cobas c 513 analyzer

Basic Analytical Principles – Version 2.0
Software Version 02-01, 02-02

Roche

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Publication information

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Revision history

Edition notice

This publication is intended for operators of the **cobas c** 513 analyzer.

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Table of contents

Preface

The basic analytical principles describe the core algorithms of the **cobas c** 513 analyzer software. The description of the core algorithms covers the calibration as needed for result calculation for HbA1c applications.

In this section

Intended use

The **cobas c** 513 analyzer is a fully automated, standalone clinical chemistry analyzer intended for the in-vitro quantitative determination of analytes in body fluids.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following descriptors are used for the product names.

Product name	Abbreviation
cobas c 513 analyzer system	system
cobas c 513 analyzer	analyzer
cobas c 513 analyzer software	software

Product names

Symbols

Symbol	Explanation
•	List item
	Related topics containing further information
	Tip. Extra information on correct use or useful hints.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.
√xy	Equation. Used in cross-references to equations.

Symbols used in the publication

Abbreviations

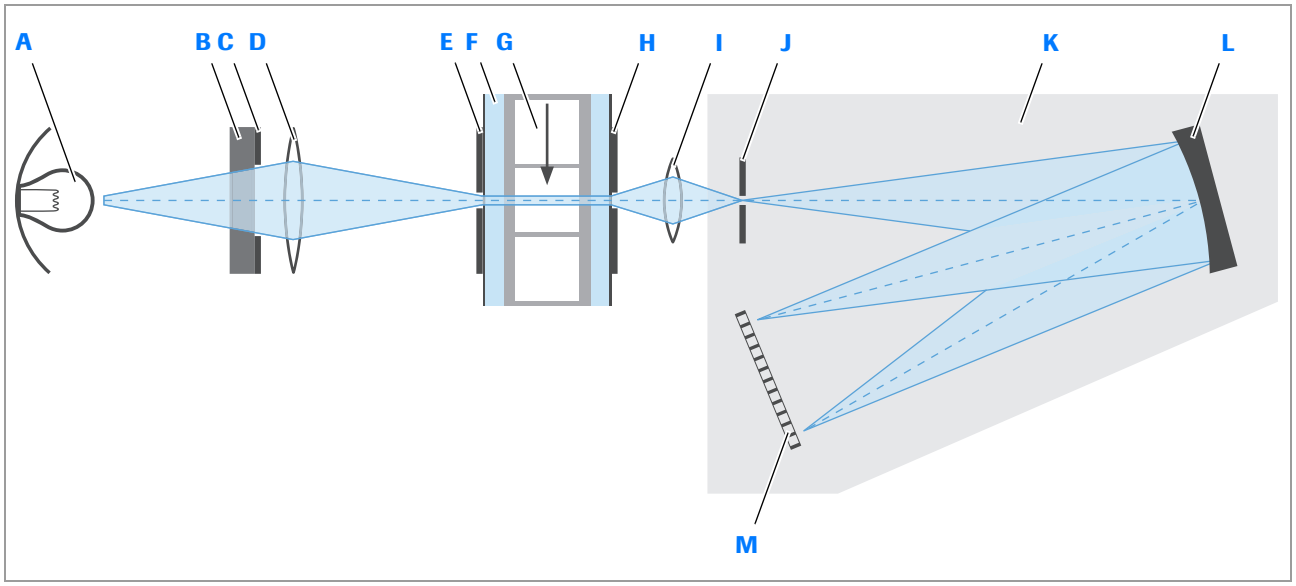
The following abbreviations are used:

Abbreviation	Definition
EC	European Community
EFTA	European Free Trade Association
QC	Quality control
RCM4	Reaction calculation mode 4
SD	Standard deviation
STAT	Short turn-around time

Abbreviations

About photometric technology

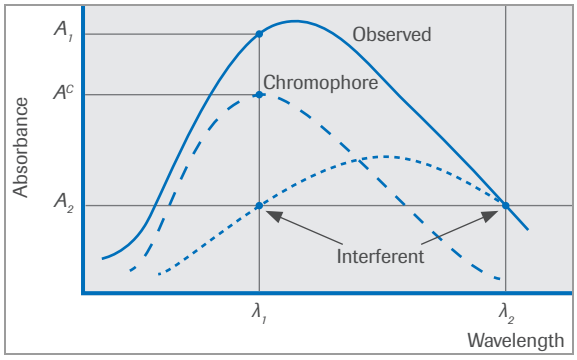
The photometric technology uses a photometer lamp to beam light through the sample. A detector measures the absorbance of the light. From this absorbance, the system calculates the concentration of the sample. The photometer light path passes different lenses, slits, and the sample probe before it hits a detector.



A Photometer lamp
B Infrared cut filter
C Mask
D Condenser lens
E Slit (IN)
F Incubation bath
G Reaction cell and dispersion
H Slit (OUT)
I Imaging lens
J Slit
K Photometer unit
L Diffraction grating
M Detector

When the light beam enters the photometer unit, it strikes a diffraction grating. It separates the light into its constituent wavelengths and reflects them onto a fixed array of 12 photodiodes. Each photodiode is permanently positioned to detect light at a different wavelength.

