Helena Laboratories
Point of Care

Actalyke® MINI

Activated Clotting Time Test System

Operator's Manual

Catalog Number 5752 120/240 V AC (single well / dual detector)
Catalog Number 5750, 120/240 V AC (single well / dual detector with printer)

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Section 1 - Instrument Use and Function

Actalyke® MINI 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 MINI is intended for in-vitro diagnostic use only, and is for use in a laboratory or point-of-care environment.

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

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

The ACTALYKE MINI 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 MINI System is available in two models, as a dual-detector analyzer with, or without a printer. The instrument is modular in construction for enhanced durability, portability, and flexible storage options.

ACTALYKE MINI contains preprogrammed test parameters. You may not alter the test parameters. With printer option, results are printed.

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
Reagent Preparation
Sample Application
Test Procedure
Performance Characteristics
Stability of End Product
Expected Results
References
Interpretation of Results
Bibliography

The functional units of the ACTALYKE MINI are shown in Figure 6-1.

Figure 1-1. ACTALYKE MINI with Printer Option

Section 2 - Principles of Operation

Operation is controlled by a microprocessor, its program and memory, and by one push-button controlling selections.

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

If an error is detected, the computer responds by beeping three times. In the event of a hardware error, an alternating “E ##” and “####” will display (see section 10.2).

The test well of the instrument incorporates a highly sensitive clot detection mechanism. The clot detection mechanism operates 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 another at 90°, with respect to the test tube. When a test tube is inserted into the 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 endpoint 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, the microcomputer turns on the motor, which rotates the test tube. The heater remains at a constant 37°C $\pm$ 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 and by displaying the results on the light emitting diode (LED) display.

Section 3 - Precautions and Limitations

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.

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

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.

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 of in accordance with the user's policy regarding contaminated and biohazardous materials.

3.15. Should instruments be contaminated by blood or blood derivatives, spray commercial virucidal and germicidal agent onto the area contaminated. 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 and 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.

3.19. Test results, which do not agree with expected values or 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 7.2.

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: 70° to -20°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.

Section 4 - Hazards

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. Do not attempt to operate the instrument 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. Do **not** lubricate the instrument.

4.5. 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.

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

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

4.8. Particular symbols may be used to provide information to the user. Refer to Section 11.

4.9. Use only specified printer paper.

Section 5 - Installation Instructions

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

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 are used to cut the plastic or binding tape, take care not to scratch the instrument.

4. Inspect the instrument for any obvious signs of damage. If damage is found, notify 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

5752 Actalyke MINI-A single-well, dual detector model

includes:
ACTALYKE MINI Instrument
Power Cord
Operator's Manual

5750 Actalyke MINI-AP single-well, dual detector model with printer

includes:
ACTALYKE MINI Instrument
Power Cord
Operator's Manual
Roll of Actalyke Thermal Printer Paper

Table 5-2. Additional Materials

Required Materials

Electronic Clotting Tube (either model):

A-ECT	ACT Electronic Clotting Tube
XL-ECT	Actalyke Electronic Clotting Tube
A-PPR	Actalyke Thermal Printer Paper (for model 5750 only)

Available Materials

5757	Actalyke Thermometer
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 a 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.

3. The one connector, accessible from the rear, is an IEC connector. Plug the power cord into this connector and plug the other end into a grounded wall outlet of the proper voltage and frequency. 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.

4. If the unit has a printer, load the roll of printer paper; see section 10.1.5 for instructions.

5.3. Verification of Functionality

Read the entire Operator's Manual. Complete the applicable section of the **Actalyke MINI Installation Report** as the following steps are performed:

1. Using the power switch located at the rear of the instrument, turn the unit on. Four dashes will appear across the instrument display.

2. 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.

3. Perform **Test Well Temperature Check**. Refer to section 10.1.3 for instructions. Make the necessary notations on the installation report.

4. Perform **Clotting Time Check**. Refer to section 8.1.1 for instructions. Make the necessary notations on the installation report.

5. Perform a **QC of Individual Coagulation Assay**. Refer 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.

Section 6 - Controls and Displays

6.1. Controls and Indicators

The following descriptions refer to Figure 6-1.

1. START button: Starts or stops a clotting test.

2. Detector indicator: Illuminates when the detector has sensed the presence of the rotating magnet within the tube and flashes when the current clotting test is complete.

