Urgent Field Safety Notice

FCA2525

8th Dec 2025

TS-10: Lift Drop Incident during Rack Jam Clearance

Product Name	TS-10
Product Description	Automated Tube Sorter
Device Identifier	UDI-DI: 04987562433155 UPC: 636090433154 REF: BN168792 Serial numbers affected: 11001-12305、12307-12317: Serials prior to Ver 00-17
Type of Action	IVD modification

Dear Valued Customer,

This Field Safety Notice (FSN) is intended to provide information regarding a potential risk of lift drop incident during rack jam clearance on the TS-10 Automated Tube Sorter prior to Ver.00-17.

Description of the situation:

Sysmex has received a report of a hand injury sustained by an operator while manually removing a jammed rack from the carry-in line of the TS-10 Automated Tube Sorter prior to Ver.00-17.

The incident occurred when the operator attempted to clear a rack jam. During this process, the lift's magnetic holding force was unexpectedly released, causing the lift to drop suddenly and the operator's hand to become caught between moving parts.

Our internal investigation confirmed that, under specific conditions, the lift's electromagnetic holding force may disengage unexpectedly, allowing unintended downward movement of the lift. This event may occur during the procedure described in the TS-10 Instructions for Use (IFU), Chapter 5.7 "Removing a rack or foreign object from the carry-in line."

Risk to health:

There is a risk of hand or finger injury directly associated with the lift dropping unexpectedly during rack jam removal.

Actions to be taken by the customer:

To prevent injury, never place your hands around the lift section at any time.

In addition, please follow these instructions when handling rack jams or similar errors:

- ✓ Pay special attention not to insert your hands around the lift section during any intervention.
- ✓ If a rack, tube, or any object becomes lodged around the lift section, turn off the power. After confirming that the lift section has moved to the bottom dead point, carefully remove the rack and blood collection tubes.
- ✓ If the rack or blood collection tubes are jammed in the lift section and cannot be removed with one hand, contact Sysmex and request an FSR for assistance.

Please ensure this notice is communicated to all relevant personnel and retained in a visible location until the software update is completed.

Actions to be taken by Sysmex:

Sysmex will implement a software update to improve lift position control to prevent unintended sudden drops of the lift section by ensuring that, after an error occurs, the lift automatically returns to the home position. Our service team will contact you to schedule the installation of software version 00-18 or later.

Communication of this Field Safety Notice:

Distribute this FSN to all responsible persons within your organization and return the Acknowledgement of Receipt (AoR) with your signature to your authorized local Sysmex representative.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours