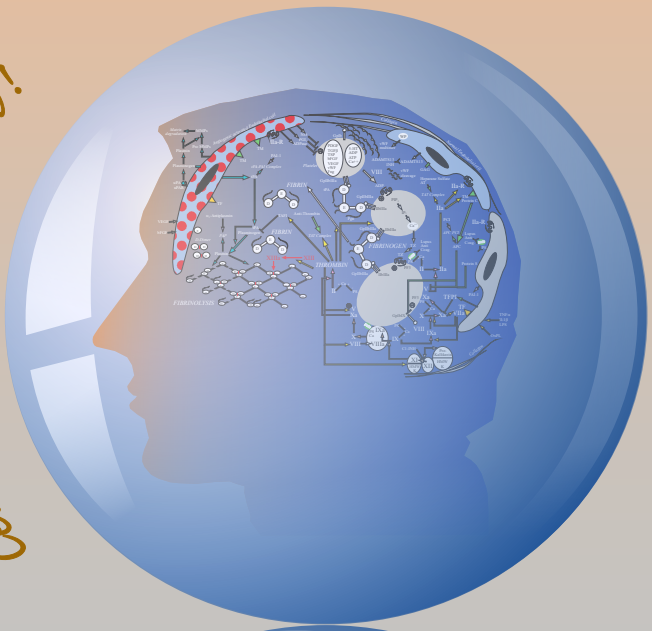
ceveron on your mind!



ceveron®

100 series

User Manual

USER MANUAL
Automated Blood Coagulation Analyzer

CEVERON **100 series**

CEVERON c100; CEVERON t100; CEVERON s100

Software : 3.0

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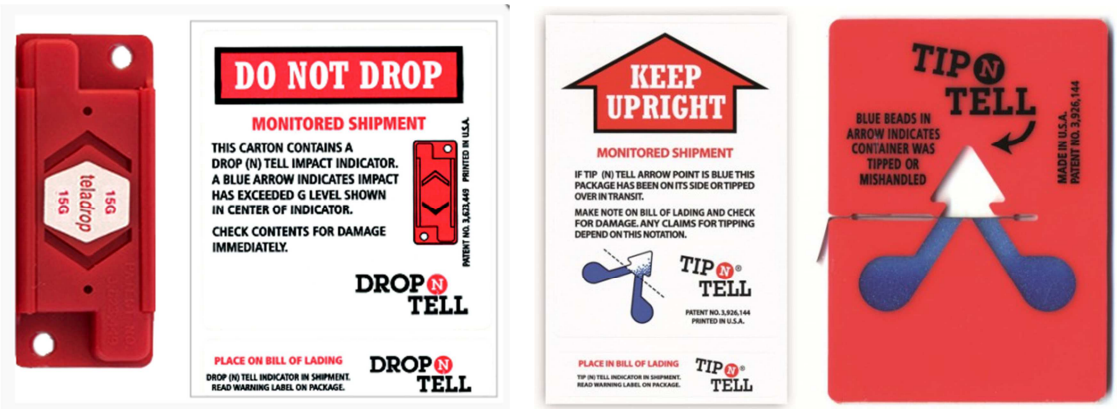
RECEIVING INSTRUCTIONS

The CEVERON 100 series instrument has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Follow these guidelines when the system arrives:

- Check to see that the arrows on the sides of the packages are pointing up and the indicators for manipulation are intact. If the arrows do no point up or the indicators are broken, remark this information on the bill of lading.

  Examples for indicators:



- Perform a visual inspection of the outside for any kind of possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. This is for your protection!
- Notify your service representative that the CEVERON 100 series system and its components have arrived.
- Wait for your service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided in the package. Special requirements are clearly marked on the outside of the cardboard and will be included in the unpacking instructions and package inserts.
- All passwords are printed in the service manual.

WARRANTY INFORMATION

All instruments manufactured by Technoclone are warranted against defective materials or workmanship for a period of one year commencing on the installation date at the customer's required location.

This warranty does not cover any defect, malfunction, or damage due to:

1. Accident, neglect or willful mistreatment of the product.
2. Failure to use, operate, service, or maintain the product in accordance with this manual.
3. Failure to use the appropriate reagents or chemicals specified for the product.

IMPORTANT

- It is prohibited to reproduce parts or all of the contents of this manual without permission.
- The display screens shown in this manual may differ slightly from the actually displays.
- As a result of product improvements, details described in this manual may differ slightly from the actual product.
- Patient names and doctor names are entered for information and illustration purposes only, and do not imply real specific persons.

HAZARD AND PRECAUTIONS

The cautions and safety regulations in this instruction manual correspond to international classification.

Danger

Warns of a risk of injury or of a risk to life (for example, by electrical shock).

Caution

Warns of a risk of injury or of the instrument being severely damaged.

The following caution and safety regulations must be observed at all times:

All blood and plasma samples and products have to be regarded as potentially infectious. They have to be handled with appropriate care and in compliance with the biosafety regulations in force. They must be disposed of in the same way as hospital waste.

Warns of a risk of the eyes being severely damaged.

EMERGENCY SHUTDOWN PROCEDURE

Should the analyzer ever need to be shut down in an emergency, such as an unexpected loss of power to the laboratory, turn off the power switch of the main unit.

Danger

1. Electrical safety	Check that the **operating voltage is set correctly** before you connect the device to the main supply. To connect the device to the main supply, use only sockets with an **earthen** contact. In order to keep the risk of an electrical shock as low as possible. Use only extension cables with a **protective conductor** and **earthen** contact. Never knowingly interrupt the earthen contacts. There is the risk of an electrical shock if: - the protective conductor is interrupted within or outside the device, and - the grounding contact has been disconnected from the mainline. Never remove protective guards or secured components since you could expose live parts in this way. Electrical connection contacts (plugs, sockets etc.) can be electrically live. Even after the device has been switched off, components (e.g, capacitors) can be under voltage as the result of an electrical charge. All current-carrying parts are sources of danger for an electrical shock. Surfaces (floors, work tables, etc.) have to be dry when you are working with the device. Do not use the device on a moist base. Carry out only the maintenance work and/or the replacement of parts described in these operating instructions. Unprofessional work on the device can lead to the guarantee obligation becoming null and void and to expensive service work being necessary. Switch the device off and disconnect it from all source of electrical power before you **open the device** in order to carry out an alignment of parts. If an alignment, maintenance or a repair has to be carried out on the device when it is open and live, then **this** work may only be carried out by an expert who is familiar with the risk related hereto. Use only **replacement** fuses (250V T 2A) of the stated type and with the stated nominal current. Never use fuses which have been replaced. Never short-circuit the fuse holder.

 Caution	
2. Fire and explosion hazards	Do not place any fire or hazardous explosive material in the proximity of the analyzer. Electrical sparks could cause fire or explosions.
3. Mechanical safety	• Never open screw-attached housing parts while the instrument is ON. There is a risk of injury due to moving parts (fan, motor drives). • Avoid touching the pipettor and other moving parts while the analyzer is in operation or during teach-in process. There is a risk of injury by moving parts. Close cover immediately after teach-in process. • Do not open any covers as long as a measuring series is not finished or interrupted. The pipettor may be damaged by opened covers.
4. Samples	Risk of infection: Avoid any direct contact with samples which are potentially infectious or which may generate other risks to the human body. If samples material is spilled onto the analyzer, wipe it off immediately.
5. Reagents	Observe the suggestion in the package insert for a correct use of the reagents.
6. Waste solution	Dispose of waste solution in compliance with legal provisions.
7. Accuracy and precision of the measurement results	In order to ensure a flawless operation of the analyzer, measure control samples and watch the function of the instrument closely. Wrong results of measurements may result in an incorrect diagnosis and thus to a risk for the patient.
8. Restrictions for samples and reagents	For cuvettes, sample tubings and waste solution tubings, no guarantee can be provided for any resistance against organic solvent. For this reason, do not use any organic solvents unless such solvents are expressly authorized.
9. Operator qualification	***The analyzer should be operated by trained personnel only.***

Frequently used abbreviations

TC…....Technoclone

LIS……..Laboratory Information System

QC……..Quality Control

TGA…...Thrombin Generation Assay

ASTM….American Society for Testing Materials

LED……Light-Emitting Diode

INR…….International Normalized Ratio

ISI……...International Sensitivity Index for prothrombin time reagents

ROS…...Retry - On/Off - Service

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1. Introduction

1.1 Intended use

The CEVERON 100 series analyzer is a summary of three different types of a fully automatic, coagulation measuring instrument, used to perform all plasma coagulation tests for routines and research for *In Vitro Diagnostic Use*. The CEVERON c100 runs samples using clotting, chromogenic and turbidimetric methods.

The CEVERON t100 runs samples using clotting, chromogenic, turbidimetric methods and fluorometric tests. Such as thrombin generation assays (TGA).

The CEVERON s100 runs samples using clotting, chromogenic, turbidimetric and TGA tests. Furthermore the CEVERON s100 is able to perform coagulation assays, based on quenching technology. Such as TECHNOFLUOR Factor XIII Activity and TECHNOFLUOR ADAMTS13 Activity.

1.2 General description

The CEVERON 100 series instruments consist of an analyzer and a personal computer as control module. CEVERON 100 series instruments operate on the photometric measurement principle. This measurement method identifies the clotting time by an optical detection of the change of turbidity caused by the formation of fibrin fibers. For chromogenic methods, the change of the colorimetric absorbance is detected after a direct or indirect reaction of the analyte with a chromogenic substrate. For immunological methods the change of absorbance is detected during the reaction of antigen and antibody complex formation.

At TGA the forming and the depletion of the clot is continuously measured over the whole reaction time using a fluorogenic substrate, phospholipids and tissue factor. Therefore the relative strength of pro- and anticoagulant drivers can be measured.

Quenching is using high sensitive fluorescence measurement, where quenching molecules emit light after the reaction with the analyte.

Emergency samples (STAT) can be loaded at any time and will be processed immediately after the last started test has been finished.

Single methods can be combined to profiles. Measurement results and calibration curves can be printed via an external printer or transferred to a host computer. To save measurement results over long periods, data can be stored in an archive.

Samples will be loaded in their primary tubes into the analyzer. Various primary tubes can be used. Special sample cups and adapters are available for small volumes.

Samples, controls, calibrators and reagents including their lot specific information can be identified by two independent bar code readers.

1.3 Structure of this manual

To ensure an optimal operation of the CEVERON 100 series analyzer, please read this instruction manual carefully before you start working with the instrument.

This instruction manual contains 9 chapters:

1. **Introduction**
2. **System description**
3. **Installation**
4. **Software description and Operation**
5. **Maintenance**
6. **Consumables and spare parts**
7. **Errors**
8. **Disposal**
9. **Update via www.technoclone.com**

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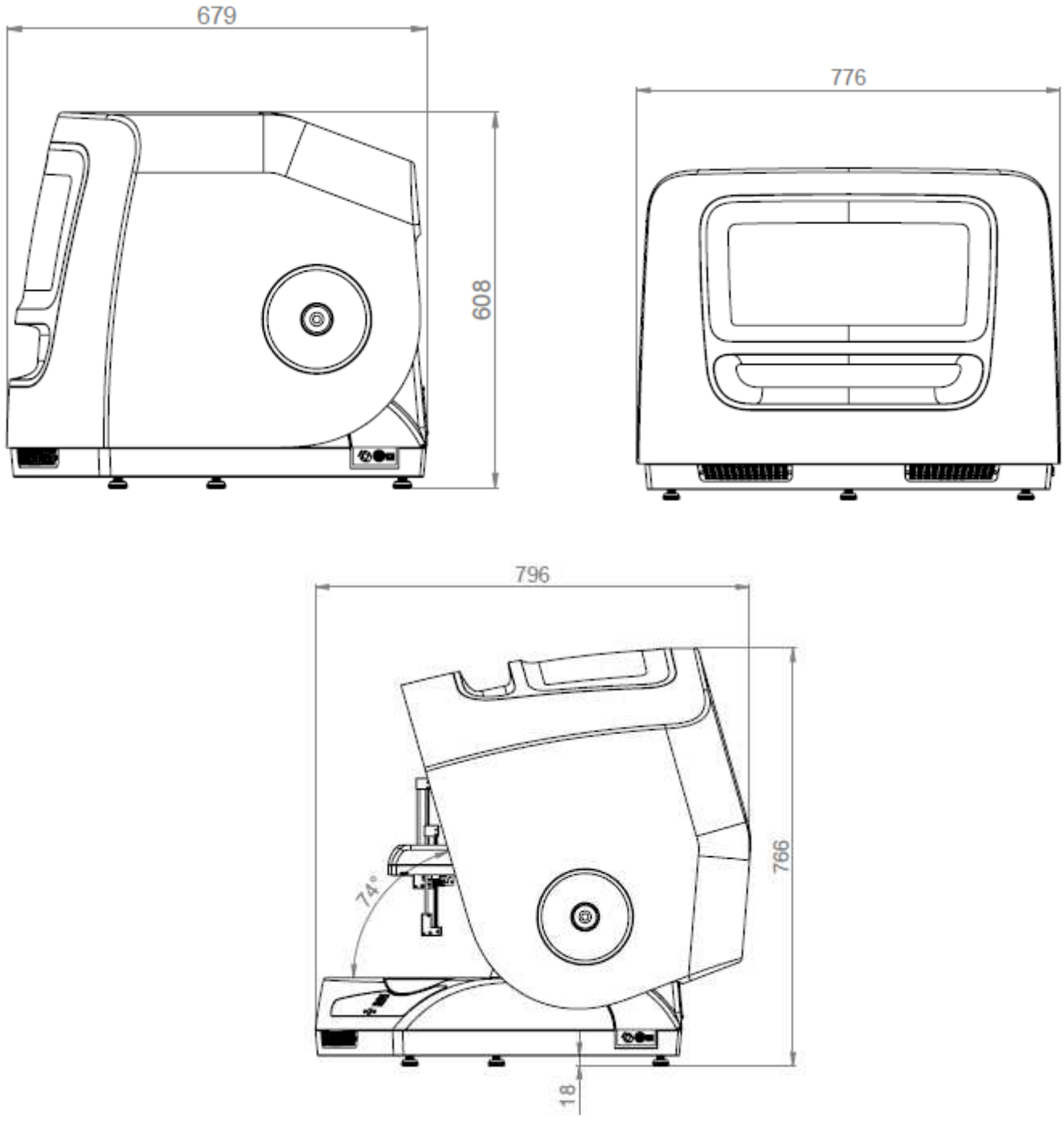
2. System description

2.1 Content of Package

Each CEVERON 100 series system is delivered with a control module (including Windows 10 operating PC, touch screen monitor, keyboard, external barcode reader and mouse) and following listed items.

	CEVERON c100	**CEVERON t100**	**CEVERON s100**
CEVERON Heated Pipettor Probe	1	1	1
CEVERON Pipettor Probe	1	1	1
CEVERON Syringe	2	2	2
CEVERON System Liquid Tubes	2	2	2
CEVERON Bottle clip black	2	2	2
CEVERON Sample tube clip black	4	4	4
CEVERON Sample tube clip red	2	2	2
CEVERON Sample rotor	1	1	1
CEVERON Cuvette rotor	1	1	1
CEVERON Waste tube	1	1	1
CEVERON Waste sensor	1	1	1
CEVERON Waste canister	1	1	1
CEVERON 100 series cuvette segments	4	4	4
CEVERON PE bottle 750 mL	1	1	1
CEVERON F-Standard	-	1	1
USB cable	1	1	1
USB stick	1	1	1
Power cord	1	1	1

2.2 Measurements



Weight: approx. 40kg / without system liquid container

2.3 Parts

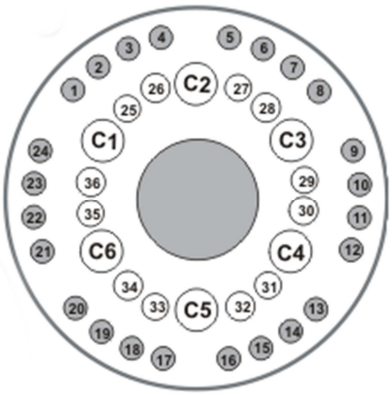
2.3.1 Sample rotor

The sample rotor has 42 positions which are arranged in 2 rings.

24 positions for primary tubes and STAT samples in the outer ring (positions 1 to 24, barcode scanned).

The inner ring has 6 positions for controls and calibrators (positions C1 to C6, barcode scanned), 6 for Eppendorf tubes (positions 25, 27, 29, 31, 33 and 35) and 6 for sample cups 3mL (positions 26, 28, 30, 32, 34 and 36).

The Eppendorf tube and sample cup positions are provided for small volumes (e. g. paediatric samples) and are not barcode scanned. In addition, adaptors can be used to place Eppendorf tubes to the positions in the outer ring.



2.3.2 Barcode reader for samples

To load primary tubes, sample cups, controls, standards or reagents the instrument cover must be opened.

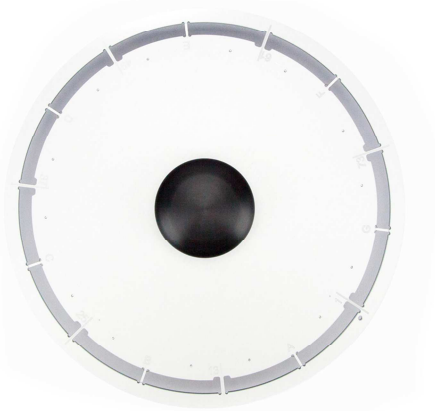
In order to avoid a damage of the probes, the position of the cover (open or closed) is automatically checked during operation and blocked in closed position. These positions are indicated on the screen and on the LEDs right on the chassis.

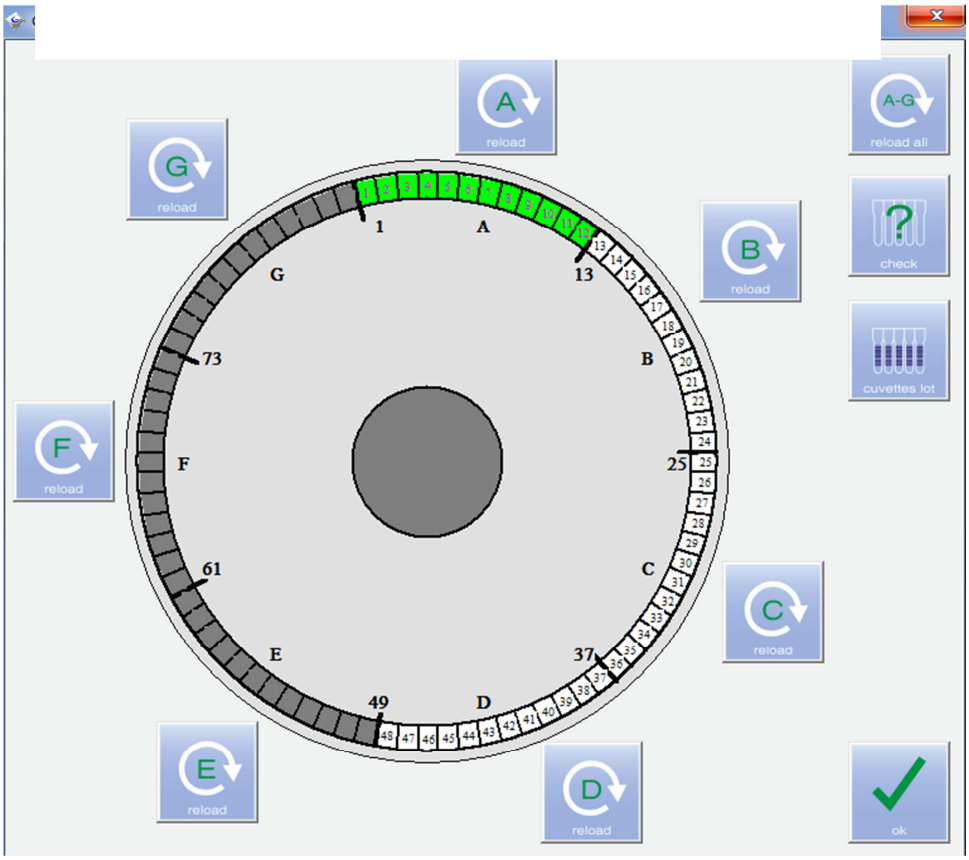
a) Red, attention: indicates a failure

b) Yellow, busy: instrument is working

c) Green, open: instrument is in standby, cover can be opened

2.3.3 Measuring rotor





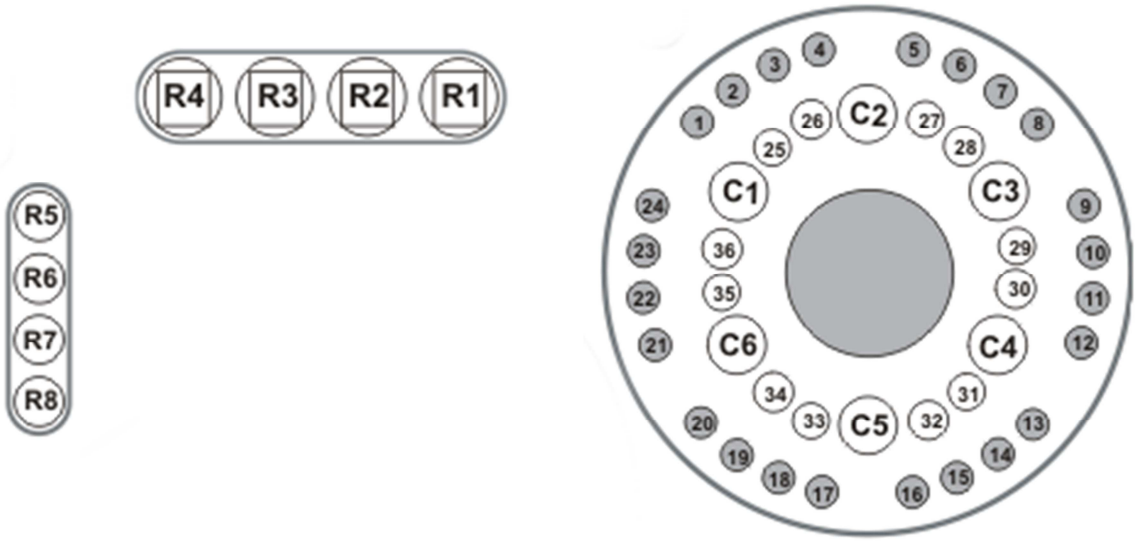
The measuring rotor has 84 cuvette positions. This rotor is loaded with 7 cuvette racks. These racks are entitled with A to G on the rotor. The temperature of the measuring rotor has been set to 37 °C. At the CEVERON 100 series instrument 4 simultaneous measuring channels are available. The intensity 4 LEDs is continuously monitored and adapted in case of intensity loss (405, 570, 630 and 740 nm).

2.3.4 Sample arm access area

R1 – R4: 4 positions for 30 mL vials at ambient temperature.

R5 – R8: 4 positions for 3 mL vials at ambient temperature.

C1 – C6: 6 positions for 5 mL vials in the sample rotor.



2.3.5 Reagent arm access area

R9 – R12: 4 positions for 30 mL vials at ambient temperature.

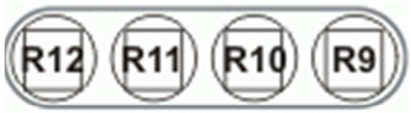
R13 – R26: 14 positions cooled at 12 °C-18 °C.

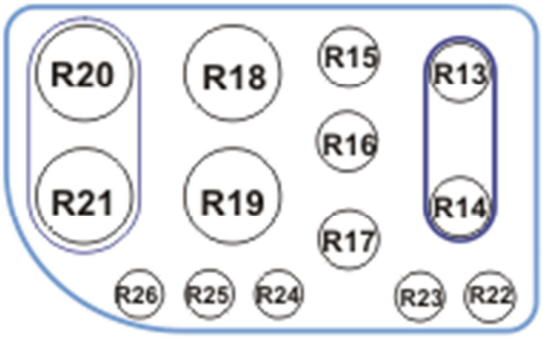
4 positions for 20 mL vials, two positions are stirred (R20 and R21).

5 positions for 5 mL vials, two positions are stirred (R13 and R14).

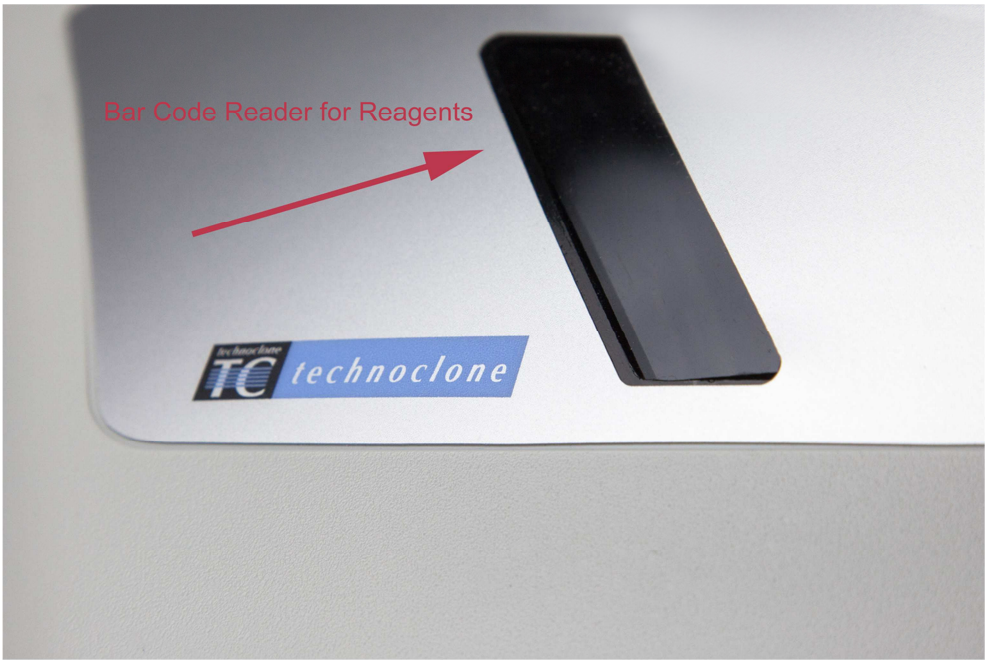
These mixers are driven magnetically by motors underneath the rotors.

R22 – R26: 5 positions for Eppendorf cups cooled at 12 °C – 18 °C.





2.3.5 Barcode reader for reagents



The barcode reader for reagents and calibrators is automatically switched on, when the cover is open and the instrument menu "**LOADING"** is active.

2.3.6 Syringes

The two syringes perform all pipetting of samples and reagents. The pipetting range for each arm is 5 – 400 µL.

2.3.7 Probes

The heated reagent probe (37 °C) aspirates all reagents placed on the reagent side of the instrument and dispenses them into the cuvettes.

The sample probe automatically aspirates sample material and all other material placed at the instrument´s sample side and dispenses them into the cuvettes.

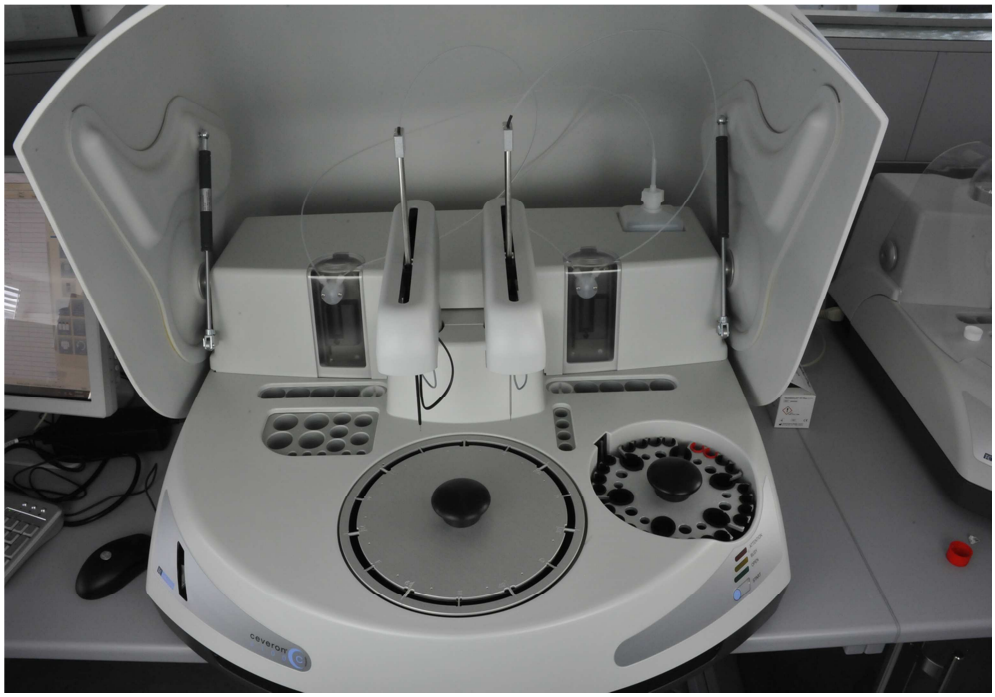
In order to prevent contamination, the probes are rinsed after each pipetting step at the washing station.

Both probes are fitted with a level sensing system, to ensure that the proper volume is pipetted.

2.3.8 Rinsing System

The system solution on the right back side of the CEVERON is providing the two washing stations (one on each side).

System solution is used for wash / rinse the probes. The liquid waste can be disposed to the waste container or directly to the sewage.



Ceveron 100 series instruments have four main rinsing programs:

- normal rinsing with system liquid
- intensive rinsing with system liquid
- normal wash with CEVERON Wash Solution
- intensive wash with CEVERON Wash Solution

The CEVERON Wash Solution should then be located next to the washing station in a 30 mL bottle.

The waste container is fitted with a level sensor. When the waste solution container is full, an appropriate message is displayed on the screen.

Dispose the waste in accordance with your laboratory´s disposal procedure.

The volume of the system liquid is calculated by the CEVERON software. If no message is set, the available volumes, including a completely loaded analyzer, will be sufficient for all measurements.

2.3.9 Computer and Monitor

Your CEVERON 100 series instrument is delivered with a control module (CM).

This Windows 10, installed personal computer has the minimal requirements of:

1 Gigahertz (GHz) or faster 32-bit (x86) or 64-bit (x64) processor (AMD or Intel)

1 Gigabyte (GB) RAM (32-bit) or 2 GB RAM (64-bit); recommended 4GB RAM

20 GB available hard disk space (32-bit) or 20 GB (64-bit); recommended >= 120GB

DirectX 9 graphics device with WDDM 1.0 or higher driver

There will be pre-installed:

Ceveron SW

Team Viewer

Any additional software installation or windows upgrades must not be installed on the CM without the permission of Technoclone, to avoid any errors running the Ceveron software.

2.3.10 Connecting to LIS

Please contact your local Technoclone representative for detailed instructions and specifications.

2.3.11 Assay list

Listed assays are stored on the USB-stick which is included to your Ceveron 100 series instrument.
To install the assays to your instrument please refer to Chapter 4.2.13.1 Test Definitions.

ADAMTS13 Activity**	Anti Xa (Apixaban; Arixtra; Edoxaban; LMWH; Orgaran; Rivaroxaban; UFH)
Antithrombin	APC-R
aPTT	C1- Inhibitor
D-Dimer	Direct Thrombin Inhibitors (Argatroban, Dabigatran)
Factor II	Factor IX
Factor V	Factor VII
Factor VIII	Factor VIII Chromogen
Factor X	Factor XI
Factor XII	Factor XIII Actitvity**
Fibrinogen	Fitzgerald Trait
Fletcher Trait	Lupus Diagnostic
Protein C	Protein S
PT	PT Owren
Thrombin Generation *	Thrombin Time

State at System launch (2020)
*(Ceveron t100 and Ceveron s100)
** (Ceveron S100)

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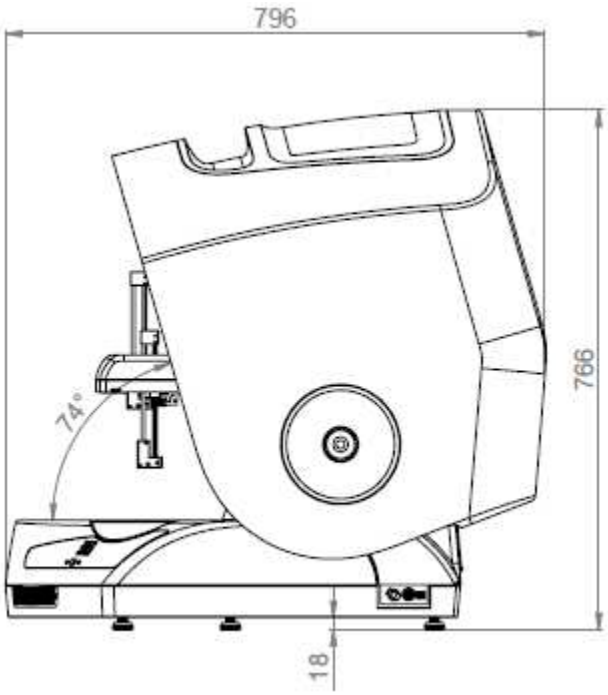
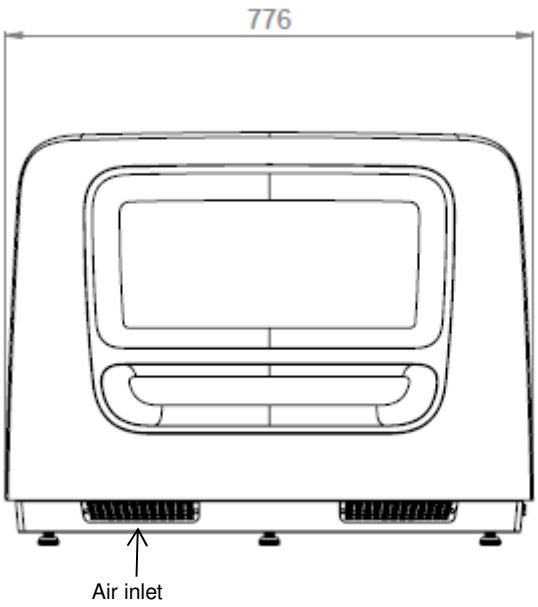
3. Installation of CEVERON 100 series

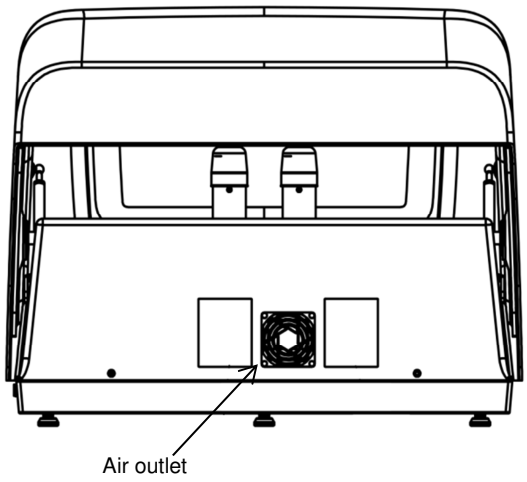
Only Technoclone personnel or an authorized representative of Technoclone is allowed to unpack, install and set up the CEVERON 100 series instrument!

3.1 Positioning

- Please install CEVERON 100 series system on a flat surface, with a minimum of 10 cm clearance from the rear of the wall.
- Avoid direct exposition to sunlight and fluorescent lamps.
- Avoid direct contact with liquids.
- Avoid places with dust, solvents, acid vapours and vibrations.
- The ambient temperature should be within 15 ºC and 32 ºC.
- On the left or right side of CEVERON instrument has to be enough space for the PC, and waste container.
- Avoid any interferences of the air flow of the apertures at the rear side of the device.
- Make sure that the CEVERON system is at least 1 meter away from other devices.




776
Air inlet


Air outlet

3.2 Power connection

- Read the rating plate located on the back of the device before connecting the main power cable with CEVERON 100 series instrument.
- Make sure that the instrument is switched to the local power requirements.
- Main voltage: 90 – 240 VAC
- Power consumption: max. 180 VA
- Frequency range: 50 / 60 Hz
- Protection class: I

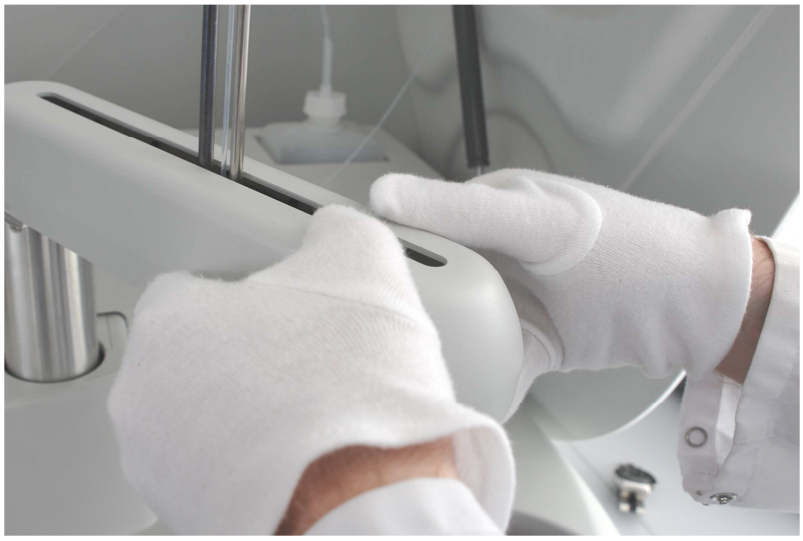
3.3 Operating, storage and transport conditions

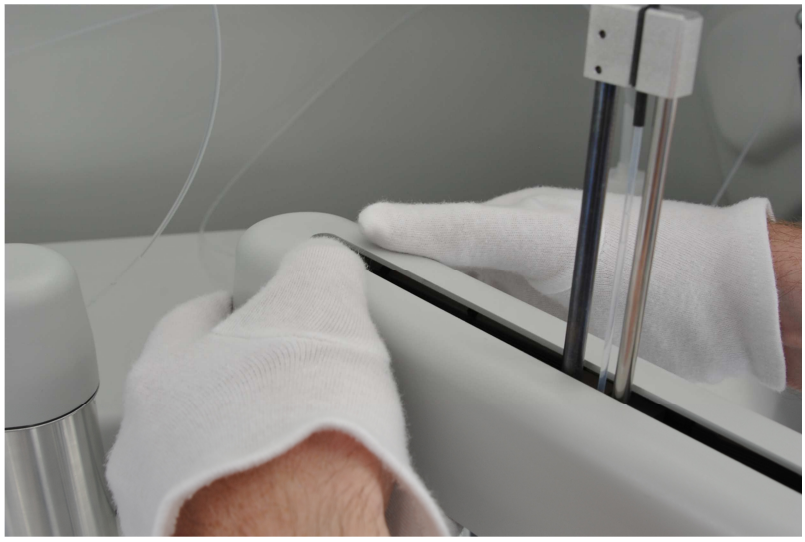
- Operating temperature range for normal use: +15 ºC - +32 °C
- Temperature range for storage and transport: -20 ºC - +55 ºC
- Operating humidity range for normal use: 20 % - 80 % rel. humidity (not condensing)
- Humidity for storage and transport: 0 % - 90 % rel. humidity (not condensing)

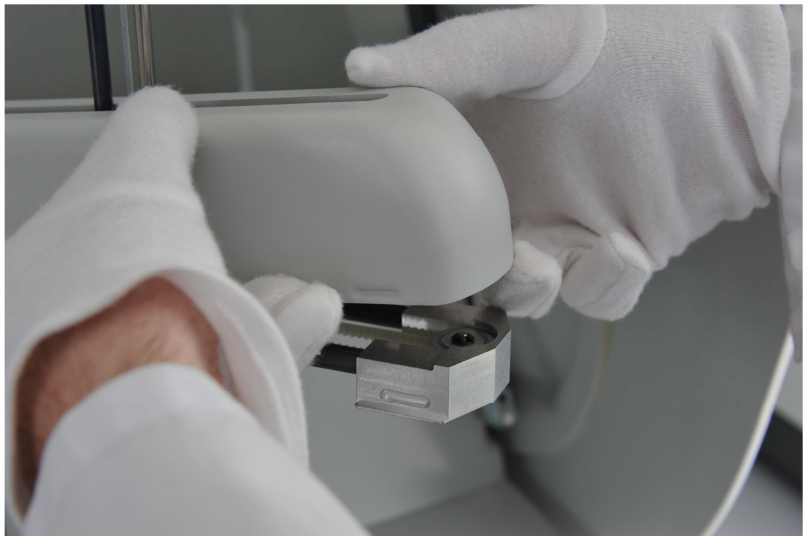
FOR ALL FOLLOWING INSTALLATION STEPS CEVERON 100 SERIES INSTRUMENT MUST BE SWITCHED OFF!

3.4 Mounting of the probes of sample and reagent arm

Remove the protection covers of both arms as shown below:





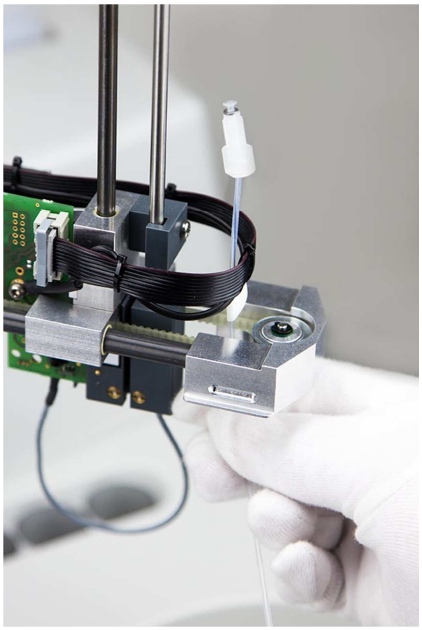


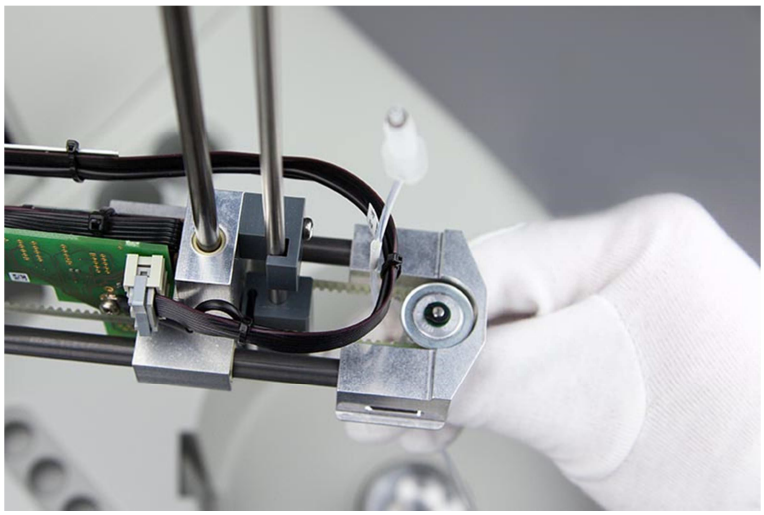
How to assembly the probes:

For all the following steps locate the respective arm to a position with sufficient space underneath for mounting the probe. For the sample arm this is above the sample rotor with the sample rotor taken out. For the reagent arm this is above the cooling block.

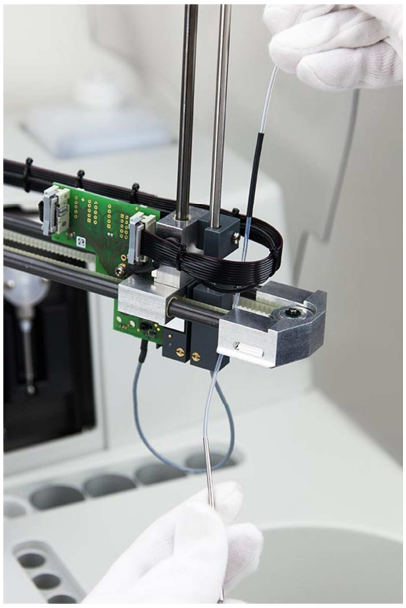
- Mounting the sample probe (right):

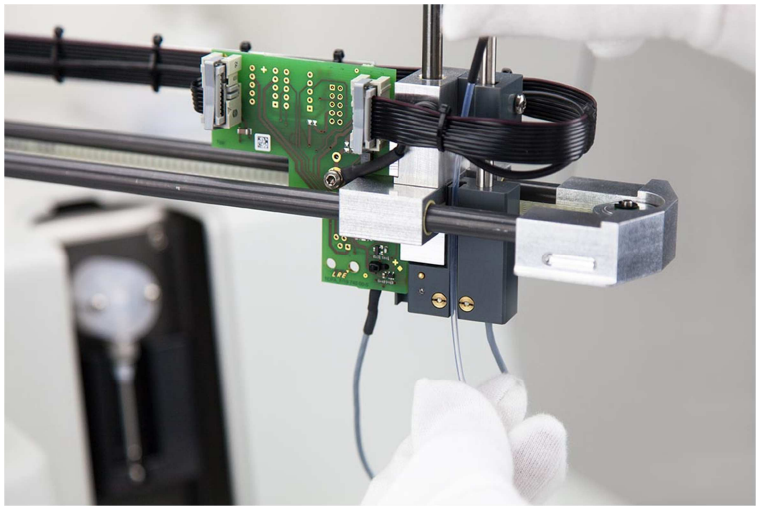
1. Take out the sample rotor
2. Move the vertical part of the pipettor up
3. Guide the tube of the sample probe through the middle of the drive belt

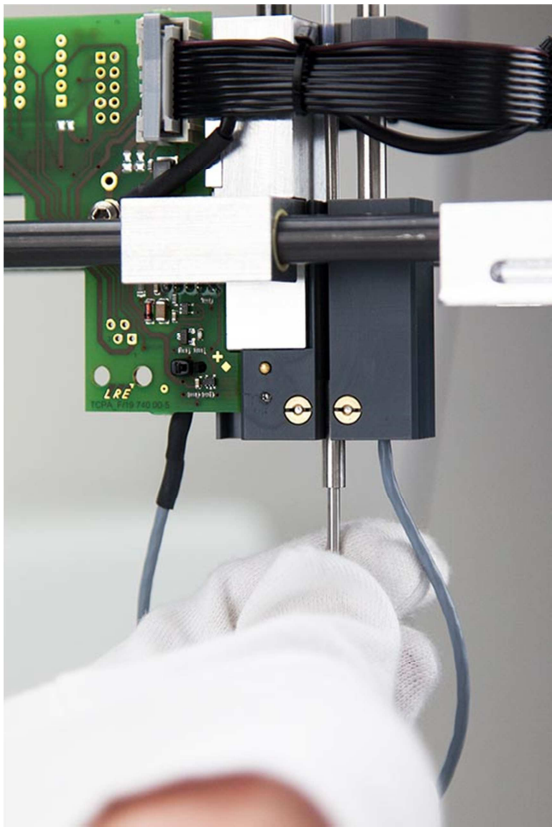




4. Fit the transparent part of the tube into the groove and lift the tube until the metal needle is “metal to metal”



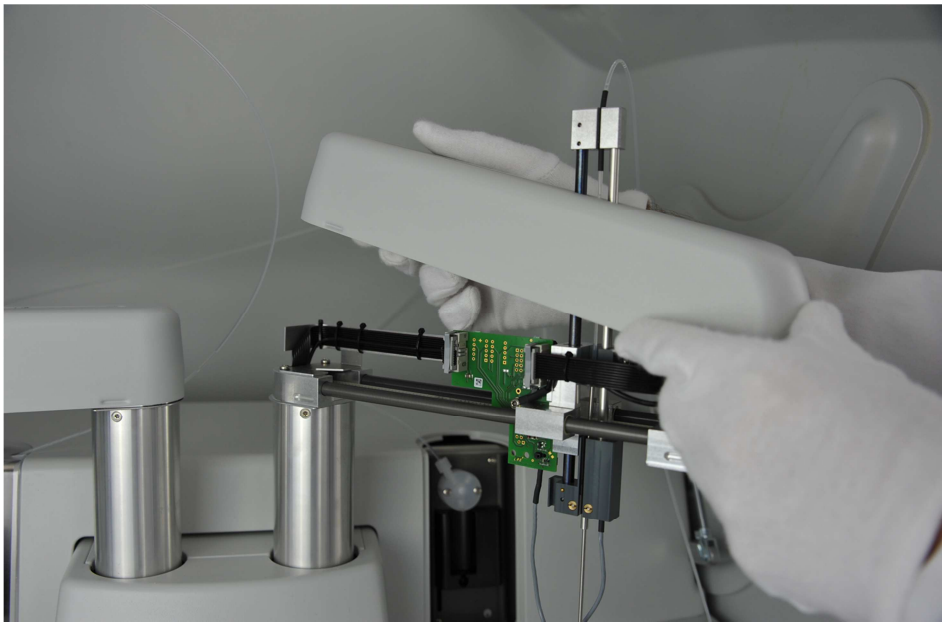




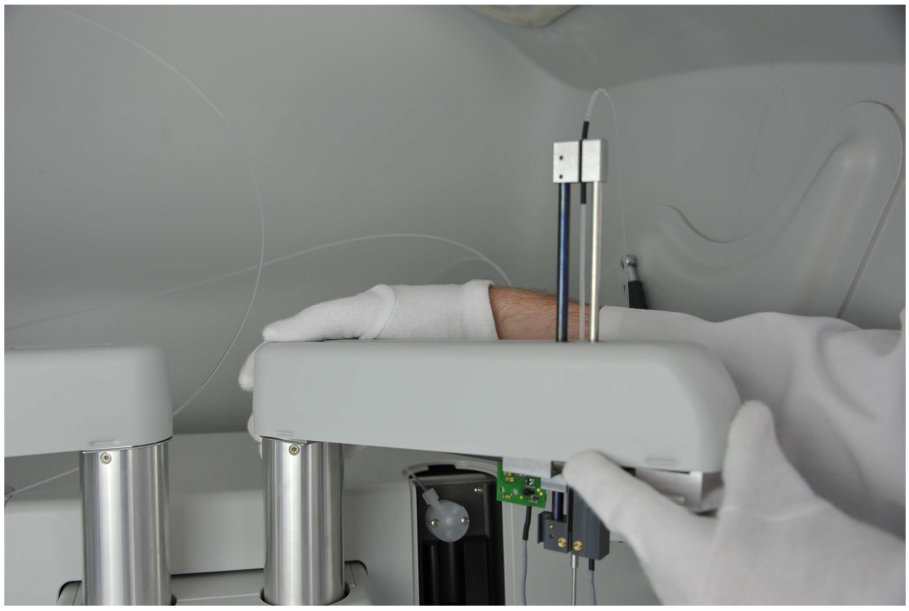
5. Fix the needle carefully with the screw (hand tight)

6. Fit the tube with the holding adaptor (black rubber) into the upper groove

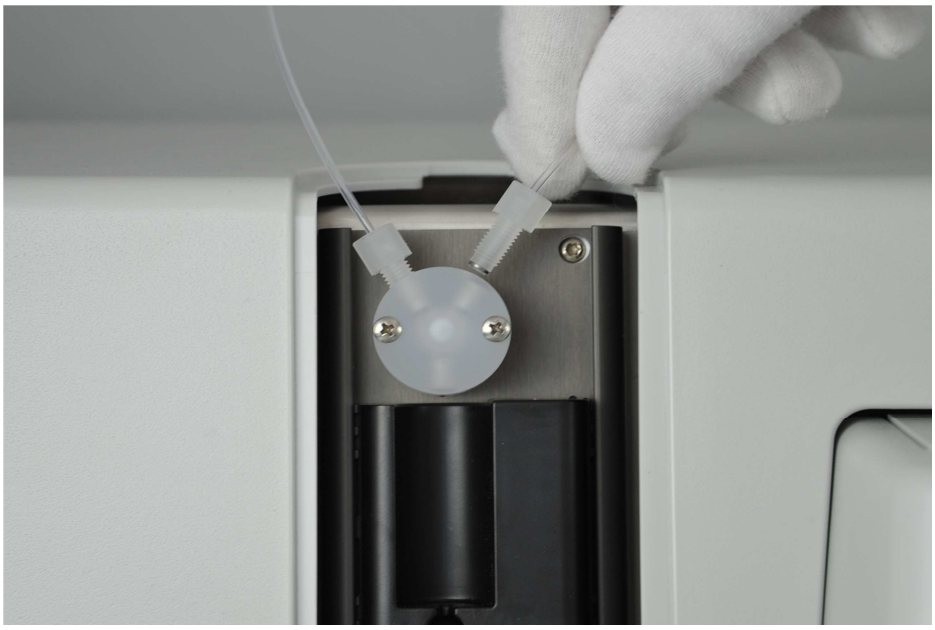
7. Mount the tube through the cover



8. Fix the cover

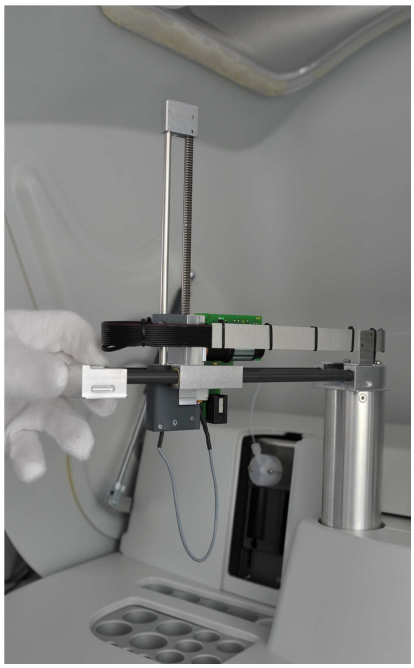


9. Mount the screw of the tube carefully on the right well of the valve

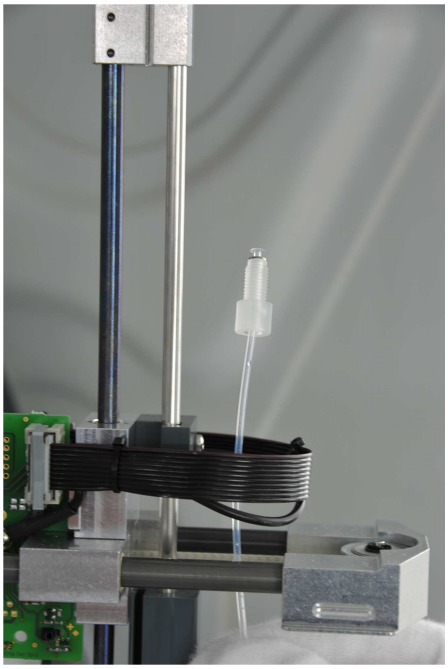


- Mounting the heated reagent probe (left):

