

**SonoView Data
Management Software
Operator's Manual**
Revision 1.4

For In Vitro Diagnostic Use

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SonoView Data Management Software

Version 1.2

Overview

SonoView Data Management Software is designed to retrieve and manage data collected on the Sonoclot Coagulation Analyzer (the analyzer), Model SC1.

Installing SonoView

PC

To install SonoView, run the SonoViewInstaller.exe program.

SonoView requires Java version 1.5 or greater. If Java 1.5 is not already installed on your computer, also run the Java installer included with SonoView.

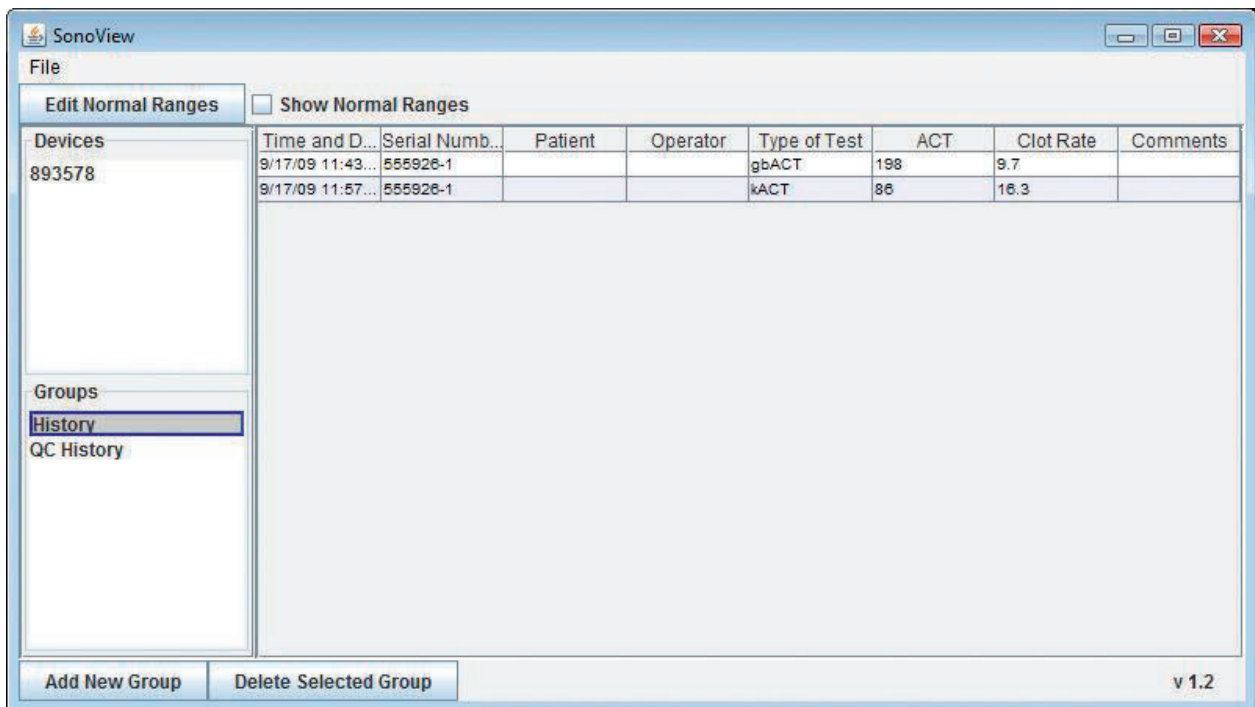
Connecting the Sonoclot Coagulation Analyzer to a Computer:

- 1) Plug one end of USB cable into the USB port on the back of the analyzer and the other end into the USB port on your computer.
- 2) Open the SonoView application on your computer.

NOTE: Do not run SonoView while collecting data.

The SonoView Window

The SonoView window consists of a list of groups displayed in the left column of the window and a corresponding collection of test data displayed in the main data table. Data is sorted in the table by time and date.

