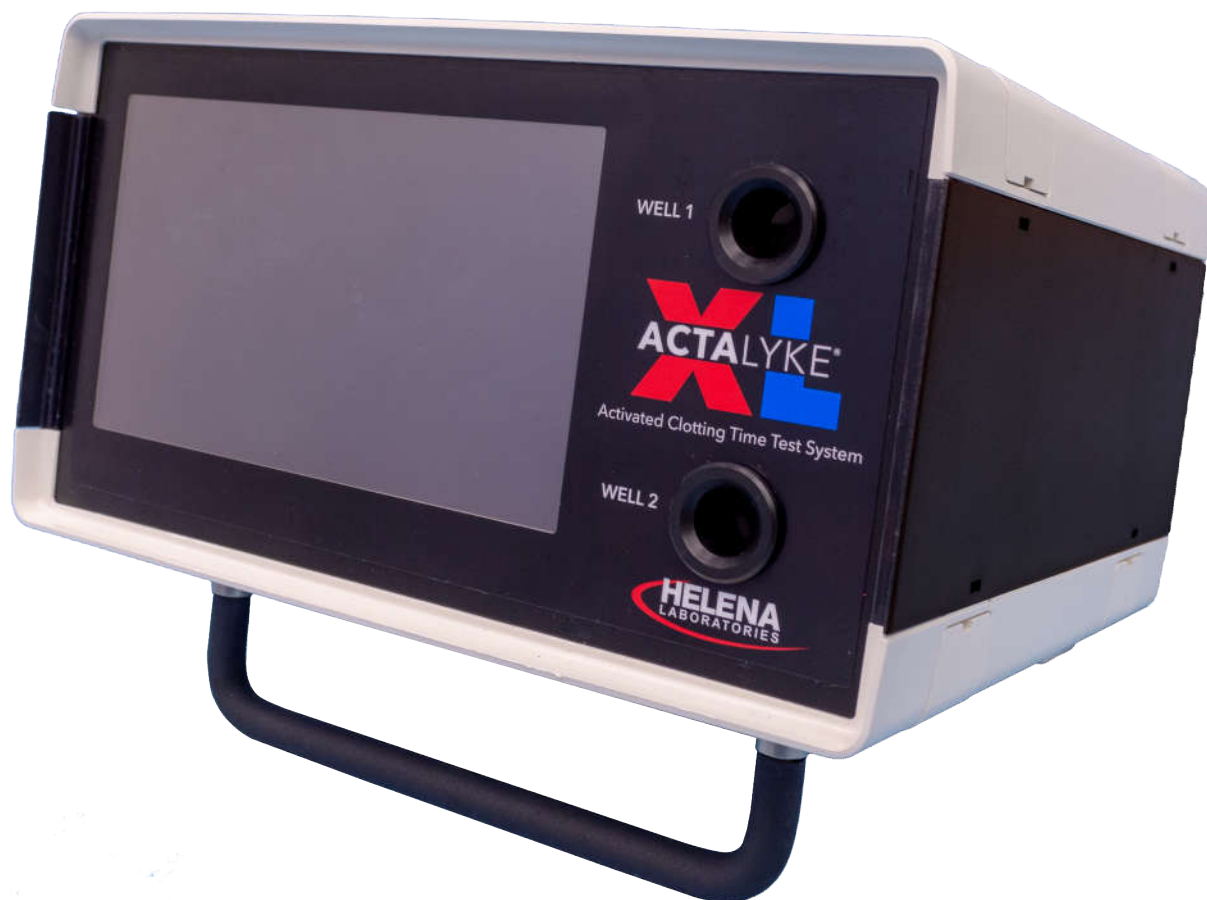


Helena Laboratories
Point of Care



Actalyke[®] XL

Activated Clotting Time Test System



Operator's Manual

Catalog Number 5770, 110-220 VAC, 50-60 Hz

Actalyke[®] XL

Activated Clotting Time Test System

Operator's Manual

WARNING!
**DO NOT ATTEMPT TO MOVE, INSTALL, OR
OPERATE THIS INSTRUMENT BEFORE READING
AND UNDERSTANDING THE CONTENTS OF THIS
MANUAL, PARTICULARLY THE PRECAUTIONS,
LIMITATIONS AND HAZARDS IN SECTIONS
THREE AND FOUR.**

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Section 1 - Instrument Use and Function

Note: *The floppy disk drive from the Actalyke XL has been removed. Any functions associated with it are no longer available.*

Actalyke® XL Activated Clotting Time Test System (Figure 1-1) is used to perform the Activated Clotting Time (ACT) test, a whole blood coagulation assay used at the patient site to monitor heparin therapy. The system is portable and designed to perform a range of whole blood coagulation tests at the point-of-care, using Activated Clotting Time (ACT) measurement techniques.

ACTALYKE XL is intended for in-vitro diagnostic use only, and is for use in a laboratory or point-of-care environment.

The ACTALYKE XL System can be used whenever and wherever ACT testing is desired, such as:

- Hemostasis Laboratory
- Cardiopulmonary Bypass Surgery
- Hemodialysis
- Extracorporeal Membrane Oxygenation (ECMO)
- Percutaneous Transluminal Coronary Angioplasty
- Cardiac Catherization
- Critical Care

The ACTALYKE XL System provides an alternative to other Activated Clotting Time (ACT) methodologies. The instrument monitors moderate to high levels of heparin during various surgical and medical procedures, with good sensitivity, linearity and precision.

The ACTALYKE XL System is a dual-detector analyzer with a printer. The instrument is modular in construction for enhanced durability, portability, and flexible storage options.

The ACTALYKE XL System has programmable test and output parameters.

Actalyke Test Tubes are manufactured to the highest specification for accurate and

precise test results. Each tube contains a clotting activator and magnet.

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

- Summary
- Principle
- Reagents
- Instruments
- Specimen Collection and Handling Procedure
- Performance Characteristics
- Reference Ranges
- Bibliography



Figure 1-1. ACTALYKE XL

Section 2 - Principles of Operation

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

Operation is controlled by a microprocessor, its program and memory, and a touch screen liquid-crystal display (LCD) controlling selections.

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

Setup access can be controlled using operator identification numbers, passwords, and the three levels of security access.

The test wells of the instrument incorporate a test tube identification sensor and a highly sensitive clot detection mechanism. The test tube identification sensor reads and enters the test type for the ACT tube(s) in use. The clot detection mechanism operates by using a magnet contained in a test tube and a set of two solid-state, magnetic detectors located in the test well.

One magnetic detector is located at 0° and the other at 90°, with respect to the test tube. When a test tube is inserted into a test well, the detector at 0° senses the presence of the magnet as the tube slowly rotates.

As a clot forms, the fibrin strands cause the magnet in the tube to rotate. The detector at 90° senses the motion of the tube magnet and a clotting end-point is determined. This two-point detection sensing system minimizes the possibility of a missed end-point.

The test well holds the test tube. When *Start* is pressed for the test well in use, the microcomputer turns on the motor, which rotates the test tube. The heater remains at a constant 37°C ± 0.5, and is monitored by the internal electronics. When the clotting end-point is detected, the instrument notifies the operator that the procedure is complete by activating an audible indicator, displaying the results and/or printing the results.

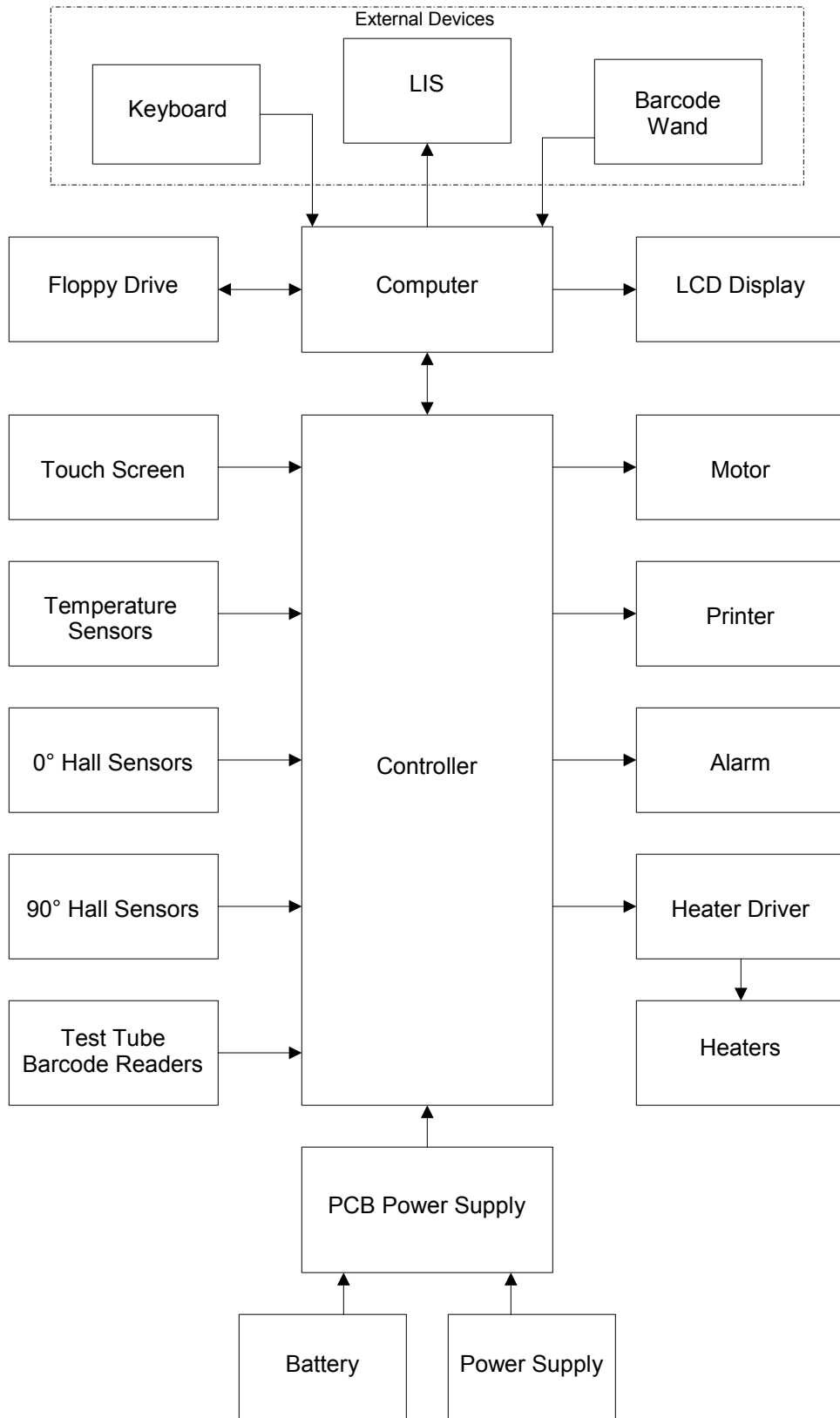


Figure 2-1. Block Diagram

Section 3 - Precautions and Limitations

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

3.1. The entire Operator's Manual should be read and understood before attempting instrument operation.

3.2. Refer to the procedures supplied with the activator kits for proper testing protocols.

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

3.4. Do not expose the instrument to drafts or to direct sunlight. Do not operate at temperatures above 30°C (86°F), or below 15°C (59°F), or allow prolonged exposure to high humidity.

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

3.6. **WARNING:** Do not use the instrument in any area, which has, or is thought to have, been exposed to explosive gases.

3.7. For AC outlet specification, see the serial number plate located on the back of the instrument.

3.8. For emergency shut down, unplug the instrument power cord. To unplug the instrument from the power supply, always disconnect from the AC outlet. Firmly grasp the plug and pull. Do not remove the plug by pulling the line cord. With the power cord disconnected, turn the power switch *Off*.

3.9. No operation or maintenance should be undertaken by the operator, which requires the removal of the instrument's covers unless specified in this manual.

3.10. Do not use excessive force when making selections on the instrument display.

3.11. Do not attempt to insert any material into the instrument other than an ACT tube, an Electronic Clotting Tube, the temperature probe holder supplied with the Actalyke

Thermometer, or an item this manual indicates as appropriate.

3.12. If resistance is encountered when inserting a tube into the test well, or there is resistance when the tube is rotating, do not force the test tube into the test well. Carefully remove the test tube and check the well. Remove any obstruction before using the instrument further.

Warning: Do not leave anything in the test wells when instrument is not in use. This can affect functionality of the instrument

3.13. All guidelines pertaining to the handling of fresh whole human blood should be adhered to when handling the test tubes and operating the instrument.

3.14. Used test tubes should be considered contaminated and may represent a biohazard. These should be handled and disposed in accordance with the user's policy regarding contaminated and biohazardous materials.

3.15. Should instruments be contaminated by blood or blood derivatives, clean the area contaminated with a commercial virucidal and germicidal agent. Observe where specimens are used inside the instrument, and confine cleaning to that area. Wipe up the agent residue, as these materials may contain alcohol, which is corrosive to metal surfaces.

No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. **ALWAYS TURN THE POWER SWITCH OFF AND UNPLUG THE MAIN POWER CORD BEFORE CLEANING.**

3.16. The instrument's systems are designed for use only with ACT tubes. Do not use the instrument with test tubes that are past the expiration date marked on the tube label or on the corresponding test tube box.

3.17. With a properly maintained and operated instrument, the prime external factor affecting the accuracy and precision of the test is the quality of the blood specimen

used. Specimen contamination, inappropriate operating technique and excessive temperature variations will also affect the test results.

3.18. The ACT test results may be affected by hemodilution, hypothermia, pharmacologic compounds and various coagulopathies. Test results should be interpreted with respect to the patient's condition and the clinical circumstances, such as anticoagulation therapy.

Test results, which do not agree with expected values or test results that are inconsistent, should be repeated. Any test result of ≥ 1500 seconds has no clinical value, and the test should be repeated immediately. These samples should be further evaluated using other diagnostic methods, if indicated. See section 7.3.

3.19. If further validation of the system is required, several tests should be run using Actalyke Quality Control Materials or other commercial coagulation controls.

3.20. If a printout is to be part of a permanent record, photocopy the printout and save the photocopy.

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

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

3.23. Requirements for handling biohazards: Due to potential biohazard risk from human blood, guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other protective equipment as warranted for safe handling and disposal of test tubes and use, transportation and disposal of this device. For

information on minimizing biohazard risk, see to section 3.15.

3.24. Storage and transport environmental requirements:

Operating Temperature range: 15° to 30° C

Storage and shipping temperatures: -20° to 45° C

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

3.26. Use standard precautions when handling disks. Refer to the disk jackets or inserts for appropriate precautions.

3.27. The disks should be removed when not in use, to prevent damage.

3.28. Keep disks away from magnets (including ACT tubes and ECT devices), as stored information may be lost. Do not place disks near a magnetic source or a strong source of electromagnetic interference.

3.29. Formatting a disk, which already contains data, will erase the original data.

Section 4 - Hazards

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

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

4.2. This unit contains high voltages, which can be extremely dangerous. **ALWAYS TURN OFF THE POWER, DISCONNECT THE MAIN POWER CORD, AND USE EXTREME CARE** when attempting to clean or repair.

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

4.4. Running this instrument in the US on 220 V AC is prohibited. This instrument requires a zero reference on AC input, so cannot be run on 220V AC in the US. Fire protection is not assured if this is not followed.

4.5. Do **not** lubricate the instrument.

4.6. Use only the test tubes specified by the Helena Laboratories procedure in use. Damage to the instrument may result from introducing some types of solutions into the instrument.

4.7. Follow safe handling and disposal procedures for test tubes used with this device.

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

4.9. Particular symbols may be used to provide information to the user. Refer to section 11.

4.10. Use only specified printer paper.

4.11. WARNING: Do not use non-rechargeable batteries.

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

Section 5 - Installation Instruction

WARNING: Read section three, Precautions and Limitations, and section four, Hazards, before attempting installation or device operation.

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

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 instrument and accessories from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.
3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife is used to cut the plastic or binding tape, take care not to scratch the instrument.
4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.
5. Inventory all items. If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

Table 5-1. Inventory

ACTALYKE XL Instrument
Power Cord
Operator's Manual
Operator's Manual on CD
Roll of Actalyke Thermal Printer Paper
Actalyke XL Installation Report Form
Actalyke XL Program Disk

Table 5-2. Additional Materials

Required Materials	
XL-ECT	Actalyke Electronic Clotting Tube
A-PPR	Actalyke Thermal Printer Paper
Available Materials	

5757	Actalyke Thermometer
5758	Barcode Reader and Cable
5759	Actalyke XL Battery Pack
C-ACT	Celite Tube
K-ACT	Kaolin Tubes
G-ACT	Glass Bead Tubes
MAX-ACT	MAX-ACT Tubes
AQC-H	Actalyke Whole Blood QC (for C-ACT, K-ACT, & MAX-ACT)
AQC-L	Actalyke Whole Blood QC (for G-ACT)

5.2. Installation

This instrument is an installation Category II device under EN 61010-1, for use in a laboratory or similar environment.

1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and temperature fluctuations. Ambient temperature should be between 15°C to 30°C (59°F to 86°F).
2. Place the instrument on a flat, rigid, horizontal surface, preferably located near the patient. Using the carrying handle/stand, prop up the instrument (**Error! Reference source not found.**).
3. Confirm the instrument is Off (). The one connector, accessible from the rear (), is an IEC connector. Plug the power cord into this connector. Secure the power cord in the clip located on the rear of the instrument (). Plug the other end into a grounded wall outlet of the proper voltage and frequency. Supply voltage should not fluctuate more than +/- 10% of the nominal rating. Because the power cord is the mains disconnect device, the wall outlet used should be easily accessible. These specifications can be found on the serial number plate located on the back of the instrument.

The wall outlet should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument circuitry contains filters to reduce the effect of line voltage fluctuations; however, they should still be avoided.

An additional caution for US users: This instrument requires a zero reference on AC input, so it cannot be run on 220V AC in the US. Fire protection is not assured if this is not followed.

4. To connect the instrument and the optional barcode reader or an external keyboard and/ or to connect to an external computer (LIS): Confirm the instrument is *Off* (). On the left side of the instrument (**Error! Reference source not found.** or **Error! Reference source not found.**), remove the appropriate panel to access the desired connection(s). Plug the device and/or LIS into the instrument.

5. Turn the instrument *On* (). When the *Enter Operator ID* screen (Figure 6-1) displays, select *OK*. When the *Run Test* screen (Figure 6-2) displays, confirm the screen reads *Charging* in the lower left corner. The instrument's battery may need charging for up to 18 hours to be at full capacity. See section 7.4 for more information on the battery.

6. Load the roll of printer paper (and **Error! Reference source not found.**); see section 10.1.7 for instructions.

7. Install the F2 fuse (the fuse and fuse holder are secured to the front of the instrument during shipping). To install the fuse, place the fuse in the fuse holder and then place the holder in the F2 fuse position located on the left rear of the instrument. Using a small flathead screwdriver, push the holder in and rotate clockwise until it is seated.

5.3. Verification of Functionality

Read the entire Operator's Manual. With the instrument turned *On*, complete the applicable section of the **Actalyke XL Installation Report** as the following steps are performed:

1. Verify the **Operating Environment Temperature** falls within the specified range. Refer to section 9.1 for specifications. Make the necessary notations on the installation report.

2. Perform the **Test Well Temperature Check** for each test well. Refer to section 8.1.6 for instructions. Make the necessary notations on the installation report.

3. Perform the **Clotting Time Check** for each test well. Refer to section 8.1.1 for instructions. Make the necessary notations on the installation report.

4. Perform a **QC of Individual Coagulation Assay** for each test well. Refer to section 8.1.2 and to the procedure supplied with the Actalyke tubes for instructions. Make the necessary notations on the installation report.

Should any problems occur during installation, refer to section 10.2, or call Helena Laboratories.



Figure 5-1. Actalyke XL, Front View



Figure 5-2. Actalyke XL, Back View

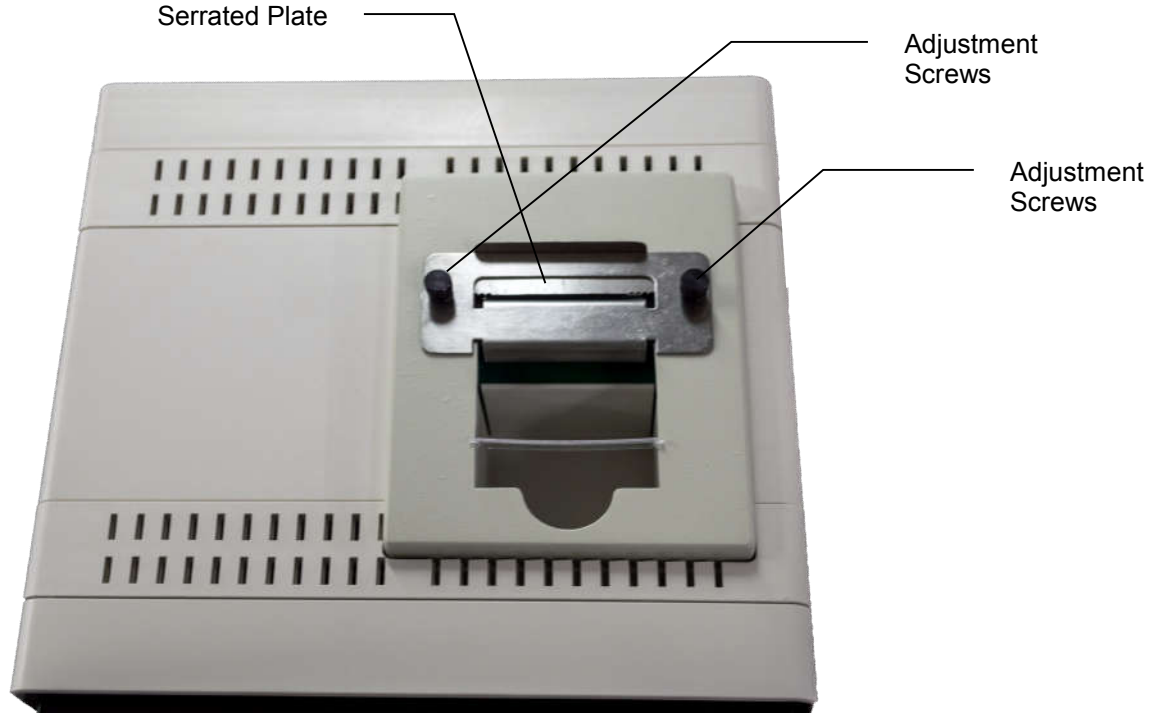


Figure 5-3. Actalyke XL, Top View

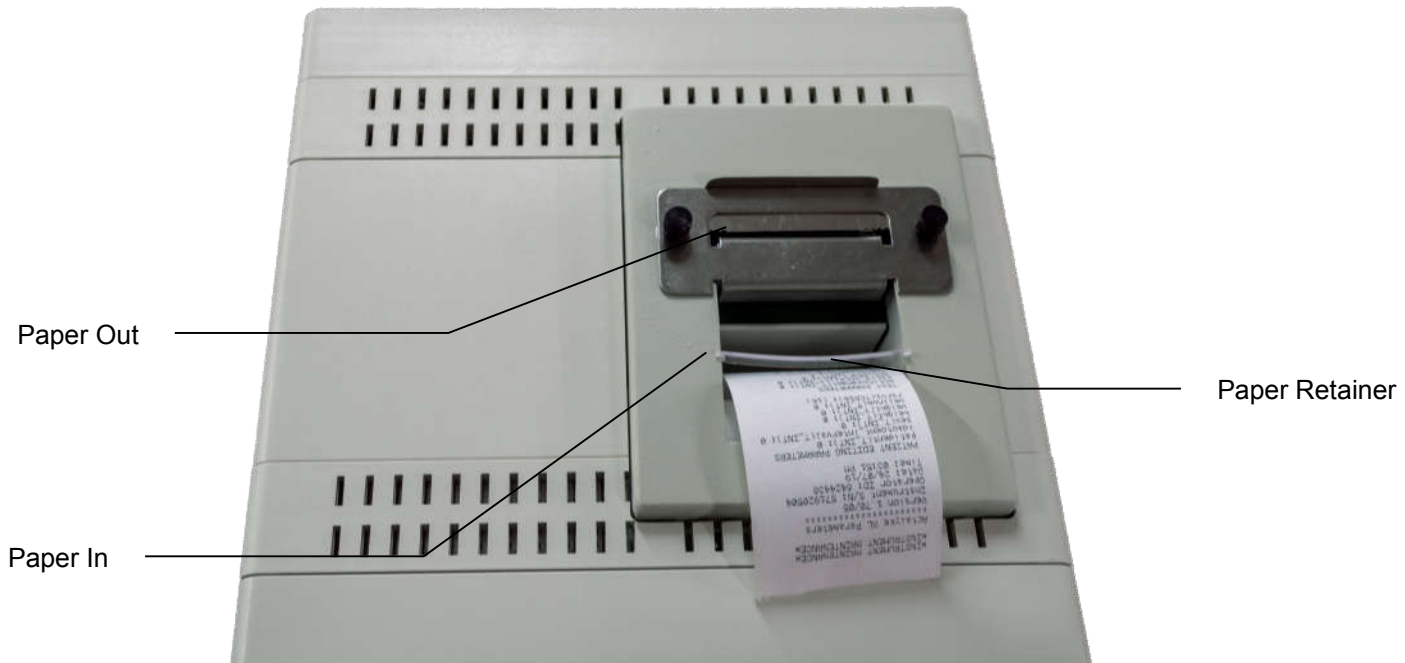


Figure 5-4. Actalyke XL, Top View with Paper

The instrument's left side will resemble either Figure 5-5 or 5-6



Figure 5-5. Actalyke XL, Left Side

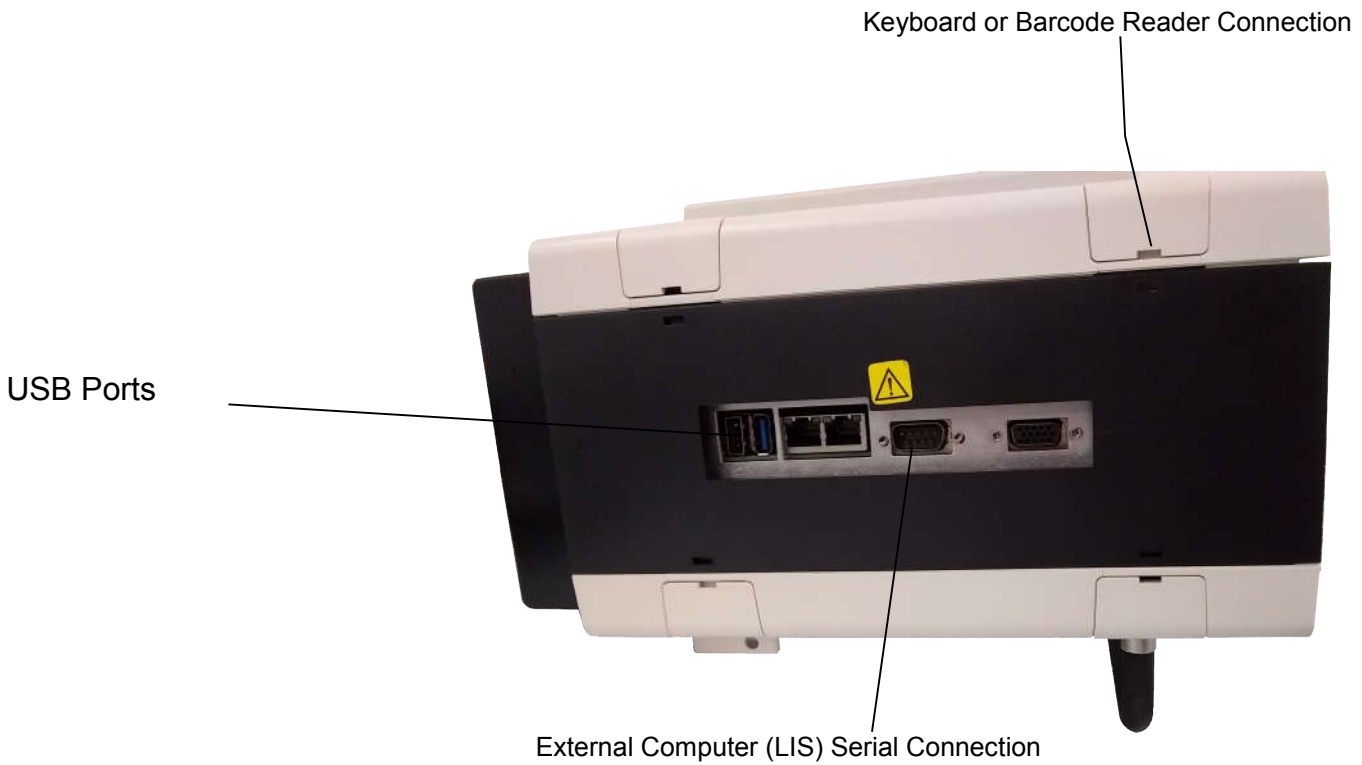


Figure 5-6. Actalyke XL, Left Side



Figure 5-7. Actalyke XL, Right Side

Section 6 - Setup

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

1. An external keyboard and barcode reader may be used for portions of the instrument setup. The device should be connected prior to powering up the instrument (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection location).

