Host Interface Manual

for

Roche/Hitachi

cobas® 6000 analyzer series

Version 1.3

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1 Overview

1.1 Purpose

This document details the specifications for the **cobas**[®] 6000 analyzer series host interface. This interface regulates data transmissions between the core of the system and the host computer. Questions concerning this document should be referred to Technical Support.

1.2 Scope

Detailed information on operation of the system is beyond the scope of this document. The information offered here is strictly to aid programmers in grasping very basic operational features of the analyzer. Please refer to the Operator's Manual for more detailed information.

1.3 Conventions

This document consists primarily of a series of tables that show the information needed to successfully interface to the system. The basic concept of data transfer in this interface is the exchange of data and control frames between the host system and the analyzer.

1.4 Content

This document gives the reader a basic understanding of the system operation with a host, and describes the following:

- Basic System Architecture
- Sample Processing
- Sample Types
- Rerun Modes
- Test Selections
- Operational Modes.

2 cobas[®] 6000 analyzer series System Architecture

2.1 Overview

Before discussing how the host communication works, it is important to understand the basic architecture of the system. This section provides an overview of the architecture and discusses some specialized items of interest pertaining to the analytical system.

The system consists of three types of devices: (Refer to Figure 1)

- The Control Unit that displays and edits the results of analysis, allows operator interaction with the system, and allows configuration settings
- One or more analytical units (AU), also known as modules, that measure samples using reagents
- A core that physically transfers samples between the analytical units and communicates with the host system.

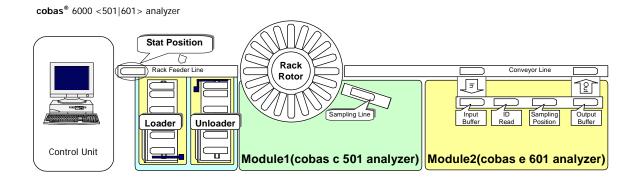


Figure 1: cobas® 6000 analyzer series System Architecture

2.2 Sample Carriers

The **cobas**® 6000 analyzer series uses 5-position racks to process samples. These racks hold tubes, standard sample cups, micro sample cups, or standard sample cups on tubes. During analysis, the analyzer reads the rack number, identifies the type of samples according to the rack number range, identifies the sample, and then analyzes it according to the test selections for that sample.

The host can download a microcup container type.

Note:

If microcups are used, they are not processed on the **cobas** e 601 analyzer. Refer to Table 1 for the types of samples, racks and their relationships to rack number ranges.

2.3 Samples

Samples that are handled by the analyzer are separated into:

- · Standard samples used for calibration
- Control samples for quality control
- · Patient samples.

2.4 Sample Type

Patient samples and controls are classified into five (5) types. Each type can have separate parameters for calibration, normal ranges, etc., within the system:

Ser/PI: Blood Serum/Plasma

Urine: Urine

CSF: Cerebral Spinal Fluid (not used on the cobas e 601 analyzer)
 Suprnt: Supernatant (not used on the cobas e 601 analyzer)

Other: Other Fluids.

2.5 Automatic vs. Manual Rerun

As seen in Table 2, Routine and Stat samples can be processed in a mode called Auto Rerun. This is different from a manual rerun sample. Each mode is described below.

2.5.1 Automatic Rerun

Each test defined on the analyzer can have parameters that indicate when a sample needs to be reprocessed because the result is outside the pre-determined value. Usually, this means running the sample through the system once more while using a different sample volume. When the system is configured with the Auto Rerun mode enabled, a sample rack is held at a rack rotor until results are available.

Note: Auto Rerun is requested from the Start Conditions/Automatic Rerun window.

When automatic rerun is selected, if one or more of the results falls outside the predetermined rerun parameter values (data flagged results), the rack is automatically resent through the system and reprocessed, usually with a new sample volume, where on **cobas** e 601 analyzer, the dilutions are made using the original sample volumes only. The host has an opportunity to modify the test selections before Auto Rerun samples are processed (refer to Section 3.1.1.5). A sample with a triggering data alarm attached to the result stays in the rotor for further processing.

Samples being automatically rerun use either a normal, decreased, increased, or diluted sample volume, depending on the module, type of data alarm, and test parameter configuration. The analyzer applies the appropriate correction to the results of the rerun. Results for the original test and the rerun are reported separately to the host.

A sample is only automatically rerun once; however, any result that causes another applicable data alarm allows the operator to include the sample in a manual rerun process. Rerun samples with tests that still have flags appear on the manual rerun list and can be manually rerun by the operator.

2.5.2 Manual Rerun

The operator can manually process reruns. To do so, the operator can place samples on a rack, program test selections either at the core or at the host, then place the rack onto the system for processing. Any tests with flags from the previous analysis would also process.

2.6 Sample Number and ID Modes

The analyzer can be operated in one of two modes for identifying samples:

- Sample Number Mode
- ID Mode.

The most common mode used is ID Mode, which has provisions for processing samples that have damaged, unreadable or missing barcode labels (see Section 3.1.2.7). The user can switch between ID Mode and Sample Number Mode during standby without clearing the database, but switching is not recommended. Generally, once a mode is decided upon, it is rarely changed.

2.6.1 Sample Number Mode

In this mode, the barcode reader is turned off. Samples are tracked by an internal sample number that increments sequentially as samples are processed, and also by the rack ID and position number.

The sample number mode requires the operator to either load the analyzer by using a load list generated by the host system, or make test selections manually on the analyzer.

2.6.2 ID Mode

This is a random mode that allows barcoded samples to be placed on the system in any order. In ID Mode, samples without barcodes and samples with damaged or unreadable barcodes can be processed by a manual setting. The ID mode is applicable for both routine and Stat samples.

2.7 Rack Types

Patient samples can use three separate racks. These racks indicate to the system how the samples on a particular rack are to be processed. Rack types include:

- Routine rack for routine analysis
- Stat rack that interrupts between routine analysis
- Rerun rack for Manual Rerun.¹

Rack Type	Rack Numbers	Visible Label	Purpose	Auto Rerun ¹
Routine*	5001 ~ 8999	001 ~ 3999	Routine analysis of patient samples	Yes
Stat*	4001 ~ 4080	E001 ~ E080	Emergency analysis	Yes
Rerun*#	A001 ~ A200	R001 ~ R200	Routine sample manual rerun ¹	No
Control	3001 ~ 3999	C001 ~ C999	Quality control	No
Calibration	2001 ~ 2999	S001 ~ S999	Calibration	No
Wash	W999	W999	Wash solution for sample probe	No

Table 1: Types of Samples and Rack Numbers

Above Rack Numbers are valid if the 'Change Rack ID' option on the Host Communication Utility/System/Host Communication Setting/Text Setting screen is disabled. See for the alternative Rack IDs.

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¹ The differences between Auto and Manual rerun are described in Section 2.5.

^{*} Subsets of the above routine, Stat, and rerun rack ranges are user-definable by sample type (Ser/PI, Urine, CSF, Suprnt, Other on the Utility/System screen).

 $^{^{\#}}$ Applies only to Sample Number mode. For ID mode use Routine racks for Rerun.

3 Sample Processing

3.1 Realtime Communication

The relationships between Realtime Communication functions and types of samples are shown in Table 2. The following are the details regarding communication procedures and communication functions.

Communication Functions	Patient Samples			Control	Standard
	Routine	Stat	Rerun	Sample	Sample
Test selection inquiry	0	0	0	Х	Х
Analytical data transmission	0	0	0	0	0
Automatic Rerun test selection information reception	0	0	х	х	Х
Automatic Rerun test selection inquiry	0	0	х	Х	Х
Automatic Rerun analytical data transmission	0	0	х	Х	Х

⁽o = Possible; x = not possible)

Table 2: Realtime Communication Functions

3.1.1 Rack Flow

The best way to understand the types of communication a host system can have with the **cobas**[®] 6000 analyzer series is to understand the flow of samples through the system.

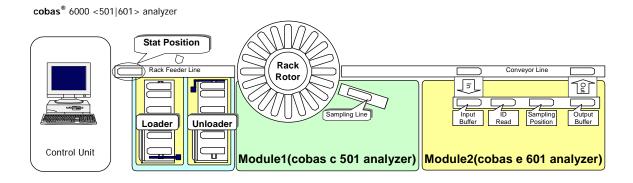


Figure 2: Rack Flow

3.1.1.1 Sample Introduction

Samples are placed into 5-position racks, then onto the sample loader, which consists of one tray. The tray feeds racks onto the system sequentially until it is empty.

3.1.1.2 Sample Identification and Test Selecting

Multiple racks (a maximum of five samples per rack) are fed continually from the sample loader. At the read station, the system reads the rack ID and sample ID and uses the information read as the key. The system looks for test selections for each sample, depending on configuration settings. Test selections can come from:

- The host prior to testing
- The host as a result of a TS Information Inquiry initiated by the analyzer
- Manually programmed TS on the analyzer by the operator
- A Default Profile set on the analyzer for any sample without TS information from one of the other sources.

3.1.1.3 Rack Routing

The **cobas**[®] 6000 analyzer series has a very sophisticated scheduler that determines where a sample should be processed. It is possible to have the same test on more than one analytical unit (**cobas** c 501 or **cobas** e 601 analyzer). The scheduler decides the optimal rack routing to maximize throughput. Also, because of different processing times for different tests and multiple modules, it is possible for samples to be completed and results reported in a different order than they were sampled.

3.1.1.4 Sample Aspiration

A rack is sent to one or more of the installed modules for sampling. At each module, a rack with a sample to be processed on a particular module is moved off the main line, then through that analyzer's sample pipetting station. This method allows racks to pass each other, thereby optimizing system throughput.

3.1.1.5 Rack Rotor

After sampling, when Auto Rerun is enabled, racks are held in a Rack Rotor until all test results for all samples on that rack are complete.

• If Auto Rerun TS is enabled on the Utility/System/Host Communication Setting/Text Setting window and Autorerun is checked for the assay in Utility/Application/Range screen, the host can alter test selection for rerun.

In the Auto Rerun mode with Auto Rerun TS enabled on the Utility/System/Host Communication Setting/Text Setting window, the rack stays on the rack rotor until results are available. The host can, at this time, modify and download any new and rerun test selections on the sample. Once the results for all samples within the rack are available, the rack moves depending on the following factors:

- If the host does not respond by expiration of the Auto Rerun TS Timeout interval set on the Utility/System/Host Communication Setting/Text Setting window, the rack moves to the sample unloader.
- If the host responds with test selections for any samples on the rack, the rack moves to the module for reruns.
- If the host sends cancellation messages for all samples, the rack moves to the sample unloader. Generally, the host would not do this if any of the samples had a qualifying flag. If no samples have flags, and the host does not want to make additional test selections, the host sends a cancellation message.

Note: The Auto Rerun TS Timeout can be configured at the analyzer. Great care should be taken when changing the timeout from the default (25 seconds), as increasing this timeout could adversely affect system throughput.

3.1.1.6 Sample Unloader

Racks that have completed processing are moved to the sample unloader. Eventually, the operator removes the completed racks. On the analyzer, the operator can locate a sample in the sample unloader by checking the Sample Tracking window. To access this window, go to the System Overview screen and touch Sample Tracking.

3.1.1.7 Modular Pre-Analytics System

The system has provisions for integration to a Modular Pre-Analytics System (MPA). When connected to an MPA, samples from the MPA are fed into the Stat position. The normal sample loader then becomes the entry port for Stat samples.

3.1.2 Communication Types

This section discusses the different types of communications between host and analyzer. The following shows how test selection works in realtime and for reruns.

3.1.2.1 Test Selection Information Inquiry

If the analyzer needs to ask the host for test selections, it uses a Test Selection Information Inquiry. Each Test Selection Information Inquiry contains information for one sample. Normally, the analyzer looks into its internal database for Test Selection (TS) information. If it finds TS information, processing proceeds using those test selections. Exceptions occur when the TS Inquire Always option is enabled.

3.1.2.1.1 If the Host Does Not Respond

If the analyzer does not receive TS information for a sample within the set timeout, an error is issued and the system shifts to the next sample. If a default profile has been configured on the analyzer, it is used for the sample that did not receive TS information from the host.

It is possible for the host to respond with TS information for samples not requested. The TS information for the sample not requested is registered in the database. The analyzer accepts the TS for samples requested up to the specified timeout period.

3.1.2.1.2 Inquiry Timeout

The Test Selection Information Inquiry has an associated timeout interval that can be set on the Utility/System/Host Communication Setting/Text Setting window of the analyzer. Its range is from 10 seconds to 9999. If the TS Timeout interval is not enabled, the analyzer waits indefinitely until test selections are available from the host.

Note: Increasing the TS Timeout interval from the default of 25 seconds can significantly delay processing. The system delays processing for the time specified if the host has not responded. This can have significant impact on system throughput.

If the host has a good response time, setting the timeout longer should not reduce throughput, but would allow for the occasional delay from the host.

3.1.2.1.3 TS Inquire Always

If TS Inquire Always is enabled, the analyzer sends a TS inquiry to the host regardless of whether test selections exist internally. If the host does not respond, the internal database is searched and test selections are used, if found. If internal test selections are not available, the default profile, if defined, is processed. If no default profile is defined, the sample is skipped and an alarm is issued.

Note: This only applies to samples that do not already have test results.

3.1.2.2 Analytical Data Transmission

At the Analytical Unit (module), the analysis is performed based on the rack and the TS information received from the core. When the analysis is completed, the result of the analysis is reported to the core and then compiled there.

Test results are output to the host according to the upload setting in Utility/System/Host Communication Setting/Text Setting/Stat Sample Host Upload Setting or Routine Sample Host Upload Setting screen when the test of a sample becomes available. While this occurs, the rack is held in the Rack Rotor if Auto Rerun is enabled.

The patient sample test result with *Review by exception* data flag attached is not sent to the host. Control sample test result is sent to the host even with *Review by exception* data flag. The data flags for this feature may be selected on the Utility/System/Review by Exception screen.

For controls, the test results are output to the host test by test as soon as the result becomes available if the corresponding option is set on the Utility/System/Host Communication Setting/Text Setting screen. The data is sent before the real-time QC processing. If this option is disabled, the results are sent module by module.

3.1.2.3 Automatic Rerun Test Selection Information Reception

In case Routine/STAT Sample HOST upload setting is specified as "by Sample" mode in Utility/System/Host Communication Setting/Result Upload Setting screen, the host can transmit Automatic Rerun Test Selection Information after receiving results until the specified TS Timeout interval is reached. Except for "by Sample" mode, the analyzer sends the host a Rerun Test Selection Inquiry.

The host can transmit Automatic Rerun Test Selection Information after receiving Rerun Test Selection Inquiry until the specified TS Timeout interval is reached.

The host can select additional tests for any sample on a rack.

If no Auto Rerun flags exist for any sample in a rack, and the host does not want to rerun any tests or add any additional tests, the host can send a cancellation message for each sample in the rack. The rack then proceeds to the sample unloader. This can help increase system throughput.

3.1.2.4 Automatic Rerun Analytical Result Data Transmission

The transmission of analytical results from Auto Rerun samples includes results for those tests that have been rerun and any additional tests ordered as explained in Section 3.1.2.3.

Since Auto Rerun is not repeated, the racks that have finished with a rerun are carried to the sample unloader without waiting for the output of the result.

3.1.2.5 Analysis Test Masking

The **cobas**® 6000 analyzer series has a function called Auto Masking that stops the analysis of a test if an abnormality should occur in reagent supply or in calibration results. The operator can also stop the analysis of test activities by performing a Manual Masking at the analyzer. Entire Analytical Unit (module) activities can also be stopped by an operator-initiated instruction at the analyzer referred to as Module Masking. Tests masked using these masking functions do not process even if there is a request from the host.

3.1.2.6 Manual Rerun Method

An operator can initiate Manual Rerun by placing the sample onto the system again. This option can be used instead of the Auto Rerun function or with the Auto Rerun function if the operator wishes to make manual test selections at the analyzer. In addition, the analyzer can be configured to ask the host for test selections for Manual Reruns by enabling the Manual Rerun TS field on the Utility/System/Host Communication Setting/Text Setting window. This function is available for routine and Stat samples.

3.1.2.7 Analysis of Erred Barcode Reading of the Samples During ID Mode

If a barcode cannot be read or is missing, the operator can manually register the sample on the Workplace/Test Selection/Barcode Read Error window when in barcode mode. An ID is entered for the rack number and position that carries the sample. The analyzer then uses this information to identify and process the sample, including TS inquiries to the host.

