thermoscientific

Reference manual
Gallery

Version 6.0

N11481 Revision A • October 2016

Thermo Fisher
SCIENTIFIC

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
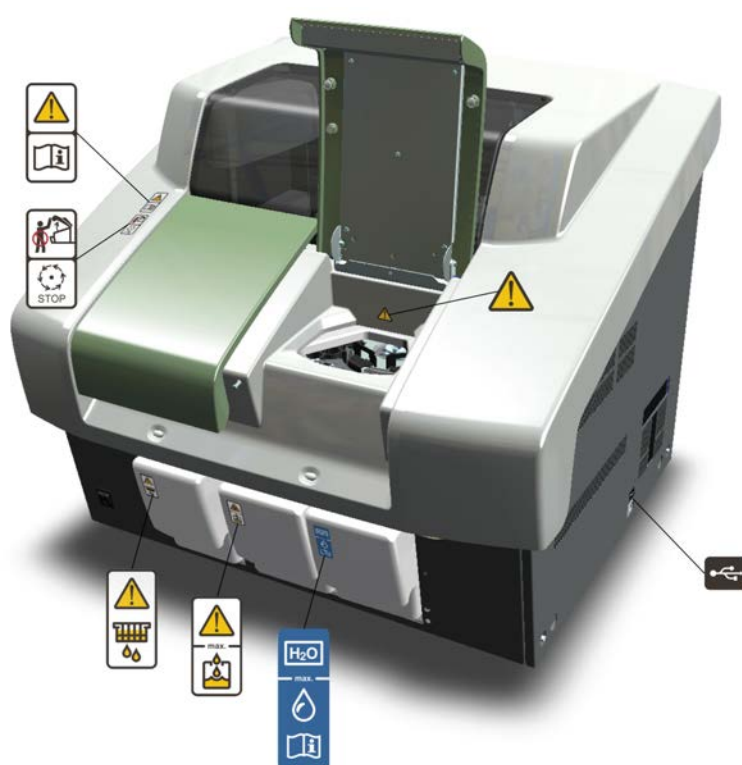
Safe operation	
	Warning Follow the instructions to ensure the correct and safe operation. All surfaces under the main cover are potential sources of toxicants and irritating biological agents. Use protective gloves, spectacles and clothes.

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

[USB icon]	**Information** Use only for connection between the analyzer and workstation. The maximum length of the USB cable is 2 meters.

Figure 2. Safety labeling inside analyzer
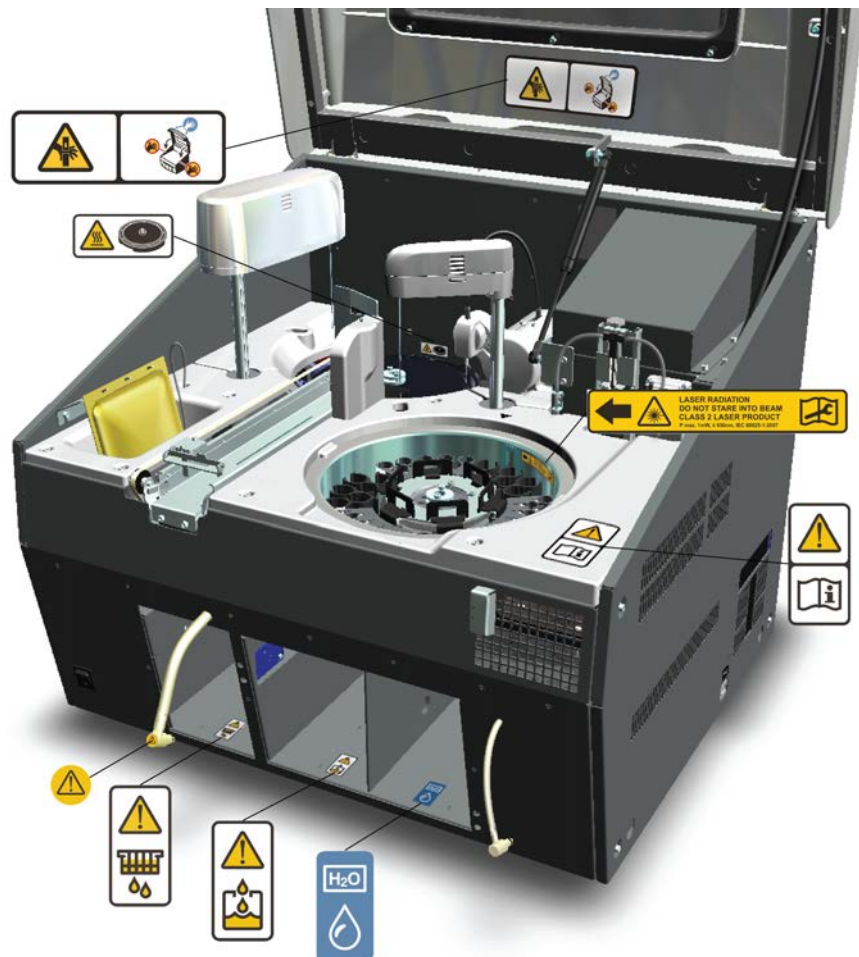
Safe operation

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 3. 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

LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT
P max. 1mW, λ 650nm, IEC 60825-1:2007

Caution

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

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.

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

$C\epsilon$	The CE mark attached on Gallery (chemistry analyzer, type 861) 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.

Contents

Contents

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 is a discrete, automated chemistry analyzer. In addition to photometric measurement, the analyzer supports electrochemical measurement (ECM) technique.

Gallery is specifically designed e.g. for food, beverages, water, environmental and different bioprocess applications. Thermo Scientific Gallery is offered with various system applications. Furthermore, the analyzer supports user definable application setup.

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.

- 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/July 2010	N11481	1.0	Document created.
B/September 2010	N11481	1.0	Additional information added about ECM measurement.
A/December 2010	N11481	2.0	Additional information added about new features.
A/July 2011	N11481	3.0	Information about maintenance and archive features, standard addition method and ECM measurement updated.
A/February 2012	N11481	4.0	UPS recommendations and information about the system water action in defining test flow added.
A/July 2012	N11481	4.1	Information about ECM measurement and system configuration updated.
B/October 2012	N11481	4.1	PC configuration and instructions for clearing daily files updated.
A/June 2013	N11481	5.0	Information about dilution and configuration updated.
A/October 2013	N11481	5.1	Checked the content against 5.1 software.
B/December 2013	N11481	5.1	Added a disclaimer note in Creating test procedure section.
A/July 2014	N11481	5.2	Checked the content against 5.2 software.
A/June 2015	N11481	5.3	Updated configuration settings and instructions for restoring default database. Added new result units. Updated contact information.
A/October 2016	N11481	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.

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`.

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 3rd 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	75 cm	29.5 in
Height (cover closed/open)	62 cm / 130 cm	24.4 in / 51.2 in
Depth	70 cm	27.6 in
Weight	85 kg	187.4 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%

Description	Value
Power consumption	250 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 ºC
- Relative humidity: 40 - 80%, non-condensing
- Altitude: < 2000 m from the sea level
- Heat output: 480 (without ECM) / 550 (with ECM) 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	≥ 10 MΩ · cm referenced to 25 ºC
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 test procedure:

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.

Figure 4. 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:

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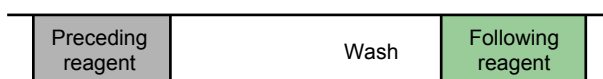
- Always before dispensing the next reagent if the previous dispensed reagent was the Preceding reagent and Following reagent is "All".

Preceding reagent	Wash	Any reagent

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

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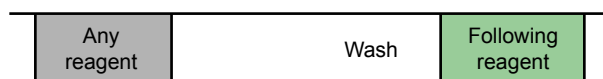
- Always before dispensing Following reagent if wash is "Reagent (large)". In the Reagent (large) wash, Preceding reagent must always be "All".

Any reagent	Wash	Following reagent

- If previous dispensing was sample dispensing, wash will not be done.

Preceding reagent		Sample		Following reagent
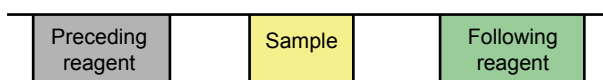
- If previous and next dispensings belong to same request, wash will not be done.

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 µl of wash reagent, which is aspirated up to 300 µl 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.

- 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 µl) is performed. This is followed by the small wash with the reagent (30 µl) 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 5. Defining extra wash
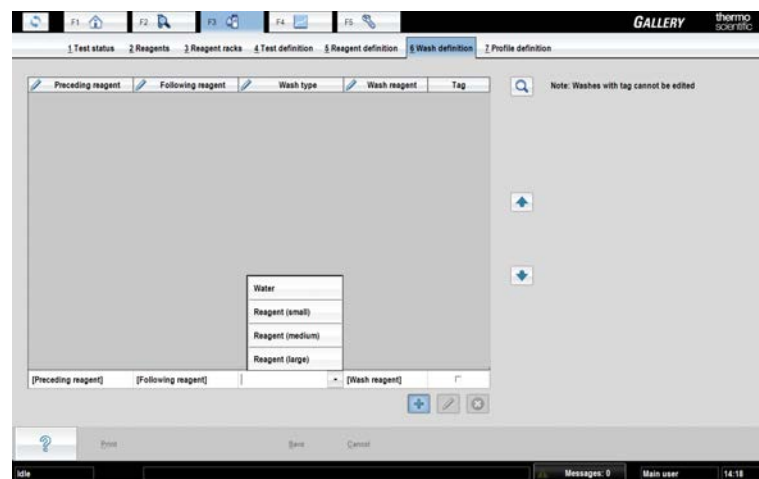
Clot detection

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 6. **Calibrator definition** view
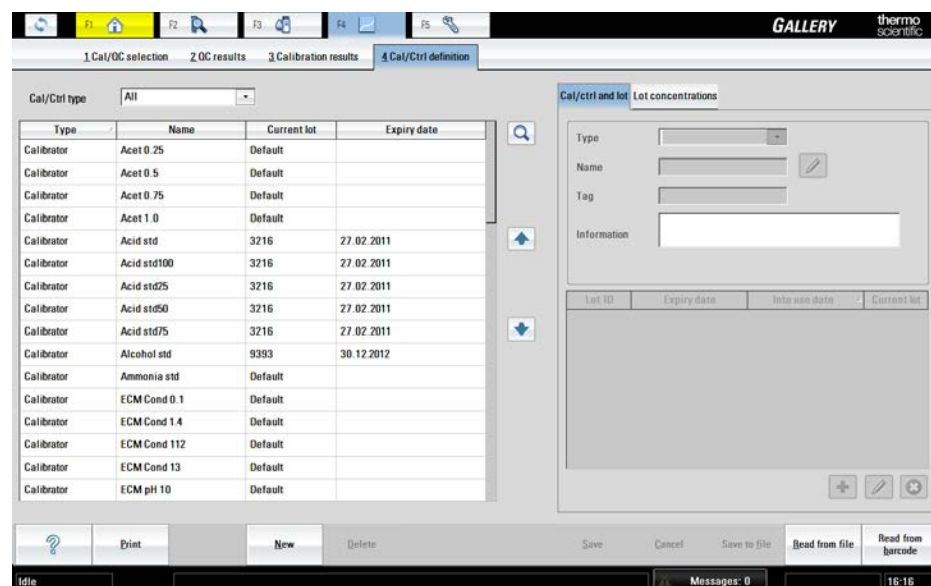
- Defining calibrators

- 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 7. Defining concentrations
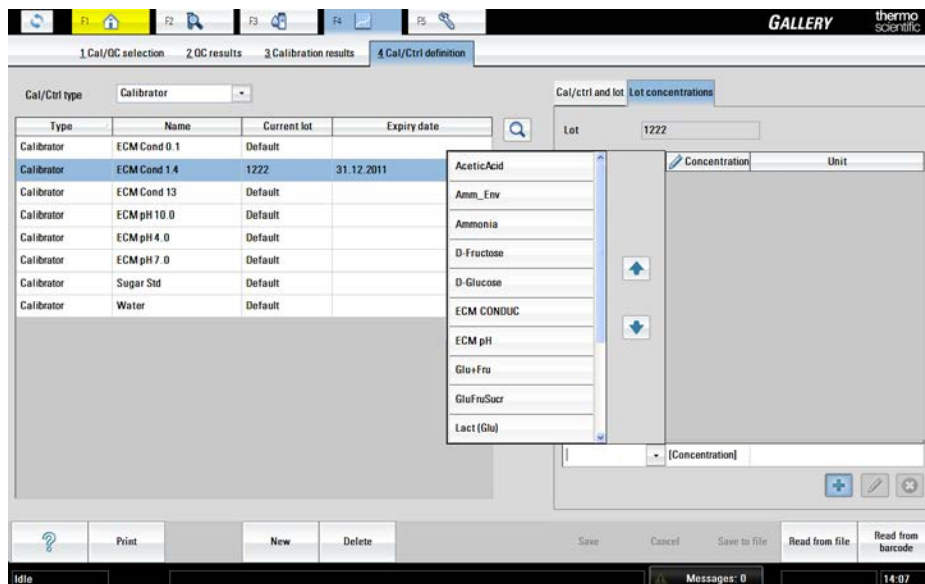
Saving lot values to file

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**.
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 8. **Control definition** view
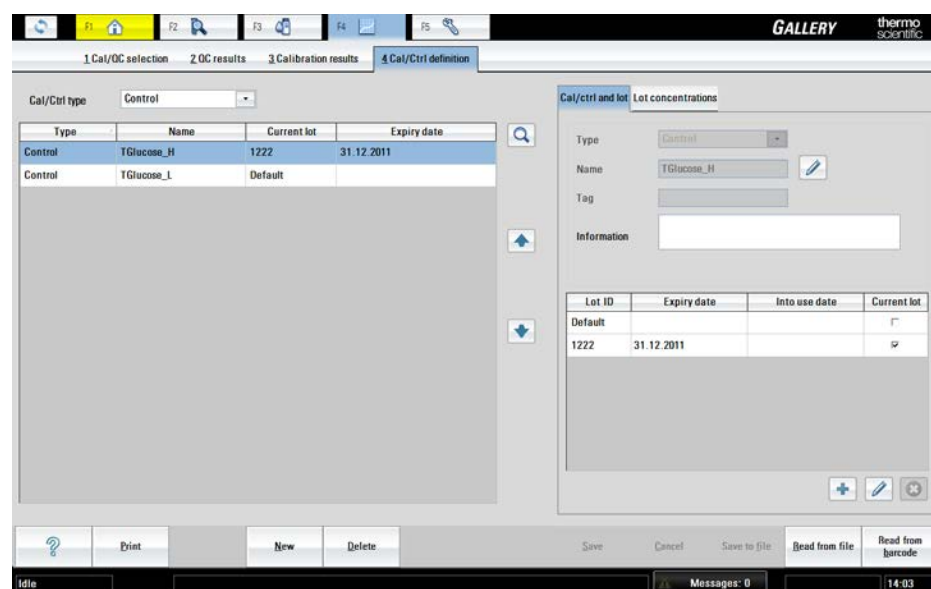
- Creating quality control profile

- 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 36.

