

# Chapter 1 - Setup and Operation

## Introduction

### **About the Sonoclot® Coagulation & Platelet Function Analyzer**

The Sonoclot® Coagulation & Platelet Function Sonoclot Analyzer (the “Sonoclot Analyzer”) is a versatile instrument for measuring coagulation and platelet function. Each test analysis provides accurate information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis. The Sonoclot Analyzer generates both a qualitative graph, known as the Sonoclot Signature, and quantitative results on the clot formation time (Onset) and the rate of fibrin polymerization (Clot RATE) for identifying numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis.

The Sonoclot Analyzer is a reliable and simple to use instrument that can be used in operating rooms, coagulation labs, STAT labs and intensive care units. The Sonoclot Analyzer can provide numerous benefits including:

- Improved hemostasis management in surgery
- Reduced usage of donor blood products
- Fast identification of mechanical versus hemostatic bleeders
- Accurate and inexpensive heparin anticoagulation management
- Quick and easy screening for hypercoagulable patients

Healthcare professionals are pursuing a balance between quality of care and cost containment. Sienco is dedicated to helping you meet this challenge through cost-effective products of superior quality and reliability. In the prevailing hospital economic climate, the ability to provide cost savings while improving patient care is a powerful incentive for Sienco’s Sonoclot Analyzer and related tests.

### **Test Supplies and Consumables for the Sonoclot Analyzer**

The Sonoclot Analyzer can run a variety of coagulation tests. Different tests incorporate different reagents for testing specific aspects of hemostasis. Sienco, Inc. (“Sienco”) manufactures packaged test kits and basic supplies for general use with the Sonoclot Analyzer. These products are:

SonACT™ Kit (Part Number (P/N) 800-0432): A general purpose celite activated test for coagulation, platelet function, hypercoagulable and hyperfibrinolysis screening

Cuvettes (P/N 800-0118), Probes (P/N 800-0200), and Stir Bars (P/N 800-0303): Supplies for general use testing applications with the Sonoclot Analyzer

Probe Extractor (P/N 800-0601): Plastic hand-held tool for removing used probes.

Lamp Bulb (P/N 290-0010): Replacement bulb for platen surface.

Please refer to page 4-1 for a list of quality control products available for the Sonoclot Analyzer. Additional tests are under development. Contact Sienco for a current list of available tests.

## Organization of the Manual

The manual includes six major sections. **Chapter 1** covers setup, principle of operation and normal use. **Chapter 2** discusses clinical uses beginning with an explanation of the Sonoclot Signature related to hemostasis, interpretation of a Sonoclot Signature, and guidelines for use of the instrument system in several clinical areas. This section is very important in order to properly choose an appropriate Sonoclot test, determine preferred instrument setup, and correctly interpret the test results. **Chapter 3** contains a library of Sonoclot Signatures that illustrate normal and abnormal hemostasis as captured with a Sonoclot Signature. **Chapter 4** contains quality control procedures for the Sonoclot Analyzer. **Chapter 5** describes how to configure the Sonoclot Analyzer for specific applications. This section is not essential for normal users, but does address numerous convenience features of the Sonoclot Analyzer. **Chapter 6** covers maintenance and troubleshooting. The **Appendix** covers hazards, additional technical information, references and warranty information.

## Technical Support

If you have read this manual and have further questions or your instrument requires service, our address and phone numbers are:

Sienco, Inc.  
11485-A W. 48<sup>th</sup> Ave.  
Wheat Ridge, CO 80033 USA  
1-800-432-1624  
303/420-1148  
303/420-2204 (FAX)  
<sienco@ sienco.com> (e-mail)

Our technical support staff can assist with both proper operation of the Sonoclot Analyzer and with clinical interpretation of specific Sonoclot Signatures. If you do wish to discuss interpretation of a Sonoclot Signature, please include relevant patient history data so we can be as effective in assisting you as possible.

# **Installation and Setup**

## **Package Contents**

The package you received from Sienco should contain one each of the following items:

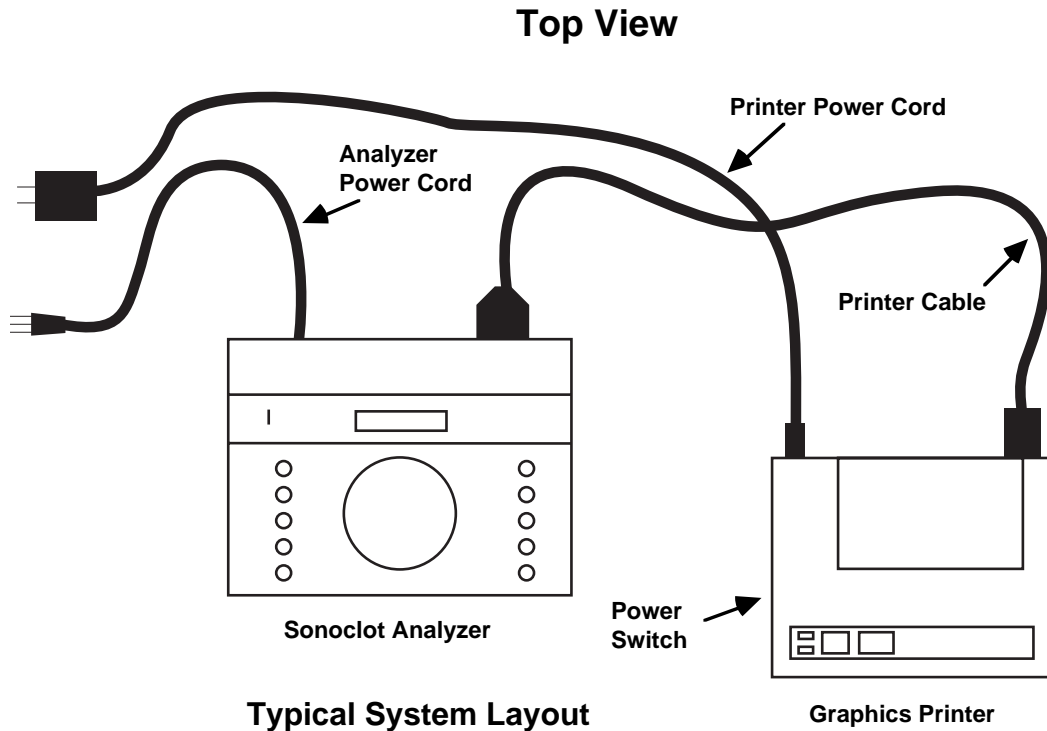
<b><u>Part</u></b>	<b><u>Part Numbers</u></b>
Sonoclot Analyzer	Model DP-2951
Printer and Power Module	800-1108
Power Cord (not supplied outside North America)	260-0125
25 Pin Serial Cable	260-0115
Operator's Manual	020-1001

## **Initial Setup**

Unpack the instruments from the shipping container. Set the Sonoclot Analyzer and Printer side-by-side on a sturdy table or cart. Gently remove the wood blocks from around the head of the Sonoclot Analyzer by pulling them towards the front of the instrument. Twenty inches of surface space is required for side-by-side placement of the Sonoclot Analyzer and the Printer.

