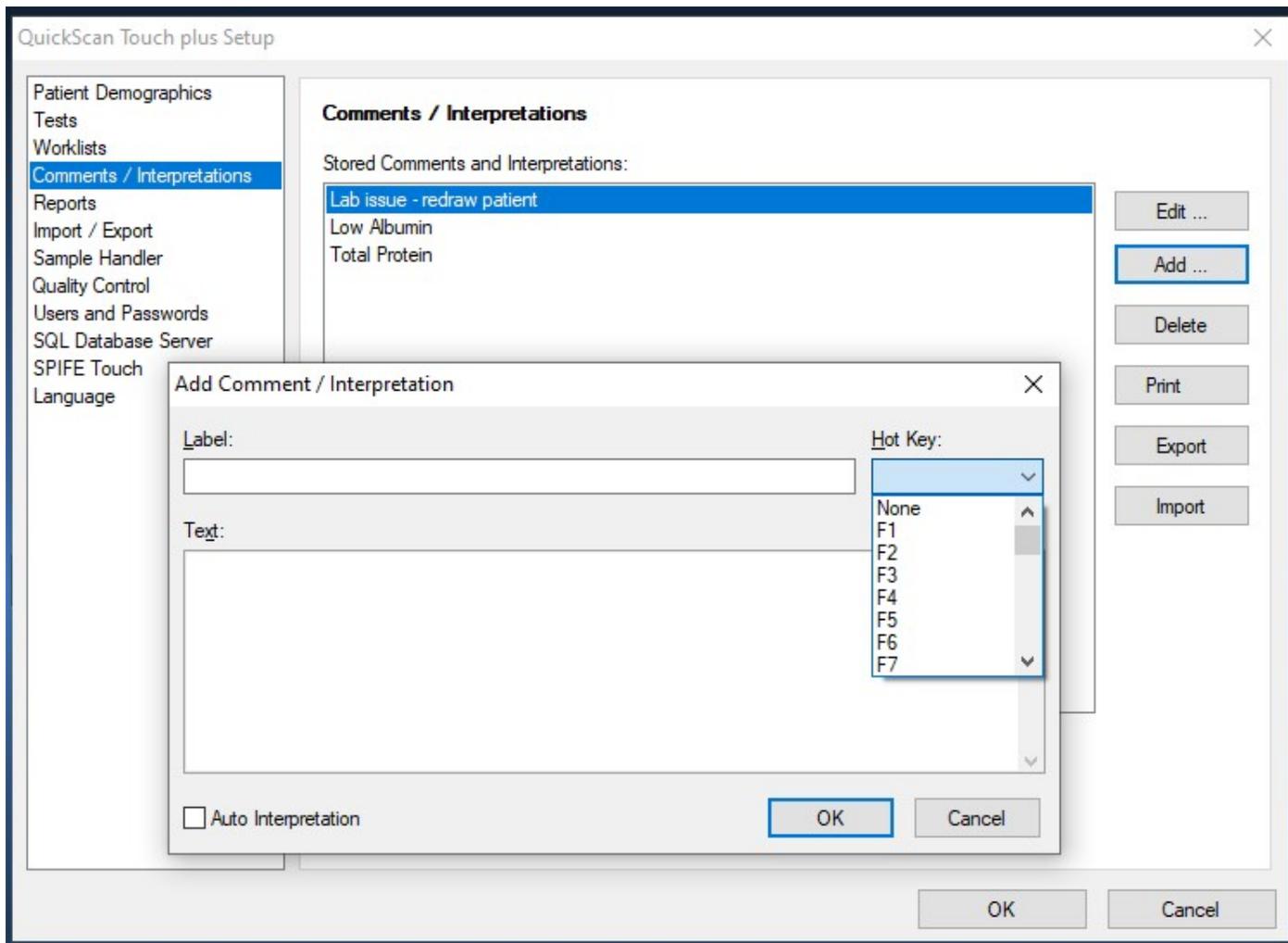


Figure 6-15 Setup, Comments

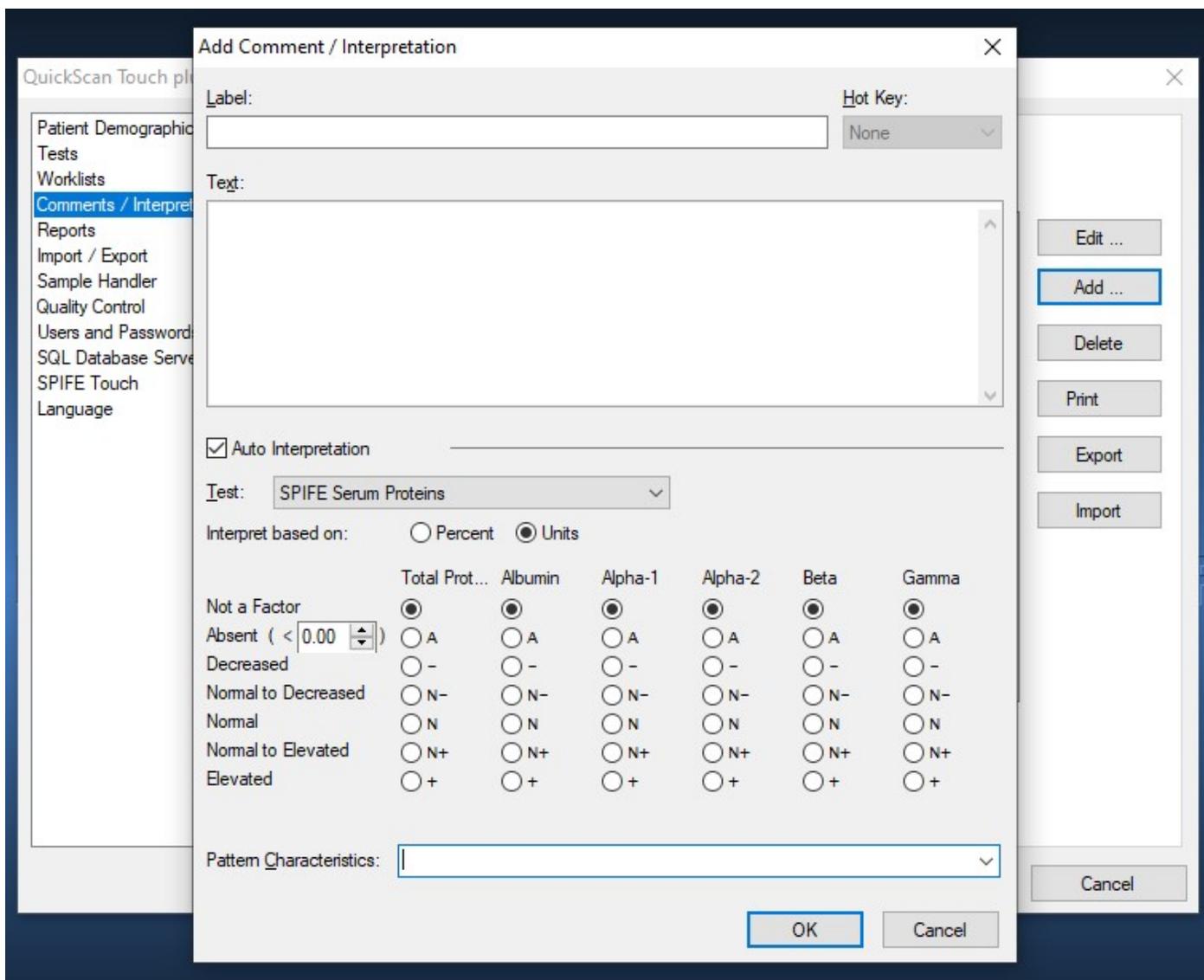


Figure 6-16 Comments with Auto Interpretation

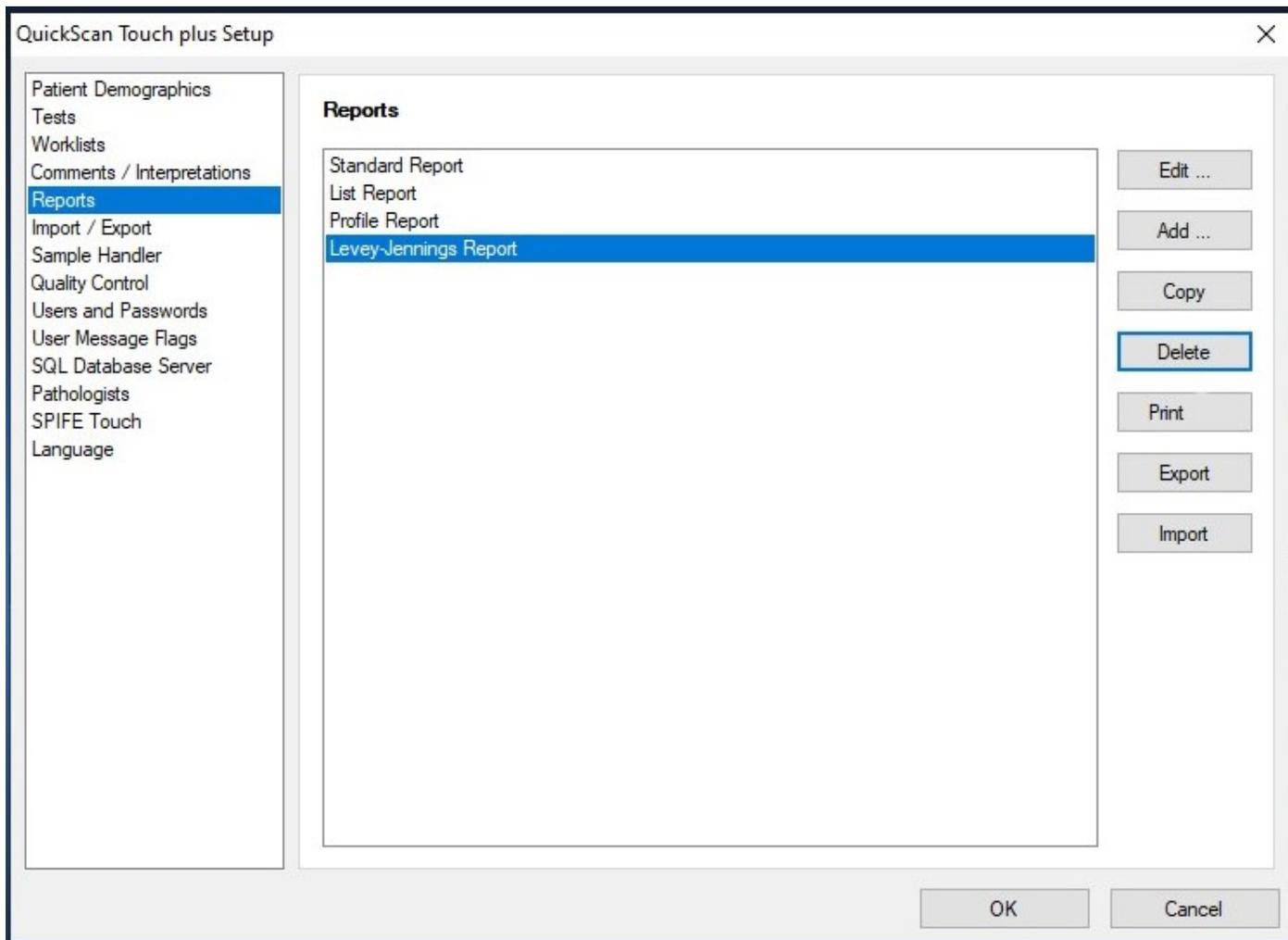


Figure 6-17 Setup, Reports

Edit Report X

Report Name:

Paper Size: Orientation:

QuickScan List Report

Serum Proteins												
Date and Time Scanned Demographic Label 1 Demographic Label 2	Albumin		Alpha 1		Alpha 2		Beta		Gamma		Total gm/dl	A/G
	%	gm/dl	%	gm/dl	%	gm/dl	%	gm/dl	%	gm/dl		
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	48.58	4.86	3.48	0.35	9.02	0.90	10.42-	1.04-	28.50+	2.85+	10.00	0.94-
01/01/2011 12:59:59:0 Patient Demographic 1 Patient Demographic 2	52.56	5.26	4.01	0.40	11.87	1.19	15.46	1.55	16.10	1.61	10.00	1.11

