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Stago Compact Max® Start Up and Basic Operations Procedure

Purpose

This procedure provides instructions for start-up and operation of the STA Compact Max® coagulation analyzers.

Principle

The **STA Compact Max® system** is an in vitro diagnostic medical device that comprises a laboratory analyzer and software intended to be used in combination with disposables and reagent products.

The system has been designed to perform in vitro tests for the diagnosis and monitoring of disorders related to hemostasis. It can be used to perform chronometric tests (measurement of coagulation time), colorimetric tests or immunological tests on plasma samples.

Chronometry measurement principle:
The principle consists in measuring changes in the oscillation amplitude of the ball inside the cuvette, using electromagnetic sensors. An algorithm uses these magnetic field changes to calculate the oscillation amplitude to precisely determine the clotting times.

Photometry measurement principle:
The detection principle for chromogenic or immunological analyses on the STA Compact Max® is based on the absorbance (optical density, O.D.) of monochromatic (405 nm or 540 nm) light passing through a cuvette as an enzymatic or immunological reaction takes place.

Scope

This procedure is to be performed by trained and competent Clinical Laboratory Scientist (CLS) and Medical Laboratory Technician (MLT).

Safety

All staff members performing these procedures must adhere to regional and local workplace safety policies. These will include but may not be limited to:

- Equipment safety, proper body mechanics, share exposure
- Proper use of gloves/personal protective equipment while performing these procedures
- Exposure to body fluids
- Proper handling of regular and biohazardous waste
- Handling of regular and infectious waste.
- Proper cleaning of work area
- Proper handwashing
- Proper storage and disposal of chemical hazardous waste

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Specimen collection and storage

Sample collection must be in conformity with the recommendations for hemostasis tests.

- Blood (9 vol.) is collected in 0.109 M (i.e., 3.2 %) trisodium citrate anticoagulant (1 vol.) according to CLSI guidelines H03-A2 and H21-A5.

See specific requirements for each test procedure.

Specimen rejection

The followings specimens will be rejected:

- Specimens improperly labeled.
- Specimens that are clotted.
- Specimens collected in the wrong tube.
- Specimens that have less than 70% of expected fill volume (etched mark on the tube)
- Specimens that are overfilled.
- Grossly hemolyzed samples.
- Specimen not meeting storage and stability requirements
- Specimens with a hematocrit value >55% (i.e. polycythemia patients) should be rejected and redrawn using a reduced volume Sodium Citrate tube. Increased Hematocrit (>55%) may lead to spurious coagulation (PT, APTT, & some factor assays) results due to increased plasma citrate concentration.

Reagents

Pre-analytic conditions relating to products and reagents:

- The laboratory must strictly comply with the instructions provided by the manufacturer in the product and reagent documentation. Poor preparation of the reagent with respect to reconstitution volume, stabilization time, stirring, the presence of bubbles, or the emission or inappropriate presence of a magnetic stir bar may lead to incorrect results.
- Follow the instructions specific in each test procedure.

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Materials and supplies

a. Cuvette roll – 1000 (REF 38669)
b. Distilled Water/Reagent-grade water
c. Cleaner Solution
d. Pipettes & tips

Equipment & Software

a. Stago Compact Max Analyzer
b. Centrifuge
c. Stago Coag Expert

Analyzer Preparation Procedure

A. Powering Up Compact Max and Sta Coag Expert
Ensure all covers and the product drawer are closed properly.

Powering Up Compact Max and Sta Coag Expert	
Step	**Action**
1	Power on the monitor and printer.
2	Power on the Compact Max analyzer using the on/off switch located on the left side of the analyzer.
3	Power on the STA Coag Expert by pressing the button located on the front of the black Dell computer unit.
4	Once Windows loads, two icons will appear on the screen: STA Coag Expert and Stago Admin. Click on Stago Coag Expert (the one on the left).
5	Log in to the STA Coag Expert account using the assigned username and password. The STA Coag Expert application starts automatically.
6	The STA Coag Expert login screen appears. Log in using the user specific STA Coag Expert username and password.
7	The main menu of the STA Coag [illegible]. Click on the STA Compact Max® icon on the right: 
8	 Double-click on the Windows desktop. The home screen appears.
9	Type the username and password then click Confirm The TEST PANEL appears, and the analyzer is ready to use.

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Screen Resolution
If the screen resolution is incorrect after the analyzer is powered on, follow the steps below:

Step	Action
1	Return to the Windows desktop for the STA Compact Max®.
2	Click on the 1280x1024 resolution shortcut  located on the STA Compact Max® desktop.
3	Click on the STA Coag Expert icon on the left at the top of the screen.
4	Then click on the STA Compact Max® icon on the right and the resolution is corrected.