## Connecting the Sonoclot Analyzer and Printer

Plug the power cords into the back of the Sonoclot Analyzer and Printer and then into a grounded wall outlet. **We recommend you do not use an ungrounded extension cord or plug adaptor with this instrument.** Check voltage setting to assure voltage is concurrent with your power mains. The voltage setting is on the fuse block located on the back of the Sonoclot Analyzer. Connect the Sonoclot Analyzer to the Printer by plugging the 25 pin connector on the Printer cable into the 25 pin connector located on the back of the Sonoclot Analyzer. Connect the 9 pin cable connector to the Graphics Printer.



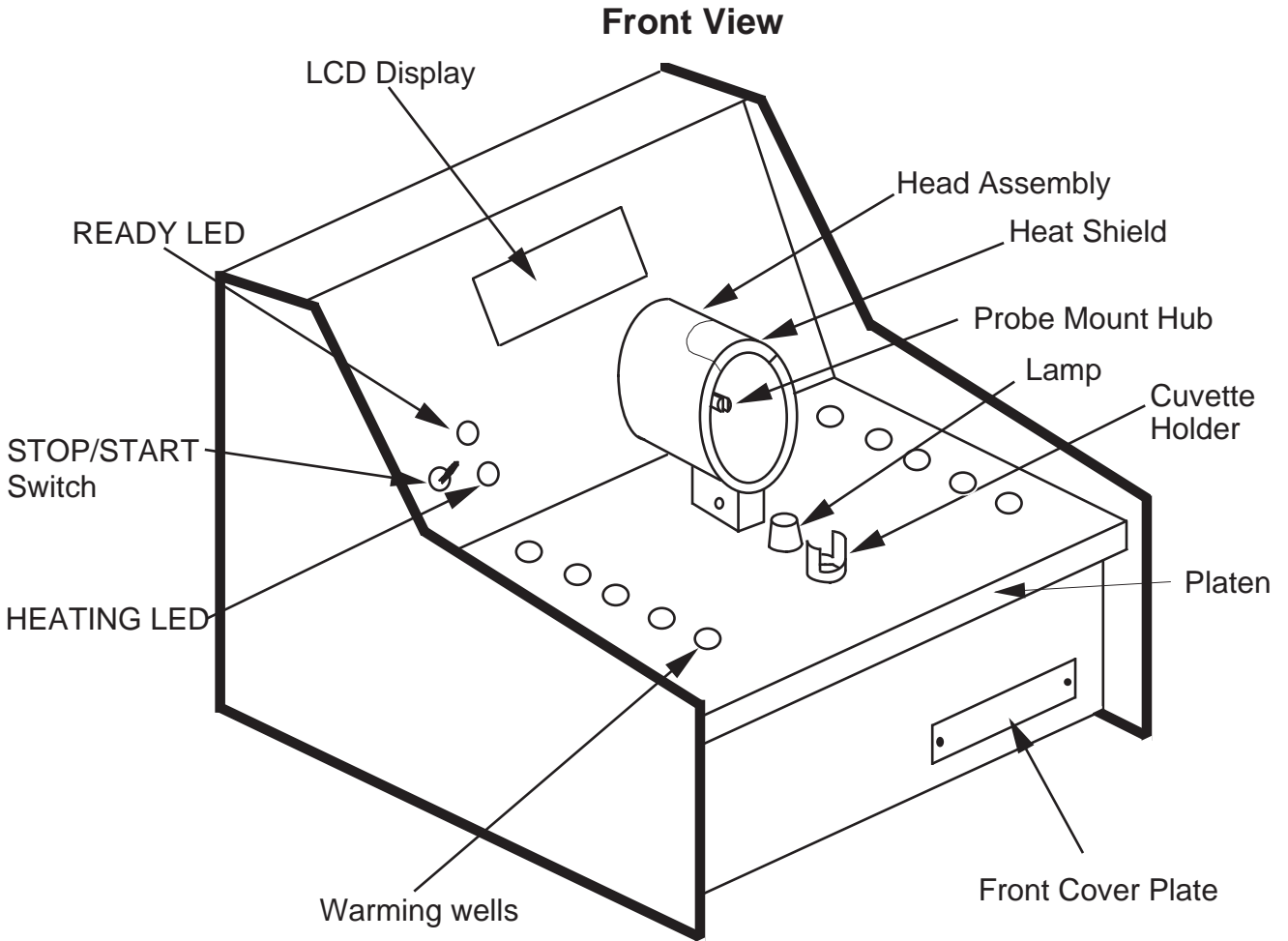
The Printer power switch is located on the left side of the instrument. A green light on the front of the Printer indicates the power is ON. The green/orange lights on the top indicates the Printer is ON-LINE/OFF-LINE respectively. The Printer paper is pre-loaded and ready for use. See Chapter 6 for instructions on re-loading Printer paper.

The Sonoclot Analyzer power switch is found on the back of the instrument just above the power cord plug. When turned on, the Sonoclot Analyzer will beep and display a start-up message on the front Liquid Crystal Display ("LCD"). The Printer will also print a start-up message.

The Sonoclot Analyzer indicates that power is on when either the yellow HEATING LED or green READY LED is illuminated. The Sonoclot Analyzer is at proper operating temperature (normally 37.0 °C) when the green READY LED is illuminated and the front panel "LCD" message reads "Ready".