1. Move the vertical part of the pipettor up and the left arm to the left

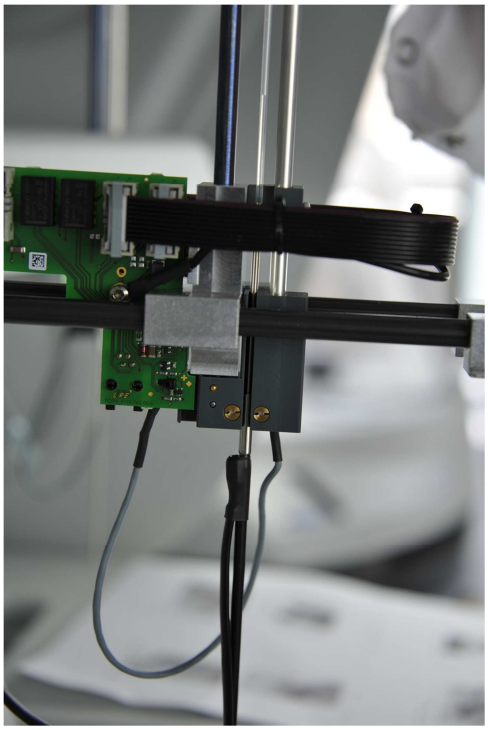


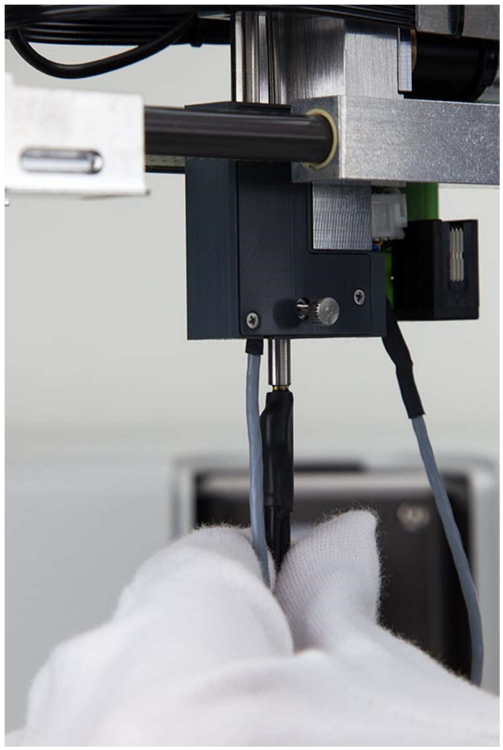
2. Guide the tube of the reagent tube through the middle of the drive belt



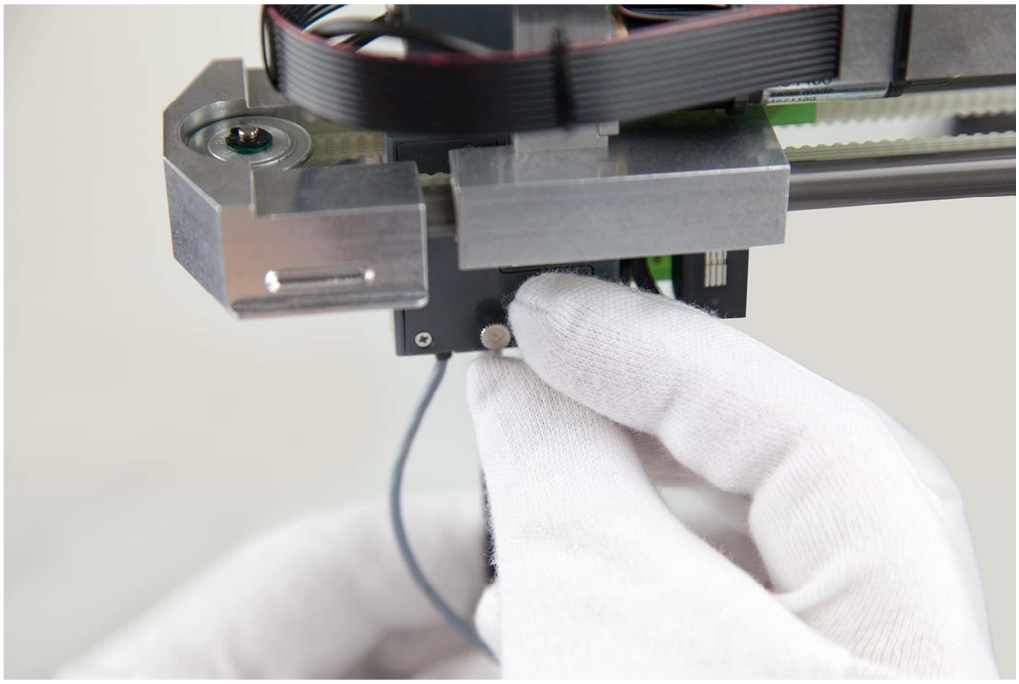
3. Use the empty space below the arm to place the probe

4. Fit the transparent part of the tube into the groove and lift the tube until the metal needle is “metal to metal”





5. Fix the needle carefully with the screw (hand tight)

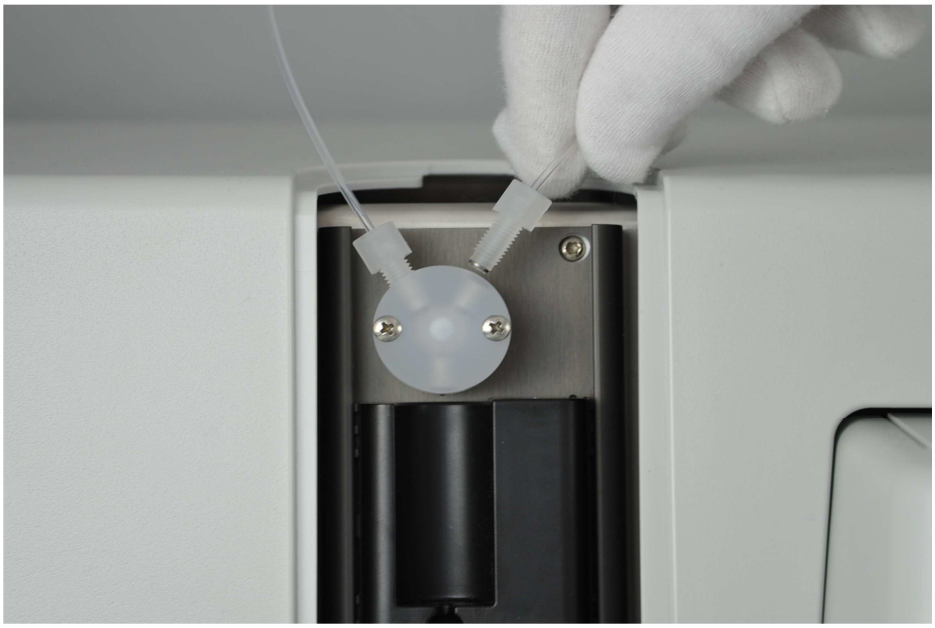


6. Fit the tube with the holding adaptor (black rubber) into the upper groove

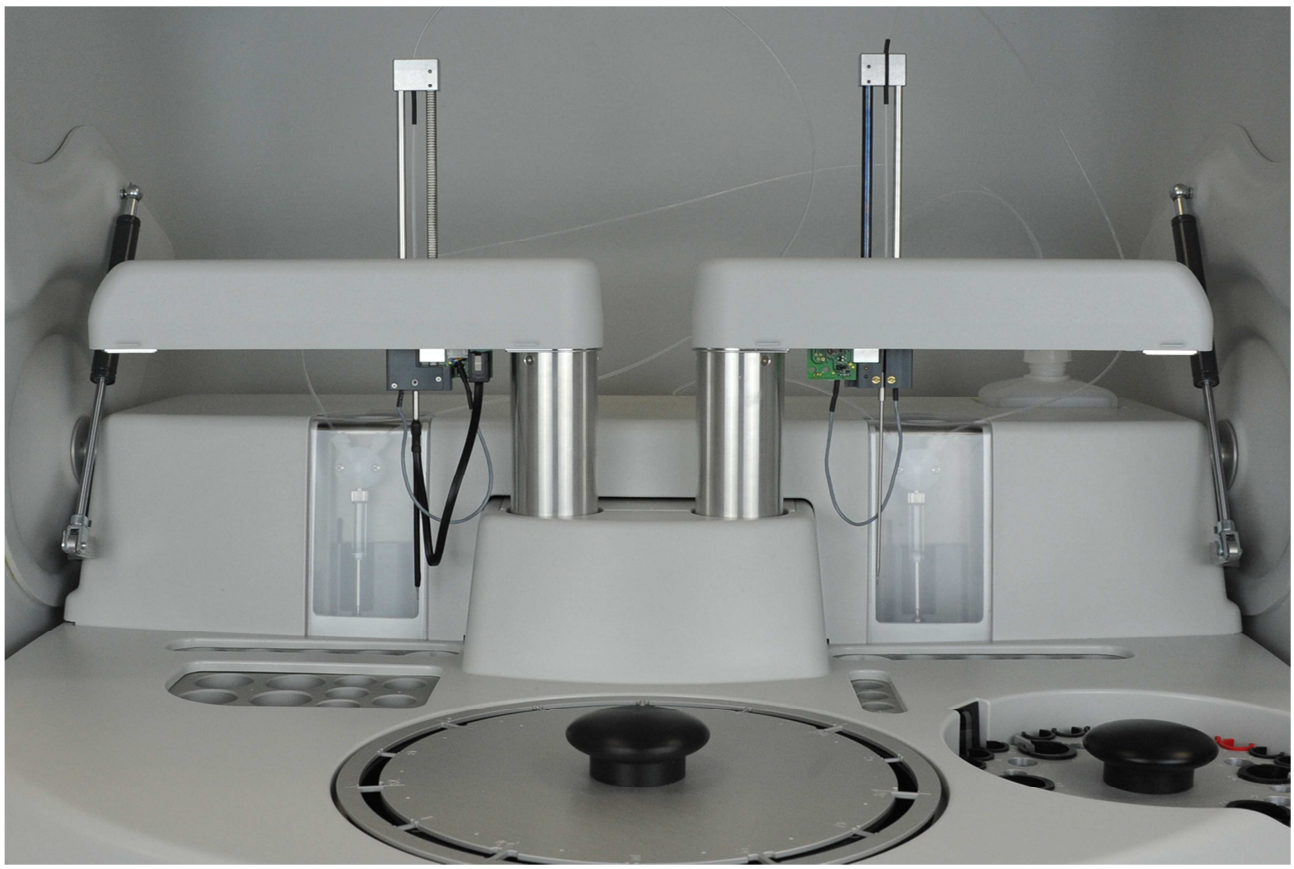
7. Connect the heated probe

8. Mount the tube through the cover and fix the cover

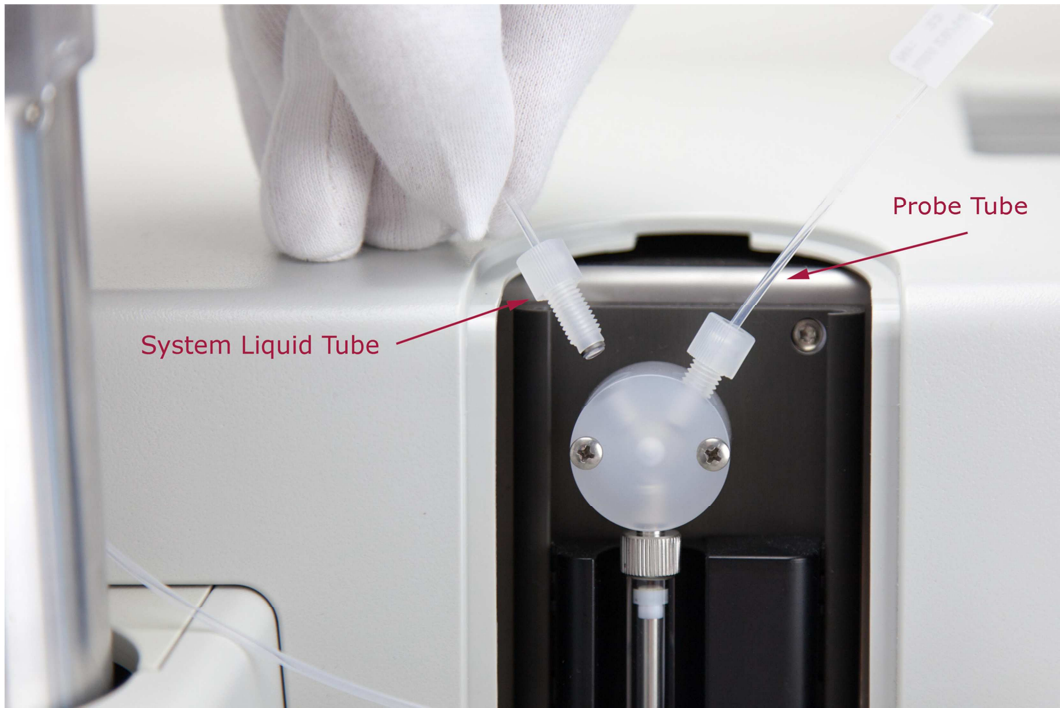
9. Carefully mount the screw of the tube on the right well of the valve



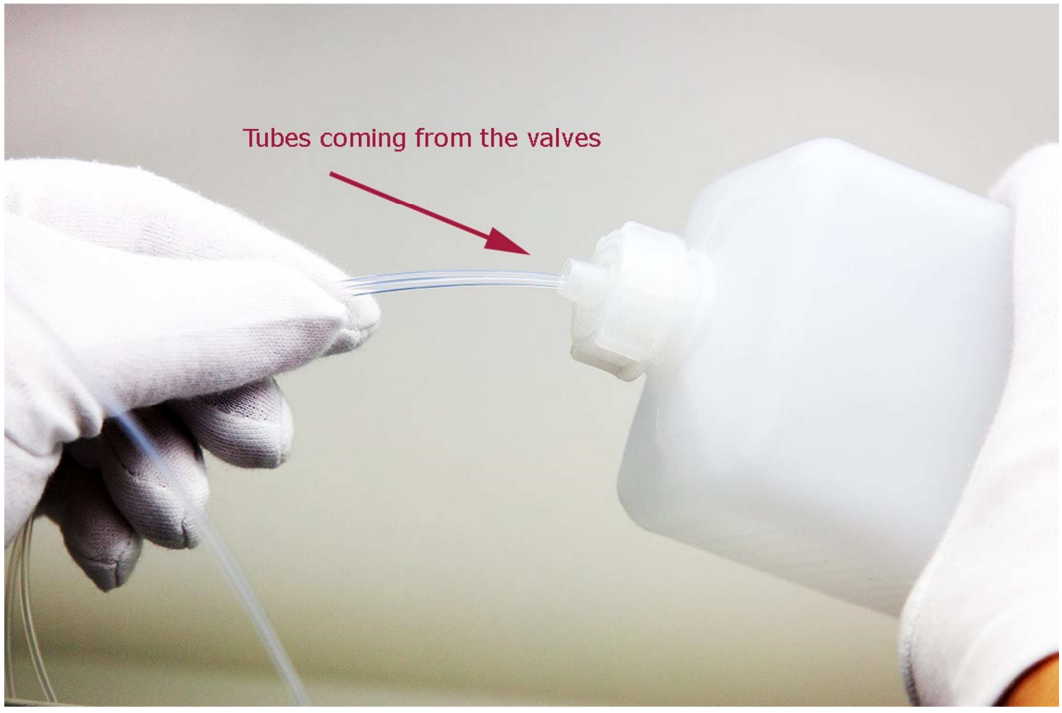
Setup before connecting the system liquid tubes:



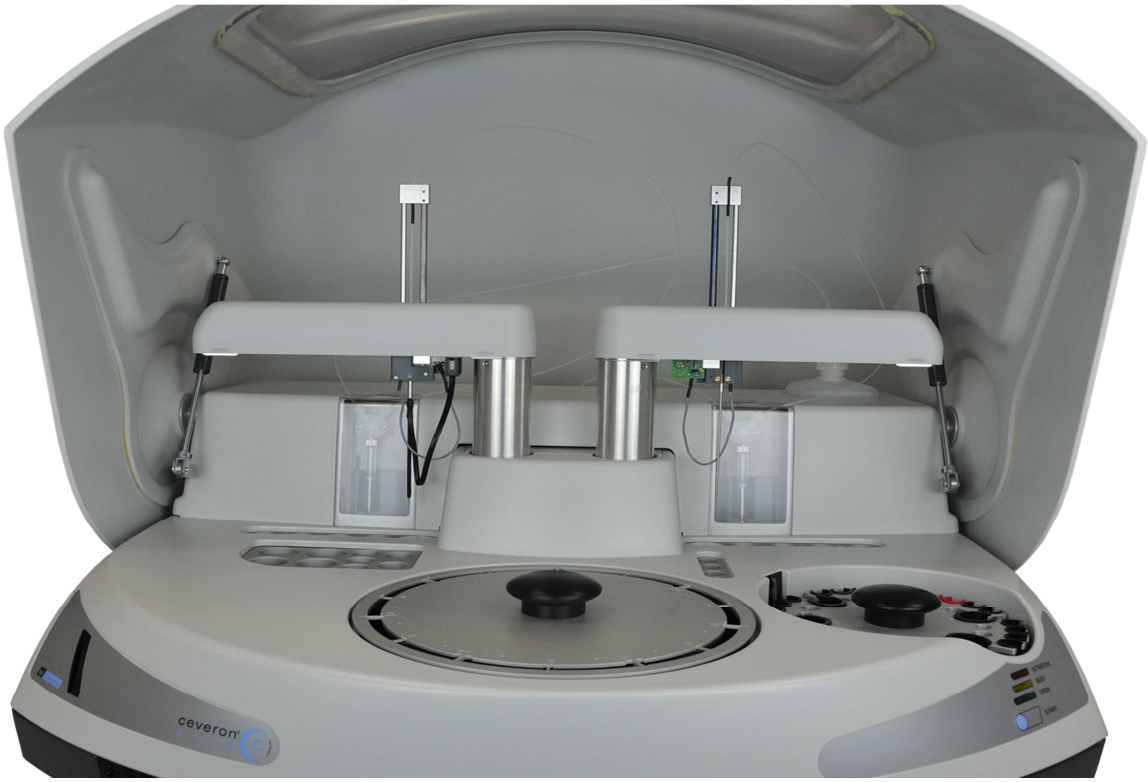
3.5 Connecting the system liquid tubes



Carefully fasten the system liquid tube screw to the valves as shown in the picture. The positions are identical for reagent and sample arm side.
Fit the other end of the system liquid tubes into the special inlet down to the base of the system liquid bottle.



Complete setup

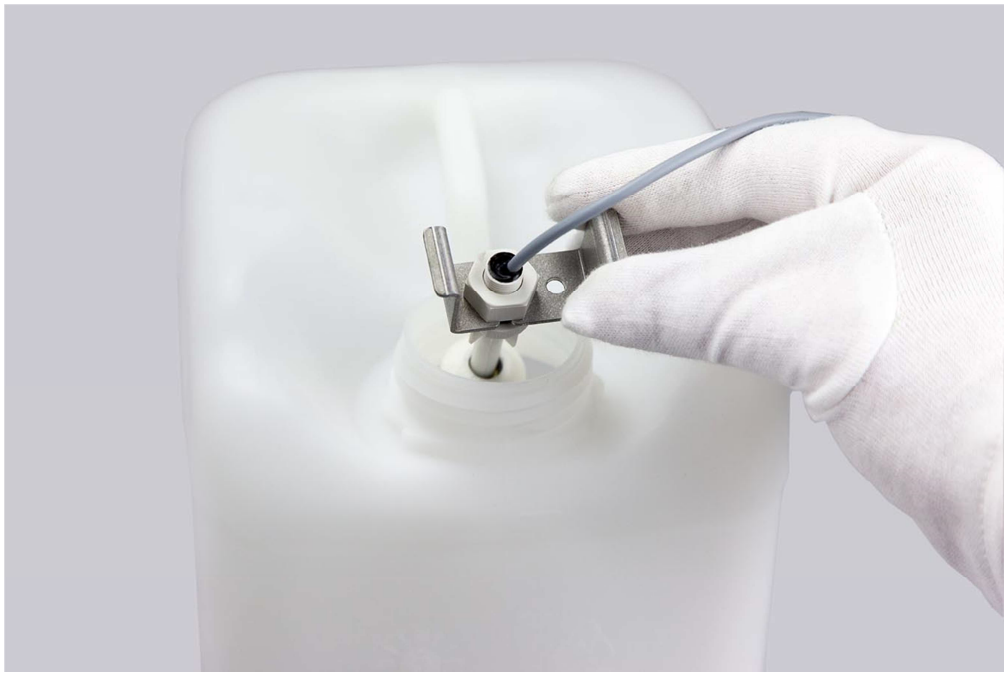


3.6 Connecting the waste tube and the waste sensor to the instrument

Connect the tubing of the waste tube and the waste sensor cable to the inlets on the right of CEVERON 100 series Instrument.

3.7 Connecting the waste tube and the level sensor to the waste container

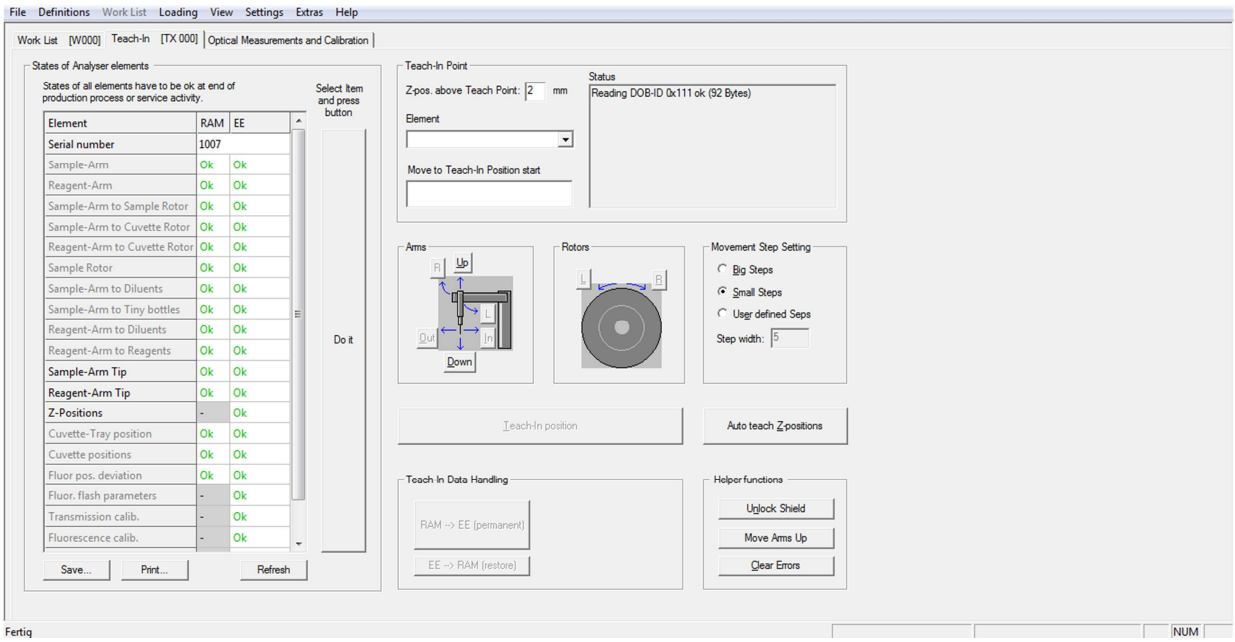
Insert the metal carrier holding the liquid waste level sensor into the waste container.



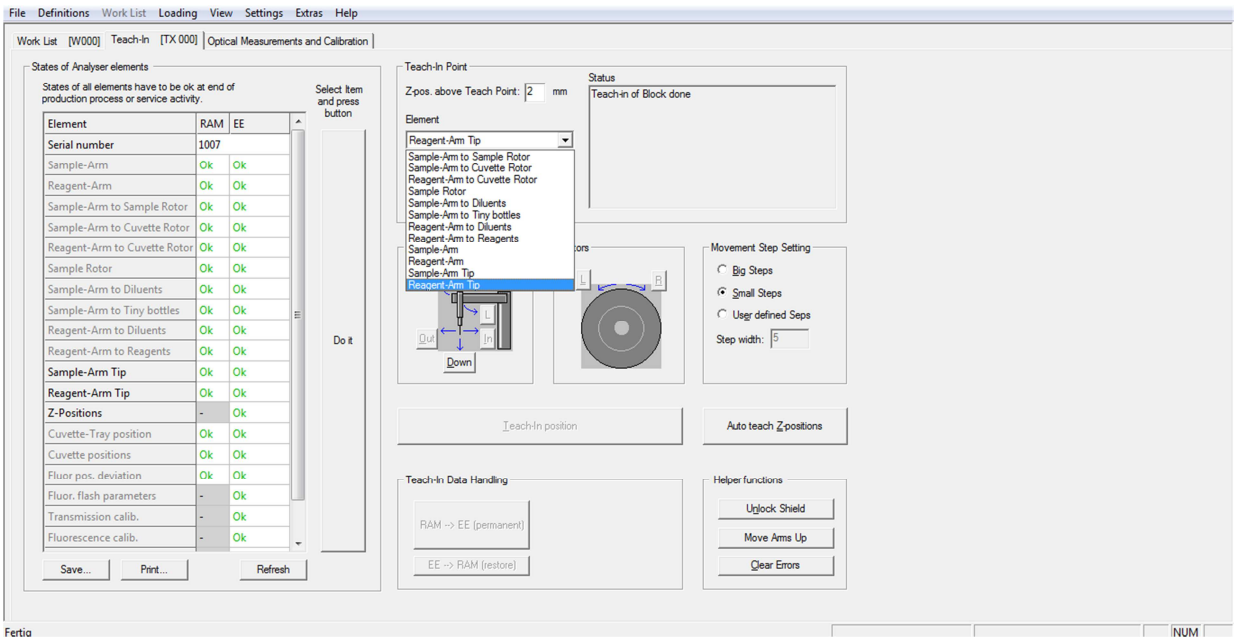
Carefully fit the waste tube through the opening of the metal carrier.

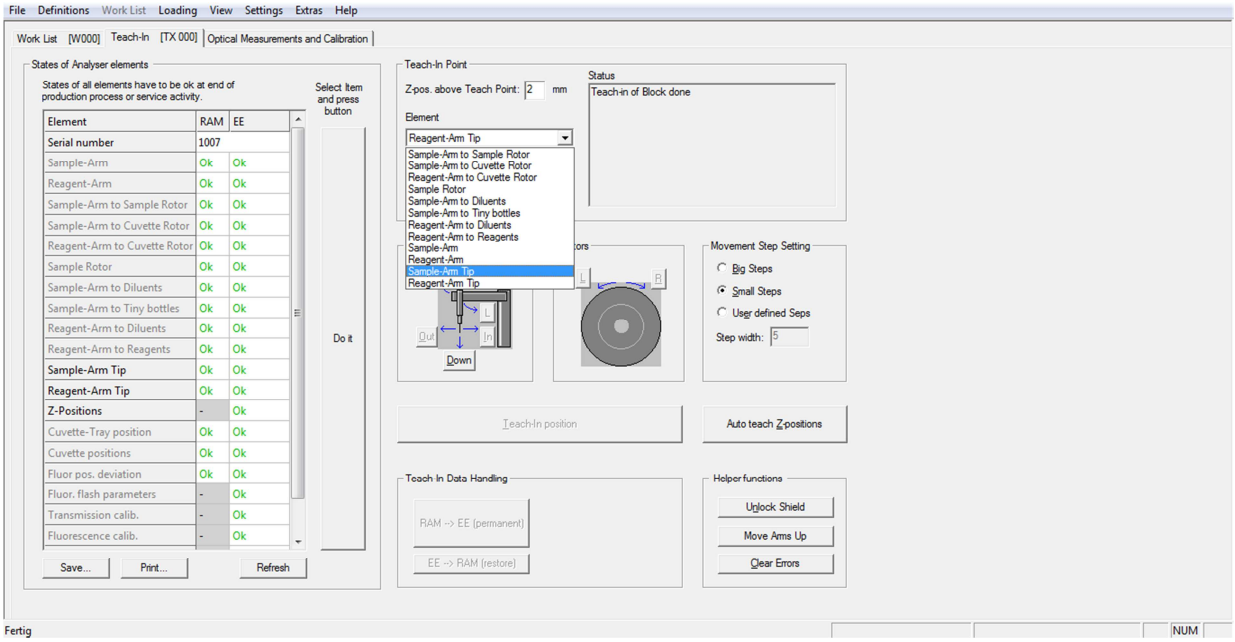
3.8 Adjustment of the probes

Select the menu tab **“Teach-In”** from the working list

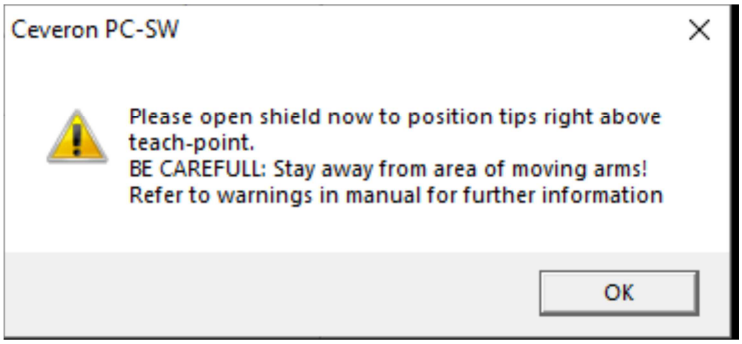


Select Reagent Arm Tip or Sample Arm tip. Press Do it and confirm the opened information window. Then select T1 at Move to teach-In position start. After confirming the teach-in with the teach-in password, the tip will automatically move to the teach-in position.





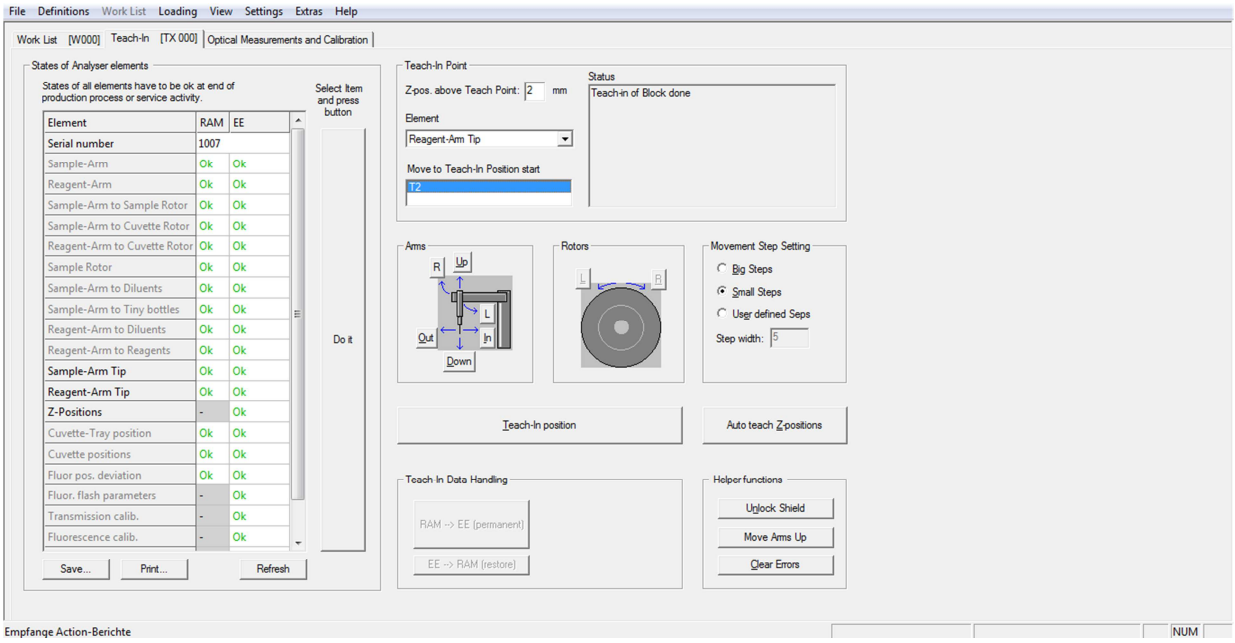
Click ok on the information window and open the CEVERON 100 series cover.



Now use the left mouse button and click on down once by once (!!!) until the tip is about 0.5 cm above the borehole and click on **“small steps”**.

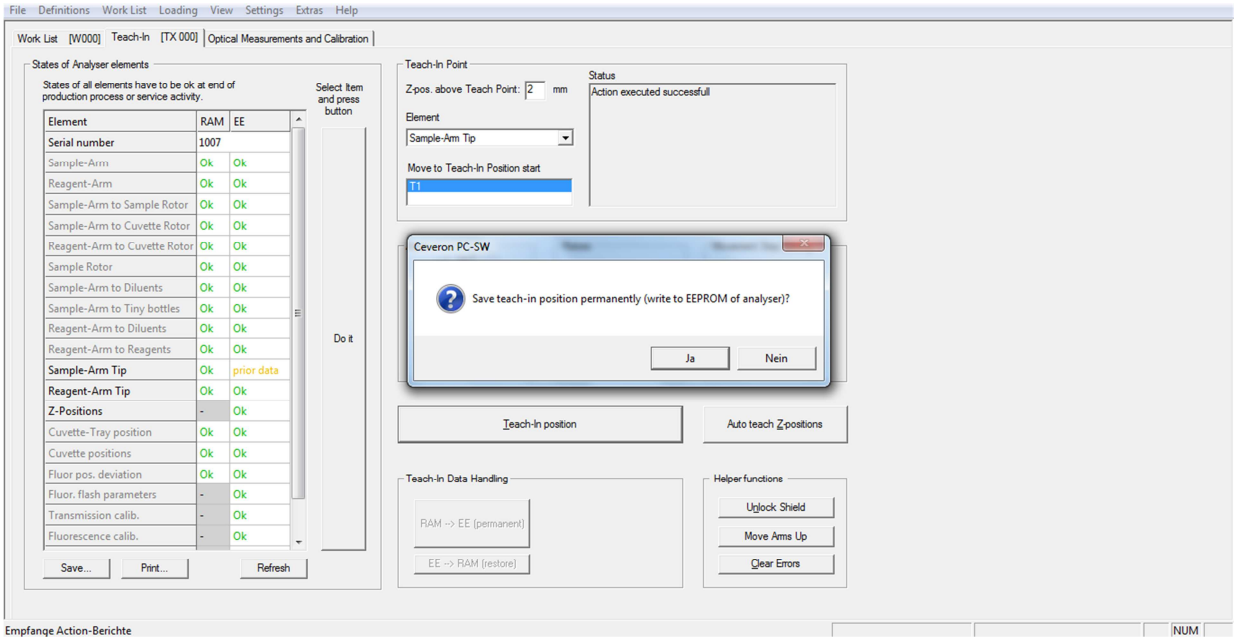
Carefully adjust the tip exactly above the borehole using **“out”** and **“in”** and **“left” and “right”** buttons.

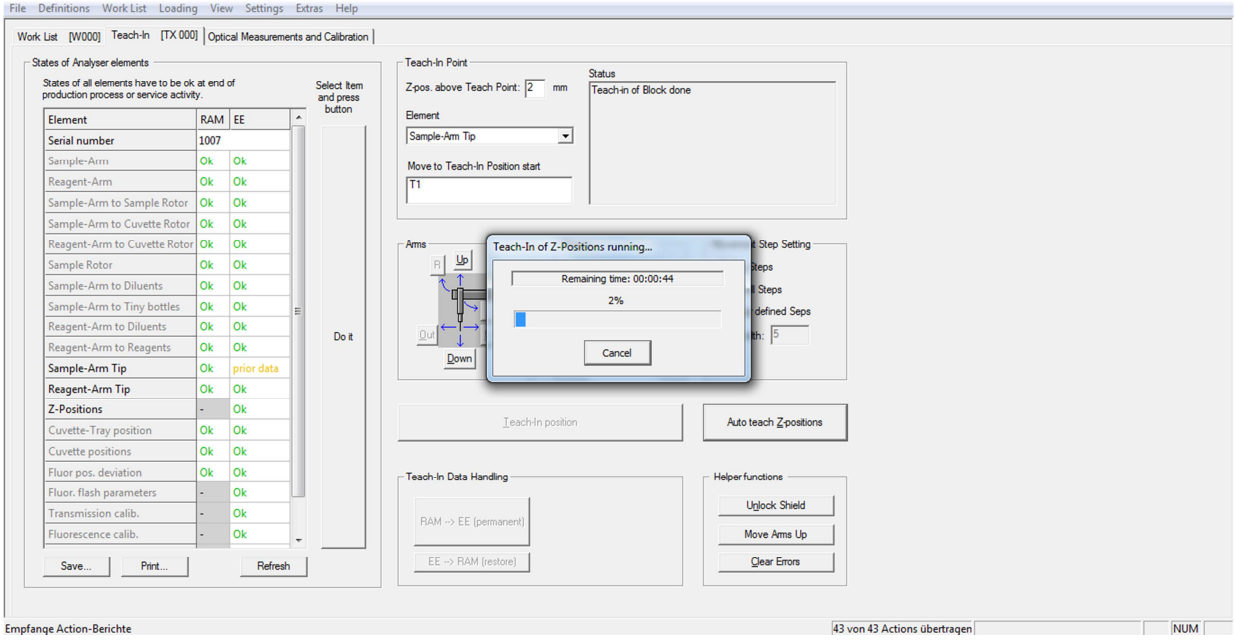
Please note, that the left and right buttons turn the arm like you are sitting in a car. If you are standing in the front of CEVERON, pressing **“right”** will result a movement to the left.



After you finished the adjustment, first close the CEVERON 100 series cover and click on **“Teach-in position”**.

After that you will be asked again if you want to save the settings permanently to EEPROM. Click on **“Yes”**.





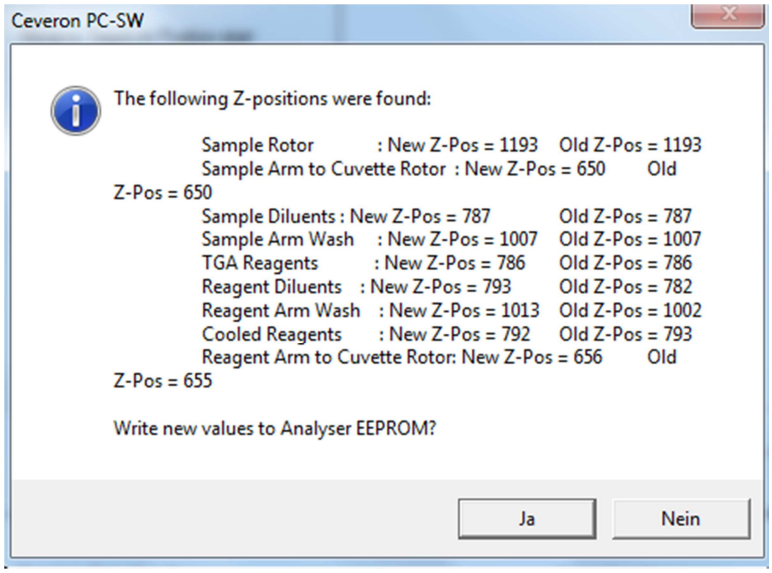
Now click on **“Sample Arm”** within **“T1”** and repeat the same procedure with the sample arm.

After you finished the adjustment, first close the CEVERON 100 series cover and click on **“Teach-in position”**.

Then you will be asked if you want to save the settings permanently to EEPROM. Click on **“Yes”**.

The adjustment of the **“Z”** position for both probes will be done full automatically if you click on the **“Auto teach Z positions”** button.

When finished the summary of the new adjustments is shown in a new window. Confirm by saving it to EEPROM.



After the Ceveron 100 series instrument is switched off and on again the teach in positions are saved permanently.

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4. Software description

After you have switched on the computer you have to enter username and password for Windows first.

Click on the CEVERON icon to start the software. Please enter your CEVERON username and your password to start the program.

4.1 How to operate the software

Control via mouse or touch screen

If you are using the mouse to operate the CEVERON software, normally only the left mouse button is active. For some operations the right mouse button is active. These are specially mentioned in the user manual.

The Ceveron 100 series software is touch screen optimized, therefore the main software interfaces are designed for interaction using a touch screen.

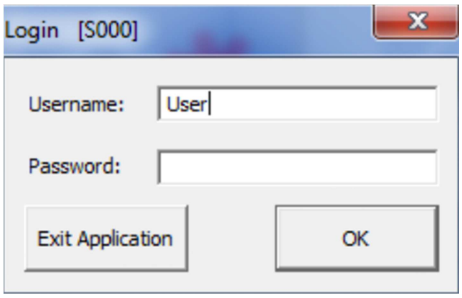
Control via arrow keys

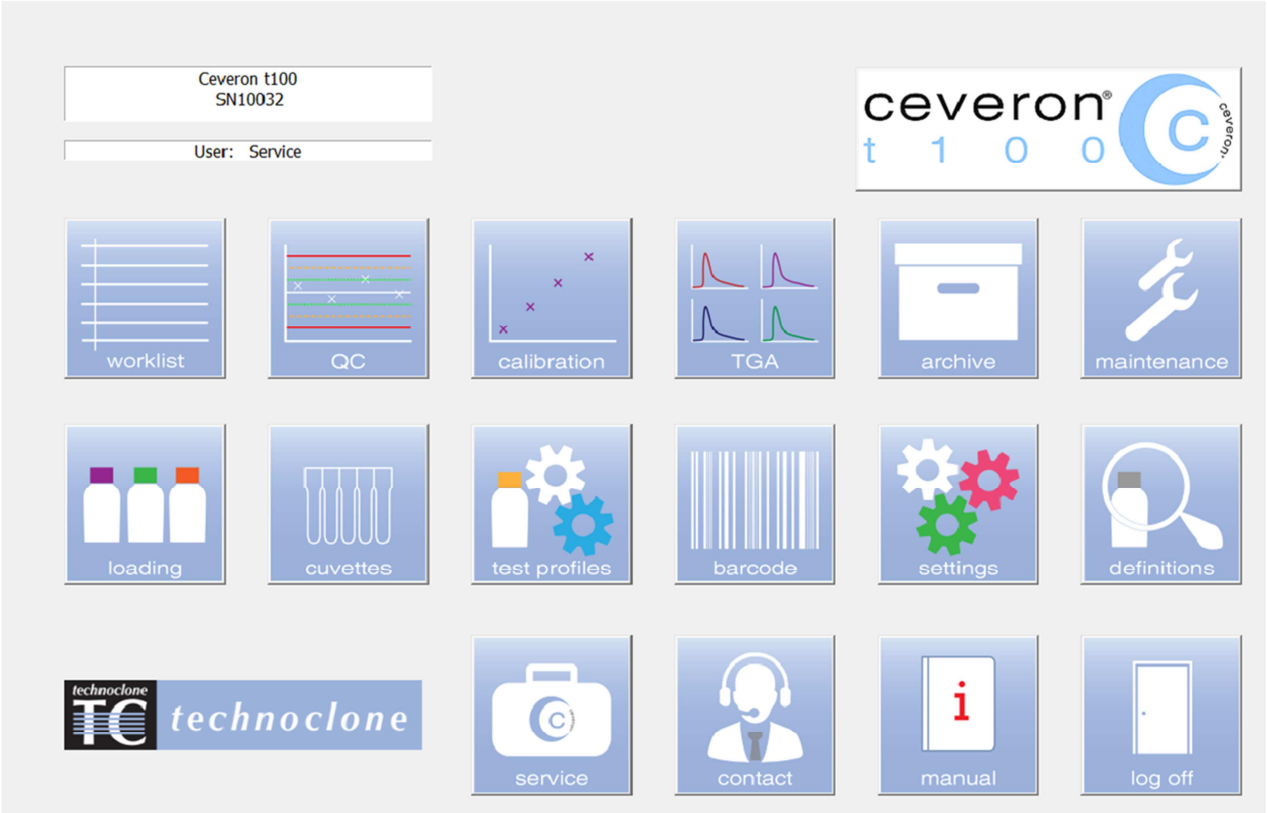
In tables such as the working list it is also possible to use the arrow keys on the keyboard to move within the screen.

4.2 Menus

This chapter is used as an overview for the setup and function of the menus accessible via the main menu or home screen.

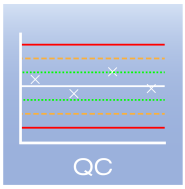
4.2.1 Login and main menu





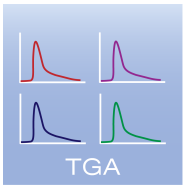
Description of buttons

Load samples and select tests.
Measurement results are displayed at the end of the procedure.
For further details refer to ***4.2.2. Worklist.***



Display, delete or activate QC results.
For further details refer to chapter ***4.2.3 QC – Quality control.***

Display, edit, delete or run calibration curves.
For further details refer to chapter ***4.2.4 Calibration.***



Display reaction curves of TGA.
For further details refer to chapter ***4.2.5 TGA.***

Display measured results from the archive, or the backup database.
For further details refer to chapter ***4.2.6 Archive.***

Priming and cleaning options.
For further details refer to chapter ***4.2.7 Maintenance.***

Load controls, calibrators, reagents and other liquids into the analyzer.
For further details refer to chapter ***4.2.8 Loading.***

Display and load cuvettes, including cuvette lot management.
For further details refer to chapter ***4.2.9 Cuvettes.***

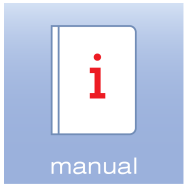
Display, edit, delete or add test profiles.
For further details refer to chapter ***4.2.10 Test profiles.***

Define or load material information using barcodes.
For further details refer to chapter ***4.2.11 Barcode.***

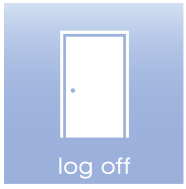
Edit software settings.
For further details refer to chapter ***4.2.12 Settings.***

Display, add, edit or delete reagent and test definitions.
For further details refer to chapter ***4.2.13 Definitions.***

Contact information and remote access.
For further details refer to chapter ***4.2.14 Contact.***



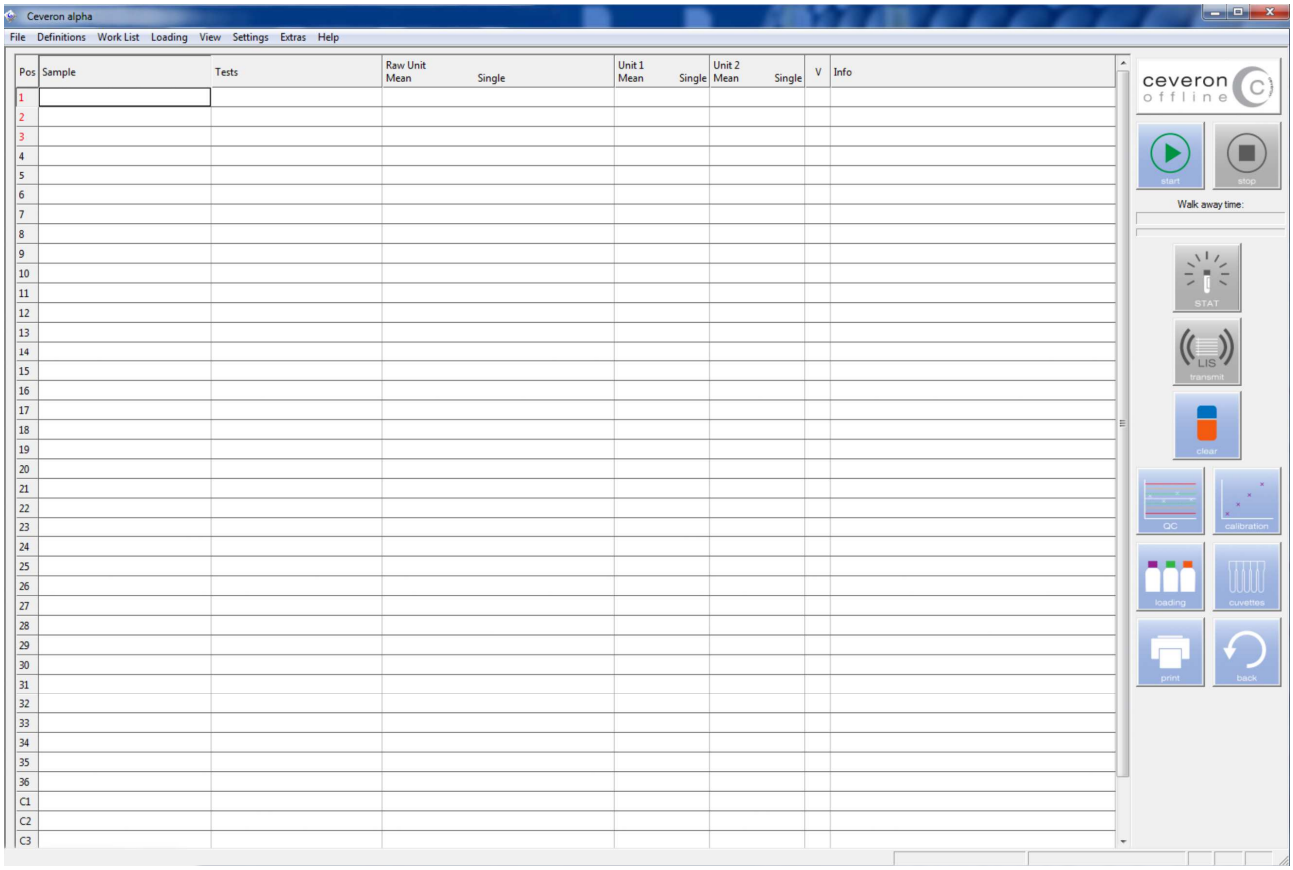
Display User manual.
For further details refer to chapter ***4.2.15 Manual.***



Close the CEVERON software.
For further details refer to chapter ***4.2.16 Log off.***

4.2.2 Worklist

By clicking the “**Worklist**” icon, the worklist will be opened.



In the worklist all daily routine used operations can be performed: Sample management, QC testing, calibration and loading the reagents.

Ceveron Icons

CEVERON 100 series instrument is offline.

By clicking the button, the detailed instrument system status is depicted.

CEVERON 100 series instrument ready.

By clicking the button, the detailed instrument system status is depicted.

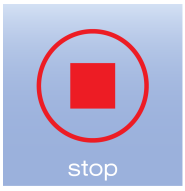
CEVERON 100 series instrument is working.

By clicking the button, the detailed instrument system status is depicted.

CEVERON 100 series instrument has an error.

By clicking the button, the detailed instrument system status is depicted.

Start test measurement.

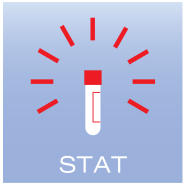


Immediately stop all measurements. Started actions and measurements will be lost.

To be confirmed in a second screen.

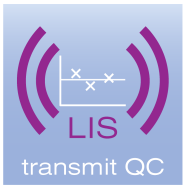
Stop measurement after already scheduled/started actions are completed. No data will be lost.

To be confirmed in a second screen.

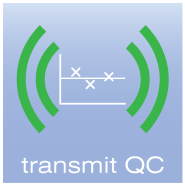


Pause measurement to load STAT samples.

To be confirmed in a second screen.



Send QC results to host computer (LIS).



Send QC data to local QC database.

Send sample results to host computer (LIS).

Send samples results to local archive.

Clear data from work list.

To be defined and confirmed in a second screen.

The walk away time bar shows the time until all started tests are finished.

For easier and faster workflow the functions **“QC”**, **“calibration”**, **“loading” “cuvettes” “print” and “back”** are also available via direct links. For further information please refer to the respective chapters.

Loading STAT samples

On the sample rotor, the first (1-3 upon delivery) positions are dedicated for emergency or STAT samples. For your convenience, they are marked by red numbers in the software and red inserts on the samples rotor. These positions are handled with priority and all tests from these samples are finished prior commencing the rest of the loaded samples. The number of STAT samples can be modified from 0-8 in the instrument settings. If the CEVERON is currently running, press the ‘**STAT**’ button to pause the instrument in order to load the STAT samples.

Loading samples

Samples with barcode:

Load the barcoded samples into the sample rotor in position 1-24. Please ensure that the barcode faces the outside of the sample rotor to ensure that it can be read by the barcode reader.

- If the CEVERON is connected to a host computer (LIS), the sample identifications and requested tests are transferred automatically to the instrument. After loading the samples, close the cover and press the START button on the instrument. Upon scanning the sample identification and requested tests will appear in the work list.

- If the CEVERON is not connected to a host computer (LIS) only the sample identifications will be added automatically. After loading the samples, close the cover and press the START button on the instrument. Upon scanning the sample identification will appear in the work list. Then the requested tests need to be added manually for each sample (see below).

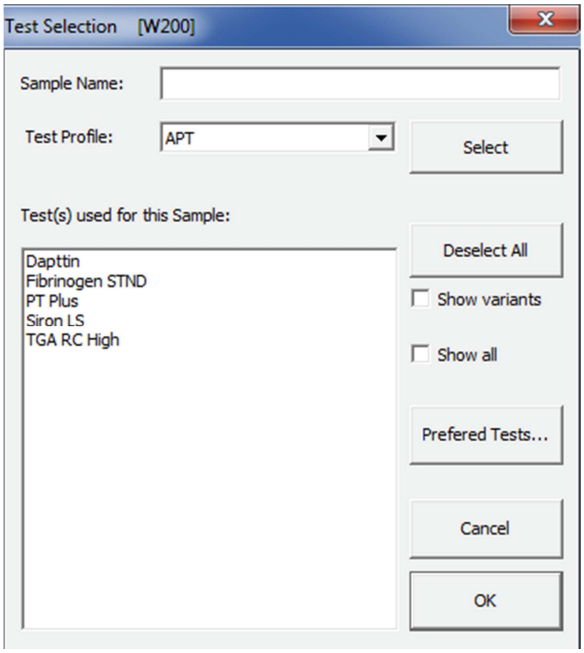
Samples without barcode:

Load samples into the sample rotor in position 1-24. Manually enter the sample identification and requested tests (see below) next to the respective position.

