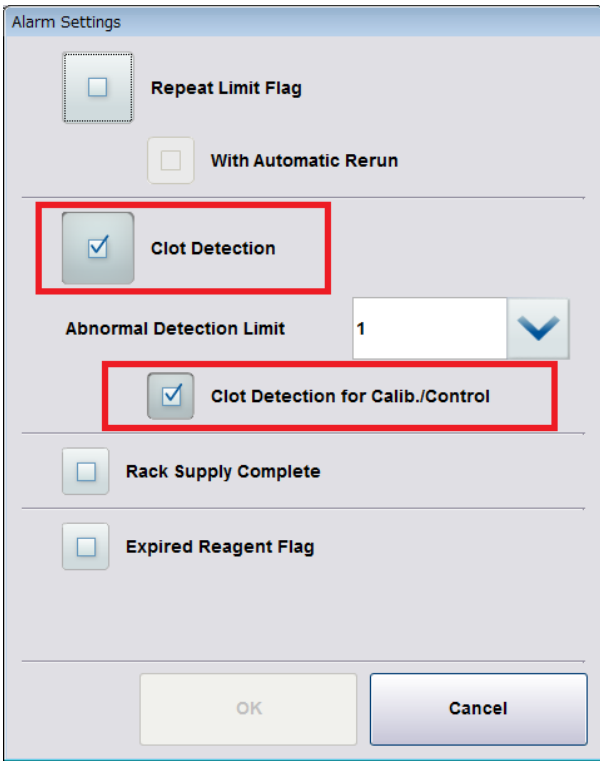
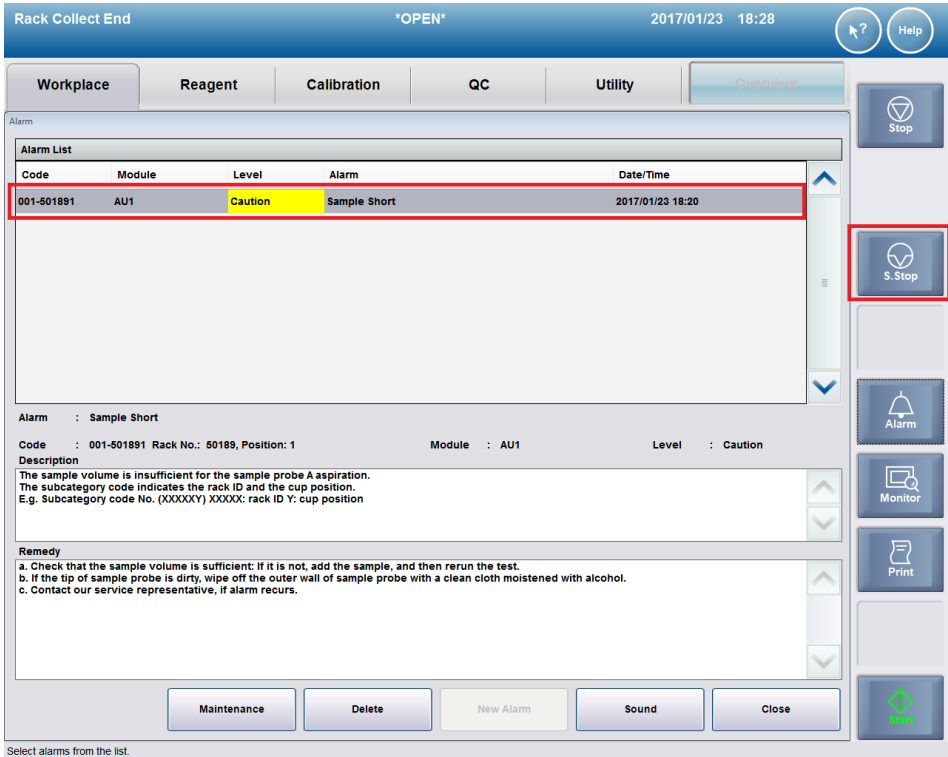


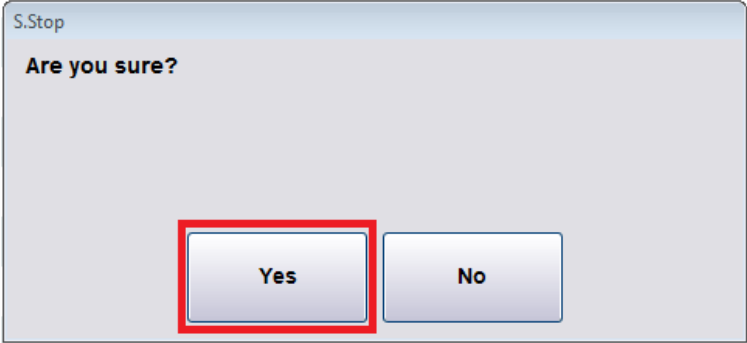
Att FSN-CPS-2017-005 How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued on cobas® 8000

When the system alarm *Sample Short* or *Abnormal Aspiration* is issued while there is still sufficient amount of sample volume, it is necessary to replace the sample probe. A verification of the measurement results is required.

