



**Reporting Program**  
**For**  
**Automated Glycohemoglobin Analyzer**  
**HLC-723RP**

Operator's Manual for G8 Transmission Format  
Revision C





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## Preface

Thank you for purchasing the HLC-723RP Glycohemoglobin Reporting Program. This document comprises the operation manual for the Reporting Program designed for use with the Glycohemoglobin Analyzer.

This software can be used only with HLC-723G8.

To ensure correct operation of the HLC-723RP Reporting Software Program, you are recommended to carefully read and familiarize yourselves with the G8 Operator's Manual, its safety precautions and basic operating procedures.

The information displayed with the following symbols is designed to alert you to important precautionary points regarding operation.



**Caution**

Cautions are designed to alert you to potential hazards in system operation that can cause personal harm or damage to property.



These are designed to alert you to potential operational errors or to provide helpful hints on getting the most from system operation.



**Caution**

- 
- You are recommended to carefully read and familiarize yourselves with the information in this manual to ensure proper and safe operation of the Glycohemoglobin analyzer and the Reporting Program.
  - Keep this application CD-ROM in a secure location where it is always available for use as a reference.
  - All safety precautions outlined in this manual must be strictly adhered to.
  - This program manages results and patient information by barcode information.
  - Please use a barcode of specimen and please do not use the duplicating barcode.
  - When barcodes duplicates, editing patient information of a result reflect to the sample information of all the other results which has the same barcode. Please check that there is no duplicating barcode before editing patient information.
  - The barcode containing the character “@” can not be used in Thalassemia mode. This software uses this character for another purpose.

## **Terms of Use for the User's Guide**

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- The information contained herein is subject to change without prior notification due to ongoing improvements to system performance and functionality.**
- You are forbidden from reselling or distributing this application to a third party.**
- You are requested to immediately notify a Tosoh Bioscience technical support specialist or authorized representatives if you notice any discrepancies, errors or omissions in the information provided herein.**
- The information contained in this manual may not be copied or transferred, in whole or in part, without the express written permission of Tosoh Corporation.**

## **TRADEMARKS**

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# 1 Basic System Precautions

## 1.1 Registering Operations

The HLC-723RP Reporting Program requires you to register the application before commencing operations. Operator registration information is entered in the system log file.



**Caution**

Only those persons that have undergone proper training should be registered as an operator.

## 1.2 Training for System Operation

A TOSOH Bioscience representative or authorized representatives will install the HLC-723RP Reporting Program and follow the users guide for basic system orientation. It is important that you are thoroughly trained in the operation of this application and the analyzer unit.

For diagnostic purposes, the results obtained from this application should be used in conjunction with other data.

## 1.3 Transmission Format Compatibility

This application may be used for transmitting data between the G8 Analyzer and a host computer in configurations where it is connected to both. This application is designed to output assay results to the host computer based on the G8 transmission specifications. However, that does not guarantee communication. It may not be able to communicate depending on the specifications of the host computer.

## 1.4 System Management

Please check the G8 Instrument settings before use. In order to obtain correct results, it is important to use the instrument and the reagents in accordance with the G8 Operator's Manual.

## 1.5 Definitions

Terms used in this manual are defined below.

**HbA1c** : Identical in meaning to SA1c.

**HbA1** : T-A1 (Total-A1%) represents the sum of A1a%, A1b%, and SA1c%.  
The Components to be summed are selected by entering the appropriate settings in the Environment Settings screen.

**Protocol** : Transmission format.

**Host computer** : LIS

**Query** : The instrument requests the assay schedule from the HOST computer, when a specimen barcode is read.

**EMF** : EMF means enhanced metafiles.

**Real time printing** : Printing of the results immediately after receiving them.

**Trend chart** : Line chart of personal result history.

**QC Materials** : Materials with known-values used for confirming that instruments are meeting specifications.

## 2 System Description

### 2.1 Introduction

This application is used to data manage the results from different configurations comprising either a single or two Glycohemoglobin Analyzers. It is designed to store and manage the received data and makes reports as necessary. It can also be used to send the results to a host LIS computer.

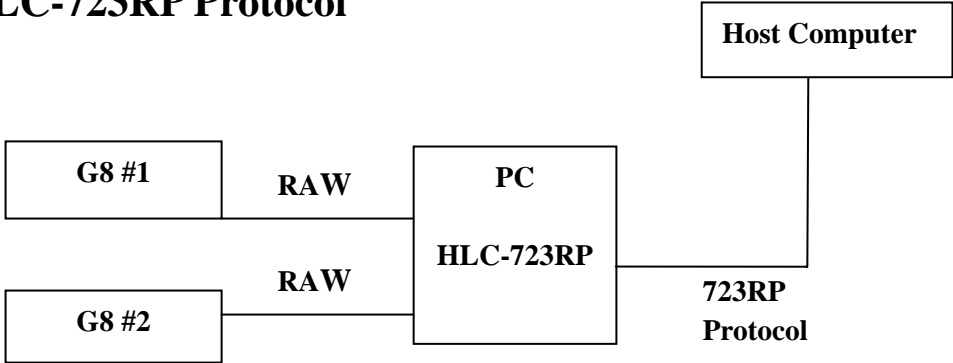
### 2.2 System Configuration

HLC-723RP is designed to connect up to two units Glycohemoglobin analyzers and is equipped with one transmission protocols. The transmission protocol is HLC-723 RP protocol (see Fig. A), used when connecting to the host computer with a single transmission line.

Transmissions between G8 and PC uses the G8's Raw mode protocol found under the RS 232 screen.

Transmissions between PC and the host computer use HLC-723RP protocol.

#### A) HLC-723RP Protocol



\*Specimen queries are enabled.

## 2.3 Requirements

Please ensure this application is installed on a type of PC recommended by Tosoh. Note that the Reporting Software does not include a printer or transmission cables as standard accessories.

Please provide the necessary equipment for connecting the PC to a host computer and printing analysis reports. The equipment required will depend upon the number of Glycohemoglobin Analyzers and related systems included in the system operation configurations.

While the equipment required depends on the type of configuration installed, all necessary equipment is included in the list below. Contact authorized representative for detailed equipment specifications.

### Requirements

<b>Operating System:</b>	<b>Windows XP Professional</b>
<b>CPU:</b>	<b>Pentium 4</b>
<b>Memory:</b>	<b>1GB</b>
<b>Hard drive:</b>	<b>80GB or more</b>
<b>Serial Port:</b>	<b>Total number of Analyzers and HOST</b>
<b>RS232C cable:</b>	<b>Analyzer to PC</b> <b>(9-pin × 9-pin female/female crossover)</b>
<b>RS232C cable:</b>	<b>PC to Host</b> <b>(9-pin × 25 or 9-pin crossover)</b>

**USB-SERIAL converter and USB cable (1.8m)**

**If Glycohemoglobin analyzers are connected with USB port,  
USB convert and cable are necessary.**

**PRINTER:** **Cut-Sheet Printer**

## 2.4 Restrictions

- Barcodes must be used when operating in the query mode.
- The application software recognizes where to store results by use of the barcode so that the same barcode for another specimen should not be used.
- The barcode containing the character “@” can not be used in Thalassemia mode.
- The real time report function automatically prints reports when assay results arrive from the Glycohemoglobin Analyzer.

### 3 Installing and Running the Application

#### 3.1 Installing Application

The setup does not launch automatically when the CD-ROM is inserted in the CD drive. There are three folders in CD-ROM. Double-click “Setup.exe” in the G8 root folder. Setup installs the application in the “C:\CopulaG8” folder using the folder/file configuration shown below.

Refer to the printer instructions to install the Printer Driver.

CopulaG8	Program files
— Data	Assay data folder
— SPEC.mdb	Result database
— Documents	Operation documentation in HTML format
— Log	Operation and transmission log files
— Picture	Temp folder for image files
— Resource	Language resource files
— Settings	Settings folder
— Copula.ini	General settings
— Copula Search.ini	Registered find conditions
— Environment.ini	Environment settings
— System	System folder
— SPEC.org	Specimen database template
— Operator.mdb	User management database
— QC.mdb	QC data management database
— QC.org	QC database template
— Print.mdb	Temporary database for report
— Real Print.mdb	Temporary database for real time report
— Recorded_PID.mdb	Patient ID management database



#### Caution

The installation and setup procedures are performed by authorized representatives.

Contact must be made to the authorized representative whenever moving the system to a new location, regardless of proximity.



#### Caution

Assay data is stored in the “Data” folder.

Note that system may not work properly if the folders are deleted.

## 3.2 Connecting Cables

The connecting of cables is performed by the authorized representative using the following procedures.

### Connecting USB-SERIAL Converter

If the serial port is not available on the PC, the USB port can be used as a serial port through the USB-SERIAL converter.

### Connecting RS232C Cable

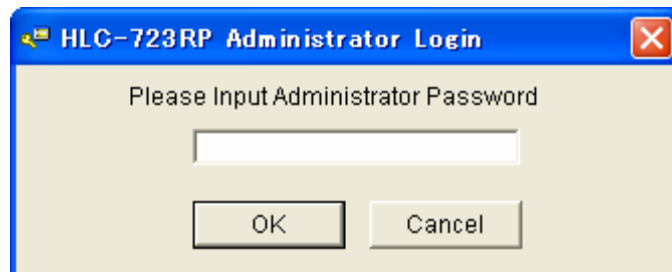
Note that the serial port number changes by the connection order of USB, when the USB-SERIAL converter is used.

## 3.3 Registering Operators

The Administrator can register you for the application by the User Manager, as follows:

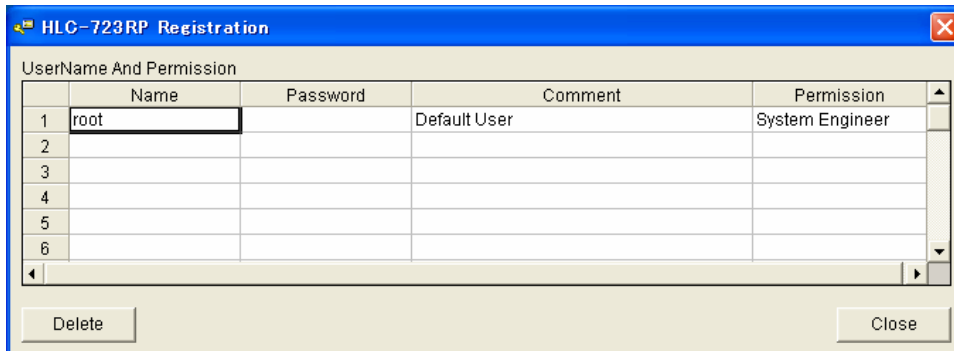
Select All Programs from the Start menu, and then click User Manager in the HLC-723RP menu.

Enter password and click the OK button. An authorized representative will perform the installation and provide the Administrator with the User Manager password.



Administrator Password Entry

The default user name is 'root'. If 'root' is used a password is not needed. Enter information in all required fields using alphanumeric characters. If a password is to desired use the Registration screen by entering NAME, choose a password and permission.



User Registration

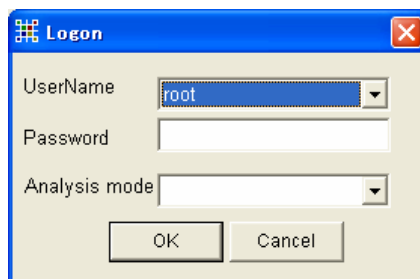
### 3.4 Application Startup

Use the Start menu or click the desktop icon to start the HLC-723RP Reporting Program.



HLC-723RP Shortcut Icon

Enter user name and Glycohemoglobin Analyzer Analysis mode in the following screen. For Analysis mode choose Variant from the drop down menu



Log on and Mode Select

Choose Variant for Analysis Mode



## 4 OPTIONS Environment Settings

### 4.1 QC

Refer to section 7 for a detailed description of the QC management tab in the Environment Settings screen.

### 4.2 Environment

The Environment tab is used to manage specifications in the system environment. Follow the instructions provided at the bottom of the screen, when choosing the needed option.

The screenshot displays the HLC-723RP software interface. The main window title is "HLC-723RP [ Variant ] root". The menu bar includes "Database", "Result List", "Report", "View", and "Help". The toolbar contains icons for "Result View", "Levey Jennings", "Trend", "Find", "Upload", "Options", "Result Report", and "Restore Cell".

The "Options" menu is open, showing a tree structure under "Analyte":

- Communication
  - 1st Instrument
    - Name: Instrument1
    - Port: COM2
    - Baudrate: 9600bps
    - Data length: 8bit
    - Stop bit: 1bit
    - Parity: NON
    - Flow Control: X-OFF
  - 2nd Instrument
    - Name: Instrument2
    - Port: COM5
    - Baudrate: 9600bps
    - Data length: 8bit
    - Stop bit: 1bit
    - Parity: NON
    - Flow Control: X-OFF
  - 1st Host Computer
    - Port: COM7
    - Baudrate: 9600bps
    - Data length: 8bit
    - Stop bit: 1bit
    - Parity: NON
    - Flow Control: X-OFF
  - 2nd Host Computer
    - Port: disconnect
    - Baudrate: 9600bps
    - Data length: 8bit

Below the tree, an "Explanation" box states: "RS232C Settings When a communicative setup is changed, please re-start this application."

The "Environment" tab is selected at the bottom, and the "QC" sub-tab is active. A callout box labeled "Options" points to the "Options" menu item in the toolbar. Another callout box labeled "Environment Tab" points to the "Environment" tab at the bottom.

