Optilite®

OPTIMISED PROTEIN SYSTEM


# Reference Manual

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Revision 7.0B, March 2022

The Specialist Protein Company

Binding Site

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Use of this analyzer in a manner not specified by the manufacturer could impair any protection provided by the analyzer. No responsibility and no liability is assumed for any errors, omissions, damage or loss that might arise out of the use or inability to use this analyzer.

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**MANUFACTURER**

The Binding Site Group Limited
8 Calthorpe Road
Edgbaston
Birmingham
B15 1QT
United Kingdom

**Commercial vendor**

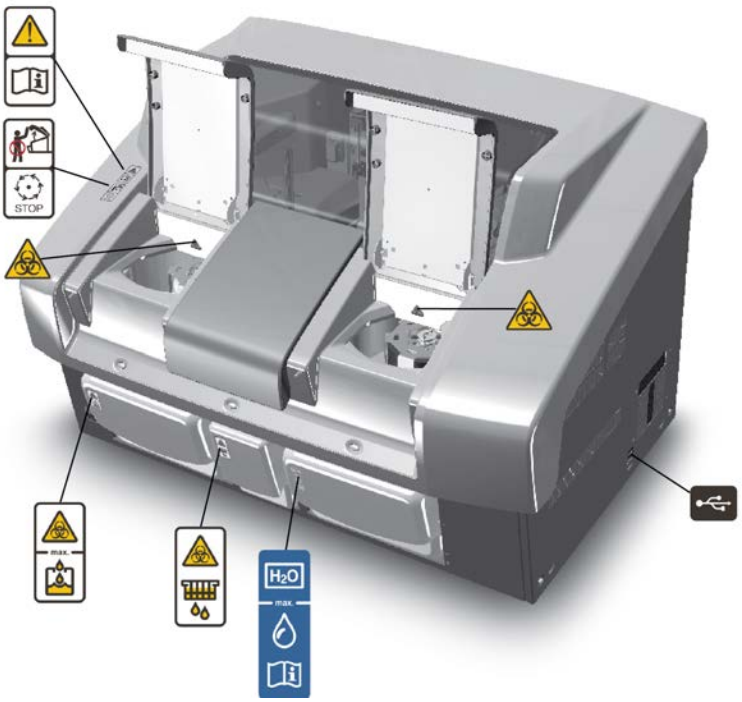
The Binding Site Group Limited
8 Calthorpe Road
Edgbaston
Birmingham
B15 1QT
United Kingdom
Tel: +44 (0) 121 456 9500
Fax: +44 (0) 121 456 9749
E-mail: info@bindingsite.co.uk

# Safety information

**Note** Report any serious incident that happens in relation to analyzer to the manufacturer and when required by law to the regulatory authority of the country in which the user and/or the patient is established.

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 infectious 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 - biological risks**

The cuvette waste bin and cuvettes are potential sources of infectious 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 cuvette waste bin. The operator must be cautious when working with the cuvette waste bin.

## Waste water container


**Warning - biological risks**

The waste water container is a potential source of infectious 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**

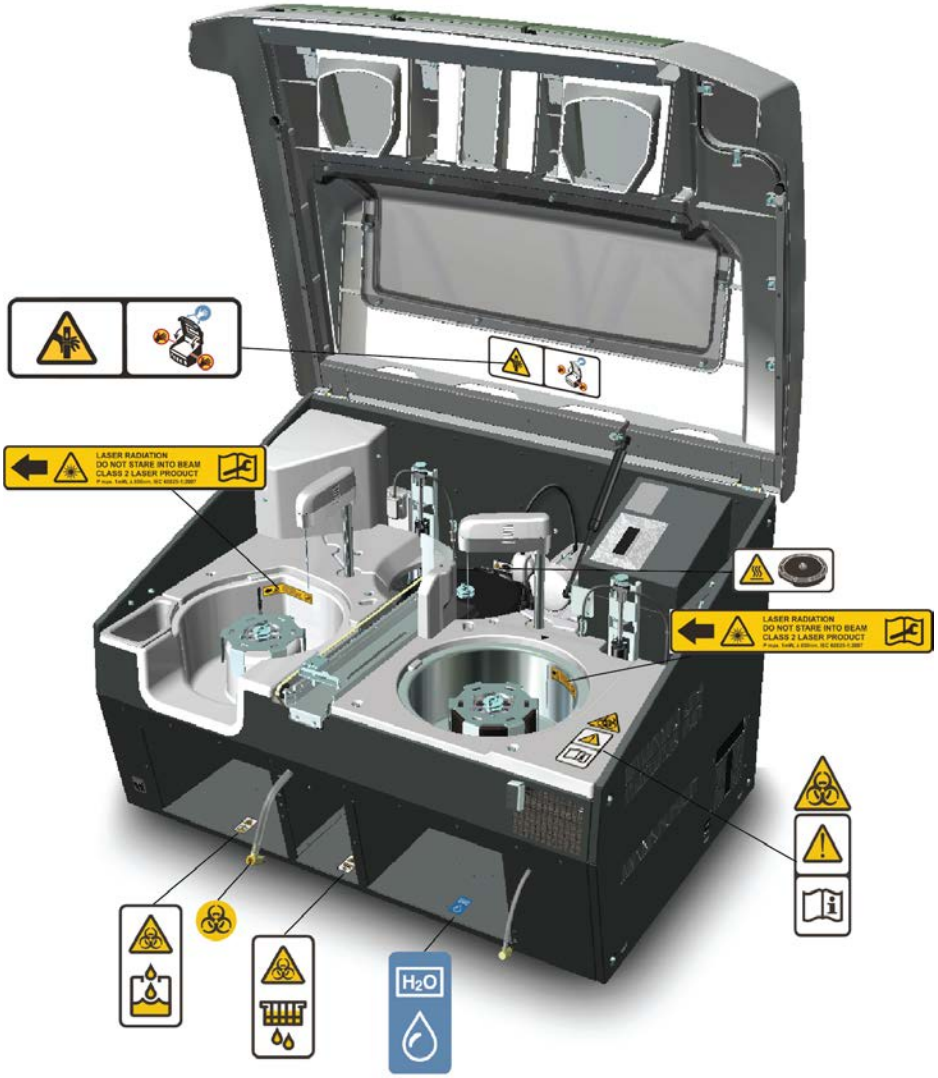
Keep the deionized water container away from a potential source of infectious agents.

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

| Racks | |
|---|---|
|  | **Caution - biological risks**<br>Racks are potential sources of infectious agents. |

| USB cable | |
|---|---|
|  | **Information**<br>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.

**Figure 3.** Tubing connector

## Tubing connector

**Warning**

The tubing connector of the waste water container is a potential source of infectious agents.

## Main cover

**Caution**

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

## Incubator

**Caution**

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

## Barcode reader


**Caution**

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

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 13485 | Medical devices - Quality management systems - Requirements for regulatory purposes. |
| • EN ISO 14971 | Medical devices - Application of risk management to medical devices. |
| • EN 61010-1<br>• IEC 61010-1<br>• UL 61010-1<br>• 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<br>• IEC 61010-2-010<br>• 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 61010-2-101<br>• IEC 61010-2-101<br>• CAN/CSA-C22.2 No. 61010.2.101 | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment. |
| • EN 61326-1 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements. |
| • EN 61326-2-6 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment. |
| • FCC CFR 47 Part 15 | Subpart B, Class B. EMC Requirements for US. |

| Standard | Title |
|---|---|
| • EN 62304<br>• IEC 62304 | Medical device software - Software life-cycle processes. |
| • EN 50581 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances. |

## CE

| | |
|---|---|
| CE<br><br>IVD | The CE mark attached on Optilite® analyser (clinical chemistry analyser, type 864) indicates the conformity with the IVD (in vitro diagnostic devices) regulation (EU) 2017/746 of the European Parliament and of the council on in vitro diagnostic medical devices and RoHS directive (Restriction of the use of certain hazardous substances in electrical and electronic equipment) 2011/65/EU. |

## 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:

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# Contents

# Preface

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

**Table 2.** Product code

| Product | Code |
|---|---|
| Optilite® analyser | IE700 |

## Intended use/Intended purpose

The Optilite® analyser is a fully automated random access analyser for quantitative in vitro measurement of analytes in serum, plasma, urine and cerebrospinal fluid used in conjunction with the Binding Site assays designed to work on the Optilite® analyser.

## Intended audience

This manual is addressed to main users, 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/October 2013 | INS700.REF | 5.1 | Document created. |
| B/December 2013 | INS700.REF | 5.1 | Added a disclaimer note in Creating test procedure section. |
| A/July 2014 | INS700.REF | 5.2 | Checked the content against 5.2 software. Added information about sample probe and mixer wash. |
| A/June 2015 | INS700.REF | 5.3 | Updated configuration settings and instructions for restoring default database. Added new result units. Updated contact information. |
| A/October 2016 | INS700.REF | 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 and Automatic start. |
| A/October 2018 | INS700.REF | 7.0 | Added information about multiple reagents, third party controls and TVR limit. Improved instructions about Defining user levels and Quality control procedure definition. |
| B/31 March 2022 | INS700.REF | 7.0 | Verified the conformity with the IVD (in vitro diagnostic medical devices) regulation 2017/746/EU. Updated manufacturer information. Updated intended use and changed analyser name as Optilite® analyser. |

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`.

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# Operating environment

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

**Note** Installing any 3rd party software to the workstation PC is not supported by The Binding Site. 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”. The Binding Site is not responsible for possible errors due to 3 rd party software installed by customer.

**Note** It is not recommended to connect the workstation to the Internet due to the risk of viruses, unless specifically requested by The Binding Site.

❖ **Dimensions**

**Table 3.** Dimensions and weight of the analyzer

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

**Note** Dimensions are given without workstation and display.

❖ **Power supply**

**Table 4.** Power supply to the analyzer

| Description | Value |
|---|---|
| Voltage | 100 - 240 VAC ± 10% |
| Frequency | 50 - 60 Hz ± 5% |
| Power consumption | 300 W |

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

**Table 5.** Minimum recommendation for UPS

| Description | Value |
|---|---|
| UPS minimum recommendation, VA | 1100 |

### ❖ Analyzer's decibel level (dB)

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

### ❖ Environmental conditions

- Ambient temperature: 18...30 °C
- Relative humidity: 40 - 80%, non-condensing
- Altitude: < 2000 m from the sea level
- Heat output: 680 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 6.** Clinical laboratory reagent water requirements

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

# Decontamination procedure for analyzers

❖

- Wear protective gloves, protective glasses and respiration protector. Use gloves during the entire decontamination process.
- Cover spills with absorbent material (e.g., paper towels), then pour disinfectant on to saturate the area, and allow bleach to soak into spills for at least 30 minutes before cleaning to allow it to kill any virus or other infectious agents that may be present.
- Use tools, such as tongs, from a spill kit as much as possible, rather than doing cleanup work directly with gloved hands.
- Spray all the covers with decontamination liquid (for example Virkon).
- Let the solution take effect on the instrument surface for approximately 10 minutes.
- Remove all consumables from the instrument.
- Treat any visible contamination or bulk spill matter with a suitable disinfectant before cleaning up and removing bulk material.
- After disinfection and removal of any bulk material, clean and decontaminate the surface using a disinfectant.
- Spray inside of the instrument with decontamination liquid (for example Virkon). Spray areas where there might be dry sera.
- Let the solution take effect inside the instrument for approximately 10 minutes.
- Wipe the instrument with a tissue. Used tissues and gloves must be disposed of like material with risk of infection.
- Wash your hands with disinfectant fluid (for example Isosept).
- Avoid cleaning techniques, such as pressurized air or water sprays, that may result in the generation of bio-aerosols (aerosolized droplets containing infectious particles that can be inhaled).
- **All potentially contaminated waste including fluids, sample vials, cuvettes, etc. consumables are labeled as biohazardous and should be discarded according to proper biosafety procedures.**

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# Creating test procedure

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

Creating user-definable tests requires using a dongle that enables these tests. The dongle is installed in the computer's USB port. The number of user-definable tests is configured in dongle at the factory. If the **New** button in the Test definition window is grayed, the dongle does not contain any user-definable tests, all the tests in the dongle have been used or the dongle has not been installed. If the dongle is missing, the system gives an error message in the user interface start-up.

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.

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# Reagents

Optilite® analyser uses only barcoded reagents. The barcode of a system reagent may define lot IDs for quality controls and calibrators that are valid for that particular reagent. If these lot IDs of quality controls and calibrators are defined in the system reagent's barcode, the system test requires that these IDs match each other. However, all the system reagent barcodes do not contain specific calibrator or quality control lot IDs. If a user-defined quality control is defined for a system test, this control's lot ID does not need to match the reagent's barcode, even though the test would be a lot bound system test.

The analyzer can use several reagent lots for a test. Each reagent lot must be calibrated separately. If there are several calibrated reagent lots inside the analyzer, they are used in the same order as in which the lots have been originally inserted into the analyzer. Within the reagent lot, vials are used from oldest to newest.

Diluents and wash reagents are not lot specific.

All system reagents require a certain version of a test. The reagent lot contains only a major version of the test and all the requests are always performed with the latest subversion. If the test version required by the system reagent lot is different than the test version in the database, the system reagent lot cannot be used and the software gives an error message. Update the test or use another reagent lot which matches the test version. If the inserted reagent vial requires older test version, the software uses old test version from the database.

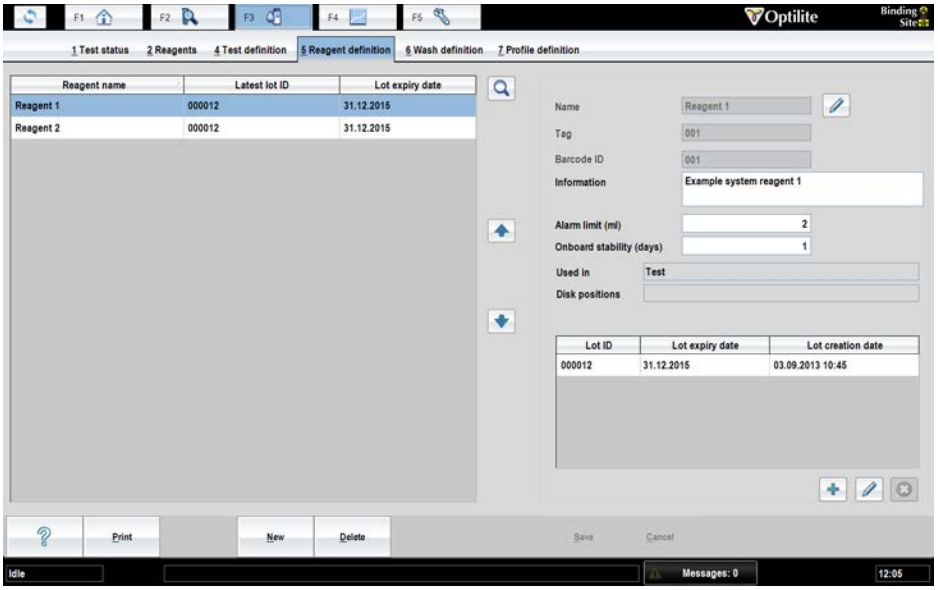
It is not possible to edit old test versions but you can print them by clicking **Print** in the **Test definition** window.

It is also possible to define user-definable reagents to be used in user-definable tests.

To view reagent parameters, select F3 > **Reagent definition**. The main reagent details are listed on the left. The list shows the reagent name, the latest lot ID and when the lot expires. The user-definable 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

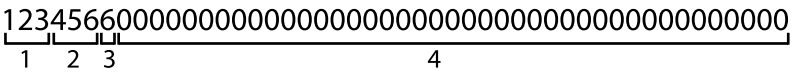
# Defining user-definable reagents

In the user-definable test you have to use user-defined reagents. You must order empty barcoded reagent vials from The Binding Site and pour the the reagent to be used into these vials. User-defined reagent vials can be refilled with the same reagent.

The user-definable reagent's barcode contains:

- Barcode ID 1
- Barcode ID 2 (only with double reagent vial, 15/30 ml)
- Vial size

**Figure 5.** Structure of the barcode




1 - Barcode ID 1 (50 ml, double reagent vial 15 ml)
2 - Barcode ID 2 (double vial 30 ml) (if applicable)
3 - Vial size (6 = double vial, 7 = single vial)
4 - 41 zeros (unused digits)

**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. Type the 1st, 2nd and 3rd number from the vial's barcode in the **Barcode ID** box.
4. Click the confirmation button to check that the given name and the barcode ID are unique.

