v-TAC Standalone software

User Guide

Publication version 1.0

Software version 1.5

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.5	March 2022	First version

Revision history

Edition notice

This publication is intended for users of the v-TAC Standalone software.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Guide** contains all information about the product, including the following:

- Routine operation
- Safety
- Troubleshooting information
- Background information

⚠ General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

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- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

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Do not use this product unless it has been installed by your Roche Service representative.

Training

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Approvals

The v-TAC Standalone software meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Compliance with the applicable directives is provided by means of the declaration of conformity.

The following marks demonstrate compliance:

IVD

For *in vitro* diagnostic use.

CE

Complies with the provisions of the applicable EU directives.

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Table of contents

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Intended use

v-TAC Standalone is an in vitro diagnostic medical device software intended to automatically convert peripheral venous blood gas values (pH_v, p_vO_2, p_vCO_2) in combination with venous oximetry values (S_vO_2, tHb_v, $MetHb_v$, $COHb_v$) and an arterial saturation value (SpO_{2a}) by pulse oximetry, to quantitatively estimate arterial blood gas values (p_aO_2, p_aCO_2, pH_a).

v-TAC Standalone is an aid for the calculation of the arterial blood gas values in hemodynamically stable adult patients (age 18 and above).

v-TAC Standalone is intended to be used with Blood gas analyzers that meet the acceptance criteria for analytical performance and functional requirements defined by Roche and Pulse oximeters certified according to ISO 80601-2-61.

Intended user

v-TAC is intended to be used by healthcare professionals in a near patient testing environment and laboratory. Not for self-testing.

Symbols and abbreviations

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product name	Descriptor
v-TAC Standalone software	software
cobas b 221 system	analyzer
cobas b 123 POC system	analyzer

Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Cross-reference to another topic
	Figure, used in figure titles and cross-references to figures

Symbols used in the publication

Symbol	Explanation
	Table, used in table titles and cross-references to tables
√xy	Equation, used in cross-references to equations
	Code example, used in code titles and cross-references to codes
	Tip, used for extra information on correct use or for useful hints
	Extra information within a task
	Result of an action within a task
	Frequency of a task
	Duration of a task
	Materials that are required for a task
	Prerequisites of a task

Symbols used in the publication

Symbols used on product

Symbol	Explanation
	Catalogue number
	Global Trade Item Number
	Date of manufacture
	Manufacturer
	Device for near-patient testing
	Device not for self-testing
	Consult instructions for use

Symbols used on product

Symbol	Explanation
	Caution

Symbols used on product

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
a (as subscript, i.e., X_a)	arterial
A-V	arterio-venous
ABE	Actual base excess
ABG	Arterial blood gas
ANSI	American National Standards Institute
BE	Base excess
BGA	Blood gas analyzer
CAR	Calculated arterial results (arterial results calculated by the software)
COHb	Carboxyhemoglobin
c (as subscript, i.e., X_c)	calculated
Δ	delta
DPG	Diphosphoglycerate
EC	European Community
EN	European standard
Hb	Hemoglobin
HIS	Hospital information system
IEC	International Electrical Commission
IVD	*In vitro* diagnostic
kPa	kilopascal
L	liter
LIS	Laboratory information system
MetHb	Methemoglobin
mmol	millimole
n/a	not applicable
p (as subscript, i.e., X_p)	Plasma
pCO_2	Partial pressure of carbon dioxide
pO_2	Partial pressure of oxygen
POC	Point of care
QC	Quality control
RQ	Respiratory quotient
s	seconds
SD	Standard deviation

Abbreviations

Abbreviation	Definition
SO_2	Oxygen saturation
SpO_2	Peripheral arterial oxygen saturation
tCO_2	Total carbon dioxide concentration
tHb	Total hemoglobin
tNBB	Total concentration of non-bicarbonate buffer
tO_2	Total oxygen concentration
UL	Underwriters Laboratories Inc.
v (as subscript, i.e., X_v)	venous
VBG	Venous blood gas

Abbreviations

Safety

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General safety information

In this chapter 1

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Introduction

General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING!

Warning…

- …indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION!

Caution…

- …indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE!

Notice...

- ...indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

User qualification

Insufficient knowledge and skills

As a user, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation unless Roche Diagnostics has trained you to do so.
- Leave installation or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures for operation specified in the instructions.
- Follow laboratory best practices, especially when you work with biohazardous material.

Caution messages

In this section

Loss of sample

Missing SpO_2 value

If it is forgotten or omitted to take the peripheral arterial oxygen saturation value (SpO_2), if the pulse oximeter is missing or defective, or if the SpO_2 value is not entered on the analyzer, the SpO_2 value is missing. A missing SpO_2 value prevents the calculation of the arterial results and a new venous blood sample must be taken.

- Always take the SpO_2 value simultaneously with the venous blood sample using a calibrated pulse oximeter.

Inadequate treatment

Inaccurate or incorrect SpO_2 value

If the pulse oximeter is defective, if the measurement with the pulse oximeter is inaccurate or fluctuating, if the peripheral arterial oxygen saturation value (SpO_2) is entered incorrectly on the analyzer, or if the limitations and contraindications are not observed, the SpO_2 value will be inaccurate or incorrect. An inaccurate or incorrect SpO_2 value may cause the software to calculate inaccurate or incorrect arterial results that may lead to inadequate treatment.

- Always observe the limitations and contraindications for the software.
- Do not use the software if the SpO_2 value cannot be measured properly. Obtain arterial results from an arterial blood sample instead.
- Clinically assess the patient for sufficient peripheral perfusion for pulse oximetry.
- Always take the SpO_2 value simultaneously with venous blood sample using a calibrated pulse oximeter.
- Ensure to enter the SpO_2 value correctly on the analyzer.
- Observe that the calculated arterial pO_2 value is strongly dependent on the SpO_2 value.

List of limitations and contraindications (30)

About the accuracy of the calculated arterial results (33)

Incorrect or compromised blood sample

Using an incorrect or compromised blood sample may cause the software to calculate incorrect arterial results that may lead to inadequate treatment.

- Always observe the limitations and contraindications for the software.
- Take an anaerobic peripheral venous blood sample for analysis.
- Ensure there are no air bubbles in the blood sample.
- Analyze the blood sample within a reasonable time.
- Follow the user documentation of the analyzer and local guidelines for taking, handling, and processing of blood samples for blood gas analysis.

Misinterpretation of parameters

Misinterpretation of parameters may lead to inadequate treatment.

- Ensure you are familiar with the validated ranges of the software.
- Ensure you are familiar with the input parameters and the calculated arterial results of the software.

Contraindications (30)

List of input parameters and calculated arterial results (32)

Data security

Weak passwords

Weak passwords may allow unauthorized access to the analyzer and/or to the software, data manipulation or loss, or unauthorized access to personal information which may lead to a delayed treatment.

- Use strong passwords.
- Do not share passwords.
- Do not write passwords down.
- Do not share user accounts.

Incorrectly configured user access

Incorrectly configured user access on the analyzer and/or to the software may allow unauthorized access, data manipulation or loss, or unauthorized access to personal information which may lead to a delayed treatment.

- Grant access to the analyzer and the software to dedicated users only.
- Control allowed user actions by appropriate role assignment.
- Do not share user accounts.

Compromised data security

Unprotected IT infrastructure and unrestricted physical access to the analyzer, the computer the software is installed on, and attached infrastructure may allow for infection with malicious software, manipulation of components, or misuse which may lead to unauthorized access to personal information, or inadequate or delayed treatment.

- Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the system from uncontrolled networks, as well as measures that ensure that the connected network is free of malicious code.
- Ensure other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- Restrict physical access to the components and all attached IT infrastructure (computer, cables, network equipment, etc.).
- If parts of your network, which the system uses to exchange data, are connected by WLAN, secure the WLAN.
- Ensure that any external storage devices (such as USB flash drives) connected to the analyzer or the computer the software is installed on are free of malicious software.

Unprotected export files

Insecure transfer or storage of backups and archive files may allow for data manipulation which may cause inadequate or delayed treatment.

- Ensure that backups and archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain backups and archive files are protected against unauthorized access.

Notices

In this section

Pulse oximeter

Missing SpO_2 value

If the pulse oximeter is missing or defective, the peripheral arterial oxygen saturation value (SpO_2) will be missing. A missing SpO_2 value prevents the calculation of the arterial results and a new venous blood sample must be taken.

- The software is intended for use with pulse oximeters certified according to ISO 80601-2-61.

Fluctuating, inaccurate, or incorrect SpO_2 value

If the measurement with the pulse oximeter fluctuates or is inaccurate, or if the peripheral arterial oxygen saturation value (SpO_2) is entered incorrectly on the analyzer, the SpO_2 value will be less accurate, inaccurate, or incorrect. A less accurate, inaccurate, or incorrect SpO_2 value may cause the software to calculate less accurate, inaccurate, or incorrect arterial results that may lead to inadequate treatment.

- The software is intended for use with pulse oximeters certified according to ISO 80601-2-61.
- Use a calibrated pulse oximeter.
- Use the pulse oximeter on a peripheral with sufficient perfusion. Poor perfusion is a contraindication for the software and will also impact the SpO_2 value.

IT architecture

Error in IT infrastructure

If any part of the IT infrastructure (e.g., the LIS, data manager server, or server the software is installed on) is unresponsive, inaccessible, or has a software or hardware error, the calculation, sending, or receiving of the arterial results may be inadequate or not possible which may cause data loss or a delayed treatment.

- If the LIS or a connected printer does not receive the data from the software, contact your local IT support for network and server troubleshooting.