Reviewed by _____

X: 2.94 Y: 2.97 Inches

Figure 6-18 List Report

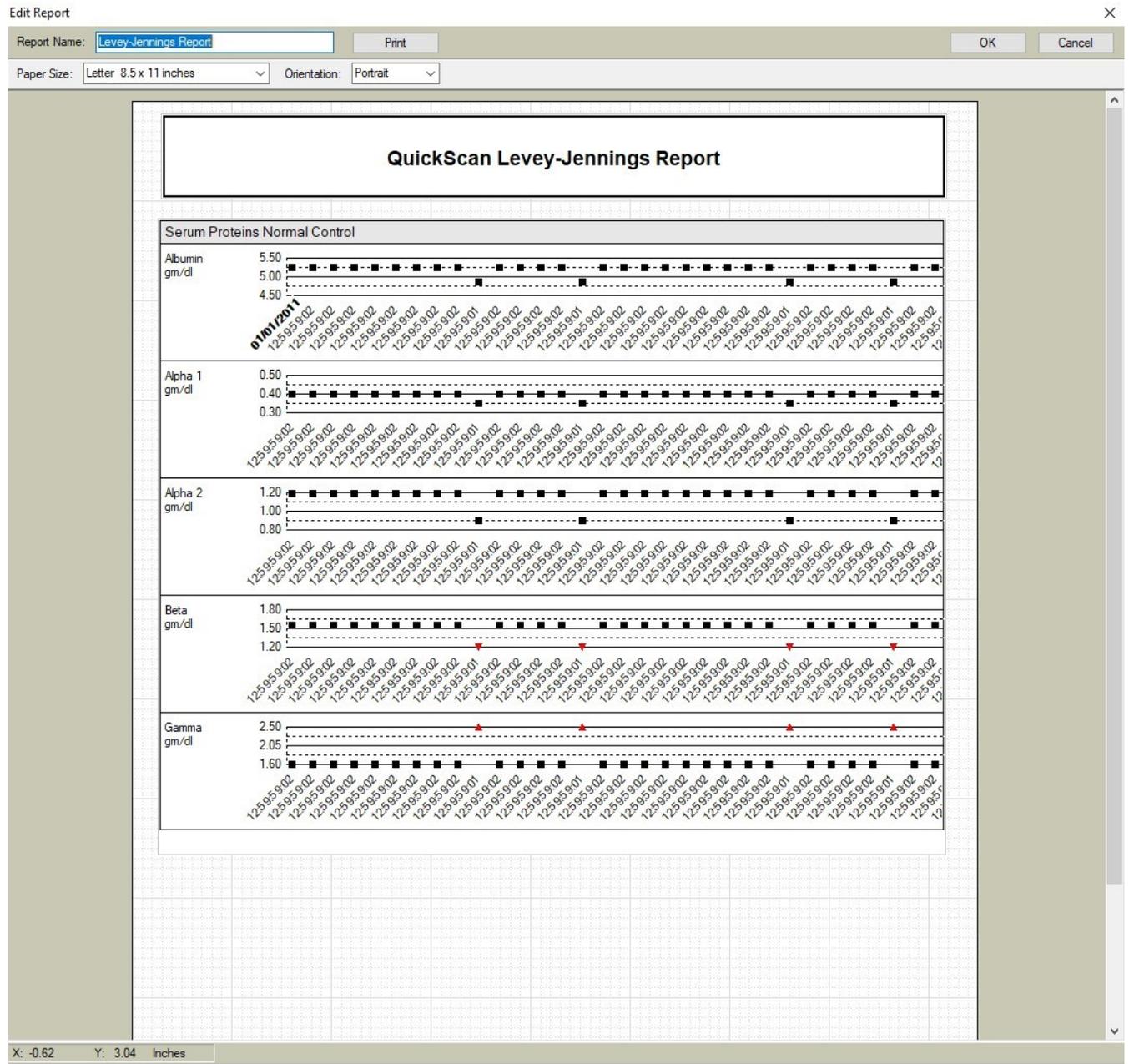


Figure 6-19 Levey-Jennings Report

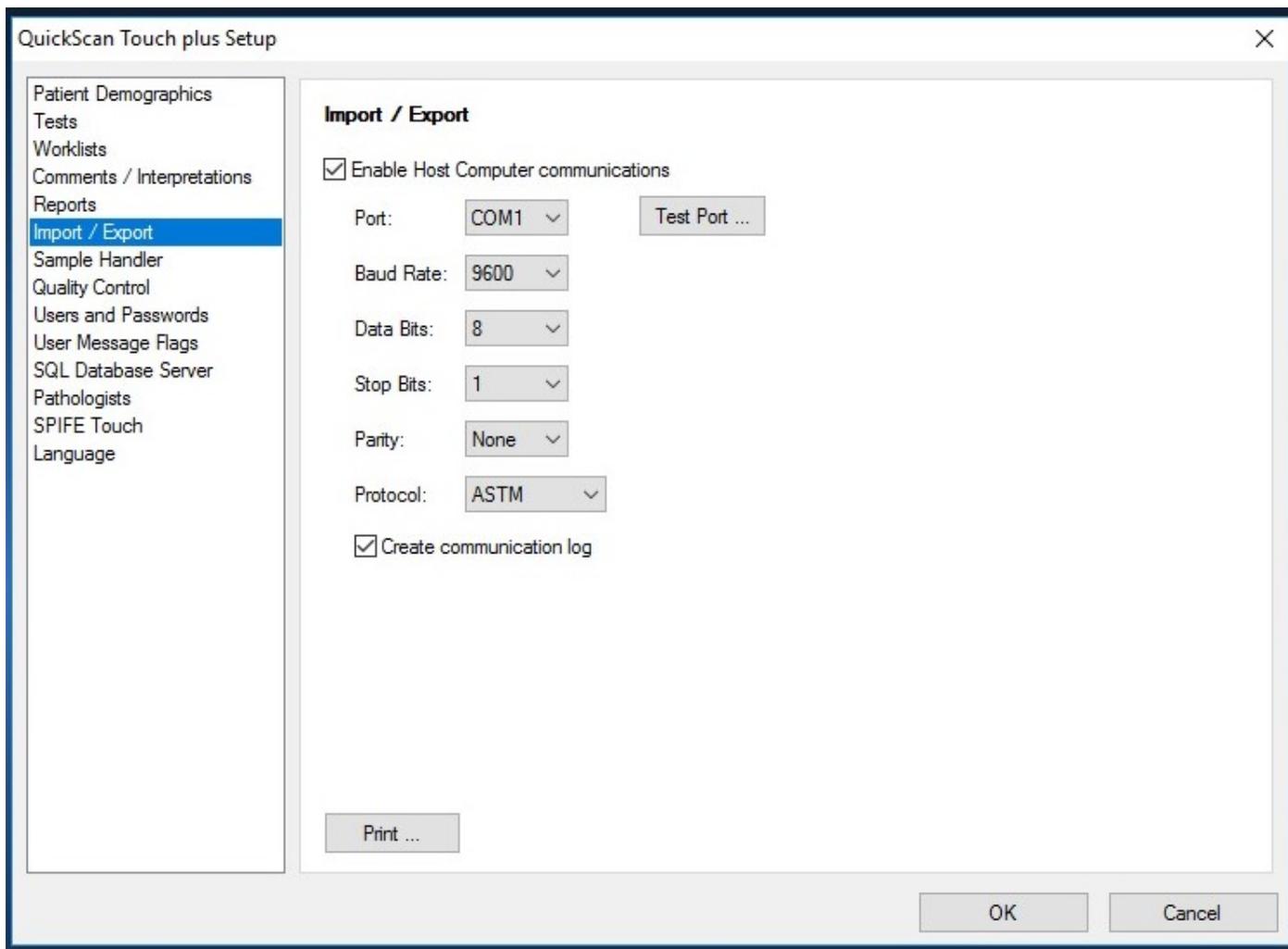


Figure 6-21 Setup, Import/Export

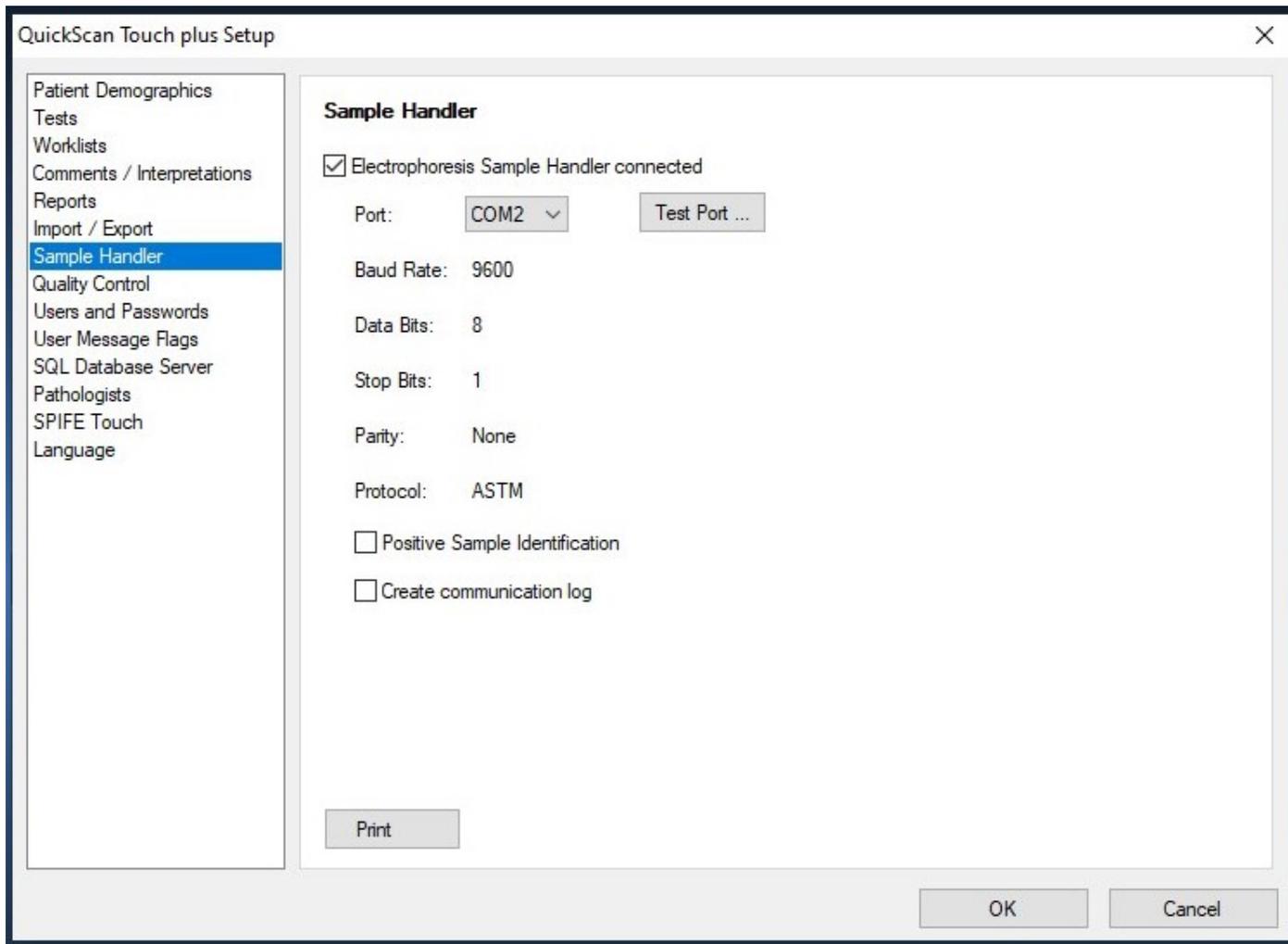


Figure 6-22 Setup, Sample Handler

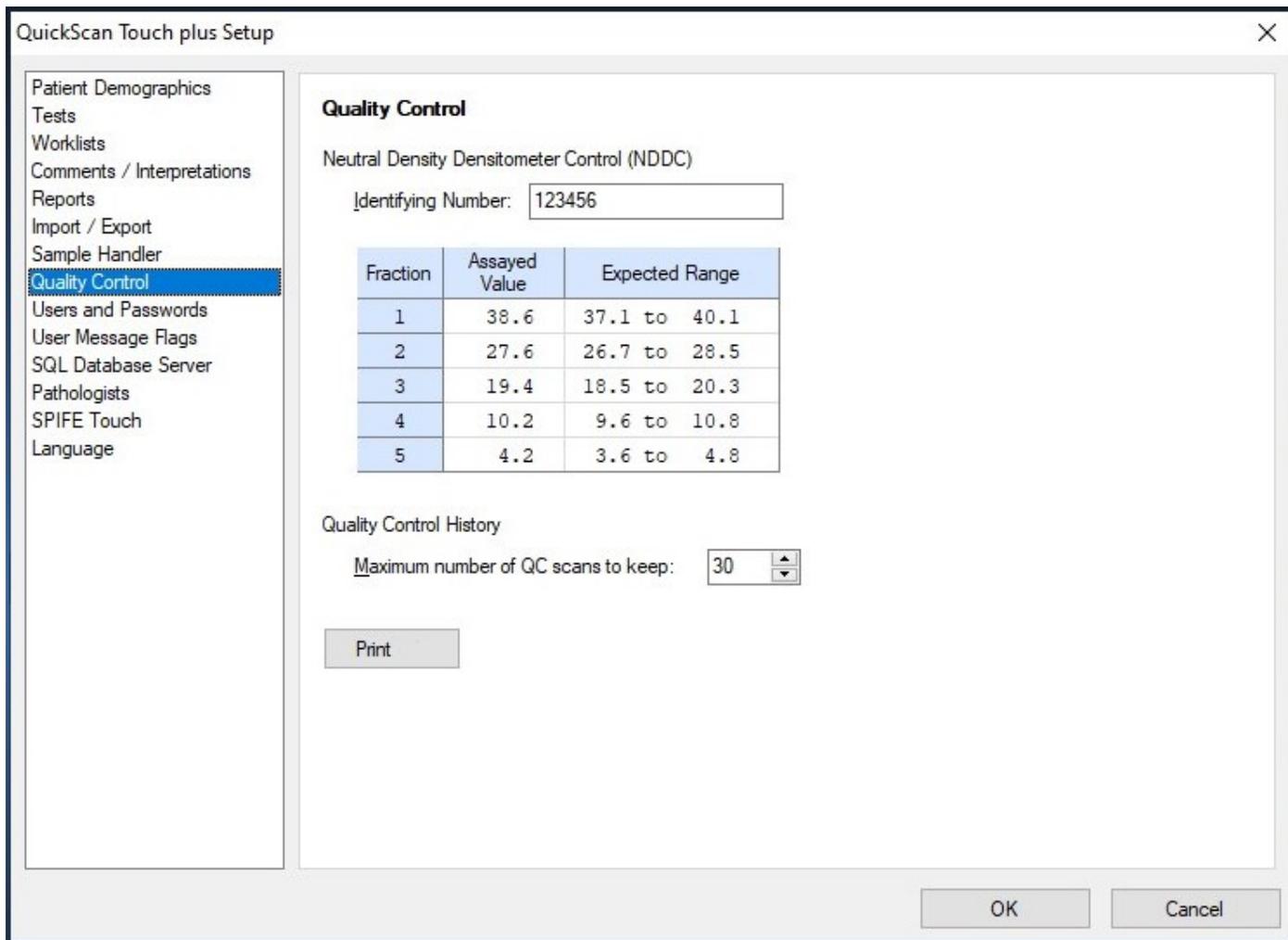


Figure 6-23 Setup, Quality Control

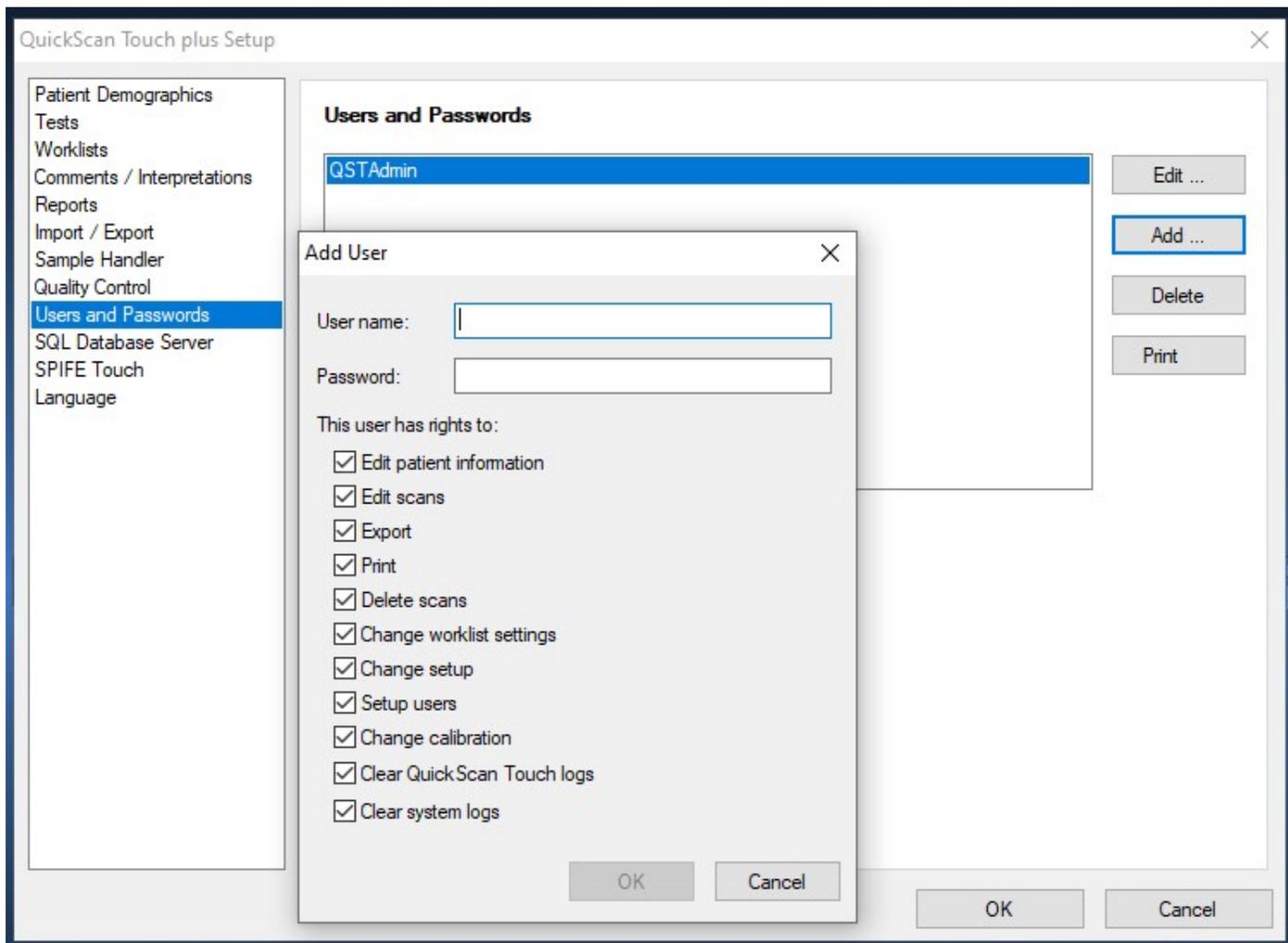


Figure 6-24 Setup, Users and Passwords

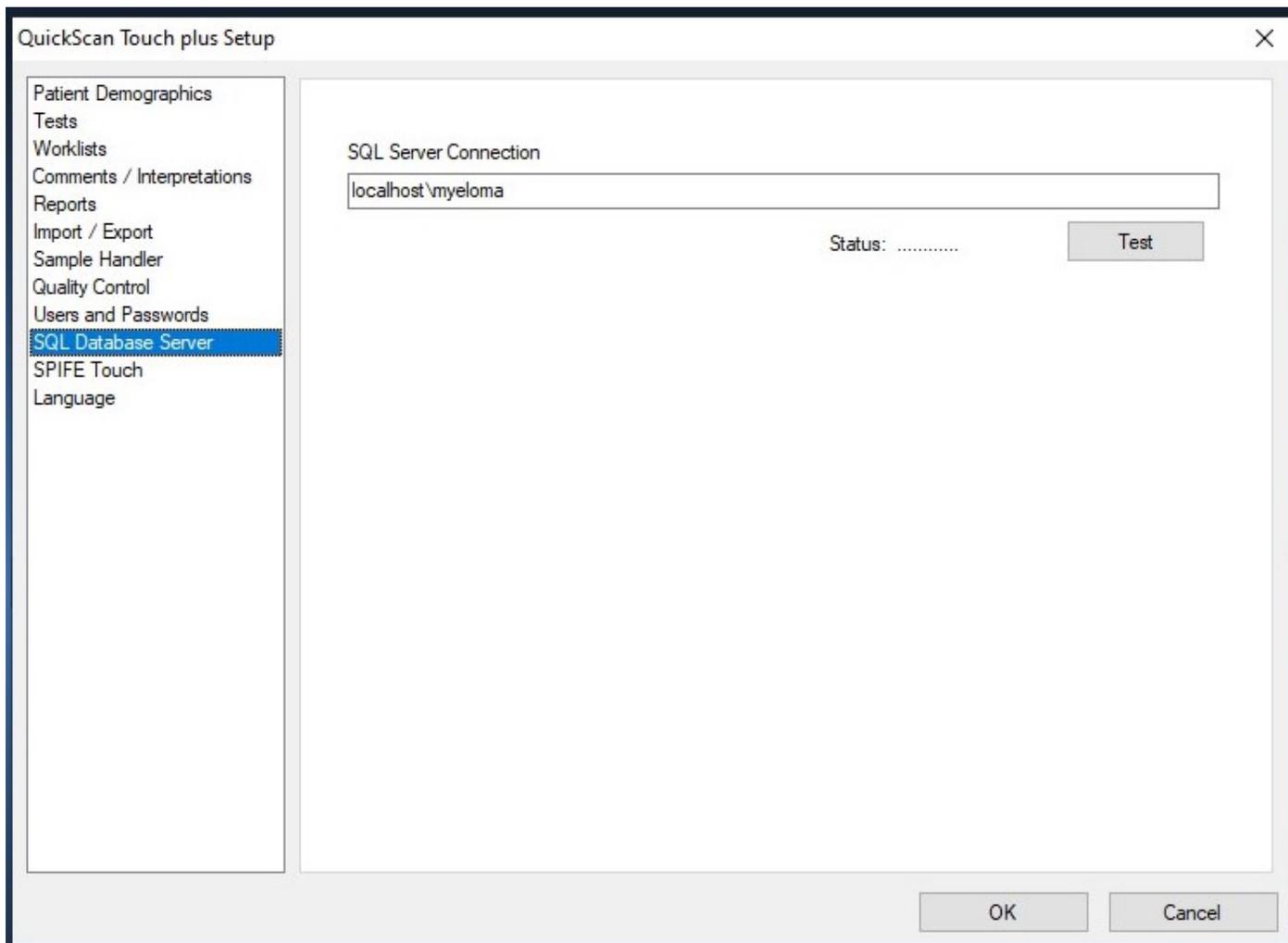


Figure 6-25 Setup, SQL Server Connection

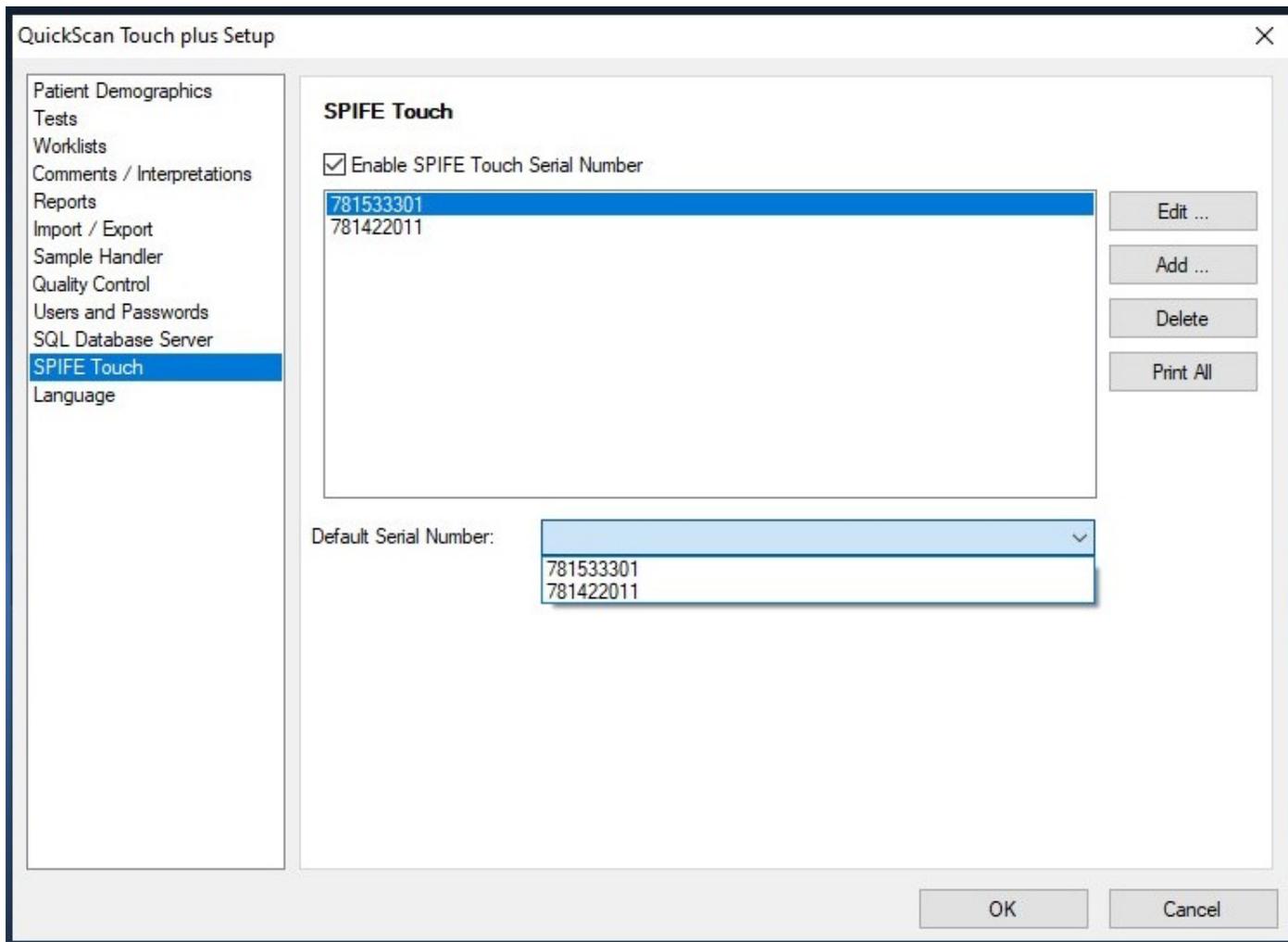


Figure 6-26 Setup, SPIFE Touch

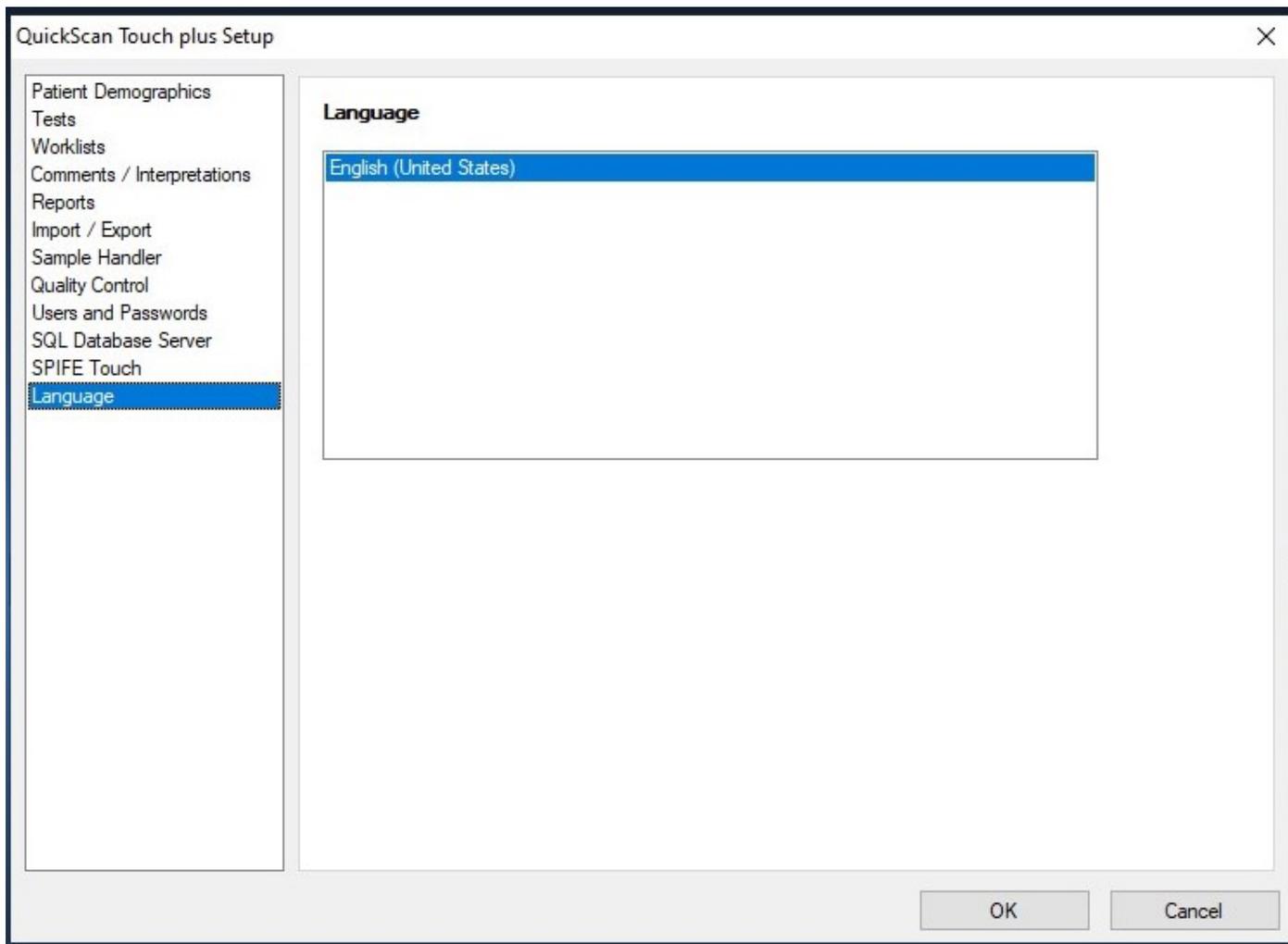


Figure 6-27 Setup, Language

Section 7 - Operating Instructions

CAUTION: Do not attempt to operate this instrument until you have read and understood this manual.

If the system has not been setup, go through all of section six before proceeding. Proceeding without completing setup may result in difficulty completing the instructions contained in this section.

If the system is turned off, turn the power on for the scanner, printer, and monitor and then the computer. The Microsoft® Windows® program opens and displays the QuickScan Touch *plus* 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 instead or the instrument does not perform as described in this manual, refer to Section 10 and contact Helena Laboratories.

7.1. Summary Instructions

Use these instructions only after reading the detailed instructions in the rest of Section seven. These instructions summarize operations required for a typical scan. Detailed instructions begin in Section 7.2.

7.1.1. Summary for worklists

The number of worklists that may be created and stored in the QuickScan Touch *plus* software is essentially unlimited (by disc or network space.) Worklists are automatically created by scanning a plate, or may be created prior to scanning using the New function. All worklists are automatically saved into the default worklist folder which may be set up locally or on a network location. **It is**

strongly recommended that worklists be backed up to a backup folder, as well as to a remote location.

7.1.1.1. Create a New Worklist

1. Under *File*, select the *New* worklist item or click on the *New*

Worklist icon  and create a new worklist. A dialog box opens in which the user is prompted to select a worklist template.

2. Select the desired worklist template.

3. An empty worklist opens, with a dialog box. Label the new worklist.

4. Select the *Enter Patient Info*  icon, and select the desired test when prompted.

5. Enter the patient data either manually or by importing patient data. (Section 7.2).

6. After entering patient information, click the red X to close the patient list. The new worklist will be created and populated with the patient information.

Note that imported data will overwrite any manually entered data. If additional manually entered data is desired, add the information after importing demographics

7.1.1.2. Creation of Worklist

Alternatively, the gel can be scanned first which will automatically create a worklist after the desired test is selected. The worklist will be identified by

date, time, and test. The user may choose to create a label by right clicking over the gel image, selecting *Worklist*, then *Worklist label*.

7.1.1.3. Scanning

Note: *If using a SPIFE Nexus to scan a plate, reference Section 15 on the proper steps and gel cassette placement.*

1. Open the scanner lid.
2. Position the gel on the scanner: If scanning a Helena gel with a round and an obround hole, place the round hole over the right pin on the scanner and the obround hole over the left pin. If scanning a gel with no holes, place the gel so that the first sample is on the right, back corner of the scanner with the samples oriented left to right. If needed the gel may be taped down to the scanner bed to make it lie flat.
3. Close the lid and select the *Scan* icon.
4. If it is necessary to correct scan positions, select the *Scan and Pre-Scan setup*. (Section 6.2.4) If desired, most *Scan Settings*, display, print, and export options can be altered temporarily using the *Pre-Scan Setup option*. The gel is rescanned and displayed with the colored alignment lines. Use the colored lines to correct the scan position, and click on *Scan Sample*. This change is for this particular scan only. It does not permanently change *Scan Begin* and *Scan End* settings.
5. Edit, print, and/or export scan(s) will occur as programmed in *Worklist Setup* (Section 6.3) or *Pre-Scan* options, and may be modified for each individual scan.

7.1.1.4. Summary for Open Worklist

1. Select the *Open Worklist* icon  or menu item. A menu appears in which the user may designate a folder in which to search and search criteria.
2. The worklist folder will be open by default, and all worklists in the folder will be listed in reverse chronological order.
3. Worklists may be sorted by label, date, gel ID or number of scans.
4. Search criteria for worklists include worklist label, test, Gel ID, and timeframe.
5. Enter the desired parameters and click *Apply*.
6. Highlight the desired worklist and click *Open*.

7.1.2. Editing Summary

1. The user may begin to edit the scans when the worklist opens and scans are displayed. There are three ways in which the user may edit the scans.
2. With the scan(s) displayed, click on the desired scan and do one of the following:
 - a. Use the icons across the top of the screen.
 - b. Place the arrow over the scan, right click the mouse and select the function to be performed.
 - c. Use the editing Hotkeys.
 - d. Select and perform the desired editing actions.

- e. Exit edit when scan editing is complete.

7.1.3. Saving and Exporting Summary

1. Select *Export Scan(s)*, as desired.



2. Scans are automatically saved to the worklist folder. Edits are saved in real time.

3. After completing all scan edits, the user may choose to export an individual scan or the entire worklist by clicking on

the Export Icon . An export scans menu opens with a list of all scans in the worklist. At the bottom of the menu are options to Select All, Export Setting, Export, and Cancel. If the user did not set up export options in Setup or Pre-Scan, they may click on Export Setting and enter export criteria.

4. A worklist may be setup to automatically export results, however, this is not recommended as the export will take place immediately after scanning and thus prior to review. Results may be exported to the host computer (LIS system) or to a text file) Note that the Export function exports numeric results only.

7.1.4. Save to File

The *Save to File* function may be used to save the current worklist folder to another location, including a network or flash drive. This function will save the actual scan and gel image (if enabled). Worklist files may only be opened and interpreted by QuickScan Touch *plus* software.

7.1.5. Load to File

The *Load to File* function may be used to open a worklist saved in another

location. This location can be on the same computer, a network location, or a flash drive.

7.1.6. Gel Image

Gel Image files are saved as image files (bitmap by default) and may be opened by most image viewing software.

7.1.7. Print

1. To manually print reports, select the *Print Scan(s)* icon.

3. As needed, select *Print Settings*. A menu opens giving the user choices to select Report, Patient Information, Overlays, Results Ranges and Levey-Jenning Chart. Enter the appropriate parameters and select *OK*.

4. With the desired scans indicated, select *Print*.

5. A worklist may be setup to automatically perform the print function. Automatic printing is not recommended as reports will print immediately after scanning, prior to review or edit.

7.2. File

To access the options in the *File* menu, on the main menu page (Figure 7-1) select *File*. The options are explained in the manual in the order they appear in the *File* drop down list; however, which options are accessible at any given time depends on which worklist is active and user privilege. An option is accessible with the selected worklist through the *File* drop down list, when it is shown in black text and through

the applicable icon, when it is shown in color.

7.2.1. New Worklist

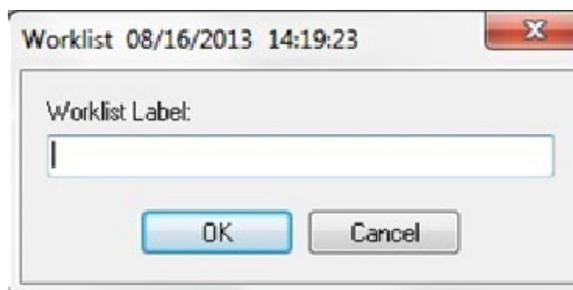
1. From the main menu, select the *New* worklist item under *File*, or click on the new worklist icon  and create a new worklist.

2. The *New Worklist* dialog box opens in which a list of all previously setup worklist templates appears.

3. The user is prompted to select a worklist template.

4. Select the desired worklist template.

5. An empty worklist opens, with a dialog box. Label the new worklist.



6. Select *Edit*, and *Patient Info*, or click on the Edit Patient Info icon , and select the desired test when prompted.

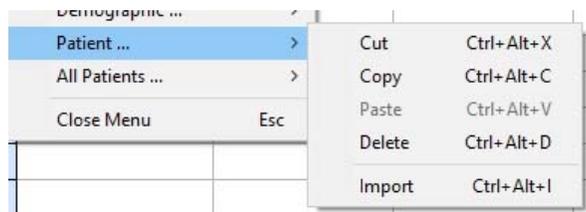
7. The worklist may be closed and used later, or patient information may be added at this point.

8. Patient data may be manually typed in, or imported. To manually enter data, type in the desired information.

9. To import data, the lab information system must be connected, and the host computer import/export communication settings enabled.

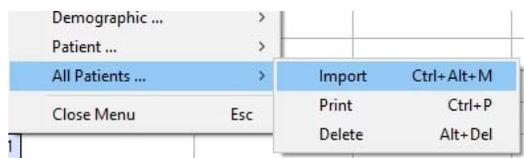
10. Right click on the patient information screen.

11. To import a single patient, select the patient row, right click, and then select *Import*.



12. Scan or type in the patient identifier, then click “import patient information.” See Figures 7-4 through 7-6. For step-by-step directions, see Sections 7.3.2.11 through 7.3.2.13.

13. To import multiple patients, click on *All Patients*, then *Import*.



14. Scan in one barcode at a time into the sample identifier box, clicking on “*Add sample identifier*” after each addition. When all identifiers are added, click on *Import Patient Information*, and the demographic information is imported from the Host Computer.

Patient Information - split beta 09/20/2013 14:27:42 SPIFE Split Beta Val Serum Protein

	Patient ID	Patient Name	Patient Sex	Total Protein
1	123alpha456	Minnie, Mouse		5
2	23456	Kermit, the Frog	frog	9
3	9999888765	Easter, Bunny	m	7
4	444444444	Chicken, Little	f	7.5
5	5852433072	Sponge, B. Square Pant	m	8
6				

15. To import a list of patients, ensure that the Electronic Sample Handler (ESH) has completed sampling, and that the connection is enabled. Right click on the patient information screen, and select *All Patients*.

The sample identifiers will be added to a list as they are imported from the ESH. When all identifiers are added, click on Import Patient Information, and the demographic information is imported from the Host Computer.

16. To import multiple patients simultaneously, the user may create a task list in the Host Computer. To create a task list, patients must be assigned sequential sample identifiers in the Host computer, (for example, patients 1,2,3,4 and 5) Click on All patients, then Import, then enter the sequence of patient IDs. (For examples, (1-5)) into the “Add Identifier” box.

Note: *If the Edit Patient Info is left open and idle for more than 20 minutes, the QuickScan Touch plus will log out the user and not retain any of the added changes.*

7.2.2. Positive Patient Identity/ Electronic Sample Handler

1. In order to take advantage of positive patient Identity with the use of the ESH (also see the manual for the Electronic Sample Handler), ensure that the sample handler connection with the ESH is enabled, and that the communication settings in the ESH are identical to those in the QuickScan Touch *plus* software. (Section 6.7)

2. The host computer connection must also be enabled. To import patient information into the QuickScan Touch *plus*, sample identifiers are imported from the ESH to the QuickScan Touch *plus*, and the patient information is imported from the Lab Information system (Host Computer) to the Quick Scan Touch *plus*.

3. Ensure that the sample tubes are appropriately bar-code labeled, and that

the sample tray barcode is scanned. Sample the tubes per ESH procedure.

4. When the ESH is finished sampling, the operator may choose to either create a new worklist, or open a previously existing worklist as long as the worklist was created with the test entered on the ESH. Open the patient information screen, and right click on the screen, and select All Patients, then Import.

5. The Import All patient information dialog box opens. There is a space at the top to “Add Identifier” and a larger box at the bottom with options to Import Patient Information, Import Patient Identifiers, and Clear All.

6. Select Import Patient Identifiers. The Sample Identifiers (bar code numbers) are imported from the ESH into the lower section of the import screen. If a bar code was not read, there will be a blank space.

7. Click Import patient information. The patient information is imported into the worklist, and the sample identifiers are deleted from the box. There will be a blank space for a missing tube or unread barcode.

8. Missing demographics may either be typed into the patient information screen manually, or the operator may right click on the blank row, click on patient, import, and scan or type in the barcode and import a single patient. Of note, manually

entered information appears in italics.

9. Note that any information imported over manually typed information will over write pre-existing information - even missing information. Importing empty data fields will erase manually entered data.

7.2.3. Open

1. To open a previously created worklist, from the Main Menu select *File*, then *Open*, or select the Open Worklist icon.



A menu appears where the user may designate a folder in which to search and search criteria.

2. The worklist folder will open by default, and all worklists in the folder are listed in reverse chronological order.

3. Worklists may be sorted by label, date, gel ID or number of scans.

4. Search criteria for worklists include worklist label, test, Gel ID, and timeframe. Any one or combination of search parameters may be applied. Clear may be used to clear parameters.

5. Enter the desired parameters and click *Apply*. Highlight the desired worklist and click *Open*. The Open button must be touched or clicked; clicking *Enter* will not open the worklist.

7.2.4. Find

1. A scan may also be located using the Find feature. To retrieve a scan select either select *File* and then *Find* or select

the *Find* icon .

2. A window opens giving the user options to enter different search parameters and a location to search for the scan. It contains the fields *Search for*, *Test*, *Gel Identifier*, matching criteria, and date range. The previous search criteria are cleared each time the window is opened.

3. The first parameter is the labeled *Search for*. In this parameter the user may enter a Key ID, a control, or whatever demographic the user is searching for. On the right side of the Search for space is a down arrow icon. The user may click the down arrow icon and select a reference, normal, or abnormal.

4. Across from the Search for parameter is a drop down menu. This menu gives the user the option to choose an area with in the scan to search for a *Key Demographic* or *All Demographics*. The user may click the down arrow to change the Demographic.

Note: *The default demographic is either the Key Demographic or the Composite Identifier depending on which option has been enabled by the user in the Setup menu.*

5. Under the *Search for* parameter is the Test parameter.

This gives the user the option to choose a specific test to search in. The user simply clicks on the down arrow located on the right and highlight the test to search for a scan.

6. Under test is a search parameter labeled *Gel Identifier*. Under this parameter the user is able to narrow the search by entering a specific *Gel Identifier*. The user may click the down arrow located on the right hand side or typing it in the space provided.

7. Under *Gel Identifier* is a group of small boxes the user may check to narrow the search to specific criteria. For instance, the user may tell the software to Match whole words only, Match case, Must be normal, Must be pathological, or Must be reviewed.

8. The last area the user may use for a search criterion is the Date, which is located under the Gel Identifier and search boxes. The user may enter a date range in this search criterion or simply type it in the space provided.

9. At the bottom of the Find Scan Menu are three buttons labeled *Search*, *Clear*, and *Cancel*. After the user has entered the entire search criteria needed, click on *Search*.

10. The user may use *Clear* to clear all previous search criteria or *Cancel* to cancel the search all together.

Note: *If only default criteria are entered, all scans from all worklists will appear in Search.*

11. The contents of a worklist need not be cleared prior to scanning. Unlimited worklists may be created and stored. (Storage is limited by computer memory only.)

12. Worklists are automatically saved in the worklist folder, and may be backed

up as desired.) Each time a gel is scanned, a new worklist is generated, unless the scan is designated as a re-scan. A re-scan occurs when the worklist is open and the user clicks the scan button. The QuickScan Touch plus will ask the user if this is a re-scan. Selecting Yes will overwrite the current worklist, while No generates a new worklist.

7.2.5. Archive

The *Archive* function is no longer available. Worklists may be individually saved using the *Save to File* function to a different location (Section 7.1.4). All worklists are stored in the database.

7.2.6. Delete

1. From the main menu (Figure 7-1), select *File* and *Delete*. The *Delete Worklist* window will appear.

2. The user may enter search criteria to find a specific worklist(s) by entering information in *Label*, *Test*, *Gel Identifier*, and *Date*. Use the drop down arrows and highlight or type in the information needed for the search. Click on *Apply* to start the search or *Clear* to clear all parameters.

3. A list of matching worklists will appear. The user may select one or more worklists, or may use the *Select All* button at the bottom of the screen. After selecting the desired worklist(s), click *Delete*. A confirmation prompt will appear

prior to deletion. Select *Yes* or *Yes to All* to proceed.

7.2.7. Print Scans

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

Print or select the *Print icon* . The Print option is only accessible with a worklist open.

2. A *Print Scans* Menu opens in the center of the screen with a colored square, *Key ID*, *Test name*, *Gel ID*, *sample number date* and *time scanned and test*, and *Gel ID*. Across the bottom of the menu are the buttons *Select All*, *Print Settings*, *Printer Setup*, *Print*, and *Cancel*.

3. The color of the square represents the following:

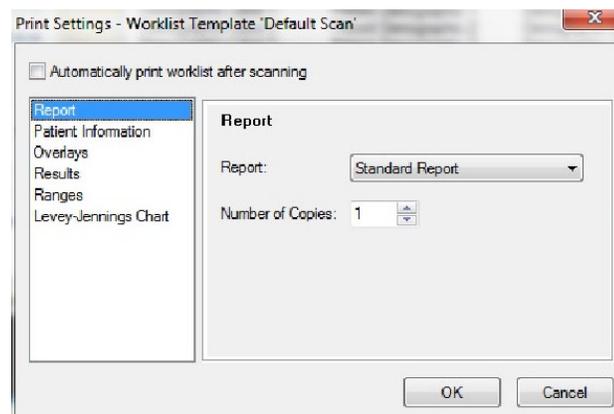
- a. Blue, indicates the scan has the proper number of fractions and all the fractions are within range values.
- b. Red indicates the scan does not have the proper number of fractions and/or one or more fraction is out of range.
- c. Yellow indicates the scan has been viewed in the edit mode; however, still does not have the proper number of fractions and/or one or more fraction is out of range.

7.2.7.1. Print Settings

From the *Print Scans* window, select *Print Settings* to alter the contents of the report from the currently setup parameters. The following print related settings are listed; *Report*, *Patient Information*, *Overlays*, *Results*, *Ranges*, and *Levey-Jennings Chart*.

7.2.7.1.1. 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* - from one to one hundred copies may be printed at once.

7.2.7.1.2. Patient Information

1. *Print Key Identifier Only* - select to have only the demographic classified as Key printed.

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

7.2.7.1.3. Overlays

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

2. *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.

a. *Print Reference Delimiters* - select to have fraction marks printed on the reference overlay

3. *Overlay Patient 1* - Select to have fraction marks printed on patient 2 overlays.

a. *Print Patient 1 Delimiters* - select to have the patient's first scan overlaid on the current scan.

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

a. *Print Patient 2 delimiters* – Select to have fraction marks printed on patient 2 overlays.

5. *Print Overlay Thumbnails* – prints the overlay thumbnail when at least one Overlay is selected. Legend is included for identifying the overlays.

7.2.7.1.4. Results

1. *Results* – The options accessible depend on which of the Report Types is selected, except for a scan worklist with an IFE test selected, and then only the last option is available. Select as needed:

- a. *Print Percent*
- b. *Print Units*
- c. *Print Integrals*
- d. IFE - *Print Units*

7.2.7.1.5. Ranges

1. *Ranges* – The options accessible depend on which of the Report Types is selected, on selections 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. *Print IFE Range*
- e. *Flag Percent Out*
- f. *Flag Units Out*
- g. *Flag Ratio Out*
- h. *Flag IFE Out*

7.2.7.1.6. Levey-Jennings Chart

1. *Levey-Jennings Chart* - Select either:

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

Note: A Levey-Jennings chart will only print results that are of the same test name and test version. If edits are made to a test (such as updating ranges or changing test options) results from both versions of the test cannot be included in a single chart.

7.2.7.1.7. 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.

7.2.7.2. Select Scans to Print

- 1. To select all of the scans listed, 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.

7.2.7.3. Printer Setup

1. Select *Printer Setup*.

- a. *Name* – from the drop down list select the appropriate printer.
- b. *Properties* – select properties such as orientation for the desired printer.
- c. *Status* – displays the status of the printer and if it is ready to print.
- d. *Type* – displays how the worklist or scan will be printed (hard copy, pdf).
- e. *Where* - is automatically entered based on the Printer Name selected.
- f. *Comment* - comments regarding printer.

7.2.7.4. Print and Cancel

1. *Print* - with all the desired scans selected, select to print the highlighted scans.
2. *Cancel* - select to exit without printing.

7.2.8. Export

1. With a worklist open, to export scans, from the main menu either select File and Export Scan(s) or select the Export

Scan(s) icon .

The Export Scans window displays listing all the scans within the worklist in use. The list of scans contains key demographic, the test name, the Gel ID, the sample number, the date and time scanned, and a colored square. The

color of the square represents the following:

- a. Blue indicates the scan has the proper number of fractions and all the fractions are within range values.
- b. Red indicates the scan does not have the proper number of fractions and/or one or more fraction is out of range.
- c. Yellow indicates the scan has been viewed in the edit mode; however, it still does not have the proper number of fractions and/or one or more of the fraction is out of range.
- d. There are options at the bottom of the screen to *Select All*, *Export Settings*, *Export*, and *Cancel*.

7.2.8.1. Export Settings

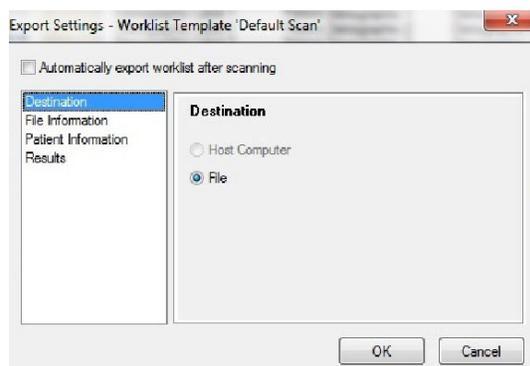
From the *Export Scans* window, select *Export Settings* to alter the contents of the report from the currently setup parameters. The following export related settings are listed; *Destination*, *File Information*, *Patient Information*, *Graph*, *Results*, *Ranges*, and *Comment*.

7.2.8.1.1. Destination

The user may elect to export data to a file or to the Host computer.

1. *Host Computer Communications* - is enabled under the Import/Export options in User Setup. If this is not enabled, the option will be greyed out.
2. *File* - the default destination is to a file.

Note: Depending on which destination is selected, different options will be available.



7.2.8.1.2. File Information

This section is only accessible when File is selected.

1. *File* - if selected then the following option is accessible under File Information:

a. *Save In* – drop down folder allows user to choose a destination to save file.

b. *File Name* - enter a file name and extension. For example, an Excel file would be entered as “.xls”.

Note: The file must have an extension to open. The extension .txt is the default and will work in Excel. To open a txt file in Excel the data must be imported into Excel. Refer to the Excel Help for instructions appropriate to each software version.

c. *Column Headers* - check if user wants a column header.

d. *Delimiter* - Tab, Space, Comma, Semicolons, or Other may be used as delimiters.

e. *Results* - Data exported to a file may be exported as percent, units, or integrals.

Note: Data exported to a file does not include ranges or flags, and restricted bands are **NOT** exported.

7.2.8.1.3. Patient Information

Select one of the following:

1. *Don't Export* – no patient information will be exported.

2. *Export Key Identifier Only* – only the key identifier will be exported.

3. *Export All Patient Information*– all patient information will be exported.

7.2.8.1.4. Graph

This section is only accessible when Host Computer is selected and is not accessible for a scan worklist with an IFE test selected).

1. *Export Graph* - Numerical graphical data only is exported.

7.2.8.1.5. Results

The last option is only available for a scan worklist with an IFE test selected. Select as needed:

1. Export Percent

2. Export Units

3. Export Integrals

7.2.8.1.6. Ranges

This section is only accessible when *Host Computer* is selected. The options accessible depend on selections made in *Results* and/or within *Ranges*. Select as needed:

1. *Export Percent Range*

2. *Export Units Range*

3. *Export Ratio Range*

4. *Export IFE Range*
5. *Flag Percent Out*
6. *Flag Units Out*
7. *Flag Ratio Out*

7.2.8.1.7. Comments

This section is only accessible when Host Computer is selected.

1. *Export Comment* - Numerical graphical data only is exported.

7.2.8.1.8. 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.