When there is no replacement sample probe available, clean the inside and outside of the sample probe. This is described in the Operator’s Manual Version 5.1 and in the manual “cobas 8000 modular analyzer series Interlock Manual c 502 module –Version 2.1 Software version 06-02”. The inside cleaning maintenance actions of the cobas c502 module series can only be performed by specially trained operators. Please refer to the coinciding procedures “Eliminating clogging of the sample probe” and “Cleaning all pipetter probes and rinse nozzles”.

	Step	Action
<p>Preparation: Clot Detection ON</p>	<p>1</p>	<p>Enable the Clot Detection and Clot Detection for Calib./Control settings in <i>Utility-System-Alarm Settings</i>.</p> 

	Step	Action																														
<p>Check the Sample Short and Sample Clot alarm</p>	<p>2</p>	<p>The table below shows the system alarm list of Sample Short and Sample Clot.</p> <table border="1" data-bbox="537 342 1511 972"> <thead> <tr> <th>Alarm</th> <th>Module</th> <th>Alarm Code</th> <th>Alarm Sub Category</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Sample Short</td> <td>ISE</td> <td>010</td> <td>XXXXXY XXXXX: rack No. Y: cup position</td> </tr> <tr> <td>c701/c702</td> <td>001 - 002</td> <td>XXXXXY XXXXX: rack No. Y: cup position</td> </tr> <tr> <td>c502</td> <td>401 – 440 (The cup position is indicated by alarm code)</td> <td>0XXXXX XXXXX: rack No.</td> </tr> <tr> <td rowspan="5">Abnormal Aspiration (The alarm of Sample Clot is issued as "Abnormal Aspiration")</td> <td>ISE</td> <td>441</td> <td>000001</td> </tr> <tr> <td>ISE</td> <td>007</td> <td>XXXXXY XXXXX: rack No. Y: cup position</td> </tr> <tr> <td>c701/c702</td> <td>004 - 005</td> <td>XXXXXY XXXXX: rack No. Y: cup position</td> </tr> <tr> <td>c502</td> <td>451 – 490 (The cup position is indicated by alarm code)</td> <td>0XXXXX XXXXX: rack No.</td> </tr> <tr> <td>c502</td> <td>491</td> <td>000001</td> </tr> </tbody> </table>	Alarm	Module	Alarm Code	Alarm Sub Category	Sample Short	ISE	010	XXXXXY XXXXX: rack No. Y: cup position	c701/c702	001 - 002	XXXXXY XXXXX: rack No. Y: cup position	c502	401 – 440 (The cup position is indicated by alarm code)	0XXXXX XXXXX: rack No.	Abnormal Aspiration (The alarm of Sample Clot is issued as "Abnormal Aspiration")	ISE	441	000001	ISE	007	XXXXXY XXXXX: rack No. Y: cup position	c701/c702	004 - 005	XXXXXY XXXXX: rack No. Y: cup position	c502	451 – 490 (The cup position is indicated by alarm code)	0XXXXX XXXXX: rack No.	c502	491	000001
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	c502	491	000001																													
<p>Sampling Stop</p>	<p>3</p>	<p>a) When the alarm is issued, select the <i>S. Stop</i> button.</p>  <p>The screenshot shows the 'Rack Collect End' screen with the 'Alarm' section active. The 'Alarm List' table has the following data:</p> <table border="1" data-bbox="537 1178 1333 1419"> <thead> <tr> <th>Code</th> <th>Module</th> <th>Level</th> <th>Alarm</th> <th>Date/Time</th> </tr> </thead> <tbody> <tr> <td>001-501891</td> <td>AU1</td> <td>Caution</td> <td>Sample Short</td> <td>2017/01/23 18:20</td> </tr> </tbody> </table> <p>The 'S.Stop' button is highlighted with a red box. Below the alarm list, the details for the 'Sample Short' alarm are shown, including the code, module, level, and a description: 'The sample volume is insufficient for the sample probe A aspiration. The subcategory code indicates the rack ID and the cup position. E.g. Subcategory code No. (XXXXXY) XXXXX: rack ID Y: cup position'. Remedies are listed: 'a. Check that the sample volume is sufficient: if it is not, add the sample, and then rerun the test. b. If the tip of sample probe is dirty, wipe off the outer wall of sample probe with a clean cloth moistened with alcohol. c. Contact our service representative, if alarm recurs.' At the bottom, there are buttons for 'Maintenance', 'Delete', 'New Alarm', 'Sound', and 'Close'.</p>	Code	Module	Level	Alarm	Date/Time	001-501891	AU1	Caution	Sample Short	2017/01/23 18:20																				
Code	Module	Level	Alarm	Date/Time																												
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	Step	Action
	3b	b) When the [S. Stop] window appears, choose <i>[Yes]</i> .  A screenshot of a software dialog box titled "S.Stop". The dialog box has a light blue header and a light gray body. The text "Are you sure?" is displayed in the center. At the bottom, there are two buttons: "Yes" and "No". The "Yes" button is highlighted with a red rectangular border.
Wait until racks are unloaded	4	Wait until all of racks are collected in the unloading area. (Waiting time may vary depending on the condition of the ordered analysis)