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Software description

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Overview of the software

In this chapter 2

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Software overview

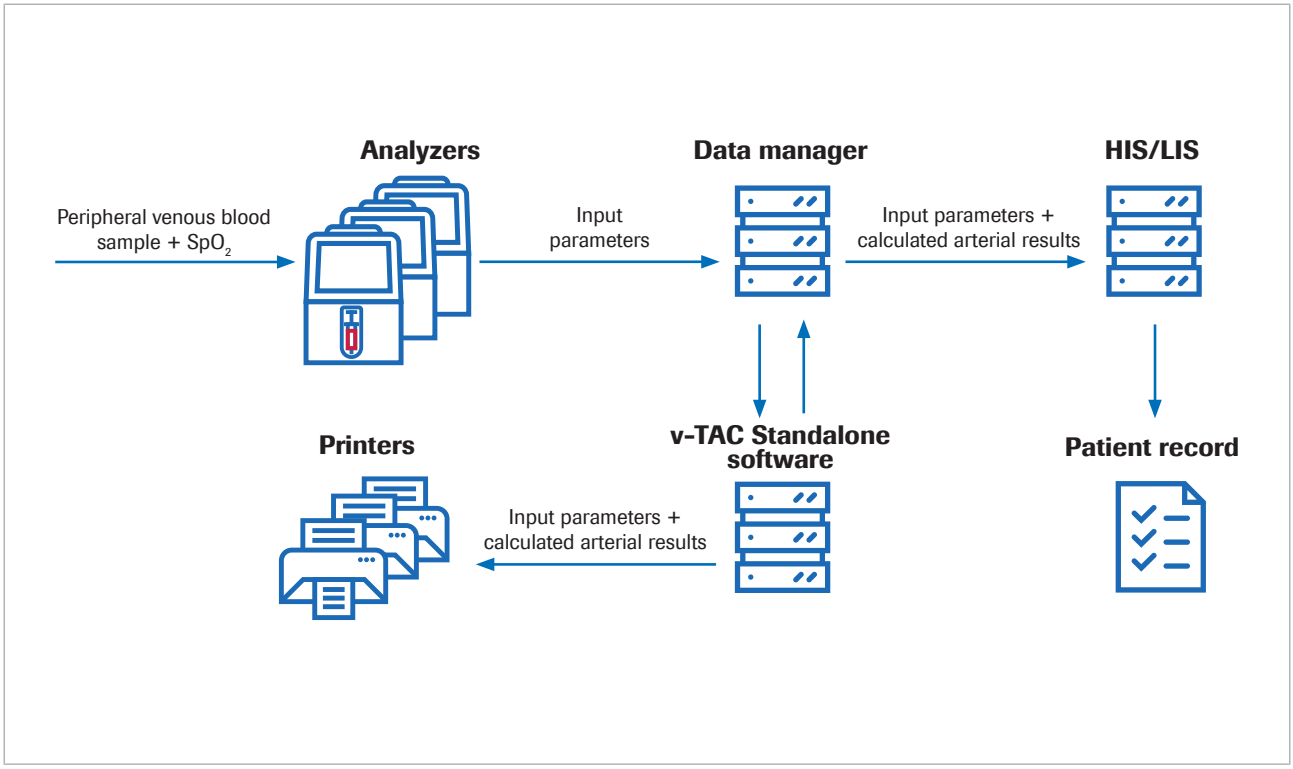
The software calculates arterial acid-base and blood gas results from the arterial oxygen saturation value (SpO_2, measured by pulse oximetry) and peripheral venous acid-base and blood gas results (measured by an analyzer from an anaerobic peripheral venous blood sample).

For details on the steps and mathematical transformations performed by the software, refer to Working principles (61).

For an overview of the user actions necessary to obtain the calculated arterial results, refer to Overview of the user workflow (45).

About the IT architecture

The following overview illustrates the IT architecture and the data flow:



The software is a standalone web application that is installed on a standard PC or a virtual server. For configuration purposes, the software is accessed via an internet browser.

List of limitations and contraindications

The software can only be used if the specified limitations and contraindications are observed.

Limitations

The software can be used on patients age 18 and above who are hemodynamically stable and who have been clinically assessed with sufficient peripheral perfusion so that a venous blood sample can be taken and pulse oximetry can be used.

Pulse oximeters must be certified according to ISO 80601-2-61.

Contraindications

Contraindications:

- Patients with poor peripheral blood circulation in the extremity from where the blood sample is taken.
- The software has not been validated outside the following ranges (venous values)[1]:
  - SpO_2 (measured by pulse oximetry): 80 – 100%
  - pH_v: 7.23 – 7.55
  - p_vO_2: 2.2 – 10.8 kPa (16.5 – 81 mmHg)
  - p_vCO_2: 4.1 – 12.5 kPa (31 – 94 mmHg)
  - S_vO_2: 0.20 – 0.95
  - tHb_v: 5.0 – 11.0 mmol/L
  - $MetHb_v$: 0.000 – 0.012
  - $COHb_v$: 0.000 – 0.065
- The software has not been validated for:
  - Preterm and full-term neonates (0 – 30 days of age)
  - Children and adolescents (up to the age of 18)
  - Pregnant women
  - Hemodynamically unstable patients (including cardiac assist devices and extra corporeal life support devices)
  - Symptomatic hemoglobinopathies
  - Central and mixed venous blood
- Pulse oximetry indications and limitations for use shall be followed.
- Blood gas analyzer indications and limitations for use shall be followed.

List of input parameters and calculated arterial results (32)

[1] The subscript v denotes peripheral venous parameters.

About input and output checks (35)

List of input parameters and calculated arterial results

The software uses the input parameters for the calculation of the arterial results.

About checks

The software only reports the calculated arterial results if the input parameters and the calculated arterial results pass the input and output checks.

About input and output checks (35)

About input parameters

The software uses the following input parameters for the calculation of the arterial results:

Parameter[(a)]	Description	Comment
SpO_2	Peripheral arterial oxygen saturation	Mandatory
pH_v	Measured venous pH	Mandatory
p_vCO_2	Measured venous partial pressure of carbon dioxide	Mandatory
p_vO_2	Measured venous partial pressure of oxygen	Mandatory
S_vO_2	Measured venous oxygen saturation	Mandatory
tHb_v	Measured total venous hemoglobin	Mandatory
$MetHb_v$	Measured venous methemoglobin	Optional If not measured, a constant can be configured (default value = 0.7%).
$COHb_v$	Measured venous carboxyhemoglobin	Optional If not measured, a constant can be configured (default value = 1.3%).

(a) The subscript v denotes peripheral venous parameters.

Input parameters

The input parameters comprise the following:

- The SpO_2 value that is entered directly on the analyzer.
- The peripheral venous results that are measured from a peripheral venous blood sample on the analyzer. The peripheral venous results are available on the analyzer.

About calculated arterial results

As output parameters, the software calculates the following arterial results from the input parameters:

Parameter[a]	Description	Comment
$pH_{a,c}$	Calculated arterial pH	
$p_aCO_{2,c}$	Calculated arterial partial pressure of carbon dioxide	
$p_aO_{2,c}$	Calculated arterial partial pressure of oxygen	If calculated pO_2 exceeds 10 kPa (75 mmHg), the software reports pO_2 > 10 kPa (">pO2 > 75 mmHg")
$BE_{a,c}$	Calculated arterial base excess[b]	The concentration of strong acid necessary to titrate fully oxygenated blood to a pH = 7.4, at a pCO_2 = 5.33 kPa. Equivalent to ABE. The software accounts for the Bohr-Haldane effects.[c]
$HCO_3^-(P)_{a,c}$	Calculated actual arterial bicarbonate concentration	$HCO_3^-(P)_{a,c} = 0.23 * p_aCO_{2,c} * 10^{(pHa,c-6.1)}$ for $p_aCO_{2,c}$ in [kPa] and $HCO_3^-(P)_{a,c}$ in [mmol/L]
$tO_{2a,c}$	Calculated total arterial oxygen concentration[b]	
$tCO_2(B)_{a,c}$	Calculated total arterial carbon dioxide concentration[b]	

(a) The subscript a denotes arterial parameters. The subscript c denotes calculated parameters.

(b) The parameter is not validated.

(c) In comparison, the conventional definition (called actual base excess – BE or ABE) is defined without fully oxygenating the blood. Actual base excess values, therefore, depend upon oxygen level and are not the same in arterial and venous blood, even in the absence or addition of acid or base into the blood from the perfused tissues. In the definition of BE (not ABE), values of BE are independent of O_2 level and will only change if strong acids or bases are added [1].

Calculated arterial results

The calculated arterial results are **not** available on the analyzer or in the result reports from the analyzer.

About the accuracy of the calculated arterial results

The accuracy of the calculated arterial results depends on the accuracy of the SpO_2 value, among others.

The following applies:

- $pH_{a,c}$ and $p_aCO_{2,c}$ are robust against inaccurate SpO_2 input values.
- $p_aO_{2,c}$ depends on the accuracy of the SpO_2 measurement and on the specific SpO_2 value:
  - $p_aO_{2,c}$ is less sensitive to inaccurate SpO_2 values from approximately 95% and below.
  - $p_aO_{2,c}$ is more sensitive to inaccurate SpO_2 values from approximately 96% and above.

Reasons for inaccurate SpO_2 values can include the following:

- Poor performance of the pulse oximeter.
- Poor signal quality on the pulse oximeter due to poor peripheral perfusion, incorrect probe positioning, or similar.
  For details, refer to the user documentation of the pulse oximeter.
- Inaccurate entry of the SpO_2 value on the analyzer.

Consequences of faulty or inaccurate SpO_2 measurements (73)

About input and output checks

Before and after the calculation of the arterial results, the software performs input and output checks. If limits are exceeded or if the combination of values is implausible, the software generates flags and errors.

About input checks

The software checks the input parameters against the following validated ranges and minimum and maximum input limits:

Parameter[a]	Minimum input limit	Validated range		Maximum input limit
		Minimum	Maximum	
SpO_2 [%]	75%[b]	80%	100%	-
pH_v	6.7	7.23	7.55	7.7
p_vCO_2 [kPa]	2	4.1	12.5	31
p_vO_2 [kPa]	1	2.2	10.8	20
S_vO_2 [Fraction]	0.10	0.20	0.95	0.999
tHb_v [mmol/L]	2.5	5.0	11.0	15
$COHb_v$ [Fraction]	0.000	0.000	0.065	0.20
$MetHb_v$ [Fraction]	0.000	0.000	0.012	0.20

(a) The subscript v denotes peripheral venous parameters.

(b) Default value is 80%

Validated ranges, and minimum and maximum input limits

The input checks **fail**, if one of the following applies:

- The physiological plausibility check fails.
- At least 1 input parameter exceeds the input limits.
- At least 1 input parameter is missing.

After a fail, the software generates an error. No arterial results are calculated or reported.

