

ABL800 FLEX

Reference manual

Contents

1. Potentiometric measuring principles

2. Amperometric measuring principles

3. Optical measuring principles

4. User-defined corrections

5. Performance specifications

6. Parameters

7. Solutions and gas mixtures

Index

Date of Issue

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

ABL™, Deep Picture™, QUALICHECK™ and Radiometer™ are trademarks of Radiometer Medical ApS, Denmark.

ABL is registered in the USA.

QUALICHECK is registered in the USA and in some other countries.

COPYRIGHT

The contents of this document may not be reproduced in any form or communicated to any third party without the prior written consent of Radiometer Medical ApS.

While every effort is made to ensure the correctness of the information provided in this document Radiometer Medical ApS assumes no responsibility for errors or omissions which nevertheless may occur.

This document is subjected to change without notice.

©Radiometer Medical ApS, DK-2700 Brønshøj, Denmark, 2006. All Rights Reserved.

Contents

| | |
|---|------------|
| 1. Potentiometric measuring principles | 1-1 |
| Overview | 1-1 |
| General information | 1-2 |
| Reference electrode | 1-8 |
| pH electrode | 1-9 |
| <i>p</i> CO ₂ electrode | 1-14 |
| Electrolyte electrodes | 1-22 |
| References | 1-34 |
| 2. Amperometric measuring principles | 2-1 |
| Overview | 2-1 |
| General information | 2-2 |
| pO ₂ electrode | 2-4 |
| Metabolite electrodes | 2-12 |
| 3. Optical measuring principles..... | 3-1 |
| Overview | 3-1 |
| Optical system | 3-2 |
| Correcting for interferences..... | 3-7 |
| Measurement and corrections..... | 3-9 |
| References | 3-14 |
| 4. User-defined corrections | 4-1 |
| Overview | 4-1 |
| General information | 4-2 |
| Correction factors for oximetry parameters and bilirubin..... | 4-4 |
| Electrolyte and metabolite parameters | 4-7 |
| 5. Performance characteristics | 5-1 |
| Overview | 5-1 |
| Definition of terms and test conditions | 5-2 |
| Performance test results – chart description..... | 5-5 |
| Performance test results - pH | 5-8 |
| Performance test results – <i>p</i> CO ₂ | 5-10 |
| Performance test results – <i>p</i> O ₂ | 5-13 |
| Performance test results – <i>c</i> K ⁺ | 5-16 |

| | |
|--|------------|
| Performance test results – $c\text{Na}^+$ | 5-18 |
| Performance test results – $c\text{Cl}^-$ | 5-20 |
| Performance test results – $c\text{Ca}^{2+}$ | 5-22 |
| Performance test results – $c\text{Glu}$ | 5-24 |
| Performance test results – $c\text{Lac}$ | 5-26 |
| Performance test results – $c\text{tHb}$ | 5-28 |
| Performance test results - oximetry | 5-30 |
| Performance test results - bilirubin..... | 5-40 |
| Additional information about FLEXMODE | 5-46 |
| Interference tests..... | 5-47 |
| References | 5-55 |
| | |
| 6. Parameters | 6-1 |
| Overview | 6-1 |
| General information | 6-2 |
| Measured parameters..... | 6-5 |
| Input parameters | 6-14 |
| Derived parameters..... | 6-17 |
| Units and numerical format of derived parameters | 6-22 |
| List of equations | 6-27 |
| Oxyhemoglobin dissociation curve (ODC)..... | 6-43 |
| Conversion of units | 6-48 |
| Default values..... | 6-50 |
| Altitude correction..... | 6-51 |
| References | 6-52 |

Index

Date of Issue

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 advice

- 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 °C (122 °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, $p\text{CO}_2$ and electrolyte electrodes that are based on this principle.

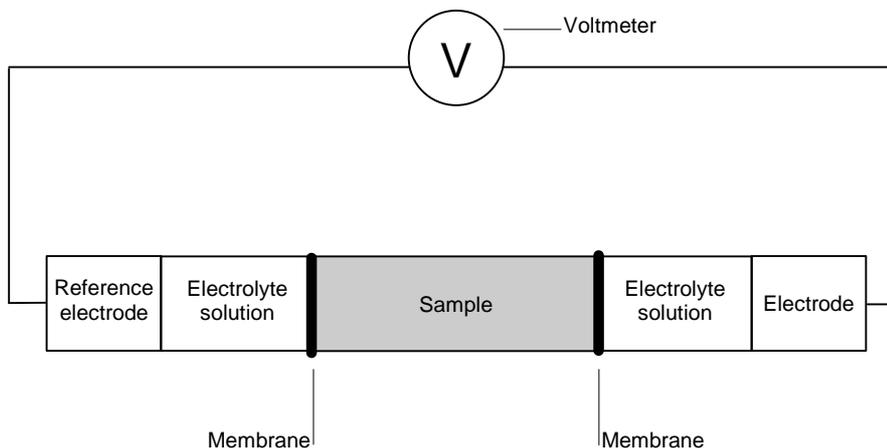
Contents This chapter contains the following topics.

| | |
|--------------------------------|------|
| General information | 1-2 |
| Reference electrode | 1-8 |
| pH electrode | 1-9 |
| $p\text{CO}_2$ electrode | 1-14 |
| Electrolyte electrodes | 1-22 |
| References | 1-34 |

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, $p\text{CO}_2$, 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.

$$E_{total} = E_{sample} - E_{Ref}$$

where the final unknown potential (E_{sample}) can be calculated knowing the total electrode chain potential (E_{total}) and the reference potential (E_{Ref} that is constant between two subsequent calibrations).

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

$$E_{sample} = E_0 + \frac{2.3RT}{nF} \log a_x$$

where:

- E_0 = standard electrode potential
- R = gas constant ($8.3143 \text{ Joule} \times \text{K}^{-1} \times \text{mol}^{-1}$)
- 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 \times 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.

Continued on next page

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/pCO₂/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.

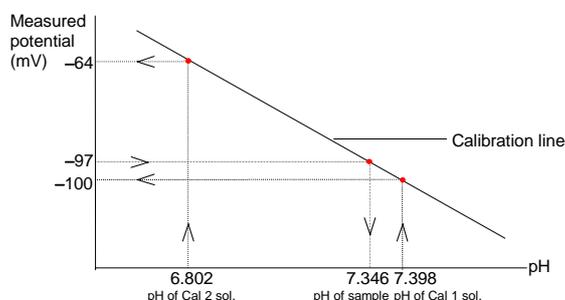
Calibration line

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:



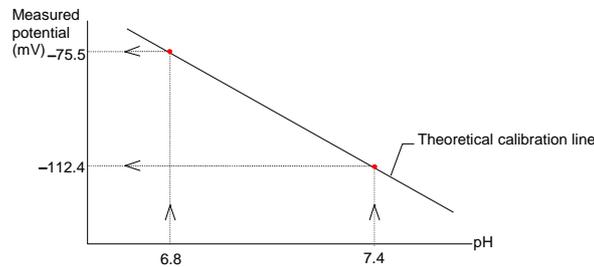
This is a two-point calibration. In one-point calibration, only the position of the calibration line is determined. The slope of the calibration line is maintained from the last 2-point calibration.

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.

Continued on next page

General information, *Continued*

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

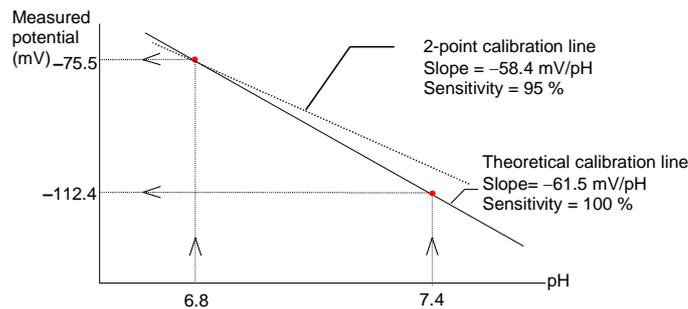


The theoretical electrode is defined to measure the following:
 -112.4 mV at pH 7.400,
 -75.5 mV at pH 6.800.

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:

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

where 61.5 = sensitivity of theoretical electrode.

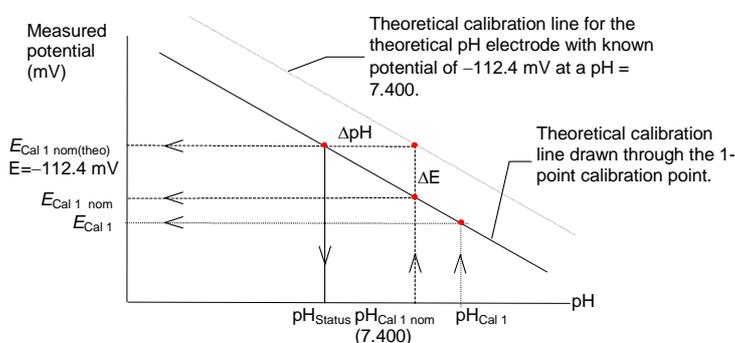
Each electrode has its own sensitivity limits.

Continued on next page

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:

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

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 $p\text{CO}_2$ 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 $p\text{CO}_2$ electrode |

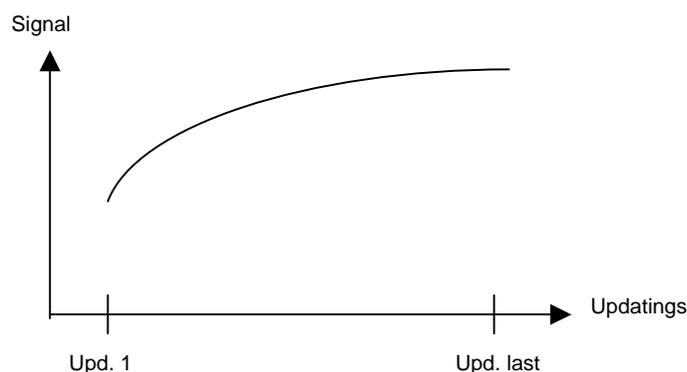
The Chemical Reference Laboratory at Radiometer is responsible for the accuracy of the calibrating solutions. Traceability certificates for the individual solutions are enclosed in Chapter 7: *Solutions and Gas Mixtures*.

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.



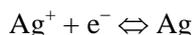
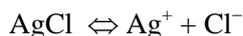
Reference electrode

Description

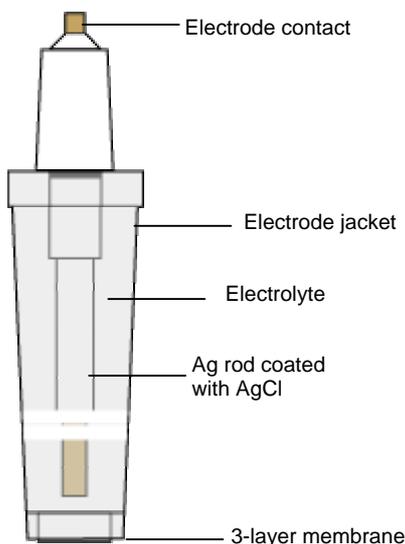
The reference electrode is used in the measurement of pH and electrolyte parameters and is located in the pH/Blood Gas module.

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:



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:

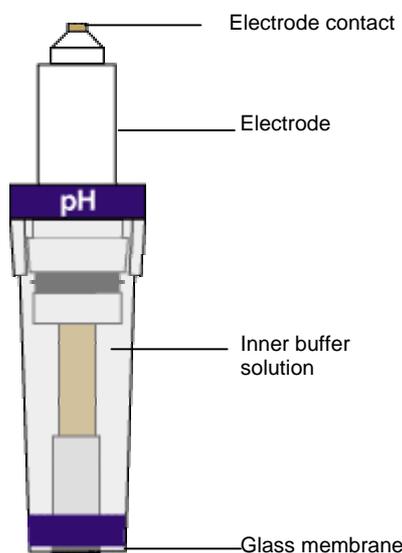
| Membrane | Function |
|----------|---|
| Inner | To limit diffusion through the membrane and stabilizes the whole membrane system. |
| Middle | To prevent protein interference. |
| Outer | To reduce the interchange of sample or rinse solution and HCOONa solution. |

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 $\text{pH} = -\log [\text{H}^+]$, and converting concentration to activity, the Nernst equation can be expressed as:

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

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:

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

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:

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

NOTE: Under normal circumstances, $pH(Cal1) - pH(Cal1, \text{prev}) = 0$. However in instances where the Cal 1 solution container has been replaced between two consecutive calibrations, $pH(Cal1) - pH(Cal1, \text{prev}) \neq 0$.

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

Drift 2 is calculated from the following equation:

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

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

Continued on next page

pH electrode, *Continued*

Measurement The sample pH is calculated as follows:

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

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

Equation A:

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

where:

pH(sample) = uncorrected pH value of the sample

pH(sample,corr.) = corrected pH value of the sample.

A₀ = instrument-dependent correction factor

A₁ = 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 | Mode | A ₀ | A ₁ | Equation |
|------------------|------------------------|----------------|----------------|----------|
| 35/25/15 FLEX | 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+ |
| | FLEXMODE (message 870) | 1.030 | -0.216 | A+ |
| | FLEXMODE (message 869) | 1.030 | -0.216 | A+ |

Continued on next page

pH electrode, *Continued***Corrections
(*continued*)**

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|-------------------------------------|------------------------|----------------|----------------|----------|
| 30/20/10/ 10 BG only FLEX | 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 FLEX | 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+ |
| 00 BASIC | 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+ |

Continued on next page

pH electrode, *Continued*

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

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

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

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

where:

$\text{pH}(\text{sample, upd.last}) =$ pH value from the last updating with a measurement on calibration solution or sample. (The last updating is number 30).

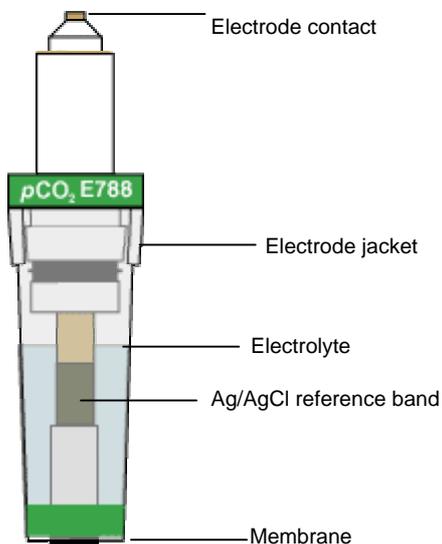
$\text{pH}(\text{sample, upd.i}) =$ pH value for a given updating with a measurement on calibration solution or sample. (The relationship must be fulfilled for at least one of the updating numbers 20 or 21).

$\text{pH}(\text{limit}) =$ pH limiting value for the stability criterion (0.005).

pCO₂ electrode

Description

The pCO₂ electrode (E788) is a combined pH and Ag/AgCl reference electrode mounted in a plastic jacket, which is filled with a bicarbonate electrolyte.



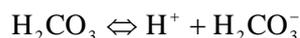
The jacket is covered by a 20 µm silicone membrane moulded on a 50 µm nylon net. The net both reinforces the silicone membrane and serves as a spacer in order to trap a layer of the electrolyte between the membrane and the glass tip of the electrode. The electrolyte also contains glycerol to prevent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

The membrane allows any uncharged molecules of CO₂, O₂, N₂ to pass through it. Charged ions such as H⁺ will not pass. Consequently, dissolved CO₂ from the sample will diffuse into the thin layer of bicarbonate electrolyte until the equilibrium is reached.

This produces carbonic acid:



Carbonic acid dissociates according to the following equilibrium reaction:



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:

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

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

Continued on next page

pCO₂ electrode, Continued

Nernst equation (continued) The pH value is related to the partial pressure of CO₂ in the sample by the following equation:

$$\text{pH} = \text{pK}_a + \log \frac{c\text{HCO}_3^-}{p\text{CO}_2 \times \alpha_{\text{CO}_2}}$$

where:

$\text{pK}_a = -\log K_a$, the equilibrium constant for the dissociation of carbonic acid in water

α_{CO_2} = solubility coefficient for CO₂ in water

The bicarbonate concentration $[\text{HCO}_3^-]$ is so large compared to $[\text{H}^+]$ that it can be considered constant. At constant temperatures α_{CO_2} is also constant. So the equation can be simplified to:

$$\text{pH} = K' - \log p\text{CO}_2$$

where:

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

$K_a = \frac{c\text{H}^+ \times c\text{HCO}_3^-}{\text{CO}_2}$ is the equilibrium constant for carbonic acid.

$p\text{CO}_2$ of the sample is then calculated from the equation above.

Designation

The following symbols are used:

| | | |
|---|---|--|
| $p\text{CO}_2(\text{Gas1}),$ $p\text{CO}_2(\text{Gas2})$ | = | Pressure of CO ₂ in Gas 1 or Gas 2, respectively |
| $F\text{CO}_2(\text{Gas1}),$ $F\text{CO}_2(\text{Gas2})$ | = | Fraction of CO ₂ in Gas 1 or Gas 2, respectively |
| $B_{\text{Gas 1 or 2}}$ | = | Pressure inside the measuring chamber during a measurement on Gas 1 or Gas 2 respectively |
| $p\text{H}_2\text{O}$ | = | Water vapor pressure (6.2751 kPa at 37 °C) |
| $E(\text{CO}_2, \text{Gas1}),$ $E(\text{CO}_2, \text{Gas2})$ | = | Potential of the $p\text{CO}_2$ electrode from a measurement on Gas 1 or Gas 2, respectively |
| $\text{Sens}(p\text{CO}_2, \text{theo})$ | = | Theoretical (absolute) sensitivity of the $p\text{CO}_2$ electrode at 37 °C |
| $\text{Sens}(p\text{CO}_2, \text{prev})$ | = | Relative sensitivity of the $p\text{CO}_2$ electrode from the previous 2-point calibration |

Continued on next page

pCO₂ electrode, Continued

| | | | |
|------------------------------------|-------------------------------------|---|--|
| Designation (continued) | $E_0(\text{CO}_2, \text{Gas1})$ | = | Standard potential of the $p\text{CO}_2$ electrode with Gas 1 |
| | $E(\text{CO}_2, \text{Gas1, prev})$ | = | Potential of the $p\text{CO}_2$ electrode from the previous measurement on Gas 1 |
| | δ | = | difference between $p\text{CO}_2$ (sample) from the first and last updatings. |
| | predict | = | extrapolated value for $p\text{CO}_2$. |

Sensitivity The $p\text{CO}_2$ 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:

$$p\text{CO}_2(\text{Gas1}) = F\text{CO}_2(\text{Gas1}) \times (B_{\text{Gas1}} - p\text{H}_2\text{O}) \quad \text{kPa}$$

$$p\text{CO}_2(\text{Gas2}) = F\text{CO}_2(\text{Gas2}) \times (B_{\text{Gas2}} - p\text{H}_2\text{O}) \quad \text{kPa}$$

The relative sensitivity of the $p\text{CO}_2$ electrode is calculated as follows:

$$\text{Sens}(p\text{CO}_2) = \frac{E(\text{CO}_2, \text{Gas2}) - E(\text{CO}_2, \text{Gas1})}{\text{Sens}(p\text{CO}_2, \text{theo}) \times \log \frac{p\text{CO}_2(\text{Gas2})}{p\text{CO}_2(\text{Gas1})}}$$

The sensitivity of the $p\text{CO}_2$ electrode should fall between 0.85 -1.00 or 85 - 100 %.

Status The status of the $p\text{CO}_2$ electrode is calculated as follows:

$$\text{Status}(p\text{CO}_2) = p\text{CO}_2(\text{Gas1}) \times 10^{\frac{E(\text{CO}_2, \text{Gas1}) - E_0(\text{CO}_2, \text{Gas1})}{\text{Sens}(p\text{CO}_2, \text{theo})}} \quad \text{kPa}$$

The status of the $p\text{CO}_2$ electrode should fall between 6.2-260 mmHg /(0.83-34.66 kPa).

Drift Drift 1 is calculated as follows:

$$\text{Drift 1}(p\text{CO}_2) = p\text{CO}_2(\text{Gas1}) \times 10^{\frac{E(\text{CO}_2, \text{Gas1}) - E(\text{CO}_2, \text{Gas1, prev})}{\text{Sens}(p\text{CO}_2, \text{prev}) \times \text{Sens}(p\text{CO}_2, \text{theo})}} - p\text{CO}_2(\text{Gas1, prev}) \text{ kPa}$$

Drift 2 is calculated as follows:

$$\text{Drift 2}(p\text{CO}_2) = p\text{CO}_2(\text{Gas2}) \times 10^{\frac{E(\text{CO}_2, \text{Gas2}) - E(\text{CO}_2, \text{Gas1, prev})}{\text{Sens}(p\text{CO}_2, \text{prev}) \times \text{Sens}(p\text{CO}_2, \text{theo})}} - p\text{CO}_2(\text{Gas2, prev}) \text{ kPa}$$

Continued on next page

pCO₂ 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 $p\text{CO}_2$ value for a sample is calculated from the following equations:

$$p\text{CO}_2(\text{sample, updi}) = p\text{CO}_2(\text{gas1}) \times 10^{\frac{E(\text{CO}_2\text{sample, updi}) - E(\text{CO}_2\text{Gas1})}{\text{Sens}(p\text{CO}_2, \text{prev}) \times \text{Sens}(p\text{CO}_2, \text{theo})}}$$

$$\delta = |p\text{CO}_2(\text{sample, upd30}) - p\text{CO}_2(\text{sample, upd1})|$$

$$\text{predict} = \frac{p\text{CO}_2(\text{sample, upd6}) \times p\text{CO}_2(\text{sample, upd30}) - [p\text{CO}_2(\text{sample, upd18})]^2}{p\text{CO}_2(\text{sample, upd6}) + p\text{CO}_2(\text{sample, upd30}) - 2 \times p\text{CO}_2(\text{sample, upd18})}$$

For $\delta < 1.33$ kPa, $p\text{CO}_2(\text{sample}) = p\text{CO}_2(\text{sample, upd30})$

For $1.33 \text{ kPa} < \delta < 2.66 \text{ kPa}$

$$p\text{CO}_2(\text{sample}) = \frac{\text{predict} \times (\delta - 1.33) + p\text{CO}_2(\text{sample, upd30}) \times (2.66 - \delta)}{1.33}$$

For $\delta \geq 2.66$ kPa, $p\text{CO}_2(\text{sample}) = \text{predict}$.

Corrections - blood samples The $p\text{CO}_2$ measured on a sample is then corrected for systematic deviations from the reference method using the following equations:

Equation A:

$$p\text{CO}_2(\text{sample, corr}) = A_3 \times p\text{CO}_2(\text{sample})^3 + A_2 \times p\text{CO}_2(\text{sample})^2 + A_0 \times p\text{CO}_2(\text{sample}) + A_1 \times (B - p\text{H}_2\text{O})$$

and

Equation B:

$$p\text{CO}_2(\text{sample, corr}) = B_1 \times p\text{CO}_2(\text{sample}) + B_0$$

where: $p\text{CO}_2(\text{sample})$ = uncorrected value of $p\text{CO}_2$ in the sample.

$p\text{CO}_2(\text{sample, corr})$ = corrected value of $p\text{CO}_2$ in the sample.

A_0 = correction factor

A_1 = correction factor

A_2 = correction factor

A_3 = correction factor

Continued on next page

pCO₂ electrode, Continued**Corrections -
blood samples
(continued)**

| | |
|-------------------|--|
| B | = barometric pressure in kPa |
| pH ₂ O | = partial pressure of saturated water vapor (6.2751 kPa) |
| B ₀ | = correction cut-off |
| B ₁ | = correction factor |

| ABL8XX | Mode | A ₀ | A ₁ | A ₂ | A ₃ | B ₀ | B ₁ | Eq. |
|---------------------------------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|------|
| 35/25/15 FLEX | 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/ 10 BG only FLEX | S85 | -0.003573 | 1.1126 | 0.0051 | -0.0000002 | | | A |
| | 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 | 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

pCO₂ electrode, Continued**Corrections -
blood samples
(continued)**

| ABL8XX | Mode | A ₀ | A ₁ | A ₂ | A ₃ | B ₀ | B ₁ | Eq. |
|-------------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|------|
| 05 FLEX | 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 BASIC | 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 = FLEXMODE.

**Corrections -
expired air
samples**

The pCO₂ measured from the sample is then corrected for systematic deviations from the reference method using the following equation:

$$p\text{CO}_2(\text{sample, corr}) = A_0 \times p\text{CO}_2(\text{sample}) + A_1 \times (B - p\text{H}_2\text{O}) \quad \text{Equation A}$$

where:

pCO₂(sample) = uncorrected pCO₂ value of a expired air sample

pCO₂(sample, corr) = corrected pCO₂ value of a expired air sample

A₀ = instrument dependent correction factor

A₁ = instrument-dependent correction factor

B = barometric pressure during the measurement

pH₂O = partial pressure of saturated water vapour = 6.2751 kPa

Continued on next page

pCO₂ electrode, Continued

**Corrections -
expired air
samples
(continued)**

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|-----------------------|-------------|----------------|----------------|----------|
| All FLEX and BASIC | Expired air | 1.0196 | -0.00106 | A |

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

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

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

| Parameter | pCO 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) | |

pCO₂(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:

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

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

For $\delta > 1.33$ kPa:

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

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

or

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

Continued on next page

pCO₂ electrode, Continued

Stability criteria Expired air samples:
(*continued*)

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

$$|p\text{CO}_2(\text{sample,upd.30}) - p\text{CO}_2(\text{sample,upd.24})| \leq 0.40 \text{ kPa (3.0 mmHg)}$$

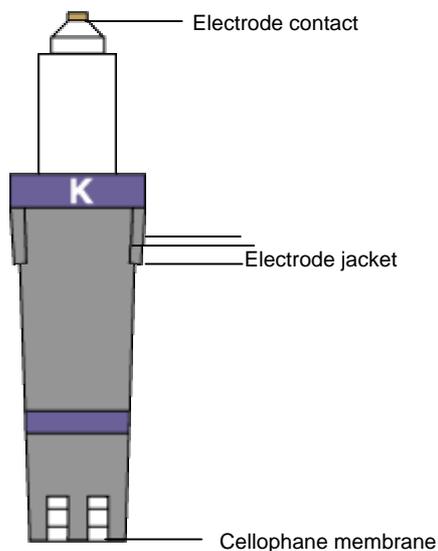
or

$$|p\text{CO}_2(\text{sample,upd.30}) - p\text{CO}_2(\text{sample,upd.24})| \leq 0.04 \times p\text{CO}_2(\text{sample,upd.30}).$$

Error message "Measurement unstable" (= $p\text{CO}_2$ response fault during electrode monitoring in Expired air mode) is displayed if the stability criterion is not fulfilled.

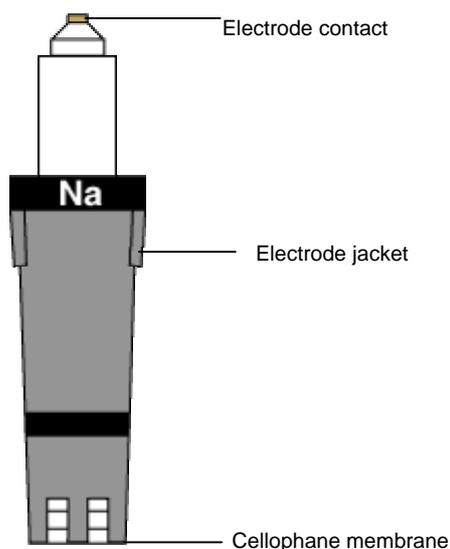
Electrolyte electrodes

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.