   **Note** For a double vial, which consists of 15 ml and 30 ml reagents, you have to define both reagents. The procedure is similar to defining a normal reagent but for the 30 ml reagent, in step 4, you have to type the 4th, 5th and 6th number of the barcode in the **Barcode ID** box.
5. Type the additional reagent information in the **Information** box. For example, the reagent's full name.
6. Define the alarm limit in milliliters in the **Alarm limit** box.
7. Define in the **Onboard stability (days)** box how many days the reagents can be stored in the analyzer.
8. Click **Save**.
9. 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.
10. Press Enter.
11. Click **Save**.

    After a user-definable reagent is defined, it can be used in future by inserting it into the analyzer and the analyzer reads its information from the vial's barcode.

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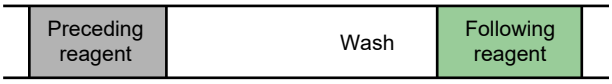
# Wash definition

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.




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


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


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


- 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.

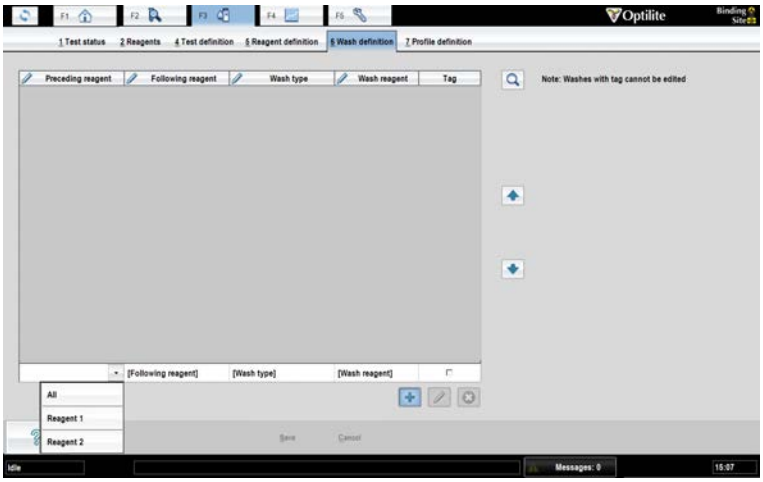
- Medium reagent wash
  - First, the probe is washed with wash reagent. The probe aspirates 220 µl of wash reagent, which is moved up to 300 µl height of tubing, and dispenses the wash reagent into a cuvette cell. The probe is then washed with water. The mixer mixes in the cuvette cell where the wash 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 6.** Defining extra wash



# Clot detection

To secure result integrity, the analyzer has the ability to automatically detect a clot in the sample. Clot detection is based on differential pressure technology, and the sample dispenser is equipped with a pressure sensor. The operation of the pressure sensor is checked by making a series of aspirations at start up. Only patient samples are detected for clots.

If the clot algorithm detects faulty sample, the aspiration is failed. The failed request is repeated and if the clot is detected again, the sample is marked with red colour in the main view.

When a clot is detected, the user is informed and no further dispensing is made from that sample. Usually a normal wash between sample aspirations is enough to clear the probe but if the sample probe is blocked, analysis stops immediately and an error message is given.

The user can check the operation of the pressure sensor used in clot detection in the F5 > **Actions** window and a successful check acknowledges all pressure sensor error messages. The system will only be able to detect clots if the pressure sensor check is successfully performed.

The user is also 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.

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# 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.

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# Calibrators

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

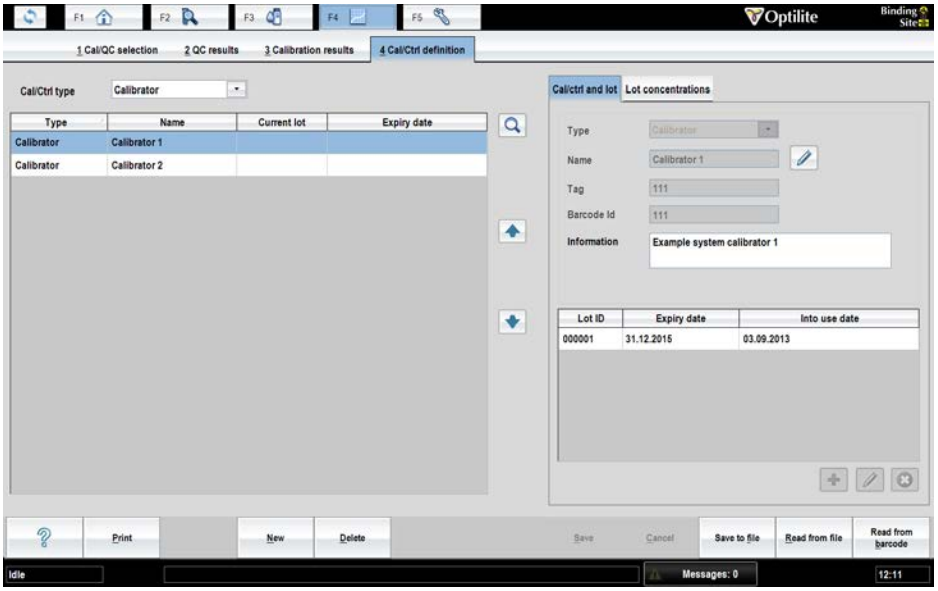
Optilite® analyser uses three kinds of calibrators:

- System calibrators which are inserted using barcoded vials
- Multicalibrators which are system calibrators used in several tests
- User-definable calibrators which are inserted using sample cups

The values of a system calibrator are read from the barcode. A multicalibrator contains several analytes and it can be used in several tests. The values of a multicalibrator for a specific test have to be read from file or from the Cal/Ctrl report by using a handheld barcode scanner. The values of a user-definable calibrator have to be defined manually for the analyzer.

To view calibrator 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 for user-defined calibrators can be defined on the right. Once a user-defined calibrator is placed into the analyzer, it is not possible to edit the calibrator's parameters.

**Figure 7. Calibrator definition** view




- Defining lot concentrations for multicalibrators
- Defining user-definable calibrators

# Defining lot concentrations for multicalibrators

**Note** If you use ordinary system calibrators, you cannot define the lot concentration in the software. The values of these system calibrators are read from the barcode when the calibrator is inserted into the analyzer. If you use system multicalibrators, the values are read from Cal/Ctrl report or from file.

Define the lot concentrations for a multicalibrator when it is used for the first time in a specific test.

1. Insert barcoded multicalibrators into the calQC rack. Ensure that the barcodes on the vials are facing towards the barcode reader.
2. Insert the rack into the analyzer.

   The analyzer reads the IDs of the multicalibrators from the barcode. The program asks to read the calibrator values.
3. Click **Read from barcode** or **Read from file**.
4. Scan the barcode in the Cal/Ctrl report by using a hand held barcode scanner or select the file.
5. Click **Save**.

   After the multicalibrator lot values are defined for a specific test, this multicalibrator lot can be used in future for this test by inserting the calibrator into the analyzer. In this case, the analyzer uses the lot values previously read into the user interface.

**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 Binding Site products.

# Defining user-definable calibrators

You can define user-definable calibrators and add them for the user-definable tests. The user-defined calibrators do not have a barcode and they are inserted in sample cups into the sample rack.

## 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 The Binding Site products from the other products.
- **Barcode ID** shows the system calibrator's barcode ID.
- **Into use date** shows the date when the calibrator has been taken into use.

# Defining lot concentrations for calibrators

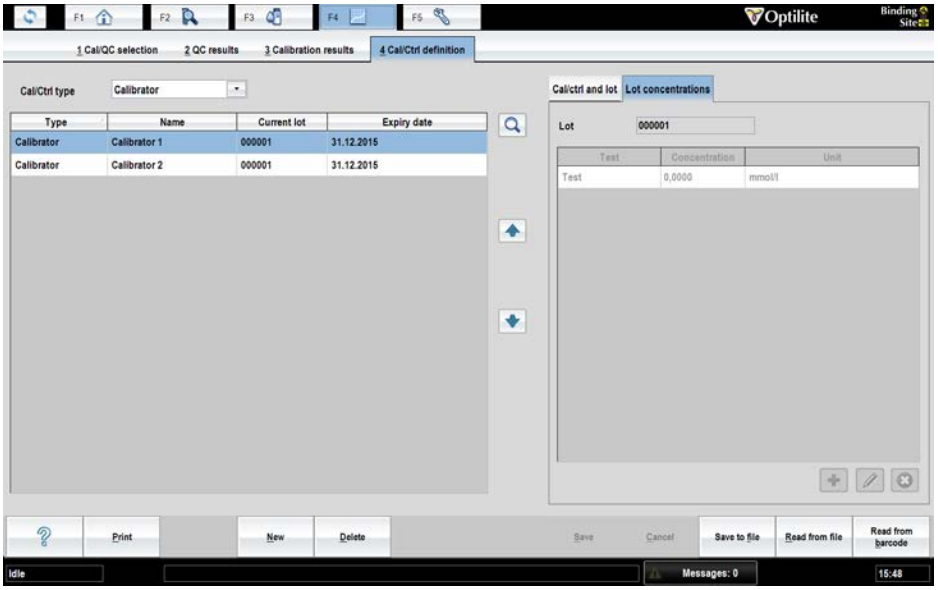
Calibrator lot is a production batch of the calibrator. The test-based calibrator values can vary from lot to lot. Each test where calibrator is used has a separate concentration. The lot concentration for a test can be defined after the test has been created. Use the current lot for the analysis.

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

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

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

**Figure 8.** Defining concentrations




# 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)

Optilite® analyser uses three kinds of controls:

- System controls which are inserted using barcoded vials
- Multicontrols which are system controls used in several tests
- User-definable controls which are inserted using sample cups

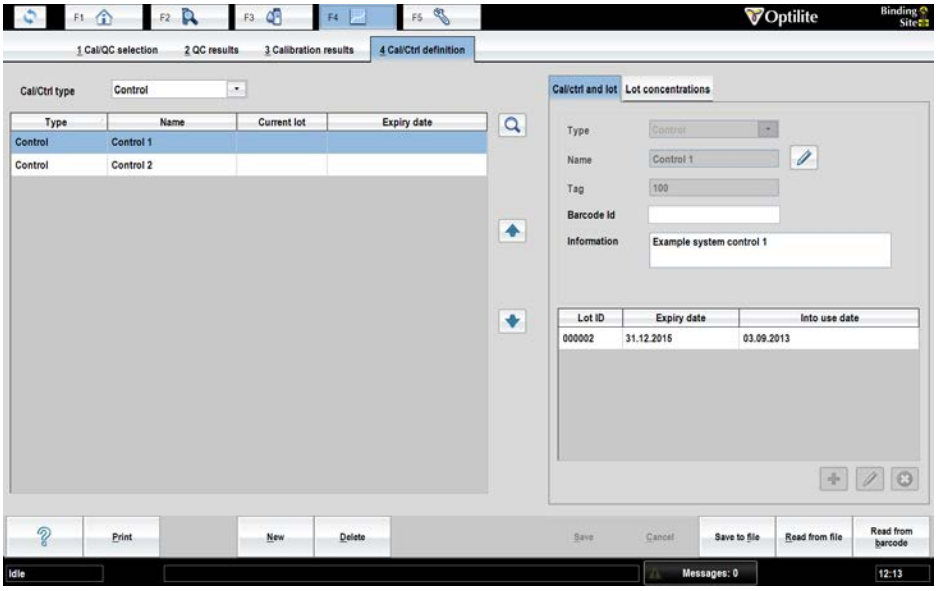
The values of a system control are read from the barcode. A multicontrol contains several analytes and it can be used in several tests. The values of a multicontrol for a specific test have to be read from file or from the Cal/Ctrl report by using a handheld barcode scanner. The values of a user-definable control must be defined manually for the analyzer.

To view control parameters, select F4 > **Cal/Ctrl definition**. The main control details are listed on the left. The list shows the control type and name, the current lot and the expiry date. The user-definable control's details can be defined on the right. Once a user-defined control is placed into the analyzer, it is not possible to edit the control's parameters.The *Special* type is used for defining washing solutions. The system vendor can define and name two washing solutions to be used in the sample probe and mixer wash.

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

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

**Figure 9. Control definition** view




- Creating quality control profile

- Defining lot concentrations for multicontrols
- Defining user-definable quality controls

# Creating quality control profile

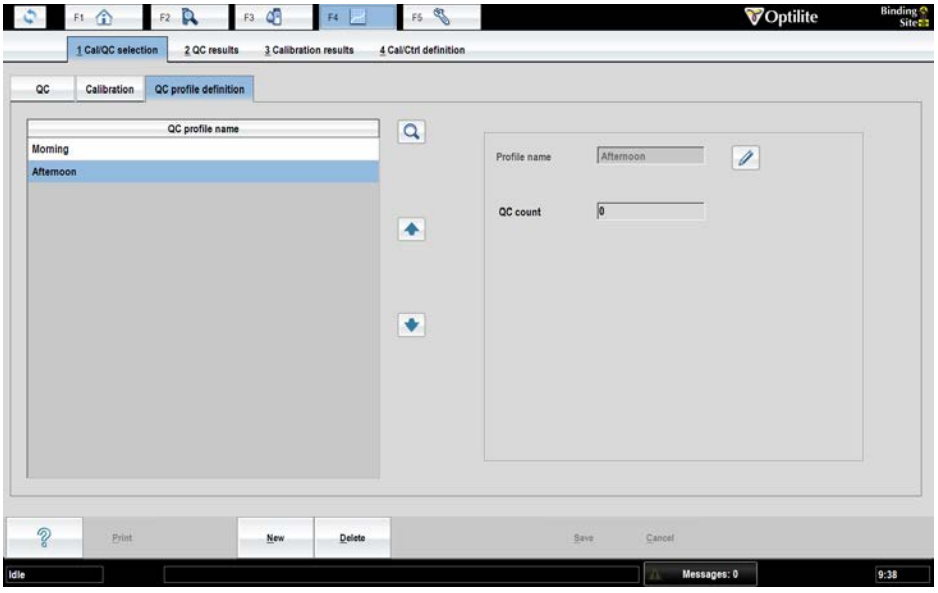
The quality control profiles contain quality controls that are run at the same time. For example, all quality controls that are run before daily routines can be included in the profile “Morning”. The quality control profile has to be defined if the quality control's **Trigger** in the F3 > Test definition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

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

To create a new profile:

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

**Figure 10. Quality control profile** view




# Defining lot concentrations for multicontrols

**Note** If you use ordinary system controls, you do not need to define the lot concentration in the software. The values of these system controls are read from the barcode when the control is inserted into the analyzer. If you use system multicontrols, the values are read from Cal/Ctrl report or from file.

Define the lot concentrations for a multicontrol when it is used for the first time in a specific test.

1. Insert barcoded multicontrols into the calQC rack. Ensure that the barcodes on the vials are facing towards the barcode reader.
2. Insert the rack into the analyzer.

   The analyzer reads the IDs of the multicontrols from the barcode. The program asks to read the control values.
3. Click **Read from barcode** or **Read from file**.
4. Scan the barcode in the Cal/Ctrl report by using a hand held barcode scanner or select the file.
5. Click **Save**.

   After the multicontrol lot values are defined for a specific test, this multicontrol lot can be used in future for this test by inserting the control into the analyzer. In this case, the analyzer uses the lot values previously read into the user interface.

**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 Binding Site products.

# Defining user-definable quality controls

You can define user-definable quality controls and add them for the system tests and user-definable tests. The user-defined quality controls do not have a barcode and they are inserted in sample cups into the sample rack. You can also use these quality controls in several tests such as the multicontrols are used.

## Defining quality controls

The supplier can provide barcoded pre-defined control vials to be used with 3rd party controls. These pre-defined vials have a barcode ID and the vial type defined by the supplier.

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. If you are defining pre-defined user-definable controls, type the barcode ID given by the supplier in the **Barcode Id** box.
7. Type the additional information in the **Information** box. For example, the official name.
8. Click **Save**.

9. 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.
10. Press Enter.
11. Click **Save**.

The following parameters are read-only:

- **Tag**
- **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.

