Field Safety Notice

SB-CPS-2016-024

Version 1
25-Nov-2016

cobas b 123 – Neonatal Bilirubin Results with Software SW4.7

Product Name	cobas b 123 <3> POC system cobas b 123 <4> POC system SYSTEM SOFTWARE 4.7 cobas b 123 POC system
GMMI / Part No **Device Identifier**	05122279001 05122287001 05064694001 Affected Software version not in use in Singapore
Production Identifier (Lot No./Serial No.)	All
Type of Action	Field Safety Corrective Action

Dear Valued **cobas b** 123 <3> and <4> system Customer,

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.

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Description of Situation

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]
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

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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.

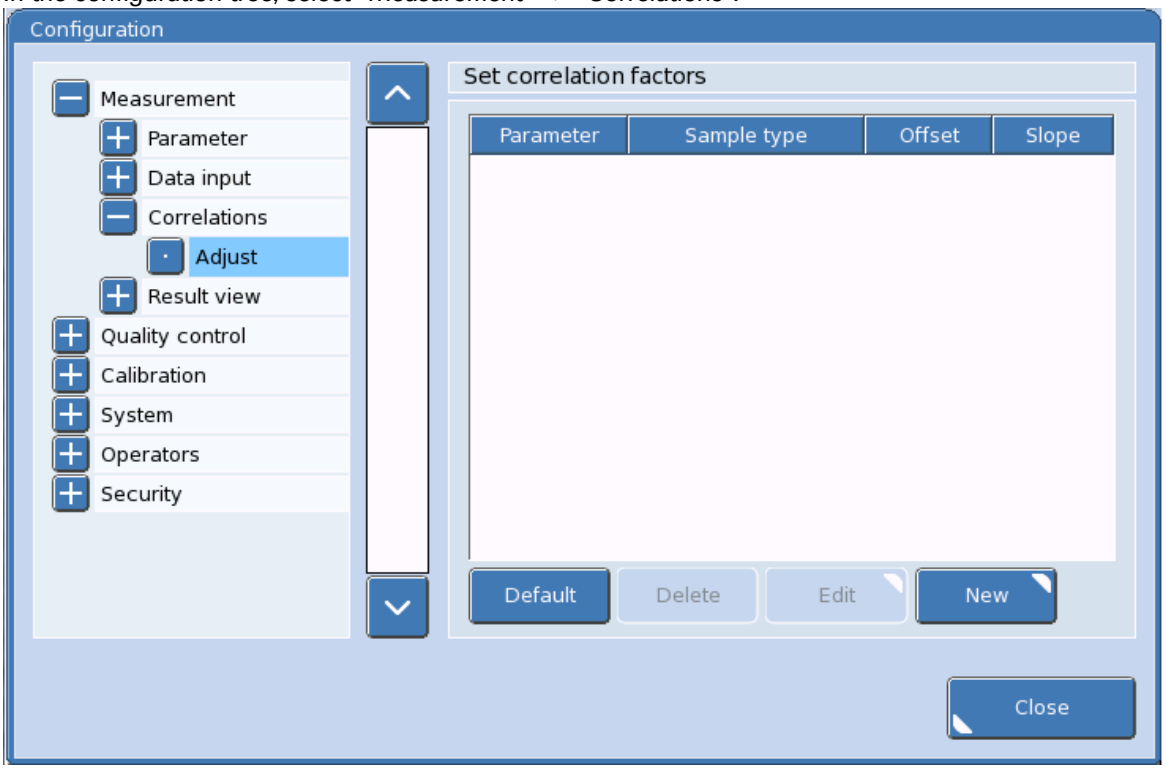
Actions to be taken by the customer/user

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 below:

Configuration of correlation factors on **cobas b** 123 POC systems running SW V4.7:

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

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



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:

