

To Healthcare institute, Health Organization,
Service Provider,

To whom it may concern

Ref: 22024

Saint Priest, 09th December 2022

Subject: FlowSens® Injector in Saudi Arabia market

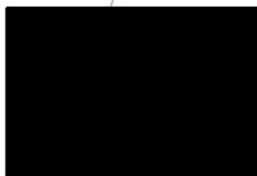
Dear Customer,

This letter is to notify you that TAMER (distributor in Saudi Arabia) is conducting a product update of the FlowSens® injector on behalf of MEDEX (Legal Manufacturer). It deals with the implementation of a new software version (released in December 2021) on the FlowSens® injector.

Reason	After several injection when using the automatic priming function, the remaining volume displayed was incorrect and not enough to finalize the injection of the Contrast Media for a CT exam which stops the injection process and could potentially lead to repeat the exam.
Affected product details	All FlowSens® Injectors: <ul style="list-style-type: none">FlowSens® Injector – Stand Version product ref: FSI001FlowSens® Injector - Ceiling Suspension Version product ref: FSI002Software version 5.5 or previous
Product correction	The software version 5.6 was corrected to improve the accuracy and matching data between the injector screen and the actual ScanBag® volume after a Secufill Priming. TAMER will contact you in order to organize the update of the injector.
Action to be taken by Customer	For multi-patient use, Medex recommends to use temporarily the manual priming mode until getting the next software update (version 5.6 or higher). Additional information to end users related to good practice with regard to the use time of the FlowSens® injector disposables: the end user shall not use the disposables (MonoFlow® and ManyFlow®) for more than 12 hours as mentioned on the labelling.
Contact information	If you have any questions or concerns regarding this notification, please contact RAPMS@tamergroup.com

We apologize for any inconvenience this letter might cause and thank you for your continued cooperation and support.

Sincerely,



MEDEX

MEDEX
240 allée Jacques Monod – 69800 Saint-Priest – France
Tél. : + 33 (0) 4 72 79 20 50 – Fax : + 33 (0) 4 72 79 20 69

SRN : FR-MF-000000414

Forme juridique : SAS – Capital social : 180 000 € – Siège social : 240 allée Jacques Monod
69800 – Saint-Priest – France - RCS : Lyon 340 598 978

22024 – Customer Acknowledgement Form – Response is required

FlowSens Injector FSI001 / FSI002

Date: _____

Healthcare institute / Health Organization: _____

Street Address: _____

City/State/ZIP/Country: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone Number: _____

Email address: _____

I have read and understand the instructions provided and acknowledge receipt of the information regarding the use of FlowSens Injector and have successfully updated the embedded software to 5.6 version.

Name: (print)

Signature: