

eQAPSM User's Guide

Real-time QC data for operational efficiency

Version 10

cobas b 123 POC system

cobas b 221 blood gas system

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On-Line Quality Assurance Program

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Notes

Introduction

Welcome to eQAP real-time peer review. This inter-laboratory statistical service, available through the Roche Diagnostics USA website, offers our customers access to a peer analysis program by providing secure web-based access to customer data and reports.

Enjoy the benefits of:

- instantaneous reporting - receive up to the minute, live, quality control information the moment you log on
- error checking for data entry - the centralized database manages and error-checks all data entries, flagging any results outside established parameters
- extra data entry - simply provide data in summary format, submit via daily entry, or download files saved from the **cobas b** 123 POC system and **cobas b** 221 blood gas system
- customized reports - receive a detailed custom report, highlighting inter-laboratory and peer group statistics.

Overview

Our On-Line Peer Analysis program is an internet-based system for review of Quality Control and Linearity information.

Contact Information

For questions regarding data entry in the eQAP real-time peer review group reporting, contact the Roche Diagnostics Customer Support Center at 1-800-526-2272.

Accessing Roche Diagnostics USA

eQAP peer group reporting program is available through the Roche Diagnostics USA website.

If you are not currently registered, instructions can be found at: usdiagnostics.roche.com/en/document/Login_Registration_instructions.pdf.

Accessing eQAP

Enroll an instrument in eQAP

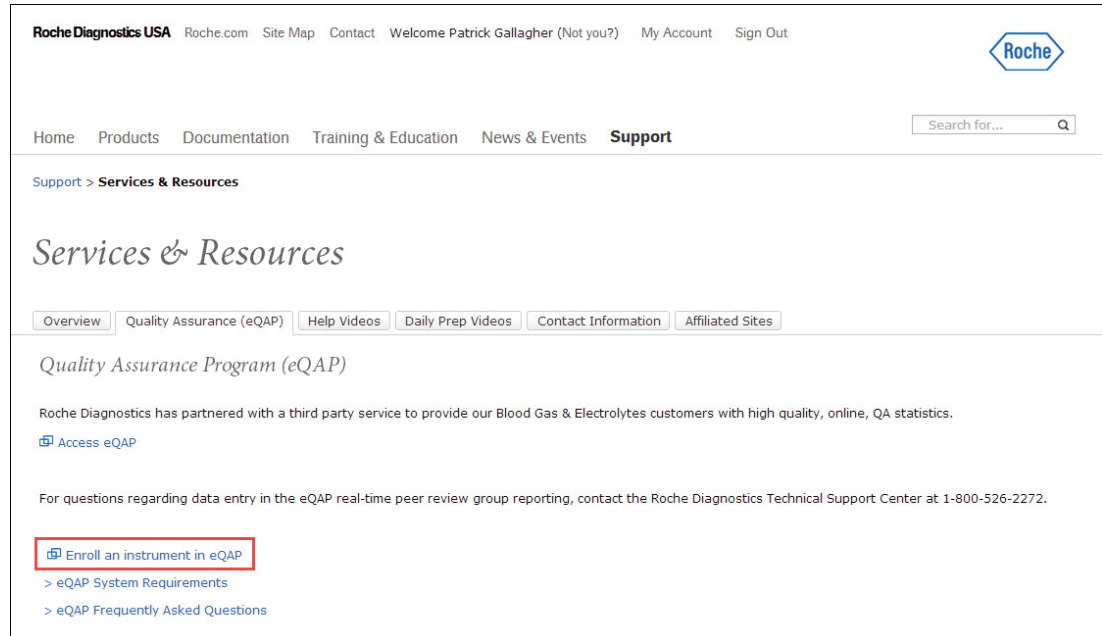
1. Log in to Roche Diagnostics USA.

The screenshot shows the 'Sign in to My Account' page of the Roche Diagnostics USA website. The top navigation bar includes links for Roche Diagnostics USA, Roche.com, Site Map, Contact, and a highlighted 'Sign in to My Account' link. The main content area features a login form with fields for 'Email address' and 'Password', a 'Sign in' button, and a 'Forgot your password?' link. To the right, there is a 'We're Here to Help' section with contact information and a 'Find Your Roche Rep' link. At the bottom, there are links for 'Need to register?', 'Has your Roche Sales Representative set up an Evaluation account for you?', and 'Has your email changed since your last login?'.

2. Click **Quality Assurance Program (eQAP)** from the Support menu.

The screenshot shows the 'Support' page of the Roche Diagnostics USA website. The top navigation bar includes links for Roche Diagnostics USA, Roche.com, Site Map, Contact, 'Welcome Patrick Gallagher (Not you?)', 'My Account', and 'Sign Out'. The main content area features a 'Support Overview' section with a 'Quality Assurance Program (eQAP)' link highlighted. Below this, there is a 'Roche Support Network' section with links for 'Overview', 'Sales and Support Teams', 'Customer Engagement', and 'Awards and Recognition'. At the bottom, there is a 'Related Links' section with links for 'Services & Resources' and 'Roche Support Network'.

- Click the **Enroll an Instrument in eQAP** link. For questions regarding instrument enrollment, contact Roche Technical Support at 1-800-526-2272 ext. 13555, for assistance.



- Enter the instrument model number. Click **Next**.

The screenshot shows the eQAP enrollment form. The title is 'eQAP'. Below the title is the text 'Online Quality Assurance Program Enrollment Form'. The description states: 'To access eQAP for your blood gas instrument, you must first have that instrument enrolled in the program. Enrollment is quick and easy... to begin the process, just complete the required information below and click "Next >>". You will receive a response to this request within two business days.' The 'Instrument Enrollment' section has a text input field for 'Instrument Model:' and a 'Next >>' button. An image of a Roche blood gas analyzer is shown on the right.


- Enter the information in the appropriate fields of the Enrollment form.

eQAP
Online Quality Assurance Program Enrollment Form

Page 2 of 3
In order to enroll your COBAS B 123 , we need the following information.
Required information is indicated by a red asterisk (*)

Sequestor Information

Instrument Model:	COBAS B 123		
> Serial No.:	12345	*	
> Control Material:	AUTO-TROL Plus B	*	
Control Level 1			
> No. of boxes / year:	26	*	
> Lot Numbers:	21412345	*	



- Complete the Enrollment form contact information. Click **Done** once the form is completed.


eQAP
Online Quality Assurance Program Enrollment Form

Almost done! Just review and complete the information below and we'll process your request. You will receive a response within two business days.
Required information is indicated by a red asterisk (*)

Instrument Enrollment Information

Instrument:	COBAS B 123 (Currently installed)		
Account No.:	55123456	*	
Institution:	Roche Diagnostics Test Account	*	
> Street	9115 Hague Road		
> City	Indianapolis		
> State	IN		
> Zip	46250		
> Contact Person:	Roche Support	*	
> Department:	Lab	*	
	(ie. location of instrument)		
> Phone number:	317.521.2000	*	
> Fax number:	317.521.1234	*	
> Email Address:	rochesupport@roche.com	*	
Request Date:	2014-01-24		