2. Turn the power switch On ().

3. The first displayed screen is the *Enter Operator ID* screen (Figure 6-1).

a. If the instrument is being used for the first time, either enter an identification number in the *Operator ID* field, using the keypad, *Bksp* (backspace), and *Clear* keys, or a barcode reader, and select *OK*, or simply select *OK*.

b. If the instrument has been setup to use operator identification number / password / security access level combinations (section 6.2.1), enter an appropriate operator ID number in the *Operator ID* field using the keypad, *Bksp* (backspace), and *Clear* keys or a barcode reader. Then enter the corresponding password in the *Password* field using the keypad, *Bksp* (backspace), and *Clear* keys. Use the ▲ up and the ▼ down keys to move between the two fields. For information on the type of access allowed with each of the three access levels, see section 6.2.1. With the operator ID and password entered, press *OK*.

(1) If the Allow 2nd Operator for Well 2 feature (section 6.2.3) is in use, the access level of the operator ID entered here determines the access level of both operators.

c. If the instrument has been setup to use operator identification number / password / security access level combinations for Supervisor Full Rights and Setup Access operators only (section 6.2.1), either:

(1) Enter an appropriate Supervisor Full Rights or Setup Access *Operator ID* and *Password* per the instructions in step 3.b.

(2) Or, to access the instrument with Operation Only access, either enter any number as the *Operator ID* and press *OK*, or simply press *OK*. With no Operation Only IDs setup, accessing the instrument in this manner allows the user to have Operation Only access.

4. Once *OK* is selected, the *Run Test* screen (Figure 6-2) displays.

6.1. Interface Parameters

All of the parameters available may be setup through the *Interface Parameters* menu without returning to the *Run Test* screen after each selection; however, selections are not saved until the instrument is returned to the *Run Test* screen.

To access the Interface Parameters menu, from the *Run Test* screen, select *Setup*. From the *Setup* screen, select *Interface Parameters*.

6.1.1. Keypad

A numeric keypad is displayed on several screens to enter data. The keypad displays in one of two user-selected formats: Calculator or Phone. The instrument's default keypad setting is the *Phone* format. To alter the format, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Keypad* (Figure 6-4).
4. From the *Select Preferred Keypad* screen (Figure 6-5), select either *Phone* or *Calculator*.
5. Select *OK* to return to the *Setup Interface Parameters* screen (Figure 6-4).
6. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.2. Time and Date

The instrument allows for the desired date format to be selected and the current date and time to be set.

6.1.2.1. Date Format

The date can be displayed in several different formats. To choose a format from the selections, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Time & Date* (Figure 6-4).
4. Select *Date Format* (Figure 6-6).
5. The *Set Date Format* screen (Figure 6-7) contains seven different date format styles. The six formats presented in all lower case letters will display the date numerically in the order indicated. For example, the *dd/mm/yy* format will appear as 14/12/01. For the seventh format, *MMM dd, yyyy*, the same date will appear as Dec 14, 2001. Note that date formats using more than six digits will appear, in some instances, in the six-digit format closest to the selected format. For example, *MMM dd, yyyy* appears as *mm/dd/yy* and *yyyy/mm/dd* as *yy/mm/dd*. Select the desired format.
6. Select *OK* to return to the *Setup Time & Date* screen (Figure 6-6).
7. Select one of the following:
 - a. To enter or edit the current date, see section 6.1.2.2 step 4.
 - b. To enter or edit the current time, see section 6.1.2.3 step 4.
 - c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.2.2. Date

To set the current date, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *Interface Parameters* (Figure 6-3).
3. Select *Time & Date* (Figure 6-4).
4. Select *Date* (Figure 6-6).
5. On the *Set Date* screen (Figure 6-8), use the keypad, the < key (to move the cursor to the left), and the > key (to move the cursor to the right) to enter the current date. The date will appear in the currently selected format, except if the *MMM dd, yyyy* format is currently in use. In this case, the date will appear on this screen in the *mm/dd/yyyy* format.
6. Once the date is entered, select *Set Date*.
7. Select *OK* to return to the *Setup Time & Date* screen (Figure 6-6).
8. Select one of the following:
 - a. To change the selected date format, see section 6.1.2.1 step 4.
 - b. To enter or edit the current time, see section 6.1.2.3 step 4.
 - c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.2.3. Time

To set the current time, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Time & Date* (Figure 6-4).
4. Select *Time* (Figure 6-6).
5. From the *Set Time* screen (Figure 6-9), select the *12/24 Hr* key to change the format of the time from its current setting to either 12 or 24 hours.
6. Select the *AM/PM* key in the 12-hour format to identify the entered time as am or pm. Select the *AM/PM* key in the 24-hour format to change the entered time to its 24 hour equivalent.

7. Use the keypad, the < key (to move the cursor to the left), and the > key (to move the cursor to the right) to enter the time.

8. Once the *New Time* is entered as needed, select *Set Time*.

9. Select *Exit* to return to the *Setup Time & Date* screen (Figure 6-6).

10. Select one of the following:

a. To change the selected date format, see section 6.1.2.1 step 4.

b. To enter or edit the current date, see section 6.1.2.2 step 4.

c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.3. Sound

The instrument can emit sounds for user notification. To alter the sounds, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *Interface Parameters* (Figure 6-3).

3. Select *Sound* (Figure 6-4).

4. On the *Setup Sound* screen (Figure 6-10), for each of the three events, *Click*, *Warning*, and *Run Done*, a sound may be emitted. A *Click* is emitted whenever a key is pressed. A *Warning* is emitted whenever a selected time period has expired or a test falls outside of selected parameters. A *Run Done* is emitted whenever a test is completed. Select *None*, *1*, *2*, *3*, *4*, or *5* for each of the three events. Select *NONE* and no sound is emitted. Or select from *1* through *5* for the desired sound.

5. Select *OK* to return to the *Setup Interface Parameters* screen (Figure 6-4).

6. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.4. Backlight

To aid in viewing the screens, the backlight may be altered to affect the screens contrast. To alter the backlight setting, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *Interface Parameters* (Figure 6-3).

3. Select *Backlight* (Figure 6-4).

4. On the *Set Backlight* screen (Figure 6-11), select from *Off* or *1*, for the darkest setting, through *Full On* or *6*, for the brightest setting.

5. Select *OK* to return to the *Setup Interface Parameters* screen (Figure 6-4).

6. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.5. Printer

The information included on the printouts and included with spreadsheet files may be customized. To set the preferred options, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *Interface Parameters* (Figure 6-3).

3. Select *Printer* (Figure 6-4).

4. The *Setup Printer* screen (Figure 6-12) displays four options. Select *Yes* for each option desired to appear on the printout and in spreadsheet files:

a. *Serial Number* - the serial number, of the instrument, only prints when set to *Yes* on this screen and when the results chart prints, either automatically (section 6.2.6) or manually (section 7.1.2).

b. *Operator ID* - the operator ID of the operator who ran the test and/or the operator currently in use.

c. *Date* - the date the test (or, when printing the results chart, the date the first test) was completed.

d. *Time* - the time the test (or, when printing the results chart, the time the first test) was completed.

5. From the *Setup Printer* screen (Figure 6-12), select from the following:

a. To set the contrast of the printouts, see section 6.1.5.1 step 4.

b. To add a header and/or footer to printouts, see section 6.1.5.2 step 4.

c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.5.1. Contrast

The contrast of the paper and text on the printouts can be altered to aid in reading printouts. To alter the contrast, follow these steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Printer* (Figure 6-4).
4. On the *Setup Printer* screen (Figure 6-12), select *Contrast*.
5. The *Printer Contrast Adjustment* screen (Figure 6-13) displays.

a. Use the ▲▲, ▼▼, ▲, and ▼ keys to adjust the contrast from 0 to 25. Zero is the least contrast and twenty-five is the greatest. The ▲▲ and ▼▼ keys change the contrast by five. The ▲ and ▼ keys change the contrast by one.

b. Each time the contrast setting is changed the printer prints, "Contrast: xx", with xx the current contrast setting.

c. Note that higher contrast settings may cause problems with printouts requiring the contrast setting be lowered. These problems may appear intermittently because they are most evident on lines where the text is preprogrammed to appear bolded.

6. To reenter the contrast set when the screen was accessed, select *Undo*.

7. Select *OK* to return to the *Setup Printer* screen (Figure 6-12).

8. Select one of the following:

a. To alter the information included on printouts and in spreadsheet files, see section 6.1.5 step 4.

b. To add a header and/or footer to the printout, see section 6.1.5.2 step 4.

c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.5.2. Header/Footer

The printout may contain a header and/or footer. To enter a header and/or footer, an external keyboard is needed. To connect a keyboard to the instrument, turn the instrument *Off*, plug in the keyboard (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection location), and turn the instrument *On*. With the keyboard connected, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Printer* (Figure 6-4).
4. From the *Setup Printer* screen (Figure 6-12), select either *Header* or *Footer*.
5. The screen displays, "Enter report header (footer) using an external keyboard."
6. Use an external keyboard to enter, edit or remove the header or footer. The header and footer can contain up to twenty-seven characters.
7. Select *OK* to return to the *Setup Printer* screen (Figure 6-12).

8. Select one of the following:

a. To enter a header or footer, return to step 4 of this section.

b. To adjust the contrast, see section 6.1.5.1 step 4.

c. To alter the information included on printouts and in spreadsheet files, see section 6.1.5 step 4.

d. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.6. Export

1. The data generated can be exported to an external computer or LIS (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection location).

2. The content of the data exported for tests is determined by automatically included data and selections made in setup.

a. For patient tests, patient ID must be in use for data to be exported (section 6.2.2).

(1) The minimum data exported is: the type of test run; the date and time the test was run; the clotting time results; the patient identification number; the instrument's serial number; and the sequential run number.

(2) If in use, the patient demographics (section 6.2.2) and/or the ACT test range limits (section 6.2.3) are exported.

b. For QC tests, the data exported is: the type of the test run; the level of the test run; the test well used; the date and time the test was run; the clotting time results; the standard deviation index; the instrument's serial number; and the sequential run number.

6.1.6.1. Export Parameters

To setup the instrument to export test data, use the following steps beginning at the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Export* (Figure 6-4).

4. From the *Setup Export Parameters* screen (Figure 6-14), select the appropriate options for *Protocol*, *Data Bits*, *Parity*, *Stop Bits*, and *Baud Rate*. See section 12 for additional information.

5. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.7. Spreadsheet

1. The clot data generated can be saved to a 3½" disk for use with a spreadsheet program (see **Error! Reference source not found.** for floppy disk drive location). The data can be saved automatically (section 6.2.6) and/or manually (section 7.1.2 and 8.1.3).

2. The content of the data saved is determined by automatically included data and by selections made in setup:

a. For patient tests, patient ID must be in use for data to be saved (section 6.2.2).

(1) The minimum data saved is: the type of test run; the date and time the test was run; the clotting time results; and the patient identification number (if entered).

(2) If in use, patient demographics (section 6.2.2) and/or the ACT test range limits (section 6.2.3) are saved.

(3) Additionally, if any heparin is administered, the last dosage, the time administered, and the total dosage are saved.

b. For QC tests, the minimum data saved is: the type of test run; the level of the test run; the test well used; the date and time the test was run; the clotting time results; and the standard deviation index.

c. For both patient and QC data, any of the following may also be included, if setup for use (section 6.1.5): the instrument's serial number; the date and/or time the data is saved; and the operator's ID.

6.1.7.1. Spreadsheet Parameters

An external keyboard may be needed to setup the instrument for use with a spreadsheet. The device should be connected prior to powering up the instrument (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection location).

To setup the instrument, use the spreadsheet manufacturer's recommended parameters and the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *Spreadsheet* (Figure 6-4).
4. On the *Set Spreadsheet Parameters* screen (Figure 6-15), select the desired *Item Separation Character* from the four options. If the data will be used with Microsoft® Excel®, select the comma.
5. Select up to five desired *Line Termination String* from the three displayed (*Carriage Return*, *Linefeed* and *;*) and/or use an external keyboard to enter other characters. The selections made appear in the box below *Line Termination String*. Note that if carriage return is selected, *<CR>* appears in the box, and, if linefeed is selected, *<LF>* appears. If the data will be used with Microsoft® Excel®, select *Carriage Return*.
6. To remove the selected line termination string, select *Clear*.
7. Select *Yes* for *Include column labels* to have the column labels saved with the data. If the data will be used with Microsoft® Excel®, select *Yes*.

a. For patient tests, with all available data saved, the labels are: Test, Patient ID, Run Date, Run Time, Clotting Time (sec), Sex, Height, Weight, S/N, Operator ID, Date, Time, Range (lower), Range (upper), Last Heparin Dosage (IU), Time Administered, and Total Heparin.

b. For QC tests, with all available data saved, the labels are: Test, Level, Well No., Run Date, Run Time, Clotting Time (sec), SD, S/N, Operator ID, Date, and Time.

8. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.8. System Timers

The instrument has two timers available for operator use, the System Shutdown and the Operator ID Entry. The time selected for the System Shutdown determines the time interval the instrument can be idle, while on battery power, before the instrument automatically powers off. The time interval selected for the Operator ID Entry determines the time duration the instrument can remain idle before requiring operator identification to be entered in order to access the instrument.

6.1.8.1. System Shutdown

The instrument contains a battery as a backup power supply. The instrument will automatically shutdown after a specific period of inactivity when it is running on the battery.

To select the amount of time desired to elapse before shutdown, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *System Timers* (Figure 6-4).
4. On the *Select Timer* screen (Figure 6-16), for *System Shutdown*, select *Set Time*.
5. On the *Select Shutdown Time-out* screen (Figure 6-17), use the up ▲ and down ▼ keys to select a time period of *15 min* through *3 Hr - 0 min* (3 hours), in fifteen minute increments.

6. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.1.8.2. Operator ID Entry

The instrument can be setup to require an operator ID be entered after a selected time interval of remaining idle. When setup to do this, once the selected time has elapsed, the screen returns to the *Enter Operator ID* screen (Figure 6-1).

The Operator ID Entry requirement only applies to the main operator ID. If the Allow 2nd Operator for Well 2 feature (section 6.2.3) is in use, the Operator ID Entry requirement will not prompt to re-enter the well 2 operator ID. However, if a different ID is required for well 2, it must be re-entered once the main/well 1 ID is entered (section 7.1.3).

To select or edit this time interval, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Interface Parameters* (Figure 6-3).
3. Select *System Timers* (Figure 6-4).
4. On the *Select Timer* screen (Figure 6-16), for *Operator ID Entry*, select *Yes* to use the timer or *No* to turn the timer off.
5. If *Yes* is selected, the *Select Operator ID Time-out* screen (Figure 6-18) displays. Use the keypad, *Bksp* (backspace), and *Clear* keys to select a time interval of *1 minute* to *999 minutes*, in one-minute increments.
6. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2. General Parameters

All of the parameters available may be setup through the *General Parameters* menu without returning to the *Run Test* screen after each selection; however, selections are not saved until the instrument is returned to the *Run Test* screen.

To access the General Parameters menu, from the *Run Test* screen, select *Setup*, and then from the *Setup* screen, select *General Parameters*.

6.2.1. Operator ID/Passwords

1. The instrument's use can be associated with an operator identification number or an operator identification number / password / access level combination.
2. Up to 1000 sets of operator identification information can be stored.
3. If the operator identification numbers do not need to be controlled, they do not need to be stored in the instrument's memory and this section does not need to be completed.
 - a. Keep in mind however, that without the use of operator identification number / password / access level combinations, all users will have access to all areas of instrument setup.
 - b. Alternatively, if only Supervisor Full Rights and/or Setup Access operator ID numbers and passwords are setup, then any main/well 1 user can gain Operation Only access by entering only an ID number in the *Enter Operator ID* screen. Note that if even one ID number and password combination is setup with Operation Only access, this feature is no longer available.
4. The three security access levels are:
 - a. *Operation only* allows access to run patient tests, QC tests, and enter patient demographics; however, cannot alter the instrument setup or delete QC data.
 - b. *Setup Access* allows the same access as Operation Only plus access to all

instrument setup except *Operator ID/Passwords*.

c. *Supervisor Full Rights* allows the same access as Setup Access plus access to *Operator ID/ Passwords*.

5. Note that if no operator ID is given *Supervisor Full Rights* access, then the operator ID(s) given the next highest access level will have access to all of instrument setup.

6.2.1.1. Enter/Edit Operator ID/ Passwords

To enter and/or edit operator ID numbers, passwords, and access levels, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *Operator ID/Passwords* (Figure 6-19).
4. On the *Enter Operator ID List* screen (Figure 6-20), an operator ID number can be entered/edited. Select one of the following:
 - a. To enter a new operator ID number, containing up to 15 characters, use the keypad, *Bksp* (backspace), and *Clear* keys, or a barcode reader.
 - b. To edit the password and/or access level for an existing ID number, use the ▲▲, ▼▼, ▲, and ▼ keys to indicate the desired operator ID from the displayed list and press the *Sel* key.
5. With the desired number in the *New Operator ID* field, select *Enter/Edit Password*.
6. On the *Enter password* screen (Figure 6-21), enter or edit the password, containing up to 15 characters, using the keypad, *Bksp* (backspace), and *Clear* keys.
7. With the password entered, select *OK*.

8. The screen displays, "*Operation Only Setup Access Supervisor Full Rights*." Select the appropriate access level.

9. The screen returns to the *Enter Operator ID List* screen (Figure 6-20).

10. Select one of the following:

- a. To enter or edit additional operator IDs, see step 4 of this section.
- b. To remove any operator IDs, see section 6.2.1.2 step 4.
- c. To archive the current operator IDs to a floppy disk, see section 6.2.1.3 step 4.
- d. To change the initial/current operator ID feature, see section 6.2.1.4 step 4.
- e. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.1.2. Delete Operator ID/ Passwords

To delete an operator ID/password, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *Operator ID/Passwords* (Figure 6-19).
4. On the *Enter Operator ID List* screen (Figure 6-20), use the ▲▲, ▼▼, ▲, and ▼ keys to indicate the desired operator ID from the displayed list.
5. Select the *Delete Selected* key. The screen displays, "*Delete xx? No Yes*," with *xx* the operator ID number to be deleted. To retain the operator ID/password, select *No*. To remove the operator ID/password, select *Yes*. The screen returns to *Enter Operator ID List*.
6. Select one of the following:
 - a. To remove additional operator IDs, see step 4 of this section.

b. To enter or edit operator IDs, passwords, and/or access levels, see section 6.2.1.1 step 4.

c. To archive the current operator IDs to a floppy disk, see section 6.2.1.3 step 4.

d. To change the initial/current operator ID feature, see section 6.2.1.4 step 4.

e. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.1.3. Archive and Retrieve Operator IDs

The currently entered list of operator identification number / password / access level combinations can be archived to a floppy disk. Archiving the operator IDs allows: the list to be retrieved if the instrument's list is inadvertently altered; the same list to be saved on multiple instruments thus eliminating the need to reenter each ID. To archive (save) or retrieve (restore) operator IDs, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *Operator ID/Passwords* (Figure 6-19).
4. The *Enter Operator ID List* screen (Figure 6-20) displays. Confirm the appropriate floppy disk is in the disk drive (see **Error! Reference source not found.** for floppy disk drive location).
5. Select the *Save/Restore* key and the screen displays, "Save/Restore IDs to/from floppy. Save Restore Cancel."
6. Select one of the following:
 - a. Select *Save* and the operator IDs currently entered are saved to the floppy disk. If the disk in use has been used before to save IDs, the instrument prompts to notify that the file will be overwritten. To proceed, select *Yes*.

b. Select *Restore* and the screen displays, "This will overwrite the existing Operator ID List. Continue? No Yes." Select *No* to return to the *Enter Operator ID List* screen without altering the list. Select *Yes* and the operator IDs saved on the floppy disk are copied to the instrument.

c. Select *Cancel* to neither save nor restore the operator IDs.

7. The screen returns to *Enter Operator ID List* (Figure 6-20). If IDs were restored, turn off the instrument, wait 10 seconds, and turn on the instrument; otherwise, select one of the following:

a. To enter or edit operator IDs, passwords, and/or access levels, see section 6.2.1.1 step 4.

b. To remove any operator IDs, see section 6.2.1.2 step 4.

c. To change the initial/current operator ID feature, see section 6.2.1.4 step 4.

d. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.1.4. Initial Operator ID

The current operator ID can show on the *Enter Operator ID* screen requiring that only the password be re-entered, if preferred. To set the initial/current ID to show, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *Operator ID/Passwords* (Figure 6-19).
4. On the *Enter Operator ID List* screen (Figure 6-20), select *Initial*.
5. The screen displays, "Use previous ID entry as default when entering new ID? No Yes." To leave the current operator ID showing on the *Enter Operator ID* screen whenever it is accessed, select *Yes*. To remove the operator ID, select *No*.

6. From the *Enter Operator ID List* screen, select one of the following:

a. To enter or edit additional operator IDs, see section 6.2.1.1 step 4.

b. To remove any operator IDs, see section 6.2.1.2 step 4.

c. To archive the current operator IDs to a floppy disk, see section 6.1.2.3 step 4.

d. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.2. Patient

The instrument can be setup to allow patient identification and demographic information to be entered and used to identify test results. Note that Patient ID Entry must be set to *On*, *Always* or *Immediate* for the following available options to function: viewing and printing patient data in chart form, exporting data to an external computer (LIS), saving data to a floppy disk, and entering heparin dosages. To select which, if any, patient information is to be entered, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *General Parameters* (Figure 6-3).

3. Select *Patient* (Figure 6-19).

4. On the *Select Editable Demographics* screen (Figure 6-22), for *Patient ID Entry* select one of the following:

a. Select *Off* and no patient information can be entered, displayed, printed, saved, or exported.

b. Select *On* and patient information can be entered, displayed, printed, saved and/or exported. With *On* selected, patient information is entered at the user's discretion, unless *ID Auto Entry Interval* is in use. If no patient ID is entered, the printout will contain "Patient ID _____" allowing the ID to be handwritten.

c. Select *Always* and patient information can be entered, displayed, printed, saved and/or exported. With *Always* selected, patient information must be entered with every test run; however, when the information is entered, before, during or after the test, is at the user's discretion. If the information is not entered before running a test, once the test is started, the instrument prompts the user that patient information must be entered. If the information is not entered during the run of the test, once the test is **complete**, the instrument displays the screen used to enter patient information.

d. Select *Immediate* and patient information can be entered, displayed, printed, saved and/or exported. With *Immediate* selected, patient information must be entered with every test run. If the information is not entered before starting a test, once a test is **started**, the instrument displays the screen used to enter patient information.

5. *Default Test* is recommended for use if only one test type (C-ACT, K-ACT, G-ACT, or MAX-ACT) will be run. With this feature in use, the test type only needs to be selected once (or possible once per well) until/unless the entire patient list is cleared at that time a test will again have to be selected (per well). If multiple test types will be used, do not use this feature. To use the *Default Test* feature, select *Yes*; otherwise, select *No*.

6. *ID Auto Entry Interval (Hrs)* is only available when *Patient ID Entry* is set to *On*. The *ID Auto Entry Interval* is used to control if, and when, the instrument prompts the user that no change in the patient ID has occurred for a given amount of time. Select from *Off*, 1, 2, 3, 4, and 5. Select *Off* if no prompt to enter a patient ID is desired. Select from 1 through 5, to have that number of hours pass between a patient ID being entered and the instrument prompting the user that no change has occurred in the patient ID. With this feature

activated, a patient ID must be entered when prompted.

7. Up to three patient demographics, *Sex*, *Height*, and *Weight*, may be included in the patient ID information. Select *No* or *Yes* to indicate the desired demographics. Note that *Patient ID Entry* must be set to *On*, *Always* or *Immediate* to use any of the demographics. (Note that if Patient IDs are currently attributed to the test wells and then any of the three patient demographics are set to *Yes*, the instrument will not automatically require the demographics be selected for the current Patient IDs. It is recommended the correct demographics be selected prior to running additional tests.)

8. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.3. Test

The instrument can be setup to allow a different operator ID for well 2, to prompt when a specified amount of time has elapsed since the last ACT test was run, and/or to include the ACT test ranges when printing, saving, and exporting. To setup these parameters, use the following steps beginning at the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *Test* (Figure 6-19).
4. The *Setup Test Parameters* screen (Figure 6-23) displays.
5. Use *Allow 2nd Operator for well 2* to allow a different operator ID to be assigned to well 2. Select *Yes* to allow an operator for well 2. With this feature in use:

a. The access level of the ID assigned to well 1, the main ID, determines the access level for both users;

b. If no ID is assigned to well 2, and well 2 is used, the well 1 ID will be attributed to the results;

c. Only setup operator ID / passwords (section 6.2.1) can access the unit as well 2 operator;

d. If the well 1/main operator ID is changed (section 7.1.3), the well 2 ID must be re-entered/changed or the well 1 ID will be attributed to both wells;

e. If the operator ID is set to printout (section 6.1.5), then if the results chart is printed, it includes the ID of the operator who ran the tests and the operator currently in use;

f. Care should be taken that the correct operator uses their assigned well.

6. Use *ACT Timing Sequence* to have the instrument prompt after a specified amount of time has passed since the last ACT test was run. (Note the timing sequence does not begin until an ACT test is run. If the timing sequence setting is altered, the timer does not begin again until another ACT test is run.) (Note, with this feature in use, once the selected time interval has elapsed, for the prompt to run an ACT test to display, the instrument must not be in QC mode and the *Run Test* screen must be clear of any clotting time results.)

a. Select *Yes* to set, or change, the time interval.

b. The *ACT Timing Sequence* screen (Figure 6-24) displays.

c. Use the keypad, *Bksp* (backspace) and *Clear* keys to enter the desired time duration, from one to 999 minutes, between tests.

d. With the desired time entered, select *OK* to return to the *Setup Test Parameters* screen (Figure 6-23).

