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

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

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

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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

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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

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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

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1909CE1117	1910CE0397	1911CE1029	1912CE0358	2006CE0485	2008CE0115	2012CE0720	2103CE0444
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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
1909CE1123	1910CE0560	1911CE1107	2002CE0990	2006CE0533	2008CE0211	2102CE0327	2103CE0806
1909CE1124	1910CE0561	1911CE1108	2002CE0991	2006CE0534	2008CE0212	2102CE0328	2103CE0807
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

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2104CE0708	2105CE0747	2108CE0555	2111CE0551	2112CE0768	2205CE0059	2209CE0814	2209CE0924
2104CE0709	2105CE0748	2108CE0556	2111CE0552	2112CE0769	2205CE0060	2209CE0815	2209CE0925
2104CE0710	2105CE0749	2108CE0557	2111CE0553	2112CE0819	2205CE0061	2209CE0828	2209CE0956
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
2104CE0832	2106CE0094	2108CE0728	2111CE0871	2112CE0824	2206CE0461	2209CE0833	2209CE0961
2104CE0833	2106CE0095	2108CE0729	2111CE0872	2112CE0825	2206CE0462	2209CE0834	2209CE0962
2104CE0834	2106CE0096	2108CE0730	2111CE0873	2112CE0826	2206CE0463	2209CE0835	2209CE0963
2104CE0835	2106CE0097	2108CE0731	2111CE0874	2112CE0827	2206CE0464	2209CE0836	2209CE0964
2104CE0836	2106CE0098	2108CE0732	2111CE0875	2112CE0828	2206CE0465	2209CE0837	2209CE0965
2104CE0837	2106CE0099	2108CE0733	2111CE0876	2112CE0849	2209CE0766	2209CE0878	2209CE0986
2104CE0838	2106CE0100	2108CE0734	2111CE0877	2112CE0850	2209CE0767	2209CE0879	2209CE0987
2104CE0839	2106CE0101	2108CE0735	2111CE0878	2112CE0851	2209CE0768	2209CE0880	2209CE0988
2104CE0840	2106CE0102	2108CE0736	2111CE0879	2112CE0852	2209CE0769	2209CE0881	2209CE0989
2104CE0841	2106CE0103	2109CE0215	2111CE0920	2112CE0853	2209CE0770	2209CE0882	2209CE0990
2105CE0402	2107CE0256	2109CE0216	2111CE0921	2112CE0854	2209CE0771	2209CE0883	2209CE0991
2105CE0403	2107CE0257	2109CE0217	2111CE0923	2112CE0855	2209CE0772	2209CE0884	2209CE0992
2105CE0404	2107CE0258	2109CE0218	2111CE0924	2112CE0856	2209CE0773	2209CE0885	2209CE0993
2105CE0405	2107CE0259	2109CE0219	2111CE0925	2112CE0857	2209CE0774	2209CE0886	2209CE0994
2105CE0406	2107CE0260	2109CE0220	2111CE0926	2112CE0858	2209CE0775	2209CE0887	2209CE0995
2105CE0407	2107CE0261	2109CE0221	2111CE0927	2112CE0859	2209CE0776	2209CE0888	2210CE0089
2105CE0408	2107CE0262	2109CE0222	2111CE0928	2201CE0359	2209CE0777	2209CE0889	2210CE0090
2105CE0409	2107CE0263	2109CE0223	2111CE0929	2201CE0360	2209CE0778	2209CE0890	2210CE0091
2105CE0410	2107CE0264	2109CE0224	2112CE0101	2201CE0361	2209CE0779	2209CE0891	2210CE0092
2105CE0411	2107CE0265	2109CE1026	2112CE0102	2204CE0475	2209CE0780	2209CE0892	2210CE0093
2105CE0597	2107CE0508	2109CE1027	2112CE0103	2204CE0476	2209CE0781	2209CE0893	2210CE0094
2105CE0598	2107CE0510	2109CE1028	2112CE0104	2204CE0477	2209CE0782	2209CE0894	2210CE0095
2105CE0599	2107CE0511	2109CE1029	2112CE0105	2204CE0478	2209CE0783	2209CE0895	2210CE0096
2105CE0600	2107CE0512	2109CE1030	2112CE0106	2204CE0479	2209CE0784	2209CE0896	2210CE0097
2105CE0601	2107CE0513	2109CE1031	2112CE0107	2204CE0480	2209CE0785	2209CE0897	2210CE0098
2105CE0602	2107CE0514	2109CE1032	2112CE0108	2204CE0481	2209CE0806	2209CE0916	2210CE0143
2105CE0603	2107CE0515	2109CE1033	2112CE0109	2204CE0482	2209CE0807	2209CE0917	2210CE0144
2105CE0604	2107CE0516	2109CE1034	2112CE0110	2204CE0483	2209CE0808	2209CE0918	2210CE0145
2105CE0605	2107CE0517	2109CE1035	2112CE0763	2205CE0053	2209CE0809	2209CE0919	2210CE0146
2105CE0606	2108CE0551	2111CE0547	2112CE0764	2205CE0055	2209CE0810	2209CE0920	2210CE0147
2105CE0744	2108CE0552	2111CE0548	2112CE0765	2205CE0056	2209CE0811	2209CE0921	2210CE0148
2105CE0745	2108CE0553	2111CE0549	2112CE0766	2205CE0057	2209CE0812	2209CE0922	2210CE0149
2105CE0746	2108CE0554	2111CE0550	2112CE0767	2205CE0058	2209CE0813	2209CE0923	2210CE0150