	DateTime	Barcode	F	SA1c
1	2004/11/15 10:51:41	111020051459	0.8	4.6
2	2004/11/15 10:51:26	111020051532	0.8	4.6
3	2004/11/14 10:50:07	111020051533	0.8	4.5
4	2004/11/14 10:49:52	38542106	0.8	4.6
5	2004/11/13 10:49:38	38542106	0.8	4.6
6	2004/11/13 10:49:23	38542106	0.8	4.6
7	2004/11/13 10:49:08	38542106	0.8	4.5
8	2004/11/12 10:48:19	38542106	0.8	4.5
9	2004/11/12 10:48:04	38542106	0.8	4.5
10	2004/11/11 10:47:27	38542106	0.8	4.5
11	2004/11/11 10:47:12	38542106	0.8	4.6
12	2004/11/11 10:46:58	38542106	0.8	4.6
13	2004/11/10 10:45:59	38542106	0.8	4.6
14	2004/11/10 10:45:44	38542106	0.8	4.5
15	2004/11/09 10:44:58	38542106	0.8	4.6
16	2004/11/09 10:44:43	38542106	0.8	4.5
17	2004/11/09 10:44:28	38542106	0.8	4.5
18	2004/11/09 10:44:13	38542106	0.8	4.6
19	2004/11/08 10:42:59	38542106	0.8	4.5
20	2004/11/08 10:42:44	38542106	0.8	4.6
21	2004/11/08 10:42:30	38542106	0.8	4.5
22	2004/11/08 10:42:15	38542106	0.8	4.6
23	2004/11/08 10:42:00	38542106	0.8	4.6
24	2004/11/07 10:41:08	38542106	0.8	4.5
25	2004/11/06 10:40:17	38542106	0.8	4.6
26	2004/11/06 10:40:02	38542106	0.8	4.5
27	2004/11/06 10:39:47	38542106	0.8	4.6
28	2004/11/05 10:38:44	38542106	0.8	4.6
29	2004/11/05 10:38:29	38542106	0.8	4.5
30	2004/11/04 10:37:13	38542106	0.8	4.5
31	2004/11/04 10:36:58	38542106	0.8	4.5
32	2004/11/04 10:36:43	38542106	0.8	4.6
33	2004/11/03 10:33:21	38542106	0.8	4.6
34	2004/11/03 10:33:06	38542106	0.8	4.6
35	2004/11/03 10:32:51	38542106	0.8	4.5
36	2004/11/03 10:32:36	38542106	0.8	4.5

Environment Settings Screen

The environment Settings parameters are listed in the table below.  
Before using system, the following parameters need to be set:

<b>Communication</b>	<b>RS232C Settings</b>
<b>1st instrument</b>	Use same settings as analyzer.
<b>Name</b>	Enter analyzer name.
<b>Port</b>	Enter Com port number.
<b>Baud rate</b>	Enter same transmission speed as analyzer.
<b>Data length</b>	Use same settings as analyzer.
<b>Stop bit</b>	Use same settings as analyzer
<b>Parity</b>	Use same settings as analyzer.
<b>Flow control (yes/no)</b>	Use same settings as analyzer.
<b>2nd instrument</b>	Use same settings as analyzer.
<b>Name</b>	Enter analyzer name.
<b>Port</b>	Enter Com port number.
<b>Baud rate</b>	Enter same transmission speed as analyzer.
<b>Data length</b>	Enter Data Length
<b>Stop bit</b>	Use same settings as analyzer.
<b>Parity</b>	Use same settings as analyzer.
<b>Flow control (yes/no)</b>	Use same settings as analyzer.
<b>Host computer</b>	Use same settings as host.
<b>Port</b>	Enter Com port number.
<b>Baud rate</b>	Enter same transmission speed as host.
<b>Data length</b>	Use same settings as host.
<b>Stop bit</b>	Use same settings as host.
<b>Parity</b>	Use same settings as host.
<b>Flow control (yes/no)</b>	Use same settings as host.
<b>HOST Connection Method</b>	Protocol depends on line type.
<b>Query (yes/no)</b>	Select whether or not to allow specimen queries.
<b>QCQuery (yes/no)</b>	Select whether or not to allow control queries.
<b>Auto upload (yes/no)</b>	Select whether to automatically send results to host.
<b>Instrument Information</b>	Enter analyzer information settings
<b>Composition of instrument</b>	Do not modify after operation commences.
<b>No. of sample number length</b>	Do not modify after operation commences.
<b>Print Conditions</b>	Entered information for printing.
<b>Add patient information</b>	Add patient information to printout.
<b>Total Area Option</b>	Indicate presence of addition for each Component using “0” or “1” setting.
<b>Automatic Report</b>	Prints results real time
<b>1 data/page default</b>	Specify paper
<b>TM-J2000 (yes/no)</b>	Specify whether printer is available.
<b>Paper size (A4/Letter)</b>	Specify printer paper size.
<b>Patient Header right</b>	Enter customized comment
<b>Patient Header center</b>	Enter customized comment
<b>Patient Header left</b>	Enter customized comment
<b>List Header right</b>	Enter customized comment

List Header center	Enter customized comment
List Header left	Enter customized comment
Trend Header right	Enter customized comment
Trend Header center	Enter customized comment
Trend Header left	Enter customized comment
QC Header right	Enter customized comment
QC Header center	Enter customized comment
QC Header left	Enter customized comment
Footer right	Enter customized comment
Footer center	Enter customized comment
Footer left	Enter customized comment
Entitle comment	Enter customized comment
Format of date	Normally, do not change.
Format of time	Normally, do not change.
Checking results	Color codes cell background color according to assay results.
For Result List	Recorded on worksheet of assay results list.
A1a	Specify whether to check value A1a.
Marker	Central value
+/-	Central value $\pm$ value
A1b	Specify whether to check value A1b.
Marker	Central value
+/-	Central value $\pm$ value
F	Specify whether to check value F.
Marker	Central value
+/-	Central value $\pm$ value
LA1c	Specify whether to check value LA1c.
Marker	Central value
+/-	Central value $\pm$ value
SA1c	Specify whether to check value SA1c.
Marker	Central value
+/-	Central value $\pm$ value
AO	Specify whether to check value A0.
Marker	Central value
+/-	Central value $\pm$ value
T-A1	Specify whether to check value T-A1.
Marker	Central value
+/-	Central value $\pm$ value
A2	Specify whether to check value A2.
Marker	Central value
+/-	Central value $\pm$ value
Glu	Specify whether to check value Glu.
Marker	Central value
+/-	Central value $\pm$ value
For Trend Chart (Statistics)	
A1c	Line for threshold value displayed for A1c.
Line color	Specifies line color.

<b>Mark</b>	<b>Specifies mark shape.</b>
<b>Marker</b>	<b>Central value</b>
<b>+/-</b>	<b>Central value <math>\pm</math> value</b>
<b>F</b>	<b>Line for threshold value displayed for F.</b>
<b>Line color</b>	<b>Specifies line color.</b>
<b>Mark</b>	<b>Specifies mark shape.</b>
<b>Marker</b>	<b>Central value</b>
<b>+/-</b>	<b>Central value <math>\pm</math> value</b>
<b>A2</b>	<b>Line for threshold value displayed for A2.</b>
<b>Line color</b>	<b>Specifies line color.</b>
<b>Mark</b>	<b>Specifies mark shape.</b>
<b>Marker</b>	<b>Central value</b>
<b>+/-</b>	<b>Central value <math>\pm</math> value</b>
<b>Glu</b>	<b>Line for threshold value displayed for glucose.</b>
<b>Line color</b>	<b>Specifies line color.</b>
<b>Mark</b>	<b>Specifies mark shape.</b>
<b>Marker</b>	<b>Central value</b>
<b>+/-</b>	<b>Central value <math>\pm</math> value</b>
<b>Chromatogram conditions</b>	<b>Effective for chromatogram Y axis settings.</b>
<b>X max (min)</b>	<b>Factory default is 1.2</b>
<b>X min (min)</b>	<b>Factory default is 0.0</b>
<b>Y max (%)</b>	<b>Factory default is 50</b>
<b>Y min (%)</b>	<b>Factory default is 0</b>
<b>Correlation Chart</b>	<b>Adjusts correlation chart.</b>
<b>A1c Line color</b>	<b>Specifies line color.</b>
<b>Shape of A1c mark</b>	<b>Specifies mark shape.</b>
<b>Zone Factor</b>	<b>Line indicating border position entered using <math>\pm</math>nSD.</b>
<b>Lot</b>	<b>Checks expiry date when application is started.</b>
<b>HWS lot (1)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 1 lot (1)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 2 lot (1)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 3 lot (1)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Column lot (1)</b>	<b>Lot number listed on label</b>
<b>Calibrator lot (1)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>HWS lot (2)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 1 lot (2)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 2 lot (2)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Eluent 3 lot (2)</b>	<b>Lot number listed on label</b>

<b>Period</b>	<b>Expiration listed on label</b>
<b>Column lot (2)</b>	<b>Lot number listed on label</b>
<b>Calibrator lot (2)</b>	<b>Lot number listed on label</b>
<b>Period</b>	<b>Expiration listed on label</b>
<b>Screen</b>	<b>Specifies display font</b>
<b>Font</b>	<b>Factory default is Arial</b>



## 5 Receiving Results

### 5.1 Preparing to Receive Results

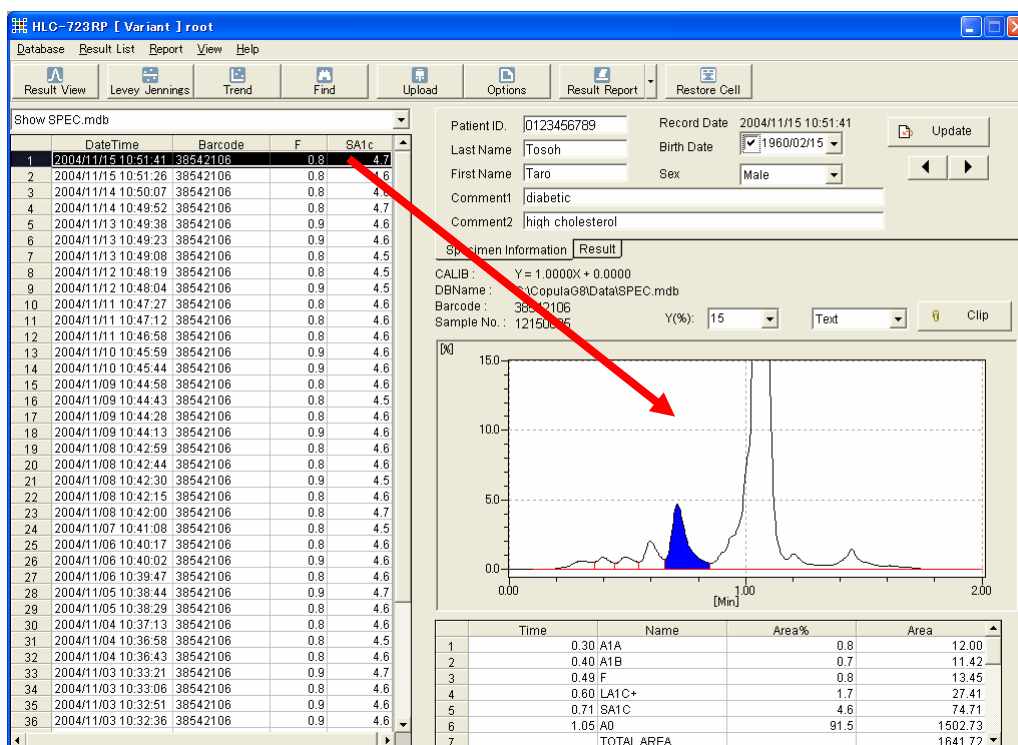
The HLC-723RP Reporting Program is available when the computer starts up. It is designed to automatically receive results and stores them in SPEC.mdb database.

All results are listed on the screen in Result View.

The barcode is used to identify primary tubes.

### 5.2 Displaying Results

Selecting the Result View displays the chromatogram and the results.



Chromatogram View Screen

Select 'Result' tab to view lot numbers

Result of Glucose	Item Code	Comment	Flag	Update
115	0101	OL01	A0	
HWS Lot.	COL Lot.	CAL Lot.		
120	120	120		
Eluent1 Lot.	Eluent2 Lot.	Eluent3 Lot.		
120	120	120		
Specimen Information	Result			

In G8 instrument, the invalid data with the error flag about Area% may be measured.

When HLC-723RP receives the invalid data, the data is displayed by “---“.

	DateTime	Barcode	F	SA1c
1	2005/11/15 11:09:58	99999991125	---	---
2	2004/11/15 10:51:41	38542106	0.8	4.7
3	2004/11/15 10:51:26	38542106	0.8	4.6

When the invalid QC data is received, the following dialogs are displayed and it is not added to QC data.

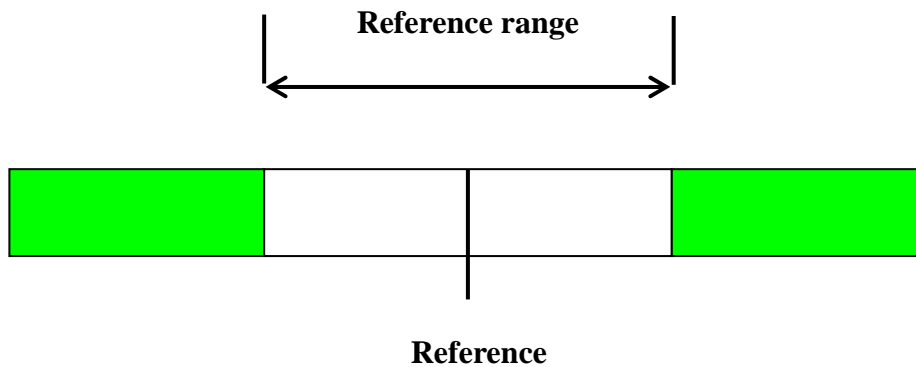


The color of the results list is as follows:

Results from primary tubes shows in black characters. The result with a flag shows the background in pink.

Results from calibrators are blue and results of controls shows the background of barcode cell in gray.

If the reference value is  $5.0 \pm 1.0$  for SA1c, coloring defined in the Environment Setting screen will be applied to all SA1c value results that fall outside the 4.0 to 6.0% range.



The chromatogram scale can be changed by choosing from the Y (%) combo box. Y (%) can also be directly entered in the combo box. The results can also be displayed on a fixed scale by entering the Y- and X-axis values in the Environment Settings screen.

The Restore cell button resets the cell width of results list.