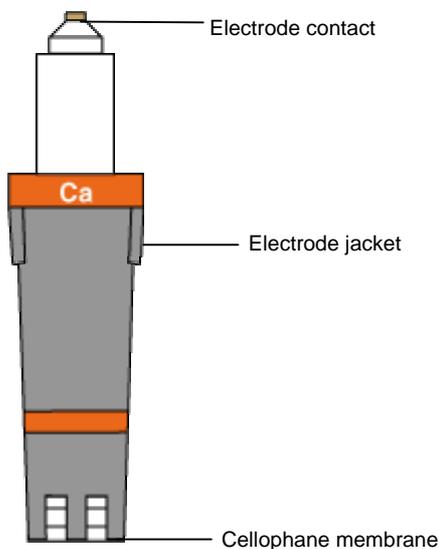
The Na electrode (E755) is an ion-selective electrode whose sensing element is a Na⁺-sensitive ceramic pin contained in the tip of the jacket.

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.

Continued on next page

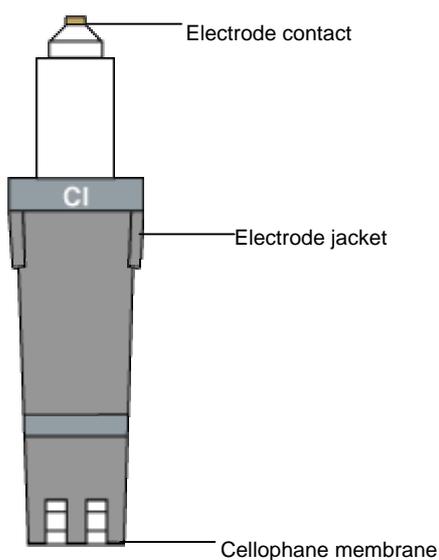
Electrolyte electrodes, *Continued*

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 $c\text{Ca}^{2+}$ 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 $c\text{Cl}^-$ in both solutions is the same, the potential across the electrode tip will be 0 V.

Continued on next page

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:

$$E_{\text{Sample}} = E_{\text{tot}} - (E_{\text{ref}} + E_{\text{MJ}} + E_{\text{E}}) \quad \text{mV}$$

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

$$E_{\text{Sample}} = E_0 + \frac{2.3RT}{nF} \times \log a_{\text{ion}} \quad \text{mV}$$

where:

E_0 = standard electrode potential

R = gas constant (8.3143 J×K⁻¹mol⁻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 Ca²⁺)

F = Faraday constant (96487 coulomb × mol⁻¹)

a_{ion} = activity of the specific ion

Continued on next page

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 calibration 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 |
| $cX (Cal1)$ | = | Concentration of the respective electrolyte ion in Cal 1 solution |
| $cX (Cal2)$ | = | Concentration of the respective electrolyte ion in Cal 2 solution |
| $E_0(X, Cal1)$ | = | Standard potential of the respective electrolyte electrode chain |
| $cX (Cal1, nom)$ | = | 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 |
| $cX (Cal1, prev)$ | = | Concentration of the respective electrolyte ion in Cal 1 solution in the previous calibration |

Continued on next page

Electrolyte electrodes, *Continued*

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

K electrode

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

Na electrode

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

Ca electrode

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

Cl electrode

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

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

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

Na electrode

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

Continued on next page

Electrolyte electrodes, *Continued*

Status
(*continued*)

Ca electrode

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

Cl electrode

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

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

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

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

Na electrode

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

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

Ca electrode

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

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

Continued on next page

Electrolyte electrodes, *Continued*

Drift (*continued*) Cl electrode

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

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

NOTE: If Cal 1 solution bottle has not been changed between two consecutive calibrations, the $cX(\text{Cal1,prev}) - cX(\text{Cal1}) = 0$, 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:

$$cX(\text{sample}) = cX(\text{Cal 1}) \times 10^{\frac{E(X,\text{sample}) - E(X,\text{Cal,prev})}{\text{Sens(theo)} \times \text{Sens(X,prev)}}$$

where:

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

Continued on next page

Electrolyte electrodes, *Continued*

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

Equation A:

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

and

Equation B:

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

where:

$cX(\text{sample})$ = uncorrected value of the electrolyte ion in the sample

$cX(\text{sample,corr})$ = corrected value of the electrolyte ion in the sample

A_0 = instrument-dependent correction factor

A_1 = instrument-dependent correction cut-off

Chloride is corrected for $c\text{HCO}_3^-$ interference. The default value $c\text{HCO}_3^- = 24.5$ mmol/L is used in

Equation C:

$$c\text{Cl}^-(\text{sample,corr})_{195\mu\text{L}} = A_{0(195\mu\text{L})} \times (c\text{Cl}^-(\text{sample}) - 0.0956 \times c\text{HCO}_3^-) + A_{1(195\mu\text{L})}$$

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 $c\text{Na}^+$:

| ABL8XX | Mode | A_0 | A_1 | Equation |
|----------|-------------------|-------|-------|----------|
| 35/25/15 | S195 | 0.995 | -3.00 | A |
| FLEX | 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.

Continued on next page

Electrolyte electrodes, *Continued*

Corrections (*continued*)

Corrections for $c\text{Na}^+$ (cont):

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|----------|-------------------|----------------|----------------|----------|
| 05 FLEX | 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 |
| 00 BASIC | S195 | 0.995 | -3.00 | A |
| | S95 | 1.01 | 1.80 | A, B |
| | C95 | 1.03 | -1.09 | A, B |

*FM = FLEXMODE.

Corrections for $c\text{K}^+$:

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|------------------|-------------------|----------------|----------------|----------|
| 35/25/15 FLEX | 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 FLEX | 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 |
| 00 BASIC | S195 | 0.985 | -0.065 | A |
| | S95 | 1.05 | -0.13 | A, B |
| | C95 | 1.11 | -0.37 | A, B |

*FM = FLEXMODE.

Continued on next page

Electrolyte electrodes, *Continued*

Corrections
(*continued*)

Corrections for cCa^{2+} :

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|------------------|-------------------|----------------|----------------|----------|
| 35/25/15 FLEX | 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 FLEX | 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 |
| 00 BASIC | S195 | 1.004 | -0.022 | A |
| | S95 | 1.05 | -0.004 | A, B |
| | C95 | 1.08 | -0.04 | A, B |

*FM = FLEXMODE.

Corrections for cCl^- :

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|------------------|-------------------|----------------|----------------|----------|
| 35/25/15 FLEX | S195 | 1.225 | -30.7 | A |
| | 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 FLEX | 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 |
| 00 BASIC | S195 | 1.225 | -30.7 | A |
| | S95 | 1.000 | 0.0 | C, B |
| | C95 | 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:

$$|cX(\text{Cal, upd.last}) - cX(\text{Cal, upd.i})| \leq K \times cX(\text{Cal, upd.last})$$

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

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

$cX(\text{Cal, upd.i}) =$ 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:

$$|cX(\text{sample, upd.last}) - cX(\text{sample, upd.i})| \leq K \times (|cX(\text{sample, upd.last}) - cX(\text{Rinse})| + cX(\text{Rinse}))$$

where:

$cX(\text{sample, upd.last}) =$ Concentration of the electrolyte ion from the median of the last 5 updatings (for Ca²⁺: 3 last updatings) when measuring on a sample. The last updating number is 30 (or 10 for some micromodes).

$cX(\text{sample, upd.i}) =$ 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, subtract 20 from number above.

Continued on next page

Electrolyte electrodes, *Continued*

| | | |
|---|---------------------|---|
| Stability criteria <i>(continued)</i> | 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.

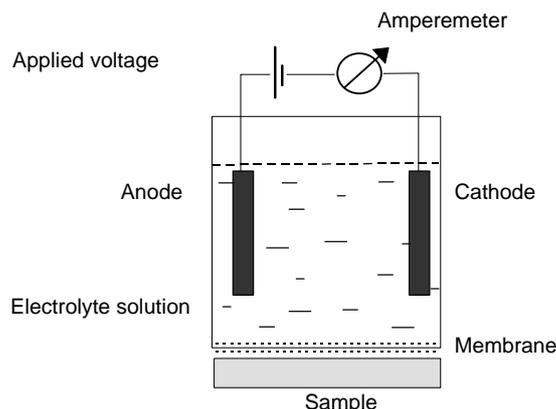
Contents This chapter contains the following topics.

| | |
|-----------------------------|------|
| General information | 2-2 |
| pO_2 electrode | 2-4 |
| Metabolite electrodes | 2-12 |

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 **A⁻**.
- there is a species **X** in the electrolyte which is oxidized at the anode to **X⁺**.

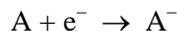
Continued on next page

General information, *Continued*

Amperometric method
(*continued*)

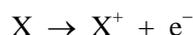
The membrane is selective to the species **A**, allowing no other species but it to pass through from the sample into the electrolyte solution.

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



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:



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

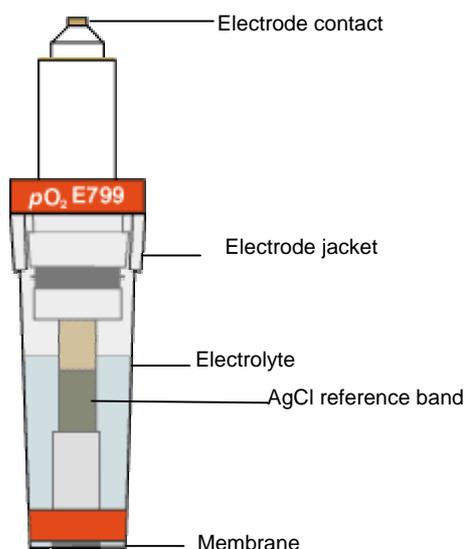
The following calibration materials are used:

| | |
|--|--|
| 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

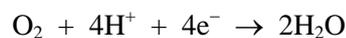
Description

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.



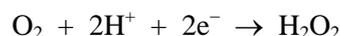
The electrode chain is polarized with constant voltage of -630 mV.

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:

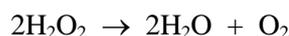


The H^+ ions come from the electrolyte solution.

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



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



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:

$$I = \text{Sens}(pO_2) \times pO_2 + I_0 \quad \text{pA}$$

where:

$\text{Sens}(pO_2)$ = Sensitivity of the pO_2 electrode

pO_2 = Partial pressure of O_2 in the sample

I_0 = 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^+ :



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:



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:

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

Continued on next page

pO₂ electrode, Continued

Sensitivity (continued)

The partial pressures of O₂ in the gas mixtures Gas 1 and Gas 2 are calculated from the following equation:

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

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

The sensitivity of the *pO₂* electrode should fall between 5 - 40 pA/mmHg or 37.5 - 300 pA/kPa.

Zero point

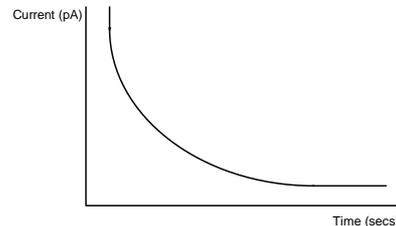
The zero point of the *pO₂* electrode is the electrode current at *pO₂*=0. It is calculated from the current measured at the electrode with Gas 2 (0 % O₂), and the sensitivity:

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

The zero point value of the *pO₂* electrode should be less than 6.0 mmHg or 0.80 kPa.

The zero point current is the current measured at the *pO₂* electrode with Gas 2 in the measuring chamber. When the measurement on Gas 2 begins, a relatively high current is recorded due to residual O₂ 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:

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

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.

Continued on next page

pO_2 electrode, *Continued*

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

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

Constant K_1 describes the gas/liquid relationship for the electrode.

This constant is defined as:

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

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

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

where:

| | |
|---------------------------------|---|
| $I(O_2, \text{sample, updi}) =$ | Current recorded at the pO_2 electrode from updating number i with a measurement on the sample. |
| $I(O_2, \text{gas2, prev}) =$ | 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 $pO_2(\text{sample})$ from the first and last updatings. |
| $\text{predict} =$ | Extrapolated value for pO_2 . |

For $\delta < 2.66$ kPa,

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

For $2.66 \text{ kPa} < \delta < 5.32 \text{ kPa}$

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

For $\delta \geq 5.32$ kPa

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

Continued on next page

pO₂ 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:

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

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 | = $e_0 \times pO_2(\text{sample, v1}) + e_1$ |
| 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 $pO_2(\text{sample})$ 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 $pO_2(\text{sample})$ 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

pO₂ electrode, Continued**Corrections – blood samples (continued)**

| ABL 8XX | Mode | e ₀ | e ₁ | e ₂ | e ₃ | e ₄ | A ₀ | A ₁ | Eq. |
|--|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----|
| 35/25/ 15 FLEX | S195 | -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+ | |
| 30/20/ 10/ 10 BG only FLEX | S85 | -2.30300 | 5.96942 | 0.83281 | -6.07310 | 1.30565 | | | A |
| | 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 FLEX | 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 BASIC | S195 | -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 = FLEXMODE.

Continued on next page

pO₂ 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:

| | |
|----------------------------|---|
| $pO_2(\text{sample})$ | = uncorrected pO_2 value of a expired air sample |
| $pO_2(\text{sample,corr})$ | = 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 |

| ABL8XX | Mode | A₀ | A₁ | Equation |
|--------------------|-------------|----------------------|----------------------|-----------------|
| All FLEX and BASIC | 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**:

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

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

| Parameter | <i>pO₂ value from the last updating number...</i> | |
|---|---|--------------------|
| | ABL8X5 FLEX/ ABL800 BASIC | ABL8X0 FLEX |
| $pO_2(\text{Gas 1, upd.last})$ | 92 | 62 |
| $pO_2(\text{Gas 1, upd.i})$ | 86 or 87 | 56 or 57 |
| (the relationship must be fulfilled for at least one of the updating numbers) | | |

$pO_2(\text{limit})$ value for the stability criterion is 0.80 kPa/6.0 mmHg.

Continued on next page

pO_2 electrode, *Continued*

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

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

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

For $\delta > 2.66$ 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

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

Expired air samples:

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

$$|pO_2(\text{sample, upd.30}) - pO_2(\text{sample, upd.24})| \leq 0.80 \text{ kPa} / 6.0 \text{ mmHg},$$

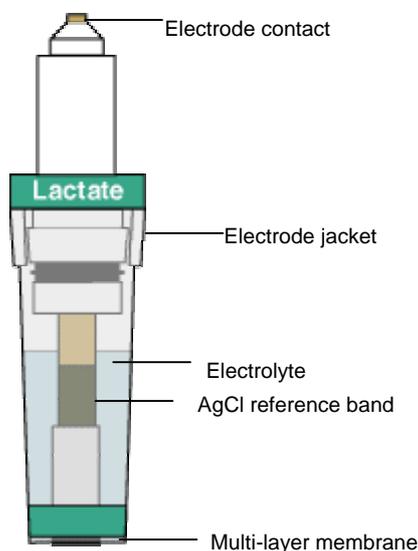
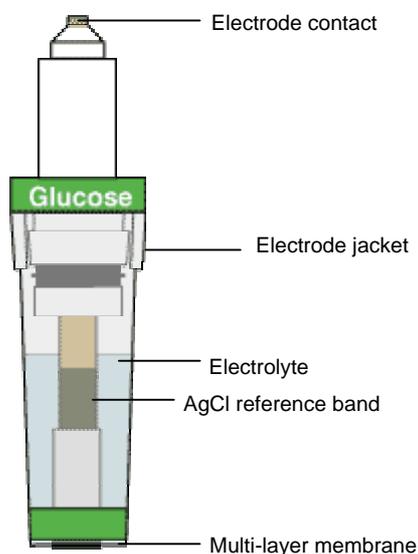
or

$$|pO_2(\text{sample, upd.30}) - pO_2(\text{sample, upd.24})| \leq 0.05 \times pO_2(\text{sample, upd.30}).$$

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.

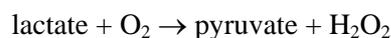
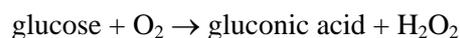
The membrane consisting of three layers:

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:



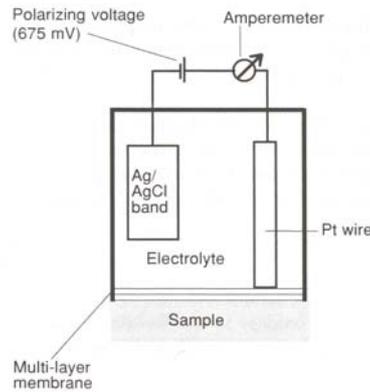
O_2 for this reaction is supplied by the outer membrane layer and also by the oxidation of H_2O_2 at the Pt anode.

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

Continued on next page

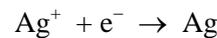
Metabolite electrodes, *Continued*

Description (continued)



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.

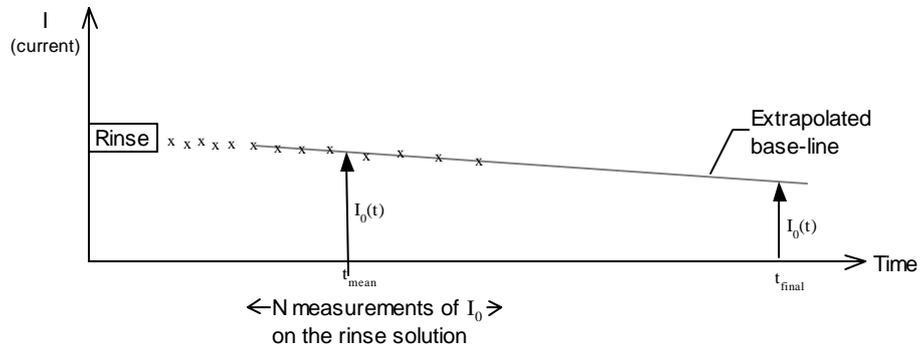
To complete the electrical circuit a reduction reaction (where electrons are consumed) at the cathode converts Ag^+ (from AgCl) to Ag :



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 throughout 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:

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

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:

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

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

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

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

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

Continued on next page

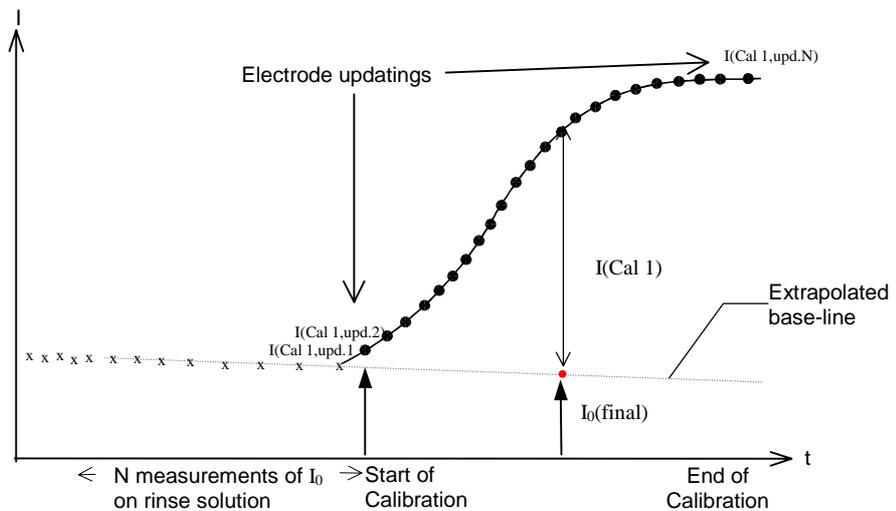
Metabolite electrodes, *Continued*

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, $I(\text{Cal } 1)$, 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 the 30th for the lactate electrode) and the zero current at that time point:

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

The sensitivities of the electrodes are calculated as follows:

$$\text{Sens} = \frac{I(\text{Cal } 1)}{cX(\text{Cal } 1)} T \quad \mathbf{T}$$

Continued on next page

Metabolite electrodes, *Continued*

Sensitivity (*continued*)

where:

- $cX(\text{Cal 1})$ = Actual concentration of glucose/lactate in the Cal 1 solution.
- $I_0(\text{final})$ = Extrapolated final zero current value of the metabolite electrode at the time of the last updating.
- $TI(\text{Cal 1})$ = 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:

$$\text{Drift} = \frac{I(\text{Cal 1, final}) - I_0(\text{final})}{\text{Sens}} - cX(\text{Cal 1})$$

where:

- $I(\text{Cal 1, final})$ = Current at the final measurement on Cal 1 solution.
- Sens = Sensitivity of the glucose/lactate electrode from the previous calibration.
- $cX(\text{Cal 1})$ = Actual concentration of glucose/lactate in the Cal 1 solution.
- $I_0(\text{final})$ = 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:

- $I(\text{sample})$ = Current of the metabolite electrode measured on the sample.
- $I_0(\text{final})$ = 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:

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

and

Equation B:

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

where:

- $cX(\text{sample})$ = uncorrected measured metabolite concentration from a sample
- $cX(\text{sample, corr})$ = 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 $cX(\text{sample})$ 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)”.

Continued on next page

Metabolite electrodes, *Continued*

Corrections (*continued*)

Corrections for *c*Glu :

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|------------------|-------------------|----------------|----------------|----------|
| 35/25/15 FLEX | 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 FLEX | 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 |
| 00 BASIC | 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 = FLEXMODE.

Corrections for *c*Lac:

| ABL8XX | Mode | A ₀ | A ₁ | Equation |
|------------------|-------------------|----------------|----------------|----------|
| 35/25/15 FLEX | 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 | Mode | A ₀ | A ₁ | Equation |
|----------|-------------------|----------------|----------------|----------|
| 05 FLEX | 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 |
| 00 BASIC | 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 |

*FLEXMODE = adaptive measuring mode.

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

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

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

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

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

$I(\text{Cal 1, upd.30})$ = Electrode current at the 30th/21st/11th/1st updating during measurement on Cal 1 solution, respectively.

$I(\text{Cal 1, upd.21})$

$I(\text{Cal 1, upd.11})$

$I(\text{Cal 1, upd.1})$

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

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

Continued on next page

Metabolite electrodes, *Continued*

Stability criteria (*continued*)

$$\tau = \text{Should be less than or equal to 50,}$$

and

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

should be negative or equal zero.

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

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

where:

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

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

The (glucose or lactate) in the sample is $cX(\text{sample,corr})$.

If the corrected concentration of the metabolite, $cX(\text{sample,corr}) > 1$, the following criteria must be fulfilled:

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

otherwise

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

where:

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

$I_0(\text{zero})$ = 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.

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

$$I(\text{sample, upd.16}) > I(\text{sample, upd.12})$$

$$I(\text{sample, upd.12}) > I(\text{sample, upd.9})$$

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

where:

| | | |
|-------------------|---|--|
| I(sample, upd.30) | = | Electrode current at the 30 th /23 rd /16 th /12 th /9 th |
| I(sample, upd.23) | | updating during measurement on sample, |
| I(sample, upd.16) | | respectively. |
| I(sample, upd.12) | | |
| I(sample, upd.9) | | |
| cX(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..... | 3-2 |
| Correcting for interferences | 3-7 |
| Measurement and corrections | 3-9 |
| References | 3-14 |

Optical system

Measured parameters

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

| Parameter | Description |
|--------------------|---|
| ctHb | concentration of total hemoglobin |
| sO ₂ | oxygen saturation |
| FO ₂ Hb | fraction of oxyhemoglobin |
| FCOHb | fraction of carboxyhemoglobin |
| FHHb | fraction of deoxyhemoglobin |
| FMetHb | fraction of methemoglobin |
| FHbF | fraction of fetal hemoglobin |
| ctBil | concentration of total bilirubin (the sum of unconjugated and conjugated bilirubin) in plasma |

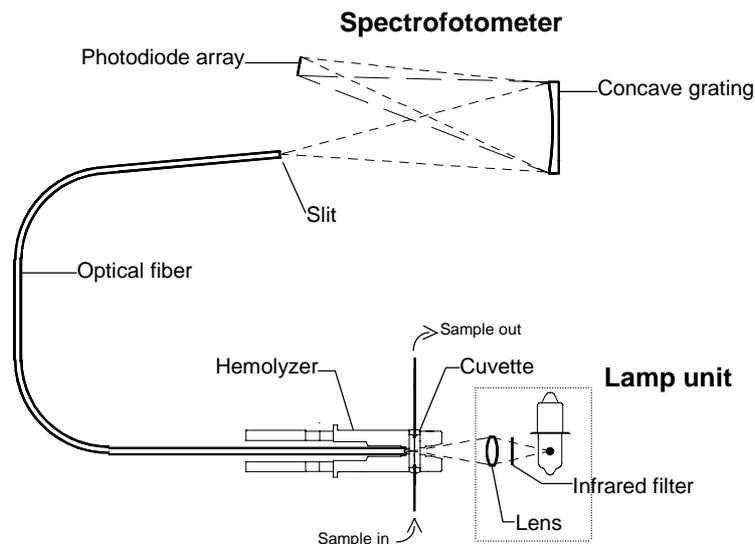
NOTE: ctBil can be measured on a whole blood or plasma sample. Plasma samples provide the optimal measurement performance. To obtain optimal accuracy when following a patient trend in ctBil, use the same aspiration mode and the same analyzer.

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.



Continued on next page

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 <i>Measurement and Corrections</i> 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]:

$$A_y^\lambda = \epsilon_y^\lambda \times c_y \times l$$

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, \dots, y_6 , the total absorbance measured for that sample at wavelength λ_1 is:

$$\begin{aligned} A_{\text{total}}^{\lambda_1} &= A_{y_1}^{\lambda_1} + A_{y_2}^{\lambda_1} + A_{y_3}^{\lambda_1} + A_{y_4}^{\lambda_1} + A_{y_5}^{\lambda_1} + A_{y_6}^{\lambda_1} \\ &= l \left(\epsilon_{y_1}^{\lambda_1} c_{y_1} + \epsilon_{y_2}^{\lambda_1} c_{y_2} + \epsilon_{y_3}^{\lambda_1} c_{y_3} + \epsilon_{y_4}^{\lambda_1} c_{y_4} + \epsilon_{y_5}^{\lambda_1} c_{y_5} + \epsilon_{y_6}^{\lambda_1} c_{y_6} \right) \end{aligned}$$

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 :

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

where:

λ_n = the individual wavelengths.

