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E-mail: system.support.fi@thermofisher.com

Safety information

Physical handling of this analyzer requires a team effort. The analyzer is too heavy and bulky for one person alone to handle safely.

Figure 1. Safety labeling outside analyzer



Figure 2. Safety labeling on BC system liquid bottle



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Safe operation



Warning

Follow the instructions to ensure the correct and safe operation.

All surfaces under the main cover are potential sources of toxicants and irritating biological agents. Use protective gloves, spectacles and clothes.

Main cover



Warning

Do not open the cover, if the analyzer is in the Running or Analyzing state.

If the cover is opened when analysis is going on, tests under processing are lost. Mechanical parts may move a few seconds after opening the main cover. Refer to Operation Manual on how to stop analyzer safely.

Cuvette waste bin



Warning

The cuvette waste bin and cuvettes are a potential source of toxicants and irritating biological agents.

Treat the cuvette waste bin and used cuvettes as other dangerous material in laboratory. Use protective gloves, spectacles and clothes when working with the waste water container. The operator must be cautious when working with the cuvette waste bin.

Waste water container



Warning

The waste water container is a potential source of toxicants and irritating biological agents.

Treat the waste water container as other dangerous material in laboratory. Use protective gloves, spectacles and clothes when working with the waste water container. The operator must be cautious when working with the waste water container.

Deionized water container





Information

Keep the deionized water container away from a potential source of toxicants and irritating biological agents.

Use only as a deionized water container and clean as instructed. Do not overfill the container, see the maximum water limit.

Racks



Caution

Racks are potential sources of toxicants and irritating biological agents.

USB cable



Information

Use only for connection between the analyzer and workstation. The maximum length of the USB cable is 2 meters.

BCM tubing connector



Warning

Use protective gloves, spectacles and clothes when working with the BCM tubing connector. The operator must be cautious when working with the BCM tubing connector.

BC system liquid bottle



Warning

Follow the instructions to ensure the correct and safe operation.

The BC system liquid is irritating. Use protective gloves, spectacles and clothes when working with the BC system liquid bottle. The operator must be cautious when working with the BC system liquid bottle.

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Figure 3. Safety labeling inside analyzer

Safe operation



Warning

Follow the instructions to ensure the correct and safe operation.

All surfaces under the main cover are potential sources of toxicants and irritating biological agents. Use protective gloves, spectacles and clothes.

Figure 4. Tubing connector



Tubing connector



Warning

The tubing connector of the waste water container is a potential source of toxicants and irritating biological agents.

Main cover



Caution

When closing the cover, put your hands to the left and right side on its outer front surface (see the blue areas in the sign) and press the cover downwards until you hear a "click" sound.

Incubator



Caution

The surface of the incubator might be hot. Always keep the insulating cover in its place.

Barcode reader



Caution

Laser detects the barcodes. Keep the covers closed during analysis.

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Barcode reader

Laser radiation. Do not stare into beam. Class 2 laser product.

- The laser follows the IEC 60825-1:2007 standard.
- The maximum output of laser radiation is 1 mW.
- The emitted wavelength is 650 nm.

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Notices

When the system is delivered to you, it meets the pertinent electromagnetic compatibility (EMC) and safety standards as described below.

Standards

Table 1. Conformity with the following international standards and regulations

Standard	Title	
• EN ISO 12100	Safety of machinery – General principles for design – Risk assessment and risk reduction.	
 EN 61010-1 IEC 61010-1 UL 61010-1 CAN/CSA-C22.2 No. 61010-1 	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.	
 EN 61010-2-010 IEC 61010-2-010 CAN/CSA-C22.2 No. 61010-2-010 	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material.	
 EN 61010-2-081+A1 IEC 61010-2-081+A1 CAN/CSA-C22.2 No. 61010.2.081 	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.	
• EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.	
• EN 61000-6-2	Electromagnetic compatibility (EMC) – Part 6-2: Generic standards – Immunity for industrial environments.	
• EN 61000-6-3	Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments.	
• FCC CFR 47 Part 15	Subpart B, Class B. EMC Requirements for US.	

Standard	Title
• EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

CE



The CE mark attached on Gallery Plus (chemistry analyzer, type 862) indicates the conformity with the EMC (electromagnetic compatibility) directive 2004/108/EC and Machinery Directive 2006/42/EC and RoHS directive (Restriction of the use of certain hazardous substances in electrical and electronic equipment) 2011/65/EU.

Changes that you make to your system may void compliance with one or more of these EMC and safety standards. Changes to your system include replacing a part or adding components, options, or peripherals not specifically authorized and qualified by Thermo Fisher Scientific. To ensure continued compliance with EMC and safety standards, replacement parts and additional components, options, and peripherals must be ordered from Thermo Fisher Scientific or one of its authorized representatives.

FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WEEE Compliance

This product is required to comply with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:



Thermo Fisher Scientific has contracted with one or more recycling/disposal companies in each EU Member State, and these companies should dispose of or recycle this product. For further information on Thermo Fisher Scientific's compliance with these directives, the recyclers in your country, and information on Thermo Fisher Scientific products which may assist the detection of substances subject to the RoHS Directive contact us by e-mail: weee.recycle@thermofisher.com.



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Preface

Reference Manual contains operation and analysis principle descriptions for analyzer. This manual also lists the test parameters for the analyzer.

Intended use

Thermo Scientific Gallery Plus is a discrete, automated chemistry analyzer using photometric measurement. Thermo Scientific Gallery Plus is offered with various system applications. Furthermore, the analyzer supports user definable application setup.

Gallery Plus *Beermaster* model equipped with Bitterness Column Module (BCM) is dedicated for beer and wort quality control and analysis.

Intended audience

This manual is addressed to chemists, who use technical data while defining tests and their behavior. The operator must have a thorough knowledge of the operation and analysis principles.

Note It is recommended to follow good laboratory practices (GLP).

Product documentation

The product documentation consists of the following manuals:

- Operation Manual contains instructions on how to operate the analyzer during normal operation once it has been installed. The manual can be used to find out what needs to be done before running analyses and how to run analyses. The manual also contains daily maintenance task descriptions and a troubleshooting guide.
- Reference Manual contains operational and analysis principle descriptions and lists test parameters per test.
- Installation Manual contains instructions on how to install the analyzer. The manual describes procedures for mechanical and electrical installation. The chapters are organized in the chronological order in which the analyzer should be installed.
- Service Manual contains instructions on how to service and maintain the analyzer. The
 manual also describes procedures for adjusting the analyzer and information about the
 analyzer parts. The manual also lists spare parts and accessories. Service Manual is provided
 only to the trained service engineers.

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• The LIS Interface manual contains instructions on how to integrate the analyzer into the Laboratory Information System (LIS). The manual describes the communication between the analyzer and the host, using the RS-232 or TCP/IP interface.

Document revision history

Document version and date	Document code	Software version	History
A/February 2012	N12715	4.0	Document created.
A/July 2012	N12715	4.1	Instructions for new quality control parameter added.
B/October 2012	N12715	4.1	PC configuration and instructions for clearing daily files updated.
A/June 2013	N12715	5.0	Information about dilution and system configuration added.
A/October 2013	N12715	5.1	Checked the content against 5.1 software.
B/December 2013	N12715	5.1	Added a disclaimer note in Creating test procedure section.
A/July 2014	N12715	5.2	Checked the content against 5.2 software.
A/June 2015	N12715	5.3	Updated configuration settings and instructions for restoring default database. Added new result units. Updated contact information.
A/October 2016	N12715	6.0	Added information about clot detection and instructions for using "In use" parameter in Maintenance tasks. Added instructions for new configuration settings: Help language selection, Clot detection in use, Result acceptance mode, Use max volume for cuvette dilution and Automatic start. Added new result unit: IBU.

The original language of these instructions is English.

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Document symbols and conventions

Symbols in manual

This manual uses notes that point out important information related to the correct and safe operation of the analyzer. Therefore, comply fully with all notices.

Note The note icon informs the operator of relevant facts and conditions.

CAUTION The caution icon indicates important information or warnings related to the concept discussed in the text. It might indicate the presence of a hazard which could result in the corruption of software or damage to equipment or property.

Document conventions

- Important abbreviations and terms in this manual are spelled out in Glossary.
- The last command of the user interface menu path is presented in bold, for example: Select F2 > Samples > **New**.
- Menu names in the user interface are shown in bold, for example: Select the correct test from the **Test name** drop-down menu in the Results view.
- Parameter names are shown in italics, for example: The test can be taken into or out of use with the *In use* parameter.
- Parameter values are indicated with quotation marks, for example: The values of the *In use* parameter are "Yes" and "No".
- The statuses and messages are shown in Courier font, for example No valid calibration.

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Operating environment

Note The electromagnetic environment should be evaluated prior to operation of the analyzer. Do not use this analyzer in close proximity to sources of strong electromagnetic radiation, for example, unshielded intentional RF-sources. They may interfere with the proper operation.

Note Installing any 3rd party software to the workstation PC is not supported by Thermo Fisher Scientific. The 3rd party software (e.g. antivirus software) can interfere with the analyzer performance and, for instance, generate error messages like "internal timing error" or "master used too much time". Thermo Fisher Scientific is not responsible for possible errors due to 3 rd party software installed by customer.

Note It is not recommended to connect the workstation to the Internet due to the risk of viruses, unless specifically requested by Thermo Fisher Scientific in order to join a remote support session. To use remote connection, refer to the instructions in the Operation Manual.

Dimensions

Table 2. Dimensions and weight of the analyzer

Description	cm / kg	in / lb
Width	94 cm	37.0 in
Height	62 cm / 130 cm	24.4 in / 51.2 in
Depth	70 cm	27.6 in
Weight	110 kg	242.5 lb

Note Dimensions are given without workstation and display.

Power supply

Table 3. Power supply to the analyzer

Description	Value
Voltage	100 - 240 VAC ± 10%
Frequency	50 - 60 Hz ± 5%

1 Operating environment

Operating environment

Description	Value
Power consumption	300 W

Note It is recommended to have UPS for power loss protection in analyzer and workstation. Connect UPS only to the workstation, monitor and analyzer. Do not connect UPS to the printer.

Table 4. Minimum recommendation for UPS

Description	Value
UPS minimum recommendation, VA	1500

Analyzer's decibel level (dB)

Average noise level at 1 meter <60 dB(A).

Environmental conditions

- Ambient temperature: 18...30 °C
- Relative humidity: 40 80%, non-condensing
- Altitude: < 2000 m from the sea level
- Heat output: 680 (without BCM) / 750 (with BCM) BTU/h
- Electromagnetic environment:
 - basic electromagnetic environment (residential, office, laboratory, light industry)
 - industrial electromagnetic environment

❖ Water requirements

Follow the local water regulations set for the laboratory. The following specification is a minimum requirement for water. Requirements for Clinical Laboratory Reagent Water (CLRW) developed by Clinical and Laboratory Standards Institute (CLSI).

Table 5. Clinical laboratory reagent water requirements

Description	Value	
Resistivity	\geq 10 M Ω · cm referenced to 25 °C	
TOC	< 500 ppb	
Micro-organisms	< 10 CFU/ml	
Particle-free	≥ 0.22 µm	

Creating test procedure

Note Each laboratory is responsible to validate the user-defined applications to prove the performance of the test.

To create a bitterness test prodecure with pretreatment:

- 1. Select F4 > Cal/QC selection > **QC profile definition** to add QC profiles.
- 2. Select F4 > Cal/Ctrl definition to add controls and calibrators.
- 3. Select F3 > **Pretreatment definition** to define the pretreatment parameters.
- 4. Select F3 > **Test definition** to define the test parameters.
- Select F4 > Cal/Ctrl definition > Lot concentrations to define the lot concentrations for controls and calibrators.

To create a test procedure without pretreatment:

- 1. Select F3 > **Reagent definition** to add reagents.
- 2. Select F4 > Cal/QC selection > **QC profile definition** to add QC profiles.
- 3. Select F4 > Cal/Ctrl definition to add controls and calibrators.
- 4. Select F3 > **Test definition** to define the test parameters.
- 5. Select F4 > Cal/Ctrl definition > **Lot concentrations** to define the lot concentrations for controls and calibrators.

CAUTION Ensure that reagents and/or samples used in user-defined tests do not cause hazardous chemical reaction as they mix up in the cuvette and waste water container.



Reagents

To define a new reagent or to edit the existing reagent parameters, select F3 > **Reagent definition**. The main reagent details are listed on the left. The list shows the reagent name, the lot ID and when the lot expires. The reagent's details can be defined on the right. Once a reagent is placed into the analyzer, it is not possible to edit the reagent's parameters.

Note You can edit all parameters of user-definable reagents and add and change lot information for system reagents if lots are not defined by barcode.

Note Bitterness tests only use pretreatment reagents. To check the status of pretreatment reagents, select F3 > **Pretreatment racks**.

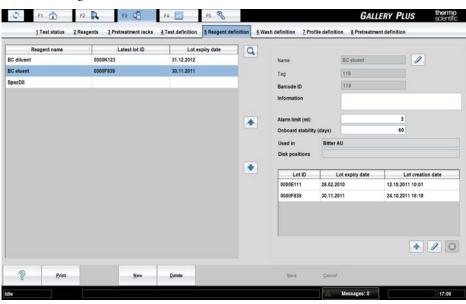


Figure 5. Reagent definition view

• Defining user-definable reagents

Defining user-definable reagents

Note Do not use special characters in reagent definition fields.

To define a new reagent:

3 Reagents

Reagents

- 1. Click New.
- 2. Type identification in the **Name** box.
 - The software does not distinguish lower case characters from upper case characters.
- 3. Click the confirmation button to check that the given name is unique.
- 4. Type the additional reagent information in the **Information** box. For example, the reagent's full name.
- 5. Define the alarm limit in milliliters in the **Alarm limit** box.
- 6. Define in the **Onboard stability (days)** box how many days the reagents can be stored in the analyzer.
- 7. Click Save.
- 8. Click the add button to define the following details:
 - Lot ID shows the identification number of the lot.
 - **Expiry date** shows the date when the reagent expires. Define the date in the format of dd.mm.yyyy.
- 9. Press Enter.
- 10. Click Save.

The following parameters are read-only:

- The **Tag** information distinguishes Thermo Scientific products from the other products.
- Lot creation date shows the date when the reagent has been created.
- Used in lists the tests that are using the reagent.
- **Disk positions** shows the reagent's location.

Wash definition

The extra wash is used to wash the probe between dispensing two reagents when the first reagent (Preceding reagent) has a risk of contaminating the second reagent (Following reagent). The extra wash and the reagents in question must be defined in the database. The extra wash is performed:

• Before dispensing Following reagent if the previous dispensed reagent was the Preceding reagent.

Preceding reagent	Wash	Following reagent	
-------------------	------	-------------------	--

• Always before dispensing the next reagent if the previous dispensed reagent was the Preceding reagent and Following reagent is "All".

Preceding reagent Was	Any reagent	
-----------------------	----------------	--

• Always before dispensing Following reagent if Preceding reagent is "All".

Any reagent	Wash	Following reagent	
-------------	------	-------------------	--

• Always before dispensing Following reagent if wash is "Reagent (large)". In the Reagent (large) wash, Preceding reagent must always be "All".

	Any reagent	Wash	Following reagent	
--	----------------	------	-------------------	--

• If previous and next dispensings belong to same request, wash will not be done.

If the wash reagent is not in the analyzer, the request is not performed. If there are multiple rules defining the extra washes, the rule with the biggest wash is used.

Wash types:

- Water wash
 - Both probe and mixer are washed with water.
- · Small reagent wash
 - First, the probe is washed with wash reagent. The probe aspirates 30 μ l of wash reagent, which is aspirated up to 300 μ l height to the probe. Then the probe dispenses the wash reagent into the waste well. Finally, both the probe and the mixer are washed with water.

4 Wash definition

Wash definition

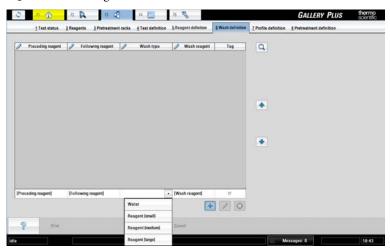
- · Medium reagent wash
 - First, the probe is washed with wash reagent. The probe aspirates 220 μl of wash reagent, which is moved up to 300 μl height of tubing, and dispenses the wash reagent into a cuvette cell. The probe is then washed with water. The mixer mixes in the cuvette cell where the wash reagent was dispensed. Finally, the mixer is washed with water.
- · Large reagent wash
 - First, the medium wash with wash reagent (220 $\mu l)$ is performed. This is followed by the small wash with the reagent (30 $\mu l)$ that will be used in the next test. Set value "All" for Preceding reagent.

To define an extra wash:

- 1. Select F3 > Wash definition.
- 2. Click the add button.
- 3. Define Preceding reagent.
- 4. Define Following reagent.
- 5. Define the wash type.
- 6. Define the wash reagent.
- 7. Click the add button to add the definition into the list.
- 8. Click Save.

Note If the **Tag** check box is selected, it is not allowed to modify the washing procedure.

Figure 6. Defining extra wash



Clot detection

Clot detection is based on differential pressure technology, and the sample dispenser is equipped with a pressure sensor. If the clot detection is in use and pressure change is detected, the user is informed and no further dispensing is made from that sample. The clot detection is not in use by default.

