ABL800 FLEX

Reference manual

Contents

SYSTEM PERFORMANCE AND WARRANTY DISCLAIM

Radiometer cannot provide or verify instrument performance characteristics and accept warranty claims or product liability claims if the recommended procedures are not carried out, if accessories other than those recommended by Radiometer are used, or if instrument repairs are not carried out by authorized service representatives.

The instructions given in the Operator's Manual for the ABL800 FLEX must be observed in order to ensure proper instrument performance, and to avoid electrical hazards.

TRADEMARKS

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Contents

Warnings/Cautions

Definitions

Throughout the manual, the descriptions may contain operational precautions and warnings.

Notice	Definition
WARNING	Warning alerts users to potential serious outcomes to themselves or the patient (such as death, injury, or serious adverse events).
PRECAUTION	Precaution alerts users to exercise special care necessary for the safe and effective use of the device. Precaution may include actions to be taken to avoid effects on patients or users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precaution may also alert users to adverse effects on the device by use or misuse, and the care necessary to avoid such effects.
NOTE	Notes give practical information.

WARNING/ CAUTION

In this manual a distinction between a warning and a caution is not made. Any notice that alerts the user to possible dangers of any kind is given the title *WARNING/CAUTION*.

List of WARNING/ CAUTION Notices

All *WARNING/CAUTION* notices that appear in this manual are listed here in alphabetical order.

(*NOTES* are not presented in list form.)

- S5370 Cleaning Additive:

  Very toxic by inhalation, in contact with skin and if swallowed. Danger of cumulative effects. May cause sensitisation by inhalation and skin contact. Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing. In case of accident or if you feel unwell seek medical advice immediately (show the label if possible). The material and its container must be disposed of as hazardous waste.

- Electrolyte for E1001 Reference Electrode:

  *Irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advic*e

- Gas cylinders:

  Pressurized container. Non-flammable compressed gas. Do not breathe gas. Gas mixtures containing less than 19.5 % oxygen may cause suffocation. Protect from sunlight and do not expose to temperatures exceeding 50 ^{o}C (122 ^{o}F). Store and use with adequate ventilation. Keep away from oil and grease. Do not refill.

1. Potentiometric measuring principles

Overview

Introduction

This chapter describes the potentiometric measuring principles and the pH, pCO_2 and electrolyte electrodes that are based on this principle.

Contents

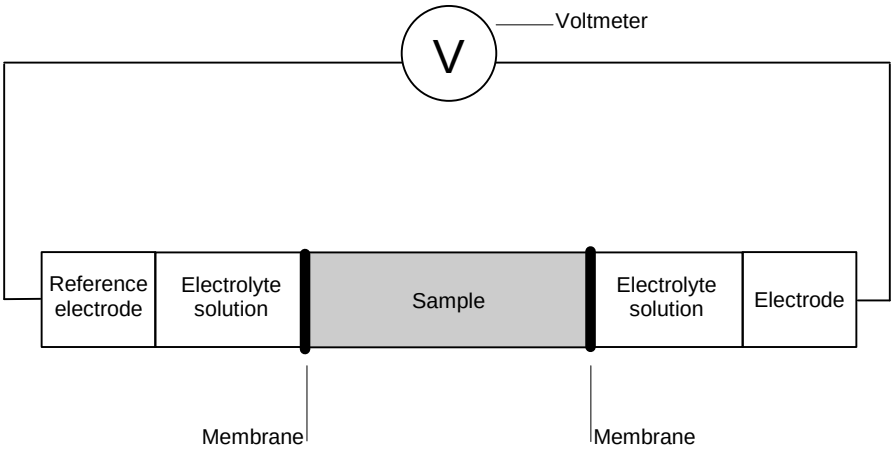
This chapter contains the following topics.

General information

Potentiometric method

The potential of an electrode chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation).

An electrode chain describes an electrical circuit consisting of a sample, electrode, reference electrode, voltmeter, membranes, and electrolyte solutions.



Every element in the electrode chain contributes a voltage to the total potential drop through the chain. Thus:

- When immersed in the appropriate electrolyte solution, both electrodes have separate potentials.
- The membrane junctions between the sample and electrolyte solutions also have separate potentials.

The potentiometric measuring principle is applied to pH, pCO_2, and electrolyte electrodes.

Nernst equation

The complete electrode chain potential therefore, is the sum of these separate potentials and is the quantity measured by the voltmeter.

$$E_{total} = E_0 + E_{sample}$$

where the final unknown potential (E_{sample}) can be calculated knowing the total electrode chain potential (E_{total}) and the standard potential (E_0).

Having measured the unknown potential (E_{sample}), the Nernst equation is then applied to determine the activity (a_x) of the species under study:

$$E_{sample} = E_0 + \frac{2.3RT}{n\mathrm{F}} \log a_x$$

where:

E_0	=	standard electrode potential
R	=	gas constant (8.3143 Joule × K^{-1} × mol^{-1})
T	=	absolute temperature (310 K (37 °C))

Continued on next page

General information, *Continued*

Nernst equation *(continued)*

n	=	charge on the ion
F	=	Faraday constant (96487 coulomb × mol^{-1})
a_x	=	activity of x

The Nernst equation is rearranged to express the activity as a function of the potential E_{sample}. Having measured E_{sample} the activity can be calculated since all other quantities are already known. Finally the analyzer converts activity to concentration.

Strictly speaking, the potential of an electrode chain or the magnitude of current flowing through an electrical chain is related to the activity of a substance, and not its concentration.

Activity expresses the 'effective concentration' of a species, taking non-ideality of the medium into account.

Activity and concentration are related by the following equation:

$$a_x = \gamma\, c_x$$

where:

a_x	=	the activity of the species x
γ	=	the activity coefficient of species x under the measurement conditions (for ideal systems $\gamma = 1$)
c_x	=	the concentration of species (mmol/L)

NOTE: *To be exact, activity is related to the molality of species x, i.e., the number of mmoles per kg of solvent. However molality is converted to concentration (molarity).*

The analyzer automatically converts activities into concentrations [1]. The term concentration is therefore used in explanations of the measuring principles for each of the electrodes further on in this chapter.

The potentiometric measuring principle is applied in the pH, pCO_2, and electrolyte electrodes. It is slightly different for the pCO_2 electrode, however, since the Nernst equation is not directly applied.

Calibration

Calibration is an analytical process defining the functional relationship between the obtained readings or analytical responses and the concentration or other quantities present in the calibration material (liquid or gas). Thus, a calibrating solution or a gas mixture (for pCO_2 calibrations) is drawn into the measuring chamber and the analyzer adjusts itself to measure the known value of the liquid or gas.

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General information, *Continued*

Calibration *(continued)*

The electrodes are active elements and must be calibrated regularly. Signals from the electrodes change because of, e.g., protein build-up, worn-out membranes, aging electrodes, etc.

The responses from the electrodes when measuring on the calibrating solutions are checked to ensure that the amplified signals from the electrodes are converted to accurate values for an unknown sample. The relationship between the electrode amplifiers' output and the pH/pCO_2 /electrolyte electrodes are simple mathematical functions. Calibration data can therefore be determined by relating the electrode signals during the calibration process to the values of the calibrating solutions.

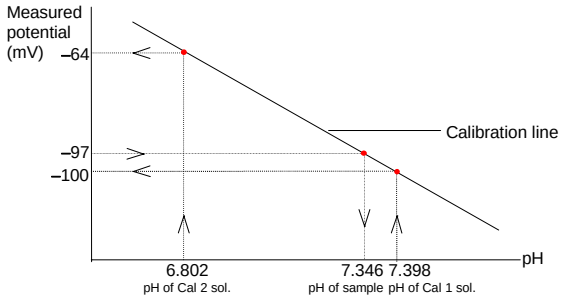
Calibration line

The calibration line expresses the relationship between the potential measured at an electrode, and the concentration of the species specific to the electrode. The calibration line forms the basis of the scale used by the analyzer to convert electrode chain potentials to concentrations. Each electrode has a different calibration line.

The pH electrode is used as an example to illustrate how the calibration line is derived from two calibration solutions with known pH.

The calibration solutions give the following two points: –64 mV at pH 6.802 (Cal 2) and –100 mV at pH 7.398 (Cal 1)

Within the coverage range 6.300 to 8.000 the pH electrode is linear, and the relationship between potential and pH is linear, so a line can be drawn between the two points, as shown below:



This is a two-point calibration. In one-point calibration, only the position of the calibration line is determined. The slope of the calibration line is maintained from the last 2-point calibration.

The calibration line is stored in the computer and is used during measurement to convert the potential measured at the pH electrode during sample analysis to an actual pH value.

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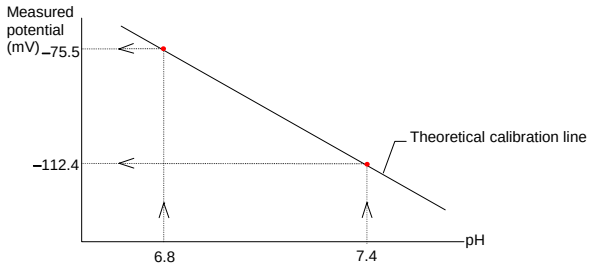
General information, *Continued*

Calibration line *(continued)*

To describe the actual condition of the electrode, its calibration line is compared to the calibration line of the theoretical electrode.



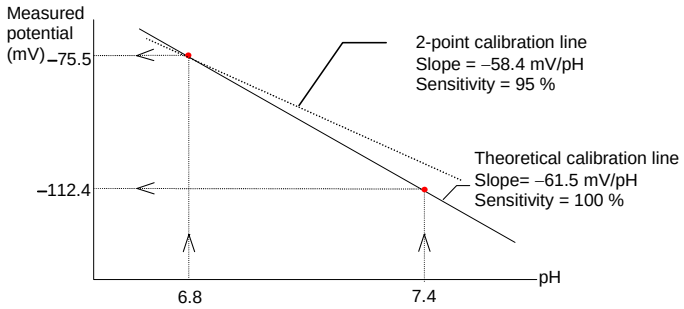
The theoretical electrode is defined to measure the following:
–112.4 mV at pH 7.400,
–75.5 mV at pH 6.800.

The position and slope of the calibration line compared to the theoretical calibration line are described by the status and sensitivity.

Sensitivity

The electrode sensitivity illustrates the slope of the calibration line compared to the slope of the theoretical electrode.

The sensitivity of the theoretical electrode is 100 % or 1.00.



If an electrode has a sensitivity of 95 % or 0.95, its sensitivity is 5 % lower than the theoretical electrode.

The sensitivity of an electrode is calculated as:

$$Sensitivity = \frac{Potential\ \ at\ 6.802 - Potential\ at\ 7.398}{61.5 \times (7.398 - 6.802)} \quad (\%)$$

where 61.5 = sensitivity of theoretical electrode.

Each electrode has its own sensitivity limits.

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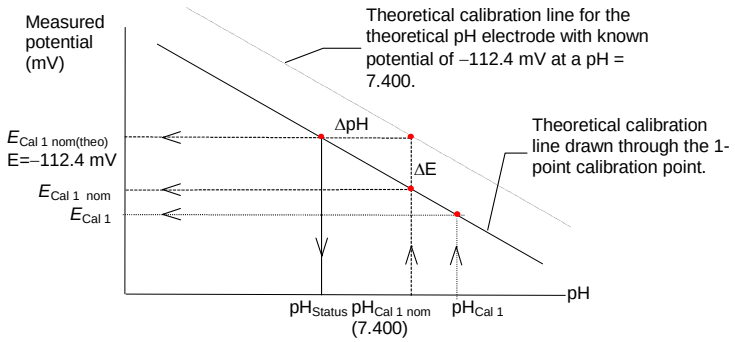
General information, *Continued*

Status

Status reflects the deviation from the theoretical electrode at pH 7.400 and, therefore indicates the position of the calibration line.



A calibration line with the same slope as the theoretical calibration line (–61.5 mV/ pH) is drawn through this point.

The calibration line for the actual electrode deviates from that of the theoretical electrode. The status value describes this deviation.

Status of the actual pH electrode at pH 7.400 is calculated as:

$$Status = 7.400 - \frac{Meas.\ potential\ at\ 7.400 - Potential\ of\ theoretical\ electr.\ at\ 7.400}{61.5 \times 100}$$

Each electrode has its own status limits.

Drift

Drift of an electrode is a measure of stability obtained by comparing the last accepted calibration with the previous calibration.

The following drift values are used:

- Drift 1 - obtained on Cal 1 and/or Gas 1;
- Drift 2 – obtained after a 2-point calibration.

The obtained drift values should not exceed the calibration drift tolerances. The drift tolerances can be changed in the Setup program, but Radiometer recommends using the default drift tolerances. Too narrow drift tolerances will cause electrode drift errors even for normal electrode fluctuations. If the drift tolerances are made wider, no warning will be given if the electrodes should become unstable. Significant measurement errors could result.

Continued on next page

General information, *Continued*

Calibration materials

The following calibration materials are used:

Calibration Material	Used for...
Calibration Solutions 1 and 2: the exact composition of the calibration solutions is given in the barcode on the bottle label, which can be read into the analyzer using the barcode reader, or entered manually via the keyboard.	Calibration of the pH, and electrolyte electrodes
Gas 1 and Gas 2: each gas has a precise composition essential for determining the accuracy of the analyzer in each pCO_2 measurement; the exact composition of the calibration solutions is given in the barcode on the bottle label, which can be read into the analyzer using the barcode reader, or entered manually via the keyboard.	Calibration of the pCO_2 electrode

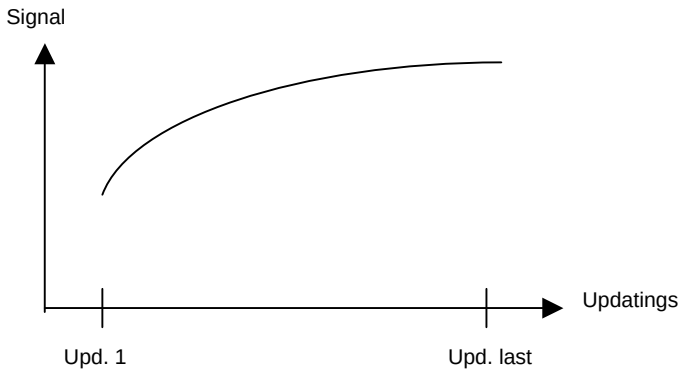
The Chemical Reference Laboratory at Radiometer is responsible for the accuracy of the calibrating solutions. Traceability certificates for the individual solutions are enclosed in Chapter 7: *Solutions and Gas Mixtures*.

Measuring time

The measuring time of the electrode is independent of the electrode type. Electrode signals are registered at 0.982 second intervals during both calibrations and measurements. The registration of each electrode signal begins after the samples, calibration solutions, and calibration gases are in position in the measuring modules. The duration of each calibration is predetermined, as is the number of updatings of the electrodes' signals.

Updatings

In general, the updatings from an electrode response are numbered from 1 to *upd. last*, where updating number 1 is the first updating and *upd.last* is the last. The diagram below schematically illustrates the electrode response that is calculated on uncorrected electrode updating values.



Reference electrode

Description

The reference electrode is used in the measurement of pH and electrolyte parameters and is located in the pH/Blood Gas module.

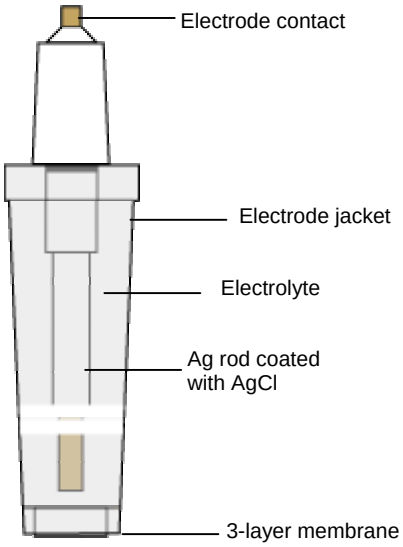
The reference electrode maintains a stable, fixed potential against which other potential differences can be measured. The potential is not altered by sample composition.

A fixed potential is maintained at the reference electrode by the following equilibrium reactions:

$$AgCl \Leftrightarrow Ag^{+} + Cl^{-}$$

$$Ag^{+} + e^{-} \Leftrightarrow Ag$$

These reactions are possible because the electrode is made from a Ag rod coated with AgCl to provide the Ag/Ag^{+} equilibrium and determine the reference potential.



The electrolyte solution acts as a salt-bridge solution that maintains an electrical contact between the coated Ag wire and the sample. The solution is 4 M sodium formate (HCOONa), adjusted to pH 5.5 with hydrochloric acid.

The chloride concentration in the electrolyte solution is adjusted in accordance with the chloride concentration in the rinse solution, to reduce Cl^{-} exchange across the membrane, thereby obtaining a more stable potential.

The electrode is encased in the electrode jacket: The rubber ring seals the electrode in the jacket to prevent evaporation or leakage of the electrolyte solution.

The membrane consists of three separate membranes:

Membrane	Function
Inner	To limit diffusion through the membrane and stabilizes the whole membrane system.
Middle	To prevent protein interference.
Outer	To reduce the interchange of sample or rinse solution and HCOONa solution.

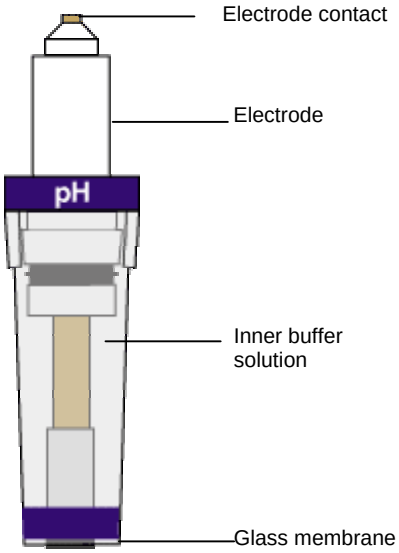
Packaging

The E1001 reference electrode comes in a box with an insert explaining the preparation of the electrode and its use.

pH electrode

Description

The pH electrode (E777) is a pH-sensitive glass electrode. The pH-sensitive glass membrane is located at the tip and seals the inner buffer solution with a constant and known pH.



The air bubble allows for expansion of the inner buffer solution when the electrode is thermostatted to 37 °C.

The potential difference across the glass membrane is due to a change in the charge balance at the membrane.

The glass membrane is sensitive to H^+ ions. The metal ions in the glass are exchanged with protons on either side of the membrane, from the inner buffer solution on one side and the sample on the other.

A difference in the ion exchange on either side of the membrane occurs if the H^+ concentration (and therefore pH) is unequal on both sides. The number of positive and negative ions is no longer equal, so the potential difference across the membrane changes. If the H^+ concentrations on either side of the membrane are equal, the potential difference will theoretically be 0 mV.

Nernst equation

The theoretical sensitivity of the pH electrode at 37 °C being equal to –61.5 mV per pH unit, using pH = –log [H^+], and converting concentration to activity, the Nernst equation can be expressed as:

$$E_{sample} = E_0 - 61.5 \times pH \qquad mV$$

Designation

The following symbols are used:

–61.5 mV/pH	=	Theoretical sensitivity of the pH electrode at 37 °C
E(pH,Cal2)	=	Potential of the pH electrode chain from a calibration measurement on Cal 2 solution
E(pH,Cal1)	=	Potential of the pH electrode chain from a calibration measurement on Cal 1 solution
E_0(pH,Cal1)	=	Standard potential of the pH electrode chain with a nominal pH = 7.4 (the approximate pH of Cal 1 solution)

Continued on next page

pH electrode, *Continued*

Designation *(continued)*

pH(Cal1,nom)	=	Nominal pH of Cal 1 solution (pH = 7.4)
pH(Cal1)	=	pH of Cal 1 solution
E(pH,Cal1prev)	=	Potential of the pH electrode chain from the previous calibration measurement on Cal 1 solution
Sens(pH,prev) fraction	=	Sensitivity of the pH electrode from the previous 2-point calibration
pH(Cal1,prev)	=	pH of Cal 1 solution in the previous calibration measurement
pH(Cal2)	=	pH of Cal 2 solution
Sens(pH)	=	Relative sensitivity of the pH electrode chain.

Sensitivity

The sensitivity of the pH electrode ($Sens_{pH}$) is obtained from the calibration line obtained from a 2-point calibration on Calibration Solutions 1 and 2 (Cal 1 and Cal 2), and is calculated from the following equation:

$$Sens(pH) = \frac{E(pH,Cal2) - E(pH,Cal1)}{-61.5 \times [pH(Cal2) - pH(Cal1)]} \quad \text{(fraction)}$$

The sensitivity of the pH electrode should fall between 0.92 - 1.03 or 92 -103 %.

Status

The status of the pH electrode is calculated from the following equation:

$$Status(pH) = \frac{E(pH,Cal1) - E_0(pH,Cal1)}{-61.5} + 2\,pH(Cal1,nom) - pH(Cal1)$$

The status of the pH electrode should fall between a pH of 6.7 and 8.1.

Drift

Drift 1 is calculated from the following equation:

$$Drift\,1(pH) = \frac{E(pH,Cal1) - E(pH,Cal1prev)}{-61.5 \times Sens(pH,prev)} - [pH(Cal1) - pH(Cal1,prev)]$$

NOTE: *Under normal circumstances,* pH(Cal1)–pH(Cal1,prev) = 0. *However in instances where the Cal 1 solution container has been replaced between two consecutive calibrations,* pH(Cal1)–pH(Cal1,prev) ≠ 0.

The default drift tolerances set by Radiometer for Drift 1 are ± 0.020.

Drift 2 is calculated from the following equation:

$$Drift\,2(pH) = \frac{E(pH,Cal2) - E(pH,Cal1prev)}{-61.5 \times Sens(pH,prev)} - [pH(Cal2) - pH(Cal1,prev)]$$

The default drift tolerances set by Radiometer for Drift 2 are ± 0.020.

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pH electrode, *Continued*

Measurement The sample pH is calculated as follows:

$$pH(sample) = \frac{E(pH,sample) - E(pH,Cal1)}{-61.5 \times Sens(pH)} + pH(Cal1)$$

Corrections The measured pH value is then corrected for systematic deviations from the reference method using the following equation:

Equation A:

$pH(sample,corr.) = A_0 \times pH(sample) + A_1$

where:

pH(sample)	= uncorrected pH value of the sample
pH(sample,corr.)	= corrected pH value of the sample.
A_0	= instrument-dependent correction factor
A_1	= instrument-dependent cut-off

Equation A+:

When an additional correction is needed, equation A is first used together with the constants for the FLEXMODE (195 and 165 µL, no message) mode. Then the obtained results are put back into equation A as pH(sample) and then treated again, using the constants for the specific sample handling to obtain the corrected value.

Corrections are as follows:

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	0.9964	0.0150	A
	S95	0.9964	0.0150	A
	S85	0.9964	0.0150	A
	C95	1.007	–0.053	A+
	C55	1.025	–0.1880	A+
	FLEXMODE (no message)	0,9964	0.0150	A
	FLEXMODE (message 874)	1.007	–0.0530	A+
	FLEXMODE (message 873)	1.007	–0.0530	A+
	FLEXMODE (message 872)	1.0216	–0.1639	A+
	FLEXMODE (message 871)	1.025	–0.1880	A+

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pH electrode, *Continued*

Corrections *(continued)*

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	FLEXMODE (message 870)	1.030	–0.216	A+
(cont.)	FLEXMODE (message 869)	1.030	–0.216	A+
30/20/10	S85	0,9964	0.0150	A
	C55	1.025	–0.1880	A+
	FLEXMODE (no message)	1.0006	–0.0035	A+
	FLEXMODE (message 872)	1.0209	–0.1575	A+
	FLEXMODE (message 871)	1.025	–0.1880	A+
	FLEXMODE (message 870)	1.030	–0.216	A+
	FLEXMODE (message 869)	1.030	–0.216	A+
05	S165	0,9964	0.0150	A
	S95	0,9964	0.0150	A
	S85	0,9964	0.0150	A
	C95	1.007	–0.053	A+
	C55	1.025	–0.1880	A+
	FLEXMODE (no message)	0,9964	0.0150	A+
	FLEXMODE (message 874)	1.007	–0.053	A+
	FLEXMODE (message 873)	1.007	–0.053	A+
	FLEXMODE (message 872)	1.0216	–0.1639	A+
	FLEXMODE (message 871)	1.025	–0.1880	A+
	FLEXMODE (message 870)	1.030	–0.216	A+
	FLEXMODE (message 869)	1.030	–0.216	A+
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pH electrode, *Continued*

Stability criteria The following stability criterion must be met to obtain a stable electrode response during 1- and 2-point **calibration**:

$$\left|\mathrm{pH(sample, upd.last)} - \mathrm{pH(sample, upd.i)}\right| \leq \mathrm{pH(limit)}$$

The following stability criterion must be met to obtain a stable electrode response during **measurement**:

$$\left|\mathrm{pH(sample, upd.last)} - \mathrm{pH(sample, upd.i)}\right| \leq \mathrm{pH(limit)}$$

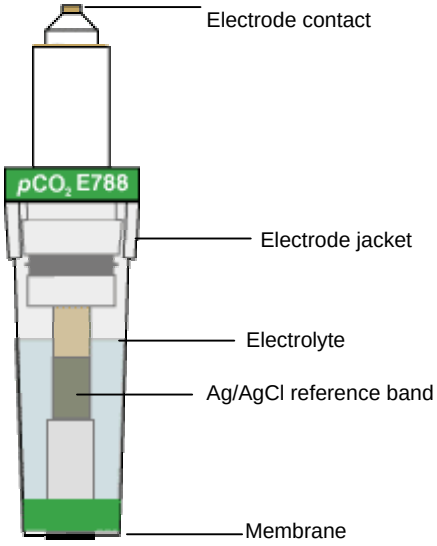
where:

pH(sample,upd.last) =	pH value from the last updating with a measurement on calibration solution or sample. (The last updating is number 30).
pH(sample,upd.i) =	pH value for a given updating with a measurement on calibration solution or sample. (The relationship must be fulfilled for at least one of the updating numbers 20 or 21).
pH(limit) =	pH limiting value for the stability criterion (0.005).

pCO_2 electrode

Description

The pCO_2 electrode (E788) is a combined pH and Ag/AgCl reference electrode mounted in a plastic jacket, which is filled with a bicarbonate electrolyte.



The jacket is covered by a 20 µm silicone membrane moulded on a 50 µm nylon net. The net both reinforces the silicone membrane and serves as a spacer in order to trap a layer of the electrolyte between the membrane and the glass tip of the electrode. The electrolyte also contains glycerol to prevent collection of air bubbles in the electrode jacket thus improving electrode stability.

The membrane allows any uncharged molecules of CO_2, O_2, N_2 to pass through it. Charged ions such as H^+ will not pass. Consequently, dissolved CO_2 from the sample will diffuse into the thin layer of bicarbonate electrolyte until the equilibrium is reached.

This produces carbonic acid:

$$H_2O + CO_2 \Leftrightarrow H_2CO_3$$

Carbonic acid dissociates according to the following equilibrium reaction:

$$H_2CO_3 \Leftrightarrow H^+ + H_2CO_3^-$$

The release of H^+ ions changes the H^+ concentration, and therefore the pH of the solution on one side of the pH-sensitive glass membrane.

The concentration gradient of H^+ ions on the other side of the membrane affects the potential difference across the glass membrane. This change in potential across the glass membrane is measured by the voltmeter.

Nernst equation

The Nernst equation is used to convert the potential reading into a pH value:

$$E_{glass} = E_0 - 61.5 \times pH \text{ (mV)}$$

where:

E_{glass}	=	potential difference across the glass membrane
E_0	=	standard electrode potential
61.5 mV/pH	=	theoretical sensitivity of the pH electrode at 37 °C

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pCO_2 electrode, *Continued*

Nernst equation *(continued)*

The pH value is related to the partial pressure of CO_2 in the sample by the following equation:

$$pH = pK_a + \log \frac{cHCO_3^-}{pCO_2 \times \alpha_{CO_2}}$$

where:

pK_a = $-\log K_a$, the equilibrium constant for the dissociation of carbonic acid in water

α_{CO_2} = solubility coefficient for CO_2 in water

The bicarbonate concentration $[HCO_3^-]$ is so large compared to $[H^+]$ that it can be considered constant. At constant temperatures α_{CO_2} is also constant. So the equation can be simplified to:

$$pH = K' - \log pCO_2$$

where:

K' is a constant incorporating the equilibrium constant for carbonic acid (K_a), the bicarbonate concentration, and the solubility coefficient α_{CO_2}.

$K_a = \frac{cH^+ \times cHCO_3^-}{CO_2}$ is the equilibrium constant for carbonic acid.

pCO_2 of the sample is then calculated from the equation above.

Designation

The following symbols are used:

pCO_2(Gas1), pCO_2(Gas2)	=	Pressure of CO_2 in Gas 1 or Gas 2, respectively
FCO_2(Gas1), FCO_2(Gas2)	=	Fraction of CO_2 in Gas 1 or Gas 2, respectively
$B_{Gas\ 1\ or\ 2}$	=	Pressure inside the measuring chamber during a measurement on Gas 1 or Gas 2 respectively
pH_2O	=	Water vapor pressure (6.2751 kPa at 37 °C)
E(CO_2,Gas1), E(CO_2,Gas2)	=	Potential of the pCO_2 electrode from a measurement on Gas 1 or Gas 2, respectively
Sens(pCO_2,theo)	=	Theoretical (absolute) sensitivity of the pCO_2 electrode at 37 °C
Sens(pCO_2,prev)	=	Relative sensitivity of the pCO_2 electrode from the previous 2-point calibration

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pCO_2 electrode, *Continued*

Designation *(continued)*

$E_0(CO_2,Gas1)$	=	Standard potential of the pCO_2 electrode with Gas 1
$E(CO_2,Gas1,prev)$	=	Potential of the pCO_2 electrode from the previous measurement on Gas 1
δ	=	difference between pCO_2 (sample) from the first and last updatings.
predict	=	extrapolated value for pCO_2.

Sensitivity

The pCO_2 electrode is calibrated on two gases with known CO_2 contents:

Gas 1: 5.61 % CO_2 and Gas 2: 11.22 % CO_2.

The exact composition of the calibration gases is contained in their bar codes.

The partial pressures of CO_2 in Gas 1 and Gas 2 are calculated from the following equations:

$$pCO_2\,(Gas1) = FCO_2\,(Gas1) \times \left(B_{\text{Gas 1}} - pH_2O\right) \quad \text{kPa}$$

$$pCO_2\,(Gas2) = FCO_2\,(Gas2) \times \left(B_{\text{Gas 2}} - pH_2O\right) \quad \text{kPa}$$

The relative sensitivity of the pCO_2 electrode is calculated as follows:

$$\text{Sens}(pCO_2) = \frac{E(CO_2,Gas2) - E(CO_2,Gas1)}{\text{Sens}(pCO_2,\text{theo}) \times \log\dfrac{pCO_2(Gas2)}{pCO_2(Gas1)}}$$

The sensitivity of the pCO_2 electrode should fall between 0.85 -1.00 or 85 - 100 %.

Status

The status of the pCO_2 electrode is calculated as follows:

$$\text{Status}(pCO_2) = pCO_2(Gas1) \times 10^{\frac{E(CO_2,Gas1) - E_0(CO_2,Gas1)}{\text{Sens}(pCO_2,\text{theo})}} \quad \text{kPa}$$

The status of the pCO_2 electrode should fall between 6.2-260 mmHg /(0.83-34.66 kPa).

Drift

Drift 1 is calculated as follows:

$$\text{Drift}\,1(pCO_2) = pCO_2(Gas1) \times 10^{\frac{E(CO_2,Gas1) - E(CO_2,Gas1,prev)}{\text{Sens}(pCO_2,prev) \times \text{Sens}(pCO_2,\text{theo})}} - pCO_2(Gas1,prev)\,\text{kPa}$$

Drift 2 is calculated as follows:

$$\text{Drift}\,2(pCO_2) = pCO_2(Gas2) \times 10^{\frac{E(CO_2,Gas2) - E(CO_2,Gas1,prev)}{\text{Sens}(pCO_2,prev) \times \text{Sens}(pCO_2,\text{theo})}} - pCO_2(Gas2,prev)\,\text{kPa}$$

Continued on next page

pCO_2 electrode, *Continued*

Drift *(continued)* The default drift tolerances set by Radiometer are as follows:

- for Drift 1 are ± 0.33 kPa (2.5 mmHg)
- for Drift 2 are ± 0.67 kPa (5.0 mmHg)

Measurement The pCO_2 value for a sample is calculated from the following equations:

$$pCO_2(\text{sample,upd}i) = pCO_2(\text{gas1}) \times 10^{\frac{E(CO_2\text{sample,upd}i) - E(CO_2\text{Gas1})}{\text{Sens}(pCO_2\text{,prev}) \times \text{Sens}(pCO_2\text{,theo})}}$$

$$\delta = \left| pCO_2(\text{sample, upd30}) - pCO_2(\text{sample, upd1}) \right|$$

$$\text{predict} = \frac{pCO_2(\text{sample, upd6}) \times pCO_2(\text{sample, upd30}) - \left[pCO_2(\text{sample, upd18}) \right]^2}{pCO_2(\text{sample, upd6}) + pCO_2(\text{sample, upd30}) - 2 \times pCO_2(\text{sample, upd18})}$$

For $\delta < 1.33$ kPa, $pCO_2(\text{sample}) = pCO_2(\text{sample,upd30})$

For 1.33 kPa < δ < 2.66 kPa

$$pCO_2(\text{sample}) = \frac{\text{predict} \times (\delta - 1.33) + pCO_2(\text{sample, upd30}) \times (2.66 - \delta)}{1.33}$$

For $\delta \geq 2.66$ kPa, $pCO_2(\text{sample}) = \text{predict}$.

Corrections - blood samples The pCO_2 measured on a sample is then corrected for systematic deviations from the reference method using the following equations:

Equation A:

$$pCO_2(\text{sample,corr}) = A_3 \times pCO_2(\text{sample})^3 + A_2 \times pCO_2(\text{sample})^2 + A_0 \times pCO_2(\text{sample}) + A_1 \times (B - pH_2O)$$

and

Equation B:

$$pCO_2(\text{sample,corr}) = B_1 \times pCO_2(\text{sample}) + B_0$$

where:

pCO_2(sample)	=	uncorrected value of pCO_2 in the sample.
pCO_2(sample, corr)	=	corrected value of pCO_2 in the sample.
A_0	=	correction factor
A_1	=	correction factor
A_2	=	correction factor
A_3	=	correction factor

Continued on next page

pCO_2 electrode, *Continued*

Corrections - blood samples *(continued)*

B = barometric pressure in kPa

pH_2O = partial pressure of saturated water vapor (6.2751 kPa)

B_0 = correction cut-off

B_1 = correction factor

ABL8XX FLEX	Mode	A_0	A_1	A_2	A_3	B_0	B_1	Eq.
35/25/15	S195	-0.003573	1.1126	0.0051	-0.0000002			A
	S95	-0.003573	1.1126	0.0051	-0.0000002	1.000	-0.016	A, B
	S85	-0.003573	1.1126	0.0051	-0.0000002			A
	C95	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	C55	-0.003573	1.1126	0.0051	-0.0000002	1.12	-0.28	A, B
	*FM (no message)	-0.003573	1.1126	0.0051	-0.0000002			A, B
	*FM (message 874)	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	*FM (message 873)	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	*FM (message 872)	-0.003573	1.1126	0.0051	-0.0000002	1.0884	-0.1619	A, B
	*FM (message 871)	-0.003573	1.1126	0.0051	-0.0000002	1.090	-0.150	A, B
30/20/10	S85	-0.003573	1.1126	0.0051	-0.0000002			A
	C 55	-0.003573	1.1126	0.0051	-0.0000002	1.12	-0.28	A, B
	*FM (no message)	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.050	A, B
	*FM (message 872)	-0.003573	1.1126	0.0051	-0.0000002	1.0819	-0.0495	A, B
	*FM (message 871)	-0.003573	1.1126	0.0051	-0.0000002	1.090	-0.150	A, B

*FM = FLEXMODE

Continued on next page

pCO_2 electrode, *Continued*

Corrections - blood samples *(continued)*

ABL8XX FLEX	Mode	A_o	A_1	A_2	A_3	B_0	B_1	Eq.
05	S165	-0.003573	1.1126	0.0051	-0.0000002			A
	S95	-0.003573	1.1126	0.0051	-0.0000002	1.000	-0.016	A, B
	S85	-0.003573	1.1126	0.0051	-0.0000002			A
	C95	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	C55	-0.003573	1.1126	0.0051	-0.0000002	1.12	-0.28	A, B
	*FM (no message)	-0.003573	1.1126	0.0051	-0.0000002			A, B
	*FM (message 874)	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	*FM (message 873)	-0.003573	1.1126	0.0051	-0.0000002	1.013	0.010	A, B
	*FM (message 872)	-0.003573	1.1126	0.0051	-0.0000002	1.0884	-0.1619	A, B
	*FM (message 871)	-0.003573	1.1126	0.0051	-0.0000002	1.090	-0.150	A, B
00								

*FM = FLEXMODE.

Corrections - expired air samples

The pCO_2 measured from the sample is then corrected for systematic deviations from the reference method using the following equation:

$$pCO_2(\text{sample,corr}) = A_0 \times pCO_2(\text{sample}) + A_1 \times (B - pH_2O)$$ **Equation A**

where:

pCO_2(sample)	= uncorrected pCO_2 value of a expired air sample
pCO_2(sample,corr)	= corrected pCO_2 value of a expired air sample
A_0	= instrument dependent correction factor
A_1	= instrument-dependent correction factor
B	= barometric pressure during the measurement
pH_2O	= partial pressure of saturated water vapour = 6.2751 kPa

ABL8XX FLEX	Mode	A_0	A_1	Equation
All	Expired air	1.0196	-0.00106	A

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pCO_2 electrode, *Continued*

Stability criteria The following stability criterion must be met to obtain a stable electrode response during calibration:

$$\left|p\mathrm{CO}_2(\text{sample, upd.last}) - p\mathrm{CO}_2(\text{sample, upd.i})\right| \leq p\mathrm{CO}_2\ (\text{limit})$$

This criterion is valid for calibrations using Gas 1 and Gas 2 where:

Parameter	*p*CO_2 value from the last updating number...	
	ABL805/835 FLEX	ABL800/830 FLEX
pCO_2(sample,upd.last)	92	62
pCO_2(sample,upd.i)	86 or 87	56 or 57
	(the relationship must be fulfilled for at least one of the updating numbers)	

pCO_2(limit) value for the stability criterion is 0.40 kPa/3.0 mmHg.

The following stability criteria must be met to obtain a stable electrode response during measurement:

$$\delta = \left|p\mathrm{CO}_2(\text{sample, upd.30}) - p\mathrm{CO}_2(\text{sample, upd.i})\right|$$

For δ	Criterion
≤1.33 kPa	$\left\|p\mathrm{CO}_2(\text{sample, upd.30}) - p\mathrm{CO}_2(\text{sample, upd.16})\right\| \leq 0.40$
>1.33 kPa	$-0.1 \leq \frac{p\mathrm{CO}_2(\text{sample, upd.30}) - p\mathrm{CO}_2(\text{sample, upd.16})}{p\mathrm{CO}_2(\text{sample, upd.16}) - p\mathrm{CO}_2(\text{sample, upd.1})} < 0.5$

For δ >1.33 kPa:

if the following criteria are fulfilled, then no result is reported:

$$\frac{p\mathrm{CO}_2(\text{sample, upd.30}) - p\mathrm{CO}_2(\text{sample, upd.16})}{p\mathrm{CO}_2(\text{sample, upd.16}) - p\mathrm{CO}_2(\text{sample, upd.1})} < -1.0$$

or

$$\frac{p\mathrm{CO}_2(\text{sample, upd.30}) - p\mathrm{CO}_2(\text{sample, upd.16})}{p\mathrm{CO}_2(\text{sample, upd.16}) - p\mathrm{CO}_2(\text{sample, upd.1})} \geq 0.5$$

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pCO_2 electrode, *Continued*

Stability criteria *(continued)*

Expired air samples:

Measurement on an expired air sample is accepted if the following criterion is fulfilled:

$$|pCO_2 \text{ (sample,upd.30)} - pCO_2 \text{ (sample,upd.24)}| \leq 0.40 \text{ kPa (3.0 mmHg)}$$

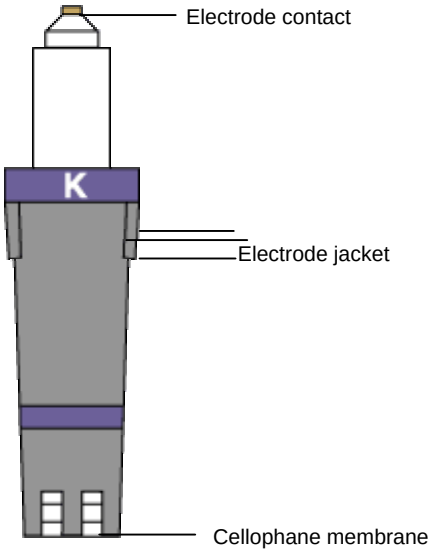
or

$$|pCO_2 \text{ (sample,upd.30)} - pCO_2 \text{ (sample,upd.24)}| \leq 0.04 \times pCO_2 \text{ (sample,upd.30)}.$$

Error message "Measurement unstable" (= pCO_2 response fault during electrode monitoring in Expired air mode) is displayed if the stability criterion is not fulfilled.

