

Berlin, 17.07.23

Urgent Field Safety Notice (FSN) – MEDICAL DEVICE RECALL

Aquilex® Fluid Control System Pump – REF AQL-100PBS and AQL-100P

WOM reference no.: 2023-0001

RESPONSE REQUIRED BY August 7th, 2023

Information on Affected Devices:

The Aquilex® Fluid Control System is a combined suction and irrigation pump for use in gynecological interventions. The Aquilex® Fluid Control System is intended to provide fluid distension of the uterus during diagnostic and operative hysteroscopies 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 the software of your Aquilex® Fluid Control System of the pump is subject to a Field Safety Corrective Action:

- **Aquilex® Fluid Control System Pump REF AQL-100PBS and**
- **Aquilex® Fluid Control System Pump REF AQL-100P (starting with serial number 1802CEXXXX)**



The Aquilex® Fluid Control System Scale (REF AQL-100CS as well as AQL-100CBS), accessories and tube sets 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)

This field safety notification is being issued following a low number of reports from customers that the display of inflow volume on the Aquilex® Fluid Control System can reach its limit of 30,000 ml during very long procedures. In the event that such an extraordinary high amount of fluid is used for distension of the patient's uterus, the calculation of the inflow and outflow volumes reach their limit, and the inflow volume display will freeze at the maximum value while the deficit will start counting backwards until 0 ml is reached.

There is a risk of distension fluid reaching the circulatory system of the patient's soft tissue. This can be affected by distension pressure, flow rate, perforation of the distended body cavity and duration of the endoscopic surgery. Therefore, it is critical to closely monitor the input and outflow of the distending liquid at all times.¹

Our investigation has identified a software anomaly as the cause for this display freeze. The reason for this is that at 30,000 ml an internal software calculation threshold is being reached. As the outflow measurement will continue, the result is that the deficit accumulated up to this point will start counting backwards until 0 ml is reached.

Display of total inflow volume



Figure 1 Note: To show the total inflow volume please hold down both the Increase- and Decrease-deficit limit -buttons.

Risk to Health:

This incorrect display of fluid inflow can result in fluid overload at worst. Fluid overload can be affected by distension pressure, flow rate and duration of the hysteroscopic surgery. Therefore, it is critical to closely monitor the inflow and outflow of the distending fluids at all times. The pressure should be kept as low as possible to allow for a sufficient intrauterine distension and to reduce the forces that could allow fluid, ambient air, and/or gas into the circulatory system.

¹ Aquilex® Fluid Control System IFU (MAN-05183-4320, MAN-07766-4320, MAN-05323-4020), chapter 3.1.2 Hysteroscopy Specific Warnings

Mitigating Factors:

To be performed by the user as intended:

When an inflow volume of **30,000 ml** has been reached as shown on the device display, the current procedure should be concluded as quickly and safely as possible.

Implemented design change:

W.O.M. WORLD OF MEDICINE GmbH has developed a software version, which, among others, starts emitting visual and acoustic signals when an inflow volume of 28,000 ml is reached. Additionally, the system will pause when an inflow volume of 30,000 ml is reached and is designed to prepare the user for a manual fluid deficit determination.

Action To Be Taken by the User:

Ensure that the affected devices receive their preventive maintenance on time, every two years, as prescribed by the manufacturer. A new software version and an updated version of the IFU are implemented during the next due preventive maintenance of the pump of the Aquilex® Fluid Control Systems AQL-100PBS as well as AQL-100P. Also, please complete Customer Acknowledgement Form (Annex 2).

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.

Thank you for executing hereon with the appropriate priority and your patience and commitment to W.O.M. WORLD OF MEDICINE GmbH as we continually strive to ensure that all components of the Aquilex® Fluid Control System best meet your needs.

Attachments:

- Annex 1: list of affected units
- Annex 2: Customer Acknowledgement Form

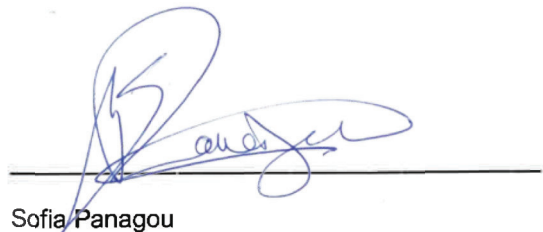
Sincerely,

W.O.M. WORLD OF MEDICINE GmbH



Timo Bauernsachs

Senior Vice President Global Quality Management
Quality Management Representative



Sofia Panagou

Director of Regulatory Affairs



Urgent Field Safety Notice – MEDICAL DEVICE RECALL
Pump of Aquilex® Fluid Control System — REF AQL-100PBS and AQL-100P

Annex 1 – List of affected serial numbers

1802CE0538	1803CE0125	1803CE0377	1803CE0986	1803CE1136	1804CE0316	1804CE0618	1804CE0898
1802CE0539	1803CE0126	1803CE0378	1803CE0987	1803CE1137	1804CE0317	1804CE0620	1804CE0899
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1802CE0543	1803CE0130	1803CE0531	1803CE0991	1803CE1181	1804CE0321	1804CE0624	1804CE0943
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1902CE0597	1902CE0844	1903CE0588	1904CE0754	1905CE1036	1906CE0367	1906CE0947	1908CE0617