Continued on next page

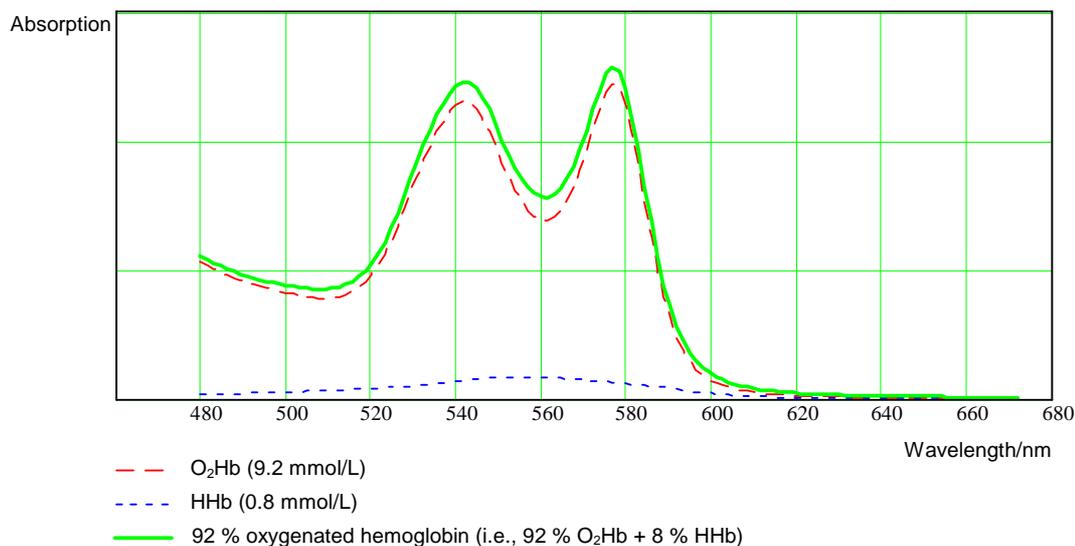
Optical system, *Continued*

Continuous spectrum

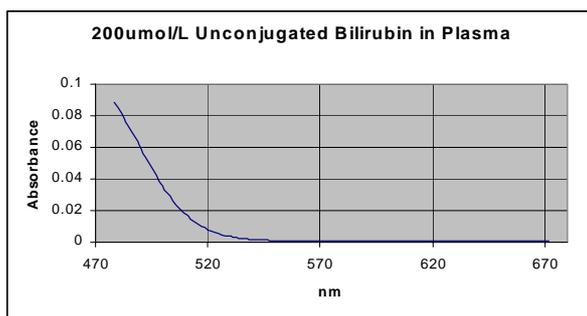
$A_{total}^{\lambda_n}$ can be depicted graphically as a function of wavelength, and if the differences between the wavelengths are small enough, a continuous spectrum is produced.

EXAMPLES:

The figure below shows three spectra; pure O₂Hb, pure HHb in a low concentration, a spectrum of 92 % oxygenated hemoglobin obtained by adding the spectra of O₂Hb 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.

Continued on next page

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:

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

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

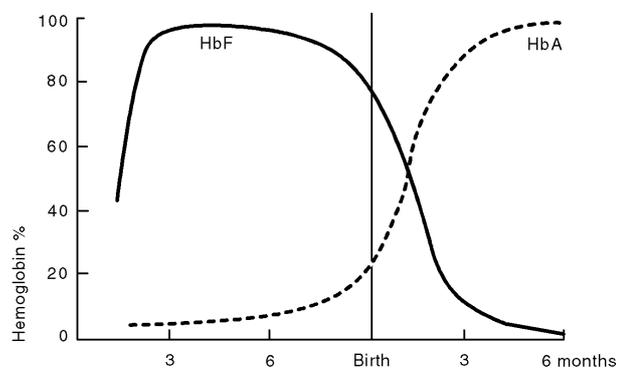
Fetal hemoglobin (HbF) does not have the same spectrum as adult hemoglobin (HbA) due to a slight variation in molecular structure. The presence of HbF in a sample will interfere with the result if it is not corrected for.

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.

NOTE: *Hb types other than HbA and HbF interfere with hemoglobin measurements and are not compensated for in the ABL800 FLEX analyzers.*

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



This graph is only schematic and cannot be used to determine $FHbF$.

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 (FCO_{Hb}), 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 $FHbF$.

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 *ctHb*, *sO₂*, *FO₂Hb*, *FCOHb*, *FMetHb*, *FHHb*, *FHbF* and *ctBil*.

The same action is taken if one of the following conditions exist and *FHb_{deriv}* is defined as one of the parameters *sO₂*, *FO₂Hb*, *FCOHb*, *FMetHb*, *FHHb*:

- $ctHb < -0.1 \text{ mmol/L}$ or $ctHb > 25 \text{ mmol/L}$.
- $FHb(\text{deriv}) < -2\%$ or $FHb(\text{deriv}) > 102\%$.
- 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 |
|---------------------|--|
| $ctHb(\text{meas})$ | $= cO_2Hb + cCOHb + cHHb + cMetHb$ |
| sO_2 | $= \frac{cO_2Hb}{ceHb}$ $ceHb = cHHb + cO_2Hb$ (effective hemoglobin) |
| FO_2Hb | $= \frac{cO_2Hb}{ctHb}$ |
| $FCOHb$ | $= \frac{cCOHb}{ctHb}$ |
| $FHHb$ | $= \frac{cHHb}{ctHb}$ |
| $FMetHb$ | $= \frac{cMetHb}{ctHb}$ |
| $FHbF$ | $= \frac{cHbF}{ctHb}$ |

where:

- cO_2Hb = concentration of oxyhemoglobin in the sample
- $cCOHb$ = concentration of carboxyhemoglobin in the sample
- $cHHb$ = concentration of deoxyhemoglobin in the sample
- $cMetHb$ = concentration of methemoglobin in the sample
- $cHbF$ = concentration of fetal hemoglobin in the sample

Bilirubin

Bilirubin is calculated as follows:

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

where:

- $ctBil(P)$ = concentration of total bilirubin in plasma
- $ctBil(B)$ = concentration of diluted plasma bilirubin after sample hemolyzation
- $Hct(\text{calc})$ = calculated hematocrit (a fraction).

Continued on next page

Measurement and corrections, *Continued*

Bilirubin (*continued*)

$$\text{Hct}(\text{calc}) = \frac{0.0301}{\text{g/dL}} \times \text{ctHb}$$

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... |
|---|--|
| <i>sO</i> ₂ , <i>F</i> COHb, <i>F</i> MetHb, <i>F</i> HbHb | <i>ce</i> Hb = <i>c</i> HHb + <i>c</i> O ₂ Hb < 0.75 mmol/L; <i>ct</i> Hb < 1 mmol/L |
| <i>ct</i> Bil | <i>ct</i> Hb > 15.5 mmol/L |

The following conditions are required to exclude HbF interference:

| Parameter or Feature | Requirement |
|--|---|
| <i>ce</i> Hb | > 3 mmol/L |
| <i>F</i> COHb | < 15 % |
| <i>F</i> MetHb | < 10 % |
| "HbF correction" has not been activated | If <i>ct</i> Hb < 5 mmol/L, <i>c</i> O ₂ HbF should be more than 1 mmol/L. If <i>ct</i> Hb > 5 mmol/L, <i>c</i> O ₂ HbF/ <i>ct</i> Hb should be more than 0.2. |
| "HbF correction" has been activated | No lower limit value for <i>c</i> O ₂ HbF 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 <i>F</i> HbF can be lower than 20 % and significant deviations of oximetry parameters and bilirubin can occur. |
| HbF suppression has been activated | The <i>F</i> HbF value is displayed by the ABL835/30 FLEX. Message "HbF detected" is displayed on the other analyzer versions with the oximetry module installed. |
| <i>s</i> O ₂ < 50 % or <i>ct</i> Hb < 5 mmol/L | Message " <i>F</i> HbF measurement is not possible" is displayed by the ABL835/30 FLEX if a HbF suppression has been activated. |

Continued on next page

Measurement and corrections, *Continued*

Corrections for ctHb The uncorrected hemoglobin concentration, ctHb(sample), measured on capillary or syringe samples is corrected as follows:

Equation A:

$$ctHb(sample,corr) = \frac{ctHb(sample)}{F_{cuv} F_{dil}}$$

where:

ctHb(sample,corr) = corrected ctHb

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 | Mode | F_{dil} | Equation |
|------------------|-------------------|------------------------|-----------------|
| 35/25/15 FLEX | 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 ctHb (*continued*)

| ABL8XX | Mode | F _{dil} | Equation |
|---------------------------------|-------------------|------------------|----------|
| 30/20/10/ 10 BG only FLEX | 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 |
| 00 BASIC | S195 | 1.0000 | A |
| | S95 | 0.9630 | A |
| | S85 | 1.0050 | A |
| | C95 | 0.9630 | A |
| | C35OXI | 0.9570 | A |

*FM = FLEXMODE

Corrections for ctBil

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

Equation A:

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

where:

ctBil(sample,corr) = corrected ctBil

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 ctBil dilution in the different aspiration modes.

Continued on next page

Measurement and corrections, *Continued*

Corrections for
ctBil (*continued*)

| ABL8XX | Mode | F _{air} | Equation |
|---------|-------------------|------------------|----------|
| 35 FLEX | 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 FLEX | 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 | 4-2 |
| Correction factors for oximetry parameters and bilirubin..... | 4-4 |
| Electrolyte and metabolite parameters | 4-7 |

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.

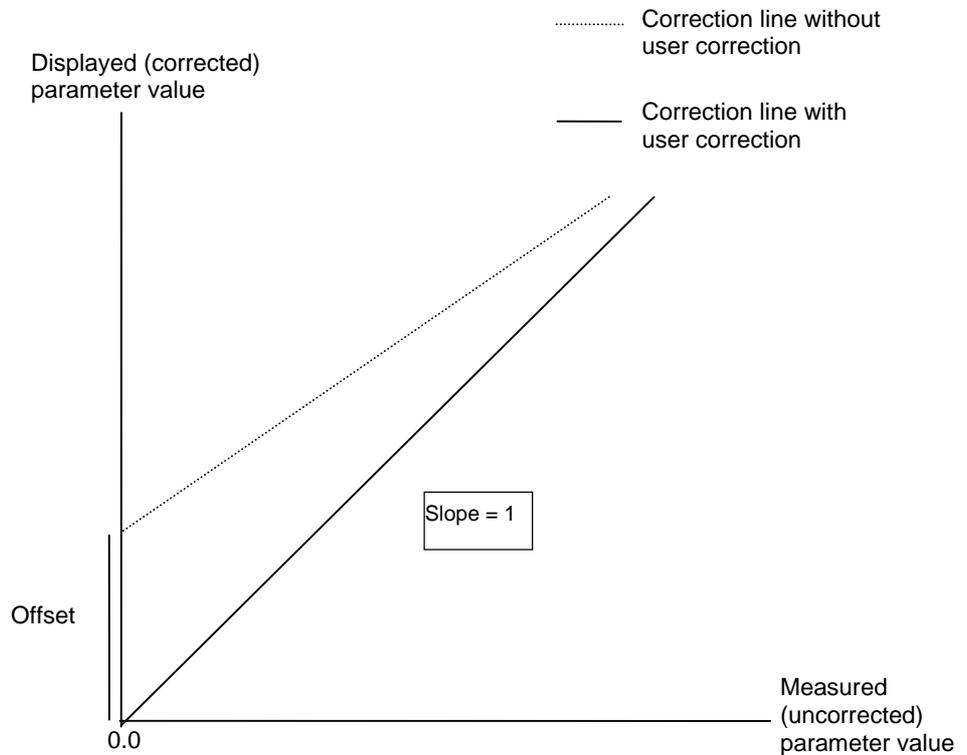
NOTE: *Since the performance of all analyzers is tested as described in Chapter 5, Performance Characteristics, and each instrument is assumed to operate accurately and optimally, the unnecessary correction of parameter values by the user can lead to inaccurate measurements being reported.*

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.



Continued on next page

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 |
| ctHb | Yes | No |
| sO₂ | Yes | Yes |
| FCOHb | No | Yes |
| FMetHb | No | Yes |
| FO₂Hb | No | No |
| FHHb | No | No |
| FHbF | Yes | Yes |
| ctBil | 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.

ctHb

The following recommendations apply to ctHb:

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

sO₂

The following recommendations apply to sO₂ :

| Item | Description |
|--------|---|
| Units | Fraction |
| Sample | Set ctHb 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

FCO_{Hb}

The following recommendations apply to *FCO_{Hb}*:

| Item | Description |
|-------------|---|
| Units | Fraction |
| Sample | The zero point (<i>FCO_{Hb}</i> \approx 0) is saturated to approximately SAT100, and ctHb is set to \approx 15 g/dL (9.3 mmol/L) and pH \approx 7.4. |
| Offset | \pm 0.050 |

FMetHb

The following recommendations apply to *FMetHb*:

| Item | Description |
|-------------|---|
| Units | Fraction |
| Sample | The zero point (<i>FMetHb</i> \approx 0) is saturated to approximately SAT100, and ctHb is set to \approx 15 g/dL (9.3 mmol/L) and pH \approx 7.4. |
| Offset | \pm 0.050 |

FHbF

The following recommendations apply to *FHbF*:

| Item | Description |
|-------------|--|
| Units | Fraction |
| Sample | Radiometer recommends that ctHb in the adult samples (with <i>FHbF</i> = 0) and fetal samples (with high <i>FHbF</i>) is set to \approx 15 g/dL (9.3 mmol/L), <i>sO₂</i> \approx 100 %, and pH \approx 7.4. The "Correction for HbF levels less than 20 %" function should be enabled in order to have the <i>FHbF</i> 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 | \pm 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 | <p>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.</p> <p>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.</p> <p>Commercial bilirubin standards can interfere with bilirubin measurement because they may have an absorbance spectrum different from that of human plasma.</p> |
| Slope | 0.5 - 1.5 |
| Offset | ± 100 |

FO₂Hb and FHHb

The units for FO₂Hb and FHHb are [Fraction].

After the user-defined corrections of the parameters *sO₂*, *FCO_{Hb}* and *FMetHb* have been carried out, *FO₂Hb* and *FHHb* are automatically calculated using the formulae stated below, since the sum of the fractions *FCO_{Hb}*, *FMetHb*, *FO₂Hb* and *FHHb* as defined must be equal to 1.0:

FO₂Hb:

$$FO_2Hb = (1 - FCO_{Hb} - FMetHb) \times sO_2$$

FHHb:

$$FHHb = (1 - FCO_{Hb} - FMetHb) \times (1 - sO_2)$$

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) |
|------------|----------------|
| cK^+ | 0.750 - 1.250 |
| cNa^+ | 0.850 - 1.150 |
| cCa^{2+} | 0.800 - 1.200 |
| cCl^- | 0.850 - 1.150 |
| $cGlu$ | 0.750 - 1.250 |
| $cLac$ | 0.750 - 1.250 |

Correcting the offset

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

| Parameter: | cK^+ | cNa^+ | cCa^{2+} | cCl^- | $cGlu$ | $cLac$ |
|------------------|--------|---------|------------|---------|--------|--------|
| 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 | 5-2 |
| | Performance test results – chart description..... | 5-5 |
| | Performance test results - pH | 5-8 |
| | Performance test results – $p\text{CO}_2$ | 5-10 |
| | Performance test results – $p\text{O}_2$ | 5-13 |
| | Performance test results – $c\text{K}^+$ | 5-16 |
| | Performance test results – $c\text{Na}^+$ | 5-18 |
| | Performance test results – $c\text{Cl}^-$ | 5-20 |
| | Performance test results – $c\text{Ca}^{2+}$ | 5-26 |
| | Performance test results – $c\text{Glu}$ | 5-24 |
| | Performance test results – $c\text{Lac}$ | 5-26 |
| | Performance test results – $c\text{tHb}$ | 5-28 |
| | Performance test results - oximetry..... | 5-30 |
| | Performance test results - bilirubin | 5-40 |
| | Additional information about FLEXMODE | 5-46 |
| | Interference tests | 5-47 |
| | References | 5-55 |

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:

$$\text{Bias}_{\text{Ref}} = X_{\text{ABL800 FLEX}} - X_{\text{Primary Reference method}}$$

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

$$\text{Bias}_{\text{ABL}} = X_{\text{ABL800 FLEX}} - X_{\text{ABL735}}$$

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 | <p>Repeatability</p> <p>This is a standard deviation obtained from repeated measurements within a short interval of time using:</p> <ul style="list-style-type: none"> • The same instrument and location • The same measurement procedure • Identical portions of the same sample • One operator per instrument <p>S_0 for each level is pooled for all test instruments and test days.</p> |
| S_D | <p>Day-to-day variation</p> <p>This is a standard deviation obtained from repeated measurements over all test days.</p> <p>Includes contributions from differences in calibration states of the analyzers throughout the test days.</p> |
| S_{ABL} | <p>Uncertainty of bias on a random instrument</p> <p>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.</p> |
| S_X | <p>Uncertainty of bias on a random instrument for a single measurement</p> <p>S_X is a standard deviation which includes S_{ABL}, S_D and S_0.</p> |

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, $p\text{CO}_2$, $p\text{O}_2$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$, $c\text{K}^+$, $c\text{Na}^+$, $c\text{Glu}$, $c\text{Lac}$, $c\text{Hb}$ 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: |
| | <ul style="list-style-type: none"> • Syringe: S195, S165, S95, S85 • Capillary: FLEXMODE, C95, C85, C55, C35 OXI, C35 MET. |
| Whole blood samples | Heparinized whole blood samples from healthy, voluntary donors. 11 whole 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 macromode |
| x | Observation in micromode |
| 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 |
| cGlu | 423 | 1825 | 2248 |
| cLac | 412 | 1829 | 2241 |
| ctHb | 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}

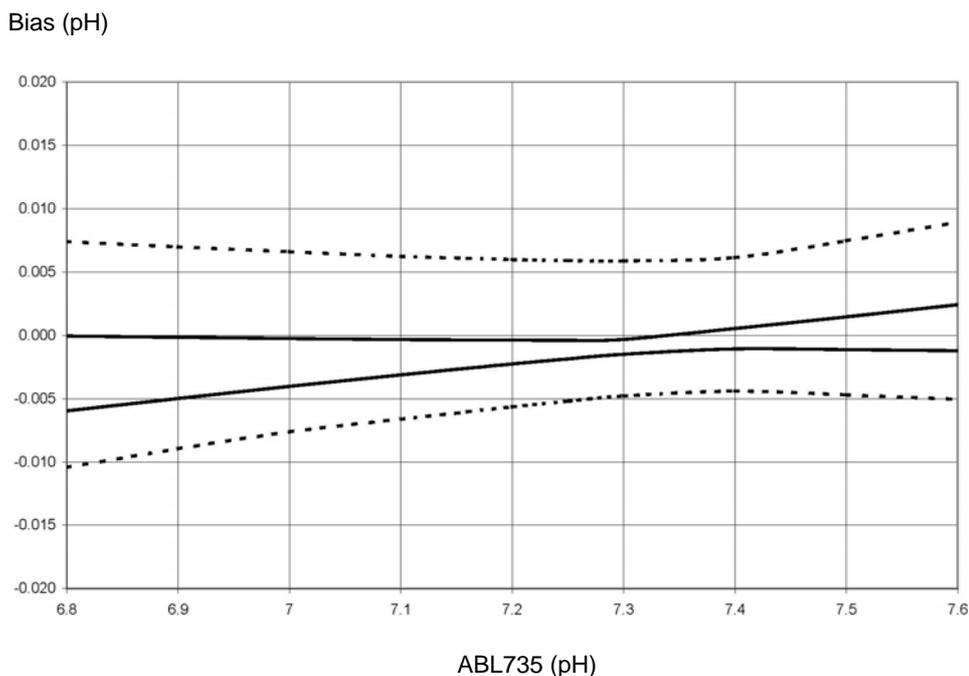
The FLEXMODE on the ABL805/30/35 analyzers was tested:

| 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

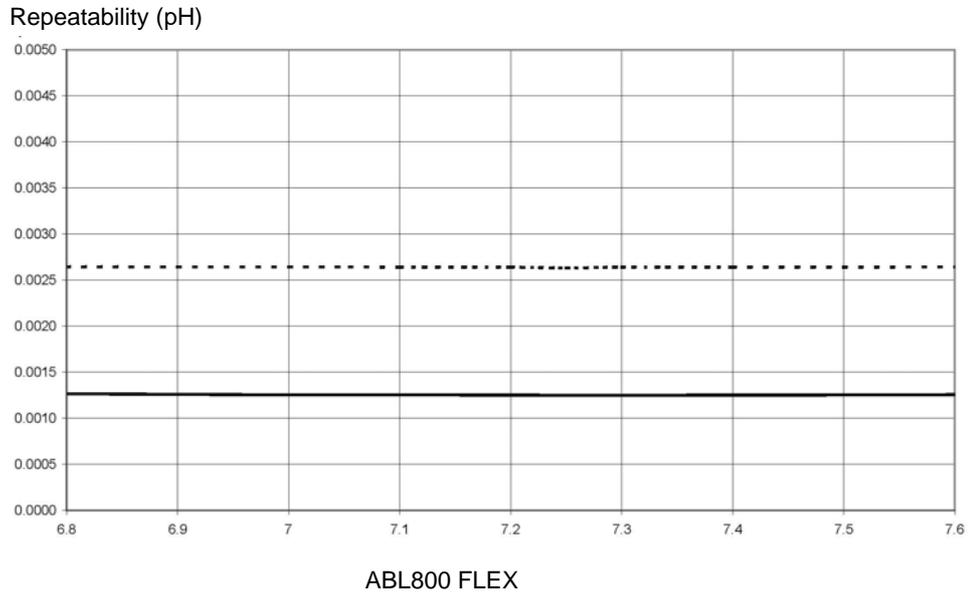
This bias is presented by the following chart:



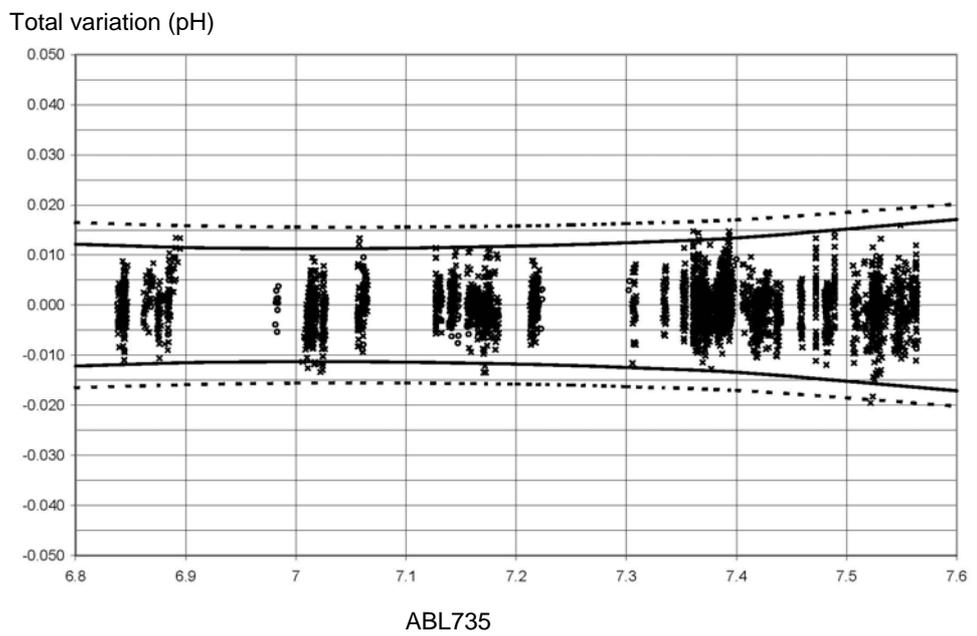
Continued on next page

Performance test results - pH, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – $p\text{CO}_2$

Primary reference method

Tonometry [3].

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

Bias_{REF}

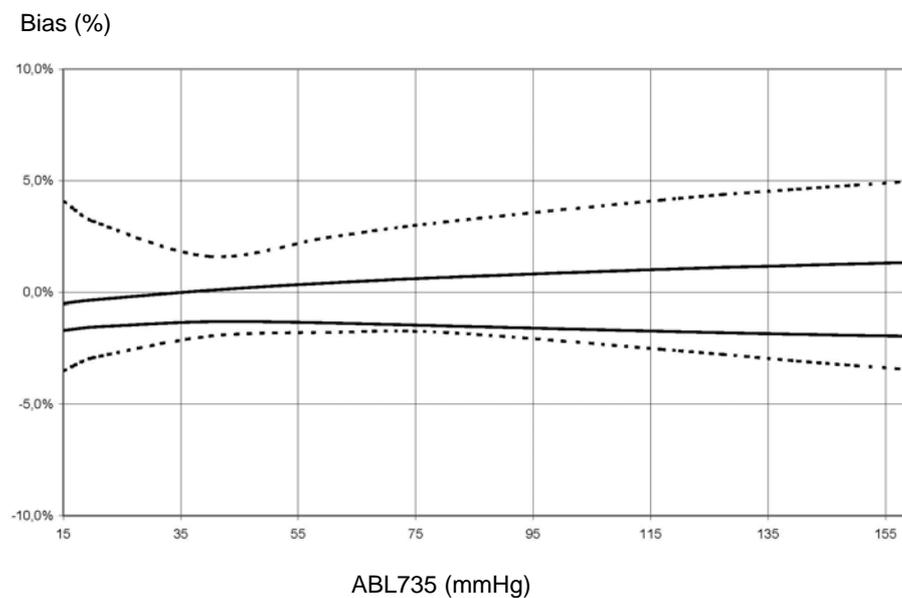
The FLEXMODE on the ABL805/30/35 analyzers was tested:

| $p\text{CO}_2$ (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:

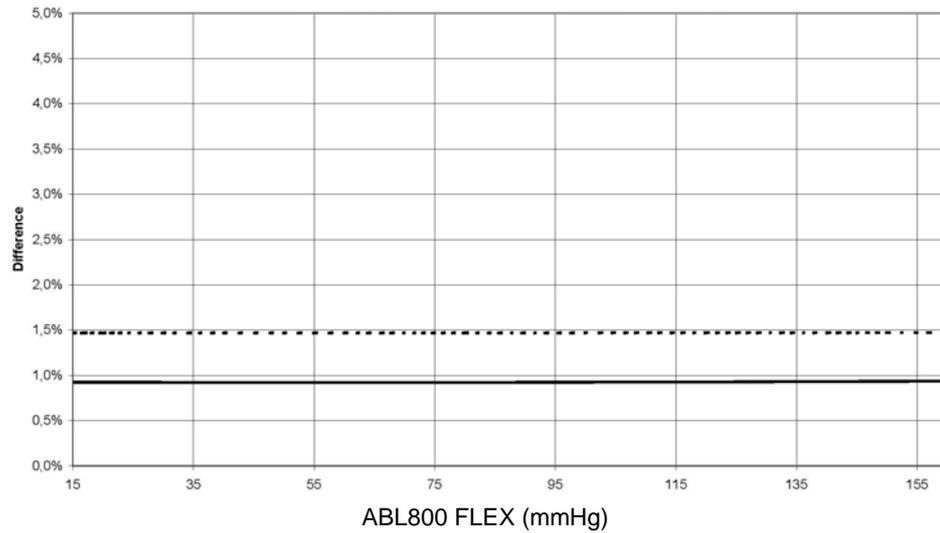


Continued on next page

Performance test results – $p\text{CO}_2$, *Continued*

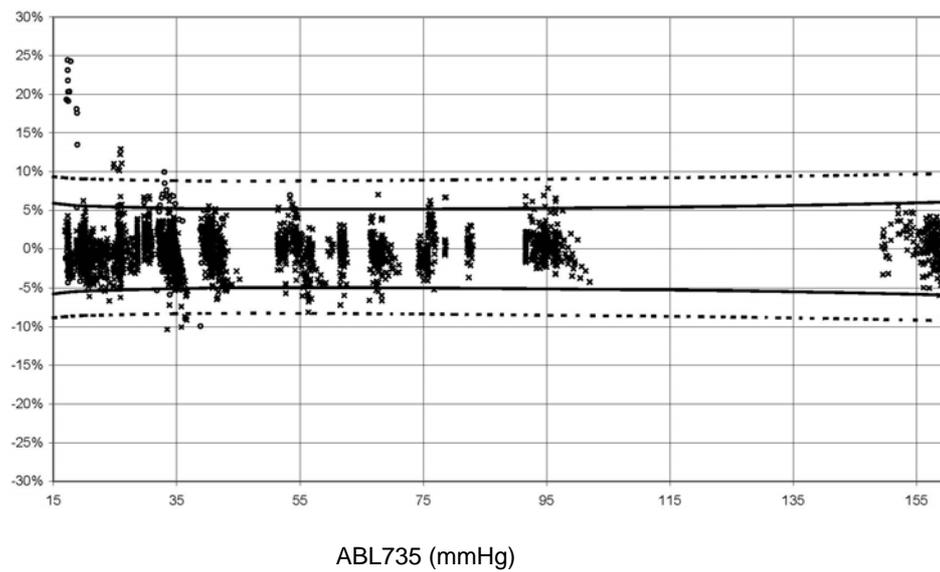
Repeatability Repeatability is presented by the following chart:

Repeatability (%)



Total variation Total variation is presented by the following chart:

Total variation (%)



Continued on next page

Performance test results – $p\text{CO}_2$, *Continued*

Bias and imprecision - expired air samples

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

| $p\text{CO}_2$ (mmHg) | Bias ABL835/30/25/20/15/10/05 |
|-----------------------|----------------------------------|
| 15 | 0.2 |
| 40 | -0.2 |
| 60 | -0.4 |
| 80 | -0.2 |
| 150 | 1.6 |

| $p\text{CO}_2$ (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}

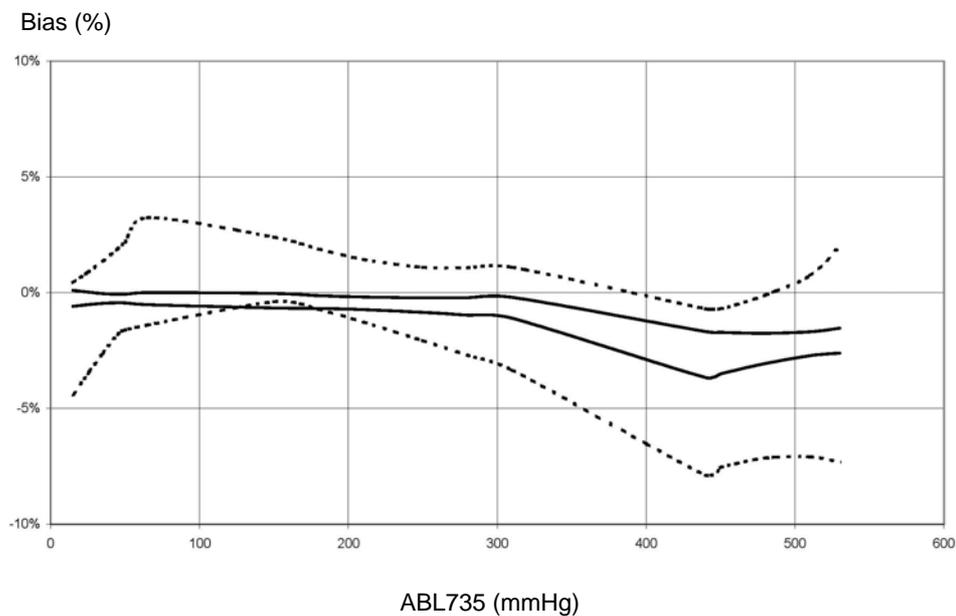
The FLEXMODE on the ABL805/30/35 analyzers was tested:

| 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

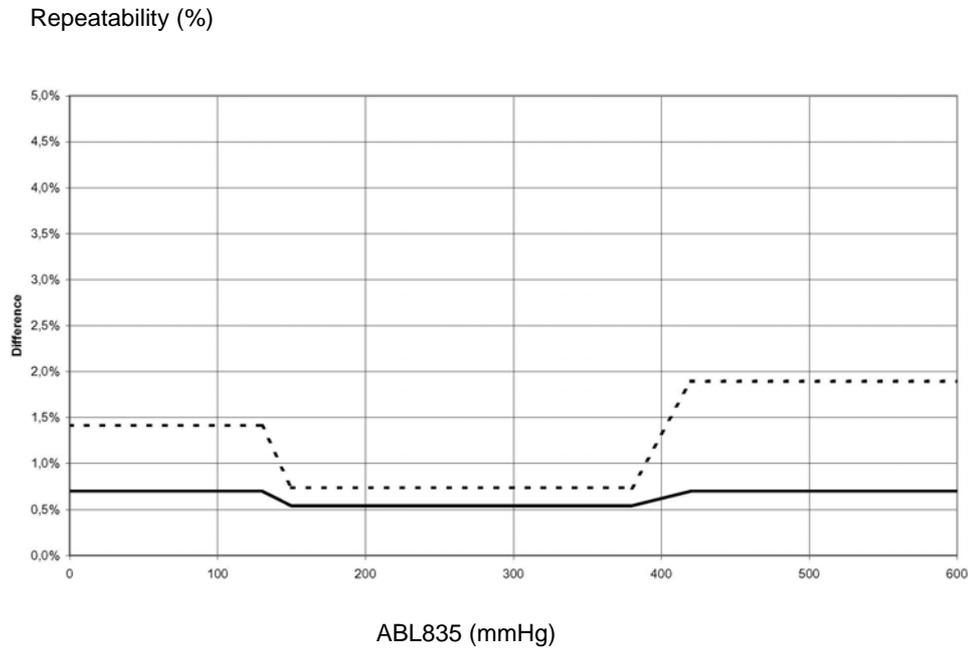
This bias is presented by the following chart:



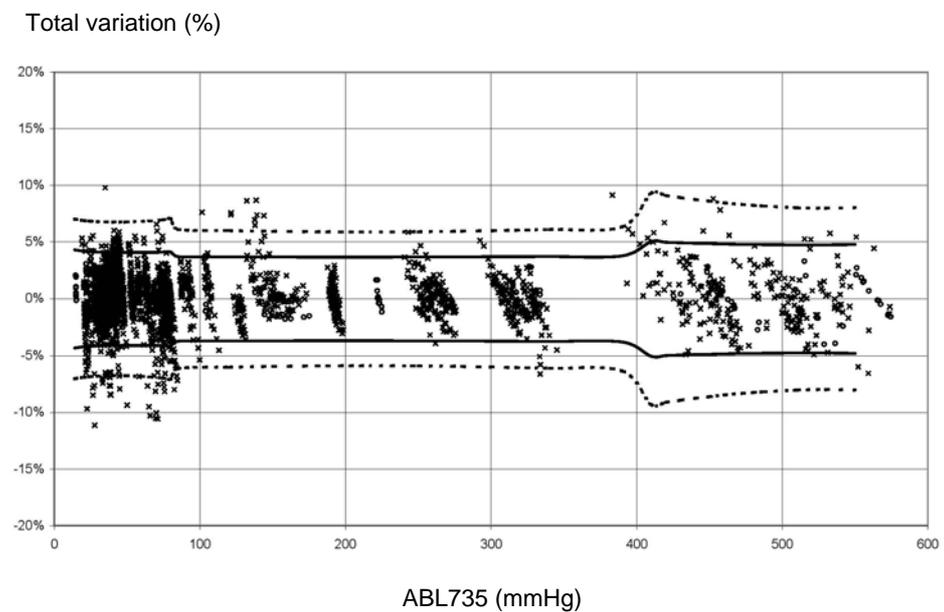
Continued on next page

Performance test results – pO_2 , *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



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 – cK⁺

Primary reference methods

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

Bias_{REF}

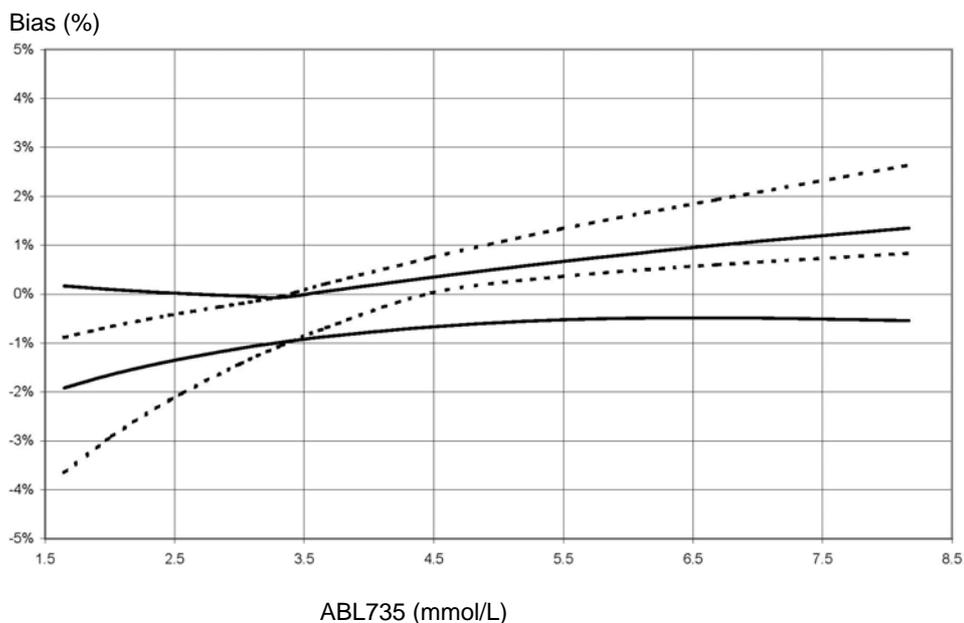
The FLEXMODE on the ABL805/35 analyzers was tested using SRM 909b:

| 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

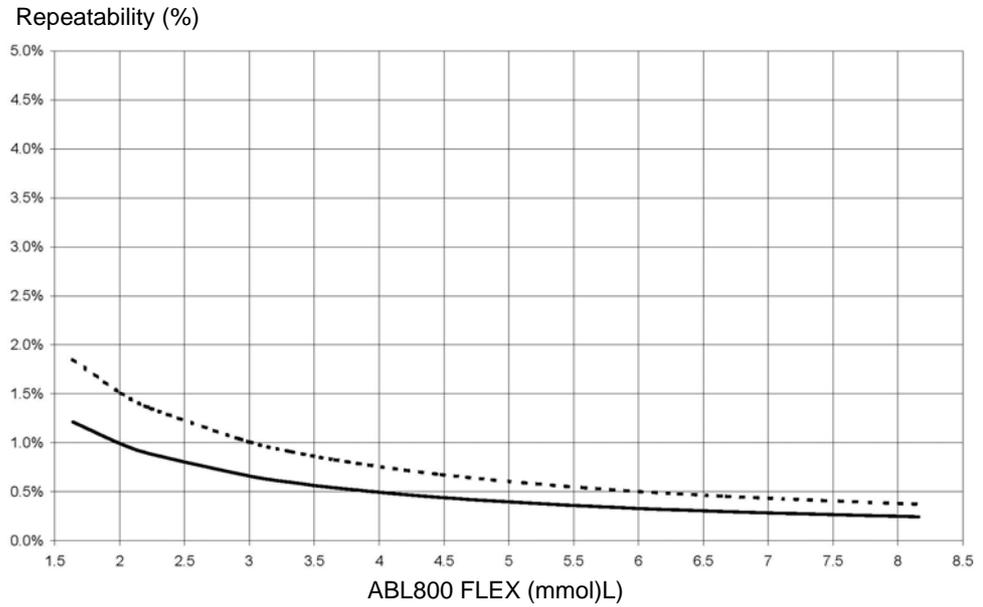
This bias is presented by the following chart:



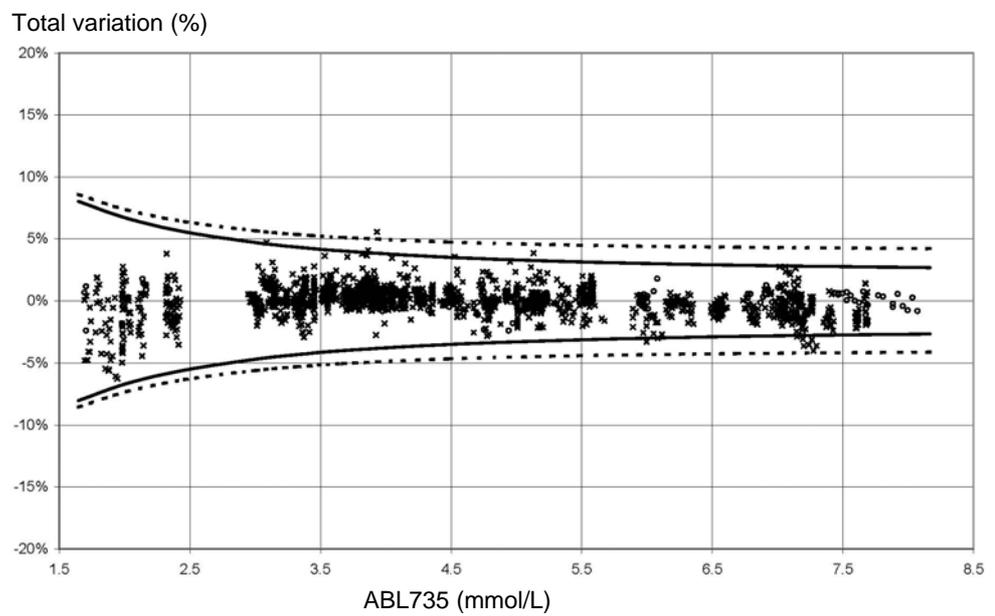
Continued on next page

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 – cNa⁺

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:

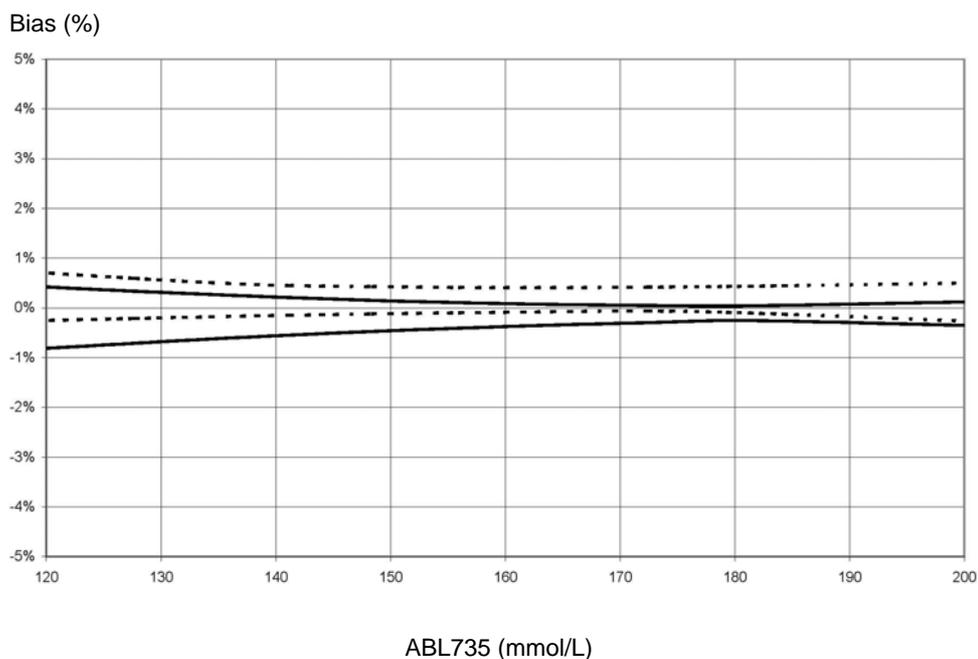
| cNa ⁺ (mmol/L) | Bias _{REF} | N |
|---------------------------|---------------------|----|
| 120.76* | -0.25 | 20 |
| 138.5** | -0.28 | 30 |

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

(*NIST certified Standard Reference Material

** Serum (Radiometer specified).

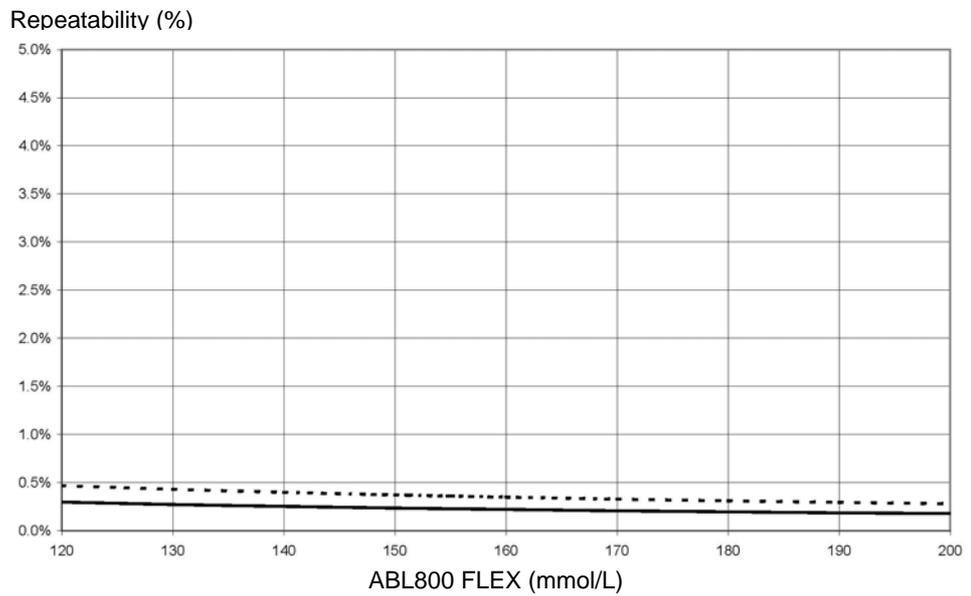
Bias_{ABL} – blood samples This bias is presented by the following chart:



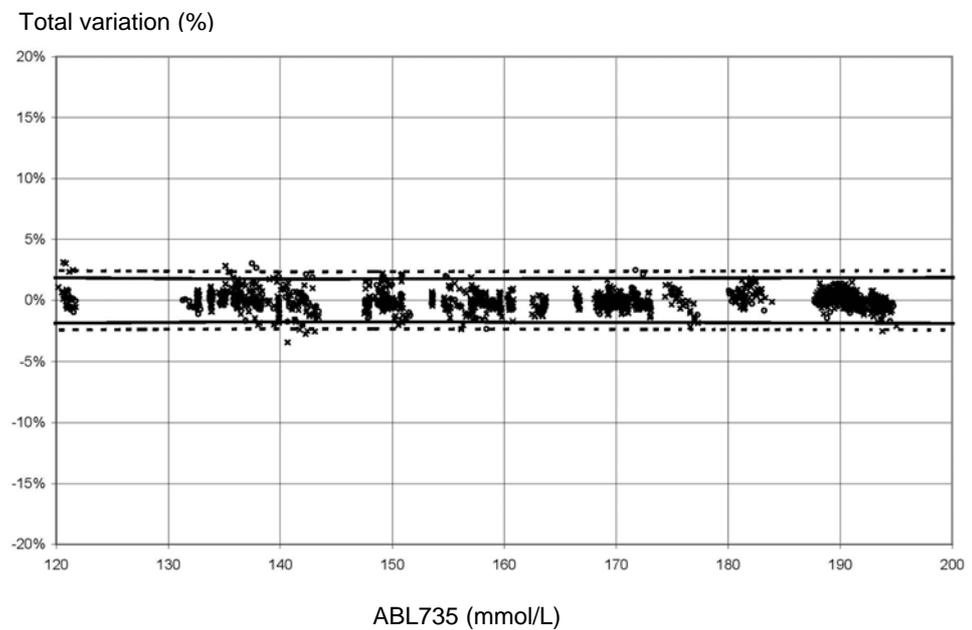
Continued on next page

Performance test results – cNa⁺, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – $c\text{Cl}^-$

Primary reference method

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

Bias_{REF}

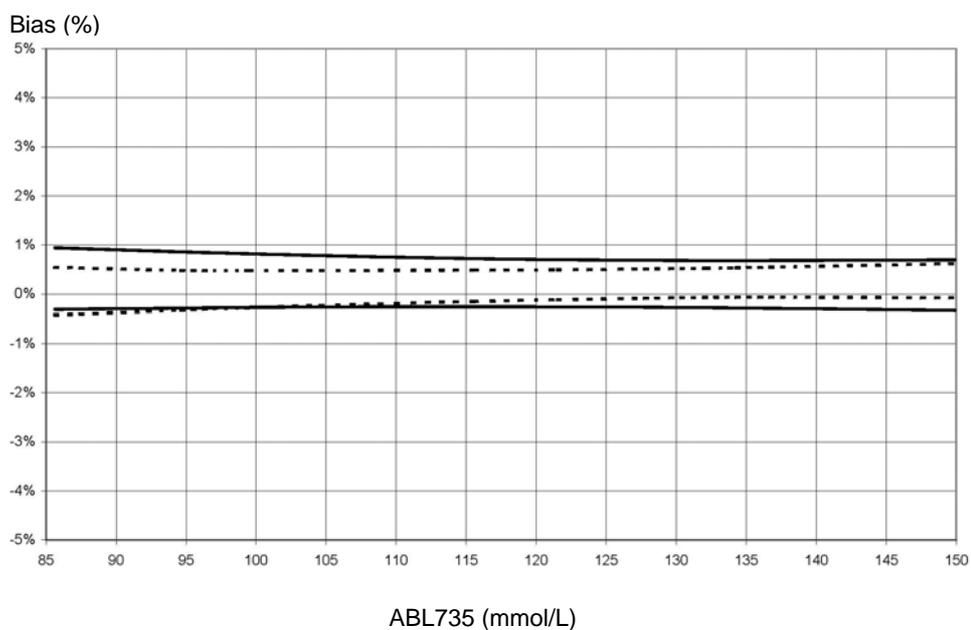
The FLEXMODE on the ABL805/35 analyzers was tested using SRM 909b:

| $c\text{Cl}^-$ (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

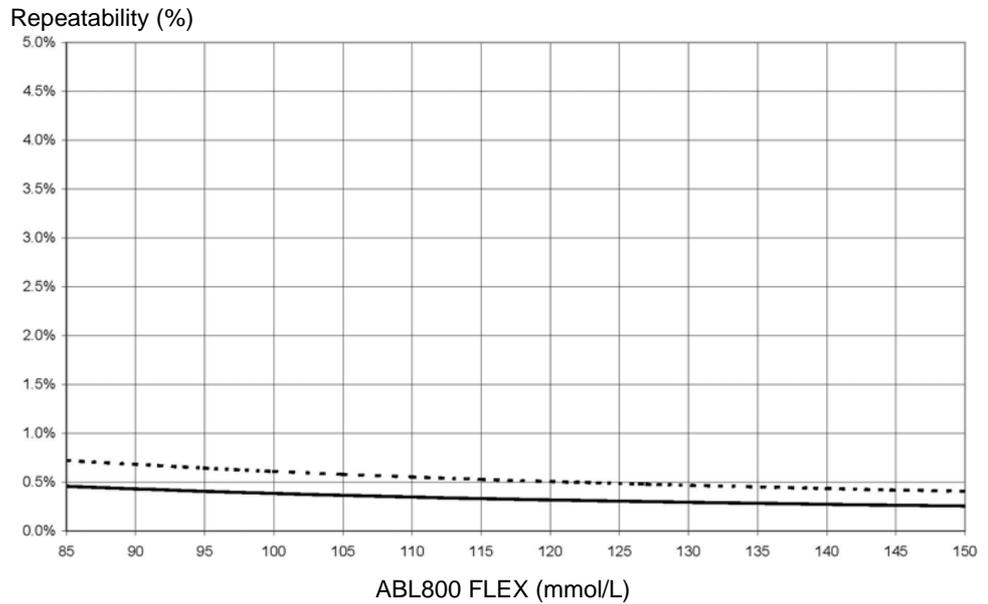
This bias is presented by the following chart:



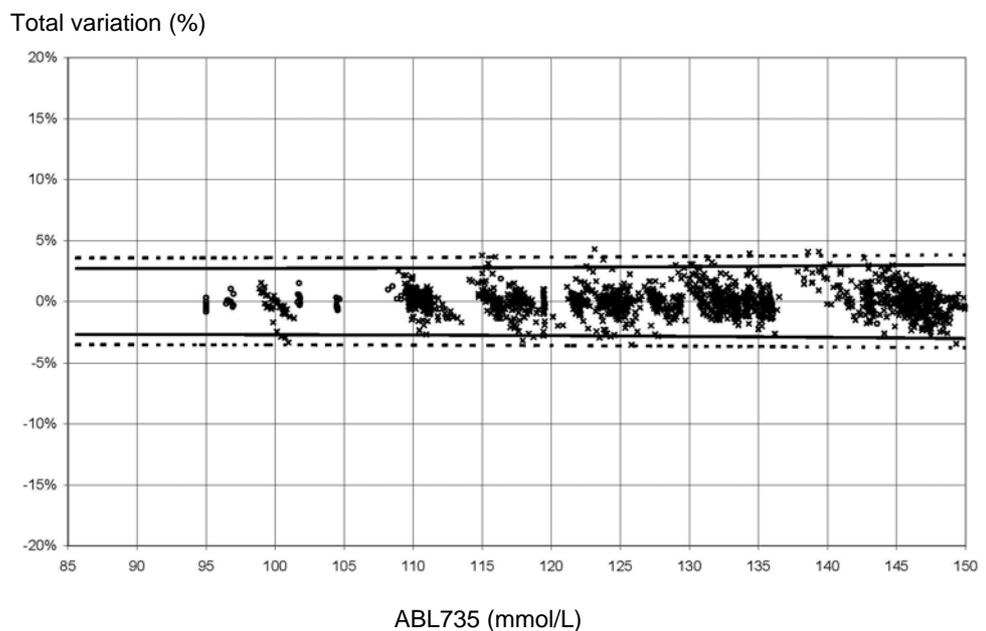
Continued on next page

Performance test results – $c\text{Cl}^-$, *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}

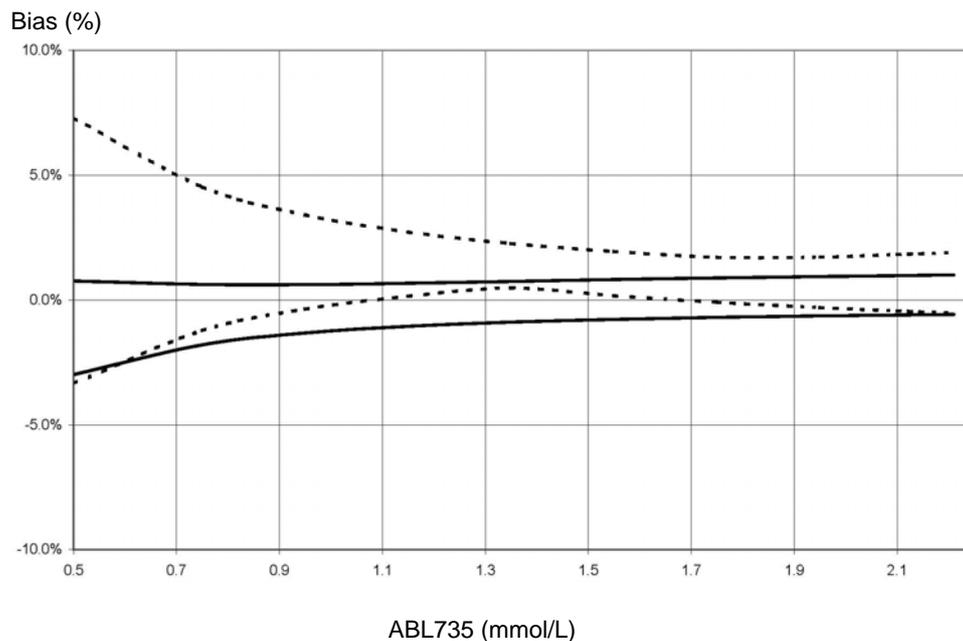
The FLEXMODE on the ABL805/35 analyzers was tested:

| 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:

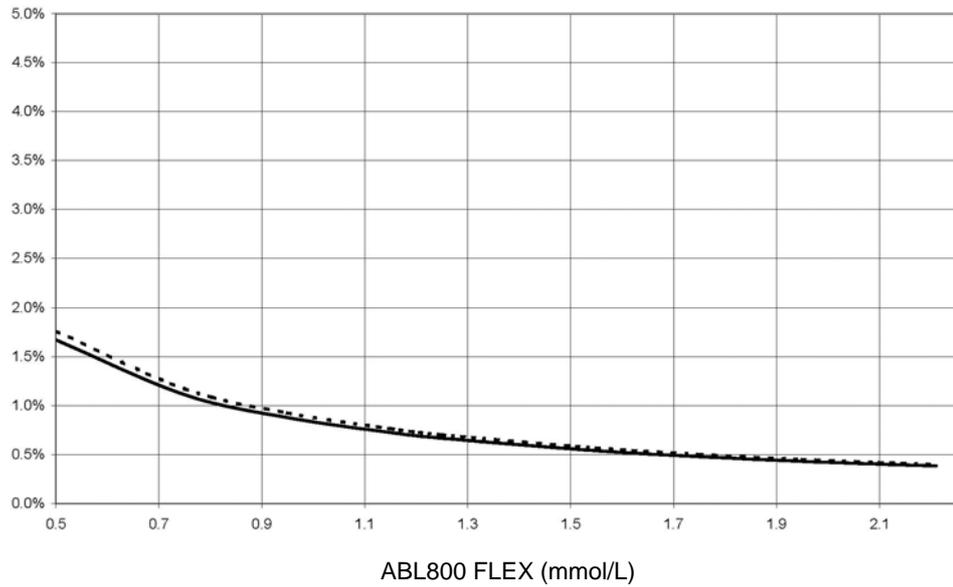


Continued on next page

Performance test results – cCa²⁺, *Continued*

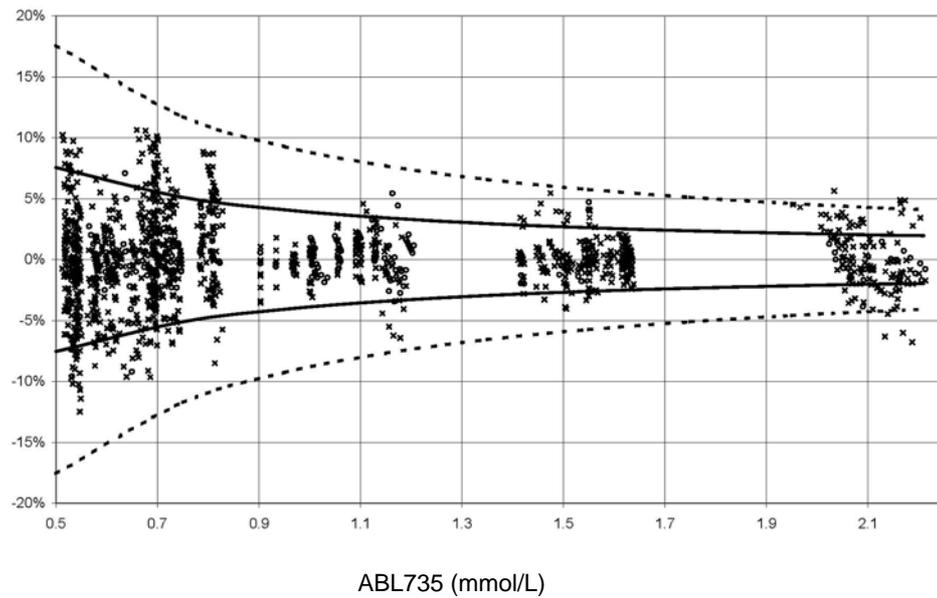
Repeatability Repeatability is presented by the following chart:

Repeatability (%)



Total variation Total variation is presented by the following chart:

Total variation (%)



Performance test results – cGlu

Primary reference method

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

Bias_{REF}

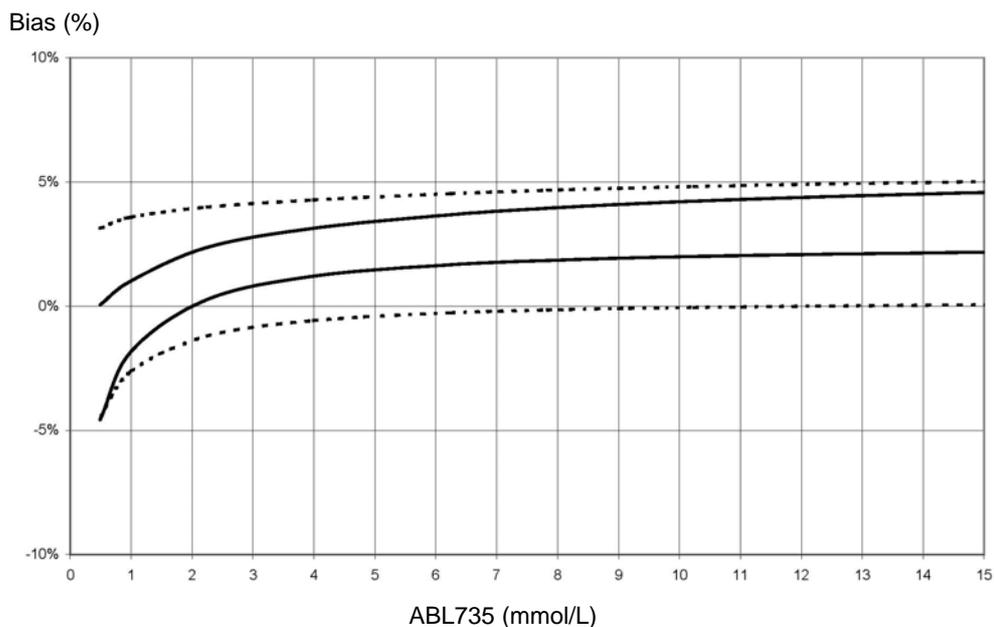
The FLEXMODE on the ABL805/35 analyzers was tested:

| cGlu(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

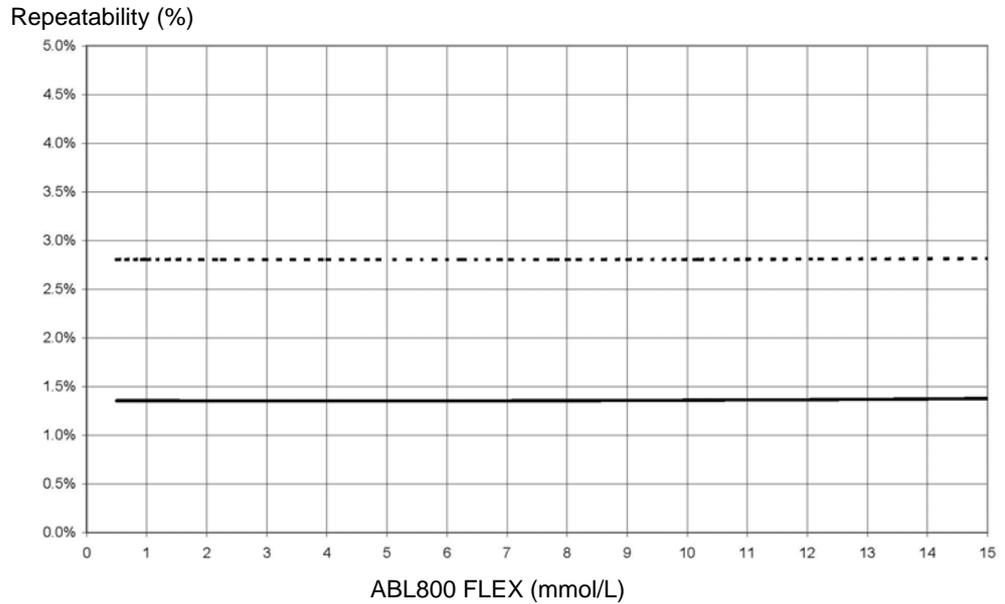
This bias is presented by the following chart:



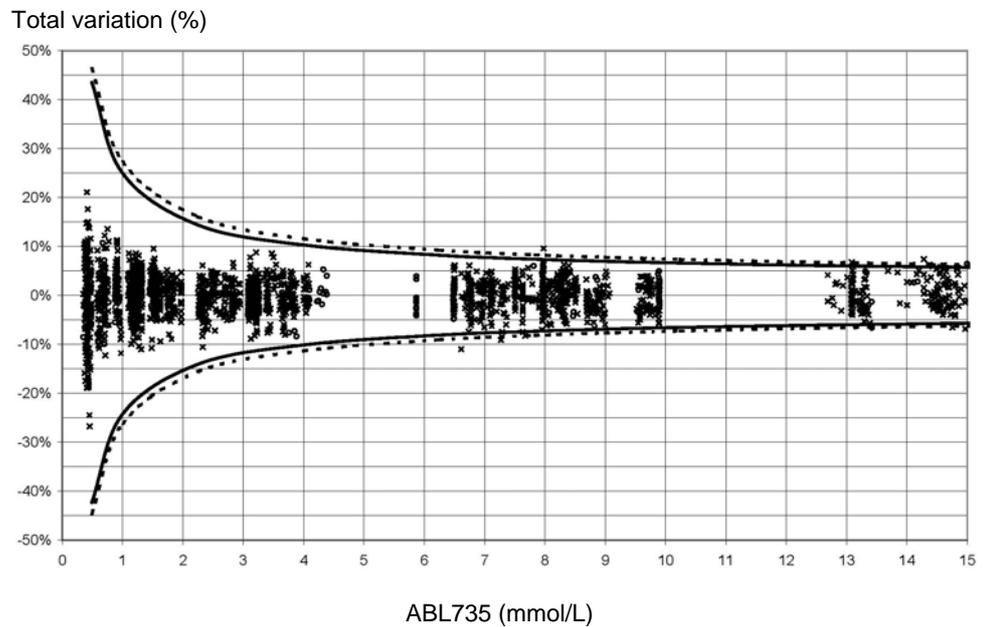
Continued on next page

Performance test results – cGlu, *Continued*

Repeatability Repeatability is presented by the following chart:



Total variation Total variation is presented by the following chart:



Performance test results – cLac

Primary reference methods

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

Bias_{REF}

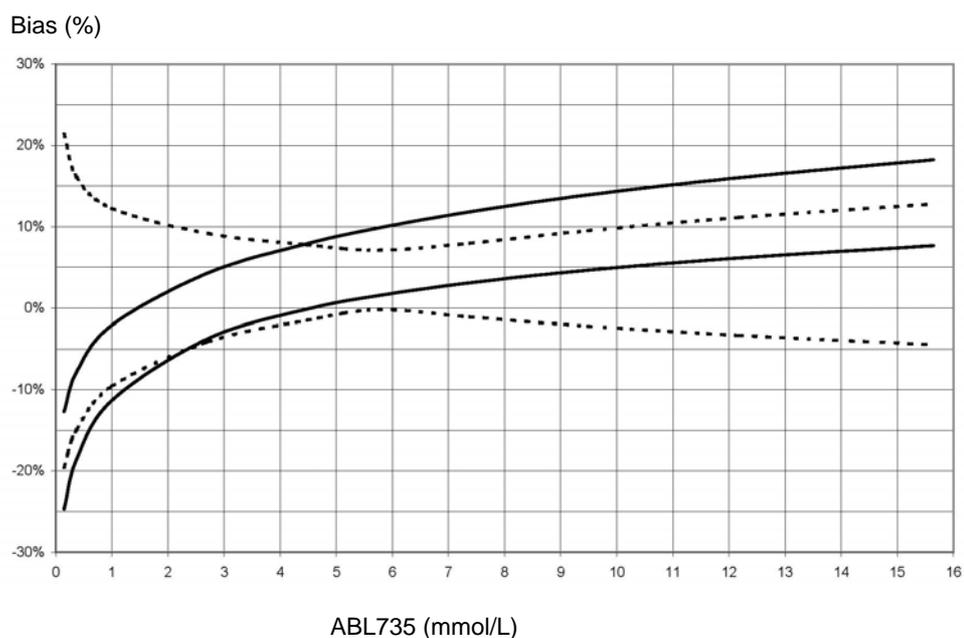
The FLEXMODE on the ABL805/35 analyzers was tested:

| cLac (mmol/L) | Bias _{REF} | N |
|---------------|---------------------|----|
| 0.36 | -0.08 | 30 |
| 2.06 | 0.12 | 30 |
| 8.3 | -0.62 | 30 |
| 11.3 | -0.81 | 30 |

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

Bias_{ABL} – blood samples

This bias is presented by the following chart:

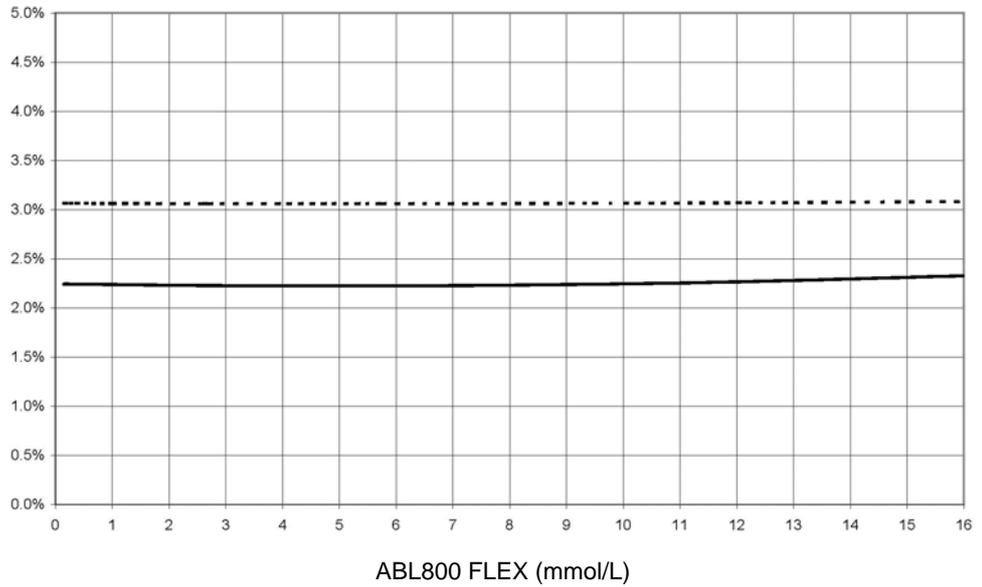


Continued on next page

Performance test results – cLac, *Continued*

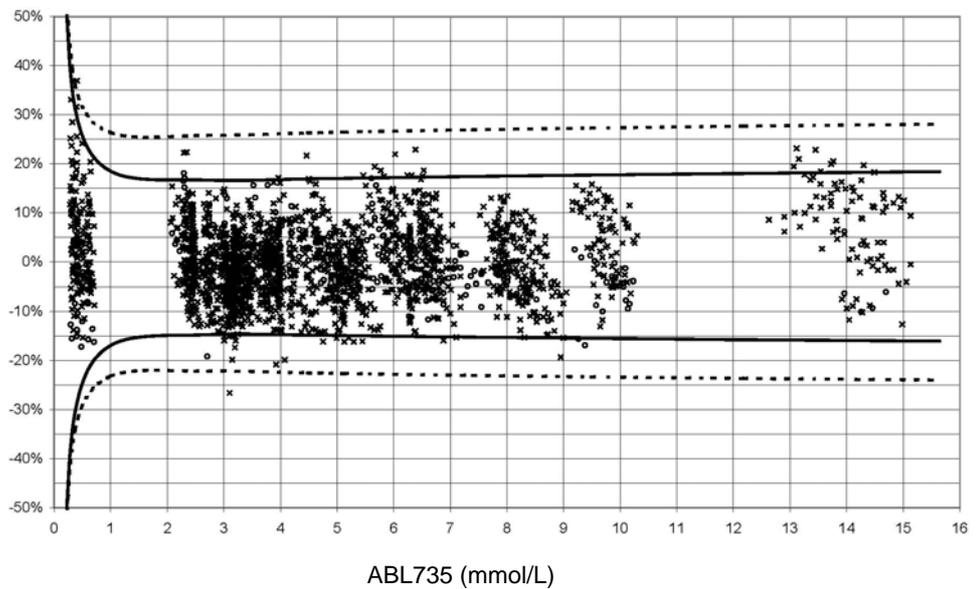
Repeatability Repeatability is presented by the following chart:

Repeatability (%)



Total variation Total variation is presented by the following chart:

Total variation (%)



Performance test results – ctHb

Primary reference method

HiCN method recommended by NCCLS [6].

Bias_{REF}

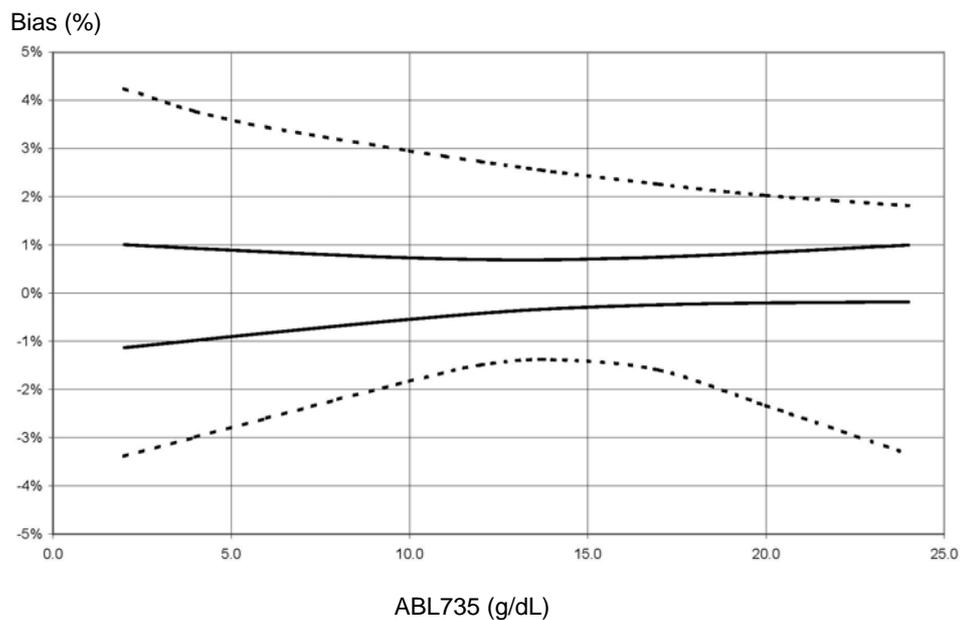
The FLEXMODE on the ABL830/35 analyzers was tested:

| ctHb (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}

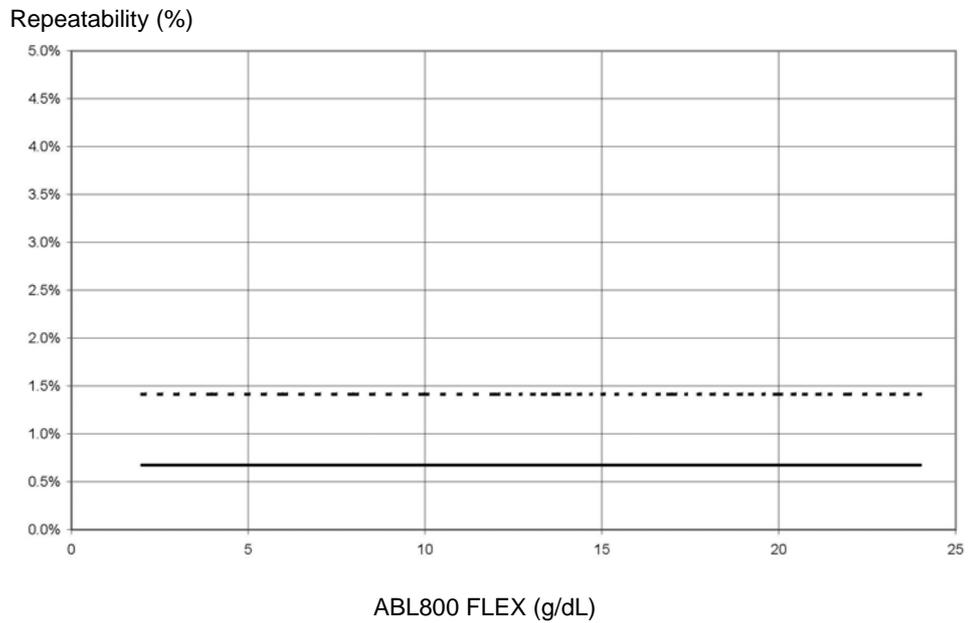
This bias is presented by the following chart:



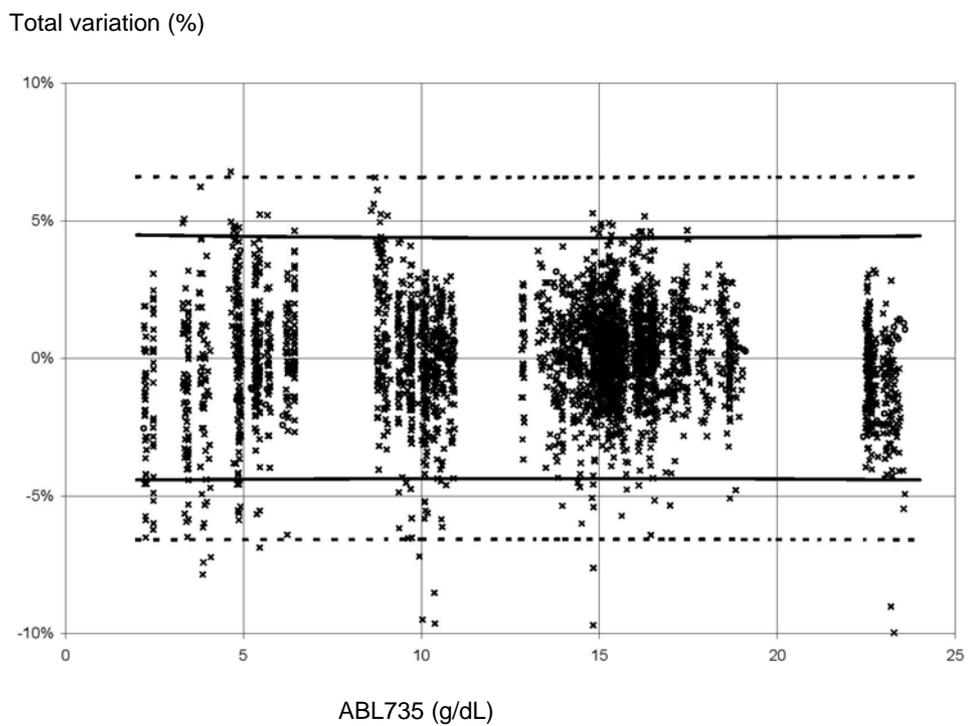
Continued on next page

Performance test results – ctHb, *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 ctHb 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 , $FCOHb$, $FMetHb$, $FHHb$, $FHbF$) are derived from ctHb, 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 . |
| $FHHb$ | The standard is blood (ctHb = 13 - 15 g/dL) treated with dithionite. |
| $FCOHb$ | 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). |
| $FMetHb$ | Spectrometry, modified Evelyn-Malloy method [7]. |
| $FHbF$ | Alkali denaturation method [8]. Corresponds to NCCLS guideline [9]. |

Test conditions for oximetry parameters

| Test | Description |
|-----------|--|
| Reference | <p>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.</p> <p>Each parameter is tested on 3-6 levels over at least 3 days, with 5 repetitions each day.</p> <p>(5 new analyzers with all parameters available were tested against the reference methods for $FHbF$).</p> <p>Bias for each parameter in the C195 measuring mode against the reference method is determined.</p> |

Continued on next page

Performance test results - oximetry, *Continued*

Test conditions for oximetry parameters
(continued)

| Test | Description |
|----------------------|---|
| Verification | <p>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.</p> <p>Bias against the reference method is determined as follows:</p> <p>Bias = bias against C195 + C195 bias against reference method.</p> <p>The following parameters: $s\text{O}_2$, FCOHb, FMetHb and FO_2Hb, are measured directly against the reference built in the analyzer, and these parameters are independent of the reference method.</p> |
| Reduced verification | <p>6 - 10 new analyzers are used over at least 1 day for selected levels.</p> <p>Bias for the tested mode is calculated as follows:</p> <p>Bias = bias against C195 + C195 bias against reference method.</p> <p>Modes which are not tested are described as "N/A".</p> |
| Simple verification | <p>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.</p> |

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 |
|-------------|------------|--------------|-------|--------------|
| ctHb (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:

| 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 |

sO_2 - micromodes

Bias:

| sO_2 | | ABL835/25/15 | | | | | ABL830/20/10 | | |
|-------------|------------|--------------|-------|-------|-------|-------|--------------|-------|-------|
| ctHb (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*

FO₂Hb - macromodes

Bias:

| <i>FO₂Hb</i> | | <i>ABL835/25</i> | | <i>ABL830/20</i> |
|-------------------------|-----------------------------|------------------|------------|------------------|
| <i>ctHb (g/dL)</i> | <i>FO₂Hb (%)</i> | <i>S195</i> | <i>FM*</i> | <i>S85</i> |
| 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:

| <i>ctHb (g/dL)</i> | <i>FO₂Hb (%)</i> | <i>S₀</i> | <i>S_D</i> | <i>S_{ABL}</i> | <i>S_X</i> |
|--------------------|-----------------------------|----------------------|----------------------|------------------------|----------------------|
| 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 |

FO₂Hb - micromodes

Bias:

| <i>FO₂Hb (%)</i> | | <i>ABL835/25</i> | | | | |
|-----------------------------|-----------------------------|------------------|------------|------------|------------|------------|
| <i>ctHb (g/dL)</i> | <i>FO₂Hb (%)</i> | <i>S95</i> | <i>C95</i> | <i>S85</i> | <i>C55</i> | <i>C35</i> |
| 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 |

| <i>FO₂Hb</i> | | <i>ABL830/20</i> | | |
|-------------------------|-----------------------------|------------------|------------|------------|
| <i>ctHb (g/dL)</i> | <i>FO₂Hb (%)</i> | <i>C85</i> | <i>C55</i> | <i>C35</i> |
| 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*

FO₂Hb - micromodes (continued)