The input checks **pass with flags**, if at least 1 input parameter exceeds the validated ranges but still falls within the input limits.

The input checks **pass**, if all input parameters fall within the validated ranges.

The software **calculates** the arterial results if all input parameters pass the input checks (with or without flags).
However, the software only **reports** the calculated arterial results, i.e., you can obtain them, if the calculated arterial results pass the additional output checks.

For more details on the performed input checks, refer to Details on input checks (72).

About output checks

After calculating the arterial results, the software checks them against the following output limits:

Parameter[(a)]	Minimum output limit	Maximum output limit
$pH_{a,c}$	6.7	7.8
$p_aCO_{2,c}$ [kPa]	1	31
$p_aO_{2,c}$ [kPa]	4	95
	If pO_2 > 10 kPa, the software reports pO_2 > 10 kPa	
$BE_{a,c}$ [mmol/L]	-20	20

(a) The subscript a denotes arterial parameters. The subscript c denotes calculated parameters.

Minimum and maximum output limits

The output checks **fail**, if at least 1 calculated arterial result exceeds the output limits. The software generates an error. No calculated arterial results are reported.

The output checks **pass**, if all calculated arterial results fall within the output limits. The software reports the calculated arterial results together with any flags from the input checks.

Utilizing flagged arterial results that were calculated from input parameters outside of the validated ranges is the responsibility of the health care professional.
It is recommended to obtain arterial results from an arterial blood sample instead.

About the parameter reports

If configured, a parameter report is printed on a network printer.

About the content

The content of the parameter reports may vary depending on analyzer and report configuration.

The default parameter reports comprise the following information:

- Patient information, analyzer ID, date and time
- The input parameters and their values:
  - SpO_2 value entered on the analyzer
  - Peripheral venous results measured on the analyzer
- The arterial results calculated by the software (if reported)
- Flags and errors

The parameter reports shown in this publication are examples only from the software used with the **cobas b** 123 POC system.

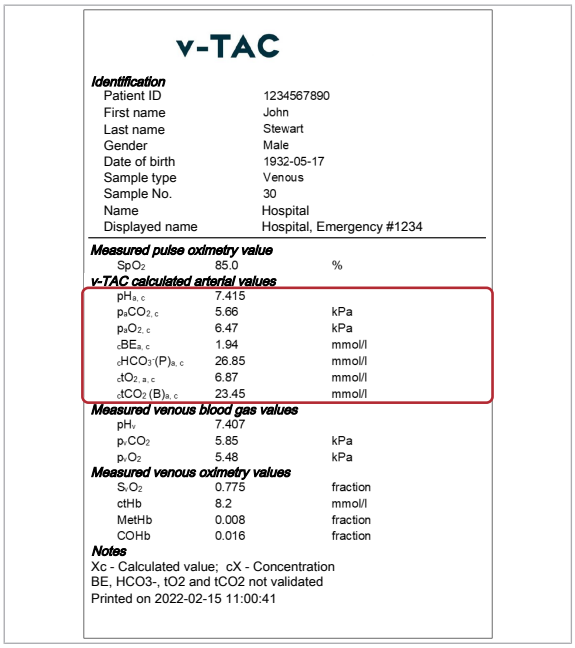
List of input parameters and calculated arterial results (32)

About flags and errors

It depends on the outcome of the input and output checks if the parameter report contains flags or errors.

About input and output checks (35)

No flags or errors



v-TAC

Identification		
Patient ID	1234567890	
First name	John	
Last name	Stewart	
Gender	Male	
Date of birth	1932-05-17	
Sample type	Venous	
Sample No.	30	
Name	Hospital	
Displayed name	Hospital, Emergency #1234	
Measured pulse oximetry value		
SpO_2	85.0	%
v-TAC calculated arterial values		
$pH_{a,c}$	7.415	
$p_aCO_{2,c}$	5.66	kPa
$p_aO_{2,c}$	6.47	kPa
$_cBE_{a,c}$	1.94	mmol/l
$_cHCO_3^-(P)_{a,c}$	26.85	mmol/l
$_ctO_{2,a,c}$	6.87	mmol/l
$_ctCO_2(B)_{a,c}$	23.45	mmol/l
Measured venous blood gas values		
pH_v	7.407	
p_vCO_2	5.85	kPa
p_vO_2	5.48	kPa
Measured venous oximetry values		
S_vO_2	0.775	fraction
ctHb	8.2	mmol/l
MetHb	0.008	fraction
COHb	0.016	fraction

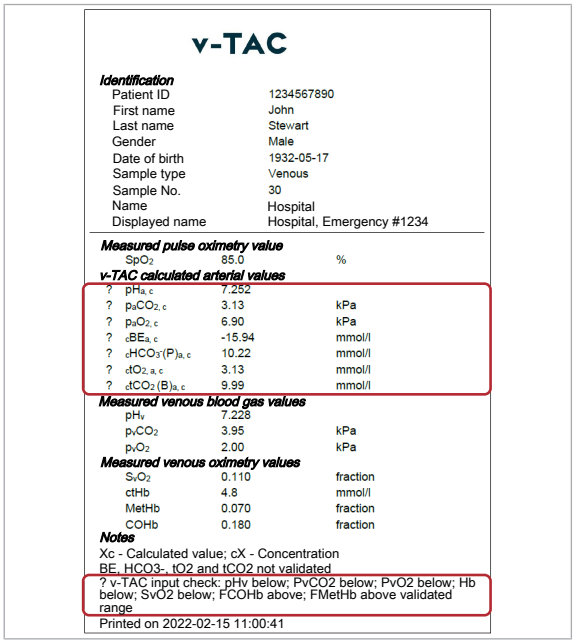
Notes
Xc - Calculated value; cX - Concentration
BE, HCO3-, tO2 and tCO2 not validated
Printed on 2022-02-15 11:00:41

The calculated arterial results are reported without flags and errors if the following applies:

- The input parameters pass the plausibility check.
- The input parameters fall within the validated ranges.
- The calculated arterial results fall within the output limits.

On the parameter report, calculated arterial results with no flags and errors are reported with their values and no further marks.

With flags



v-TAC

Identification			
Patient ID	1234567890		
First name	John		
Last name	Stewart		
Gender	Male		
Date of birth	1932-05-17		
Sample type	Venous		
Sample No.	30		
Name	Hospital		
Displayed name	Hospital, Emergency #1234		
Measured pulse oximetry value			
SpO_2	85.0	%	
v-TAC calculated arterial values			
?	$pH_{a,c}$	7.252	
?	$p_aCO_{2,c}$	3.13	kPa
?	$p_aO_{2,c}$	6.90	kPa
?	$_cBE_{a,c}$	-15.94	mmol/l
?	$_cHCO_3^-(P)_{a,c}$	10.22	mmol/l
?	$_ctO_{2,a,c}$	3.13	mmol/l
?	$_ctCO_2(B)_{a,c}$	9.99	mmol/l
Measured venous blood gas values			
	pH_v	7.228	
	p_vCO_2	3.95	kPa
	p_vO_2	2.00	kPa
Measured venous oximetry values			
	S_vO_2	0.110	fraction
	ctHb	4.8	mmol/l
	MetHb	0.070	fraction
	COHb	0.180	fraction

Notes
Xc - Calculated value; cX - Concentration
BE, HCO3-, tO2 and tCO2 not validated
? v-TAC input check: pHv below; PvCO2 below; PvO2 below; Hb below; SvO2 below; FCOHb above; FMetHb above validated range
Printed on 2022-02-15 11:00:41

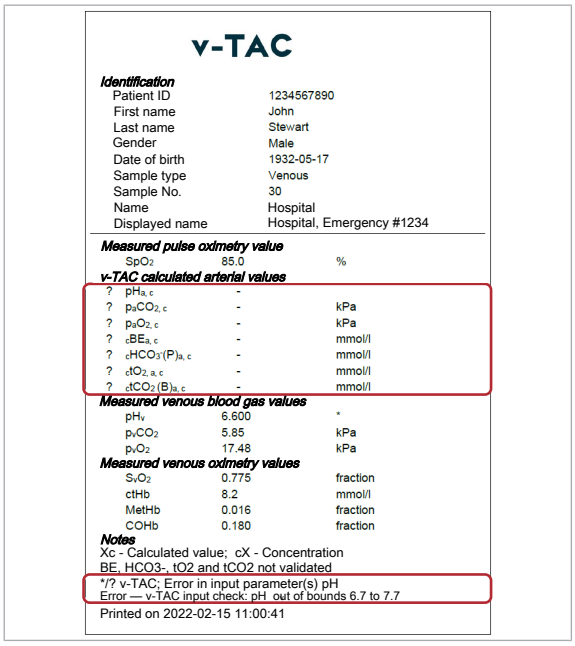
The calculated arterial results are reported with flags if the following applies:

- The input parameters pass the plausibility check.
- At least 1 input parameter exceeds the validated ranges, but still falls within the input limits.
- The calculated arterial results fall within the output limits.

Utilizing flagged arterial results that were calculated from input parameters outside of the validated ranges is the responsibility of the health care professional.
It is recommended to obtain arterial results from an arterial blood sample instead.

On the parameter report, calculated arterial results with flags are marked with a "?". The specific flags are listed in the Notes section of the report.

With errors



v-TAC

Identification

Patient ID	1234567890
First name	John
Last name	Stewart
Gender	Male
Date of birth	1932-05-17
Sample type	Venous
Sample No.	30
Name	Hospital
Displayed name	Hospital, Emergency #1234

Measured pulse oximetry value

SpO_2	85.0	%

v-TAC calculated arterial values

?	$pH_{a,c}$	-	
?	$p_aCO_{2,c}$	-	kPa
?	$p_aO_{2,c}$	-	kPa
?	$_cBE_{a,c}$	-	mmol/l
?	$_cHCO_3^-(P)_{a,c}$	-	mmol/l
?	$_ctO_{2,a,c}$	-	mmol/l
?	$_ctCO_2(B)_{a,c}$	-	mmol/l

Measured venous blood gas values

pH_v	6.600	*
p_vCO_2	5.85	kPa
p_vO_2	17.48	kPa

Measured venous oximetry values

S_vO_2	0.775	fraction
ctHb	8.2	mmol/l
MetHb	0.016	fraction
COHb	0.180	fraction

Notes

Xc - Calculated value; cX - Concentration
BE, HCO3-, tO2 and tCO2 not validated
*/? v-TAC; Error in input parameter(s) pH
Error — v-TAC input check: pH out of bounds 6.7 to 7.7
Printed on 2022-02-15 11:00:41

Errors and no calculated arterial results are reported if one of the following applies:

- The physiological plausibility check fails.
- At least 1 input parameter exceeds the input limits.
- At least 1 calculated arterial result exceeds the output limits.