Absorbance readings are taken each time a reaction cell rotates past the photometer. When the reaction cell passes through the photometer light path, absorbance at the 12 wavelengths is measured for each individual assay.



Most Roche Diagnostics photometric tests use 2 wavelength readings to calculate results. The end product of a chemical reaction absorbs the most light at 1 particular wavelength. But sometimes interferences are found when using a single wavelength (monochromatic system). Therefore, using the difference between readings at 2 wavelengths (bichromatic system) eliminates the effect of interferences. Readings at 2 wavelengths also compensate for most of the photometric noise which improves the photometric resolutions.

One of the bichromatic wavelengths is at or near the peak absorbance of the chromogen produced by the reaction. A second wavelength is chosen, where little or no absorbance of the desired chromogen occurs.

Any absorbance (A_2) that occurs due to interference from other substances in the sample is measured at the secondary wavelength. This amount is then subtracted from the total absorbance (A_1) occurring at the primary wavelength to yield the net absorbance (A^C).

The optimum measuring points for each test are part of the application parameters, which are available via download.

The application parameters determine how final results are calculated for each test.

About test principles

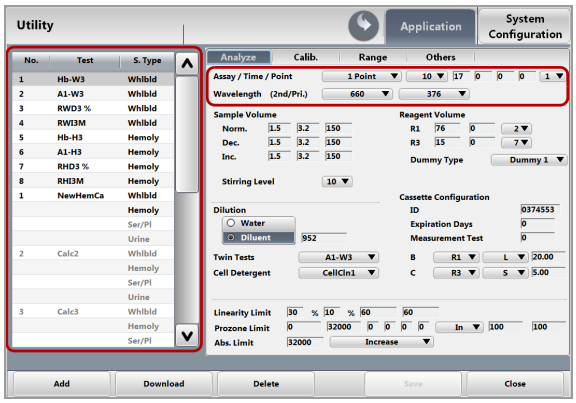
The photometric test principles use absorbance measurements for result calculation.

In this section

About how assays are displayed in the software

The **Analyze** option on **Utility > Application** displays the assay type and measuring points among other application parameters for a selected test.

Assay types and measuring points



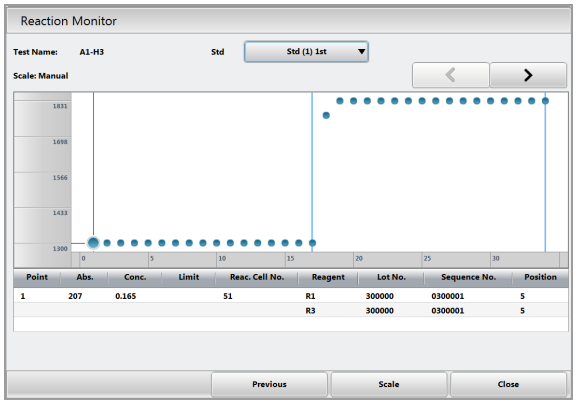
In the list on the left side of **Utility > Application > Analyze**, you can select the test that you want to view.

There are 7 **Assay/Time/Point** fields:

- The first entry displays the assay type selected.
- The second entry displays the reaction time in minutes, that is the time after which the result is reported (reporting time).
- The third through sixth entries display chosen measuring points.
- The seventh entry displays the calculation method.

Measurements used for calculation

Independent of the programmed application parameters, the system measures the absorbance of a reaction mixture in fixed intervals of 18 seconds. However not all of the measurements are used for calculating the result. Therefore, the numbering of the photometer measuring points differs form the numbering of the measuring points used in calculations.



The **Reaction Monitor** window on **Calibration > Result** displays which measuring points are used for calculation. The example of a **Reaction Monitor** window, displays an endpoint assay programmed for 2 measuring points (mp_1 and mp_2). The application parameters define the 17th photometer measuring point to be mp_1 and the 34th photometer measuring point to be mp_2.

The values on the **Reaction Monitor** window are absorbance $\times 10^4$. Moreover, these values are already corrected for the cell blank value, which is determined during the cell blank measurement.

Related topics

- About 1-point assays (12)
- About 2-point end assays (14)

Data in the software used for calculations

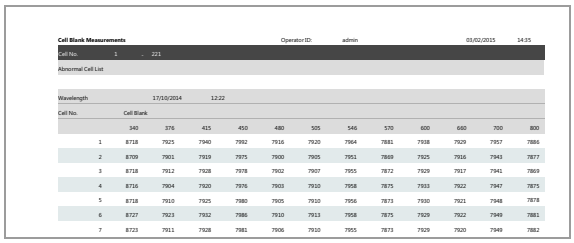
The data used for the calculation of the assay types are displayed in different places of the software.

The cell blank measurement report contains data necessary for the calculation of absorbance values, which are the basis for all other calculations.

The **Working Information** window on **Calibration > Result** displays calibration information for individual tests and calibrators.