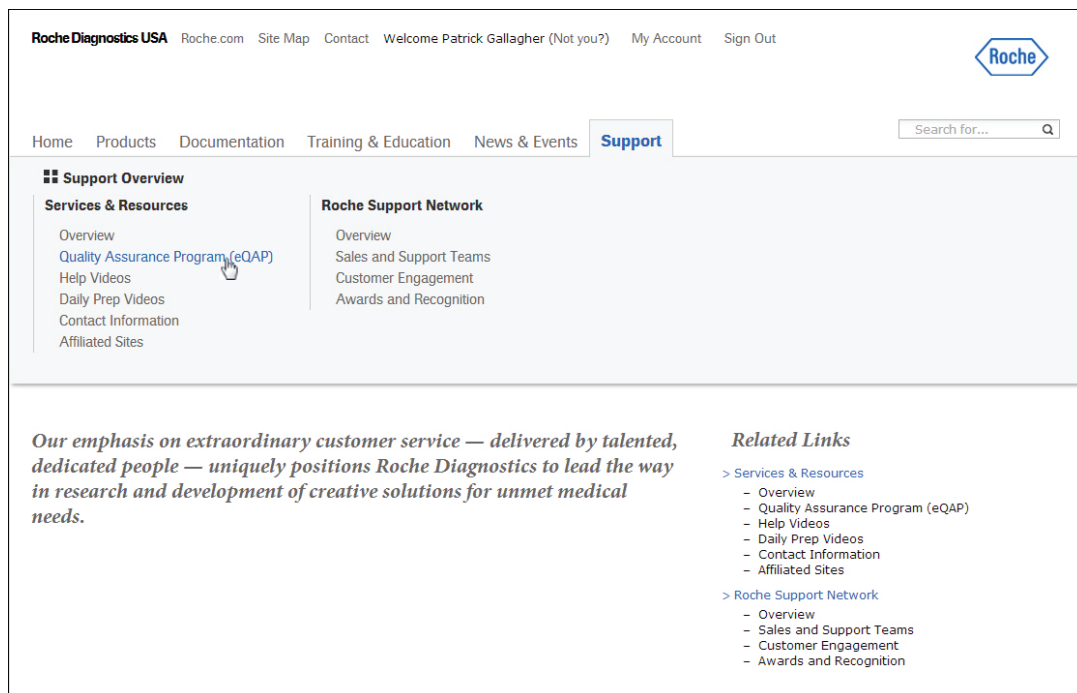
<< Previous Done



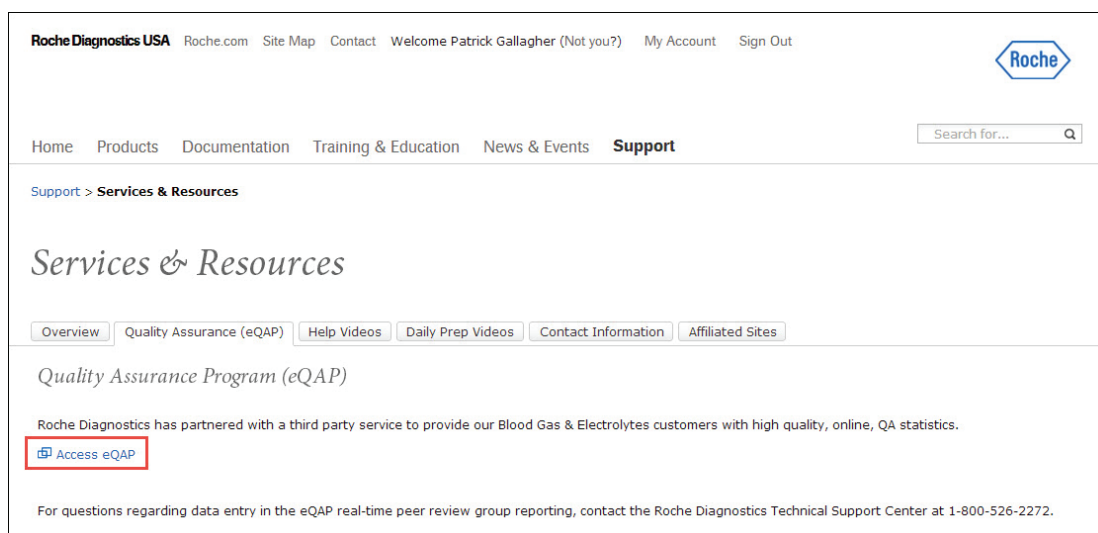
- Click the **Close Window** link to return to the eQAP main menu.

Log in to eQAP and enter data

1. Click **Quality Assurance Program (eQAP)** from the Support menu.

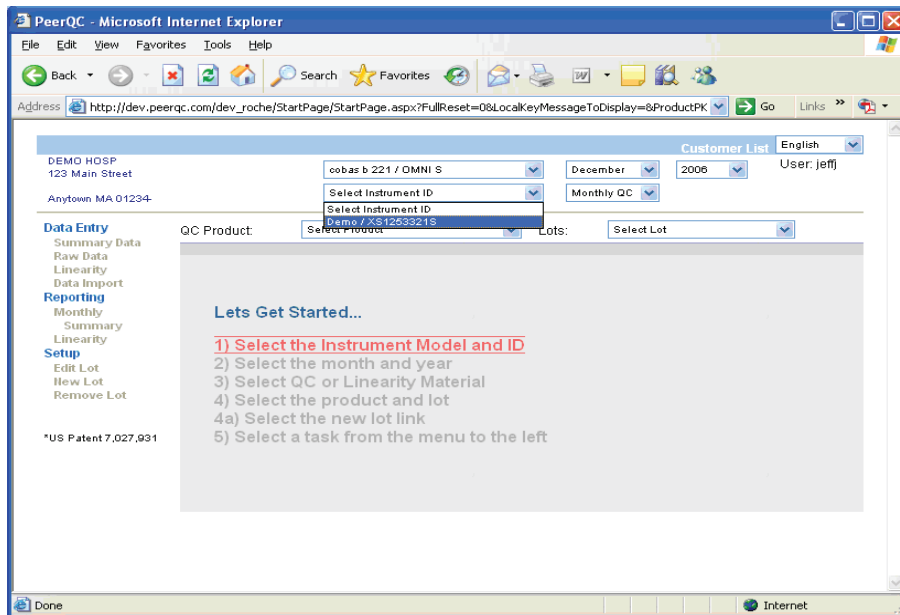


2. Click **Access eQAP** from the eQAP screen.



Selecting the Header Information

Prior to entering your monthly data you must first select the appropriate instrument, data entry month and QC Product criteria.



Selecting the Instrument

The first thing that must be selected is the instrument Model. This pull-down lists all instrument models that are registered for your hospital account.

Once you select your instrument model you must select the specific Instrument ID for that model. This pull-down list displays the instrument's name, serial number or other unique identifier.

Selecting the Month and Year

Next select the Month and Year for which you are entering data. The system allows you to go back and enter, edit or view historical data.

Select Monthly QC from the Select Function pull-down menu if you are entering QC information. To enter Linearity material, select Linearity and refer to the "Entering Linearity Data" section.



The header information must be filled out completely and in order before QC Product and Lot are selectable.

Selecting the Product and Lot

Once you complete all of the instrument parameters you need to set the QC or Linearity Product and Lot filter criteria. The product pull-down list contains all of the individual QC or Linearity products that you are currently using. The Lot pull down menu displays the lot numbers that you are currently using for the selected product.

The level is displayed at the end of the lot number for easy distinction between the levels.

QC Data

Data Entry Methods

Now you may select your preferred method of data entry by clicking the link on the left side of the site. You may choose:

- [Data Import](#)
- [Summary Data](#)
- [Raw Data.](#)

Data Import

Data Import is available for customers who prefer to utilize the data management capabilities of their instrument. This method requires saving the monthly QC data to a USB device or diskette and then uploading the file from a PC with web access.

How to Import Monthly Data

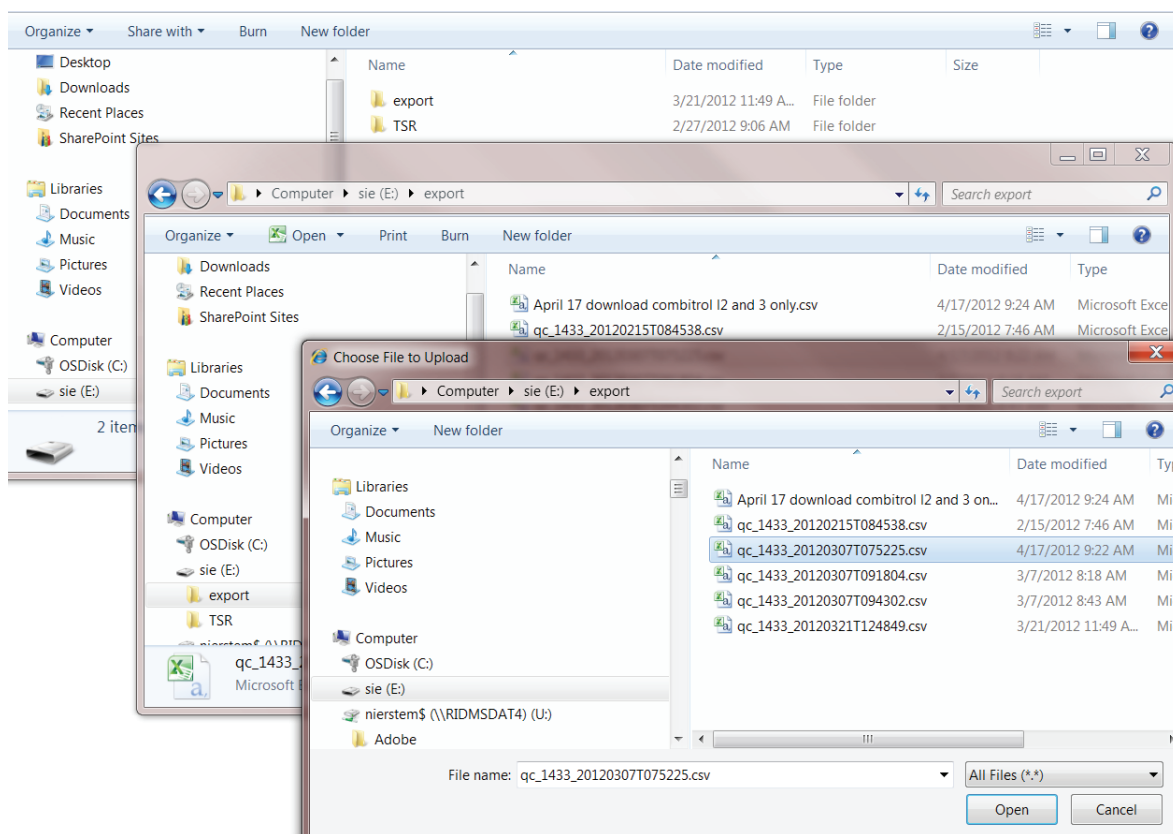
1. Make the appropriate instrument and reporting period selections in the header area, and select the QC product with lot information. Select **Data Import** from the left menu.

The screenshot shows the eQAP web interface. At the top, there's a header with 'Log Out' and 'English' dropdowns. Below this, contact information for Roche Technical Support is listed. The main header area contains dropdowns for 'cobas b 221', 'August', '2012', '5099', and 'Monthly QC'. A left sidebar menu has 'Data Entry' selected, with 'Data Import' highlighted in a red box. The main content area is titled 'Lets Get Started...' and lists five steps: 1) Select the Instrument Model and ID, 2) Select the month and year, 3) Select QC or Linearity Material, 4) Select the product and lot, and 5) Select a task from the menu to the left. The 'QC Product' is set to 'AUTO-TROL PLUS B' and 'Lots' is '21400723-1'. A red box highlights step 5 in the instructions.

