URGENT - FIELD SAFETY NOTICE

GETINGE *Fibro Cleaner*
Field Action *2018-15*

Date: <month> <day>,<year>

Product Issue: Based on customer outcomes, it was highlighted that Fibrocleaner can generate issues from smoke and overheating until fire of the device.

Affected Product: 533 units are concerned by this letter

Part No.:	
01030911	FIBRO-CLEANER ADU VERSION DUODENOSCOPE
01039707	FIBRO-CLEANER FC1 FOR ENDOSCOPES
01039708	FIBRO-CLEANER FC1 VERSION DUODENOSCOPE
01039709	FIBRO-CLEANER FC1+1 ASRDU
01010036	FIBRO-CLEANER FC2 VERSION DUODENOSCOPE
01030913	FIBRO-CLEANER FC2 ASR FOR ENDOSCOPES
01030914	FIBRO-CLEANER FC2 ASRDU VERSION
01030916	FIBRO-CLEANER FC2 ASRDUDP VERSION
01010003	FIBRO-CLEANER FC2 GLUTARALDEHYDE
01039701	FIBRO-CLEANER FC4 ASRDU VERSION DUODENO
01039702	FIBRO-CLEANER FC4 ASRDUDP VERSION DUODEN

Resolution: A safe state was determined by the Legal Manufacturer based on Technical History on this device. A review of the device will be performed at the customer site in order to check if it is in the safe state and modifications will be implemented accordingly if needed.

Affected Serial Nos.: See document attached consignee_list_per_country

Pages: 5

Dear Customer,

Our records indicate that you bought one or more Fibrocleaners with a serial number listed as above.

This letter is to inform you of a corrective action that will be performed to prevent a possible hazard to persons and equipment.

The issue we found can cause smoke, overheating or fire in the device. This can cause significant skin burns, evaporation of chemicals and the release of toxic fumes. The inhalation of these substances could lead of different degrees of respiratory symptoms from simple irritation to a more life threatening compromise like ARDS(Acute Respiratory Distress Syndrome) . Additionally, eyes could be severely irritated by the fumes. We have received several complaints resulting in equipment shut down and fires in the devices. From our investigation, which includes evaluation of worst-case scenarios it, was concluded that there is only a remote chance of the injuries described above occurring. However, it is possible.

This potential for malfunction is caused by a design error: the current solenoid valve is not resistant enough to chemicals and the location of the one-way valve does not prevent leakage. The device was officially discontinued in 2015. We have developed a solution that includes replacement of solenoid valves, implementation of protection caps and repositioning of the one-way valve. We see the issue as a potential long-term hazard and want to prevent any related event from reoccurring with our customers.

Next Steps

1. Please make sure that all Fibrocleaner users are made aware of this Field Notice and all listed devices at your facility are available to be checked and modified accordingly during the Getinge service technician visit.

2. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.

3. Note: A Getinge Sales or Service person will contact the person listed on the Customer Response Form to schedule service to review and if necessary modify your device, free of charge.

Transmission of this Field Notice:

This Getinge Fibrocleaner Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Additional Comment

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Customer Response Form

Appendix 1 Field Action 2018-15

Reference: Urgent Field Safety Notice, Getinge Fibrocleaner.

Our records indicate that one of the devices shown below was delivered to your location. Please verify that you have one of the listed devices that are potentially affected and complete the information below.

Part No.:	
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01039708	FIBRO-CLEANER FC1 VERSION DUODENOSCOPE
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01039702	FIBRO-CLEANER FC4 ASRDUDP VERSION DUODEN

Record the total number of affected device currently located at your facility here please ➔ ___.

Please check the appropriate boxes below:

☐ We have read the *Fibrocleaner* Field Safety Notice and we understand the communication and the required actions.

If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes)			
City, State, Zip			
Phone Number		**Fax:**	
E-Mail Address:			

Form: SOP-0921-A7 rev1

☐ We have sold/moved our *Fibrocleaner* to another facility.

If checked : please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		**Fax:**	
E-Mail Address:			

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL	**CONTACT**
<local SSU address line 1>	*<contact ddress>*@getinge.com
<local SSU address line 2>	Tel: *<SSU contact phone number>*
<local SSU address line 3>	Fax: *<SSU contact fax number>*
<local SSU address line 4>	