

# QuickScan 2000 WIN Version 2

**Visible Scanning Densitometer** 



**Operator's Manual** 

Catalog Numbers 1660, 1661, 1662, 1663, 1673, 1678, and 1679

# **QuickScan 2000 WIN Version 2 Visible Scanning Densitometer**

**Operator's Manual** 

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### **Section 1 - Instrument Use and Function**

Helena's **QuickScan 2000 WIN** (Figure 1-1) is a visible scanning densitometer used to scan electrophoretic gels, quantitate data, and display and print results. The QuickScan 2000 WIN is intended for in-vitro diagnostic use only, in a laboratory or similar environment.

Visible sample gels are placed in the Quick-Scan 2000 WIN 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. The system could include a CD drive, a Zip drive, a floppy disk drive, internal hard disk, a flatbed scanner, a color monitor, a printer, a mouse, and a keyboard.

Varieties of test types are preprogrammed in the QuickScan 2000 WIN. Presently, these tests are Serum and Urine Proteins using acid blue stain, Serum Proteins using Ponceau S stain, Alkaline Hemoglobins, Alkaline Phosphatase, Cholesterol Profile, CK - Creatine Kinase, LD - Lactic Dehydrogenase, IFE - Immunofixation, L/S - Lecithin/Sphingomyelin and Lipoproteins. Parameters for up to 20 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 2000 WIN System

#### **Section 2 - Principles of Operation**

The QuickScan 2000 WIN 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 2000 WIN 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. 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. 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. Excessive data slows the computer, so periodic archiving of data is recommended.

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

When the results are displayed on the monitor, the user can elect to edit the pattern at that time, or later. If a 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 disk. The user can also "export" data through a serial output port to an external computer and data can be emailed.

QuickScan 2000 WIN 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 or keyboard. 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).

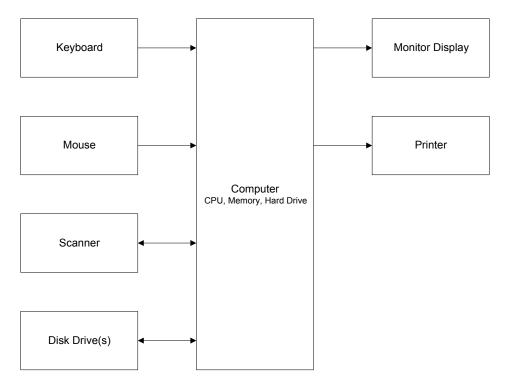


Figure 2-1. Functional Units of the QuickScan 2000 WIN Block Diagram

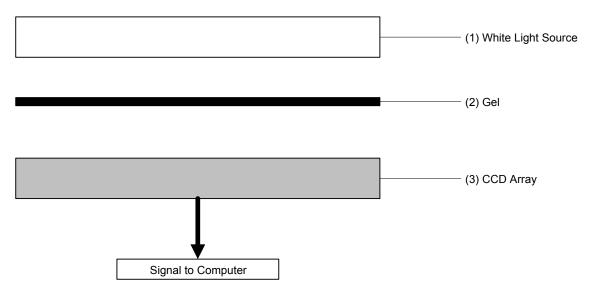


Figure 2-2. Visible Scan Optics

#### 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 diskettes. Refer to the diskette jackets or inserts for appropriate precautions.
- 3.11. The diskette should be removed when not in use, to prevent damage.
- 3.12. Keep magnets away from diskettes or stored information may be lost. Do not place diskettes near a magnetic source or a strong source of electromagnetic interference.
- 3.13. Formatting a diskette, which already contains data, will erase the original data. Make sure that only a blank diskette, or one containing only unwanted data, is inserted into the instrument when formatting.
- 3.14. 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.
- 3.15. Although the QuickScan 2000 WIN is factory programmed for some procedures, you may alter scanning parameters if desired. If scanning problems occur, return to default parameters.
- 3.16. Provide adequate room at the sides and back of the instrument for good air circulation.
- 3.17. 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.
- 2. 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.
- 3. Remove the plastic wrappings from the components. If scissors or a knife are used to cut the plastic or binding tape, take care not to scratch the components.
- 4. 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

### 1660 QuickScan 2000 (110V):

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 Key
- 1 QuickScan 2000 WIN Operator's Manual
- 1 QuickScan 2000 WIN Field Installation Form
- 1 QuickScan 2000 WIN Computer
  - 1 Mouse
  - 1 Keyboard with interface cable
  - 1 Power Cord
- 1 QuickScan 2000 WIN Scanner
  - 1 Transparency Lid
  - 1 USB Cable
  - 1 Power Cord
  - 1 Owner's Guide
- 1 Color Monitor
  - 1 Interface Cable
  - 1 Power Cord
  - 1 Owner's Guide
- 1 Mouse Pad

- 1 Printer Interface Cable
- 1 Printer
  - 1 Printer Toner Cartridge
  - 1 Power Cord
  - 1 Owner's Guide

# 1661 QuickScan 2000, Export Version I:

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 Key
- 1 QuickScan 2000 WIN Operator's Manual
- 1 Mouse Pad
- 1 Printer Interface Cable
- 1 Scanner Bed Template

# 1662 QuickScan 2000, Export Version II:

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 Key
- 1 QuickScan 2000 WIN Operator's Manual
- 1 QuickScan 2000 WIN Field Installation Form
- 1 QuickScan 2000 WIN Scanner
  - 1 Transparency Lid
  - 1 USB Cable
  - 1 Power Cord
  - 1 Owner's Guide
- 1 Mouse Pad
- 1 Printer Interface Cable

# 1663 QuickScan 2000, Export Version III:

- 1 NDDC Plate
- 1 10 Step Optical Density Step Tablet
- 1 Key
- 1 QuickScan 2000 WIN Operator's Manual
- 1 Mouse Pad
- 1 Printer Interface Cable
- 1 Scanner Bed Template

# 1673 QuickScan 2000 Windows and Key

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 Key
- 1 QuickScan 2000 WIN Operator's Manual

# 1679 QuickScan 2000 Software and Computer:

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 QuickScan 2000 WIN Operator's Manual
- 1 QuickScan 2000 WIN Field Installation Form
- 1 QuickScan 2000 WIN Computer

#### 1678 QuickScan 2000 Software:

- 1 QuickScan 2000 WIN Software CD
- 1 Scanner Update CD
- 1 QuickScan 2000 WIN Operator's Manual
- 1 QuickScan 2000 WIN Field Installation Form
- 1 QuickScan 2000 WIN Software Installation Instructions Letter

# **Table 5-2. System Requirements**

Computer - IBM compatible PC, Pentium 300 MHz or higher, minimum 64MB of RAM, SVGA, minimum 2GB hard drive space, Microsoft<sup>®</sup> Windows<sup>®</sup> 2000 or Windows<sup>®</sup> XP operating systems (if network and/or internet connections will be used, the use of the latest security patch and service pack is recommended), modem, CD drive, and optional Zip and/or CD/RW drive.

Scanner - Epson models Expression 800, Expression 1600, Expression 1680, Perfection 4870, Perfection 4990, or Perfection V700. Note that the Perfection 4870 or 4990 model scanners are not intended for use with L/S Fetal Tek plates.

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 as shown in Figure 5-1.
- 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. Route cables as shown in Figure 5-2.

# 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 (Figure 5-1). 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 (Figure 5-2).

#### 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, as shown in Figure 5-1.

- 3. Plug the provided Key into the bottom USB port on the back of the computer as shown in Figure 5-2.
- 4. Plug the printer interface cable into the back of the printer (Figure 5-2).
- 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 5-2.
- 6. Plug the female end of the printer's power cord into the back of the printer (Figure 5-2).
- 7. For information on installing and removing toner or ink cartridges and on loading printer paper, see the printer owner's guide.

#### 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, as shown in Figure 5-1.
- 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 5-2. 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, as shown in Figure 5-1.

- 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 (Figure 5-2).
- 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, as shown in Figure 5-1.
- 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, as shown in Figure 5-1.
- 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. Powering Up and Scanner Parameter Installation

#### 5.4.1. Components

With the components interfaced with the computer, turn each of the power switches on for the scanner, printer and monitor. The QuickScan 2000 WIN software will automatically setup all of the components for operation once the computer power is on. For additional information, refer to each component owner's guide.

#### 5.4.2. Computer

Once the scanner, printer and monitor are powered on, then turn on the computer's power switch. The Windows program opens and displays the QuickScan 2000 WIN icon.

# 5.4.3. Installing Scanner Parameters

- 1. With the computer on and the QuickScan 2000 WIN software closed, insert the scanner parameters CD into the computer's CD drive.
- 2. Once the drive is closed, the installation automatically begins.
- 3. If installation does not automatically begin:
- a. Double click on the *My Computer* folder on the computer desktop.
  - b. Double click on the CD drive.
  - c. Double click on the file SETUP.EXE.
- d. Once the *Welcome* window displays, follow the displayed prompts to complete installation.
- 4. Once installation is complete, the *Setup* window closes.
- 5. Place the CD in the sleeve(s) located at the end of this manual.
- 6. To confirm the parameters for all the compatible scanners are installed, see section 6.9.1 for instructions on accessing the list of scanner parameters installed.

# 5.4.4. Opening/Starting QuickScan 2000 Software

Select the QuickScan 2000 WIN icon. If the main menu (Figure 6-1) 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. 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. QuickScan 2000 WIN 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.

# 5.6. Verification of Functionality

After reading and understanding the Operator's Manual, complete the applicable section of the Field Installation Verification Form QuickScan 2000 WIN as the following steps are performed:

- 1. Record on the verification form the serial numbers of each component recorded in section 5.3.
- 2. Record the software version and serial number. Refer to section 7.7.1 for instructions on obtaining the software information.
- 3. Enter the QC values; see section 6.8.1. Perform a calibration QC; see section 7.4.4. Printout the QC results and include the printout with the Verification Form.
- 4. Return the Verification Form as instructed on the form.

# 5.7. Programming Setup

The QuickScan 2000 WIN software is ready to operate once the desired test(s) and the worklist(s) are setup. Setup instructions are in Section 6 - User Setup.

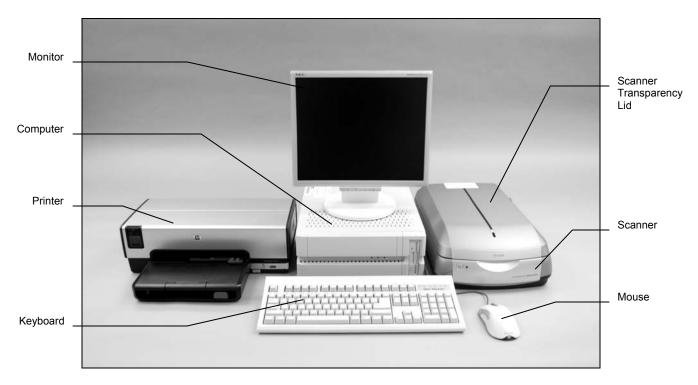


Figure 5-1. Front view of the QuickScan 2000 WIN

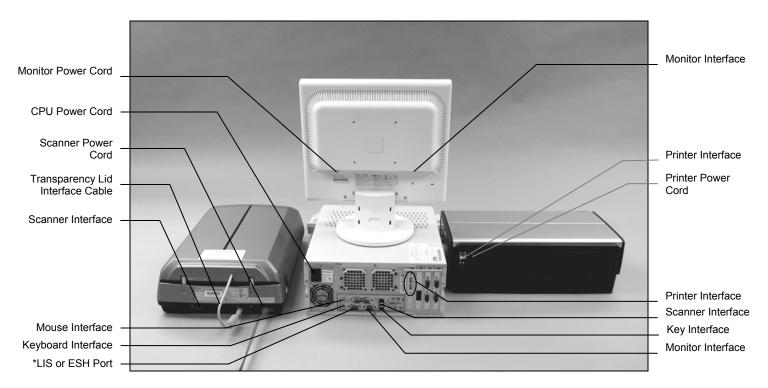


Figure 5-2. Back view of QuickScan 2000 WIN

\*LIS (Laboratory Information System) or ESH (Electrophoresis Sample Handler)

#### Section 6 - User Setup

Turn power on for the scanner, printer and monitor and then for the computer. The Microsoft<sup>®</sup> Windows<sup>®</sup> program opens and displays the QuickScan 2000 WIN icon. Select the icon. **Take care to select the icon only once. Opening multiple copies may corrupt files.** If the main menu (Figure 6-1) appears on the monitor, the system is operating correctly. If an error message appears instead, refer to section 10.2.

User Setup is accessed by selecting Edit on the main menu (Figure 6-1). A drop down menu displays; select User Setup. Note that access to User Setup can be controlled, at the users discretion, with a password, see section 6.12. If the User Setup Password: window displays, enter the password and select OK. The *User Setup* window (Figure 6-2) displays allowing for Setup, Print, Backup, and/or Restore to be used with the following features: Worklists, Demographics, Reports, Tests. Comments / Interpretations, Import / Export, Archive, QC, Scanner, Printer, Date and Time, The instructions on using and Password. Setup and Print (as applicable) are included in the following sections dedicated to each of the features. The instructions for using Backup and Restore are in sections 6.13 and 6.14, respectively. To most easily utilize the Quick-Scan 2000 WIN setup, it is recommended the features be setup in the following order:

Password (if applicable) - section 6.12
Scanner - section 6.9
Archive (if default file location needs to be altered) - section 6.7
Date and Time - section 6.11
Printer - section 6.10
QC - section 6.8
Demographics - section 6.3
Tests - section 6.1
Import / Export (if applicable) - section 6.6
Reports (if the default reports need to be altered and/or new reports created) - section 6.4
Comments / Interpretations (if a database of comments is needed and/or auto interpretation is to be used) - section 6.5

Worklists - section 6.2

### 6.1. Tests

# 6.1.1. Tests Setup

The following instructions can be used to setup tests for the first time, setup user-defined tests, alter parameters of previously setup tests, and return a test to the default parameters. Up to twenty tests may be setup for use.

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Tests*.
- 3. The right side of the window lists the names of any setup tests and the words [New Test]. Note that the [New Test] option is removed once twenty tests are setup. From this window select one of the following:
- a. If a test using default parameters is being setup for the first time, highlight [New Test], select Setup, and see section 6.1.1.1.
- b. If a test has been setup but needs the default parameters reloaded, highlight the desired test, select *Setup*, and see section 6.1.1.1.
- c. If a user-defined test is being setup for the first time, highlight [New Test], select Setup, and see section 6.1.1.2.
- d. If a test has been setup but needs its parameters re-programmed, highlight the desired test, select *Setup*, and see section 6.1.1.2.

# 6.1.1.1. Default Test Parameters

- 1. From the *Setup Test* window (Figure 6-3), select *Default*.
- 2. The Load Default Test Parameters window contains a list of default tests. Highlight the desired test name and select *OK*. If no default is listed for the desired test, select

Cancel and see section 6.1.1.2. for instructions on inputting user-defined test parameters. Duplicate tests may be setup; however, the *Test Name* must be altered for differentiation (section 6.1.1.2.1).

- 3. The Setup Test window now contains the default parameters specific to the test selected. Normally these parameters are used; however, operations can be customized by changing the parameters. Proceed, as needed, to one of the following:
- a. To use the default parameters, no other parameters need to be altered, except when first setting up a test then the gel's scan begin and end positions should be set (section 6.1.1.2.2 step 6). Once the test is setup, select *OK* and the *User Setup Test* window displays the list of currently setup tests (Figure 6-2).
- b. To customize the parameters, see section 6.1.1.2.

# **6.1.1.2. Customizing/Altering Test Parameters**

Note that if scanning problems are encountered after customizing parameters, the customized parameters can be altered or the default parameters can be reloaded. To reload the default parameters, see section 6.1.1.1.

The Setup Test window (Figure 6-3) contains three tabs titled Test Properties, Scan Setup and Reference Ranges. These tabs contain any parameters currently programmed for the selected test. Enter and/or alter parameters on these tabs, as needed according the following:

# 6.1.1.2.1. Test Properties

- 1. With the *Setup Test* window displayed, confirm the *Test Properties* tab is selected (Figure 6-3).
- 2. Test Name may be entered/altered as needed and contain up to twenty characters.

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. Gel Properties

- a. Immunofixation Electrophoresis (IFE) this option should only be selected for IFE imaging to create a copy of the individual patient gel image.
  - b. Rows per Gel may be 1, 2, 3, 4 or 5.
- c. Sample Application per Row may be from 1 to 20.
- d. Gel Stain Type includes Acid Blue, Acid Violet, Amido Black, Fat Red 7B, Ponceau S, Neutral 1, and Neutral 2 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.

#### 4. Results

- a. *Unit of Measure* may be any unit, except %, and can contain up to 10 characters, for example g/L, g/mL, U/L, U/dL.
- b. Total Unit of Measure is only available with Immunofixation Electrophoresis (IFE) selected. It may be any unit for proteins, for example g/L, g/mL, except %, and can contain up to 10 characters.
- c. *Decimal Places* select desired number of decimal places numeric results need to display containing, 0, 1, or 2.

- d. Auto Interpretation enables automatic interpretation of the scan results and requires user-defined interpretations be setup (section 6.5.1).
- e. Report Total LDL (Lp(a) + 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.

#### 5. Labels

- a. Ratio 1 and 2 for each ratio setup (see step 7), enter a label of up to ten characters, for example A/G, L/S, etc.
- b. Restricted Band enter a label, of up to 12 characters (for example M-Spike or M-Protein) for use when a restricted band is marked.
- 6. Demographics The only demographics accessible on this window are those designated as Test type demographics during demographics setup (section 6.3.1). Test demographics are demographics which are not appropriate for use with all tests, for example Total. On this window, assign the label and type for any test specific demographics the test being setup needs. As needed, use the vertical slide bar to view/access all ten demographics and setup the test demographics as follows:
- a. Label enter a label of up to twenty characters.
- b. *Type* select either *Patient* or *Scan*. A Patient demographic is one that will vary with each patient, such as birthdate or sex. A Scan demographic is one that will vary with each scan, such as draw date and time.
- 7. Fractions / Ratios Total plus ten labels are available (nine labels if Immunofixation Electrophoresis (IFE) is selected). Default parameters contain default label titles, some of which contain default ratio assignments. As needed, use the vertical slide bar to view/access the Fractions / Ratios and setup as follows:

- a. *Label* titles may be entered/altered as needed and contain up to twelve characters. To have access to the *Combine Split Beta* feature, one label, other than the *Total* label, must be "Beta".
- b. Ratio 1 and Ratio 2 For each label, indicate the ratio assignments as N, for numerator, D, for denominator, or leave the space blank, to indicate it is neither. Each Label may be part of one, two or no ratios. For example, if the two ratios Total/HDL and LDL/HDL are desired, with HDL and LDL entered as labels, then for:

Total Ratio 1 is N Ratio 2 is blank HDL Ratio 1 is D Ratio 2 is D LDL Ratio 1 is blank Ratio 2 is N

# 6.1.1.2.2. Scan Setup

- 1. Select the *Scan Setup* tab (Figure 6-4) and the top of the window will include the information in a. or b. as follows:
- a. Scan Aperture may be from 1 to 12, see section 9.6 for the measurement that corresponds to each aperture setting.

### b. For IFE tests:

- i. Channel Width (mm) enter the numeric value of the channel width from 1 to 10. This is not related to spacing, it represents the width of the pattern that will be displayed on the window and is analogous to an aperture size in a standard scan. No units need be entered into this field.
- ii. Channels per Sample may be from 1 to 6 for Protein, IqG, etc.
- 2. 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. 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 autoscanned 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.

### 4. 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 as long as it is scanned before the scans to which it will be used. 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 (section 7.3.1) 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 (section 7.3.1) 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.

#### 5. Scan Tasks

- a. Auto Slope Correction select the software to automatically compare the scan baseline beginning and end and, if they are different, the software automatically makes a slope correction so that they are the same. This is a helpful feature for use with hemoglobins. Do not select this feature for use on L/S tests.
- b. Smooth Do not select unless the procedure recommends otherwise; the graph will not be smoothed. Smoothing does affect the results. Increasing the smoothing level

decreases the background noise and lowers smaller fractions. Smoothing could affect small paraprotein spikes. This smoothing is applied when a gel is scanned and cannot be undone through the Edit mode; however, even with this smoothing option is use additional smoothing can be done through the Edit mode.

- i. Smoothing Level is accessible with Smooth selected. Set a value from 1 to 10, with 1 being minimal smoothing and 10 being maximum smoothing.
- c. Combine Split Beta is only available for selection when, for Test Proprieties Fractions / Ratios, a label is titled "Beta" (section 6.1.1.2.1). With this feature selected, if the number of fractions is one greater than the number of fraction labels then the fraction that follows the "Beta" fraction and the "Beta" fraction are combined.
- d. Auto Edit is only available for tests with "Chol" in the test name (section 6.1.1.2.1). 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 looses the label identity so that all fractions labels will be used in order. Example: If a sample contains only HDL and LDL with auto edit selected only those labels will show on the screen and report with the cholesterol protein content divided between them. Insertion of a fraction mark between HDL and LDL will not alter curve interpretation but will add a label and override the original pattern fraction identification resulting in three fractions labeled HDL, Lp(a) and vLDL. The LDL fraction is now misidentified as vLDL. Addition of a second fraction mark results in 4 labels all correctly identified. With Auto Edit in use,

scans should be reviewed and can be edited, as needed, to evaluate the auto edit performance. Any sample without HDL should be restored. On some occasions, the HDL may be very low in value or may move faster causing the software to eliminate it. These patterns must be manually edited at the edit screen.

- i. Auto Edit Settings select and the Auto Edit Settings window displays and allows for selection of the following:
- 1) Cholesterol Auto Edit, Force Lp(a) Fraction selection of this feature provides for automatic marking of an Lp(a) fraction, based on the Reference, if no Lp(a) is found during auto edit. The Lp(a) fraction is marked once HDL, LDL and, as applicable, vLDL are marked. 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. If no vLDL is present, no fraction label will display/print.

Caution: this feature is based on the absolute position of the Lp(a) on the reference. Optimally a reference may be put 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.

- 6. Scan Positions to setup the scan begin and end positions and the sample to sample step over positions, proceed as follows:
  - a. Open the scanner lid.
- b. 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.

- c. Close the lid.
- d. Select *Update Image*. The scanner scans the gel and the message "Scanning in Progress" displays. An image of the gel displays under *Scan Positions*. 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.
- e. 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.
- f. 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.
- g. The QuickScan 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.

# 6.1.1.2.3. Reference Ranges

If no ranges for the test being setup need to be used, select *OK* and see step 8. Note that the default parameters for Cholesterol Profile 60 include Reference Range parameters based on NCEP Guidelines and can be altered when different ranges need to be used.

- 1. Select the *Reference Range* tab (Figure 6-5). Each range is setup in the same manner.
- 2. A B C D E F G H I nine available reference ranges. When using control ranges, the patient reference range is usually placed in range A, because this is the default range.
- 3. Range Type Patient, Normal Control, and 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 Reference Normal or Reference Abnormal as appropriate.
- 4. Sex / Age Requirements only available with Range Type Patient selected.
- a. Sex may contain only one character and is often used as the index for selection of range. For example, use M, for male, F, for female, or P, for Pediatric. 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.
- b. 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.
- 5. Range Limits enter the numeric range limits for the desired range types, percent and/or units. When range limits are in use, it is recommended that for all applicable worklists the Display Settings options Display Percent and Display Percent Range and/or Display Units and Display Units Range be selected even if that information will not be printed or exported.

a. Fraction - includes Total and any labels assigned on the Test Properties tab for Fractions/Ratios (section 6.1.1.2.1). Total can also include a unit of measure in parentheses, if with Immunofixation Electrophoresis (IFE) selected, a unit is entered in Total Unit of Measure.

# b. Percent Range

- i. Low Limit and High Limit enter from 0.0 to 100.0 the percentages in numeric characters; however, do not include the % symbol. Enter the limits for all needed fractions.
- c. *Units Range* if, on the Test Properties tab, for Results, a Unit of Measure is entered (section 6.1.1.2.1), then *Units* is replaced with the entered Unit of Measure.
- i. Low Limit and High Limit enter from 0.0 to 99999.0 the units in numeric characters; however, do not include the unit label. Enter the limits for all needed fractions.

# d. Ratio Range

- i. Labeled 1 and 2 or, if on the Test Properties tab, for Labels, Ratio labels are assigned (section 6.1.1.2.1), those labels replace 1 and/or 2.
- ii. Low Limit and High Limit Enter for each ratio label that is required. The limits can only be numeric characters from 0.0 to 99999.0 and are the reference ranges for the ratio.
- 6. When all the information for the reference range has been entered, another reference range may be entered by returning to step 2 and selecting the next letter.
- 7. When all the needed reference ranges are entered, select *OK* to save the test parameters.
- 8. The *User Setup* window displays and includes all the setup tests (Figure 6-2).

