



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Reference: FSCA 4538

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS 3 (software versions 1.2 and higher) Status of expired calibration not updated

Dear valued Customer,

You are a VIDAS 3 user and we thank you for your continued confidence.

The VIDAS® 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application configuration).

Description of the issue :

Following Customers complaints, investigations have been initiated on potentially false results obtained on VIDAS 3 with an expired calibration.

Indeed, the calibrations of assays were valid in the calibration menu whereas in fact the calibrations were expired and no alarm displayed to warn the users about the expiration date of the calibrations. Software computes results of analysis for assays with expired calibrations. The anomaly is due to an incorrect update of the calibration status by the software.

This issue is due to a software anomaly regarding the software versions 1.2 and higher. The issue occurred only VIDAS 3 instrument (with software versions 1.2.0 and higher). VIDAS Legacy and mini-VIDAS instruments are not affected by this issue.

The issue occurs if the following conditions coexist at customer site :

- VIDAS 3 installed with software versions 1.2.0 and higher
- Archiving mode is configured as "when results are reported"
- One calibration in "TO DO" status in the calibration menu
- Expiration of the lot(s) concerned by the "TO DO" calibration

We remind that, according to the User Manual ref 161150-314 VIDAS 3 : Section ASSAY CALIBRATION: “Single reagent strip assays are calibrated using one or two standards/calibrators supplied with the assay kit. Calibration using the standard(s)/calibrator(s) provided in the kit should be run the first time the assay kit lot is used, after the master lot data have been entered. The calibration obtained can be used for a programmed period of days (14 or 28 days depending on the VIDAS products used). After that, the software automatically expires the calibration, requiring that you run another one from the same lot.”

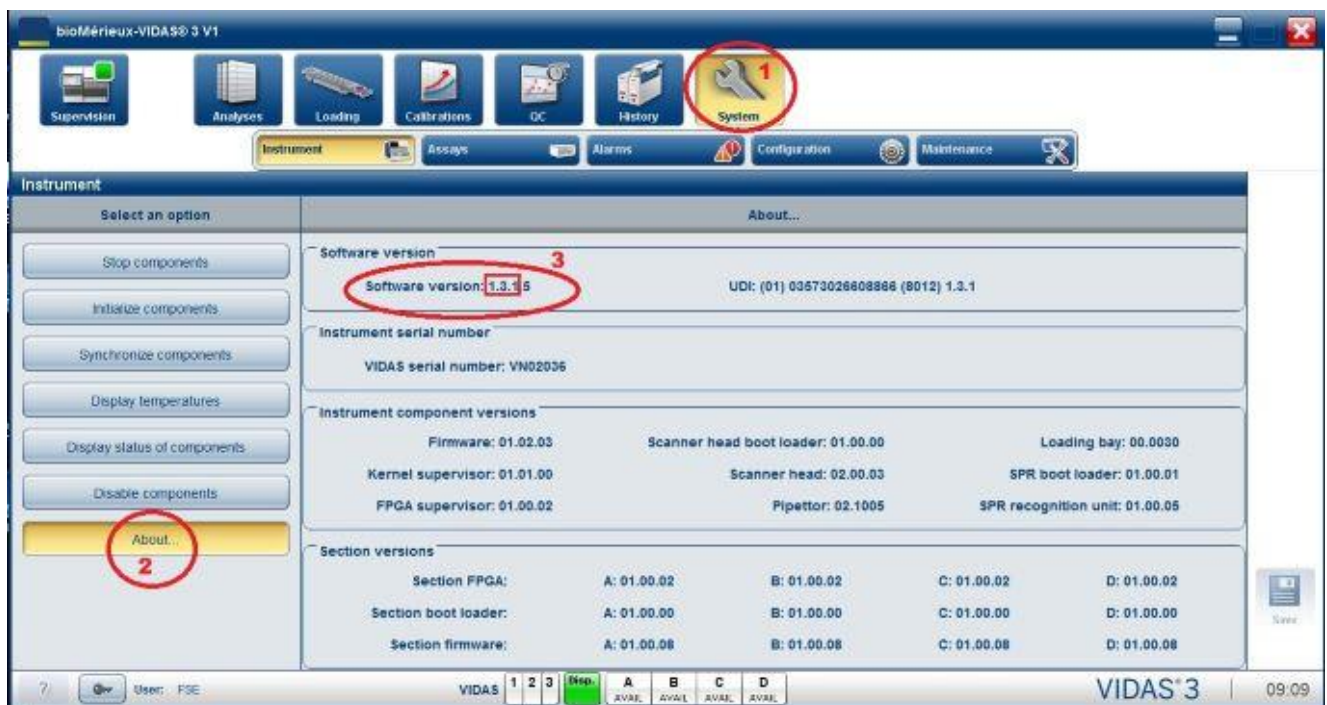
Impact to customer:

The associated risk is potential false results obtained with an expired calibration.

