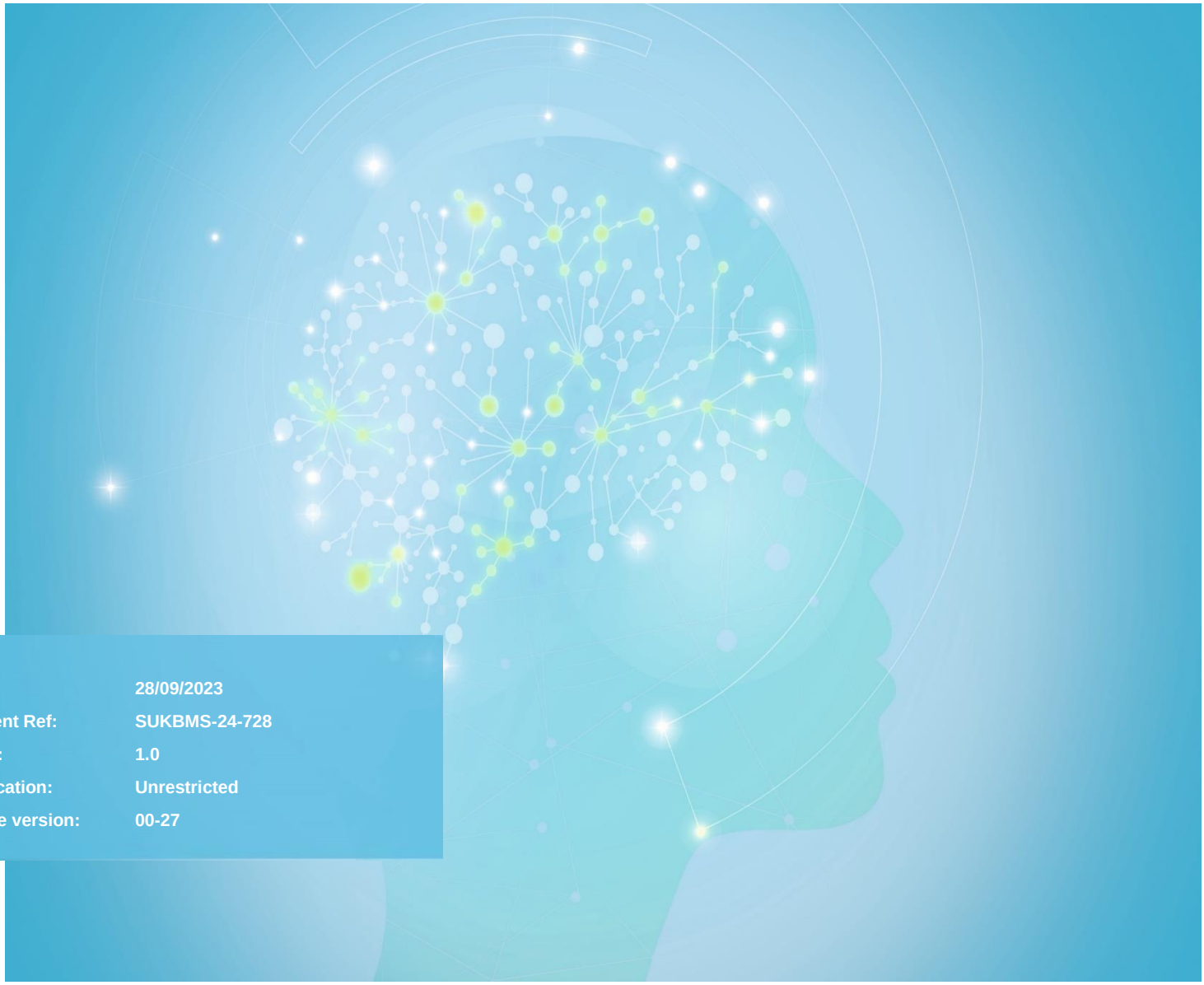
Routine Use Training Workbook

CA-660



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Disclaimer

Please note, the information contained in training resources provided by Sysmex should not be used as an alternative to your sites Standard Operating Procedure (SOP)/Contract. If you have any particular questions regarding any site-specific use of reagents, consumables and/or equipment please contact your Management Team.

Revision History

Revised section	Alteration	Name	Date
New Document	New document to replace the following documents: - CA-600 Series Training Manual	A Caldeira	July 2023

Reference Documents

Document title	Version	Date
CA-660 Instructions for Use	00-27	January 2022

Explanation of Symbols

Symbol	Explanation
	**Risk of infection -** Always be aware of the dangers of infection, use caution and take appropriate measures
	**Risk of Injury -** Always be aware of the dangers of injury due to sharp objects, use caution and take appropriate measures.
	**Caution –** Potentially hazardous situation, use caution and take appropriate measures to avoid injury or harm.

CA-660 Overview

The CA-660 is a compact and fully automated haemostasis analyser, performing all the main clinically important clotting, chromogenic and immunological analyses. The primary sample for analysis is the plasma component of human blood with added anti-coagulant (sodium citrate).

CA-660 is great as a primary analyser for routine haemostasis testing in low-volume haemostasis laboratories and/or as a powerful backup instrument in a larger lab.

Facts and figures	
Analysers	CA-660
Analytical Principles	Clotting Assays Chromogenic Assays Immunoassays
Detection Methods	Photo-optical clot detection
Evaluation Methods	Percentage detection method – clotting assays only Rate method – Chromogenic assays, immunoassays VLin Integral method – immunoassays only
Modes of Analysis	Sampler Rack mode STAT Mode
Aspiration Methods	Sampler Analysis (Cap off) Manual Analysis (Cap off)
Aspiration Volumes	PT: 50µl APTT: 50µl FibC: 10µl DDimer: 8µl

CA-660 Components

External Front Components

1. **Power Switch** – Used to turn the analyser ON and OFF.

2. **Sampler -** Where the sample rack is placed for samples to be processed. One rack of 10 samples can be placed onboard.

3. **Light shield** – Prevents photoelectric detection from being affected by scattered light from external sources. Can be opened to install reagents and perform maintenance.

4. **Mechanical Stop Button** - The stop button is a mechanical stop button which will halt the analyser and all tests currently being processed will be immediately aborted.

5. **Printer** – Can be used to print settings, error messages and results using thermal paper.

6. **Touch Screen**– The touch screen acts as the user interface and contains the operating software for the analyser. It holds up to 600 complete sample records in its database and can be connected with a bi-directional interface to a hospital LIMS allowing upload of test orders and patient demographics along with downloading of test results back to the host. All settings, calibration files, and flagging limits are also stored on the IPU.