B. Powering off the system: Shutting down the Compact Max and Sta Coag Expert

Powering off the system: Shutting down the Compact Max and Sta Coag Expert	
Step	**Action**
1	From the STA Compact Max® Test Panel, click 
2	A following message will appear: "**STOP THE PROGRAM**"? Select Yes to stop the program. The system starts a backup of the current status of the analyzer and the following messages appear: PROGRAM STOPPED Saving in progress Please wait... **DO NOT SWITCH OFF**
3	Move the cursor to the bottom of the screen to display the Windows taskbar.
4	Click Start and then Shut Down.

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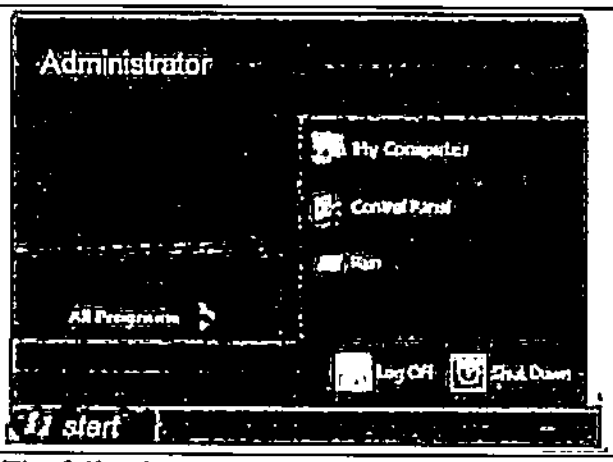
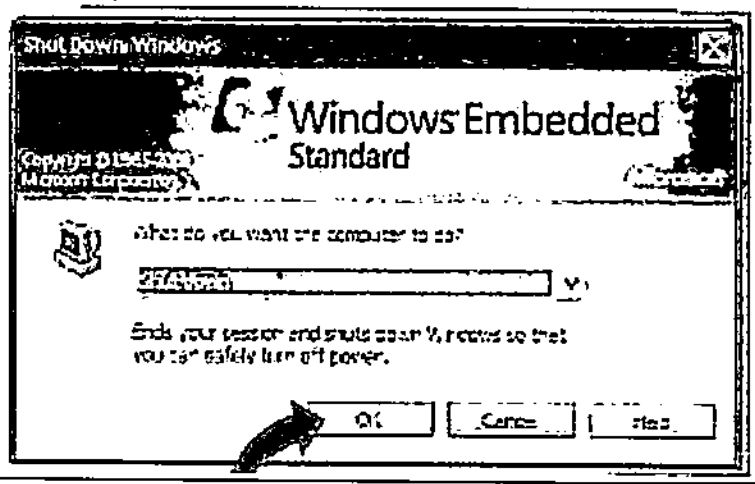
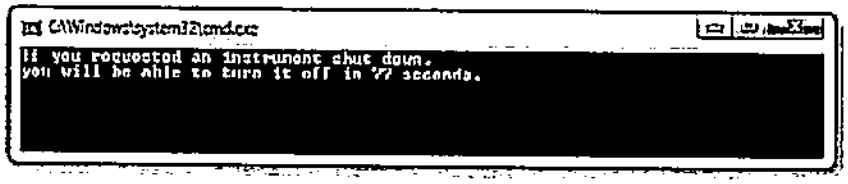
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

	
5	The following screen will appear. Select OK. Once you click OK, the system will take you to STA Coag Expert® software. 
6	Close the Coag Expert® software using the "power off" button 
7	The following message will be displayed:  Once the message in green is displayed (see the image below), proceed to next step.

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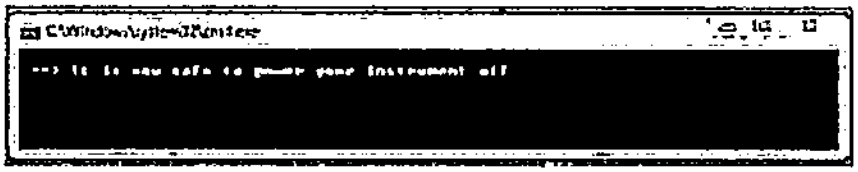
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

	
8	Power off the STA Compact Max®. The switch is located on the left-hand side of the STA Compact Max®.
9	Move the cursor to the bottom of the screen to display the Windows task bar.
10	Click the Windows Start icon and then Shut down. You have now powered off Coag Expert®.
11	Power off the monitor and the printer.

C. Loading Products in the Product Drawer and Replacing Consumables

Prepare reagents. Follow manufacturer's recommendations in reconstituting and handling.

