

Atellica® IM 1300 Analyzer  
Atellica® IM 1600 Analyzer

**Follow-up Communication for:**  
**Humidity Packs Incorrectly Identified as Expired (Lot 0010)**

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In version A of this Urgent Field Safety Notice (UFSN) we informed you of customer complaints stating Atellica IM Humidity Packs, Lot 0010, had been incorrectly identified by the analyzer as expired. This caused the analyzer to eject the humidity packs and stop processing samples. The affected product is listed below in Table 1.

**Table 1. Atellica® Solution Affected Product(s):**

Product	Siemens Material Number (SMN)
Atellica IM Humidity Pack (Qty 5)	11313505

**Reason for Follow-up Urgent Medical Device Correction**

The purpose of this follow-up is to communicate the available solutions that must be implemented **before February 29, 2020 to ensure sample processing is not halted.**

On January 16, 2020, Siemens released Atellica Solution system software (SW) version (V) 1.21.0 SP1, which is available through Smart Remote Services or from your local technical support provider. The new version of software **will not** identify humidity packs as expired and will set the onboard stability (OBS) to not exceed 240-days from when the humidity pack was loaded into the analyzer.

Siemens has also updated the information in the humidity pack barcode label. Humidity packs starting with unique identifier (serial number) 063000 and above can be loaded on any Atellica IM Analyzer, regardless of the SW version your analyzer is operating on.

If your analyzer is operating on Atellica Solution SW V 1.21.0 SP1, the “Actions to be Taken by the Customer” section, does not apply to you. Please complete and return the Field Action Correction Effectiveness Check Form attached to this letter within 30 days.

If your Atellica IM Analyzer has not been updated to SW V 1.21.0 SP1 you will need to follow the steps in the section, “Actions to be Taken by the Customer”.

## Risk to Health

The potential exists for an apparent delay in testing when this issue occurs. Siemens is not recommending a review of previously generated results as the accuracy of results is not affected by this issue.

## Actions to be Taken by the Customer

Humidity packs loaded into the Reagent Compartment using the information provided in revision A of this UFSN will reach the end of their OBS on February 29, 2020, if your system SW has not been updated to V 1.21.0 SP1.

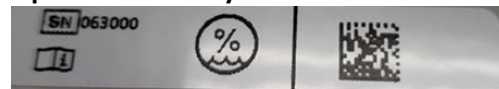
**The actions below, are required to be performed before February 29, 2020 to ensure sample processing is not interrupted on March 1<sup>st</sup>.**

1. Remove the humidity packs in your Reagent Compartment and replace them with fresh humidity packs.  
Before loading the new packs in the Reagent Drawer, check the unique identifier (serial number) printed on the flat side of the humidity pack label, below the 2D barcode.

### Initial humidity packs



### Updated Humidity Packs



If you have humidity packs with unique identifier numbers higher than 063000, no further actions are required. The humidity packs can be loaded into the reagent drawer and the system will read the humidity pack barcode.

If the humidity packs in your inventory have unique identifier numbers lower than 063000 proceed to step 2.

2. Cover the existing Humidity Pack 2D barcode with permanent marker so it cannot be read by the system. Do not remove the original barcode. (top view)