Cell blank measurement report (11)
Working Information window (11)

Cell blank measurement report



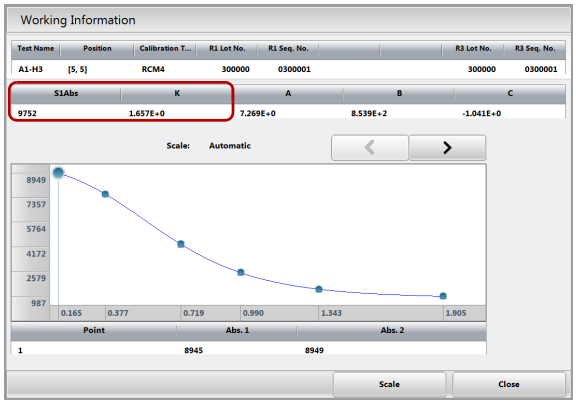
The cell blank measurement report is requested as part of weekly maintenance and measures the current cell blank values. The current cell blank values are compared to the real-time cell blank values that are measured before every measurement. The real-time cell blank values are displayed on the reaction monitor report.

The real-time cell blank value is defined as the mean value of the cell blank measurements 2 and 3 performed before every sample measurement: $(C2 + C3)/2$.

If the difference between the real-time cell blank values and the current cell blank value is greater than 0.1 absorbance units (Abs), an alarm is issued.

▸ Measurements used for calculation (10)

Working Information window



The **Working Information** window displays the current calibration curve and values for the application selected under **Calibration > Result**.

For endpoint assays based on an RCM4 or linear calibration, the value under S1 Abs. equals the absorbance value of calibrator 1 $\times 10^4$ (A_b). S1 Abs. is subtracted from the reaction absorbance of all samples including calibrators 2 to 6, QC, STAT, and routine samples.

The K-factor, as well as S1 Abs., is used in the result calculation of every measured test.

About endpoint assays

The fundamental type of photometric test principle used on the system is the endpoint assay.

Measurements are taken by the photometer at specific measuring points. If measurements are taken after the reactions are completed, the intensity of the colored (or turbidimetric) product is an indicator of the sample component's concentration. These measurements are called endpoint assays.

Assay types

There are 2 different assay types for endpoint assays:

Fundamental assay type	Assay type	Characteristic
Endpoint assays	1-point	Endpoint assay programmed for a single measuring point
	2-point end	Endpoint assay with sample blank

Assay types

Data for calculation

The values corresponding to the variables used in the calculation of the 2 endpoint assay types are displayed on the **Working Information** window on **Calibration > Result**.

Data in the software used for calculations (10)

In this section

About 1-point assays

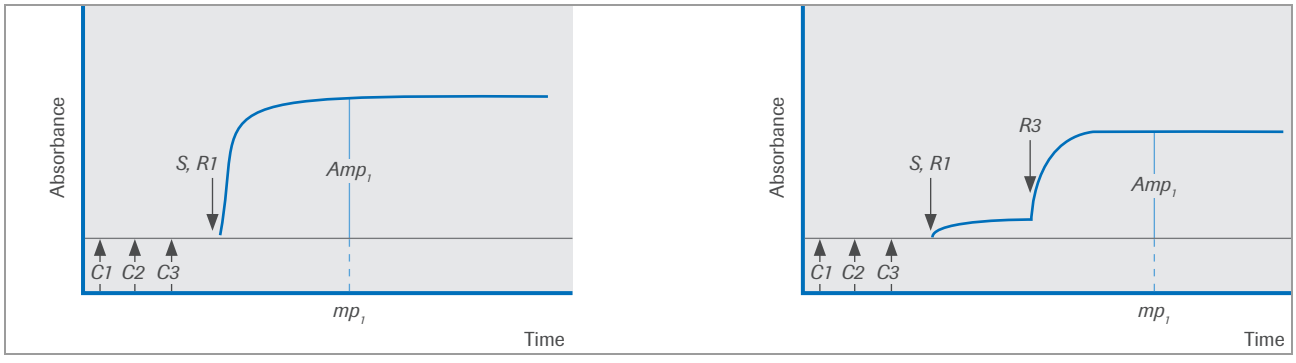
A 1-point assay is an endpoint assay without sample blank measurement. It can be programmed for one or more reagents. 1-point means that there is a reading at 1 measuring point.

Further assay characteristics are the following:

- The measuring point is between 1 and 34: $1 \leq mp_1 \leq 34$
- The absorbance reading can be taken during any disk rotation after addition of the final reagent.
- The reaction times for the selected application are within the interval of 3-10 minutes.
- The reaction volume lies between 75 µL and 185 µL.

1-point assay calculation

A 1-point assay can have reagents dispensed either at *R1* timing or at *R1* and *R3* timing. The graphs can show an increase or decrease in absorbance as the reaction occurs.



1-point assay graph with left: R1 timing and right: R1 and R3 timing

$C1, C2, C3$	Cell blank values of the reaction cell[a]
S	Pipetting of sample
$R1$	Pipetting of reagent at $R1$ timing
$R3$	Pipetting of reagent at $R3$ timing
mp_1	Measuring point 1, endpoint (after reaction has reached equilibrium)
Amp_1	Absorbance at measuring point 1

(a) See Cell blank measurement report (11).