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 9. **Quality control profile** view
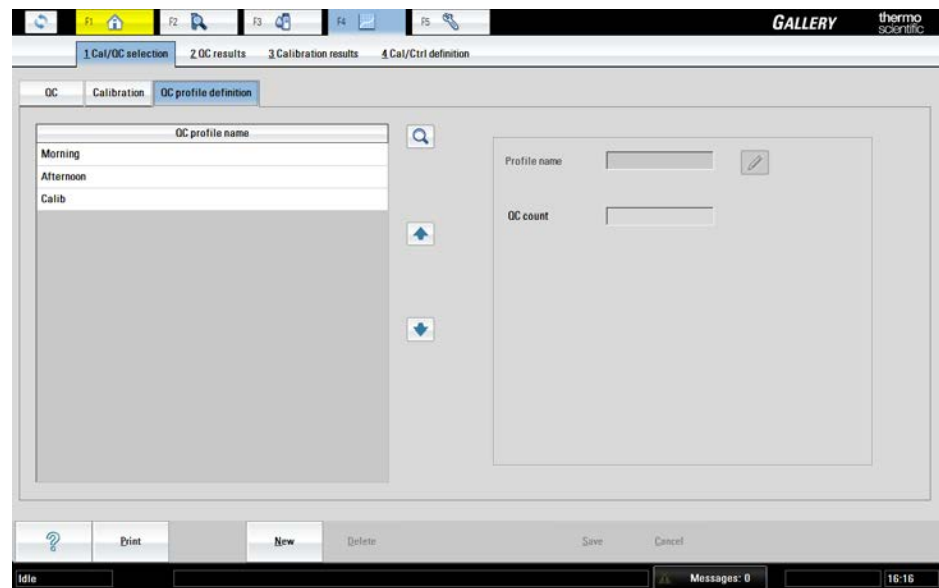
Defining quality controls

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.

Figure 10. Defining concentrations
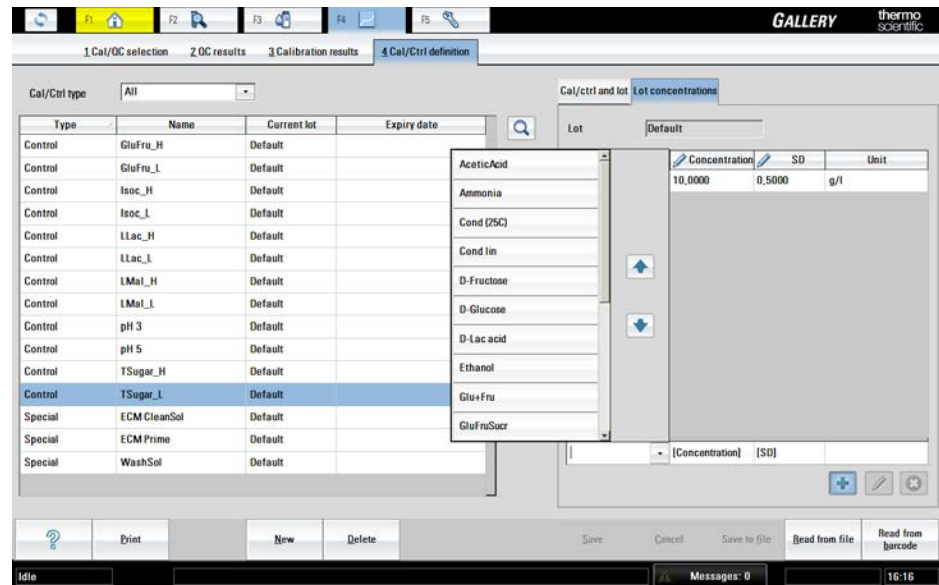
Saving lot values to file

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**.

Test definition

- 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
- ECM
- External
- Calculated

Figure 11. Defining test
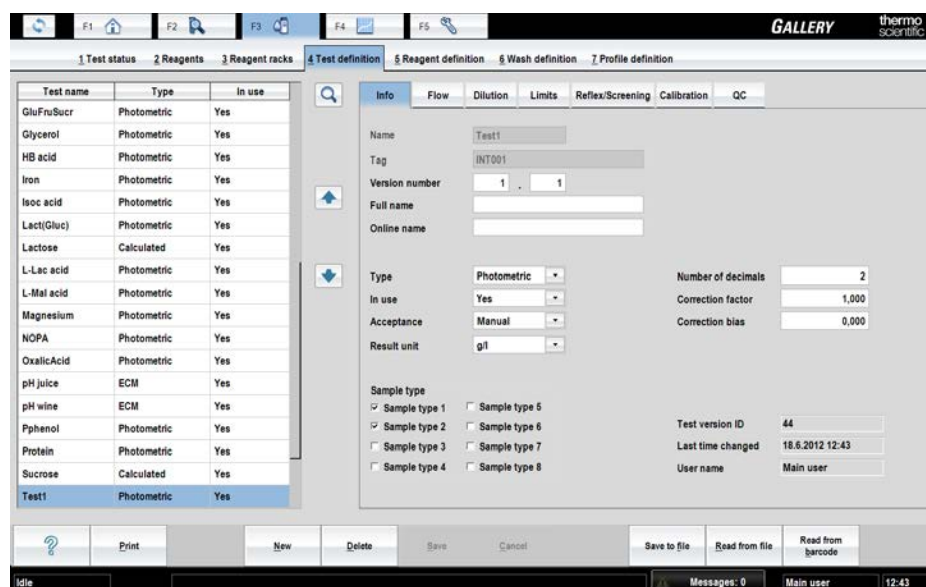
The test definition view consists of different parameter groups and depending on the test type, different tabs and parameters are enabled.

- 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 and ECM tests.
- The **QC** tab shows the quality control parameters for photometric and ECM 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 6. Test types and related tabs

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

General parameters

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

Table 7. 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.
Type	Photometer, ECM, 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/ml, g/l, g/dl, mg/l, mg/dl, mg/ml, µg/l, µg/dl, 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 8. 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.

Parameter	Description
User name	Shows the user who modified the test definition the last time.

Table 9. Parameters for photometric tests

Parameter	Values	Description
Sample type	Sample type 1-8	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 10. Parameters for ECM tests

Parameter	Values	Description
ECM electrode	Red, Yellow, Grey, Blue, White, Green, Conductivity	Select which electrode is used in a test. One test per sample type can be connected to one electrode.
ECM sample type	Sample type 1-8	Select the correct test type for an ECM test. One test per sample type can be connected to one electrode.
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 11. 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

Parameter	Description
	– - subtraction
	* - multiplication
	/ - division
	Use brackets () if an operation must be calculated before another. For example,
	(<A>/<B>)*<C>
	First, A is divided by B and then the result is multiplied by C.
	<A>/(<B>*<C>)
	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 or ECM test, select F3 > Test definition > **Dilution**.

Figure 12. Defining dilution parameters
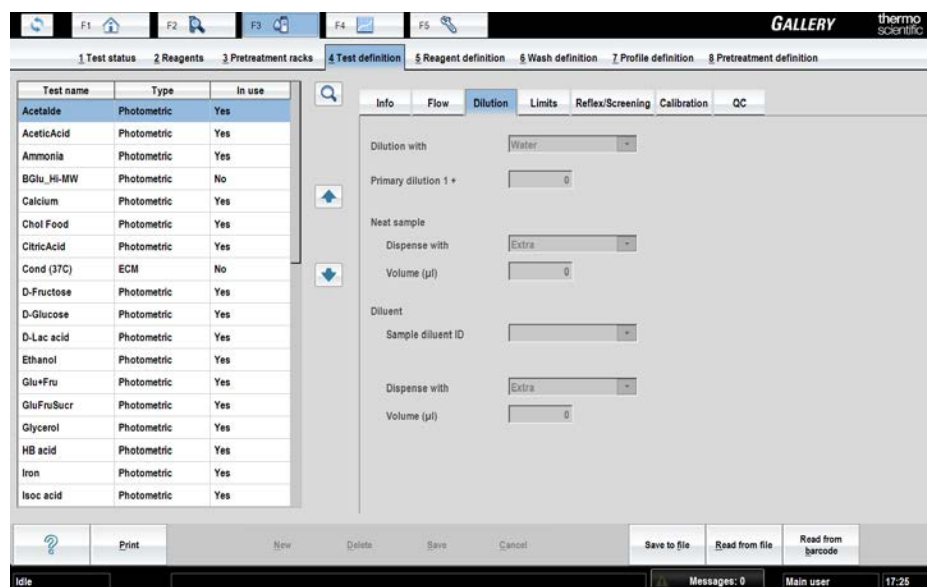
Table 12. Dilution parameters for photometric test

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.

Parameter	Values	Description
		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 *Primary dilution*.
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.
		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 µl.
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 13. Defining limit parameters
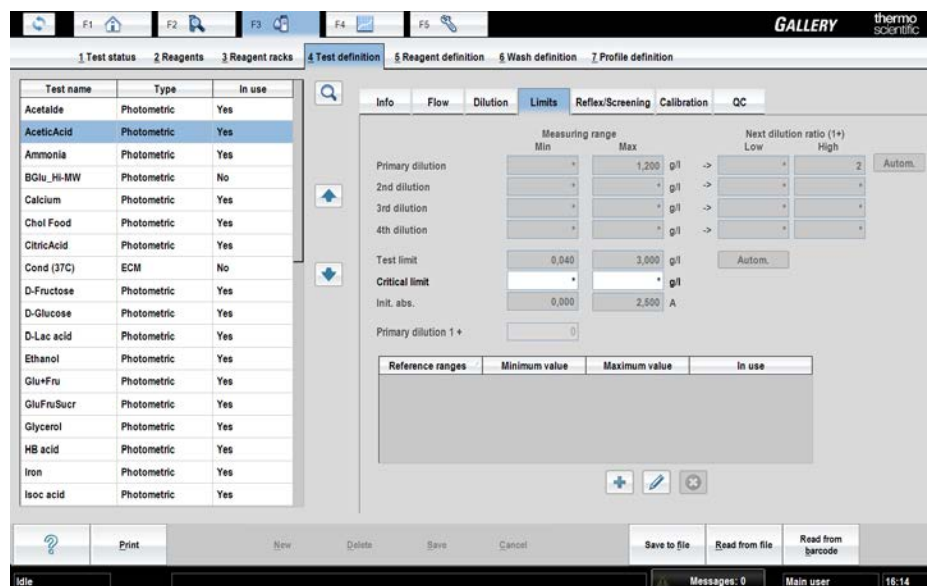
The analyzer supports high dilution ratios for samples. If the dilution steps are defined, separate steps are performed automatically until the required dilution ratio is reached and the result is within the limits or until the test has been analyzed using the last defined dilution ratio.

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 13. 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 *Test limit* has been exceeded, it is shown in the *Results view* and the result must be accepted manually. If the dilution steps have been defined, the *Test limit Max* must be equal or higher than the highest dilution limit, and the *Test limit Min* 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 test. If a test result is not within the limits, it must be accepted manually. It is not recommended to set the |

Parameter	Description
	lower limit to 0, because then the zero results cannot be detected: the critical limit error is raised but the result is still shown.

Table 14. Read-only parameters for photometric tests

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

Table 15. Limit parameters for photometric tests

Parameter	Description
Primary dilution, 2nd dilution, 3rd dilution, 4th dilution	The *Measuring range* values must be within the *Test limit*'s value range.
	Define the *Min* value and/or *Max* value for the *Primary dilution* when needed. The *Max* value can always be defined, but the *Min* value can only be defined if the *Primary dilution* defined in the *Dilution* tab is > 0.
	The other dilution limits in the *Min* and *Max* fields of *Measuring range* are calculated according to defined *Next dilution ratio* 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 *High* has to be higher than primary dilution but less than or equal to the maximum allowed value (9999). The value of *Low* 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)
	• 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 *Low* field has to decrease and the value in the *High* 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 16. 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 *Test limit*'s minimum and maximum value. If the sample result is below the *Minimum value*, 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 *Test limit*'s minimum and maximum value. If the sample result is above the *Maximum value*, 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 *In use* parameter.

Parameters for reflex test

To define reflex and screening parameters for a photometric or ECM 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 14. Defining reflex test parameters

Table 17. 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.
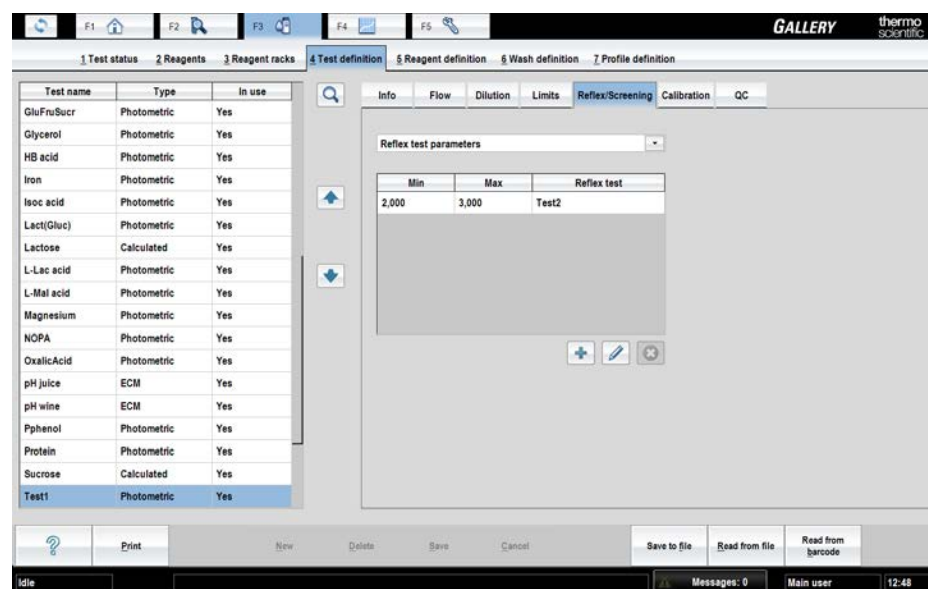
Parameters for calibration

To define the calibration parameters for a photometric or ECM 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**.

Figure 15. Defining calibration parameters

Table 18. 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.

Parameter	Values	Description
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.
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. (photometric) Slope limit min. / Slope limit max. (ECM))		Define the maximum and minimum limit for the factor/slope. If an asterisk (*) is used, the checking is not in use.
Bias limit min. / Bias limit max. (photometric) E^0 limit min. / E^0 limit max. (ECM)		Define the maximum and minimum limit for the bias/E^0. 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

Parameter	Values	Description
		equation is used. Otherwise, the 2nd 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 the list.
✏️		Edit existing row in the list.
✖️		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**.
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 or ECM 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**.
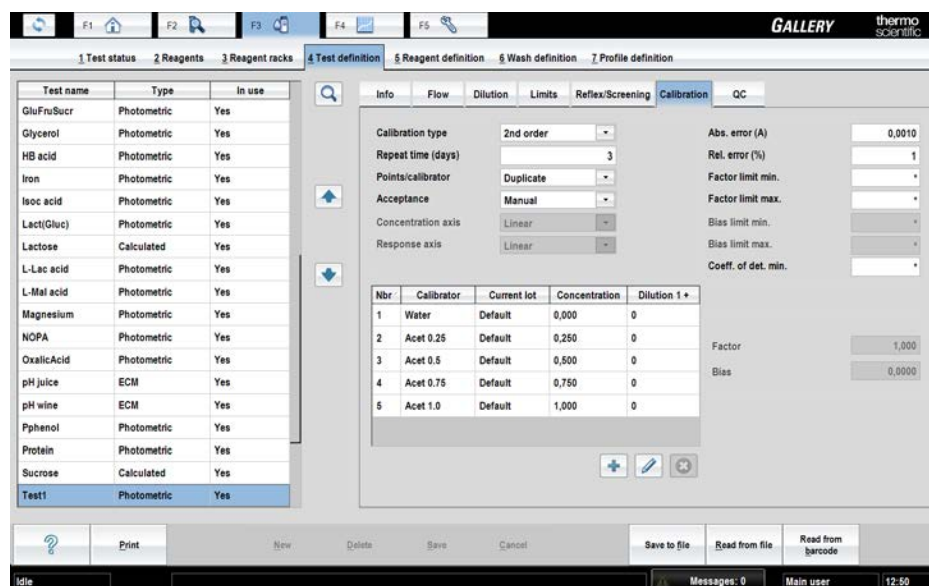
Figure 16. Defining QC parameters
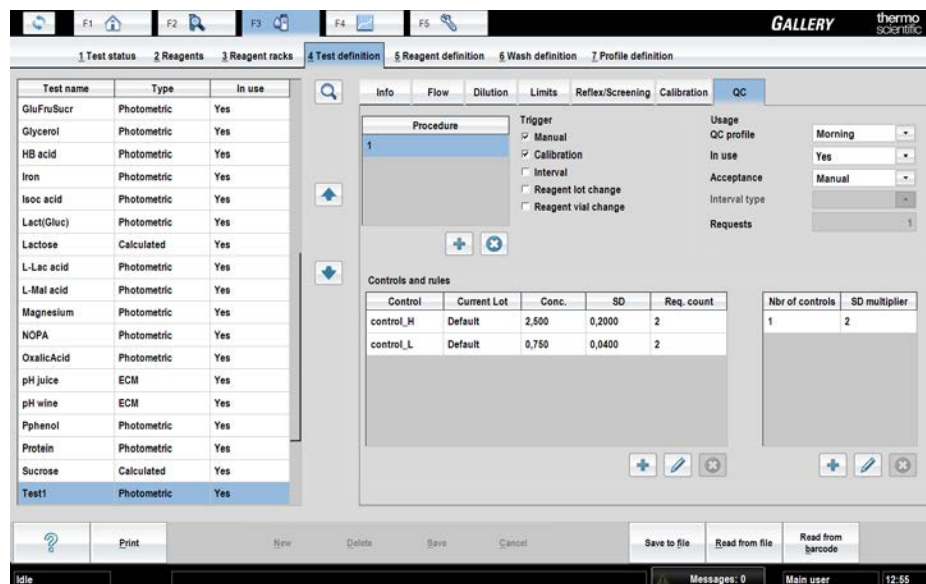
Table 19. Quality control parameters

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.

