



W.O.M. WORLD OF MEDICINE GmbH | Salzufer 8 | 10587 Berlin

Enter Address

Berlin, 17.09.19

Urgent Field Safety Notice (FSN) Aquilex Fluid Control System (AQL-100CBS)

WOM reference no.: Recall_AQL100-CBS_001

Information on Affected Devices:

The Aquilex Fluid Control System is intended to provide fluid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

The purpose of this letter is to inform you that a component of your Aquilex Fluid Control System, the Fluid Monitoring System (AQL-100CBS), is subject to a Field Safety Corrective Action.

The Aquilex Fluid Management Pump (AQL-100P / AQL-100PBS) and Aquilex Fluid Management tube sets (AQL-110, AQL-111 and AQL-114) as well as all other components are not impacted by this recall.

Affected serial numbers:

A list of affected serial numbers can be found in Annex 1

Reason for Field Safety Corrective Action (FSCA)

WOM has received some complaints regarding incorrect fluid deficit measurements. If the displayed fluid deficit is lower than the actual deficit the patient could be overexposed to distention media. Exceeding the deficit limit can lead to a serious risk such as gynaecological TUR syndrome (when using electrolyte-free solutions are used as distending media) or pulmonary/cerebral edemas (when using electrolyte-containing solutions).

This potential incorrect display of fluid deficit has been attributed to lose or lost bag deflectors on the cart scales.

No serious adverse events or deaths have been reported related to this Field Safety Corrective Action.



Recommendation for users:

Please perform a visual inspection of your Aquilex system looking for obvious damage to the bag deflector using the criteria in Annex 2. If you notice **any damage or abnormality** during the inspection, please **stop using your Aquilex Fluid Control System**. Contact your local representative to arrange replacement as soon as possible.

Perform a Fluid Deficit Measurement Test (FDM-test). The fluid deficit measurement test is described in chapter 9.2.4 of the Instructions for Use. Annex 3 provides also a detailed instruction on how to perform this test. The displayed fluid deficit after the test should be 0 ml with permissible tolerance is ± 50 ml. If the Fluid Deficit Measurement Test is **not passed successfully**, please **stop using your Aquilex Fluid Control System**. Contact your local representative to arrange replacement as soon as possible.

If both visual inspection and the FDM-test are passed successfully, you may continue to use your unit. The affected unit still needs to be returned to W.O.M (manufacturer) within the coming month. Please contact your local representative to arrange a replacement.

Transmission of this Field Safety Notice:

This notice should be provided to all personnel who need to be made aware of this issue within your organization.

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

Please acknowledge the receipt of this Field Safety Notice by returning the Customer Reply Form to:

be-reception@hologic.com

Attachments:

- Annex 1: list of affected units
- Annex 2: Visual Inspection Instructions
- Annex 3 Aquilex Fluid Deficit Measurement Instruction

Urgent Field Safety Notice AQL-100CBS – Annex 1
List of affected serial numbers

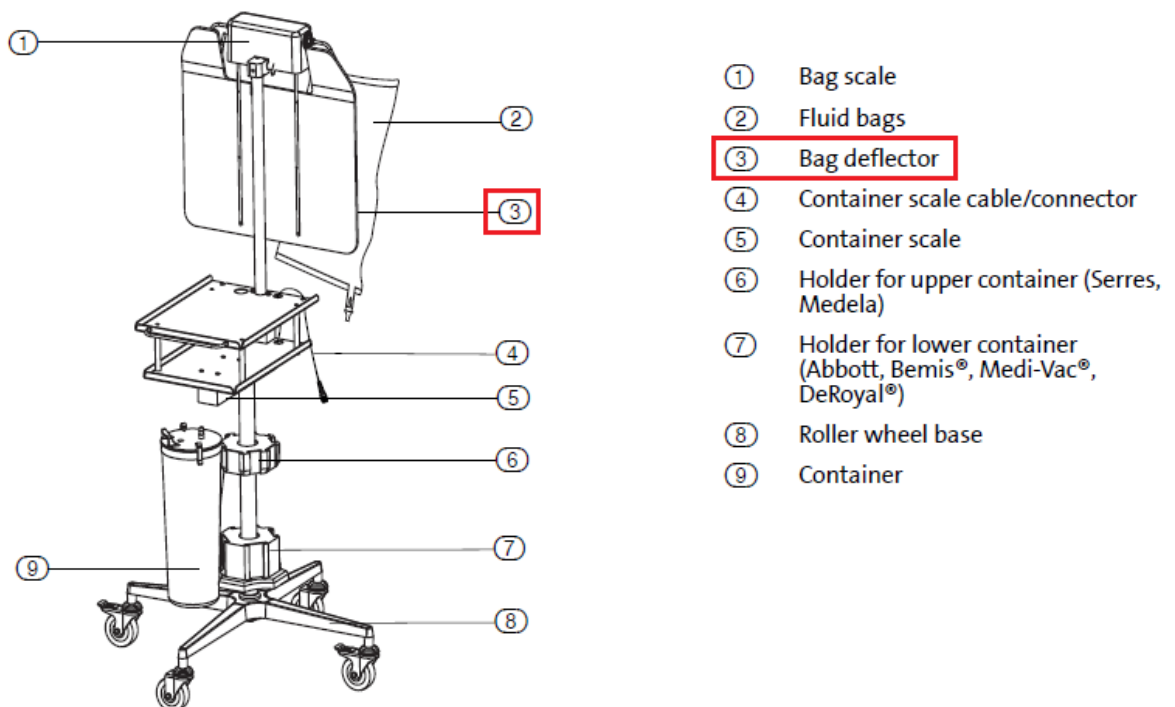
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Urgent Field Safety Notice AQL-100CBS — Annex 2 Visual Inspection Instructions