3.1.3 Realtime TS Flowchart

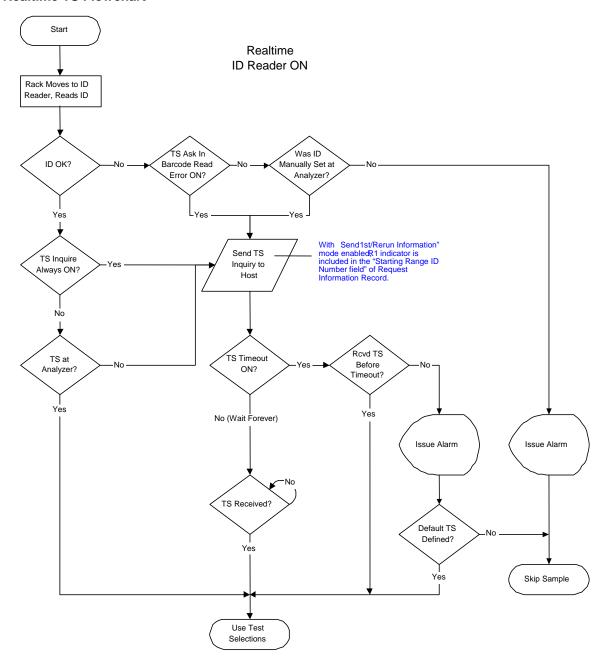


Figure 3: Realtime Test Selection Flow Diagram

3.1.4 Realtime TS Flowchart

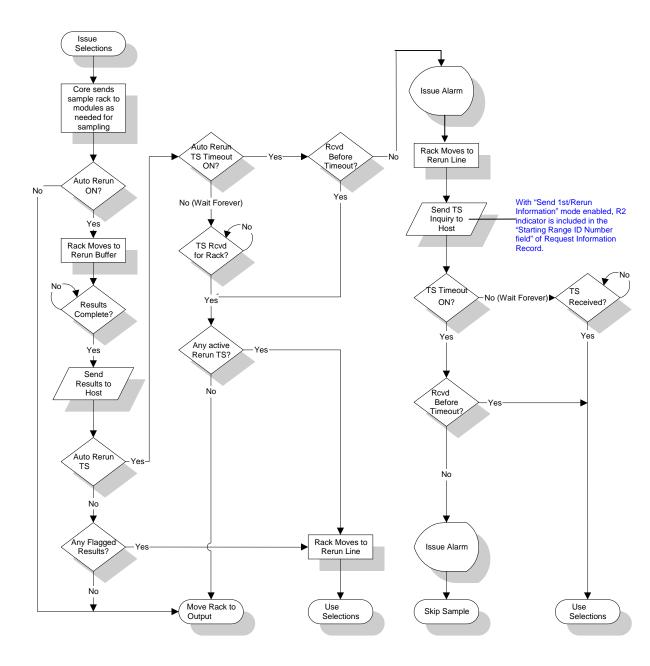


Figure 4: Rerun Test Selection Flow Diagram for "By Sample" mode

3.1.4. Realtime TS Flowchart, Continued

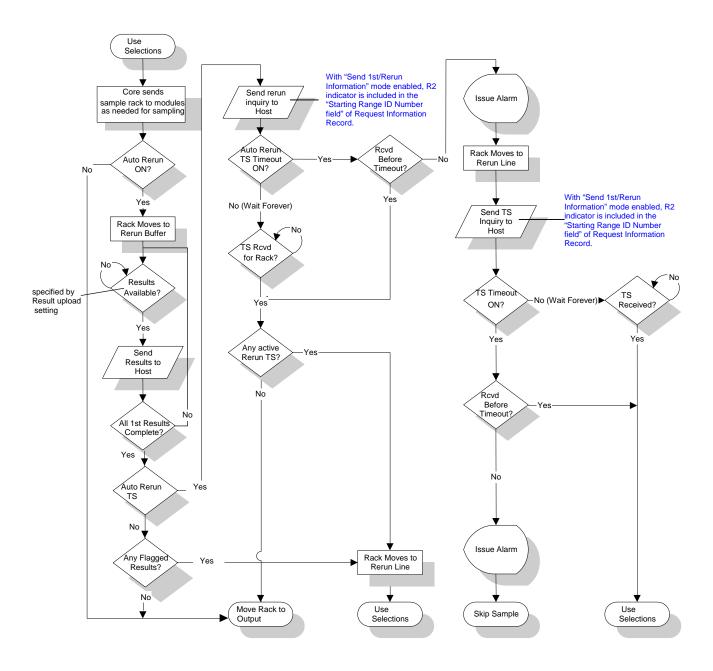
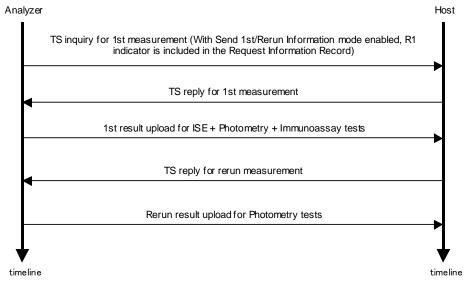


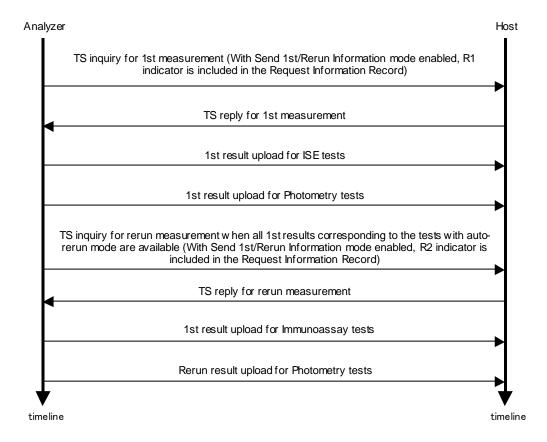
Figure 5: Rerun Test Selection Flow Diagram except for "By Sample" mode

The following three figures are examples of host communication flow showing each result upload setting.



- <u>Conditions</u>
 A routine sample has orders for ISE, Photo metry and Immunoassay tests.
- ISE and Photometry tests are specified as auto-rerun mode.
- Immunoassay tests are not specified as auto-rerun mode.
- Routine Sample HOST upload setting is specified as By Sample.
- Rerun measurements for Photometry tests are requested.

Figure 6: An example of communication flow in case of By Sample setting

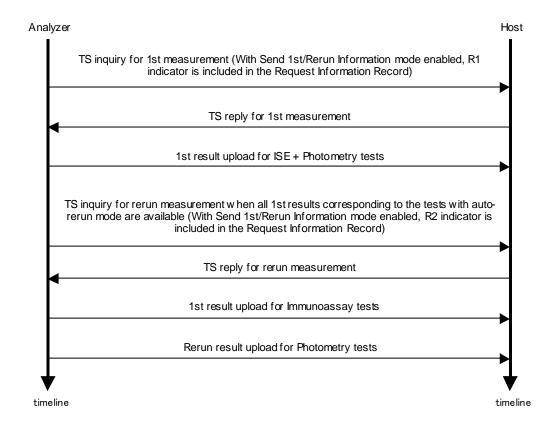


Conditions

- A routine sample has orders for ISE, Photometry and Immunoassay tests.
- ISE and Photometry tests are specified as auto-rerun mode.
- Immunoassay tests are not specified as auto-rerun mode. Routine Sample HOST upload setting is specified as ISE / Chemistry / Immunoassay.
- Rerun measurements for Photometry tests are requested.

Figure 7: An example of communication flow in case of ISE / Chemistry / Immunoassay setting

^{*} Result upload timing depends on some conditions. Normally the immunoassay test results are available after the chemistry tests results are available.



Conditions

- A routine sample has orders for ISE, Photometry and Immunoassay tests.
- ISE and Photometry tests are specified as auto-rerun mode.
- Immunoassay tests are not specified as auto-rerun mode.
- Routine Sample HOST upload setting is specified as Chemistry incl. ISE/ Immunoassay.
- Rerun measurements for Photometry tests are requested.

Figure 8: An example of communication flow in case of Chemistry incl. ISE / Immunoassay setting

^{*} Result upload timing depends on some conditions. Normally the immunoassay test results are available after the chemistry tests results are available.

3.2 Batch Communication

The Batch Communication function is shown in Table 3. Each of the communication functions is explained in detail below.

Communication Functions	Request	Patient Sample			Standard	Control
	Originator	Routine	Stat	Rerun	Sample	Sample
Test Selection Information Reception	Host	0	0	0	Х	Х
Analytical Data Transmission	Host	0	0	0	Х	Х
Analytical Bata Transmission	Analyzer	0	0	0	Х	0
Photometric and Elecsys Raw Data Transmission	Analyzer	0	0	0	х	0

(o = available; x = not available)

Table 3: Batch Communication Function Table

3.2.1 Test Selection Information Reception

A host can send Test Selection Information for patient sample(s) prior to introduction of the sample(s) on the analyzer. Since there are large amounts of information to be exchanged with a host, it is recommended that the Test Selection Information be sent before introduction of the sample on the analyzer. Performing analysis using this option lightens the communication load.

3.2.1.1 Key Information Used for Registration

In Batch Mode, the type of key information is the same as in Realtime Mode. If key information of a patient sample is the same as the one already registered, the patient sample is over-written; otherwise, it is registered as a new sample. Key information to be registered on the analyzer's database for Batch Communications is shown in Table 4.

Analysis Made	Key Information						
Analysis Mode	Type of Sample	Sample Type*	Sample Number	ID Number	Rack Position		
	Routine Sample	0	0	Х	х		
Sample Number Mode	Stat Sample	0	0	Х	0		
line do	Rerun Sample	0	0	Х	x		
	Routine Sample	0	X	0	х		
ID Mode	Stat Sample	0	х	0	х		
	Rerun Sample	0	х	0	х		

(o = key Information used; x = not available)

Table 4: Key Information Used to Register in the System Database

3.2.1.2 Number of Samples Possible for Registration

The system database holds a maximum of 10,000 samples for both routine and Stat records, combined. Due to this restriction, an error occurs if the TS information received from a host exceeds this limit. If the limit is exceeded, the TS information is not registered.

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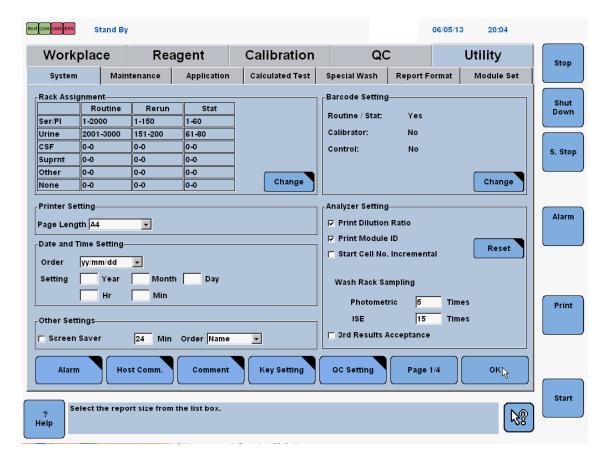
^{*} Set the rack number ranges at the analyzer for every sample type under Utility / System / Rack Assignment, otherwise an error occurs.

3.2.2 Batch Analytical Data Transmission

The operator can initiate a Batch Data Transmission of routine results and of control sample results from the Workplace/Data Review screen on the analyzer. The host can also request results for a given sample, but control sample results cannot be requested from the host.

3.3 3rd Result Acceptance

The latest result overwrites the existing 2nd result if the 3rd Results Acceptance option is enabled in Utility/System screen. This only happens if the option is enabled and the second run result was successfully transmitted to the host.



4 Host Communication Settings

4.1 Host Communication Setting Screen

The Utility/System/Host Communication Setting screen is viewable only with an analyzer logon of administrator level or above.

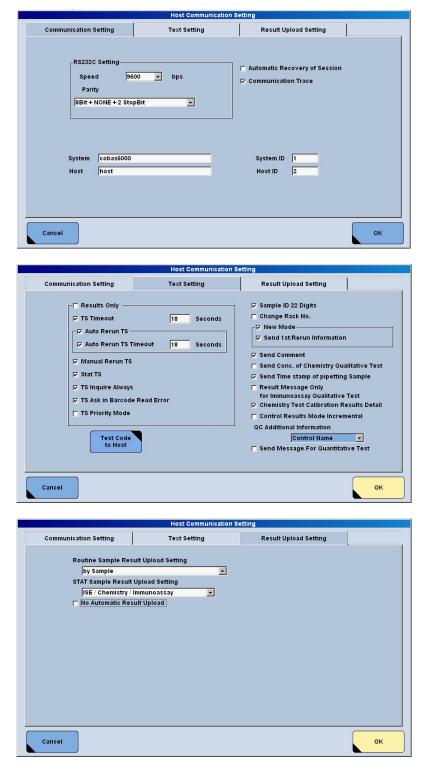


Figure 9: Host Communication Setting Screen

4.2 Definitions

RS232C Settings

Description in chapter 5.

Automatic Recovery of Session

If this function is enabled, the analyzer restarts the communication session if an error occurs. When this happens, the current communication message is lost.

During the initial setup of the host, it is recommended that this function not be enabled so errors can be detected. After the host interface has been successfully established, this function can be enabled, and can help resolve occasional interface errors without requiring operator intervention.

Communication Trace

This function applies to all host communications. When this function is enabled, the content of the communication with the host can be stored at the analyzer. The Communication Trace report can be printed from the global Print screen. This report can be used as an analysis tool if a problem occurs.

Note: Due to the trace file size, it is recommended that the Communication Trace report not be routinely used. When enabled for troubleshooting purposes, it is recommended that the print buffer be printed prior to printing this report, as the size of it might overwrite other buffered printouts.

How to store a host communication trace file

It is possible to get a host communication trace by the following procedure. (The analyzer must be in Standby mode.)

- > Touch the Print button.
- Select Utility tab.
- Select the Communication Trace in the list box.
- Select the radio button "Print."
- > Touch OK button.

After above procedure, touch View button, and backup the communication trace in the view on the media.

System

Name used on reports and in communications for the **cobas**® 6000 analyzer series.

Host

Name used on reports and in communications for the host system.

System ID

The ID number used to identify the system in communications with the host.

Host ID

The ID number used to identify the host in communications with the analyzer.

Results Only

This function applies to all Realtime Communications. This does not apply to the Batch Mode. When this function is enabled, communication during analysis is limited only to the analytical data transmissions. Inquiries for the Test Selection Information or Auto Rerun Selection Information are not made. Test selections would need to be made either manually by the operator at the analyzer, by Batch Mode from the host, or by use of the Default Profile if selected in the Start Conditions screen.

TS Timeout

This function allows the operator to set a timeout interval for Test Selection Information Inquiry for Realtime Communications and for routine, Stat and rerun samples. The specified timeout interval determines how long the analyzer will wait for a 'Response from the host'. The range is 10-9999 seconds, with a default of 10 seconds. Enabling this function optimizes the throughput of the system. If the function is not enabled, the analyzer will wait indefinitely for Test Selection Information.

Auto Rerun TS

This function applies to Auto Rerun TS inquiry within the Realtime Communications. When this function is enabled in the Auto Rerun mode during analysis, an inquiry is made for the Auto Rerun selections. When this function is not enabled, no inquiry for the Auto Rerun Selection is made.

Auto Rerun TS Timeout

This function applies to the reception of Auto Rerun Test Selection Information in Realtime Communications. Racks with any samples to which the host did not respond within the timeout interval are carried to the unloader. The range is 10-9999 seconds, with a default of 25 seconds. If the function is not enabled, the analyzer waits indefinitely for Rerun Test Selection Information.

Manual Rerun TS

This function applies to the Test Selection Information inquiry for Manual Rerun samples in Realtime Communication. When this function is enabled, an inquiry is made for the test selections for rerun samples during analysis. Any samples that have previously been processed create a TS inquiry to the host. When this function is not enabled, no TS inquiry for Manual Rerun samples is made.

Stat TS

This function applies to the Test Selection Information inquiry for Stat samples in Realtime Communications. When this function is enabled, an inquiry is made for the test selections for Stat samples during analysis. When this function is not enabled, no TS inquiry for Stat samples is made.

TS Inquire Always

This function applies to the Test Selection Information inquiry for routine and Stat samples in Realtime Communications. This does not apply to TS information inquiry for rerun samples or Auto Rerun Selection inquiries. When this function is enabled, an inquiry is made whether the TS information is in the analyzer or not. When not enabled, an inquiry is made only for the samples that do not have test selections.

TS Ask in Barcode Read Error

(Only available if in Utility/System, Barcode Setting, Stat/Routine = YES to enable the barcode reader)

If this function is enabled, and the analyzer cannot read a sample barcode, it will send the rack ID and position to the host as key information. The sample ID is sent as '***...' [13 or 22 characters of '*']. If the host has the table of the rack ID, position and Sample ID, the host can send the analyzer the correct Sample ID instead of '***...'.

The only currently known use for this function is with a Modular Pre-Analytics system that 'manufactures' sample aliquots for the analyzer. This type of system would track samples by rack and position numbers. Unless the MPA system can perform this function, it is strongly recommended that it not be used

In this mode, rerun by gray racks (racks for 1st run) is not permitted, as the analyzer cannot tell if this is the first or second presentation of the rack.

TS Priority Mode

If this function is enabled, after a Test Selection inquiry the analyzer will stop sending any information, i.e. result data, until the analyzer receives the answer to the inquiry from the host or the TS timeout period passes. This option applies to both the inquiry at the bar code reader and the implied inquiry at the decision point.

The range of the TS Timeout and Auto Rerun TS Timeout is from 1 to 18 seconds with this mode on. With this mode off the TS Timeout options remain at 10 to 9999 seconds. If this mode is enabled and the TS Timeout checkbox is off, TS timeout is handled as 18 seconds.

Sample ID 22 Digits

The maximum length of the sample ID is increased from 13 to 22 characters.

Change Rack No.

The rack No. occurs in field 4 of the Order record (O) and field 3 of the Request record (Q). The following table shows which Rack No. the **cobas**® 6000 analyzer series sends if the 'Change Rack No.' option is on or off:

Rack Type	Change Rack No. = OFF	Change Rack No. = ON
Normal	5001	0001
STAT	4001	E0001
Rerun	A001	R0001
QC	3001	C0001
Calibration	2001	S0001

Table 5: Rack No. according to 'Change Rack No.' setting

New Mode

The host interface protocol description in this manual is based on this 'New Mode' setting enabled.

If disabled the protocol is identical with the protocol of the Clinchem Modular software for purpose of 100% compatibility with already connected CC Modular systems.

Concerning detail of the CC Modular host interface specification refer to

Roche/Hitachi MODULAR System Host Interface Document Version 1.0 Ident. No. 011632701 (US ID)

In addition, this protocol of the Clinchem Modular software can be also applied to **cobas**® 6000 analyzer series.

Refer to Appendix E for a list of differences between the two specifications.

Send 1st^t / Rerun Information

With this mode enabled, additional information that shows whether a query is 1st or rerun measurement is added to Request Information Record. <u>This mode is applied to only "Inquiry for the Requested Tests" message from the analyzer to the host, but not applied to "Inquiry of Result" from the host to the analyzer.</u>

If the function is not enabled, no information is added to Request Information Record.

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Send Comments

This function applies to host communications. When this function is enabled, the host can send patient comments to the analyzer. Patient comments stored in the analyzer can also be transmitted to the host along with analytical data and Reaction Monitor data. When this function is not enabled, no patient comments are accepted or sent.

Send Concentration Of Chemistry Qualitative Test

With this mode enabled, the concentration of the chemistry qualitative tests is sent to the host.

QC Additional Information

With this function it is possible to select if 'Control Name' or 'Lot Number' shall be sent in field 3 of the Order record within a control result message.

Send Message For Quantitative Test

When this function is enabled, message value for quantitative immunoassay is sent to the host.

Send Time stamp of pipetting of Sample

When this function is enabled, pipetting date and time for each test result is sent to the host.

Result Message Only for Immunoassay Qualitative Test

When this function is enabled, cut off index for immunoassay is not sent to the host.

Chemistry Test Calibration Results Detail

When this function is enabled, the detail information (reagent lot number, reagent bottle sequence number, expired flag, calibrator lot number and pipetting date and time) corresponding to the calibration result is sent to the host.

Control Results Mode Incremental

With this mode enabled, the control results are sent test oriented; i.e. as soon as one test result is available it is sent to the host.

Routine Sample HOST upload setting

With this function it is possible to select how the routine sample results are uploaded to the host in real time.

