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United States

Berlin, 25.10.21

Field Notice

HysteroLux™ Fluid Management System Control Unit – REF 72205000

WOM reference no.: 2021-0002

Information on Affected Devices:

The HysteroLux™ Fluid Management System is a combined suction and irrigation control unit for use in gynecological interventions. The HysteroLux™ Fluid Management System is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the distension fluid flowing into and out of the uterus.

The purpose of this letter is to inform you that a component of your HysteroLux™ Fluid Management System is subject to a corrective action:

- HysteroLux™ Fluid Management System Control Unit REF 72205000

The HysteroLux™ Fluid Management System Scale (72205001), 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 Corrective Action

This field notification is being issued following reports from customers from the USA that the display of inflow volume on the HysteroLux™ Fluid Management System can reach its limit of 32,450 ml during long procedures. In these cases, the display does not indicate the actual inflow volume. In cases where an unusually high amount of fluid is used for distension of the patient's uterus, the calculation of the inflow and outflow volumes reaches its limit and the Control Unit display will freeze at the maximum value.

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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. 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 32,450 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.

There are no reports from Europe of high inflow volumes of more than 32,450 ml and thus no occurrence of this situation. According to the information available to us, inflow volumes of more than 32,450 ml are not common in Europe.

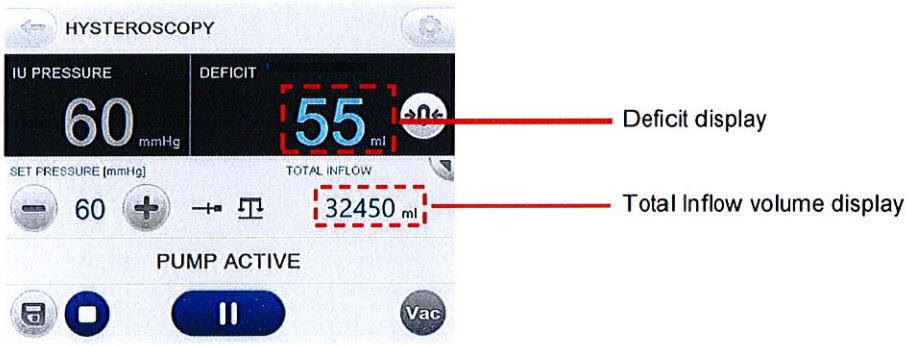

Figure 1 Pump Control Unit display showing the calculated deficit (Deficit display) and inflow volume count (Total Inflow volume display). The latter will freeze, once 32,450 ml has been reached.

This incorrect display of fluid inflow can result in fluid overload. Fluid overload can be affected by distension pressure, flow rate and duration of the hysteroscopic surgery. 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.

W.O.M. WORLF OF MEDICINE GmbH has developed a software version, which, when an inflow volume of 28.000 ml is reached, alerts the user that the limit is being approached and is designed to prepare the user for a manual determination of the deficit.

Recommendation for users:

The new software version is implemented during the next preventive maintenance of your HysteroLux™ Fluid Management System Control Unit. If you wish to update the software of your device at an earlier date, please contact your sales representative of Medtronic Inc., who will assist in returning the unit and providing an exchange unit.

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Transmission of this Field Notice:

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

W.O.M. WORLD OF MEDICINE GmbH

Timo Bauernsachs
SVP Global Quality Management
Quality Management Representative

Dr. Sören Markworth
Head of Regulatory Affairs

Attachments:

- Annex 1: list of affected units

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Annex 1 — List of affected serial numbers

1803CE0680	1812CE0507	2001CE0523	2001CE0605	2001CE0747
1803CE0681	1812CE0508	2001CE0524	2001CE0606	2001CE0748
1803CE0682	1901CE0110	2001CE0525	2001CE0607	2001CE0749
1803CE0683	1901CE0111	2001CE0544	2001CE0608	2001CE0750
1803CE0684	1901CE0112	2001CE0545	2001CE0609	2001CE0751
1803CE0685	1901CE0113	2001CE0546	2001CE0610	2004CE0468
1803CE0686	1901CE0114	2001CE0547	2001CE0611	2004CE0469
1803CE0687	1901CE0115	2001CE0548	2001CE0612	2004CE0470
1803CE0688	1901CE0116	2001CE0549	2001CE0613	2004CE0471
1803CE0689	1901CE0117	2001CE0550	2001CE0614	2004CE0472
1803CE1024	1901CE0118	2001CE0551	2001CE0655	2004CE0473
1803CE1025	1901CE0119	2001CE0552	2001CE0656	2004CE0474
1803CE1026	1903CE0245	2001CE0553	2001CE0657	2004CE0475
1803CE1027	1903CE0246	2001CE0555	2001CE0658	
1803CE1028	1903CE0247	2001CE0556	2001CE0659	
1803CE1029	1903CE0248	2001CE0557	2001CE0660	
1803CE1030	1903CE0249	2001CE0558	2001CE0661	
1803CE1031	1903CE0250	2001CE0559	2001CE0662	
1803CE1032	1903CE0251	2001CE0560	2001CE0663	
1803CE1033	1903CE0252	2001CE0561	2001CE0664	
1803CE1084	1903CE0253	2001CE0562	2001CE0715	
1803CE1085	1903CE0254	2001CE0563	2001CE0716	
1803CE1086	1905CE0359	2001CE0564	2001CE0717	
1809CE1121	1905CE0360	2001CE0565	2001CE0718	
1812CE0499	1905CE0361	2001CE0566	2001CE0719	
1812CE0500	1905CE0362	2001CE0568	2001CE0720	
1812CE0501	1905CE0363	2001CE0569	2001CE0721	
1812CE0502	1905CE0364	2001CE0570	2001CE0722	
1812CE0503	1905CE0365	2001CE0571	2001CE0723	
1812CE0504	1910CE0165	2001CE0572	2001CE0724	
1812CE0505	1910CE0166	2001CE0573	2001CE0745	
1812CE0506	2001CE0522	2001CE0574	2001CE0746	