7.2.8.2. Select Scans to Export

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.

7.2.8.3. Export and Cancel

1. *Export* - With all the desired scans selected, select *Export* to export the highlighted scans. The export destination selected determines which of the following occurs:
 - a. *Host Computer* - the scan(s) is exported and the *Export* window closes.
 - b. *File* - the scan(s) is exported and the *Export* window closes.
2. *Cancel* – Select to cancel and return to the *Export Scans* window.

7.2.9. Backup

NOTE: *It is strongly recommended that user settings and calibration information are backed up after installation, as well as periodically, both to the default as well as a different location!*

7.2.9.1. Backup Setup

1. User Settings may be backed up with this feature. From the *Main Menu* select *File*, then *Backup*, then *Backup Setup*.
2. *The Backup Setup window is displayed. The default location is in the Program Data QuickScan Touch plus folder. The folder destination can be changed to backup settings to a network, flash drive, or other destination.*

7.2.9.2. Backup Calibration

1. Calibration information may be backed up with this feature. From the *Main Menu* select *File*, then *Backup*, then *Backup Calibration*.
2. *The Backup Calibration window is displayed. The default file is in the Program Data QuickScan Touch plus folder. The folder destination can be changed to backup calibration to a network, flash drive or other destination.*

7.2.10. Restore

7.2.10.1. Restore Setup

1. User Settings may be restored with this feature. From the *Main Menu* select *File*, *Restore*, then *Restore Setup*.

2. The *Restore Setup* window is displayed. The default folder is in the Program Data QuickScan Touch *plus* folder. If one wishes to restore settings from another location, the folder may be changed to a network, flash drive or other destination. Click *OK* to restore the saved User Settings. The Restore Setup function may also be used to transfer User Settings from another instrument by backing up settings to a flash drive from one instrument, and restoring files from the flash drive to the second instrument.

7.2.10.2. Restore Calibration

1. Calibration information may be restored with this feature. From the *Main Menu* select *File, Restore*, then *Restore Calibration*.

2. The *Restore Calibration* window is displayed. The default folder is in the Program Data QuickScan Touch *plus* folder. Click *OK* to restore the saved Calibration information.

7.2.11. Sign out

From the *Main Menu*, select *File*, then *Sign Out* to log out of the software. A confirmation prompt will appear. A new user must then either sign in or exit the program.

7.2.12. Exit

To exit the QuickScan Touch *plus* 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. Edit Patient Information

7.3.1. Patient Information Window

1. Open or select a scan worklist. If patient information has been imported automatically from the ESH, it is recommended that the patient data is reviewed to ensure that all bar codes labels were read and imported

2. To enter patient demographic information, with a scan open, either touch or select *Edit* from the main menu either select *Edit* and then *Patient Info*, or select the *Enter Patient Info* icon .

Patient Information - SPE Demo 1 08/01/2013 15:45:11 SPIFE Serum Proteins 00023929859

	Patient Identifier	Patient Name	Date Drawn	Time Drawn
1	NORMAL			
2	ABNORMAL			
3				
4				
5	T23A	Nermil the Frog		
6	T23abc456	Minnie Mouse		

3. The Patient Information window displays.

7.3.2. Demographic Labels

7.3.2.1. Columns

1. The titles of each column in the table are the demographic labels assigned in setup (These include any test specific demographics (Section 6.2.6) applicable to the test attributed to the worklist in use). The first column is always the demographic designated as the Key identifier.

2. 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, release the button. Use caution not to resize a column so narrow that it is not visible or appears to be removed.

7.3.2.2. Rows

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 (section 6.2.2)

7.3.2.3. Reference

Often, the first sample is used as the Reference sample. The Reference may be labeled manually, by selecting Ctrl + R in the Key ID field. Confirm the cursor is in the row one, column one field, Ctrl + R or right click the mouse. The reference scan may be labeled before or after scanning, or at any time. More than one scan may be labeled reference, and all scans following that labeled scan will use the reference scan that is closest behind. For example, a reference may be designated at the beginning of each row, to be applied to each row.

7.3.2.4. Controls

A control or patient scan may also be labeled as a reference. 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. If using a normal and/or abnormal reference range, label the sample Reference Normal (Ctrl + N) or Reference Abnormal (Ctrl + A), as applicable.

7.3.2.5. Entering Patient Data

1. With row 1 most likely the Reference, enter patient information beginning in the first field of row 2. 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.

2. To move through a row entering information, press Tab after each entry and Tab or 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, scroll up or down, and/or the Page Up and Page Down keys. Errors can be typed over to correct them. Repeat until all patient information is entered. Imported data will over-write any manually entered data, and an imported blank field will also erase any manually typed data.

7.3.2.6. Import Patient

Patient information can also be entered by scanning the barcode for the patient sample. Select the Key ID column in the designated patient row and right click. A drop down menu lists the options Undo, Demographic Patient, All Patients, and Close. Select Patient, then Import. A dialog box opens where the user may scan the barcode into the Sample Identifier box, then Import the Patient information.

7.3.2.7. Positive Patient ID

1. If the Positive Patient ID feature is in use (section 6.7), the worklist label, date and time the worklist was created/ scanned, Gel ID and worklist label is displayed on the top of the window. When the scanning begins, the instrument will request the gel ID.

Data imported automatically from the Sample Handler using Positive Patient ID will appear in regular font, manually imported or entered data will appear in italics

2. Note that if patient identification and sample ID (barcoded labels) have been imported, the sample ID will remain associated with the scan, even if the identification is manually overwritten. For example, if the user were to attempt to manually change a patient ID from the imported patient ID (for example, if the incorrect label had been applied), the original bar code number would remain associated with the scan when exported.

If attempting to overwrite positive patient ID, the user MUST reimport data by rescanning the correct barcode and reimporting the correct information.

7.3.2.8. Patient Information

With the cursor in the appropriate row, right click the mouse. A window opens displaying five icons: *Undo*, *Demographic*, *Patient*, *All Patients*, and *Close Menu*.

7.3.2.8.1. Undo

Undoes the last task the user performs. (Hotkey Ctrl + Z).

7.3.2.8.2. Demographic

1. Right Click and select *Demographic*. Another window opens that contains fourteen tabs located on the side of the first window.

a. *Find* – is used to search for patients within the worklist. The user may enter criterion from any demographic within the worklist. Right click mouse, highlight *Demographic*, and highlight *Find* (or Hotkey: Ctrl + F). Enter information in Search for, check the box Match whole words only or Match case. Click *Find* or *Cancel*. If the information is found in the worklist, the cursor will move to its location and highlight it. If the information cannot be found, a message will appear No instance was found.

b. *Find again* - used to find other instances of the previously found data in the worklist (Hotkey: F3).

c. *Cut* - select to have information in the column removed. (Hotkey: Ctrl + X).

d. *Copy* - select to have the indicated column of patient information copied to clip board (Hotkey: Ctrl +C).

e. *Paste* - select to have the patient information that has been cut or copied entered into the indicated column (Hotkey: Ctrl + V).

f. *Delete* - select to have the indicated patient information deleted. (Note: information must

be highlighted before it can be deleted). (Hotkey Ctrl +D).

g. *Select* - used to highlight patient information in a column (Hotkey: Ctrl +S).

h. *Paste to following Patients* - select to have the patient information that has been cut or copied, for example Tech ID, entered into all the fields under the indicated field (Hotkey: Ctrl + W).

i. *Increment and Paste to following Patients* - select to have the patient information that has been cut or copied 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 (Hotkey Ctrl + I).

j. *Reference* - select to designate a sample as a Reference sample (Hotkey: Ctrl + R).

k. *Normal* - select to designate a sample as a Normal sample (Hotkey: Ctrl + N).

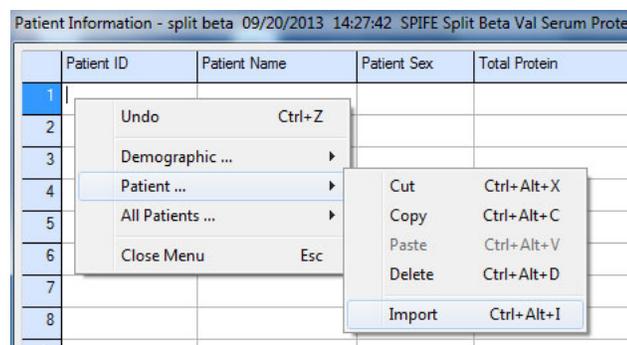
l. *Abnormal* - select to designate a sample as an Abnormal sample (Hotkey: Ctrl + A).

m. *Today's Date* - select to enter today's date in the indicated field (Hotkey: Ctrl + T).

n. *Yesterday's Date* - select to enter yesterday's date in the indicated field (Hotkey: Ctrl + Y).

7.3.2.8.3. Patient

This allows a user to insert patient information into the entire row for a single patient. Within the Patient menu there are five options: *Cut*, *Copy*, *Paste*, *Delete*, and *Import*.



1. *Cut* - cuts the entire row of patient information (Hotkey: Ctrl + Alt+X).

2. *Copy* - copies the entire row of patient information to the clipboard (Hotkey: Ctrl + Alt + C.)

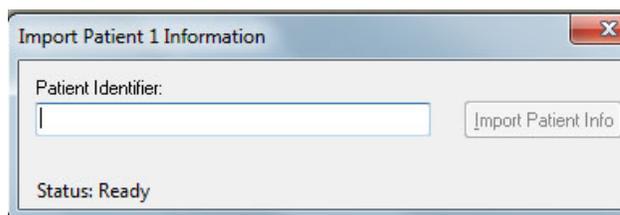
3. *Paste* - Pastes the entire row of patient information (Hotkey: Ctrl + Alt+V).

4. *Delete* - Deletes the entire row of patient information (Hotkey: Ctrl+Alt+D). A *Confirm Delete* dialog will prompt the user for confirmation.

5. *Import* - if enabled in setup, and connected to the Host Computer Laboratory Information System (LIS) a complete set of demographic data for that patient may be imported. Select import, and a dialog box opens where the user may scan a barcode into the Sample Identifier box, then click *Import the Patient information*. The Key Identifier is imported, then the box closes, and the patient information is imported from the LIS.

6. In the QuickScan Touch *plus* software, the patient data is not directly imported from the ESH; the "Sample Identifiers" are imported from the ESH to the QuickScan computer, and then the patient information is

imported and exported from a direct connection with the LIS.

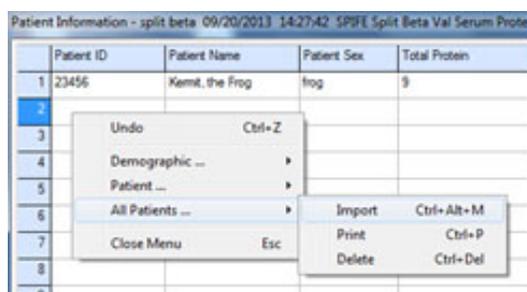


7.3.2.8.4. All Patients

This allows a user to insert patient information into the entire row for multiple patients simultaneously. Within the *All Patients* menu, there are five options: *Cut*, *Copy*, *Paste*, *Delete*, and *Import*.

7.3.2.8.4.1. Import

1. Click *All Patients*, then *Import* (Hotkey: Ctrl+Alt+M). The *Import Patient Information* menu opens with a small text box at the top. Sample Identifiers are imported automatically from the ESH if the Sample Handler option has been enabled. If not, they can also be entered manually one at a time.



2. The user then clicks *Import Patient Info*, and the Patient IDs are imported from the LIS into the menu.

3. The menu closes, and the patient information has been imported into the worklist.

4. If a barcode was not read, a blank space will appear in the sample

identifiers as they are imported, and a corresponding blank row will appear in the patient information list.

Note: *More than one patient may be imported simultaneously from the Host Computer by the use of a list. To do this, one must create a list of patients in the Host Computer in the same sequence that samples will be applied to the plate. Sample identifiers must be in sequential order. (for example, 1-60. Positive patient identity is not applicable.)*

5. From the *Main Menu*, click on the *New Worklist* icon or select *File* then *New*.

6. In the *New Worklist* window, select a worklist template, such as *Default Scan*.

7. A text box appears for the user to enter a *Worklist label* (a name for the worklist) Select *OK* when finished and a new blank worklist will be displayed.

8. Select the *Patient Icon* at the top of the screen.

9. The user is prompted to select a test from a dropdown menu. Select a test, click *OK*, and the *Patient Information* Menu opens.

10. With the cursor in position one, right click on the mouse and another menu opens.

11. Scroll down to *All Patients* and select *Import*.

12. Another menu opens where the user may enter patient sample identifiers.

13. Enter the desired sequence of sample identifiers (for example

1-60) under *Patient Identifiers*, and click on *Add Patient*.

14. The specific sequence will appear in the sample identifier list below. (for example 1-60) click *Import Identifiers*.

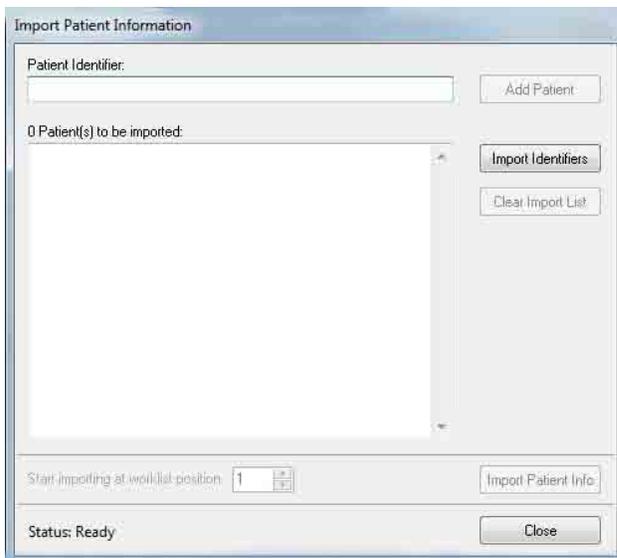
15. The Patient Information imports from the LIS Task list.

16. Click on the Red X to close the Patient Information screen.

17. Scan the plate.

Note: If using an ESH, the *Import Patient Info* will be greyed out and not available.

Below is a list of hotkeys for editing Demographics in the Patient Worklist window.



7.3.2.8.4.2. Print

Print - when selected, the Print Patient List window displays. Select a Printer from the drop down list and indicate the Number of Copies needed. Select Print to print the list. Select Cancel to exit without printing.

7.3.2.8.4.3. Delete

Delete - select and the alert, “Are you sure you want to delete patient...” appears. Select Yes or Yes to All to clear the patient information. Select No to exit without clearing the patient information.

Action	Hotkey Combo
Demographics	
Undo	Ctrl + Z
Find	Ctrl + F
Cut	Ctrl + X
Copy	Ctrl + C
Delete	Ctrl + D
Find Again	F3
Paste	Ctrl + V
Select	Ctrl + S
Paste to Following Patients	Ctrl +W
Increment and Paste to Following Patients	Ctrl + I
Reference	Ctrl + R
Abnormal	Ctrl + A
Normal	Ctrl + N
Today's Date	Ctrl + T
Yesterday's Date	Ctrl + Y

Below is a list of hotkeys for editing Patient Information in the Patient Worklist window.

Action	Hotkey Combo
Patient Information	
Cut Entire Row	Ctrl + Alt + X
Copy Entire Row	Ctrl + Alt + C
Paste Entire Row	Ctrl + Alt + V
Delete Entire Row	Ctrl + Alt + D
Import	Ctrl + Alt + I
All Patient Information	
Import All Patients	Ctrl + Alt + M
Print	Ctrl + P
Delete	Alt + Del
Close Menu	Esc

7.3.2.9. Close

To exit the Patient List and return to the worklist, click the red X in the upper right hand corner.

7.4. Edit Scans

7.4.1. Navigation

1. A scan displayed in an open worklist window includes the scan, image, and any demographics, fractions, overlay thumbnails, and comments associated with the scan. In the upper left corner of the screen there is a space where the image of the gel may be displayed (if Save Gel Image is enabled).

2. To select a scan for editing, the user may click on the image of the gel located in the top left side of the screen and select the number of the scan.

3. A scan may also be selected for editing by selecting a thumbnail image

located in the bottom left corner of the screen.

4. To move between the scans in the worklist, click on the thumbnail or the gel image located on the left hand side of the screen.

5. Scans may be edited by using the touchscreen, icons, right clicking on the scan and accessing the pull down menus, or with Hotkeys.

6. Note that moving the cross hair causes a corresponding move in the indicator bar on the display of the sample.

7. Once an edit function is performed, the last function or all functions performed can be undone by using either the Undo or Restore feature. See section 7.3.2.9 for additional information.

8. Fraction marks can be placed one on top of the other. If additional fractions are listed but not seen, delete the fractions until the correct one is found.

7.4.2. Auto Edit

7.4.2.1. Application

1. The *Auto Edit* function may be used to automatically edit the scan based on a reference overlay.

2. *Auto Edit* may be accessed by touching or clicking the icon  or by right clicking on the scan and accessing the pull down menus.

3. *Auto Edit* is only accessible when the name of the test in use contains "Chol" and only if Auto

Edit was not already applied. (For example if Auto-Edit was already selected in the test setup or Pre-Scan Setup, the edits would have already been applied).

4. *Auto Edit* is based on the absolute position of the Lp(a) on the reference. Optimally a reference is included on each row of samples. These scans must always be reviewed because faulty fraction marking can compromise not only Lp(a) values but also HDL quantitation. On some occasions, the HDL may be very low in value or may move faster causing the software to eliminate the HDL. Any sample without HDL should be manually edited. To do so, use the Restore function to remove the automatic edits.

7.4.3. Auto Edit Settings

1. There are two Auto Edit Settings, *Auto Edit*, and *Auto Edit with Force Lp(a)*. To access Auto Edit Settings, right click on the scan and access *Auto Edit*, *Auto Edit Settings* from the pull down menu, or click Ctrl-S. Select the box next to *Force Lp(a)* to enable or disable this option.

2. *Cholesterol Auto Edit*, *Force Lp(a) Fraction* - selection of this feature provides for automatic marking of an Lp(a) fraction, based on the Reference. In order to keep Lp(a) values on the report, the software marks automatically this small amount of Lp(a) based on an amount indicated by the Lp(a) area on the reference.

Note: *With Auto Edit in use, scans should be reviewed and edited, as needed, to evaluate the auto edit performance.*

7.4.4. Delimit Bands

Right click on the scan to access Delimit Bands, which provides access to

Fractions, Restricted Bands, and Reposition Delimiter. The user may also use the individual icons.

7.4.5. Insert Fraction

1. Although the QuickScan Touch *plus* 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.**

2. Up to 10 fractions may be inserted. 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 the mouse-highlight Delimit Bands and select Insert Fraction. The user may also use the Hotkey Ctrl+Ins. A fraction delimiter appears on the graph at that point and the fraction data is automatically recalculated when editing causes a change in values.

Note: *Fraction marks cannot be placed on top of each other.*

7.4.6. 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 Hotkey: Ctrl+Del. The closest fraction mark is deleted and the fraction data is automatically

recalculated when editing causes a change in values.

7.4.7. Force Fraction

Fractions are automatically marked by the software based on detection of change in the slope in the pattern. The position of fractions can also be modified based on the reference overlay, if present, and edited. There are three options for fraction placement. Use the

menu item or icon  to access these options.

7.4.8. No

Fraction marks are placed based on the individual scan without regard to the reference overlay. (Recommended).

7.4.9. Float

Fraction marks are based on the individual scan, but will also be guided by the reference overlay.

7.4.10. Fixed

Scans will be edited with fraction delimiters in the exact position as the reference delimiters.

7.4.11. Fraction Identification

With the Fraction ID feature, the user may renumber or relabel fractions based on labels assigned in User Setup. With the Touch or Select the Fraction ID

icon  or right click on the scan, select Delimit Bands, then Fraction Identification to access this feature.

Before using this feature, be sure to mark the correct number of fractions.

7.4.12. Fraction Number

A menu opens with a list of all fractions for the selected scan identified by number and label (if available) to the left. Up to 10 fractions may be marked on a scan. 0 to 10 fraction labels may be assigned in Test Setup. The list will include as many fractions as marked.

7.4.13. Unused Labels

On the right hand side of the menu, there is a column for unused fraction labels. If there are fewer marked fractions than labels identified in test setup, additional labels are listed in this box.

7.4.14. Fraction Labeling

There are two arrows between the columns. To remove an undesired label from a fraction, select the label then click on the arrow pointing towards the right. The label will be moved into the unused column, and the fraction will now be identified by number. To relabel the fraction, highlight the label from the unused box, and click on the arrow pointing left. To label an unlabeled fraction, highlight the blank space in the “Labeled” column, select the desired label from the “Unused Label” column, and click the arrow pointing left. Note that the order of fraction labeling can be altered as well.

Note: *If using this feature in combination with Auto Interpretation, keep in mind that the correct number of fractions must be labeled in test setup,*

auto-interpretation, and marked in order for auto-interpretation criteria to be appropriately applied.

7.4.15. Clear

Select Clear to remove all fraction labels and replace with numbers.

7.4.16. OK

Select OK to apply and save changes.

7.4.17. Cancel

Select Cancel to exit without making changes.

7.4.18. Reset

Select Reset to reset all fraction labels to original labels.

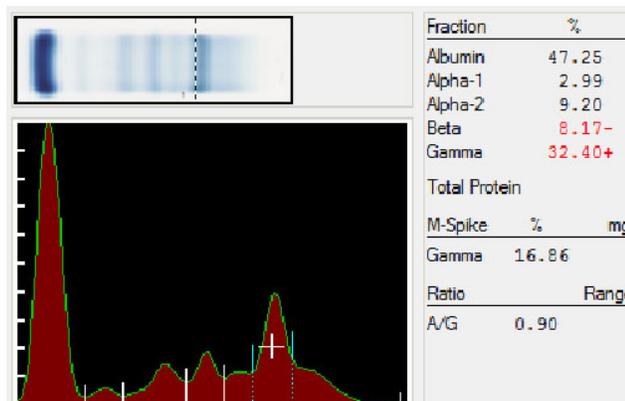
7.4.19. Mark Sliced Restricted Band

1. 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 QuickScan Touch *plus* software, *Sliced*, and *Skimmed*. Up to ten restricted bands in total may be marked. Traditionally, restricted bands/M-proteins have been marked using the "Sliced" method, as seen below.

2. The Sliced (or **Perpendicular Drop**) marking method will include in the measurement all protein in 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 Hotkey: Ctrl+M for Sliced.

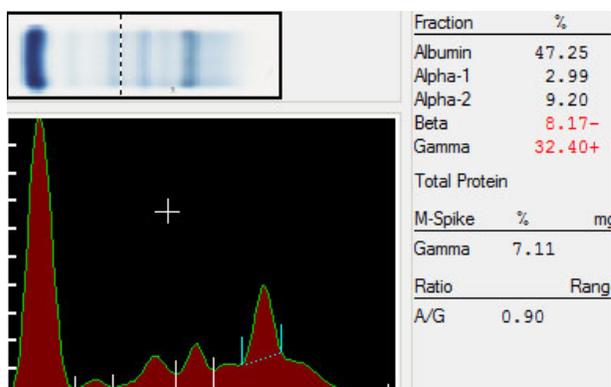


7.4.20. Mark Skimmed Restricted Band

1. 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 QuickScan Touch *plus* software, *Sliced*, and *Skimmed*. Up to ten restricted bands combined may be marked.

2. The Skimmed (or **Tangent Skimming**) 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 is 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 Hotkey: Ctrl+Alt+M for skimmed.



7.4.21. Unmark

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

7.4.22. Reposition Delimiter

1. To adjust the position of a delimiter, touch or click on the  icon then touch or use the cursor to click and drag one of the delimiters to the desired location.

2. 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 the potential to affect treatment. It is HIGHLY RECOMMENDED to discuss changes in marking methods with pathologists and treating clinicians.*

7.4.23. Delete Area

1. An area of the scan may be deleted if necessary. To access this function, either right click on the scan and select the delete function, or use the below icons.



a. *Mark* - Place the cursor on one side of the area needing deletion and then select Mark.

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

c. *Apply* - Once Mark is used, Apply becomes accessible. Place the cursor on the other side of the area needing deletion and then select Apply. The area between and above the marks is deleted. Repeat as needed.

7.4.24. Baseline Correction

1. The *Baseline Correction feature may be* used if the baseline needs to be moved or if the pattern has a non-linear baseline due to irregularities in background intensity. To access this feature one may either use the icons or right click on the scan and select Baseline

Correction. .

a. *Mark* - Place the cursor in the desired location of the new baseline and then select Mark. A straight, horizontal line is then placed at the specified location indicating the new baseline.

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

c. 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.

d. *Apply* - With the baseline marked as desired, select Apply. The pattern is readjusted so the baseline is a straight line and the numeric data reflects the change.

Note: *Baseline correction is NOT recommended for routine use in most electrophoretic patterns, as removing baseline “noise” may in fact be deleting true results.*

7.4.25. Auto Scale

Auto Scale may be accessed either by right clicking on the scan, and selecting the Appearance item, or by selecting the



icon. 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.

7.4.26. Smooth

This feature can be accessed either by right clicking on the scan, and selecting the Appearance item then Smooth, or by



selecting the icon: The Smooth window displays. Select the desired Smooth setting of 1 through 10. Select Ok and the Edit Scan(s) window displays with the scan smoothed as indicated. Select Cancel to exit without smoothing.

Smoothing, in most cases, is not recommended. Smoothing DOES affect results.

Increasing the smoothing level decreases the background noise and lowers smaller fractions.

Smoothing may affect quantitation of small monoclonals.

7.4.27. Zoom

This feature can be accessed either by right clicking on the scan, and selecting the Appearance item, or by clicking on



the icon. 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. Zoom does not affect printed results.

7.4.28. Image Contrast

1. Image Contrast can be accessed either by right clicking on the scan, and selecting the Appearance item, or by touching/selecting the Image



Contrast Icon. (Hotkey: Ctrl + I)

2. The default setting for image contrast is selected during Test setup or Pre-Scan Setup (Section 6.2.3) 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. To reset to the default setting, select Reset.

7.4.29. Negative Image-IFE scans

As an aid to viewing IFE scans electronically, a **negative image may be viewed** simultaneously with a positive image (Hot key: Ctrl + N). See Section 7.4.39. The contrast may be adjusted from -10 to +10, and will be adjusted in both the positive and negative images at the same time. Select OK to close the view of the negative image.

7.4.30. Calculate Total LDL

This feature is available for Cholesterol Tests, and will calculate the total LDL; Lp(a) + LDL. To access this feature, touch or click on the Lp(a) + LDL icon or right click on the scan.

7.4.31. Calculate Total non-HDL

This feature is available for Cholesterol tests and will calculate the total non-HDL fraction (LDL + VLDL + Lp(a)). To access this feature, either enable in Setup, or click on the icon.

7.4.32. Overlays

WARNING: *Patient Overlays may be assigned automatically in Test Setup, in Pre-Scan Setup, or at the level of the scan. Patient overlays may also be manually selected and pasted. Patient Overlays are labeled with patient identification, demographics, and results. It is recommended that patient identification be reviewed on each overlay.*

The option to print overlays by right clicking on the thumbnail will be available in a later version of the software.

Overlays  allows for overlaying Unedited, Reference and/or Patient scans. One or two patient overlays may be applied.

7.4.32.1. Viewing/Printing Overlays

In order to view/print overlays, the Display/Print settings must be enabled as desired. Settings may be enabled or disabled in User Setup under Test Setup, Worklist Template Setup, Report Setup, or in Pre-Scan Settings. Display and Print Settings may also be altered at the level of the scan.

Select the Display icon,  or the Print icon,  or use the drop down menu under File to access these options. Options include Display/Print Unedited, Reference, Patient 1, Patient 2, Overlay of Thumbnail Images, and display of delimiters. Alternatively, (Hot Key: Ctrl + O) may be used.

7.4.32.2. Unedited

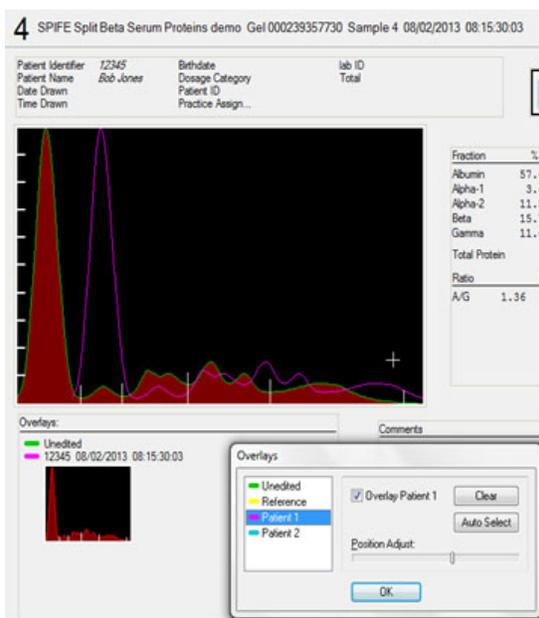
Under *Overlay*, select *Unedited*. A green line will appear tracing the outline of the original scan. Once an editing function, which alters the pattern's appearance, is performed, the green line will remain in the same location as the original scan, shown relative to the edited scan, appearing in red.

7.4.32.3. Reference Overlay

1. Select Reference to overlay a previously scanned reference pattern on the scan. This makes a comparison of the patient to a reference very easy. A reference scan must be identified on the worklist and located prior to the scan in which the overlay is to be displayed. The reference scan may be labeled at any time, including after the gel has been

scanned. The reference appears in yellow over the sample, which is in red.

- a. *Adjust* - Once Reference is selected, the Adjust slide bar becomes available. Use the slide bar to position the overlay on the scan as desired.



7.4.32.4. Patient Overlay 1 and/or 2

1. Patient Overlays may be assigned automatically in Test Setup, in Pre-Scan Setup, or at the level of the scan. Patient overlays may also be manually selected and pasted. **Patient Overlays are labeled with patient identification, demographics, and results. It is recommended that patient identification be reviewed on each overlay.**

2. Click on the thumbnail image of the patient overlay to view the full, original scan results, demographics, and comments.

3. Note that IFE scans can be used as patient overlays using the following steps; however, patient overlays cannot be applied to IFE scans.

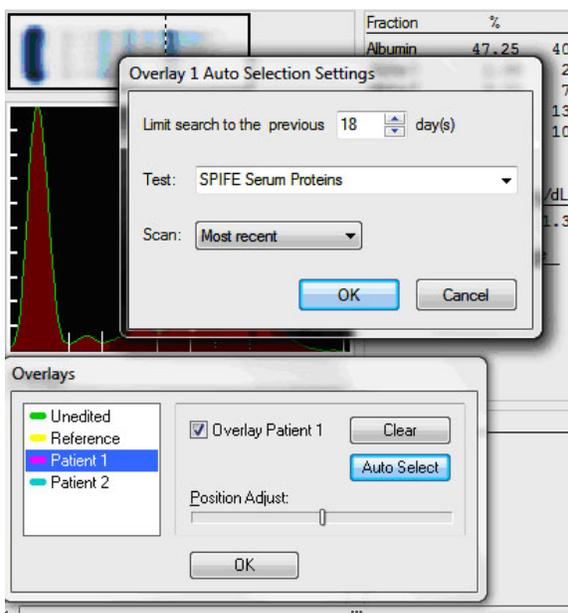
4. Select Overlay, then select either 1 or 2 to overlay a saved patient pattern.

5. A window opens with a check box to enable the patient overlay and the options *Auto Select*, *Clear*, *Position Adjust*, and *Cancel*.

7.4.32.5. Auto Select

Auto Select criteria may be entered in *Test Setup*, *Pre-scan Setup*, or by selecting *Patient Overlay* on the scan. If Auto Select criteria have been entered in setup, the criteria may be viewed by clicking on *Auto Select*. Enter the time frame in which to search (1-365 days) the test, and *Oldest*, *Prior Oldest*, *Next Most Recent*, or *Most Recent*. The scan which best fits the matching criteria is applied.

Note: the scan that best matches the criteria may be altered as patient samples are repeated. For example, the *Most Recent* overlay will change each time a new sample is scanned. The update will take place whenever a worklist is closed and reopened, or by using the *Auto Overlay* function. (Ctrl-O, or right click on the Gel Image area, select Scan, and select *Auto Overlay*).



7.4.32.6. Clear

1. To remove the patient overlay currently applied, select *Clear*. An automatically applied Overlay will remain in place unless cleared, even if the selection criteria are altered.
2. With a patient overlay selected, the *Adjust* slide bar becomes available. Use the slide bar to position the overlay on the scan as desired.
3. *Auto Overlay* - To update and apply changes to Overlay search criteria, either close and reopen the worklist, or use the Auto Overlay feature. Right click on the area of the *Gel Image*, select scan, then select *Auto Overlay*, or click Ctrl O. Copy and paste Overlay.
4. An Overlay may also be applied manually. The pattern can be from the same patient or a different patient.

7.4.32.7. Copy and paste from worklist

1. Any overlay may be selected from any worklist by selecting and right clicking on the thumbnail of the scan, located at the lower left corner of the

worklist. Select the Scan option, then Copy. Next, select the scan in which the overlay is to be applied, right click on the thumbnail image of the scan, select Scan, then Paste, and Paste to Patient Overlay 1 or 2.