3. Heater indicator: Illuminates when the test tube heater is active.

4. LED display: A 4-character light emitting diode (LED) display is provided. The display shows test results and error messages.

5. Test Well: Insert test tube here to perform clotting test.

6. Paper Advance button: If the instrument has a printer, it will also have a paper advance button. Use the paper advance button to load new paper rolls and to advance the paper to read or remove a printout.

6.2. Sound Volume and Tone Adjustment

The instrument's sound and tone can be adjusted. The instrument has twelve different volume/tone combinations.

With the instrument in normal run mode and with no tube in the test well, press and hold the **Start** button. After three seconds of pressing and holding the button, the instrument will begin emitting the different sound combinations and displaying an *L* and a number for each combination.

The instrument will continuously progress through the twelve combinations, in one-second intervals, until you release the **Start** button.

The sound emitted immediately prior to releasing the **Start** button is now the selected volume/tone combination.

With a combination selected, the instrument returns to the normal run mode and is ready for operation.

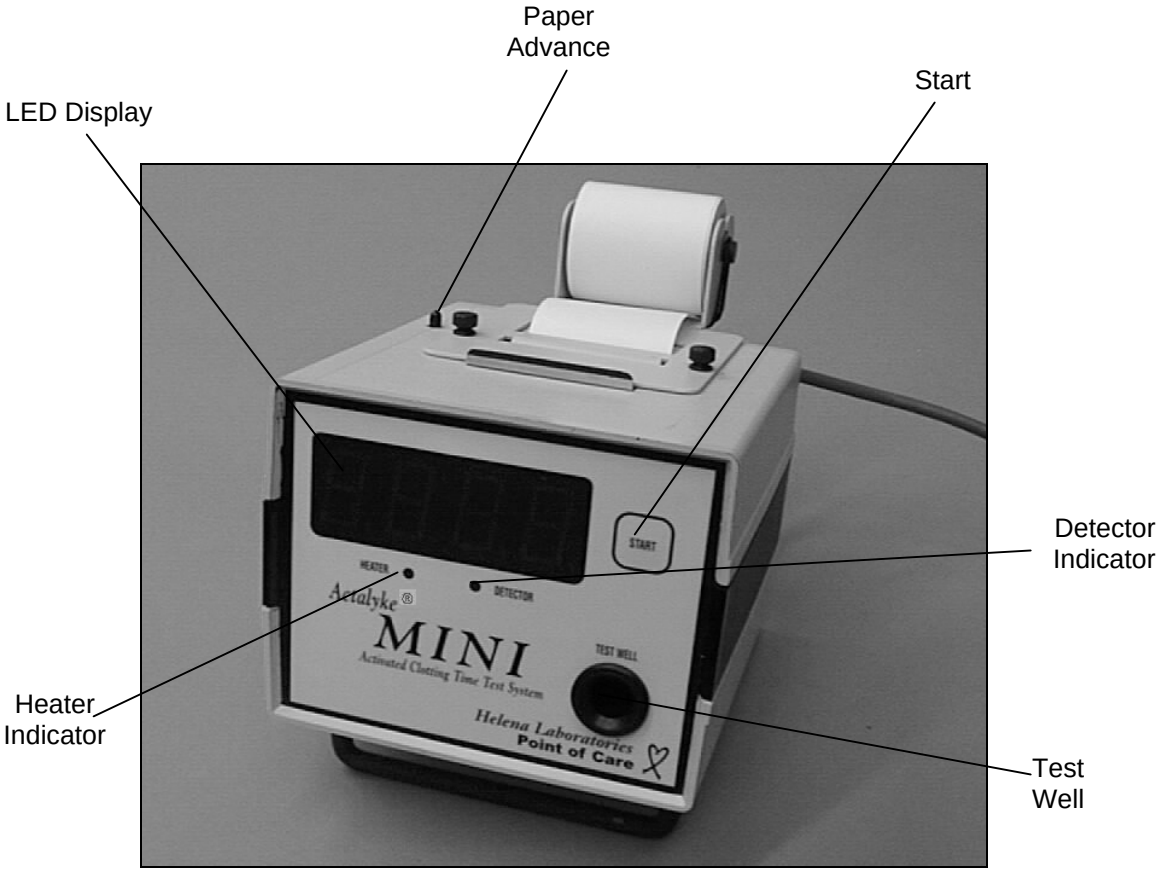


Figure 6-1. ACTALYKE MINI Front Panel Controls and Displays shown with Printer Option

Section 7 - Operating Instructions

Please refer to activator package insert (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, activator preparation, and preparation of patient samples and controls, are in the appropriate sections of the activator procedure supplied with the tubes.