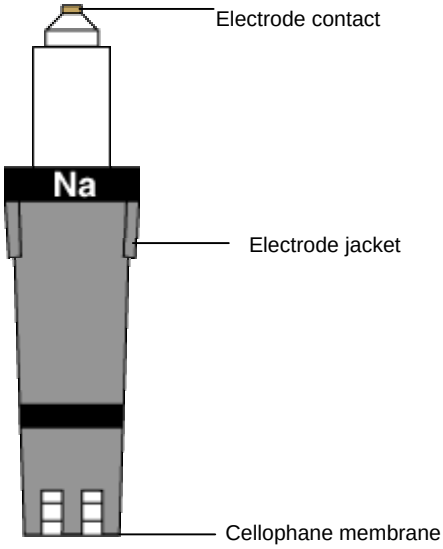
Electrolyte electrodes

Description



The K electrode (E722) is an ion-selective electrode whose sensing element is a PVC membrane containing a potassium-neutral ion carrier. The ion-sensitive membrane is covered with a cellophane membrane in order to protect it from the samples.

The electrolyte has a constant and known concentration of potassium ions. When a sample is brought in contact with the electrode, a potential develops across the PVC and cellophane membranes. The potential depends on the difference between the potassium (more precisely, activity) in the electrolyte and the sample. If the cK^+ in both solutions is the same, the potential across the electrode tip will be 0 V.



The Na electrode (E755) is an ion-selective electrode whose sensing element is a Na^+-sensitive ceramic pin contained in the tip of the jacket.

The electrolyte has a constant and known concentration of sodium ions. When a sample is brought in contact with the electrode, a potential develops across the ceramic pin. The potential depends on the difference between the sodium (more precisely, activity) in the electrolyte and the sample. If the cNa^+ in both solutions is the same, the potential across the electrode tip will be 0 V.

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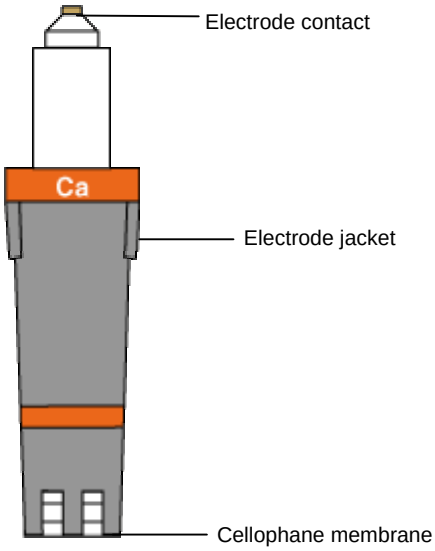
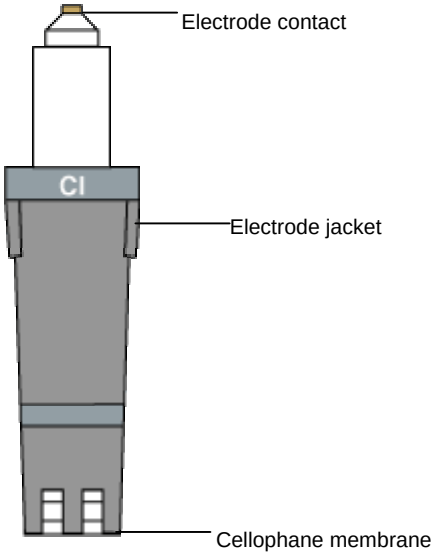
Electrolyte electrodes, *Continued*

Description *(continued)*



The Ca electrode (E733) is an ion-selective electrode whose sensing element is a PVC membrane containing a calcium-neutral ion carrier. The ion-sensitive membrane is covered with a cellophane membrane in order to protect it from the samples.

The electrolyte has a constant and known concentration of calcium ions. When a sample is brought in contact with the electrode, a potential develops across the PVC and cellophane membranes. The potential depends on the difference between the calcium (more precisely, activity) in the electrolyte and the sample. If the $c\mathrm{Ca}^{2+}$ in both solutions is the same, the potential across the electrode tip will be 0 V.



The Cl electrode (E744) is an ion-selective electrode whose sensing element is a PVC membrane containing a chloride ion carrier. The ion-sensitive membrane is covered with a cellophane membrane in order to protect it from the samples.

The electrolyte has a constant and known concentration of chloride ions. When a sample is brought in contact with the electrode, a potential develops across the PVC and cellophane membranes. The potential depends on the difference between the chloride (more precisely, activity) in the electrolyte and the sample. If the $c\mathrm{Cl}^{-}$ in both solutions is the same, the potential across the electrode tip will be 0 V.

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Electrolyte electrodes, *Continued*

Electrode chain potential

The total potential across the electrode chain is a sum of the potential differences at each of the elements in the chain, all but one of which is known and constant.

Element	Potential	Symbol
Ag/AgCl electrode /electrolyte solution. (Reference electrode)	Known and constant when the Ag/AgCl wire is immersed in the electrolyte solution.	E_{ref}
Membrane junction between the electrolyte solution in the reference electrode and the sample.	Known and constant, independent of sample composition.	E_{MJ}
Ion-sensitive membrane (or pin) junction separating the sample and the electrode.	**Unknown**, dependent on sample composition.	E_{Sample}
Ag/AgCl electrode/inner buffer solution. (Electrolyte electrode)	Known and constant when the Ag/AgCl wire is immersed in the electrolyte solution.	E_E
Total potential.	Measured by the voltmeter.	E_{tot}

The unknown potential difference across the ion-sensitive membrane or pin is then the difference between the measured total potential and the sum of the known potentials:

$$E_{Sample} = E_{tot} - \left(E_{ref} + E_{MJ} + E_E\right) \qquad \text{mV}$$

Nernst equation

The potential difference at the membrane (or pin) in the electrolyte electrodes can be expressed by the Nernst equation:

$$E_{Sample} = E_0 + \frac{2.3RT}{n\mathrm{F}} \times \log a_{ion} \qquad \text{mV}$$

where:

E_0	=	standard electrode potential
R	=	gas constant (8.3143 $J \times K^{-1} mol^{-1}$)
T	=	absolute temperature (310.15 K at 37 °C)
n	=	charge on the ion (n = 1 for K^+ and Na^+, n = –1 for Cl^-, n = 2 for Ca^{2+})
F	=	Faraday constant (96487 coulomb × mol^{-1})
a_{ion}	=	activity of the specific ion

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Electrolyte electrodes, *Continued*

Calibration solution values

Cal 1 solution S1720 has the following nominal electrolyte concentrations:

cK^+	4.0 mmol/L
cNa^+	145 mmol/L
cCa^{2+}	1.25 mmol/L
cCl^-	102 mmol/L

Cal 2 solution S1730 has the following nominal electrolyte concentrations:

cK^+	40.0 mmol/L
cNa^+	20.0 mmol/L
cCa^{2+}	5.0 mmol/L
cCl^-	50 mmol/L

The precise concentration of each electrolyte ion is contained in the solution's bar codes.

Designations

The following designations are used (X = K/Na/Ca/Cl):

E(X,Cal1)	=	Potential of the respective electrolyte electrode chain from a calibration on Cal 1 solution
E(X,Cal2)	=	Potential of the respective electrolyte electrode chain from a calibrration on Cal 2 solution
61.5	=	Theoretical sensitivity of the K and Na electrodes at 37 °C
30.75	=	Theoretical sensitivity of the Ca electrode at 37 °C
–61.5	=	Theoretical sensitivity of the Cl electrode at 37 °C
*c*X (Cal1)	=	Concentration of the respective electrolyte ion in Cal 1 solution
*c*X (Cal2)	=	Concentration of the respective electrolyte ion in Cal 2 solution
E_0(X,Cal1)	=	Standard potential of the respective electrolyte electrode chain
*c*X (Cal1,nom)	=	Nominal concentration of the respective electrolyte ion in Cal 1 solution
E(X,Cal 1,prev)	=	Potential of the respective electrolyte electrode chain from the previous calibration on Cal 1 solution
Sens(X,Cal2,prev)	=	Sensitivity of the respective electrolyte electrode from the last 2-point calibration
*c*X (Cal1,prev)		Concentration of the respective electrolyte ion in Cal 1 solution in the previous calibration

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Electrolyte electrodes, *Continued*

Sensitivity

The sensitivity of the electrolyte electrodes is calculated from the following equations:

K electrode

$$\text{Sens(K)} = \frac{\text{E(K,Cal1)} - \text{E(K,Cal2)}}{61.5 \times \log \frac{c\text{K}^+(\text{Cal1})}{c\text{K}^+(\text{Cal2})}} \quad \text{(fraction)}$$

Na electrode

$$\text{Sens(Na)} = \frac{\text{E(Na,Cal1)} - \text{E(Na,Cal2)}}{61.5 \times \log \frac{c\text{Na}^+(\text{Cal1})}{c\text{N}a^+(\text{Cal2})}} \quad \text{(fraction)}$$

Ca electrode

$$\text{Sens(Ca)} = \frac{\text{E(Ca,Cal1)} - \text{E(Ca,Cal2)}}{30.75 \times \log \frac{c\text{Ca}^{2+}(\text{Cal1})}{c\text{Ca}^{2+}(\text{Cal2})}} \quad \text{(fraction)}$$

Cl electrode

$$\text{Sens(Cl)} = \frac{\text{E(Cl,Cal1)} - \text{E(Cl,Cal2)}}{-61.5 \times \log \frac{c\text{Cl}^-(\text{Cal1})}{c\text{Cl}^-(\text{Cal2})}} \quad \text{(fraction)}$$

The sensitivity limits of the electrolyte electrodes are as follows:

Electrode	Sensitivity Limits
K	92 - 105 %
Na	90 - 105 %
Ca	90 - 105 %
Cl	85 - 105 %

Status

The status of each of the electrolyte electrode is calculated from the following equations:

K electrode

$$\text{Status(K)} = \frac{10^{\frac{\text{E(K,Cal1)} - \text{E}_0\text{(K,Cal1)}}{61.5}} \times c\text{K}^+(\text{Cal1,nom})^2}{c\text{K}^+(\text{Cal1})} \text{ mmol/L}$$

Na electrode

$$\text{Status(Na)} = \frac{10^{\frac{\text{E(Na,Cal1)} - \text{E}_0\text{(Na,Cal1)}}{61.5}} \times c\text{N}a^+(\text{Cal1,nom})^2}{c\text{N}a^+(\text{Cal1})} \text{ mmol/L}$$

Continued on next page

Electrolyte electrodes, *Continued*

Status *(continued)*

Ca electrode

$$\text{Status(Ca)} = \frac{10^{\frac{E(Ca,Cal1)-E_0(Ca,Cal1)}{30.75}} \times cCa^{2+}(Cal1,nom)^2}{cCa^{2+}(Cal1)} \text{ mmol/L}$$

Cl electrode

$$\text{Status(Cl)} = \frac{10^{\frac{E(Cl,Cal1)-E_0(Cl,Cal1)}{-61.5}} \times cCl^{-}(Cal1,nom)^2}{cCl^{-}(Cal1)} \text{ mmol/L}$$

The status limits of the electrolyte electrodes are as follows:

Electrode	Status Limits
K	0.5 - 12 mmol/L
Na	10 - 250 mmol/L
Ca	0.1 - 20 mmol/L
Cl	30 - 900 mmol/L

Drift

Drift equations are given below.

K electrode

$$\text{Drift 1(K)} = 10^{\frac{E(K,Cal1)-E(K,Cal1,prev)}{61.5\times Sens(K,prev)}} \times cK^{+}(Cal1,prev) - cK^{+}(Cal1) \text{ mmol/L}$$

$$\text{Drift 2(K)} = 10^{\frac{E(K,Cal2)-E(K,Cal1,prev)}{61.5\times Sens(K,prev)}} \times cK^{+}(Cal1,prev) - cK^{+}(Cal2) \text{ mmol/L}$$

Na electrode

$$\text{Drift 1(Na)} = 10^{\frac{E(Na,Cal1)-E(Na,Cal1,prev)}{61.5\times Sens(Na,prev)}} \times cNa^{+}(Cal1,prev) - cNa^{+}(Cal1) \text{ mmol/L}$$

$$\text{Drift 2(Na)} = 10^{\frac{E(Na,Cal2)-E(Na,Cal1,prev)}{61.5\times Sens(Na,prev)}} \times cNa^{+}(Cal1,prev) - cNa^{+}(Cal2) \text{ mmol/L}$$

Ca electrode

$$\text{Drift 1(Ca)} = 10^{\frac{E(Ca,Cal1)-E(Ca,Cal1,prev)}{30.75\times Sens(Ca,prev)}} \times cCa^{2+}(Cal1,prev) - cCa^{2+}(Cal1) \text{ mmol/L}$$

$$\text{Drift 2(Ca)} = 10^{\frac{E(Ca,Cal2)-E(Ca,Cal1,prev)}{30.75\times Sens(Ca,prev)}} \times cCa^{2+}(Cal1,prev) - cCa^{2+}(Cal2) \text{ mmol/L}$$

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Electrolyte electrodes, *Continued*

Drift *(continued)* **Cl electrode**

$$\text{Drift 1(Cl)} = 10^{\frac{E(Cl,Cal1) - E(Cl,Cal1,prev)}{-61.5 \times Sens(Cl,prev)}} \times c\text{Cl}^-(\text{Cal1, prev}) - c\text{Cl}^-(\text{Cal1}) \text{ mmol/L}$$

$$\text{Drift 2(Cl)} = 10^{\frac{E(Cl,Cal2) - E(Cl,Cal1,prev)}{-61.5 \times Sens(Cl,prev)}} \times c\text{Cl}^-(\text{Cal1, prev}) - c\text{Cl}^-(\text{Cal2}) \text{ mmol/L}$$

NOTE: *If Cal 1 solution bottle has not been changed between two consecutive calibrations, the* cX(Cal1,prev) $-$ cX(Cal1) = 0, *where X is the respective electrolyte ion.*

The default drift tolerances set by Radiometer are as follows:

Electrode	Drift 1 Tolerances	Drift 2 Tolerances
K	± 0.2 mmol/L	± 1.5 mmol/L
Na	± 3 mmol/L	± 1 mmol/L
Ca	± 0.05 mmol/L	± 0.2 mmol/L
Cl	± 2 mmol/L	± 3 mmol/L

Measurement The electrolyte concentration in a sample is calculated from the following equation:

$$c\text{X(sample)} = c\text{X(Cal1)} \times 10^{\frac{E(X,sample) - E(X,Cal,prev)}{Sens(theo) \times Sens(X,prev)}}$$

where:

E(X,sample) =	Potential of the electrolyte electrode chain from a measurement on the sample.
E(X,Cal,prev) =	Potential of the electrolyte electrode chain from the previous calibration on Cal 1 solution.
cX(Cal 1) =	Specific (true) concentration of the electrolyte ion in Cal 1 solution.
Sens (theo) =	Theoretical sensitivity of the electrolyte electrode.
Sens(X,prev) =	Relative sensitivity of the electrolyte electrode chain from the last 2-point calibration.

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Electrolyte electrodes, *Continued*

Corrections

The measured electrolyte concentration is then corrected for systematic deviations from the reference method by the following equations:

Equation A:

$$c\mathrm{X(sample,corr)}_{195\,\mu L} = \mathrm{A}_{0\,(195\,\mu L)} \times c\mathrm{X(sample)} + A_{1(195\,\mu L)}$$

and

Equation B:

$$c\mathrm{X(sample,corr,micromode)} = \mathrm{A_0(micromode)}_{195\,\mu L} \times c\mathrm{X(sample,corr)} + \mathrm{A_1(micromode)}$$

where:

cX(sample)	= uncorrected value of the electrolyte ion in the sample
cX(sample,corr)	= corrected value of the electrolyte ion in the sample
$\mathrm{A_0}$	= instrument-dependent correction factor
$\mathrm{A_1}$	= instrument-dependent correction cut-off

Chloride is corrected for $c\mathrm{HCO_3^-}$ interference. The default value $c\mathrm{HCO_3^-} = 24.5$ mmol/L is used in

Equation C:

$$c\mathrm{Cl^-(sample,corr)}_{195\mu L} = \mathrm{A}_{0(195\mu L)} \times \left(c\mathrm{Cl^-(sample)} - 0.0956 \times c\mathrm{HCO_3^-}\right) + A_{1(195\mu L)}$$

Note that subscript "195 µL" in the equations above is used for convenience sake and stands for "FLEXMODE (no message)" and "FLEXMODE (message 874)".

Corrections for $c\mathrm{Na^+}$:

ABL8XX FLEX	Mode	$\mathrm{A_0}$	$\mathrm{A_1}$	Equation
35/25/15	S195	0.995	-3.00	A
	S95	1.01	1.80	A, B
	C95	1.03	-1.09	A, B
	*FM (no message)	0.995	-3.00	A
	*FM (message 874)	1.030	-1.00	A, B

*FM = FLEXMODE.

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Electrolyte electrodes, *Continued*

Corrections *(continued)*

Corrections for cNa^+ (cont):

ABL8XX FLEX	Mode	A_0	A_1	Equation
05	S165	0.995	-3.00	A
	S95	1.01	1.80	A, B
	C95	1.03	-1.09	A, B
	*FM (no message)	0.995	-3.00	A
	*FM (message 874)	1.030	-1.00	A, B

*FM = FLEXMODE.

Corrections for cK^+ :

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	0.985	-0.065	A
	S95	1.05	-0.13	A, B
	C95	1.11	-0.37	A, B
	*FM (no message)	0.985	-0.065	A
	*FM (message 874)	1.11	-0.37	A, B
05	S165	0.985	-0.065	A
	S95	1.05	-0.13	A, B
	C95	1.11	-0.37	A, B
	*FM (no message)	0.985	-0.065	A
	*FM (message 874)	1.11	-0.37	A, B

*FM = FLEXMODE.

Continued on next page

Electrolyte electrodes, *Continued*

Corrections *(continued)*

Corrections for cCa^{2+}:

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	1.004	-0.022	A
	S95	1.05	-0.004	A, B
	C95	1.08	-0.04	A, B
	*FM (no message)	1.004	-0.022	A
	*FM (message 874)	1.08	-0.04	A, B
05	S165	1.004	-0.022	A
	S95	1.05	-0.004	A, B
	C95	1.08	-0.04	A, B
	*FM (no message)	1.004	-0.022	A
	*FM (message 874)	1.08	-0.04	A, B

*FM = FLEXMODE.

Corrections for cCl^-:

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	1.225	-30.7	C
	S95	1.000	0.0	C, B
	C95	1.01	-1.7	C, B
	*FM (no message)	1.225	-30.7	C
	*FM (message 874)	1.01	-1.7	C, B
05	S165	1.225	-30.7	C
	S95	1.000	0.0	C, B
	C95	1.01	-1.7	C, B
	*FM (no message)	1.225	-30.7	C
	*FM (message 874)	1.01	-1.7	C, B

*FM = FLEXMODE.

Continued on next page

Electrolyte electrodes, *Continued*

Stability criteria The following stability criterion must be met to obtain a stable electrode response during calibration:

$$\left|c\mathrm{X}(\mathrm{Cal},\mathrm{upd.last}) - c\mathrm{X}(\mathrm{Cal},\mathrm{upd.i})\right| \le \mathrm{K} \times c\mathrm{X}(\mathrm{Cal},\mathrm{upd.last})$$

This criterion is valid for calibrations using Cal 1 and Cal 2 solutions where:

cX(Cal,upd.last) = Concentration of the electrolyte ion from the last updating when measuring on calibration solution. (The last updating is number 30).

cX(Cal,upd.i) = Concentration of the electrolyte ion for a given updating when measuring on calibration solution. (The relationship must be fulfilled for at least one of the updating numbers 18 or 19).

K = Constant for the stability criterion.

Electrolyte Ion	Cal1 solution	Cal2 solution
K^+	0.01	0.01
Na^+	0.01	0.02
Ca^{2+}	0.02	0.02
Cl^-	0.022	0.022

The following stability criterion must be met to obtain a stable electrode response during measurement:

$$\left|c\mathrm{X}(\mathrm{sample},\mathrm{upd.last}) - c\mathrm{X}(\mathrm{sample},\mathrm{upd.i})\right| \le$$
$$\mathrm{K} \times \left(\left|c\mathrm{X}(\mathrm{sample},\mathrm{upd.last}) - cX(Rinse)\right| + cX(Rinse)\right)$$

where:

cX(sample,upd.last) = Concentration of the electrolyte ion from the median of the last 5 updatings (for Ca^{2+}: 3 last updatings) when measuring on a sample. The last updating number is 30 (or 10 for some micromodes).

cX(sample,upd.i) = Concentration of the electrolyte ion for a given updating when measuring on a sample. (The relationship must be fulfilled for at least one of the updating numbers shown below).

K^+	Na^+	Ca^{2+}	Cl^-
22	22	26	22
23	23	27	23

In some micromodes, substract 20 from number above.

Continued on next page

Electrolyte electrodes, *Continued*

Stability criteria *(continued)*

K	Constant for the stability criterion; it equals to: K^+ = 0.012; Na^+ = 0.012; Ca^{2+} = 0.022; Cl^- = 0.012
cX_{Rinse}	Constant used indicates the concentration of the electrolyte ion level in rinse solution: K^+ = 4.0; Na^+ = 130.0; Ca^{2+} = 1.25; Cl^- = 137.7

References

List of references Linnet N. pH measurements in theory and practice. 1st ed. Copenhagen: Radiometer Medical A/S, 1970.

2. Amperometric measuring principles

Overview

Introduction This chapter describes the amperometric measuring principles and the pO_2 and metabolite electrodes that are based on this principle.

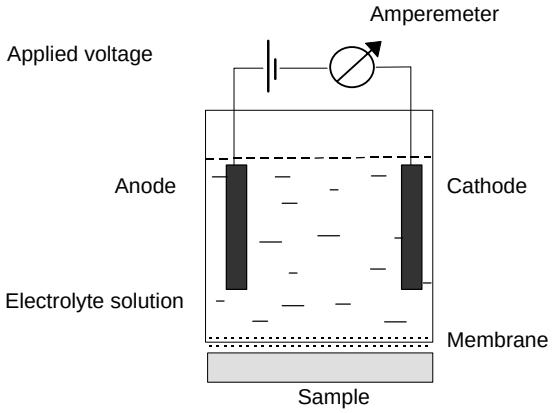
Contents This chapter contains the following topics.

General information

Amperometric method

The magnitude of an electrical current flowing through an electrode chain, which is in turn proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain

The electrode chain in amperometric measurements consists of the sample, the two electrodes (anode and cathode), an amperemeter, a voltage source, the membranes, and the electrolyte solutions.



Part	Function
Cathode	Negative electrode where a reduction reaction occurs and electrons are consumed.
Anode	Positive electrode where an oxidation reaction occurs and electrons are released.
Electrolyte solution	Provides electrical contact between the anode and cathode.
Membrane	Allows the appropriate molecules to pass through from the sample.
Sample	Contacts the membrane.
Applied voltage	Applies the necessary potential for the reduction or oxidation reaction under study.
Amperemeter	Measures the current flowing through the circuit.

To simplify the description of the measuring process in an amperometric electrode, we make the following assumptions:

- there is a species **A** in the sample which is reduced at the cathode to $\mathbf{A}^-$.
- there is a species **X** in the electrolyte which is oxidized at the anode to $\mathbf{X}^+$.

Continued on next page

General information, *Continued*

Amperometric method *(continued)*

The membrane is selective to the species **A**, allowing no other species but it to pass through from the sample into the electrolyte solution.

As an appropriate potential is applied across the electrodes, the species **A** is reduced at the cathode according to the following reaction:

$$A + e^- \rightarrow A^-$$

The reduction of **A** produces a flow of electrons, i.e. an electrical current.

To complete the electrical circuit an oxidation reaction where electrons are released is necessary. Therefore species **X** is oxidized according to the following reaction:

$$X \rightarrow X^+ + e^-$$

The magnitude of the current flowing through the circuit is proportional to the concentration of the species being reduced, in this case species **A**. The analyzer thereby automatically calculates the concentration of **A** in the sample.

The amperometric measuring principle is applied in the pO_2, glucose and lactate electrodes.

Calibration

The electrodes are active elements and must be calibrated regularly as the signals from the electrodes change with, e.g. age or deposits on the membrane.

Calibration relates the electrode signals during the calibration sequence to the values of the calibrating solutions and must be performed at regular intervals so that the accuracy can be constantly refined after inevitable minor changes in the electrodes' behavior.

Actual electrode condition is described by zero point and sensitivity and compared with theoretical conditions for an "ideal" electrode. In addition to zero point and sensitivity, an electrode condition is described by drift.

Calibration material

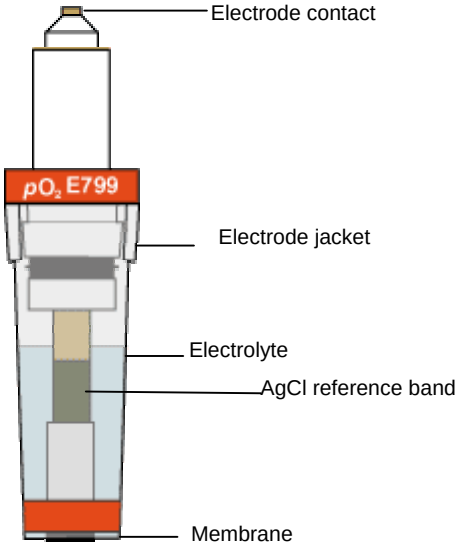
The following calibration materials are used:

Gas 1 and Gas 2: each gas has a precise composition essential for determining the accuracy of the analyzer in each pO_2 measurement.	Calibration of the pO_2 electrode
Calibration Solution 1	Calibration of the metabolite electrodes

pO_2 electrode

Description

The pO_2 electrode is an amperometric electrode which consists of a silver anode, platinum cathode and Ag/AgCl reference band, all protected by an electrode jacket which is filled with electrolyte solution. At the tip of the electrode jacket an oxygen-permeable membrane protects the Pt cathode from protein contamination and is covered on the inner side with Pt-black.



The electrode chain is polarized with constant voltage of -630 mV.

Oxygen from the sample diffuses across the membrane into the electrolyte and is reduced on the cathode (electrons are consumed) according to the following equation:

$$O_2 + 4H^+ + 4e^- \rightarrow 2H_2O$$

The H^+ ions come from the electrolyte solution.

This represents the complete reduction of O_2. Some of the O_2 however is only partially reduced according to the following equation:

$$O_2 + 2H^+ + 2e^- \rightarrow H_2O_2$$

In the presence of Pt- black, H_2O_2 produced by the incomplete reduction of O_2 at the cathode is immediately decomposed:

$$2H_2O_2 \rightarrow 2H_2O + O_2$$

This oxygen is then also reduced at the cathode. The reduction of oxygen produces a flow of electrons (an electrical current) the size of this current, I, proportional to the amount of oxygen and measured by the amperemeter:

$$I = \text{Sens}(pO_2) \times pO_2 + I_o \qquad \text{pA}$$

where:

$\text{Sens}(pO_2)$	=	Sensitivity of the pO_2 electrode
pO_2	=	Partial pressure of O_2 in the sample
I_o	=	Zero current i.e. the current flowing through the circuit when pO_2 = 0 kPa (mmHg)

To complete the electrical circuit, an oxidation reaction where electrons are released is necessary. The reaction at the silver anode is the conversion of Ag to Ag^+:

$$Ag \rightarrow Ag^+ + e^-$$

In order to maintain a charge balance between the anode and cathode, 4 atoms of Ag need to be oxidized for one molecule of O_2 to be reduced.

Continued on next page

pO_2 electrode, *Continued*

Description *(continued)*

The Ag^+ ions are released into the electrolyte solution where they react with the Cl^- ions present, producing AgCl which is insoluble and forms a layer on the silver rod:

$$Ag^+ + Cl^- \rightarrow AgCl$$

Not all Ag+ ions can be removed from the solution. Some reach the cathode where they are converted back to Ag and form a deposit of silver. This deposit must be periodically removed with the brush provided in the electrode box.

Designations

The following designations are used to describe sensitivity, zero point and drift:

$I(O_2,gas1)$	=	Current recorded at the pO_2 electrode from a measurement on Gas 1
$I(O_2,gas2)$	=	Current recorded at the pO_2 electrode from a measurement on Gas 2
$pO_2(gas1)$	=	Partial pressure of O_2 in Gas 1
$pO_2(gas2)$	=	Partial pressure of O_2 in Gas 2
$FO_2(gas1)$	=	Fraction of O_2 in Gas 1
$FO_2(gas2)$	=	Fraction of O_2 in Gas 2
B	=	Ambient pressure
pH_2O	=	Water vapor pressure =6.2571 kPa at 37 °C.
Sens(pO_2, prev)	=	Sensitivity of the pO_2 electrode measured at the previous 2-point calibration
$I(O_2,gas2,prev)$	=	Current recorded at the pO_2 electrode from the previous measurement on Gas 2

Sensitivity

The pO_2 electrode is calibrated on two gases with known O_2 content.

Gas 1 contains 19.76 % O_2 and Gas 2 contains 0.0 % O_2.
The exact composition of the calibration gases is contained in their bar codes.

The sensitivity of the pO_2 electrode, Sens(pO_2), is calculated as follows:

$$\text{Sens}(pO_2) = \frac{I(O_2,gas1) - I(O_2,gas2)}{pO_2(gas1) - pO_2(gas2)} \text{ pA/kPa}$$

Continued on next page

pO_2 electrode, *Continued*

Sensitivity *(continued)*

The partial pressures of O_2 in the gas mixtures Gas 1 and Gas 2 are calculated from the following equation:

$$pO_2(\text{gas1}) = FO_2(\text{gas1}) \times \left[B - pH_2O\right] \text{ kPa}$$

$$pO_2(\text{gas2}) = FO_2(\text{gas2}) \times \left[B - pH_2O\right] \text{ kPa}$$

The sensitivity of the pO_2 electrode should fall between 5 - 40 pA/mmHg or 37.5 - 300 pA/kPa.

Zero point

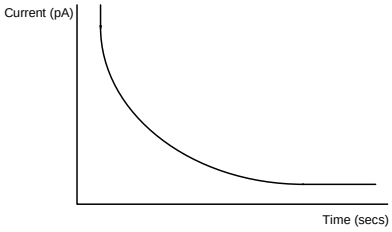
The zero point of the pO_2 electrode is the electrode current at pO_2=0. It is calculated from the current measured at the electrode with Gas 2 (0 % O_2), and the sensitivity:

$$\text{Zero point}(pO_2) = \frac{I(O_2, \text{gas2})}{\text{Sens}(pO_2, \text{prev})} \text{ kPa}$$

The zero point value of the pO_2 electrode should be less than 6.0 mmHg or 0.80 kPa.

The zero point current is the current measured at the pO_2 electrode with Gas 2 in the measuring chamber. When the measurement on Gas 2 begins, a relatively high current is recorded due to residual O_2 from the rinse solution in the measuring chamber. This current falls exponentially with time while Gas 2 is present in the measuring chamber.

Forty seconds into the measurement the current reaches a steady state which is then considered as the zero point current.



Drift

Drift 1 is a measurement of the difference between two consecutive measurements on Gas 1, and is calculated from the following equation:

$$\text{Drift 1}(pO_2) = \frac{I(O_2, \text{gas1}) - I(O_2, \text{gas1, prev})_{)}}{\text{Sens}(pO_2, \text{prev})} - pO_2(\text{gas1}) \text{ kPa}$$

Drift 2 reflects the change in sensitivity between 2-point calibrations and is calculated from the following equation:

$$\text{Drift 2}(pO_2) = \frac{I(O_2, \text{gas2}) - I(O_2, \text{gas2, prev})_{)}}{\text{Sens}(pO_2, \text{prev})} - pO_2(\text{gas2}) \quad \text{kPa}$$

The default drift tolerances set by Radiometer are ± 0.80 kPa (6.0 mmHg) for Drift 1 and Drift 2. The Drift tolerances can, however, be user-defined in the Setup program.

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pO_2 electrode, *Continued*

Measurement

The pO_2 value for a sample is calculated from the following equations:

$$pO_2(\text{sample},\text{upd.i}) = \frac{I(O_2,\text{sample},\text{upd.i}) - I(O_2,\text{gas2},\text{prev})}{\text{Sens}(pO_2)} \times K_1$$

Constant K_1 describes the gas/liquid relationship for the electrode.
This constant is defined as:

$$K_1 = 1 + 0.01\left(-5.8370 + \sqrt{21.712 + \frac{\text{Sens}(pO_2)}{3.66294}}\right)$$

$$\delta = \left|pO_2(\text{sample},\text{upd.30}) - pO_2(\text{sample},\text{upd.1})\right|$$

$$\text{predict} = \frac{pO_2(\text{sample},\text{upd.6}) \times pO_2(\text{sample},\text{upd.30}) - \left(pO_2(\text{sample},\text{upd.18})\right)^2}{pO_2(\text{sample},\text{upd.6}) + pO_2(\text{sample},\text{upd.30}) - 2 \times pO_2(\text{sample},\text{upd.18})}$$

where:

$I(O_2,\text{sample},\text{updi}) =$	Current recorded at the pO_2 electrode from updating number *i* with a measurement on the sample.
$I(O_2,\text{gas2},\text{prev}) =$	Current recorded at the pO_2 electrode from the previous measurement on Gas 2.
$\text{Sens}(pO_2) =$	Relative sensitivity of the pO_2 electrode determined from the last calibration on Gas 1 and Gas 2.
$\delta =$	Difference between pO_2(sample) from the first and last updatings.
predict =	Extrapolated value for pO_2.

For $\delta < 2.66$ kPa,

$pO_2(\text{sample}) = pO_2(\text{sample, upd.30})$

For 2.66 kPa $< \delta <$ 5.32 kPa

$$pO_2(\text{sample}) = \frac{\text{predict} \times (\delta - 2.66) + pO_2(\text{sample},\text{upd.30}) \times (5.32 - \delta)}{2.66}$$

For $\delta \geq 5.32$ kPa

$pO_2(\text{sample}) = \text{predict}$

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pO_2 electrode, *Continued*

Corrections - blood samples

Gas/liquid relationship:

K_1 is a constant that describes the gas/liquid relationship for the electrode. The constant is defined as follows:

$$K_1 = 1 + \frac{1}{100}\left(-5.8370 + \sqrt{21.712 + \frac{\text{Sens}(pO_2)}{3.66294}}\right)$$

The pO_2 measured from the sample is then corrected for systematic deviations from the reference method using the following equation:

Equation A:

$$pO_2(\text{sample,corr}) = \frac{-d_1 + \sqrt{d_1^2 - 4 \times \left(e_2 + e_3 \times pO_2(\text{sample,v1}) + e_4 \times pO_2(\text{sample,v1})^2\right)}}{2}$$

where:

- pO_2 value of the sample after the first part of correction is as follows:

$$pO_2(\text{sample,v1}) = pO_2(\text{sample}) + (k_1 - k_2 \times e^{k_3 \times pO_2(\text{sample})^4}) \times (100.398 - B)$$

- and:

d_1	= $e_0 \times pO_2$(sample, v1) + e_1
k_1	= correction constant = 0.02614
k_2	= correction constant = 0.02107
k_3	= correction constant = –0.00281
e_0, e_1, e_2, e_3, e_4	= correction constants
B	= barometric pressure in kPa

Equation A+:

When an additional correction is needed, equation A is first used together with the constants for the FLEXMODE (C195 and 165) – no message. Then the obtained results are put back into equation A as pO_2(sample) and then treated again, using the constants for the specific mode.

Or

Equation B:

When an additional correction is needed, equation A is first used together with the constants for the FLEXMODE (C195 and 165) – no message. Then the obtained results are put back into equation B as pO_2(sample) and then treated again, using the constants for the specific mode.

$cX(\text{sample,corr}) = A_0 \times cX(\text{sample}) + A_1$

Continued on next page

pO_2 electrode, *Continued*

Corrections – blood samples ***(continued)***

ABL 8XX FLEX	Mode	e_0	e_1	e_2	e_3	e_4	A_0	A_1	Eq.
35/25/	S195	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
15	S95						1.020	-0.200	B
	S85	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	C95						0.9965	-0.0254	B
	C55	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
	*FM (no message)	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	*FM (message 874)						0.9965	-0.0254	B
	*FM (message 873)						0.9965	-0.0254	B
	*FM (message 872)	-2.20159	5.70807	-0.41342	-5.42718	1.19023			A+
	*FM (message 871)	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
30/20/	S85	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
10	C55	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
	*FM (no message)	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	*FM (message 872)	-2.19314	5.81012	-0.96320	-5.46921	1.18037			A+
	*FM (message 871)	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
05	S165	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	S95						1.020	-0.200	B
	S85	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	C95						0.9965	-0.0254	B
	C55	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
	*FM (no message)	-2.30300	5.96942	0.83281	-6.07310	1.30565			A
	*FM (message 874)						0.9965	-0.0254	B
	*FM (message 873)						0.9965	-0.0254	B
	*FM (message 872)	-2.20159	5.70807	-0.41342	-5.42718	1.19023			A+
	*FM (message 871)	-2.1199	4.7210	-1.0156	-4.2974	1.1035			A+
00									

*FM = FLEXMODE.

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pO_2 electrode, *Continued*

Corrections - expired air samples

The pO_2 measured from the sample is then corrected for systematic deviations from the reference method using the following equation:

$$pO_2(\text{sample,corr}) = A_0 \times pO_2(\text{sample}) + A_1 \times (B - pH_2O)$$

where:

pO_2(sample)	= uncorrected pO_2 value of a expired air sample
pO_2(sample,corr)	= corrected pO_2 value of a expired air sample
A_0	= instrument dependent correction factor
A_1	= instrument-dependent correction factor
B	= barometric pressure during the measurement
pH_2O	= partial pressure of saturated water vapour = 6.2571 kPa

ABL800FLEX	Mode	A_0	A_1	Equation
All	Expired air	1.016	-0.004	A

When measuring on gas samples, the constant K_1 (describes the gas/liquid relationship for the electrode) is equal to 1.

Stability criteria

The following stability criterion must be met to obtain a stable electrode response during **calibration**:

$$\left|pO_2(\text{sample,upd.last}) - pO_2(\text{sample,upd.i})\right| \leq pO_2(\text{limit})$$

This criterion is valid for 1-point calibrations (Gas 2 contains no oxygen) where:

Parameter	pO_2 value from the last updating number...	
	ABL8X5 FLEX	ABL8X0 FLEX
pO_2(Gas1,upd.last)	92	62
pO_2(Gas1,upd.i)	86 or 87	56 or 57
	(the relationship must be fulfilled for at least one of the updating numbers)	

pO_2(limit) value for the stability criterion is 0.80 kPa/6.0 mmHg.

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pO_2 electrode, *Continued*

Stability criteria *(continued)* The following stability criteria must be met in order to obtain a stable electrode response during **measurement**:

$\delta = |pO_2(\text{sample,upd.30}) - pO_2(\text{sample,upd.1})|$

For δ	Criterion
≤ 2.66 kPa	$\left\lvert pO_2(\text{sample}) - pO_2(\text{sample, upd.16})\right\rvert \le 0.80$
> 2.66 kPa	$-0.2 \le \frac{pO_2(\text{sample, upd.30}) - pO_2(\text{sample, upd.18})}{pO_2(\text{sample, upd.18}) - pO_2(\text{sample, upd.6})} < 0.6$

For δ > 2.66 kPa:

if the following criteria are fulfilled then no result is reported:

$$\frac{pO_2(\text{sample, upd.30}) - pO_2(\text{sample, upd.18})}{pO_2(\text{sample, upd.18}) - pO_2(\text{sample, upd.6})} < -1.0$$

or

$$\frac{pO_2(\text{sample, upd.30}) - pO_2(\text{sample, upd.18})}{pO_2(\text{sample, upd.18}) - pO_2(\text{sample, upd.6})} \ge 0.6$$

Expired air samples:

Measurement on an expired air sample is accepted if the following criterion is fulfilled:

$\left\lvert pO_2(\text{sample,upd.30}) - pO_2(\text{sample,upd.24})\right\rvert \le 0.80$ kPa/6.0 mmHg,

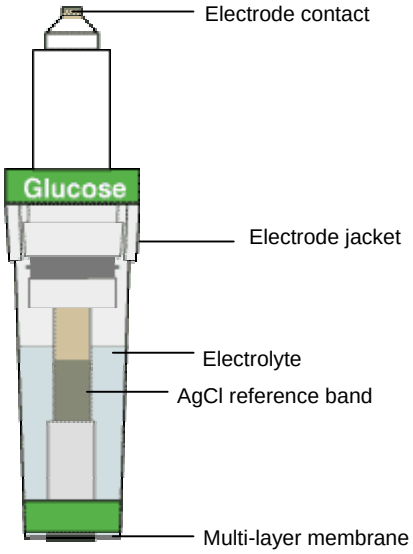
or

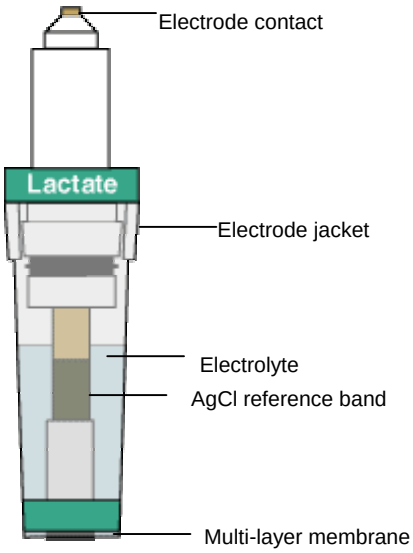
$\left\lvert pO_2(\text{sample,upd30}) - pO_2(\text{sample,upd.24})\right\rvert \le 0.05 \times pO_2(\text{sample,upd.30})$.

Error message "Measurement unstable" (= pO_2 response fault during electrode monitoring in Expired air mode) is displayed if the stability criterion is not fulfilled.

Metabolite electrodes

Description





The glucose electrode (E7066) and the lactate electrode (E7077) have similar construction described below.

The electrode consists of a silver cathode and a platinum anode. The electrode is protected by an electrode jacket filled with electrolyte solution and a multi-layer membrane mounted at the tip.

The membrane consisting of three layers:

1. outer membrane layer permeable to glucose/lactate.
2. middle enzyme layer.
3. inner membrane layer permeable to H_2O_2.

A polarization voltage of 675 mV is applied to the electrode chain and the current through the chain is measured by an ampere meter.

Glucose or lactate molecules are transported across the outer membrane of the multi-layer membrane.

The enzyme glucose oxidase or lactate oxidase immobilized between the inner and outer membrane layers converts the glucose or lactate according to the following reactions:

glucose + O_2 → gluconic acid + H_2O_2

lactate + O_2 → pyruvate + H_2O_2

O_2 for this reaction is supplied by the outer membrane layer and also by the oxidation of H_2O_2 at the Pt anode.

The H_2O_2 produced by the enzyme reaction is transported across the inner membrane to the Pt anode.

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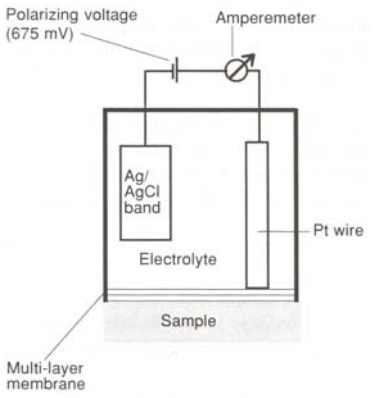
Metabolite electrodes, *Continued*

Description ***(continued)***



$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$

When a potential is applied to the electrode chain, the oxidation of H_2O_2 produces an electrical current proportional to the amount of H_2O_2, which in turn is directly related to the amount of glucose or lactate.

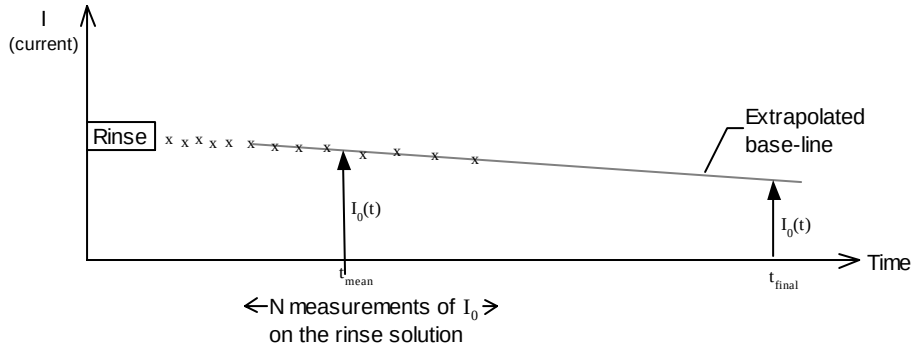
To complete the electrical circuit a reduction reaction (where electrons are consumed) at the cathode converts Ag^+ (from AgCl) to Ag:

$$Ag^+ + e^- \rightarrow Ag$$

In order to maintain a charge balance between the anode and the cathode, two Ag^+ ions need to be reduced for one molecule of H_2O_2 to be oxidized.

Zero current

The zero current is a small background current measured at the electrode when no glucose or lactate is present in a solution. As the rinse solution contains no glucose or lactate, a baseline representing the zero current, I_0 as a function of time (I_0 = f(t)), is obtained from continuous measurements on the rinse solution.



This I_0 baseline is obtained as follows:

- At the end of a rinse, with the rinse solution in the measuring chamber, zero current of the metabolite electrodes is measured periodically (the intervals between these measurements become longer if the analyzer is idle).
- The previous N (N = 8) measurements on the rinse solution – before a calibration or a sample measurement starts - are used to obtain a baseline representing the time function of I_0.

Continued on next page

Metabolite electrodes, *Continued*

Zero current *(continued)*

- The baseline is extrapolated thoughout the whole electrode calibration or sample measurement period, and represents the zero current time function.
- The I_0 baseline is used to determine the sensitivity of the metabolite electrode.

The extrapolated final zero current value at the metabolite electrodes at the last updating (illustrated by the I_0 baseline) is determined as follows:

$$I_0(\text{final}) = A_1 \times I_{slope} \times (t_{final} - t_{mean}) + I_0\ (\text{mean}) \quad \text{pA}$$

where:

A_1 = Empirical constant dependent on electrode and determined from tests against the reference method

t_{final} = Time of the last measurement updating on the calibration solution or sample.

t_{mean} = The mean time of the N zero current measurements on the rinse solution:

$$t_{mean} = \frac{\sum_{n=1}^{N} t_n}{N} \quad \text{sec}$$

where t_n is the time of the n^{th} measurement on the rinse solution.

$I_0(\text{mean})$ = The zero current at the mean time (t_{mean}):

$$I_0(\text{mean}) = \frac{\sum_{n=1}^{N} I_{0,n}}{N} \quad \text{pA}$$

where $I_{0,n}$ is the zero current at the n^{th} measurement on the rinse solution.

I_{slope} = The slope or gradient of the I_0 baseline

$$I_{slope} = \frac{\sum_{n=1}^{N} (t_n - t_{mean}) \times (I_{0,n} - I_0(\text{mean}))}{\sum_{n=1}^{N} (t_n - t_{mean})^2} \quad \text{pA/second}$$

If $I_{slope} > 0.0$, it is set to 0.0

The zero current of the metabolite electrodes should be less than 10000 pA.

Continued on next page

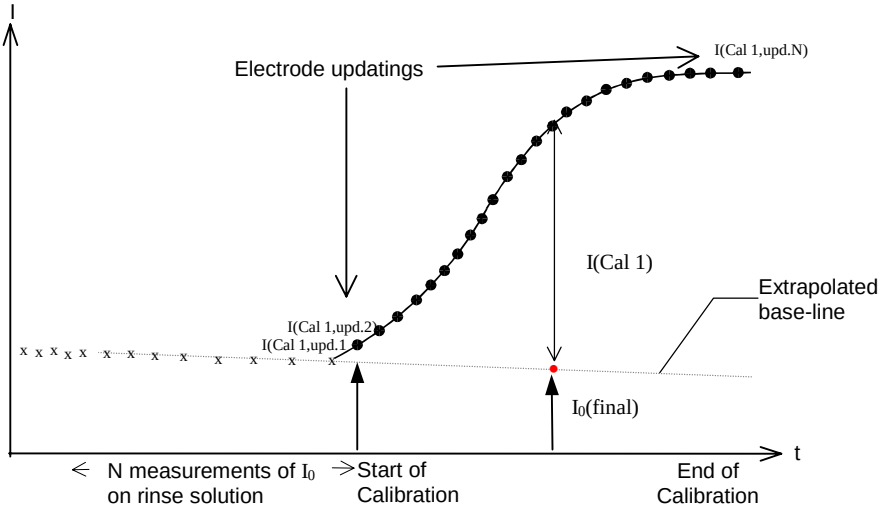
Metabolite electrodes, *Continued*

Sensitivity

The sensitivities of the metabolite electrodes are calculated by measuring the current on Calibration Solution 1 (Cal 1) and then correcting for the zero current using the extrapolated I_0 baseline.

Cal 1 has a nominal glucose concentration of 10 mmol/L and a nominal lactate concentration of 4 mmol/L. The precise values are batch-individual and contained in the bar codes of the Cal 1 bottles.

The diagram below, together with the table, describes in principle how the sensitivities for the metabolite electrodes are obtained.



The current at the metabolite electrodes with Cal 1 in the measuring chamber, I(Cal 1), is measured 30 times at regular intervals. The current at the 15th updating is used to determine sensitivity of the glucose electrode, and the current at the 30th updating is used to determine sensitivity of the lactate electrode.

The current due to the glucose or lactate presence in the sample is then calculated as the difference between the current at the final updating (the 15th for the glucose and the30th for the lactate electrode) and the zero current at that time point:

$$I(Cal\ 1) = I(Cal\ 1,final) - I_0(final)$$

The sensitivities of the electrodes are calculated as follows:

$$Sens = \frac{I(Cal\,1)}{cX(Cal\,1)}\,T \qquad \mathbf{T}$$

Continued on next page

Metabolite electrodes, *Continued*

Sensitivity *(continued)*

where:

*c*X(Cal 1)	=	Actual concentration of glucose/lactate in the Cal 1 solution.
I_0(final)	=	Extrapolated final zero current value of the metabolite electrode at the time of the last updating.
TI(Cal 1)	=	electrode current due to presence of glucose/lactate.

The sensitivity limits of the metabolite electrodes are as follows:

Electrode	Sensitivity Limits
Glucose	100 - 1800 pA/mM
Lactate	150 - 2000 pA/mM

Drift

The drift in the sensitivity of the metabolite electrodes is calculated from the following equations:

$$\text{Drift} = \frac{\text{I(Cal 1, final)} - \text{I}_0\text{(final)}}{\text{Sens}} - c\text{X(Cal 1)}$$

where:

I(Cal 1,final)	=	Current at the final measurement on Cal 1 solution.
Sens	=	Sensitivity of the glucose/lactate electrode from the previous calibration.
*c*X(Cal 1)	=	Actual concentration of glucose/lactate in the Cal 1 solution.
I_0(final)	=	Extrapolated final zero current value of the metabolite electrode measured at the time of the last updating.

The default drift tolerances set by Radiometer for the metabolite electrodes are:

± 0.5 mM for the glucose electrode

± 0.2 mM for the lactate electrode.

Continued on next page

Metabolite electrodes, *Continued*

Measurement

The glucose/lactate concentration in a sample is calculated from the following equation:

$$cX(\text{sample}) = \frac{I(\text{sample}) - I_0(\text{final})}{\text{Sens}}$$

where:

I(sample)	=	Current of the metabolite electrode measured on the sample.
I_0(final)	=	Extrapolated final zero current value of the metabolite electrode at the time of the last sample updating.
Sens	=	Relative sensitivity of the metabolite electrode.

Corrections

The measured metabolite concentration is corrected for systematic deviations from the reference method by the following equations:

Equation A:

$$cX(\text{sample},\text{corr})_{195\,\mu L} = A_{0(195\,\mu L)} \times cX(\text{sample}) + A_{1(195\,\mu L)}$$

and

Equation B:

$$cX(\text{sample},\text{corr})_{\text{micromode}} = A_{0,\text{micromode}} \times cX(\text{sample},\text{corr})_{195\,\mu L} + A_{1,\text{mocromode}}$$

where:

*c*X(sample)	= uncorrected measured metabolite concentration from a sample
*c*X(sample, corr)	= corrected measured metabolite concentration from a sample
A_0	= instrument-dependent correction factor
A_1	= instrument-dependent cut-off

When an additional correction is needed, equation A is first used together with the constants for the 195 µL mode. Then the obtained results are put back into equation B as *c*X(sample) and then treated again, using the constants for the specific mode.

Note that subscript “195 µL” in the equations above is used for convenience sake and stands for “FLEXMODE (no message)”, “FLEXMODE (message 874)”, and “FLEXMODE (message 873)”.

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Metabolite electrodes, *Continued*

Corrections *(continued)*

Corrections for *c*Glu :

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	0.94	0.1	A
	S95	1.00	0.0	A, B
	C95	1.06	0.0	A, B
	C35	1.16	0.0	A, B
	*FM (no message)	0.94	0.1	A
	*FM (message 874)	1.06	0.0	A, B
	*FM (message 873)	1.06	0.0	A, B
05	S165	0.94	0.1	A
	S95	1.00	0.0	A, B
	C95	1.06	0.0	A, B
	C35	1.16	0.0	A, B
	*FM (no message)	0.94	0.1	A
	*FM (message 874)	1.06	0.0	A, B
	*FM (message 873)	1.06	0.0	A, B

*FM = FLEXMODE.

Corrections for *c*Lac:

ABL8XX FLEX	Mode	A_0	A_1	Equation
35/25/15	S195	0.97	-0.04	A
	S95	1.03	0.03	A, B
	C95	1.03	0.18	A, B
	C35	1.13	0.05	A, B
	*FM (no message)	0.97	-0.04	A
	*FM (message 874)	1.03	0.18	A, B
	*FM (message 873)	1.03	0.18	A, B

*FM = FLEXMODE.

Continued on next page

Metabolite electrodes, *Continued*

Corrections *(continued)*

ABL8XX FLEX	Mode	A_0	A_1	Equation
05	S165	0.97	-0.04	A
	S95	1.03	0.03	A, B
	C95	1.03	0.18	A, B
	C35	1.13	0.05	A, B
	*FM (no message)	0.97	-0.04	A
	*FM (message 874)	1.03	0.18	A, B
	*FM (message 873)	1.03	0.18	A, B

*FLEXMODE = adaptive measuring mode.

Stability criteria The following stability criteria must be met to obtain a stable electrode response during calibration:

$$I(\text{Cal 1,upd.30}) - I(\text{Cal 1, upd.21}) - 9 \times I_{slope} \leq 0$$

$$S_{d,zero} < S_{d,max}$$

$$\tau = \frac{-9.5}{\log \frac{I(\text{Cal1, upd.1}) - I(\text{Cal1, upd.11})}{I(\text{Cal1, upd.11}) - I(\text{Cal1, upd.21})}} \leq 50$$

All of the three criteria must be fulfilled for a calibration using Cal 1 solution where:

I(Cal 1,upd.30) I(Cal 1,upd.21) I(Cal 1,upd.11) I(Cal 1,upd.1)	=	Electrode current at the $30^{th}/21^{st}/11^{th}/1^{st}$ updating during measurement on Cal 1 solution, respectively.
$S_{d,zero}$	=	Spreading of the zero point current updatings around the regression line.
$S_{d,max}$	=	If Sens > 400 pA/mM, then $S_{d,max} = 0.025 \times \text{Sens}$, otherwise $S_{d,max} = 10.0$.

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Metabolite electrodes, *Continued*

Stability criteria *(continued)*

τ = Should be less than or equal to 50,

and

$$\log \frac{I(Cal1, upd.1) - I(Cal1, upd.11)}{I(Cal1, upd.11) - I(Cal1, upd.21)}$$

should be negative or equal zero.

The following stability criterion must be met to obtain a stable electrode response during measurement:

$S_{d,zero} < S_{d,max}$

where:

$S_{d,zero}$ = Spreading of the zero point current updatings around the regression line.

$S_{d,max}$ = If Sens > 400 pA/mM, then $S_{d,max} = 0.025 \times$ Sens, otherwise $S_{d,max} = 10.0$.

The (glucose or lactate) in the sample is *c*X(sample,corr).

If the corrected concentration of the metabolite, *c*X(sample,corr) > 1, the following criteria must be fulfilled:

$$0 \le \frac{I(sample, upd.30) - I(sample, upd.21) - 9 \times I_{slope}}{I(sample, upd.30) - I_0(zero)} \le 0.20$$

otherwise

$$\left| \frac{I(sample, upd.30) - I(sample, upd.21) - 9 \times I_{slope}}{Sens} \right| \le 0.14$$

where:

I(sample,upd.30) I(sample,upd.21) = Electrode current at the 30th/21st updating during measurement on sample, respectively.

I_0(zero) = zero current extrapolated to the time of the measurement.

Continued on next page

Metabolite electrodes, *Continued*

Stability criteria *(continued)* If all the criteria below are fulfilled, then the result of the measurement will be marked with an interference error.

$$\frac{I(sample,upd.30) - I(sample,upd.23)}{I(sample,upd.16 - I(sample,upd.9)} \geq 1$$

$$I(sample,upd.16) > I(sample,upd.12)$$

$$I(sample,upd.12) > I(sample,upd.9)$$

$$cX(sample,corr) > 1.5 \text{ mmol/L}$$

where:

I(sample,upd.30) I(sample,upd.23) I(sample,upd.16) I(sample,upd.12) I(sample,upd.9)	=	Electrode current at the $30^{th}/23^{rd}/16^{th}/12^{th}/9^{th}$ updating during measurement on sample, respectively.
*c*X(sample,corr)	=	Corrected concentration of glucose or lactate in the sample.

3. Optical measuring principles

Overview

Introduction This chapter describes the optical system, its construction, and the measuring method used.

Contents This chapter contains the following topics.

Optical system

Measured parameters

The optical system of the ABL800 FLEX analyzer is designed to measure the following parameters:

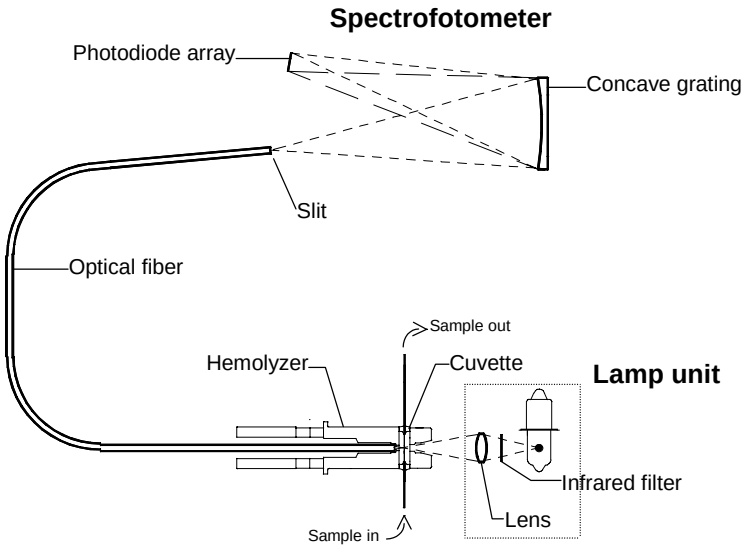
Parameter	Description
*c*tHb	concentration of total hemoglobin
sO_2	oxygen saturation
FO_2Hb	fraction of oxyhemoglobin
*F*COHb	fraction of carboxyhemoglobin
*F*HHb	fraction of deoxyhemoglobin
*F*MetHb	fraction of methemoglobin
*F*HbF	fraction of fetal hemoglobin
*c*tBil	concentration of total bilirubin (the sum of unconjugated and conjugated bilirubin) in plasma

NOTE: *c*tBil *can be measured on a whole blood or plasma sample. Plasma samples provide the optimal measurement performance. To obtain optimal accuracy when following a patient trend in c*tBil*, use the same aspiration mode and the same analyzer.*

*Hematocrit (*Hct*) is also available as a derived parameter.*

Construction

The optical system is based on a 128-wavelength spectrophotometer with a measuring range of 478 - 672 nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.



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Optical system, *Continued*

Construction *(continued)* The method used in the analyzer's optical system is visible absorption spectroscopy.

Step	Description
1	The blood sample is transported to the cuvette positioned in the hemolyzer unit. The temperature of the cuvette is regulated to 37 °C.
2	1 µL of the sample is ultrasonically hemolyzed in the cuvette at a frequency of about 30 kHz in order to rupture the walls of the red blood cells so that their content is mixed with the blood plasma, giving an optically clear solution. There is no bilirubin in the red blood cells, so after hemolyzation the red blood cell intracellular fluid dilutes the plasma bilirubin. The calculation discussed in *Measurement and Corrections* corrects for this dilution. To eliminate air bubbles in the sample and to enhance hemolyzation, an over-pressure of one atmosphere is maintained throughout hemolyzation and measurement.
3	Light from a 4 Watt halogen lamp is sent to the cuvette via an infra-red filter and a biconvex lens. The voltage across the halogen lamp is regulated by a thermostatted photodiode so that the amount of light sent to the cuvette has a constant intensity.
4	The light transmitted through the cuvette is guided to the spectrometer via an optical fiber.
5	The light passes through a slit that directs it towards a combined mirror and concave grating.
6	The grating separates the light into 128 single wavelengths and the mirror focuses the 128 light signals on a photodiode array.
7	The photodiode array has 128 diodes or pixels, one for each wavelength, which convert the monochromatic light signals to currents.
8	The currents and therefore the intensity of the light signals are measured at each of the 128 diodes, which form the basis for the absorption spectrum for a particular sample.
9	The spectrum is sent to the analyzer’s computer, where the calculations of the oximetry parameter values are made.

Continued on next page

Optical system, *Continued*

Lambert-Beer's law

Absorption spectroscopy is based on Lambert-Beer's law which states that the measured absorbance for a single compound is directly proportional to the concentration of the compound and the length of the light path through the sample [1]:

$$A_y^{\lambda} = \varepsilon_y^{\lambda} \times c_y \times l$$

where:

A_y^{λ}	=	absorbance of compound y at wavelength λ
ε_y^{λ}	=	extinction coefficient of compound y at wavelength λ (a constant, characteristic of the compound)
c_y	=	concentration of compound y in sample
l	=	length of the light path

Absorbance

The absorbance (A) of a compound is defined as the logarithm of the ratio of the light intensity before and after transmission through the compound.

In practice it is the logarithm of the ratio of the light intensity transmitted through water to the light intensity transmitted through the compound.

$$A = \log \frac{I_0}{I}$$

where:

I_0	=	intensity of light transmitted through water (I_0 is measured as the intensity of light transmitted through the Cal 1 or Cal 2 solutions)
I	=	intensity of light transmitted through the compound

Total absorbance

For samples containing more than one optically active compound, the total absorbance (A_{total}) is the sum of the individual compounds' absorbance, since absorbance is an additive quantity.

For example, if a sample contains 6 compounds y_1, y_2, ….y_6, the total absorbance measured for that sample at wavelength λ_1 is:

$$A_{total}^{\lambda_1} = A_{y_1}^{\lambda_1} + A_{y_2}^{\lambda_1} + A_{y_3}^{\lambda_1} + A_{y_4}^{\lambda_1} + A_{y_5}^{\lambda_1} + A_{y_6}^{\lambda 1}$$

$$= l\left(\varepsilon_{y_1}^{\lambda_1} c_{y_1} + \varepsilon_{y_2}^{\lambda_1} c_{y_2} + \varepsilon_{y_3}^{\lambda_1} c_{y_3} + \varepsilon_{y_4}^{\lambda_1} c_{y_4} + \varepsilon_{y_5}^{\lambda_1} c_{y_5} + \varepsilon_{y_6}^{\lambda_1} c_{y_6}\right)$$

If there are Y compounds and measurements are taken at *n* wavelengths, a general expression can be written for A_{total} at the wavelength λ_n:

$$A_{total}^{\lambda_n} = \sum_{y=1}^{Y} \varepsilon_y^{\lambda_n} \times c_y \times l$$

where:
λ_n = the individual wavelengths.

Continued on next page

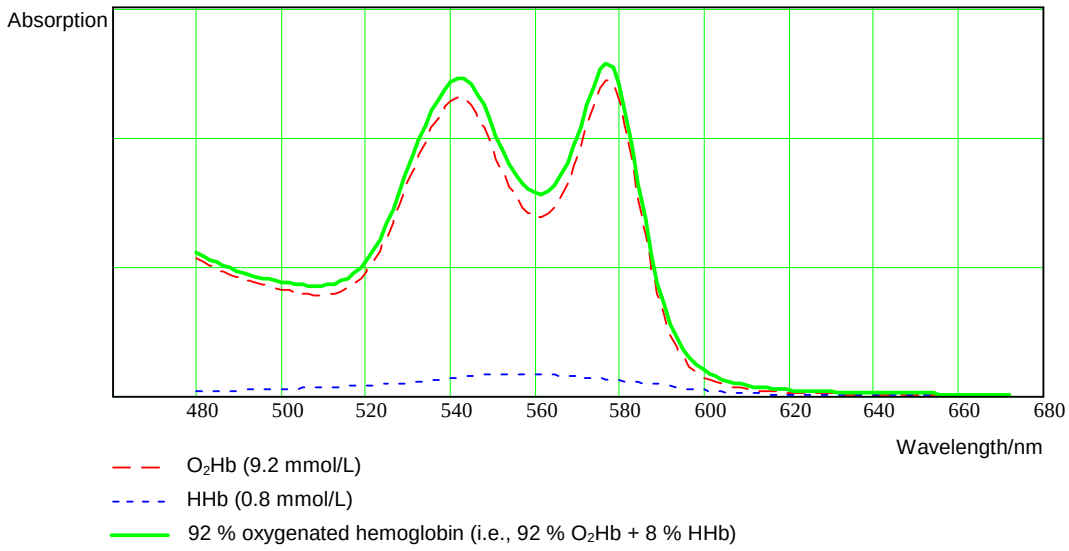
Optical system, *Continued*

Continuous spectrum

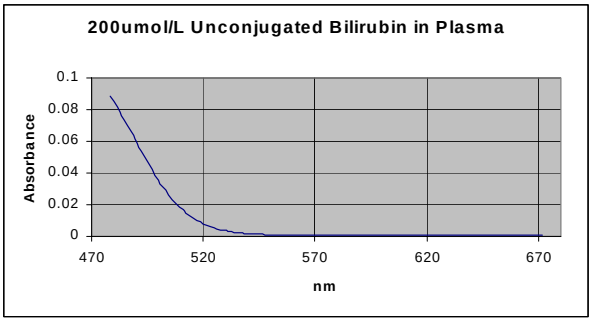
$A_{\text{total}}^{\lambda_n}$ can be depicted graphically as a function of wavelength, and if the differences between the wavelengths are small enough, a continuous spectrum is produced.

EXAMPLES:

The figure below shows three spectra; pure O_2Hb, pure HHb in a low concentration, a spectrum of 92 % oxygenated hemoglobin obtained by adding the spectra of O_2Hb and HHb. The additivity of absorption and the continuity of the spectra can clearly be seen.



Example of the spectrum obtained from unconjugated bilirubin at concentration of 200 µmol/L.



The spectrum of conjugated bilirubin is slightly different.

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Optical system, *Continued*

Determining concentrations

In the spectrum taken of a sample, the absorption recorded at each wavelength contains contributions from each of the compounds in the sample. The task then is to determine the magnitude of that contribution and thereby the concentration of each compound in the sample.

The concentrations are determined using the following equation:

$$c_y = \sum_{n=1}^{128} K_y^{\lambda_n} \; A_{total}^{\lambda_n}$$

where:

$K_y^{\lambda_n}$ = a constant specific to compound y at wavelength λ_n.

Matrix of constants

The constants ($K_y^{\lambda_n}$) are determined using Multivariate Data Analysis [2] where the spectra of the calibration compounds were considered together with the reference values of the calibration compounds. The essential interfering substances were also taken into account.

Correcting for interferences

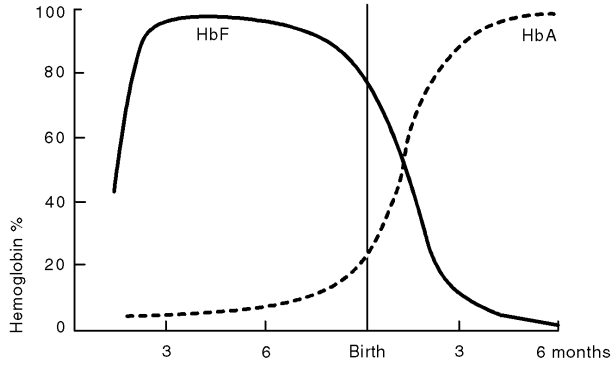
HbF versus HbA

Fetal hemoglobin (HbF) does not have the same spectrum as adult hemoglobin (HbA) due to a slight variation in molecular structure. The presence of HbF in a sample will interfere with the result if it is not corrected for.

It is thus important when measuring hemoglobin levels in premature neonates and neonates aged 0 to 3 months, as well as adults suffering from thalassemia, to take into account this difference [3].

The ABL800 FLEX analyzers automatically correct for HbF.

The diagram below shows the transition from fetal hemoglobin to adult hemoglobin [4].



This graph is only schematic and cannot be used to determine *F*HbF.

Deviation of Results

If the difference between the two types of hemoglobin is not accounted for in measurements on samples containing HbF, e.g. from premature neonates and neonates aged 0 to 3 months, then a deviation in the measurement will arise.

The deviation is most important for measurements of oxygen saturation (sO_2) and the fraction of carboxyhemoglobin (*F*COHb), since inaccurate measurements of these parameters can lead to incorrect diagnostic interpretation of the results, and consequent risk of inappropriate treatment.

Detecting HbF

The presence of HbF in a sample is detected from the difference spectrum between fetal and adult oxyhemoglobin. From the size of the difference spectrum the concentration of fetal oxyhemoglobin, cO_2HbF, can be measured.

Correcting for HbF

The amount of cO_2HbF exceeding a certain level indicates HbF interference. The analyzer automatically corrects for this interference by subtracting the difference spectrum of fetal oxyhemoglobin from the measured spectrum. It then makes further calculations, using cO_2HbF to measure *F*HbF.

Continued on next page

Correcting for interferences, *Continued*

Most likely interfering substances

Fetal hemoglobin and non-hemoglobin substances present in blood that absorb light within the same wavelength range used to measure the oximetry parameters and bilirubin, will interfere with the true spectra of the blood samples.

The optical system in the ABL800 FLEX analyzers compensates for the most likely interfering substances by repressing their spectra.

The interference from following substances the analyzer compensates for when measuring the oximetry parameters:

Intralipids (turbidity)

Sulfhemoglobin, SHb

Repressing spectra

Repressing the spectra of the likely interfering substances is done in two ways depending on the substance:

- **Either** the substance is taken account of in the calculation of the matrix of constants, K (see the section *Measuring Principle* in this chapter). This applies to Intralipids and Sulfhemoglobin,
- **Or** the substance is detected, and the measured spectrum is corrected accordingly. This applies to HbF.

Residual spectrum

A measured spectrum is compared to a model spectrum calculated from the determined concentrations. The difference between the two spectra is then called the residual spectrum. If the difference is too high a warning (Oxi spectrum mismatch) is issued on all the oximetry module parameters *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *F*HbF and *c*tBil.

The same action is taken if one of the following conditions exist and FHb_{deriv} is defined as one of the parameters *s*O2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb:

- *c*tHb<–0.1mmol/L or *c*tHb>25mmol/L.
- *F*Hb(deriv)<-2% or *F*Hb(deriv)>102%.
- Negative fraction of SHb<–2% is detected.
- Value of Turbidity<–0.5%.

Measurement and corrections

Oximetry parameters

The oximetry parameters are calculated as follows:

Parameter	Equation
*c*tHb(meas)	$= cO_2Hb + cCOHb + cHHb + cMetHb$
sO_2	$= \frac{cO_2Hb}{ceHb}$ $ceHb = cHHb + cO_2Hb$ (effective hemoglobin)
FO_2Hb	$= \frac{cO_2Hb}{ctHb}$
*F*COHb	$= \frac{cCOHb}{ctHb}$
*F*HHb	$= \frac{cHHb}{ctHb}$
*F*MetHb	$= \frac{cMetHb}{ctHb}$
*F*HbF	$= \frac{cHbF}{ctHb}$

where:

cO_2Hb = concentration of oxyhemoglobin in the sample

*c*COHb = concentration of carboxyhemoglobin in the sample

*c*HHb = concentration of deoxyhemoglobin in the sample

*c*MetHb = concentration of methemoglobin in the sample

*c*HbF = concentration of fetal hemoglobin in the sample

Bilirubin

Bilirubin is calculated as follows:

$$ctBil(P) = \frac{ctBil(B)}{1 - Hct(calc)}$$

where:

*c*tBil(P) = concentration of total bilirubin in plasma

*c*tBil(B) = concentration of diluted plasma bilirubin after sample hemolyzation

Hct(calc) = calculated hematocrit (a fraction).

Continued on next page

Measurement and corrections, *Continued*

Bilirubin *(continued)*

$$\mathrm{Hct(calc)} = \frac{0.0301}{\mathrm{g/dL}} \times c\mathrm{tHb}$$

For further details on Hct(calc) please refer to *Interference Tests* and the explanation of MCHC (Mean Corpuscular Hemoglobin Concentration) in *chapter 5* in this manual.

Restrictions

The following parameters will not be calculated:

Parameter	Is not calculated if…
$s\mathrm{O_2}$, *F*COHb, *F*MetHb, *F*HHb	ceHb = cHHb + $c\mathrm{O_2Hb}$< 0.75 mmol/L; ctHb< 1 mmol/L
ctBil	ctHb > 15.5 mmol/L

The following conditions are required to exclude HbF interference:

Parameter or Feature	Requirement
ceHb	> 3 mmol/L
*F*COHb	< 15 %
*F*MetHb	< 10 %
“HbF correction" has not been activated	If ctHb < 5 mmol/L, $c\mathrm{O_2HbF}$ should be more than 1 mmol/L. If ctHb > 5 mmol/L, $c\mathrm{O_2HbF}/c$tHb should be more than 0.2.
“HbF correction" has been activated	No lower limit value for $c\mathrm{O_2HbF}$ is required, i.e. even adult blood samples will be corrected for HbF. It may be of value when analyzing blood samples from newborns who received adult blood transfusion. In these cases *F*HbF can be lower than 20 % and significant deviations of oximetry parameters and bilirubin can occur.
HbF suppression has been activated	The *F*HbF value is displayed by the ABL835/30 FLEX. Message “HbF detected” is displayed on the other analyzer versions with the oximetry module installed.
$s\mathrm{O_2}$<50 % or ctHb<5 mmol/L	Message “*F*HbF measurement is not possible” is displayed by the ABL835/30 FLEX if a HbF suppression has been activated.

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Measurement and corrections, *Continued*

Corrections for *c*tHb

The uncorrected hemoglobin concentration, *c*tHb(sample), measured on capillary or syringe samples is corrected as follows:

Equation A:

$$c\text{tHb}(\text{sample},\text{corr}) = \frac{c\text{tHb}(\text{sample})}{F_{cuv}\ F_{dil}}$$

where:

*c*tHb(sample,corr)	=	corrected *c*tHb
F_{cuv}	=	Analyzer-dependent constant determined at tHb calibrations and automatically stored by the analyzer
F_{dil}	=	Analyzer dependent constant determined during tests against the reference method, which corrects for Hb dilution in the different aspiration modes.

ABL8XX FLEX	Mode	F_{dil}	Equation
35/25/15	S195	1.0000	A
	S95	0.9630	A
	S85	1.0050	A
	C95	0.9630	A
	C55	0.9220	A
	C35OXI	0.9570	A
	*FM (no message)	1.0110	A
	*FM (message 874)	0.9630	A
	*FM (message 873)	0.9630	A
	*FM (message 872)	0.9490	A
	*FM (message 871)	0.9440	A
	*FM (message 870)	0.9230	A
	*FM (message 869)	0.9230	A

*FM = FLEXMODE

Continued on next page

Measurement and corrections, *Continued*

Corrections for *c*tHb *(continued)*

ABL8XX FLEX	Mode	F_{dil}	Equation
30/20/10	S85	1.0050	A
	C55	0.9220	A
	C35 OXI	0.9570	A
	*FM (no message)	0.9570	A
	*FM (message 872)	0.9490	A
	*FM (message 871)	0.9440	A
	*FM (message 870)	0.9230	A
	*FM (message 869)	0.9230	A

*FM = FLEXMODE

Corrections for *c*tBil

The uncorrected total bilirubin concentration, *c*tBil(sample), measured on capillary or syringe samples is corrected as follows:

Equation A:

$$c\text{tBil(sample, corr)} = \frac{c\text{tBil(sample)}}{F_{cuv}\ F_{dil}}$$

where:

*c*tBil(sample,corr)	=	corrected *c*tBil
F_{cuv}	=	Analyzer-dependent constant determined at tHb calibrations and automatically stored by the analyzer
F_{dil}	=	Analyzer dependent constant determined during tests against the reference method, which corrects for *c*tBil dilution in the different aspiration modes.

Continued on next page

Measurement and corrections, *Continued*

Corrections for *c*tBil *(continued)*

ABL8XX	Mode	F_{dil}	Equation
35	S195	1.0050	A
	S95	0.9320	A
	S85	1.0000	A
	C95	0.9320	A
	C55	0.8640	A
	C35oxi	0.9160	A
	*FM (no message)	0.9900	A
	*FM (message 874)		
	*FM (message 873)		
	*FM (message 872)		
	*FM (message 871)		
	*FM (message 870)		
30	S85	1.0000	A
	C55	0.8640	A
	C35 OXI	0.9160	A
	*FM (no message)	0.9570	A
	*FM (message 872)		
	*FM (message 871)		
	*FM (message 870)		

*FM = FLEXMODE.

References

List of references

The list of the references for *Chapter 3, The Optical Measuring Principles:*

1. Ewing GW. Instrumental methods of chemical analysis. 5th ed. McGraw-Hill, 1985.
2. Martens H. Multivariate calibration: quantitative interpretation of non-selective chemical data. Dr. Techn. Thesis, NTH Univ. of Trondheim, 1986.
3. Krzeminski A. Why correct for fetal hemoglobin in blood oximetry measurements? Radiometer Publication Info. No. 1992-3. Copenhagen: Radiometer Medical A/S, 1992.
4. Huehns ER, Beaven GH. Developmental changes in human hemoglobins. Clin Dev Med 1971; 37: 175-203.

4. User-defined corrections

Overview

Introduction This chapter describes the basis of the user-defined corrections available for all the measured parameters.

Contents This chapter contains the following topics.

General information

Purpose of use

User-defined corrections are most commonly implemented in situations where the values measured for a particular parameter by two or more analyzers, deviate consistently from each other.

NOTE: *Since the performance of all analyzers is tested as described in Chapter 5, Performance Characteristics, and each instrument is assumed to operate accurately and optimally, the unnecessary correction of parameter values by the user can lead to inaccurate measurements being reported.*

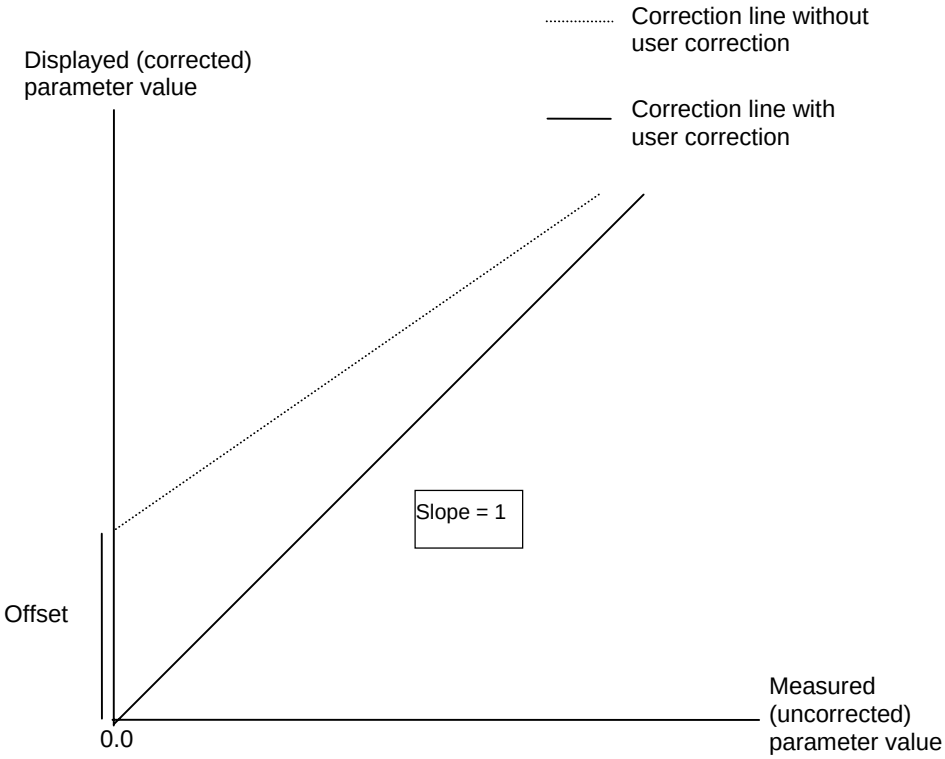
User-defined corrections

User-defined corrections are based on a linear correlation between the measured values (without user-defined corrections) and the displayed values (with user-defined corrections).

The correction factors for each measured parameter are the slope and the offset of the correction line. With user-defined corrections it is possible to change the values of either one or both of these correction factors, depending on the parameter type.

$$\text{Corrected value} = \text{Slope} \times \text{Uncorrected value} + \text{Offset}$$

The diagram below is a schematic representation of the relationship between correction lines without and with user-defined correction.



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General information, *Continued*

Entering user-defined corrections

The slope/offset for each parameter are configured in the **Parameters Setup** under General Setup. User-corrected values are marked with a "*" after the result.

NOTE: *The user-defined corrections will be applied to measurements on QC solution unless the "Apply parameter corrections to QC" option was deactivated in Miscellaneous Setup.*

For detailed instructions on how to enter user-defined corrections, refer to the section *Parameter Setup* in *Chapter 3* of the *Operator's Manual*.

Correction factors for oximetry parameters and bilirubin

Allowed corrections

The following corrections can be user-defined for the oximetry parameters and bilirubin:

Parameter	Allowed User-defined Corrections	
	Slope	**Offset**
***c*tHb**	Yes	No
***s*O_2**	Yes	Yes
***F*COHb**	No	Yes
***F*MetHb**	No	Yes
***F*O_2Hb**	No	No
***F*HHb**	No	No
***F*HbF**	Yes	Yes
***c*tBil**	Yes	Yes

NOTE: *In order to define the corrections accurately, the measurements of the oximetry parameters and bilirubin on the ABL800 FLEX analyzers should be made without any entered corrections. To avoid truncation errors from an enabled "Out of range suppression" function it is important to disable the function.*

***c*tHb**

The following recommendations apply to *c*tHb:

Item	Description
Units	g/dL; g/L; mmol/L
Sample	Set *c*tHb of a SAT100 sample to ≈15 g/dL (9.3 mmol/L) and pH ≈ 7.4
*c*tHb, maximum point	Uncorrected or corrected: ≈ 15 g/dL or 9.3 mmol/L
Slope	0.950 - 1.050

***s*O_2**

The following recommendations apply to *s*O_2 :

Item	Description
Units	Fraction
Sample	Set *c*tHb of gas equilibrated SAT0 and SAT100 samples to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4
Slope	0.900 - 1.100
Offset	± 0.050

Continued on next page

Correction factors for oximetry parameters and bilirubin, *Continued*

***F*COHb** The following recommendations apply to *F*COHb:

Item	Description
Units	Fraction
Sample	The zero point (*F*COHb ≈ 0) is saturated to approximately SAT100, and *c*tHb is set to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4.
Offset	± 0.050

***F*MetHb** The following recommendations apply to *F*MetHb:

Item	Description
Units	Fraction
Sample	The zero point (*F*MetHb ≈ 0) is saturated to approximately SAT100, and *c*tHb is set to ≈ 15 g/dL (9.3 mmol/L) and pH ≈ 7.4.
Offset	± 0.050

***F*HbF** The following recommendations apply to *F*HbF:

Item	Description
Units	Fraction
Sample	Radiometer recommends that *c*tHb in the adult samples (with *F*HbF = 0) and fetal samples (with high *F*HbF) is set to ≈ 15 g/dL (9.3 mmol/L), sO_2 ≈ 100 %, and pH ≈ 7.4. The “Correction for HbF levels less than 20 %” function should be enabled in order to have the *F*HbF value displayed for the adult sample. Averaging repeated measurements on blood from different donors gives an optimized accuracy of the correction. Averaging repeated measurements on blood from the same donor also improves the accuracy.
Slope	0.800 - 1.200
Offset	± 0.20

Continued on next page

Correction factors for oximetry parameters and bilirubin, *Continued*

ctBil

The following recommendations apply to ctBil:

Item	Description
Units	μmol/L
Sample	Radiometer recommends that human plasma or serum is used with pH ≈ 7.4 (the analyzer reading). Zero point sample could be adult sample (ctBil ≈ 0 μmol/L) and maximum point could be an unconjugated bilirubin sample with ctBil ≈ 300 - 400 μmol/L. Averaging repeated measurements on samples from different donors gives an optimized accuracy of the correction. Averaging repeated measurements on samples from the same donor also improves the accuracy. Commercial bilirubin standards can interfere with bilirubin measurement because they may have an absorbance spectrum different from that of human plasma.
Slope	0.5 - 1.5
Offset	± 100

FO$_2$Hb and FHHb

The units for FO$_2$Hb and FHHb are [Fraction].

After the user-defined corrections of the parameters sO$_2$, FCOHb and FMetHb have been carried out, FO$_2$Hb and FHHb are automatically calculated using the formulae stated below, since the sum of the fractions FCOHb, FMetHb, FO$_2$Hb and FHHb as defined must be equal to 1.0:

FO$_2$Hb:

$$F\mathrm{O_2Hb} = (1 - F\mathrm{COHb} - F\mathrm{MetHb}) \times s\mathrm{O_2}$$

FHHb:

$$F\mathrm{HHb} = (1 - F\mathrm{COHb} - F\mathrm{MetHb}) \times (1 - s\mathrm{O_2})$$

Electrolyte and metabolite parameters

Preparatory actions

Prior to entering corrections for the electrolyte and metabolite parameters, the user must obtain the reference values for the chosen parameters using the method accepted in his/her laboratory.

It should be noted that in order to define corrections:

- Measurements should be taken on the analyzer without user-defined corrections, and on the reference analyzer.
- A series of measurements that cover the entire measuring range should be performed.
- The measurements should be made simultaneously on the ABL800 FLEX and reference analyzers, and samples must be handled correctly.
- The slope and the offset must be calculated. The user may, for example, make a linear correlation between the values measured on the ABL800 FLEX and the reference analyzers, using the ABL800 FLEX as an independent variable.
- If the measurements are carried out on samples with values within the normal reference range, then the user may change the offset and leave the slope unchanged.
- The user must verify the corrections that are entered.

Details of these procedures may be found in the section *Definitions and Test Conditions* in *Chapter 5*.

Correcting the slope

The following corrections to the slope are possible within the stated limits:

Parameter	Slope (mmol/L)
$c\mathrm{K}^+$	0.750 - 1.250
$c\mathrm{Na}^+$	0.850 - 1.150
$c\mathrm{Ca}^{2+}$	0.800 - 1.200
$c\mathrm{Cl}^-$	0.850 - 1.150
*c*Glu	0.750 - 1.250
*c*Lac	0.750 - 1.250

Correcting the offset

The following corrections to the offset are possible within the stated limits:

Parameter:	$c\mathrm{K}^+$	$c\mathrm{Na}^+$	$c\mathrm{Ca}^{2+}$	$c\mathrm{Cl}^-$	*c*Glu	*c*Lac
Offset (mmol/L):	± 0.3	± 5	± 0.05	± 5	± 0.5	± 0.5

Continued on next page

Electrolyte and metabolite parameters, *Continued*

Resetting corrections to default values

The Radiometer default values for the electrolyte and metabolite parameters must be reset manually by the user to 1.000 for each parameter via the **Parameters Setup** screen.

5. Performance characteristics

Overview

Introduction This chapter describes performance characteristics for each measured parameter and test conditions to obtain them.

Contents This chapter contains the following topics.

Definition of terms and test conditions

General information

Performance specifications are achieved by comparison between the ABL800 FLEX analyzers and the primary reference methods, and by comparison between the ABL800 FLEX analyzers and the ABL735.

Performance specifications of the ABL800 FLEX analyzers are described, using the following:

- $Bias_{Ref}$ = the mean difference between the ABL800 FLEX and the primary reference methods.
- $Bias_{ABL}$ = the mean difference between the ABL800 FLEX and the ABL735.
- Repeatability
- Reproducibility
- Total variation range
- Imprecision.

Bias

The bias of a quantity is defined as the mean difference between the measured value on a group of test instruments and the estimated true value (as assayed by the reference method). $Bias_{Ref}$ is determined as follows:

$$Bias_{Ref} = X_{ABL800\ FLEX} - X_{Primary\ Reference\ method}$$

$Bias_{ABL}$ is a relative bias between the ABL835 in FLEXMODE and the ABL735 in C195 µL mode, and is determined as follows:

$$Bias_{ABL} = X_{ABL800\ FLEX} - X_{ABL735}$$

Repeatability

Samples, assumed to be identical, repeatedly measured on one analyzer will not necessarily yield identical results. The degree of variation in the results is a measure of the repeatability of the analyzer.

The repeatability is obtained from repeated measurements within a short interval of time using:

- The same instrument and location
- The same measurement procedure
- Identical portions of the same sample
- One operator per instrument

The repeatability for each level is pooled for all test instruments and test days.

Continued on next page

Definition of terms and test conditions, *Continued*

Reproducibility

Reproducibility is obtained from repeated measurements within several days using:

- Random instrument
- Random sample
- Random operators.

Reproducibility for each level is pooled for all test instruments and test days.

Total variation range

The total variation range is given as $\pm 2 \times S_X$, where S_X is the reproducibility.

Imprecision

Repeated measurements using one analyzer on samples assumed to be identical will not necessarily yield identical results. The degree of variation in the results is a measure of the precision of the analyzer.

The following table describes the parameters used to characterize precision obtained via the performance tests on the ABL700 Series of analyzers.

Parameter	Description
S_0	**Repeatability** This is a standard deviation obtained from repeated measurements within a short interval of time using: • The same instrument and location • The same measurement procedure • Identical portions of the same sample • One operator per instrument S_0 for each level is pooled for all test instruments and test days.
S_D	**Day-to-day variation** This is a standard deviation obtained from repeated measurements over all test days. Includes contributions from differences in calibration states of the analyzers throughout the test days.
S_{ABL}	**Uncertainty of bias on a random instrument** S_{ABL} is used for repeated determinations on one sample. This standard deviation includes the inter-instrument variations, sample variations, and uncertainties from standard solutions and reference methods.
S_X	**Uncertainty of bias on a random instrument for a single measurement** S_X is a standard deviation which includes S_{ABL}, S_D and S_0.

Continued on next page

Definition of terms and test conditions, *Continued*

Test conditions Test conditions to determine $bias_{ABL}$, repeatability and total variation for pH, pCO_2, pO_2, cCa^{2+}, cCl^-, cK^+, cNa^+, cGlu, cLac, ctHb were as follows:

Item	Description
Reference analyzers	5 ABL735 with AutoCheck module were used as a reference. The C195 mode was used as a reference for all measured parameters.
Primary reference methods	As specified for each parameter further in this chapter.
Analyzers and test modes	5 ABL835, 3 ABL830, and 3 ABL805 were tested over 11 days in the following modes:
	• Syringe: S195, S165, S95, S85
	• Capillary: FLEXMODE, C95, C85, C55, C35 OXI, C35 MET.
Blood samples	Heparinized blood samples from healthy, voluntary donors. 11 Blood pools were prepared to cover test ranges for all measured parameters.
Blood measurements	The measurements were performed by different operators.
Calibration solution and gases	All calibration solutions and gases used for the tests are traceable to Primary Reference Standards. Traceability certificates for the ABL800 FLEX calibration solutions and gases are found at the end of chapter 7: Solutions.
Experimental conditions	Ambient temperature: 22 – 25 °C Relative humidity: 30 – 50 %.

NOTES:

- *The solutions used in the performance tests are those recommended by Radiometer. Performances using other solutions cannot be guaranteed.*
- *The performance tests are performed under conditions where the analyzers are not influenced by electromagnetic fields.*

Performance test results – chart description

Modes

Tests were performed in the following modes:

Mode	Syringe	Capillary
Macro	S195, S165	FLEXMODE ABL835 (no message) FLEXMODE ABL805 (no message)
Micro	S95, S85	C95, C85, C55, C35 OXI, C35 MET; FLEXMODE ABL830 (no message) FLEXMODE (message 869) FLEXMODE (message 870) FLEXMODE (message 871) FLEXMODE (message 872) FLEXMODE (message 873) FLEXMODE (message 874)

$Bias_{ABL}$ chart description

The legend of $Bias_{ABL}$ chart is given below:

Chart	Description
x - axis	The ABL735 mean values obtained as follows: To determine the best possible ABL735 reference value for each parameter of a specific sample, the measurements on 5 ABL735 are plotted as a function of time. A regression line is made to represent the best possible mean ABL735 measurement at a given time thus compensating the metabolism of the sample during repeated measurements on it.
y - axis	Bias in %; bias for pH in pH units.
————	95 % statistical confidence range for bias in macromodes.
.....	95 % statistical confidence range for bias in micromodes.
N_{macro}	Number of measurements in macromodes.
N_{micro}	Number of measurements in micromodes.

Continued on next page

Performance test results – chart description, *Continued*

Repeatability chart

Repeatability is presented as a plot of the coefficient of variation (CV %). Contribution to variation, such as sample matrix and environmental conditions, are not directly included, but compensated for by extending the repeatability values shown in the chart.

Chart	Description
x - axis	The ABL800 FLEX mean value.
y - axis	Repeatability in %; repeatability for pH in pH units.
————	Repeatability in macromodes.
.....	Repeatability in micromodes.
N_{macro}	Number of measurements in macromodes.
N_{micro}	Number of measurements in micromodes.

Total variation chart

Total variation chart is presented as a difference plot against the regression line at 5 ABL735. The individual measurements are plotted directly.

Chart	Description
x - axis	The ABL735 mean values obtained as follows: To determine the best possible ABL735 reference value for each parameter of a specific sample, the measurements on 5 ABL735 are plotted as a function of time. A regression line is made to represent the best possible mean ABL735 measurement at a given time thus compensating the metabolism of the sample during repeated measurements on it.
y - axis	Total variation in %; total variation for pH in pH units.
————	At least 95 % statistical confidence range for total variation in macromodes.
.....	At least 95 % statistical confidence range for total variation in micromodes.
o	Observations in macro-mode
x	Observation in micro-mode
N_{macro}	Number of measurements in macromode – see the next page.
N_{micro}	Number of measurements in micromode – see the next page.

Continued on next page

Performance test results – chart description, *Continued*

Number of measurements

The number of measurements in macro- and micromodes, and the total number of measurements during the test is listed below:

Parameter	N_{macro}	N_{micro}	Total
pH	3334	421	3755
pCO_2	2768	397	3165
pO_2	282	2912	3194
cK^+	422	1364	1786
cNa^+	423	1362	1785
cCa^{2+}	407	1148	1555
cCl^-	426	1360	1786
*c*Glu	423	1825	2248
*c*Lac	412	1829	2241
*c*tHb	415	3032	3447

Performance test results - pH

Primary reference method

Capillary-type glass pH electrode with a saturated calomel reference electrode and a liquid junction saturated with KCl (BMS™ Mk2) [1,2].

The calibration standards are traceable to the Primary Reference Standards for pH.

$Bias_{REF}$

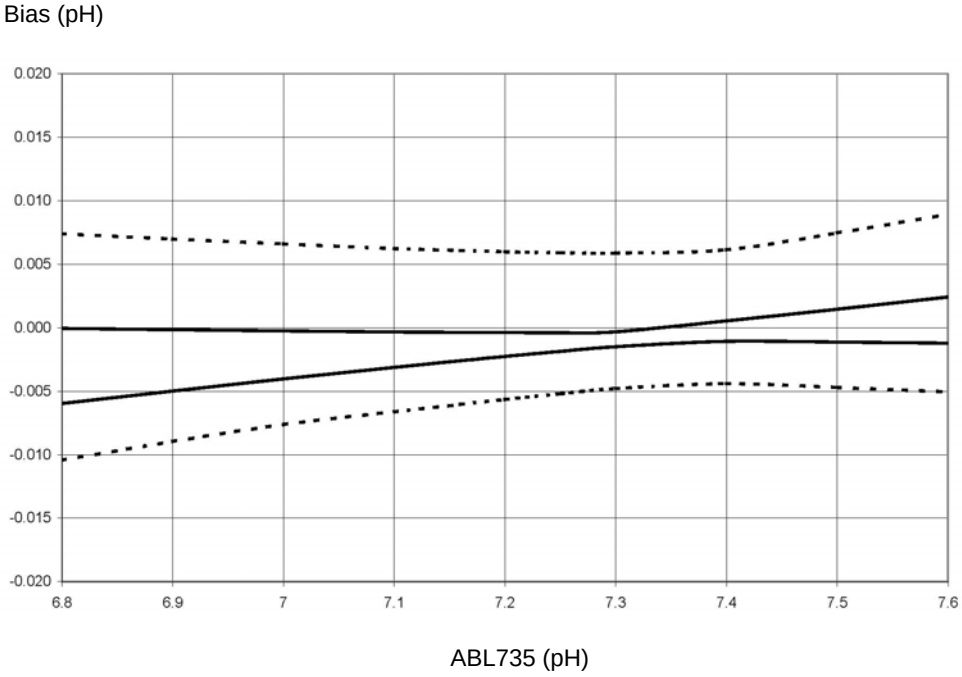
The FLEXMODE on the ABL805/30/35 analyzers was tested:

pH	Bias $_{REF}$	N
7.0	-0.002	90
7.4	-0.002	90
7.7	-0.002	90

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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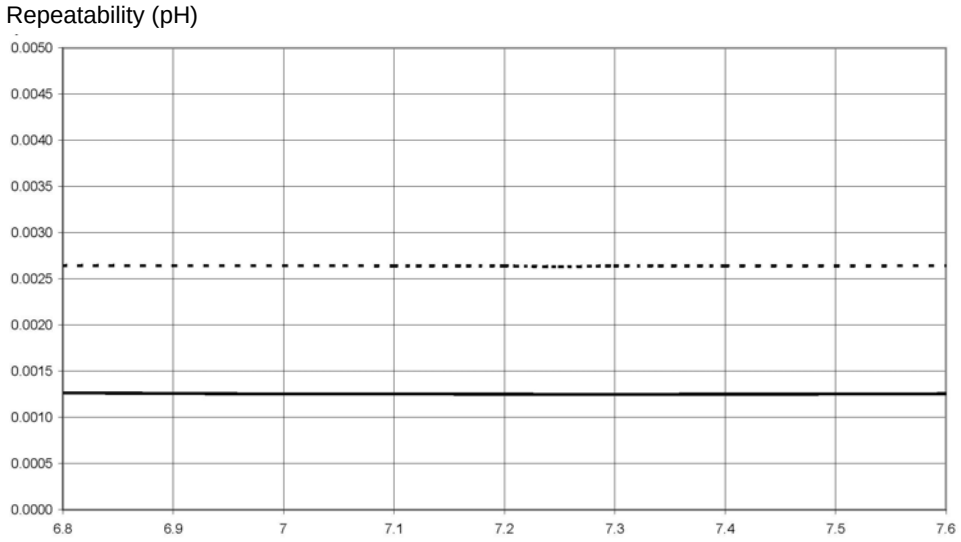
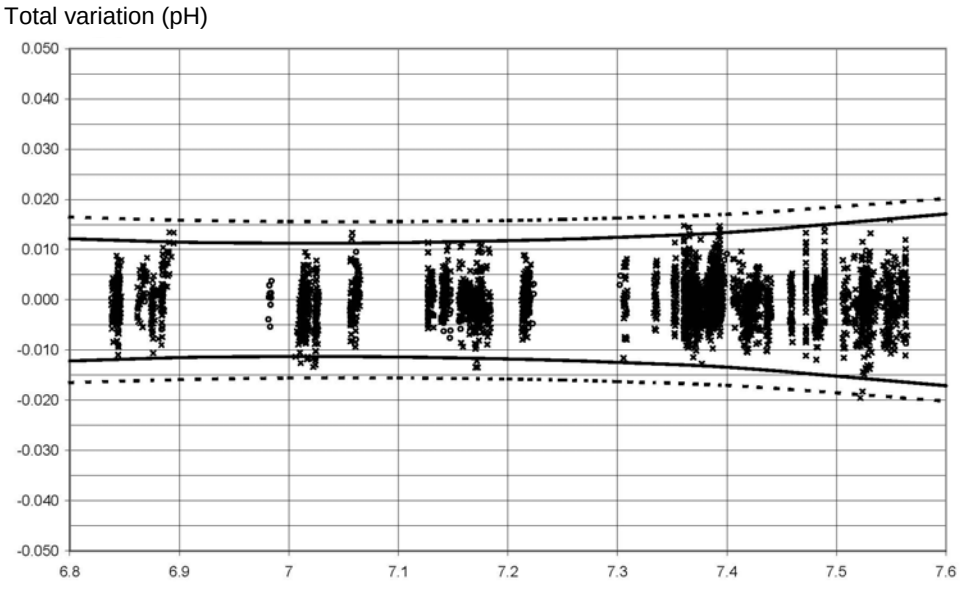
Performance test results - pH, *Continued*

Repeatability Repeatability is presented by the following chart:



ABL800 FLEX

Total variation Total variation is presented by the following chart:



ABL735

Performance test results – pCO_2

Primary reference method

Tonometry [3].

The gases used for tonometry are traceable to NIST certified Standard Reference Materials.

$Bias_{REF}$

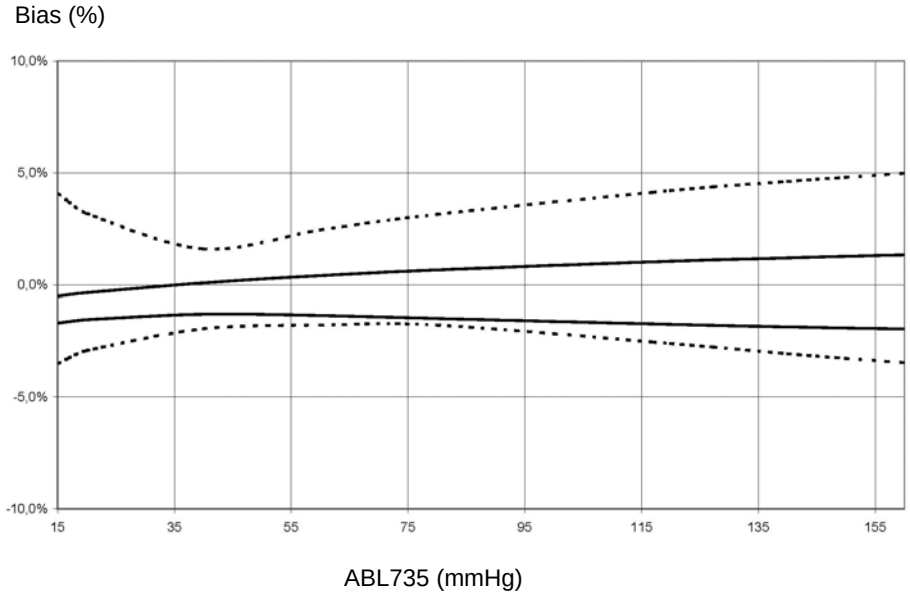
The FLEXMODE on the ABL805/30/35 analyzers was tested:

pCO_2 (mmHg)	Bias $_{REF}$	N
15	-0.11	60
40	-0.38	60
60	0.29	60
80	-0.20	60
150	-0.21	60

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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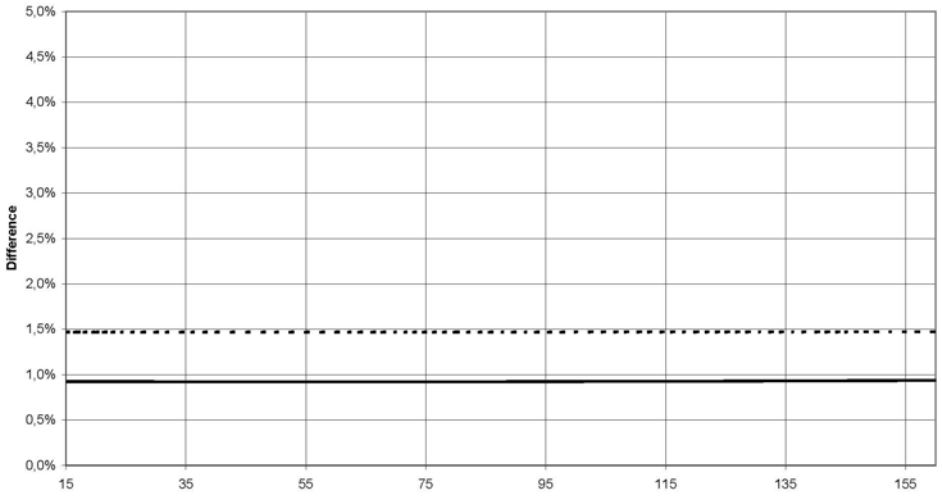
Performance test results – pCO_2, *Continued*

Repeatability Repeatability is presented by the following chart:

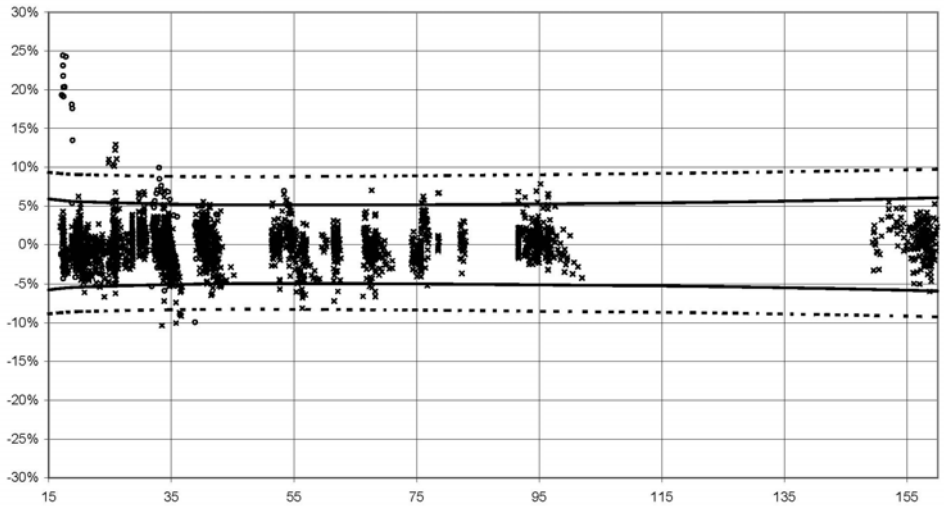
Repeatability (%)



ABL800 FLEX (mmHg)

Total variation Total variation is presented by the following chart:

Total variation (%)



ABL735 (mmHg)

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Performance test results – *p*CO_2, *Continued*

Bias and imprecision - expired air samples

The bias and imprecision for expired air samples are as follows*:

***p*CO_2 (mmHg)**	**Bias ABL835/30/25/20/15/10/05**
15	0.2
40	–0.2
60	–0.4
80	–0.2
150	1.6

***p*CO_2 (mmHg)**	**S_0**	**S_D**	**S_{ABL}**	**S_X**
15	0.25	0.35	0.59	0.73
40	0.40	0.30	0.43	0.66
60	0.50	0.35	0.79	1.00
80	0.70	0.40	1.10	1.44
150	1.00	1.10	3.07	3.41

* The Expired air mode is unchanged in the ABL800 FLEX analyzers compared to the ABL700 Series and, consequently was not re-tested for the ABL800 FLEX analyzers.

Performance test results – pO_2

Primary reference method

Tonometry [3].

The gases used for tonometry are traceable to NIST certified Standard Reference Materials.

$Bias_{REF}$

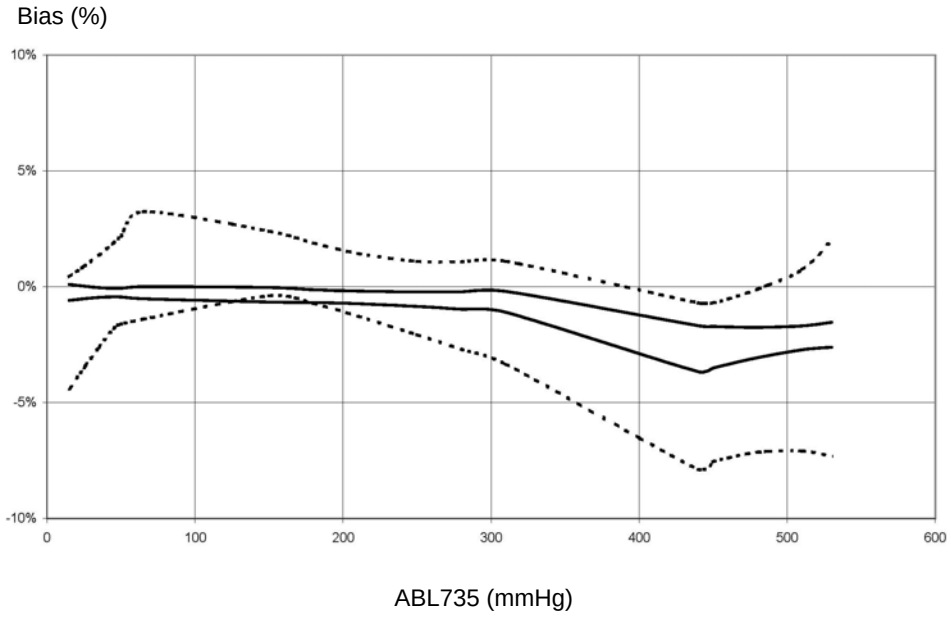
The FLEXMODE on the ABL805/30/35 analyzers was tested:

pO_2 (mmHg)	Bias $_{REF}$	N
15	0.47	60
50	-0.24	60
150	-0.45	60
250	-2.17	60
530	1.01	60

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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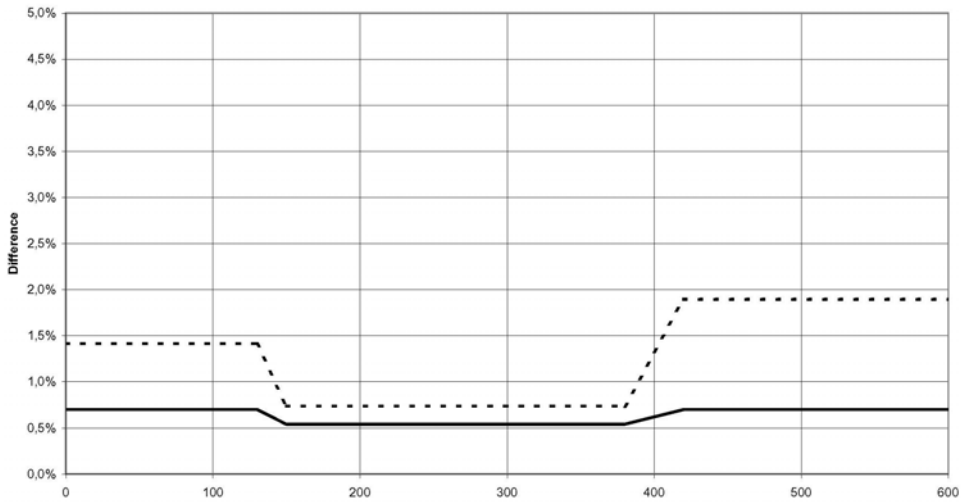
Performance test results – pO_2, *Continued*

Repeatability Repeatability is presented by the following chart:

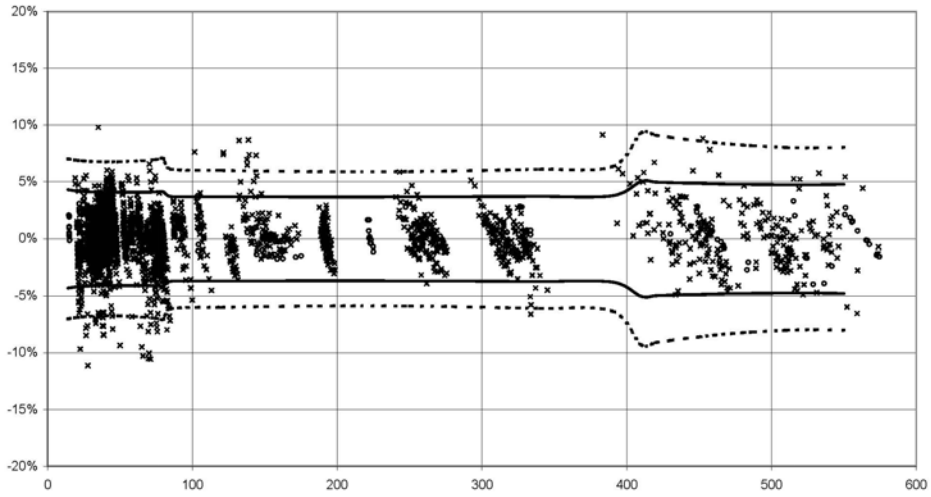
Repeatability (%)



ABL835 (mmHg)

Total variation Total variation is presented by the following chart:

Total variation (%)



ABL735 (mmHg)

Continued on next page

Performance test results – pO_2, *Continued*

Bias and imprecision – expired air samples

The bias and imprecision for expired air samples are as follows:

pO_2, mmHg	Bias ABL835/30/25/20/15/10/05
15	0.8
40	0.4
130	–0.4
230	–0.9
570	4.2

Imprecision:

pO_2 mmHg	S_0	S_D	S_{ABL}	S_X
15	0.3	0.3	1.2	1.3
40	0.3	0.3	1.0	1.1
130	0.3	0.3	0.7	0.8
230	2	2	3	4
570	5	5	13	15

15 ABL700 Series and ABL800 FLEX analyzers are tested over three days for all levels. Bias is determined against certified gases at sea level.

Performance test results – *c*K^+

Primary reference methods

NIST certified Standard Reference Material SRM 909b (human serum).

$Bias_{REF}$

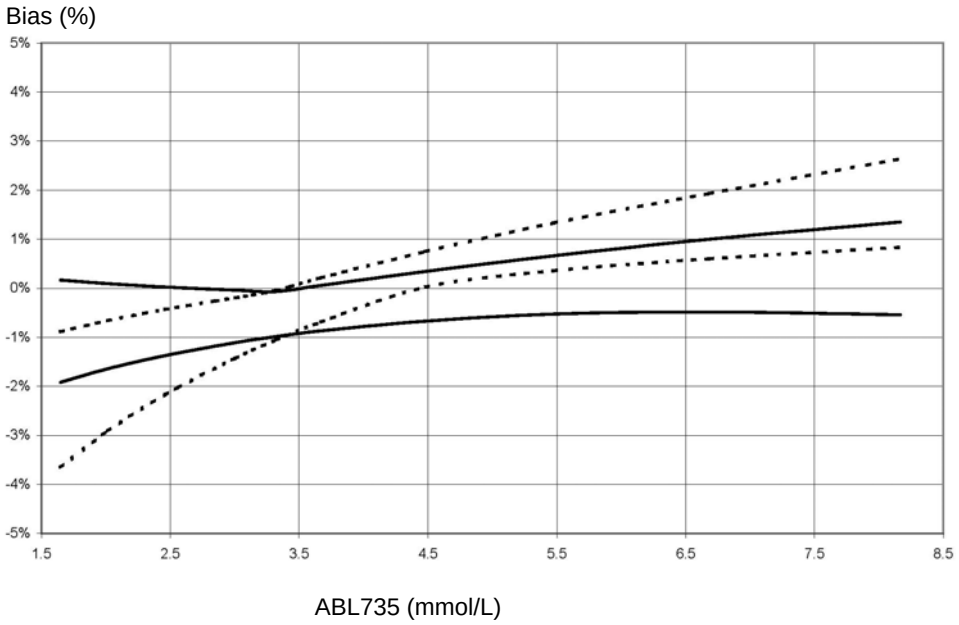
The FLEXMODE on the ABL805/35 analyzers was tested using SRM 909b:

cK^+ (mmol/L)	Bias $_{REF}$	N
3.424	-0.03	20
6.278	0.23	20

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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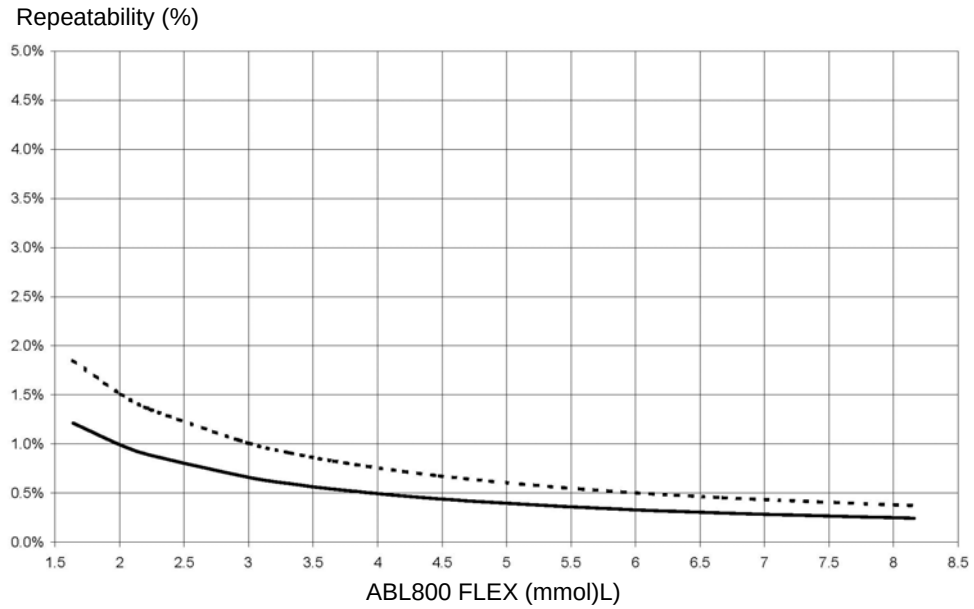
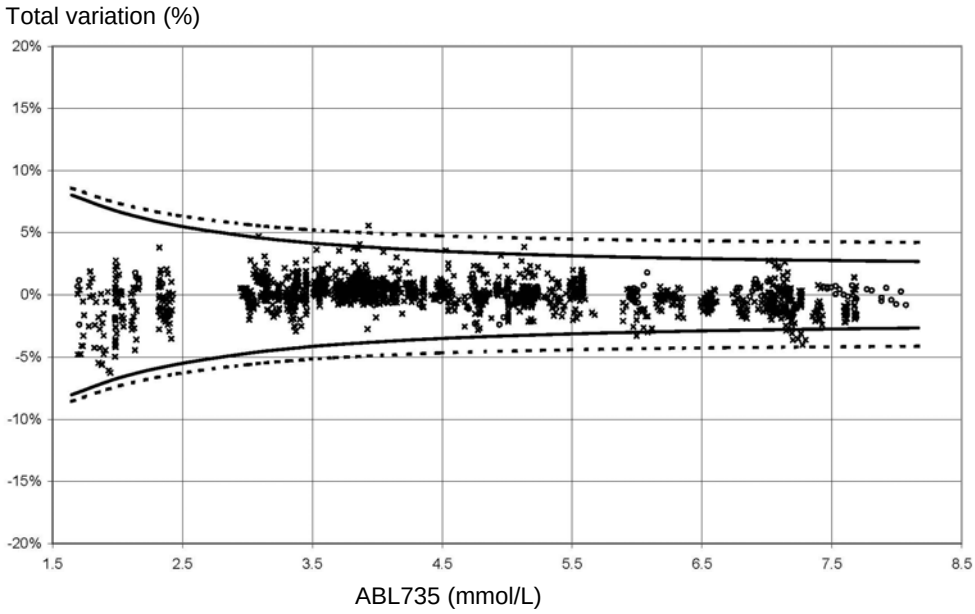
Performance test results – cK^+, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – *c*Na$^+$

Primary reference method

NIST certified Standard Reference Material SRM 909b (human serum) and Radiometer specified standard serum material (specified using flame photometry).

Bias$_{REF}$

The FLEXMODE on the ABL805/35 analyzers was tested:

*c*Na$^+$ (mmol/L)	Bias $_{REF}$	N
120.76*	-0.25	20
138.5**	-0.28	30

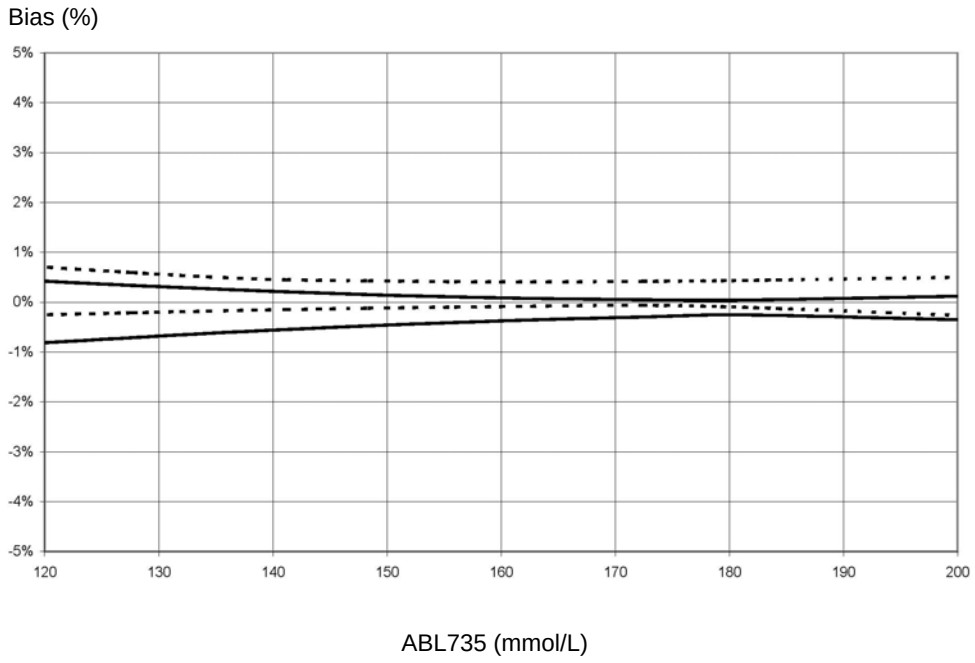
N = number of measurements on several analysers used for the test.