Note: Remove any bubbles or foaming that may be present prior to loading.

The Product Drawer of the Compact Max has:

- 45 reagent vials may be loaded in the Product drawer.
- 5 stirring positions for STA®-Neoplastine® CI and CI Plus.
- No specific position dedicated to a type of product.

I. Loading Reagents, Controls, and Calibrators Using the Barcode Identification	
Step	**Action**
1	Click  or click the Products menu on the Test Panel screen, then Loading Products.
2	Scan the vial barcode label with either the handheld or external barcode reader. The remaining information will be automatically filled in by the software.
3	The cursor is located on the product volume. Confirm this volume by pressing [Enter] or edit the volume if the vial contains a lesser amount. a. If the product has been transferred into a microcup, check the Micro Volume box. b. If the volume has been changed, the stability also must be confirmed by the user.
4	Place the vial in a position corresponding to its diameter in the drawer specified in each test procedure.

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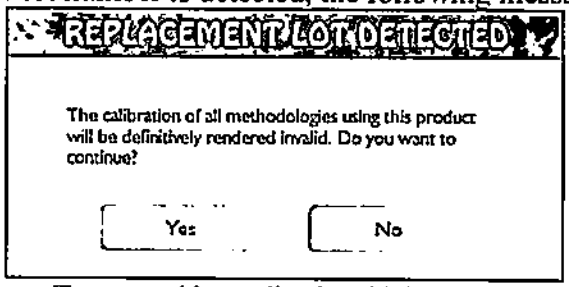
Stago Compact Max® Start Up and Basic Operations
Procedure, Continued

	If the product requires stirring, place the vial in a stirring position.
5	The LED adjacent to the vial position lights up and a beep sounds. The products appear in the [Products on board]. If a new lot number is detected, the following message is displayed:  c. To proceed immediately with barcode reading, click [Yes]. d. Scan the sheet (provided inside the product box) in front of the barcode reader, then click [Validate]. Note: If there is a change of lot – • For a reagent, the calibrations run with the other lot numbers are not invalidated. • For a control, confirm the message indicating that all the controls will be blocked until the new threshold values are indicated. • For a calibrator, confirm the message indicating that the new concentration must be indicated when the calibration is run.
6	Repeat the process for all products that need to be loaded.
7	Click to close the product drawer.

II.	Loading Products Using Manual Identification
Step	**Action**
1	If the product being loaded does not have a barcode, it will have to be manually loaded. Follow the same steps as above, but instead of barcoding in the selected product, type the name and ID of the product into the STA Compact Max®.
2	Type the product ID and name of product exactly as it is defined in Test Setup. The lot number must also be typed in correctly; otherwise, the STA Compact Max® will assume it is a new lot number.
3	Follow all necessary steps as in using barcode identification.

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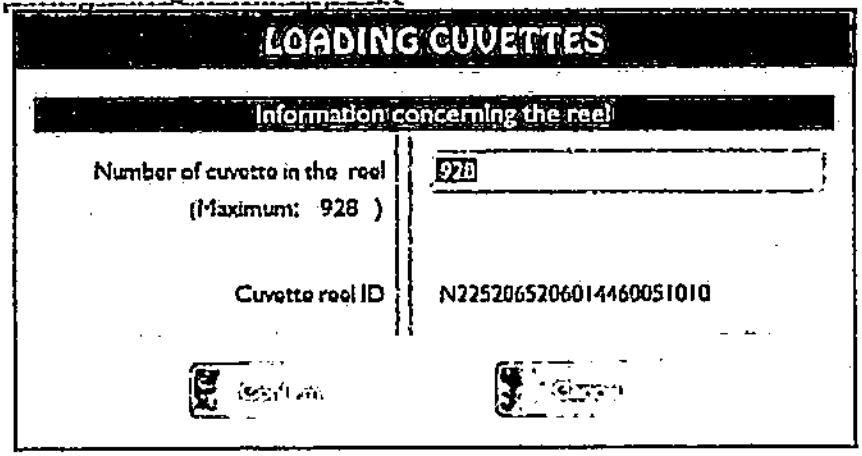
Procedure, Continued

III. Replacing the Cuvette Roll and the Cuvette Disposal Bag	
Step	**Action**
1	Click Products then Loading Cuvettes.
2	The cuvette roll identification window appears: Note: the cuvettes roll loading window is also available from certain error messages.
3	One after the other, pass the two cuvette roll barcodes in front of the barcode reader. · When a barcode passes in front of the reader, the system beeps. · When a barcode is read, the corresponding area of the window is filled in. In case of barcode reading failure, cuvette rolls may be manually identified. Type the data located under the barcodes. It is also possible to use the handheld barcode reader to scan the barcodes individually. Exercise caution in scanning the correct barcode into the correct window.
4	Click Confirm.
5	The following window will appear.  Click Confirm. Indicate the number of cuvettes remaining in the cuvette roll if it is less than what appears in the window prior to clicking Confirm.
6	Follow the instructions indicated on the screen to replace the cuvette roll. Hold the roll so that the reel is on the right. Slide the cuvette roll along its spindle and lower the catch holding the roll.
7	Guide the film under the two black positioning rollers. Do not twist the film. The film will adjust itself in the slide.