Identify sample for which alarm was issued

5

Identify the sample for which the system alarm was issued according to the code of the system alarm (refer to the following figure).

The screenshot displays the 'Alarm List' window with the following data:

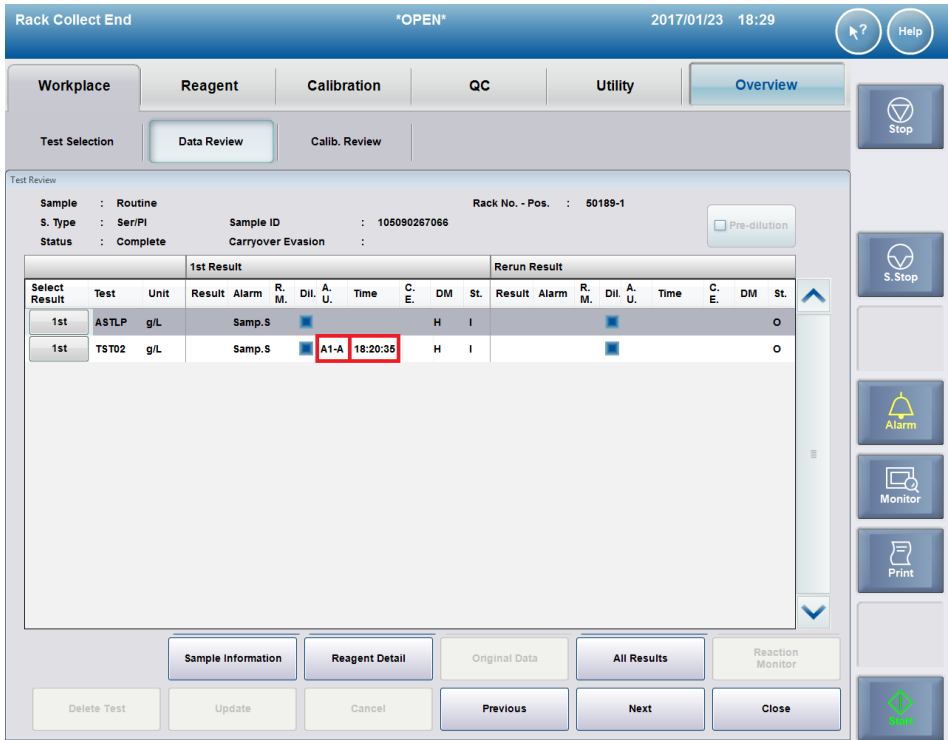
Code	Module	Level	Alarm	Date/Time
001-501891	AU1	Caution	Sample Short	2017/01/23 18:20

Below the alarm list, the 'Description' and 'Remedy' sections are visible. The 'Remedy' section includes instructions such as: 'a. Check that the sample volume is sufficient; if it is not, add the sample, and then rerun the test.', 'b. If the tip of sample probe is dirty, wipe off the outer wall of sample probe with a clean cloth moistened with alcohol.', and 'c. Contact our service representative, if alarm recurs.'

The 'Sample List' window shows a table of samples with the following columns: DM, C, E, St, S, ID, Rack No., S. Type, Name, Date/Time, C, E, Dil, Unit, Result, Unit, Alarm, A. U., Rg, St, Strd. The sample '50189-1' is highlighted in red, corresponding to the alarm code.