Selectable item	Function
By Sample	All results of routine sample are uploaded by round.
	Notes: Exceptions from this upload behavior: a) Precondition: Immunology test (Normal Priority level in Application screen) without automatic rerun and CC test with automatic rerun are requested for the routine sample. Consequence: Chemistry results (ISE/C) and Immunoassay results will be uploaded separately.
	b) Precondition: At least one Immunology test (High Priority level in Application screen) with automatic rerun is requested for the routine sample. Consequence: Chemistry results (ISE/C) and Immunoassay results will be uploaded separately.
Chemistry incl. ISE / Immunoassay	Chemistry results (ISE/C) and Immunoassay results of routine sample are uploaded separately.
ISE / Chemistry / Immunoassay	ISE results, Chemistry results (C) and Immunoassay results of routine sample are uploaded separately.

STAT Sample HOST upload setting

With this function it is possible to select how the stat sample results are uploaded to the host in real time.

Selectable item	Function
By Sample	All results of Stat sample are uploaded by round.
	Notes: Exceptions from this upload behavior: a) Precondition: Immunology test (Normal Priority level in Application screen) without automatic rerun and CC test with automatic rerun are requested for the STAT sample. Consequence: Chemistry results (ISE/C) and Immunoassay results will be uploaded separately. b) Precondition: At least one Immunology test (High Priority level in Application screen) with automatic rerun is requested for the STAT sample. Consequence: Chemistry results (ISE/C) and Immunoassay results will be uploaded separately.
Chemistry incl. ISE / Immunoassay	Chemistry results (ISE/C) and Immunoassay results of Stat sample are uploaded separately.
ISE / Chemistry / Immunoassay	ISE results, Chemistry results (C) and Immunoassay results of Stat sample are uploaded separately.
By Test	As soon as one test result is available it is sent to the host.

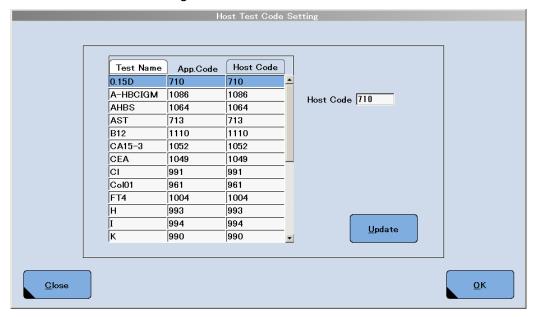
No Automatic Result Upload

This function is applied to Realtime communication for routine and Stat samples.

When this function is enabled, no result is uploaded in real time. In this case, the results can be uploaded manually by selecting samples from the Workplace/Data Review screen.

Test Code to Host

Use the Host Test Code Setting window to edit the test code sent to the host.



Host Code

Use this text box to edit the host code for the test selected in the Test list. After editing the code, touch Update to save the change.

Update

Changes are saved and the updated contents of the list are displayed.

5 Physical Layer Specifications

5.1 Communication Options

Host communication options such as baud rate can be found on the Utility/System/Host Communication Setting/ Communication Setting screen.

Item	Specifications	Remarks
Communication Speed	4800, 9600, 19200 bps	Specified on Analyzer
Character Configurations	Refer to diagram below	Specified on Analyzer
Communication Port	1	
Electrical Signal	In accordance with EIA-232-D-1986	
Cable Length	Maximum 15m	

Table 6: Physical Level Specifications

One character is made up of one start bit + data bit + parity bit + stop bit. Data bit, parity bit and stop bit are selected from the table below.

No.	Data Bit	Parity Bit	Stop Bit
1	7 bits	Even	2 bits
2	7 bits	Odd	2 bits
3	7 bits	Even	1 bit
4	7 bits	Odd	1 bit
5	8 bits	None	2 bits
6	8 bits	None	1 bit
7	8 bits	Even	1 bit
8	8 bits	Odd	1 bit

Table 7: Character Configurations

5.2 Analyzer/Host Communication Cable

Figure 10 shows the wiring diagram of the connection cable between the **cobas**® 6000 analyzer series and the host. The plug for the RS232 host interface cable is on the backside of the sampler unit below the rotor.

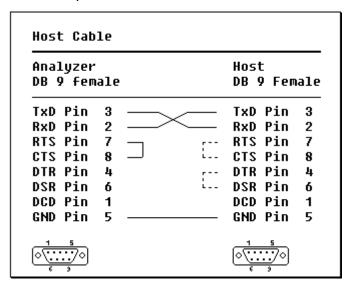


Figure 10: Host Interface Connection Cable of the cobas® 6000 analyzer series

The dashed lines indicate jumpers at host if required by the host system.

6 ASTM Protocol

6.1 Background

ASTM (American Society of Testing and Material) has a plan for communications between automatic analyzers and host computers for standards E1381-91 (Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems) and E1394-91 (Standard Specifications for Transferring Information Between Clinical Instruments and Computer Systems). The basic specifications of the standards are regulated on X12 of ANSI.

The host communication interface installed in the **cobas**® 6000 analyzer series meets the standards of ASTM.

6.2 Communication Processing Layers

The communication process between the system and the host is divided into four layers as shown below. This specification explains the processing and operation methods for the application layer.

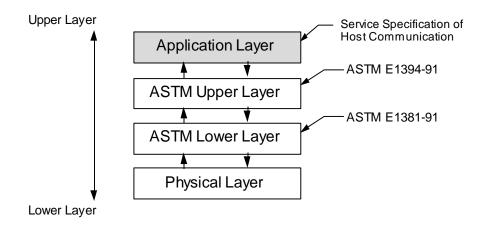


Figure 11: Host Communication Processing Layers

Details of the ASTM protocol can be found in the Annual Book of ATSM Standards.

Copyright American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, USA.

ASTM E1381-91 Low Level Protocol

Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems

ASTM E1394-91 High Level Protocol

Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems.

6.3 ASTM Lower Layer

ASTM lower layer receives messages for a transmission request from the upper layer. These messages are then split into frames and sent to a communication medium to be transmitted to other parties. ASTM lower layer also constructs frames received from a communication medium to recreate messages to be transferred to the ASTM upper layer as reception messages. Configuration and communication procedures for transmission and reception of frames are explained in the following chapters.

Item	Method	Explanation	
Frame Configurations	For Middle Frame <stx> FN text <etb> C1 C2 <cr><lf> For Last Frame <stx> FN text <etx> C1 C2 <cr><lf></lf></cr></etx></stx></lf></cr></etb></stx>	 Control character (characters enclosed in <>): is control character (HEX 02) is control character (HEX 17) is control character (HEX 0D) is control character (HEX 0A) is control character (HEX 03) FN: FN is a single ASCII number. FN indicates the sequence number for a frame (the frame number modulus 8). Frames of a single transmission phase are consecutively numbered beginning with 1, so FN runs from 1 to 7, then continues with 0, 1, and so on. Text: the data content of a frame (maximum 240 characters). Records are sub-divided into intermediate (middle) frames with 240 or fewer characters. Text is part of a split message. C1 and C2: When 1 byte resulting from adding each byte, FN to <etb> for the middle frame and FN to <ext> for the last frame, is expressed in hexadecimal, the upper character (16¹) is C1 and the lower character (16¹) is C2. Characters used are '0' to '9' or 'A' to 'F'.</ext></etb> 	
Frame Character Configuration of Text	Characters other than <soh><stx><etx> <eot><enq><ack> <dle><nak><syn> <etb><cr><lf> <dc1><dc2><dc3> <dc4></dc4></dc3></dc2></dc1></lf></cr></etb></syn></nak></dle></ack></enq></eot></etx></stx></soh>	<soh> is control character (HEX 01) <eot> is control character (HEX 04) <enq> is control character (HEX 05) <ack> is control character (HEX 06) <dle> is control character (HEX 10) <nak> is control character (HEX 15) <syn> is control character (HEX 16) <dc1> ~ <dc4> are control characters (HEX 11 ~ 14)</dc4></dc1></syn></nak></dle></ack></enq></eot></soh>	
Maximum Length of the Frame	247 characters	For one frame, maximum of 240 characters for text, 7 characters for frame control characters. Messages equal to or less than 240 characters are transmitted as one final frame. Messages greater than 240 characters are split into frames that have character lengths that fall within the 240-character limit. The only or final remaining frame becomes the last frame and is indicated by <etx>. All others are intermediate (middle) frames and are indicated by <etb>.</etb></etx>	

Table 8: ASTM Lower Layer Communication Methods

6.4 ASTM Syntax

The structure of the sentences to be transferred, according to ASTM Communication Regulation, is explained in this section. Between the analyzer and the host, various data such as Test Requests and Results are transferred back and forth. All of these data conform to this syntax.

6.4.1 Definitions

Message A message is constructed with an arrangement of several records (refer to the next

item). It is the smallest unit of information transferred between a host and an analyzer. Messages begin with a 'Message Header Record' that indicates the beginning of a message and end with a 'Message Termination Record' that indicates

the end of a message.

Record A record is constructed from several fields and expresses a single purpose (such as

to specify result reports or test requests). A record may be repeated or used singularly in a message. Code that indicates the purpose of a record is noted in the

first character of that record.

Field A field is the ASTM's smallest element to construct information. Attributes for a field

(name, format, and meanings) are defined in units in a record.

6.4.2 Coding Rules for the Messages

This section deals with message coding rules as well as special characters, such as delimiters, used to develop messages provided by records and fields.

6.4.2.1 End of Record Character

The ASCII CR character (HEX 0D) is always used to indicate the end of a record.

6.4.2.2 Field Delimiter = Vertical Bar '|'

A Field delimiter is a character used to separate fields that are next to each other in a record. This is also a delimiter for the first Record ID (character that appears in the beginning of a record) and the next field. According to the 2nd character that appears in the Message Header Record (record that appears in the front of a message), a Field delimiter can be defined with an optional character through the Message Header Record; however, it is recommended that a vertical bar '|' be used.

6.4.2.3 Repeat Delimiter = Backslash '\'

When a field is constructed by the same data repeated several times, it is referred to as a Repeated Field. The delimiter between the repeated items for the Repeated Field is called the Repeat delimiter. Repeat delimiters can be defined with an optional character through the Message Header Record; however, it is recommended that a backslash '\' be used.

6.4.2.4 Component Delimiter = caret '^'

When a field is constructed by several elements, it is referred to as a Component Field. The delimiter between these elements is the Component delimiter. The Component delimiter can be defined with an optional character through the Message Header Record; however, it is recommended that a caret '^' be used.

6.4.2.5 Escape Character = Ampersand '&'

An Escape character is provided to indicate a delimiter for the fields that include general text. When this character occurs in a relevant field, the next character holds a special meaning (discussed below). An Escape character can be defined with an optional character through the Message Header Record; however, it is recommended that an ampersand '&' be used.

6.4.2.6 Expression of Special Characters with Escape Character

The following Escape sequence (starting with & and ending with &) is defined. When this sequence is detected in a field, it is changed to a corresponding character and deleted.

Escape sequences other than these are skipped and treated as NULL value.

&F& Indicates Field delimiter
&S& Indicates Component delimiter
&R& Indicates Repeat delimiter
&E& Indicates Escape

6.4.3 Message Transmission Phases

To establish which system sends and which system receives information and to assure the actions of sender and receiver are well coordinated, there are three distinct phases in transferring information:

- Establishment Phase
- Transfer Phase
- Termination Phase

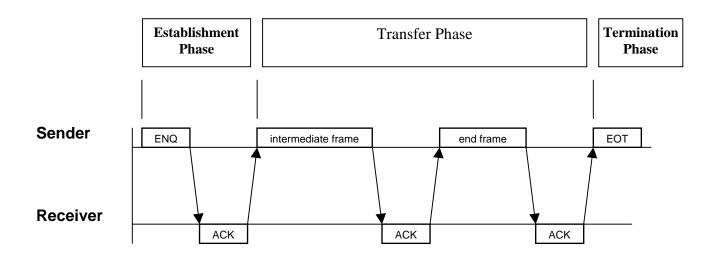


Figure 12: Message Transmission Phases

Within the transfer phase, all records of the corresponding message are grouped into longer frames to increase speed. The records are separated through a [CR] character. Therefore, to obtain pure ASTM records again, the receiver must concatenate all the frames and wait for a [EOT] character. Then, the receiver can process the frame and split it into different records using the [CR] as the separator.

6.5 Checksum Calculation/ Message Frame

The Intermediate Frame

[STX] FN	N Text first char.	 Text last char.	ETB	СН	С	[CR]	[LF]
					L		

The End Frame

[STX]	FN	Text first char.	 Text last char.	ETX	СН	C	[CR]	[LF]
						L		

[STX] The ASCII code 2, indicating the beginning of a frame transmission.

The frame number modulus 8. Frames of a single Transmission Phase are consecutively numbered beginning with 1. So FN runs from 1 to 7, continues with 0, 1, and so on. Use ASCII codes for the digits '0' to '7' (48-55).

Text The data content of a frame (max. 240 characters).

Records are sub-divided into intermediate frames with 240 characters.

Maximum is indicated by [ETB]. The only or last remaining frame is indicated by [ETX]. Different records must be sent in different frames.

[ETB] The ASCII code 23 (17hex), indicating the end of the text block of an intermediate frame.

[ETX] The ASCII code 3, indicating the end of the text block of an end frame.

CH, CL Represents the high nibble (= most significant 4 bit) respectively, the low nibble (=least significant 4 bit) of the 8-bit checksum. CH and CL are represented as two digits of hex numbers. The checksum is the modulus 8 of the sum of ASCII values of the frame characters starting with and including 'FN' and completing with [ETX] respectively [ETB].

Example for Checksum Calculation

[STX]1Test[ETX]

Character	Value (hex)		Sum
[STX]	02h	00h	
'1'	31h	31h	
'T'	+54h	85h	
'e' 's'	+65h	EAh	
's'	+73h	15Dh	
't'	+74h	1D1h	
[ETX]	+03h	1D4h	
	= 1D4h	1	
	Mod 10	00h	
	= D4 h		

to be sent:

[STX]1Test[ETX]D4[CR][LF]

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7 Communication Text Content

7.1 Record Levels

The following table shows the Standard Record types and levels (see ASTM E 1394-91 Section 5, 'Information Requirements in Clinical Testing')

Level	Record Name	Identifier
0	Message Header Record	Н
1	Patient Information Record	Р
2	Test Order Record	0
3	Result Record	R
13	Comment Record	С
13	Manufacturer Information Record	М
0	Message Termination Record	L
1	Request Information Record	Q

Table 9: Standard Record Types and Levels

The Manufacturer Specific Records are specific for the **cobas**® 6000 analyzer series and must be received by the host

Level	Record Name	Identifier
1	Photometry Calibration Result	M-PCR
1	ISE Calibration Result	M-ICR
1	cobas e 601 analyzer Calibration Result	M-ECR
3	Photometric Raw Data	M-ABS
3	cobas e 601 analyzer Raw Data	M-EFS

Table 10: Manufacturer Defined Record Types and Levels

7.2 Messages used in cobas® 6000 analyzer series Communication

All messages are shown in Table 11. The following section shows detailed descriptions of each of the message and the included ASTM records.

Communication Text	Communication Direction	Realtime Communication	Batch Communication
Test Selection Inquiry	Analyzer → Host	0	х
Auto Rerun Selection Inquiry	Analyzer → Host	0	х
Test Selection Information	Host → Analyzer	0	0
Automatic Rerun Selection Information	Host → Analyzer	0	х
Patient Sample Analytical Data	Analyzer → Host	0	0
Control Sample Analytical Data	Analyzer → Host	0	0
Photometric Calibration Data	Analyzer → Host	0	х
ISE Calibration Data	Analyzer → Host	0	х
cobas e 601 analyzer Calibration Data	Analyzer → Host	0	х
Photometric Raw Data	Analyzer → Host	х	0
cobas e 601 analyzer Raw Data	Analyzer → Host	х	0
Analytical Data Transmission Request	Host → Analyzer	x	0

(o = available; x = not available)

Table 11: Communication Text Table

7.2.1 Messages Transmitted by the Analyzer

Messages transmitted by the analyzer (messages received by the host) are indicated in the table on the following page.

The identifier is set in the Comment or Special Instruction Field in the Message Header Record with the reason for the messages.

Messages	Syntax / Records	Comment or	Reasons
		Special Instructions	
Inquiry for the Requested Tests	H Q L	TSREQ^REAL	Inquiry is made for the requested test just before loading the sample rack (passing through the ID reader). Rerun Inquiry is sent to host in case the
			result upload setting is specified as "Chemistry incl. ISE / Immunoassay" or "ISE / Chemistry / Immunoassay" or "By test".
Result Report	H P O	RSUPL^REAL	Reports on the result at the point when the results for the sample have been accumulated.
	C {R	RSUPL^REPLY	Reports on the result as a response for the inquiry from a host.
	C} _n	RSUPL^BATCH	Transmits results of the selected sample(s) by instruction at the analyzer.
Photometry	n = 0~160	PCUPL^REAL	Reports at the point when the Photometry
Calibration Result Report	M-PCR L	TOOK E KEKE	calibration results are output.
ISE Calibration Result Report	H M-ICR L	ICUPL^REAL	Reports at the point when the ISE calibration result is output.
cobas e 601 analyzer Calibration Result Report	H M-ECR L	ECUPL^REAL	Reports at the point when the cobas e 601 analyzer calibration result is output.
Photometric Raw Data Report	H P O C R C M-ABS	ABUPL^BATCH	Reports absorbance of the photometric tests
cobas e 601 analyzer Raw Data Report	H P O C R C M-EFS	EFUPL^BATCH	Reports absorbance of the cobas e 601 analyzer tests

Table 12: Messages Transmitted by the Analyzer

7.2.3 Messages Transmitted by the Host

Messages transmitted by the host are shown in the table below (messages received by the analyzer).

Messages	Syntax / Records	Comment or Special Instructions	Reasons
Order for Test Request	H P O C	TSDWN ^ REPLY TSDWN ^ BATCH	Orders test request for a sample as answer to a Test Selection Inquiry Orders test request for a sample by instruction at the host
Inquiry of Result	H Q L	RSREQ ^ REAL	Makes inquiry for the result of a test.

Table 13: Messages Transmitted by the Host

7.3 Record Description

7.3.1 Field Attributes

Types of attributes held by a field are explained below.