7. Use *High/Low Limits* to include the ACT test range limits on ACT chart printouts and when test data is saved and/or exported. Additionally, with this feature in use, if test results fall outside the limits, a notation is included along with the test time, on all printouts and when data is saved and/or

exported. If the results are below the lower limit, an "L" appears after the test time, and, if they are over the upper limit, an "H" appears. Note: Do not use this feature if multiple ACT test types are to be run. The range limits will not include the name of the ACT test and will print, save and transmit with all patient data generated.

a. Select *Yes* to enter, or change, the limits.

b. The *ACT Test Range Limits* screen (Figure 6-25) displays.

c. Select either the *Lower* or *Upper* key and use the keypad, *Bksp* (backspace) and *Clear* keys to enter the limit. Refer to the procedure provided with the ACT test for "reference" or "expected" ranges. Select the other limit key, either *Lower* or *Upper*, and use the keypad, *Bksp* (backspace) and *Clear* keys to enter that limit.

d. With the range limits entered, select *OK* to return to the *Setup Test Parameters* screen (Figure 6-23).

8. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.4. QC (Bio)

The instrument can be setup to require certain levels of biological QC tests pass before patient tests are run, see section 6.2.4.1.

The instrument can also be setup to prompt the user when a specified amount of time has elapsed since the last biological QC test was run, see section 6.2.4.2.

To require biological QC be run on a routine basis, both of these features must be setup for use. Note that this requirement can be temporarily overridden by Supervisor Full Rights access operators and, if the *Allow 2nd Operator for Well 2* feature is in use, by both operators the well 1/main operator ID in use has Supervisor access.

The range limits included with the biological QC test procedures should be entered. They

are then used to determine the mean. There are two ways to enter the range limits (and lot numbers). One uses an optional barcode reader, see section 8.1.2. The second uses the instrument's touch screen to key in the information, see section 6.2.4.3.

6.2.4.1. QC(bio) Levels Which Must Pass

If desired, the instrument can require that certain levels of biological QC pass before patient tests can be run.

To select the level or levels required, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *QC (Bio)* (Figure 6-19).
4. The *Setup QC(bio)* screen (Figure 6-26) displays. Select the desired *QC(bio) levels which must pass*, 1, 2, and/or 3. The level number(s) will display. To de-select a level, select that level number and it will be removed from the list of must pass levels.
5. Select one of the following:
 - a. To alter the Schedule, see section 6.2.4.2 step 4.
 - b. To enter lot numbers and/or range limits for an ACT control, see section 6.2.4.3 step 4.
 - c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.4.2. Set QC(bio) Schedule

The interval between biological QC tests can be from 1 to 200 hours. The shortest time duration remaining, QC(bio) or ECT (section 6.2.5), is displayed on the *Run Test* screen on the top, left corner. Once the time elapses, the instrument alerts the user a QC(bio) test is due. If a QC(bio) test is run prior to the next scheduled time, the instrument will reset based on when that test is run. (Note that once the selected time interval has elapsed, the prompt to run a

QC/ECT test will not appear until any existing time results displayed on the *Run Test* screen are cleared.)

To select the desired time interval between biological QC tests, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *QC (Bio)* (Figure 6-19).
4. On the *Setup QC(bio)* screen (Figure 6-26), select *Set QC(bio) Schedule*.
5. On the *QC(bio) Schedule* screen (Figure 6-27), use the keypad, *Bksp* (backspace), and *Clear* keys to enter or alter the desired time interval between biological QC tests. For example, if weekly biological QC is required, set the schedule to 168 hours.
6. To return to the *Setup QC(bio)* screen without restarting the timer or changing the time, select *Cancel*.
7. Select *OK* to return to the *Setup QC(bio)* screen (Figure 6-26). Note that the instrument starts the timer for the QC tests once *OK* is selected.
8. Select one of the following:
 - a. To alter the QC(bio) Levels Which Must Pass, see section 6.2.4.1 step 4.
 - b. To enter lot numbers and/or range limits for an ACT control, see section 6.2.4.3 step 4.
 - c. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.4.3. C-ACT, K-ACT, G-ACT, and MAX-ACT

For each biological QC test type and level, the lot number and/or range limits can be entered. The instrument uses the entered range limits to calculate mean. The information can be entered either by using the touch screen (instructions to follow) or using an optional barcode reader (section 8.1.2).

To use the touch screen to enter lot numbers and/or range limits, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *General Parameters* (Figure 6-3).
3. Select *QC (Bio)* (Figure 6-19).
4. On the *Setup QC(bio)* screen (Figure 6-26), select *C-ACT*, *K-ACT*, *G-ACT*, or *MAX-ACT*.
5. On the *QC Lot Numbers* screen (Figure 6-28), to enter or change the lot number for a specific level, select the desired *Level* of 1, 2 or 3.
6. On the *Enter Lot Number* screen (Figure 6-29), use the keypad, *Bksp* (backspace), and *Clear* keys to enter or change the lot number containing up to ten characters.
7. Select *OK* and the screen returns to the *QC Lot Number* screen (Figure 6-28) and includes the entered lot number. To enter or edit the lot numbers of the other levels, see step 5. To enter the range limits of the levels displaying lot numbers, select *OK* and see step 8. To exit without entering any range limits, select *OK* until the *Setup QC(bio)* screen (Figure 6-26) displays and see step 12.
8. Use the *QC Mean and Range* screen (Figure 6-30) to enter or edit the range limits. Select the desired *Level* of 1, 2 or 3. Note that only the levels for which lot numbers have been entered appear on this screen.
9. On the *Enter Lower Limit* screen (Figure 6-31), use the keypad, *Bksp* (backspace), and *Clear* keys to enter or edit the *Lower Limit* and select *OK*.
10. On the *Enter Upper Limit* screen (Figure 6-31), use the keypad, *Bksp* (backspace), and *Clear* keys to enter or edit the *Upper Limit* and select *OK*.
11. The screen returns to the *QC Mean and Range* screen (Figure 6-30) and includes

the entered range limits and the mean, calculated by the instrument from the entered limits. To enter or edit limits for other levels, see step 8. To return to the *Setup QC(bio)* screen (Figure 6-26), select *OK*.

12. From the *Setup QC(bio)* screen (Figure 6-26), select one of the following:

a. To alter the QC(bio) Levels Which Must Pass, see section 6.2.4.1 step 4.

b. To alter the Schedule, see section 6.2.4.2 step 4.

c. To enter or edit QC lot numbers and/or range limits for additional tests, see step 4 of this section.

d. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.5. ECT

The instrument can be setup to require certain levels of ECT tests pass before patient test can be run, see section 6.2.5.1.

The instrument can also be setup to prompt the user when a specified amount of time has elapsed since the last ECT test was run, see section 6.2.5.2.

To require ECTs be run on a routine basis, both of these features must be setup for use. Note that this requirement can be temporarily overridden by Supervisor Full Rights access operators and, if the Allow 2nd Operator for Well 2 feature is in use, by both operators if the well 1/main operator ID in use has Supervisor access.

6.2.5.1. ECT Levels Which Must Pass

If desired, the instrument can require that certain ECT levels pass before patient tests can be run.

To select the level or levels required, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *General Parameters* (Figure 6-3).

3. Select *ECT* (Figure 6-19).

4. The *Setup ECT* screen (Figure 6-32) displays. Select the desired *ECT levels which must pass*, 1, 2, and/or 3. The level number(s) will display. To de-select a level, select that level number and it will be removed from the list of must pass levels.

5. Select one of the following:

a. To alter the Schedule, see section 6.2.5.2 step 4.

b. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.5.2. Set ECT Schedule

The interval between ECT tests can be from one to 200 hours. The shortest time duration remaining, QC(bio) (section 6.2.4) or ECT, is displayed on the *Run Test* screen on the top, left corner. Once the time elapses, the instrument alerts the user an ECT test is due. If an ECT test is run prior to the next scheduled time, the instrument will reset based on when that test is run. (Note that once the selected time interval has elapsed, the prompt to run a QC/ECT test will not appear until any existing time results displayed on the *Run Test* screen are cleared.)

To select the desired time interval between ECT tests, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *General Parameters* (Figure 6-3).

3. Select *ECT* (Figure 6-19).

4. On the *Setup ECT* screen (Figure 6-32), select *Set ECT Schedule*.

5. On the *ECT Schedule* screen (Figure 6-33), use the keypad, *Bksp* (backspace), and *Clear* keys to enter or alter the desired time interval between ECT tests. For example, if ECT testing is required once every 8 hours, set to 8 hours.

6. To return to the *Setup ECT* screen without restarting the timer or changing the time, select *Cancel*.

7. Select *OK* to return to the *Setup ECT* screen (Figure 6-32). Note that the instrument starts the timer for the ECT tests once *OK* is selected.

8. Select one of the following:

a. To alter the ECT Levels Which Must Pass, see section 6.1.5.1 step 4.

b. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.2.6. Auto Output

The instrument can display, print, save, and/or transmit test data automatically. To setup the instrument to automatically output these functions, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *General Parameters* (Figure 6-3).

3. Select *Auto Output* (Figure 6-19).

4. Select, on the *Setup Automatic Output* screen (Figure 6-34), the desired setting for the following parameters:

a. *View Chart* - select *Yes* to have QC Levey-Jennings charts and patient Results ACT charts automatically displayed once a test is complete. If *No* is selected, the charts can be displayed at user request, see sections 7.1.2 and 8.1.3. Note that if patient data is to be viewed, either automatically or manually, Patient ID Entry (section 6.2.2) must be in use. Also, note that when tests are run in well 2, the chart will not always automatically display, but can be accessed manually.

b. *Print* -

(1) Select *None* to have no information automatically print.

(2) Select *Simple* to have all test results automatically print once a test is complete. For patient data, if Patient ID

Entry is not in use, this automatic printing is the only way to print test results.

(3) Select *Chart* to have QC Levey-Jennings charts and patient ACT results charts automatically printed once a test is complete. Regardless of selection, the charts can be printed at user request, see sections 7.1.2 and 8.1.3. Note that if patient data is to be printed in chart form, either automatically or manually, Patient ID Entry (section 6.2.2) must be in use.

c. *Transmit* - allows patient and QC data to be automatically sent to an external computer (LIS). Note if patient data is to be transmitted, either automatically or manually, Patient ID Entry (section 6.2.2) must be in use.

(1) Select *All* to have the complete curve from both the patient Results ACT chart and QC Levey-Jennings chart automatically transmitted. The curve is automatically transmitted at the completion of a test.

(2) Select *One* to have a single point from both the patient Results ACT chart and QC Levey-Jennings chart automatically transmitted. The point is automatically transmitted at the completion of a test.

(3) If *No* is selected, the data can be transmitted at user request, see sections 7.1.2 and 8.1.3.

d. *Save Patient (spreadsheet)* - select *Yes* to have patient ACT results automatically saved on a 3½" floppy disk. All clotting times for the current patients are saved each time a run is completed. The results are saved as file name Pxxxxxxx.csv, with xxxxxxx the last 7 digits of the unit's serial number. If *No* is selected, the results can be saved at user request, see section 7.1.2. Note if patient data is to be saved, Patient ID Entry (section 6.2.2) must be in use.

e. *Save QC (spreadsheet)* - select *Yes* to have the QC results containing all data per lot-to-date automatically saved on a

3½" floppy disk. The results are saved as file name Qxxxxxxx.csv, with xxxxxx the last 7 digits of the unit's serial number. If *No* is selected, the results can be saved at user request, see section 8.1.3.

5. To save selections, return to the *Run Test* screen (Figure 6-2) by selecting *OK* until the *Run Test* screen appears.

6.3. Paper Feed

The *Paper Feed* key is used to advance the printer paper to aid in loading a roll of paper and in reading and/or removing a printout. This key will appear on the *Run Test* screen if the operator ID in use has an Operation Only access level. However the *Paper Feed* key is accessed, press the key as many times as needed for the paper to advance the desired amount. To access this key for other operator ID access levels, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Paper Feed* (Figure 6-3) and the printer advances the paper.
3. Continue to select *Paper Feed* until the paper has advanced as far as needed.
4. To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.4. Archive

To access the Archive menu, from the *Run Test* screen, select *Setup*. From the *Setup* screen, select *Archive*.

6.4.1. Save Parameters

The currently set parameters can be saved to a 3½" floppy disk. This can then be used to restore the parameters if needed or to save on to a different instrument (section 6.4.2). To save the parameters, with a disk in the floppy disk drive, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Archive* (Figure 6-3).

3. From the *Save/Restore/Print* screen (Figure 6-35), select *Save Parameters*.

4. If the disk in use has been used before to save parameters, the instrument prompts to notify that the file will be overwritten. To proceed, select *Yes*.

5. The parameters are saved and the *Save/Restore/Print* screen displays.

6. To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.4.2. Restore Parameters

If setup parameters have been saved to a 3½" floppy disk, they can be restored to the instrument or restored to a different instrument. To restore the parameters, with the appropriate disk in the floppy disk drive, use the following steps beginning from the *Run Test* screen (Figure 6-2):

Select *Setup* (Figure 6-2).

Select *Archive* (Figure 6-3).

From the *Save/Restore/Print* screen (Figure 6-35), select *Restore Parameters*.

The instrument prompts to notify that the instrument's file will be overwritten. To proceed, select *Yes*.

The parameters are saved to the instrument and the *Save/Restore/Print* screen displays.

To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.4.3. Print Setup Parameters

To obtain a printout of the selections made during setup, except operator IDs (section 6.4.6), and some of the current settings in QC, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Archive* (Figure 6-3).
3. From the *Save/Restore/Print* screen (Figure 6-35), select *PRINT Setup Parameters*. The screen prompts with the length of

time the printout will take. To proceed, select Yes.

4. A printout containing the following information plus the instruments currently entered settings for each parameter prints.

```

Actalyke XL Parameters
=====
Version
Instrument S/N:
Operator ID:
Date:
Time:
PATIENT EDITING PARAMETERS
patient:
idautoent_interval:
sex:
height:
weight:
TEST PARAMETERS
act_seq:
limit:
act_seq_tim:
limit_hi:
limit_lo:
opid2:
OpIdUsePrev:
DefaultTest:
AUTO-OUTPUT PARAMETERS
aviewchart:
adataprint:
atransmit:
apatstorage:
aqcstorage:
QC PARAMETERS
well_lvl:
tubetype:
mean:
ECT:
MAX-ACT:
G-ACT:
K-ACT:
C-ACT:
range_hi:
ECT:
MAX-ACT:
G-ACT:
K-ACT:
C-ACT:
range_lo:
ECT:
MAX-ACT:
G-ACT:
K-ACT:
C-ACT:
lotnum:
ECT:
MAX-ACT:
G-ACT:
K-ACT:
C-ACT:
qc_forced:
ect_forced:

```

```

qc_sched:
ect_sched:

REPORT/INTERFACE PARAMETERS
date_format:
time_mode:
snd_click:
snd_warn:
snd_RunDone:
prn_header:
prn_footer:
prn_sn:
prn_techid:
prn_date:
prn_time:
xp_prot:
xp_databits:
xp_stopbits:
xp_parity:
xp_baudofs:
backlite:
linterm:
sepchar:

```

5. The following is an explanation of the above printout. Note that all the text presented in bold could appear on the printout similar to this.

a. This explanation includes the section number where additional information can be found related to setting up the parameters. For example, **PATIENT EDITING PARAMETERS** is in section 6.2.2.

b. The explanation also includes clarifications of the headings that appear on the printout (presented within parentheses). For example, the **patient** heading is short for Patient ID Entry.

c. Lastly, the explanation includes the possible settings that appear after the headings (presented in bold) and their meanings (presented within parentheses). For example, **0** can represent Off, No or none.

Actalyke XL Parameter

=====

Version: (printout will list current software version information)

Instrument S/N (instrument serial number): (printout will list the pre-programmed instrument serial number)

Operator ID: (the identification number of the operator currently accessing the instrument)

Date: (current date)

Time: (current time)

PATIENT EDITING PARAMETERS

(section 6.2.2)

patient (Patient ID Entry): **0** (Off), **1** (On), **2** (Always), or **3** (Immediate)

idautoent_interval (ID Auto Entry Interval): **0** (Off), **1** (1), **2** (2), **3** (3), **4** (4), or **5** (5)

sex: **0** (No) or **1** (Yes)

height: **0** (No) or **1** (Yes)

weight: **0** (No) or **1** (Yes)

TEST PARAMETERS (section 6.2.1, 6.2.2, and 6.2.3)

act_seq (ACT Timing Sequence): **0** (No) or **1** (Yes)

limit (ACT Test Range Limits): **0** (No) or **1** (Yes)

act_seq_tim (ACT Timing Sequence): (the selected interval of time in minutes between ACT tests)

limit_hi (ACT Test Range Limits Upper): (the entered upper limit in seconds)

limit_lo (ACT Test Range Limits Lower): (the entered lower limit in seconds)

Opid2 (Allow 2nd Operator for Well 2): **0** (No) or **1** (Yes)

OpidUsePrev (Initial): **0** (No) or **1** (Yes)

DefaultTest (Default Test): **0** (No) or **1** (Yes)

AUTO-OUTPUT PARAMETERS

(section 6.2.6)

aviewchart (automatically View Chart): **0** (No) or **1** (Yes)

adataprint (automatically Print): **0** (None), **1** (Simple) or **2** (Chart)

atransmit (automatically Transmit chart): **0** (No), **1** (One) or **2** (All)

apatstorage (automatically Save Patient): **0** (No) or **1** (Yes)

aqcstorage (automatically Save QC): **0** (No) or **1** (Yes)

QC PARAMETERS (section 6.2.4 and 6.2.5)

well_lvl (well level): (printout will list the current level for each test well)

0 (1), **1** (2) or **2** (3)

tubetype (test tube type): (printout will list the pre-selected tube type for each test well) **0** (none), **1** (ECT), **2** (MAX-ACT), **3** (G-ACT), **5** (K-ACT), or **6** (C-ACT)

mean (Set QC Mean and Range):

ECT: 100, 300, 500

MAX-ACT:

(level 1 automatically calculated mean),
(level 2 automatically calculated mean),
(level 3 automatically calculated mean)

G-ACT:

(level 1 automatically calculated mean),
(level 2 automatically calculated mean),
(level 3 automatically calculated mean)

K-ACT:

(level 1 automatically calculated mean),
(level 2 automatically calculated mean),
(level 3 automatically calculated mean)

C-ACT:

(level 1 automatically calculated mean),
(level 2 automatically calculated mean),
(level 3 automatically calculated mean)

range_hi (QC Mean and Range Upper Limit):

ECT: 110, 310, 510

MAX-ACT:

(level 1 upper limit),
(level 2 upper limit),
(level 3 upper limit)

G-ACT:

(level 1 upper limit),
(level 2 upper limit),
(level 3 upper limit)

K-ACT:

(level 1 upper limit),
(level 2 upper limit),
(level 3 upper limit)

C-ACT:

(level 1 upper limit),
(level 2 upper limit),
(level 3 upper limit)

range_lo (QC Mean and Range Lower Limit):

ECT: 90, 290, 490

MAX-ACT:

(level 1 lower limit),
(level 2 lower limit),
(level 3 lower limit)

G-ACT:

(level 1 lower limit),
 (level 2 lower limit),
 (level 3 lower limit)

K-ACT:

(level 1 lower limit),
 (level 2 lower limit),
 (level 3 lower limit)

C-ACT:

(level 1 lower limit),
 (level 2 lower limit),
 (level 3 lower limit)

lotnum (QC test Lot Numbers):

ECT: ‘ ’, ‘ ’, ‘ ’

MAX-ACT:

‘(lot number for level 1)’,
 ‘(lot number for level 2)’,
 ‘(lot number for level 3)’

G-ACT:

‘(lot number for level 1)’,
 ‘(lot number for level 2)’,
 ‘(lot number for level 3)’

K-ACT:

‘(lot number for level 1)’,
 ‘(lot number for level 2)’,
 ‘(lot number for level 3)’

C-ACT:

‘(lot number for level 1)’,
 ‘(lot number for level 2)’,
 ‘(lot number for level 3)’

qc_forced (QC(bio) Levels Which Must Pass): **0** (none), **1** (1), **2** (2), **3** (1 and 2), **4** (3), **5** (1 and 3), **6** (2 and 3), or **7** (1, 2 and 3)

ect_forced (ECT Levels Which Must Pass): **0** (none), **1** (1), **2** (2), **3** (1 and 2), **4** (3), **5** (1 and 3), **6** (2 and 3), or **7** (1, 2 and 3)

qc_sched (Set QC(bio) Schedule): (printout will list the entered time interval in hours)

ect_sched (ECT Schedule): (printout will list the entered time interval in hours)

REPORT/INTERFACE PARAMETERS

(sections 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.1.6, and 6.1.7)

date_format (Date Format):

0 (dd/mm/yy), **1** (dd/mm/yyyy),
2 (yy/mm/dd), **3** (yyyy/mm/dd),
4 (mm/dd/yy), **5** (mm/dd/yyyy), or
6 (MMM dd, yyyy)

time_mode (Time mode):

0 (12 Hr mode) or **1** (24 Hr mode)

snd_click (Sound Click):

0 (None), **1** (1), **2** (2), **3** (3), **4** (4), or **5** (5)

snd_warn (Sound Warning):

0 (None), **1** (1), **2** (2), **3** (3), **4** (4), or **5** (5)

snd_RunDone (Sound Run Done):

0 (None), **1** (1), **2** (2), **3** (3), **4** (4), or **5** (5)

prn_header (Print Header):

(printout will list the header, if entered)

prn_footer (Print Footer):

(printout will list the footer, if entered)

prn_sn (Print Serial Number):

0 (No) or **1** (Yes)

prn_techid (Print Operator ID):

0 (No) or **1** (Yes)

prn_date (Print Date): **0** (No) or **1** (Yes)

prn_time (Print Time): **0** (No) or **1** (Yes)

xp_prot (Export Parameters Protocol):

0 (None), **1** (XON-XOFF), or **2** (ASTM)

xp_databits (Export Parameters Data Bits):

0 (7) or **1** (8)

xp_stopbits (Export Parameters Stop Bits):

0 (1) or **1** (2)

xp_parity (Export Parameters Parity):

0 (None), **1** (Odd), or **2** (Even)

xp_baudofs (Export Parameters Baud

Rate): **0** (300), **1** (1200), **2** (2400), **3** (4800), **4** (9600), **5** (14400), **6** (19200), **7** (28800), **8** (38400), or **9** (57600)

backlite (Backlight): **0** (Off), **1** (1), **2** (2), **3** (3), **4** (4), **5** (5), **6** (6), or **7** (Full On)

linterm (Spreadsheet Parameters Line

Termination String): **x0 x0 x0 x0 x0**

[Up to five line terminators may be selected. The four most common codes to printout are **x0** (no line terminator selected), **xd** (carriage return), **xA** (line feed), and **;** (semicolon).]

sepchar (Spreadsheet Parameters Item Separation Character): , (comma), **Tab** (tab), : (colon), or ; (semicolon)

6. To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.4.4. Save Operator IDs

The current operator IDs can be saved to a 3½" floppy disk. They can then be used to restore to the same instrument or to copy onto a different instrument (section 6.4.5). To save the IDs, with a disk in the floppy disk drive, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Archive* (Figure 6-3).
3. From the *Save/Restore/Print* screen (Figure 6-35), select *Save Operator IDs*.
4. If the disk in use has been used before to save IDs, the instrument prompts to notify that the file will be overwritten. To proceed, select *Yes*.
5. The IDs are saved and the *Save/Restore/Print* screen displays.
6. To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.4.5. Restore Operator IDs

If operator IDs have been saved to a 3½" floppy disk, they can be restored to the instrument or restored to a different instrument. To restore the IDs, with the appropriate disk in the floppy disk drive, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Archive* (Figure 6-3).
3. From the *Save/Restore/Print* screen (Figure 6-35), select *Restore Operator IDs*.
4. The instrument prompts to notify that the instrument's file will be overwritten. To proceed, select *Yes*.

5. The IDs are saved to the instrument and the *Save/Restore/Print* screen displays.

6. To complete the restore, turn the instrument off, wait 10 seconds, and turn the instrument on.

6.4.6. Print Operator ID List

To obtain a printout of the current operator IDs, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Archive* (Figure 6-3).
3. From the *Save/Restore/Print* screen (Figure 6-35), select *PRINT Operator ID List*. The screen prompts with the length of time the printout will take. To proceed, select *Yes*.
4. A printout containing the currently entered user ID numbers and access level prints. The access levels are represented as follows: **0** for no access level assigned, **1** for Operation Only, **2** for Setup Access, and **3** for Supervisor Full Rights.
5. To return to the *Run Test* screen (Figure 6-2), select *OK* until the *Run Test* screen appears.

6.5. Maintenance

The instrument provides for three maintenance functions, which are accessed through the *Setup* key. For information on these maintenance functions, see section 10.1.9, Mag Sensor Calibration, section 10.1.6, Drain Battery, and Touch Panel Calibration, section 10.1.5.