2. Patient overlays may be automatically applied or manually cut and pasted from any worklist.

3. To select a scan to use as a patient overlay, left click on the desired scan. Then right click on that same scan and a menu containing *Copy* and *Paste* displays. Left click on *Copy*. To place the indicated patient overlay on the desired scan, left click on the scan to receive the patient overlay. Then right click on that same scan and a menu containing *Copy* and *Paste* displays. Left click on *Paste*.

Note: When manually pasting a patient overlay, positive patient identity is NOT applicable, and it is the user's responsibility to ensure that the desired overlay is applied.

7.4.32.8. Find and Paste Patient Overlay

A Patient Overlay may also be manually located and pasted to a scan using the find feature. Select the scan in which the overlay is to be pasted. From the Main Menu, select *File*, then *Find*,

or use the icon . Enter the criteria in which to locate the desired scan, and a list of scans will be displayed, described by worklist name, key demographic, Test, gel ID, sample number, and

date and time Scanned. From the list, select the scan that is to be used as the overlay, and click on the *Paste* to the *Patient Overlay 1* or *Patient Overlay 2* button.

7.4.32.9. View Overlay

Right click on the *Patient Overlay* to open a screen displaying the original overlaid scan, with image, scan, results, demographics, and comments.

Note: *Patient Overlay matching criteria is based on date and time of the worklist, rather than scan. For example, if “Most Recent” is used as the matching criteria, and a patient scan has been copied and pasted to a second worklist, the scan from the most recent worklist will be pasted. Patient Overlay thumbnails are labeled by Key ID and Date and Time Scanned. For further demographics, click on the thumbnail.*

7.4.33. Auto Interpretation

7.4.33.1. Auto Interpretation:

The user may elect to enter customized comments based on user-specified criteria. Comments are then applied to scans with results meeting the specified criteria. Criteria must be entered in Setup, and assigned to a specific test. 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 enabled in Test Setup, Pre-Scan Setup, or enabled at the level of

the screen by selecting the AI  icon. See section 6.4 Comments/Interpretation for further information.

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.

7.4.33.2. Pattern Characteristics

1. Pattern Characteristics may also be used as optional descriptions to describe the appearance of a scan. Multiple pattern characteristics may be entered in User Setup to be available for application to a scan with numeric results that might meet the same Auto Interpretation criteria. (Section 6.4). For example, a scan with a high gamma fraction may appear monoclonal, polyclonal, or oligoclonal.

2. Select *Pattern Characteristics* under the *Auto Interpretation* criteria to view the list of available/ applicable pattern characteristics for a scan. A window displays which contains None and any pattern characteristics setup for the test in use (section 6.4). Select the desired pattern characteristic and select *OK*. To exit without making a selection, select *Cancel*.

3. When applying a comment with Pattern Characteristics enabled to a scan, it will “toggle off” any other comments that have been applied. To display the other comments again, simply remove the comment with Pattern Characteristics.

7.4.34. Comments

1. Touch, or select the  (third from left- the picture of quotation marks), or right click on the scan, and select Comments, or elect Ctrl-Alt-C from the scan window to access the Comments feature. Alternatively, (Hot Key: Ctrl + C) may be used. A menu box opens with a blank space. At the bottom of the window are the Options: Open, OK, and Cancel.
2. To manually enter a free-text comment, type the comment into the blank space, and click OK.
3. To add a comment from those added in User Setup, select *Open*.
4. The *Open Comment* window opens. The window lists Available Comments (all the currently setup comments by label) and the highlighted comments contents to the right of the list. To select a comment, highlight the desired comment and select *Select*. The text will appear the large box on the upper right corner. Click *Open* to apply, and *Cancel* to exit the screen. Repeat as needed to include all the desired comments. Clicking open more than once will add the comment more than once.
5. Comments may be removed by manual deletion from the comment. (Auto Interpretation comments must be cleared).
6. To apply the comments as displayed, select *Ok*.
7. To exit without changing the comments, select *Cancel*. If any comments have been added/alterd, then a Confirmation Cancel prompt displays. To exit without changing the comments, select *Yes*. To return to the Add Comments window, select *No*.

7.4.35. Restore

Touch or select the first icon from the right, , click Ctrl-alt-R, or right click on the scan and select *Restore* to return the pattern to its appearance prior to all editing. Editing may then need to be repeated.

7.4.36. Undo

Touch or select the second to last icon on the left, , Ctrl-Z, or right click on the scan and select *Undo* to undo the last editing function performed and return the pattern to its appearance prior to the most recent editing function performed.

7.4.37. Edit IFE Scans

7.4.37.1. Indicator Tool

An indicator bar appears over the scan to aid in viewing. To move the indicator 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.

7.4.38. Image Contrast

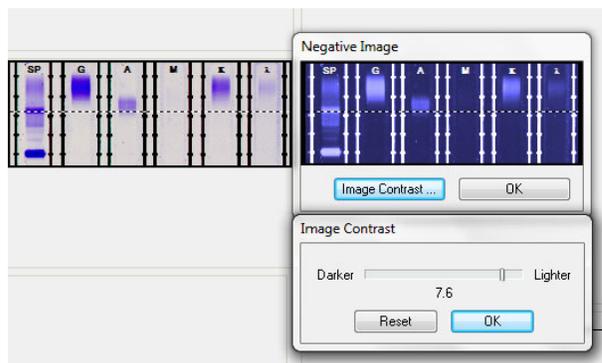
1. Image Contrast may be accessed either by right-clicking on the scan, and selecting the Appearance item, or by touching/selecting the Image Contrast Icon.
2. The default setting for image contrast is selected during *Test* setup or *Pre-Scan* Setup.

(Section 6.2) *Image Contrast* 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. To reset to the default setting, select *Reset*.

7.4.39. Negative Image-IFE scans

1. As an aid to viewing IFE scans electronically, a negative image may be viewed simultaneously with a positive image. To access this feature, right click on the scan and select *Negative Image*, or touch/click on the *Negative Image* icon.

 (4th from the right on an IFE scan.)



2. A window opens with a negative image of the IFE scan, and the options to adjust the image contrast. The contrast may be adjusted from -10 to +10, and will be adjusted in both the positive and negative images at the same time. Select *OK* to close the view of the negative image.

7.4.40. Immunototals

Note: *If Total is included as a demographic, it will not be shown on the Immunoglobulins window and can be edited inside the Patient List window.*

1. The *Immunototals* window allows for entering total immunoglobins. Touch or select

2. The *Immunototal* icon,  (Third from the right) or right click on the scan and select *Immunototals* (Hotkey: Ctrl + T). The *Immunoglobulin Totals* window displays:

- a. The window contains labels and spaces for *Immunototals*, and total protein (if not selected as a demographic during test setup).
- b. Enter the totals, as needed, using the keyboard. Each total may be from 0.0 to 99999.0
- c. To remove all the displayed totals, select *Clear* and *Yes* in response to the prompt.
- d. Once the totals are as needed, select *OK* and the *Edit Scan(s)* displays.
- e. To exit without entering or altering the totals, select *Cancel*. If any alterations where made, an *Alert* prompt is displays. To exit without applying the changes, select *Yes*. To return the *Immunoglobulin Totals* window, select *No*.

3. *Comments* - functions the same as *Comments* on non-IFE edit windows.

4. *Auto Interpretation and Pattern Characteristics* functions the same from this edit window as from non-IFE edit windows. This function will be added in a future version of software.

Below is a list of hotkeys for editing scans in the worklist window.

Action	Hotkey Combo
--------	--------------

Editing Scans	
Image Contrast	Ctrl + I
Undo	Ctrl + Z
Delete Area	Ctrl + D
Cancel Delete Area	Ctrl + Q
Apply Delete Area	Ctrl + Enter
Baseline Corrections	Ctrl + B
Mark Baseline	Ctrl + B
Cancel Baseline	Ctrl + Q
Apply Baseline	Ctrl + Enter
Overlays	Ctrl + Alt + O
Comments	Ctrl + Alt + C
Flags	Ctrl + Alt + F
Restore	Ctrl + Alt + R
Message Flags	Ctrl + Alt + F
Close Menu	Esc

Below is a list of hotkeys for delimiting bands in the worklist window.

Action	Hotkey Combo
Delimit Bands	
Insert Fraction	Ctrl + Ins
Delete Fraction	Ctrl + Del
Mark Sliced Restricted Band	Ctrl + M
Mark Skimmed Restricted Band	Ctrl + Alt + M
Fraction Identification	Ctrl + I
Reposition Delimiter	Ctrl + R
Unmark Restricted Band	Ctrl + Bksp

Below is a list of hotkeys for the scan menu in the worklist window.

Action	Hotkey Combo
Scan Menu	
Find	Ctrl + F
Find Again	Ctrl + A

Cut	Ctrl + X
Copy	Ctrl + C
Paste	Ctrl + V
Auto Overlay	Ctrl + O

Below is a list of hotkeys for editing IFE scans in the worklist window.

Action	Hotkey Combo
Editing IFE Scans	
Negative IFE Image	Ctrl + N
Negative Image	Ctrl + T
Immuno Totals	Ctrl + Q
Overlays	Ctrl + Alt + O
Comments	Ctrl + Alt + C
Flags	Ctrl + Alt + F
Restore	Ctrl + Alt + R
Close Menu	Esc

Below is a list of hotkeys for editing Cholesterol scans in the worklist window.

Action	Hotkey Combo
Editing Cholesterol Scans	
Auto Edit	Ctrl + Alt + A
Auto Edit Settings	Ctrl + S

7.5. Scanning Gels

7.5.1. Scan

To aid in the scanner's function, remember to keep the scanner lid closed, not to place objects on the glass surface, other than items to be scanned, and to keep all the scanner's glass surfaces clean at all times. Failure to do so may compromise results.

1. To position the gel, open the lid and place the gel on the scanner. If the gel has two holes, then place the round hole in the gel over the right pin in the scanner and the obround hole over the left pin. If the gel has no holes, place the gel so that the first sample is on the right, back corner of the scanner with the samples oriented left to right. If needed the gel may be taped down to the scanner bed to make it lie flat. The agarose side of the gel should be up. Close the lid.

2. Once the gel is in the scanner, the user may begin scanning by touching or selecting the *Scan* icon  *Scan* or the *Scan* option from the menu at the top of the screen.

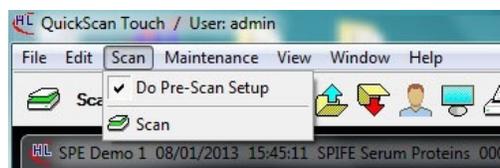
3. If there is no worklist open at the time of scanning, the user will be asked to designate a test.

4. If positive patient Identity is enabled, the user will be prompted to type in or scan the Gel ID number. By clicking *OK* without entering a Gel ID number, the gel will still be scanned, but no patient information will be imported.

5. When a gel is scanned, the window displays “Scanning in Progress.” If Pre-scan Setup is not enabled, the worklist containing all scans will open immediately after scanning.

7.5.2. Pre-Scan Setup

Pre-Scan Setup may be enabled either in Test Setup, or before rescanning a gel such that a window opens after imaging the gel, but prior to scanning. This gives the user the opportunity to adjust Scan locations, Scan Settings, and Worklist Settings.



7.5.2.1. Scan Locations

Note: If using a SPIFE Nexus to scan a plate, reference Section 15 on the proper steps and gel cassette placement.

1. Select this option to display an image of the gel and the scan begin and end lines. The scan position can be temporarily adjusted if needed. Note that if a test repeatedly needs scan parameters and/or scan position adjusted, the test setup may need to be altered (see section 6.2).

2. For each row of the gel there will be a green scan begin line and a red scan end line. In addition, there will be a blue line, indicating the first sample position on a row, and a purple line, indicating the last sample position on a row, for each row of samples.

3. For each row, use the mouse to move the green lines to the front of the pattern to set the scan begin and the red lines to the other end of the pattern to set the scan end.

4. For each row, use the mouse to set the sample step over by placing the blue lines on the center of the samples located on the left of the window (the first sample) and placing the purple lines on the center of the samples located on the right of the window (the last sample).

5. This operation defines the distance from one sample to the next. The purple line must be centered in the last sample position regardless of the number of samples in a row. The QuickScan software will use the position of these lines to automatically calculate the space between each sample.

7.5.2.2. Scan Settings

1. *Scan Settings* may be altered in Pre-Scan Setup in a manner similar to Test Settings in User Setup.

2. Scan Settings contains the currently setup settings for the test and worklist in use. Only alter those parameters that need to be changed from the setup settings (the changes will only apply to the worklist for this scan).

7.5.2.3. Scan Sequence

Scan Sequence can be altered by entering the sample positions needed, position numbers with a comma and/or designating a set of positions with a hyphen. For example 3, 5, 8-12, 15, 20.

7.5.2.4. Scan Aperture

Scan Aperture may be from 1 to 12, see section 9 for the measurement that corresponds to each aperture setting.

7.5.2.5. Smooth

Smooth - Do not select unless procedure recommends otherwise; the graph will not be smoothed. With Smooth selected, set the Smoothing Level to a value from 1 to 10, with 1 being minimal smoothing and 10 being maximum smoothing. Smoothing does affect the results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing could affect small **monoclonals**.

7.5.2.6. Auto Interpretation

See Section 6.2

7.5.2.7. Auto Edit/Auto edit Settings

See Section 6.2

7.5.2.8. Report Total LDL Report Total non HDL

See Section 6.2

7.5.2.9. Overlays and Auto Settings

See Section 6.2

7.5.2.10. Image Contrast

See Section 6.2

7.5.2.11. Gain Mode

1. *Auto* - the maximum fraction amplitude is set to 100% of the graph height with the rest of the fraction heights proportional to it.

2. *Manual* - the fraction amplitude is proportional to concentration and is the gain of choice for light patterns such as urines. This option is selected because an auto-scanned sample that is light will show many fractions. With Manual gain selected, Auto Scale is accessible in the Edit mode for use if a specific pattern over ranges because that pattern is not light. Patterns of varying intensity are usually scanned in Manual gain, for example, Urine Proteins and CK Isoenzymes.

3. *Manual Gain* - is set in a range of 0.0 Min to 10.0 Max, in 0.1 increments. Set using the slide bar accessible only when Manual is selected. Adjust the slide bar as needed to achieve the desired

amplitude with the highest peak at the desired level when scanned. Start at a manual gain of five and increase or decrease gain as needed. Note that Manual Gain should be selected for Urine gels in order to minimize noise.

7.5.2.12. Fraction Detection

See Section 6.2

7.5.2.13. Sensitivity

Sensitivity - sets the “sensitivity” of the instrument to +/- slope changes when detecting fractions. Set, using the slide bar, within a range of 0.0 Min to 10.0 Max, in 0.1 increments. A sensitivity of zero turns off the auto fraction selector thus causing no fraction marks on the scan.

7.5.2.14. Forced Fractions

1. *No* - select to pick fractions based only on pattern slope change.
2. *Float* - select 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 selected, a sample will need to be labeled Reference for each gel and will need to be scanned prior to any sample for which it will be the overlay.
3. *Fixed* - select to use the same fraction locations as those of a previously scanned Reference. If selected, a sample will need to be labeled Reference for each gel and will need to be scanned prior to any sample for which it will be the overlay.

7.5.2.15. Worklist Settings

Worklist Settings may be altered in a manner similar to Worklist Template Setup (Section 6.3).

1. *Display Settings* - select and the Display Settings window displays. Use this window to customize the appearance of the window displayed once scanning is complete.

2. *Print Settings* - select and the Print Settings window displays. Use this window to customize the print related settings. These settings will be used whether printing occurs automatically or at operator request. Automatic printing is not recommending as printing will occur prior to operator review. See section 6.3 for additional information on this window.

3. *Export* - select to automatically export scans. Whether or not Export is selected, scans can be exported at operator request. Automatic export is not recommending as export will occur prior to operator review. See section 6.3 for additional information on this window.

4. *Save* - Save is not listed as an option in the QuickScan Touch *plus* software as all scans are automatically saved in the worklist folder.

7.5.3. Scan Samples

1. When all desired options have been reviewed and/or selected in Pre-Scan setup, click on *Scan Samples*.

2. Select *Scan Samples* to finish scanning the gel after Pre-Scan

Setup settings have been viewed and/or edited.

7.5.4. Rescan

To rescan the gel and attribute it to the demographic content of the current worklist, select *Scan* with the current worklist open. A prompt will appear as to whether the scan is a rescan. Rescanning a plate will remove edits for each sample selected for rescanning.

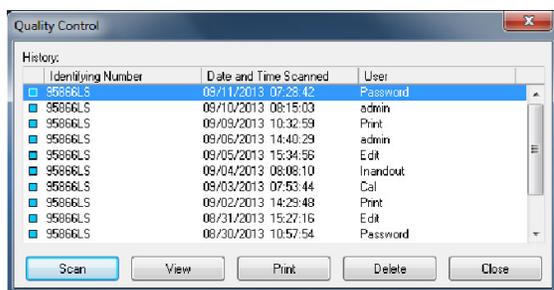
7.6. Quality Control

7.6.1. See Section 6.8 for QC Setup

To perform QC using the NDDC and OD Step Tablet and/or to manage previous QC results, touch or select *Maintenance*, then *Quality Control*. The *Quality Control* Window will open.

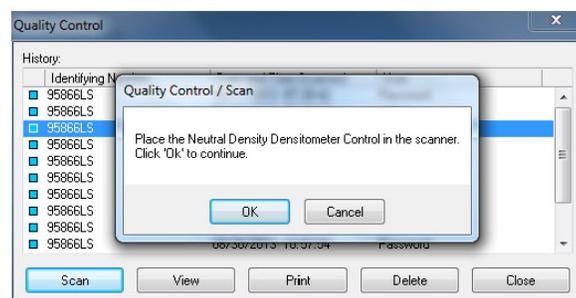
7.6.2. Quality Control History

The window displays a history of all QC scans, listed by the NDDC identifying number, Date and Time Scanned, and User ID. The number of scans stored is set in QC Setup. (Section 6.8). There are options to *Scan*, *View*, *Print*, *Delete*, and *Close*. *View*, *Print*, and *Delete* are only available if there have been previous scans stored.



7.6.3. Scan

1. Select *Scan* to QC using the NDDC/OD Step Tablet. The message *Place the QC Plate in the scanner, click 'OK' to continue* displays.



2. Open the scanner lid and place the NDDC plate in the scanner. The round hole in NDDC/OD Step Tablet is aligned over the right pin in the scanner and the obround hole over the left pin. Close the lid.

3. Select *OK* and *Scanning in Progress* is displayed. The NDDC results are automatically compared to and displayed with the Assayed Value and Expected Range entered in setup.

4. 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 6 steps.

7.6.4. Troubleshooting

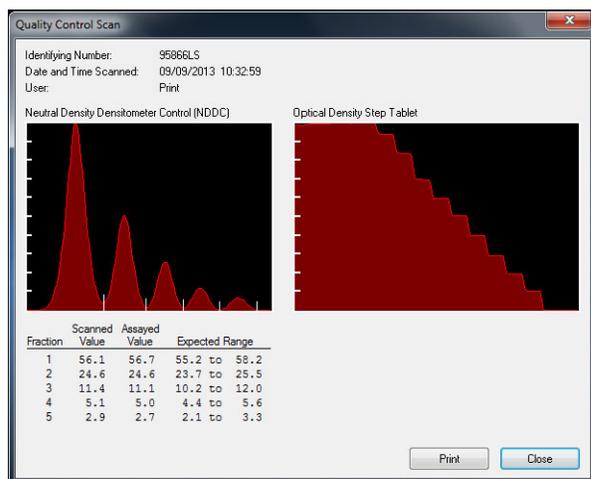
1. If the results are not acceptable, troubleshooting may proceed as follows.

2. Verify that the lid is completely closed and repeat the scan. If the lid is not completely closed, fewer than the applicable number of distinct steps on the OD Step Tablet may be presented.

3. Clean all the glass surfaces in the scanner with a standard glass cleaner and a lint free tissue. Repeat the scan.

Verify that there is no debris on the NDDC plate, and that the NDDC plate is not scratched or otherwise damaged.

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



7.6.5. View

Select a scan from the history of saved scans and click View to view the QC scan. The selected scan opens. There is an option to print the individual scan from this screen. It is recommended that a permanent record of the QC results be kept.

7.6.6. Print

From the Quality Control History window, the user may print a report containing all previously run and saved scans. Each scan is recorded by NDDC registration number, date and time scanned, User ID, 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. It is recommended that a permanent record of the QC results be kept.

7.6.7. Delete

Select *Delete* to delete the selected QC scans. A confirmation prompt displays. Select *Yes* to exit and delete the selected QC, or *No* to exit without deleting QC.

7.6.8. Close

Select *Close* to close the QC window. Scans are automatically saved up to the limit set in QC Setup. When the total number of scans to be saved exceeds the limit established in QC Setup, the oldest scan will be deleted as new scans are saved.

7.6.9. Delete

Select *Delete* to delete the indicated QC scan.

7.6.10. Exit

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

7.7. View

7.7.1. Display Options/Set Display Options

1. Either select *View* and *Display Options* or select the *Set Display Options* icon. The *Display Settings* window (Figure 6-14) displays. This window allows for the display parameters for the indicated worklist to be temporarily altered.

2. *Overlay* - is not available for a scan worklist with an IFE test selected. Select as needed:

- a. *Unedited* - select to have the unedited pattern overlaid on the edited pattern.
 - b. *Reference* - select to have the reference pattern, shown in blue, overlaid on the sample pattern, shown in red. If selected, a sample will need to be labeled Reference for each gel scanned (section 7.11.2).
 - c. *Patient 1* - select to have a patient's scan overlaid on the current scan (section 7.3.22)
 - d. *Patient 2* - select to have a second patient's scan overlaid on the current scan (section 7.3.22)
3. *Results* - select as needed:
- a. *Display Percent*
 - b. *Display Units*
 - c. *Display Integrals*
 - d. *Display IFE Units* - is the only option available with an IFE test is selected.
4. *Ranges* - the options available depend on selections made in Results and within Ranges. Select as needed:
- a. *Display Percent Range*
 - b. *Display Units Range*
 - c. *Display Ratio Range*
 - d. *Display IFE Range*
 - e. *Flag Percent Out*
 - f. *Flag Units Out*
 - g. *Flag Ratio Out*
 - h. *Flag IFE Out*
5. *Cancel* - select to exit the window without altering the display settings.
6. *OK* - select to exit the window and implement any altered display settings.

7.7.2. Communication Logs

There are three types of logs that may be maintained in the QuickScan Touch *plus*

software. The logs may be useful for diagnostic purposes in case of importing or exporting difficulties, error reporting, or a record of users.

7.7.2.1. Sign In Log

Under *View*, select the *Sign In Log* to view a list of each user and the date and time of sign in and sign out.

7.7.2.2. Host Communications

1. The Communications log can be very useful in troubleshooting importing and exporting failures of patient data and results. To be able to access the Host Computer Communications log, the Host Computer must be connected, and the following must be active/ enabled:

- a. Host Computer Connection Enabled in Setup, Import/ Export.
- b. Communication log created in Setup

2. From the Main Menu, touch or click on *View*, then *Communications*, then select *Host Computer*.

7.7.2.3. Communications Log

1. A window opens with a list of all the incoming and outgoing communications with the Host Computer, and the options listed below.

- a. *Clear* – to clear the communications log.
- b. *Print* – to print the log.
- c. *Close* – to close the window.

7.7.2.4. Sample Handler Log

1. To be able to access the Sample Handler Log, the Sample Handler must be connected, and the following must be active/ enabled:

- a. Sample Handler Connection Enabled in Setup, Import/ Export.
- b. Sample Handler log created in Setup.

2. From the Main Menu, touch or click on View, then Communications, then select Sample Handler.

3. A window opens with a list of all the incoming and outgoing communications with the Sampler Handler. This log may be very useful in troubleshooting difficulties with importing patient identifiers. The following options are listed.

- a. *Clear* - to clear the communications log.
- b. *Print* - to print the Sample Handler log.
- c. *Close* – to close the window.

7.7.2.5. Error Log

1. Select *View* and *Error Log*. The *Error Log* window is displayed.

2. The Error log maintains a list of all reportable errors. The log may be cleared or printed. This log provides useful information to a Helena technical or service representative in the case of dysfunction.

7.7.3. List of Open Worklists

With multiple worklists open, to select a worklist for use, select *Windows* and click on the desired worklist. Note that check in the box to the left of each worklist indicated which worklist is currently active.

Note: If the cursor does not appear to respond, the active window may be behind the displayed window, Click Enter to correct.

7.8. Help

7.8.1. About

1. Select *Help* and *About* to display a window containing the current software version and system serial number.

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.

7.8.2. OK

OK - select to exit the window.

7.9. Worklists

There are three components to an open worklist; the scan, the thumbnails, and the Gel Image (if enabled). The open worklist is labeled along the top of the screen by the worklist name, date scanned, time scanned, test, and Gel number.

7.10. Scans

7.10.1. Scan Components

1. *Resizing* – Scan components may be added, resized, or removed as desired by creating custom worklist templates. The default worklist scan components are the demographics, image of the sample, scan, results, space for overlays, and comments.

2. *Relocating* – Scan components may also be altered on the display by clicking and dragging individual elements. For example, the image of the sample may be enlarged.

3. *Label* – The scan itself is labeled across the top with the Test Name, Gel number, sample number, date, and time scanned.

7.10.2. Thumbnails

1. With a worklist open, thumbnail images are displayed at the bottom left of the screen. The scans for the selected thumbnail will be displayed. Thumbnails may be scrolled through with the arrow keys, mouse, or touch screen. Resize the window containing the thumbnails as desired to display scans in rows or columns.

2. Touch or click on the thumbnail to select the desired scan.

3. Each thumbnail is labeled by the key identifier information, and a colored square indicated its status. Blue, indicates the scan has the proper number of fractions and all the fractions are within range values. Red indicates the scan does not have the proper number of fraction and/or one or more fraction is out of range. Yellow indicates the scan has been viewed in the edit mode; however, it still does not have the proper number of fractions and/or one or more of the fraction is out of range.

4. Using the *Scan* option, individual scans may be searched for within the worklist. Right click on the Gel Image area and select *Scan*. The following options appear: *Find*, *Find Again*, *Cut*, *Copy*, *Paste*, and *Delete*.

a. *Find* – use the following

i. *.Search for* – Enter in a partial or complete demographic.

ii. *Match whole words only* – must enter the complete ID or demographic.

iii. *Match Case* – match the case.

b. *Find Again* – Find the next instance.

c. *Cut* - Cut a scan from a worklist. The scan may be pasted to the same worklist, or to another worklist. A scan may not be cut and pasted as an overlay. A scan may not be pasted twice to the same worklist.

d. *Copy* - Copy a scan from the worklist. The scan may not be pasted to the same worklist. The scan may be pasted to another worklist, or as an overlay to the same or other worklist. A scan may not be pasted twice to the same worklist

e. *Paste* - Only active if a scan has been copied or cut. A cut scan may not be pasted as an overlay) or a scan may pasted to the end of a worklist. Two copies of the same scan cannot be pasted to the same worklist.

f. *Delete* – Choose to delete a scan. The user will be prompted with a *Confirm Delete*

g. *Auto Overlay* – Auto overlay may be used to apply overlays based on the most currently available scans and overlay selection criteria.

h. *Scan Properties*: The following may be located by right clicking on the Gel Image

Area and selecting Scan Properties.

- i. *Test name and serial number of test.*
- ii. *Sample Identifier* - Sample ID from the bar code tube of the Sample Handler if positive Patient Identity was enabled
- iii. *Gel Identifier* - ID number of gel.
- iv. *Sample Number* - Sample lane number of specific patient to indication position on the gel.
- v. *Scanned:* Date, Time, User ID.
- vi. *Rescanned:* Date, Time, User ID.3
- vii. *Reviewed:* Date, Time, User ID.
- viii. **Edited:** Date, Time, User ID of most recent edit.
- ix. *Scan Resolution:* (DPI of scan. 200, 400, 600, 800, or 1200, selected during test setup)
- x. *Scanned Status* (OK or error).

7.10.3. Gel Image Properties

1. In the upper left corner of the displayed worklist, there is an area for the Gel Image to be displayed, if enabled in Test Setup.
2. Right clicking on this area reveals several options: *Worklist*, *Gel Image*, *Scan*, and *Close*. If the Gel Image was not saved, there is a blank gray space in this area with a message “Gel image not available. “ The Gel Image option is grayed out and not accessible when the screen is clicked on.
3. *Worklist Label* - Right click on the image of the gel, and select *Worklist* to add a specific label, to view, or to edit the worklist label. Note that the worklist label may be free text, and is not the same as the Gel ID number. Every worklist may be individually named.

7.10.4. Worklist Properties

Right click on the image on the gel, select *Worklist*, and then *Worklist Properties*. A screen opens which displays the worklist label, Date and Time created, Worklist Template used, Location or folder that the worklist is stored in, Test name and serial number, Gel ID, and the number of completes scans in the worklist. Click OK or the X in the upper right corner to exit.

7.10.5. Gel Image

Note: *If Save Gel Image is enabled, the gel image is automatically saved with the worklist. The Save As and Print options discussed here refer to saving the gel image outside of the QuickScan Touch plus software.*

1. Right click on the Gel Image if available. There are options to *Print* or *Save*.
2. *Print* – Select a printer, and print.
3. *Save As* – To save the gel as a bitmap file, click on *Gel Image*, then *Save*. A menu appears where the user may designate a name for the file, and destination. The image may be saved to any folder, include a flash drive, network, etc. The image will be saved exactly as the gel appears, such that any identifying information must either be written manually on the gel itself, or noted in the name of the file.
4. Users are welcome to save and email gel images to Helena

Technical Services for troubleshooting purposes.

5. Scan Navigation using Gel Images.

- a. If the Save Gel Image feature is enabled, an image of the entire gel will be displayed above the thumbnails in the upper left corner of the screen. This image may be resized as desired by clicking and dragging. The sample lane of the currently selected scan will be identified on the gel image. A scan may be select by touching the displayed sample, or clicking with the mouse.

7.11. Tips

7.11.1. Scanning

The contents of a worklist need not be cleared prior to scanning. Unlimited worklists may be created and stored. (Storage is limited by computer memory only Worklists are automatically saved in the worklist folder, and may be backed up as desired.) Each time a gel is scanned, a new worklist is generated.

To remove water spots on the gel, use an alcohol prep pad or water and wipe off the back of the gel.

Any external flaw, for example a spot of stain, located on the gel within the area to be scanned will be visible on the scan image displayed in the Edit mode. The operator can then determine if the flaw can be safely removed in the Edit mode or if the scan is unusable.

7.11.2. Edit

7.11.2.1. Reference Ranges and Reference Overlays

If using normal and/or abnormal control ranges, the applicable sample(s) must be designated as Reference Normal or

Reference Abnormal in order for the correct range to be used.

The use of a Reference Overlay is recommended as an aid when scans are displayed. Note that viewing, printing and exporting overlay information are each separate setup selections.

Scanning using the float or fixed option is based on the assumption that the scan distance is the same for all rows. Any pattern may be named Reference to serve as a fraction mark guide as long as it is scanned before the scans to which it will be used. It is recommended that a representative sample of each row be identified as Reference.

Any scan(s) designated as Reference must be scanned prior to the scans for which it is the reference. This can be accomplished either by placing the reference sample(s) on the gel before the applicable samples or by setting the scan sequence to scan the reference sample(s) position and then the applicable sample positions (section 6.2.3).

7.11.3. Editing

The best guide to the interpretation of scans, especially scans with results that are out of range, is physical examination of the gel.

Noise is best corrected in the edit mode using the delete area feature and not by smoothing.

Do not use smoothing unless the procedure recommends. Smoothing does affect results. Increasing the smoothing level

decreases the background noise and lowers smaller fractions. Smoothing could affect small paraprotein spikes.

7.11.4. Urine and Serum Proteins

Gels containing both urine and serum protein samples can be scanned on the QuickScan Touch *plus*. Setup the tests and worklists for urine proteins and for serum proteins. The gel may be scanned twice, creating two worklists.

Open or create a serum protein worklist, enter the applicable patient information, use Scan Settings to specify the sequence of the serum protein samples on the gel, and scan the gel. Then, without moving the gel, open or create a urine protein worklist, enter the applicable patient information, and use Scan Settings to specify the sequence of the urine protein samples on the gel, and scan the gel.

When scanning urine protein gels it may be helpful to use a serum protein as a reference overlay because the urine protein samples may be too low to determine the fraction area. This is also an opportune time to use fixed fractions.

7.11.5. Cholesterol profiles

Cholesterol profile scans using the auto edit feature should be reviewed and manually edited as needed. If the user selects the *Restore* option, the QuickScan Touch *plus* software will restore the scans to a point before the fractions were combined.