No.	Attribute	Description					
1	Field Name	Name of the relevant field.					
2	Reference	Position of the field. Order in which the relevant fields appear in a record.					
3	Format	The format for a field is one of the following:					
		ST: String: A character string					
		TX: Text: A group of character strings that can be printed at the terminal. It is an optional character string; however, a special escape sequence is defined for a display at the terminal.					
		NM: Numeric: A numeric value. Positive (+) or negative (-) is indicated before the numeric value. If it is not indicated, it is treated as positive (+).					
		If a decimal point is not included, the numeric value is treated as an integer. There are no restrictions for placing '0' in the front and for '0s' placed at the end of numbers with decimal points.					
		DT: Date. Always use the 4-digit Christian year. The format is YYYYMMDD (YYYY is the 4-digit Christian year, MM is the month, DD is the day). For example, September 5, 1998 is indicated 19980905.					
		TM: Time: Military time.					
		The format is HHMMSS (HH is the hour, MM is the minute, and SS is the second).					
		TS: Time Stamp. A combination of DT and TM.					
		The format is: YYYYMMDDHHMMSS.					
		CM: Combination. A field in which multiple data are combined by a component delimiter.					
4	Maximum Length	The maximum value of the number of valid characters for the relevant field excluding escape delimiters.					
5	Comments	Contains field contents and any relevant field comments.					
	(Data Content)	Note: A field with the message 'Field does not contain data' in the column means that even though it is provided by ASTM, it may be ignored when received.					

Table 14: Field Attributes

7.3.2 Message Header Record

This record occurs in the front of a message and indicates the goal of the message, such as origination and destination.

H|\^&|||H7600^1|||||host|RSUPL^BATCH|P|1 Mandatory

Field Name	Reference	Format	Max Length	Comments (Data Content) H 7.1.
Record Type ID (H)*	07.1.01	ST	1	Use 'H'
Delimiter Definition*	07.1.02	ST	4	Defines Field delimiter, Repeat delimiter, Component delimiter, and four (4) Escape characters. The first character defines the Field delimiter and also corresponds to the Field delimiter of the Record Type ID. Four characters for this are: \^ & *
Message Control ID	07.1.03			Field does not contain data
Access Password	07.1.04			Field does not contain data.
Sender Name or ID	07.1.05	СМ	36	Name of the machine transmitting this message. When transmitting from the analyzer, the registered name of the Roche/Hitachi cobas6000 system ² communication program version is transmitted.
Sender Street Address	07.1.06			Field does not contain data.
Reserved Field	07.1.07			Field does not contain data.
Sender Telephone Number	07.1.08			Field does not contain data.
Characteristics of Sender	07.1.09			Field does not contain data.
Receiver ID	07.1.10	ST	30	Name of the machine receiving this message. cobas® 6000 analyzer series transmission process Enter registered host name³. cobas® 6000 analyzer series reception process Currently, the receiving machine uses this field to confirm whether or not the message is addressed to it. However, this field is not sent by the analyzer. This field, therefore, is relevant for Communication Log use only.

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^{*} Indicates a field or field component required in ID and Sample No. modes.

²The name of the **cobas**[®] 6000 analyzer series is registered on the Utility/System/Host Communication Setting window. Characters that can be used are either numbers or the minus sign '-'.

 $^{^3}$ The name of the host computer registered on the Utility/System/Host Communication Setting window. Characters that can be used are either numbers or the minus sign '-'.

Message Header Record, Continued

Field Name	Reference	Format	Max Length	Comments (Data Content) H 7.1.
Comment or Special Instructions	07.1.11	CM	11	A comment regarding the message is entered here. cobas® 6000 analyzer series transmission process To indicate classification of the transmitted message from the analyzer, one of the following is transmitted. TSREQ^REAL PCUPL^REAL RSUPL^REAL ICUPL^REAL RSUPL^REAL ICUPL^REAL RSUPL^REPLY ABUPL^BATCH EFUPL^BATCH EFUPL^BATCH EFUPL^BATCH EFUPL^BATCH The first component element indicates the purpose for the message. TSREQ: Test request inquiry RSUPL: Result report PCUPL: Photometry calibration report ICUPL: ISE calibration report ECUPL: Elecsys calibration report EFUPL: Effective signal report The second component element indicates the cause of the message. REAL: Message automatically generated by the analyzer. BATCH: Message generated with an instruction by an operator from the working terminal. REPLY: Response message for inquiry from a host. cobas® 6000 analyzer series reception process To indicate classification of the transmitted message from the host, one of the following is transmitted. TSDWN^REPLY RSREQ^REAL TSDWN/BATCH The first component element indicates the purpose for the message. TSDWN: Registration of test request RSREQ: Inquiry for the result The second component element indicates the cause of the message. REAL: Message automatically generated by a host. BATCH: Message to indicate downloading from a host. REPLY: Response message for the inquiry from the
Processing ID	07.1.12	ST	1	analyzer. Indicates the processing method for the messages. Currently 'P' is always used.
Version No.	07.1.13	NM	1	Enter version number of the communication program. Currently '1' is always used.
Date and Time of Message	07.1.14			Send only in debugging mode

7.3.3 Message Termination Record

This record occurs at the end of a message to indicate the end of a message.

L|1|N

Field Name	Reference	Format	Max Length	Comments (Data Content) L 13.1.
Record Type ID (L)*	13.1.01	ST	1	Use 'L'
Sequence Number*	13.1.02	NM	1	Always '1'.
Termination Code*	13.1.03	ST	1	Input the value shown below. N Normal termination T Forced termination of the transmitting side R Forced termination of the receiving side E System error Q Request error for the last reception (request is rejected) I No information that corresponds to the inquiry in the last reception F The last request was processed

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^{*} Indicates a field or field component required in ID and Sample No. modes.

7.3.4 Patient Information Record

This record is used to transfer patient sex and age to the analyzer (within test selection message) or to the host (within result message).

P|1||||M||||35^Y

Field Name	Reference	Format	Max Length	Comments (Data Content) P 7.1.
Record Type ID (P)*	08.1.01	ST	1	Use 'P'
Sequence Number*	08.1.02	NM	6	Sequence number of the Patient Information Record in the message. It begins with '1'.
Practice Assigned Patient ID	08.1.03			Field does not contain data.
Laboratory Assigned Patient ID	08.1.04			Patient ID - same length as sample ID
Patient ID No.3	08.1.05			Field does not contain data.
Patient Name	08.1.06			Field does not contain data.
Mothers Maiden Name	08.1.07			Field does not contain data.
Date of Birth	08.1.08	DT	8	Date as defined by ASTM 6.6.2
Patient Sex	08.1.09	ST	1	Field ValueDescriptionMMaleFFemaleUUnknown
Patient Race-Ethnic Origin	08.1.10			Field does not contain data.
Patient Address	08.1.11			Field does not contain data.
Reserved Field	08.1.12			Field does not contain data.
Patient Telephone Number	08.1.13			Field does not contain data.
Attending Physician ID	08.1.14			Field does not contain data.
Special Field 1	08.1.15	СМ	5	Format Age Age Vnit>ElementMax LengthFormatAge3NMAge Unit1STElementDescriptionAgeAge of the Patient from whom the sample was collected. Range 1-200Age UnitSpecify 'Y', 'M' or 'D'. Indicates unit of the age. 'Y' is the year, 'M' is the month, and 'D' is the day.
Special Field 2	08.1.16			Field does not contain data.
Patient Height (in cm)	08.1.17			Field does not contain data.

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^{*} Indicates a field or field component required in ID and Sample No. modes.

Patient Information Record, Continued

Field Name	Reference	Format	Max Length	Comments (Data Content) P 7.1.
Patient Weight in kg	08.1.18			Field does not contain data.
Patient's Known or Suspected Diagnosis	08.1.19			Field does not contain data.
Patient Active Medications	08.1.20			Field does not contain data.
Patient's Diet	08.1.21			Field does not contain data.
Practice Field No.1	08.1.22			Field does not contain data.
Practice Field No.2	08.1.23			Field does not contain data.
Admission and Discharge Dates	08.1.24			Field does not contain data.
Admission Status	08.1.25			Field does not contain data.
Location	08.1.26			Field does not contain data.
Nature of Alternative Diagnostic Code and Classifiers	08.1.27			Field does not contain data.
Alternative Diagnostic Code and Classification	08.1.28			Field does not contain data.
Patient Religion	08.1.29			Field does not contain data.
Marital Status	08.1.30			Field does not contain data.
Isolation Status	08.1.31			Field does not contain data.
Language	08.1.32			Field does not contain data.
Hospital Service	08.1.33			Field does not contain data.
Hospital Institution	08.1.34			Field does not contain data.
Dosage Category	08.1.35			Field does not contain data.

7.3.5 Test Order Record

This record holds information regarding analysis request and sample information to the analyzer (within test selection message) and to the host (within result message).

```
O|1|000003·····|3^5238^3^\$1\$C|\^^2\1|R||20000529125
556||||N|||1|||||20000529125645|||F
```

Field Name	Reference	Format	Max Length	Comments (Data Content) 0 9.4.			
Record Type ID (O)*	09.4.01	ST	1	Use 'O'			
Sequence Number*	09.4.02	NM	6	Indicates the sequence number of the Test Order Record at the current layer. This record is in the layer following the Patient Information Record and is rese to 1 for each occurrence of a new Patient Informatic Record. It is numbered consecutively; 1, 2, etc., for each occurrence of this record.			
Specimen ID*	09.4.03	ST	22	Identification procedure for samples by the analyzer. Sample ID Barcode attached to the test tube. The barcode label is read by the system's barcode reader. The total valid character number is 13/22 (see Host Communication Setting/text Setting screen). Note: In S.No. mode, becomes patient comment Control: Control name			

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^{*} Indicates a field or field component required in ID and Sample No. modes.

Field Name	Reference	Format	Max Length	Comments (Data	a Content)	O 9.4.
Instrument Specimen ID*	09.4.04	ST	20	<u>Format</u>	cedure for samples l	
				Sample No>^ <f< p=""> Type>^<contained< p=""></contained<></f<>	Rack ID>^ <position <br="">er Type></position>	No>^^ <rack< td=""></rack<>
				Element	Max Length	<u>Format</u>
				Sample No [⊕] Rack ID	5 5	NM ST
				Position No $^\Phi$	1	NM
				Rack Type* Container Type	2 2	ST ST
				Element	Description	
				Sample	numbered in sequences of QC mater	ber when samples are lence in order of input. In ial, 'Control Number * No. sample' is used.
					ex. Control No. = written as 1002	1, Sequence No. = 2 is
				Rack ID	ID of the Sample There are two way	Rack with 5 samples. ys of reading: reading in the rack or from the
				Position No	forward direction,	Inting from the rack's the position of the first ne last sample is 5.
				Rack Type	S1: Blood serum / S2: Urine S3: CSF S4: Suprnt S5: Others	/ Plasma
				Container Type	no value F	Standard cup Priority is given to the ed on the instrument.

^{*} Indicates a field or field component required in ID and Sample No. modes.

 $^{^{\}mbox{$\Phi$}}$ Indicates a field or field component required in Sample No. mode only.

Field Name	Reference	Format	Max Length	Comments (Data	Content)	O 9.4.
Universal Test IDΩ	09.4.05	СМ	10	Specifies test requester format	lication Code>^ <dilution> and third component elem are referred to as the Uni until Standard Code is made tests. d repeatedly with delimite imum of 160 tests can be Max Length 5 3 Description</dilution>	rents for this format versal Test ID. ade that uniquely rs when ordering specified. Format NM ST The test with 3-digit 3-digit numbers. In code is expanded CI=991 E993, I=994 etting and testing
Priority*	09.4.06	ST	1		parameters. ity order of the Patient Sa es. Values are one of the Description Indicates routine analys samples Indicates Stat analysis of samples	following: is of the patient

 $^{^{\}Omega}$ The record should be sent with this field left blank when the host has no Test Selections. See example on page 80. * Indicates a field or field component required in ID and Sample No. modes.

Field Name	Reference	Format	Max Length	Comme	ents (Data Conten	t)	O 9.4.
Requested/Or dered Date and Time	09.4.07			Field do	es not contain dat	a.	
Specimen Collection Date and Time	09.4.08	TS	14		d time specimens MDDHHMMSS.	were collected	d is designated by
Collection End Time	09.4.09			Field do	es not contain dat	a.	
Collection Volume	09.4.10			Field do	es not contain dat	a.	
Collector ID	09.4.11			Field do	es not contain dat	a.	
Action Code*	09.4.12	ST	1	Indicate	s type of information	on for the repo	ort.
				<u>Value</u> A	Communication Transmit by the h		<u>Description</u> Indicates an add-on request for the test item.
				C N	Transmit by the h	analyzer	to cancel an order Indicates report for the routine sample's analytical data.
				Q	Transmit by the a	analyzer	Indicates report for the control sample's analytical data.
Danger Code	09.4.13			Field do	es not contain dat	а.	
Relevant Clinical Information	09.4.14			Field do	es not contain dat	a.	
Date/Time Specimen Received	09.4.15			Field do	es not contain dat	a.	
Specimen Descriptor*	09.4.16	NM	1		d indicates the type eld Value 1 2 3 4 5	e of sample <u>Description</u> Serum/Plasr Urine CSF Suprnt Others	
Ordering Physician	09.4.17			Field do	es not contain dat	a.	
Physician's Telephone Number	09.4.18			Field do	es not contain dat	a.	
User Field No. 1	09.4.19			Field do	es not contain dat	a.	
Users Field No. 2	09.4.20			Field do	es not contain dat	a.	

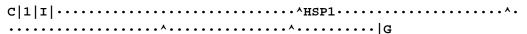
* Indicates a field or field component required in ID and Sample No. modes. If the sample type is missing in the Specimen Descriptor, an Alarm 340/102 "Host receiving Error/Class outside the range" is generated.

Field Name	Reference	Format	Max Length	Comments (Data Content) 0 9.4.			
Laboratory Field No. 1	09.4.21			Field does not contain data.			
Laboratory Field No. 2	09.4.22			Field does not contain data.			
Date/Time Last sample arrived time	09.4.23	TS	14	Indicates the date and time the sample was arrived. (sample barcode reading time as displayed in "Data Review" screen) This field is not specified by a host.			
Instrument Charge to Computer System	09.4.24			Field does not contain data.			
Instrument Section ID	09.4.25			Field does not contain data.			
Report Types*	09.4.26	ST	1	Indicates type of communications. Value Communication Direction O Transmit by the host Indicates request for the test item. F Transmit by the analyzer Indicates a report for the analytical data.			
Reserved Field	09.4.27			Field does not contain data.			
Location or Ward of Specimen Collection	09.4.28			Field does not contain data.			
Nosocomial Infection Flag	09.4.29			Field does not contain data.			
Specimen Service	09.4.30			Field does not contain data.			
Specimen Institution	09.4.31			Field does not contain data.			

* Indicates a field or field component required in ID and Sample No. modes.

7.3.6 Comment Record (following the order record)

Record to transfer comments regarding the patient's demographic data. This record is transmitted by the host (within test selection message) and the analyzer (within result message).



layer following the Test Request Record, it is reset to each time a new Test Request Record is presented a then numbered consecutively; 1, 2, etc. Comment Source 11.1.03 ST 1 Indicates the source of the Comment. If issued by the analyzer, it is 'I', if issued by the host it is 'L'. Comment Text 11.1.04 CM 104 Format Comment1>^ <comment2>^<comment3>^Comment Comment5> 5 types of comments regarding the sample can be specified. These comments can be read or edited at tanalyzer. From Host to Analyzer</comment3></comment2>	Field Name	Reference	Format	Max Length	Comments (Da	ta Content)	C 11.1.	
Record in the current layer. Since this record is in the layer following the Test Request Record, it is reset to each time a new Test Request Record, it is reset to each time a new Test Request Record is presented a then numbered consecutively; 1, 2, etc. Comment Source 11.1.03 ST 1 Indicates the source of the Comment. If issued by the analyzer, it is 'I', if issued by the host it is 'L'. Comment Text 11.1.04 CM 104 Format Comment2>^Comment3>^Comment Comment5> 5 types of comments regarding the sample can be specified. These comments can be read or edited at analyzer. From Host to Analyzer Element Max Length Format Comment1 30 ST Comment3 20 ST Comment4 15 ST Comment5 10 ST From Analyzer to Host Element Length (fixed) Format Comment1 30 ST Comment1 30 ST Comment1 45 ST Comment1 5 ST Comment1 5 ST Comment1 5 ST Comment2 25 ST Comment1 5 ST Comment2 5 ST Comment1 5 ST Comment1 5 ST Comment1 5 ST Comment1 5 ST Comment2 5 ST Comment3 20 ST Comment3 20 ST Comment3 20 ST Comment4 15 ST Comment5 ST Comment5 ST ST ST Comment5 ST ST ST Comment5 ST	Record Type ID*	11.1.01	ST	1	Use 'C'.			
analyzer, it is 'I', if issued by the host it is 'L'. Comment Text	Sequence Number	11.1.02	NM	6	Record in the culayer following the each time a new	Record in the current layer. Since this record is in the layer following the Test Request Record, it is reset to '1' each time a new Test Request Record is presented and		
Comment1>^ <comment2>^<comment3>^Comment 5 types of comments regarding the sample can be specified. These comments can be read or edited at analyzer. From Host to Analyzer Element</comment3></comment2>	Comment Source	11.1.03	ST	1				
ex. <comment 5=""> 'ABCDEF' is sent as: 'ABCDEF'</comment>	Comment Text	11.1.04	СМ	104	Format <comment1>^< <comment5> 5 types of commspecified. These analyzer. Element Comment1 Comment2 Comment3 Comment4 Comment5 Element Comment1 Comment5 Note: In the commenth length specified.</comment5></comment1>	recomment2>^ <comment (fixed)="" 10="" 15="" 20="" 25="" 30="" a="" analyzer="" be="" can="" case="" comment="" comments="" ent="" fixed="" from="" hold="" host="" is="" length="" lessied="" max="" ments="" number,="" of="" read="" regarding="" sample="" st="" string<="" td="" the="" to=""><td>ST ST S</td></comment>	ST S	
Important: Even if one or all comments are empty the host must send 4 component delimiters in this field. Comment Type 11.1.05 ST 1 Always G for generic/free text comment	Commont Time	11.1.05	e.r.		ex. <comment 5=""> 'ABCDEF' is sent as</comment>			

 $[\]ensuremath{^{\ast}}$ Indicates a field or field component required in ID and Sample No. modes.

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7.3.7 Result Record

Record to transmit analytical data.

```
R | 1 | ^^^2/1/not | 8.60 | nmol/L | | N | | F | | BMSERV | | | E11
```

An example in case that Send Time stamp of pipetting of Sample is disabled.

```
R | 1 | ^^^2/1/not | 8.60 | nmol/L | | N | | F | | BMSERV | | | E11
```

An example in case that Send Time stamp of pipetting of Sample is enabled.

```
R|1|^^^2/1/not|8.60|nmol/L||N||F||BMSERV|20050912165312||E11
```

An example in case that Send Message For Quantitative Test is disabled.

```
R|1|^^^64/1/not|46.22|IU/L||H||F||BMSERV|20050915150011||E11
```

An example in case that Send Message For Quantitative Test is enabled.

An example in case that Result Message Only for Immunoassay Qualitative Test is disabled.

An example in case that Result Message Only for Immunoassay Qualitative Test is enabled.