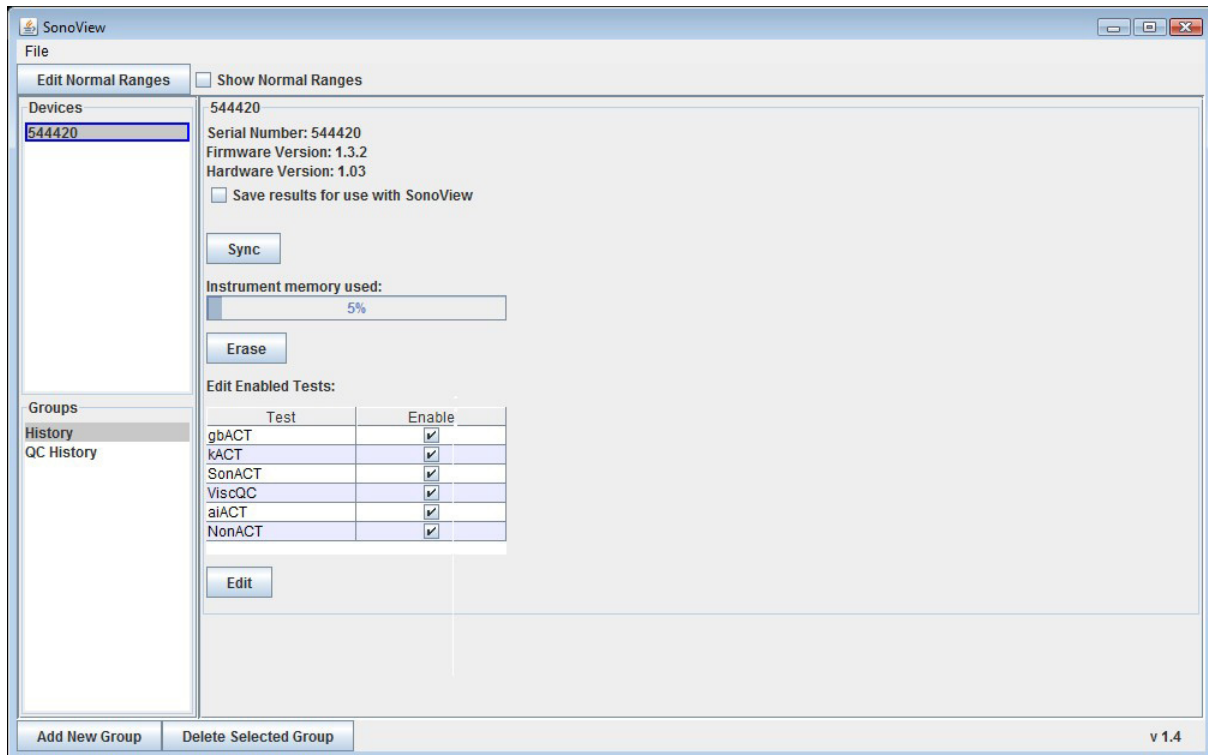


- File Menu
 - Language - opens a dialog to allow the user to change the language.
 - Print - opens a dialog to print a group summary report or individual test reports.
 - Exit - Exits the program.
- Edit Normal Ranges
 - Allows user to edit normal ranges for tests.
- Show Normal Ranges
 - Displays or hides normal range information alongside test results in the results table.
- Devices
 - Lists the analyzers connected to the computer. If no analyzers are connected to the computer, this field will not be visible.
- Groups
 - Lists default (History, QC History) and custom data groups.
- Add New Group
 - Allows user to add custom data groups.
- Delete Selected Group
 - Allows user to delete custom data groups. History and QC History cannot be deleted.
- Time and Date
 - Shows the date and time of the test.

- Serial Number
Shows the serial number of the analyzer the test was run on.
- Patient
Allows user to edit the patient data for a test.
- Operator
Allows user to edit the operator data for a test.
- Type of Test
Displays the type of test run.
- ACT
Displays the ACT test results.
- Clot Rate
Displays the Clot Rate test results.
- ProbInAir
Displays the ProbInAir test results.
- ProbInOil
Displays the ProbInOil test results.
- Comment
Allows user to enter comments for a test.

The Device Window

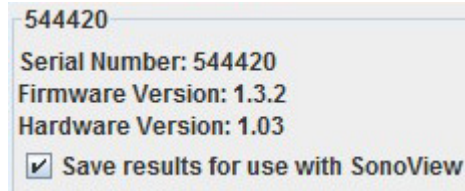
When an analyzer is selected from the device list, the SonoView window displays information and options for that particular analyzer. This window allows the user to import data, delete saved data, and configure the analyzer. Serial number, firmware, and hardware information is listed at the top of the window.



- Save results for use with Sonoview
Allows the user to configure the analyzer to save or not save test results.
- Sync
Allows user to import saved test results.
- Instrument memory
Displays the amount of instrument memory used.
- Edit Enabled Tests
Allows the user to edit the tests available for use on the analyzer.

