TOSOH

G7/G8 Reporting Software User's Guide

P/N 997002
Version 6.0

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Contents

Preface

Thank you for purchasing the HLC-723RP Glycohemoglobin Reporting Software 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-723G7 or HLC-723G8.

To ensure correct operation of the HLC-723RP Reporting Software Program, operators are recommended to carefully read and familiarize themselves with the G7 and G8 Operators Manual, its safety precautions and basic operating procedures.

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


Caution

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

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


Caution

Users are recommended to carefully read and familiarize themselves with the information in this manual to ensure proper and safe operation of the Glycohemoglobin Analyzer and the Reporting Software Program.
Keep the 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 for specimens and please do not use duplicate barcodes.
When barcodes are duplicated, editing patient information will affect all results which have the same barcode. Please check that there is no duplicate barcodes before editing patient information.
The barcode containing the character "@" can not be used in the Thalassemia mode. This software uses this character for another purpose.

The information contained herein is subject to change without prior notification due to ongoing improvements to system performance and functionality.
Users are forbidden from reselling or distributing this application to a third party.
Users are requested to immediately notify a Tosoh Bioscience technical support specialist if they notice any discrepancies, errors or omissions in the information provided herein.

TRADEMARKS

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1 Basic System Precautions

1.1 Registering Operations

The HLC-723RP Reporting Program requires the operators 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 will install the HLC-723RP Reporting Program and follow the user's guide for basic system orientation. It is important that system operators be 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 G7/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 G7/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 G7/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 G7/G8 Operation Manual. The Automatic Transmit must be turned on. On the G7 this is found on page 3 under parameter. On the G8 this is found on the RS232 screen.

PROCEDURE FOR G7:
Press **Menu**
Press **Parameter**
Scroll down twice to page 3
Press **AUTO TRANS** and an asterisk will appear
Press **1** and **Enter**

PROCEDURE FOR G8:
Press **Menu**
Press **Utility**
Press **RS232**
Press **AT TRANS**

The RS232 settings must specify 'RAW' mode in both the G7 and G8
PROCEDURE:
Press **Menu**
Press **Utility**
Press **RS232**
Press **RAW** so it is back-highlighted

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

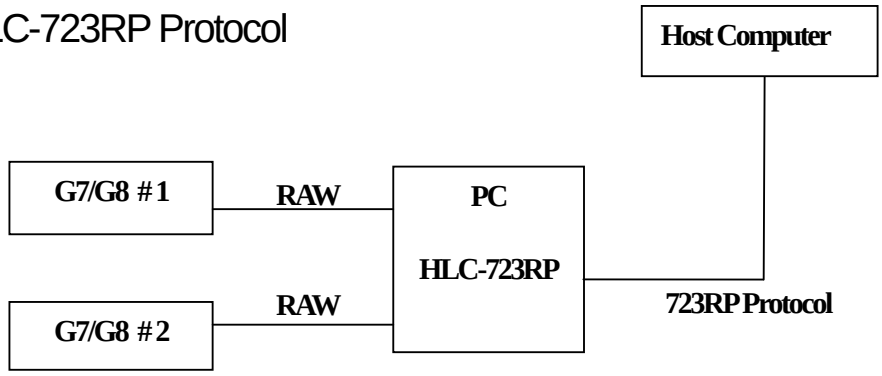
2.1 Introduction

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

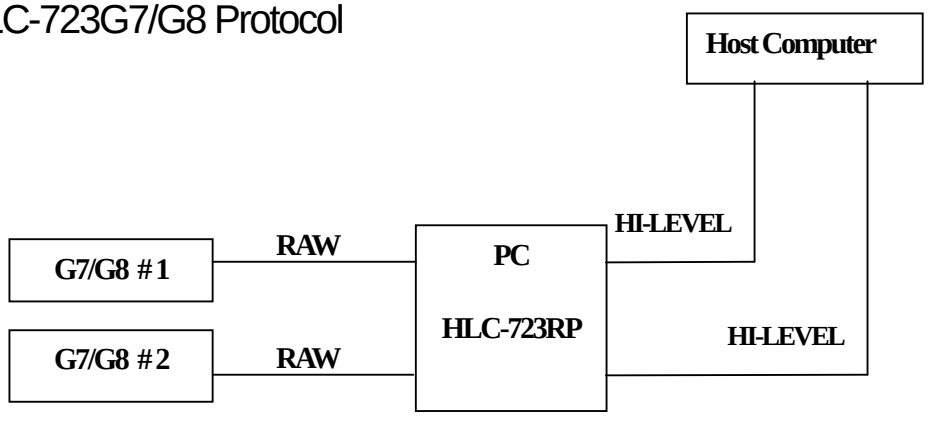
HLC-723RP is designed to connect up to two Glycohemoglobin Analyzers and is equipped with two transmission protocols. One transmission protocol is HLC-723 RP protocol (see Fig. A), used when connecting to the host computer with a single transmission line, and the other protocol is the G7/G8 protocol (see Fig. B), used when connecting to the G7/G8 using their transmission specifications.
Transmissions between G7/G8 and PC uses the G7/G8's Raw mode protocol found under the RS232 screen.
Transmissions between PC and host computer use the high-Level mode protocol or HLC-723RP protocol.

A) HLC-723RP Protocol



* Specimen queries are enabled.

B) HLC-723G7/G8 Protocol



* Specimen queries are enabled.

** Version 2.xxE can not use this configuration.

2.3 Equipment Required by the Reporting Program

Please ensure this application is installed on the type of personal computer 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.

Equipment

Designated PC DELL Optiplex GX520 , DELL Optiplex GX620

Operating System	Windows XP Professional
CPU	Pentium 4 2.8 – 3.4 GHz
Memory	1 GB
Hard drive	80 – 160 GB
Serial Port	2 or more if the PC is interfaced to HOST

RS232C cable (9-pin × 9-pin cross) Analyzer to CPU

RS232C cable (9-pin × 25 or 9-pin cross) CPU to Host

USB-SERIAL converter- if two Glycohemoglobin Analyzers are to be connected with a USB port

USB cable (1.8m)

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

Caution

The installation and setup procedures are performed by an authorized representative.
Contact must be made to the authorized representative whenever moving the system to a new location, regardless of proximity.

The reporting program the HLC-723RP has three different version 2.xxS, 2.xxE and 2.xxDS for same version number 2.xx. The following programs shown in Table 1 are contained in the CD-ROM. Table 2 shows appropriate program version numbers to be applied in accordance with the connection structure. There are 3 folders in the CD-ROM as shown in the Table 1 below.

Table 1 HLC-723RP CD-ROM

	Folder Name	Software Program Version Number
Contents of the HLC-723RP CD-ROM	G7	Ver. 2.09S
	G8	Ver. 2.09E
	DS-120 (*)	Ver. 2.09DS

(*) The DS-120 is a sample transportation unit which is available only in Japan, and it is connected between a Tosoh GHb analyzer and a glucose analyzer supplied by another company in Japan.

Table 2 Program Version Number for each connection structure

Connection structure	Program Version Number to be applied
G7	Ver. 2.09S
G7 – G7	Ver. 2.09S
G7 – G8	Ver. 2.09S
G8 (In the case the communication protocol will not be changed from that used for the G7 even the G7 is replaced with the G8)	Ver. 2.09S
G8 – G8 (In the case the communication protocol will not be changed from that used for the G7 even the G7 is replaced with the G8)	Ver. 2.09S
G8 (In the case the RP will be newly installed or the current communication protocol will be changed accompanying a replacement of the G7s with the G8s)	Ver. 2.09E
G8 – G8 (In the case the RP will be newly installed or the current communication protocol will be changed accompanying a replacement of the G7s with the G8s)	Ver. 2.09E

When using the program Ver. 2.09S for the G8, please note that the "TRANS G5/7 MODE" parameter in the instrument should be set to 7 (G7 communication format) and the seventh digit of the "#OPTION M" should be set to 1 ("0" will be transmitted to the host computer as the area% value if an error occurs).

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 G7/G8 root folder.
Setup installs the application in the "C:\Copula" folder using the folder/file configuration shown below.
Refer to the printer instructions to install the Printer Driver.

Copula(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

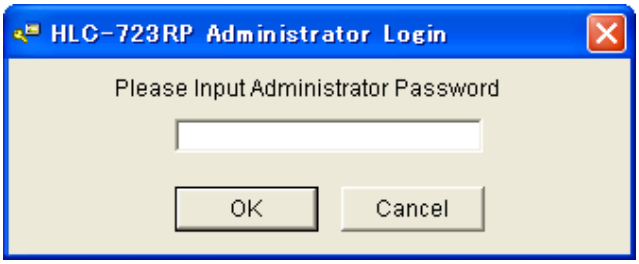
The connecting of cables is performed by the authorized representative using the following procedures.

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

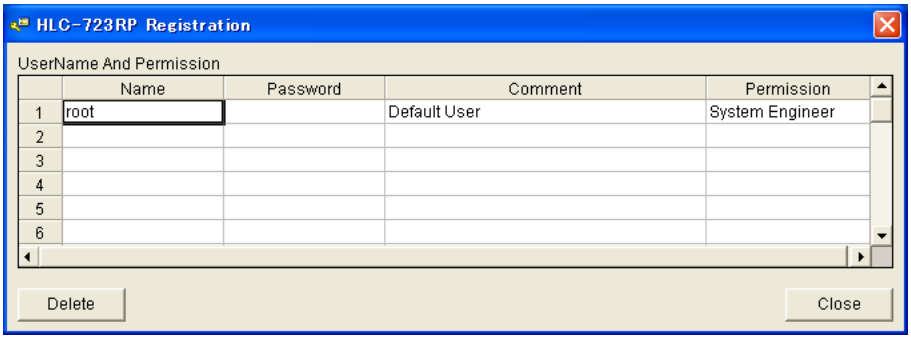
The Administrator can register operators for the application by the User Manager, as follows: Select All Programs from the Start menu, and then click User Manager in the HLC-723RP menu. Enter password and click the OK button. An authorized representative will perform the installation and provide the Administrator with the User Manager password.



Administrator Password Entry

Note: 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 desired use the Registration screen by entering a Name, and choosing a Password and Permission.



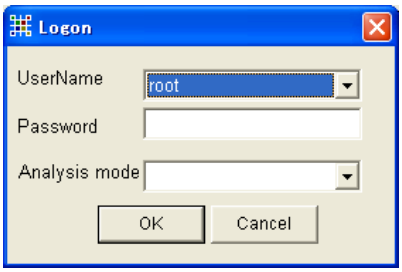
User Registration

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

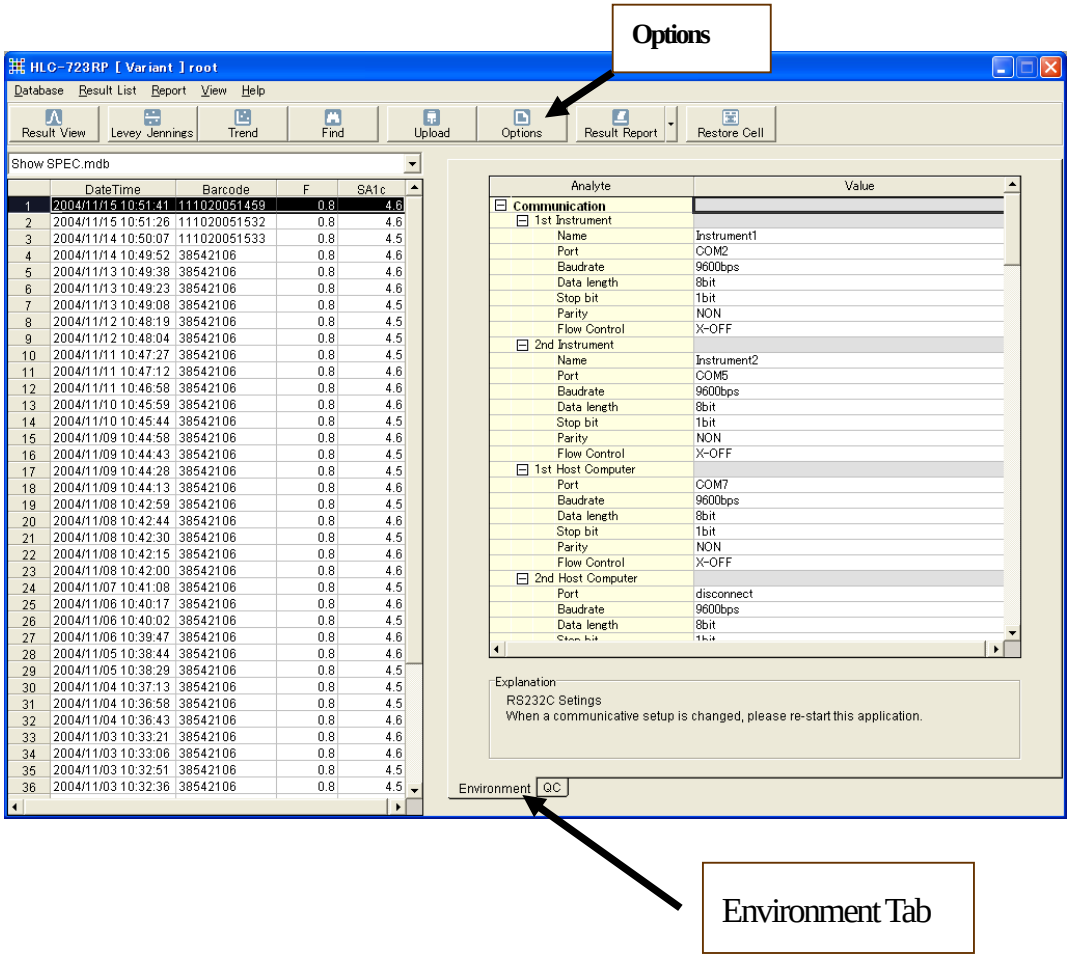
4 Options Environment Settings

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.



Environment Settings Screen

The environment Settings parameters are listed in the table below for version 2.xxS. Before using system, the following parameters need to be set:

Communication	RS232C Settings
1st instrument	Use same settings as analyzer.
Name	Enter analyzer name.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as analyzer.
Data length	Use same settings as analyzer.
Stop bit	Use same settings as analyzer.
Parity	Use same settings as analyzer.
Flow control (yes/no)	Use same settings as analyzer.
2nd instrument	Use same settings as analyzer.
Name	Enter analyzer name.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as analyzer.
Data length	Enter Data Length.
Stop bit	Use same settings as analyzer.
Parity	Use same settings as analyzer.
Flow control (yes/no)	Use same settings as analyzer.
1st host computer	Use same settings as host.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as host.
Data length	Use same settings as host.
Stop bit	Use same settings as host.
Parity	Use same settings as host.
Flow control (yes/no)	Use same settings as host.
2nd host computer	Use same settings as host.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as host.
Data Length	Use same settings as host.
Stop bit	Use same settings as host.
Parity	Use same settings as host.
Flow control (yes/no)	Use same settings as host.
HOST Connection Method	Protocol depends on line type.
GHb Com format	G5 or G7 format
Connection method	Unity- one cable connection
Query (yes/no)	Select whether or not to allow specimen queries.
QCQuery (yes/no)	Select whether or not to allow control queries.
Auto upload (yes/no)	Select whether to automatically send results to host.
Instrument Information	Enter analyzer information settings.
Composition of instrument	Do not modify after operation commences.
No. of sample number length	Do not modify after operation commences.
GA:protocol	Do not modify after operation commences.
Print Conditions	Entered information for printing.
Add patient information	Add patient information to printout.
Total Area Option	Indicate presence of addition for each Component using “0” or “1”.