## Sonoclot Analyzer Indicators and Controls

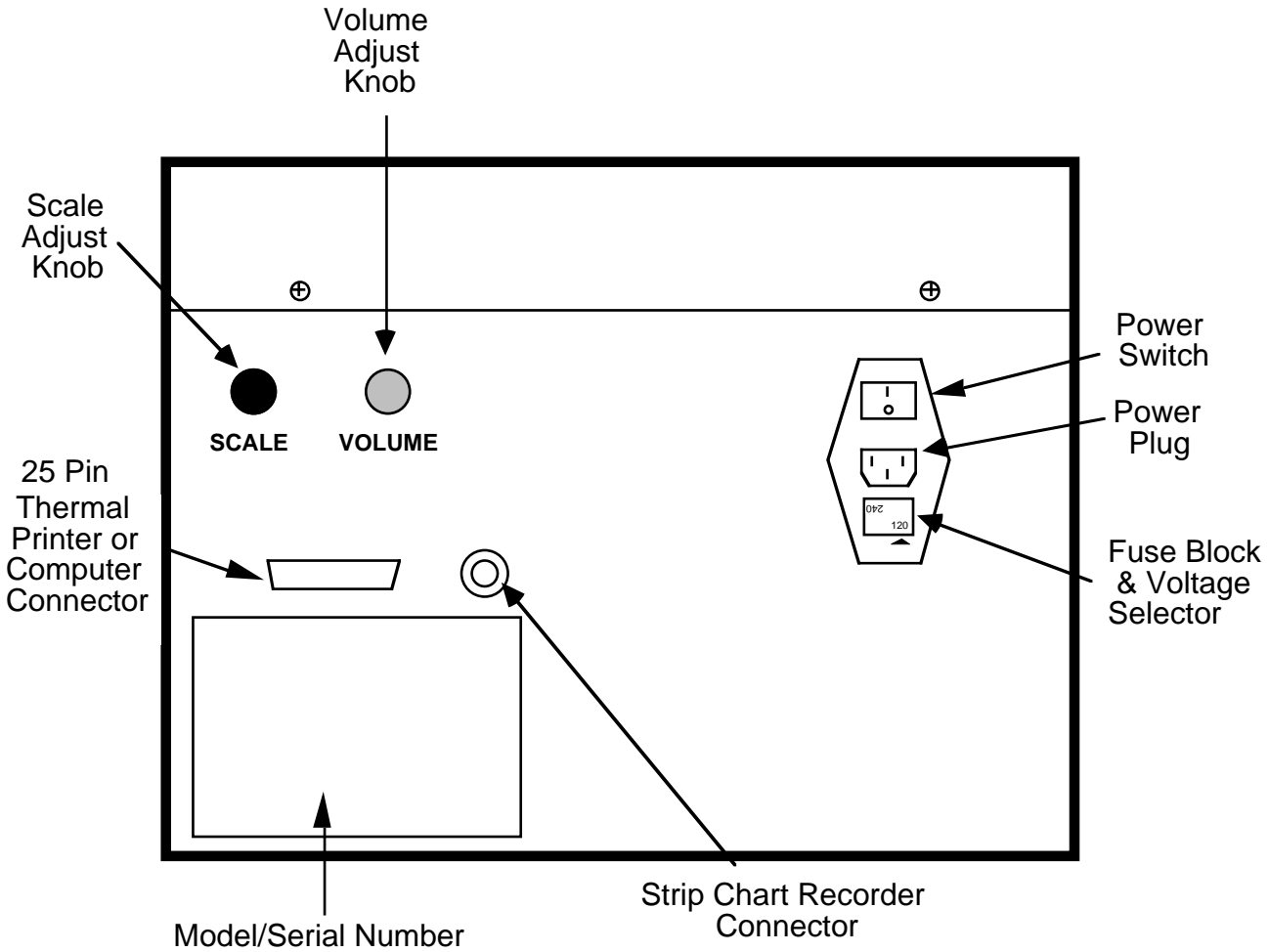
Before continuing, please take a few minutes to examine the front and rear view diagrams of the Sonoclot Analyzer.



<b>Controls</b>	<b>STOP/START Switch</b>	Operator functions are performed using this momentary switch
<b>Indicators</b>	<b>“LCD” Display Switch</b>	Liquid Crystal Display (“LCD”) reports results, data and user prompts
	<b>READY LED</b>	Green light emitting diode (“LED”) indicates Sonoclot Analyzer has reached operating temperature
	<b>HEATING LED</b>	Yellow LED indicates Sonoclot Analyzer is on and warming up

Several user selectable features are controlled with dip switches located under the front cover plate. For information regarding these features, see Chapter 5 - Configuring the Sonoclot Analyzer.

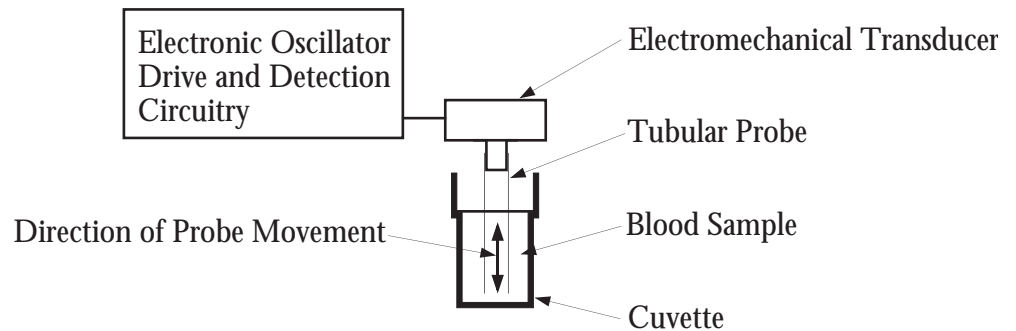
## Rear View



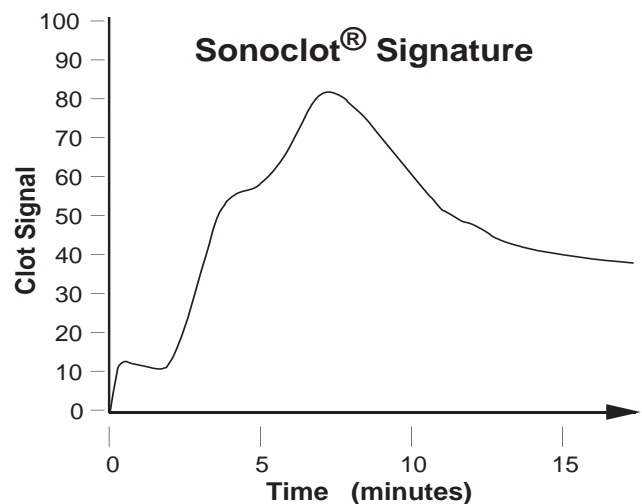
<b>Controls</b>	<b>Volume Control Knob</b>	Controls tone volume
	<b>Scale Select Knob</b>	Selects range for Sonoclot Clot Signal on graphic printout
	<b>Power Switch</b>	Enables/disables power to the Sonoclot Analyzer
	<b>Fuse Block</b>	Holds fuses and selects proper line voltage

## Principle of Operation

The detection mechanism within the Sonoclot Analyzer responds to mechanical changes that occur within the blood sample. This mechanism consists of a tubular probe that oscillates up and down within a blood sample. The electronic drive and detection circuitry senses the resistance to motion that the probe encounters as the blood sample progresses through the various stages of hemostasis. The resulting analog electronic signal is processed by a microcomputer within the Sonoclot Analyzer and is reported as the Clot Signal.