A callout box points to the alarm code with the text: '001-501891: Sample Short -> Routine Rack No.: 50189 Position: 1'

Example of a sample with Sample Short alarm on a routine rack.

<p>Check sample volume</p>	<p>6</p>	<p>Check</p> <p>a) the sample volume in the sample container, and</p> <p>b) whether there is any substance adhered to the sample probe.</p> <p>No action is required when the sample volume is insufficient, and the sample probe is clean.</p> <p>When there is sufficient sample volume, replace the sample probe and move on to step 7.</p>
<p>Module and sampling time in Test Review</p>	<p>7</p>	<p>Check the module and the sampling time for which the alarm was issued in the <i>Test Review</i> screen (<i>Workplace-Data Review-patient sample (in sample list)-Test Review</i>).</p> 

Set filter for the specific module

8

Set an "Analyzed Unit" filter for samples for which sampling was performed on the specific module from step 7 (in *Workplace-Data Review-Filter*).

The screenshot shows the 'Workplace' tab of the cobas 8000 software. The 'Filter' button in the top navigation bar is highlighted with a red box. Below the main interface, a 'Filter' dialog box is open, showing various filter options. The 'Analyzed Unit' filter is selected and set to 'A1-A', which is also highlighted with a red box.

Select samples from the list.

Filter

Sample:

Routine

Stat

Control

S. Type:

Ser/PI

Urine

CSF

Suprnt

Others

WhiBld

OraFlu

Hemoly

AmniF

Stool

Sample Status:

Ordered

Processing

Complete

Incomplete

DM Status:

DM Sent

Analyzed Unit: A1-A

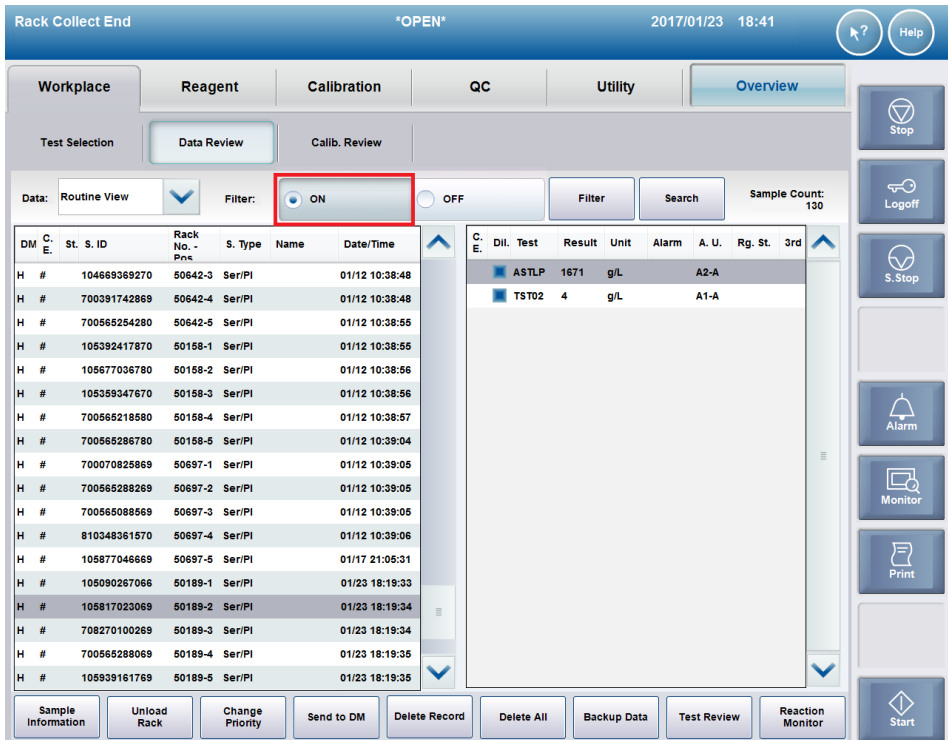
Analyzed Test

Results with Rerun Only

Arrived Date: / / - / /

Arrived Time: : - :

OK Cancel

<p>Filter for the specific module</p>	<p>9</p>	<p>Select the [ON] radio button for Filter on Data Review screen.</p>  <p>The screenshot shows the 'Data Review' screen with the 'Filter' radio button selected. The 'Data' section shows a list of samples with columns for DM, C.E., St. S. ID, Rack No., S. Type, Name, and Date/Time. The 'Test Results' section shows two tests: ASTLP (1671 g/L, A2-A) and TST02 (4 g/L, A1-A). The 'Filter' radio button is highlighted with a red box.</p>
<p>Verify the results or discard the samples</p>	<p>10</p>	<p>Check the test results which were measured after the sampling time in step 7 on the <i>Data Review</i> screen in step 9.</p> <p>All affected samples have to be verified/ discarded according to the local rules.</p> <p>An example of tests to be verified is described on the next page.</p>

Example

11

On the *Data Review* screen, select all samples that were sampled on the analyzer unit after the sample with the sample short alarm, including the sample concerned.