Automatic Report	Prints results real time.
1 data/page default	Specify paper.
TM-J2000 (yes/no)	Specify whether printer is available.
Paper size (A4/Letter)	Specify printer paper size.
Patient Header right	Enter customized comment.
Patient Header center	Enter customized comment.
Patient Header left	Enter customized comment.
List Header right	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 ± value
A1b	Specify whether to check value A1b.
Marker	Central value
+/-	Central value ± value
F	Specify whether to check value F.
Marker	Central value
+/-	Central value ± value
LA1c	Specify whether to check value LA1c.
Marker	Central value
+/-	Central value ± value
SA1c	Specify whether to check value SA1c.
Marker	Central value
+/-	Central value ± value
AO	Specify whether to check value A0.
Marker	Central value
+/-	Central value ± value
T-A1	Specify whether to check value T-A1.
Marker	Central value
+/-	Central value ± value
A2	Specify whether to check value A2.
Marker	Central value

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

Period	Expiration listed on label
Eluent 1 lot (2)	Lot number listed on label
Period	Expiration listed on label
Eluent 2 lot (2)	Lot number listed on label
Period	Expiration listed on label
Eluent 3 lot (2)	Lot number listed on label
Period	Expiration listed on label
Column lot (2)	Lot number listed on label
Calibrator lot (2)	Lot number listed on label
Period	Expiration listed on label
Screen	Specifies display font.
Font	Factory default is Arial.

The environment Settings parameters are listed in the table below for version 2.xxE. Before using system, the following parameters need to be set:

Communication	RS232C Settings
1st instrument	Use same settings as analyzer.
Name	Enter analyzer name.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as analyzer.
Data length	Use same settings as analyzer.
Stop bit	Use same settings as analyzer
Parity	Use same settings as analyzer.
Flow control (yes/no)	Use same settings as analyzer.
2nd instrument	Use same settings as analyzer.
Name	Enter analyzer name.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as analyzer.
Data length	Enter Data Length
Stop bit	Use same settings as analyzer.
Parity	Use same settings as analyzer.
Flow control (yes/no)	Use same settings as analyzer.
Host computer	Use same settings as host.
Port	Enter Com port number.
Baud rate	Enter same transmission speed as host.
Data length	Use same settings as host.
Stop bit	Use same settings as host.
Parity	Use same settings as host.
Flow control (yes/no)	Use same settings as host.
HOST Connection Method	Protocol depends on line type.
Query (yes/no)	Select whether or not to allow specimen queries.
QCQuery (yes/no)	Select whether or not to allow control queries.
Auto upload (yes/no)	Select whether to automatically send results to host.
Instrument Information	Enter analyzer information settings
Composition of instrument	Do not modify after operation commences.
No. of sample number length	Do not modify after operation commences.
Print Conditions	Entered information for printing.
Add patient information	Add patient information to printout.
Total Area Option	Indicate presence of addition for each Component using “0” or “1” setting.
Automatic Report	Prints results real time
1 data/page default	Specify paper
TM-J2000 (yes/no)	Specify whether printer is available.
Paper size (A4/Letter)	Specify printer paper size.
Patient Header right	Enter customized comment
Patient Header center	Enter customized comment
Patient Header left	Enter customized comment
List Header right	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 ± value
A1b	Specify whether to check value A1b.
Marker	Central value
+/-	Central value ± value
F	Specify whether to check value F.
Marker	Central value
+/-	Central value ± value
LA1c	Specify whether to check value LA1c.
Marker	Central value
+/-	Central value ± value
SA1c	Specify whether to check value SA1c.
Marker	Central value
+/-	Central value ± value
AO	Specify whether to check value A0.
Marker	Central value
+/-	Central value ± value
T-A1	Specify whether to check value T-A1.
Marker	Central value
+/-	Central value ± value
A2	Specify whether to check value A2.
Marker	Central value
+/-	Central value ± value
Glu	Specify whether to check value Glu.
Marker	Central value
+/-	Central value ± value
For Trend Chart (Statistics)	
A1c	Line for threshold value displayed for A1c.
Line color	Specifies line color.
Mark	Specifies mark shape.
Marker	Central value
+/-	Central value ± value

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

Screen	Specifies display font
Font	Factory default is Arial

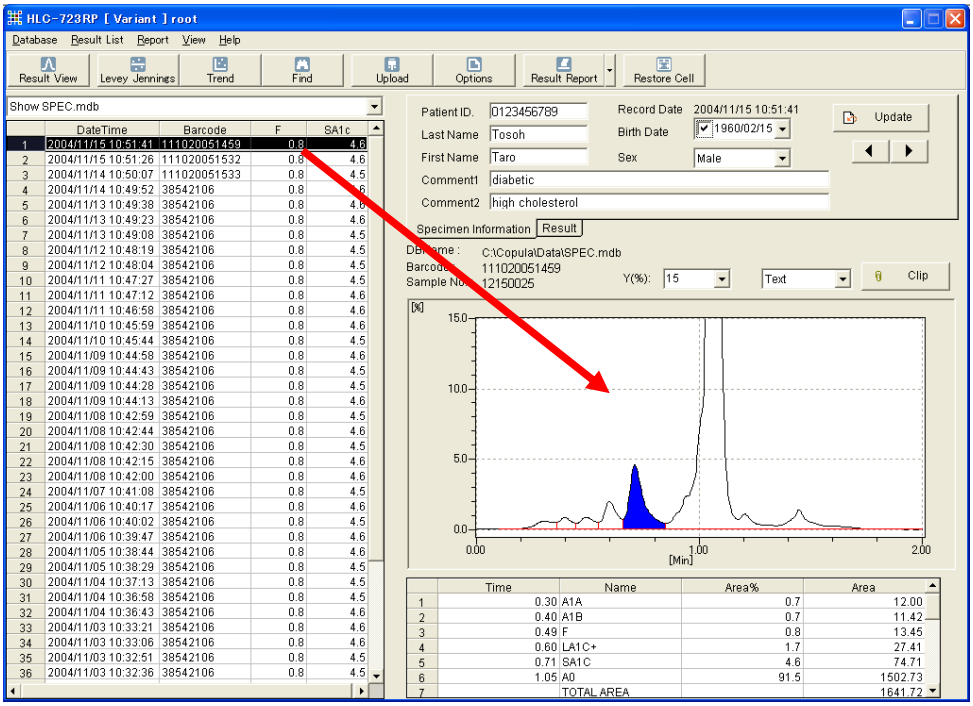
5 Receiving Results

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.

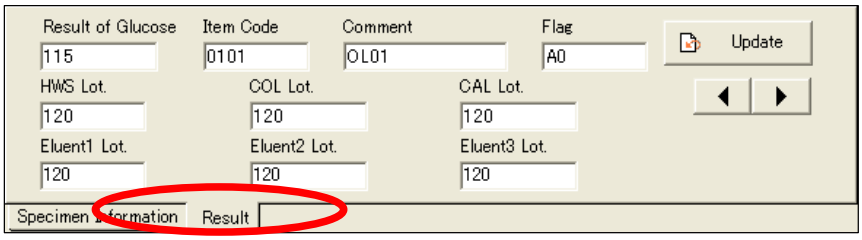
5.2 Displaying Results

Selecting Result View displays the chromatogram and the results.



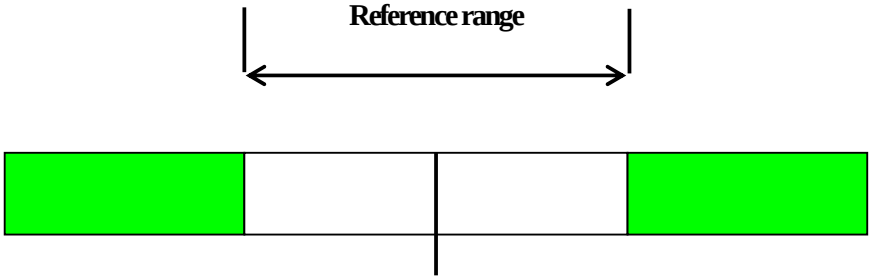
Chromatogram View Screen

Select the “Result” tab to view lot numbers

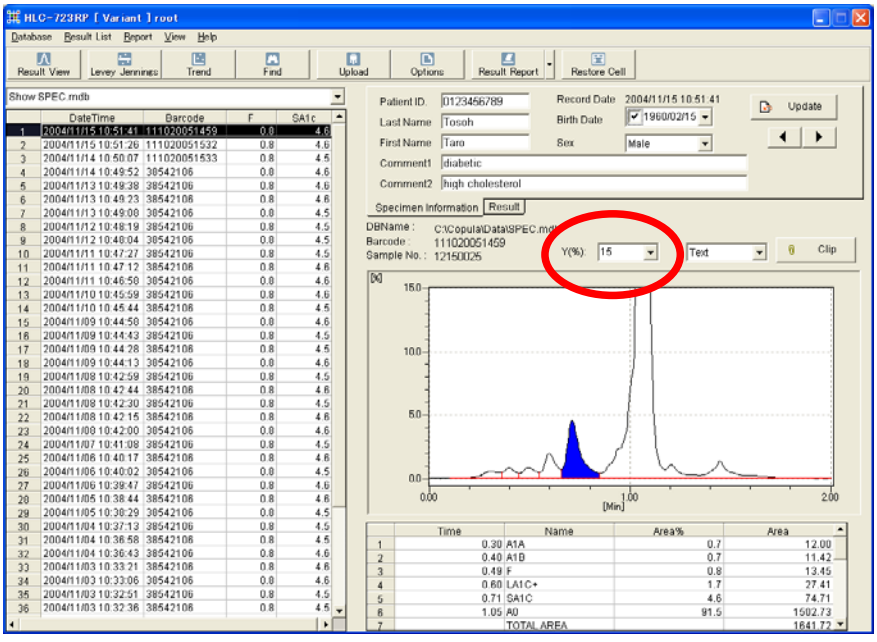


The color of the results list is as follows:
Results from primary tubes shows in black characters. The results with a flag show the background in pink.
Results from calibrators are blue and results of controls shows the background of the barcode cell in gray.

If the reference value is 5.0 ±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.



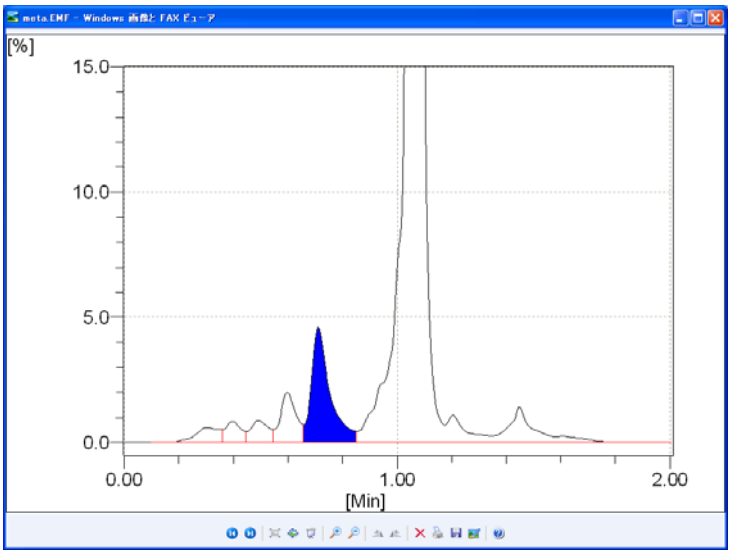
The chromatogram scale can be changed by choosing from the Y (%) combo box.
Y (%) can also be directly entered in the combo box. The results can also be displayed on a fixed scale by entering the Y- and X-axis values in the Environment Settings screen.
The Restore Cell button resets the cell width of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



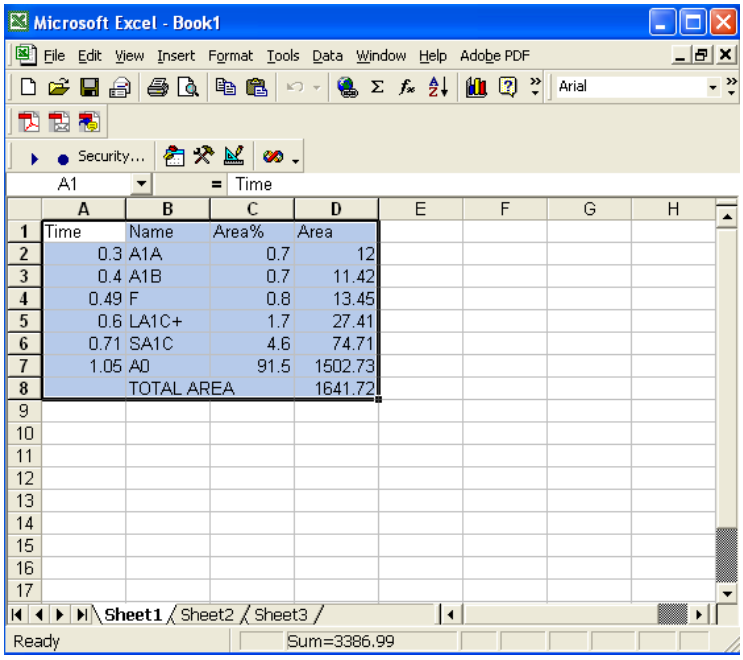
Chromatogram View Screen

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 a word or excel document.