As the blood sample clots, numerous mechanical changes related to the performance of the patient's hemostasis system occur that alter the Clot Signal value. The record of the clot evolution is saved as a graph of the Clot Signal value versus time and is printed on a thermal graphics printer. This graph is called the Sonoclot Signature. A typical Sonoclot Signature is shown to the right.



# Performance Characteristics and Specifications

## **Sonoclot Analyzer Model DP-2951**

Width	8.5"	21.5 cm
Depth	9.6"	24.5 cm
Height	7.5"	19 cm
Weight	12 lbs	5 kg
Electrical voltage requirement	100 to 120V~ or 230V~ ±10%	
Electrical power requirement	55 watts	
Frequency	50/60 Hz	
Fuse specification	(2) T1A,250V	
Temperature regulation of platen	37°C ±0.5°C	
Viscosity range for test sample	< 300 cP	

## **Printer P/N 800-1108**

Width	6.75"	17 cm
Depth	6.75"	17 cm
Height	3.75"	9.5 cm
Weight	3 lbs	1.4 kg
AC Adaptors	PW-4007-J1(100V ±10% @ 50-60 Hz) PW-4007-U1(120V ±10% @ 60 Hz) PW-4007-E1(230V ±10% @ 50 Hz) 6.5V DC @ 2000 mA	
Printing method	thermal serial dot	
Character	9 dots high x 8 dots wide	
Characters per line	80	
Dots per line	640	
Printing width	89.6 mm	

## **Operating Conditions**

Ambient temperature	15-30 °C
Relative humidity	30-80% RH
Other restrictions	avoid direct sunlight avoid air drafts

Sienco recommends that the Sonoclot Analyzer and the Printer be left on 24 hours a day so the instruments will always be warm and ready for use.

# Running a Hemostasis Test

The Sonoclot Analyzer monitors the mechanical changes that occur during hemostasis. This section presents the specific steps to prepare and run a hemostasis test with the Sonoclot Analyzer. Interpretation of test results is discussed in Chapter 2.

The time required to complete an analysis depends on the hemostasis information desired and the specific test used. Coagulation cascade test results require a few minutes; information on platelet function requires 10 to 30 minutes; information on fibrinolysis requires longer analysis - the time that it takes for lysis to occur.

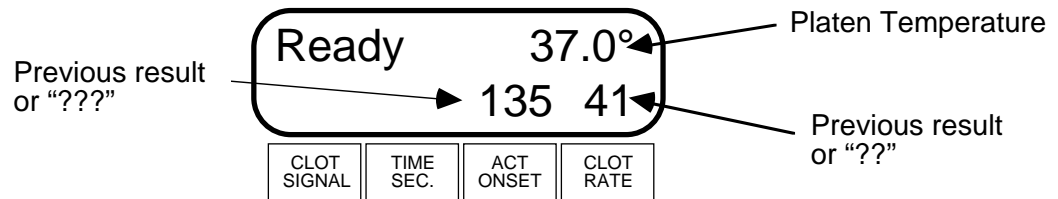
## **Sonoclot Analyzer Preparation Before Running a Hemostasis Test**

Cuvettes should be placed in the warming holes in advance so they will be warm and ready to go when the blood is drawn. Probes fit into the lids of the cuvettes so that they may be conveniently stored for use.

If the Sonoclot Analyzer has just been turned on, allow it to warm up with head assembly in the down position until the Sonoclot Analyzer reaches the desired controlled temperature.

Check that the Printer is ON and ON-LINE.

Prior to running a sample the Sonoclot Analyzer display should display the following:

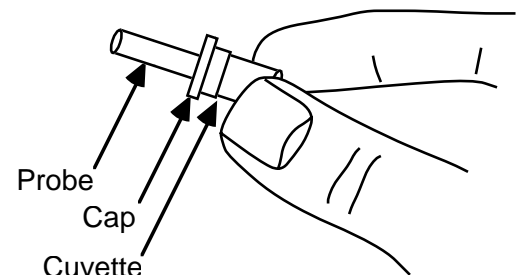


The Time Scale and Clot Signal Scale settings affect scaling of the Sonoclot Signature. These settings normally will be pre-set to the operator's desired values. The default settings are appropriate for whole blood coagulation tests. See Chapter 5 - Configuring the Sonoclot Analyzer if you wish to modify these settings.

## **Cuvette and Probe Setup**

Open head assembly by tilting it backwards.

Insert a clean disposable tubular probe over the probe mount hub inside the head assembly. The probe must be fully seated on the probe mount hub for proper operation. If the probe had been placed into the recess of the cuvette cap, then the cuvette can be used to mount the probe to



the probe mount hub. Use the cuvette as a convenient probe mounting tool, as pictured, by holding the cuvette to position the probe over the probe mount hub. Gently push the cuvette to push the probe fully over the probe mount hub. When the probe is fully seated on the probe mount hub, remove the cuvette; the probe remains on the hub.

If you are using an activated test cuvette, the activated cuvette contains a stir bar and activation powder. **Sharply tap** the cuvette on a hard surface to dislodge any activation powder from the sides and lid of the cuvette.

**Remove the lid from the cuvette before placing the cuvette in the cuvette holder.** To remove the cuvette lid, place the cuvette in a warming hole and pop the lid off with your thumb. **Do not remove the cuvette lid while the cuvette is in the cuvette holder;** the cuvette holder may break.

With a slight twisting motion, insert the cuvette into the cuvette holder. Ensure that the cuvette is fully seated in the cuvette holder.

## Obtaining the Blood Sample

Native whole blood must be analyzed by the Sonoclot Analyzer within 2 minutes or less of collection. When drawing the blood sample please observe the following precautions:

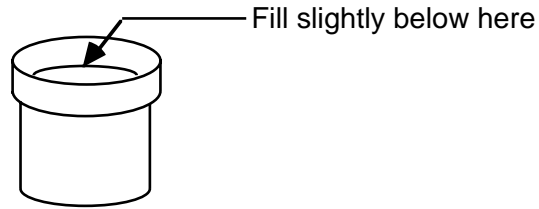
Sample withdrawal must be smooth, slow and atraumatic. While this holds true for any type of blood study, the sensitivity of platelets to disturbance makes good sampling techniques especially important when the Signature will be used to evaluate platelet function. Under no conditions should a sample be drawn with force.

Care should also be exercised in deciding where the sample will be drawn. For example, heparin contamination from a heparinized line or a heparin impregnated catheter will modify the Signature producing inaccurate results inconsistent with the patient's actual hemostatic condition. Heparin contamination may also occur from surgery prep saline lines. Sometimes identification of the source of heparin contamination can involve some careful troubleshooting.