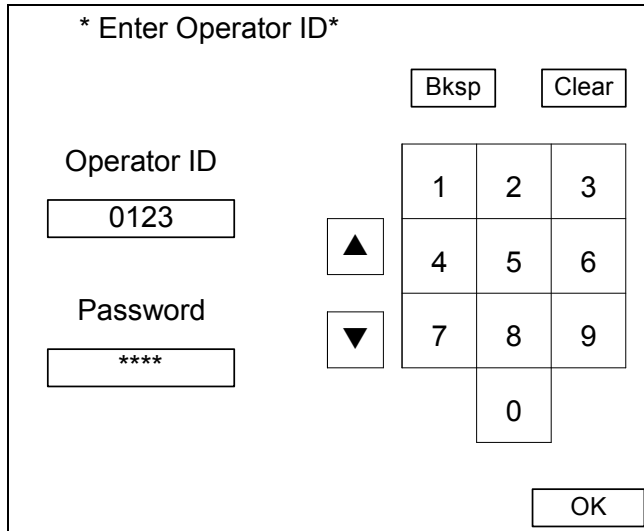


Figure 6-1. Enter Operator ID Screen*

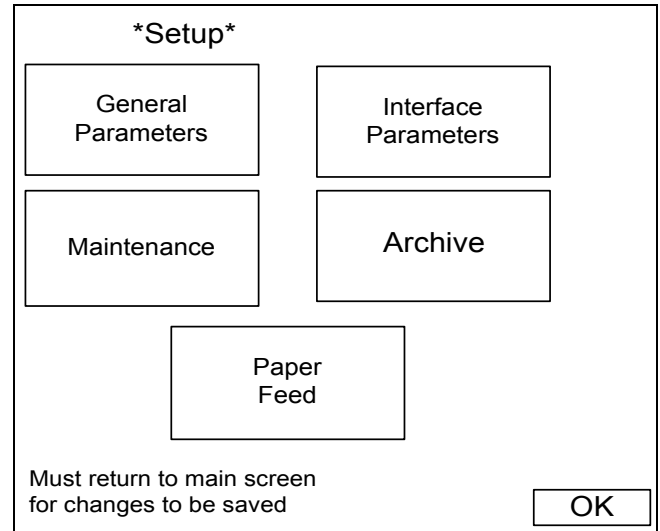


Figure 6-3. Setup Screen

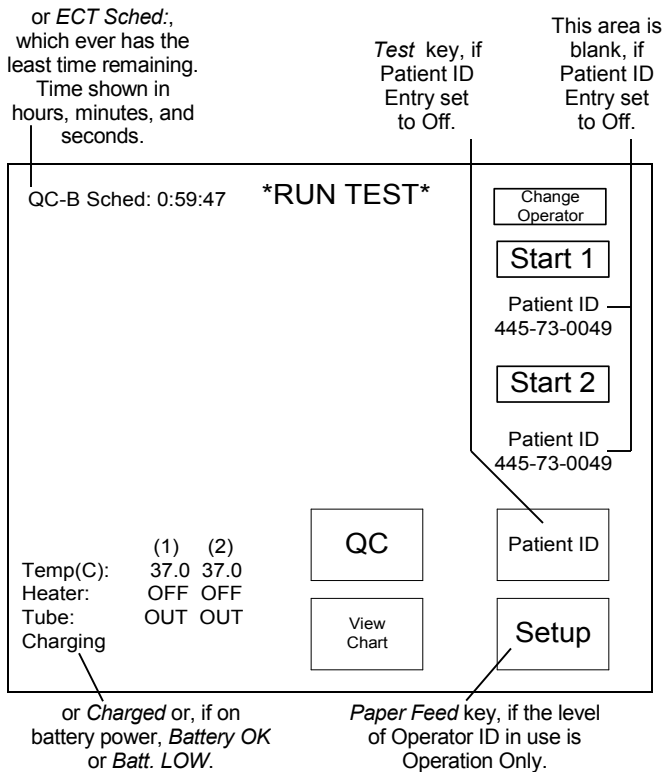


Figure 6-2. Run Test Screen

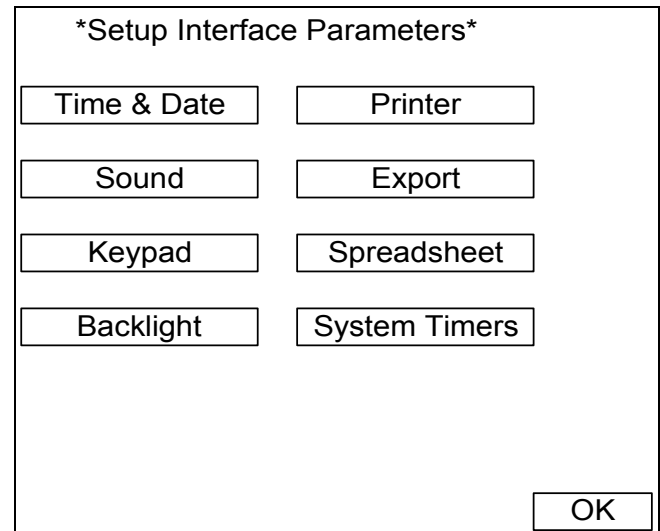


Figure 6-4. Setup Interface Parameters Screen

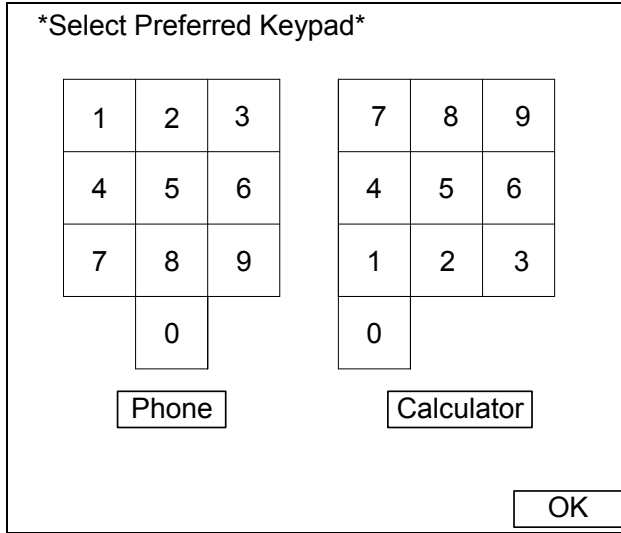


Figure 6-5. Select Preferred Keypad Screen

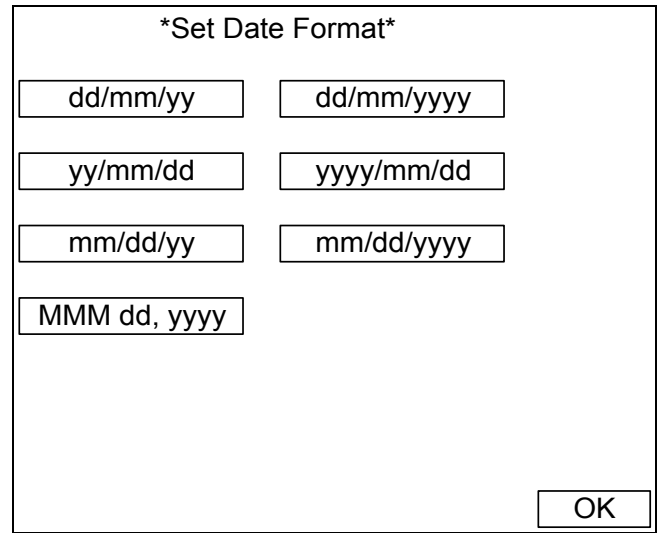


Figure 6-7. Set Date Format Screen

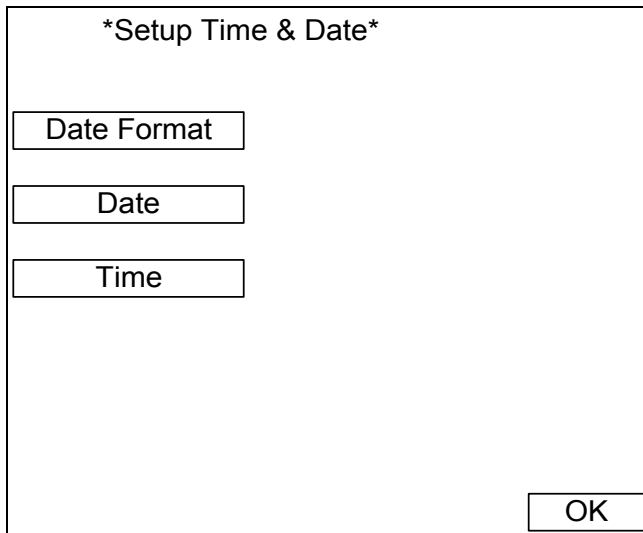


Figure 6-6. Setup Time & Date Screen

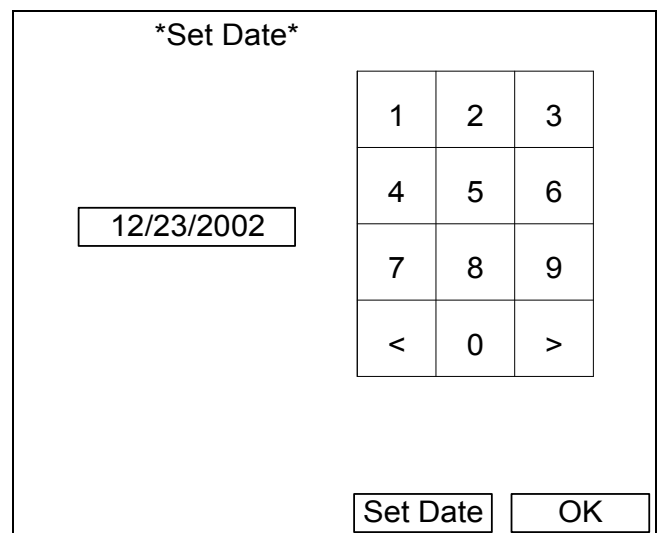


Figure 6-8. Set Date Screen*

Set Time

Current Time
09:01:00 AM

New Time

1	2	3
4	5	6
7	8	9
<	0	>

Figure 6-9. Set Time Screen*

Set Backlight

Select Backlight Brightness Level

Figure 6-11. Set Backlight Screen

Setup Sound

Click-----

Warning-----

Run Done--

Figure 6-10. Setup Sound Screen

Setup Printer

Include on printed report
(and with spreadsheet file):

Serial Number-----
(chart only)

Operator ID-----

Date-----

Time-----

Figure 6-12. Setup Printer Screen

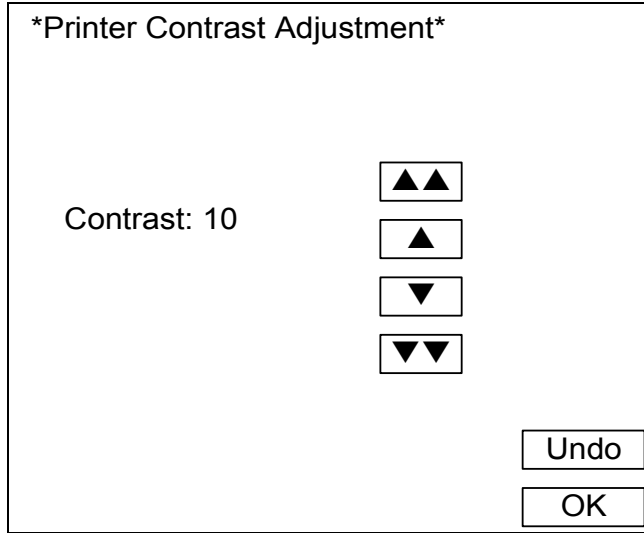


Figure 6-13. Printer Contrast Adjustment Screen

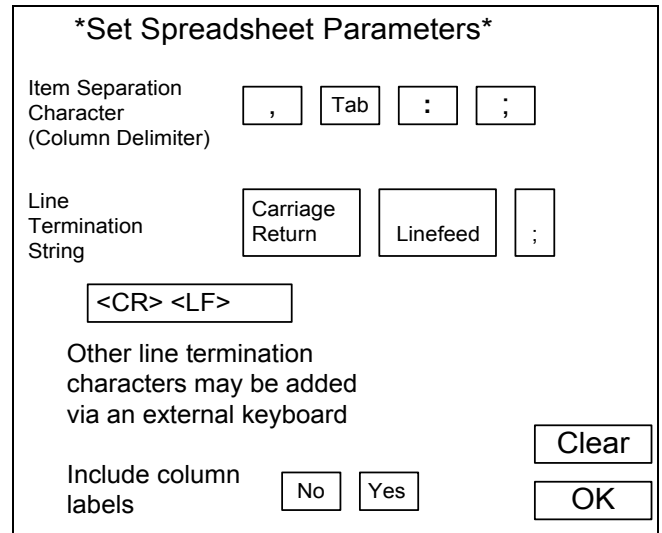


Figure 6-15. Set Spreadsheet Parameters Screen

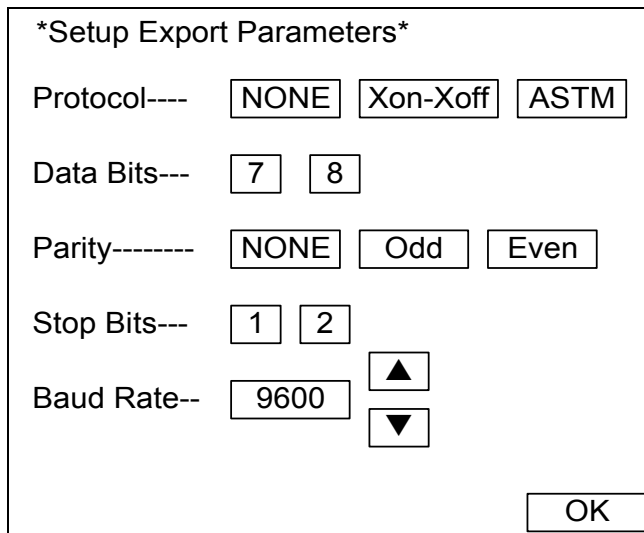


Figure 6-14. Setup Export Parameters Screen

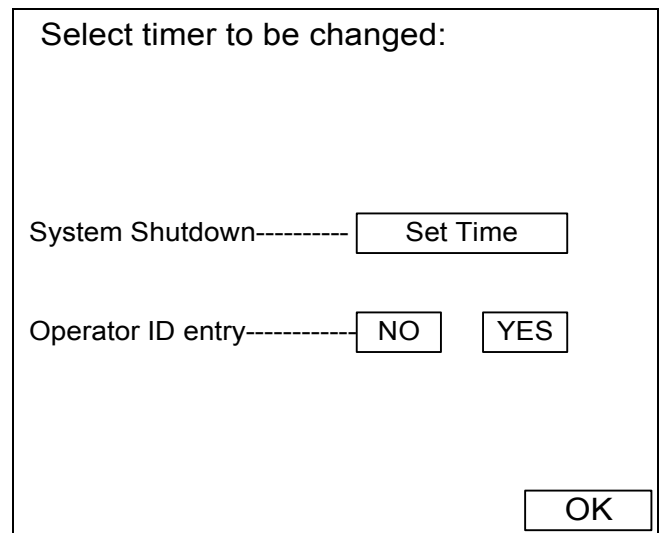


Figure 6-16. Select Timer Screen

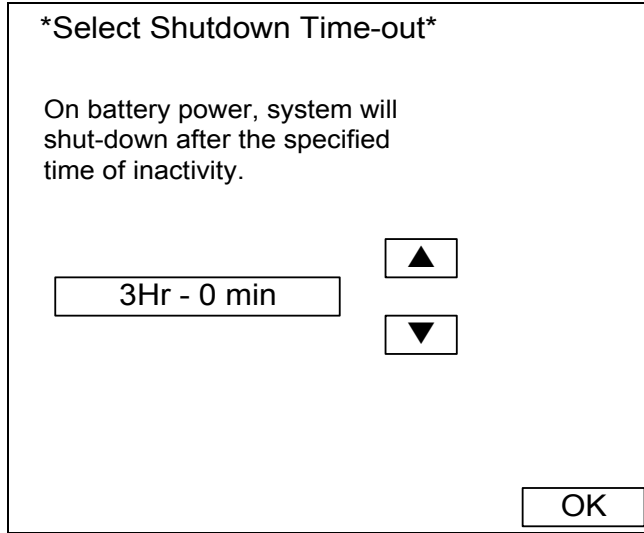


Figure 6-17. Select Shutdown Time-out Screen

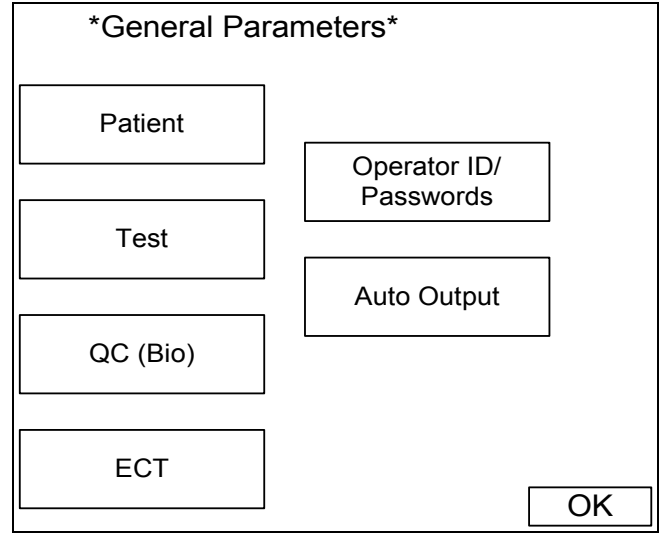


Figure 6-19. General Parameters Screen

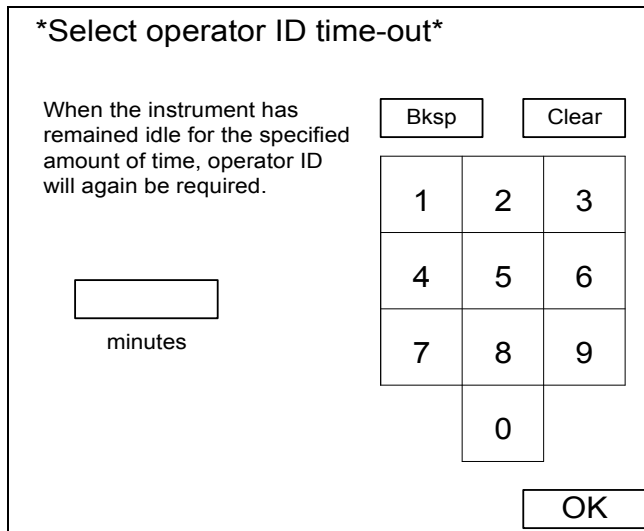


Figure 6-18. Select Operator ID Time-out Screen*

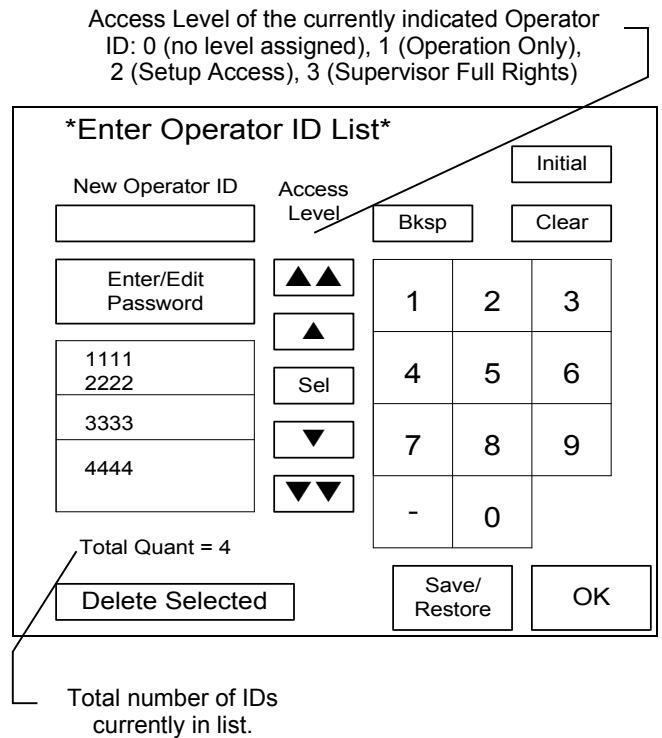


Figure 6-20. Enter Operator ID List Screen*

Enter password

Bksp Clear

1	2	3
4	5	6
7	8	9
-	0	

OK

Figure 6-21. Passwords Screen*

Setup Test Parameters

Allow 2nd Operator----- NO YES
for well 2

ACT Timing Sequence--- NO YES

High/Low Limits----- NO YES

OK

Figure 6-23. Setup Test Parameters Screen

Select Editable Demographics

Patient ID Entry OFF ON Always Immediate

ID Auto Entry Interval (Hrs) OFF 1 2 3 4 5

Sex NO YES

Height NO YES

Weight NO YES

Default Test NO YES

OK

Figure 6-22. Select Editable Demographics Screen

ACT Timing Sequence

Perform ACT every minutes

Bksp Clear

1	2	3
4	5	6
7	8	9
	0	

OK

Figure 6-24. ACT Timing Sequence Screen*

ACT Test Range Limit

Enter Acceptable Limits

Lower (seconds)

Upper (seconds)

Bksp Clear

1	2	3
4	5	6
7	8	9
	0	

OK

Figure 6-25. ACT Test Range Limits Screen*

QC(bio) Schedule

Run QC(bio) every hour(s)

Bksp Clear

1	2	3
4	5	6
7	8	9
	0	

OK Cancel

Figure 6-27. QC(bio) Schedule Screen*

Setup QC(bio)

QC(bio) levels which must pass: 1 2 3

Set QC(bio) Schedule

Enter Parameters for:

C-Act K-Act

G-Act Max-Act

OK

Figure 6-26. Setup QC(bio) Screen

QC Lot Numbers

Test: C-ACT

Level	Lot Number
<input type="text"/> 1	
<input type="text"/> 2	
<input type="text"/> 3	

OK

Figure 6-28. QC Lot Numbers Screen

Enter Lot Number

Bksp Clear

1	2	3
4	5	6
7	8	9
-	0	

OK

Figure 6-29. Enter Lot Number Screen*

or Upper

Enter Lower Limit (sec)

Bksp Clear

1	2	3
4	5	6
7	8	9
	0	

OK

Figure 6-31. Enter Lower/Upper Limit Screen*

QC Mean and Range

Test: C-ACT

Level	Mean	Lower Limit	Upper Limit
1			
2			
3			

OK

Figure 6-30. QC Mean and Range Screen

Setup ECT

ECT levels which must pass: 1 2 3

Set ECT Schedule

OK

Figure 6-32. Setup ECT screen

ECT Schedule

Run ECT every

hours

1	2	3
4	5	6
7	8	9
	0	

Figure 6-33. ECT Schedule screen*

Save/Restore/Print

Save Parameters	Save Operator IDs
Restore Parameters	Restore Operator IDs
PRINT Setup Parameters	PRINT Operator ID List

Figure 6-35. Save/Restore/Print Screen

Setup Automatic Output

Make Selections for Automatic:

View Chart-----

Print -----

Transmit-----

Save Patient-----
(spreadsheet)

Save QC-----
(spreadsheet)

Figure 6-34. Setup Automatic Output Screen

Section 7 - Operating Instructions

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

1. If transmitting data to an external computer (LIS) and/or using an optional barcode reader, connect the LIS and/or barcode reader to the instrument (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection locations) prior to powering up the instrument.

2. Turn the power switch On ().

3. The first displayed screen is the *Enter Operator ID* screen (Figure 7-1).

a. If operator identification number / password / security access level combinations have been setup for all three access levels, enter an appropriate operator ID number in the *Operator ID* field using the keypad, *Bksp* (backspace), and *Clear* keys or a barcode reader. Then enter the corresponding password in the *Password* field using the keypad, *Bksp* (backspace), and *Clear* keys. Use the ▲ up and the ▼ down keys to move between the two fields. With the operator ID and password entered, press *OK*.

(1) If the Allow 2nd Operator for Well 2 feature (section 6.2.3) is in use, the access level of the operator ID entered here determines the access level of both operators. If the well 2 operator ID is not entered (section 7.5), and well 2 is used, data generated from that well is attributed to the well 1/main operator ID.

b. If either no operator IDs or no Operation Only access level IDs have been setup, either enter an identification number in the *Operator ID* field, using the keypad, *Bksp* (backspace), and *Clear* keys, or a barcode reader, and select *OK*, or simply select *OK* and:

(1) If Supervisor Full Rights and/or Setup Access level operator IDs have been setup but no IDs have been given Opera-

tion Only access, then this allows Operation Only access to the instrument.

(2) If the instrument has not been setup to use any operator ID number / password combinations, then this allows Supervisor Full Rights access to the instrument.

4. If saving data for use on a spreadsheet, insert a floppy disk into the disk drive (see **Error! Reference source not found.** for disk drive location).

7.1. Instructions for Clotting Time Tests

7.1.1. Run Test

Please refer to the activator package inserts (Actalyke test tube: C-ACT, K-ACT, G-ACT, and MAX-ACT) for a detailed description of performing an ACT clotting test.

The instructions for specimen collection and handling and preparation of patient samples and controls, are in the appropriate sections of the procedure supplied with the tubes.

1. Confirm the instrument is ready for use by observing that the *Run Test* screen is displayed and that the test well temperatures read 37°C. If the instrument is on battery power, it may have begun its battery conservation sequence and as a result need to be reactivated. For information on the battery conservation sequence and reactivating the instrument, see section 7.4.2.

2. If the *Patient ID* key is displayed on the *Run Test* screen (Figure 7-2), select *Patient ID* and enter the appropriate patient information (section 7.1.1.1).

a. Depending on the selections made in setup, patient information may or may not be required input with the run of each test (section 6.2.2).

b. For the instrument to retain patient data, Patient ID Entry (section 6.2.2) must be in use. The instrument's maximum storage capacity is 25 ACT test results and 8 heparin dosages for each of up to 15 patients. If more than 25 ACT results are attributed to a

patient, the first result is deleted from memory and the most recent 25 results are retained.

3. Collect the patient sample according to the procedure for the tube in use.

4. Open the flip top of the tube.

5. Dispense the required amount into the tube and start the instrument's timer by pressing the *Start* key for the appropriate well. When the timer begins, the *Start* key becomes an *Abort* key. For instructions on aborting a test, see section 7.2.

6. Close the tube flip top and mix the tube's contents according to the procedure.

7. Insert the tube into the test well.

a. If the tube is not inserted into the test well within 45 seconds, the instrument alerts that no tube has been detected. If the tube is not inserted, the instrument repeatedly prompts until 90 seconds have elapsed. The instrument then automatically aborts the test and resets the well to *Start*.

8. Rotate the tube according to the procedure. The *Tube* status, located on the bottom left of the *Run Test* screen, should read *In* for the test well in use. If the status reads *Out*, rotate the tube clockwise to ensure the tube is fully inserted. If *Out* remains, see section 10.2.

9. During a test, if the keys are available, the user may select the *View Chart* key (section 7.1.2), the *Patient ID* key (section 7.1.1.1), or may run a test in the other test well (see step 1 of this section).

10. Upon clot detection, the following occurs:

a. the beeper sounds.

b. the screen displays one of the following:

(1) the clotting time results on the *Run Test* screen.

(2) the *Results ACT* chart, see section 7.1.2 for information on using and exiting this screen.

(3) a prompt to enter the type of test run, *C-ACT*, *K-ACT*, *G-ACT*, or *MAX-ACT*. Select the test type and the screen display changes to the screen described in either step 10.b.(1) or 10.b.(2).

(4) a prompt to enter the patient ID, see section 7.1.1.1 for instructions on using and exiting this screen. The screen display changes to the screen described in step 10.b.(1), 10.b.(2) or 10.b.(3).

c. if set to print, the printer prints at minimum: the type of test run, the number of the well used, and the clot time. If the temperature of the test well used was out of range (section 9.1) when the test was run, the printout includes "T-" for lower than the low limit, or "T+" for higher than the high limit. Additional information may print depending on the selections made in setup, see sections 6.1.5, 6.2.2, 6.2.3, and 6.2.6.

11. On the *Run Test* screen, the *Start/Abort* key becomes a *Reset* key. To run additional tests and reset the timer to zero, remove the previously run test tube and select *Reset*. Some keys cannot be accessed until *Reset* is selected. Once selected, the *Reset* key returns to the *Start* key function. (Note that if the ACT Timing Sequence and/or the QC/ECT Schedule time intervals have elapsed while the *Run Test* screen contains clotting time results, the prompt to run the required ACT and/or QC test will not appear until the timer(s) are reset to zero.)

7.1.1.1. Patient ID/Patient Demographics

If patient ID numbers and any patient demographics are enabled as required input for running ACT tests, the *Patient ID* key will appear on the *Run Test* screen (Figure 7-2). The patient identification information is entered either prior to or during a test. The only exceptions to this is if the Patient ID

Entry is set to On with ID Auto Entry Interval setup for use and the time interval has expired, or if the Patient ID Entry is set to Always (section 6.2.2). In either case, the patient information can be entered after the test is complete.

Once *Patient ID* is selected, the *Patient Demographics* screen (Figure 7-3) displays. The following sections describe the features on this screen. Note that any displayed information for quantity of ACT points, number of times heparin has been administered, and the total heparin dosage administered are the cumulative amounts for the patient currently indicated run on the displayed test type.

7.1.1.1.1. Well Number

To select the applicable well number, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.
2. Use the *Well #* key to indicate the well number to be used, 1 or 2.
3. Select one of the following:
 - a. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.
 - b. To select a demographic, sex, height, and/or weight, see step 2 of section 7.1.1.1.3, 7.1.1.1.4, and/or 7.1.1.1.5, respectively.
 - c. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.
 - d. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.
 - e. To return to the *Run Test* screen, select *OK*.

