SEKISUI MEDICAL CO., LTD.

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Dear CP3000 customers,

Re: Customer Notification

SEKISUI MEDICAL CO., LTD. (SEKISUI) has become aware of several issues with the CP3000. The details of each and their impact are listed below, along with instructions for actions that should be taken when using the CP3000 until the release of future software updates that will resolve the issues.

1 - Discrepancy between measured results and the results shown on CP3000 screen after changing channel allocations

Description:

If the order of assays in the Channel Allocation screen is altered, there may be a discrepancy between the measured results and the results shown on the CP3000 when the "Show results" button on the Data List screen is pressed unless the CP3000 PC is shut down and restarted.

Impact:

There is a risk that an incorrect result could be reported if it is read directly from the screen. Measured results are correctly transmitted to the LIS and printer.

Immediate actions to be taken:

After making changes to the Channel Allocation screen, shut down and restart the CP3000 PC which will prevent this situation from occurring. It is only necessary to carry out the shut down and restart one time after making change.

2 - Discrepancy between measured results and reaction profile display on CP3000 screen after changing assay result display order

Description:

There may be a discrepancy between the measured results and the reaction profile shown on the CP3000 Data List screen if the order of tests is changed using "Reverse Order" check box in the Search pop up of the Request List or Profile List screens, and then changing to view results on the Data List unless the CP3000 PC is shut down and restarted.

Impact:

The reaction profile may differ from measured result for the test and results could be misinterpreted. Results printed directly from the reaction profile popup screen would reflect the mismatched measured results/reaction profile. Measured results are correctly transmitted to the LIS and are printed correctly when selected using the Edit function on the Data List screen.

Immediate actions to be taken:

Shut down and restart the CP3000 PC after changing the order of assays using the "Reverse Order" check box in the Request List and Profile List "Search" screen. It is only necessary to carry out the shut down and restart one time after making change.

3 - Additional rinsing steps are not carried out when reagent insufficient occurs
Description:
If a reagent runs out, any additional reagent probe rinsing steps that are required before using the next reagent do not occur.
Impact:
There is a risk of reagent carryover and potentially incorrect results for subsequent tests carried out using the contaminated reagent.
Immediate actions to be taken:
Load sufficient reagent on the CP3000 to cover testing requirements, and monitor to ensure they do not run out. Details of reagents requiring a rinse can be found in the table in Appendix 1 at the end of this document, or in the Reagent Master screen on the CP3000. If a reagent requiring rinses becomes insufficient, discard all potentially contaminated reagents and replace with new bottles. Rerun any tests which may have been measured using the affected reagents.

4 - CP3000 may not be able to detect all abnormal reaction profile variations
Description:
The CP3000 has the functionality to detect abnormal reaction profile variations for colorimetric (chromogenic and immunoturbidimetric) assays and a flag is generated and attached to the affected measurement results. However, there may be some abnormal reaction profile variations due to noise that are not detected by the CP3000. This issue does not affect coagulation assays.
Impact:
There is a risk of reporting an incorrect result if the undetected abnormal variation affects measurement values.
Immediate actions to be taken:
Any data errors should be investigated prior to reporting results. In the event of any unexpected measurement result even in the absence of a data error flag, the operator should review the reaction profile on the CP3000. If an abnormal reaction profile is observed, take appropriate action, for example check the sample, rerun the sample, etc.

5 - If noise and prozone flags occur at the same time for a measured result, the re-analysis conditions for noise are preferentially used rather than those for prozone
Description:
If noise and prozone flags occur at the same time for a measured result, the re-analysis conditions for noise are preferentially used rather than those for prozone. The measured result will have both a noise and prozone flag, but the sample will not have been rerun at the settings required when prozone has been detected. SEKISUI assays with prozone rerun settings are Nanopia® D-dimer Reagent and Nanopia® FDP Reagent.
Impact:
There is a risk of reporting an incorrect result if the operator does not investigate the noise flag and then manually rerun the sample according to the assay-specific prozone rerun settings.
Immediate actions to be taken:
Any data errors should be investigated prior to reporting results. If a noise flag is accompanied by a prozone flag, the assay should be manually rerun using the sample dilution rerun settings for prozone

for that assay. Only a single flag is transmitted to the LIS, so all flags should be reviewed on the CP3000 to determine if more than one flag is present.
Nanopia® D-dimer Reagent: Rerun the sample using a 1 in 5 dilution
Nanopia® FDP Reagent: Rerun the sample using a 1 in 10 dilution

