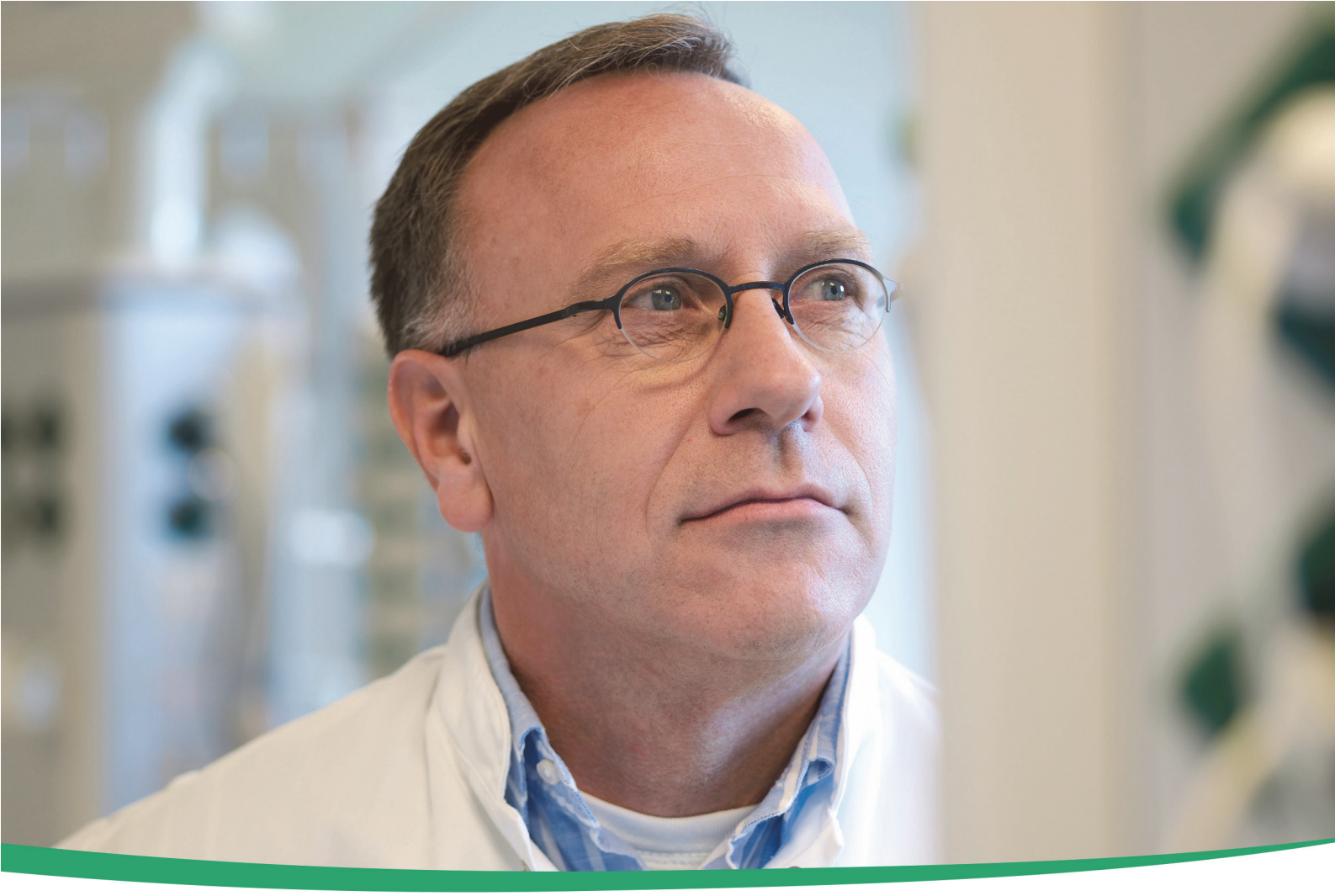


cobas c 111 analyzer

Operator's Manual version 4.1
Software version 4.1

Addendum version 1.0

Roche

cobas®
Life needs answers

Publication information

Publication version	Revision date	Changes
1.0	November 2016	First version

Table 1 Revision history

Edition notice This addendum is for users of the **cobas c** 111 instrument with software version 4.1.