#### 6.1.2. Tests Print Setup

It is recommended that all the currently setup test parameters be printed and safely stored. Use the steps that follow to obtain printouts:

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Tests*.
- 3. To print the parameters of a specific test, highlight the desired test name from the list displayed on the right side of the window and then select *Print*. Otherwise, simply select *Print*.
- 4. The *Print Test Setup* window displays.
- 5. For *Printer Name*, select the appropriate printer from the drop down list.
- 6. For *Print Range*, to print the parameters for the test highlighted when *Print* was selected in step 3, select *Selected Test*. To print the parameters for all the currently setup tests, select *All Tests*.
- 7. For *Copies*, select the quantity needed.
- 8. To exit the window without printing, select *Cancel.*
- 9. To print the desired information, select *Print.*
- 10. The *User Setup* window displays.

#### 6.2. Worklists

The worklist setup defines the operation to be performed and the disposition of the data.

#### 6.2.1. Worklist Setup

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.

- 2. From the *User Setup* window (Figure 6-2), select *Worklists*. The right side of the window allows access to thirty worklists (Figure 6-6). Each worklist *Label* and *Assigned Test* name (or *Retrieve*) will appear on this window once a worklist is setup.
- 3. Highlight the needed worklist and select *Setup*.
- 4. The *Setup Worklist* window (Figure 6-7) displays. Setup the worklists as needed using the following steps:

#### 6.2.1.1. Label

- 1. If the selected worklist is not currently in use (*Inactive* is selected for *Activity*, see section 6.2.1.2), the *Label* field is inaccessible.
- 2. The default worklist label is *Worklist* plus the worklist number, for example *Worklist 14*.
- 3. With the *Label* field accessible, the label title can be customized and contain up to twenty characters, for example Retrieve and Edit, Retrieve and Delete, SPE-A, SPE-B, and Fast Hgb.

# 6.2.1.2. Activity

- 1. Inactive when selected, prevents access to the worklist through the main menu. Inactive worklists do not appear on the list of available worklists making worklist selection easier.
- 2. Scan select to designate a worklist for use to scan gels. Once selected, the following options are accessible:
- a. *Test* from the drop down list choose one of the tests listed. The list consists of all the currently setup tests (section 6.1.1).
- b. Sequence determines the order in which the patterns on the gel are scanned. Once a Test is selected, the sequence is automatically entered based on the total number of samples the selected test is setup to run. The sequence can be altered on a

- scan by scan basis (section 7.4.3) and/or can be altered on this screen for use with the worklist. To designate the sequence, enter the sample position numbers needed, up to 32 characters, separating the numbers with a comma and/or designating a set of numbers with a hyphen. It is required that when using Reference Overlay and/or Float or Fixed Fractions, that the reference be scanned first. An example of this feature's usefulness is when the laboratory protocol is to place the reference in a position other than the first position. In that situation, say for example the reference is always in sample position 10 on a 60 sample gel, then the sequence set for the worklist would be 10, 1-9, 11-60.
- 3. Retrieve select to designate a worklist for use to retrieve saved scans. A maximum of 1,000,000 can be retrieved per retrieve worklist. Note that scans retrieved using a Retrieve Worklist are handled as the Retrieve Worklist in used is setup (section 6.2.1.3) and not as the Scan Worklist used when the samples were first scanned and saved. Once selected the following option is accessible:
- a. Source the default source location is automatically selected. To select a different Source, select ... (to Browse). The Retrieve Source window displays.
- i. *Drive* use the drop down list to select the source for file retrieval. The content of the drop down list is determined by the drives installed on the system.
- ii. *Folders* open the appropriate folder within the selected drive for file retrieval.
- iii. *OK* select to exit to the *Setup Worklist* window and save selections made.
- iv. Cancel select to exit to the Setup Worklist window without changing the retrieval source.

# 6.2.1.3. Tasks (Scan Tasks or Retrieve Tasks)

With *Inactive* selected, none of the tasks are available for selection. With *Scan* or *Retrieve* selected, the window allows access to the following tasks, as indicated:

#### 6.2.1.3.1. Edit

Edit - available for selection with the Activity set to Scan or Retrieve. Select Edit for the instrument to automatically display the scans in the Edit mode immediately after scanning. If Edit is not selected, the Edit mode can be accessed at operator request; however, it is not recommended that Print and/or Export be selected without selecting Edit. For a scan worklist, an appropriate reason not to select Edit is if the laboratory practice will be to scan and save samples for retrieval and editing later. And for a retrieve Worklist, an appropriate reason not to select Edit is if the purpose of the retrieval is to transfer the data to another location or to delete old data.

# 6.2.1.3.2. Display Settings

Display Settings - select and the Display Settings window (Figure 6-8) displays. Use this window to customize the appearance of the window displayed once scanning or retrieving is complete and to customize the automatic actions in the Edit mode. These settings can be temporarily altered for a single use, if needed (section 7.5.1).

- 1. *Preview* choose *No*, to view scans one at a time, or choose *6*, *9*, *15*, *20*, *30*, *60*, or *100* to view the selected quantity of scans at once. The selection applies to viewing scans when not in Edit mode.
- 2. *Edit* is not available for a scan worklist with an IFE test selected. Select one of the following:
- a. All select to have all the scans accessible in the Edit mode.

- b. *Pathological* select to have only the scans that fall outside of the reference range, accessible in the Edit mode.
- 3. Overlay is not available for a scan worklist with an IFE test selected. All overlay function choices made here may be overridden later once in the edit mode. Select as needed:
- a. *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. Reference select to have the reference pattern, shown in blue, overlaid on the sample pattern. If selected, a sample will need to be labeled Reference for each gel (section 7.3.1) and will need to be scanned prior to any sample for which it will be the overlay. This feature is a useful tool to aid in marking fractions on a sample that is not well delineated.
- c. Patient 1 select to have a patient's scan, shown in pink, overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- d. *Patient 2* select to have a second patient's scan, shown in yellow, overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- 4. Results select as needed:
  - a. Display Percent
- b. *Display Units -* require that a total demographic exist.
- c. Display 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.
- d. *Display IFE Units* allows entering external totals for immunoglobulins from nephelometry or some other total method. This is the only option available with an IFE test selected.

- 5. 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
- 6. *OK* select to save the selections and exit the window.
- 7. Cancel select to exit the window without saving the selections.

#### 6.2.1.3.3. Print

Print - available for selection with the Activity set to Scan or Retrieve. With Print selected, reports print automatically. Whether or not Print is selected, reports can be printed at operator request. Most operators prefer that reports not print automatically but at their request so selection of Print is not recommended.

# 6.2.1.3.4. Print Settings

*Print Settings* - select and the *Print Settings* window (Figure 6-9) displays. The settings selected on this window are used whether printing occurs automatically, *Print* is selected (section 6.2.1.3.3), or at operator request (section 7.2.4).

# 6.2.1.3.4.1. Printer

- 1. *Name* from the drop down list select the appropriate printer.
- 2. Where is automatically entered based on the *Printer Name* selected.

# 6.2.1.3.4.2. Report

- 1. Label from the drop down list select one of the reports. The list consists of all the currently setup reports (section 6.4.1).
- 2. *Type -* is automatically entered based on the *Report Label* selected.
- 3. *Number of Copies* select from one to one hundred copies printed at once.
- 4. Demographics accessible with all but Levey-Jennings Report Types. Select one of the following:
- a. *Print Key Only* select to have only the demographic classified as *Key* printed.
- b. *Print All* select to have all the demographics printed.
- 5. Overlay accessible only with Standard Report Types and is not available for scan worklists with an IFE test selected. 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. *Unedited* select to have the unedited pattern overlaid on the edited pattern.
- b. Reference select to have the reference pattern overlaid on the sample pattern. If selected, a sample will need to be labeled Reference for each gel scanned (section 7.3.1).
- c. Patient 1 select to have a patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- d. *Patient 2* select to have a second patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- e. *Print Legend* is only available when at least one *Overlay* is selected. Select to include a legend identifying the overlays.
- 6. Levey-Jennings Graph accessible only with a Levey-Jennings Report Type selected. 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.
- 7. Results accessible with all but Levey-Jennings Report Types. 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* requires that a total demographic exist.
- c. *Print 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.
- d. *Print IFE Units* allows printing immunological totals as part of the IFE report.
- 8. Ranges accessible with all but Levey-Jennings Report Types. 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
- 9. *OK* select to save the selections and exit the window.
- 10. *Cancel* select to exit the window without saving the selections

#### 6.2.1.3.5. Export

Export - available for selection with the Activity set to Scan or Retrieve. With Export selected, scans are automatically exported. Whether or not Export is selected, scans can be exported at operator request. Most operators prefer that not to export automatically but at their request so selection of Export is not recommended.

# 6.2.1.3.6. Export Settings

Export Settings - select and the Export Settings window (Figure 6-10) displays. Use this window to customize the export parameters used whether scans are exported automatically or at operator request.

- 1. Destination select one of the following:
  - a. Host Computer
- b. *Export File* if selected then the following option is accessible:
- i. File Name enter a file name of up to 20 characters including the file extension. The file extension for an Excel file, for example, is ".xls".
  - c. E-mail
- 2. *Demographics* select one of the following:
  - a. Export All
  - b. Export Key Only
  - c. Don't Export
- 3. *Graphics* is only accessible when *Host Computer* is selected and is not accessible for a scan worklist with an IFE test selected). Select as needed:
  - a. Export Graph
- 4. Comments is only accessible when Host Computer is selected. The last option is only available for a scan worklist with an IFE test selected. Select as needed:
  - a. Export Comments
  - b. Export Auto Interpretation
  - c. Export IFE Interpretation

- 5. Results is not accessible when E-Mail is selected. The last option is only available for a scan worklist with an IFE test selected. Select as needed:
  - a. Export Percent
- b. *Export Units* require 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.
- d. Export IFE Units is the display of a fluid in which quantities of immunoglobulins may be entered.
- 6. Ranges is only accessible when Host Computer is selected. The options accessible depend on selections made in Results and/or selections made within Ranges. Select as needed:
  - a. Export Percent Range
  - b. Export Units Range
  - c. Export Ratio Range
  - d. Export IFE Range
  - e. Flag Percent Out
  - f. Flag Units Out
  - g. Flag Ratio Out
  - h. Flag IFE Out
- 7. *OK* select to save the selections and exit the window
- 8. Cancel select to exit the window without saving the selections.

### 6.2.1.3.7. Save

Save - available for selection with the Activity set to Scan or Retrieve. The default save destination is automatically selected. With Save selected, scans are automatically saved. Whether or not Save is selected, scans can be saved at operator request.

- 1. Destination the default save destination can only be altered with the Activity set to Retrieve. To select a different Destination, select ... (to Browse) and the Save Destination window displays.
- a. *Drive* use the drop down list to select the drive for the save destination. The content of the drop down list is determined by the drives installed on the system.
- b. *Folders* open the appropriate folder within the selected drive for the save destination.
- c. *OK* select to exit to the *Setup Worklist* window and save selections made.
- d. Cancel select to exit to the Setup Worklist window without changing the save destination.

#### 6.2.1.3.8. Delete

Delete - available for selection with the Activity set to Retrieve. To select Delete with the Retrieve Source and the Save Destination the same, Save cannot be selected. To select both Delete and Save, the Retrieve Source and the Save Destination must be different. With Delete selected, files that match the file retrieval parameters are automatically deleted.

#### 6.2.1.3.9. OK

*OK* - Once the worklist is setup, select *OK* to save selections. The *User Setup* window displays and lists the setup worklists (Figure 6-6).

#### 6.2.2. Worklist Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Worklists*.
- 3. To print the parameters of a specific worklist, highlight the desired worklist name from

the list displayed on the right side of the window and then select *Print*. Otherwise, simply select *Print*.

- 4. The *Print Worklist Setup* window displays.
- 5. For *Printer Name*, select the appropriate printer from the drop down list.
- 6. For *Print Range*, to print the parameters for the worklist highlighted when *Print* was selected in step 3, select *Selected Worklist*. To print the parameters for all the currently setup worklists, select *All Worklists*.
- 7. For *Copies*, select the quantity needed.
- 8. To exit the window without printing, select *Cancel*.
- 9. To print the desired information, select *Print*.
- 10. The *User Setup* window displays.

## 6.3. Demographics

## 6.3.1. Demographics Setup

- 1. When deciding on the setup for the demographics, keep the following in mind:
- a. Once the demographics are setup and data has been collected, it is not recommended that the demographics setup be altered because prior data will be incorrectly retrieved. The only exception to this would be if the need arose to use an unused label as a Test specific label. This change could be made without causing data retrieval problems.
- b. Determine the demographics all the displays and reports, regardless of test, will need to contain. Those demographic labels common to all tests are setup in *Demographics Setup*.
- c. Consider the demographics that will vary based on the type of test. For example, *Total* is a demographic often best designated as a test specific demographic. Determine the quantity of test specific demographics

- each test run needs. Use the quantity from the test requiring the greatest number of test specific demographics as the quantity of *Test* demographics setup in *Demographics Setup*.
- d. Establish the order preferred when entering and viewing the demographics. The position assigned to a demographic label, one through ten, will be the order the demographic appears, except:
- i. If the *Key* label is not assigned to position one, then the *Key* label will appear in position one when entering patient demographic information (section 7.3.1); however, on other windows and on printouts, the demographics will appear in the order assigned.
- ii. If an assigned *Test* specific position has no demographic label assigned within test setup (section 6.1.1), the remaining demographics are moved up in position when viewed and printed.
- 2. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 3. From the *User Setup* window displayed (Figure 6-2), select *Demographics* and *Setup*.
- 4. The *Setup Demographics* window (Figure 6-11) displays and allows for up to ten demographic labels.
- 5. Label enter those labels that apply to all tests. Each label may contain up to twenty characters. Some common labels include: Patient Name, Patient ID, Birthdate, Sex, Draw Date, Draw Time, and Tech ID.
- 6. *Type* designate each label entered as one of the following four demographic types:
- a. *Patient* a demographic that varies with each patient, such as birthdate or sex.
- b. Scan a demographic that varies with each scan, such as draw date and time.

- c. Test reserves a position for and allows for retrieval of any test specific demographics assigned in test setup (section 6.1.1.2.1). Labels designated Test type must remain blank within the label field on this window. When setup during test setup, these Test type labels are assigned a Label and a Type of either Patient or Scan, as needed.
- d. Key any Patient demographic that is unique to each patient, such as the patient's name or a patient ID number. One, and only one, demographic must be indicated as Key.
- 7. When the demographic information is setup, select *OK* and the *User Setup* window displays.

## 6.3.2. Demographic Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Demographics* and then select *Print*.
- 3. The *Print Demographic Labels* window displays.
- 4. For *Printer Name*, select the appropriate printer from the drop down list.
- 5. For *Copies*, select the quantity needed.
- 6. To exit the window without printing, select *Cancel*.
- 7. To print the desired information, select *Print*.
- 8. The *User Setup* window displays.

## 6.4. Reports

#### 6.4.1. Reports Setup

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.

- 2. From the *User Setup* window (Figure 6-2), select *Reports*. The right side of the *User Setup* (Figure 6-12) window allows access to the six preprogrammed reports, any other currently setup reports, and *[New Report]*. Once a report is setup, the report *Label* and *Type* (*Standard*, *List*, *Statistics*, or *Levey-Jennings*) will appear on this window. See Section 13 Reports for printouts of the preprogrammed reports setup.
- 3. From this window select one of the following:
- a. To create a new report, highlight [New Report] and select Setup. Proceed to step 4.
- b. To create a new report using one of the six preprogrammed reports or any previously setup report as a template, highlight the needed report and select *Setup*. The *Setup Report* window (Figure 6-13) displays. In order not to permanently alter the report being used as a template, enter the desired *Label* (section 6.4.1.1) and select *Ok.* When the *Save and Exit* prompt displays, select *Yes.* The *User Setup* window with *Reports* selected displays and included on the right side is the *Label* and *Type* of the new report. Highlight the report's label and select *Setup*. Proceed to step 4.
- c. To alter a previously setup report, highlight the needed report and select *Setup*. Proceed to step 4.
- d. To rename a currently setup report, highlight the needed report and select *Setup*. The *Setup Report* window (Figure 6-13) displays. Enter the new *Label* (section 6.4.1.1) and select *Ok*. When the *Save and Exit* prompt displays, select *No*. When the *Alert* prompt displays, select *Yes*. The *User Setup* window with *Reports* selected displays and included on the right side is the renamed report *Label* in place of the previous report label.
- 4. The Setup Report window (Figure 6-13) displays and contains any currently setup components.

#### 6.4.1.1. Label

Label - enter the desired label containing up to twenty characters. This label is only used for quick identification of the report and is not printed on the report; however, all reports must have a label.

## 6.4.1.2. Type

Type - determines which features are accessible for inclusion on the report and as applicable which features are automatically included on the report. Note that with this version of software, report types List and Statistics cannot be printed with the Auto Edit feature in use. Select one of the four types:

- 1. Standard report is useful for reports including graphs, results, comments, and auto interpretations. With Standard selected, the screen appears as shown in Figure 6-13.
- 2. *List* report is used for a patient profile, a list of control results, a list of data generated on a given day, ect. It automatically contains a *Table* component, which can include up to two patient demographics; however, the report cannot include a graph. With *List* selected, the screen appears as shown in Figure 6-14.
- 3. Statistics report is used for monitoring controls. It automatically contains a Table component, similar to a list report; however, includes, on the bottom of the report, the statistics mean, standard deviation and coefficient of variation of each fraction listed. With Statistics selected, the screen appears as shown in Figure 6-14.
- 4. Levey-Jennings report automatically includes a Levey-Jennings Graph component. With Levey-Jennings selected, the screen appears as shown in Figure 6-15.

### 6.4.1.3. Scans per Report

Scans per Report - is only accessible with Standard Type report selected and can be

set to include from 1 to 100 scans on a multiscan, single page report.

#### 6.4.1.4. Size and Orientation

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

#### 6.4.1.5. Add

Add - select to access the drop down menu of components available to add to the report. Note that only with Standard Type reports are all the components available. For the other three report types, only the last three components are available.

Select the component needed and the drop down menu closes.

Click on the location, within the report, the selected component needs to appear. The component appears. Note that for *Text* and *Picture*, once a location is selected, a window appears requiring additional selections prior to the component appearing (steps 11 and 12).

Note that each component appears with a gray frame around it. On the top left of the frame is a solid gray box and on the bottom right is a box outlined in gray. The top left box is used to move the component location around the report. The bottom right box is used to resize the width and/or height of the component.

The components available through *Add* are as follows:

- 1. Scan Identifier includes the name of the test, the sample number, and the date and time the sample was scanned.
- 2. Patient Information includes the demographic labels and applicable, entered patient information. Note that the Print Settings selected determine if all or only the Key demographic print (section 6.2.1.3 or 7.2.4.1).
- 3. Sample Image
- 4. Graph
- 5. Overlay Legend select to include a legend of any overlays included. The legend only prints if the Print Settings specify (section 6.2.1.3 or 7.2.4.1).
- 6. IFE Overlay
- a. *IFE Scan Identifier* includes the name of the test, the sample number, and the date and time the sample was scanned.
  - b. IFE Image
  - c. IFE Results
  - d. IFE Interpretation
  - e. IFE Auto Interpretation
- 7. Scan Status
- 8. Results
- 9. Comments
- 10. Auto Interpretation
- 11. Text once the position for this component is selected, the Add Text Component 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.
- 12. Picture once the position for this component is selected, the Open Picture window displays. On this window, use the Drive drop down list to select the need drive location. Then use Folders to open the needed folder from the selected drive. Next, use Files to select the needed picture from the selected

drive and folder (only bitmap files may be used). With a picture file selected, a preview displays in *Picture*. Once the needed picture is indicated, select *Ok* and the picture component is placed on the report. The picture can be resized to enlarge or reduce the picture; however, when resizing keep the width and height changes the same proportions so not to distort the picture.

13. *Line* - use to place a line in a desired location. With a *Line* added, see section 6.4.1.6.17 to modify the line's orientation, color, width, and/or style.

## 6.4.1.6. Modify

Modify - only accessible with a component selected. With the component needing modifying selected, select *Modify*. Depending on the component selected, the following window displays. For information on moving and/or resizing a component, see section 6.4.1.5.

# 6.4.1.6.1. Modify Scan Identifier Component

- 1. Association
- a. Scan can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- 2. Element Scan Identity
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.
- 4. Font Settings
- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.2. Modify Patient Information Component

#### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.

## 2. Options

- a. *Number of Columns* select the number of columns, 1 or 2, the patient information prints.
- 3. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Label
  - b. Demographic
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 5. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.3. Modify Sample Image Component

### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.

#### 2. Options

a. *Frame* - select to place a frame around the component.

# 6.4.1.6.4. Modify Graph Component

#### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.

## 2. Options

- a. *Frame* select to place a frame around the component.
- b. *Print Vertical Scale* select to include a scale positioned vertically on the component.
- c. *Fill Graph* select to fill the area under the curve with a user selected color.
- 3. *Element* highlight the *Element* needing modification and then use *Color* to modify.
  - a. Graph Outline
  - b. Graph Fill
  - c. Reference Overlay
  - d. Patient Overlay 1
  - e. Patient Overlay 2
  - f. Fraction Delimiter
  - g. Restricted Band Delimiter
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

# 6.4.1.6.5. Modify Overlay Legend Component

#### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.

#### 2. Options

- a. *Frame* select to place a frame around the component.
- 3. Element Label
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 5. Font Setting

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.6. Modify IFE Overlay: Scan Identifier Component

#### 1. Association

- a. Scan can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- b. Patient Overlay select 1 or 2 to specify which patient overlay is associated with this component.
- 2. Element Scan Identity
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 4. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.7. Modify IFE Overlay: Image Component

#### 1. Association

- a. Scan can only be altered for multi-scan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- b. Patient Overlay select 1 or 2 to specify which patient overlay is associated with this component.

# 6.4.1.6.8. Modify IFE Overlay: Results Component

#### 1. Association

- a. Scan if Scans Per Report is greater than 1 then Scan is accessible. With Scan accessible, select the applicable number. The numbers available is based on the Scans Per Report setting.
- b. Patient Overlay select 1 or 2 to specify which patient overlay is associated with this component.
- 2. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Label
  - c. Results In
  - d. Results Out
  - e. Range
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

#### 4. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.9. Modify IFE Overlay: Interpretation Component

#### 1. Association

- a. Scan can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- b. Patient Overlay select 1 or 2 to specify which patient overlay is associated with this component.

## 2. Options

- a. *Print Header* select to include the header "Interpretation" with the component.
- 3. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Interpretation
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 5. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.10. Modify IFE Overlay: Auto Interpretation Component

### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting. b. Patient Overlay - select 1 or 2 to specify which patient overlay is associated with this component.

## 2. Options

- a. *Print Header -* select to include the header "Interpretation" with the component.
- 3. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Interpretation
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 5. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.11. Modify Scan Status Component

### 1. Association

- a. Scan can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- 2. *Elements* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Label
  - b. Status Ok
  - c. Status Fault
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

#### 4. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.12. Modify Results Component

#### 1. Association

- a. Scan can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.
- 2. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Label
  - c. Results In
  - d. Results Out
  - e. Range
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 4. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.13. Modify Comments Component

#### 1. Association

a. *Scan* - can only be altered for multi-scan reports when *Scans Per Report* is greater than 1. Select the applicable number to designate the component. The available numbers are based on the *Scans Per Report* setting.

#### 2. Options

- a. *Print Header -* select to include the header "Comment" with the component.
- 3. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Comment
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

## 5. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.14. Modify Auto Interpretation Component

#### 1. Association

a. Scan - can only be altered for multiscan reports when Scans Per Report is greater than 1. Select the applicable number to designate the component. The available numbers are based on the Scans Per Report setting.

#### 2. Options

- a. *Print Header -* select to include "Interpretation" with the component.
- 3. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Interpretation
- 4. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.
- 5. Font Settings

- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.15. Modify Text Component

Use this window to add/alter text, indicate text to use with *Cut*, *Copy*, and/or *Paste*, alter the font, font size, color, and/or style of text, and/or alter the text alignment, as needed.

# 6.4.1.6.16. Modify Picture Component

- 1. Options
- a. *Frame* select to place a frame around the component.

# 6.4.1.6.17. Modify Line Component

- 1. Orientation select Horizontal or Vertical.
- 2. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.
- 3. Width select the desired width.
- 4. Style select the desired style.

## 6.4.1.6.18. Modify Levey-Jennings Graph Component

This component is automatically included with a Levey-Jennings report type.

- 1. Options note that for both Options, depending on the Size and Orientation selected and/or the size of the component, excessive Data Points and/or Vertical Divisions may make the Levey-Jennings Graph difficult to read.
- a. Number of Data Points select from 0 to 999.
- b. Vertical Divisions select from 2 to 20 in increments of two.

- 2. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Label
  - b. Results In
  - c. Results Out
- 3. Color either use the drop down list to select the desired color or enter numeric values in the *Red*, *Green* and/or *Blue* fields to create the desired color.
- 4. Font Settings
- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.6.19. Modify Table Component

This component is automatically included with Statistics and List report types.