Configuring Analyzer Memory

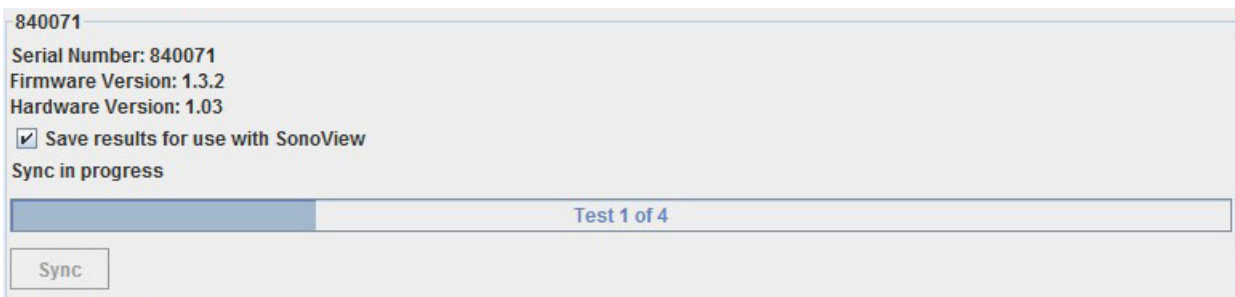
The analyzer can be configured to either save or not save test results. To configure the analyzer to save test results for later import into SonoView, check the “Save results for use with SonoView” box in the device window. The default factory setting is Test Saving Off. Current analyzer configuration will be displayed in the startup dialog on the analyzer LCD display.



Importing Data

To upload test data from the analyzer:

- 1) Connect the analyzer to the computer via USB cable and open SonoView.
- 2) Select the instrument you would like to import data from in the list of connected devices on the left of the SonoView window. For the selected analyzer, SonoView displays the serial number, firmware version, hardware version, and the percent of analyzer memory used.
- 3) In the window for the selected analyzer, click the “Sync” button. Data may take several minutes to import. During data upload, the selected analyzer window will read “Sync in progress” and will display information about the test being uploaded.



- 4) When data upload is complete, the selected analyzer window will read “Sync completed”.



Erasing Imported Tests

The selected analyzer window displays the percentage of memory used on the analyzer.

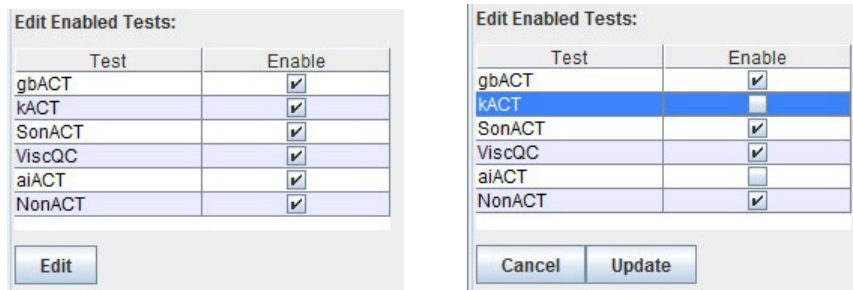
To make sure that no tests are lost due to insufficient memory it is necessary to erase tests from the instrument after they have been imported. It is good practice to erase tests on a regular basis to avoid approaching the memory limits.

To erase imported tests from the instrument's memory, click the "erase" button after syncing data.

Editing Enabled Tests

Enabled tests for each analyzer can be edited in SonoView.

In the device window, click the Edit button under Edit Enabled Tests. Check or uncheck the tests to enable or disable them. When finished, click the Update button to save changes.



Setting the Clock

If the clock in the instrument does not match the host computer's system time, a message will appear at the bottom of the device window.

To set the clock, press the "Set Clock" button.

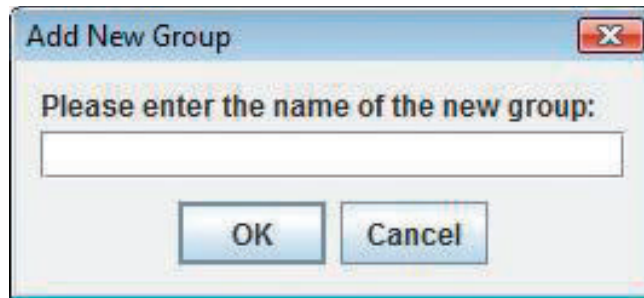
Groups

All imported blood test data is automatically stored in the History group. All imported QC data is automatically stored in the QC History group.