Parameter	Values	Description
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 *Trigger* parameter and the value "Requests" is set to *Interval type* , the quality controls are run after defined number of requests. For example, if the value is set to "20" for the *Requests* parameter, the quality control is run for every 20th request.
Time (hh:mm)		If the value "Interval" is set to *Trigger* parameter and the value "Time (hh:mm)" is set to *Interval type* , the quality controls are run after defined time interval. For example, if the value is set to "02:00" for the *Time (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**).

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:

$$X{:}y \ SD$$

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`.

Figure 17. 4:1 SD rule violation
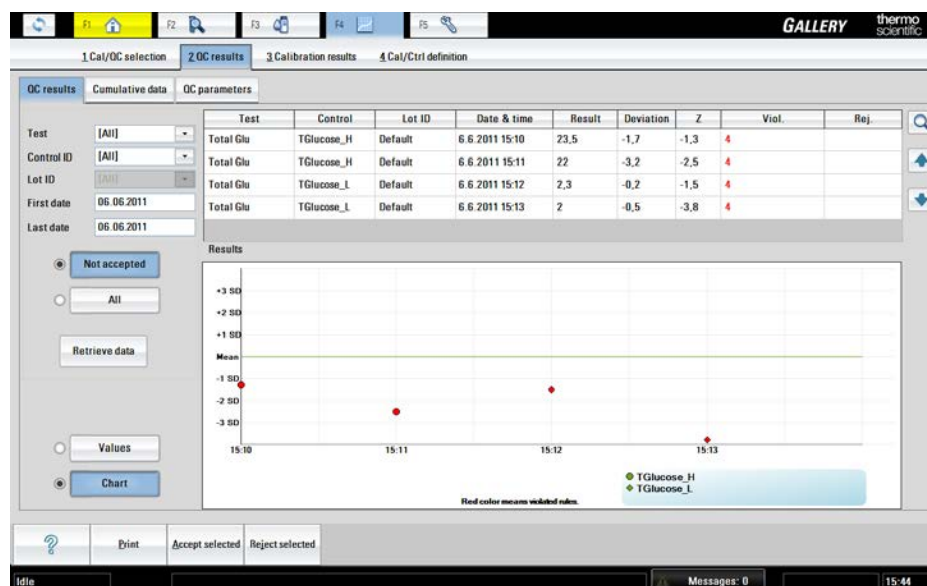
❖ **Number of controls is less than batch size**

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`.

Figure 18. 2:2 SD rule violation
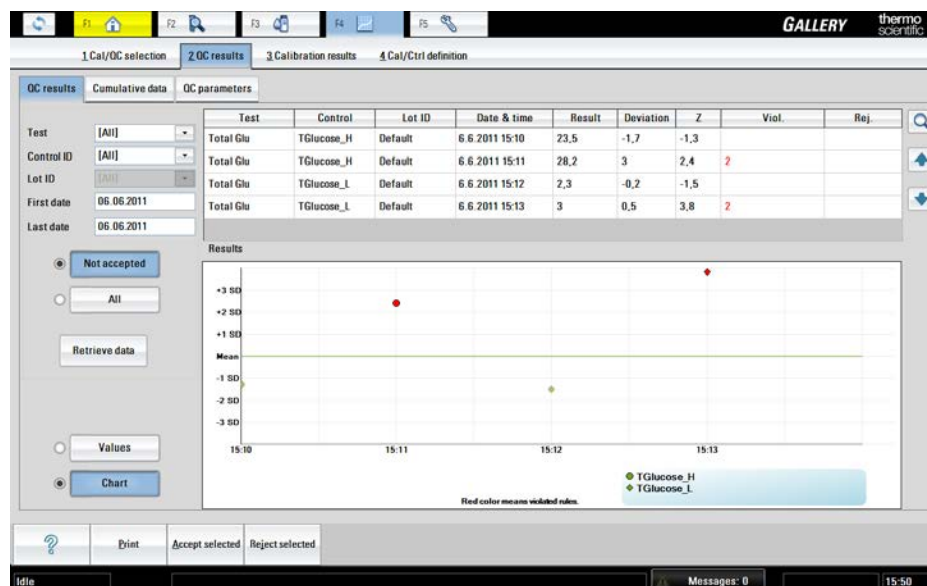
❖ **Number of controls is one**

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 19. 1:2 SD rule violation
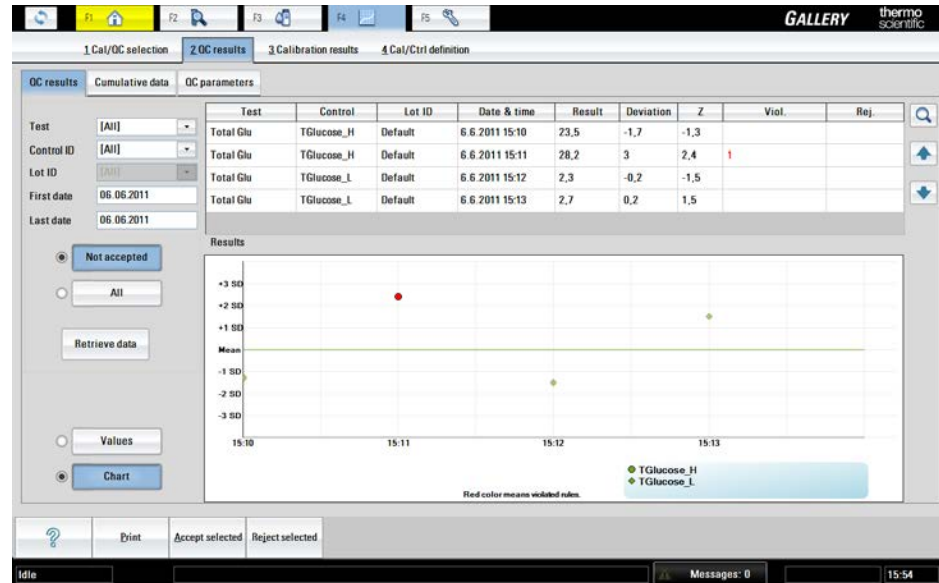
❖ **All results are lower or higher than control value**

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 20. 6:0 SD rule violation
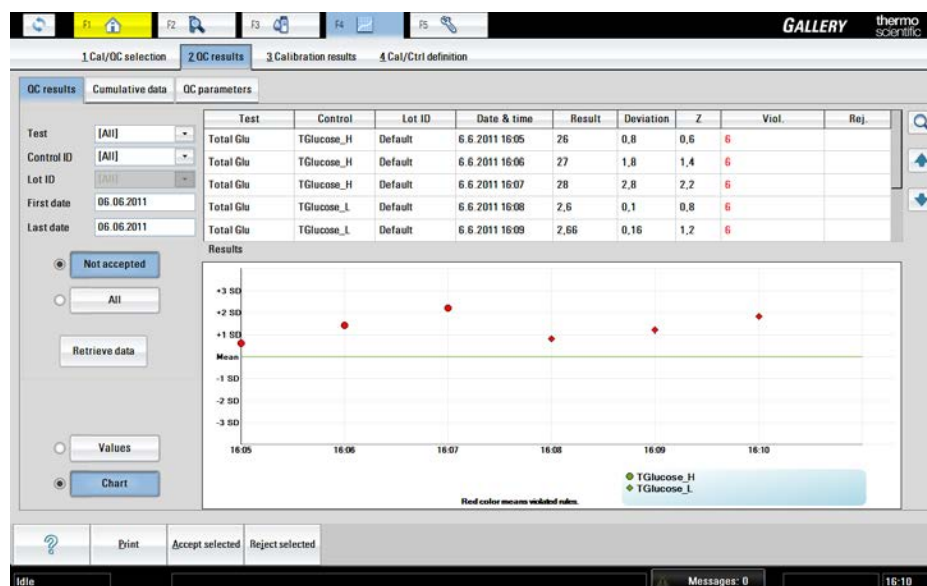
❖ R rule

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 21. R:4 SD rule violation
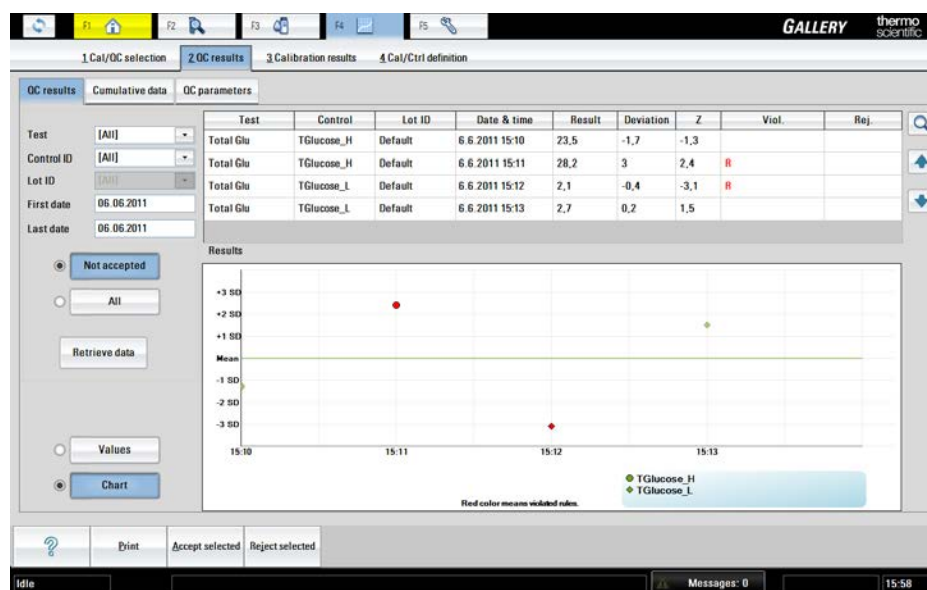
Defining test flow

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.

Figure 22. 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.
		"True sample" - The blank is measured in a separate cuvette position. In the blank measurement, the test reagent is replaced with a selected

Parameter	Values	Description
		blank reagent. The test flow requires one measurement for the sample.
Primary dilution 1+		A read-only parameter. Shows the total dilution of the sample.
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 43.
Dispense with	Water, Extra	Define whether the reagent is dispensed with water or reagent extra.
Extra volume (µl)	See Reagent dispensing on page 43	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 *Blank Type* is "True sample", define a replacing reagent for the reagent dispensing. Select the reagent from the drop-down menu.

Table 20. 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

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 µl for a single dispensing. When dispensing twice, the total volume can be 240 µl.
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.
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 21. 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.
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 22. End-point measurement

Parameter	Description
Main wavelength	Select the main wavelength from the drop-down menu. The alternatives are set by the manufacturer.

Parameter	Description
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.
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.
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.
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, 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.

Parameter	Values	Description
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.

Standard addition

> **Note** Standard addition can only be performed with photometric tests.

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**.

Figure 23. 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 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.
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.

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 24. Managing test profiles
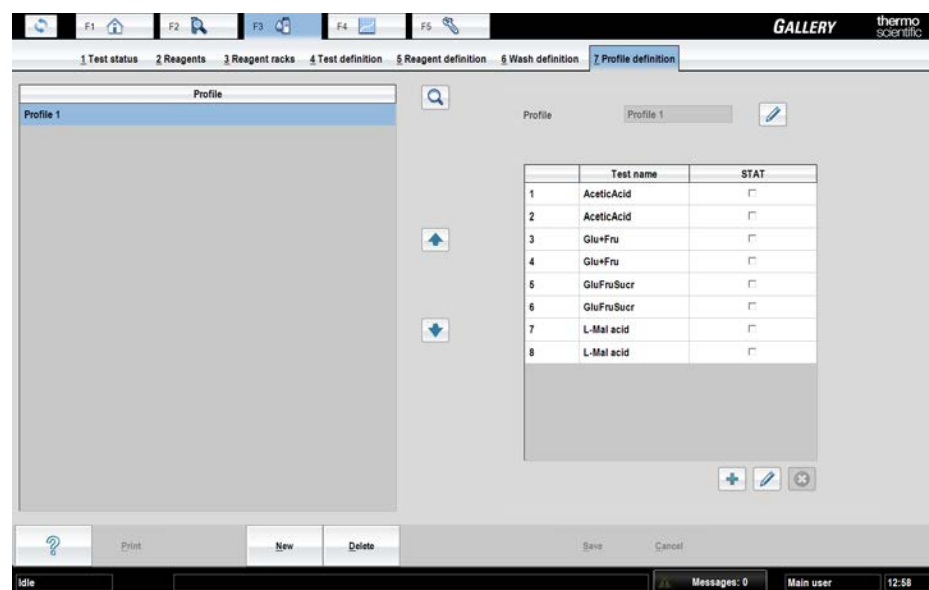
Photometric measurement

- 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 25. Analysis process
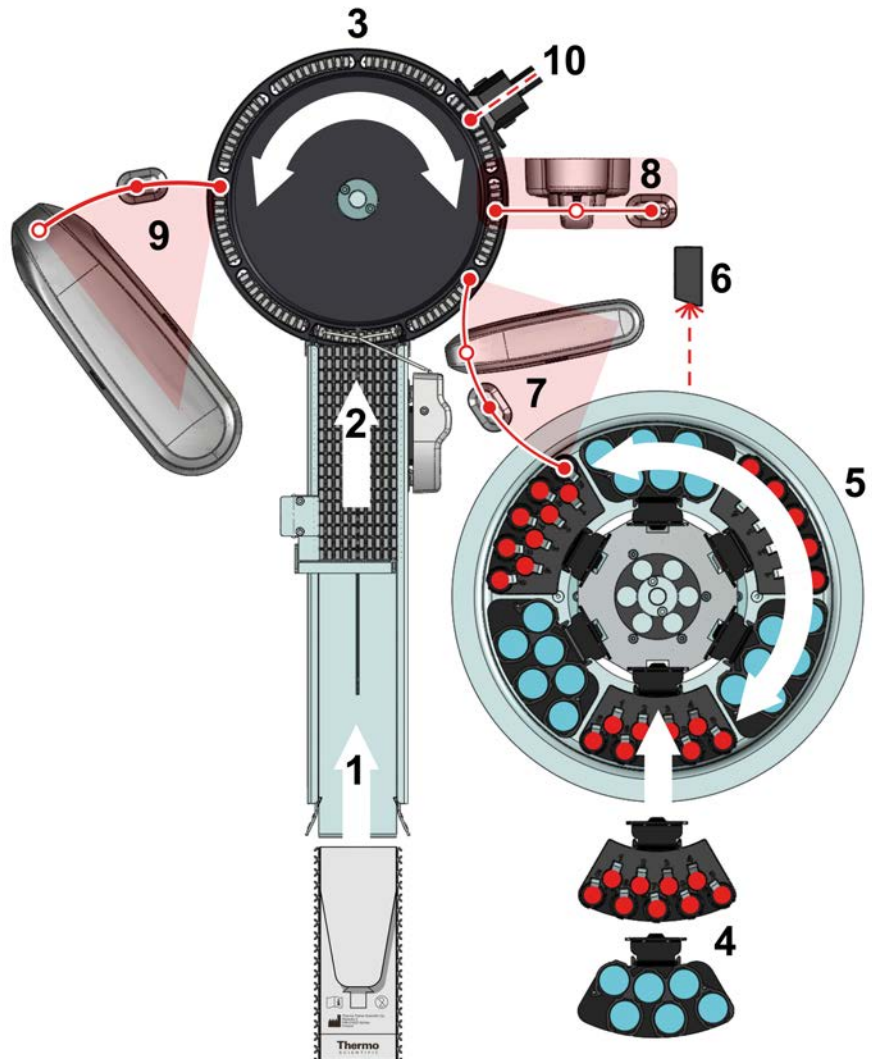
1 - DECACELL™ cuvettes entry point
2 - Cuvette loader
3 - Incubator
4 - Sample and reagent racks
5 - Sample and reagent rack disk
6 - Barcode reader
7 - Sample and reagent dispenser
8 - Mixer
9 - ECM dispenser
10 - Photometer unit