Selecting tests

If the CEVERON is connected to a host computer (LIS) the requested tests will be added automatically upon scanning the barcoded samples.

To manually enter tests for a given sample select the sample, using a double-click or the right mouse button and select **'Properties'**. The **'Test selection'** window opens where the tests can be selected either:



- Individually select the tests as individually or

- Select a Test Profile and press the **'Select'** button.

The list of test will only show the preferred tests. The preferred test list can be changed by pressing **'Preferred Test'**, or directly in by clicking at the **'Test Profiles'** icon on the main screen.
By selecting **'show variants',** all variants of the tests will be displayed. Variants of tests, are tests using a higher or lower sample dilution or an extended measure time than the parent test, depending on the specific parameter.
'Show all' all tests which are stored on the CEVERON will be displayed.

For your convenience, multiple samples can be selected either by pressing SHIFT and left-click (all samples between two clicks) or by pressing CTRL and left-click (individually selected samples upon click).
Test profiles can also be added automatically upon sample entry (manually entered or barcoded samples). These settings can be altered in the **'Tests and Calibration'** Tab in the **'Settings'** menu.

Test results

After successful measurement of QC samples and / or patient samples, the **'transmit'** buttons will appear colored. If the CEVERON is connected to a host computer (LIS) the button will include the abbreviation **'LIS'** to indicate that transmission is done to the host computer.

First the QC sample results are validated and transmitted. Depending on the systems settings QC results are stored locally or sent to the host computer.
With a second click, the sample results are validated and transmitted either to the local archive or to the host computer.
The results can also be uploaded automatically to the LIS.
Settings for validation and LIS communication of results are described in chapter 4.2.12.8 Validation and LIS

Clearing the worklist and unloading samples

After the sample results are validated and no additional test is required, the worklist can be cleared using the 'clear' button. There are several options for clearing the worklist.

- Clear completed Samples and Tests
  Only samples with all tests completed are cleared.

- Clear all Tests (keep Samples)
  All tests are cleared. Sample identification remains in the worklist.

- Clear total worklist
  Clear all samples and tests (both completed and non-completed).

- Including Control
  Perform the clear option also with controls. If not selected, controls will remain in the worklist.

Press **'OK'** to confirm the clearing step.

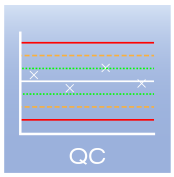
Pausing measurement

In order to pause the instrument while it is running, press the 'Pause' button. After confirmation, CEVERON will finish already started actions (pipetting, measurement) and switches into **'ready'** mode. No data will be lost.

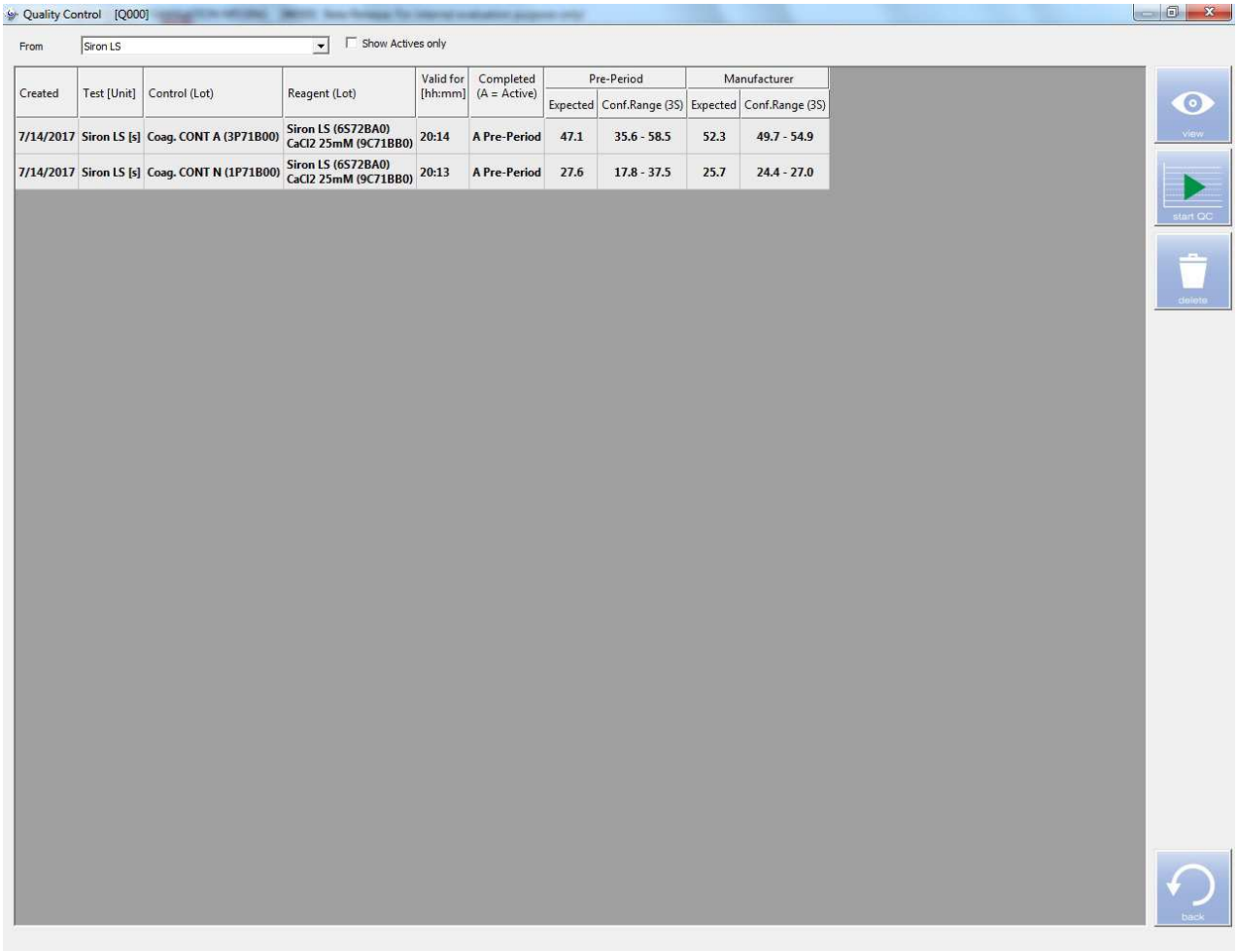
Stop measurement

In order to immediately stop the instrument while it is running, press the **'Stop'** button. After confirmation, CEVERON will immediately stop all actions and switches to 'ready' mode. **CAUTION: all data will be lost, except already finished measurements!**

4.2.3 QC - Quality control

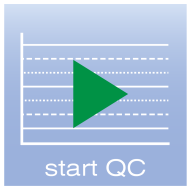


By clicking the **"QC"** icon, the quality control overview will be opened.



Description of buttons

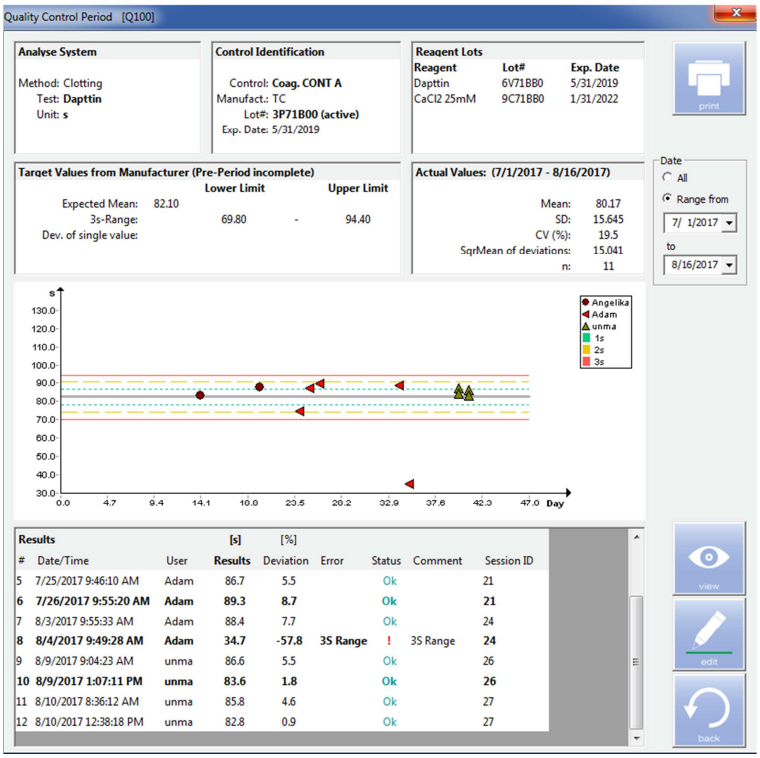
Open and view details of selected QC.



Start or activate selected QC sample/test combination.

Delete selected QC.

Select a control lot – reagent lot combination and click the **‘view’** button.



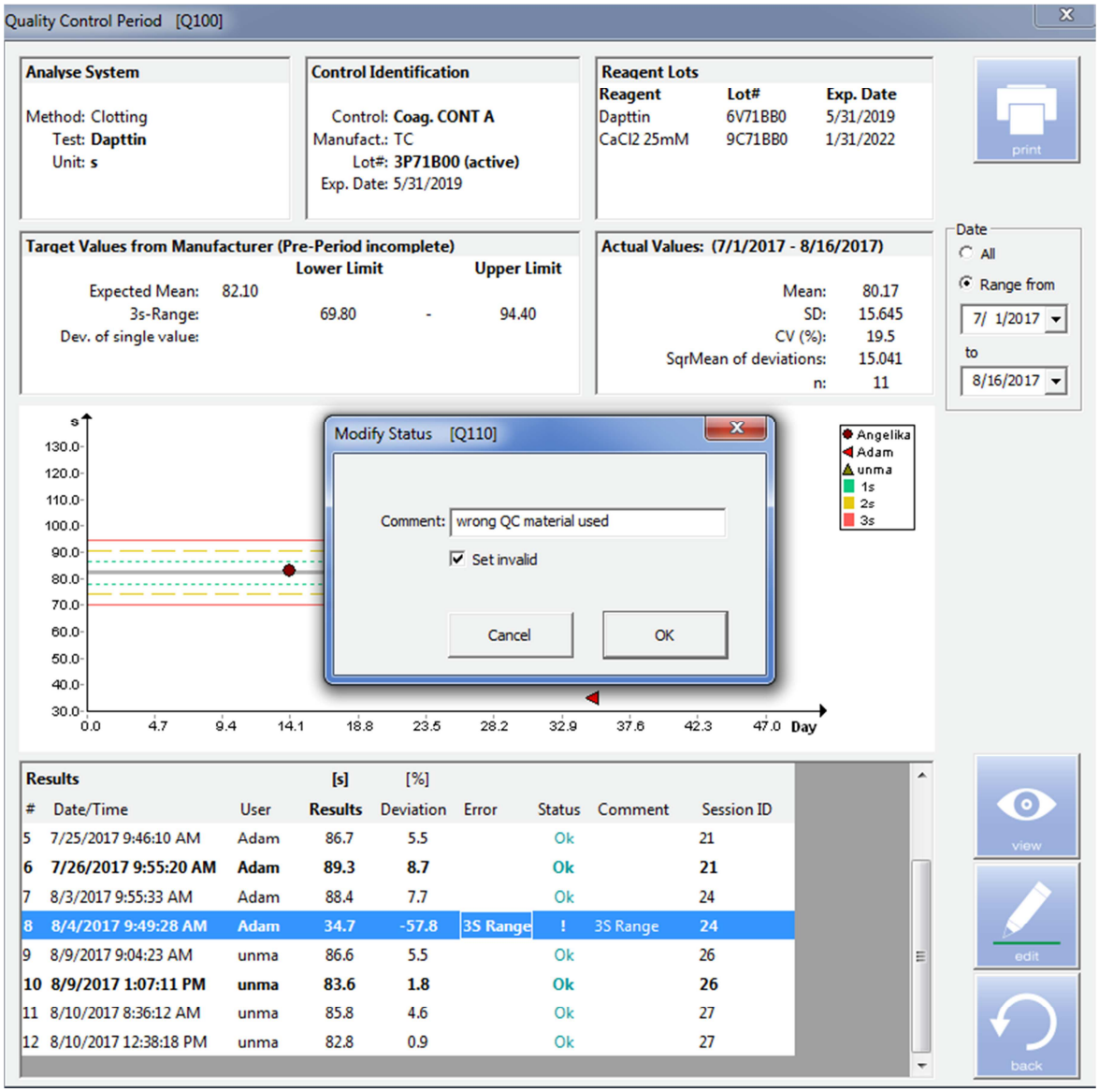
On the **‘Quality Control Period’** window all details of this quality control can be viewed, including

- Analyze System (Test and unit used)
- Control Identification (details of the QC sample)
- Reagent Lots (details on the reagents used)
- Target Values (target values and acceptance ranges from the manufacturer)
- Actual Values (actual measured values with statistics)
- A graphical plot of measured results
- A list of the individual results with
    - Date and Time of measurement
    - User
    - Result
    - Deviation of mean value (Manufacturer or pre-period according to QC settings)
    - Error description
    - Status of the Result (OK, ! for error, X for excluded)
    - Comment
    - Session ID

QC results can be viewed and analyzed for all available measurements or with a limited time window set in **‘Range from…to…’**.
To view the raw data curve of a specific result, select the result and click the **‘view’** button.

Editing a QC result

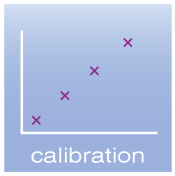
In the example shown above, the result from 8/4/2017 clearly presented an outlier which was caused by mixing up the QC samples. To modify a result and set it as excluded from calculations, select the result and press the **‘edit’** button. Remember: Only user at modify level are allowed to edit QC results. Deletion of a QC result is not possible!



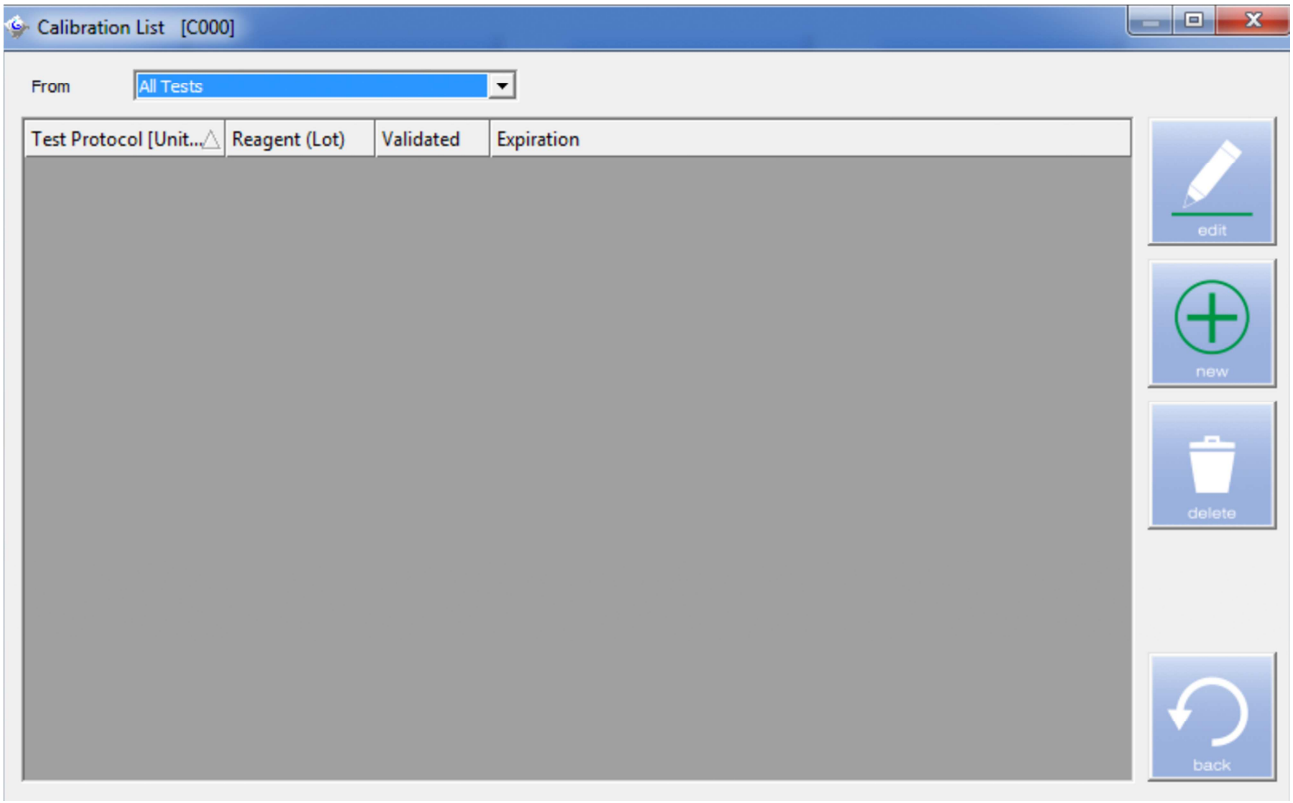
Insert a comment and select **'Set invalid'**. Confirm changes by pressing **'OK'**.

Now the status of the result is changed to **'x'** and the comment entered is added to the **'Comment'** field. In addition, the result is now excluded both from the graph and the statistics found in the **'Actual Values'** tab.

4.2.4 Calibration



By clicking the **“Calibration”**” icon, the calibration list will be opened.



The calibration of an assay is defined within the test protocol.

The **‘Calibration List**’ can be filtered using the **‘From’** drop-down menu

- All Tests
- Preferred Test only
- A specific test by name

Description of buttons

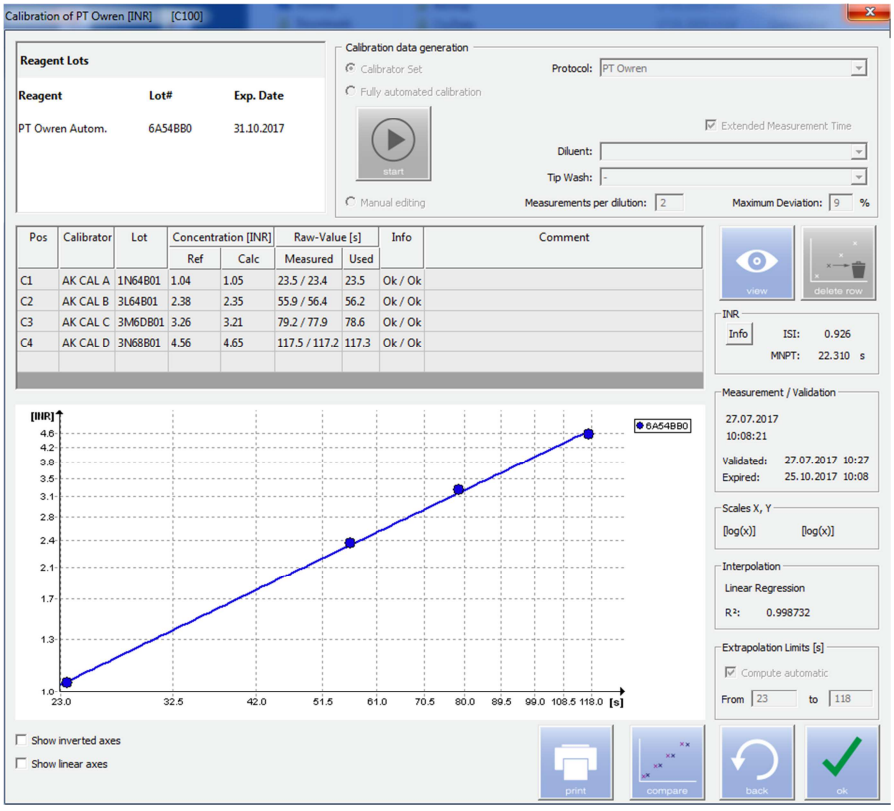
Open, view and edit details of the selected calibration.

Start a new calibration.

Delete selected calibration.

View or modify a calibration.

Calibrations can be viewed, compared and modified, which may be useful when developing an application. Only not validated calibrations can be modified.

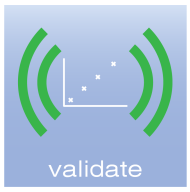


Description of buttons

Start measurement of the calibration.

View raw data and details of a selected calibration point.

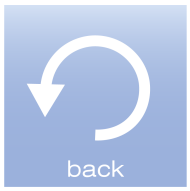
Delete selected calibration point.



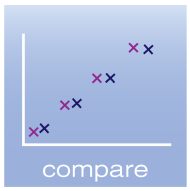
Validate calibration.

No changes can be made to a validated calibration.

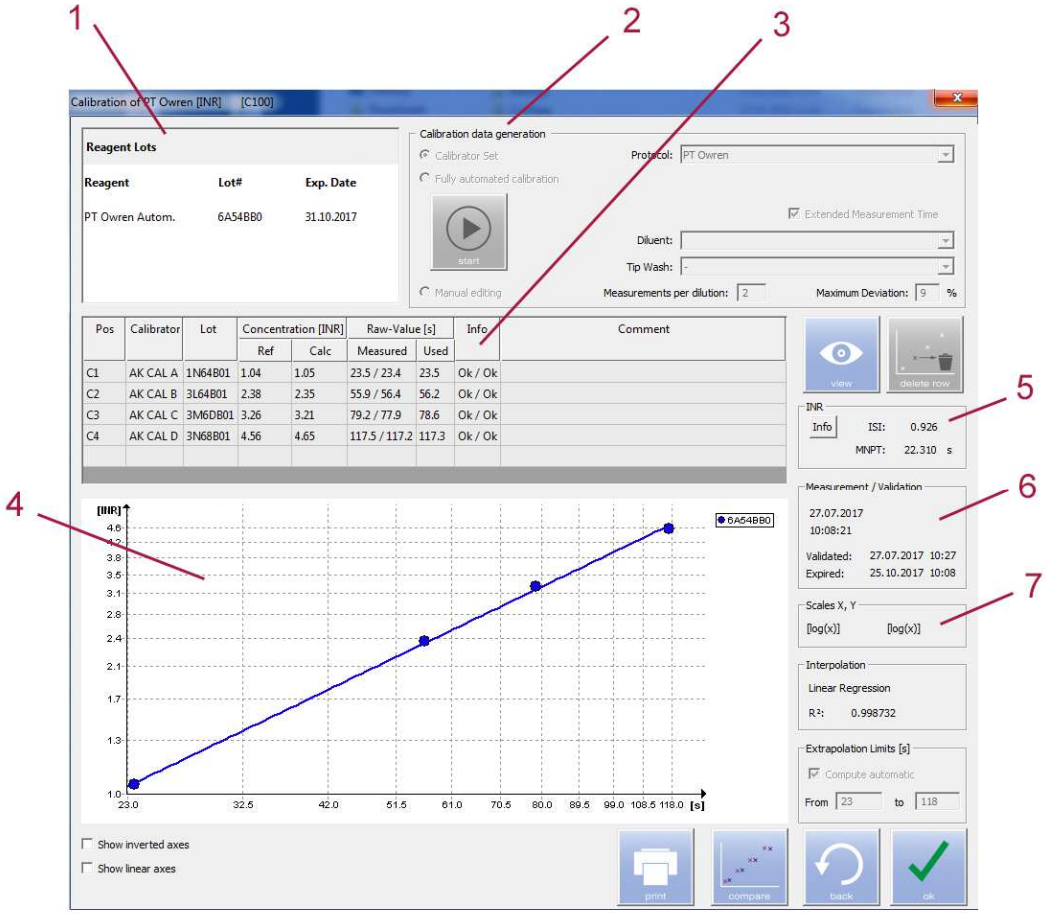
Save and close calibration details.



Close calibration details without saving.



Compare different calibration curves.
Remember: only one calibration can be stored for each lot of reagent.



(1) **'Reagent Lots'** tab, all reagents and buffers used for this calibration are noted including their lot and the expiry date.

(2) **'Calibration data generation'** tab, general calibration settings shown. These settings include whether the calibration is based on a calibrator set, an automatic dilution of a calibrator or manual entering of concentrations. For predefined tests, you could change the number of replicates and the maximum allowed deviation within the replicates.

(3) Calibration tab describes the position, lot number, dilution and concentration of the calibrators or calibrator dilutions to be used for the calibration curve.

(4) In the graph tab the calibration data points and regression line is plotted.

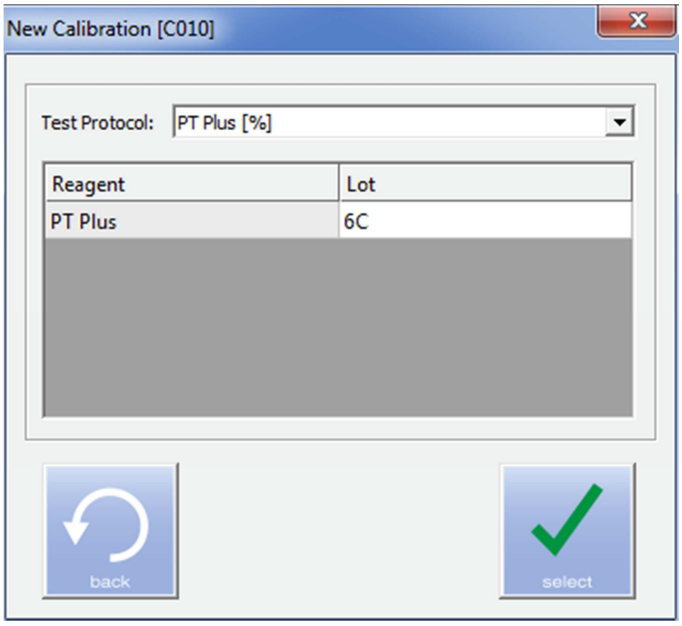
(5) **'INR'** tab ISI and MNPT of a PT reagent with an INR calibration curve (e.g. AK Calibrant) can be calculated.

(6) **'Measurement / Validation'** tab date and time of the calibration and validation is displayed. After successful confirmation of a calibration by running appropriate QC samples, a calibration has to be validated. Date and Time of validation will be logged in this tab. Each measurement of a sample with a not validated calibration curve will be flagged accordingly.

(7) **'Scales X, Y'** and **'Interpolation'** depict mathematical basis for the calibration including the regression results and extrapolation limits.

Add a new calibration

To create a new calibration, load the respective reagent, calibrator, diluent and auxiliaries and press the **'new'** button. Remember that only one calibration can be stored for each lot of reagent.



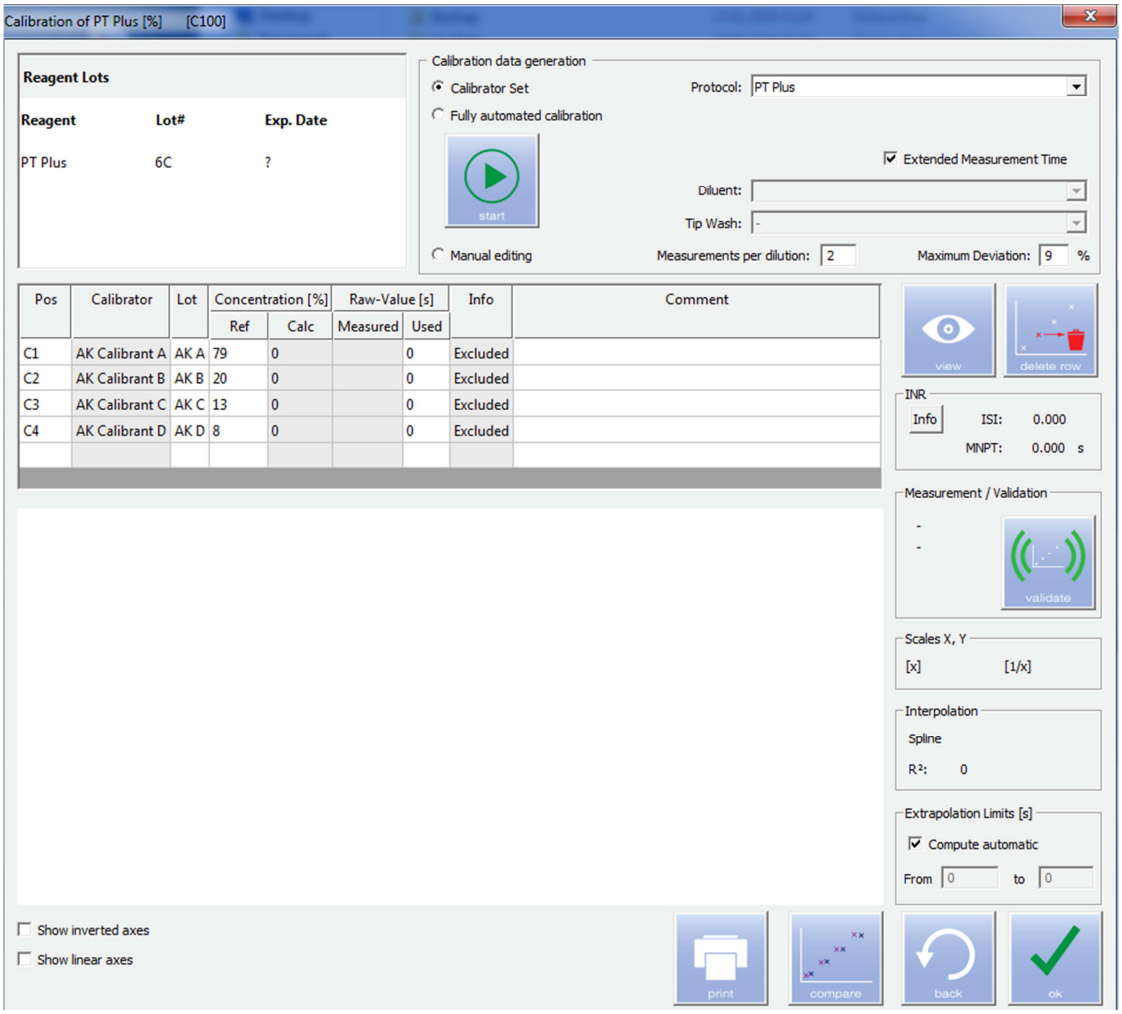
In the **'New Calibration**' window select the **'Test Protocol'** to be calibrated from the drop-down menu.

NOTE: Prior calibration, all respective reagents, calibrator and auxiliaries must be loaded.

Be sure that the correct lot number of the reagent is placed and click **'select'**.

The **'Calibration'** window opens.

Calibration using a Calibrator Set



Please ensure that the required reagent calibrator and auxiliaries are loaded at the appropriate positions and the correct lot numbers are entered into the software.

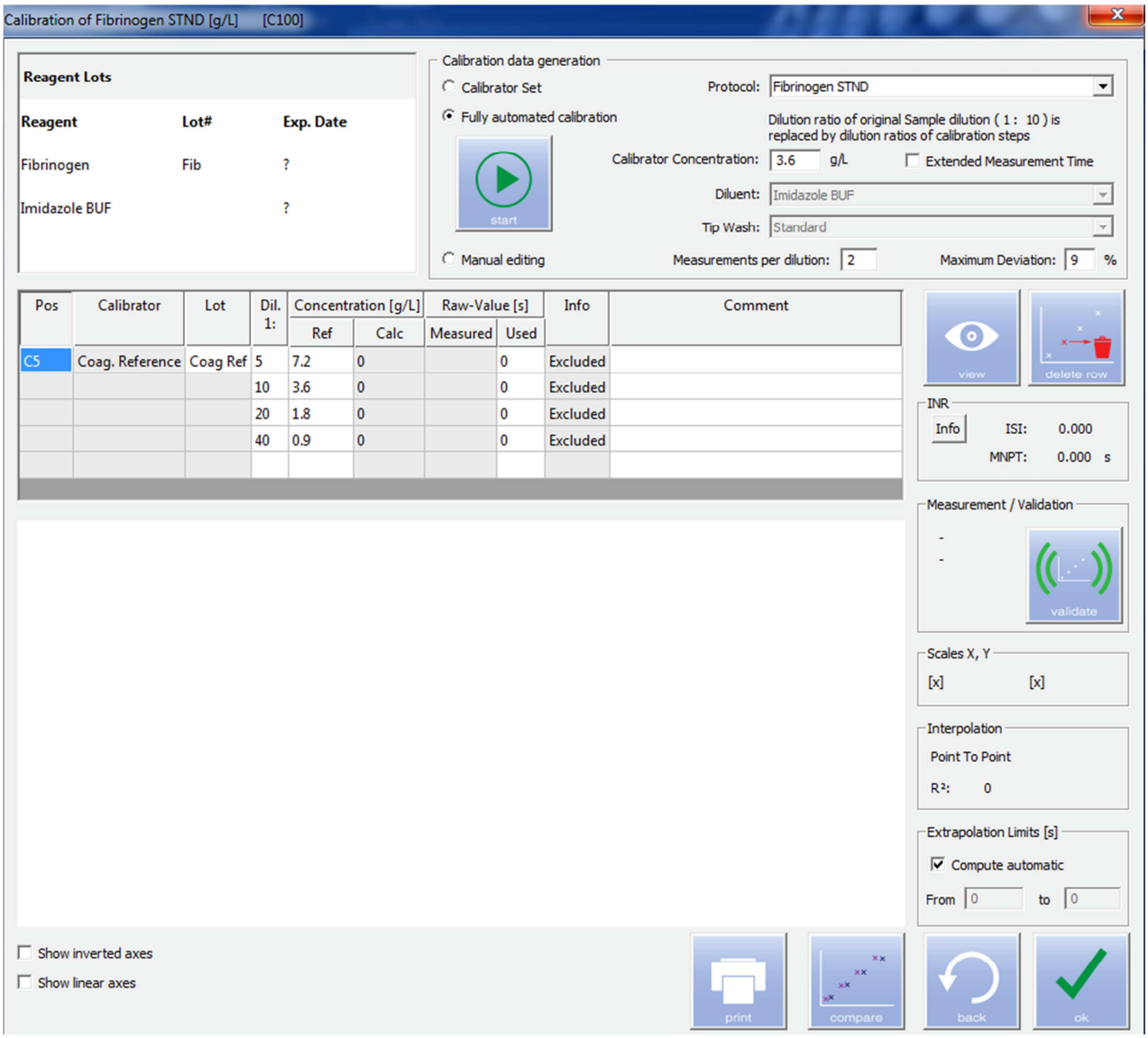
If using Technoclone reagent, the barcode provided in the package includes all relevant information (e.g. barcode, expiry date, calibrated value).

In the calibration tab, the position of each calibrator is noted according to the loading. Next to the position, Calibrator name, lot number and calibrated value is depicted.

After confirming these information, press the **'start'** button to run the calibration. During calibration, no other actions can be performed.

NOTE: If two different calibration units are used for one test (e.g. % and INR for PT reagents) the calibration is initially performed with calibration unit 1. Thereafter, CEVERON will automatically compile the calibration curve for calibration unit 2 and save it as a separate calibration.

Calibration using Fully automated calibration



Please ensure that required reagent, calibrator and auxiliaries are loaded at the appropriate positions and the correct lot number are entered into the software.

If using Technoclone reagents, the barcode provided on the reagents box includes all relevant information (e.g. barcode, expiry date, calibrated value).

In the calibration tab, the position of the calibrator including name and lot number is noted according to the loading. Below the pre-defined dilutions are listed. Additional calibrations points can be added or deleted using the delete row button.

In the **'Calibration data generation'** tab, now two additional features are present:

- A note which dilution is used originally for sample. This is for information purpose only as the calibration uses the dilutions noted next to each calibration point.

- Calibrator Concentration
  The concentration of the calibrator is entered into this field. Using this concentration, CEVERON then calculates the concentration of each dilution step and depicts them next to the dilution in the calibration tab. For Technoclone calibrators and reagent, the concentration will be inserted automatically.

After confirming the dilution and lot information, press the **'start'** button to begin measurement. During calibration, no other actions can be performed.

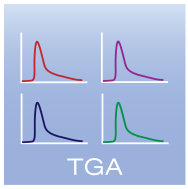
If there is an error message in the comment field for one of the calibration points, the calibration has to be repeated.

Upon clicking the start button again, following options can be selected:

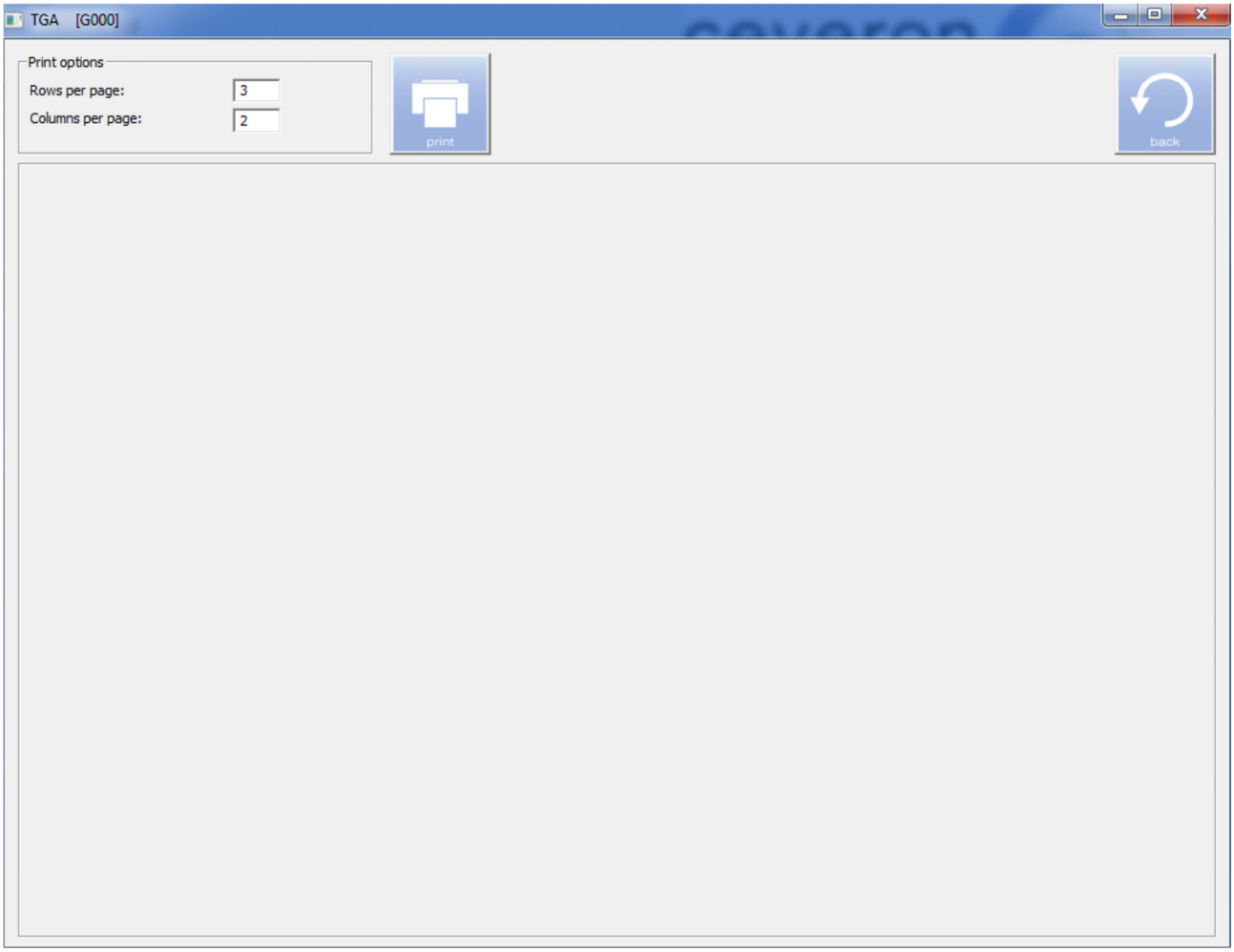
- Keep measured values
- Repeat measurement of excluded values (repeat calibration of measurements resulted in an error message)
- Repeat all measurements (repeat the whole calibration)

Calibration curves can also be added manually by selecting manual editing. For Technoclone defined test this is not possible. However, measured calibration curves can be modified. After alteration of a measured result, the data point is flagged with (M) for manual editing. Validated calibration curves cannot be edited.

4.2.5 TGA



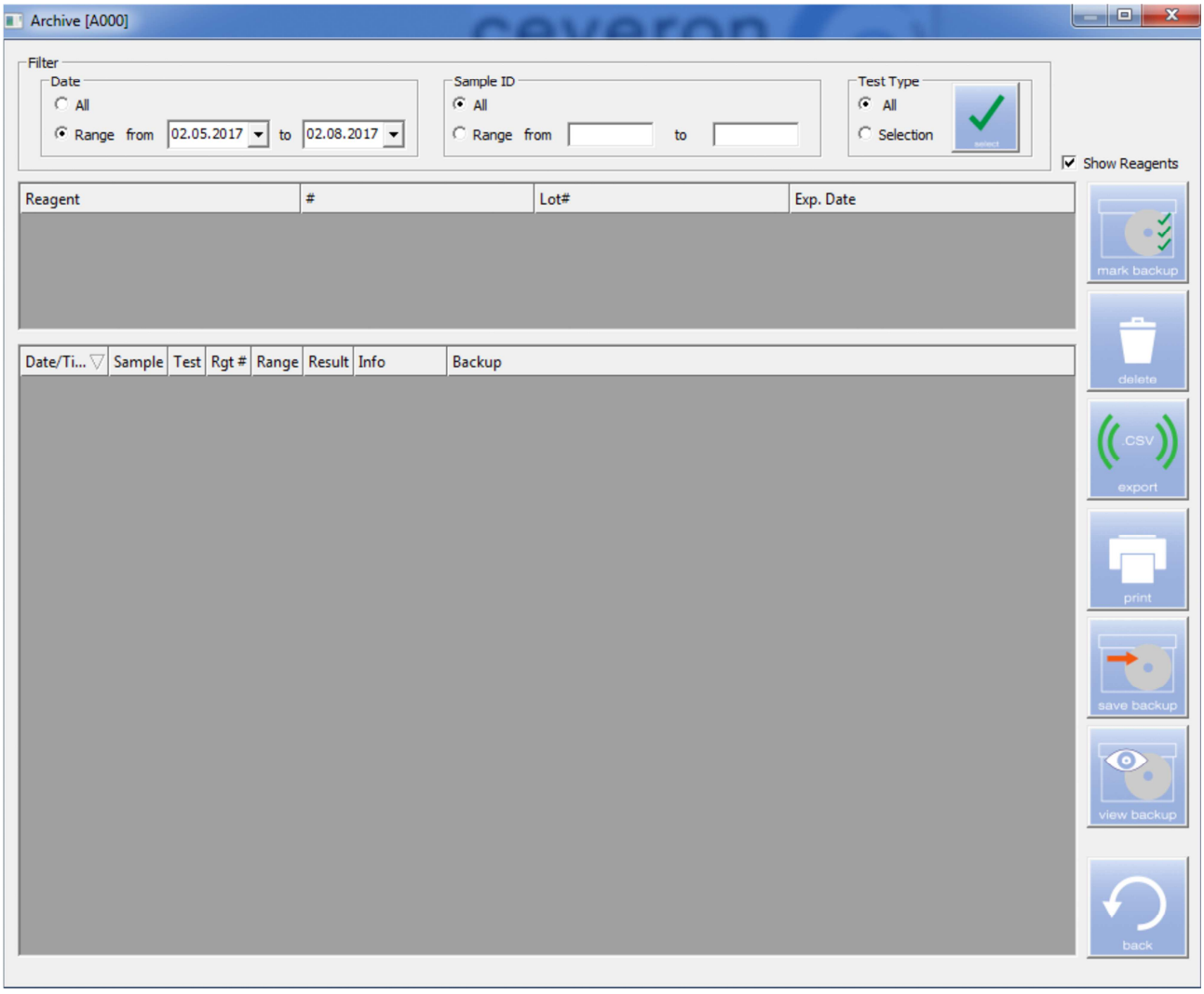
By clicking the **“TGA”** icon, the window TGA will be opened.



The TGA monitor depicts the thrombin generation of each TGA reaction run in real time. This TGA monitor is for information purpose only!

4.2.6 Archive

By clicking the **"Archive"** icon, the archive of the sample results opens.



In the archive, all sample measurements including raw data curves and reagent information are stored. In addition, data can be exported or selected for backup and already created backups can be viewed.

Description of buttons

Select all entries which already have been saved in a backup.

Delete selected entries.

Export all entries displayed (.csv file).

Entries can be limited by selecting the appropriate filters (date, sample ID, test type).

Print all displayed entries.

Saves a backup of all data.

Load and view a backup the backup will be opened in a separate window.

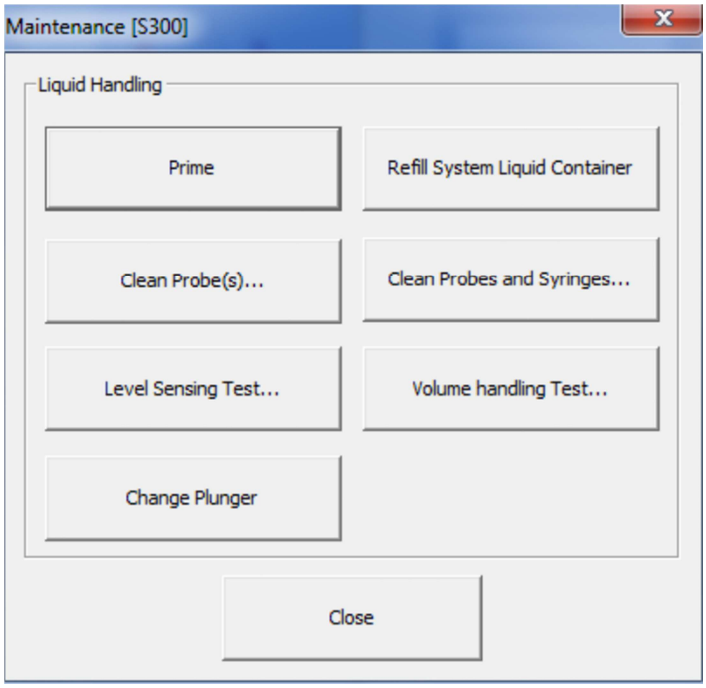
To facilitate the search within the archive sample database following filters can be selected

- Date: Select a period between two dates.
- Sample ID: Select a range between two sample ID using mathematical alpha numeric logic.
- Test Type: Select the results from which tests will be listed.

Upon double click on a sample result a new window opens with measurement details including the reaction curve.

4.2.7 Maintenance

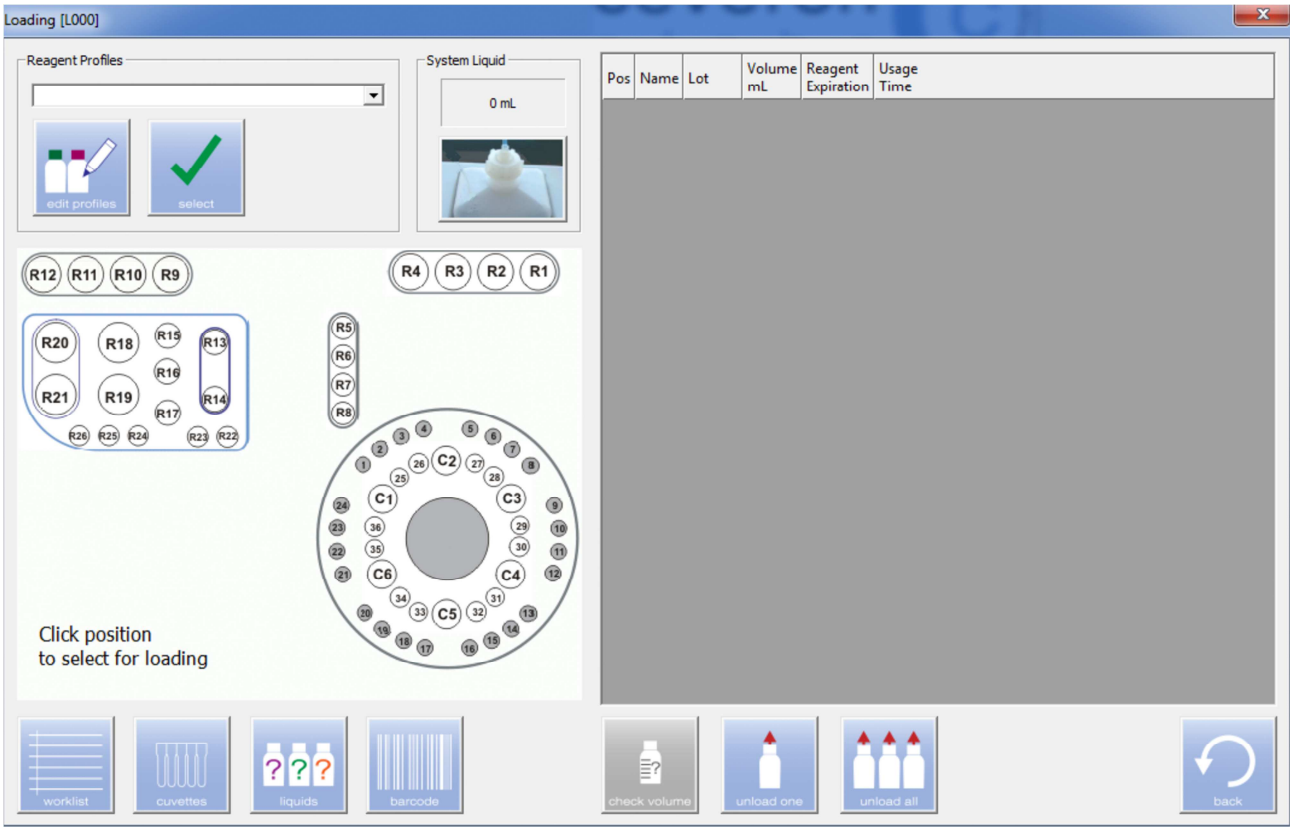
By clicking the **“Maintenance”**” icon, the maintenance window will be opened.



For detailed instructions refer to chapter **“5. Maintenance”**

4.2.8 Loading

By clicking the icon **“Loading”**, the window to load all liquids opens**.** If the Ceveron 100 series is not analyzing samples and shows standby mode, the cover can be opened.



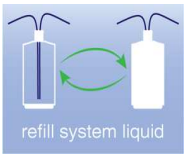
For your convenience the functions **“worklist”**, **“cuvettes”, liquids”** and **“barcode”** are also available via direct links. For further information please refer to the respective chapters.

Description of buttons

Reagent profiles can be created, edited and deleted.

Reagent profiles define reagent combinations to facilitate one click loading of several reagents.

Select the chosen reagent profile to be loaded.



Refill system liquid.

Perform fully automatic volume determination of loaded reagents.

Unload a selected reagent, calibrator or control.

Unload all reagents, calibrator and controls.

Opens the liquids table, summarizing the required reagents and their amounts for test selected in the work list.

Loading reagents individually

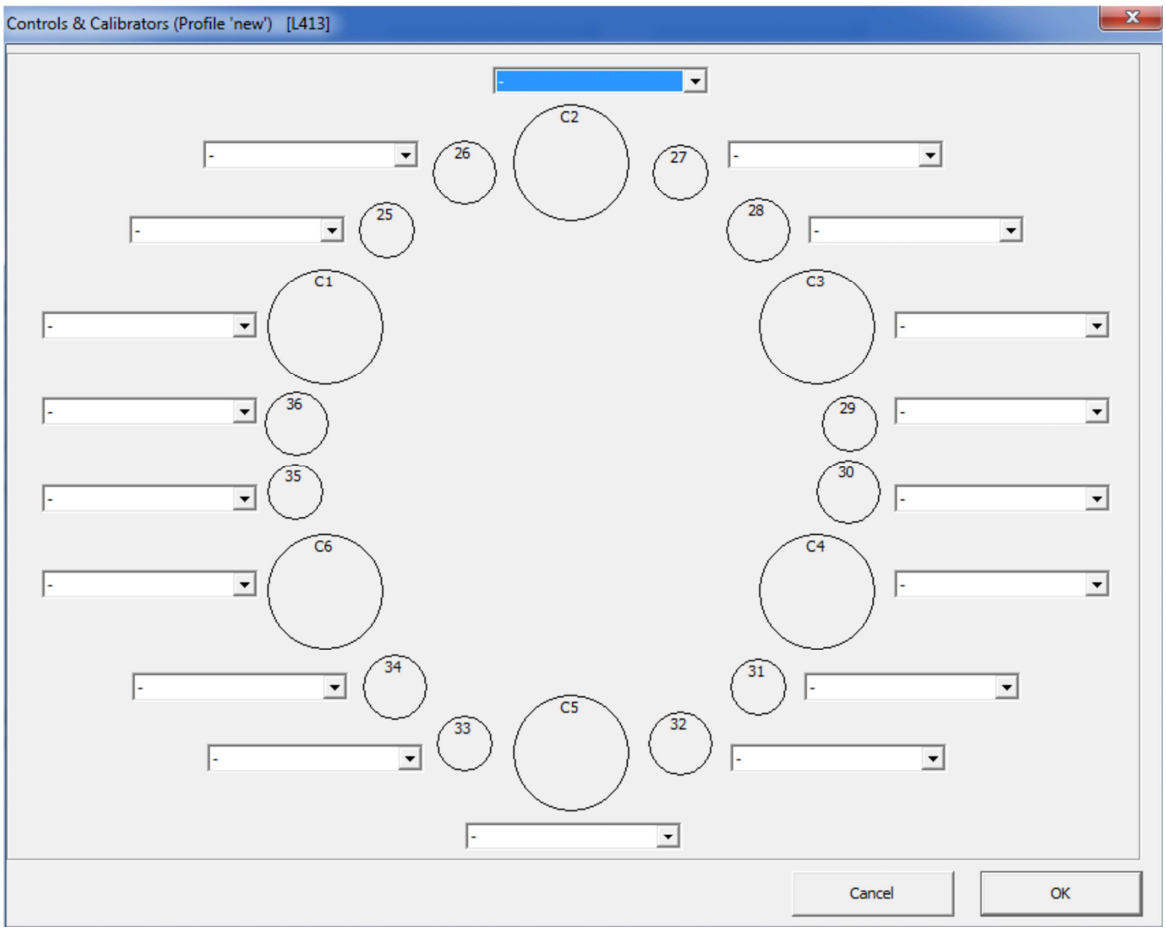
Upon opening of the shield of the analyzer, the reagent barcode reader is automatically switched on.