If an error occurs, no values for the calculated arterial results are reported.

On the parameter report, calculated arterial results with errors are marked with a "?" and have no values. The specific errors are listed in the Notes section of the report.

In the shown example, pH_v is marked with an * indicating the input check for this input parameter failed and caused the errors for the calculated arterial results.

List of flags and errors (53)

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Operation

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Routine operation

In this chapter 3

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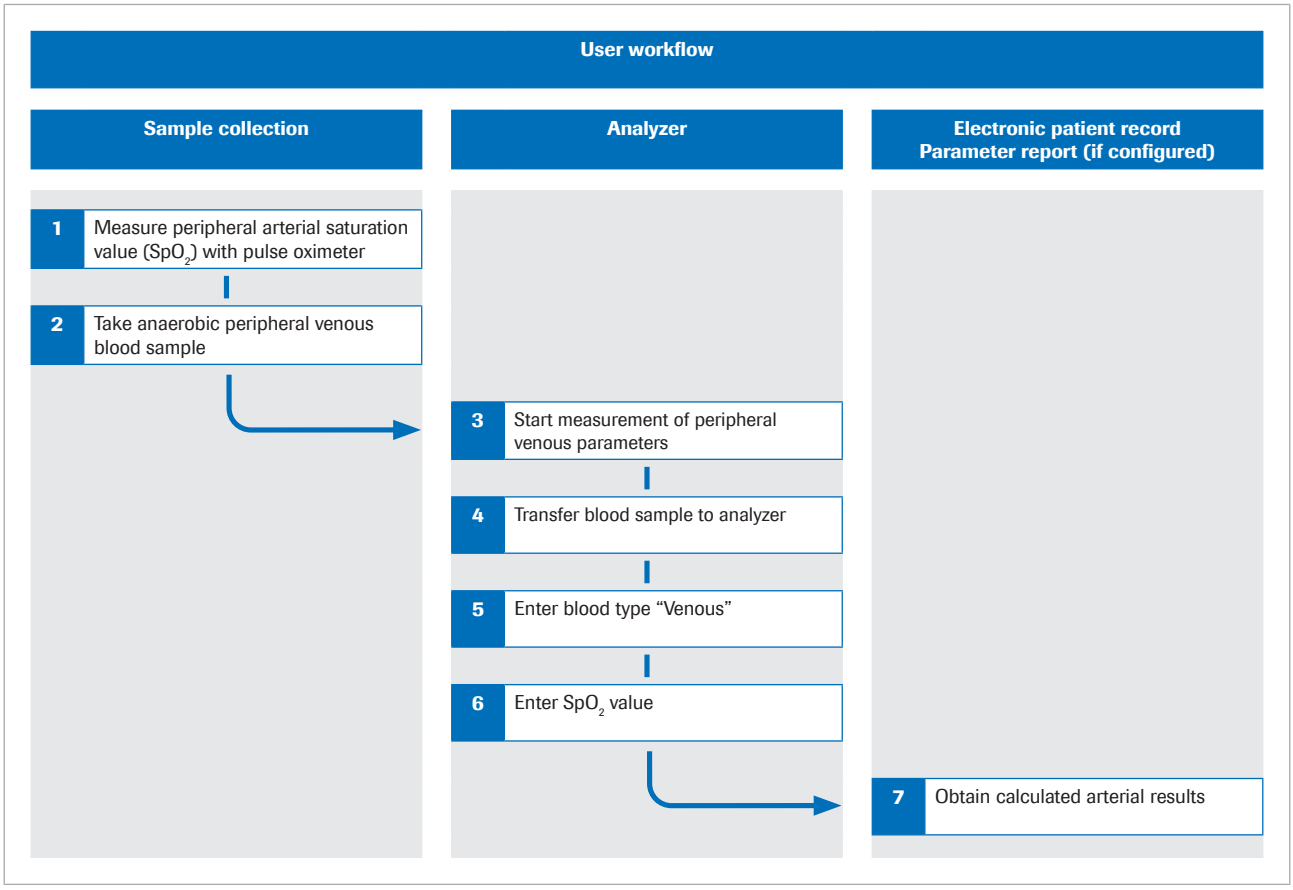
Overview of the user workflow

To obtain the calculated arterial results from the software, you must provide the necessary input and start the measurement on the analyzer.

The software is running as a background process without direct user interaction.

The details of how to use the software may vary depending on the specific analyzer type and the software configuration.

The following overview illustrates the user actions necessary to obtain the calculated arterial results from the software together with the **cobas b** 221 system or the **cobas b** 123 POC system:



Overview of user workflow

For details on the steps and mathematical transformations performed by the software, refer to Working principles (61).

Obtaining calculated arterial results from the software

For the software to calculate the arterial results, you must simultaneously measure the arterial oxygen saturation and take a peripheral venous blood sample, and then analyze the blood sample on an analyzer.

The procedure below provides general instructions on how to use the software with the **cobas b** 221 system or the **cobas b** 123 POC system.

For more details on the **cobas b** 221 system or the **cobas b** 123 POC system, refer to the respective user documentation.

The details of how to use the software may vary depending on the specific analyzer type and the software configuration.

- ☐ Calibrated pulse oximeter certified according to ISO 80601-2-61.
- ☐ Blood gas analyzers that meet the acceptance criteria for analytical performance and functional requirements defined by Roche
- ☐ Sample container suitable for the analyzer.

Obtaining calculated arterial results from the software

1 CAUTION! Risk of sample loss or inadequate treatment.
Always take the SpO_2 value simultaneously with the venous blood sample using a calibrated pulse oximeter. Always observe the limitations and contraindications for the software.

Before you place a tourniquet, measure arterial oxygen saturation (SpO_2) with a pulse oximeter.

2 CAUTION! Risk of inadequate treatment.
Always observe the limitations and contraindications for the software. Ensure that you take and handle the blood sample correctly.

On the same arm, take an anaerobic peripheral venous blood sample:

- Use a needle or vacutainer holder, a butterfly, or a peripheral venous catheter.
- Use a sample container for anaerobic samples.

- Fill extension tubes or catheters with fresh blood before you take the venous blood sample.
- You can take the venous blood sample either as a single sample or in combination with other venous blood samples.
- Follow the user documentation of the analyzer and local guidelines for taking, handling, and processing of blood samples.

3 On the analyzer, ensure that the parameters chosen for measurement include the following:

- pH
- pCO_2
- pO_2
- SO_2
- tHb
- MetHb
- COHb

4 Transfer the blood sample to the analyzer.

5 Enter the blood type **Venous**.

6 CAUTION! Risk of inadequate treatment.
Ensure to enter the SpO_2 value correctly.

Enter the SpO_2 value, e.g., 90%, with the following syntax:
SPO2=90%

- On the **cobas b** 221 system, enter the SpO_2 value in the **Remark** field.
- On the **cobas b** 123 POC system, enter the SpO_2 value in the **Remark 1** field.

➔ The analyzer measures the venous results.

➔ The input parameters are sent to the software.

➔ The software performs the checks and calculates the arterial results.

7 Obtain the calculated arterial results from the electronic patient record or the printed parameter report (if configured):

- For details on flags and errors, refer to About input and output checks (35).
- For details on the parameter reports, refer to About the parameter reports (37).

ⓘ The calculated arterial results are **not** available on the analyzer or in the result reports from the analyzer.

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Troubleshooting

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Troubleshooting

In this chapter 4

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List of flags and errors

If at least 1 input parameter or calculated arterial result fails the input or output checks, the software flags all calculated arterial results or generates an error, depending on which check failed.

Utilizing flagged arterial results that were calculated from input parameters outside of the validated ranges is the responsibility of the health care professional.
It is recommended to obtain arterial results from an arterial blood sample instead.

About input and output checks (35)

Flags and errors on the parameter report

On the parameter report, calculated arterial results with flags and errors are marked accordingly.

System errors

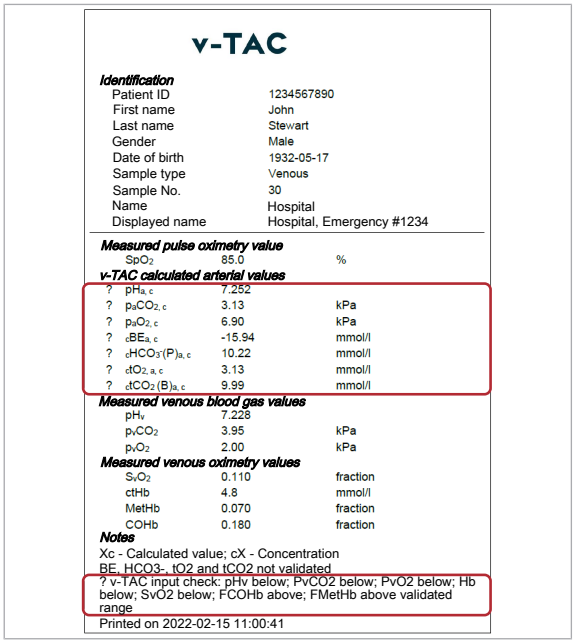
If measurement on the analyzer fails, the software generates the following errors:

Code	Text string
290	**Limitation reached**
291	**Blood gas analyzer disabled**

System errors

Flags and errors

If any of the input or output checks fails or is passed with flags, the software generates the following errors and flags:



v-TAC

Identification

Patient ID	1234567890
First name	John
Last name	Stewart
Gender	Male
Date of birth	1932-05-17
Sample type	Venous
Sample No.	30
Name	Hospital
Displayed name	Hospital, Emergency #1234

