Penang KLS - Field Safety Notice_20210716 (Easmed-MDA)_Signed

EASMED Sdn Bhd

6TH FLOOR, SUITE 6.01 & 6.02,
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PERSIARAN KEWAJIPAN, USJ 1
47600 UEP SUBANG JAYA
SELANGOR DARUL EHSAN, MALAYSIA
TEL: (603) 8025 9328
FAX: (603) 8025 9326
CO. REG. NO.: 200501027832 (709966-T)

URGENT - Field Safety Notice

To all users of the Heinemann MODULA ENT Diagnostic and Treatment Unit

Re: Heinemann MODULA ENT Diagnostic and Treatment Unit with potential risk due to faulty Aquastop valve

Dear customers,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the Aquastop valve of the ENT treatment units from MODULA series manufactured between 22 August 2020* and 10 May 2021. Please find the details of affected device as below.

*The date of start of installation of this type of aquastop valve.

Medical Device Name: Heinemann MODULA ENT Diagnostic and Treatment Unit

Model	Serial No.	Affected Part
MODULA Paris	MOD20-330	Aquastop valve
MODULA Paris	MOD20-366	Aquastop valve

When does this malfunction occur and what are the potential risks?

During a service call, G. Heinemann Medizintechnik Gmbh has detected call that a faulty component (manufacturing defect at the supplier) could cause the treatment unit to fail. The fault would occur on the Aquastop valve and cause the water supply to fail, and thus functions such as suction systems, ear irrigation or tube rinsing.

Due to a defect in the guide tube of the solenoid valve, a small amount of water will presumably leak out as a result of corrosion and may enter the coil core or the integrated electronics of the solenoid valve, which may lead to a short circuit at this point. The solenoid valve is then no longer actuated correctly, which in turn causes the upstream fuse to fail. In some cases, a malfunction caused by not opening has been detected.

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Any risk to the user can be assessed as low. The solenoid valve is
installed outside the treatment unit. This valve is controlled via a humidity sensor in the unit in order to protect the premises from any escaping water in the event of a fault. The built-in pressure switch in the device detects the lack of water pressure and blocks further ear irrigation processes. During glass or tube rinsing, the function does not work, but this does not pose a risk. Treatment without the available water inflow is not possible, so there are no risks for the patient.

What steps can the user take to avoid the potential risk of this issue?

- At the end of each working day, switch off the treatment unit at the main switch and disconnect the water supply.
- Avoid touching the solenoid valve as it may briefly heat up in the event of a fault.
- Should the Aquastop valve fail, please switch off the treatment unit at the main switch and leave it switched off until our service technician or authorized service partner has carried out the repair.
- Please confirm that have read this Safety information by returning the enclosed reply (see contact details) via e-mail, fax or post.
- Our service technicians will contact you and discuss the further course of action (arrangements for the replacement of the Aquastop valve).

How will the issue finally be resolved?

Conversion/replacement to an alternative valve will solve the potential problem. Our service technician will contact you to arrange an appointment to replace the affected Aquastop valve of the ENT treatment unit.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

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Sincerely Yours

Name: Sim Sing Yee
Position: Regulatory Affairs & Quality Assurance (RAQA)
Date: 13th July 2021

Contact person of this notification
Sim Sing Yee
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