The user is informed if the tubings lack diluent water, in this case the analysis is interrupted. The system recognizes the lack of diluent water regardless of the clot detection configuration.



Test scheduling principles

The analyzer performs several analyses simultaneously. Test requests prioritizing principles are as follows:

- 1. Calibrations of the STAT requests
- 2. STAT requests
- 3. Calibration requests
- 4. QC requests
- 5. Up to the first 300 requests starting from the first position of a rack. The prioritizing for a sample's request is as follows:
 - a. Requests containing contaminative reagents, which have been defined as a following reagent in a large wash.
 - b. Requests containing contaminative reagents, which have been defined as a following reagent in other than a large wash.
 - c. All other requests based on the duration of the test, the longest first.
- 6. The sequence is repeated starting from the step 5 for all racks in inserting order as long as higher priority requests (steps 1-4) are not made.

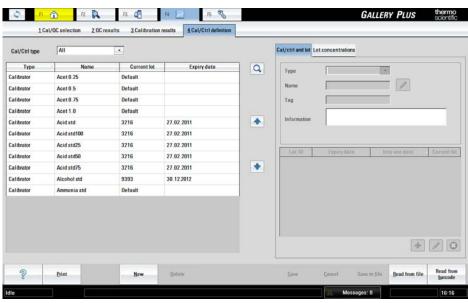


Calibrators

The known samples (calibrators) are used for calibrating the test. To define calibrators for the test, select F3 > Test definition > **Calibration**.

To define a new calibrator or to edit the existing parameters, select F4 > **Cal/Ctrl definition**. The main calibrator details are listed on the left. The list shows the calibrator type and name, current lot and the expiry date. The calibrator's details can be defined on the right. Once a calibrator is placed into the analyzer, it is not possible to edit the calibrator's parameters.

Figure 7. Calibrator definition view



- Defining calibrators
- Defining lot concentrations for calibrators
- Saving lot values to file
- Reading lot values from barcode
- Reading lot values from file
- Changing lot

Defining calibrators

To add a new calibrator:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click New.
- 3. Select **Calibrator** from the **Type** drop-down menu.
- 4. Type identification in the **Name** box.

The software does not distinguish lower case characters from upper case characters.

- 5. Click the confirmation button to check that the given name is unique.
- 6. Type the additional information in the **Information** box. For example, the official name.
- 7. Click Save.
- 8. Click the add button to define the following details:
 - Lot ID shows the identification number of the lot.
 - **Expiry date** shows the date when the calibrator expires. Define the date in the format of dd.mm.yyyy.
 - Current lot shows the lot ID that is in use.
- 9. Press Enter.
- 10. Click Save.

The following parameters are read-only:

- The Tag information distinguishes Thermo Scientific products from the other products.
- Into use date shows the date when the calibrator has been taken into use.

Defining lot concentrations for calibrators

Calibrator lot is a production batch of the calibrator. The test-based calibrator values can vary from lot to lot. Each test where calibrator is used has a separate concentration. The lot concentration for a test can be defined after the test has been created. Use the current lot for the analysis.

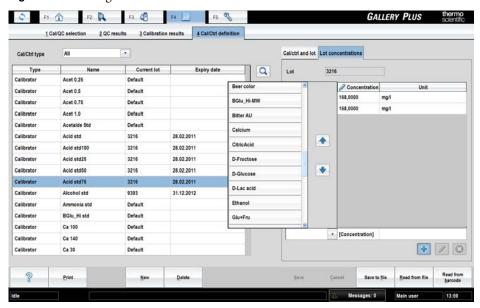
To define concentrations for the calibrator to be used in different tests:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select the correct calibrator from the list on the left.
- 3. Select the Cal/ctrl and lot tab.
- 4. Select the correct lot from the **Lot ID** column.
- 5. Select the **Lot concentrations** tab.
- 6. Click the add button.
- 7. Select the correct test from the drop-down menu.
- 8. Define concentration in its box.
- 9. Press Enter.

10. Click Save.

Note The result units shown in the **Lot concentrations** tab are defined in the **Info** tab under the **Test definition** view.

Figure 8. Defining concentrations



Saving lot values to file

It is possible to save lot values for a system test to a file:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select calibrator.
- 3. Select lot.
- 4. Click Save to file.
- 5. Select folder.
- 6. Click OK.

Reading lot values from barcode

It is possible to read system calibrators' lot values for a test from a barcode:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click Read from barcode.

7 Calibrators

Reading lot values from file

- 3. Read the barcode.
- 4. Click Save.

Note If the test unit differs from the current test unit, the test values in the barcode are converted to the current test unit before saving.

Note The function is enabled for the Thermo Scientific products.

Reading lot values from file

It is possible to read system calibrators' lot values for a test from a file:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click Read from file.
- 3. Select the file.
- 4. Click Save.

Note If the test unit differs from the current test unit, the test values in the file are converted to the current test unit before saving.

Note The function is enabled for the Thermo Scientific products.

Changing lot

If multiple lots are available, it is possible to change the lot to be used in the analysis. To change the lot in use:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select the calibrator whose lot is to be changed.
- 3. Click the edit button.
- 4. Remove the selection from the **Current lot** check box.
- 5. Select the Current lot check box to select the lot to be used.
- 6. Click Save.

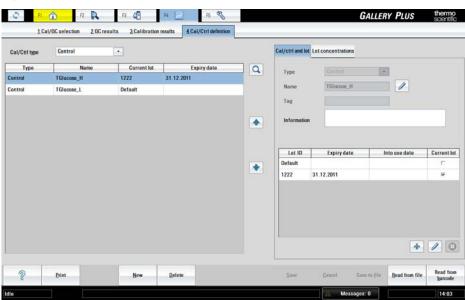
Quality controls (QC)

To define a new control or to edit the existing controls, select F4 > **Cal/Ctrl definition**. The main control details are listed on the left. The list shows the control type and name, the lot ID and the expiry date. The control's details can be defined on the right. Once a control is placed into the analyzer, it is not possible to edit the control's parameters.

Note You can only edit the parameters of user-definable controls.

The quality control procedure is defined in the F3 > Test definition > QC tab.

Figure 9. Control definition view



- Creating quality control profile
- Defining quality controls
- Defining control lot concentrations
- Saving lot values to file
- Reading lot values from barcode
- Reading lot values from file
- · Changing lot

Creating quality control profile

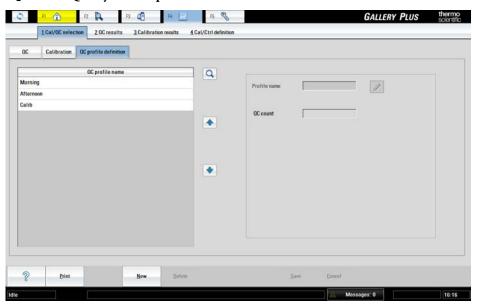
The quality control profiles contain quality controls that are run at the same time. For example, all quality controls that are run before daily routines can be included in the profile "Morning". The quality control profile has to be defined if the quality control's **Trigger** in the F3 > Test definition > **QC** tab is "Manual". For more information, see Parameters for quality control on page 42.

To create, update and delete the quality control (QC) profiles, select F4 > Cal/QC selection > **QC profile definition**. The **QC count** shows how many quality control tests the profile includes.

To create a new profile:

- 1. Click New.
- 2. Type identification in the **Profile name** box.
- 3. Click **Confirm** to check that the given name is unique.
- 4. Click Save.

Figure 10. Quality control profile view



Defining quality controls

To add a new control:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click New.
- 3. Select **Control** from the **Type** drop-down menu.
- 4. Type identification in the **Name** box.

The software does not distinguish lower case characters from upper case characters.

- 5. Click the confirmation button to check that the given name is unique.
- 6. Type the additional information in the **Information** box. For example, the official name.
- 7. Click Save.
- 8. Click the add button to define the following details:
 - Lot ID shows the identification number of the lot.
 - **Expiry date** shows the date when the control expires. Define the date in the format of dd.mm.yyyy.
 - Current lot shows the lot ID that is in use.
- 9. Press Enter.
- 10. Click Save.

The following parameters are read-only:

- The Tag information distinguishes Thermo Scientific products from the other products.
- Into use date shows the date when the control has been taken into use.

Defining control lot concentrations

The lot concentration for a test can be defined after the test has been created.

To define concentrations for the control to be used in different tests:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select the correct control from the list on the left.
- 3. Select the Cal/ctrl and lot tab.
- 4. Select the correct lot from the Lot ID column.
- 5. Select the **Lot concentrations** tab.
- 6. Click the add button.
- 7. Select the correct test from the drop-down menu.
- 8. Define the concentration and SD in their boxes.
- 9. Press Enter.
- 10. Click Save.

Note The result units shown in the **Lot concentrations** tab are defined in the **Info** tab under the **Test definition** view.

Note The correction factor and correction bias are not applied to the QC samples.

F2 R F3 0 GALLERY PLUS Calictri and lot Lot concentration Q D-Glucose D-Lac acid Mg std Ethanol 4 GluFruSucr Glycerol Default 3215 Sugar sto 1178 L-Lac acid Default L-Mal acid Default Control 2 · [Concentration] [SD] BC System · / 3

Figure 11. Defining concentrations

Saving lot values to file

It is possible to save lot values for a system test to a file:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select control.
- 3. Select lot.
- 4. Click Save to file.
- 5. Select folder.
- 6. Click OK.

Reading lot values from barcode

It is possible to read system controls' lot values for a test from a barcode:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click Read from barcode.
- 3. Read the barcode.
- 4. Click Save.

Note If the test unit differs from the current test unit, the test values in the barcode are converted to the current test unit before saving.

Note The function is enabled for the Thermo Scientific products.

Reading lot values from file

It is possible to read system controls' lot values for a test from a file:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Click Read from file.
- 3. Select the file.
- 4. Click Save.

Note If the test unit differs from the current test unit, the test values in the file are converted to the current test unit before saving.

Note The function is enabled for the Thermo Scientific products.

Changing lot

If multiple lots are available, it is possible to change the lot to be used in the analysis. To change the lot in use:

- 1. Select F4 > Cal/Ctrl definition.
- 2. Select the control whose lot is to be changed.
- 3. Click the edit button.
- 4. Remove the selection from the **Current lot** check box.
- 5. Select the **Current lot** check box to select the lot to be used.
- 6. Click Save.



Pretreatment definition

Note This section applies only to analyzers equipped with the BCM unit.

- Saving pretreatment parameters
- Printing pretreatment parameters
- Deleting pretreatment procedure
- Pretreatment parameter settings
- Defining pretreatment flow

Saving pretreatment parameters

After defining the pretreatment parameters, save the parameters for further use:

- 1. Select F3 > **Pretreatment definition**.
- 2. Click Save.

Printing pretreatment parameters

To print pretreatment parameters:

- 1. Select F3 > Pretreatment definition.
- 2. Select the pretreatment procedure from the list.
- 3. Click Print.

Deleting pretreatment procedure

You can delete a pretreatment procedure that you have defined. It is not possible to delete system procedures.

To delete a pretreatment procedure:

- 1. Select F3 > Pretreatment definition.
- 2. Select the pretreatment procedure from the list.
- 3. Click Delete.

Pretreatment parameter settings

To define a new pretreatment procedure or edit the existing parameters, select F3 > **Pretreatment definition**. You can only edit the pretreatment procedures that you have defined. It is not possible to edit system procedures.

The pretreatment procedures are listed on the left. The pretreatment definition view consists of different parameter groups, and the following tabs and parameters can be edited:

- 1. The **Information** tab shows the general parameters for the pretreatment procedure.
- 2. The **Flow** tab shows the workflow of the pretreatment procedure.
- 3. The **Dilution** tab shows the dilutions used in the pretreatment procedure.

General pretreatment parameters

To define general parameters for a pretreatment procedure, select F3 > Pretreatment definition > **Info**.

Table 6. Common parameters

Parameters	Description
Name	Define a name for the procedure.
Version number	The version number is updated when the new settings for the parameters are saved.
Information	Type in additional information about the pretreatment procedure (optional).

Table 7. Common read-only parameters

Parameters	Description
Tag	Shows the tag number of the procedure. User-defined procedures start with the prefix INT.
Procedure version ID	The program defines an ID for the pretreatment procedure. The ID is unique for each procedure.
Last time changed	Shows the date and time when the pretreatment procedure was changed the last time.
User name	Shows the user who changed the procedure the last time.
Used in	Shows the tests in which this pretreatment procedure is used.

Pretreatment dilution parameters

To define the dilution parameters for a pretreatment procedure, select F3 > Pretreatment definition > **Dilution**.

Table 8. Dilution parameters

Parameters	Values	Description
Dilution 1+	0.00 - 120.00	Use one part of the sample and X parts of diluent. Notice that, for example, 1+9 and 1:10 have the same dilution.
Neat sample		
Dispense with	Water, Extra	Select whether the neat sample is dispensed with water or sample extra.
Volume (µl)	0 - 120	Define the volume of water or sample extra.
Diluent		
Diluent ID		Select the pretreatment diluent.
Dispense with	Water, Extra	Select whether the diluent is dispensed with water or diluent extra.
Volume (µl)	0 - 300	Define the volume of water or diluent extra.
Mix diluted sample	Yes, No	Define wheter the diluted sample is mixed in the cell. It is recommended to set the value as "Yes".
Incubation time	0 - 3600 s	Define how long the diluted sample is incubated in the cell.
Actual incubation time		Shows the actual incubation time, which may differ from the user-defined incubation time due to operation cycle time.

Defining pretreatment flow

To define a pretreatment procedure flow or edit existing parameters, select F3 > Pretreatment definition > **Flow**.

Note

The *Dispensed volume* parameter shows the total volume of sample and reagent dispensed in the pretreatment procedure (max. $800 \mu l$). The dispensed volume here must be bigger than or equal to the combined volume of sample and extra in the actual test flow using the pretreatment + $100 \mu l$, divided by 0.9:

Dispensed volume \geq (Sample volume_{Test} + Extra volume_{Test} + 100 μ l) / 0.9

Reagent

Parameter	Values	Description
Reagent		Select the correct pretreatment reagent.

9 Pretreatment definition

Sample

Parameter	Values	Description
Volume (µl)	5 - 800 (5 - 3000)	Define the volume of the reagent. The volume dispensed to the storage is 5 - 800 μ l and the volume dispensed to the waste is 5 - 3000 μ l.
Air buffer	Yes, No	Define whether an air buffer is used before the reagent.
Aspiration speed	Low, Medium, High	Define the speed in which the reagent is aspirated into the BCM dispenser. The recommended speed depends on the reagent's viscosity.
Dispensing speed	Low, Medium, High	Define the speed in which the reagent is dispensed from the BCM dispenser. The recommended speed depends on the reagent's viscosity.
Dispense to	Waste, Storage	Define wheter the reagent is dispensed into the waste or the sample prep block.
Incubation time	0 - 600 s	Define how long the reagent is incubated in the BCM dispenser. In bitterness applications, the value must always be "0".
Actual incubation time		Shows the actual incubation time, which may differ from the user-defined incubation time due to operation cycle time.
Liquid transfer cycles	1 - 10	Define how many times the reagent is run through the column. One cycle consists one back-and-forth run.
Flush volume (µl)	0-5000	Define the volume of BC system liquid that is used to flush the BCM dispenser after the last liquid transfer cycle. The flush volume is dispensed to the same location as the reagent, defined in parameter <i>Dispense to</i> .

Sample

Parameter	Values	Description
Volume (µl)	5 - 800	Define the volume of the sample.
Air buffer	Yes, No	Define whether an air buffer is used before the sample.
Aspiration speed	Low, Medium, High	Define the speed in which the sample is aspirated into the BCM dispenser. The recommended speed depends on the sample's viscosity.
Dispensing speed	Low, Medium, High	Define the speed in which the sample is dispensed from the BCM dispenser. The recommended speed depends on the sample's viscosity.
Dispense to	Waste, Storage	Define wheter the sample is dispensed into the waste or the sample prep block.

Parameter	Values	Description
Incubation time	0 - 600 s	Define how long the sample is incubated in the BCM dispenser. In bitterness applications, the value must always be "0".
Actual incubation time		Shows the actual incubation time, which may differ from the user-defined incubation time due to operation cycle time.
Liquid transfer cycles	1 - 10	Define how many times the sample is run through the column. One cycle consists one back-and-forth run.
Flush volume (µl)	0 - 5000	Define the volume of BC system liquid that is used to flush the BCM dispenser after the last liquid transfer cycle. The flush volume is dispensed to the same location as the sample, defined in parameter <i>Dispense to</i> .



- Reading test parameters from file
- Reading test parameters from barcode
- Saving test parameters
- Printing test parameters
- Deleting tests
- Test parameter settings
- Defining test flow
- Managing test profiles

Reading test parameters from file

To read test parameters for a test from a file:

- 1. Select F3 > **Test definition**.
- 2. Click Read from file.
- 3. Select the file.

The software opens the directory C:\Arc\save\ApplicationLibrary which contains pre-installed default applications. You can also browse to other locations.

You can select and save multiple tests by holding down CTRL or SHIFT key while selecting the tests.

4. If you are updating the test, the program asks: *Preserve QC of existing test version?* Answer "Yes" or "No".

If you answer "Yes", the software preserves the existing quality controls. The test is updated but the default quality controls of the new test are discarded.

If you answer "No" and confirm it in the confirmation dialog, the test and its quality controls are updated. If the test had user-defined quality controls, they are overridden.