To load a reagent, first click on the loading area.

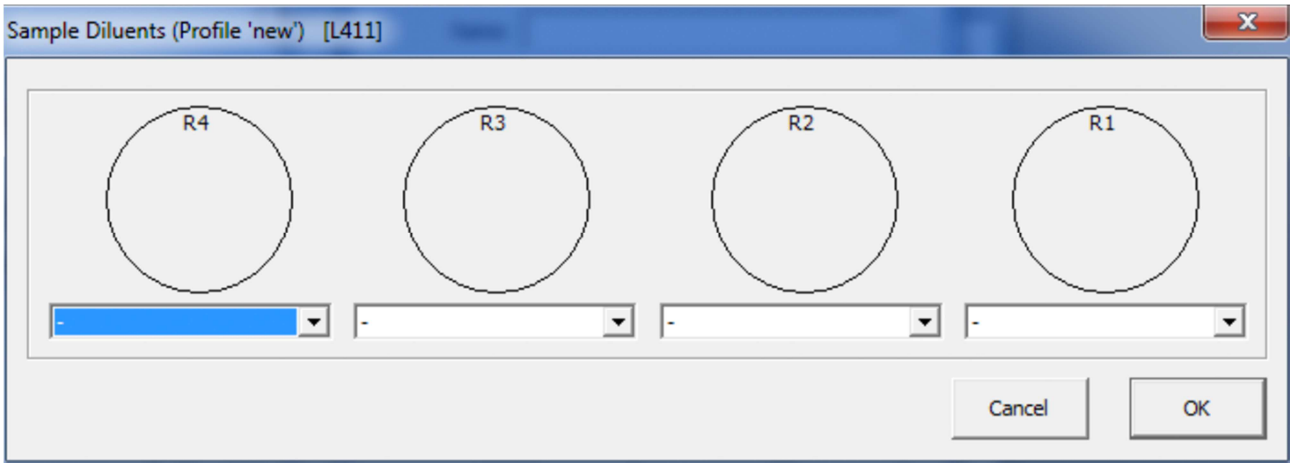
- Sample rotor (e.g. calibrator material, QC material or deficient plasma)
- Reagent position R1 – R4 (e.g. dilution buffers)
- Reagent position R5 – R8 (e.g. TGA reagents)
- Reagent position R9 – R12 (e.g. wash buffer or calcium chloride)
- Reagent position R13 – R26 for all cooled reagents

Position R13, R14 and R20, R21 are stirred positions. If the reagent has to be stirred, do not forget to add a magnetic stir bar into the reagent vial.

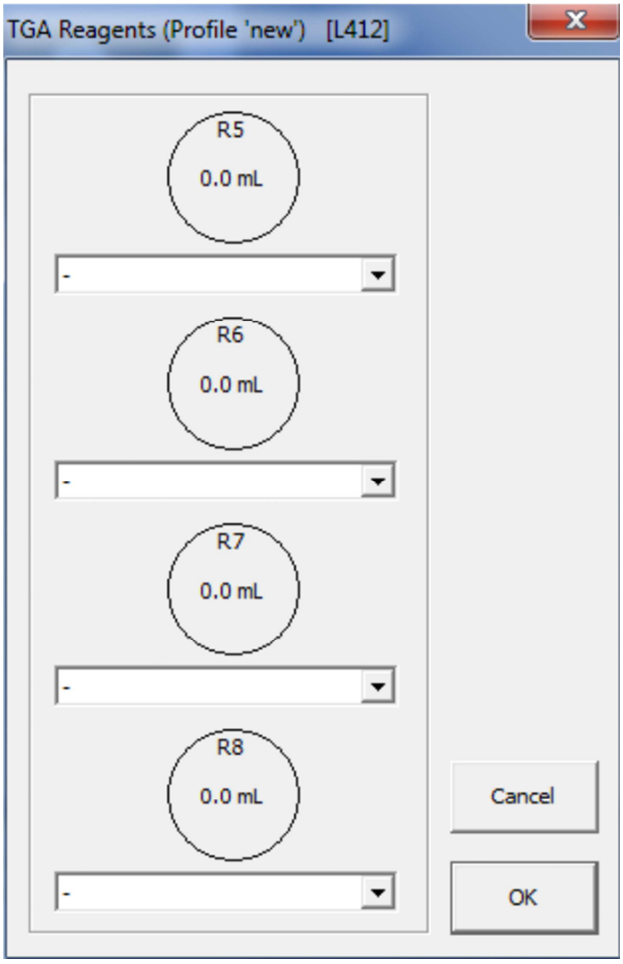
Sample Rotor



Sample diluents

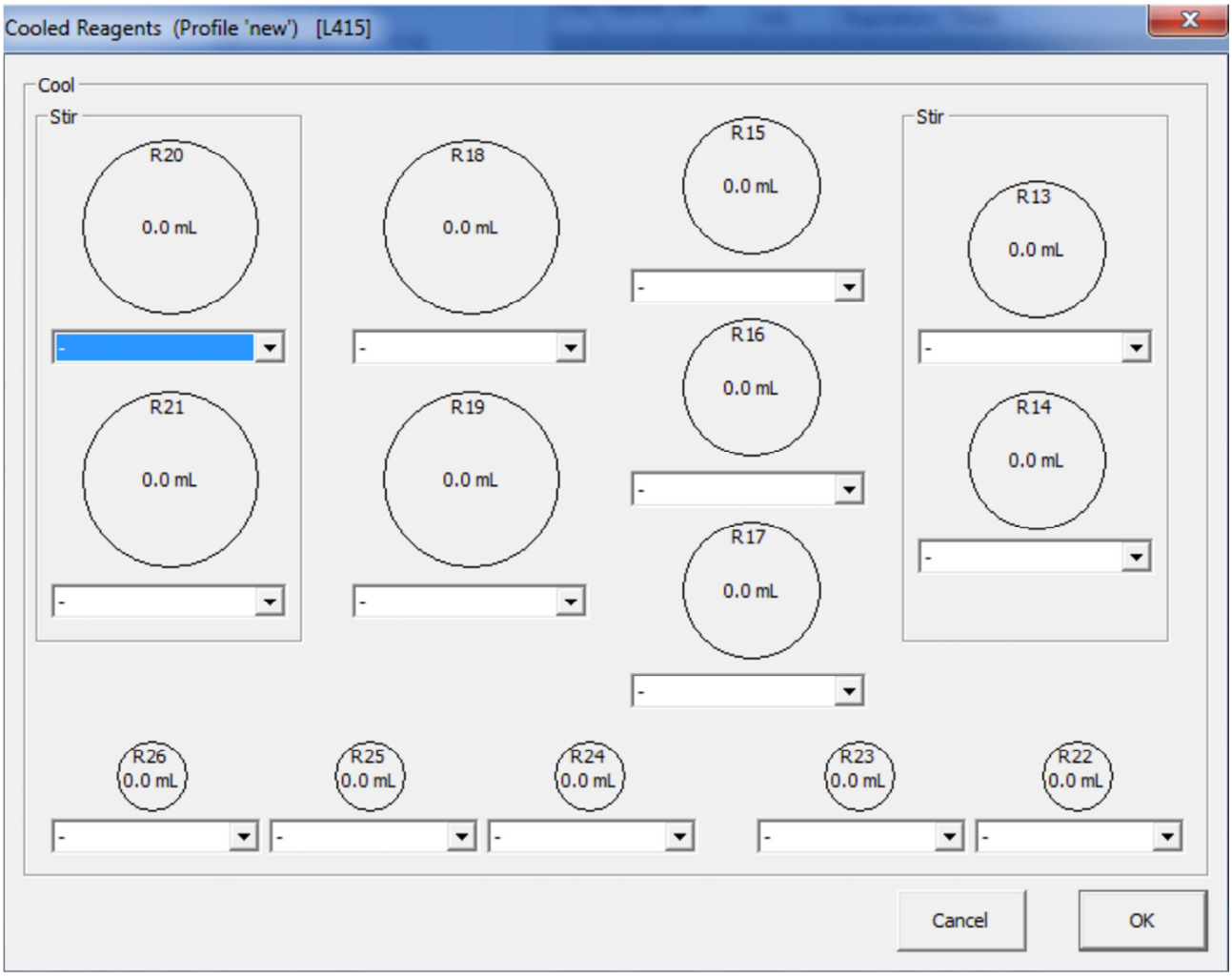


TGA Reagents



Reagent Diluents

Cooled Reagents



Select a position where the material will be placed and select the reagent from the dropdown list. If the reagent is not in the list, the reagent cannot be loaded at that position. Please check whether cooling or stirring is required, or if the reagent needs to be accessible to the respective other probe.

After completing the loading list, use the barcode on the reagent to finish loading. Upon scanning the lot number and expiry date will be added to the loading list. For your convenience, the position where the reagent should be placed will be highlighted by a blinking blue circle.

If no barcode is available, the lot number and expiry date need to be added manually.

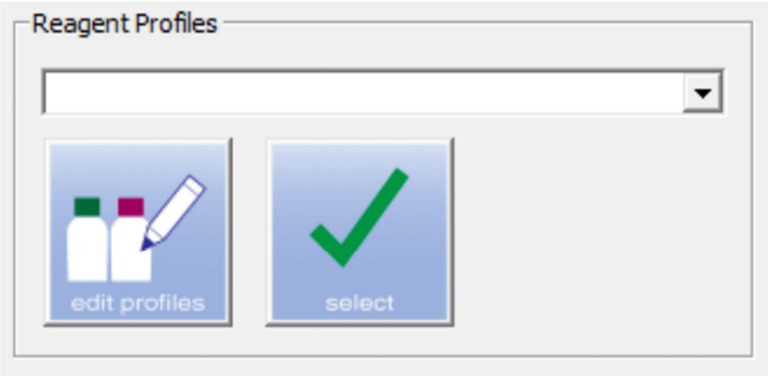
If a barcode is available, but not yet stored in the instrument (e.g. new reagent lot), lot information need to be added using the **'barcode'** button. Details for this are described in the respective section.

Reagent Profiles

Reagent profiles can be set for groups of reagents which are typically loaded at the same time. Select the Reagent Profile from the drop-down list a confirm using the **'select'** button. The reagents defined in this Reagent Profile will automatically be added to the loading list.

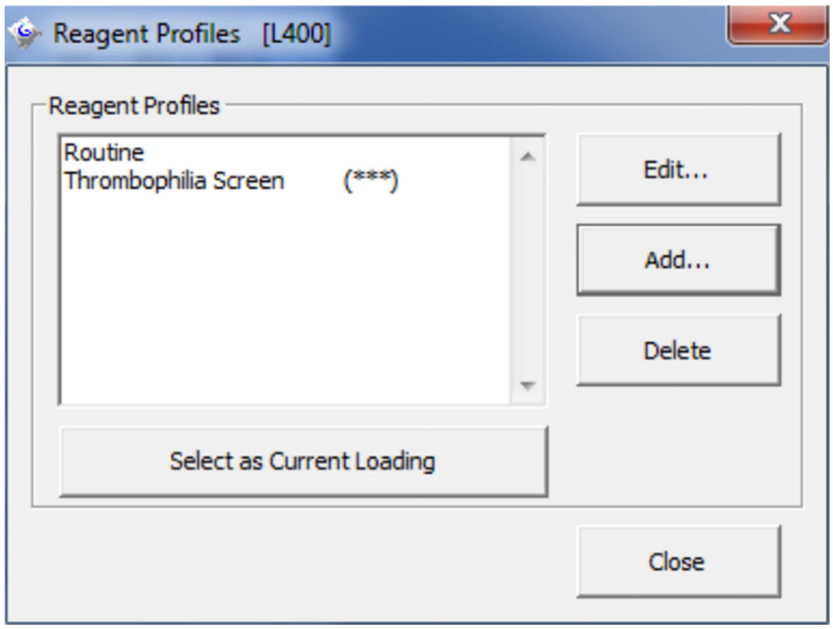
After completing the loading list, use the barcode on the reagent to finish loading. Upon scanning the lot number and expiry date will be added to the loading list. For your convenience, the position where the reagent should be placed will be highlighted by a blinking blue circle.

Reagent Profiles

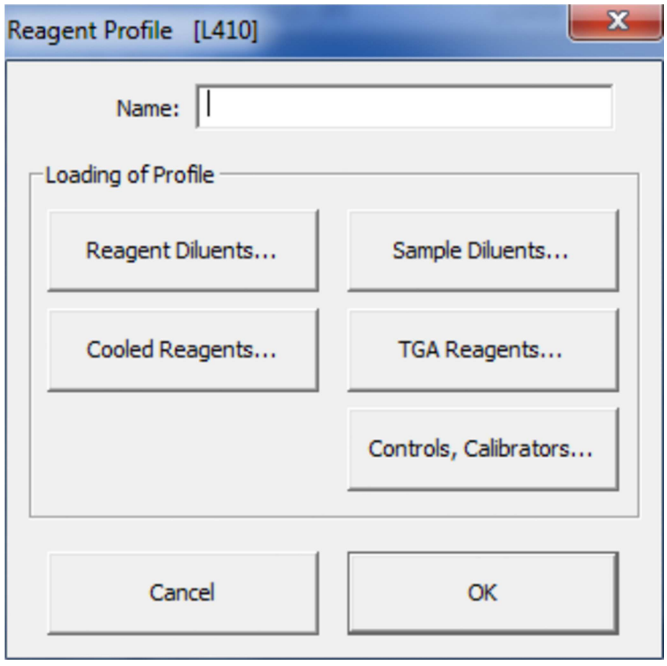


Click **"edit profiles"** to add, view or modify reagent profiles.

In a new window the list of profiles will be depicted.



To add a new profile, press the **"Add"** button.



Similar to the loading of individual reagents, select an area where reagents should be positioned. Select the position and then the reagent from the drop-down list. After having selected all required reagents and assigned positions, name the reagent profile and save by pressing the **"OK"** button.

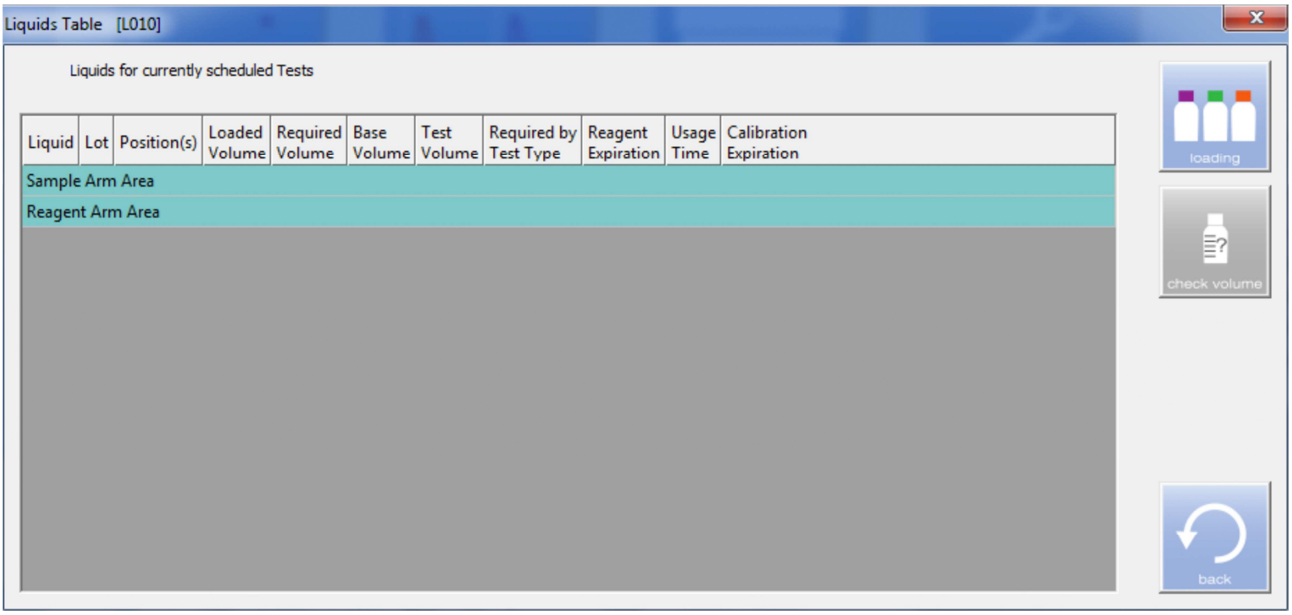
Unloading Reagents

Unloading can be performed individually by selecting the reagent to unload and clicking the **"unload one"** button or by clicking the **"unload all"** button to unload all loaded reagents, including calibrator, controls and auxiliaries.

Required Liquids

By clicking 

the required liquids for running the ordered tests are listed.



When tests are already selected in the worklist, the liquid table summarizes the required reagents information including:

- Name and Lot of reagent
- Loaded and Required volume
- Reagent expiration
- Usage time remaining
- Calibration status (Expiration, missing, not validated)

For your convenience, the functions **"check volume"** is also available via a direct link. For further information please refer to the respective chapter.

Check volume

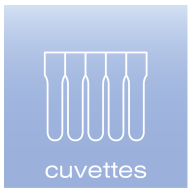
After all reagents are loaded and the lot numbers are scanned or manually entered, close the shield and press the **"check volume"** button. CEVERON will automatically determine the volume of the loaded reagents.

Refill System Liquid

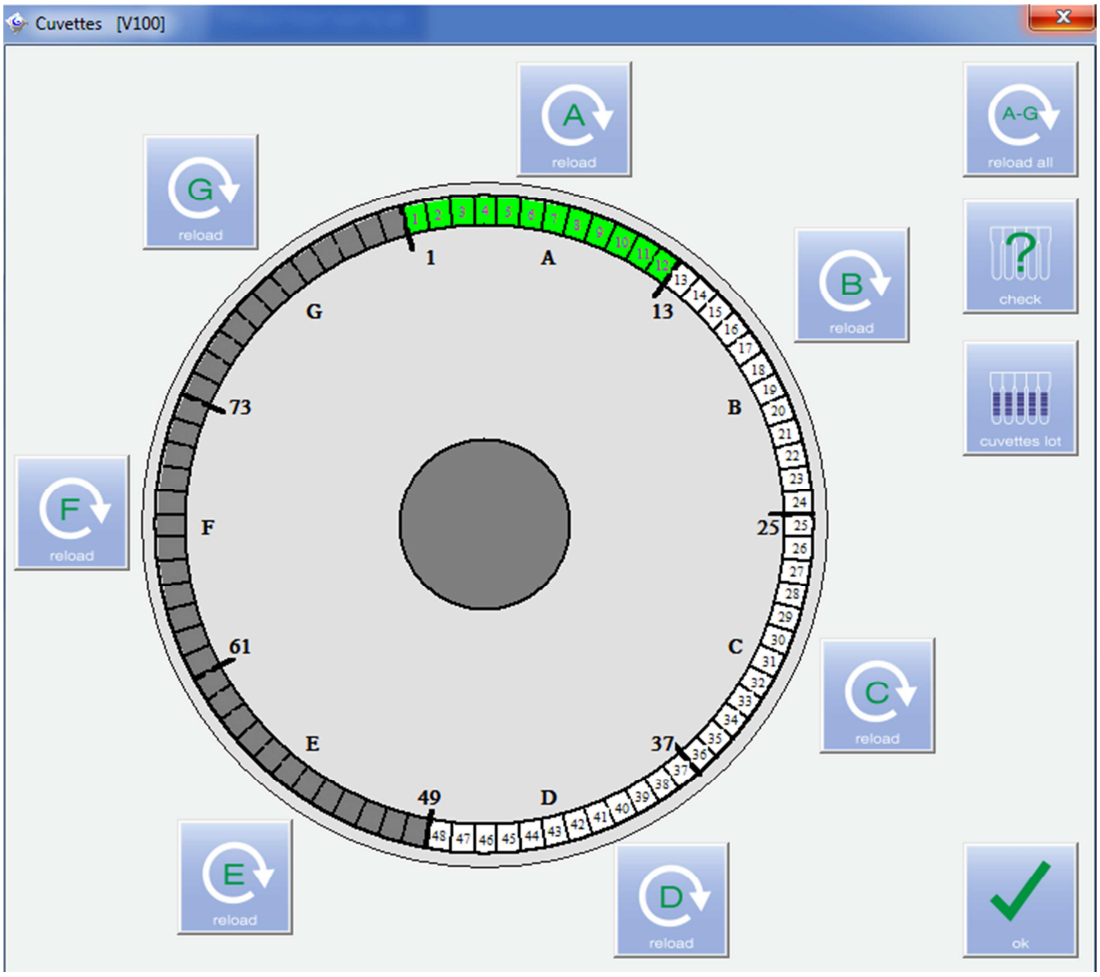
Upon replacing the empty system liquid container with a fresh full 750ml CEVERON System Solution container, press the refill system liquid button.

Only use original CEVERON System Solution supplied by Technoclone. Using other liquids, may lead to carry over between samples or reagents and will damage the liquid handling system of the instrument!

4.2.9 Cuvettes



By clicking the **“Cuvettes”** icon, the cuvette handling window opens.



Color code for cuvettes:

- ☐ empty
- ■ used with measurement (OK)
- ■ used without measurement (dilution, error)
- ■ currently in use
- ■ missing (only after ‘check’ is performed)

Description of buttons

Reload all cuvette segments.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment A.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment B.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment C.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment D.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment E.

ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment F.

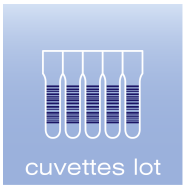
ATTENTION: remember to replace the used segment with a fresh one!

Reload cuvette segment G.

ATTENTION: remember to replace the used segment with a fresh one!

Check for the presence of cuvette segments.

ATTENTION: CEVERON will not determine whether cuvettes are used or not!

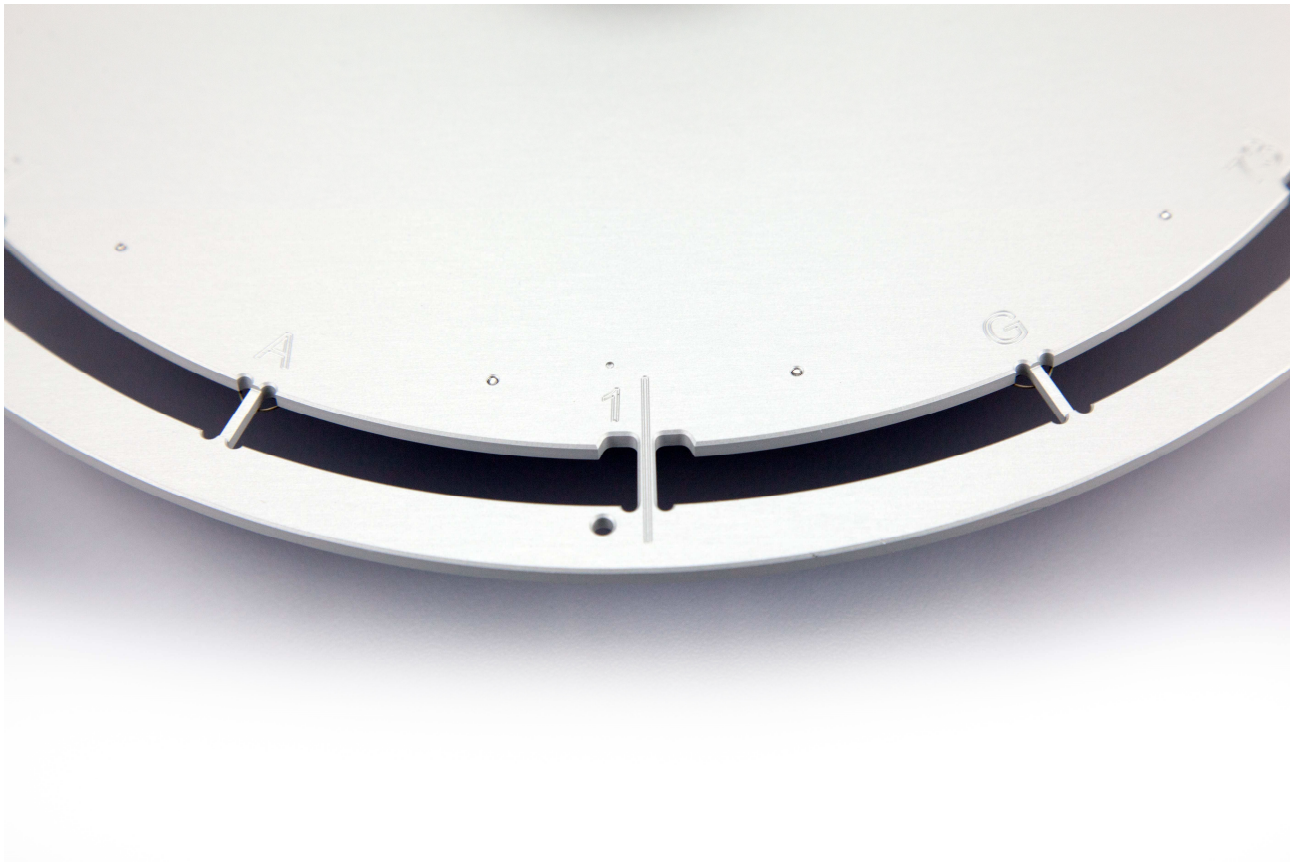


Check and load a new lot of cuvettes into the system.

Close the cuvette menu.

Loading new cuvette segments

Insert new cuvette segments into the CEVERON cuvette rotor. Press the button corresponding to the segment location (A-G) which has been reloaded. The segment location is engraved into the cuvette rotor.



If all cuvette segments have been replaced with fresh ones, simply press the **'reload all'** button.

Cuvettes cannot be re-used and need to be treated as potentially infectious and handled with appropriate care. In compliance with the biosafety regulations in force they must be disposed as hospital waste.

ATTENTION: To avoid possible erroneous results, please be sure not to touch the cuvettes in the under area of the segment, where the measurement is taking place, when loading them on your CEVERON instrument!

Correct

Wrong

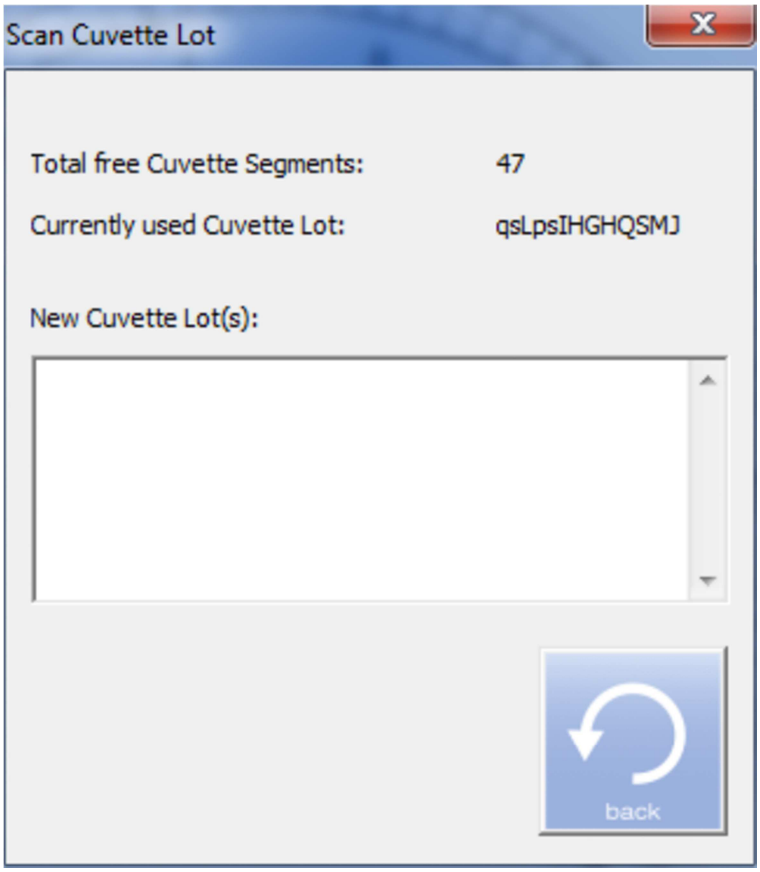
Leaving out cuvette segments

If not all cuvette segments are needed, load the required amount and click the **'check'** button. CEVERON will determine where no cuvette segments are present and will ignore them for further testing. Empty segments are colored dark grey.

ATTENTION: Ceveron 100 series instrument will not determine whether cuvettes are used or not!

Cuvette lot

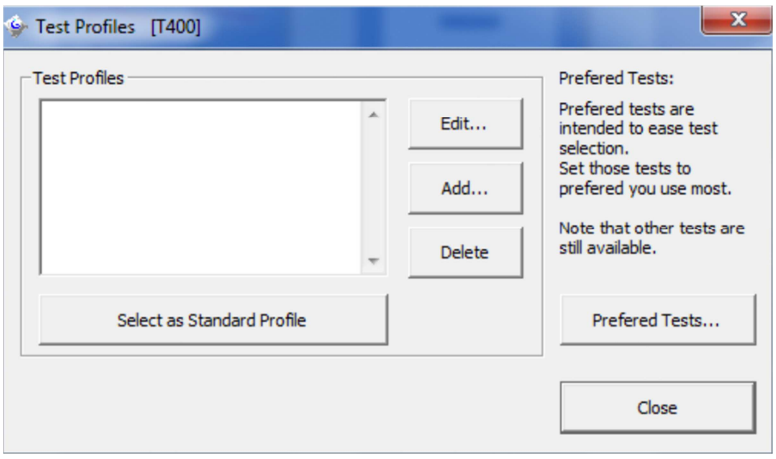
In order to scan a new lot of cuvettes, click the **'cuvette lot'** button to open the cuvette manager.



This will activate the reagent barcode scanner. Scan the barcode present on the outer box of the cuvettes to load the new lot into the CEVERON software. In addition, the cuvette manager, will also keep track of the amount of unused cuvette segments.

4.2.10 Test profiles

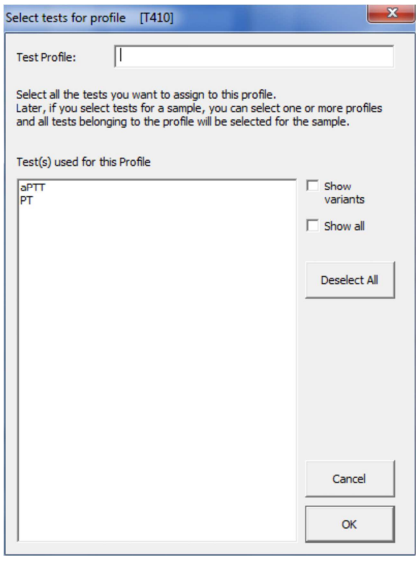
By clicking the icon **“Test Profiles”,** the window test profiles opens**.**



Test profiles are groups of tests, which are typically tested together in one run. The **‘Preferred Test’** option is intended to reduce the list of test during the test selection process, so only test which are commonly run appear. Remember, that all test are still available and can be viewed using the **‘show all’** option during test selection.

Adding a new Test Profile

Add a test profile by clicking the **“Add”** button. In the **‘Select Tests for profile**’ window enter a name for the profile and select which test should be included.

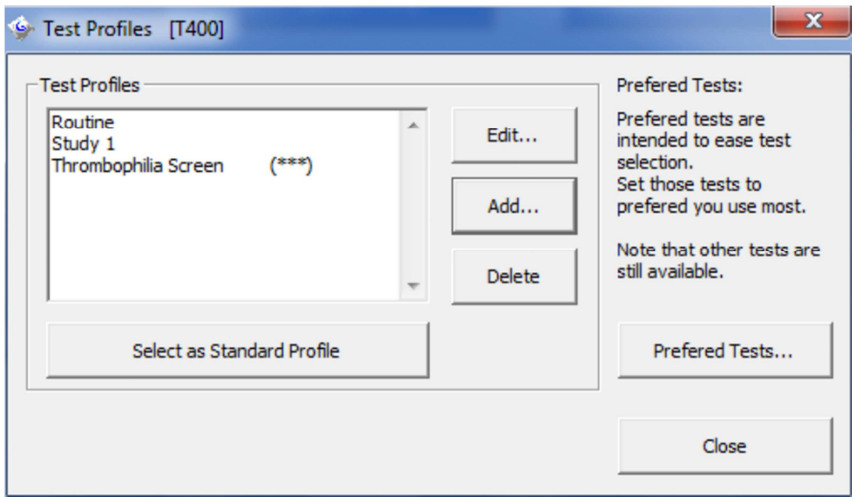


Confirm your selection by pressing the **‘OK’** button.

Edit and Delete a Test Profile

In order to edit an existing Test profile, select the profile and press the **'Edit'** button. To delete a test profile, select the profile and press the **'Delete'** button.

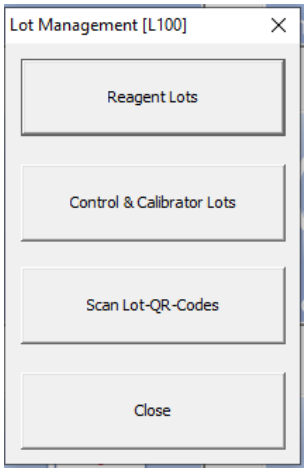
Use of Standard Profile



Standard profile is the option to auto assign a test profile to either all barcoded samples or manually entered samples. Activate or inactivate this option in the **'Test and Calibration'** tab in the **'settings'** menu. The standard profile is indicated with (***) in the test profile list. In order to change the standard profile, select a test profile and press the **'Select as Standard Profile'** button.

4.2.11 Barcode

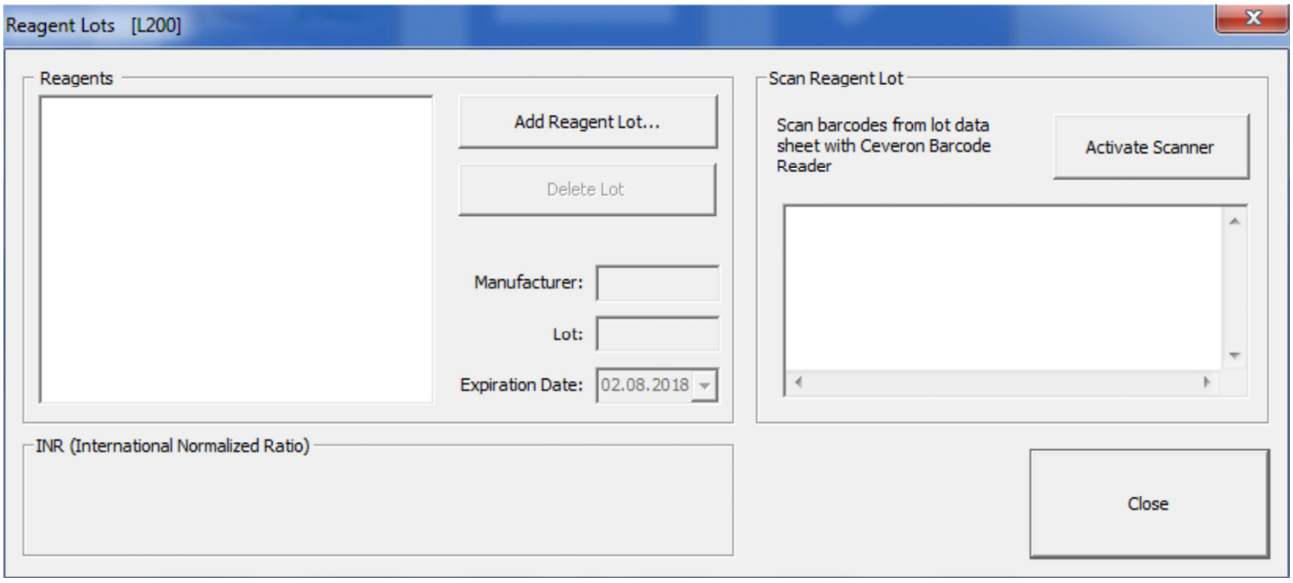
By clicking "**barcode**" icon, the window lot management will be opened**.**



Using the **‘Lot Management’**, new lot of reagent, calibrators and controls are entered into the CEVERON software. Cuvette lots are added using the cuvette manager from the **‘Cuvette’** menu.

Reagent lots

To add or delete a reagent lot click the **“Reagent Lots”** button and the following window opens:



Adding a reagent lot using lot data sheet

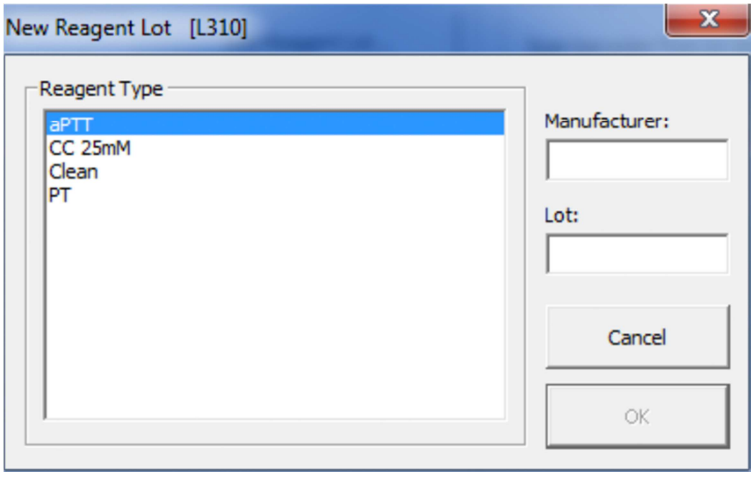
For your convenience, Technoclone reagents packages include a lot data sheet providing barcodes to transfer lot specific information into the CEVERON software.

Simply activate the reagent barcode scanner of the instrument using the **‘Activate Scanner’** button. Scan all the barcodes of the respective lot data sheet.

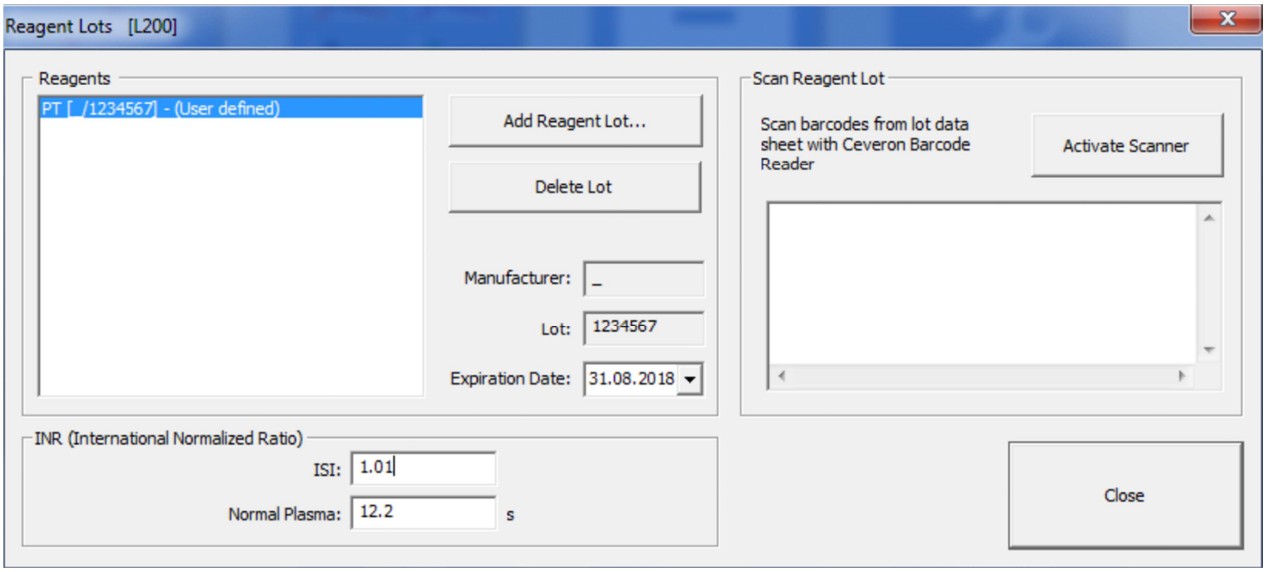
The software will confirm the successful scanning of the lot data sheet. Click the **‘Close’** button to close the dialogue and switch off the barcode reader.

Manually add a reagent lot

If you want to add lot specific information of non-barcoded reagents, click the **“Add Reagent Lot”** button.



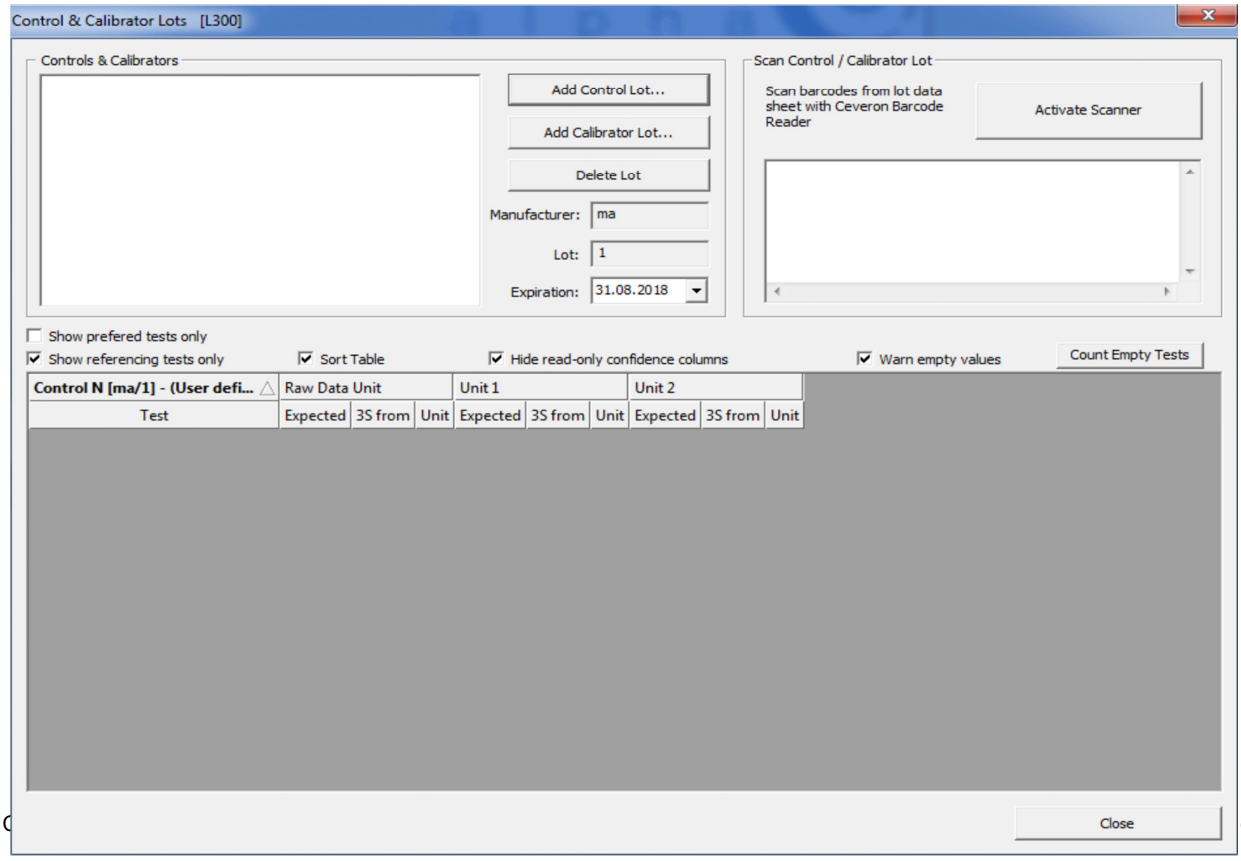
Select the reagent you want to add, insert the name or abbreviation of the manufacturer as well as the lot number. Confirm the inserted data by pressing the **'OK'** button.



The expiration date of the reagent needs to be set in the **'Expiration Date'** field. For PT reagents, the ISI and the MNPT need to be added for INR calculation. The instrument specific ISI value should be determined and added into the **'ISI'** field. The instrument specific MNPT value should be determined and added into the **'Normal Plasma'** field. Confirm by adding another reagent (**'Add Reagent Lot'**) or closing the window using the **'Close'** button.

Control and Calibrator Lots

To add or delete a Control and Calibrator lot click the **"Control and Calibrator Lots"** button.

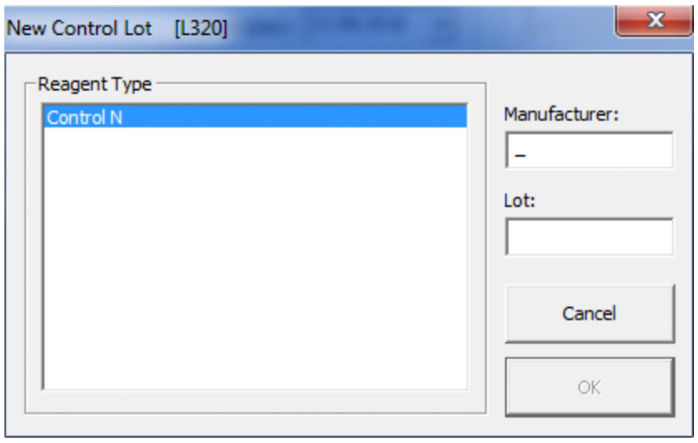


Adding a Control and Calibrator lot using lot data sheet

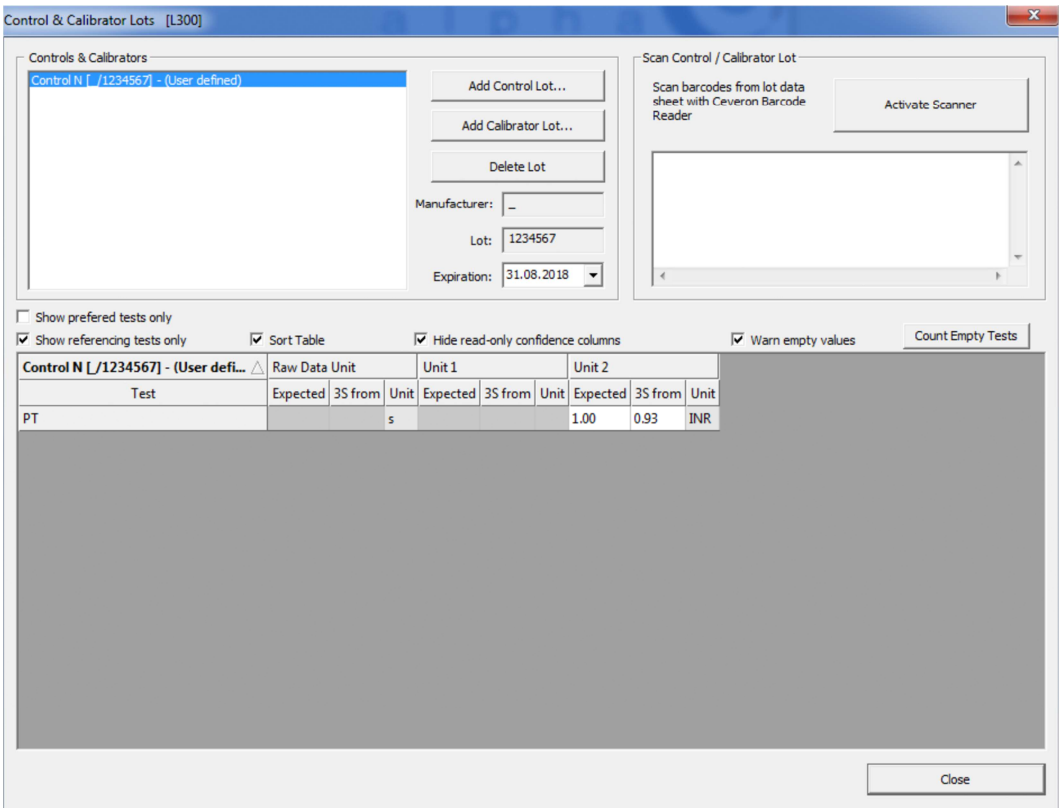
For your convenience, Technoclone calibrator and control packages include a lot datasheet providing barcodes to transfer lot specific information into the CEVERON software. Simply activate the reagent barcode scanner of the instrument using the **"activate scanner"** button. Then scan all the barcodes of the respective lot data sheet. The software will confirm the successful scanning, press the **"close"** button to close the dialogue and switch off the barcode reader.

Manually add a control lot

If you want to add lot specific information of a material without a barcode press the **'add control lot'** button.



Select the control you want to add, insert the name or abbreviation of the manufacturer as well as the lot number. Confirm the inserted data by pressing the **"OK"** button.



The expiration date of the control need to be entered in the **'Expiration'** field.

In the lower tab a table of test is listed. Using the filter options, the list can be sorted.

- Show preferred test only: Only test from the preferred test selection are listed
- Show referencing tests only: Only test referring to this control in the test definition are listed
- Sort Table: Sort table by clicking to the header row ascending or descending

Enter the expected value for each parameter in the **'Expected'** field depending on the unit.

Raw units (e.g. seconds)

- Unit 1 (as defined in the test definition, e.g. %)
- Unit 2 (as defined in the test definition, e.g. INR)

Enter the lower acceptance value for each parameter in the **'3S from'** field depending on the Unit.

- Raw units (e.g. seconds)
- Unit 1 (as defined in the test definition, e.g. %)
- Unit 2 (as defined in the test definition, e.g. INR)

Confirm by adding another reagent (**'Add Control Lot'**) or closing the window using the **'Close'** button.

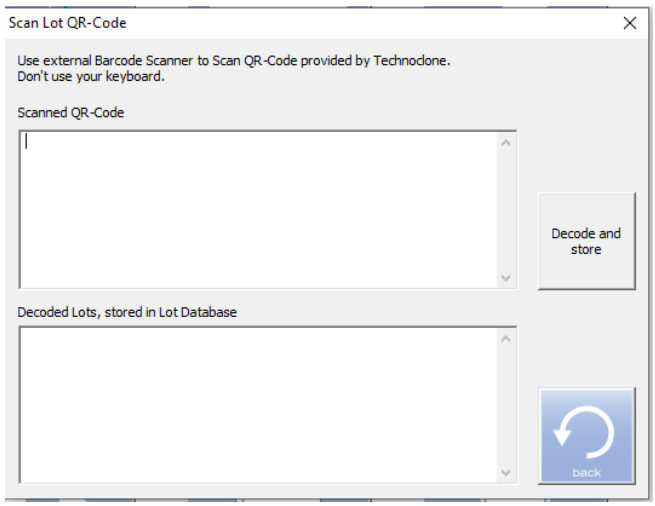
For further information on test definition and referencing tests, please refer to the **'Definitions'** menu.

Manually add a calibrator lot

If you want to add lot specific information of a calibrator without a barcode click the **"add calibrator lot"** button. Proceed as described in **"Manually add a control lot"**. Here you just have to enter the calibrator value (target value). Entering acceptance values for calibrator material is not possible.

Scan Lot-QR-Codes

After scanning the reagent Lot QR Code using an external Barcode Scanner all required data such as lot number and expiration date will be automatically decoded and stored on your Ceveron 100 series instrument.

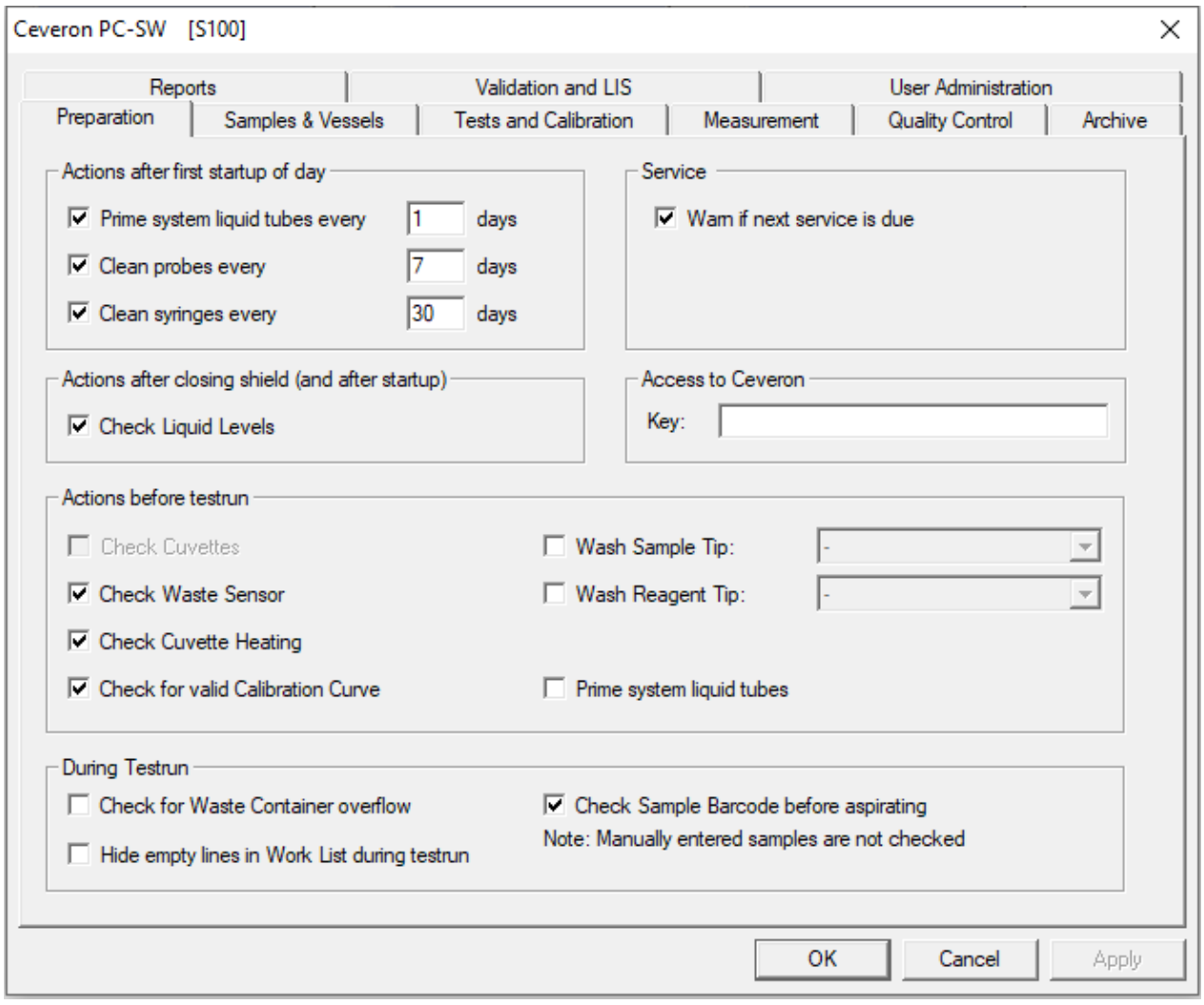


4.2.12 Settings

By clicking the **"Settings"** icon, the Ceveron PC –SW window opens.

