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Medtronic 60 Middletown Ave Mailstop #64 North Haven, CT 06473 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 rM 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.



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 endoscopie 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 O 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 overlaad. Fluid overlaad 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 fora manual determination of the deficit.

Recommendation for users:

The new software version is implemented during the next preventive maintenance of your Hysterolux TM 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 Ine., who will assist in returning the unit and providing an exchange unit.



A Novanta Company

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

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Attachments:

• Annex 1: list of affected units

Managing Directors: Robert Buckley, Florian Denk, Gerald Nastran Commercial Reg.stry of the Regional Court of Charlottenburg - HRB 149578 B USt-IdNo. DE 136593967 VII1::EE-Reg -No DE 60787320



Field Notice HysteroLux™ Fluid Management System Control Unit- REF 72205000

Annex 1 - List of affected serial numbers

1803CE0680 1812CE0507 2001CE0523 2001CE0605 2001CE0747 1803CE0681 1812CE0508 2001CE0524 2001CE0606 2001CE0749 1803CE0682 1901CE0110 2001CE0525 2001CE0607 2001CE0750 1803CE0683 1901CE0111 2001CE0545 2001CE0609 2001CE0751 1803CE0684 1901CE0113 2001CE0546 2001CE0610 2004CE0468 1803CE0685 1901CE0114 2001CE0547 2001CE0612 2004CE0469 1803CE0686 1901CE0115 2001CE0548 2001CE0612 2004CE0470 1803CE0687 1901CE0116 2001CE0550 2001CE0613 2004CE0471 1803CE1028 1901CE0118 2001CE0550 2001CE0655 2004CE0472 1803CE1026 1901CE0118 2001CE0553 2001CE0655 2004CE0473 1803CE1026 1903CE0245 2001CE0553 2001CE0655 2004CE0474 1803CE1027 1903CE0246 2001CE0555 2001CE0659 2004CE0475 1803CE1028 1903CE0251 2001CE0555 2001CE0663 1 </th <th></th> <th></th> <th></th> <th></th> <th></th>					
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