External Rear Components

1. **Reaction Tube Trash Box** – Collects used reaction tubes and can hold up to 60 tubes, approximately.

2. **Pneumatic Trap Chamber** – Prevents waste fluid flowing back into the vacuum pump. Should be checked as part of daily maintenance.

3. **Fuse Holder** – Location of the two time-lag type fuses.

4. **Power Connector** – Connects analyser to the main power supply.

5. **Host Computer Connection** (not shown) – Location of the connection to the LIS system.

Internal Components

1. **CA Clean and Buffer Holder** –Holds CA Clean I, CA Clean II and Buffer.

2. **Barcode Scanner (Not shown)** – Moves in front of the sample rack and reads the barcode label automatically.

3. **Detection Wells** – Reaction tubes containing samples and reagents (as required) are placed here during the detection process of coagulation, chromogenic and immunologic assays.

4. **Probe** – Used to aspirate both samples and reagents.

5. **Reaction Tube Racks** – Each rack holds up to 30 reaction tubes and two reaction tube racks can be loaded at any one time.

6. **Reagent Holder** – Main reagent storage area. Within this area, 4 reagents are kept at ~15°C (positions 1 – 4), whereas the others are left at room temperature (positions 5-10). The position the reagent is placed in, is dependent on reagent position set up within analysis settings.

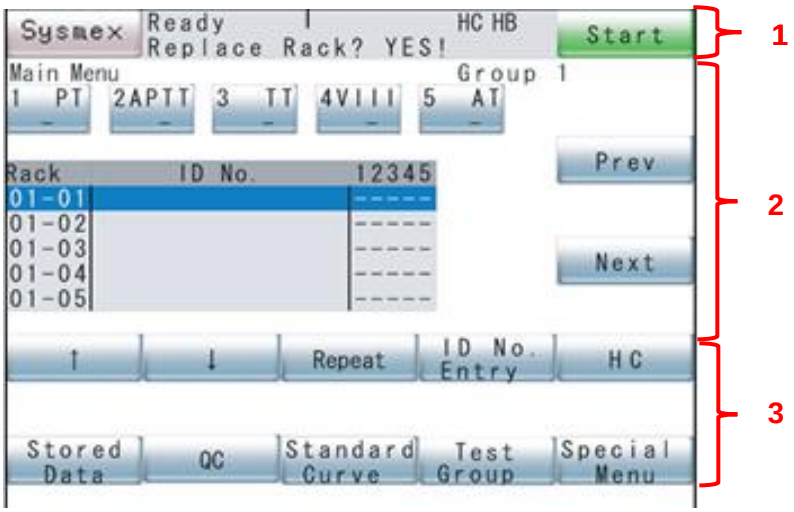
Other Components

1. **Waste Key (Grey)** – 5 L container for collection of waste. Should be emptied as part of daily maintenance.

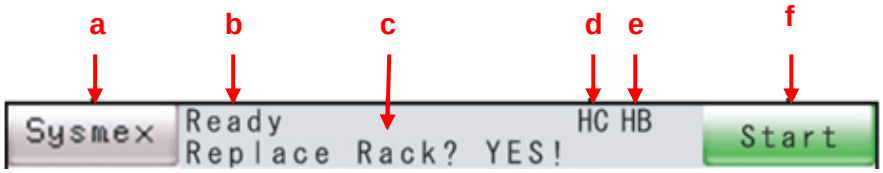
2. **Rinse Keg (Blue)** – Holds the 5L of rinse (distilled or deionized water. ***IMPORTANT:*** *the rinse MUST be changed as part of daily maintenance to prevent possible algae growth in the kegs. Failure to replace rinse on a daily basis could result in contaminated lines which can affect QC and patient results.*

Software Layout

Menu Layout



1. **System Status Area:**



a. Sysmex Key – Displays error list, temperatures and paper feed.

[**ALARM RESET**]	Displayed when an error occurs. Used to silence alarm.
[**Error List**]	Can be used to display error history.
[**Temperature**]	Can be used to display the temperature of various units.
[**P.FEED**]	Used to feed printer paper

b. Analysis Status – Displays system status, '*Ready*', '*Analyzing*' and '*Waiting'.*

c. Rack replacement – Indicates whether the sample rack can be replaced or not.

d. HC (Host Computer) – Indicates the status of the host computer.

HC	Host computer is set to be connected
HC	Communicating with host computer
HC	Error in communication with host computer

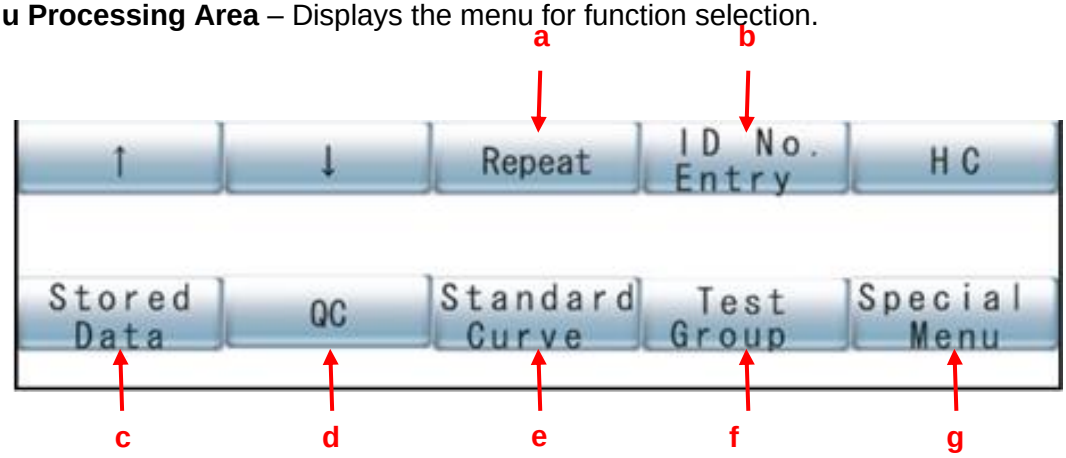
e. **HB (Hand-held Barcode reader)** – Indicates the connection status of the hand-held barcode reader.

HB	Host computer is set to be connected
HB	Communicating with host computer
HB	Error in communication with host computer

f. **[Start]/[INTERR]** – Used to start or interrupt analysis. For STAT sample analysis [Start STAT] will appear.