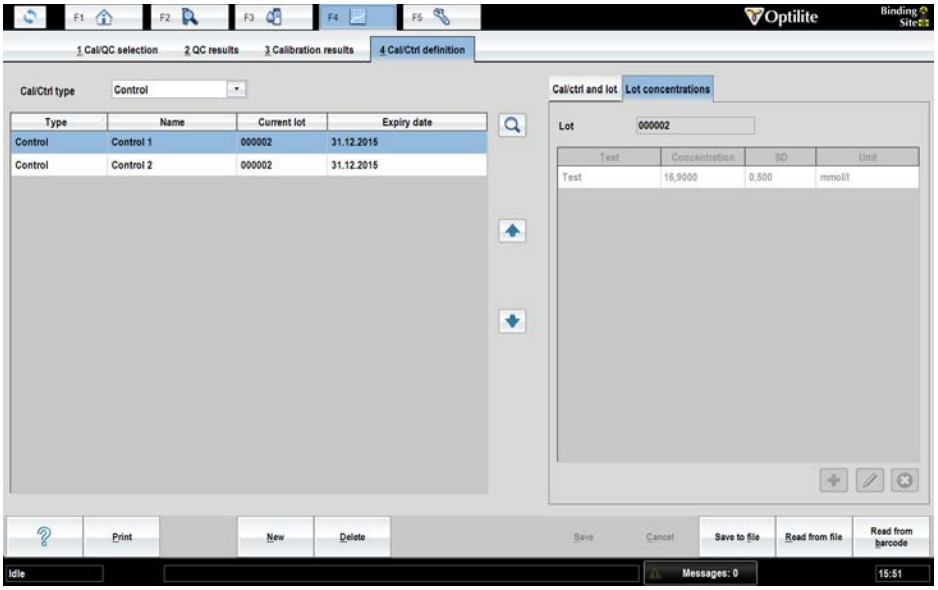
To define concentrations for the control to be used in different tests:

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** QC results are corrected with correction factor and correction bias.

**Figure 11.** Defining concentrations




# 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**.

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# Test definition

Creating user-definable tests requires using a dongle that enables these tests. The dongle is installed in the computer's USB port. The number of user-definable tests is configured in dongle at the factory. If the **New** button in the Test definition window is grayed, the dongle does not contain any user-definable tests, all the tests in the dongle have been used or the dongle has not been installed. If the dongle is missing, the system gives an error message in the user interface start-up.



## Installing dongle

The number of user-definable tests is defined by the dongle. To install the dongle in the computer's USB port:

1. If the computer has a used dongle, remove it from the USB-port.
2. Install a new dongle to the USB-port in the keyboard.
3. Select F5 > Configuration > **Additional.**
4. Check the number of user-definable tests from the display.

**Note** The dongle is computer-specific. When it is once connected to certain computer it cannot be connected to another one.

# Reading test parameters from file

**Note** This operation requires that the user's access level is main user or higher.

**Note** You must have available tests in the dongle when you want to read the user-definable test details from a barcode or a file.

**Note** Applications saved from software version 7.0 or later cannot be read with earlier software versions.

To read test parameters for a test from a file:

1. Select F3 > **Test definition**.
2. Click **Read from file**.
3. Select the file.
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 and it is not possible to restore them later on.

   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 removed.

**Note** It is recommended to answer "Yes" to keep the existing QC parameters.

**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.

**Note** Software 7.0 contains new definitions for sample type dilutions. If the user reads the test parameters from file that is created by software 6.0 or earlier, the sample type dilutions are overwritten.

# Reading test parameters from barcodes

**Note** This operation requires that the user's access level is main user or higher.

**Note** You must have available tests in the dongle when you want to read the user-definable test details from a barcode or a file.

**Note** Applications saved from software version 7.0 or later cannot be read with earlier software versions.

To read test parameters for a test from barcodes:

1. Select F3 > **Test definition**.
2. Click **Read from barcode**.
3. Read the 2D barcodes in ascending order from the Test parameters printout and click **Save** after every reading.
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 and it is not possible to restore them later on.

   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 removed.

**Note** It is recommended to answer "Yes" to keep the existing QC parameters.

**Note** Software 7.0 contains new definitions for sample type dilutions. If the user reads the test parameters from barcode that is created by software 6.0 or earlier, the sample type dilutions are overwritten.

# Saving test parameters

To save the test parameters for further use:

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

   File name is automatically constructed from test short name, tag and version number.
4. Click **Save**.

# Printing test parameters

To print test parameters:

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

# Deleting tests

To delete test:

1. Select F3 > Test definition > **Info.**

2. Select a test from the list.
3. Click **Delete**.
4. At the prompt, click **Yes** to delete the test.

Tests cannot be deleted if:

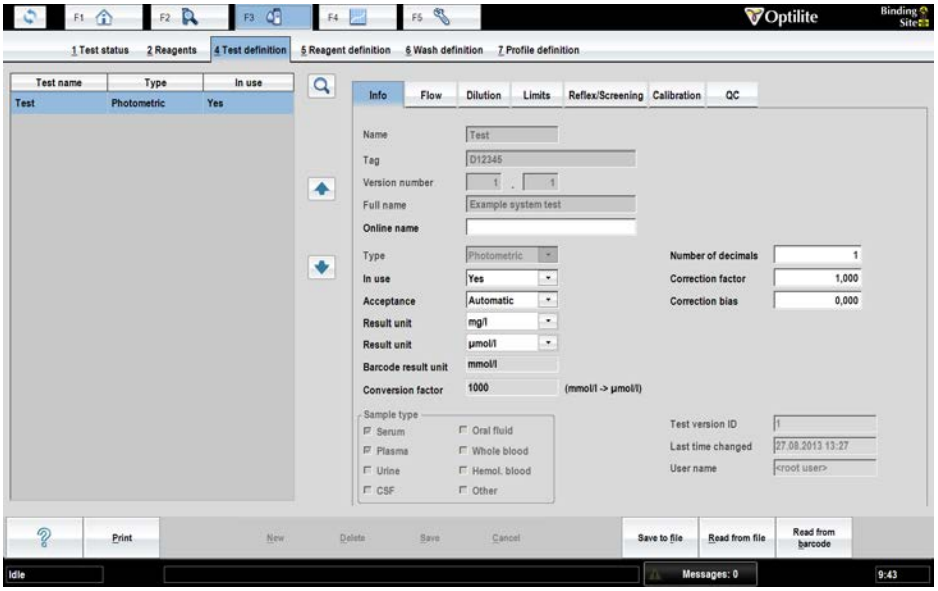
- the test is a system test
- the test has a request to calibration (which has not been run yet)
- the calibration has been run for the test
- the test has sample or quality control results
- the test has sample or quality control results in the archive

# Test parameter settings

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

- Photometric
- External
- Calculated

**Figure 12.** Defining test




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 test flow for photometric tests.
- The **Dilution** tab shows the dilutions for photometric tests.
- The **Limits** tab shows the limits for all test types.

- The **Reflex/Screening** tab shows the reflex tests that are run if the result of the test is within the defined limits.
- The **Calibration** tab shows the calibration parameters for photometric tests.
- The **QC** tab shows the quality control parameters for photometric tests.

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

**Note** Do not use special characters in the definition fields.

**Table 7.** Test types and related tabs

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

# General parameters

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

**Table 8.** 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. |
| 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, External, Calculated | Select the correct type of a test. |

| Parameter | Values | Description |
|---|---|---|
| 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.<br>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.<br>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 | Select the correct unit for a test. |
| 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 barcode 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 barcode unit before you can change it once again. The software asks the conversion factor only once for each unit pair. |

**Table 9.** Common read-only parameters

| Parameter | Description |
|---|---|
| Tag | **Tag** information distinguishes The Binding Site tests from user-definable tests. |
| Barcode result unit | Shows the original test unit of the system test. |
| Test version ID | The program defines an ID for the test. The ID is unique for each test. |
| Last time changed | Shows the date and time when the test definition was changed the last time. |
| User name | Shows the user who modified the test definition the last time. |

**Table 10.** Parameters for photometric tests

| Parameter | Values | Description |
|---|---|---|
| Sample type | Serum, Plasma, Urine, CSF, Oral fluid, Whole blood, Hemolyzed blood, Other | 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). |
| 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). |

**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.<br>The operators for the formula:<br>+ - addition<br>– - subtraction<br>* - multiplication<br>/ - division<br>Use brackets () if an operation must be calculated before another. For example,<br>*(<A>/<B>)*<C>*<br>First, A is divided by B and then the result is multiplied by C.<br>*<A>/(<B>*<C>)*<br>First, B is multiplied by C and then A is divided by the result. |

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

# Parameters for dilution

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

**Figure 13.** Defining dilution parameters

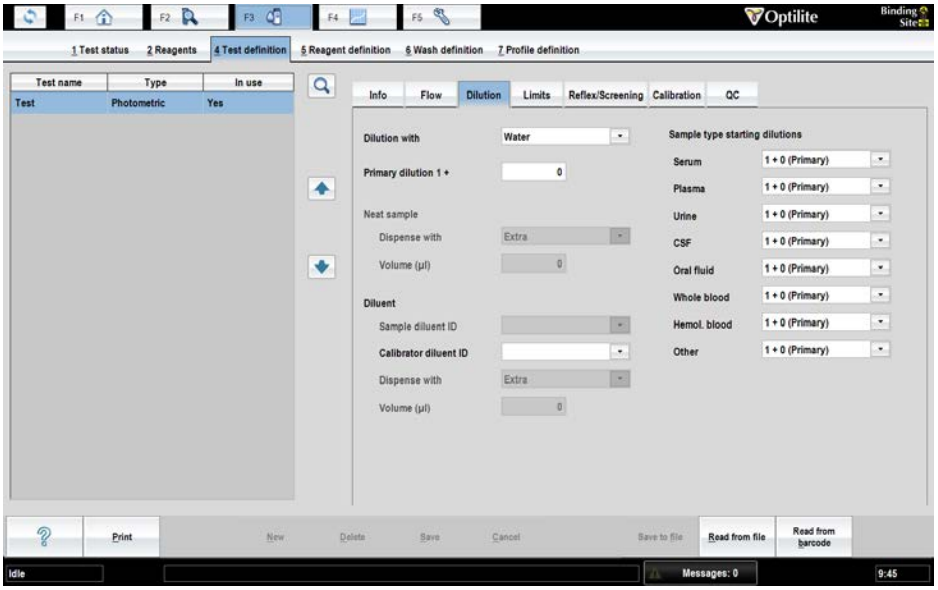



**Table 12.** Dilution parameters for photometric test

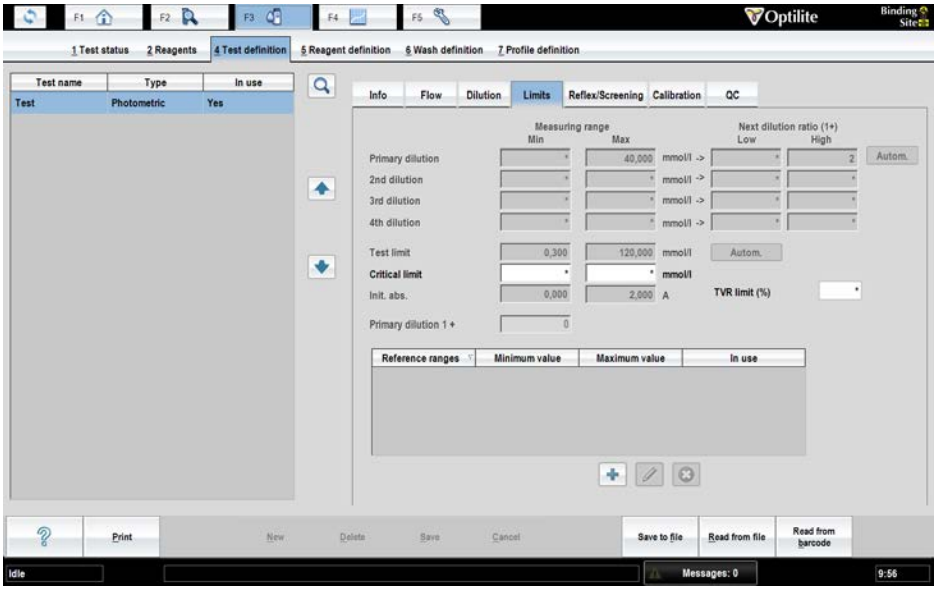
| Parameter | Values | Description |
|---|---|---|
| Dilution with | Water, Diluent, None | Select the dilution for the test.<br>If you select "Water":<br>• samples are diluted with water<br>• calibrators are diluted with water if nothing is selected in the **Calibrator diluent ID** field<br>• calibrators are diluted with a specific diluent if it is selected in the **Calibrator diluent ID** field<br>If you select "Diluent", you must select diluents both for the sample and for the calibrator.<br>If you select "None", you will not be able to define a dilution for this test at any stage. |
| Primary dilution 1+ | 0-9999 | Samples are always diluted according to primary dilution ratio.<br>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.<br>If the dilution ratio is greater than 1 + 120, the dilution is performed in two steps.<br>The accepted dilution ratio values are as follows:<br>• In the range 1 ... 120, accepted values at intervals of one number (e.g. 1, 2, ... 119, 120) |

| Parameter | Values | Description |
|---|---|---|
| | | • In the range 199 ... 999, accepted values at intervals of 100 (e.g. 199, 299, ... 899, 999)<br>• In the range 1999 ... 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, ... 8999, 9999)<br>If the entered value cannot be used, the program proposes the nearest acceptable values.<br>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 | | You can select the diluent for a sample if the value in the **Dilution with** field is "Diluent". |
| Calibrator diluent ID | | Select the correct type of a diluent for a calibrator. If the value in the **Dilution with** field is "Diluent", you must select a calibrator diluent. If the value in the **Dilution with** field is "Water", you can either select a diluent or leave the field empty, in which case the calibrators are diluted with water. |
| 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. |
| **Sample type starting dilutions** | | |
| Serum, Plasma, Urine, CSF, Oral fluid, Whole blood, Hemol. blood, Other | Primary dilution ratio , Low/ High dilution ratios defined in the **Limits** tab | Select a sample type dilution ratio for each sample type, if needed. The sample type dilution is used as the starting dilution for samples of that type.<br>The default value is a primary dilution ratio. |

# Parameters for limits

To define limit parameters for a photometric, external, or calculated test, select F3 > Test definition > **Limits**.

**Figure 14.** Defining limit parameters




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

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

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

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

**Table 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.<br><br>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 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,<br>2nd dilution,<br>3rd dilution,<br>4th dilution | The *Measuring range* values must be within the *Test limit*'s value range.<br>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.<br>The other dilution limits in the *Min* and *Max* fields of *Measuring range* are calculated according to defined *Next dilution ratio* limits.<br>The value in the *Max* field increases and the value in the *Min* field decreases after every dilution step.<br>To define limits from the calibration, click **Autom.** The limits must be set manually but they are recalculated during calibration, if **Autom.** is selected.<br>You can select any defined dilution step as the starting point for diluting a sample in the F2 > **Samples**. |
| 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.<br>The accepted dilution ratio values are as follows:<br>• In the range 1 ... 120, accepted values at intervals of one number (e.g. 1, 2, ... 119, 120)<br>• In the range 199 ... 999, accepted values at intervals of 100 (e.g. 199, 299, ... 899, 999)<br>• In the range 1999 ... 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, ... 8999, 9999)<br>If the entered value cannot be used, the program proposes the nearest acceptable values.<br>The value in the *Low* field has to decrease and the value in the *High* field has to increase after every dilution step. |
| Init. abs. (initial absorbance) | Define the lowest and highest allowable values for the initial absorbance. |
| TVR limit (technical validation required) | The TVR limit is a percentage defined in the assay parameters. If the TVR limit is set to *, the TVR flag is never applied.<br>If the result is the last result of its dilution series and it has at least one previous dilution, then the result will receive the TVR flag if one of the following is true:<br>1. The previous result in the series has an *Activity check* error and the last result is less than the previous result by a value greater than the TVR limit.<br>2. The previous result was above the measuring range and the last result is less than the highest calibrator at the previous dilution by a value greater than the TVR limit.<br>3. The second to last result has an *Activity check* error and the last result is below the calibration range. |

| Parameter | Description |
|---|---|
| | 4. The second to last result is above the calibration range and the last result is below the calibration range.<br>If the previous and last results are from different test versions that have different result units, then the previous result (case 1 above) or highest calibrator (case 2) is converted to the unit of the latest result before performing the comparison.<br>The TVR flag is only applied to automatic reruns. If the last result is a manual rerun, the TVR check is not done.<br>If the result receives the TVR flag, it is not automatically accepted. |