The screenshot displays the HLC-723RP software interface. The main window is titled "HLC-723RP [ Variant ] root". The interface is divided into several sections:

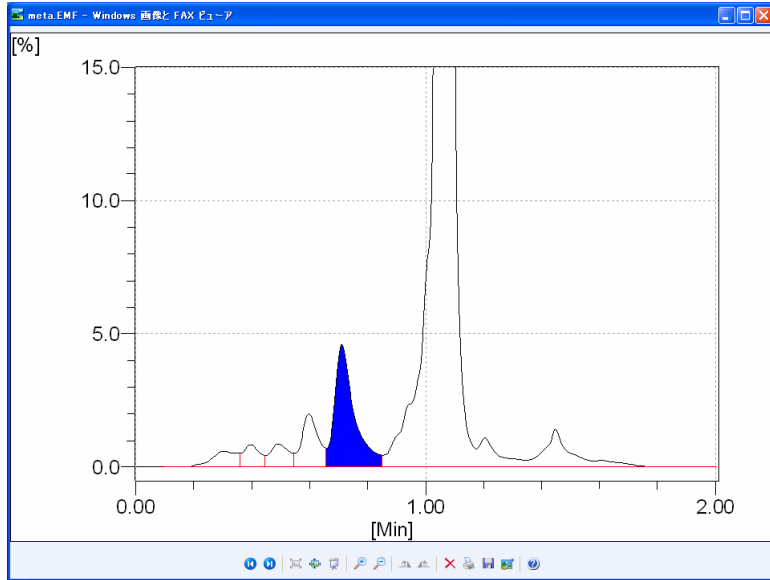
- Menu Bar:** Database, Result List, Report, View, Help.
- Toolbar:** Result View, Levey Jennings, Trend, Find, Upload, Options, Result Report, Restore Cell.
- Data Table (Left):** A table with columns: DateTime, Barcode, F, SA1c. It lists 36 rows of data.
- Patient Information (Right):**
  - Patient ID: 0123456789
  - Record Date: 2004/11/15 10:51:41
  - Last Name: Tosoh
  - Birth Date: 1960/02/15
  - First Name: Taro
  - Sex: Male
  - Comment1: diabetic
  - Comment2: high cholesterol
- Specimen Information (Right):**
  - CALIB: Y = 1.0000X + 0.0000
  - DBName: C:\CopulaO8\Data\SPEC.mdb
  - Barcode: 38542106
  - Sample No.: 12150025
  - Y(%): 15 (highlighted with a red circle)
  - Text: [ ]
  - Clip: [ ]
- Chromatogram Plot (Center):** A line graph showing detector response over time (0.00 to 2.00 minutes). A prominent peak is visible at approximately 0.71 minutes. The Y-axis is labeled "Y(%)" and ranges from 0.00 to 15.00.
- Peak Area Table (Bottom Right):**

Time	Name	Area%	Area
0.30	A1A	0.8	12.00
0.40	A1B	0.7	11.42
0.49	F	0.8	13.45
0.60	LA1C+	1.7	27.41
0.71	SA1C	4.6	74.71
1.05	A0	91.5	1502.73
TOTAL AREA			1641.72

Chromatogram View Screen

The chromatogram can be saved as an enhanced metafile (EMF) by using the Clip button. The results item can also be clipped as numerical values. The chromatogram and results may be copied and pasted to office application's documents.

### Enhanced Metafile Format



### Numerical Format

	A	B	C	D	E	F	G	H
1	Time	Name	Area%	Area				
2	0.3	A1A	0.7	12				
3	0.4	A1B	0.7	11.42				
4	0.49	F	0.8	13.45				
5	0.6	LA1C+	1.7	27.41				
6	0.71	SA1C	4.6	74.71				
7	1.05	A0	91.5	1502.73				
8		TOTAL AREA		1641.72				
9								
10								
11								
12								
13								
14								
15								
16								
17								

## 5.3 Deleting Records

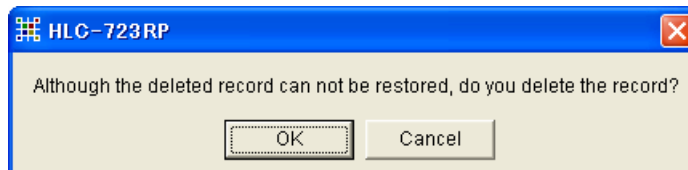
The records can be deleted after analysis as following procedure.  
The deleted records can not be restored.

Chose a record or multiple records, then click “Delete Recode” of the “Result List” menu.

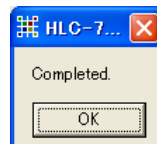
The screenshot shows the HLC-723RP software interface. The 'Result List' menu is open, and 'Delete Record' is selected. The main window displays a table of records, a patient information form, a chromatogram, and a peak table.

Time	Name	Area%	Area
1	0.30 A1A	0.8	12.00
2	0.40 A1B	0.7	11.42
3	0.49 F	0.8	13.45
4	0.60 LA1C+	1.7	27.41
5	0.71 SA1C	4.6	74.71
6	1.05 A0	91.5	1502.73
7	TOTAL AREA		1641.72

When the following dialog box appears, click the OK button.



Selected records are deleted and the following dialog box appears.

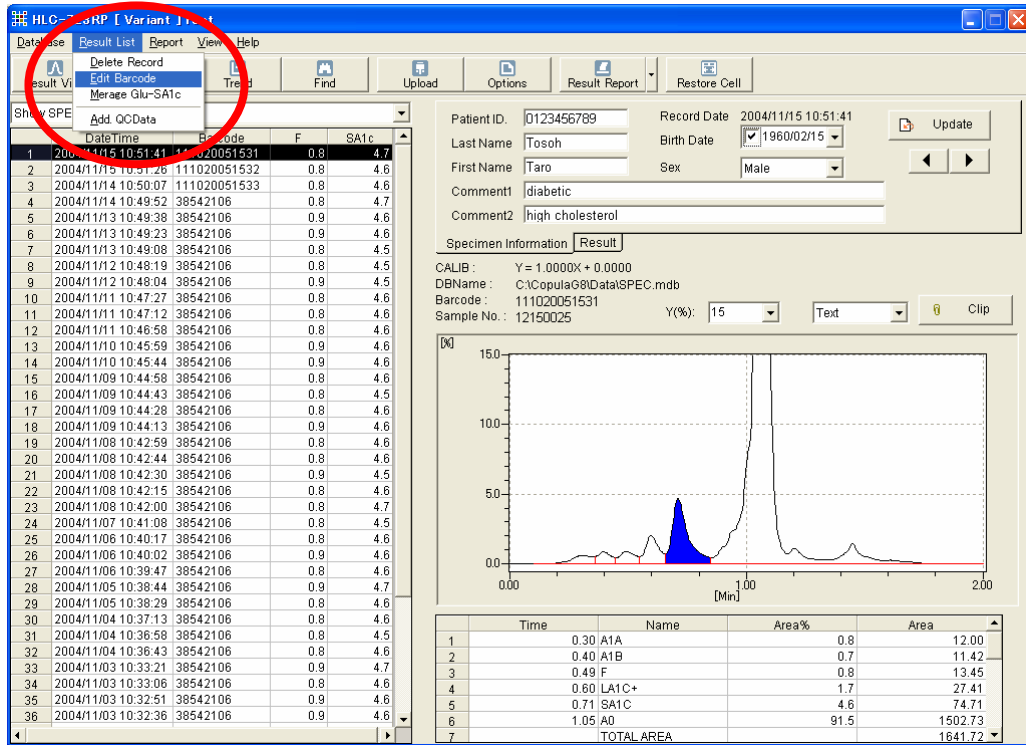


The deleted records cannot be restored.

## 5.4 Editing Barcode

The Glycohemoglobin Analyzer will analyze samples, even if it fails to read the barcode. The failed sample is displayed as a rack # and position #. This can be edited after analysis as follows:

Select a result in the “Result List” as shown below.



Chromatogram View Screen

Select “Edit Barcode” from the drop down menu.

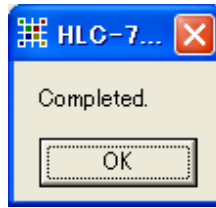
Enter the barcode, up to 20 alphanumeric characters, in the dialog box shown below.

Then select the OK button.

The screenshot shows the 'Value' dialog box for entering a barcode. The text '38542106' is entered in the 'Barcode' field.

Barcode Entry Dialog Box

When the following dialog box appears, click the OK button.



The Result List containing the barcode is updated.

	DateTime	Barcode	F	SA1c
1	2004/11/15 10:51:41	38542106	0.8	4.6
2	2004/11/15 10:51:26	111020051532	0.8	4.6
3	2004/11/14 10:50:07	111020051533	0.8	4.5
4	2004/11/14 10:49:52	38542106	0.8	4.6
5	2004/11/13 10:49:38	38542106	0.8	4.6



**Please be careful. If barcodes is edited, Patient information such as the patient ID, a family name, and a name is lost. When there exist some results which have the same barcode as the edited barcode, the patient information of the edited result are replaced by that of the other results which have the same barcode as the edited barcode. Please check that the barcode does not duplicate before editing.**

## 5.5 Entering Patient Information

**Specimen Information tab**

Patient ID: 0123456789    Record Date: 2004/11/15 10:51:41    Update  
 Last Name: Tosoh    Birth Date: 1960/02/15  
 First Name: Taro    Sex: Male  
 Comment1: diabetic  
 Comment2: high cholesterol

CALIB: Y = 1.0000X + 0.0000  
 DBName: C:\CopulaG8\Data\SPEC.mdb  
 Barcode: 38542106  
 Sample No.: 12150025    Y(%): 15    Text    Clip

Time    Name    Area%    Area  
 1    0.30    A1A    0.8    12.00  
 2    0.40    A1B    0.7    11.42  
 3    0.49    F    0.8    13.45  
 4    0.60    LA1C+    1.7    27.41  
 5    0.71    SA1C    4.6    74.71  
 6    1.05    AD    91.5    1502.73  
 7    TOTAL AREA          1641.72

Chromatogram View Screen

Patient ID: 1234567890120    Record Date: 2004/07/25 13:53:21    Update  
 Last Name: Tosoh    Birth Date: 1960/11/30  
 First Name: Taro    Sex: Male  
 Comment1: diabetic  
 Comment2: high cholesterol

Specimen Information    Result

Specimen Information tab

Patient clinical information may be added to the result in the Specimen Information tab.

Enter information then select the Update button. Note that the entered information will not be saved if other information screens are selected prior to clicking the Update button.

Note that patient information can be sent from the host computer using the unify protocol.



**Caution**

**Please ensure the entered information is correct, as this will result in inaccurate reports.**

**The edited results are reflected in the patient information on other results which have the same barcode as the edited result. Please check there is no duplicating barcode before edit this information.**



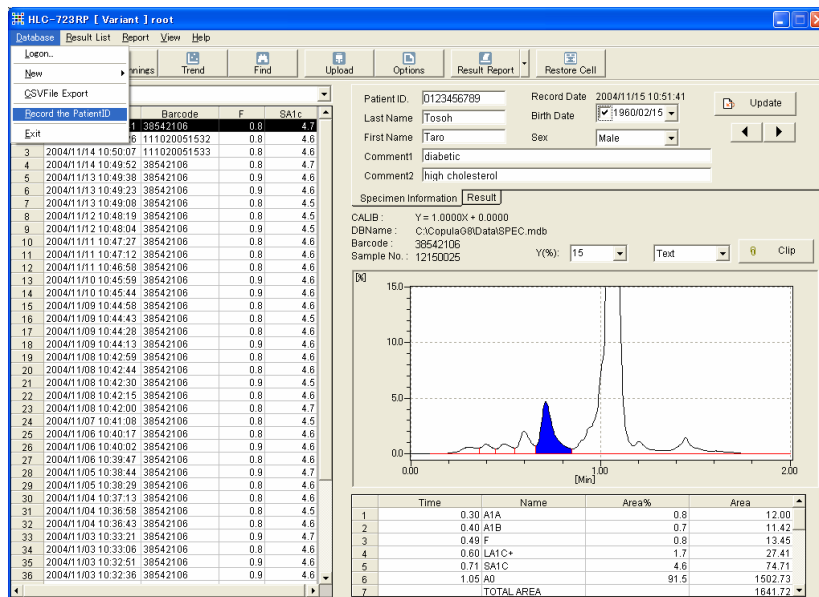
**Please disable the Automatically Refresh function when editing the patient information, otherwise the editing information may be lost at a new result is obtained.**

## 5.6 PatientID Management

This software can remember the specific PatientID and indicates that the sample with the same PatientID was measured in the past. For example, the PatientID of the abnormal hemoglobin sample is recorded. You can know when the sample is measured again. The background of the Barcode cell for the selected data is shown in yellow. Even if it changes to a new database, the specific PatientID data is memorized.

The specific PatientID is registered in the following procedures.

Select the data with PatientID.



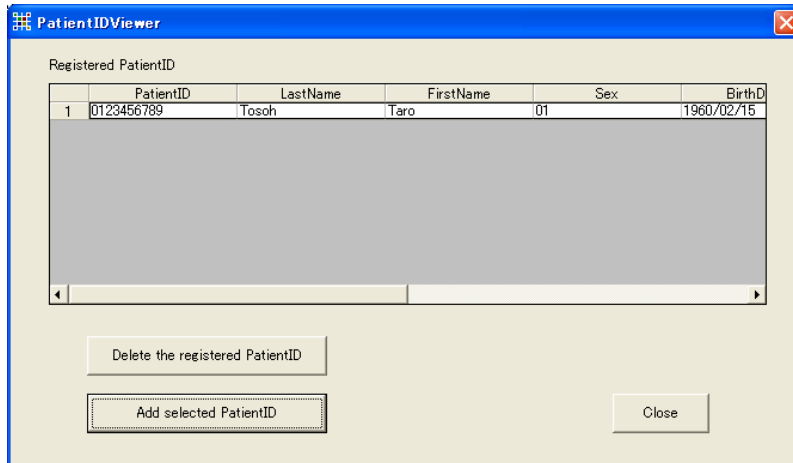
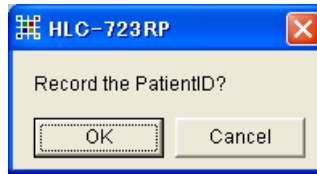
Chromatogram View Screen

Click “Record the PatientID” from the drop down menu of the Database. PatientIDViewer is displayed.

The screenshot shows the PatientIDViewer software window. It features a table with the following columns: PatientID, LastName, FirstName, Sex, and BirthD. The table is currently empty. Below the table are three buttons: "Delete the registered PatientID", "Add selected PatientID", and "Close".

PatientIDViewer

Click the button “Add selected PatientID”.  
 Since a checking dialog is displayed, click the OK button.  
 The selected PatientID is registered as a specific sample.



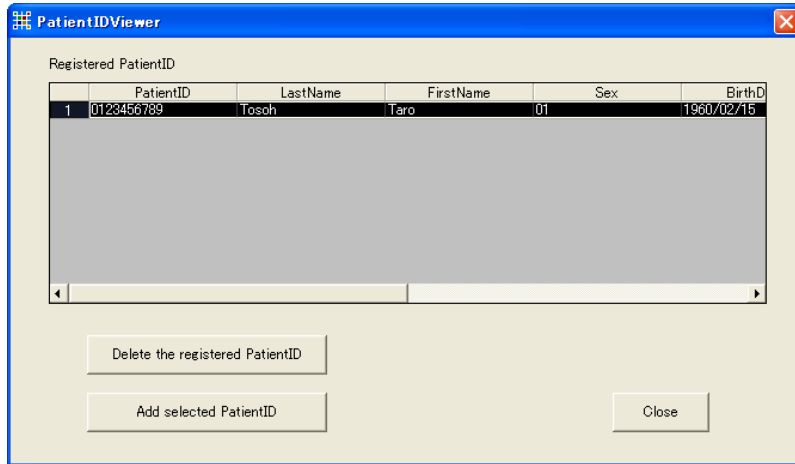
Chromatogram View Screen

The background of the Barcode cell of the registered special sample data becomes yellow.

