FIELD SAFETY CORRECTIVE ACTION

Number:	**5707**	Action:	**Correction**	Unit Name:	**Immunology**
Product Name:	**VIDAS® 3 Software v1.4.0 and v1.4.1**				
Issue Date:	**12-AUG-2022**	Manufacturing Site:	**La Balme**	**Required Actions**	

Section A: Details

Affected Product

- **System:** VIDAS®
- **REF:** 423694
- **Lot/Serial:** N/A
- **Expiry:** N/A
- **Product:** VIDAS® 3 Software v1.4.0 and v1.4.1
- **GMDN Code:** 56705
- **Unique Device Identifier:** 03573026617622

Manufacturing Beginning & End Date: N/A

Distribution Beginning & End Dates: N/A

Quantity on hand: N/A

Date of Decision to take Action in the Field: 01-AUG-2022

Name and Address of Legal Manufacturer

Name & Address of Recalling Firm:
bioMérieux SA
376 Chemin de l'Orme
69280 MARCY L'ETOILE
FRANCE

Name & Address of Manufacturing Site:
bioMérieux SA
3 Route De Port Michaud,
38390 La Balme
FRANCE

Product Intended Use

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

Is there a PSS associated with this FSCA? YES ☐ NO ■ PSS Number: _____
Is this FSCA associated with a customer complaint? YES ■ NO ☐
Customer Complaint Number(s): CN-211169, CN-251639, CN-255661, CN-335079, CN -337125
Investigation Reference Number: INV-12331

In April 2022, bioMérieux received a complaint from the field related to an unexpected error after performing a calibration that was followed by a shutdown of the VIDAS® 3 Version 1.4.1 software. The customer could no longer restart the VIDAS® 3 User software and was not able to use the VIDAS® 3 instrument until the database is restored with bioMérieux support.

bioMérieux initiated an investigation to assess product issue and identify the root-cause, while the investigation is still ongoing the following were identified:

- The issue was confirmed by analysis of the database provided by the complaining customer.
- When the anomaly occurs, the customer is not able to open the VIDAS® 3 User software because there is an unexpected value present in the database. The software uses a cache memory management mechanism which could, in certain circumstances, corrupt the database during a calibration. When this occurs, a database (list of previous results recorded by the system) prior to the problem must be restored with bioMérieux support in order to open the software.
- This issue is related to a new memory management system that was introduced for Version 1.4.0 and 1.4.1 for the VIDAS® 3 instrument. Therefore, this issue can only occur with VIDAS® 3 instruments that have these software versions. The new Version 1.4.2 does not have this memory management system and will correct the issue.
- The issue could only be encountered when the customer performs a second calibration from the same assay and same lot number after having performed 11 different VIDAS® parameters calibrations without restarting the VIDAS® PC. Restarting the PC is not a mandatory step that is mentioned in the User Manual. There is also a random factor to take into account, which is when the memory of the application becomes full. This can vary between each customer depending on the quantity and frequency of testing being performed.
- A daily data backup is automatically performed each day by the VIDAS® 3 system at 2 AM. When the system is restored, the data obtained before the previous daily back up can be restored and the VIDAS® system restarted. Nevertheless, if the anomaly leading to the shutdown occurs, all data collected between the previous automatically daily back-up and the moment when the system shuts down will be lost.
- Restarting the VIDAS® PC every week at the Customer level will avoid this issue to occur regardless of the frequency and quantity of calibrations being performed by the customer.

As a conclusion:

- **The investigation confirmed that if a customer uses a VIDAS® 3 Instrument (Software Version 1.4.0 or 1.4.1) and performs a second calibration from the same assay and same lot number after having performed 11 different VIDAS® parameters calibrations without restarting the VIDAS® PC could induce this unexpected error to occur.**
- **The risk of this issue is a loss of data between the last daily backup and when the issue occurred. The second risk is delayed results due to the loss of data from tests being run at the time of the unexpected error**.