WOM

A Novanta Company

1908CE0618	1909CE1150	1911CE0095	1911CE1151	2002CE1064	2006CE0877	2008CE0558	2102CE0364
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1909CE1119	1910CE0556	1911CE1103	1912CE0360	2006CE0529	2008CE0207	2102CE0323	2103CE0801
1909CE1120	1910CE0557	1911CE1104	1912CE0361	2006CE0530	2008CE0208	2102CE0324	2103CE0802
1909CE1121	1910CE0558	1911CE1105	2002CE0987	2006CE0531	2008CE0209	2102CE0325	2103CE0804
1909CE1122	1910CE0559	1911CE1106	2002CE0989	2006CE0532	2008CE0210	2102CE0326	2103CE0805
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1909CE1145	1910CE0562	1911CE1109	2002CE0992	2006CE0535	2008CE0213	2102CE0329	2103CE0808
1909CE1146	1910CE0563	1911CE1110	2002CE1060	2006CE0536	2008CE0214	2102CE0330	2103CE0809
1909CE1147	1910CE0564	1911CE1111	2002CE1061	2006CE0537	2008CE0215	2102CE0331	2104CE0705
1909CE1148	1910CE0565	1911CE1149	2002CE1062	2006CE0538	2008CE0556	2102CE0362	2104CE0706
1909CE1149	1911CE0094	1911CE1150	2002CE1063	2006CE0876	2008CE0557	2102CE0363	2104CE0707



2104CE0708	2105CE0747	2108CE0555	2111CE0551	2112CE0768	2205CE0059	2209CE0814	2209CE0924
2104CE0709	2105CE0748	2108CE0556	2111CE0552	2112CE0769	2205CE0060	2209CE0815	2209CE0925
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2104CE0711	2105CE0750	2108CE0558	2111CE0554	2112CE0820	2205CE0062	2209CE0829	2209CE0957
2104CE0712	2105CE0751	2108CE0559	2111CE0555	2112CE0821	2206CE0457	2209CE0830	2209CE0958
2104CE0713	2105CE0752	2108CE0560	2111CE0556	2112CE0822	2206CE0458	2209CE0831	2209CE0959
2104CE0714	2105CE0753	2108CE0727	2111CE0870	2112CE0823	2206CE0459	2209CE0832	2209CE0960
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2104CE0834	2106CE0096	2108CE0730	2111CE0873	2112CE0826	2206CE0463	2209CE0835	2209CE0963
2104CE0835	2106CE0097	2108CE0731	2111CE0874	2112CE0827	2206CE0464	2209CE0836	2209CE0964
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2105CE0405	2107CE0259	2109CE0219	2111CE0925	2112CE0857	2209CE0774	2209CE0886	2209CE0994
2105CE0406	2107CE0260	2109CE0220	2111CE0926	2112CE0858	2209CE0775	2209CE0887	2209CE0995
2105CE0407	2107CE0261	2109CE0221	2111CE0927	2112CE0859	2209CE0776	2209CE0888	2210CE0089
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2105CE0601	2107CE0513	2109CE1031	2112CE0107	2204CE0480	2209CE0785	2209CE0897	2210CE0098
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2210CE0151	2210CE0820	2212CE0356	2212CE0532	2301CE0637	2302CE0389	2303CE0459	2303CE0606
2210CE0152	2211CE0227	2212CE0357	2212CE0533	2301CE0638	2302CE0390	2303CE0460	2303CE0607
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2210CE0203	2211CE0230	2212CE0360	2212CE0536	2301CE0641	2302CE0393	2303CE0463	2303CE0610
2210CE0204	2211CE0231	2212CE0361	2212CE0537	2301CE0642	2302CE0394	2303CE0464	2303CE0651
2210CE0205	2211CE0232	2212CE0362	2212CE0538	2301CE0643	2302CE0395	2303CE0497	2303CE0652
2210CE0206	2211CE0233	2212CE0363	2212CE0539	2301CE0644	2302CE0437	2303CE0498	2303CE0653
2210CE0207	2211CE0234	2212CE0364	2212CE0540	2301CE0665	2302CE0438	2303CE0499	2303CE0654
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2210CE0819	2211CE0281	2212CE0531	2301CE0636	2302CE0388	2303CE0458	2303CE0605	



HOLOGIC®

Urgent Field Safety Notice – MEDICAL DEVICE RECALL **Pump of Aquilex® Fluid Control System — REF AQL-100PBS and AQL-100P**

Annex 2 – Customer Acknowledgement Form Instructions

Please complete the Online Acknowledgement Form online within **three (3) business days** upon receipt of this notification.



STEP 1 - Scan the QR Code or visit the link below to access the response form

www.novasyte.com/hologic/aquilex-2023

STEP 2 – Enter your Unique Identifier:

Your Unique Identifier - XXXXX

STEP 3 – Acknowledge the receipt of this notice & complete the form online

Call Novasyte for any questions/concerns with response form

Ph: (999) 999-9999 | E: aquilex-2023@iqvia.com

Hologic, has partnered with Novasyte, now an IQVIA MedTech company, to assist in this action. Novasyte specializes in providing outsourced commercial service teams and technologies for the medical device industry.

For any assistance regarding online response processing please contact Novasyte using the information above.

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WEEE-Reg.-No. DE 60787320

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