(*NIST certified Standard Reference Material

** Serum (Radiometer specified).

Bias$_{ABL}$ – blood samples

This bias is presented by the following chart:



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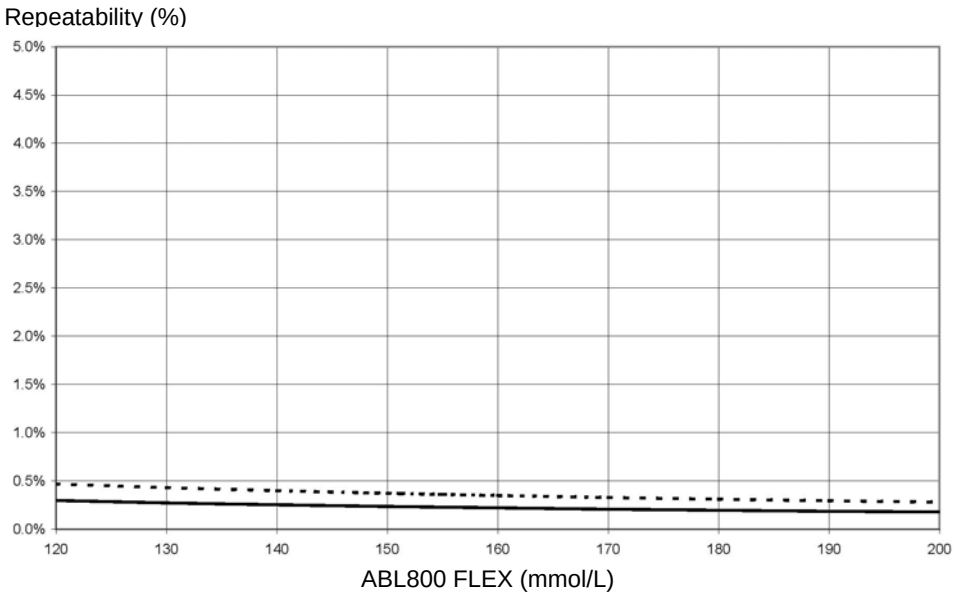
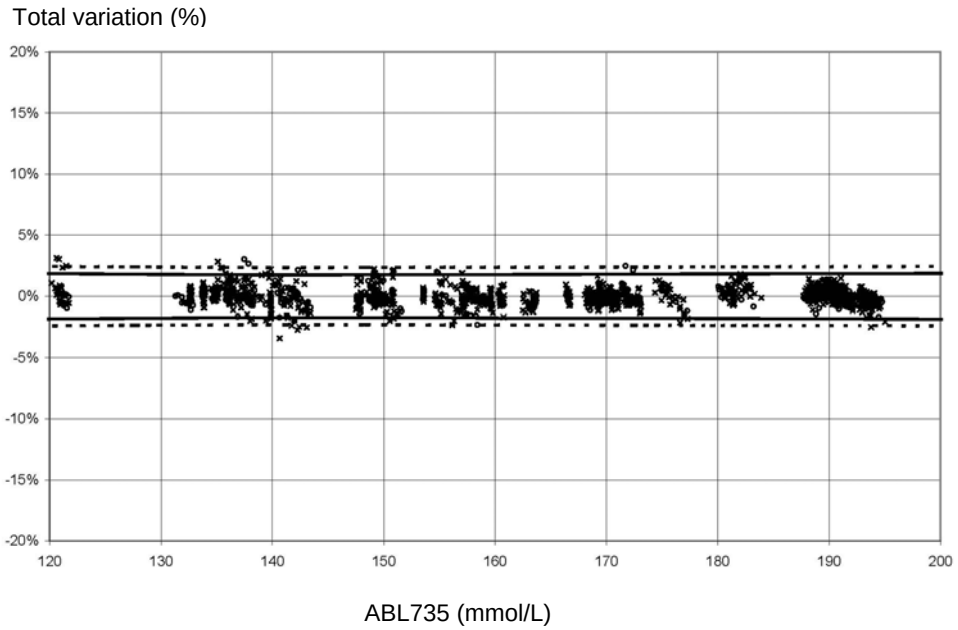
Performance test results – *c*Na^+, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – *c*Cl^-

Primary reference method

NIST certified Standard Reference Material SRM 909b (human serum).

$Bias_{REF}$

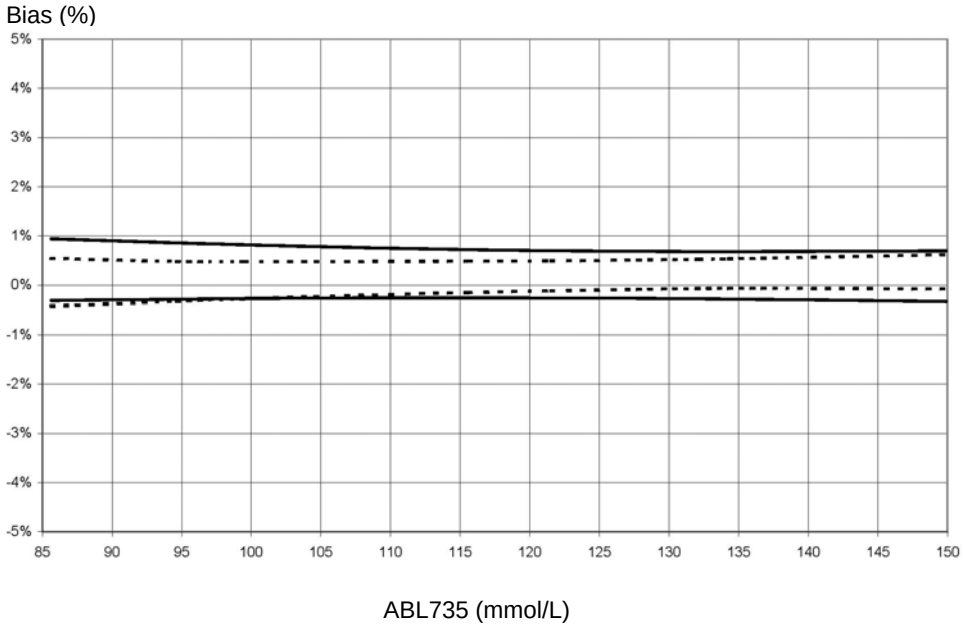
The FLEXMODE on the ABL805/35 analyzers was tested using SRM 909b:

cCl^- (mmol/L)	Bias $_{REF}$	N
89.11	0.6	20
119.43	2.4	20

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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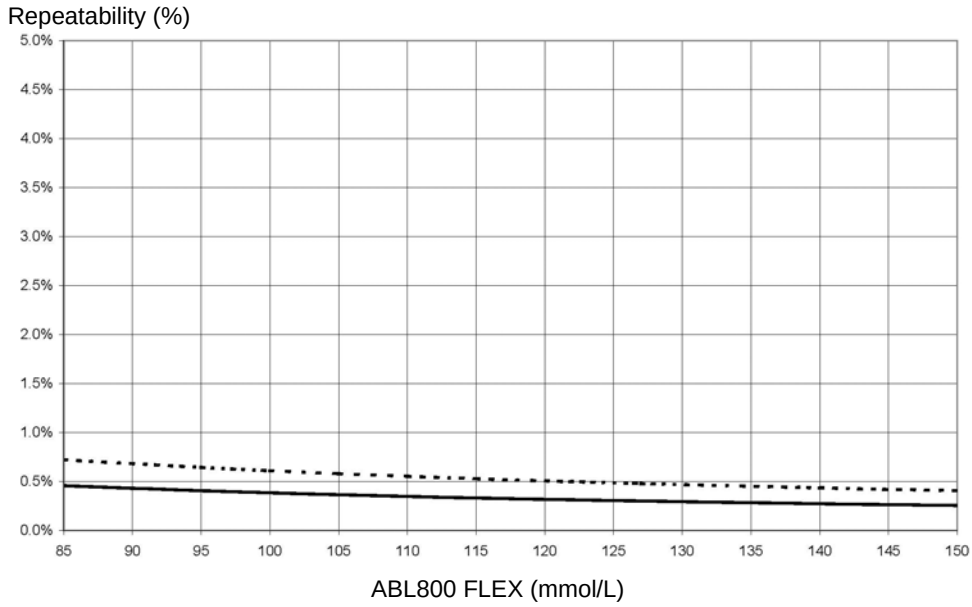
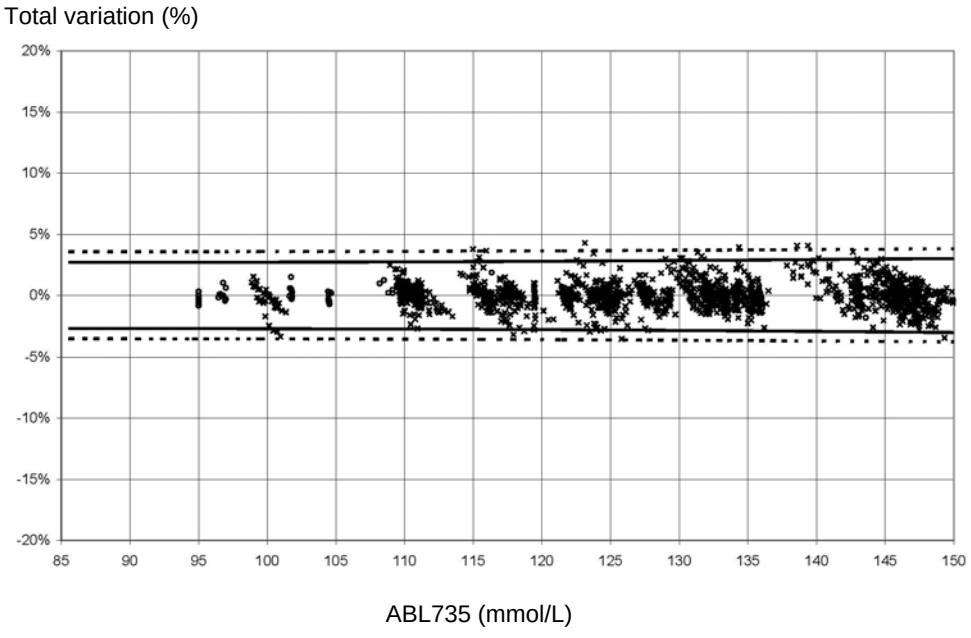
Performance test results – *c*Cl^-, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – cCa^{2+}

Primary reference methods

The calcium transfer standards were used. These are traceable to NIST SRM915 and have an ionic strength of 160.0 mmol per kg of water and pH 7.40 at 37 °C, using 1 mmol/L (37 °C) HEPES buffer.
The standards were produced as indicated in [4].

$Bias_{REF}$

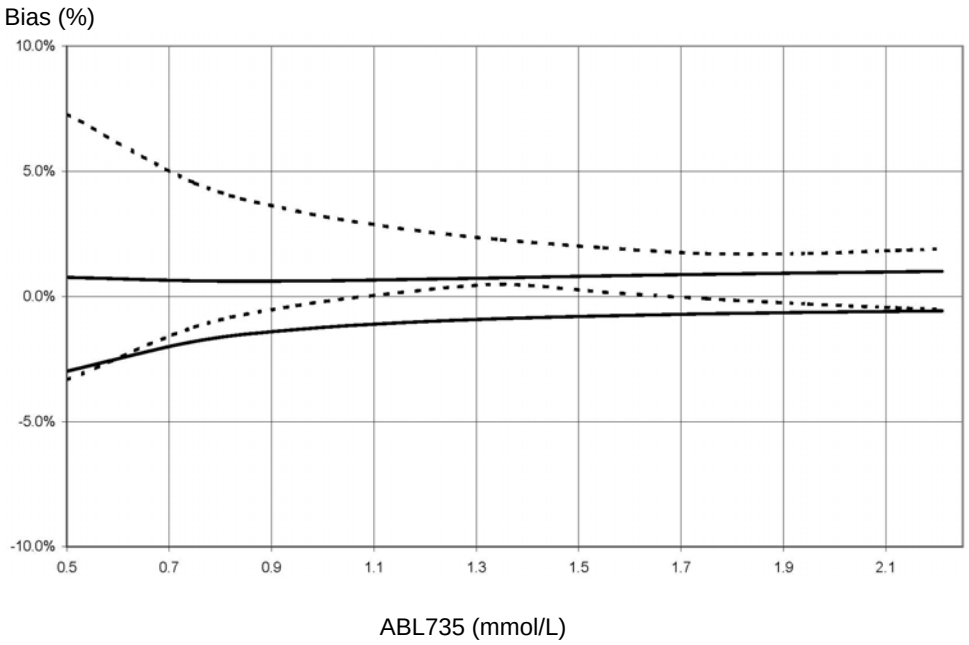
The FLEXMODE on the ABL805/35 analyzers was tested:

cCa^{2+} (mmol/L)	$Bias_{REF}$	N
0.4879	0.038	150
1.2700	0.025	150
2.5657	0.052	150

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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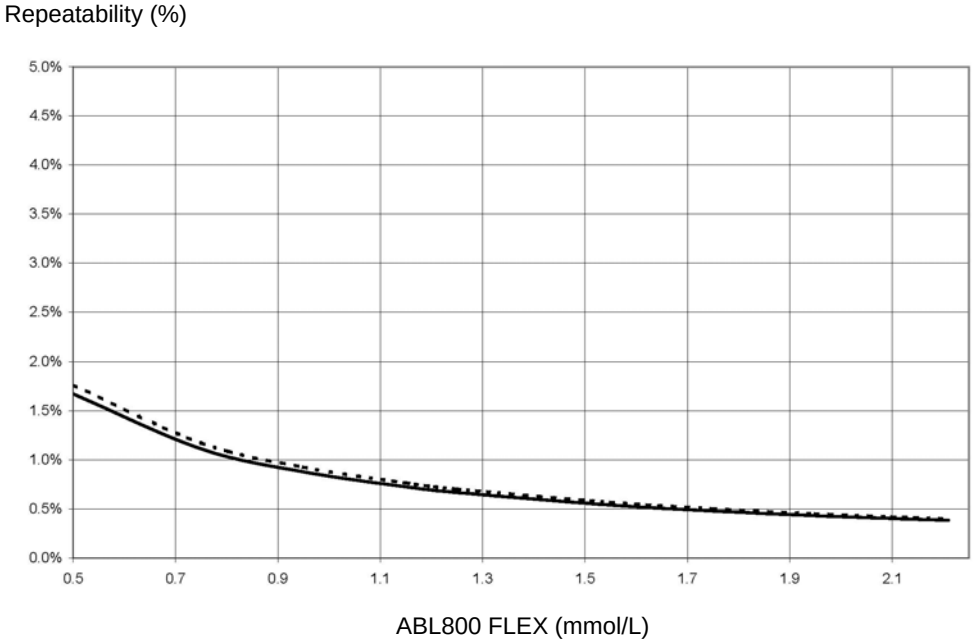
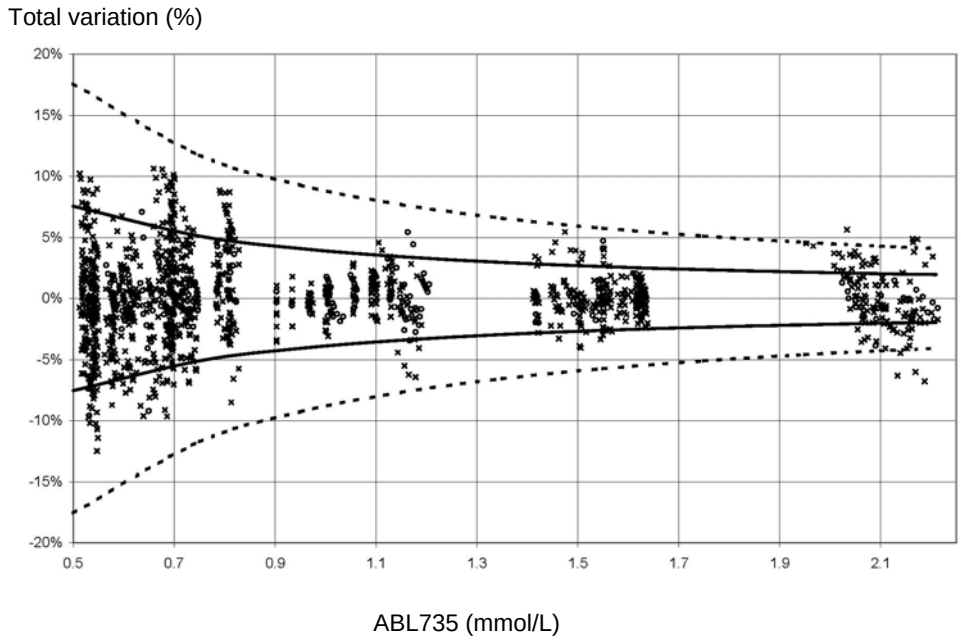
Performance test results – cCa^{2+}, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – *c*Glu

Primary reference method

Spectrophotometry, using the hexokinase (HK) method recommended by NCCLS [5], measured on serum.

$Bias_{REF}$

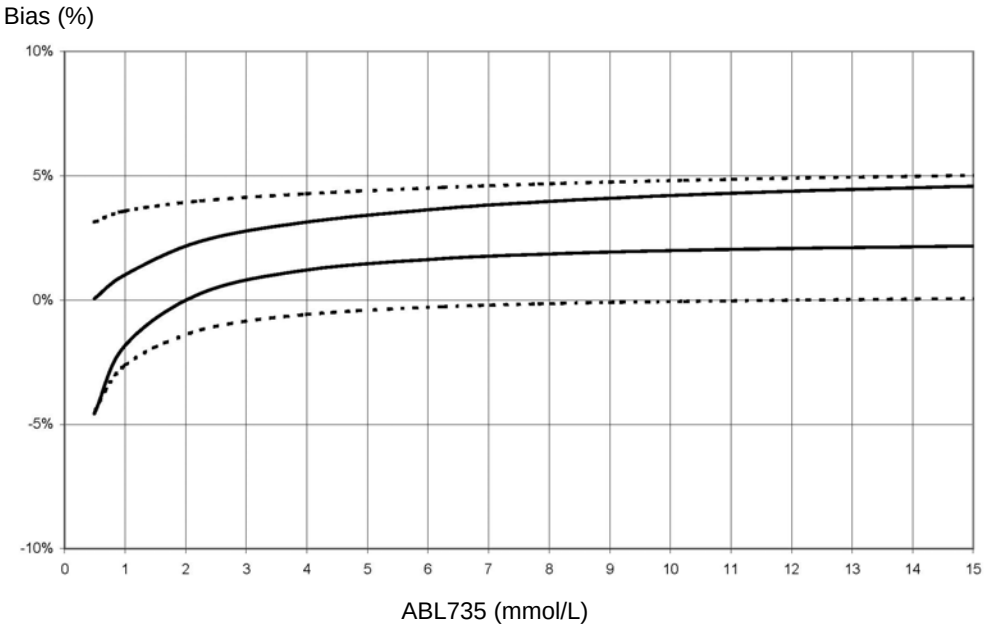
The FLEXMODE on the ABL805/35 analyzers was tested:

*c*Glu(mmol/L)	$Bias_{REF}$	N
0.08	0.03	30
2.09	0.06	30
5.08	0.12	30
14.73	-0.02	30

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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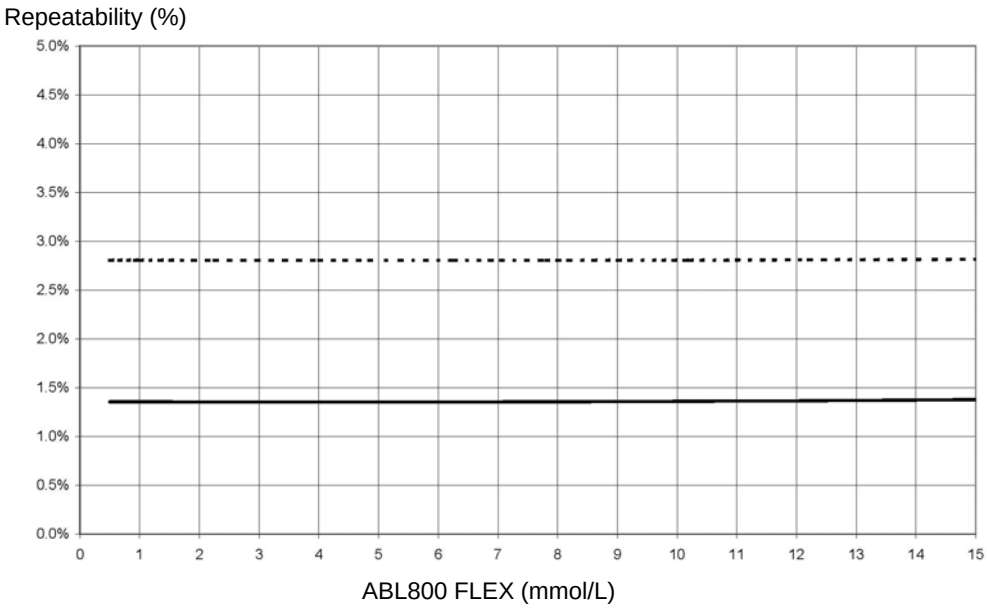
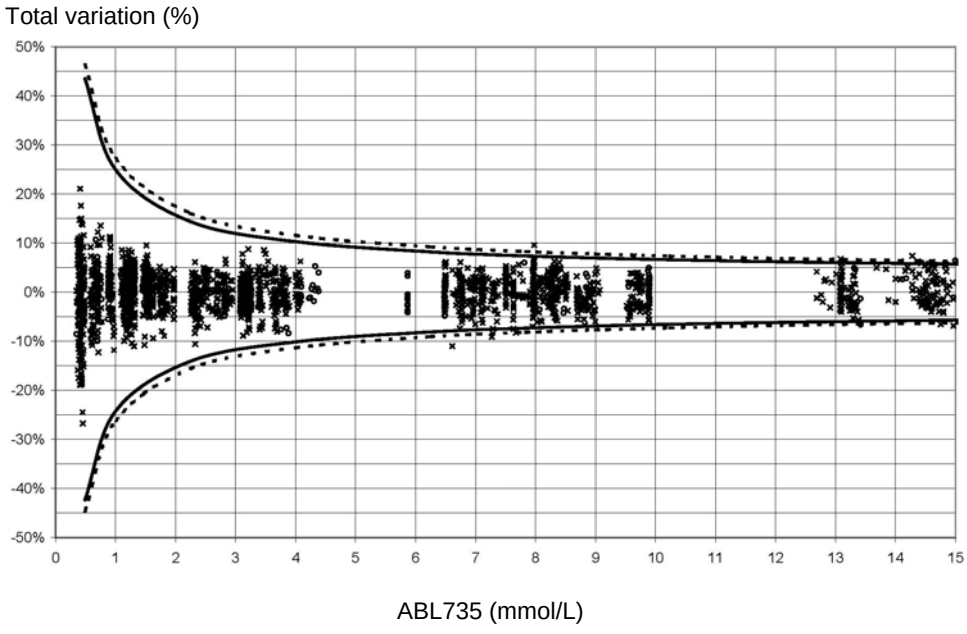
Performance test results – *c*Glu, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – *c*Lac

Primary reference methods

Spectrophotometry using a lactate dehydrogenase (LDH) method, measured on serum [10].

$Bias_{REF}$

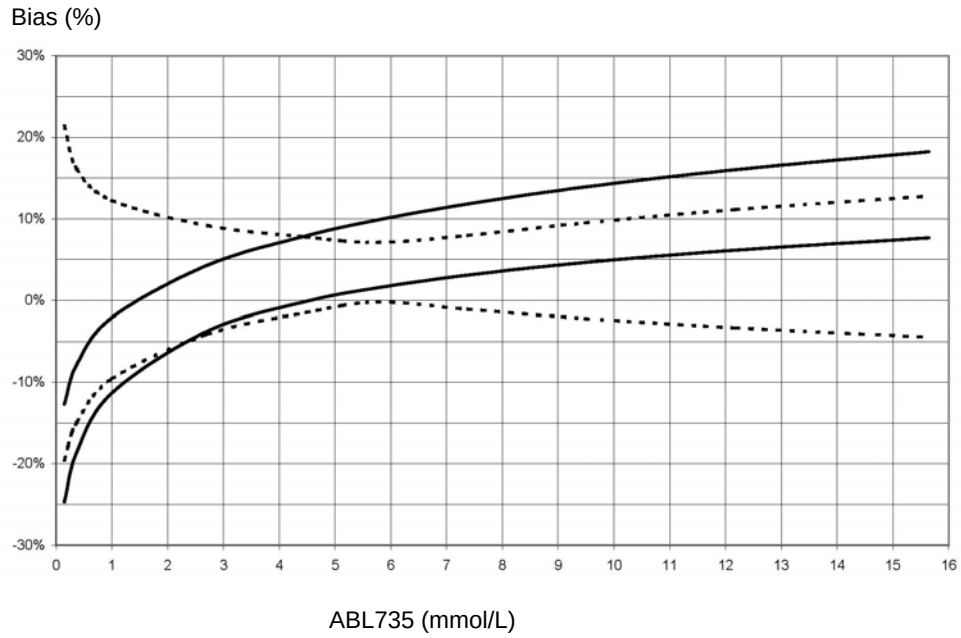
The FLEXMODE on the ABL805/35 analyzers was tested:

***c*Lac (mmol/L)**	**$Bias_{REF}$**	**N**
0.36	-0.08	30
2.06	0.12	30
8.3	-0.81	30
11.3	-0.62	30

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$ – blood samples

This bias is presented by the following chart:



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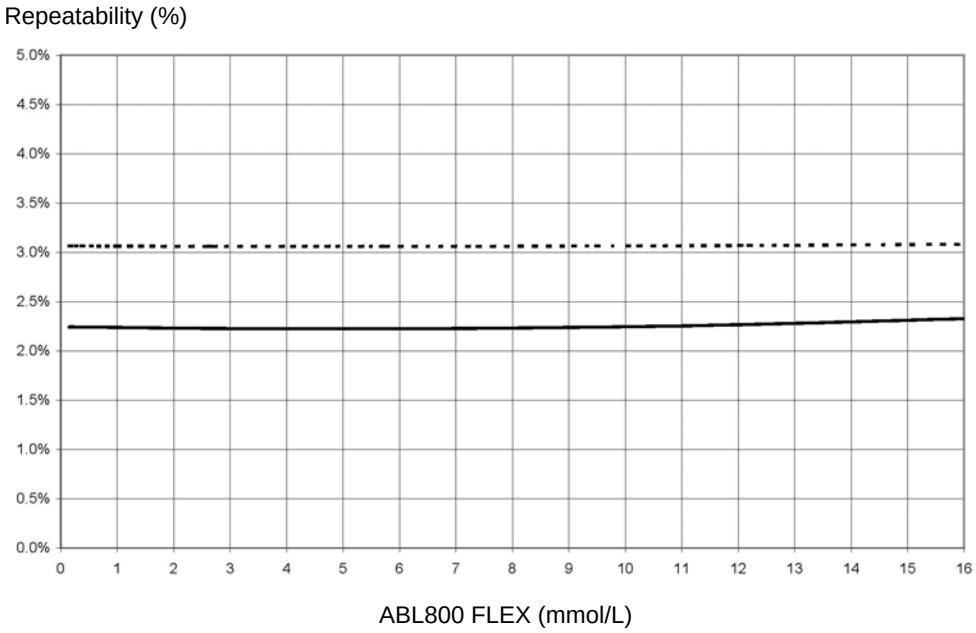
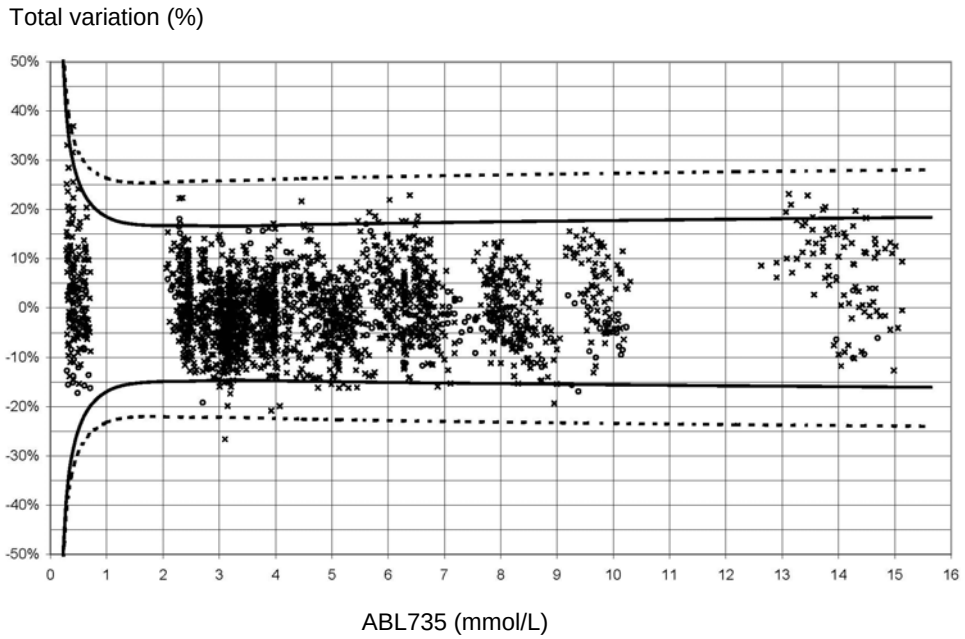
Performance test results – *c*Lac, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – *c*tHb

Primary reference method

HiCN method recommended by NCCLS [6].

$Bias_{REF}$

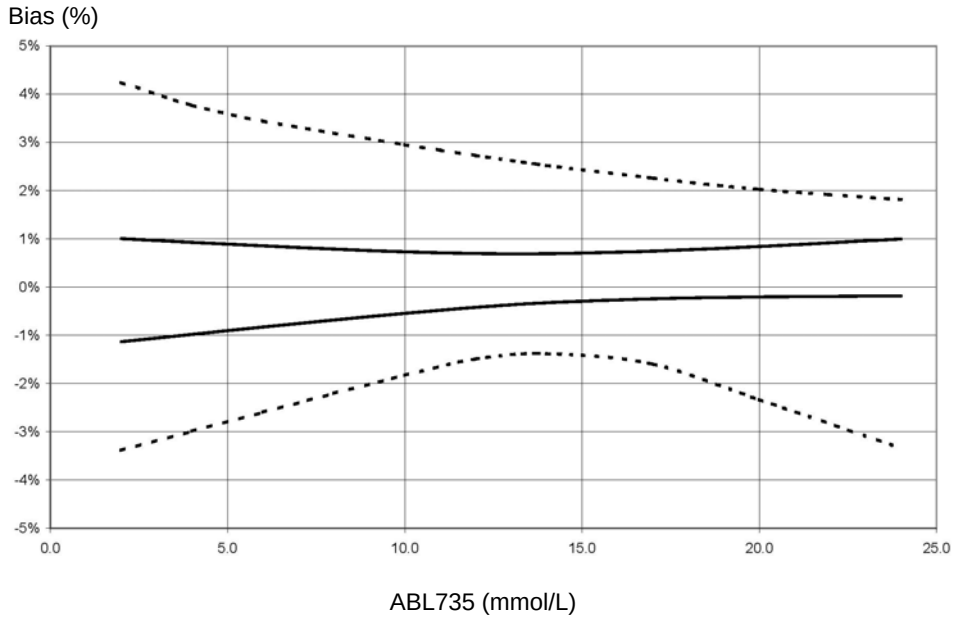
The FLEXMODE on the ABL830/35 analyzers was tested:

***c*tHb (mmol/L)**	**$Bias_{REF}$**	**N**
15 (SAT0)	0.32	145
7 (SAT100)	0.04	145
15 (SAT100)	0.37	145
25 (SAT100)	0.97	145

N = number of measurements on several analysers used for the test.

$Bias_{ABL}$

This bias is presented by the following chart:



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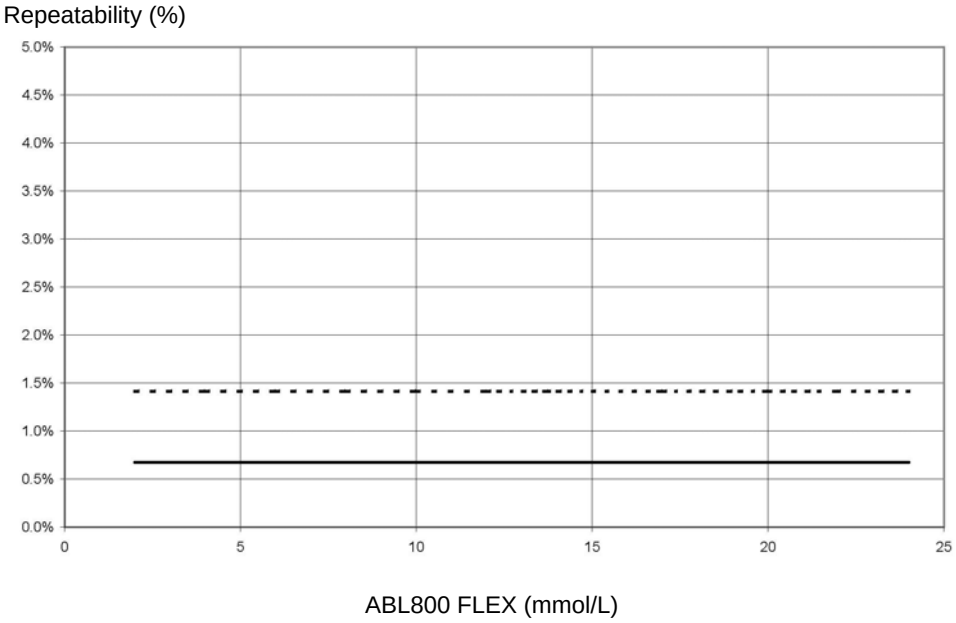
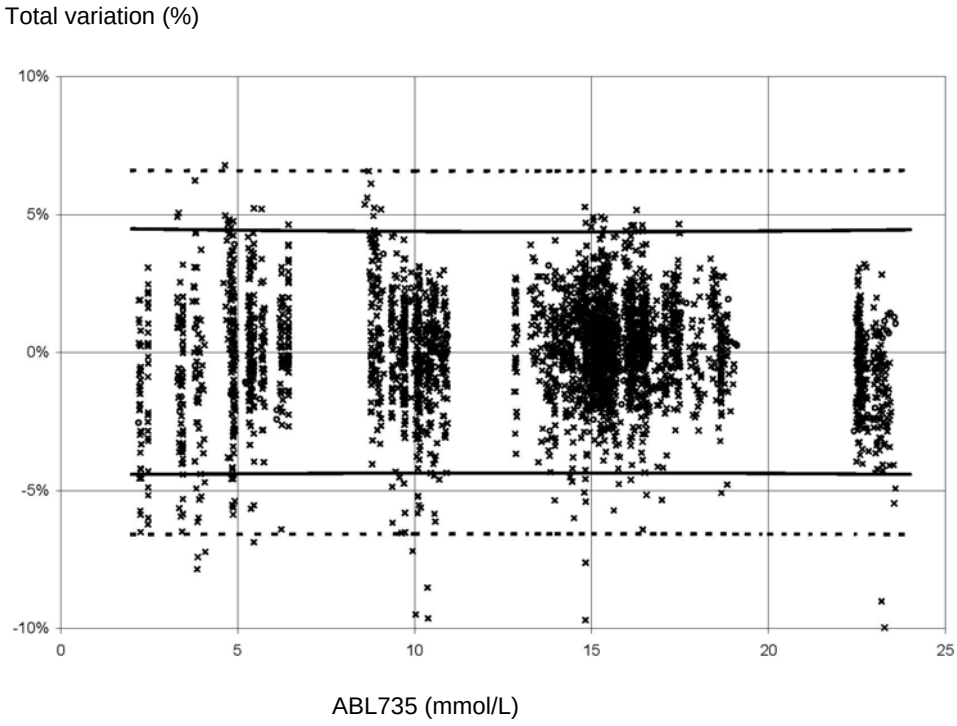
Performance test results – *c*tHb, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results - oximetry

Explanation

The optical system is unchanged in the ABL800 FLEX analyzers compared to the ABL700 Series. Test of *c*tHb on the ABL800 FLEX analyzers has been conducted (results given on pages 5-29 to 5-30). As the other oximetry parameters (sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *F*HbF) are derived from *c*tHb, these parameters have not been re-tested; the information and results below are from the ABL700 Series.

Primary reference method

The reference method established for the oximetry parameters uses modified ABL520 analyzers as the reference instruments. The ABL520 analyzers have been validated and their performance specifications determined according to primary reference methods.

The modified ABL520 analyzers are used in accordance with IFCC's recommendations for traceability of reference methods.

The reference methods used for the oximetry parameters on the ABL520 analyzers are those presented below.

Parameter	Primary reference method
sO_2	Tonometry: whole blood is tonometered with a gas mixture containing 94.4 % O_2 and 5.6 % CO_2.
*F*HHb	The standard is blood (*c*tHb = 13 - 15 g/dL) treated with dithionite.
*F*COHb	Gas chromatography. The standards are carbon monoxide mixtures with atmospheric air, whose purity is validated in accordance with NIST SRM 1678 (50 ppm CO in N_2).
*F*MetHb	Spectrometry, modified Evelyn-Malloy method [7].
*F*HbF	Alkali denaturation method [8]. Corresponds to NCCLS guideline [9].

Test conditions for oximetry parameters

Test	Description
Reference	To verify that the correction constants have been accurately determined, 10 analyzers with all parameters available are tested in C195 mode against the reference methods. Each parameter is tested on 3-6 levels over at least 3 days, with 5 repetitions each day. (5 new analyzers with all parameters available were tested against the reference methods for *F*HbF). Bias for each parameter in the C195 measuring mode against the reference method is determined.

Continued on next page

Performance test results - oximetry, *Continued*

Test conditions for oximetry parameters *(continued)*

Test	Description
Verification	6-10 ABL700 Series analyzers are tested over at least 2 days for all levels. Bias for the given mode is calculated as difference compared to the C195 µL mode. Bias against the reference method is determined as follows: Bias = bias against C195 + C195 bias against reference method. The following parameters: sO_2, *F*COHb, *F*MetHb and FO_2Hb, are measured directly against the reference built in the analyzer, and these parameters are independent of the reference method.
Reduced verification	6 - 10 new analyzers are used over at least 1 day for selected levels. Bias for the tested mode is calculated as follows: Bias = bias against C195 + C195 bias against reference method. Modes which are not tested are described as "N/A".
Simple verification	6-10 analyzers are tested at one extreme level over 1 day. Bias is not determined; bias values for the modes with similar wet section programs are used.

The measuring modes were tested as follows:

Test	Analyzer	Mode
Reference	ABL735/25/15	C195
Verification	ABL735/25/15	S195, S95, S85, C95, C55, C35 MET, C35 OXI

Continued on next page

Performance test results - oximetry, *Continued*

sO_2 - macromodes

Bias:

sO_2 (%)		ABL835/25/15		ABL830/20/10
*c*tHb (g/dL)	sO_2 (%)	S195	FM*	S85
15	0	0.00	0.05	–0.02
7	100	0.01	0.22	N/A
15	100	0.01	–0.08	0.00
25	100	0.00	–0.29	N/A

* FM = FLEXMODE (no message) corresponding to C195 mode on the ABL735/25/15.

Imprecision:

*c*tHb (g/dL)	sO_2 (%)	S_0	S_D	S_{ABL}	S_X
15	0	0.05	0.05	0.25	0.30
7	100	0.10	0.10	0.25	0.30
15	100	0.05	0.10	0.25	0.30
25	100	0.05	0.10	0.30	0.35

sO_2 - micromodes

Bias:

sO_2		ABL835/25/15					ABL830/20/10		
*c*tHb (g/dL)	sO_2 (%)	S95	C95	S85	C55	C35	FM*	C55	C35
15	0	–0.04	–0.02	-0.02	-0.03	-0.03	N/A	–0.03	–0.03
7	100	–0.10	–0.19	N/A	-0.22	-0.10	N/A	–0.22	–0.10
15	100	–0.10	–0.16	0.00	-0.16	-0.10	-0.05	–0.16	–0.10
25	100	–0.10	–0.17	N/A	-0.14	-0.09	N/A	–0.14	–0.09

* FM = FLEXMODE (no message) corresponding to C195 mode on the ABL735/25/15.

