14-021
04/25/14

Roche Diagnostics
9115 Hague Road, PO Box 50457
Indianapolis, IN 46250-0457 USA
Tel. + 1-317-521-2000
+ 1-800-428-5074

Roche

Software Bulletin

cobas® 6000 analyzer series – Software Version 05-02 Upgrade

Introduction

Roche Diagnostics is pleased to announce the release of software version 05-02 for the **cobas** 6000 analyzer series. Software version 05-02 supersedes all other versions of software and applies to all configurations of the **cobas** 6000 analyzer series.

NOTE

The upgrade to cobas 6000 analyzer series software version 05-02 is mandatory.

Use this Software Bulletin as a resource guide to understand the changes from your current software version to software version 05-02.

New Features or Improved Functionalities with Software Version 05-02

The new features or most significantly improved functionalities with software version 05-02 are listed below and explained in detail in pages 2-20 of this Software Bulletin:

- PT Link: shows link status of reagents for the **cobas e** 601 module
- EP17-A2 implementation for **cobas c** 501 module
- Data storage to USB device: a new storage concept
- Calibrator update: new confirmation windows
- Special washes for Elecsys® assays update
- Bath detergent: name change
- Reagent disk: introduction of additional movement during pre-operation for **cobas c** 501 modules

NOTE

TraceDoc Export is a new backup function that will be available in the future. You will receive a separate communication explaining this new feature when it becomes available.

over...

☑ **cobas c** 501
☑ **cobas e** 601

Software Installation

Your Roche Field Service Representative (FSR) will contact your laboratory to schedule the software installation.

Updated Operator's Manual and Host Interface Manual

The updated **cobas®** 6000 analyzer series Operator's Manual, V6.0.1 and Host Interface Manual are available on the Roche Diagnostics USA website (usdiagnostics.roche.com). The Operator's Manual will be mailed at a later date.

Enclosure

cobas c 501 analyzer Verification Checklist Prior to your Software Installation, literature number 5334-00-0414

Actions Required Prior to Installation of 05-02 Software Version

- Before your scheduled software installation date, complete the enclosed "**cobas c** 501 analyzer Verification Checklist Prior to your Software Installation" for the applications on the list that are currently installed on your **cobas c** 501 module. Have it available for your FSR. The completed list informs your FSR which assays need the technical limit updated.
- On the day prior to the software installation, load the minimal number of **cobas c** packs for the assays listed on the "**cobas c** 501 analyzer Verification Checklist Prior to your Software Installation" that are currently installed on your **cobas c** 501 module. All **cobas c** packs, including Standby **cobas c** packs, for the chemistries requiring an updated technical limit (i.e., on the checklist) must be "Dumped" and discarded upon installation of the software.

Actions Required

- Review the information contained in this Software Bulletin.
- Distribute this Software Bulletin appropriately in your facility and file for future reference.
- Discard Software Bulletin 10-227 and Analyzer Bulletin 12-130 once software version 05-02 is installed on your **cobas** 6000 analyzer series.
- Discard any **cobas c** packs removed ("Dumped") from your **cobas c** 501 module due to the software installation per your local guidelines.
- Following the installation of software version 05-02, fax the completed "**cobas c** 501 analyzer Verification Checklist Prior to your Software Installation" to 1-800-722-7222 to receive replacement products.

Questions

Please contact the Roche Support Network Customer Support Center at 1-800-428-2336 if you have questions about the information contained in this Software Bulletin.

PT Link: Link Status of Reagents for the cobas e 601 module

Explanation of PT Link

After registration, a pretreatment **cobas e** pack always forms a pair with a reagent **cobas e** pack of the same test and the same lot. This function is called PT link and it ensures that only one pretreatment **cobas e** pack can be calibrated, controlled, and used for testing with one linked assay **cobas e** pack.

- Once a reagent **cobas e** pack and a pretreatment **cobas e** pack are linked together, neither of them can be linked to another **cobas e** pack.
- The lower number of remaining tests in one of the linked **cobas e** packs determines the number of available tests. A liquid level detection is performed during aspiration of pretreatment.
- If one **cobas e** pack in the pair becomes empty, the remaining number of tests for the linked **cobas e** pack is set to 0. Neither **cobas e** pack can be used any longer.
- This new feature allows multiple packs of Anti-TSHR to be on board at one time.

Changes in the Detail Window Based on Linked cobas e packs

With software version 05-02, the link status is displayed in the reagent Detail window. If the assay **cobas e** pack does not require a pretreatment, the fields for the link status are not displayed.

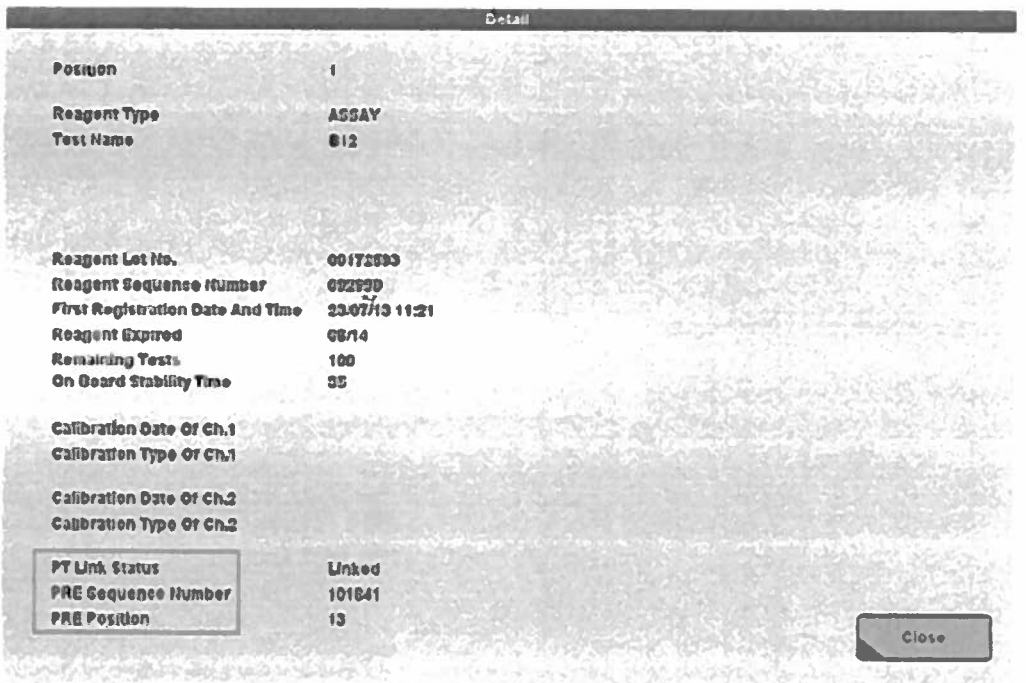


Figure 1. Reagent Detail window for assay showing link for Pretreatment cobas e pack (System Overview > Reagent Overview > Detail)

For pretreatment **cobas e** packs and assays that require a pretreatment, the Detail window offers three new fields (i.e., PT Link Status, PRE/ASSAY Sequence Number, PRE/ASSAY Position). Refer to the example in Figure 1 above. These fields are only available for **cobas e** packs that can be linked to a partner **cobas e** pack. The table on the following page describes the new fields in more detail.

Changes in the Detail Window, continued

Explanation of New Fields in the Detail window:

Assay cobas e pack	Pretreatment cobas e pack	Explanation
PT Link Status	PT Link Status	Displays the link status. Only assay **cobas e** packs that require pretreatments have a link status. Possible link statuses are "Free" or "Linked." • **Free**: The **cobas e** pack is not yet linked to any other **cobas e** pack and has not been used before. Free **cobas e** packs are not available for measurement. • **Linked**: The **cobas e** packs are linked together. If both **cobas e** packs are on board, the reagent is available for use. If one **cobas e** pack becomes empty, both reagents are not available for measurement.
PRE Sequence Number	ASSAY Sequence Number	Displays the sequence number of the linked **cobas e** pack. • Example: 101841 • If "-----" is displayed, there is no linked **cobas e** pack (link status: Free).
PRE Position	ASSAY Position	Displays the position of the linked **cobas e** pack on the reagent rotor. • Example in Figure 1: 13 • A position is displayed only if the **cobas e** pack is linked (link status: Linked) and if the linked **cobas e** pack is on board. • Nothing is displayed if the linked **cobas e** pack is not on board or if the **cobas e** pack is not yet linked (link status: Free).

Linking Procedure and Priority Rules

The analyzer registers **cobas e** packs automatically when the reagent disk cover is closed. When a new **cobas e** pack is loaded on the **cobas e** 601 module, the software checks if this **cobas e** pack has a link status. If the **cobas e** pack has the link status "Free," the software tries to find an appropriate **cobas e** pack.