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

**Figure 15.** Defining reflex test parameters

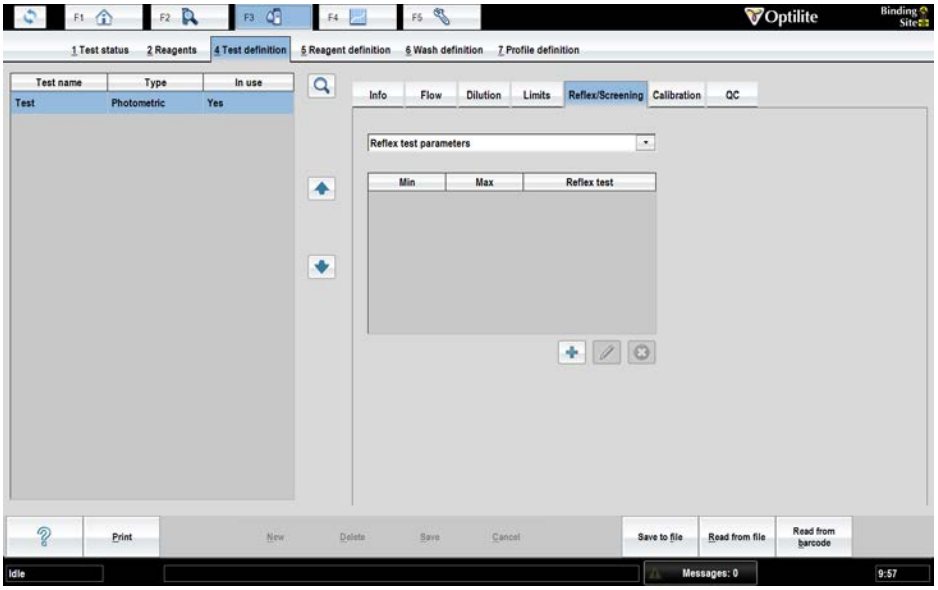



**Table 17.** Reflex parameters

| 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 Test 2 if Test 1 > 20 µmol/L, set value "20" to minimum limit and set value "*" to maximum limit. |
| Reflex test | Select the reflex test from the drop-down list. |

# Parameters for calibration

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

**Figure 16.** Defining calibration parameters

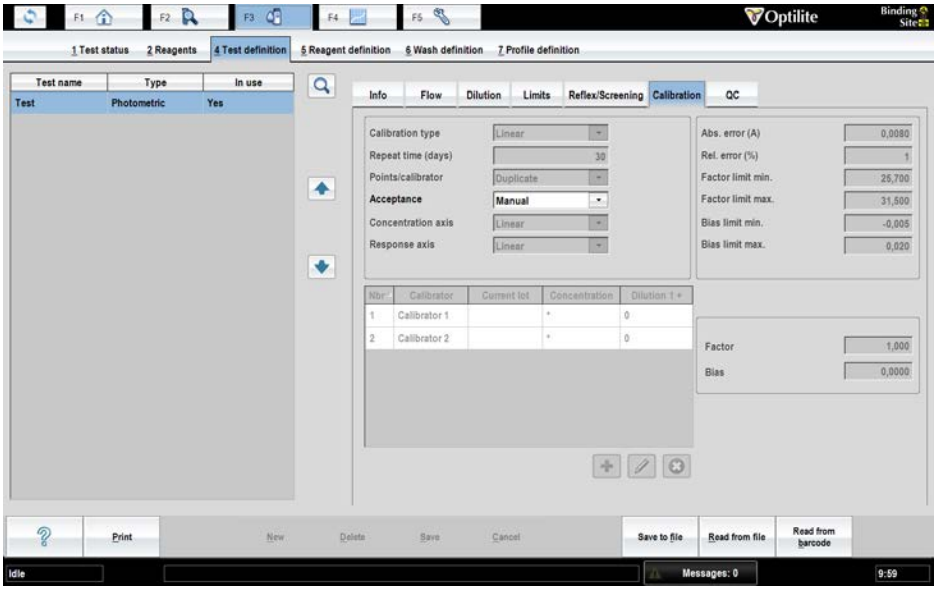



**Table 18.** Calibration parameters

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

| Parameter | Values | Description |
|---|---|---|
| Response axis | Linear, Logarithmic | Define the axis type for the calibration curve. The calibration type restricts the selection. |
| Abs. error (A) | | Define the maximum allowable deviation between the single calibration point and the calculated calibration curve. If an asterisk (*) is used, the checking is not in use. |
| Rel. error (%) | | Define the maximum allowable deviation between the single calibration point and the calculated calibration curve. If an asterisk (*) is used, the checking is not in use. |
| Factor limit min. / Factor limit max. | | Define the maximum and minimum limit for the factor. If an asterisk (*) is used, the checking is not in use. |
| Bias limit min. / Bias limit max. | | Define the maximum and minimum limit for the bias. If an asterisk (*) is used, the checking is not in use. |
| 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 | | For user-defined calibrators, the value is read-only and defined in the F4 > **Cal/Ctrl definition**. For system calibrators, the values are read from the vial's barcode when the vial is inserted into the analyzer, and the values are shown in this field when the first dispension from this particular vial is performed. |
| Concentration | | For user-defined calibrators, the value is read-only and defined in the F4 > **Cal/Ctrl definition**. For system calibrators, the values are read from the vial's barcode when the vial is inserted into the analyzer, and the values are shown in this field when the first dispension from this particular vial is performed. |
| Dilution 1+ | 0-9999 | Type the dilution ratio. |

| Parameter | Values | Description |
|---|---|---|
| | | The accepted dilution ratio values are as follows:<br>• In the range 1 ... 120, accepted values at intervals of one number (e.g. 1, 2, ... 119, 120)<br>• In the range 199 ... 999, accepted values at intervals of 100 (e.g. 199, 299, ... 899, 999)<br>• In the range 1999 ... 9999, accepted values at intervals of 1000 (e.g. 1999, 2999, ... 8999, 9999)<br>If the entered value cannot be used, the program proposes the nearest acceptable values. |

# Parameters for quality control

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

**Note** Controls of the system tests are also editable.

**Note** You can add only the user-definable controls or system controls, which have existed in the original test version, for the system test.

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

**Figure 17.** Defining QC parameters

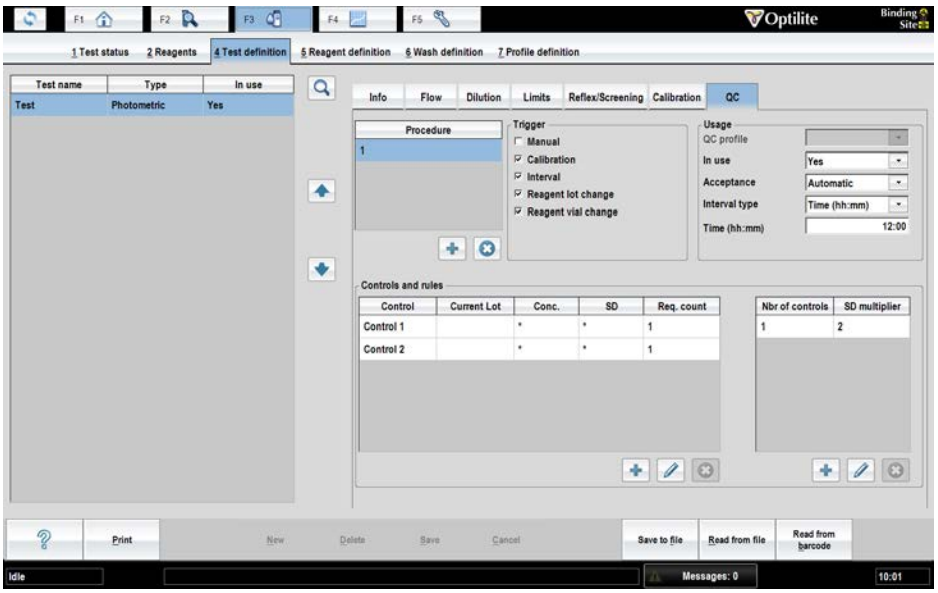


**Table 19.** Quality control parameters

| 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.<br>• Manual - the procedure is performed manually<br>• Calibration - the procedure is performed with calibration<br>• Interval - the procedure is performed according to the interval settings<br>• Reagent lot change - the procedure is performed when the reagent lot is changed for the test<br>• Reagent vial change - the procedure is performed when the reagent vial is changed for the test<br>If calibration, and changing vial or lot are performed at the same time, the QC is requested only once. |
| **Usage** | | |
| QC profile | | Select the QC profile to be used. Profiles can be defined in the **QC profile** tab (F4 > Cal/QC selection > **Profile definition**). The QC profile can be defined only if the Trigger is set to Manual and then it is mandatory. |
| In use | Yes, No | Only QC procedures in use are shown in the **QC** and **Calibration** tabs under the **Cal/QC selection** view. |
| Acceptance | Automatic, Manual | Define how to accept the quality control. |
| Interval type | Requests, Time | Define the interval type. |
| Requests | | If the value “Interval” is set to *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 20$^{th}$ 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. |
| **Controls and rules** | | |
| Control | | Select the controls to be used in this procedure. |
| Current Lot | | Shows the current lot of the selected control. |
| Conc | | Shows the concentration of the selected lot. |
| SD | | Shows the SD (standard deviation) of the selected lot. |

| Parameter | Values | Description |
|---|---|---|
| Req. count | | Define how many requests are analyzed from each control. |
| Nbr of controls | | Define how many control requests are compared. |
| SD multiplier | | Define how many SDs the measured control result is allowed to deviate from the given mean value. |

## Defining quality control procedure

1. If you need to define manually triggered QC, you have to define the quality control profile as instructed in Creating quality control profile on page 22.
2. Define controls as instructed in Defining quality controls on page 23.
3. Select F3 > **Test definition**.
4. Select a test from the test list.
5. Select **QC** tab.
6. Click **Add** button under the Procedure area.
7. Type a procedure name to the **Procedure** field and press Enter key.
8. Select needed triggers by ticking the check boxes under the **Trigger** heading.

   **Note** Following triggers can be used only in one procedure: Calibration, Interval, Reagent lot change and Reagent vial change. In addition the triggers Interval, Reagent lot change and Reagent vial change must be in the same procedure.
9. Define usage of the procedure.
10. Click Add button under the **Controls and rules** list.
11. Add needed controls and define how many times each control is requested.
12. Click Add button under the **Controls and rules** section on the right.
13. Add needed QC rules by defining the number of controls and SD multiplier.
14. Click **Save** to save QC procedure for the test.

## 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 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.

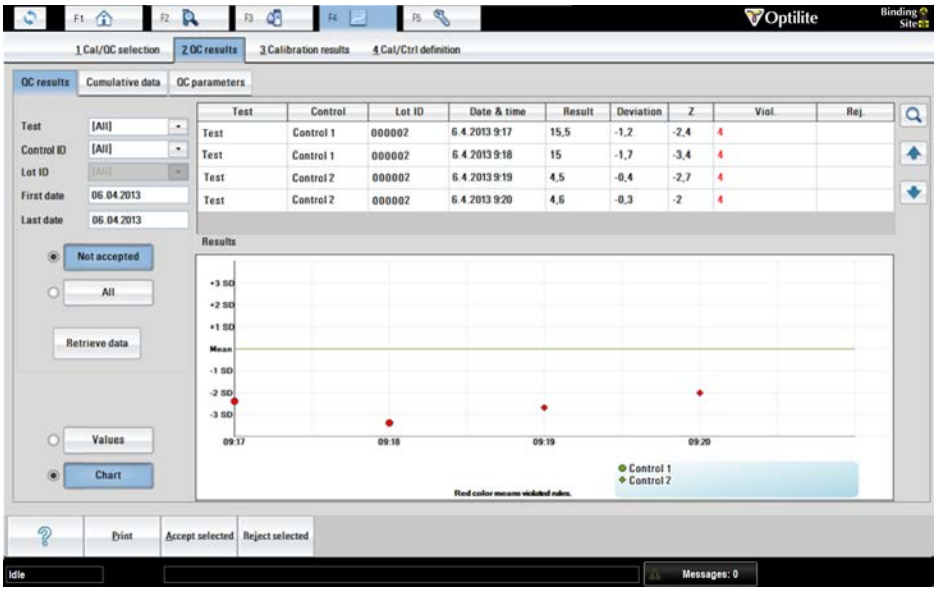
More information about the Westgard rules is available at http://www.westgard.com/.