In the **'settings'** menu, CEVERON software can be adjusted to local requirements and preferences. Use the tabs to switch between the respective chapters.

4.2.12.1 Preparation



The standard settings for the Preparation tab are depicted above.

Actions after first startup of the day

- Activating the selection next to the maintenance tasks will prompt the user to perform the respective task. Upon confirmation, CEVERON will start the task automatically. For more details on **'Maintenance'** please consult chapter 5.

Service

- Upon activation of the selection, CEVERON software will automatically remind the user when the next service is due.

Actions after closing shield

- Upon activation of the selection, CEVERON will automatically determine the volume of loaded reagents, calibrator and controls.

Access to Ceveron

- This unique code secures the connection between the software and the CEVERON 100 series instrument.

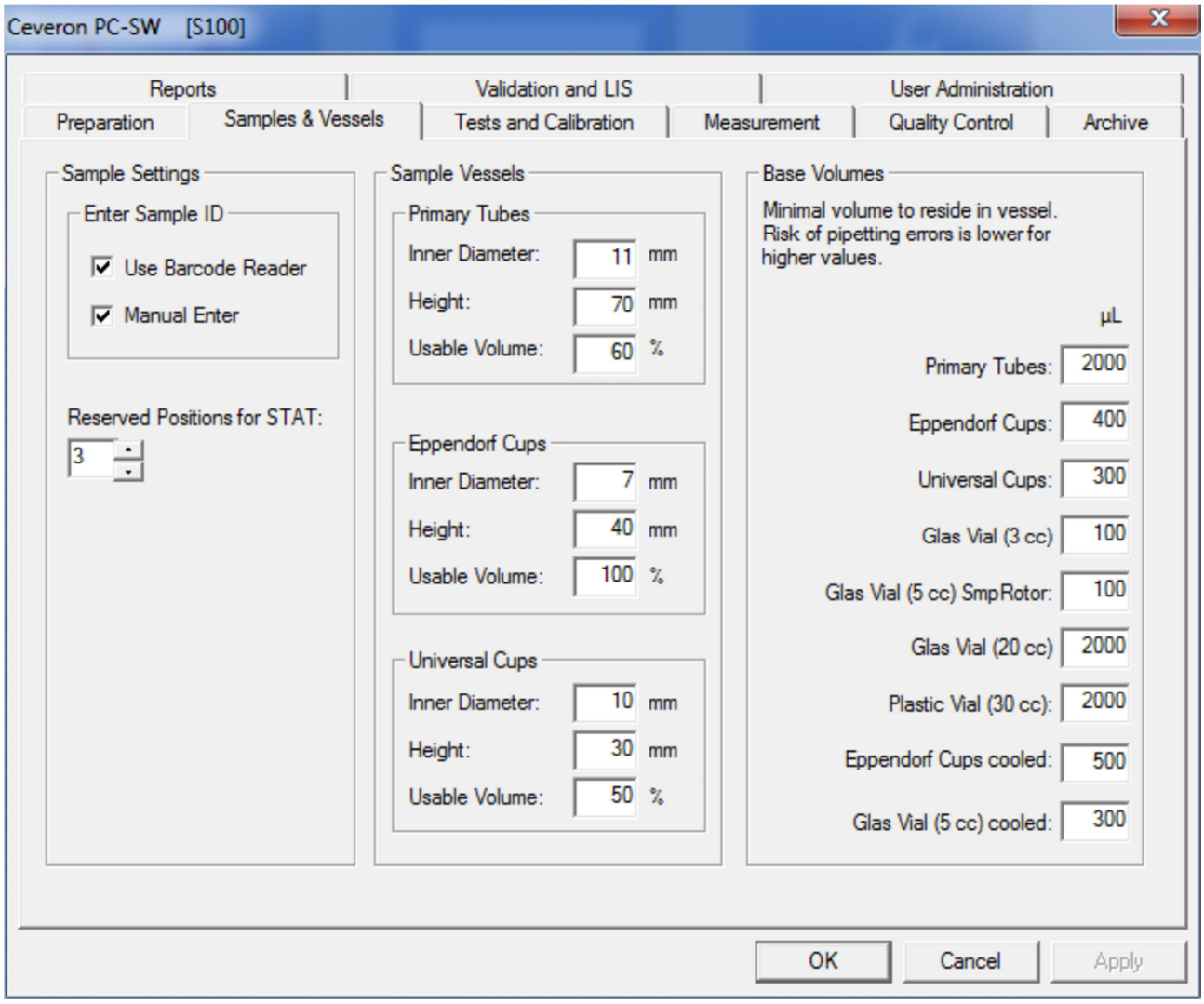
Actions before testrun

- Upon activation of the selection, CEVERON will perform the respective tasks automatically when measurement is started.

During Testrun

- Upon activation of the selection, CEVERON will perform the respective tasks during the measurement.

4.2.12.2 Samples & Vessels



The standard settings for the Samples & Vessels tab is depicted above.

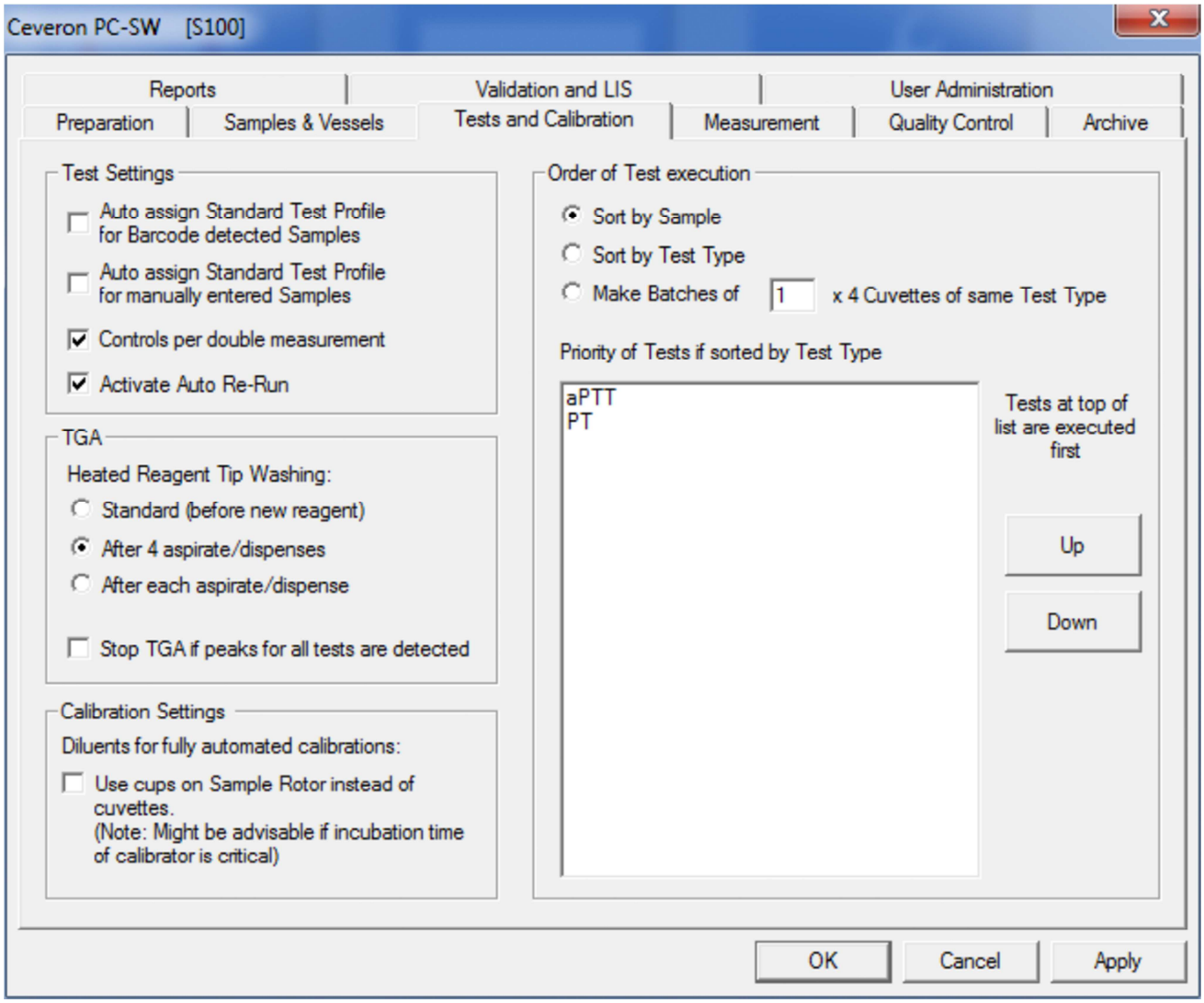
Sample Settings

- Upon activation of the selection, CEVERON will allow sample identification to be added using the barcode reader and / or manual entry.

Select how many positions of the sample rotor are reserved for emergency or STAT samples. It can be chosen between 0 – 8. STAT positions are located on the sample rotor starting at position 1. In the **'worklist'** the STAT positions are colored in red. For your convenience, the adaptors in the sample rotor are also colored red. If you change the number of STAT samples, we recommend to also change the adaptors of the sample rotor accordingly. Remember, that STAT samples are always processed to perform all tests by sample, to minimize time to result for these samples. When **"normal"** samples are run in STAT positions, this will reduce the overall throughput of the instrument unnecessarily.

Sample Vessels and Base Volumes

Standard Sample Vessels and Base Volumes are set in these fields. If using non-standard vessels, please contact your service engineer to adapt these according to your specifications. Manipulation may lead to pipetting errors or damaging of the pipettor probe!



4.2.12.3 Tests and Calibration

The standard settings for the Tests and Calibration tab is depicted above.

Test Settings

Upon activation of the selection, CEVERON will automatically perform the respective tasks including:

- To Auto assign the Standard Test Profile to all barcoded and / or manually entered samples.
- To run controls in duplicate measurement.
- To activate the Auto Re-Run.

Auto Re-Run is an option to automatically perform tests according to settings made in the **'Test Definition'** menu. These include, repeating the measurement with extended measurement time or performing reflex testing with other sample pre dilutions. For more details please refer to the **'Test Definition'** menu.

TGA

Upon activation of the selection, CEVERON t100 and CEVERON s100 will automatically perform the respective tasks including:

- Different washing of the heated reagent probe.
- Stopping TGA measurement when all samples reached peak thrombin, minimizing time to result for TGA measurements.

Calibration Settings

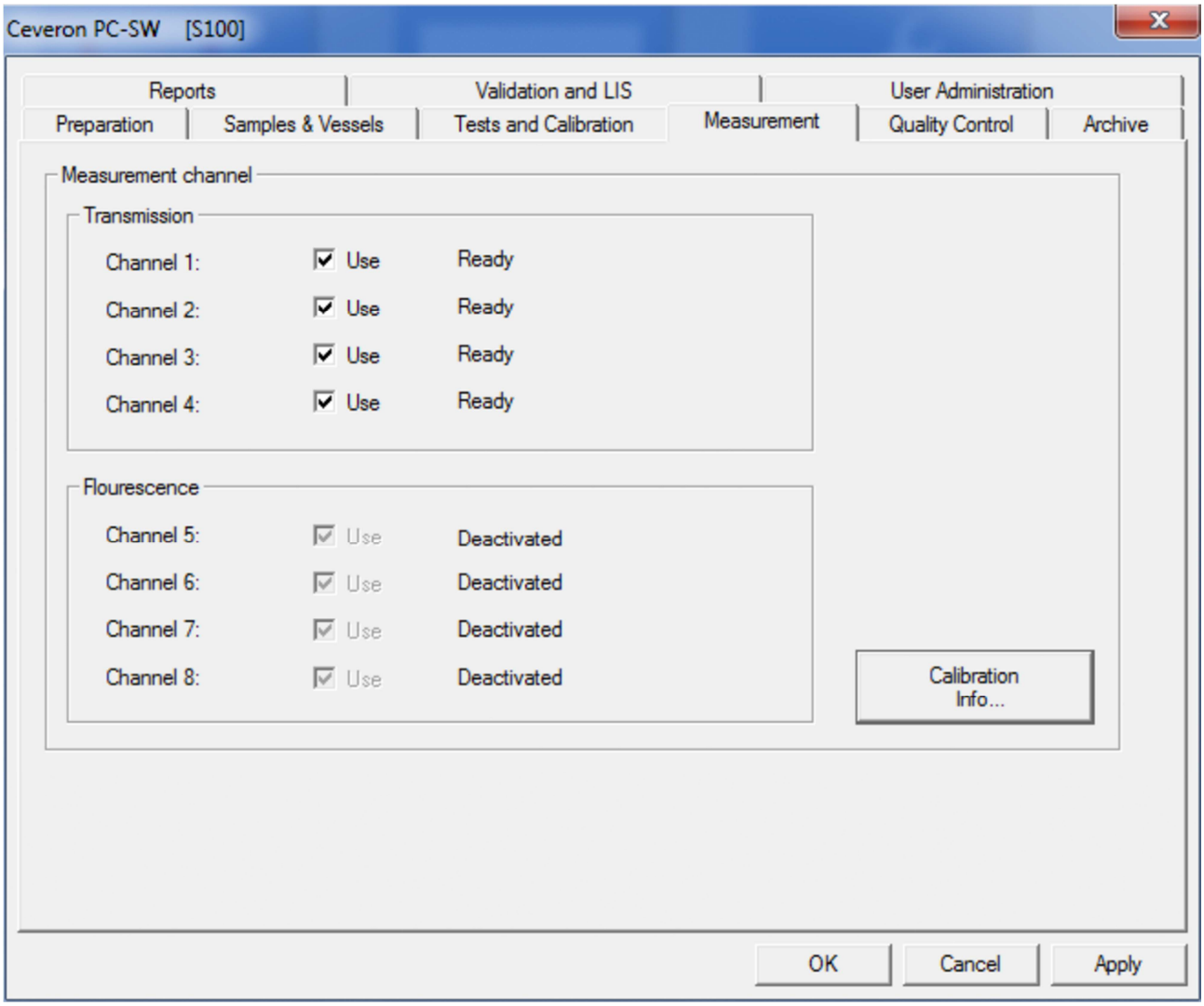
- Upon activation of the selection, CEVERON will always use cups positioned in the sample rotor to prepare dilutions.

Order of Test execution

Upon activation of the selection, CEVERON will automatically perform the respective tasks.

- Sort by sample: all test of a sample are performed before starting the next sample (default for STAT samples).
- Sort by test: same tests are performed in the order which can be adjusted in the **'Priority of Tests'** list. Use the UP and DOWN buttons to change the order of the tests. In the shown example aPTT will be performed prior PT.
- Making batches of n x 4 cuvettes of same test type reduces the number of test performed simultaneously to the entered number "n". Use this option, if TGA is run in parallel with other tests prior to the test performance. In the example aPTT will be performed prior to TGA.

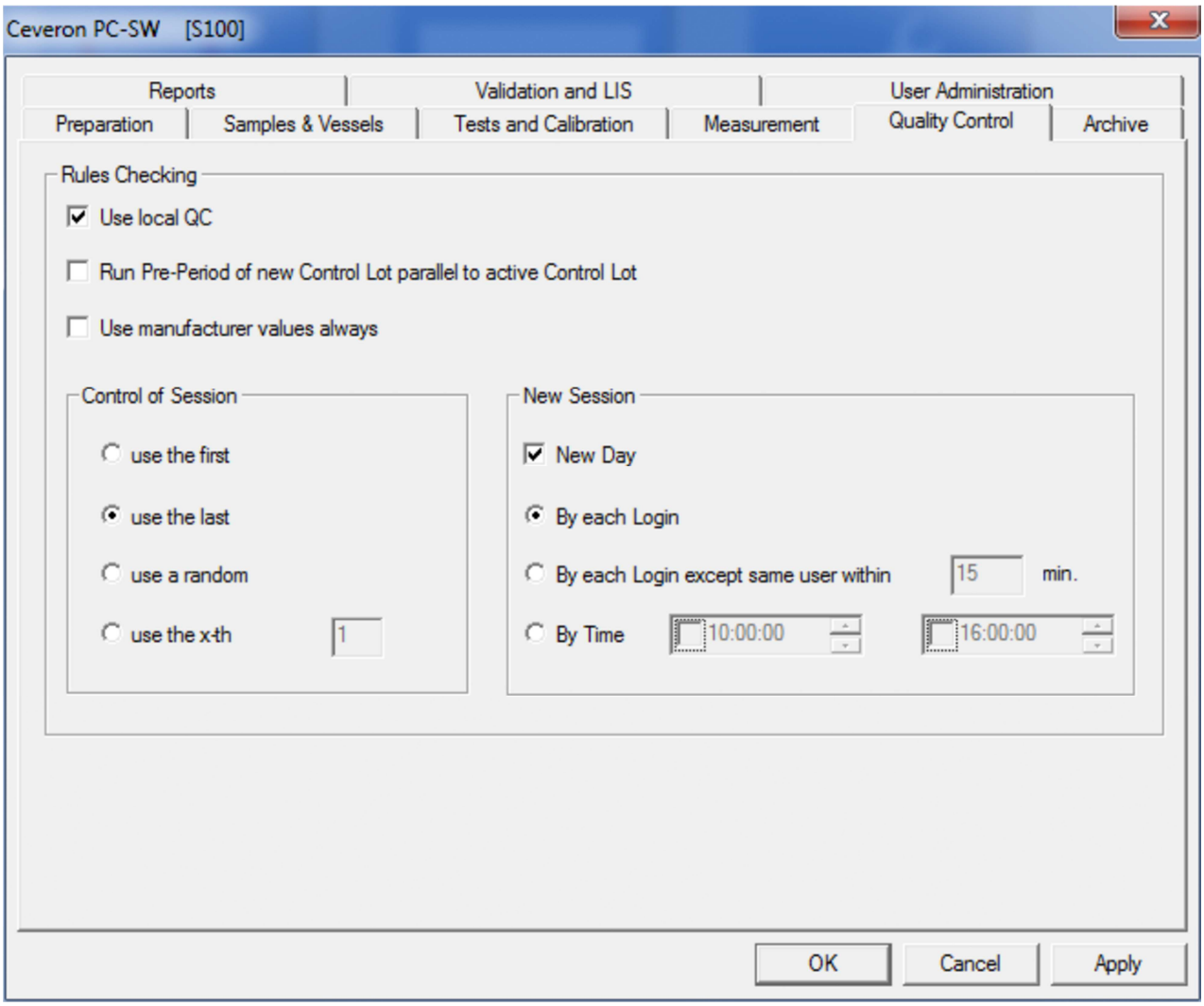
4.2.12.4 Measurement



The standard settings for the Measurement tab are depicted above.

This tab including the **'Calibration Info'** is for service engineers only! Any manipulation may lead to a malfunction of the instrument.

4.2.12.5 Quality Control



The standard settings for the Quality Control tab are depicted above.

Rules Checking

Upon activation of the selection, CEVERON will automatically perform the respective tasks including:

- Use the local QC or send QC results to a Host computer (LIS).
- Allow to run a pre-period for new control lot together with the current active control lot or only allow one control to be run.
- Always use the confidence range provided by the manufacturer or replace the confidence range according to the date generated during a pre-period.

Control of Session

Select which Control value should be used for calculation, when a control is run multiple times during a session.

New session

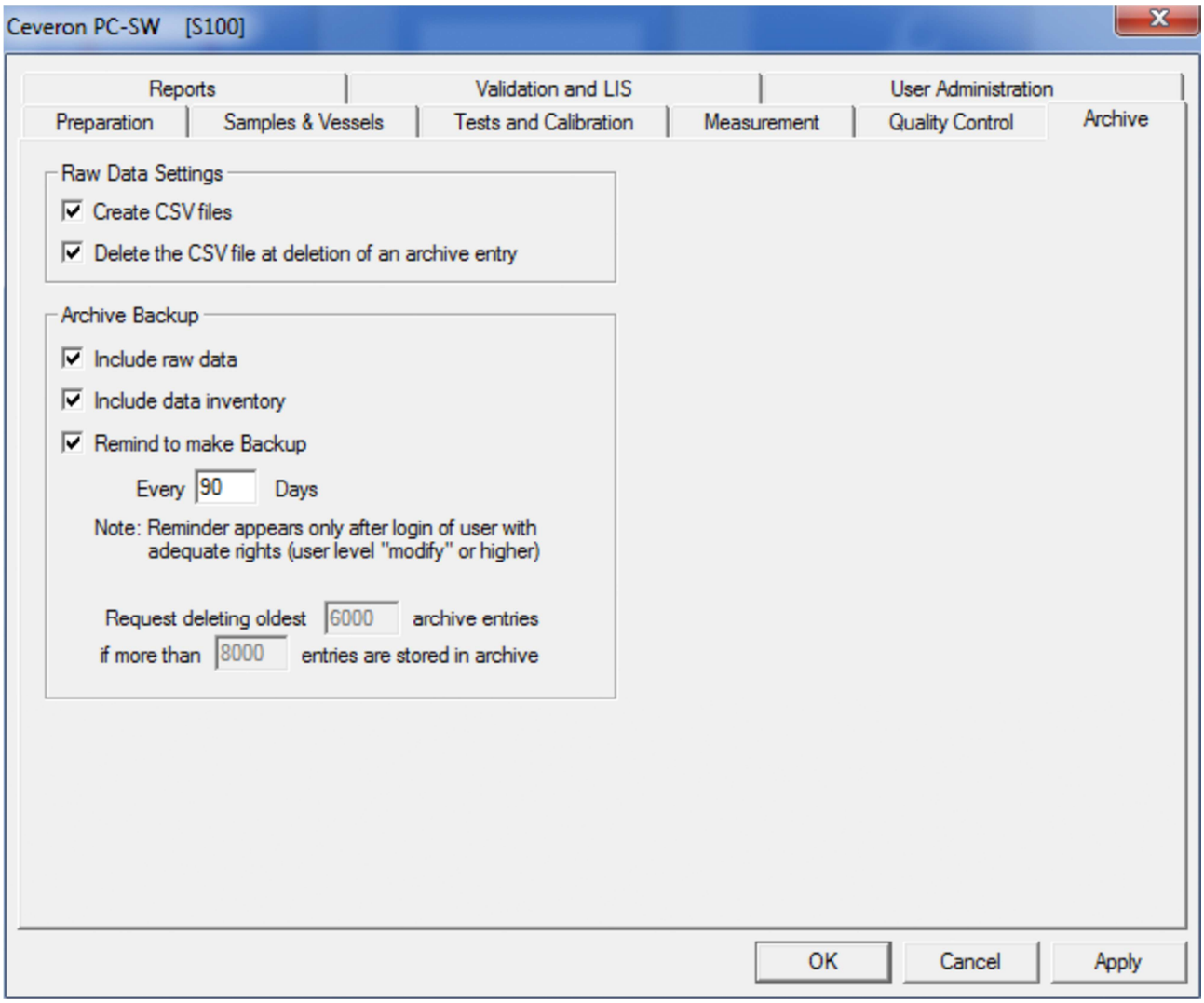
Specify, when a new session starts

- New calendar day
- Login (with or without except same user within a certain period)
- By time (e.g. two shifts)

Assay specific QC rules

More detailed settings, which QC rules are applied are found in the respective **'Test Definition'** of the test. These settings include using the Guidelines of the German Medical Association (RiLiBäk) or Westgard Rules and which controls are used for QC of a respective test.

4.2.12.6 Archive



The standard setting for the Archive tab is depicted above.

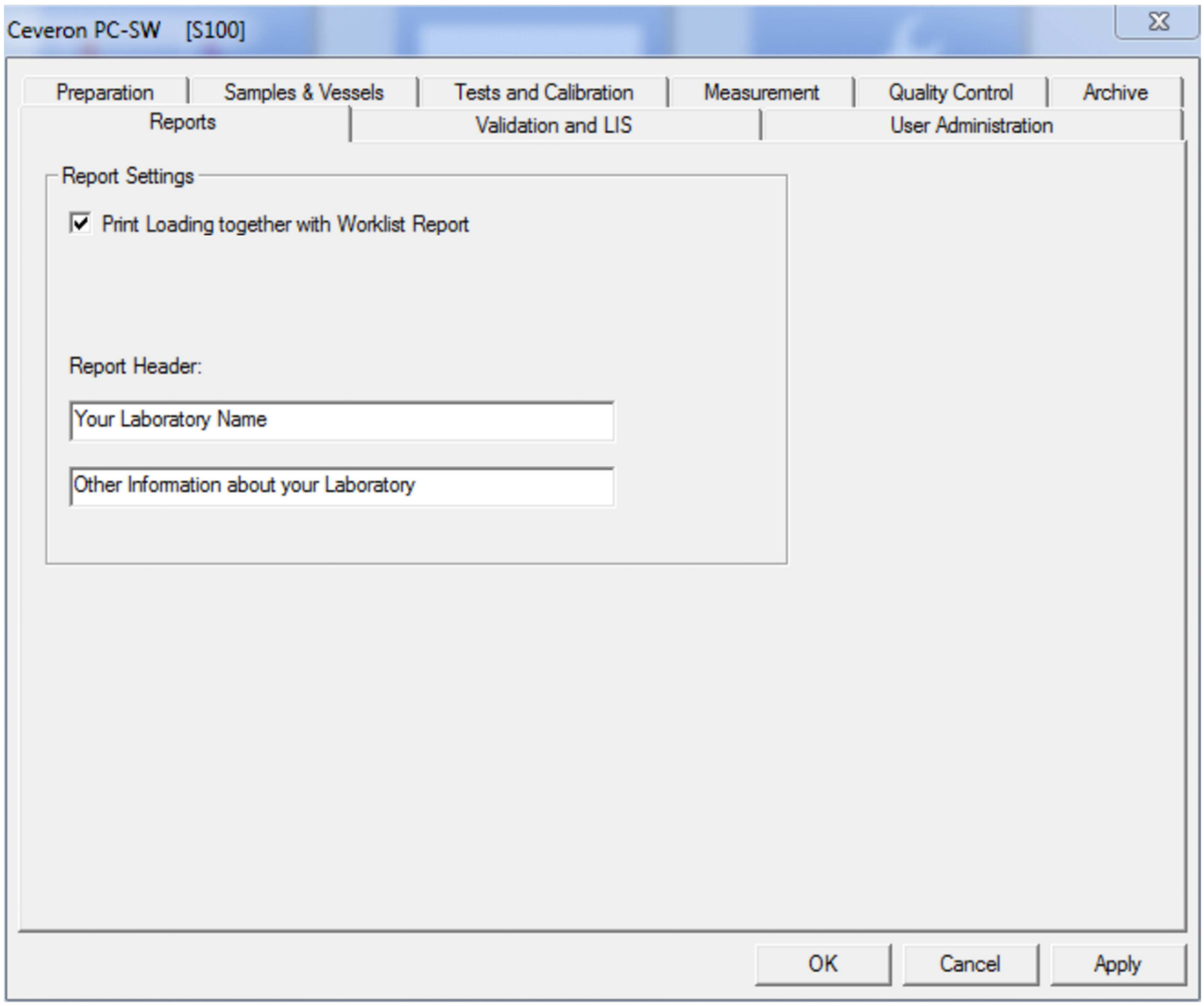
Raw Data Settings:

- Create CSV files: CSV files include all raw data and can be opened, e.g. with Microsoft EXCEL.
- Delete the CSV file at the deletion of an archive entry: This option enables the parallel deletion of both corresponding files.

Archive Backup:

- Include raw data: If this option is activated also the raw data are stored and the reaction curves can be displayed.
- Remind to make Backup: This option automatically reminds to create a backup after a defined time (only for user levels **"modify"** or above).

4.2.12.7 Reports

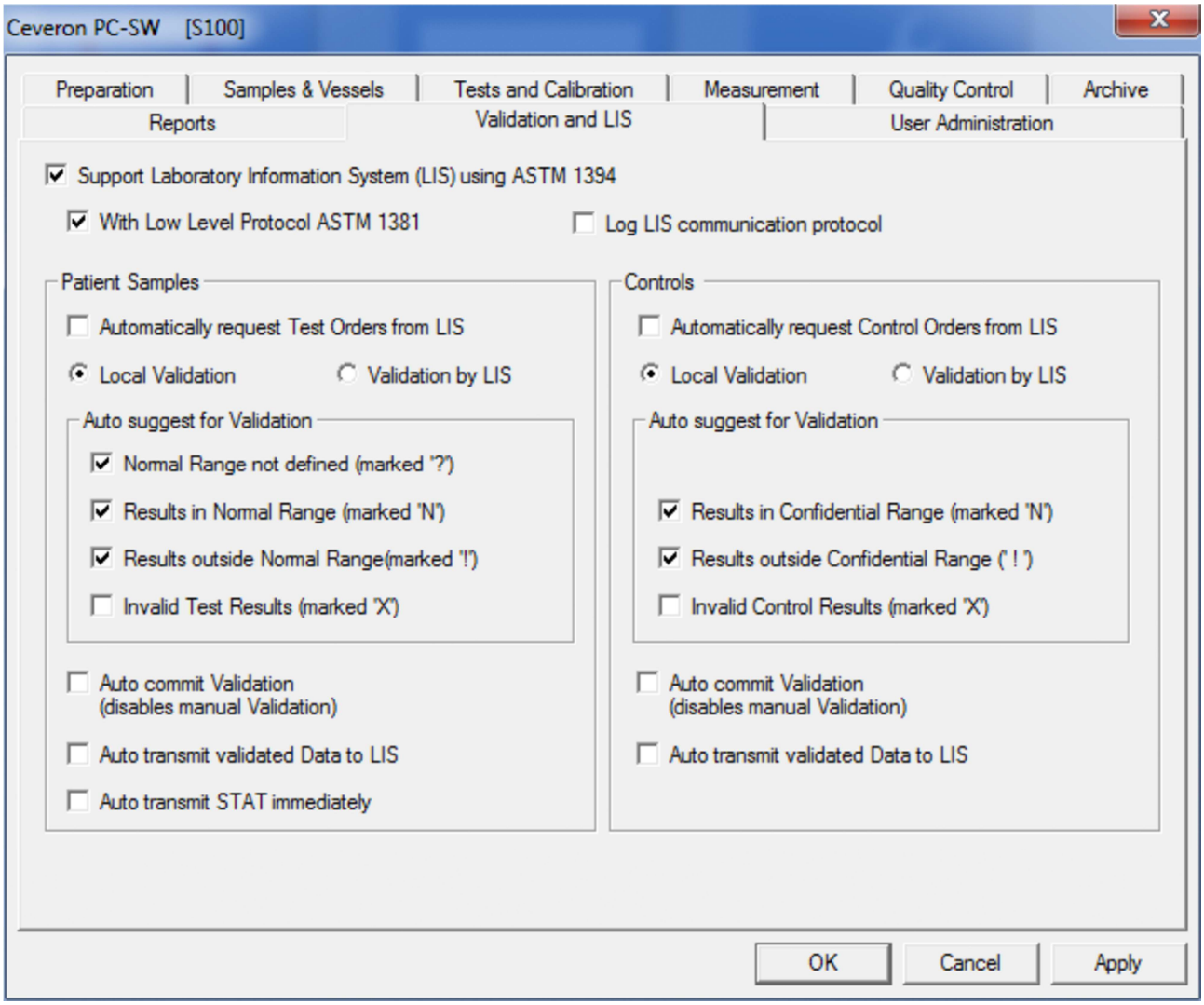


Upon activation of the selection **'Print loading…'**, CEVERON will automatically print the current loading together with a worklist report.

Report Header

- Individualize your CEVERON instrument. This information is added to the home screen of the software and will be printed in the header of each report.

4.2.12.8 Validation and LIS

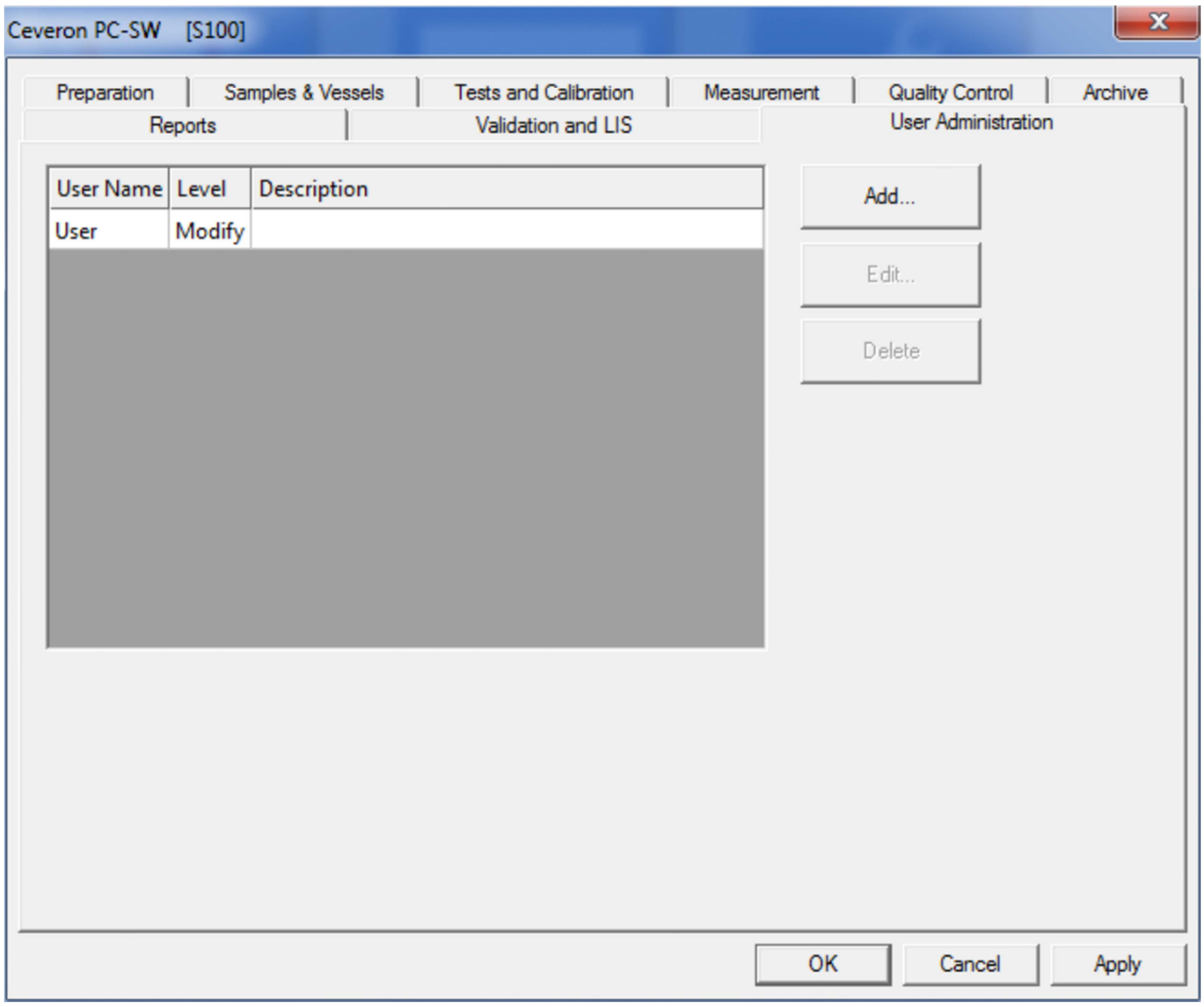


The standard settings for the validation and LIS tab for a CEVERON which is not connected to a Host computer (LIS), is depicted above.

Upon activation of the selection, CEVERON will perform the respective tasks including suggesting predefined validation, automatically validation and automatically transmit results for Controls and samples.

For more details on communication to a Host computer (LIS) please contact your local distributor or Technoclone directly at ceveron@technoclone.com.

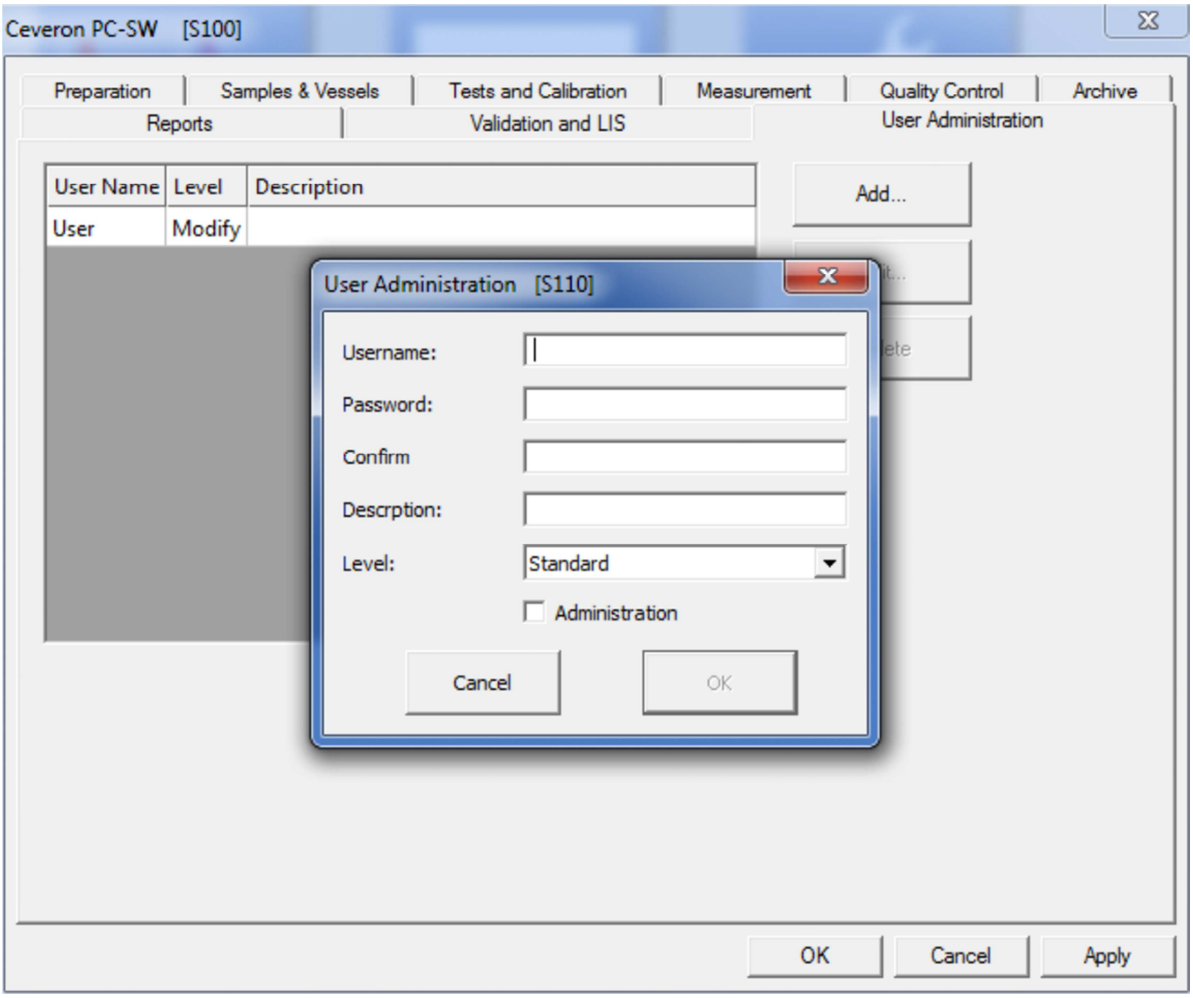
4.2.12.9 User Administration



In the **'User Administration'** tab users can be added, edited and deleted.

Adding a new User

To add a new user, press the **'Add'** button.



In the User Administration window enter the requested information. User can only add, edit or delete users up to their own level and when the **'Administration'** option is selected. Password protection is provided.

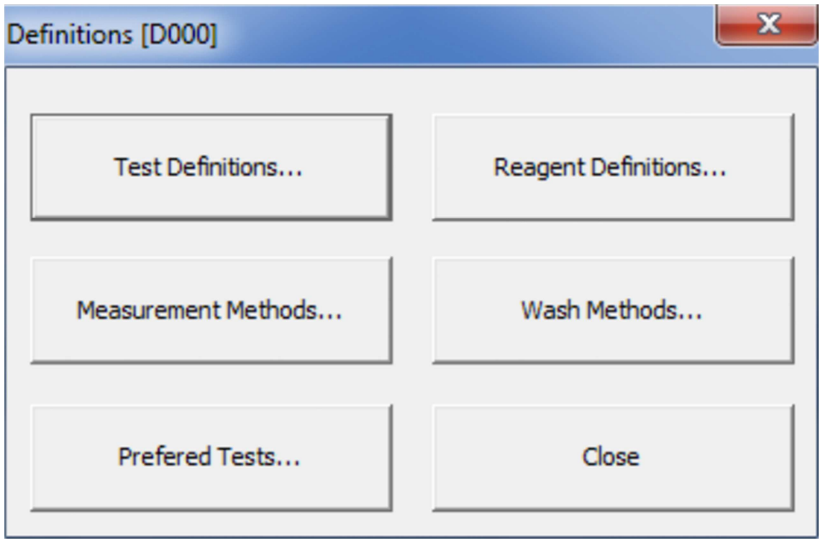
Following User levels are available:

- **Basic:** Basic user can only load reagents, samples and run tests.
- **Standard:** This level is intended for the routine work. Users may additionally perform calibrations and run controls. Standard users are not allowed to add or modify tests and reagents, validate calibration curves.
- **Modify:** Modify user may perform all task, including to set a QC result as invalid

Note: For Technoclone defined reagents and tests only limited editing is allowed (e.g. running duplicates, QC settings)

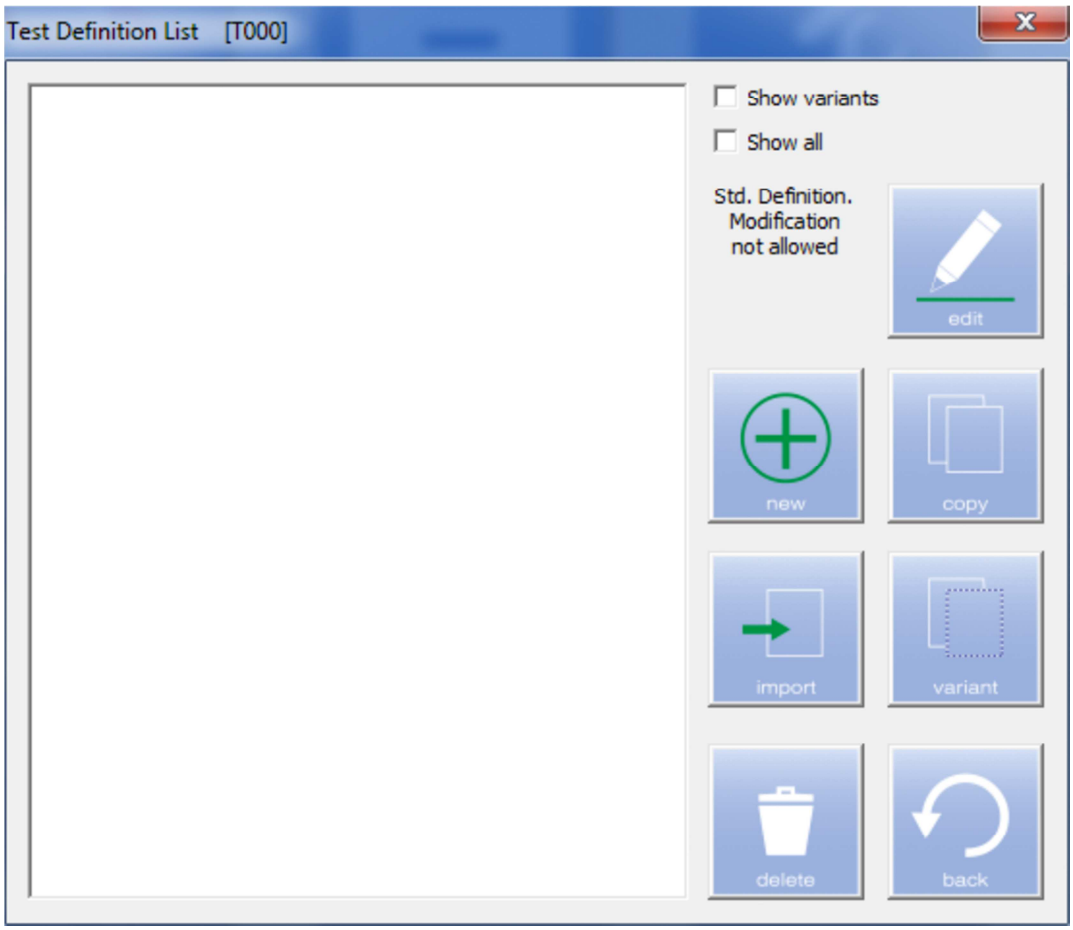
4.2.13 Definitions

By clicking the **“definitions”** icon, the opens the window definitions is opened.



Using the **‘Definitions’** window the respective definitions are available. Select the type of definition or method to view, edit, add or delete.

4.2.13.1 Test Definitions



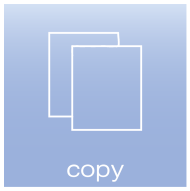
The **'Test Definition List'** displays the preferred test. To include variants of a test, select **'Show variants'**. Variants are applications which are linked to a standard test (e.g. different sample dilution). To view all tests installed, select **'Show all'**.

Description of buttons

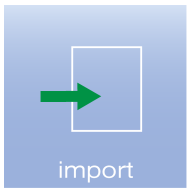
View or edit an existing test.

Attention: for Technoclone defined tests only limited editing is possible.

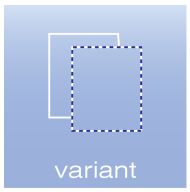
Create a new test.



Create a copy of an existing test.



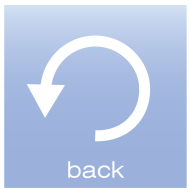
Import a new test definition.



Create a variant of an existing test.

Delete an existing test.

Caution: deleting an existing test will also affect raw data display of samples in the archive, when this this was used.



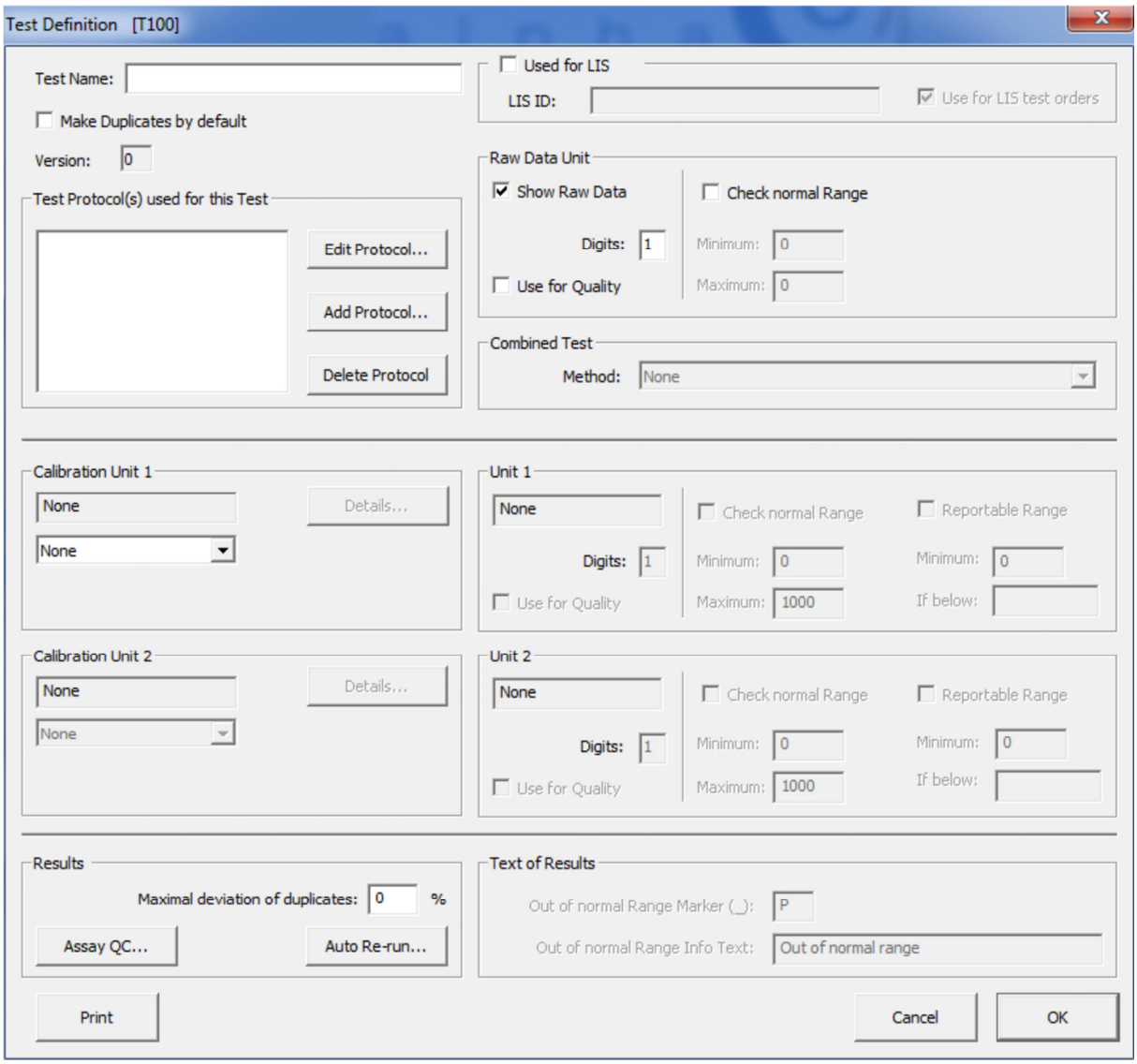
Close the window.

Import a test definition

To import a test definition, load the '.cax' file provided by Technoclone onto the computer. Press the **'import'** button and locate the '.cax' file to be installed. CEVERON software will confirm successful installation of the new test definition.

Create a new test definition

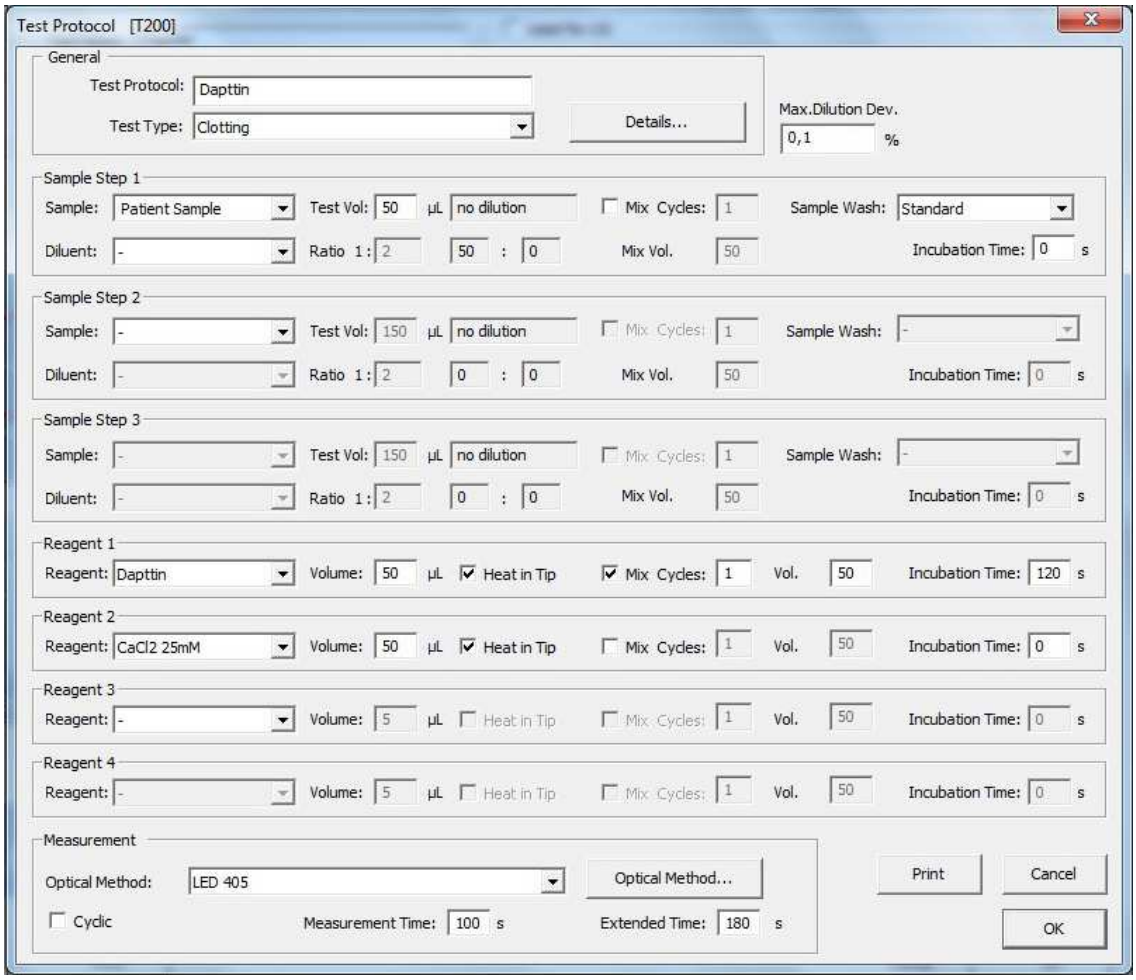
To create a new test, press the **'new'** button.



