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Urgent Field Safety Notice:

**Dimension[®] clinical chemistry system
 AMM Flex[®] Reagent Cartridge (DF119/10711991)**
 High rate of “Abnormal assay” test report messages - Resolution

Dear Sirs,

Our records indicate that your facility may have received the following product:

Table 1. Dimension[®] Affected Product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Numbers
Ammonia	AMM	DF119	10711991	All in-date lots

Reason for Notification

In September 2014, Siemens Healthcare Diagnostics issued Customer Notification 14-62 that addressed a high rate of “Abnormal assay” test report messages for its Dimension[®] Ammonia (AMM) assay. With this letter, Siemens is reducing the AMM open well stability from 3 days to 1 day (24 hours) and providing instructions for managing this change. Dimension AMM IFU revision E will reflect this change.

The new version of Dimension software, 10.2, will do the following:

- Automatically move to a new well every day. This decrease in the open well maximum duration reduces the amount of time the AMM reagent is exposed to any potential contaminants, reduces the need for customers to manually move to a new reagent well, and aids in the prevention of erroneous flagging.
- Contain the Below Mean Factor limit of 0.90.

Siemens is working to make Dimension software 10.2 available to all customers as quickly as possible.

Risk to Health

The risk to health as a result of the revisions described in this letter is negligible.

Actions to be Taken by the Customer

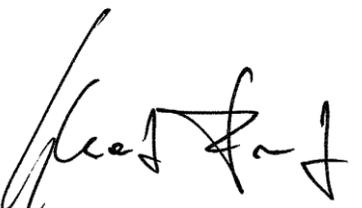
- Please review this letter with your Medical Director.
- To reduce the likelihood of false AMM “Abnormal assay” messages, verify that the Below Mean Factor for the Result Monitor is set to the revised limit of 0.90 by performing the following:
 1. From the Operating Menu, display the Result Monitor screen by selecting **F5: Process Ctrl> F8: More Options > F2: RSLT MONITOR**.
 2. Select the **AMM method key** or press **F1: Next Method**, until the AMM method is displayed.
 3. Ensure “Result Monitoring in Effect” displays **On**.
 4. If “Result Monitoring in Effect” displays Off, Select F7: Method On/Off to turn the result monitor feature ON.
 - If the Below Mean Factor is 0.90, exit to the main Operating menu.
 - If the Below Mean Factor is not 0.90:
 1. Move the cursor down to the “**Below Mean Factor**” in column A, and type **0.90**.
 2. Select F8: **STORE PARAMS**.
- Until Dimension 10.2 software is installed on your instrument, manually move to a fresh AMM well of reagent every day. Customers will need to keep track of this. There are 5 AMM tests per well of reagent; to conserve reagent cartridge supply, customers can limit Ammonia testing to one Dimension instrument in the laboratory. To manually move to a fresh well, perform the following:
 1. From the Operating Menu, display the Inventory screen by selecting: **F4: System Prep > F1: Inventory**
 2. Move the cursor to the appropriate AMM Flex® reagent cartridge and then select **F3: Remove Reag**.
 3. When the red loader light begins blinking, remove the reagent cartridge from the loader.
 4. Select **F1: Confirm Remove**.
 5. Place the reagent cartridge back in the reagent loader.

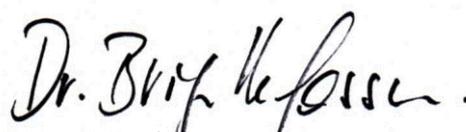
Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical s Support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH


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Head of RAQS Austria & SEE


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