Required actions:

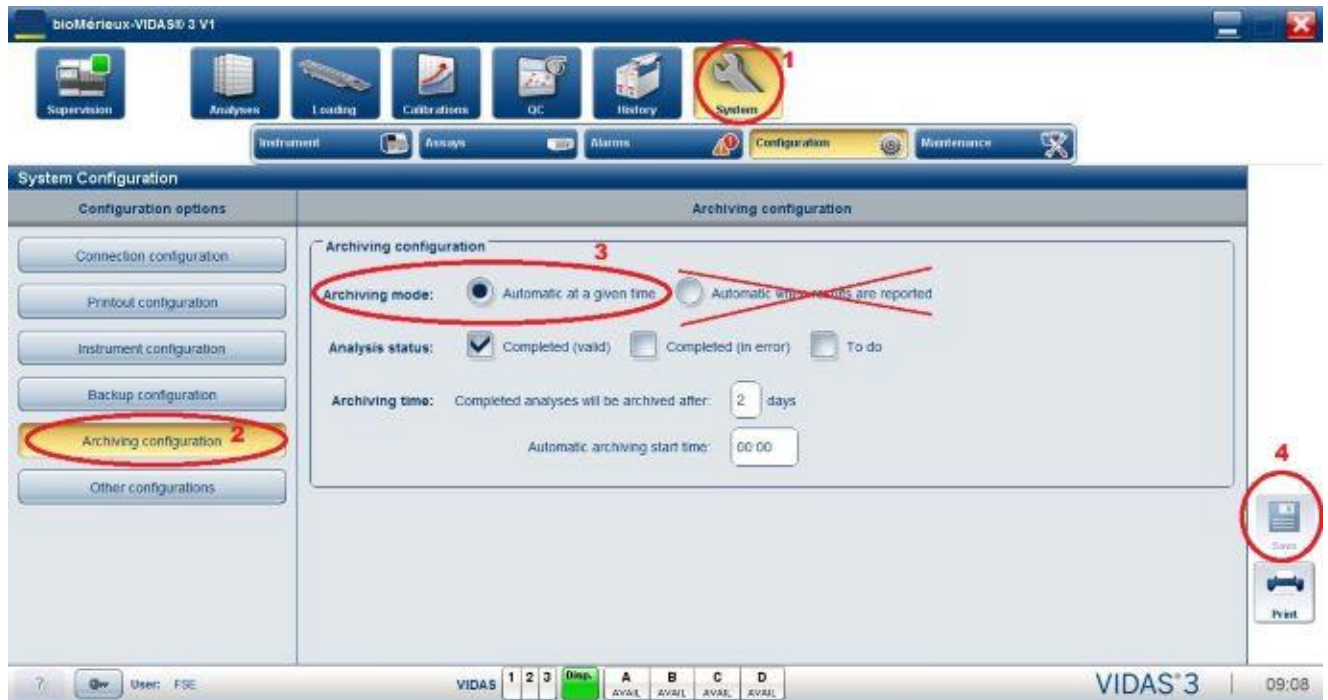
We request you to take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- To check if you might be concerned by the incorrect software configuration, follow the instructions mentioned hereunder :
 - o Check the VIDAS 3 software version, follow the different steps listed below :



If the VIDAS 3 software version is 1.1.4, you are not concerned by the issue.

- If the VIDAS 3 software version is between 1.2.0 and 1.3.1, check the archiving mode : To do so follow the different steps listed below :



If the archiving mode is “Automatic at a given time” , you are not concerned by the issue.

- If the archiving mode is “Automatic when results are reported”, you might be concerned by the issue only if the four conditions listed above are verified at the same time.
- To solve the problem, change manually the archiving mode “Automatic when results are reported” and **select the archiving mode “Automatic at a given time”**. Save the modification and reboot the computer .
- Contact your local customer service if you have the incorrect software configuration and if you have a doubt regarding your results.
- Discuss any concerns you may have regarding previously reported patient results obtained with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service



Attachment A: Acknowledgement Form.

FIELD SAFETY NOTICE
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TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the **“VIDAS 3 (software versions 1.2 and higher) Status of expired calibration not updated”**
- I will implement the required actions as indicated in the Urgent Product Safety Correction Notice.

REF #	Product Name	SN #
412590	VIDAS 3 Software versions 1.2 and higher	NA

DATE

SIGNATURE :