Enhanced Metafile Format



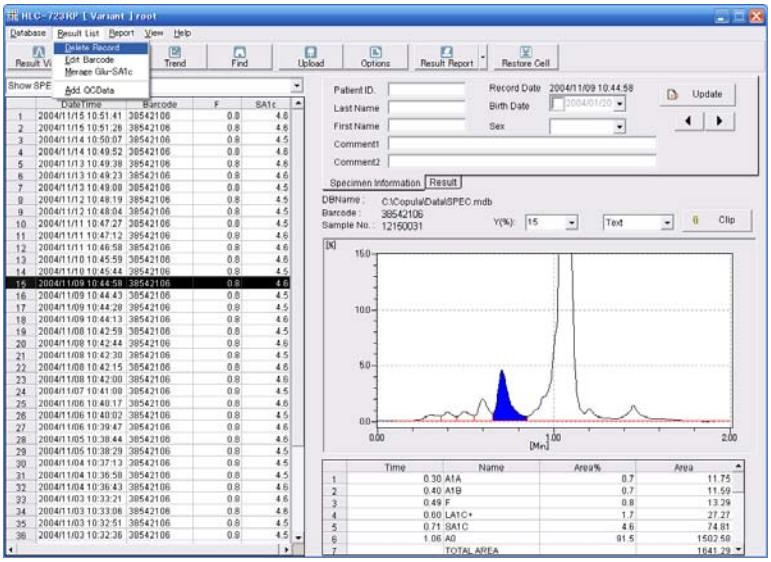
Text Format



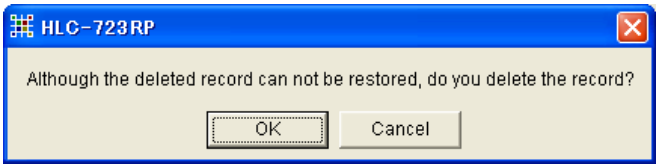
5.3 Deleting Records

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

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



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

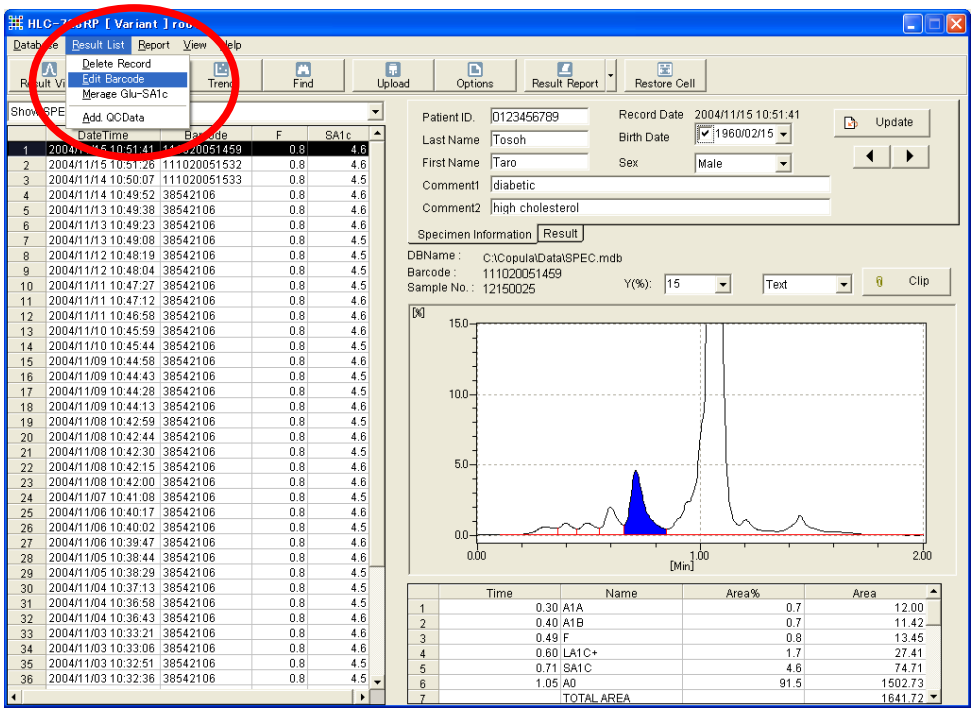


Selected records are deleted and the following dialog box appears.

The deleted records cannot be restored.

5.4 Editing Barcode

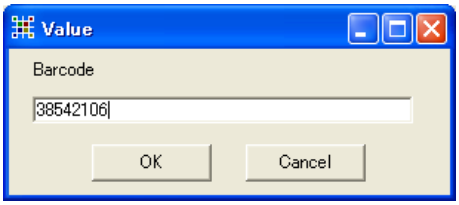
The Glycohemoglobin Analyzer will analyze samples, even if it fails to read the barcode.
The failed sample is displayed as a rack # and position #. This can be edited after analysis as follows:
Select a result in the Result List as shown below.



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 barcode length should be the same as the instrument barcode settings. Choose the barcode length in the Environment Settings screen.



Barcode Entry Dialog Box

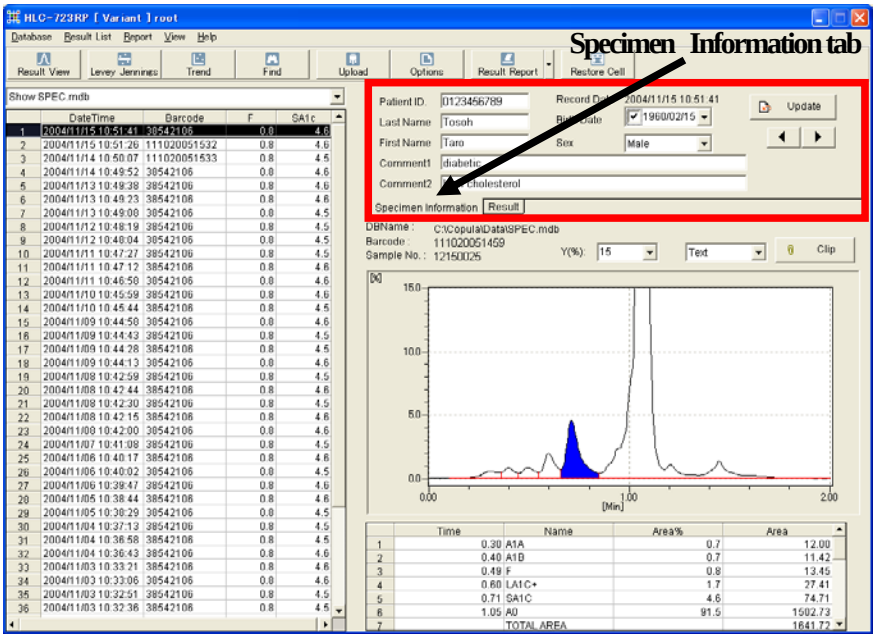
When the following dialog box appears, click the OK button.

The Result List containing the barcode is updated.

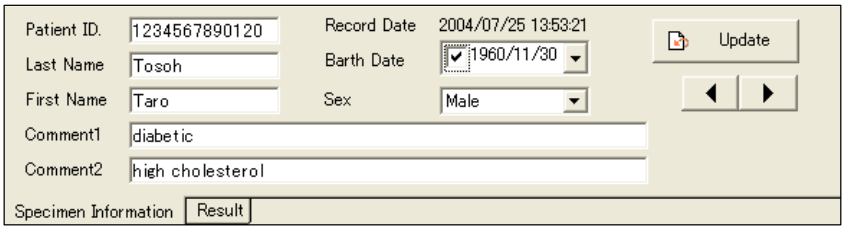
	DateTime	Barcode	F	SA1c
1	2004/11/15 10:51:41	38542106	0.8	4.6
2	2004/11/15 10:51:26	111020051532	0.8	4.6
3	2004/11/14 10:50:07	111020051533	0.8	4.5
4	2004/11/14 10:49:52	38542106	0.8	4.6
5	2004/11/13 10:49:38	38542106	0.8	4.6

Be careful. Please check that there are no duplicated barcodes before editing.
If barcodes are edited, Patient information such as the patient ID, or last name, may be lost.
If there exists some results which have the same barcode as the edited barcode, the patient information of the edited result is replaced by that of the other results which have the same barcode as the edited barcode.

5.5 Entering Patient Demographics



Chromatogram View Screen



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

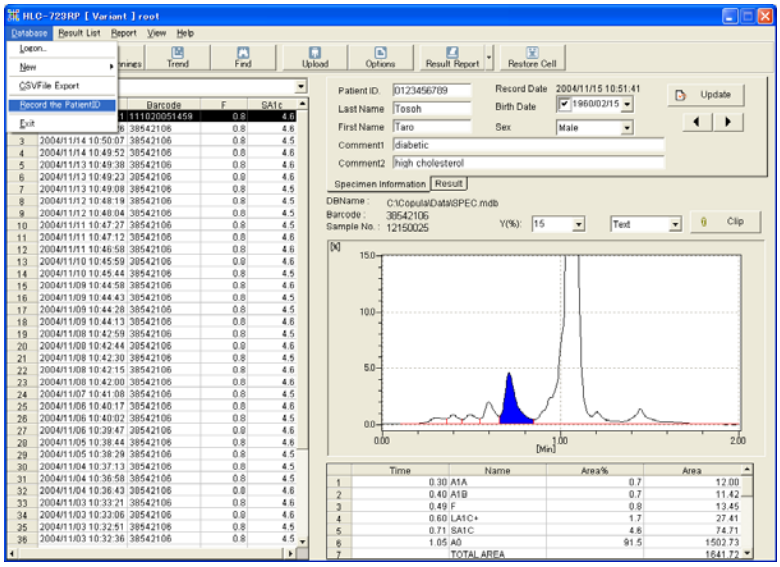
Please ensure the entered information is correct, as this will result in inaccurate reports.
The edited results are reflected in the patient information on other results which have the same barcode as the edited result. Please check there is no duplicated barcode before edit this information.

Please disable the Automatically Refresh function in the View drop down menu when editing the patient information, otherwise the editing information may be lost at a new result is obtained.

5.6 Patient ID Management

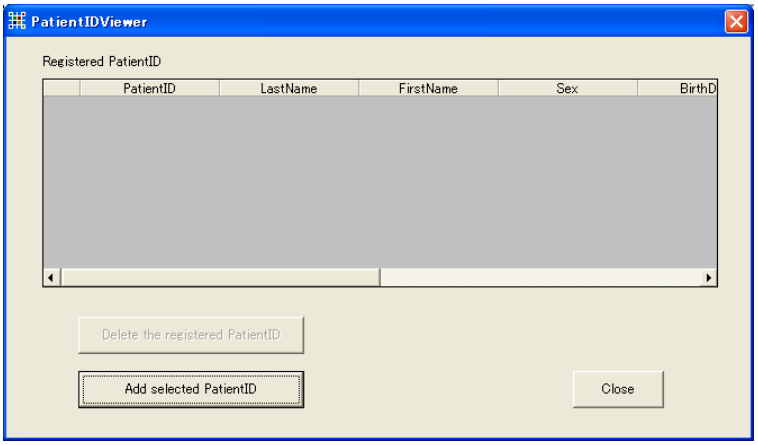
The software can remember the specific Patient ID and indicates that the sample with the same Patient ID was measured in the past. The background of the Barcode cell for the selected data is shown in yellow. Even if it changes to a new database, the specific Patient ID data is memorized.
The specific Patient ID is registered by the following procedure.

Select the data with Patient ID.



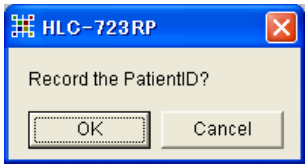
Chromatogram View Screen

Click “Record the Patient ID” from the Database drop down menu. The Patient IDViewer is displayed.

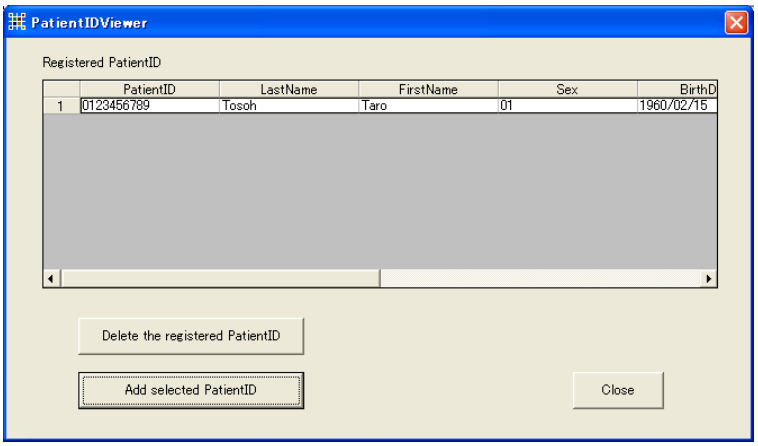


Patient ID Viewer

Click the Add selected Patient ID button.
When the following dialog box appears, click the OK button.



The selected Patient ID is registered as a specific sample.



Patient ID Viewer

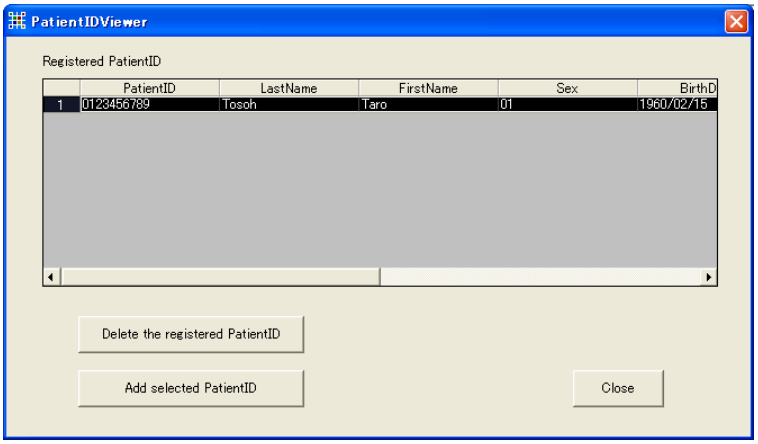
The background of the Barcode cell of the registered specific sample data becomes yellow.

	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 Patient ID and QC data cannot be registered as a specific sample.

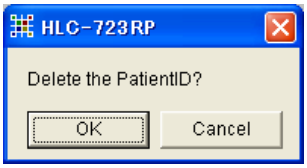
Delete a specific registered Patient ID by the following procedure.

Select a record to delete in Patient ID Viewer.

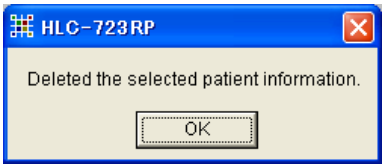


Patient ID Viewer

Click the Delete the registered Patient ID button.
When the following dialog box appears, click the OK button.



