

# 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<sup>®</sup> 400 plus after at least every 50 IRON2 determinations out of one **cobas c** pack. Several workaround possibilities are described below separated by

- **Customers performing < 50 IRON2 determinations per day out of one cobas c pack**
- **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 except for the calibration on the COBAS Integra<sup>®</sup> 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**<sup>®</sup> 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

Workplace		Reagent		Calibration		QC		Utility		
System		Maintenance		Application		Calculated Test		Special Wash		
Report Format		Module Set		Analyze		Calib.		Range		
Other		Point		Span		Weight		Update Type		
11	GGT2	C	Ser/PI	Linear	2	2	0	None	0	0
12	GLUH2	C	Suprnt							
13	HAPT2	C	Ser/PI							
14	IRON2	C	Ser/PI							
15	STFR	C	Ser/PI							
16	TRSF2	C	Ser/PI							
17	FERR4	C	Ser/PI							
18	HBDH2	C	Ser/PI							
19	L2HBD	C	Ser/PI							
20	L3HBD	C	Ser/PI							
21	LDHI2	C	Ser/PI							
22	L2LDH	C	Ser/PI							
23	L3LDH	C	Ser/PI							
24	LDIP2	C	Ser/PI							
25	L2LDP	C	Ser/PI							
26	L3LDP	C	Ser/PI							
27	BUPS	C	Ser/PI							
			Urine							
28	6AMS1	C	Ser/PI							
			Urine							
29	HCYS	C	Ser/PI							

Auto Calibration

Timeout

Lot: Cancel

0 Day

Cassette: Blank

1 Day

Changeover

Lot: Cancel

Cassette: 2 Point

QC Violation

Method: Blank

Rule: 1s

Control1: None

Control2: None

Control3: None

Save

Help Touch the screen, click the mouse, press <Enter>

### cobas c 311

Workplace		Reagent		Calibration		QC		Utility		
System		Maintenance		Application		Calculated Test		Special Wash		
Report Format		Module Set		Analyze		Calib.		Range		
Others		Point		Span		Weight		Update Type		
9	Dumy3	Ser/PI		Linear	2	2	0	None	0	0
0	Dumy4	Ser/PI								
1	Dumy5	Ser/PI								
2	Dumy6	Ser/PI								
3	Dumy7	Ser/PI								
4	IRON2	Ser/PI								
0	SI2	Ser/PI								
7	Na	Ser/PI								
			Urine							
8	K	Ser/PI								
			Urine							
9	Cl	Ser/PI								
			Urine							
0	L	Ser/PI								
			Urine							
1	H	Ser/PI								
			Urine							
2	I	Ser/PI								
			Urine							

Auto Calibration

Changeover

To Lot: Cancel

To Cassette: 2 Point

Timeout

To Lot: Cancel

0 Days

To Cassette: Blank

1 Days

QC Violation

Method: Blank

Rule: 1s

Control: None

None

None

Save

Help Type the SD limit from 0.1 to 999.9 (Abs x 10000), then press <Enter>

**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”.

No.	Test	Module	S. Type
25	IGAP2	c 702	Ser/PI
26	IGG-2	c 702	Ser/PI
27	IGGU2	c 702	Ser/PI
Urine			
28	CO1S2	c 702	Urine
29	LAMB2	c 702	Ser/PI
30	PREA	c 702	Ser/PI
31	B2MGS	c 502	Ser/PI
32	TRSF2	c 702	Ser/PI
33	TRSFU	c 702	Ser/PI
Urine			
34	IRON2	c 502	Ser/PI
36	CO-R1	c 702	Ser/PI
41	CREA2	c 702	Ser/PI
44	LPA2	c 702	Ser/PI
47	BILT3	c 702	Ser/PI
c 502			
48	1BILT	c 502	Ser/PI