Imprecision:

ctHb (g/dL)	sO_2 (%)	S_0	S_D	S_{ABL}	S_X
15	0	0.05	0.05	0.25	0.30
7	100	0.10	0.10	0.25	0.30
15	100	0.05	0.10	0.25	0.30
25	100	0.05	0.10	0.30	0.35

Continued on next page

Performance test results - oximetry, *Continued*

FO_2Hb - macromodes

Bias:

FO_2Hb		ABL835/25		ABL830/20
ctHb (g/dL)	**FO_2Hb (%)**	**S195**	**FM***	**S85**
15	0	0.00	–0.04	–0.02
7	100	–0.07	N/A	N/A
15	100	–0.03	N/A	–0.15
25	100	–0.05	N/A	N/A

* FM = FLEXMODE (no message)

Imprecision:

ctHb (g/dL)	**FO_2Hb (%)**	**S_0**	**S_D**	**S_{ABL}**	**S_X**
15	0	0.05	0.05	0.25	0.30
7	100	0.25	0.20	0.50	0.60
15	100	0.15	0.15	0.45	0.50
25	100	0.10	0.10	0.40	0.45

FO_2Hb - micromodes

Bias:

FO_2Hb (%)		ABL835/25				
ctHb (g/dL)	**FO_2Hb (%)**	**S95**	**C95**	**S85**	**C55**	**C35**
15	0	–0.04	–0.02	–0.02	–0.03	–0.03
7	100	–0.47	–0.39	N/A	–0.48	–0.18
15	100	–0.33	–0.40	–0.15	–0.39	–0.31
25	100	–0.29	–0.46	N/A	–0.36	–0.33

FO_2Hb		ABL830/20		
ctHb (g/dL)	**FO_2Hb (%)**	**C85**	**C55**	**C35**
15	0	N/A	–0.03	–0.03
7	100	N/A	–0.48	–0.18
15	100	–0.16	–0.39	–0.31
25	100	N/A	–0.36	–0.33

Continued on next page

Performance test results - oximetry, *Continued*

FO_2Hb - micromodes *(continued)*

Imprecision:

*c*tHb (g/dL)	FO_2Hb (%)	S_0	S_D	S_{ABL}	S_X
15	0	0.05	0.05	0.25	0.30
7	100	0.25	0.20	0.50	0.60
15	100	0.15	0.15	0.45	0.50
25	100	0.10	0.10	0.40	0.45

FCOHb - macromodes

Bias:

*F*COHb			ABL835/25		ABL830/20
*c*tHb (g/dL)	sO_2 (%)	*F*COHb (%)	S195	FM*	S85
15	100	0	0.03	0.08	0.12
7	100	20	N/A	0.47	N/A
15	100	20	N/A	0.10	N/A
25	100	20	N/A	–0.47	N/A

* FM = FLEXMODE (no message)

Imprecision:

*c*tHb (g/dL)	sO_2 (%)	*F*COHb (%)	S_0	S_D	S_{ABL}	S_X
15	100	0	0.05	0.10	0.35	0.40
7	100	20	0.10	0.10	0.75	0.80
15	100	20	0.05	0.10	0.70	0.75
25	100	20	0.05	0.10	0.70	0.75

FCOHb - micromodes

Bias:

*F*COHb			ABL835/25				
*c*tHb (g/dL)	sO_2 (%)	*F*COHb (%)	S95	C95	S85	C55	C35
15	100	0	0.10	0.10	0.12	0.08	0.08
7	100	20	N/A	N/A	N/A	N/A	N/A
15	100	20	N/A	N/A	N/A	N/A	N/A
25	100	20	N/A	N/A	N/A	N/A	N/A

Continued on next page

Performance test results - oximetry, *Continued*

_F_COHb – micromodes *(continued)*

Bias:

***F*COHb**			**ABL830/20**		
***c*tHb (g/dL)**	***s*O_2 (%)**	***F*COHb (%)**	**FM***	**C55**	**C35**
15	100	0	–0.02	0.08	0.08
7	100	20	N/A	N/A	N/A
15	100	20	N/A	N/A	N/A
25	100	20	N/A	N/A	N/A

* FM = FLEXMODE (no message)

Imprecision:

***c*tHb (g/dL)**	***s*O_2 (%)**	***F*COHb (%)**	**S_0**	**S_D**	**S_{ABL}**	**S_X**
15	100	0	0.05	0.10	0.35	0.40
7	100	20	0.10	0.10	0.75	0.80
15	100	20	0.05	0.10	0.70	0.75
25	100	20	0.05	0.10	0.70	0.75

_F_MetHb - macromodes

Bias:

***F*MetHb**			**ABL835/25**		**ABL830/20**
***c*tHb (g/dL)**	***s*O_2 (%)**	***F*MetHb (%)**	**S195**	**FM***	**S85**
15	100	0	0.01	–0.03	0.06
15	100	20	N/A	0.10	N/A

* FM = FLEXMODE (no message)

Imprecision:

***c*tHb (g/dL)**	***s*O_2 (%)**	***F*MetHb (%)**	**S_0**	**S_D**	**S_{ABL}**	**S_X**
15	100	0	0.10	0.10	0.25	0.30
15	100	20	0.05	0.10	0.35	0.40

Continued on next page

Performance test results - oximetry, *Continued*

FMetHb micromodes

Bias:

FMetHb			ABL835/25				
ctHb (g/dL)	sO_2 (%)	FMetHb (%)	S95	C95	S85	C55	C35
15	100	0	0.13	0.14	0.06	0.16	0.14
7	100	20	N/A	N/A	N/A	N/A	N/A
15	100	20	N/A	N/A	N/A	N/A	N/A
25	100	20	N/A	N/A	N/A	N/A	N/A

FMetHb			ABL830/20		
ctHb (g/dL)	sO_2 (%)	FMetHb (%)	FM*	C55	C35
15	100	0	0.13	0.16	0.14
7	100	20	N/A	N/A	N/A
15	100	20	N/A	N/A	N/A
25	100	20	N/A	N/A	N/A

* FM = FLEXMODE (no message)

Imprecision:

ctHb (g/dL)	sO_2 (%)	FMetHb(%)	S_0	S_D	S_{ABL}	S_X
15	100	0	0.10	0.10	0.25	0.30
15	100	20	0.05	0.10	0.35	0.40

FHHb - macromodes

Bias:

FHHb		ABL835/25		ABL830/20
FHHb (%)	ctHb (g/dL)	S195	FM*	S85
0	15	-0.01	0.08	–0.05

* FM = FLEXMODE (no message)

Imprecision:

FHHb (%)	ctHb (g/dL)	S_0	S_D	S_{ABL}	S_X
0	15	0.05	0.10	0.30	0.35

Continued on next page

Performance test results - oximetry, *Continued*

FHHb - micromodes

Bias:

*F*HHb		ABL835/25					ABL830/20		
*c*tHb (g/dL)	*F*HHb (%)	S95	C95	S85	C55	C35	FM*	C55	C35
15	0	0.09	N/A	N/A	0.15	0.10	N/A	N/A	0.10

* FM = FLEXMODE (no message)

Imprecision:

*c*tHb (g/dL)	*F*HHb (%)	S_0	S_D	S_{ABL}	S_X
15	0	0.05	0.10	0.30	0.35

FHbF – adult blood

Bias (macromodes):

*F*HbF		ABL835		ABL830
*F*HbF (%)	*c*tHb (g/dL)	S195	FM*	S85
0	10	3.3	3.3	3.3
0	15	5.5	5.5	5.5
0	20	5.6	5.6	5.6

* FM = FLEXMODE (no message)

Imprecision (macromodes):

*F*HbF (%)	*c*tHb (g/dL)	sO_2 (%)	S_0	S_D	S_{ABL}	S_X
0	10	100	4	4	5	8
0	15	100	2	3	7	8
0	20	100	2	2	10	11

Continued on next page

Performance test results - oximetry, *Continued*

FHbF – adult blood *(continued)*

Bias (micromodes):

FHbF		ABL835					ABL830		
ctHb (g/dL)	FHbF (%)	S95	C95	S85	C55	C35	FM*	C55	C35
10	0	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3
15	0	5.5	5.5	5.5	5.5	5.5	5.5	5.5	5.5
20	0	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6

* FM = FLEXMODE (no message)

Imprecision (micromodes):

ctHb (g/dL)	FHbF (%)	sO_2 (%)	S_0	S_D	S_{ABL}	S_X
10	0	100	4	4	5	8
15			2	3	5	**7**
20			**2**	**2**	10	11

NOTES: a, b.

FHbF – fetal blood

Bias (macromodes):

FHbF		ABL835		ABL830
FHbF (%)	ctHb (g/dL)	S195	FM*	
80	10	5.9	5.9	5.9
80	15	3.3	3.3	3.3
80	20	2.6	2.6	2.6

* FM = FLEXMODE (no message)

Imprecision (macromodes):

FHbF (%)	ctHb (g/dL)	sO_2 (%)	S_0	S_D	S_{ABL}	S_X
80	10	100	4	5	5	9
80	15	100	3	3	6	8
80	20	100	2	3	6	7

NOTES: a, b.

Continued on next page

Performance test results - oximetry, *Continued*

_F_HbF – fetal blood _(continued)_

Bias (micromodes):

***F*HbF**		**ABL835**					**ABL830**		
***c*tHb (g/dL)**	***F*HbF (%)**	**S95**	**C95**	**S85**	**C55**	**C35**	**FM***	**C55**	**C35**
10	80	5.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9
15	80	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3
20	80	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6

* FM = FLEXMODE (no message)

Imprecision (macromodes):

***F*HbF (%)**	***c*tHb (g/dL)**	***s*O$_2$ (%)**	**S_0**	**S_D**	**S_{ABL}**	**S_X**
80	10	100	4	5	6	9
	15		3	3	6	8
	20		2	3	6	7

NOTES: a, b.

Contribution to Imprecision Specifications from S7770

The following corrections should be geometrically added to S_{Inst} and S_X for the analyzer's wavelength calibrated with the S7770:

Parameter	**Mode**	**Level**	**Correction (percentage point)**
*c*tHb	Macromode	All	0
	Micromode	All	0
*s*O$_2$	All	*s*O$_2$ (100 %)	0.23
*F*O$_2$Hb	All	*F*O$_2$Hb (100 %)	0.15
*F*COHb	All	*F*COHb (20 % and 0 %)	0.40
*F*HHb	All	*F*HHb (0 %)	0.23

NOTES:

a. pH = 7.4 ± 0.1. *F*HbF is adjusted with the pH sensitivity to a nominal pH=7.4. For further details please refer to the *Interference Tests* section for oximetry parameters.

b. Specifications for imprecision are derived from worst-case values found during internal laboratory tests. 40 % relative is then added as a safety factor.

Performance test results - bilirubin

Explanation As the optical system is unchanged in the ABL800 FLEX analyzers compared to the ABL700 Series, the specifications for bilirubin have not been re-established.

Field test results The ABL735/30 performance specifications for bilirubin were made as a field test the purpose of which was to optimize bilirubin algorithm for neonatal blood samples.

For neonatal use: The bilirubin method has been evaluated on whole blood and plasma. The allowed analytical error is ± 10 % to satisfy average clinical requirements for bilirubin measurement [1,2,3,4,5]. This requirement is fulfilled for plasma. For whole blood the analytical error is slightly higher. The clinicians and clinical chemists have evaluated bilirubin measurement on whole blood, the conclusion being that the ABL735/30 has satisfactory performance and can substitute other bilirubin measuring methods.

For adult use: *Adult samples within reference range:*

The uncertainty in the bilirubin measurement on whole blood can, in some cases, exceed the level required to measure normal bilirubin levels for children older than 3 months and adults (bilirubin reference range 4-22 μmol/L). In these cases it is recommended to measure bilirubin on plasma or serum.

Adult samples with an increased bilirubin level:

Adult field tests were typically performed on samples with 80 % of the total bilirubin in the conjugated form. For these highly conjugated samples the field tests showed a negative bias of 7 % on both plasma and whole blood samples.

The patient samples represented typical variations in *c*tBil, *c*tHb, sO_2, pH and MCHC values.

A Hitachi calibrated with NIST SRM 916a standards was used as a reference. *c*tBil was measured in μmol/L. Each field test place had its own ABL735.

Continued on next page

Performance test results - bilirubin, *Continued*

Field test results *(continued)* The field test results are given below.

Pos.	Field test place	Type	N	Slope	Inter-cept µmol/L	R^2	S_{yx} µmol/L	Range µmol/L
1	A	Plasma, neonatal	46	1.026	0.0	0.9914	5.1	18 – 258
2	B		56	0.986	–1.3	0.9939	5.8	10 – 334
3	D		4	1.014	–1.4	0.9984	4.5	22 – 236
4	E		47	0.945	1.2	0.9937	5.1	4 – 253
5	D	Plasma, adult	16	0.950	–0.5	0.9977	5.2	18 – 313
6	B		59	0.924	1.4	0.9981	3.8	2 – 366
7	F		52	0.904	5.6	0.9932	12.0	4 – 635
			45 (a)	0.942	2.6	0.9941	5.3	4 – 300
8	A	Blood, neonatal	46	1.075	9.6	0.9661	10.7	18 – 258
9	B		100	1.057	–1.6	0.9819	12.0	3 – 297
10	D		32	1.000	–5.6	0.9715	14.4	3 – 254
11	C		52	0.993	–5.0	0.9790	11.3	6 – 309
12	E		47	1.019	–10.2	0.9827	9.5	4 – 253
13	D	Blood, adult	18	0.950	–6.8	0.9974	5.6	18 – 313
14	B		55	0.909	3.2	0.9974	4.6	2 – 366
15	F		25	0.939	4.9	0.9967	10.0	21 – 635

Regression table: Regression results from field tests. N = #samples, S_{yx} is standard deviation about regression line.

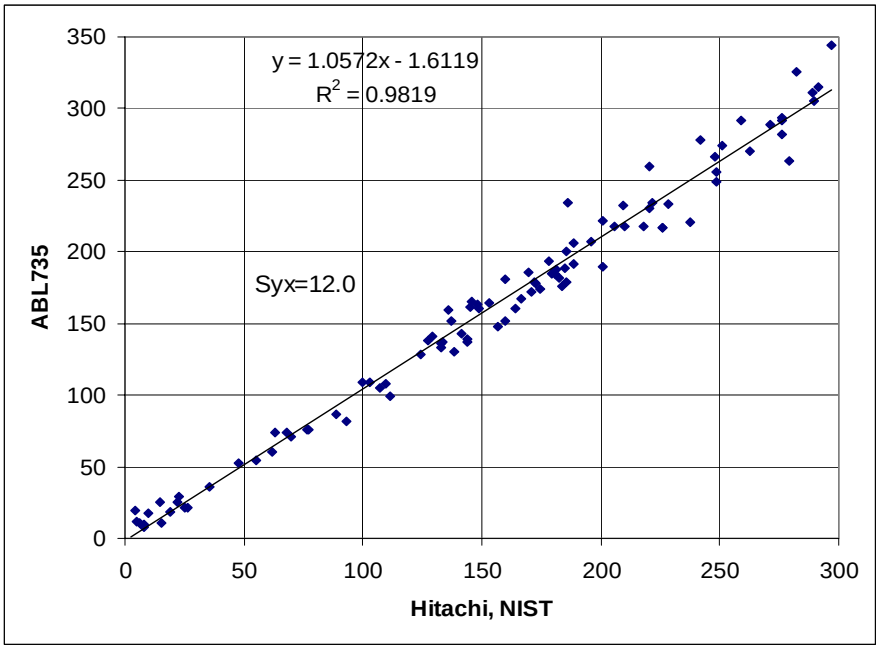
NOTE: (a) Datasubset excluding samples above 300 µmol/L.

Continued on next page

Performance test results - bilirubin, *Continued*

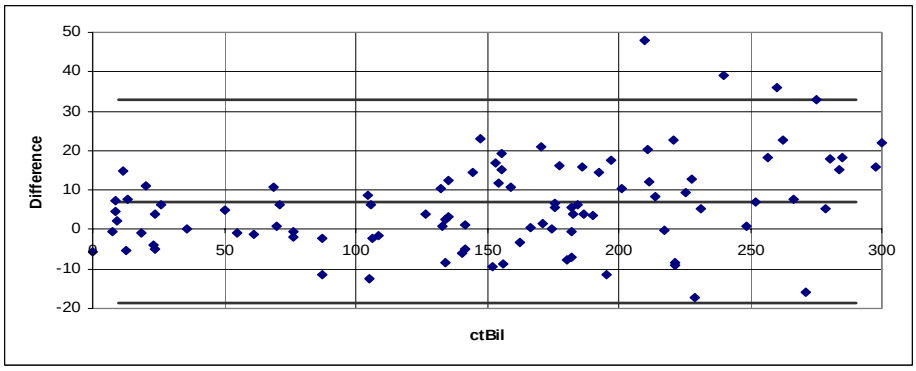
Regression and Bland-Altman plot

Data set position 9 from regression table.



Actual field test from a neonatal critical care hospital using whole blood. Values are in µmol/L.

The same data as above but depicted in a Bland-Altman plot below.



Lines indicate Mean, Mean+2SD and Mean-2SD. Values are in µmol/L.
Difference = ABL835 – Hitachi,NIST.

Continued on next page

Performance test results - bilirubin, *Continued*

Imprecision parameters

The following parameters are used to describe performance of the ABL835/30 analyzers for bilirubin measurements.

S_0: Repeatability. Measurement short time interval variation on the same sample.

S_D: Day-to-day variation

S_T: Patient-to-patient variation

S_I: ABL-to-ABL instrumental variation

S_{ABL}: ABL uncertainty. Variation including S_T, S_I and reference uncertainty

S_X: Reproducibility. Total variation including S_0, S_D and S_{ABL}

The above field test regression statistics S_{yx} include variations from S_0, S_D and S_T.

Performance test results for bilirubin

Macromodes: 195 µL and 85 µL from syringe and capillary:

*c*tBil (µmol/L)	*c*tHb (g/dL)	sO_2 (%)	S_0	S_D	S_T	S_I	S_{ABL}	S_X
≈0	Plasma		1.1	1.4	2.2	0.4	2.3	2.9
≈0	10	100	1.9	3.1	4.0	3.2	5.1	6.3
≈0	15	100	2.3	2.9	7.4	5.5	9.2	9.9
≈0	20	100	3.4	2.6	10.9	13.0	17.0	17.5
≈200	Plasma		1.3	1.7	3.1	4.7	7.4	7.7
≈200	10	100	2.4	4.4	5.8	6.6	10.1	11.3
≈200	15	100	2.6	3.7	8.5	9.3	13.6	14.4
≈200	20	100	4.2	5.0	12.1	15.4	20.4	21.4
≈400	Plasma		1.7	2.5	4.8	9.3	12.0	12.3
≈400	10	100	3.5	6.8	9.3	12.0	16.5	18.2
≈400	15	100	3.4	5.3	11.4	15.9	20.8	21.7
≈400	20	100	6.0	8.8	15.0	21.0	27.1	29.2

Notes: a, b, c

Continued on next page

Performance test results - bilirubin, *Continued*

Performance test results for bilirubin *(continued)*

Micromodes: 95 µL (syringe and capillary), 55 µL (capillary) and 35 µL (capillary):

***c*tBil (µmol/L)**	***c*tHb (g/dL)**	***s*O_2 (%)**	S_0	S_D	S_T	S_I	S_{ABL}	S_X
≈0	Plasma		1.1	1.4	2.2	0.4	2.3	2.9
≈0	10	100	1.9	3.1	4.0	3.2	5.1	6.3
≈0	15	100	2.3	2.9	7.4	5.5	9.2	9.9
≈0	20	100	3.4	2.6	10.9	13.0	17.0	17.5
≈200	Plasma		2.0	1.7	2.9	3.9	6.8	7.3
≈200	10	100	3.7	3.9	6.0	5.6	9.6	11.0
≈200	15	100	4.4	4.2	9.3	7.9	13.2	14.6
≈200	20	100	5.6	5.9	13.0	16.3	21.6	23.1
≈400	Plasma		3.5	2.5	4.3	7.8	10.6	11.4
≈400	10	100	6.7	5.7	9.9	9.6	15.2	17.6
≈400	15	100	7.9	6.7	13.5	12.5	19.7	22.3
≈400	20	100	9.5	10.9	17.8	23.6	30.7	33.9

Notes: a, b, c

NOTES:

a. Adult/fetal blood, pH = 7.4 ± 0.1, normal MCHC and albumin variation, Spiked with unconjugated bilirubin.

b. *c*tBil specification at level 200 µmol/L is interpolated from the measured specifications at 0 and 400 µmol/L.

c. The performance specifications apply to measurements performed using CLINITUBES with clot catchers and mixing wire from Radiometer.

References

1. Fraser CG. The application of theoretical goals based on biological variation data in proficiency testing. Arch Pathol Lab Med 1988; 112: 402-15.

2. Ehrmeyer SS, Laessig RH, Leinweber JE, Oryall JJ. 1990 Medicare/CLIA final rules for proficiency testing: minimum intralaboratory performance characteristics (CV and bias) needed to pass. Clin Chem 1990; 36, 10: 1736-40.

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Performance test results - bilirubin, *Continued*

References *(continued)*

3. Fraser CG, Petersen PH, Ricos C, Haeckel R. Proposed quality specifications for the imprecision and inaccuracy of analytical systems for clinical chemistry. Eur J CLin Chem Clin Biochem 1992; 30: 311-17.
4. Westgard JO, Seehafer JJ, Barry PL. Allowable imprecision for laboratory test based on clinical and analytical test outcome criteria. Clin Chem 1994; 40, 10: 1909-14.
5. Vanderline RE, Goodwine J, Koch D, Scheer D, Steindel S, Cembrowski G. Guidelines for providing quality stat laboratory services. 1987 Laboratory Quality Assurance Commitee.

Additional information about FLEXMODE

Introduction

With the FLEXMODE

- Varying sample volumes can be introduced to obtain a given parameter profile, and
- Two different parameter profiles can be reported for the same sample volume as the sample volume intervals overlap one another.

See the ABL800 FLEX Operator's Manual, chapter 4, page 4-3, for an overview of sample volume intervals and parameter profiles.

Most of the variation contributed by the difference in sample volume and parameter profile is included in the performance test results (bias, repeatability and imprecision) given in this chapter. Special tests with emphasis on extreme scenarios were conducted. The following scenarios were studied:

- Bias and repeatability for minimum and maximum sample volumes
- Bias and repeatability for parameter profiles with same sample volume.

These special studies were conducted for each of the individual parameter profiles. The parameters with the variation exceeding the Performance Characteristics are listed below.

Worst-case observations

Sample volume < 55 µL:

Parameter	Values	Bias	Repeatability
pH	7.15 7.40	0.015 0.013	0.005 0.005
pCO_2 (mmHg)	29 80	1.0 -2.9	0.9 2.6
pO_2 (mmHg)	130 230	3.0 -3.7	3.9 3.6

Interference tests

pH/blood gas The following interference results are found for the pH and blood gas electrodes:

Substance	Test Conc.	Interference on pO_2 Electrode
Halothane	3 %	5 % increased sensitivity

Intralipid (20 % solution) in a concentration greater than 4 % (the final Intralipid level being 0.8 %) will give interference on pH measurements.

Electrolytes The following interference results are found for the electrolyte electrodes:

Substance	Test Conc.	Interference on…			
		cK^+ (4 mmol/L level)	cNa^+ (150 mmol/L level)	cCa^{2+} (1.25 mmol/L level)	cCl^- (110 mmol/L level)
Li^+	4 mmol/L	0	0	0	
K^+	12 mmol/L		–1	–0.01	
Na^+	100 - 180 mmol/L	0.1 to –0.1			
NH_4^+	1 mmol/L	0	0		
Ca^{2+}	5 mmol/L		0		
Mg^{2+}	5 mmol/L	0	0	0.05	
Br^-	10 mmol/L				41
F^-	1 mmol/L				0
I^-	3.0 mmol/L				30-90
ClO_4^-	1.5 mmol/L				8-30
HCO_3^-	25-50 mmol/L				0.1 mmol/L Cl^- per mmol/L HCO_3^-
Lactate	10 mmol/L				0
Acetyl-salicylic acid	3.0 mmol/L				2

Continued on next page

Interference tests, *Continued*

Electrolytes *(continued)*

Substance	Test Conc.	Interference on…			
		***c*K$^+$ (4 mmol/L level)**	***c*Na$^+$ (150 mmol/L level)**	***c*Ca^{2+} (1.25 mmol/L level)**	***c*Cl$^-$ (110 mmol/L level)**
Ascorbic acid	1.0 mmol/L				0
pH ≤ 7.2	7.2	0	0	0.01	–1
pH ≥ 7.6	7.6	0	0	–0.01	1

Sulphide will give erroneously high *c*Cl$^-$ results.

Metabolites

The following interference results are found for the metabolite electrodes:

Substance	Test Conc. (mmol/L)	Interference on …	
		***c*Glucose (4.0 mmol/L level)**	***c*Lactate (1.5 mmol/L level)**
Acetoacetic acid	2	<| 0.1|	<| 0.1|
Acetylsalicylic acid	3	<| 0.1|	<| 0.1|
Ascorbic acid	2	<| 0.1|	<| 0.1|
Bilirubin (conjugated)	0.46	<| 0.1|	<| 0.1|
Bilirubin (unconjugated)	0.34	<| 0.1|	<| 0.1|
Chlorpromazine HCl	0.2	<| 0.1|	<| 0.1|
Citrate	50	–0.37	0.19
Creatinine	3	<| 0.1|	<| 0.1|
D-glucose	67		<| 0.1|
Dopamine HCl	1.0	<| 0.1|	<| 0.1|
EDTA	3	<| 0.1|	<| 0.1|
Ethanol	79	<| 0.1|	<| 0.1|
Fluoride	50	–0.36	<| 0.1|
Galactose	3.3	up to 1.88*	
Glucosamine	2	up to 1.06*	

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Interference tests, *Continued*

Metabolites *(continued)*

Substance	Test Conc. (mmol/L)	Interference on …	
		***c*Glucose (4.0 mmol/L level)**	***c*Lactate (1.5 mmol/L level)**
Glycolic acid	1	<| 0.1|	Interference
Heparin	8000 IU/dL	<| 0.1|	<| 0.1|
Ibuprofen	2	<| 0.1|	<| 0.1|
Intralipid		<| 0.1|	<| 0.1|
Lactic acid	12	<| 0.1|	
Maltose	5	up to 0.4*	
Mannose	1	up to 0.4*	
Oxalate	90	–0.47	0.14
Paracetamol-4-acetamidophenol	2	<| 0.1|	<| 0.1|
Pyruvate	2	<| 0.1|	<| 0.1|
Salicylic acid	4	<| 0.1|	<| 0.1|
Thiocyanic acid	24	Interference	Interference
Urea	84	<| 0.1|	<| 0.1|
Uric acid	1.5	<| 0.1|	<| 0.1|
Xylose	1	up to 0.34*	

* Values determined at *c*Glu = 0 mmol/L. Interference at *c*Glu 4.0 mmol/L is expected to be the same.

Hematocrit %	Δ*c*Lactate % at :	
	5 mmol/L level	15 mmol/L level
0	0.7 %	0.7 %
45	0.0 %	0.0 %
60	–0.5 %	–2.0 %
75	–2.2 %	–5.0 %

Continued on next page

Interference tests, *Continued*

Oximetry parameters

The substances against which the oximetry parameters (*c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, *F*HbF) and *c*tBil were tested for interference are given in the table below:

(SAT100 blood reference test sample: *c*tHb=15 g/dL, sO_2=100 %, *F*COHb=0.7 %, *F*MetHb=0.5 %, *c*tBil=0, pH=7.4. Parameter sensitivity from the influence on the absorbance spectrum from various substances.)

Substance	Test conc.	Change on …							
		***c*tHb (g/dL)**	**sO_2 (%)**	**FO_2Hb (%)**	***F*COHb (%)**	***F*MetHb (%)**	***F*HHb (%)**	***F*HbF *(%)***	***c*tBil *(μmol/L)***
Intralipid	4 Vol % [e]	–0.5	0.1	–1.3	0.5	0.9	–0.1	11	0 4 [b]
Intralipid	2 Vol % [f]	–0.4	0.1	–0.3	0.3	0.1	–0.1	11	7 2 [b]
HbF [a), c)]	20 %	–0.02	1.17	0.04	0.73	0.37	–1.14	0	–14
*S*Hb	10 %	0	–1.0	0.9	–0.1	0.1	–0.9	Not tested	
pH	7.1 7.9	–0.5 –0.6	–0.5 0.6	–0.2 –0.5	–0.4 1.0	0.1 0.1	0.5 –0.6	–19 13	0 –5
Cardio Green [c)]	5 mg/L	–0.16	0.29	1.14	0.07	–0.93	–0.29	–5	–20
Evans Blue [c)]	5 mg/L	–0.04	0.14	0.28	–0.20	–0.20	0.14	–5	5
Betacarotene in plasma [c)]	3.7 μmol/L	0.0	–0.02	0.03	–0.01	–0.04	0.02	0.1	–0.2
Patent Blue V [c)]	10 mg/L	–0.16	0.39	0.86	–0.47	0.00	–0.38	–21	38
Methylene Blue [c)]	30 mg/L	–0.7	–3.4	5.6	–3.0	–6.2	3.6	–37	–25
HiCN [c)]	0.11 mmol/L	0.26	–1.5	–3.0	–0.5	0.5	1.5	24	47
MCHC [c), d)] newborn range	320 g/L 350 g/L	No interference							–12 17
Sedimentation rate	100 arb. Units	≤ ± 0.5	No interference						Not tested

Notes:

a) If function “Correction for HbF levels less than 20 %” is activated, the change is 0 for all parameters.

b) Plasma sample.

c) Calculated value from mathematical superposition of measured pure interference spectrum on measured reference spectrum.

d) *c*tBil = 400 μmol/L.

e) Intralipid (20 % solution) at 4 Vol % gives final test level of 0.8 %.

f) Intralipid (20 % solution) at 2 Vol % gives final test level of 0.4 %.

There is no interference from fetal hemoglobin (HbF) when the analyzer applies HbF correction.
There is no interference from bilirubin (conjugated/unconjugated) up to 1000 μmol/L.

Continued on next page

Interference tests, *Continued*

Contribution to imprecision specifications from HbF correction

The process of HbF correction introduces additional noise compared to measurement on adult samples. The following tables list the extra contribution which must be added geometrically to the imprecision specifications for adult samples in order to obtain the imprecision specifications for fetal samples (also for adult samples if function "Correction for HbF levels less than 20 %" is activated).

$S_{fetal} = \sqrt{S_{adult}^2 + S_{HbF}^2}$; geometrical addition of imprecision

where S_{fetal} is the calculated fetal imprecision; S_{adult} is the corresponding adult imprecision; S_{HbF} is the extra contribution from HbF correction which is listed in the following tables.

HbF correction contribution to 10 g/dL SAT100 fetal sample:

	S_0	S_D	S_{ABL}	S_X
sO_2 %	0.15	0.20	0.19	0.31
*F*HHb %	0.14	0.19	0.19	0.30
FO_2Hb %	0.01	0.01	0.01	0.01
*F*COHb %	0.09	0.13	0.12	0.20
*F*MetHb %	0.05	0.06	0.06	0.10

HbF correction contribution to 15 g/dL SAT100 fetal sample:

	S_0	S_D	S_{ABL}	S_X
sO_2 %	0.09	0.12	0.29	0.33
*F*HHb %	0.09	0.11	0.28	0.32
FO_2Hb %	0.00	0.00	0.01	0.01
*F*COHb %	0.06	0.07	0.18	0.21
*F*MetHb %	0.03	0.04	0.09	0.11

HbF correction contribution to 20 g/dL SAT100 fetal sample:

	S_0	S_D	S_{ABL}	S_X
sO_2 %	0.09	0.12	0.20	0.25
*F*HHb %	0.09	0.11	0.19	0.25
FO_2Hb %	0.00	0.00	0.01	0.01
*F*COHb %	0.06	0.07	0.13	0.16
*F*MetHb %	0.03	0.04	0.06	0.08

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Interference tests, *Continued*

FHbF sensitivity for pH changes

FHbF is sensitive to pH deviations from the nominal value of pH = 7.4. If pH is converted into $c\mathrm{H}^+$ (hydrogen ion concentration), the relationship between the changes in $c\mathrm{H}^+$ and FHbF is linear as seen from the following equation:

$$\Delta F\mathrm{HbF} = -0.48\ \%/(\mathrm{nmol/L}) \times (c\mathrm{H}^+ - 40\ \mathrm{nmol/L})$$

where pH = 7.4 corresponds to $c\mathrm{H}^+ = 40$ nmol/L.

EXAMPLE: pH = 7.25 corresponds to $c\mathrm{H}^+ = 56$ nmol/L. Then:

$$\Delta F\mathrm{HbF} = -0.48 \times (56 - 40) = -7.7\ \%.$$

ctBil sensitivity for MCHC variations

MCHC (Mean Corpuscular Hemoglobin Concentration) is used to estimate hematocrit, Hct, which is used in the ctBil measurement. MCHC is an average Hb concentration in the red blood cell (RBC). If the RBC volume decreases, MCHC increases. If a RBC has iron deficit, MCHC decreases.

Hct is determined from ctHb as follows:

$$\mathrm{Hct} = \frac{c\mathrm{tHb}}{\mathrm{MCHC}}$$

A standard value of 332 g/L is assumed for MCHC which gives

Hct = ctHb x 0.0301 if the unit for ctHb is g/dL.

MCHC can, however, deviate from this standard value as illustrated in the following table (see the next page).

Erythrocytometric values given for “apparently healthy” white and black subjects of different ages are taken from: “Geigy Scientific Tables, Physical Chemistry, Composition of Blood, Hematology, Somametric Data”, CIBA-GEIGY, 1984; 3, 207.

Continued on next page

Interference tests, *Continued*

ctBil sensitivity for MCHC variations *(continued)*

Subjects	Age	Hct mean	Hct 95 % range	MCHC mean, g/L	MCHC 95 % range, g/L
Men	Adults	0.47	0.39 - 0.55	340	310 - 370
Women	Adults	0.42	0.36 - 0.48	330	300 - 360
Boys	Newborn	0.59	0.53-0.65	330	320-340
	1 month	0.50	0.44-0.56	320	310-330
	3 months	0.45	0.39-0.52	330	320-340
	6 months	0.46	0.39-0.51	300	290-310
	9 months	0.45	0.39-0.52	280	270-300
	1 year	0.41	0.37-0.45	290	280-300
	2 years	0.40	0.36-0.47	300	280-310
	4 years	0.37	0.30-0.44	280	270-290
	8 years	0.41	0.37-0.45	290	280-300
	14 years	0.41	0.36-0.46	300	290-310
Girls	Newborn	0.58	0.51-0.65	340	330-350
	1 month	0.49	0.42-0.56	320	310-330
	3 months	0.44	0.39-0.51	330	320-340
	6 months	0.44	0.39-0.50	320	310-330
	9 months	0.43	0.37-0.50	300	290-310
	1 year	0.43	0.37-0.49	300	290-310
	2 years	0.43	0.36-0.50	300	290-310
	4 years	0.43	0.36-0.51	280	270-290
	8 years	0.40	0.36-0.46	280	270-290
	14 years	0.40	0.36-0.47	290	280-300

If ΔMCHC is defined as ΔMCHC = 332 g/L – MCHC, then the contribution to the relative error on the *c*tBil measurement is as follows:

$$\frac{\Delta c\text{tBil}}{c\text{tBil}} = -\frac{\text{Hct}}{1-\text{Hct}} \times \frac{\Delta\text{MCHC}}{\text{MCHC}}$$

A worst-case example, using 95 % confidence values:

A newborn girl with Hct = 0.58, MCHC = 350 g/L and ctBil = 400 µmol/L. *c*tHb may be derived as Hct x MCHC = 0.58 x 350 g/L = 20.3 g/dL (reference range is 18.0 – 21.0 g/dL).

Continued on next page

Interference tests, *Continued*

ctBil sensitivity for MCHC variations *(continued)*

$$\frac{\Delta c\text{tBil}}{c\text{tBil}} = -\frac{0.58}{1-0.58} \times \frac{-18}{350} = +0.071$$ And Δ*c*tBil = 0.071 x 400 = 28 µmol/L.

If the reference value for Hct is known, it is possible to correct the displayed *c*tBil value, using the following equation:

$$c\text{tBil(corrected)} = c\text{tBil(displayed)} \times \frac{1 - c\text{tHb(displayed)} \times 0.0301}{1 - \text{Hct(reference)}}$$

*c*tHb is measured in g/dL.

ctBil sensitivity for pH changes

*c*tBil is slightly sensitive to pH deviations from the nominal value of pH = 7.4.

The following table shows the changes in Δ*c*tBil compared to the value at pH = 7.4.

Sample Type	***c*tHb g/dL**	**Nominal ctBil µmol/L**	**Δ*c*tBil (7.4→7.1) µmol/L**	**Δ*c*tBil (7.4→7.9) µmol/L**
Adult/fetal plasma	0	0	3	0
Adult blood, sO_2 = 100 %	15	0	0	–5
Fetal blood, sO_2 = 100 %	15	0	–13	4
Adult/fetal plasma spiked with unconjugated bilirubin	0	400	–2	–1
Adult/fetal plasma spiked with conjugated bilirubin	0	400	9	–11
Adult blood spiked with unconjugated bilirubin, sO_2 = 100 %	15	400	10	–26
Fetal blood spiked with unconjugated bilirubin, sO_2 = 100 %	15	400	–4	–16
Adult blood spiked with conjugated bilirubin, sO_2 = 100 %	15	400	14	–35
Fetal blood spiked with conjugated bilirubin, sO_2 = 100 %	15	400	0	–26

References

List of references

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6. Parameters

Overview

Introduction The measured, input, and derived parameters are described in this chapter.

Contents This chapter contains the following topics.

General information

The Deep Picture™

The Deep Picture developed by Radiometer [1], (visit our website www.deep-picture.com) expands traditional pH and blood gas analysis by evaluating the capability of arterial blood to carry sufficient oxygen to tissues and to release it. It simplifies interpretation by dividing the process into three stages:

Stage	Description
Oxygen Uptake	Oxygen uptake in the lungs indicates whether the pulmonary gas exchange is efficient enough to oxygenate arterial blood. The uptake of oxygen in the lungs can be described by parameters in combination, primarily the arterial oxygen tension (pO_2(a)), fraction of O_2 in dry inspired air (FO_2(I)), and shunt fraction of perfused blood ($\dot{Q}_s/\dot{Q}_t$) However other parameters may also be used, such as the difference in alveolar air and arterial blood oxygen tension (pO_2(A-a)).
Oxygen Transport	Oxygen transport reveals whether arterial blood contains sufficient oxygen. The oxygen concentration of arterial blood (ctO_2(a)) also termed oxygen content is determined by the concentration of total hemoglobin (*c*tHb(a)), the fraction of oxygenated hemoglobin (FO_2Hb(a)), and the arterial oxygen tension (pO_2(a)). Other parameters which should be known are the oxygen saturation (sO_2(a)) and the fractions of dyshemoglobins (*F*COHb(a) and *F*MetHb(a)).
Oxygen Release	Oxygen release describes the ability of arterial blood to release oxygen to the tissues. The release of oxygen from capillaries to tissues is determined by the oxygen tension gradient between the two. This release of oxygen is also influenced by the hemoglobin-oxygen affinity, which is indicated by the oxygen tension at 50 % saturation, *p*50.

Symbols

The symbols for the parameters are based on the principles described by Wandrup [2]. Each symbol consists of three parts, described below:

1. *Quantity*	A symbol in italics describing the quantity	*p* for pressure *c* for concentration *F* for fraction *V* for volume etc.
2. Component	An abbreviation of the component name	O_2 for oxygen CO_2 for carbon dioxide COHb for carboxyhemoglobin, etc.

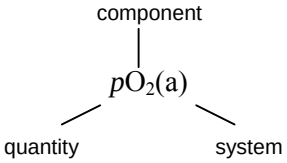
Continued on next page

General information, *Continued*

Symbols *(continued)*

3. (System)	Specification of the system	B for blood P for plasma a for arterial blood $\bar{v}$ for mixed venous blood A for alveolar air *T* for patient temperature

Example:



The parameters are listed by symbol in three groups: measured, input, and derived.

Ranges and limits

The following ranges are used:

Range	Description
Measuring	The *measuring range* for a parameter is the range within which the analyzer is physically capable of measuring. The measuring range corresponds to the "range of indication" as defined in the "International vocabulary of basic and general terms in metrology (VIM).
Reportable	Is user-defined; is equal to or narrower than the measuring range. Can be selected for all measured and derived parameters.
Reference	"Reference ranges are valuable guidelines for the clinician, but they should not be regarded as absolute indicators of health and disease. Reference ranges should be used with caution since values for 'healthy' individuals often overlap significantly with values for persons afflicted with disease. In addition, laboratory values may vary significantly due to methodological differences and mode of standardization" [10]. Ref. 10 has been the source for the reference ranges given in this section. In some cases the values are taken from other sources marked by their reference number. When possible the reference ranges for arterial blood have been listed. Reference ranges must be used with caution as they depend on a number of factors, such as sex, age, and normal physiological condition.

Critical limits are user-defined and can be entered into the analyzer software - see *Chapter 3: Setup Programs (section Analysis Setup)* in the *Operator's Manual*.

Continued on next page

General information, *Continued*

Derived parameters

Derived parameters are calculated according to the equations stated.

If…	Then…
the required measured or input values are unknown	default values are used, unless a measured parameter does not have a value or is outside the measuring range.
all values are known	the derived parameter is designated *calculated* and a 'c' is added to the result.
a default value is used	the derived parameter is designated *estimated* and an 'e' is added to the result.

If one or more default values have been used in the calculation, the result may deviate significantly from the true value. The deviation on "estimated" oxygen status parameters may become particularly significant if default values are used instead of measured blood oximetry data.

In some cases however, the default value is not accepted as the input for the calculation. This is because the actual values of the missing parameter may deviate significantly from the default value, thus making the estimation clinically inappropriate. If sO_2 cannot be measured due to severe errors, it will be calculated.

Measured parameters

Some of the listed parameters are measured, depending on the analyzer configuration. In these cases the equation given only applies if that parameter is *not* directly measured by the analyzer.

Sample type

Unless otherwise stated, a parameter will be calculated or estimated irrespective of the choice on the **Patient Identification** screen: 'Arterial', 'Capillary', 'Venous', 'Mixed venous', or 'Not specified'. Some parameters however are defined for arterial samples only; they will be calculated only for sample types entered as 'Arterial' or 'Capillary'.
The symbol for system (blood (B) or plasma (P)) is not stated in the equations unless it is important for the calculation.

Units

The units given for each parameter refer to the units available on the analyzer for that parameter.

Default values

The default values are listed in *Default Values* at the end of this chapter.

Measured parameters

General information

The following is the used:

m =	male
f =	female
Reference range	for adult's arterial blood
Reference:	[10] Tietz NW, Logan NM. Reference ranges. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders Company 1987: 944-75.
	(unless otherwise specified)

pH

Definition	Indicates the acidity or alkalinity of the sample.
Unit	-
Measuring range	6.300-8.000
Reference range	7.35-7.45 (m, f)

***c*H$^+$**

Definition	Concentration of hydrogen ions in blood.
Unit	nmol/L
Measuring range	10.0-501
Reference range	35.5-44.7 (m, f)

***p*CO$_2$**

Is used both for blood and expired air samples.