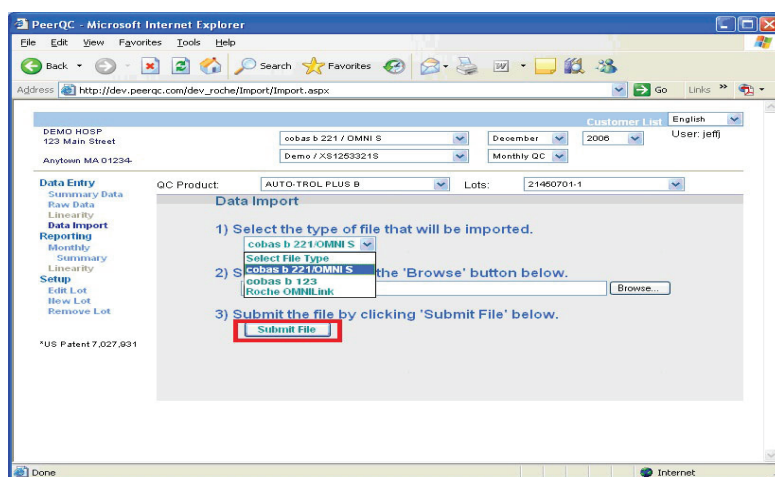
2. Select the type of file to import. The system supports files that were exported from the **cobas b 221** blood gas system and the **cobas b 123** POC system.

This screenshot shows the 'Data Import' section of the eQAP interface. The header area is similar to the previous screenshot but with 'cobas b 123', 'May', '2012', 'Test #2', and 'Monthly QC' selected. The left sidebar menu has 'Data Import' highlighted in a red box. The main content area is titled 'Data Import' and lists three steps: 1) Select the type of file that will be imported, with a 'Select File Type' dropdown highlighted in a red box; 2) Select the file using the 'Browse' button below, with a 'Browse...' button; and 3) Submit the file by clicking 'Submit File' below, with a 'Submit File' button. The 'QC Product' is 'AutoQC' and 'Lots' is '21412802-1'.

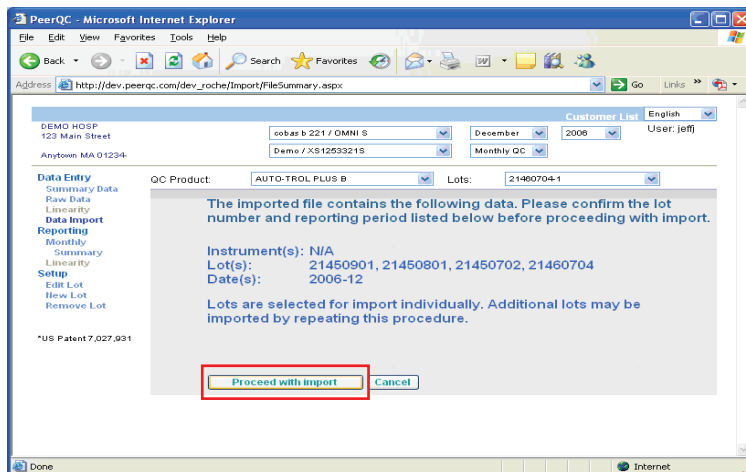
3. Select the **Browse** button. This opens a window allowing you to browse to the location on your PC where the file is stored.
4. Select the file and click **Open**.



5. After selecting the appropriate QC file from the Browse menu, click **Submit File**.



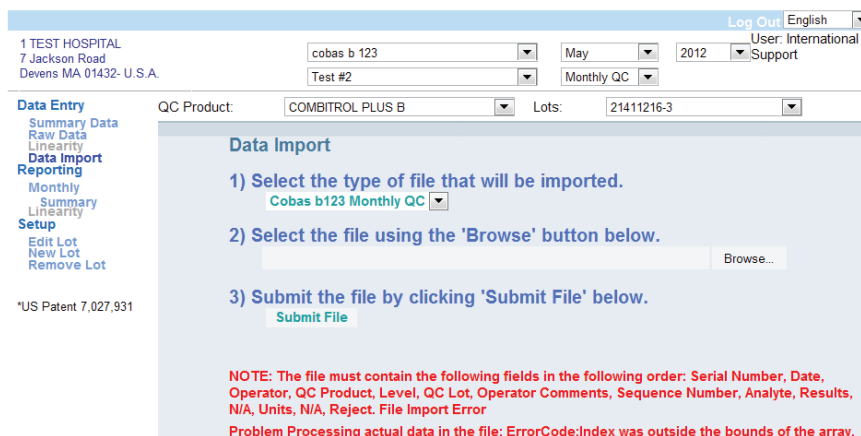
6. The following information screen appears, summarizing the data that was found to import:



Click the **Proceed with import** button to proceed, or **Cancel** to return to the main screen. Only the lot currently selected at QC Product and Lot is imported.

If there is no matching lot contained within the data file to that selected at QC Product and Lot, the message, “the file contains no relevant data” is displayed.

The following screen displays if data fails to import:



- Click the **Submit** button to save the imported data into the database. A pop-up window appears confirming the successful download of data.



NOTE

You may view the actual raw data imported by selecting Raw Data under Data Entry options. Data may be edited in the Raw Data screen.

ROCHE TECHNICAL SUPPORT
9115 Hague Road
Indianapolis IN 46250-0457
U.S.A.

QC Product: AUTO-TROL PLUS B Lots: 21400916-3

Analyte	Unit	Method	Rgt. Lot	Points	Mean	SD	Validation Message	Cum. Mean	Cum. SD
pH	pH			3	7.567			0.000	0.000
pCO2	mmHg			3	23.73	0.05		0.00	0.00
pO2	mmHg			3	133.97	0.76		0.00	0.00
THb	g/dL			3	20.70			0.00	0.00
O2Hb	%							0.00	0.00
HHb	%							0.00	0.00

*US Patent 7,027,931

Buttons: Edit, **Submit**, Cancel, Close, Next Lot

Message from webpage

⚠ Data saved successfully. To review or edit individual data points, select raw data.

OK

- Click **OK** to confirm.
- Click **Next Lot**, at the lower right of the screen, after completing data entry for each lot number (Next Lot button becomes inactive after last lot is selected).
- After all data is imported, click **Summary** to run a monthly report.



NOTE

If the pop-up blocker is ON, you may need to temporarily allow pop-ups. Click on the pop-up message at the top of the screen and select "temporarily allow pop-ups."



NOTE

For information on how to generate a monthly report, refer to the Printing Reports section.

PeerQC

Pop-ups temporarily allowed. To always allow pop-ups from this site, click here...

ROCHE TECHNICAL SUPPORT
9115 Hague Road
Indianapolis IN 46250-0457
U.S.A.

QC Product: AUTO-TROL PLUS B Lots: 21400916-3

Analyte	Unit	Method	Rgt. Lot	Points	Mean	SD	Validation Message	Cum. Mean	Cum. SD
pH	pH			3	7.567			0.000	0.000
pCO2	mmHg			3	23.73	0.05		0.00	0.00
pO2	mmHg			3	133.97	0.76		0.00	0.00
THb	g/dL			3	20.70			0.00	0.00
O2Hb	%							0.00	0.00
HHb	%							0.00	0.00
COHb	%							0.00	0.00

*US Patent 7,027,931

Buttons: Edit, Submit, Cancel, Close, Next Lot

Left Sidebar: Data Entry, Summary Data, Raw Data, Linearity, Data Import, Reporting, Monthly, **Summary**, Setup, Edit Lot, New Lot, Remove Lot

Summary Data

Summary data entry is the entry method for those customers who have used the instrument or calculated their own Mean and Standard Deviations using a data manager or manual method.

Entering Summary Data

The data entry screen is where you enter all of your QC data for that particular instrument.

How to Enter Summary Data

1. In the Data Entry section on the left side of the screen, click **Summary Data**, then click **Edit** located at the bottom of the data entry grid.
2. For each analyte, click in the Points field. Enter the total number of QC samples run during the month for the respective analyte.
3. Press the **TAB** key to advance to the Mean field.
4. Enter your calculated mean for the month.
5. Press the **TAB** key to advance to the SD field.
6. Enter your calculated 1 SD.
7. Continue entering your data for all analytes of the selected lot number.
8. Click **Submit** located at the bottom of the data entry grid and click **OK**.
9. Click **Next Lot** after completing data entry for each lot number. Repeat steps 1-9 until data for all lots is entered (Next Lot button becomes inactive after last lot is selected).

PeerQC - Microsoft Internet Explorer

Address: http://dev.peerqc.com/dev_roche/SummaryData/SummaryData_ManualEntry.aspx?EditMode=0&UseDataImporter=

Customer List: English User: jeff

DEMO HOSP
123 Main Street
Anytown MA 01234

QC Product: AUTO-TROL PLUS B Lots: 21460701-1

Analyte	Unit	Method Rgt.	Rgt. Lot	Points	Mean	SD	Validation Message	Cum. Mean	Cum. SD
pH	pH			1	7.192	.001		0.000	0.000
pCO2	mmHg							0.00	0.00
pO2	mmHg							0.00	0.00

*US Patent 7,027,931

Edit Submit Cancel Close Next Lot



NOTE

For information on how to generate a monthly report, refer to the Printing Reports section.