Note If a test is copied from an analyzer to another, check that the analyzer has the used wavelength(s) of the test. If the filter of the used wavelength is missing, the test cannot be taken into use.

Reading test parameters from barcode

To read test parameters for a test from a barcode:

- 1. Select F3 > **Test definition**.
- 2. Click Read from barcode.
- 3. Read the first barcode.

The barcode includes values for reagents, quality controls and calibrations.

- 4. Click Save.
- 5. Read the second barcode.

The barcode includes the test parameters.

- 6. Click Save
- 7. If you are updating the test, the program asks: *Preserve QC of existing test version?* Answer "Yes" or "No".

If you answer "Yes", the software preserves the existing quality controls. The test is updated but the default quality controls of the new test are discarded.

If you answer "No" and confirm it in the confirmation dialog, the test and its quality controls are updated. If the test had user-defined quality controls, they are overridden.

Saving test parameters

To save the test parameters for further use:

- 1. Select F3 > **Test definition**.
- 2. Click Save to file.
- 3. Select the correct folder.

File name is automatically constructed from test short name, tag and version number.

4. Click Save.

Printing test parameters

To print test parameters:

- 1. Select F3 > **Test definition**.
- 2. Select a test from the list.
- 3. Click Print.
- 4. If older versions of the parameters exist, select which version to print in the list and click OK.

Deleting tests

To delete test:

- 1. Select F3 > Test definition > **Info.**
- 2. Select a test from the list.
- 3. Click Delete.
- 4. At the prompt, click **Yes** to delete the test.

Tests cannot be deleted if:

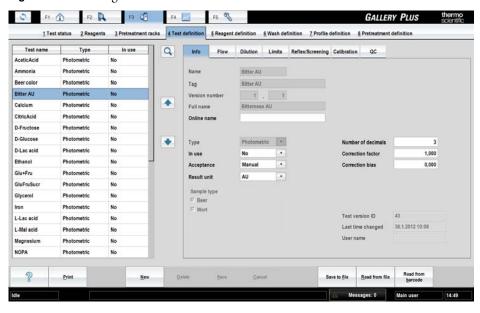
- the test is a system test
- the test has a request to calibration (which has not been run yet)
- the calibration has been run for the test
- the test has sample or quality control results
- the test has sample or quality control results in the archive

Test parameter settings

To define a new test or to edit the existing parameters, select F3 > **Test definition.** The main test details are listed on the left. The list shows the test name and type, and whether the test is in use or not. The possible test types that you can create and edit are:

- Photometric
- External
- Calculated

Figure 12. Defining test



General parameters

The test definition view consists of different parameter groups and depending on the test type, different tabs and parameters are enabled.

- The **Info** tab shows the general parameters for all test types.
- The **Flow** tab shows the work flow for photometric tests.
- The **Dilution** tab shows the dilutions for photometric tests.
- The **Limits** tab shows the limits for all test types.
- The **Reflex/Screening** tab shows the reflex tests that are run if the result of the test is within the defined limits.
- The Calibration tab shows the calibration parameters for photometric tests.
- The **QC** tab shows the quality control parameters for photometric tests.

Note Recalibration is not needed if you change following parameters: Online name, In use, Acceptance, Number of decimals, Correction factor, Correction bias, Critical limit min, Critical limit max, Reference range limits, all reflex parameters, Calibration acceptance and all QC parameters.

Note Do not use special characters in the definition fields.

Table 9. Test types and related tabs

	Photometric	External	Calculated
Info	X	X	X
Flow	X		
Dilution	X		
Limits	X	X	X
Reflex/Screening	X		
Calibration	X		
QC	X		

General parameters

To define general parameters for a test, select F3 > Test definition > **Info**.

Table 10. Common parameters

Parameter	Values	Description
Name		Define the test's name to be shown in the program. The software does not distinguish lower case characters from upper case characters.
Full name		Define the official name of the test.

Parameter	Values	Description
Version number		The version number is updated when the new settings for the test parameters are saved. If the version number of the test changes, the test must be calibrated once again.
Online name		Define the test's name to be shown in the online connection.
Туре	Photometer, External, Calculated	Select the correct type of a test.
In use	Yes, No	Only tests in use are shown in the Samples view. A test can be taken into use after both the calibration and flow parameters have been defined. It is not possible to take a test out of use if the test has pending requests.
Acceptance	Automatic, Manual	Define how to accept the test.
		If you select Automatic , the request is accepted automatically, if it has no error flags or quality control violations waiting. If it is not possible to accept the request automatically, the request is moved under the Tests to accept list which can be found from the main view.
		If you select Manual , the request is always moved under the Tests to accept list.
Result unit	mmol/l, µmol/l, nmol/l, U/l, IU/l, IU/l, IU/ml, g/l, g/dl, mg/l, mg/dl, mg/ml, µg/l, µg/ml, µkat/l, ng/ml, mS/cm, µS/cm, mS/m, BUN mg/dl, mEq/l, U/ml, AU, BU, EBC, IBU	Select the correct unit for a test or define the result unit by typing it into the Result unit box.
Number of decimals		Define how many decimals are shown in the results.
Conversion factor		Define the conversion factor when there is a need to have a result unit that differs from the original unit. The software asks to enter the conversion factor when you have changed the result unit. When the result unit has been changed once, you must change it back to the original unit before you can change it once again. The software asks the conversion factor only once for each unit pair.

 Table 11.
 Common read-only parameters

Parameter	Description
Tag	Tag information distinguishes Thermo Scientific tests from user-definable tests.
Test version ID	The program defines an ID for the test. The ID is unique for each test.
Last time changed	Shows the date and time when the test definition was changed the last time.
User name	Shows the user who modified the test definition the last time.

Parameters for dilution

Table 12. Parameters for photometric tests

Parameter	Values	Description
Sample type	Beer, Wort	Select the correct sample type for a test.
Correction factor		Define the correction factor as a decimal. The correction factor is used for calculations: Corrected result = (correction factor) x (result calculated according to the calibration). The correction factor is not applied to QC samples.
Correction bias		Define the correction bias as a decimal. The correction bias is subtracted from the result that is calculated according to the calibration: Corrected result = (result – correction bias) x (correction factor). The correction bias is not applied to QC samples.

Table 13. Parameters for calculated tests

Parameter	Description		
Calculation formula	Click the pencil icon to add a calculation formula. Define the calculation formula as a mathematical formula. Select the test from the Test list. Enter the number when needed, and click Enter. The calculation formula can contain a maximum of five tests. The calculated test cannot be part of other calculation formula.		
	The operators for the formula:		
+ - addition			
	– - subtraction		
	* - multiplication		
	/ - division		
	Use brackets () if an operation must be calculated before another. For example,		
	(<a>/)*<c></c>		
	First, A is divided by B and then the result is multiplied by C.		
	< <i>A</i> >/(< <i>B</i> >*< <i>C</i> >)		
	First, B is multiplied by C and then A is divided by the result.		

See instructions how to define calculated test request from the Operation manual.

Parameters for dilution

To define the dilution parameters for a photometric test, select F3 > Test definition > **Dilution**.

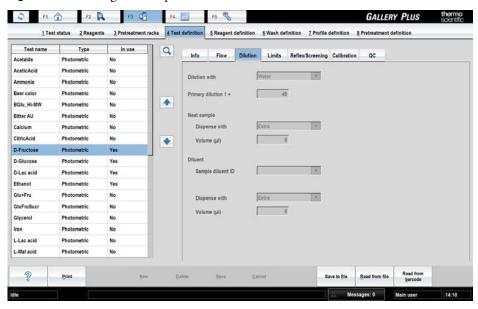


Figure 13. Defining dilution parameters

Table 14. Dilution parameters for photometric test

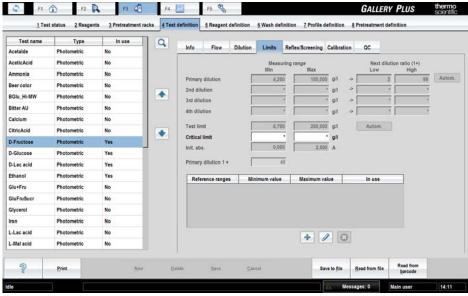
·	n vi			
Parameter	Values	Description		
Dilution with	Water, Diluent, None	Select the dilution for the test.		
		If you select "None", you will not be able to define a dilution for this test at any stage.		
		If you do not want to define a dilution in the test definition, but you still want to be able to define an individual dilution when you request this test for a sample in F2 > Samples , select "Water" or "Diluent" and enter "0" as <i>Primary dilution</i> .		
Primary dilution 1+	0-9999	Samples are always diluted according to primary dilution ratio.		
		Use one part of the sample and X parts of diluent. Notice that, for example, 1+9 and 1:10 have the same dilution. It is not recommended to use dilution ratio 1+1.		
		If the dilution ratio is greater than 1 + 120, the dilution is performed in two steps.		
		The accepted dilution ratio values are as follows:		
		• In the range 1 120, accepted values at intervals of one number (e.g. 1, 2, 119, 120)		
		 In the range 199 999, accepted values at intervals of 100 (e.g. 199, 299, 899, 999) 		
		 In the range 1999 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, 8999, 9999) 		
		If the entered value cannot be used, the program proposes the nearest acceptable values.		

Parameters for limits

Parameter	Values	Description
		Control samples are diluted as normal tests according to the primary dilution ratio. Other dilutions are not done for control samples.
Neat sample		
Dispense with	Water, Extra	Select whether the neat sample is dispensed with water or sample extra.
Volume (μl)	0 - 120	Define the volume of water or sample extra. The maximum volume is $120\ \mu l.$
Diluent		
Sample diluent ID		Select the diluent for a sample.
Dispense with	Water, Extra	Select whether the diluent is dispensed with water or diluent extra.
Volume (µl)	0 - 120	Define the volume of water or diluent extra.

Parameters for limits

Figure 14. Defining limit parameters



The analyzer supports high dilution ratios for samples. If the dilution steps are defined, separate steps are performed automatically until the required dilution ratio is reached and the result is within the limits or until the test has been analyzed using the last defined dilution ratio.

If a dilution has been performed and the result is above the *Max* value of the *Measuring range*, the Dil. limit high error flag is set to the result and the next dilution step is performed using the *High* value of the *Next dilution ratio* (1+).

Respectively, if a dilution has been performed and result is below the Min value of the Measuring range, the Dil. limit low error flag is set to the result and the next dilution step is performed using the Low value of the Next dilution ratio (1+).

If the test has been analyzed with all defined dilutions and it is still outside test limits, the Test limit high/low error flag is set to the result, and the test has to be accepted manually.

Table 15. Common limit parameters

Parameter	Description		
Test limit	Define the lowest and highest allowable limit for the test. Pay attention to the linearity of the method. If the <i>Test limit</i> has been exceeded, it is shown in the <i>Results view</i> and the result must be accepted manually. If the dilution steps have been defined, the <i>Test limit Max</i> must be equal or higher than the highest dilution limit, and the <i>Test limit Min</i> must be equal or less than the lowest dilution limit.		
	To define limits from the calibration, click Autom. The limits must be set manually but they are recalculated during calibration, if Autom. is selected.		
Critical limit	Define the lowest and highest critical limits for the test. The critical limit is a reference limit for the If a test result is not within the limits, it must be accepted manually. It is not recommended to set t lower limit to 0, because then the zero results cannot be detected: the critical limit error is raised bu result is still shown.		

Table 16. Read-only parameters for photometric tests

Parameter	Description
Primary dilution 1+	Defined in the Dilution tab.

Table 17. Limit parameters for photometric tests

Parameter	Description		
Primary dilution, 2 nd dilution, 3 rd dilution, 4 th dilution	The Measuring range values must be within the Test limit's value range.		
	Define the <i>Min</i> value and/or <i>Max</i> value for the <i>Primary dilution</i> when needed. The <i>Max</i> value can always be defined, but the <i>Min</i> value can only be defined if the <i>Primary dilution</i> defined in the <i>Dilution</i> tab is > 0.		
	The other dilution limits in the <i>Min</i> and <i>Max</i> fields of <i>Measuring range</i> are calculated according to defined <i>Next dilution ratio</i> limits.		
	The value in the Max field increases and the value in the Min field decreases after every dilution step.		
	To define limits from the calibration, click Autom. The limits must be set manually but they are recalculated during calibration, if Autom. is selected.		
Next dilution ratio (1+)	The values can vary from 0 to 9999. The value of <i>High</i> has to be higher than primary dilution but less than or equal to the maximum allowed value (9999). The value of <i>Low</i> has to be lower than primary dilution.		
	The accepted dilution ratio values are as follows: • In the range 1 120, accepted values at intervals of one number (e.g. 1, 2, 119, 120)		

Parameters for reflex test

Parameter	Description		
	• In the range 199 999, accepted values at intervals of 100 (e.g. 199, 299, 899, 999)		
	• In the range 1999 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, 8999, 9999)		
	If the entered value cannot be used, the program proposes the nearest acceptable values.		
	The value in the <i>Low</i> field has to decrease and the value in the <i>High</i> field has to increase after every dilution step.		
	To analyze the sample by using some other dilution ratio than primary dilution, define the dilution in the F2 > Samples view. If the defined dilution ratio is one step in the dilution serie defined in the Test definition > Limits , the dilution steps are performed from this step forward according to dilution serie when needed.		
Init. abs. (initial absorbance)	Define the lowest and highest allowable values for the initial absorbance.		

 Table 18.
 Reference range parameters

Parameter	Description	
Reference ranges	Click Add and select reference ranges from the drop-down list. The list shows the reference ranges created in the F5 > Configuration > Reference ranges tab.	
Minimum value	Define the minimum value for the reference range. The value must be within <i>Test limit</i> 's minimum and maximum value. If the sample result is below the <i>Minimum value</i> , the Reference range low error flag is set to the sample and the sample has to be accepted manually. If an asterisk (*) is used, the checking is not in use.	
Maximum Value	Define the maximum value for the reference range. The value must be within <i>Test limit</i> 's minimum and maximum value. If the sample result is above the <i>Maximum value</i> , the Reference range high error flag is set to the sample and the sample has to be accepted manually. If an asterisk (*) is used, the checking is not in use.	
In use	The reference range can be taken into or out of use with the <i>In use</i> parameter.	

Parameters for reflex test

To define reflex and screening parameters for a photometric test, select F3 > Test definition > **Reflex/Screening**. If the test result is within the defined limits, the reflex test request is created. The reflex test request is created for the tests defined in the **Reflex test** field.

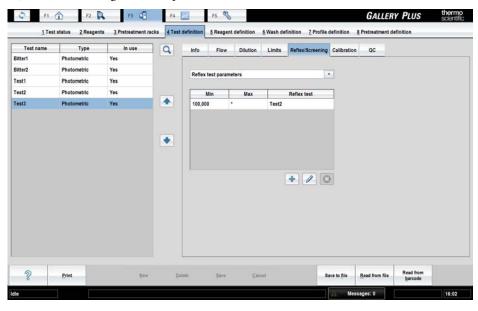


Figure 15. Defining reflex test parameters

Table 19. Reflex parameters

Parameter	Description
Min / Max	Define the minimum and maximum limit for the reflex test. It is possible to set value "*" to minimum or maximum limit. For example, to perform D-Glucose if Ethanol < 11.8 g/l, set value "*" to minimum limit and set value "11.8" to maximum limit.
Reflex test	Select the reflex test from the drop-down list.

Parameters for calibration

To define the calibration parameters for a photometric test, select F3 > Test definition > **Calibration**. Furthermore, define the calibrators and their dilutions in the table. To define the calibrators, their lot information and concentrations, select F4 > Cal/ctrl definition.

Calibrator | Current lot | Concentration | Dilution | Factor | Manual | Factor |

Figure 16. Defining calibration parameters

 Table 20.
 Calibration parameters

Parameter	Values	Description
Calibration type	None, Linear, Bias, Factor, 2nd order, Spline, Logit-Log 4, Logit-Log 5, Point-to- point	In the Calibration type box, select the correct type of a calibration.
		The calibration type defines the calculation formula.
		If "None" is selected, define the factor and bias. The calibration is always valid.
		If "Bias" is selected, define the factor.
		If "Factor" is selected, define the bias.
Repeat time (days)	0 - 365	Define the regular calibration interval in days. When the time has elapsed, the program notifies to run the calibrators. If you do not want to receive the calibration notifications, set the value to 0.
Points/calibrator	Single, Duplicate, Triplicate	Define how many times to replicate at each concentration level of a calibrator.
Acceptance	Automatic, Manual	Define how to accept the calibration. The calibration can be accepted automatically when the following conditions are met:
		Acceptance is set to "Automatic"
		 No factor, bias or error limits have been exceeded
		 No error flags set to QCs or calibrations
		QC requests do not violate QC rules
Concentration axis	Linear, Logarithmic	Define the axis type for the calibration curve. The calibration type restricts the selection.

