

Product Notification

June 2026

UD-10: Inappropriate Assay Range of PCD_M for Recent UF-Control lots

Dear Valued Customer

Cc : to the Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities

Introduction:

Sysmex Corporation has become aware of a reported case in which, with recent UF-Control lots, the PCD_M values fell below the lower limit defined in the UD-10 analyzer QC program.

Affected Products

Product Code	Name of Product	Affected Lot/Serials
CJ445012	UD-10	All serials
UCK-900A	UF-CONTROL	UK0342 and subsequent lots

Problem Description:

With the concerned lot UK0342 and subsequent lots, the PCD_M values fell below the lower limit defined in the UD-10 analyzer QC program.

From the affected UK0342, the particle size of UF-Control was changed due to raw material change; however, an appropriate QC range was not established for UD-10 QC program.

The issue has been assessed as posing a negligible health risk. Although Quality Control related issues may potentially occur, there is no direct impact on the performance of the UD-10 or on patient test results.

Actions to be taken:

Please distribute this product notification to all relevant personnel within your facility.

The appropriate lower and upper limits for lot UK0342 and subsequent lots are provided below.

QC range of UD-10 PCD_M

Control Type	Lower Limit	Upper Limit
UF-CONTROL-H	6.1	7.6
UF-CONTROL-L	6.4	7.9

Please select one of the following options in consultation with your regional Sysmex representative.

Option A

Please manually enter the above upper and lower limits for each lot in the [Register Lot Information] dialog. The values must be entered individually for each lot.

Option B

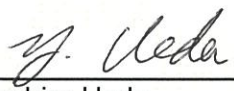
A Sysmex representative will visit your facility and adjust the QC range in the analyzer QC program via service mode. The updated QC range will be applied as the default value for all lots, and manual entry for each lot will not be required.

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We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours
Sysmex Corporation



Yoshiro Ueda

Vice President of Quality Assurance & Management System/ Regulatory Affairs & Quality Assurance

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Appendix.

For Option A, please manually enter the appropriate QC range in the [Register Lot Information] dialog box.

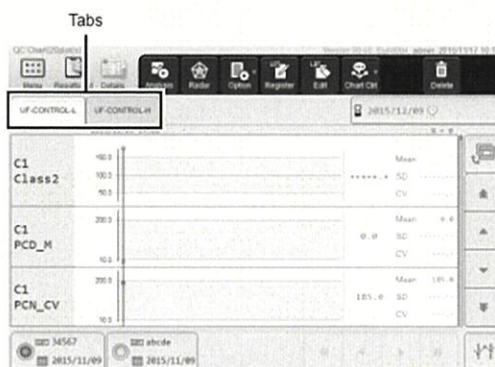
For instructions on how to access the [Register Lot Information], please refer to the relevant section in the UD-10 Basic Operation. An example is provided below.

2.5 Registering the lot information manually

This section explains how to register new control lot information manually.

1 Touch the [QC] icon on the [Menu] screen.

The [QC Chart] screen appears.



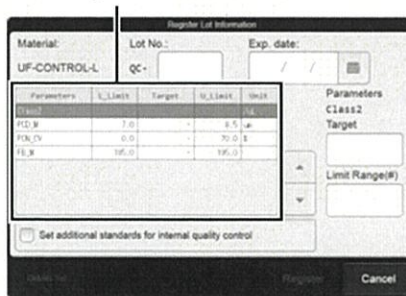
[QC Chart] screen

2 Touch the tab of the control that you want to register lot information.

3 Touch the [Register] button on the toolbar.

The [Register Lot Information] dialog box appears.

List of target/limit value



The screenshot shows the [Register Lot Information] dialog box. It contains fields for Material (UF-CONTROL-L), Lot No. (QC-), and Exp. date. Below these fields is a table of target/limit values. The table is as follows:

Parameters	L_Limit	Target	U_Limit	Unit
PCD_M	7.0	7.0	8.5	μm
PCN_CV	0.0	0.0	70.0	%
PCN_CV	100.0	100.0	100.0	Mean

There is also a checkbox for "Get additional standards for internal quality control" and a "Limit Range(%)".

[Register Lot Information] dialog box

- When 3 lots are already registered for the control
The dialog box on the right appears.
The registered lot information is displayed. Select the lot information that you want to delete and touch [New Regist].



The screenshot shows the Lot Registration dialog box. It contains a list of registered lots with their Lot No., QC, and Register Date. The list is as follows:

Lot No.	QC	Register Date
QC-123	QC-123	2015/11/26
QC-456	QC-456	2015/11/26
QC-789	QC-789	2015/11/26

There are buttons for "New Regist" and "Cancel".