	DateTime	Barcode	F	SA1c
1	2004/11/15 10:51:41	111020051459	0.8	4.6
2	2004/11/15 10:51:26	111020051532	0.8	4.6
3	2004/11/14 10:50:07	111020051533	0.8	4.5
4	2004/11/14 10:49:52	38542106	0.8	4.6

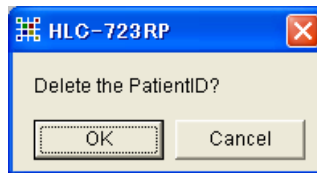
Data without PatientID and QC data cannot be registered as a specific sample.

**Delete some registered Patient ID in the following procedures.  
Select a record to delete by PatientIDViewer.**



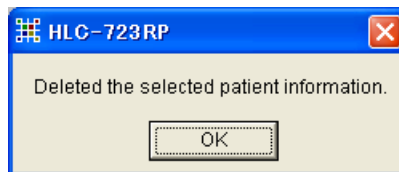
### Chromatogram View Screen

**Click the button “Delete the registered PatientID”.**



**Since a checking dialog is displayed, click the OK button.**

**The following message is displayed after the deletion of selected data.**



## 5.7 Export to the CSV file

The result list can be exported to a CSV file.

Click the “CSVFile Export” in the menu bar. The exported file is saved in “C:\CopulaG8\Data” folder.

The screenshot displays the HLC-723RP software interface. The main window is titled "HLC-723RP [ Variant ] root". The menu bar includes "Database", "Result List", "Report", "View", and "Help". The toolbar contains icons for "New", "Trend", "Find", "Upload", "Options", "Result Report", and "Restore Cell".

On the left, a "CSVFile Export" menu is open, showing a list of records with columns: "Record the PatientID", "Barcode", "F", and "SA1c". The first record is highlighted.

The patient information section on the right includes:

- Patient ID: 200511141157
- Last Name: Tosoh
- First Name: Taro
- Record Date: 2004/11/15 10:51:41
- Birth Date: 2004/01/20
- Sex: Male
- Comment1: diabetic
- Comment2: high cholesterol

Below the patient information, there is a "Specimen Information" section with a "Result" tab. It shows the calibration equation:  $Y = 1.0000X + 0.0000$ . Other fields include DBName, Barcode, and Sample No. with a "Y(%)" dropdown set to 15 and a "Clip" button.

The chromatogram shows a plot of detector response versus time in minutes. The x-axis ranges from 0.00 to 2.00 minutes, and the y-axis ranges from 0.00 to 150.00. A prominent peak is visible at approximately 1.05 minutes, highlighted in blue. Other smaller peaks are present at 0.30, 0.40, 0.49, 0.60, and 0.71 minutes.

At the bottom, a table summarizes the peak data:

Time	Name	Area%	Area
1	0.30 A1A	0.8	12.00
2	0.40 A1B	0.7	11.42
3	0.49 F	0.8	13.45
4	0.60 LA1C+	1.7	27.41
5	0.71 SA1C	4.6	74.71
6	1.05 A0	91.5	1502.73
7	TOTAL AREA		1641.72

Chromato View Screen

## 5.8 Managing Results

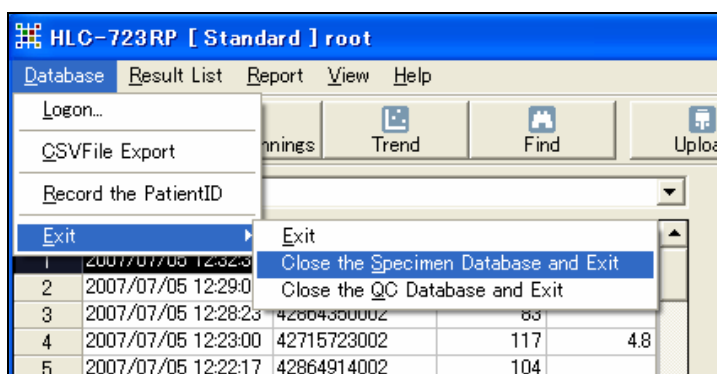
The results are stored in the “SPEC.mdb” contained in the “C:\CopulaG8\Data” folder.

If the result database has too many records, the Print Preview function will slow significantly for displaying results.

It is recommended that a new database be created approximately once a month or when the record count has reached approximately 3,000.

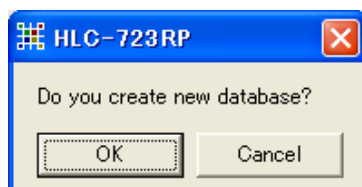
The procedures for changing to a new database are described below.

Select the “Exit” menu. Then select “Close the Specimen Database and Exit”.



Exit Menu

Once the new database has been created, the following dialog box appears. Select the OK button.



**Enter file name and select the Save button. This completes the creation of the new database. HLC-723RP Reporting Program is ended.  
Saved databases can be accessed in the FIND function.**



**If the result database has too many records, the Print Preview function will slow displaying results significantly. It is recommended that a new database be created approximately once a month or when the record count has reached approximately 3,000.**



## 6 Sending results to Host Computer

### 6.1 Send Procedure

To automatically upload to the host computer, check the “Automatic upload” (see red circle in screen below) in the Environment Settings screen found under **OPTIONS**. In order to upload the selected result manually, use the upload button in the Tool bar.

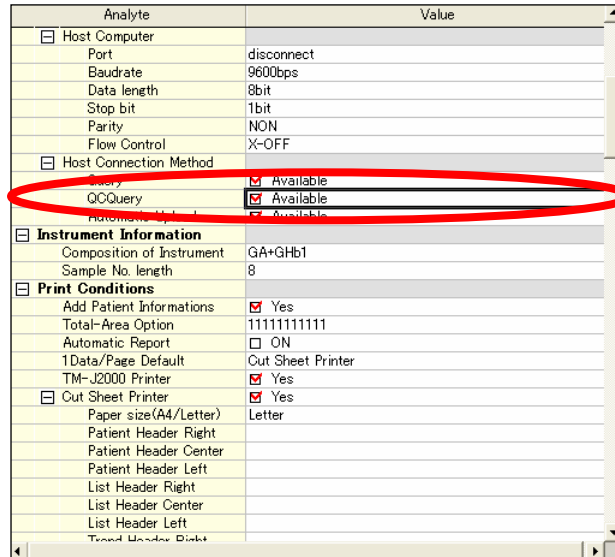
Analyte	Value
<input type="checkbox"/> Host Computer	
Port	disconnect
Baudrate	9600bps
Data length	8bit
Stop bit	1bit
Parity	NON
Flow Control	X-OFF
<input type="checkbox"/> Host Connection Method	
Query	<input checked="" type="checkbox"/> Available
CC Query	<input checked="" type="checkbox"/> Available
Automatic Upload	<input checked="" type="checkbox"/> Available
<input type="checkbox"/> Instrument Specifications	
Composition of Instrument	GA+GHb1
Sample No. length	8
<input type="checkbox"/> Print Conditions	
Add Patient Informations	<input checked="" type="checkbox"/> Yes
Total-Area Option	111111111111
Automatic Report	<input type="checkbox"/> ON
1Data/Page Default	Cut Sheet Printer
TM-J2000 Printer	<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> Cut Sheet Printer	<input checked="" type="checkbox"/> Yes
Paper size(A4/Letter)	Letter
Patient Header Right	
Patient Header Center	
Patient Header Left	
List Header Right	
List Header Center	
List Header Left	
Trans Header Right	

Environment Settings Screen (Environment Tab)

Note that the HLC-723RP Reporting Program is not able to manually upload results when the instruments are connected to the host individually.

## 6.2 Query for Control

Glycohemoglobin analyzer queries a host computer all samples in the query mode. When using HLC-723RP, it can be set whether the query for control is done to a host computer. It is decided by QC query setting (see red circle in screen below). In order to query to a host computer, Check to QC query.



Analyte	Value
<input type="checkbox"/> Host Computer	
Port	disconnect
Baudrate	9600bps
Data length	8bit
Stop bit	1bit
Parity	NON
Flow Control	X-OFF
<input type="checkbox"/> Host Connection Method	
Query	<input checked="" type="checkbox"/> Available
QCQuery	<input checked="" type="checkbox"/> Available
Automatic Report	<input checked="" type="checkbox"/> Available
<input type="checkbox"/> Instrument Information	
Composition of Instrument	GA+GHb1
Sample No. length	8
<input type="checkbox"/> Print Conditions	
Add Patient Informations	<input checked="" type="checkbox"/> Yes
Total-Area Option	1111111111
Automatic Report	<input type="checkbox"/> ON
1Data/Page Default	Cut Sheet Printer
TM-J2000 Printer	<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> Cut Sheet Printer	<input checked="" type="checkbox"/> Yes
Paper size(A4/Letter)	Letter
Patient Header Right	
Patient Header Center	
Patient Header Left	
List Header Right	
List Header Center	
List Header Left	
Trand Header Right	

Environment Settings Screen (Environment Tab)

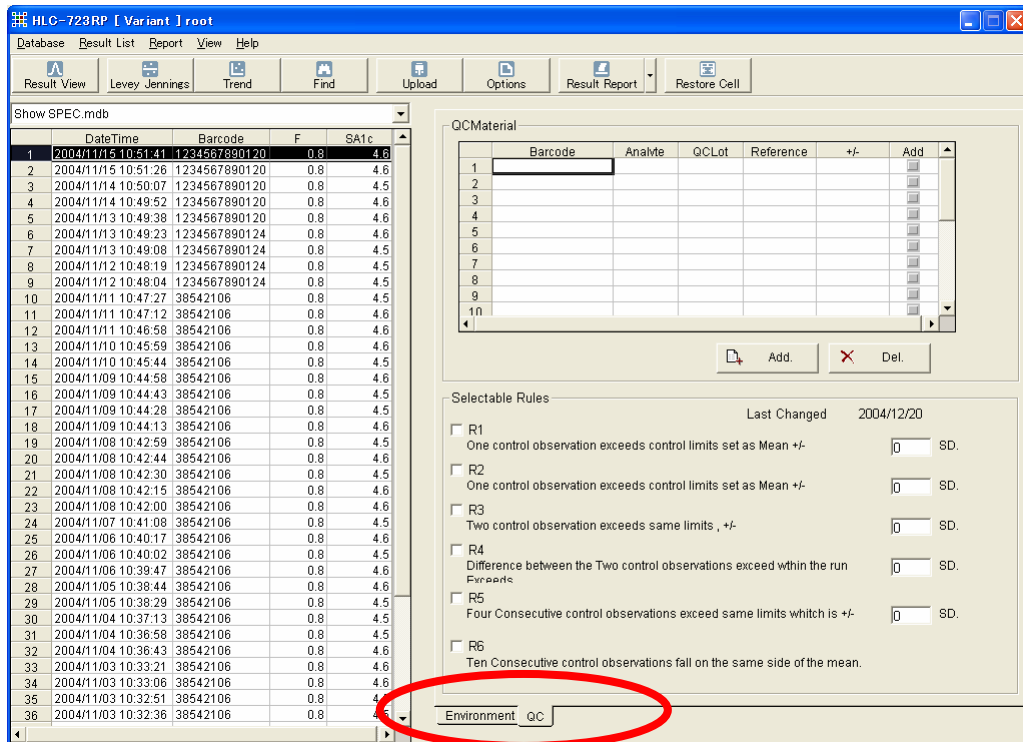
In order to carry out Quality Control by this software, it is necessary to register the control barcode as QC materials. Refer to Chapter 7 for details. Note that it cannot carry out Quality Control by control without barcode.

## 7 Quality Control (QC)

### 7.1 QC Materials

It is necessary to define QC materials in advance. This application can identify the controls using barcodes. QC materials are registered using the following procedure:

Select Options and then choose the QC tab in the Environment Settings screen.



Environment Settings Screen (QC tab)

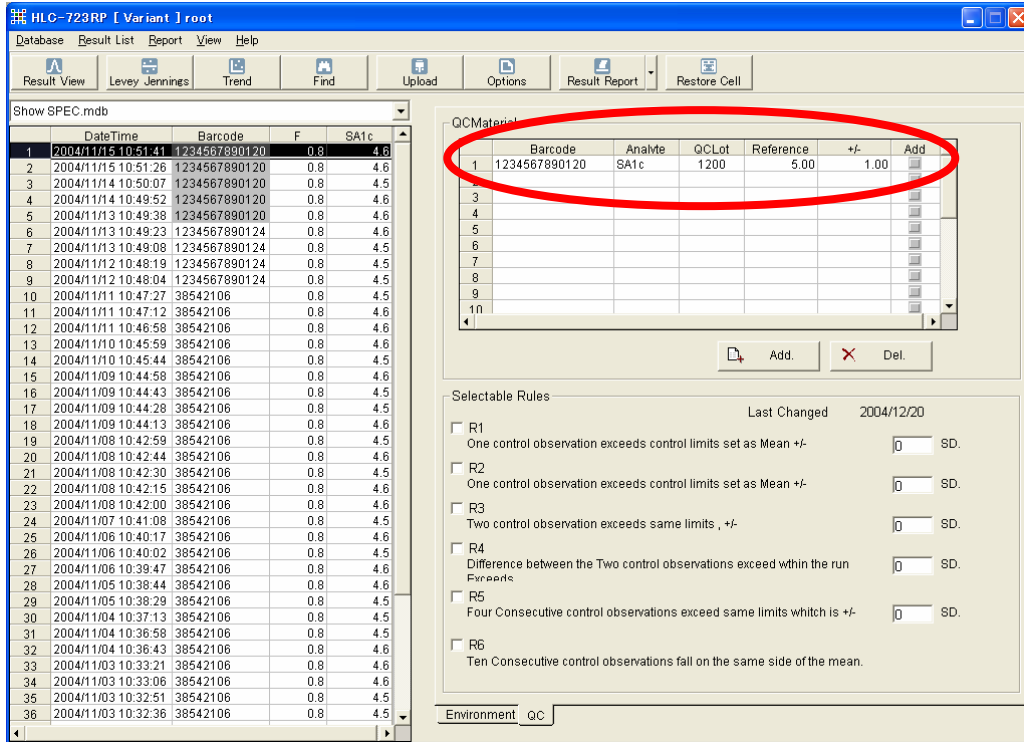
Selecting the “Add” QC materials button shows the following dialog box.