- 1. Options
- a. *Demographic 1* From the drop down list, select either [N/A] or one of the demographics listed. The demographic selected is then included on the report. The list is based on demographics setup (section 6.3.1)
- b. *Demographic 2* From the drop down list, select either [N/A] or one of the demographics listed. The demographic selected is then included on the report. The list is based on demographics setup (section 6.3.1)
- 2. *Element* highlight the *Element* needing modification and then use *Color* and/or *Font Settings* to modify.
  - a. Header
  - b. Demographic
  - c. Results In
  - d. Results Out
- 3. Color either use the drop down list to select the desired color or enter numeric

values in the *Red*, *Green* and/or *Blue* fields to create the desired color.

- 4. Font Settings
- a. Size use the drop down list to select the desired font size.
- b. Effects select Bold, Italic and/or Underline as needed.

# 6.4.1.7. Cut, Copy, Paste, Undo, Print, and Clear

- 1. *Cut* with the component to be removed selected, select *Cut*.
- 2. Copy with the component to be copied selected, select Copy.
- 3. Paste once Cut or Copy is performed, indicate the desired location and select Paste. The component is placed as indicated.
- 4. *Delete* with the component to be permanently removed selected, select *Delete*.
- 5. Undo select to undo the last command.
- 6. *Print* select to print the current parameters of the displayed report.
- 7. Clear to remove all the components added to the displayed report, select Clear. The Alert "The current report is about to be cleared. Do you wish to continue? Yes No" displays. Select Yes to clear the report.

#### 6.4.1.8. OK and Cancel

- 1. *OK* When the report is setup as needed, select *Ok*. The *User Setup* window displays and lists the currently setup reports.
- 2. Cancel select to exit the window without saving any changes.

## 6.4.2. Reports Print Setup

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.

- 2. From the *User Setup* window (Figure 6-2), select *Reports*.
- 3. To print the parameters of a specific report, highlight the desired report name from the list displayed on the right side of the window and then select *Print*. Otherwise, simply select *Print*.
- 4. The Print Report Setup window displays.
- 5. For *Printer Name*, select the appropriate printer from the drop down list.
- 6. For *Print Range*, to print the parameters for the report highlighted when *Print* was selected in step 3, select *Selected Report*. To print the parameters for all the currently setup reports, select *All Reports*.
- 7. For *Copies*, select the quantity needed.
- 8. To exit the window without printing, select *Cancel.*
- 9. To print the desired information, select *Print*.
- 10. The User Setup window displays.

## 6.5. Comment / Interpretation

### 6.5.1. Comment / Interpretation Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Comment / Interpretation*. The right side of the *User Setup* window (Figure 6-16) allows access to the currently setup comments and interpretations plus [New Comment / Interpretation].
- 3. Highlight the needed comment/ interpretation or [New Comment / Interpretation] and select Setup. The Setup Comment / Interpretation window (Figure 6-17) displays.
- 4. *Label* enter or edit the label for the comment. The label can contain up to twenty 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.

- 5. Comment / Interpretation use the keyboard to enter or edit the comment which can contain up to 770 characters with each line a maximum of 75 characters. Font size and type can affect the number of characters.
- 6. Auto Interpretation select to designate the comment as an Auto Interpretation. Note that the test the auto interpretation is to be use for must be setup to use reference ranges of units and/or percent and have auto interpretation selected for use (section 6.1.1). With Auto Interpretation selected the following is accessible:
- a. *Test* using the drop down list, select a test. The contents of the list are based on the currently setup tests (section 6.1.1).
  - b. Select one of the following:
    - i. Interpret Based on Percent
    - ii. Interpret Based on Units
- c. 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:
  - i. Not a Factor
- ii. Absent (< 0.0) A enter the desired absent threshold of from 0.0 to 99.9.
  - iii. Decreased -
  - iv. Normal to Decreased N -
  - v. Normal N
  - vi. Normal to Elevated N+
  - vii. Elevated +

- d. Pattern Characteristic either enter the same label used for Restricted Bands in the test setup or make a selection from the drop down list. The source of the list is the currently entered Pattern Characteristic from all the setup comment/interpretations.
- 7. Once the comment is entered as desired, select *OK* and the *User Setup* window displays and includes the list of comment/interpretations.

# 6.5.2. Comment / Interpretation Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Comment / Interpretation*.
- 3. To print the parameters of a specific comment/interpretation, highlight the desired comment/interpretation from the list displayed on the right side of the window and then select *Print*. Otherwise, simply select *Print*.
- 4. The *Print Comments / Interpretations* window displays.
- 5. For *Printer Name*, select the appropriate printer from the drop down list.
- 6. For *Print Range*, to print the parameters for the comment/interpretation highlighted when *Print* was selected in step 3, select *Selected Comment / Interpretation*. To print the parameters for all the currently setup comment/interpretations, select *All Comments / Interpretations*.
- 7. For *Copies*, select the quantity needed.
- 8. To exit the window without printing, select *Cancel.*
- 9. To print the desired information, select *Print*.
- 10. The *User Setup* window displays.

## 6.6. Import / Export

## 6.6.1. Import / Export Setup

For additional information, see Section 12 - Communication Specifications.

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Import / Export*. The right side of the window allows access to the three *Source / Destination* options: *Host Computer*, *Export File* and *E-mail* (Figure 6-18). See the following for information on each option:

## 6.6.1.1. Host Computer

- 1. Select *Host Computer* and *Setup.* The *Setup Host Computer Interface* window (Figure 6-19) displays. Setup as the following describes:
- 2. Maintain compatibility with QuickScan version 1 select if the interface used will be the same as the interface used with version 1. Note that selection does not allow for retrieval of data generated in version 1. Only for the use of the same interface.
- 3. *Import* If the *Import* and *Export Port* numbers are the same, then all of the other parameters are automatically the same. If the *Port* numbers are different, then the parameters for each can also be different.

#### a. Port - select 1 or 2

- i. Settings select and the Port Communications Settings window (Figure 6-20) displays. Select the needed parameters for the following:
  - 1) Protocol
  - 2) Baud Rate
  - 3) Data Bits
  - 4) Stop Bits

- 5) Parity
- 6) Diagnostics
- a) Create trace log may be used as a troubleshooting tool. When enabled, a record is kept of all communication between the QuickScan 2000 WIN and the LIS. The log is accessible from the main menu; see section 7.5.3.
- b) Test Port use with a loop back plug to test the communications port.
- 7) *Default* select to return the settings to the pre-programmed settings.
- 8) Cancel select to exit the window without changing the settings.
- 9) *Ok* select to save the settings and exit the window.
- b. Positive Sample Identification select if the Helena Electrophoresis Sample Handler will be used for Positive Sample Identification. Both the QuickScan 2000 and the Electrophoresis Sample Handler parameters must match.
- 4. Export If the Import and Export Port numbers are the same, then all of the other parameters are automatically the same. If the Port numbers are different, then the parameters for each can also be different.

#### a. Port - 1 or 2

- i. Settings select and the Port Communications Settings window (Figure 6-20) displays. Select the needed parameters for the following:
  - 1) Protocol
  - 2) Baud Rate
  - 3) Data Bits
  - 4) Stop Bits
  - 5) Parity
  - 6) Diagnostics

- a) Create trace log may be used as a troubleshooting tool. When enabled, a record is kept of all communication between the QuickScan 2000 WIN and the LIS. The log is accessible from the main menu; see section 7.5.3.
- b) Test Port use with a loop back to test the communications port.
- 7) *Default* select to return the settings to the pre-programmed settings.
- 8) Cancel select to exit the window without changing the settings.
- 9) Ok select to save the settings and exit the window.
- 5. Exporter Information enter the Name, Address, and Telephone Number of the exporter (each may contain up to 40 characters).
- 6. ASTM Setup If the Import and/or Export settings are set to ASTM, then setup the following:
- i. *Demographic* the demographic labels setup in *Demographics* (section 6.3.1) are listed on the left under *Demographic*.
- ii. ASTM Field Number: Field Name assign the applicable ASTM demographic to the ASTM fields as needed. Each of the ASTM fields contains a drop down list of ASTM demographics. Note that if the demographic Total is used or a Test specific demographic is Total, then the ASTM Field must be assigned 15: Special Field 1 or 16: Special Field 2, as applicable.
- 7. With the parameters set, select *OK* to save selections and return to the *User Setup* window.

## 6.6.1.2. Export File

1. Select *Export File* and *Setup*. The *Setup Export File* window (Figure 6-21) displays. Setup as the following describes:

- 2. File Name enter the desired file name containing up to twenty characters. This file is automatically created. Data saved to this file overwrites any previously saved data.
- 3. Destination select ... (to Browse) and the Save Destination window displays:
- a. *Drive* use the drop down list to select the desired drive destination. The content of the drop down list is determined by the drives installed on the system.
- b. *Folders* open the appropriate folder within the selected drive.
- 4. With the destination selected, select *Ok* to save the selections and return to the *Setup Export File* window.
- 5. Delimiter select Tab, Semicolon, Comma, Space, or Other. If Other is selected, enter the desired delimiter. Comma is the recommended delimiter.
- 6. Format Include column labels select to have the column labels exported. Use of this feature is recommended if data is to be downloaded to a spreadsheet.
- 7. With the parameters set, select *OK* to save selections and return to the *User Setup* window.

#### 6.6.1.3. E-mail

- 1. Select *E-mail* and *Setup*. The *Setup E-mail* window (Figure 6-22) displays and contains two tabs: *General* and *Servers*. Setup as the following describes:
- 2. General
- a. Connection Dial-up or Local Area Network
  - b. User Information
- i. *Name* enter the name (up to 128 characters) to appear on the e-mail.
- ii. *E-Mail Address* enter the e-mail address (up to 128 characters).

- iii. Reply Address if desired, enter a different e-mail address for receipt of replies to e-mails (up to 128 characters).
- c. Server Information refer to the Internet server in use for this information.
- i. *Incoming Mail (POP3)* specify the server for incoming messages (up to 128 characters).
- ii. Outgoing Mail (SMTP) specify the server for outgoing messages (up to 128 characters).

#### 3. Servers

## a. Incoming Mail Server

- i. Account Name is usually the same as the part of the e-mail address preceding the "at", @, symbol (up to 128 characters).
- ii. Password is assigned by the Internet server in use. When entered each character will appear as an asterisk for security (up to 128 characters).

## b. Outgoing Mail Server

- i. My server requires authentication select if required to log on the outgoing mail server. When selected the following is accessible:
- 1) Log on Information select one of the following:
- a) Use same settings as my incoming mail server
- b) Log on using when selected enter the following information:
- i) Account Name is usually the same as the part of the e-mail address preceding the "at", @, symbol (up to 128 characters).
- ii) Password is assigned by the Internet server in use. When entered each character will appear as an asterisk for security (up to 128 characters).

- c. Server Port Numbers these two fields contain defaults for the port numbers to connect to for incoming/outgoing mail servers. They may be altered as needed.
  - i. *Incoming Mail (POP3)* (up to 5 digits)
  - ii. Outgoing Mail (SMTP) (up to 5 digits)
- iii. Use Defaults select to reenter the default settings
- 4. With the parameters selected, select *OK* to save selections and return to the *User Setup* window.

## 6.6.2. Import / Export Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Import / Export*.
- 3. To print the parameters of a specific import/export option, highlight the desired import/export from the list displayed on the right side of the window and then select *Print*. Otherwise, simply select *Print*.
- 4. The *Print Import / Export Setup* window displays.
- 5. For *Printer Name*, select the appropriate printer from the drop down list.
- 6. For *Print Range*, to print the parameters of the option highlighted when *Print* was selected in step 3, select *Selected Import / Export Setup*. To print the parameters for all the options, select *All Import / Export Setup*.
- 7. For *Copies*, select the quantity needed.
- 8. To exit the window without printing, select *Cancel.*
- 9. To print the desired information, select *Print*.
- 10. The User Setup window displays.

#### 6.7. Archive

## 6.7.1. Archive Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Archive* and *Setup*.
- 3. The *Setup Archive* window (Figure 6-23) displays and shows the *Archive File Path*.
- 4. To alter the file path, select ... (to Browse) and the *Setup Archive* window displays. Caution: The archive file path determines where the main archive is located. Drives that are removable media (Floppy, ZIP, or CD) should not be used for the main archive. Changing the file path after scans have been saved should be avoided as unpredictable operation could occur.
- a. *Drive* use the drop down list to select the desired drive destination. The content of the drop down list is determined by the drives installed on the system.
- b. *Folders* open the appropriate folder within the selected drive.
- c. With the destination selected, select *Ok* to save the selections and return to the *Setup Archive File* window.
- 5. To return the file path to the default, select *Default.*
- 6. With the file path set as needed, select *OK* to save selections and return to the *User Setup* window.

### 6.7.2. Archive Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Archive* and then select *Print*.

- 3. The *Print Archive Location* window displays.
- 4. For *Printer Name*, select the appropriate printer from the drop down list.
- 5. For Copies, select the quantity needed.
- 6. To exit the window without printing, select *Cancel.*
- 7. To print the desired information, select *Print*.
- 8. The *User Setup* window displays.

### 6.8. QC

## 6.8.1. QC Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *QC* and *Setup*.
- 3. The *Setup QC* window displays (Figure 6-24). Setup as the following describes:

#### 4. Scan Positions

- a. Place the Optical Density Step Tablet (OD Step Tablet) on the NDDC plate to use as the QC plate. Place the OD Step Tablet in the slots located on each side of the rectangle opening.
- b. 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. Select *Update Image*. The scanner will scan the QC plate and the window will display the message "Scanning in Progress".
- c. An image of the NDDC and the OD Step Tablet will appear on the window.
- d. On the NDDC image, use the mouse to move the blue line so that it bisects lengthwise the middle of the NDDC; this establishes

where the aperture will scan. Use the mouse to move the green line so that it is positioned on the outer edge of the darkest fraction; this establishes the scan begin. Move the red line so that it is positioned on the outer edge of the lightest or clearest fraction; this establishes the scan end.

- e. On the OD Step Tablet, use the mouse to move the purple line so that it bisects lengthwise the middle of the OD Step Tablet; this establishes where the aperture will scan. Use the mouse to move the green line so that it is positioned on the outer edge of the lightest or clearest fraction; this establishes the scan begin. Move the red line so that it is positioned on the outer edge of the darkest fraction; this establishes the scan end.
- 5. Neutral Density Demsitometer Control (NDDC) enter the information contained on the card supplied with the Neutral Density Densitometer Control (NDDC) as follows:
  - a. Registration Number
  - b. Fraction Value
  - c. Expected Range
    - i. Low Limit
    - ii. High Limit
- 6. QC History set the Maximum number of QC scans to keep from 0 to 9999 scans.
- 7. Once complete, select *OK* to save the information. Return the main menu and verify the scan beginning and ending positions are correct see section 7.4.4. If the positions are incorrect, repeat this section and section 7.4.4 until correct.

## 6.8.2. QC Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *QC* and then select *Print*.

- 3. The *Print QC Setup* window displays.
- 4. For *Printer Name*, select the appropriate printer from the drop down list.
- 5. For *Copies*, select the quantity needed.
- 6. To exit the window without printing, select *Cancel.*
- 7. To print the desired information, select *Print*.
- 8. The *User Setup* window displays.

#### 6.9. Scanner

## 6.9.1. Scanner Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Scanner* and *Setup*.
- 3. The Setup Scanner window (Figure 6-25) displays. This window indicates the Scanner and the Gel Boundaries currently selected. With a default, preprogrammed scanner selected, the boundaries are set to cover minimum scanning area of 6" x 8".
- 4. To alter the scanner indicated, select *Default.*
- a. The Load Default Scanner Setup window displays. Highlight the name of the scanner in use, Epson Expression, Epson Perfection 4780, Epson Perfection 4990 or Epson Perfection V700. If Epson Perfection 4990 is not available, see section 5.4.3. If the Epson Perfection 4870 model is to be used, select Epson Perfection 4780. Select Ok.
- b. The Setup Scanner window again displays and indicates the selected Scanner and the Gel Boundaries display the default settings.
- 5. User-defined Gel Boundaries can be entered; however, are not recommended. To enter user defined *Gel Boundaries*, place the

cursor in the appropriate cell: *Right*, *Left*, *Top*, and/or *Bottom*. Enter/alter the desired information. Each of the *Gel Boundaries* is relative the top, right corner of the scanner glass. Each boundary entered may contain up to 10 characters consisting of digits and a period. Once any boundary is user-defined, the name of the *Scanner* automatically changes to read *User Defined*.

- 6. To save the selections made, select Ok.
- 7. To exit the window without saving any changes, select *Cancel*.
- 8. The *User Setup* window displays.

#### 6.9.2. Scanner Print Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Scanner* and then *Print*.
- 3. The Print Scanner Setup window displays.
- 4. For *Printer Name*, select the appropriate printer from the drop down list.
- 5. For *Copies*, select the quantity needed.
- 6. To exit the window without printing, select *Cancel.*
- 7. To print the desired information, select *Print*.
- 8. The *User Setup* window displays.

#### 6.10. Printer Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Printer* and *Setup*.
- 3. The *Print Setup* window (Figure 6-26), displays.

- 4. *Printer* in the *Name* field use the drop down list to select the printer to be used. The contents of the list are determined by the printers installed.
- a. Properties select to alter as needed. The features available through this screen depend on the printer indicated. If available, use the watermark feature to unobtrusively add text, such as the institution name or the word "Confidential", to printouts. Refer to the printer owner's guide for additional information.
- 5. *Paper* alter, using the drop down list, the paper *Size* and *Source*, as needed.
- 6. Orientation select Portrait or Landscape (Portrait is the preferred setting).
- 7. Network select and the *Connect to Printer* window displays. Enter information as needed. To exit, select *Ok* or *Cancel* as needed.
- 8. To save the selections made, select *Ok.*
- 9. To exit the window without saving any changes, select *Cancel*.
- 10. The *User Setup* window displays.

## 6.11. Date and Time Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Date and Time* and *Setup*.
- 3. The Set Date and Time window (Figure 6-27) displays with the Current Date and Time shown.
- 4. Date alter the day, month, year, and/or the Format the date is displayed in as needed.
- 5. Time alter the time as needed.
- 6. Select *Apply* to save and view changes.

- 7. To exit the window without saving any changes (if *Apply* was not selected), select *Cancel* (and if the *Alert* prompt displays, select *Yes*).
- 8. To exit the window and save any changes made, select *Ok.*
- 9. The User Setup window displays.

## 6.12. Password Setup

- 1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Password* and *Setup*.
- 3. The Set Password window (Figure 6-28), displays.
- 4. *Password -* enter up to ten characters. The password is case sensitive. Make a note of this password.
- 5. Password Enabled to require a password, confirm that Password Enable is selected. If no password is required, confirm the Password Enable is not selected.
- 6. Select *Ok* to save the selections made and return to the *User Setup* window.

### 6.13. Backup

All currently, setup parameters can be saved to create a backup file. A backup should be performed each time a change to the setup parameters is made. This backup can be saved to the computers hard drive; however, should always be saved to external storage (i.e. CD). Note that if a re-writable CD will be used, prior to its first use, it must be formatted. The backup media should be labeled with the instrument's serial number and stored with the QuickScan 2000 software disk.

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

- enabled, the *User Setup Password* window displays. Enter the password and select *OK*.
- 2. From the *User Setup* window (Figure 6-2), select *Backup*.
- 3. The *Backup User Setup* window (Figure 6-29) displays. Use this window to create a backup file of all the currently setup parameters.

## 4. Backup to:

- a. To backup to the drive and file indicated, select *Ok.* Once the backup is complete, the *User Setup* window displays.
- b. A different drive and/or file may be used for backup; however, note that whenever the *Backup User Setup* window is entered, the default drive and file is indicated even if last backed up to a different drive and/or file. To backup to a different drive and/or file:
- i. *Drive* use the drop down list to select the desired drive. The content of the drop down list is determined by the drives installed on the system.
- ii. *Folders* open the appropriate folder within the selected drive.
- iii. Select *Ok* to return to the *Backup User Setup* window. Select *Ok* and the *User Setup* is backed up to the selected drive and folder. Once complete the *User Setup* window displays.
- 5. To exit without backing up, select *Cancel* and the *User Setup* window displays.

#### 6.14. Restore

If the setup parameters have been saved to a backup file (section 6.13), if needed, the parameters may restored.

1. From the main menu (Figure 6-1), select *Edit* and then *User Setup*. If password is enabled, the *User Setup Password* window displays. Enter the password and select *OK*.

- 2. From the *User Setup* window (Figure 6-2), select *Restore*.
- 3. The *Restore User Setup* window (Figure 6-30) displays.
- 4. Restore from:
- a. To restore from the drive and file indicated, select *Ok.* Once the restore is complete, the *User Setup* window displays.
- b. A different drive and/or file may be used for restore; however, note that whenever the *Restore User Setup* window is entered the default drive and file is indicated even if last restored from a different drive and/or file. To restore from a different drive and/or file:
- i. *Drive* use the drop down list to select the desired drive. The content of the drop down list is determined by the drives installed on the system.
- ii. *Folders* open the appropriate folder within the selected drive.
- iii. Select *Ok* and the *Restore User* Setup window displays. Select *Ok* and the *User Setup* is restored from the selected drive and folder. Once complete the *User Setup* window displays.
- 5. To exit without restoring, select *Cancel* and the *User Setup* window displays.