Root-cause:

The investigation confirmed that the anomaly is linked to the cache memory management of the software Versions 1.4.0 and v1.4.1.

CAPA:

No CAPA will been initiated because the root cause has already been identified. The issue is already corrected in the new software version 1.4.2 to be released in Q1 2023 US and Q2 2023 WW.

Field Action Decision:

- Impacted products are IVD products and used in clinical and veterinary contexts.
- Considering the overall risk that is minor and the severity Critical for a loss of data, the FA Board determined that a Field Safety Corrective Action (FSCA 5707) would be appropriate to inform customer having implemented VIDAS® 3 software Version 1.4.0 and Version 1.4.1 and any new VIDAS® 3 customers until the installation of Version 1.4.2 by bioMérieux field service engineer (FSE) at the customer site. The release of this new software version 1.4.2 is expected in Q2 2023 .The Urgent Field Safety notice will inform the customers about the issue and require them to restart their VIDAS® 3 PC weekly in order to avoid the occurrence of this anomaly.
- This corrective action is considered as a FSCA as it will reduce a safety risk in the field. The Field Safety Corrective Action notification (FSCA 5707) with associated Urgent Field Safety Notice, will be sent to the impacted subsidiaries and distributors.

<u>Short-term actions:</u>

- Actions required at subs/distributors levels:
    - Translate and Send the Urgent field Safety Notice associated to FSCA 5707 to all customers having received the VIDAS® 3 software Version 1.4.0 and 1.4.1 and any new VIDAS® 3 customers until the installation of Version 1.4.2 by bioMérieux field service engineer (FSE) at the customer site.

- Actions required at customers level:
  - Restart their VIDAS® 3 PC weekly until a bioMérieux field service engineer (FSE) installs the VIDAS® 3 software Version 1.4.2 on their VIDAS® 3 instrument.

Risk Assessment / Health Hazard Assessment

The potential risks associated with the reported issue is the “delay of result > 1h” and “loss of data”.

Based on the Hazard definition of VIDAS 3 (BMX.1.008574 - Hazards definition for VIDAS family products), the problem may lead to “delay of result > 1h” and “loss of data”.

The severity of "delay of result > 1h" and “loss of data” were assessed as **SERIOUS** and **CRITICAL** respectively. (Hazard definition of VIDAS 3: BMX.1.008574 - Hazards definition for VIDAS family products)

P1 Probability (Probability of Hazard)

The occurrence (P1) for “delay of result > 1h” and “loss of data” has been assessed as **REMOTE (Unlikely to occur, but is possible to occur very rarely over the life of the product).** This was determined using the installed base of VIDAS® 3 Instruments on the market with Software Version 1.4.0 or 1.4.1.

The Probability of hazardous situation leading to harm (P2) is assessed as **FREQUENT**. This is per the Hazard definition of VIDAS 3: BMX.1.008574 - Hazards definition for VIDAS family products.

Based on the severity and probability, the overall risk of the identified hazard is **MINOR** as follows:

Hazard	P1 (Probability of hazardous situation occurring)	P2 (Probability of hazardous situation leading to harm)	P (Overall probability)	Severity	OVERALL RISK
Delayed result	REMOTE	FREQUENT	REMOTE	SERIOUS	MINOR
Loss of Data	REMOTE	FREQUENT	REMOTE	CRITICAL	MINOR

Notification to the Regulatory Authority

Recipients of this notification must assess the product issue and any associated patient risk in accordance with local regulations to determine if it is reportable to their local regulatory authority. Notification to your regulatory authority must include device classification when required.