If there are multiple possible assay or pretreatment **cobas e** packs with the link status "Free," the software selects based on the following priority rules:

Based on cobas e pack Type...	the analyzer processes the cobas e pack type in the following order:
Assay **cobas e** pack	1. Current assay **cobas e** pack 2. Assay **cobas e** pack that expires first 3. Assay **cobas e** pack first registered on the instrument 4. Assay **cobas e** pack with the least number of determinations 5. Assay **cobas e** pack with the lowest position number
Pretreatment **cobas e** pack	1. Pretreatment **cobas e** pack first registered on the instrument 2. Pretreatment **cobas e** pack with the least number of determinations 3. Pretreatment **cobas e** pack with the lowest position number

NOTE

After updating to the current software version with the PT link function, some cobas e packs may still have the link status "Free" even though they have been used. The PT link function will be used for the next fresh cobas e pack.

Software Response to Loading a New cobas e pack Without its Required Partner cobas e pack

If you load a new **cobas** e pack without its required partner **cobas** e pack, the software issues a red reagent warning.

In the examples below, the B12 assay **cobas** e pack is loaded and the required pretreatment pack is missing.

System Overview screen: Required pretreatment **cobas** e pack is missing (Figure 2).

- The Module button for the **cobas** e 601 module in the Module Overview area turns red.
- The Reagent Preparing button in the Work Flow Guide area turns red.
- The Reagent Load List button in the Reagent Preparing window turns red. The Reagent Load/ Unload List will indicate which **cobas** e pack is missing.

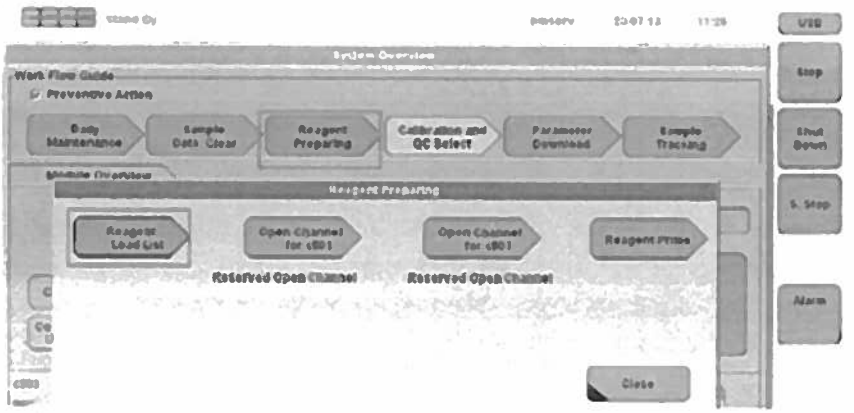


Figure 2. System Overview screen - cobas pack without partner pretreatment cobas e pack

Reagent Overview screen: Required pretreatment **cobas** e pack for B12 assay is missing (Figure 3).

- The **cobas** e pack is marked as "RP: Caution (red)."
- No status (e.g., current, SB1) is displayed.
- Available Tests are zero, although in this example, the B12 assay **cobas** e pack is new and full.

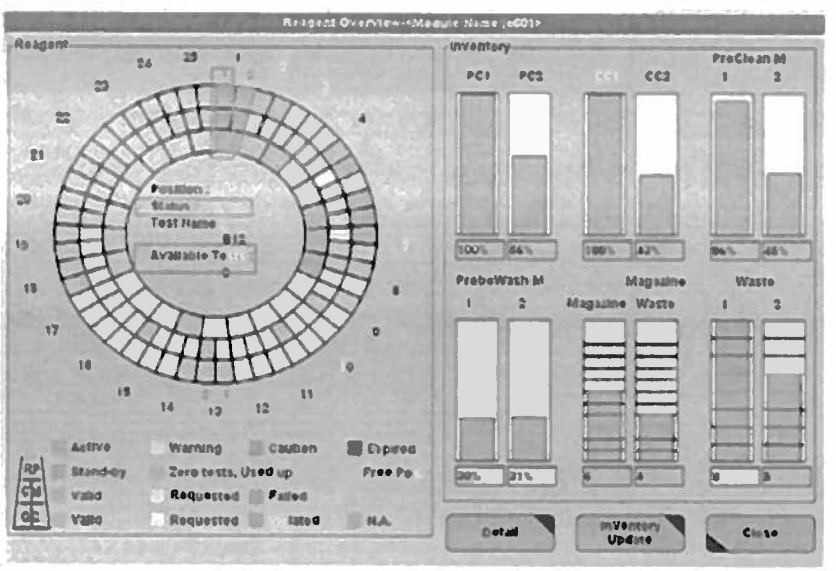


Figure 3. Reagent Overview screen - assay cobas e pack without partner pretreatment cobas e pack

Software Response to Loading a New cobas e pack Without its Required Partner cobas e pack, continued

Detail window: Required pretreatment **cobas e** pack for B12 assay is missing (Figure 4).

- Remaining Tests is displayed in red, but shows the maximum number of tests for this B12 **cobas e** pack.
- PT Link Status is "Free." This B12 **cobas e** pack is not yet linked; it requires a partner pretreatment **cobas e** pack.
- Sequence Number is "-----" because this B12 **cobas e** pack is not linked; therefore, the sequence number of the partner pretreatment **cobas e** pack is unknown.
- Position is "Nothing" as there is no partner pretreatment **cobas e** pack on board; therefore, its position is unknown.

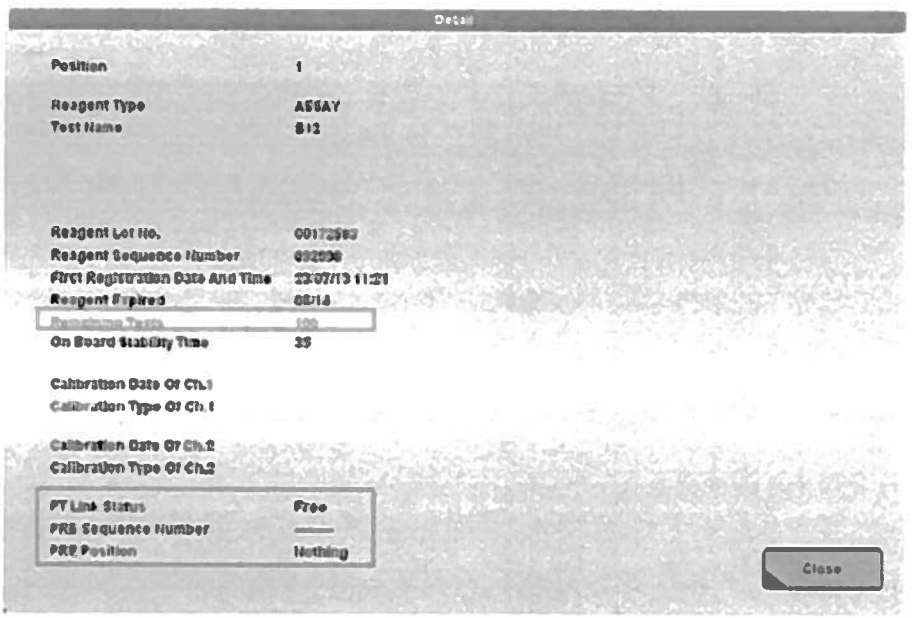


Figure 4. Detail window - B12 assay cobas e pack without partner pretreatment cobas e pack

Software Response to Removing a Linked cobas e pack Without Removing its Partner cobas e pack

If a linked assay **cobas e** pack or pretreatment pack is removed from the reagent rotor and the partner pretreatment pack or assay **cobas e** pack is still on board, the software acts similar to the examples when an assay **cobas e** pack/pretreatment pack did not have its required partner pretreatment/assay **cobas e** pack. The only difference is found in the Detail window. (See Figure 5 on the next page.)

- PT Link Status is "Linked." Both the assay **cobas e** pack and the pretreatment pack are linked to each other and cannot be linked to another pretreatment pack or assay **cobas e** pack.
- Sequence Number is 101841 (as an example). This is the sequence number of the linked partner pretreatment pack.
- Position is "Nothing" because the linked partner pretreatment pack is not on board. It is impossible to display a position number if the partner **cobas e** pack is not on board.

Once a partner assay **cobas e** pack or pretreatment pack is placed back on board the analyzer, the link is re-established.