2. **Data Processing Area** – displays analysis progress status, worklist, stored data list, reaction curve, quality control data, standard curve and instrument setup status. Worklist screen acts as the main menu.

3. **Menu Processing Area** – Displays the menu for function selection.



a. **Repeat** – Used to request repeat testing on an entire rack of samples.

b. **ID No. Entry** – Used to manually enter sample ID or quality control.

c. **Stored Data** – Displays sample, QC and standard curve results.

d. **QC** – Display QC Levy-Jennings chart.

e. **Standard curve** – Used to review, input standard curve data as well as order calibrations.

f. **Test Group** – Used to change the test group displayed and available to order.

g. **Special Menu** – Navigates to other areas of the software such as set reagents and rinse probe.

Quick Guides

Maintenance

Detailed instructions for daily, weekly, quarterly and as required maintenance can be found in CA-660 Instructions for Use.

Daily Maintenance 

On a daily basis the following maintenance should be performed:

- Power off analyser, wait 15 secs, and power back on
- Replace distilled water **IMPORTANT: Do NOT** top up rinse water.
- Load fresh buffer (as required)
- Discard waste fluid
- Check the pneumatic trap chamber for fluid
- Replenish reaction tubes.
- Empty/Clean reaction tube trash box
- Load CA Clean I and CA Clean II
- Run ‘Rinse Probe’
    - **Special Menu > Rinse Probe**
- Clean sample probe
- Check Temperatures
    - **Sysmex > Temperatures**
- Remove Condensation from reagent rack.

NOTE: Trans light calibration is automatically performed at start up and every 24hrs, if chromogenic or immunologic assay is included in the active test group. If this is the case, **OVB is required on-board at start up of the instrument.**

Weekly Maintenance 

On a weekly basis the following maintenance should be performed:

- Clean external instrument surfaces
  - Wipe off stains using a cloth soaked with water and/or neutral detergent.
  - Wipe off exterior using a dry cloth.
- Clean internal instrument surfaces
  - Open the light shield cover and take out the reaction tube racks and reagent rack.
  - Using a cloth soaked with water and/or neutral detergent, wipe off any stains. Also, clean both racks, that were taken out before.
  - Close the light shield cover/

Quarterly Maintenance 

On a quarterly basis the following maintenance procedure should be performed:

- Perform LED Calibration **NOTE:** Perform monthly if Derived Fibrinogen is required.
- Clean rinse container (250-300 mL of 70% isopropyl alcohol
- Filter inspection and cleaning (Filter No. 598, located underneath the sampler in the front of the instrument)

As Required Maintenance 

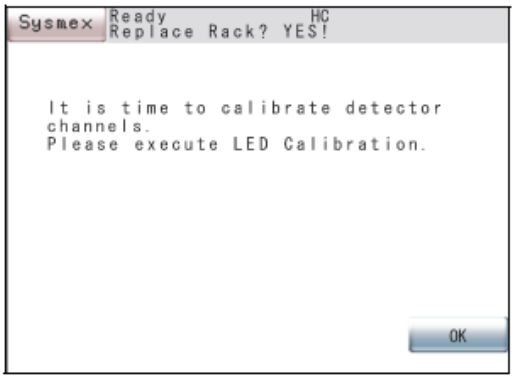
As required maintenance consists of:

- Replace Fuse (Please turn off the instrument power supply and disconnect the power cord, when conducting this)
- Replace Printer Paper

LED Calibration

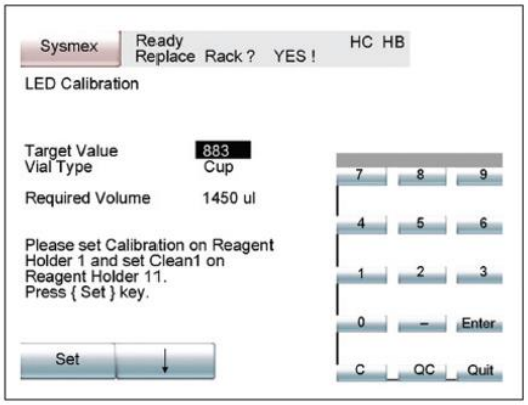
Note: Before using CA Cal S, it is essential to mix the contents of each vial of CA Cal S thoroughly, before placing on-board the CA-660 instrument. Failure to do so, may result in errors during the calibration of the LED channels.

When this task is due, the LED calibration confirmation window will appear at the instrument power ON, indicating the user that one month (if DFbg) or 3 months have passed from the last day of LED calibration.



Press [OK] key, and follow the steps below to complete the LED Calibration

1. From the Main Menu, press **[Special Menu]** followed by **[Special Operate].**
2. Press **[LED Calibration]** and then **[Calibration]**
3. The screen on the right is then displayed prompting the user to enter the target value (100-999) found in the calibrators insert sheet (use the numeric keys to enter the value and then press **[Enter]**).
4. Move the cursor to “Vial Type” using **[↑]** and **[↓]** keys and choose the container in use, by pressing **[Next]**.
5. Set the calibrator solution in reagent holder 1 (ensuring the minimum required volume), as well as CA Clean I in reagent holder 11.
6. Press **[Set]**, confirmation screen will appear, and then press **[OK]**. The LED Calibration will start, and the screen indicating the progress will be displayed.



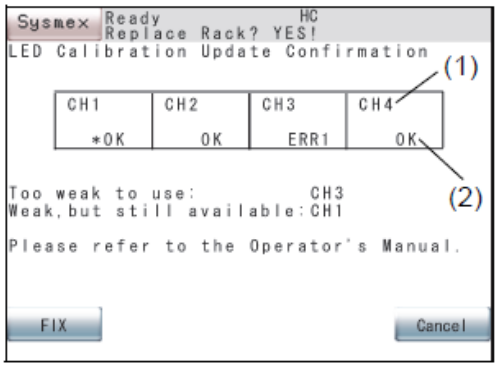
When the operation is completed, the LED Calibration Update Confirmation screen will appear:

1. Check each well that is displayed (1), and the respective contents (2):

   OK – Available

   *OK – Available. However, replacement is required within a few months.

   ERRxx – Not available
2. Press **[FIX]** to update the new adjustments when all well are OK. Press **[Cancel]** to rerun the LED Calibration.



Reagents

There are numerous reagents that can be used on the CA-600 Series analysers, the list below gives information on the routine reagents for the most common tests. The name of the test, reagent name, recommended quality controls and calibrators are given in the table. Please refer to the appropriate application sheet for further details, including Onboard stability for each reagent used.