7.1.1.1.2. Patient ID & Test

To enter, select, edit, and/or delete a patient ID number and/or select a test type to be run, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.
2. Confirm the correct well number is indicated, and change if needed (section 7.1.1.1.1). Select the *Patient ID & Test* key and the *Patient ID Entry/Selection* screen (Figure 7-4) displays.
3. To enter a patient ID either:
 - a. Use an optional barcode reader (see **Error! Reference source not found.** and **Error! Reference source not found.** for connection location). If the input field contains an ID number, press *Clear*. Scan in the ID and the *Patient Demographics* screen displays.
 - b. Use the keypad, *Bksp* (backspace), and *Clear* keys (Figure 7-4). The patient ID number can contain up to 15 characters.
4. To select a previously entered patient ID, use the up ▲ and down ▼ keys to indicate the ID number and press the *Sel* key.
5. To edit the patient ID number of a previously entered patient (do not use this feature when the same ID number is already selected for the other well as data may be lost):
 - a. Use the up ▲ and down ▼ keys to indicate the ID number and press the *Sel* key.
 - b. Enter the new number using the keypad, *Bksp* (backspace), and *Clear* keys.
 - c. Select *Update*.
 - (1) If the main/well 1 operator ID in use has Setup/Supervisor access, the screen displays, "*Reassign previous data run as patient ID X to patient ID XX? No Yes.*" Select *Yes* to have the data currently attributed to patient ID 'X' attributed to 'XX'; otherwise, select *No*.
 - (2) If the main/well 1 operator ID in use has Operation Only access, the operator cannot alter the number and the screen displays, "*Requires Setup Access. Previous data run as patient ID X will be*

reassigned to patient XX." Touch the screen to continue.

(3) If the ID being changed has already been used and has data attributed to it, the screen displays, "*Patient ID X already exists and contains Y runs. Cannot merge with data from XX.*" Touch the screen to continue.

d. The Patient ID Entry/Selection screen displays and contains, regardless of the prompt displayed or the response selected, the altered ID. To use this number (either as a new patient ID or as the altered ID), proceed to step 10; otherwise, enter or select the desired ID (see step 3 or 4, respectively).

6. To alter the demographics of a previously entered patient, use the up ▲ and down ▼ keys to indicate the ID number and press *Sel.* Press *OK* to exit the screen. To alter the demographics displayed, see step 2 of section 7.1.1.1.3, 7.1.1.1.4, and/or 7.1.1.1.5.

7. To delete a patient ID, select the patient ID from the list of ID numbers using the up ▲ and down ▼ keys to indicate the ID number. Press *Delete Selected.* The screen displays, "*Delete patient X (test name)? No Yes.*" Select *Yes* or *No*, as appropriate, and the *Patient ID Entry/Selection* screen displays.

8. To delete all patients, select *Clear List.* The screen prompts, "*Delete all patient files? No Yes.*" Select *Yes* or *No*, as appropriate, and the *Patient ID Entry/Selection* screen displays.

9. With a patient ID entered or selected, to indicate the test to be run, select *Test.* The *Select Test* screen displays. Select the appropriate test name and the *Patient ID Entry/Selection* screen displays.

10. Once all the required selections are made, select *OK* to return to the *Patient Demographics* screen (Figure 7-4)

11. Select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To select a demographic, sex, height, and/or weight, see step 2 of section 7.1.1.1.3, 7.1.1.1.4, and/or 7.1.1.1.5, respectively.

c. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.

d. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.

e. To return to the *Run Test* screen (Figure 7-2), select *OK.*

7.1.1.1.3. Sex

If the demographic Sex is setup for use (section 6.2.1.4), to indicate the applicable sex for the current patient ID, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.

2. To select the applicable sex for the displayed patient ID, press *Sex* until *Male* or *Female* displays as needed. If a different patient ID needs to be entered/selected or the other well number selected, see step 2 of section 7.1.1.1.2 or 7.1.1.1.1.

3. Select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.

c. To select a demographic, height and/or weight, see step 2 of section 7.1.1.1.4 and/or 7.1.1.1.5.

d. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.

e. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.

f. To return to the *Run Test* screen (Figure 7-2), select *OK*.

7.1.1.1.4. Height

If the demographic *Height* is setup for use (section 6.2.1.4), to indicate the height for the current patient ID, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.

2. To indicate the height for the displayed patient ID, press *Height*. If a different patient ID needs to be entered/selected or the other well number selected, see step 2 of section 7.1.1.1.2 or 7.1.1.1.1.

3. The *Select Patient Height* screen (Figure 7-5) displays.

4. Use the ▲▲, ▼▼, ▲, and ▼ keys to indicate the correct height from the list. The list contains heights from 0.0m to 4.0m in 0.1 meter increments plus each height measurement in the equivalent feet and inches.

5. With the correct height indicated, press *Select*.

6. With the selected height displayed in the *Current Height* field, select *OK*.

7. If the screen displays, "*Unsaved changes made. Exit anyway?*" then the height was changed and *Select* was not pressed. To exit without using the new height, select *Yes*. To return to the *Select Patient Height* screen and correctly complete the selection, select *No* and repeat steps 4 and 5.

8. From the *Patient Demographics* screen (Figure 7-4), select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.

c. To select a demographic, sex and/or weight, see step 2 of section 7.1.1.1.3 and/or 7.1.1.1.5.

d. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.

e. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.

f. To return to the *Run Test* screen (Figure 7-2), select *OK*.

7.1.1.1.5. Weight

If the demographic *Weight* is setup for use (section 6.2.1.4), to indicate the weight for the current patient ID, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.

2. To indicate the weight for the displayed patient ID, press *Weight*. If a different patient ID needs to be entered/selected or the other well number selected, see step 2 of section 7.1.1.1.2 or 7.1.1.1.1.

3. The *Select Patient Weight* screen (Figure 7-6) displays.

4. Use the ▲▲, ▼▼, ▲, and ▼ keys to indicate the correct weight from the list. The list contains weights from 0kg to 350kg in one-kilogram increments plus each weight measurement in the equivalent pounds.

5. With the correct weight indicated, press *Select*.

6. With the selected weight displayed in the *Current Weight* field, select from *OK*.

7. If the screen displays, "*Unsaved changes made. Exit anyway?*" then the weight was changed and *Select* was not pressed. To exit without using the new weight, select *Yes*. To return to the *Select Patient Weight* screen and correctly complete the selection, select *No* and repeat steps 4 and 5.

8. From the *Patient Demographics* screen (Figure 7-4), select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.

c. To select a demographic, sex and/or height, see step 2 of section 7.1.1.1.3 and/or 7.1.1.1.4.

d. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.

e. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.

f. To return to the *Run Test* screen (Figure 7-2), select *OK*.

7.1.1.1.6. Clear ACT Points

To delete any test data for the current patient, use the following beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.

2. To delete all clotting times attributed to the displayed patient ID run on the displayed test type, select *Clear ACT Points*. If a different patient ID needs to be entered/selected or the other well number selected, see step 2 of section 7.1.1.1.2 or 7.1.1.1.1.

3. Once *Clear ACT Points* is selected, the screen display "*Delete all data for patient #?*" with # being the patient ID number. To exit without deleting, select *No*. To delete all the test results and any heparin data attributed to the indicated patient, select *Yes*.

4. From the *Patient Demographics* screen (Figure 7-4), select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.

c. To select a demographic, sex, height, and/or weight, see step 2 of section

7.1.1.1.3, 7.1.1.1.4, and/or 7.1.1.1.5, respectively.

d. To enter any heparin dosage information for the currently displayed patient ID, see section 7.1.1.1.7 step 2.

e. To return to the *Run Test* screen, select *OK*.

7.1.1.1.7. Heparin Dosage Documentation

Up to eight heparin dosages with the times administered per patient can be stored. This heparin dosage information will be printed, saved and/or transmitted with the Results ACT chart. (For an example of the printout, see Figure 7-9.)

The heparin dosage is manually entered and the instrument automatically attributes the time the dosage is entered as the Administered at time.

The total number of times heparin has been administered and the total heparin dosage administered are displayed on the *Patient Demographics* screen after each entry. Once entered, this data cannot be alerted or corrected.

To enter a heparin dosage for the patient ID in use, use the following steps beginning from the *Run Test* screen (Figure 7-2):

1. Select *Patient ID* and the *Patient Demographics* screen (Figure 7-3) displays.

2. To enter heparin dosage information for the displayed patient ID, select *Heparin* (Figure 7-4). If a different patient ID needs to be entered/selected or the other well number selected, see step 2 of section 7.1.1.1.2 or 7.1.1.1.1.

3. From the *Heparin Dosage* screen (Figure 7-7), select one of the following:

a. To exit the screen without entering a heparin dosage, select *Cancel*.

b. To enter the dosage, use the keypad, *Bksp* (backspace), and *Clear* keys. With the dosage entered, select *OK*.

4. From the *Patient Demographics* screen (Figure 7-4), select one of the following:

a. To select the other well, see section 7.1.1.1.1 step 2.

b. To enter/select a patient ID and/or test type, see section 7.1.1.1.2 step 2.

c. To select a demographic, sex, height, and/or weight, see step 2 of section 7.1.1.1.3, 7.1.1.1.4, and/or 7.1.1.1.5, respectively.

d. To delete any test data for the currently displayed patient ID, see section 7.1.1.1.6 step 2.

e. To return to the *Run Test* screen (Figure 7-2), select *OK*.

7.1.1.2. Test

The test type to be run can be manually entered, either prior to or during the test. Also, each test well contains a test tube identification sensor to scan the barcode on the test tubes. If the test well is unable to read the barcode and if the user did not select the test prior to running, the instrument will prompt the user to select the test type once the test is complete. This prompt appears similar to that discussed in step 3 of this section; however, once a test type is selected, the displayed screen depends on the selections made in setup.

If the test type needs to be entered and patient ID is in use, see section 7.1.1.1.2 for instructions. If patient ID is not in use, the *Test* key is located on the *Run Test* screen.

To enter the test type using this key, use the following steps beginning from the *Run Test* screen (Figure 7-2):

1. Select *Test* (Figure 7-2).

2. The *Select Test* screen displays.

3. Select the correct test from the four tests available, *C-ACT*, *K-ACT*, *G-ACT*, and *MAX-ACT*.

4. The *Run Test* screen (Figure 7-2) displays.

7.1.2. View Chart

If patient ID is in use, once a patient assigned to a test well has clot time data, that data can be viewed and printed in chart form and/or transmitted to an LIS. Additionally, data for all current and stored patients can be saved to a floppy disk. To view any stored data, select the needed patient using the instructions in section 7.1.1.1.2 and then the instructions in this section.

To access the charted data, use the following steps beginning from the *Run Test* screen (Figure 7-2):

1. Select *View Chart* (Figure 7-2).

2. If neither well contains data, the instrument prompts, "*No data to display at this time.*" Touch the screen, press *OK*, and the *Run Test* screen returns.

3. With a *Results ACT* chart (Figure 7-8) displayed:

a. To view the chart for the other test well, select *Well*.

b. To save the data on a 3½" floppy disk, select *Save*.

c. To print the displayed chart, select *Print Chart* (see Figure 7-9 for an example printout).

d. To export the displayed data to an external computer (LIS), select *Transmit*. The instrument displays, "*Transmit point or complete curve? Single Point Complete Curve.*" To transmit the last point of the chart displayed when *Transmit* was selected, select *Single Point*. To transmit all of the points of the chart displayed when *Transmit* was selected, select *Complete Curve*. Once a selection is made, the *Results ACT* chart (Figure 8-4) displays.

e. To view any clotting time result not currently visible in the list, use the up ▲ or down ▼ key. This numbered list corresponds to the points plotted on the displayed chart. The results appear in order based on the time of completion for each test except if both wells were simulta-

neously in use for the same patient. In that case, the results are ordered well 1 and then well 2 regardless of when the tests were started or concluded. This ordering holds true for the plotted chart results both on the display and when printed.

f. To return to the *Run Test* screen (Figure 7-2), select *OK*.

7.1.3. Change Operator

To access the instrument using a different operator ID, or, if the Allow a 2nd Operator for well 2 feature (section 6.2.3) is in use, to assign an operator to that well, follow these steps beginning from the *Run Test* screen (Figure 7-2):

1. Select *Change Operator* (Figure 7-2).
2. If the Allow 2nd Operator for well 2 feature is in use, the screen displays, "*Select Main Operator or Well 2 Operator Main Well 2.*"

a. To enter the ID assigned to well 1, this ID will determine the access level for both users, select *Main* and see step 3.

b. To enter the ID assigned to well 2, select *Well 2*. The *Enter Well 2 Operator ID* screen displays. It is used the same as the *Enter Operator ID* screen described in steps 3 through 6, except that a saved operator ID and password must be entered even though this user will have the same access/ restriction to setup as the main/well 1 operator.

3. On the *Enter Operator ID* screen (Figure 7-1), enter an appropriate operator ID number in the *Operator ID* field (Figure 7-1) using a barcode reader or keypad, *Bksp* (backspace), and *Clear* keys.

a. This does not apply to Well 2 IDs: If Supervisor Full Rights and/or Setup Access level operator IDs have been setup but no IDs have been given Operation Only access, any ID number entered in the *Operator ID* field can gain Operation Only access to the instrument. With the operator

ID entered and the password blank, proceed to step 6.

4. Use the ▲ up and the ▼ down keys to move between the *Operator ID* and *Password* fields.

5. Enter the corresponding password in the *Password* field (Figure 7-1) using the keypad, *Bksp* (backspace), and *Clear* keys.

6. Select *OK*, to return to the *Run Test* screen (Figure 7-2).

7.2. To Abort Operation

Once a test(s) has begun, the *Start* key(s) becomes an *Abort* key(s). To abort a test, remove the test tube from the test well and press the *Abort* key for that test well.

7.3. Results

Refer to the procedure supplied with the ACT tubes for a complete discussion of Performance Characteristics.

If results on a patient show ≥ 1500 seconds, verify proper unit function by performing the clotting time quality control verification in section 8.1.1.

If further validation of the system is required, several tests should be run using Actalyke Quality Control Materials or other commercial coagulation controls, see section 8.1.2.

To view and print, if necessary, any clot time data, presented in chart form, see section 7.1.2.

7.4. Battery

The instrument contains a rechargeable battery (Catalog Number 5759) as a backup power source. The battery used in this instrument is a nickel metal hydride. This type of battery does not require full discharge prior to re-charging. Therefore, when the instrument is plugged into an AC outlet and the power switch is *On*, the battery is being continuously recharged for one hundred percent capacity at all times. If the battery becomes fully discharged, it should be recharged for a minimum of eighteen hours to restore the battery to one hundred percent capacity.

7.4.1. Battery Charge

The battery charge will vary with the amount of testing being performed. The battery power status is continuously displayed on the bottom left of the *Run Test* screen to allow for easy verification of the remaining capacity. When the instrument is on AC power, the screen reads *Charging* or *Charged*. When the instrument is on DC (battery) power, the screen reads *Battery OK* or *Batt. LOW*.

7.4.2. Battery Conservation

When the instrument is running on battery power, the instrument will respond by conserving the battery in stages based on the time elapsed since the instrument's last use.

After ten seconds of non-use, the heaters turn off.

After two minutes of non-use, the display turns off, leaving the screen black.

After the pre-selected time interval of non-use has elapsed (section 6.1.8.1), the instrument powers down.

To continue using the instrument on battery power, touch the screen to turn on the heaters, reactivate the display, and/or restart the program depending on the current status. The test wells should be back to temperature within 1 to 3 minutes. To provide for the needed time to rewarm the wells, the instrument must be prevented from again starting the conservation sequence and turning off the heaters, this can be accomplished by performing the ECT test procedure described in section 8.1.1 repeatedly, as needed.

Note that if an error message is displaying when the two minutes of non-use elapse, instead of the display turning off, an alarm sounds. Once the error message is cleared, the battery conservation timer will begin again if the instrument is idle.

If on battery the instrument's battery runs completely down, the screen will appear the same as if the instrument has powered

down. To restart the instrument, remove the F2 fuse, plug the power cord into an appropriate AC wall outlet, and turn the power switch *On*. Once the instrument is on, the F2 fuse can be reinstalled. Note the battery should be recharged for a minimum of eighteen hours to restore the battery to one hundred percent capacity.

7.4.3. Battery Usage

If the instrument is rarely or never used on battery power, the battery will not maintain maximum capacity. The sign of a less than optimal battery is when the instrument is plugged in and turned on for at least 8 hours with the *Run Test* screen reading *Charging* (so never reads *Charged*).

If this condition arises (or at least every 3 months), perform the Drain Battery function (section 10.1.6) in order to reestablish battery performance. If this does not resolve the problem, the battery can be replaced (section 10.1.10).

7.5. Operator ID

If the instrument is setup to use the Operator ID timer (section 6.1.8.2) and the selected time interval has elapsed, the screen will return to the *Enter Operator ID* screen (Figure 7-1). Enter the appropriate operator ID or operator ID / password combination needed to gain access to the *Run Test* screen (Figure 7-2). If the Allow 2nd Operator for well 2 feature (section 6.2.3) is in use, no prompt to re-enter the well 2 ID will occur. This prompt only applies to the main or well 1 operator ID. The well 2 ID must be re-entered/changed (section 7.1.3) or the well 1 ID will be attributed to both wells.

7.6. Software Installation

If the option to remove all current data files (step 7.b.) will be used, the currently entered information can be backed up prior to software installation and then restored once installation is complete (section 6.4).

NOTE: *The software must be reinstalled by a qualified service person using an external USB Floppy drive to perform the installation.*

1. Turn the instrument *Off*. Insert the software upgrade floppy disk into the floppy disk drive located on the right side of the instrument. Turn the instrument *On*.
2. Once the software installation is complete, the instrument displays, "*Remove disk from drive A.; reboot, and see Actalyke XL Operator's Manual Software Installation section for further instruction.*" Press the button located on the instrument's floppy disk drive to remove the disk.
3. Turn the instrument *Off*, wait 10 seconds, and turn the instrument *On*. The screen displayed should contain the current software version. Please record this software version with your instrument maintenance records.
4. The screen may prompt for the *Touch Panel Calibration* to be completed, see section 10.1.5).
5. When the instrument displays the *Technician ID* screen, select *OK*.
6. If the instrument displays, "*Error Log File Exists. Move it to floppy? No Yes,*" **the user should press NO. Pressing YES will cause the instrument display to freeze. If YES is accidentally selected, restart the instrument.**
7. With the *Run Test* screen (Figure 7-2) displayed, select *Setup, Maintenance,* and *Software Update*. Select one of the following:
 - a. To install the software and retain current data files, select *Update Only*.
 - b. To install the software and remove current data files, select *New System*. The instrument displays, "*Warning: This will delete all data files (QC, patients, & parameters) and set batch files to start in normal mode (non-maintenance). Continue? No Yes.*" Select *Yes*.
8. Once the *Enter Operator ID* screen (Figure 7-1) displays:
 - a. If data files were retained, enter the appropriate *Operator ID* and *Password* and select *OK*.
 - b. If data files were removed, select *OK*.
9. The new software is now installed. Verify functionality (section 5.3).
10. The new software is now ready for use. See section 6 for setup instructions:
 - a. If data files were retained, setup any new and/or altered features.
 - b. If data files were removed, setup all features, or, if the setup data was backed up to a floppy disk, restore the data (section 6.4.2) and then setup any new and/or altered features.

If the Allow 2nd Operator for Well 2 feature is in use and Change Operator and then Well 2 are selected, then this is the Enter Well 2 Operator ID screen.

*** Enter Operator ID***

Bksp Clear

Operator ID
0123

▲

▼

1	2	3
4	5	6
7	8	9
	0	

OK

Figure 7-1. Enter Operator ID Screen*

Once a Patient ID is entered, the ID number will display.

Number of ACT points attributed to the patient and test type displayed

Patient Demographics

Normal ACT

Well # 1 Clear ACT points 0

Patient ID & Test

Sex Male Heparin (0) Total 0 IU

Height 0.0m - 0' 0"

Weight 0 kg - 0 lb

OK

Sex, Height, and/or Weight are accessible based on selections made in setup.

Total number of times heparin and total dosage administered for the patient and test type displayed.

Figure 7-3. Patient Demographics Screen

or ECT Sched., which ever has the least time remaining. Time shown in hours, minutes, and seconds.

Test key, if Patient ID Entry set to Off.

This area is blank, if Patient ID Entry set to Off.

QC-B Sched: 0:59:47

RUN TEST

Change Operator

Start 1

Patient ID 445-73-0049

Start 2

Patient ID 445-73-0049

QC Patient ID

View Chart Setup

Temp(C): (1) 37.0 (2) 37.0
Heater: OFF OFF
Tube: OUT OUT
Charging

or Charged or, if on battery power, Battery OK or Batt. LOW.

Paper Feed key, if the level of Operator ID in use is Operation Only.

Figure 7-2. Run Test Screen

Input Field

Patient ID Entry/Selection

Well: 1

0333333333 Update Bksp Clear

Test C-ACT

1	0333333333
2	0111111111
	0222222222
	0444444444
	0555555555
	0666666666

▲ Sel ▼

1	2	3
4	5	6
7	8	9
-	0	

Clear List Delete Selected OK

1 and 2 indicate the patient IDs currently assigned to each well.

Figure 7-4. Patient ID Entry/Selection Screen*

Select Patient Height

Current Height

0.0m - 0' 0"

0.0m - 0' 0"
0.1m - 0' 3"
0.2m - 0' 7"
0.3m - 0' 11"
0.4m - 1' 3"
0.5m - 1' 7"

▲▲

▲

Select

▼

▼▼

OK

Figure 7-5. Select Patient Height Screen

Heparin Dosage

Bksp Clear

Enter Dosage

(IU)

1	2	3
4	5	6
7	8	9
	0	

Cancel OK

Figure 7-7. Heparin Dosage Documentation Screen*

Select Patient Weight

0 kg - 0 lb
1 kg - 2 lb
2 kg - 4 lb
3 kg - 6 lb
4 kg - 8 lb

▲▲

▲

Select

▼

▼▼

Current Weight

0 kg - 0 lb

OK

Figure 7-6. Select Patient Weight Screen

Results ACT

Patient ID: 451

Well 1

1	99
2	280
3	350

▲

▼

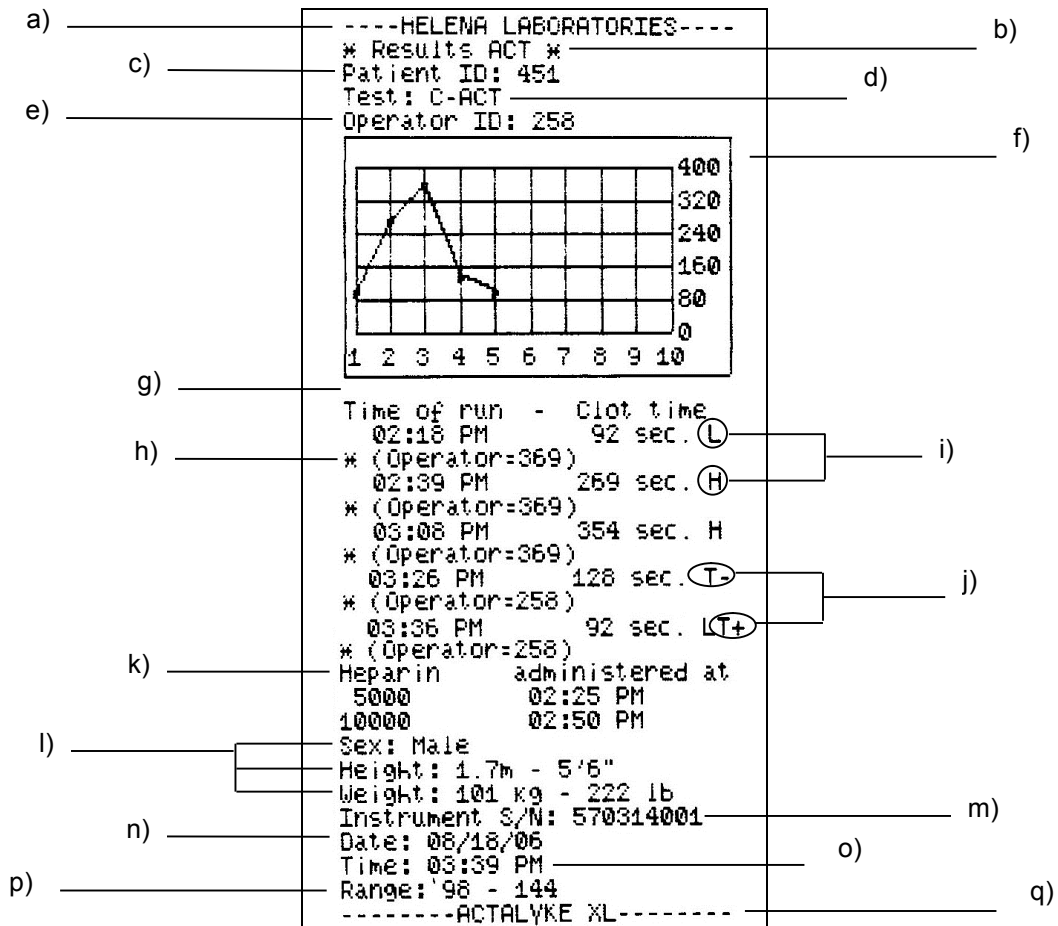
Save

Print Chart

Transmit

OK

Figure 7-8. Results ACT Chart Screen



Description of printed information	To include/exclude from printout, see section
a) Header	6.1.5.2
b) Printout title	always included
c) Patient ID	6.2.2 & 7.1.1.1
d) Test	always included
e) Operator ID currently in use	6.1.5
f) Clot time results charted	always included (6.2.2, 6.2.6 & 7.1.2)
g) Clot time results listed	always included
h) Operator ID that ran test	6.1.5 & 6.2.3
i) Test results outside of ACT Test Range Limits (H if above high limit and L if below low limit)	included if ACT range limits (6.2.3) in use and the test results are not within range
j) Test well temperature outside of range limits (T+ if above high limit and T- if below low limit)	included if the temperature of the test well used was not within range (9.1)
k) Heparin Documentation	6.2.2 & 7.1.1.1
l) Patient Demographics	6.2.2 & 7.1.1.1
m) Instrument Serial Number	6.1.5
n) Date printed	6.1.5
o) Time printed	6.1.5
p) ACT Test Range Limits	6.2.3
q) Footer	6.1.5.2

Figure 7-9. Results ACT Chart Printout

Section 8 - Test Functions and Quality Control

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

Routine quality control testing and tracking should be part of a comprehensive quality assurance program. Quality Control products are available for routine Actalyke tests.

8.1. QC

The instrument automatically performs a self-test any time the power is turned *On*. Should an error message appear on the display, see section 10.2.

Entering and Exiting the QC Mode

The QC mode can be manually entered at any time by selecting the *QC* key on the *Run Test* screen, and then, by making a selection from the *QC OPTIONS* screen (Figure 8-2).

When the QC mode is manually entered and when no tests are run, the QC mode is manually exited by selecting the *Patient* key.

The QC mode is automatically entered, when *QC(bio) Schedule* and *QC(bio) Levels Which Must Pass* and/or *ECT Schedule* and *ECT Levels Which Must Pass* are in use, once a selected schedule time elapses. At that time, the test or tests required must be run.

When a biological QC and/or ECT test is run and the well(s) used reset (and, if in use, any *Levels Which Must Pass* requirements are complete), the instrument automatically exits the QC mode.

8.1.1. Run ECT Self Check (Clotting Time Check)

The Actalyke Electronic Clotting Tube (ECT), Catalog Number XL-ECT, is available for verification of clotting time. Follow the instructions provided in the ECT package insert and the following steps beginning from the *Run Test* screen (Figure 8-1):

1. Select *QC* (Figure 8-1).
2. Select *Run ECT Self Check* (Figure 8-2).

3. The instrument displays, "Select Well for QC ECT: Well #1 Well #2 Cancel." Select one of the following:

- a. Select *Cancel* and then *OK* to return to the *Run Test* screen (Figure 8-1).