Enter the QC Material Name (barcode # or letter), select analyte from the drop down menu, type in the Lot. Type in the Mean Value (reference value) and +/- acceptable range from the control material package inserts. Select the OK button.

The "Add QC Material" dialog box contains the following fields and controls:

- QC Material Name: 1234567890120
- Analyte: SA1c (dropdown menu)
- Lot: 1200
- Reference value: 5.00
- Reference range: 1.00
- Buttons: OK, Cancel

Example above is a mean value of 5.00%. The QC range is 4.0 to 6.0. The range is +/-1.0. The new QC materials will be added to the worksheet (see circle in the screen below).

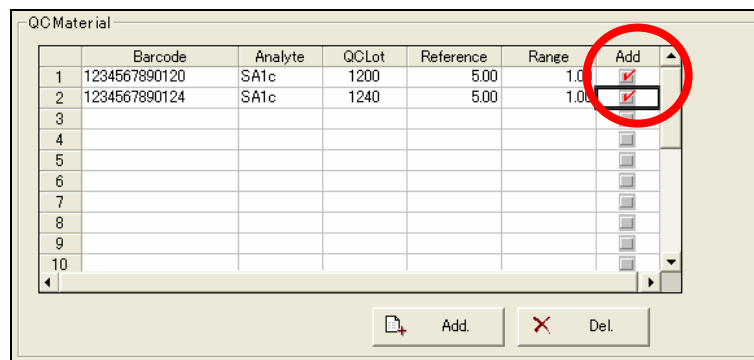


Environment Settings Screen (QC Tab)

In Thalassemia mode, the system creates temporal barcode to manage F and A2 results for one barcode. For example, the temporal barcode for 200001 will be 200001@1 for F and 200001@2 for A2.

Select the “Add” checkbox (see circle in the screen below). The analytes with the “Add” checkbox checked will be designated for QC data when the QC barcode is read.

Selecting the “Del.” button deletes the selected QC material.



QC Materials Screen

## 7.2 Selectable Rules

These rules are used to set the control range and control procedures for QC materials.

### [Rules]

**R1: Result is R1-flagged when discrepancy between the mean and observed value exceeds a specified SD value.**

**R2: Result is R2-flagged when discrepancy between the mean and observed value exceeds another specified SD value.**

**R3: Result is R3-flagged when discrepancy between the mean and two consecutive observed values exceed a specified SD value.**

**R4: Result is R4-flagged when the difference between two consecutive control observations exceeds the specified SD value.**

**R5: Result is R5-flagged when four consecutive observed values exceed a specified SD value in the same direction..**

**R6: Result is R6-flagged when ten consecutive control values fall on the same side of the mean.**

**The R1 to R6 flag assessment results, which are entered using the Selectable Rules are displayed in the chart.**

Selectable Rules		Last Changed	2004/07/16
<input checked="" type="checkbox"/>	R1 One control observation exceeds control limits set as Mean +/-	<input type="text" value="2"/>	SD.
<input checked="" type="checkbox"/>	R2 One control observation exceeds control limits set as Mean +/-	<input type="text" value="2"/>	SD.
<input checked="" type="checkbox"/>	R3 Two control observation exceeds same limits , +/-	<input type="text" value="2"/>	SD.
<input checked="" type="checkbox"/>	R4 Difference between the Two control observations exceed within the run Exceeds	<input type="text" value="2"/>	SD.
<input checked="" type="checkbox"/>	R5 Four Consecutive control observations exceed same limits which is +/-	<input type="text" value="2"/>	SD.
<input checked="" type="checkbox"/>	R6 Ten Consecutive control observations fall on the same side of the mean.		

### Selectable Rules

If a QC barcode is not read it is possible to EDIT the barcode and enter the data into the QC database. Under RESULT LIST, select 'Barcode Edit' and the Value entry dialog box will appear. Enter the barcode ID (QC barcode), up to 20 alphanumeric characters. Select the line where the edit was placed.

Under RESULT LIST, select QC tab and select 'Add'. This data will now be added to the QC database.

## 7.3 Levey-Jenning's Chart

Levey-Jenning's Chart screen shows the Xbar control chart. The control used is decided with analyte, lot, barcode, and instrument name. The black line on the Xbar control chart is a data, and the red point is the average of data.

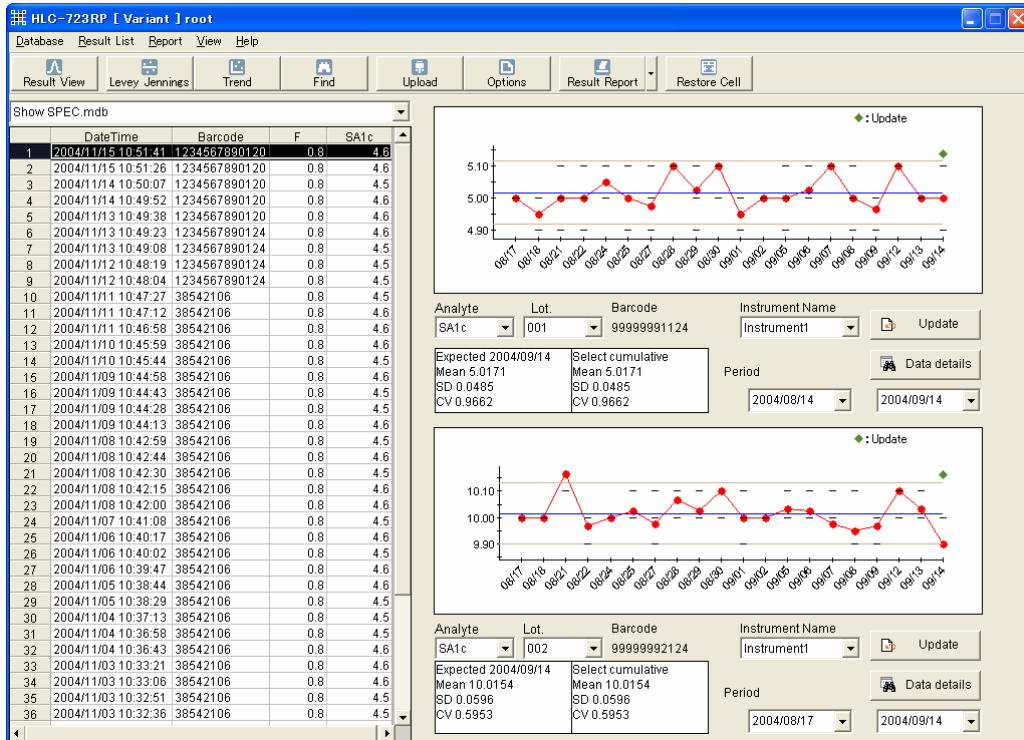
Levey-Jenning's charts are made automatically whenever the barcoded controls are run.

If barcodes are not used for controls, the QC results can be entered in the following way:

Select one QC data from the result list.

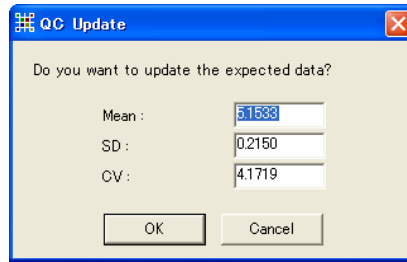
Select "Result List" button and then select "Add QC data".

Note that two or more data points must be added in order to plot a Levey-Jenning chart. The "Remove data" from "Result List" button can be used to exclude QC data points. Choose analyte and lot from the boxes and the Levey-Jenning chart will appear. Complete the procedure by selecting the time frame found in the drop down menu called PERIOD.



Levey-Jenning's chart Screen

Selecting the Update button shows the following QC update dialog box containing fields for entering the Mean, SD and CV (expected values), allowing you to update the QC screen.



**[Statistical Information]**

**Control range ( Expected ) :**

- Date:** The updated date
- Mean:** Mean = (Range High + Range Low) / 2, using the inputted values if no “Update” was performed
- SD:** SD = (Range High - Mean) / 2, using the inputted values if no “Update” was performed
- CV:** Expected CV%. If no “Update” was performed, this is calculated as below using the inputted values.  

$$CV = (SD / Mean) \times 100$$

**Displayed Period (Selected Cumulative)**

This is a statistical value for the graph display period (date range).The mean data for a single day is calculated as a single point. If the control material is run more than once in one day, the data can be viewed in “data details”. Individual point can be deleted.

- Mean:** Average value
- SD:** Standard deviation
- CV:** CV%

While displayed the QC update field, displayed Mean, SD and CV can be switched by pressing the Function keys F1 and F2 as:

- F1:** Expected Values
- F2:** Select Cumulative values.

Selecting F1 will use all QC data in the database to calculate the Mean, SD, and CV. If F2 is selected then the Mean, SD, and CV will be calculated based on the period of time selected in the drop down menu under Period.

## 8 Trend Analysis

### 8.1 Trend Charts

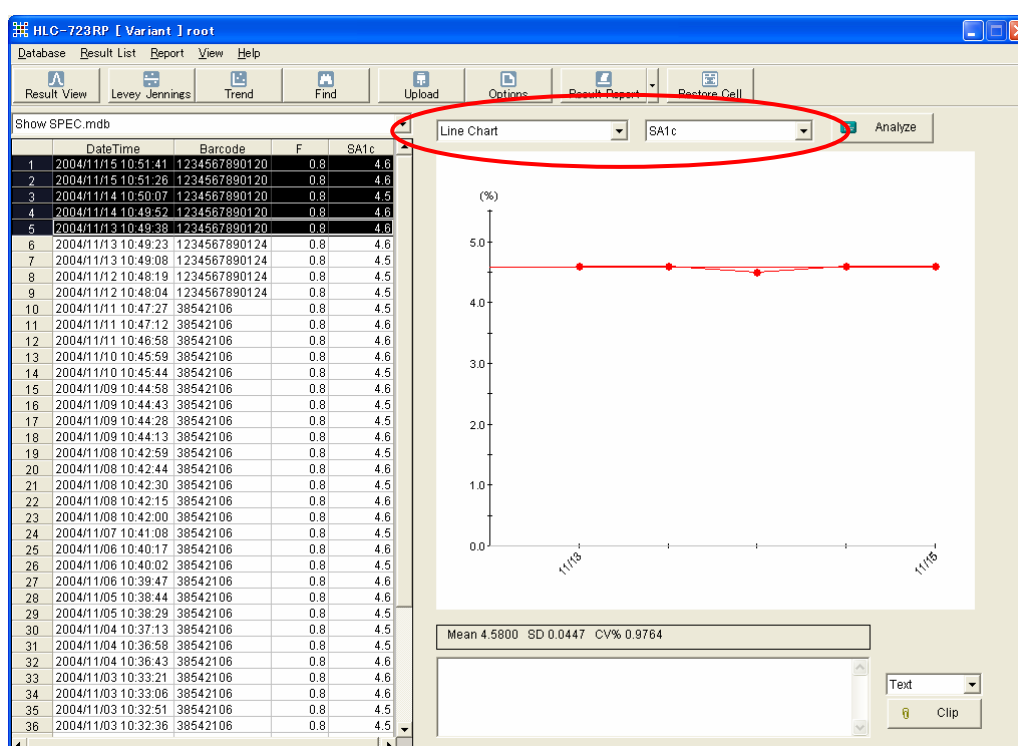
The HLC-723RP Reporting Program can display the trend chart of specific patients. Data relating to specific conditions can be extracted using the search function. See Chapter 10 for a detailed description.

The procedures for plotting charts are described below.

Choose the results from the result list.

Select the chart type and analyte (see red circle in screen below).

Click the Analyze button. The results using for the trend chart are decided.



#### Analysis Screen

Clicking the Analyze button displays a chart of the selected data and calculates the Mean, SD and CV. The control line is inserted in the chart by setting the "Statistics & Charts" marker in the environment settings. The Clip button allows to save the chart as EMF or to copy the text to clipboard.

Comments can be added to the trend Reports.



If the number of data exceeds 100 results, it will become difficult to distinguish each data clearly.

In order to avoid misinterpretation, we recommend to use it with suitable number of data.



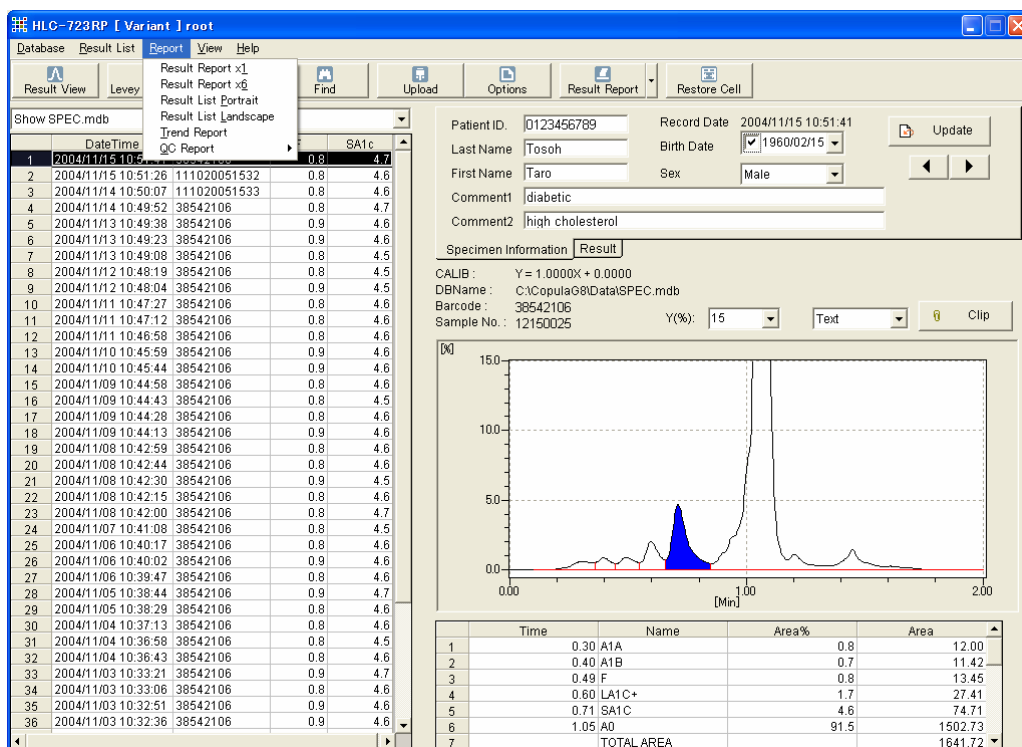
## 9 Printing Reports

The following reports are available:

- A. Result Report- One patient per page with chromatogram
- B. Result Report- Six patients per page with chromatograms
- C. Result List Report with Patient Information
- D. Result List Report without Patient Information
- E. Result List Report (Landscape)
- F. Trend Reports
- G. QC Reports

### 9.1 Result Reports

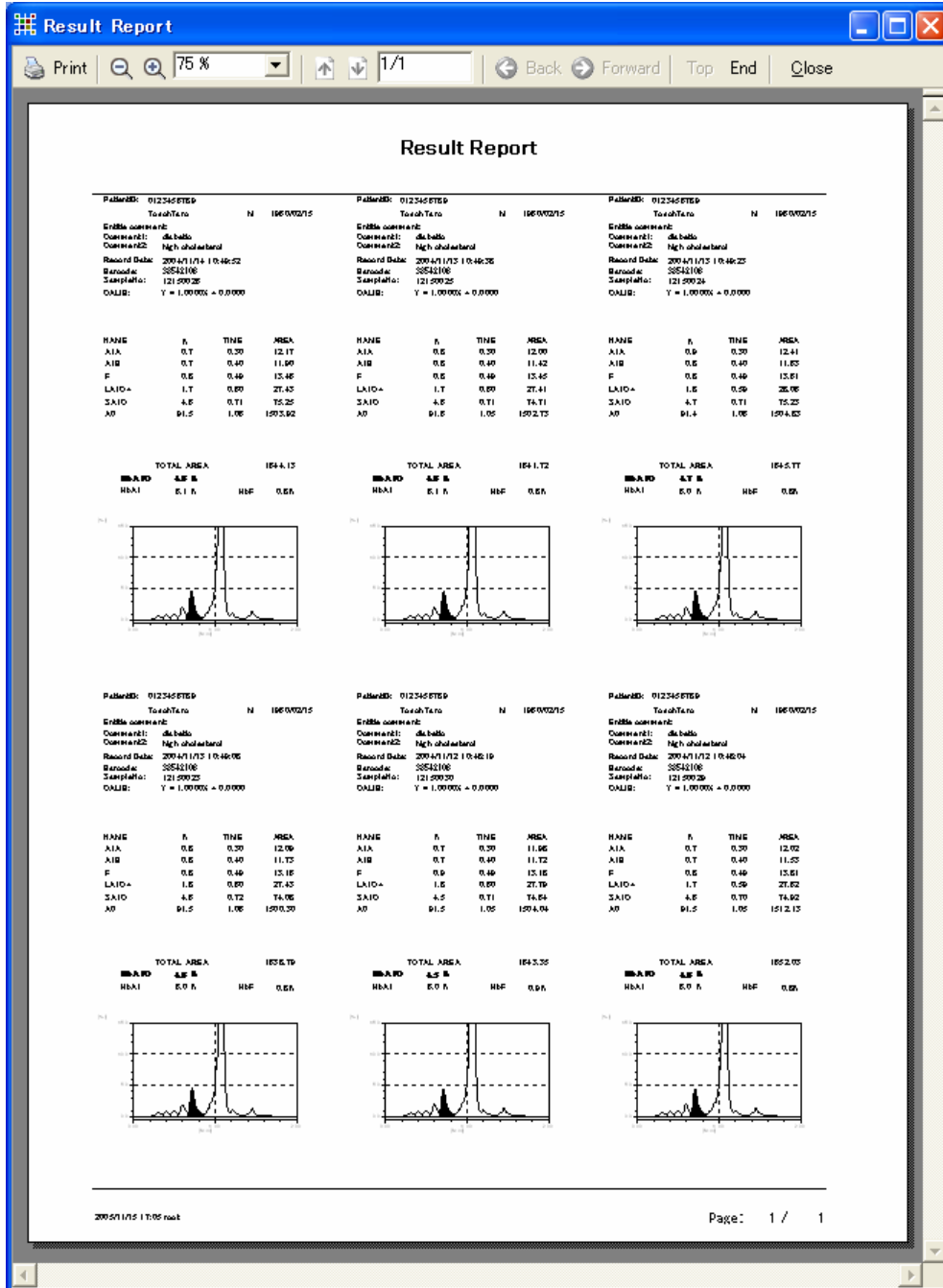
Single-report/page forms and six-report/page forms are the choices for Result Reports. Reports printed in real-time use the single-report/page form. Print previews and print operations are conducted using the following procedure: Select one result in the list. Then Select Result Report Tab. From the drop down menu select “Result Report x 1”.



Chromatogram View Screen



First select 6 results from the list. Then choose “Result Report x 6” from the Report menu. This setting displays the Print Preview with 6 result reports on each page. Select the Print Button to print the report. You may choose to select just 2, 3, 4, or 5 results to print as well.



Print Preview Screen for the Six-Report/Page Result Report

## 9.2 Result List

A list of the data is printed. As a printer format, there are the Portrait and the Landscape type of A4 (Letter).

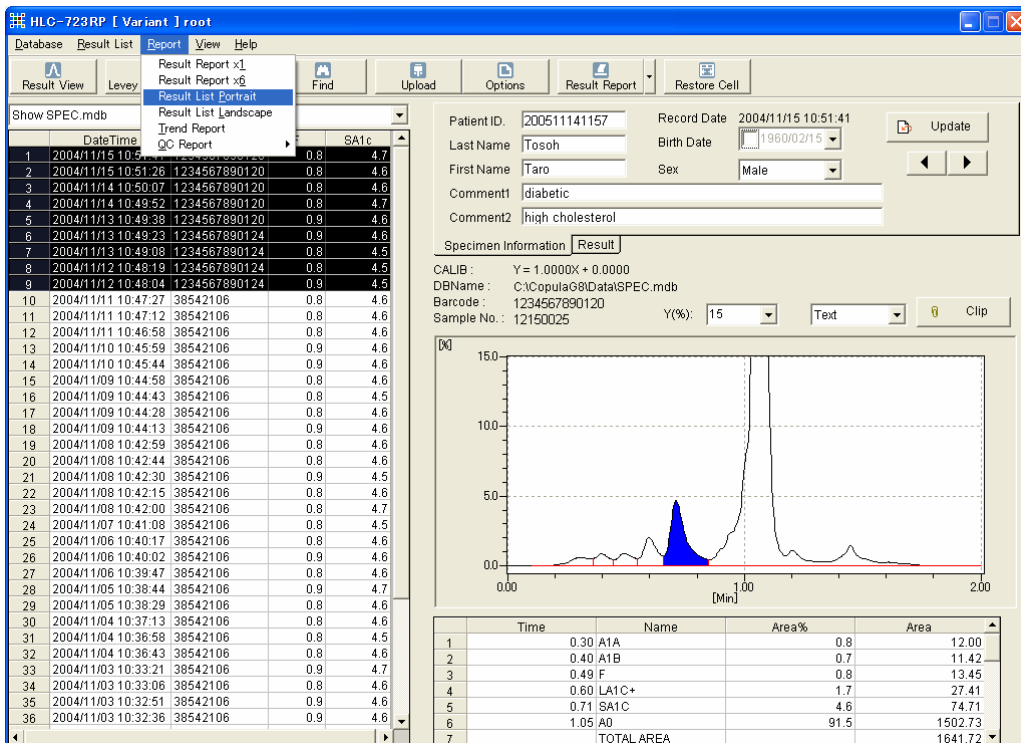
In case Patient information is added:

In the Environment tab, check the “Add patient information” item.

Analyte	Value
<input type="checkbox"/> Host Computer	
Port	disconnect
Baudrate	9600bps
Data length	8bit
Stop bit	1bit
Parity	NON
Flow Control	X-OFF
<input type="checkbox"/> Host Connection Method	
Query	<input checked="" type="checkbox"/> Available
QCQuery	<input checked="" type="checkbox"/> Available
Automatic Upload	<input checked="" type="checkbox"/> Available
<input type="checkbox"/> Instrument Information	
Composition of Instrument	GA+GHb1
Sample No. length	8
<input type="checkbox"/> Print Conditions	
Add Patient Informations	<input checked="" type="checkbox"/> Yes
Total-Area Option	111111111111
Automatic Report	<input type="checkbox"/> ON
1Data/Page Default	Cut Sheet Printer
TM-J2000 Printer	<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> Cut Sheet Printer	
Paper size(A4/Letter)	<input checked="" type="checkbox"/> Yes
Patient Header Right	Letter
Patient Header Center	
Patient Header Left	
List Header Right	
List Header Center	
List Header Left	
Trend Header Right	

Environment Settings Screen (Environment Settings Tab)

Select one or more results in the list, then select the Report menu and click the “Result List”. Or just select the Result Report Tab.



Chromatogram View Screen

The example of printing of the Result list with Patient information

The screenshot shows a software window titled "Result List" with a standard Windows-style interface. The window contains a table of patient information and test results. The table is divided into sections for patient details and a detailed list of test results.

EHR comment						
Patient ID	Last Name	First Name	Comment1/Comment2	Sex	Birth Date	
200511141157	Torah	Taro	diabetes	Unknown		
High cholesterol						
Specimen ID	Sample No	Patient ID	F	S/Alo	HYS Lot	Date
125-686-TSP-0120	121-59025	200511141157	0.6	4.8		2004/1/15 10:51:41
125-686-TSP-0120	121-59024	200511141157	0.6	4.8		2004/1/15 10:51:28
125-686-TSP-0120	121-59021	200511141157	0.6	4.5		2004/1/14 10:29:07
125-686-TSP-0120	121-59026	200511141157	0.6	4.8		2004/1/14 10:46:52
125-686-TSP-0120	121-59025	200511141157	0.6	4.8		2004/1/15 10:46:36
Patient ID	Last Name	First Name	Comment1/Comment2	Sex	Birth Date	
200511142357	Torah	Taro	diabetes	Male	1969/02/15	
High cholesterol						
Specimen ID	Sample No	Patient ID	F	S/Alo	HYS Lot	Date
125-686-TSP-0124	121-59024	200511142357	0.6	4.8		2004/1/15 10:46:25
125-686-TSP-0124	121-59025	200511142357	0.6	4.5		2004/1/15 10:46:06
125-686-TSP-0124	121-59030	200511142357	0.6	4.5		2004/1/12 10:46:19
125-686-TSP-0124	121-59029	200511142357	0.6	4.5		2004/1/12 10:46:04

2005A 1/14 14:40 raat Page: 1 / 1

Print Preview of Result List with Patient Information

## The example of printing of the Result list without Patient information

**Result List**

Specimen ID	Sample No	PatientID	p	SAto	WVS Lot	OOL Lot	OAL Lot	Ekt Lot	Ekt2 Lot	Ekt3 Lot	Date
125 406 YEP 0120	121 59025	200511 141 15T	0.6	4.8							2004/1/15 15:51:44
125 406 YEP 0120	121 59024	200511 141 15T	0.6	4.8							2004/1/15 15:51:28
125 406 YEP 0120	121 59027	200511 141 15T	0.6	4.5							2004/1/14 15:53:07
125 406 YEP 0120	121 59026	200511 141 15T	0.6	4.8							2004/1/14 15:48:52
125 406 YEP 0120	121 59025	200511 141 15T	0.6	4.8							2004/1/15 15:48:36
125 406 YEP 0124	121 59024	200511 142 35T	0.6	4.8							2004/1/15 15:48:22
125 406 YEP 0124	121 59025	200511 142 35T	0.6	4.5							2004/1/15 15:48:06
125 406 YEP 0124	121 59029	200511 142 35T	0.6	4.5							2004/1/12 15:48:19
125 406 YEP 0124	121 59026	200511 142 35T	0.6	4.5							2004/1/12 15:48:04

2005A 1/14 15:12 root Page: 1 / 1

## Print Preview of Result List without Patient Information

## The example of printing of a data list (Landscape)

Result List

Specimen ID	Sample No	Patient ID	Last Name	First Name	Comment1	Comment2	Sex	Birth Date	F	S41c	Date
1234587890120	12150023	200511141157	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.8	2004/11/13 10:31:41
1234587890120	12150024	200511141157	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.8	2004/11/13 10:31:28
1234587890120	12150027	200511141157	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.3	2004/11/14 10:30:07
1234587890120	12150028	200511141157	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.8	2004/11/14 10:49:32
1234587890120	12150025	200511141157	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.8	2004/11/13 10:49:38
1234587890124	12150024	200511142357	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.8	2004/11/13 10:49:23
1234587890124	12150023	200511142357	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.3	2004/11/13 10:49:08
1234587890124	12150030	200511142357	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.3	2004/11/12 10:48:19
1234587890124	12150029	200511142357	Tosoh	Taro	dlab-etc	High cholesterol	Male	1960/02/15	0.8	4.3	2004/11/12 10:48:04

2005/11/14 15:33 root Page: 1 / 1

## Print Preview of Result List (Landscape)

## 9.3 Trend Reports

Trend graph can be created on Analysis screen and the graph and the data can be printed. The HLC-723RP Reporting Program can display the trend chart of specific patients. It can also trend the same patient for performing a precision study. Data relating to specific conditions can be extracted using the find function. The procedures for plotting trend charts are described below.

Choose the results from the result list.