Software Response to Removing a Linked cobas e pack Without Removing its Partner cobas e pack, continued

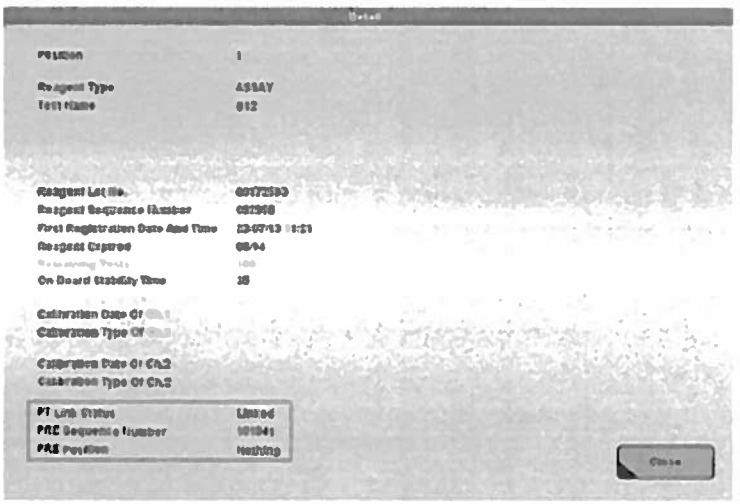


Figure 5. Detail window - linked cobas e pack has been removed with partner cobas e pack still on board

NOTE

For additional information concerning the PT link, refer to the cobas 6000 analyzer series Operator's Manual (Part B, Operation > 10 Reagents > Reagent concept - cobas e 601 module) or the cobas® 6000 analyzer series Online Help.

Roche Diagnostics is gradually implementing the requirement of the CLSI (Clinical and Laboratory Standards Institute) guideline EP17-A2 to suppress results below the technical limit.

Software Changes Related to EP17-A2

The 05-02 software has a new function, "Suppress Result <Test," located in the Alarm Setting (Utility > System [Page 1/4] > Alarm), that must be activated to meet this requirement.

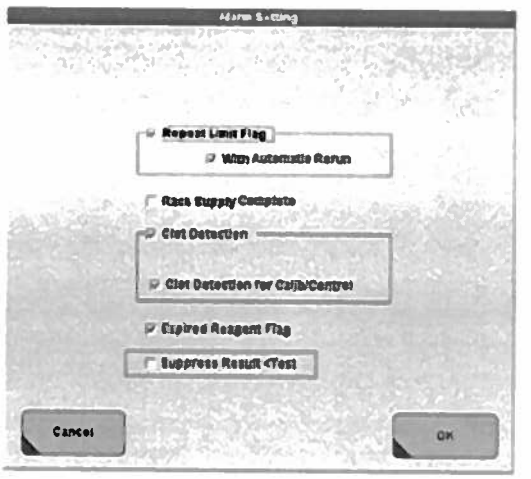


Figure 6. Alarm Setting window - Utility > System (Page 1/4)> Alarm

NOTE ***Upon installation of software version 05-02, your FSR will activate the "Suppress Result <Test" setting.***

NOTE ***The Alarm Setting can be accessed/updated only by an operator with Administrator level or higher.***

When the "Suppress Result <Test" is activated and the measurement result is below the technical limit, the lower limit of the technical limit is displayed as the result flagged with a data alarm. The displayed data alarm depends on the data alarm priority.

If no other alarm occurs, a "<Test" alarm is attached to results below the technical limit.

The effect of the enabled "Suppress Result <Test" on reruns follows:

- Automatic rerun: If the normal and increased volumes (Utility > Application > Analyze) are identical, automatic reruns are not performed for results flagged with a "<Test" alarm. In this case, reruns can still be requested manually.
- Rerun for the % HbA1c application: The rerun is performed even if normal (Norm.) and increased (Inc.) volume have the same values, because it is a calculated test. However, it is generally recommended that you clear the test-specific Automatic Rerun check box in Utility > Application > Range to avoid ratio calculations with results from two different runs.

Application Changes Related to EP17-A2

In addition to the software changes due to CLSI guideline EP17-A2, changes to the application parameters are necessary.

For certain **cobas** c 501 tests, the following application parameters are updated:

- The increased sample volume (Inc.) is set equal to the normal volume (Norm.) to avoid automatic rerun for results below the technical limit.
- The lower Technical Limit is set to the defined lower limit of measurement.

In the example below, the following changes are shown for the CREA2 (ACN 452) test:

- The increased sample volume is changed from 4.0 to 2.0 µL to match the normal sample volume.
- The lower Technical Limit is changed from 0 to 5 µmol/L - the lower limit of measurement.

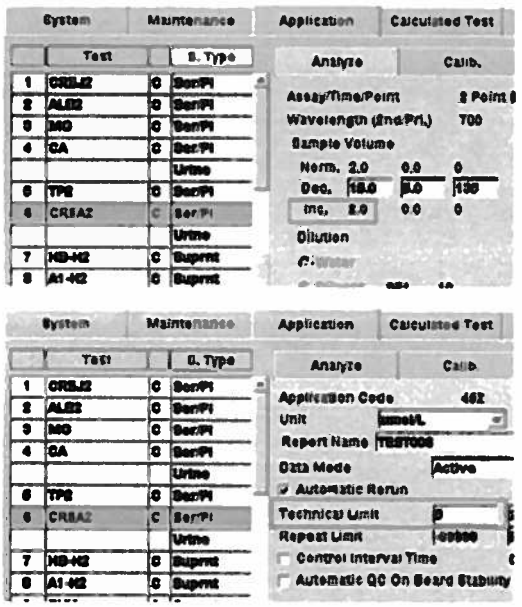


Figure 7. Example of changes in Application parameters - CREA2

Application parameter changes will be reflected in new e-barcodes.

NOTE

Upon installation of software version 05-02, your FSR will update the technical limit fields for applications on your cobas c 501 module. After installation of the software, always ensure the latest version of e-barcodes (i.e., latest release date) has been downloaded.

Data Alarms

The system displays one data flag for each result in the Alarm column. If more than one data flag is associated with a test result, the system displays the alarm depending on the data alarm priority.

NOTE

For information concerning data alarm priority, refer to the cobas 6000 analyzer series Operator's Manual (Part D, Troubleshooting > 19 Data alarms > Introduction > Data alarm priority).

External Data Storage to USB Device

The means of external data storage for the **cobas®** 6000 analyzer series have been improved. USB storage devices can be used for software version 05-02 and higher.

General Information About USB Storage Device Requirements

Only USB flash drives, commonly referred to as *pen drives* or *memory sticks* are released for use as USB storage devices. External USB hard drives are not supported.

A USB storage device must fulfill the following conditions:

- No password protection function
- No program of its own already installed
- Can be used without password input or biometrics authentication

A maximum of 2000 files, irrespective of their size, can be stored on any media used for backup. This limitation also applies to USB storage devices.

When using a USB storage device, observe the following requirements:

- Insert or remove a USB storage device only when the analyzer is in Standby mode.
- Only remove USB storage devices after choosing USB (global button).
- At any one time, only **one** USB storage device can be in use. Before inserting a USB storage device, check that no other USB storage device is inserted.

Although only one USB storage device can be in use at a time, different USB storage devices can be used for different data.

Software Changes in 05-02 Software Related to USB Storage Devices

In the Print View window, the button name has changed from Floppy Disk Write to Media Write (Figure 8).

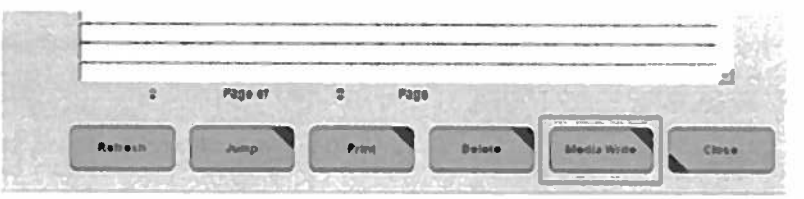


Figure 8. Media Write Button in Print View window (Print [global button] > View)

Software Changes in 05-02 Software Related to USB Storage Devices, continued

The Floppy Disk Write window name has been changed to Media Write. In the Media area of the Media Write window, you can choose between Floppy Disk or Mass Storage. Mass Storage should be selected when using USB storage devices (Figure 9), and for DVDs.

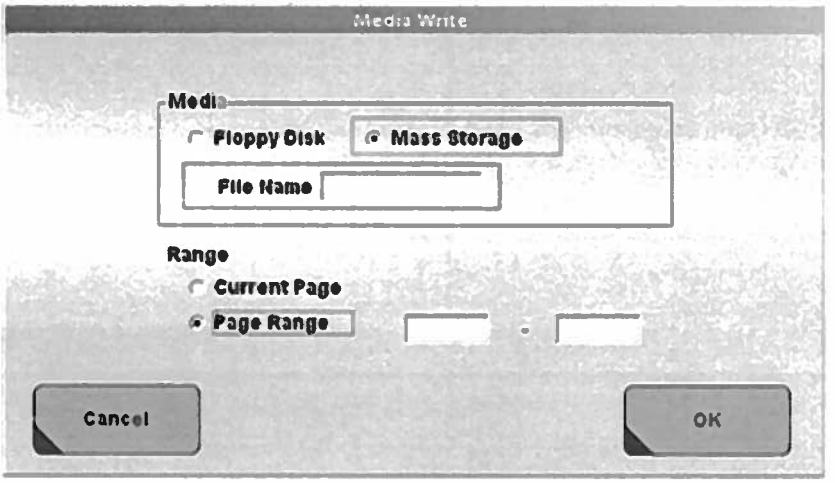


Figure 9. Media Write window (Print [global button] > View > Media Write)

In the Parameter Read/Write window, there is a new Media area to choose between Floppy Disk and Mass Storage (Figure 10).