Product Distribution

Ref.VIDAS 3 412590 / 412590R / 412590U				
Type	**Sold-to pt**	**Sold to Party Name**	**Country name**	**Country code**
Subsidiaries	**AR01**	**BIOMERIEUX ARGENTINA**	**Argentina**	**AR**
	AT01	**BIOMERIEUX AUSTRIA GMBH**	**Austria**	**AT**
	AU01	**Biomerieux Australia Pty Ltd**	**Australia**	**AU/PG**
	BE01	**bioMerieux Benelux SA/NV**	**Belgium**	**BE/LU**
	BR01	**BIOMERIEUX BRASIL INDUSTRIA E**	**Brazil**	**BR**
	CH01	**BIOMERIEUX SUISSE S.A.**	**Switzerland**	**CH**
	CL01	**BIOMERIEUX CHILE SpA**	**Chile**	**CL**
	CN01	**BIOMERIEUX SHANGHAI**	**China**	**CN**
	CO01	**BIOMERIEUX COLOMBIA S.A.S**	**Colombia**	**CO**
	CZ01	**BIOMERIEUX CZ S.R.O.**	**Czech Republic**	**CZ/SK**
	DE01	**BIOMERIEUX DEUTSCHLAND GMBH**	**Germany**	**DE**
	ES01	**BIOMERIEUX ESPAÑA, S.A.**	**Spain**	**ES/IC**

	FR01	**BIOMERIEUX S.A**	**France**	**FR**
	GB01	**BIOMERIEUX UK LTD**	**United Kingdom**	**GB/IE**
	GR01	**BIOMERIEUX HELLAS S.A.**	**Greece**	**GR**
	HK01	**BIOMERIEUX CHINA LIMITED**	**Hong Kong**	**HK**
	HU01	**BIOMERIEUX HUNGARIA KFT.**	**Hungary**	**HU**
	IN01	**BIOMERIEUX INDIA PVT. LTD**	**India**	**IN**
	IT01	**BIOMERIEUX ITALIA S.P.A.**	**Italy**	**IT**
	JP01	**bioMerieux Japan LTD**	**Japan**	**JP**
	KR01	**BIOMERIEUX KOREA CO., LTD**	**South Korea**	**KR**
	MX01	**BIOMERIEUX MEXICO SA DE CV**	**Mexico**	**MX**
	NL01	**BIOMERIEUX BENELUX BV**	**Netherlands**	**NL**
	PH01	**BIOMERIEUX PHILIPPINES CORPORATION**	**Philippines**	**PH**
	PL01	**bioMerieux Polska Sp. z o.o.**	**Poland**	**PL**
	PT01	**BIOMERIEUX PORTUGAL, LDA**	**Portugal**	**PT**
	RU02	**BIOMERIEUX RUSS LLC,**	**Russian Fed.**	**RU**
	SE01	**BIOMERIEUX SWEDEN AB**	**Sweden**	**SE/FI/NO**
	SG01	**BIOMERIEUX SINGAPORE Pte LTD**	**Singapore**	**SG**
	TH01	**BIOMERIEUX THAILAND LTD**	**Thailand**	**TH**
	TR01	**BIOMERIEUX DIAGNOSTIK A.S.**	**Turkey**	**TR**
	ZA01	**BIOMERIEUX SOUTH AFRICA PTY**	**South Africa**	**ZA**
Office	**TW01**	**bioMérieux China Limited,**	**Taiwan**	**TW**
Distributors	**1126205**	**LABOPHARMA LTD**	**Albania**	**AL**
	1039376	**INDUSTRIES MEDICO-CHIRURGICALES**	**Algeria**	**DZ**
	1063040	**ORGANIZACOES MAURO RUI, LDA**	**Angola**	**AO**
	1049008	**OZEL NESIL**	**Azerbaijan**	**AZ**
	1038802	**GULF PHARMACY AND GENERAL STORE**	**Bahrain**	**BH**
	1032146	**BGL SYSMET**	**Benin**	**BJ**
	1032570	**TUZLA FARM**	**Bosnia-Herz.**	**BA**
	1039252	**BROMA BEL D.O.O.**	**Bosnia-Herz.**	**BA**
	1107336	**MEDICLIM EOOD**	**Bulgaria**	**BG**
	1107059	**MEDIC BURKINA**	**Burkina Faso**	**BF**
	1035066	**BIOFASO SARL**	**Burkina Faso**	**BF**
	1055441	**TYM MEDICAL**	**Cote d'Ivoire**	**CI**
	1035919	**A & B d.o.o.**	**Croatia**	**HR**
	1035835	**SUED & FARGESA S. R. L.**	**Dominican Rep/**	**DO**
	1037316	**FARMINPEX N.V.**	**Dutch Antilles**	**AN**
	1089884	**SIMED S.A. (CL)**	**Ecuador**	**EC**
	1039305	**TECNO DIAGNOSTICA DE EL SALVADOR,**	**El Salvador**	**SV**
	1054907	**MEDPHARM**	**Guam**	**GU**
	1076188	**LABYMED S.A.**	**Guatemala**	**GT**
	1103797	**PRODYLAB, PRODUCTOS DE DIAGNOSTICO**	**Honduras**	**HN**
	1029326	**PT. ENSEVAL MEDIKA PRIMA**	**Indonesia**	**ID**
	1039948	**PISHRO TASHKHIS FARD AVAR**	**Iran**	**IR**
	1039792	**ISMAILIYA TRADING AGENCIES &**	**Iraq**	**IQ**
	1038017	**ILEX MEDICAL LTD**	**Israel**	**IL**
	1030908	**HASS SCIENTIFIC & MEDICAL SUPPLIES**	**Kenya**	**KE**