Definition	Partial pressure (or tension) of carbon dioxide in blood. High and low *p*CO$_2$ values of arterial blood indicate blood hypercapnia and hypocapnia respectively.
Unit	mmHg; kPa; torr

Continued on next page

Measured parameters, *Continued*

p*CO$_2$ *(continued)	Measuring range	mmHg; torr: 5.0-250
		kPa: 0.67-33.3
	Reference range	mmHg: 35– 48 (m); 32-45 (f)
		kPa: 4.67-6.40 (m); 4.27-6.00 (f)
	Conversion of units	p (kPa) = $0.133322 \times p(\text{mmHg}) = 0.133322 \times p$ (torr)
		p (mmHg) = p (torr) = $7.500638 \times p$ (kPa)
***p*O$_2$**	Is used for both blood and expired air samples.	
	Definition	Partial pressure (or tension) of oxygen in blood.
		High and low pO_2 values of arterial blood indicate blood hyperoxia and hypoxia, respectively.
	Unit	mmHg; kPa; torr
	Measuring range	mmHg; torr: 0.0-800
		kPa: 0.00-107
	Reference range	mmHg: 83-108 (m, f)
		kPa: 11.07-14.40 (m, f)
	Conversion of units	p (kPa) = $0.133322 \times p(\text{mmHg}) = 0.133322 \times p$ (torr)
		p (mmHg) = p (torr) = $7.500638 \times p$ (kPa)
Baro	Definition	Ambient barometric pressure (p(amb)).
	Unit	mmHg; kPa; torr
	Measuring range	mmHg; torr: 450-800
		kPa: 60.0-106.7
	Reference range	-
	Conversion of units	p (kPa) = $0.133322 \times p(\text{mmHg}) = 0.133322 \times p$ (torr)
		p (mmHg) = p (torr) = $7.500638 \times p$ (kPa)

Continued on next page

Measured parameters, *Continued*

***c*tHb**	Definition	Concentration of total hemoglobin in blood. Total hemoglobin includes all types of hemoglobin: deoxy-, oxy-, carboxy-, met-.
	Unit	g/dL; g/L; mmol/L
	Measuring range	g/dL: 0.00- 27.7 g/L: 0.0-277 mmol/L: 0.00-17.2
	Reference range	g/dL: 13.5-17.5 (m); 12.0-16.0 (f) g/L: 135-175 (m); 120-160 (f) mmol/L: 8.4-10.9 (m); 7.4-9.9 (f)
	Conversion of units	*c*tHb (g/dL) = 1.61140 × *c*tHb (mmol/L); *c*tHb (g/L) = 16.1140 × *c*tHb (mmol/L); *c*tHb (mmol/L) = 0.62058 × *c*tHb (g/dL) = 0.062058 × *c*tHb (g/L)
	Default value:	9.3087 mmol/L, (15.0 g/dL or 150 g/L)
***s*O$_2$**	Can also be calculated.	
	Definition	Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins.
	Unit	%; fraction
	Measuring range	%: 0.0-100.0 Fraction: 0.000-1.000
	Reference range	%: 95-99 (m, f) Fraction: 0.95-0.99 (m, f)

Continued on next page

Measured parameters, *Continued*

sO_2 *(continued)*

Reference: Siggaard-Andersen O, Wimberley PD, Fogh-Andersen N, Gøthgen IH. Arterial oxygen status determined with routine pH/blood gas equipment and multi-wavelength hemoximetry: reference values, precision and accuracy. Scand J Clin Lab Invest 1990; 50, Suppl 203: 57-66. Available as AS106.

Equation: The ODC is determined as described in equation for *Oxyhemoglobin Dissociation Curve* (points I and III).

$$sO_2 = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$$

where

S = ODC(P,A,*T*)

$$P = pO_2 + \frac{pO_2 \times FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}$$

A = a

T = 37.0 °C

FO_2Hb Can also be calculated.

Definition: Fraction of oxyhemoglobin in total hemoglobin in blood.

Unit: %; fraction

Measuring range: %: 0.0-100.0

Fraction: 0.000-1.000

Reference range: %: 94-98 (m, f)

Fraction: 0.94-0.98 (m, f)

Equation: $FO_2Hb = sO_2 \times (1 - FCOHb - FMetHb)$

If sO_2 is not measured, it will be calculated.

If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.

Continued on next page

Measured parameters, *Continued*

***F*COHb**	Definition	Fraction of carboxyhemoglobin in total hemo-globin in blood.
	Unit	%; fraction
	Measuring range	%: 0.0-100.0
		Fraction: 0.000-1.000
	Reference range	%: 0.5-1.5 (m, f)
		Fraction: 0.005-0.015 (m, f)
	Default value	0.004 (0.4 %)
***F*MetHb**	Definition	Fraction of methemoglobin in total hemoglobin in blood.
	Unit	%; fraction
	Measuring range	%: 0.0-100.0
		Fraction: 0.000-1.000
	Reference range	%: 0.0-1.5 (m, f)
		Fraction: 0.00-0.015 (m, f)
	Default value	0.004 (0.4 %)
***F*HHb**	Can also be calculated.	
	Definition	Fraction of deoxyhemoglobin in total hemoglobin in blood.
		Deoxyhemoglobin is the part of total hemoglobin which can bind oxygen forming oxyhemoglobin. It is also termed reduced hemoglobin, RHb.
	Unit	%; fraction
	Measuring range	%: 0.0-100.0
		Fraction: 0.000-1.000

Continued on next page

Measured parameters, *Continued*

FHHb ***(continued)***	Equation	$FHHb = 1 - sO_2 \times (1 - FCOHb - FMetHb) - FCOHb - - FMetHb$ If sO_2 is not measured, it will be calculated from equation 39. If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.
***F*HbF**	Definition	Fraction of fetal hemoglobin in total hemoglobin in blood
	Unit	%; fraction
	Measuring range	%: 0-100 Fraction: 0.00-1.00
	Reference range (neonates)	%: ≈80 (m, f) Fraction: ≈0.80 (m, f)
***c*K$^+$**	Definition	Concentration of potassium ions in plasma.
	Unit	mmol/L; meq/L
	Measuring range	mmol/L; meq/L: 0.5-25.0
	Reference range	m, f: 3.4 – 4.5 mmol/L
	Conversion of units	mmol/L = meq/L
***c*Na$^+$**	Definition	Concentration of sodium ions in plasma.
	Unit	mmol/L; meq/L
	Measuring range	mmol/L; meq/L: 7-350
	Reference range	m, f; 136 – 146 mmol/L
	Conversion of units	mmol/L = meq/L

Continued on next page

Measured parameters, *Continued*

***c*Ca^{2+}**	Definition	Concentration of calcium ions in plasma.
	Unit	mmol/L; meq/L; mg/dL
	Measuring range	mmol/L: 0.20-9.99 meq/L: 0.40-19.98 mg/dL: 0.80-40.04
	Reference range	m, f: 1.15-1.29 mmol/L; 2.30-2.58 meq/L
	Conversion of units	meq/L = 2 mmol/L mg/dL = 4.008 mmol/L
	Reference	Siggaard-Andersen O, Thode J, Wandrup JH. The concentration of free calcium ions in the blood plasma ionized calcium. In: Siggaard-Andersen O, ed. Proceedings of the IFCC expert panel on pH and blood gases held at Herlev Hospital 1980, Copenhagen: Radiometer Medical A/S, 1981: 163-90. Available as AS79.
***c*Cl-**	Definition	Concentration of chloride ions in plasma.
	Unit	mmol/L; meq/L
	Measuring range	mmol/L; meq/L: 7 – 350
	Reference range	98 – 106 mmol/L (m, f)
	Conversion of units	mmol/L = meq/L
***c*Glu**	Definition	Concentration of glucose in plasma.
	Unit	mmol/L; mg/dL
	Measuring range	mmol/L: 0.0-60 mg/dL: 0-1081
	Reference range	m, f: 3.89 - 5.83 mmol/L; 70-105 mg/dL
	Conversion of units	*c*Glucose (mg/dL) = 18.016 × *c*Glucose (mmol/L) *c*Glucose (mmol/L) = 0.055506 × *c*Glucose (mg/dL)

Continued on next page

Measured parameters, *Continued*

***c*Lac**	Definition	Concentration of lactate in plasma.
	Unit	mmol/L; meq/L; mg/dL
	Measuring range	mmol/L: 0.0-30 meq/L: 0.0-30 mg/dL: 0-270
	Reference range	m, f: 0.5 - 1.6 mmol/L; 4.5 - 14.4 mg/dL
	Conversion of units	*c*Lactate (mg/dL) = 9.008 × *c*Lactate (mmol/L) *c*Lactate (mmol/L) = 0.11101 × *c*Lactate (mg/dL) (conversion based on the molecular weight of lactic acid)
***c*tBil**	Definition	Concentration of total bilirubin in plasma. Total bilirubin includes its two forms: conjugated and unconjugated.
	Unit	µmol/L; mg/dL; mg/L
	Measuring range	µmol/L: 0-1000 mg/dL: 0.0-58.5 mg/L: 0-585
	Reference range	See the table on the next page.
	Conversion of units	*c*tBil (µmol/L) = 17.1 × *c*tBil (mg/dL) *c*tBil (µmol/L) = 1.71 × *c*tBil (mg/L) *c*tBil (mg/dL) = 0.0585 × *c*tBil (µmol/L) *c*tBil (mg/L) = 0.585 × *c*tBil (µmol/L)

Continued on next page

Measured parameters, *Continued*

c*tBil *(continued) The reference ranges are as follows:

Age	***c*tBil**
≤24 hrs, premature	103 – 205 µmol/L 1.0 – 8.0 mg/dL 10 – 80 mg/L
≤24 hrs, full-term	34 – 103 µmol/L 2.0 – 6.0 mg/dL 20 – 60 mg/L
≤48 hrs, premature	103 – 205 µmol/L 6 – 12 mg/dL 60 – 120 mg/L
≤48 hrs	103 – 171 µmol/L 6 – 10 mg/dL 60 – 100 mg/L
3-5 days, premature	171 – 239 µmol/L 10 – 14 mg/dL 100 – 140 mg/L
3-5 days, full-term	68 – 137 µmol/L 4 – 8 mg/dL 40 – 80 mg/L
>1 month	3.4 – 17 µmol/L 0.2 – 1.0 mg/dL 2 – 10 mg/L

Input parameters

Definition Input parameters are the parameters keyed in by the operator on the Patient Identification screen or transferred from an interfaced database.

All input parameters are given in this section.

T

Definition	Patient temperature
Unit	°C; °F
Measuring range	°C: 15.0-45.0 °F: 59-113
Conversion	$T\,°\mathrm{F} = \frac{9}{5}T\ {}^{o}C + 32$; $T\,°\mathrm{C} = \frac{5}{9}(T\ {}^{o}F - 32)$

***F*O$_2$(I)**

Definition	Fraction of oxygen in dry inspired air.
Unit	%; fraction
Input range	%: 0-100 fraction: 0.000-1.000
Reference range	35.5-44.7 (m, f)

***c*tHb** Is used in the ABL800/05 FLEX.

Definition	Concentration of total hemoglobin in blood.
Input range /Unit	g/dL: 0.0-33.0 g/L: 0-330 mmol/L: 0.0-20.5
Conversion	*c*tHb (g/dL) = 1.61140 × *c*tHb (mmol/L); *c*tHb (g/L) = 16.1140 × *c*tHb (mmol/L); *c*tHb (mmol/L) = 0.62058 × *c*tHb (g/dL) = 0.062058 × *c*tHb (g/L)

RQ

Definition	Respiratory quotient, ratio between the CO_2 production and the O_2 consumption.
Input range	0.00 - 2.00

Continued on next page

Input parameters, *Continued*

$pO_2(\bar{v})$	Definition	Oxygen tension of mixed venous blood.
	Input range/Unit	mmHg; torr: 0.0-750.0 kPa: 0.00-100
	Conversion	p(kPa) =0.133322 × p(mmHg) p(mmHg) = 7.500638 × p(kPa)
$sO_2(\bar{v})$	Definition	Oxygen saturation of mixed venous blood.
	Input range/Unit	%: 0.0 – 100.0 fraction: 0.000 – 1.000
$\dot{Q}_t$	Definition	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. Also termed CO or C.O.
	Input range/Unit	0.0 - 1000.0 L/min
$\dot{V}O_2$	Definition	Oxygen consumption; total amount of oxygen utilized by the whole organism per unit of time.
	Input range/Unit	mL/min: 0 - xxxx mmol/min: 0.0 - xxx.x
	Conversion	(mmol/L)min = (mL/dLmin)/22.41
VCO	Definition	Volume of carbon monoxide added to the patient for measurement and calculation of V(B) [5].
	Input range/Unit	0.0 - 1000.0 mL

Fortsættes på næste side

Input parameters, *Continued*

p50(st) Can also be a derived parameter.

Definition	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood at standard conditions: temperature = 37 °C pH = 7.40 pCO_2 = 5.33 kPa *F*COHb, *F*MetHb, *F*HbF set to 0 p50(st) may however vary due to variations in 2,3-DPG concentration or to the presence of abnormal hemoglobins.
Input range/Unit	mmHg; torr: 0.01 - 100.00 kPa: 0.001 - 13.332
Conversion	p(kPa) =0.133322 × p(mmHg; torr) p(mmHg; torr) = 7.500638 × p(kPa)

FCOHb(1)

Definition	The fraction of COHb measured before the CO-injection.
Input range/Unit	%: 0.0 - 100.0 fraction: 0.000 - 1.000

FCOHb(2)

Definition	The fraction of COHb measured after the CO-injection.
Input range/Unit	%: 0.0 - 100.0 fraction: 0.000 - 1.000

Derived parameters

General information

In the **Type** column the following symbols are used:

- ms for measured parameters
- dv for derived parameters

Acid-Base derived parameters

Symbol	Definition	Type	Eq.
pH(*T*)	pH of blood at patient temperature.	dv	**1**
$cH^+(T)$	Concentration of hydrogen ions in blood at patient temperature.	dv	**2**
$pCO_2(T)$	Partial pressure (or tension) of carbon dioxide at patient temperature.	dv	**3**
$cHCO_3^-$(P)	Concentration of hydrogen carbonate in plasma (also termed actual bicarbonate).	dv	**4**
*c*Base(B) or ABE	Actual Base Excess, the concentration of titrable base when the blood is titrated with a strong base or acid to a plasma pH of 7.40, at pCO_2 of 5.33 kPa (40 mmHg) and 37 °C, at the actual oxygen saturation [4,5]. Positive values (base excess) indicate a relative deficit of noncarbonic acids; negative values (base deficit) indicate a relative excess of non-carbonic acids.	dv	**5**
*c*Base(B,ox)	*c*Base(B) of fully oxygenated blood.	dv	**6**
*c*Base(Ecf) or SBE	Standard Base Excess, an *in vivo* expression of base excess [5, 6]. It refers to a model of the extracellular fluid (one part of blood is diluted by two parts of its own plasma) and is calculated using a standard value for the hemoglobin concentration of the total extracellular fluid.	dv	**7**
*c*Base(Ecf,ox)	*c*Base(Ecf) of fully oxygenated blood.	dv	**8**
$cHCO_3^-$(P,st)	Standard Bicarbonate, the concentration of hydrogen carbonate in the plasma from blood which is equilibrated with a gas mixture with pCO_2 = 5.33 kPa (40 mmHg) and $pO_2 \geq$ 13.33 kPa (100 mmHg) at 37 °C [4,5].	dv	**9**
$ctCO_2$(P)	Concentration of total carbon dioxide, (free CO_2 + bound CO_2) in plasma.	dv	**10**

Continued on next page

Derived parameters, *Continued*

Acid-Base derived parameters *(continued)*

Symbol	Definition	Type	Eq.
*c*tCO_2(B)	Concentration of total carbon dioxide in whole blood (also termed CO_2 content). Calculated based on the total CO_2 concentrations in the two phases: plasma and erythrocyte fluid [5].	dv	**11**
pH(st)	Standard pH (or eucapnic pH), defined as the pH of plasma of blood equilibrated to pCO_2 = 5.33 kPa (40 mmHg). By ensuring the normal value of pCO_2, the respiratory influence from pH is removed, and pH(P,st) therefore reflects the metabolic status of the blood plasma.	dv	**12**
VCO_2/V(dry air)	The volume fraction of carbon dioxide in dry air.	dv	**51**

Oximetry derived parameters

Symbol	Definition	Type	Eq.
*F*HHb	Fraction of deoxyhemoglobin in total hemoglobin in blood. Deoxyhemoglobin is the part of total hemoglobin which can bind oxygen forming oxyhemoglobin. It is also termed reduced hemoglobin, RHb.	ms/dv	**41**
FO_2Hb	Fraction of oxyhemoglobin in total hemoglobin in blood.	ms/dv	**40**
sO_2	Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins.	ms/dv	**39**
Hct	Hematocrit, the ratio between the volume of erythrocytes and the volume of whole blood.	dv	**13**

Continued on next page

Derived parameters, *Continued*

Oxygen derived parameters

Symbol	Definition	Type	Eq.
$pO_2(T)$	Partial pressure (or tension) of oxygen at patient temperature.	dv	**14**
pO_2(A)	Partial pressure (or tension) of oxygen in alveolar air.	dv	**15**
pO_2 (A,T)	Partial pressure (or tension) of oxygen in alveolar air at patient temperature.	dv	**16**
pO_2(a)/ FO_2(I)	Oxygen tension ratio of arterial blood and the fraction of oxygen in dry inspired air	dv	**17**
pO_2(a,T)/ FO_2(I)	Oxygen tension ratio of arterial blood at patient temperature and the fraction of of oxygen in dry inspired air	dv	**18**
p50	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood. High and low values indicate decreased and increased affinity of oxygen to hemoglobin, respectively.	dv	**19**
p50(T)	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood at patient temperature.	dv	**20**
p50(st)	Partial pressure (or tension) of oxygen at half saturation (50 %) in blood at standard conditions: temperature = 37 °C pH = 7.40 pCO_2 = 5.33 kPa FCOHb, FMetHb, FHbF set to 0 p50(st) may however vary due to variations in 2,3-DPG concentration or to the presence of abnormal hemoglobins.	dv/in	**21**
pO_2(A–a)	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood. Indicates the efficacy of the oxygenation process in the lungs.	dv	**22**
pO_2(A–a,T)	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood at patient temperature.	dv	**23**

Continued on next page

Derived parameters, *Continued*

Oxygen derived parameters *(continued)*

Symbol	Definition	Type	Eq.
pO_2(a/A)	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air. Indicates the efficacy of the oxygenation process in the lungs.	dv	**24**
pO_2(a/A,*T*)	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air at patient temperature.	dv	**25**
pO_2(x) or p_x	Oxygen extraction tension of arterial blood. Reflects the integrated effects of changes in the arterial pO_2(a), ctO_2, and $p50$ on the ability of arterial blood to release O_2 to the tissues [8].	dv	**26**
pO_2(x,*T*) or p_x(*T*)	Oxygen extraction tension of arterial blood at patient temperature.	dv	
ctO_2(B)	Total oxygen concentration of blood. Also termed O_2 content.	dv	**27**
ctO_2(a–$\bar{v}$)	Oxygen concentration difference between arterial and mixed venous blood.	dv	**28**
BO_2	Hemoglobin oxygen capacity; the maximum concentration of oxygen bound to hemoglobin in blood saturated, so that all deoxyhemoglobin is converted to oxyhemoglobin.	dv	**29**
ctO_2(x)	Extractable oxygen concentration of arterial blood. Defined as the amount of O_2 which can be extracted per liter of arterial blood at an oxygen tension of 5.0 kPa (38 mmHg), maintaining constant pH and pCO_2 [8].	dv	**30**
$\dot{D}O_2$	Oxygen delivery; the total amount of oxygen delivered to the whole organism per unit of time.	dv	**31**
$\dot{Q}_t$	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. Also termed CO or C.O.	dv/in	**32**
$\dot{V}O_2$	Oxygen consumption; total amount of oxygen utilized by the whole organism per unit of time.	dv/in	**33**
FO_2(I)	Fraction of oxygen in dry inspired air.	in	

Continued on next page

Derived parameters, *Continued*

Oxygen derived parameters *(continued)*

Symbol	Definition	Type	Eq.
*F*Shunt	Relative physiological shunt or concentration-based shunt [5,8,9]. • Calculated from the pulmonary shunt equation: $\frac{\dot{Q}_s}{\dot{Q}_t} = \frac{1}{1 + \frac{c\mathrm{tO}_2(\mathrm{a} - \bar{\mathrm{v}})}{c\mathrm{tO}_2(\mathrm{A}) - c\mathrm{tO}_2(\mathrm{a})}}$ if both arterial and mixed venous blood samples are used. • May be estimated from one arterial sample by assuming a constant difference in the concentrations of total oxygen in arterial and mixed venous blood: $c\mathrm{tO}_2(\mathrm{a} - \bar{\mathrm{v}}) = 2.3$ mmol / L (5.1 mL / dL)	dv	**34**
*F*Shunt (*T*)	*F*Shunt at patient temperature.	dv	**35**
RI	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood.	dv	**36**
RI(*T*)	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood at patient temperature.	dv	**37**
$V\mathrm{O}_2/V$(dry air)	Volume fraction of oxygen in dry air.	dv	**52**
Q_x	Cardiac oxygen compensation factor of arterial blood defined as the factor by which the cardiac output should increase to allow release of 2.3 mmol/L (5.1 mL/dL) oxygen at a mixed venous $p\mathrm{O}_2$ of 5.0 kPa (38 mmHg) [5,8].	dv	**38**
V(B)	Volume of blood, calculated when *F*COHb and *V*(CO) values are keyed in [5].	dv	**42**

Units and numerical format of derived parameters

Calculated versus estimated parameters

Derived parameters are calculated or estimated on the basis of measured and keyed in data. Calculations are made using equations programmed into the analyzer. The accuracy of the calculations depends on the input parameters keyed into the analyzer's computer.

If the calculation of a parameter requires input from the operator, but this input is not forthcoming, the analyzer will use certain default values (refer to the section *Default Values* in this chapter).

Not all input parameters are stored as defaults. In these instances the dependent derived parameter will not be reported if the relevant input parameter(s) is/are *not* entered.

If the default values are used in the calculation of a parameter, then a parameter is considered *estimated* ("e") rather than *calculated* ("c").

Acid-base parameters

The table below lists the acid-base derived parameters.

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL8 10/15/ 20 FLEX	ABL820/ 25/30/35 FLEX	Input parameter	Sample type
pH(*T*)	-	x.xxx	c	c	c	*T*	
$cH^+(T)$	nmol/L	xxx.x	c	c	c	*T*	
$pCO_2(T)$	mmHg; torr	xxx.x	c	c	c	*T*	
	kPa	xx.xx	c	c	c		
$cHCO_3^-$(P)	mmol/L	xx.x	c	c	c		
*c*Base(B)	mmol/L	Range: ±30.0	c	c	c	*c*tHb	
			e	c	c		
*c*Base(B,ox)	mmol/L	xxx.x	e	c	c	*c*tHb	
			e	c	c		
*c*Base(Ecf)	mmol/L	Range: ±30.0	c	c	c		
*c*Base(Ecf,ox)	mmol/L	xxx.x	e	c	c		
$cHCO_3^-$(P,st)	mmol/L	xx.x	c	c	c	*c*tHb	
			e	c	c		
$ctCO_2$(P)	Vol %, mL/dL, mmol/L	xx.x	c	c	c		

Continued on next page

Units and numerical format of derived parameters, *Continued*

Acid-base parameters *(continued)*

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL 810/15/20 FLEX	ABL820/25/30/35 83X FLEX	Input parameter	Sample type
$ctCO_2(B)$	Vol %, mL/dL, mmol/L	xx.x	c	c	c	*c*tHb	
pH(st)	-	x.xxx	c	c	c		
VCO_2/V(dry air)	%, fraction	xx.x x.xxx	c	c	c		

Oximetry parameters

The table below lists the oximetry derived parameters.

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL 810/15/20 FLEX	ABL820/25/30/35 83X FLEX	Input parameter	Sample type
Hct	% fraction	xx x.xxx	c	c	c	*c*tHb	
sO_2	% fraction	xx.x x.xxx	e				
FO_2Hb	% fraction	xx.x x.xxx	e	e	c		
*F*HHb	% fraction	xx.x x.xxx	e	e	c		

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Units and numerical format of derived parameters, *Continued*

Oxygen parameters

The table below lists the oxygen derived parameters.

(ABL83X corresponds to an ABL82X, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL 810/15/20 FLEX	ABL 820/25/30/35 83X FLEX	Input parameter	Sample type
$pO_2(T)$	mmHg; torr	xxx.x	e	e	c	*T*	
	kPa	xxx.xx					
pO_2(A)	mmHg; torr	xxx.x	c	c	c	FO_2(I)+RQ	Arterial,
	kPa	xx.xx	e	e	e		capillary
pO_2(A,*T*)	mmHg; torr	xxx.x	c	c	c	FO_2(I)+RQ+*T*	Arterial, capillary
	kPa	xx.xx	e	e	e		
*p*50	mmHg; torr	xx.xx	e	e	e*		
	kPa	xx.xx					
*p*50(*T*)	mmHg; torr	xx.xx	e	e	c*	*T*	
	kPa	xx.xx					
*p*50(st)	mmHg; torr	xx.xx	e	e	c*		
	kPa	xx.xx					
pO_2(A–a)	mmHg; torr	xxx.x	c	c	c	FO_2(I)+ RQ	Arterial,
	kPa	xx.xx	e	e	e		capillary
pO_2(A–a,*T*)	mmHg; torr	xxx.x	e	e	c	FO_2(I)+RQ+*T*	Arterial,
	kPa	xx.xx	e	e	e		capillary
pO_2(a/A)	%	xx.x	c	c	c	FO_2(I)+RQ	Arterial,
	fraction	x.xxx	e	e	e		capillary
pO_2(a/A, *T*)	%	xx.x	c	c	c	FO_2(I)+RQ+*T*	Arterial,
	fraction	x.xxx	e	e	e		capillary
pO_2(a)/FO_2(I)	%	xxx.x	c	c	c	FO_2(I)	Arterial,
	fraction	xx.xx					capillary
pO_2(a,*T*)/	%	xxx.x	c	c	c	FO_2(I)+*T*	Arterial,
FO_2(I)	fraction	xx.xx					capillary

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Units and numerical format of derived parameters, *Continued*

Oxygen parameters *(continued)*

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL 810/15/20 FLEX	ABL 820/25/30/35 FLEX	Input parameter	Sample type
pO_2(x)	mmHg; torr	xxx.x	e	e*	c*	*c*tHb+*p*50(st)	Arterial,
	kPa	xx.xx	-	e*	c*		capillary
pO_2(x,*T*)	mmHg; torr	xxx.x	e	e*	c*	*c*tHb+*p*50(st) +*T*	Arterial,
	kPa	xx.xx	-	e*	c*		capillary
ctO_2(B)	Vol %, mL/dL, mmol/L	xx.x	e	e	c	*c*tHb	
$ctO_2(a-\bar{v})$	Vol %, mL/dL, mmol/L	xx.x	e	e	c	*c*tHb	Venous + Arterial
BO_2	Vol %, mL/dL, mmol/L	xx.x	e	e	c	*c*tHb	
ctO_2(x)	Vol %, mL/dL, mmol/L	xx.x	e	e*	c*	*c*tHb +*p*50(st)	Arterial, capillary
$\dot{D}O_2$	mL/min	xxxx	e	e	c	$\dot{Q}_t$	Arterial,
	mmol/min	xxx.x					capillary
$\dot{Q}_t$	L/min	xxx.x	e	e	c	$\dot{V}O_2$	Venous + arterial
$\dot{V}O_2$	mL/min	xxxx	e	e	c	$\dot{Q}_t$	Venous +
	mmol/min	xxx.x					arterial
*F*Shunt	%	xx.x	e	e	c*	*c*tHb	Venous
	fraction	x.xxx					+ arterial
*F*Shunt(*T*)	%	xx.x	e	e	c*	*c*tHb + *T*	Venous +
	fraction	x.xxx					arterial
RI	%	xx	c	c	c	FO_2(I)+RQ	Arterial,
	fraction	x.xx	e	e	e		capillary

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Units and numerical format of derived parameters, *Continued*

Oxygen parameters *(continued)*

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure *c*tBil and *F*HbF).

Symbol	Unit	Numerical format of result	ABL 805 FLEX	ABL 810/15 /20 FLEX	ABL 820/25 /30/35 FLEX	Input parameter	Sample type
RI(*T*)	%	xx	e	e	c	FO_2(I)+RQ+*T*	Arterial, capillary
	fraction	x.xx	e	e	e	*T*	
VO_2/V(dry air)	%	xxx.x	c	c	c		
	fraction	x.xxx					
Q_x	-	xx.x	e	e*	c*	*c*tHb[1)]+*p*50(st) [1)]	Arterial, capillary
			e	e*	c*		
V(B)	L	x.x	c	c	c	*c*tHb+*V*CO+*F*COHb(1)+*F*COHb(2)	

***** If the sO_2 value for establishing the ODC is greater than 0.97, the calculation of the parameter is not performed unless the *p*50(st) value is keyed in.

[1)] If not measured, e.g. *c*tHb (or derived by analyzer, e.g. *p*50(st)).

Electrolyte Parameters

The table below lists the electrolyte derived parameters for the ABL800 FLEX analyzers.

Symbol	Unit	Numerical format of result	ABL8X5 FLEX	Input parameter	Sample type
Anion Gap, K^+	meq/L, mmol/L	xxx.x	c[2)]		
Anion Gap	meq/L, mmol/L	xxx.x	c[3)]		
cCa^{2+}(7.4)	meq/L, mg/dL, mmol/L	xx.x	c[4)]		
*m*Osm	mmol/kg	xxx.x	c[5)]		

2) If the analyzer includes K, Na and Cl electrodes.

3) If the analyzer includes Na and Cl electrodes.

4) If the analyzer includes Ca electrode.

5) If the analyzer includes Na and Glucose electrodes.

List of equations

Units and symbols

All definitions and equations are based on SI units. If 'T' for patient temperature is not stated, the calculation is based on a temperature of 37.0 °C.

The following SI units are used:

concentration in mmol/L

temperature in °C

pressure in kPa

fractions (not %)

The following symbols are used in the equations:

$\log(x) = \log_{10}(x)$

$\ln(x) = \log_e(x)$

pH(*T*)

Eq. 1 [13]:

$$\mathrm{pH}(T) = \mathrm{pH}(37) - \left[0.0146 + 0.0065 \times \left(\mathrm{pH}(37) - 7.40\right)\right]\left[T - 37\right]$$

***c*H$^+$(*T*)**

Eq. 2:

$$c\mathrm{H}^+(T) = 10^{(9 - \mathrm{pH}(T))}$$

***p*CO$_2$(*T*)**

Eq. 3 [4]:

$$p\mathrm{CO}_2(T) = p\mathrm{CO}_2(37) \times 10^{\left[0.021 \times (T - 37)\right]}$$

***c*HCO$_3^-$(P)**

Eq. 4 [5]:

$$c\mathrm{HCO}_3^-(\mathrm{P}) = 0.23 \times p\mathrm{CO}_2 \times 10^{(\mathrm{pH} - \mathrm{pK}_p)}$$

where

$$\mathrm{pK}_p = 6.125 - \log\left[1 + 10^{(\mathrm{pH} - 8.7)}\right]$$

*c*HCO$_3^-$(P) includes ions of hydrogen carbonate, carbonate, and carbamate in the plasma.

***c*Base(B)**

Eq. 5 [4,14]:

$$c\mathrm{Base(B)} = 0.5 \times \left(\frac{8a' - 0.919}{a'}\right) + 0.5 \times \sqrt{\left(\frac{0.919 - 8a'}{a'}\right)^2 - 4 \times \frac{24.47 - c\mathrm{HCO}_3^-(5.33)}{a'}}$$

Continued on next page

List of equations, *Continued*

cBase(B) *(continued)*

where

Eq.	Description
5.1	$a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4}\, c\mathrm{tHb}$
5.2	$c\mathrm{HCO_3^-}(5.33) = 0.23 \times 5.33 \times 10^{\left[\frac{(\mathrm{pH(st)} - 6.161)}{0.9524}\right]}$
5.3	$\mathrm{pH(st)} = \mathrm{pH} + \log\left(\frac{5.33}{p\mathrm{CO_2}}\right) \times \left(\frac{\mathrm{pH(Hb)} - \mathrm{pH}}{\log p\mathrm{CO_2(Hb)} - \log(7.5006\, p\mathrm{CO_2})}\right)$
5.4	$\mathrm{pH(Hb)} = 4.06 \times 10^{-2}\, c\mathrm{tHb} + 5.98 - 1.92 \times 10^{(-0.16169\, c\mathrm{tHb})}$
5.5	$\log p\mathrm{CO_2(Hb)} = -1.7674 \times 10^{-2}\, c\mathrm{tHb} + 3.4046 + 2.12 \times 10^{(-0.15158 c\mathrm{tHb})}$

cBase(B,ox) **Eq. 6** [4]:

$$c\mathrm{Base(B,ox)} = c\mathrm{Base(B)} - 0.3062 \times c\mathrm{tHb} \times (1 - s\mathrm{O_2})$$

If *c*tHb is not measured or keyed in, the default value will be used.

If $s\mathrm{O_2}$ is not measured, it will be calculated from equation 39.

cBase(Ecf) **Eq. 7** [5]:

*c*Base(Ecf) = *c*Base(B) for *c*tHb = 3 mmol/L

cBase(Ecf,ox) **Eq. 8**:

*c*Base(Ecf,ox) = *c*Base(B,ox) for *c*tHb = 3 mmol/L

cHCO₃⁻(P,st) **Eq. 9** [4,14]:

$$c\mathrm{HCO_3^-(P,st)} = 24.47 + 0.919 \times Z + Z \times a' \times (Z - 8)$$

where

Eq.	Description
9.1	$a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4} \times c\mathrm{tHb}$
9.2	$Z = c\mathrm{Base(B)} - 0.3062 \times c\mathrm{tHb} \times (1 - s\mathrm{O_2})$

ctCO₂(P) **Eq. 10** [4,5]:

$$c\mathrm{tCO_2(P)} = 0.23 \times p\mathrm{CO_2} + c\mathrm{HCO_3^-(P)}$$

Continued on next page

List of equations, *Continued*

ctCO$_2$(B) **Eq. 11** [5]:

$$c\mathrm{tCO_2(B)} = 9.286\times10^{-3}\times p\mathrm{CO_2}\times c\mathrm{tHb}\times\left[1+10^{\left(\mathrm{pH_{Ery}}-p\mathrm{K_{Ery}}\right)}\right] + c\mathrm{tCO_2(P)}\times\left(1-\frac{c\mathrm{tHb}}{21.0}\right)$$

where

Eq.	Description
9.1	$\mathrm{pH_{Ery}} = 7.19 + 0.77\times\left(\mathrm{pH} - 7.40\right) + 0.035\times\left(1 - s\mathrm{O_2}\right)$
9.2	$\mathrm{pK_{Ery}} = 6.125 - \log\left[1+10^{\left(\mathrm{pH_{Ery}} - 7.84 - 0.06\times s\mathrm{O_2}\right)}\right]$

pH(st) **Eq. 12** [14]:

pH(st): see equations 5.3 - 5.5.

Hct **Eq. 13** [15]:

Hct = 0.0485×ctHb + 8.3×10^{-3}

Hct cannot be calculated on the basis of a default ctHb value.

pO$_2$(T) **Eq. 14** [16,17]:

The standard Oxygen Dissociation Curve (ODC) is used (i.e. p50(st) = 3.578 kPa) at actual values of pH, pCO$_2$, FCOHb, FMetHb, FHbF (see equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*).

pO$_2$(T) is calculated by a numerical method using:

$$\mathrm{t_i}(T) = c\mathrm{tHb}\times\left(1 - F\mathrm{COHb} - F\mathrm{MetHb}\right)\times s\mathrm{O_{2,i}}(T) + \alpha\mathrm{O_2}(T)\times p\mathrm{O_{2,i}}(T)$$

where

Eq.	Description	See…
14.1	S = ODC(P,A,T)	Eq. 47
14.2	$s\mathrm{O_{2,i}}(T) = \frac{\mathrm{S}\times\left(1 - F\mathrm{MetHb}\right) - F\mathrm{COHb}}{1 - F\mathrm{COHb} - F\mathrm{MetHb}}$	Eq. 46.12
14.3	$p\mathrm{O_{2,i}}(T) = \frac{\mathrm{P}}{1 + \frac{F\mathrm{COHb}}{s\mathrm{O_{2,i}}(T)\times\left(1 - F\mathrm{COHb} - F\mathrm{MetHb}\right)}}$	Eq. 46.10

Continued on next page

List of equations, *Continued*

p*O$_2$(*T*) *(continued)

Eq.	Description	See…
14.4	$\alpha O_2 = 9.83\times10^{-3}\, e^{\left[-1.15\times10^{-2}(T\text{-}37.0)+2.1\times10^{-4}\times(T\text{-}37.0)^2\right]}$	
14.5	P is the variable during iteration.	
14.6	$A = ac\text{-}1.04\times\frac{\partial pH}{\partial T}\times(T\text{-}37.0)$	
14.7	T= patient temperature in ^{o}C (keyed-in).	
14.8	$\frac{\partial pH}{\partial(T)} = -1.46\times10^{-2} - 6.5\times10^{-3}\times\left(pH(37)-7.40\right)$ When $t_i(T) = t_i(37.0)$, then $pO_{2,i}(T) = pO_2(T)$	

***p*O$_2$(A)**

Eq. 15 [5]:

$$pO_2(A) = FO_2(I)\times\left(p(amb)\text{-}6.275\right) - pCO_2\times\left[RQ^{-1} - FO_2(I)\times\left(RQ^{-1}-1\right)\right]$$

If $FO_2(I)$ and RQ are not keyed in, they are set to the default values.

The calculation requires entering the sample type as "Arterial" or "Capillary".

***p*O$_2$(A,*T*)**

Eq. 16 [4,5,18]:

$$pO_2(A,T) = FO_2(I)\times\left[p(amb)\text{-}pH_2O(T)\right] - pCO_2(T)\times\left[RQ^{-1} - FO_2(I)\times\left(RQ^{-1}-1\right)\right]$$

$$pH_2O(T) = 6.275\times10^{\left[2.36\times10^{-2}\times(T-37.0)-9.6\times10^{-5}\times(T-37.0)^2\right]}$$

If $FO_2(I)$ and RQ are not keyed in, they are set to the default values.

The calculation requires entering the sample type as "Arterial" or "Capillary".

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List of equations, *Continued*

pO_2(a)/FO_2(I) **Eq. 17**:

$$pO_2(a)/FO_2(I) = \frac{pO_2(a)}{FO_2(I)}$$

The calculation cannot be performed on the basis of the default FO_2(I) value, and the calculation requires entering the sample as “Arterial” or “Capillary”.

pO_2(a,*T*)/FO_2(I) **Eq. 18**:

$$pO_2(a,T)/FO_2(I) = \frac{pO_2(a,T)}{FO_2(I)}$$

The calculation cannot be performed on the basis of the default FO_2(I) value, and the calculation requires entering the sample as “Arterial” or “Capillary”.

***p*50** **Eq. 19** Refer to Eq. 46.10:

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$p50 = \frac{P}{1 + \frac{FCOHb}{0.5 \times (1 - FCOHb - FMetHb)}}$$

where

Description	See...
P = ODC(S,A,*T*)	Eq. 47
$S = \frac{0.5 \times (1 - FCOHb - FMetHb) + FCOHb}{1 - FMetHb}$	Eq. 46.11
A = a	
T = 37.0 °C	Eq. 46.13

***p*50(*T*)** **Eq. 20**:

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$p50(T) = \frac{P}{1 + \frac{FCOHb}{0.5 \times (1 - FCOHb - FMetHb)}}$$

where

Continued on next page

List of equations, *Continued*

p*50(*T*) *(continued)

Description	See…
P = ODC(S,A,*T*)	Eq. 47
$S = \frac{0.5 \times \left(1 - F\text{COHb} - F\text{MetHb}\right) + F\text{COHb}}{1 - F\text{MetHb}}$	Eq. 46.11
$A = a - 1.04 \times \frac{\partial \text{pH}}{\partial (T)} \times \left(T - 37.0\right)$	
$\frac{\partial \text{pH}}{\partial (T)} = -1.46 \times 10^{-2} - 6.5 \times 10^{-3} \times \left(\text{pH}(37) - 7.40\right)$	
T = patient temperature in °C (keyed-in)	

***p*50(st)**

Eq. 21:

*p*50 is calculated for pH = 7.40, pCO_2 = 5.33 kPa, *F*COHb = 0, *F*MetHb = 0, *F*HbF = 0.

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*, see equation 47.

