

Urgent Field Safety Notice

SB-RPD-2014-007

RPD / Blood Gas & Electrolytes
Version 1 Update
01-Sep-2014

Reference Ranges Update cobas b 221

Product Name	cobas b 221<1> =Roche OMNI S1 system cobas b 221<2> =Roche OMNI S2 system cobas b 221<3> =Roche OMNI S3 system cobas b 221<4> =Roche OMNI S4 system cobas b 221<5> =Roche OMNI S5 system cobas b 221<6> =Roche OMNI S6 system
GMMI / Part No	03337103001
Device Identifier	03337111001 03337120001 03337138001 03337146001 03337154001
Production Identifier (Lot No./Serial No.)	all
Type of Action	Customer information Customer action Field Implementation Mandatory

Dear Valued **cobas b 221** system/OMNI S Customer,

We regret to inform you that the default Reference ranges on print outs and in Instructions for Use (Operator Manuals) refer to different sources and are inconsistent between different **cobas b 121**, **123** and **221** systems.

Description of Situation

We have received a complaint related to different default reference ranges between **cobas b 123** POC and **cobas b 221** systems. Early investigation identified that the default reference ranges of several parameters differ in comparison with each other on different systems (**cobas b 121**, **cobas b 221** and **cobas b 123** POC) and do not fit to the corresponding manuals. The different reference ranges show up on the instrument's display and on the printout of results, if they were not adapted by the customer. The results of tests are flagged accordingly.

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The Instructions for Use (Operator Manual) provide an extensive overview of results depending on age, gender, blood type and clinical conditions.

Further investigation revealed that for the default reference ranges an update is required in this regard.

The purpose of this FSN is to provide updated values with according sources until revised Instructions for Use (Operator Manuals) are available.

Reference ranges are intended as an additional help for users to identify results out of normal range. The Hb derivatives COHb (%COHb), MetHb (% of total Hb), O₂Hb (%O₂Hb), SO₂ (%Saturation), HHb (%HHb), tHb (g/dL), pCO₂ (mmHg), pO₂ (mmHg) and Hct (%) refer to several scientific sources with slight differences in the reference range..

The reference range for SO₂ combines arterial and venous range (lower limit venous reference range, upper limit arterial reference range). As clinical status of patients is directly related to SO₂ the detectability is certain. Nevertheless the reference range for SO₂ will be split in arterial and venous reference ranges to prevent confusion.

Reference ranges for other parameters related to a medical risk depend strongly on the individual patient population. Those parameters need special attention.

The detectability is certain as physicians and care workers know reference ranges by memory.

Actions taken by Roche Diagnostics

Adapted default reference ranges as part of SW version 8.0 will be implemented for the **cobas b 221** system in Q1/2015. In addition, the statement "Note: ensure reference ranges match sample type" will be visible with this new SW version in order to actively remind customers to do so. Revised Instructions for Use will be published in Q4/2015, in accordance with the MSS Gen II sensor launch.

Customers are able to enter individual reference ranges manually (see **cobas b 221** systems Reference Manual, Vers. 13).

Nevertheless, we would like to reiterate (according to Instruction for Use):

Reference intervals, although useful as guideline for clinicians, should not be used as absolute indicators of health and disease. The reference intervals presented in this FSN are for general information purposes only. Individual laboratories should generate their own set of reference intervals.

Actions to be taken by the customer/user

Customers must check their current set of reference values and, if appropriate, amend the reference ranges accordingly.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and support.

Yours faithfully,

Roche Diagnostics GmbH

Contact Details

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Appendix

Table 1 Updated reference ranges

Parameter	Reference range	Sample type	On print outs of b 221 today	On print outs of b 221 SW 8.0	Source
COHb (%) :	<3% nonsmoker	Whole blood (EDTA)	0.5-2.5	0 - 3	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1
MethHb (% of total Hb):	0.04-1.52	Whole blood (EDTA, heparinized or ACD)	0.4-1.5	0.04 –1.52	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
O₂Hb (%O ₂ Hb):	94.0-98.0	Arterial blood, Mixed venous blood	95-99	94-98	Lothar Thomas, Labor und Diagnose, 8. Auflage
SO₂ (O ₂ Saturation;%)	94-98	Whole blood, arterial	75-99	94 - 98	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
HHb (%HHb):	<3%		1.0-1.5	0-3.0	Kenneth A. Wyka, Paul J. Mathews, John Rutkowski: Foundations of respiratory care
tHb (g/dL):	F 11.5-16.0 M 13.5 -17.8	Capillary blood	11.5-17.4	11.5-17.4	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1 p. 827
Bilirubin (µmol/L)	0 – 2.0 mg/dL 0 - 34.2 µmol/L	Serum	51 – 850	0 - 34.2	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pH	7.350-7.450	Whole blood, arterial	7.350-7.450	7.350-7.450	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pCO₂ (mmHg)	F 32-45 M 35-48	Whole blood, arterial (heparinized)	35-45	35-45	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
pO₂ (mmHg)	83-108 (2d - 60y)	Arterial whole blood	80-100	83-108	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Na⁺ (mmol/L)	136-145	Serum	135-148	136-145	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
K⁺ (mmol/L)	3.5 – 5.1	Serum	3.5-4.5	3.5 – 5.1	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Ca²⁺ (mmol/L)	1.15 – 1.33	Serum, Plasma	1.120-1.320	1.15 –1.33	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Cl⁻ (mmol/L)	98-107 (Adult)	Serum	98-107	98-107	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012

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Parameter	Reference range	Sample type	On print outs of b221 today	On print outs of b221 SW 8.0	Source
Hct (%)	Caucasian F 36-48 Caucasian M 40-53 Black F 34-43 Black M 34-48 Athletes F 37-45 Athletes M 40-50	Whole blood	35-50	35-50	Lothar Thomas, Labor und Diagnose, 8. Auflage, Band 1
Glu (mmol/L)	3.5 – 5.3	Whole blood, heparinized	3.3 – 6.1	3.5 – 5.3	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Lac (mmol/L)	0.36 – 0.75	Whole blood, venous	0.4 – 2.2	0.36 – 0.75	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012
Urea (mmol/L)	2.1 – 7.1	Serum	2.5 – 6.4	2.1 – 7.1	Tietz Textbook of clinical chemistry and molecular diagnostics 5th edition 2012