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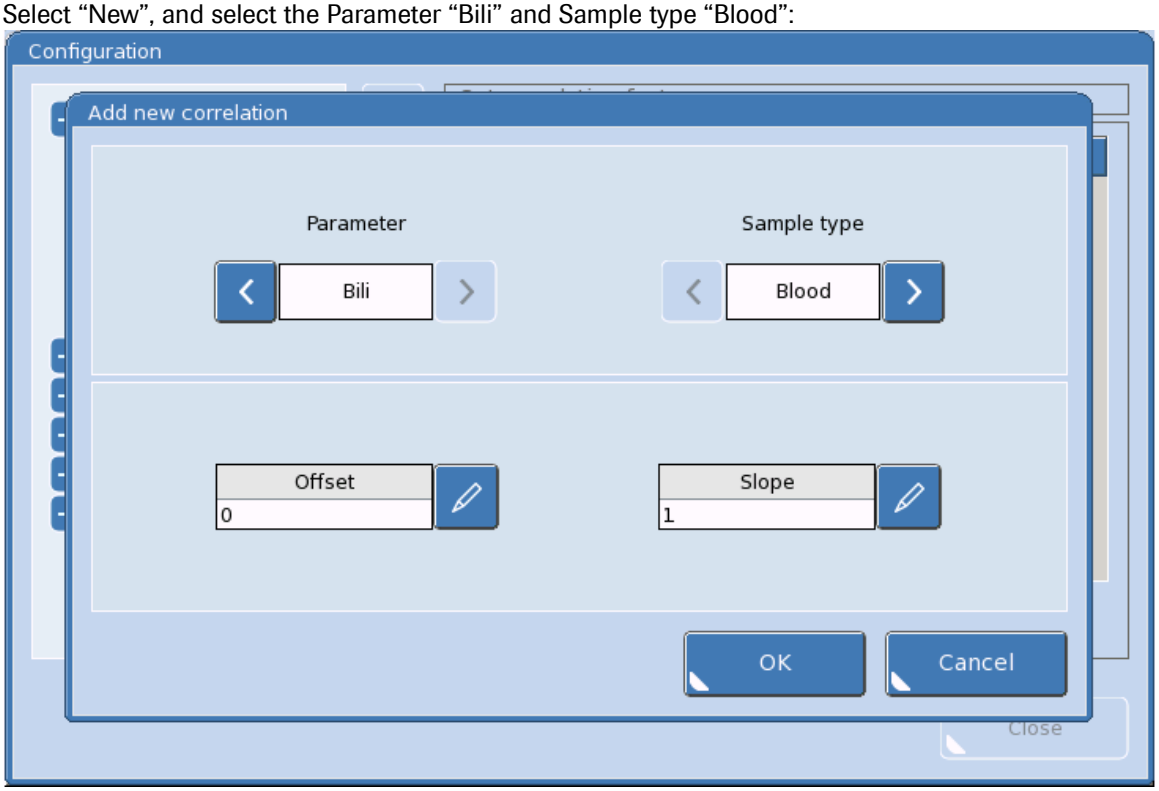
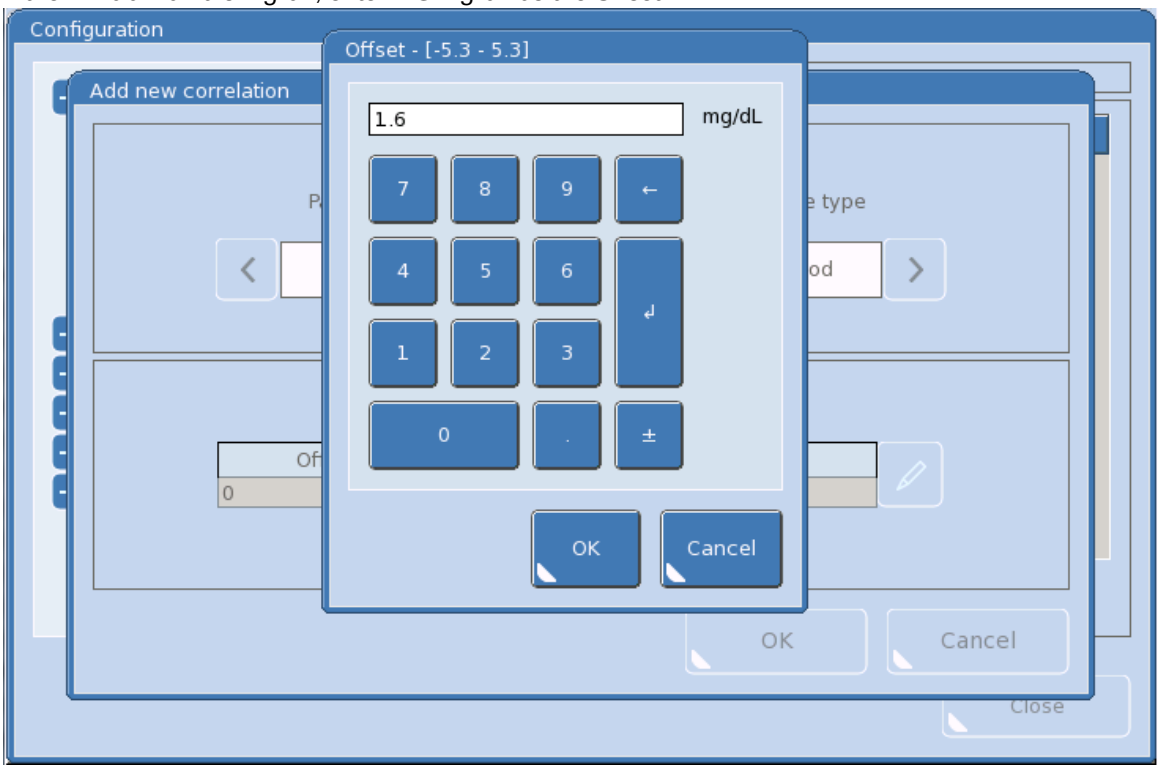
Select “New”, and select the Parameter “Bili” and Sample type “Blood”:



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



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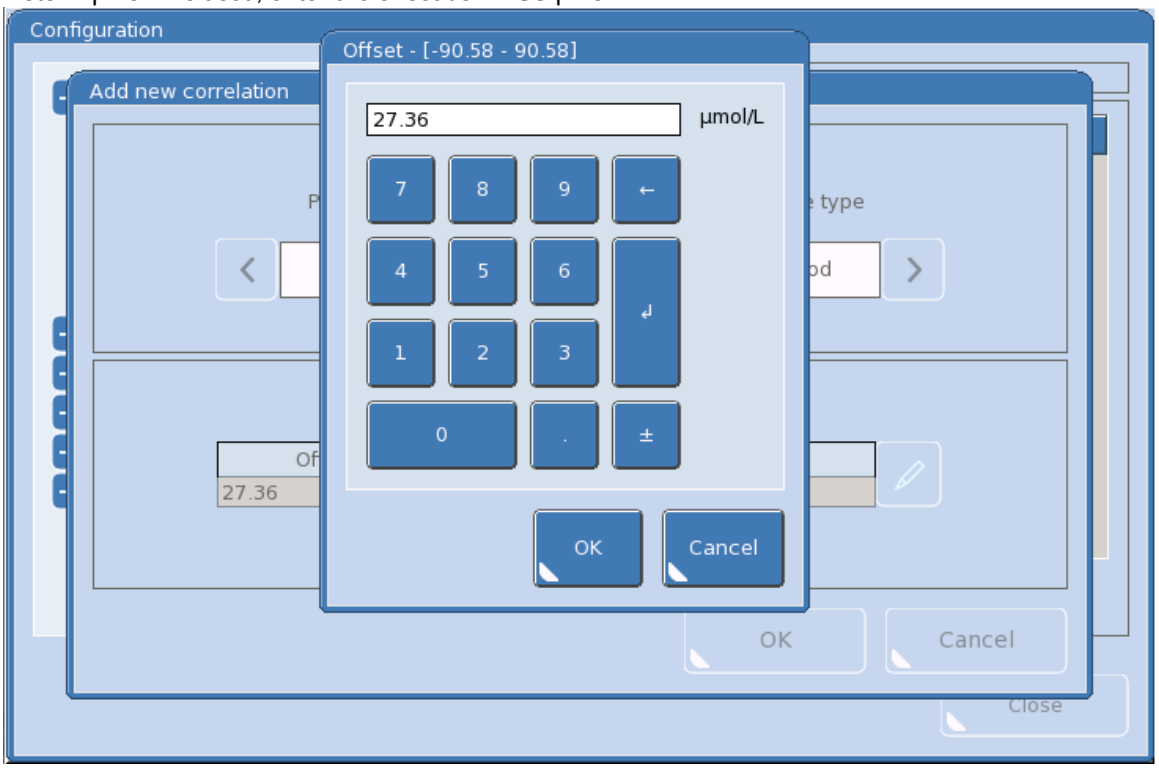
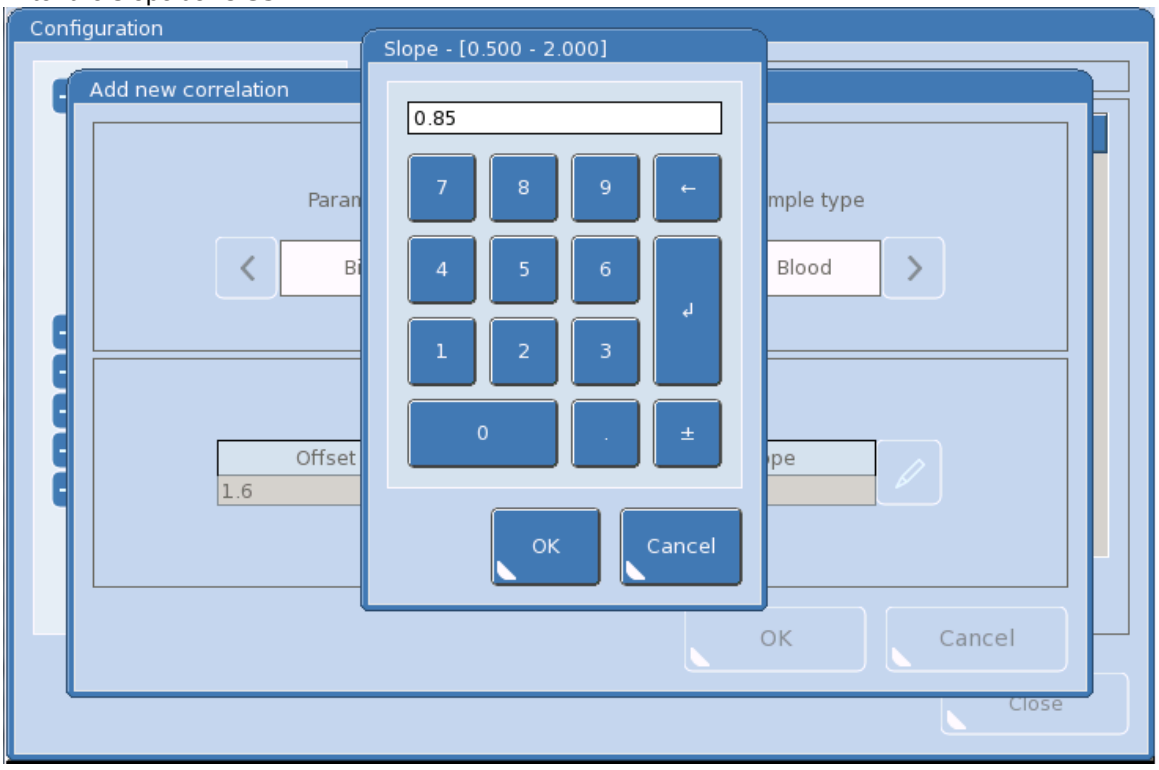
Note: If µmol/L is used, enter the offset as **27.36** µmol/L:



Enter the Slope as "**0.85**":