Measured pulse oximetry value

SpO_2	85.0	%

v-TAC calculated arterial values

?	$pH_{a,c}$	7.252	
?	$p_aCO_{2,c}$	3.13	kPa
?	$p_aO_{2,c}$	6.90	kPa
?	$_cBE_{a,c}$	-15.94	mmol/l
?	$_cHCO_3^-(P)_{a,c}$	10.22	mmol/l
?	$_ctO_{2,a,c}$	3.13	mmol/l
?	$_ctCO_2(B)_{a,c}$	9.99	mmol/l

Measured venous blood gas values

pH_v	7.228	
p_vCO_2	3.95	kPa
p_vO_2	2.00	kPa

Measured venous oximetry values

S_vO_2	0.110	fraction
ctHb	4.8	mmol/l
MetHb	0.070	fraction
COHb	0.180	fraction

Notes

Xc - Calculated value; cX - Concentration
BE, HCO3-, tO2 and tCO2 not validated
? v-TAC input check: pHv below; PvCO2 below; PvO2 below; Hb below; SvO2 below; FCOHb above; FMetHb above validated range
Printed on 2022-02-15 11:00:41

Code	Text string
301	**License is invalid or is expired.**
302	**Conversion not possible**
303	**Input unit for %s cannot be determined.** with **%s** replaced by the name of the parameter.
304	**SpO2 %s%% below SvO2. Conversion not possible** with **%s%%** replaced by the percentage. Example: v-TAC input check: SpO_2 5% below S_vO_2. Conversion not possible.
305	**v-TAC input check: SvO2 is outside of plausible range.**

Flags and errors

Code	Text string
306	**v-TAC input check: %s cannot be empty.** with **%s** replaced by the name of the parameter.
307	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: SpO2 out of bounds 80 to 100 %
308	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: PvCO2 out of bounds 2.0 to 31.0 kPa
309	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: PvO2 out of bounds 1.0 to 20.0 kPa
310	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: SvO2 out of bounds 0.1 to 0.999 fraction
311	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: Hb out of bounds 2.5 to 15.0 mmol/L
312	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: FCOHb out of bounds 0.0 to 0.2 fraction
313	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: FMetHb out of bounds 0.0 to 0.2 fraction
314	**v-TAC input check: %s out of bounds %s to %s %s** with **%s** replaced as follows: v-TAC input check: pHv out of bounds 6.7 bis 7.7
315	**v-TAC: Error in 1 or more input parameters**
317	**%s is outside reportable range.** with **%s** replaced by the name of the parameter.

Flags and errors

Code	Text string
318	**v-TAC input check: %s out of bounds %s to %s %s** **v-TAC output check: %s out of bounds %s to %s %s** with **%s** replaced by (in order of occurrence): parameter name, numerical value, numerical value, unit Example: v-TAC input check: FiO_2 out of bounds 21.0 to 100.0%
319	**SpO2 %s%% below SvO2. SvO2 used as SpO2 for conversion.** with **%s%%** replaced by the percentage. Example: SpO_2 2% below S_vO_2. S_vO_2 used as SpO_2 for conversion.
320	**v-TAC input check: %s% above validated range** **v-TAC input check: %s% below validated range** with **%s** replaced by the name of the parameter. Example: v-TAC input check: pH_v below validated range

Flags and errors

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Performance principles and data

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Performance principles and data

In this chapter 5

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Working principles

The software calculates arterial acid-base and blood gas results from the arterial oxygen saturation value (SpO_2, measured by pulse oximetry) and peripheral venous acid-base and blood gas results (measured by an analyzer from an anaerobic peripheral venous blood sample).

For the calculations, the software uses algorithms and mathematical models that simulate the transport of blood back through the tissues.

In this section

Assumptions

To perform this simulation, 2 assumptions are required.

First assumption

It is assumed that the amount of strong acid added to the blood on its passage through the tissues is minimal or zero, such that a change in base excess (BE) from the venous sampling site to the arterial site (ΔBE_{a-v}) is approximately zero.

For peripheral venous blood, this is likely to be true if the peripheral limb has a clearly recognizable arterial pulse, a normal capillary response, and a normal color and temperature.

For central or mixed venous blood this assumption is less likely to be true, as the different organ systems can add different and substantial amounts of acid into the blood circulation in situations with, e.g., anaerobic metabolism.

Second assumption

It is assumed that the respiratory quotient RQ (i.e., the rate of CO_2 production (VCO_2) to O_2 utilisation (VO_2)) over the tissue sampling site cannot vary outside the range of 0.7 to 1.0.

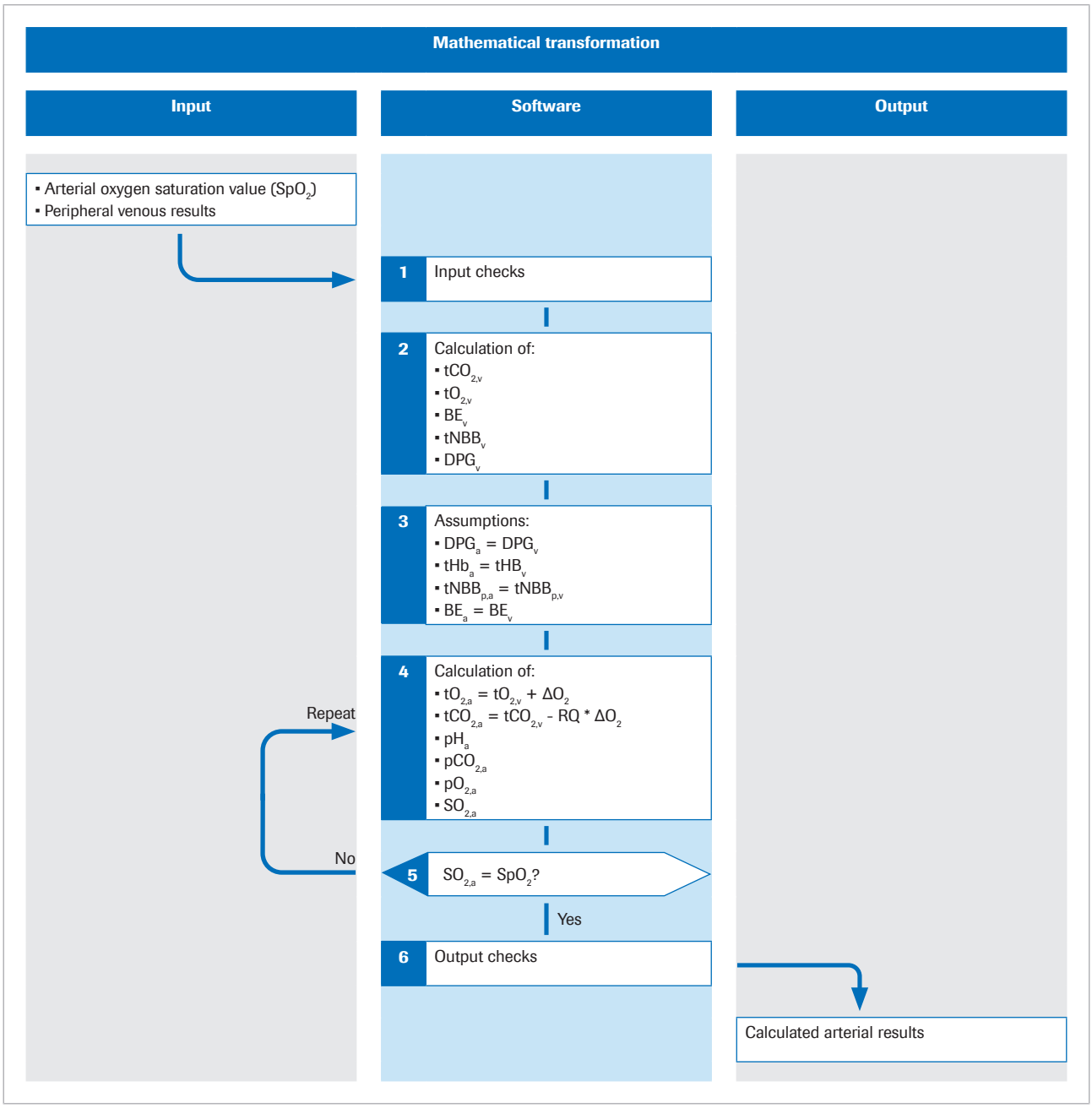
The RQ of the tissue cells can only vary between 0.7 and 1.0, being 0.7 in aerobic metabolism of fat and 1.0 in aerobic metabolism of carbohydrate. Whilst R, the respiratory exchange ratio measured at the mouth, may vary outside this range, the RQ over the tissue sampling site can only do so if there is a rapid flow of acid, base, or CO_2 in or out of the tissues where peripheral venous sampling occurs. This may occur in situations involving rapid disturbance of acid–base status, such as in exercise. However, in a warm, well perfused extremity this rapid redistribution is less likely.

This means that anaerobically sampled venous blood can be “arterialized” mathematically by simulating the removal/addition, respectively, of a constant ratio (RQ) of CO_2 and O_2 over the tissues. This simulation is being performed until the arterialised oxygen saturation matches the arterial oxygen saturation measured by a pulse oximeter [1]. Therefore, S_aO_2 is not displayed as it is equal to the SpO_2 value.

The software uses an approximation of RQ=0.82 for the conversion.

Steps and transformations

The principle steps of the software and the details of the mathematical transformation are illustrated in the following overview:



The subscript p denotes the plasma fraction of blood.

More details of the algorithm can be found in the original scientific publication [1].

Input

Peripheral arterial oxygen saturation SpO_2 is measured by a pulse oximeter. An anaerobic peripheral venous blood sample is taken to provide values of the acid-base and oxygen status of the peripheral venous blood.

The software uses the values of the following input parameters:

- SpO_2
- pH_v

- p_vCO_2
- p_vO_2
- tHb_v
- S_vO_2
- Methemoglobin ($MetHb_v$)
- Carboxyhemoglobin ($COHb_v$)

$MetHb_v$ and $COHb_v$ are optional and can be replaced by constants through configuration.

About input parameters (32)

Step 1 The software performs input checks on SpO_2 and on the venous results measured on the analyzer.