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

2. Open the flip top of the tube.

3. Dispense the required amount into the tube and, if desired, manually start the instrument's timer by pressing the **Start** button. Note that the tube must be inserted into the test well within 85 seconds of **Start** being pressed, or the test will abort.

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

5. Insert the tube into the test well and, if the timer was not manually started in step 3, the timer automatically starts.

6. Rotate the tube according to the procedure. The green detector indicator should be on. If it is not, rotate the tube clockwise until it is.

7. For the remainder of the test, the tube is automatically rotated until clotting is detected in the sample. If the tube is removed from the test well or **Start** is pressed during the test, the test will abort.

8. The red heater indicator will turn on and off periodically throughout the testing time.

9. During a test, if the instrument detects an error, its response depends on the type of error and when the error is detected. If the instrument detects a stuck magnet during the first 45 seconds of a test, the beeper sounds every five seconds until either the problem is resolved or until 45 seconds have elapsed. At 45 seconds, or if a stuck magnet is detected after 45 seconds, the instrument aborts the test, the error message *-S-1* is displayed, and if the instrument has a printer, prints “Stuck magnet detected Test aborted”. If the instrument detects a missing test tube after 45 seconds have elapsed, the beeper sounds every 5 seconds until the tube is inserted or the timer reaches 85 seconds, at which point the test is aborted and, if the instrument has a printer, prints “Test aborted”. For more information, see section 10.2.

10. Upon clot detection, the beeper sounds, the clotting test result is displayed in seconds, and the detector indicator flashes five times. Additionally, if the instrument has a printer, the results printout.

11. When the test tube is removed from the instrument, the unit is then ready to start a new test. The clotting time will remain on the display until another tube is inserted or **Start** is pressed.

7.1. Results

Refer to the procedure supplied with the ACT tubes for a complete discussion of Results and Interpretation of Results, Stability of End Product, Expected Values, and Performance Characteristics.

If results on a patient show $\geq$ 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.

7.2. To Abort Operation

To abort operation, press **Start**. A test cannot be aborted for the first 5 seconds.

7.3. Printer (optional feature)

1. The printer automatically prints information and cannot be customized.

2. For instructions on loading printer paper see section 10.1.5.

3. To read or remove printout, press the paper advance button until the paper has advanced enough for it to be read or removed.

4. The printer assembly includes a serrated plate. This plate is used to tear off printouts or excess paper. The printer assembly also includes two black thumbscrews located one on each side of the plate. These screws are used to control the position of the plate. The plate's position may need to be adjusted when loading paper or dealing with a paper jam.

Section 8 - Test Functions and Quality Control

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. Daily 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.

8.1.1. Clotting Time QC

The ACT Electronic Clotting Tube (ECT), Catalog Number A-ECT, and the Actalyke Electronic Clotting Tube (ECT), Catalog Number XL-ECT, are available for verification of clotting time. Follow the instructions provided in the package insert for operation of the ECT in use.

8.1.2. Temperature QC (Test Well Temperature Check)

1. If using an Actalyke Thermometer, Catalog Number 5757, to perform a temperature check of the test well, 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°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 the test well. Allow the test tube to equilibrate for a minimum of five minutes.

4. Then, 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.

8.2. QC of Individual Coagulation Assays

Each box of Actalyke Activated Clotting Time tubes contains 50 agonist tubes from a single manufactured lot. Before use, perform a verification test one time with the appropriate Actalyke Whole Blood QC Kit (AQC-H, or AQC-L). 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.

Section 9 - Performance Specifications

9.1. Instrument Performance Specifications

Measurement Range: 90 - 1500 seconds

Incubation Temperature: 36.5°C - 37.5°C

Dimensions: width x height x length
6.1" x 4.8" x 6.3"

Weight (with printer): 5.3 pounds

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

Power (watts): ~ 110

Fuses, located internally. Do not attempt to replace fuses.