The calculation of the concentration of the analyte in the sample uses the following equation:

√xy **1** $$C_x = [K(A_x - A_b) + C_b] \cdot IF_A + IF_B$$

A_x	Absorbance value for concentration calculation[a]
C_x	Concentration of the analyte in the sample
K	Calibration factor[b]
A_b	Absorbance of calibrator 1 (S1 Abs.)[2]
C_b	Concentration value for calibrator 1
IF_A, IF_B	System constants for a slope of 1 and an intercept of 0

(a) See reaction monitor list

(b) See **Working Information** window

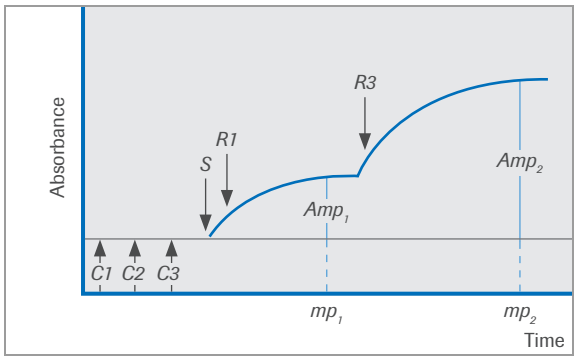
About 2-point end assays

A 2-point end assay is an endpoint assay with sample blank measurement. It can be programmed for two or more reagents. 2-point means that there are readings at 2 measuring points. The first measuring point is the sample blank reading, the second measuring point is the final absorbance reading (endpoint).

Further assay characteristics are the following:

- The measuring points are between 1 and 34: $1 \leq mp_1 < mp_2 \leq 34$
- The first absorbance reading can be taken during any disk rotation. Usually it is taken before or shortly after the final reagent is added.
- The second absorbance reading can be taken during any disk rotation after the final reagent is added.
- The reaction times for the selected application are within the interval of 3-10 minutes.
- The reaction volume lies between 75 µL and 185 µL.

2-point end assay calculation



For a 2-point end assay, using reagents dispensed at $R1$ and $R3$ timing, the following variables are used in the graph and the calculation:

$C1$, $C2$, $C3$	Cell blank values of the reaction cell[(a)]
S	Pipetting of sample
$R1$, $R3$	Pipetting of reagent at $R1$ timing and at $R3$ timing
mp_1	Measuring point 1, sample blank (here before final reagent addition)
mp_2	Measuring point 2, endpoint (after reaction has reached equilibrium)
Amp_1, Amp_2	Absorbance values at measuring point 1 and measuring point 2

(a) See Cell blank measurement report (11).

After the mixture of sample and $R1$ reagent is measured as sample blank, it is diluted by the addition of $R3$ reagent. Therefore, the readings cannot be subtracted, unless a correction for the dilution is taken into account. A dilution factor (d) is calculated as follows and applied to the sample + R1 absorbance:

$$\sqrt{xy}\ \mathbf{2} \quad d = \frac{V_{samp} + V_{R1}}{V_{samp} + V_{R1} + V_{R3}}$$

d	Dilution factor
V_{samp}	Sample volume
V_{R1}	R1 volume
V_{R3}	R3 volume

The result calculation is based on a calculated value for the absorbance of the final reaction product A_x. To determine the reaction absorbance A_x, the sample blank value is corrected for dilution and then subtracted from the endpoint absorbance:

$$\sqrt{xy}\ \mathbf{3} \quad A_x = Amp_2 - d \cdot Amp_1$$

A_x	Absorbance value for concentration calculation
Amp_2	Absorbance at measuring point 2[(a)]
Amp_1	Absorbance at measuring point 1[(1)]
d	Dilution factor

(a) See reaction monitor list.

The calculation of the concentration of the analyte in the sample uses the following equation:

$$\sqrt{xy}\ \mathbf{4} \quad C_x = [K(A_x - A_b) + C_b] \cdot IF_A + IF_B$$

C_x	Concentration of the analyte in the sample
K	Calibration factor[(a)]
A_x	Absorbance value calculated above
A_b	Absorbance of calibrator 1 (S1 Abs.)[(1)]
C_b	Concentration value for calibrator 1
IF_A, IF_B	System constants for a slope of 1 and an intercept of 0

(a) See **Working Information** window.

About calibration

The term calibration refers to the determination of a valid relation between the measured concentration value and the actual concentration of the analyte. For endpoint assays, the measured value is the absorbance. The graphical representation of such an absorbance/concentration relation is the calibration curve also referred to as working curve.

In this section

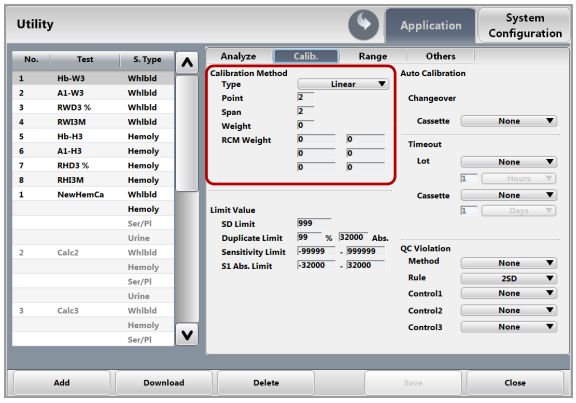
About calibration types

The calibration types describe the behavior of a calibration curve and its mathematical function.