General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Trademarks The following trademarks are acknowledged:

COBAS, COBAS C and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Contact address

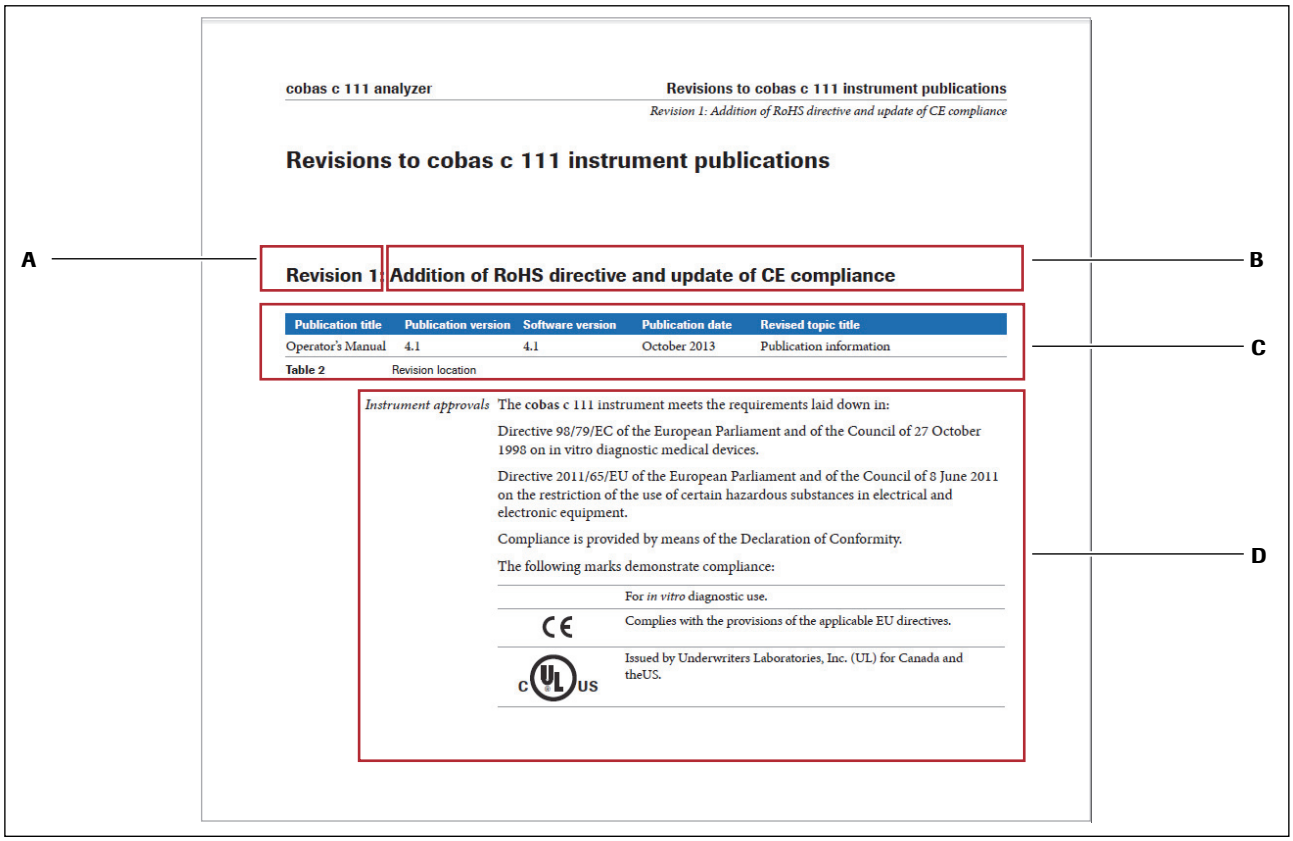
Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Made in Switzerland

Table of contents

About the addendum content

Roche recommends that you familiarize yourself with the new and/or revised content provided in this addendum.

The following illustration explains how this content is presented in this document.



A Change ID

B Change summary

C Topic affected

D Changed element

Figure 1 Structure of a revision

If you print these pages, Roche recommends printing them single-sided. In this way, you can easily insert the new and/or revised content in its appropriate location(s) in the existing document.

Revisions to cobas c 111 instrument publications

Revision 1: Addition of RoHS directive and update of CE compliance

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	Publication information

Table 2 Revision location

Instrument approvals The **cobas c** 111 instrument meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

	For *in vitro* diagnostic use.
CE	Complies with the provisions of the applicable EU directives.
c UL US	Issued by Underwriters Laboratories, Inc. (UL) for Canada and theUS.

Revision 2: Additional information for sample measurements with a post-dilution

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Introduction to the instrument > Daily operation > Sample handling**

Table 3 Revision location

Dilution Pre-dilution may be used when performing calibrations and measurements. Predilution is part of the application definition and cannot be changed the operator.