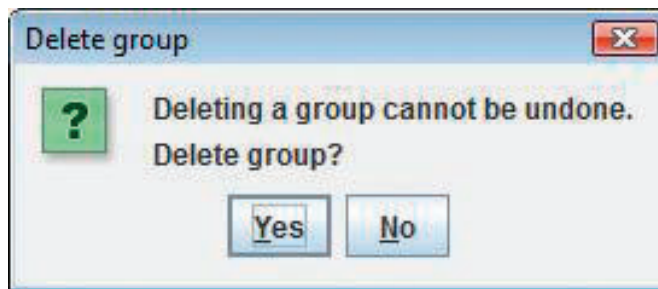
Adding and Deleting Groups

Users can create their own custom groups.

To add a group, click the “Add New Group” button at the bottom of the SonoView window. Type the name of the group in the dialog box and click OK.



To delete a group, select the group from the list and click the “Delete Group” button at the bottom of the SonoView window. The History, QC History, and Last Import groups cannot be deleted.



Adding and Deleting Tests in Groups

To add tests to a group, select the tests from the History group and drag them into the desired group.

To select multiple consecutive tests, hold down the shift key while selecting your tests.

To select multiple non-consecutive tests, hold down the control key while selecting your tests.

To delete tests from a group, select the tests in the group and delete with the delete key on the keyboard.

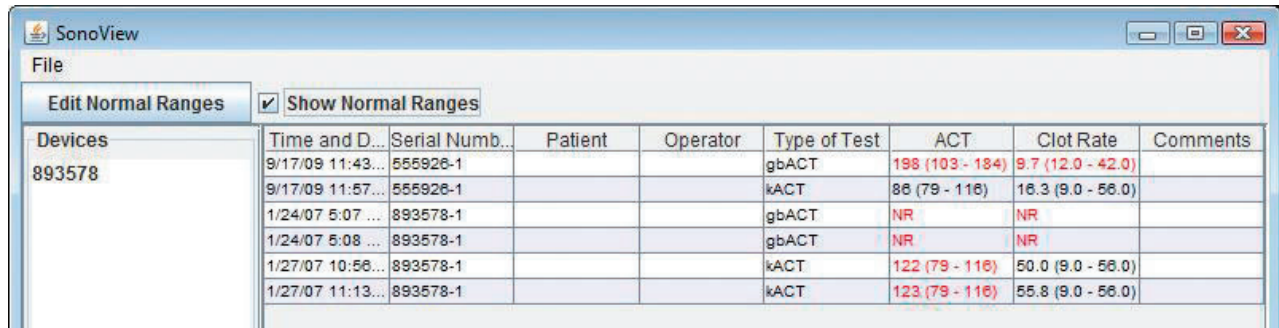
Note: Tests that are deleted from user created groups remain in the History group. Tests that are deleted from the History group are permanently removed and cannot be retrieved.

Normal Ranges

SonoView provides normal range reference values for each test. The default values are those for healthy populations published in the product inserts. Reference values for healthy populations may be different than reference values for specific patient populations. Each institution should establish reference values based upon their own patient populations and clinical applications.

By default, normal ranges are only displayed when a test result is out of range. If a test result is out of range, it is displayed in red and the normal range is given next to the test result.

To display normal ranges for all test results, check the box next to Normal Ranges at the top of the SonoView window.

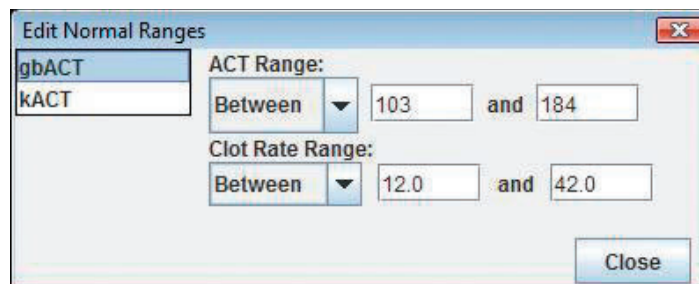


The screenshot shows the SonoView window with the 'Show Normal Ranges' checkbox checked. The table below displays test results with normal ranges shown in parentheses next to the values.