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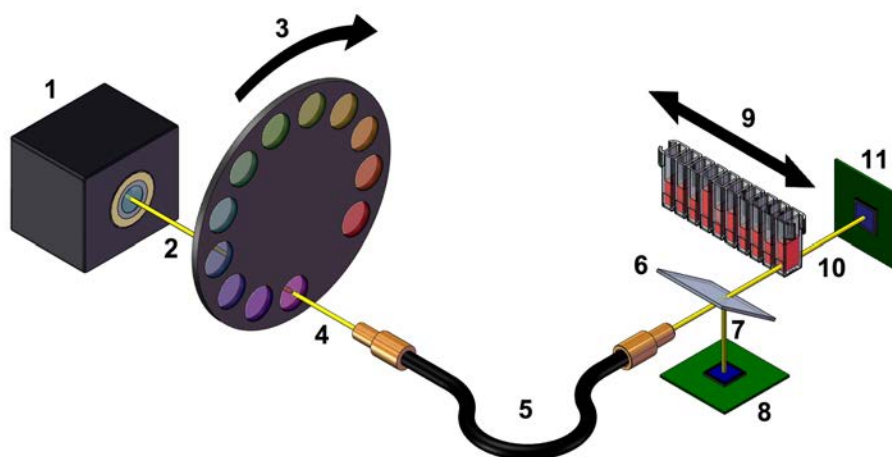
1 - Light source
2 - Light beam
3 - Filter disk
4 - Filtered beam
5 - Optical fiber
6 - Beam splitter
7 - Reference beam
8 - Reference detector
9 - Cuvette
10 - Signal beam
11 - Signal detector

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:

$$A_R = \frac{\log_{10}\left(\dfrac{I_R}{I_S}\right)}{0.675}$$

A_R - raw absorbance
I_R - measured light intensity from reference channel
I_S - 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:

$$A = A_R - A_{WBL}$$

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.

◆ - 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.

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

$Response_{\text{ActualMeas}}$ - response of actual measurement
$Response_{\text{Blank Meas}}$ - 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 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 ($\Delta Response_{\text{first}}$) and the last ($\Delta Response_{\text{last}}$) points.

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

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

$$Linearity\_error = \text{Abs}\left(Result_{\text{first}} - Result_{\text{last}} \right)$$

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

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 63 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:

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

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:

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

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.

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

$\Delta Result$ = 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

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

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

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

Logit-Log 5

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

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

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.

$$Result_{\text{corrected}} = Result_{\text{measured}} \cdot \left(1 + AutomaticDilutionRatio \right)$$

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.

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

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.

$$Result_{\text{AfterManualDilution}} = Result_{\text{AfterAutomaticDilution}} \cdot \left(1 + ManualDilutionRatio \right)$$

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

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

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:

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

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:

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

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:

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

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.

Figure 27. Point error
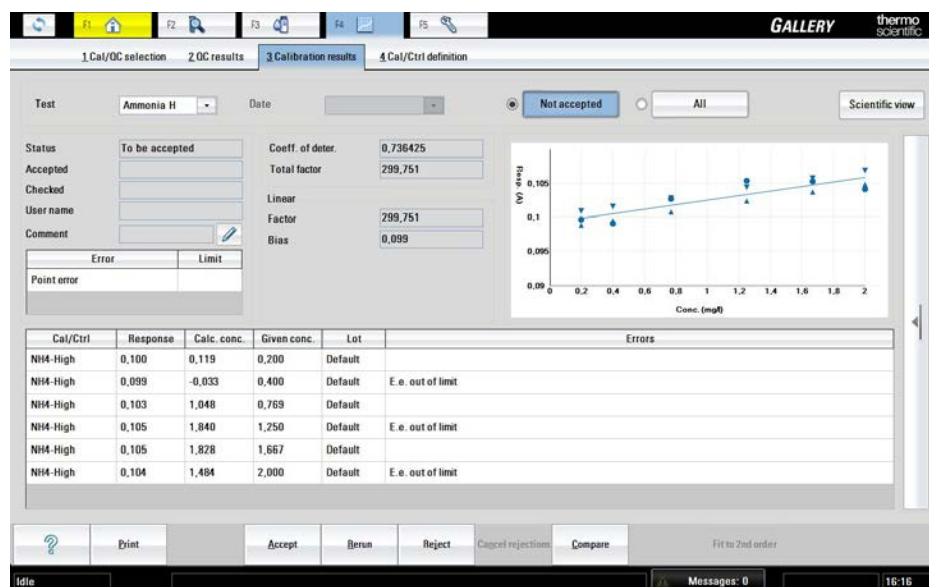
Factor calibration calculation

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

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 2nd 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.

Δ*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.

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.

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

Δ*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.

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

Δ*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

Δ*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.

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

Δ*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:

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

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.

Figure 28. Valid spline calibrator curve
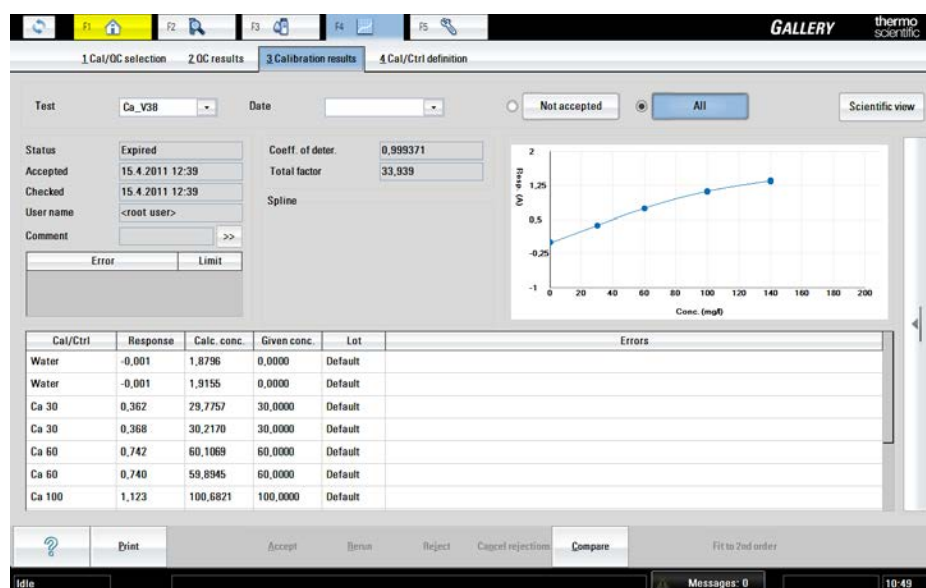
Checking spline calibration

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.

Δ*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:

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

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.

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

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

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

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
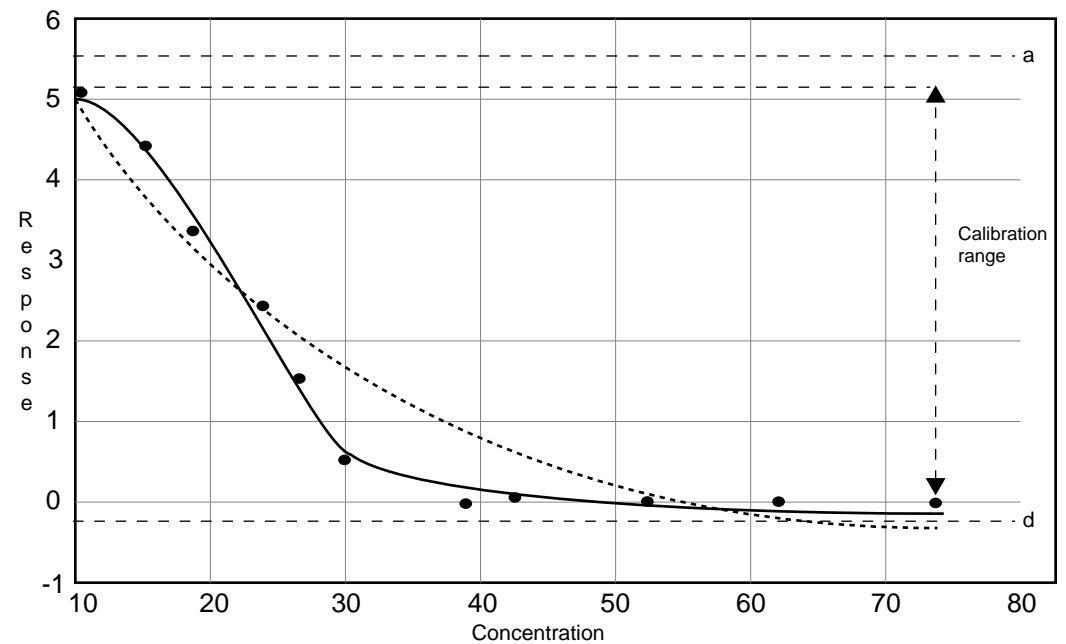
●	Measurement points
....	Fitting using the least square method

<u>   </u>　　Fitting after iterations

Checking 4-parameter logit calibration

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

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

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.

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* ∈ **R**
b, c, e > 0
Result ≥ 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.

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

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.

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
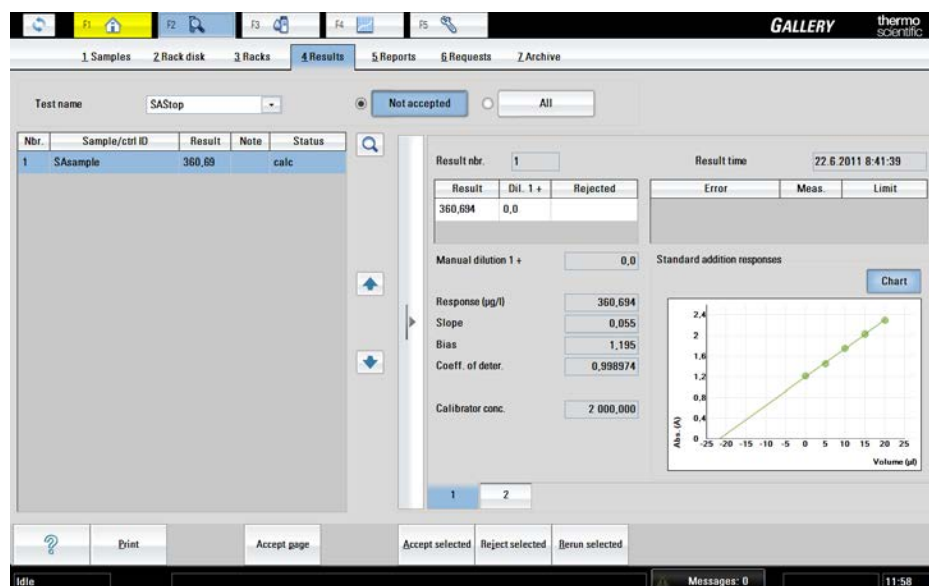
Result calculation in standard addition

Linear regression uses the following equation:

$$S = m V_{Std} + b$$

S = instrument response (signal)
m = slope
V_{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_S = volume of sample aliquot
V_{Std} = volume of standard
c_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:

$$c_S = \frac{b \cdot c_{Std}}{m \cdot V_S}$$

c_S = concentration of the sample
b = y-intercept
c_{Std} = concentration of the standard
m = slope
V_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.

ECM measurements

The analyzer measures pH and conductivity in beverage and environmental water samples.

The conductivity measurement is performed via two electrodes placed in the middle of the ECM block and at the end of the ECM block in the probe side, between which the application of a sine wave potential gives rise to a current, from which measurement the sample conductivity can be calculated. The pH measurement is performed with a pH-sensitive glass electrode versus a Ag/AgCl reference electrode. Both electrodes are part of a block additionally consisting of one spacer slice. The potentials produced at the glass membrane are measured once per second until the measurement algorithm confirms a stable response. The measured sample conductivity and pH are compared to calibrators.

One dispensing arm and one pump are provided for the ECM measurements in the analyzer. A sample is aspirated through the probe from the sample cup or test tube via a cuvette cell in the incubator. The sample is moved to the electrode block where the measurement takes place.

The cuvette is moved from the loader into a free slot in the incubator. The incubator rotates the cuvette to a dispensing position where the dispensing arm dispenses the sample. Then the incubator rotates the cuvette to the final position so that the ECM dispenser can aspirate the contents of the cuvette.

The ECM unit aspirates several sample buffers (separated by air buffers) to clean out any remaining contaminants and the ECM rinse liquid, after which it aspirates the main 80 µL sample.

Sample conductivity is measured first immediately followed by the pH measurement from the same sample. Sample measurements are followed by ECM block rinsing with the ECM rinse liquid. The ECM dispensing pump transfers ECM rinse liquid from the bag to the block, washing out the previous sample into the waste well and preparing the unit for the next sample.

Block washing is performed during the standby operation. The tubes and the measurement channel of the ECM block are washed with washing solution. The solution is dispensed via the dispensing arm into a cuvette cell from where the ECM probe aspirates it into the block. From there it is pushed by the ECM washing pump into the wastewater container. This is followed by second-stage washing with cleansing solution, which is necessary for proper pH electrode function.

- pH
- Conductivity

pH

pH is defined as *pH = -log a_H*, where a_H is the relative activity. The quantity pH is a measure of the activity of hydrogen ions in solution. pH is measured using a two-electrode galvanic cell: the indicator pH electrode and the reference electrode. The cell potential developed is dependent on both electrodes. The measured potential can be expressed by the Nernst equation as follows:

$$E = E°_T + \frac{RT}{F} \ln a_{H^+}$$

E - measured potential (V)
$E°_T$ - temperature dependent constant (V) determined in the calibration
R - gas constant (8.31 J/(mol·K))
T - temperature (K; $T_{°C} = T_{°K} - 273$)
F - Faraday constant (96500 C/mol)
a_{H^+} - activity of hydrogen ion

Switching to the base ten logarithms, the formula can be rewritten.

$$E = E°_T + 2.303 \cdot \frac{RT}{F} \log a_{H^+}$$

Using the definition pH = -log a_{H^+}, pH can then be expressed at the temperature T as follows:

$$pH = \frac{E°_{Cal} - E}{S_{Cal}}$$

$E°_{cal}$ - the standard or asymmetry potential value at pH = 0 calculated from the calibration.
S_{cal} - the experimental slope calculated from the calibration, which also takes into account that the electrode response may differ from the theoretical value.

Stabilizing-parameters

As the measurement-loop runs, the result values for the pH measurement channel are stored in a channel result buffer. The stored points can be considered to define a curve. The shape of that curve is gradually converging to the horizontal as time advances, that is, as the slope of the curve diminishes. The channel is said to be 'stabilized' when the points do not differ from each other beyond the defined limits.