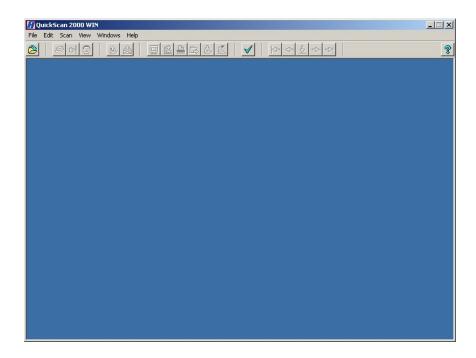


Figure 6-1. Main Menu

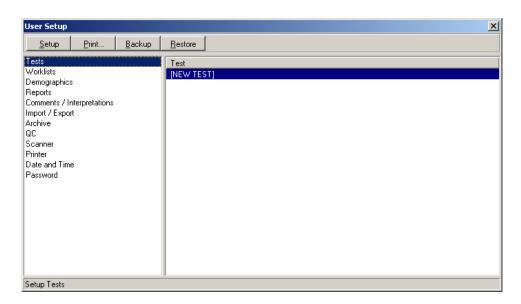


Figure 6-2. User Setup, Tests

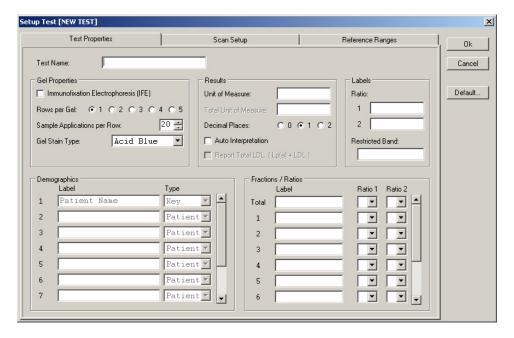


Figure 6-3. Setup Test, Test Properties

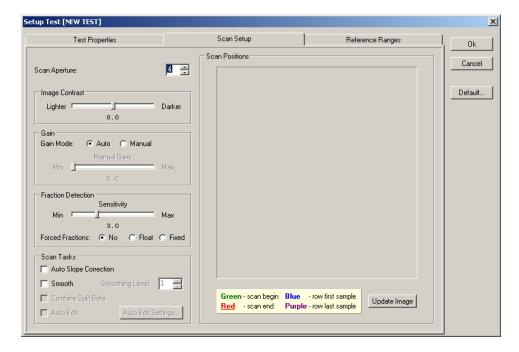


Figure 6-4. Setup Test, Scan Setup

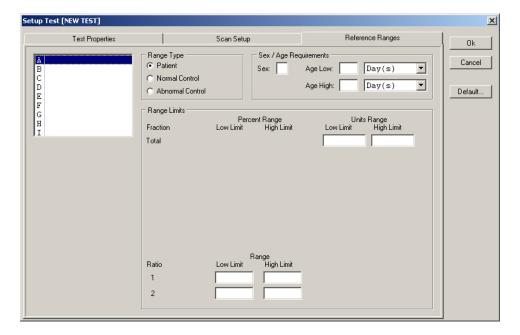


Figure 6-5. Setup Test, Reference Range

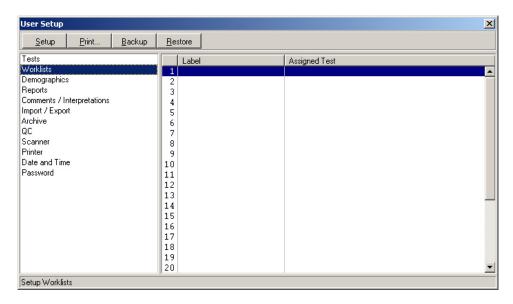


Figure 6-6. User Setup, Worklists

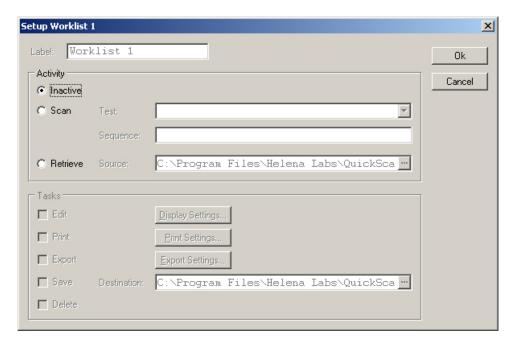


Figure 6-7. Setup Worklist

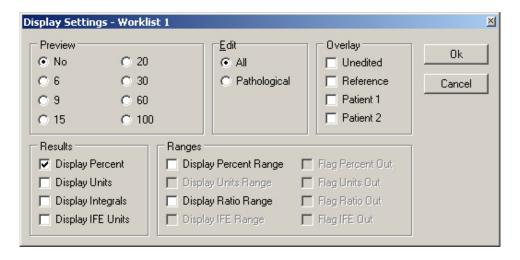


Figure 6-8. Display Settings

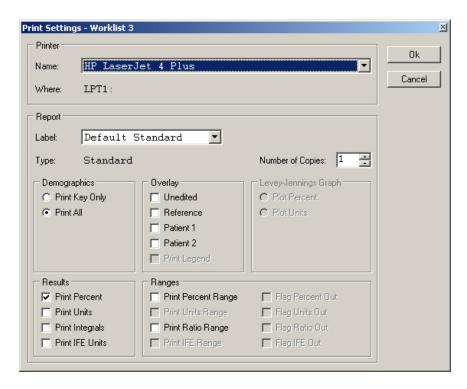


Figure 6-9. Print Settings

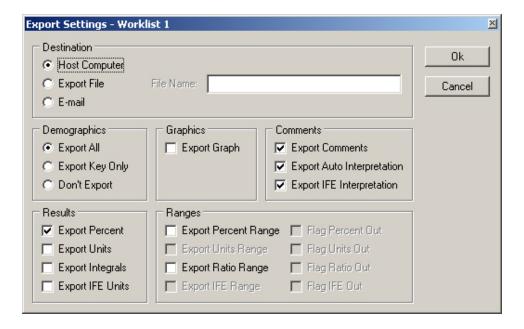


Figure 6-10. Export Settings

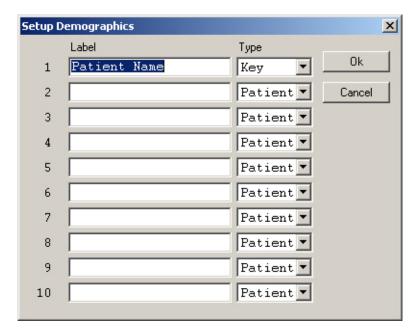


Figure 6-11. Setup Demographics

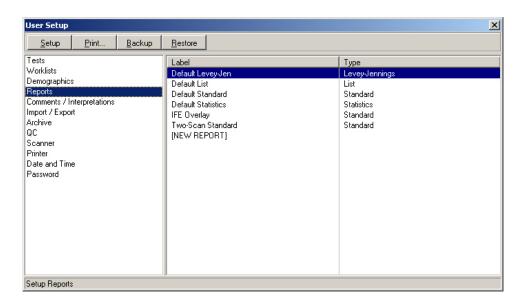


Figure 6-12. User Setup, Reports

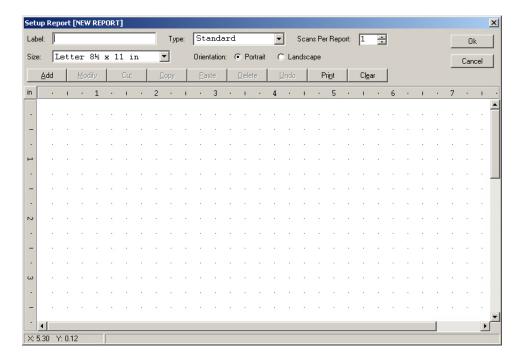


Figure 6-13. Setup Report (Type - Standard)

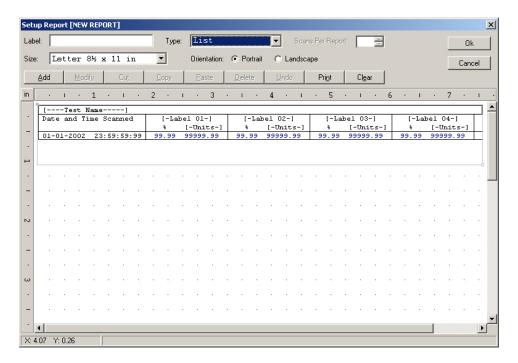


Figure 6-14. Setup Report (Type - List and Statistics)

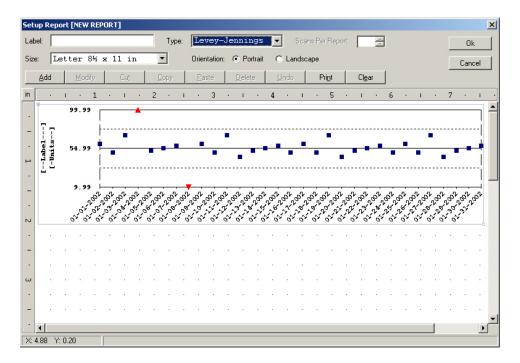


Figure 6-15. Setup Report (Type - Levey-Jennings)

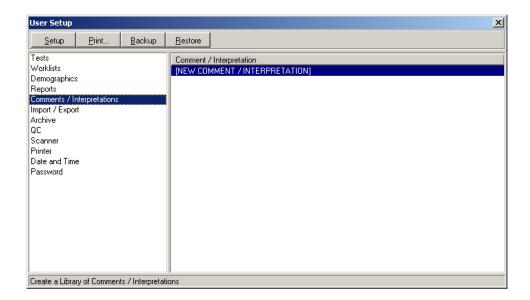


Figure 6-16. User Setup, Comments / Interpretations

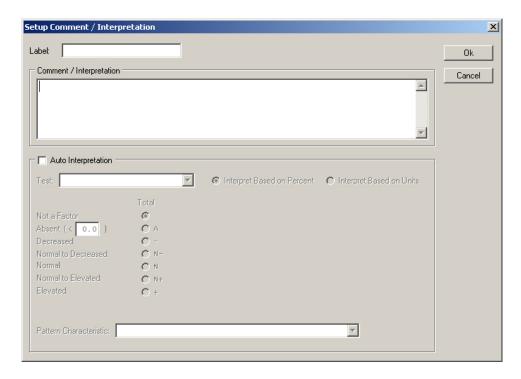


Figure 6-17. Setup Comments / Interpretations

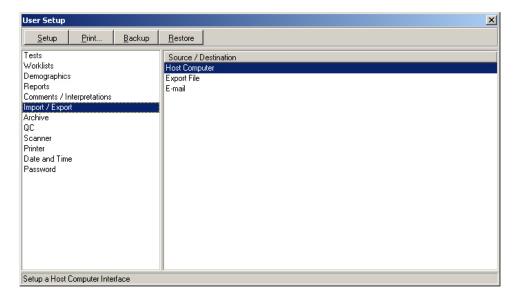


Figure 6-18. User Setup, Import / Export

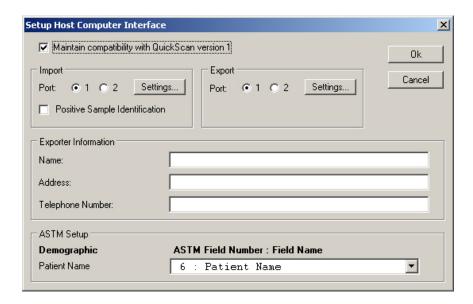


Figure 6-19. Setup Host Computer Interface

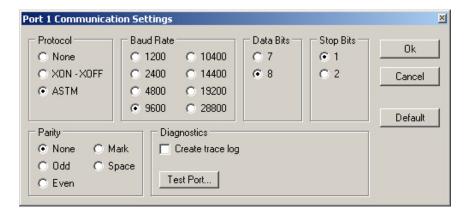


Figure 6-20. Port Communications Settings

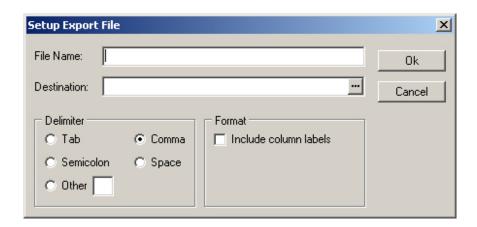


Figure 6-21. Setup Export File

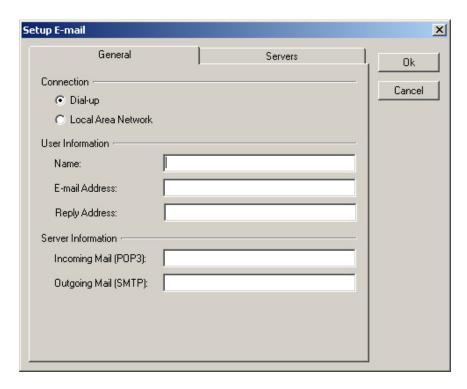


Figure 6-22. Setup E-mail

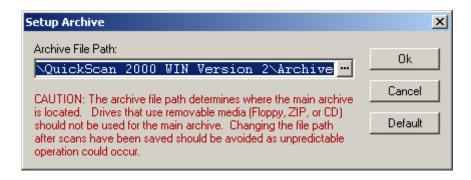


Figure 6-23. Setup Archive

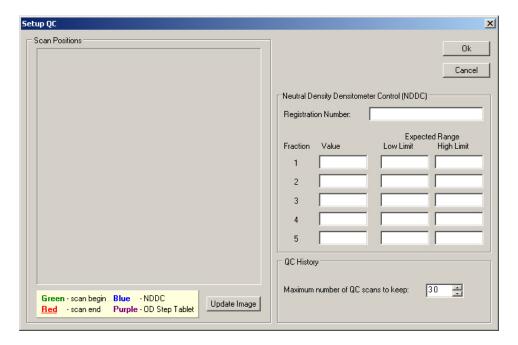


Figure 6-24. Setup QC

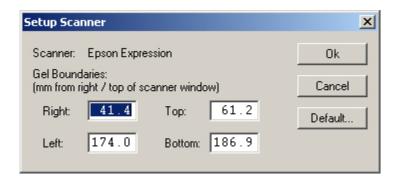


Figure 6-25. Setup Scanner



Figure 6-26. Print Setup

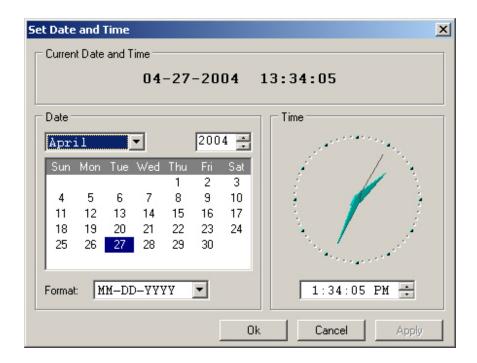


Figure 6-27. Set Date and Time



Figure 6-28. Set Password

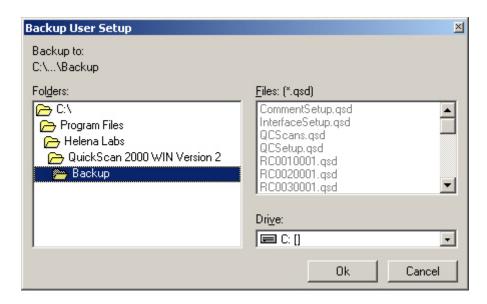


Figure 6-29. Backup User Setup

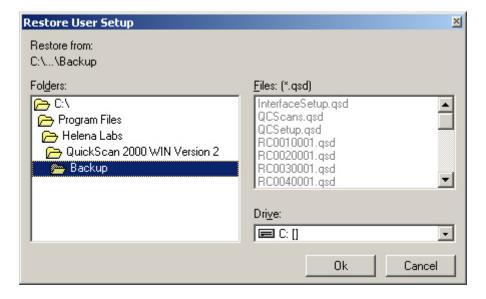


Figure 6-30. Restore User Setup

## **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 2000 WIN 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 10.2 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 a Scan Worklist

- 1. Select the *Open/Close/Select Worklist* icon and open the appropriate scan worklist.
- 2. Select Clear Worklist to clear any contents.
- 3. Select the *Enter Patient Info* icon and enter the patient data.
- 4. Open the scanner lid.
- 5. 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.

- 6. Close the lid and select the *Scan New Gel* icon.
- 7. If it is necessary to correct scan positions, select the *Scan Options* icon. Select *Update Image*. The gel is rescanned and displayed with the colored alignment lines. Use the colored lines to correct the scan position. To confirm the scan position, select *Update Image*. The repositioned scan is displayed. When satisfied with the scan position, select *OK* to return to the main menu. To use the new scan positions, select *Scan* and *Rescan Previous Gel*. This change is for this particular scan only. It does not permanently change *Scan Begin* and *Scan End* settings.
- 8. Edit, print, save, and/or export scan(s) will occur as programmed in *Worklist Setup*.
- 9. If necessary display, print and export options can be altered temporarily using the *Scan Options* icon.

### 7.1.2. Summary for a Retrieve Worklist

- 1. Select the *Open/Close/Select Worklist* icon and open the appropriate retrieve worklist.
- 2. Select either the Retrieve Scan(s) from Archive or the Retrieve Scan(s) from E-Mail icon, as desired.
- 3. Enter the in retrieval parameters and select *Retrieve* or *Open* the needed e-mail, as applicable.
- 4. Edit, print, save, and/or export scan(s) as necessary.

## 7.1.3. Editing Summary

- 1. With the scan(s) displayed, indicate the desired scan and select the *Edit Scan(s)*icon.
- 2. Select and perform the desired editing actions.
- 3. Exit edit when scan editing is complete.

## 7.1.4. Saving and Exporting Summary

- 1. Select Export Scan(s) or Save Scan(s) to Archive, as desired.
- 2. A worklist may be setup to automatically perform these functions.

## 7.1.5. Reports Printing Summary

- 1. To manually print reports, select the *Print* Scan(s) icon.
- 2. As needed, select *Print Settings*. Enter the appropriate parameters and select *OK*.
- 3. With the desired scans indicated, select *Print*.
- 4. A worklist may be setup to automatically perform the print function.

#### 7.2. File

To access the options in *File*, on the main menu (Figure 7-1) select *File*. The options are discussed 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. 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. Open/Close/Select Worklist

- 1. From the main menu (Figure 7-1), to select a currently setup worklist, either select *File* and *Open/Close/Select Worklist* or select the *Open/Close/Select Worklist* icon (the first icon).
- 2. The Worklist Manager window displays and lists the currently setup worklists (section 6.2.1). Each worklist is setup to perform either a scan function, which associates them with a specific test, or a retrieve function, which associates them with a source retrieve drive. When setup, the worklists are programmed to automatically present or perform functions affecting display, printing, exporting, saving, and deleting.

- a. To open a worklist, either select the desired worklist and then select *Open* or select the square preceding the desired worklist. The *Worklist Manager* window closes and the selected worklist window opens. Repeat steps as needed to open all the desired worklists.
- b. To close a worklist, either select the desired open worklist and *Close* or select the square preceding the desired open worklist. The *Worklist Manager* window closes and the selected worklist window closes. Note that a worklist can also be closed by selecting the **X** on the top right corner of the worklist window.
- c. To select or make an open worklist active, select the desired open worklist and then select *Select*. The *Worklist Manager* window closes and the selected worklist window is active. Note that a worklist can also be selected using the *Window* option (section 7.6) or by minimizing the other open worklist windows until the desired worklist is active.
- 3. To exit the *Worklist Manager* window without opening, closing or selecting a worklist, select *Cancel*.

# 7.2.2. Retrieve from File / Retrieve Scan(s) from Archive

- 1. Open or select a retrieve worklist (section 7.2.1). To retrieve scan files from the archive, from the main menu (Figure 7-1), select either select *File* and then *Retrieve from File* or select the *Retrieve Scan(s) from Archive* icon (the fifth icon).
- 2. The *Retrieve* window (Figure 7-2) opens. It contains four buttons (*Search*, *Retrieve*, *Cancel*, and *Reset*) on the right side of the window and two sections (*Search* and *Retrieve Tasks*). The four buttons may be used at any point; see section 7.2.2.1 for information. The retrieve parameters are defined within the *Search* section, see section 7.2.2.2. The tasks performed with the retrieved scans can be altered from the worklist setup using the *Retrieve Tasks* section, see section 7.2.2.3.

# 7.2.2.1. Search, Retrieve, Cancel and Reset Buttons

- 1. Search button select to obtain the list of scans that conform to the retrieve parameters entered in the Search section. The Search Results window displays contained the list of scans:
- a. To select all of the scans listed, select Select All.
- b. 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. Multiple scans can also be selected by holding down the SHIFT key while using the mouse.
- c. With the desired scan(s) selected, select *Retrieve*. If the worklist in use contains scans, an *Alert* prompt displays. To replace the worklist contents with the retrieved scans, select Yes in response. Both the *Search Results* and the *Retrieve* windows close. The selected scan(s) displays as prescribed per the setup for the worklist is use or per selections made within the *Retrieve Tasks* section of the *Retrieve* window.
- d. To return to the *Retrieve* window without selecting any scans, select *Cancel*.
- 2. Retrieve button with the desired retrieve parameters set, select Retrieve. If the worklist in use contains scans, an Alert prompt displays. To replace the worklist contents with the retrieved scans, select Yes in response. The Retrieve window closes. The selected scan(s) displays as prescribed per the setup for the worklist is use or per selections made within the Retrieve Tasks section of the Retrieve window.
- 3. Cancel button select to exit the window without retrieving any scans.
- 4. Reset button select to return to the retrieve parameters to those setup for the worklist in use.

#### 7.2.2.2. Search

Use this section of the *Retrieve* window to define the retrieve parameters. Information may be entered in as many or as few of the fields displayed in this section as needed to define the search parameters.

# 7.2.2.2.1. Source and Properties

- 1. Source drive (and/or folders) shown is as selected during worklist setup (section 6.2.1).
- a. ... (Browse) select to alter the *Source* drive (and/or folders). The *Retrieve Source* window displays. Use the *Drive* field and then *Folder* section to select the source as needed. With the source selected, select *Ok*. To exit without changing the source, select *Cancel*.
- 2. Properties With a Source drive (and folder) indicated, select Properties and the Source Properties window displays. This window contains information on the Archive Location, the number of Archived Scans, the Drive Type, the Used Space, the Free Space, and the Capacity of the archive location. Select Ok to exit.

# 7.2.2.2. Basic Search

Use this tab to define the following parameters:

- 1. Key Identifier also displayed is the demographic label designated as the Key identifier in setup. As needed, enter information, up to 20 characters, to define this retrieve parameter. As needed, use the Reference, Normal, Abnormal, Today, and Yesterday buttons to assist in entering the specific information. Use a question mark, ?, to designate a single unknown character or an asterisk, \*, to designate a group of unknown characters at the end of the identifier, as needed.
- 2. Date and Time Scanned as needed, for Date, enter Start and/or End to define the retrieval parameter. The corresponding Time Start and/or End may be entered as needed.

The information under these fields gives the format required when entering the date and time criteria. As needed, use the *Today*, *Yesterday*, *This Month* and *Last Month* buttons to assist in entering the information.

- 3. *Test* as needed, use the drop down list to select the applicable test name. The content of the list is based on the currently setup tests (section 6.1.1). To specify no test, leave the field blank.
- 4. Run ID appears only with Positive Sample Identification enabled (section 6.6.1.1). As needed, enter the run number, of up to 14 characters, to identify the scan(s) to be retrieved.

#### 7.2.2.2.3. Advanced Search

Use this tab to define the following parameters (Figure 7-3):

- 1. Identifier 2, Identifier 3 and Identifier 4 use these fields to select additional demographic identifiers. For each Identifier, as needed, use the drop down list to choose a demographic identifier and/or [NA]. The list is based on the currently setup demographics. For each Identifier needed, use the field to the right of the selected demographic to enter up to 20 characters to define the retrieve parameter. As needed, use the Reference, Normal, Abnormal, Today, and Yesterday buttons to assist in entering the information. Use a question mark, ?, to designate a single unknown character or an asterisk, \*, to designate a group of unknown characters at the end of the identifier, as needed.
- 2. Reference, Pathological, Edited, and Reviewed use as many or few as needed to define the retrieve parameter. Once selected, select Must Be, to require a scan have the selected characteristic, or Must Not Be, to require a scan not have the selected characteristic.

# 7.2.2.2.4. Reference, Normal, Abnormal, Today, Yesterday, This Month, Last Month, and Clear Buttons

- 1. Reference select to enter Reference as a retrieve parameter for the indicated field.
- 2. *Normal* select to enter *Normal* as a retrieve parameter for the indicated field.
- 3. Abnormal select to enter Abnormal as a retrieve parameter for the indicated field.
- 4. *Today* select to enter today's date as a retrieve parameter in the indicated field.
- 5. Yesterday select to enter yesterday's date as a retrieve parameter in the indicated field.
- 6. This Month select to enter the current month's first day, in Start Date, and last day, in End Date for use as retrieve parameters.
- 7. Last Month select to enter the previous month's first day, in Start Date, and last day, in End Date for use as retrieve parameters.
- 8. *Clear* select to remove all entered retrieve parameters.

#### 7.2.2.3. Retrieve Tasks

This section of the *Retrieve* window displays the currently setup *Retrieve Tasks* for the worklist in use. The task settings can be altered, as needed, without altering the worklist setup.

- 1. *Edit* select to automatically display the scans in the Edit mode. If *Edit* is not selected the Edit mode can be accessed at operator request.
- 2. Display Settings select and the Display Settings window displays. Use this window to customize the appearance of window once retrieving is complete and to customize the automatic actions in the Edit mode. See section 7.5.1 for additional information on this window.

- 3. *Print* select to have reports print automatically. Whether or not *Print* is selected, reports can be printed at operator request. Most operators prefer to have reports print at their request.
- 4. *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. See section 7.2.4.1 for additional information on this window.
- 5. Export select to automatically export scans. Whether or not Export is selected, scans can be exported at operator request. Most operators prefer to have scans exported at their request.
- 6. Export Settings select and the Export Settings window displays. Use this window to customize the export parameters. These settings are used whether scans are exported automatically or at operator request. See section 7.2.5.1 for additional information on this window.
- 7. Save select to automatically save scans. Whether or not Save is selected, scans can be saved at operator request. (Note that if a re-writable CD will be used, prior to its first use, it must be formatted.)
- a. Destination displays the save destination currently setup for the worklist in use. To select a different Destination, select ... (to Browse) and the Save Destination window displays. See section 7.2.6 for additional information on this window.
- b. *Properties -* select and the *Destination Properties* window displays. See section 7.2.6 for additional information on this window.

8. Delete - to select with the Retrieve Source and the Save Destination the same, Save cannot be selected. To select both Delete and Save, the Retrieve Source and the Save Destination must be different. With Delete selected, files that match the file retrieval parameters are automatically deleted.

# 7.2.3. Retrieve from E-mail / Retrieve Scan(s) from E-mail

- 1. With a retrieve worklist active, scan files from e-mails with subject lines of <\_QuickScan\_E-mail\_Export\_> can be retrieved. From the main menu (Figure 7-1), either select *File* and then *Retrieve from E-mail* or select the *Retrieve Scan(s) from E-mail* icon (the sixth icon).
- 2. The window displays "Checking for mail" and the e-mail address setup for use (section 6.6.1.3).
- 3. The display contains either a list of the received e-mails on the *Retrieve from E-mail* window or the message "There are no new messages".
- 4. With the *Retrieve from E-mail* window displayed, highlight the desired e-mail and select either:
  - a. Open to access the indicated e-mail.
  - b. Delete to delete the indicated e-mail.
- c. Cancel to exit the window without accessing/deleting e-mail.
- 5. Once an e-mail is opened, the window displays the *From* (sender) information, the number of *Attached Scans*, and the *Message*. The window also provides three buttons:
  - a. Print select to print the e-mail.
- b. *Retrieve* select to place the attached scans into the worklist.
- c. Cancel select to exit the window without printing/retrieving the scans.

# **7.2.4. Print Scan(s)**

- 1. Open or select the worklist (section 7.2.1) containing the scans to be printed. From the main menu (Figure 7-1), either select *File* and *Print Scan(s)* or select the *Print Scan(s)* icon (the ninth icon).
- 2. The Worklist -- Print window (Figure 7-4) displays listing all the scans within the worklist in use. The list of scans contains the test name, the sample number, the date and time scanned, the key demographic, and a colored square. The color of the square represents the following: Blue, indicates the scan has the proper number of fractions and all the fractions are within range values. Red indicates the scan does not have the proper number of fractions and/or one or more fraction is out of range. Yellow indicates the scan has been viewed in the edit mode; however, still does not have the proper number of fractions and/or one or more fraction is out of range. This window also indicates the currently selected Printer, Report and Number of Copies.

