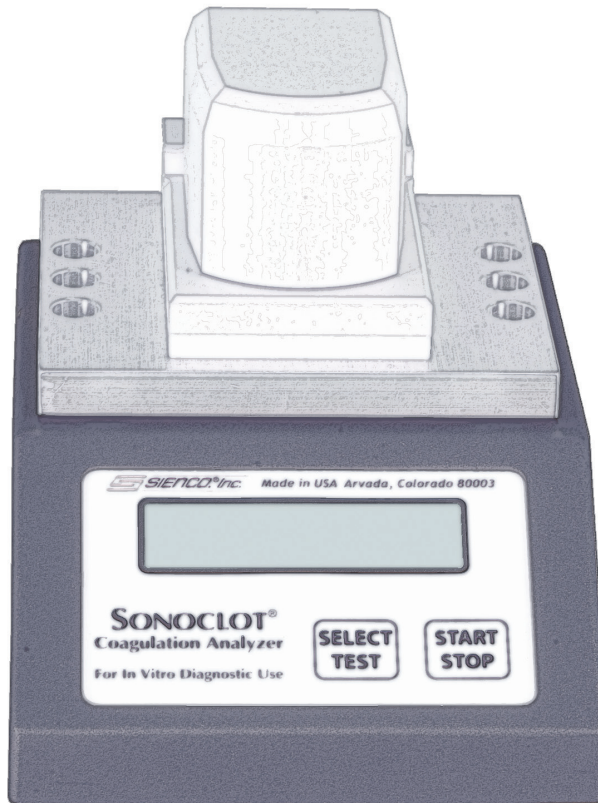


Sonoclot[®] Coagulation Analyzer Operator's Manual

REF SC1 Revision 2.1



Manufactured for: ***Sienco, Inc.***
7985 Vance Drive, Suite 104 Arvada, CO 80003 USA
303-420-1148 1-800-432-1624 Fax 303-379-4403
www.sienco.com e-mail: sienco@sienco.com

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Sonoclot Analyzers are protected under U.S. and foreign patents.



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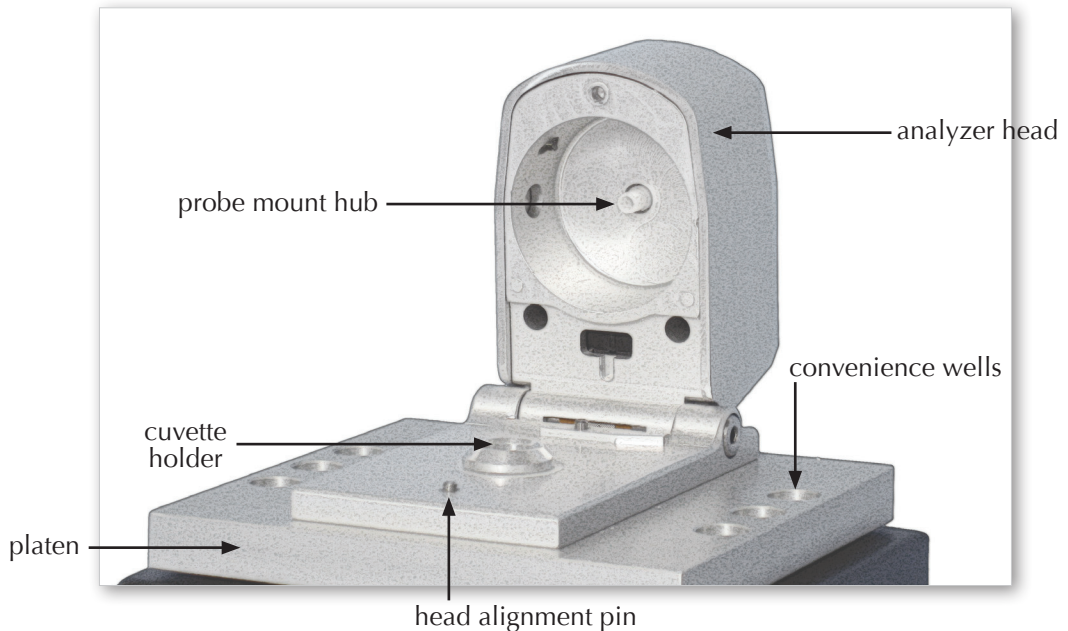
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Chapter 1: Installation and Setup