The slope of the curve generally gets smaller because of the characteristics of ion-selective electrodes. Values of succeeding points (*n*, *n+1*, *n+2*) do not necessarily increase or decrease consistently, however. This is why the buffer values must be fitted within windowed limits in any stability check.

There are several parameters which are used to determine the 'stability' of a channel. Parameters are of two distinct types:

- measurement times
- window limits, which set limits for the final (acceptable) slope of the curve

Calculations

Linear and point-to-point calibration

A linear calibration calculation is used when calibration types are "Bias" or "Linear". In a Bias calibration, the analyzer calculates E°_{cal} from a measurement in a single calibrator. The operator defines a theoretical, experimental or calculated slope. If the pH calibration is done using two calibrators, a linear calibration must be used. More than two calibrators requires a point-to-point calibration. The calibration type is definable in the **Calibration** tab under the **Test definition** view.

With a point-to-point calibration separate linear equations are generated between each set of two calibrators. For example if the calibration is done using five calibration levels, four separate equations are generated for the four linear segments.

$$E = E^\circ_T - S_{cal} \cdot pH$$

E - measured potential (V)
E°_T - temperature dependent constant (V) determined in the calibration
F - Faraday constant (96500 C/mol) S_{cal} - the slope is stated in units of mV per unit change of pH and is directly dependent on sample temperature

The calibration buffers and samples are always measured at the same temperature (within 0.5 °C) as long as the laboratory ambient temperature is within 18…30 °C. The buffers should ideally bracket the measuring interval; for instance, for sample measurements between pH 4.3 and 6.9, it is recommended to use a linear calibration with the pH 4.0 and 7.0 buffers. However, the software will generate results for samples outside of the measuring range along with a warning message informing the operator of this fact.

Table 23. pH values of pH standards at various temperatures

t(°C)	pH 2	pH 4	pH 7	pH 10	pH 12
20.0	1.68	4.01	7.01	10.06	12.53
21.0	1.68	4.01	7.01	10.05	12.51
22.0	1.68	4.01	7.01	10.04	12.50
23.0	1.68	4.01	7.00	10.03	12.48
24.0	1.68	4.01	7.00	10.02	12.46
25.0	1.68	4.01	7.00	10.01	12.45
26.0	1.68	4.01	6.99	10.00	12.43
27.0	1.68	4.01	6.99	9.99	12.41
28.0	1.68	4.01	6.99	9.99	12.40
29.0	1.68	4.02	6.99	9.98	12.38

t(°C)	pH 2	pH 4	pH 7	pH 10	pH 12
30.0	1.68	4.02	6.98	9.97	12.36
31.0	1.68	4.02	6.98	9.96	12.34
32.0	1.69	4.02	6.98	9.95	12.32
33.0	1.69	4.02	6.98	9.94	12.31
34.0	1.69	4.02	6.98	9.93	12.29
35.0	1.69	4.02	6.97	9.93	12.27
36.0	1.69	4.03	6.97	9.92	12.25
37.0	1.69	4.03	6.97	9.91	12.23
38.0	1.69	4.03	6.97	9.90	12.21
39.0	1.69	4.03	6.97	9.90	12.19
40.0	1.69	4.03	6.97	9.89	12.17
50.0	1.71	4.06	6.96	9.83	11.96
60.0	1.72	4.09	6.97	9.79	11.73

Temperature plays an important role with regard to sample and buffer pH and an electrode's characteristics. The temperature dependency of the calibration buffers is fully known and is available in table above. The pH variation due to temperature is minimal for inorganic acid buffers, whereas it is significant for alkaline buffers.

To define the buffer pH values, select F4 > Cal/Ctrl definition > **Calibration**. For instructions, see Defining calibrators on page 14. If the operator changes the unit temperature, the buffer values would also need to be changed according to the table above.

Sample result calculations

For both linear and point-to-point calibrations, the result is calculated by using the following equation:

$$pH = \frac{E^{\circ}_{\text{Cal}} - E}{S_{\text{Cal}}}$$

E°_{cal} - the standard or asymmetry potential value at pH = 0 calculated from the calibration
S_{cal} - the experimental slope calculated from the calibration, which also takes into account that the electrode response may differ from the theoretical value

If the response is below the calibration range and an estimate for the result is calculated using linear extrapolation from the lowest calibration point, the `Out of calibration range` flag is set to the result. If the response is above the calibration range and an estimate for the result is calculated using a linear extrapolation from the highest calibration point, the `Out of calibration range` flag is set to the result.

Figure 32. Response outside calibration range
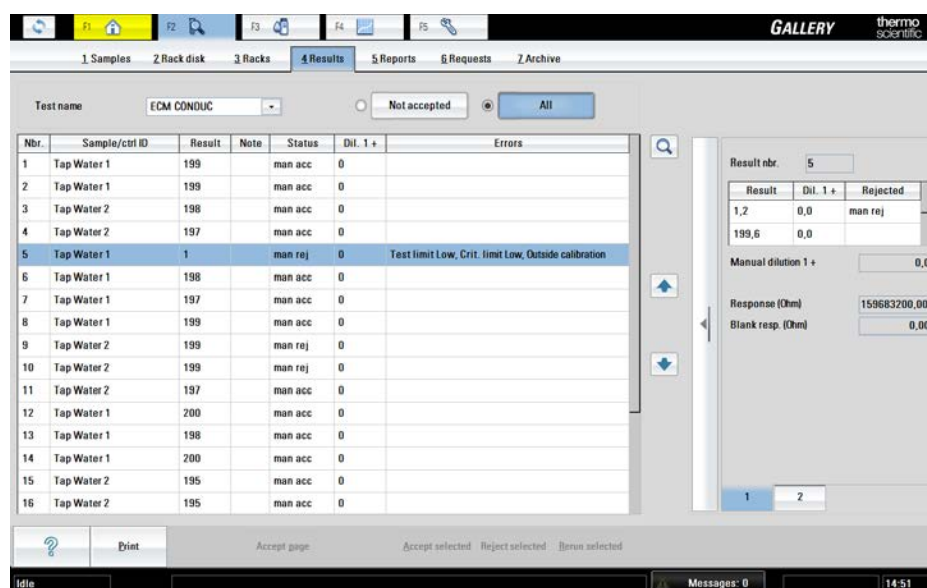
Temperature compensation

Temperature compensation can be made for the influence of temperature on the calibration slope. No compensation is possible, however, for pH shifts caused by altered reference potentials or a change of pH in the inner solution in the glass bulb. Additionally, very little is known about the influence of temperature on samples' pH. It is therefore important that the temperature is reported alongside the pH value.

Samples, buffers and electrodes should all be at the same temperature during measurement cycles. Compensation can be performed, but it is not entirely possible to calculate the pH of a sample measured at one temperature back to the sample pH at another (reference) temperature.

Because cooling is not possible in the ECM unit, and because it is always at least 7 °C warmer than the ambient conditions, the analyzer measures at the minimum higher temperature at which the temperature has been shown to be very stable (within 0.5 °C variation) regardless of ambient conditions at temperatures between 18…30 °C. No correction for temperature is by default installed in the unit software. At the discretion of the operator, the corrections presented below may be taken into use. To correct the temperature-dependent slope, use the general equation.

$$\mathrm{pH_T} = \left(\frac{T_{\mathrm{cal}}}{T}\right) \cdot \left[\mathrm{pH} + \mathrm{pH_{ISO}} \cdot \left(\frac{T_{\mathrm{cal}}}{T}\right) - 1\right]$$

pH - pH at calibration temperature (310 K)
pH_T - pH corrected to temperature T
T_{cal} - ECM measurement temperature (310 K)
T - correction temperature
$\mathrm{pH_{ISO}}$ - pH isopotential point

The above equation is of the form: $\mathrm{pH_{corr}} = C_{\mathrm{factor}}(\mathrm{pH} - C_{\mathrm{bias}})$, which makes it possible to use the software's built-in correction functionality by equating T_{cal}/T with C_{factor} and $-\mathrm{pH_{ISO}} \cdot (T/T_{\mathrm{cal}} -1)$ with C_{bias}. The following table lists example correction factors and biases and various measurement and correction temperatures.

Table 24. Nernstian temperature compensation correction factors and biases at example measurement and correction temperatures.

Calibration and measurement temperature	Correction temperatures	T_{cal} / T (C_{factor})	$pH_{ISO}(T / T_{cal} - 1)$ (C_{bias})
37.0	20.0	1.058	0.4275
	25.0	1.040	0.3018
	30.0	1.023	0.1760
30.0	20.0	1.034	0.2573
	24.0	1.020	0.1544

If the Nernstian correction described above is not satisfactory, the software comes prepared with a robust system with which the calibration may be corrected or correlated to a reference analyzer. The correction factor C_{factor} may be used in combination with the measured pH and correction bias C_{bias} to calculate the corrected pH_{corr}.

$$pH_{corr} = C_{factor}\left(pH - C_{bias}\right)$$

The operator must measure a series of representative samples covering the correct measurement range on both analyzers. The slope and intercept of the linear relationship between the two sets of measurements must then be calculated, using the reference analyzer results as the independent variables. C_{factor} is the inverse of the slope and C_{bias} is the unmodified y-intercept.

$$C_{factor} = \frac{1}{slope\left(Gallery : reference\right)}$$

$$C_{bias} = intercept\left(Gallery : reference\right)$$

Figure 33. C$_{factor}$ and C$_{bias}$
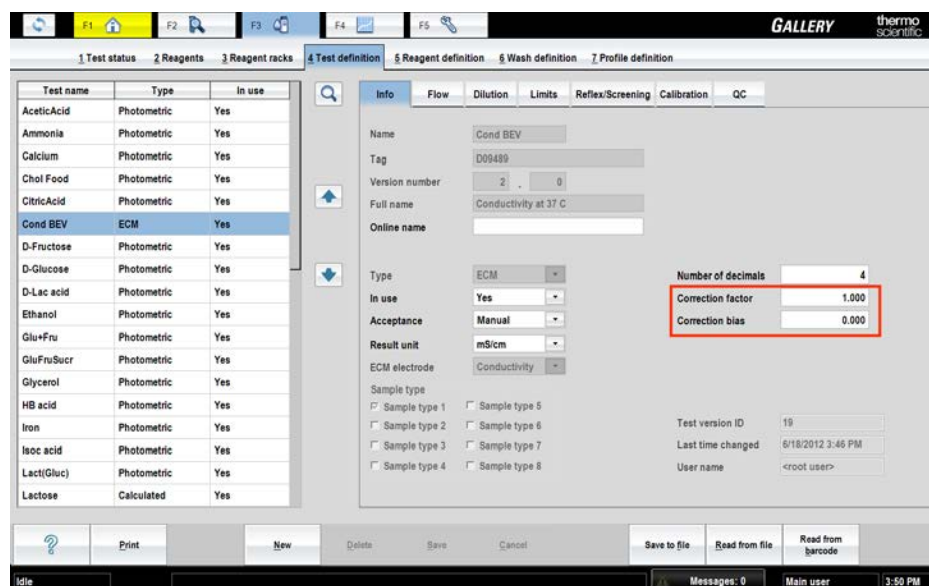
It is possible to use this method to correct for both analyzer-specific idiosyncrasies and temperature.

Standards

The standards available are listed below.

Table 25. NIST traceable pH standards available

pH Standard	Product Code
ECM pH 2 Standard	984330
ECM pH 4 Standard	984331
ECM pH 7 Standard	984332
ECM pH 10 Standard	984333
ECM pH 12 Standard	984334

Note It is recommended, to avoid matrix-related errors, that the calibration standards' composition be as close as possible to that of the sample.

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

pH electrode

The pH ion-selective electrode (ISE) has a cylindrical H+ ion-selective glass membrane mounted inside the pH electrode body to suit a flow through system. This membrane will partition the H

+ ion between the membrane and sample phases when the sample solution comes into contact with it, giving rise to an interfacial potential. The potential of the pH glass electrode is measured against that of the reference electrode. This potential is read and amplified. It should reach steady state within a given time interval. If the measurement does not stabilize in the allowed time, the measurement is repeated once. In case of repeated instability an error message is given.

Alkali metal ions may interfere at high pH, which is known as the alkaline error. This is evidenced by falsely high potentials leading to falsely low pH measurements.

The response of the electrode arises from the difference in potentials developed on both the inside and outside of the glass membrane. The surface layers of glass at the interfacial regions absorb water and become swollen. The pH response arises from ion exchange at these surfaces, controlled by the concentrations of H+. Because the structure of both sides of the (swollen) glass membrane is never absolutely identical, an asymmetry potential develops even if the pH is the same on both sides. This asymmetry potential also changes with time, meaning that the pH electrode must be calibrated frequently to assure accurate results.

Maintenance

Proper electrode maintenance ensures:

- Faster response
- Longer lifetime
- More reliable measurements

The glass membrane must always be clean. Running the daily standby procedure is usually enough for use with common aqueous solutions. The standby procedure rinses the electrodes with Washing solution, which contains alkaline hypochlorite to rinse away fats and proteins, and Cleansing solution, primarily an ammonium hydrogen difluoride solution, to refresh the glass surface.

If the pH electrode will be in regular use, the humid atmosphere within the block is enough and no extra storage steps need be taken. However, if the analyzer will be out of use for an extended period of time (>3 days) the glass electrode should be removed and stored dry in a refrigerator (+2 … +8°C). To establish a stable, swollen, glass layer around the pH-sensitive glass, new or dry-stored glass electrodes should be rinsed with Cleansing Solution (980659; manually inject via syringe through the flow channel), rinsed with tap water, dried and inserted into the instrument. Then make sure to run an analyzer start-up procedure before using. If the test displays any instability, one may soak the pH electrode in 1 M HCl for approximately 24 hours before taking it back into use. If measurements are required before this soaking is complete, calibrations should be carried out more frequently due to drifting potentials.

Air bubbles trapped around the inner reference electrode can lead to unstable readings. Tap the electrode gently or fling it in your hand in a rapid, downward direction to remove any bubbles. If air bubbles are trapped and cannot be removed via these normal methods, it is also possible to heat the electrode gently to a maximum of 60°C in a water bath.

> **Note** Loosen the cap to avoid overpressure. If these steps do not solve the problem, contact your vendor.

Lifetime

The glass electrode lifetime depends on a variety of factors. Good maintenance will extend the lifetime. High temperatures, alkaline solutions, repeated etchings and improper or infrequent

maintenance will diminish an electrode's lifetime. Regardless, even stored dry, a glass membrane will gradually deteriorate. Analyzer glass pH electrodes under normal use conditions can last for 6 months to a year.

Replacing ECM pH electrode

For instructions on replacing the ECM pH electrode, refer to the package insert.

Reference electrode

The inner reference electrode in the ECM unit is a 3 M silver/silver chloride electrode (Ag/ AgCl). The liquid junction, that is the contact to the measuring solution, is achieved through a porous sinter. Overpressure on the internal solution, ensuring constant outflow, is provided via the inner solution bag clamp located above and to the rear of the electrode block. The potential of the reference electrode is ideally independent of the sample solution, owing to the almost equitransferrent mobilities of the K^+ and Cl^- ions. This is the case for the majority of samples in the pH range 1 to 13 and when a 3 M KCl salt-bridge solution is used. Any deviation from this optimal situation gives rise to liquid junction potentials and therefore measurement errors.

Maintenance

Proper electrode maintenance ensures:

- Faster response
- Longer lifetime
- More reliable measurements

Use washing and cleansing solution regularly to keep the reference electrode in good condition.

The lifetime of the reference electrode depends on maintenance and especially on the liquid junction zone not becoming blocked. The electrode must never dry out and should therefore always be filled with the proper salt-bridge solution. If the below recommendations are followed, a proper calibration should be able to be performed easily. If this is not the case, the electrode should be changed or examined more closely.

❖ **Refresh the reference electrode filling solution**

The direction of flow in the reference electrode should always be from the inner reference chamber out into the measuring solution. As this one-way flow cannot be unilaterally achieved, the reference electrode filling solution should be refreshed regularly, for example once a month.