About input checks (35)

Details on input checks (72)

Step 2 The venous results pH_v, p_vCO_2, p_vO_2, S_vO_2, tHb_v, $MetHb_v$, and $COHb_v$ are used to calculate the total CO_2 concentration (t_vCO_2), total O_2 concentration (t_vO_2), base excess (BE_v), and the concentration of 2,3-diphosphoglycerate ($2,3\text{-}DPG_v$) in the venous blood for which the oxygen dissociation curve passes through the measured venous $pO_{2,v}$ and $SO_{2,v}$. [2].

These calculations are performed using an acid-base mass action and mass balance simulator described in the following section:

The acid-base mass-action and mass-balance simulator (66)

Step 3 It is assumed that the concentration of haemoglobin (tHb), the total concentration of plasma non-bicarbonate buffer ($tNBB_p$), the concentration of 2,3-DPG, and BE are the same in arterial and venous blood:

$tHb_a = tHb_v$
$tNBB_{p,a} = tNBB_{p,v}$
$2,3\text{-}DPG_a = 2,3\text{-}DPG_v$
$BE_a = BE_v$

Step 4 The total concentration of O_2 and CO_2 in arterial blood is calculated by simulating the addition of a concentration of O_2 (ΔO_2) to the venous blood, and removal of a concentration of CO_2 (ΔCO_2, where $\Delta CO_2 = RQ\ \Delta O_2$) from the venous blood:

$tO_{2,a} = tO_{2,v} + \Delta O_2$
$tCO_{2,a} = tCO_{2,v} - RQ * \Delta O_2$

Calculated values of arterialized blood $tCO_2(B)_{a,c}$, $tO_2(P)_{a,c}$, tHb_a, $BE_{a,c}$, t_aNBB_p, and DPG_a are then used to calculate the remaining variables describing arterialized blood, i.e., $pH_{a,c}$, $p_aCO_{2,c}$, $p_aO_{2,c}$, and $S_aO_{2,c}$. This calculation also uses the acid-base mass action and mass balance simulator, but in a reversal of the process.

Step 5

The calculated arterialized oxygen saturation S_aO_2 is compared with that measured by the pulse oximeter (SpO_2). The difference between the two gives an error = S_aO_2 - SpO_2.

By varying the value of ΔO_2 and repeating step 4, a value of ΔO_2 is found for which the error is zero. This ΔO_2 represents the concentration of O_2 added, and RQ multiplied by ΔO_2 the concentration of CO_2 removed, that transforms venous to arterialized blood. For this value of ΔO_2, calculated values of all variables describing arterialized blood should be equal to measured arterial values.

The calculated arterial results include the following:

- $pH_{a,c}$
- $p_aCO_{2,c}$
- $p_aO_{2,c}$ (up to 10 kPa)
- $HCO_3^-(P)_{a,c}$
- Base excess ($BE_{a,c}$)
- $tO_{2a,c}$
- $tCO_2(B)_{a,c}$

Optional feature:
If FiO_2 is entered on the analyzer, the software calculates the P/F index = p_aO_2/FiO_2. The P/F index represents the oxygenation index and is used for calculation of the SOFA score and assessment of hypoxemia, e. g., in ventilated patients.

About calculated arterial results (32)

Step 6

Before the mathematical process is completed, the software performs several output checks on the calculated arterial results.

About output checks (36)

The acid-base mass-action and mass-balance simulator

The algorithm uses mathematical models of acid-base and blood chemistry by Rees and Andreassen [2].

The combined model is a comprehensive set of connected mass-action and mass-balance equations. It keeps track of the masses of CO_2, O_2, binding effects to hemoglobin (oxygen-carrying and non-oxygen-carrying), and the relationship between values of pO_2 and SO_2 in the blood (known as the oxygen dissociation curve). It represents plasma bicarbonate and non-bicarbonate buffers, and the buffering on the amino end and side chains of the hemoglobin molecule.

The model accounts for the Bohr-Haldane effects [3] [2]. In this model, BE is defined as the concentration of strong acid necessary to titrate fully oxygenated blood to a
pH_p = 7.4, at a pCO_2 = 5.33 kPa.

The subscript p denotes the plasma fraction of blood.

In the conventional definition (called actual base excess (ABE)), BE is defined without fully oxygenating the blood. Because of Bohr-Haldane effects, ABE values therefore depend upon oxygen level and are not the same in arterial and venous blood, even in the absence or addition of acid/base into the blood from the tissue. In the definition of BE used here, values of BE are independent of O_2 level and will only change if strong acids or bases are added. The model therefore accounts for the Bohr-Haldane effects [1].

Validation

The performance of the software has been validated in several performance validation studies in which venous blood gas and SpO_2 measurements converted to arterial results by the software were compared to simultaneous arterial blood gas measurements.

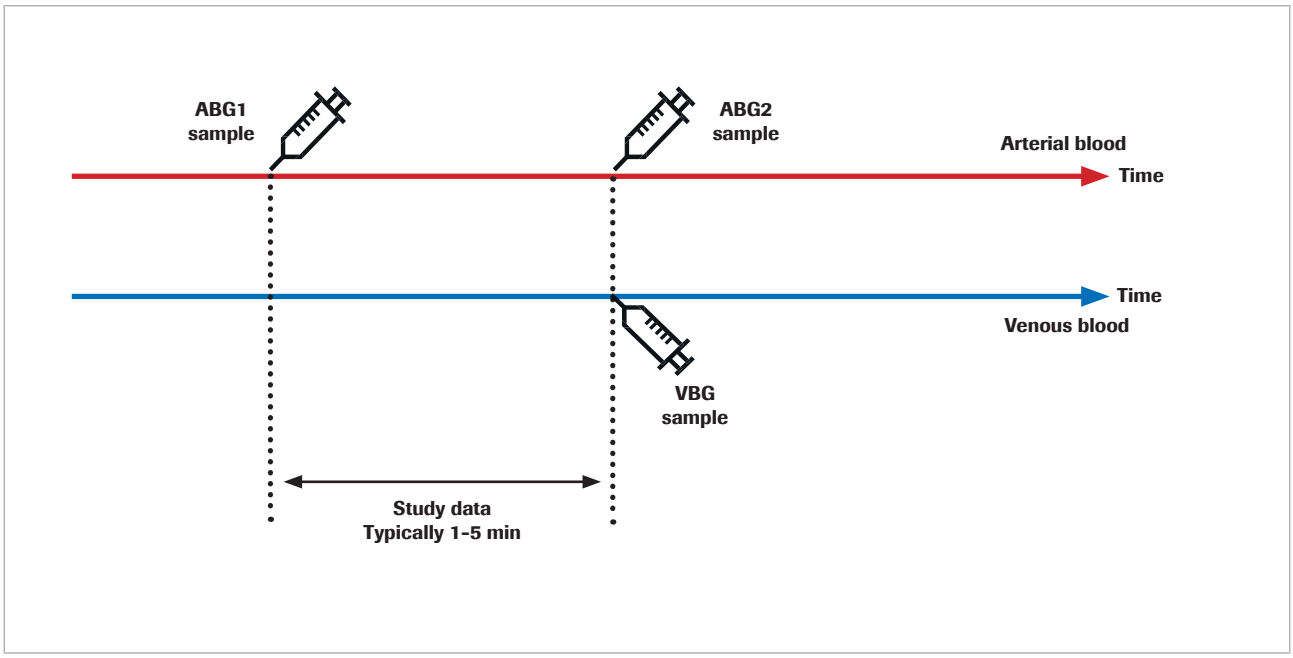
In this section

Methods and materials

The included subjects were adult patients (>18 years) from emergency departments, pulmonary departments, and intensive care units with various diagnoses, including COPD, sepsis, asthma, pneumonia, and lung cancer.

Ideally, the pair of samples should be collected simultaneously. In the studies, the time between taking of the arterial blood gas (ABG) samples and the peripheral venous blood (VBG) samples that were used for calculation of the arterial results was typically between 1 and 5 minutes.

The following figure illustrates the technique used in the studies for taking blood samples:



The repeatability of both arterial blood gas and venous blood gas is affected by pre-analytical errors in the time span from taking to analyzing the blood sample, and by analytical errors. Additionally, both arterial blood gas and venous blood gas are affected by biological fluctuations.

When comparing two subsequent measurements on a human specimen, the biological change has an impact on the result. This becomes evident when comparing the reference arterial blood gas measurements to arterial results calculated by the software and to repeated arterial blood gas measurements.

A study by Toftegaard et al. [4] showed that the repeatability of the results calculated by the software versus arterial blood gas is comparable to the repeatability of arterial blood gases for blood gas parameters, including pH, pCO_2, and pO_2 (up to 10 kPa / 75 mmHg).

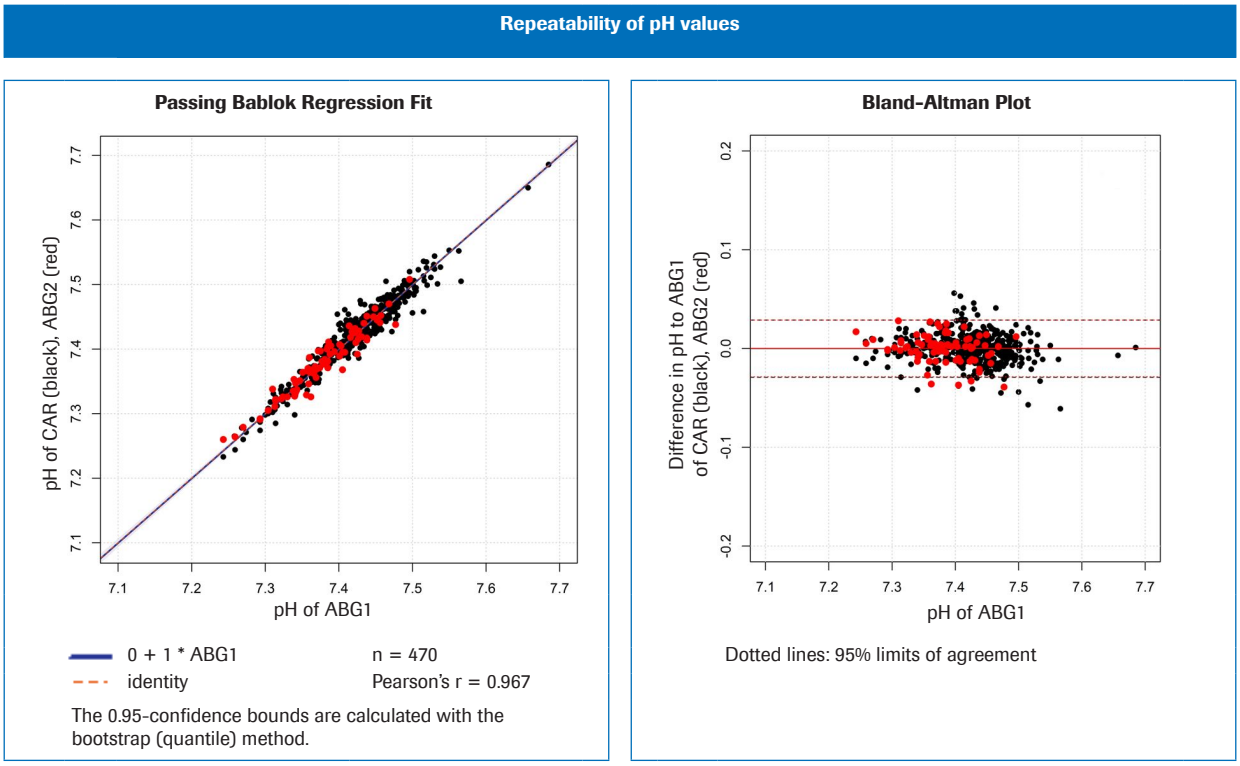
In pilots and clinical studies using measured arterial blood gas as the reference, note the following precautions:

- Collect arterial and venous blood samples simultaneously.
- Ensure high quality in sample collection. Exclude samples with signs of pre-analytical errors.
- Ensure patient ventilatory stability before and during sample collection.

Results of statistical analysis for pH

For pH, the following plots show the performance of the software and a repeat arterial blood gas measurement in comparison with a reference arterial blood gas measurement:

- Black dots:
  Arterial results calculated by the software (CAR) plotted versus arterial blood gas values (ABG1) (pooled data from [4] [5] [6] [7])
- Red dots:
  Arterial blood gas values (ABG2) plotted versus arterial blood gas values (ABG1) [4]



Left: method comparison for pH; right: Bland-Altman plot for pH

pH 95% limits of agreement[(a)]	pH unit
CAR versus ABG1 [4] [5] [6] [7]	0.000 ± 0.028
ABG2 versus ABG1 [4]	-0.001 ± 0.027

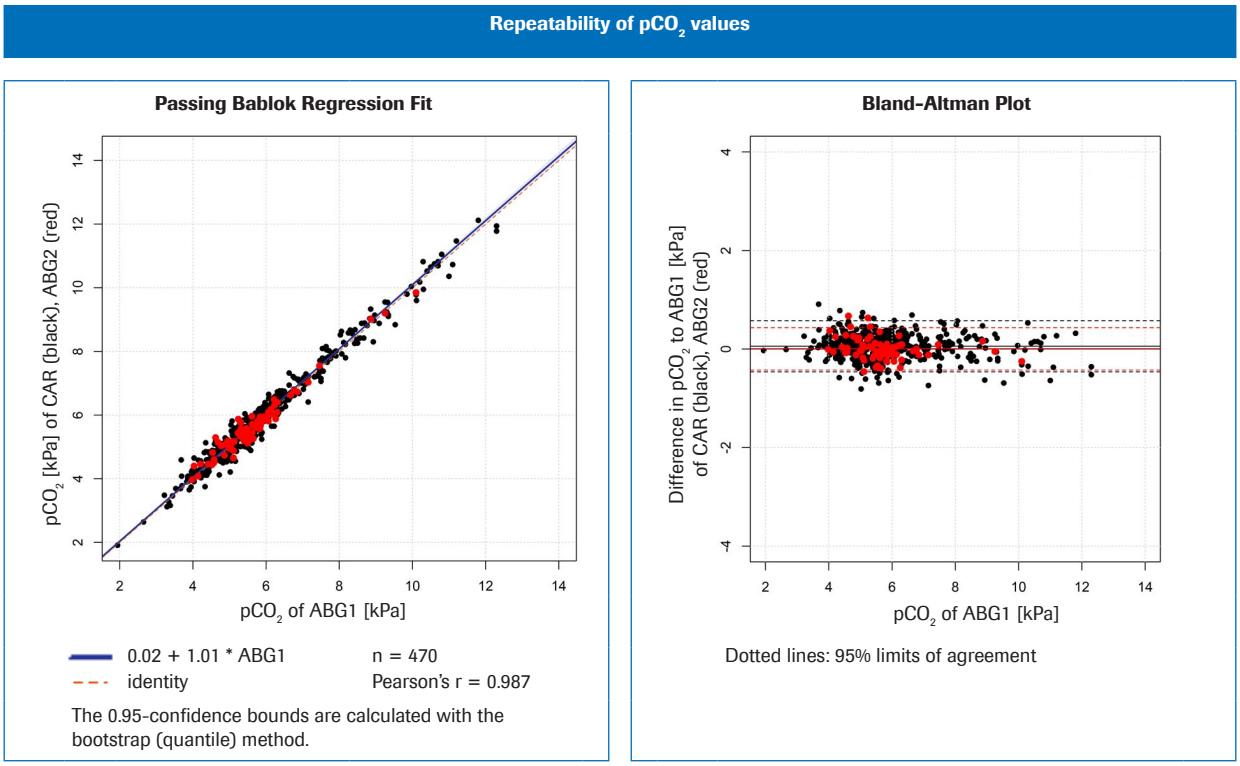
(a) 95% limits of agreement = mean difference ±1.96 * standard deviation (SD)

Statistical variation for pH pooled data

Results of statistical analysis for pCO_2

For pCO_2, the following plots show the performance of the software and a repeat arterial blood gas measurement in comparison with a reference arterial blood gas measurement:

- Black dots:
  Arterial results calculated by the software (CAR) plotted versus arterial blood gas values (ABG1) (pooled data from [4] [5] [6] [7])
- Red dots:
  Arterial blood gas values (ABG2) plotted versus arterial blood gas values (ABG1) [4]



Left: method comparison for pCO_2; right: Bland-Altman plot for pCO_2

pCO_2 95% limits of agreement[(a)]	kPa	mmHg
CAR versus ABG1 [4] [5] [6] [7]	0.06 ±0.51	0.42 ± 3.83
ABG2 versus ABG1 [4]	0.02 ±0.44	0.14 ± 3.28

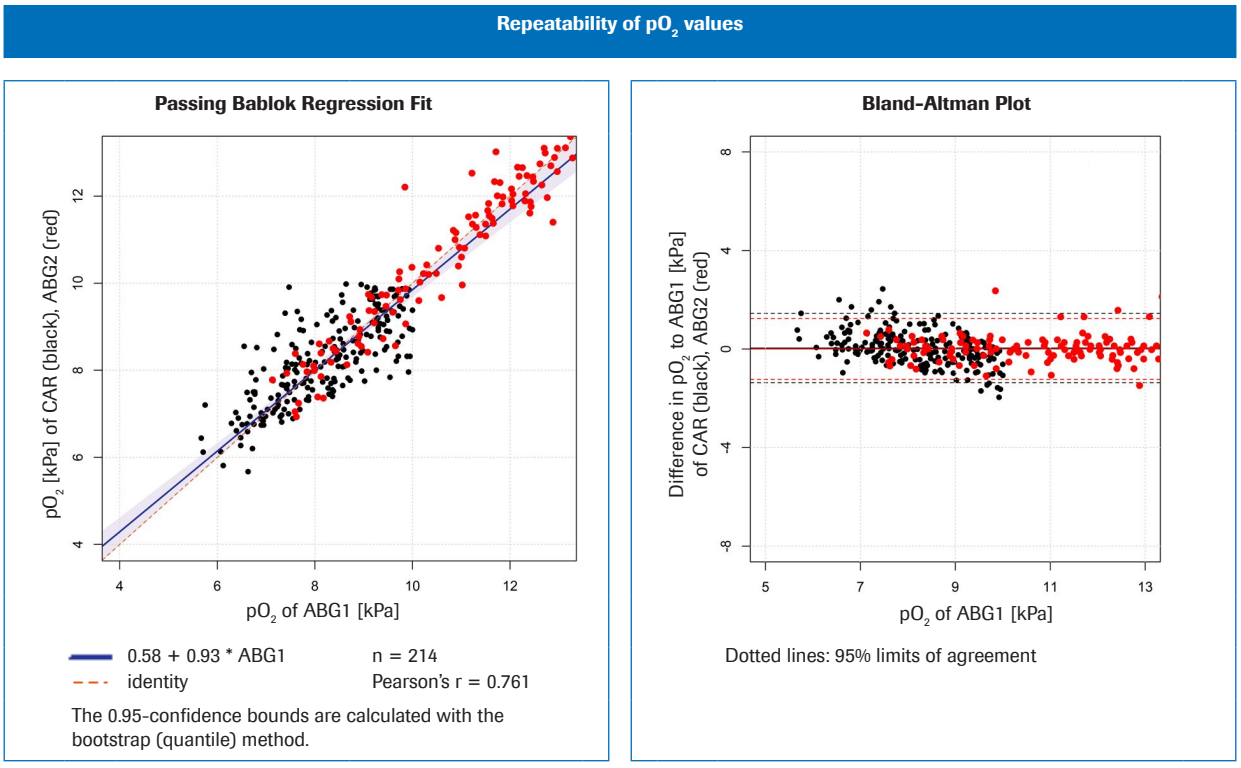
(a) 95% limits of agreement = mean difference ±1.96 * standard deviation (SD)

Statistical variation for pCO_2 pooled data

Results of statistical analysis for pO_2

For pO_2, the following plots show the performance of the software and a repeat arterial blood gas measurement in comparison with a reference arterial blood gas measurement:

- Black dots:
  Arterial results calculated by the software (CAR) plotted versus arterial blood gas values (ABG1) (pooled data from [4] [5] [6] [7])
- Red dots:
  Arterial blood gas values (ABG2) plotted versus arterial blood gas values (ABG1) [8]



Left: method comparison for pO_2; right: Bland-Altman plot for pO_2

pO_2 95% limits of agreement[(a)]	kPa	mmHg
CAR versus ABG1 [4] [5] [6] [7]	0.04 ±1.38	0.31 ±10.35
ABG2 versus ABG1 [8]	± 1.21	± 9.09