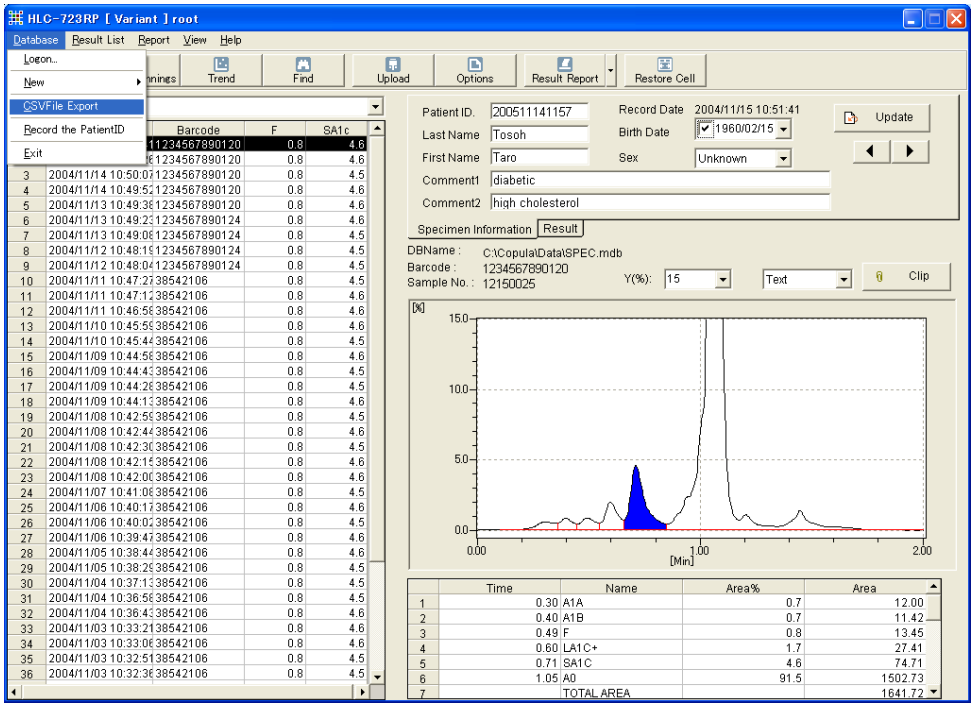
The following message is displayed after the deletion of selected data.



Click the OK button.
Click the Close button when completed.

5.7 Export to a CSV file

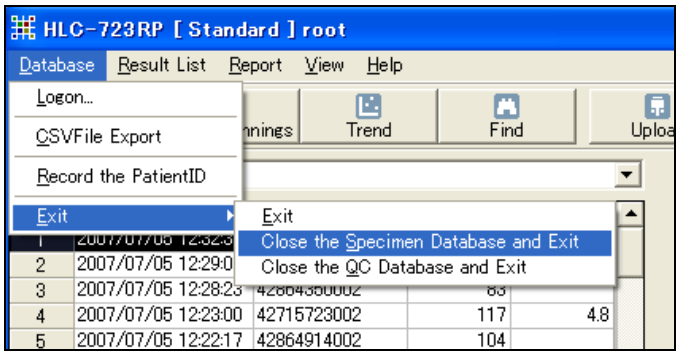
The result list can be exported to a CSV file.
Click “CSVFile Export” from the Database drop down menu. The exported file is saved in “C:\Copula\(G8)Data” folder.



Chromatogram View Screen

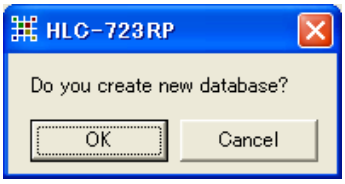
5.8 Managing Results

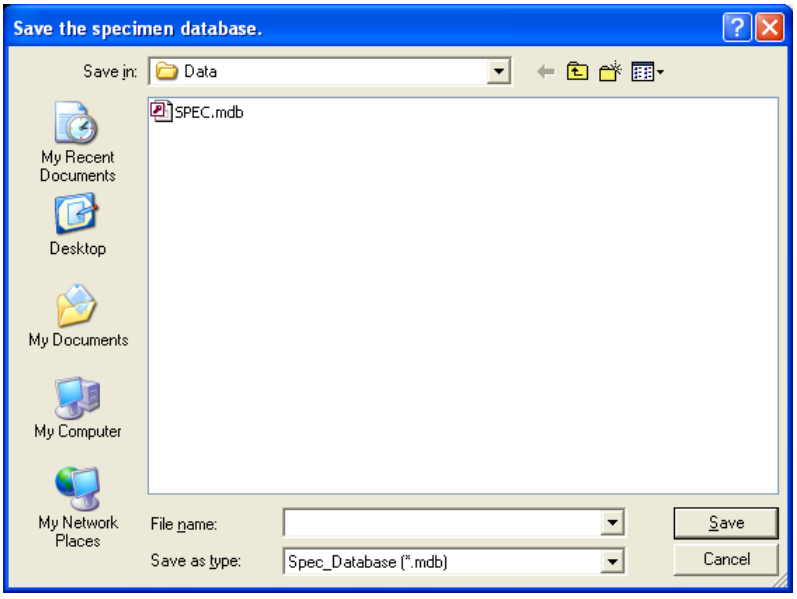
The results are stored in the "SPEC.mdb" contained in the "C:\Copula(G8)\Data" folder.
The procedure for changing to a new database is described below.
Select "Exit" from the Database drop down menu and then select "Close the Specimen Database and Exit".



Chromatogram View Screen

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

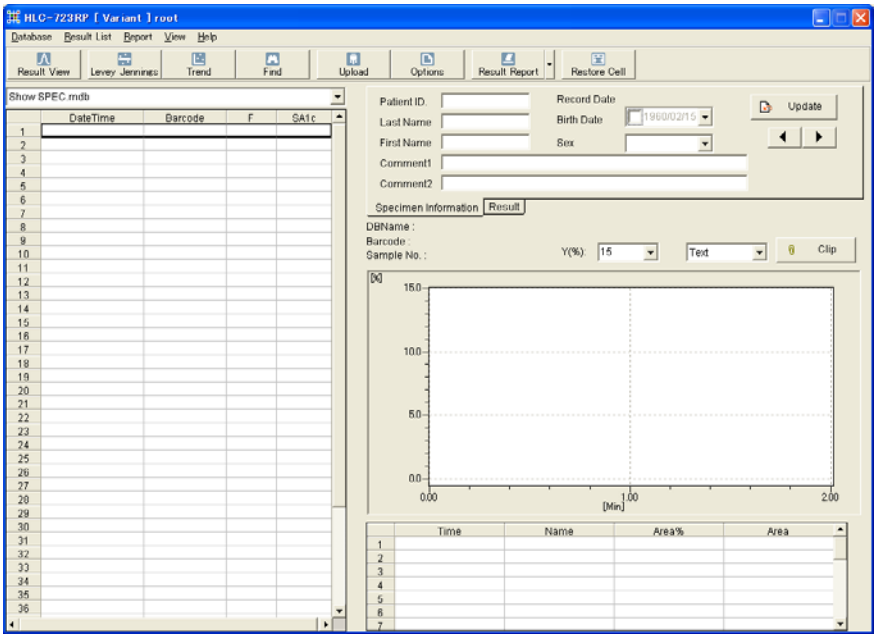




Enter file name and select the Save button.

This completes the creation of the new database. Use the Start menu or click the desktop icon to restart the HLC-723RP Reporting Program.

Saved databases can be accessed in the Find function.



Chromatogram View Screen (empty database)

Database files can be backed up to a CD from the hard drive by the following procedure.
You cannot be using the G7/G8 Reporting Software while you perform this function.

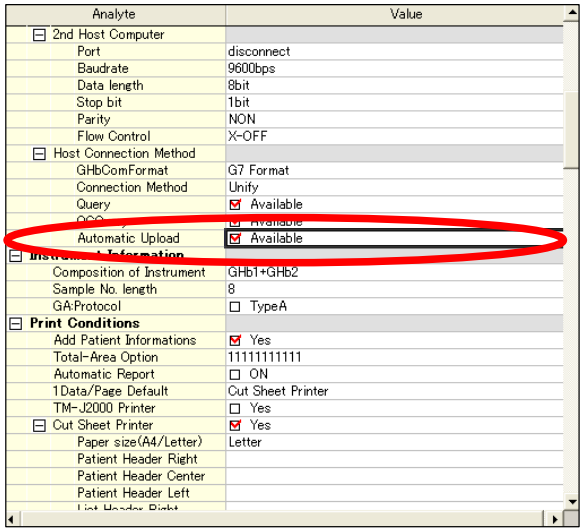
Put a blank CD in the CD drive.
On the screen - click the START icon
My Computer,
C Drive,
Copula Folder,
Data Folder,
Select the files you want to archive. For example you have 16 files for the last 4 months - select all 16 files and right click to COPY,
Then go to My Computer
D drive,
Paste the 16 files you had copied previously.
There is a message that reads, 'Do you want to write to the CD'
Click 'YES' and the files will be written to the CD.

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.

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.

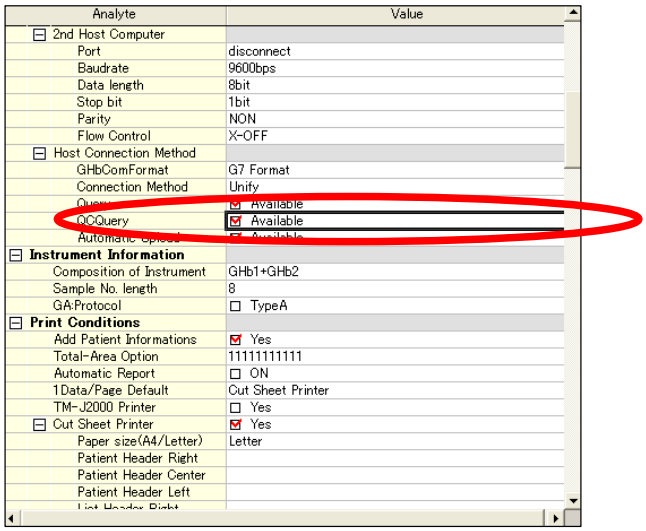


Environment Settings Screen (Environment Tab)

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

The 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. In order to query controls to a host computer, check the “QC query” (see red circle in screen below) in the Environment Settings screen found under Options.



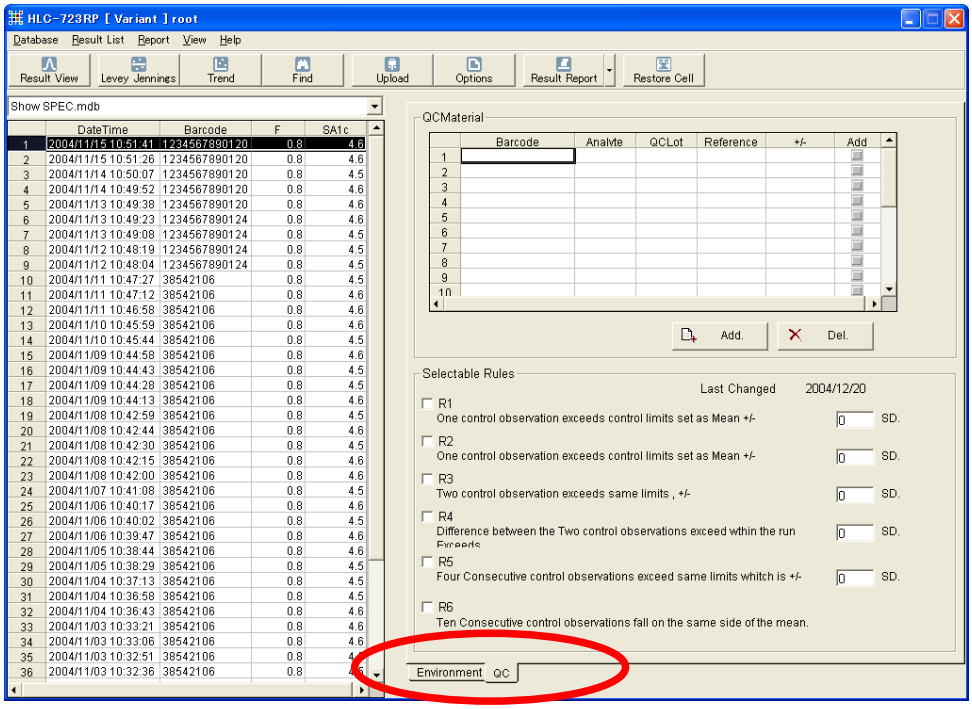
Environment Settings Screen (Environment Tab)

In order to use the Quality Control feature in the software, it is necessary to register the control barcodes as QC materials. Refer to Chapter 7 for details. Note that barcodes for QC material must be used when operating in the query mode.

7 Quality Control (QC)

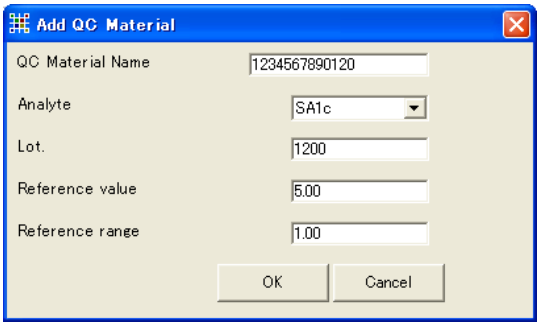
7.1 QC Materials

It is necessary to define QC materials in advance. Barcodes can be used to identify the controls. QC materials are defined by the following procedure.
Select Options and then choose the QC tab in the Environment Settings screen.



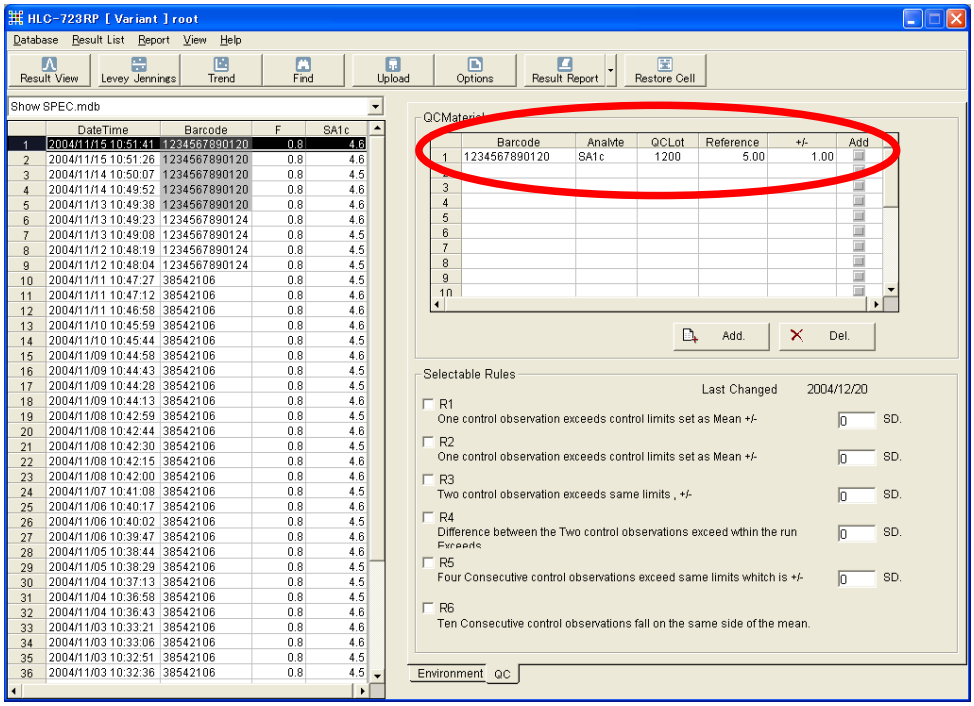
Environment Settings Screen (QC tab)

Select the Add QC Material button to show the following dialog box.
Enter the QC Material Name (barcode # or text). Do not use any spaces in the name field. Select SA1c from the drop down menu. Type in the Lot. Type the Mean Value in the Reference value field and +/- acceptable range from the control material package insert. Select the OK button.