### ❖ 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 18.** 4:1 SD rule violation

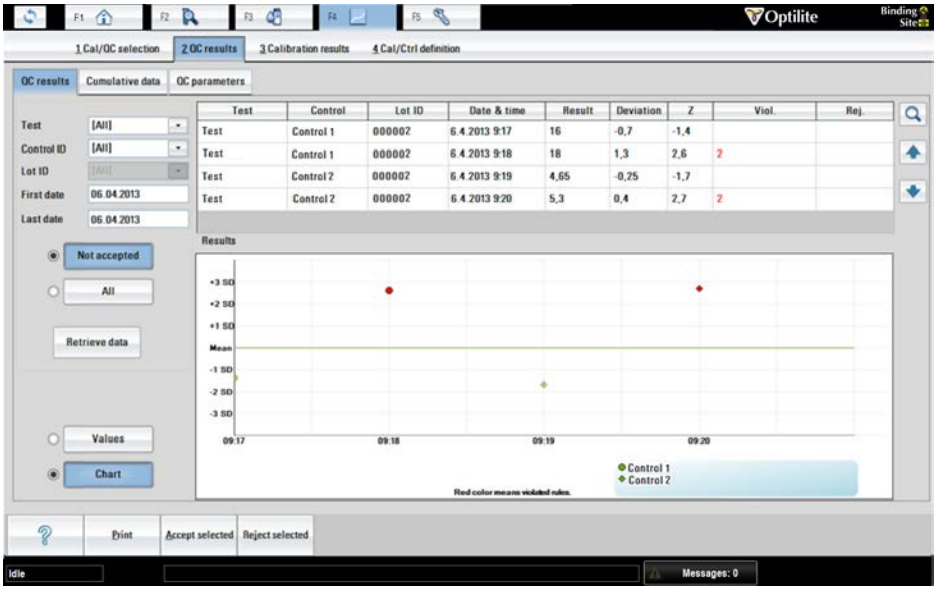



### ❖ Number of controls is less than batch size

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

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

**Figure 19.** 2:2 SD rule violation

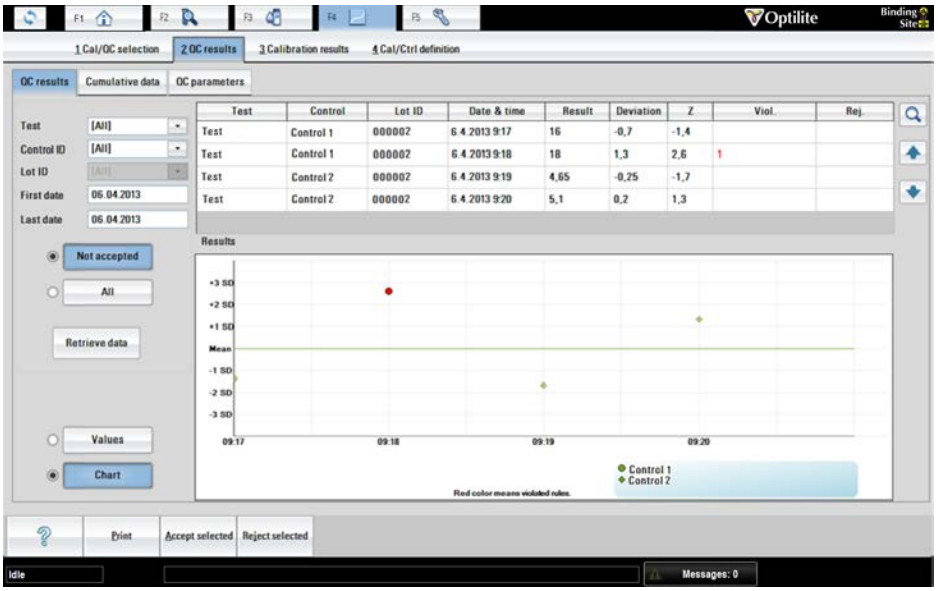



### ❖ Number of controls is one

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

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

**Figure 20.** 1:2 SD rule violation

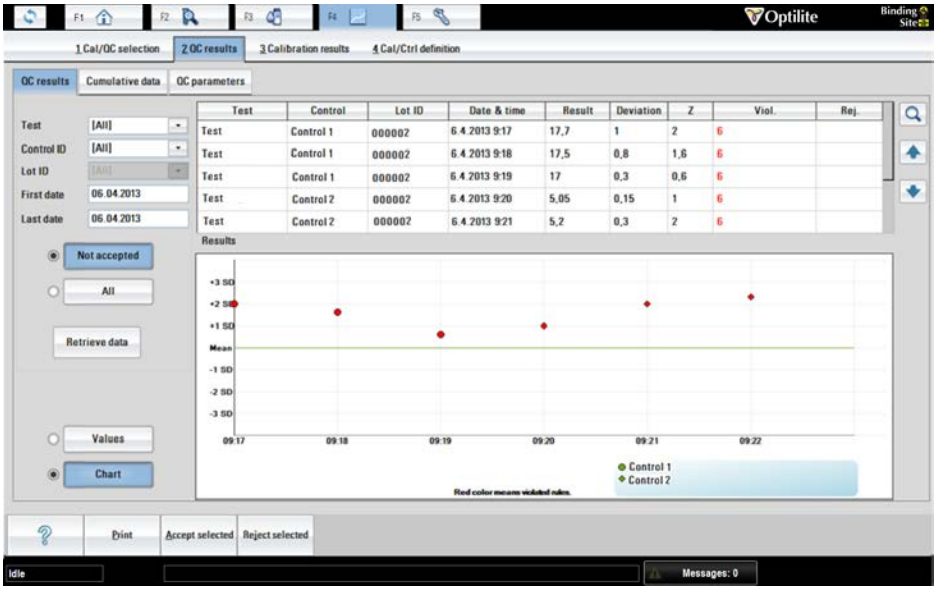


### ❖ All results are lower or higher than control value

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

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

**Figure 21.** 6:0 SD rule violation

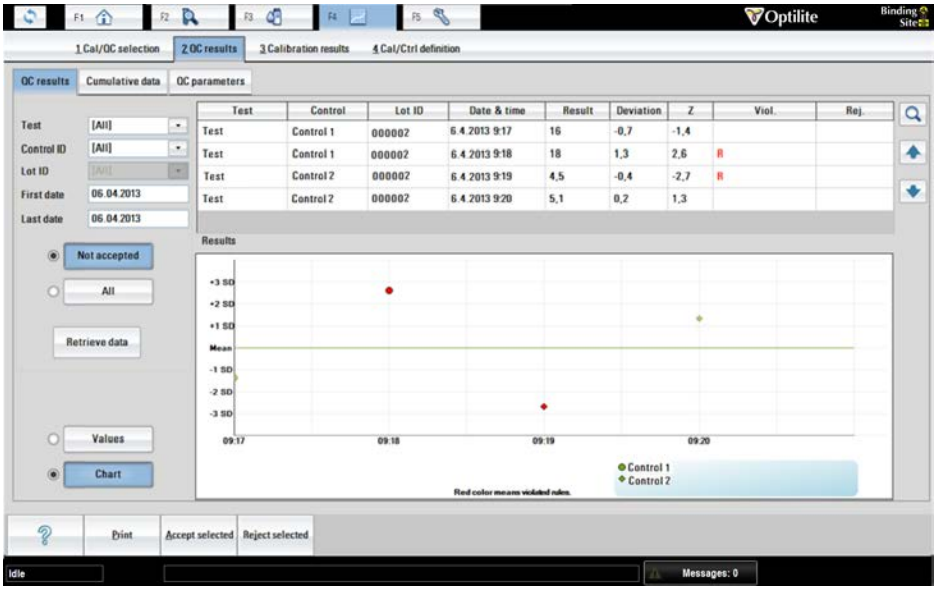



### ❖ R rule

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

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

**Figure 22.** R:4 SD rule violation



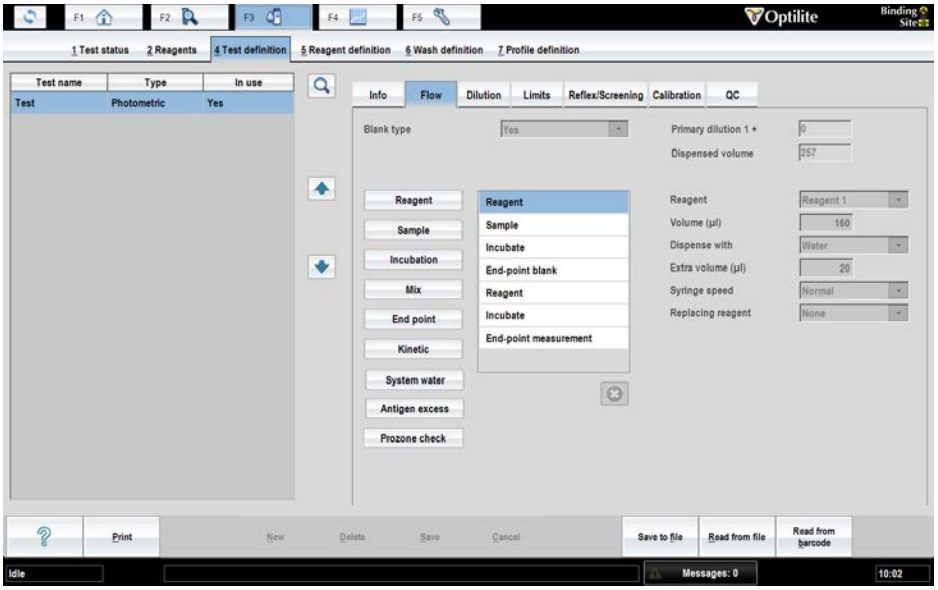

# Defining test flow

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

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

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

**Figure 23.** Defining test flow




# Common parameters

| Parameter | Values | Description |
|---|---|---|
| Blank type | No, Yes, True Sample | Define the correct blank for the test:<br>"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.<br>"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.<br>"True sample" - The blank is measured in a separate cuvette position. In the blank measurement, the test reagent is replaced with a selected blank reagent. The test flow requires one measurement for the sample. |
| Primary dilution 1+ | | A read-only parameter. Shows the total dilution of the sample. |

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

## Reagent

| Parameter | Values | Description |
|---|---|---|
| Reagent | | Select the reagent that will be used in a test from the drop-down menu. One reagent can be connected to a maximum of 20 tests. If you want to run more than 20 tests with the same reagent, define the reagent with a different name and connect a part of the tests to that reagent. |
| Volume (µl) | 2 - 240 µl | Define the reagent's volume. The reagent volume depends on the syringe speed. See Reagent dispensing on page 50. |
| Dispense with | Water, Extra | Define whether the reagent is dispensed with water or reagent extra. |
| Extra volume (µl) | See Reagent dispensing on page 50 | 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 is performed or not. If the Extra wash is set on, the wash is performed every time when the sample is dispensed. |
| Washing solution | Water, [Washing solution 1], [Washing solution 2] | This selection list is shown when the **Extra wash** is set "Yes".<br>Define whether the extra wash is performed with water or with Washing solution. The Washing solutions are defined and named in the F4 > **Cal/Ctrl definition** by the system vendor. |
| Wash target | Sample probe, Probe and mixer | This selection list is shown when the **Extra wash** is set "Yes".<br>Define whether the wash target is the probe or the probe and mixer. |
| Wash sequence | Before dispense, After dispense, Before and after | This selection list is shown when the **Extra wash** is set "Yes".<br>Define whether the wash is performed before dispense, after dispense or before and after dispense. |

# 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. |
| Side wavelength | Select the side wavelength from the drop-down menu (not for prozone check test). 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. |
| Delta abs. check min. (A) | Define the minimum required absorbance change for the prozone check test. If the test has prozone check in the flow and the absorbance change is lower than the required value, the prozone error flag is not set in any case. The default value (*) indicates that checking is not in use. |

# 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. |

| Parameter | Values | Description |
|---|---|---|
| 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<br>Cut 18 - 3600/s | Define the measurement time in seconds. The minimum measurement time for a linear measurement type is 9 seconds, and at least 2 measurement points are required. The minimum measurement time for a linear cut measurement type is 18 seconds, and at least 3 measurement points are required. |
| Points / Interval | 2 - 12 meas. points / interval (s) | Define the number of the measurement points and the intervals in seconds. The number of measurement points can be defined between 2 and 12 depending on measurement time. The minimum measurement time for a linear measurement type is 9 seconds, and at least 2 measurement points are required. The minimum measurement time for a linear cut measurement type is 18 seconds, and at least 3 measurement points are required. |
| Actual meas. time (sec) | | A read-only parameter shows the actual time of measurement. |
| Rate check in use | Yes, No | Select whether the reaction rate is checked or not. The reaction rate is checked immediately after the last dispensing by using 2 measurement points. |
| Max rate (A/min) | 0.0 - 2.0 | Define the maximum rate of change. The automatic calculation uses the higher dilution limit value for calculating the limit. To avoid false alarms, it is recommended to set the max rate (A/min) limit 10% higher than the calculated limit. |

## System water

| Parameter | Values | Description |
|---|---|---|
| Volume (µl) | 2 - 240 | Define the volume of system water that is dispensed into a cuvette. |

## Antigen excess

| Parameter | Values | Description |
|---|---|---|
| AE detection liquid | Antigen control, Patient sample | Select the detection liquid that will be used to measure if the sample is in an antigen excess. |
| Control ID | | Select the control that will be used to measure if the sample is in an antigen excess. |
| Volume (µl) | 2 - 120 | Define the volume of the selected AE detection liquid that will be dispensed into the cuvette for testing. |
| Dispense with | Water, Extra | Define whether the selected AE detection liquid is dispensed with water or sample extra. |
| Extra volume (µl) | 0 - 120 | Define the volume of the water or AE detection liquid extra. If the AE detection liquid is dispensed with AE detection liquid extra, the recommended volume is two times the AE detection liquid volume. |
| Time (sec) | 18 - 3600 | Define the incubation time. The default value is 18 s. |
| Antigen limit min. | | Define the minimum allowed measurement change as a concentration unit. The default value is set to 0. |
| Antigen limit max. | | Define the maximum allowed measurement change as a concentration unit. The default value is set to *. |

## Prozone check

The prozone check is added to the test flow before the end-point measurement, or before the incubation if the end-point measurement follows incubation immediately.

| Parameter | Values | Description |
|---|---|---|
| 1st window start,<br>2nd window start,<br>3rd window start | | Define the start time of the measuring window [1-3] in seconds to the Start measure field.<br>Actual time (sec) shows the actual time, which may differ from the user-defined time due to operation cycle time. |

| Parameter | Values | Description |
|---|---|---|
| 1st window end, 2nd window end, 3rd window end | | Define the end time of the measuring window [1-3] in seconds to the End measure field. E.g. If the Start measure 1 = 18 and the End measure 1 = 27, the first measuring window is 18-27 sec.<br>Actual time (sec) shows the actual time, which may differ from the user-defined time due to operation cycle time. |
| 2nd window limit % | | Define the limit as a percentage against which the *Second window reaction ratio* is compared. For more information, see Prozone check on page 69. |
| 2nd window check | Low, High | If **Low** is selected, the Prozone flag is given to the result when the 2nd window reaction ratio is below the 2nd window limit %.<br>If **High** is selected, the Prozone flag is given to the result when the 2nd window reaction ratio is above the 2nd window limit %. |
| 3rd window limit % | | Define the limit as a percentage against which the *Third window reaction ratio* is compared. For more information, see Prozone check on page 69. |
| 3rd window check | Low, High | If **Low** is selected, the Prozone flag is given to the result when the 3rd window reaction ratio is below the 3rd window limit %.<br>If **High** is selected, the Prozone flag is given to the result when the 3rd window reaction ratio is above the 3rd window limit %. |

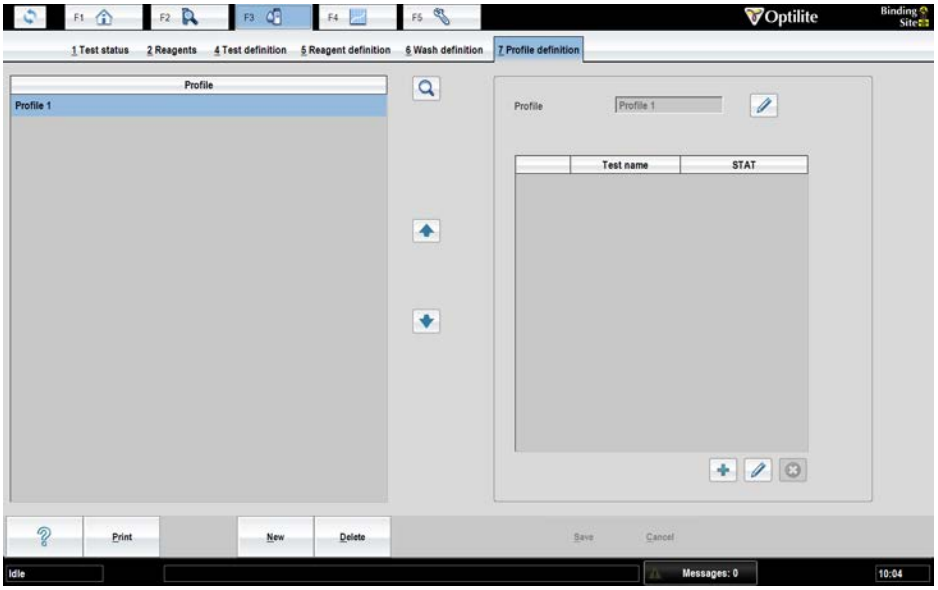
# Managing test profiles

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



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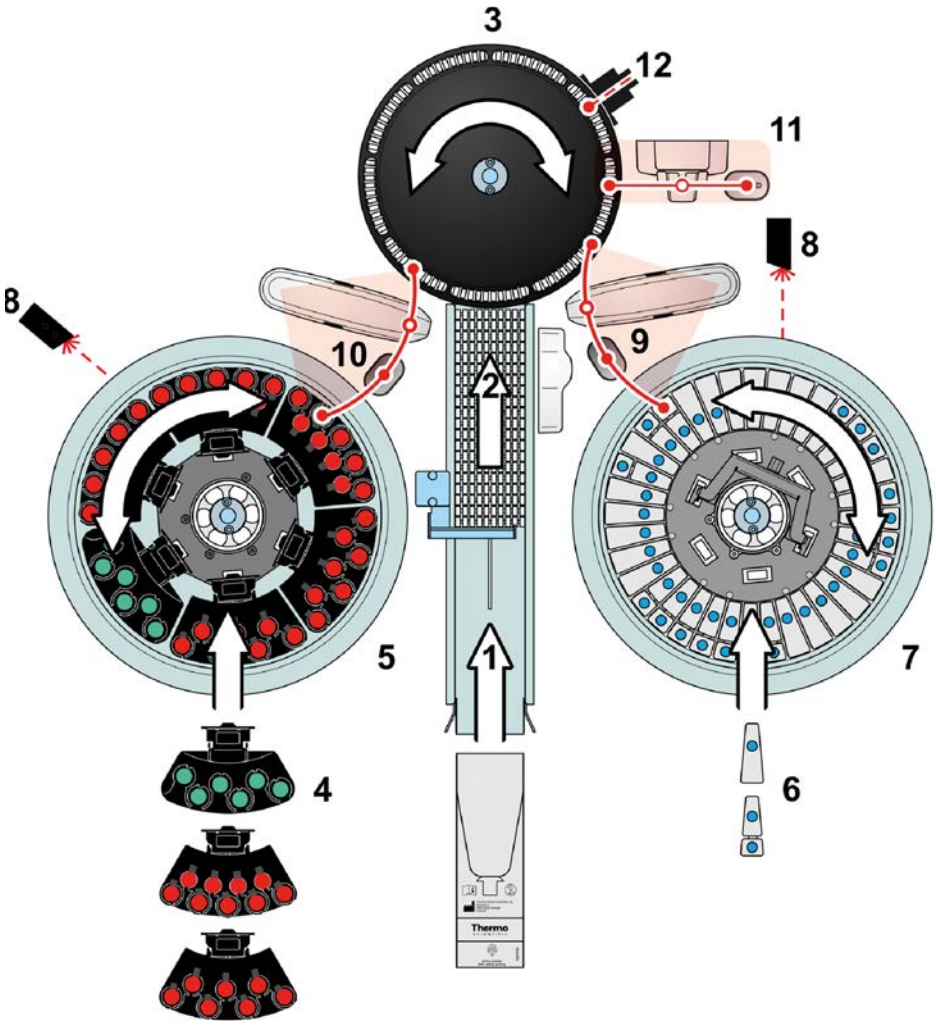
# Photometric measurement

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

## 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 cuvette cells, 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 the measurement, the cuvette is discarded to the cuvette waste bin.

**Figure 25.** Analysis process




1 - TENCELL™ cuvettes entry point
2 - Cuvette loader
3 - Incubator
4 - Sample and calQC racks
5 - Sample disk
6 - Reagents
7 - Reagent disk
8 - Barcode reader
9 - Reagent dispenser
10 - Sample dispenser
11 - Mixer
12 - Photometer unit

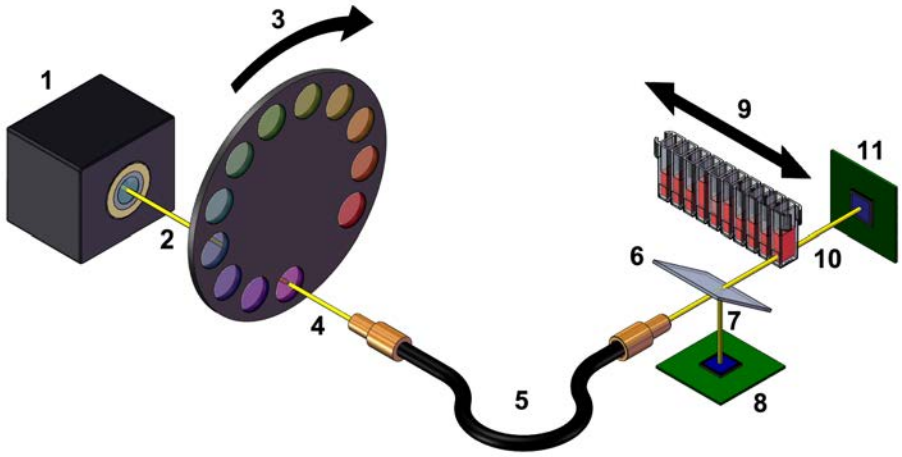
# Photometer

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:

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

$A_R$ - 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.