Test	Reagents	QC material	Calibrator
Prothrombin Time	Innovin OR Thromborel S	CiTrol 1 & 2	PT Multi-Calibrator or in house mean normal PT
APTT	Actin FS OR Actin FSL OR Pathromtin SL and $CaCl_2$	CiTrol 1 & 2	Mean Normal APTT In House Calibration
Thrombin Time	Thromboclotin	CiTrol 1	None Required
Clauss Fibrinogen	Thrombin (100NIH – sometimes called Fbg on analyser) and OVB*	CiTrol 1 & Control Plasma P or Dade Data-Fi Abn Fibrinogen Control	Standard Human Plasma
D-Dimer	Innovance DD Kit (4 reagents)	D-Dimer Control 1 & 2	D-Dimer Calibrator

* Owren's Buffer (OVB)is also required for 'Pre' and 'Post' rinses

IMPORTANT: Always check the application sheets/reagent inserts for possible changes. Pink application sheets indicate something has changed, for example, onboard stability. Application sheets can be found in the 'Regulatory section' of Sysmex Academy. Siemens no longer provide paper package inserts inside each reagent box as they are progressing to electronic package inserts for all their reagents. These can now be located on 'Siemens Document Library'.

Cleaning Reagents

Two reagents are required for cleaning the tubing between sample testing, cleaning the probes and for the daily shutdown procedure:

1. **CA Clean I:** Bleach based solution used for general cleaning of the lines and used during daily maintenance. CA Clean I is aliquoted manually into a SLD or PV10 vial, before being placed on the CA-660 analyser.

2. **CA Clean II:** Acid based solution used to clean the probe inside and our following thromboplastin usage. CA Clean II is aliquoted manually into a 4ml cup before being placed on the CA-660 analyser.

Reagent Vial Types

Vial type		Max. Volume (ml)	Dead Volume (ml)	Used for
Sysmex 4ml Cup*		4.0	0.2	CA Clean II Reagents Calibrators Control
SLD		5.0	0.4	Reagents CA Clean I
GW5		5.0	0.8	Reagents
PV10		10.0	0.9	CA Clean I Buffer

* Use adaptor in reagent holder

Reagent Holder Positions

Positions	Temperature	Vial Types	Reagents
1 to 4	Cooled to 15°C	GW5, PV10, SLD Vials directly 4 ml cup*	PT, APTT, Fbg
5 to 10	Room temperature	GW5, PV10, SLD Vials directly 4 ml cup*	Any other reagents
Position I (11)	Room temperature	GW5, PV10, SLD Vials directly 4 ml cup*	CA Clean I
Position B (12)	Room temperature	GW5, PV10, SLD Vials directly 4 ml cup*	Buffer
Position II (13)	Room temperature	4 ml cup directly	CA Clean II

*adaptor required

Setting Reagent Positions

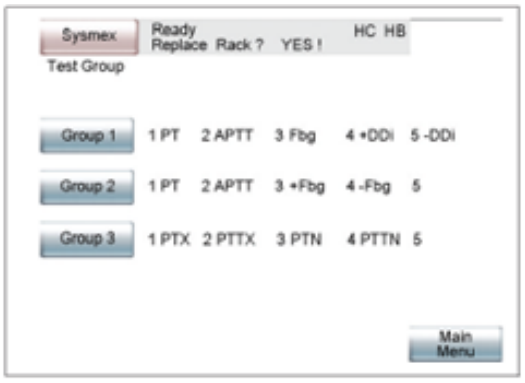
Reagents should be placed according to the test protocol and label on the reagent holder.

1. From the ‘Main Menu’ select [Special Menu] to [Set Reagents]
2. Set reagents in their appropriate positions in the reagent holder.
3. Enter the reagent volume if the alarm is ON. ***NOTE****: it is not necessary to enter the reagent volume if the reagent status alarm is OFF as the CA-660 has level sensing capability.*

Selecting a test group

A maximum of 5 analysis parameters can be displayed in a menu test group. If other parameters are required, the test group must be changed. Test groups may only be changed when the cursor is on a rack that has not yet been analysed and “Start” is displayed in the upper right-hand box.

1. Select [Test Group] from the ‘Main Menu’.
2. Select the desired test group [Group 1], [Group 2] or [Group 3].
3. Press [Main Menu].
4. Press [Fix] to return to ‘Main Menu’.



Calibration

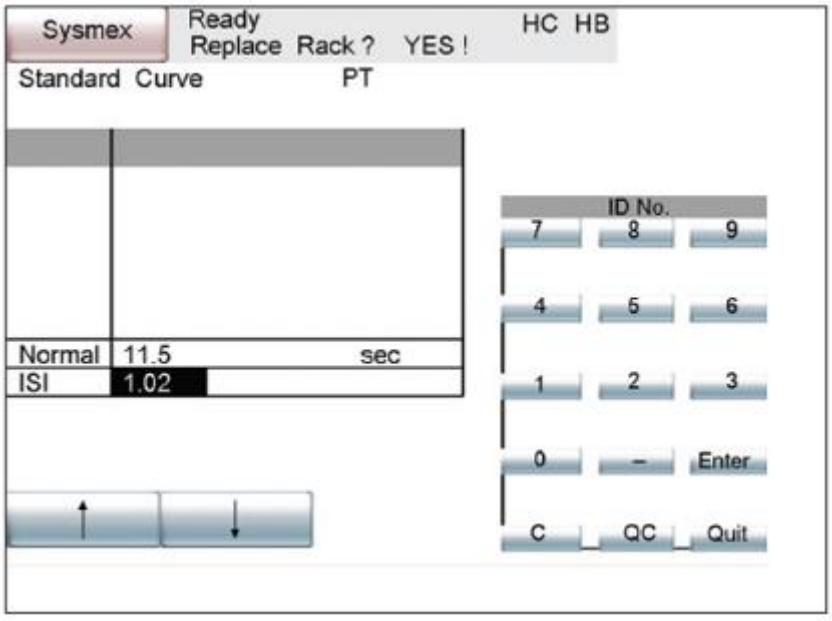
Manual Entry

Manual entry is used for the input of PT ISI, MNPT (when PT Multicalibrator is not used) or dFbg.