7.11.6. QuickGel

For QuickGel IFE gels, Test Setup must include the following: Test Properties - Rows per Gel set to 2; Scan lanes per Row set to 6, Scan lanes per sample set to 6. Scan Setup; Scan Positions set the two sets of scan position lines so that the

lines identified as A are located on the top and define channels one through six for sample one, B are located on the bottom, left and define channels one through six for sample two.

For all other QuickGels, Test Setup must include Rows per Gel set to 4 and Sample Applications per Row set to 5.

If scanning a QuickGel with fewer rows and/or samples per row, use the Pre-Scan window to alter the sequence of samples scanned. Alternatively, the user may scan the entire plate and delete any “empty” samples.

7.11.7. IFE

Note that when scanning an IFE gel, scan from the gamma end to the albumin end.

7.11.8. Hemoglobins

Smoothing is not recommended when scanning Hemoglobin plates.

7.11.9. Patient Overlays/Reports

1. To print a report with multiple patient results (for example, a Serum Protein and IFE scan, select a report setup to print overlays, for example the Standard profile report.

2. Designate the desired IFE scan as the patient overlay 1 for the desired Serum Protein scan.

3. When the Serum Protein scan is printed using the Profile Report, the IFE image used as the Patient Overlay will appear as well as the results.

4. Refer to Section 6.5 or contact Helena for further information on how to create unique reports that may contain multiple test types and gel images.

7.11.10. Results

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.

7.11.11. Software Troubleshooting

If an Abnormal program termination occurs, such as a power failure, on attempting to reopen and log into the software, an Invalid username/password error may be generated due to the server thinking the user is already logged in. If this situation should occur, the MSS will automatically log out the user after 30 minutes.

If deleting a worklist, do not delete more than 50 in a single transaction. The worklists will be deleted, but this will cause an Invalid Exception error.

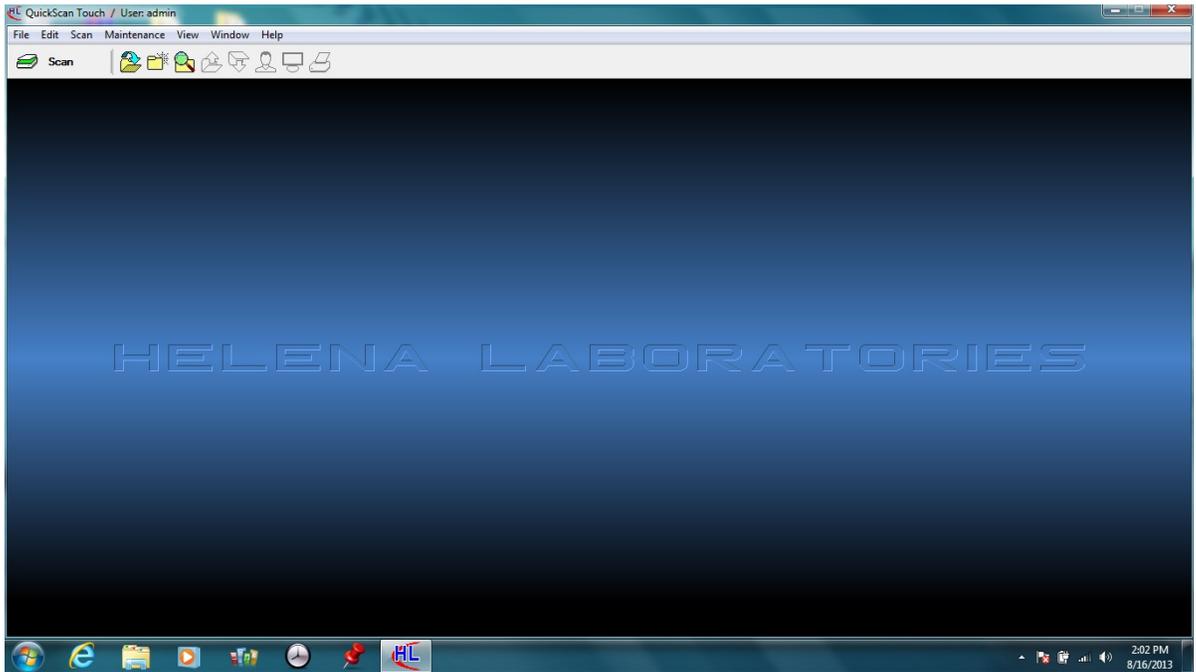


Figure 7-1 Main Menu

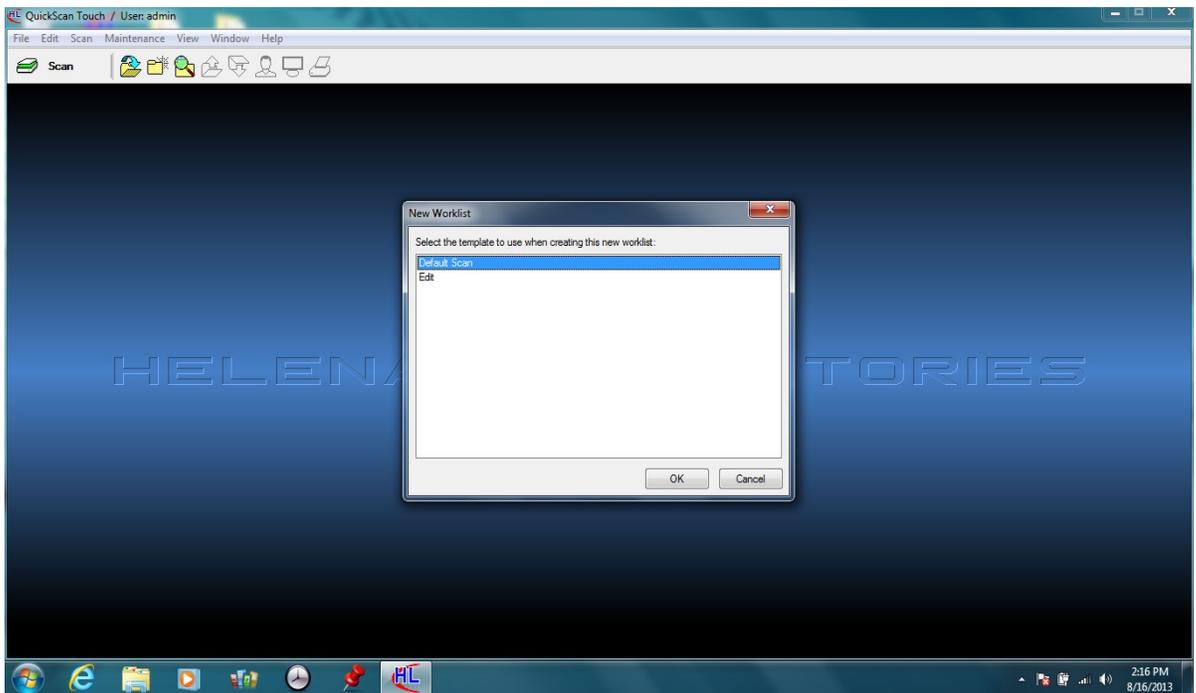


Figure 7-2 New Worklist

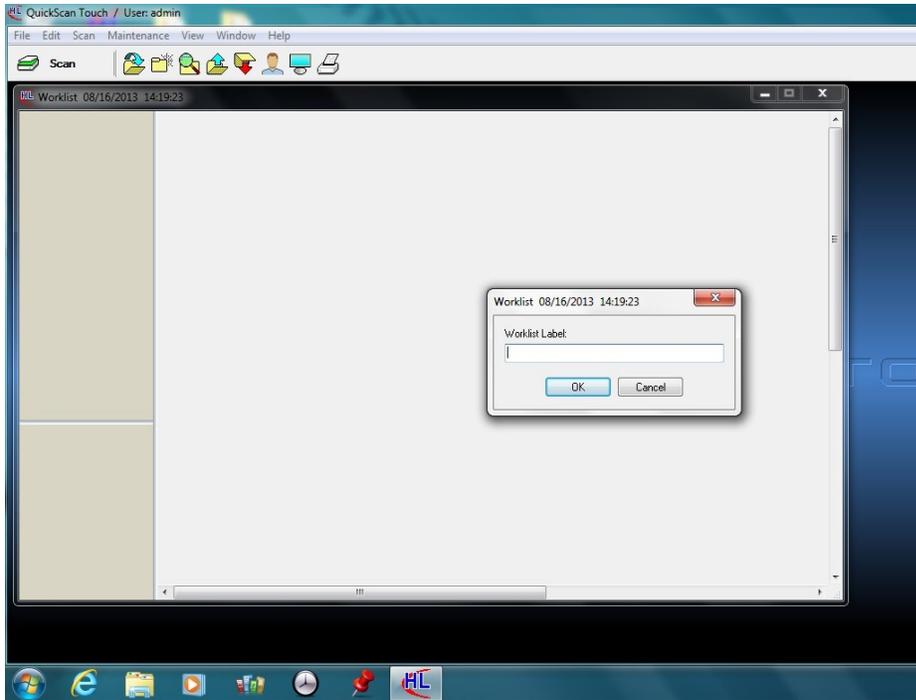


Figure 7-3 Label Worklist

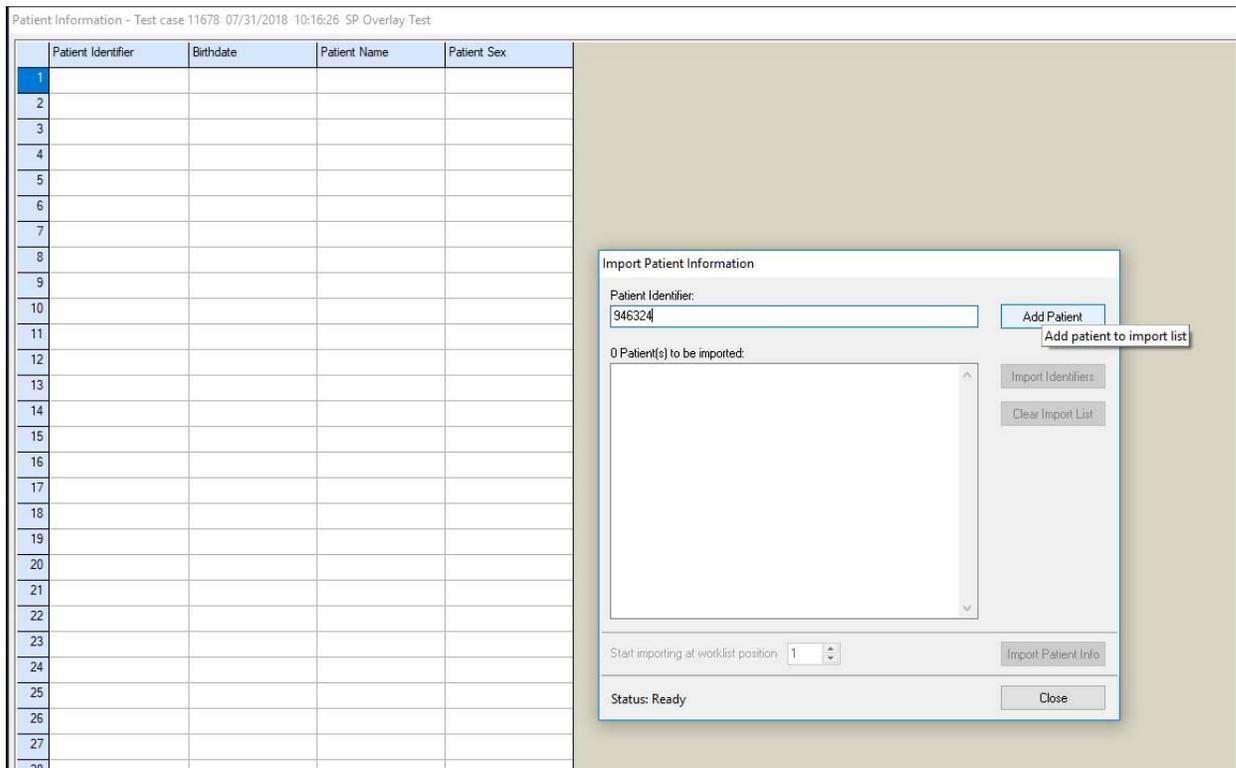


Figure 7-4 Add Patient ID

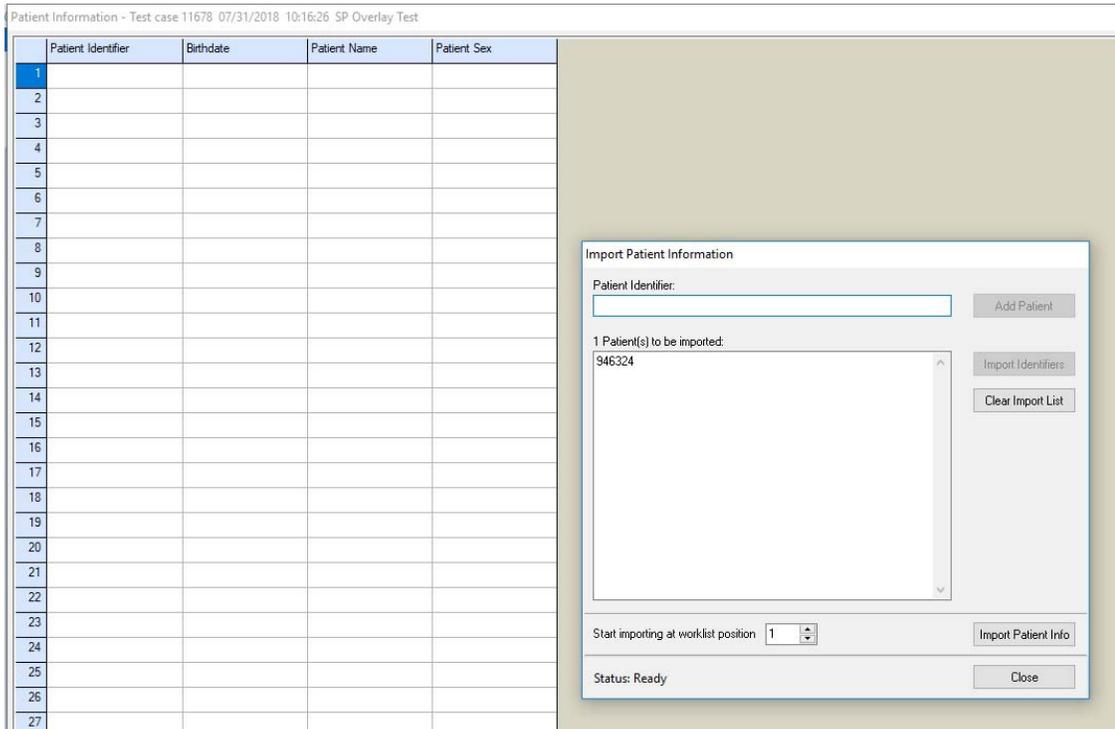


Figure 7-5 Add Patient to Import List

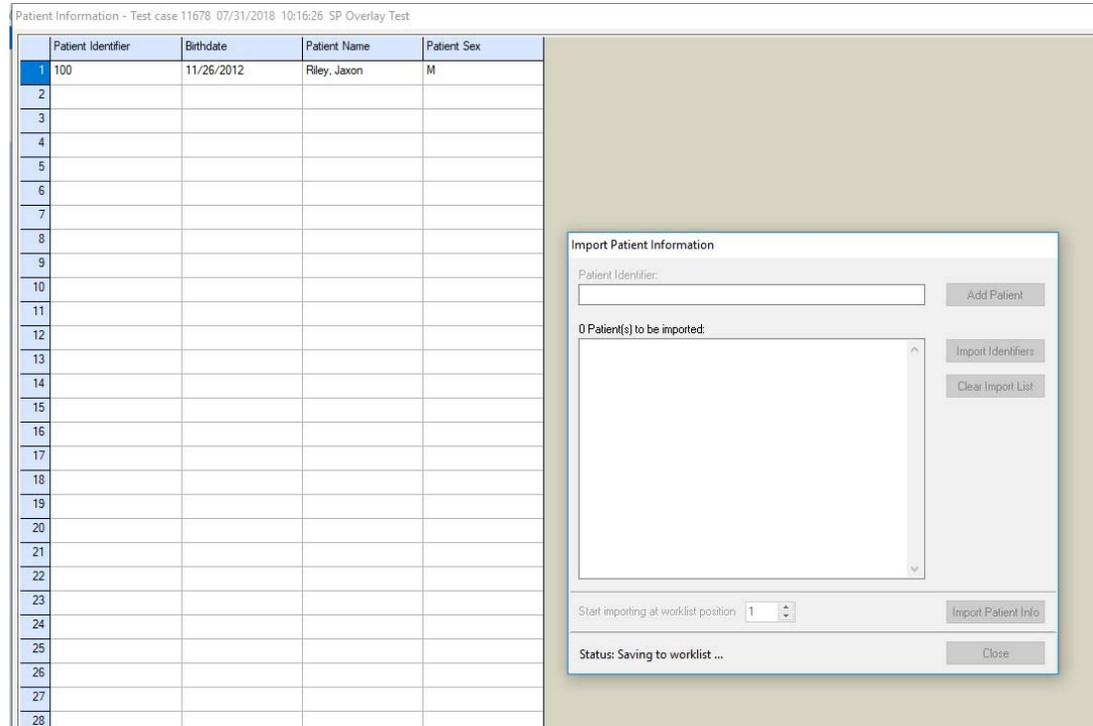


Figure 7-6 Import Patient Info

Section 8 - Test Functions and Quality Control

8.1. Tests

1. The instrument automatically performs a self-test any time the power is turned on. Should an error message appear on the display, see section 10-2.
2. Refer to the appropriate owner's guide for tests of the monitor and printer.

8.2. Quality Control

8.2.1. Controls

1. 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.
2. 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.
3. It is recommended that each laboratory set up an effective quality control program based on licensing requirements.

8.3. Instrument Performance Check

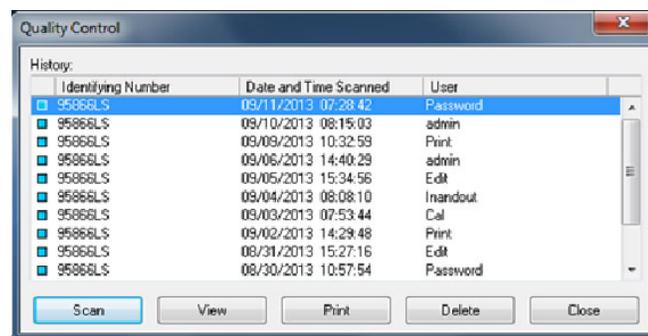
8.3.1. Neutral Density Densitometer Control (NDDC)

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

8.3.2. 10 Step Optical Density (OD) Step Tablet

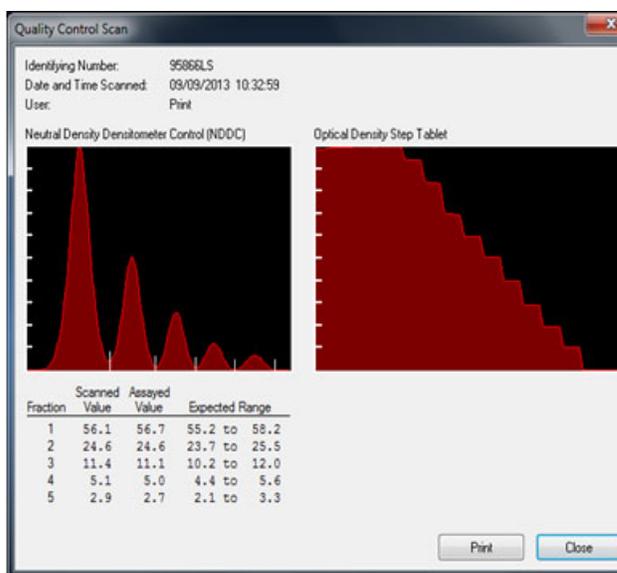
1. The OD Step Tablet checks linearity and analog response of the visible light source and detector
2. A list of the quantitative ranges for the NDDC bands should have been entered during QC setup.
3. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, either select *Maintenance and then Quality Control*. The QC window displays. A list of all saved QC scans is displayed, with the options to view, Print, Scan, Delete, and Cancel.

8.3.3. QC Main Menu



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

- a. *View* - A single scan may be selected from the list for view.



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

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

8.3.4. Scan

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

2. Open the scanner lid and place the QC plate in the scanner. The round hole in the QC plate is aligned over the right pin in the scanner and the obround hole over the left pin. Close the lid.

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

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

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

8.3.5. Unacceptable results

If the results are not acceptable:

1. Verify that the lid is completely closed and repeat the scan. If the lid is not completely closed, fewer than the applicable number of distinct steps on the OD Step Tablet may be presented.

2. Clean all the glass surfaces in the scanner with a standard glass cleaner and a lint free tissue. Repeat the scan.

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

8.3.6. Print

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

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

8.3.7. Delete

From the main QC window, use the delete function to delete the indicated QC. Select *Delete* and *Alert* displays. Select *Yes* to exit and delete the selected QC, or *No* to exit without deleting QC.

8.3.8. Cancel

Cancel - select to exit the QC History window.

8.3.9. Exit

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

Section 9 - Performance Specifications**9.1. General Specifications****Tests:**

Serum Proteins, Urine Proteins, Acid and Alkaline Hemoglobins, Alkaline Phosphatase, Cholesterol Profile, CK, LD, IFE, L/S and Lipoproteins.

User-Programmable:

Test Parameters:

Test, Test Name, Scan Sequence, Gel Stain Type, Immunofixation Electrophoresis, Sample Image Color Intensity, Aperture, Gain Mode, Fraction Detect Sensitivity, Forced Fractions, Smoothing, Unit of Measure, Total Unit of Measure, Decimal Places, (Cholesterol Profile only) Auto Edit and Report Total LDL (Lp(a) + LDL), Report total non-HDL (Total cholesterol – HDL), Auto Interpretation, Combine Split Beta, Test Specific Demographics, Channel Width, Scan Positions, Fraction Labels and Ratios, Ratio Labels and Limits, Restricted Band Label, Restricted band marking method (Skimmed or Sliced) and Reference Ranges.

Display Parameters:

Display Scans, Overlay, Overlay Thumbnails, Overlay Delimiters, Display Percent, Display Units, Display Ranges, Display Integrals.

Report Parameters:

Report Label, Type of Report, Scans per Report, Paper Size and Orientation, Number of Copies, Print Scan Identifier, Print Patient Information, Print Sample Image, Print Graph, Print Overlay Legend, Overlay Reference, Patient(s), Unedited on Graph, Print IFE Overlay, Print IFE information, Scan Status, Print Results, Print Comments/Interpretations, Print Auto

Interpretation, Print User-Defined Text (Headers, Footers, etc.), Print Picture, Bar Code, List/Statistics, Profile, Reports Print Selected Demographics, Levey-Jennings Reports Select Graph Size

Import /Export Parameters:

Communication Parameters including XON-XOFF and ASTM Protocol, and Positive Sample Identification, Exporter Information, Export Demographics, Export Graph, Export Comments, Export Auto Interpretations, Export IFE Interpretation, Export Percent, Export Units, Export Integrals, Export IFE Units, Export Ratio Range, Export Ranges, Export File Name and Delimiter, and ASTM Fields, Host Computer and Sample Handler Communication logs.

Additional User-Programmable Selections:

System Demographic Labels, Comments and Interpretations, QC, Date and Time, Printer, and Users and Passwords for Setup

Media Types:

Agarose and cellulose acetate gels

Maximum Sample Size:

5 x 5 in. (12.7 x 12.7 cm)

Input Power:

120 VAC, 50/60 Hz, 1000 Watts

240 VAC, 50/60 Hz, 1000 Watts

1983 BTU/hr

Leakage Current:

Less than 5 mA

Dimensions Height x Width x Depth:

Computer, Monitor, and Keyboard:

22 x 18 x 24 in. (56 x 48 x 61 cm)

Scanner:

≤ 8 x 13 x 22 in. (20 x 33 x 56 cm)

Printer:

10 x 14 x 14 in. (26 x 36 x 36 cm)

Total Weight: 104 lbs (47 kg)

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

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

9.2. User Programming

Although QuickScan Touch *plus* is factory programmed for each default test, the user may modify instrument operation.

9.2.1. Programming Test

Unit of Measure: Any units, such as mg/dL, mg/24hrs, g/L, or U/L.

Ratio Names: Any name for one or two ratios.

Sensitivity: Set sensitivity for optimal results for each test.

Forced Fractions: Choose to have fraction marks "fixed" at the same location as that of the Reference, "floating" (left where they occur if within a window around Reference fraction marks or, if none occur in window, put at the Reference fraction mark position), or forced fractions "off".

Reference Ranges: Normal ranges (determined from previous runs) assigned for total and each fraction. Can have ranges based on age or sex.

Fraction Names: Up to 10 labeled fractions.

Ratios, Numerator and Denominator: Denote which fractions are in the

numerator and denominator of zero, one, or two ratios.

9.2.2. Programming Worklists

Choose how scans are displayed, whether to edit, print, or export data to an external source.

9.2.3. Programming Report Style

The title, report type, the quantity of scans per report, the paper size and orientation, scan identifier, patient demographics, sample image, graph, overlay legend, scan status, results, comments, auto interpretation, text, pictures, lines, overlays, barcodes, Levey-Jennings Graph plots, ranges, and number of copies can be selected.

9.2.4. Programming Patient Demographics

Determine what information is to be included in the patient data, and the order in which it will appear. Include essentially unlimited demographic labels (such as Patient Name, ID Number, Patient Age, Patient Sex, etc.).

If using the Composite Identifier option, ensure all necessary demographics are included during the Setup. It is recommended that once the Composite Identifier is created, the specific demographics are not changed. In addition, enabling the Composite Identifier will disable the Primary Key Identifier, which will affect the pairing of previous scans with newer ones.

9.2.5. Programming Comments

You can write and save comments. Saved comments can be recalled and used with other comments in any patient files. Auto interpretation comments based on user defined parameters may be programmed and applied.

9.3. Editing

Choose whether or not to edit each scan before storing, printing, or exporting the data. Editing features include: restoring the graph to an unedited form, automatically editing a pattern, automatically setting the scale to bring all peaks onto the graph, overlaying a reference pattern on the graph, aligning the reference with the sample, adding comments, inserting or deleting fraction marks, marking restricted bands using the skimmed or sliced method, deleting an area from the pattern, baseline adjustment, overlaying an unedited pattern on an edited pattern, overlaying other patient patterns, and smoothing a pattern.

- 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 12.18 x 12.18

9.4. File Retrieval

Determine what information the computer will search for when retrieving files. The selections are similar to Patient Demographics.

Scan Length:
Variable from 0.01 to 221.5 mm

9.5. Automatic Data Analysis, Each Scan

Analog curve, fractions, percent, units, integrals, one or two ratios, fractions, integrals, high and low indicators when outside normal ranges, and total.

Zeroing:
Automatic
Light Source:
Cold Cathode Fluorescent (white light)
Light Detectors:

9.6. Densitometer Specifications

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

CCD Array
Optical Density Linearity:
0.05 to 3.05 OD - Epson Expression scanner model V700

Optics Mode:

Operating System:
*Microsoft® Windows® 10

Visible Transmittance (white light)

*Windows is a registered trademark of Microsoft Inc.

Aperture Sizes (mm):

- 1 1 x .1
- 2 2 x .2
- 3 3 x .3

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 QuickScan Touch *plus* is factory lubricated. Do NOT lubricate the instrument.

NOTE: No daily maintenance is required.

10.1.1. General Cleaning

Visually inspect and clean the QuickScan Touch *plus* once a month.

TURN OFF THE POWER AND UNPLUG THE POWER CORDS BEFORE PROCEEDING. Should an instrument be contaminated by blood or blood derivatives, 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 alcohol, which is corrosive to metal surfaces.

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

10.1.2. Cleaning Scanner Glass

If the glass appears soiled or dusty, clean with a standard glass cleaning solution and a lint free tissue. All glass surfaces in the scanner must be kept clean for best operation.

10.1.3. Cleaning Touchscreen Monitor

The QuickScan Touch *plus* touchscreen monitor is designed for medical use. Turn off and unplug the monitor prior to cleaning. The monitor may be cleaned using a clean, soft, cloth. Apply a non-abrasive cleaner to the cloth prior to cleaning the screen. Handle the touchscreen with care, without applying any stress to the cables.

Do not use any vinegar based or abrasive cleaners on the monitor.

Other cleaners that may be used include: Quaternary ammonium (Virex, PDI Sanicloth HB), Bleach 5.25% or 6.25% at (1:10 dilution-1:100), or Quaternary ammonium in combination with 70% alcohol (iso or ethanol) (PDI Sanicloth or PDI Super Sanicloth).

10.2. Troubleshooting

When using the QuickScan Touch *plus* 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 10-1 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.
Power switch on, no power	Power cord not plugged in	Plug in power cord.
	Bad wall outlet	Use another outlet.
Not all Setup Options available	Hard lock key not inserted or poorly seated	Check for dark blue flash drive inserted into USB port. Restart software
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.
Unable to scan, scan icon not accessible	Hard lock key not inserted or poorly seated	Check for dark blue flash drive inserted into USB port. Restart software
Unable to scan, scan icon not accessible	Scanner not connected	Connect scanner. Restart software
No presentation on display	Loose interface or power cable	Push cable connections in fully.
	Defective interface cable	Call Helena Laboratories.
Sample Identifiers not importing from ESH	Closure of Import Identifier Window before import complete	Reimport
Sample Identifiers not importing from ESH	Comm port set to "Auto"	Work with IT and have Comm ports given appropriate assignments
Sample Identifiers not importing from ESH	Sample Handler connection disabled	Ensure connection physically sound, enable in User Setup
Sample Identifiers not importing from ESH	Communications settings between Sample Handler and QuickScan Touch <i>plus</i> not identical	Review Comm Settings
Sample Identifiers not importing from ESH	Loose or faulty connection	Check Connections
Sample Identifiers not importing from ESH	Bar codes not read	Check labels Check position of labels/ tubes in ESH
Sample Identifiers not importing from ESH	Incorrect Gel ID	Rescan/confirm ID
Sample Identifiers not importing from ESH	Bar Code reader failure	Call Helena Laboratories
No printout is produced	Did not select Print	Select Scan Options, select Print, select a Printer, a Report, Number of copies, and OK.
No printout is produced	Loose interface cable	Push cable connections in fully.
No printout is produced	Paper installed improperly	Reinstall paper.
No printout is produced	Defective interface cable	Replace cable.

PROBLEM	POSSIBLE CAUSE	SOLUTION
No printout is produced	Improper printer setup	Refer to printer owner's guide for settings.
No printout is produced	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	Cable disconnected	Firmly insert keyboard or mouse plug into receptacle on back of computer.
No response to keystrokes or mouse movement	Mouse located on screen behind active screen	Click Enter
No response to keystrokes or mouse movement	Undetermined cause	Press Alt-Ctrl-Del key to reset program (unsaved data will be lost).
No response to keystrokes or mouse movement	Undetermined cause	Call Helena Laboratories.
No response to touch screen	Undetermined cause	Use mouse/ keyboard/hotkeys Call Helena Laboratories
No fraction marks on patterns	Float or Fixed Fraction detection in use	Put Reference as key identifier and/or scan first
No fraction marks on patterns	Fraction detection/sensitivity set to zero	Increase fraction sensitivity to desired level.
Restricted band not marked/ marked incorrectly	Selected marking method not enabled	Check test setup
	Band too small for automatic marking	Mark manually
Control and/or NDDC out of range	Power surge	Call Helena Laboratories.
Control and/or NDDC out of range	Damaged plate	Examine plate. Replace as needed
Control and/or NDDC out of range	Dirty NDDC plate	Gently remove debris with dry lint free tissue.
Control and/or NDDC out of range	Scanner not calibrated, calibrated incorrectly	Call Helena Laboratories.
Control and/or NDDC out of range	Scanner lamp failure	Call Helena Laboratories.
Scan image and scan lines (begin/end and step-over lines) do not line up	Scan lines setup incorrectly in test setup, incorrect plate/test selection	Review scan image in test setup.
Ranges not displayed	Display not enabled	Enable display
Ranges not displayed	Ranges not entered in Setup	Check test setup
Ranges not printed	Print Ranges not enabled	Select 'print ranges' (units or percent) in print settings
Ranges not printed	Ranges not entered in Setup	Check test setup

PROBLEM	POSSIBLE CAUSE	SOLUTION
Ranges not printed	Range values are not printed on List Reports	Normal function
Ranges not exported	Export Ranges not enabled	Enable export
Ranges not exported	Ranges not entered in Setup Range values are not exported to file destination	Check test setup
Ranges not exported	Range values are not exported to file destination	Normal function
Barcode on report not printed	Undetermined Cause	Attempt to reprint
Barcode on report not printed	Incorrect type	Check bar code type in setup
Barcode on report not printed	Incorrect format	Ensure correct bar code format
Units not calculated	Total demographic not set up	Check test setup
Units not calculated	Total value not entered	Enter correct total
Auto interpretation not applied	Auto interpretation not enabled	Review test setup, pre-scan setup
Auto interpretation not applied	Units not entered	Verify units
Auto interpretation not applied	Ranges not entered	Review test setup,
Auto interpretation not applied	Incorrect number of fractions	Edit scan
Auto interpretation not applied	Auto Interpretation criteria not entered in Setup/ not entered for designated test.	Check comment setup Check test setup
Patient Overlay not applied	No matching overlay available	Use Find function to search for patient scans by Key ID
Patient Overlay not applied	Overlay Display not enabled	Check Display criteria
Patient Overlay not applied	Incorrect Overlay criteria entered	Check overlay search criteria
No Lp(a) when forced	Reference scan must be labeled reference.	Check patient info screen and label reference
No Lp(a) when forced	Lp(a) must be marked	Check reference overlay
No Lp(a) when forced	Auto Edit must be enabled.	Check auto edit
No Lp(a) when forced	Force Lp(a) setting must be on	Restore, then check auto edit criteria
Invalid user/password error	Abnormal termination of QSTp	The MSS timer will reset itself after 30 minutes
Comment is truncated on printed copy of comments	Word wrap isn't apply	Hitting the return key at the end of each line will prevent this.
Invalid exception error	Deleting more than 50 worklists in a single transaction	Worklists will remain deleted, but the error will cause the user to log out, close the program, reopen the program, and log back in again.
EAccess Violation	User was idle for more than 30 minutes in Patient List window	Add all patient info and close out of window to retain changes

PROBLEM	POSSIBLE CAUSE	SOLUTION
Access Violation	Clicking on the screen multiple times while the QSTp is performing an operation such as saving a worklist	Wait until operation is complete

10.3. Warranty

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies. In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of 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 QuickScan Touch *plus* for any purpose other than that described in this manual. Modification of the software or the use of the QuickScan Touch *plus* 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)
---	--

Section 12 - Communication Specifications

INTERFACE SPECIFICATIONS:

The QuickScan Touch *plus* 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, 14400, or 19200. 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 XON-XOFF flow control or ASTM protocol. The QuickScan Touch *plus* does not order the tests.