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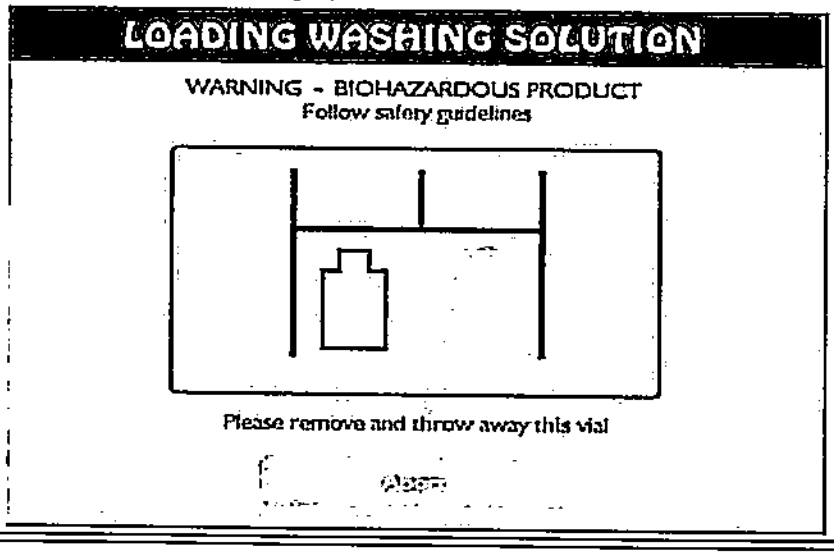
Stago Compact Max® Start Up and Basic Operations
Procedure, Continued

8	Slide the cuvette roll along its spindle, lower the catch holding the roll. Turn the take up reel as indicated in the displayed message.
9	Push the cuvette roll drawer back in and close the right front door. The system will perform an automatic test after a new roll has been installed.
10	Each time the cuvette roll is changed, the cuvette bin must be emptied. The Cuvette bin replacement screen is then displayed. Remove the cuvette disposal drawer.
11	Close the plastic bag with its thread. Take the bag out and discard it following local regulations.
12	Take one of the plastic bags provided with the cuvette roll box. Open the plastic bag and place it into the cuvette disposal drawer.
13	Press the bag to the bottom of the cuvette disposal drawer. Fold the plastic bag over the edges of the cuvette disposal drawer.
14	Put the cuvette disposal drawer back in place, pushing it fully back in and making sure it is properly adjusted on its rail.
15	Click **Confirm.** A message indicating the end of the cuvette roll loading procedure is displayed.

IV. Removal of Liquid Waste container and Loading the Cleaner solution	
Step	**Action**
1	Click Products then Washing Liquid The Loading Washing Solution screen appears.
2	Open the right-side door.
3	Open the container access panel.
4	Carefully lift the used liquid container represented in yellow on the screen (bottle on the right).



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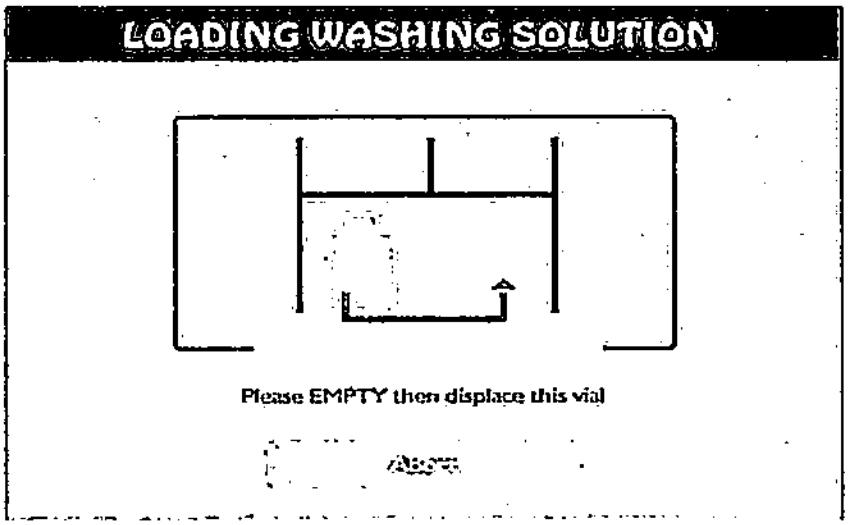
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