Imprecision:

| <i>ctHb (g/dL)</i> | <i>FO₂Hb (%)</i> | <i>S₀</i> | <i>S_D</i> | <i>S_{ABL}</i> | <i>S_X</i> |
|--------------------|-----------------------------|----------------------|----------------------|------------------------|----------------------|
| 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:

| <i>FCOHb</i> | | | <i>ABL835/25</i> | | <i>ABL830/20</i> |
|--------------------|---------------------------|------------------|------------------|------------|------------------|
| <i>ctHb (g/dL)</i> | <i>sO₂ (%)</i> | <i>FCOHb (%)</i> | <i>S195</i> | <i>FM*</i> | <i>S85</i> |
| 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:

| <i>ctHb (g/dL)</i> | <i>sO₂ (%)</i> | <i>FCOHb (%)</i> | <i>S₀</i> | <i>S_D</i> | <i>S_{ABL}</i> | <i>S_X</i> |
|--------------------|---------------------------|------------------|----------------------|----------------------|------------------------|----------------------|
| 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:

| <i>FCOHb</i> | | | <i>ABL835/25</i> | | | | |
|--------------------|---------------------------|------------------|------------------|------------|------------|------------|------------|
| <i>ctHb (g/dL)</i> | <i>sO₂ (%)</i> | <i>FCOHb (%)</i> | <i>S95</i> | <i>C95</i> | <i>S85</i> | <i>C55</i> | <i>C35</i> |
| 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*

**FCO_{Hb} –
micromodes
(continued)**

Bias:

| FCO _{Hb} | | | ABL830/20 | | |
|-------------------|---------------------|-----------------------|-----------|------|------|
| ctHb (g/dL) | sO ₂ (%) | FCO _{Hb} (%) | 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:

| ctHb (g/dL) | sO ₂ (%) | FCO _{Hb} (%) | 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 |

**FMetHb -
macromodes**

Bias:

| FMetHb | | | ABL835/25 | | ABL830/20 |
|-------------|---------------------|------------|-----------|-------|-----------|
| ctHb (g/dL) | sO ₂ (%) | FMetHb (%) | 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:

| 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 |

Continued on next page

Performance test results - oximetry, *Continued*

FMetHb micromodes

Bias:

| <i>FMetHb</i> | | | ABL835/25 | | | | |
|-----------------------|---------------------------|----------------------|-----------|------|------|------|------|
| <i>ctHb</i> (g/dL) | <i>sO₂</i> (%) | <i>FMetHb</i> (%) | 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 |

| <i>FMetHb</i> | | | ABL830/20 | | |
|--------------------|---------------------------|-------------------|-----------|------|------|
| <i>ctHb</i> (g/dL) | <i>sO₂</i> (%) | <i>FMetHb</i> (%) | 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:

| <i>ctHb</i> (g/dL) | <i>sO₂</i> (%) | <i>FMetHb</i> (%) | 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:

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

* FM = FLEXMODE (no message)

Imprecision:

| <i>FHHb</i> (%) | <i>ctHb</i> (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:

| FHHb | | ABL835/25 | | | | | ABL830/20 | | |
|--------------------|-----------------|------------------|------------|------------|------------|------------|------------------|------------|------------|
| ctHb (g/dL) | FHHb (%) | 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:

| ctHb (g/dL) | FHHb (%) | S₀ | S_D | S_{ABL} | S_X |
|--------------------|-----------------|----------------------|----------------------|------------------------|----------------------|
| 15 | 0 | 0.05 | 0.10 | 0.30 | 0.35 |

FHbF – adult blood

Bias (macromodes):

| FHbF | | ABL835 | | ABL830 |
|-----------------|--------------------|---------------|------------|---------------|
| FHbF (%) | ctHb (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):

| FHbF (%) | ctHb (g/dL) | sO₂ (%) | S₀ | 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):

| <i>FHbF</i> | | ABL835 | | | | | ABL830 | | |
|--------------------|-----------------|--------|-----|-----|-----|-----|--------|-----|-----|
| <i>ctHb</i> (g/dL) | <i>FHbF</i> (%) | 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):

| <i>ctHb</i> (g/dL) | <i>FHbF</i> (%) | <i>sO₂</i> (%) | <i>S₀</i> | <i>S_D</i> | <i>S_{ABL}</i> | <i>S_X</i> |
|--------------------|-----------------|---------------------------|----------------------|----------------------|------------------------|----------------------|
| 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):

| <i>FHbF</i> | | ABL835 | | ABL830 |
|-----------------|--------------------|--------|-----|--------|
| <i>FHbF</i> (%) | <i>ctHb</i> (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):

| <i>FHbF</i> (%) | <i>ctHb</i> (g/dL) | <i>sO₂</i> (%) | <i>S₀</i> | <i>S_D</i> | <i>S_{ABL}</i> | <i>S_X</i> |
|-----------------|--------------------|---------------------------|----------------------|----------------------|------------------------|----------------------|
| 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*

FHbF – fetal blood
(*continued*)

Bias (micromodes):

| FHbF | | ABL835 | | | | | ABL830 | | |
|-------------|----------|--------|-----|-----|-----|-----|--------|-----|-----|
| ctHb (g/dL) | FHbF (%) | 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):

| FHbF (%) | ctHb (g/dL) | sO 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) |
|--------------------|-----------|----------------------------|-------------------------------|
| ctHb | Macromode | All | 0 |
| | Micromode | All | 0 |
| sO ₂ | All | sO ₂ (100 %) | 0.23 |
| FO ₂ Hb | All | FO ₂ Hb (100 %) | 0.15 |
| FCOHb | All | FCOHb (20 % and 0 %) | 0.40 |
| FHHb | All | FHHb (0 %) | 0.23 |

NOTES:

- pH = 7.4 ± 0.1. FHbF 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.
- 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 $\pm 10\%$ 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 $\mu\text{mol/L}$). 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 ctBil, ctHb, sO₂, pH and MCHC values.
- A Hitachi calibrated with NIST SRM 916a standards was used as a reference. ctBil was measured in $\mu\text{mol/L}$. Each field test place had its own ABL735.

Continued on next page

Performance test results - bilirubin, *Continued*

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

| Pos. | Field test place | Type | N | Slope | Intercept $\mu\text{mol/L}$ | R^2 | S_{yx} $\mu\text{mol/L}$ | Range $\mu\text{mol/L}$ |
|------|------------------|---------------------|--------|-------|--------------------------------|--------|-------------------------------|----------------------------|
| 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.

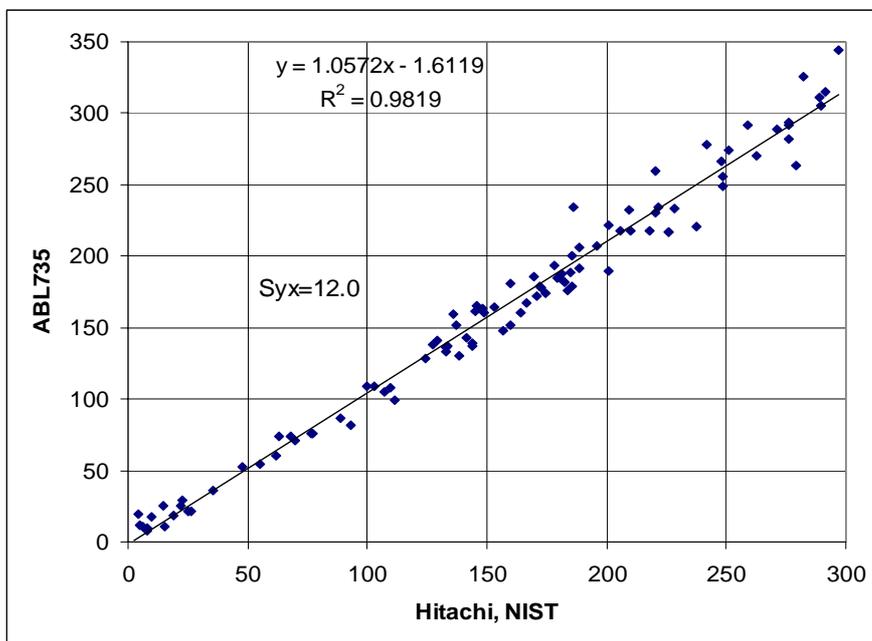
NOTE: (a) Datasubset excluding samples above 300 $\mu\text{mol/L}$.

Continued on next page

Performance test results - bilirubin, *Continued*

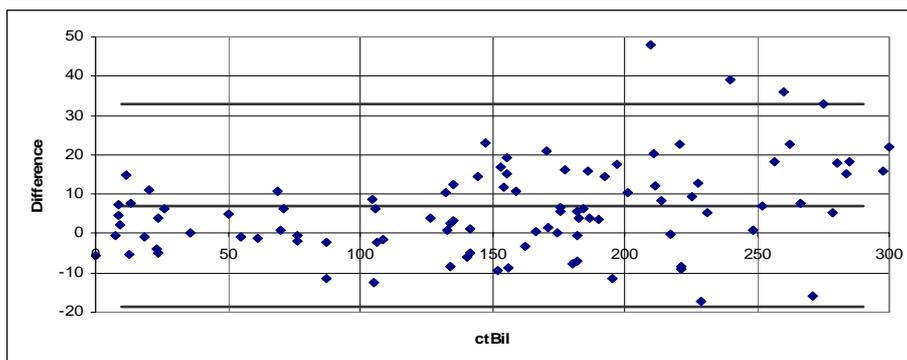
Regression and Bland-Altman plot

Data set position 9 from regression table.



Actual field test from a neonatal critical care hospital using whole blood. Values are in $\mu\text{mol/L}$.

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



Lines indicate Mean, Mean+2SD and Mean-2SD. Values are in $\mu\text{mol/L}$.
 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 μ L and 85 μ L from syringe and capillary:

| ctBil (μ mol/L) | ctHb (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):

| ctBil ($\mu\text{mol/L}$) | ctHb (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 | | 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:

- Adult/fetal blood, pH = 7.4 ± 0.1 , normal MCHC and albumin variation, Spiked with unconjugated bilirubin.
- ctBil specification at level 200 $\mu\text{mol/L}$ is interpolated from the measured specifications at 0 and 400 $\mu\text{mol/L}$.
- The performance specifications apply to measurements performed using CLINITUBES with clot catchers and mixing wire from Radiometer.

References

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

Continued on next page

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 Committee.

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 μ L:

| Parameter | Values | Bias | Repeatability |
|-----------------------|--------|-------|---------------|
| pH | 7.15 | 0.015 | 0.005 |
| | 7.40 | 0.013 | 0.005 |
| $p\text{CO}_2$ (mmHg) | 29 | 1.0 | 0.9 |
| | 80 | -2.9 | 2.6 |
| $p\text{O}_2$ (mmHg) | 130 | 3.0 | 3.9 |
| | 230 | -3.7 | 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 |
| Salicylic acid | 4.0 mmol/L | | | | 7 |

Continued on next page

Interference tests, *Continued*

Electrolytes (*continued*)

| 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) |
| 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 cCl⁻ results.

Metabolites

The following interference results are found for the metabolite electrodes:

| Substance | Test Conc. (mmol/L) | Interference on ... | |
|--------------------------|------------------------|--------------------------------|--------------------------------|
| | | cGlucose (4.0 mmol/L level) | cLactate (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* | |

Continued on next page

Interference tests, *Continued*

Metabolites (*continued*)

| Substance | Test Conc. (mmol/L) | Interference on ... | |
|-----------------------------------|------------------------|--------------------------------|--------------------------------|
| | | cGlucose (4.0 mmol/L level) | cLactate (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 cGlu = 0 mmol/L. Interference at cGlu 4.0 mmol/L is expected to be the same.

| Hematocrit % | Δ cLactate % 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 (*ctHb*, *sO₂*, *FO₂Hb*, *FCOHb*, *FMetHb*, *FHHb*, *FHbF*) and *ctBil* were tested for interference are given in the table below:

(SAT100 blood reference test sample: *ctHb*=15 g/dL, *sO₂*=100 %, *FCOHb*=0.7 %, *FMetHb*=0.5 %, *ctBil*=0, pH=7.4. Parameter sensitivity from the influence on the absorbance spectrum from various substances.)

| Substance | Test conc. | Change on ... | | | | | | | |
|---|-----------------------|-----------------------|------------------------------|--------------------------------|---------------------|----------------------|--------------------|--------------------|--------------------------------|
| | | <i>ctHb</i> (g/dL) | <i>sO₂</i> (%) | <i>FO₂Hb</i> (%) | <i>FCOHb</i> (%) | <i>FMetHb</i> (%) | <i>FHHb</i> (%) | <i>FHbF</i> (%) | <i>ctBil</i> (μ mol/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 |
| SHb | 10 % | 0 | -1.0 | 0.9 | -0.1 | 0.1 | -0.9 | Not tested | |
| pH | 7.1 | -0.5 | -0.5 | -0.2 | -0.4 | 0.1 | 0.5 | -19 | 0 |
| | 7.9 | -0.6 | 0.6 | -0.5 | 1.0 | 0.1 | -0.6 | 13 | -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 μ mol/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 | No interference | | | | | | | -12 |
| | 350 g/L | No interference | | | | | | | 17 |
| Sedimentation rate | 100 arb. Units | $\leq \pm 0.5$ | No interference | | | | | | Not tested |

Notes:

- If function "Correction for HbF levels less than 20 %" is activated, the change is 0 for all parameters.
- Plasma sample.
- Calculated value from mathematical superposition of measured pure interference spectrum on measured reference spectrum.
- ctBil* = 400 μ mol/L.
- Intralipid (20 % solution) at 4 Vol % gives final test level of 0.8 %.
- 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 μ mol/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).

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

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 |
| FHHb % | 0.14 | 0.19 | 0.19 | 0.30 |
| FO ₂ Hb % | 0.01 | 0.01 | 0.01 | 0.01 |
| FCOHb % | 0.09 | 0.13 | 0.12 | 0.20 |
| FMetHb % | 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 |
| FHHb % | 0.09 | 0.11 | 0.28 | 0.32 |
| FO ₂ Hb % | 0.00 | 0.00 | 0.01 | 0.01 |
| FCOHb % | 0.06 | 0.07 | 0.18 | 0.21 |
| FMetHb % | 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 |
| FHHb % | 0.09 | 0.11 | 0.19 | 0.25 |
| FO ₂ Hb % | 0.00 | 0.00 | 0.01 | 0.01 |
| FCOHb % | 0.06 | 0.07 | 0.13 | 0.16 |
| FMetHb % | 0.03 | 0.04 | 0.06 | 0.08 |

Continued on next page

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 cH^+ (hydrogen ion concentration), the relationship between the changes in cH^+ and *FHbF* is linear as seen from the following equation:

$$\Delta FHbF = -0.48 \text{ \%}/(\text{nmol/L}) \times (cH^+ - 40 \text{ nmol/L})$$

where pH = 7.4 corresponds to $cH^+ = 40 \text{ nmol/L}$.

EXAMPLE: pH = 7.25 corresponds to $cH^+ = 56 \text{ nmol/L}$. Then:

$$\Delta FHbF = -0.48 \times (56 - 40) = -7.7 \text{ \%}.$$

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:

$$\text{Hct} = \frac{\text{ctHb}}{\text{MCHC}}$$

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

$$\text{Hct} = \text{ctHb} \times 0.0301 \text{ if the unit for ctHb is g/dL.}$$

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 $\Delta\text{MCHC} = 332 \text{ g/L} - \text{MCHC}$, then the contribution to the relative error on the ctBil measurement is as follows:

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

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

A newborn girl with Hct = 0.58, MCHC = 350 g/L and ctBil = 400 $\mu\text{mol/L}$. ctHb 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) $\frac{\Delta \text{ctBil}}{\text{ctBil}} = -\frac{0.58}{1-0.58} \times \frac{-18}{350} = +0.071$ And $\Delta \text{ctBil} = 0.071 \times 400 = 28 \mu\text{mol/L}$.

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

$$\text{ctBil}(\text{corrected}) = \text{ctBil}(\text{displayed}) \times \frac{1 - \text{ctHb}(\text{displayed}) \times 0.0301}{1 - \text{Hct}(\text{reference})}$$

ctHb is measured in g/dL.

ctBil sensitivity for pH changes ctBil is slightly sensitive to pH deviations from the nominal value of pH = 7.4. The following table shows the changes in ΔctBil compared to the value at pH = 7.4.

| Sample Type | ctHb g/dL | Nominal ctBil $\mu\text{mol/L}$ | ΔctBil (7.4→7.1) $\mu\text{mol/L}$ | ΔctBil (7.4→7.9) $\mu\text{mol/L}$ |
|--|-----------|---------------------------------|---|---|
| Adult/fetal plasma | 0 | 0 | 3 | 0 |
| Adult blood, $s\text{O}_2 = 100 \%$ | 15 | 0 | 0 | -5 |
| Fetal blood, $s\text{O}_2 = 100 \%$ | 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, $s\text{O}_2 = 100 \%$ | 15 | 400 | 10 | -26 |
| Fetal blood spiked with unconjugated bilirubin, $s\text{O}_2 = 100 \%$ | 15 | 400 | -4 | -16 |
| Adult blood spiked with conjugated bilirubin, $s\text{O}_2 = 100 \%$ | 15 | 400 | 14 | -35 |
| Fetal blood spiked with conjugated bilirubin, $s\text{O}_2 = 100 \%$ | 15 | 400 | 0 | -26 |

References

List of references

1. Kristensen HB, Salomon A, Kokholm G. International pH scales and certification of pH.
2. Definition of pH scales, standard reference values, measurement of pH and related terminology (Recommendations 1994). *Pure and Appl Chem* 1985; 57, 3: 531 - 42.
3. Burnett RW, Covington AK, Maas AHJ, Müller-Plathe O *et al.* *J Clin Chem Clin Biochem* 1989; 27: 403 - 08.
4. IFCC reference methods and materials for measurement pH, gases and electrolytes in blood. *Scand J Clin Lab Invest* 1993; 53, Suppl 214: 84 - 94.
5. Glucose. NCCLS Publication RS1-A. Villanova, Pa: NCCLS, 1989.
6. Reference and selected procedures for the quantitative determination of hemoglobin in blood. Approved Standard (3rd edition), NCCLS Publication H15-2A. Villanova, Pa: NCCLS, 2000.
7. Evelyn K, Malloy H. Microdetermination of oxyhemoglobin, methemoglobin and sulfhemoglobin in a single sample of blood. *Biological Chem* 1938; 126: 655 - 62.
8. Kristoffersen K. An improved method for the estimation of small quantities of alkali-resistant hemoglobin in blood. *Scand J Clin Lab Invest* 1961; 13: 402.
9. Quantitative measurement of fetal hemoglobin using the alkali denaturation method. Approved Guideline. NCCLS Publication H13-A 1989; 9, 18.
10. Bergmeyer. *Methods of enzymatic analysis*. 3rd ed., Verlag Chemie Deerfield Beach 1984; 6: 582-88.

6. Parameters

Overview

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

| | | |
|-----------------|--|------|
| Contents | This chapter contains the following topics. | |
| | General information | 6-2 |
| | Measured parameters | 6-5 |
| | Input parameters..... | 6-14 |
| | Derived parameters | 6-17 |
| | Units and numerical format of derived parameters | 6-22 |
| | List of equations..... | 6-27 |
| | Oxyhemoglobin dissociation curve (ODC)..... | 6-43 |
| | Conversion of units | 6-48 |
| | Default values | 6-50 |
| | Altitude correction | 6-51 |
| | References..... | 6-52 |

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 | <p>Oxygen uptake in the lungs indicates whether the pulmonary gas exchange is efficient enough to oxygenate arterial blood.</p> <p>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)</p> <p>However other parameters may also be used, such as the difference in alveolar air and arterial blood oxygen tension ($pO_2(A-a)$).</p> |
| Oxygen Transport | <p>Oxygen transport reveals whether arterial blood contains sufficient oxygen.</p> <p>The oxygen concentration of arterial blood ($ctO_2(a)$) also termed oxygen content is determined by the concentration of total hemoglobin ($ctHb(a)$), the fraction of oxygenated hemoglobin ($FO_2Hb(a)$), and the arterial oxygen tension ($pO_2(a)$).</p> <p>Other parameters which should be known are the oxygen saturation ($sO_2(a)$) and the fractions of dyshemoglobins ($FCO_2Hb(a)$ and $FMetHb(a)$).</p> |
| Oxygen Release | <p>Oxygen release describes the ability of arterial blood to release oxygen to the tissues.</p> <p>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, $p50$.</p> |

Symbols

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

| | | |
|--------------------|---|---|
| 1. <i>Quantity</i> | 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. |

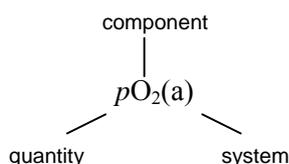
Continued on next page

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 <i>measuring range</i> 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 <i>calculated</i> and a 'c' is added to the result. |
| a default value is used | the derived parameter is designated <i>estimated</i> 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)

cH⁺

Definition Concentration of hydrogen ions in blood.

Unit nmol/L

Measuring range 10.0-501

Reference range 35.5-44.7 (m, f)

pCO₂

Is used both for blood and expired air samples.

Definition Partial pressure (or tension) of carbon dioxide in blood.

High and low pCO₂ values of arterial blood indicate blood hypercapnia and hypocapnia respectively.

Unit mmHg; kPa; torr

Continued on next page

Measured parameters, *Continued*

| | | |
|---|---|--|
| <i>pCO₂</i> <i>(continued)</i> | 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 | $p \text{ (kPa)} = 0.133322 \times p \text{ (mmHg)} = 0.133322 \times p \text{ (torr)}$ $p \text{ (mmHg)} = p \text{ (torr)} = 7.500638 \times p \text{ (kPa)}$ |
| <i>pO₂</i> | Is used for both blood and expired air samples. | |
| | Definition | Partial pressure (or tension) of oxygen in blood. High and low <i>pO₂</i> 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 | $p \text{ (kPa)} = 0.133322 \times p \text{ (mmHg)} = 0.133322 \times p \text{ (torr)}$ $p \text{ (mmHg)} = p \text{ (torr)} = 7.500638 \times p \text{ (kPa)}$ |
| <i>Baro</i> | Definition | Ambient barometric pressure (<i>p(amb)</i>). |
| | Unit | mmHg; kPa; torr |
| | Measuring range | mmHg; torr: 450-800 kPa: 60.0-106.7 |
| | Reference range | - |
| | Conversion of units | $p \text{ (kPa)} = 0.133322 \times p \text{ (mmHg)} = 0.133322 \times p \text{ (torr)}$ $p \text{ (mmHg)} = p \text{ (torr)} = 7.500638 \times p \text{ (kPa)}$ |

Continued on next page

Measured parameters, *Continued*

| | | |
|-------------|---------------------|---|
| ctHb | 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 | ctHb (g/dL) = 1.61140 × ctHb (mmol/L); ctHb (g/L) = 16.1140 × ctHb (mmol/L); ctHb (mmol/L) = 0.62058 × ctHb (g/dL) = 0.062058 × ctHb (g/L) |
| | Default value: | 9.3087 mmol/L, (15.0 g/dL or 150 g/L) |

| | | |
|-----------------------|-------------------------|---|
| sO₂ | 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*

| | | |
|---|-------------------------|--|
| <i>sO₂</i> (<i>continued</i>) | 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 <i>Oxyhemoglobin Dissociation Curve</i> (points I and III). $sO_2 = \frac{S \times (1 - F\text{MetHb}) - F\text{COHb}}{1 - F\text{COHb} - F\text{MetHb}}$ <p>where</p> $S = \text{ODC}(P,A,T)$ $P = pO_2 + \frac{pO_2 \times F\text{COHb}}{sO_2 \times (1 - F\text{COHb} - F\text{MetHb})}$ $A = a$ $T = 37.0 \text{ } ^\circ\text{C}$ |
| <i>FO₂Hb</i> | 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 | $FO_2\text{Hb} = sO_2 \times (1 - F\text{COHb} - F\text{MetHb})$ If <i>sO₂</i> is not measured, it will be calculated. If dyshemoglobins (<i>FCOHb</i> , <i>FMetHb</i>) are not known, they are set to the default values. |

Continued on next page

Measured parameters, *Continued*

| | | |
|---------------------|-----------------|--|
| <i>FCOHB</i> | 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 %) | |

| | | |
|----------------------|-----------------|---|
| <i>FMetHb</i> | 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 %) | |

| | | |
|--------------------|-------------------------|--|
| <i>FHHb</i> | 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 (<i>continued</i>) | Equation | $FHHb = 1 - sO_2 \times (1 - FCOHb - FMetHb) - FCOHb - FMetHb$ <p>If sO_2 is not measured, it will be calculated from equation 39.</p> <p>If dyshemoglobins ($FCOHb$, $FMetHb$) are not known, they are set to the default values.</p> |
| | | |
| FHbF | 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) |
| | | |
| cK⁺ | 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 |
| cNa⁺ | 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*

| | | |
|-------------------------|---------------------|--|
| cCa²⁺ | 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. |
| cCl⁻ | 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 |
| cGlu | 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 | $c\text{Glucose (mg/dL)} = 18.016 \times c\text{Glucose (mmol/L)}$ $c\text{Glucose (mmol/L)} = 0.055506 \times c\text{Glucose (mg/dL)}$ |

Continued on next page

Measured parameters, *Continued*

| | | |
|--------------|---------------------|---|
| cLac | 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 | $c\text{Lactate (mg/dL)} = 9.008 \times c\text{Lactate (mmol/L)}$ $c\text{Lactate (mmol/L)} = 0.11101 \times c\text{Lactate (mg/dL)}$ (conversion based on the molecular weight of lactic acid) |
| ctBil | Definition | Concentration of total bilirubin in plasma. Total bilirubin includes its two forms: conjugated and unconjugated. |
| | Unit | $\mu\text{mol/L}$; mg/dL; mg/L |
| | Measuring range | $\mu\text{mol/L}$: 0-1000 mg/dL: 0.0-58.5 mg/L: 0-585 |
| | Reference range | See the table on the next page. |
| | Conversion of units | $ct\text{Bil } (\mu\text{mol/L}) = 17.1 \times ct\text{Bil (mg/dL)}$ $ct\text{Bil } (\mu\text{mol/L}) = 1.71 \times ct\text{Bil (mg/L)}$ $ct\text{Bil (mg/dL)} = 0.0585 \times ct\text{Bil } (\mu\text{mol/L})$ $ct\text{Bil (mg/L)} = 0.585 \times ct\text{Bil } (\mu\text{mol/L})$ |

Continued on next page

Measured parameters, *Continued*

ctBil (*continued*) The reference ranges are as follows:

| Age | ctBil |
|---------------------|---|
| ≤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 | $T^{\circ}\text{F} = \frac{9}{5}T^{\circ}\text{C} + 32$; $T^{\circ}\text{C} = \frac{5}{9}(T^{\circ}\text{F} - 32)$ |
| FO₂(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) |
| ctHb | 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 | $\text{ctHb (g/dL)} = 1.61140 \times \text{ctHb (mmol/L)}$; $\text{ctHb (g/L)} = 16.1140 \times \text{ctHb (mmol/L)}$; $\text{ctHb (mmol/L)} = 0.62058 \times \text{ctHb (g/dL)} =$ $0.062058 \times \text{ctHb (g/L)}$ | |
| 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 | $p(\text{kPa}) = 0.133322 \times p(\text{mmHg})$ $p(\text{mmHg}) = 7.500638 \times p(\text{kPa})$ |
| $sO_2(\bar{v})$ | 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 | $(\text{mmol/L})\text{min} = (\text{mL/dLmin})/22.41$ |
| 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*

| | | |
|-----------------------------------|----------------------------------|---|
| <i>p50(st)</i> | 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 $p\text{CO}_2 = 5.33 \text{ kPa}$ <i>FCO_{Hb}</i> , <i>FMetHb</i> , <i>FHbF</i> set to 0 <i>p50(st)</i> 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 | $p(\text{kPa}) = 0.133322 \times p(\text{mmHg; torr})$ $p(\text{mmHg; torr}) = 7.500638 \times p(\text{kPa})$ |
| <i>FCO_{Hb}(1)</i> | Definition | The fraction of COHb measured before the CO-injection. |
| | Input range/Unit | %: 0.0 - 100.0 fraction: 0.000 - 1.000 |
| <i>FCO_{Hb}(2)</i> | 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 |
| $cBase(B)$ 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 |
| $cBase(B,ox)$ | $cBase(B)$ of fully oxygenated blood. | dv | 6 |
| $cBase(Ecf)$ or SBE | Standard Base Excess, an <i>in vivo</i> 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 |
| $cBase(Ecf,ox)$ | $cBase(Ecf)$ 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. |
|---------------------------|---|------|-----------|
| $ctCO_2(B)$ | 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 |
| $VCO_2/V(\text{dry air})$ | The volume fraction of carbon dioxide in dry air. | dv | 51 |

Oximetry derived parameters

| Symbol | Definition | Type | Eq. |
|----------|--|-------|-----------|
| $FHHb$ | 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 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 FCO_{Hb} , $FMetHb$, $FHbF$ 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. |
|--|---|------|-----------|
| <i>F</i> Shunt | <p>Relative physiological shunt or concentration-based shunt [5,8,9].</p> <ul style="list-style-type: none"> Calculated from the pulmonary shunt equation: $\frac{\dot{Q}_s}{\dot{Q}_t} = \frac{1}{1 + \frac{ctO_2(a - \bar{v})}{ctO_2(A) - ctO_2(a)}}$ 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: $ctO_2(a - \bar{v}) = 2.3 \text{ mmol / L (5.1 mL / dL)}$ | dv | 34 |
| <i>F</i> Shunt (<i>T</i>) | <i>F</i> 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(<i>T</i>) | 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 |
| <i>V</i> O ₂ / <i>V</i> (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 <i>p</i> O ₂ of 5.0 kPa (38 mmHg) [5,8]. | dv | 38 |
| <i>V</i> (B) | Volume of blood, calculated when <i>F</i> COHb and <i>V</i> (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 ctBil and FHbF. ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations).