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 QuickScan Touch *plus* software.

COMMUNICATIONS PROTOCOL:

The protocol used by the QuickScan Touch *plus* software is user selectable (see section 6.6). Listed below are the protocol options available.

No Protocol:

Data is transmitted and received as ASCII text with no flow control or error checking/ correction. This option is not recommended unless the QuickScan Touch *plus* is to be connected to a terminal.

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 QuickScan Touch *plus* software will transmit an XOFF character when its communications buffer becomes three quarters full. Data transmission should stop at this point. The QuickScan Touch *plus* 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 QuickScan Touch *plus* 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.

ASTM Protocol (E1381-95 and 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>.

There are three distinct phases in transferring information between the QuickScan Touch *plus* 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.

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 QuickScan Touch *plus* 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.

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 and 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:

1 - Any character errors are detected (parity error, framing error, etc.)

2 - The frame checksum doesn't match the checksum computed on the received frame.

3 - 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.

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.

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.

DATA TRANSFER FORMAT

The QuickScan Touch *plus* 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 QuickScan Touch *plus* 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 QuickScan Touch *plus* demographics to match those defined in the ASTM standard, if strict adherence to the standard is required.

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 QuickScan Touch *plus*: 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.

Header Record

The header record must always be the first record in a transmission. When the QuickScan Touch *plus* transmits a header record it will have the following format:

```
H|\^&||HELQS3|Helena  
Laboratories^QuickScan Touch plus  
^serial number|P.O. Box 752  
Beaumont^Texas^77704-0752^USA|Toll  
Free: 800-231-5663 Local: 409-842-3714  
HELQS3 Password indicating the  
sending instrument is a Helena  
QuickScan Touch plus.
```

serial number – the serial number of the QuickScan Touch *plus* will be listed here.

When the QuickScan Touch *plus* receives a header record it considers the all five characters to be significant. The five ASCII characters that immediately follow the H (the header ID) define the delimiters to be used throughout the subsequent records of the message. The second character in the header record is the field delimiter, the third character is the repeat delimiter, the fourth character is the component delimiter, and the fifth is the escape character. A field delimiter follows these characters to separate them from subsequent fields. Another way to view this is that the first field contains H and the second field contains the repeat, component, and escape delimiters. An example of the first six characters in the header record would appear as follows: H|\^&|.

Patient Record

When importing data using ASTM, demographic data will automatically be assigned to an ASTM field based on the demographic label. The user may override this automatic assignment in Import / Export setup.

Graph Data Record

The QuickScan Touch *plus* will transmit the graph data in the following format:

M|1|*test name*|*yyyymmddhhmmsshs*|*ndata*[^]
*d*₁,*d*₂,*d*₃,...*d*_{*ndata*}|*nfractions*[^]*f*₁,*f*₂,*f*₃,...*f*_{*nfraction*}
ction|*nmspikes*[^]:*m*₁₁:*m*₁₂:*m*₂₁:*m*₃₁:
*m*₃₂<CR>

test name - Name of test performed.

yyyymmddhhmmsshs - Date and time test was performed. The date is transmitted with the year first, month second, and day last. hs=hundredths of a second.

ndata - The number of data points in the scan. There can be a maximum of 1100 scan data points.

*d*₁,*d*₂,*d*₃,...- Scan data points.

nfractions - Number of fractions for the scan. There can be a maximum of 10 fractions.

*f*₁,*f*₂,*f*₃ - Location of fraction boundaries within the scan data.

nmspikes - Number of m-spikes. There can be a maximum of 3 m-spikes.

*m*₁₁:*m*₁₂ - Location of the m-spike within the scan data. The first value is the start boundary and the second value is the end boundary.

Order Record

The QuickScan Touch *plus* will transmit an order record immediately preceding any result records for a patient as required in the ASTM specification. The format will be as follows:

O|1||gel id-sample number|^{^^^}*test name*<CR>

test name - Name of the test performed.

gel ID – unique identifier. If using positive sample ID, this will be the bar code on the gel

sample number – the position of the sample on the gel.

The QuickScan Touch *plus* currently does not recognize test order records transmitted by the computer system.

Result Record

Each fraction and each ratio of a patient scan will be transmitted as a separate result record. 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*||
yyyymmddhhmmsshs<CR>

A ratio result will be transmitted in the following format:

R|*n*|^{^^^}*test name*[^]*ratio name*|*nnnn.nn*||||*F*||
yyyymmddhhmmsshs<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 performed.

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 (integrals).

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 reference range.

f - Result abnormal flag. Will be one of the following: L (low), N (normal), or H (high).

yyyymmddhhmmsshs - Date and time the test was performed. The date is transmitted with the year first, month second and day last. *hs* = hundredths of seconds

The QuickScan Touch *plus* does not recognize result records transmitted by the computer system.

Comment Record

The QuickScan Touch *plus* will transmit comment records in the following format:

C|1||comment text|G<CR>

The comment record will be transferred immediately following the order record.

The QuickScan Touch *plus* does not recognize comment records transmitted by the computer system.

Request Information Record

The QuickScan Touch *plus* 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 QuickScan Touch *plus* does not recognize request information records transmitted by the computer system.

Terminator Record

The terminator record must be the last record in a transmission. When the QuickScan Touch *plus* transmits a terminator record it will have the following format:

L|1|<CR>

When receiving a terminator record, the QuickScan Touch *plus* only considers the first character significant, all other characters up to the carriage return will be ignored.

Importing External Data into QuickScan Touch *plus*

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||20030
121|F|black|||Alford^G.[9]|4'
11"|129|||||2000000||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 *plus*. 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 QuickScan Touch *plus*. 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 QuickScan Touch *plus*.

Section 13 - V8 interface (optional)

This section details the steps required to import Serum Protein results from the V8 Clinical Capillary Electrophoresis system.

Note: Hemoglobin test results should **not** be imported from the V8 Platinum software into the QuickScan Touch *plus* software. The Platinum software excludes portions of the curve from its calculations while the QuickScan Touch *plus* utilizes all data in its computations; therefore, the final results will differ slightly on the two software programs.

13.1. Main Menu

When the V8 interface is enabled, an *Import V8 CE scans* icon will be displayed on the menu bar (Figure 13-1). Clicking on this icon will open a new window to download scans imported from the V8 (see Section 13.4).

13.2. V8 Setup

1. From the QuickScan Touch *plus* main menu, select *Edit* and then *User Setup*.
2. From the *QuickScan Touch plus Setup* window, select *V8 CE System*.
3. Connect the V8 system to the QuickScan Touch *plus* using an Ethernet cable. Enable the *V8 Capillary Electrophoresis System connected* option by checking it. (Figure 13-2).
4. *Port* – Select the necessary port.
5. *Print* – Select to print the information for the port.

13.2.1. Platinum interface

1. From the Platinum Main menu, select *File*, then *Customise*. The *Customisation* window appears.

2. Select the *Sending to LIMS* tab.
3. Under *Ethernet selection*, there are options for *TCP/IP*, *IP Address*, and *Port*.

Note: The IP address and Port will vary with the configuration of the V8 and QuickScan Touch *plus* setup. Helena Service will consult with the institution's IT department to determine the correct information to be added.

3. Select *Connect*.
4. Click *OK* to close and save the information.

13.3. Test Setup

1. From the QuickScan Touch *plus* main menu, select *Edit* and then *User Setup*.
2. From the *QuickScan Touch plus Setup* window, select *Tests*. The window displays the existing tests. (Figure 6-4).
3. *Edit* - To edit an existing test, highlight the needed test and select *Edit*. The *Edit Test* window appears containing the test name and its current parameters. See sections 6.2.1 through 6.2.6 for instructions on using this window.

Note: Once a test has been edited and saved, the new test will overwrite the original test.

Note: The *Edit Test* and *Add Test* windows use the same window for entering information concerning test setup.

4. *Add* - To add a new test, select *Add* and the *Add Test* window displays. (See section 6.2.1 for further detail.)
5. *Delete* - To delete an existing test, highlight the needed test and select

Delete. A *Confirm Delete* prompt displays:

- a. Select *Yes* to delete the test.
- b. Select *No* to retain the test

6. The *Print Settings* window appears allowing the user to select the desired printer, print range, and number of copies.

7. *Export* – A *named test with settings may be exported to a file for use in another QuickScan Touch plus system.* Select *Export* to export the test settings. Select a file name and source in which to save the test. The test will be saved as a Test Export File (.xtf) and can only be opened in the QuickScan Touch *plus* software. Note that the gel image and Scan Location in Test Setup is not exported with the test settings.

8. *Import* – Select to import test setting from another file or location. Select the folder and file name and click on *Open*. Select the desired test file. The test file will be a Test Export File (.xtf) and can only be opened in the QuickScan Touch *plus* software.

9. Once the test has been set up and/or altered as desired:

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

13.3.1. 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 13-3). The user may either choose to enter de novo settings, or click *Default Settings* choose from a drop down list of available default test settings for that test type. **Note:** do not name the test until after clicking on the *Default Settings* button as the *Default Settings* button will clear the test name.

2. *Test Name* - may be entered/altered as needed. The test name will automatically include the maximum number of samples and the stain type the test is setup to use *plus* the name entered in this field. Each test setup must have a unique *Test Name*. Additionally, for Serum Proteins to have access to the *Restricted Bands* feature in the edit mode, the test name must include either "Proteins" or "SPE".

3. *Capillary Electrophoresis* – this must be enabled to create a test to import V8 test results in to the QuickScan Touch *plus* software.

4. After enabling the *Capillary Electrophoresis* option from the previous step, three additional tabs will be displayed; *CE Scan Settings*, *Fractions / Ratio / Ranges*, and *Patient Demographics*. Each tab contains menus for setting up test-specific parameters.

13.3.2. CE Scan Settings

1. *CE Analysis Name* – must correspond to the test name used in the V8. For Serum Proteins, spe should be used here.

2. *Auto Slope Correction* – automatically corrects the slope.

a. *Smooth* - Do not select unless procedure recommends otherwise; the graph will not be smoothed. With *Smooth* selected, set the *Smoothing Level* to a value from 1 to 10, with 1 being minimal smoothing and 10 being maximum smoothing. Smoothing will affect the results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing **could affect** small monoclonals.

b. *Auto Interpretation* - enables automatic interpretation of the scan results and requires user-defined interpretations be setup.

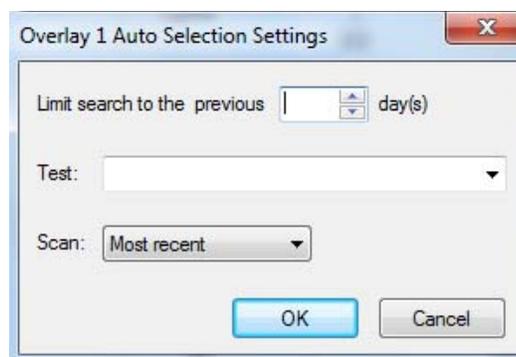
c. *Auto Edit* -  only available for tests with "Chol" in the test name. See Section 6.2.3 for more detail.

3. *Patient Overlay 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. Select *Overlay 1 Auto Selection Settings* and choose from the following:

a. *Limit search to the previous days* – search from any number of previous days.

b. *Test* - select from any available test

c. *Scan* – choose from *Most recent*, *Next most recent*, *Prior oldest*, and *Oldest*.



4. *Patient Overlay 2* - select to have a second patient's scan, shown in blue, overlaid on the current scan. Select *Overlay 2 Auto Selection Settings* and choose from the following:

a. *Limit search to the previous days* – search from any number of previous days

b. *Test* - select from any available test.

c. *Scan* – choose from *Most recent*, *Next most recent*, *Prior oldest*, and *Oldest*.



Image –

d. *Simulate gel image* – may be enabled to include a “simulated” gel image that will be included with the worklist.

e. *Stain Type* – includes *Acid Blue*, *Acid Violet*, *Fat Red 7B*, and *Ponceau S*. Since the gel image is being simulated, any stain may be selected.

f. *Image Contrast* - is set, using a slide bar, in a range of *-10.0 Lighter* to *10.0 Darker*, in 0.2 increments. The setting affects only the appearance of the scan image when displayed and printed and does not affect the quantitation

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

4. Once the test has been set up and/or altered as desired:

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

b. *Cancel* - to exit 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*.

13.3.3. Fractions / Ratios / Ranges

Setup is identical in the original QuickScan Touch *plus*. See Section 6.2.5 for more information.

13.3.4. Patient Demographics

Setup is identical in the original QuickScan Touch *plus*. See Section 6.2.6 for more information.

13.4. Importing scans from the V8

1. On the main menu bar, click the *Import V8 CE Scans* icon .

2. The *Import V8 CE Scans* window appears. Any scans that have been received from the V8 will be displayed here (Figure 13-4). The scans will be stored here until they are either imported or deleted.

3. Once the scans are imported into a worklist, they will be linked with the test specifically set up for the V8 (Section 13.3.2).

a. *Select All* – may be used to select all the scans shown. Alternatively, the user may highlight selected scans using the mouse and Control key.

b. *Import* – will import the scans into a worklist and prompt the user for a worklist name.

c. *Clear* – select to clear all scans displayed

d. *Cancel* - to exit without saving any changes made.

Note: Do NOT attempt to manually import patients from the V8 or import the same patient from the same run more than once. If the same scan is imported from the Platinum software multiple times, each scan will be viewed as a different scan with a different time and date stamp in the Quick Scan Touch software.

4. After selecting the scans, click the *Import* button.

5. When the *New Worklist* window appears, select either *Default Scan* or the desired template and click *OK*.

6. Name the worklist and click *OK* again. The scans are imported into the QuickScan Touch *plus* and displayed on the screen. A progress bar will alert the user the scans are being imported.

7. If when importing a scan from the V8, the Total Protein result (set up as an independent result record and not a demographic) is not imported from the LIS, the QuickScan Touch plus software will allow the user to add the result by clicking the Edit Patient Info icon and then adding the total into the patient list. The QuickScan Touch plus will not allow the user to overwrite a total that has been brought in from the LIS.

8. The QuickScan Touch plus will not import scans with no results

automatically. These results will have to be imported manually by the user.

Note: When importing V8 scans, only one test should be designated as a CE test. Having multiple tests will have the QuickScan Touch plus use the first one it finds, which may not be the one the user selected.

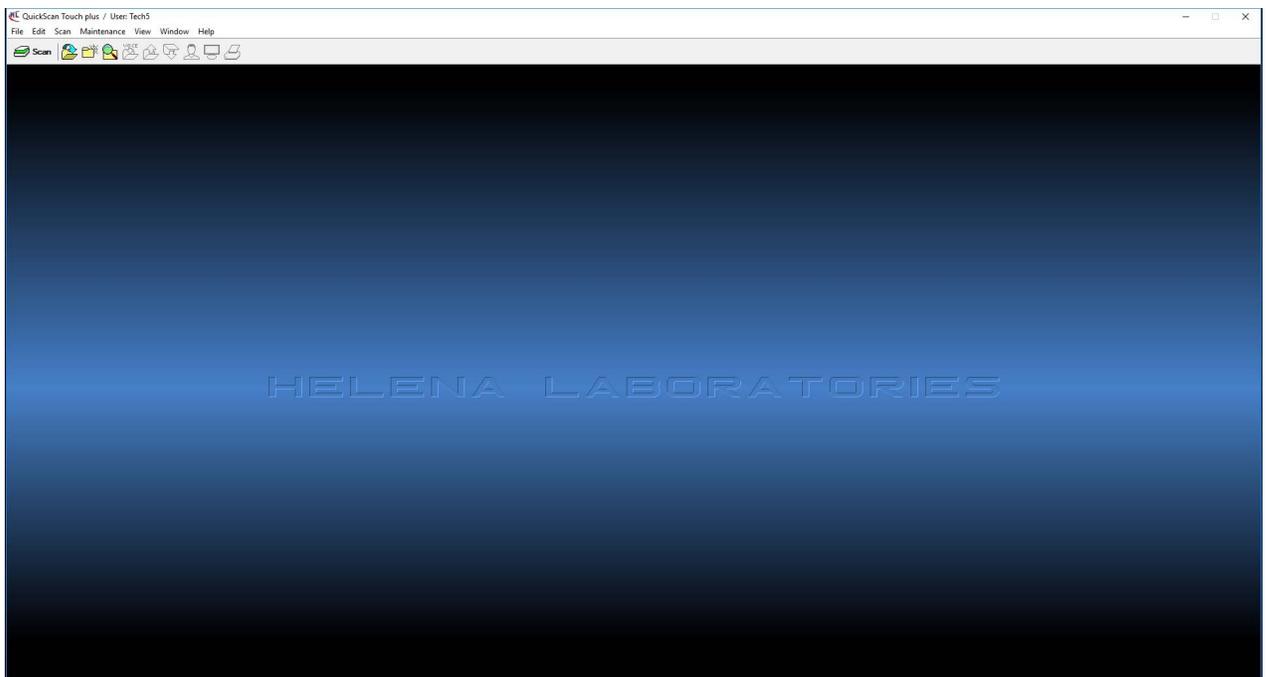


Figure 13-1 Main menu with V8 icon

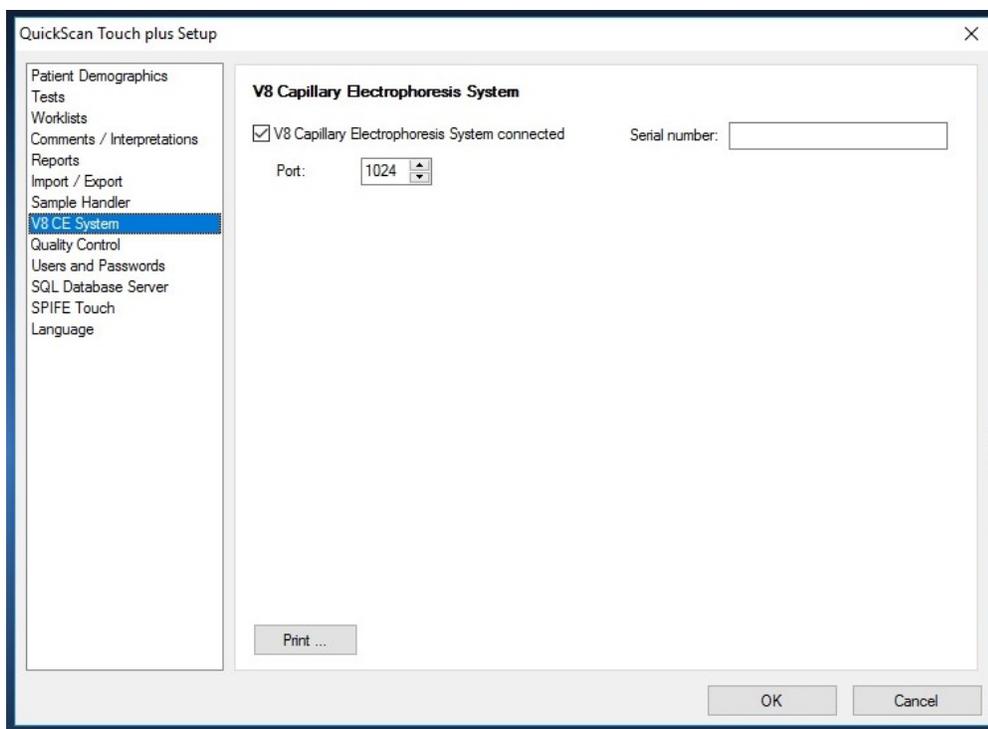


Figure 13-2 Connecting the QST to the V8

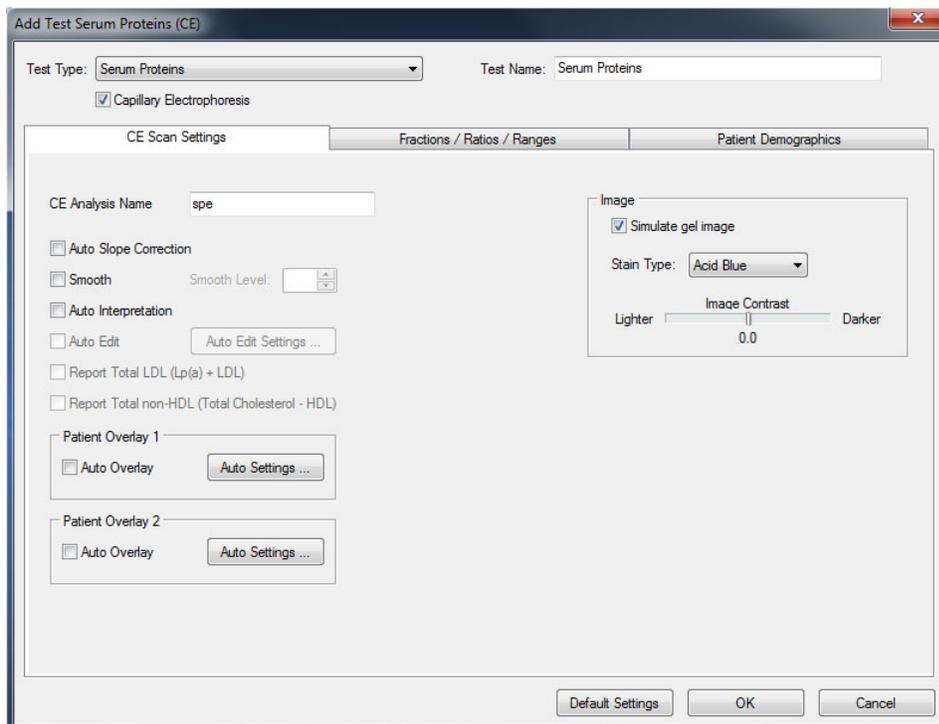


Figure 13-3 V8 Test Setup

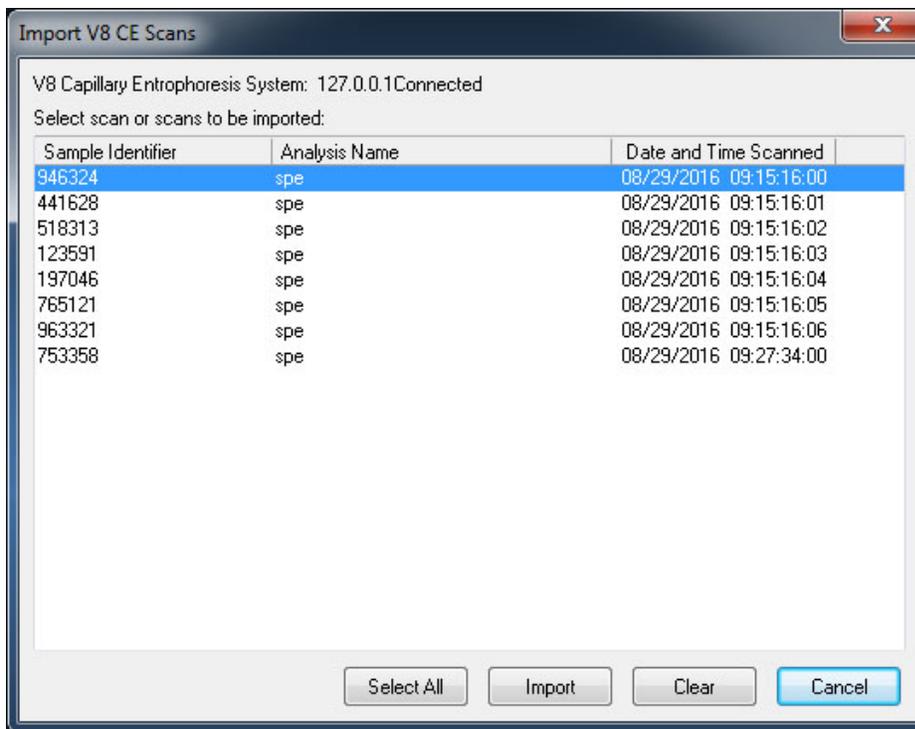


Figure 13-4 Import V8 Scans

Section 14 - Myeloma Module (optional)

The Myeloma Module software available from Helena Laboratories may be used for tracking patient's QuickScan Touch *plus* scans as well as scans imported from the V8 system. Figure 14-1 displays the main menu with the new icons on the menu bar.

Once a gel plate is scanned by a technician at the instrument, it creates a worklist in the QuickScan Touch *plus* system software with the patient scan results. Patient results can be tracked throughout the various folders using the demographic field selected as the "Key Identifier". With the Myeloma Module Software Option enabled, the state of the scan can be changed to reflect its progress through editing, re-editing, review, consultation, and acceptance. Technicians edit the scans to prepare them for review by pathologists which can be done onsite or remotely. Pathologists review the scans, annotate them, and then accept them, send them out for consultation to another pathologist, or send them back to a technician for further editing. See Figure 14-12 for work flow.

All four folders (*Review, Re-Edit, Confer, and Accept*) have the same layout. The associated scans will be displayed as thumbnails on the left hand side of the screen in chronological order with the oldest at the bottom. The thumbnail with a **blue** background is the most recent scan. The thumbnail with the red background is the "baseline scan". All other thumbnails will have a **green** background.

14.1. User Setup

1. From the main menu select *Edit* and then *User Setup*.
2. From the *QuickScan Touch plus Setup* window, select *Users and Passwords*. The default *QSTAdmin* user will be displayed.
3. *Edit* – To edit an existing user, highlight the desired user and select *Edit* and the *Edit User* window displays. See the instructions for the *Add User* window to use this window.
4. *Add* - To add a new user, select *Add* and the *Add User* window displays (Figure 14-2).
 - 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:
 - ii. *Edit patient information*
 - iii. *Edit scans*
 - iv. *Export*
 - v. *Print*
 - vi. *Delete scans*
 - vii. *Change worklist settings*
 - viii. *Change setup*
 - ix. *Setup users* (this option is only available if *Change Setup* has been selected).
 - x. *Change calibration*
 - xi. *Clear QuickScan Touch log files*

xii. Review Option:

- 1) *Edit 'Review' worklist*
- 2) *Review to Accept*
- 3) *Review to Re-Edit*
- 4) *Review to Consult*
- 5) *Re-Edit to Accept*
- 6) *Re-Edit to Review*
- 7) *Consult to Accept*
- 8) *Consult to Review*
- 9) *Accepted to Review*

Note: *If users with permissions will be created and utilized, Edit 'Review' worklist must be enabled to accept scans and send them to the Accept folder.*

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

e. *Cancel* – select to reject the changes made. A *Confirm Cancel* prompt will be displayed.

i. Select *Yes* to continue or

ii. *No* to return the *Add User* window.

5. *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.

6. *Print* - Select to print the selected report. The *Printer Setup* window appears allowing the user to select the desired printer, print range, and number of copies

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 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*.

14.2. Pathologists

The QuickScan Touch allows the user to create a list of pathologists (maximum of 5) with a stored email address for each entry.

1. From the main menu, select *Edit* and then *User Setup*.

2. From the QuickScan Touch plus Setup window, select *Pathologists*.

3. *Edit* – To edit an existing pathologist, highlight the desired pathologist and select *Edit* and the *Pathologist Edit Dialog* window displays. See the instructions for the *Add* window to use this window.

4. *Add* - To add a new pathologist, select *Add* and the *Pathologist Edit Dialog* window displays (Figure 14-11).

a. *Name* – enter the pathologist's name.

b. *Email address* – enter the pathologist's email.

c. *SMS* – *This function will be available in a future release.*

5. *Delete* - To delete an existing pathologist, highlight the desired

pathologist and select *Delete*. A *Confirm Delete* prompt displays.

- a. Select *Yes* to delete.
- b. Select *No* to retain and return to the Pathologist window.

6. Once all the pathologists 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*.

ii. 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*.

14.3. Sending Scans to the Review Folder

1. From the main menu, select *File* then *Open* to open the desired worklist.
2. With the worklist open, click the *Save Scans to Review* Icon on the menu bar.



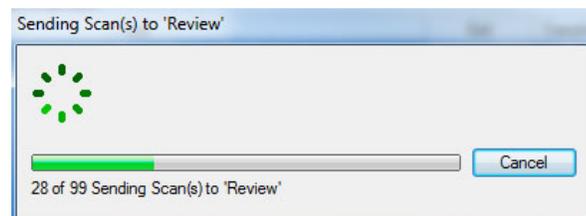
3. The Send Scans window will appear with all the scans listed from the currently displayed worklist (Figure 14-10). *Select All*, *Send*, and *Cancel* buttons are displayed as well as the worklist name and time/date stamp.

4. Scans may be selected by using the mouse and Ctrl and/or Shift key or by clicking *Select All*.

5. Once all the desired scans have been selected, click *Send*.

6. A dialog box will be displayed alerting the user the scans are being imported to 'Review'.

7. When sending a worklist to the Review folder, the software will close any open worklists when the action is completed.



Note: Only scans with a Patient Identifier will be sent to the Review folder.

Note: Any scan that with the words *Normal*, *Abnormal*, *Control*, or *Reference* will not be sent to the review folder.

14.4. Review folder

1. Click *Review* Icon on the menu bar.



2. The *Open Worklist 'REVIEW'* folder is displayed, Figure 14-3.

3. The window contains the fields Patient Identifier, Test Type, Date, Apply, Bar Code Reader, Open, and Cancel.

a. *Patient Identifier* - the user has the option to search by the Patient Identifier.

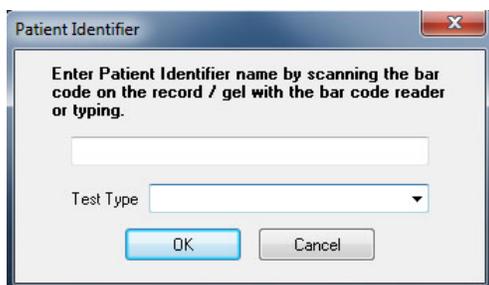
b. *Test Type* – the user has the option to use the drop down list to select from the test types contained in the folder.

c. *Date* - the user has the option to search by time periods.

d. *Apply* – click to apply the search parameters.

e. *Bar Code Reader* – clicking this opens the *Patient Identifier* box. Here,

the user can enter the specific Gel Identifier number to locate the worklist. Additionally, a test type can be selected from the dropdown menu.



- i. *OK* – to save all the changes made and exit, select *OK*.
- ii. *Cancel* – to exit without saving any changes made.
- f. *Open* – click to open the selected worklist.
- g. *Cancel* – click to exit without saving any changes.

14.4.1. Reviewing scans

Note: *The user must have the “Review Option” permissions enabled from Section 14.1 to be able to edit and then send scans to other folders.*

On the main screen, the most recent scan will be displayed on the left hand side with the other side of the main screen displaying any other scan that has been selected for comparison as the “baseline scan” (Figure 14-4). All associated scans are displayed as thumbnails along the left hand side vertically.

Once at least four or more scans are stored, a “slide bar” is available at the top left of the screen for quickly paging through the scans to visually check differences between them.

All “accepted scans” associated with it, will be locked to editing.

To unlock and “edit” any of the older scans, the user will have to right click on the scan’s thumbnail and select *Scan*, *Review*, and then *Edit Scan*. The QuickScan Touch *plus* will prompt the user and ask them, “*Are you sure you want to edit?*” If *Yes* is selected, the most recent scan will be removed from the main screen (not from the thumbnails) so the older scan may be edited.

The editing menu has the same features as any other editing menu available in the QuickScan Touch *plus* (see Section 7.4 for detailed instructions on editing scans).