Sienco recommends a two-syringe technique in drawing the blood sample from the patient, drawn from a port on the pump or from the anesthesia port. The first syringe of 2 to 3 ml is discarded and the second syringe is used for the sample. Plastic syringes are mandatory to avoid uncontrolled glass activation.

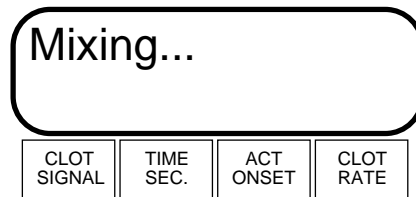
## Running the Sonoclot Analyzer

Fill the warmed cuvette with the blood sample so that the fluid level is slightly below the inner rim of the cuvette as shown below. This volume is approximately 360  $\mu\text{l}$ . Transfer the whole blood sample from the syringe into the cuvette. You may transfer the sample either without a needle or with a blunt needle.



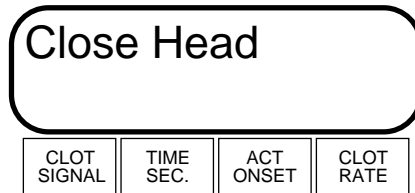
Depress the START Switch immediately. The magnetic stirrer will automatically rotate and the Printer will begin to print.

The display will now read:



and the Printer will start printing.

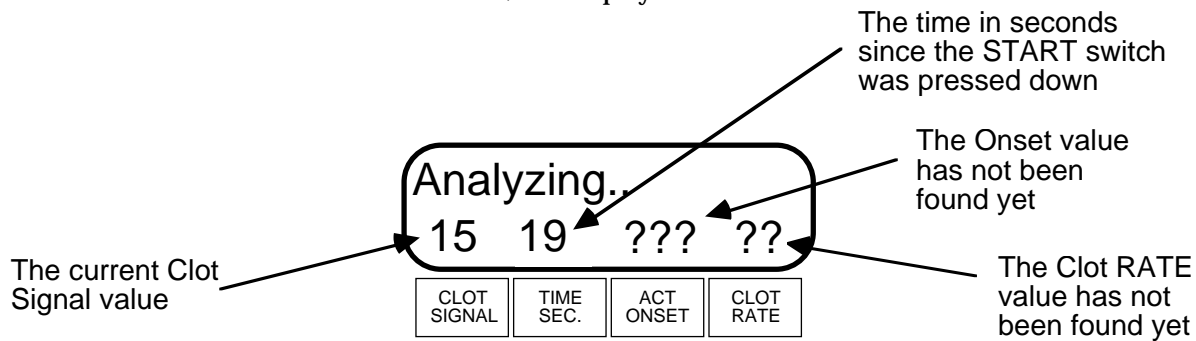
After 10 seconds, the Sonoclot Analyzer will beep and the display will read:



Close the head assembly.

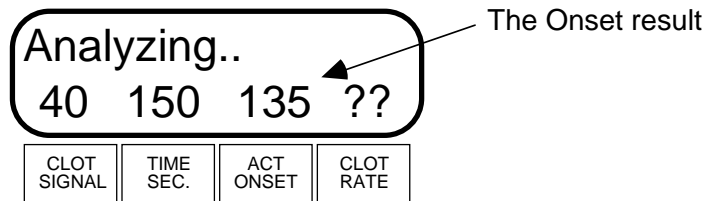
At this time, if you wish to run an analysis for more than twenty to thirty minutes, carefully place a drop of SonOil™ on top of the sample. This will prevent the clot from drying out and forming a crust across the top of the sample.

After another 5 seconds, the display will read:



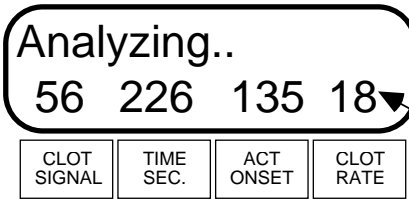
The question marks are displayed because no results have been found at this time.

The sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The instrument detects this initial clot formation, beeps and displays the time that the sample remained a liquid above the ACT legend on the front panel.

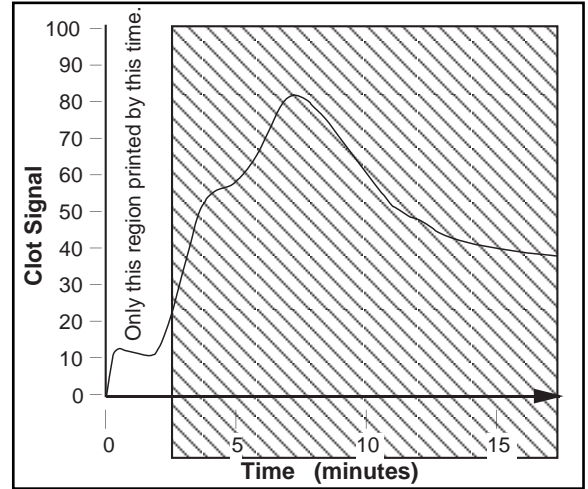


During the next several minutes of the analysis, the fibrinogen converts into a fibrin gel. The rate of the fibrin formation is clinically significant for some Sonoclot tests. The Sonoclot Analyzer determines this rate of formation by calculating the rate of change in the Clot Signal value. When the Clot RATE result is available, the Analyzer beeps and reports the result on the LCD display and Graphics Printer.

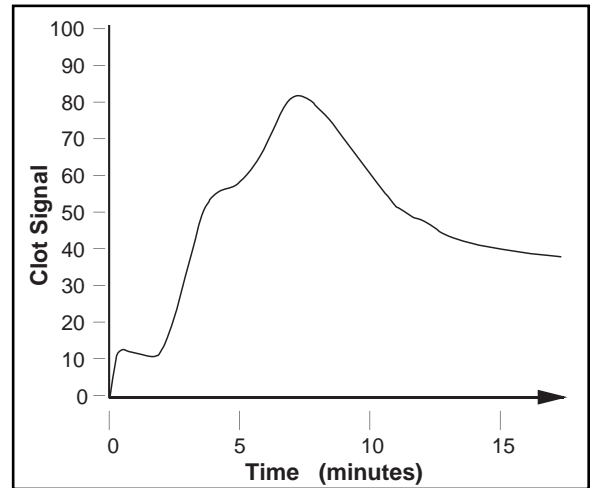
After the Clot RATE has been determined, the Analyzer beeps and the display appears as:



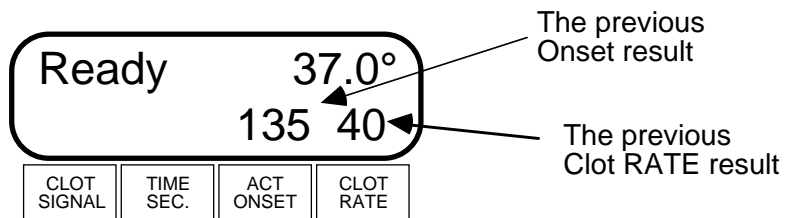
At this time in the analysis the Sonoclot Signature on the Printer will have displayed only the beginning of the clot formation.