Raw Data

Raw Data entry is for those customers who do not have the capabilities to process summary statistics. This system is meant to replace the “old” method of plotting daily QC results on a Levy-Jennings chart. With this method customers can log on after they run their controls and enter the data into our system, where it will be stored in our database.

Entering Raw Data

The Raw Data Entry Screen is where all of your individual QC values are calculated into mean and SD values.

How to Enter Raw Data

1. In the “Data Entry” section at the left side of the screen, click **Raw Data**, then select your analyte.
2. Click **Edit** located at the bottom of the data entry grid, then click in the first field of the Value column.
3. Enter your individual value and press the **TAB** key on your keyboard to advance to the next field.
4. Continue entering your data.
5. Click **Submit** when you finish entering values for all analytes or pick the next analyte.
6. Repeat steps 2 through 5 for all remaining analytes.
7. Click **Next Lot** after completing data entry for each lot. Repeat steps 1-9 until data for all lots is entered. (Next Lot Button becomes inactive after last lot is selected).



The Raw Data screen is designed to display data points, mean and SD only when that particular analyte is selected. To view an update of the calculations for each parameter added in the Raw Data screen, click the Summary Data link under the data entry header.

Validation Message

As you enter data, the system automatically checks each entry to ensure that values entered are correct. If a value falls outside of the range a message appears in the column on the far right of the data entry grid. This is to provide you with a means of correcting possible transcription errors before saving your data. If a message does appear, verify that the value entered is correct and make any necessary changes or continue entering data.

Error Detection

To help ensure quality, our system uses the manufacturer's insert ranges to check for errors. Any value that falls outside of this range are excluded from the peer group calculations. This protects the integrity of the peer group by preventing erroneous data from corrupting the group.

Example: If the insert ranges are 7.150 - 7.210 any value above or below the range is excluded from the peer group.



When using the Data Import feature, you must scroll to each parameter to see the warnings on screen for values that are out of range.

All excluded values are periodically reviewed for possible trends in QC degradation. This involves looking at each entry that was excluded and searching for possible errors in the insert ranges.

Example: If, out of a possible 20 analyzers reporting Ca values on Lot # A, 15 were reporting outside of the insert ranges, Bionostics would notify the manufacturer of changes recommended for insert ranges to accurately reflect the lot performance. After investigation, if values are verified as needing a change, customers will be notified.

Analyte	Unit	Method	#	Value	Validation Message
pH			1	7.170	
pCO2			2	7.182	
pO2			3	7.190	
Thb			4	79.10	Range: 7.150-7.210
COHb			5		
MetHb			6		
K+			7		
BUN			8		

Points: 4 Mean: 25.161 SD: 35.96

Printing Reports

You may run your monthly report at any time during the month to compare values against the peer group. All reports are calculated **live** so that your peer group is up to date at the time that you print it.

To run a monthly report click the **Monthly Summary** link on the left side of the web page. Note that the report may take several minutes to generate.

Roche Diagnostics Quality Assurance Report
 Report Period : December 2011
 Data Submitted : Summary Data

Instrument ID: pr 5943 ICU
 Instrument Model: AIL CHN 3
 Serial Number: 5943
 QC Lot #: 1124
 QC Product: AUTO-TROL COMB
 9132 AUTO-TROL COMB
 9230 AUTO-TROL COMB

Attn: Cardiorespiratory Services

December 2011 STATISTICS										CUMULATIVE STATISTICS										PEER GROUP STATISTICS (# All Sites Included)				
Level	Lot #	N	Ac	Rej	Mean	SD	2 SD Range	CV %	SDI	N	Mean	SD	2 SD Range	CV %	SDI	N	Mean	SD	CV %	CVI				
pH																								
1	1132	35			7.355	0.005	7.345 - 7.365	1.14	-1.20	303	7.353	0.005	7.343 - 7.363	1.11	-0.26	12659	7.354	0.009	2.02	87				
1	1134	35			7.355	0.005	7.345 - 7.365	1.14	-0.97	98	7.357	0.004	7.348 - 7.365	1.01	-0.63	1140	7.356	0.012	2.62	44				
2	9230	32			7.392	0.004	7.384 - 7.400	0.82	-1.01	446	7.395	0.005	7.385 - 7.404	1.05	-0.71	20546	7.401	0.008	1.10	47				
pCO2																								
1	1132	35			72.66	0.40	71.89 - 73.63	0.67	2.62	303	72.66	0.72	70.82 - 73.50	1.00	1.58	12663	70.88	1.26	1.62	37				
1	1134	35			73.17	0.40	72.20 - 74.14	0.66	1.76	98	72.67	0.80	70.71 - 74.63	1.35	1.41	1146	70.87	1.42	2.02	33				
2	9230	32			45.57	0.33	44.91 - 46.23	0.73	1.35	446	45.34	0.43	44.40 - 46.25	0.95	1.03	20734	44.59	0.73	1.63	45				
pO2																								
1	1132	35			58.47	2.66	53.15 - 63.80	4.55	-0.20	303	60.36	3.84	52.40 - 67.84	6.30	0.17	12625	59.40	4.56	7.68	59				
1	1134	35			58.47	2.66	53.15 - 63.80	4.55	-0.10	98	59.10	2.31	54.49 - 63.71	3.90	0.09	1179	58.80	3.41	5.79	29				
2	9230	32			97.26	2.01	95.75 - 101.79	2.06	0.46	446	95.14	2.20	93.27 - 102.50	2.40	0.55	20936	96.80	2.71	3.06	53				
pH6																								
1	1132	35			18.64	0.22	18.24 - 19.12	1.17	1.09	303	18.46	0.26	17.93 - 19.07	1.40	0.50	10306	18.25	0.25	2.15	24				
1	1134	35			18.68	0.22	18.24 - 19.12	1.17	0.63	98	18.70	0.23	18.25 - 19.15	1.20	0.60	113	18.37	0.50	2.71	43				
2	9230	32			13.23	0.20	12.83 - 13.64	1.52	0.62	446	13.20	0.18	12.82 - 13.64	1.35	0.67	20399	13.07	0.31	2.39	64				
O2Hb																								
1	1132	35			-11.33	0.24	-11.82 - -10.84	-2.15	-0.30	303	-11.73	0.41	-12.54 - -10.91	-3.49	-0.57	9168	-11.24	0.84	-3.48	29				
1	1134	35			-11.33	0.24	-11.82 - -10.84	-2.15	-0.36	98	-11.45	0.20	-12.21 - -10.69	-3.33	-0.52	772	-11.05	0.77	-4.57	31				
2	9230	32			-11.71	0.26	-12.24 - -11.13	-2.23	0.36	446	-12.14	0.20	-12.74 - -11.53	-2.51	-0.13	22091	-12.02	0.88	-7.20	21				
COHb																								
1	1132	35			0.45	0.32	0.01 - 0.70	0.33	0.69	303	0.59	0.43	0.02 - 0.96	0.71	0.96	9706	0.80	1.25	1.30	26				
1	1134	35			0.45	0.32	0.01 - 0.70	0.33	1.09	98	0.54	0.44	0.07 - 0.92	0.86	1.09	115	0.52	1.03	1.39	24				
2	9230	32			0.50	0.32	0.02 - 0.98	0.31	0.95	446	0.51	0.34	0.02 - 0.97	0.33	0.77	23021	0.57	0.84	82	29				

Notes:
 1. "Mean" are test values in excess of +3 SD from the instrument mean. "Sig" data has been excluded from the current month and all cumulative statistics.
 2. Only those lots for which the current month data has been submitted are included in the summary.
 3. **REMOVED** data indicates that when the Mean or SD value is outside of the assigned peak range (report range) or system acceptance values (the unassigned controls).
 The data has been excluded from the peer group. You may resubmit all completed data within 30 days to receive an updated report.
 4. CV% for pH has been calculated on the basis of the ion concentration (mmol/L).
 5. Unless otherwise indicated, all units for pCO2 and pO2 are reported in mmHg and all electrolyte values are reported in mmol/L.

Roche Diagnostics Corporation 9115 Hague Road Indianapolis, IN 46250-0457 Tel: 800-526-2272 Fax: 800-526-2272
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Be sure to save a copy of the report.

To print, click **Summary** to run a monthly report.

PeerQC
Page Safety Tools

Pop-ups temporarily allowed. To always allow pop-ups from this site, click here...

