Attachment 1:

Installation instruction for the workaround

Version 2: Update is color coded in blue

Section 1 describes how to determine the IRON2 throughput of the instrument

New recommendations for **cobas c** 311/501/502 for the calibration are given based on the throughput of the analyzer in Sections 3.1.1, 3.1.2, 4.1.1 and 4.1.2. These new methods overrule the recommendations given in the first version of the attachment.

It is recommended to run a blank calibration with the zero standard using deionized water on the **cobas c** 311/501/502 analyzers or perform a full calibration on COBAS INTEGRA® 400 plus after at least every 50 IRON2 determinations out of one **cobas c** pack. Several workaround possibilities are described below separated by

- o **Customers performing < 50 IRON2 determinations per day out of one cobas c pack**
- o **Customers performing ≥ 50 IRON2 determinations per day out of one cobas c pack**

The specified workarounds, which are applicable depending on the device, can be installed with a time interval by the customer itself as described below <u>except for</u> the calibration on the COBAS Integra® 400 plus. However, the customers should be aware that the calibration is not carried out automatically by the device. Rather the customer should perform the calibration when the message occurs. This is already the case with the usual calibrations.

In addition, an optimal hardware and maintenance status of the module might reduce the risk of the occurrence of the issue. The following steps can also be recommended as mitigating measures depending on the device: optimizing piercer, reagent probe, reagent rotor adjustment as well as outside wash adjustment and gear pump pressure adjustment also mitigates the issue.

1. **Determination of throughput of IRON2 of the instrument**

IRON2 throughput can be determined by reviewing the number of tests remaining in the c packs and calculating the throughput in comparison e.g. to the day before. A new cassette contains 200 tests.

   1.1. **cobas c** 311/501/502

Please select on the analyzer:

Reagent >> Setting

The number of remaining tests for each IRON2 c pack is listed in the column "Remaining".

1.2. **COBAS INTEGRA**® 400 plus analyzer

Please select on the analyzer:

Status >> Cassettes

Number of tests left in the IRON2 c packs are written under the cassette's names.

2. **Customers performing < 50 IRON2 determinations per week out of one cobas c pack**

Customers performing less than 50 determinations per week do not need to update the calibration settings.

3. **Customers performing < 50 IRON2 determinations per day out of one cobas c pack**

3.1. **cobas c** 311/501/502

Modules running < 50 IRON2 determinations per day out of one **cobas c** pack need to perform a blank calibration with the zero calibrator using deionized water, which can be set on the analyzer by changing the cassette/R. Pack calibration "Timeout" to "blank" and a "timeout" to "1 day" as follows:

3.1.1. **cobas c** 311/501:

Please select on the analyzer:

Utility >> Application >> Calib. >> Auto Calibration >> Cassette Blank 1 Day >> Save

Please see also the cobas 6000 analyzer series Operator's Manual Version 8.2 EN with the Software Version 06-03 Part B Chapter 14 "Configuration" "Description of the application parameters" >> "Calib. Tab" on page B-270 for **cobas c** 501 and the Practical Guide Version 1.1 EN for **cobas c** 311 on page 123 in Chapter "Software" >> Utility main menu 1-5.

cobas c 501

cobas c 311

Important:

According to the method sheets of IRON2, the calibration recommendation for cassette calibration Timeout is a 2-point calibration every 7 days. After Changing the cassette calibration "Timeout" to "Blank" every day, customers are still required to perform a 2-Point calibration manually after 7 days if the cassette is on board for at least 7 days.
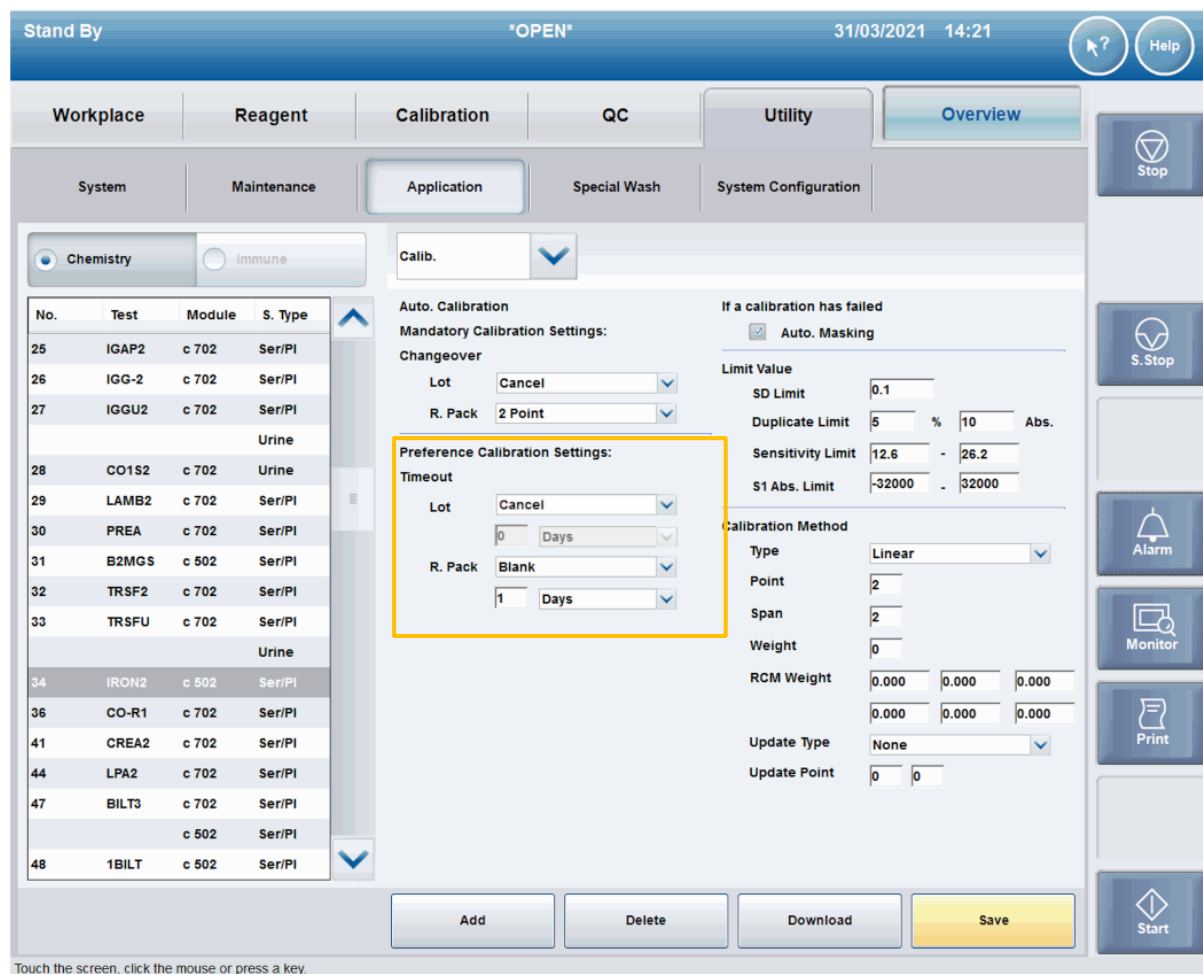
The changed calibration pattern applies only to cassettes loaded after changing the setting.

      3.1.2. **cobas c** 502:

Please select on the analyzer:

Utility >> Application >> Calib. >> Preference Calibration Settings >> R. Pack Blank 1 Days >> Save

Please see also the Complete User Documentation Version 5.4 Chapter 11 on page 721 following "Configuration calibration parameters".

Important:

According to the method sheets of IRON2, the calibration recommendation for cassette calibration Timeout is a 2-point calibration every 7 days. After Changing the cassette calibration "Timeout" to "Blank" every day, customers are still required to perform a 2-Point calibration manually after 7 days if the cassette is on board for at least 7 days.

The changed calibration pattern applies only to R. Packs loaded after changing the setting.

3.1.3. **COBAS INTEGRA**® 400 plus analyzer

COBAS Integra® 400 plus modules performing < 50 IRON2 determinations per day need to perform a full calibration with timeout "1 day".

Please select on the analyzer:

Configuration >> Double click Tests in the Definition group >> Select the required test from the installed tests list>> Select the chapter "General" >> Select calibration >> Select Main interval >> Choose Cassette & Interval >> Enter "1" in the corresponding text box "Days" to define the period to repeatedly define the calibration