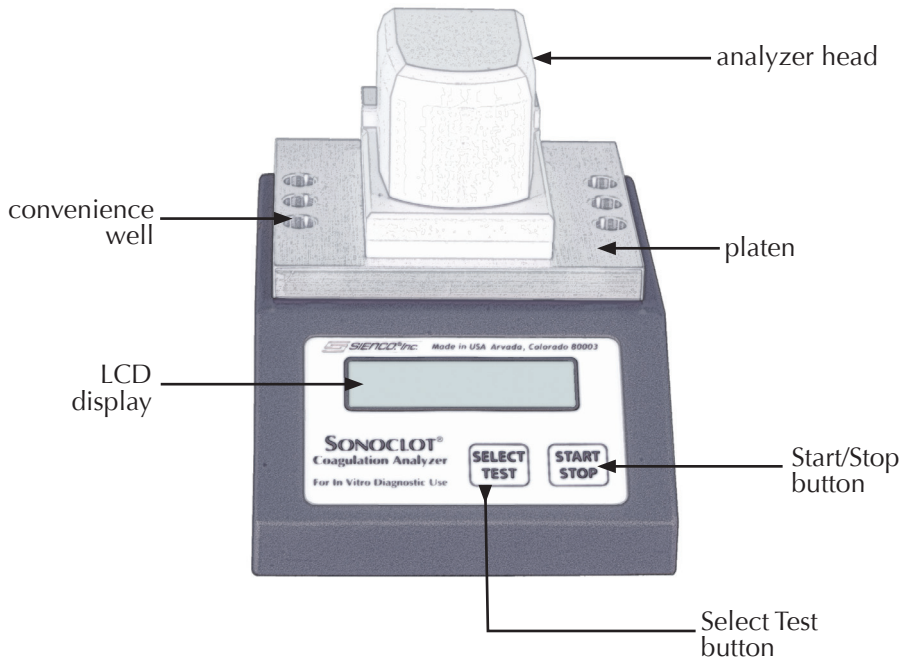
Principle of Operation and Intended Use

The Sonoclot Coagulation Analyzer calculates onset of clot formation and clot rate for in vitro coagulation studies by monitoring mechanical changes that occur in blood samples during hemostasis. The mechanism is a tubular probe that moves up and down within a blood sample. As the sample progresses through various stages of clotting, the electronic circuitry detects increasing resistance. This produces a series of electronic signals that are processed by a microcomputer. Results are reported on the LCD display panel.

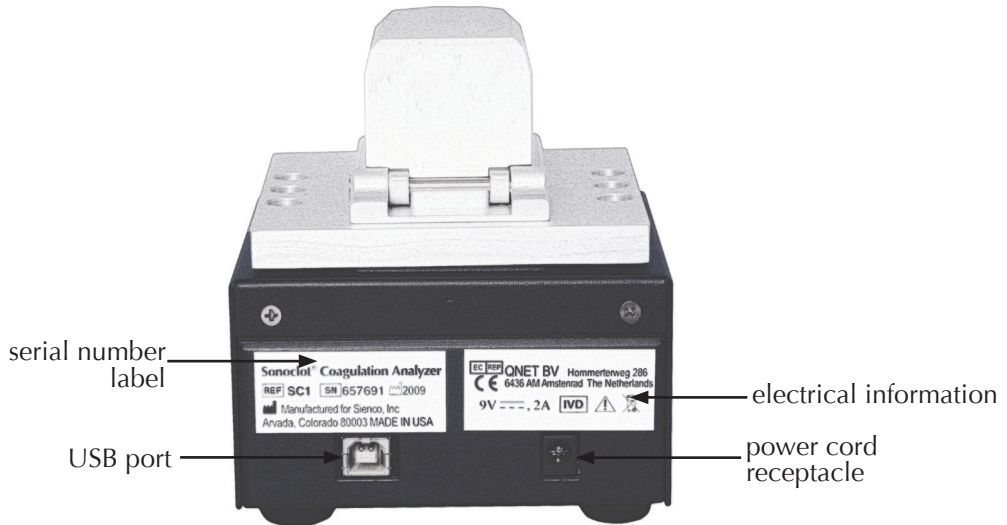
Head Assembly



Model SC1 - Front View



Model SC1 - Back View



Package Contents

- Sonoclot Coagulation Analyzer (Model SC1)
- power adaptor and cord
- probe extractor
- operator's manual
- USB cord
- SonoView installation CD

Installation

- 1) Unpack the contents of the shipping container and check you have all the above items.