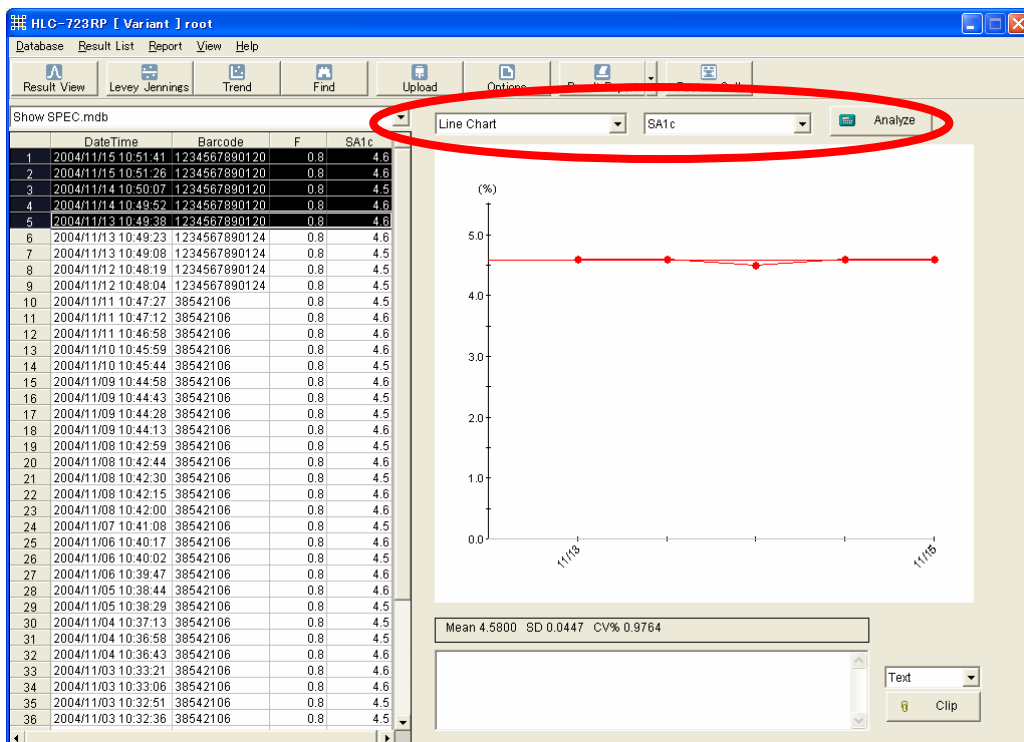
Select the chart type (line or bar) and SA1c (see red circle in screen below).

Select the Analyze button.

To print the trend reports after the trend charts have been made, first select the “Trend Reports” from the Result Report menu.

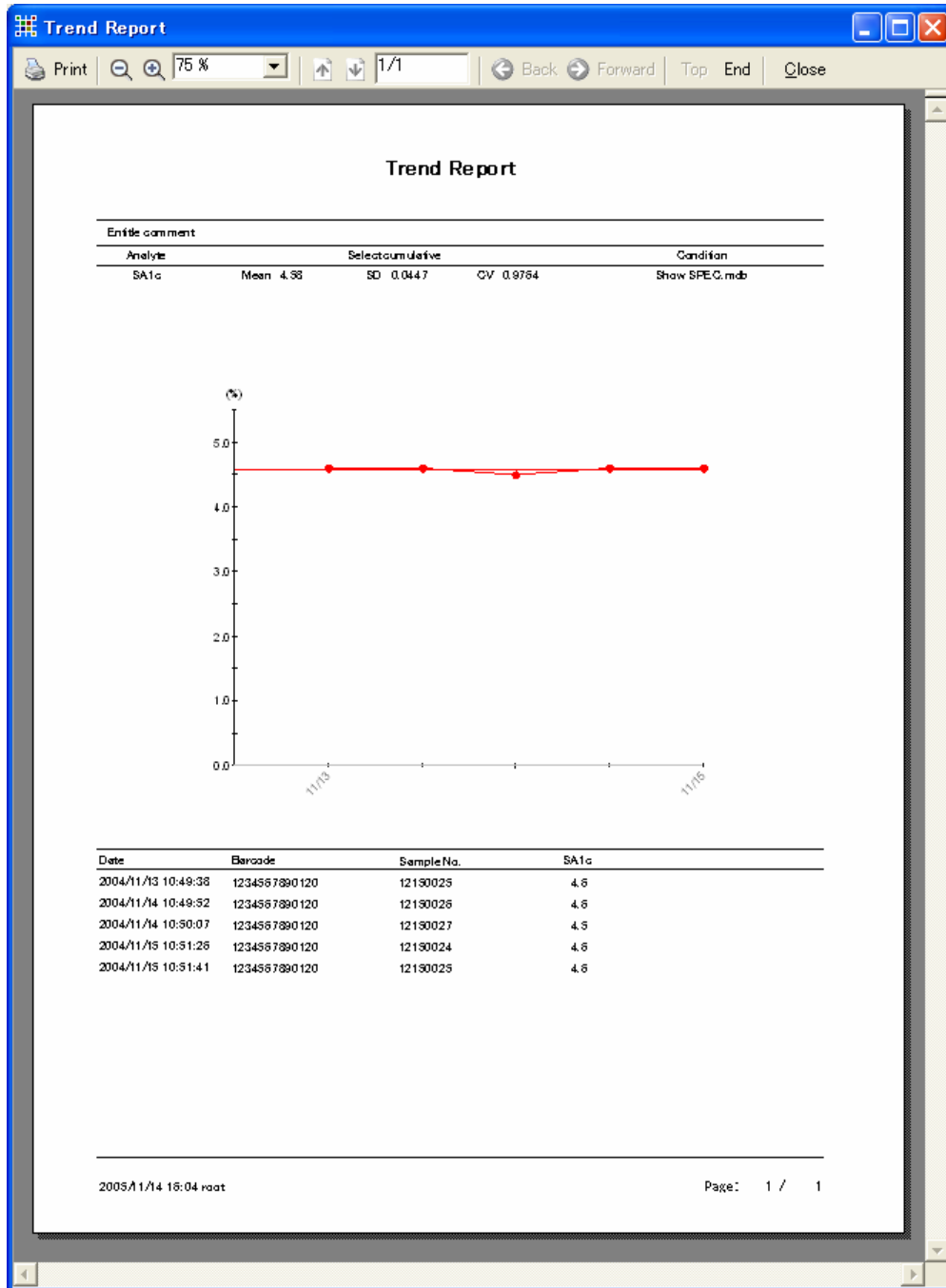
Clicking the Analyze button displays a chart of the selected data and calculates the Mean, SD and CV.

The control line is inserted in the chart by setting the marker in the environment settings. The Clip button allows to save the chart as EMF or to copy the text to clipboard. Comments can be added to the Trend Reports.



Trend chart

This displays a print preview of the trend report. Click the Print button to print the report.



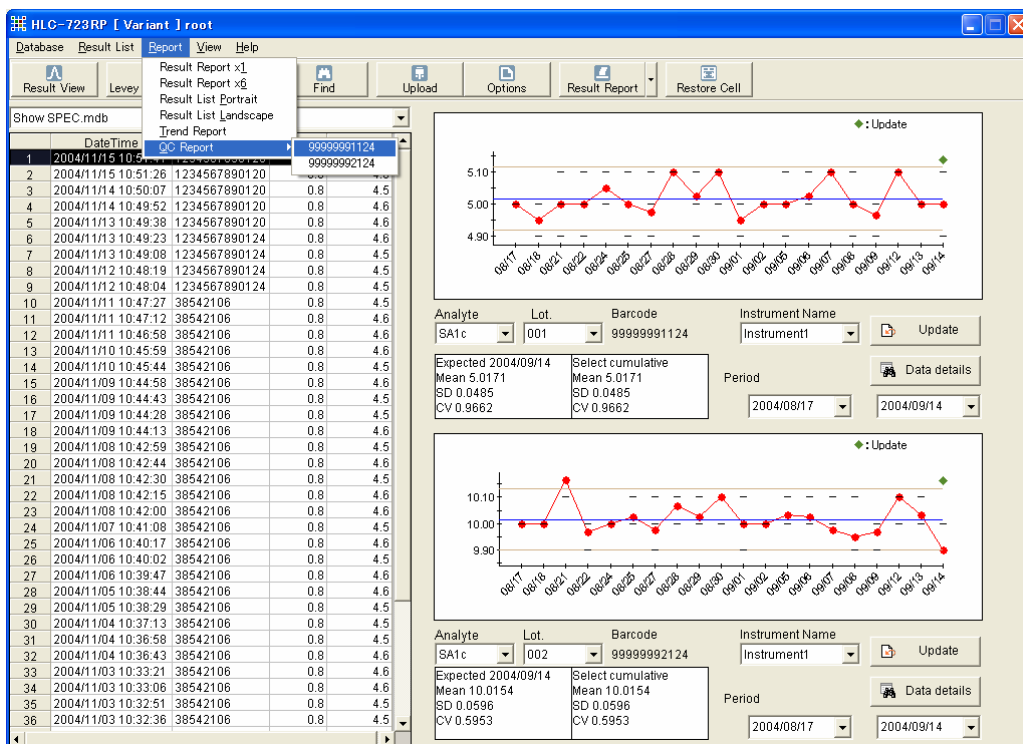
Print Preview of Trend Report

## 9.4 Quality Control (QC) Reports

Select the “QC Report” from the Result menu.

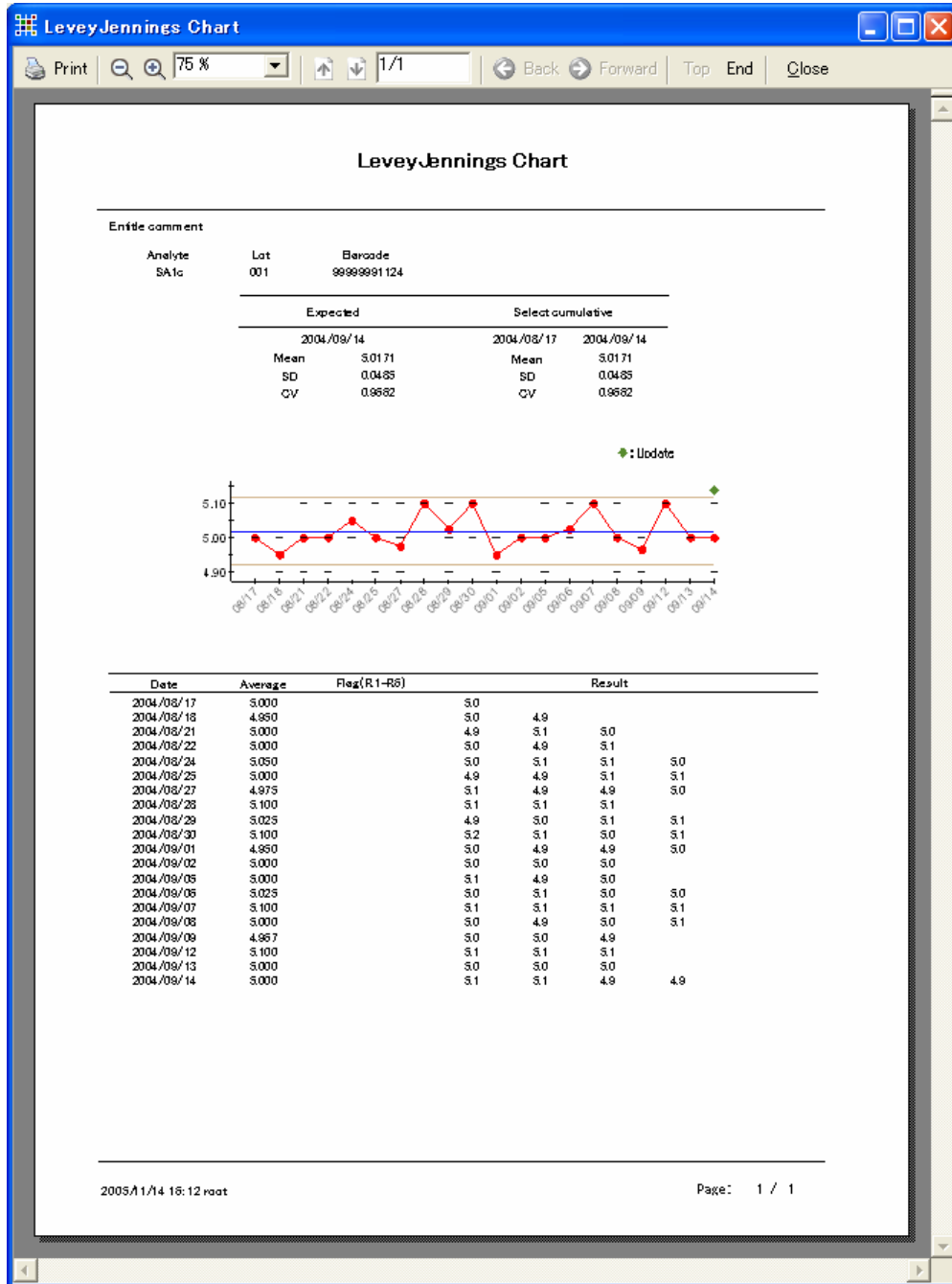
The two analyte charts displayed in this screen are provided as selectable options for the QC reports. QC reports print the Levey-Jennings chart generated from selected results.

Select the lot # from the drop down menu whenever the program is entered



Levey-Jennings Chart Screen

A print preview of the QC report is displayed. Click the Print button to print the report.



Print Preview of QC Report



# 10 Results Find Function

## 10.1 Find

The find function allows you to enter barcode, name, and others, as search keys. This screen is used for finding specific data.

Click the Find button to display the list of results.

To return to the original result list, choose the "Show SPEC.mdb" box at the top of the list.

Example:

For searching data from November 1, 2004 on wards.

Select "Date Time" Property from the Properties box (The property box has many choices).

Enter "2004/11/01" in the VALUE field.

In the CONDITION field select 'after' then click the Add (AND/OR) condition button.

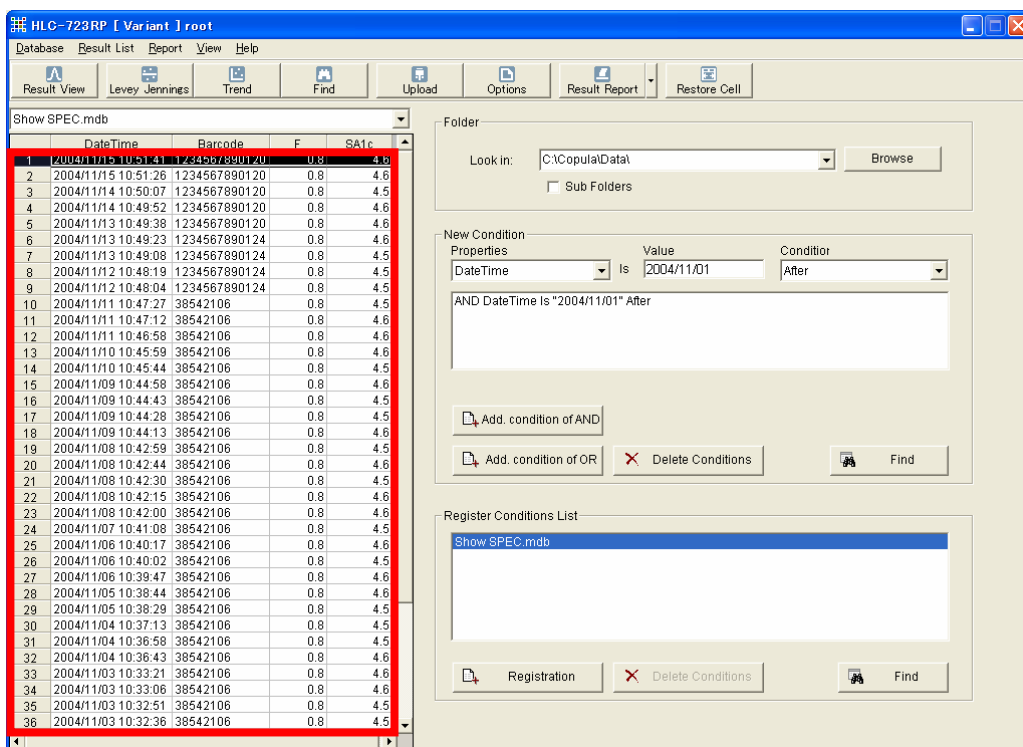
Clicking the Find button displays all found results (see square in screen below).