Then display the *Test Review* window.

Rack Collect End *OPEN* 2017/01/23 18:41

Workplace Reagent Calibration QC Utility Overview

Test Selection Data Review Calib. Review

Data: Routine View Filter: ON OFF Filter Search Sample Count: 130

DN	C	St.	S. ID	Rack No. - Pos.	S. Type	Name	Date/Time	C. E.	Dil.	Test	Result	Unit	Alarm	A. U.	Rg. St.	3rd
H	#		104669369270	60642-3	Ser/PI		01/12 10:38:48			ASTLP	1671	g/L	A2-A			
H	#		700391742869	60642-4	Ser/PI		01/12 10:38:48			TST02	4	g/L	A1-A			
H	#		700565254280	60642-5	Ser/PI		01/12 10:38:55									
H	#		105392417870	50158-1	Ser/PI		01/12 10:38:55									
H	#		105677036780	50158-2	Ser/PI		01/12 10:38:56									
H	#		105369347670	50158-3	Ser/PI		01/12 10:38:56									
H	#		700565218890	50158-4	Ser/PI		01/12 10:38:57									
H	#		700565286780	50158-5	Ser/PI		01/12 10:39:04									
H	#		700070825889	50897-1	Ser/PI		01/12 10:39:05									
H	#		700565288269	50897-2	Ser/PI		01/12 10:39:05									
H	#		700668088669	50897-3	Ser/PI		01/12 10:39:05									
H	#		810348361570	50897-4	Ser/PI		01/12 10:39:06									
H	#		105877046669	50897-5	Ser/PI		01/17 21:05:31									
H	#		105090287068	50189-1	Ser/PI		01/23 18:19:33									
H	#		105817023069	50189-2	Ser/PI		01/23 18:19:34									
H	#		708270100269	50189-3	Ser/PI		01/23 18:19:34									
H	#		700565288059	50189-4	Ser/PI		01/23 18:19:35									
H	#		105939161769	50189-5	Ser/PI		01/23 18:19:35									

Sample Information Unload Rack Change Priority Send to DM Delete Record Delete All Backup Data **Test Review** Reaction Monitor Start

001-501891: Sample Short
Routine Rack No.: 50189 Position 1
Pipetting time in Test Review T=18:20:35

Confirm the module and the time on which the sampling was performed.

Rack Collect End *OPEN* 2017/01/23 18:42

Workplace Reagent Calibration QC Utility Overview

Test Selection Data Review Calib. Review

Test Review

Sample : Routine Rack No. - Pos. : 50189-2
S. Type : Ser/PI Sample ID : 105817023069
Status : Complete Carryover Evasion : Pre-dilution

Select Result	Test	Unit	Result	Alarm	R. M.	Dil.	A. U.	Time	C. E.	DM	St.	Rerun Result	Result	Alarm	R. M.	Dil.	A. U.	Time	C. E.	DM	St.
1st	ASTLP	g/L	1671					A2-A 18:22:20		H											
1st	TST02	g/L	4					A1-A 18:20:39		H											

Sample Information Reagent Detail Original Data All Results Reaction Monitor

Delete Test Update Cancel Previous Next Close

The example *Test Review* window of samples on *Data Review* screen is described in the table below.

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Rack	Test	Alarm	A.U.	Time	St.	Judgment of measurement result
50189-1	TST02	Samp.S	A1-A	01/23 18:20:35		Target for verification (Sample for which the sample short alarm was issued) Time T=18:20:35, Module A1-A
	ASTLP				M	
50189-2	TST02		A1-A	01/23 18:20:39		Target for verification (pipetted on module A1-A after 18:20:35)
	ASTLP		A2-A	01/23 18:22:20		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-3	TST02		A1-A	01/23 18:20:42		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:26		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-4	TST02		A1-A	01/23 18:20:46		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:32		Target for verification (sample pipetted on module A1-A after time 18:20:35)
50189-5	TST02		A1-A	01/23 18:20:49		Target for verification (pipetted on module A1-A after time 18:20:35)
	ASTLP		A2-A	01/23 18:22:38		Target for verification (sample pipetted on module A1-A after time 18:20:35)