Create a new test name in the field **"Test Name"**

Click **"Add Protocol..."**

This opens the window **"Test Protocol"**, see next page.

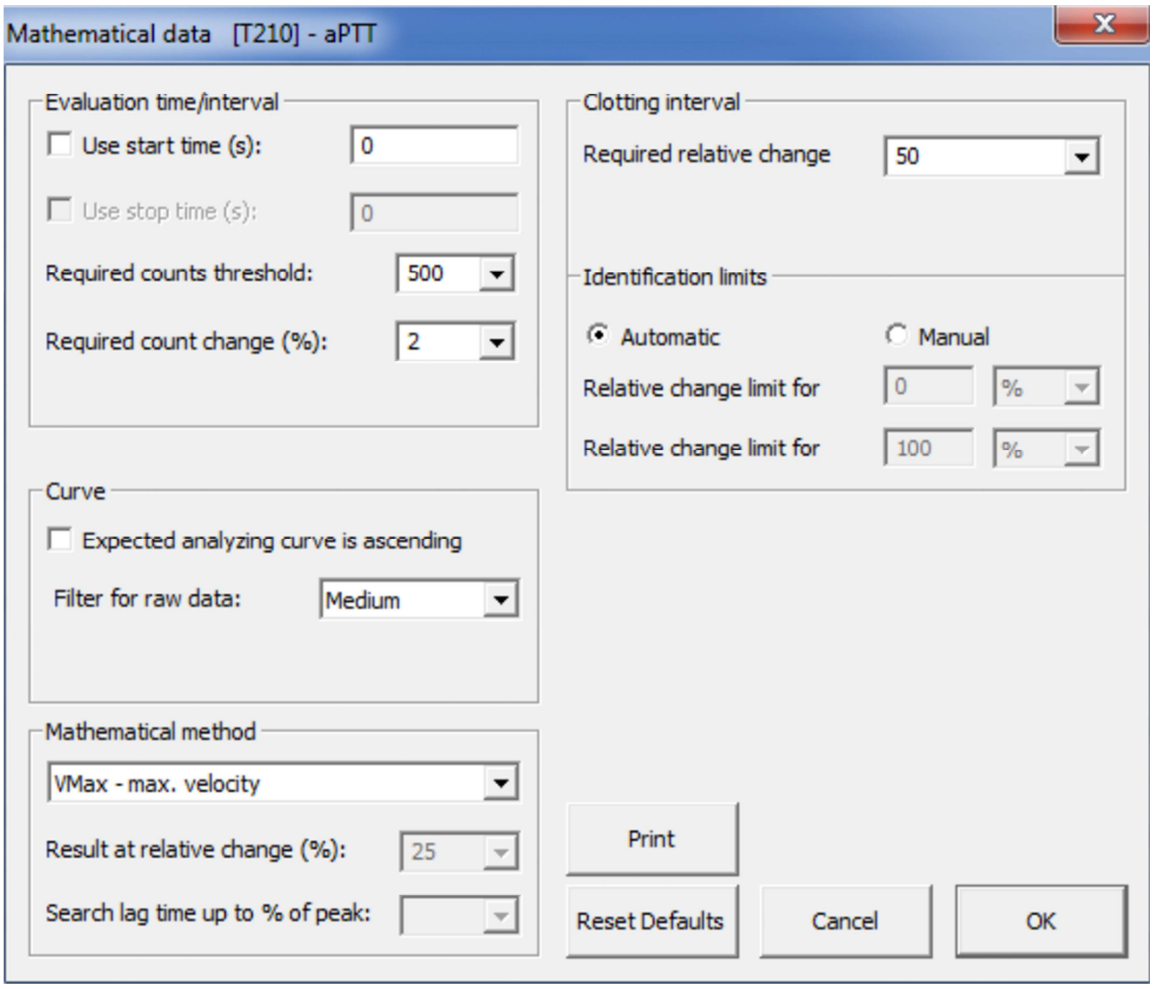


The **'Test Protocol'** defines pipetting steps, mathematical data and optical methods.

Select the **'Test Type'** using the dropdown menu choosing from

- Clotting
- Chromogenic Kinetik
- Chromogenic Endpoint
- Turbidimetric Kinetic
- Turbidimetric Endpoint
- TGA

Clicking **"Details..."** will open the window **"Mathematical data"**, see next page



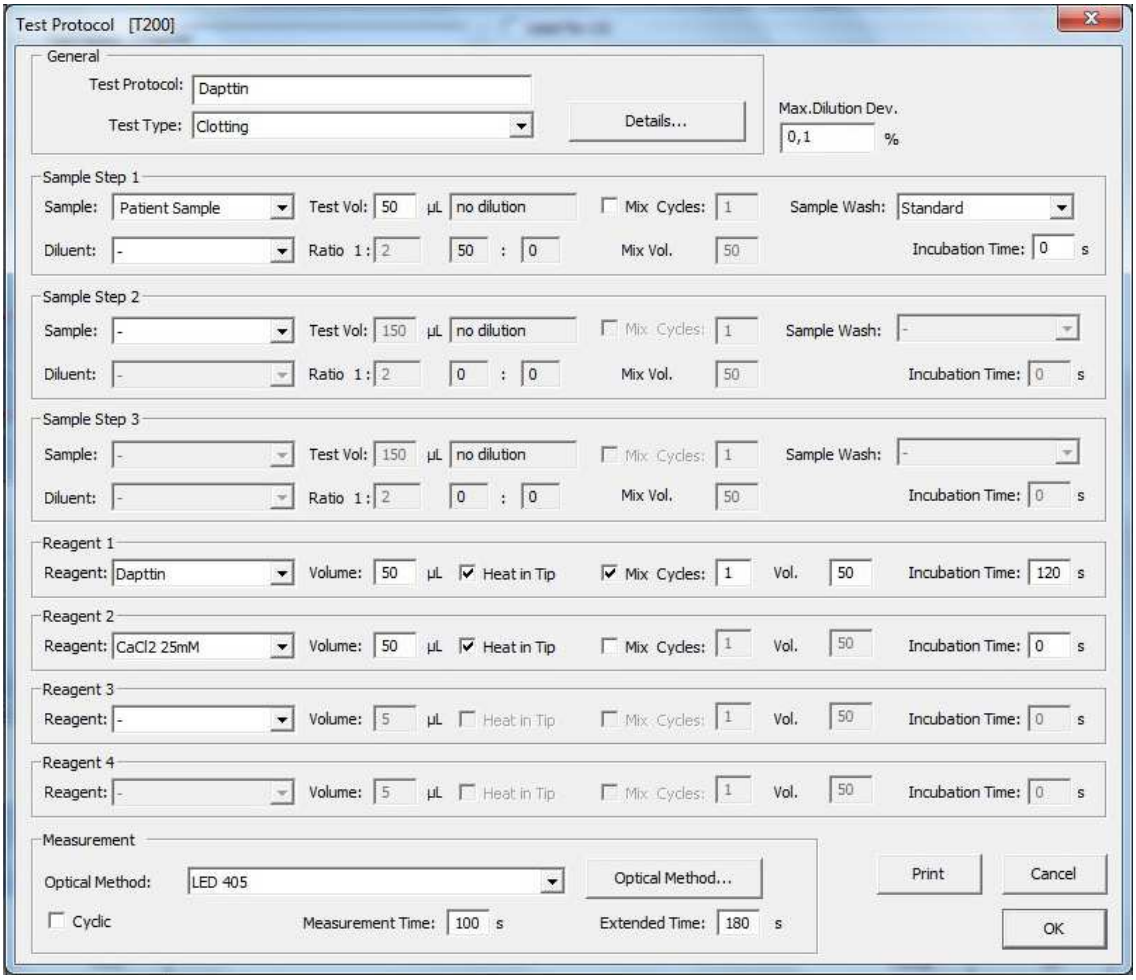
The **'Mathematical Data'** window summarizes the details for analysis.

Modify the settings according to the requirements.

Modifications may include:

- Evaluation Time or Interval
- Minimum requirements for evaluation
- Raw data filtering (none, low, medium, high, moving average)
- Clotting Mathematical method
  - Maximum velocity
  - Maximum acceleration
  - Absolute change
  - Delta OD
- Requirements for clotting detection

Press **'OK'** to confirm the changes you made and return to **'Test Protocol'**.



Next select the maximum allowed deviation of a dilution prepared by CEVERON to the theoretical dilution.

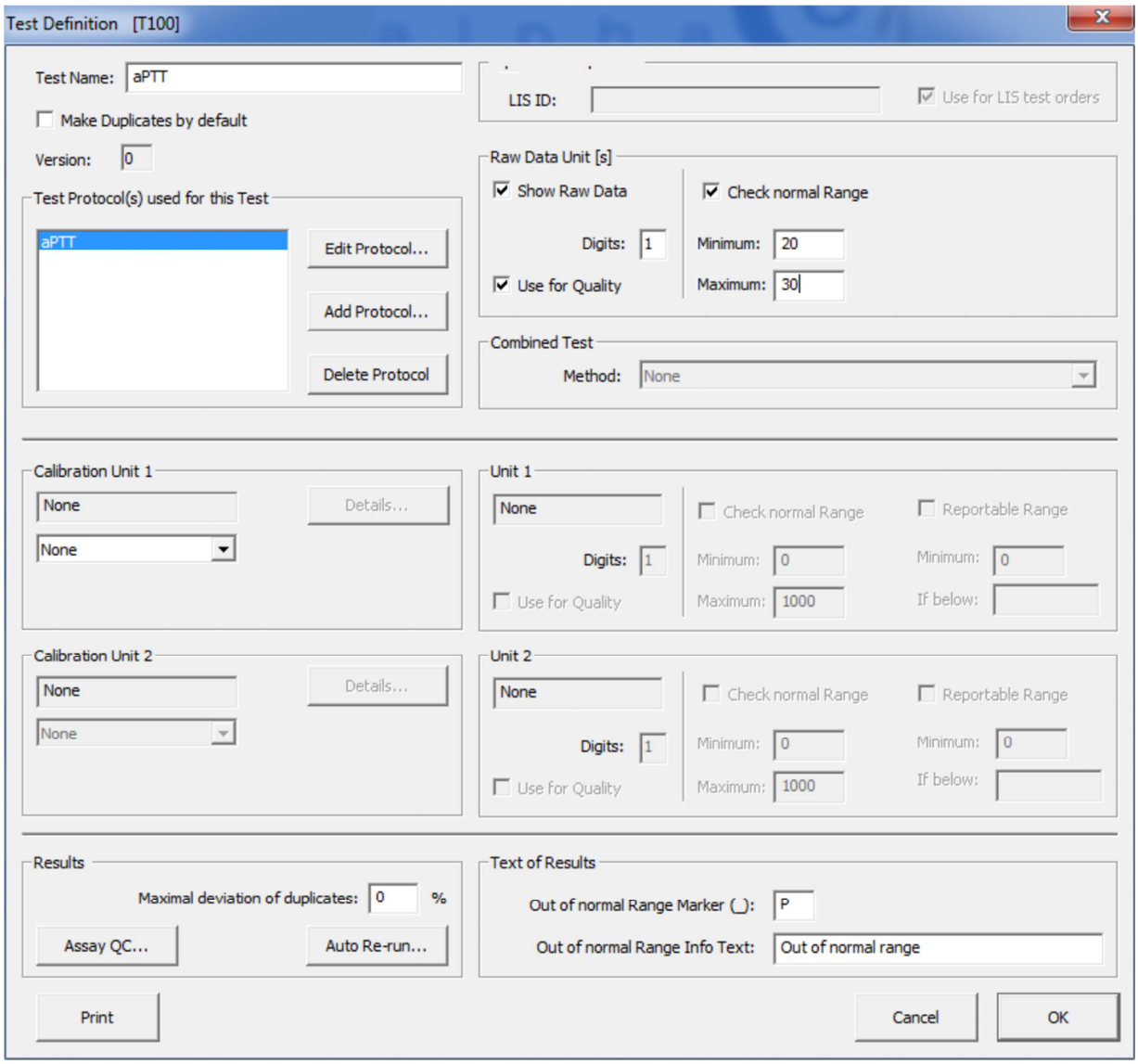
Enter the pipetting steps according to your requirements both for the sample probe and the reagent probe using the dropdown options or entering values to the respective fields.

Option include:

- Choice of sample
- Choice of diluent
- Amount sample volume
- Dilution ratio
- Mixing cycles and volume
- Wash procedure after sample pipetting step (regent probe wash procedures are defined in the '**Reagent Definitions**')
- Incubation time
- For reagent probe steps only: heating of pipetted volume in the probe tip prior dispensing

In the **‘measurement’** settings, the optical method (choice of primary and secondary wavelength) can be selected as well as the measurement time. Extended measurement time can be used for reflex testing, when extended measurement is likely to result in a reportable measurement (e.g. aPTT measurement of heparinized samples). Cyclic measurement is to be selected for TGA.

Press **‘OK’** to confirm the changes and return to the **‘Test Definition’** window.

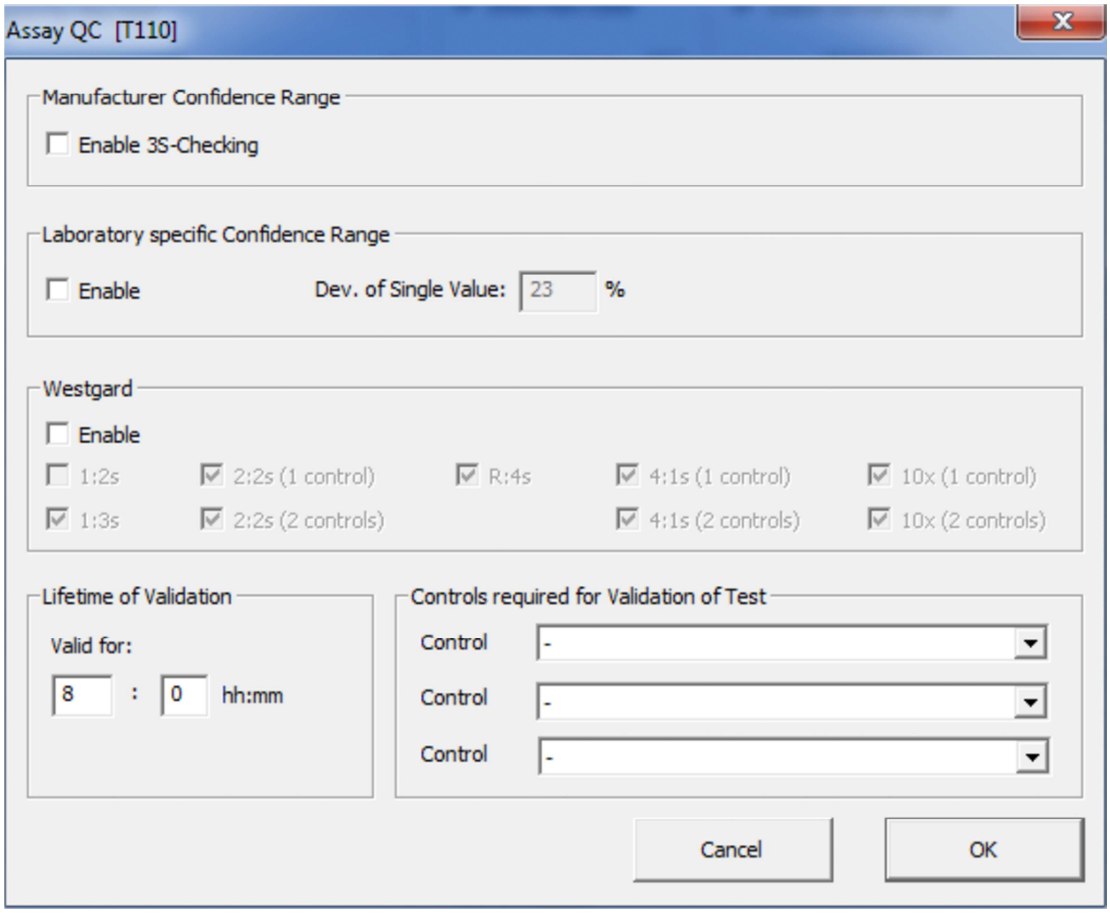


In the **‘Test Definition’** window, continue to fill out the form. Information might include:

- Information on Units (raw data or calibrated units)
- Which units to be used for QC samples
- Whether to check normal Range
- Whether to limit reporting according to a lower limit of quantification (LLoQ)
- Maximal allowed deviation between duplicates
- How to flag samples which measured out of normal range

Press **‘OK’** to save the settings and return to the **‘Test List’**.

Setting Assay QC



Press the **'Assay QC'** button in the **'Test Definition'** window to modify test specific QC parameters. Options include:

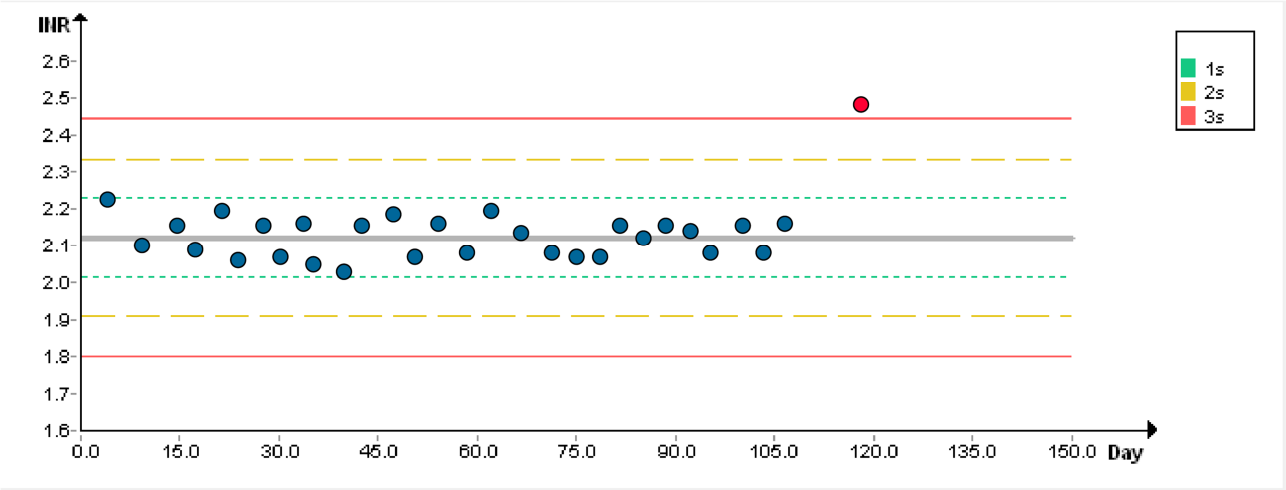
- To use the confidence or 3S range of the manufacturer
- To use a laboratory specific confidence range, including a maximum allowed deviation of the single value (RiLiBÄK)
- To use Westgard rules

The Westgard Rules can be used for any test. It's a so-called multiple rule procedure. These rules are listed within the table:

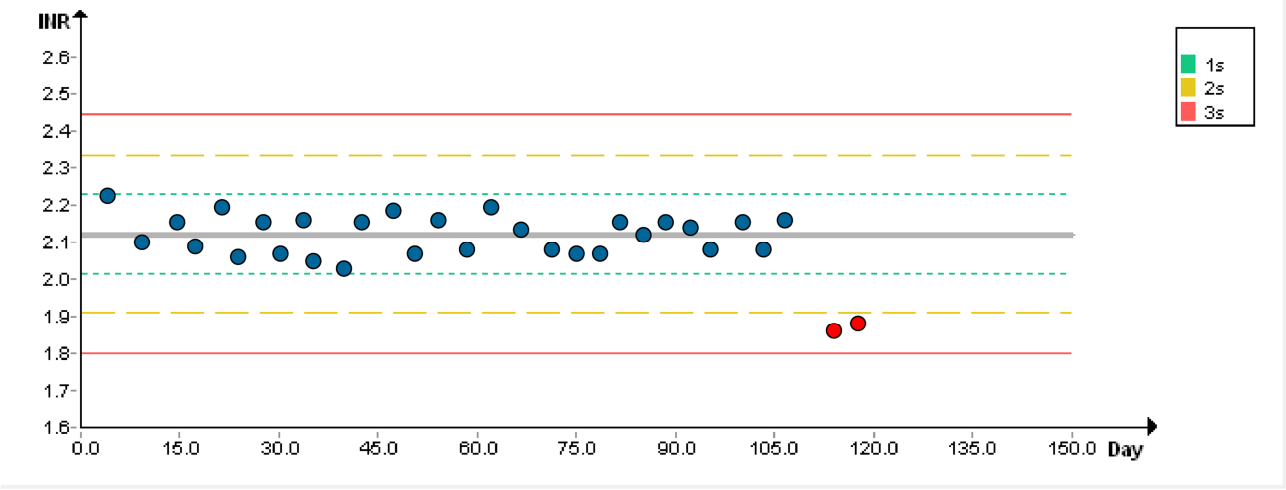
Description	Rule
1 point is outside 2 SD (warning rule)	(1:2s)
1 point is outside 2 SD, then reject when: 1 point is outside 3 SD	(1:3s)
2 consecutive points are outside 2 SD on the same side of the centre line	(2:2s)
Range of 2 points is greater than 4 SD	(R:4s)
4 consecutive points exceed 1 SD on the same side of the centre line	(4:1s)
10 consecutive points are above or below the mean	(10x)

Examples for Westgard Rules

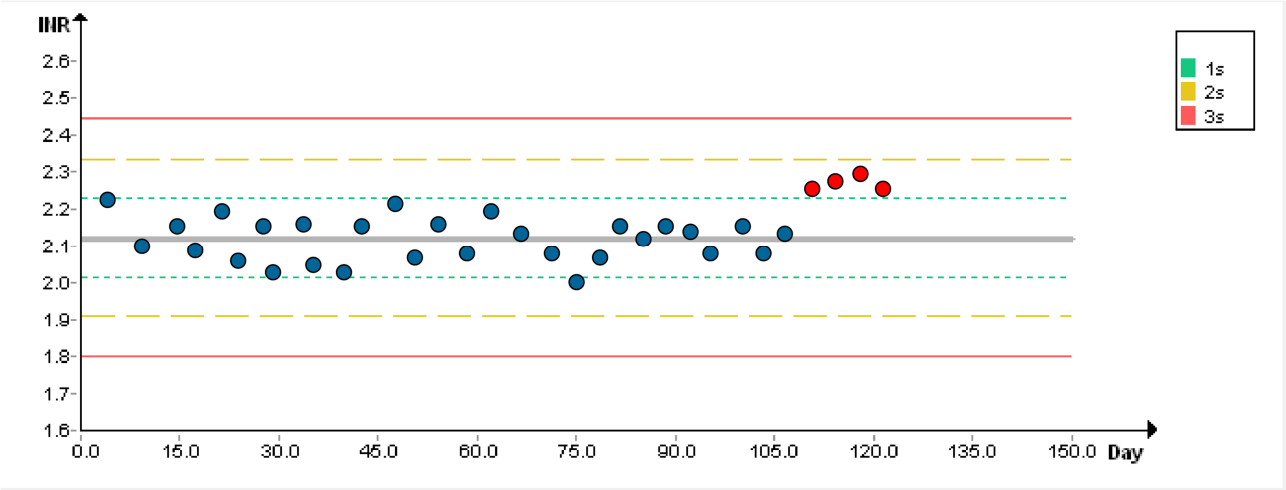
Example for 1:3s- Either value is outside 3 SD limits



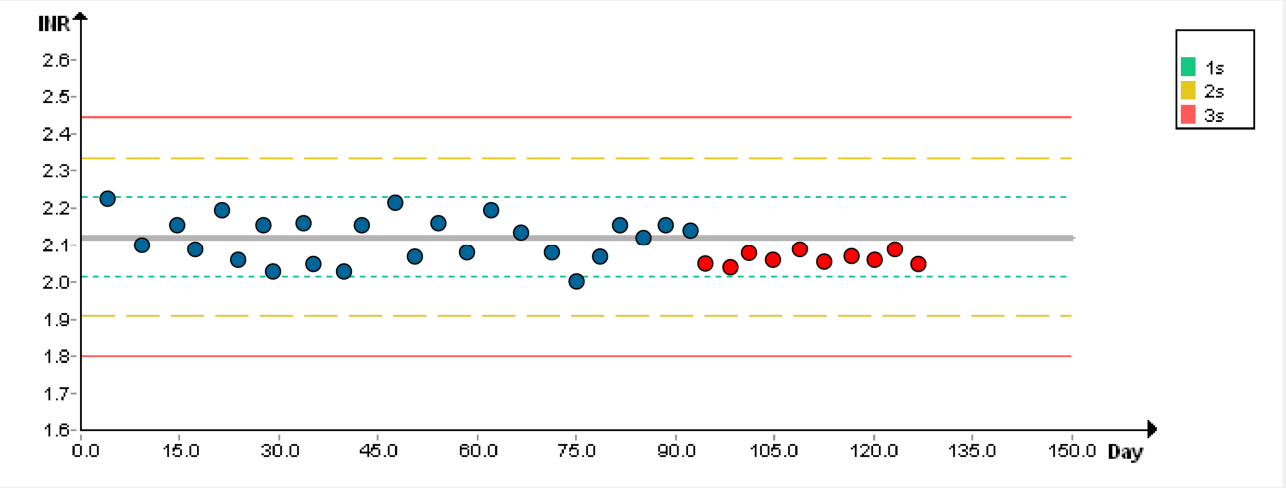
Example for 2:2s - Both values are outside 2 SD limits on the same side



Example for 4:1s - 4 consecutive points exceed 1 SD on the same side of the mean



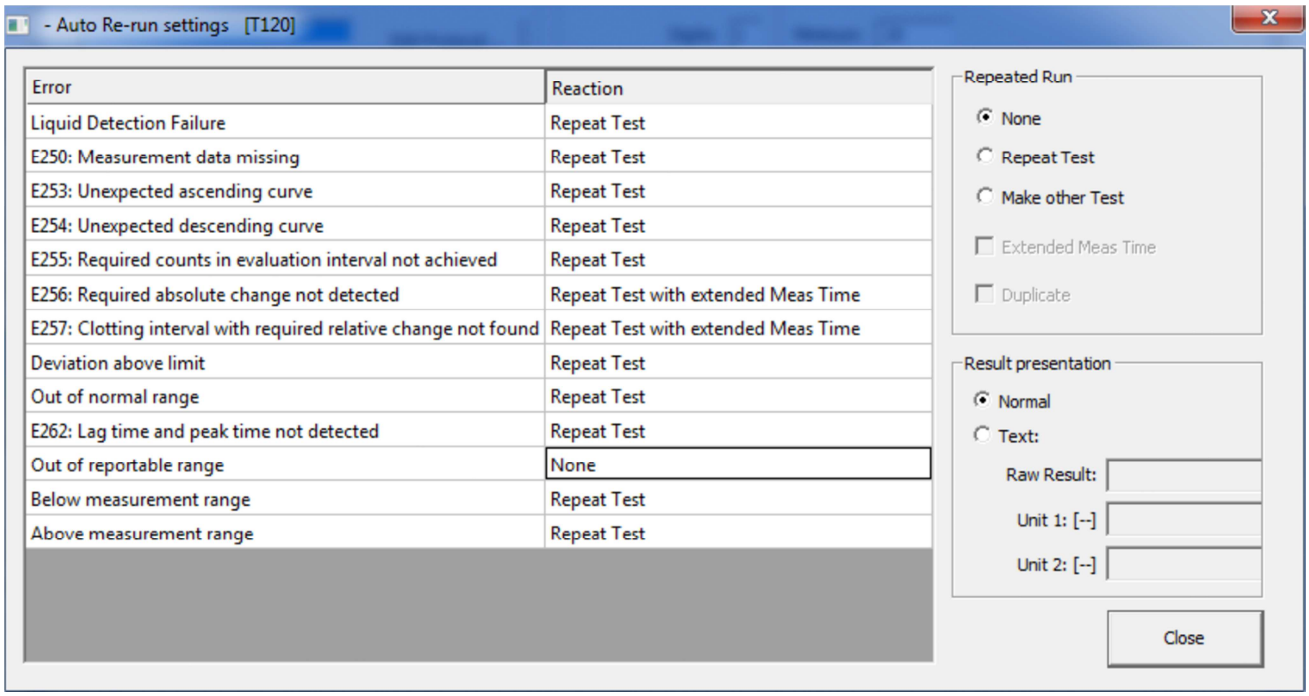
Example for 10x - Ten values from the same control are above or below the mean.



In the **'Lifetime of Validation'** tab the time to re-run a control can be adjusted. Running samples without validation using QC samples, will result in the sample results to be flagged accordingly. Moreover, the validity of the test result must be doubted.

In the **'Controls required for the Validation of Test'** tab the controls linked to the test are selected. Only successful measurement of all selected QC samples within the acceptance criteria, will allow to start measurement of patient samples. Only tests which are linked to a control will be visible in the **'Add Control lot'** menu.

Adjust Auto Re-run setting



Press the **'Auto Re-run'** button in the **'Test Definition'** window to modify test specific Auto Re-run parameters.

Options include:

- None (No action is needed)
- Repeat a test (with duplicates and/or extended measurement time)
- Make another test
- How results should be presented

To modify the action upon Re-run, select an Error from the list, and modify the settings on the right side of the window. Changing to another Error will automatically save the changes been made.

Press the **'Close'** button to return to the **'Test Definition'** window.

Defining a Calibration procedure

Most tests require calibration using a calibrator set or a single calibrator using serial dilution.
In the settings of the respective test, the **'Test Definition**', calibration settings can be adjusted. Up to two calibration units may be derived from one raw data curve (e.g. % and INR for PT tests). Remember that the respective reagent needs to be selected to require a calibration. This can be adjusted in the **'Reagent Definition'**.

For 'Calibration Unit 1' following options are available as a calibration options:

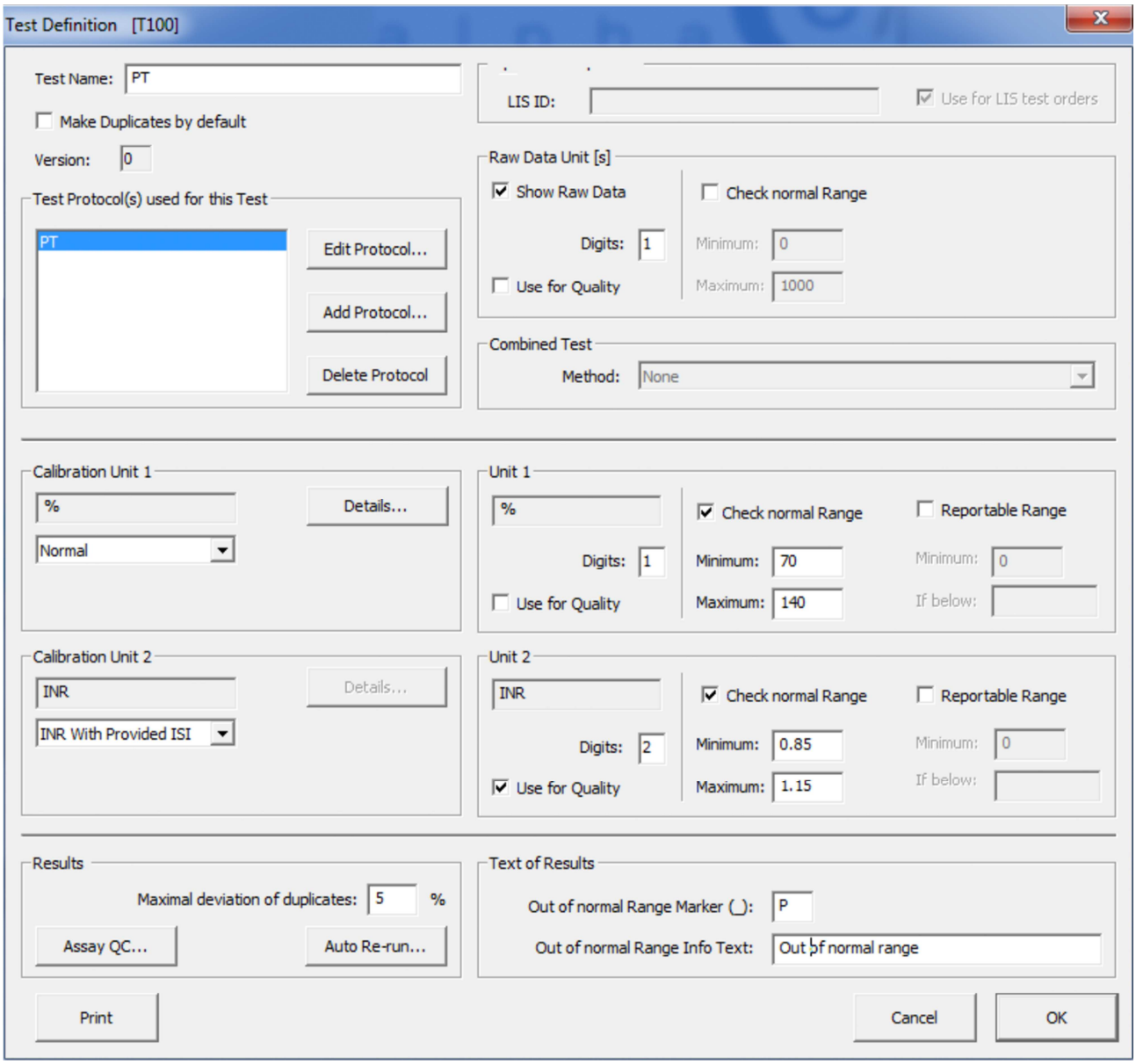
- None
- Normal, perform a calibration according to settings made and **'Details'**
- From other test, uses the calibration data from a different test. This setting is used when creating variants of a test using the same calibration but different predilutions of the sample to enlarge the measuring range.
- Ratio, calculating a ratio between two **'Test Protocols'** (e.g. dRVVT screen / dRVVT confirm)
- INR with Provided ISI, calculates the INR value of a sample using the reagent specific ISI and MNPT. ISI and MNPT of a PT reagent is defined in the **'Reagent Lot'** under the **'barcode'** menu.

For 'Calibration Unit 2' there is one additional option

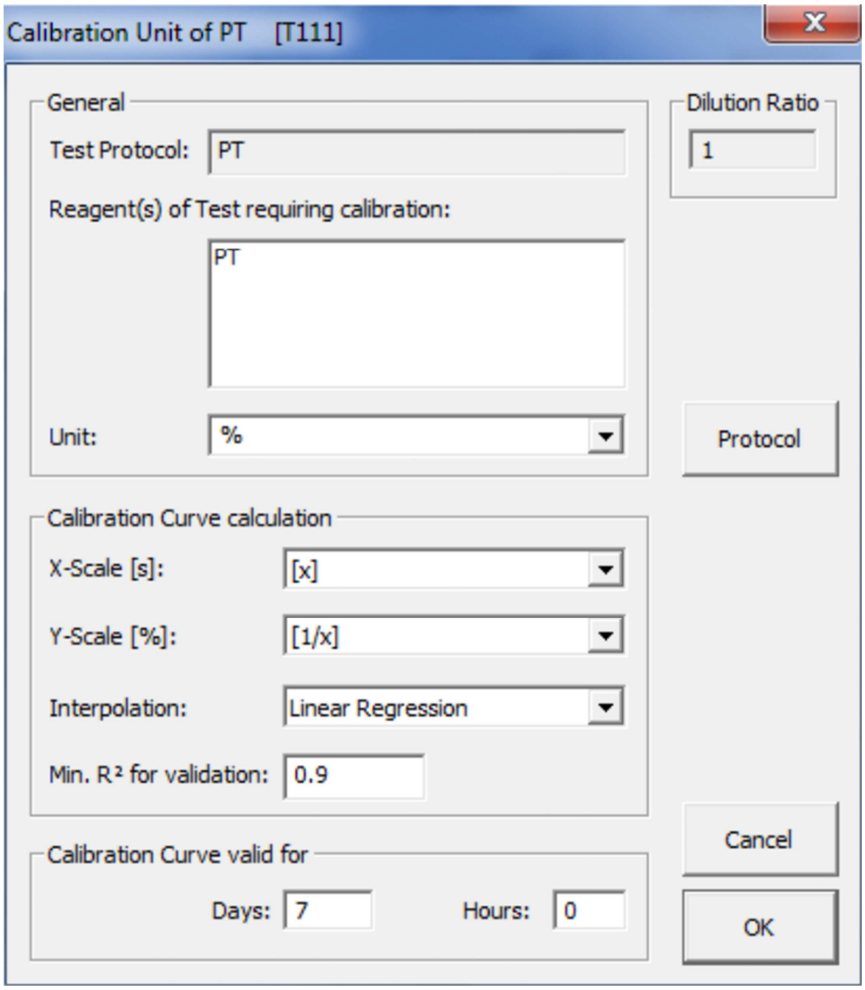
- INR from Unit 1, uses the raw data and calibration points from unit one with a different calibration value. This is used when calibration % and INR of a PT reagent directly using a INR calibration set such as AK Calibrant.

Calibration with Calibrator Set

As an example for a calibration using a calibrator set, we chose a PT reagent calibrated with AK-Calibrant.



For Calibration Unit 1 **'Normal'** is selected and the **'Details'** button is clicked.

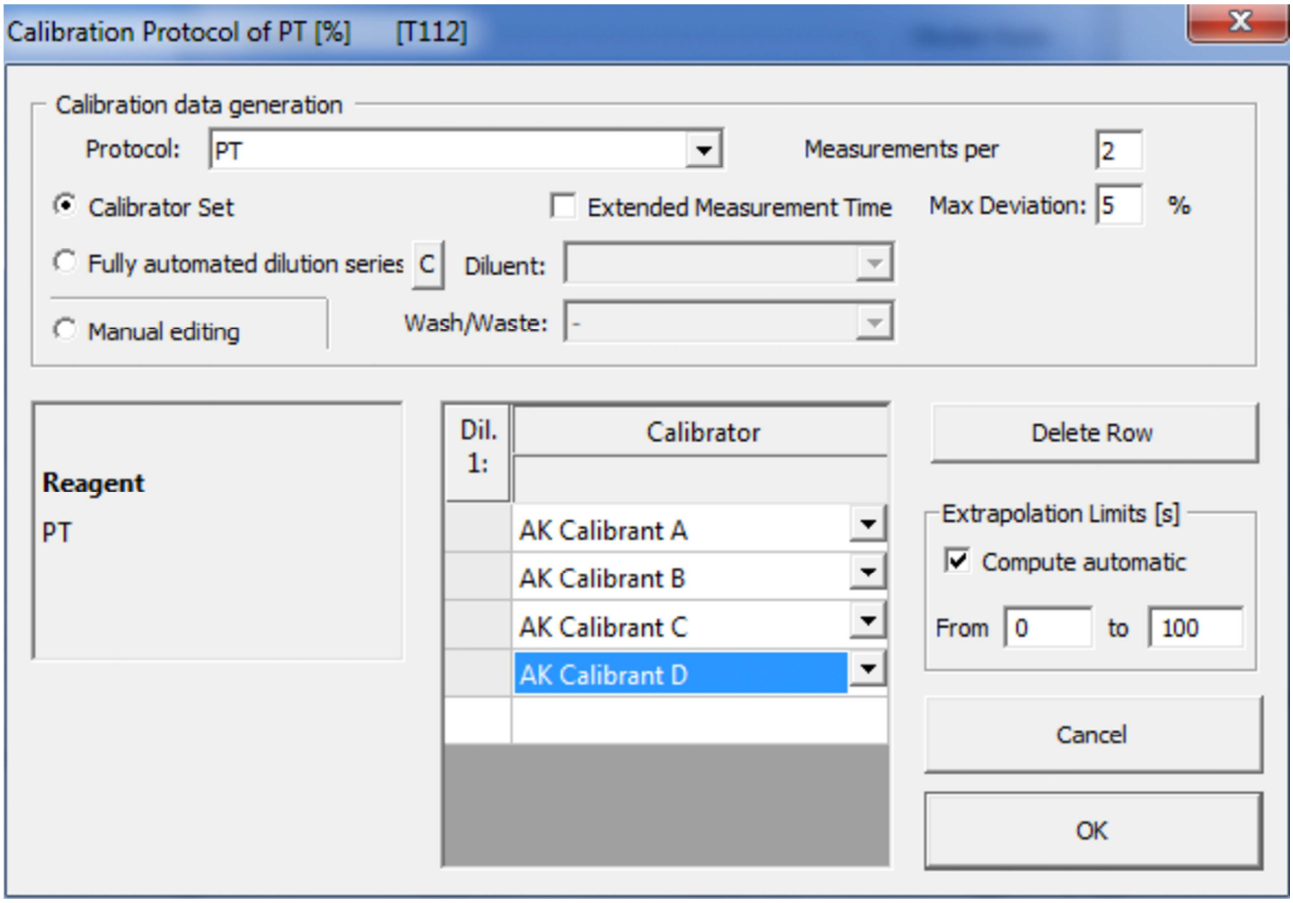


In the **'Calibration Unit'** window the initial settings are entered.

These settings include

- calibrated Unit (either using the dropdown menu or entering a unit)
- transformations of the X- and Y-axis (note that the abbreviation is always called **'x'** both on X- and Y-axis)
- Interpolation method to generate the calibration curve
- Minimal requirement of R2 for validation
- The maximal time until re-calibration as **'Calibration Curve valid for'**

To further define the calibration protocol, click the **'Protocol'** button.

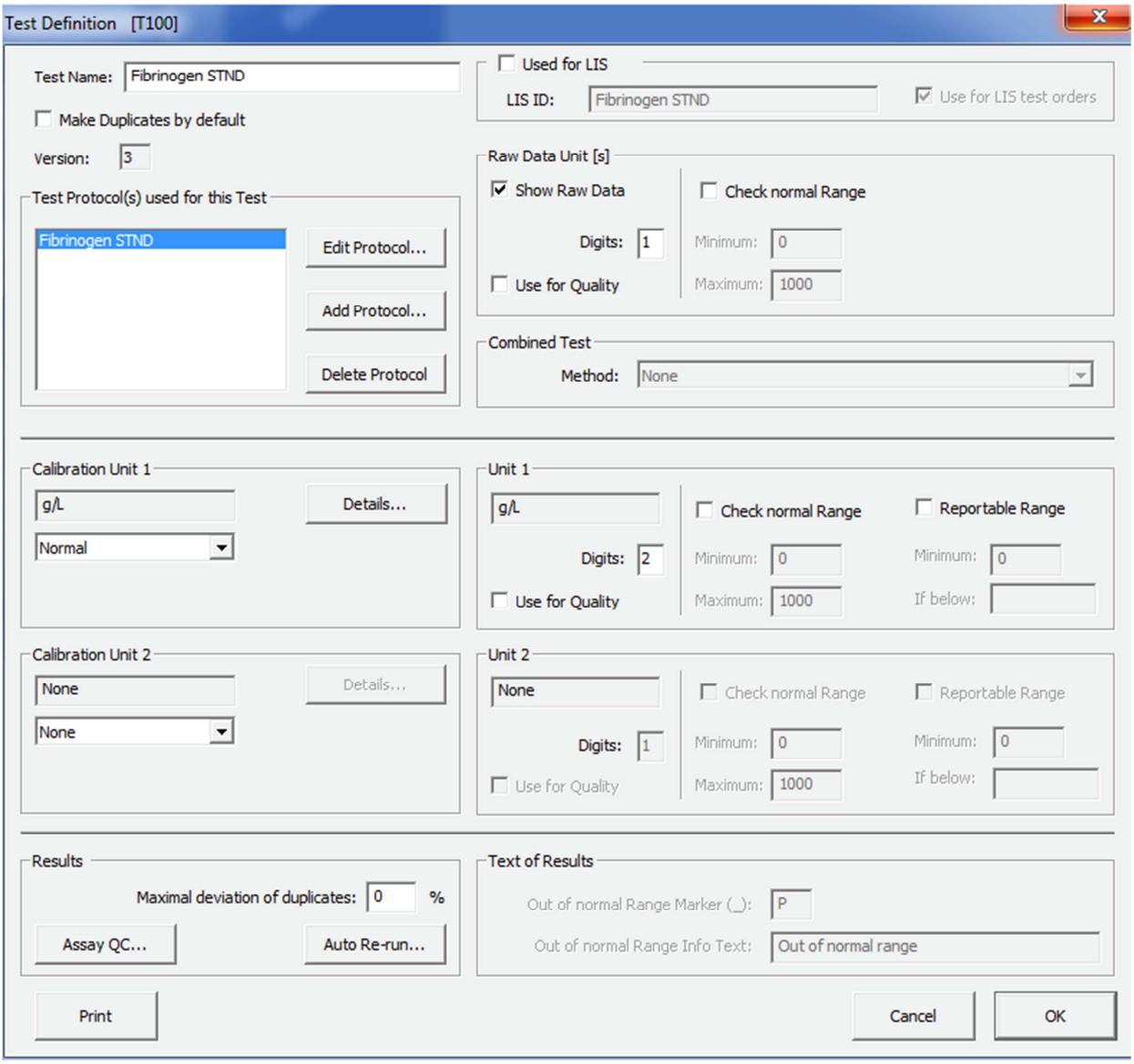


In the **'Calibration Protocol**' window the calibrator settings can be altered. Select **'Calibrator Set'** and adjust settings concerning the maximal allowed deviation for replicates and the number of replicates per calibration point should be performed.

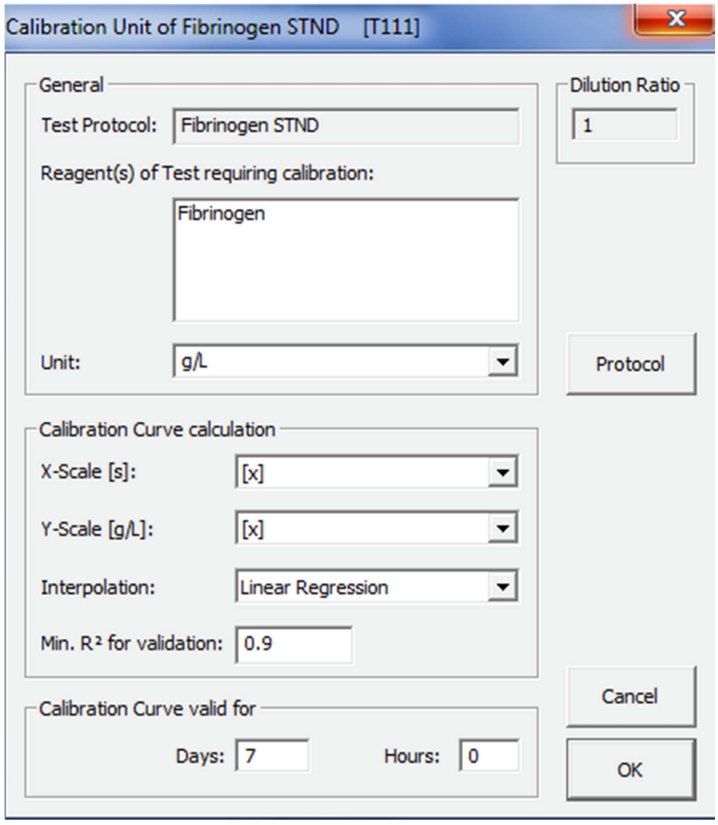
In the **'Calibrator'** list select the individual calibrators using the drop-down menu. Click **'OK'** to confirm and close the window.

Calibration with single Calibrator

As an example for a calibration using a single calibrator, we chose a fibrinogen reagent calibrated with Coagulation Reference.



For Calibration Unit 1 **'Normal'** is selected and the **'Details'** button is clicked.

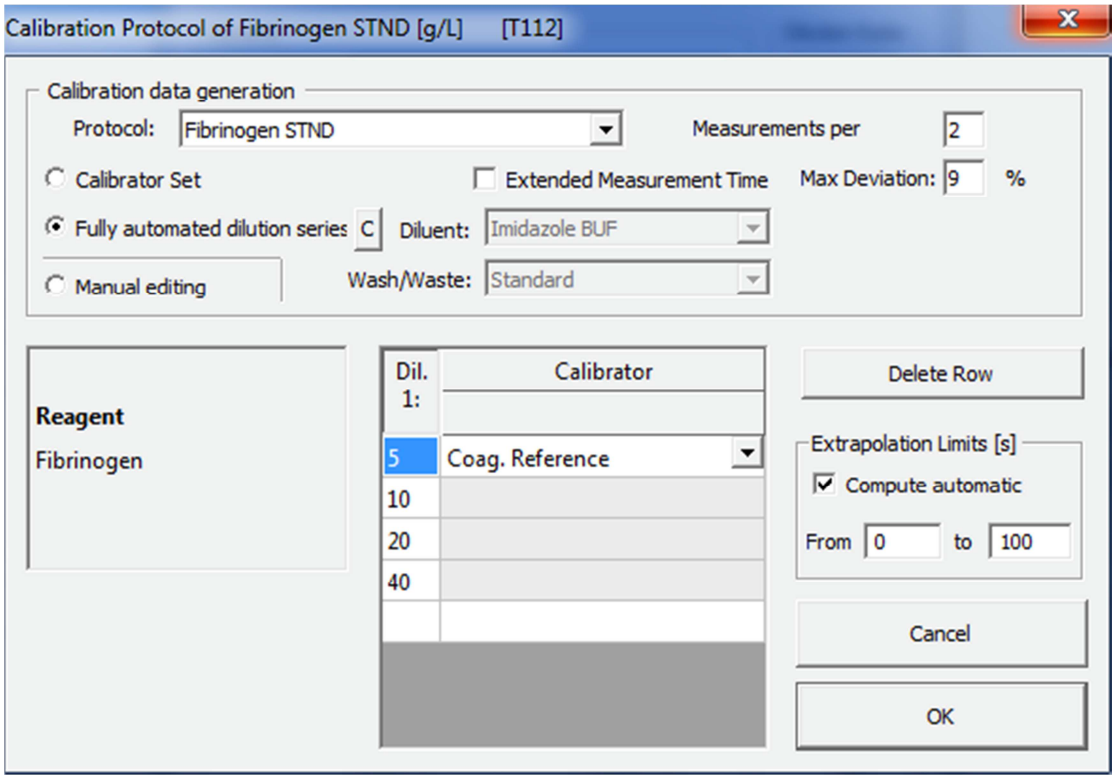


In the **'Calibration Unit'** window the initial settings are entered.

These settings include

- calibrated Unit (either using the dropdown menu or entering a unit)
- transformations of the X- and Y-axis (note that the abbreviation is always called **'x'** both on X- and Y-axis)
- Interpolation method to generate the calibration curve
- Minimal requirement of R2 for validation
- The maximal time until re-calibration as **'Calibration Curve valid for'**

To further define the calibration protocol, click the **'Protocol'** button.



In the **'Calibration Protocol**' window calibrator settings can be altered.

Select **'Fully automated dilution series'** and adjust settings concerning the maximal allowed deviation for replicates and the number of replicates per calibration point should be performed. Additionally, for calibrator dilutions define the **'Diluent'** used and what wash method to use during preparation of dilutions.

In the **'Calibrator'** list select the calibrators using the drop-down menu. In the column titled **'Dil 1:'** select the dilutions used to generate the calibration curve. Remember to be aware of potential sample pre-dilutions! If samples are pre-diluted 1:10, a calibration starting at 1:1 would begin 10-fold concentrated.

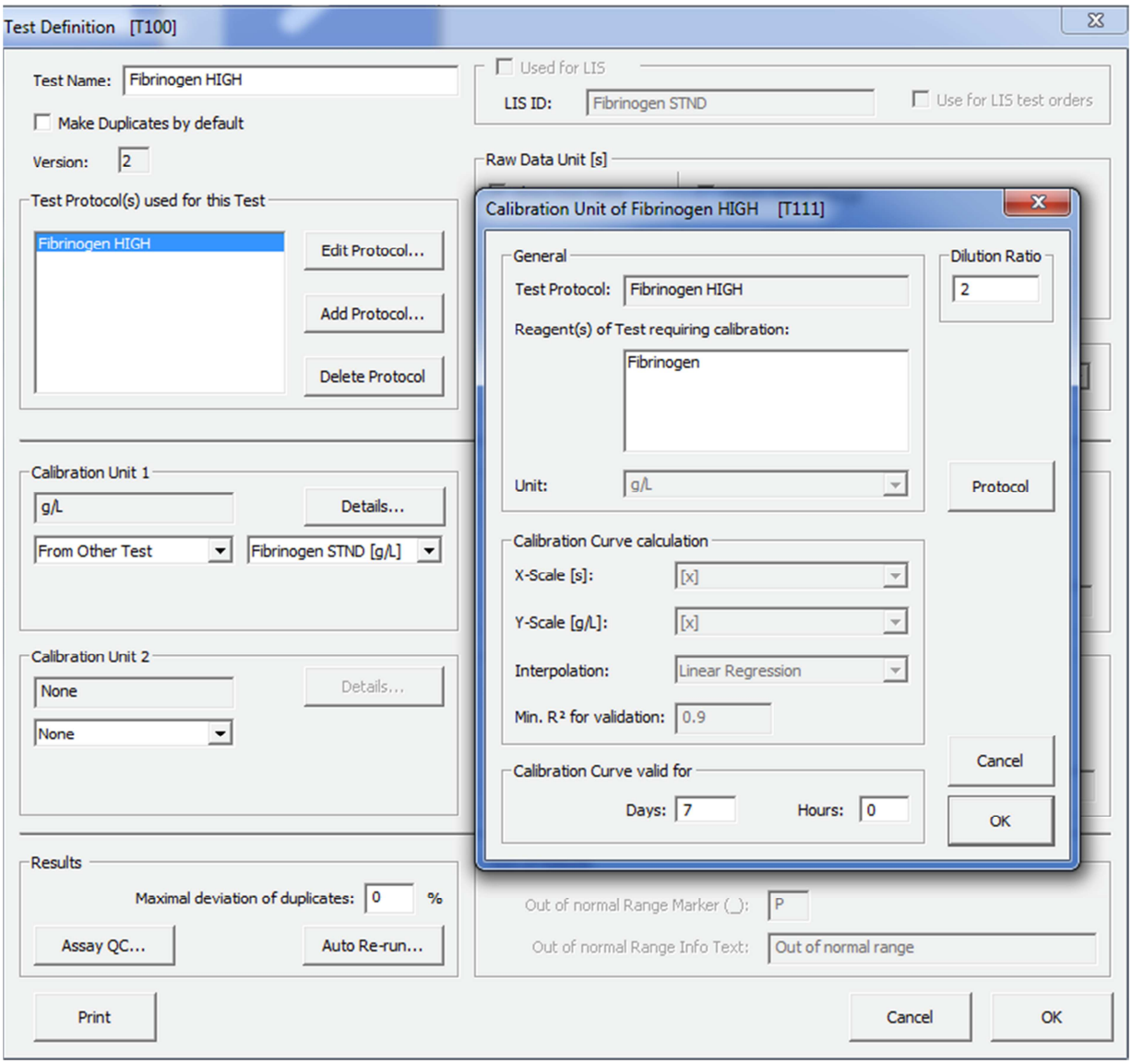
Click **'OK'** to confirm and close the window.