ROCHE TECHNICAL SUPPORT
 9115 Hague Road
 Indianapolis IN 46250-0457
 U.S.A.

cobas b 221 / OMNI S
 5099

December 2011
 Monthly QC

User:

Data Entry
 Summary Data
 Raw Data
 Linearity
 Data Import
Reporting
 Monthly
 Summary
 Setup
 Edit Lot
 New Lot
 Remove Lot
 *US Patent 7,027,931

QC Product: AUTO-TROL PLUS B

Lots: 21400910-3

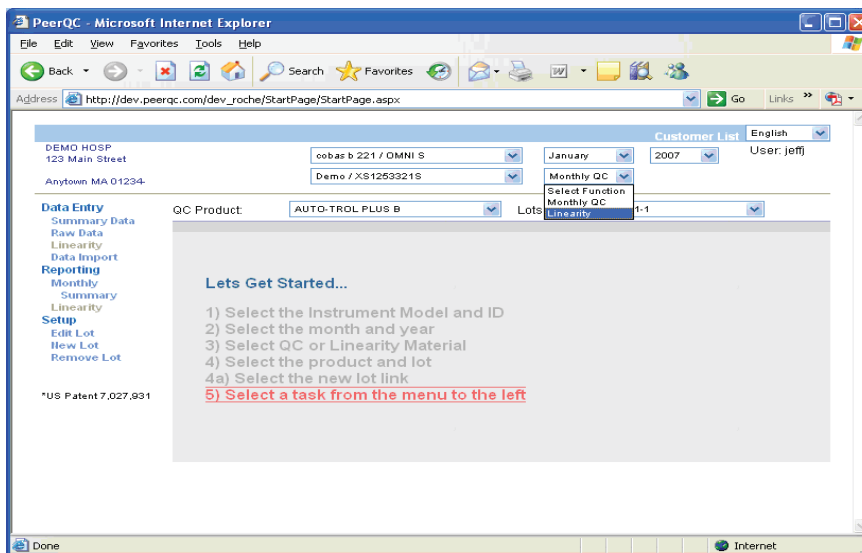
Analyte	Unit	Method Rgt.	Rgt. Lot	Points	Mean	SD	Validation Message	Cum. Mean	Cum. SD
pH	pH		3	7.567			0.000	0.000	
pCO2	mmHg		3	23.73	0.05		0.00	0.00	
pO2	mmHg		3	133.97	0.76		0.00	0.00	
Thb	g/dL		3	20.79			0.00	0.00	
O2Hb	%						0.00	0.00	
HHb	%						0.00	0.00	
COHb	%						0.00	0.00	

Edit Submit Cancel Close Next Lot

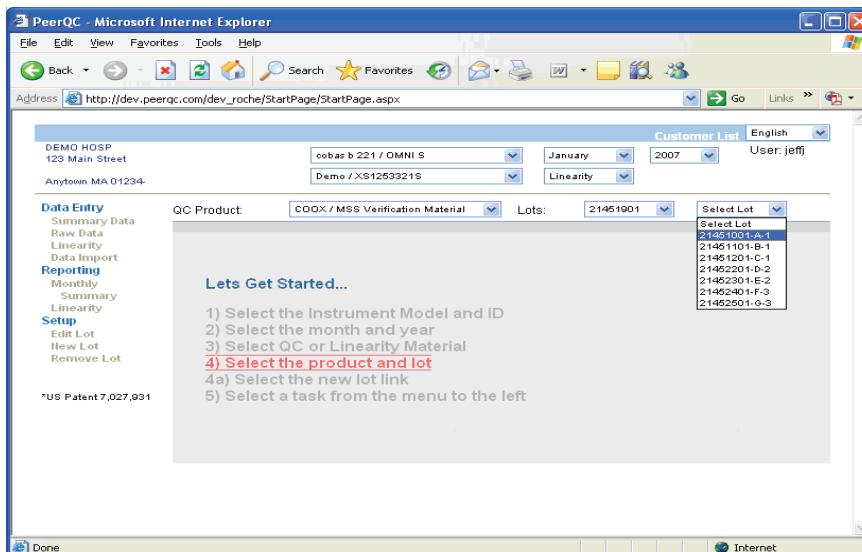
Linearity Data

Entering Linearity Data

1. Select **Linearity** from the Select Function menu.



2. Select the Linearity Product, Kit lot and Lot number from the QC Product and Lot menu listings.



3. Select the **Linearity** link located under Data Entry in the left column.

PeerQC - Microsoft Internet Explorer

Address: http://dev.peerqc.com/dev_roche/Linearity/LinearityEntry.aspx

DEMO HOSP
123 Main Street
Anytown MA 01234

Customer List English
User: jeff

QC Product: COOX / MSS Verification Material Lots: 21451001 21451001-A

Data Entry
Summary Data
Linearity
Reporting
Monthly
Summary
Linearity
Setup
Edit Lot
New Lot
Remove Lot

*US Patent 7,027,931

Analyte	Unit	Method	#	Value	Validation Message
pH			1		
pCO2			2		
pO2			3		
THb			4		
O2Hb			5		
COHb			6		
Methb			7		
K+			8		
BUN					
Ca++					
Na					
Cl-					
Glucose					

Target Low: 7.150 Target High: 7.210

Points: 0 Mean: SD:

Edit Submit Cancel Close

4. Click **Edit**.
5. Select the analyte to enter data (e.g., pH).
6. Click in the first field of the **Value** column.
7. Enter individual Linearity data values.



Press <Tab> to advance to each additional value.

NOTE

PeerQC - Microsoft Internet Explorer

Address: http://dev.peerqc.com/dev_roche/Linearity/LinearityEntry.aspx

DEMO HOSP
123 Main Street
Anytown MA 01234

Customer List English
User: jeff

QC Product: COOX / MSS Verification Material Lots: 21451001 21451001-A

Data Entry
Summary Data
Raw Data
Linearity
Data Import
Reporting
Monthly
Summary
Linearity
Setup
Edit Lot
New Lot
Remove Lot

*US Patent 7,027,931

Analyte	Unit	Method	#	Value	Validation Message
pH			1	7.170	
pCO2			2	7.182	
pO2			3	7.190	
THb			4	79.10	Range: 7.150-7.210
O2Hb			5		
COHb			6		
Methb			7		
K+			8		
BUN					
Ca++					
Na					
Cl-					
Glucose					

Target Low: 7.150 Target High: 7.210

Points: 4 Mean: 25.161 SD: 35.96

Edit Submit Cancel Close

- If you enter a value that is outside of the expected range, a Validation Message may appear. You may accept the value, if correct or edit the entry.

The screenshot shows the eQAP Data Entry interface. At the top, there's a header with 'ROCHE TECHNICAL SUPPORT' and contact information. Below that, there are input fields for 'cobas b 123', 'April', '2014', and 'User: mn'. A 'Customer List' dropdown is set to 'English'. The 'Data Entry' section on the left has a sidebar with links like 'Summary Data', 'Raw Data', 'Linearity', 'Data Import', 'Reporting', 'Monthly', 'Summary', 'Linearity', 'Setup', 'Edit Lot', 'New Lot', and 'Remove Lot'. The main area shows a table with columns: Analyte, Unit, Method, #, Value, and Validation Message. The table contains data for various analytes including pH, pCO2, pO2, THb, O2Hb, HHb, COHb, MetHb, O2sat, K+, Ca++, Na, Glu, and Lac. The pO2 row shows a value of 7.0980 and a validation message 'Range: 7.099-7.179'. At the bottom, there are buttons for 'Edit', 'Submit', 'Cancel', and 'Close'. A status bar at the bottom indicates 'Target Low: 7.099 Target High: 7.179' and 'Points: 3 Mean: 7.11 SD: 0.02'.

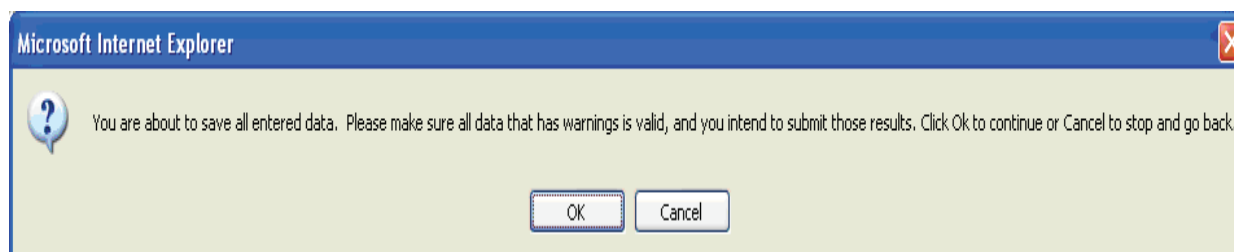
Analyte	Unit	Method	#	Value	Validation Message
pH			1	7.0990	
pCO2			2	7.0980	Range: 7.099-7.179
pO2			3	7.1330	
THb			4		
O2Hb			5		
HHb			6		
COHb			7		
MetHb			8		
O2sat			9		
K+			10		
Ca++			11		
Na			12		
Glu			13		
Lac			14		

Submitting Linearity Data

- Click **Submit** after entering all Linearity values.
- A message appears verifying you wish to save. Click **OK**.
- A message appears verifying the data was saved correctly. Click **OK**.

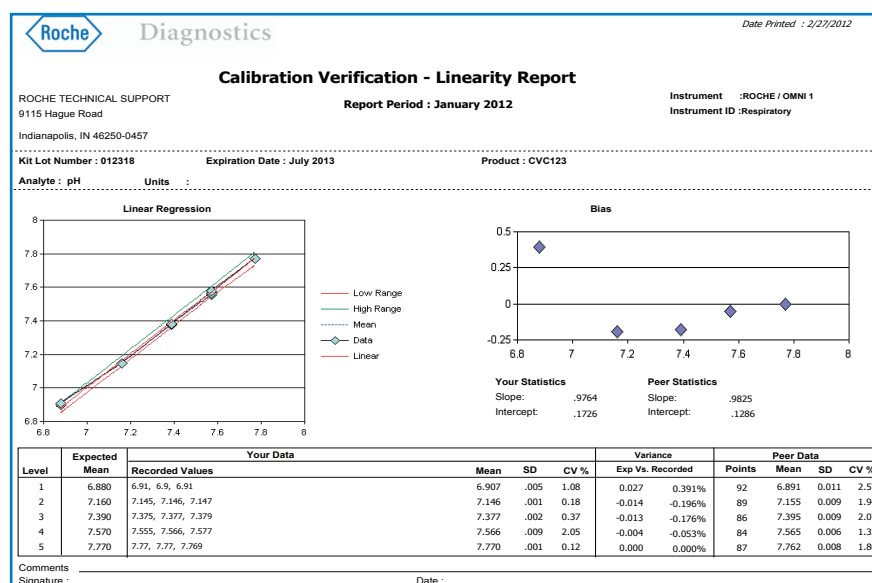


Pushing the cancel button prompts you to save the data. If the data has been saved using the submit button, click OK to leave the screen.



