

Field Safety Corrective Action (FSCA) for Tomcat™ Instrument Pipettor Arm Error

Affected Instruments:

All Tomcat™ instruments Catalogue Number: ASY-07379 / RASY-07379

Description of the problem:

To date, Hologic has identified four Tomcat instruments displaying incorrectly error code 18 and/or making a clicking or scraping sound while pipetting, all of which are linked to the same root cause.

The Tomcat instrument error code 18 is intended to provide a warning that the input container's volume is too high, however, customer reports associated with this anomaly have indicated that the input container volume is not too high.

Hologic's investigation has identified the root cause of this issue to be a software anomaly which, in rare cases, can impact the Tomcat instrument's pipettor arm (Figure 1) causing the sample pipette tip position to offset slightly lower than normal. If this occurs, error code 18 may be displayed and/or a clicking or scraping sound may be heard due to sample tip contact with the mucous shelf (Figure 2).



Figure 1. Location of the Tomcat instrument pipettor arm.

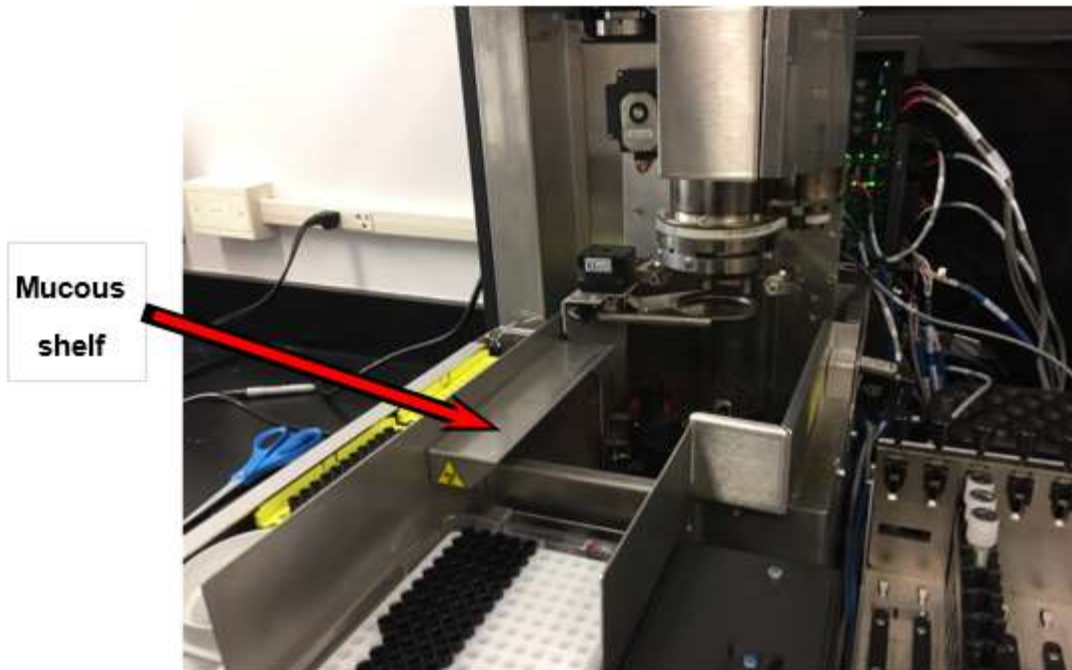


Figure 2. Location of the mucous shelf.

This issue can occur during pipettor arm initialization when the system is jostled by an external source or by the pipettor's own movement.

There have been **no reports of incorrect sample results** being associated with this anomaly. While sample pipette tip position offset appears to occur at a low frequency, if it occurs, sample tip contact with the mucous shelf could result in incorrect sample results due to sample tip contamination, or due to volume loss from the tip. NOTE: Tomcat does not produce any results, however, these potential incorrect results could occur when tested subsequent to sample processing on the Tomcat.

The appropriate Competent Authorities have been notified of this field safety corrective action.

Advice on action to be taken by the user:

- A software update to correct the software anomaly is available for onsite installation by a Hologic field representative. This software update will prevent this issue from occurring by correcting the initialization movements during the pipettor arm homing routine. Hologic will be contacting customers to schedule the software update installation.
- If error code 18 is observed prior to receiving the software update, or if a clicking or scraping sound is heard as the Tomcat instrument's pipettor arm moves across the mucous shelf, please discontinue using the Tomcat instrument and contact Hologic

Technical Support. A Hologic field representative will then contact you to prioritize the software update installation.

- Please transfer this notice to other organisations which may be affected by this action.
- Please complete, sign and return the included Customer Response form to Hologic Molecular Support via the contact information provided on the form or as listed below.

Please contact support by phone at the number corresponding to your country:

Belgium	0800 77378	Slovakia:	420 7347 51527
Denmark:	8088 1378	Spain:	900 994197
France:	0800 913659	Sweden:	020 797943
Ireland (Rep):	1 800 554144	Switzerland:	0800 298921
Italy:	800 786308	Turkey:	90 212 347 8470
Luxembourg:	8002 7708	UK:	0800 0323318
Netherlands:	0800 0226782	All International:	00800.800.29892

Fax: 0041-445830843 or 0800-883885

Email: EUTechnicalSupport@hologic.com

For additional information, questions, or concerns, please contact Hologic Molecular Support using the details above.

Yours sincerely,

Angel Estrada

Vice President, Quality & Regulatory Affairs – International

Customer Response Form

Tomcat® Instrument Pipettor Arm Error

Hologic Deutschland GmbH
 Molecular Support
 Otto-von-Guericke Ring 15
 65205 Wiesbaden
 Nordenstadt
 Germany

Technical Support Phone: See table above.
 Technical Support Fax:
 0041-445830843 or 0800-883885

Technical Support Email:
 EUTechnicalSupport@hologic.com

Instructions

Please review the accompanying field safety notification. Completing and signing the Customer Response Form acknowledges receipt of the notification and compliance with it. Return the completed Customer Response Form to Hologic Molecular Technical Support using the fax, email or address above, and please notify us if there are any changes to your contact information.

Please print your account information, name, title, phone number, sign and date to acknowledge your receipt and compliance with the accompanying field safety notification. Please return to Hologic Technical Support using the fax, email or address above.

Completed By:

Account Name		Address	
City/ State/ Zip code		Country	
Print Name and Title:		Phone:	
Email:			
Signature:		Date:	
Comments:			