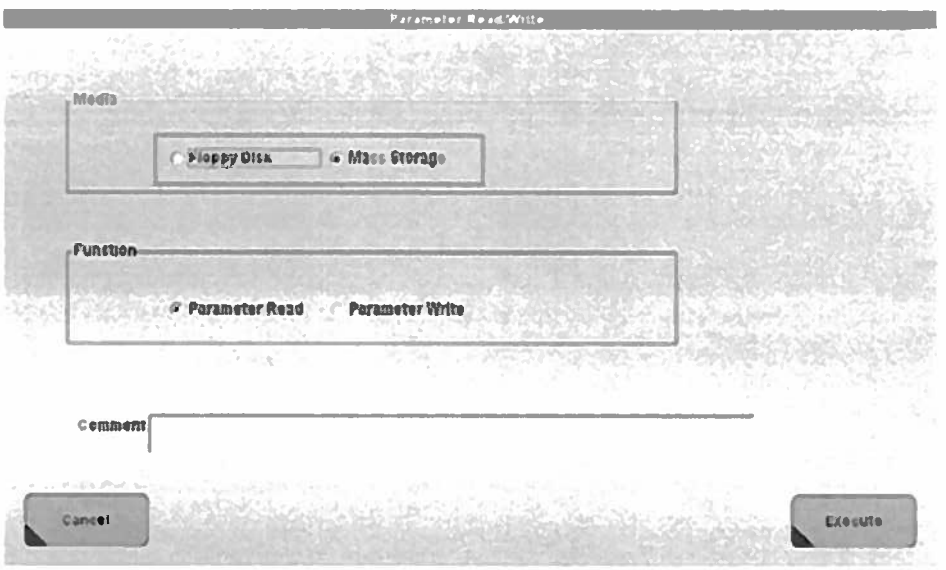


Figure 10. Parameter Read/Write window (Utility > Maintenance > Maintenance [Maintenance Type] > (15) Parameter Read/Write > Select)

Software Changes in 05-02 Software Related to USB Storage Devices, continued

In the Media area of the Check Disk window, the Zip option is changed to Mass Storage (Figure 11). If you select this option, the instrument checks files on the DVD or USB storage device:

- If a USB storage device is inserted, the instrument uses the USB as mass storage.
- If no USB storage device is inserted, the instrument uses a DVD as mass storage.

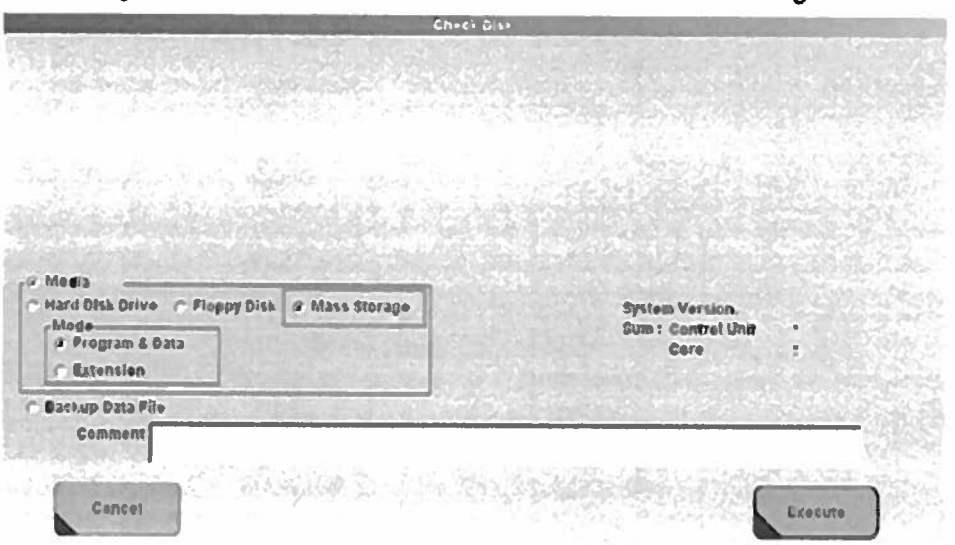


Figure 11. Check Disk window (Utility > Maintenance > Check [Maintenance Type] > (1) Check Disk > Select)

To Insert a USB Storage Device

1. Ensure the analyzer is in Standby mode.
2. Ensure that no other USB device is plugged into the Control Unit computer.
3. Plug the USB storage device into any USB port of the Control Unit computer.

To Remove a USB Storage Device

A new global USB button is implemented for using USB storage devices. Follow the steps below for removing a USB storage device using the global USB button.

1. Ensure the analyzer is in Standby mode.
2. Use the USB button to remove a USB storage device.

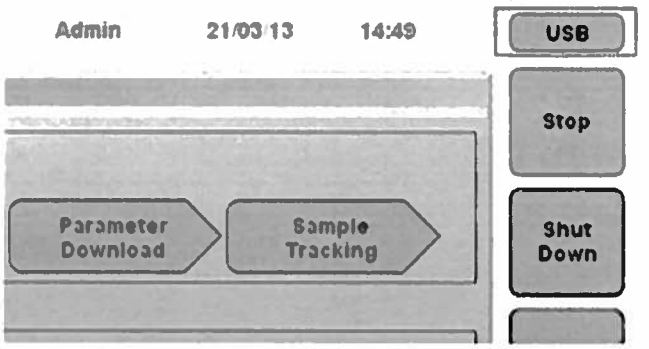


Figure 12. Global USB button

After choosing the global USB button, the following Confirmation window is displayed.

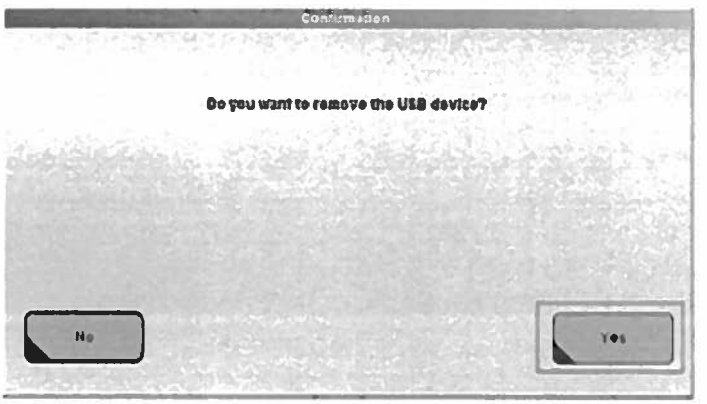


Figure 13. Confirmation window to remove USB device

3. Choose the Yes button and an additional Confirmation window is displayed. Remove the USB device and choose OK.

Figure 14. Confirmation window to remove the USB device

Saving the Print Buffer

You can save the content of the print buffer. The analyzer writes the content of the print buffer into a text file (*.txt). Follow the steps below to save the print buffer.

1. Choose Print (global button) > View to display the Print View window. If you want to save one specific page only, scroll to that specific page.

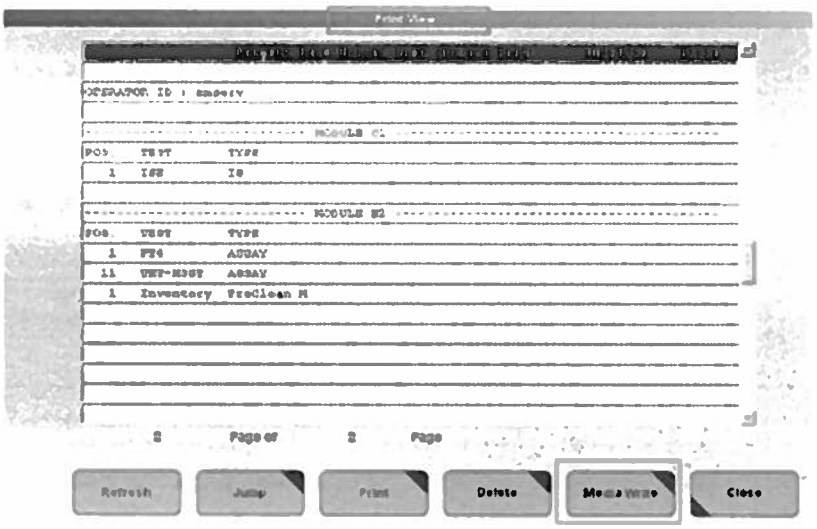


Figure 15. Print View window

2. Choose the Media Write button to display the Media Write window.
   - In the Media area, select Mass Storage to save the print buffer to the USB storage device.
   - Enter a file name in the File Name text box.
   - If you want to save the current page only, select Current Page.
   - If you want to save more pages, select Page Range and enter the first and last page numbers.