Leakage Current - Less than 100 **:**A

Instrument Operating Environment:
- Ambient Temperature Range - 15°C to 30°C (59 to 86 °F)
- Operating Relative Humidity - 10% to 80%, non-condensing

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 well automatically incubated to 37°C (± 0.5°C).
- Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of Low Voltage Directive 72/23/EEC).
- Microprocessor controlled for enhanced reliability and reporting of fault conditions.
- LED (4) 0.8” x 1.0” for easy readability.
- Printer option available for hard copy recording of test 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.: Reagent 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 catherization) 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

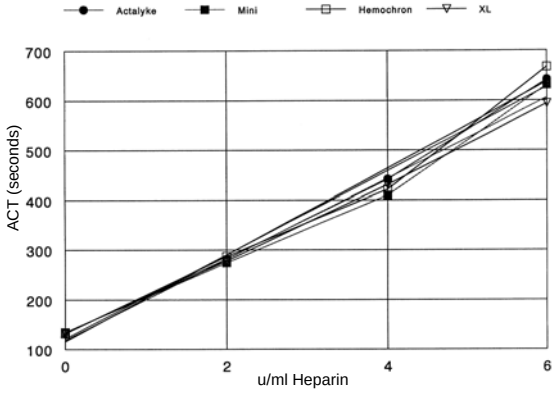
The Actalyke XL and the MINI were compared to the Actalyke using MAX-ACT tubes. The data was as follows:

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.

MAX-ACT Heparin Response



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%.

	C-ACT		K-ACT		G-ACT	
Level	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%.

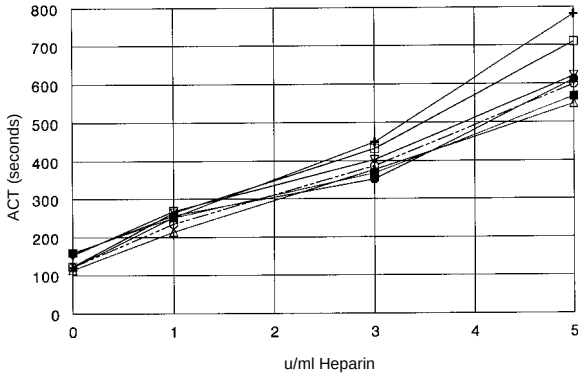
	C-ACT		K-ACT		G-ACT	
Level	I	III	I	III	I	II
mean	131.9	395.3	128.7	398.6	145.7	282.9
sd	6.3	15.3	4.6	16.7	16.7	15.8
% cv	4.8	3.9	3.6	4.2	4.2	5.6

Accuracy Data

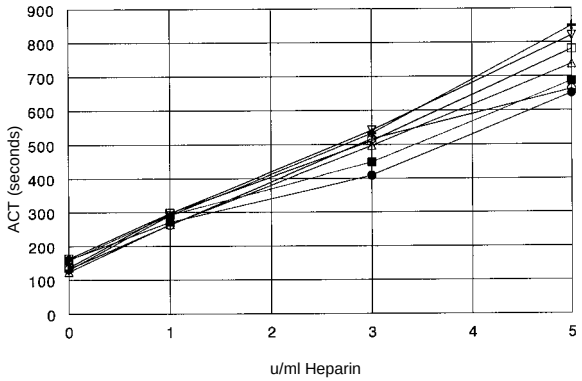
The accuracy of the Actalyke Activated Clotting Time Test System was evaluated by performing multiple Activated Clotting Time tests using varied combinations of instruments and tubes. Citrated pooled blood was heparinized to create the below concentrations yielding the following results:

Heparin Sensitivity

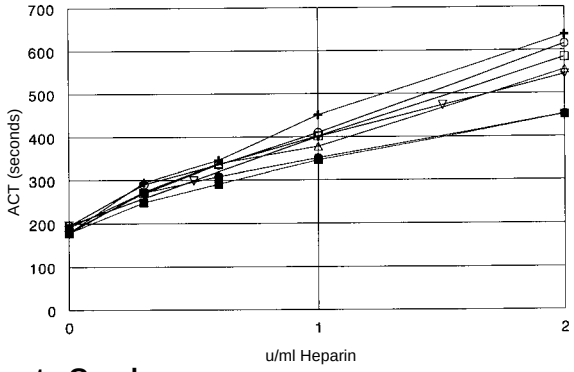
Celite Response to Heparin



Kaolin Response to Heparin



Glass Beads Response to Heparin



Key to Graphs

A-A* M-A* H-H H-A
A-H A-A XL-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

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 MINI is factory lubricated. Do NOT lubricate instrument.