In this section

Overview of calibration types

The system uses different mathematical models to describe the relation between the measured absorbance and the concentration of the analyte of interest.



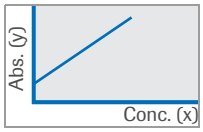
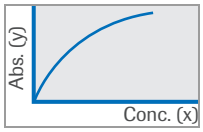
Typically, the calibration curve types are developed by Roche Diagnostics. The definitions for the curve types are set in the **Type**, **Point**, **Span**, and **Weight** fields on **Utility > Application > Calib.**.

Linear calibrations

Linear calibrations are used for tests whose absorbance values at different concentrations form a straight line. If a linear calibration is based on 2 calibrator measurements, it is termed linear 2-point calibration.

Nonlinear calibrations

Nonlinear calibrations are used for tests whose absorbance values at different concentrations form a nonlinear but reproducible plot. A minimum of 5 and maximum of 6 calibrators is required for calibration. The RCM4 calibration type is a nonlinear calibration.

Calibration type	Mathematical model	Field entries in the software	
Linear	$y = a + b \cdot x$	**Point**: 2 **Span**: 2	
RCM4	$A = \frac{a-d}{1+\left(\frac{C-e}{b}\right)^{c}} + d$	**Point**: 5–6 **Span**: 2–6	

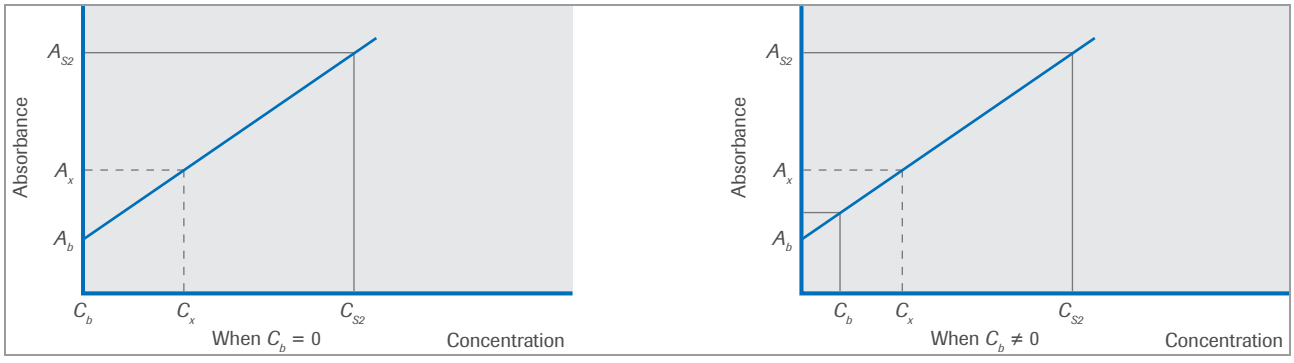
Overview of calibration types

The linear and the RCM4 calibration type can be used with 1-point assays as well as 2-point end assays.

About 1-point assays (12)
About 2-point end assays (14)

About linear calibration

For linear 2-point calibration, the absorbance of 2 calibrators is measured, with calibrator 1 being a dilution of calibrator 2. These 2 points are used to establish a linear plot, and its slope is used in the calculation of subsequent QC and patient results.



Linear 2-point calibration graph

A_x	Sample absorbance value
A_b	Absorbance of calibrator 1 (S1 Abs.)
A_{S2}	Absorbance of calibrator 2
C_b	Concentration value for calibrator 1
C_x	Concentration of the analyte in the sample
C_{S2}	Concentration value for calibrator 2

Linear 2-point calculation

The mathematical model for a linear 2-point calibration is the equation for a straight line $y = a + b \cdot x$, where a is the y-intercept and b is the slope. The equation's variables are defined as follows:

$x = C$	Concentration of the analyte
$y = A$	Absorbance
a	Absorbance when the concentration of the analyte is 0
b	Ratio of the change in absorbance to the change in concentration

Slope

The slope of a straight line can be derived either by the formula $b = (\Delta y)/(\Delta x)$ (when 2 points are used) or by the least squares method (when multiple points are used). For the first case, comparison with the linear 2-point calibration graph $C_b \neq 0$ shows $\Delta y = A_{S2} - A_b$ and $\Delta x = C_{S2} - C_b$. The formula for the slope can then be solved to $b = (A_{S2} - A_b)/(C_{S2} - C_b)$. This equation shows that b is equal to the reciprocal K-factor. Therefore, $b = 1/K$.

