Medtronic
Mechanical Circulatory Support
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URGENT MEDICAL DEVICE COMMUNICATION

Medtronic HeartWare™ HVAD™ Monitor AutoLogs

May 2023

Dear Healthcare Professional,

This letter is to inform you of an issue with the HVAD™ System Autologs web portal. Medtronic has identified that the logfiles downloaded from the recently updated Model 1521 monitors (Serial Numbers: MON4xxxxxx for OUS and MON5xxxxxx for US), are unable to be processed by the Autologs web portal. When attempting to submit logfiles to the Autologs web portal (autologs.medtronic.com) from these recently updated monitors, an error will be displayed stating that the files cannot be processed (see Appendix A below). This issue affects all logfiles downloaded from these recently updated Model 1521 monitors. There is **no impact** on the monitor's functionality or ability to download the logfiles to the USB flash drive, display system performance, or adjust controller parameters.

You are receiving this letter because Medtronic records indicate your facility has received a new Model 1521 monitor that would experience this issue. Medtronic is working on an update to the Autologs web portal to resolve the issue. Until the update is complete, logfiles can be sent to **dl.mcsclinicalengineering@medtronic.com** for report generation. Please contact your Medtronic field representative for additional assistance.

Worldwide, as of 26-Apr-2023, Medtronic has received two (2) complaints associated with this issue when submitting logfiles to the Autologs web portal. No patient impact or harm has been reported for these two complaints.

Medtronic will notify all applicable regulatory agencies about this matter.

Customer Actions:

- Until the update is complete, logfiles can be sent to **dl.mcsclinicalengineering@medtronic.com** for report generation. Please note in the email that you have received a logfile upload error and are requesting a logfile report.
- If you need additional assistance in submitting patient logfiles, please contact your Medtronic Field Representative.
- This notice must be shared with all those who need to be aware within your organization or to any organization where patients have been transferred.
- Please complete the enclosed Confirmation Form and return via email to RS.CFQFCA@medtronic.com

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Additional details:

Medtronic has made the FDA aware of this course of action.

Adverse reactions or quality problems experienced with this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form from www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

We appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support (MCS)

Appendix A – Example Error Message