Parameter	Values	Description
Response axis	Linear, Logarithmic	Define the axis type for the calibration curve. The calibration type restricts the selection.
Abs. error (A)		Define the maximum allowable deviation between the single calibration point and the calculated calibration curve. If an asterisk (*) is used, the checking is not in use.
Rel. error (%)		Define the maximum allowable deviation between the single calibration point and the calculated calibration curve. If an asterisk (*) is used, the checking is not in use.
Factor limit min. / Factor limit max.		Define the maximum and minimum limit for the factor. If an asterisk (*) is used, the checking is not in use.
Bias limit min. / Bias limit max.		Define the maximum and minimum limit for the bias. If an asterisk (*) is used, the checking is not in use.
Coeff. of det. min. (Coefficient of determination)		Define a minimum limit to be achieved for automatic acceptance. If the application area selection is set to other than "Water", coefficient of determination calculated for the calibration is compared against the defined limit. An error is given for a calibration if the coefficient of determination is under the limit. If the application area selection is set to "Water", the linear equation is calculated first. Coefficient of determination calculated from linear equation is compared against the defined limit. If the calculated coefficient is over the limit, the linear equation is used. Otherwise, the 2 nd order equation is calculated and used.
Factor		If the calibration type is set to "None" or "Bias", define the factor for the test.
Bias		If the calibration type is set to "None" or "Factor", define the bias for the test.
Adding calibrators		
+		Add a new row to the list.
0		Edit existing row in the list.
0		Remove existing row from the list.
Calibrator		Select the calibrator. The calibrators are defined in the $F4 > Cal/Ctrl$ definition.
Current lot		The value is read-only and defined in the F4 > Cal/Ctrl definition.

Parameters for quality control

Parameter	Values	Description
Concentration		The value is read-only and defined in the F4 > Cal/Ctrl definition .
Dilution 1+	0-9999	Type the dilution ratio.
		The accepted dilution ratio values are as follows:
		• In the range 1 120, accepted values at intervals of one number (e.g. 1, 2, 119, 120)
		 In the range 199 999, accepted values at intervals of 100 (e.g. 199, 299, 899, 999)
		 In the range 1999 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, 8999, 9999)
		If the entered value cannot be used, the program proposes the nearest acceptable values.

Parameters for quality control

To define the quality control parameters for a photometric test, select F3 > Test definition > QC.

Note Controls of the system tests are also editable.

To define the controls, their lot information, concentrations and SDs, select F4 > **Cal/ctrl definition**.

Figure 17. Defining QC parameters

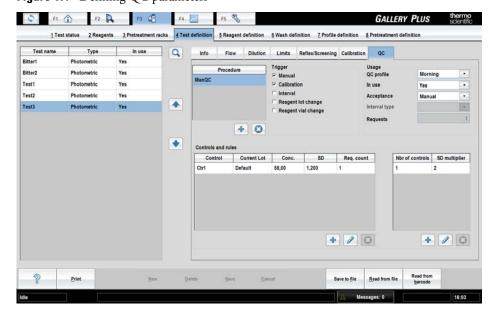


Table 21. Quality control parameters

Parameter	Values	Description
Procedure		Define a name for a QC procedure. One QC procedure can have six control requests at maximum.
Trigger	Manual, Calibration, Interval, Reagent lot change, Reagent vial change	 Define the correct trigger type(s) for the quality control. Manual - the procedure is performed manually Calibration - the procedure is performed with calibration Interval - the procedure is performed according to the interval settings Reagent lot change - the procedure is performed when the reagent lot is changed for the test Reagent vial change - the procedure is performed when the reagent vial is changed for the test If calibration, and changing vial or lot are performed at the same time, the QC is requested only once.
Usage		
QC profile		Select the QC profile to be used. Profiles can be defined in the QC profile tab (F4 > Cal/QC selection > Profile definition). The QC profile can be defined only if the Trigger is set to Manual and then it is mandatory.
In use	Yes, No	Only QC procedures in use are shown in the QC and Calibration tabs under the Cal/QC selection view.
Acceptance	Automatic, Manual	Define how to accept the quality control.
Interval type	Requests, Time	Define the interval type.
Requests		If the value "Interval" is set to <i>Trigger</i> parameter and the value "Requests" is set to <i>Interval type</i> , the quality controls are run after defined number of requests. For example, if the value is set to "20" for the <i>Requests</i> parameter, the quality control is run for every 20 th request.
Time (hh:mm)		If the value "Interval" is set to <i>Trigger</i> parameter and the value "Time (hh:mm)" is set to <i>Interval type</i> , the quality controls are run after defined time interval. For example, if the value is set to "02:00" for the <i>Time</i> (hh:mm) parameter, the quality control is run at intervals of two hours.
Req. count		Define how many requests are analyzed from each control.

Quality control rules

In the **Controls and rules** field, the table shows which controls are run for the test. To add controls for the test, click the add button. Controls are defined in the **Cal/Ctrl definition** view (F4 > **Cal/Ctrl definition**).

Test definition

The number of controls and the SD multiplier should be defined based on how many controls are selected. The rules are handled according to the Westgard rules, which are defined separately for each test. The test can have more than one rule and all rules are checked. The quality control rule:

- *X* The number of control requests to be compared (the **Nbr of controls** field)
- *y* The multiplier defining how many SDs (standard deviations) the measured control result is allowed to deviate from the the given mean value. SD is defined in the **Cal/Ctrl definition** view.

If the routine QC is analyzed as an incomplete batch, only the applicable rules are used. For example, if X = 3 but only two controls are analyzed, only the rules for the first and second controls are used. The rule for the third control is not used.

More information about the Westgard rules is available at http://www.westgard.com/.

Number of controls is equal to batch size

If the rule is equal to the batch size, the rule is violated when all control results are either under or over the control limit.

For example, in the following picture, four results are analyzed in the same batch. All control measurements exceed the same mean plus or minus 1 SD control limit. The rule 4:1 SD is violated and the results are flagged as QC rule 4 violation.

FZ A F3 🐠 1 Cal/OC selection 2 OC results 3 Calibration results 4 Cal/Ctrl de Cumulative data QC para Test Control Lot ID Q Test [All] Control ID [AII] Total Glu 6.6.2011 15:11 22 -3,2 -2,5 4 Lot ID 6.6.2011 15:12 Total Glu -0,2 -1,5 + 06.06.2011 Total Glu 6.6.2011 15:13 0,5 -3,8 Retrieve data 15:13 Values ◆ TGlucose_H
 ◆ TGlucose L

Figure 18. 4:1 SD rule violation

Number of controls is less than batch size

If the number of controls to be compared is less than the batch size and the number of the control results (X) is under or over the control limit, the rule is violated.

For example, in the following picture, two results exceed the same mean plus or minus 2 SD control limit. The rule 2:2 SD is violated and the results are flagged as QC rule 2 violation.

F1 👔 F2 🔼 F3 🐠 F4 🔛 1 Cal/OC selection 2 OC results 3 Calibration results 4 Cal/Ctrl definition Cumulative data | QC param Q Total Glu TGlucose_H 6.6.2011 15:10 23,5 -1,7 -1,3 [AII] 4 Default 6.6.2011 15:11 3 Total Glu TGlucose H 28.2 2,4 Lot ID Default Total Glu TGlucose L 6.6.2011 15:12 2.3 -0.2 -1.5 + 06.06.2011 6 6 2011 15:13 Total Glu TGlucose L 0.5 3.8 -1 SD Values ● TGlucose_H ◆ TGlucose_L Chart Accept selected Reject selected

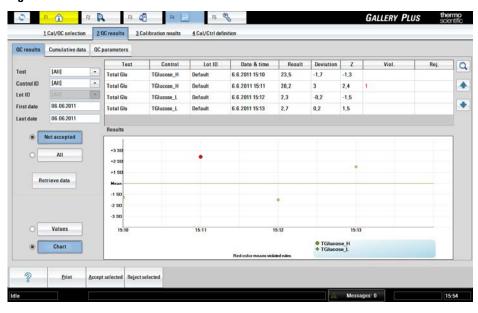
Figure 19. 2:2 SD rule violation

Number of controls is one

If the number of controls to be compared is 1 and the number of the control results (*X*) is under or over the control limit, the rule is violated.

For example, in the following picture, the results are analyzed in the same batch. One result is over the 2 SD control limit. The rule 1:2 SD is violated and the result is flagged as QC rule 1 violation.

Figure 20. 1:2 SD rule violation

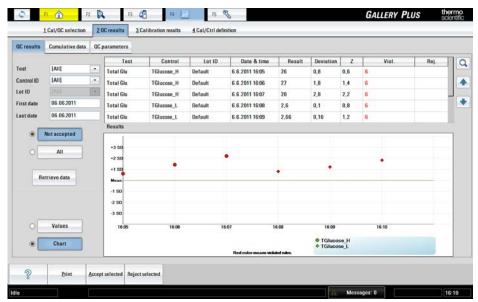


All results are lower or higher than control value

If y = 0, the rule is violated when the number of the control results (X) is under or over the control limit.

For example, in the following picture, the batch size is six and the control results fall on one side of the mean. The rule 6:0 SD is violated and the results are flagged as QC rule 6 violation.

Figure 21. 6:0 SD rule violation



R rule

The R rule can be defined for checking the highest and lowest measurement in a batch. When R has been selected, the quality control rule is violated when the difference between the biggest and smallest deviation is over the selected limits.

For example, in the following picture, the control result exceeds the mean plus 2SD and another result exceeds the mean minus 2SD. The rule R:4 SD is violated and the two results are flagged as QC rule R violation.

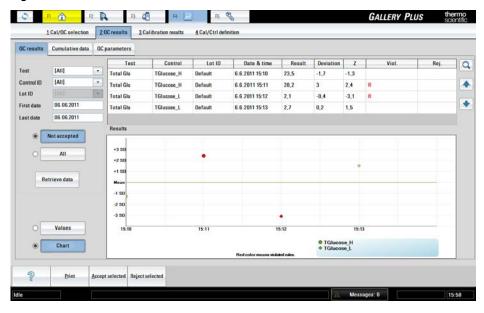


Figure 22. R:4 SD rule violation

Defining test flow

To define a test flow or to edit the existing parameters, select F3 > Test definition > **Flow**. Test can be defined/edited if analysis is not in progress and the test has no unaccepted or pending requests. After the test flow has been defined or updated, calibrate the test.

Note An additional mixing has no parameters. To add an additional mixing, click **Mix**.

CAUTION Ensure that reagents and/or samples used in user-defined tests do not cause hazardous chemical reaction as they mix up in the cuvette and waste water container.

Test status 2 Reagents 3 Pretreatment racks 5 Test definition 5 Reagent definition 5 Wash definition 7 Profile definition 8 Pretreatment definition 7 Pretreatment definition 9 Wash definition 7 Pretreatment definition 9 Wash def

Figure 23. Defining test flow

Common parameters

Parameter	Values	Description
Blank type	No, Yes, True Sample	Define the correct blank for the test:
		"No" - The water blank is measured during the start-up procedure. The measurement is used in the calculations as a blank measurement. The test flow requires one measurement for the sample.
		"Yes" - The blank is measured during the test flow. The blank point can be, for example, an end-point or kinetic measurement. If the kinetic blank measurement is selected, the sample measurement must also be kinetic. The test flow requires two measurements for the sample: one for blank and one for sample. For bitterness tests, the value must always be "Yes."
		"True sample" - The blank is measured in a separate cuvette position. In the blank measurement, the test reagent is replaced with a selected blank reagent. The test flow requires one measurement for the sample.
Pretreatment procedure	None, [Name of pretreatment procedure]	Define whether the test uses pretreatment, and if so, which preatreatment procedure is used. In bitterness tests, a pretreatment procedure must always be included. The parameters for pretreatment procedure are defined in F3 > Pretreatment definition .
Primary dilution 1+		A read-only parameter. Shows the total dilution of the sample.

Parameter	Values	Description
Dispensed volume	120 µl - 300 µl	A read-only parameter. Shows the total volume that will be dispensed into a cuvette during the test flow.

Reagent

Parameter	Values	Description
Reagent		Select the reagent that will be used in a test from the drop-down menu. One reagent can be connected to a maximum of 20 tests. If you want to run more than 20 tests with the same reagent, define the reagent with a different name and connect a part of the tests to that reagent.
Volume (μl)	2 - 240 µl	Define the reagent's volume. The reagent volume depends on the syringe speed. See Reagent dispensing on page 49.
Dispense with	Water, Extra	Define whether the reagent is dispensed with water or reagent extra.
Extra volume (µl)	See Reagent dispensing on page 49	Define the volume of the water or reagent extra, if needed.
Syringe speed	Normal, Medium, Slow	Select normal, medium, or slow syringe speed for reagent dispensing. The slow syringe speed can be useful with viscous reagents.
Replacing reagent		If the value of <i>Blank Type</i> is "True sample", define a replacing reagent for the reagent dispensing. Select the reagent from the drop-down menu.

Table 22. Reagent dispensing

Syringe Speed	Dispense with water, maximum volumes	Dispense with extra, maximum volumes
Normal	Total volume (reagent + water) 240 µl	Reagent 240 μl + extra 60 μl
Medium	Reagent 160 μl + water 30 μl	Total volume (reagent + extra) 160 μl
Slow	Reagent 80 μl + water 50 μl	Total volume (reagent + extra) 80 μl

Sample

Sample

Parameter	Values	Description
Volume (μl)	2 - 120/240	Define the volume that will be dispensed into the cuvette for testing. The maximun volume is 120 μ l for a single dispensing. When dispensing twice, the total volume can be 240 μ l.
Dispense with	Water, Extra	Define whether the sample is dispensed with water or sample extra.
Extra volume (μl)	0 - 120	Define the volume of the water or sample extra. If the sample is dispensed with water, the minimun volume is 20 µl and the maximum volume is 120 µl. If the sample is dispensed with sample extra, the recommended volume is two times the sample volume and the maximum volume is 60 µl. Furthermore, the total volume of the sample (sample and extra) dispensed can be 180 µl.
		In bitterness tests, the combined volume of sample and extra in the actual test flow must be smaller than or equal to $0.9 *$ the <i>Dispensed volume</i> in the pretreatment procedure - $100 \mu l$:
		Sample volume + Extra volume ≤ 0.9 x Dispensed volume - 100 µl
		To check or edit the pretreatment parameters, select F3 > Pretreatment definition > Flow .
Extra wash	Yes, No	Define whether the extra wash with water is performed or not.

Incubation

Parameter	Values	Description
Time (sec)	18 - 3600 s	Define the incubation time.
Actual time (sec)		Shows the actual incubation time, which may differ from the user-defined incubation time due to operation cycle time.

End-point

 Table 23.
 End-point blank

Parameter	Description	
Blank resp. min. (A)	Define the minimum allowed response value for the blank measurement. The default value (*) indicates that checking is not in use.	

Parameter	Description	
Blank resp. max. (A)	Define the maximum allowed response value for the blank measurement. The default value (*) indicates that checking is not in use.	

 Table 24.
 End-point measurement

Parameter	Description	
Main wavelength	Select the main wavelength from the drop-down menu. The alternatives are set by the manufacturer.	
	It is not allowed to use the 275 nm filter for other tests than bitterness tests. In tests using the 275 nm filter, a blank measurement must always be included in the test flow.	
Side wavelength	Select the side wavelength from the drop-down menu. The alternatives are the same as for the main wavelength. The "None" value means that the measurement is monochromatic.	
	It is not allowed to use the 275 nm filter for other tests than bitterness tests. In tests using the 275 nm filter, a blank measurement must always be included in the test flow.	
Residual net abs. (A)	Define the value of the residual net absorbance if the side wavelength has been defined. The residual net absorbance determines the minimum allowable difference between the absorbances measured with the main and the side wavelengths. If the difference is lower than the allowed value, an error message is shown in the acceptance views and reports.	

Kinetic

Parameter	Values	Description
Main wavelength		Select the main wavelength from the drop-down menu. The alternatives are set by the manufacturer.
		It is not allowed to use the 275 nm filter for other tests than bitterness tests. In tests using the 275 nm filter, a blank measurement must always be included in the test flow.
Side wavelength		Select the side wavelength from the drop-down menu. The alternatives are the same as for the main wavelength. The "None" value means that the measurement is monochromatic.
		It is not allowed to use the 275 nm filter for other tests than bitterness tests. In tests using the 275 nm filter, a blank measurement must always be included in the test flow.
Residual net abs.	(A)	Define the value of the residual net absorbance if the side wavelength has been defined. The residual net absorbance determines the minimum allowable difference between the absorbances measured with the main and the side wavelengths. If the difference is lower

Test definition

Parameter	Values	Description
		than the allowed value, it is shown in the acceptance views and reports.
Curve direction	Ascending, Descending	Define whether the direction of the curve is ascending or descending. If the result differs from the parameter's value, an error message is shown and the result must be accepted manually.
Measurement type	Linear, Linear cut	Select the measurement type from the drop-down menu. The value "Linear cut" indicates that only the linear part of the curve is used for the measurement.
Nonlinearity		Define the rate of the nonlinearity limit in concentration units when the curve type is linear. Define the rate of the nonlinearity limit in mA/min when the curve type is linear cut.
Nonlinearity %	0 - 100%	Define the maximum allowable nonlinearity for a reaction when the curve type is linear. If both concentration and percentage limits have been exceeded, an error message is shown in the acceptance views.
Measurement time (sec)	Linear 9 - 3600/s Cut 18 - 3600/s	Define the measurement time in seconds. The minimum measurement time for a linear measurement type is 9 seconds, and at least 2 measurement points are required. The minimum measurement time for a linear cut measurement type is 18 seconds, and at least 3 measurement points are required.
Points / Interval	2 - 12 meas. points / interval (s)	Define the number of the measurement points and the intervals in seconds. The number of measurement points can be defined between 2 and 12 depending on measurement time. The minimum measurement time for a linear measurement type is 9 seconds, and at least 2 measurement points are required. The minimum measurement time for a linear cut measurement type is 18 seconds, and at least 3 measurement points are required.
Actual meas. time (sec)		A read-only parameter shows the actual time of measurement.
Rate check in use	Yes, No	Select whether the reaction rate is checked or not. The reaction rate is checked immediately after the last dispensing by using 2 measurement points.
Max rate (A/min)	0.0 - 2.0	Define the maximum rate of change. The automatic calculation uses the higher dilution limit value for calculating the limit. To avoid false alarms, it is recommended to set the max rate (A/min) limit 10% higher than the calculated limit.