Example above is a mean value of 5.00%. The QC range is 4.0 to 6.0. The range is +/- 1.0.

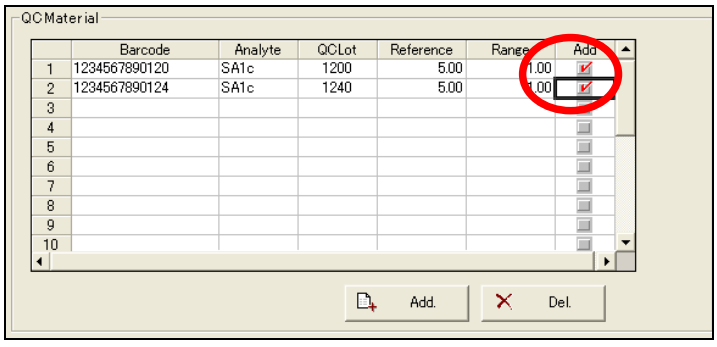
The new QC materials will be added to the worksheet. See circle in the screen below.



Environment Settings Screen (QC Tab)

In Thalassemia mode, the system creates a 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 Material 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.

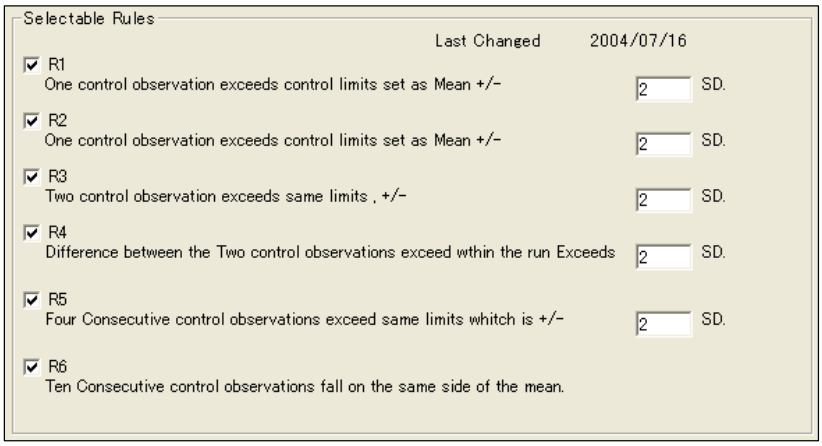
R3: Result is R3-flagged when discrepancy between the mean and two consecutive observed values exceed a specified SD value.

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.



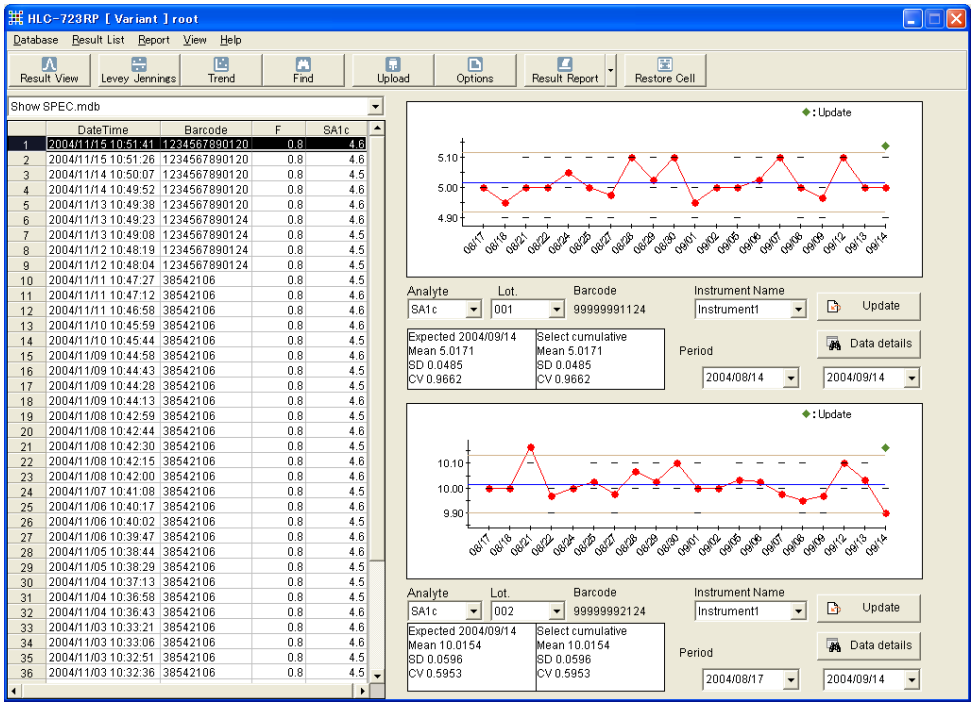
Selectable Rules Screen

If a QC barcode is not read it is possible to edit the barcode and enter the data into the QC database by the following procedure.
Select the line of the barcode to be edited from the result list.
Under the Result List drop down menu, select “Edit Barcode” and the Value entry dialog box will appear.
Enter the barcode ID (QC barcode), up to 20 alphanumeric characters.
Under the Result List drop down menu, select “Add QCData”.
This data will now be added to the QC database.

7.3 Levey-Jennings Chart

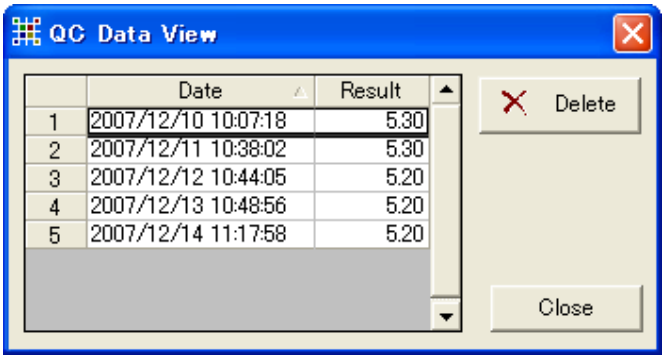
The Levey-Jennings Chart screen shows the Xbar control chart. The control used is decided by analyte, lot, barcode and instrument name. The blue line on the Xbar control chart is the entered mean, and the red point is the average of data run on a particular day.
Levey-Jennings charts are made automatically whenever barcoded controls are run.
If barcodes are not used for controls, the QC results can be entered by the following procedure.
Select one QC data from the result list.
Under the Result List drop down menu select "Add QCData".

Note that two or more data points must be added in order to plot a Levey-Jennings chart.
Choose analyte and lot from the boxes and the Levey-Jennings chart will appear.
Complete the procedure by selecting the time frame found from the Period drop down menus.



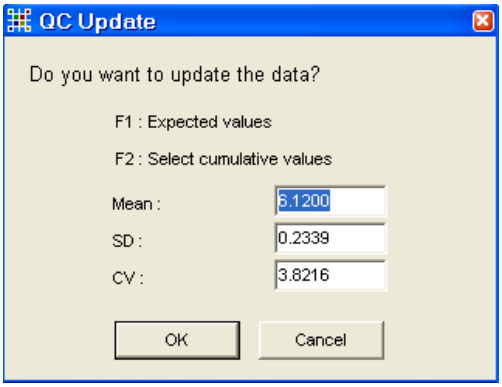
Levey-Jennings Chart Screen

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". Selecting the Data details button shows the following QC Data View dialog box containing the individual data points and the date and time they were run. Points can be deleted by selecting the line from the list and then selecting the Delete button.



On the "QC Data View" screen, double-clicking on the header cells circled in red in the above figure initiates a record sorting in ascending or descending order.

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



Statistical Information

Control range (Expected)

These are the values entered in the Environment Settings QC tab.

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.

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

Control range (Select Cumulative)

This is a statistical value for the graph display period (date range).

Mean: Average value

SD: Standard deviation

CV: CV%

The Mean, SD and CV can be changed by pressing the Function keys F1 and F2 as follows:

F1 : Expected Values

Selecting F1 will use all QC data in the database to calculate the Mean, SD, and CV.

F2: Select cumulative values

If F2 is selected then the Mean, SD, and CV will be calculated based on the period of time selected in the Period drop down menu.

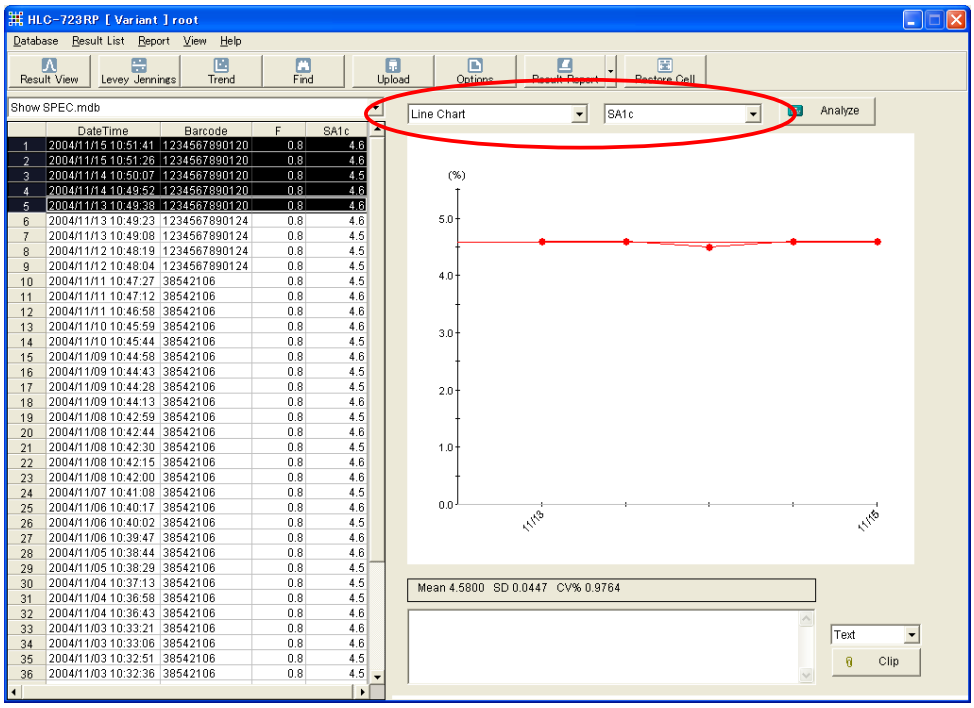
8 Trend Analysis

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 find function. See Chapter 10 for a detailed description.

The procedures for plotting charts are described below.

Click the Trend button.
Choose the results from the result list.
Select the chart type and analyte. See red circle in screen below.
Click the Analyze button. The selected results will be displayed with a calculated Mean, SD and CV.



Trend Chart

The control line is inserted in the chart by setting the marker in the Environment Settings under 'For Trend chart'. The Clip button allows the chart to be saved as EMF or to copy the text to the clipboard. Comments can be added to the Trend Report in the box field to the left of the Clip button.

If the number of selected results exceeds 100, it will become difficult to distinguish each result clearly.
In order to avoid misinterpretation, a suitable number of results should be selected.

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 Report
G. QC Report

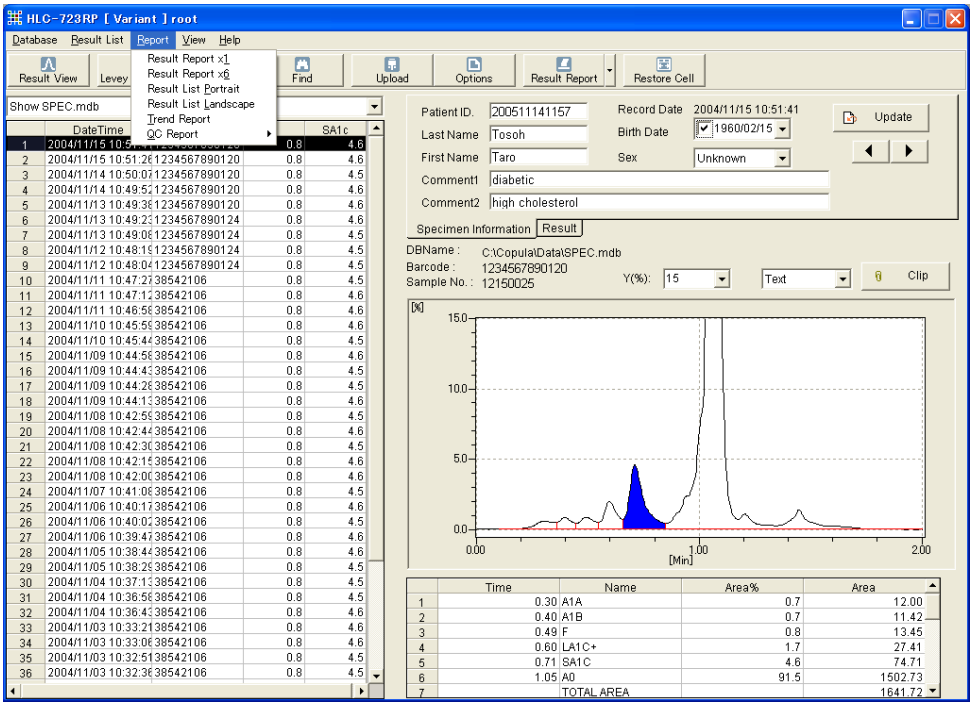
9.1 Result Reports

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 by the following procedures.