Table 10-1. Maintenance Schedule

Daily, if Used
Clean the Instrument
Clotting Time Check (ECT)
Weekly
Test Well Temperature Check
Monthly
Clean the Test Well
As Needed
Replace Printer Paper

Should any technical difficulties arise, it is recommended that multiple tests be run with Whole Blood Quality Control kits and an Electronic Clotting Tube. 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. Cleaning the Instrument

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, spray any contaminated surface 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 ACT Electronic Clotting Tube (ECT), Catalog Number A-ECT, and the Actalyke Electronic Clotting Tube (ECT), Catalog Number XL-ECT, are available for verification of clotting time. Follow the instructions provided in the package insert for operation of the ECT in use.

10.1.3. Test Well Temperature Check

1. If using an Actalyke Thermometer, Catalog Number 5757, to perform a temperature check of the test well, 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°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 the test well. Allow the test tube to equilibrate for a minimum of 5 minutes.

4. Then, 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.

10.1.4. Cleaning the Test Well

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, 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. Spray 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. Replacing Printer Paper

1. Unwrap a new printer paper roll.

2. Remove the empty paper roll, the black printer paper core and the black elastic band from the instrument. Retain the black printer paper core and the black elastic band.

3. Ensure that the new paper roll has a tapered, sharp, even leading edge.

4. Place the new paper roll on the printer paper core. Place the printer core on the printer with the paper feeding from underneath the roll and not from the top. Secure the printer paper core using the elastic band.

5. Insert the leading edge of the paper into the back slot. It may be necessary to adjust the printer assembly's serrated plate's position using the two black thumbscrews. Press and hold the paper advance button (on top of unit) until paper feeds through. If the serrated plate's position was altered, reposition the plate to allow for ease of paper/printout removal.

10.2. Troubleshooting

If 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.

A hardware error is indicated by an alternating display. If the instrument displays an alternating pattern of "E ##" and "####" where '#' represents some numbers, write down the numbers and report the problem to Helena Laboratories.

The following table lists other symptoms and possible fault conditions and causes.

Table 10-2. Troubleshooting

Symptom	Possible Causes(s)	Action Required
Excessive sample clotting time	Test well temperature out of range	Verify Temperature QC (section 8.1.2), 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 in 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 8.1.2), if OK, rerun patient test, if out of range, call Helena Laboratories.
Segments missing from LED display	Defective display module	Call Helena Laboratories.

Symptom	Possible Causes(s)	Action Required
Detector indicator does not illuminate	Tube not fully inserted into the test well	Reinsert tube.
	Magnet in tube stuck	Turn tube 3 times, to dislodge magnet.
	Magnet inverted in tube	Discard tube.
	Faulty tube	Remove tube and insert ECT, if detector illuminates, discard tube.
	Detector malfunction	Insert ECT, if detector does not illuminates, call Helena Laboratories.
Tube will not rotate	Obstruction in test well	Clean test well.
	Defective drive mechanism	Call Helena Laboratories.
START key non-responsive	Instrument malfunction	Call Helena Laboratories.
Printer not working	Paper jammed	Adjust serrated plate position and inspect mechanism.
	Printer mechanism/driver fault	Call Helena Laboratories.
Clotting time ECT not in range	Insufficient charge in ECT battery	Replace battery; see the ECT instructions.
	Magnetic detector malfunction	Call Helena Laboratories.
Temperature quality control not in range	Insufficient charge in thermometer battery	Replace battery.
	Test well control problem	Call Helena Laboratories.
Individual coagulation assays QC not in range	Faulty tube	Repeat test. If remains out of range, call Helena Laboratories.

Symptom	Possible Causes(s)	Action Required
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 tube and inserting tube into the instrument	Refer to procedure supplied with the tubes for instructions.
Alarm sounds every 5 seconds during the first 45 seconds of test	Magnet in tube stuck	Turn tube 3 times to dislodge magnet.
Error code ***-S-1*** on LED display, test aborted, (if printer model, “Stuck magnet detected Test aborted” prints)	Magnet in tube stuck	Discard tube.
LED displays error	Instrument needs to be reset	Turn power off and on.
	Defective display module	Call Helena Laboratories.

10.3. Warranty

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

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

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 MINI instrument will void this Warranty.

10.4. Regulatory Information

The Actalyke MINI 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

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 - Bibliography

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Actalyke® MINI

Operator's Manual

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