5	Remove the used liquid container plug. Place a paper towel under the plug.
6	Completely release the used liquid container. Replace the original cap on the used liquid container. Mark the full liquid waste container as Waste to avoid any risk of incorrect results from inadvertently using the liquid waste as a new Cleaner bottle.
7	Dispose of the used liquid container in accordance with local regulations.
8	The empty STA® Cleaner container becomes the new used liquid container. Carefully lift the empty STA® Cleaner bottle (bottle on the left). 
9	Remove the plug. Place the tip of the plug tubing in a container to avoid any risk of contamination. Use paper towel if necessary.
10	Empty the bottle. Place the empty bottle in front of the right-hand side position and put the plug on the empty bottle.
11	After putting the empty bottle in place, the closing of the switch detecting the presence of the bottle should be heard. Click Confirm.
12	Obtain a new STA® Cleaner bottle and remove the cap. The cap can be stored for future use.
13	Place the new bottle of STA® Cleaner in front of the left-hand side position and put the plug on the new bottle.
14	The closing of the switch detecting the presence of the bottle should be heard. Click Confirm. If a new bottle is used, click Confirm to validate the indicated volume (2500 ml). Otherwise, type the remaining volume, then click Confirm.
15	Close the right-side door.

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Preventive Maintenance

This schedule is provided for a laboratory performing up to 500 tests a day. It should be adapted on the basis of the laboratory's test volume.

Daily

- Check the condensation trap.
- Clean the piercing needle (only if the analyzer is equipped with the cap piercing option).

Weekly

- Clean the washing wells and purge the needles.
- Clean the suction tip. Run a suction tip test after cleaning.
- Data backup; save methodologies and system parameters.
- Shut down and restart the analyzer.
- Clean the air filters – vacuum.
- Clean the incubation and measurement cells.
- Check the Peltier reservoir.
- Clean the sample and product drawer.

Monthly

- Replace the Teflon tips and the O-rings. Failure to replace the Teflon tip after it reaches 0% results in alarm code "L" assigned to every patient run until the Teflon tip is replaced.

Routine

- Replace the air filters

Every 100,000 piercings

- Replace the piercing needle (only if the analyzer is equipped with the cap piercing option). Failure to change the cap-piercing needle after 100,000 piercings results in alarm code "N" (maintenance overdue) assigned to every patient run until the cap-piercing needle is replaced.

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Calibration

A. Performing Calibration	
Step	**Action**
1	Click the  icon to access the Calibration menu.
2	Double click on the methodology to be calibrated.
3	Click the Calibrate A Lot button.
4	Select the lot to be calibrated in the **Lot Selection** window. • Lot displayed in **green**: the vial is present and may be used. • Lot displayed in **red**: the vial is present but cannot be used (insufficient volume and/or stability exceeded). • Lot displayed in **gray**: the vial is not present. • Lot unknown: the vial is missing, or the vial is on board, but the calibration parameters have not been read. • Out-of-date lots are not displayed in the list. • The calibration controls, when specified in the Methodology section, are automatically run by the analyzer, provided the consistency check does not lead to a blocking of the sample pipetting.
5	Click  .

B. For Prothrombin Time (PT): Entering or Modifying the ISI ratio and/ or the reference time (geometric mean)	
Step	**Action**
1	Click the  icon to access the Calibration menu.
2	Click the PT test abbreviation.
3	Click Modify Parameters. If the user has the correct access level, they will be able to modify the parameters. If they do not have the correct access level, an error message will appear telling them they do not have the access rights to perform the task.
4	Click arrow for drop down list of reagent lot.
5	Click the correct lot number.
6	If necessary, enter the ISI ratio value.
7	Enter the value of the laboratory's reference time in seconds. **Note:** It is used as the reference for the INR calculation.
8	Click Confirm.

