Ö	**Immediate Action Required**
	Action Required
	Information Only

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: BFSN_03_14 Reference Ranges SB-RPD-2014-007
Document Date: 01/10/2014
Type of Action: < Field Corrective Action >

System Affected:	**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
Summary of Issue:	**Default reference ranges on print outs and in Instructions for Use (Operator Manuals) are inconsistent between different cobas b 121, cobas b 123 and 221 systems.**

Material No:	03337103001 03337111001 03337120001 03337138001 03337146001 03337154001

Reason for Notice:	We regret to inform you that the default Reference ranges on printouts and in Instructions for Use (Operator Manuals) are inconsistent and also differ between **cobas b** 121 **cobas b** 221 and **cobas b** 123 POC systems. We have received a complaint related to different default reference ranges between **cobas b** 123 POC and **cobas b** 221 systems. 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 not adapted by the customer. The results of tests are flagged accordingly.

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

Further investigation revealed that for the default reference ranges (i.e. ranges that are pre-programmed into the system during installation) 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.

Risk Assessment

Frequency of Occurrence

This is a general issue and as such affects all systems in the field. Printouts and flags are affected only in those cases where the default reference ranges were never changed by the customer.

Detectability

Differences can only be detected if sources are checked actively by the customer or in case different instrument types are available at the same customer site.

The critical parameter within this issue is SO2 (see also 'Severity'), the table below shows the different "normal ranges" provided for the different analysers.

Parameter	Manuals	Source	cobas b 123 POC (normal range	cobas b 221 (normal range)
SO2 (% Saturation)	94 – 98	95 – 98.5	95 – 98	75 – 99

The reference range for SO2 combines arterial and venous range (lower limit venous reference range, upper limit arterial reference range). As the clinical status of patients is directly related to SO2 the detectability is certain. Nevertheless the reference range for SO2 has to be split into arterial and venous reference ranges to prevent confusion.
For **cobas b** 123 POC the normal range for SO2 is correct, therefore it is not affected by this notice.

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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.

Severity

A Health Hazard Evaluation was performed, please find the summary below:

COHb (%COHb), MetHb (% of total Hb), O2Hb (%O2Hb), SO2 (%Saturation), HHb (%HHb), tHb (g/dL), pCO2 (mmHg), pO2 (mmHg) and Hct (%) show per default different references for normal values on **cobas b** 123 and **b** 221. The reference ranges differ in comparison with each other and in comparison with Operators Manual and source. The differentiating reference ranges show up on the instrument's display and on the printout of results. The results are flagged accordingly. The patient results are correct.

Reference ranges are intended as an additional help for users to identify results out of normal range. They are not intended as substitute for medical knowledge. Additionally within the Operators Manual a warning is added: "…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 chapter are for general information purposes only. Individual laboratories should generate their own set of reference intervals."

Nevertheless it cannot be excluded that reference values being different to each other, source and Operators Manual may cause confusion as the default references would not change according to the type of sample chosen by the customer.

In life-critical situations which follow a rigid structure, as trained within Mega-Code or Advanced Cardiac Life Support trainings, correct communication is essential and confusion may raise a medical risk for the patient.

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Actions taken by Roche Diagnostics

As part of SW version 8.0 adapted default reference ranges will be implemented for the **cobas b** 221 system in Q1/2015, which means adapted values will be visible on the display and on printouts as listed within the table in BFSN_03_14 Attachment 1. 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, within the time frame of the MSS Gen II sensor launch. Customers or Field Service Representatives (FSRs) are able to enter individual reference ranges manually, please follow the instructions described in BFSN_03_14 Attachment 2.

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.

Action Required:

1. Customers must check their current set of reference values and, if appropriate, amend the reference ranges accordingly.
2.
3. Please complete the fax back and return no later than 15th October 2014.

Attachments:

BFSN_03_14 Reference Ranges SB-RPD-2014-007 fax back.
BFSN_03_14 Attachment 1 - Reference Ranges
BFSN_03_14 Attachment 2 - Instructions

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

** Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. **

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If you require any further information please contact our Professional Services Department / Technical Support Hotline on:
UK: 0808 100 19 20
Ireland：1800 40 9 564

A copy of this notice can also be found on www.cobas-roche.co.uk

To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.

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