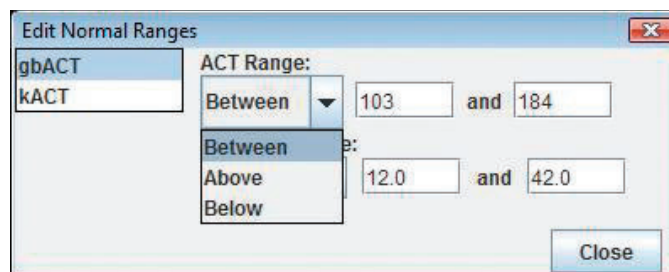
| Devices | Time and D... | Serial Numb... | Patient | Operator | Type of Test | ACT | Clot Rate | Comments |
|---------|------------------|----------------|---------|----------|--------------|-----------------|-------------------|----------|
| 893578 | 9/17/09 11:43... | 555926-1 | | | gbACT | 198 (103 - 184) | 9.7 (12.0 - 42.0) | |
| | 9/17/09 11:57... | 555926-1 | | | kACT | 88 (79 - 116) | 16.3 (9.0 - 56.0) | |
| | 1/24/07 5:07 ... | 893578-1 | | | gbACT | NR | NR | |
| | 1/24/07 5:08 ... | 893578-1 | | | gbACT | NR | NR | |
| | 1/27/07 10:56... | 893578-1 | | | kACT | 122 (79 - 116) | 50.0 (9.0 - 56.0) | |
| | 1/27/07 11:13... | 893578-1 | | | kACT | 123 (79 - 116) | 55.8 (9.0 - 56.0) | |

To edit normal ranges:

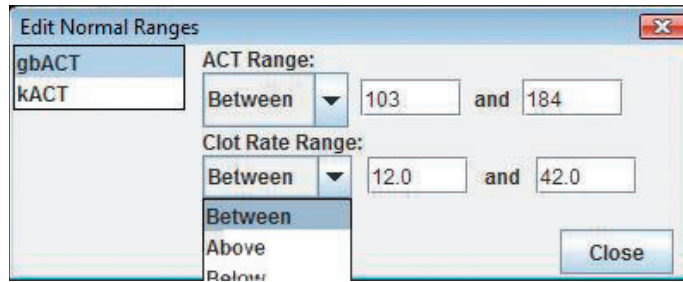
- 1) Click the "Edit Normal Ranges" button at the top of the SonoView window.
- 2) Select the type of test you wish to edit.



- 3) Set the ACT range for the selected test by choosing "Between", "Above", or "Below" under "ACT Range" and entering the values in the text field.



- 4) Set the Clot Rate range for the selected test by choosing “Between”, “Above”, or “Below” under “Clot Rate Range” and entering the value in the text field.



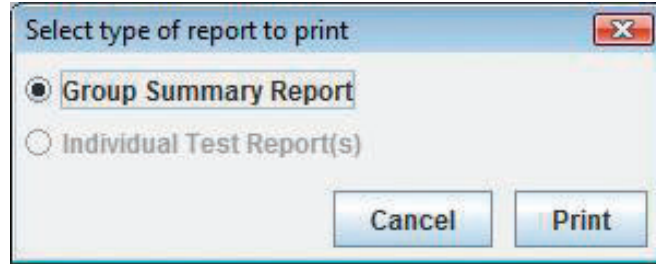
- 5) When finished, click “Close” to close the window.

Printing

SonoView prints both group summary reports and individual test reports.

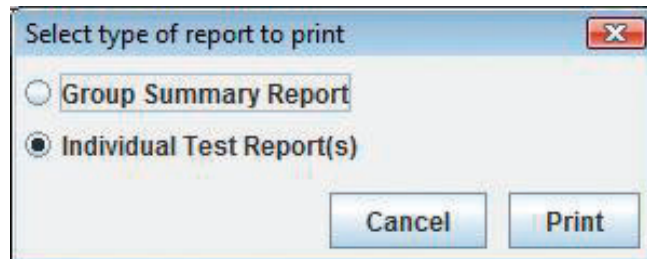
To print a group summary report:

- 1) Select the data group to print from the group list on the left of the SonoView window.
- 2) Select Print from the File menu and select Group Summary Report.
- 3) Click Print.



To print individual test reports:

- 1) Select the test(s) to print from the group summary table.
- 2) Select Print from the File menu and select Individual Test Report.
- 3) Click Print.



Troubleshooting

Make sure that the analyzer is connected before opening the SonoView application.




















If the analyzer is connected to the computer but the Import Data button does not appear in the SonoView window, quit SonoView. Check the USB connection on both the analyzer and the computer and restart SonoView.

Technical Support

For technical support on SonoView, please contact Sienco at:

Phone: 303-420-1148
Toll Free: 800-432-1624
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Mail: Sienco Service Department
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Arvada, CO 80003 USA

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 | | |