1. From the ‘Main Menu’ press [Standard Curve] followed by [Select test].

2. Select the appropriate parameter.

3. Press [Manual Entry] and enter the appropriate data, using the numeric keypad and the **[↓] [↑]** to move to the desired positions. Confirm data by pression **[Enter].**

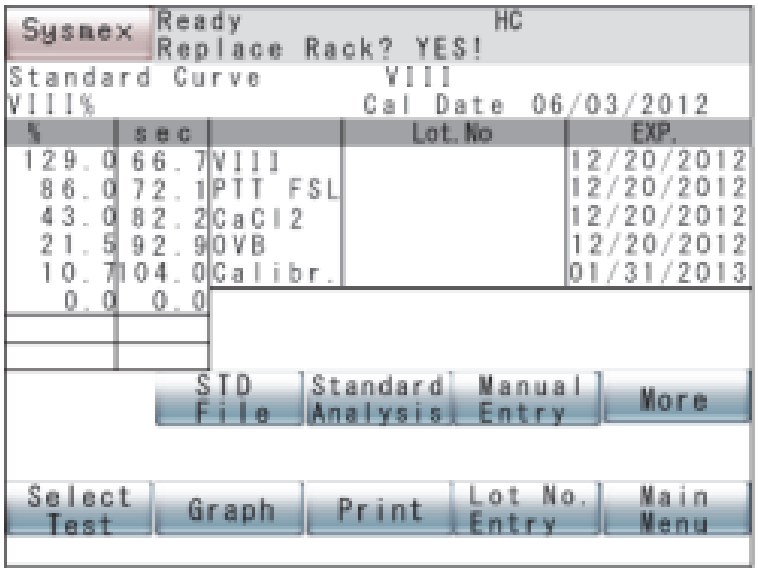


4. Press **[Quit]** on numeric keypad, once all the correct standard curve data is entered. A confirmation screens appears, with the following options:
    a. Continue: Returns to the Manual Entry Screen
    b. Set: Sets the entered data as Standard Curve data and returns to the Standard Curve Screen
    c. Quit: Discards the entered data and returned to the Standard Curve Screen.

Calibration by measurement

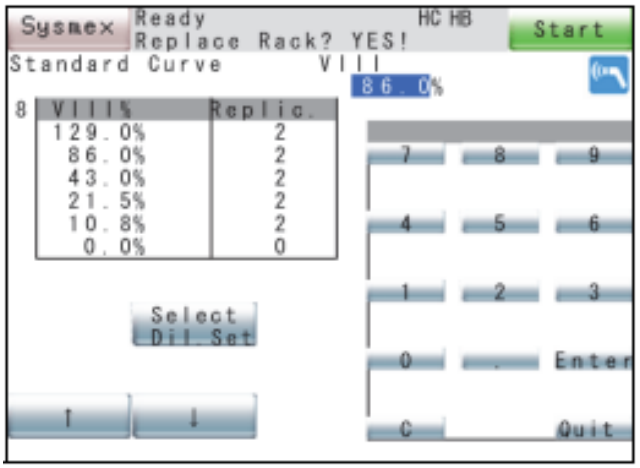
Used for calibrations requiring measurement, PT-Multicalibrator, Fibrinogen and D-Dimer. **Note:** Before starting a new calibration print the old curve and set all required reagents in their appropriate positions (check **Special Menu > Set Reagents**, to confirm).

1. From the 'Main Menu' press [Standard Curve] followed by [Select test].



2. Select the appropriate parameter.

3. Press [Standard Analysis] and enter the calibrator reference value, as per insert sheet. This can be done, using the hand-held barcode reader when the icon (displayed to the right) appears on the screen.



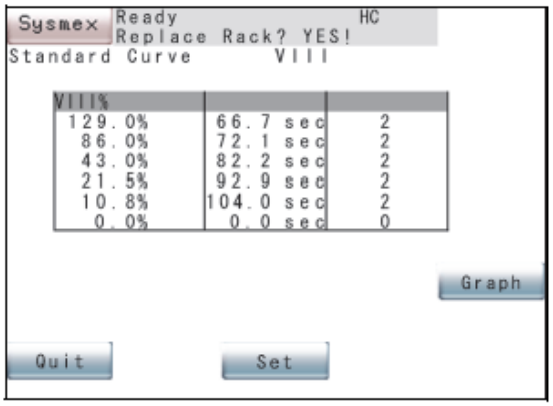
4. Select [Dil.set]. and select the series of dilution required:

   #9 Fibrinogen
   #1 INNOVANCE DDimer

5. Place the calibrator in position 1 on the sample rack.

6. Press [Start].

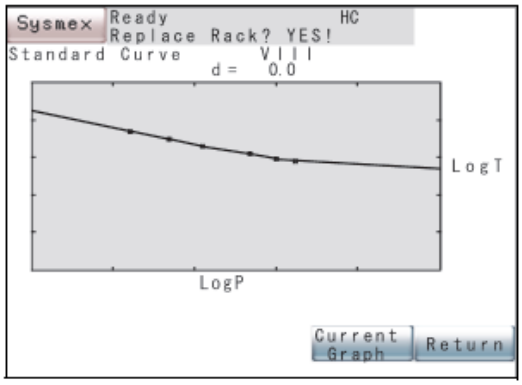
5. Once analysis is complete the Standard Curve Data screen will be displayed.



6. Select [Quit] to discard the analysis data and return to the Standard Curve Data Screen.

7. Select [Graph] to view the new curve (solid line with square plots). [Current graph] can be used to overlay the current standard curve (dotted line with triangular plots). Press it again to hide the current graph.

8. Press [Set] to save the entered data as Standard Curve data and returns to the Standard Curve Screen.



Note: When running PT- Multi Calibrator; if the dFbg method is also used on the instrument, the Derived Fibrinogen method must be disabled during the calibration with PT-Multi Calibrator to avoid overwriting the Derived Fibrinogen master curve.