Check also that the reference filling solution is at optimal level:

1 - Optimal filling solution level

❖ **Remove blockage from liquid junctions**

Liquid junctions can occasionally become blocked due to crystallization. To remove the crystals, try the following:

- Flick the crystals out:
  1. Remove the electrode Ag/AgCl pin.
  2. Rinse the Ag/AgCl pin with deionized water.
  3. Detach the filling solution bag.
  4. Flick the electrode upside down to remove any loose crystals.
  5. If crystals are still present:
     a. Rinse the Ag/AgCl pin with 3 M KCl.
     b. Flick the electrode upside down to remove any loose crystals.
  6. Reassemble and refill the electrode.

Other types of blockage can also occur, for example, in the form of a precipitate (black) of silver chloride. In case the silver chloride coating has been removed from the inner pin (inner electrode), change the inner pin or the whole reference electrode.

A malfunction can also be caused by trapped air bubbles. These bubbles can be removed by gently tapping the electrode or, if tapping is ineffective, by flinging it in your hand in a rapid, downward motion. Ensure also that there are no air bubbles in the filling tube.

❖ **Ensure sufficient humidity**

If the reference electrode is in regular use, the humid atmosphere within the block is enough and no extra storage steps need be taken. However, if the analyzer is out of use for an extended period of time (>1 week), store the reference electrode:

1. Remove the reference electrode from the ECM block.
2. If the original cap of the reference filling solution bag is available, disconnect the bag from the electrode and close the cap.
3. If the cap is not available, leave the bag attached to the electrode.
4. Soak a lint- and contaminant-free paper in 3 M KCl, and wrap it gently around the electrode.
5. Place the whole assembly in a sealed zipper storage bag.

6. Store the assembly in a refrigerator (+2 … +8 °C).

Replacing ECM reference electrode

For instructions on replacing the ECM reference electrode, refer to the package insert.

Conductivity

Conductivity is the ability of a material to conduct electric current. In its simplest form, the measurement principle consists of the placement of two electrodes, typically plates, in the sample, applying a sine wave AC potential across them and measuring the resulting current. Ohm's law is used to determine conductivity (G), the opposite of resistivity (R), from the voltage and current values. The basic unit of conductivity is the siemens (S). Since cell geometry affects conductivity values, measurements are normalized to specific conductivity units (S/cm).

Operational principle

The conductivity electrodes are mounted in the electrodes White Assembly B and EC Assembly of the ECM block. Between these electrodes is a 1,2 mm diameter and 9 mm long flow channel into which the sample is pumped for measurement.

The function of the conductivity measurement is to make A/D-conversions repeatedly for the conductivity signal channel (multiplexer channel input on the 24-bit converter) while the detector signal is being generated. There are three hardware-selectable measurement gains HIGH, MID and LOW. Conversions may be performed using any of these gains.

> **Note** A single A/D-conversion result is actually a filtered result of several more conversions. For example, a 50 or 60 Hz interference from the power grid must be filtered off by averaging or integrating conversion results over a 20 ms (=50 Hz for Europe) or 16,6 ms (=60 Hz for U.S) time interval.

The resistance value is sent to the software for final processing.

Calculations

Linear and point-to-point calculation

A linear calibration calculation is used when calibration types are "None", "Bias", "Factor" or "Linear". If the pH calibration is done using 2 calibrators, a linear calibration must be used. The calibration type is definable in the **Calibration** tab under the **Test definition** view.

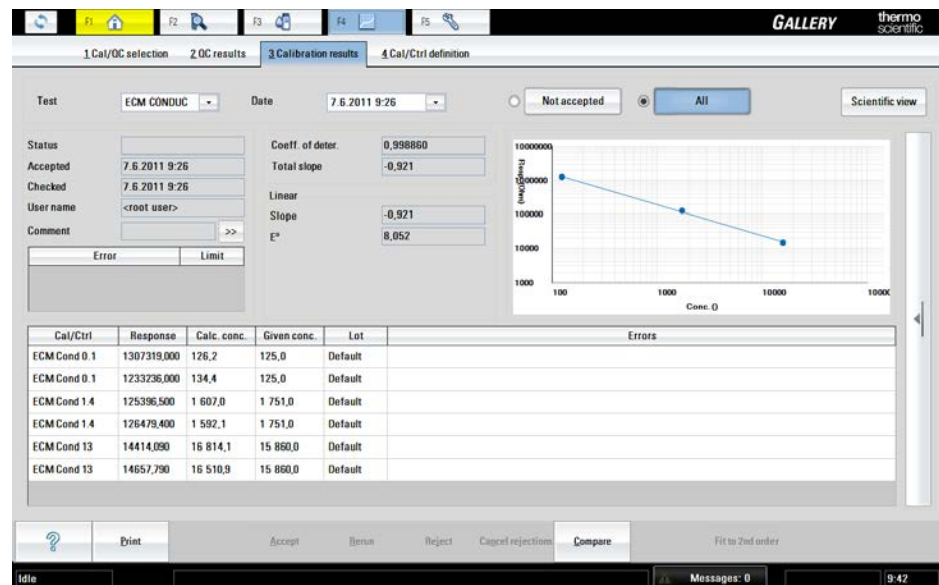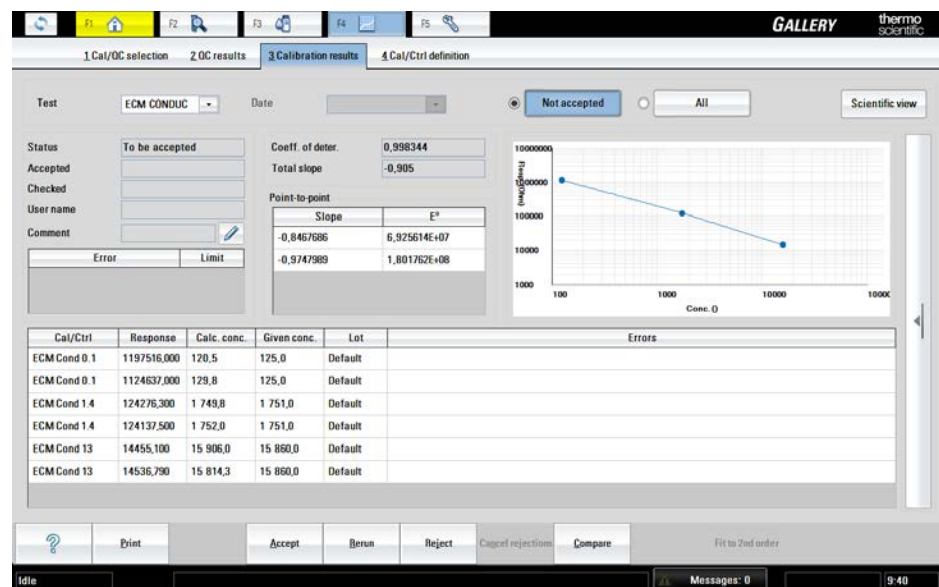**Figure 34.** Linear calibration

Figure 35. Point-to-point calibration

If the calibration is done using more than two calibrators, a point-to-point calibration is used. The calibration type is definable in the **Calibration** tab under the **Test definition** view. With a point-to-point calibration separate linear equations are generated between each set of two calibrators. For example if the calibration is done using five calibration levels, four separate equations are generated for the four linear segments.

The x- and y-axes are both logarithmic for conductivity calculations. Therefore, whereas the response for a non-logarithmic linear test is generally calculated using a linear equation, that is, $Res = m \cdot x + b$, in this case one must account for the logarithms.

$$\log r = m \cdot \log \gamma + b$$

r - the measured signal response described in the previous section
m - the slope of the resulting curve
γ - the conductivity of the calibrator standards (µS/cm or mS/cm)
b - the y-intercept at log γ = 0

The majority of material on the subject of conductivity discusses cell constants. The software treats conductivity much as any other test and uses two to four standards to calibrate the method over a wide range of conductivities. This method was found to give more accurate results over a wider range of conductivities on the analyzer.

Sample result calculations

For both linear and point-to-point calibrations, the conductivity result is calculated by using the following equation:

$$\gamma = 10^{\left[\log(r-b)/m\right]}$$

If the response is below the calibration range, an estimate for the result is calculated using linear extrapolation from the lowest calibration point. The result is flagged with an `Out of calibration range` flag. If the response is above the calibration range, an estimate for the result is calculated using a linear extrapolation from the highest calibration point. The result is also flagged with an `Out of calibration range` flag.

Temperature compensation

Electrical conduction in aqueous solutions depends on the solution composition, concentration of free ions, temperature, and the specific conductivity of the free ions in the solution. Temperature compensation calculates what that value would be at a reference temperature (typically 25.0 °C) from the measured conductivity at the actual measurement temperature. The temperature coefficient (α) of conductivity in water solutions is normally positive, nearly linear and ranges between 2-7% per °C depending on the sample matrix. Fairly dilute water solutions have a compensation factor of approximately 2% per °C.

For example, water with α = 2% per °C (0.02) and 1000 µS/cm at 25.0 °C would read 1020 µS/cm at 26.0 °C if the measurement was not properly temperature compensated. Information on specific temperature coefficients for most chemicals can be found in published reference books and periodicals. The overall accuracy of a conductivity system is governed to a large extent by the accuracy of its temperature compensator rather than by any other single factor and, many times, by all other factors combined.

To calculate the corrected conductivity using the temperature coefficient $\alpha_{\theta,25}$.

$$\gamma_{25} = \left(\frac{\gamma_\theta}{1+\left(\alpha_{\theta,25}\right)\left(\theta - 25\right)}\right) = \left(\frac{1}{1+\left(\alpha_{\theta,25}\right)\left(\theta - 25\right)}\right) \cdot \gamma_\theta$$

$\gamma_\square$ - the conductivity measured at the measurement temperature
γ_{25} - the calculated conductivity at 25.0 °C

Using the analyzer's inherent correction functions C_{factor} and C_{bias} it is most natural to equate the term in brackets to C_{factor}.

$$C_{\text{factor}} = \left(\frac{1}{1 + \left(\alpha_{\theta,25} \right) \left(\theta - 25 \right)} \right)$$

$$\gamma_{25} = C_{\text{factor}} \cdot \gamma_{\theta}$$

If the operator would rather use a different temperature or a different alpha coefficient, they may recalculate C_{factor} for the new temperature according to the equation above. Temperature coefficients and C_{factor} values for common substances are listed in the following table. If you are measuring in a solution for which there is no known alpha coefficient, simply measure in that solution at a variety of temperatures and divide the slope by γ_{Tcal}.

Table 26. Temperature coefficients and C_{factor} values for common substances

Substance at 25.0 °C	Alpha (α)	C_{factor}
5% H2SO4	0.96	0.897
10% HCl	1.32	0.863
5% NaOH	1.72	0.829
10% KCl	1.88	0.816
Dilute Ammonia	1.88	0.816
50% H2SO4	1.93	0.812
10% NaCl	2.14	0.796
98% H2SO4	2.84	0.746
Ultrapure Water	4.55	0.647
Sugar Syrup	5.64	0.596
1.5% HF	7.20	0.536
31% HNO3	31.0	0.212

The C_{factor} values for natural water samples, based on numerous measurements in natural samples are published and the equation with which to calculate C_{factor} values for environmental temperatures has been derived. This value is termed f_{25} in the relevant literature, and the values from 0…40.0 °C are provided in the following table. The analyzer comes with the f_{25} value for measurements at 37 °C installed as the default for natural water sample conductivity measurements.

- Laxen, D.P.H., A specific conductance method for quality control in water analyses. In: Water Research, Vol 11, 1977, pp 91-94.
- Wagner, R. Über die Temperaturabhängigkeit der elektrischen Leitfähigkeiet von Wässern. Vom Wasser 38 1971: 27-48.
- Wagner, R. Temperaturkorrekturfaktoren für die elektrische Leitfähigkeit von Wässern. Z. Wasser- Abwasserforsch. (2) 1980.

- SFS-EN 27888:1985, Suomen Standardisoimisliitto SFS. Water quality. Determination of electrical conductivity.

Figure 36. C_{factor} and C_{bias}
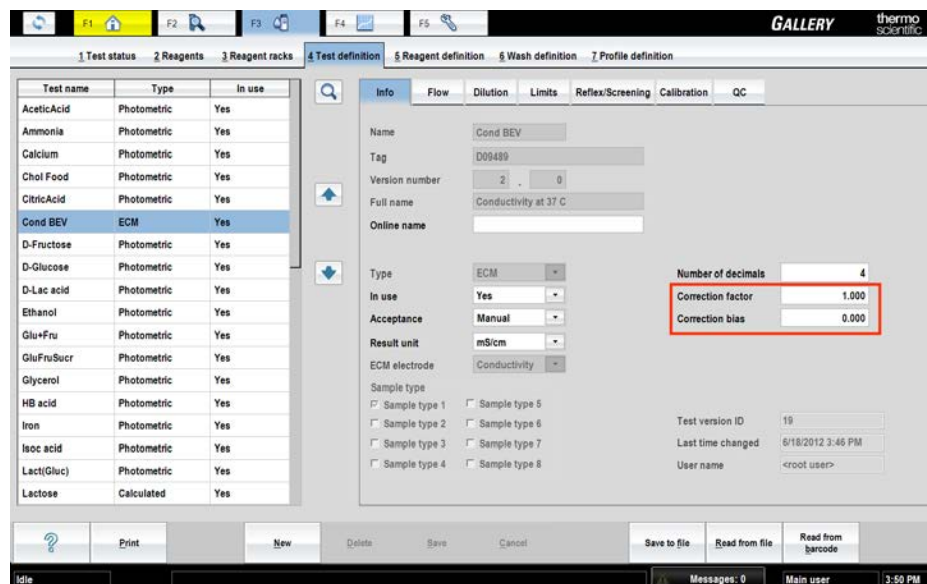
The operator may measure at another temperature than 37.0 °C, keeping in mind that the analyzer is unable to maintain a constant temperature at less than 6-7 degrees more than the ambient laboratory temperature. Calibrator values and the C_{factor} should also then be updated to reflect the new measuring temperature.

Table 27. Temperature correction factor, f_{25} (= C_{factor}), for the conversion of conductivity values of natural waters from 15.0 °C to 40.0 °C

t °C	f_{25}									
	.0	.1	.2	.3	.4	.5	.6	.7	.8	.9
15.0	1.256	1.253	1.249	1.246	1.243	1.240	1.237	1.234	1.231	1.228
16.0	1.225	1.222	1.219	1.216	1.214	1.211	1.208	1.205	1.202	1.199
17.0	1.196	1.193	1.191	1.188	1.185	1.182	1.179	1.177	1.174	1.171
18.0	1.168	1.166	1.163	1.160	1.157	1.155	1.152	1.149	1.147	1.144
19.0	1.141	1.139	1.136	1.134	1.131	1.128	1.126	1.123	1.121	1.118
20.0	1.116	1.113	1.111	1.108	1.105	1.103	1.101	1.098	1.096	1.093
21.0	1.091	1.088	1.086	1.083	1.081	1.079	1.076	1.074	1.071	1.069
22.0	1.067	1.064	1.062	1.060	1.057	1.055	1.053	1.051	1.048	1.046
23.0	1.044	1.041	1.039	1.037	1.035	1.032	1.030	1.028	1.026	1.024
24.0	1.024	1.019	1.017	1.015	1.013	1.011	1.008	1.006	1.004	1.002

t °C	.0	.1	.2	.3	.4	.5	.6	.7	.8	.9
					f_{25}					
25.0	1.000	0.998	0.996	0.994	0.992	0.990	0.987	0.985	0.983	0.981
26.0	0.979	0.977	0.975	0.973	0.971	0.969	0.967	0.965	0.963	0.961
27.0	0.959	0.957	0.955	0.953	0.952	0.950	0.948	0.946	0.944	0.942
28.0	0.940	0.938	0.936	0.934	0.933	0.931	0.929	0.927	0.925	0.923
29.0	0.921	0.920	0.918	0.916	0.914	0.912	0.911	0.909	0.907	0.905
30.0	0.903	0.902	0.900	0.898	0.896	0.895	0.893	0.891	0.889	0.888
31.0	0.886	0.884	0.883	0.881	0.879	0.877	0.876	0.874	0.872	0.871
32.0	0.869	0.867	0.866	0.864	0.863	0.861	0.859	0.858	0.856	0.854
33.0	0.853	0.851	0.850	0.848	0.846	0.845	0.843	0.842	0.840	0.839
34.0	0.837	0.835	0.834	0.832	0.831	0.829	0.828	0.826	0.825	0.823
35.0	0.822	0.820	0.819	0.817	0.816	0.814	0.813	0.811	0.810	0.808
36.0	0.807	0.806	0.804	0.803	0.801	0.800	0.799	0.797	0.796	0.794
37.0	0.793	0.791	0.790	0.789	0.787	0.786	0.784	0.783	0.782	0.780
38.0	0.779	0.778	0.776	0.775	0.773	0.772	0.771	0.769	0.768	0.767
39.0	0.765	0.764	0.763	0.761	0.760	0.759	0.757	0.756	0.755	0.754
40.0	0.752	0.751	0.750	0.748	0.747	0.746	0.745	0.743	0.742	0.741

The values in the table above were calculated according to the following equation:

$$f_{25} = \left[(1-a) + a \cdot \left(A + \exp\left(B + \frac{C}{\theta + D} \right) \right)^n \right] \cdot 1.116$$

a = 0.962
n = 0.965
A = -0.198
B = -1.992
C = 231.176
D = 86.391
θ : measurement temperature

Standards

The standards available are listed below, with their pH values at the common reporting temperatures (20 °C, 25 °C) and the measurement temperature (37 °C).