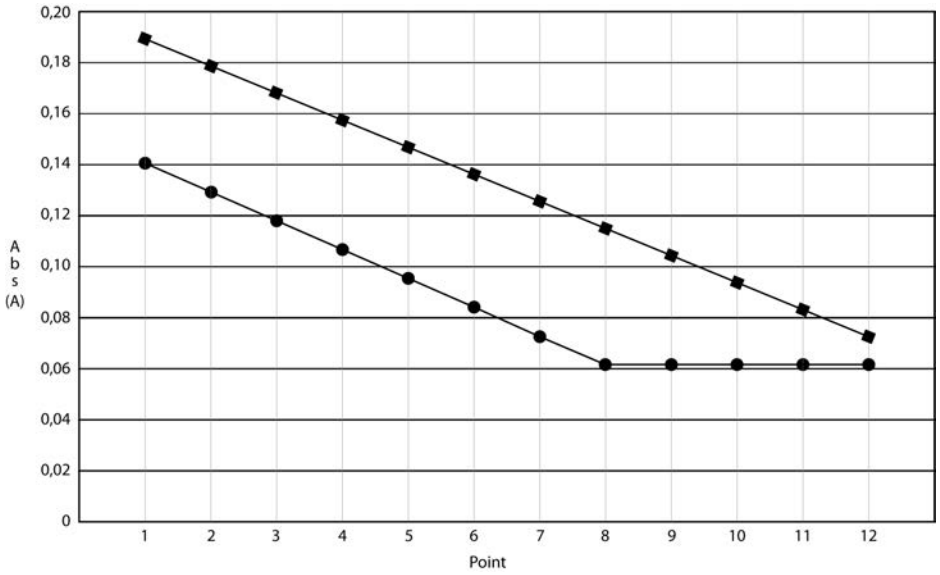
## Linear cut

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
$Vol_{\text{Corr}}$ - 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 72 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**

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

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**

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

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.

## Antigen excess check

After the normal measurement has been measured and calculated, an extra result can be measured and handled. The antigen excess is added to the same cuvette cell with the actual sample and after that the antigen excess (AE) measurement can be performed.

The antigen excess check is possible only for the end-point measurements.

The antigen excess result is calculated based on the parameters defined for a normal measurement. The results are compared by using the cuvette concentrations. The cuvette concentration result is calculated directly from the response without dilution and manual corrections. If the difference between the antigen excess result and normal result is less than the set lower limit, the request is re-analyzed by using the dilution steps. After the antigen excess check, the calculated flag is set to the result. The result and check value for antigen excess are shown in the **Results** view.

If the antigen excess result is violated or re-analyzing with the dilution ratio is not possible, the `Antigen limit Low` flag is set to the result.

## Prozone check

The purpose of the prozone check is to determine whether the sample is in antigen excess. If the antigen excess is found, the result cannot be defined reliably and the sample has to be diluted and re-analyzed.

The prozone check measures the absorbance change in three time windows, calculates the ratios between the changes and compares these values to the defined limits. If the measured values do not meet the limits, the sample is diluted automatically according to dilution steps, if they are defined, until the accepted result is reached. If the prozone check result is still violated after the last dilution step or dilution steps are not defined, the Prozone check error flag is set to the result and the result has to be accepted manually.

The software also determines the total absorbance change and sets an error flag to the result if the total absorbance is lower than the required minimun value. In this case, the prozone error flags are not set even if the defined prozone check limits are violated.

The absorbance changes in the time windows 2 and 3 are compared to the change in the time window 1 and these values are converted to percentages by using the following equations:

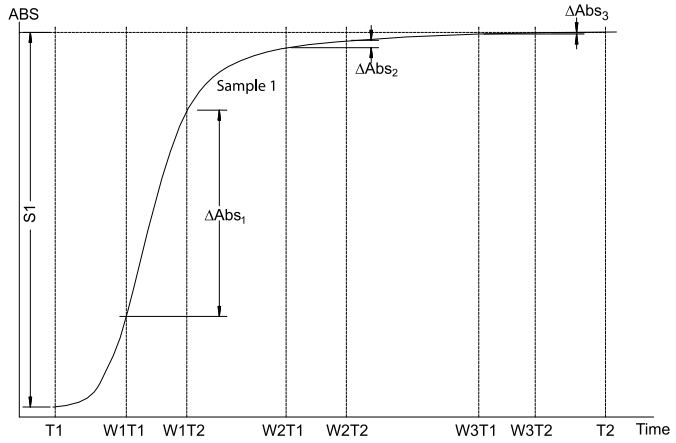
$$2^{nd}\,WindowReactionRatio = \left(\frac{\Delta Abs_2}{\Delta Abs_1}\right) \cdot 100$$

$$3^{rd}\,WindowReactionRatio = \left(\frac{\Delta Abs_3}{\Delta Abs_1}\right) \cdot 100$$

$\Delta Abs_1$ = Change in absorbance for sample through window 1
$\Delta Abs_2$ = Change in absorbance for sample through window 2
$\Delta Abs_3$ = Change in absorbance for sample through window 3

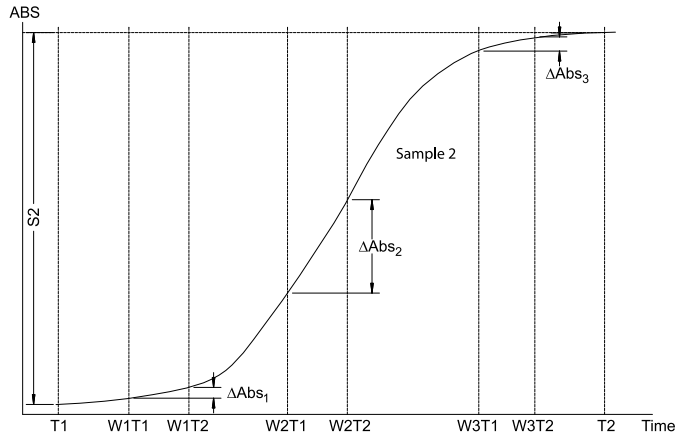
The values of 2nd window reaction ratio and 3rd window reaction ratio are compared to the defined values 2nd window limit % and 3rd window limit %. The prozone check can be defined to measure values lower than the limit or higher than the limit depending on the values of 2nd window check and 3rd window check.

**Figure 27.** Sample 1, high concentration, flagged as a prozone



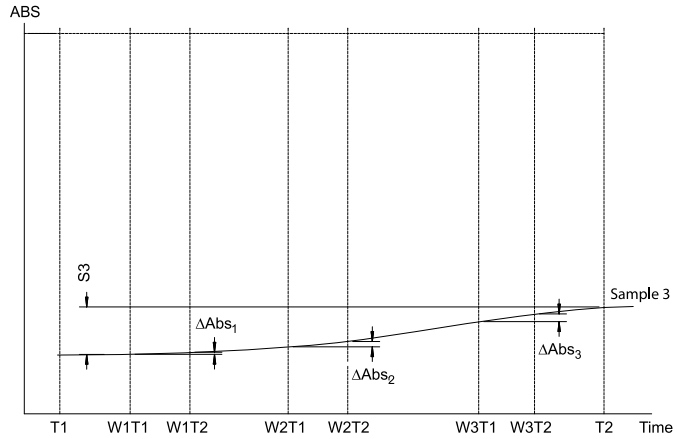

T1 - Test start point
T2 - Test end point
W1T1 - Start point of window 1
W1T2 - End point of window 1
W2T1 - Start point of window 2
W2T2 - End point of window 2
W3T1 - Start point of window 3
W3T2 - End point of window 3
S1 = Overall change in ABS for sample 1
$\Delta Abs_1$ = Change in absorbance for sample 1 through window 1
$\Delta Abs_2$ = Change in absorbance for sample 1 through window 2
$\Delta Abs_3$ = Change in absorbance for sample 1 through window 3

**Figure 28.** Sample 2, normal concentration, not flagged a prozone



T1 - Test start point
T2 - Test end point
W1T1 - Start point of window 1
W1T2 - End point of window 1
W2T1 - Start point of window 2
W2T2 - End point of window 2
W3T1 - Start point of window 3
W3T2 - End point of window 3
S2 = Overall change in ABS for sample 2
$\Delta Abs_1$ = Change in absorbance for sample 2 through window 1
$\Delta Abs_2$ = Change in absorbance for sample 2 through window 2
$\Delta Abs_3$ = Change in absorbance for sample 2 through window 3

**Figure 29.** Sample 3, low concentration/low total absorbance change




T1 - Test start point
T2 - Test end point
W1T1 - Start point of window 1
W1T2 - End point of window 1
W2T1 - Start point of window 2
W2T2 - End point of window 2
W3T1 - Start point of window 3
W3T2 - End point of window 3
S3 = Overall change in ABS for sample 3
$\Delta Abs_1$ = Change in absorbance for sample 3 through window 1
$\Delta Abs_2$ = Change in absorbance for sample 3 through window 2
$\Delta Abs_3$ = Change in absorbance for sample 3 through window 3

# 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.

### 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.

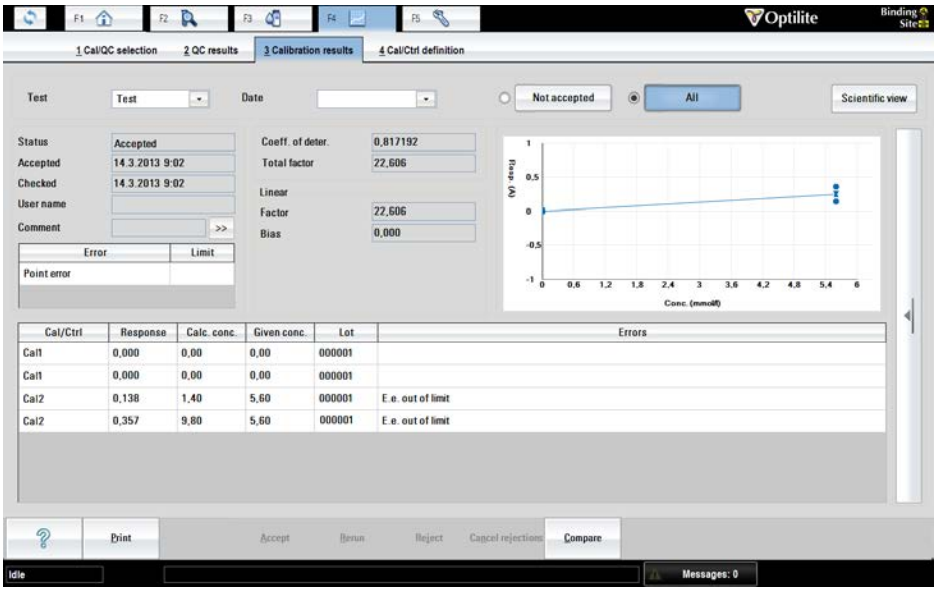
All measured points are compared with the calculated error limit value to check for a possible point error. The permissible is calculated by using the following equation:

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

*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 30.** 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.

### Checking 2nd order calibration

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

Calibration is automatically rejected.

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

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

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

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

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

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

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

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

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

# Point-to-point calibration calculation

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

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

$\Delta Result$ = 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.

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

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

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

**Factor**

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

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

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.

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

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

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

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

*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.

## Checking spline calibration

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

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

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

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

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.

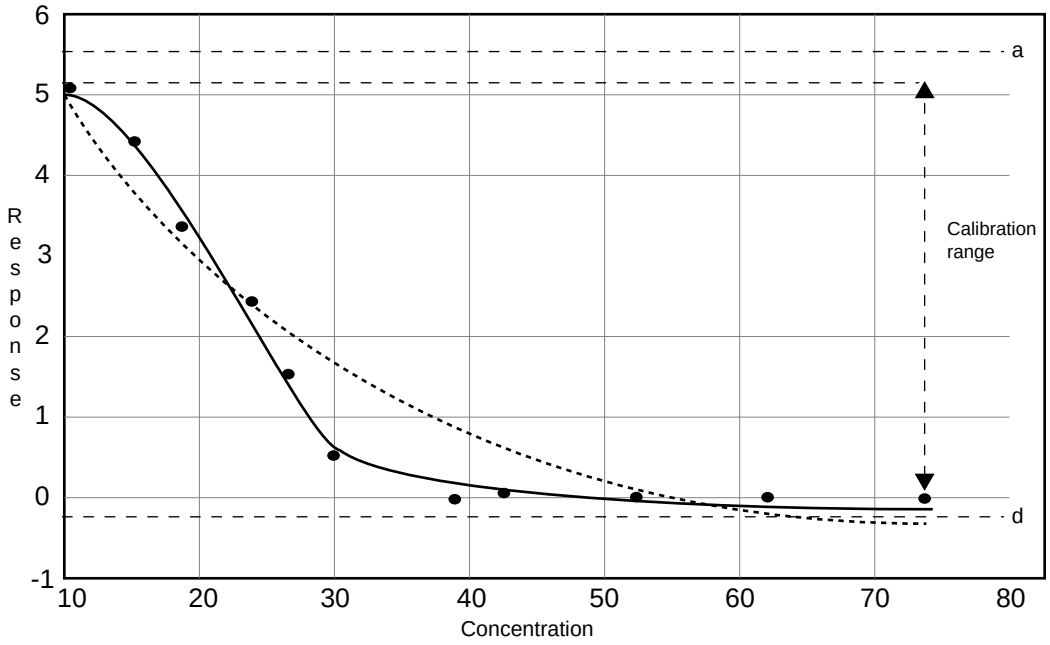
**Logit-Log 4**

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

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 31.** 4-parameter logit log




| | |
|---|---|
| ● | Measurement points |
| ..... | Fitting using the least square method |
| ———— | Fitting after iterations |

## Checking 4-parameter logit calibration

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

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

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

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

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

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

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

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

You cannot manually accept the calibration.

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

# 5-parameter logit calibration calculation

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

**Logit-Log 5**

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

where
*a, b, c, d, e, Result* ∈ **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.

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

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

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

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

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

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

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

You cannot manually accept the calibration.

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

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# User definition

- Creating new user account
- Viewing existing users
- Removing user
- Adding user access level
- Defining restrictions for access level
- Removing restrictions from access level

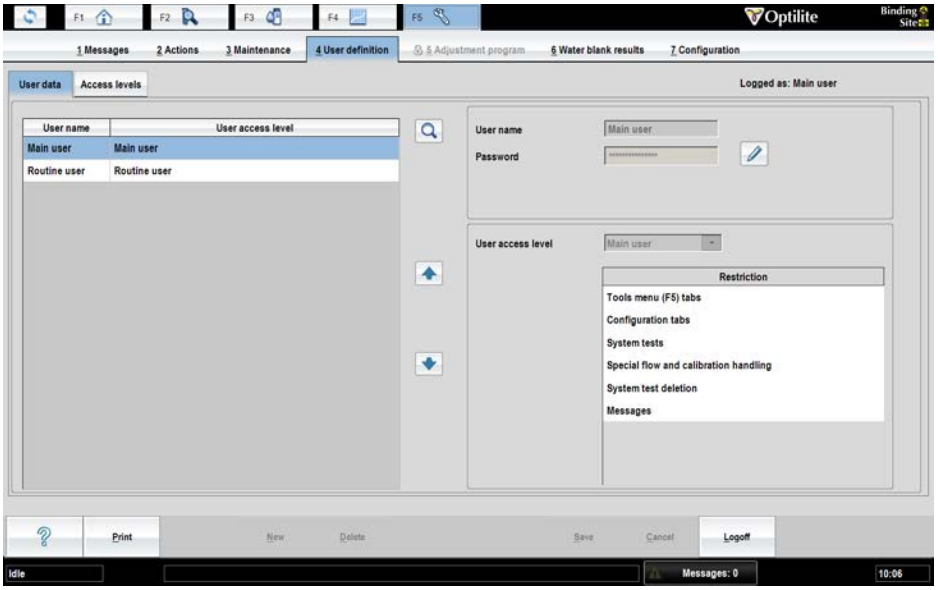
## Creating new user account

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. The Restrictions list shows which functions or parts of the software are not in use for selected **User access level**.
9. Click **Confirm**.
10. Click **Save**.