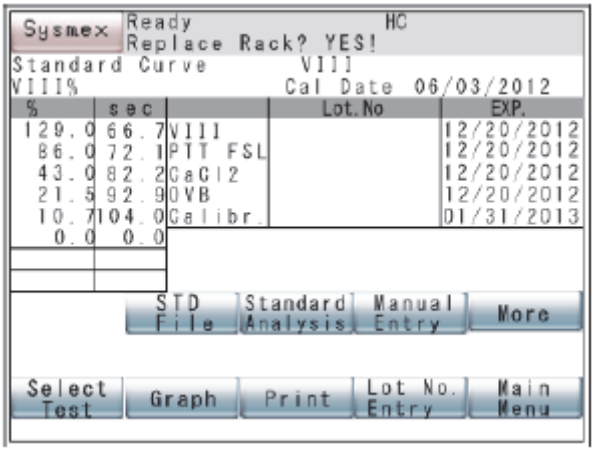
- Press [Standard Curve] – [Select Param.], disable the parameter No. 4 “dFbg”
- Perform calibration with PT-Multi Calibrator according to the Application Sheet
- Press [Standard Curve] – [Select Param.], enable the parameter No. 4 “dFbg”
- Please check all calibration curve data afterwards

Save and Restore a Calibration Curve

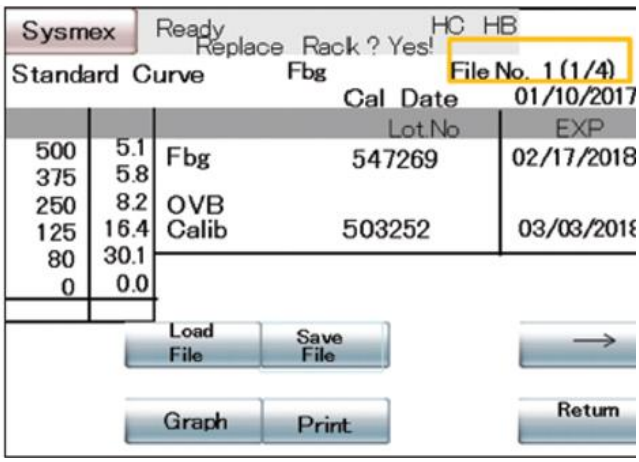
For each measurement parameter, standard curve information (standard curve data, ISI, normal values, reagent information, calculation parameter settings) is stored in a standard curve file and can be loaded.

The standard curve file contains all information on the standard curve, once saved:

1. Press **[Standard Curve]** followed by **[Select Test]** to choose the appropriate assay and most recent Standard Curve data.
2. Press **[STD File]** and select the standard curve file to save, using **[→]** and **[←]** keys to make the selection.



3. Press **[Save File]**, followed by **[Set]** to save the data of the standard curve currently in use to the respective standard curve file. **[Cancel]** does not save the data to the standard curve file and returns to the Standard Curve data screen.



In order to restore/load a Standard Curve file that has been previous saved, please follow the same steps above, and press [Load File]. The standard curve that was used up to that time is automatically saved to a backup file.

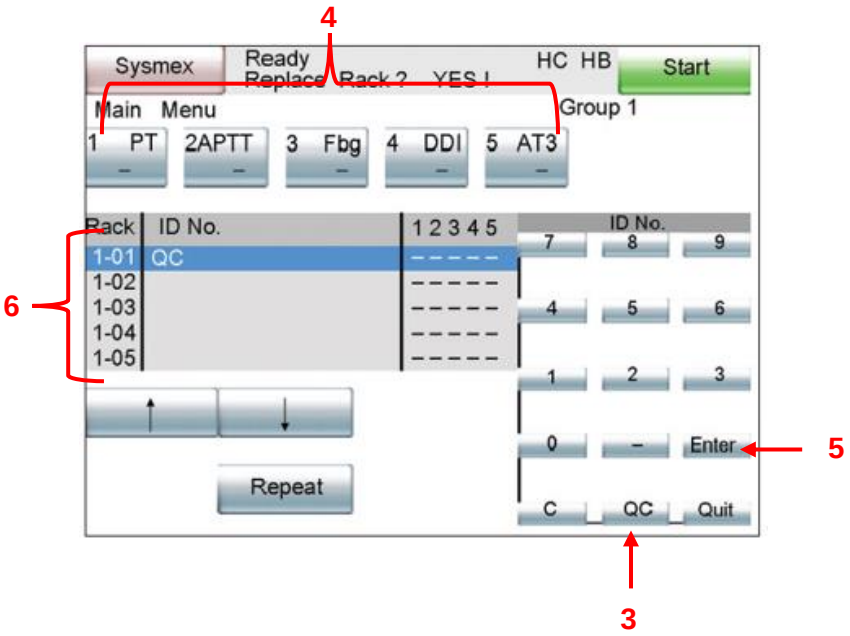
Note: Only save and restore from files 1, 2 and 3, as file number 4 is kept for an automatic backup, whenever a standard curve file is loaded.

Quality Control (QC)

In order to process QC material on the CA-660 it must be placed in a 4ml cup and in the correct holder in the rack.

Ordering and Running a QC

1. Pour QC material into a cup.
2. From the ‘Main Menu’ press **[ID No. Entry]**
3. Select **[QC]** followed by the appropriate file number.

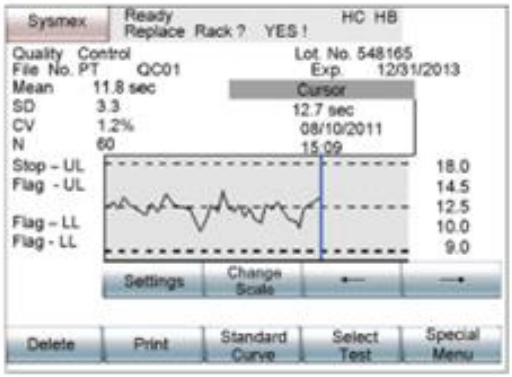


4. Select the appropriate tests to run, where ‘O’ indicates ordered and ‘–‘ indicates not ordered.
5. Press **[Enter]** to confirm settings.
6. Place the rack into the sampler ensuring the QC material has been placed in the correct rack position and press **[Start].**

Viewing QC Results

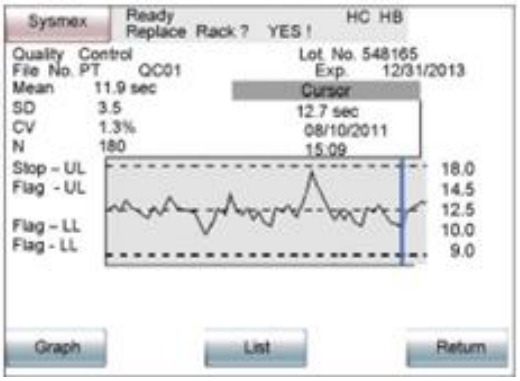
The CA-660 can store up to 6 QC files for each test parameter, with each file storing up to 180 QC data points. If more than 180 data points are added a first in – first out rule is applied, and the oldest data points will be deleted.