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2210CE0151	2210CE0820	2212CE0356	2212CE0532	2301CE0637	2302CE0389	2303CE0459	2303CE0606
2210CE0152	2211CE0227	2212CE0357	2212CE0533	2301CE0638	2302CE0390	2303CE0460	2303CE0607
2210CE0201	2211CE0228	2212CE0358	2212CE0534	2301CE0639	2302CE0391	2303CE0461	2303CE0608
2210CE0202	2211CE0229	2212CE0359	2212CE0535	2301CE0640	2302CE0392	2303CE0462	2303CE0609
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
2210CE0208	2211CE0235	2212CE0365	2301CE0613	2301CE0666	2302CE0439	2303CE0500	2303CE0655
2210CE0209	2211CE0236	2212CE0484	2301CE0614	2301CE0667	2302CE0440	2303CE0501	2303CE0656
2210CE0210	2211CE0272	2212CE0485	2301CE0615	2301CE0668	2302CE0441	2303CE0502	2303CE0657
2210CE0811	2211CE0273	2212CE0486	2301CE0616	2301CE0669	2302CE0442	2303CE0503	2303CE0658
2210CE0812	2211CE0274	2212CE0487	2301CE0617	2301CE0670	2302CE0443	2303CE0504	2303CE0659
2210CE0813	2211CE0275	2212CE0488	2301CE0618	2301CE0671	2302CE0444	2303CE0505	2303CE0660
2210CE0814	2211CE0276	2212CE0489	2301CE0619	2301CE0672	2302CE0445	2303CE0506	2303CE0661
2210CE0815	2211CE0277	2212CE0490	2301CE0620	2301CE0673	2302CE0446	2303CE0601	
2210CE0816	2211CE0278	2212CE0491	2301CE0621	2301CE0674	2303CE0455	2303CE0602	
2210CE0817	2211CE0279	2212CE0492	2301CE0622	2302CE0386	2303CE0456	2303CE0603	
2210CE0818	2211CE0280	2212CE0493	2301CE0635	2302CE0387	2303CE0457	2303CE0604	
2210CE0819	2211CE0281	2212CE0531	2301CE0636	2302CE0388	2303CE0458	2303CE0605	

NOTE: Appendix 2 "Customer Acknowledgement Form" is only an example. This is customer specific and will be provided to each customer individually.

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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.