3. On the Command bar, select **Inventory**.

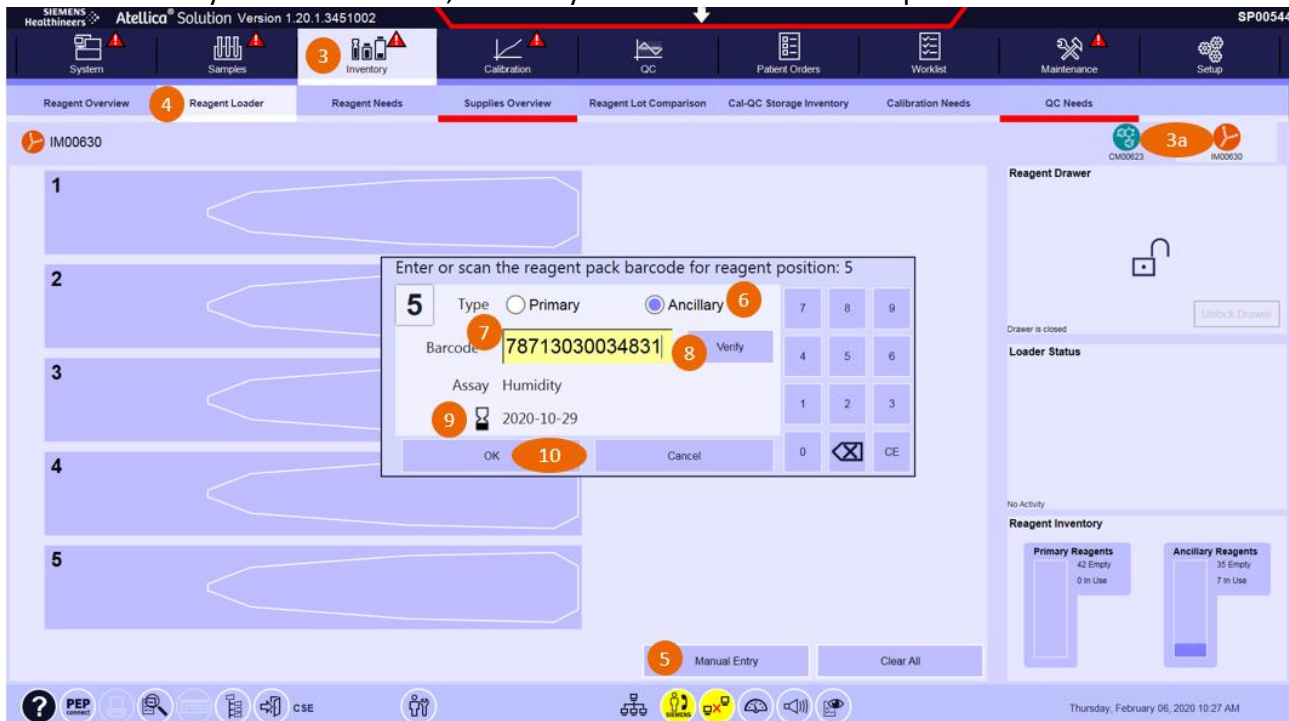
Note: Steps 3 through 9 correspond to the screen shot below.

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4. Select the **Reagent Loader** tab.
5. Select the **IM module** where the packs are to be loaded. Select **Manual Entry**.
6. Select pack type as **Ancillary**.
7. Enter the following barcode number.
  - a. 78713030PPPPPP
  - b. PPPPPP is a unique six-digit pack number. Use the unique identifier on the Humidity Pack being manually entered.
  - c. The unique identifier on the Humidity Pack label is depicted below. In this example the unique identifier is 034831. (side view)



8. Select Verify.
9. Confirm Assay equals Humidity and the date next to the hourglass symbol is 2020-10-29.
10. Select OK.
11. Load the Humidity Pack in position 5 of the reagent tray.
12. Repeat this procedure for all required Humidity Packs. Each analyzer will require, 7 to 10 packs based on analyzer environmental requirements. When the full set of required Humidity Packs are loaded, the analyzer will resume normal operation.



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Note: Anytime the analyzer must repeat the “Startup” routine, the humidity packs with covered barcodes will be identified as “unknown.” This will require the above actions to be completed again. The analyzer will perform the “Startup” routine after a module reboot and certain operator diagnostics.

- If your analyzer SW has not been upgraded to V 1.21.0 SP1, please order new humidity packs.
- Please contact your Siemens Customer Care Center or local technical support provider to schedule the installation of Atellica Solution SW V 1.21.0 SP1.
- If your Atellica IM Analyzer has been upgraded to SW V 1.21.0 SP1 no further actions are required.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Technical Support representative.

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 technical support provider.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

**Humidity Packs Incorrectly Identified as Expired**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW20-02.B.OUS, dated February 2020 titled "Humidity Packs Incorrectly Identified as Expired (Lot 0010)". Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes  No

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Phone: \_\_\_\_\_ Country: \_\_\_\_\_

Please send a scanned copy of the completed form via email to the following e-mail address:  
CruinnFSNGroup@cruinn.ie,

Or fax this completed form to the Customer Care Center at 01-6297401.

If you have any questions, contact your local Siemens technical support representative.