System water

Parameter	Values	Description
Volume (μl)	2 - 240	Define the volume of system water that is dispensed into a cuvette. In bitterness tests, the system water action is used for blank measurement and the minimum volume is $120~\mu l$.

Standard addition

Note Standard addition can only be performed with photometric tests. In bitterness tests with pretreatment, however, standard addition is not included in the test flow.

To define a test with standard addition:

- 1. Define the standard solution.
 - The standard is defined as a calibrator (see Defining calibrators on page 14).
- 2. Define the diluent solution.
 - The diluent is defined as a reagent (see Reagents on page 5).
- 3. Define the test flow.
 - Define parameters for standard addition and end-point measurement. See instructions in the following sections.
- 4. Define the lot concentration.
 - See Defining lot concentrations for calibrators on page 14.

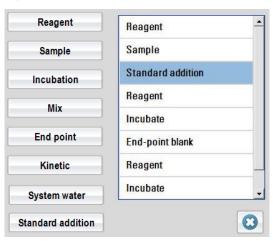
Standard addition parameters

Add the **Standard addition** action in the test flow after **Sample**.

10 Test definition

Test definition

Figure 24. Standard addition in test flow



Parameter	Values	Description
Blank type	No, Yes	Define whether the blank is measured during the test flow. True sample blank is disabled for tests with standard addition.
Calibrator ID		Select the calibrator that will be used as the standard in a test from the drop-down menu.
Calibrator volumes (μl)	2 - 120	Define the calibrator volumes as an ascending series. The volume should be kept small to avoid dilution of the unknown impurities. Calibrator volume must be lower or equal than the combined volume of calibrator and diluent.
Dispense with	Water, Extra	Define whether the calibrator is dispensed with water or calibrator extra.
Extra volume (µl)		Define the extra volume for the calibrator. Define the volume of the water or sample extra. If the sample is dispensed with water, the minimun volume is $20~\mu l$ and the maximum volume is $120~\mu l$. If the sample is dispensed with sample extra, the recommended volume is two times the sample volume and the maximum volume is $60~\mu l$. Furthermore, the total volume of the sample (sample and extra) dispensed can be $180~\mu l$.
Diluent ID		Select the diluent that will be used in a test from the drop-down menu.
Calibr. + dil. volume (μl)		Define the combined volume of calibrator and diluent. The combined volume of calibrator and diluent must be higher or equal than the calibrator volume.
Dispense with	Water, Extra	Define whether the diluent is dispensed with water or diluent extra.

Parameter	Values	Description
Extra volume (µl)		Define the extra volume for the diluent, if needed.

End-point measurement parameters

When **Standard addition** is added to the test flow, additional parameters must be defined for **End-point measurement**.

Parameter	Description
Points/calibrator volume	A read-only parameter. A single replication is performed at each concentration level of a calibrator.
Coeff. of det. min. (Coefficient of determination)	Define the minimum limit to be achieved for automatic acceptance. Coefficient of determination is calculated from linear equation.
Slope limit min.	Define the minimum limit for the slope of the standard addition curve. If an asterisk (*) is used, the checking is not in use.
Slope limit max.	Define the maximum limit for the slope of the standard addition curve. If an asterisk (*) is used, the checking is not in use.
Bias limit min.	Define the minimum limit for the bias of the standard addition curve. If an asterisk (*) is used, the checking is not in use.
Bias limit max.	Define the maximum limit for the bias of the standard addition curve. If an asterisk (*) is used, the checking is not in use.

Restrictions

The following restrictions apply to tests with standard addition:

- In the **Dilution** tab, *Dilution with* must be set to "None".
- In the **Calibration** tab:
 - *Calibration type* must be set to "None".
 - Factor must be set to "1".
 - Bias must be set to "0".
- True sample blank is not allowed.
- Kinetic measurement is not allowed.

It is recommended to click through the **Info ... QC** tabs after setting the test flow parameters to avoid incorrect settings. Once a tab is opened, the software does not allow incorrect settings to be saved there.

Managing test profiles

To create, update and delete the test profiles, select F3 > **Profile definition**. The profile name and related tests are shown. The maximum number of profiles is 50. Each profile can contain 20 tests.

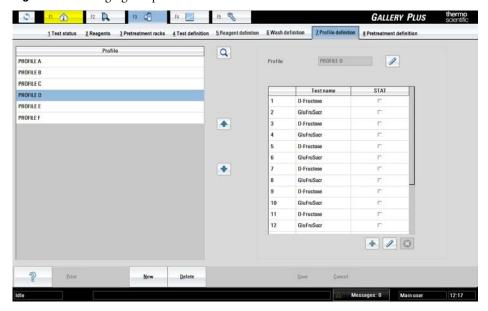
10 Test definition

Test definition

To create a new profile:

- 1. Click New.
- 2. Type identification in the **Profile** box.
- 3. Click **Confirm** to check that the given name is unique.
- 4. Click the add button to add a test.
- 5. Select the test from the drop-down menu.
- 6. Press Enter.
- 7. Click Save.

Figure 25. Managing test profiles



Bitterness measurement

Note This section applies only to analyzers equipped with the BCM unit.

- Operational principle
- BCM column

Operational principle

Bittering compounds responsible for the bitterness in beer are extracted from the sample using the BCM column and measured photometrically at 275 nm.

The method can be used to measure bitterness from packed beer and beer/wort at different stages of the brewing process.

An aliquot of the primary sample is mixed with an aliquot of the BC diluent on the sample prep block. The diluted sample is aspirated into the BCM column, where the bittering compounds are trapped. All other beer/wort components are washed out of the column by the BC system liquid. The bittering compounds are released from the column into the sample prep block by the BC eluent. From the sample prep block, the sample dispenser dispenses the pretreated sample into a cuvette cell in the incubator, where the absorbance of the eluent at 275 nm is measured against a water blank.

BCM column

The BCM column is a stainless steel tube with an active internal surface.

Maintenance

The bitterness column requires no additional maintenance actions, besides the daily start-up and standby procedures.

Lifetime

The bitterness column is expected to last at least 6 months or 2000 samples analyzed under normal conditions. Monitor the need to change the BCM column by running QCs.

BCM maintenance

Removing BCM column

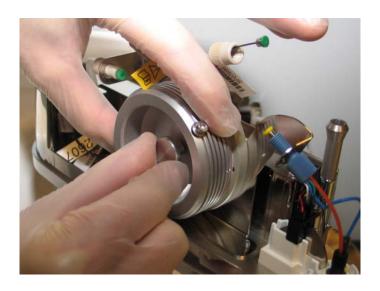
CAUTION Wear protective gloves, spectacles and clothes when removing the BCM column.

To remove the BCM column:

- 1. Select F5 > Actions > **Empty BCM column** to empty the BCM column of any liquids.
- 2. Switch off the analyzer.
- 3. Open the main cover and the BCM dispenser cover.
- 4. Disconnect the column ends from the BCM dispenser tubing.



- 5. If you have the caps of the column connectors available, place them on the connectors.
- Open the thumb screw in the middle of the column.
 Keep the thumb screw after you open it, do not throw it away. It is needed when installing a new column.



7. Take the column out of the BCM dispenser.

Installing BCM column

CAUTION Wear protective gloves, spectacles and clothes when installing the BCM column.

Note Be careful not to bend the column or pull from the connectors. Do not lift the column only by the connectors.

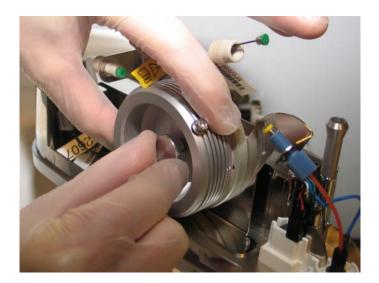
Before installing the column, ensure the analyzer is switched off and the main cover and BCM dispenser cover are open.

To install the column:

- 1. Take the column out from the packing material.
- 2. Place the column holder in the BCM dispenser.
- 3. Tighten the thumb screw in the middle of the column.

11 Bitterness measurement

Bitterness measurement



- 4. Remove the caps from the connectors on the column ends.
- 5. Connect the column ends to BCM dispenser tubing by tightening the connectors firmly. It does not require a great amount of effort.



- 6. Close the BCM dispenser cover.
- 7. Switch on the analyzer.
- 8. Select F5 > Actions > **Add BC system liquid** to add BC system liquid in the column. Type the BC system liquid bottle's barcode or read the barcode with barcode scanner and click **OK**.
- 9. Open the BCM dispenser cover and check that the connections between the column and the BCM dispenser tubing are not leaking.
- 10. Close the BCM dispenser cover and the analyzer's main cover.

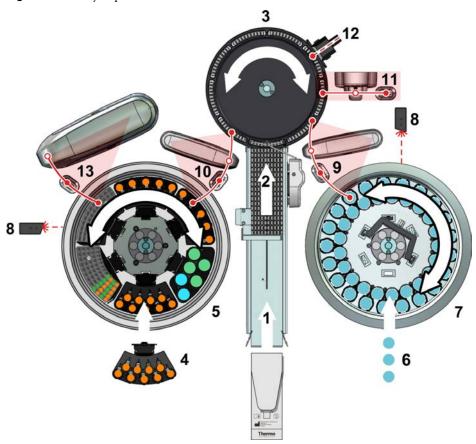
Photometric measurement

- Operational principle
- Photometer
- Response calculation
- Response check
- Result calculation
- Result correction and check
- Calibration calculation
- Standard addition

Operational principle

The cuvette is moved from the cuvette loader into an available slot in the incubator. There are designated positions around the incubator for dispensing reagents and samples into the cuvettes, for mixing, and for absorbance measurement. The incubator rotates to move the cuvette cells to different positions around the incubator according to the steps in the tests that are run. After all the cells of one whole cuvette strip are used and measured, a new cuvette is loaded to the same slot in the incubator and the used cuvette is discarded to the cuvette waste bin.

Figure 26. Analysis process



- 1 DECACELL™ cuvettes entry point
- 2 Cuvette loader
- 3 Incubator
- 4 Sample and pretreatment racks, sample prep blocks
- 5 Sample disk
- 6 Reagents
- 7 Reagent disk
- 8 Barcode reader
- 9 Reagent dispenser
- 10 Sample dispenser
- 11 Mixer
- 12 Photometer unit
- 13 BCM dispenser

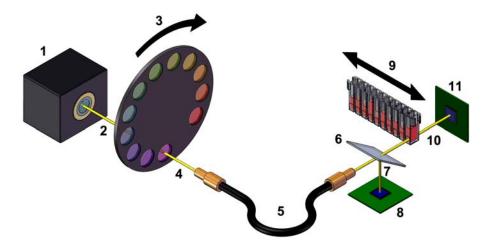
Photometer

The light passes from the flash lamp through the filters, which are mounted on a filter disk. The filter wheel is on constant rotation. The standard instrument has 12 positions for filters of different wavelengths. The light flashes only when the needed filter is on the light path. In bichromatic measurements, the two measurements are separated by less than 60 milliseconds.

The light is directed via optical fiber to the beam splitter. The beam splitter divides the light to the reference and signal channels. Part of the light is reflected directly to the reference channel,

which monitors the fluctuations in the light. The rest of the light is directed to the signal channel through the cuvette. The signal detector measures the amount of the light after absorption.

Figure 27. Schematic of photometer



- 1 Light source
- 2 Light beam
- 3 Filter disk
- 4 Filtered beam
- 5 Optical fiber
- 6 Beam splitter
- 7 Reference beam
- 8 Reference detector
- 9 Cuvette
- 10 Signal beam
- 11 Signal detector

Response calculation

Absorbance

The primary analytical response can be measured as:

- Absorbance, *A* (end-point measurement)
- Absorbance change per minute, A/min (kinetic measurement)

After a measurement, the analyzer sends results for calculation. The raw absorbance is calculated by using the following equation:

$$A_{\rm R} = \frac{\log_{10}\left(\frac{I_{\rm R}}{I_{\rm S}}\right)}{0.675}$$

12 Photometric measurement

End-point response calculation

A_R - raw absorbance

 $I_{\rm R}$ - measured light intensity from reference channel

Is - measured light intensity for light through cuvette

0.675 - correction for modifying the length of the light path in cuvette to 10 mm

The water blank is measured during the start-up procedure. In the water blank measurement, cuvette is filled with water and cells are measured against all wavelengths. The standard deviation in absorbance for the cuvette is calculated. If the standard deviation is above 2 mA (configurable), an error message is shown during the start-up procedure.

After calculating the raw absorbance, the absorbance *A* is calculated by using the following equation:

$$A = A_{\rm R} - A_{\rm WBL}$$

A - absorbance

A_R - raw absorbance

 A_{WBL} - water blank absorbance, which has been measured with system water in advance

End-point response calculation

The test measurement type can be kinetic or end-point. To define the measurement type, select F3 > Test definition > **Flow**. If the value of the measurement type is set to "End-point", response is calculated by using one measurement point.

The test can use one or two different wavelengths. The response of each measurement point is calculated by using the main wavelength. The side wavelength may be used, for instance, to compensate sample-related interferences when sample blank is not possible or suitable, or to compensate cuvette-related interferences when blank is not measured.

If the test uses only the main wavelength, the response is calculated by using the following equation:

$$Response = A_{MainW}$$

 A_{MainW} - The absorbance has been measured by using the main wavelength filter

If the test uses the main and side wavelengths, the response is calculated by using the following equation:

$$Response = A_{MainW} - A_{SideW}$$

 A_{MainW} - absorbance measured by using the main wavelength filter A_{SideW} - absorbance measured by using the side wavelength filter

Kinetic response calculation

The test measurement type can be kinetic or end-point. To define the measurement type, select F3 > Test definition > Flow. If the value of the measurement type is set to "Kinetic", the response is the rate of absorbance change, which is calculated by using several measurement points.

The test can use one or two different wavelengths. The response of each measurement point is calculated by using the main wavelength. The side wavelength is only used in residual net calculation, not in the result calculation.

$$Response = A_{MainW}$$

 A_{MainW} - absorbance measured by using the main wavelength filter

Linear method

The response is defined by drawing a straight line through all the points by using the least squares method.

The software checks whether an outlier point exists among the measured points or not. The outlier point exists if the uncertainty in linear fitting is higher than the defined blank error limit (Max. water blank SD (A)) and if the absorbance change is lower than 15* uncertainty.

If an outlier point exists among the measured points, the point that differs most from the linear fitting is removed. The response is re-calculated by using the remaining points.

Linear cut

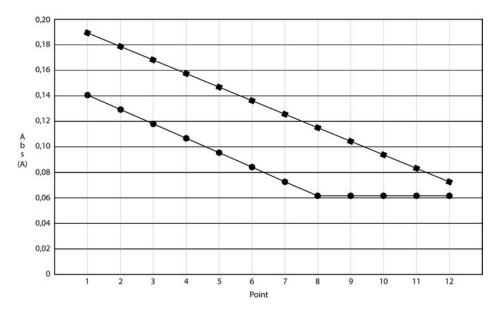
First, the software checks whether the reaction stops. The software does this by calculating the reaction rate using the first and last three points and then comparing these rates. If the difference of the rates is less than the defined nonlinearity limit, all points are used for calculation. The reaction is stable during the measurement. See Sample 1 in the following picture.

If the reaction stops during the measurement, the software then finds out the point where rate of the reaction rate is maximum. Points that are measured before this point are used for calculations. See Sample 2 in the following picture. The rate of reaction rate is maximum at point 8, and therefore the points from 1 to 7 are used for calculations.

If reaction rate change maximum is found and some points are going to be cut off, the following check is done before the linear cut: If concentration is less than dilution limit high * 0.5, no linear cut is done.

If only 1-2 points exist in a linear area, the reaction rate is calculated by using all the points and the Linearity flag is set to the result.

Blank measurements



- ◆ Sample 1
- - Sample 2

Blank measurements

In the test flow, you can add a blank measurement to the request. The blank measurement will reduce, for example, the effect of sample interferences and reagent deterioration. The response of the separate blank measurement is subtracted from the response of the primary sample measurement.

In tests using the 275 nm filter, such as the bitterness test, a blank measurement must always be included in the test flow.

$$Response = Response_{ActualMeas} - Vol_{Corr} \cdot Response_{Blank Meas}$$

Response Actual Meas - response of actual measurement

ResponseBlank Meas - response of blank measurement

Vol_{Corr} - Volume correction: [Volume of liquid in a cell during blanking] divided by [Volume of liquid in a cell during actual measurement]

The possible blank types are:

- End-point blank
- Kinetic blank
- True sample blank

If the blank measurement is set as an end-point, the actual measurement can be an end-point or kinetic. If the actual measurement is kinetic, the end-point blank value is only used for checking the limits that have been defined for the blank.