To print a single-report/page:

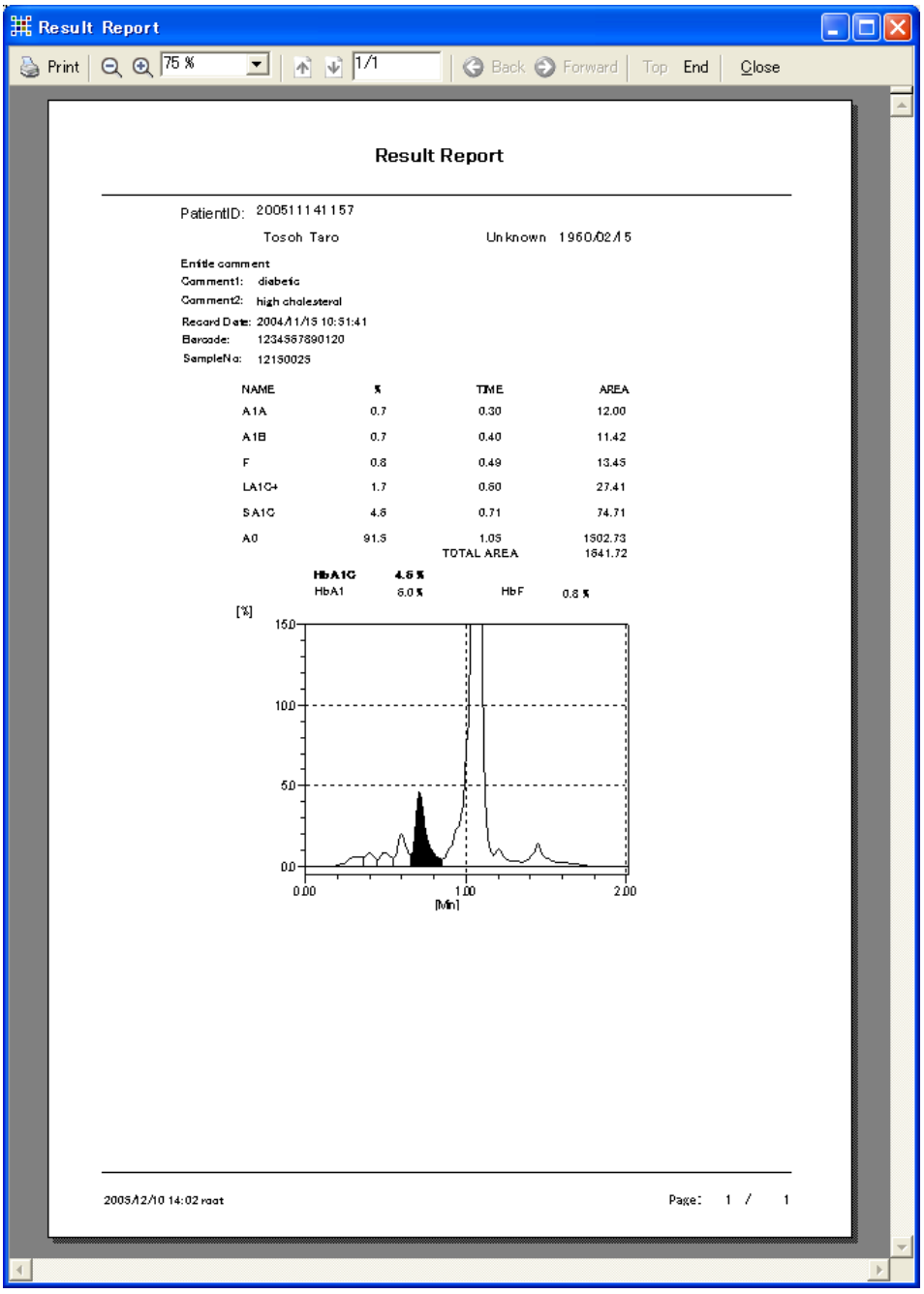
Select one result in the list. Then Select Result Report tab.

From the drop down menu select “Result Report x1”.



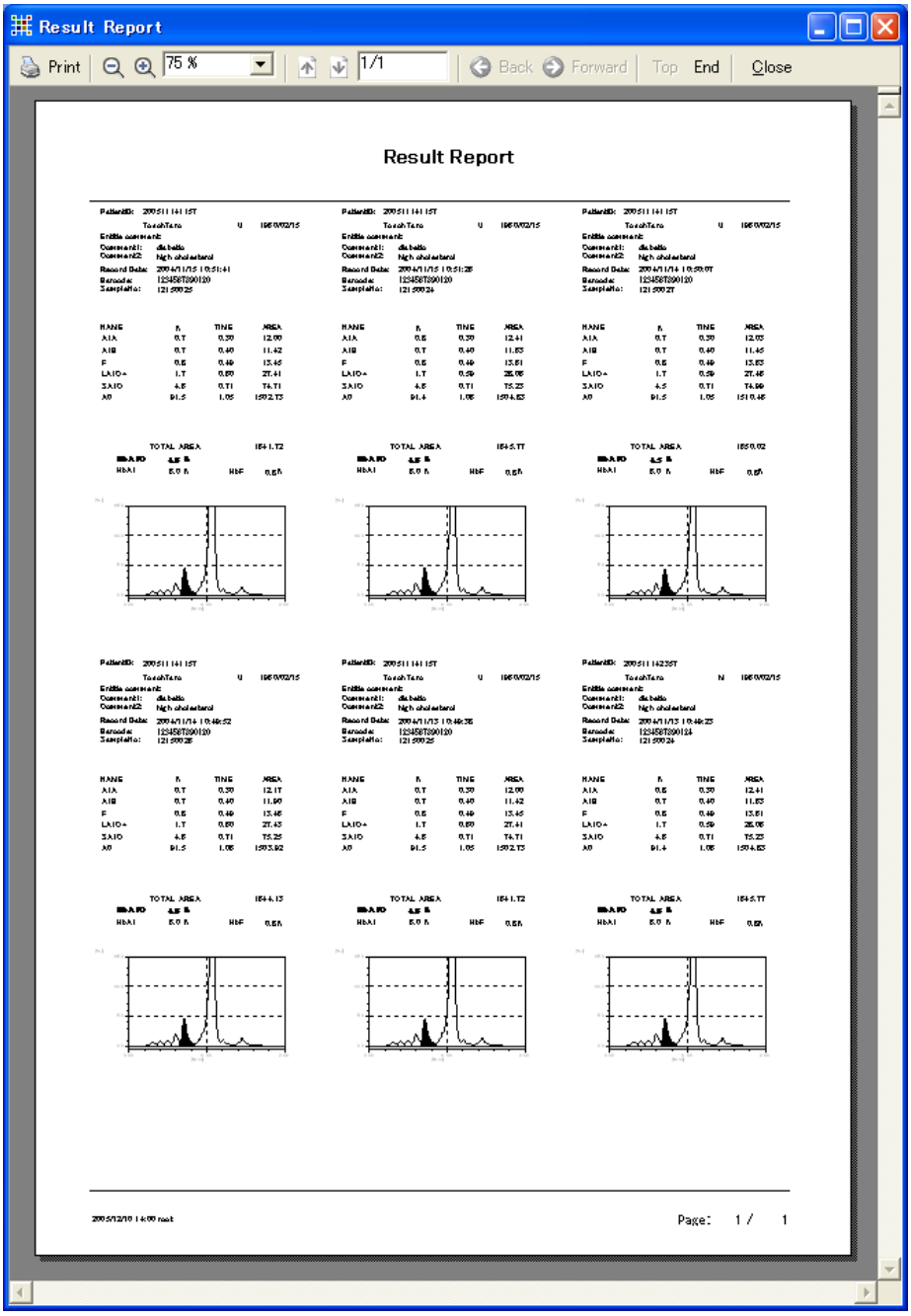
Chromatogram View Screen

This screen displays the print preview with a single report per page. Select the Print button to print the report.



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

To print six-reports/page:
Select 6 or more results from the list. Then Select Result Report tab.
From the drop down menu select “Result Report x6”.
This screen displays the print preview with 6 result reports on each page. Select the Print Button to print the report(s).
In the same manner 2, 3, 4, or 5 results may be selected to print.



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

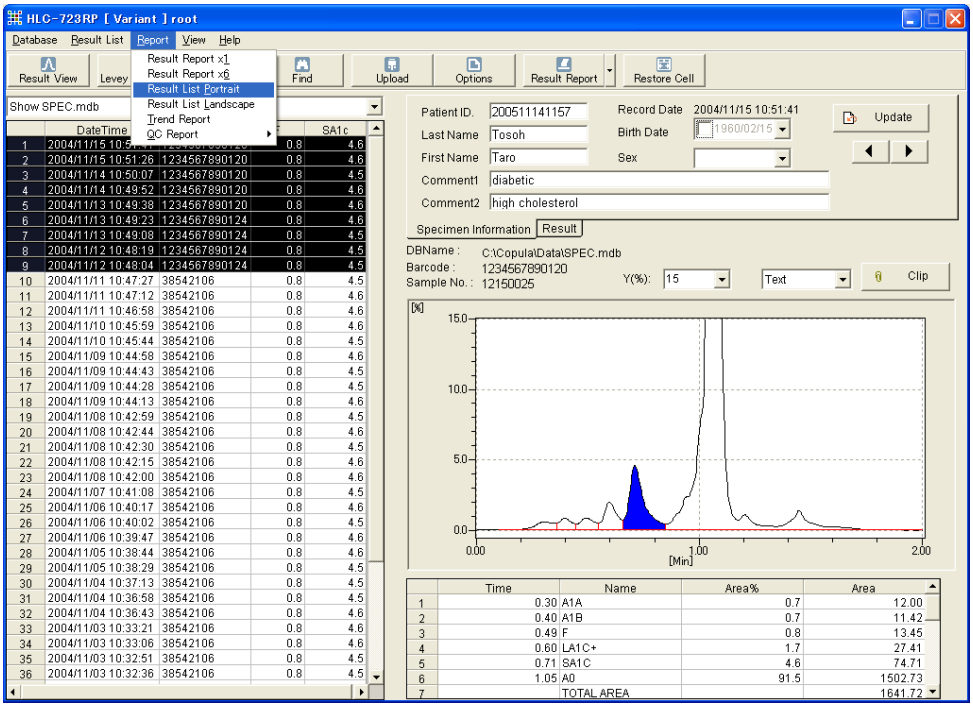
9.2 Result List

The result list is a printed list of the data. There are two printer formats available: Portrait and Landscape type A4 (Letter).
There are two types of result list printouts: Without patient information and with patient information.
The following procedures are used to preview and print the result list.
In case Patient information is added:
In the Environment tab, check the "Add Patient Information" box under "Print Conditions".

Analyte	Value
Host Connection Method	
GHbComFormat	G7 Format
Connection Method	Unify
Query	☑ Available
QCQuery	☑ Available
Automatic Upload	☑ Available
Instrument Information	
Composition of Instrument	GHb1+GHb2
Sample No. length	8
GA:Protocol	☐ TypeA
Print Conditions	
Add Patient Informations	☑ Yes
Total-Area Option	11111111111
Automatic Report	☐ ON
1Data/Page Default	Cut Sheet Printer
TM-J2000 Printer	☐ Yes
Cut Sheet Printer	☑ Yes
Paper size(A4/Letter)	Letter
Patient Header Right	
Patient Header Center	
Patient Header Left	
List Header Right	
List Header Center	
List Header Left	
Trend Header Right	
Trend Header Center	
Trend Header Left	
QC Header Right	

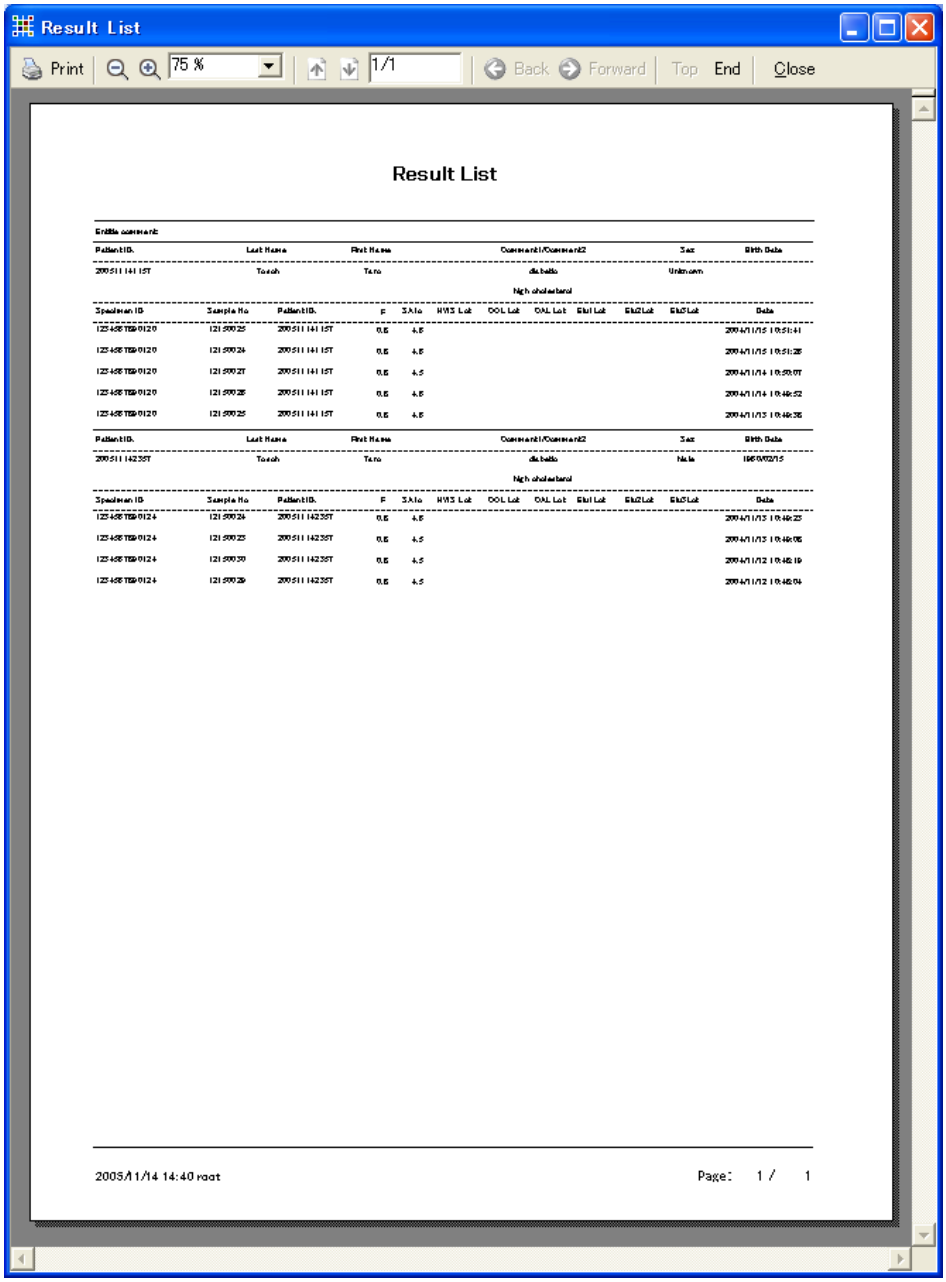
Environment Settings Screen (Environment Tab)

Select one or more results in the list, then click on "Report" and select "Result List Portrait" or "Result List Landscape". Or just click on the down arrow next to the Result Report button and select Result List (Portrait) or Result List (Landscape).