# 7.2.4.1. Print Settings

From the *Worklist -- Print* window, to alter the contents of the report from the currently setup parameters, select *Print Settings*. From *Print Settings* window (Figure 7-5), as needed, customize the following print related settings:

# 7.2.4.1.1. Printer

- 1. Name from the drop down list select the appropriate printer. Note that if the instrument is connected to a phone line, a report can be faxed by selecting Fax from the drop down list, if available, making the remaining selections on this window, then, once Print is selected on the Worklist -- Print window, following the prompts.
- 2. Where is automatically entered based on the *Printer Name* selected.

# 7.2.4.1.2. Report

- 1. *Label* from the drop down list, select one of the reports shown. The list consists of all the currently setup reports (section 6.4.1).
- 2. *Type* is automatically entered based on the *Report Label* selected. Note that with this version of software, the report types List and Statistics cannot be used with the Auto Edit feature.
- 3. *Number of Copies* from one to one hundred copies may be printed at once.
- 4. Demographics accessible with all but Levey-Jennings Report Types. Select one of the following:
- a. *Print Key Only* select to have only the demographic classified as *Key* printed.
- b. *Print All* select to have all the demographics printed.
- 5. Overlay accessible only with Standard Report Types and is not available for scan worklists 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, overlaid on the sample pattern. If selected, a sample will need to be labeled Reference for each gel scanned (section 7.3.1).
- c. Patient 1 select to have a patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- d. *Patient 2* select to have a second patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- e. *Print Legend* is only available when at least one *Overlay* is selected. Select to include a legend of identifying the overlays.
- 6. Levey-Jennings Graph accessible only with a Levey-Jennings Report Type selected. 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.
- 7. Results accessible with all but Levey-Jennings Report Types. 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. Print IFE Units
- 8. Ranges accessible with all but Levey-Jennings Report Types. 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

#### 7.2.4.1.3. 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.

#### 7.2.4.2. Select Scans to Print

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

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

#### 7.2.4.3. Print and Cancel

- 1. *Print* with all the desired scans selected, select to print the highlighted scans. Caution: Due to memory limitations, do not initiate additional print jobs until the first print job is entirely complete.
- 2. Cancel select to exit without printing.

# 7.2.5. Export Scan(s)

- 1. With a worklist open, to export scans, from the main menu (Figure 7-1) either select *File* and *Export Scan(s)* or select the *Export Scan(s)* icon (the tenth icon).
- 2. The Worklist -- Export window (Figure 7-6) displays listing all the scans within the worklist in use. The list of scans contains the test name, the sample number, the date and time scanned, the key demographic, and a colored square. The color of the square represents the following: Blue, indicates the scan has the proper number of fractions and all the fractions are within range values. Red indicates the scan does not have the proper number of fractions 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. This window also indicates the currently selected Destination.

# 7.2.5.1. Export Settings

From the *Worklist -- Export* window, to alter the export parameters, select *Export Settings*. From the *Export Settings* window (Figure 7-7), as needed, customize the following export related settings:

# 7.2.5.1.1. **Destination**

Select one of the following:

- 1. Host Computer
- 2. Export File if selected then the following option is accessible:
- a. File Name enter a file extension of up to 20 characters. For example, an Excel file would be entered as ".xls".
- 3. E-mail

# 7.2.5.1.2. Demographics

Select one of the following:

- 1. Export All
- 2. Export Key Only
- 3. Don't Export

# 7.2.5.1.3. Graphics

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

1. Export Graph

#### 7.2.5.1.4. Comments

This section is only accessible when *Host Computer* is selected. The last option is only available for a scan worklist within IFE test selected. Select as needed:

- 1. Export Comments
- 2. Export Auto Interpretation
- 3. Export IFE Interpretation

### 7.2.5.1.5. Results

This section is not accessible when *E-Mail* is selected. 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
- 4. Export IFE Units

# 7.2.5.1.6. 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

#### 7.2.5.1.7. 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.

# 7.2.5.2. 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.

# 7.2.5.3. 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.
- c. E-Mail the Export to E-Mail window displays. In the To field, enter the desired

recipient's e-mail address or use the drop down list to select an address. The list consists of addresses previously used. In the *Message* field, type the message desired sent with the scan(s).

- i. Cancel select to exit without exporting via e-mail.
- ii. Send select to export the scan(s) and message.
- 2. Cancel select to exit the window without exporting.

# **7.2.6. Save Scan(s)**

- 1. With a worklist open, to save scans, from the main menu (Figure 7-1), either select *File* and *Save Scan(s)* or select the *Save Scan(s)* to *Archive* icon (the eleventh icon).
- 2. The Worklist -- Save window (Figure 7-8) displays listing all the scans within the worklist in use. The list of scans contains the test name, the sample number, the date and time scanned, the key demographic, and a colored square. The color of the square represents the following: Blue, indicates the scan has the proper number of fractions and all the fractions are within range values. Red indicates the scan does not have the proper number of fractions 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.
- 3. Destination is also indicated on this window. A 3.5" diskette will store 60 scans, and a zip disk will store approximately 4700. Note that if a re-writable CD will be used, prior to its first use, it must be formatted. If more data than will fit on one disk is being saved, a prompt will indicate when to insert another disk. A different Destination may be selected if ... (to Browse) is accessible. Select ... and the Save Destination window displays. Alter the following as needed:

- a. *Drive* use the drop down list to select the drive for the save destination. The content of the drop down list is determined by the drives installed on the system.
- b. *Folders* open the appropriate folder within the selected drive for the save destination.
- c. OK select to exit to the Setup Worklist window and save selections made.
- d. Cancel select to exit to the Setup Worklist window without changing the save destination.
- 4. Properties select and the Destination Properties window displays. This window contains information on the Archive Location, the number of Archived Scans, the Drive Type, the Used Space, the Free Space, and the Capacity of the Destination. Select Ok to exit.
- 5. To select all of the scans listed, select *Select All.*
- 6. 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. Save with all the desired scans selected, select to save the highlighted scans.
- 8. Cancel select to exit without saving.

#### 7.2.7. Clear Worklist

- 1. With a worklist open, to clear the worklist contents, from the main menu (Figure 7-1) either select *File* and then *Clear Worklist* or select the *Clear Worklist* icon (the twelfth icon).
- 2. The Alert, Worklist is about to be cleared. Do you wish to continue displays.
- 3. To return to the worklist without clearing the contents, select *No.*
- 4. To clear the contents and return to the empty worklist, select Yes.

#### 7.2.8. Exit

To exit the QuickScan 2000 WIN 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

#### 7.3.1. Patient Info/Enter Patient Info

- 1. Open or select a scan worklist (section 7.2.1). To enter patient demographic information, from the main menu (Figure 7-1) either select *Edit* and then *Patient Info* or select the *Enter Patient Info* icon (the fourth icon).
- 2. The *Patient Information* window (Figure 7-9) displays. The window contains two tabs, *Patient Identification* and *Patient Management*, and a table for entering patient demographic information.
- 3. The titles of each column in the table are the demographic labels assigned in setup (section 6.3.1). These include any test specific demographics (section 6.1.1) applicable to the test attributed to the worklist in use. The first column is always the demographic designated as the Key identifier.
- a. The column width may be adjusted. Place the cursor on the line separating the column to be adjusted and the next column. Click and hold the left button on the mouse while moving the mouse left or right as needed to resize the column. When the desired width, release the button. Use caution not to resize a column so narrow that it is not visible or appears to be removed.
- 4. The titles of each row in the table are 1 through the total number of samples the test attributed to the worklist in use specifies (section 6.1.1).
- 5. Most often, the first sample is used as the Reference sample. Confirm the cursor is in the row one, column one field, and select *Reference* (section 7.3.1.1). *Reference* will

- appear in the location indicated by the cursor. When designated as the reference, the control can then be used for forced fractions or as a reference overlay. Samples scanned following the reference may be displayed and/or printed with the reference overlay. If using a normal and/or abnormal reference range, label the sample Reference Normal or Reference Abnormal, as applicable.
- 6. With row 1 most likely the Reference, enter patient information beginning in the first field of row 2. Each cell of information may contain up to 20 characters, more may be entered however only the first 20 characters will be used. Enter the patient information in the row that corresponds to the patient sample on the gel and in the column that corresponds with the demographic label assigned to the column. Patient information can also be entered by scanning the barcode for the patient sample.
- 7. To move through a row entering information, press **Tab** after each entry and **Enter** at the end of the row. The **arrow** keys move the cursor up, down, left and right within the patient information window. For large moves, use the mouse and/or the **Page Up** and **Page Down** keys. Errors can be typed over to correct them. Repeat until all patient information is entered.
- 8. If the Positive Patient ID feature is in use (section 6.6.1.1), *Run ID* displays on the bottom of the window. Do not enter information into this field. When the scan of the gel is started, the instrument will request the information (section 7.4.1).
- 9. Before entering patient information into a worklist already containing patient information and/or scans, the worklist or patient information should be cleared (sections 7.2.7 or 7.3.1.2).
- 10. Use the keys accessible through the *Patient Identification* (section 7.3.1.1) and *Patient Management* (section 7.3.1.2) tabs to assist in entered patient information.

11. If the patient information is to be imported, see section 7.3.1.2.

# 7.3.1.1. Patient Identification

- 1. The first tab on the *Patient Information* window (Figure 7-9) is the *Patient Identification* tab. With this tab selected, there are seven keys located at the top of the window to aid in entering patient information.
- 2. Reference select to designate a sample as a Reference sample.
- 3. *Normal* select to designate a sample as a *Normal* sample.
- 4. Abnormal select to designate a sample as an Abnormal sample.
- 5. *Today* select to enter today's date in the indicated field.
- 6. Yesterday select to enter yesterday's date in the indicated field.
- 7. Duplicate select to have the indicated demographic, for example Tech ID, entered into all the fields under the indicated field.
- 8. *Increment* select to have the indicated numeric demographic entered into all the fields under the indicated field increased by one in each field. For example if the indicated field contains the number 123, the next would be 124, then 125, and so on.

# 7.3.1.2. Patient Management

- 1. The second tab on the *Patient Information* window is the *Patient Identification* tab (Figure 7-10). With this tab selected, there are nine keys located at the top of the window to aid in entering patient information.
- 2. Search is used to search, by Key identifier, for previously saved patient demographics to import into the current patient information list. Place the cursor in the row of the applicable sample and select Search. The Patient Search window (Figure 7-11) displays:
  - a. Search

- i. Key Identifier also shown is the demographic label designated as the Key identifier.
- 1) If, when Search was selected, the row where the cursor was located contained data in the first (or key identifier) column, then that data is automatically displayed in this field and any matches are displayed in Matching Patients Found.
- 2) If, instead, the row contained no key demographic when *Search* was selected, then this field is blank and all available patient information is displayed in *Matching Patients Found*.
- 3) To perform a new search, enter (up to 20 characters) in this field to define the search parameters. A question mark, ?, to designate a single unknown character, or an asterisk, \*, to designate a group of unknown characters at the end of the identifier, may be used as needed.
- ii. Search button with data entered in to the Key Identifier field, select Search to obtain any Matching Patients Found.
- iii. Matching Patients Found: plus the quantity of matches found -
- 1) A list of key identifiers that match the *Search* criteria displays on the left side of this section.
- 2) All the demographic labels and data, less the test specific demographics, for the currently highlighted match, displays on the right side of this section.
- 3) Select the desired match from the list and the demographic information displays.
- iv. Select with the desired match from the *Matching Patients Found* list selected, select *Select*. The patient information is entered into the appropriate columns of the applicable sample row.

- v. Cancel select to exit without selecting a match.
- 3. *Cut* select to have the indicated row of patient information removed and made available for placement in a row to be indicated. (To remove information from only one column within a row, use the backspace or delete key on the keyboard.)
- 4. Copy select to have the indicated row of patient information made available for duplicated to a row to be indicated.
- 5. Paste select to have the patient information that has been cut or copied entered into the indicated row.
- 6. *Insert* select to have the indicated row of patient information and all the rows after it moved down one position. There must be at least one empty row under the indicated row in order to use *Insert*.
- 7. Delete select to have the indicated row position and patient information deleted and any rows following it moved up one position. (To remove information from only one column within a row, use the backspace or delete key on the keyboard.)
- 8. *Import* once selected, select the Import Source from either Laboratory Information System (LIS) or Electrophoresis Sample Handler.
- a. If Laboratory Information System (LIS) is selected, then enter the Import Request (up to 255 characters) that identifies the patient(s) to be imported. The patient data is entered into the displayed Patient Information window.
- b. If Electrophoresis Sample Handler is selected, then select the Import key. The patient data is entered into the appropriate Patient Information window.
- 9. *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.

- 10. Clear select and the Alert, All patient information in the current worklist is about to be cleared. Do you wish to continue displays. Select Yes to clear all the patient information. Select No to exit without clearing the patient information.
- 11. When all the patient information is entered, select *Ok* to return to the main menu.
- 12. To return to the main menu without entering patient information, select *Cancel*.
- 13. As needed, resave the scan data (section 7.2.6).

# 7.3.2. Edit Scan(s)

- 1. The worklist in use may not automatically display scans in the edit mode. In this case, to select a scan for editing, indicate the desired scan. Then either select *Edit* and *Edit Scan(s)* or select the *Edit Scan(s)* icon (the eighth icon). A scan can also be selected for editing by double clicking on the scan. Note that if *Displays Settings* for the worklist in use is set to *Edit Pathological*, then only pathological scans are accessible in the edit mode and the first pathological scan in the worklist will be the first displayed in the edit mode.
- 2. When the scan is selected for editing, the *Edit Scan(s)* window (Figure 7-12) displays. (For information on editing IFE, scans see section 7.3.2.8.)
- a. The window includes the scan and any demographics, fractions, and comments associated with the scan.
- b. To move between the scans in the worklist, use the arrow keys located at the top of the window (section 7.8).
- c. Use the cursor located on the scan and the seven tabs (section 7.3.2.1 through 7.3.2.7) located on the bottom of the window to edit the scan.
- 3. The cursor on the scan is represented as a white cross hair and is controlled with the mouse. To move the cursor, place the white

arrow on the cross hair, press and hold the button on the left side of the mouse. Move the mouse, which moves the arrow and cross hair, to the desired location and release the button on the mouse. The cursor can also be moved by pressing the **Alt** key while pressing the appropriate **arrow** key. Note that moving the cross hair causes a corresponding move in the indicator bar on the display of the sample (Figure 7-12).

- 4. Once an edit function is preformed, the last function or all functions performed can be undone. See section 7.3.2.7 for additional information.
- 5. Once all the editing is complete on the scan, select another scan to edit or select the X at the top right of the window to exit and return to the main menu. If the worklist has save, export and/or print as a selected parameter, the newly edited scan(s) are saved, exported and/or printed when the edit mode is exited. If save is not an automatic function as needed, resave the scan data (section 7.2.6).
- 6. The following explains each of the seven tabs:

#### 7.3.2.1. Delimit Bands

1. The first tab, *Delimit Bands* (Figure 7-12) provides access to *Fractions*, *Restricted Bands* and *Auto Edit* (for Cholesterol tests).

#### 2. Fractions

- a. *Insert* is only available when the total number of fractions is less than ten. To indicate a fraction, place the cursor on the appropriate location on the scan and select *Insert*. A fraction delimiter appears on the graph at that point and the fraction data is automatically recalculated when editing causes a change in values.
- b. *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 *Delete*. The closest fraction mark is deleted and the fraction data

- is automatically recalculated when editing causes a change in values.
- 3. Restricted Bands is only available when the name of the test in use contains "Proteins" or "SPE".
- a. *Mark* is only available when the total number of restricted bands is less than three. To indicate a band, place the cursor on the appropriate location on the scan and select *Mark*.
- b. *Unmark* place the cursor between the band marks needing deletion and select *Unmark*.
- 4. Auto Edit is only accessible when the name of the test in use contains "Chol" and only if Auto Edit was not previously selected in the test setup. 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 looses the label identity so that four fractions will be required. Example: If a sample contains only HDL and LDL with auto edit selected only those labels will show on the screen and report with the cholesterol protein content divided between them. Insertion of a fraction mark between HDL and LDL will not alter curve interpretation but will add a label and override the original pattern fraction identification resulting in three fractions labeled HDL, Lp(a) and vLDL. The LDL fraction is now misidentified as vLDL. Addition of a second fraction mark results in 4 labels all correctly With Auto Edit in use, scans identified. should be reviewed and edited, as needed, to evaluate the auto edit performance. Any sample without HDL should be restored. On some occasions, the HDL may be very low in value or may move faster causing the software to eliminate it. These patterns must be manually edited at the edit screen. Note that with this version of software, if Auto Edit is in use, List and Statistics report types cannot be printed.

- a. *Edit* select to *Auto Edit* the scan one the *Settings* are set.
- b. Settings select and the Auto Edit Settings window displays.
- i. Cholesterol Auto Edit, Force Lp(a) Fraction selection of this feature provides for automatic marking of an Lp(a) fraction, based on the Reference, if no Lp(a) is found during auto edit. The Lp(a) fraction is marked once HDL, LDL and, as applicable, vLDL are marked. 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. If no vLDL is present, no fraction label will display/print.

Caution: this feature is based on the absolute position of the Lp(a) on the reference. Optimally a reference may be put 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.

# 7.3.2.2. Delete Area

- 1. The second tab, *Delete Area* (Figure 7-13) allows for removing areas of the scan.
- 2. *Mark* Place the cursor (section 7.3.2) on one side of the area needing deletion and then select *Mark*.
- 3. *Unmark* Once *Mark* is used, *Unmark* is accessible. Select if the location marked is incorrect.
- 4. Apply Once Mark is used, Apply becomes accessible. Place the cursor on the other side of the area needing deletion and then select Apply. The area between and above the marks is deleted.
- 5. Repeat as needed.

#### 7.3.2.3. Baseline Correction

1. The third tab, *Baseline Correction* (Figure 7-14) is used if the baseline needs to be

- moved or if the pattern has a non-linear baseline due to irregularities in background intensity.
- 2. *Mark* Place the cursor (section 7.3.2) on 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.
- 3. *Unmark* Once *Mark* is used, *Unmark* becomes available. Select *Unmark* to remove the line indicating the new baseline.
- 4. To create a non-linear baseline, place the cursor on another location and again select *Mark*. The line indicating the new baseline is drawn between the marked locations. Repeat until the baseline is indicated as desired.
- 5. 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.

# 7.3.2.4. Overlay

The fourth tab, *Overlay* (Figure 7-15) allows for overlaying *Unedited*, *Reference* and/or *Patient* scans.

#### 7.3.2.4.1. Unedited

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

### 7.3.2.4.2. Reference

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

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

#### 7.3.2.4.3. Patient

- 1. Patient Select Patient and then select either 1 or 2 to overlay a saved patient pattern. The pattern can be from the same patient or a different patient. For instructions on using a saved patient scan as an overlay, proceed to step 2. For instructions on using a patient scan from any currently open worklist, even if the scan has not been saved, see section 7.9.3.
- 2. Select Once Patient is selected, Select is available and is used to identify a saved patient scan as an overlay. Select Select and the Select Patient Overlay window (Figure 7-16) displays. This window contains four buttons (Select, Clear, Search, and Cancel) on the right side of the window and two sections (Search and Matching Scans Found).
- a. Select button To select a scan, high-light the desired scan in the Matching Scans Found list and Select becomes available. Select Select and the Edit Scan(s) window displays. The selected scan is displayed, in magenta for Patient 1 and in yellow for Patient 2, over the original patient scan, which is in red.
- b. Clear button If the scan has a patient overlay already selected, the Clear is available when the Select Patient Overlay window is first accessed. To remove the patient overlay currently selected, select Clear and the Edit Scan(s) window displays with the overlay removed, either Patient 1 or Patient 2.
- c. Search button With the search parameters defined, select Search. Any scans found which conform to the search parameters are listed in the Matching Scans Found section of the window.

- d. *Cancel* button select to exit without selecting or unselecting an overlay.
- e. Search this section of the window shows the default Source drive, the two tabs, Basic Search and Advanced Search, and the eight buttons used to assist in defining the Search. As needed, use this section to define the search parameters. See section 7.2.2.2 for information this section.
- f. Matching Scans Found this section lists any saved scans that meet the Search criteria given.
- 3. With a patient overlay selected, the *Adjust* slide bar becomes available. Use the slide bar to position the overlay on the scan as desired.

# 7.3.2.5. Appearance

- 1. The fifth tab, *Appearance* (Figure 7-17), allows access to options that alter the appearance of the scans without altering the results.
- 2. Auto Scale is only accessible when the pattern has been scanned in manual gain. When Auto Scale is selected, the pattern is adjusted to full scale as if it had been scanned in auto gain.
- 3. Smooth select and the Smooth window 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. Note that smoothing, in most cases, is not recommended. Smoothing does affect the results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing could affect small monoclonals.
- 4. Zoom use the slide bar to enlarge or reduce the pattern from 1x to 10x, in increments of 0.1. The final magnification is shown in red in the right bottom corner of the pattern.

- 5. *Image* the default setting is selected during *Test* setup (section 6.1.1) 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.
- a. To reset to the default setting, select Reset.

# 7.3.2.6. Input / Output

The sixth tab, *Input / Output* (Figure 7-18) allows for entering *Patient Info* and scan *Comments*, choosing *Auto Interpretation*, and access to the *Print*, *Export* and *Save* functions.

#### 7.3.2.6.1. Patient Info

- 1. Patient Info to enter or alter patient demographic information, select Patient Info. The Patient Information window displays and lists the demographic labels, including any test specific labels for the test in use, and any entered patient demographic information.
- 2. Use the buttons provided at the top of the window as needed to designate a demographic as *Normal* or *Abnormal*.
- 3. Use *Today* and *Yesterday*, as needed, to enter today or yesterday's date as a demographic.
- 4. To remove all of the displayed patient information, select *Clear* and select *Yes* in response to the *Alert* prompt.
- 5. When the information is as desired, select *Ok* and the *Edit Scan(s)* window displays.
- 6. To exit without entering or altering any patient information, select *Cancel*. If information was input, an *Alert* prompt displays. To exit to the *Edit Scan(s)* window without applying the changes, select *Yes*. To return to the *Patient Information* window, select *No*.

#### 7.3.2.6.2. Comments

- 1. Comments select, to add or edit comments to the scan, and the Add Comments window (Figure 7-19) displays.
- 2. Comments can be entered or edited using the keyboard.
- 3. To add a setup comment (section 6.5.1), select *Retrieve*. The *Retrieve Comment / Interpretation* window (Figure 7-20) displays.
- a. This window lists all the currently setup comments under *Available* and the high-lighted comment's contents to the right of the list.
- b. The top of the window, *Selected*, indicates which *Available* comments have been selected for inclusion.
- c. To select a comment, highlight the desired comment and select *Select*.
- d. Repeat as needed to include all the desired comments.
- e. Select *Ok* to return to the *Add Comment* window, which now includes the selected comment(s).
- f. To exit the *Retrieve Comment / Interpretation* window without selecting any comments, select *Cancel*.
- 4. To remove all currently entered comments, select *Clear* and in response to the *Alert* prompt, select *Yes.*
- 5. To apply the comments as displayed, select *Ok.*
- 6. To exit without changing the comments, select *Cancel*. If any comments have been added/altered, then an *Alert* displays. To exit without changing the comments, select *Yes*. To return to the *Add Comments* window, select *No*.

# 7.3.2.6.3. Auto Interpretation

1. Auto Interpretation - select to enable auto interpretation of scan results based on user-defined interpretations (section 6.5.1).

- 2. Pattern select and the Pattern Characteristic window (Figure 7-21) displays. The window contains None and any pattern characteristics setup for the test in use (section 6.5.1).
- a. Select the desired pattern characteristic and select *OK*.
- b. To exit without making a selection, select *Cancel*.

# 7.3.2.6.4. Print, Export and Save

- 1. *Print* functions the same from this window as from the main menu (section 7.2.4), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.
- 2. Export functions the same from this window as from the main menu (section 7.2.5), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.
- 3. Save functions the same from this window as from the main menu (section 7.2.6), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.

# 7.3.2.7. Restore

- 1. The seventh tab, *Restore* (Figure 7-22), allows for the last editing function performed to be undone or the scan to be returned to its non-edited state.
- 2. *Undo -* select to return the pattern to its appearance prior to the last editing function performed.
- 3. Restore select to return the pattern to its appearance prior to all editing. Editing may then need to be repeated.

# 7.3.2.8. Edit IFE Scans

- 1. For IFE scans, the *Edit Scan(s)* window (Figure 7-23) contains two tabs, *Appearance* and *Input/Output*.
- 2. An indicator bar appears over the scan to aid in viewing. To move the indicated bar up or down, use the mouse to place the white arrow on the indicator bar. Press and hold the button on the left side of the mouse. Move the mouse, which moves the indicator bar, to the desired location, and then release the button.