*p*50(st) = ODC(S,A,*T*)

where

Description	See…
S = 0.5	Eq. 46.11
A = a6 corresponds to pH = 7.40, pCO_2 = 5.33 kPa, *F*COHb = 0, *F*MetHb = 0, *F*HbF = 0	Eq. 46.13
T = 37.0 °C	

***p*O₂(A-a)**

Eq. 22:

$$pO_2(\text{A} - \text{a}) = pO_2(\text{A}) - pO_2(\text{a})$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

***p*O₂(A-a,*T*)**

Eq. 23:

$$pO_2(\text{A} - \text{a}, T) = pO_2(\text{A}, T) - pO_2(\text{a}, T)$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

Continued on next page

List of equations, *Continued*

pO_2(a/A) **Eq. 24**:

$$pO_2(\text{a/A}) = \frac{pO_2(\text{a})}{pO_2(\text{A})}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

pO_2(a/A,*T*) **Eq. 25**:

$$pO_2(\text{a/A},T) = \frac{pO_2(a,T)}{pO_2(\text{A},T)}$$

The calculation requires entering the sample type as "Arterial" or "Capillary".

pO_2(x) **Eq. 26** [8]:

(or p_x) The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

pO_2(x) is calculated by a numerical method, using:

Eq.	Description	See…
26.1	S = ODC(P,A,*T*)	Eq. 47
26.2	$sO_{2,i} = \frac{S \times (1 - F\text{MetHb}) - F\text{COHb}}{1 - F\text{COHb} - F\text{MetHb}}$	Eq. 46.12
26.3	$pO_{2,i} = \frac{\text{P}}{1 + \frac{F\text{COHb}}{sO_{2,i} \times (1 - F\text{COHb} - F\text{MetHb})}}$	Eq. 46.10
26.4	$t_i = c\text{tHb} \times (1 - F\text{COHb} - F\text{MetHb}) \times sO_{2,i} + 9.83 \times 10^{-3} \times pO_{2,i}$	
26.5	A = a	
26.6	T = 37 °C	

When $t_i = ctO_2 - 2.3$ mmol/L, then $pO_{2,i} = pO_2$(x), where ctO_2 is determined as described in equation 27.

pO_2(x) cannot be calculated on the basis of a default *c*tHb value.

pO_2(x) can only be calculated if the measured sO_2(a) ≤ 0.97 (or *p*50(st) keyed in).

The calculation requires entering the sample type as "Arterial" or "Capillary".

Continued on next page

List of equations, *Continued*

ctO_2

Eq. 27 [5]:

$$ctO_2 = \alpha O_2 \times pO_2 + sO_2 \times (1 - FCOHb - FMetHb) \times ctHb$$

αO_2 is the concentrational solubility coefficient for O_2 in blood (here set to 9.83 x 10^{-3} mmol$L^{-1}kPa^{-1}$ at 37 °C [5,19].

ctO_2 cannot be calculated on the basis of a default *c*tHb value.

$ctO_2(a-\bar{v})$

Eq. 28:

$$ctO_2(a - \bar{v}) = ctO_2(a) - ctO_2(\bar{v})$$

where $ctO_2(a)$ and $ctO_2(\bar{v})$ are calculated from equation 27 for arterial and mixed venous blood, respectively. The calculation requires two measurements.

BO_2

Eq. 29 [7]:

$$BO_2 = ctHb \times (1 - FCOHb - FMetHb)$$

BO_2 cannot be calculated on the basis of a default *c*tHb value.

$ctO_2(x)$ (or c_x)

Eq. 30 [8]:

The ODC is determined, as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$ctO_2(x) = ctO_2(a) - t_i$$

where

Eq.	Description	See…
30.1	$t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 9.83 \times 10^{-3} \times pO_2(5)$	
30.2	$pO_2(5) = 5.00$ kPa	
30.3	S = ODC(P,A,*T*)	Eq. 47
30.4	$P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}\right]$	Eq. 46.9
30.5	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{(1 - FCOHb - FMetHb)}$	Eq. 46.12
30.6	A = a	
30.7	T = 37.0 °C	

Continued on next page

List of equations, *Continued*

$ctO_2(x)$ (or c_x) *(continued)*

$ctO_2(a)$ is determined as described in equation 27.

$ctO_2(x)$ cannot be calculated on the basis of a default *c*tHb value.

$ctO_2(x)$ can only be calculated if the measured $sO_2(a) \leq 0.97$ (or if *p*50(st) is keyed in).

The calculation requires entering the sample type as "Arterial" or "Capillary".

$\dot{D}O_2$

Eq. 31:

$$\dot{D}O_2 = ctO_2 \times \dot{Q}_t$$

$\dot{Q}_t$ is the cardiac output and is an input parameter for calculation of $\dot{D}O_2$.

If $\dot{Q}_t$ is not keyed in, $\dot{D}O_2$ will not be calculated.

The calculation requires entering the sample type as "Arterial" or "Capillary".

$\dot{Q}_t$

Eq. 32:

$$\dot{Q}_t = \frac{\dot{V}O_2}{ctO_2(a - \bar{v})}$$

If $\dot{V}O_2$ is not keyed in, $\dot{Q}_t$ will not be calculated.

$\dot{V}O_2$

Eq. 33:

$$\dot{V}O_2 = \dot{Q}_t \times ctO_2(a - \bar{v})$$

If $\dot{Q}_t$ is not keyed in, $\dot{V}O_2$ will not be calculated.

***F*Shunt**

Eq. 34 [5]:

$$F\text{Shunt} = \frac{ctO_2(c) - ctO_2(a)}{ctO_2(c) - ctO_2(\bar{v})}$$

and

Eq.	Description
34.1	$F\text{Shunt} \cong \frac{ctO_2(A) - ctO_2(a)}{ctO_2(A) - ctO_2(\bar{v})}$

Continued on next page

List of equations, *Continued*

F*Shunt *(continued)

Eq.	Description
34.2	$FShunt = \left[1 + \frac{ctO_2(a) - ctO_2(\bar{v})}{ctO_2(A) - ctO_2(a)}\right]^{-1}$
	where
	$ctO_2(c)$: total oxygen in pulmonary capillary blood
	$ctO_2(a)$: total oxygen in arterial blood
	$ctO_2(A)$: total oxygen in alveolar blood. Oxygen tension = $pO_2(A)$
	$ctO_2(\bar{v})$: total oxygen in mixed venous blood
34.3	$ctO_2(a) = 9.83 \times 10^{-3}\, pO_2(a) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(a)$
34.4	$ctO_2(A) = 9.83 \times 10^{-3}\, pO_2(A) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(A)$
34.5	$ctO_2(\bar{v}) = 9.83 \times 10^{-3}\, pO_2(\bar{v}) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(\bar{v})$
	where:
	$pO_2(a)$: oxygen tension in arterial blood; measured.
	$pO_2(A)$: oxygen tension in alveolar blood. See equation 15.
	$pO_2(\bar{v})$: oxygen tension in mixed venous blood; measured and then entered.
	$sO_2(a)$: oxygen saturation in arterial blood; can be measured.
	$sO_2(A)$: oxygen saturation in (alveolar) blood calculated from equation 39 where P = $pO_2(A)$. If $sO_2(a) > 0.97$, a keyed-in $p50(st)$ will be used to determine the ODC. If $sO_2(a) > 0.97$ and no $p50(st)$ has been keyed in, the default value (3.578 kPa) will be used to determine the ODC.
	$sO_2(\bar{v})$: oxygen saturation in mixed venous blood.
	If not keyed in, it will be calculated from equation 39 where P = $pO_2(\bar{v})$. If $sO_2(a) > 0.97$, a keyed-in $p50(st)$ will be used to determine the ODC.
	The calculation requires entering the sample type as “Arterial” or “Capillary”. If $sO_2(a) > 0.97$ and no $p50(st)$ has been keyed in, the default value (3.578 kPa) will be used to estimate the ODC.
	If no venous sample is measured, *F*Shunt is estimated assuming:
	$ctO_2(a) - ctO_2(\bar{v})$ = 2.3 mmol/L in equation 34.2

Continued on next page

List of equations, *Continued*

***F*Shunt(*T*)** **Eq. 35** [5,16]:

$$F\text{Shunt}(T) = \left[1 + \frac{c\text{tO}_2(\text{a},T) - c\text{tO}_2(\bar{\text{v}},T)}{c\text{tO}_2(\text{A},T) - c\text{tO}_2(\text{a},T)}\right]^{-1}$$

where

$c\text{tO}_2(\text{a},T)$: total oxygen in arterial blood at patient temperature

$c\text{tO}_2(\text{A},T)$: total oxygen in alveolar blood at patient temperature

$c\text{tO}_2(\bar{\text{v}},T)$: total oxygen in mixed venous blood at patient temperature

Eq.	Description	See…
35.1	$c\text{tO}_2(\text{a},T) = c\text{tO}_2$ calculated from equation 25 for arterial $p\text{O}_2$ and $s\text{O}_2$ values at 37 °C.	
35.2	$c\text{tO}_2(\text{A},T) = \alpha\text{O}_2(T) \times p\text{O}_2(\text{A},T) + c\text{tHb} \times \left(1 - F\text{COHb} - F\text{MetHb}\right) \times s\text{O}_2(\text{A},T)$	
35.3	$\alpha O_2(T) = 9.83 \times 10^{-3} \text{e}^{\left[-1.15\times10^{-2}\times(T-37.0)+2.1\times10^{-4}\times(T-37.0)^2\right]}$	
35.4	$p\text{O}_2(\text{A},T)$ is calculated from equation 15.	
35.5	$s\text{O}_2(\text{A},T) = \text{S}$	
35.6	$\text{S} = \text{ODC}(\text{P},\text{A},T)$	Eq. 47
35.7	$\text{P} = p\text{O}_2(\text{A},T)$	
35.8	$\text{A} = \text{a} - 1.04 \times \frac{\partial \text{pH}}{\partial(T)} \times \left(T - 37.0\right)$	
35.9	T = patient temperature (keyed-in)	
35.10	$\frac{\partial \text{pH}}{\partial(T)} = 1.46 \times 10^{-2} - 6.5 \times 10^{-3}\left(\text{pH}(37) - 7.40\right)$ If $s\text{O}_2(\text{a}) > 0.97$, a keyed-in $p50$(st) will be used to determine the ODC. If $s\text{O}_2(\text{a}) > 0.97$ and no $p50$(st) has been keyed in, the default value (3.578 kPa) will be used to determine the ODC.	
35.11	$c\text{tO}_2(\bar{\text{v}},T) = c\text{tO}_2(\bar{\text{v}})$ at 37 °C is calculated from equation 27 for mixed venous blood values of $p\text{O}_2$ and $s\text{O}_2$. If $s\text{O}_2(\bar{\text{v}}) > 0.97$, a keyed-in $p50$(st) will be used to determine the ODC. If $s\text{O}_2(\bar{\text{v}}) > 0.97$ and no $p50$(st) has been keyed in, the default value (3.578 kPa) will be used to estimate the ODC. If no mixed venous sample is measured, the $F\text{Shunt}(T)$ is estimated assuming $c\text{tO}_2(\text{a},T) - c\text{tO}_2(\bar{\text{v}},T) = 2.3$ mmol/L in equation 35.	

Continued on next page

List of equations, *Continued*

RI

Eq. 36:

$$\mathrm{RI} = \frac{p\mathrm{O}_2(\mathrm{A}) - p\mathrm{O}_2(\mathrm{a})}{p\mathrm{O}_2(\mathrm{a})}$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

RI(*T*)

Eq. 37:

$$\mathrm{RI}(T) = \frac{p\mathrm{O}_2(\mathrm{A},T) - p\mathrm{O}_2(\mathrm{a},T)}{p\mathrm{O}_2(\mathrm{a},T)}$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

Q_x

Eq. 38 [8]:

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$Q_x = \frac{2.3}{c\mathrm{tO}_2(\mathrm{a}) - \mathrm{t_i}}$$

Eq.	Description	See…
38.1	$\mathrm{t_i} = c\mathrm{tHb} \times \left(1 - F\mathrm{COHb} - F\mathrm{MetHb}\right) \times s\mathrm{O}_{2,\mathrm{i}} + 9.83 \times 10^{-3}\, p\mathrm{O}_2(5)$	
38.2	$p\mathrm{O}_2(5) = 5.00$ kPa	
38.3	$\mathrm{S} = \mathrm{ODC}(\mathrm{P},\mathrm{A},T)$	
38.4	$P = p\mathrm{O}_2(5) \times \left[1 + \frac{F\mathrm{COHb}}{s\mathrm{O}_{2,\mathrm{i}} \times \left(1 - F\mathrm{COHb} - F\mathrm{MetHb}\right)}\right]$	Eq. 46.9
38.5	$s\mathrm{O}_{2,\mathrm{i}} = \frac{\mathrm{S} \times \left(1 - F\mathrm{MetHb}\right) - F\mathrm{COHb}}{1 - F\mathrm{COHb} - F\mathrm{MetHb}}$	Eq. 46.12
38.6	$\mathrm{A} = \mathrm{a}$	
38.7	$T = 37.0\ ^{\circ}\mathrm{C}$	

$c\mathrm{tO}_2(\mathrm{a})$ is determined as described in equation 27.

Qx cannot be calculated on the basis of a default *c*tHb value.

Qx can only be calculated if the measured $s\mathrm{O}_2(\mathrm{a}) \leq 0.97$ (or if $p50(\mathrm{st})$ is keyed in).

The calculation requires entering the sample type as “Arterial” or “Capillary”.

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List of equations, *Continued*

sO_2

Eq. 39:

The ODC is determined as described in equation 46 (points I and III). See the section *Oxyhemoglobin Dissociation Curve*.

$$sO_2 = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$$

where

Description	See…
S = ODC(P,A,*T*)	
$P = pO_2 + \frac{pO_2 \times FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}$	Eq. 46.9
A = a	
$T = 37.0\ ^oC$	

FO_2Hb

Eq. 40:

$$FO_2Hb = sO_2 \times (1 - FCOHb - FMetHb)$$

If sO_2 is not measured, it will be calculated from equation 39.

If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.

***F*HHb**

Eq. 41:

$$FHHb = 1 - sO_2 \times (1 - FCOHb - FMetHb) - FCOHb - FMetHb$$

If sO_2 is not measured, it will be calculated from equation 39.

If dyshemoglobins (*F*COHb, *F*MetHb) are not known, they are set to the default values.

***V*(B)**

Eq. 42 [5]:

$$V(B) = \frac{1 \times 10^3 \times V(CO)}{24 \times (FCOHb(2) - FCOHb(1)) \times 0.91 \times ctHb}$$

Continued on next page

List of equations, *Continued*

V(B) *(continued)*

Eq.	Description
42.1	$V(B) = \dfrac{V(\mathrm{CO})}{2.184 \times 10^{-2} \times \left(F\mathrm{COHb}(2) - F\mathrm{COHb}(1)\right) \times c\mathrm{tHb}}$
42.2	V(CO) = volume (in mL) of carbon monoxide injected according to the procedure and the value keyed-in.
42.3	FCOHb(1) = fraction of COHb measured before the CO injection
42.4	FCOHb(2) = fraction of COHb measured after the CO injection

Anion Gap,K^+ **Eq. 43**:

$$\text{Anion Gap},\mathrm{K}^+ = c\mathrm{Na}^+ + c\mathrm{K}^+ - c\mathrm{Cl}^- - c\mathrm{HCO}_3^-$$

Anion Gap **Eq. 44:**

$$\text{AnionGap} = c\mathrm{Na}^+ - c\mathrm{Cl}^- - c\mathrm{HCO}_3^-$$

cCa^{2+}(7.4) **Eq. 45** Ref. [12]:

$$c\mathrm{Ca}^{2+}(7.4) = c\mathrm{Ca}^{2+}\left[1 - 0.53 \times \left(7.40 - \mathrm{pH}\right)\right]$$

Due to biological variations this equation can only be used for a pH value in the range 7.2 - 7.6.

Eq. 46-47 See *Oxyhemoglobin dissociation curve (ODC)*.

***m*Osm** **Eq. 48:**

$$m\mathrm{Osm} = 2c\mathrm{Na}^+ + c\mathrm{Glu}$$

***F*HbF** **Eq. 49:**

An iterative method is used to calculate FHbF. The input parameters are $s\mathrm{O}_2$, ceHb (effective hemoglobin concentration), and $c\mathrm{O}_2$HbF (concentration of fetal oxyhemoglobin).

In the calculations the following are assumed: pH = 7.4, $p\mathrm{CO}_2$ = 5.33 kPa, FCOHb = 0, FMetHb = 0, cDPG = 5 mmol/L, and temp = 37 °C.

Step	Description	See…
1.	An estimate of FHbF is made: $F\mathrm{HbF}_{est}$ = 0.8	
2.	$p\mathrm{O}_{2,est}$ = ODC ($s\mathrm{O}_2$,A,T); where the constant A depends on FHbF = $F\mathrm{HbF}_{est}$	Eq. 47

Continued on next page

List of equations, *Continued*

F*HbF *(continued)

Step	Description	See…
3.	sO_2 (for fetal blood) = ODC ($pO_{2,est}$, A,*T*); where *F*HbF = 1	Eq.47
4.	$cO_2HbF_{est} = sO_2$ (fetal blood) × *c*eHb × $FHbF_{est}$	
5.	$\Delta FHbF_{est} = \frac{cO_2HbF_{meas.} - cO_2HbF_{est}}{c\text{eHb}}$	
6.	If $\lvert\Delta FHbF_{est}\rvert \geq 0.001$, proceed to step **7**. If $\lvert\Delta FHbF_{est}\rvert < 0.001$, proceed to step 9.	
7.	$FHbF_{est,\,new} = FHbF_{est,\,old} + \Delta FHbF_{est}$	
8.	Return to step **2**.	
9.	End of iteration. The value for *F*HbF has converged.	

***p*O₂(x,*T*)**

Eq. 50 [8]:

The ODC is determined as described in equations 46 - 47 in *Oxyhemoglobin Dissociation Curve*.

$pO_2(x)$ is calculated by a numerical method, using:

Eq.	Description	See…
50.1	S = ODC(P,A,*T*)	Eq. 47
50.2	$sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
50.3	$pO_{2,i}(T) = \frac{P}{1 + \frac{FCOHb}{sO_{2,i}(T) \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
50.4	$t_i(T) = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$	
50.5	A = a	
50.6	*T* = patient temperature	
50.7	$\alpha O_2(T) = 0.00983 \times e^{\left[-0.115 \times (T-37) + 21 \times 10^{-5} \times (T-37)^2\right]}$	

Continued on next page

List of equations, *Continued*

p*O$_2$(x,*T*) *(continued)

Eq.	Description
50.8	$pO_{2,i} = pO_2(x,T)$ when $t_i(T) = ctO_2(37\ °C) - 2.3$ mmol/L

$pO_2(x,T)$ is calculated in accordance with OSA V3.0.

$pO_2(x,T)$ can only be calculated if the measured $sO_2(a) \leq 0.97$ (or $p50$(st) keyed in).

$pO_2(x,T)$ is tagged with "?" if any of the following parameters: sO_2, *F*MetHb, *F*COHb, pO_2, pCO_2, pH or *c*tHb is tagged with "?".

The calculation requires entering the sample type as “Arterial” or “Capillary”.

***V*CO$_2$/*V*(dry air)** **Eq. 51**:

$$VCO_2/V(\text{dry air}) = \frac{pCO_2}{p(\text{amb}) - 6.275}$$

***V*O$_2$/*V*(dry air)** **Eq. 52**:

$$VO_2/V(\text{dry air}) = \frac{pO_2}{p(\text{amb}) - 6.275}$$

Oxyhemoglobin dissociation curve (ODC)

ODC equations

These equations account for the effect of *F*COHb on the shape of the Oxyhemoglobin Dissociation Curve (ODC) in accordance with the Haldane equation.

Eq. 46 [16,18]:

$$y - y^{o} = (x - x^{o}) + h \times \tanh\left[k^{o}\left(x - x^{o}\right)\right]$$

where $k^{o} = 0.5343$

Eq.	Description
46.1	$x = \ln p$
46.2	$y = \ln \frac{s}{1 - s}$
46.3	$y^{o} = \ln \frac{s^{o}}{1 - s^{o}}$ where $s^{o} = 0.867$
46.4	$x^{o} = x^{oo} + a + b = \ln(p^{oo}) + a + b$ where $p^{oo} = 7$ kPa

The actual position of the ODC in the coordinate system (ln(s/(1–s)) vs ln(*p*)) used in the mathematical model, is expressed by equations 46.3 and 46.4.

The symbols 'a' and 'b' reflect the ODC displacement from the reference position to its actual position in this coordinate system:

'a' describes the displacement at 37 °C.
'b' the additional displacement due to the patient temperature difference from 37 °C.

The ODC reference position

The reference position of the ODC was chosen to be the one that corresponds to the default value for *p*50(st) = 3.578 kPa, which is traditionally considered the most likely value of *p*50 for adult humans under standard conditions, namely:

pH = 7.40

pCO_2 = 5.33 kPa

*F*COHb, *F*MetHb, *F*HbF = 0

*c*DPG = 5 mmol/L

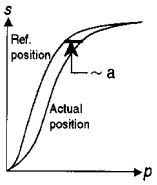
Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

The ODC displacement

The ODC displacement which is described by 'a' and 'b' in the coordinate system ($\ln(s/(1-s))$ vs $\ln(p)$), is given by the change in $p50$ from the default to its actual value in a more common coordinate system (sO_2, pO_2).

Eq.	Description
46.5	$x - x^o = \ln\frac{p}{7} - a - b$
46.6	$h = h^o + a$ where $h^o = 3.5$
46.7	$b = 0.055 \times (T - T^o)$ $T^o = 37\ ^oC$
46.8	$p = pO_2 + M \times pCO$ where M×*p*CO is taken from the Haldane equation [20]: $\frac{pO_2}{cO_2Hb} = M \times \frac{pCO}{cCOHb}$, to give eq. 46.9
46.9	$p = pO_2 + \frac{pO_2}{sO_2} \times \left[\frac{FCOHb}{1 - FCOHb - FMetHb}\right]$ or equation 46.10
46.10	$pO_2 = \frac{p \times \left[sO_2 \times (1 - FCOHb - FMetHb)\right]}{1 + FCOHb}$



The ordinate, *s*, may loosely be termed the combined oxygen/carbon monoxide saturation of hemoglobin and is described by equation 46.11 below:

Eq.	Description
46.11	$s = \frac{cO_2Hb + cCOHb}{cO_2Hb + cCOHb + cHHb}$ or $= \frac{sO_2 \times (1 - FCOHb - FMetHb) + FCOHb}{1 - FMetHb}$
46.12	$sO_2 = \frac{s \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$

Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

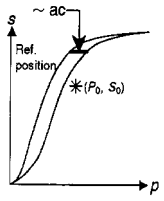
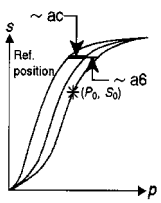
The actual ODC position

The actual position of the ODC at 37 °C for a given sample is, in principle, determined in two steps:

1. The calculation of the combined effect on the ODC position at 37 °C of all known causes for displacement (= ac in equation 46.13), and based on this position:
2. The computation by a numerical method of the actual position of the ODC curve by shifting it to pass through the known set of coordinates (P_0, S_0).

Eq.	Description
46.13	$a = ac + a6$
46.14	$ac = a1 + a2 + a3 + a4 + a5$
46.15	$a1 = -0.88 \times (pH - 7.40)$
46.16	$a2 = 0.048 \times \ln \frac{pCO_2}{5.33}$
46.17	$a3 = -0.7 \times F\text{MetHb}$
46.18	$a4 = (0.06 - 0.02 F\text{HbF}) \times (c\text{DPG} - 5)$
46.19	$a5 = -0.25 \times F\text{HbF}$

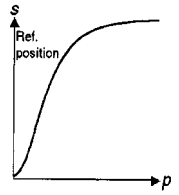
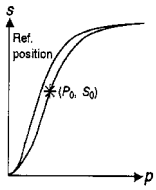
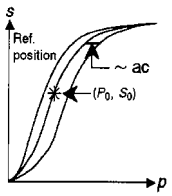
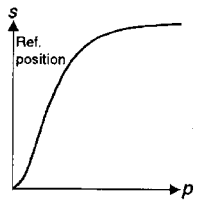
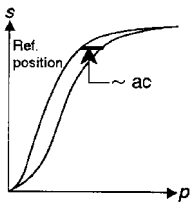
Determining the actual displacement

Step	Description
(I):  	pO_2, sO_2 can be used. If $sO_2 > 0.97$, the calculation is based on (II) or (III) - *see below*. Coordinates (P_0, S_0) are calculated from equations (46.9) and (46.11). If *F*COHb and *F*MetHb are not known, the default values are used. The ODC is shifted from the reference position to a position which corresponds to the effect of all measured parameters according to step (I). The magnitude of the shift is "ac". The ODC is then further shifted to pass through the point (P_0, S_0). The magnitude of the shift is "a6".

Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

Determining the actual displacement *(continued)*

Step	Description
(II): 	sO_2 > 0.97 (or erroneous) and $p50$(st) is keyed in. Coordinates (P_0, S_0) are calculated from ($p50$(st), 0.5) using equations 46.9 and 46.11. Reference position of the ODC.
	The ODC is shifted from the reference position to pass through the point (P_0, S_0). In this position, the ODC reflects the $p50$(st) of the patient, i.e., the particular patient but at standard conditions.
	The ODC is further shifted, as determined by the effect of the measured parameters ("ac"), to its actual position. This position reflects the $p50$(act) of the patient.
(III): 	sO_2 > 0.97 (or erroneous) and no $p50$(st) has been keyed in. Reference position of the ODC.
	The position of the actual ODC can now be approximated from the reference position, using the actual values of pH, pCO_2, *F*COHb, *F*MetHb and *F*HbF to determine the shift 'ac'.

NOTE: *The curves are used only to illustrate the principles of the ODC determination*

Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

Coordinates on the ODC

Calculation of a set of coordinates on the ODC is symbolized by:

Eq. 47:

S = ODC(P, A, *T*) or P = ODC(S, A, *T*)

These equations are symbolic representations of the relationship between saturation (S), tension (P), displacement (A), and temperature (*T*).

To calculate S or P and to further calculate sO_2 and pO_2, the other variables should be specified. S and P are calculated using numerical methods.

P is input to equation 46.1.

S is input to equation 46.2.

A is input to equation 46.5.

T is input to equation 46.7.

Conversion of units

SI units

The equations stated above are based on the SI-unit-system. If parameters are known in other units, they must be converted into a SI-unit before entering the equations. The result will be in a SI-unit.

After the calculation the result may be converted to the desired unit. Conversion of units may be performed, using the equations stated below:

Temperature

$$T\,°\mathrm{F} = \frac{9}{5}T\,^{\circ}C + 32$$

$$T\,°\mathrm{C} = \frac{5}{9}(T\,^{\circ}F - 32)$$

***c*K$^+$, *c*Na$^+$, *c*Cl$^-$**

*c*X (meq/L) = *c*X (mmol/L) where X is K^+, Na^+ or Cl^-.

***c*Ca^{2+}**

$c\mathrm{Ca}^{2+}$ (meq/L) = 2 × $c\mathrm{Ca}^{2+}$ (mmol/L) or

$c\mathrm{Ca}^{2+}$ (mg/dL) = 4.008 × $c\mathrm{Ca}^{2+}$ (mmol/L)

$c\mathrm{Ca}^{2+}$ (mmol/L) = 0.5 × $c\mathrm{Ca}^{2+}$ (meq/L)or

$c\mathrm{Ca}^{2+}$ (mmol/L) = 0.2495 × $c\mathrm{Ca}^{2+}$ (mg/dL)

Pressure

p (mmHg) = *p* (torr) = 7.500638 × *p* (kPa)

p (kPa) = 0.133322 × *p*(mmHg) = 0.133322 × *p* (torr)

***c*tHb**

[4]

*c*tHb (g/dL) = 1.61140 × *c*tHb (mmol/L)

*c*tHb (g/L) = 16.1140 × *c*tHb (mmol/L) or

*c*tHb (mmol/L) = 0.62058 × *c*tHb (g/dL)

*c*tHb (mmol/L) = 0.062058 × *c*tHb (g/L)

***c*tCO$_2$, *c*tO$_2$, *c*tO$_2$(a–$\bar{v}$), *B*O$_2$**

Vol % = 2.241 × (mmol/L)

Vol % = mL/dL

mmol/L = 0.4462 × (mL/dL)

Continued on next page

Conversion of units, *Continued*

$\dot{V}O_2$ $\dot{V}O_2$ (mmol/L)/min = $\dot{V}O_2$/22.41 (mL/dL)/min

***c*Glucose** [22]

*c*Glucose (mg/dL) = 18.016 × *c*Glucose (mmol/L) or

*c*Glucose (mmol/L) = 0.055506 × *c*Glucose (mg/dL)

***c*Lactate** [22]

*c*Lactate (mg/dL) = 9.008 × *c*Lactate (mmol/L) or

*c*Lactate (mmol/L) = 0.11101 × *c*Lactate (mg/dL)

*c*Lactate (meq/L) = *c*Lactate (mmol/L)

(conversion based on the molecular weight of lactic acid)

***c*tBil**

*c*tBil (µmol/L) = 17.1 × *c*tBil (mg/dL)

*c*tBil (µmol/L) = 1.71 × *c*tBil (mg/L) or

*c*tBil (mg/dL) = 0.0585 × *c*tBil (µmol/L)

*c*tBil (mg/L) = 0.585 × *c*tBil (µmol/L)

NOTE: *All conversions of units are made by the analyzer.*

Default values

Values

The following default values are used in the ABL800 FLEX analyzers, if other values are not keyed-in.

T	=	37.0 °C (99 °F)
FO_2(I)	=	0.21 (21.0 %)
RQ	=	0.86
*c*tHb	=	9.3087 mmol/L, (15.00 g/dL or 150 g/L)
*F*COHb	=	0.004 (0.4 %)
*F*MetHb	=	0.004 (0.4 %)
*p*50(st)	=	3.578 kPa (26.84 mmHg)

Altitude correction

Equation for altitude correction

The barometric pressure is measured by the analyzer's built-in barometer, and the effect of barometric pressure on blood samples is compensated by the analyzer's software.

Quality control result for pO_2 obtained on aqueous quality control solutions at low barometric pressure (at high altitudes) is affected as the properties of aqueous solutions differ from those of blood. The deviation from the pO_2 value obtained at sea level can be expressed by an altitude correction that can be added to the control ranges.

The relationship between the altitude and barometric pressure can be expressed by the following equation:

$$A = 16000 \times (1 + 0.004T) \times \frac{B_{ref} - B_{act}}{B_{ref} + B_{act}}$$

where:

A = altitude in m

T = temperature in °C

B_{ref} = standard barometric pressure at sea level = 760 mmHg

B_{act} = actual barometric pressure in mmHg.

Reference [23].

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7. Solutions and gas mixtures

Overview

Introduction

This chapter gives information about all the solutions and gases used with the ABL800 FLEX analyzer, their composition, use, and consumption.

The Certificates of Traceability for the calibrating solutions are found at the end of the chapter.

Contents

This chapter contains the following topics.

General information

In Vitro Diagnostic Use	All the solutions described in this chapter are for *in vitro* diagnostic use.
Solution numbers	Each solution is identified with an "S" and is followed by 4 or 5 digits. The name of the solution comes after the number.
Gas names	The two gas mixtures used by the analyzer are named Gas 1 and Gas 2.
Expiration date	The expiration date of a solution found on the label or on a sticker on the side of the container is stated as a month and year. Do not use a product after its expiration date.
Safety Data Sheets	Safety Data Sheets for all solutions are available from your Radiometer distributor.
Re-ordering	Information for re-ordering solutions from Radiometer can be found in the ABL800 FLEX Operator’s Manual, *Chapter 14*.

Calibration solutions

S1820 and S1830

Use: For calibration of the pH, electrolyte and metabolite electrodes.

Quantity: 200 mL

Composition: Contains the following substances with the stated nominal concentrations:

Solution	Substance	Concentration (mmol/L)
S1820	K^+	4
	Na^+	145
	Ca^{2+}	1.25
	Cl^-	102
	*c*Glu	10
	*c*Lac	4
	buffer	Maintains a pH of 7.40
S1830	K^+	40
	Na^+	20
	Ca^{2+}	5
	Cl^-	50
	buffer	Maintains a pH of 6.9

The exact values are included in the bar code.

Additives: Preservatives and surfactants.

Storage: At 2-25 °C (36-77 °F).

Stability: Expiration date and Lot No. are printed on a label.

Stability in use: 4 weeks for S1820

8 weeks for S1830.

S7770 tHb

Use: For calibration of the cuvette optical path length in the ABL700 Series analyzers. The calibrated value can be *c*tHb, *c*tHb and *c*tBil, or *c*tBil depending on the analyzer version.

Quantity: 2 mL

Composition: Salts, a buffer, preservative and a coloring agent.

Storage: Keep in a dark place at 2 - 25 °C (36 - 77 °F).

After opening the solution must be used at once.

Rinse and Cleaning solutions

S4980 Rinse Solution	Use:	For rinsing the liquid transport system after each measurement or calibration.
	Quantity:	600 mL
	Composition:	Contains salts, buffer, anticoagulant, preservative, and surfactants.
	Storage:	At 2-32 ^{o}C (36-90 ^{o}F).
	Stability:	Expiration date and Lot No. are printed on a separate label.
		When stored between 2-32 ^{o}C (36-90 ^{o}F), S4970 is stable for 25 months from the date of production, if unopened.
S8370 Cleaning Solution	Use:	For cleaning the liquid transport system automatically or called by operator.
	Quantity:	200 mL
	Composition:	Contains salts, buffer, anticoagulant, preservatives, and surfactants.
	Storage:	At 2-32 ^{o}C (36-90 ^{o}F).
	Stability	Expiration date and Lot No. are printed on a separate label.
S5370 Cleaning Additive	Use:	For adding to the S8370 Cleaning solution.
	Composition:	Contains powdered streptokinase and streptodornase.
	Storage:	At 2-8 ^{o}C (36-46 ^{o}F).
	Stability:	Expiration date and Lot No. are printed on a separate label.
		The Cleaning Solution with the Cleaning Additive is stable for 2 months in use.
	WARNING/ CAUTION:	*Very toxic by inhalation, in contact with skin and if swallowed. Danger of cumulative effects. May cause sensitisation by inhalation and skin contact. Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing. In case of accident or if you feel unwell seek medical advice immediately (show the label if possible). The material and its container must be disposed of as hazardous waste.*

Electrolyte solutions

List of solutions The following electrolyte solutions contained in the electrode jackets of the Radiometer electrodes are used:

Electrolyte for…	Quantity	Composition
E1001 reference electrode	0.6 mL in 4 pre-filled electrode jackets per D711 Membrane Box	Organic compounds and inorganic salts*
E788 pCO_2 electrode	0.6 mL in 4 pre-filled electrode jackets per D788 Membrane Box	Inorganic salts, buffer, hygroscopic compound, preservative and surfactant.
E799 pO_2 electrode	0.6 mL in 4 pre-filled electrode jackets per D799 Membrane Box	Inorganic salts, organic compounds, buffer, preservative and surfactant.
E722 K electrode	0.6 mL in 4 pre-filled electrode jackets per D722 Membrane Box	Organic compounds, inorganic salts, buffer, acid, and preservative.
E755 Na electrode	0.6 mL in 4 pre-filled electrode jackets per D755 Membrane Box	Inorganic salts, organic compounds, preservative and surfactant.
E733 Ca electrode	0.6 mL in 4 pre-filled electrode jackets per D733 Membrane Box	Inorganic salts, organic compounds, buffer, preservative and surfactant.
E744 Cl electrode	0.6 mL in 4 pre-filled electrode jackets per D744 Membrane Box	Inorganic salts, organic compounds, preservative, surfactant and hygroscopic products.
E7066 Glucose and E7077 Lactate electrodes	0.6 mL in 5 plastic capsules to fill the electrode jackets (4 units) per D7066 and D7077 Membrane Boxes	Buffer, inorganic salts, thickening agent, preservative and surfactant.

****WARNING/CAUTION**: Irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advic*e.

Storage

Temperature:	Electrolyte solution:
2-25 °C (36-77 °F)	For glucose electrode
2-10 °C (36-50 °F)	For lactate electrode
2-32 °C (36-90 °F)	For all other electrodes

Stability Expiration date and Lot No. are printed on a label on the side of the membrane box.

S5362 Hypochlorite solution

S5362 Hypochlorite Solution	Use:	For protein removal and decontamination according to the procedures described in the Operator's Manual, chapter 4: *Analyzer Menus and Programs*.
	Quantity:	100 mL. Delivered with a 1 mL syringe.
	Composition:	Contains sodium hypochlorite (pH ≈12).
	Storage:	Keep in a dark place at 2-8 ^{o}C (36-46 ^{o}F). After use, keep the bottle tightly capped to avoid contamination and decomposition.
	Stability:	Expiration date and Lot No. are printed on a separate label on the bottle.

Gas mixtures (Gas 1 and Gas 2)

Use For calibration of the pCO_2 and pO_2 electrodes.

Cylinder types The following types of Gas 1 cylinders are used depending on the geographical location of the analyser:

	Gas 1			**Gas 2**
	EU	USA	Japan	
Cylinder Volume	1 L	1 L	1 L	1 L
Gas Volume	10 L	33 L	25 L	10 L
Fill Pressure at 25 °C	140 psi (10 bar)	500 psi (34 bar)	375 psi (26 bar)	140 psi (10 bar)
Composition	19.76 % O_2, 5.60 % CO_2 74.64 % N_2			< 0.04 % O_2, 11.22 % CO_2 88.78 % N_2

WARNING/ CAUTION: *Pressurized container. Non-flammable compressed gas. Do not breathe gas. Gas mixtures containing less than 19.5 % oxygen may cause suffocation. Protect from sunlight and do not expose to temperatures exceeding 50 °C (122 °F). Store and use with adequate ventilation. Keep away from oil and grease. Do not refill.*

NOTE: *The exact composition of each gas mixture is given in the barcode on the gas cylinder label. The barcode is entered by the barcode reader or manually.*

Stability Gas 1 and Gas 2 are stable for 25 months from the date of filling.

Storage The gas cylinders should be stored between 2 - 32 °C (36 - 90 °F).

Traceability certificates

Certificate of Traceability

Product name: Calibration Solution 1

Type: S1820

Code: 944-128

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
pH		The IUPACK pH scale and the NIST pH scale. The Chemical Reference Laboratory of Radiometer Medical A/S, which is the primary Danish national laboratory within pH, establishes the IUPAC pH scale under accreditation No. 119, granted by Danish Accreditation (DANAK).	0,009
cK^+	mmol/L (37 °C)	NIST SRM	0,03
cNa^+	mmol/L (37 °C)	NIST SRM	0,8
cCa^{2+}	mmol/L (37 °C)	Calcium transfer standards according to IFCC	0,01
cCl^-	mmol/L (37 °C)	NIST SRM	1,1
*c*Glucose	mmol/L (37 °C)	NIST SRM	0,3
*c*Lactate	mmol/L (37 °C)	L8+) Lactici AcidLithium Salt. SIGMA L-2250	0,2

Certification: Each lot of this product has been tested, and the control limits, specified on the insert included with this product, have been established with the above traceability.

Kristin Visby
Head of Production Laboratory

Bjarne Kristensen
H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

RADIOMETER COPENHAGEN

Certificate of Traceability

Product name: Calibration Solution 2

Type: S1830

Code: 944-129

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
pH		The IUPAC pH scale and the NIST pH scale. The Chemical Reference Laboratory of Radiometer Medical ApS, which is the primary Danish national laboratory within pH, establishes the IUPAC pH scale under accreditation No. 119, granted by Danish Accreditation (DANAK).	0.006
cK^+	mmol/L (37 °C)	NIST SRM	0.37
cNa^+	mmol/L (37 °C)	NIST SRM	0.4
cCa^{2+}	mmol/L (37 °C)	Calcium transfer standards according to IFCC	0.06
cCl^-	mmol/L (37 °C)	NIST SRM	0.5

Certification: Each lot of this product has been tested, and the true values given in the barcode of the label for this product have been established with the above traceability.

Kristin Visby
Head of Production Laboratory

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

RADIOMETER COPENHAGEN

Certificate of Traceability

Product name: tHB Calibration Solution

Type: S7770

Code: 944-021

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
*c*tHb	g/dl	NIST SRM (absorbance, wavelength). Hemoglobin-cyanide standard. J.T. Baker (Product No. 3061)	0.2
sO_2	%	NIST SRM (absorbance, wavelength). NIST SRM gas, whole blood sample, pH = 7.4, *c*tHb = 15 g%, sO_2 = 100 %	0.4

Certification: Each lot of this product has been tested, and the control limits, specified on the insert included with this product, have been established with the above traceability.

Helle Søderstrøm
Head of Production Laboratory

Bjarne Kristensen
H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

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RADIOMETER COPENHAGEN

Certificate of Traceability

Product name: Calibration Gas 1, EUR

Type: Gas mixture, 1 L

Code: 962-169

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.03
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

RADIOMETER COPENHAGEN

Certificate of Traceability

Product name: Calibration Gas 2, EUR

Type: Gas mixture, 1 L

Code: 962-170

Traceability of parameters:

Parameter	Unit	Traceable to	Expanded Uncertainty
CO_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.03
O_2	mol %	Primary, gravimetrically prepared standards. Traceable to NIST traceable weights.	0.03

Certification: Each lot of this product has been tested, and the nominal values, specified on the label of this product, have been established with the above traceability.

Bjarne Kristensen

H.B. Kristensen
Head of Chemical Reference Laboratory

The traceability of the above parameters is fully described in booklet AS 117: *Traceability to the Primary Reference Standards at Radiometer*, available from Radiometer.

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RADIOMETER COPENHAGEN

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Date of Issue

Manufacturer: RADIOMETER COPENHAGEN

Radiometer Representative:

ABL800 FLEX Reference Manual
from software identification version 4.12

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