**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.**

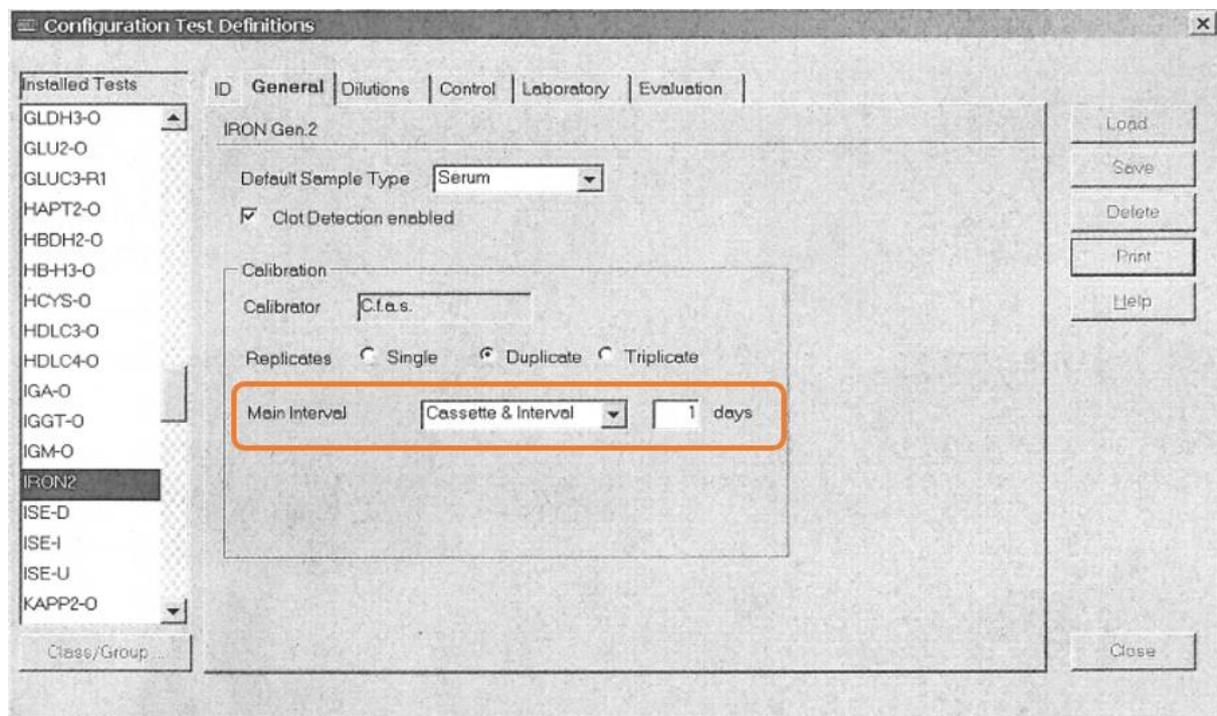
3.1.3. **COBAS INTEGRA® 400 plus analyzer**

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 $\geq$ 50 IRON2 determinations per day out of one cobas c pack**

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

Modules running  $\geq$  50 IRON2 determinations per day need to

- Perform a blank calibration manually at least after every 50 IRON2 determinations with the zero calibrator using deionized water OR
- 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](#).

**cobas c 501**

Workplace		Reagent		Calibration		QC		Utility	
System		Maintenance		Application		Calculated Test		Special Wash	
Report Format		Module Set		Analyze		Calib.		Range	
Other		Calibration Type		Point		Span		Weight	
11	GGT2	C	Ser/PI	Linear	2	2	0	<b>Auto Calibration</b> Timeout Lot: Cancel 0 Day Cassette: Blank 1 Hour	
12	GLUH2	C	Suprnt					<b>Changeover</b> Lot: Cancel Cassette: 2 Point	
13	HAPT2	C	Ser/PI					<b>QC Violation</b> Method: Blank Rule: 1s Control1: None Control2: None Control3: None	
14	IRON2	C	Ser/PI					<input checked="" type="checkbox"/> Auto Masking	
15	STFR	C	Ser/PI					<input type="button" value="Save"/>	
16	TRSF2	C	Ser/PI					<input type="button" value="Add"/>	
17	FERR4	C	Ser/PI					<input type="button" value="Delete"/>	
18	HBDH2	C	Ser/PI					<input type="button" value="Download"/>	
19	L2HBD	C	Ser/PI						
20	L3HBD	C	Ser/PI						
21	LDHI2	C	Ser/PI						
22	L2LDH	C	Ser/PI						
23	L3LDH	C	Ser/PI						
24	LDIP2	C	Ser/PI						
25	L2LDP	C	Ser/PI						
26	L3LDP	C	Ser/PI						
27	BUPS	C	Ser/PI						
			Urine						
28	6AMS1	C	Ser/PI						
			Urine						
29	HCYS	C	Ser/PI						

