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URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: **BFSN 02_2016** cobas b 123 - Neonatal Bilirubin Results with Software SW4.7 **SBN-CPS-2016-024**

Document Date: **22/11/2016**

Type of Action: **Field Corrective Action**

Product Affected:	**SYSTEM SOFTWARE 4.7 cobas b123 POC system**
System Affected:	**cobas b 123 <3> POC system** **cobas b 123 <4> POC system**
Summary of Issue:	We have become aware of an issue that may lead to discrepancies in neonatal bilirubin results measured on cobas b 123 POC systems running software version 4.7 (SW V4.7) compared to cobas b 123 POC systems running software version 4.5 (SW V4.5). The software issue has already been corrected in cobas b 123 POC system software version 4.8 (“SW V4.8”). However, for customers that measure neonatal bilirubin and where an immediate update to software version SW V4.8 is not possible, workaround instructions when using software version SW V4.7 are included.

Details of Affected Devices:	
Material No:	05122279001 05122287001 05064694001
Lot: No:	ALL

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

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Reason for Notice:

During an investigation of a complaint, we have become aware of a software issue that may cause discrepancies between neonatal bilirubin results obtained with cobas b 123 <3> and <4> systems running SW V4.7 compared to systems running SW V4.5. The deviations are mainly apparent at high bilirubin values.

The impact on results is show in Table 1:

Result SW V4.7 [mg/dL]	Result SW V4.5 & SW V4.8 [mg/dL]	Result SW V 4.7 [µmol/L]	Result SW V4.5 & SW V4.8 [µmol/L]
3	4.2	51.3	70.97
6	6.7	102.6	114.57
9	9.3	153.9	158.18
12	11.8	205.2	201.78
15	14.4	256.5	245.39
18	16.9	307.8	288.99
21	19.5	359.1	332.60
24	22.0	410.4	376.20
27	24.6	461.7	419.81
30	27.1	513.0	463.41
33	29.7	564.3	507.02
36	32.2	615.6	550.62
39	34.8	666.9	594.23
42	37.3	718.2	637.83
45	39.9	769.5	681.44
48	42.4	820.8	725.04
50	44.1	855.0	754.11

Table 1: comparison of expected results for neonatal bilirubin on cobas b 123 systems with different cobas b 123 POC System Software versions

In [mg/dL]:

Result SW 4.7 [mg/dL]= (Result SW 4.5 – 1.6)/0.85 [mg/dL]

Result SW 4.8 [mg/dL] = Result SW 4.5 [mg/dL] = Result SW 4.7 * 0.85 + 1.6 [mg/dL]

In [µmol/L]:

Result SW 4.7 [µmol/L] = (Result SW 4.5 – 27.36)/0.85 [µmol/L]

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Result SW 4.8 [µmol/L] = Result SW 4.5 [µmol/L] = Result SW 4.7 * 0.85 + 27.36 [µmol/L]

At 10.6 mg/dL (182.4 µmol/L) software versions SW4.7 and SW4.5 give identical results.

For the overall population it is not likely that the differences in results at the medical decision point would lead to an incorrect medical treatment. In the worst case most likely the sample will be re-tested respectively when a second blood sample will be drawn.

For population most at risk (newborns under 28 days, particularly premature neonates borne 23+ week of gestation) a medical risk cannot be excluded. Incorrect medical decisions, due to discrepant results of Bilirubin, at the medical decision point according to the threshold tables and the treatment threshold graphs, provided with pediatric guidelines for management of hyperbilirubinemia, cannot be entirely ruled out.

Action Required:

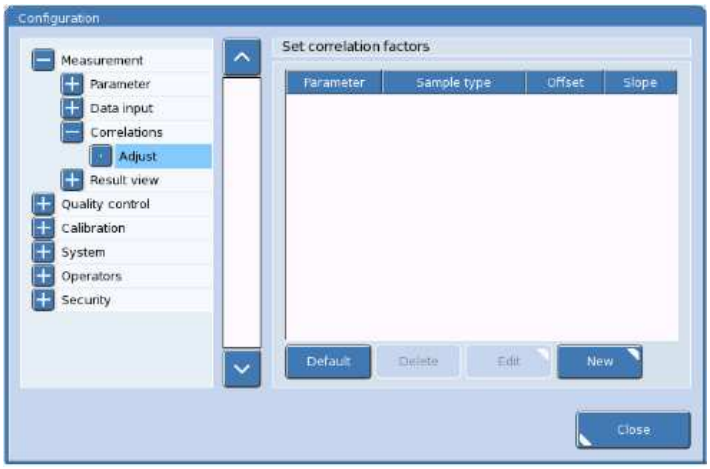
Actions to be taken by the customer/user

If you are measuring neonatal bilirubin with SW 4.7 and an update to SW 4.8 is not immediately possible, please use the workaround as described in below:

<u>Configuration of correlation factors on cobas b 123 POC systems running SW V4.7:</u>

In the tab “Utilities”, select “Configuration”.