Continue to allow the instrument to run in order to obtain information on platelet function and fibrinolysis. If you are interested in monitoring clot retraction (platelet function), you should allow the analysis to continue for 20 to 30 minutes or until clot retraction completes. The example Signature to the right has substantially completed clot retraction after about 15 minutes.



When your analysis is complete, momentarily press the START/STOP switch to the STOP position to stop the Printer. The display contains results from the test and the "Ready" message as shown below.



Open the head assembly. Remove the tubular probe (using the probe extractor) and the cuvette and properly discard them. Lower the head assembly to maintain temperature control of the head assembly.

When the Printer has stopped advancing, you may tear off the paper to analyze the Sonoclot Signature.

If you forget to press the STOP switch to discontinue printing, the Printer will automatically stop after 60 minutes (default value). The automatic shut-off feature can be customized to your specific requirements; see Chapter 5 - Configuring the Sonoclot Analyzer.

## Operational Precautions and Limitations

The quality of the Sonoclot Analyzer test results depend heavily on proper technique. Carefully observe or apply the following precautions.

- 1: Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.
- 2: As with any laboratory test result, diagnosis should not be based solely on the Sonoclot test result but should also consider the patient's condition and other test results.
- 3: Avoid heparin contamination from catheters.
- 4: Avoid blood sample contamination with tissue thromboplastin. Never use the first sample from a new line.
- 5: If the platen is not at the desired temperature setpoint (normally 37 °C) then the Sonoclot Analyzer will display an error message and not run the test.
- 6: For consistent results the cuvettes must be pre-warmed prior to running the test. Place cuvettes in the warming wells for at least 5 minutes to pre-warm them.
- 7: If using an activation cuvette, tap it sharply on a hard surface to deposit the contact activator on the bottom of the cuvette.
- 8: The disposable probe must be fully seated against the shoulder of the probe mount hub to avoid interference between the probe and stir-bar.
- 9: The disposable cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir-bar.
- 10: For best results, do not overfill the cuvette. The proper fill level is slightly below the inner rim of the cuvette.
- 11: Never reuse either a probe or cuvette. Thrombin contamination may result.

- 12: Avoid contaminating the electromechanical transducer in the head assembly by keeping blood, dirt or other contaminants away from the probe mount hub.
- 13: Periodically use QC testing to verify proper operation of the Sonoclot Analyzer and activation cuvettes.
- 14: Use proper handling techniques to dispose of probes and cuvettes.
- 15: The mechanical oscillator may be affected by mechanical disturbances. These disturbances may rarely result in incorrect results. Always inspect the Sonoclot Signature to ensure that the results are consistent.
- 16: For extremely high viscosity blood samples, > 8.0 cp, stratification may occur during mixing. For these types of blood samples, external mixing prior to analysis should be performed.

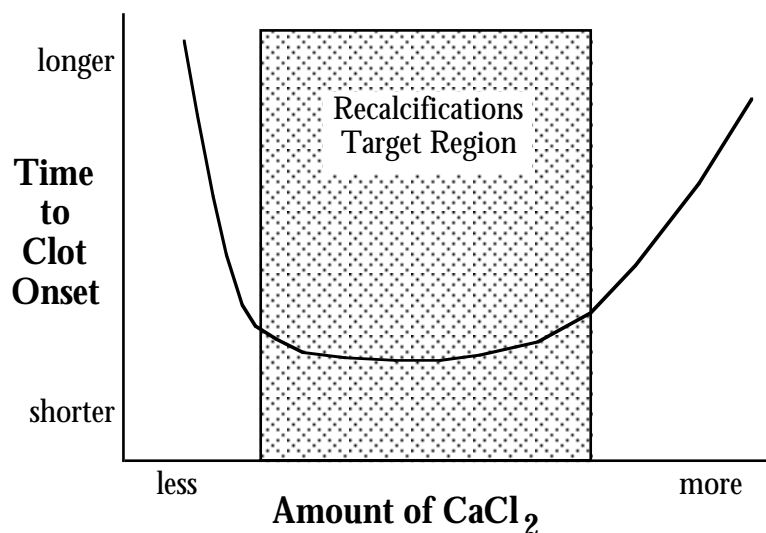
# Using Citrated Blood Samples

## Background

Citrated blood samples can be used with the Sonoclot Analyzer. However, citrated samples are different than native whole blood samples and the results that are obtained are also different. **When interpreting results, do not apply the same normal ranges for citrated samples that you would apply to native whole blood samples.**

Special care should be used when testing citrated samples in order to ensure consistent results. Test results are effected by the accuracy of recalcification and sample aging.

The quantity of calcium chloride added to the sample during recalcification affects the test results. A typical dose response curve for the time the blood sample remains a liquid versus varying quantity of  $\text{CaCl}_2$  for recalcification has the general shape drawn below.



Fortunately, the dose response curve is relatively flat in the region of proper recalcification so small recalcification error will not result in significant test error. For standard blue top vacutainers, the recommended recalcification is  $\approx 15 \mu\text{l}$  of 0.25M calcium chloride ( $\text{CaCl}_2$ ) for whole blood or  $\approx 30 \mu\text{l}$  of 0.25M calcium chloride for plasma or platelet rich plasma. For accurate results, it is best to run a dose response curve to determine proper recalcification for your specific collection tube. For applications such as testing sequestered platelets, the amount of citrate is unknown and proper recalcification will require determining the actual recalcification dose response curve.

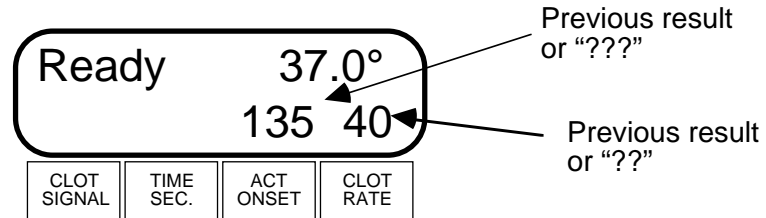
Analyzing a citrated sample is similar to analyzing a native whole blood sample but requires additional steps for proper incubation and recalcification. The following steps are often duplications of the steps for analyzing a native whole blood sample but are repeated for your convenience.