Help Touch the screen, click the mouse, press <Enter>

**cobas c 311**

Workplace		Reagent		Calibration		QC		Utility	
System		Maintenance		Application		Calc. Test		Special Wash	
Report Format		Module Set		Analyze		Calib.		Range	
Others		CalibType		Point		Span		Weight	
9	Dumy3	Ser/PI		Linear		2	0	<b>Auto Calibration</b> Changeover To Lot: Cancel To Cassette: 2 Point <b>Timeout</b> To Lot: Cancel 0 Days To Cassette: Blank 1 Hours	
0	Dumy4	Ser/PI						<b>QC Violation</b> Method: Blank Rule: 1s Control: None None None	
1	Dumy5	Ser/PI						<input type="button" value="Save"/>	
2	Dumy6	Ser/PI						<input type="button" value="Add"/>	
3	Dumy7	Ser/PI						<input type="button" value="Delete"/>	
4	IRON2	Ser/PI						<input type="button" value="Download"/>	
0	SI2	Ser/PI							
7	Na	Ser/PI							
			Urine						
8	K	Ser/PI							
			Urine						
9	Cl	Ser/PI							
			Urine						
0	L	Ser/PI							
			Urine						
1	H	Ser/PI							
			Urine						
2	I	Ser/PI							
			Urine						

Help Type the number of calibration points from 1 to 6, then press <Enter>



**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”.

Stand By \*OPEN\* 31/03/2021 14:21

Workplace Reagent Calibration QC Utility Overview

System Maintenance Application Special Wash System Configuration

Chemistry Immune Calib.

No.	Test	Module	S. Type
25	IGAP2	c 702	Seri/PI
26	IGG-2	c 702	Seri/PI
27	IGGU2	c 702	Seri/PI
		Urine	
28	CO1S2	c 702	Urine
29	LAMB2	c 702	Seri/PI
30	PREA	c 702	Seri/PI
31	B2MGS	c 502	Seri/PI
32	TRSF2	c 702	Seri/PI
33	TRSFU	c 702	Seri/PI
		Urine	
34	IRON2	c 502	Seri/PI
36	CO-R1	c 702	Seri/PI
41	CREA2	c 702	Seri/PI
44	LPA2	c 702	Seri/PI
47	BILT3	c 702	Seri/PI
		c 502	Seri/PI
48	1BILT	c 502	Seri/PI

Auto. Calibration

Mandatory Calibration Settings:

Changeover

Lot Cancel

R. Pack 2 Point

Preference Calibration Settings:

Timeout

Lot Cancel

0 Days

R. Pack Blank

1 Hours

If a calibration has failed

Auto. Masking

Limit Value

SD Limit 0.1

Duplicate Limit 5 % 10 Abs.

Sensitivity Limit 12.6 - 26.2

S1 Abs. Limit -32000 - 32000

Calibration Method

Type Linear

Point 2

Span 2

Weight 0

RCM Weight 0.000 0.000 0.000

0.000 0.000 0.000

Update Type None

Update Point 0 0

Add Delete Download Save

Stop S.Stop Alarm Monitor Print Start

Touch the screen, click the mouse or press a key.

### 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<sup>®</sup> 400 plus analyzer

COBAS Integra<sup>®</sup> 400 plus modules performing  $\geq 50$  IRON2 determinations per day need to perform a full calibration manually at least after every 50 determinations.