**Figure 32.** Creating new user account

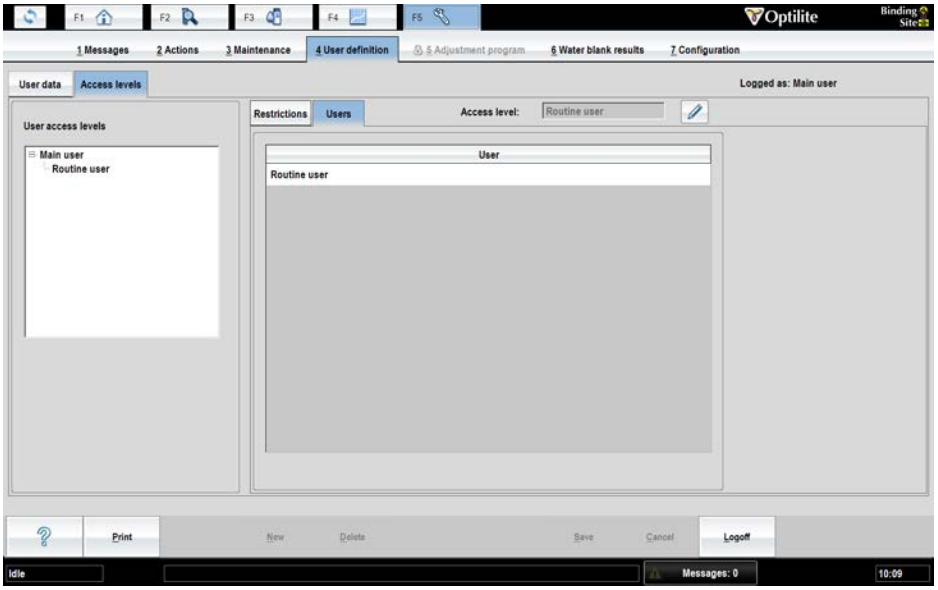



# Viewing existing users

To view the users and their access levels:

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

**Figure 33.** Viewing users



# Removing user

To remove a user:

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

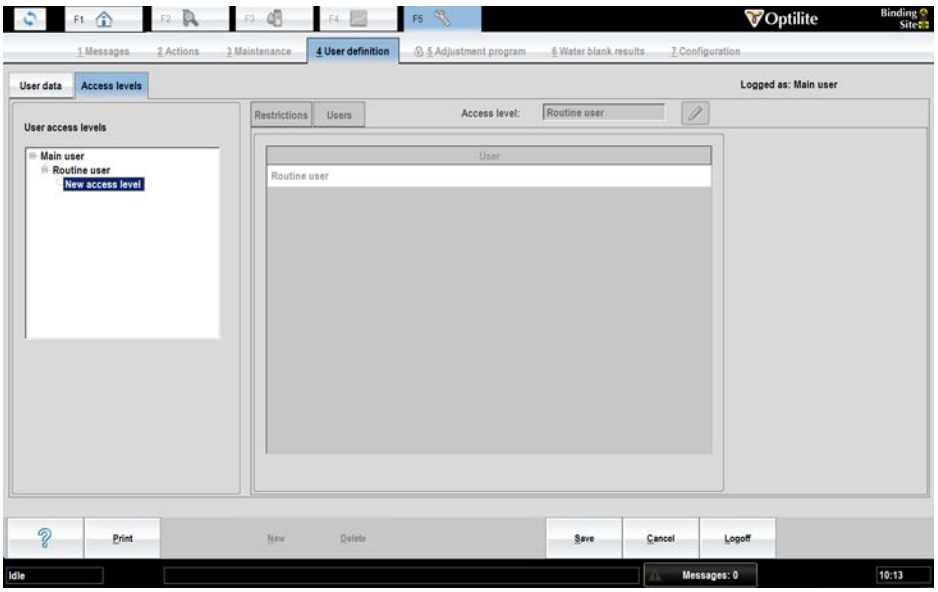
# Adding user access level

**Note** Exercise caution when creating access levels because it is not possible to remove them later on.

To define a new user access level:

1. Select F5 > User definition > **Access levels**.
2. Select a parent user access level for the new access level.
3. Click **New**.
4. Type a name for the new user access level.
5. Click **Save**.

**Figure 34.** Adding access levels




# Defining restrictions for access level

It is possible to define restrictions for a certain user access level. When you change the rights and restrictions of a user access level, these changes are applied to all users connected to that access

level. Also, the restrictions given for a certain user access level are inherited by the lower level user access levels. This means that e.g. all restrictions defined for the Main user also apply to the Routine user.

To add restrictions for user access levels:

1. Select F5 > User definition > Access levels > **Restrictions** tab.
2. Select a user level.
3. Click the add button.
4. Click the arrow button next to **[Restriction target]** text and select the window from the drop-down menu.
5. Click the arrow button next to **[Description]** text and select the function for the restriction. See the table belowTable 23. Restriction windows and descriptions on page 86.
6. Press **Enter**.
7. Click **Save**.

**Figure 35.** Defining restrictions

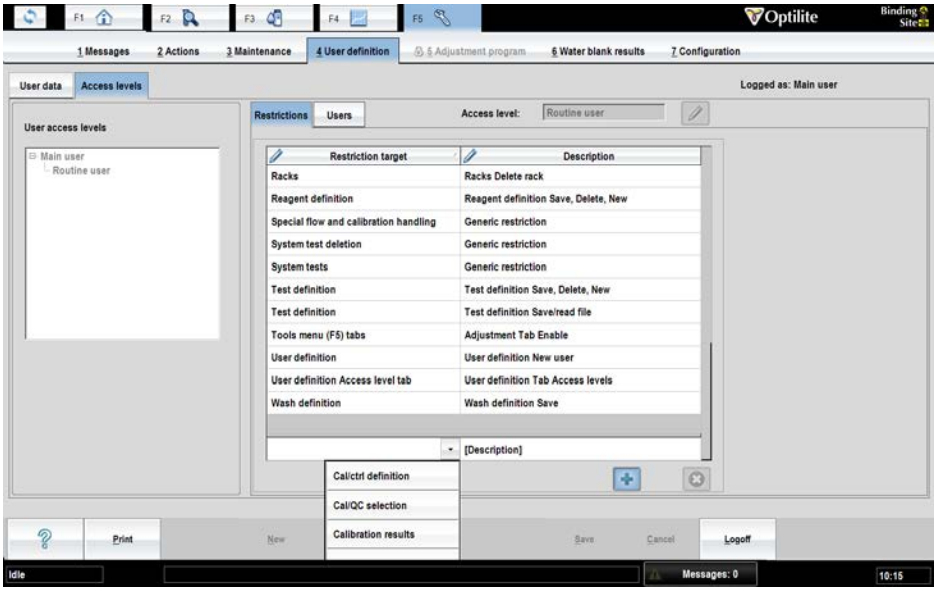



**Table 23.** Restriction windows and descriptions

| Window | Restriction |
|---|---|
| Actions | Debug, DB Save/Restore/Restore default |
| Archive | Delete |
| Base window | Adjustment program (tab) |
| Cal/Ctrl definition | Save, delete, new |
| Cal/Ctrl definition | Save, Save/read file |
| Cal/QC selection | Calibrate/perform QC |

| Window | Restriction |
|---|---|
| Calibration results | Accept, reject |
| Configuration | Save |
| Configuration | Config save/restore/restore default |
| Configuration | Barcode checkdigit modify |
| Configuration | Analyzer (tabs) |
| Configuration | Filter (tabs) |
| Configuration | Temperatures (tabs) |
| Configuration | LIS, Test LIS (tabs) |
| Configuration | Reports (tab) |
| Configuration | Sample types (tab) |
| Configuration | Additional (tab) |
| Maintenance | Operation definition Save |
| Maintenance | Operations Delete |
| Messages | Accept selected/all |
| Messages | Delete all |
| Profile definition | Save, delete, new |
| Reagent definition | Save, delete, new |
| Results | Accept, reject |
| Sample racks | Delete rack |
| Test definition | Save, delete, new |
| Test definition | Save/read file |
| Test definition | Delete Thermo tests |
| Test definition, Pretreatment definition | Special flow and calibration handling |
| Test definition (et al) | Edit Thermo/System test parameters |
| User definition | New user |
| User definition | Access levels (tab) |

| Window | Restriction |
|---|---|
| Wash definition | Save |

# Removing restrictions from access level

When you change the rights and restrictions of an access level, these changes are applied to all users connected to that access level.

To remove restrictions from user levels:

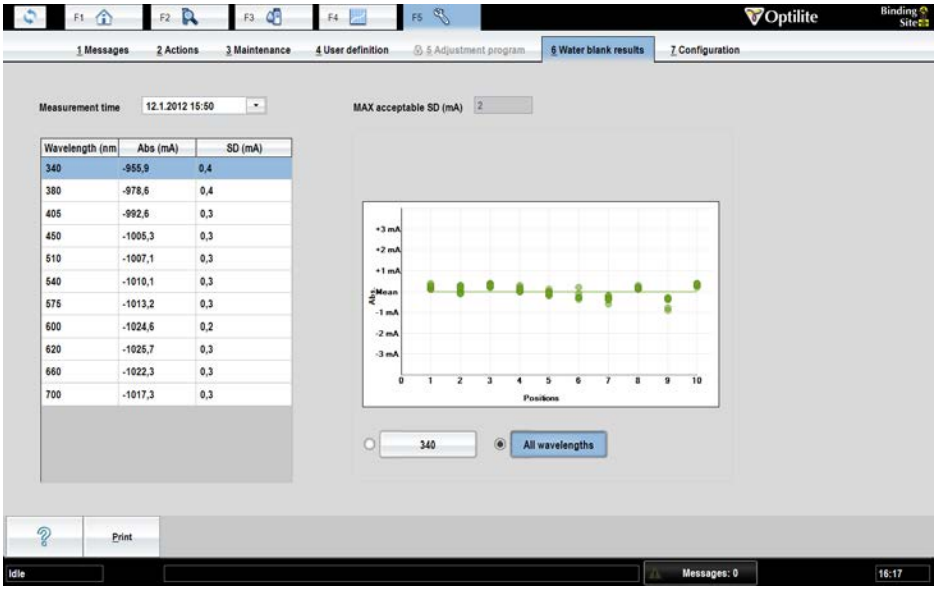
1. Select F5 > User definition > Access levels > **Restrictions** tab.
2. Select a user level.
3. Click the restriction to be removed.
4. Click the delete button.
5. Click **Save**.

# 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 36.** Reviewing water blank results




- Requesting water blank

# Requesting water blank

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

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

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# Managing database

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

**Note** If the database has been created with Windows 10, it cannot be used with Windows 7.

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

## Saving database

**Note** This operation requires that the user's access level is main user or higher.

**Note** It is not possible to restore the database that is saved on Windows 10 to Windows 7.

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 37.** Saving database


1 - USB 3.1 port - for backing up
2 - USB 2.0 ports for handheld barcode reader
3 - Power button

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.

**Note** It is not possible to restore the database that is saved on Windows 10 to Windows 7.

**Note** If the number of user-defined tests exceeds the number of tests defined in the dongle, the system cannot restore the database and the error dialog *DB user test count of [x] exceeds the licensed value of [y]. Resuming previous DB.* is displayed.

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. 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 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**.

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# 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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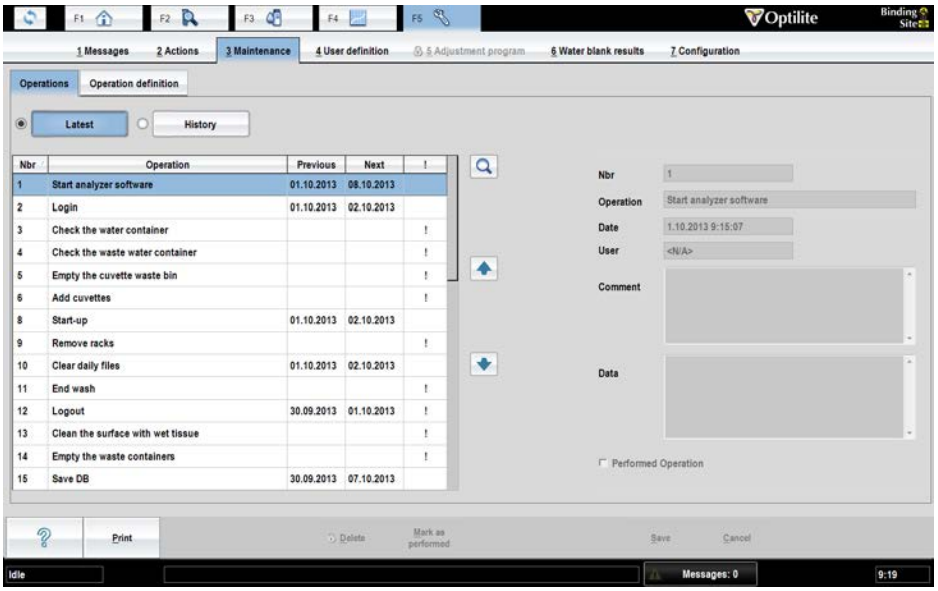
# Managing maintenance tasks

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

**Figure 38.** Maintenance view




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

## Adding maintenance task

To add a maintenance task:

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

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

**Note** It is possible to change the interval time of user-defined maintenance tasks. Changing the interval time of predefined tasks is allowed only for the **Save DB** operation.

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** and **Additional** configuration settings.

**Table 24.** Minimum user level requirements for changing configuration settings

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

The **Filter**, **Sample types** and **Additional** configuration settings are read-only information.

- 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 39.** Laboratory settings

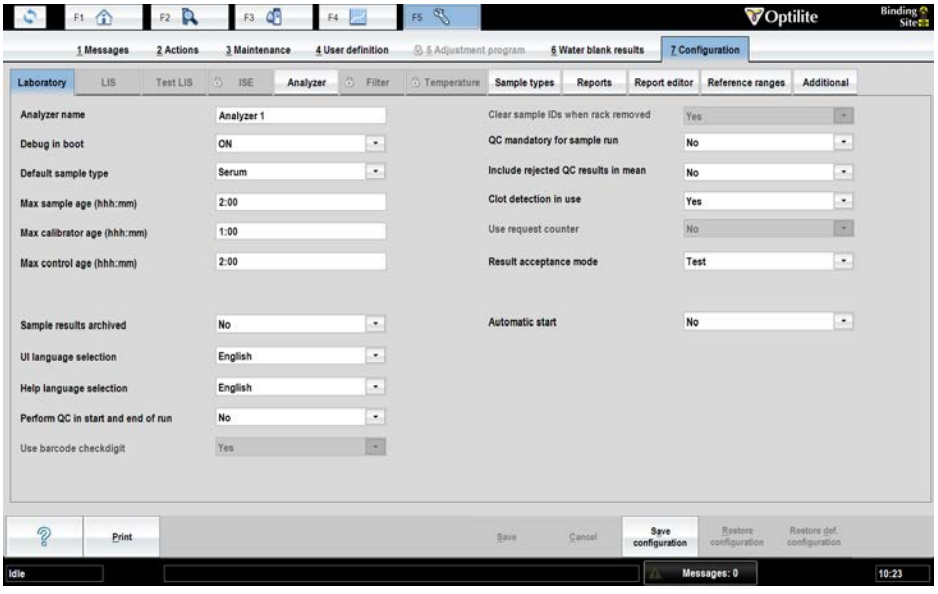


**Table 25.** Laboratory configuration parameters

| 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**.<br>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 | Serum, Plasma, Urine, CSF, Oral fluid, Whole blood, Hemolyzed blood, Other | Select a default sample type. |
| 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. |

| 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 **Yes** . 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. 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, Patient, 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 **Patient** is selected, the results are ready for acceptance after all requests for the patient are measured. If **Sample** is selected the results are ready for acceptance after all requests for the sample are measured. |
| 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**.<br>Automatic start is active only when Main window of user interface is selected. |