If the blank measurement is kinetic, the actual measurement must also be kinetic. The kinetic blank measurement uses the linear method.

A true sample blank measurement is similar to the primary sample measurement, but the reagent is replaced with a low absorbing reagent. The substitutive reagent is predefined. The primary analysis is done in a cuvette cell, and the other analysis with substitutive reagent is made in another cell. Both cuvette positions are measured, and the response of the true sample blank measurement is subtracted from the response of the primary sample measurement. The substitutive reagent has low absorbance in the used wavelength, and the purpose of the measurement response subtraction is to eliminate the effects of sample turbidity or color, for example.

Response check

Response is checked after it has been calculated.

Initial absorbance check

The **Limits** tab under the **Test definition** view includes initial absorbance limits. If the value is set to *, checking is not in use.

If the end-point measurement is in use, the initial absorbance is checked by using the measured main absorbance.

If the kinetic measurement is in use, the initial absorbance check is done by using the first point of the measured main absorbance.

If initial absorbance is lower than the set value for *Init abs. min*, the Init abs Low flag is set to the result. If the initial absorbance is higher than the set value for *Init abs. max*, the Init abs High flag is set to the result.

Bichromatic net absorbance check for kinetic measurement

If "Kinetic" is selected in the **Flow** tab under the Test definition view and the test is bichromatic, the measurement includes the minimum limit for the difference of measured wavelengths. The measurement is bichromatic if both the main and side wavelength are defined. The check is done using the last point of the measured absorbance at the main and side wavelength. If the value is set to *, checking is not in use. The absorbance difference limit can be set in the test definition, in the **Residual net abs. (A)** field, after the wavelength definitions have been set. If the absorbance difference is lower than the defined limit, the **Bichr. net abs** flag is set to the result.

Blank checks

If the end-point or kinetic test uses blanking, you can define the blank response check limits for the blanking in F4 > Test definition > Flow. If the value is set to *, checking is not in use. If the absolute value of blank response is lower than the defined minimum limit, the Blank resp.

low flag is set to the result. If the absolute value of blank response is higher than the defined maximum limit, the Blank resp. high flag is set to the result.

If the kinetic test uses kinetic blanking, you can define initial blank level check limits for the blanking in F4 > Test definition > **Flow**. The blank absorbance check is done by using the first point of the measured main absorbance. If the value is set to *, checking is not in use. If the

Kinetic response check for linear and linear-cut methods

absolute value of blank response is lower than the defined minimum limit, the Blank init abs. low flag is set to the result. If the absolute value of blank response is higher than the maximum limit, the Blank init abs. high flag is set to the result.

Kinetic response check for linear and linear-cut methods

If "Kinetic" is selected in the **Flow** tab under the **Test definition** view, the direction of the reaction curve must be defined. The curve can be ascending or descending. If the direction of the reaction curve is wrong, the **Reaction direction** flag is set to result.

If any point used for the calculation is outlier, the Point(s) out of curve flag is set to the result. A point is an outlier if uncertainty in linear fitting is higher than the defined blank error limit (Max. water blank SD (A)) and if the absorbance change is lower than 15* uncertainty. The scattering of the measurement points from the linear fitting is too high, and results cannot be accepted automatically.

If an error occurs during the linear fitting, an error message is shown and the Calculation error flag is set to the result.

Kinetic response check for linear-method

Linearity check is done by sub-dividing absorbance points into two sections. Absorbance points are divided by (n/2) + 1 where n is the number of measurement points. For example, if 12 points are measured, they are divided into two 7-point sections. The first section consists of first (n/2) + 1 points and the second section consists of last (n/2) + 1 points.

The **Flow** tab under the **Test definition** view includes the *Nonlinearity* % field for linearity error % and the *Nonlinearity limit conc.* field for linearity error. The values must be positive or zero for both fields. To check the linearity of the reaction, the rate of changes is calculated by using the first $(\Delta Response_{first})$ and the last $(\Delta Response_{fast})$ points.

$$Linearity_error\% = Abs \left(\frac{\Delta Response_{first} - \Delta Response_{last}}{\Delta Response} \right) \cdot 100$$

 $\Delta \textit{Response}_{last} \text{ - the first points used for calculation} \\ \Delta \textit{Response}_{last} \text{ - the last points used for calculation} \\ \Delta \textit{Response} \text{ - all points used for calculation}$

$$Linearity_error = Abs(Result_{first} - Result_{last})$$

Result_{first} - calculated from $\Delta Response_{first}$ Result_{last} - calculated from $\Delta Response_{last}$

If both limits are exceeded, the Linearity flag is set to the result.

Kinetic response check for linear cut

If an absolute value of the reaction rate of measurement's first three points is lower than the last three points, the reaction rate is calculated by using all points and the Linearity flag is set to the result. The check is done only if the non-linearity limit has been exceeded.

Reaction rate check

If a reaction is kinetic, it is possible to check the reaction rate immediately after the last dispensing. The reaction rate check is done by two measurements.

You can set the limit or allow automatic limit calculation. The automatic calculation uses the higher dilution limit value for calculating the limit. To avoid false alarms, it is recommended to set the max rate (A/min) limit 10% higher than the dilution max limit value.

If the limit is exceeded, the Dil limit high flag is set to the result. The flag is not shown in the main view. Request can be automatically analyzed by using the modified dilution ratio.

Result calculation

When the response calculation of the sample request gives a usable value, the result is calculated by using a valid calibration. Calibration calculation produces parameters that are used to calculate the results. See Calibration calculation on page 73 for a description on how the calibration parameters are calculated.

Logarithmic axis

If the response is defined as logarithmic, the response is modified before calculation:

$$Response_{Final} = \log_{10}(Response)$$

If the result is defined as logarithmic, the result is modified after calculation:

$$Result_{Final} = 10^{Result}$$

If an error occurs during the calculation, the Calculation error flag is set to the result.

Linear calibration

The linear calibration model is used when the calibration type is set to "None", "Bias", "Factor" or "Linear". The result can be calculated from the response by using the following equation:

$$Result = Factor \cdot (Response - BIAS)$$

Response = absorbance or the change of absorbance per minute

The equation is valid both inside and outside the calibration range.

The measurement range is defined by using test limit high and low.

2nd order calibration

If the value of the calibration type is set to "2nd order", the result can be calculated from the response by using the following 2nd order equation:

$$Response = C \cdot Result^2 + B \cdot Result + A$$

The equation is valid and used inside the calibration range. The result for response is calculated by finding the root that exists inside the calibration range. Only one root is inside the calibration range.

If the response is below the calibration range, an estimate for a result is calculated by using the linear extrapolation from the lowest calibration point, and the Outside calibration flag is set to the result.

If the response is over the calibration range, an estimate for a result is calculated by using the linear extrapolation from the highest calibration point, and the Outside calibration flag is set to the result.

Point-to-point calibration

Coefficients are generated during the calibration calculation. During the calibration, separate linear equations are generated between the measurement points. For example, if five (5) calibration levels are used for the calibration, four (4) separate equations are generated.

$$Response = A + \Delta Result \cdot B$$

 $\Delta Result$ = the difference between the result and lower calibrator of target area

The result calculation starts by searching the calibration area to use the correct coefficients of the equation. The equation is valid and used inside the calibration range.

If the response is below the calibration range, an estimate for a result is calculated by using the linear extrapolation from the lowest calibration point, and the Outside calibration flag is set to the result.

If the response is over the calibration range, an estimate for a result is calculated by using the linear extrapolation from the highest calibration point, and the Outside calibration flag is set to the result.

Spline calibration

Coefficients are generated during the calibration calculation. During the calibration, separate 3rd degree equations are generated between the measurement points. For example, if five (5) calibration levels are used for the calibration, four (4) separate equations are generated.

$$Response = A + \Delta Result \cdot \left(B + \Delta Result \cdot \left(C + \Delta Result \cdot D\right)\right)$$

 $\Delta \textit{Result}$ = the difference between the result and lower calibrator of target area

The result calculation starts by searching the calibration area to use the correct coefficients of the equation. The equation is valid and used inside the calibration range.

If the response is below the calibration range, an estimate for a result is calculated by using the linear extrapolation from the lowest calibration point, and the Outside calibration flag is set to the result.

If the response is over the calibration range, an estimate for a result is calculated by using the linear extrapolation from the highest calibration point, and the Outside calibration flag is set to the result.

4-parameter logit and 5-parameter logit

If the value of the calibration type is set to "Logit-Log 4" or "Logit-Log 5", non-linear calibrations are used.

Logit-Log 4

$$Response = d + \frac{a - d}{1 + \left(\frac{Result}{c}\right)^{b}}$$

where

 $a, b, c, d, Result \in \mathbf{R}$

b, c > 0

 $Result \ge 0$

a - measured response when concentration is zero

d - measured response when concentration is infinite

b, *c* - change of reaction

y - response

Logit-Log 5

$$Response = d + \frac{a - d}{1 + \left(\left(\frac{Result}{c}\right)^{\frac{b}{e}}\right)^{e}}$$

where

 $a, b, c, d, e, Result \in \mathbf{R}$

b, c, e > 0

 $Result \ge 0$

a - measured response when concentration is zero

d - measured response when concentration is infinite

b, c - change of reaction

y - response

The equations are valid and used inside the calibration range. If the response is below the calibration range, the concentration value of the lowest calibration point is shown as a result and the Outside calibration flag is set to the result. If the response is over the calibration range, the concentration value of the highest calibration point is shown as a result and the Outside calibration flag is set to the result.

Result correction and check

After the result has been calculated, it is corrected and checked against the result correction rules before it can be used.

Result dilution correction and check

The result is corrected by using the dilution ratio used in the automatic dilution done by the analyzer.

$$Result_{corrected} = Result_{measured} \cdot (1 + Automatic Dilution Ratio)$$

Result test limit check

The test limit is checked if the limit is set and it is not *.

If the result is lower than the minimum test limit, the Test limit low flag is set to the result. If the automatic dilution is not defined and the result is higher than the maximum test limit, the Test limit high flag is set to the result.

If the result has been analyzed by using the upper secondary dilution and is higher than the maximum test limit, the Test limit high flag is set to the result.

If the result has been analyzed by using a bigger automatic dilution ratio than the upper secondary ratio, the test limit is temporarily modified by using the following equation. If the result is higher than the modified limit, the Test limit high flag is set to the result.

$$TestLimit_{ForChecking} = TestLimit \cdot \left(\frac{1 + DilutionRatio_{Used}}{1 + DilutionRatio_{UpperSecondary}} \right)$$

Result manual dilution correction and critical limit check

The manual dilution ratio corrects the result. Define the manual dilution ratio for the sample in the **Samples** view.

$$Result_{AfterManual Dilution} = Result_{AfterAutomatic Dilution} \cdot (1 + Manual Dilution Ratio)$$

The result is also corrected by the correction factor and bias defined for the test.

$$Result_{\texttt{Final}} = CorrectionFactor \cdot \left(Result + CorrectionBias\right)$$

If the minimum critical limit is defined and the corrected result is lower than the minimum critical limit, the Crit. limit low flag is set to result. If maximum critical limit is defined and the corrected result is higher than the maximum critical limit, the Crit. limit high flag is set to result.

Reference ranges

The reference ranges are the more specific result ranges within the *Test limits*. If the sample result is within the defined *Reference range*, the result is automatically accepted. If the sample result is not within the defined *Reference range*, the Reference range low/high error flag is set to the sample and the sample has to be accepted manually.

The reference ranges are defined in F5 > Configuration > **Reference ranges** and taken into use in F3 > Test definition > **Limits**. The reference range is set to a sample in F2 > **Samples**.

Calibration calculation

The parameters obtained in calibration calculation are used for calculating the result.

Log-axes for calibration

The default setting for both axes is linear. If the measured phenomenon is logarithmic, axes can be defined separately as logarithmic. The definition is used in the calculations and the curve is shown in the **Calibration results** view.

Logarithmic concentration axis

The concentration axis can be defined as logarithmic if the value of the calibration type is set to "Linear", "Factor", or "Point-to-point". If the axis is defined as logarithmic, the log_{10} value is taken from the concentration value.

If the concentration is zero (0) or negative, the following error message is shown: 2012 Calculation error: log from negative (RH), and the calibration is not calculated. You can re-run or manually reject the calibration.

You can also define the concentration axis for the ECM tests. Typically, a pH test is linear and other tests are logarithmic.

Logarithmic response axis

The response axis can be defined as logarithmic, if the value of the calibration type is set to "Linear", "Factor", or "Point-to-point". If the axis is defined as logarithmic, the log_{10} value is taken from the response value.

Predefined calibration

If the value of the calibration type is set to "None", the calibration is defined beforehand for the test and it is not run for the test. The result can be calculated from the response by using the following equation:

$$Result = Factor \cdot (Response - BIAS)$$

Bias calibration calculation

If the value of the calibration type is set to "Bias", the bias calibration is measured with one calibrator by using 1-3 measurement points. Define a factor before measuring the bias of the calibration line. After the measurement, bias is calculated as a mean of measured responses.

Checking bias calibration

If bias is lower than the set value for *Bias limit min*, the Resp. limit min. flag is set to the calibration. If bias is higher than the set value for *Bias limit max*, the Resp. limit max. flag is set to the calibration. If the value is set to *, the calibration is not checked.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

Linear calibration calculation

If the value of the calibration type is set to "Linear", the linear calibration is used. The result is calculated from the response by using the following equation:

$$Result = Factor \cdot (Response - BIAS)$$

Both factor and bias are calculated by using separate calibrators or different dilution series of one calibrator. All possible combinations are allowed. The following equation shows the normal presentation of the linear equation:

$$y = A \cdot x + B$$

x = horizontal axis

y = vertical axis

Parameters for the first equation are calculated from the normal presentation of the linear equation as follows:

Factor = 1/A Bias = B

The minimum number of calibrators is 2 and maximum 10. From 1 to 3 measurement points are used. After the measurements, factor and bias are calculated by using the least squares analysis of measured points.

Checking linear calibration

If bias is lower than the set value for *Bias limit min*, the Resp. limit min. flag is set to the calibration. If bias is higher than the set value for *Bias limit max*, the Resp. limit max. flag is set to the calibration. If the value is set to *, the calibration is not checked.

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

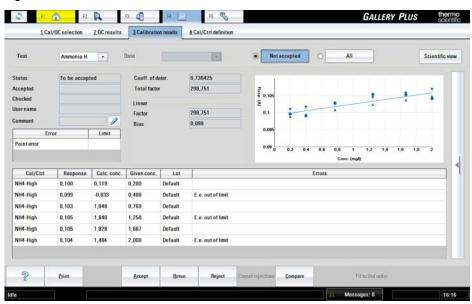
All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + (Response \cdot RelError/100)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

Figure 28. Point error



Factor calibration calculation

If the value of the calibration type is set to "Factor", the factor calibration is measured with one calibrator by using 1-3 measurement points. Define a bias before measuring the factor of the calibration line.

After the measurements, factor is calculated by using the following equation:

$$y = A \cdot x + B$$

x = horizontal axis

y = vertical axis

Parameters for the first equation are calculated from the normal presentation of the linear equation as follows:

Factor - 1/A Bias - B

2nd order calibration calculation

If divider or factor is zero (0) during the calculation, the following error message is shown: Calculation error: zero divider (RH), and the Calculation flag is set to the calibration.

Checking factor calibration

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

2nd order calibration calculation

If the value of the calibration type is set to "2nd order", the 2^{nd} order calibration is used. The result is calculated from the response by using the following equation. A, B and C are measured by using separate calibrators or different dilutions of one calibrator.

$$Response = C \cdot Result^2 + B \cdot Result + A$$

The minimum number of calibrators is 3 and maximum 10. From 1 to 3 measurement points are used. After the measurements, coefficients A, B and C are calculated by using the least squares analysis of measured points.

If divider or factor is zero (0) during the calculation, the following error message is shown: Calculation error: zero divider (RH), and the Calculation flag is set to the calibration.

2nd order calibration in water chemistry

It is possible to define a minimum level for coefficient of determination. First, the software tries the linear fitting to the measured data. If the value of the coefficient of determination is below the minimum level, the 2nd order fitting is then used.

Checking 2nd order calibration

If the equation has a minimum or maximum inside the calibration area, the Extreme found flag is set.

Calibration is automatically rejected.

 $\Delta \textit{Response}$ indicates the difference between absorbances, which are calculated from the lowest and the highest calibrator by using the following equation:

$$Total\ factor = \frac{Calib_{\text{High}} - Calib_{\text{Low}}}{\Delta Response}$$

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

Point-to-point calibration calculation

The value of the calibration type can be set to "Point-to-point" if the result has a non-linear dependence from the response.

$$Response = A + \Delta Result \cdot B$$

 $\Delta \textit{Result}$ = the difference between the result and lower calibrator of target area

The minimum number of calibrators is 3 and maximum 10. Single, duplicate, or triplicate points can be used.

Checking point-to-point calibration

Extreme

If the equation has a minimum or maximum inside the calibration area, the Extreme found flag is set.

The extreme is checked by using the B term in the following equation. Note that all B terms must have the same sign.

Spline calibration calculation

$$Response = A + \Delta Result \cdot B$$

 $\Delta Result$ = the difference between the result and lower calibrator of target area

If extreme exists, the Extreme found flag is set to the calibration. You cannot accept the calibration.