- b. Select *Well #1* or *Well #2* for the desired test well and proceed to step 4.

4. From the displayed options, *100 seconds*, *300 seconds* and *500 seconds*, select the same time as the time set on the ECT (see the ECT instructions for information on setting the time).

5. Turn the ECT *On* (see the ECT instructions for information on turning *On* the ECT), and simultaneously press the *Start* key for the appropriate test well.

6. Insert the ECT into the appropriate test well.

7. When the test is complete, depending on selections made in setup, the results are printed and/or the screen displays either the time on the *Run Test* screen (Figure 8-1) or the *Levey-Jennings* chart (Figure 8-4). (See section 8.1.3 for information on the *Levey-Jennings* chart.)

8. From the *Run Test* screen (Figure 8-1), remove the ECT and press *Reset* to reset the timer to zero and allow additional tests to be run. (Note: If the *Run Test* screen contains time results when the time interval between QC/ECT tests elapses, the prompt to run the next QC/ECT test will not display. Once the timer(s) is reset to zero, the prompt will display. For ACT tests, in addition to the timer being reset to zero, the instrument must be out of the QC mode for the prompt to run the next ACT test to display.)

9. Repeat steps for the other test well.

10. Once complete, remove the ECT from the well and store it in the tube provided with the ECT.

8.1.2. Run Biological QC Test (QC of Individual Coagulation Assays)

Each box of Actalyke Activated Clotting Time tubes contains 50 tubes from a single manufactured lot. Before use, perform a verification test one time with the appropriate Actalyke QC Kit. Perform this test on one box of each lot, each time a shipment of tubes is received. Acceptable ranges for the various Actalyke coagulation assays are included in the appropriate Quality Control procedure. Biological QC tests should then be performed at least weekly to verify system function.

The range limits and lot numbers can be entered either using the instrument's touch screen (section 6.2.4.3) or, **from the Run Test screen**, using an optional barcode reader to scan the QC test barcode labels included with the QC tests. Range limits must be entered before tests can be run.

If the barcode reader is used, when the barcode label is scanned, the instrument confirms the scanned test information matches the currently entered data. (See **Error! Reference source not found.** and **Error! Reference source not found.** for barcode reader connection location.) If the test information is different and the main operator ID in use has a Supervisor Full Rights or Setup Access access level, the instrument prompts the operator, "Do you wish to backup the previous QC lot data? No Yes Cancel." To cancel without altering the test information, select *Cancel*. To backup the data, confirm a floppy disk is in the disk drive and select *Yes*. To continue without backing up the data, select *No*. With a selection made (and the data backed up, if selected) the new test information, lot number and ranges, are entered. Note that QC ranges and lot numbers cannot be entered by operators with Operation Only access.

To perform the biological QC test, see the procedure supplied with the QC tests for instructions and follow these steps beginning from the *Run Test* screen (Figure 8-1):

1. Select QC (Figure 8-1).
2. Select *Run Biological QC Test* (Figure 8-2).
3. From the *QC (Biological)* screen (Figure 8-3), select *Change Test* for the test well to be used.
4. From the displayed choices of *C-ACT*, *K-ACT*, *G-ACT*, and *MAX-ACT*, select the test being performed and the screen returns to the *QC (Biological)* screen (Figure 8-3).
5. For the test well being used, select 1, 2 or 3 for the level of the test being run.
6. Biological QC tests can be run on both wells simultaneously, so if a test and a level need to be selected for the other well, see step 3. If all the needed selections have been made, see step 7.
7. Select *OK* until the screen returns to the *Run Test* screen (Figure 8-1).
8. Follow the procedure for preparing the QC test. Unless directed to do otherwise, press the *Start* key for the appropriate test well(s) at the same time the test tube(s) is prepared. Insert the test tube(s) into the appropriate test well(s).
9. When the test is complete, depending on selections made in setup, the results are printed and/or the screen displays either the time on the *Run Test* screen (Figure 8-1) or the *Levey-Jennings* chart (Figure 8-4). If the test was run in well 2, the *Levey-Jennings* chart must be manually accessed, if needed. (See section 8.1.3 for information on the *Levey-Jennings* chart.)
10. From the *Run Test* screen (Figure 8-1), remove the test tube and press *Reset* to reset the timer to zero and allow additional tests to be run. (Note: If the *Run Test* screen contains time results when the time interval between QC/ECT tests elapses, the prompt to run the next QC/ECT test will not display. Once the timer(s) is reset to zero, the prompt will display. For ACT tests, in addition to the timer being reset to

zero, the instrument must be out of the QC mode for the prompt to run the next ACT test to display.)

8.1.3. View/Output View Chart (Levey-Jennings Chart)

The Levey-Jennings Chart's maximum storage capacity is 200 points of QC clot times per QC test type and level.

To view, save, transmit and/or print a Levey-Jennings Chart, either press *View Chart* from the *Run Test* screen (Figure 8-1) and see step 3, or use the following steps beginning from the *Run Test* screen:

1. Select QC (Figure 8-1).
2. Select *View/Output* (Figure 8-2).
3. The *Levey-Jennings Chart* (Figure 8-4) displays the test results for the test type currently selected for well 1.
4. To view a different test's chart, select *Test* and on the screen displayed select from *C-ACT*, *K-ACT*, *G-ACT*, *MAX-ACT*, or *ECT*.
5. To view the data generated on the other test well, select *Well*.
6. If the currently displayed chart contains more data points than can be displayed at once, use the *Previous Page* and/or *Next Page* keys to view the remaining data.
7. To save the data on a 3½" floppy disk, select *Save*.
8. To print the chart, select *Print Chart* (see Figure 8-5 for an example printout).
9. To export the data to an external computer (LIS), select *Transmit*. The instrument displays, "Transmit point or complete curve? *Single Point Complete Curve*". To transmit the last point of the chart displayed when *Transmit* was selected, select *Single Point*. To transmit all of the points of the chart displayed when *Transmit* was selected, select *Complete Curve*. Once a selection is made, the *Levey-Jennings Chart* (Figure 8-4) displays.

10. To return to the *Run Test* screen (Figure 8-1), select *OK* until the *Run Test* screen appears.

8.1.4. Delete Complete QC Test Data

The data generated from one test well for a specific QC test can be deleted. Note that operator IDs with *Operation Only* access cannot delete data. Additionally note that if QC data is saved to a floppy disk for use on a spreadsheet, and the same disk is used repeatedly, the data will also be deleted from that file the next time data is saved. To prevent this, a new floppy disk must be used. To delete data, use the following steps beginning from the *Run Test* screen (Figure 8-1):

1. Select QC (Figure 8-1).
2. Select *Delete Complete QC Test Data* (Figure 8-2).
3. The instrument displays, "Select Well for QC ECT: *Well #1 Well #2*." Select the appropriate well number.
4. The instrument displays, "All QC clotting times for all levels of the selected test will be deleted. *C-ACT K-ACT G-ACT MAX-ACT ECT Cancel*." Select one of the following:
 - a. To return to the *QC Options* screen (Figure 8-2) without deleting any QC data, select *Cancel*.
 - b. To delete all the QC data for the selected test type, select *C-ACT*, *K-ACT*, *G-ACT*, *MAX-ACT*, or *ECT*. The data for that test is deleted and the screen returns to the *QC Options* screen (Figure 8-2).
5. To return to the *Run Test* screen (Figure 8-1), select *OK*.

8.1.5. Delete Single QC Clot Point

A clot point from a specific QC test level can be deleted. Note that operator IDs with *Operation Only* access cannot delete data. Additionally note that if QC data is saved to a floppy disk for use on a spreadsheet, and the same disk is used repeatedly, the data will also be deleted from that file the next time data is

saved. To prevent this, a new floppy disk must be used. To delete a specific data point, use the following steps beginning from the *Run Test* screen (Figure 8-1):

1. Select *QC* (Figure 8-1).
2. Select *Delete Single QC Clot Point* (Figure 8-2).
3. The instrument displays, “*Select test C-ACT K-ACT G-ACT MAX-ACT ECT Cancel.*” Select one of the following steps:
 - a. To return to the *QC Options* screen (Figure 8-2) without deleting any QC data, select *Cancel*, see step 6.
 - b. Select *C-ACT*, *K-ACT*, *G-ACT*, *MAX-ACT*, or *ECT* to access the desired QC test data. See step 4.
4. The *QC Point Deletion* screen (Figure 8-6) displays.
5. To change the test type displayed, select *Test*. From the *Select Test* screen, select the test type. The *QC Point Deletion* screen displays.
6. To change the well number, select *Well*.
7. To change the level displayed, press *Level* until the correct level number displays, 1, 2, or 3.
8. If no data exists for a test, well, and level, an error message displays. Touch the screen to remove the prompt and press *Test*, *Well*, or *Level* to access a different list.
9. To indicate the clot point to be deleted, use the up ▲ and down ▼ keys.
10. If needed, use the *Previous Page* and *Next Page* keys to view any clot points not currently displayed.
11. With the correct data point indicated, select the *Delete* key. The prompt, “*Delete the selected QC data point? No Yes*” displays.

(1) To remove the point, select *Yes* and the *QC Point Deletion* screen returns.

(2) To return to the *QC Point Deletion* screen without removing the clot point, select *No*.

12. To return to the *Run Test* screen (Figure 8-1), select *OK* until the *Run Test* screen displays.

8.1.6. Temperature QC (Test Well Temperature Check)

1. If using an Actalyke Thermometer, Catalog Number 5757, to perform temperature checks of the test wells, refer to the installation instructions included with the Actalyke Thermometer. Then proceed to step 5.
2. To use a different temperature-sensing device, the device must have a minimum accuracy at 37°C of ± 0.2°C. Also needed are an empty glass test tube (100 mm long x 13 mm diameter) and 1 mL of water.
3. Fill the test tube with the water and place the test tube into a test well. Allow the test tube to equilibrate for a minimum of five minutes.
4. Place the temperature-sensing device into the water filled test tube. Allow the device to stabilize for three minutes and note the temperature registered.
5. The temperature should remain in a range of 36.5 to 37.5°C. If the temperature exceeds this range, see section 10.2.
6. Repeat steps for the other test well.

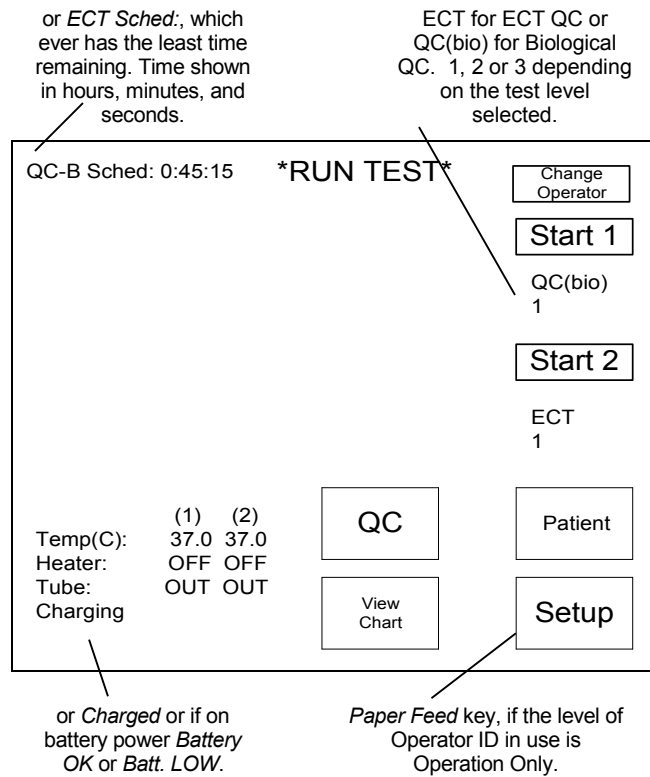


Figure 8-1. Run Test (QC mode) Screen

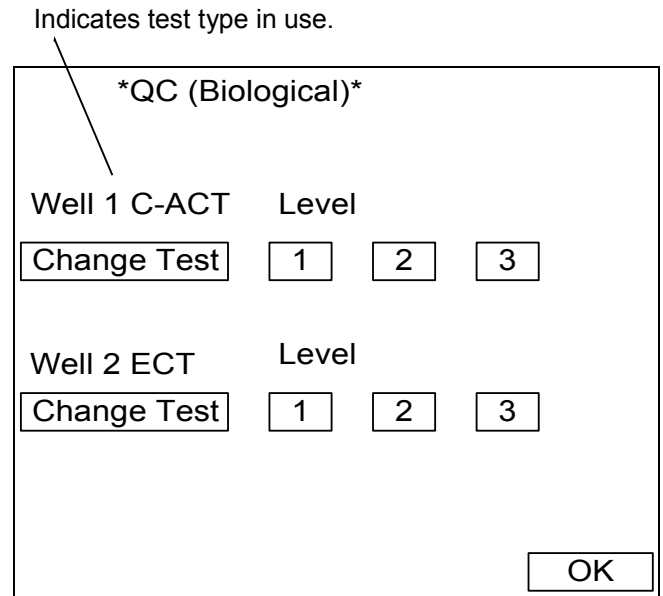


Figure 8-3. QC Biological Screen

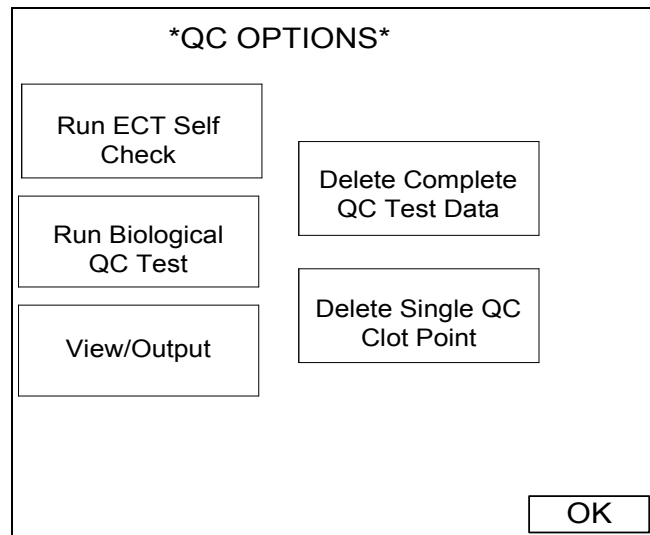


Figure 8-2. QC Options Screen

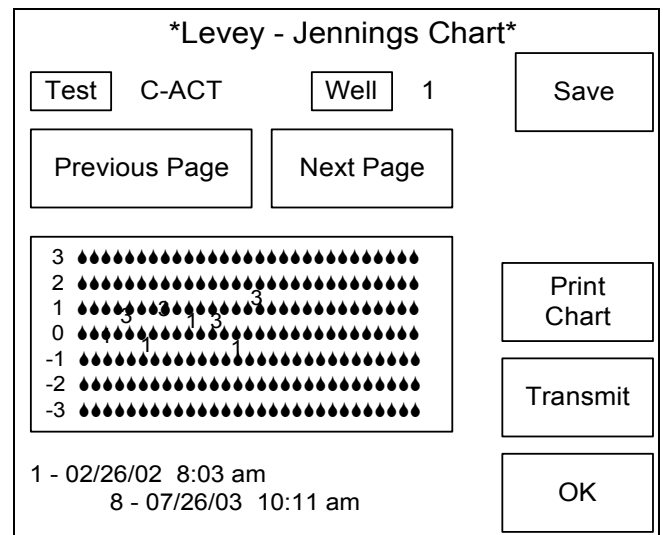


Figure 8-4. Levey-Jennings Chart Screen

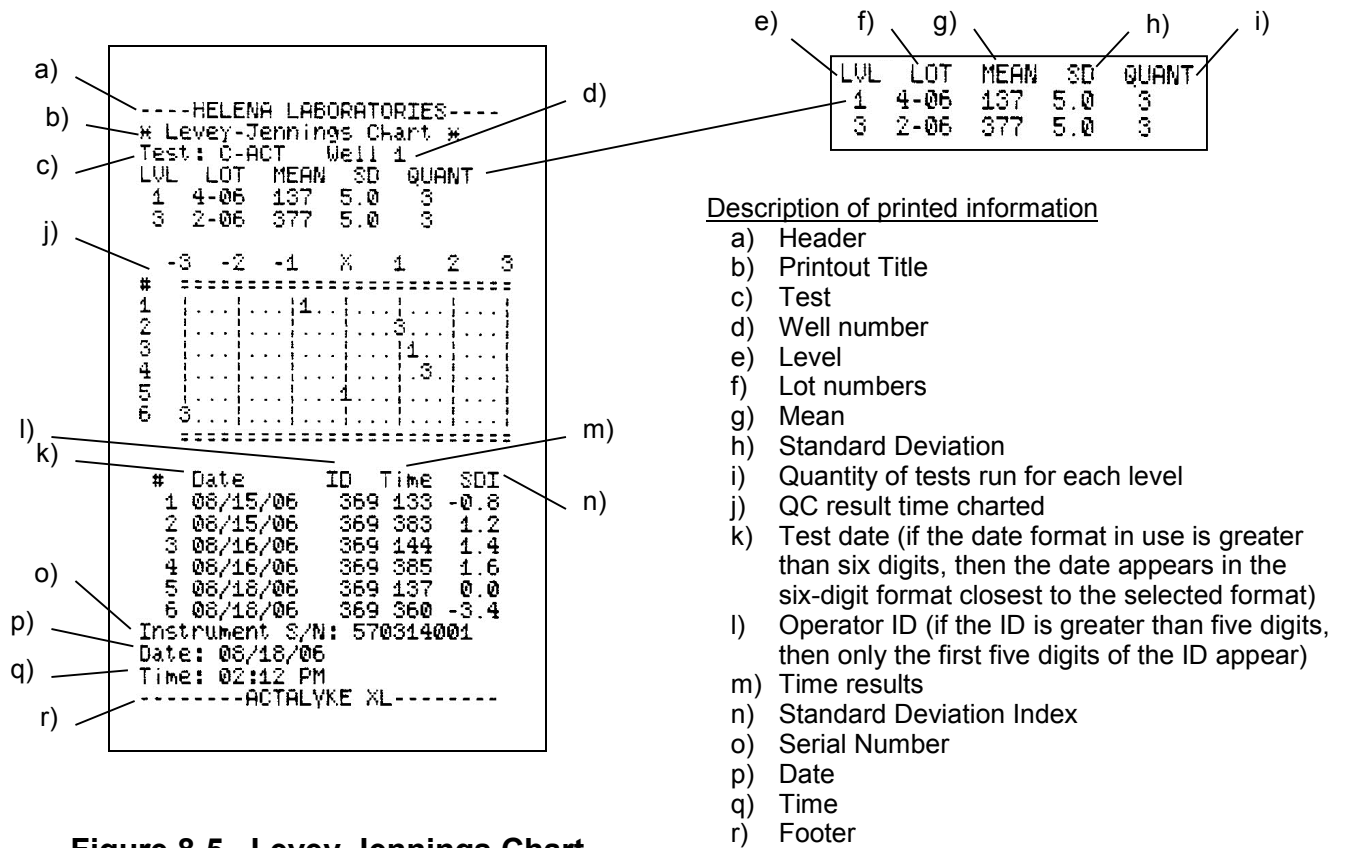


Figure 8-5. Levey-Jennings Chart Printout

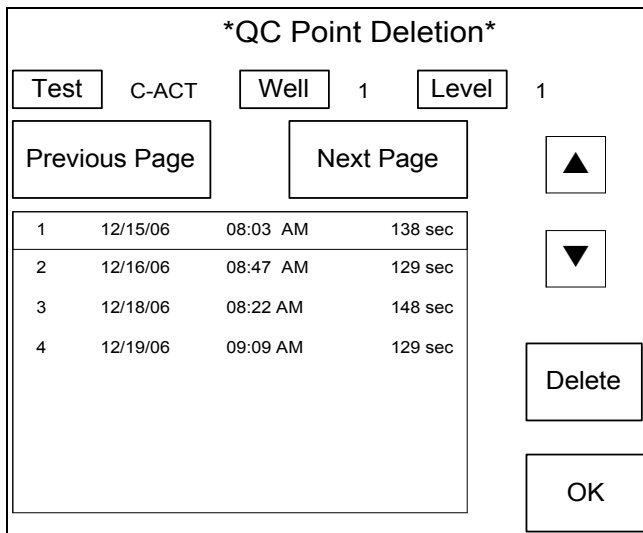


Figure 8-6. QC Point Deletion Screen

Section 9 - Performance Specifications

9.1. Instrument Performance Specifications

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

Measurement Range: 90-1500 seconds

Incubation Temperature: 36.5°C - 37.5°C

Dimensions: width x height x length
10.7" x 8.0" x 12.0"

Weight (with printer): 15 pounds

Line Voltage: 50 - 60 Hz, 110 - 220 V A/C

Power (watts): ~ 220

Leakage Current - Less than 100 :A

Two fuses located on the back panel. Only replace with equivalent fuses.

Instrument Operating Environment:

Ambient Temperature Range -
15°C to 30°C (59 to 86°F)

Operating Relative Humidity -
10% to 80%, non-condensing

Altitude 2000 M

The features of the Actalyke System include:

Testing at point-of-care or laboratory.

Uses fresh whole blood.

Test results within minutes.

Fully portable system.

Test wells automatically incubated to 37°C
(± 0.5°C).

Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class I of Low Voltage Directive 72/23/EEC).

Pollution degree 2

Microprocessor controlled for enhanced reliability and reporting of fault conditions.

LCD 3.2" x 4" for easy readability.

Printer for hard copy recording of test results.

3½" floppy disk drive for archiving results.

Test Tube:

Dimensions:

Length - 100 mm

External Diameter - 13 mm

Material: Borosilicate glass or plastic

Style: Round Bottom or Flat Bottom

Label: (for operator identification and tracking)

Test Type: Activator type.

Lot No.: Activator lot number.

Exp.: Expiration date of tubes.

9.2. System Performance Characteristics

9.2.1. MAX-ACT

REFERENCE RANGES

MAX-ACT test tubes were run on normal healthy patients using multiple Actalyke (Models XL, A2P and MINI) and Hemochron® Instruments (Model 8000). Quality control tests were performed on each instrument prior to testing of Actalyke tubes for this study. The results were as follows:

	N	Mean	2SD	Reference Range
Actalyke XL	66	118	17	100-136 seconds
Actalyke MINI	49	115	18	97-133 seconds
Actalyke A2P	49	117	22	98-136 seconds
Hemochron		112	17	95-129 seconds

Mean data from each patient was used to establish the mean ± 2SD normal range.

PERFORMANCE CHARACTERISTICS

Clinical Data Performance

Studies were also conducted clinically at numerous institutions. A total of 330 paired blood samples were collected from patients (including adult bypass, pediatric bypass, and cardiac catheterization) before, during, and following heparinization.

Using a reference celite-based ACT test (FTCA510/C-ACT) in CPB patients, the data yielded a correlation coefficient of $r^2 = 0.82$ and $r^2 = 0.89$ when samples from the reference group were omitted which were outside the published linear range (0-600 seconds) for the reference tube.

Results obtained using a reference kaolin-based ACT test (ACTII/K-ACT/FTKACT) were compared to those obtained using MAX-ACT test tubes, and the data yielded a correlation coefficient of $r^2 = 0.89$.

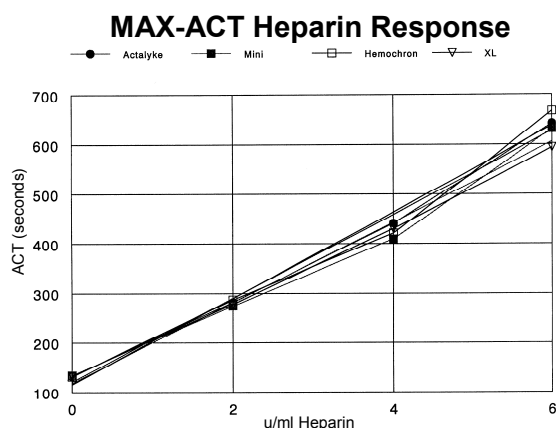
Correlation Data

The Actalyke XL and the MINI were compared to the Actalyke using MAX-ACT tubes. The data was as follows:

MINI n=166 Y=0.995X - 4 r=0.989
 XL n=104 Y=0.983X + 2.7 r=0.985

Heparin Sensitivity

Heparin response was determined with multiple heparin concentrations added to the blood of normal donors. Curves were generated using the mean of the pooled data from 5 donors (r values are >0.99) yielding the following results.



Heparin Linearity

Linearity studies were done according to NCCLS EP-6 guidelines. The MAX-ACT demonstrated an upper linearity limit of 6 units of heparin per milliliter of patient blood.

Precision Data

All precision studies were done according to NCCLS EP-5 guidelines.

Actalyke MINI

The precision of the MAX-ACT tubes with the Actalyke Mini ACT system was evaluated by performing multiple replicates on twenty separate days with heparinized and non-heparinized Actalyke Whole Blood Control samples, levels I and III.

Level	I	III
mean	125.5	401.9
SD	3.57	23.54
%CV	2.8	5.9

Actalyke XL

The precision of the MAX-ACT tubes with the Actalyke XL ACT system was evaluated by performing multiple replicates on twenty separate days with heparinized and non-heparinized Actalyke Whole Blood Control samples, levels I and III.

Level	I	III
Mean	126.3	402.2
SD	4.5	25.4
%CV	3.5	6.3

9.2.2. C-ACT, K-ACT and G-ACT

REFERENCE RANGES

Actalyke ACT test tubes were run on Actalyke instruments (Model A2P, MINI and XL) and Hemochron Instrument (Model 8000). Quality control tests were performed on each instrument prior to testing of Actalyke tubes for this study. Each tube type was run with normal volunteers on each instrument. The results are as follows:

Test	Instrument	N	Mean	2SD	Reference Range
C-ACT	Actalyke	30	123	26	97-149 seconds
	Actalyke MINI	30	123	29	94-152 seconds
	Actalyke XL	66	126	21	105-148 seconds
	Hemochron	15	126	15	111-141 seconds
K-ACT	Actalyke	35	123	28	93-150 seconds
	Actalyke MINI	35	125	25	100-150 seconds
	Actalyke XL	64	132	21	102-153 seconds
	Hemochron	15	129	23	106-152 seconds
G-ACT	Actalyke	44	185	38	147-223 seconds
	Actalyke MINI	44	181	34	147-215 seconds
	Actalyke XL	63	189	42	147-233 seconds
	Hemochron	15	167	20	147-187 seconds

PERFORMANCE CHARACTERISTICS

Precision Studies

All precision studies were done according to NCCLS EP-5 guidelines.

Actalyke MINI

The precision of the Actalyke Activated Clotting Time Test System was evaluated by performing multiple replicates on twenty separate days with heparinized and non-heparinized Actalyke Whole Blood Control samples. C-ACT and K-ACT tests were run with levels I and III; G-ACT with levels I and II. The coefficient of variation for each test type was less than 10%.

Level	C-ACT		K-ACT		G-ACT	
	I	III	I	III	I	II
mean	127.0	388.2	125.1	389.9	146.8	286.3
sd	4.60	18.44	4.97	16.40	6.76	16.37
% cv	3.6	4.8	4.0	4.2	4.6	5.7

Actalyke XL

The precision of the Actalyke Activated Clotting Time Test System was evaluated by performing multiple replicates on twenty separate days with heparinized and non-heparinized Actalyke Whole Blood Control samples. C-ACT and K-ACT tests were run with levels I and III; G-ACT with levels I and II. The coefficient of variation for each test type was less than 10%.