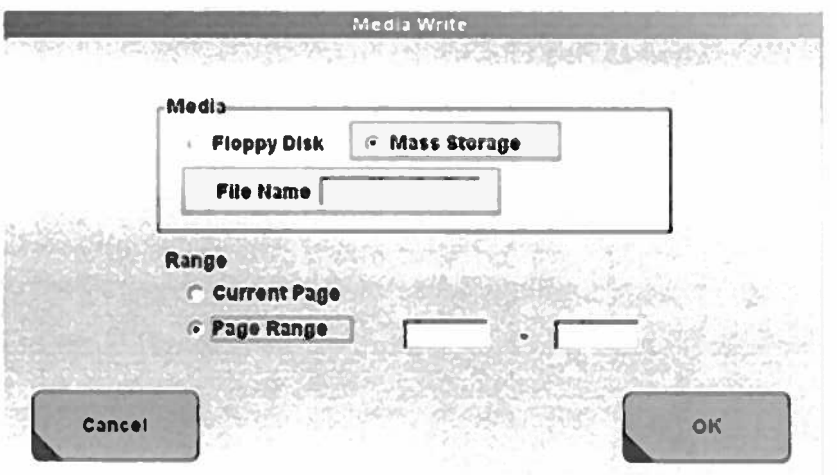


Figure 16. Media Write window

3. Select OK. A Confirmation window is displayed. Confirm with Yes.

4. If a file with the given name already exists, the system displays a Confirmation window. The file will not be overwritten, so you must choose another file name.

Figure 17. Confirmation window for a file with an existing name

5 The saving process is complete when the next Confirmation window closes.

Figure 18. Final confirmation window showing completion of save

Saving System Parameters

Use maintenance item (15) Parameter Read/Write to save parameters such as application data, carryover evasion settings, and maintenance pipes.

To save system parameters to a USB storage device:

1. Select Mass Storage.
2. Select Parameter Write.
3. Choose Execute.
4. Confirm with Yes.
5. Wait until the mass storage writing message (Confirmation window) closes.

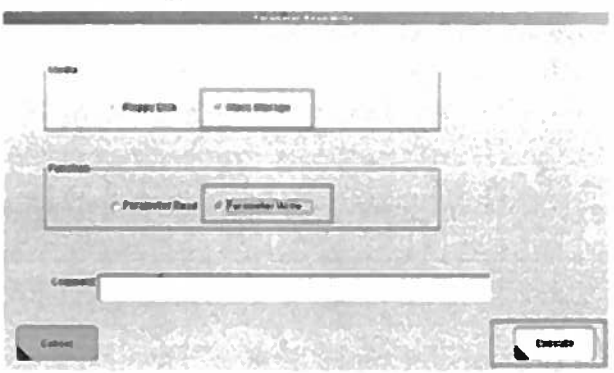
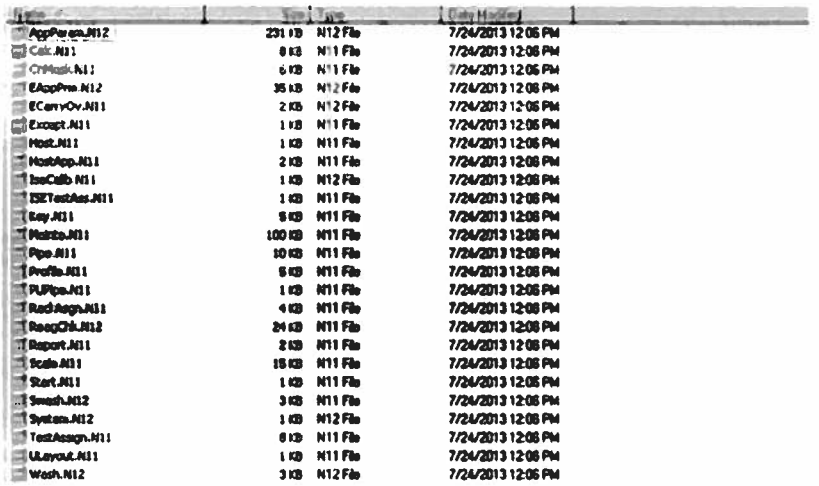


Figure 19. Parameter Read/Write window (Utility > Maintenance > Maintenance (Maintenance Type) > (15) Parameter Read/Write > Select)

Data is overwritten without warning! The analyzer gives no warning if existing data are overwritten.

WARNING

The following example shows 25 parameter files written to the folder E:\7600 on the USB storage device.



Name	Size	Type	Date Modified
AppParam.N12	231 KB	N12 File	7/24/2013 12:06 PM
Calc.N11	8 KB	N11 File	7/24/2013 12:06 PM
CrMask.N11	6 KB	N11 File	7/24/2013 12:06 PM
EAppPrm.N12	35 KB	N12 File	7/24/2013 12:06 PM
ECarryOv.N11	2 KB	N12 File	7/24/2013 12:06 PM
Except.N11	1 KB	N11 File	7/24/2013 12:06 PM
Host.N11	1 KB	N11 File	7/24/2013 12:06 PM
HostApp.N11	2 KB	N11 File	7/24/2013 12:06 PM
IseCalib.N11	1 KB	N12 File	7/24/2013 12:06 PM
ISETestAss.N11	1 KB	N11 File	7/24/2013 12:06 PM
Key.N11	9 KB	N11 File	7/24/2013 12:06 PM
Palette.N11	100 KB	N11 File	7/24/2013 12:06 PM
Pipe.N11	10 KB	N11 File	7/24/2013 12:06 PM
Profile.N11	6 KB	N11 File	7/24/2013 12:06 PM
PUPipe.N11	1 KB	N11 File	7/24/2013 12:06 PM
RedAsgn.N11	4 KB	N11 File	7/24/2013 12:06 PM
ReagChk.N12	24 KB	N11 File	7/24/2013 12:06 PM
Report.N11	2 KB	N11 File	7/24/2013 12:06 PM
Scale.N11	15 KB	N11 File	7/24/2013 12:06 PM
Start.N11	1 KB	N11 File	7/24/2013 12:06 PM
Swash.N12	3 KB	N11 File	7/24/2013 12:06 PM
System.N12	1 KB	N12 File	7/24/2013 12:06 PM
TestAssgn.N11	8 KB	N11 File	7/24/2013 12:06 PM
ULayout.N11	1 KB	N11 File	7/24/2013 12:06 PM
Wash.N12	3 KB	N12 File	7/24/2013 12:06 PM

Figure 20. Example of parameter files written to folder in USB storage device

New pop-up messages (Confirmation windows) during calibration update are implemented and previously existing messages are modified in software 05-02. **Calibrator data can be downloaded or manually edited only by an operator with Supervisor level or higher.**

Calibrator Download for cobas c 501 module

If calibrator data for a calibrator code not currently loaded on the ***cobas*** *c 501 module is downloaded via the* ***cobas***® *link* (Calibration > Install > Download), a Confirmation window is displayed. The Confirmation window now includes "Calibrator Code" and "Expiration Date" fields in the Download Parameters section.

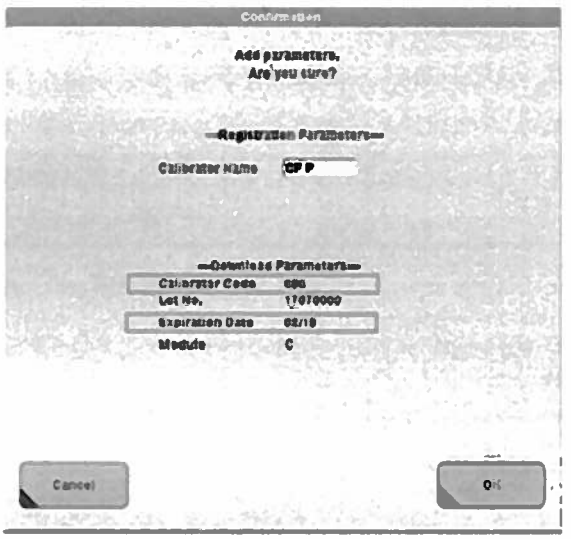


Figure 21. Confirmation window new calibrator data for cobas c 501 module

If calibrator data for an existing calibrator code for the ***cobas*** *c 501 module is updated with data of a different lot via the* ***cobas*** *link* (Calibration > Install > Download), a Confirmation window is displayed. In addition to new "Calibrator Code" and Expiration Date" fields in the Download Parameters section, there are changes in confirmation wording (Figure 22). After pressing OK, another confirmation window appears (Figure 23).