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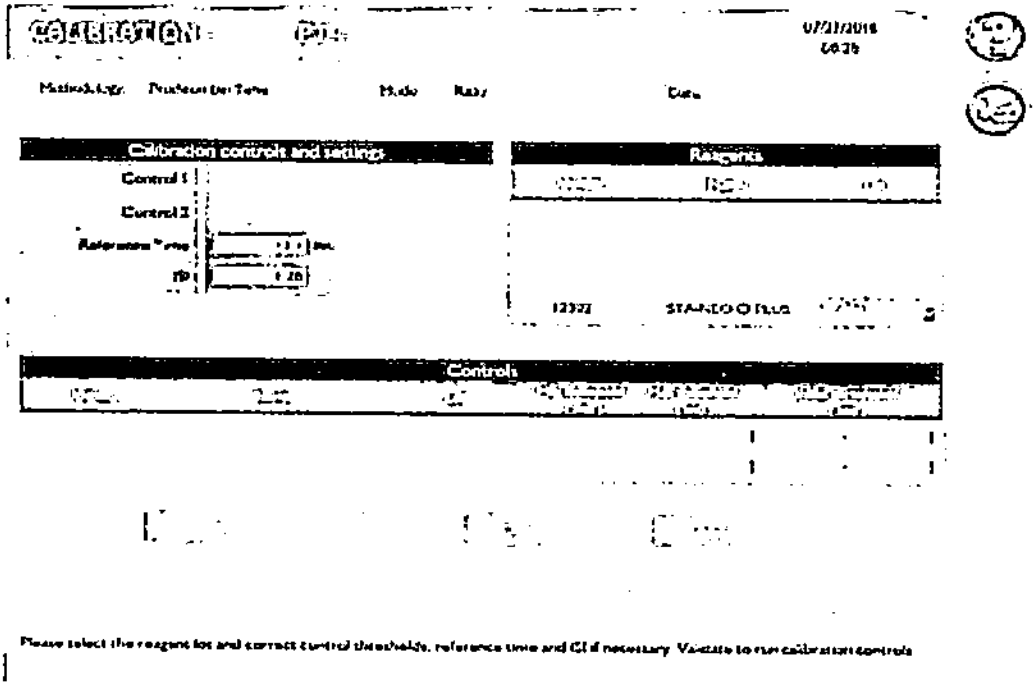
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Calibration, continuation

RISK OF INCORRECT RESULTS

In order to avoid any risk of incorrect results:
The ISI value for the Prothrombin time must be the value indicated on the insert included in the STA line product. The operator must check the ISI value before quitting the menu if there has been a lot change, a software update or any other major change.



Note ISI and Reference Time fields highlighted in yellow here for emphasis.

Quality Control

- The [QUALITY CONTROLS] menu consists of a main screen listing the Methodologies, and a [QUALITY CONTROLS – Graphics/Tables] screen.
- The quality controls for a given test are automatically run by the analyzer as soon as it has to carry out an analysis corresponding to this test and when one of the criteria for running QCs defined in the methodologies screens has been met. This criterion may be the time (beginning of shift), calibration or a change of reagent vial (if the vial is on board).
- The quality controls can also be run manually.
- As soon as the quality control results are completed, they are compared to the acceptable range. If the result fall outside of the range, an error message is generated stating that QC is out and a dark blue triangle will be displayed instead of green.

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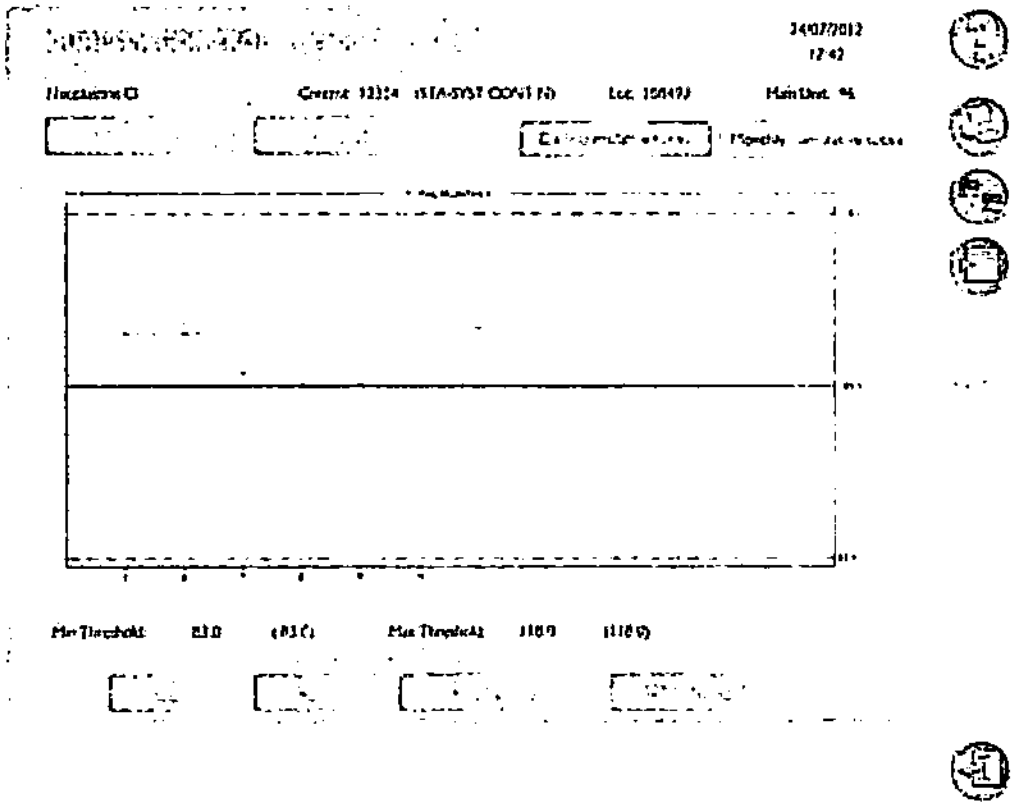
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