1. From the main menu select **[QC].**
2. Press **[Select Test]** in the QC menu.
3. To view the QC chart select the test parameter followed by the appropriate QC file

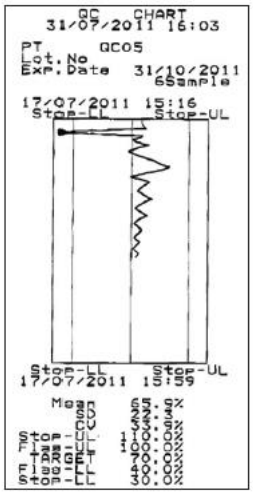


Printing QC Results

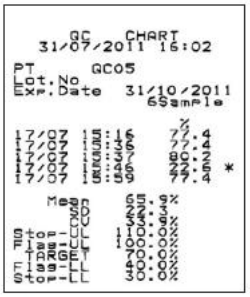
1. From the main menu select **[QC]**.
2. Press **[Select Test]** in the QC menu.
3. To view the QC chart select the test parameter followed by the appropriate QC file
4. Press **[Print]** and select the format you wish to be printed



Graph	Prints out QC data and QC chart
List	Prints out QC data and data list



Graph



List

Running Patient Samples

Sample Requirements

Citrated plasma samples are to be used on the CA-Series analysers. The correct filling of samples is essential as both under and over filled samples can affect the results obtained. Depending on the type of sample being used (plasma only or centrifuged blood), the CA-series analysers will alert the user only when the sample volume is insufficient to perform analysis, by showing a “Probe Crash” or “Sampling error” message. A minimum dead volume is required depending on the type of sample and tube being used, to avoid air bubbles (if plasma only samples) or even blood cells (if centrifuged sample) from being aspirated. Therefore, it is important to ensure local laboratory procedures are followed with regards to sample fill volumes.

Adult and pediatric samples can both be loaded into the sample racks and placed on the sampler unit, although various rack inserts are required for use of certain tube types (pediatric specimens).

Modes of Analysis

There are 2 modes of analysis available on the CA-660 as summarized in the table below:

Mode	Sample Cap	Daughter Aliquot (Reflex Tests Available)
Normal ‘Uncapped’ Mode	OFF	No
STAT Mode	OFF	No

Samples run in STAT mode are given priority over other samples loaded but not yet started.

Patient samples are run in racks and can be ordered via host interrogation, ordered manually or through ‘STAT’ mode. ***IMPORTANT*: SAMPLE LIDS MUST ALWAYS BE REMOVED.**

Sample Analysis Symbols

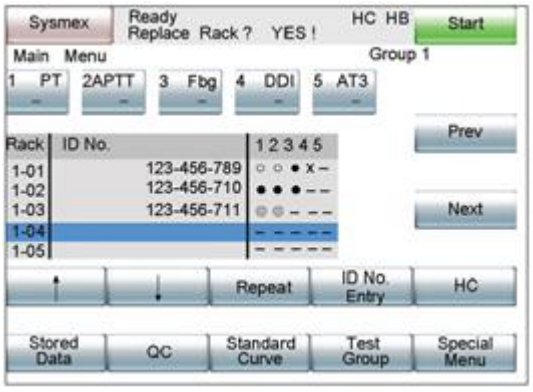
— Analysis is not ordered for the parameter

○ Analysis is ordered

⊙ Analysis in progress

● Analysis is completed

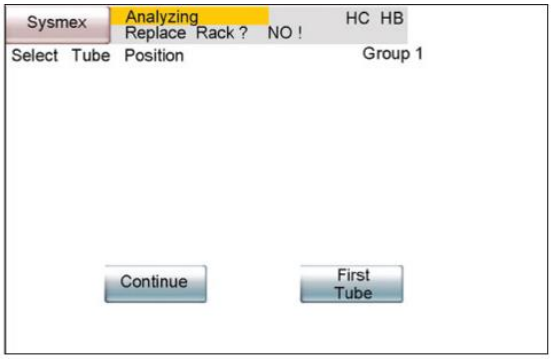
X Analysis is not completed due to interruption or error



Running Patient Sample with Host Interrogation

1. Place sample(s) into the sample rack with the barcode facing away from the analyser. ***IMPORTANT: SAMPLE LIDS MUST ALWAYS BE REMOVED.***

2. From the main menu press [Start] and select tube position.



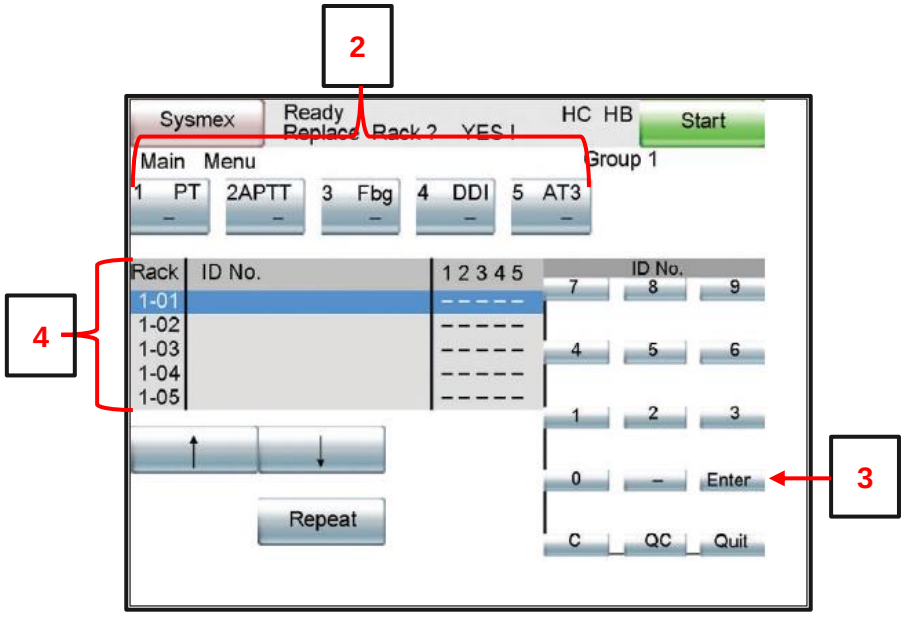
First tube Start at the first sample reaction tube position

Continue Start at the next sample reaction tube position after the last run

Running Patient Sample Ordered Manually

1. From the main menu select **[ID No. Entry]** and enter sample ID number.

2. Select the parameter to be tested, where 'O' indicates ordered and '–' indicates not ordered.



3. Confirm order has been set up correctly and press **[Enter].**

4. Repeat steps 1 to 3 if multiple sample need ordering or alternatively use the [↓] and [↑] to move to next or previous rack position.