Y-intercept

Comparison with the linear 2-point calibration graph $C_b \neq 0$ shows the y-intercept $a = A_b - (b \cdot C_b)$, where A_b is the absorbance and C_b the concentration value for calibrator 1. With slope and y-intercept determined, it is possible to solve the equation $y = a + b \cdot x$ to x to calculate the analyte concentration in a sample C_x:

√xy **5** $y = a + b \cdot x$

yields $x = \frac{1}{b}(y - a)$, where

$a = A_b - (b \cdot C_b)$ $b = 1/K$ $x = C_x$ $y = A_x$

By substitution of a, b, x, and y the following equation is obtained:

$$\sqrt{xy}\ \mathbf{6} \quad C_x = K[A_x - (A_b - b \cdot C_b)]$$

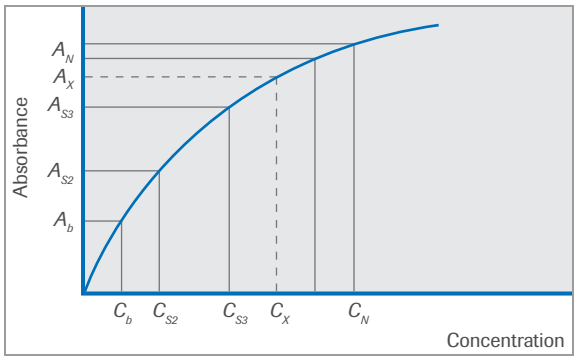
which is equivalent to $C_x = [K(A_x - A_b) + C_b]$

Two additional constants are applied to this formula to correct the result for systematic bias deriving from the system. The calculation of the sample concentration is shown in the following equation:

$$\sqrt{xy}\ \mathbf{7} \quad C_x = [K(A_x - A_b) + C_b] \cdot IF_A + IF_B$$

C_x	Concentration of the analyte in the sample
K	K-factor
A_x	Sample absorbance value
A_b	Absorbance of calibrator 1 (S1 Abs.)
C_b	Concentration value for calibrator 1
IF_A, IF_B	System constants representing a slope of 1 and an intercept of 0

About RCM4 calibration



The RCM4 calibration applies a calibration curve in which the absorbance increases or decreases in a nonlinear manner to the increase in concentration.

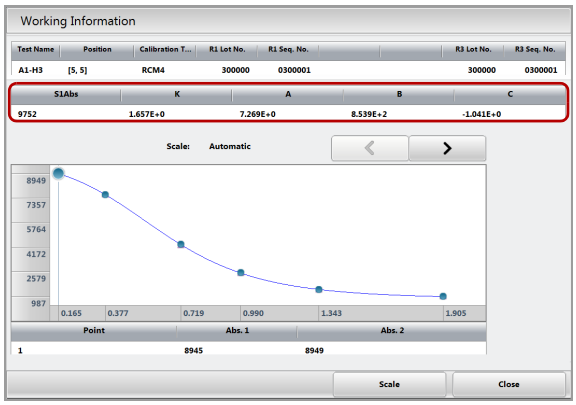
A_x	Sample absorbance value
A_b	Absorbance value for calibrator 1 (S1 Abs.)
A_{S2}, A_{S3}, ...	Absorbance value for calibrators 2 to 6
A_N	Absorbance value for calibrator (N)
C_x	Concentration value for the analyte in the sample
C_b	Concentration value for calibrator 1
C_{S2}, C_{S3}, ...	Concentration value for calibrators 2 to 6
C_N	Concentration value for calibrator (N)

RCM4 calculation

To calculate the RCM4 calibration curve approximation, use the following mathematical model:

$$\sqrt{xy}\ \mathbf{8} \quad A = \frac{a-d}{1+\left(\frac{C-e}{b}\right)^c} + d$$

A	Absorbance
C	Concentration of the analyte.
a	Parameter representing the absorbance at concentration C = e. For parameter e = 0, it equals 0 concentration (A_b).
b	Parameter representing the concentration where the absorbance is ½ of the span between A_{inf} and A_b.
c	Parameter describing the curvature of the calibration curve.
d	Parameter representing the predicted absorbance for infinite concentration (A_{inf}).
e	Parameter representing a shift along the concentration axis.



The values on **Calibration > Result > Working Information** correspond to the calibration curve parameters as follows:

The **S1 Abs.** column displays parameter a.
The **K** column displays parameter b.
The **A** column displays parameter c.
The **B** column displays parameter d.
The **C** column displays parameter e.

The calculation of the sample concentration is shown in the following equation:

√xy **9** $C_x = (C + C_b) \cdot IF_A + IF_B$

with $C = b \cdot \left(\frac{a - A_x}{A_x - d}\right)^{1/c} + e$

C_x	Concentration value for the analyte in the sample
C_b	Concentration value for calibrator 1
C	Concentration value before system constants adjustment
IF_A, IF_B	System constants representing a slope of 1 and an intercept of 0
A_x	Sample absorbance value
a, b, c, d, e	Calibration curve parameters as in previous equation[(a)]