Note: *All patient information may be altered except for the demographic that links the scans, whether it is a patient name or patient ID.*

Once the editing is completed, clicking on any other thumbnail will relock the scan.

There are certain functions listed below that aren’t available such as *gel image*, *cut*, *copy*, etc. These functions aren’t available inside the Myeloma Module software folders and are *only* available in the original worklists processed on the QuickScan Touch *plus*. Only the available options will be listed below.

1. *Accept* – click to send the scan to the Accept folder.
2. *Re-Edit* – click to send the scan to the Re-Edit folder.
3. *Consult* – click to send the scan to the consult folder and generate an email to notify the pathologist.
4. To access thumbnail options, right click on the desired scan
5. *Worklist*

a. *Worklist Label* – name of the worklist

b. *Worklist Properties* – displays the properties associated with the scan. This includes *Label, Date Created, Template, Location, Test, Gel Identifier,* and *Completed Scans.*

6. Scan

a. *Delete* - is only available for the most recent scan. Any other scans cannot be deleted.

b. Review -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan.

c. Scan Properties – contains the following information for the selected scan: Test, Sample Identifier, Gel Identifier, Sample Number, Scanned, Rescanned, Reviewed, Edited, Reviewer Id, Scan Resolution, and Scan Status.

Close Menu – select to close the menu.

Note: *Once scans are in the Review folder, PENDING REVIEW will be displayed on the original worklist.*

PENDING REVIEW

14.4.2. Sending scans for Consult

From the Review folder, scans can be edited and prepared by Technicians to be sent for review to pathologists which can be done onsite or remotely. The Consult feature sends the Pathologist an email alerting the person a scan needs to be reviewed. Pathologists review the scans, annotate them, and then can accept them, send them out for consultation to another pathologist, or

send them back to a technician for further editing. To send a scan for a Consult, the technician must have adequate privileged assigned in User Setup.

1. After opening and selecting the desired scan, press the *Consult* button. The *Consult Dialog* window appears (Figure 14-13).

2. From the list displayed, select the desired Pathologist by enabling the box to the left of the name. More than one may be enabled at a time.

3. Click *Mail* to proceed (or *Cancel* to return to the *Review* folder).

4. After clicking *Mail*, the *Send Mail* window is displayed (Figure 14-14).

a. *Host* – Helena Service will consult with the institution's IT department to determine the correct information to be added.

b. *Port* – Helena Service will consult with the institution's IT department to determine the correct information to be added.

c. *Server requires authentication* – enable if necessary

d. *Username* – the username of the person sending the email.

e. *Password* - the password of the person sending the email.

f. *Authentication* – will be available in a future version.

g. *From* – The username or name of the person sending the email

h. *To* – this is the pathologist that was selecting in the window before

i. *Subject* – default Subject is displayed that can be customized

- j. *Scan Info* – contains the information for which scan needs to be reviewed.
- k. *Message* – customizable message may be added here.
- l. *Status* – Updates the sending of the status of the email.



- m. *Back* – click to cancel the email.
 - n. *Send Mail* – select to send the email.
5. Once all the information has been added, select *Send Mail* to send the email.
 6. The status box will alert the user if the email failed to send. If the email is successfully sent, the window will automatically close.

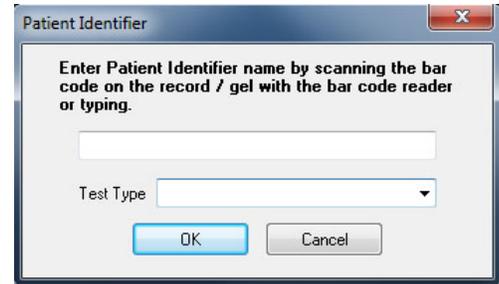
14.5. Re-Edit Folder

1. Click *Re-Edit* Icon on the menu bar.



2. The *Open Worklist 'RE-EDIT'* folder is displayed, Figure 14-5.
3. The window contains the fields *Patient Identifier*, *Test Type*, *Date*, *Apply*, *Bar Code Reader*, *Open*, and *Cancel*.
 - a. *Patient Identifier* - the user has the option to search by the Patient Identifier.
 - b. *Test Type* – the user has the option to use the drop down list to select from the test type contained in the folder.
 - c. *Date* - the user has the option to search by time periods.

- d. *Apply* – click to apply the search parameters.
- e. *Bar Code Reader* – clicking this opens the *Patient Identifier box*. Here, the user can enter the specific Gel Identifier number to locate the worklist. Additionally, a test type can be selected from the dropdown menu.



- i. *OK* – to save all the changes made and exit, select *OK*.
 - ii. *Cancel* – to exit without saving any changes made.
- f. *Open* – click to open the selected worklist.
 - g. *Cancel* – click to exit without saving any changes

14.5.1. Re-Editing scans

Note: The user must have the “Review Option” permissions enabled from Section 14.1 to be able to edit and then send scans to other folders.

On the main screen, the most recent scan will be displayed on the left hand side with the other side of the main screen displaying any other scan that has been selected for comparison as the “baseline scan” (Figure 14-6). All other associated scans are displayed as thumbnails along the left hand side vertically.

Once at least four or more scans are stored, a “slide bar” is available at the top

left of the screen for quickly paging through the scans to visually check differences between them.

Only the newest scan will be able to be edited. Any other “accepted scans” associated with it, will be locked to editing.

To unlock and “edit” any of the older scans, the user will have to right click on the scan’s thumbnail and select *Scan*, *Review*, and then *Edit Scan*. The QuickScan Touch *plus* will prompt the user and ask them, “*Are you sure you want to edit?*” If *Yes* is selected, the most recent scan will be removed from the main screen (not from the thumbnails) so the older scan may be edited.

The editing menu has the same features as any other editing menu available in the QuickScan Touch *plus* (see Section 7.4 for detailed instructions on editing scans).

Note: *All patient information may be altered except for the demographic that links the scans, whether it is a patient name or patient ID.*

Once the editing is completed, clicking on any other thumbnail will relock the scan.

There are certain functions listed below that aren’t available such as *gel image*, *cut*, *copy*, etc. These functions aren’t available inside the Myeloma Module software folders and are *only* available in the original worklists processed on the QuickScan Touch *plus*. Only the available options will be listed below.

1. *Review* – click to send the scan back to the Review folder.

2. *Accept* – click to send the scan to the Accept folder

3. To access thumbnail options, right click on the desired scan.

4. *Worklist*

a. *Worklist Label* - name of the worklist.

b. *Worklist Properties* – displays the properties associated with the scan. This includes Label, Date Created, Template, Location, Test, Gel Identifier, and Completed Scans. .

Scan

c. *Delete* - is only available for the most recent scan. Any other scans cannot be deleted.

d. *Review* -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan.

e. *Scan Properties* – contains the following information for the selected scan: *Test*, *Sample Identifier*, *Gel Identifier*, *Sample Number*, *Scanned*, *Rescanned*, *Reviewed*, *Edited*, *Reviewer Id*, *Scan Resolution*, and *Scan Status*.

f. *Close Menu* – select to close the menu.

Note: *Once scans are in the Re-Edit folder, PENDING RE-EDIT will be displayed on the original worklist.*

PENDING RE-EDIT

14.6. Accept folder

Note: *The user must have the “Review Option” permissions enabled from Section 14.1 to be able to edit and then send scans to other folders.*

1. Click the *Review* Icon on the menu



bar.

5. The *Open Worklist 'ACCEPT'* folder is displayed, Figure 14-7.

6. The window contains the fields *Patient Identifier*, *Test Type*, *Date*, *Apply*, *Bar Code Reader*, *Open*, and *Cancel*.

- a. *Patient Identifier* - the user has the option to search by the Patient Identifier.

- b. *Test Type* – the user has the option to use the drop down list to select from the test type contained in the folder.

- c. *Date* - the user has the option to search by time periods.

- d. *Apply* – click to apply the search parameters

- e. *Bar Code Reader* – clicking this opens the *Patient Identifier box*. Here, the user can enter the specific Gel Identifier number to locate the worklist. Additionally, a test type can be selected from the dropdown menu.

- i. *OK* – to save all the changes made and exit, select *OK*.
 - ii. *Cancel* – to exit without saving any changes made.
- f. *Open* – click to open the selected worklist.

- g. *Cancel* – click to exit without saving any changes

14.6.1. Accepting scans

On the main screen, the most recent scan will be displayed on the left hand side with the other side of the main screen displaying any other scan that has been selected for comparison as the “baseline scan” (Figure 14-8). All other associated scans are displayed as thumbnails along the left hand side vertically.

Once at least four or more scans are stored, a “slide bar” is available at the top left of the screen for quickly paging through the scans to visually check differences between them.

All patient Information is locked in the Accept folder. To unlock and “edit” any of the scans, the user will have to right click on the scan’s thumbnail and select *Scan*, *Review*, and then *Edit Scan*. The QuickScan Touch *plus* will prompt the user and ask them, “Are you sure you want to edit?” If *Yes* is selected, the most recent scan will be removed from the main screen (not from the thumbnails) so the older scan may be edited.

The editing menu has the same features as any other editing menu available in the QuickScan Touch *plus* (see Section 7.4 for detailed instructions on editing scans).

Note: All patient information may be altered except for the demographic that links the scans, whether it is a patient name or patient ID.

Once the editing is completed, clicking on any other thumbnail will relock the scan.

There are certain functions listed below that aren't available such as *gel image*, *cut*, *copy*, etc. These functions aren't available inside the Myeloma Module software folders and are *only* available in the original worklists processed on the QuickScan Touch *plus*. Only the available options will be listed below.

Once a scan has been Accepted, the user will be blocked from editing the scan in the original worklist.

1. *Review* – click to send the scan back to the Review folder.

2. To access thumbnail options, right click on the desired scan.

3. *Worklist*

a. *Worklist Label* - name of the worklist

b. *Worklist Properties* – displays the properties associated with the scan. This includes *Label, Date Created, Template, Location, Test, Gel Identifier*, and *Completed Scans*.

Scan

a. *Review* -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan.

b. *Scan Properties* – contains the following information for the selected scan: *Test, Sample Identifier, Gel Identifier, Sample Number, Scanned, Rescanned, Reviewed, Edited, Reviewer Id, Scan Resolution*, and *Scan Status*.

Scan

c. *Delete* – scans can no longer be deleted from the *Accept* folder. To

delete a scan, it must be sent back to the *Review* folder first. This two-step process is to help prevent accidental scan deletion.

d. *Review* -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan

e. *Scan Properties* – contains the following information for the selected scan: *Test, Sample Identifier, Gel Identifier, Sample Number, Scanned, Rescanned, Reviewed, Edited, Reviewer Id, Scan Resolution*, and *Scan Status*.

Close Menu – select to close the menu.

Note: Once scans are accepted, *ACCEPTED* will be displayed on the original worklist.

ACCEPTED

14.7. Confer folder

Note: The user must have the “Review Option” permissions enabled from Section 14.1 to be able to edit and then send scans to other folders.

1. Click the *CONFERENCE* Icon on the menu bar.



2. The *Open Worklist 'Consult'* folder is displayed, Figure 14-7.

3. The window contains the fields *Patient Identifier, Test Type, Date, Apply, Bar Code Reader, Open*, and *Cancel*.

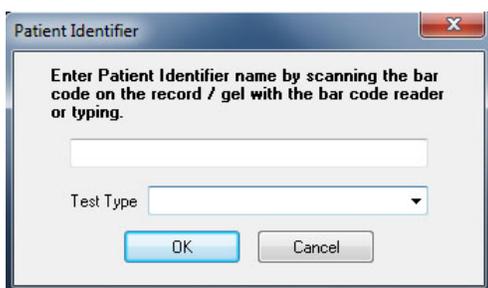
a. *Patient Identifier* - the user has the option to search by the Patient Identifier.

b. *Test Type* – the user has the option to use the drop down list to select from the test type contained in the folder.

c. *Date* - the user has the option to search by time periods.

d. *Apply* – click to apply the search parameters

e. *Bar Code Reader* – clicking this opens the *Patient Identifier box*. Here, the user can enter the specific Gel Identifier number to locate the worklist. Additionally, a test type can be selected from the dropdown menu.



i. *OK* – to save all the changes made and exit, select *OK*.

ii. *Cancel* – to exit without saving any changes made.

f. *Open* – click to open the selected worklist.

g. *Cancel* – click to exit without saving any changes.

14.7.1. Consult scan review

Note: *Attempting to open a scan in the Consult folder while another user has already opened the original worklist can generate an Access Violation exception.*

On the main screen, the most recent scan will be displayed on the left hand side with the other side of the main screen displaying any other scan that has been selected for comparison as the

“baseline scan” (Figure 14-8). All other associated scans are displayed as thumbnails along the left hand side vertically.

Once at least four or more scans are stored, a “slide bar” is available at the top left of the screen for quickly paging through the scans to visually check differences between them.

All patient Information is locked in the Accept folder. To unlock and “edit” any of the scans, the user will have to right click on the scan’s thumbnail and select *Scan, Review*, and then *Edit Scan*. The QuickScan Touch *plus* will prompt the user and ask them, “Are you sure you want to edit?” If Yes is selected, the most recent scan will be removed from the main screen (not from the thumbnails) so the older scan may be edited.

The editing menu has the same features as any other editing menu available in the QuickScan Touch *plus* (see Section 7.4 for detailed instructions on editing scans).

Note: *All patient information may be altered except for the demographic that links the scans, whether it is a patient name or patient ID.*

Once the editing is completed, clicking on any other thumbnail will relock the scan.

There are certain functions listed below that aren’t available such as *gel image, cut, copy*, etc. These functions aren’t available inside the Myeloma Module software folders and are *only* available in the original worklists processed on the QuickScan Touch *plus*. Only the available options will be listed below.

1. *Review* – click to send the scan back to the Review folder.

2. To access thumbnail options, right click on the desired scan.

3. *Worklist*

a. *Worklist Label* - name of the worklist

b. *Worklist Properties* – displays the properties associated with the scan. This includes *Label, Date Created, Template, Location, Test, Gel Identifier,* and *Completed Scans.*

Scan

a. *Review* -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan.

c. *Scan Properties* – contains the following information for the selected scan: *Test, Sample Identifier, Gel Identifier, Sample Number, Scanned, Rescanned, Reviewed, Edited, Reviewer Id, Scan Resolution,* and *Scan Status.* .

Scan

d. *Delete* – click to delete the scan from the CONFER folder.

e. *Review* -

i. *Select Baseline* – select to change the highlighted scan to the baseline scan for the group.

ii. *Edit Scans* – select to edit the scan

f. *Scan Properties* – contains the following information for the selected scan: *Test, Sample Identifier, Gel Identifier, Sample Number, Scanned, Rescanned, Reviewed, Edited,*

Reviewer Id, Scan Resolution, and Scan Status.

Close Menu – select to close the menu.

Note: *Once scans are accepted, PENDING CONSULT will be displayed on the original worklist.*

PENDING CONSULT

14.8. Message Flags

Message flags can be created to mark scans. They are displayed in the comments section of the scan. (Hot key: Ctrl + Alt+ F).

1. To create a message flag, from the *Main Menu*, select *Edit* then *User Setup*.

On the left hand side of the *QuickScan Touch plus Setup* window, select *User Message Flags* (Figure 14-9).

The window displays 10 different empty text boxes, each with a different color as well as *Clear All* and *Defaults* buttons.

To create a User Message Flag, click inside and white text box and type the desired wording.

Clear All – clears all the text from all the fields.

Defaults – fills in the text boxes with “User Message Flag” with a sequential number.

OK – select to accept, save the changes made to the flags, and close the *QuickScan Touch plus Setup* window.

Cancel – select to reject, delete the changes made, and close the *QuickScan Touch plus Setup* window.

Flags may be added to individual scans in an opened worklist by clicking the

message flag icon  at the top of the screen.

14.9. Delete

There are five different delete options for each of the different statuses of a scan: *Original*, *Review*, *Accept*, *Re-Edit*, and *Consult*.

1. From the main menu (Figure 7-1), select *File* and *Delete*. From the displayed options, select the folder from which the scan will be deleted. The Delete Worklist for that folder window will appear. If the selected folder is empty, no window will appear.

2. The user may enter search criteria to find a specific worklist(s) by entering information in *Patient Identifier*, *Test Type*, and *Date*. Use the drop down arrows and highlight or type in the information needed for the search. Click on *Apply* to start the search or *Clear* to clear all parameters.

3. A list of matching worklists will appear. The user may select one or more worklists, or may use the *Select All* button at the bottom of the screen. After selecting the desired worklist(s), click *Delete*. A confirmation prompt will appear prior to deletion. Select *Yes* or *Yes to All* to proceed.

4. A confirmation prompt will appear prior to deletion.

14.10. Editing the Review Template

The Review Template determines the appearance of the worklists in the Myeloma folders. The Review Template may also be edited like a worklist template, but it is *strongly recommended* the Review Template not be altered dramatically. Doing so can cause conflicts with the placement of the worklist components. Refer to Section 6.3 for more detail on the various components of the Template.