Table 28. NIST traceable conductivity standards available and their values at various temperatures

Conductivity standard	Product code	Conductivity (mS/cm) at temperature		
		20.0 °C	**25.0 °C**	**37.0 °C**
ECM Conductivity Standard 100 µS/cm	984335	0.090	0.100	0.125
ECM Conductivity Standard 1413 µS/cm	984336	1.277	1.413	1.751
ECM Conductivity Standard 12.9 mS/cm	984337	11.64	12.85	15.86
ECM Conductivity Standard 111.9 mS/cm	984338	102.0	111.9	136.7

> **Note** To avoid matrix-related errors, it is recommended that the calibration standards' composition be as close as possible to that of the sample.

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

Conductivity electrodes

Electrode White Assembly A and electrode White Assembly B come completely assembled and placed correctly in the ECM unit. Electrode EC Assembly comes with ECM Start Up kit 986299 and is installed by the service engineer. Conductivity is measured between electrodes EC Assembly and White Assembly B. The White Assembly A electrode is not connected to the unit electronics. The electrode White Assembly B is connected to the unit electronics via the wire with the transparent female connector and EC Assembly is connected to the unit electronics via the wire with the black female connector. Make sure that these connectors are pushed down all the way onto the electrode pins.

Maintenance

The conductivity electrodes will eventually need replacement. Regular cleaning of the electrodes sensor will assure long, reliable, and accurate service. Other than the daily standby procedure to remove contaminants, no other maintenance should be required. The electrodes must be examined carefully to be certain that they have not corroded, eroded and that they are properly seated. Deterioration of the electrodes can be difficult to discern. Scheduled replacement can be a better alternative. If any discoloration or roughness of the steel surface is observed, contact your service representative.

Lifetime

Conductivity electrodes can be expected to last 6-12 months under normal use conditions. If they are commonly exposed to concentrated salt solutions, strong acids or bases, this lifetime can be foreshortened.

Replacing ECM conductivity electrodes

The ECM conductivity electrodes are replaced by the service engineer.
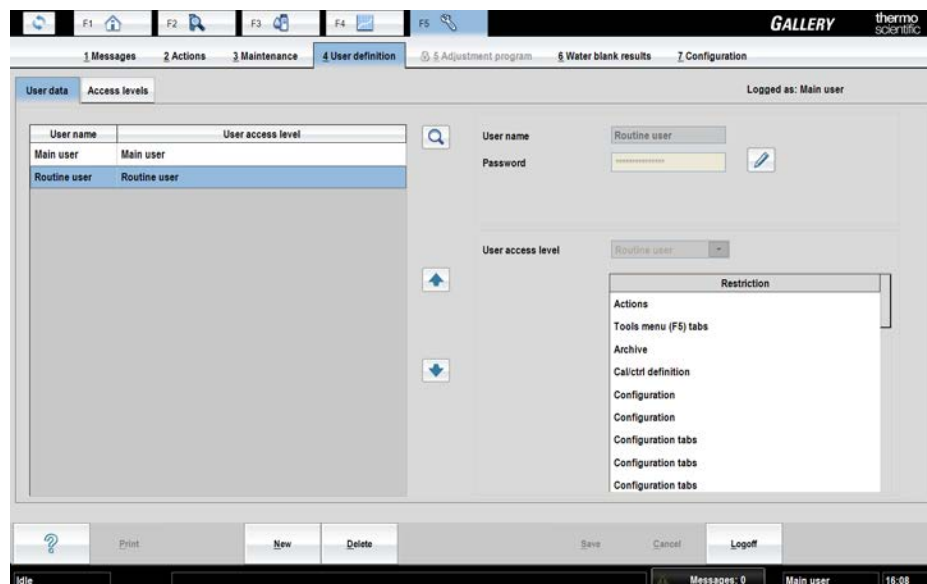
Defining user accounts

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 37. Creating new user account

- Viewing existing users
- Removing user

- 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 38. Viewing users
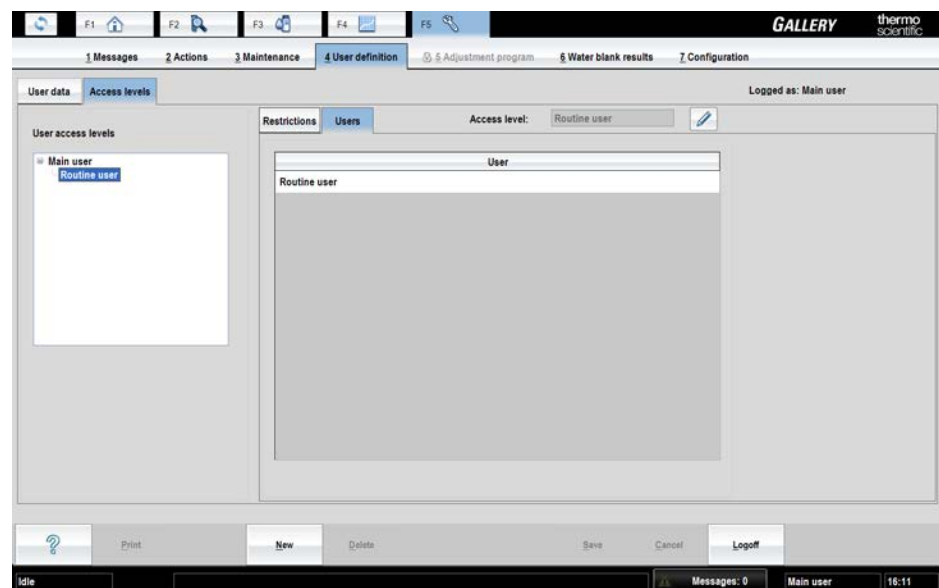
Removing user

To remove a user:

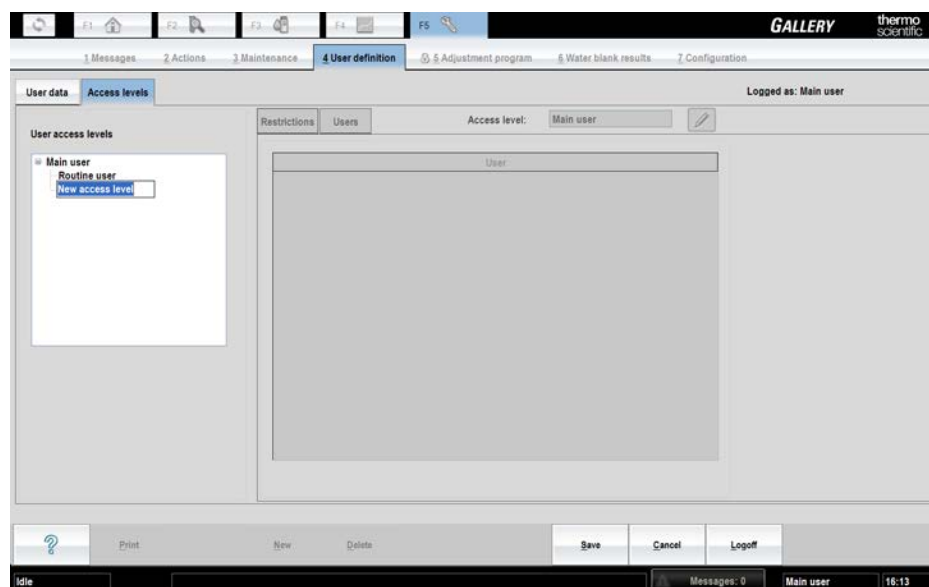1. Select F5 > User definition > **User data**.

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 39. 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**.

Figure 40. Defining restrictions
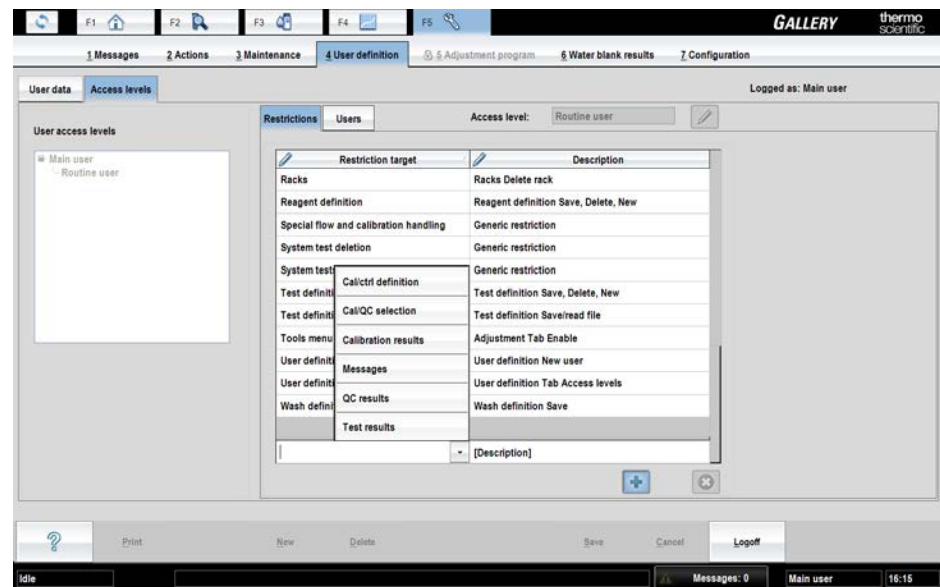
Removing restrictions from access level

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.

Figure 41.   Reviewing water blank results
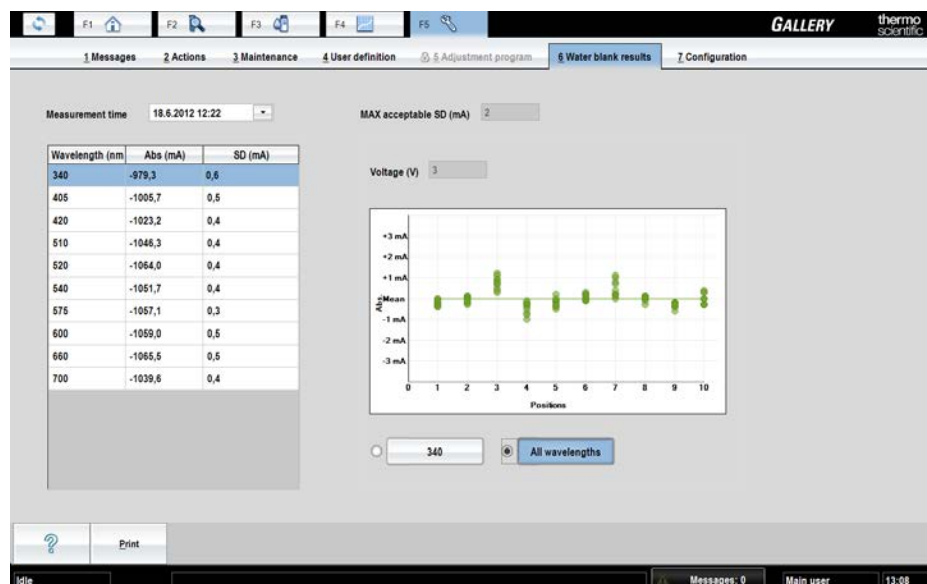
• Requesting water blank

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.

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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.

Figure 42. 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 23 and Reading test parameters from barcode on page 24.

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.

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Managing maintenance tasks

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

Figure 43. Maintenance view
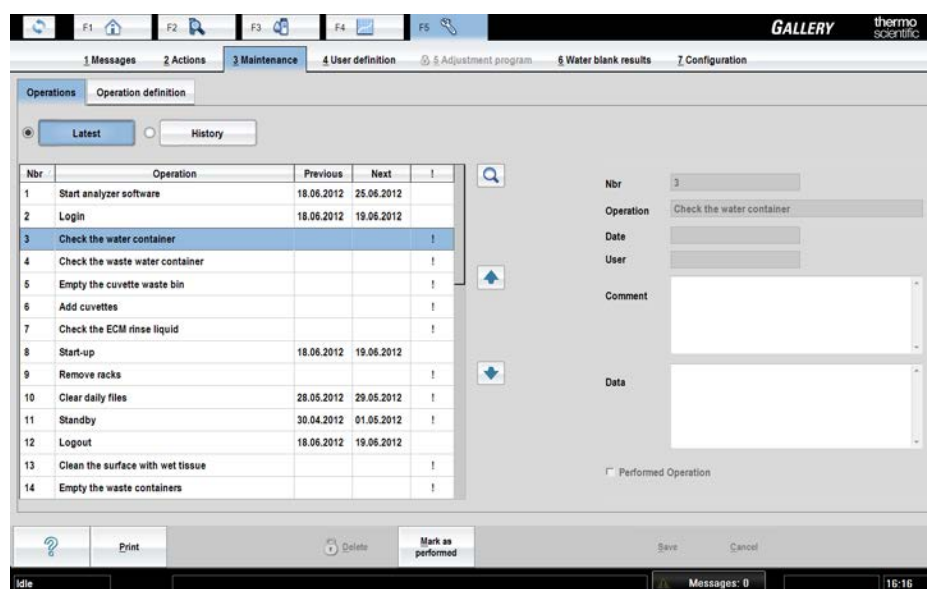
- Adding maintenance task
- Taking maintenance task in use
- Changing interval time
- Removing maintenance task
- Acknowledging maintenance task
- Viewing maintenance history
- Deleting maintenance history

Adding maintenance task

To add a maintenance task:

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

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.

3. 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 exception is Wash water container and tubing, which is 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.

2. 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**.

4. 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.

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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 29. Minimum user level requirements for changing configuration settings

Configuration tab	Laboratory main user	Service engineer
Laboratory	X	
LIS	X	
Test LIS	X	
ECM		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**.
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 44.   Laboratory settings

Table 30. 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.
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 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).

