

Field Safety Notice

Toulouse

Date
2015-04-21

GETINGE LANCER

Revision

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Model:	<i>ED FLOW</i>
Type of action:	<i>Field Safety Notice</i>
Details on affected devices:	
ED FLOW with serial number with 4 last digits lower than 0276 Serial number is xHxxzzzz. Machines with zzzz <0276 are concerned by this field safety notice.	
Description of the problem:	
The position of the needle in the machine is too low. In some cases, it is possible to perforate the membrane of the chemical containers not in the middle of the membrane. If the hole is too low on the membrane, the hole can be on the thinner part of the membrane so the silicone membrane will not tighten the needle.	
Description of Potential Risk	
If the silicone membrane does not tighten the needle, a leakage of chemical can occur. A vinegar odor can be smelled and users can be bothered.	
Advise on action to be taken by end customer:	
Customers have to contact their local representative to schedule a replacement of the plates where the needles are fixed. During this time, customers will have to verify when they change chemical container if there is a leak or not. They can verify by sliding an absorbent paper between the container and the plate. When removing the paper they will be able to verify if there is a leak or not.	
Field Correction Kit	
New plates have the following part numbers : 46030460 and 46030461.	
Contact reference person:	
<i>GETINGE LANCER</i> <i>Att. To : F. ROY-PINCHOT</i> <i>Quality director</i> <i>30 boulevard de l'industrie – ZI Pahin Concerto</i> <i>31170 TOURNEFEUILLE - FRANCE</i> <i>vigilance.lancer@getinge.com</i> <i>Tel : 05 61 15 11 11</i>	

Quality director
Getinge Lancer