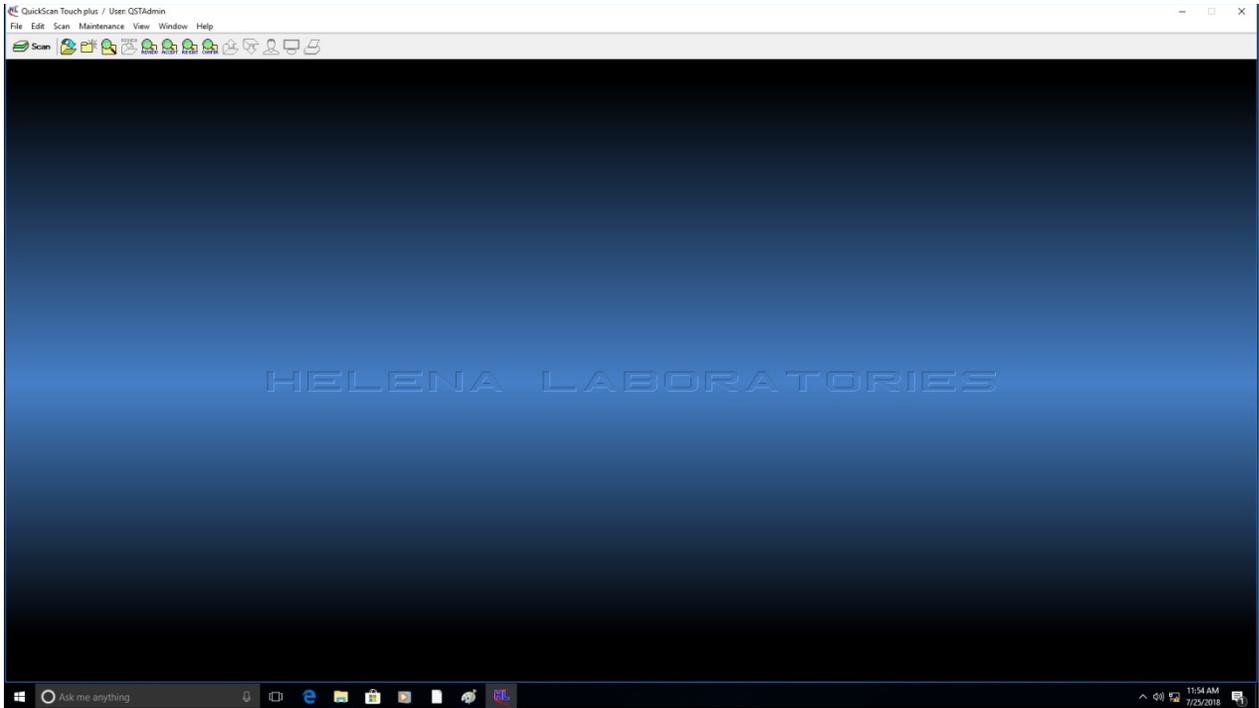


Figure 14-1 Main Menu

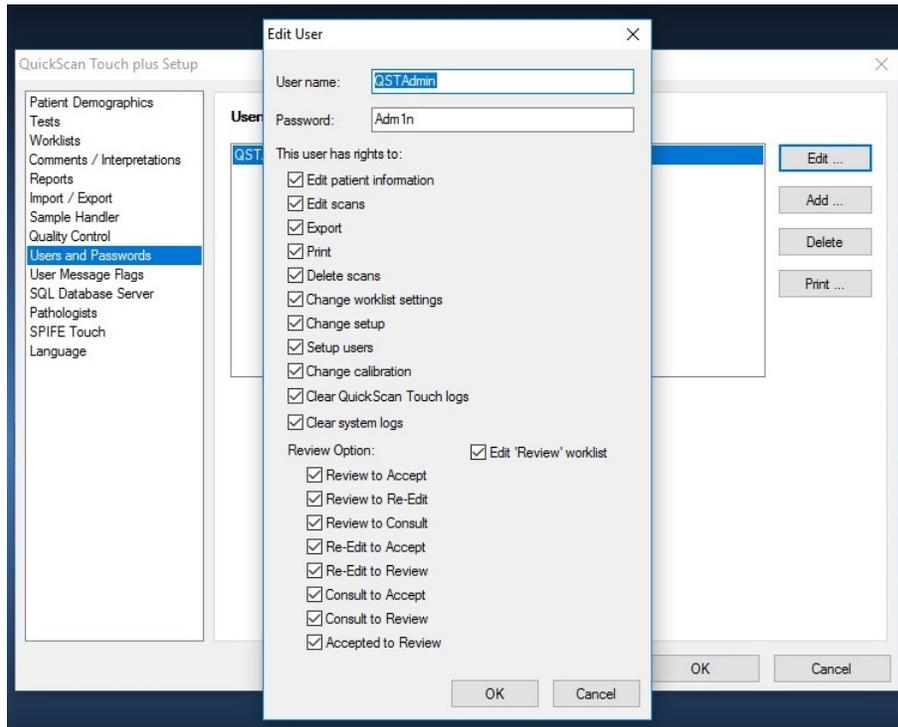


Figure 14-2 Users and Passwords

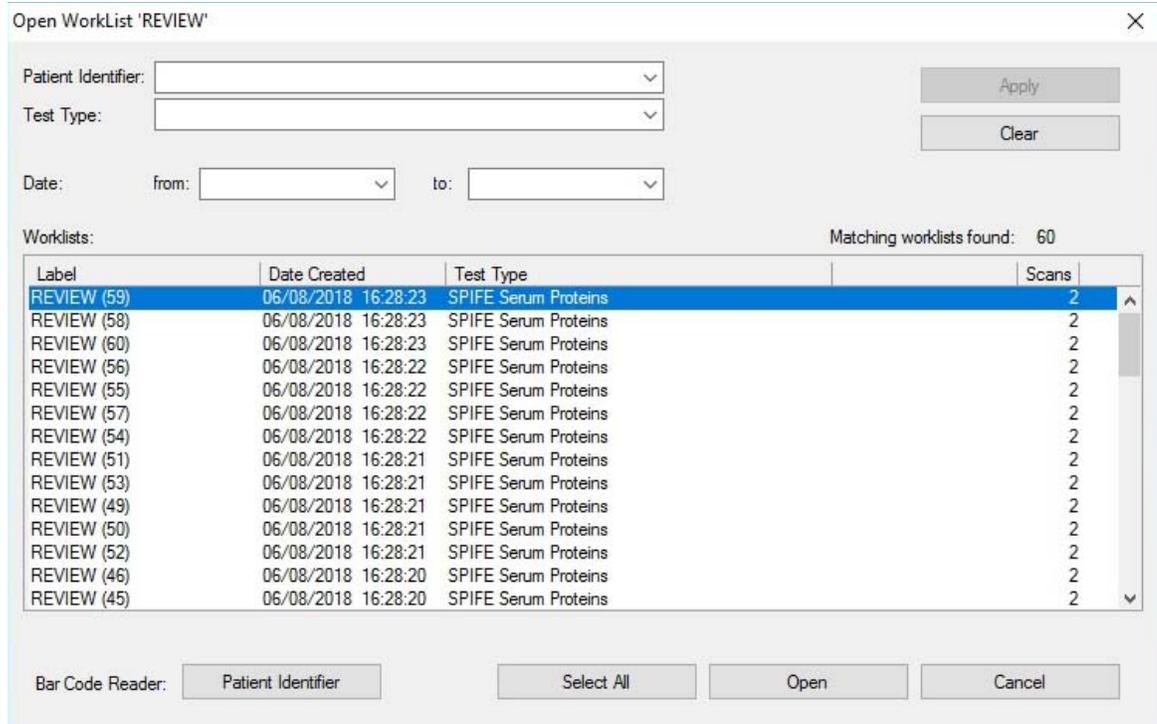


Figure 14-3 Open Worklist in the Review folder

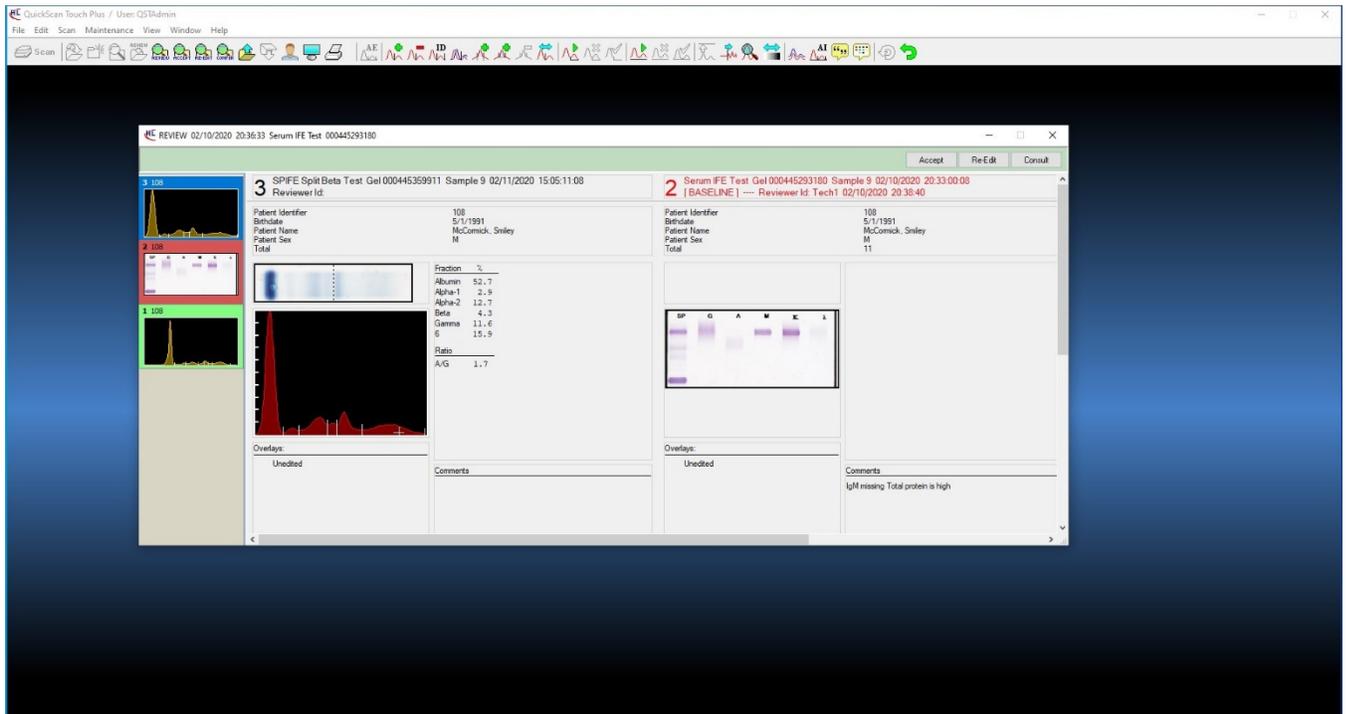


Figure 14-4 Review folder

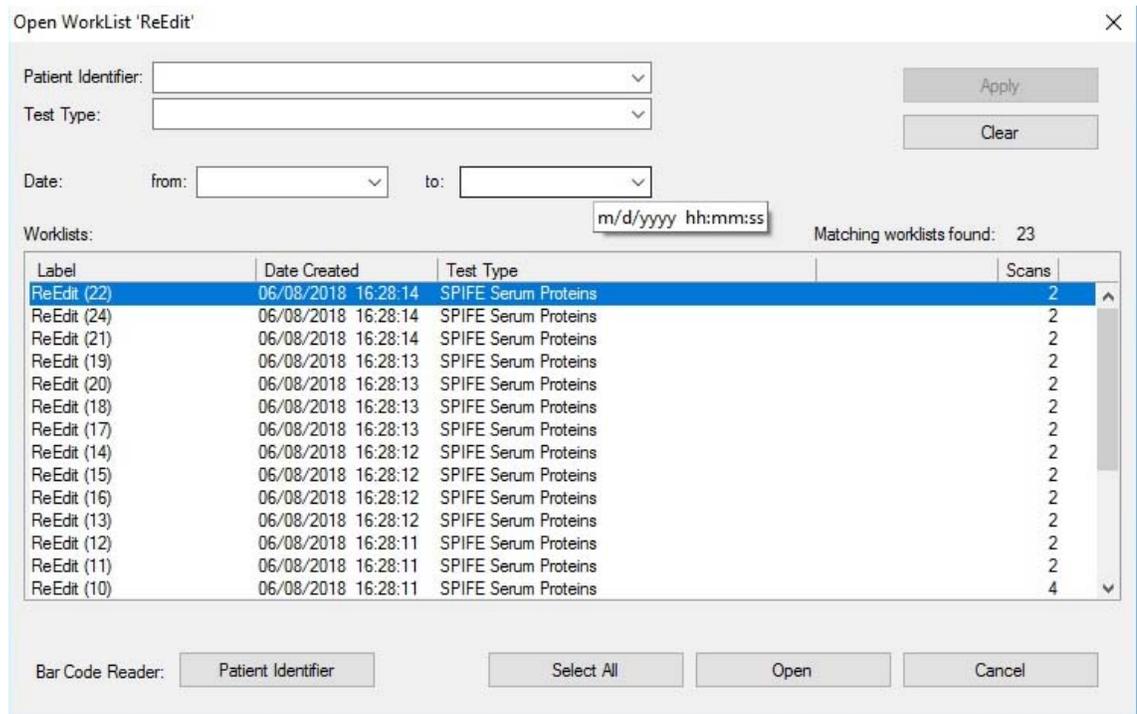


Figure 14-5 Open Worklist in the Re-Edit folder

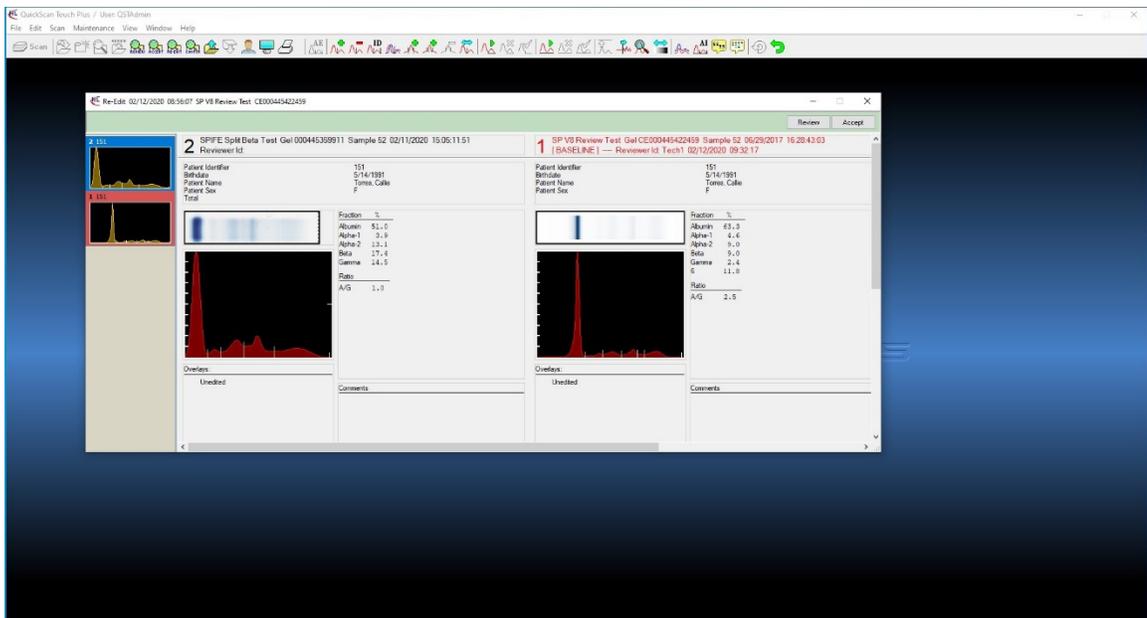


Figure 14-6 Re-Edit folder

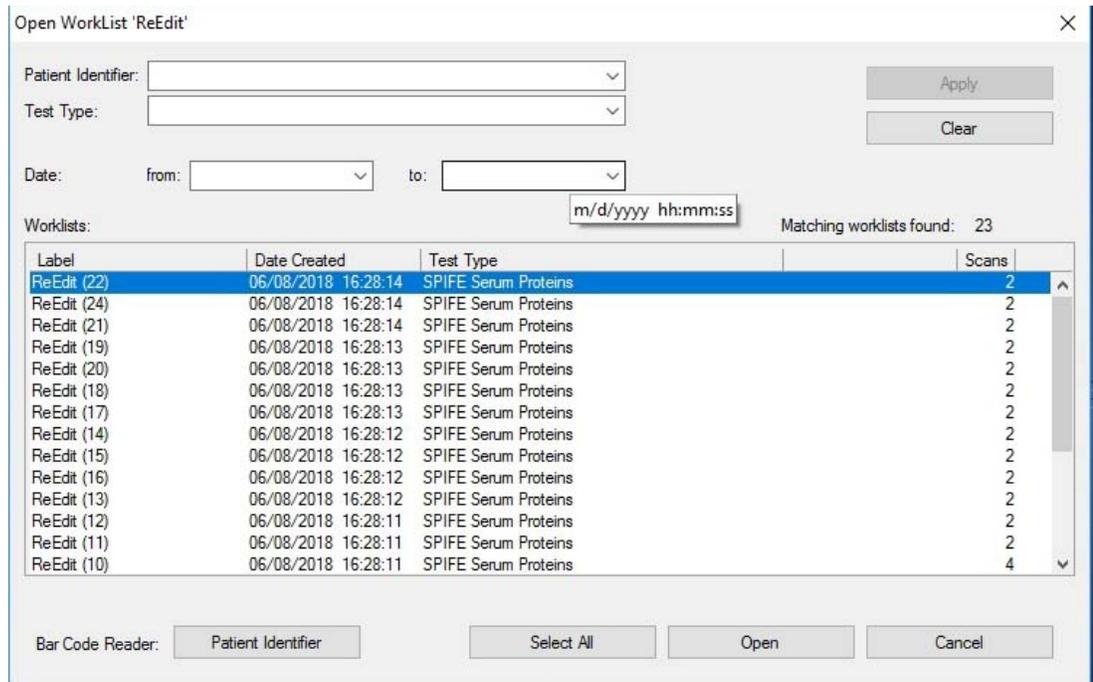


Figure 14-7 Open Worklist in the Accept folder

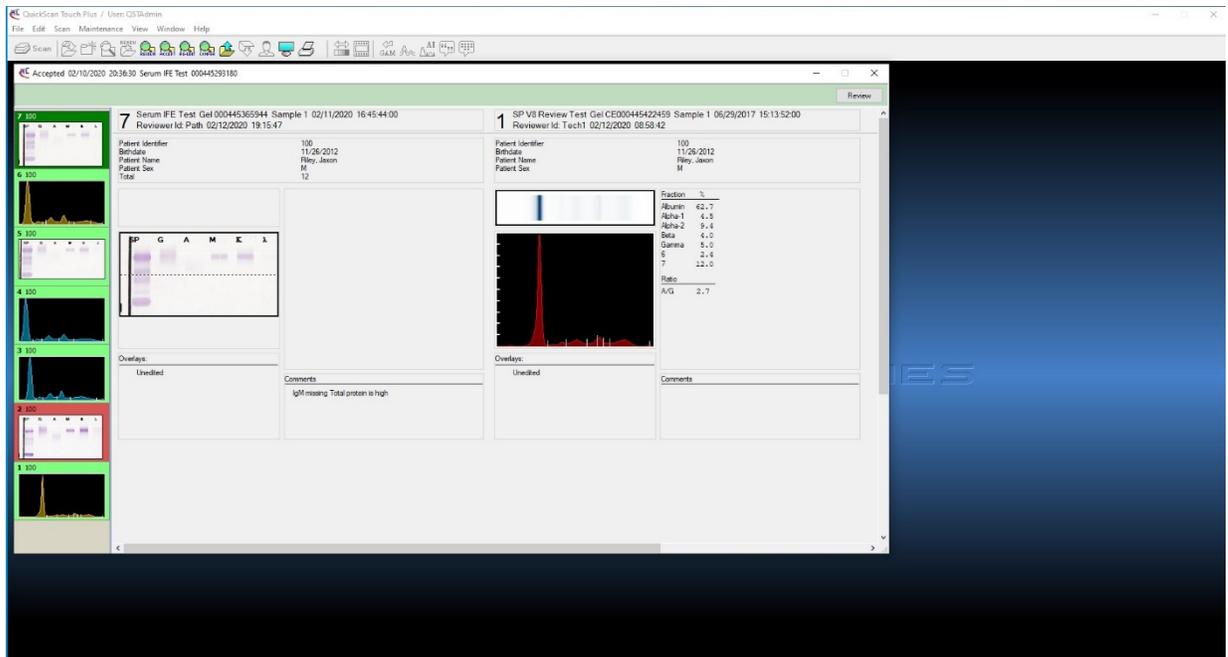


Figure 14-8 Accept folder

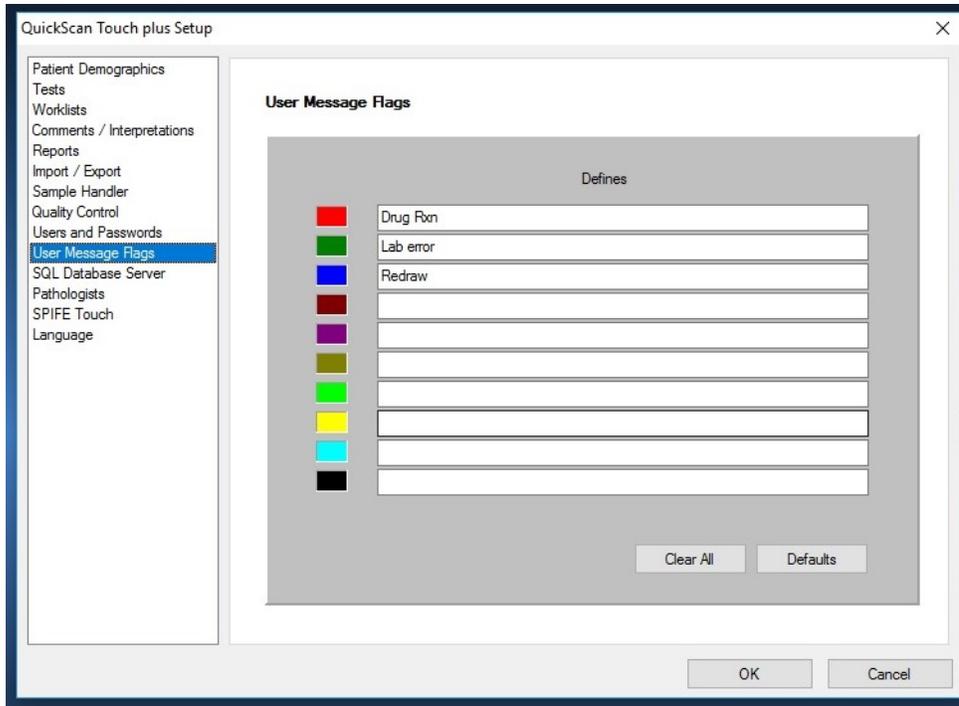


Figure 14-9 Message Flags

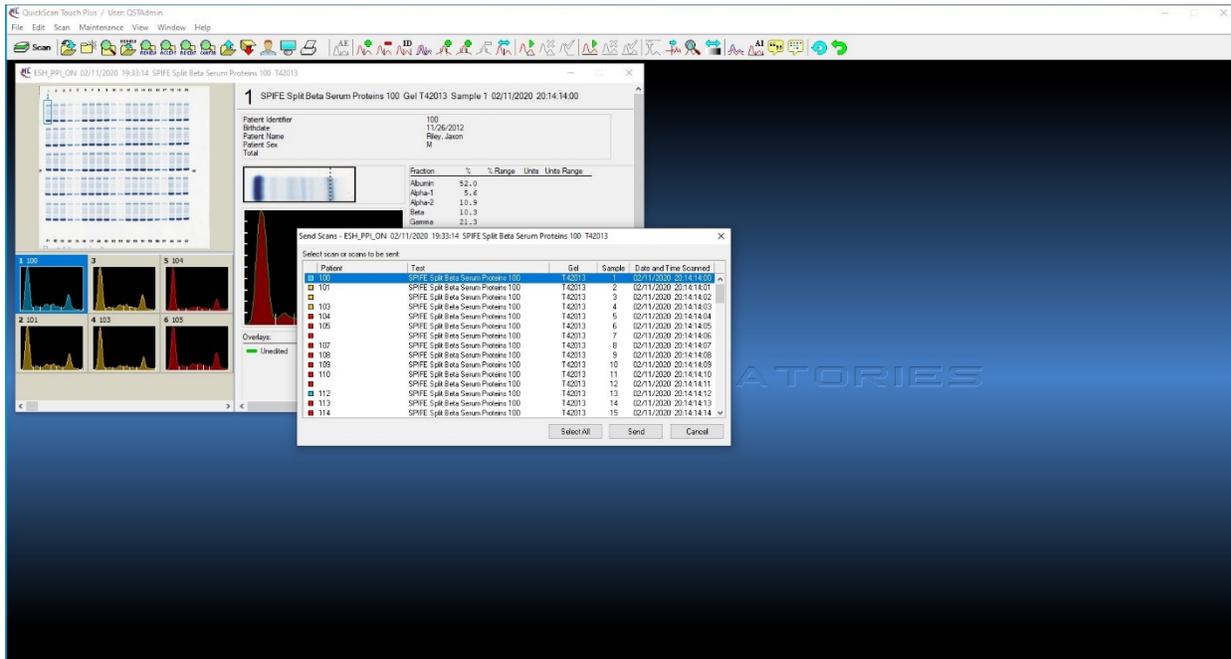


Figure 14-10 Sending Scans to Review

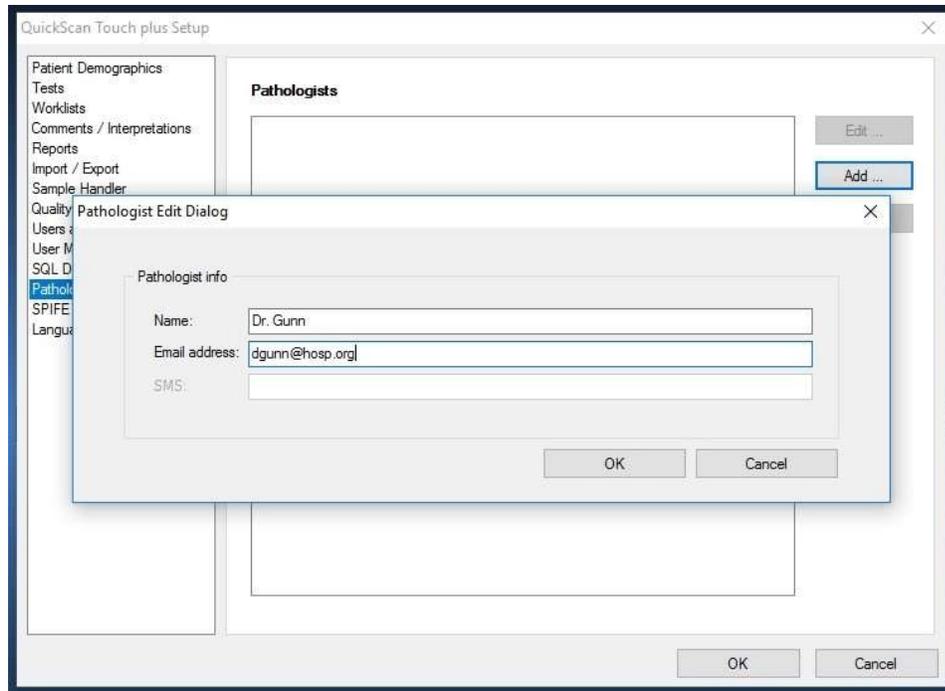


Figure 14-11 Adding a Pathologist

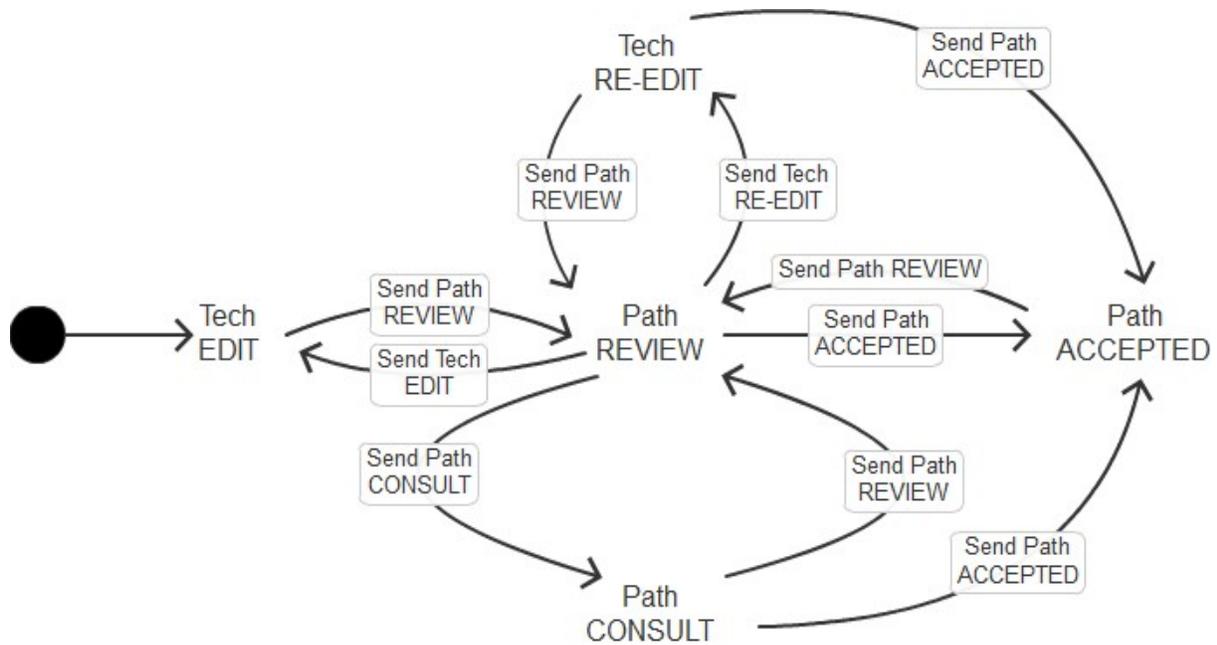


Figure 14-12 Scan Lifecycle

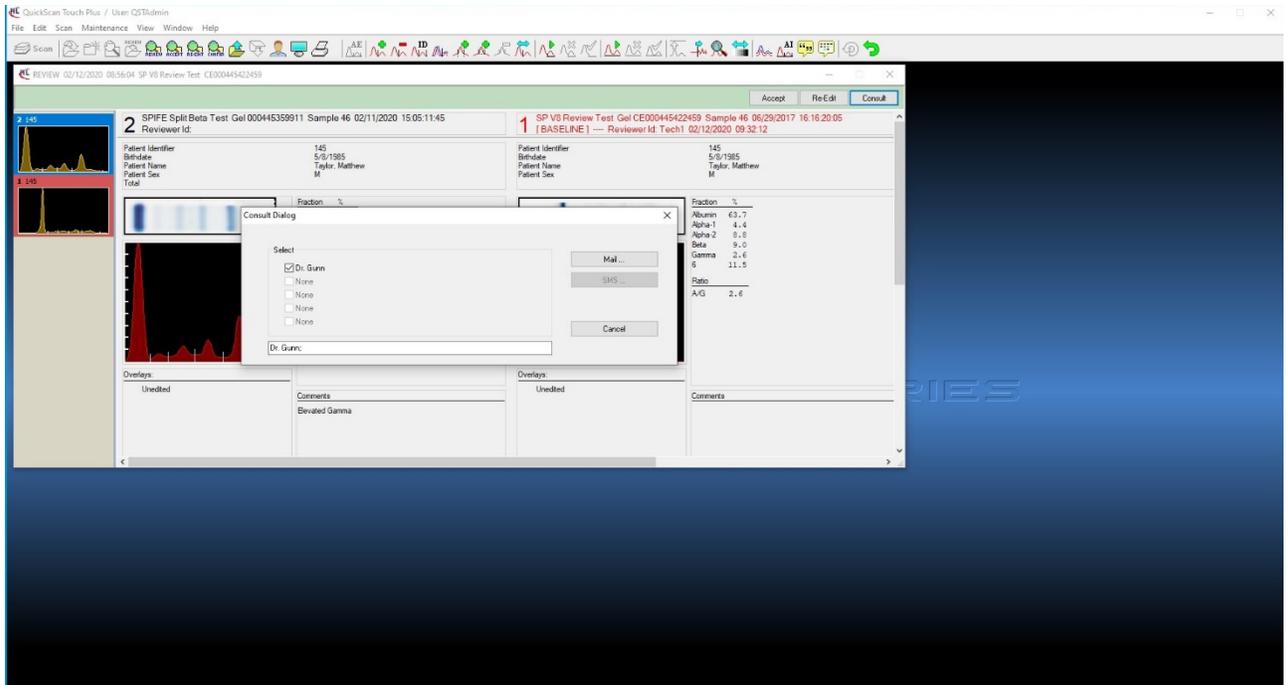


Figure 14-13 Consult Dialog window

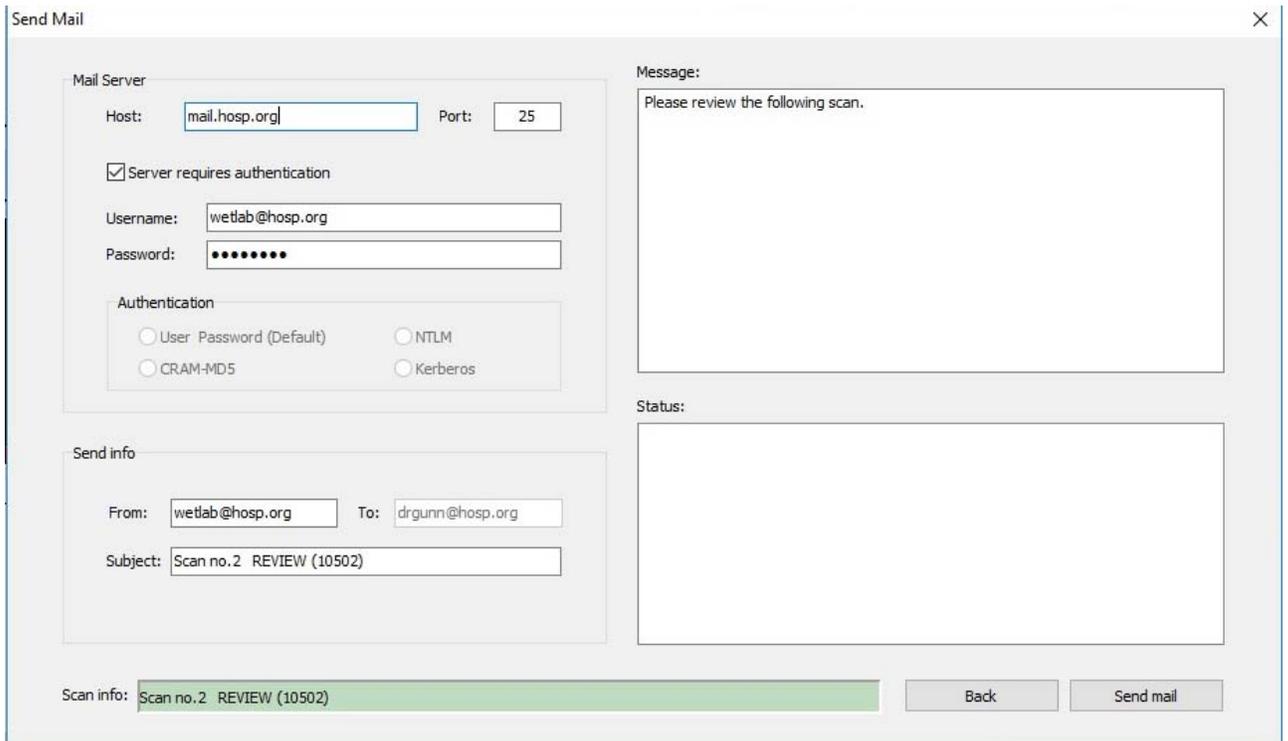


Figure 14-14 Send Mail

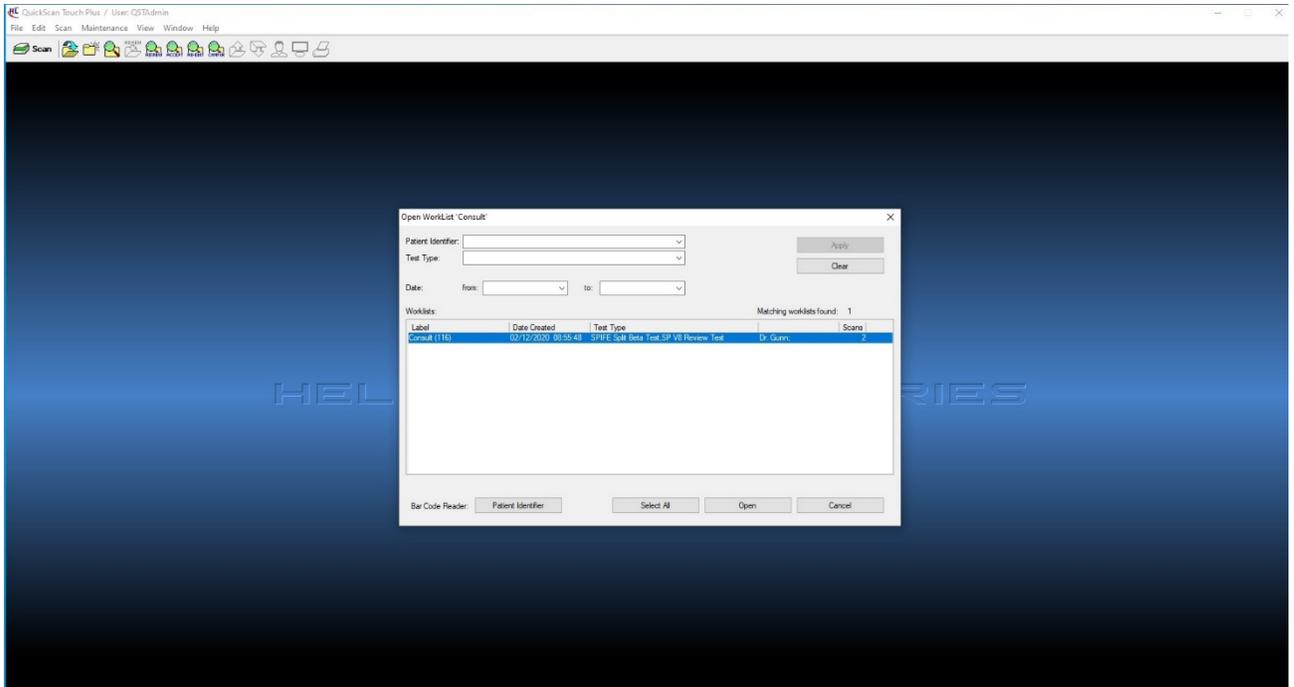


Figure 14-15 Open Worklist in the CONFER folder

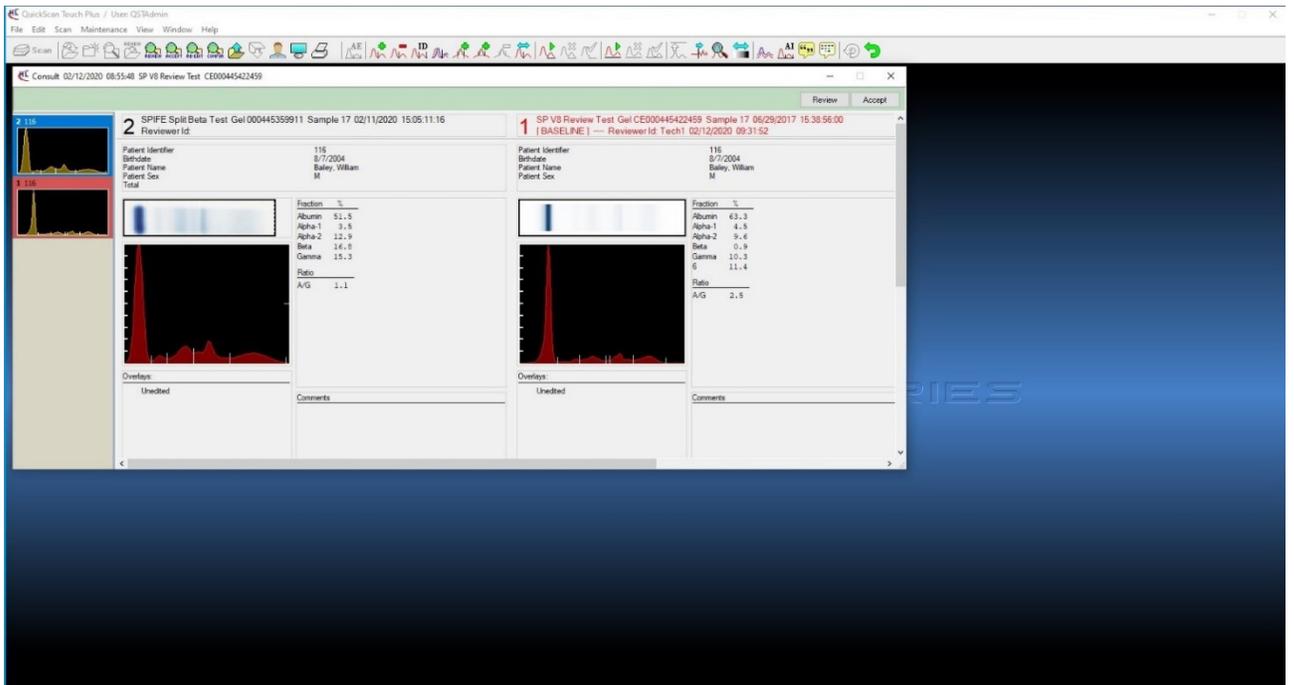


Figure 14-16 CONFER folder

Section 15 - SPIFE Nexus (optional)

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

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

Stored results can be retrieved in seconds and full editing features are provided with the QuickScan Touch *plus* software.

In order for imported samples to be automatically pulled into a worklist, a corresponding test must be created in the Nexus software that is identical to the current QuickScan Touch *plus* test.

Note: *The test name must be the same in both the SPIFE Nexus software as well as the QuickScan Touch software. It is also case-sensitive.*

However, if a corresponding test has not been created, the QuickScan Touch will instead prompt the user to select a test to be used from a dropdown menu. The selected test needs to already have had the scan lines set in User Setup (see Section 6.2.4).

Note: *When the SPIFE Nexus scans a plate, if another worklist or any QuickScan Touch *plus* menu is open, the SPIFE Nexus will prompt the operator to close the open windows.*

Scanning a plate that was not previously processed by the SPIFE Nexus will result in **only** the scan results being imported. Any patient information will have to be **entered** afterwards by the user. See Section 6 of the SPIFE Nexus Operator's Manual for more detailed information on setting up a test.

Note: *The QuickScan Touch *plus* user permissions also define the SPIFE Nexus software permissions. See Sections 6.9 and 14.1 for more detail.*

15.1. Scanning a SPIFE Touch Plate

1. If a traditional QuickScan Touch *plus* system is not available, a SPIFE Touch may be scanned using the SPIFE Nexus.
2. The finished gel should be placed into a SPIFE Nexus cassette.
3. Separate the two magnetic pieces of the cassette. The obround hole of the gel slides over the bottom left pin of the cassette. The round hole of the gel slides over the round pin of the cassette.
4. Snap the two pieces of the cassette together and place it into the scanning slot of the SPIFE Nexus.
5. Click the *Scan* icon.

6. A prompt is displayed, “*To scan using the SPIFE Nexus instrument, ensure the gel plate is loaded in a cassette and placed on the platen. Then press the ‘Start’ button above and press ‘Rescan’. To scan any other type of gel plate, press ‘OK’ to continue. Ensure the plate is loaded in a cassette and placed in the scanner.*”

7. Select *OK*.

8. The QuickScan Touch *plus* prompts the user for a Test Name. Once one has been selected, it will scan the plate and display the results.

15.2. Scanning an NDDC plate

The same NDDC/OD Step Table is used for both SPIFE Nexus and the QuickScan Touch *plus*.

1. To run a QC scan in the SPIFE Nexus, in the QuickScan Touch *plus* software, select Scan, click on *Maintenance*, then QC, and then *Scan*. The message “*Place the QC Plate in the scanner, click ‘OK’ to continue*” is displayed.

2. The NDDC/OD Step Table should be placed into a SPIFE Nexus cassette.

3. Separate the two magnetic pieces of the cassette. The obround hole of the gel slides over the bottom left pin of the cassette. The round hole of the gel slides over the round pin of the cassette.

4. Snap the two pieces of the cassette together and place it into the scanning slot of the SPIFE Nexus.

5. Select *OK* and “Scanning in Progress” is displayed.

6. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup. Out of range values are

indicated by a *plus* or *minus* on the display and report.

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



Figure 15-1 SPIFE Nexus

Section 16 - INDEX

A

Abnormal Control, 8-1
Accept folder, 14-7
Aperture, 7-32
Archive, 7-7
ASTM, 12-1, 12-4, 12-5, 12-6
Auto Edit, 6-5, 7-18, 7-19, 10-4
 Settings, 6-6, 7-19
Auto Interpretation, 6-6, 7-29, 13-3
Auto Scale, 7-30

B

Backup, 7-12
Baseline Correction, 7-22

C

Calibration, 8-1
CE Scan Settings, 13-2
Cholesterol, 6-5, 7-19
Cleaning, 10-1
Comment / Interpretation, 6-24, 7-28
Communication Specifications, 12-1
Computer, 5-2

D

Delete, 7-35
 Fraction Delimiter, 7-19
Delimit Bands, 7-30
Demographics, 6-1, 6-2, 6-5, 6-11, 13-2
Display Options, 7-35
Display Settings, 7-33, 7-35

E

Edit, 6-6, 7-12
 Patients, 7-13
 Scans, 7-23, 7-29
Electrophoresis Sample Handler, 6-25
Exit, 7-12
Export, 7-9, 7-33
 Scans, 7-9

F

File, 7-3, 7-9
Force Lp(a) Fraction, 6-6, 7-19
Forced Fractions, 6-7, 7-33
 Fixed, 6-7, 6-8
 Float, 6-7, 6-8, 7-33
Fraction Detection Sensitivity, 6-7, 7-32
Fractions / Ratios / Ranges, 6-9

G

Gain Mode, 6-7
 Auto, 6-7, 7-32
 Manual, 6-7, 7-32
Graph, 6-16, 6-19, 6-21, 6-22

H

Help and About, 7-37

I

Import, 12-5
Import / Export, 12-5
Importing scans from the V8, 13-4
Installation, 5-1
Inventory, 5-1

K

Keyboard, 5-3

L

Laboratory Information Systems (LIS), 7-15
Levey-Jennings, 6-16, 6-20

M

Maintenance, 10-1
Message Flags, 14-11
Message Options, 6-1
Monitor, 5-3
Mouse, 5-3

N

Neutral Density Densitometer Control
(NDDC), 7-33, 7-34, 7-35, 8-1, 8-2, 15-2

O

Optical Density Step Tablet (OD Step
Tablet), 7-33, 7-34, 8-1, 8-2, 15-2
Overlay, 7-24, 7-35
Overlay Thumbnails, 6-13

P

Parity, 12-1
Patient Information, 7-13
Patient Overlay, 6-21
Preparation, 6-5, 13-2
Print, 7-35, 8-2
Print Scans, 7-7
Print Settings, 6-19, 7-33
Printer, 5-2

Protocol, 12-1

Q

Quality Control, 6-1, 6-2, 6-25
Quality Control (QC), 6-26, 7-33, 7-34, 7-35, 8-1, 8-2, 8-3, 14-1

R

Ranges, 6-14, 6-16
Re-Edit Folder, 14-6
Reference, 7-24, 7-35
Reports, 6-1, 6-2, 6-18
Restore, 7-28
Restricted Band, 6-21, 6-22
Results, 7-35, 7-41, 8-2
Review folder, 14-3

S

Save, 7-33
Scan
 New Gel, 7-30
Scan Identifier, 6-19
Scanner, 5-3
Smooth, 7-30, 7-32
SPIFE Nexus, 15-1
System Requirements, 5-2

T

Tracking Software, 14-1
Troubleshooting, 10-1

U

Unit of Measure, 6-9
Unpacking and Inspection, 5-1
Users and Passwords, 6-1, 6-2

V

V8 interface, 13-1
Verification of Functionality, 5-5
View, 7-35, 7-37, 8-1

W

Warranty, 10-5
Windows, 7-37
worklist template, 6-1, 6-12, 6-13
Worklists, 6-1

Z

Zoom, 7-30

QuickScan Touch *plus*

Catalog Numbers 1640, 1646, 1647

Software Version 2.4.1.0

Operator's Manual

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



**Helena Laboratories, Corp.
1530 Lindbergh Drive
Beaumont, Texas
77707
U.S.A.**