NOTE: Sienco recommends that you retain the original shipping box in case you need to return your instrument for service.



- 2) Pull the ribbon to remove the packaging from the top of the instrument. Then pull the ribbon to lift the instrument out of the packaging foam in the bottom of the box.
- 3) Remove the analyzer from the plastic bag.
- 4) Carefully remove the tape from the top and back of the instrument.
- 5) Remove the spacer tabs from between the analyzer case and the head assembly platen. Keep these tabs with the original packaging.
- 6) Plug the power cord into the analyzer and an easily accessible grounded wall outlet. Do not use an ungrounded extension cord or adaptor. Do not obstruct access to the outlet.
- 7) The analyzer will automatically turn on. First, the LCD display will illuminate. Next, the analyzer will display the version number, product name, and copyright.
- 8) The analyzer will begin warming. While warming, the display reads:

gbACT	
Heating	36.3°
- 9) When the analyzer has reached 37.0°C, the display indicates the default test. The analyzer is now ready to run a test.
- 10) Review the remainder of this chapter.

Installing & Using SonoView Data Management Software (SonoView)

The analyzer indicates real time results on the LCD display. It also collects and stores data much like a digital camera. This data can be accessed by connecting the analyzer to a computer running SonoView.

To install SonoView on your computer:

- 1) Read the installation instructions and hardware specifications on the CD sleeve. Instructions are also located in PDF format on the CD.
- 2) Plug a USB cord into the back of the analyzer and a USB port on your computer. NOTE: The analyzer requires a 1.1 USB Port or higher.
- 3) Open SonoView on your computer. For software instructions, please see the SonoView operator's manual PDF file on the installation disk.

Good Operating Procedures (applicable for all tests)

The quality of test results depends on proper technique. Carefully follow these precautions:

- 1) Operator should read this operator's manual in its entirety before attempting to operate the analyzer.
- 2) Only properly trained lab personnel and healthcare professionals should operate the analyzer.
- 3) Diagnosis should be based on test results in combination with clinical observations.
- 4) Handle materials with care:
 - When taking a blood sample, avoid heparin contamination from catheters.
 - Never use the first sample from a new line to avoid sample contamination with tissue thromboplastin.
 - Keep blood, dirt, and other substances away from the probe mount hub to avoid contaminating the electromechanical transducer.
 - Never reuse a probe or cuvette to prevent thrombin contamination.
- 5) For consistent results, the cuvettes should be warmed prior to analysis. To warm, place the cuvette in its holder at least 30 seconds prior to running a test.
- 6) Always insert and remove the probe by moving it vertically over the probe mount hub. Never move the hub horizontally. Make sure the probe is fully seated to avoid interference with the stir-bar.
- 7) Always remove the cap from the cuvette prior to placing it into the cuvette holder. Failure to do so can damage the transducer.
- 8) The cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir-bar.
- 9) Do not overfill the cuvette. The proper fill level is slightly below the inner rim of the cuvette.
- 10) Native whole blood must be analyzed within 2 minutes or less of collection.
- 11) Perform QC testing to verify proper operation of the analyzer and activation cuvettes. See page 1-6.
- 12) Use proper biohazard handling techniques to dispose of probes and cuvettes.
- 13) On rare occasions, mechanical disturbances may cause incorrect results. Always inspect results to ensure that they are consistent.
- 14) High viscosity blood samples (immersion response > 25 clot signal units as displayed on the instrument) can stratify. Use an external device to mix the blood sample before placing it in the cuvette.

Warnings, Cautions, and Hazards

- 1) **WARNING:** As with any laboratory test result, diagnosis should not be based solely on the analyzer test results. The attending physician is responsible for interpreting the analyzer test results in conjunction with the patient's condition, other test results, and clinical observations.
- 2) **WARNING:** To safeguard against electrical shock, only use a grounded electrical outlet.
- 3) **WARNING:** Use only as specified by Sienco, Inc. Otherwise, equipment protection may be impaired.
- 4) **CAUTION:** Only properly trained laboratory personnel and/or other appropriate health care professionals should use the analyzer.
- 5) **CAUTION:** A biomedical engineering department should check the analyzer at least once a year for compliance with leakage standards.
- 6) **HAZARD:** Human blood is a biohazardous material. The operator should wear appropriate protective gear when handling blood and/or test cuvettes containing blood samples. Biocontaminated materials should be handled and disposed of properly in accordance with hospital, local, state, and federal regulations.
- 7) **CAUTION:** Do not place the analyzer on counter tops where other vibrating instruments, such as centrifuges, are located. Mechanical vibration may cause erratic results.



Quality Control

Proper performance requires regular quality control (QC) tests:

- 1) Daily, run a reference viscosity test for the analyzer. This requires QC kit 900-1303.
- 2) Monthly, and prior to the use of a new shipment, validate the activated cuvettes. This requires QC kit 900-1318.

Complete instructions for running each QC test are included in the kits. The kits also include forms for recording QC results.

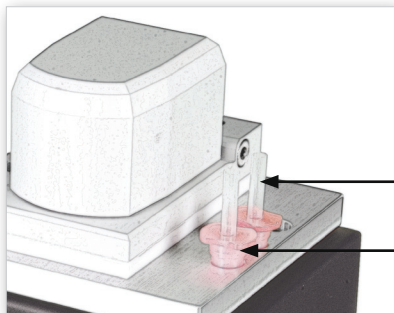
To order quality control kits, contact Sienco at 800-432-1624 or contact your distributor.

Chapter 2:

Running a Whole Blood Sample

The analyzer monitors mechanical changes that occur during hemostasis. This section describes how to prepare and run a test with native whole blood samples. Use only test kits available from Sienco, Inc. Sienco offers different tests for different applications. Choose the test best suited for your application.

Analyzer Preparation



- 1) Cuvettes should be placed in the convenience wells so they will be ready when the blood is drawn. Place probes into the lids of the cuvettes.

- 2) If the analyzer has just been recently turned on, allow it to warm, with head assembly in the down position, until the analyzer reaches 37°C. If the analyzer is not at the desired temperature it will display an error message and not run the test.

- 3) When the analyzer is ready the display reads:

NOTE: Results from the previous test may be displayed on the bottom of the LCD display.

gbACT

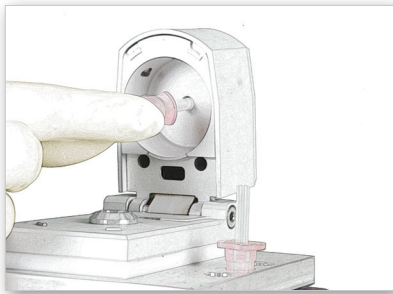
- 4) Press the "Select Test" button on the front panel until the desired test is displayed on the LCD.

Cuvette and Probe Setup



- 1) Open the head by tilting it backwards. The display will read "Open."

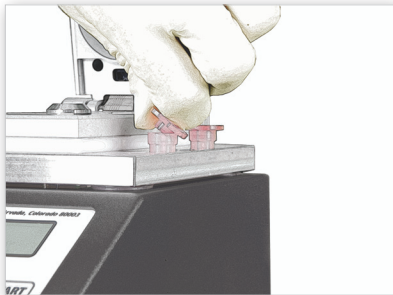
- 2) Sharply tap the cuvette on a hard surface to dislodge activation powder from the sides and lid.



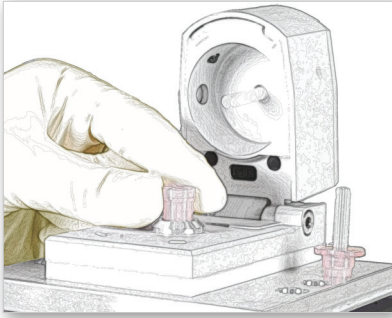
- 3) With a slight twisting motion, use the cuvette to seat the probe on the mount hub. This motion should result in the probe sliding straight over the probe mount hub. The hub should not move sideways. The probe must be fully seated for proper operation.



- 4) Remove the cuvette, leaving the probe on the hub.



- 5) Remove the lid from the cuvette by placing it in a convenience well and popping the lid off with your thumb.



- 6) Insert the cuvette into the cuvette holder. Make sure it is fully seated. Close the head. Allow the cuvette to warm in the cuvette holder for at least 30 seconds.

DO NOT close the head on a lidded cuvette. It will damage the instrument.

Different tests have different set-up requirements. Please refer to the product insert for detailed instructions.

Obtaining the Blood Sample

Native whole blood must be analyzed within 2 minutes of collection. When drawing blood, observe the following precautions:

- 1) Carefully decide where to draw the sample. Contamination (from a heparinized line, a heparin-impregnated catheter, or a surgery prep line) will cause inaccurate results.
- 2) Withdraw blood in a smooth, slow, and non-traumatic manner. Do not use force.
- 3) When drawing from an anesthesia or pump port, use a 2-syringe technique. Discard the first syringe of 2 to 3 ml. Use the second syringe for the sample. You **MUST** use plastic syringes to avoid uncontrolled glass activation.

Running the Analyzer

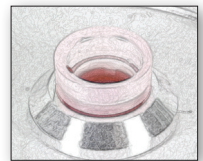


- 1) Transfer the whole blood sample from the syringe into the warmed cuvette. Use a blunt cannula tip for a clean and controlled fill.

Fill the warmed cuvette with the blood sample until the fluid level is slightly below the inner rim of the cuvette. This volume is approximately 330 to 360 μ l.



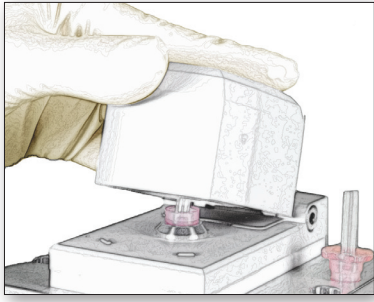
Fill slightly below here



- 2) Leaving the head open, immediately press the START/STOP button.
- 3) The magnetic stirrer will rotate and the display will read:
- 4) When mixing is completed, the analyzer will beep and the display will read: "Close Head."

gbACT
Mixing

gbACT
Close Head



- 5) Close the analyzer head. Make sure it is fully seated over the head alignment pin.

- 6) During data collection, the LCD display will show the test being run, the clot signal reading (CS), the time in seconds, and "???" for each result. When the analyzer is calculating a result, the display will flash the number the result is greater than.

```
gbACT    13    11
ACT=???? CR=???
```

- 7) The sample is initially a liquid. After several minutes the sample begins to evolve into a clot. The analyzer detects this initial clot formation and calculates the time the sample remained a liquid (ACT). During the next several minutes of analysis, the fibrinogen converts into a fibrin gel. The analyzer calculates the rate of change in the clot signal (Clot Rate).

- 8) When a result has been calculated, the analyzer will beep and display the time that the sample remained a liquid (ACT) and the Clot Rate (CR). Times for results vary from 2 to 20 minutes depending on heparin levels and clinical conditions. The numeric result is displayed next to the corresponding text for the appropriate channel. "NR" is displayed if no results were found for the test sample.

```
gbACT
ACT= 177    CR= 19
```

- 9) The analyzer will automatically stop data collection when results for ACT and Clot Rate have been calculated or after 30 minutes.



- 10) Open the head and remove the probe from the hub with a probe extractor. Avoid moving the hub sideways. Properly discard the probe and the cuvette. Lower the head assembly to maintain temperature control of the instrument.

Chapter 3:

Maintenance and Troubleshooting

Maintenance

Cleaning

Clean after use to reduce biohazard risks. The analyzer can be sprayed or wiped with a disinfectant approved by your institution. Close the heads when spraying to avoid contaminating the transducers. Avoid excess wetting. Place a clean probe on the probe adaptor to protect the sensing mechanism while cleaning. Gently wipe around the cuvette holders or inside the heads. Do not clean the probe mount hubs, unless absolutely necessary. The transducers attached to the probe mount hubs can easily be damaged by debris or liquids.

NOTE: Do not use isopropyl alcohol or other solvents on the front panel or LCD cover.

Calibration & Service

The user cannot calibrate or service the analyzer. Running a reference viscosity QC test (PN 900-1302) will verify if the analyzer is operating within calibration standards. Sienco recommends performing the reference viscosity QC test daily, prior to use of the analyzer.

If the analyzer requires calibration or service, contact Sienco, Inc. or your distributor.

Troubleshooting

If you have a problem with the analyzer, follow these steps:

- 1) Review “Warnings, Cautions, and Hazards” on page 1-6.
- 2) Review “Good Operating Procedures” on page 1-5.
- 3) Review the operating instructions that come with the test you are running.
- 4) If problems persist, contact the Sienco service department:

Phone: 303-420-1148
Toll Free: 800-432-1624
Fax: 303-379-4403
E-mail: sienco@sienco.com
Mail: Sienco Service Department
7985 Vance Drive, Suite 104
Arvada, CO 80003 USA

Warning and Error Messages

The Sonoclot Analyzer will occasionally display messages that may not be familiar. Below are some examples of these messages and procedures to follow, if necessary.

“NOISE” indicates that the clot signal is being disturbed by either mechanical noise, such as bumping the analyzer, or by interference between the probe and the cuvette. Check to ensure that the probe is tight against the mount hub and the cuvette is in contact with the bottom of the cuvette holder. The message should disappear within a few seconds.

“ERROR” indicates that the self test routine has detected a problem. Normally, the message will disappear after several seconds. You can resume testing then. If the error message remains, make a note of the error number and call Sienco’s service department.

“TEST NOT RUN, NOT AT TEMP” indicates that the analyzer is not to temperature and the test was not run. The analyzer must be at 37°C to run a test.

“NR” indicates that no results were found for the last test analysis. This can occur due to operator error (i.e. failure to close instrument head within 60 seconds of “Close Head” message), instrument error, or an unusual clot that cannot be analyzed.

NUMBERED ERROR CODES: The analyzer is programmed to display various numbered error codes. Should your analyzer display a numbered error code, record the number displayed and contact your distributor or Sienco’s service department.

If you have any questions in regards to a display message, call Sienco’s service department at 800-432-1624 or 303-420-1148.

Factory Service or Repair

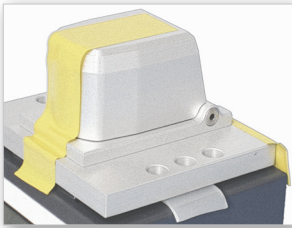
Contact Sienco prior to shipping your analyzer for repairs.

The analyzer should be shipped in its original packing materials, if possible. If you do not have the original packing materials please contact Sienco. We will ship you packing materials or you may use the packaging materials from your loaner.

We charge a minimum fee for testing the instruments, even if you decide not to have it repaired. Damages caused by poor packaging are your responsibility.

To ship, follow these steps:

- 1) Remove cuvettes, probes, power cord, and other supplies.
- 2) Photocopy the decontamination form at the end of this manual.
- 3) Clean and decontaminate the analyzer according to your institutional guidelines and fill out the decontamination form. Failure to fill out form and include with the analyzer will result in a \$150 decontamination fee.



- 4) Carefully slide the spacer tabs between the instrument case and platen. Tape the back of the platen and the top of the instrument case as shown. Tape the instrument head down as shown. Place the analyzer in a large, clean plastic bag and fold the open end under the instrument.

- 5) Place the instrument in the molded foam in the bottom of the box, with the ribbon running underneath the analyzer as shown.

If you are also returning your power adaptor and cord, fold the power cords, secure each with a rubber band, and place in the spaces on either side of the analyzer.

- 6) Place the top of the molded foam over the analyzer. Make sure the foam is securely packed around the analyzer head.
- 7) Make sure the decontamination form is complete. Be sure to include a brief description of the problem along with a contact name, phone number, and purchase order.
- 8) Place the completed form on top of the molded foam.
- 9) Tape the box shut and ship the package to:

Sienco, Inc.
Service Department
7985 Vance Drive, Suite 104
Arvada, CO 80003 USA



References

Sonoclot Analysis is used in many clinical and research applications and consequently is referenced in numerous studies and articles. For a complete list of references, please visit our web site at www.sienco.com.

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Warranty

The Sonoclot Coagulation Analyzer has a 2-year warranty that it conforms to specifications and is free of defects in material and workmanship. The warranty is limited to the replacement or repair of defective parts and components. The warranty shall be voided if the product is:

- 1) Used in any manner or subjected to any condition that is inconsistent with its intended purpose or accepted industry practice; or
- 2) Modified in any way without prior written approval by Sienco; or
- 3) Repaired in any manner so as to adversely affect its operation or reliability by persons other than Sienco or its agents.

Warranty claims shall be submitted in writing to Sienco during the 2-year warranty period. The claim shall state the nature and details of the analyzer defect and the serial number of the analyzer. The claim must accompany any defective product submitted for repair or replacement.

Purchasers must decontaminate and package the analyzer per instructions on pages 3-1 and 3-3. Such products shall, at Sienco's election, be either repaired, replaced or returned.

Technical Specifications

Width	4.25"	10.8 cm
Depth	5.75"	14.6 cm
Height	4.75"	12.1 cm
Weight	2.5 lbs	1.13 kg
Electrical voltage requirement	100 to 240V	
Electrical power requirement	9V $\overline{=}$, 2A	
Frequency	50 to 60 Hz	
Temperature regulation of platen	37°C \pm 0.5°C	
Viscosity range for test sample	<80 cP	

Environmental Conditions for Transportation and Storage



Transport and store within the ambient temperature range of -25°C and 70°C.



Transport and store to a maximum relative ambient humidity of 95%.

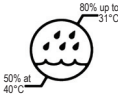
Environmental Conditions for Use

Indoor use only.

Use at a maximum altitude of 2000m.



Use within the ambient temperature range of 18°C and 27°C.



Use at a maximum relative humidity of 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.

Mains supply voltage fluctuation shall not exceed $\pm 10\%$.

The unit is intended for INSTALLATION CATEGORY II.

Installation Category II: Local level, appliances, Portable equipment etc., with smaller transient overvoltages than Installation Category III.

The unit is intended for use in a POLLUTION DEGREE 2 ENVIRONMENT.

Pollution Degree 2 is nonconductive pollution of the sort where occasionally a temporary conductivity caused by condensation must be expected. This is the usual pollution degree used for equipment being evaluated to 60950 and is suitable for equipment employed in an office environment.

Electrical Classification

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the US FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in its installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. If this equipment does cause harmful interference the user will be required to correct the interference.

Disposal Instructions



Sienco, Inc. expects end-users to dispose of the Sonoclot Coagulation Analyzer in an environmentally friendly way. Electrical and electronic equipment is labeled with the following 'crossed out wheeled bin' symbol indicating that the equipment should be disposed of, by the end-user, separate from other types of waste.




















End-users should contact their dealer/distributor or Sienco, Inc. for disposal, collection and recycling options and terms and conditions in your country.

In 2002 the European Union introduced the Directive on Waste Electrical and Electronic Equipment (WEEE). The main aim of the Directive is to ensure that WEEE is collected and

treated separately. WEEE may contain hazardous substances that should not end-up in the (human) environment and can have adverse effects on it if they do.

WEEE is a vast source of raw materials. With the ever rising worldwide demand for new equipment and the ever decreasing volume of natural raw materials, letting this potential source go to waste is unacceptable. If equipment is collected separately, the equipment can be recycled and up to 85 to 90% of the equipment can be re-used as new material, saving the use of virgin raw materials and energy of producing these.

Glossary of International Symbols

	Manufacturer		Do not reuse
	In Vitro Diagnostic medical device		Model Number
	Authorized representative in the European community		Lot Number
	CE marking of conformity		Manufacture date
	Biological risk		Expiration date
	Temperature limitation		Consult instructions for use
	Humidity limitation		Contains sufficient for ,n. tests
	Direct current (DC)		Caution, consult accompanying documents
	Serial number		Control
	Do not dispose of electrical equipment as municipal waste		

Decontamination Form

This decontamination form must be filled out and returned with the Sonoclot Coagulation Analyzer when shipping the analyzer to Sienco for any reason, or a \$150.00 biohazard decontamination charge will be assessed.

Please photocopy this page, complete, and include with your analyzer.

We require you to thoroughly clean and decontaminate the analyzer per guidelines followed by your institution. Here are some tips to follow when decontaminating the analyzer:

- Place a clean probe on the probe adapter to protect the sensing mechanism while cleaning. Do not spray any cleaning solvent into the head since fluid will damage the sensor.
- Decontaminate all surfaces of the analyzer using a product certified by your institution.
- Remove and discard all probes and cuvettes before packing the analyzer.

Institution: _____ Dpmt: _____

Serial Number: _____ Model: _____

Decontaminated by: _____ Date: _____

Decontaminate Used: _____

Probe removed Cuvette removed Power cord & adaptor returned? Y N

Contact Person: _____ Phone: _____

Reason for Service: _____

We will call with an estimated cost for repairs before any work is done. Please make sure to include a contact name and phone number.

Ship the Sonoclot Coagulation Analyzer to:

Sienco, Inc.
Attn.: Service Manager
7985 Vance Drive, Suite 104
Arvada, CO 80003 USA

If you have any questions, please contact:

Service Manager
800/432-1624
303/420-1148