Parameter	Values	Description
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.
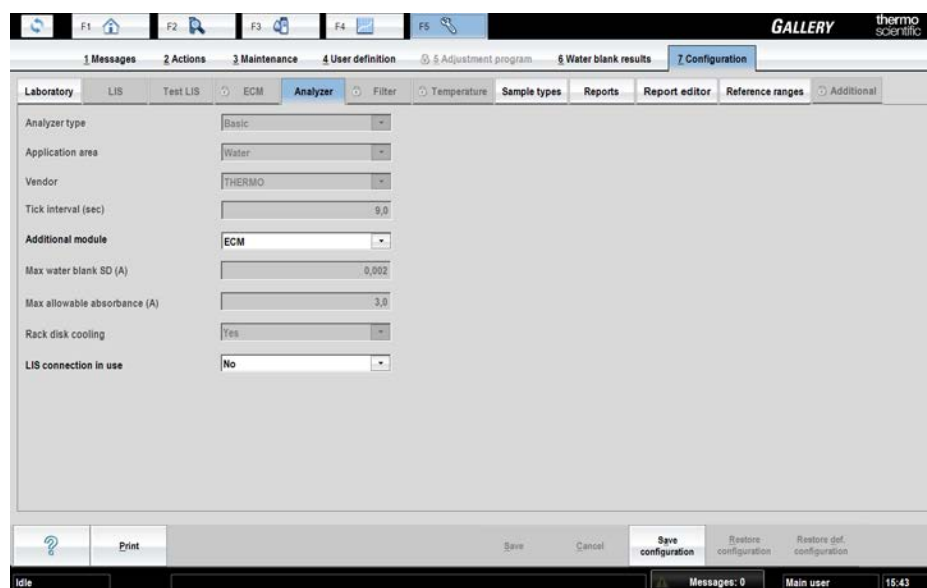
Figure 45. Configuring test online names
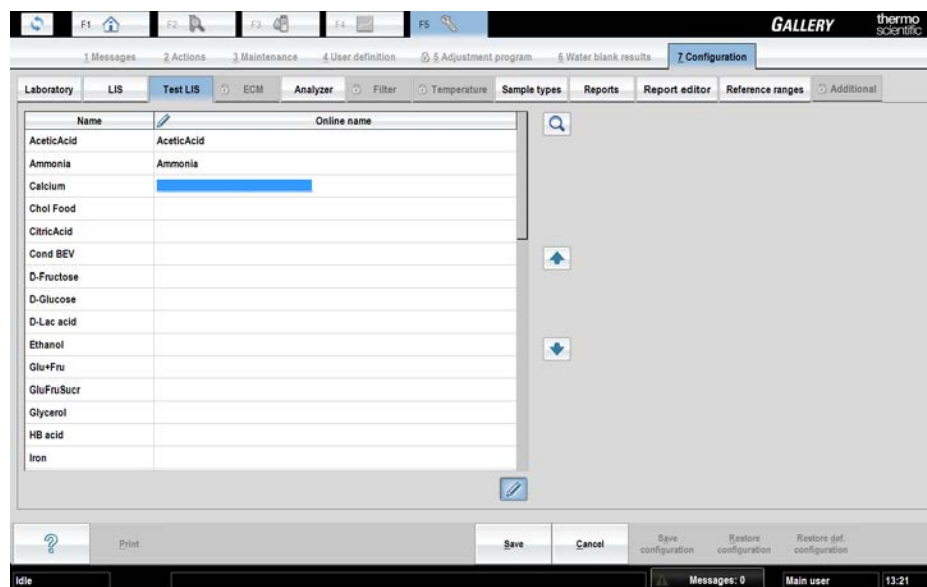
Analyzer

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 46. Analyzer settings

Table 31. 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 *None*. The default value is set by the manufacturer.
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.
Rack disk cooling	Shows whether the rack 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 47. Sample type settings
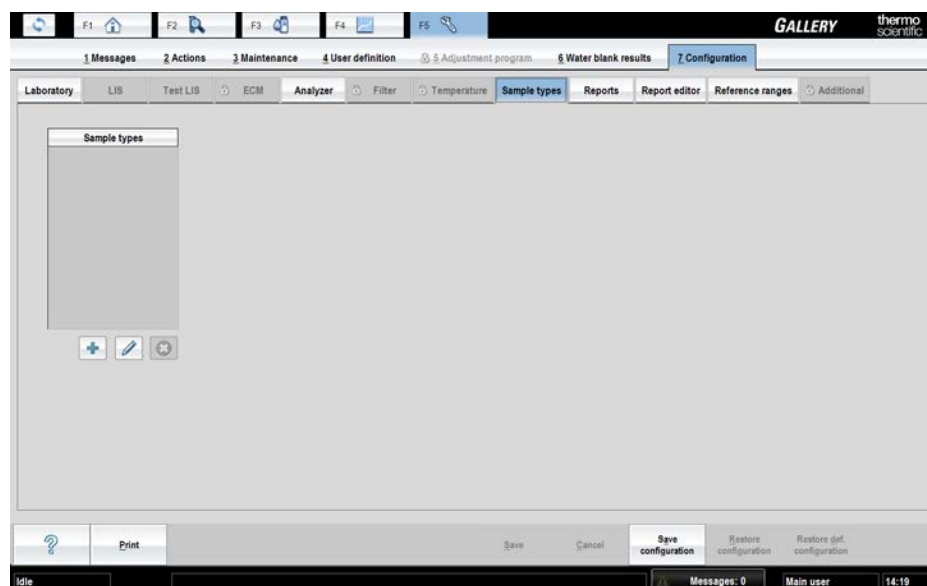
Reports

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**.
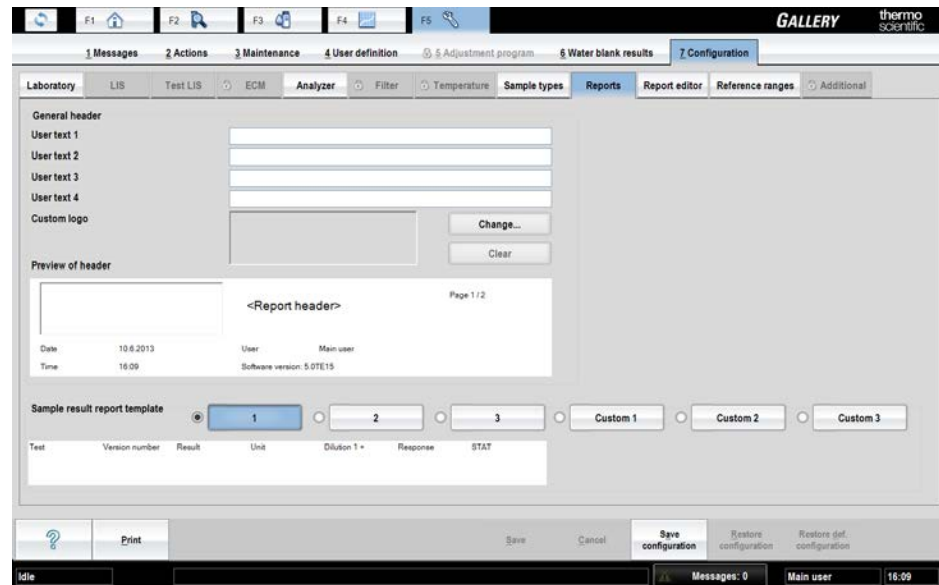5. Click **Save**.

Table 32. Logo size

Width	Height
5.69 cm	1.70 cm

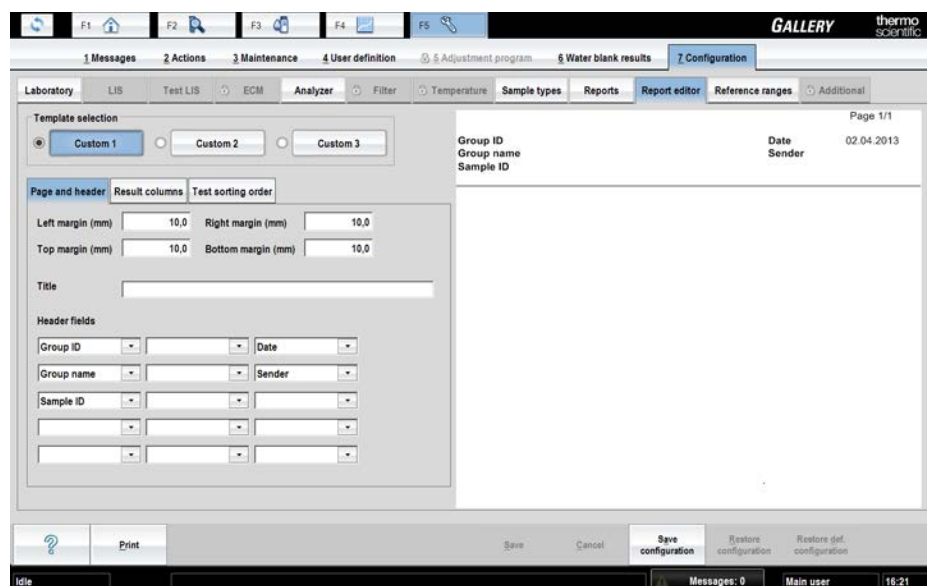| Width	Height
2.24 in.	0.67 in.
672 pixels (300 ppi)	200 pixels (300 ppi)

Figure 48. 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 49. 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.
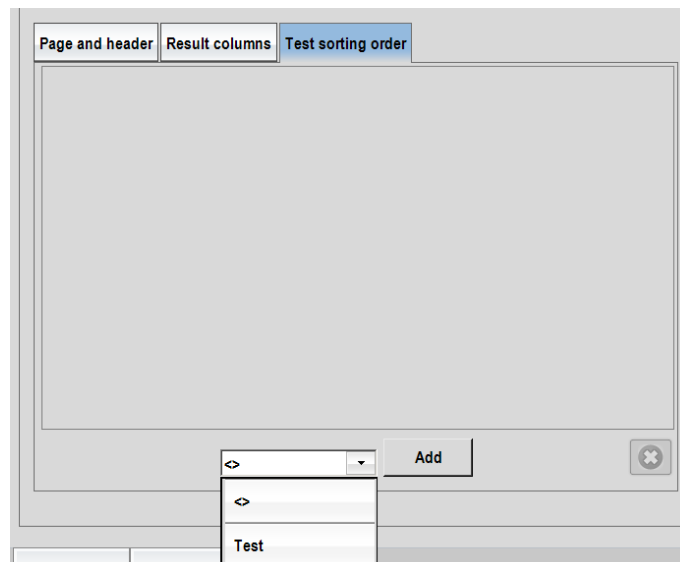
9. Click **Add**.
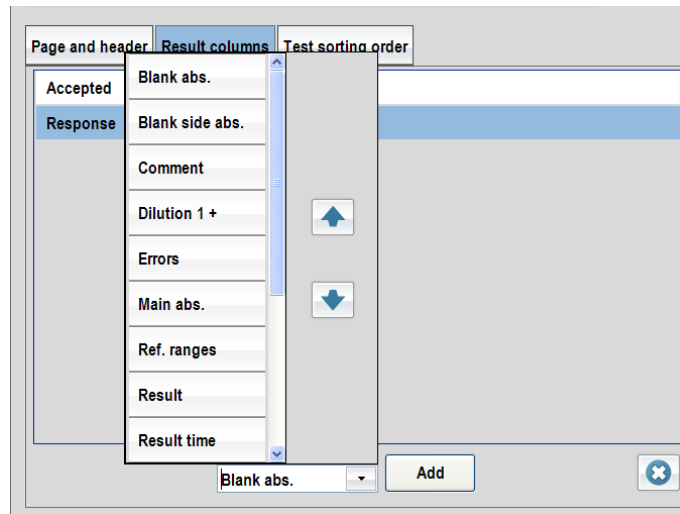
Repeat steps 8 and 9 until all the needed result columns are defined.

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**.

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

See Reports on page 115.

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 50. Reference ranges
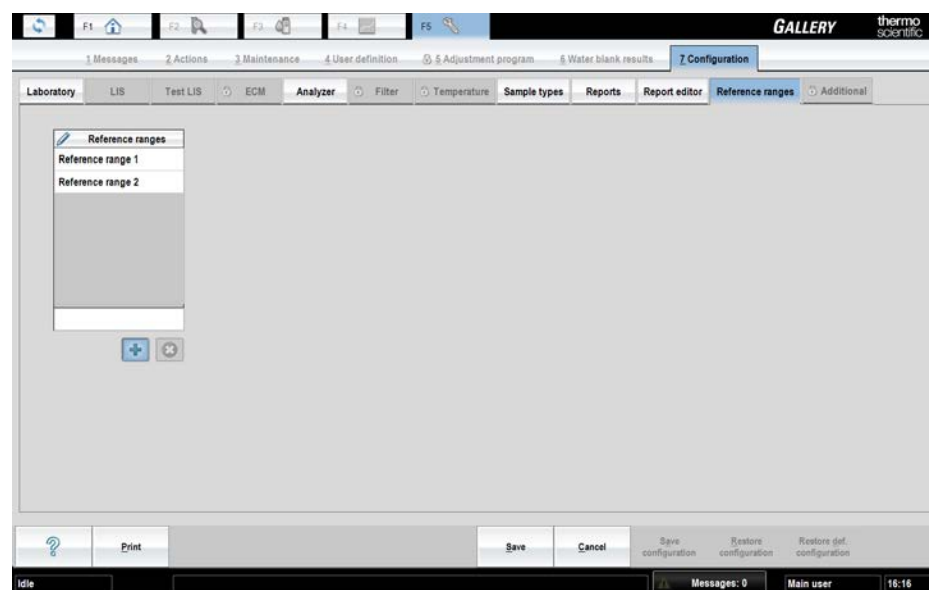
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Barcode specification

> **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 ± 5° according to NCCLS LIS7-A and less than ±7% according to CLSI AUTO2-A2 with respect to the axis of the sample container.

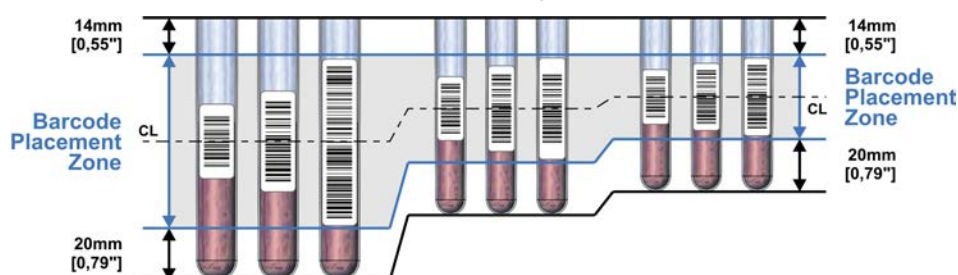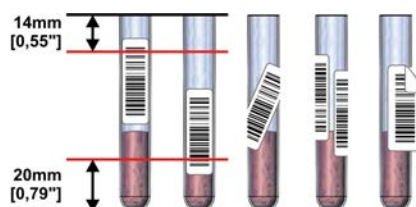**Figure 51.** Correct placement of barcode according to CLSI AUTO2-A2

**Figure 52.** 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 x 0.127 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 53. Reading zone
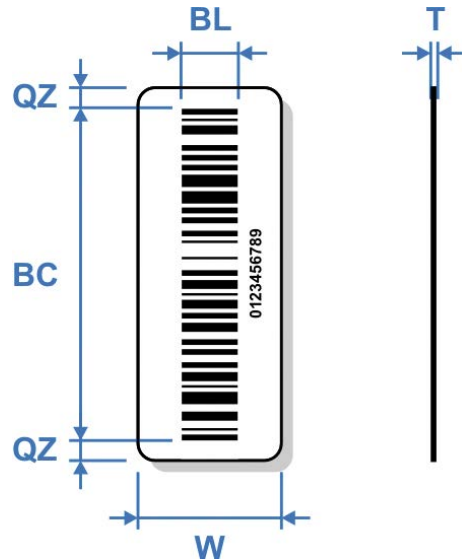
BC - Barcode
- min. line thickness: 0.127 mm (5.9 mil)
- min. number of characters: 3
BL - Barcode length: min. 10 mm (0.4 in.)
QZ - Quiet zone: recommended 3.5 mm (0.14 in.)
T - Label thickness (including adhesive): max. 0.090 mm (3.6 mil)
W - Label width: 5 mm (0.2 in.) less than the circumference 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

C

CLRW   Clinical Laboratory Reagent Water

CLSI   Clinical and Laboratory Standards Institute

D

DB   Database

E

ECM   Electrochemical Measurement

G

GLP   Good Laboratory Practices

I

ID   Identification

L

LIS   Laboratory Information System

Q

QC   Quality Control

S

SD   Standard Deviation

U

UPS   Uninterruptable Power Supply