6 - Reagent carryover when the lid is left on detergent bottle on the CP3000 reagent carousel
Description:
If the lid is left on the detergent bottle, a probe collision error occurs resulting in an S-STOP of the CP3000. Any additional reagent probe rinsing steps that are required before using the next reagent do not occur.
Impact:
There is a risk of reagent carryover and potentially incorrect results for subsequent tests carried out using the contaminated reagent.
Immediate actions to be taken:
Ensure that lids are removed from the detergent bottle and all bottles loaded on the reagent carousel. Details of reagents requiring a rinse can be found in the table in Appendix 1 at the end of this document, or in the Reagent Master screen on the CP3000. If a probe collision with a detergent lid occurs, discard all affected reagents and replace with new bottles. Rerun any assays which may have been measured using the potentially contaminated reagent.

7 - Insufficient deficient plasma may cause incorrect results
Description:
If deficient plasma runs out during factor assay measurements which require a sample pre-dilution step, the remaining pre-diluted samples in the reaction cuvette may be analyzed even though the deficient plasma is not added. The instrument generates a system message that the deficient plasma is insufficient but no error message or data flag are generated attached to incorrect results.
Impact:
Incorrect results may be generated for some factor assay sampling conditions.
Immediate actions to be taken:
Ensure that sufficient deficient plasma is prepared and loaded on board the CP3000 prior to running factor assays and monitor levels so that deficient plasma does not run out during analysis. Review results if an error message stating that deficient plasma is insufficient occurs. Rerun the test if unexpected results have been generated.

CP3000 connected to LAS only:
8 - Incorrect sampling by a CP3000 connected to a Laboratory Automation System (LAS)
Description:
This issue only affects CP3000 systems connected to a LAS. If the test request information for a sample is not received by the CP3000 by the time it arrives at the sampling position, an error message stating "PID not received error (error code 0x0001AD)" is generated, the system stops and the LAS status switches to offline. If the CP3000-LAS connection is switched back online, the last sample ID remains in the CP3000 and the next sample arriving at the CP3000 sampling position on the LAS is measured and reported as if it were the original sample.
Impact:
The CP3000 may aspirate a different sample to that identified and report incorrect results.
Immediate actions to be taken:
If a "PID not received error (error code 0x0001AD)" occurs on a CP3000 connected to LAS, carry out the following process:

a. Remove all samples from the LAS including any sample at the CP3000 sampling position.
b. Confirm the CP3000 is in measurement stop status.
c. Restart the CP3000 PC.
d. Reconnect the CP3000 to LAS.
e. Once the LAS status is back online, restart measurement on the CP3000.
f. Samples that were removed in step "a" can be reloaded and rerun as required.

We regret any inconvenience caused. If you have any questions concerning any of the items described in this notification, please contact your local area Abbott customer service team.

Appendix 1.
Additional rinse settings

Preceding reagent (Giver)	**Following reagent (Taker)**				
Coagpia® Fbg	Coagpia® PC-R2	Coagpia® dRVV Screen	Coagpia® dRVV Confirm		
Coagpia® TT	Coagpia® PT-N	Coagpia® APTT-N	Coagpia® APTT-FS	Coagpia® $CaCl_2$	Coagpia® AT-R1
Coagpia® AT-R1	Coagpia® PT-N	Coagpia® APTT-N	Coagpia® APTT-FS	Coagpia® $CaCl_2$	
Coagpia® AT-R2	Coagpia® PT-N	Coagpia® APTT-N	Coagpia® $CaCl_2$	Coagpia® PC-R2	
Nanopia® FDP-R2	Coagpia® PC-R2				
Nanopia® D-Dimer-R2	Coagpia® PC-R2				
Coagpia® PC-R2	Coagpia® Fbg				