R|1|^^^66/1/not|-1|COI||N||F||BMSERV|20050822191251||E11

Field Name	Reference	Format	Max Length	Comments (Data	Content)	R 10.1.
Record Type ID	10.1.01	ST	1	Use 'R'.		
Sequence Number	10.1.02	NM	6	Indicates sequence numbers for the Test Request Record in the current layer. Since this record is the layer that follows the Test Request Record, it resets to 1 for each occurrence of a new Test Request Record. It is numbered consecutively; 1, 2, etc., for each occurrence of this record.		
Universal Test ID	10.1.03	СМ	22	The first, second a format are empty. Test ID. These values made that will under the second and the second analyzer automatic However, the host on separate analyte.	est. ication Code>/ <diluti 11="" 3="" 3-digit="" 5="" analyzer="" applic<="" are="" component="" description="" digit="" fu="" ident="" identify="" iquely="" length="" max="" nd="" numbers.="" of="" range="" referred="" reserved="" s="" td="" the="" these="" third="" to="" ues="" unt=""><td>elements for this as the Universal standard Code ture tests. Format NM ST ST iffies the test with pecify these 3- eation code is panded to 5-digit. 0 290, CI=991 22, H=993, I=994 261-968 lnc, 00 to the standard rest. 400 dr, pipetting and rest and rest as eats requiring and rest and rest as eats requiring and rest as eats required and rest as eats required as eats required as eats rest as eats required as eats rest as eats required as eats require</td></diluti>	elements for this as the Universal standard Code ture tests. Format NM ST ST iffies the test with pecify these 3- eation code is panded to 5-digit. 0 290, CI=991 22, H=993, I=994 261-968 lnc, 00 to the standard rest. 400 dr, pipetting and rest and rest as eats requiring and rest and rest as eats requiring and rest as eats required and rest as eats required as eats required as eats rest as eats required as eats rest as eats required as eats require

Result Record, Continued

Field Name	Reference	Format	Max Length	Comments (Data Content) R 10.1.
Data or Measurement Value	10.1.04	NM	15	Cobas c 501 analyzer results: Quantitative: 6-digit measurement value or 6 spaces if no result Qualitative: -2, -1, 0, 1, 2, 3 or 6 spaces if no result If an option of "Send concentration of chemistry qualitative test" is selected on the Host Communication Setting/Text Setting screen, the following rule is applied. qualitative value ^ measurement value In case that qualitative value is 0 and concentration is 8.60, example is as follows. Example: 0^8.60 See Table 15 below for qualitative result information. cobas e 601 analyzer results: Quantitative: 7-digit measurement value or 7 spaces if no result If an option of "Send Message For Quantitative Test" is selected on the Host Communication Setting/Text Setting screen, the following rule is applied. measurement value ^ cut off index or 7 spaces if no result qualitative value: 1 (positive) 0 (border line) -1 (negative) If an option of "Result Message Only for Immunoassay Qualitative Test" is selected on the Host Communication Setting/Text Setting screen, only qualitative value is sent to the host. See Table 15 below for qualitative result information.
Units	10.1.05	ST	6	Indicates units of the analytical data.
Reference Ranges	10.1.06			Field does not contain data.
Result Abnormal Flags	10.1.07	ST	2	Field Value LL Lower than technical limit/measuring range HH Higher than technical limit/measuring range Lower than expected value Higher than expected value Abnormal (any data flag except alarm code 23, 26, 27) Normal (expected range)
Nature of Abnormality Testing	10.1.08			Field does not contain data.

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Result Status	10.1.09	ST	1	Indicates the number of the test conducted for the analytical data. Field Value F Indicates analytical data from the first test C Indicates analytical data from the rerun
Date of Change in Instrument Normative Values Units	10.1.10			Field does not contain data.
Operator Identification	10.1.11	ST	6	Identifies the operator. This field is not specified by a host.
Date/Time Test Started	10.1.12			Date and time corresponding the test was pipetted is designated by YYYYMMDDHHMMSS. This data is sent to the host only when an option of "Send Time stamp of pipetting of Sample" is selected.
Date/Time Test Completed	10.1.13			Field does not contain data.
Instrument Identification	10.1.14	ST	4	Indicates the ID of the analytical unit (module) that performed the analysis. Module P1 to P4 ISE1, ISE2 Exy Cobas c 501 analyzer ISE Module Cobas e 601 analyzer with x=1 to 4 module no. y=1 to 2 measuring cell e.g: E11, E12) If the measurement is canceled before detection, y becomes 0. e.g: E10)

Qualitative result format for **cobas c** 501 tests can be activated on the Utility/Application/Range screen.

Analytical Result Range	Transmis- sion Data
Analytical Result ≤ Qualitative Analysis Concentration 1	-2
Qualitative Analysis Concentration 1 < Analytical Result ≤ Qualitative Analysis Concentration 2	-1
Qualitative Analysis Concentration 2 < Analytical Result ≤ Qualitative Analysis Concentration 3	0
Qualitative Analysis Concentration 3 < Analytical Result ≤ Qualitative Analysis Concentration 4	1
Qualitative Analysis Concentration 4 < Analytical Result ≤ Qualitative Analysis Concentration 5	2
Qualitative Analysis Concentration 5 < Analytical Result	3

Table 15: Qualitative Analysis Transmission Data (cobas c 501 analyzer)

Result message for Quantitative immunoassay is output only when an option of "Result Message Border Range" is selected in the Utility/Application/Range screen.

Analytical Result Range for immunoassay					
Analytical Result < Analysis Concentration (lower)	-1				
Analysis Concentration (lower) ≤ Analytical Result ≤ Analysis Concentration (higher)	0				
Analysis Concentration (higher)< Analytical Result	1				

Table 16 Qualitative/Quantitative Analysis Transmission Data (cobas e 601 analyzer)

7.3.8 Comment Record (following the result record)

Record to transfer comments regarding the analytical data. This record is transmitted by the analyzer only; it is not transmitted by the host.

C|1|I|43|I

Field Name	Reference	Format	Max Length	Comments (Data Content) C 11.1.
Record Type ID	11.1.01	ST	1	Use 'C'.
Sequence Number	11.1.02	NM	6	Indicates the sequence number of the Test Request Record in the current layer. Since this record is in the layer following the Test Request Record, it is reset to '1' each time a new Test Request Record is presented and then numbered consecutively; 1, 2, etc.
Comment Source	11.1.03	ST	1	Indicates the source of the Comment. Currently, this record is issued only from the analyzer, so 'l' is always used.
Comment Text	11.1.04	NM	3	Data Flag number for the results confirmed by the analyzer. (See Appendix A.)
Comment Type	11.1.05	ST	1	Character limiting the comment format. Currently, this record is issued only from the analyzer, so 'l' is always used.

7.3.9 Request Information Record

Record to request information from the other device. It is sent by the analyzer (within test selection request message) and the host (within result request message)

In case that Send 1st / Rerun Information is disabled.

In case that Send 1st / Rerun Information is enabled.

[Test selection request for 1st measurement]

[Test selection request for rerun measurement]

Field Name	Reference	Format	Max Length	Comments (Data Content) Q 12.1.
Record Type ID	12.1.01	ST	1	Use 'Q'.
Sequence Number	12.1.02	NM	6	Indicates the sequence numbers for the Test Request Record in the current layer. Since this record is the layer that follows the Test Request Record, it resets to '1' each time a new Test Request Record is presented, and then it is numbered consecutively; 1, 2, etc.

Request Information Record, Continued

Field Name	Reference	Format	Max Length	Comments (Dat	a Content)	Q 12.1.
Starting Range ID Number	12.1.03	СМ	48	^^ <sample id="">^<sample no="">^<rack id="">^<position no="">^ <rack type="">^<container type="">^<kind></kind></container></rack></position></rack></sample></sample>		
<u>indifiber</u>				Element	Max Length	<u>Format</u>
				Sample ID	22	ST
				Sample No	5	NM
				Rack ID	5	ST
				Position No Rack Type	1 2	NM ST
				Container Type	2	ST
				Kind	2	ST
				Element	Description	
				Sample ID	attached to the tes a barcode reader in	er number is 13/22 nication
					In S. No. mode, thi patient comment.	is becomes the
				Sample No	In ID mode, this nu In S. No. mode, the	ımber is reserved. e range is 1-60000.
				Rack ID	ID of the sample ra samples. The ID ca ways: from the ope from the barcode ca rack.	an be read two ening in the rack or
				Position No	Values 1 ~ 5, coun forward direction. This sample is '1' a is '5'.	
				Rack Type	Type of sample. Saidentified by S1 ~ S	
					S1: Blood Serum/F S2: Urine S3: CSF S4: Suprnt S5: Others S0: None rack QC: Control	Plasma
				Container Type	MC: Micro cup SC: Standard cup no value: Standard	cup
				Kind	R1: For 1 st measur R2: For rerun measur	ement
					only when an o	on is sent to the host option of "Send 1stt ation" is specified.

Request Information Record, Continued

Field Name	Reference	Format	Max Length	Comments (Dat	a Content)	Q 12.1.
Ending Range ID Number	12.1.04			Field does not co	ontain data.	
Universal Test ID	12.1.05		3	'ALL'		
Nature of Request Time Limits	12.1.06			Field does not co	ontain data.	
Beginning Request Results Date and Time	12.1.07			Field does not co	ontain data.	
Ending Request Results Date and Time	12.1.08			Field does not contain data.		
Requesting Physician Name	12.1.09			Field does not contain data.		
Requesting Physician Telephone Number	12.1.10			Field does not co	ontain data.	
User Field No. 1	12.1.11			Field does not co	ontain data.	
User Field No. 2	12.1.12			Field does not co	ontain data.	
Request Information Status Codes	12.1.13	ST	1	Field Value F A	Description The final result. Rejects the previous requaccepts the new request can only be requested th Request Record one at a this code, it is necessary current request for inform requesting the next. Request for Test Request results). Inquiry is sent to the analyzer using this code.	Information rough the a time. To use to reject a nation before

7.3.10 Photometric Calibration Result Record

Record used to transfer results of photometric calibration measurement.

An example in case that Chemistry Test Calibration Results Detail mode is disabled.

M|1|PCR|adm···|^^675|P1|15||5953^6009^5948^6009^^\10005^10535^1 0059^10589^^\^^^^\^^^\^^^\

An example in case that Chemistry Test Calibration Results Detail mode is enabled.

M|1|PCR|BMSERV|^^^714|P1|||2782^2805^2839^2860^^\6119^6577^6134^6592^^\
^^^^\^^^\^^^\^^^\649252^^649252^|24615^^10363^|1|

18689700^16627800^^^|20051016144610

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.PCR		M.PCR	
Record Type ID	BM.PC.01	ST	1	Use 'M'.	Use 'M'.		
Sequence Number	BM.PC.02	NM	6	This record appears as the next Record. For one record, the fiel several, sequence numbers sta	d value is '1'; for	specifying	
Record Type Sub ID	BM.PC.03	ST	3	Use 'PCR'.			
Operator ID	BM.PC.04	ST	6	ID of the operator who performs analyzer.	ed the calibration	n at the	
Test Code	BM.PC.05	СМ	10	Format ^^ <appcode> Photometrics: 1-910 The range of application code is</appcode>	s expanded to 5	-digit.	
Module ID	BM.PC.06	ST	2	ID of the analytical unit (module) the test belongs to. The ID gives the first character of the module that performed the analysis, then the number from the loader side (example: P1, P2, D3, D4, etc.).			
Calibration Alarm	BM.PC.07	NM	3	Calibration alarm. See Appendix A.			
SD Data Field	BM.PC.08	NM	6	SD value data.			
STD Data	BM.PC.09	СМ	38	Repeat Field. Repeated from STD1 to STD6 for as many as there are. Format <absorbance data="" first="" for="" the="" time="">^<first absorbance="" data="" final="" first="" for="" one="" or="" the="" time="">^<absorbance data="" of="" second="" the="" time="">^<second absorbance="" data="" final="" first="" for="" one="" or="" the="" time="">^<data alarm="">^<prozone value=""></prozone></data></second></absorbance></first></absorbance>			
				Detail specification is shown be Element	Max Length	Format	
				<absorbance data="" first="" for="" the="" time=""></absorbance>	6	NM	
				<first 6="" absorbance="" data="" final="" first="" for="" nm="" one="" or="" the="" time=""></first>		NM	
				<absorbance 6="" data="" nm="" of="" second="" the="" time=""></absorbance>		NM	
				<second absorbance="" data="" final="" first="" for="" one="" or="" the="" time=""></second>	6	NM	
				<data alarm=""> (See Appendix A)</data>	3	NM	
				<prozone value=""></prozone>	6	NM	

Photometric Calibration Result Record, Continued

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.PCR
Reagent lot number	BM.PC.10	NM	8	Reagent lot number 1 to 99999999 This data is sent to the host only when an option of "Chemistry Test Calibration Results Detail" is selected.
Reagent bottle number	BM.PC.11	NM	5	Reagent sequence number 1 to 99999 This data is sent to the host only when an option of "Chemistry Test Calibration Results Detail" is selected.
Expired Flag	BM.PC.12	NM	1	Expired Flag 0:Calibration performed with "Not Expired Bottle" 1:Calibration performed with "Expired Bottle" This data is sent to the host only when an option of "Chemistry Test Calibration Result Detail" is selected.
Calibrator lot number	BM.PC.13	NM	8	1 to 99999999 This data is sent to the host only when an option of "Chemistry Test Calibration Result Detail" is selected.
Result Date and Time	BM.PC.14	TS	14	Date and time when the calibration result was obtained is designated by YYYYMMDDHHMMSS. This data is sent to the host only when an option of "Chemistry Test Calibration Result Detail" is selected.

7.3.11 ISE Calibration Result Record

Record used to transfer results of ISE calibration measurement.

```
M|1|ICR|adm···|ISE1||||^^^^^^\^\|^^\^\|^^\|^-32.4^-35.1^-28.1
^-32.2^56.0^134.2^135.2^-0. 7|-34.9^-46.3^-25.8^-33.7^55.7^4.8^5
.04^-0.06|121.4^125.8^118.4^121.9^-42.0^102.0^99.5^-3.7
```

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.ICR
Record Type ID	BM.IC.01	ST	1	Use 'M'.
Sequence Number	BM.IC.02	NM	6	This record appears as the next layer of the Message Header Record. The field value is '1' for one record. To specify several records, a sequence number starting from 1 is assigned.
Record Type Sub ID	BM.IC.03	ST	3	Use 'ICR'.
Operator ID	BM.IC.04	ST	6	ID of the operator that performed the calibration at the analyzer.
Module ID	BM.IC.05	ST	5	ID of the analytical unit (module) the test belongs to. Either ISE10 or ISE20 is transmitted.
Na Calibration Alarm	BM.IC.06	NM	3	Na test calibration alarm. (See Appendix A.)
K Calibration Alarm	BM.IC.07	NM	3	K test calibration alarm. (See Appendix A.)
CI Calibration Alarm	BM.IC.08	NM	3	CI test calibration alarm. (See Appendix A.)

ISE Calibration Result Record, Continued

Field Name	Reference	Format	Max Length	Comments (Data Content)	BM.IC	R	
Na Data Alarm	BM.IC.09	СМ	31	Na test data alarm. (See Appendix A.) <internal alarm="" data="" electromotive="" force="" solution="" standard="">^<low alarm="" data="" electromotive="" force="" solution="">^<high alarm="" data="" electromotive="" force="" solution="">^<calibrator alarm="" data="" electromotive="" force="" solution="">^<slope alarm="" data="" display="" for="">^<internal alarm="" concentration="" data="" solution="" standard="">^<calibrator alarm="" concentration="" data="" solution="">^<numbers alarm="" compensation="" data="" for=""></numbers></calibrator></internal></slope></calibrator></high></low></internal>			
				Detail specification is shown below Element	Max Len	Format	
				<internal alarm="" data="" electromotive="" force="" solution="" standard=""></internal>	3	NM	
				<low alarm="" data="" electromotive="" force="" solution=""></low>	3	NM	
				<high alarm="" data="" electromotive="" force="" solution=""></high>	3	NM	
				<calibrator alarm="" data="" electromotive="" force="" solution=""></calibrator>	3	NM	
				<slope alarm="" data="" display="" for=""></slope>	3	NM	
				<internal alarm="" concentration="" data="" solution="" standard=""></internal>	3	NM	
				<calibrator alarm="" concentration="" data="" solution=""></calibrator>	3	NM	
				<numbers alarm="" compensation="" data="" for=""></numbers>	3	NM	
K Data Alarm	BM.IC.10	СМ	31	K test data alarm. Refer to Na dat (See Appendix A.)	a alarm.		
CI Data Alarm	BM.IC.11	СМ	31	CI test data alarm. Refer to Na da (See Appendix A.)	ta alarm.		
Na Data	BM.IC.12	СМ	55	Na test calibration analytical data. (All Elements: Max Length = 6, Type =NM) <internal data="" electromotive="" force="" solution="" standard="">^<low data="" electromotive="" force="" solution="">^<calibrator data="" electromotive="" force="" solution="">^<slope data="" display="" for="">^<internal concentration="" data="" solution="" standard="">^<calibrator concentration="" data="" solution="">^<numbers compensations="" data="" for=""></numbers></calibrator></internal></slope></calibrator></low></internal>			
K Data	BM.IC.13	СМ	55	K test calibration analytical data. Refer to Na data.			
Cl Data	BM.IC.14	СМ	55	Cl test calibration analytical data.	Refer to Na	data.	

7.3.12 cobas e 601 analyzer Calibration Result Record

Record used to transfer results of cobas e 601 analyzercalibration measurement.