The time required to complete an analysis depends on the hemostasis information desired and the specific test used. Coagulation cascade test results require a few minutes; information on platelet function requires 10 to 30 minutes; information on fibrinolysis requires longer analysis - the time that it takes for lysis to occur.

## Initial Sonoclot Analyzer Preparation Before Running a Citrated Blood Test

If the Sonoclot Analyzer has just been turned on, allow it to warm up with the head assembly in the down position until the READY LED is illuminated.

Check that the Printer is ON and ON-LINE. Prior to running a sample the Sonoclot Analyzer LCD should display the following:



The Time Scale and Clot Signal Scale settings affect scaling of the Sonoclot Signature. These settings normally will be pre-set to the desired values. The default settings are appropriate for citrated whole blood tests. See Chapter 5 - Configuring the Sonoclot Analyzer if you wish to modify these settings.

## Obtaining a Blood Sample

The coagulation test results run on citrated blood samples are affected by the storage time of the citrated sample. For best results test the citrated sample within 30 minutes of collection. Draw the blood by observing the following precautions:

- 1: Sample withdrawal must be smooth, slow and atraumatic. While this holds true for any type of blood study, the sensitivity of platelets to disturbance makes good sampling techniques especially important when the Signature will be used to evaluate platelet function. Under no conditions should a sample be drawn with force.
- 2: Care should also be exercised in deciding where the sample will be drawn. For example, heparin contamination from a heparinized line or a heparin impregnated catheter will modify the Signature producing inaccurate results in comparison to the patient's actual hemostatic condition. Heparin contamination also may occur from surgery prep saline lines. Sometimes identification of the source of heparin contamination can involve difficult troubleshooting.
- 3: Sienco recommends a two step technique in drawing the blood sample from the patient, which should be drawn from a port on the pump or from the anesthesia port. The first syringe of 2 to 3 ml is discarded and the second syringe or vacutainer is used for the sample.

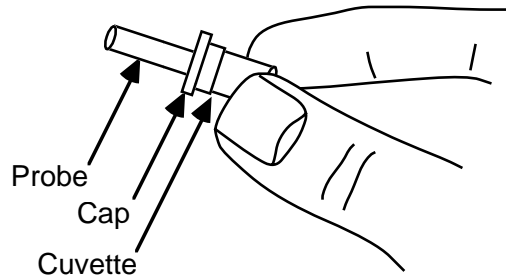
## Sample Incubation

The blood sample should be incubated to 37 °C prior to testing. Do not use an activated cuvette for incubation.

## Cuvette and Probe Setup

Open head assembly by tilting it backwards.

Insert a clean disposable tubular probe over the probe mount hub inside the head assembly. The probe must be fully seated on the probe mount hub for proper operation. If the probe had been placed into the recess of the cuvette cap, then the cuvette can be used to mount the probe to the probe mount hub. Use the cuvette as a convenient probe mounting tool, as pictured, by holding the cuvette to position the probe over the probe mount hub. Gently push the cuvette to push the probe fully over the probe mount hub. When the probe is fully seated on the probe mount hub, remove the cuvette; the probe remains on the hub.



If you are using an activated test cuvette, the activated cuvette contains a stir bar and activation powder. **Sharply tap** the cuvette on a hard surface to dislodge any activation powder from the sides and lid of the cuvette.

**Remove the lid from the cuvette before placing the cuvette in the cuvette holder.** To remove the cuvette lid, place the cuvette in a warming hole and pop the lid off with your thumb. **Do not remove the cuvette lid while the cuvette is in the cuvette holder;** the cuvette holder may break.

With a slight twisting motion, insert the cuvette into the cuvette holder. Ensure that the cuvette is fully seated in the cuvette holder.

## Recalcifying

Add the proper amount of calcium chloride ( $\text{CaCl}_2$ ) for recalcification to the cuvette.

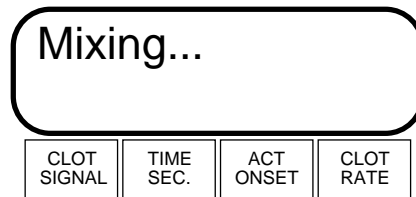
## Running the Sonoclot Analyzer

Fill the cuvette with 360  $\mu\text{l}$  of the blood sample. Use a pipette to transfer the sample from the collection tube into the cuvette.

Depress the START Switch immediately. The magnetic stirrer will automatically turn on and the Printer will begin to print.

If you wish to check for fibrinolysis, carefully place a drop of SonOil on top of the sample. This will prevent the clot from drying out and forming a crust across the top of the sample as fibrinolysis measurements must run for longer periods of time.

The display will now read:



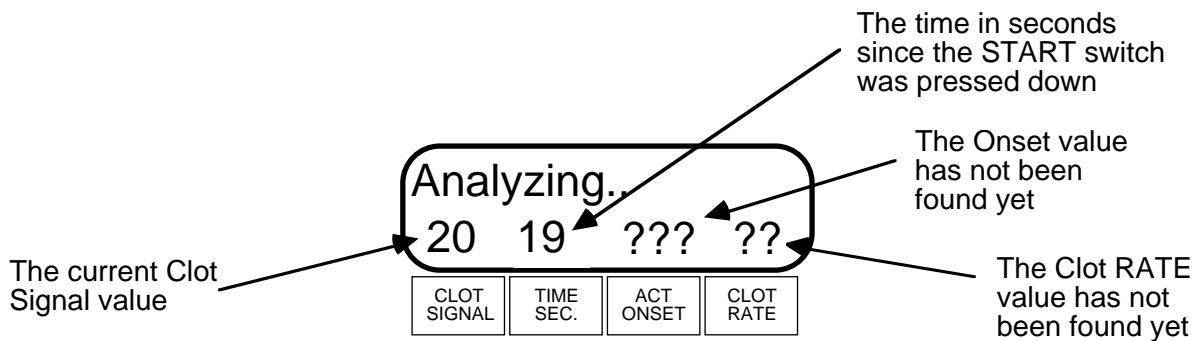
and the Printer will start printing.

After 10 seconds, the Sonoclot Analyzer will beep and the display will read:



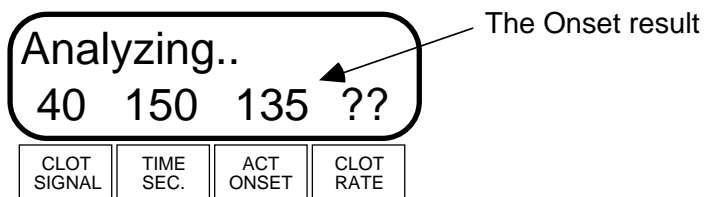
Close the head assembly.