Post-dilution is run when a re-run is requested by the operator after a measurement has finished. The post-dilution factor cannot be changed or altered by the operator; it is predefined.

(The dilution factor is part of the application definition and therefore does not need to be defined by the operator.)

Revision 3: Note for color interpretation for alarm button added

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Working with the user interface > Messages > Alarm monitor**

Table 4 Revision location

Interpreting the alarm LED

No color, off		**There are no unconfirmed alarm messages.**
Yellow		There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
Red		There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so. **Note:** When the alarm message results from a timing error, all tests run or results obtained after the time of the error time stamp should be retested.
Acoustic signal		An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities > Configuration > System > Volume**).

Revision 4: Replace "sample area ventilation" by "display module fan"

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Key screens > Overview tab > System status**

Table 5 Revision location

System status The **System Status** button displays both the icon and the color of one of the buttons of the underlying system status screen (see System status on page A-95).

The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.

This button can show either of the following icons.

	Analyzer (main cover)
	Reagent cooler and cuvette ring temperature
	Display module fan
	External fluid containers
	Maintenance
	Printer

Revision 5: Additional information for handling cuvettes

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Hardware overview > Fluid containers > Handling cuvettes**

Table 6 Revision location

Handling cuvettes

Cuvettes are supplied in boxes containing cuvette sets. Each set contains a number of cuvette segments. This way, the cuvettes can easily be handled without touching them.

Loading and removing cuvettes is guided by the system software. When handling is required, the rotor moves the cuvette segments to the cuvette port, where you can load or remove them. You handle one segment at a time. Cuvette segments are placed in the cuvette ring of the rotor.

To avoid timing errors ensure that all available cuvette segment positions are filled. Always replace any completely used cuvette segments. A partially used cuvette segment does not have to be replaced.

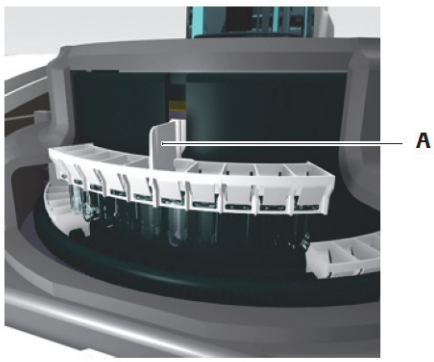
See Preparing cuvettes on page B-28.

WARNING

Incorrect results due to scratched or soiled cuvettes

Scratches and impurities on the cuvettes distort the measurements.

- Do not touch the cuvettes and make sure they do not touch other items when handling them.



A Hold the segment by its handle. Make sure not to touch the cuvettes.

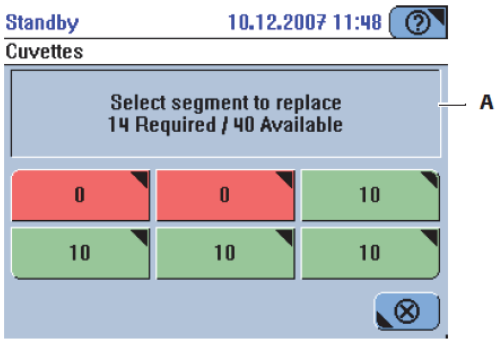
Figure 2 Figure A-21 Handling a cuvette segment

Revision 6: Additional information for cuvette status

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Key screens > Overview tab > Cuvette status**

Table 7 Revision location

Cuvette status **Overview >** 



A Overview of required and available cuvettes

Figure 3 Figure A-55 Cuvette status

The six cuvette segments are represented by buttons. The number in the button indicates how many cuvettes are free to be used.

Press a segment button to exchange the corresponding segment.

To avoid timing errors ensure that all available cuvette segment positions are filled. Always replace any completely used cuvette segments. A partially used cuvette segment does not have to be replaced.

	All cuvettes are used.
	Up to two cuvettes are free to be used.
	More than two cuvettes are free to be used.

Revision 7: Replace "sample area fan" by "display module fan"

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Key screens > System status**

Table 8 Revision location

System status Check the texts for the status of hardware items and on IDs of installed software.