Another example to find all results from one days run:

Type in the day in the VALUE field and in the condition field selects THE DAY.

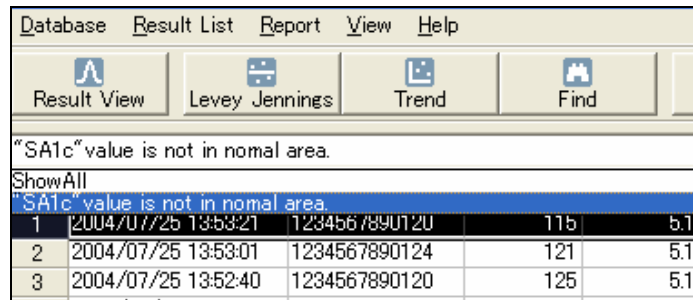
Click the Add (AND/OR) condition button and then FIND.

If a specific barcode is known then for condition choose MATCH CASE.



Find Screen

**You can select and register as many conditions as needed.**

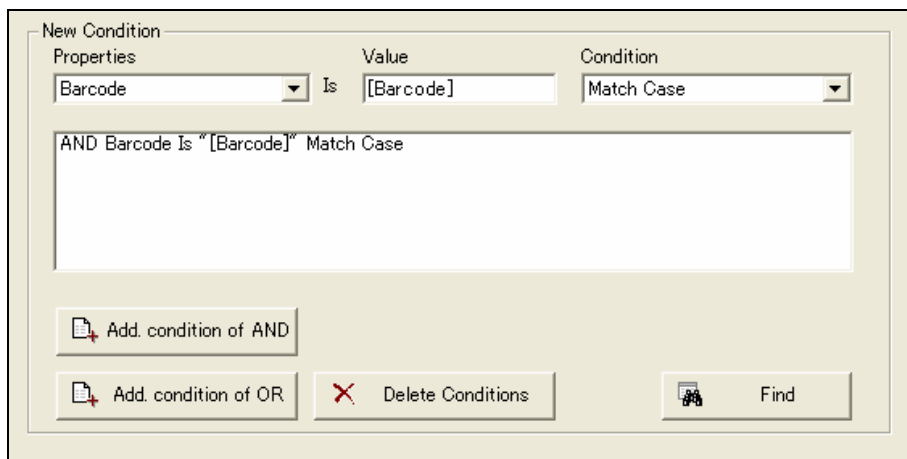


	"SA1c" value is not in normal area.			
	ShowAll			
	"SA1c" value is not in normal area.			
1	2004/07/25 13:53:21	1234567890120	11b	5.1
2	2004/07/25 13:53:01	1234567890124	121	5.1
3	2004/07/25 13:52:40	1234567890120	125	5.1

**Example:**

**Find the result whose barcode corresponds with inputted number.**

**The barcode is entered as a value by enclosing it in [ ] brackets (property name).**



New Condition

Properties	Value	Condition
Barcode	[Barcode]	Match Case

AND Barcode Is "[Barcode]" Match Case

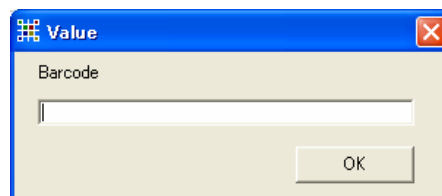
Add. condition of AND

Add. condition of OR

Delete Conditions

Find

**Using this condition displays the following dialog box enabling the barcode to be entered as a search key.**



Value

Barcode

OK

## **11 Diagnosing Problems**

Contact authorized representative.

### **11.1 Error Messages and Logs**

Records of any system faults or malfunctions are contained in system log files. You can check log file records by opening the log in the “C:\CopulaG8\Log” folder, which displays the log in Windows Notebook.

Examples:

- a) Incorrect GHb result protocol
- b) When connecting for every machine: Incorrect GHb reply of order protocol.
- c) When connecting collectively: Incorrect GHb reply of order protocol.
- d) Could not insert GHb data
- e) Communication timeout

### **11.2 Error Messages**

When errors relating to sending and receiving occur, check that the RS232C baud rate and parity settings are correct and that the barcode character length has not been changed.

Examples:

- a) Incorrect port number.
- b) Port is already open.
- c) Device is not open.
- d) Device is already open.
- e) Unable to establish transmission conditions. May be due to incorrect transmission parameters
- f) Attempted operation only valid when port is open.
- g) Unable to process received data.
- h) Unable to process sent data.
- i) Set percent decimal of instrument as “1”.
- j) Communication settings of instrument are G8 format.

To check any of the above problems, check the Environmental Settings under the OPTIONS tab.



## 12 Transmission Specifications

### 12.1 Transmission Procedures

Transmissions are conducted using the handshake mode. The control codes are listed in the table below.

Code (hexadecimal)	Name	Definition
02	STX	Start of text
03	ETX	End of text
04	EOT	End of transmission
06	ACK	Normal receive acknowledge
0D	CR	Carriage return
11	XON	Resume send requests
13	XOFF	Suspend send requests
15	NAK	Not acknowledged

#### Transmission Process

<STX> text <ETX> →  
← <ACK> or <NAK>  
<EOT> →

#### (Note)

- Resend is attempted up to five times after the <NAK> response is received. After the fifth attempt, the <EOT> is sent and the transmission procedure is initialized.
- In cases where multiple data items exist, the <EOT> is sent with the last data item.
- The response of <ACK> or <NAK> must be sent within a 10 second interval.
- Host's response to the query from HLC-723RP must be sent within 10 second interval.

**<Example using 1 data item>**

<STX> text 1<ETX> →  
← <ACK>  
<EOT> →

**<Example using multiple data items>**

<STX> text 1<ETX> →  
← <ACK>  
<STX> text 2<ETX> →  
← <ACK>  
:  
:  
<STX> text n<ETX> →  
← <ACK>  
<EOT> →

**<Example of success after 1 resend>**

<STX> text 1<ETX> →  
← <NAK>  
<STX> text 1<ETX> →  
← <ACK>  
<EOT> →

**<Example of resend attempts exceeding 5>**

<STX> text 1<ETX> →  
← <NAK>  
<STX> text 1<ETX> →  
← <NAK>  
<STX> text 1<ETX> →  
← <NAK>  
<STX> text 1<ETX> →  
← <NAK>  
<STX> text 1<ETX> →  
← <NAK>  
<EOT> →

**<Example of ACK receive timeout>**

<STX> text 1<ETX> →  
(after 10sec)  
Communication timeout

The HLC-723RP is designed to use the following three separate transmission procedures for transmissions conducted with host computer units.

1) Patient information

<STX> Patient information <ETX> →  
← <ACK> or <NAK>  
<EOT> →

2) GHb results

<STX>GHb results <ETX> →  
← <ACK> or <NAK>  
<EOT> →

3) Reserved record

STX>Reserved record <ETX> →  
← <ACK> or <NAK>  
<EOT> →

## 12.2 Result Transmission Formats

The results are transmitted using the following data formats.

### 1) Patient information

Information	Character count	Description
[ResultID]	1	R
[Result Discernment ID]	1	A
[Device ID]	2	No. used to identify device (00=Ghb1, 01=Ghb2, 02=Glu, 03= manual upload).
[Specimen ID]	20	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Sample no.]	3,5,8	Sample no
[Patient ID]	13	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[First name]	10	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Last name]	10	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Sex]	2	00: unknown, 01: male, 02: female
[Birth date]	10	9999/99/99
[Comment1]	20	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Comment2]	20	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.

### 2) GHb Results

Information	Character count	Description
[ResultID]	1	R
[Result Discernment ID]	1	B
[Operating mode]	1	0= standard method, 1= variant method, 2= $\beta$ thalassemia method
[Specimen position]	1	0=STAT, 1= transport, 2= loader
[Sample no.]	3,5,8	Sample no
[No.1 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.2 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.3 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.4 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.5 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.6 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces

[Component]		6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.7 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.8 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.9 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[No.10 Component]	5 or 6	5 : 0.0 ~ 100.0(Aligned right) or spaces 6 : 0.00 ~ 100.00(Aligned right) or spaces
[SA1c/F Coefficient A]	8	±z9.9999(Aligned right)
[SA1c/F Coefficient B]	8	±z9.9999(Aligned right)
[A2 Coefficient A]	8	±z9.9999(Aligned right)
[A2 Coefficient B]	8	±z9.9999(Aligned right)
[HWS Lot]	7	7 characters(Aligned right)
[COL Lot]	7	7 characters(Aligned right)
[CAL Lot]	7	7 characters(Aligned right)
[Eluent1 Lot]	7	7 characters(Aligned right)
[Eluent2 Lot]	7	7 characters(Aligned right)
[Eluent3 Lot]	7	7 characters(Aligned right)
[Flag result]	2	00 ~ 20(00= normal)
[Specimen ID]	20	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.

**No.1 Component - No.10 Component: The following values are taken by measurement mode.**

	Standard	Variant	Thalassemia
[No.1 Component]	FP%	A1a%	(HbF%)
[No.2 Component]	A1a%	A1b%	(A0%)
[No.3 Component]	A1b%	F%	(HbA2%)
[No.4 Component]	F%	LA1c%	(HbD+%)
[No.5 Component]	LA1c%	SA1c%	(HbS+%)
[No.6 Component]	SA1c%	A0%	(HbC+%)
[No.7 Component]	A0%	H-V0%	(Reserve)
[No.8 Component]	(Reserve)	H-V1%	(Reserve)
[No.9 Component]	(Reserve)	H-V2%	(Reserve)
[No.10 Component]	T-A1	T-A1	(Reserve)

While it is possible to use settings that do not specify the specimen ID in the GHb unit, the HLC-723RP Reporting Program requires the use of barcodes when issuing specimen queries. This makes it essential those specimens IDs (barcodes) are used.

Please make the number of characters of [No.1 ~ No.10 Component] into five characters.

### 3) Reserved record (Glu Results)

Information	Character count	Description
[ResultID]	1	R
[Result Discernment ID]		C
[Effective flag]	1	0= invalid, 1= valid
[Device ID]	2	No. used to identify device (00=Ghb1, 01=Ghb2, 02=Glu, 03=manual upload)
[Specimen ID]	20	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Patient ID]	13	Aligned left and filled in with spaces if maximum digit count not used. Zero suppressing not used.
[Analyte no.]	4	0101= glucose,0303=urine, C999=control,S999=stat
[Glu result]	10	99999999 (Aligned right), 2 extra digits
[Comment]	4	9999 (Aligned right)
[Verification flag]	2	X0: Verified, X1: reassayed data

## 12.3 Request Query Transmission Format

### HLC-723RP to Host Computer

Information	Character count	Description
G	1	Request query code (fixed as alphanumeric character G)
[Query item]	2	Request query unit (00=GHb1, 01=GHb2, 02= Glu)
,	1	comma
[Specimen ID]	20	Aligned left and filled in with spaces if maximum 20 digits count not used. Zero suppressing not used.

**Host to HLC-723RP**

Information	Character count	Description
A	1	Order code (fixed as alphanumeric character A)
[Response item]	2	Response item (00=Ghb1, 01=Ghb2, 02= Glu)
,	1	comma
[Specimen ID]	20	Aligned left and filled in with spaces if maximum 20 digits count not used. Zero suppressing not used. Specimen ID for query set.
,	1	comma
[Patient ID]	13	Aligned left and filled in with spaces if maximum 13 digits count not used. Zero suppressing not used.
,	1	comma
[First name]	10	Aligned left and filled in with spaces if maximum 10 digits count not used.
,	1	comma
[Last name]	10	Aligned left and filled in with spaces if maximum 10 digits count not used.
,	1	comma
[Sex]	2	00: unknown, 01: male, 02: female
,	1	comma
[Birth date]	10	9999/99/99
,	1	comma
[Comment 1]	20	Aligned left and filled in with spaces if maximum 20 digits count not used. 20 single-byte characters
,	1	comma
[Comment 2]	20	Aligned left and filled in with spaces if maximum 20 digits count not used. 20 single-byte characters
,	1	comma
[Specimen type ]	2	00=Whole blood, 01= diluted
[Container type]	2	00= primary tube, 01= sample cup
[Spare]	2	(fixed as space)
,	1	comma
[A1c analyte]	2	00= no request, 01= request present
[Spare]	6	(fixed as space)
,	1	comma
[Type]	2	Normally "10"
[ContainerType (Glu)]	2	01= container 1
[Analyte no.]	4	0101= glucose, 0303=urine, space = not assayed
[Spare]	2	(fixed as space)
,	1	Comma
[Glu analyte]	2	00= no request, 01= request present
[Spare]	6	(fixed as space)
,	1	comma
[Spare]	8	(fixed as space)

## 12.4 The actual example of Transmission

"S:" expresses the communication to a host computer from HLC-723RP, and "R:" expresses the communication to HLC-723RP from the host computer.

### Query of GHb

```
S:<STX>G00,05410469029      <ETX>
R:<ACK>
S:<EOT>
R:<STX>A00,05410469029      ,0000011978293,LastName ,FirstName ,01
,      ,      ,      ,0000 ,01      ,10010101 ,00      ,      <ETX>
S:<ACK>
R:<EOT>
```

### Transmitting result of GHb

```
S:<STX>RA0005410469029      091800050000011978293LastName
FirstName 01      <ETX>
R:<ACK>
S:<EOT>
S:<STX>RB10209180005 0.0 0.4 0.9 0.3 1.9 5.0 92.1 0.0 0.0 6.4 1.0000
0.0000      1.0000
0.0000aaaaaaabbbbbbbccccccddddddeeeeeeffffff0005410469029
<ETX>
R:<ACK>
S:<EOT>
S:<STX>RC00005410469029      0      <ETX>
R:<ACK>
S:<EOT>
```



TOSOH

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