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.ECR
Record Type ID	BM.EC.01	ST	1	Use 'M'.
Sequence Number	BM.EC.02	NM	6	This record appears as the next layer of the Message Header Record. The field value is '1' for one record. To specify several records, a sequence number starting from 1 is assigned.
Record Type Sub ID	BM.EC.03	ST	3	Use 'ECR'.
Operator ID	BM.EC.04	ST	6	ID of the operator that performed the calibration at the analyzer.
Test Code	BM.EC.05	ST	6	^^App code
Calibration Method	BM.EC.06	ST		LOT, RackPack
Module ID	BM.EC.07	ST	3	ID of the analytical unit (module) the test belongs to (Format: Exy with x=1 to 4 module no. y=1 to 2 measuring cell e.g: E11, E12)
Rack Pack Lot No.	BM.EC.08	NM	8	1 to 99999999
Rack Pack No.	BM.EC.09	NM	5	1 to 199999
Expired Rack Pack Flag	BM.EC.10	NM	1	O Calibration performed with 'Not Expired Rack Pack" Calibration performed with 'Expired Rack Pack'
Calibrator Lot No.	BM.EC.11	NM	8	1 to 99999999
Result Status	BM.EC.12	ST	1	O Ok Q Question F Failed
Result Characteristics	BM.EC.13			Repeat Field *1 Characteristic ID^Criteria result^Detail\
Calibrator Signals	BM.EC.14			Repeat Field *2
Target Value	BM.EC.15			Level1^Level2^Level3^Level4^Level5 (quantitative test only)
Unit	BM.EC.16	ST		Unit
Cut off	BM.EC.17			(qualitative test only)
Border Line Area	BM.EC.18			Lower Limit^Upper Limit (qualitative test only)
Measurement Date	BM.EC.19	TS	14	Date and time measurement was performed is designated by YYYYMMDDHHMMSS

^{*1} Result characteristics Criteria result and *2 Calibrator signals on the following pages

[For Quantitative tests]

Criteria	Characteristic ID	Criteria result	Detail
Missing Values	I	O:OK Q:Questionable F:Failed	*1-1
Monotony of curve	М	O:OK F:Failed	*1-2
Minimum signal	S	O:OK Q:Questionable F:Failed	*1-1
Calibration factor	R	Value of Calibration factor	[NONE]
Deviation of dupl.measurement	D	O:OK Q:Questionable F:Failed	*1-2
Minimum acceptable difference	F	O:OK F:Failed	[NONE]
System Error	Υ	O:OK Q:Questionable	*1-2

Details on the following page.

[For Qualitative tests]

Criteria	Characteristic ID	Criteria result	Detail
Missing Values	I	O:OK	*1-3
		Q:Questionable	
		F:Failed	
Deviation of dupl.measurement	D	O:OK	*1-4
·		Q:Questionable	
		F:Failed	
Slope	L	O:OK	[NONE]
		F:Failed	
Min/Max signal	В	O:OK	*1-5
		Q:Questionable	
		F:Failed	
Minimum acceptable difference	F	O:OK	[NONE]
·		F:Failed	
System Error	Υ	O:OK	*1-4
		Q:Questionable	

Details on the following page.

*1-1 : Flag string with 20 positions: Format: <Level1 1^{st} ><Level1 2^{nd} ><Level1 4^{th} >.....<Level5 1^{st} ><Level5 2^{nd} ><Level5 3^{rd} ><Level5 4^{th} >

each flag can be '-' (= ok) or <level no.> (= not ok)

11-----33-----example:

meaning:

Level	1st	2nd	3rd	4 th
1	not ok	not ok	ok	ok
2	ok	ok	ok	ok
3	not ok	not ok	ok	ok
4	ok	ok	ok	ok
5	ok	ok	ok	ok

*1-2: Flag string with 5 positions:

Format: <Level 1><Level 2><Level3><Level4><Level5>

each flag can be '-' (= ok) or <level no.> (= not ok)

example 1-34-

meaning:

Level		
1	not ok	
2	ok	
3	not ok	
4	not ok	
5	ok	

*1-3: Flag string with 8 positions:

Format: <Level1 1st ><Level1 2nd ><Level1 3rd ><Level1 4th ><Level2 1st ><Level2 2nd ><Level2 3rd ><Level2 4th >

each flag can be '-' (= ok) or <level no.> (= not ok)

example: 1---22--

meaning:

Level	1st	2nd	3rd	4 th
1	not ok	ok	ok	ok
2	not ok	not ok	ok	ok

*1-4: Flag string with 2 positions:

Format: <Level 1><Level 2>

each flag can be '-' (= ok) or <level no.> (= not ok)

example: 1-

meaning:

Level	
1	not ok
2	ok

*1-5: Flag string with 8 positions:

Format: <Level1 1st >< Level1 2nd >< Level1 3rd >< Level1 4th >< Level2 1st >< Level2 2nd >< Level2 3rd >< Level2 4th ><

each flag can be '-' (= ok), '>' (= signal > Max signal) or '<' (= signal < Min signal)

example: >-<->-<-

meaning:

Level	1st	2nd	3rd	4 th
1	>max	ok	<min< th=""><th>ok</th></min<>	ok
2	>max	ok	<min< th=""><th>ok</th></min<>	ok

*2 Calibrators signals

Format:

<Level1 1st signal>^<Level1 2nd signal>^<Level1 3rd signal>^<Level1 4th signal>\

<Level2 1st signal>^<Level2 2nd signal>^<Level2 3rd signal>^<Level2 4th signal>\

.

<Level5 1st signal>^<Level5 2nd signal>^<Level5 3rd signal>^<Level5 4th signal>

7.3.13 Photometric Absorbance Data Record

Record used to transfer raw absorbance data of photometric tests.

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.AD
Record Type ID	BM.AD.01	ST	1	Use 'M'.
Sequence Number	BM.AD.02	NM	6	This record appears as the next layer of the Message Header Record. The field value is '1' for one record. To specify several records, sequence numbers starting from 1 are assigned.
Record Type Sub ID	BM.AD.03	ST	3	Use 'ABS'.
Module ID	BM.AD.04	ST	2	ID of the analytical unit (module) the test belongs to. The ID gives the first character of the module that performed the analysis, then the number from the loader side (example: P1, P2, etc.).
Cell No	BM.AD.05	NM	3	Number of the Reaction Cell. Input value cobas c 501 analyzer : 1-160
In Out Information	BM.AD.06	ST	1	Internal/External information. There is no value in this field when no distinction is made between internal or external. Field Value Description Internal reaction cell line O External reaction cell line
Reaction Time	BM.AD.07	NM	2	Reaction time (Unit: minutes). Input values 1 to 22.
Point Num	BM.AD.08	NM	2	Reaction point number. Input values 1 to 70.
Cell Blank Data	BM.AD.09	ST	6	Repeat field. Cell blank absorbance. The difference between the main wavelength and sub-wavelength absorbance data [(main wavelength absorbance data) - (sub-wavelength absorbance data)] can be repeated up to 4 points.
Delta ABS Data	BM.AD.10	NM	6	Repeat field. The difference between the main wavelength and the subwavelength absorbance data [(main wavelength absorbance data) - (sub-wavelength absorbance data)] repeated up to the value indicated by Point Num.

7.3.14 cobas e 601 analyzer Raw Data (Effective Signal)

Record used to transfer raw absorbance data of cobas e 601 analyzer tests.

M|1|EFS|E11|4965\5786\5719\6553\8006\8050\6724\5765\5982\7806\87 21\9716\9948\9243\8396\6998\6045\5440\6130\6604\7431\7841\7567\7 398\6836\6472\69446139\6091\6800\7223\7013\7170\7855\8799\9128\8 763\8129\7112\7916\7246\6655\5967\5660\5260\5474\5730\7462\8610\ 8777\8041\7779\7869\7995\8563\9204\8519\6994\5938\5551\6600\7292 \7869\7516\6955\7403\7295\7583\7670\6714\5653\5662\5965\7502\780 8\7210\6652\6808\6741\8256\8071\29512\40715\45306\47094\47755\47 944\47931\47852\47731\47604\47473\47340\47226\47098\46980\46861\ 46750\46642\46530\46440\46340\46238\46147\46058\45975\45898\4581 3\45742\45653\45563\45488\45429\45356\45284\45235\45150\45102\45 025\44967\44909\44849\44794\44733\44681\44623\44553\44507\44460\ 44407\44356\44317\44260\44210\44166\44134\44071\44030\43983\4394 9\43899\43862\43821\43786\43740\43686\43645\43620\43580\43534\43 496\43463\43418\43387\43346\43313\43284\43253\43210\43223\43225\ 43241\43243\43188\43171\43144\43074\43026\42960\42871\42833\4279 2\42761\42720\42678\42649\42621\42606\42580\42541\42511\42486\42 439\42440\42503\42500\42509\42509\42481\42414\42361\42332\42282\ 42268\42236\42192\42178\42164\42164\42148|1095000

Field Name	Reference	Format	Max Length	Comments (Data Content) BM.EFS
Record Type ID	BM.EFS.01	ST	1	Use 'M'.
Sequence Number	BM.EFS.02	NM	6	This record appears as the next layer of the Message Header Record. The field value is '1' for one record. To specify several records, sequence numbers starting from 1 are assigned.
Record Type Sub ID	BM.EFS.03	ST	3	Use 'EFS'.
Module ID	BM.EFS.04	ST	3	ID of the analytical unit (module) the test belongs to. (Format: Exy with
Raw Data	BM.EFS.05	ST	6	Repeat field.
Effective Signal	BM.EFS.06	NM	6	

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.g	00

Appendix A - Data Alarm List

All the test results are checked by the criteria of the system and if the result is not normal, the reason with highest priority for the abnormal result is attached to the result as data flag.

The following table describes which alarms are applicable to the photometric, ISE, and immunoassay tests; and the way the alarm is displayed on the report, screen and the host. The number in the host column shown below is sent in field four of the comment record (C) that follows the result record (R) when the results are transmitted to the host.

Alarm code	Alarm	Result Data	Photo- metry	ISE	Immuno- assay	Screen/ Printer	Host
	no alarm						0
1	ADC abnormal		Χ	Χ	X	ADC.E	1
2	Cell blank abnormal		Χ			>Cuvet	2
3	Sample short	SPACE*	Х	Χ	X	Samp.S	3
4	Reagent short	SPACE*	Х	Х	X	Reag.S	4
5	ABS over		Х			>Abs	5
6	Prozone error		Х			>Proz	6
7	Reaction limit over(all photometry points)		Х			>React	7
8	Reaction limit over(second and subsequent photometry points)		Х			>React	8
9	Reaction limit over(third and fourth and subsequent photometry points)		Х			>React	9
10	Linearity abnormal(nine or more)		Х			>Lin	10
11	Linearity abnormal(eight or less)		X			>Lin	11
12	Standard Solution 1 Absorbance Abnormal		X			S1A.E	12
13	Duplicate Error		X		Х	Dup.E	13
14	STD Error		X	Х		Std.E	14
15	Sensitivity Error		X			Sens.E	15
16	Calibration Error		Х	Х		Cal.E	16
17	Convergence Error		X			SD.E	17
18	Noise error			Х		ISE.N	18
19	Level error			Х		ISE.E	19
20	Slope Error			Х	Х	Slop.E	20
21	ISE Slope Marginal			Х		Prep.E	21
22	Internal Concentration Abnormal			Х		IStd.E	22
23	Sample range over			Х		<>Test	23
24	Data error in Compensate test		Х	Х		CmpT.E	24
25	Unable to calculate compensate test	SPACE	Х	Х		CmpT.?	25
26	PANIC value over (upper)		Х	Х	Х	>Test	26
27	PANIC value over (lower)		Х	Х	X	<test< td=""><td>27</td></test<>	27
28	Random Error [R-4s]		Х	Х	Х	R4SD	28
29	System Error 1 [2-2sA]		Х	Х	Х	S2-2Sa	29
30	System Error 2 [2-2sW]		Х	Х	Х	S2-2Sw	30
31	System Error 3 [4-1sA]		Х	Х	Х	S4-1Sa	31
32	System Error 4 [4-1sW]		Х	Х	Х	S4-1Sw	32
33	System Error 5 [10xA]		Х	Х	X	S10Xa	33
34	System Error 6 [10xW]		Х	Х	Х	S10Xw	34
35	QC Error 1		Х	Х	X	Q3SD	35
36	QC Error 2		Х	Х	X	Q2.5SD	36
37	Calculated test error		Х	Х		ClcT.E	37
38	Overflow	SPACE	Χ	X	X	Over.E	38
39	Calculation not possible	SPACE	Х	Х	Х	Calc.?	39
40	Outside of expected value(upper)		Х	Х	Х	n.a.	
41	Outside of expected value(lower)		Х	Х	Х	n.a.	
42	Edited test		Х	Х	Х	Edited	42
43	Calibration result abnormal		Χ	X	X	Cal.E	43
44	Repeat limit over(upper)		Х	Х	Х	>Rept	44
45	Repeat limit over(lower)		Χ	X	Χ	<rept< td=""><td>45</td></rept<>	45
46	ABS maximum over	SPACE	Χ			Samp.?	46

Data Alarm List, Continued

Alarm code	Alarm	Result Data	Photo- metry	ISE	Immuno- assay	Screen/ Printer	Host
51	Response Error 1			Х		Rsp1.E	51
52	Response Error 2			Х		Rsp2.E	52
53	Conditioning Error			Х		Cond.E	53
56	Kinetic unstable/ Prozone error 2		Х			>Kin	56
57	Serum index 1 interference		Х	Χ		>Index	57
58	Serum index multiple interference		Х	Χ		>Index	58
59	Ultrasonic mixing error		X	Χ		Mix.E	59
60	Mixing power low level		Х	Х		<mix< td=""><td>60</td></mix<>	60
62	System Reagent short	SPACE			X	SysR.S	62
63	AB level range over				Х	>AB	63
64	AB level check error				Х	AB.E	64
65	Current range over				Х	>Curr	65
66	Current range check error				Х	Curr.E	66
67	Sample hovering	SPACE			Х	Samp.H	67
68	Sample air bubble	SPACE			Х	Samp.B	68
69	Reagent hovering	SPACE			Х	Reag.H	69
70	Reagent film detection	SPACE			Х	Reag.F	70
71	Potential carry over				Х	CarOvr	71
72	Sample Clot	SPACE	Х	Х	Х	Samp.C	72
73	Carry over detergent short		X			Det.S	73
74	Reagent disk temperature				X	Reag.T	74
75	Incubator temperature				X	Inc.T	75
76	System reagent temperature				X	SysR.T	76
77	Cell temperature				X	Cell.T	77
83	Sample probe carry over between modules		Х		X	Samp.O	83
86	Sample LLD abnormal				X	SLLD.E	86
87	Sample LLD noise				X	SLLD.N	87
93	Washing buffer temperature				X	WB.T	93
94	Washing buffer short	SPACE			X	WB.S	94
95	Clot pressure sensor ADC underflow	SPACE			X	Clot.E	95
96	Clot pressure sensor ADC overflow	SPACE			X	Clot.E	96
97	Clot pressure abnormal	SPACE			X	Clot.E	97
98	Sample pipetter air bubble	SPACE			X	Samp.B	98
99	Current range over (during Operation)	0.7102			X	>Curr	99
100	Lower signal level	SPACE			X	<sigl< td=""><td>100</td></sigl<>	100
101	Expired reagent	OI / LOL	Х		X	ReagEx	101
103	Serum index interference lipaemia		X	X	1 ~	>I.L	103
104	Serum index interference hemolysis		X	X		>I.H	104
105	Serum index interference icteric	+	X	X		>1.11	105
106	Serum index interference lipaemia / hemolysis		X	X		>I.LH	106
107	Serum index interference		X	X		>I.LI	107
107	lipaemia / icteric		^	^		/I.LI	107
108	Serum index interference		Χ	X		>I.HI	108
.00	hemolysis / icteric		^	,		· · · · · ·	
109	Serum index interference	1	Χ	Χ		>I.LHI	109
	lipaemia / hemolysis / icteric		•				

[Result Data]

Where a column for "Result Data" is blank, the result is output as a value..

Where the column for "Result Data" is "SPACE," the result is output as a space. Where a column for "Result Data" is "SPACE*", it is dependent on whether a result is output as a value or it is output as a space.

Appendix B - Application Codes

B-1: Application Codes - cobas c 501 analyzer

Please note that not all assays are available or approved for use by the FDA in the United States. Refer to the appropriate package insert information.

App	Chemistry	Short
Code	·	names
48	a-1-Antitrypsin	AAT2
229	a-1-acid Glycoprotein	AAGP2
614	a-1-Microglobulin	A1MG2
414	Acetaminophen	ACETA
21	Acid Phos Total	ACP
253	Albumin (Tina-quant) urine (former MAU)	ALBU2
128	Albumin (Tina-quant) serum	ALBS2
412	Albumin (Tina-quant) CSF	ALBC2
413	Albumin BCG	ALB2
683	Alk Phosphatase IFCC Gen 2	ALP2L
158	Alk. Phosphatase IFCC Gen 2	ALP2S
684	ALT IFCC with PYP	ALTLP
685	ALT IFCC	ALTL
456	Amikacin	AMIK2
478	Ammonia	NH3L
485	Amphetamines qual 1000 ng/mL Cutoff	AM1Q
486	Amphetamines semi-quant 1000 ng/mL Cutoff	AM1S
815	Amphetamines Gen II qual	AMPS2
	500 ng/mL Cutoff	
816	Amphetamines Gen II qual	AMPS2
	1000 ng/mL Cutoff	
740	Amphetamines qual 500 ng/mL Cutoff	AM5Q
461	Amphetamines semi-quant 500 ng/mL	AM5S

App Code	Chemistry	Short names
466	Anti-thrombin III	AT
168	APO A1	APOAT
151	APO B	APOBT
37	ASLO	ASLOT
687	ASTL	ASTL
587	ASTL STAT	SASTL
686	AST IFCC with PYP	ASTLP
572	Barbiturates Plus qual 200 ng/mL	BA2QP
	Cutoff	
573	Barbiturates Plus semi-quant	BA2SP
	200 ng/mL Cutoff	
611	Benzodiazepines Plus qual 100 ng/mL	BZ1QP
	Cutoff	
612	Benzodiazepines Plus qual 200 ng/mL	BZ2QP
	Cutoff	
613	Benzodiazepines Plus qual 300 ng/mL	BZ3QP
	Cutoff	
615	Benzodiazepines Plus semi-quant	BZ1SP
	100 ng/mL Cutoff	
616	Benzodiazepines Plus semi-quant	BZ2SP
	200 ng/mL Cutoff	
617	Benzodiazepines Plus semi-quant	BZ3SP
	300 ng/mL Cutoff	

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-		the state of the s
	Cutoff	
551	Amphetamines/MDMA qual 300 ng/mL	AM3Q
	Cutoff	
82	Amphetamines/MDMA semi-quant 300	AM3S
	ng/mL Cutoff	
814	Amphetamines Gen II qual 300 ng/mL	AMPS2
	Cutoff	
570	Amylase liquid ver. 2	AMYL2
566	Amylase liquid ver. 2 STAT	SAMY2
571	p-Amylase liquid	AMY-P

222	B-2-microglobulin	B2MG
156	Bicarbonate liquid CO2-L	CO2-L
763	Bicarbonate liquid STAT	SCO2L
006	Bilirubin, Direct	DBILI
294	Bilirubin, Direct (Jendrassik)	BIL-D
103	Bilirubin, Direct (Jendrassik)	D-BIL

