[Urgent] Field Safety Notice

ID: VGCA-26014

Date: 30.04.2026

Counter change in SW script TVAC error

Product Name	CyFlow™ Counter
Product Description/ Intended Purpose	The CyFlow™ Counter is intended as aid to diagnosis of immune and clinical status of patients and for monitoring, initiation or follow-up of treatment for people living with HIV. The CyFlow™ Counter is a manual, quantitative clinical flow cytometer designed for the determination of the absolute number of CD4+ T lymphocytes and the percentage of CD4+ cells in lymphocytes in human EDTA venous whole blood samples. The use of the CyFlow™ Counter is limited to healthcare professionals, trained by staff of Sysmex Partec GmbH or authorized distributors.
Basic UDI-DI	425087890485646
Device Identifier = UDI-DI	04250878904856
Production Identifier = UDI-PI (Lot No./Serial No.)	2507079647 2507079347
SRN (of manufacturer)	DE-MF-000019810
FSCA-identifier (if applicable):	VGCA-26014
Type of Action (advisory notice)	Restore default settings of devices and perform a daily quality check

Dear Valued Customer,

Description of Situation:

Sysmex Partec GmbH received information about two CyFlow Counter instruments in India where scripts were corrupted and the TVAC error message was disabled without authorization by Sysmex Partec GmbH. On both devices the DQC (daily quality check) was successfully performed as specified by the manufacturer.

Risk to Health (if applicable):

Disabling the TVAC error message can lead to inaccurate measurement results if DQC is not performed. Inaccurate measurement could result in overcount or undercount of CD4 positive cells. Overcounting of CD4 cells might give results of > 350 or > 200 or > 100 CD4 cells per µL for patients whose true CD4 counts are below these cutoffs. This could result in a failure

to prescribe the appropriate treatment.

Since the DQC was successfully performed the risk of obtaining inaccurate measurements is low.

Actions taken by Sysmex (if applicable):

Sysmex Partec GmbH has identified corrective actions to address the issue. Affected devices have been identified. Service organisations are being informed through this Field Safety Notice.

Actions to be taken by the field service:

Please take the following actions,

1) *Restore the default scripts provided by Sysmex Partec GmbH.*
2) *Perform a DQC on the device.*
3) *Send Sysmex Partec GmbH the complete service report including the DQC data.*

Communication of this Field Safety Notice (if applicable):

This Field Safety Notice will be provided to the Regional Headquarter (Sysmex Asia Pacific Pte Ltd) with the request to ensure its dissemination to all relevant service technicians responsible of restoring affected products. The RHQ will be requested to confirm that this information has been forwarded accordingly.

Other information (if applicable):

In addition, the case will be notified to the World Health Organization (WHO) through the appropriate reporting channels established for international vigilance communication.

Contact details:

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We thank you for your support in resolving this situation.

Sincerely yours

Sysmex Partec GmbH

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