	Status of the instrument.
	The main cover is open.
	A development channel application is run without using extra wash cycles.
	• Roche strongly recommends to always use extra wash cycles with development channel applications, and also to always load extra cleaner when tests with extra wash cycles are used. • Roche Diagnostics Ltd. assumes only limited liability when using the **cobas c** 111 instrument in conjunction with the **cobas c** 111 Development Channel Programming Software. For detailed information on this matter refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.
	Temperature status for reagent cooler and cuvette ring.
	The temperature is outside the acceptable range.
	Status of the display module fan
	The fan is not running.
	Display information on the fill status of each of the external bottles. The color of the underlying buttons is displayed. See Checking the external bottles on page A-96.
	Display the maintenance actions list. The color of the most urgent maintenance action is displayed. See Maintenance on page A-110.
	Status of the printer paper.
	The printer is out of paper.

Revision 8: Note for color interpretation for LEDs added

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Color interpretation for LEDs**

Table 9 Revision location

Color interpretation for LEDs

LED	Color	Meaning
Alarm LED	Off	There are no unconfirmed alarm messages.
		There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
		There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so. **Note:** When the alarm message results from a timing error, all tests run or results obtained after the time of the error time stamp should be retested.
	An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities > Configuration > System > Volume**).	

Table A-11 LEDs and their meaning

Revision 9: Replace "sample area fan" by "display module fan"

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Software > Buttons**

Table 10 Revision location

Buttons

The following tables list the buttons used in **cobas c** 111 screens and describe their use. The buttons are grouped according to the kind of function they represent.

Interactive functions

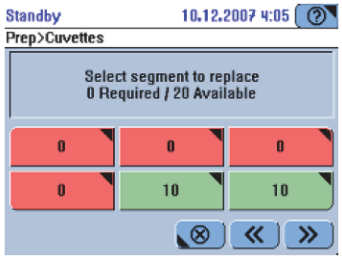
Icon	Name	Use
	Fan Status	Show when there is a failure of the display module fan.

Revision 10: Additional information for preparing cuvettes in the short guide

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Daily operation > Preparing the system > Short guide**

Table 11 Revision location

Preparing the system The following table provides an overview of the steps that make up the preparation process.

6	Prepare the cuvettes.		To avoid timing errors ensure that all available cuvette segment positions are filled. Always replace any completely used cuvette segments. A partially used cuvette segment does not have to be replaced. Replace all red cuvette segments. 1. Press the cuvette button. 2. Open the main cover. 3. Replace the cuvette segment. 4. Press to confirm the replacement. 5. Replace the remaining segments that need replacing. 6. Press to proceed to the next stage in the **Prepare** wizard.

Revision 11: Additional information for preparing cuvettes

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Daily operation > Preparing the system > Preparing cuvettes**

Table 12 Revision location

Preparing cuvettes

Cuvettes are supplied and handled in cuvette segments. Each segment contains ten cuvettes. The segments are placed on the cuvette ring of the rotor.

For information on cuvette segments, see Cuvette segments on page A-55.
For information on the cuvette ring, see Cuvette ring on page A-60.

Each segment on the cuvette ring is represented by a button on the screen.

To avoid timing errors ensure that all available cuvette segment positions are filled. Always replace any completely used cuvette segments. A partially used cuvette segment does not have to be replaced.

CAUTION

Make sure that you have read and understood section Safety information on page B-5. The following warning messages in particular are relevant:

- Personal injury or damage to the analyzer due to contact with instrument mechanism on page B-5.
- Infection by waste solution on page B-5.

Revision 12: Replace "sample area ventilation" by "display module fan"

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Daily operation > Analyzing samples > Checking the instrument status buttons**

Table 13 Revision location

Interpreting the instrument status buttons

Icon	Meaning	Possible action
System Status	The **system status** button displays both the icon and the color of one of the buttons of the underlying **system status** screen. (The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.)	
	Analyzer (main cover)	Press the button and, on the **System Status** screen, check the text about the status of the main cover.
	Reagent cooler and cuvette ring temperature	Press the button and, on the **System Status** screen, check the text about the temperature.
	Display module fan	Press the button and, on the **System Status** screen, check the text about the ventilation status.
	External fluid containers	Press the button and, on the **System Status** screen, press it again to display the screen for handling the external fluid containers.
	Maintenance	Press the button and, on the **System Status** screen, press it again to display the maintenance actions list.
	Printer	Press the button and, on the **System Status** screen, check the text about the printer status.