- Check if the bag deflector (see picture below, item 3) is fitting properly and is not showing any damage or has become loose.

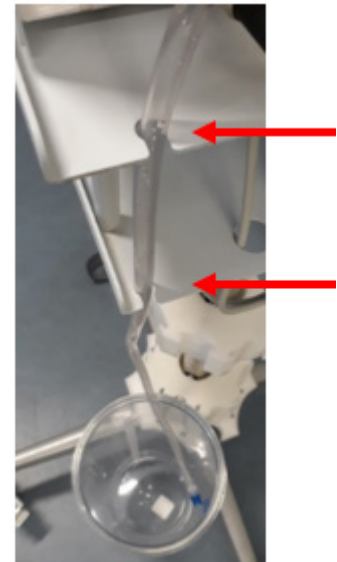


- The bag deflector must be properly installed, according to the figure identified above.
- Because the bag deflector is a co-weighed part of the scale it must hang straight and must not touch any parts of the pump nor the mounting pole of the bag scale.
- The bag deflector must not hang at an angle (seen from front and side).
- Mounting rods of the bag deflector must not be bent.
- Up and down movement must not be possible on either side of the mounting.
- The bag deflector must be firmly fastened to the load cell so that no upward or downward movement is possible.

Urgent Field Safety Notice AQL-100CBS – Annex 3 **Fluid Deficit Measurement Test Instructions**

It is critical that the collection container is positioned on the scale. The outflow tube set must not rest on the collection container, but the fluid must be collected in the container.

1. Assure that the inflow bag contains at least 1.5 l fluid, to prevent the bag from running empty during the test procedure. Hang the fluid bag onto one of the hooks of the bag scale.
2. Position one collection container properly in the respective holders of the container scale. Use one of the places on the back of the scale.
3. Turn the system on.
4. Once the display depicts **Insert Tube Set**, insert a tube set into the pump and close clamps on the bags.
5. Insert the tap spike into the fluid bag and open the related clamp.
6. Fasten the other end of the tube in the recesses on the back of the pump tray (see photo on the right) so that the tube end with the luer lock hangs freely in the container.
7. Place the middle tube section e.g. on the pump so that it does not touch either the Container Scale or the Bag Scale.
8. Press the **PRIME** button to start the calibration, which fills the tube set completely with fluid.
9. Once the display depicts **Prime Successful Close Stopcock**, press the **Pause/Resume** button to stop fluid transport,
10. Set the fluid deficit display to zero by pressing the **Zero** button
11. Press the **Pause/Resume** button to start fluid transport.
12. Allow system to run for 1 minute (use a stopwatch).
13. Press the **Pause/Resume** button to stop fluid transport



14. The displayed fluid deficit should be 0 ml.
The permissible tolerance is ± 50 ml.



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Customer Reply Form

- I confirm receipt of the Field Safety Notice and that I read and understood its content.
- I have/will perform the actions as described in the Field Safety Notice have been brought to the attention of all relevant users.
- The information and required actions in the Field Safety Notice have been brought to the attention of all relevant users.
- I do not have, or no longer have an Aquilex Fluid Control System at my facility.

Institution: _____

Name: _____

Phone/E-mail: _____

Address: _____

City: _____

Country: _____

Date: ____ / ____ / 20____ Signature: _____

It is important that your organization takes the actions detailed in this letter and confirms that you have received this notice for regulatory tracking purposes.

Please e-mail scanned copy to:
be-reception@hologic.com