# 7.3.2.8.1. Appearance

- 1. Appearance the first tab (Figure 7-23), allows the setting defined in setup to be altered. Appearance affects only the displayed image of the scan and does not affect the results.
- a. Using the slide bar, set from *Lighter* to *Darker*, as needed.
- b. To reset to the setup settings, select *Reset.*

# 7.3.2.8.2. Input / Output

- 1. *Input / Output* the second tab (Figure 7-24) allows for entering Immuno Totals, Patient Info, and Interpretations, choosing Auto Interpretation, and access to the Print, Export, and Save functions.
- 2. *Immuno Totals -* select and *Immunoglobulin Totals* window displays:
- a. The window contains labels and the units of measure (for up to ten totals), all selected during test setup (section 6.1.1).
- b. Enter the totals, as needed, using the keyboard. Each total may be from 0.0 to 999999.0 total protein Immunoglobulin concentration.
- 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. *Patient Info* functions the same from this edit window as from non-IFE edit windows. For information, see section 7.3.2.6.
- 4. *Interpretation -* functions the same as *Comments* on non-IFE edit windows. For information see section 7.3.2.6
- 5. Auto Interpretation functions the same from this edit window as from non-IFE edit windows. For information, see section 7.3.2.6.
- 6. *Print* functions the same from this window as from the main menu (section 7.2.4), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.
- 7. Export functions the same from this window as from the main menu (section 7.2.5), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.
- 8. Save functions the same from this window as from the main menu (section 7.2.6), expect if Display Settings, Edit, Pathological is selected. The window still functions the same; however, only the scans that are outside of the reference range are accessible.

# 7.3.3. User Setup

See section six.

#### 7.4. Scan

# 7.4.1. Scan New Gel

- 1. 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.
- 2. If the gel is being scanned for the first time, 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 in 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.
- 3. Once the gel is in the scanner and a scan worklist is in use (section 7.2.1), to scan the gel either select *Scan* and *Scan New Gel* or select the *Scan New Gel* icon (the second icon).
- 4. If the worklist in use contains scan data, the window displays the message: "Worklist # is not empty. The worklist must be cleared before scanning can proceed. Clear the worklist and proceed? Yes No".
- a. Yes all the current patient information will be cleared and the gel will be scanned.
- b. No the main menu will display without the altering the contents of the worklist.
- 5. If Positive Patient ID is in use (section 6.6.1.1), the instrument requests the *Run ID*. Using a barcode reader, read the barcode label attached to the gel.
- 6. When a gel is scanned, the window displays "Scanning in Progress".
- 7. The window displays the position on the gel the scanner has scanned. The window

then displays the scans in the layout selected for the worklist in use.

# 7.4.2. Rescan Previous Gel

- 1. To rescan the gel and attribute it to the content of the current worklist, select *Scan* and *Rescan Previous Gel*.
- 2. The window displays "Scanning in Progress".
- 3. The window displays the position on the gel the scanner has scanned. The window then displays the scans in the layout selected for the worklist in use and includes the current content of the worklist.

# 7.4.3. Options/Scan Options

The scan parameters and/or 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 6.1.1.

- 1. Either select *Scan* and *Options* or select the *Scan Options* icon (the third icon). The *Scan Options* window (Figure 7-25) displays and 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).
- 2. Sequence can be altered by entering the sample positions needed, up to 32 characters, 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. The window will include either a. or b. as follows:
- a. Scan Aperture may be from 1 to 12, see section 9.6 for the measurement that corresponds to each aperture setting.
- b. Channel Width (mm) enter the numeric value of the channel width from 1 to 10.

This is not related to spacing, it represents the width of the pattern that will be displayed on the window and is analogous to an aperture size in a standard scan. No units need be entered into this field. The recommended channel width setting for Helena IFE gels is 4.

Channels per Sample - may be from 1 to 6.

# 4. 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.
- 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 autoscanned 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.

# 5. 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.

- 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 as long as it is scanned before the scans to which it will be used. 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 (section 7.3.1) and will need to be scanned prior to any sample for which it will be the overlay.
- 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 (section 7.3.1) and will need to be scanned prior to any sample for which it will be the overlay.

#### 6. Scan Tasks

- a. Auto Slope Correction select the software to automatically compare the scan baseline beginning and end and if they are different, the software automatically makes a slope correction so that they are the same. This is a helpful feature for use with hemoglobins. Do not select this feature for use on L/S tests.
- b. 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.
- c. *Edit* select to automatically display the scans in the Edit mode. If *Edit* is not selected, the Edit mode can be accessed at operator request.
- d. *Display Settings* select and the *Display Settings* window displays. Use this window to customize the appearance of the window displayed once scanning is complete and to customize the automatic actions in the Edit mode. See section 7.5.1 for additional information on this window.
- e. *Print* select to have reports print automatically. Whether or not *Print* is selected, reports can be printed at operator request. Most operators prefer to have reports print at their request.
- f. *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. See section 7.2.4.1 for additional information on this window.
- g. Export select to automatically export scans. Whether or not Export is selected, scans can be exported at operator request. Most operators prefer to export at their request.
- h. Export Settings select and the Export Settings window displays. Use this window to customize the export parameters used whether scans are exported automatically or at operator request. See section 7.2.5.1 for additional information on this window.
- i. Save select to save scans. Whether or not Save is selected, scans can be saved at operator request.
- 7. Scan Position to setup the scan begin and end positions and the sample to sample step over positions, proceed as follows:

- a. Open the scanner lid.
- b. 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.
  - c. Close the lid.
- d. Select *Update Image*. The scanner will scan the gel and "Scanning in Progress" displays. An image of the gel displays under *Scan Positions*. 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.
- e. 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.
- f. Once these lines are set they should almost never require altering. 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 a row.
- g. The QuickScan software will use the position of these lines to automatically calculate the space between each sample.
- 8. *Reset* select to reset any altered parameters to the setup settings.

- 9. Cancel select to exit the window without altering any parameters.
- 10. *Ok* select to exit the window and implement any alterations.
- 11. To rescan using the adjusted parameters, see section 7.4.2. If adjustments fail to produce acceptable scans, confirm that rescanning was performed within the time parameters given in the procedure supplied with the gel kit. Repeat the scan position adjustment steps within this section. If scans remain unacceptable, contact Helena Laboratories for assistance.

#### 7.4.4. QC

- 1. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, either select *Scan* and *QC* or select the *QC* icon (the thirteenth icon). The *QC* window (Figure 7-26) displays.
- 2. Scan select to QC using the NDDC/OD Step Tablet. The message "Place the QC Plate in the scanner, click 'OK' to continue" displays.
- a. 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.
- b. Select *OK* and "Scanning in Progress" displays.
- c. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup.
- d. 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, on the Epson Expression scanners model numbers 800, 1600, and 1680, at least 8 steps or, on the Epson Perfection scanners, model numbers 4870, 4990, & V700 at least 7 steps.
  - e. If the results are not acceptable:

- i. 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.
- ii. clean all the glass surfaces in the scanner with a standard glass cleaner and a lint free tissue. Repeat the scan.
- iii. optics alignment or instrument servicing may be required. Contact Helena Laboratories for assistance.
- 3. Print is available with a QC 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 QC results (see Figure 13-7 for an example of a QC printout). Select Cancel to exit without printing. It is recommended that a permanent record of the QC results be kept.
- 4. *History* select to access previous QC results. The availability of previous QC results is dependent upon selections made in setup (section 6.8.1). The *QC History* window (Figure 7-27) displays. The list of QC 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 select and the QC window displays containing the selected QC.
- b. *Print* use to print a report containing all previously run QC (Figure 13-8). 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. 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.

- c. *Delete* use 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.
- d. Cancel select to exit the QC History window.
- 5. To exit the *QC* window select the **X** located on the top right of the window.

#### 7.5. View

# 7.5.1. Display Options/Set Display Options

- 1. Either select *View* and *Display Options* or select the *Set Display Options* icon (the seventh icon). The *Display Settings* window (Figure 7-28) displays. This window allows for the display parameters for the indicated worklist to be temporarily altered.
- 2. *Preview* choose *No*, to review scans one at a time, or choose *6*, *9*, *15*, *20*, *30*, *60*, or *100* to view the selected quantity of scans at once. The selection applies to viewing when not in Edit mode.
- 3. *Edit* is not available for a scan worklist with an IFE test selected. Select one of the following:
- a. All select to have all the scans accessible in the Edit mode.
- b. *Pathological* select to have only the scans that fall outside of preset parameters, such as normal ranges or number of fractions, accessible in the Edit mode.
- 4. 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 7.3.1).

- c. Patient 1 select to have a patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- d. *Patient 2* select to have a second patient's scan overlaid on the current scan (section 7.3.2.4 or 7.9.3).
- 5. 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.
- 6. 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
- 7. Cancel select to exit the window without altering the display settings.
- 8. *OK* select to exit the window and implement any altered display settings.

# **7.5.2. Error Log**

- 1. Select *View* and *Error Log.* The *Error Log* window displays.
- 2. *Print* select to print the displayed error log.
- 3. *Clear* select to delete the displayed error log.
- 4. To exit the window, select the **X** on the top right of the window.

#### **7.5.3. Trace Log**

1. Select View, Trace Log and either Communication Port 1 or Communication Port 2.

The appropriate *Port Trace Log* window displays.

- 2. *Print* select to print the displayed trace log.
- 3. *Clear* select to delete the displayed trace log.
- 4. To exit the window, select the **X** on the top right of the window.

# 7.5.4. Memory Status

- 1. Select *View* and *Memory Status*. The *Memory Status* window displays.
- 2. The window displays the percent or byte information for *Memory Used*, *Total Physical Memory*, *Available Physical Memory*, *Total Virtual Memory*, and *Available Virtual Memory*.
- 3. Ok select to exit the window.

#### 7.5.5. OS Information

- 1. Select *View* and *OS Information*. The *Memory Status* window displays.
- 2. The window displays the name, version information and *Service Pack* number of the operating system in use.
- 3. Ok select to exit the window.

### 7.6. Windows

#### **7.6.1. Cascade**

With multiple worklists restored and/or maximized, to display the worklists in overlapping windows, select *Windows* and *Cascade*.

### 7.6.2. Tile

With multiple worklists restored and/or maximized, to display all the worklists at once, select *Windows* and *Tile*.

# 7.6.3. Arrange Icons

This feature is not available on this software.

#### 7.6.4. Close All

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

# 7.6.5. List of Open Worklists

With multiple worklists open, to select a worklist for use, select *Windows* and click on the desired worklist. Note that the numbers on the left attributed to each worklist represent the order in which the worklists were open. To access all the open worklists at once, use either the *Cascade* (section 7.6.1) or *Tile* (section 7.6.2) features.

# 7.7. Help

#### 7.7.1. About

- 1. Either select *Help* and *About* or select the *About* icon (the last icon). A window displays 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.
- 3. OK select to exit the window.

#### 7.8. Arrows

- 1. With a worklist open containing more than one scan, the arrow icons are available. Use these icons to assist in moving through the scans contained within the worklist in use.
- 2. The accessibility of each arrow icon at any given time depends on which scan within the worklist is currently displayed.
- 3. The icons appear in order from left to right on the window as discussed below:
- a. *First* select to return to the first scan in the worklist.
- b. *Previous* select to return to the scan viewed immediately prior to the currently displayed scan.

- c. Go To allows a specific scan to be displayed. Select Go To and the Worklist --Go To window displays. This window lists all the scans within the worklist in use and includes the name of the test, the sample number, the date and time scanned, 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.
- i. Ok with the desired scan highlighted, select and the indicated scan is displayed.
- ii. Cancel select and the window returns to the currently displayed scan.
- d. *Next* select to go to the scan immediately following the currently displayed scan.
- e. *Last* select to go to the last scan in the worklist.

# **7.9. Tips**

# 7.9.1. Scanning

- 1. Prior to entering new patient data, clear the contents of the worklist in use (section 7.2.7).
- 2. To remove water spots on the gel, use an alcohol prep pad or water and wipe off the back of the gel.
- 3. Positioning gels on the scanner:
- a. 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. This places the first sample on the right side.
- b. 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.

- c. If needed the gel may be taped down to the scanner bed to make it lie flat.
- 4. 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.

# 7.9.1.1. Edit Pathological

- 1. With Edit Pathological in use, when in the edit mode, only those scans which are outside the reference ranges are accessible for printing, exporting, and saving. To perform any of these activities on all the scans within a worklist regardless of their results, use the print, export, and save functions accessible through the main menu (sections 7.2.4, 7.2.5, and 7.2.6).
- 2. With Edit Pathological in use, using the auto interpretation feature (section 6.5.1) to include interpretations on patterns which fall within the reference ranges may be helpful.
- 3. Because Edit Pathological restricts access in the edit mode to scans that fall outside the reference ranges, it is not recommended that Edit Pathological be used for scans that are to be additionally interpreted based on appearance.

# 7.9.1.2. Reference Ranges and Reference Overlays

- 1. 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.
- 2. 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.

- 3. 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.
- 4. 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 7.4.3).

# 7.9.1.3. Editing

- 1. The best guide to the interpretation of scans, especially scans with results which are out of range, is to visualize the gel.
- 2. Noise is best corrected in the edit mode using the delete area feature and not by smoothing.
- 3. Do not use smoothing unless the procedure recommends. Smoothing does affect the results. Increasing the smoothing level decreases the background noise and lowers smaller fractions. Smoothing could affect small paraprotein spikes.
- 4. To allow for reviewing prior to printing and exporting, it is recommended that neither Print nor Export be setup as automatic worklist tasks (section 6.2.1) but instead that printing/exporting be operator initiated (sections 7.2.4 and 7.2.5).

#### 7.9.1.4. Urine and Serum Proteins

1. Gels containing both urine and serum protein samples can be scanned on the QuickScan. Setup the tests and worklists for urine proteins and for serum proteins. Open and clear the serum protein worklist, enter the applicable patient information, use Scan

Options to specify the sequence of the serum protein samples on the gel, and scan the gel. Then, without moving the gel, open and clear the urine protein worklist, enter the applicable patient information, use Scan Options to specify the sequence of the urine protein samples on the gel, and scan the gel.

- 2. 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.
- 3. Tests setup to scan Titan Gel serum proteins should be set to use Acid Blue instead of Amido Black in order to obtain results with the best correlation to other Helena densitometers.

# 7.9.1.5. Cholesterol profiles

1. Cholesterol profile scans using the auto edit feature should be reviewed and can be manually edited as needed.

#### 7.9.1.6. QuickGel

1. For QuickGel IFE gels, Test Setup must include the following: Test Properties - Rows per Gel set to 4; Sample Applications per Row set to 3. Scan Setup - Channel Width set to 6; Channels per Sample set to 6; Scan Positions set the four sets of scan position lines so that the lines identified as A are located on the top, left and define channels one thru three for sample one, B are located on the top, right and define channels four thru six for sample one, C are located on the bottom, left and define channels one thru three for sample two, and D are located on the bottom, right and define channels four thru six for sample two.

2. 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 Scan Options window to alter the sequence of samples scanned.

#### 7.9.1.7. Fetal Tek

- 1. Fetal Tek plates can only be scanned on the Epson Expression models 800, 1600, 1680, and the Perfection V700. They cannot be scanned on the Epson Perfection 4870 or 4990 scanners.
- 2. When scanning Fetal Tek plates, because it is difficult to see the lines through the silica, it is recommended that the scan begin and end positions be marked on the plate with a marker in the glass area on either side. Then place the marked plate so that the preadsorption area is on the left of the scanner with the silica layer facing up so that the first sample is in the proper position. Place the green scanbegin line to the right of the second major band, which is Sphingomyelin (S) and the red scan-end line on the preadsorbant side of the first large band, which is Lecithin (L).
- 3. Do not use the auto slope correction feature with Fetal Tek plates. Studies have shown that a badly charred plate cannot be salvage through editing due to the unevenness of background charring. If the control samples are out of range, the plate should be recharred or rerun.

# 7.9.1.8. IFE

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

# 7.9.1.9. Hemoglobins

1. Auto slope correction is recommended when scanning Hemoglobins (sections 6.1.1.2.2 and 7.4.3) because the HbA2 accuracy is improved.

2. Smoothing is not recommended when scanning Hemoglobins.

# 7.9.2. Why My Scans Are Displayed This Way and How to Change Them

# 7.9.2.1. One Scan At A Time Displayed

- 1. If *Display Settings Preview No* is selected for the worklist currently in use, only one scan will display on the window at a time.
- 2. To move from one scan to another use the arrow icons described in section 7.8.
- 3. To change the display to display multiple scans, see section 7.5.1. To change the worklist display default, see section 6.2.1.

# 7.9.2.2. Multiple Scans Displayed

- 1. If *Display Settings Preview 6* through *100* is selected for the worklist currently in use, the selected quantity of scans will display on the window.
- 2. To view an individual pattern, double click on the desired pattern. The window displays the indicated scan in the *Edit Scan(s)*window. To return to the window displaying the entire selected quantity of scans, select the **X** on the top right of the window.
- 3. If the quantity of scans set to display is less than the quantity of samples scanned, use the arrow icons described in section 7.8 to move between the windows of scans.
- 4. When multiple scans are displayed, they are color coded to indicate status if reference ranges are in use. 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 fractions 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 fraction is out of range.

5. To change the quantity of scans currently displayed, see section 7.5.1. To change the worklist display default, see section 6.2.1.

# 7.9.3. Patient Overlays

- 1. Patient overlays can be quickly designated from one open worklist to another or from within the same worklist, even before the scans have been saved. Using the following steps, the indicated patient overlay will automatically be attributed as Patient 1 unless a Patient 1 overlay has been previously indicated. In which case, the overlay will then be attributed as Patient 2.
- 2. The worklist(s) to be used must be displayed in the *Preview* mode and not in the *Edit Scan*(s) mode. Note that IFE scans can be used as patient overlays using the following steps; however, patient overlays cannot be attributed to IFE scans.
- 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*.
- 4. 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.
- 5. To confirm the overlay was applied, view the scan in the *Preview No* display setting. With the scan receiving the patient overlay displayed, the overlay scan is indicated on the window under the word *Overlay* (s) located under the scan. Depending on the *Display Settings* in use, a *Patient 1* overlay appears is magenta and a *Patient 2* in yellow. If an IFE scan is overlaid, the IFE scan appears under the list of *Overlay*(s).

# 7.9.4. How To Print a Serum Protein and IFE Scan On One Report

- 1. Designate the desired IFE scan as the patient overlay for the desired Serum Protein scan (section 7.3.2 or 7.9.3).
- 2. Select *Print* and see section 7.2.4 for information on printing. Select a report setup to print overlays, for example the preprogrammed *IFE Overlay* report.
- 3. When the Serum Protein scan is printed, the IFE image will appear on the report as specified by the report used (Figure 13-5).