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15 /20 FLEX | ABL825/ 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 kPa | xxx.x | c | c | c | T | |
| | | xx.xx | c | c | c | | |
| cHCO ₃ ⁻ (P) | mmol/L | xx.x | c | c | c | | |
| cBase(B) | mmol/L | Range: ±30.0 | c | c | c | ctHb | |
| | | | e | c | c | | |
| cBase(B,ox) | mmol/L | xxx.x | e | c | c | ctHb | |
| | | | e | c | c | | |
| cBase(Ecf) | mmol/L | Range: ±30.0 | c | c | c | | |
| cBase(Ecf,ox) | mmol/L | xxx.x | e | c | c | | |
| cHCO ₃ ⁻ (P,st) | mmol/L | xx.x | c | c | c | ctHb | |
| | | | 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 (ABL83X FLEX corresponds to ABL82X FLEX, but it can measure ctBil and FHbF. ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations).
(*continued*)

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15/20 FLEX | ABL825/30/35 FLEX | Input parameter | Sample type |
|------------------------------|----------------------|----------------------------|--------------|--------------------|-------------------|-----------------|-------------|
| ctCO ₂ (B) | Vol %, mL/dL, mmol/L | xx.x | c | c | c | ctHb | |
| 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 ctBil and FHbF. ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations).

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15/20 FLEX | ABL825/30/35 FLEX | Input parameter | Sample type |
|--------------------|---------------|----------------------------|--------------|--------------------|-------------------|-----------------|-------------|
| Hct | % fraction | xx x.xxx | c | c | c | ctHb | |
| sO ₂ | % fraction | xx.x x.xxx | e | | | | |
| FO ₂ Hb | % fraction | xx.x x.xxx | e | e | c | | |
| FHHb | % fraction | xx.x x.xxx | e | e | c | | |

Continued on next page

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 ctBil and FHbF.

ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations).

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15 /20 FLEX | ABL 825/30/ 35 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, |
| | kPa | xx.xx | e | e | e | | capillary |
| $p50$ | mmHg; torr | xx.xx | e | e | e* | | |
| | kPa | xx.xx | | | | | |
| $p50(T)$ | mmHg; torr | xx.xx | e | e | c* | T | |
| | kPa | xx.xx | | | | | |
| $p50(st)$ | 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 |
| $pO_2(a,T)/FO_2(I)$ | % | xxx.x | c | c | c | $FO_2(I)+T$ | Arterial, |
| | fraction | xx.xx | | | | | capillary |

Continued on next page

Units and numerical format of derived parameters, *Continued*

Oxygen parameters (*continued*)

(ABL83X FLEX corresponds to ABL82X FLEX, but it can measure ctBil and FhbF. ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations).

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15 /20 FLEX | ABL 825/30/ 35 FLEX | Input parameter | Sample type |
|----------------------------------|----------------------|----------------------------|--------------|---------------------|---------------------|----------------------------|---------------------|
| $pO_2(x)$ | mmHg; torr | xxx.x | e | e* | c* | ctHb+p50(st) | Arterial, capillary |
| | kPa | xx.xx | - | e* | c* | | |
| $pO_2(x,T)$ | mmHg; torr | xxx.x | e | e* | c* | ctHb+p50(st)+T | Arterial, capillary |
| | kPa | xx.xx | - | e* | c* | | |
| ctO ₂ (B) | Vol %, mL/dL, mmol/L | xx.x | e | e | c | ctHb | |
| ctO ₂ (a- \bar{v}) | Vol %, mL/dL, mmol/L | xx.x | e | e | c | ctHb | Venous + Arterial |
| BO ₂ | Vol %, mL/dL, mmol/L | xx.x | e | e | c | ctHb | |
| ctO ₂ (x) | Vol %, mL/dL, mmol/L | xx.x | e | e* | c* | ctHb+p50(st) | Arterial, capillary |
| DO ₂ | mL/min | xxxx | e | e | c | Q _t | Arterial, capillary |
| | mmol/min | xxx.x | | | | | |
| Q _t | L/min | xxx.x | e | e | c | V _{O₂} | Venous + arterial |
| V _{O₂} | mL/min | xxxx | e | e | c | Q _t | Venous + arterial |
| | mmol/min | xxx.x | | | | | |
| FShunt | % | xx.x | e | e | c* | ctHb | Venous + arterial |
| | fraction | x.xxx | | | | | |
| FShunt(T) | % | xx.x | e | e | c* | ctHb + T | Venous + arterial |
| | fraction | x.xxx | | | | | |
| RI | % | xx | c | c | c | FO ₂ (I)+RQ | Arterial, capillary |
| | fraction | x.xx | e | e | e | | |

Continued on next page

Units and numerical format of derived parameters, *Continued*

Oxygen parameters (ABL83X FLEX corresponds to ABL82X FLEX, but it can measure ctBil and FHbF. ABL800 BASIC corresponds to ABL815 FLEX with the former's limitations) (continued)

| Symbol | Unit | Numerical format of result | ABL 805 FLEX | ABL 810/15 /20 FLEX | ABL 825/30 /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* | ctHb ¹ +p50(st) ¹ | Arterial, capillary |
| | | | e | e* | c* | | |
| V(B) | L | x.x | c | c | c | ctHb+VCO+FCOH b(1)+FCOHb(2) | |

* If the sO₂ value for establishing the ODC is greater than 0.97, the calculation of the parameter is not performed unless the p50(st) value is keyed in.

¹) If not measured, e.g. ctHb (or derived by analyzer, e.g. p50(st)).

Electrolyte Parameters The table below lists the electrolyte derived parameters.

| 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⁾ | | |
| mOsm | 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]:

$$\text{pH}(T) = \text{pH}(37) - \left[0.0146 + 0.0065 \times (\text{pH}(37) - 7.40) \right] [T - 37]$$

cH⁺(T)

Eq. 2:

$$c\text{H}^+(T) = 10^{(9 - \text{pH}(T))}$$

pCO₂(T)

Eq. 3 [4]:

$$p\text{CO}_2(T) = p\text{CO}_2(37) \times 10^{[0.021 \times (T - 37)]}$$

cHCO₃⁻(P)

Eq. 4 [5]:

$$c\text{HCO}_3^-(P) = 0.23 \times p\text{CO}_2 \times 10^{(\text{pH} - \text{pK}_p)}$$

where

$$\text{pK}_p = 6.125 - \log \left[1 + 10^{(\text{pH} - 8.7)} \right]$$

cHCO₃⁻(P) includes ions of hydrogen carbonate, carbonate, and carbamate in the plasma.

cBase(B)

Eq. 5 [4,14]:

$$c\text{Base}(B) = 0.5 \times \left(\frac{8a' - 0.919}{a'} \right) + 0.5 \times \sqrt{\left(\frac{0.919 - 8a'}{a'} \right)^2 - 4 \times \frac{24.47 - c\text{HCO}_3^-(5.33)}{a'}}$$

Continued on next page

List of equations, *Continued*

cBase(B)
(*continued*)

where

| Eq. | Description |
|-----|-------------|
|-----|-------------|

$$5.1 \quad a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4} \text{ ctHb}$$

$$5.2 \quad c\text{HCO}_3^-(5.33) = 0.23 \times 5.33 \times 10^{\left[\frac{(\text{pH}(\text{st}) - 6.161)}{0.9524} \right]}$$

$$5.3 \quad \text{pH}(\text{st}) = \text{pH} + \log\left(\frac{5.33}{p\text{CO}_2}\right) \times \left(\frac{\text{pH}(\text{Hb}) - \text{pH}}{\log p\text{CO}_2(\text{Hb}) - \log(7.5006 p\text{CO}_2)}\right)$$

$$5.4 \quad \text{pH}(\text{Hb}) = 4.06 \times 10^{-2} \text{ ctHb} + 5.98 - 1.92 \times 10^{(-0.16169 \text{ ctHb})}$$

$$5.5 \quad \log p\text{CO}_2(\text{Hb}) = -1.7674 \times 10^{-2} \text{ ctHb} + 3.4046 + 2.12 \times 10^{(-0.15158 \text{ ctHb})}$$

cBase(B,ox)

Eq. 6 [4]:

$$c\text{Base}(\text{B,ox}) = c\text{Base}(\text{B}) - 0.3062 \times \text{ctHb} \times (1 - s\text{O}_2)$$

If ctHb is not measured or keyed in, the default value will be used.

If sO₂ is not measured, it will be calculated from equation 39.

cBase(Ecf)

Eq. 7 [5]:

$$c\text{Base}(\text{Ecf}) = c\text{Base}(\text{B}) \text{ for ctHb} = 3 \text{ mmol/L}$$

cBase(Ecf,ox)

Eq. 8:

$$c\text{Base}(\text{Ecf,ox}) = c\text{Base}(\text{B,ox}) \text{ for ctHb} = 3 \text{ mmol/L}$$

cHCO₃⁻(P,st)

Eq. 9 [4,14]:

$$c\text{HCO}_3^-(\text{P,st}) = 24.47 + 0.919 \times Z + Z \times a' \times (Z - 8)$$

where

| Eq. | Description |
|-----|-------------|
|-----|-------------|

$$9.1 \quad a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4} \times \text{ctHb}$$

$$9.2 \quad Z = c\text{Base}(\text{B}) - 0.3062 \times \text{ctHb} \times (1 - s\text{O}_2)$$

ctCO₂(P)

Eq. 10 [4,5]:

$$ct\text{CO}_2(\text{P}) = 0.23 \times p\text{CO}_2 + c\text{HCO}_3^-(\text{P})$$

Continued on next page

List of equations, *Continued*

ctCO₂(B) **Eq. 11** [5]:

$$ctCO_2(B) = 9.286 \times 10^{-3} \times pCO_2 \times ctHb \times \left[1 + 10^{(pH_{Ery} - pK_{Ery})} \right] + ctCO_2(P) \times \left(1 - \frac{ctHb}{21.0} \right)$$

where

| Eq. | Description |
|-----|-------------|
|-----|-------------|

| | |
|-----|---|
| 9.1 | $pH_{Ery} = 7.19 + 0.77 \times (pH - 7.40) + 0.035 \times (1 - sO_2)$ |
|-----|---|

| | |
|-----|--|
| 9.2 | $pK_{Ery} = 6.125 - \log \left[1 + 10^{(pH_{Ery} - 7.84 - 0.06 \times sO_2)} \right]$ |
|-----|--|

pH(st) **Eq. 12** [14]:
pH(st): see equations 5.3 - 5.5.

Hct **Eq. 13** [15]:
 $Hct = 0.0485 \times ctHb + 8.3 \times 10^{-3}$
Hct cannot be calculated on the basis of a default ctHb value.

pO₂(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:

$$t_i(T) = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$$

where

| Eq. | Description | See... |
|------|---|-----------|
| 14.1 | $S = ODC(P, A, T)$ | Eq. 47 |
| 14.2 | $sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$ | Eq. 46.12 |
| 14.3 | $pO_{2,i}(T) = \frac{P}{1 + \frac{FCOHb}{sO_{2,i}(T) \times (1 - FCOHb - FMetHb)}}$ | Eq. 46.10 |

Continued on next page

List of equations, *Continued*

| $pO_2(T)$ (<i>continued</i>) | Eq. | Description | See... |
|-----------------------------------|------|---|--------|
| | 14.4 | $\alpha O_2 = 9.83 \times 10^{-3} e^{[-1.15 \times 10^{-2}(T-37.0) + 2.1 \times 10^{-4} \times (T-37.0)^2]}$ | |
| | 14.5 | P is the variable during iteration. | |
| | 14.6 | $A = ac - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$ | |
| | 14.7 | T = patient temperature in °C (keyed-in). | |
| | 14.8 | $\frac{\partial pH}{\partial T} = -1.46 \times 10^{-2} - 6.5 \times 10^{-3} \times (pH(37) - 7.40)$ When $t_i(T) = t_i(37.0)$, then $pO_{2,i}(T) = pO_2(T)$ | |

 $pO_2(A)$

Eq. 15 [5]:

$$pO_2(A) = FO_2(I) \times (p(\text{amb}) - 6.275) - pCO_2 \times [RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)]$$

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”.

 $pO_2(A,T)$

Eq. 16 [4,5,18]:

$$pO_2(A,T) = FO_2(I) \times [p(\text{amb}) - pH_2O(T)] - pCO_2(T) \times [RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)]$$

$$pH_2O(T) = 6.275 \times 10^{[2.36 \times 10^{-2} \times (T - 37.0) - 9.6 \times 10^{-5} \times (T - 37.0)^2]}$$

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”.

Continued on next page

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”.

$p50$ Eq. 19 Refer to Eq. 46.10:

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$p50 = \frac{P}{1 + \frac{FCO_{Hb}}{0.5 \times (1 - FCO_{Hb} - FMetHb)}}$$

where

| Description | See... |
|--|-----------|
| $P = ODC(S,A,T)$ | Eq. 47 |
| $S = \frac{0.5 \times (1 - FCO_{Hb} - FMetHb) + FCO_{Hb}}{1 - FMetHb}$ | Eq. 46.11 |
| $A = a$ | |
| $T = 37.0 \text{ }^\circ\text{C}$ | Eq. 46.13 |

$p50(T)$ Eq. 20:

The ODC is determined as described in equations 46 - 47 in the section *Oxyhemoglobin Dissociation Curve*.

$$p50(T) = \frac{P}{1 + \frac{FCO_{Hb}}{0.5 \times (1 - FCO_{Hb} - FMetHb)}}$$

where

Continued on next page

List of equations, *Continued*

| | | |
|--|---|---------------|
| <i>p50(T)</i> <i>(continued)</i> | Description | See... |
| | $P = \text{ODC}(S, A, T)$ | Eq. 47 |
| | $S = \frac{0.5 \times (1 - \text{FCO}Hb - \text{F}MetHb) + \text{FCO}Hb}{1 - \text{F}MetHb}$ | Eq. 46.11 |
| | $A = a - 1.04 \times \frac{\partial pH}{\partial (T)} \times (T - 37.0)$ | |
| | $\frac{\partial pH}{\partial (T)} = -1.46 \times 10^{-2} - 6.5 \times 10^{-3} \times (\text{pH}(37) - 7.40)$ | |
| | $T = \text{patient temperature in } ^\circ\text{C (keyed-in)}$ | |
| <i>p50(st)</i> | Eq. 21: $p50$ is calculated for $\text{pH} = 7.40$, $p\text{CO}_2 = 5.33 \text{ kPa}$, $\text{FCO}Hb = 0$, $\text{F}MetHb = 0$, $\text{F}HbF = 0$. The ODC is determined as described in equations 46 - 47 in the section <i>Oxyhemoglobin Dissociation Curve</i> , see equation 47. $p50(\text{st}) = \text{ODC}(S, A, T)$ where | |
| | Description | See... |
| | $S = 0.5$ | Eq. 46.11 |
| | $A = a6$ corresponds to $\text{pH} = 7.40$, $p\text{CO}_2 = 5.33 \text{ kPa}$, $\text{FCO}Hb = 0$, $\text{F}MetHb = 0$, $\text{F}HbF = 0$ | Eq. 46.13 |
| | $T = 37.0 \text{ } ^\circ\text{C}$ | |
| <i>pO₂(A-a)</i> | Eq. 22: $pO_2(A - a) = pO_2(A) - pO_2(a)$ The calculation requires entering the sample type as “Arterial” or “Capillary”. | |
| <i>pO₂(A-a,T)</i> | Eq. 23: $pO_2(A - a, T) = pO_2(A, T) - pO_2(a, T)$ 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:**

$$pO_2(a/A) = \frac{pO_2(a)}{pO_2(A)}$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

$pO_2(a/A,T)$ **Eq. 25:**

$$pO_2(a/A,T) = \frac{pO_2(a,T)}{pO_2(A,T)}$$

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 | $sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$ | Eq. 46.12 |
| 26.3 | $pO_{2,i} = \frac{P}{1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}}$ | Eq. 46.10 |
| 26.4 | $t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 9.83 \times 10^{-3} \times pO_{2,i}$ | |
| 26.5 | $A = a$ | |
| 26.6 | $T = 37 \text{ }^\circ\text{C}$ | |

When $t_i = ctO_2 - 2.3 \text{ mmol/L}$, 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 $ctHb$ value.

$pO_2(x)$ can only be calculated if the measured $sO_2(a) \leq 0.97$ (or $p50(st)$ keyed in).

The calculation requires entering the sample type as “Arterial” or “Capillary”.

Continued on next page

List of equations, *Continued*

ctO₂ **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 O₂ in blood (here set to $9.83 \times 10^{-3} \text{ mmolL}^{-1}\text{kPa}^{-1}$ at 37 °C [5,19].

ctO₂ cannot be calculated on the basis of a default ctHb value.

ctO₂(a- \bar{v}) **Eq. 28:**

$$ctO_2(a - \bar{v}) = ctO_2(a) - ctO_2(\bar{v})$$

where ctO₂(a) and ctO₂(\bar{v}) are calculated from equation 27 for arterial and mixed venous blood, respectively. The calculation requires two measurements.

BO₂ **Eq. 29** [7]:

$$BO_2 = ctHb \times (1 - FCOHb - FMetHb)$$

BO₂ cannot be calculated on the basis of a default ctHb value.

**ctO₂(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 | $pO_2(5) = 5.00 \text{ kPa}$ | |
| 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 | $T = 37.0 \text{ °C}$ | |

Continued on next page

List of equations, *Continued*

ctO₂(x)
(or **c_x**)
(*continued*)

ctO₂(a) is determined as described in equation 27.
ctO₂(x) cannot be calculated on the basis of a default ctHb value.
ctO₂(x) can only be calculated if the measured sO₂(a) ≤ 0.97 (or if p50(st) is keyed in).
The calculation requires entering the sample type as “Arterial” or “Capillary”.

ḐO₂

Eq. 31:
$$\dot{D}O_2 = ctO_2 \times \dot{Q}_t$$

ḐO₂ is the cardiac output and is an input parameter for calculation of ḐO₂.
If ḐO₂ is not keyed in, ḐO₂ will not be calculated.
The calculation requires entering the sample type as “Arterial” or “Capillary”.

Ḑ_t

Eq. 32:
$$\dot{Q}_t = \frac{\dot{V}O_2}{ctO_2(a - \bar{v})}$$

If ḐO₂ is not keyed in, Ḑ_t will not be calculated.

ḐO₂

Eq. 33:
$$\dot{V}O_2 = \dot{Q}_t \times ctO_2(a - \bar{v})$$

If Ḑ_t is not keyed in, ḐO₂ will not be calculated.

FShunt

Eq. 34 [5]:
$$FShunt = \frac{ctO_2(c) - ctO_2(a)}{ctO_2(c) - ctO_2(\bar{v})}$$

and

Eq. Description

| | |
|-------------|--|
| 34.1 | $FShunt \cong \frac{ctO_2(A) - ctO_2(a)}{ctO_2(A) - ctO_2(\bar{v})}$ |
|-------------|--|

Continued on next page

List of equations, *Continued*

FShunt (*continued*)

| Eq. | Description |
|------|--|
| 34.2 | $FShunt = \left[1 + \frac{ctO_2(a) - ctO_2(\bar{v})}{ctO_2(A) - ctO_2(a)} \right]^{-1}$ <p>where</p> <p>$ctO_2(c)$: total oxygen in pulmonary capillary blood</p> <p>$ctO_2(a)$: total oxygen in arterial blood</p> <p>$ctO_2(A)$: total oxygen in alveolar blood. Oxygen tension = $pO_2(A)$</p> <p>$ctO_2(\bar{v})$: total oxygen in mixed venous blood</p> |
| 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 | $ctO_2(\bar{v}) = 9.83 \times 10^{-3} pO_2(\bar{v}) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(\bar{v})$ <p>where:</p> <p>$pO_2(a)$: oxygen tension in arterial blood; measured.</p> <p>$pO_2(A)$: oxygen tension in alveolar blood. See equation 15.</p> <p>$pO_2(\bar{v})$: oxygen tension in mixed venous blood; measured and then entered.</p> <p>$sO_2(a)$: oxygen saturation in arterial blood; can be measured.</p> <p>$sO_2(A)$: 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.</p> <p>$sO_2(\bar{v})$: oxygen saturation in mixed venous blood.</p> <p>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.</p> <p>The calculation requires entering the sample type as “Arterial” or “Capillary”.</p> <p>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.</p> <p>If no venous sample is measured, $FShunt$ is estimated assuming:</p> $ctO_2(a) - ctO_2(\bar{v}) = 2.3 \text{ mmol/L in equation 34.2}$ |

Continued on next page

List of equations, *Continued*

FShunt(T) Eq. 35 [5,16]:

$$FShunt(T) = \left[1 + \frac{ctO_2(a,T) - ctO_2(\bar{v},T)}{ctO_2(A,T) - ctO_2(a,T)} \right]^{-1}$$

where

$ctO_2(a,T)$: total oxygen in arterial blood at patient temperature

$ctO_2(A,T)$: total oxygen in alveolar blood at patient temperature $ctO_2(\bar{v},T)$: total oxygen in mixed venous blood at patient temperature

| Eq. | Description | See... |
|-------|---|--------|
| 35.1 | $ctO_2(a,T) = ctO_2$ calculated from equation 25 for arterial pO_2 and sO_2 values at 37 °C. | |
| 35.2 | $ctO_2(A,T) = \alpha O_2(T) \times pO_2(A,T) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(A,T)$ | |
| 35.3 | $\alpha O_2(T) = 9.83 \times 10^{-3} e^{[-1.15 \times 10^{-2} \times (T-37.0) + 2.1 \times 10^{-4} \times (T-37.0)^2]}$ | |
| 35.4 | $pO_2(A,T)$ is calculated from equation 15. | |
| 35.5 | $sO_2(A,T) = S$ | |
| 35.6 | $S = ODC(P,A,T)$ | Eq. 47 |
| 35.7 | $P = pO_2(A,T)$ | |
| 35.8 | $A = a - 1.04 \times \frac{\partial pH}{\partial(T)} \times (T - 37.0)$ | |
| 35.9 | $T =$ patient temperature (keyed-in) | |
| 35.10 | $\frac{\partial pH}{\partial(T)} = 1.46 \times 10^{-2} - 6.5 \times 10^{-3} (pH(37) - 7.40)$ 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. | |
| 35.11 | $ctO_2(\bar{v},T) = ctO_2(\bar{v})$ at 37 °C is calculated from equation 27 for mixed venous blood values of pO_2 and sO_2 . If $sO_2(\bar{v}) > 0.97$, a keyed-in $p50(st)$ will be used to determine the ODC. If $sO_2(\bar{v}) > 0.97$ 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 $FShunt(T)$ is estimated assuming $ctO_2(a,T) - ctO_2(\bar{v},T) = 2.3$ mmol/L in equation 35. | |

Continued on next page

List of equations, *Continued*

RI**Eq. 36:**

$$RI = \frac{pO_2(A) - pO_2(a)}{pO_2(a)}$$

The calculation requires entering the sample type as “Arterial” or “Capillary”.

RI(T)**Eq. 37:**

$$RI(T) = \frac{pO_2(A, T) - pO_2(a, T)}{pO_2(a, T)}$$

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*.

$$Q_x = \frac{2.3}{ctO_2(a) - t_i}$$

| Eq. | Description | See... |
|------|--|-----------|
| 38.1 | $t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 9.83 \times 10^{-3} pO_2(5)$ | |
| 38.2 | $pO_2(5) = 5.00 \text{ kPa}$ | |
| 38.3 | $S = ODC(P, A, T)$ | |
| 38.4 | $P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)} \right]$ | Eq. 46.9 |
| 38.5 | $sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$ | Eq. 46.12 |
| 38.6 | $A = a$ | |
| 38.7 | $T = 37.0 \text{ }^\circ\text{C}$ | |

$ctO_2(a)$ is determined as described in equation 27.

Q_x cannot be calculated on the basis of a default $ctHb$ value.

Q_x can only be calculated if the measured $sO_2(a) \leq 0.97$ (or if $p50(st)$ is keyed in).

The calculation requires entering the sample type as “Arterial” or “Capillary”.

Continued on next page

List of equations, *Continued*

sO₂ **Eq. 39:**
 The ODC is determined as described in equation 46 (points I and III). See the section *Oxyhemoglobin Dissociation Curve*.

$$sO_2 = \frac{S \times (1 - F\text{MetHb}) - F\text{COHb}}{1 - F\text{COHb} - F\text{MetHb}}$$

where

| Description | See... |
|--|----------|
| $S = \text{ODC}(P,A,T)$ | |
| $P = pO_2 + \frac{pO_2 \times F\text{COHb}}{sO_2 \times (1 - F\text{COHb} - F\text{MetHb})}$ | Eq. 46.9 |
| $A = a$ | |
| $T = 37.0 \text{ }^\circ\text{C}$ | |

FO₂Hb **Eq. 40:**
 $FO_2\text{Hb} = sO_2 \times (1 - F\text{COHb} - F\text{MetHb})$
 If sO₂ is not measured, it will be calculated from equation 39.
 If dyshemoglobins (FCOHb, FMetHb) are not known, they are set to the default values.