Calibration ‘From Other Test’

Using the calibration **‘From Other Test’** option, a test uses a calibration curve from another test. This can be useful, when generating test or variants of test using different sample pre-dilutions.

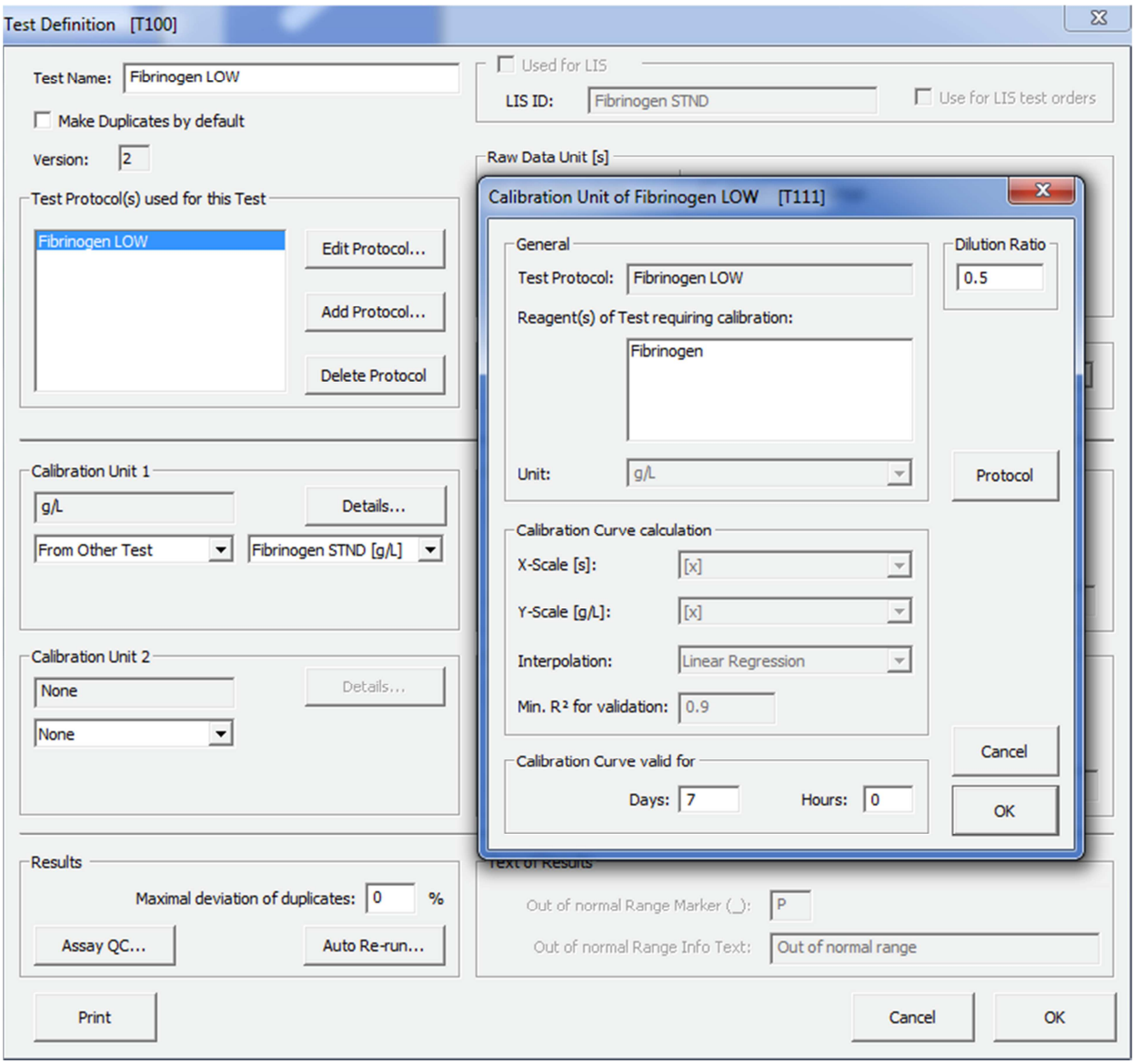
For example, a diluted fibrinogen test according to Clauss uses a 1:10 pre-dilution of the sample. Samples with very high or very low fibrinogen concentration will not be tested adequately. A different sample pre-dilution, helps measuring these samples accurately.

For samples with high fibrinogen concentration a variant of the fibrinogen test is created, but changing the sample dilution to 1:20. Using the same calibration curve as performed for the standard test.



In the **‘Calibration Unit’** window the **‘Dilution Ratio’** of the new variant needs to be change to **‘2’** accordingly, as the difference between the high range variant 1:20 and the standard 1:10 is 2-fold.

In line, for samples with low fibrinogen concentration a second variant of the fibrinogen test is created, but changing the sample dilution to 1:5. Using the same calibration curve as performed for the standard test.



In the **'Calibration Unit'** window the **'Dilution Ratio'** of the second variant needs to be change to **'0.5'** accordingly, as the difference between the low range variant 1:5 and the standard 1:10 is 0.5-fold.

Building a Ratio

To report a ratio between two tests, two **'Test Protocols'** need to be present in one **'Test Definition'**.

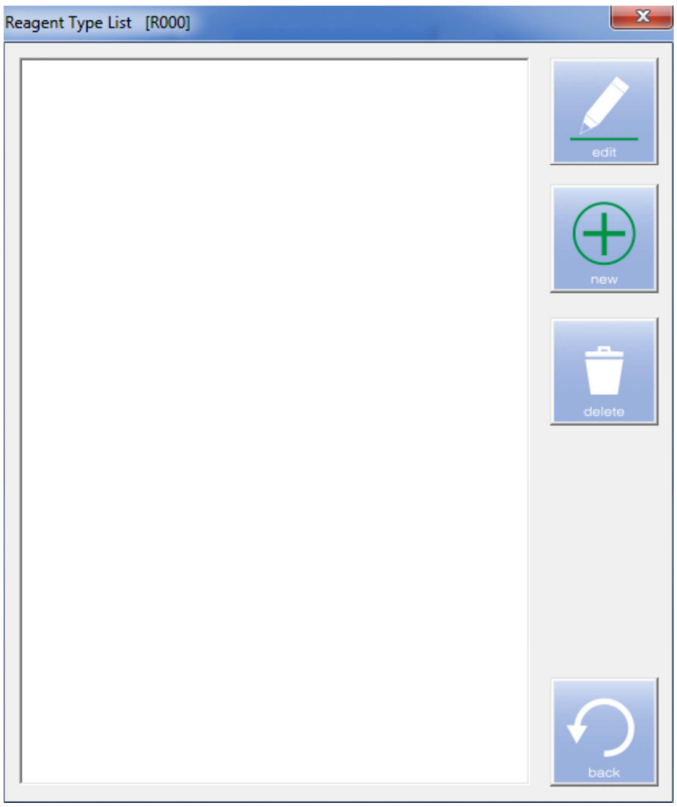
This can for example be testing a sample with two different reagents and building a ratio between the raw results.

Select **'Ratio'** for **'Calibration Unit 1'**.

In the **'Combined Test'** field select **'Ratio'** (1st Test Prot. / 2nd Test Prot.)

4.2.13.2 Reagent Definitions

In this menu, all stored reagents are displayed. Reagents include calibrators, In User controls and auxiliaries.

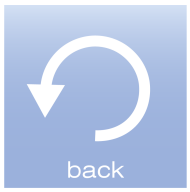


Description of buttons

View or edit an existing reagent definition.

Add a new reagent.

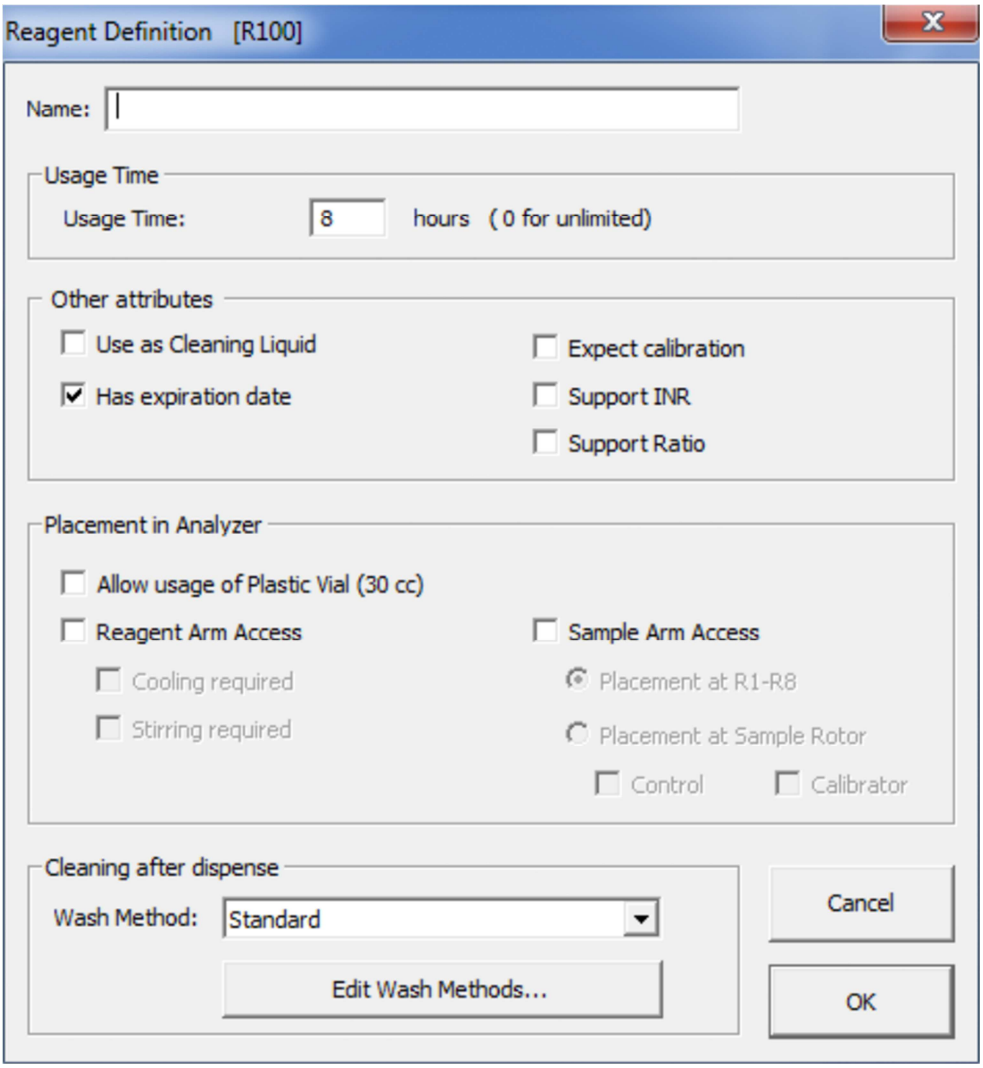
Delete an existing reagent.



Close the Reagent Type List.

Adding a new reagent

To add a new reagent, press the **'new'** button.

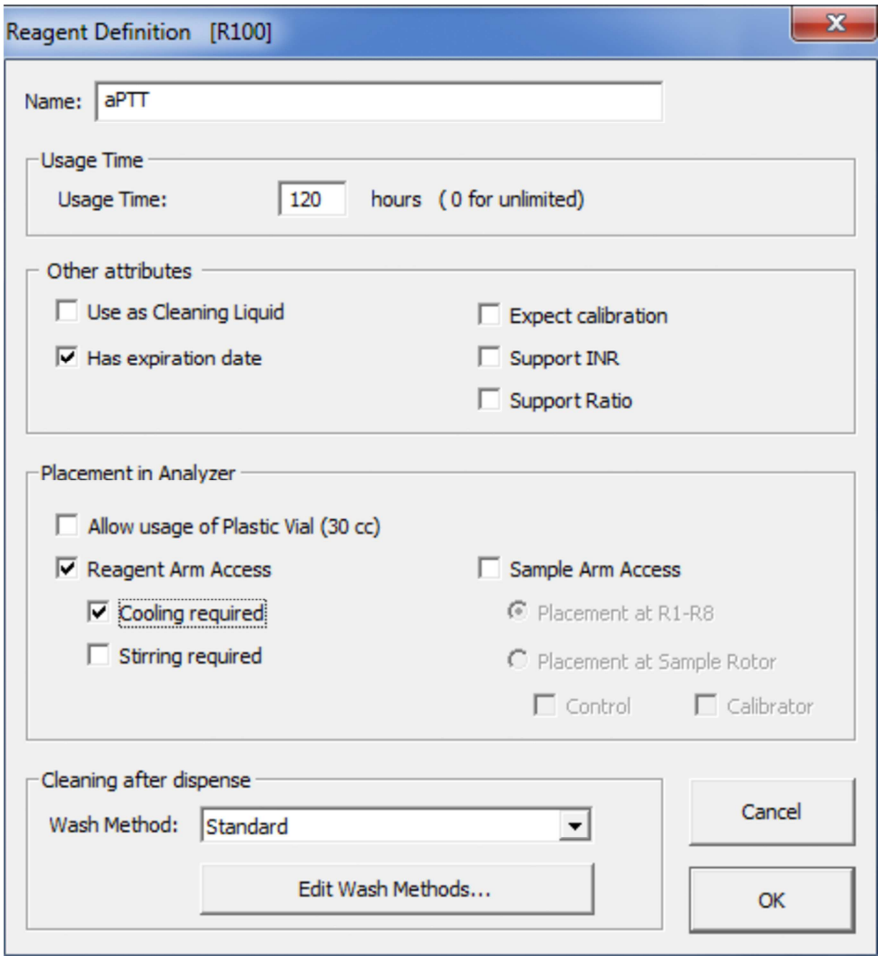


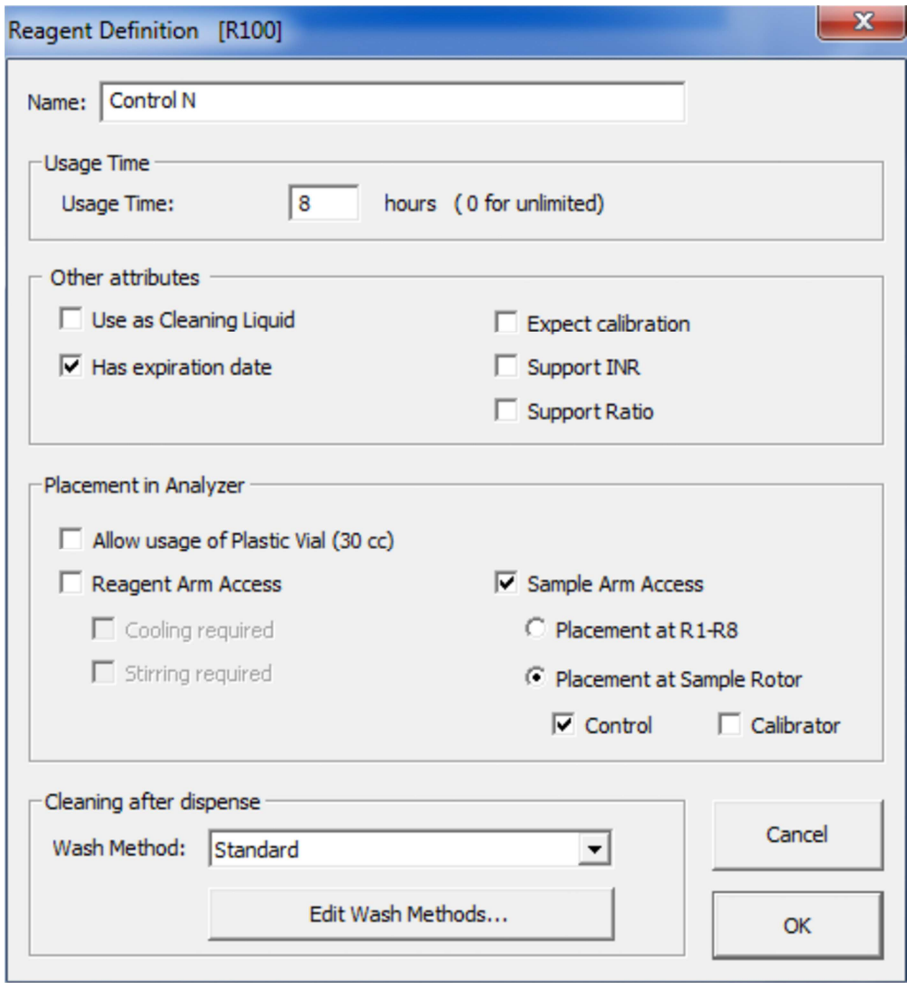
Enter the **'Name'** of the reagent to be added.

Modify the definition according to the reagent specifications, which should include:

- Usage time (on board at the given temperature, ambient temperature or cooled position depending on location on the instrument)
- General attributes
    - Is it a cleaning liquid?
    - Expiration date
    - Does the reagent require calibration?
    - Is it a PT reagent supporting INR?
    - Is it required to build a ratio?
- Placement in the instrument
    - Reagent or sample arm
    - In 30cc plastic vials?
    - Cooling required
    - Stiring required
    - To be placed in the Sample rotor
    - Is it a Control or Calibrator
- What washing method should be used after dispensing

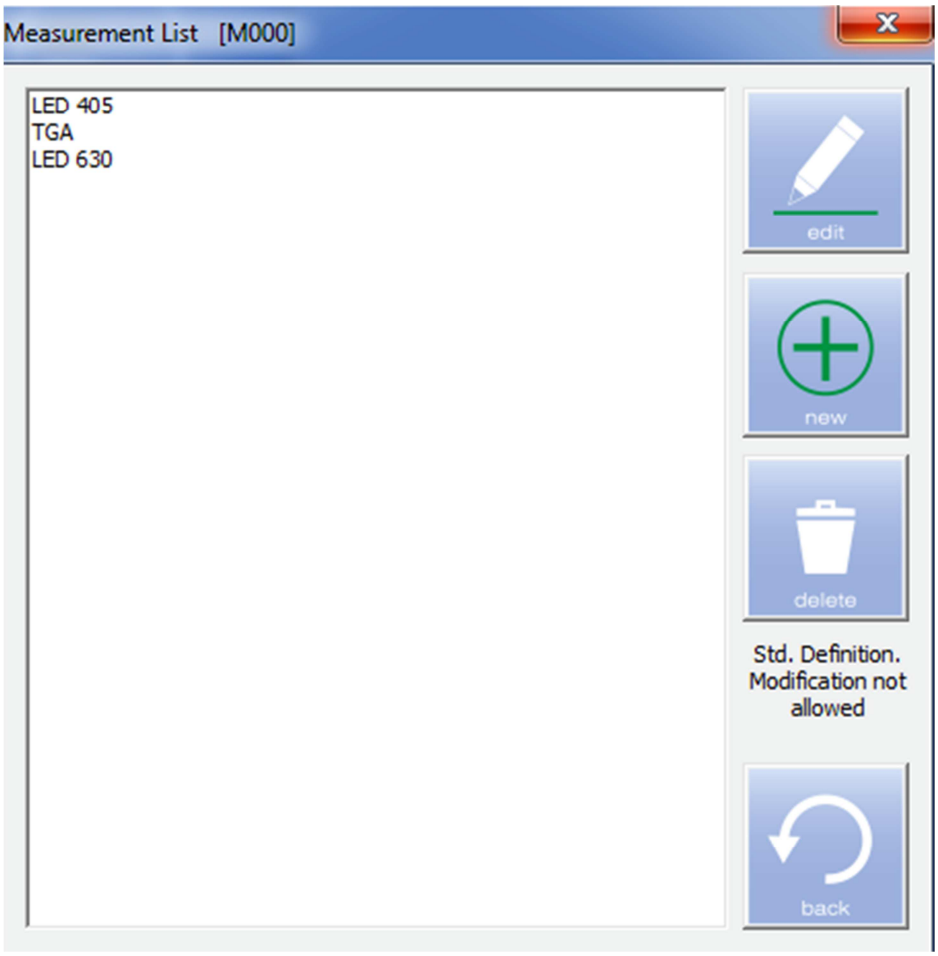
An aPTT and control plasma is shown as example below.




Reagent Definition [R100]
Name: Control N
Usage Time
Usage Time: 8 hours (0 for unlimited)
Other attributes
Use as Cleaning Liquid
Has expiration date
Expect calibration
Support INR
Support Ratio
Placement in Analyzer
Allow usage of Plastic Vial (30 cc)
Reagent Arm Access
Cooling required
Stirring required
Sample Arm Access
Placement at R1-R8
Placement at Sample Rotor
Control
Calibrator
Cleaning after dispense
Wash Method: Standard
Edit Wash Methods...
Cancel
OK

4.2.13.3 Measurement Methods

In this menu, all stored Measurement methods are displayed.



Description of buttons

View or edit an existing measurement method.

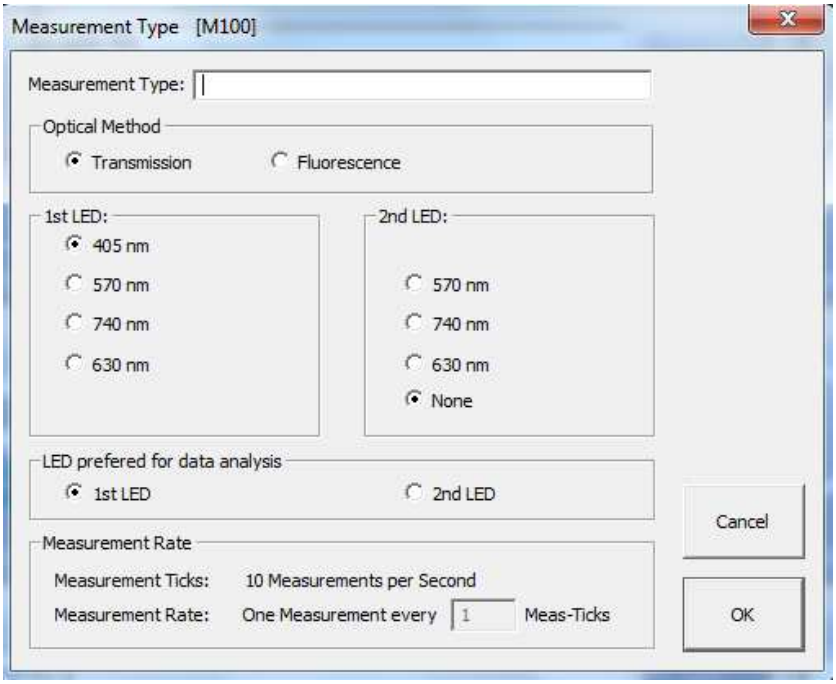
Add a new measurement method.

Delete an existing measurement method.

Close the measurement list.

Add a Measurement Type

To add a measurement method, press the '**new**' button.

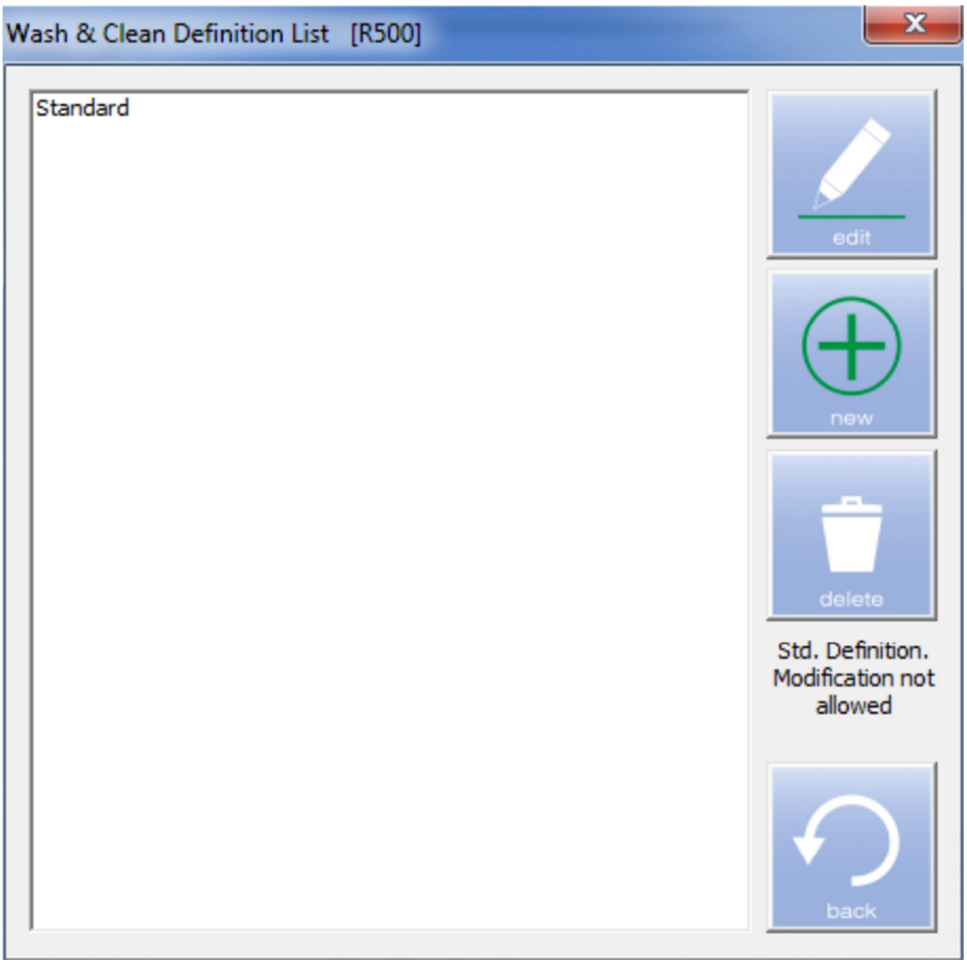


Enter the Name of the new method next to **'Measurement Type'** and select

- Optical Method
- 1st and 2nd LED
- preferred LED for data analysis
- Measurement rate

Press **'OK'** to confirm and close the window.

4.2.13.4 Wash Methods

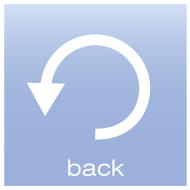


Description of buttons

View or edit an existing wash method.

Add a new wash method.

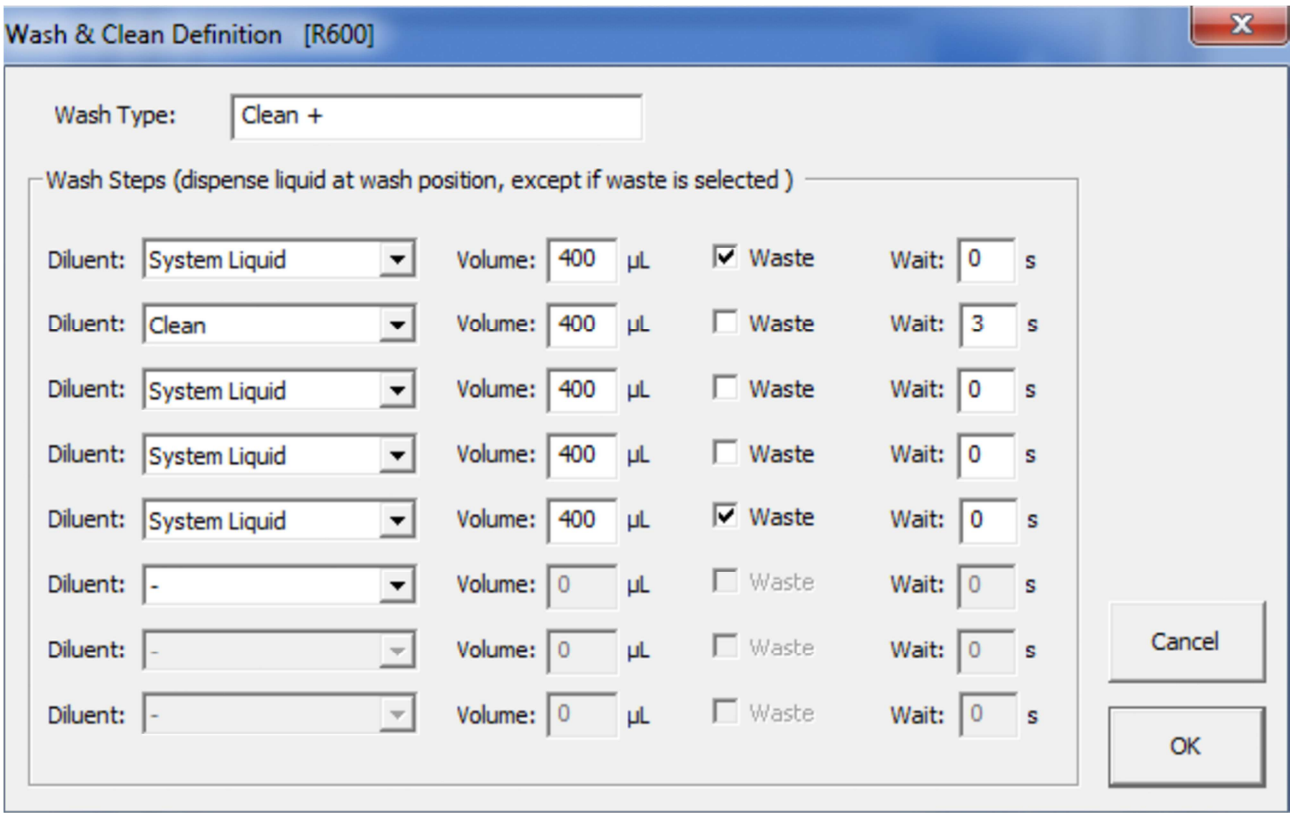
Delete an existing wash method.



Close the Wash & Clean Definition List.

Add a Wash Definition

To add a new wash method, press the **'new'** button.

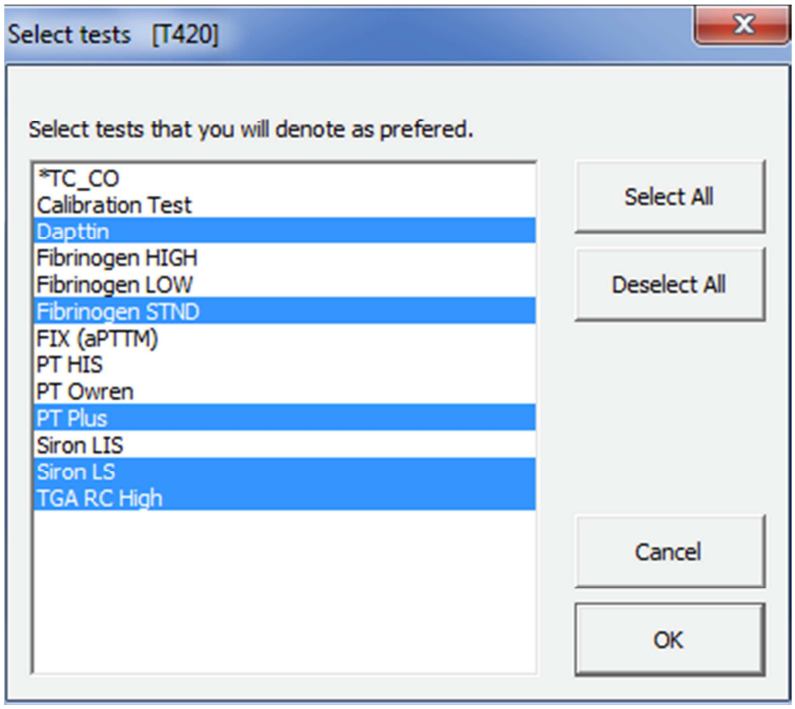


Enter the Name of the new method next to **'Wash Type'** and define the washing steps to be performed for this method.

- Select the liquid to be cleaned or washed with (System liquid or a previously defined cleaning liquid)
- Select the volume to be cleaned with
- Select whether to dispense into the wash position or the waste
- Select holding or wait time

Press **'OK'** to confirm and close the window.

4.2.13.5 Preferred Tests

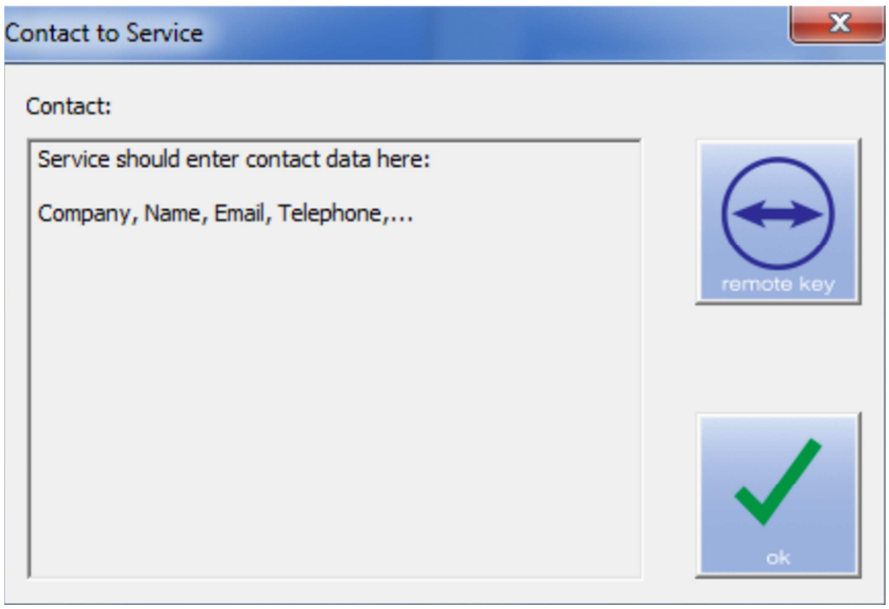


Preferred Tests option is used to shorten the list of test for routine use, when selecting a test for sample measurement. Simply click on the test to select or de-select.

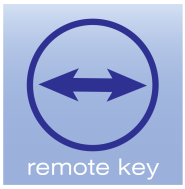
Press **'OK'** to confirm and close the window.

4.2.14 Contact

Clicking the **"Contact"** icon, opens the window to contact Ceveron service.



Description of buttons



Opens TeamViewer.

Windows will open Security Settings.

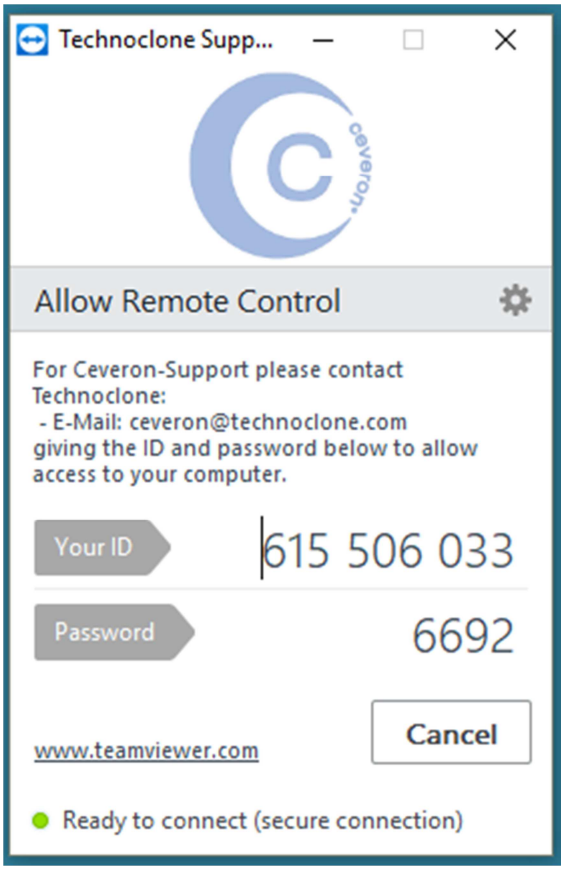
Remote access

In order to give technical support access to your PC and the CEVERON software, press the **'remote key**' button.

TeamViewer software will launch.

Some security confirmation by Microsoft might be necessary.

Loading the TeamViewer software might take a while.



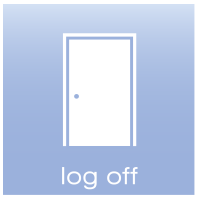
Provide your local CEVERON Support or Technoclone with the ID and the password generated, so that technical support can access your computer using a secure connection.

Press **'Cancel'** to interrupt the connection and close the remote access.

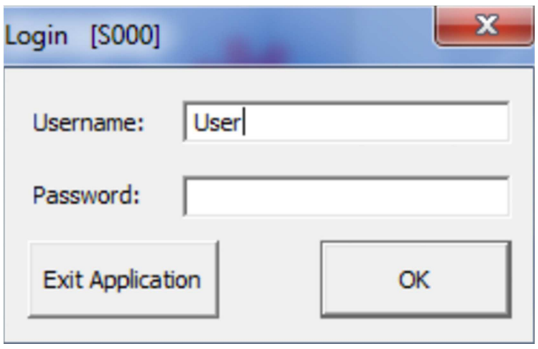
4.2.15 Manual

The **“Manual”** icon opens the user manual as a pdf document.

4.2.16 Log off



The **“Log Off”** icon immediately logs off the user and opens the window **“Log in”**.



Press the **‘Exit Application’** button to close the CEVERON software.

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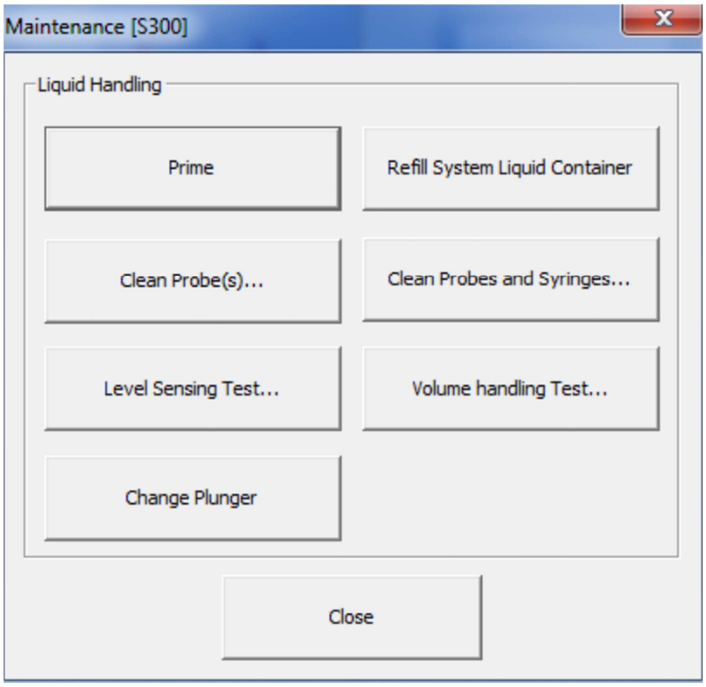
5. Maintenance and cleaning

5.1 Maintenance

The **“Maintenance”** icon opens the window **“Maintenance”**.



The following options are selectable:

- Prime
- Clean Probe(s)
- Level Sensing Test
- Change Plunger
- Refill System Liquid Container
- Clean Probes and Syringes
- Volume handling Test

5.1.1 Prime

Clicking the "**Prime**" button will automatically perform a priming procedure to sample and reagent pipettor and probe using CEVERON System Liquid.

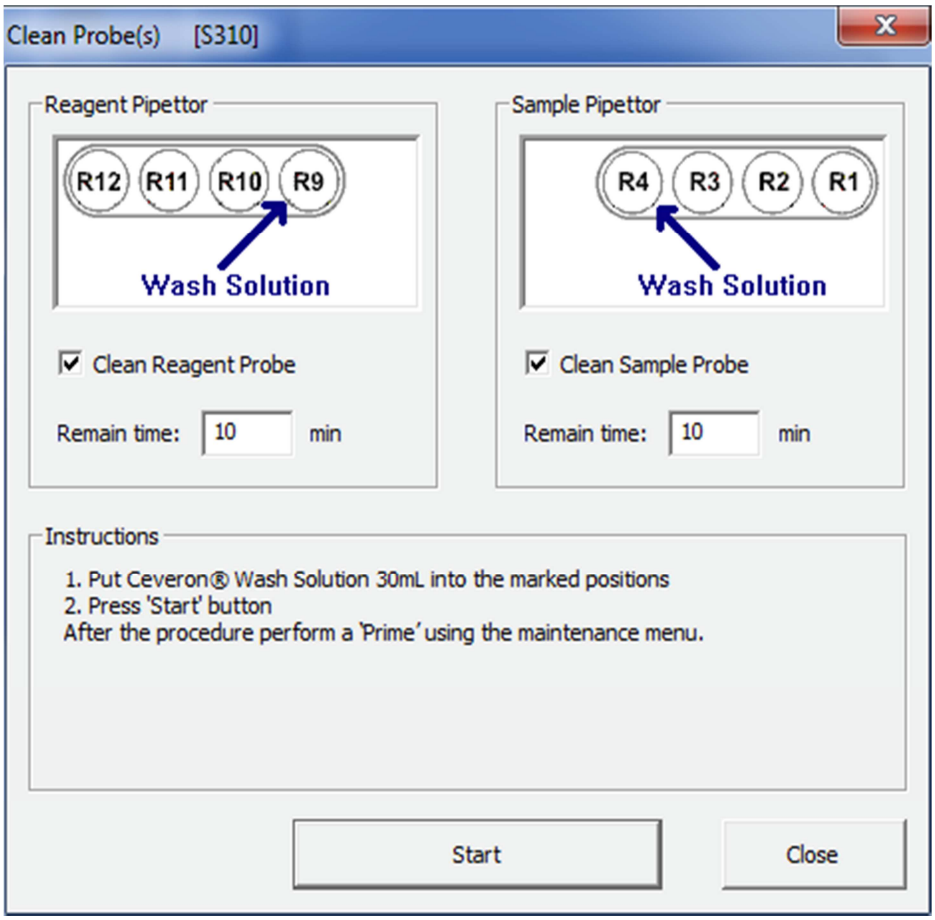
The **'Prime'** procedure is also part of the automatic maintenance schedule (see 5.3.).

A 'Prime' procedure is recommended:

- at the beginning of a working day and after start-up.
- at the end of a working day and prior shut down.
- Whenever air bubbles are seen within the tubes of one of the probes, as air bubbles may lead to inaccurate pipetting.

5.1.2 Clean Probes

Click **"Clean Probe(s)"** in the **"Maintenance"** menu.



Using this procedure, the probes are cleaned using CEVERON Wash Solution. The remain time should be at least 10 minutes.

Place a CEVERON Wash Solution (30ml), in position R4 for the sample probe and in position R9 for the reagent probe.

Press the **'Start'** button to initiate the procedure.

After completing the clean probe step, perform a **'Prime'** procedure from the maintenance menu.

A '**Clean Probe** procedure is recommended:

- at least once a week for both sample and reagent probe.
- whenever abnormal imprecision is observed.

5.1.3. Level Sensing Test

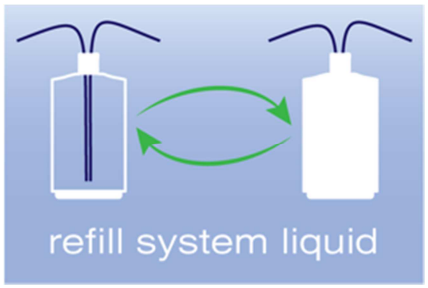
Level sensing test is for service purpose only.

5.1.4. Change Plunger

After clicking "Change Plunger" the SW asks you to remove the tubes from system liquid container and press ok.
After that, the CEVERON pumps out all the liquid from the tubes and you can change the probes and the syringes. (See Service Manual)
After changing the probe and / or the syringes put the tubes back into the system liquid container (CEVERON System Solution) and perform a prime cycle (Chapter: 5.1.1.).

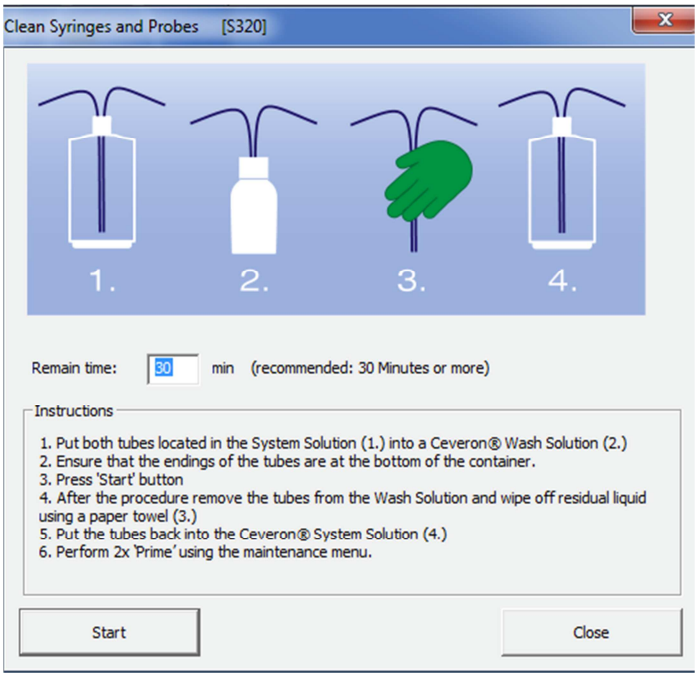
5.1.5 Refill System Liquid Container

Whenever the System Liquid container is replaced with a fresh full CEVERON System Solution container, it has to be redeemed in the software. Use this button to do so. An additional button is also available at the loading dialogue.



5.1.6 Clean probes and syringes

Click **"Clean Probes and Syringes..."** in the **"Maintenance"** menu.



Using this procedure, the whole pipettor unit (probe, tube and syringe) is cleaned using CEVERON Wash Solution. The remaining time should be at least 30 minutes.

For your convenience, a pictogram in the clean syringes and probes window describes the main steps of this procedure.

Clean probes and syringes procedure:

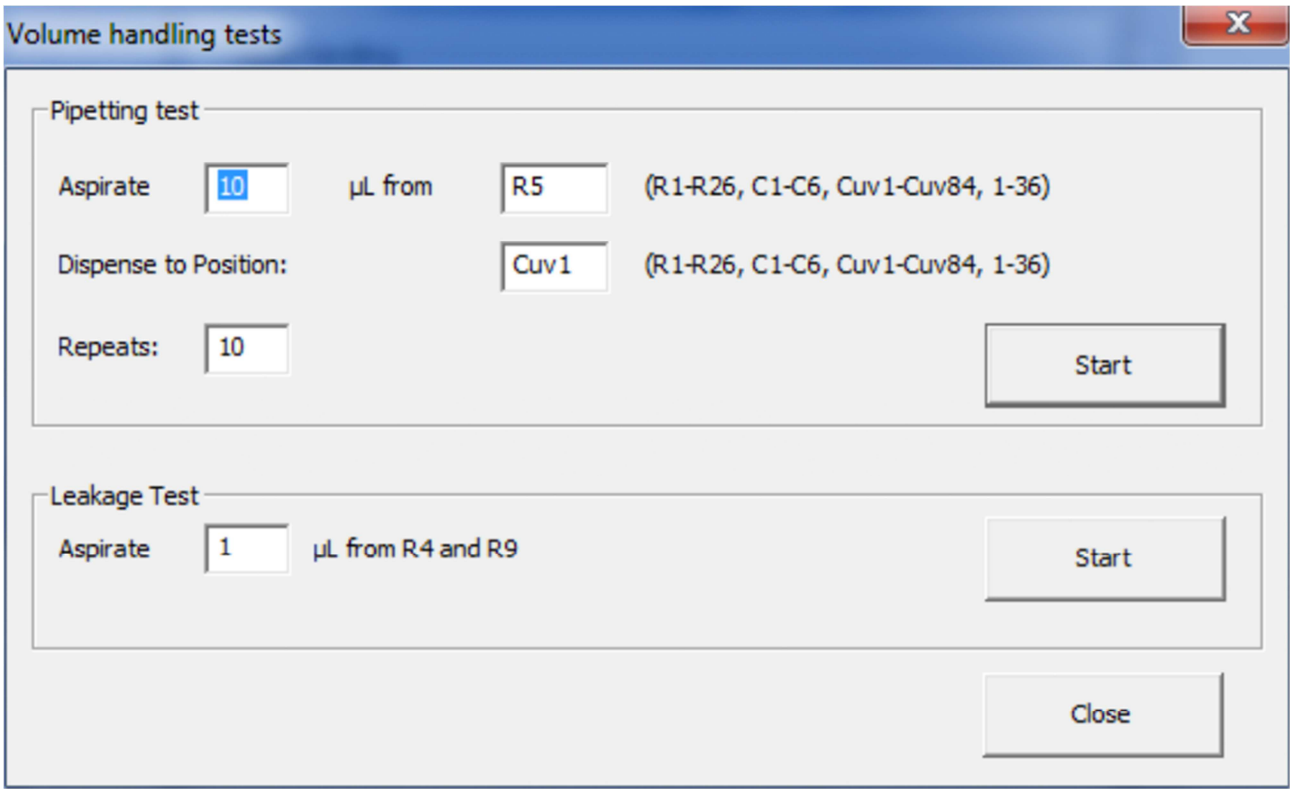
- Transfer the tubes located in the System solution Container into a CEVERON Wash Solution (30mL).
- Ensure that the endings of the tubes are at the bottom of the container.
- Use a punched screw cap to fix the CEVERON Wash Solution during the following aspiration sequence as the container might tip over or the tubes fall out.
- Press the **'Start'** button to initiate the procedure.
- After the procedure remove the tubes from the CEVERON Wash Solution.
- Using a clean paper towel remove any residual wash solution from the tubes.
- Transfer the tubes back into the CEVERON System Solution.
- Ensure that the endings of the tubes are at the bottom of the container.
- Press the **'Close'** button of this window.
- Perform 2x **'Prime'** procedure from the maintenance menu.

A '**Clean Probes and Syringes…**' procedure is recommended:

- At least once per month
- Prior and after, not using the instrument for an extended period (>2 weeks)

5.1.7 Volume handling test

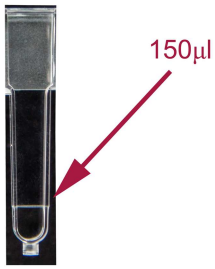
Click **"Volume handling test"** in the **"Maintenance"** menu.



5.1.7.1 Pipetting test

The pipetting test is used to check the correct volume at pipetting liquids.

With the settings made in the '**Pipetting test**' menu, CEVERON 100 series instrument will pipette a defined amount of liquid from a defined vessel in position into a second vessel in another position.



It is not recommended to use smaller volumes than 10µl.

Please be aware, that only certain areas are accessible for each probe.

- For sample probe (R1 - R8, Cuv1 - Cuv84, sample position 1 - 36, C1 - C6)
- For reagent probe (R9 - R26, Cuv1 - Cuv84)

The whole pipetting sequence is repeated according to the settings.

As a read out it is recommended to use a precision balance, before and after the pipetting and calculate the pipetted volume considering the density of the liquid.

For a quick visual estimation, pipetting of 150 µl (e.g. 15 µl with 10 repeats) into a cuvette can be employed as the CEVERON 100 series cuvettes include a mark at approximately 150 µl.

5.1.7.2 Leakage test

A leak test is performed to ensure that the pipetting system is air tight and thus very unlikely to have any leakage ensuring optimal pipetting performance.

Before starting the leakage test replace the Ceveron System Solution with a 750 mL PE bottle filled with aqua dest. and prime twice!

A vessel containing distilled water is placed on either side (in R4 for the sample arm, in R9 for the reagent arm). Please ensure that a clean vessel is used as contamination with e.g. detergents change the surface tension of the liquid making the test impossible to perform.

In the **'Leakage test'** menu the volume can be adjusted. It is recommended to perform the leakage test using volumes between 5-15 µl (standard 10 µl). Upon pressing the **'Start'** button, the defined amount of water is aspirated and above the waste position only dispensed partly. A small droplet should be visible at the tip of both probes. After finishing the pipetting carefully open the instrument cover to confirm that the droplets are still at the tip of the probes. A stable droplet confirms the leak tightness of the pipettors.

A leak test should always be performed after manipulating (e.g. exchanging the probes, the syringes, or the tubing) on the pipettor. A refill of the system solution does not require a test for leakage.

Trouble shooting:

- If no droplet is visible after the dispensing
    - ensure that the probe is filled with system liquid.
    - all air bubbles are removed.
    - perform a **'Prime'** procedure using the maintenance menu.
- If the droplet immediately falls off after partial dispensing
    - ensure that water in a clean vessel use used to perform the test.
    - loosen and re-tighten (hand tight) fixation screw for the probe.
    - loosen and re-tighten (hand tight) the connector (probe tube to syringe valve).
    - after manipulation perform 2x **'Prime'** procedure using the maintenance menu.