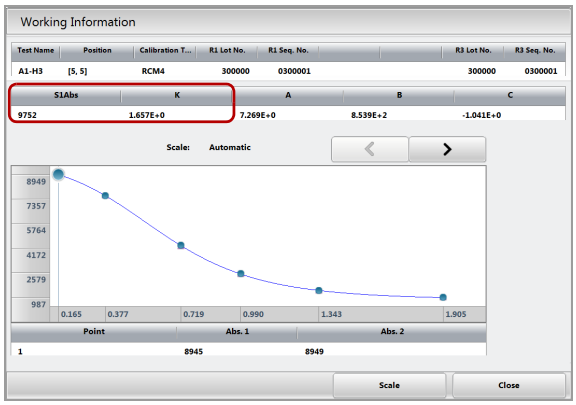
(a) See **8** √xy (19)

About the K-factor

A K-factor is used in the calculation of sample results. Any test that requires more than just a blank during calibration has its K-factor calculated with the measured absorbance values of calibrator 1 and the other calibrators.

K-factor calculation

K-factors are calculated from absorbance and concentration values for tests that are based on linear 2-point calibration curves.



After a successful calibration, an updated calibrator 1 value (**S1 Abs.** column) is displayed on the **Working Information** window. If you generate a calibration reaction monitor list under **Print > Calibration**, you can also find an updated value in the first column under **Std(1)**.

The absorbance value of the second calibrator is printed in the first column under **Std(2)** on the second page of the calibration reaction monitor list.

These new values are used to calculate the K-factor. The formula for the K-factor calculation for endpoint assays is as follows:

$$\sqrt{xy}\ \mathbf{10}\quad K = (C_N - C_b)/(A_N - A_b)$$

C_b	Concentration value for calibrator 1
C_N	Concentration value for the second calibrator (N), N > 1
A_b	Absorbance of calibrator 1 (S1 Abs.)
A_N	Absorbance of the second calibrator (N), N > 1

▸ 2-point end assay calculation (14)

About calibration methods

A calibration must be updated regularly. On the system, you can update a calibration using 2 different calibration methods.

The update of a calibration can be described in 2 ways: either as an adjustment of parameters of the calibration curve or as an adjustment of the measured value (signal correction) to compensate for changed conditions. Both of these descriptions are mathematically equivalent.

Up to 6 calibrators can be used for a full calibration. However, not all of these calibrators must be used in every calibration method.

Calibration method	Calibrators needed		Applicable calibration type
2-point	Calibrator 1 and an additional calibrator N with N > 1		Linear
Full	Calibrator 1, 2, 3, …, calibrator N	All calibrators specified for the application[a]	RCM4

Calibration methods

(a) Displayed on **Utility > Application > Other**.

The following parameters are used throughout this chapter:

S1Abs	Calibration curve parameter displayed in the **S1 Abs.** column[a]
K	Calibration curve parameter displayed in the **K** column
A, B	Calibration curve parameters displayed in the columns **A** and **B**
$'$	A diacritical mark (') denotes an updated parameter. For example, B' is the new B parameter of the calibration curve after the calibration update.

(a) See **Calibration > Result** or **Calibration > Result > Working Information**.

2-point calibration

Tests are calibrated using calibrator 1 and calibrator N with N > 1, as second calibrator. For this calibration update, the signal correction is linear: $s' = p \cdot s + q$.

The number of the second calibrator is displayed in the **Span** field on **Utility > Application > Calib.**. The calculation method depends on the calibration type.

Calibration type	S1 Abs.	K
Linear	S1Abs' $= s_b$	$K' = \frac{1}{p} \cdot K$ with $p = (s_N - s_b)/(\hat{s}_N - \hat{s}_b)$
Definitions:		
	p	Calibration update parameter
	s_b	The currently measured signal (absorbance) for calibrator 1
	s_N	The currently measured signal (absorbance) for calibrator N
	$\hat{s}_b$	Signal value calculated from the (non-updated) calibration curve for calibrator 1
	$\hat{s}_N$	Signal value calculated from the (non-updated) calibration curve for the given concentration value of calibrator N

Applicable calibration types for 2-point calibration updates

Full calibration

For a full calibration, tests are calibrated using all calibrators specified on **Utility > Application > Other**. The applicable calibration type for a full calibration is RCM4. After this calibration, all parameters of the nonlinear calibration curve are updated using a nonlinear regression algorithm. The parameters of a test's calibration curve are displayed on **Calibration > Result**.

About weighting

The entry in the **Weight** field on **Utility > Application > Calib.** is always set to 0 for this system. This means that the curve fit is optimized by varying the parameters of the calibration function to minimize the sum of the residuals.