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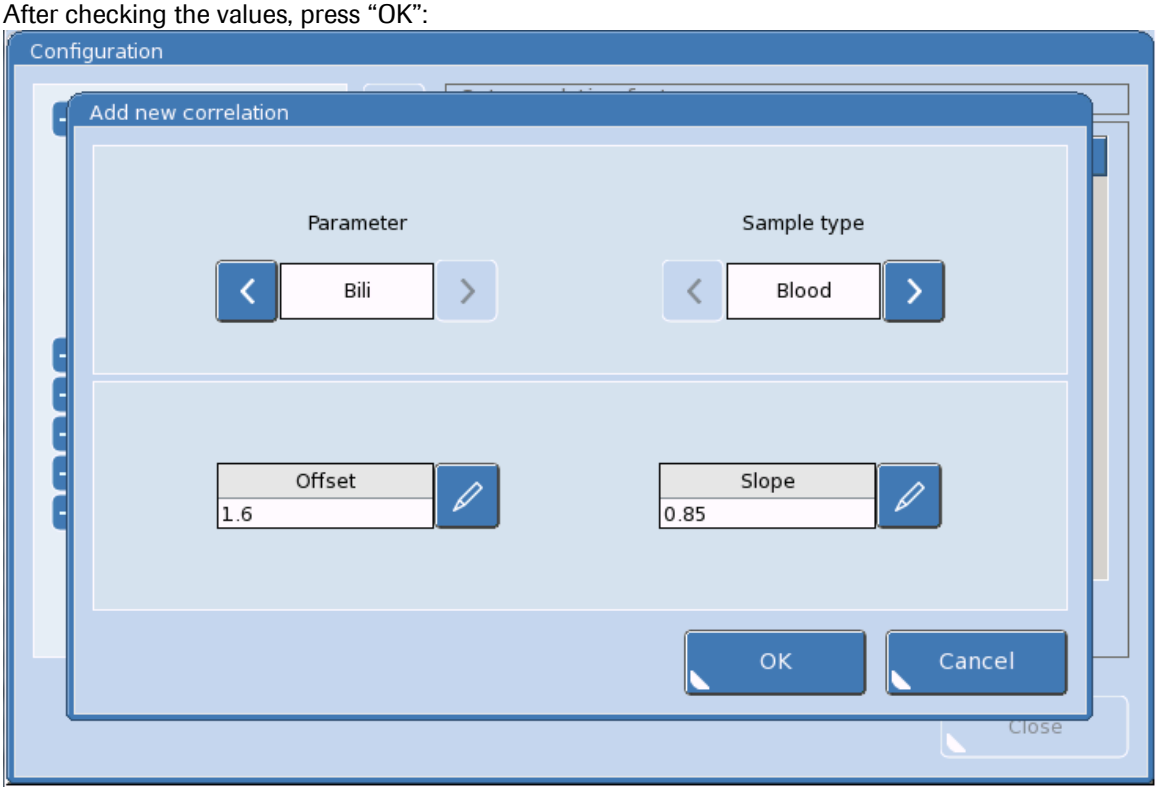
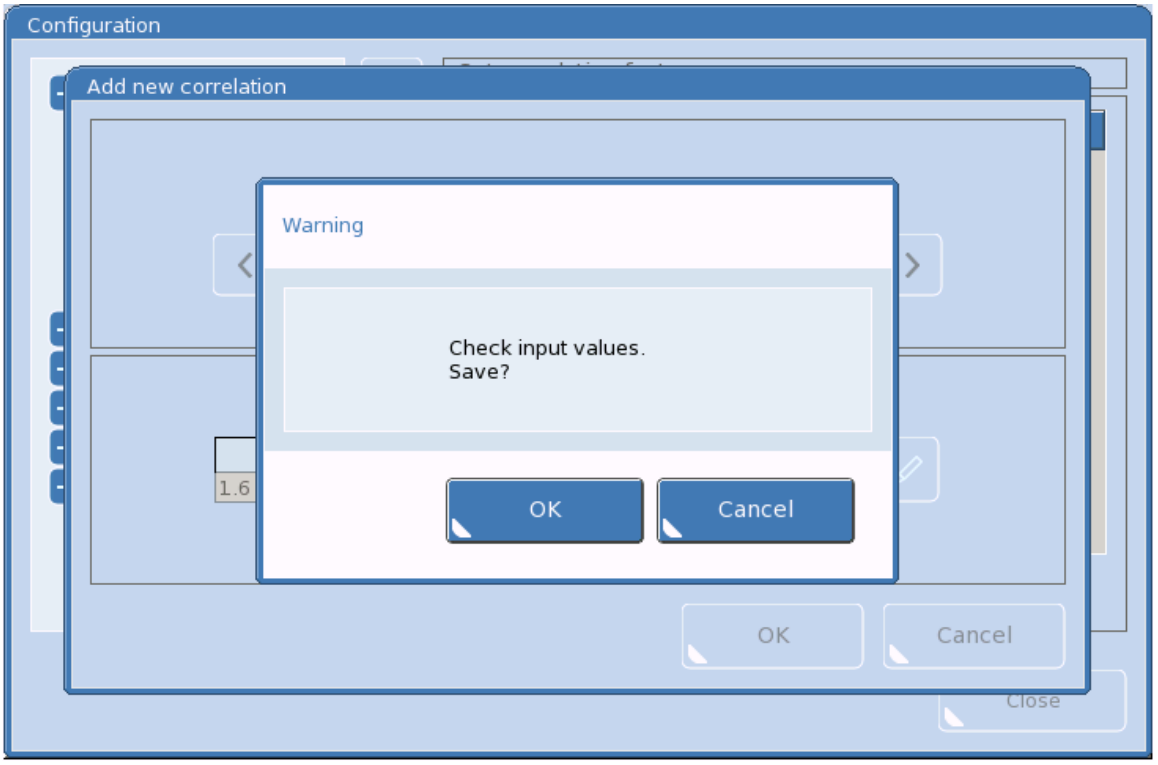
After checking the values, press “OK”:



Confirm with “OK”:



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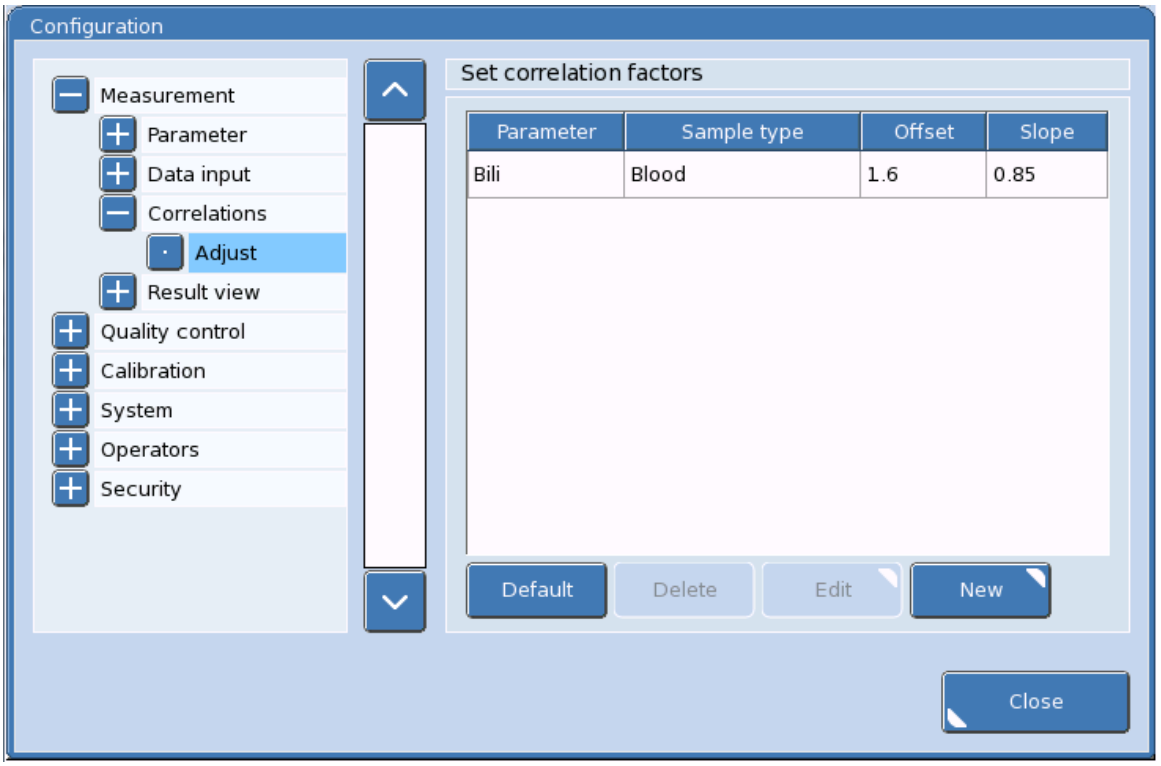
The correction values should show as such:



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
  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.

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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.

Communication of this Field Safety Notice

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

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

Respectfully yours,

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