5. Ensure the sample is placed in the sample rack in the position selected. ***IMPORTANT: SAMPLE LIDS MUST ALWAYS BE REMOVED.***

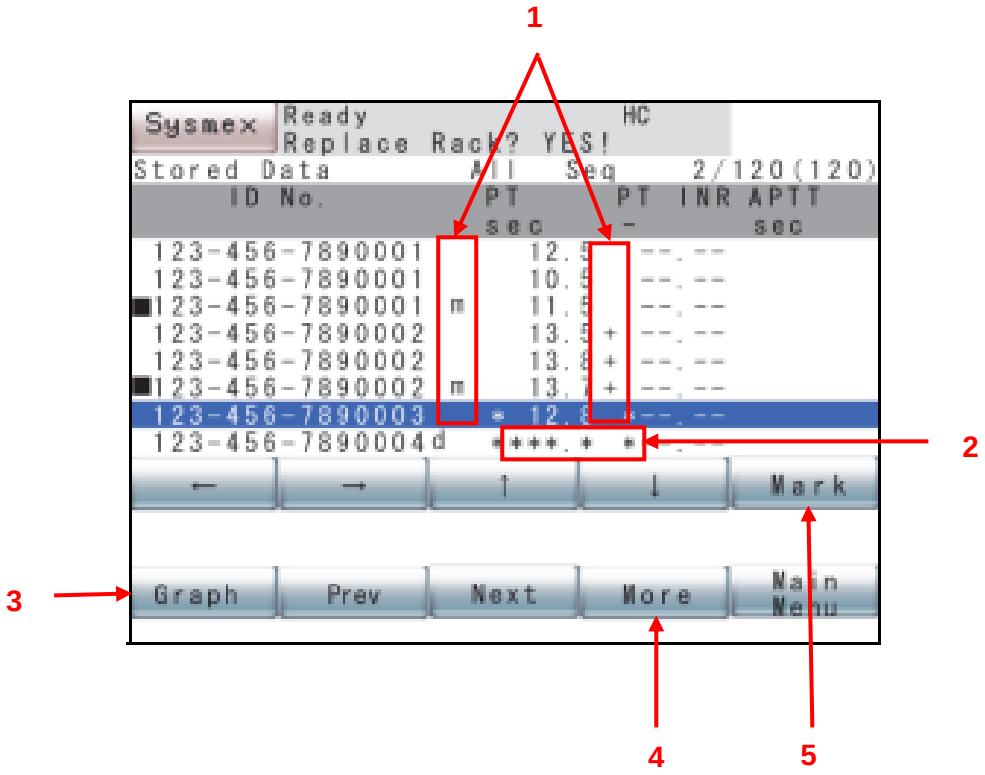
6. Press **[Start]** and select appropriate tube position.

   First tube Start at the first sample reaction tube position

   Continue Start at the next sample reaction tube position after the last run

Checking Patient Results

Sample results can be accessed from the main menu by selecting **[Stored Data]**. Sample ID, parameter, analysis results or OD/min will be displayed.



1. **Abnormal flags** – displayed to the right of the sample ID or to the right of the result:

[m]	Mean value calculated from replicates.
[d]	Dilution ratio other than 100% was used.
[*]	Error flag, or variation in repeat testing too high. **Note:** Flag supersedes > or < flag, but limits are stilled displayed: evaluate result.
[>]*	Result above the 'Upper Report Limit'.
[<]*	Result below the 'Lower Report Limit'.
[+]	Result is above the 'Upper Mark Limit'.
[-]	Result is below the 'Lower Mark Limit'.

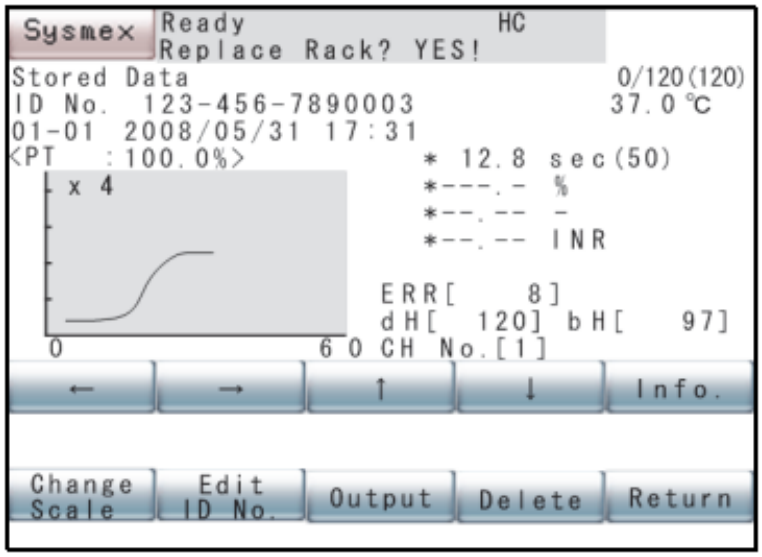
***Note:** < or > flag with Fibrinogen: redilution may be considered.

2. **Error Keys** – Displayed instead of sample results in the event of failures occurring during sample analysis:

[*.*]**	Analysis data not obtained due to error or other causes.
[- - -.-]	The calculation parameter could not be calculated

[+++.+] The calculated value exceeds the display capability.

3. **Graph** – Allows the user to view the coagulation curve in more detail.



4. **More** – Allows user to Print and/or output results as either single data point **[Current]** or batch data **[Mark]:**

IP Graph	To print with graph
IP List	To print results only
Host Computer	Transmits results to the host computer.

5. **Mark** – Allows the user to mark the analysis data selected. Mark can be used to select more than one data set. Results can then be printed out or sent to host computer as a batch. After printing or transmitting the desired results, press **[Marked All Clear]** to remove all the marked samples.

Final Task – Routine Use

1. What procedures need to be performed during daily maintenance?

   a

   b

   c

   d

   e

   f

   g

   h

   i

2. What weekly maintenance is required?

   a

   b

3. What other routine maintenance is required?

   a

   b

4. What controls are used for?

   PT

   APTT

   FibC

   DDimer

5. What is the temperature of?

Positions 1 - 4 on the Reagent Table
Positions 5 – 10 on the Reagent Table and Buffer Table

6. Explain to your trainer how you would reconstitute a reagent?

7. What is the significance of a pink package insert?

8. Order QC for the reagents available to you.

9. With the host connection off run a selection of samples for test group of your choice.

10. In the “joblist” what do the following symbols indicate?

Contact Us

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Product Hotline For urgent application support	0333 320 3466 (UK)
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