For more details, please see the User Manual Version 3.2 for COBAS INTEGRA® 400 plus on page G-20 in Chapter "Configuration".
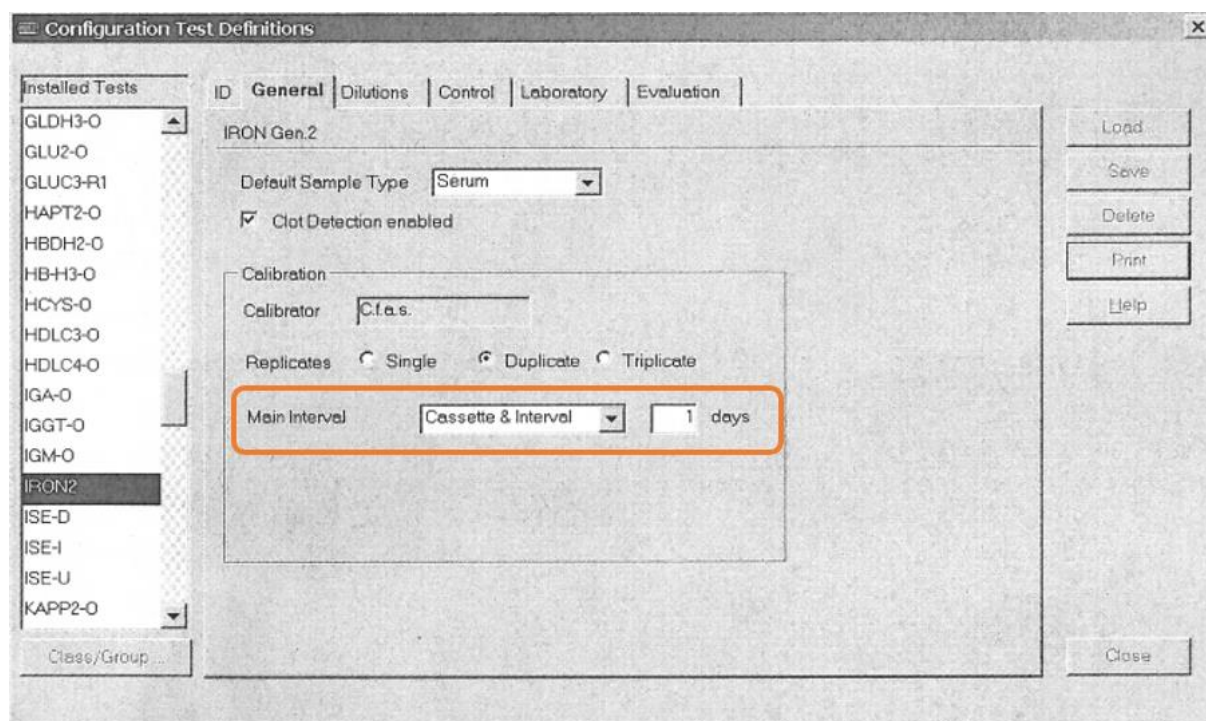
Important:

The changed calibration pattern applies only to cassettes loaded after changing the setting.

4. **Customers performing ≥ 50 IRON2 determinations per day out of one cobas c pack**

4.1. **cobas c** 311/501/502

Modules running ≥ 50 IRON2 determinations per day need to

o Perform a blank calibration manually at least after every 50 IRON2 determinations with the zero calibrator using deionized water OR
o Adjust the cassette/R. Pack timeout calibration according to the lab specific estimation of IRON2 determinations depending on the throughput in the laboratory e.g. to 1 hour, 2 hours, etc. and change it to "Blank"

Important:

The specification of the time interval must be defined by the customer according to the individual assessment. It must be ensured that no more than 50 IRON2 determinations per calibration interval are measured within the specified time interval.

4.1.1. **cobas c** 311/501:

Please select on the analyzer:

Utility >> Application >> Calib. >> Auto Calibration >> Cassette Blank "xx" Hour >> Save

Please see also the cobas 6000 analyzer series Operator's Manual Version 8.2 EN with the Software Version 06-03 Part B Chapter 14 "Configuration" "Description of the application parameters" >> "Calib. Tab" on page B-270 for **cobas c** 501 and the Practical Guide Version 1.1 EN for **cobas c** 311 on page 123 in Chapter "Software" >> Utility main menu 1-5.

Roche

cobas c 501

cobas c 311

Important:

According to the method sheets of IRON2, the calibration recommendation for cassette calibration Timeout is a 2-point calibration every 7 days. After Changing the cassette calibration "Timeout" to "Blank" every "xx" hours, customers are still required to perform a 2-Point calibration manually after 7 days if the cassette is on board for at least 7 days.

The changed calibration pattern applies only to cassettes loaded after changing the setting.

4.1.2. **cobas c** 502:

Please select on the analyzer:

Utility >> Application >> Calib. >> Preference Calibration Settings >> R. Pack Blank "xx" Hours >> Save

Please see also the Complete User Documentation Version 5.4 Chapter 11 on page 721 following "Configuration calibration parameters".

Important:

According to the method sheets of IRON2, the calibration recommendation for cassette calibration Timeout is a 2-point calibration every 7 days. After Changing the cassette calibration "Timeout" to "Blank" every "xx" hours, customers are still required to perform a 2-Point calibration manually after 7 days if the cassette is on board for at least 7 days.

The changed calibration pattern applies only to R. Packs loaded after changing the setting.

4.1.3. **COBAS INTEGRA**® 400 plus analyzer

COBAS Integra® 400 plus modules performing ≥ 50 IRON2 determinations per day need to perform a full calibration manually at least after every 50 determinations.