- The [Quality Control – Graphics] screen is used to view results in graph form for controls and daily cumulative totals.



A. Running Controls Manually	
Step	**Action**
1	Click  or click the Quality Controls menu from the Test Panel screen.
2	Select the checkboxes for all methodologies for which a quality control is to be run and click  to run all levels for the selected test(s). A yellow triangle ◺ is displayed on the right of the methodology abbreviation for the requested controls (controls in progress)
3	Exit the Quality Controls screen to run the selected test(s).

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

B. Changing the Threshold Values for a Quality Control	
Step	**Action**
1	Click  to access the Quality Control menu.
2	Look for the test for which the quality control threshold values are to be changed. Double click the abbreviation for the desired test.
3	Select Modify Threshold and enter the new thresholds
4	Click Confirm and the thresholds will change, provided the operator has the correct access level rights

C. Printing the Quality Control Graphics	
Step	**Action**
1	Click  to access the Quality Control menu.
2	Double click test abbreviation. Graphics screen displays.
3	Select the QC level. Click  .

D. Displaying and Printing the Quality Control Table	
Step	**Action**
1	Click  to access the Quality Control menu.
2	Double click test abbreviation. Graphics screen displays.
3	Select level. Click  to display table
4	Click  .

E. Transmitting a Quality Control result	
Step	**Action**
1	Click  to access the Quality Control menu.
2	Look for the test for which a quality control is to be transmitted. Double click on test for which a quality control is to be transmitted.
3	Select  to transmit the individual quality control level. If more than one result is to be transmitted, this will need to be done for each level.

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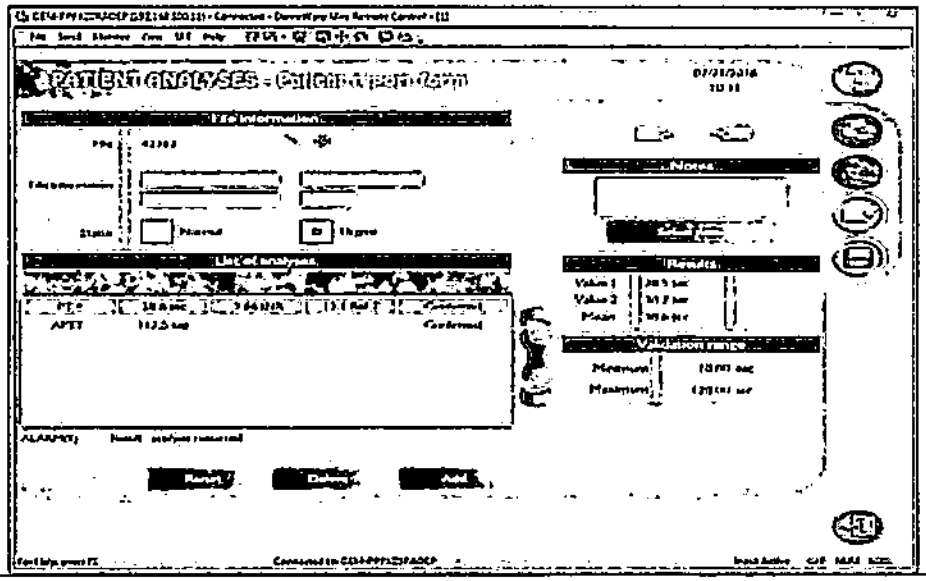
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Operator Intervention of Samples

A. Rerun, delete or add a test for a patient file in the Test Panel	
Step	**Action**
1	From the Test Panel, double click the desired patient to display the Patient report form screen.
2	Use the buttons at the bottom of the Patient report form screen to select the desired action.
3	Save your selection using the 

B. Changing the status of a test to STAT	
Step	**Action**
1	Select Urgent box in File information section of the Patient Report Form. 