	1040989	BIOTEK Kosova L.L.C.	Kosovo	XK
	1100455	Gulf Integrated Security Solutions	Kuwait	KW
	1036359	DIAR ASSLAM	Libya	LY
	1034890	UAB DIAMEDICA	Lithuania	LT
	1031183	BIOTEK D.O.O.	Macedonia	MK
	1054476	MEDIGENE SDN BHD	Malaysia	MY
	1071118	BioMali	Mali	ML
	1092723	Lifetronik LLC	Mongolia	MN
	1042795	I.M. ALLIANCE SARL	Morocco	MA
	1030694	OKKAR THIRI COMPANY LIMITED	Myanmar	MM
	1038615	GMS GLOBAL MARKETING SERVICES	Pakistan	PK
	1035981	INVERSIONES SAGRAV S.A.	Panama	PA
	1043421	FAS DIAGNOSTIC GROUP, INC.	Philippines	PH
	1035279	ALI ALSUWAIDI TRADING ESTABLISHMENT	Qatar	QA
	1031779	S.C. MEDICLIM S.R.L.	Romania	RO
	1030057	AL JEEL MEDICAL TRADING COMPANY	Saudi Arabia	SA
	1055815	SENEGALAISE DES SYSTEMES MEDICAUX	Senegal	SN
	1030995	YUNYCOM DOO	Serbia	RS
	1035226	MIKRO + POLO d.o.o.	Slovenia	SI
	1031022	MAGHREB MEDICAL MAINTENANCE	Tunisia	TN
	1034755	AL HAYAT PHARMACEUTICALS	Utd/Arab Emir/	AE
	1097670	LAVITEC TECHNOLOGY JSC	Vietnam	VN
	1071113	DKSH Vietnam Co., Ltd	Vietnam	VN
Global Health	1106687	AMEX EXPORT IMPORT GMBH	Iraq	IQ
	1114751	THE MEDICAL EXPORT GROUP	Iraq	IQ
Global Export	1107913	KAYI Holding A.S.	Turkey	TR
	1100548	VAMED Projets Hosp. Internat. Franc	France	FR
	1094117	IDEAL MEDICAL PRODUCTS	France	FR
	1038037	TEDIS SA	Nigeria	NG

Customer Letter / Attachments

Please click on the paper clip icon below to access to the Urgent Field Safety Notice