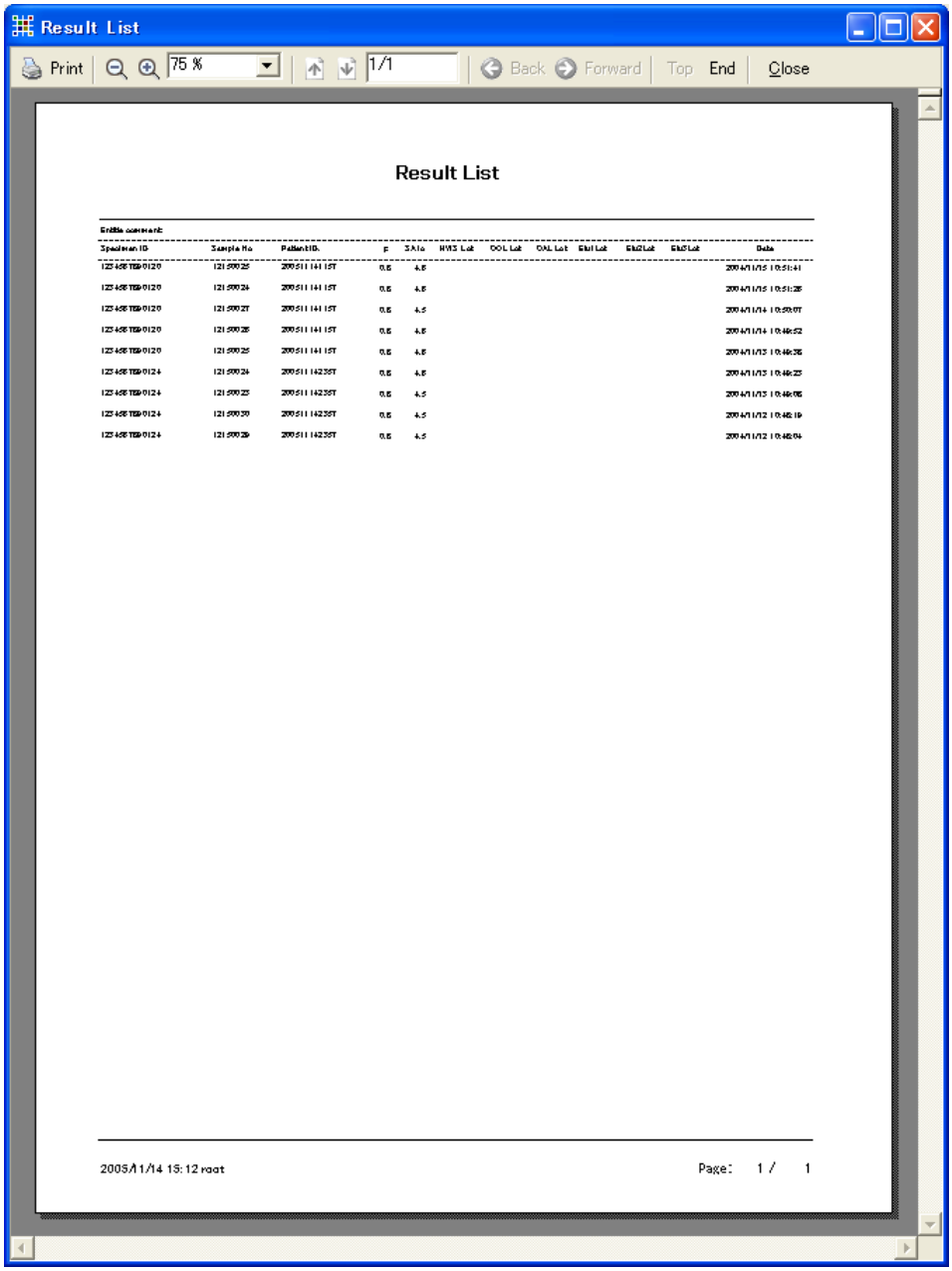
Chromatogram View Screen

This screen displays the print preview of the Result List with patient information.



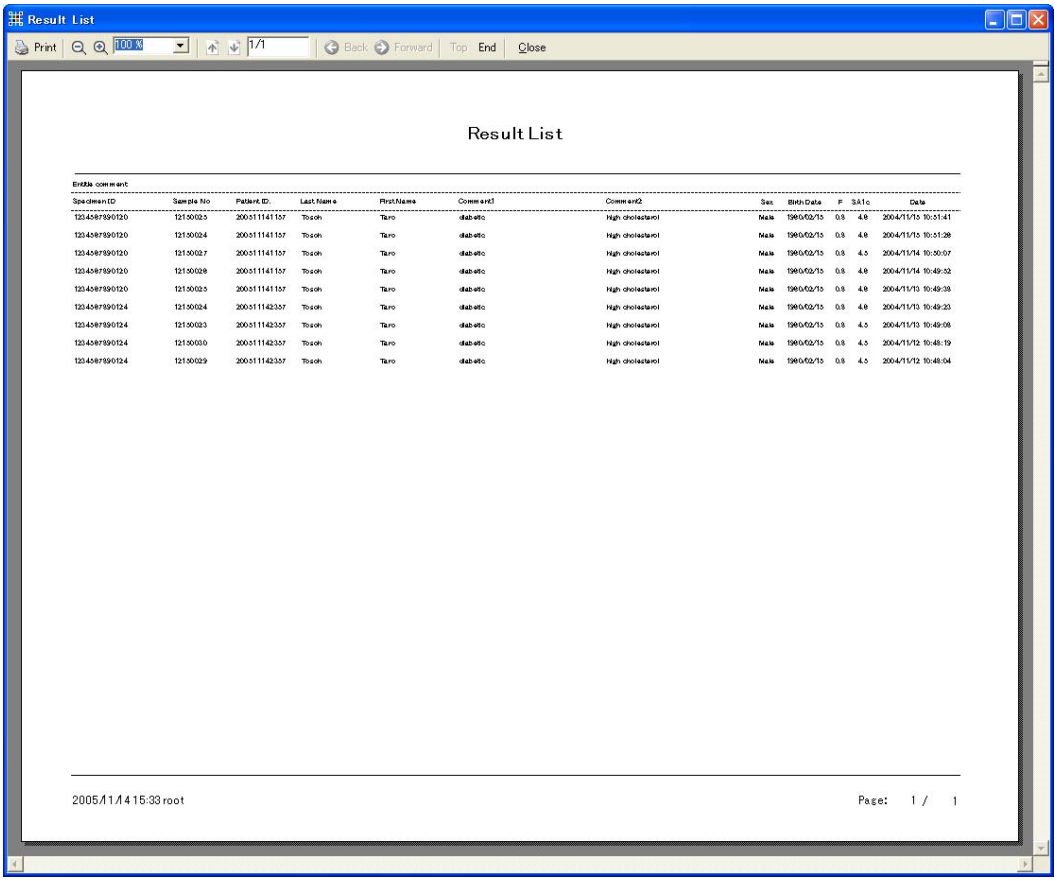
Print Preview of Result List with Patient Information

This screen displays the print preview of the Result List without patient information



Print Preview of Result List without Patient Information

This screen displays the print preview of the Result List (Landscape)



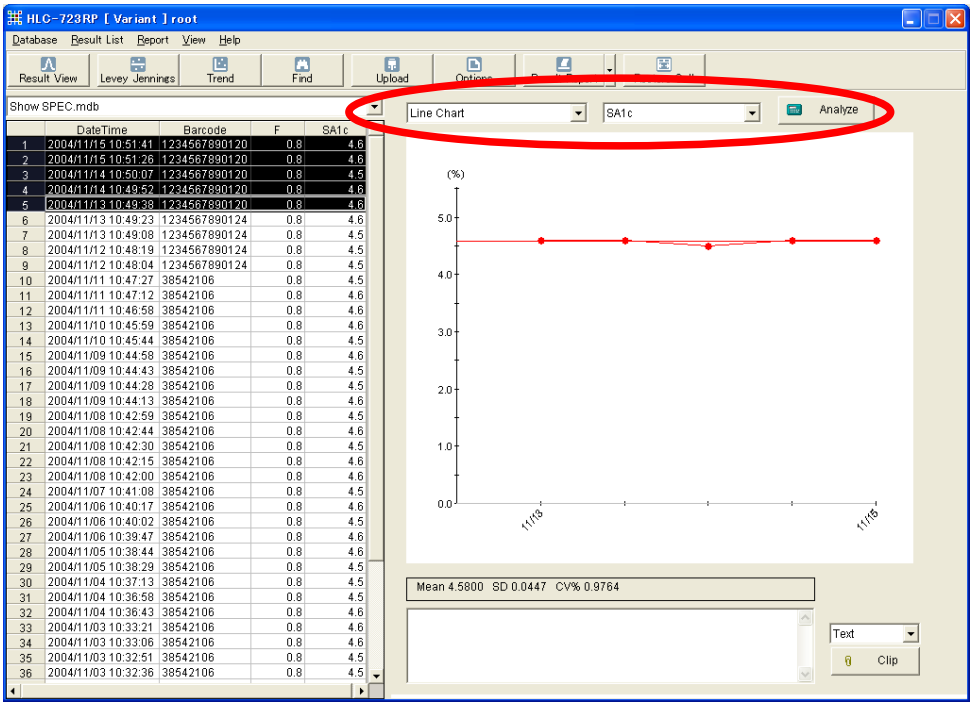
Print Preview of Result List (Landscape)

9.3 Trend Reports

Trend reports are created using data generated from selected results and 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.

Click the Trend button.
Choose the results from the result list.
Select the chart type (line or bar) and SA1c (or another peak or value). See red circle in screen below.
Click the Analyze button.

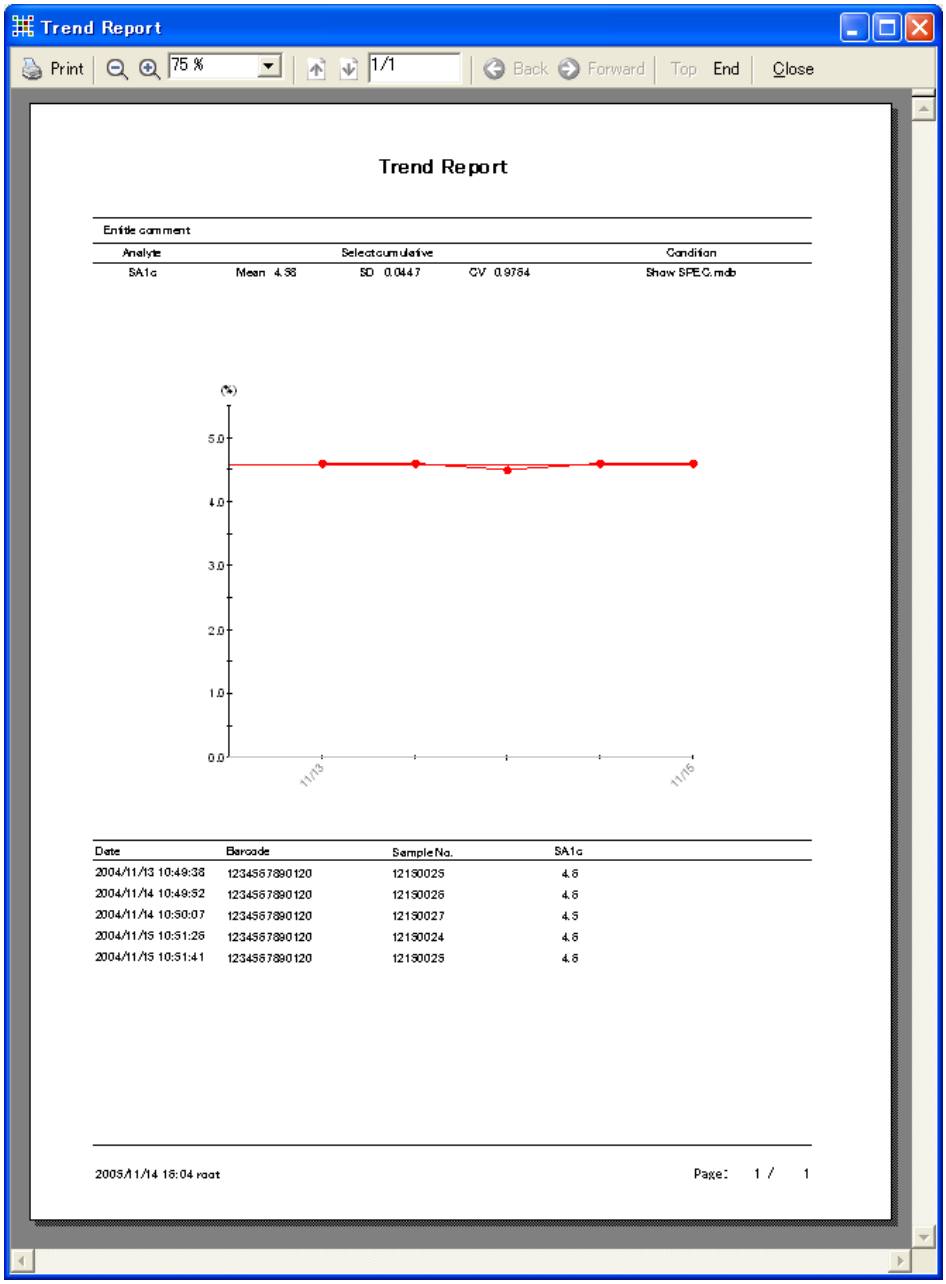
The selected results will be displayed with a calculated Mean, SD and CV.
The control line is inserted in the chart by setting the marker in the Environment Settings under "For Trend chart". The Clip button allows the chart to be saved as EMF or to copy the text to the clipboard.
Comments can be added to the Trend Reports in the box field to the left of the Clip button.



Trend Chart

To print the trend reports after the trend charts have been made, select the "Trend Report" from the Result Report menu.

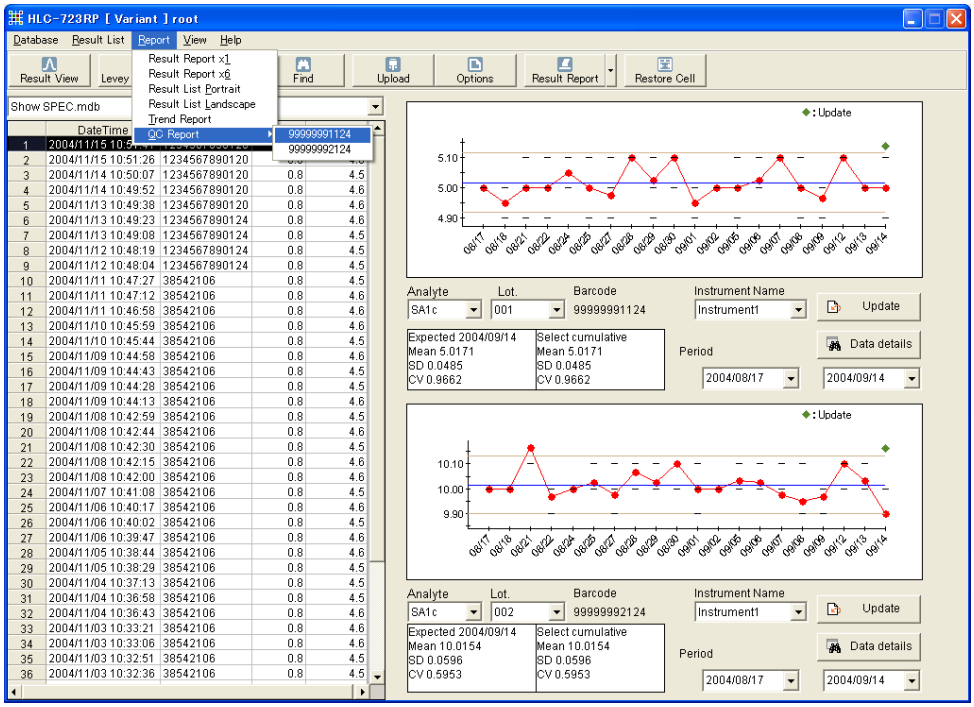
This screen displays a print preview of the Trend Report. Click the Print button to print the report.