Creating a Linearity Data Report

1. Click the **Linearity** link under Reporting on the left side of the page.
2. The Linearity report displays as a PDF in a separate window.




If the pop-up blocker is ON, you may need to temporarily allow pop-ups. Click on the pop-up message at the top of the screen and select “temporarily allow pop-ups.”

Printing Reports

You may run your monthly report at any time during the month to compare values against the peer group. All reports are calculated **live** so that your peer group is up to date at the time that you print it.

To run a monthly report click the **Monthly Summary** link on the left side of the web page. Note that the report may take several minutes to generate. Be sure to save a copy of the report.

		Roche Diagnostics Quality Assurance Report		Instrument ID: m5443 ICU
Report Period : December 2011		Data Submitted : Summary Data		Instrument Model: AUL CHN 3
				Serial Number: 5443
				QC Lot # QC Product
				1134 AUTO-TROL COMBE
				9132 AUTO-TROL COMBE
				9130 AUTO-TROL COMBE

After Cardiorespiratory Services											
December 2011 STATISTICS						CUMULATIVE STATISTICS					
Level	Lot #	N	Mean	SD	2 SD Range	CV %	SDI	N	Mean	SD	2 SD Range
pH	1 1132	35	7.105	0.005	7.146 - 7.065	1.14	-1.20	383	7.105	0.005	7.146 - 7.065
	1 1134	35	7.105	0.005	7.146 - 7.065	1.14	-0.37	50	7.107	0.004	7.146 - 7.065
	2 9200	32	7.392	0.004	7.394 - 7.400	0.32	-1.81	446	7.395	0.005	7.395 - 7.404
pO2	1 1132	35	72.66	0.49	73.63 - 73.63	0.67	2.62	383	72.06	0.72	76.62 - 73.50
	1 1134	35	73.17	0.49	72.20 - 74.54	0.66	1.76	50	72.67	0.80	76.71 - 74.63
	2 9200	32	65.57	0.33	66.51 - 66.23	0.73	1.35	446	65.24	0.43	66.40 - 66.13
pO2	1 1132	35	58.47	2.66	53.15 - 63.80	4.55	-0.20	383	60.16	3.84	52.48 - 67.84
	1 1134	35	58.47	2.66	53.15 - 63.80	4.55	-0.30	50	58.10	2.71	54.49 - 62.71
	2 9200	32	57.75	2.01	53.75 - 61.75	3.45	0.45	446	58.14	2.39	52.27 - 64.01
pH	1 1132	35	10.68	0.22	10.24 - 11.12	1.17	1.89	383	10.46	0.26	10.93 - 10.97
	1 1134	35	10.68	0.22	10.24 - 11.12	1.17	0.43	50	10.70	0.23	10.25 - 11.36
	2 9200	32	10.23	0.20	10.83 - 11.64	1.92	0.62	446	10.20	0.23	10.82 - 11.64
CHN	1 1132	35	-11.30	0.24	-11.82 - -10.84	-2.15	-0.30	383	-11.73	0.41	-12.54 - -10.91
	1 1134	35	-11.30	0.24	-11.82 - -10.84	-2.15	-0.36	50	-11.45	0.38	-12.31 - -10.69
	2 9200	32	-11.71	0.26	-12.24 - -11.19	-2.23	0.36	446	-12.14	0.39	-12.74 - -11.53
CHN	1 1132	35	96.45	0.32	96.81 - 97.30	0.33	0.49	383	96.39	0.49	95.42 - 98.36
	1 1134	35	96.45	0.32	96.81 - 97.30	0.33	1.69	50	96.54	0.54	95.47 - 97.62
	2 9200	32	102.93	0.32	102.28 - 103.59	0.31	0.55	446	103.11	0.24	102.42 - 103.79

Notes :
 1. "N" is test values in excess of +3 SD from the instrument mean. "N" data has been excluded from the current month and all cumulative statistics.
 2. Only those lots for which the current month data has been submitted are included in the summary.
 3. SDI (SD Index) data indicates that either the Mean or SD value is outside of the assigned package insert range or system acceptance values (if unassigned controls).
 4. The data has been excluded from the peer group. You may re-submit all corrected data within 30 days to receive an updated report.
 5. CV % is not calculated on the basis of the concentration (mg/dL).
 6. Unless otherwise indicated, all units for pO2 and pH are reported in mmHg and all electrolyte values are reported in mmol/L.

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Printed On: February 14, 2012

Adding or Removing Lot Numbers

Adding New Lot Numbers

To add new lot numbers you must select the new lot number as well as the analytes that you are reporting.

Only lot numbers that are still within their expiration dates are displayed. Only QC material can be added. Linearity material is preloaded for all customers.

How to Add New Lot Numbers

1. Click the **New Lot** link under Setup on the left side of the page.
2. Select the QC Product from the pull-down menu of available QC Products. This filters the list of lot numbers.
3. Select the Lot Number from the pull-down list of available lots.
4. Once you have selected your lots a grid appears displaying the list of available analytes.
5. Click **Edit** at the bottom of the grid to activate the analyte grid.
6. Click the checkbox that corresponds to the analytes that you wish to add. Use the scroll bar to the right of the screen to view the full list of analytes.
7. You may also select the appropriate units of measure for the selected analyte.



Method and Reagent are also displayed, but are not applicable for blood gas instruments.

8. Click **Submit** located at the bottom of the grid.
9. You may now click the **Data Entry** link to begin entering data for your new lot.

Removing Lot Numbers

How to Remove Lot Numbers

1. After selecting the Product and Lots from the QC Product and Lot filter selections, click **Remove Lot Link** located under setup on the left side of the screen.
2. Click **OK** at the prompt if you are sure you want to remove the selected lot



NOTE

Removing a lot from the drop-down menu does not affect any historical data or reports.

The screenshot displays the eQAP Data Entry web application. At the top, there is a header with 'ROCHE TECHNICAL SUPPORT' and contact information. Below this, there are dropdown menus for 'cobas b 123', 'April', '2014', and 'Monthly QC'. A 'Customer List' dropdown is set to 'English', and the user is identified as 'mn'. On the left, a navigation menu includes 'Data Entry', 'Summary Data', 'Raw Data', 'Linearity', 'Data Import', 'Reporting', 'Monthly', 'Summary', 'Linearity', 'Setup', 'Edit Lot', 'New Lot', and 'Remove Lot'. The 'Setup' section is currently active, showing 'QC Product: AutoQC' and 'Lots: 2142175501-1'. A 'Lets Get Started...' section lists five steps, with the fifth step, '5) Select a task from the menu to the left', highlighted in red. A modal dialog box titled 'Message from webpage' is open in the foreground, asking 'Are you sure you would like to remove the selected Lot?' with 'OK' and 'Cancel' buttons.

eQAP export cobas b 221 blood gas system

Setting the Data Export Format cobas b 221 blood gas system

To check or change the order of the data fields for the QC database export press **Setup > Displays and Reports > QC Measurement > QC Database Export**.



The QC Database Export “Selected Items” list should typically be set in the same order that they appear on the left side of the set up screen on the “Items” list. Select items using the right pointing arrow key between the “Items” list and the “Selected Items” list the field highlighted on the left side moves under the line where the cursor exists on the “Selected Items” list.

1. Date
2. Time
3. Material
4. Level
5. Lot number
6. Exp Date
7. Base
8. Equilibration Temp (Temp AQC)
9. Remark field
10. Analytes start here (e.g., pH, CO₂)

The order of the analytes (e.g., pH, pO₂, Na) in the “Selected Items” list can be in any order as long as they begin at item #10. List all analytes needed for import for the program. The additional fields do not effect the import to the eQAP program.

After setting the order of the “Selected items” for export, selected QC records may be exported for evaluation. The export is performed using **Data Manager > QC Measurements > More > Export**. The files must be imported as .txt files to the program. Typically a month’s data is exported for evaluation. Use a tab delimited file type.



See section B of the **cobas b** 221 blood gas system *Instructions for Use* of the analyzer for reference material. It shows a list of icons and the screen that must be accessed to down load the files.



You should clean up your data first by reviewing for outliers and removing bad data points that should have been rejected.

