IMPORTANT:

URGENT FIELD SAFETY NOTICE

EMAG® system Reference 418591/418591U - Error 10003 Heater timeout issue

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

8th October 2026

bioMérieux UK Ltd

First Floor, Central 40, Chineham Park, Basingstoke, RG24 8GU

Our reference: FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000085-1

Product Name	Reference Number	Lot Number/Serial Number/ Product version
EMAG® Instrument	418591	Refer to attached file: FA-TWD-000085-1_Impacted EMAG systems
EMAG® Instrument	418591U	Refer to attached file: FA-TWD-000085-1_Impacted EMAG systems

Dear bioMérieux Customer,

Our records indicate that your laboratory received the product listed in table above.

The aim of this communication is to inform you about a 10003 Error heater time-out issue when utilizing your EMAG® system Reference 418591/418591U updated with SP4 patch 2 version.

Required actions

In this context, we outline the following:

- You can continue using your EMAG® system (Reference 418591/418591U). There is no risk of false results.
- In the case of 10003 error heater time-out during an extraction run, please reinitialize the system to start run the protocol again to prevent any delay/loss of sample.
- You will be contacted as soon as possible to schedule a Field Service Engineer (FSE) visit to update your EMAG system(s) to the previous firmware patch SP4 Patch 1 that resolves the issue.

Description of the issue

bioMérieux received complaints from the field related to EMAG® system Reference 418591/418591U Error 10003 Heater timeout issues.

The risk associated with the referenced issue is a potential delayed result / no result (loss of sample).

Initial investigation of the issue identified the error started to occur on the field after firmware SP4 Patch 2 was installed. Part of the patch issued corrected a communication error related to the heater. It may be the root cause of the issue. Once the root-cause is confirmed, a CAPA will be implemented to prevent the issue from occurring.

Should you have any questions regarding the content of this letter, please do not hesitate to contact uktechnical@biomerieux.com.

Impact to User/Customer/Patients

The error can occur during the extraction protocol of an EMAG® system reference 418591 analysis run. When heater does not reach the target temperature during the extraction protocol, error 10003 heater timeout occurs. When this error occurs, the ongoing run is canceled and all samples in the run are invalidated. As a consequence, the extraction process must be repeated, resulting in a potential delay and/or no result (loss of sample) impacting patient results.

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 uktechnical@biomerieux.com.

Kind Regards,

Field Actions UK
Fieldactions.UK@biomerieux.com

On behalf of bioMérieux Global Customer Services

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000085-1 EMAG® system Reference 418591/418591U - Error 10003 Heater timeout issue

---

TO BE RETURNED TO *BIOMÉRIEUX* AT THE FOLLOWING EMAIL ADDRESS: FIELDACTIONS.UK@BIOMERIEUX.COM

Name and Address of the laboratory	
Contact information	
Customer Account Number	

☐ I am not impacted by the issue. Please provide rationale: ……

☐ I have implemented the required actions.

REF #	Product Name	Serial number #/ Version number	Quantity impacted	Quantity corrected**
418591	EMAG® Instrument	N/A		
418591U	EMAG® Instrument	N/A		

** Quantity returned to bioMerieux subsidiary or distributor*

*** Quantity corrected include software updates or instruments corrections*

If you have encountered impact on patients' results, or reports of illness or injury related to the identified issue and have not yet reported to bioMérieux, please contact your uktechnical@biomerieux.com.

DATE…….....SIGNATURE……

It is important that you complete this Acknowledgement Form and return it to bioMérieux