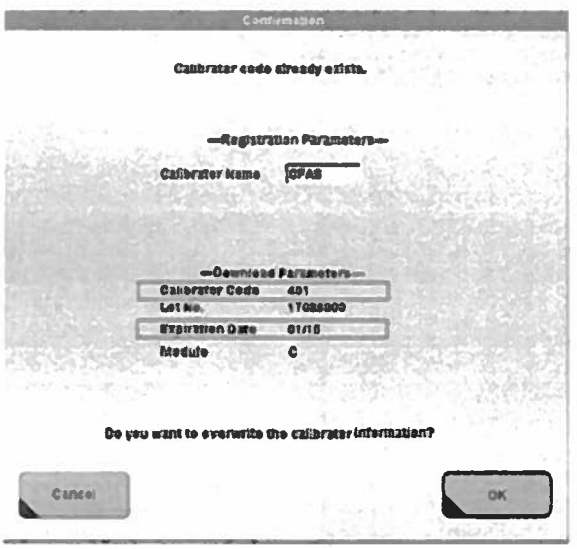


Figure 22. Confirmation window updated calibrator data for new lot on cobas c 501 module

Calibrator Download for cobas c 501 module, continued

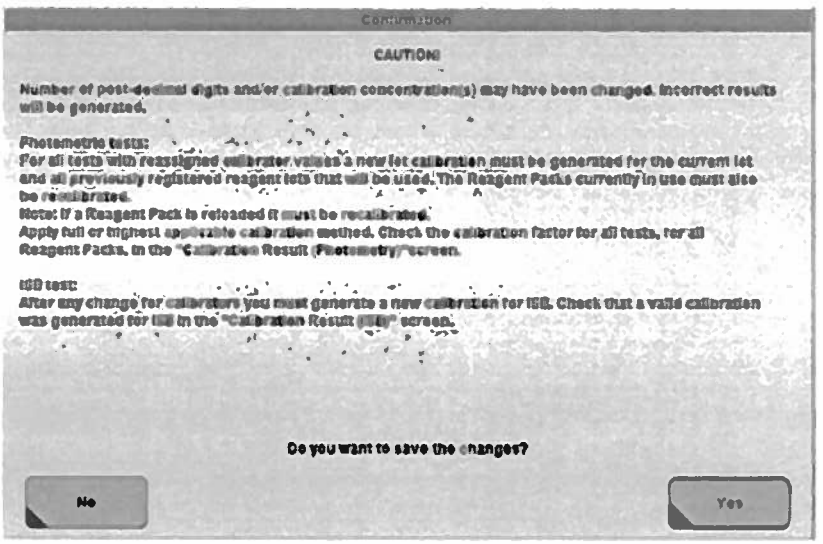


Figure 23. Confirmation window for overwriting data with new calibrator lot on cobas c 501 module

Calibrator Download for cobas e 601 analyzer

If calibrator data for a calibrator code not currently loaded on the ***cobas e*** *601 module is downloaded via the* ***cobas®*** *link* (Calibration > Install > Download), a Confirmation window is displayed. In the Confirmation window for calibrator downloads for the **cobas e** 601 analyzer, the "Calibrator Name" field has been replaced with the "Expiration Date" field under the Download Parameters section.

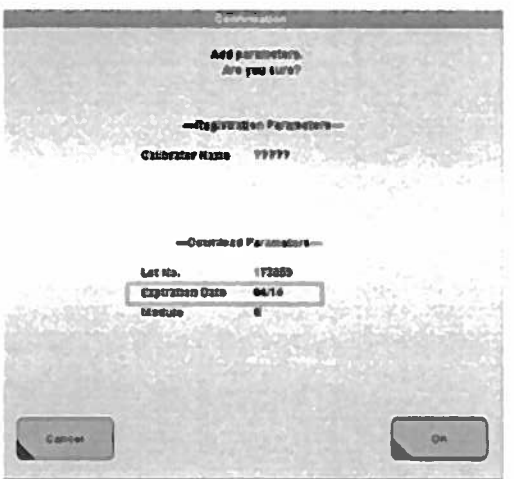


Figure 24. Confirmation window for new calibrator data for cobas e 601 analyzer

Calibrator Download for cobas e 601 module, continued

If calibrator data for an existing calibrator code for the ***cobas e*** *601 module is updated with data of a different lot via the* ***cobas®*** *link* (Calibration > Install > Download), a Confirmation window is displayed. The "Calibrator Name" field has been replaced with "Expiration Date" field in the Download Parameters section.

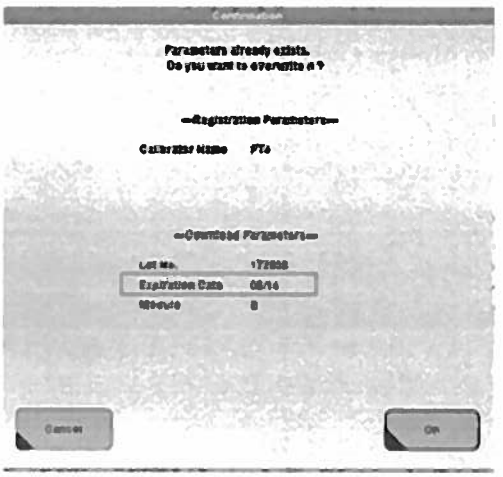


Figure 25. Confirmation window updated calibrator data for new lot on cobas e 601 module

Manually Edit Calibrator Values for cobas c 501 module

If calibrator values are edited manually in Calibrator > Install/Chemistry > Edit calibrator window, a Confirmation window is displayed. More detailed information has been provided for Photometric tests and ISE tests.

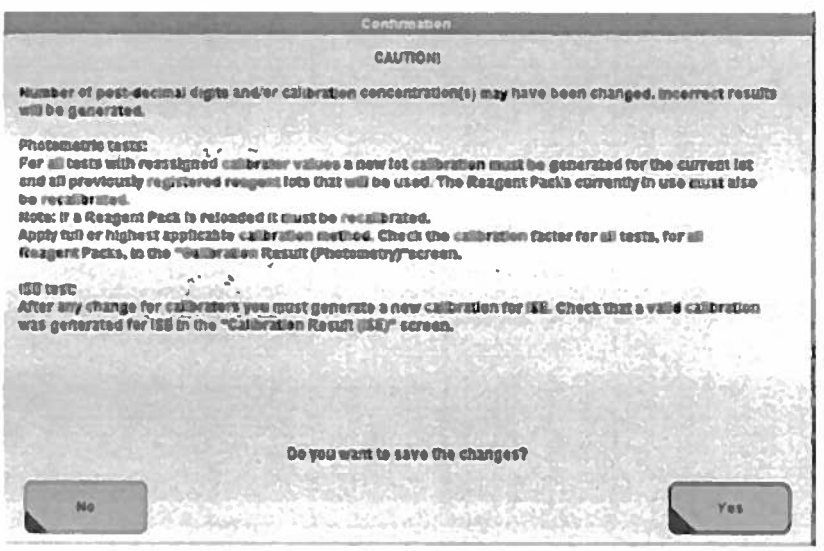


Figure 26. Confirmation window after manually editing calibrator value on cobas c 501 module

Updated Special Washes for Elecsys/cobas e assays

Previous software versions automatically downloaded the special washes for the **cobas e** assays. Upon installation of the 05-02 software, you will need to manually update any new washes. Washes currently installed on your **cobas e** 601 module prior to the installation of the 05-02 software are not affected. Refer to the table below for the assays that currently require special wash programming.

No	From			To				
	Test	ACN	Step	Test	ACN	Step 0	Step 1	Step 2
1	AHBS	64	1	HBSAG	61		x	
2	HBSAG	61	1	AHBS	64		x	

Figure 27. New default carryover evasions settings (default for new cobas e 601 modules)

Software changes related to Special Wash for Elecsys Assays

The special wash list for the **cobas e** 601 module (Utility > Special Wash > Immune) in software version 05-02 has been updated. Two additional steps have been added. Any assays not installed will display as "?????" in the special wash table. **The Special Wash screen can be accessed only by an operator with Supervisor level or higher. The Reagent probe list can be edited only by an operator with Administrator level or higher.**

Bath Detergent Name Change

In software version 05-02, any reference to Hitergent has been replaced with Bath Detergent or BathDet in the following screens:

- Reagent Overview window of the **cobas c** 501 module (System Overview > Reagent Overview): Bath Detergent
- Inventory List in Status screen (Reagent > Status): BathDet
- Yellow Alarm List and Purple Alarm List in Reagent level Check Window: (Utility > System [Page 2/4] > Reagent Level): BathDet

"EcoTergent" has replaced "Hitergent" in the wording of maintenance documents, **cobas®** 6000 analyzer series Operator's Manual, and Online Help. EcoTergent and Bath Detergent are interchangeable replacements for Hitergent wording.