Section B: Required Actions

1. Please immediately acknowledge receipt (**AR**) of this FSCA.
2. Identify all countries and customers for which you are responsible that are impacted by this FSCA.
3. Translate and send the customer letter to all customers who have **VIDAS® 3 Instruments with Software Version 1.4.0 or 1.4.1 installed and to all new VIDAS® 3 Instrument customers** until a bioMérieux field service engineer (FSE) installs the VIDAS® 3 software Version 1.4.2 on their VIDAS® 3 instrument **.**
4. Determine regulatory reporting requirements in accordance with local regulations and notify regulatory authorities as applicable. Upload evidence of reporting or justification for not reporting to your authority to the following LiveLink location: 80 - Local Reporting Decision
5. After all actions above are complete, please return the acknowledgement of completion (**AC**) for this FSCA. The **due date** for completion of the required actions and submitting the AC is **12-SEP-2022.**

Subsidiaries

- Subsidiaries using SAP, please manage both the Acknowledgment of Receipt and the Acknowledgment of Completion within SAP.

- Subsidiaries not using SAP, to Acknowledge Receipt of this FSCA, please complete all of Sections D.1 and D.2, sign and date where indicated, then upload to LiveLink. To Acknowledge Completion of the required actions, complete Sections D.1 and D.3, sign and date, then upload to LiveLink. Please remember to complete all form sections. The Acknowledgement of Completion must be uploaded to LiveLink before the due date.

Distributors

- Please immediately Acknowledge Receipt of this FSCA by completing Sections D.1 and D.2 then send it by email to fieldactions@biomerieux.com or by fax to +33 4 78 87 21 79.
- To Acknowledge Completion, complete Sections D.1 and D.3 then send it by email to fieldactions@biomerieux.com or by fax to +33 4 78 87 21 79. This form must be must be completed, signed, then emailed or faxed before the due date.

Section C: Regulatory & Quality Compliance Recall Contact

Danielle Cooper
Vigilance Specialist
595 Anglum Road
Hazelwood, MO, 63042

N/A **+33 4 89 43 00 05** **danielle.cooper@biomerieux.com**

Section D: Acknowledgement Form

Number: **5707** Title: **FSCA - VIDAS® 3 Software v1.4.0 and v1.4.1 - 423694- Unexpected error followed by VIDAS® 3 User software shutdown**	Deadline: **12-SEP-2022**

SECTION D.1

Location			
Group Company or Distributor Name(s)		Country	Account #
A			
B			
C			
D			

- -

SECTION D.2

Acknowledgement of Receipt (AR)	
Print Name	
Sign Name	
Position	
Date (dd/MMM/yyyy)	

- -

SECTION D.3

Check the appropriate box and follow the instructions for completion.

☐ **Field Action Not Applicable** (Complete the signature box below and return form.)

☐ **Field Action Applicable**

1. Complete the required information in the table below.
   a. Enter information only in the columns that are checked in the table below. Do not alter the column headers.
   b. Information must be completed for all group companies or distributors indicated in Section 1 of this form.
   c. Ensure that the column totals for Total Shipped, Total On Hand, and Total Destroyed equal the total number received. (Column 4 + Column 5 + Column 6 = Column 3).

Acknowledgement of Completion (AC)									
Group Company or Distributor (from Section 1)		**1.** REF #	**2.** LOT #	**3.** Total Received	**4.** Total Shipped	**5.** Total On Hand	**6.** Total Destroyed	**7.** Total Instruments Affected	**8.** Total Updates Completed
		☒	☐	☐	☐	☐	☐	☐	☐
A		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
B		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
C		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
D		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

2. Provide the date of issuance of the customer letter in the space below. Customer letters are always required for FCA and FSCA.

Customer Letter Issue date:	

3. Complete the signature box below and return Sections D.1 and D.3.

Print Name	
Sign Name	
Position	
Date (dd/MMM/yyyy)	