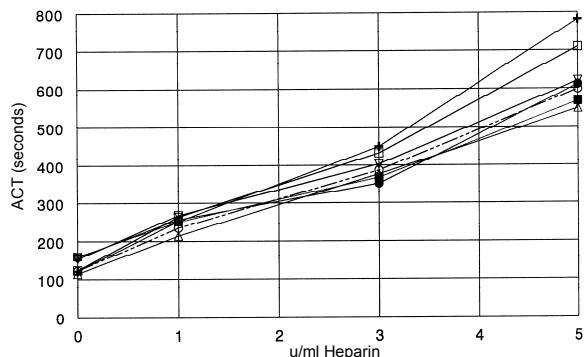
Level	C-ACT		K-ACT		G-ACT	
	I	III	I	III	I	II
mean	131.9	395.3	128.7	398.6	145.7	282.9
sd	6.3	15.3	4.6	16.7	16.7	15.8
% cv	4.8	3.9	3.6	4.2	4.2	5.6

Accuracy Data

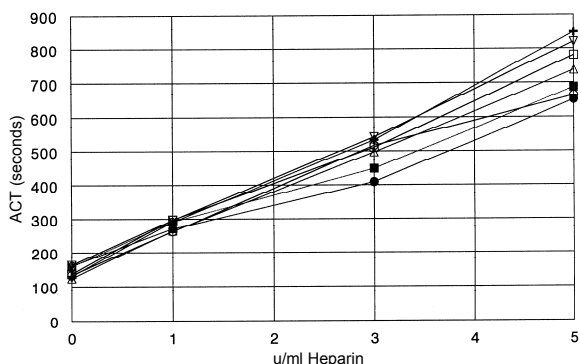
The accuracy of the Actalyke Activated Clotting Time Test System was evaluated by performing multiple Activated Clotting Time tests using varied combinations of instruments and tubes. Citrated pooled blood was heparinized to create the below concentrations yielding the following results:

Heparin Sensitivity

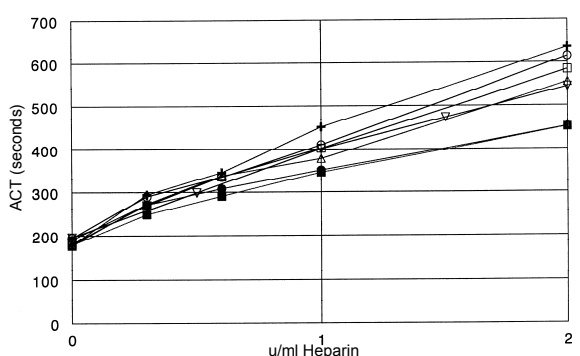
Celite Response to Heparin



Kaolin Response to Heparin



Glass Beads Response to Heparin



Key to Graphs

- A-A*
 - ▲ A-H
 - M-A*
 - A-A
 - + H-H
 - ▽ XL-A*
 - H-A
- Instrument / Tube
 A-A* = Actalyke / Actalyke
 M-A* = MINI / Actalyke
 XL-A* = Actalyke XL / Actalyke
 H-H = Hemochron / Hemochron
 H-A = Hemochron / Actalyke
 A-H = Actalyke / Hemochron
 A-A = Actalyke / Actalyke
 *run with different set of donors

Correlation Data

Patient samples from all clinical sites were tested using each tube type on the MINI, the XL and the Actalyke. The data was as follows.

C-ACT MINI	n=84	Y=0.948X + 15	r=0.979
XL	n=104	Y=0.943X + 11.7	r=0.960
G-ACT MINI	n=97	Y=0.967X + 2	r=0.979
XL	n=92	Y=0.998X - 3.0	r=0.985
K-ACT MINI	n=90	Y=0.984X + 10	r=0.966
XL	n=97	Y=0.978X + 6.9	r=0.988

Linearity

Linearity studies were done according to NCCLS EP-6 guidelines with the following results.

	C-ACT	K-ACT	G-ACT
Heparin u/mL blood	5.0	5.0	2.0

Section 10 - Maintenance, Troubleshooting, Warranty

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

10.1. Maintenance

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

WARNING: ACTALYKE XL is factory lubricated. Do NOT lubricate instrument.

Table 10-1. Maintenance Schedule

<u>Daily, if Used</u>
Clean the Instrument
Clotting Time Check (ECT)
<u>Weekly</u>
Test Well Temperature Check
<u>Monthly</u>
Clean the Test Wells
<u>Quarterly</u>
Drain Battery
Touch Panel Calibration
<u>As Needed</u>
Replace Printer Paper
Fuse Replacement
Mag Sensor Calibration
Replace Battery

Should any technical difficulties arise, it is recommended that multiple tests be run with Biological Quality Control kits (section 8.1.2) and an Electronic Clotting Tube (section 10.1.2). Results can then be discussed with Helena Laboratories Technical Services Department.

In cases where quality control results fall outside the acceptable range, patient results should be considered suspect. The cause will likely be test technique, control material, instrument, or the coagulation test tube, see section 10.2.

10.1.1. Instrument Cleaning

TURN OFF THE POWER AND UNPLUG POWER CORD BEFORE PROCEEDING.

Allow the instrument to cool, if necessary. Dampen a lint-free tissue with deionized water and wash the surface of the unit. Should an instrument be contaminated by blood or blood derivative, clean the area contaminated with a commercial virucidal and germicidal agent.

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

10.1.2. Clotting Time Check

The Actalyke Electronic Clotting Tube (ECT), Catalog Number XL-ECT, is available for verification of clotting time. Follow the instructions provided in the ECT package insert and the following steps beginning from the *Run Test* screen (Figure 8-1):

1. Select *QC* (Figure 8-1).
2. Select *Run ECT Self Check* (Figure 8-2).
3. The instrument displays, "*Select Well for QC ECT: Well #1 Well #2 Cancel.*" Select one of the following:
 - a. Select *Cancel* and *OK* to return to the *Run Test* screen (Figure 8-1).
 - b. Select *Well #1* or *Well #2* for the desired test well and proceed to step 4.
4. From the displayed options, *100 seconds*, *300 seconds* and *500 seconds*, select the same time as the time set on the ECT (see the ECT instructions for information on setting the time).
5. Turn the ECT On (see the ECT instructions for information on turning On the ECT), and simultaneously press the *Start* key for the appropriate test well.
6. Insert the ECT into the appropriate well.
7. When the test is complete, the results are printed, and the screen displays, either the time on the *Run Test* screen (Figure 8-1) or the *Levey-Jennings* chart (Figure 8-4), depending on selections made in setup. (See section 8.1.3 for information on the *Levey-Jennings* chart.)

8. From the *Run Test* screen (Figure 8-1), remove the ECT and press *Reset* to reset the timer to zero and allow additional tests to be run. (Note: If the *Run Test* screen contains time results when the time interval between QC/ECT tests elapses, the prompt to run the next QC/ECT test will not display. Once the timer(s) is reset to zero, the prompt will display. For ACT tests, in addition to the timer being reset to zero, the instrument must be out of the QC mode for the prompt to run the next ACT test to display.)

9. Repeat steps for the other test well.

10. Once complete, remove the ECT from the well and store it in the tube provided with the ECT.

10.1.3. Test Well Temperature Check

1. If using an Actalyke Thermometer, Catalog Number 5757, to perform temperature checks of the test wells, refer to the installation instructions included with the Actalyke Thermometer. Then proceed to step 5.

2. To use a different temperature-sensing device, the device must have a minimum accuracy at 37°C of $\pm 0.2^\circ\text{C}$. Also needed are an empty glass test tube (100 mm long x 13 mm diameter) and 1 mL of water.

3. Fill the test tube with the water and place the test tube into a test well. Allow the test tube to equilibrate for a minimum of five minutes.

4. Place the temperature-sensing device into the water filled test tube. Allow the device to stabilize for three minutes and note the temperature registered.

5. The temperature should remain in a range of 36.5 to 37.5°C. If the temperature exceeds this range, see section 10.2.

6. Repeat steps for the other test well.

10.1.4. Test Well Cleaning

TURN OFF THE POWER AND UNPLUG POWER CORD BEFORE PROCEEDING.

Allow the instrument to cool, if necessary. If there is an obstruction in the test well(s), carefully tilt the instrument forward and allow the obstruction to fall out. Take care when handling the obstruction in the event it has sharp edges and/or is a biohazard. Dispose of the obstruction as necessary.

If there is liquid in the test well, assume that the test well is contaminated. Clean the area with a commercial virucidal and germicidal agent. Using a lint-free tissue and a cotton swab, wipe up the residue, as these materials may contain alcohol, which is corrosive to metal surfaces. Dry the unit before plugging in the power cord or turning *On* the power switch.

10.1.5. Touch Panel Calibration

To calibrate the touch screen, use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).

2. Select *Maintenance* (Figure 6-3).

3. From the *Maintenance* screen, select *Touch Panel Calibration*.

4. The *Touch Panel Calibration* screen displays and prompts, "Touch upper left corner." Touch the upper left corner of the screen with the end of a retracted ballpoint pen or mechanical pencil.

5. Follow the other prompts to touch the screen in the upper right, lower left and lower right corners of the screen.

6. Once complete, the *Maintenance* screen displays.

7. To return to the *Run Test* screen, select *OK* until the *Run Test* screen displays.

10.1.6. Drain Battery

To maintain the battery at maximum capacity, perform the battery drain function every three months or as needed. The battery drain function needs to be performed when the instrument has been plugged in and turned on for 8 hours and still reads *Charg-*

ing. Use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Unplug the instrument and verify the bottom left of the *Run Test* screen, reads *Battery OK* or *Batt. Low*.
2. Select *Setup* (Figure 6-2).
3. Select *Maintenance* (Figure 6-3).
4. From the *Maintenance* screen, select *Drain Battery*.
5. The *Draining Battery for Cycling* screen displays and includes the *Battery State* and *Power: DC*. Note that if *Power* instead reads *AC*, unplug the instrument.
6. Leave the instrument unplugged and *On* overnight or until the instrument automatically shuts down.
7. Once the instrument has shut down, plug the instrument in and then touch the screen, in that order. Within five seconds, the instrument should restart.
 - a. If it does not restart, turn the instrument *Off*, wait 10 seconds, and turn the instrument *On*.
 - b. If the instrument again does not restart, turn the instrument *Off*, remove the F2 fuse located on the rear of the instrument, turn the instrument *On*, and replace the F2 fuse.
 - c. If the instrument again does not restart, the battery must be replaced (section 10.1.10).
8. When the *Enter Operator ID* screen displays, enter the appropriate Operator ID and password, and select *OK*. The *Run Test* screen displays and the bottom left of the screen reads *Charging*.
9. Recharge the battery for a minimum of eighteen hours by leaving the instrument plugged in and turned *On*.
10. Once the battery drain and recharge steps are complete, the *Run Test* screen should read *Charged* when the instrument is plugged in and turned *On*. If not, the

battery may need to be replaced (section 10.1.10).

10.1.7. Printer Paper Replacement

1. Unwrap a new printer paper roll.
2. Remove the empty paper roll and the paper retainer (and **Error! Reference source not found.**).
3. Ensure that the new paper roll has a tapered, sharp, even leading edge.
4. Place the new paper roll in the instrument with the paper feeding off the bottom of the roll.
5. Insert the leading edge of the paper into the back slot. It may be necessary to adjust the printer assembly's serrated plates position using the two silver screws.
6. Use the *Paper Feed* key (section 6.3) to advance the new paper.
7. If the serrated plate's position was altered, reposition the plate to allow for ease of paper/printout removal.
8. Insert the paper retainer, over the paper roll, securing it between the sides of the paper roll housing.

10.1.8. Fuse Replacement

1. Turn Off the power and unplug the power cord.
2. Using a small flathead screwdriver, which matches the slot in the fuse holder, press inward and turn the fuse holder counterclockwise to remove the fuse holder ().
3. Remove the blown fuse and replace it with one of the same type and rating.
4. Push the fuse holder in and turn clockwise, with the screwdriver, to reseal the fuse.
5. Repeat for the other fuse as necessary.
6. Plug in the power cord and turn *On* the power. If the fuse immediately blows again, call Helena Laboratories for assistance.

10.1.9. Mag Sensor Calibration

If the test wells are not accurately detecting the presence of tubes, the test wells can be calibrated. Two ECTs are required to perform the calibration. Use the following steps beginning from the *Run Test* screen (Figure 6-2):

1. Select *Setup* (Figure 6-2).
2. Select *Maintenance* (Figure 6-3).
3. From the *Maintenance* screen, select *Mag Sensor Calibration*.
4. The screen displays the prompt, "*Please remove all tubes from wells*" and two options, "*Cancel*" and "*Continue*."

a. To return to the *Maintenance* screen, select *Cancel* (see step 8).

b. To calibrate the test wells, remove any tubes from the test wells and select *Continue*.

5. The screen prompts, "*Please insert calibration tubes or ECT devices (Unset) in BOTH wells*" and two options, "*Cancel*" and "*Continue*." Calibration tubes are only for use by Helena Service Department.

a. To return to the *Maintenance* screen, select *Cancel* (see step 8).

b. To calibrate the test wells, without activating the triggers, insert an ECT into each test well and select *Continue*.

6. The screen displays the prompt, "*This procedure should take approx. 2 minutes. Please wait.*"

a. To abort the procedure, touch the screen and the *Maintenance* screen displays (see step 8).

7. When the calibration is complete, the screen displays the prompt, "*Please RE-MOVE calibration tubes. Touch the screen to continue.*" Remove the ECTs and touch the screen.

a. If the calibration was successful, the *Maintenance* screen displays (see step 8).

b. If the calibration failed, an error message displays. Record the error message, and repeat the calibration beginning with step 2. If the calibration fails for a second time, with the two error messages noted, call Helena Laboratories.

8. From the *Maintenance* screen, select *OK* until the *Run Test* screen displays.

Note that if calibration is performed while on battery power and the instrument powers off during the calibration, the calibration must be redone using AC power or with a recharged battery.

10.1.10. Battery Replacement

To replace the battery, use the Actalyke XL Battery Pack, Catalog Number 5759. Additional materials needed are 1/4" nut driver, 1/4" open end wrench, and small flathead screwdriver. This procedure should only be performed by trained electronics personnel. All directional instructions given assume the unit's control panel is facing forward toward the installer. See Figure 10-1 for additional assistance.

1. Remove the printer paper from the printer. Turn the unit's power *Off* and unplug the power cord prior to beginning installation.

2. The unit's TOP COVER is removed using the LID KEY to release the four locating tabs. Four sets of slots located on the left and right panels of the unit provide access to the locating tabs.

Beginning from the set of slots forward on the left panel of the unit and going clockwise around the unit, push the blade of the lid key into one slot per set of slots as instructed:

In the left forward set, use the BOTTOM slot.

In the left rear set, use the TOP slot.

In the right rear set, use the BOTTOM slot.

In the right forward set, use the TOP slot.

Note that the lid key does not and should not be turned in the slots. The release of the locating tabs is "silent" and will not be heard or felt.

Holding each side of the top cover, slowly lift upwards, taking care not to damage the two connections attached to the cover. One of which, the gray printer cable connected to the front panel of the unit, should be unplugged to assist in installation.

3. Remove the rear PANEL by slowly sliding the panel upward along its track in the two side panels until it is free of the unit, taking care not to damage or disconnect the connections attached to the panel.

4. The battery is located along the center of the right panel of the unit under a clear bracket. The bracket is secured with two keps nuts and two standoffs. Use the wrench to remove the keps nuts and nut driver to remove the standoffs. Remove the bracket by pulling it first free from the screws located on the floor of the unit and then free of the screws located on the right panel of the unit.

5. Trace the battery's cable from the battery to its connector on the lower of the two PCBs located in the left rear of the unit. Unplug the connector. Carefully reroute the cable and remove the battery from the unit.

6. Place the new battery on the foam pads now visible in the interior of the unit. The battery's cable and connector should come from the front left of the battery when the battery is oriented correctly within the unit.

7. Place the bracket over the battery, by aligning the holes in the bracket with the corresponding screws coming from the right panel of the unit and then the screws coming out of the floor. Insure the battery's cable is coming from between the battery and bracket toward the front of the unit.

8. Thread the battery's cable and connector between the two PCBs located in the left rear of the unit and in front of the standoff located on the right rear corner of the PCBs. Plug the connector into the lower PCB in the connection location available on the rear of the PCB. The locking clip on the

battery's connector should face the rear of the unit.

9. Use the nut driver to secure the stand-offs onto the screws coming from the floor of the unit. And use the wrench to secure the keps nuts onto the screws coming from the right panel of the unit.

10. Replace the unit's rear panel by sliding it down along the track in the two side panels until it is back in position. When reassembling, care should be taken not to crimp or damage any wiring located in these areas.

11. Replug the gray printer cable to the front panel. Replace the top cover by aligning the four locating tabs and pushing down on the cover. The cover will snap into position.

12. Prior to applying power, the F2 fuse must be removed. Insert a small flathead screwdriver into the slot on the F2 fuse holder, press inward and turn the holder counterclockwise. Remove the fuse and holder.

Plug the power cord into the unit and then into an appropriate outlet. Turn the unit *On*.

With the F2 fuse in the holder, use the flathead screwdriver to push the holder into the unit, turning it clockwise until it is reseated.

13. The battery may need to be charged for a minimum of eighteen hours to ensure it is at full capacity.

14. Dispose of the spent battery in accordance with local, state, and federal regulations.

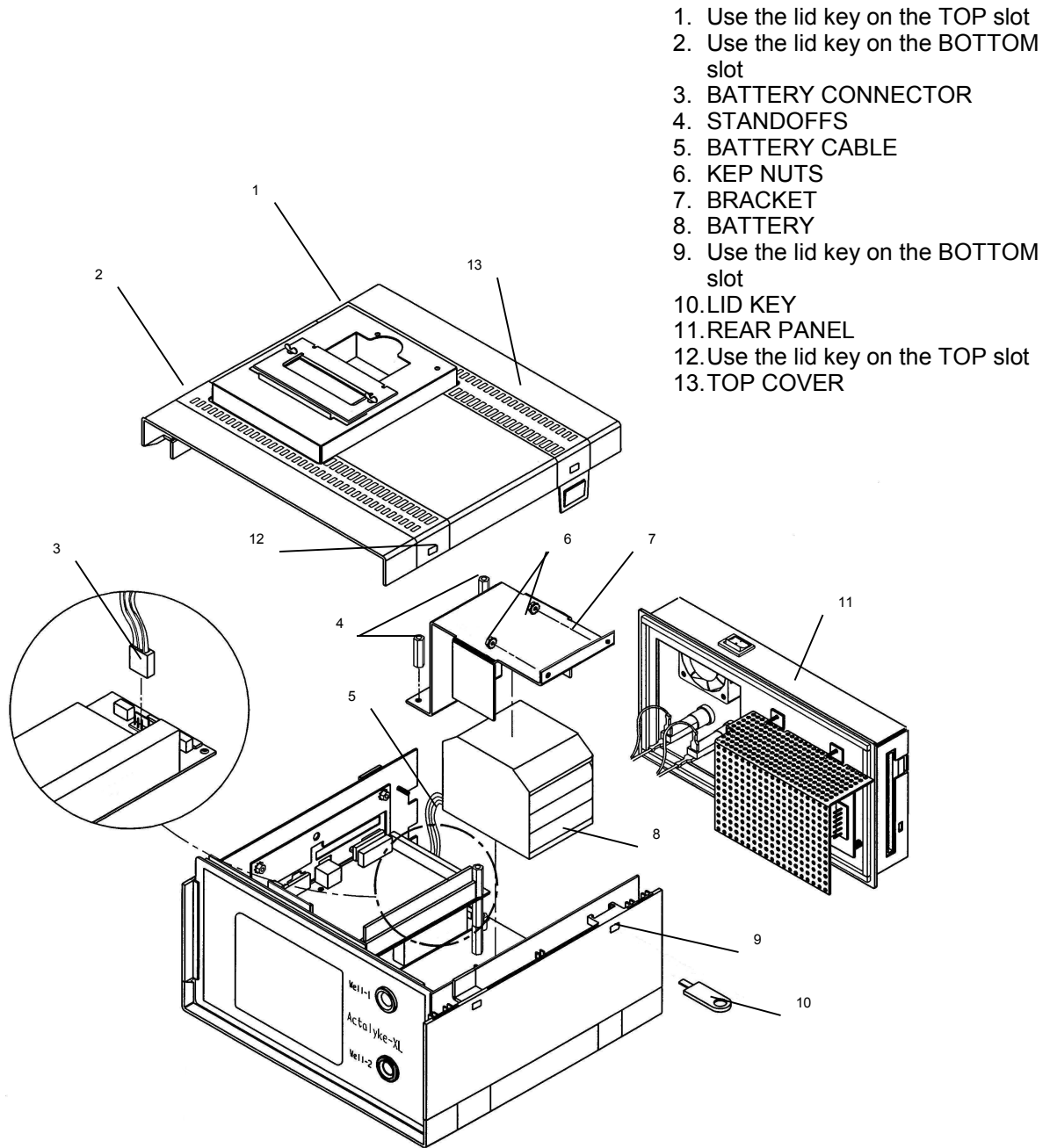


Figure 10-1. Battery Replacement

Month/Year: _____ Serial Number: _____

ACTALYKE® XL Preventive Maintenance Schedule																																
Daily, If Used	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean the Instrument																																
Check Clotting Times (ECT)																																
Weekly																																
Check Well Temperatures																																
Monthly Items																																
Clean the Test Wells																																
Quarterly																																
Drain Battery																																
Touch Screen Calibration																																
As Needed																																
Replace Printer Paper																																
Replace fuse(s)																																
Mag Sensor Calibration																																
Replace Battery																																

Note: Duplicate this page for maintenance copies. Initial each item as required. Refer to section ten, Maintenance, of the Operator's Manual for details. If you are uncertain about how to perform any step, please contact Helena Laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information.

Figure 10-2. Preventive Maintenance schedule Checklist

10.2. Troubleshooting

If the unit appears to be malfunctioning for any reason, thoroughly check for physical damage to the case, indicators, etc. caused by dropping or excessive mishandling. Should instrument problems be suspected, it is recommended that several tests be run using Actalyke Quality Control material and whichever test tubes are used clinically. Results from these tests will be helpful in identifying any potential trend in test results that could indicate a fault within the system. For further information, refer to the Actalyke Quality Control Package Insert.

The following tables list other symptoms and possible fault conditions and causes (Table 10-2, Troubleshooting and Table 10-3, Prompts and Error Messages).

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

Table 10-2. Troubleshooting

Symptom	Possible Cause(s)	Action Required
Excessive sample clotting time	Test well temperature out of range	Verify Temperature QC (section 8.1.6), if OK, rerun patient test, if out of range, call Helena Laboratories.
	Test well control problem	Verify Clotting Time QC (section 8.1.1), if OK, rerun patient test, if out of range, call Helena Laboratories.
	High heparin concentration sample	Verify QC (section 8.1), if OK, rerun patient test, if out of range, call Helena Laboratories.
Short sample clotting time	Tube not detected and instrument aborted test	Rerun patient test.
	Test well temperature out of range	Verify Temperature QC (section 8.1.6), if OK, rerun patient test, if out of range, call Helena Laboratories.
Unable to clear displayed error	Instrument needs to be reset	Turn power Off, wait 10 seconds, turn power On.
	Defective display module	Call Helena Laboratories.
LCD touch screen is slow to respond, responds erratically, or is non-responsive	Instrument needs to be reset	Turn power Off, wait 10 seconds, turn power On.
	Touch screen needs calibration	Perform the Touch Panel Calibration (section 10.1.5).
	Instrument has no power	See Troubleshooting symptom 'No power to instrument.'
	Instrument malfunction	Call Helena Laboratories.
Tube indicator not responding properly (<i>In/Out</i>)	Tube not fully inserted into test well	Reinsert tube.
	Magnet inverted in tube	Discard tube.
	Faulty tube	Remove tube and insert ECT, if detector changes to In, discard tube.

Symptom	Possible Cause(s)	Action Required
	Detector malfunction	Perform the Mag Sensor Calibration (section 10.1.9).
Tube will not rotate	Obstruction in test well	Clean test well.
	Defective drive mechanism	Call Helena Laboratories.
Poor Precision	Inaccurate tube agitation	Refer to procedure supplied with the tubes for instructions.
	Inaccurate sample volume	Refer to procedure supplied with the tubes for correct volume.
	Inconsistent time interval between inserting sample into the tube and beginning test timer	Refer to procedure supplied with the tubes for instructions.
Unable to run patient tests	Required QC/ECT tests not complete	Complete the QC and/or ECT required.
		Alter the QC and/or ECT requirements (section 6.2.4.1 and 6.2.5.1)
		Call Helena Laboratories.
Clotting time ECT not in range	Insufficient charge in ECT battery	Replace battery; see the ECT instructions.
	ECT malfunction	Perform QC (section 8.1.2). If in, call Helena Laboratories.
	Magnetic detector malfunction	Perform the Mag Sensor Calibration (section 10.1.9).
		Call Helena Laboratories.
Temperature quality control not in range	Insufficient charge in thermometer battery	Replace battery.
	Test well control problem	Call Helena Laboratories.
Unable to use barcode reader to scan in new QC range limits	Incorrect screen displayed when barcode label was scanned	Return to <i>Run Test</i> screen and re-scan label (section 8.1.2).
Printer not working	Paper jammed	Adjust serrated plate position and inspect mechanism.
	Printer mechanism/driver fault	Call Helena Laboratories.
Poor printout quality	Printout too light due to low contrast level	Increase contrast level (section 6.1.5.1)
	Printout too dark and/or illegible due to high contrast level	Decrease contrast level (section 6.1.5.1).
	Printer mechanism/driver fault	Call Helena Laboratories.
Individual coagulation assays QC not in range	Inconsistent time interval between inserting sample into the tube and beginning test timer	Refer to procedure supplied with the tubes for instructions.
	Incorrect test type and/or level selected	Repeat test.
	New lot of QC test in use and range limits not updated	Enter new range limits (section 6.2.4.3) and repeat test.