Table A-11 LEDs and their meaning

Revision 13: Note for the red Alarm LED interpretation added

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Daily operation > Analyzing samples > Checking for alarm messages**

Table 14 Revision location

Checking for alarm messages

To check for problems during processing

1 Observe the Alarm LED.

LED	Meaning	Possible action
No color (Off)	There are no unconfirmed alarm messages.	No action is required.
Yellow	There is at least one unconfirmed alarm message.	User intervention is required as soon as possible. Processing can continue for the time being. Check the details of the message.
Red	There is at least one unconfirmed alarm message.	Immediate user intervention is required. Processing may not be able to continue without it. Check the details of the message. **Note:** When the alarm message results from a timing error, all tests run or results obtained after the time of the error time stamp should be retested.

An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities > Configuration > System > Volume**).

2 Take appropriate action.

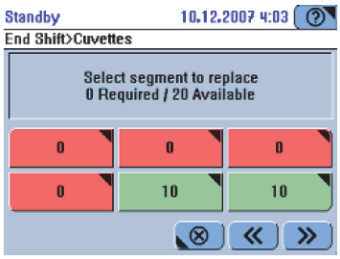
For details on dealing with alarm messages, see Alarm monitor on page D-6.

Revision 14: Additional information for checking the cuvette status in the short guide

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Daily operation > Finishing the shift > Short guide**

Table 15 Revision location

Short guide The following table provides an overview of the steps that make up the preparation process.

7	Check the cuvette status.		To avoid timing errors ensure that all available cuvette segment positions are filled. Always replace any completely used cuvette segments. A partially used cuvette segment does not have to be replaced. Replace at least all red cuvette segments. 1. Press the cuvette button. 2. Open the main cover. 3. Replace the cuvette segment. 4. Close the main cover. 5. Press ≫ to proceed to the next stage in the **End Shift** wizard.

Revision 15: Additional information for calibration definition

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Configuration > Applications > Calibration definitions**

Table 16 Revision location

Calibration definitions

ISE applications do not have calibration definitions.

Item	Values	Comment
Sequence	The sequence values define when calibration becomes due, and the system automatically informs you about due calibrations.	
	No Interval	The system does not inform you about the due status. Use this value if the reagent is stable enough over the whole period until it is empty and you replace it. Calibration is due whenever a new reagent set is loaded on the instrument.
	Interval Only	Due whenever the reagent interval has expired.
	Each Set and Interval	Due whenever a new reagent is loaded and when the interval has expired. The interval starts again whenever you place a new reagent set. You can turn off the interval check by defining its duration as 0 (zero).
	Each Lot and Interval	Due whenever the fist reagent of a new lot is loaded and then each time the interval as expired. The interval (re)starts whenever you calibrate a reagent set. You can turn off the interval check by defining its duration as 0 (zero). If you install a reagent set of the same lot, no calibration is required. (The system uses the Lot calibration result for the new reagent set. This new reagent set also has the calibration type: Lot)
Interval	Number of days. (For ISE, 1 day fixed.)	Use 0 (zero) if the **Sequence** is set to **No Interval**.
Replicates	1, 2	Number of times each measurement should be repeated.

Table B-13 Calibration definitions

Revision 16: Note for reacting to red alarm messages added

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**Messages and alarms > Alarm monitor > Reacting to alarm messages**

Table 17 Revision location

Reacting to alarm messages

To react to an alarm message

1 Observe the Alarm LED.

LED	Meaning
No color (Off)	There are no unconfirmed alarm messages.
Yellow	There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
Red	There is at least one unconfirmed alarm message. You need to deal with it as soon as possible. **Note:** When the alarm message results from a timing error, all tests run or results obtained after the time of the error time stamp should be retested.

An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities > Configuration > System > Volume**).

Revision 17: Replace "sample area ventilation" by "display module fan"

Publication title	Publication version	Software version	Publication date	Revised topic title
Operator's Manual	4.1	4.1	October 2013	**ISE operation > Daily operation > Monitoring the progress > Checking the instrument status buttons**

Table 18 Revision location

Interpreting the instrument status buttons

Icon	Meaning	Possible action
System Status	The **system status** button displays both the icon and the color of one of the buttons of the underlying **system status** screen. (The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.)	
	Analyzer (main cover)	Press the button and, on the **System Status** screen, check the text about the status of the main cover.
	Reagent cooler and cuvette ring temperature	Press the button and, on the **System Status** screen, check the text about the temperature.
	Display module fan	Press the button and, on the **System Status** screen, check the text about the ventilation status.
	External fluid containers	Press the button and, on the **System Status** screen, press it again to display the screen for handling the external fluid containers.
	Maintenance	Press the button and, on the **System Status** screen, press it again to display the maintenance actions list.
	Printer	Press the button and, on the **System Status** screen, check the text about the printer status.