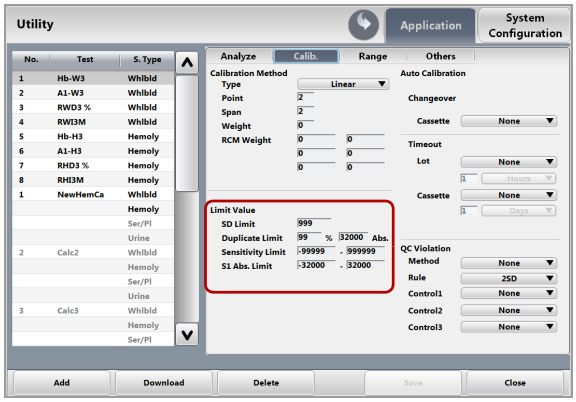
The residuals are the squares of the differences between the actual absorbance values for each calibrator and the absorbance calculated from the calibration function:

√xy **11** $\sum_{i=1}^{n} [A_i - f(C_i)]^2 \rightarrow \min$

A_i	Actual absorbance of calibrator i
$f(C_i)$	Absorbance of calibrator i calculated by the calibration function from its concentration (C_i)
$i = 1 \ldots n$	Numbers of calibrators used

Overview of calibration checks

Calibration checks automatically verify the reliability of calibrations. If a check lies outside the configured quality limits, an alarm is issued. For this system, the following calibration checks are available:



Calibration checks	Associated data alarms
SD limit	SD.E
Duplicate limit	Dup.E
Sensitivity limit	Sens.E
S1 Abs. limit	S1A.E
Standard error	Std.E

Calibration checks and associated data alarms

The limits of the calibration checks are configured on **Utility > Application > Calib.**.

SD Limit

When calibrating nonlinear or multi-point linear tests, the system performs the following check:
For each calibrator, an absorbance value is calculated from the given concentration and the current calibration curve. This calculated absorbance is compared to the measured absorbance. If the difference of the 2 absorbances exceeds the SD limit, an SD.E data alarm is issued. The SD limit value is defined in the **SD Limit** field (in Abs × 10^4). An SD limit value of 999.9 denotes that the test is omitted.

If a SD.E data alarm occurs, measurement is still possible and the calibration curve is updated. However, you must trace the cause of the alarm before you proceed to sample measurement.

Duplicate Limit

All photometric calibrations are performed in duplicate. The duplicate limit check calculates the % error ($DE_{\%}$) and the absolute absorbance error ($DE_{Abs.}$) (difference) between these duplicate measurements. The obtained values are compared to the values in the **Duplicate Limit %** field and in the **Duplicate Limit Abs.** field.

If both the % error and the absorbance error are out of range, a Dup.E data alarm is issued indicating a failed calibration. The calibration curve of the affected test is not updated.

The corresponding values are calculated as follows:

$$\sqrt{xy}\ \mathbf{12}\quad DE_{\%} = \frac{|Abs2 - Abs1|}{(Abs2 + Abs1)/2} \cdot 100$$

√xy **13** $DE_{Abs.} = |Abs2 - Abs1|$

$DE_{\%}$ Relative duplicate error: Calculated value for the % error of a calibrator's absorbance readings (duplicate)

$DE_{Abs.}$ Absolute duplicate error

$Abs1$, $Abs2$ Two absorbance readings, taken for each calibrator (duplicate readings)

Sensitivity Limit

The sensitivity limit refers to the ratio of an absorbance difference to a concentration difference. It is calculated from the measured absorbance values and given concentration values of the calibrator 1 (S_1) and the span calibrator (S_N):

√xy **14** $$\frac{Abs(S_N) - Abs(S_1)}{Conc(S_N) - Conc(S_1)}$$

The sensitivity obtained in a calibration must lie within certain limits. If the obtained sensitivity is not within these limits, a Sens.E data alarm is issued indicating a failed calibration. The calibration curve of the affected test is not updated.

S1 Abs. Limit

This calibration check sets an upper and lower absorbance limit for calibrator 1. If the absorbance for calibrator 1 falls outside these limits, the system issues a S1A.E data alarm indicating an erroneous calibration. The calibration curve of the affected test is not updated. A minimum value of -32000 and a maximum value of 32000 in the **S1 Abs. Limit** field denotes that the calibration is omitted.

For linear calibrations, the reagent blank is simply the y-intercept of the calibration curve.

Standard error

If any of the data alarms listed below occur in a calibration, a Std.E data alarm is issued. The calibration curve of the affected test is not updated. You choose the **Alarm** button to verify which data alarm has occurred.

Data alarm	Alarm name
A.Diff	Absorbance difference error
>Abs	ABS over
ADC.E	ADC abnormal
Calc.?	Calculation not possible
>Cuvet	ABS Cell blank abnormal
Dup.E	Duplicate error
>Lin	Linearity abnormal

Data alarms causing a Std.E data alarm when occurring in calibration

Data alarm	Alarm name
MIXLOW	Mixing current low
MIXSTP	Stop mixing
>React	Reaction limit over
Reag.S	Reagent short
S1A.E	S1ABS abnormal
Samp.C	Sample clot
Samp.S	Sample short

Data alarms causing a Std.E data alarm when occurring in calibration

Updated and non-updated calibration data

If the calibration curve is not updated, you must perform a recalibration. Depending on the cause of an alarm, recalibration may also be required even if the calibration curve is updated.

Data alarm	Calibration curve	Saving on hard disk	Display on Alarm screen
SD.E	Updated	Yes	Provided
Dup.E	Not updated	No	Not provided
Sens.E	Not updated	No	Provided
S1A.E	Not updated	No	Not provided
Std.E	Not updated	No	Provided

Data output in case of a data alarm during calibration