Symptom	Possible Cause(s)	Action Required
	Faulty tube	Repeat test. If remains out of range, call Helena Laboratories.
No power to instrument	Power cord unplugged and insufficient charge in battery	Plug cord into wall outlet and turn On to use and charge battery.
	Battery charge depleted (power cord plugged into wall outlet, power switch turned On and instrument remains non-functional)	Turn power Off, remove fuse F2, turn power On, replace fuse F2. Recharge the battery (section 7.4).
	Fuse blown	Check fuses and replace, if required (section 10.1.8).
Battery never reports <i>Charged</i> , always reads <i>Charging</i>	Battery is retaining charge memory	Perform Drain Battery (section 10.1.6).
	Spent battery	Replace battery (Catalog Number 5759).
	Other	Call Helena Laboratories.
Failure to initialize after the instrument has been unplugged	Battery fully discharged	Recharge the battery (section 7.4)

Table 10-3. Prompts and Error Messages

Message	Possible Cause(s)	Action Required
<i>Patient ID entry required for well #X</i>	Patient ID Entry set to On, ID Auto Entry Interval in use and time interval has elapsed.	Enter/re-enter patient ID (7.1.1.1).
<i>ACT required</i>	ACT Timing Sequence in use and time interval has elapsed.	Run an ACT test (7.1.1).
<i>QC(bio) required, ECT required, QC(bio) should be run first, or ECT should be run first</i>	QC(bio) and/or ECT Schedule selected time interval has elapsed.	Run a QC and/or ECT test (8.1).
<i>No acknowledgement from LIS, touch screen to continue. Unable to establish communication. Aborting transfer, touch screen to continue. (ASTM protocol in use)</i>	Instrument and LIS not connected.	Connect instrument and LIS.
	External computer (LIS) communication problems.	Verify LIS status.
	Instrument communication problems.	Call Helena Laboratories.
<i>Warning - Temperature out of range in well X. Touch screen to continue.</i>	If instrument on battery power, heaters not back up to temperature after instrument shut heaters down to conserve battery.	Rerun test.
	If instrument not on battery power or the problem persists, possible instrument malfunction.	Perform Temperature QC (8.1.6) and call Helena Laboratories.
<i>Maximum entries per patient (=8) reached. Touch screen to continue</i>	The maximum of eight heparin dosages have been attributed to one patient ID.	Clear clot times (7.1.1.1.6)
<i>Maximum number of QC runs reached in well X.</i>	The maximum of 200 QC test results have been stored.	Delete excess QC data (8.1.4 or 8.1.5).
<i>Exceeded maximum number of QC runs in well X.</i>	Due to the quantity of QC data, the test results will display on the Run Test screen; however, will NOT be charted, saved, or transmitted.	Delete excess QC data (8.1.4 or 8.1.5).
<i>Incomplete or invalid data for x-ACT level x. Must have a mean and range entered for QC to calculate Levey-Jennings chart. Touch screen to continue.</i>	The QC test and level selected to run has no stored lot number and/or range data.	Enter lot and range data (6.2.4.3 or 8.1.2).
<i>TPATN fails to go low after reset.</i>	Instrument powered Off and then back On too quickly.	Touch the screen, turn power Off, wait 10 seconds, turn power On.
<i>TPATN fails to go high after reset.</i>		
<i>Failed to reset ADC.</i>		
<i>Incomplete reset to ADC.</i>		
<i>Barcode is missing or unreadable in well X. Please select test.</i>	Barcode missing or unreadable and test type was not manually selected.	Select the appropriate test from those shown.

Message	Possible Cause(s)	Action Required
<i>Barcode on tube (x-ACT) in well Y disagrees with test specified. Save clotting time as z-ACT? No Yes</i>	Patient test manually entered incorrectly or barcode misread.	To save results as the test type indicated, select <i>Yes</i> ; otherwise, select <i>No</i> . If <i>No</i> is selected, use the displayed screen to select the appropriate test from those shown unless both wells contain no or the same patient ID, then the test is aborted.
<i>Barcode on tube (x-ACT) in well Y disagrees with test specified (z-ACT). Please re-select test.</i>	QC test manually entered incorrectly or barcode misread.	Select the appropriate test from those shown.
<i>Indication of stuck magnet in well #X.</i>	If performing patient test, magnet in tube not turning.	Remove tube, lightly tap bottom of tube on table top, and return tube to well.
	If performing ECT QC test or message occurs repeatedly, magnet sensor out of calibration.	Perform the Mag Sensor Calibration (section 10.1.9).
<i>No tube detected in well #X.</i>	No tube in well after 45 seconds of test (or until 90 seconds at which time test is automatically aborted).	Prior to 90 seconds, quickly insert test in well. After 90 seconds, repeat test.
<i>Failed to zero. Please ensure no tube in the well when pressing the start button.</i>	Tube in well when Start was selected.	Quickly, touch screen to clear message, remove tube, re-select Start, and re-insert tube.

10.3. Warranty

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

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In no event will Helena Laboratories be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement at the manufacturer's option.

Warranty Duration

This warranty is provided to the original purchaser for **one year from date of sale**.

Particular Exclusions

Unauthorized modification of any part of the Actalyke XL instrument will void this Warranty.

10.4. Regulatory Information

The Actalyke XL System conforms to the following general, safety and EMC requirements:

General: EMC directive 89/336/EEC and Low Voltage Directive 72/23/EEC

EMC: EN 55011; IEC 801-(2, 3, 4, 5); ENV 50204, EN 60601-1-2

















CLIA Regulations: Please refer to Section EIGHT for "Quality Control."

Trademarks and Copyright

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Section 11 - Symbology

NOTE: The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable.

	Caution, electric shock hazard, high voltages capable of causing personal injury - shut down the instrument and unplug the power cord before touching - do not operate with the cover(s) removed
	Caution, heat hazard - allow heated components to cool before handling
	Caution, general hazard - see Precautions and Hazards (Sections 3 and 4) of Operator's Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
	Frame or chassis terminal
	Equipotentiality (conductor with all parts at a single potential)
	On (power switch)
	Off (power switch)
	Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of IEC 536)
	European authorized representative
	Manufacturer
	Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC

Section 12 - Communication Specifications

Note: The floppy disk from the Actalyke XL has been removed. Any functions associated with it are no longer available.

INTERFACE SPECIFICATIONS:

The Actalyke XL import/export interface conforms to the EIA standard RS-232C 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 300, 1200, 2400, 4800, 9600, 14400, 19200, 28800, 38400, and 57600 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, or odd. Protocol options include no protocol, XON-XOFF flow control, or ASTM protocol.

MECHANICAL SPECIFICATIONS:

9 pin D-shell connector (male):

Pin	Description
1	receive line detect
2	receive data*
3	transmit data*
4	data terminal ready
5	signal common*
6	data set ready
7	request to send
8	clear to send
9	ring indicator

*only these lines are used by the Actalyke XL software.

COMMUNICATIONS PROTOCOL:

The protocol used by the Actalyke XL software is user selectable (section 6.1.6). 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 Actalyke XL is to be connected to a terminal.

XON-XOFF Flow Control:

Data is transmitted and received as ASCII text and XON/XOFF (ASCII codes 17 and 19) handshaking is used to control data flow. When exporting, the Actalyke XL 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 Actalyke XL and the computer system. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases assures that the actions of the sender and the 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 Actalyke XL 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 Actalyke XL software in general adheres to the ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer System. The exceptions concern sending a QC record.

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 5 record types used by the Actalyke XL: Header Record (H), Patient Record (P), Test Order Record (O), Result Record (R), and the Terminator Record (L).

Since the Actalyke has a minimal amount of data per run to send, only one clotting time will be sent per message and therefore only one result record, one test order record, and

one patient record (for a patient - no patient record for QC) will be sent per message.

NOTE: The record ID field shall be case insensitive.

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.

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 Actalyke XL transmits a header record, it will have the following format:

```
H|^&|||Helena Laboratories^Actalyke XL^
Versionn.nn^SNnnnnnnnn|||P|1394-97
|yyyy mmdhhmmss
```

n.nn - Actalyke XL software version number

SNnnnnnnnn - Instrument serial number

yyyymmddhhmmss - 4-digit year, 2-digit month, 2-digit day, 2-digit hour, 2-digit min., 2-digit seconds.

Patient Record

A patient record is not included when sending QC data.

EXAMPLE: P|1||12||||F|||||||0|0|

Order Record

The Actalyke XL will transmit an order record immediately preceding any results records for a patient as required in the ASTM specification. The format will be as follows:
O|1|||^test name||| |||||l|^lot number<CR>

test name - Name of the test performed.

l| - QC level when sending QC data

lot number - Lot number associated with the QC level

All order records will provide a sequential test number (up to 4 billion) in the fourth field (Instrument specimen ID).

EXAMPLE:

For a patient: O|1||7|^G-ACT|

For QC data the associated level and lot number will be included in the specimen descriptor field (field number 16) of the order record: O|1||8|^ECT|||||||Level 1|

The Actalyke XL currently does not recognize test order records transmitted by the computer system.

transmits a terminator record it will have the following format: L|1|<CR>

Result Record

Each clotting time will be transmitted as a separate result record.

For patient results, if test range limits have been entered, they will be included in the sixth (reference ranges) field.

For QC results, the range entered for the lot will be included in that field.

The ninth (result status) field always shows "F" for Final results.

An ACT result will be transmitted in the following format:

```
R|n|^^^test name|nnnn|unit of measure|nnnn-
nnnn||||F||date/timestarted|date/timecomple
ted<CR>
```

n - Sequence number - always 1.

test name - Name of the test performed.

nnnn - Clotting time

unit of measure - seconds

nnnn-nnnn - User defined reference range.

date/time started - Date and time the test was started (yyyymmddhhmmss). The date is transmitted with the year first, month second and day last.

date/time completed - Date and time the test finished

The Actalyke XL does not recognize result records transmitted by the computer system.

EXAMPLE:

For patient result record:

```
R|1|^^^G-ACT|139|sec||||F||2002050314380
9| 20020503144028|
```

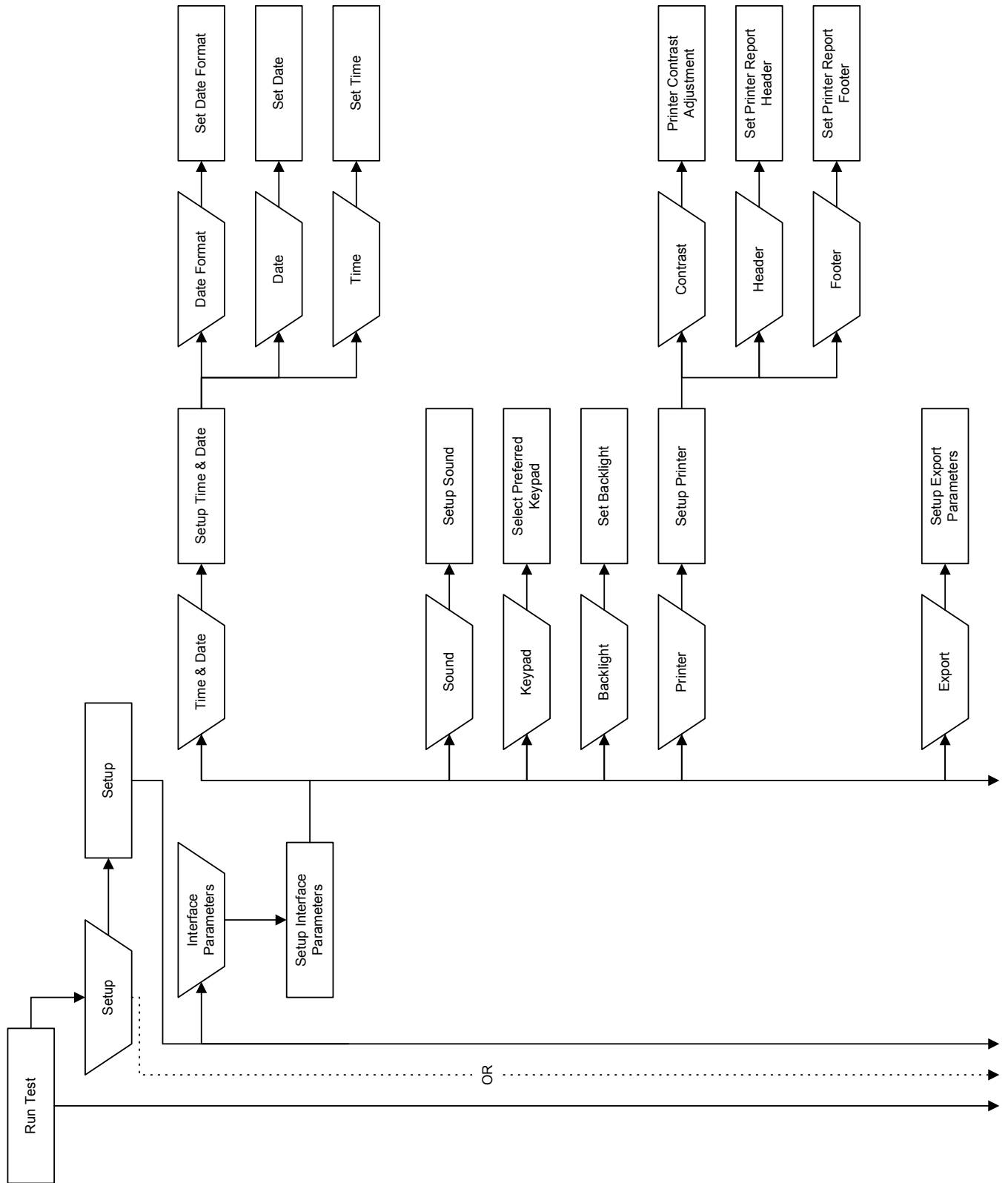
For QC result record:

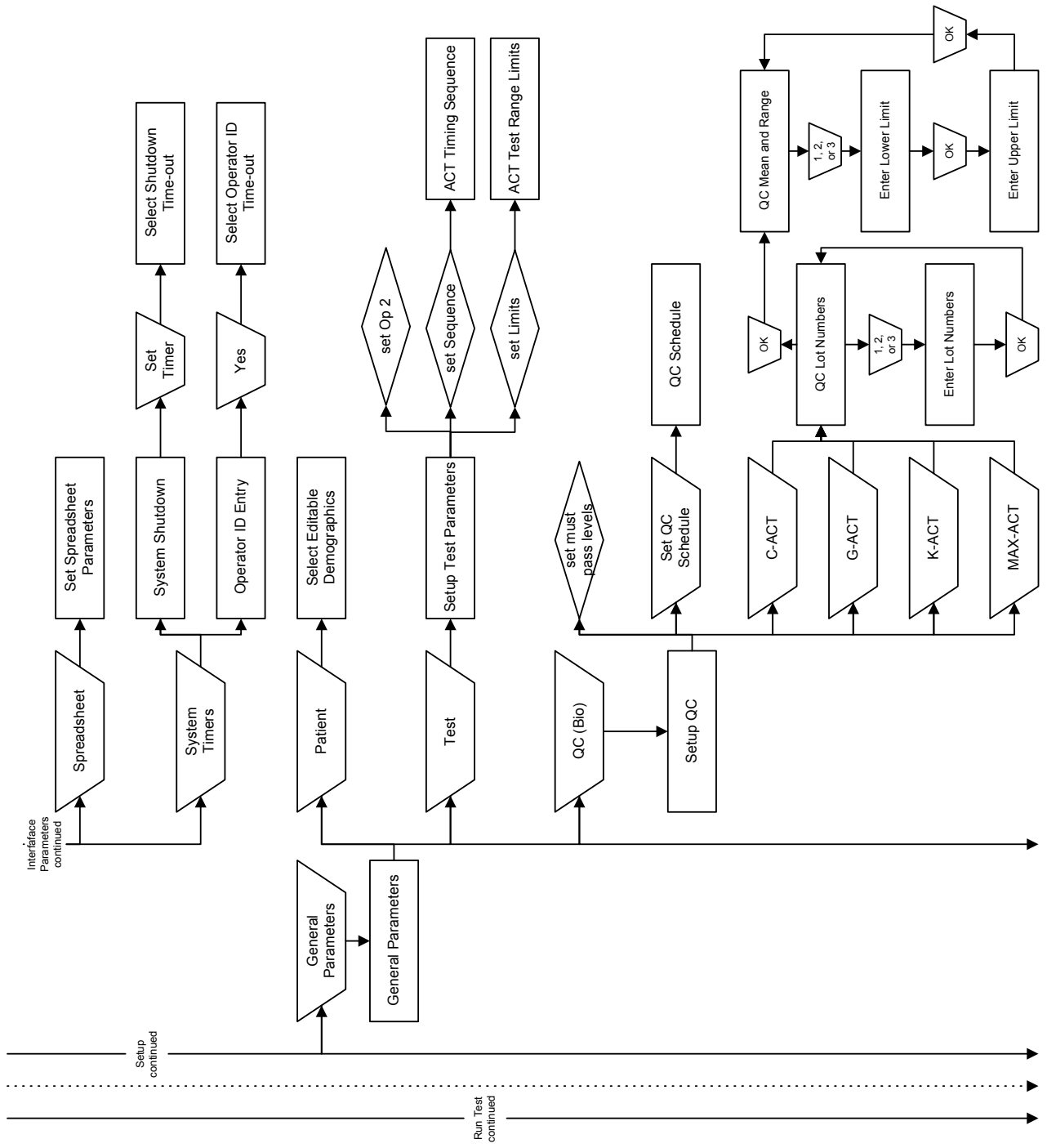
```
R|1|^^^ECT|130 |sec|90 to 10||||F||20020502
094336| 20020502094546|
```

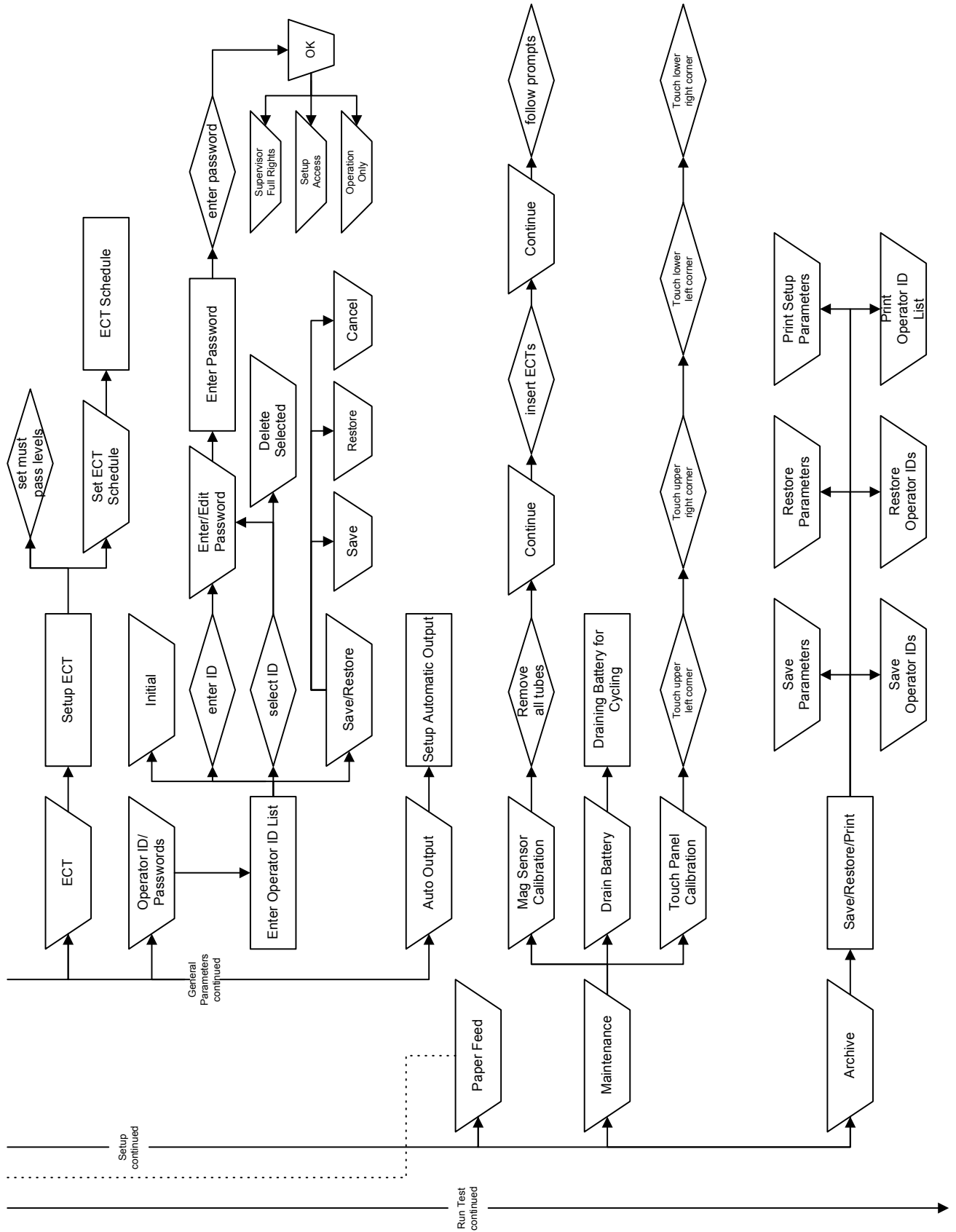
Terminator Record

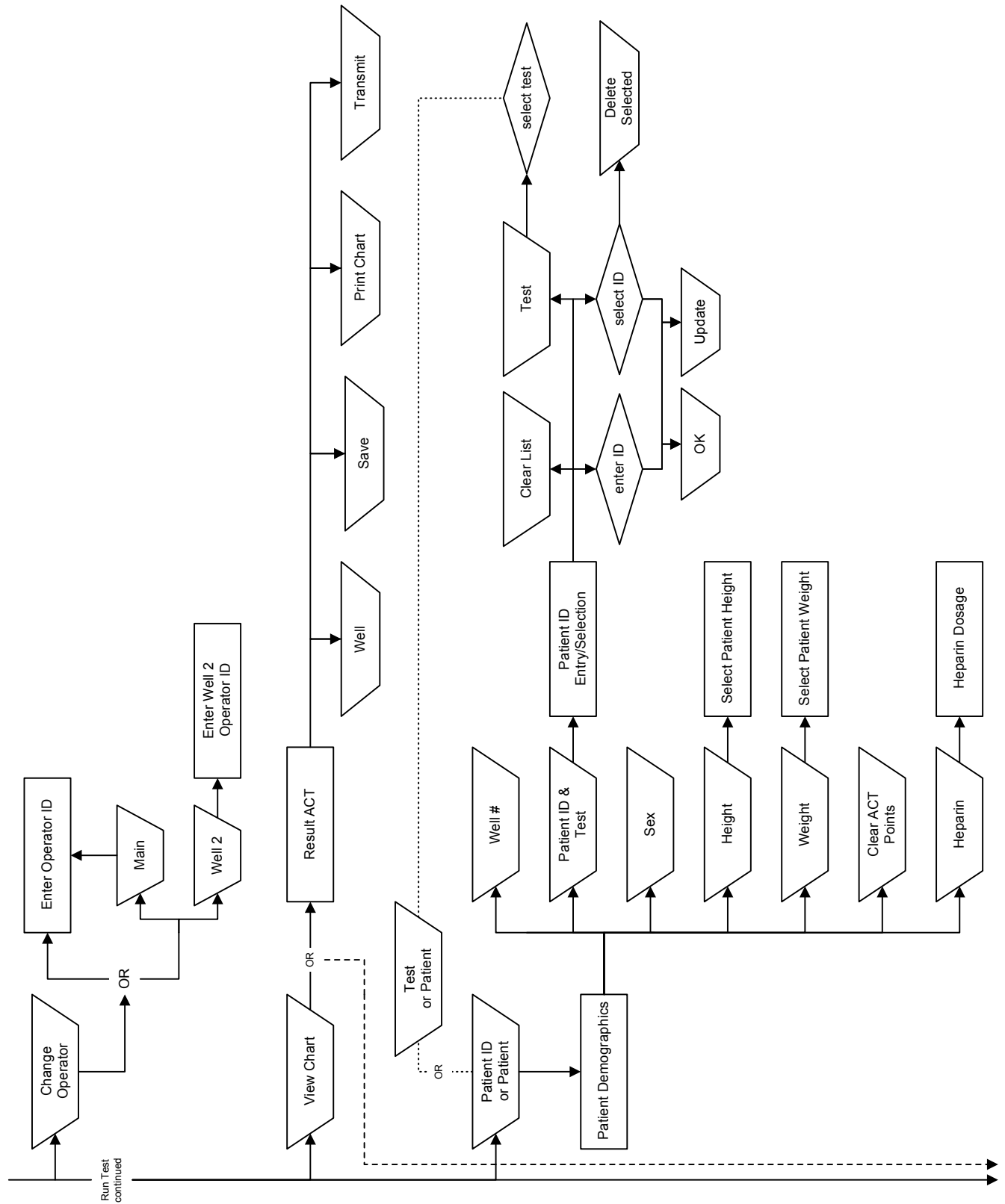
The terminator record must be the last record in a transmission. When the Actalyke XL

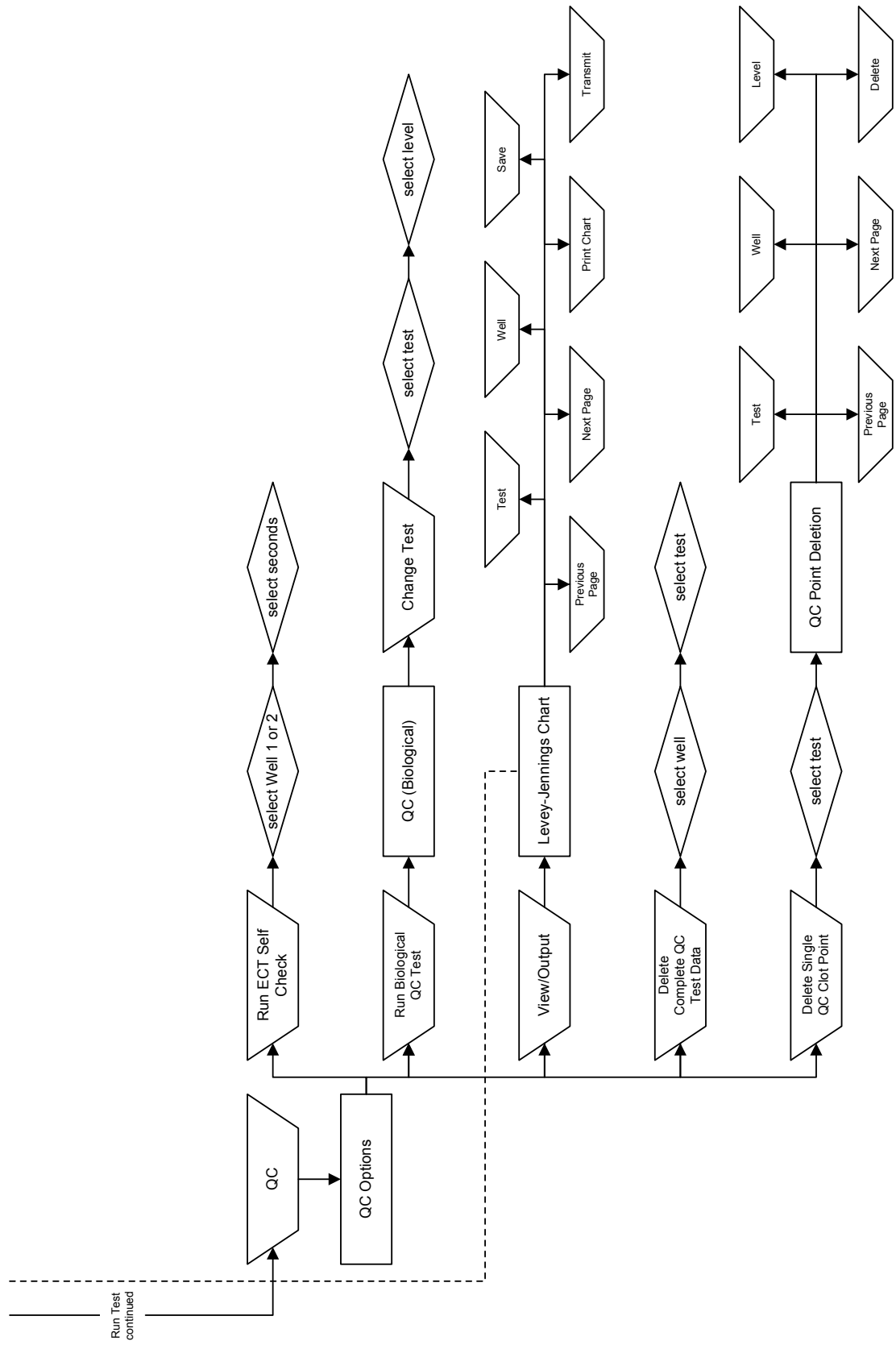
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Actalyke[®] XL

Catalog Number 5770

Software Version 1.70

Operator's Manual

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