Analysis Status Screen

The Analysis Status window displays a consistency check between the workload of the STA Compact Max® (number of analyses to perform except for blocked analyses) and the requirements for the completion of a sample run.

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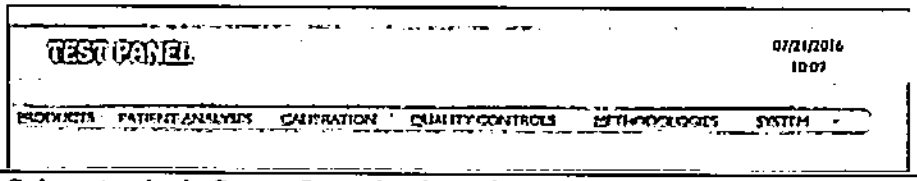
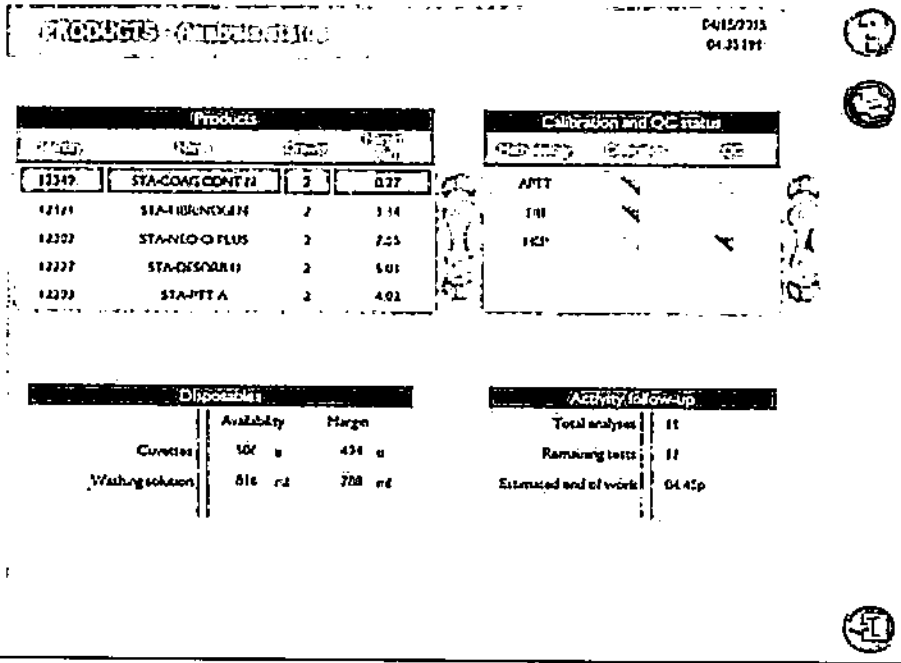
Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Analysis Status Screen continuation

A. Displaying the Analysis Status Screen

Step	Action
1	To access the Analysis Status screen, select the Products menu on the Test Panel screen. 
2	Select Analysis Status from the drop-down menu. 
3	If after the consistency check, one of the requirements to complete the workload is not met, then all the sample pipetting (sample plasma, controls and calibrators) is blocked and the Pipetting Blocked symbol is displayed at the bottom left of the screen: In that case, the operator can reactivate the sample pipetting for the analyses meeting all the conditions (correct calibration, quality control, volume and stability for all requested products) by clicking Yes when the following message is displayed when exiting the Analysis Status screen: "Analyses executions have been stopped. Do you want to reactivate them?"

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Calculations

Follow instructions specified in each test procedure.

Reference Range

See reference range specified for each test procedure.

Reporting Results

- For all tests, an option of automatic rerun in the event of a technical error "Err", QNS, linearity error "Lin", V<MMin, or V>MMax error can be activated.
- **If automatic rerun is activated:**
  a. $V<M_{Min}$ and $V>M_{Max}$ results trigger a rerun if the redilution criteria are not met.
  b. $V<M_{Min}$ and $V>M_{Max}$ results trigger a redilution if the redilution criteria are met.
- **Note:** For tests performed in duplicate, if the difference between the two measures is out of tolerance, an alarm is associated with the results with the status "To be validated". The rerun is not performed automatically, even if automatic rerun is activated.
- Follow instructions specified in each test procedure.

Limitations

See limitations specified for each test procedure.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- STA Compact Max® Reference Manual August 2018
- STA Compact Max® User Guide August 2018

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Stago Compact Max® Start Up and Basic Operations Procedure, Continued

Controlled Documents	The following controlled documents support this procedure: N/A
Author(s)	SCPMG Coagulation Working Group