App	Chemistry	Short
Code	-	names
101	Bilirubin, Total (DPD)	TBIL
257	Bilirubin, Total Gen. 2	BILT2
275	Bilirubin, Total Gen. 2 STAT	SBIL2
18	Bilirubin, Total Special (BILTS)	BILTS
62	Bilirubin, Total Special STAT	SBILS
418	Urea	UREAL
419	Urea STAT	SUREA
421	BUN urine	U-BUN
427	BUN STAT	SUBUN
706	Calcium	CA
726	Calcium STAT	S-CA
124	Carbamazepine	CARB2
31	Carbamazepine	CARB3
709	Ceruloplasmin	CERU
434	Cholinesterase Dibucaine	CHED2
534	Cholinesterase Total liquid	CHET2
510	Cholinesterase Gen. 2	CHE2
433	Cholesterol (Abell/Kendall)	CHO2A
798	Cholesterol (ID/MS)	CHO2I
057	CK	CKL
060	CK-MB	CKMBL
991	Chloride	CL
036	C3c	C3C-2
032	C4	C4-2
189	Cocaine Gen II qual 150 ng/mL	CO1Q2
	Cutoff	
267	Cocaine Gen II qual 300 ng/mL	CO3Q2
	Cutoff	

App Code	Chemistry	Short names
268	Cocaine Gen II semiquant 150 ng/mL	CO1S2
	Cutoff	
477	Cocaine Gen II semiquant 300 ng/mL	CO3S2
	Cutoff	
652	Creatinine Plus	CREP2
690	Creat Jaffe (serum only, compensated)	CREJ2
691	Creat Jaffe (urine only, compensated)	CRJ2U
773	Creat Jaffe STAT	SCRE2
	(serum only, compensated)	
774	Creat Jaffe STAT	SCR2U
	(urine only, compensated)	
217	CRP Latex HS	CRPHS
019	CRP Latex CRPLX	CRPLX
093	Cyclosporine II	CSAII
123	D. Dimer (Citrated plasma)	D-DI
125	D. Dimer (Heparinized plasma)	D-DIH
430	Digitoxin	DIGIT
081	Digoxin	DIG
671	Ethanol STAT	SETH2
703	Ethanol	ETOH2
164	Ferritin	FERRT
165	Ferritin	FERR3
692	Ferritin Gen. 4	FERR4
667	Fructosamine	FRA
416	Gentamicin	GENT2
220	GGT IFCC	GGTI2
480	GGT Szasz	GGTS2
588	GLDH	GLDH3

App	Chemistry	Short
Code		names
767	Glucose HK liquid	GLUC2
525	Glucose HK liquid STAT	SGLU2
717	Glucose HK liquid	GLUC3
668	Glucose HK liquid STAT	SGLU3
228	Haptoglobin	HAPT2
890	% HBA1c	RWI2
840	HBA1c Hemolysate (HB)	НВ-Н2
850	HBA1c Hemolysate (HBA1c)	A1-H2
860	HBA1c Hemolysate	RHI2
	(%HBA1c IFCC)	
870	HBA1c	HB-W2
880	HBA1c	A1-W2
567	HBDH	HBDH2
952	HBA1c Hemolysis	A1CD2
035	HDL Cholesterol plus Gen 2	HDL_C
435	HDL Cholesterol plus Gen 3	HDLC3
471	Homocysteine	HCYS
458	IgA	IGA-2
295	IgA Sensitive	IGAP2
674	IgG	IGG-2
673	IgG Sensitive	IGGC2
465	IgM	IGM-2
274	IgM Sensitive	IGMP2
661	Iron	IRON2
283	Kappa	KAPP2
990	Potassium	K
284	Lambda	LAMB2
040	Lactate	LACT2
047	Lactate STAT	SLAC2

App Code	Chemistry	Short names
672	Lactate Dehydrogenase	LDHL
080	LDH	LDHI2
059	LDL Cholesterol plus	LDL_C
731	Lipase	LIPC
733	Lipase STAT	SLIPC
045	Lipoprotein (a) Latex	LPALX
136	Lithium	LI
693	Magnesium	MG
695	Magnesium Urine	MGU
770	Magnesium STAT	S-MG
771	Magnesium (urine, STAT)	S-MGU
447	Methadone qual 300 ng/mL Cutoff	MD3Q0
448	Methadone semiquant 300 ng/mL	MD3S0
	Cutoff	
654	Myoglobin Gen 2	MYO2
989	Sodium	Na
022	Non-prostatic Phosphatase	NPP
495	Opiates qual 2000 ng/mL Cutoff	OP2Q2
497	Opiates qual 300 ng/mL Cutoff	OP3Q2
496	Opiates semiquant 2000 ng/mL	OP2S2
	Cutoff	
498	Opiates semiquant 300 ng/mL	OP3S2
	Cutoff	
518	PCP Plus qual 25 ng/mL	PC2QP
	Cutoff	
519	PCP Plus semiquant 25 ng/mL	PC2SP
	Cutoff	
710	Prealbumin	PREA
078	Protein Gen 3 Urinary/CSF	TPUC3

B-2: Application Codes - cobas e 601 analyzer

Please note that not all assays are available or approved for use by the FDA in the United States. Refer to the appropriate package insert information.

Test no. Reference 2010	ACN	Test name
1	1	TSH
2	2	T4
3	4	FT4
4	8	T-UP
5	7	Т3
6	10	FT3
10	12	E2
11	13	TESTO
12	16	PROG
13	14	PRL
14	20	LH
15	23	FSH
16	24	CORT
19	44	P1NP
22	39	TNT
23	43	CK-MB
24	56	MYO
26	129	Digitoxin
27	91	pro-BNP
28	29	Vitamin D
30	49	CEA
31	50	AFP
32	51	TPSA
33	52	CA15-3

Test no. Reference 2010	ACN	Test name
34	53	CA125
35	54	CA19-9
36	55	CA72-4
37	63	CYFRA
38	67	FERR
39	68	FPSA
40	61	HBSAG
41	64	A-HBS
42	65	A-HCV
43	66	A-HBE
44	73	HBEAG
45	77	A-HBC
46	86	A-HBCIGM
47	88	A-HAV
48	85	A-HAVIGM
49	89	A-HIV
50	90	HIVAG
52	98	A-TOXIGG
53	95	A-TOXIGM
54	105	A-RUBIGG
55	106	A-RUBIGM
56	104	HIVCOM
57	107	A-HGVENV
58	108	A-HELICO
60	110	B12

Test no. Reference 2010	ACN	Test name
61	114	FOL and RBC FOL
62	115	DIG
63	116	IGE
65	120	INSULIN
66	122	OSTEOC
67	127	CROSSL
68	126	PTH
70	130	TG
71	133	A-TG
72	137	A-TPO
73	141	A-TSHR
74	142	DHEA-S
75	146	SHBG
76	148	HCG-BETA
77	155	NSE
78	25	S-100
79	162	ACTH
80	170	$SCD_{40}L$
81	186	C-Peptide

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Appendix C - Instrument Alarms

Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
110	001	Abnormal Receiving	Abnormal Text has been received	a. Check the host computer. Is it ON?
		Text from Host	from Host.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	002	Abnormal TS from	No response for the inquiry within	a. Check the host computer. Is it ON?
		Host	a set time in GUI: [Utility]-	b. Verify Host Communication on Start Conditions.
			[System]-[Host Communication].	c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	003	Abnormal TS from	No response for the inquiry within	a. Check the host computer. Is it ON?
		Host	10 minutes.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	005	Abnormal TS from	Application code requested by the	a. Check the host computer. Is it ON?
		Host	host is not registered in the	b. Verify Host Communication on Start Conditions.
			analyzer; or received application	c. Check cable connections between the analyzer and host computer.
			code other than Photometric test,	d. Check the host computer transmit condition.
			ISE test or serum index test.	e. Ensure that the host and the analyzer are utilizing the same communication configuration.
	200			f. Resume operation; if alarm recurs, call Technical Support.
111	006	Abnormal TS from	Received request for other than	a. Check the host computer. Is it ON?
		Host	pair of Na, K or Na, K, Cl for ISE.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.

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Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
111	007	Abnormal TS from Host	Received request for increased or decreased quantity for other than	a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions.
		11000	Sample Type 2 (Urine) of ISE test.	c. Check cable connections between the analyzer and host computer.
			Campio Type 2 (Chino) of 162 tool.	d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	008	Abnormal TS from	Received request for ISE test is	a. Check the host computer. Is it ON?
		Host	wrong.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	009	Abnormal TS from	Received request for serum index	a. Check the host computer. Is it ON?
		Host	test is wrong.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
111	010	Abnormal TS from	Received comment even though	a. Check the host computer. Is it ON?
		Host	the mode was set for no	b. Verify Host Communication on Start Conditions.
			transmission of comments.	c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
111	044	Abnormal TS from	One or many tests required by	f. Resume operation; if alarm recurs, call Technical Support.
'''	011	Host	One or more tests requested by the host are not accepted	a. Check the 3rd. Results Acceptance setting on the Utility/System screen and set it if necessary. b. Check the previous tests results were sent to the HOST.
		11051	because the requests are for the	b. Check the previous tests results were sent to the 11031.
			3rd or further processing of the	
			tests.	
112	002	Abnormal Automatic	No response for the inquiry within	a. Check the host computer. Is it ON?
''-	002	Rerun TS from Host	a set time in GUI: [Utility]-	b. Verify Host Communication on Start Conditions.
			[System]-[Host Communication].	c. Check cable connections between the analyzer and host computer.
			tayana iy taasa aanina aananiy	d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.

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Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
112	003	Abnormal Automatic	No response for the inquiry within	a. Check the host computer. Is it ON?
		Rerun TS from Host	10 minutes.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
112	005	Abnormal Automatic	Application code requested by the	a. Check the host computer. Is it ON?
		Rerun TS from Host	host is not registered in the	b. Verify Host Communication on Start Conditions.
			analyzer; or received application	c. Check cable connections between the analyzer and host computer.
			code other than Photometric test,	d. Check the host computer transmit condition.
			ISE test or serum index test.	e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
112	006	Abnormal Automatic	Received request for other than	a. Check the host computer. Is it ON?
		Rerun TS from Host	pair of Na, K or Na, K, Cl for ISE.	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
112	007	Abnormal Automatic	Received request for increased or	a. Check the host computer. Is it ON?
		Rerun TS from Host	decreased quantity for other than	b. Verify Host Communication on Start Conditions.
			Sample Type 2 (Urine) of ISE test.	c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.
112	800	Abnormal Automatic	Received request for ISE test is	a. Check the host computer. Is it ON?
		Rerun TS from Host	wrong. Received request for other	b. Verify Host Communication on Start Conditions.
			than pair of Na, K or Na, K, Cl for	c. Check cable connections between the analyzer and host computer.
			ISE test.	d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.

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Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
112	009	Abnormal Automatic Rerun TS from Host	Received request for serum index test is wrong. Received request for increased or decreased quantity.	a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
112	010	Abnormal Automatic Rerun TS from Host	Received comment even though the mode was set for no transmission of comments.	
112	011	Abnormal Automatic Rerun TS from Host	One or more tests requested by the host are not accepted because the requests are for the 3rd or further processing of the tests.	a. Check the 3rd. Results Acceptance setting on the Utility/System screen and set it if necessary. b. Check the previous tests results were sent to the HOST.
126	001	Host Communication Error	The analyzer failed to open session.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	004	Host Communication Error	When analyzer has sent <enq> but Host sent <nak>. Analyzer stop transmission.</nak></enq>	a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	005	Host Communication Error	When analyzer has sent <enq>, but host did not send <ack> nor <nak>. (Link Time Out)</nak></ack></enq>	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.

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Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
126	006	Host Communication Error	When analyzer has sent <stx> with text frame, but host sent <nak>. Analyzer sent again.</nak></stx>	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	007	Host Communication Error	When analyzer has sent <stx> with text frame, but host did not send <ack> or <nak>. (Receiving time out) 15 Seconds</nak></ack></stx>	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	008	Host Communication Error	Re-transmission has gone over the limit (6 times).	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	009	Host Communication Error	When analyzer has sent <enq> as transmission request, host sent <enq> as transmission request (Link Contention).</enq></enq>	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	011	Host Communication Error	When the analyzer has received <ack> or <nak> as a reception request from the host and has become ready for reception, but the host did not transmit <stx> nor <eot> in 30 sec. (Reception Timeout).</eot></stx></nak></ack>	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.

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Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
126	012	Host Communication	Analyzer received reception	a. Check the host computer. Is it ON?
		Error	request from host, but not in	b. Verify Host Communication on Start Conditions.
			condition to receive.	c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
400	04.0	Haat Cameroniaatian	Buffer Over Flow	f. Resume operation; if alarm recurs, call Technical Support.
126	016	Host Communication Error	Over Flow occurred in the	a. Check the host computer. Is it ON?
		Elloi		b. Verify Host Communication on Start Conditions.c. Check cable connections between the analyzer and host computer.
			receiving buffer during message receiving.	d. Check the host computer transmit condition.
			Communication stopped between	e. Ensure that the host and the analyzer are utilizing the same communication configuration.
			analyzer and host.	f. Resume operation; if alarm recurs, call Technical Support.
126	017	Host Communication	Retry Over in Error message	a. Check the host computer. Is it ON?
120	011	Error	receiving	b. Verify Host Communication on Start Conditions.
			When the analyzer received	c. Check cable connections between the analyzer and host computer.
			incorrect message and sent	d. Check the host computer transmit condition.
			<nak> to host. Analyzer retried</nak>	e. Ensure that the host and the analyzer are utilizing the same communication configuration.
			this process more than 12 times	f. Resume operation; if alarm recurs, call Technical Support.
			(Upper Retry Limit).	
			Communication stopped between	
			analyzer and host.	
126	018	Host Communication	Undefined Error is detected in	a. Check the host computer. Is it ON?
		Error	MBSI	b. Verify Host Communication on Start Conditions.
				c. Check cable connections between the analyzer and host computer.
				d. Check the host computer transmit condition.
				e. Ensure that the host and the analyzer are utilizing the same communication configuration.
				f. Resume operation; if alarm recurs, call Technical Support.

Roche Diagnostics

Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
126	019	Host Communication Error	Although '7 Bit' format is selected in Utility/System/Host Setting screen, transmitted data contain the character that can only be represented in '8 bit' format. The character is converted into '#' in 7 bit code.	 a. Check the host communication setting in Utility/System/Host Setting screen. b. Verify the characters sent to the host. c. Resume operation; if alarm recurs, call Technical Support.
126	020	Host Communication Error	Automatic recovery of connection between host and the analyzer occurs 5 times consecutively. Host communication has stopped.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	021	Host Communication Error	No valid Record.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	022	Host Communication Error	First Record is not a Header Record.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.

Roche Diagnostics

Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
126	023	Host Communication Error	Undefined Record.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	024	Host Communication Error	Data other than specified.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.
126	025	Host Communication Error	Data other than specified.	 a. Check the host computer. Is it ON? b. Verify Host Communication on Start Conditions. c. Check cable connections between the analyzer and host computer. d. Check the host computer transmit condition. e. Ensure that the host and the analyzer are utilizing the same communication configuration. f. Resume operation; if alarm recurs, call Technical Support.

Alarm Type	Alarm No	Alarm Message	Alarm Description	Alarm Remedy
340	1	Host Receiving Text	A field pause of L record is	Please check L record.
		Error	insufficient.	
340	2	Host Receiving Text	There is no record end of L	Please check whether ' <cr>' (0x0d) is in the terminus of L record.</cr>
		Error	record.	
340	3	Host Receiving Text	Termination Code of L record is	Please check Termination Code of L record.
		Error	not effective value.	
340	4	Host Receiving Text	There is no record end of P	Please check whether ' <cr>' (0x0d) is in the terminus of P record.</cr>
		Error	record.	
340	5	Host Receiving Text	A field pause of P record is	Please check P record.
		Error	insufficient.	
340	6	Host Receiving Text	Sequence Number of P record is	Please check Sequence Number of P record.
		Error	not effective value.	

Roche Diagnostics

340	7 Host Receiving Text Error	A field pause of O record is insufficient.	Please check O record.				
340	8 Host Receiving Text Error	Sequence Number of O record is not effective value.	Please check Sequence Number of O record.				
340	9 Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.				
340	10 Host Receiving Text Error	Instrument Specimen ID is not effective value.	Please check Instrument Specimen ID.				
340	11 Host Receiving Text Error	Universal Test ID is not effective value.	Please check Universal Test ID.				
340	12 Host Receiving Text Error	Priority is not effective value.	Please check Priority.				
340	13 Host Receiving Text Error	Specimen Collection Data and Time is not effective value.	Please check Specimen Collection Data and Time.				
340	14 Host Receiving Text Error	Action Code is not effective value.	Please check Action Code.				
340	15 Host Receiving Text Error	Relevant Clinical Information is not effective value.	Please check Relevant Clinical Information.				
340	16 Host Receiving Text Error	Specimen Descriptor is not effective value.	Please check Specimen Descriptor.				
340	17 Host Receiving Text Error	User Field No.2 is not effective value.	Please check User Field No.2.				
340	18 Host Receiving Text Error	There is no record end of O record.	Please check whether ' <cr>' (0x0d) is in the terminus of O record.</cr>				
340	19 Host Receiving Text Error	Report Type is not effective value.					
340	20 Host Receiving Text Error	A field pause of Q record is insufficient.	Please check Q record.				
340	21 Host Receiving Text Error	Sequence Number of Q record is not effective value.	Please check Sequence Number of Q record.				
340	22 Host Receiving Text Error	Starting Range ID Number is not effective value.	Please check Starting Range ID Number.				
340	23 Host Receiving Text Error	There is no record end of Q record.	Please check whether ' <cr>' (0x0d) is in the terminus of Q record.</cr>				
340	24 Host Receiving Text Error	Request Information Status Code is not effective value.	Please check Request Information Status.				
340	25 Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.				
340	26 Host Receiving Text Error	Sample No. is not effective value.	Please check Sample No.				
340	27 Host Receiving Text Error	Sample ID is not effective value.	Please check Sample ID.				