#### 7.10. 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.

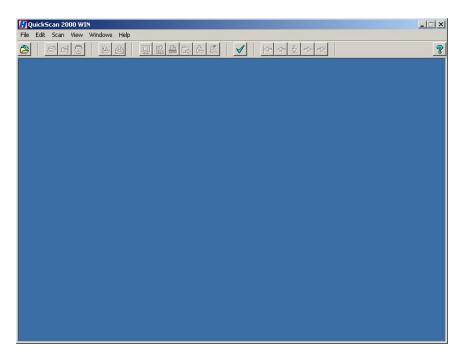


Figure 7-1. Main Menu

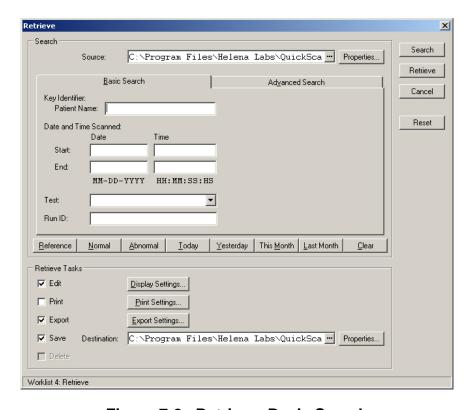


Figure 7-2. Retrieve, Basic Search

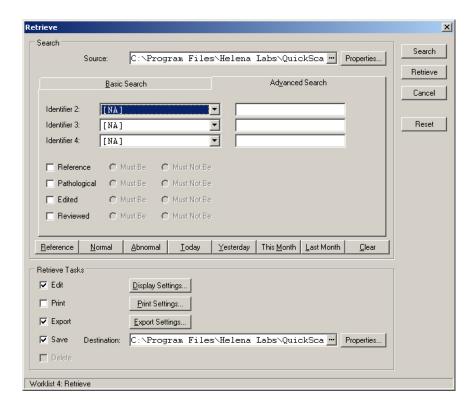


Figure 7-3. Retrieve, Advanced Search

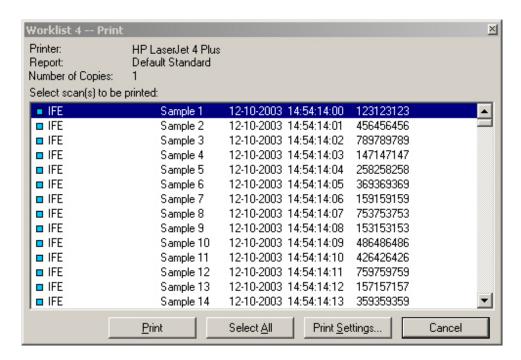


Figure 7-4. Worklist - Print

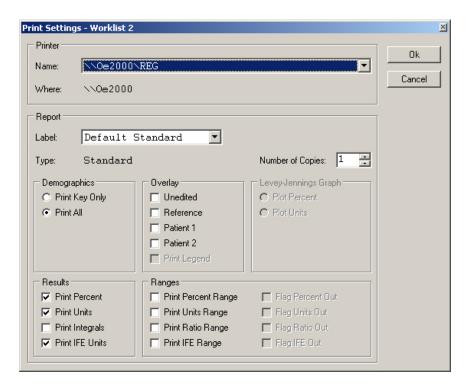


Figure 7-5. Print Settings

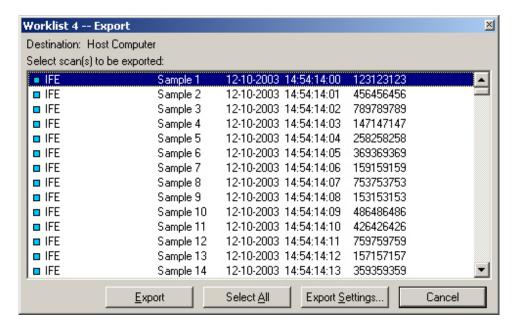


Figure 7-6. Worklist - Export

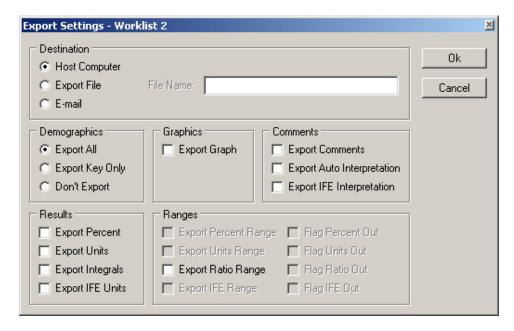


Figure 7-7. Export Settings

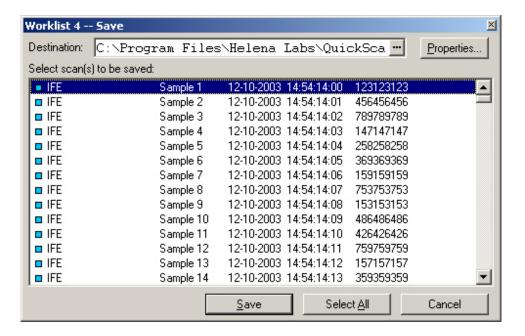


Figure 7-8. Worklist - Save

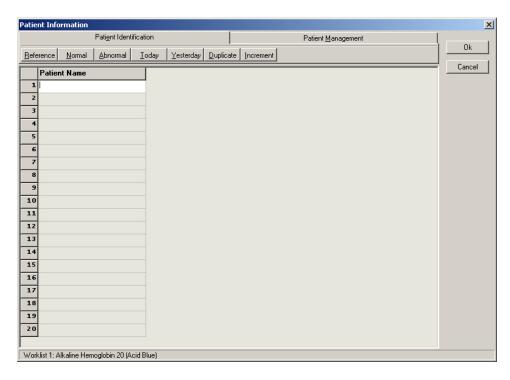


Figure 7-9. Patient Information, Patient Identification

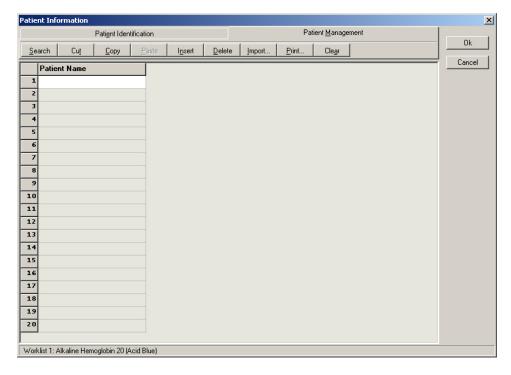


Figure 7-10. Patient Information, Patient Management

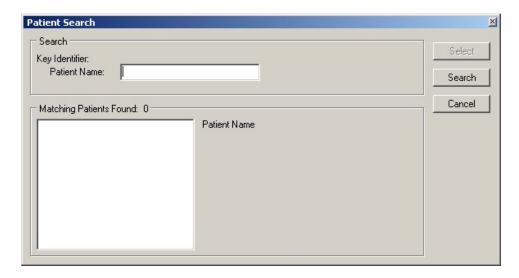


Figure 7-11. Patient Search

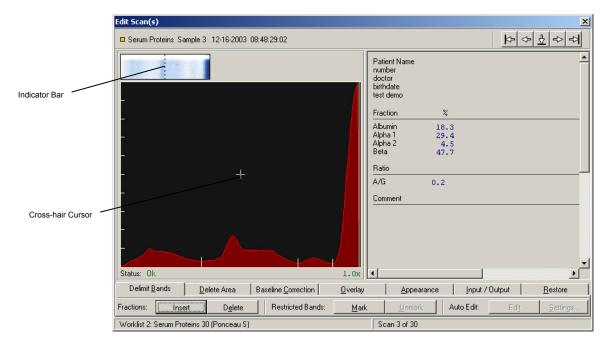


Figure 7-12. Edit Scan(s), Delimit Bands

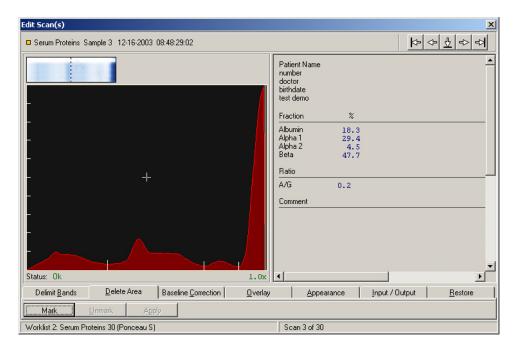


Figure 7-13. Edit Scan(s), Delete Area

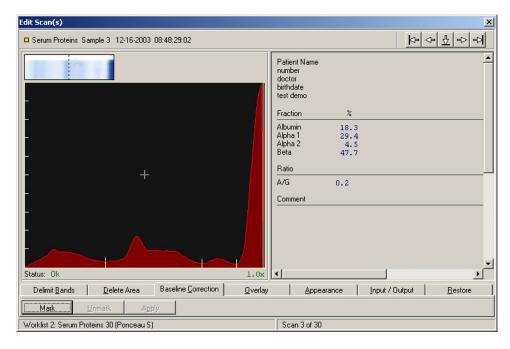


Figure 7-14. Edit Scan(s), Baseline Correction

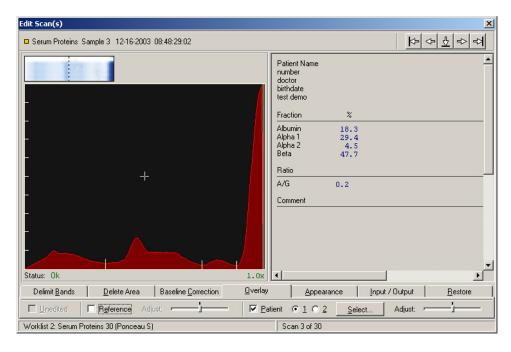


Figure 7-15. Edit Scan(s), Overlay

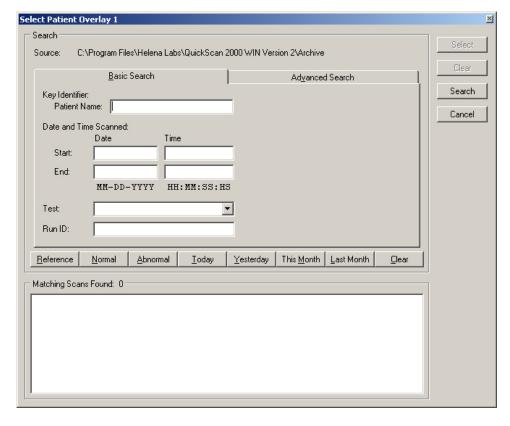


Figure 7-16. Select Patient Overlay

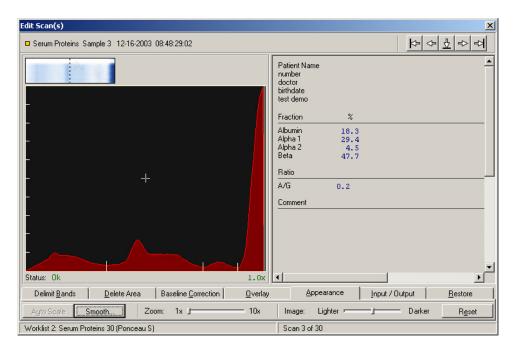


Figure 7-17. Edit Scan(s), Appearance

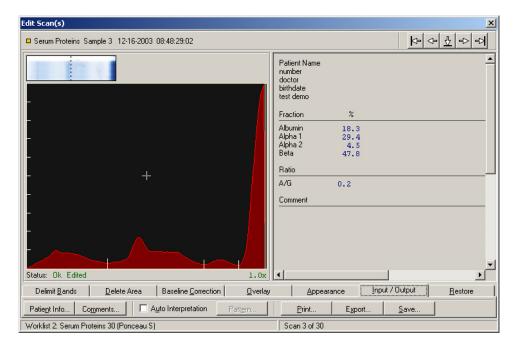


Figure 7-18. Edit Scan(s), Input/Output



Figure 7-19. Edit Scan(s), Input/Output, Comments

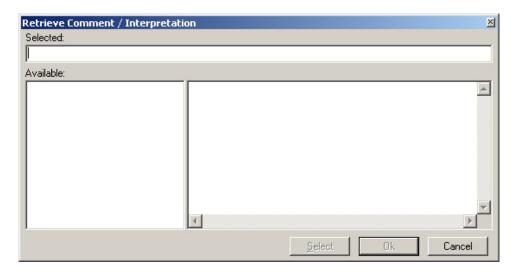


Figure 7-20. Retrieve Comment/Interpretation

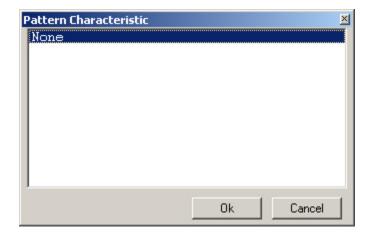


Figure 7-21. Pattern Characteristic

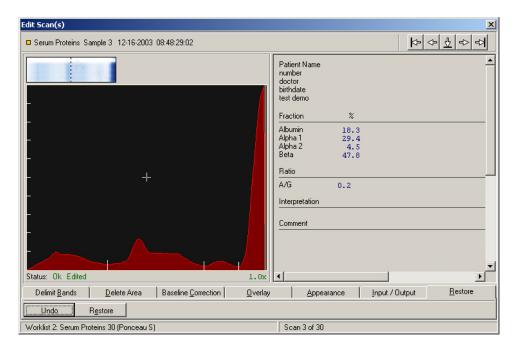


Figure 7-22. Edit Scan(s), Restore

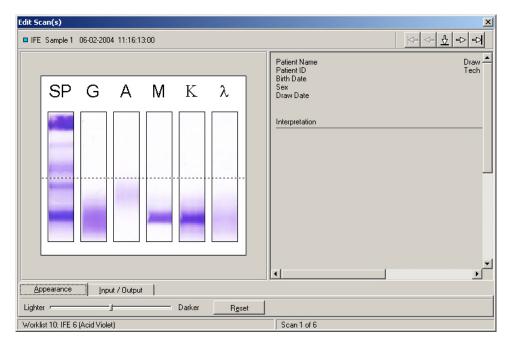


Figure 7-23. IFE Edit Scan(s), Appearance

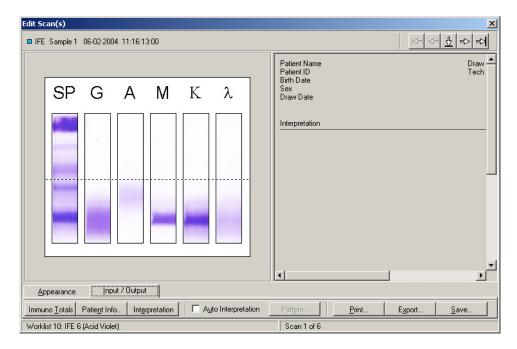


Figure 7-24. IFE Edit Scan(s), Input/Output

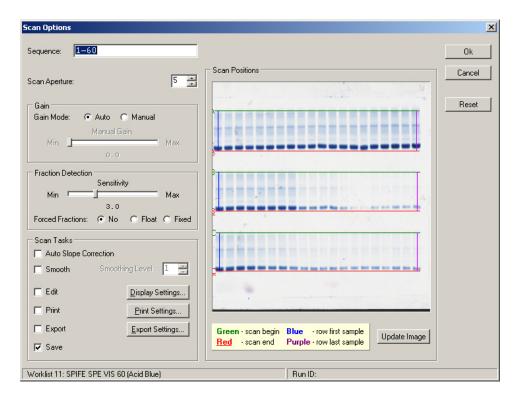


Figure 7-25. Scan Options

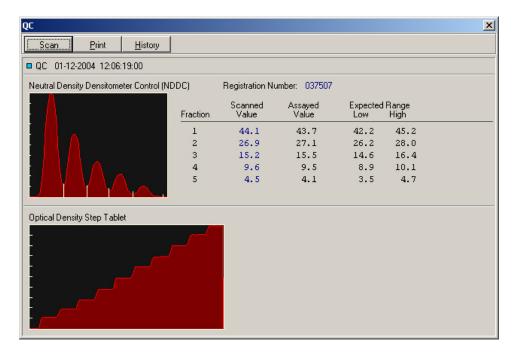


Figure 7-26. QC

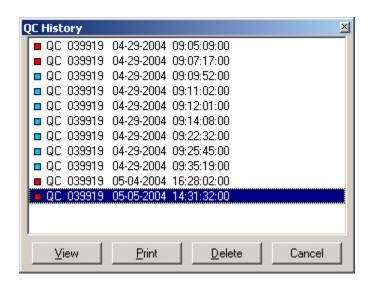


Figure 7-27. QC History

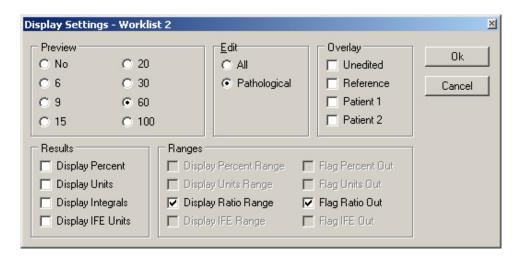


Figure 7-28. Displays Settings

# **Section 8 - Test Functions and Quality Control**

#### 8.1. Tests

The instrument automatically performs a selftest any time the power is turned on. Should an error message appear on the display, see section 10.2.

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

# 8.2. Quality Control

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

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

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

#### 8.3. Instrument Performance Check

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

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

A list of the quantitative ranges for the NDDC bands should have been entered during QC setup, see section 6.8.1. The quantitation for the five bands is compared to the entered data. Unacceptable results for the 5 bands

are indicated by a plus or minus on the display and report.

- 1. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, either select *Scan* and *QC* or select the *QC* icon (the thirteenth icon). The *QC* window (Figure 7-26) displays.
- 2. Scan select to QC using the NDDC/OD Step Tablet. The message "Place the QC Plate in the scanner, click 'OK' to continue" displays.
- a. 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.
- b. Select *OK* and "Scanning in Progress" displays.
- c. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup.
- d. 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, on the Epson Expression scanners model numbers 800, 1600, and 1680, at least 8 steps or, on the Epson Perfection scanners, model numbers 4870, 4990 and V700, at least 7 steps.
  - e. If the results are not acceptable:
- i. 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.
- ii. clean all the glass surfaces in the scanner with a standard glass cleaner and a lint free tissue. Repeat the scan.
- iii. optics alignment or instrument servicing may be required. Contact Helena Laboratories for assistance.
- 3. Print is available with a QC 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 QC results (see Figure 13-7 for an example of a QC printout). Select *Cancel* to exit without printing. It is recommended that a permanent record of the QC results be kept.

- 4. *History* select to access previous QC results. The availability of previous QC results is dependant upon selections made in setup (section 6.8.1). The *QC History* window (Figure 7-27) displays. The list of QC 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 select and the QC window displays containing the selected QC.
- b. *Print* use 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. 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 (Figure 13-8), and the display returns to the *QC History* window. Select *Cancel* to return to the window without printing.
- c. *Delete* use 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.
- d. Cancel select to exit the QC History window.
- 5. 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, 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), Auto Interpretation, Combine Split Beta, Test Specific Demographics, Channel Width, Scan Positions, Fraction Labels and Ratios, Ratio Labels and Limits, Restricted Band Label, and Reference Ranges.

# **Display Parameters:**

Display Scans, Overlay, Edit, 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, List and Statistics 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.

# **Additional User-Programmable Selections:**

System Demographic Labels, Comments and Interpretations, E-Mail, QC, Date and Time, Printer, and Password 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

# **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:

 $\leq$  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 2000 WIN 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 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, and whether or not to save test data automatically for every run.

## 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, 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 up to 10 demographic labels (such as Patient Name, ID Number, Patient Age, Patient Sex, etc.).

# 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.

# 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, deleting an area from the pattern, baseline adjustment, overlaying an unedited pattern on a edited pattern, overlaying other patient patterns, and smoothing a pattern.

#### 9.4. File Retrieval

Determine what information the computer will search for when retrieving files. The selections are similar to Patient Demographics.

# 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.

# 9.6. Densitometer Specifications

Scanning Parameters:

Gain: Automatic or Manual

Over range: > 100% of full scale

Optics Mode:

Visible Transmittance (white light)

# Aperture Sizes (mm):

- 1 1 x .1
- 2 2 x .2
- 3 3 x .3
- 4 4 x .4
- 5 6 x .6
- 6 7 x .7
- 7 8 x .8
- 8 2.5 x .25
- 9 5 x .1
- 10 5 x .25
- 11 5 x .5
- 12 12.18 x 12.18

Scan Length:

Variable from 0.01 to 221.5 mm

Zeroing:

Automatic

Light Source:

Cold Cathode Fluorescent (white light)

Light Detectors:

CCD Array

## Optical Density Linearity:

0.05 to 3.05 OD - Epson Expression scanner models 800, 1600, 1680 and Perfection model V700

0.05 to 2.3 - Epson Perfection scanner models 4870 and 4990

# Operating System:

\*Microsoft® Windows® 2000 or Windows® XP

# 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 2000 WIN 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 2000 WIN 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.

# 10.2. Troubleshooting

When using the QuickScan 2000 WIN 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.
Error message Invalid floating point operation appears and program closes	If the Combine Split Beta feature in use, then missing or incorrect Beta label	Label a Fraction/Ratio as "Beta" (section 6.1.1.2.1 step 7) and rescan gel.
Power switch on, no power	Power cord not plugged in	Plug in power cord.
	Bad wall outlet	Use another outlet.
No display (dark screen)	Brightness turned down	Turn up brightness on display, see monitor owner's guide.
	Display power switch off	Turn on display power switch.
No presentation on display	Loose interface or power cable	Push cable connections in fully.
	Defective interface cable	Call Helena Laboratories.
No printout is produced	Did not select Print	Select Scan Options, select Print, select a Printer, a Report, Number of copies, and OK.
	Loose interface cable	Push cable connections in fully.
	Paper installed improperly	Reinstall paper.
	Defective interface cable	Replace cable.
	Improper printer setup	Refer to printer owner's guide for settings.
	Printer off-line but printout requested	Leave printer on-line during operation.
Poor quality printout	Needs toner/ink	Replace toner/ink cartridge.
	Other problem	Refer to printer owner's guide.
No response to keystrokes or mouse movement	Cable disconnected	Firmly insert keyboard or mouse plug into receptacle on back of computer.
	Undetermined cause	Press Alt-Ctrl-Del key to reset program (unsaved data will be lost).
		Call Helena Laboratories.
No fraction marks on patterns	Float or Fixed Fraction detection in use	Put Reference as key identifier and/or scan first
Control and/or NDDC out of range	Power surge	Call Helena Laboratories.
Invalid floating point error	Scan begin/end not in the same order on all rows	Reset scan begin/end lines (section 6.1.1.2.2).
Scan image and scan lines (begin/end and step-over lines) do not line up	Incorrect scanner selected in setup	Select the correct scanner (section 6.9).

# 10.3. Warranty

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies. In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. 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 2000 WIN for any purpose other than that described in this manual. Modification of the software or the use of the QuickScan 2000 WIN 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.

A	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
<u> </u>	Caution, general hazard - see Precautions and Hazards (Sections 3 and 4) of Operator's Manual before proceeding
===	Direct current
$\sim$	Alternating current
$\sim$	Both direct and alternating current
<u></u>	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
<b>—</b>	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 2000 WIN import/export interface conforms to the EIA standard RS-332C and is configured as a DTE (Data Terminal Equipment). Only RECEIVE DATA, TRANSMIT DATA and SIGNAL COMMON lines are used. The baud rate is user selectable at 1200, 2400, 4800, 9600 10400, 14400, 19200, or 28800 baud. The number of data bits may be set at 7 or 8 and the number of stop bits may be either 1 or 2. Parity may be set to none, even odd, mark, or space. Protocol options include no protocol, XON-XOFF flow control, or ASTM protocol. The QuickScan 2000 WIN 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

<sup>\*</sup>only these lines are used by the QuickScan 2000 WIN software.

#### COMMUNICATIONS PROTOCOL:

The protocol used by the QuickScan 2000 WIN 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 Quick Scan 2000 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) hand-shaking is used to control data flow. When importing, the QuickScan 2000 WIN software will transmit an XOFF character when it's communications buffer becomes three quarters full. Data transmission should stop at this point. The QuickScan 2000 WIN 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 2000 WIN 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 2000 WIN 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 2000 WIN 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, 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 2000 WIN 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 2000

WIN 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 2000 WIN 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 2000 WIN: 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 shall be case insensitivity.

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 Quick-Scan 2000 WIN transmits a header record it will have the following format:

H|\^||HELQS2000|hospital ID^QuickScan 2000 WIN ^Version n.nn|address||telephone<CR>

HELQS2000 Password indicating the sending instrument is a Helena QuickScan 2000 WIN

hospital ID - Hospital or laboratory name. This field will be a maximum of 42 characters.

*n.nn* - QuickScan 2000 WIN software version number

address - Hospital or laboratory address. This field will be a maximum of 42 characters.

*telephone* - Hospital or laboratory telephone number. This field will be a maximum of 42 characters.

When the QuickScan 2000 WIN receives a header record it only considers the first two characters to be significant, all other characters up to the carriage return will be ignored. Therefore, the minimum characters the computer system needs to transmit for the header record would be:

H|<CR>

# 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, see section 6.6.1.

# **Graph Data Record**

The QuickScan 2000 WIN will transmit the graph data in the following format:

M|1|test name|yyyymmddhhmmsshs|ndata^ $d_1,d_2,d_3,...d_{ndata}$ |nfractions^ $f_1,f_2,f_3,...f_{nfraction}$ |nms pikes^: $m_{11}$ : $m_{12}$ : $m_{21}$ : $m_{31}$ :  $m_{32}$ <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 2000 WIN 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|||^^^test name<CR>

test name - Name of the test performed.

The QuickScan 2000 WIN 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.nnnnnnnnn|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 2000 WIN does not recognize result records transmitted by the computer system.

## Comment Record

The QuickScan 2000 WIN will transmit comment records in the following format:

C|1|I|line 1|line 2| ... |line 10<CR>

line - One line of the user entered comments. There can be a maximum of 10 lines, each line a maximum of 76 characters.

The QuickScan 2000 WIN does not recognize comment records transmitted by the computer system.

#### Request Information Record

The QuickScan 2000 WIN can transmit a request to import patient demographics. This request must be user initiated. The format will be as follows:

Q|1|patient ID<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 2000 WIN 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 2000 WIN transmits a terminator record it will have the following format:

# L|1|<CR>

When receiving a terminator record, the QuickScan 2000 WIN only considers the first character significant, all other characters up to the carriage return will be ignored.

## **Section 13 - Reports**

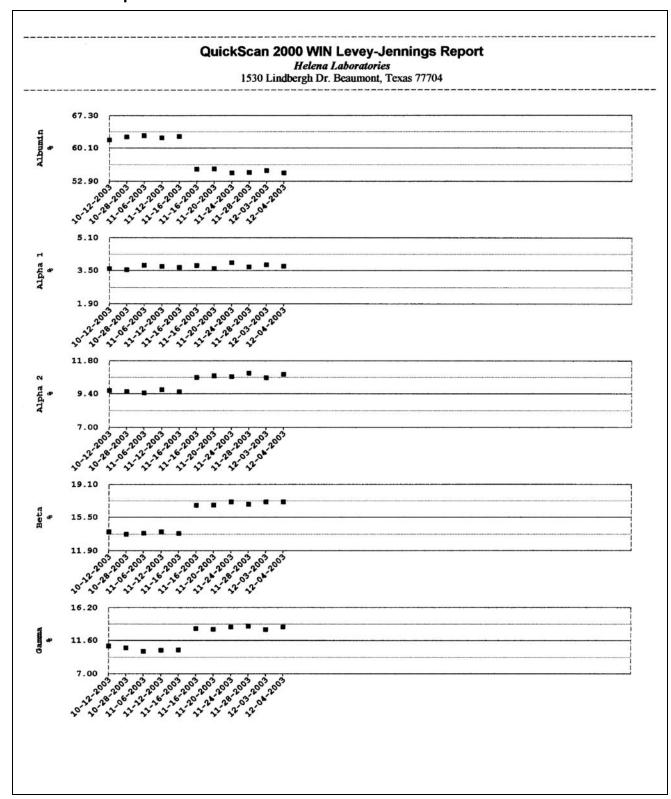


Figure 13-1. Levey-Jennings Report

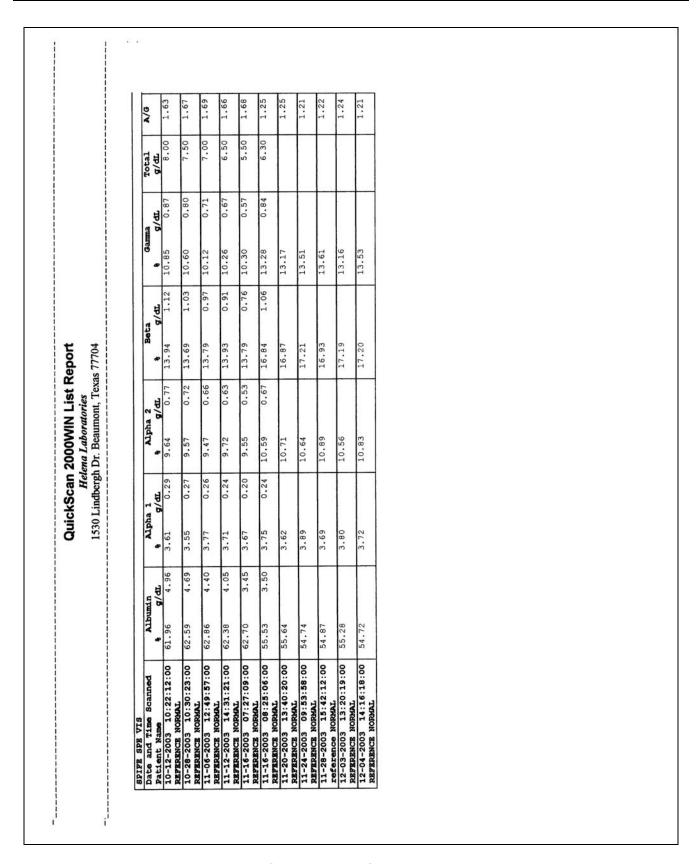


Figure 13-2. List Report

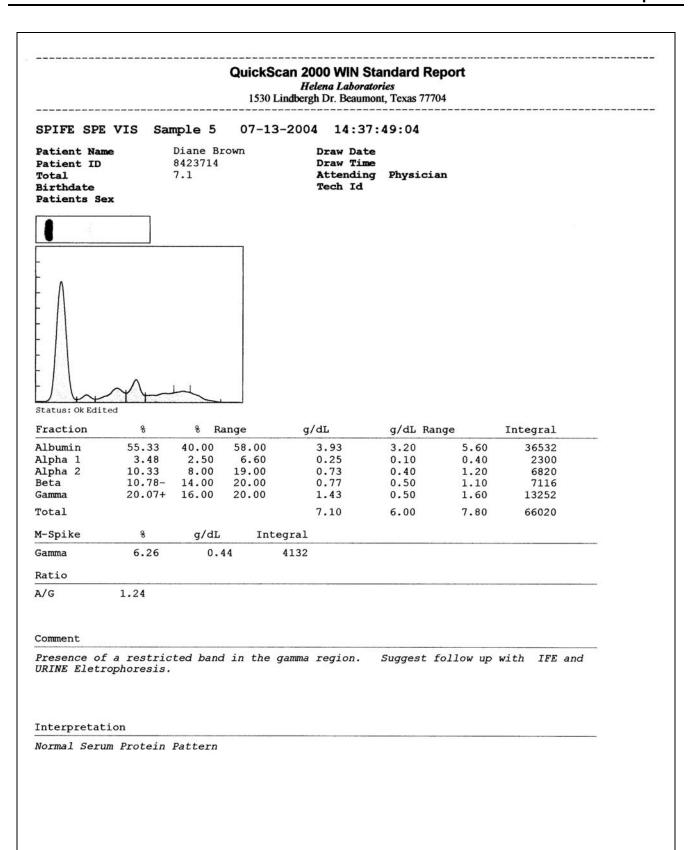


Figure 13-3. Standard Report

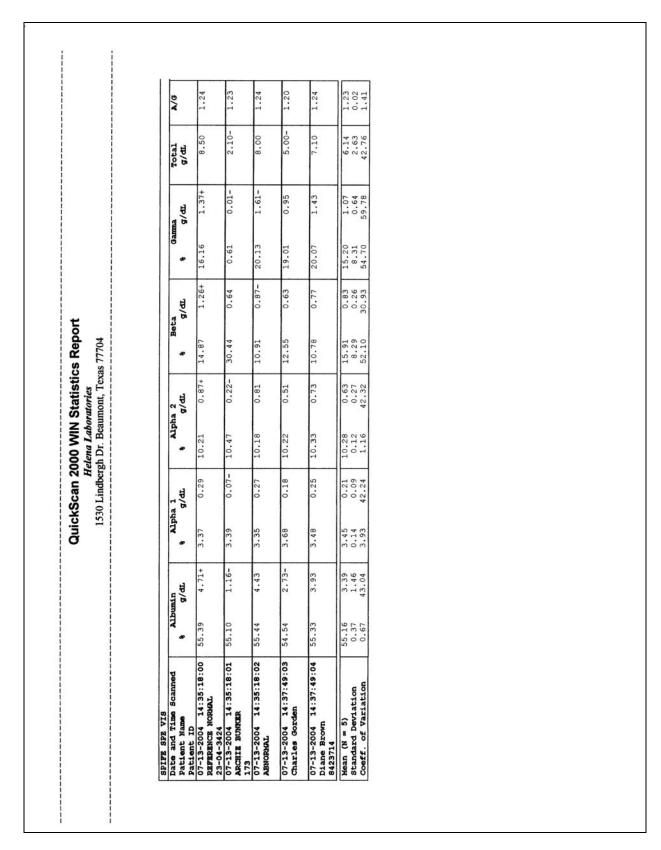


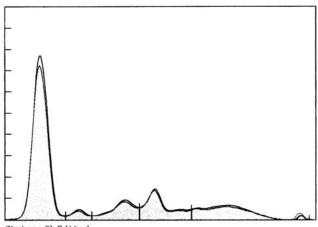
Figure 13-4. Statistics Report

# QuickScan 2000 WIN IFE Overlay Report

Helena Laboratories

1530 Lindbergh Dr. Beaumont, Texas 77704

#### SPIFE SPE VIS Sample 2 07-13-2004 14:35:18:01



Patient Name ARCHIE BUNKER
Patient ID 173
Total 2.1
Birthdate 12/12/1982
Patients Sex F
Draw Date