When any new cassette is registered in the software 05-02 (Reagent Status > Reagent Volume Reset), the volume is 70 mLs as stated in Reagent Status and Reagent Overview screens. After the first water bath exchange and liquid level detection by the ISE probe, the volume is corrected to 55 mLs.

Reagent Disk Movement

During the pre-operation cycle, an additional resuspension of particles in reagents is carried out by additional movement of the reagent rotor on the **cobas c** 501 module.

This takes place in the background and is not noticeable for the operator.

Corrected or Improved Software Limitations

The following software limitations have been corrected or improved with the release of software version 05-02.

Previous Software Limitation	Correction/ Improvement
There was a potential for incorrect rack assignment of samples when using non-barcode mode. This issue was communicated in Analyzer Bulletin 12-130.	This issue is resolved.
Test results were flagged with "<Rept" although the values were within the repeat limit. This only happened with compensated tests under the following conditions: • when the measurement result before the test compensation was applied was less than the lower repeat limit setting and • the result after the test compensation was applied was within the repeat limit setting.	This issue is resolved. The Repeat Limit is only checked for a result after "Test Compensation."
Under the following circumstances, the alarm "321-01: Sample duplicate Error" was incorrectly generated for a sample even though sample results were available for the sample: 1. "Utility > System > HOST Communication Setting > Result Upload Setting - No automatic Result Upload" was set to "OFF" 2. "Utility > System > HOST Communication Setting > Result Upload Setting - Sample Result Upload Setting" was set other than "By Sample" 3. "START > Automatic Rerun - Routine/STAT" was set to "NO" 4. "START > Host Setting > Host Communication ON" was set to "YES" 5. If a result was flagged with "Review by Exception" and all results for the applicable sample were not sent to HOST 6. The manual rerun was executed before the system went to Standby. An alarm "027-0001: No Test Performed on Rack" was generated and the measurement was performed in the manual rerun of the samples. It was recommended to perform the manual reruns after the system had gone into Standby status.	This issue is resolved. Manual rerun can be performed even if loading the applicable samples.
A "Database Management Error" alarm 602-5094 was incorrectly generated under the following conditions: 1. During sending of the measurement result to HOST, HOST communication failed and was interrupted, so the alarm 126-000X "HOST Communication Error" was generated. 2. During the communication block, the measurement results of multiple samples were output. 3. HOST communication was reconnected and the System restarted sending the result to the HOST. When these conditions were met, two possible consequences may have been observed after the restart of the communication. 1. The sample status and item status of the first sample already sent to the HOST did not get an "H." 2. The Alarm 602-5094: "Database Management Error" was generated if the second sample sent to HOST was a QC. It was recommended to make sure the <ACK> was sent back to the system within 15 seconds after receiving the <ENQ>.	This issue is resolved. The "Database Management Error" will not be generated if the database is not corrupted.
When Floppy Disk or Zip was selected on the box of Check Disk from the "Maintenance - Check - Check Disk" screen, the corresponding check report was not displayed in the Print View screen. Additionally, the Check Disk, System Version name, and SUM value disappeared from of the Check Disk screen. The missing information on the screen was displayed again if Check Disk was performed for the Hard Disk Drive or after rebooting the analyzer.	This issue is resolved.

Corrected or Improved Software Limitations, continued

Previous Software Limitation	Correction/ Improvement
Under the following conditions, changeover would not be performed for a reagent that required pretreatment (e.g., B12): 1. System had more than one pretreatment (A and B) and reagent pack (A and B) of the same lot on one **cobas e** 601 module. 2. If the current pretreatment pack became empty (A) and the current reagent pack (A) had one or more determinations left, then the analyzer issued a reagent short alarm, it didn't change over to the standby pretreatment pack (B), and no measurement took place. System had to go in Standby and the empty pretreatment pack (A) had to be unloaded to continue working with the affected test.	This issue is resolved. Even if the remaining test for a pretreatment reagent pack of a Current reagent becomes "0," changeover will occur for Standby reagents.
An "unknown alarm" was generated because the character string for the alarm "01451-0000" was not registered. This alarm was generated when a rack had not received Test Selection (TS) Data for the **cobas e** 601 module. Operators were told if this alarm occurred to immediately contact the Roche Support Network Customer Support Center so the appropriate data could be collected.	This issue is resolved.
With a <cc>/<cce> configuration, it was not possible to unload **cobas c** packs from the second **cobas c** 501 module during Operation/Maintenance. It was possible to unload from the first **cobas c** 501 module upon masking and waiting until the module was in Standby. For the second **cobas c** module, the error message "This function is not allowed in the current mode" appeared.	This issue is resolved.
At login, when the password was not entered correctly, the error message stated "Incorrect ID." When the wrong ID was typed, the error message stated "Incorrect password."	This issue is resolved. The correct error message occurs when an incorrect password or ID is typed at login.
Calculated test results could not be printed from Backup Media. Results saved on backup media could be displayed in Data Review; however, the results for the calculated test were not shown on the print out.	This issue is resolved. Calculated test results can be printed from Backup Media.
The ISE calibration rack was loaded, but ISE calibration was not performed. The ISE calibration rack was transported to **cobas c** 501 modules, the sampling operation was completed, and the system issued an Emergency STOP alarm 905- 912030 "Sample up/down error." This phenomenon occurred under the following conditions: 1. ISE calibration was requested for Internal Standard (IS) bottle 1 and IS bottle2. 2. IS bottle 1 became empty. 3. ISE calibration rack was loaded on board and the ISE calibration was performed (IS bottle 2 still contained enough reagent volume to perform the calibration; however, no calibration was done). 4. After step 3, other racks loaded during the same operation were transported to the affected **cobas c** 501 module. The E.STOP alarm "905-912030" occurred after sampling was completed.	This issue is resolved.

Corrected or Improved Software Limitations, continued

Previous Software Limitation	Correction/ Improvement
Due to a software failure in the clot cancellation process, the emergency stop alarm "916-020104" may have occurred on a **cobas** c 501 module when a sample clot was detected during sample pipetting. This phenomenon occurred under the following conditions: 1. "Clot" alarm was detected for a sample during sample pipetting (if less than 20 µL in one cycle pipetting) on a routine operation. 2. The same sample with "Clot" alarm had a test assigned which used concentrated reagent or concentrated diluent for R1. 3. Special wash for cuvette for the R1 probe was executed in the next cycle after generating the "Clot" alarm.	This issue is resolved.
When the analyzer was working with "NONE" racks (rack type used is "NONE" and the sample type Ser/Pl, Urine, etc. comes from the HOST), it was not always possible to use the Unload function. When the operator used the Search button via "Sample type" and the "Rack No." was selected for searching a sample, the analyzer issued an error message "Entry is out of range," and the Search function did not work. However, it was possible to search samples loaded in "NONE" racks using the "Patient ID" and the "Comment (name)" or using "Status" as searching filter.	This issue is resolved.
In Workplace Data Review, the operator may have observed that two samples failed because of Reagent Short (Reag. S) flag. The flag was issued because the current bottle of Diluent was empty, even though a standby bottle of Diluent was on the analyzer. Each time the customer observed this problem, there were always 2 measurements with a dilution missing. For the 3rd sample, the standby bottle was used and no alarm was issued.	This issue is resolved.
On the calibration print out (Calibration Monitor), the flag 'Diff' was missing if the calibration failed because of the criteria (for qualitative tests only). (The calibration criteria 'Diff' checks if the mean of cal1 and the mean of cal2 have a minimum difference of 30%.) This flag was correctly displayed in the 'Calibration Result' screen.	This issue is resolved.
If more than 86 tests were assigned in Utility > Module Set > Test Assignment, any additional test could not be calibrated. After a few minutes, the calibrator rack sat in the sampling position and was ejected without an alarm. Even though 117 applications can be registered (Utility > Application) for clinical chemistry tests, only up to 86 applications can be assigned for each **cobas** c 501 module (Utility > Module Set > Test Assignment). The inactivated tests are also counted under these 86 tests.	This issue is resolved. It will clear the test assignment of the inactive tests, so the new test will run.
Tests were incorrectly listed on the Calibration Load List printout. Depending upon the "On" or "Off" setting of the Test Assignment screen, data were reported in the Module Specific Rack of Calibration Load List. When there was a calibration request, the actual data of "Event" and "Volume" were printed. When there was no calibration request, "Event" and "Volume" were printed as 0 (zero). For example, a Testosterone reagent pack was assigned on the first **cobas** e module and a Ferritin reagent pack was assigned on the second **cobas** e module. When a calibration was requested for the tests, the test was printed for both **cobas** e modules in the Calibration Load list.	This issue is resolved.