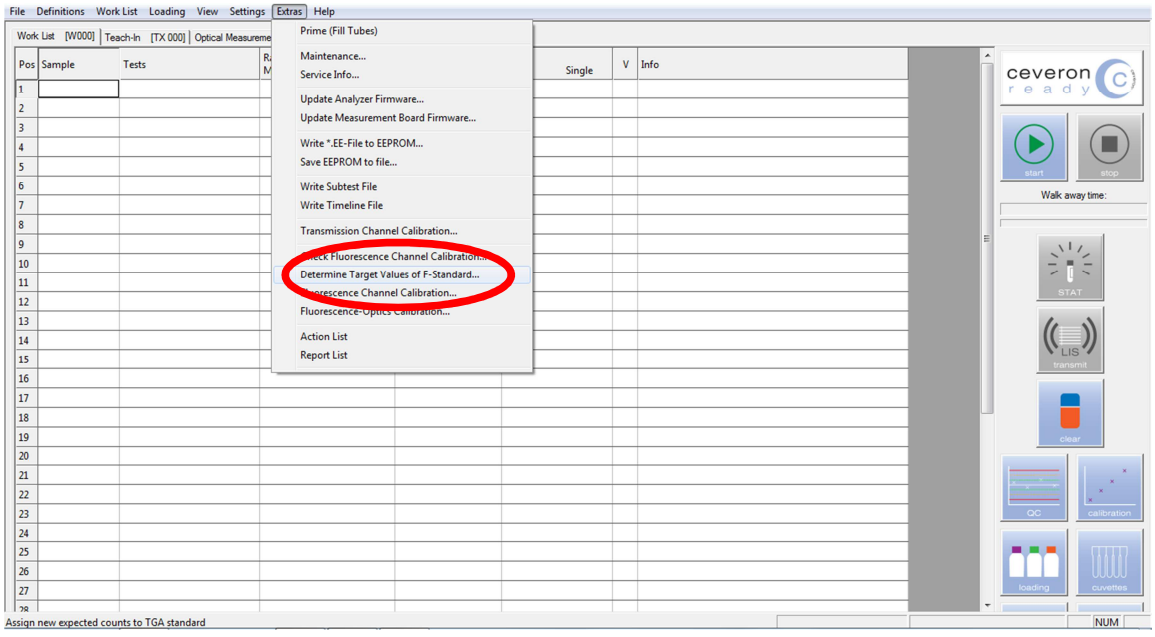
5.2. F-Standard (CEVERON t100; CEVERON s100)

The F-Standard provides a tool for maintenance and quality control of the fluorescence optic.

The F-Standard, is shaped like a cuvette segment and has to be placed into cuvette segment G position for all further applications. As fluorescence measurement is extremely dependent on temperature, it is important that the F-Standard reaches 37 °C.
To achieve optimal temperature, leave the F-Standard in the pre-heated cuvette ring for at least 10 minutes to be warmed up.

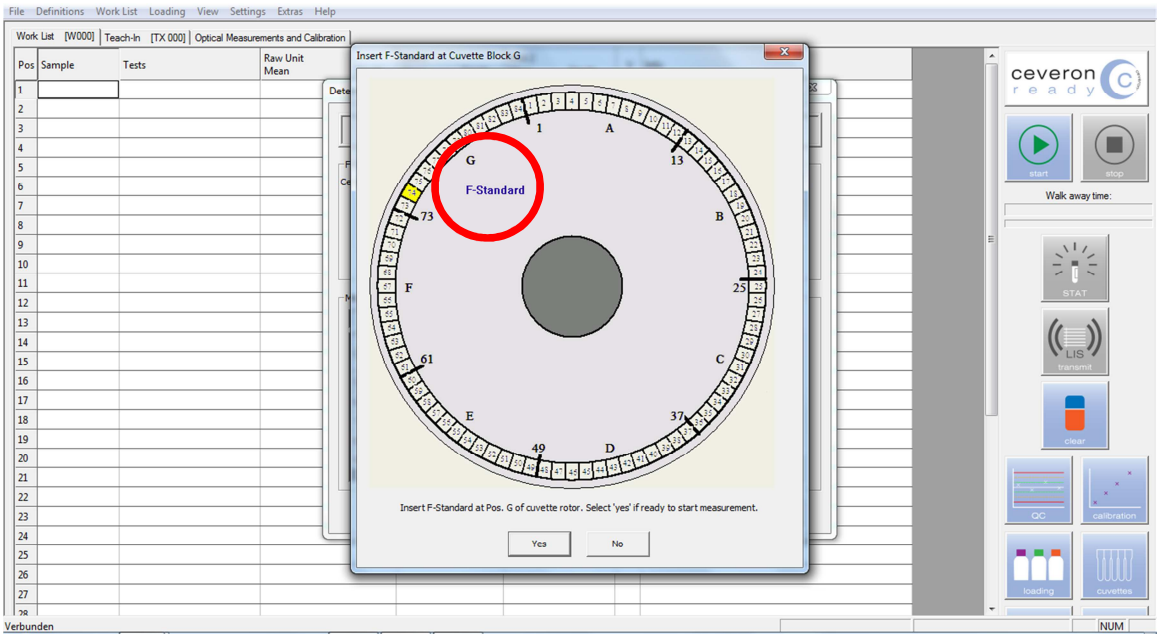
Determine target values of F-Standard

For a new F-Standard, the target values need to be calibrated into the CEVERON t100 / s100 software. Select **'Determine Target value of F-Standard'** in the **'Extras'** menu.



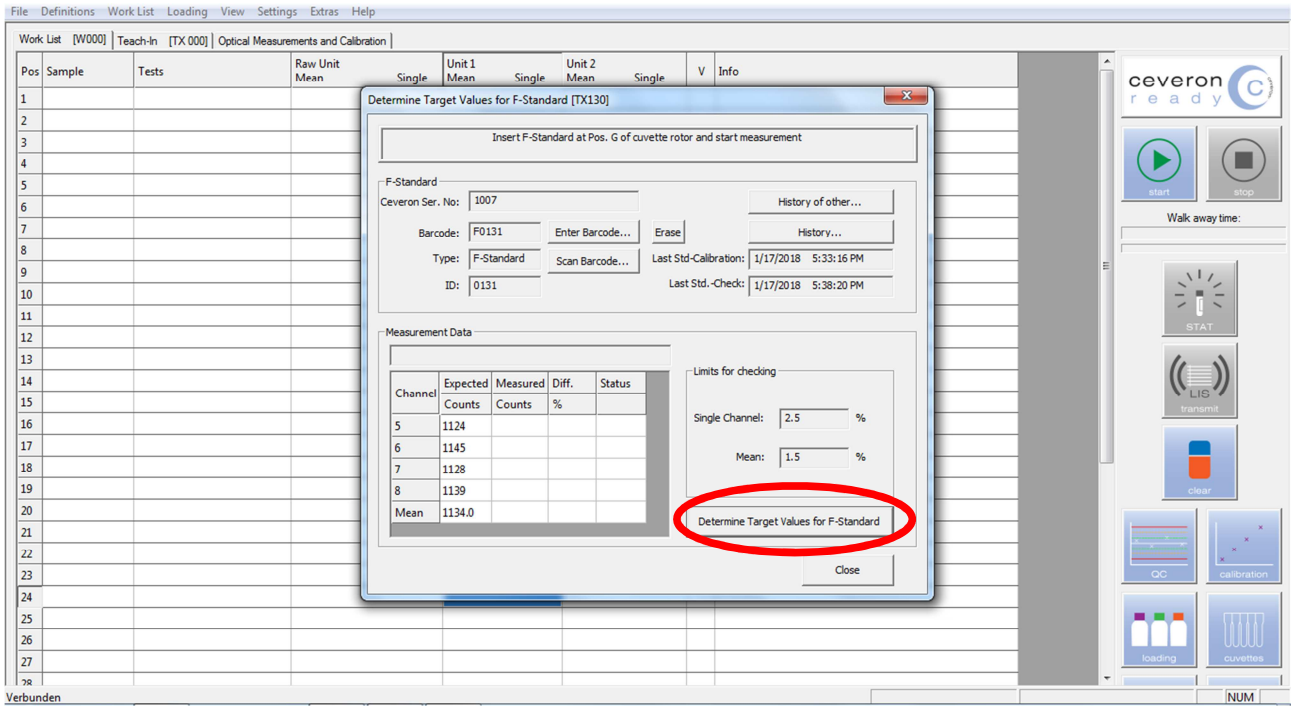
CAUTION:

The F-Standard must be warmed up at least 10 minutes in the pre-heated cuvette ring.



If this is the first F-Standard to be determined the Barcode and Type will be empty. The CEVERON t100 / s100 already switched on the reagent barcode reader. Scan the barcode on the F-Standard starting with an **'F'**.

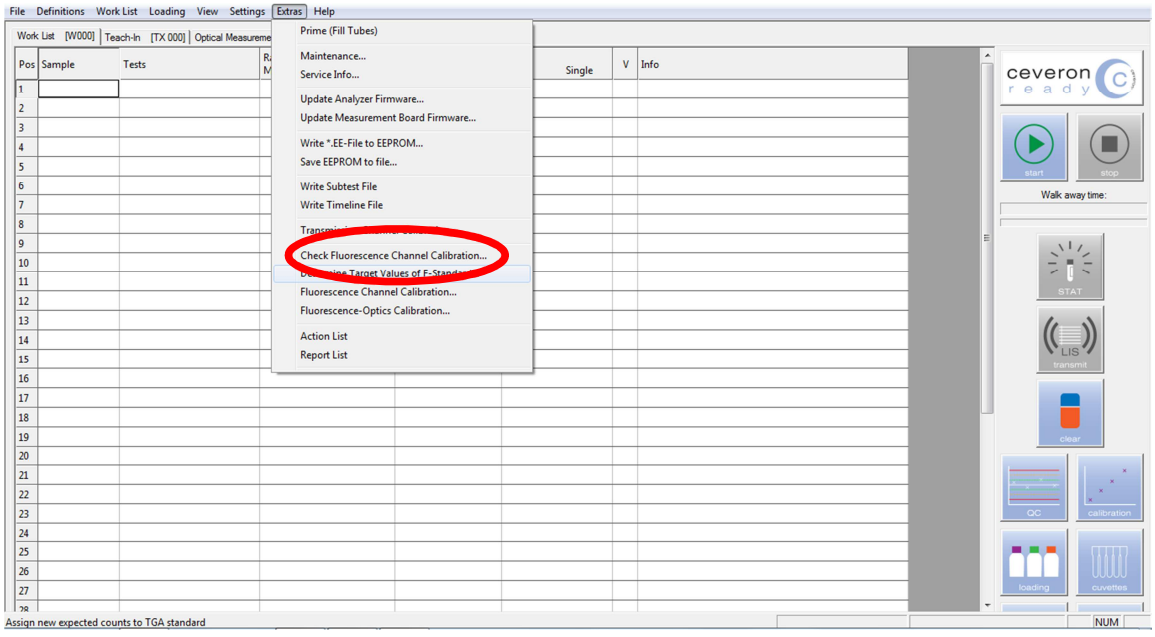
Place the F-Standard in position G of the cuvette rotor and wait for at least 10 minutes, so that the F-Standard reaches the required temperature.
Press the **'Determine Target Values for F-Standard'** button. CEVERON t100 / s100 will perform the F-Standard calibration fully automated.



Check Fluorescence Channel Calibration

The fluorescence channel calibration should be performed at least once per month to determine the quality of the fluorescence channel.

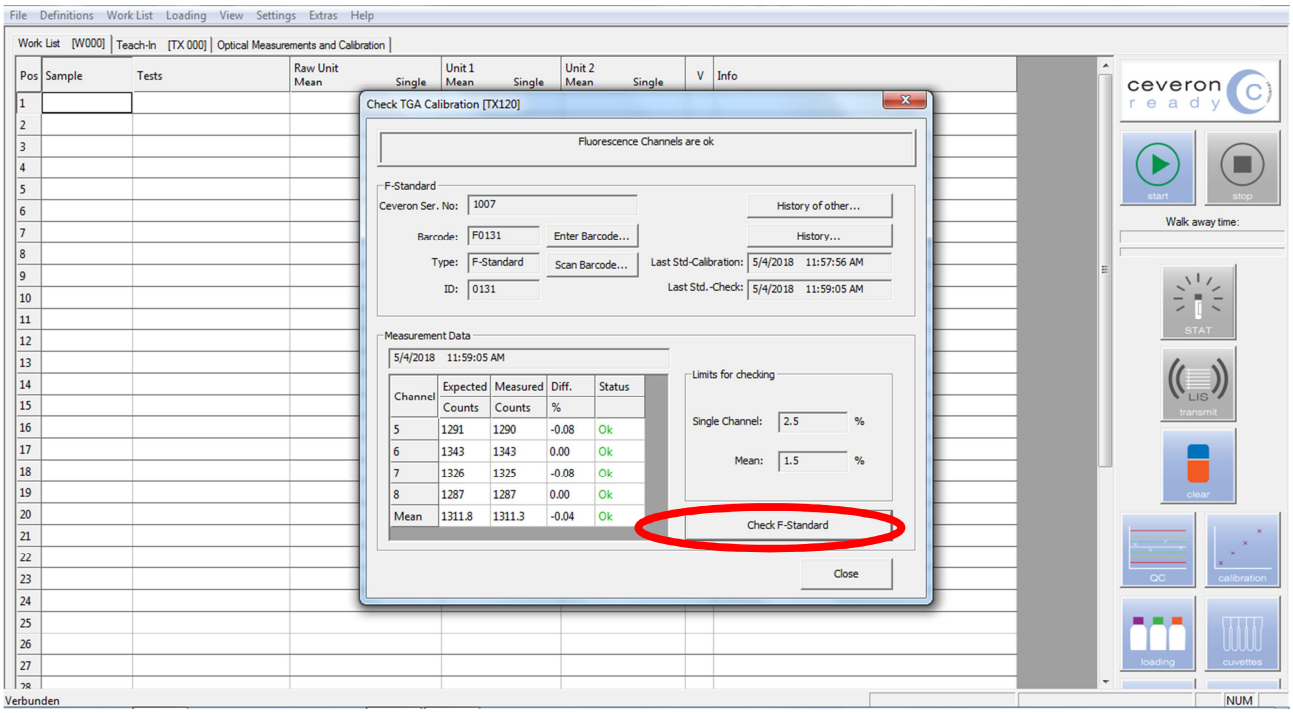
For a fluorescence channel calibration on your CEVERON t100 / s100.
Select **'CheckFluorescence Channel Calibration'** in the **'Extras'** menu.



Ensure that the F-Standard used to perform the checks is the same as the one used for determination the target values by comparing the barcode starting with an **'F'**.

Place the F-Standard in position G of the cuvette rotor and wait for at least 10 minutes, so that the F-Standard reaches the required temperature.

Press the **'Check F-Standard'** button and CEVERON t100 / s100 will perform the check fully automated. Depending on the result of the Fluorescence channel calibration your instrument will suggest further steps



Result:

All fluorescent channels are within specification and the F-Standard provides adequate results.

- No further steps necessary.

Fluorescent channels or F-Standard are out of specification

- Replace F-Standard.
- Re-determine Target values for F-Standard.
- Re-calibrate fluorescent channels (Service only).

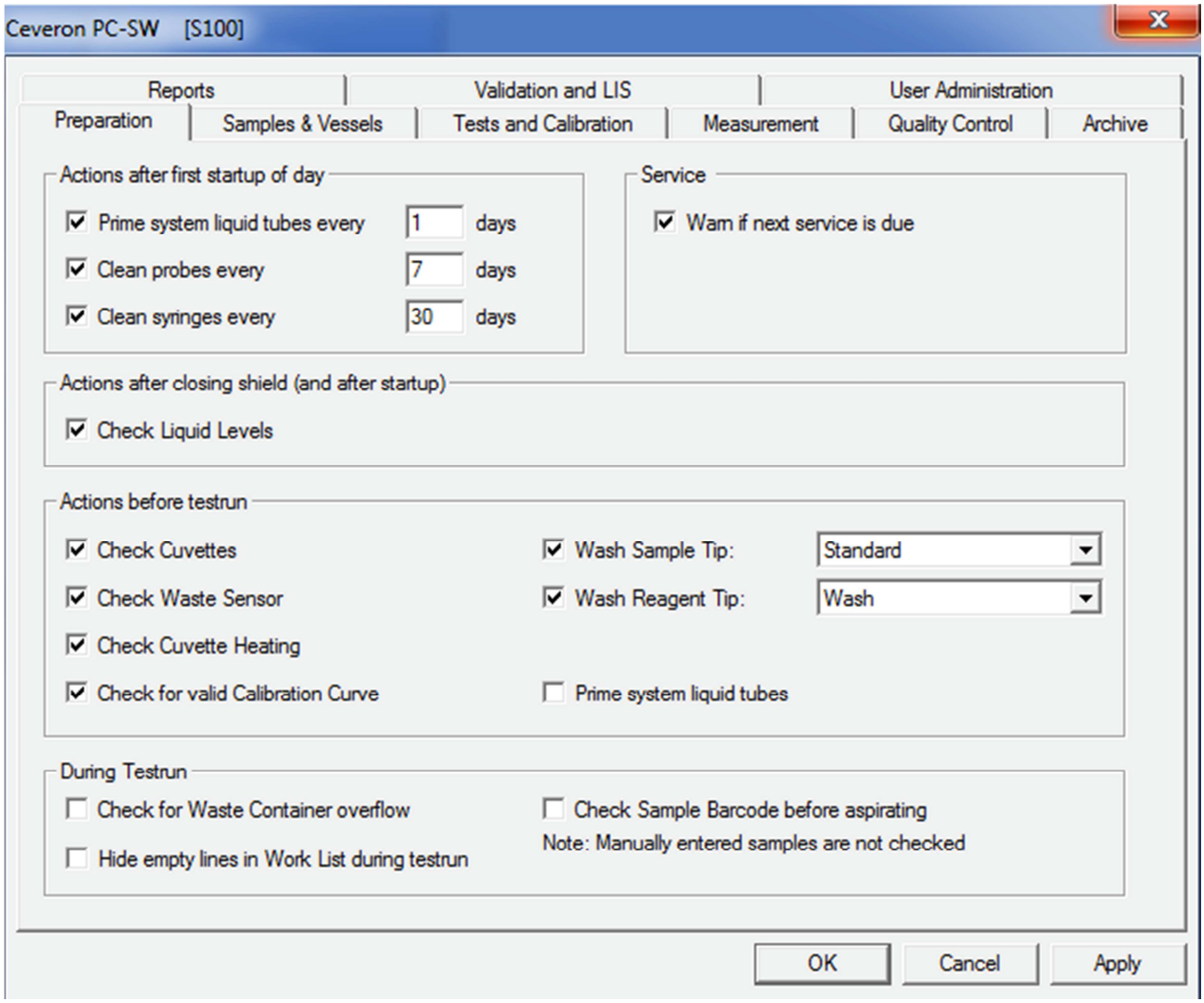
5.3. Automatic maintenance

The automatic maintenance tool helps to ensure that the minimal required maintenance actions are performed.

When appropriately scheduled, the software will prompt the user to perform the maintenance procedure upon first start-up of the day.

All maintenance actions, including their non-performance, are documented in the log book.

Within the Software Settings and the **'Preparation'** Tab the scheduling for minimal maintenance procedure can be adjusted. The default settings are depicted underneath.



5.4. Cleaning

Cleaning procedures should be performed routinely and whenever the instrument or parts of the instrument appear dirty.

Always wear protective gloves to protect from any biologically contaminated materials. **TURN OFF THE INSTRUMENT FOR CLEANING PROCEDURE**

Clean Probes	Wipe the probes with alcohol (70 %) soaked gauze downward from the arm to the tip. Do not wipe the probes upward as this may harm the isolation (reagent probe) and could lead to injuries. Ideally perform this after the 'Clean Probe(s)' maintenance procedure prior the final 'Prime' step.	Once a week
Clean surfaces	Wipe the instrument surface with moistened gauze (distilled water or diluted natural detergent) Good laboratory practices dictate that this procedure be performed as frequently as necessary, as indicated by visible blood, and at least once a day. Rubber gloves should be worn during this procedure.	Once a week
Clean liquid waste container	Drain residual liquid waste, rinse with water If necessary, rinse or soak with diluted bleach (0.5 % sodium hypochlorite) or diluted CEVERON Cleaning Solution (1 part Cleaning Solution, 5 parts distilled water) Wipe the outside of the liquid waste container and the waste tube with alcohol (70 %) soaked gauze.	Once a month

5.3 Decontamination procedure

Always wear protective gloves to protect from any biologically contaminated materials.

TURN OFF THE INSTRUMENT FOR CLEANING PROCEDURE

NOTE: Because the coagulation analyzer is in contact with all assayed samples, the surface must always be considered as contaminated areas.

Decontamination of Pipettors

This step is performed using the **'Clean Syringes and Probes'** task from the maintenance menu. However, instead of using the CEVERON Wash Solution the CEVERON Cleaning Solution (containing sodium hypochlorite) should be used. The remaining time can be reduced to 10 minutes.

Decontamination of tubing

This step is performed using the **'Prime'** task from the maintenance menu. However, similar to above the tubes (coming from the valves) located in the System Solution are transferred into a CEVERON Cleaning Solution (containing sodium hypochlorite). The priming using CEVERON Cleaning Solution should be performed three times to ensure that all tubing (including internal tubing) is rinsed with a sodium hypochlorite containing solution.

After the decontamination procedure, wipe off any residual solution from the tubes and transfer into System Solution. Repeat three prime steps using CEVERON System Solution.

Decontamination of probes

Wipe the probes with alcohol (70 %) soaked gauze downward from the arm to the tip.

Do not wipe the probes upward as this may harm the isolation (reagent probe) and could lead to injuries.

Decontamination of surface areas

All non-absorbent surface areas which may be contaminated with blood, plasma or other body fluids should be cleaned with a disinfectant, such as 1 % sodium hypochlorite solution (dilute 1 part CEVERON Cleaning Solution in 2 parts distilled water). Good laboratory practices dictate that this procedure be performed as frequently as necessary, as indicated by visible blood, and at least once a day. Rubber gloves should be worn during this procedure.

Decontamination of Liquid waste container

NOTE: The contents of the waste storage container and its associated waste line must always be considered contaminated and a source of biologically hazardous material. Avoid contact with the contents of the container or the tubing which has been in contact with the waste.

Rinse the emptied waste container with 0.5 % sodium hypochlorite solution (dilute 1 part CEVERON Cleaning Solution in 5 parts distilled water). Let take effect of bleach for a minimum of 10 minutes. Wipe off the outside of the container with disinfectant, such as 1 % sodium hypochlorite solution (dilute 1 part CEVERON Cleaning Solution in 2 parts distilled water).

Decontamination of Internal parts and mechanisms

All internal parts, mechanisms, tubing, etc., which are in contact with, or transport any portion of, the sample specimen, should be handled with caution as indicated for potentially bio-hazardous material. If these items are removed for cleaning, service or replacement purpose, they may be decontaminated with a disinfectant, such as 1 % sodium hypochlorite solution (dilute 1 part CEVERON Cleaning Solution in 2 parts water). Allow items to remain in contact with bleach for a minimum of 10 minutes. Storage of contaminated parts removed from the system should be done using the correct laboratory safety procedures for the handling of bio-hazardous material.

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6. Consumables and spare parts

6.1 Consumables

REF	Product
9820201	CEVERON 100 series System Solution 750 ml
9820300	CEVERON Cleaning Solution 3 % 25 ml
9820320	CEVERON Wash Solution 30 ml
9820328	CEVERON Wash Solution 6x30 ml
9820501	CEVERON100 series Cuvette Segments 50x12 racks
9820511	CEVERON100 series Cuvette Segments 10x50x12 racks
9820520	CEVERON Sample Cups 1000 pcs.
9830036	Punched screw cap for 30 mL bottle

6.1.1 Handling and storage conditions of consumables

6.1.1.1 Liquids

When handling with CEVERON liquids the usual precautionary measures are to be adhered to when handling chemicals. For more details please download the MSDS of the liquids at www.technoclone.com.

6.1.1.1.1 CEVERON 100 series System Solution 750 mL

CEVERON 100 Series System solution is an aldehyde free detergent solution.
It is used for maintenance of the liquid pressure of the pipetting system and cleaning of the probes between pipetting steps.
The system solution is ready to use and the expiry date printed on the labels applies to storage of the unopened bottles at room temperatures (18 … 25 C°) on a clean and dry space.

6.1.1.1.2 CEVERON Cleaning Solution 3 %, 25 mL

CEVERON cleaning solution 3% is an aqueous, sodium hypochloride solution.
It is used as decontamination of the wash stations and the tubing.
The cleaning solution is ready to use and the expiry date printed on the labels applies to storage of the unopened bottles in the refrigerator (2…8 C°).

6.1.1.1.3 CEVERON Wash solution, 30 mL or 6 x 30 mL

CEVERON wash solution is a detergent containing aqueous solution.
It is used as an additional cleaning solution for the probes at system maintenance or between pipetting steps.
The wash solution is ready to use and the expiry date printed on the labels applies to storage of the unopened bottles at room temperatures (18 … 25 C°) on a clean and dry space.

6.1.1.2 Plastics

All plastic consumable material can be stored at room temperature (18 … 25 C°). The expiry date printed on the labels applies to storage on a dry clean place.

6.2 Spare parts

REF	Product	
9820530	CEVERON Pipettor Probe 1pc	
9820532	CEVERON Heated Pipettor Probe 1pc	
9820534	CEVERON System Liquid Tube 1pc	
9820536	CEVERON Waste Tube	
9820340	CEVERON Magnetic Stir Bars 5pcs	

9820544	CEVERON Sample Tube Clip black 10pcs	
9820546	CEVERON Sample Tube Clip red 10pcs	
9820548	CEVERON1 Bottle Clip black 10pcs	
9820607	CEVERON 100 series F-Standard	
9820601	CEVERON Waste Container	

9830031	External Barcode Reader	

For ordering consumables and spare parts please contact your local distributor or Technoclone at sales@technoclone.com.

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7. Errors 2

7. Errors

Error groups

Range of numbers	Group	Description	Generator
E001 - E099	Action errors	Action execution error	Analyzer
E100 - E127	USB communication	Error in USB communication	PC
E130 - E131	Instrument data	Data stored in EEPROM are invalid	Analyzer
E132 - E151	USB communication	Error in USB communication	PC
E160	Instrument data	Data stored in EEPROM are invalid	Analyzer
E200	Start run	Appears at start if analyzer has an error	Analyzer
E201	Special run	Error during cuvette check, maintenance,…	Analyzer
E202	Test run	Stop during test run due to Bnn	Analyzer
E203	Start run	Preparing analyzer by PC failed	PC
E205 - E210	Test run	Stop during test run	Analyzer
E250 - E299	Mathematics	Error in data analysis	PC
E300	Definitions	Error in processing test definition data	PC
E350 - E399	User management	User administration etc.	PC
E400 - E449	Lot management	Reagent / control lot errors	PC
E500 - E599	Test generation	Error in creating actions for test run	PC
E600 - E699	LIS errors	Errors in communication with LIS	PC
E700 - E799	File errors	Errors in reading / writing flies	PC
E800 - E801	Serial port errors	Only for production	PC
E900 - E999	Test generation	Internal errors in creating actions for test run	PC

Error codes

Please note: entries %d are replaced by a number, entries %s are replaced with text or file number.

ROS (Retry, On/Off, Service): Try to repeat the function. If that doesn't work try turn OFF/ON of the instrument. Otherwise call service. Please inform about error number and other details.

Error Number	Explanation	Solution
E1: Movement Error.	Not all modules are ready to go on	ROS/Check system state for errors
E2: Internal error: Stop signal missing.	Initializing problem	ROS
E3: Internal error: Positioning error.	Initializing problem	ROS
E4: Internal error: Stop end switch.	Initializing problem	ROS
E5: Internal error: Motor parameter.	Initializing problem	ROS
E6: Internal error: Motor error.	Initializing problem	ROS
E7: Action execution timeout.	Initializing problem	ROS
E8: Internal error: collision danger.	Software error.	Contact support.
E9: Pump error.	Cavro pump problem.	ROS
E10: Pump plunger error.	Cavro pump problem.	ROS
E11: Pump valve error.	Cavro pump problem.	ROS
E12a: Sample '%s' at pos. %d not sensed.	Liquid not detected in indicated vial.	Check for correct position of vessel? Fill up vial with required liquid.
E12b: Pre-dilution at pos. %d not sensed.		
E12c: '%s' at pos. %s not sensed.		
E12d: Sample '%s' at pos. %d exhausted.	Liquid detected, but probe hits bottom of the vial during aspirating. Possibly not sufficient volume aspirated. Missing teach in of z axis.	Fill up vial with required liquid. Perform teach in of z axis
E12e: Pre-dilution at pos. %d exhausted.		
E12f: '%s' at pos. %s exhausted.		
E12g: Level Sensing Disturbance for Sample '%s' at pos. %d.	Level detected above plausible level. Possibly caused by electrical malfunction. Hardware failure if error remains permanent.	For rare occurrence: Retry For repeated occurrence: Service
E12h: Level Sensing Disturbance for Pre-dilution at pos. %d.		
E12i: Level Sensing disturbance for '%s' at pos. %s.		
E14: Not enough liquid (tip hits bottom of the vial)	See E12d…f.	Fill up vial with required liquid.
E15: Level sensing disturbance.	See E12d…f.	For rare occurrence: Retry. For repeated occurrence: Service.
E17: Barcode miss match (skip sample).	Mismatch of barcode ID. Barcode read in aspirate Position is different from first reading.	Check quality of barcode label (Print, position). Check if sample tube is loaded correctly.
E20: Internal Measurement error.	Software-error or hardware-problem.	ROS
E21: Measurement channel not ready.	Software-error or hardware-problem.	ROS
E22: CAN input buffer overflow.	Software-error or hardware-problem.	ROS

E23: Out of memory for measurement data.	Software-error or hardware-problem.	ROS
E24: Measurement buffer for this cuvette is not free.	Software-error or hardware-problem.	ROS
E25: Invalid LED specification for measurement.	Software-error or hardware-problem.	ROS
E26: Measurement error.	Software-error or hardware-problem.	ROS
E27: Unknown measurement command.	Software-error or hardware-problem.	ROS
E29: Measurement timeout.	Software-error or hardware-problem.	ROS
E40: Internal barcode reader error.	Software-error or hardware-problem.	ROS
E41: Unknown command for barcode reader.	Software-error or hardware-problem.	ROS
E42: barcode reader interface not initialized.	Software-error or hardware-problem.	ROS
E43: barcode reader interface currently busy for sending data.	Software-error or hardware-problem.	ROS
E44: Error in sending data to barcode reader.	Software-error or hardware-problem.	ROS
E45: Too many data received from barcode reader.	Barcode is limited to 37 letters / numbers.	Shorter barcodes necessary.
E46: Error receiving data from barcode reader.	Barcode connection to bard problem.	ROS
E50: Internal error: Shield not closed as trying to lock it.	Software-error or hardware-problem.	ROS
E51: Internal error: Invalid board specified to set port.	Software-error or hardware-problem.	ROS
E52: Internal error: Invalid port specified to be set.	Software-error or hardware-problem.	ROS
E53: Internal error: Invalid mode specified to set port.	Software-error or hardware-problem.	ROS
E54: Internal error: Invalid direction specified to set port.	Software-error or hardware-problem.	ROS
E80: Unknown state.	Software-error or hardware-problem.	ROS
E81: Unexpected message.	Software-error or hardware-problem.	ROS
E82: Unexpected event.	Software-error or hardware-problem.	ROS
E83: Unknown Message or event.	Software-error or hardware-problem.	ROS
E90: EEPROM version not valid.	Damaged or wrong EEPROM file.	ROS
E98: Action not executed in expected time.	Time of teach in process was not as expected.	Confirm to continue.
E99: Analyzer reports error %d: %s.	Caused by old soft/firmware versions or electromagnetically interferences	Check for correct soft/firmware/ROS
E100: Error in communication with analyzer.	Is the instrument switched on? USB-cable correct?	Check connections; ROS.

E101: Error transmitting actions to analyzer.	Is the instrument switched on? USB-cable correct?	Check connections; ROS.
E102: Analyzer doesn't accept transmitted data.	old firmware.	ROS
E103: Error opening HID device (%s).	Human Interface Device: Connection (cable) is ok but the instrument cannot log in.	ROS
E104: Error reading firmware version.	Problem with firmware update.	ROS
E105: Error checking ID.	Problem with firmware update.	ROS
E106: Error erasing flash memory.	Problem with firmware update.	ROS
E107: Error programming flash memory.%s.	Problem with firmware update.	ROS
E108: Error flashing boot program.	Problem with firmware update.	ROS
E120: Error reading errors from device. Try again?	Software-error.	ROS
E121: Error clearing errors in list.	Software-error.	ROS
E122: Error writing RAM data to file.	Software-error.	ROS
E123: Error reading RAM data from device: %s.	Software-error.	ROS
E124: Error reading EEPROM data from device: %s.	Damaged or wrong EEPROM file.	ROS
E125: Error writing settings to analyzer. Please try again.	Software-error.	ROS
E126: Error reading EEPROM data from device: %s.	Damaged or wrong EEPROM file.	ROS
E127: Reading device info failed.	Software-error.	ROS
E130: Vessel heights of analyzer have bad CRC -> Using default values from INI-file.	Incorrect Z-positions are stored in analyzer.	Repeat Z-Teach-In otherwise ROS .
E131: Vessel heights of analyzer not set or bad -> using defaults from INI-file.	Incorrect Z-positions are stored in analyzer.	Repeat Z-Teach-In otherwise ROS.
E132: Failed to read vessel heights from analyzer -> Using default values from INI-file.	Incorrect Z-positions are stored in analyzer.	ROS
E133: Error reading service counters from analyzer.	Software-error.	ROS
E134: EEPROM has invalid version '%d.	Damaged or wrong EEPROM file.	Restart analyzer. If this message appears again, please call service.
E150: Error writing optical calibration data to EEPROM.	Incorrect optical calibration	ROS
E151: Error writing z-positions to EEPROM.	Error during teach In.	ROS
E160: The following modules are deactivated in Analyzer EEPROM but are requested by Ceveron´s initialization file: %s.	Wrong entry in EEPROM.	Call service
E170: Error in AMC calibration with stepping.	Wrong AMC solution	Call service

E200: Not all modules of Analyzer are ready to go on! Restart Analyzer?	Some modules are not installed or connected properly.	Switch instrument off and on. Observe the movement of the arms and check for obstacles.
E201: An error occurred during check procedure processing. The check procedure will be aborted.	Error during initializing process.	ROS
E202: Analyzer error! Restart?	Choose [No] to keep action list data for error analysis.	ROS
E203: Cannot start Analyzer:%s.	Error after successful self-check.	ROS
E204: Mixture at pos. %d not sensed.	A pre-dilution was expected, but the liquid could not be detected.	Save action list and data inventory (without measurement data) and send data to service
E205: Barcode of Sample '%s' not matching. This sample cannot be skipped, thus test run has to be stopped.	Barcode error.	The barcode of the sample is not identical with the first reading.
E210: Calibration stopped due to level-sensing error.	Not enough volume of calibration plasma.	Check volume of calibration plasma. Check test protocol /calibration parameters
E250: Measurement data missing.	No clot formation or reaction.	ROS
E251: Internal error: Missing mathematical parameters to compute result.	Error caused by mathematical parameters	Check test protocol; ROS.
E252: Internal error: Missing mathematical method to compute result.		
E252: Internal error: Missing method implementation.		
E253: Unexpected ascending curve.	No clot is detected.	Retry with extended meas. Time.Check test protocol.
E254: Unexpected descending curve.	Incorrect test protocol.	Check test protocol.
E255: Required counts in evaluation interval not achieved.	Incorrect test protocol.	Check test protocol.
E256: Required absolute change not detected.	No clot is detected.	Retry with extended meas. Time. Check test protocol.
E257: Clotting interval with required relative change not found.	No clot is detected.	Retry with extended meas. Time. Check test protocol.
E258: Analysis interval not found.	Incorrect test protocol.	Check test protocol.
E259: Missing assigned raw result or test protocol.	Incorrect test protocol.	ROS
E260: No signal at start of measurement.	Damaged or wrong calibrated optics.	ROS
E261: Time interval definition for kinetics test invalid.	Incorrect test protocol.	Check test protocol.
E262: Lag time and peak time not detected.	Incorrect test protocol.	Check test protocol.
E263: Division by zero not allowed.	Internal error.	Service. Send data-inventory.
E264: Missing required calibration definition/data.	No calibration stored for this lot.	Perform calibration.
E265: INR not supported for specified	No INR calibration stored.	Check test definition.

reagent type / lot.		
E266: ISI value of reagent lot is 0.	No ISI value.	Input ISI value in reagent Lots.
E267: Normal plasma value of reagent lot is 0.	No normal plasma value.	Input normal plasma value.
E268: Invalid time definition for evaluation interval.	Incorrect test protocol.	Check the protocol.
E269: Missing calibration definition/data; only time point results computed.	No calibration.	Perform calibration.
E270: Ratio not supported for specified reagent type/lot.	Incorrect reagent lot.	Check reagent lots.
E271: No AUC because TGA stopped if all peaks reached.	Incorrect TGA Test definition.	Check test definition.
E272: Time interval for delta OD calculation invalid.	Delta OD should be calculated between invalid times (set in math parameters of test)	Adjust mathematics parameters in test protocol
E299: Internal error: Unknown result.	Internal error.	Service. Send data-inventory.
E300: Error in processing test protocol. Please check your entries.	Incorrect test protocol.	Check again the test protocol.
E301: For Test '%s no test protocol could be found. Please check your test definition data.	No test definition	Check test definitions.
E302: A test protocol of this test could not be found. The following options will fix the problem: a) If you have the required user level, modify the test by leaving following dialog with 'Ok', or b) Delete the test definition if you don't need it, or c) Import a corrected version of the test definition provided by your service, or d) Ask your service to correct the test definition.	Data inconsistency. Caused by manual manipulation of files in data-directory or by incomplete software-updates.	Follow on-screen instructions.
E350: Please enter an username.	No username	Enter an username.
E351: A user with this username already exists.	Username defined twice	Enter another username.
E352: Invalid username or password.	Incorrect username or password.	Try again with valid username or password; ROS.
E353: The passwords you typed do not match.	Incorrect password	Try again with valid username or password; ROS.
E400: Other lot of this reagent already exists.	Reagent lot definition twice.	Different lots of one reagent are not allowed at the same time. Please correct the lot number or unload the reagent.
E401: Please add missing lot code.	Missing lot number.	Input lot number.
E402: Do you want to enter the lot?	No lot number entered	Check and enter a lot number
E410: The version of loaded data is older than the actual version.	Problem with update.	Call service.
E420: FATAL error: not enough memory on heap.	Not enough memory while zipping data-inventory.	Close other applications and try again. Or restart computer.
E450: No valid test - cannot show curve.	Incorrect calibration or test protocol.	Check test protocol and repeat calibration.

E451: Cannot write date and time to Action list file.	File access error.	Make sure action list file is not write protected while being written.
E500: Currently there are no tests in worklist to be done.	Test run is started without any tests required	Check the working list.
E501: Error generating worklist.	Internal error by creating a measurement procedure or the orders for the instrument.	Call service. Send data inventory.
E502: Error generating cyclic tests.	Internal error by creating a measurement procedure or the orders for the instrument.	Call service. Send data inventory.
E503: Test protocol (ID=%d) of test '%s not found. Please check the test definition of this test.	Internal error by creating a measurement procedure or the orders for the instrument.	Clear the test causing the error or ROS.
E504: Unknown test protocol for test #%.	No test protocol for this test available.	Check the test protocols. (Similar name?) ROS.
E505: No test protocol defined.	Test definition without a Test Protocol.	Define a new Test Protocol or use another.
E506: More than 84 cuvettes are required for specified tests. Last tests are skipped and can be run later.	More tests are ordered than cuvettes are available.	After the performance of all tests, place new cuvettes and start again.
E507: Please put new cuvettes to cuvette tray and start again.	No empty cuvettes available.	After the performance of all tests, place new cuvettes and start again.
E508: Tried to aspirate liquid from cuvette %d up to rest volume of only %d µL. Required rest volume is at least %d µL. Operation will be canceled.\n. Please correct test protocol of test '%s.	Incorrect test protocol.	Check the protocol / calibration parameters; ROS.
E509: Please modify measurement settings: At least one of the measurement channels %d to %d should be selected.	Incorrect measurement settings.	Check "measurements" in menu software settings.
E550: Dilution ratio % requires a volume of %d µL. Maximal volume of vessel is %d µL. Fully automated calibration with these parameters is not possible. Reduce measurements per dilution or number of dilutions and try again \ or work with a prepared calibrator set.	Incorrect measurement settings.	Check the protocol / calibration parameters; ROS.
E551: Cuvette for dilution too far away from measurement cuvette. Make sure no gaps are between empty cuvettes or reduce number of measurements per dilution or dilution steps. A total of maximal %d cuvettes may be used for fully automated calibration.	Uses cuvettes in the first two segments.	Check the protocol / calibration parameters; ROS.
E552: For the calibration at least %d empty cuvettes are required. Currently only % empty cuvettes are loaded. Please load missing cuvettes and start again.	No empty cuvettes available.	Renew all used cuvettes.
E553: Internal Error: Could not find selected test protocol.	Incorrect test protocol.	Call service. Send data-inventory.

E554: Dilution ratio % requires aspiration of Dilution of %d µL. Minimal volume to be aspirated is %d µL. Fully automated calibration with these parameters is not possible. Please modify dilution ratio and try again \ or work with a prepared calibrator set.	Dilution ratio is not possible.	Proceed as message describes.
E555: Dilution ratio % requires aspiration of Calibrator of %d µL. Minimal volume to be aspirated is %d µL. Fully automated calibration with these parameters is not possible. Please modify dilution ratio and try again \ or work with a prepared calibrator set.	Dilution ratio is not possible.	Proceed as message describes.
E600: Missing message header in ASTM message.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E601: Missing ASTM message termination.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E602: Invalid ASTM message termination.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E603: Invalid record type in ASTM message.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E604: Missing required field(s) in ASTM message.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E605: Missing data element in ASTM message.	Incorrect ASTM messages.	LIS adaption for Ceveron is necessary.
E609: Internal ASTM parsing error	An unknown error in parsing ASTM data appeared.	LIS adaption for Ceveron is necessary., or there is a problem with the Ceveron Software.
E610: Send request to LIS failed.	No connection to LIS.	Call administrator or LIS Service.
E611: Send request to LIS failed: missing LIS client connection.	No connection to LIS.	Call administrator or LIS Service.
E612: Selected sample '%s' not ready for LIS requests.	Sample identification is empty.	Input sample ID in worklist.
E613: Send results to LIS failed.	No connection to LIS.	Call administrator or LIS Service.
E614: Send results to LIS failed. Missing LIS client connection.	No connection to LIS.	Call administrator or LIS Service.
E615: Result transmission to LIS failed: missing ready/validated data for selected sample '%s.	No Sample ID.	Input sample-identification in worklist.
E616: Result transmission to LIS failed: missing master test for selected test <%s> in sample '%s.	Incorrect LIS protocol.	Call service. Send data inventory and LIS protocol.
E617: Result transmission to LIS failed: missing ready/validated data for selected test <%s> in sample '%s.	Incorrect validation of results.	Validate also duplicates.
E620: LIS: Patient for invalid sample %s received.	Internal error	Service. Please send data inventory.
E621: No Sample completed to be transmitted to LIS.	No data to be transmitted. First start test-run.	Service. Please send data inventory.

E630: Server Socket Create failed %s.	Problem with server connection.	Contact computer administrator.
E631: no LIS connection.	No connection to LIS. Check if LIS server is ready.	Contact computer administrator.
E699: Internal error: Unknown error.	Internal error.	ROS
E700: Error opening file '%s' for reading.	The file cannot be opened or is missing.	Check the file and retry.
E701: Error reading file '%s'.	The file cannot be opened or is missing.	Check the file and retry.
E702: Error opening file '%s' for writing.	The file cannot be opened or is missing.	Check the file and retry.
E703: Error writing file '%s'.	The file cannot be opened or is missing.	Check the file and retry.
E704: Not enough memory available.	Less storage capacitiy on harddisc available than needed.	Consult local IT.
E705: Error reading file '%s'. Unknown version!	Not used.	Check the file and retry.
E720: Cannot create file: '%s'!	Damaged or incorrect file.	Restart CEVERON software.
E750: Error loading HEX file.	During loading new files for firmware update	Ask for correct hex-file from service and restart CEVERON software.
E760: File '%s' was corrupted. A backup could be restored. Your last changes might be lost. Please restart the software to complete the restoring mechanism.	Damaged file.	Restart CEVERON software. The last version of the files are loaded from backup automatically.
E761: File '%s was corrupted and could not be restored. A new file is created. Please check the manual for further advice.	Damaged file.	Restart CEVERON software. Depending on the file type, the file must be loaded from the backup CD.
E762: Could not find 'DSC_Reader.dll.	EEPROM file is not found.	Start setup program again.
E763: Sorry, file '" TR_DSC_FILE_NAME "' is not up to date --> EEPROM cannot be edited. Following entries are not ok:%s	EEPROM file is not found.	Start setup program again or upload EEPROM.DSC manually.
E764: Error writing EEPROM data to file.	Blocked file by another program.	Call Service
E765: Incomplete Installation (File 'CaCvlt' missing).	Damaged file.	Call Service
E766: File '%s could not be read. A backup could be restored. Software will terminate now, please restart.	Damaged file.	Restart CEVERON software.
E767: File '%s was not as expected. Backup path '%s invalid. Software will terminate now, please restart.	Damaged file.	Restart CEVERON software or call service.
E768: File '%s' was not as expected. A backup could be restored. Software will terminate now, please restart.	Damaged file.	Restart CEVERON software or call service.
E769: File '%s' was not as expected, no backup could be restored.	Damaged file.	Call service.
E770: Cannot read Configuration Data Files from versions before 3.0. Please don't try to use Ca* - files of	Incorrect or damaged file.	Call service.

former Software versions, instead use Software Installation provided by Technoclone.\n Software will terminate now.		
E771: Cannot import file '%s, because it was created by an older version of the Ceveron Software. Please import CAX-Files created with version 3 (or higher).	Incorrect Ceveron software	Call service.
E780: Data integrity test of selected tests failed. No export possible.	Inconsistent test data definitions.	Save data inventory (w/o measurement data) and send to service.
E800: Error accessing COM Port.	Function only for service.	Call service.
E801: Error with serial communication.	Function only for service.	Call service.
E900: Internal software error. Please notify service.	Damaged software.	Call service
E901: Internal error: Failed to allocate resources for '%s' of Sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory.
E902: Internal error: Failed to allocate meas channel for subtest '%s' of sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory.
E903: Internal error: Failed to plan cuvette tray positioning for '%s' of sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory
E904: Internal error: Failed to set test step collection for '%s' of sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory
E905: Internal error: Failed to determine target position for '%s of sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory
E906: Internal error: Invalid measurement cuvette number (%d) for %s of sample position %s.	Internal error during test run or calibration.	Call service. Send data inventory
E907: Internal error: Could not find liquid %s of test protocol '%s. Test run will not be started.	Internal error during test run or calibration.	Call service. Send data inventory
E908: Internal Error at module %d ('%s'). Error code %d. Please notify service.	Internal error during test run or calibration.	Call service. Send data inventory
E909: Internal error at cuvette tray positioning logic. Please notify service.	Internal error during test run or calibration.	Call service. Send data inventory
E910: Internal error at action generation. Please notify service.	Internal error during test run or calibration.	Call service. Send data inventory
E911: Internal error: Test protocol not found. Please notify service.	Internal error during test run or calibration.	Call service. Send data inventory
E912: Internal error: Loading object not found.	Internal error during test run or calibration.	Call service. Send data inventory
E913: Internal error: Test Object of sample '%s' not found.	Internal error during test run or calibration.	Call service. Send data inventory
E914: Internal error at preparation of test for execution.	Internal error during test run or calibration	Call service. Send data inventory

E915: Internal error (setting of shield detector port in µC not correct).	Internal error during test run or calibration	Call service. Send data inventory
E916: Internal error (setting of port in 90 µC not correct).	Internal error during test run or calibration	Call service. Send data inventory
E917: Internal Error: Service Counter structure sizes do not match.	Internal error during test run or calibration.	Call service. Send data inventory
E918: Internal Error in action creation. Please notify service.	Internal error during test run or calibration.	Call service. Send data inventory
E930: Internal Error in export of test definitions.	Internal error or damaged test definition files.	Call service. Send data inventory

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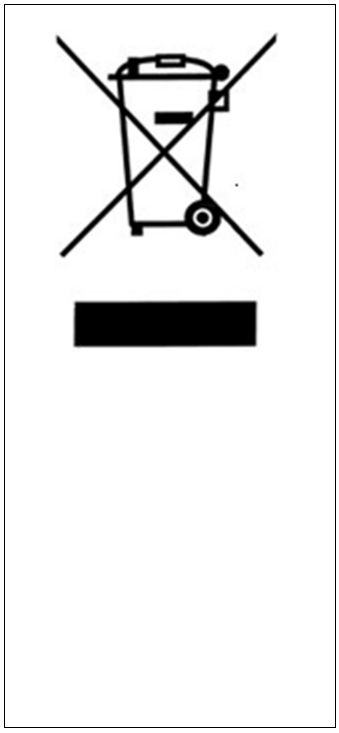
8. Disposal 2

8. Disposal

Prior to disposal, please ensure and document, that a decontamination procedure was performed according to the instructions in this manual. Please see the respective chapter under maintenance.

Information on disposal for users of waste electrical & electronic equipment

This symbol on the products and / or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.



Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details of your nearest designated collection point.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

For business users in the European Union

If you wish to discard CEVERON 100 series instrument, please contact Technoclone, your dealer or supplier for further information. Technoclone will take back the instrument and will dispose according WEEE regulations.

Information on disposal in other countries outside the European Union

This symbol is only valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

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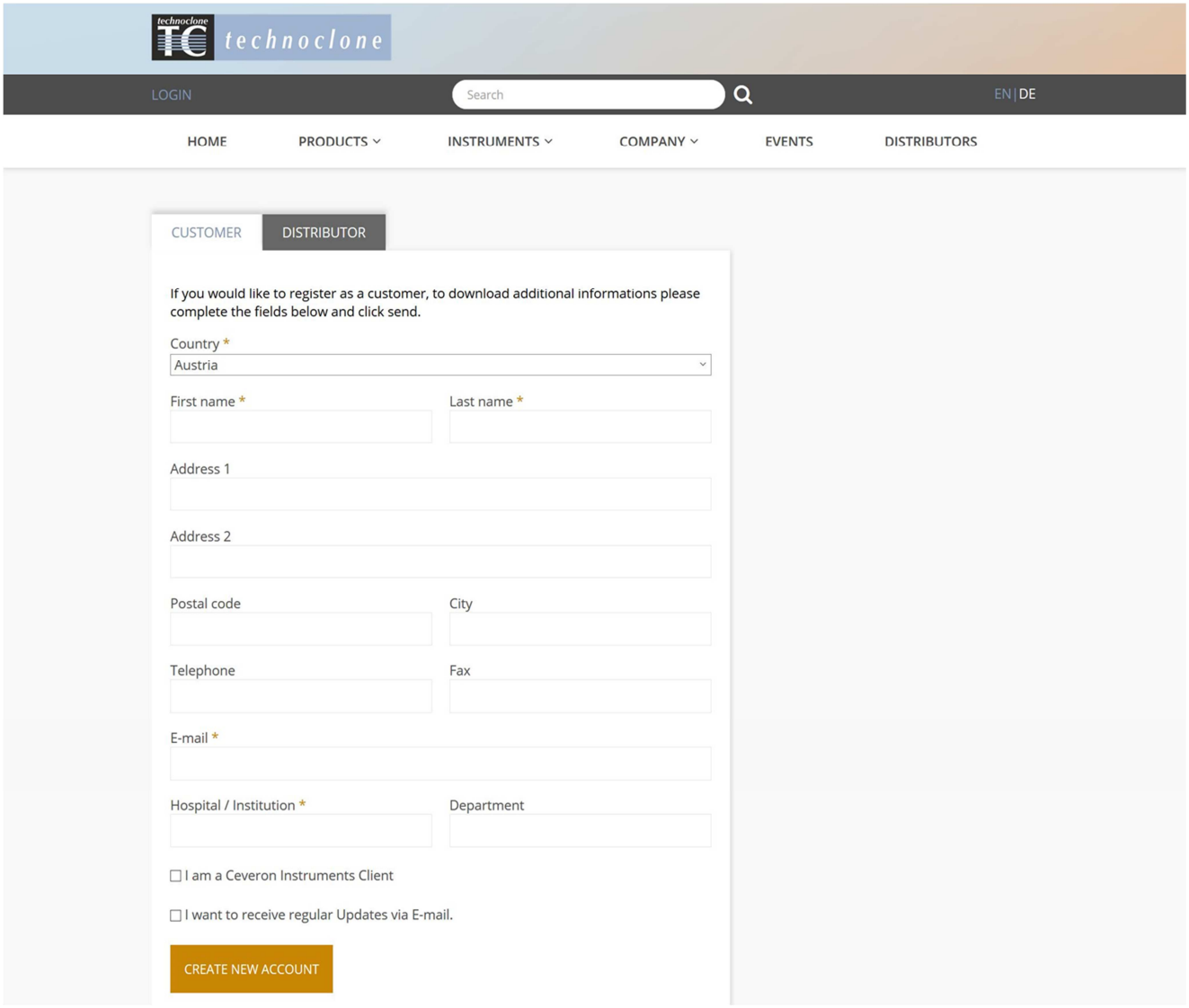
9. Update via www.technoclone.com 2

9. Update via www.technoclone.com

To receive updates please register your CEVERON100 series instrument with your serial number at the Technoclone homepage.

https://www.technoclone.com/en/user/register/customer



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