

Appendix

Warnings, Cautions, and Hazards



- 1: **WARNING:** As with any laboratory test result, diagnosis should not be based solely on the Sonoclot test result. The attending physician is responsible for interpreting the Sonoclot test result in conjunction with the patient's condition and other test results.



- 2: **WARNING:** To safeguard against electrical shock, only use a grounded electrical outlet.



- 3: **CAUTION:** Use of the Sonoclot Analyzer should be limited to properly trained laboratory personnel and/or other appropriate health care professionals.



- 4: **CAUTION:** Operator should read the Operator's Manual (this manual) before attempting to operate the Sonoclot Analyzer.



- 5: **CAUTION:** This analyzer should be checked at least once a year by a biomedical engineering department for compliance with applicable current 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: **WARNING:** To improve reliability, always avoid moving the transducer hub sideways when inserting or removing the probe. Push the probe on straight. Pull the probe off straight.



- 8: **CAUTION:** Do not place the Sonoclot Analyzer on counter tops where other vibrating instruments, such as centrifuges, are located. Mechanical vibration of the Sonoclot Analyzer may cause erratic results.



- 9: **CAUTION:** Do not drop the Sonoclot Analyzer. If the unit is dropped, contact your local Sienco service center.

References

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Warranty

The Sonoclot Coagulation & Platelet Function Analyzer includes a one year, return-to-factory Warranty. The Warranty guarantees that the Sonoclot Analyzer conforms to Sienco's current specifications for the product and is free of defects in the material and workmanship.

The Warranty covers and is limited to the replacement or repair of defective parts and components of the Sonoclot Analyzer system. This Warranty does not apply to any product which is used in any manner or subjected to any condition not consistent with its intended purpose or accepted industry practice. The Warranty shall be voided if the Sonoclot Analyzer is modified in any way without prior written approval by Sienco, or is repaired in any manner so as to adversely affect its operation or reliability by persons other than Sienco or its agents.

Claims under this Warranty shall be submitted in writing to Sienco within a reasonable time. The claim shall state the nature and details of the instrument defect and the serial number of the instrument. The statement of claim must accompany the defective product submitted for repair or replacement.

Defective products returned to Sienco shall be decontaminated and properly and adequately packaged and sent to Sienco's plant where the products were manufactured, and shall be shipped prepaid. Such products shall, at Sienco's election, be either repaired, replaced or returned collect.

Decontamination Form

Sonoclot Analyzer Decontamination and Shipping Instructions

This form must be filled out and returned with the Sonoclot Analyzer when shipping the instrument to Sienco for any reason, or a \$75.00 Biohazard Decontamination Charge will be assessed.

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

Place a clean probe on the probe adapter to protect the sensing mechanism while cleaning. **Do not spray any cleaning solvent up into the head since fluid will damage the sensor.**

Decontaminate all surfaces of the instrument using a product certified by your institution.

Remove and discard all probes and cuvettes before packing the instrument.

Institution: _____ Dept. _____

Decontaminated by: _____ Phone: _____

Decontaminate Used: _____ Date: _____

Contact Person: _____ Phone: _____

Sonoclot Analyzer Serial Number: _____

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 Analyzer to:

Sienco, Inc.
Attn.: Service Manager
11485-A W. 48th Ave.
Wheat Ridge, CO 80033

If you have any questions, please contact:

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