340	28	Host Receiving Text Error	Sample Type is not effective value.	Please check Sample Type.			
340		Host Receiving Text Error	Rack ID is not effective value.	Please check Rack ID.			
340		Host Receiving Text Error	Rack Position No. is not effective value.	Please check Rack Position No.			
340		Host Receiving Text Error	A component pause of Universal Test ID is insufficient.	Please check Universal Test ID.			
340		Host Receiving Text Error	Action Code & Value is not effective value.	Please check Action Code & Value.			
340		Host Receiving Text Error	A component pause of User Field No. 2 is insufficient.	Please check User Field No. 2.			
340		Host Receiving Text Error	Instrument Specimen ID is not effective value.	Please check Instrument Specimen ID.			
340		Host Receiving Text Error	A component pause of Comment or Special Instructions.	Please check Comment or Special Instructions.			
340		Host Receiving Text Error	Comment or Special Instructions is not effective value.	Please check Comment or Special Instructions.			
340		Host Receiving Text Error	A field pause of H record is insufficient.	Please check H record.			
340		Host Receiving Text Error	Comment or Special Instructions is not effective value.	Please check Comment or Special Instructions.			
340		Host Receiving Text Error	There is no record end of H record.	Please check whether ' <cr>' (0x0d) is in the terminus of H record.</cr>			
340		Host Receiving Text Error	A field pause of P record is insufficient.	Please check P record.			
340		Host Receiving Text Error	Sequence Number of P record is not effective value.	Please check Sequence Number of P record.			
340		Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.			
340		Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.			
340		Host Receiving Text Error	There is no record end of P record.	Please check whether ' <cr>' (0x0d) is in the terminus of P record.</cr>			
340		Host Receiving Text Error	Application Code is not effective value.	Please check Application Code.			
340		Host Receiving Text Error	Dilution is not effective value.	Please check Dilution.			
340		Host Receiving Text Error	A field pause of O record is insufficient.	Please check O record.			
340	48	Host Receiving Text Error	Sequence Number of O record is not effective value.	Please check Sequence Number of O record.			

340	49	Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.			
340		Host Receiving Text Error	Instrument Specimen ID is not effective value.	Please check Instrument Specimen ID.			
340		Host Receiving Text Error	Universal Test ID is not effective value.	Please check Universal Test ID.			
340		Host Receiving Text Error	Priority is not effective value.	Please check Priority.			
340		Host Receiving Text Error	Specimen Collection Data and Time is not effective value.	Please check Specimen Collection Data and Time.			
340		Host Receiving Text Error		Please check Action Code.			
340		Host Receiving Text Error	Specimen Descriptor is not effective value.	Please check Specimen Descriptor.			
340	56	Host Receiving Text Error	Date/Time Results Reported or Last Modified is not effective value.	Please check Date/Time Results Reported or Last Modified.			
340		Host Receiving Text Error	There is no record end of O record.	Please check whether ' <cr>' (0x0d) is in the terminus of O record.</cr>			
340		Host Receiving Text Error	Report Type is not effective value.				
340	59	Host Receiving Text Error	Sample ID is not effective value.	Please check Sample ID.			
340	60	Host Receiving Text Error	Sample No. is not effective value.	Please check Sample No.			
340	61	Host Receiving Text Error	Rack ID is not effective value.	Please check Rack ID.			
340	62	Host Receiving Text Error	Rack Position is not effective value.	Please check Rack Position.			
340		Host Receiving Text Error	A field pause of Q record is insufficient.	Please check Q record.			
340		Host Receiving Text Error	Sequence Number of Q record is not effective value.	Please check Sequence Number of Q record.			
340		Host Receiving Text Error	Specimen ID is not effective value.	Please check Specimen ID.			
340		Host Receiving Text Error	Request Information Status Code is not effective value.	Please check Request Information Status Code.			
340	67	Host Receiving Text Error	There is no record end of Q record.	Please check whether ' <cr>' (0x0d) is in the terminus of Q record.</cr>			
340	68	Host Receiving Text Error	A field pause of C record is insufficient.	Please check C record.			

340	69	Host Receiving Text Error	Sequence Number of C record is not effective value.	Please check Sequence Number of C record.			
340		Host Receiving Text Error	Comment Source is not effective value.	Please check Comment Source.			
340		Host Receiving Text Error	Comment Text is not effective value.	Please check Comment Text.			
340		Host Receiving Text Error	Comment Type is not effective value.	Please check Comment Type.			
340		Host Receiving Text Error	There is no record end of C record.	Please check whether ' <cr>' (0x0d) is in the terminus of C record.</cr>			
340		Host Receiving Text Error	Age is not effective value.	Please check Age.			
340		Host Receiving Text Error	Age Unit is not effective value.	Please check Age Unit.			
340		Host Receiving Text Error	Sample No. is outside the range.	Please check Sample No.			
340		Host Receiving Text Error	Class is outside the range.	Please check Class.			
340		Host Receiving Text Error	Rack ID is outside the range.	Please check Rack ID.			
340		Host Receiving Text Error	Cup Position is outside the range.	Please check Cup Position.			
340		Host Receiving Text Error	First run/rerun is not specified.	Please confirm whether to be the First run or rerun.			
340		Host Receiving Text Error	Application Code is outside the range.	Please check Application Code.			
340		Host Receiving Text Error	Sample Volume is outside the range.	Please check Sample Volume.			
340		Host Receiving Text Error	Draw Time (Year) is outside the range.	Please check Draw Time (Year).			
340		Host Receiving Text Error	Draw Time (Month) is outside the range.	Please check Draw Time (Month).			
340		Host Receiving Text Error	Draw Time (Day) is outside the range.	Please check Draw Time (Day).			
340		Host Receiving Text Error	Draw Time (Hour) is outside the range.	Please check Draw Time (Hour).			
340		Host Receiving Text Error	Draw Time (Min) is outside the range.	Please check Draw Time (Min).			
340		Host Receiving Text Error	Draw Time (Second) is outside the range.	Please check Draw Time (Second).			
340	114	Host Receiving Text Error	Age is outside the range.	Please check Age.			

0.40		lu	1					
340	115	Host Receiving Text Error	Age Unit is outside the range.	Please check Age Unit.				
340	116	Host Receiving Text Error	Sex is outside the range.	Please check Sex.				
340		Host Receiving Text Error	Cup size is outside the range.	Please check Cup size.				
340		Host Receiving Text Error	Sample ID is outside the range.	Please check Sample ID.				
340		Host Receiving Text Error	J T	Please check Dilution Rate.				
340	120	Host Receiving Text Error	The number of TS exceeds the number of the regulations.	Please check number of TS.				
340		Host Receiving Text Error	Sample ID is not effective value.	Please check Sample ID.				
340		Host Receiving Text Error	Dilution Rate is outside the range.	Please check Dilution Rate.				
340		Host Receiving Text Error	Sample Type is not Routine or Stat.	Please check Sample Type.				
340		Host Receiving Text Error	Sample ID is outside the range.	Please check Sample ID.				
340	125	Host Receiving Text Error	Class is outside the range.	Please check Class.				
340	126	Host Receiving Text Error	Sample No is outside the range.	Please check Sample No.				
340	127	Host Receiving Text Error	Rack ID is outside the range.	Please check Rack ID.				
340	128	Host Receiving Text Error	Rack Position is outside the range.	Please check Rack Position.				
340	129	Host Receiving Text Error	Sample ID is outside the range.	Please check Sample ID.				
340		Host Receiving Text Error	Sample ID is outside the range.	Please check Sample ID.				
340	131	Host Receiving Text Error	Age is outside the range.	Please check Age.				
340	132	Host Receiving Text Error	Sample Type is not Routine or Stat.	Please check Sample Type.				
340	133	Host Receiving Text Error	Application Code is not effective value.	Please check Application Code.				
340	134	Host Receiving Text Error	Dilution Rate is outside the range.	Please check Dilution Rate.				

341	-1	App. Code	An application code is not	Please check whether the application code for HOST is set up correctly.
		Conversion Error. (To	convertible at the time of HOST	
		HOST)	communication. * Subcode	
			indicates the application code in	
			[Utility]-[Application] screen.	
342	1	App. Code	An application code is not	Please check whether the application code for HOST is set up correctly.
		Conversion Error.	convertible at the time of HOST	
		(From HOST)	communication.	

Appendix D - Communication Examples

In this section, some examples of communication on ASTM Upper Layer are shown.

Space Character (ASCII CODE 0x20) in any text is shown as '.'.

This example text contains some non-realistic cases for standard clinical chemistry analysis to show variable examples of communication.

In this section, the analyzer is shown as 'HYBRI', External system is shown as 'HOST'.

The following words are used:

- 'S.No' means Sample Number.
- 'TS' means Test Selection.

TS Inquiry / Realtime / Barcode - YES / 1st Rerun Information - No / Analyzer to Host

```
HYBRI 17:22:41,34 [ENQ]
HOST 17:22:41,35 [ACK]
HYBRI 17:22:41,48 [STX]1H|\^&|||H7600^1|||||host|TSREQ^REAL|P|1[C
R]Q|1|^^.....000016^0^5230^1^^S1^SC|
|ALL||||||||||CR][ETX]E0[CR][LF]
HOST 17:22:41,49 [ACK]
HYBRI 17:22:41,50 [EOT]
```

TS Inquiry (BC Read Error) / Realtime / Barcode - YES / 1st Rerun Information - No / Analyzer to Host

If barcode cannot be read and 'TS Ask in Barcode Read error' option is enabled on the Utility/System/Host Communication Setting/Text Setting screen, the analyzer sends 13/22 * characters in the Sample ID field. According to the Rack and Position number the host may send back the Sample ID in its test selection message.

```
HYBRI 07:56:29,23 [ENQ]
HOST 07:56:29,24 [ACK]
HYBRI 07:56:29,38 [STX]1H|\^&|||H7600^1|||||host|TSREQ^REAL|P|1[C
R]Q|1|^^*******************0^0230^4^^S1^||A
LL||||||||||CR]L|1|N[CR][ETX]AF[CR][LF]
HOST 07:56:29,39 [ACK]
HYBRI 07:56:29,40 [EOT]
```

TS / Realtime / Barcode - YES / Host to Analyzer

Cancellation of TS / Realtime / Barcode - YES / Host to Analyzer

Routine Result / Realtime / Barcode - YES / Analyzer to Host

Routine Result / Batch / Barcode - NO / Analyzer to Host

QC Result / Realtime / Analyzer to Host

cobas e 601 analyzer Raw Data / Batch / Barcode - YES / Analyzer to Host

```
HYBRI 13:59:35,89 [ENQ]
HOST 13:59:35,89 [ACK]
HYBRI 13:59:36,20 [STX]1H\\^&|||H7600^1|||||host|EFUPL^BATCH|P|1[
                 CR]P|1|||||U||||^[CR]0|1|000001·····
                 ····|1^5238^1^^S1^SC|^^^2^1|R||20000529125554||
                 ||N|||1|||||20000529125643|||F[CR]C|1|I|····
                    ·····^HSP1·····
                 ....^....[ETB]OD[CR][LF]
HOST 13:59:36,23 [ACK]
1 | ^^^2/1/not | 8.60 | nmol/L | | N | | F | | BMSERV | | | E11 [ CR
                 ]C|1|I|0|I[CR]M|1|EFS|E11|4965\5786\5719\6553\8
                 006\8050\6724\5765\5982\7806\8721\9716\9948\924
                 3\8396\6998\6045\5440\6130\6604\7431\7841\7567\
                 7398\6836\6472\6944\[ETB]OC[CR][LF]
HOST 13:59:36,54 [ACK]
HYBRI 13:59:36,84 [STX]36139\6091\6800\7223\7013\7170\7855\8799\9
                 128\8763\8129\7112\7916\7246\6655\5967\5660\526
                 0\5474\5730\7462\8610\8777\8041\7779\7869\7995\
                 8563\9204\8519\6994\5938\5551\6600\7292\7869\75
                 16\6955\7403\7295\7583\7670\6714\5653\5662\5965
                 \7502\7808\[ETB]5B[CR][LF]
HOST 13:59:36,86 [ACK]
HYBRI 13:59:37,16 [STX]47210\6652\6808\6741\8256\8071\29512\40715
                 \45306\47094\47755\47944\47931\47852\47731\4760
                 4\47473\47340\47226\47098\46980\46861\46750\466
                 42\46530\46440\46340\46238\46147\46058\45975\45
                 898\45813\45742\45653\45563\45488\45429\45356\4
                 5284\45235\[ETB]E8[CR][LF]
HOST 13:59:37,18 [ACK]
HYBRI 13:59:37,48 [STX]545150\45102\45025\44967\44909\44849\44794
                 \44733\44681\44623\44553\44507\44460\44407\4435
                 6\44317\44260\44210\44166\44134\44071\44030\439
                 83\43949\43899\43862\43821\43786\43740\43686\43
                 645\43620\43580\43534\43496\43463\43418\43387\4
                 3346\43313\[ETB]6D[CR][LF]
HOST 13:59:37,50 [ACK]
HYBRI 13:59:37,80 [STX]643284\43253\43210\43223\43225\43241\43243
                 \43188\43171\43144\43074\43026\42960\42871\4283
                 3\42792\42761\42720\42678\42649\42621\42606\425
                 80\42541\42511\42486\42439\42440\42503\42500\42
                 509\42509\42481\42414\42361\42332\42282\42268\4
                 2236\42192\[ETB]F9[CR][LF]
HOST 13:59:37,81 [ACK]
HYBRI 13:59:37,88 [STX]742178\42164\42164\42148|1095000[CR]L|1|N[
                 CR]L|1|N[CR][ETX]E1[CR][LF]
HOST 13:59:37,89 [ACK]
HYBRI 13:59:37,90 [EOT]
```

Photometric Calibrator Result / Realtime / Analyzer to Host

ISE Calibrator Result / Realtime / Analyzer to Host

cobas e 601 analyzer Calibrator Result / Realtime / Analyzer to Host

Cancellation of TS Inquiry / Realtime / Barcode - NO / Analyzer to Host

The analyzer sends this message to cancel inquiry when the timeout interval is reached. An end 'A' in a Q record means the inquiry is cancelled.

```
HYBRI 16:16:31,24 [ENQ]
HOST 16:16:31,24 [ACK]
HYBRI 16:16:31,38 [STX]1H|\^&|||H7600^1|||||host|TSREQ^REAL|P|1[C
R]Q|1|^^.....^1^5032^1^^S1^SC|
|ALL|||||||A[CR]L|1|N[CR][ETX]6C[CR][LF]
HOST 16:16:31,39 [ACK]
HYBRI 16:16:31,40 [EOT]
```

When the host receives a cancel message from the analyzer, the host can no longer respond with the original TS request order. However, the host can transmit TS as a Batch TS Transmission after the cancel message is received.

Appendix E – Differences* between CC Modular and 'New Mode' Protocol

For more differences, please check the Record structure (Page 41 - 69) and compare it with the Record structure in the Host interface manual, Version 1 of the CC-Modular (Page 32 - 55).

Notes: Default switch setting for cobas[®] 6000 analyzer series is 'New Mode' "as introduced in the Host Interface Manual for Roche/Hitachi Modular SWA Version 1.4.

cobas e 601 analyzer specific

New information	Remarks	Record & Field	Software switch	
Number of test	change 100 to 160	O-5	Yes(auto switch)	
Dilution ratio	change component	O-5, R-3	Yes(auto switch)	
Pre-dilution flag	add component	R-3	Yes(auto switch)	
Detection channel	change component	R-14	Yes(auto switch)	
Result data/value	change digits 6 to 7	R-4	Yes(auto switch)	
Data flag code	change component	C-4	Yes(auto switch)	
Effective signal data	add record	H-11, M-EFS	Yes(auto switch)	
Elecsys calib data	add message	M-ECR	Yes(auto switch)	
Result Message Only for Immunoassay Qualitative Test	change component	R-4	Yes(function switch)	
Send Message for Quantitative Test	change component	R-4	Yes(function switch)	

Auto switch: **cobas**[®] 6000 analyzer series software automatically recognizes when the system includes **cobas e** 601 analyzer.

CC Modular enhancement

New information	Remarks	Record & Field	Software switch	
AppCode conversion	change digit 3 to 5	O-5, R-3	Yes(function switch)	
Rack ID definition	change component	O-3, Q-3	Yes(function switch)	
Routine Sample HOST upload setting	add functionality	no change	Yes(function switch)	
STAT Sample HOST upload setting	add functionality	no change	Yes(function switch)	
Review by exception	add functionality	no change	Yes(function switch)	
22 characters ID	change digit 13 to 22	O-3, Q-3	Yes(function switch)	
Rack type	change description	O-3, Q-3	Yes(function switch)	
ISE individual request	add functionality	no change	Yes(function switch)	
Dilution request for P	change component	O-5, R-3	Yes(function switch)	
Send Concentration Of Chemistry Qualitative Test	change component	R-4	Yes(function switch)	
Send Time stamp of pipetting of Sample	change component	R-12	Yes(function switch)	
Chemistry test Calibration Results Detail	add fields in record PCR	PCR-10, PCR- 11, PCR-12, PCR-13, PCR-14	Yes(function switch)	
No Automatic Result Upload	add functionality	no change	Yes(function switch)	

Function switch: ${\bf cobas}^{\it @}$ 6000 analyzer series software works only when the function switch is on.

Appendix F - ASCII Table

Char Hex Dec	Char Hex Dec			Char Hex Dec	Char Hex Dec	Char Hex Dec	Char Hex Dec
NUL 00 0	DLE 10 16	Space 20 32	0 30 48	@ 40 64	P 50 80	60 96	p 112
SOH 01 1	DC1 11 17	! 21 33	1 31 49	A 41 65	Q 51 81	a 61 97	q 71 113
STX 02 2	DC2 12 18	22 34	2 32 50	B 42 66	R 52 82	b 62 98	r 72 114
ETX 03 3	DC3 19	23 # 35	3 3 51	C 43 67	S 83	c 63 99	s 73 115
EOT 04 4	DC4 14 20	\$ 24 36	4 34 52	D 44 68	T 54 84	d 64 100	t 74 116
ENQ 05 5	NAK 15 21	25 37	5 35 53	E 45 69	55 U 85	e 65 101	u 75 117
ACK 06 6	SYN 16 22	& 26 38	6 36 54	F 46 70	V 56 86	f 66 102	v 76 118
BEL 07 7	ETB 17 23	27 39	7 37 55	G 47 71	W 57 87	g 103	w 77 119
BS 8	CAN 18 24	28 40	8 38 56	H 48 72	X 58 88	h 68 104	x 120
HT 09 9	EM 19 25	29 41	9 39 57	I 49 73	Y 59 89	i 69 105	y 79 121
LF 0A 10	SUB 1A 26	* 2A 42	3A 58	J 4A 74	Z 5A 90	j 6A 106	z 7A 122
VT 0B 11	ESC 1B 27	2B + 43	; 3B 59	K 4B 75	[5B 91	k 6B 107	7B 123
FF 0C 12	FS 1C 28	2C , 44	< 3C 60	L 4C 76	5C 92	1 6C 108	7C 124
CR 0D 13	GS 1D 29	2D 45	= 3D 61	M 4D 77	J 5D 93	m 6D 109	7D 125
SO 0E 14	RS 1E 30	2E 46	> 3E 62	N 4E 78	5E 94	n 6E 110	7E 126
SI 0F 15	US 1F 31	2F 47	? 63	O 4F 79	5F 95	o 6F 111	DEL 7F 127