In the configuration tree, select “Measurement” -> “Correlations”:



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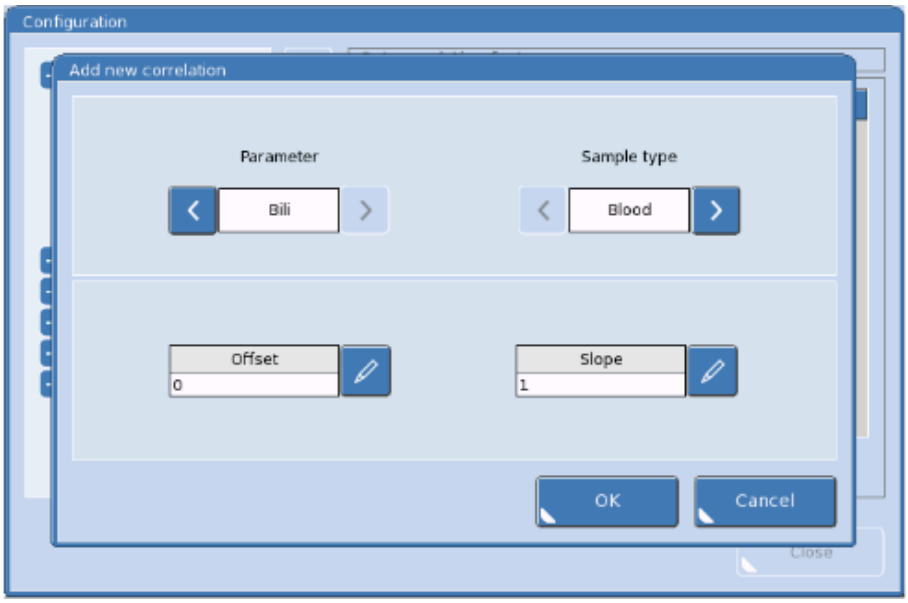
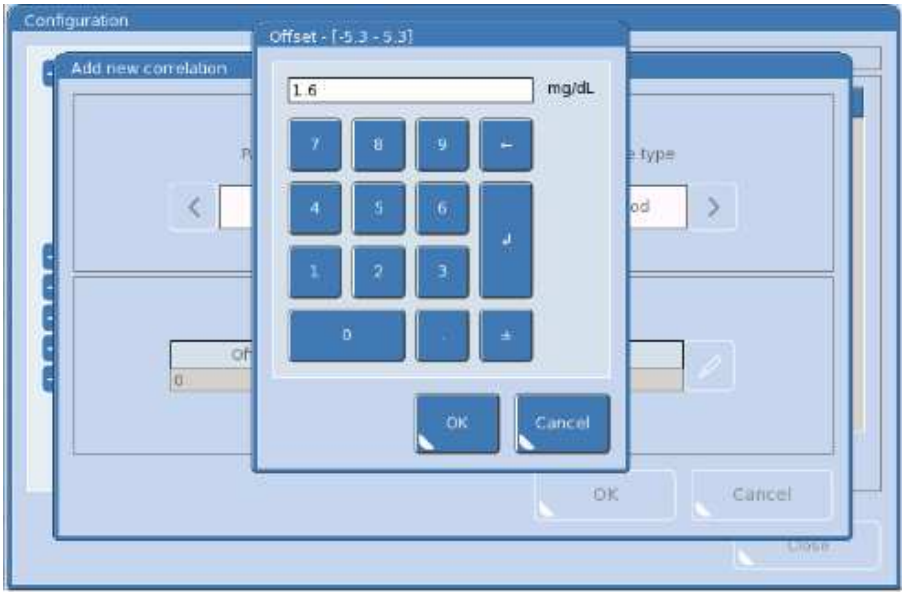
First, check if any correlation factors for neonatal bilirubin are already set in order to establish a correlation to another device with SW V4.7.

If no previous correlation factors for neonatal bilirubin have been set, proceed as follows:

Select “New”, and select the Parameter “Bili” and Sample type “Blood”:



If the Bilirubin unit is mg/dL, enter 1.6 mg/dL as the Offset:



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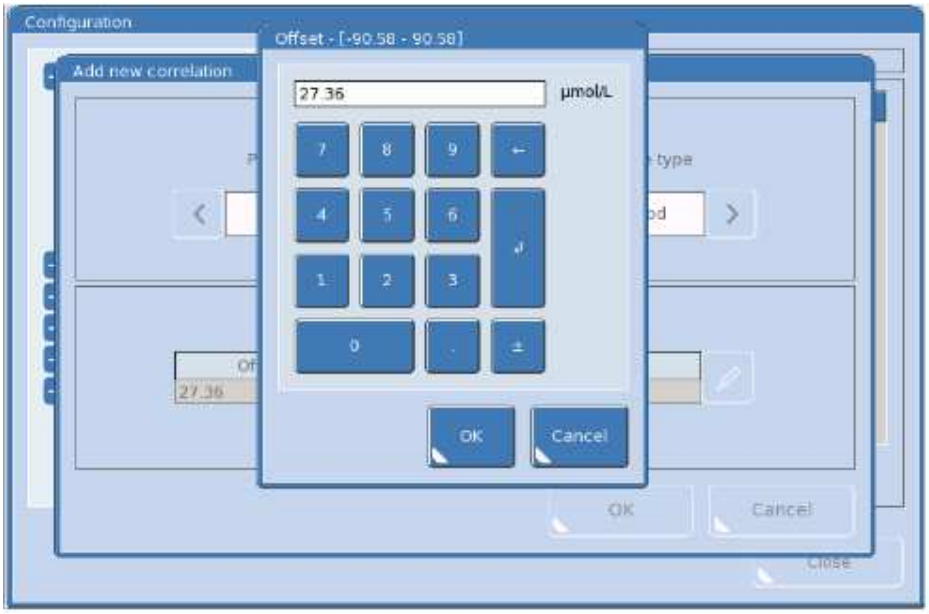
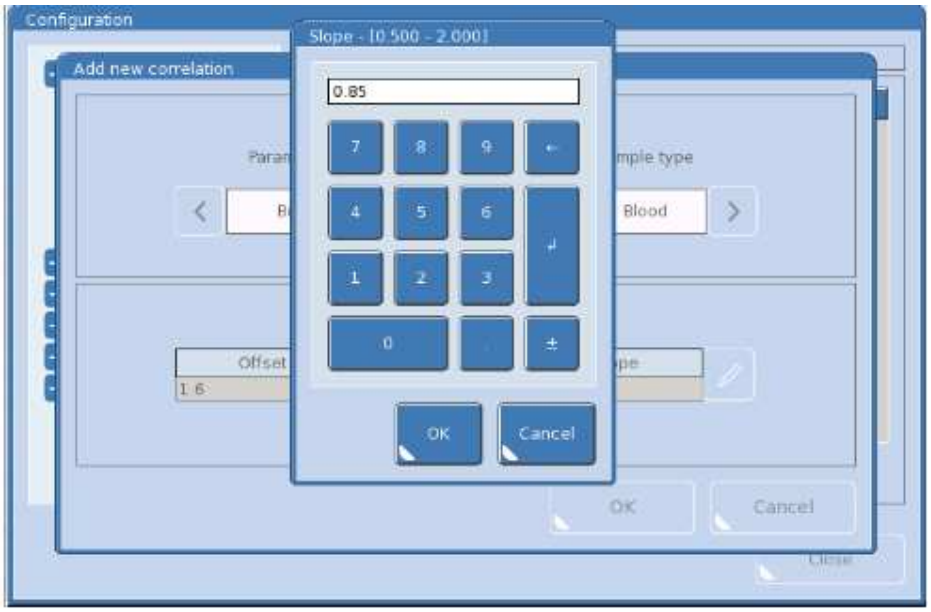
Note: If µmol/L is used, enter the offset as 27.36 µmol/L:



Enter the Slope as “0.85”:



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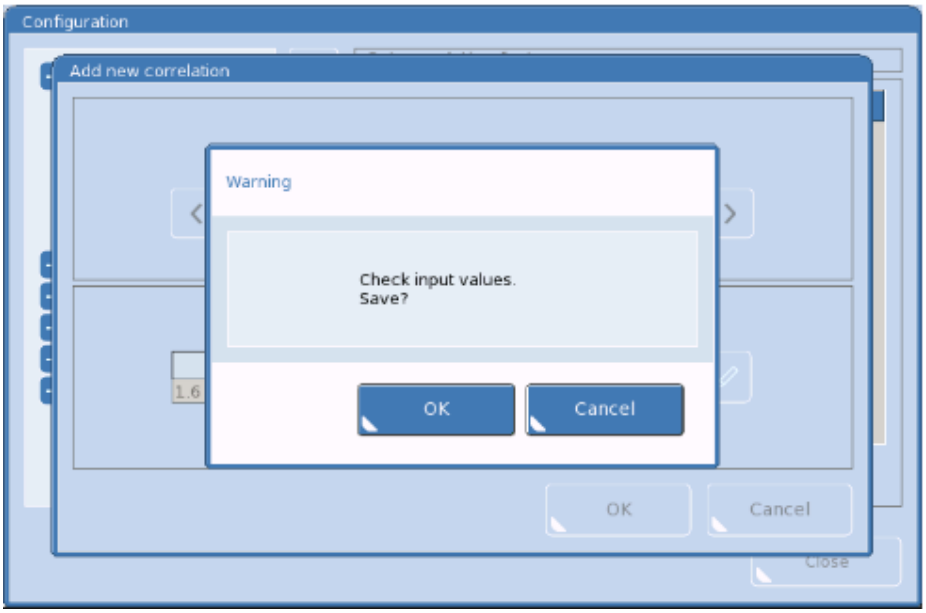
After checking the values, press “OK”:

Confirm with “OK”:



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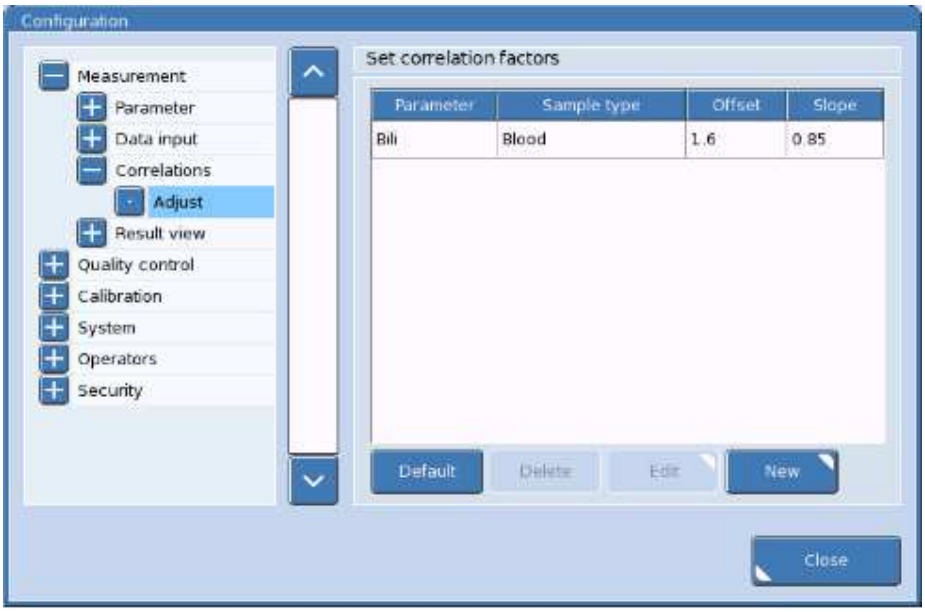
The correction values should show as such:



If previous correlation factors exist, proceed as follows:

* If previous correlation values have been already established with SW V4.7, it may be desirable to keep that correlation.

* If previous correlation factors have been established with SW V4.5 before the update to SW V4.7, it is necessary to adapt the correlation factors to have the same correlation that was established with software V4.5:

slope V4.7 = slope V4.5/0.85

offset V4.7 [mg/dL] = offset V4.5 [mg/dL] - slope V4.5 * 1.88 [mg/dL]

resp.

offset V4.7 [µmol/L] = offset V4.5 [µmol/L] - slope V4.5 * 32.19 [µmol/L]

where

slope V4.5 = slope that was established with SW V4.5

offset V4.5 = offset that was established with SW V4.5

slope V4.7 = new slope to be calculated and inserted with SW V4.7

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offset V4.7 = new offset to be calculated and inserted with SW V4.7

Enter those values as described in the previous section.

After correlation factors have been entered, all measurement results for Bilirubin are marked with a "(c)" on the result screen, the printed report and in the database detailed view.

Note:

The changes to the correlation factors as part of this workaround described above must be manually reverted after update to SW V4.8.

They are not automatically adapted or reverted in the course of a software update.

Actions taken by Roche Diagnostics

cobas b 123 POC system software version 4.8 which corrects this issue is available.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please complete the attached fax back and return via email to burgesshill.techsupportdocs@roche.com no later than 6th December 2016.

Attachments:

1. **Faxback BFSN 02_2016 cobas b 123 - Neonatal Bilirubin Results with Software SW4.7 SBN-CPS-2016-024**

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. ****

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

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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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