

## URGENT: FIELD SAFETY NOTICE

# WASSENBURG® WD4200 WASHER-DISINFECTOR

Date: 12 December 2023  
Type of action: Field Safety Corrective Action (FSCA)  
FSCA ref.: V23005CH  
FSN ref.: 20231208GM01  
For the attention of: Decontamination / Endoscopy Department Manager

### Follow-up FSN

This Field Safety Notice is a follow-up to the FSN with reference code 20230724GM01 and describes the technical solution to the issue communicated in the earlier FSN

### Contact details of local representative

Dominik Lenz  
Mositech Medizintechnik AG  
Rotzenbühlstrasse 55  
8957 Spreitenbach  
+41 (0) 58 596 51 50  
[dominik.lenz@mositech.ch](mailto:dominik.lenz@mositech.ch)

### Information on affected device

<b>Device type</b>	WASSENBURG® WD4200 washer-disinfector
<b>Intended use</b>	The WD4200 is intended for the washing and disinfection of flexible endoscopes and other re-usable thermolabile devices in the health care sector
<b>Device model</b>	The FSCA affects all WD4200 units in service
<b>UDI-DI</b>	8719324979WD01EU

Dear Customer,

In July 2023 we released an FSN informing you of gradual backflow that had been observed in the WD4200 and which may have resulted in the dosing of a volume of detergent and/or disinfectant that was lower than the validated volume. The FSN described a temporary solution to keep the dosing frequency to a maximum of 48 hours in order to ensure the validity of the dosed volume of detergent and disinfectant. A technical solution to the gradual backflow has now been developed. Once implemented, it will no longer be necessary to maintain a dosing frequency of 48 hours or less.

This follow-up FSN describes the technical solution as well as the next steps for the implementation of the solution in the affected devices.

## **Technical solution**

The technical solution consists of a machine upgrade that ensures the dosed volumes of detergent and disinfectant remain stable and within the specified and validated settings. The upgrade will be carried out on the affected devices by your Wassenburg service provider.

## **Action to be taken by the user**

Your Wassenburg service provider will contact you to arrange the upgrade to the WD4200.

Until the upgrade has been completed, it remains essential to keep the dosing frequency to a maximum of 48 hours as described in the FSN with reference code 20230724GM01. This assures the continued efficacy of the washing and disinfection cycle.

Please fill in and return the accompanying FSN Customer Reply Form to the above-mentioned local representative within the indicated time.

## **Action being taken by the manufacturer**

Your Wassenburg service provider will contact you to make an appointment for the upgrade of the affected device(s).

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

## **Transmission of this Field Safety Notice**

- This notice needs to be passed on to all those who need to be aware within your organisation.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We regret the inconvenience of this FSCA and would like to thank you for your continued cooperation in assuring that the highest standards are achieved for the safety of both patient and user.

Wassenburg Medical B.V.

Date:

Mr Alexander Vermeulen  
Medical Compliance Director

## FIELD SAFETY NOTICE CUSTOMER REPLY FORM

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	20231208GM01 / V23005CH
FSN Date	12 December 2023
Product/ Device name	WASSENBURG® WD4200 washer-disinfector
Serial Number(s)	All serial numbers

<b>2. Customer Details</b>	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone Number	
Email	

<b>3. Customer action undertaken on behalf of Healthcare Organisation to be filled in by the customer</b>		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and I acknowledge that I have read and understood its content.	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	
<input type="checkbox"/>	I have a query please contact me	
Print Name		
Signature		
Date		

<b>4. Return acknowledgement to sender</b>	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Deadline for returning the customer reply form	10 working days after receipt of the FSN

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.