Factor

 $\Delta \textit{Response}$ indicates the difference between absorbances, which are calculated from the lowest and the highest calibrator by using the following equation:

$$Total factor = \frac{Calib_{High} - Calib_{Low}}{\Delta Response}$$

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

Spline calibration calculation

The value of the calibration type can be set to "Spline" if the result has a non-linear dependence from the response.

$$Response = A + \Delta Result \cdot (B + \Delta Result \cdot (C + \Delta Result \cdot D))$$

 $\Delta Result$ = the difference between the result and lower calibrator of target area

Spline fitting allows curve smoothing, that is, the curve does not need to go through the measured points. Allowed smoothing of each point is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + (Response \cdot RelError/100)^2}$$

AbsError - the permissible error when response is zero RelError - the permissible proportional error

If calibrator is measured by using 2 or 3 points, allowed smoothing is the error limit or the measured values depending on which one has a greater value.

If the calibration cannot be done, the calculation flag is set to the calibration.

Checking spline calibration

Spline curve must not have extreme points, that is, every measured result must give a unique concentration value.

If extreme exists, the Extreme found flag is set to the calibration. You cannot accept the calibration.

 $\Delta \textit{Response}$ indicates the difference between absorbances, which are calculated from the lowest and the highest calibrator by using the following equation:

$$Total factor = \frac{Calib_{High} - Calib_{Low}}{\Delta Response}$$

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + (Response \cdot RelError/100)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

4-parameter logit calibration calculation

The value of the calibration type can be set to "Logit-Log 4" for fitting non-linear model.

Logit-Log 4

$$Response = d + \frac{a - d}{1 + \left(\frac{Result}{c}\right)^{b}}$$

where $a, b, c, d, Result \in \mathbf{R}$ b, c > 0 $Result \ge 0$

12 Photometric measurement

Photometric measurement

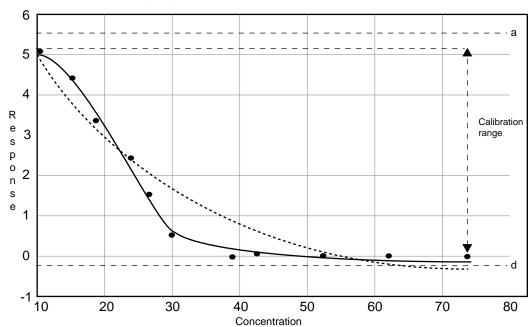
a - measured response when concentration is zero

d - measured response when concentration is infinite

b, c - change of reaction

y - response

Figure 29. 4-parameter logit log



•	Measurement points
	Fitting using the least square method
	Fitting after iterations

Checking 4-parameter logit calibration

The factor limits can be used for checking the curve direction.

$$Total\ factor = \frac{Calib_{\text{High}} - Calib_{\text{Low}}}{\Delta Response}$$

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

You cannot manually accept the calibration.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

5-parameter logit calibration calculation

The value of the calibration type can be set to "Logit-Log 5" for fitting non-linear model.

Logit-Log 5

$$Response = d + \frac{a - d}{1 + \left(\left(\frac{Result}{c}\right)^{\frac{b}{e}}\right)^{e}}$$

where $a, b, c, d, e, Result \in \mathbf{R}$ b, c, e > 0 $Result \ge 0$

a - measured response when concentration is zero
d - measured response when concentration is infinite
b, c - change of reaction
y - response

Checking 5-parameter logit calibration

The factor limits can be used for checking the curve direction.

$$Total\ factor = \frac{Calib_{\rm High} - Calib_{\rm Low}}{\Delta Response}$$

If factor is lower than the set value for *Factor limit min*, the Factor limit min. flag is set to the calibration. If factor is higher than the set value for *Factor limit max*, the Factor limit max. flag is set to the calibration. If the value is set to *, calibration is not checked.

The factor limits can be used for checking the curve direction.

All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

$$ErrorLimit = \sqrt{AbsError^2 + \left(Response \cdot RelError/100\right)^2}$$

AbsError - absolute error (A) RelError - relative error (%)

Standard addition

If the absolute difference between the measured response and response value calculated for calibration point is higher than the defined error limit, the E.e. out of limit flag is set to the calibration point and the Point error flag is set to the calibration.

You cannot manually accept the calibration.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

Standard addition

Standard addition is used in instrumental analysis to determine the concentration of a substance in an unknown sample by comparison to a set of samples of known concentration, similar to using a calibration curve. Standard addition can be applied to most analytical techniques and is used instead of a calibration curve to solve the matrix effect problem.

The matrix effect problem occurs when the unknown sample contains many impurities. If impurities present in the unknown sample interact with the analyte to change the instrumental response or themselves produce an instrumental response, then a calibration curve based on pure analyte samples will give an incorrect determination.

The procedure for standard additions is to split the sample into several even aliquots in separate cuvette cells. The sample volume is the same for all aspirations. The first cuvette contains only the sample, which is diluted with a special diluent to the volume defined the in test flow. In the next cuvettes, the standard solution is added in increasing volumes. The volume of standard solution should be kept small to avoid dilution of the unknown impurities. Each cuvette cell is then diluted with the special diluent to the same even volume defined in test flow. The number of standard additions can vary between 2 - 5 as defined in the test flow.

Figure 30. Cuvettes in standard addition test



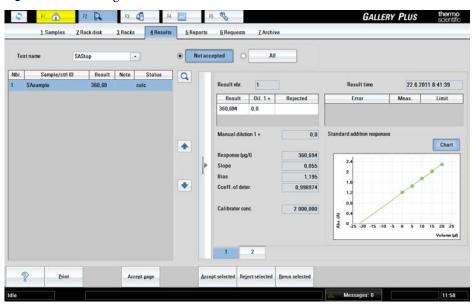
- 1 Diluent
- 2 Standard solution
- 3 Reagent
- 4 Sample

Although the initial concentration of analyte in the sample is unknown, the concentration and volume of the standard solution are known, and the readings before and after adding the standard are calculated in the test. The readings are then extrapolated, and the concentration in the unknown sample is determined.

Linear regression in standard addition

The data is plotted with volume standard added in the x-axis and instrument response in the y-axis. Outlier points are not automatically or manually removed. Linear regression is performed and the slope and y-intercept of regression are calculated.

Figure 31. Linear regression in standard addition



Result calculation in standard addition

Linear regression uses the following equation:

$$S = mV_{\text{Std}} + b$$

S = instrument response (signal)

m = slope

 $V_{\rm Std}$ = volume of standard

b = y-intercept

If the curve started where the instrument response is zero, the volume of standard $[(V_{Std})_0]$ from that point to the point of the first solution on the curve (x = 0) contains the same amount of analyte as the sample. The following equation is derived:

$$V_{S}c_{S} = |(V_{Std})_{0}|c_{Std}$$

 $V_{
m S}$ = volume of sample aliquot

 $V_{\rm Std}$ = volume of standard

 $c_{\rm S}$ = concentration of the sample

 c_{Std} = concentration of the standard

The concentration of analyte in the sample is then calculated from the slope and y-intercept of the standard addition calibration curve using the following equation:

12 Photometric measurement

Checking result in standard addition

$$c_{\rm S} = \frac{b \cdot c_{\rm Std}}{m \cdot V_{\rm S}}$$

 $c_{\rm S}$ = concentration of the sample b = y-intercept $c_{\rm Std}$ = concentration of the standard m = slope $V_{\rm S}$ = volume of sample aliquot

Checking result in standard addition

If bias of the standard addition curve is lower than the set value for *Bias limit min*, the Bias limit min. flag is set to the result. If bias is higher than the set value for *Bias limit max*, the Bias limit max. flag is set to the result. If the value is set to *, the result is not checked.

If slope of the standard addition curve is lower than the set value for *Slope limit min*, the Slope limit min. flag is set to the result. If slope is higher than the set value for *Slope limit max*, the Slope limit max. flag is set to the result. If the value is set to *, result is not checked.

The slope limits can be used for checking the curve direction.

The coefficient of determination for linear fitting is calculated and shown in the **Calibration result** view.

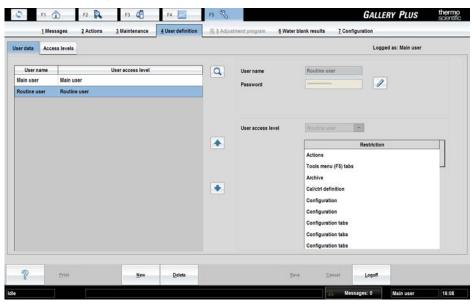
Defining user accounts

To create a new user account:

Note You can create new user accounts for access levels which are lower than yours own access level. For example, the main user can create new routine user accounts, but not new main user accounts.

- 1. Select F5 > User definition > **User data**.
- 2. Click a row in the **User access level** list to activate the **New** button.
- 3. Click New.
- 4. Type the user name in the **User name** field.
- 5. Type the password in the **Password** field.
- 6. Press Enter.
- 7. Retype the password in the **Retype password** field.
- 8. Select a user level from the User access level drop-down menu.
- 9. Click Confirm.
- 10. Click Save.

Figure 32. Creating new user account



- Viewing existing users
- Removing user

13 Defining user accounts

Viewing existing users

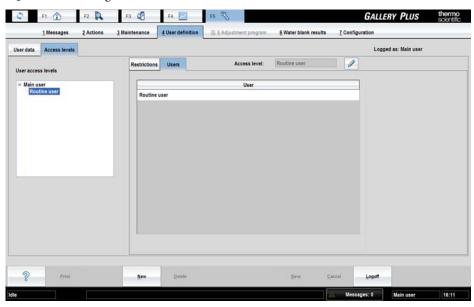
- Adding user access level
- Defining restrictions for access level
- Removing restrictions from access level

Viewing existing users

To view the users and their access levels:

- 1. Select F5 > User definition > **Access levels**.
- 2. Select Users tab.
- 3. Select an user access level to show the users belonging to that user group.

Figure 33. Viewing users



Removing user

To remove a user:

- 1. Select F5 > User definition > **User data**.
- 2. Select a user.
- 3. Click Delete.

Adding user access level

To define a new user access level:

1. Select F5 > User definition > **Access levels**.

- 2. Select a parent user access level for the new access level.
- 3. Click New.
- 4. Type a name for the new user access level.
- 5. Click Save.

Figure 34. Adding access levels



Defining restrictions for access level

It is possible to define restrictions for a certain user level. To add restrictions for user levels:

- 1. Select F5 > User definition > Access levels > **Restrictions** tab.
- 2. Select a user level.
- 3. Click the add button.
- 4. Define restrictions by selecting rules from the **Restriction target** and **Description** drop-down menus and press Enter.
- 5. Click Save.

13 Defining user accounts

Removing restrictions from access level

Figure 35. Defining restrictions



Removing restrictions from access level

To remove restrictions from user levels:

- 1. Select F5 > User definition > Access levels > **Restrictions** tab.
- 2. Select a user level.
- 3. Click the restriction to be removed.
- 4. Click the delete button.
- 5. Click Save.

Reviewing water blank results

To review the water blank results, select F5 > Water blank results.

By default, the latest measurement result is shown. Results for each wavelength are listed on the left. The graphic shows the water blank result of each cuvette position. You can view a certain wavelength or all wavelengths of the measurement in the graphic.

Note The SD in water blank results using the 275 nm filter is generally very high. This does not incidate an invalid measurement.

Figure 36. Reviewing water blank results

• Requesting water blank

Requesting water blank

To request a water blank, select F5 > Actions > **Water blank**.

This action is not possible when analyzer is in the Start-up not done state.



Managing database

CAUTION The database is designed to be analyzer specific due to traceability reasons.

- Saving database
- Restoring database
- Restoring default database
- Changing debug status
- Showing software version

Saving database

To backup the database on a USB flash drive:

- 1. Select F5 > Actions > **Save DB**.
- 2. Select the correct folder.
- 3. Click Save.

Note Regularly scan the USB flash drive with an anti-virus software to protect the workstation against viruses.

15 Managing database

Restoring database

Figure 37. Saving database



- 1 Keyboard
- 2 USB port for handheld barcode scanner / USB port for backing up

Note If a handheld barcode scanner is connected, remove it from the USB port when you need to use USB Flash drive.

This action is not possible when analyzer is in the Analyzing state.

Restoring database

CAUTION Restore database deletes all the test results and tests in the current database and restores selected database. It is recommended to save current database before the operation.

To restore a database:

- 1. Select F5 > Actions > **Restore DB**.
- 2. Confirm the action by clicking **Yes** in the confirmation window.
- 3. Select the correct database.
- 4. Click **OK**.

The software restarts after restoring the database. This action is not possible when analyzer is in the Analyzing state.

Restoring default database

CAUTION Restore default database deletes all the test results and tests in the current database, and restores empty database. It is recommended to save current database before the operation.

To restore a default database:

- 1. Select F5 > Actions > **Restore default DB**.
- 2. Click OK.

The operation restores empty database defined by Thermo Fisher Scientific. You can load tests from **Test definition** tab by **Read from file** or **Read from barcode** operations. See further information from Reading test parameters from file on page 29 and Reading test parameters from barcode on page 30.

The software restarts after restoring the database. This action is not possible when analyzer is in the Analyzing state.

Changing debug status

To change the debug status of all processes, select F5 > Actions > **Change debug status**. The possible statuses are:

- Off
- Lowest
- Low
- On
- High
- Highest

Showing software version

To show the software version, select F5 > Actions > **Show version**.



Removing archive information

To remove the archive data:

- 1. Select F2 > **Archive**.
- 2. Select test from the **Test** drop-down menu.
- 3. Define the date in the **Last date** field.
- 4. Click Retrieve data.
- 5. Click Delete.

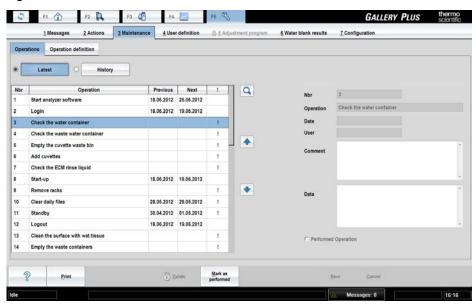
Note Information about sample results, calibrations, QC results and old test parameters that have been performed before the defined date, is removed. Only, the results from the last day are included.



Managing maintenance tasks

To check the statuses of the maintenance tasks, select F5 > Maintenance.

Figure 38. Maintenance view



- Adding maintenance task
- Taking maintenance task in use
- Changing interval time
- Removing maintenance task
- Acknowledging maintenance task
- Viewing maintenance history
- Deleting maintenance history

Adding maintenance task

To add a maintenance task:

- 1. Click F5 > Maintenance > **Operation definition**.
- 2. Click the **Add** button.

17 Managing maintenance tasks

Taking maintenance task in use

- 3. Type name for the new maintenance task.
- 4. Set the interval time in days.
- 5. Tick the **In use** check box.
- 6. Click the **Add** button again to add the task to the list.
- 7. Click Save.

If the **In use** check box is not ticked, the task is not displayed in the **Maintenance to be done** list shown during the startup and in the **Latest** list in the **Maintenance** window.

Taking maintenance task in use

To take a maintenance task in use:

- 1. Click F5 > Maintenance > **Operation definition**.
- 2. Select the task from the list.
- 3. Click the **Edit** button.
- 4. Tick the **In use** check box.
- 5. Click Save.

If the **In use** check box is not ticked, the task is not displayed in the **Maintenance to be done** list shown during the startup and in the **Latest** list in the **Maintenance** window.

Changing interval time

To change the interval time:

- 1. Click F5 > Maintenance > **Operation definition**.
- 2. Click the **Edit** button.
- Under Interval, click the interval time defined for the maintenance task.
 The interval time is defined in days.
- 4. Type the new interval time and press Enter.
- 5. Click Save.

Removing maintenance task

Note It is possible to remove user-defined maintenance tasks. Removing predefined tasks is not allowed but you can define them out of use by using **In use** parameter in F5 > Maintenance > **Operation definition** tab. Only exceptions are Replace BC column and Wash water container and tubing, which are always in use.

To remove a maintenance task:

- 1. Click F5 > Maintenance > **Operation definition**.
- 2. Select a maintenance task.

- 3. Click the **Remove** button.
- 4. Click Save.

Acknowledging maintenance task

To acknowledge a maintenance task:

- 1. Click F5 > Maintenance > **Operations** tab.
- Select the maintenance task to be acknowledged from the list.You can select and acknowledge multiple maintenance tasks by holding down CTRL or SHIFT key while selecting the tasks.
- 3. Click Mark performed.
- Enter comment and/or data in the fields on the right, if needed. If you have selected multiple
 maintenance tasks, the typed text in the comment and/or data fields is saved only for the item
 you selected last.
- 5. Click Save.

Viewing maintenance history

To view the maintenance history:

- 1. Click F5 > Maintenance > **Operations** tab.
- 2. Click History.
- 3. Narrow the search by defining a date in the First date and/or Last date fields.
- 4. Click Retrieve data.

Deleting maintenance history

To delete maintenance history:

- 1. Click F5 > Maintenance > **Operations** tab.
- 2. Click History.
- 3. Narrow the search by defining a date in the First date and/or Last date fields.
- 4. Click Retrieve data.
- 5. Click Delete.
- 6. Click **Yes** to confirm the deletion.



Configuration

To configure the analyzer, select F5 > **Configuration.** Save the existing configuration before changing the configuration.

The following users are allowed to change the configuration settings. Routine users are allowed to view the **Laboratory** configuration settings.

Table 25. Minimum user level requirements for changing configuration settings

Configuration tab	Laboratory main user	Service engineer
Laboratory	X	
LIS	X	
Test LIS	X	
Analyzer	X	
Filter		X
Temperature		X
Sample types	X	
Reports	X	
Report editor	X	
Reference ranges	X	
Additional		X

- Saving configuration
- Restoring configuration
- Configuration settings

Saving configuration

To make a backup of a configuration, and to save the backup on a USB flash drive:

1. Select F5 > Configuration > **Save configuration**.

18 Configuration

Restoring configuration

- 2. Select the correct folder.
- 3. Click Save.

Note Regularly scan the USB flash drive with an anti-virus software to protect the workstation against viruses.

Restoring configuration

To restore a configuration:

- 1. Switch off the analyzer.
- 2. Select F5 > **Configuration**.
- 3. Click **Restore configuration** to restore the saved configuration.
- 4. Confirm the configuration to be restored.
- 5. Select the correct configuration.

To restore the default configuration, click Restore def. configuration.

Configuration settings

Laboratory

To configure the laboratory settings, select F5 > Configuration > **Laboratory**. The laboratory's main user is allowed to change the settings.

Figure 39. Laboratory settings



Table 26. Laboratory configuration parameters

Parameter	Values	Description
Analyzer name		Define analyzer's name. For example, the analyzer name is printed in the reports.
Debug in boot	Off, Lowest, Low, On, High, Highest	Define the debug status. Recommended level is On .
		You can temporarily change the debugging level in the F5 > Actions tab by clicking Change debug status . This setting is in force until the analyzer is booted.
Default sample type	Sample type 1-8	Select a default sample type. To modify the sample types, select F5 > Configuration > Sample types .
Max sample age (hhh:mm)	1 min - 720 h	Define how long the sample stays valid in the analyzer. Add time given in hours (hh) and minutes (mm). The maximum allowed time is 720 hours and minimum 1 minute. When the sample is expired, it is marked as an old sample and no more sample is dispensed for new tests. However, for ongoing tests, the old samples are dispensed but new tests are not started.
Max calibrator age (hhh:mm)	1 min - 720 h	Define how long the calibrator stays valid in the analyzer. Add time given in hours (hh) and minutes (mm). The maximum allowed time is 720 hours and minimum 1 minute. When the calibrator is expired, calibrator is not dispensed and is marked as an old calibrator.
Max control age (hhh:mm)	1 min - 720 h	Define how long the control stays valid in the analyzer. Add time given in hours (hh) and minutes (mm). The maximum allowed time is 720 hours and minimum 1 minute. When the control is expired, control is not dispensed and is marked as an old control.
Max pretreated sample age	1 min - 720 h	Define how long the pretreated sample stays valid in the analyzer. Add time given in hours (hh) and minutes (mm). The maximum allowed time is 720 hours and minimum 1 minute. When the sample is expired, sample is not dispensed and marked as and old sample.
Sample result archived	Yes, No	Define whether results are archived or not. If No is selected, only the results of controls will be saved to the archive and all the test results will be lost when Clear daily files operation is performed.
UI language selection		Select language for the user interface.
Help language selection		Select language for the on-line help.
Perform QC in start and end of run	Yes, No	Define whether an additional quality control (QC) is run at the start of analysis for each test with requests to sample. When defined, this additional quality control is also run at the end of the analysis if requests to sample were run after previous quality control.
Use barcode checkdigit		Shows whether the barcode check digit is in use or not. If Yes is selected, only the barcodes with check digit are read. If No is selected, also barcodes with

Parameter	Values	Description
		out check digits are read. It is not recommended to use barcodes without checkdigits.
Report result outside of test limits	Yes, No	Define whether the test results outside of test limits are reported as exact numbers. If Yes is selected, the results are reported exactly. If No is selected the results are reported in relation to the test limits (e.g. >0,2).
Clear sample IDs when rack removed	Yes, No	Shows whether sample IDs are cleared when a rack is removed. The default value is No . Sample IDs are always cleared when the main cover is closed or the software is restarted.
QC mandatory for sample run	Yes, No	If Yes is selected, test runs are suspended if the analyzer cannot perform QC for the tests in question. If No is selected, the software gives an error message, test runs are continued but they need manual acceptance.
Include rejected QC results in mean	Yes, No	If Yes is selected, rejected QC results are included in mean in a cumulative QC result graph. If No is selected, only accepted QC results are included in mean in the cumulative QC result graph.
Clot detection in use	Yes, No	If Yes is selected, clots are detected from samples, controls and calibrators. If No is selected, clot detection is not in use.
Use request counter	Yes, No	Shows whether the request counter is in use. The counter counts the number of performed requests and used cuvettes in a certain time period. If Yes is selected, the request counter is set on and the archiving is also forced on and it is not possible to change this setting. Deleting results from the archive is prevented as well. If No is selected, the request counter is not in use.
Result acceptance mode	Test, Group, Sample	Define when the results are ready for acceptance. If Test is selected, the results are ready for acceptance when the test has at least one acceptable result. If Group is selected, the results are ready for acceptance after all requests for the group are measured. If Sample is selected the results are ready for acceptance after all requests for the sample are measured.
Use max volume for cuvette dilution	Yes, No	If Yes is selected, the sample is diluted with the maximum diluent volume. The maximum total volume is the size of the cuvette. If No is selected, the sample is the diluted to the minimum volume required by the test.
Automatic start	Yes, No	If Yes is selected, analysis starts automatically if everything in the analyzer is ready for analysis. If No is selected, analysis starts when the user clicks Start .

LIS

For more information about configuring laboratory information system (LIS), refer to the LIS Interface manual.

LIS settings can be changed when LIS connection is in use (F5 > Configuration > **Analyzer**, parameter *LIS connection in use*: "Yes").

Test LIS

To configure the online names for the tests, select F5 > Configuration > **Test LIS**. Test LIS settings can be changed when LIS connection is in use (F5 > Configuration > **Analyzer**, parameter *LIS connection in use*: "Yes"). For more information about configuring laboratory information system (LIS), refer to the LIS Interface manual.

Each test must have a test online name defined, if results or requests need to be transferred into the LIS system through the ASTM protocol. The test online name must match with the LIS test name, otherwise an error message is shown. The test online name must be unique for each test.

Analyzer

To configure the analyzer settings, select F5 > Configuration > **Analyzer.** The main user is allowed to change the *Additional module* and *LIS connection in use* settings.

Figure 40. Analyzer settings



Table 27. Analyzer configuration parameters

Parameter	Description
Analyzer type	Shows the analyzer type.
Application area	Shows the application area.
Vendor	Shows the vendor of the analyzer.
Tick interval (sec)	Shows the length of the tick in seconds. Tick is a basic measurement unit for the analyzer.
Additional module	Define the additional module used in the analyzer. If no additional module is used, select <i>None</i> . The default value is set by the manufacturer.

18 Configuration

Sample types

Parameter	Description
Max water blank SD (A)	Shows the maximum allowed limit for water blank standard deviation (SD).
Max allowable absorbance (A)	Shows the maximum allowed absorbance value. If the value exceeds the defined value, an error message is displayed in result reports.
Reagent disk cooling	Shows whether the reagent disk is cooled or not.
LIS connection in use	Define whether the LIS connection is in use or not.

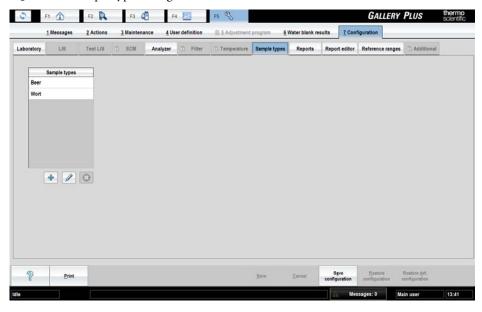
Sample types

Sample types are shown under the **Sample type** field in the **Test definition** view (F3 > Test definition > **Info**). The laboratory's main user is allowed to change the settings.

To configure sample types settings:

- 1. Select F5 > Configuration > **Sample types**.
- 2. Click the add button.
- 3. Type a name for the new test type in the field.
- 4. Press Enter.
- 5. Click Save.

Figure 41. Sample type settings



Reports

Use the F5 > Configuration > **Reports** tab to select the report template to be used in the F2 > **Reports** tab. The selection affects the sample report.

A test report has always a general header and a fixed column structure, but you can customize the general header by defining **User texts** and own logo.

The Sample report templates 1, 2 and 3 have a different fixed column structures and a general header. You can customize the header by defining **User texts** and a logo. Sample report templates **Custom 1**, **Custom 2** and **Custom 3** are completely user-definable. Define these templates in the F5 > Configuration > Report editor tab. The **User texts** defined in **User texts 1-4** fields are also available in the drop-down lists of the **Report editor**'s **Header fields**.

To configure the sample result report format:

- 1. Select F5 > Configuration > **Reports**.
- 2. Type customized texts on User text 1-4 rows, if needed.
- 3. Add a logo by clicking **Change**. The aspect ratio of the logo is 3.35.

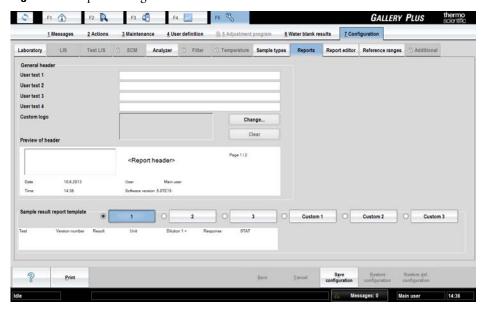
Note If the **User text** fields and logo are defined, they are shown in the sample report and test report headers.

- 4. Select a sample result report template by clicking option button 1, 2 or 3 or by clicking Custom 1, Custom 2 or Custom 3.
- 5. Click Save.

Table 28. Logo size

Width	Height
5.69 cm	1.70 cm
2.24 in.	0.67 in.
672 pixels (300 ppi)	200 pixels (300 ppi)

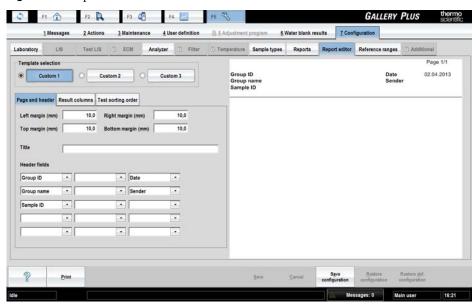
Figure 42. Report settings



Report editor

You can define three different report templates for the sample report. Select the template into use in the F5 > Configuration > **Reports** tab.

Figure 43. Report editor



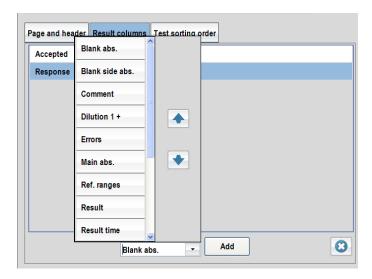
The laboratory's main user is allowed to change the settings. To configure the user-definable template for the sample result report:

- 1. Select F5 > Configuration > **Report editor**.
- 2. Select the template to be edited from the **Template selection** section.
- 3. Select the Page and header tab.
- 4. Define the left, right, top and bottom margins.
- 5. Enter the name of the report in the **Title** field.
- 6. Select the header fields from the drop-down menus.

The **User text fields** of the drop-down menu are defined in the F5 > Configuration > **Reports** tab.

- 7. Select the **Result columns** tab.
- 8. Select the result column you want to have in the report from the drop-down list.

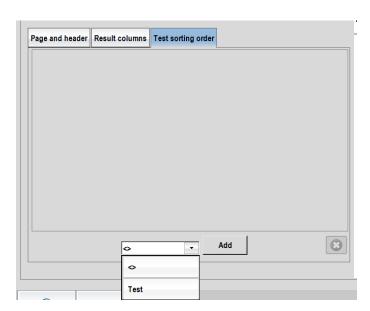
9. Click Add.



Repeat steps 8 and 9 until all the needed result columns are defined.

You can change the order of columns by dragging the added items in the list.

- 10. Select the **Test sorting order** tab to define the order of the test results in the report.
- 11. Select a test or empty row.
- 12. Click Add.



Repeat steps 11 and 12 until the test sorting order is defined.

You can change the order of tests by dragging the added items in the list.

13. Click Save.

18 Configuration

Reference ranges

14. Take the report template into use in the F5 > Configuration > **Reports** tab.

See Reports on page 106.

You can see the template preview on the right side of the view and it is updated after every modification.

Reference ranges

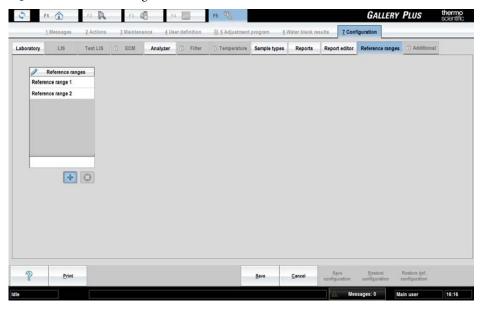
The reference range names are created in this view. They are defined into use for the test in F3 > Test Definition > **Limits** and attached to the sample in F2 > **Samples**. To create reference range names:

- 1. Select F5 > Configuration > **Reference ranges**.
- 2. Click the add icon.
- 3. Enter the name of the reference range in the text box.
- 4. Press Enter.

The program shows the created name in the list.

- 5. Repeat steps 2 and 3 until all the reference ranges are created.
- 6. Click Save.

Figure 44. Reference ranges



Barcode specification

Note It is strongly recommended that the laboratory employs check digits (CLSI AUTO02-A2) for ensuring the integrity of the sample identification process.

The analyzer supports the following barcodes:

- Code 128
- Code 39
- Codabar
- Interleaved 2 of 5

Code 128 is recommended; all other barcode types should be replaced with Code 128 according to CLSI AUTO2-A2.

Barcode placement

The center of the label should be placed at the center of the placement zone. The label should be applied below the top 14 mm of the tube and above the bottom 20 mm of the tube according to CLSI AUTO2-A2. The label width must be 5 mm less than the circumference of the tube according to NCCLS AUTO02-A2.

The label skew shall be less than \pm 5° according to NCCLS LIS7-A and less than \pm 7% according to CLSI AUTO2-A2 with respect to the axis of the sample container.

Figure 45. Correct placement of barcode according to CLSI AUTO2-A2

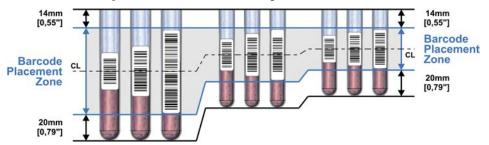
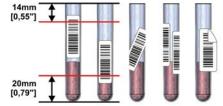


Figure 46. Wrong placement of barcode

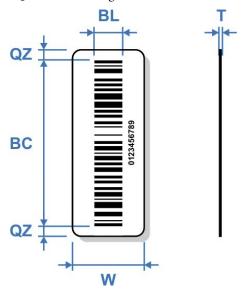


Reading zone

The minimum length of the barcode is 10 mm and minimum width is 5 mm less than the circumference of the tube according to NCCLS LIS7-A. The minimum number of characters is

3. The quiet zone must be at least ten times the minimum width of the narrow bar $(10 \times 0.127 \text{ mm})$ or greater) according to CLSI AUTO2-A2. According to the manufacturer of the barcode reader, the recommended quiet zone with the barcodes is 3.5 mm (0.14 inch) in the barcode label on both sides of the barcode.

Figure 47. Reading zone



BC - Barcode

- min. line thickness: 0.127 mm (5.9 mil)
- min. number of characters: 3
- BL Barcode length: min. 10 mm (0.4 in.)
- QZ Quiet zone: recommended 3.5 mm (0.14 in.)
- T Label thickness (including adhesive): max. 0.090 mm (3.6 mil)
- W Label width: 5 mm (0.2 in.) less than the circumference of the tube

Other Requirements

- The minimum width of a narrow bar is 0.127 mm (CLSI AUTO2-A2).
- The thickness of the label and its associated adhesive shall be less than 0.090 mm (CLSI AUTO2-A2).
- No more than four labels, including the manufacturers label, should be affixed to a tube. The maximum thickness of all labels is 0.36 mm (14.2 mil). (CLSI AUTO2-A2)
- The barcode print quality shall be at least of quality C according to ANSI X3.182-1990.
- Label opacity must be sufficient to prevent the reading of any barcode printed on an underlying label. The recommended label opacity is 90% or greater. (CLSI AUTO2-A2).

References

- CLSI AUTO2-A2: Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard – Second Edition CLSI 2006.
- NCCLS LIS7-A Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory, American Society for Testing and Materials 2003.
- ANSI Standard X3.182-1990 Bar Code Print Quality Guideline, American National Standards Institute 1990.
- Scanteam 3600 Technical Manual, Welch Allyn, Rev. C, p.3-7.

Glossary

6

60-cell storage Sample prep block; intermediate storage for sample in the sample pretreatment procedure
В
BCM Bitterness Column Module
C
CLRW Clinical Laboratory Reagent Water
CLSI Clinical and Laboratory Standards Institute
D
DB Database
G
GLP Good Laboratory Practices
1
ID Identification
L
LIS Laboratory Information System
Q
QC Quality Control

S

SD Standard Deviation

U

UPS Uninterruptable Power Supply