Draw Time

Attending Physician Dr. Ellerbrook

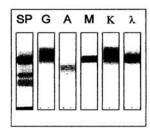
Tech Id

Status: Ok Edited

Fraction	8	g/dL	g/dL Range	•	
Albumin	55.10	1.16-	3.20	5.60	
Alpha 1	3.39	0.07-	0.10	0.40	
Alpha 2	10.47	0.22-	0.40	1.20	
Beta	14.85	0.31-	0.50	1.10	
Gamma	16.20	0.34-	0.50	1.60	
Total		2.10-	6.00	7.80	
Comment					

Presence of a restricted band in the gamma region. Suggest follow up with  $\it IFE$  and  $\it URINE\ Eletrophoresis$ .

#### IFE Sample 1 12-15-2003 07:27:26:00



	g/dL	g/dL	Range	
Total Protein	7.0			
Immunoglobulin	mg/dL	mg/dI	Range	
IgG	16.9+	8.0	16.0	
IgA	0.6	0.4	2.2	
IgM	0.8-	1.2	4.0	

Interpretation

His total protein does not reflect this pattern.

Figure 13-5. IFE Overlay Report

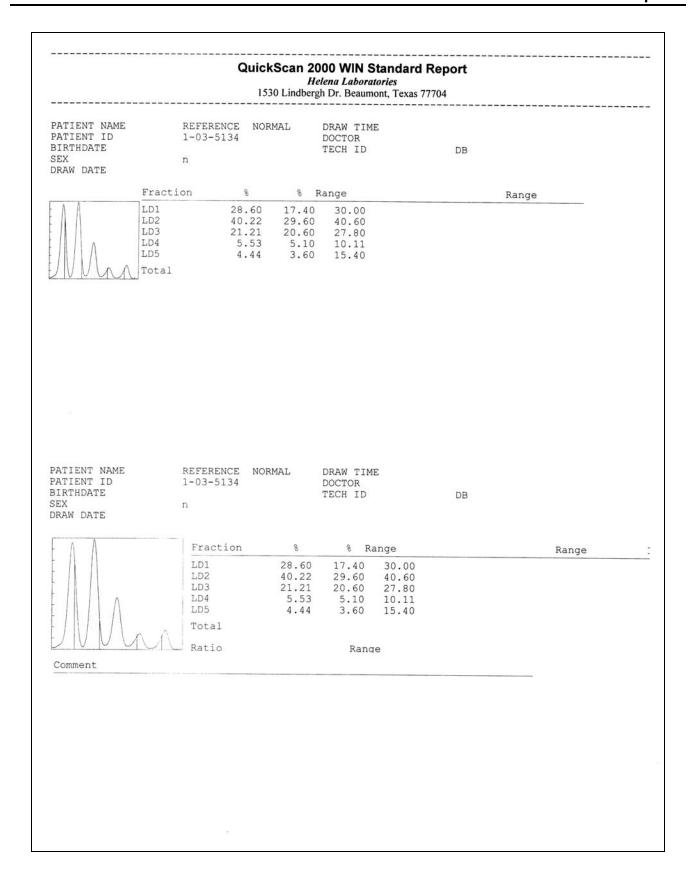


Figure 13-6. Two-Scan Standard Report

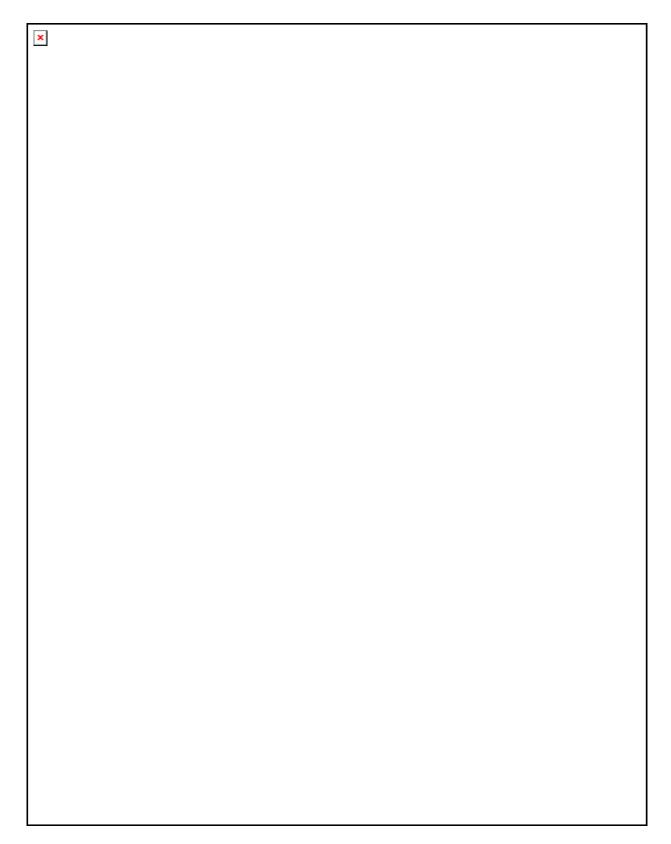


Figure 13-7. QC Results

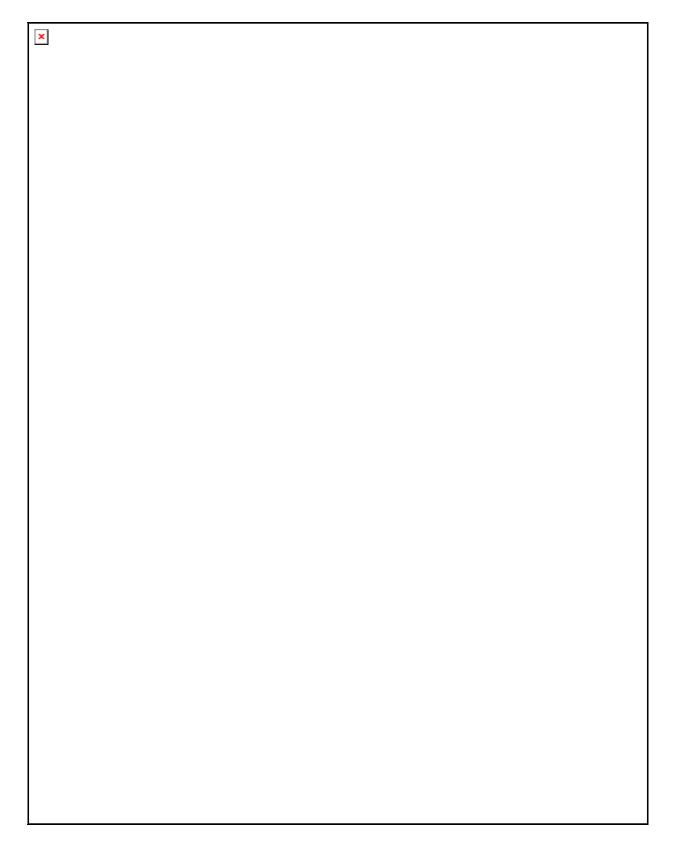
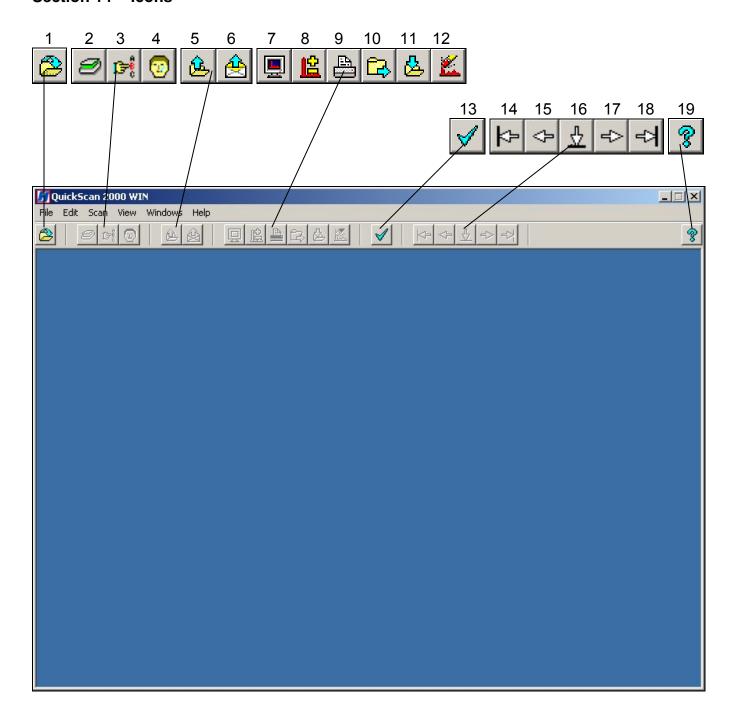


Figure 13-8. QC History Report

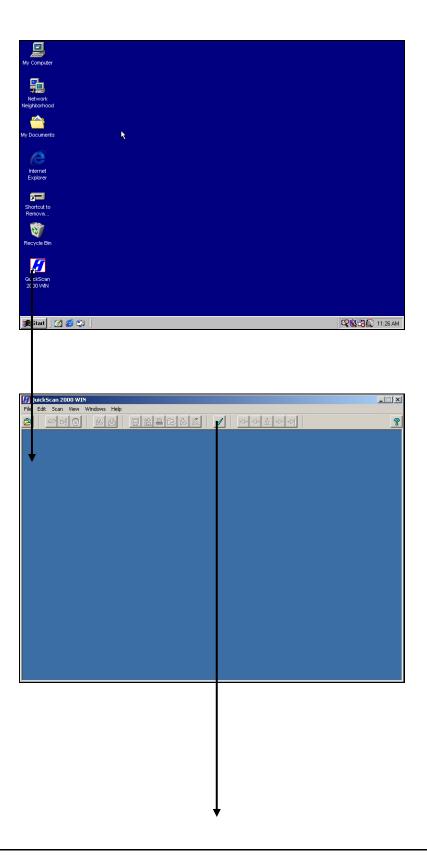
# Section 14 - Icons

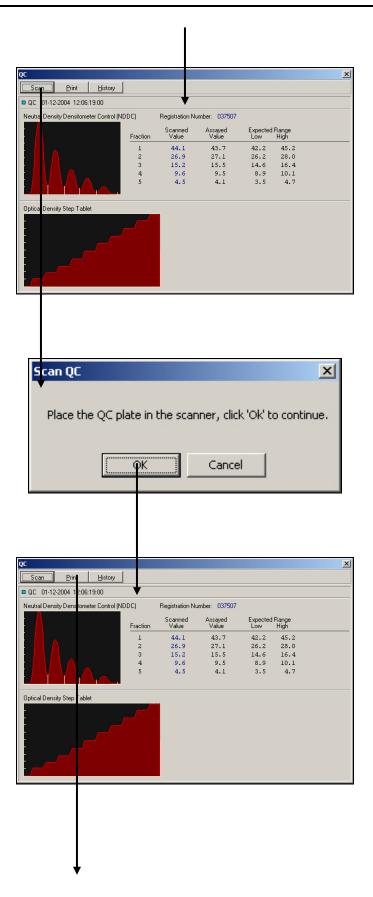


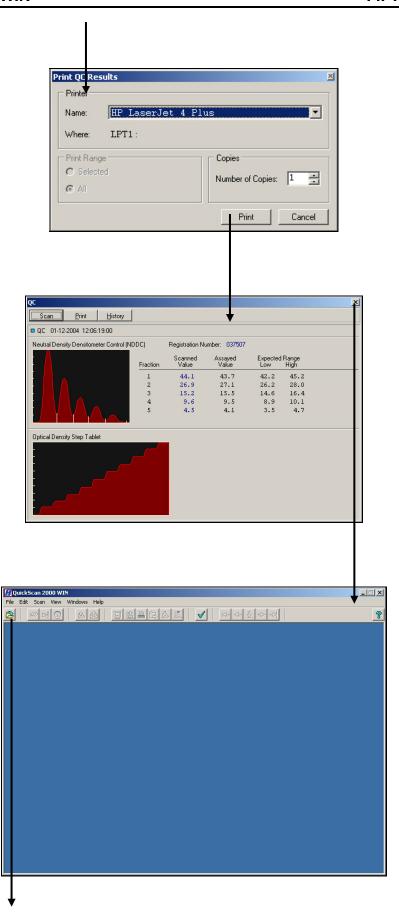
- 1. Open/Close/Select Worklist: select to access and handle the list of currently setup worklists.
- **2.** Scan New Gel: with gel in scanner, select and gel is scanned.
- **3.** Scan Options: use to temporarily alter the scan parameters and positions.
- 4. Enter Patient Info: select to access the controls needed to enter patient demographic information.
- 5. Retrieve Scan(s) from Archive: with the appropriate Retrieve Worklist selected, select to access the controls needed to retrieve saved data.
- Retrieve Scan(s) from E-Mail: with the appropriate Retrieve Worklist selected, select to access the controls needed to retrieve e-mailed data.
- 7. Set Display Options: use to temporarily alter the quantity of scans displayed, the numeric data displayed, and/or edit functions.
- 8. Edit Scan(s): select to access the controls needed to edit the current scan(s).
- 9. Print Scan(s): select to access the controls needed to print the current scan(s).
- 10. Export Scan(s): select to access the controls needed to export the current scan(s).
- 11. Save Scan(s) to Archive: select to access the controls needed to save the current scan(s).
- 12. Clear Worklist: with the appropriate Worklist selected, select and when prompted, answer Yes.

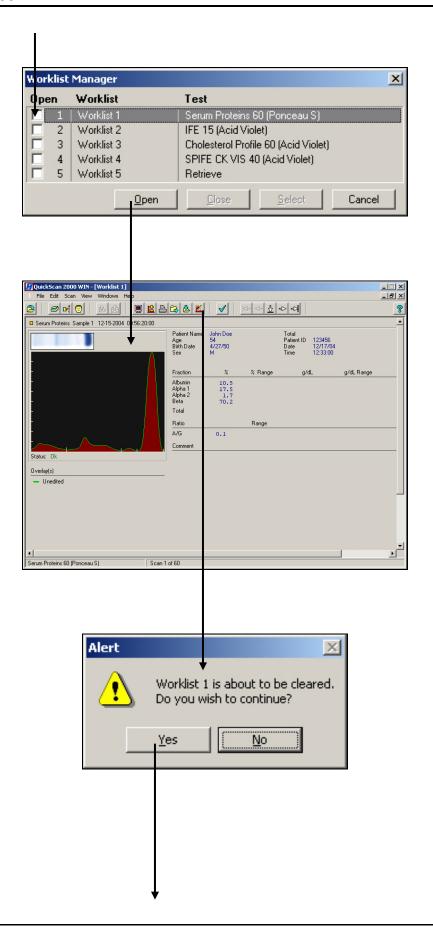
- **QC**: select to access the controls needed to perform a quality control test.
- **14.** First: select to view the first scan in the worklist.
- **15.** Previous: select to view the previously viewed scan.
- **Go To**: select, select the sample number of the desired scan, and select OK.
- 17. Next: select to view the next scan.
- **18.** Last: select to view the last scan in the worklist.
- **19.** About: select to view the software version number and the system serial number.

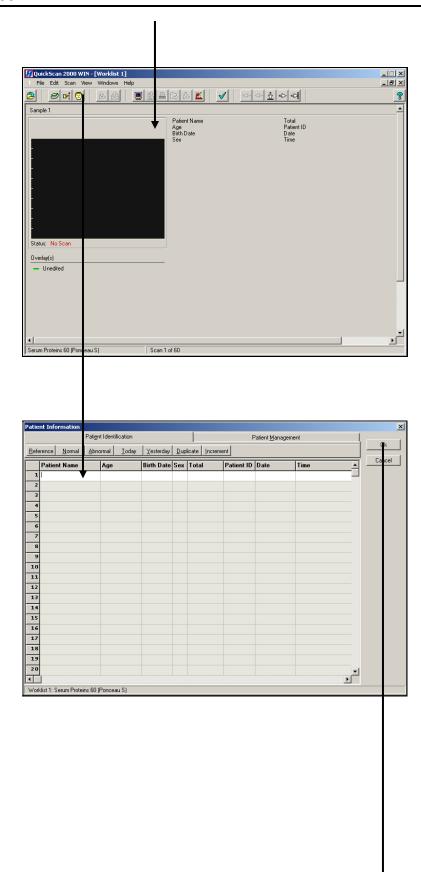
# Section 15 - Flow Chart

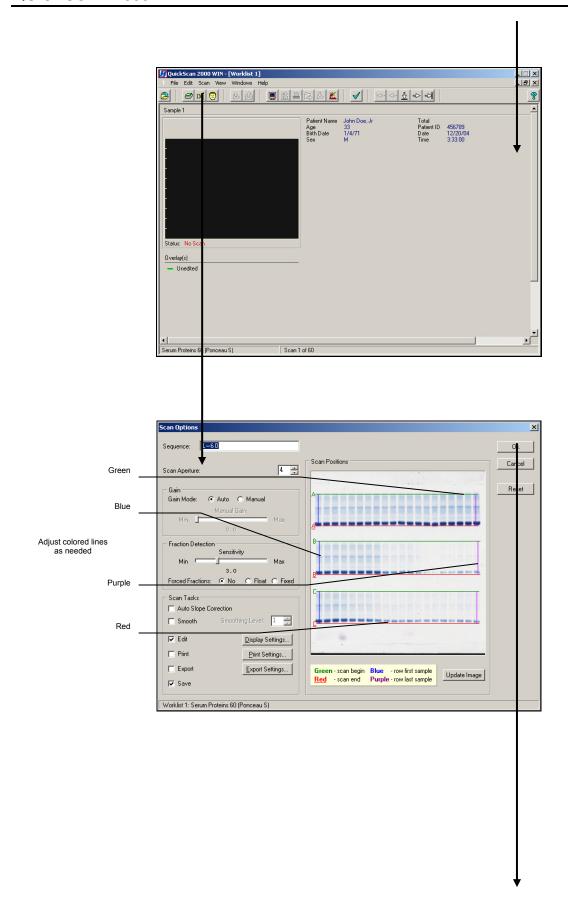


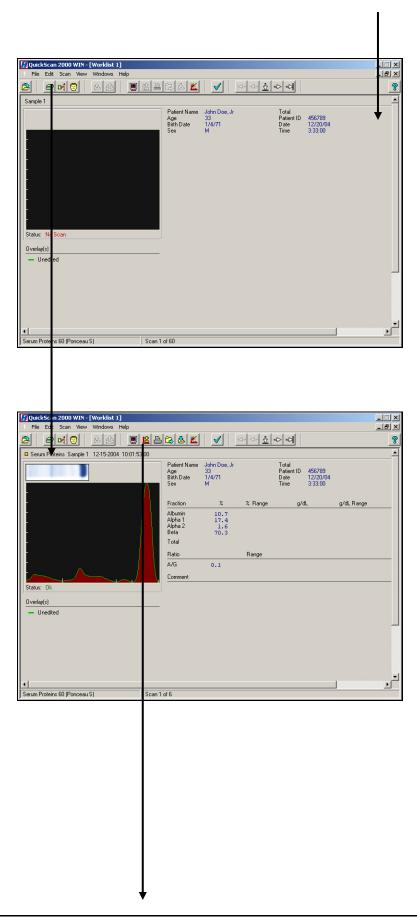


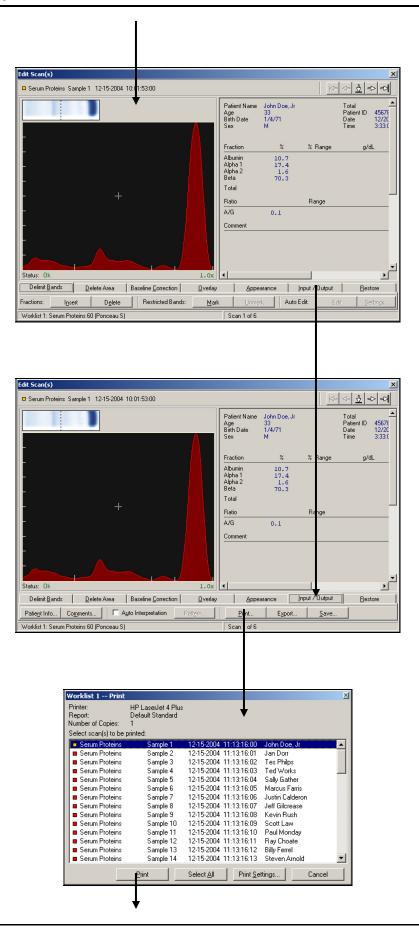


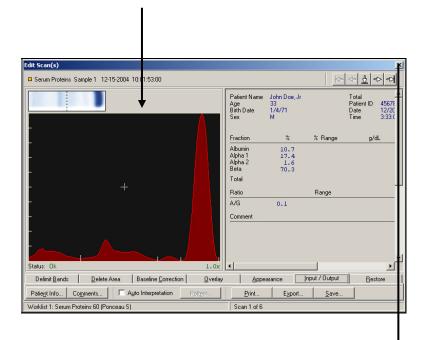


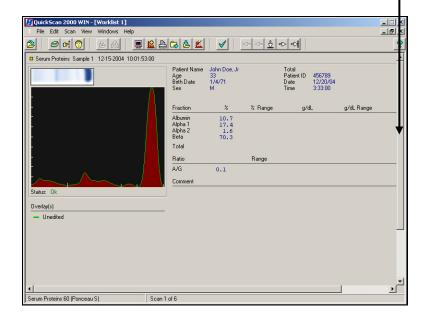












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# QuickScan 2000 WIN Version 2

Catalog Numbers 1660, 1661, 1662, 1663, 1673, 1678, and 1679

Software Version 2.02

Operator's Manual

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

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