(a) 95% limits of agreement = mean difference ±1.96 * standard deviation (SD)

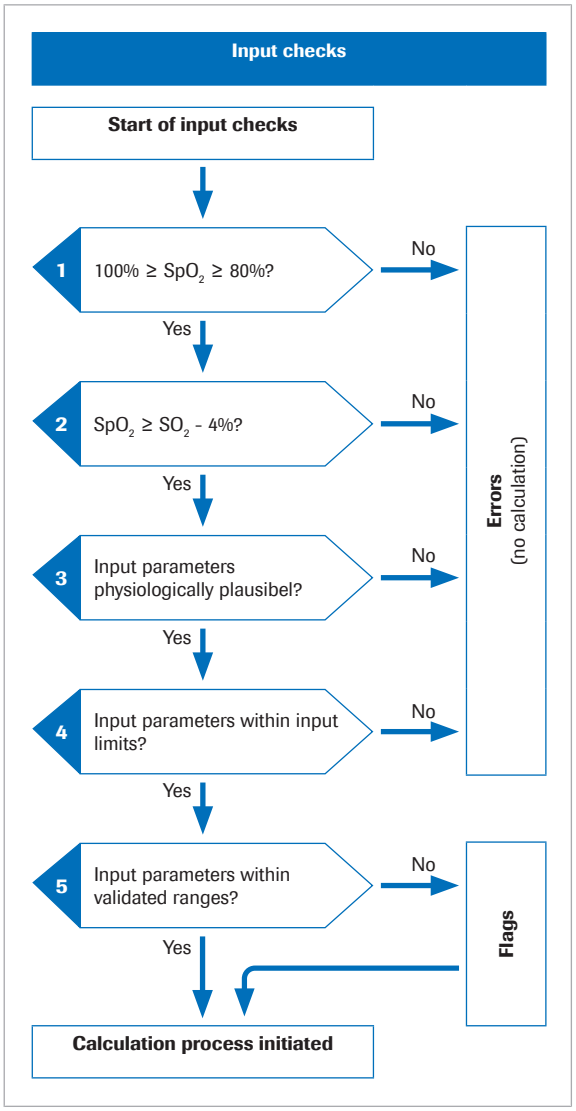
Statistical variation for pO_2 pooled data

Robustness

In this section

Robustness of input

Details on input checks



Before the mathematical process is initiated, the software performs several input checks:

1. The SpO_2 value must be within the range of 80%[(2)] to 100%.
2. The SpO_2 value must be greater than the S_vO_2 value minus 4%.

   The 4% tolerance on SpO_2 is to accommodate the following situation: In patients where the arterial blood flushes through the tissues with very small metabolism, the venous values will be close to arterial values. However, due to tolerance on pulse oximetry and blood gas testing, the SpO_2 value measured may be slightly below the S_vO_2. In such cases, the S_vO_2 value is used for the calculation of the arterial results.
3. The input parameters must be physiologically plausible.
4. The input parameters must fall within the input limits.

   If any of the input checks in steps 1 to 4 fail, the software generates an error that explains the cause of the error. No arterial results will be calculated.
5. If one or more of the input parameters exceed the validated ranges, the calculated arterial results will be flagged.

The software only reports the calculated arterial results, if they pass the additional output checks.

About input and output checks (35)

[(2)] The default is 80% but can be as low as 75% by configuration.

Software used with capillary or arterial blood

If a capillary or arterial blood sample is accidentally used in the workflow to obtain calculated arterial results, the SO_2 level that is measured on the analyzer will be very close or equal to the SpO_2 level that is measured by pulse oximetry.

Consequently, the software will report calculated blood gas results that, at the most, will differ only slightly from the values of the original capillary or arterial blood sample.

If COHb and MetHb are not measured

It is recommended to use the software only with analyzers that measure COHb and MetHb.

However, some analyzers do not measure COHb and MetHb. To use the software with such analyzers, constants can be configured and used for COHb and MetHb.

Constants should only be used when the patients do not have elevated levels of COHb and MetHb that exceed the validated ranges.

Consequences of faulty or inaccurate SpO_2 measurements

The use of pulse oximetry to estimate the arterial saturation level has a certain patient-to-patient variability. To receive ISO 80601-2-61 certification, pulse oximeters must have a performance of ±4%, but in clinical praxis it may be as much as 10%.

Underestimation of SpO_2 is not uncommon, e.g., if the pulse oximeter picks up a poor signal due to poor peripheral perfusion, incorrect positioning of the probe, or similar. Another source of error is incorrect entering of the measured SpO_2 value on the blood gas analyser.

Arterialisation of $pH_{a,c}$ and $p_aCO_{2,c}$ is dependent on the difference between SpO_2 and the venous SO_2:

- A small difference causes a small correction
- A large difference causes a large correction

The arterialisation of $p_aO_{2,c}$ is dependent on the absolute value of SpO_2 and the intersection with the oxygen dissociation curve. The accuracy of the calculated $p_aO_{2,c}$

is less sensitive to inaccurate SpO_2 values from approximately 95% and below, whilst more sensitive to SpO_2 values from approximately 96% and above.

The table illustrates the typical impact of SpO_2 variations on arterial results calculated by the software:

Error sources	Typical impact on calculated arterial results			
	pH	pCO_2 [kPa]	pO_2 [kPa]	
	Across entire range		S_aO_2 = 88%	S_aO_2 = 93%
SpO_2 + 2%	+0.004	-0.09	+0.52	n/a (> 10)
SpO_2 - 2%	-0.003	+0.07	-0.42	-0.85

Impact of variations of SpO_2 on calculated arterial results [1]

To illustrate the effect of inaccurate or faulty SpO_2 measurements, 3 examples have been selected that are based on real venous blood gas patient data and simulation of SpO_2 values.

The tables show the calculated arterial results for the measured SpO_2 value as well as for simulated SpO_2 values of ±5% and ±10%.

Example 1

- COPD patient with average arterio-venous difference.
- SpO_2 measured to 88% (slightly overestimated, S_aO_2 = 85.3%).
- SpO_2 simulation of -10% is not possible (because of lower limit of 80%).

	VBG	ABG	Calculated arterial results				
Difference [%]	-	-	-10%	-5%	0%	+5%	+10%
SpO_2 [%]	-	-	78%	83%	88%	93%	98%
pH	7.40	7.41	n/a	7.41	7.42	7.43	7.43
pCO_2 [kPa]	7.53	6.89	n/a	7.02	6.87	6.71	6.54
pO_2 [kPa]	4.69	6.56	n/a	6.31	7.23	8.87	>10
SO_2 [%]	66.60%	85.30%	-	-	-	-	-

Example 1

Example 2

- COPD patient with very small arterio-venous difference.
- SpO_2 measured to 92% (SaO_2=92.4%).
- SpO_2 simulation of ±10% are not possible (because SpO_2 = 82% is less than SO_2 = 90% - 4% and because SpO_2 = 102% exceeds 100%).

	VBG	ABG	Calculated arterial results				
Difference [%]	-	-	-10%	-5%	0%	+5%	+10%
SpO_2 [%]	-	-	82%	87%	92%	97%	102%
pH	7.37	7.37	n/a	7.37	7.37	7.38	n/a

Example 2

	VBG	ABG	Calculated arterial results				
pCO_2 [kPa]	7.34	7.27	n/a	7.34	7.28	7.13	n/a
pO_2 [kPa]	7.57	8.39	n/a	7.57	8.24	>10	n/a
SO_2 [%]	90.00%	92.40%	-	-	-	-	-

Example 2

Example 3

- Asthma patient with very large arterio-venous difference:
  $\Delta_{A\text{-}V}pH = 0.063$, $\Delta_{A\text{-}V}pCO_2 = 2.48$ kPa.
- SpO_2 measured to 99% ($SaO_2 = 97.3\%$).
- SpO_2 simulation of +5% and +10% are not possible (because they exceed 100%).

	VBG	ABG	Calculated arterial results				
Difference [%]	-	-	-10%	-5%	0%	+5%	+10%
SpO_2 [%]	-	-	89%	94%	99%	104%	109%
pH	7.32	7.39	7.40	7.40	7.41	n/a	n/a
pCO_2 [kPa]	7.72	5.24	5.50	5.35	5.17	n/a	n/a
pO_2 [kPa]	2.11	12.62	7.35	9.24	>10	n/a	n/a
SO_2 [%]	18.50%	97.30%	-	-	-	-	-

Example 3

Conclusion

$pH_{a,c}$ and $p_aCO_{2,c}$ calculated results are robust to inaccurate or faulty SpO_2 input values. The accuracy of $p_aO_{2,c}$ is dependent on the accuracy of the SpO_2 measurement.

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Glossary

2,3-diphosphoglycerate

Organic phosphate present in red blood cells that alters the affinity of hemoglobin for oxygen.

actual base excess

Base excess that is actually found in the blood.

arterial oxygen saturation

Parameter that provides information about the amount of hemoglobin oxygenation in the arterial compartment of the circulatory system.

base excess

Amount of strong acid that must be added to each liter of fully oxygenated blood to return the pH to 7.40 at a temperature of 37°C and a pCO2 of 40 mmHg (5.3 kPa).

bicarbonate

Electrolyte that is found in blood and other body fluids. It is necessary to regulate the pH level of the body.

carboxyhemoglobin

Abnormal form of hemoglobin that is attached to carbon monoxide, which impairs the release of oxygen from hemoglobin.

methemoglobin

Form of hemoglobin in which the iron in the heme group is in the ferric state and therefore unable to bind oxygen and to carry oxygen to tissues.

partial pressure of carbon dioxide

Parameter that provides information about the amount of carbon dioxide dissolved in the blood.

partial pressure of oxygen

Parameter that provides information about the amount of oxygen dissolved in the blood.

peripheral oxygen saturation

Parameter that provides information about the oxygen saturation level in peripheral blood and that is usually measured with a pulse oximeter.

pH

Parameter that provides information about the acidity or alkalinity of a sample.

total hemoglobin

Parameter that provides information about the total amount of hemoglobin in the blood.

venous oxygen saturation

Parameter that provides information about the oxygen content of the blood returning to the right side of the heart after perfusing the entire body.

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