1. Open the Data Manager file folder using the Data Manager icon in the top right corner of the screen.



2. Pick “QC data” to display a screen similar to the one below.

Ready





ID

QC measurements

Date	Time	Material	Level	PCO ₂	PO ₂
02.9.2002	16:17	AUTO-TROL TS +	3	22.5	133.5
02.9.2002	16:12	AUTO-TROL TS +	2	41.3	90.2
02.9.2002	08:10	AUTO-TROL TS +	1	57.9	54.7
01.9.2002	21:10	AUTO-TROL TS +	3	22.2	132.4
01.9.2002	21:05	AUTO-TROL TS +	2	41.5	89.0
01.9.2002	21:01	AUTO-TROL TS +	1	57.8	69.7
31.8.2002	21:10	AUTO-TROL TS +	3	22.2	132.6
31.8.2002	21:05	AUTO-TROL TS +	2	41.1	87.6

Mat change 14:10

System cal 15:02

3. The icon for mark range  at the bottom of the screen is used to select the date range (Typically a month's data is exported for evaluation).
4. After picking that icon, set the date range that is needed (One month's data e.g., 3/01/2014 to 3/31/2014). The selected lines are now highlighted in yellow.
5. Export is performed using **Data Manager > QC Data > More** (the right pointing arrow key)  **>Export** to show the Data Export icon  on the next screen.
6. Pick the Data Export icon .
7. Setup the file for export:
 - a. The files must be imported as .txt files to the program (i.e., text file with field delimiters).
 - b. Name the file in a manner that it is unique when imported (e.g., July2013).
 - c. Do not use compression. Turn it off so that a red dot is by the 0.
 - d. Use a "tab delimited" file type. You may have to select this delimiter using the right left arrow keys near that field.
 - e. Use a format style of decimal point (i.e., not a comma).

When data is selected:

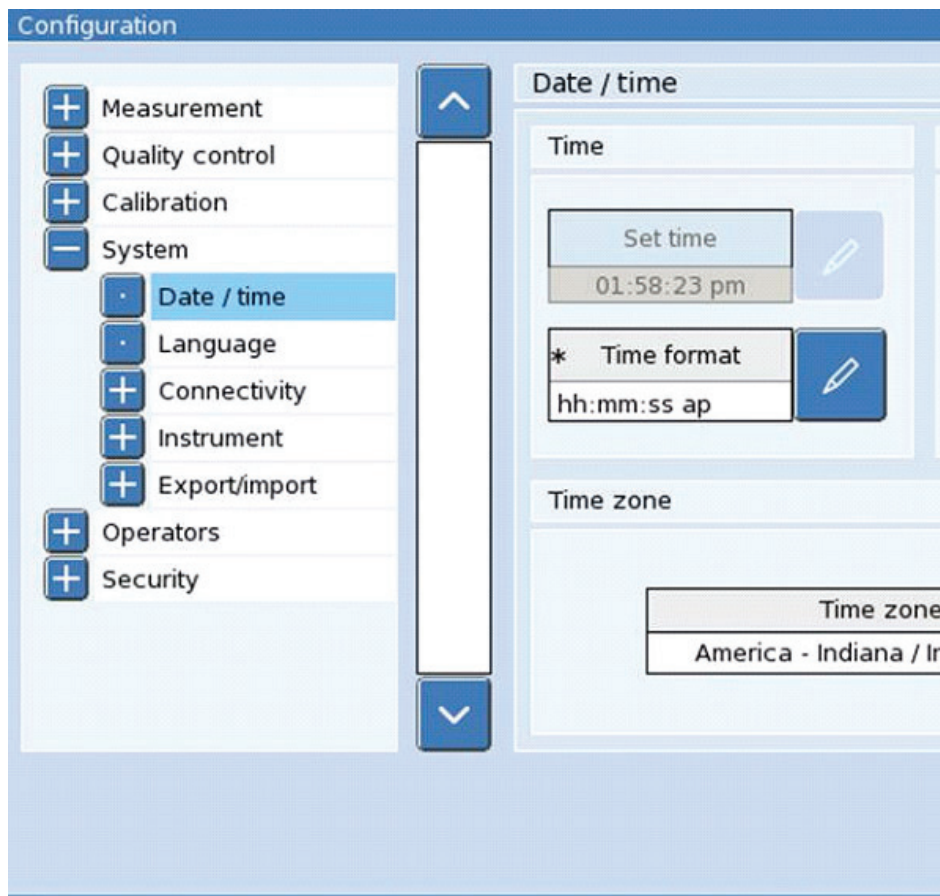
8. Press the **Start** button and insert the USB Stick (or for old SNs the floppy disk). This captures all lots of material run during that time frame.
9. Remove the storage medium.

eQAP export cobas b 123 POC system

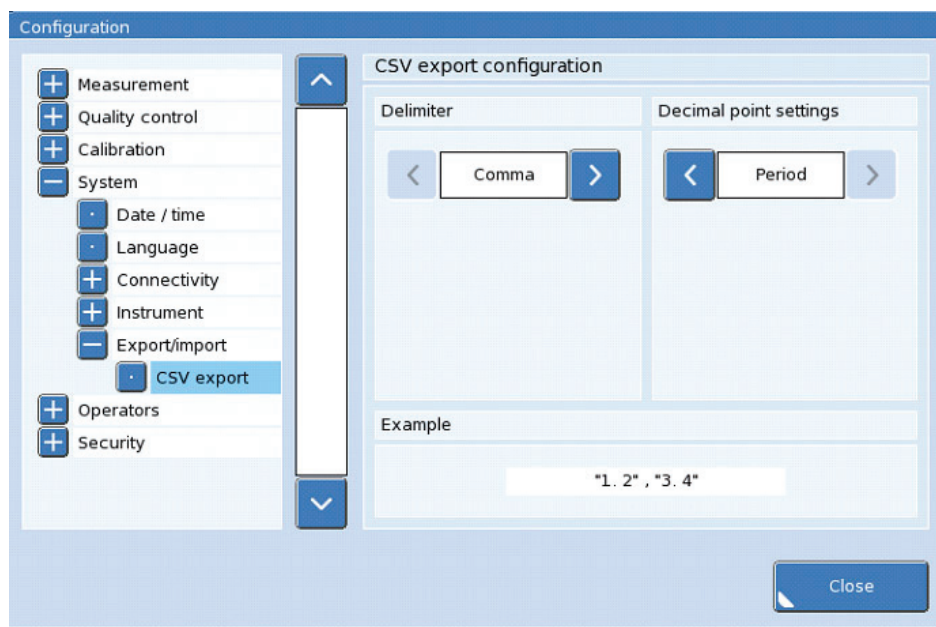
See Chapter 9, Quality Control of the **cobas b 123 POC system Instructions for Use**, for more detailed information. The following are abbreviated specific steps.

Setting the Data Export Format cobas b 123 POC system

1. Specify date format as (MM/dd/yyyy), m/dd/yy, mm/dd/yy, m/dd/yyyy, or mm/dd/yyyy for U.S. customers. For International Customers: dd/mm/yy. Include time format to 12 hour or 24 hour clock with format (e.g., 07/17/13 13:52).
To set press **Utilities > Configuration > System > Date/time**

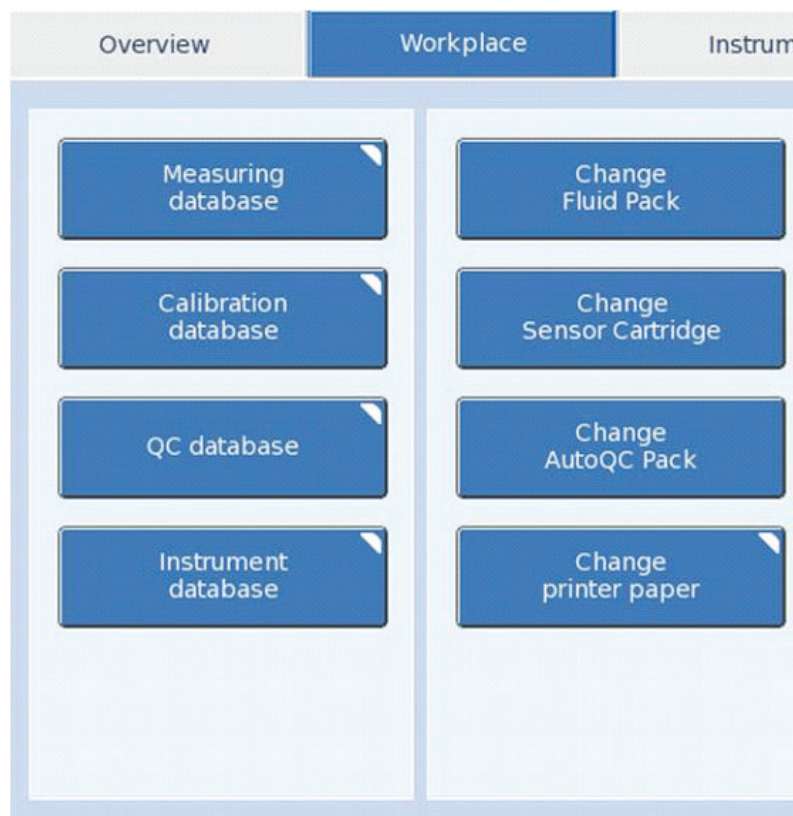


2. Set export to use comma delimited file.
To set press **Utilities > Configuration > System > Export/import** and select the delimiter to **comma**. Set the decimal point format to **period**.