# LIS

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

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

# Test LIS

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

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

# Analyzer

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

**Figure 40.** Analyzer settings

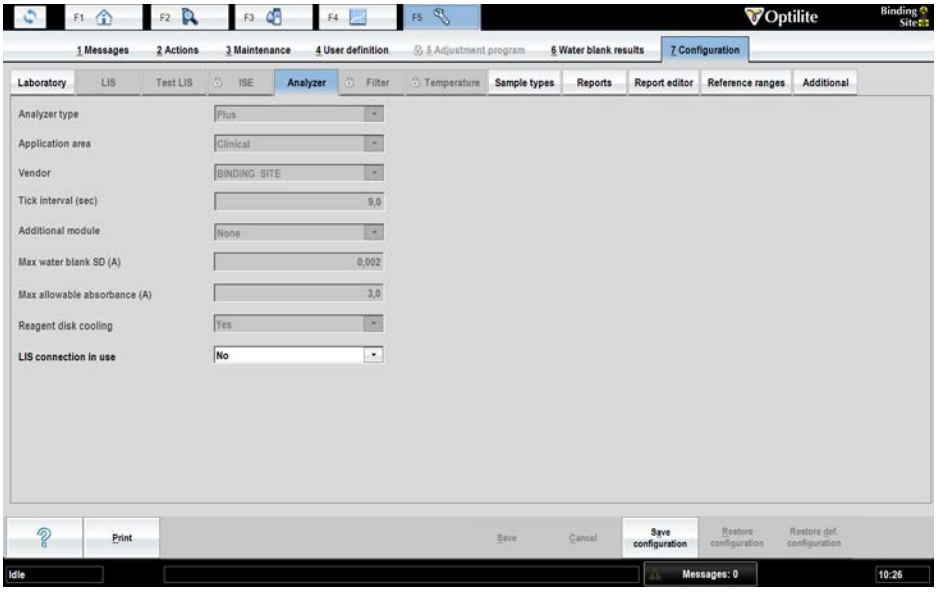



**Table 26.** Analyzer configuration parameters

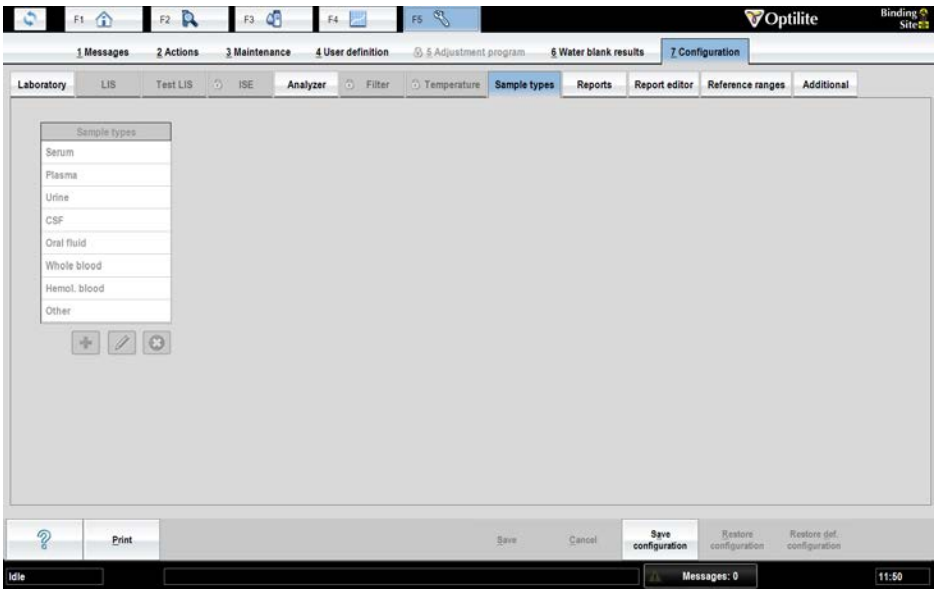
| Parameter | Description |
|---|---|
| Analyzer type | Shows the analyzer type. |
| Application area | Shows the application area. |
| Vendor | Shows the vendor of the analyzer. |
| Tick interval (sec) | Shows the length of the tick in seconds. Tick is a basic measurement unit for the analyzer. |
| Additional module | Shows the additional module. |
| Max water blank SD (A) | Shows the maximum allowed limit for water blank standard deviation (SD). |
| Max allowable absorbance (A) | Shows the maximum allowed absorbance value. If the value exceeds the defined value, an error message is displayed in result reports. |
| Reagent disk cooling | Shows that the reagent disk is cooled. |
| Reagent disk cooling | Shows that the reagent disk is cooled. |

| Parameter | Description |
|---|---|
| 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 sample types are read-only information.

**Figure 41.** Sample type settings




# Reports

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

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

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

To configure the sample result report format:

1. Select F5 > Configuration > **Reports**.
2. Type customized texts on **User text 1-4** rows, if needed.

3. Add a logo by clicking **Change**. The aspect ratio of the logo is 3.35.

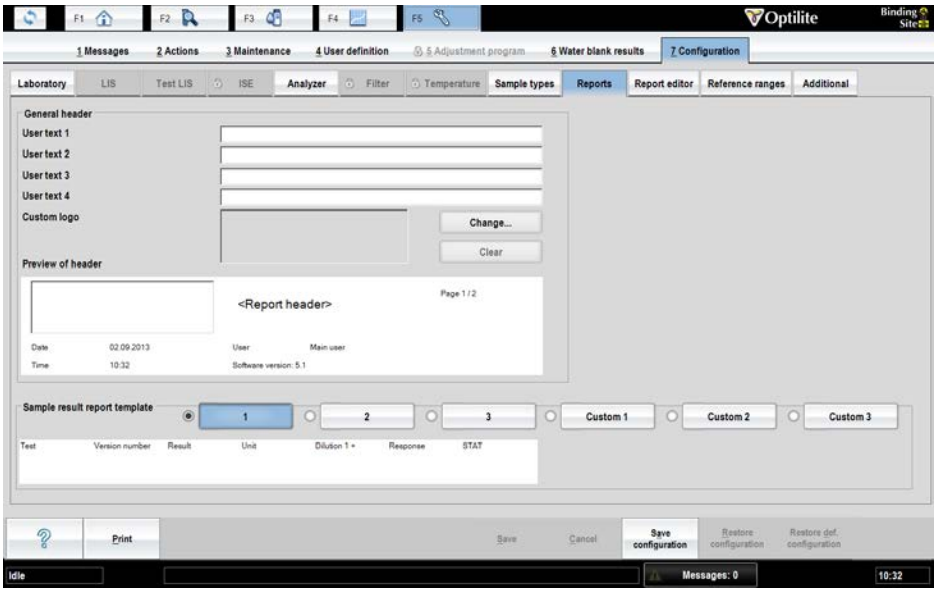
> **Note** If the **User text** fields and logo are defined, they are shown in the sample report and test report headers.

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

**Table 27.** Logo size

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

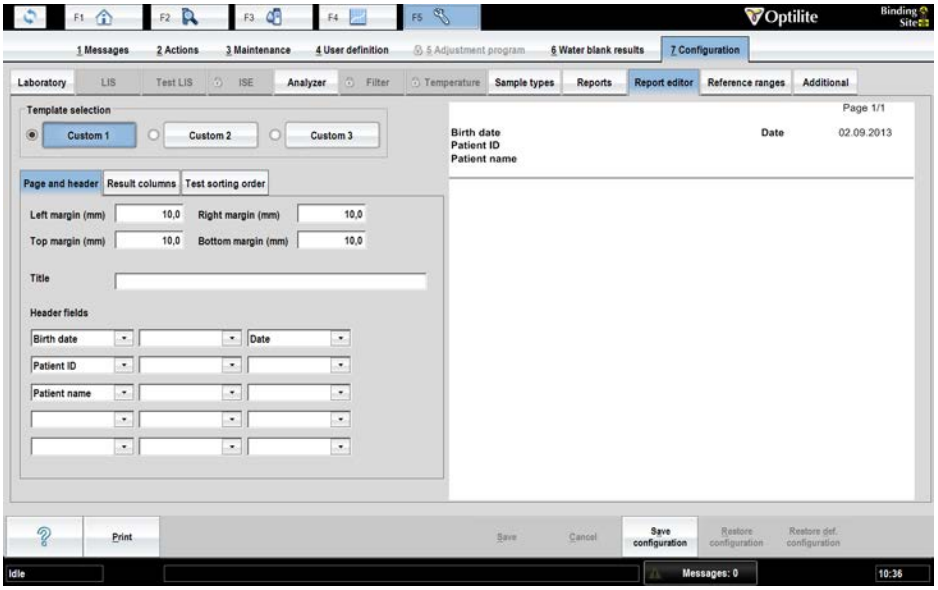
**Figure 42.** Report settings




# Report editor

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

**Figure 43.** Report editor

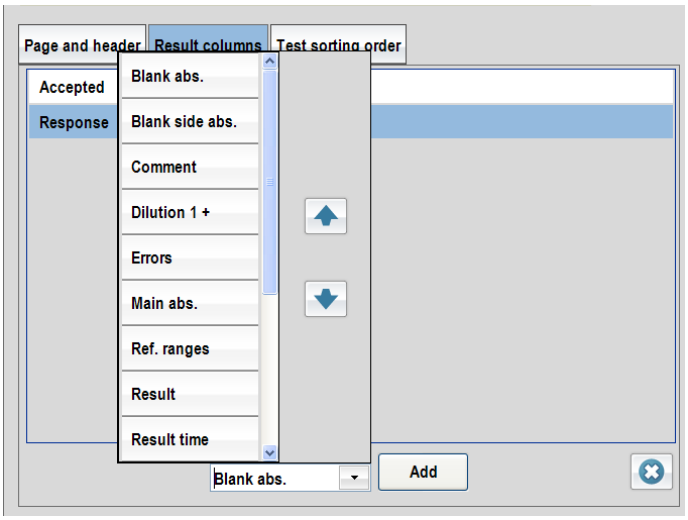



The laboratory's main user is allowed to change the settings. To configure the user-definable template for the sample result report:

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

   The **User text fields** of the drop-down menu are defined in the F5 > Configuration > **Reports** tab.
7. Select the **Result columns** tab.
8. Select the result column you want to have in the report from the drop-down list.

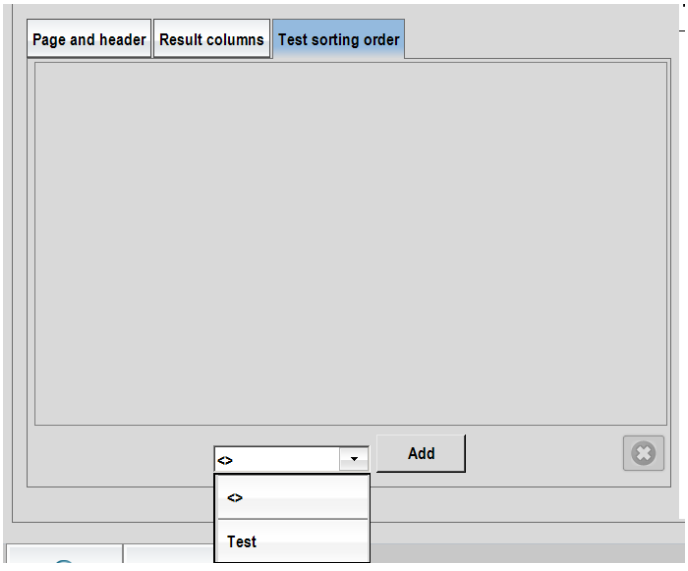
9. Click **Add**.




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

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

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




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

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

13. Click **Save**.

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

    See Reports on page 106.

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

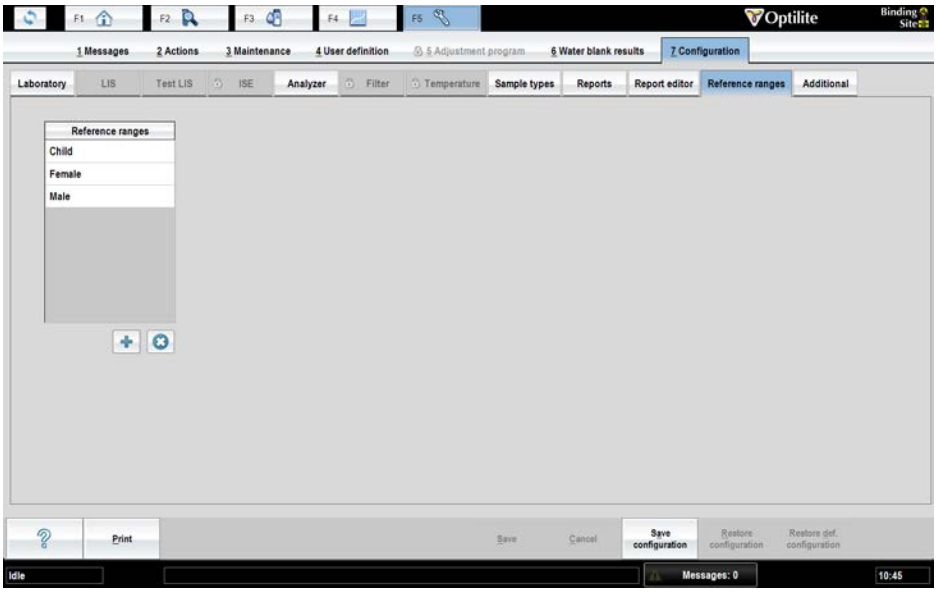
# Reference ranges

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

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

   The program shows the created name in the list.
5. Repeat steps 2 and 3 until all the reference ranges are created.
6. Click **Save**.

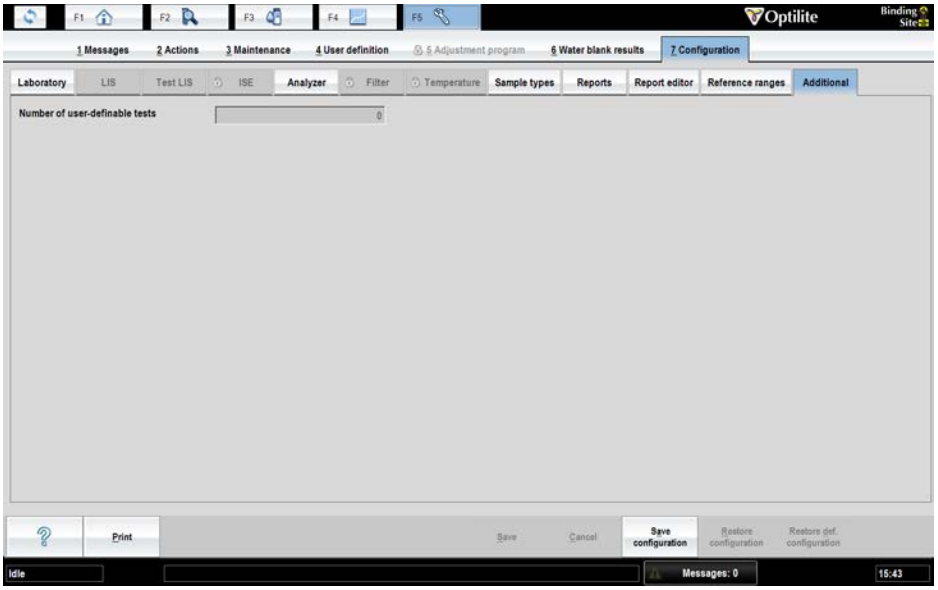
**Figure 44.** Reference ranges




# Additional tab

Additional tab displays the maximum number of user-definable tests. The number is defined in dongle configuration in the factory.

**Figure 45.** Additional tab



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

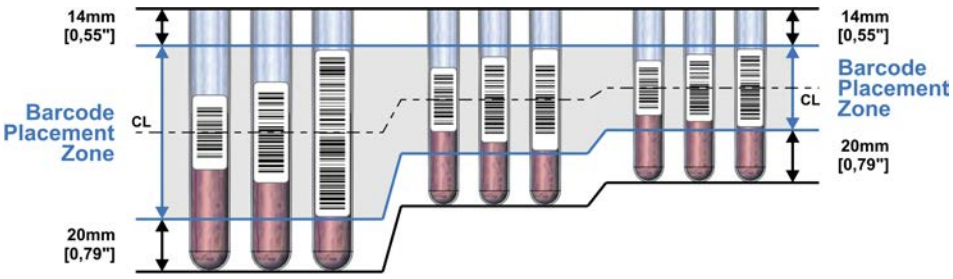
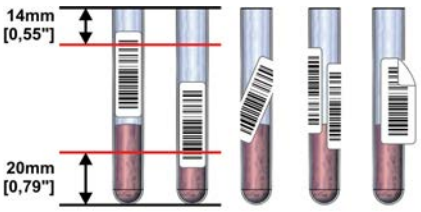



**Figure 47.** Wrong placement of barcode

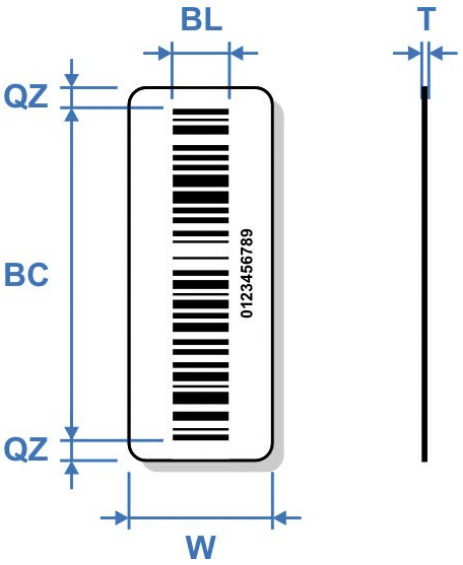



### ❖ Reading zone

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 48.** 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

## 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