FHHb **Eq. 41:**
 $F\text{HHb} = 1 - sO_2 \times (1 - F\text{COHb} - F\text{MetHb}) - F\text{COHb} - F\text{MetHb}$
 If sO₂ is not measured, it will be calculated from equation 39.
 If dyshemoglobins (FCOHb, FMetHb) are not known, they are set to the default values.

V(B) **Eq. 42 [5]:**

$$V(B) = \frac{1 \times 10^3 \times V(\text{CO})}{24 \times (F\text{COHb}(2) - F\text{COHb}(1)) \times 0.91 \times ct\text{Hb}}$$

Continued on next page

List of equations, *Continued*

| | | |
|-------------------------------------|--------------------------|---|
| V(B) (<i>continued</i>) | Eq. | Description |
| | 42.1 | $V(B) = \frac{V(\text{CO})}{2.184 \times 10^{-2} \times (FCO\text{Hb}(2) - FCO\text{Hb}(1)) \times ct\text{Hb}}$ |
| | 42.2 | V(CO) = volume (in mL) of carbon monoxide injected according to the procedure and the value keyed-in. |
| | 42.3 | FCO _{Hb} (1) = fraction of CO _{Hb} measured before the CO injection |
| | 42.4 | FCO _{Hb} (2) = fraction of CO _{Hb} measured after the CO injection |
| Anion Gap, K⁺ | Eq. 43: | $\text{Anion Gap, K}^+ = c\text{Na}^+ + c\text{K}^+ - c\text{Cl}^- - c\text{HCO}_3^-$ |
| Anion Gap | Eq. 44: | $\text{AnionGap} = c\text{Na}^+ - c\text{Cl}^- - c\text{HCO}_3^-$ |
| cCa²⁺(7.4) | Eq. 45 Ref. [12]: | $c\text{Ca}^{2+}(7.4) = c\text{Ca}^{2+} [1 - 0.53 \times (7.40 - \text{pH})]$ 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 <i>Oxyhemoglobin dissociation curve (ODC)</i> . |
| mOsm | Eq. 48: | $m\text{Osm} = 2c\text{Na}^+ + c\text{Glu}$ |
| FHbF | Eq. 49: | An iterative method is used to calculate FHbF. The input parameters are sO ₂ , ceHb (effective hemoglobin concentration), and cO ₂ HbF (concentration of fetal oxyhemoglobin). In the calculations the following are assumed: pH = 7.4, pCO ₂ = 5.33 kPa, FCO _{Hb} = 0, FMetHb = 0, cDPG = 5 mmol/L, and temp = 37 °C. |
| | Step | Description |
| | 1. | An estimate of FHbF is made: $F\text{HbF}_{\text{est}} = 0.8$ |
| | 2. | $p\text{O}_{2,\text{est}} = \text{ODC}(s\text{O}_2, A, T)$; where the constant A depends on $F\text{HbF} = F\text{HbF}_{\text{est}}$ |
| | | See... Eq. 47 |

Continued on next page

List of equations, *Continued*

| <i>FHbF</i> (<i>continued</i>) | Step | Description | See... |
|-------------------------------------|------|---|--------|
| | 3. | sO_2 (for fetal blood) = ODC ($pO_{2,est}$, A, T); where $FHbF = 1$ | Eq.47 |
| | 4. | $cO_2HbF_{est} = sO_2$ (fetal blood) \times $ceHb \times FHbF_{est}$ | |
| | 5. | $\Delta FHbF_{est} = \frac{cO_2HbF_{meas.} - cO_2HbF_{est}}{ceHb}$ | |
| | 6. | If $ \Delta FHbF_{est} \geq 0.001$, proceed to step 7. If $ \Delta FHbF_{est} < 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 $FHbF$ has converged. | |

$pO_2(x, T)$

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 | $\alpha O_2(T) = 0.00983 \times e^{[-0.115 \times (T-37) + 21 \times 10^{-5} \times (T-37)^2]}$ | |

Continued on next page

List of equations, *Continued*

| $pO_2(x,T)$ (<i>continued</i>) | Eq. | Description |
|-------------------------------------|-------------|---|
| | 50.8 | $pO_{2,i} = pO_2(x,T)$ <p>when $t_i(T) = ctO_2(37\text{ }^\circ\text{C}) - 2.3\text{ mmol/L}$</p> <p>$pO_2(x,T)$ is calculated in accordance with OSA V3.0.</p> <p>$pO_2(x,T)$ can only be calculated if the measured $sO_2(a) \leq 0.97$ (or $p50(st)$ keyed in).</p> <p>$pO_2(x,T)$ is tagged with "?" if any of the following parameters: sO_2, $FMetHb$, $FCOHb$, pO_2, pCO_2, pH or $ctHb$ is tagged with "?".</p> <p>The calculation requires entering the sample type as "Arterial" or "Capillary".</p> |

$VCO_2/V(\text{dry air})$ Eq. 51:

$$VCO_2 / V(\text{dry air}) = \frac{pCO_2}{p(\text{amb}) - 6.275}$$

$VO_2/V(\text{dry air})$ 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 FCO_{Hb} on the shape of the Oxyhemoglobin Dissociation Curve (ODC) in accordance with the Haldane equation.

Eq. 46 [16,18]:

$$y - y^{\circ} = (x - x^{\circ}) + h \times \tanh\left[k^{\circ}(x - x^{\circ})\right]$$

where $k^{\circ} = 0.5343$

| Eq. | Description |
|------|---|
| 46.1 | $x = \ln p$ |
| 46.2 | $y = \ln \frac{s}{1-s}$ |
| 46.3 | $y^{\circ} = \ln \frac{s^{\circ}}{1-s^{\circ}}$ where $s^{\circ} = 0.867$ |
| 46.4 | $x^{\circ} = x^{\circ\circ} + a + b = \ln(p^{\circ\circ}) + a + b$ where $p^{\circ\circ} = 7 \text{ kPa}$ |

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 $p50(st) = 3.578 \text{ kPa}$, which is traditionally considered the most likely value of $p50$ for adult humans under standard conditions, namely:

$$pH = 7.40$$

$$pCO_2 = 5.33 \text{ kPa}$$

$$FCO_{Hb}, FMetHb, FHbF = 0$$

$$cDPG = 5 \text{ mmol/L}$$

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 | $x - x^{\circ} = \ln \frac{p}{7} - a - b$ |
|------|---|

| | |
|------|---|
| 46.6 | $h = h^{\circ} + a$ where $h^{\circ} = 3.5$ |
|------|---|

| | |
|------|--|
| 46.7 | $b = 0.055 \times (T - T^{\circ})$ $T^{\circ} = 37^{\circ}C$ |
|------|--|

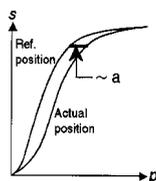
| | |
|------|---------------------------|
| 46.8 | $p = pO_2 + M \times pCO$ |
|------|---------------------------|

where $M \times pCO$ is taken from the Haldane equation [20]:

$$\frac{pO_2}{cO_2Hb} = M \times \frac{pCO}{cCOHb}, \text{ to give eq. 46.9}$$

| | |
|------|---|
| 46.9 | $p = pO_2 + \frac{pO_2}{sO_2} \times \left[\frac{FCO_{Hb}}{1 - FCO_{Hb} - FMetHb} \right]$ or equation 46.10 |
|------|---|

| | |
|-------|--|
| 46.10 | $pO_2 = \frac{p \times [sO_2 \times (1 - FCO_{Hb} - FMetHb)]}{1 + FCO_{Hb}}$ |
|-------|--|



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 | $s = \frac{cO_2Hb + cCOHb}{cO_2Hb + cCOHb + cHHb}$ <p style="text-align: right;">or</p> $= \frac{sO_2 \times (1 - FCO_{Hb} - FMetHb) + FCO_{Hb}}{1 - FMetHb}$ |
|-------|---|

| | |
|-------|---|
| 46.12 | $sO_2 = \frac{s \times (1 - FMetHb) - FCO_{Hb}}{1 - FCO_{Hb} - FMetHb}$ |
|-------|---|

Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

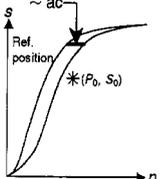
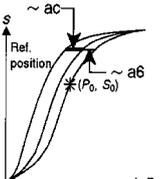
The actual ODC position The actual position of the ODC at 37 °C for a given sample is, in principle, determined in two steps:

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 (P₀, S₀).

| Eq. | Description |
|-----|-------------|
|-----|-------------|

| | |
|--------------|--|
| 46.13 | $a = ac + a6$ |
| 46.14 | $ac = a1 + a2 + a3 + a4 + a5$ |
| 46.15 | $a1 = -0.88 \times (\text{pH} - 7.40)$ |
| 46.16 | $a2 = 0.048 \times \ln \frac{p\text{CO}_2}{5.33}$ |
| 46.17 | $a3 = -0.7 \times F\text{MetHb}$ |
| 46.18 | $a4 = (0.06 - 0.02F\text{HbF}) \times (c\text{DPG} - 5)$ |
| 46.19 | $a5 = -0.25 \times F\text{HbF}$ |

Determining the actual displacement

| Step | Description |
|--|---|
| <p>(I):</p>  | <p>pO₂, sO₂ can be used.</p> <p>If sO₂ > 0.97, the calculation is based on (II) or (III) - see below.</p> <p>Coordinates (P₀, S₀) are calculated from equations (46.9) and (46.11).</p> <p>If FCOHb and FMetHb are not known, the default values are used.</p> <p>The ODC is shifted from the reference position to a position which corresponds to the effect of all measured parameters according to step (I).</p> <p>The magnitude of the shift is “ac”.</p> |
|  | <p>The ODC is then further shifted to pass through the point (P₀, S₀).</p> <p>The magnitude of the shift is “a6”.</p> |

Continued on next page

Oxyhemoglobin dissociation curve (ODC), *Continued*

Determining the actual displacement (*continued*)

| Step | Description |
|---|---|
| <p>(II):</p> <p>The first graph shows a standard sigmoidal curve labeled 'Ref. position' on the y-axis. The second graph shows a similar curve shifted to the right, with a point (P_0, S_0) marked on the curve. The third graph shows the curve shifted further to the right, with a point (P_0, S_0) marked and a horizontal arrow labeled 'ac' indicating the shift from the reference position.</p> | <p>$sO_2 > 0.97$ (or erroneous) and $p50(st)$ is keyed in.</p> <p>Coordinates (P_0, S_0) are calculated from $(p50(st), 0.5)$ using equations 46.9 and 46.11.</p> <p>Reference position of the ODC.</p> <p>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.</p> <p>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.</p> |
| <p>(III):</p> <p>The first graph shows the reference position of the ODC. The second graph shows the actual ODC position approximated from the reference position, with a horizontal arrow labeled 'ac' indicating the shift.</p> | <p>$sO_2 > 0.97$ (or erroneous) and no $p50(st)$ has been keyed in.</p> <p>Reference position of the ODC.</p> <p>The position of the actual ODC can now be approximated from the reference position, using the actual values of pH, pCO_2, FCO_{Hb}, $FMetHb$ and $FHbF$ to determine the shift 'ac'.</p> |

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:

$$S = \text{ODC}(P, A, T) \quad \text{or} \quad P = \text{ODC}(S, A, T)$$

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 $s\text{O}_2$ and $p\text{O}_2$, 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

$$T\text{ }^{\circ}\text{F} = \frac{9}{5}T\text{ }^{\circ}\text{C} + 32$$

$$T\text{ }^{\circ}\text{C} = \frac{5}{9}(T\text{ }^{\circ}\text{F} - 32)$$

cK⁺, cNa⁺, cCl⁻ $cX\text{ (meq/L)} = cX\text{ (mmol/L)}$ where X is K⁺, Na⁺ or Cl⁻.

cCa²⁺

$$c\text{Ca}^{2+}\text{ (meq/L)} = 2 \times c\text{Ca}^{2+}\text{ (mmol/L)} \text{ or}$$

$$c\text{Ca}^{2+}\text{ (mg/dL)} = 4.008 \times c\text{Ca}^{2+}\text{ (mmol/L)}$$

$$c\text{Ca}^{2+}\text{ (mmol/L)} = 0.5 \times c\text{Ca}^{2+}\text{ (meq/L)} \text{ or}$$

$$c\text{Ca}^{2+}\text{ (mmol/L)} = 0.2495 \times c\text{Ca}^{2+}\text{ (mg/dL)}$$

Pressure

$$p\text{ (mmHg)} = p\text{ (torr)} = 7.500638 \times p\text{ (kPa)}$$

$$p\text{ (kPa)} = 0.133322 \times p\text{ (mmHg)} = 0.133322 \times p\text{ (torr)}$$

ctHb

[4]

$$ct\text{Hb (g/dL)} = 1.61140 \times ct\text{Hb (mmol/L)}$$

$$ct\text{Hb (g/L)} = 16.1140 \times ct\text{Hb (mmol/L)} \text{ or}$$

$$ct\text{Hb (mmol/L)} = 0.62058 \times ct\text{Hb (g/dL)}$$

$$ct\text{Hb (mmol/L)} = 0.062058 \times ct\text{Hb (g/L)}$$

ctCO₂, ctO₂, ctO₂(a- \bar{v}), BO₂

$$\text{Vol \%} = 2.241 \times (\text{mmol/L})$$

$$\text{Vol \%} = \text{mL/dL}$$

$$\text{mmol/L} = 0.4462 \times (\text{mL/dL})$$

Continued on next page

Conversion of units, *Continued*

$$\dot{V}O_2 \quad \dot{V}O_2 \text{ (mmol/L)/min} = \dot{V}O_2/22.41 \text{ (mL/dL)/min}$$

$$c\text{Glucose} \quad [22]$$

$$c\text{Glucose (mg/dL)} = 18.016 \times c\text{Glucose (mmol/L) or}$$

$$c\text{Glucose (mmol/L)} = 0.055506 \times c\text{Glucose (mg/dL)}$$

$$c\text{Lactate} \quad [22]$$

$$c\text{Lactate (mg/dL)} = 9.008 \times c\text{Lactate (mmol/L) or}$$

$$c\text{Lactate (mmol/L)} = 0.11101 \times c\text{Lactate (mg/dL)}$$

$$c\text{Lactate (meq/L)} = c\text{Lactate (mmol/L)}$$

(conversion based on the molecular weight of lactic acid)

$$ct\text{Bil} \quad ct\text{Bil (}\mu\text{mol/L)} = 17.1 \times ct\text{Bil (mg/dL)}$$

$$ct\text{Bil (}\mu\text{mol/L)} = 1.71 \times ct\text{Bil (mg/L) or}$$

$$ct\text{Bil (mg/dL)} = 0.0585 \times ct\text{Bil (}\mu\text{mol/L)}$$

$$ct\text{Bil (mg/L)} = 0.585 \times ct\text{Bil (}\mu\text{mol/L)}$$

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.

| | | |
|--------------------------|---|--|
| <i>T</i> | = | 37.0 °C (99 °F) |
| <i>FO₂(I)</i> | = | 0.21 (21.0 %) |
| RQ | = | 0.86 |
| <i>ctHb</i> | = | 9.3087 mmol/L, (15.00 g/dL or 150 g/L) |
| <i>FCOHb</i> | = | 0.004 (0.4 %) |
| <i>FMetHb</i> | = | 0.004 (0.4 %) |
| <i>p50(st)</i> | = | 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].

References

List of references

1. The Deep Picture™, critical information from blood gas analysis. Copenhagen: Radiometer Medical A/S, 1993: 1-14.
2. Wandrup JH. Physicochemical logic and simple symbol terminology of oxygen status. *Blood Gas News* 1993; 2,1: 9-11.
3. Siggaard-Andersen O, Durst RA, Maas AHJ. Approved recommendation (1984) on physicochemical quantities and units in clinical chemistry. *J Clin Chem Clin Biochem* 1987; 25: 369-91.
4. Siggaard-Andersen O. The acid-base status of the blood. 4th revised ed. Copenhagen: Munksgaard, 1976.
5. Siggaard-Andersen O, Wimberley PD, Fogh-Andersen N, Gøthgen IH. Measured and derived quantities with modern pH and blood gas equipment: calculation algorithms with 54 equations. *Scand J Clin Lab Invest* 1988; 48, Suppl 189: 7-15.
6. Burnett RW, Noonan DC. Calculations and correction factors used in determination of blood pH and blood gases. *Clin Chem* 1974; 20,12: 1499-1506.
7. Wimberley PD, Siggaard-Andersen O, Fogh-Andersen N, Zijlstra WG, Severinghaus JW. Hemoglobin oxygen saturation and related quantities: definitions, symbols and clinical use. *Scand J Clin Lab Invest* 1990; 50: 455-59. Available as AS104.
8. Siggaard-Andersen O, Gøthgen IH, Wimberley PD, Fogh-Andersen N. The oxygen status of the arterial blood revised: relevant oxygen parameters for monitoring the arterial oxygen availability. *Scand J Clin Lab Invest* 1990; 50, Suppl 203: 17-28. Available as AS108.
9. Wandrup JH. Oxygen uptake in the lungs. *Blood Gas News* 1992; 1,1: 3-5.
10. Tietz NW, Logan NM. Reference ranges. In: Tietz NW, ed. *Fundamentals of clinical chemistry*. 3rd ed. Philadelphia: WB Saunders Company, 1987: 944-75.
11. 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.
12. 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.
13. Severinghaus JW. Blood gas calculator. *J Appl Physiol* 1966; 21,3: 1108-16. Available as ST36.
14. Christiansen TF. An algorithm for calculating the concentration of the base excess of blood. 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: 77-81.

Continued on next page

References, *Continued*

List of references (*continued*)

15. Kokholm G. Simultaneous measurements of blood pH, $p\text{CO}_2$, $p\text{O}_2$ and concentrations of hemoglobin and its derivatives - a multicenter study. *Scand J Clin Lab Invest* 1990; 50, Suppl 203: 75-86. Available as AS107.
16. Siggaard-Andersen O, Wimberley PD, Gøthgen IH, Siggaard-Andersen M. A mathematical model of the hemoglobin-oxygen dissociation curve of human blood and of the oxygen partial pressure as a function of temperature. *Clin Chem* 1984; 30: 1646-51.
17. Siggaard-Andersen O, Wimberley PD, Gøthgen IH, Fogh-Andersen N, Rasmussen JP. Variability of the temperature coefficients for pH, $p\text{CO}_2$ and $p\text{O}_2$ in blood. *Scand J Clin Lab Invest* 1988; 48, Suppl 189: 85-88.
18. Siggaard-Andersen O, Siggaard-Andersen M. The oxygen status algorithm: a computer program for calculating and displaying pH and blood gas data. *Scand J Clin Lab Invest* 1990; 50, Suppl 203: 29-45.
19. Bartels H, Christoforides C, Hedley-Whyte J, Laasberg L. Solubility coefficients of gases. In: Altman PL, Dittmer DS, eds. *Respiration and circulation*. Bethesda, Maryland: Fed Amer Soc Exper Biol, 1971: 16-18.
20. Roughton FJW, Darling RC. The effect of carbon monoxide on the oxyhemoglobin dissociation curve. *Am J Physiol* 1944; 141: 17-31.
21. Engquist A.. *Fluids electrolytes nutrition*. Copenhagen: Munksgaard, 1985: 56-68 and 118.
22. Olesen H. *et al.* A proposal for an IUPAC/IFCC recommendation, quantities and units in clinical laboratory sciences. IUPAC/IFCC Stage 1, Draft 1, 1990: 1-361.
23. Kokholm G, Larsen E, Jensen ST, Christiansen TF. 3rd ed. *Blood gas measurements at high altitudes*. Copenhagen: Radiometer Medical A/S, 1991. Available as AS109.

7. Solutions and gas mixtures

Overview

Introduction This chapter gives information about all the solutions and gases used with the ABL8XX 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 | 7-2 |
| Calibration solutions | 7-3 |
| Rinse and Cleaning solutions | 7-4 |
| Electrolyte solutions..... | 7-5 |
| S5362 Hypochlorite solution..... | 7-6 |
| Gas mixtures (Gas 1 and Gas 2)..... | 7-7 |
| Traceability certificates..... | 7-8 |

General information

| | |
|--------------------------------|--|
| In Vitro Diagnostic Use | All the solutions described in this chapter are for <i>in vitro</i> 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/ABL800 BASIC Operator's manuals, <i>Chapter 14</i> . |

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 |
| | cGlu | 10 |
| | cLac | 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. The calibrated value can be ctHb, cTHb and ctBil, or ctBil 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 °C (36-90 °F).
- Stability: Expiration date and Lot No. are printed on a separate label.
When stored between 2-32 °C (36-90 °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 °C (36-90 °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 °C (36-46 °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 $p\text{CO}_2$ electrode | 0.6 mL in 4 pre-filled electrode jackets per D788 Membrane Box | Inorganic salts, buffer, hygroscopic compound, preservative and surfactant. |
| E799 $p\text{O}_2$ 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 advice.

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: <i>Analyzer Menus and Programs</i> . |
| Quantity: | 100 mL. Delivered with a 1 mL syringe. |
| Composition: | Contains sodium hypochlorite (pH \approx 12). |
| Storage: | Keep in a dark place at 2-8 °C (36-46 °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 $p\text{CO}_2$ and $p\text{O}_2$ 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

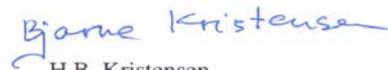
Traceability of parameters:

| 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 |
| cGlucose | mmol/L (37 °C) | NIST SRM | 0,3 |
| cLactate | 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



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.

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.

Certificate of Traceability

Product name: tHB Calibration Solution

Type: S7770

Code: 944-021

Traceability of parameters:

| Parameter | Unit | Traceable to | Expanded Uncertainty |
|-----------------|------|--|----------------------|
| ctHb | 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, ctHb = 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 Söderstrøm
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.

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.

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.

Index

A

| | |
|---|------|
| Absorbance | 3-4 |
| Additional information about FLEXMODE | 5-46 |
| Altitude Correction | 6-51 |
| Amperometric method | 2-2 |

B

| | |
|--------------------------------|-----|
| Bias | 5-2 |
| BiasABL chart description..... | 5-5 |

C

| | |
|--|----------|
| Calibration | 1-3, 2-3 |
| Calibration line | 1-4 |
| Calibration material | 2-3 |
| Calibration materials..... | 1-7 |
| Continuous spectrum | 3-5 |
| Contribution to imprecision specifications from HbF correction | 5-51 |
| Conversion of Units | 6-48 |
| Correcting for Interferences | 3-7 |
| Correction Factors for Oximetry Parameters and Bilirubin | 4-4 |
| Correction Factors for Electrolyte and Metabolite Parameters..... | 4-7 |
| ctBil sensitivity for pH changes | 5-54 |

D

| | |
|--|------|
| Default Values | 6-50 |
| Defintion of terms and test conditions | 5-2 |
| Derived Parameters..... | 6-17 |
| Determining concentrations | 3-6 |
| Drift | 1-6 |

E

| | |
|-----------------------------------|------|
| Electrolyte electrodes | |
| Calibration solution values | 1-25 |
| Corrections | 1-29 |
| Drift | 1-27 |
| Sensitivity | 1-26 |
| Stability criteria | 1-32 |
| Status | 1-26 |
| Electrolyte Electrodes | 1-22 |

F

| | |
|---------------------------------------|------|
| FHbF sensitivity for pH changes | 5-52 |
|---------------------------------------|------|

H

| | |
|----------------------|-----|
| HbF versus HbA | 3-7 |
|----------------------|-----|

I

| | |
|-------------------------|------|
| Imprecision | 5-3 |
| Imprecision chart | 5-6 |
| Input Parameters | 6-14 |
| Interference tests | |
| Electrolytes | 5-47 |
| Metabolites | 5-48 |

| | |
|--|-----------|
| Oximetry parameters | 5-50 |
| pH/blood gas..... | 5-47 |
| L | |
| Lambert-Beer's law | 3-4 |
| List of Equations | 6-27 |
| M | |
| Matrix of constants | 3-6 |
| Mean Corpuscular Hemoglobin Concentration | |
| MCHC | 5-52 |
| Measured parameters | 3-2 |
| Measured Parameters | 6-5 |
| Measuring time | 1-7 |
| Metabolite electrodes | |
| Corrections | 2-17 |
| Drift | 2-16 |
| Sensitivity | 2-15 |
| Stability criteria | 2-19 |
| Zero current | 2-13 |
| Metabolite Electrodes | 2-12 |
| N | |
| Nernst equation | 1-2, 1-24 |
| O | |
| Optical System..... | 3-2 |
| Oximetry and bilirubin | |
| Measurement and Corrections | 3-9 |
| Oxyhemoglobin Dissociation Curve (ODC)..... | 6-43 |
| P | |
| Parameters | |
| Ranges and limits | 6-3 |
| Symbols | 6-2 |
| <i>p</i> CO ₂ electrode | |
| Corrections - blood samples | 1-17 |
| Corrections - expired air samples | 1-19 |
| Drift | 1-16 |
| Sensitivity | 1-16 |
| Stability criteria | 1-20 |
| Status | 1-16 |
| <i>p</i> CO ₂ electrode..... | 1-14 |
| Performance test results - bilirubin | 5-40 |
| Performance test results – <i>c</i> Ca ²⁺ | 5-22 |
| Performance test results – <i>c</i> Cl ⁻ | 5-20 |
| Performance test results – <i>c</i> Glu | 5-24 |
| Performance test results – <i>c</i> K ⁺ | 5-16 |
| Performance test results – <i>c</i> Lac | 5-26 |
| Performance test results – <i>c</i> Na ⁺ | 5-18 |
| Performance test results – <i>c</i> tHb | 5-28 |
| Performance test results - oximetry | 5-30 |
| Performance test results – <i>p</i> CO ₂ | 5-10 |
| Performance Test Results - pH | 5-8 |
| Performance test results – <i>p</i> O ₂ | 5-13 |
| pH electrode | |
| Corrections | 1-11 |
| Drift | 1-10 |
| Sensitivity | 1-10 |
| Stability criteria | 1-13 |

| | |
|--|------|
| Status | 1-10 |
| pH electrode..... | 1-9 |
| <i>p</i> O ₂ electrode | |
| Corrections - blood samples | 2-8 |
| Corrections - expired air samples | 2-10 |
| Drift | 2-6 |
| Sensitivity..... | 2-5 |
| Stability criteria | 2-10 |
| Zero point | 2-6 |
| <i>p</i> O ₂ electrode..... | 2-4 |
| Potentiometric method..... | 1-2 |
| R | |
| Reference Electrode..... | 1-8 |
| Repeatability | 5-2 |
| Repeatability chart..... | 5-6 |
| Residual spectrum..... | 3-8 |
| S | |
| Sensitivity | 1-5 |
| Status | 1-6 |
| T | |
| Test conditions..... | 5-4 |
| The Deep Picture™ | 6-2 |
| Total absorbance | 3-4 |
| U | |
| Units and Numerical Format of Derived Parameters | 6-22 |
| Updatings..... | 1-7 |
| User-defined corrections..... | 4-2 |

Date of issue

Manufacturer:



Radiometer Representative:

**ABL800 FLEX Reference Manual
from software identification version 5.24**

Publication: March 2006

Edition: 200603C

Code Number: 989-963

Specifications are based on 33694-A4.