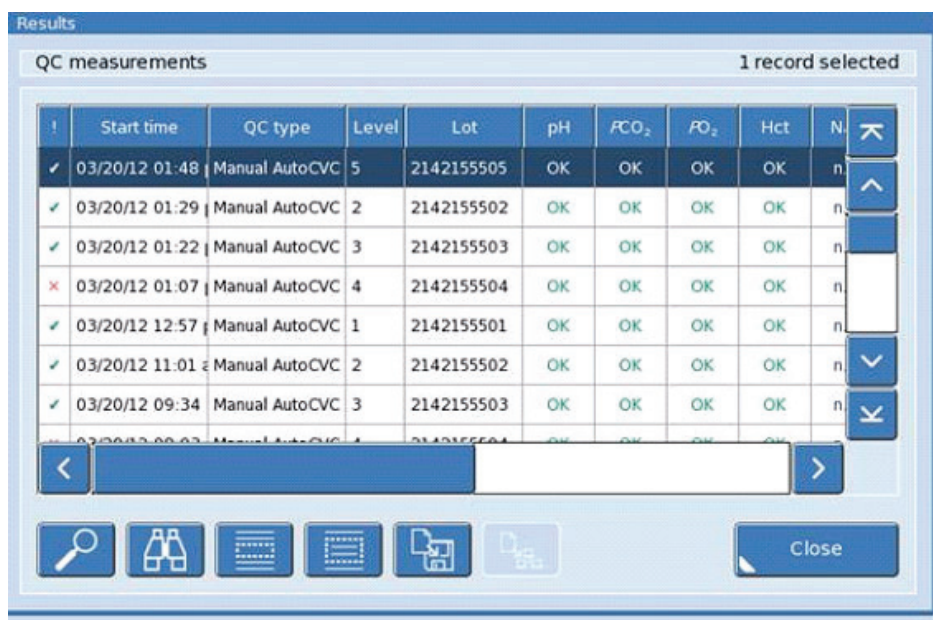


Exporting files from the cobas b 123 POC system to a USB

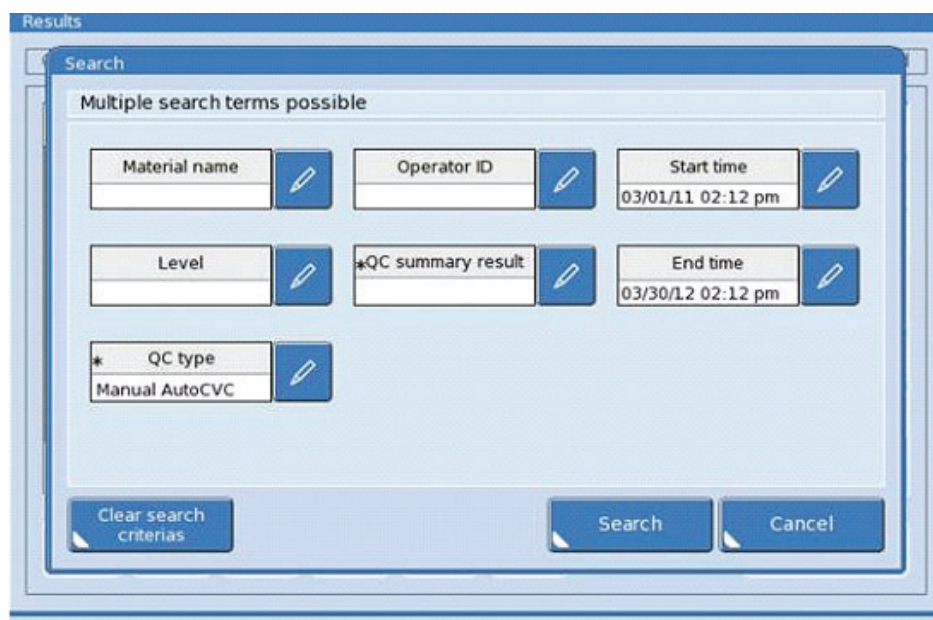
1. To open the database press **Workplace > QC Database >**



2. Designate which records to import from the database.



After selecting the QC database, a list of records appears that can be sorted. Use the search icon that appears at the bottom of the screen to filter for the appropriate record. (This icon looks like binoculars.) After opening the search feature filter by date and QC record type to select the appropriate records as seen in the picture below. Any record type, date or other selection criteria desired may be selected to obtain a specific set of records.



Appendix B

3. Select records for export. Use the icons to select required records. The records are highlighted after selection.

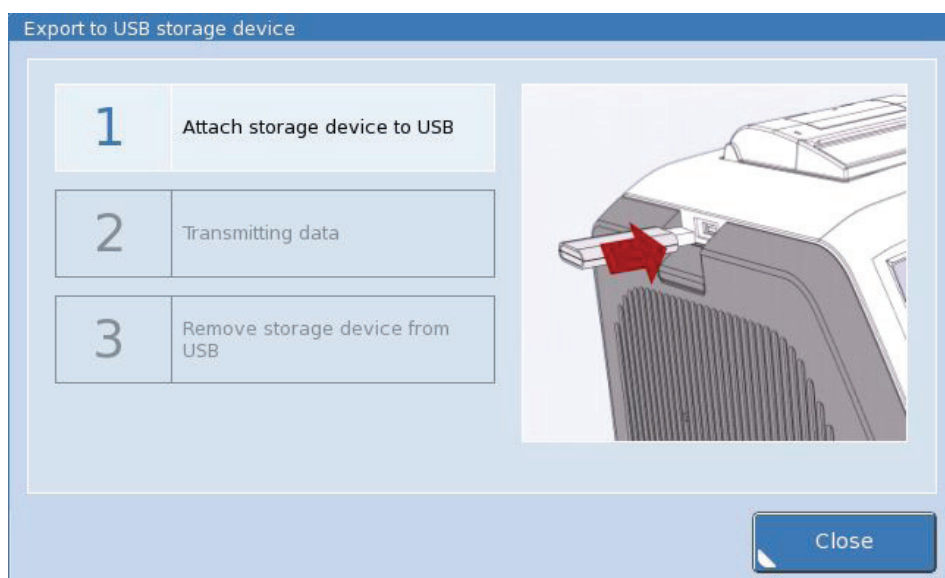


marks a single record in a file; select each record and press this button to highlight

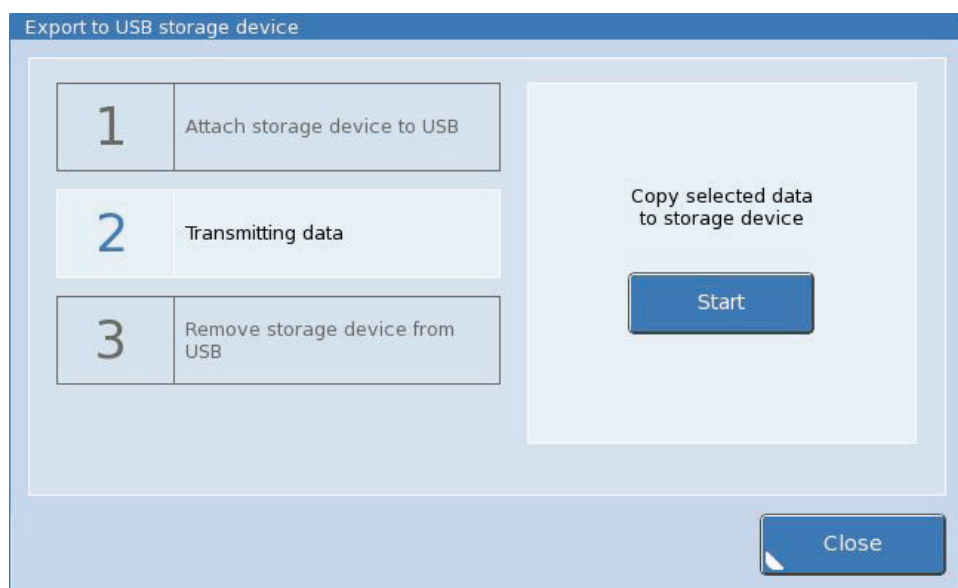


marks all records

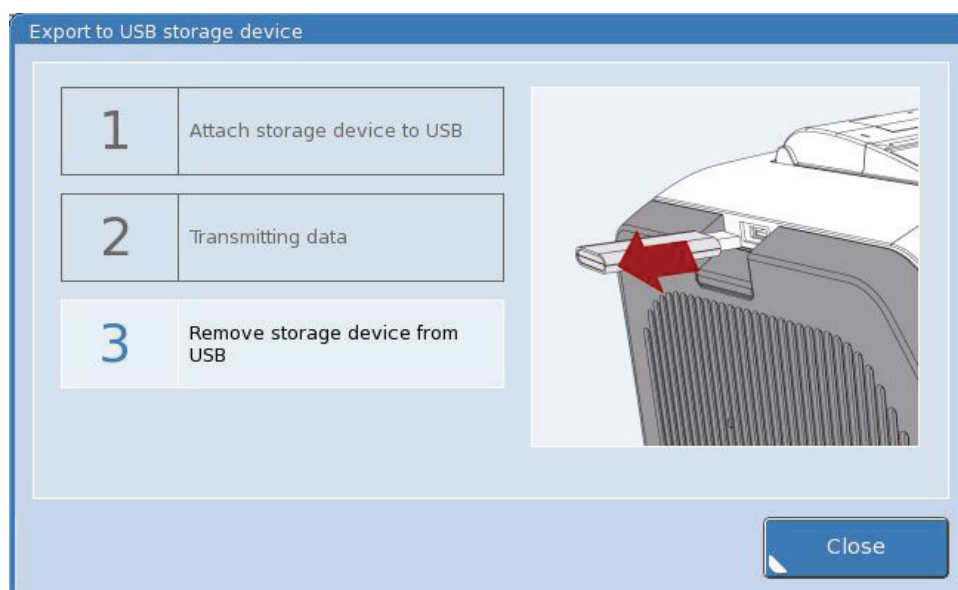
4. Export the records to USB stick.
Use the export icon to start the export process. The analyzer prompts through three steps including:
 - Add the USB storage device to the instrument's USB port:



- Start the export of data.



- Remove the USB storage device and close the window.



Notes