After another 5 seconds, the display will read:



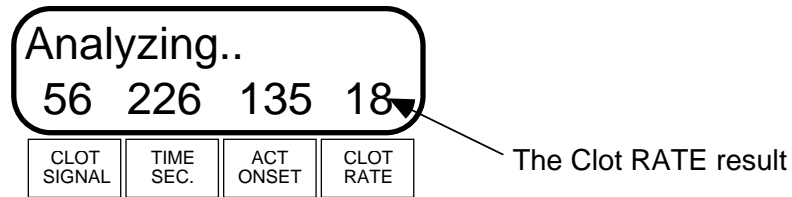
The question marks are displayed because no results have been found at this time.

The sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The instrument detects this initial clot formation, beeps and displays the time that the sample remained a liquid above the ACT legend on the front panel.

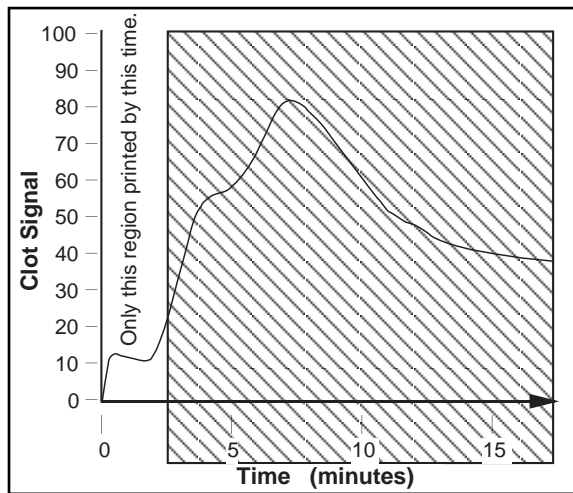


During the next several minutes of the analysis, the fibrinogen converts into a fibrin gel. The rate of the fibrin formation is clinically significant for some Sonoclot tests. The Sonoclot Analyzer determines this rate of formation by calculating the rate of change in the Clot Signal value. When the Clot RATE result is available, the Analyzer beeps and reports the result on the LCD display and Graphics Printer.

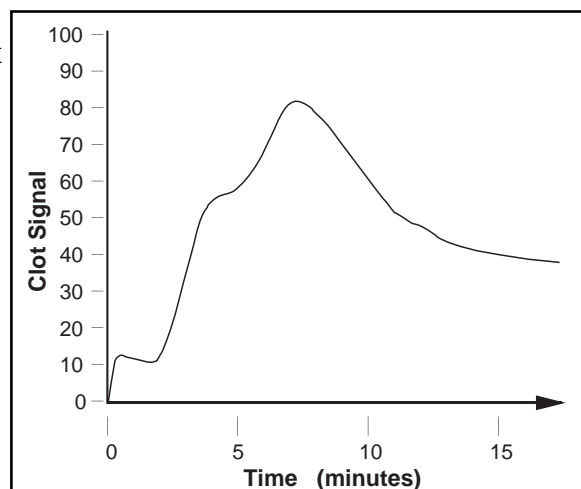
After the Clot RATE has been determined, the Analyzer beeps and the display appears as:



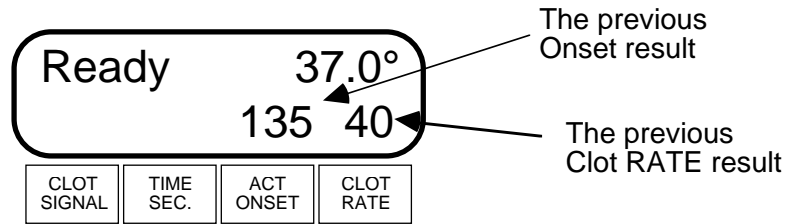
At this time in the analysis the Sonoclot Signature on the Printer will have displayed only the beginning of the clot formation.



Continue to allow the instrument to run in order to obtain information on platelet function and fibrinolysis. If you are interested in monitoring clot retraction (platelet function), you should allow the analysis to continue for 20 to 30 minutes or until clot retraction completes. The example Signature to the right has substantially completed clot retraction after about 15 minutes.



When your analysis is complete, momentarily press the START/STOP switch to the STOP position to stop the Printer. The display contains results from the test and the “Ready” message as shown below.



Open the head assembly. Remove the tubular probe (using the probe extractor) and the cuvette and properly discard them. Lower the head assembly to maintain temperature control of the head assembly.

When the Printer has stopped advancing, you may tear off the paper to analyze the Sonoclot Signature.

If you forget to press the STOP switch to discontinue printing, the Printer will automatically stop after 60 minutes (default value). The automatic shut-off feature can be customized to your specific requirements; see Chapter 5 - Configuring the Sonoclot Analyzer.

## Operational Precautions and Limitations

The quality of the Sonoclot Analyzer test results depend heavily on proper technique. Carefully observe or apply the following precautions.

- 1: Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.
- 2: As with any laboratory test result, diagnosis should not be based solely on the Sonoclot test result but should also consider the patient’s condition and other test results.
- 3: Proper incubation of the sample is important to obtain accurate results.
- 4: Proper recalcification is important to obtain accurate results. Either too little or too much calcium chloride will prolong the Onset and attenuate the Clot RATE.
- 5: The blood or plasma sample should not be exposed to any activating reagent prior to recalcification in order to obtain accurate results.
- 6: The disposable probe must be fully seated against the shoulder of the probe mount hub to avoid interference between the probe and stir bar.
- 7: The disposable cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir-bar.

- 8: For best results, do not overfill the cuvette. The proper fill level is slightly below the inner rim of the cuvette.
- 9: Avoid heparin contamination from catheters.
- 10: Avoid blood sample contamination with tissue thromboplastin. Never use the first sample from a new line.
- 11: Never reuse either a disposable probe or disposable cuvette. Thrombin contamination may result.
- 12: Use proper handling techniques when disposing of probes and cuvettes.
- 13: Avoid contaminating the electromechanical transducer in the head assembly by keeping blood, dirt or other contaminants away from the probe mount hub.
- 14: Periodically use QC testing to verify proper operation of the Sonoclot Analyzer and activation cuvettes.
- 15: The mechanical oscillator may be affected by mechanical disturbances. These disturbances may rarely result in incorrect results. Always inspect the Sonoclot Signature to ensure that the results are consistent.
- 16: For extremely high viscosity blood samples, > 8.0 cp, stratification may occur during mixing. For these types of blood samples, external mixing prior to analysis should be performed.