Print Preview of Trend Report

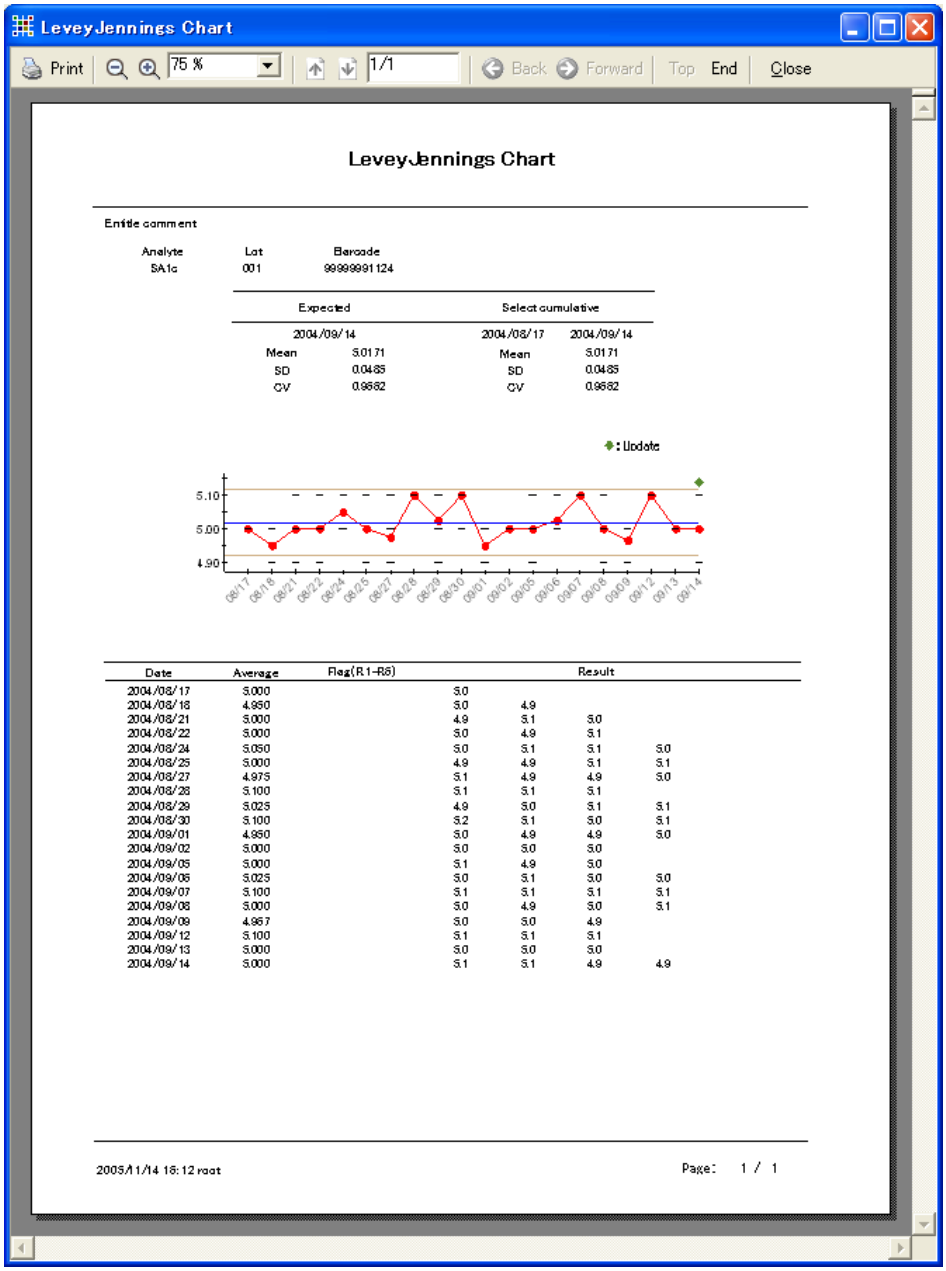
9.4 Quality Control (QC) Reports

Select "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

This screen displays a print preview of the QC Report. Click the Print button to print the report.



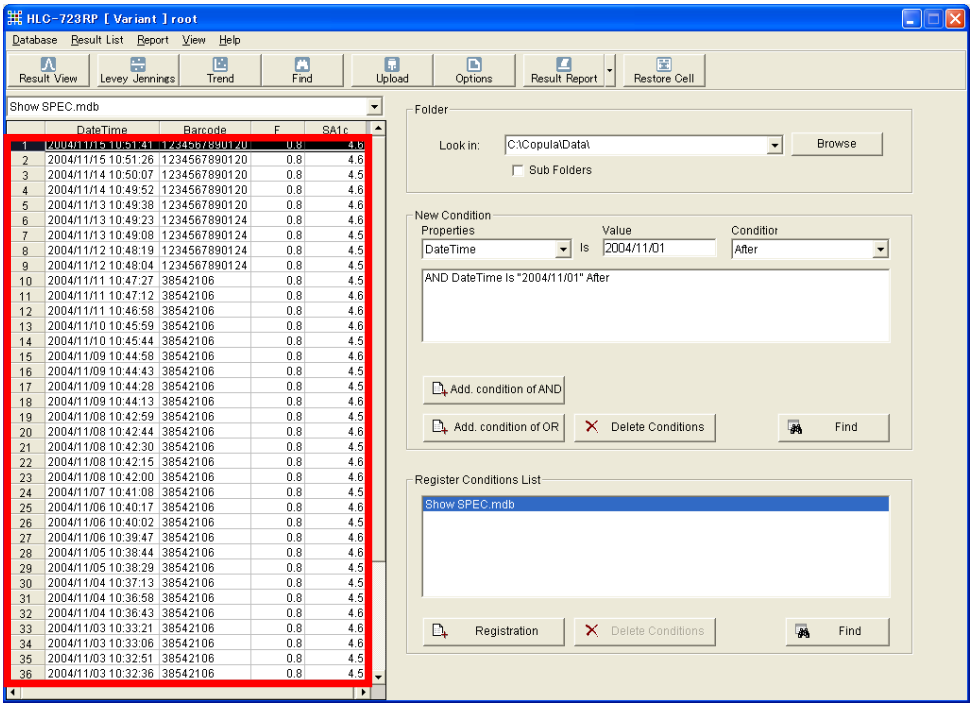
Print Preview of QC Report

10 Results Find Function

10.1 Find

The find function allows the operator to enter barcode, name, and others, as search variables. 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 (to view all results), choose “Show SPEC.mdb” from the drop down menu at the top of the result list.

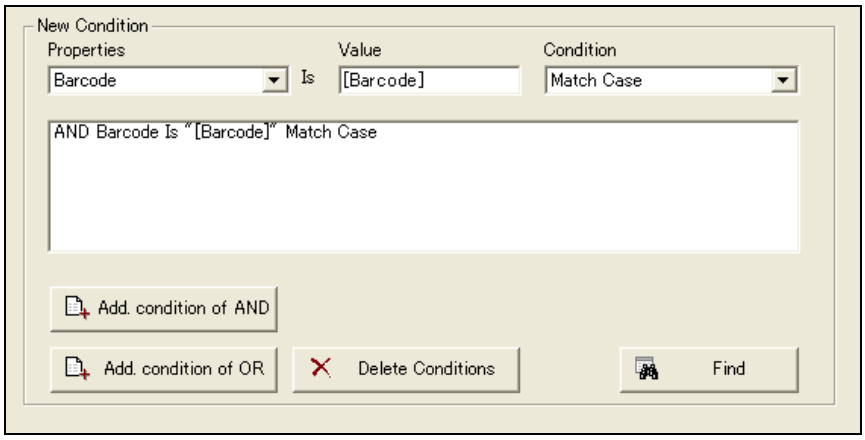
Example:
For searching data from November 1, 2004 onwards.
Select “Date Time” from the Properties box. The Properties box offers many choices.
Enter “2004/11/01” in the Value field.
In the Condition field select “After” then click the Add. condition of (AND/OR) button.
Click the Find button to display all found results. See square in screen below.



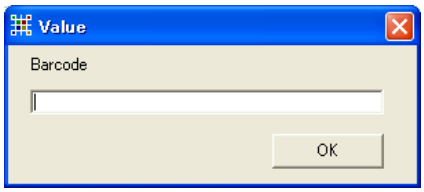
Find Screen

Another example to find all results from one day's run:
Type the date in the Value field and in the Condition field select 'The Day'. Click the Add. condition of (AND/OR) button and then click the Find button.

Another example to find the result whose barcode corresponds with inputted number.
The barcode is entered as a value by enclosing it in [ ] brackets (property name).
To find specific barcodes select "Barcode" in the Properties box, type "[Barcode]" in the Value field and then in the Condition box choose Match Case as shown below.
Click the Add. condition of AND button and then click the Find button.

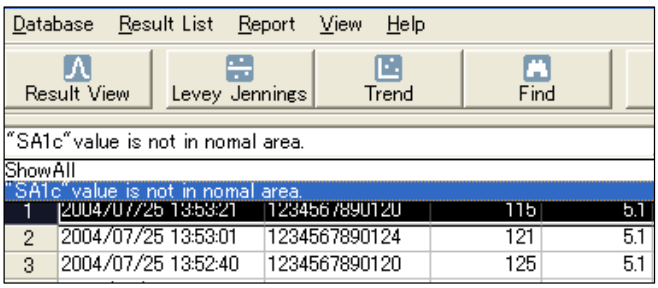


Using this condition displays the following dialog box enabling the barcode to be entered as a search key.



In this manner multiple barcodes can be searched for easily by clicking the Find button and entering a new barcode in the above dialog box.

The user can select and register as many conditions as needed. First enter the conditions as shown above and then click the Registration button. In the Registration of find conditions box enter a descriptive name for the condition and then click the OK button. Click the Find button.
Conditions registered in this manner will be shown in the Register Conditions List and in the drop down menu at the top of the results list as shown below.



11 Diagnosing Problems

Contact Tosoh Bioscience, Inc. Technical Support at 800-248-6764.

11.1 Error Messages and Logs

Records of any system faults or malfunctions are contained in system log files. Users can check log file records by opening the log in the “C:\Copula\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)COM: Invalid port number
b)COM: 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 equipment as “1”.
j) Communication settings of equipment is G7(G8) format.

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

12 Transmission Specifications

This manual does not provide information on transmission specifications concerning about the G7/G8. That information is provided in Chapter 7 of the G7 or G8 Operator's Manual.

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 of the version 2.xxS (G7 or G7 compatible)

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

Note:

- <BCC> represents the exclusive logical sum of character units beginning with the start character and ending with the <ETX> and utilizes a single-byte binary configuration.
- 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 a 10 second interval.

<Example using 1 data item>

<STX> text 1<ETX><BCC> →

← <ACK>

<EOT> →

<Example using multiple data items>

<STX> text 1<<ETX><BCC> →

← <ACK>

<STX> text 2<<ETX><BCC> →

← <ACK>

:

:

<STX> text n<<ETX><BCC> →

← <ACK>

<EOT> →

<Example of success after 1 resend>

<STX> text 1<<ETX><BCC> →

← <NAK>

<STX> text 1<<ETX><BCC> →

← <ACK>

<EOT> →

<Example of resend attempts exceeding 5>

<STX> text 1<<ETX><BCC> →

← <NAK>

<STX> text 1<<ETX><BCC> →

← <NAK>

<STX> text 1<<ETX><BCC> →

← <NAK>

<STX> text 1<<ETX><BCC> →

← <NAK>

<STX> text 1<<ETX><BCC> →

← <NAK>

<EOT> →

<Example of ACK receive timeout>

<STX> text 1<ETX><BCC> →

(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><BCC> → ← <ACK> or <NAK> <EOT> →
2) GHb results Identical to Hi-Level mode	<STX>GHb results <ETX><BCC> → ← <ACK> or <NAK> <EOT> →
3) Reserved Record	STX>reserved record <ETX><BCC> → ← <ACK> or <NAK> <EOT> →

Transmission Process of the version 2.xxE (G8)

<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 of the version 2.xxS (G7 or G7 compatible).

1) Patient information

Information	Character count	Description
[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 (see note).
[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.
[Comment 2]	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
[Effective flag]	1	0= invalid, 1= valid
[Operating mode]	1	0= standard method, 1= variant method, 2= β thalassemia method
[Specimen position]	1	0=STAT, 1= transport, 2= loader
[Sample no.]	3,5,8	Sample no (see note)
[No.1 Component]	5	0.0~100.0(Aligned right)
[No.2 Component]	5	0.0~100.0(Aligned right)
[No.3 Component]	5	0.0~100.0(Aligned right)
[No.4 Component]	5	0.0~100.0(Aligned right)
[No.5 Component]	5	0.0~100.0(Aligned right)
[No.6 Component]	5	0.0~100.0(Aligned right)
[No.7 Component]	5	0.0~100.0(Aligned right)
[No.8 Component]	5	0.0~100.0(Aligned right)
[No.9 Component	5	0.0~100.0(Aligned right)
[No.10 Component]	5	0.0~100.0(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 that specimen IDs (barcodes) are used.

The results are transmitted using the following data formats of the version 2.xxE (G8).

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
[Effective flag]	1	0= invalid, 1= valid
[Operating mode]	1	0= standard method, 1= variant method, 2= β 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 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.

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. Specimen ID for query set.
,	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.

Version 2.xxS (G7 or G7 compatible)

Query of GHb

S: <STX>G00,05410469029 <ETX>0x78
R: <ACK>
S: <EOT>
R:<STX>A00,05410469029 ,0000011978293,LastName ,FirstName ,01, ,
, ,0000 ,01 ,10010101 ,00 , <ETX>0x10
S:<ACK>
R:<EOT>

Transmitting result of GHb

S:<STX>0005410469029 0918000500000011978293LastName FirstName 01
<ETX>0x79
R:<ACK>
S:<EOT>
S:<STX>10209180005 0.0 0.4 0.9 0.3 1.9 5.0 92.1 0.0 0.0 6.40005410469029
<ETX>0x3E
R:<ACK>
S:<EOT>
S:<STX>00005410469029 0101 115 0<ETX>0x6
R:<ACK>
S:<EOT>

Version 2.xxE (G8)

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 0918000500000011978293LastName 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>

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