Corrected or Improved Software Limitations, continued

Previous Software Limitation	Correction/ Improvement
A "Database Management Error" alarm 601- 5003 occurred intermittently. This alarm was incorrectly issued due to a software malfunction in the process of storing the reaction data for QC. The alarm was generated when the QC measurement result was output. As a result, the reaction data for QC was not displayed in Routine View screen.	This issue is resolved.
Under the conditions listed below, samples could have been processed despite Auto masking being activated. All conditions must have been met simultaneously for this to occur. 1. Global Auto masking ON: Utility > System > page 2/4 > Calib Mask Setting > Check box Auto masking was selected. 2. Test specific Utility > Application > Calib. > Check box Auto Masking was selected. 3. A **cobas c** pack was on board that was already under Calib Mask conditions. 4. A **cobas c** pack was loaded during operation. Note: The **cobas c** packs in 3 and 4 could have been from different tests. When these conditions were met, all **cobas c** packs that were under Calib Mask were unmasked. If the analyzer was restarted again from Standby, the Calib Mask Setting was reset to the correct (previous) status.	This issue is resolved.
When the Reject button on the Calibration Status Screen was pressed while the exclamation mark button on the Calibration Status screen was yellow, selecting the "S.Stop," "Stop," or "Start" global buttons resulted in a error message displaying: "Function not allowed in current mode."	This issue is resolved.
If displaying the backup data from a DVD when the test number of backup data was equal to or higher than 32768, the following phenomena occurred: • For backup data saved up to and including a test number of 32767, the data was displayed correctly. • For backup data saved between test numbers 32768 and 65535, only sample information (i.e., no display for measurement results for the measured tests) was displayed. Measurement results were correctly output to "Print View" by performing Print > Data Print. • For backup data saved for test numbers over 65536, no data was displayed.	This issue is resolved. Even if the test number of backup data is equal to or higher than 32,768, the backup data will be displayed correctly.
When the following conditions were met on the **cobas e** 601 module, bottle changeover would not be performed and results may have been flagged with the "ReagEx" data alarm-even if the reagent was not expired: 1. There was a Diluent (DIL) with the same lot number and sequence number as the current **cobas e** pack on the Reagent disk. 2. The position number where the **cobas e** pack was loaded on the Reagent Disk was higher than the position number where the DIL was loaded (e.g., reagent pack on position No. 9 and the Diluent on position No. 4). This also applied for Pretreatment (PRE) or for Blank reagents with the same Lot No/ Seq. No as the **cobas e** pack. It was recommended to place the **cobas e** reagent pack in a lower position (i.e., lower number) in the Reagent Rotor than the DIL, PRE, or BLANK.	This issue is resolved.
The printout program halted when opening the Print View screen while the software was printing into the internal Print View buffer. A "System error 200-0002" alarm was generated. If the "System error 200-0002" was generated, the entire system had to be shut down and powered up again.	This issue is resolved.
When Calibration Auto Masking was set to "ON," ISE tests under Calibration Masking were not displayed on the Stand By Bottle QC screen.	This issue is resolved.

Corrected or Improved Software Limitations, continued

Previous Software Limitation	Correction/ Improvement
When "Read Mecha Adjustment Data from FD" was performed for the **cobas** e 601 module from Utility > System > FD Utility, then cell counter information was also read from the time point when the adjustment data were written on Floppy Disk. When samples were measured, the cell counter information increased. However, if "Read Mecha Adjustment Data from FD" was performed, the measuring cell counter information was overwritten with the old values previously saved on the floppy disk.	This issue is resolved.
The HbA1c test, was incorrectly assigned as a "Mandatory" test.	This issue is resolved.
A runtime error occurred due to overlap of the UI program and the Communication program processes when updating the existence or nonexistence for updating Calibration.	This issue is resolved.
The Border Limit Low value of immunoassays was not correctly displayed on the Calibration > Status > Result window.	This issue is resolved.
Under the following circumstances, a QC sequence number was duplicated: 1. QC after calibration was performed. 2. A calibration rack was then loaded into the analyzer during operation. 3. Analyzer status was changed to Standby. 4. Analyzer was restarted. 5. The same control as in step 1 was measured. When the conditions above were met, the controls measured in steps 1 and 5 had duplicate QC sequence numbers. This resulted in both QCs being displayed in the Sample List on the Data Review screen and the QC run status screen. The measurement results for the later measured QC were not displayed in Test List on the Data Review screen or the Individual QC Chart screen. If results were sent to the LIS or HOST by batch, only the first measurement result was displayed; however, each measurement result would have been sent in real-time output.	This issue is resolved.
Calculated tests containing ISE and Clinical Chemistry parameters in the equation could not be transmitted to the HOST in real-time if "ISE/Chemistry/Immunoassay" or "By Test" was set for the "Result Upload Setting" under [Utility]-[System]-[Host Communication Setting]-[Result Upload Setting]. They were transmitted correctly if they were in batch mode.	This issue is resolved.
When the following conditions were met, DATE entries of the measurement results were missing on and after the second page of the QC Individual and QC Cumulative chart print-outs. 1. More than one item was selected for a Roche Immunoassay control (e.g., two or more lot reagent packs were selected) in the QC-Individual screen and the Individual QC Chart was printed out. 2. In a printout of the Individual QC Chart, the number of printed information for measurement data of the first lot was the same as the maximum number of lines for the page (i.e., 72 lines).	This issue is resolved.

Software Limitations

The following are open issues for software version 05-02 or unresolved issues from previous software versions. These limitations will be corrected or improved with a future software version.

Description of Issue	Workaround
If the ISE configuration for type A and type B is the same (i.e., same calibrator code), the analyzer performs only one calibration for type A, and it will copy this data for type B. If both calibration type A and B are ordered, the software counts the test number twice on the Cumulative Operation List.	Select "Type A" for all items in "Utility > System > ISE calibration setting" screen in case the same calibrator is set at Type A and Type B. Then, order only ISE Type A for ISE calibration.
Under certain conditions, the module mask/unmask process may have an issue. Under the following conditions (Occurrence 1), there is a possibility that sampling will not occur: 1. During Operation, the analytical module is unmasked from "module mask" or "service mask" (Restoration process for unmasked analytical module will be carried out). 2. When the unmasked analytical module is in "Preparation" status, the "module mask" is set again. Then, the "module mask" is cancelled again. 3. The sample with test requests for the unmasked analytical module is loaded. Under the following conditions (Occurrence 2), module mask information mismatch will occur in the internal information of Core. 1. More than one module is used. 2. While racks are being loaded into an analytical module, module mask is set at the analytical module and other analytical modules. 3. While racks are still being loaded into the analytical module, the "Stop" button is pressed to stop the instrument. For the instrument reported in this case, "Maintenance > Reset" was carried out for Conveyor and the analytical module after the instrument status moved to "Standby." If the system is started with a module mask information mismatch (Occurrence 2), "Start" and "Shutdown" will not work.	If module mask information mismatch occurs, cancel the module mask on the analytical module that was set with the module mask. Then, set the "module mask" again. If "Start" or "Shutdown" does not work because the system was started under the condition of module mask information mismatch, cancel the module mask on the analytical module that was set with the module mask. Then, "Reset" by selecting only "Conveyor" in Maintenance > Reset, and stop the system by pressing the "Stop" button.

Helpful Hints

For your convenience, please refer to the following helpful hints:

- When you add a new reagent lot for Fixed-factor assays (e.g., DAT assays, D-Bili), the K factor can default to 99999. Reset the K factor to the appropriate number and calibrate.
- If Test Review displays an "M" in the status column for a test that has sufficient reagent and is not masked, check for missing special wash detergents or diluents.
- If the "Print View" is not updated, shut down and restart the **cobas** 6000 analyzer series. **Remember to power down the analyzer weekly.** Shutting down and restarting the analyzer will clear the "Print View."
- Be aware you may get a "Samp.S" or "Samp.B" data flag if using False Bottom Tubes in a "NONE" rack run on the **cobas e** 601 analyzer and conical bottom is selected.
- When implementing Sleep mode, select Sleep Pipe.

Helpful Hints, continued

- If an HbA1c test is cancelled after samples are loaded, it is possible the sample status may remain in status "P" (i.e., Processing) in the Data Review screen and upon reloading the sample, the % HbA1c result has a "Calc?" alarm. If this issue occurs, it is recommended to:
  - Put the instrument in Standby status.
  - Delete the affected samples that remained with status "P" on Data Review screen.
  - Reload the sample and select "Start" to analyze the sample.
- If you receive a "Database Management Error," call the Roche Support Network Customer Support Center at 1-800-428-2336 as soon as possible after getting this alarm. Please provide the actual alarm code numbers.
- Routinely check the Special Wash list enclosed with the NaOH-D (catalog number 04489241190) method sheet for new clinical chemistry updates or whenever a new or updated application is downloaded on your analyzer.