

Urgent Field Safety Notice

Product: Amplitude™ Platform with TaqPath™ COVID-19 HT Kit (Catalog #A50883)

13 April 2022

Institution:	«Customer Name»	«Address Line 2»
Address:	«Address Line 4»	«Address Line 3»
	«Address Line 1»	«City», «State» «Postal Code» «Country»

Dear Valued Customer,

This letter is to notify you of a mandatory upgrade to the Amplitude Platform with the TaqPath COVID-19 HT Kit relating to the replenishment and monitoring of silicone oil consumable levels.

Silicone oil is used as a consumable on the Amplitude Platform in order to help reduce risk of cross contamination that may lead to issues such as false positive results when appropriate silicone oil volume levels are not maintained.

The mandatory upgrade is intended to mitigate the risk associated with this issue, and includes updates to our hardware, software, Instructions for Use (IFU) and User guide. As part of the V2.1 Amplitude Platform upgrade, we have added silicone oil volume level detection to the Tecan™ Fluent™ 1080 Automation Workstation (Module 1). This added feature will alert the user if there is insufficient silicone oil volume and prevent the run from initiating.

Thermo Fisher is in the process of ensuring that all of our customers receive the mandatory Amplitude Platform system upgrade to mitigate the risk of false positive determinations. Once scheduled, a Field Service Engineer will visit your site and complete the software updates and hardware upgrades.

Actions Required:

- Please contact your local Thermo Fisher Scientific representative to schedule an upgrade visit.
- Notify all Amplitude Platform with the TaqPath COVID-19 HT Kit users in your facility of this communication.
- Sign and return acknowledgement of Receipt – page 2 of this communication, to EU-customer-notification@thermofisher.com

Thermo Fisher Scientific is committed to supplying innovative, high-quality products. If you still have questions or concerns, please contact Technical Support at 00 800 5345 5345 option 3 or email eurotech@thermofisher.com. We thank you for the business partnership.

Sincerely,



Richard Lubin
Director, Quality
Genetic Sciences Division

CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)

Product Name	SKU Number	Number of Amplitude Platform systems available at facility (Customer to populate)
TaqPath™ COVID-19 HT Kit	A50883	

Customer Name and Address:

Institution:	«Customer Name»	«Address Line 2»
Address:	«Address Line 4»	«Address Line 3»
	«Address Line 1»	«City», «State» «Postal Code» «Country»

I have read and understand the instructions provided in the letter dated 13 April 2022. YES NO

Acknowledgement that TFS Representative was contacted to schedule the soft ware upgrade YES NO

I have notified all Amplitude Solution users in my facility:	<input type="checkbox"/> YES <input type="checkbox"/> NO
If "No," please explain:	

Customer Signature of Receipt: _____ **Date:** _____

Please return response sheet by email to EU-customer-notification@thermofisher.com.
Due date for response is 26 April 2022.

For any questions or comments please contact Technical Support at 00 800 5345 5345 option 3 or email euotech@thermofisher.com

Thermo Fisher Scientific Reference Number: PR # 595890