



Mechanical Circulatory Support

8200 Coral Sea St. NE
Mounds View, MN 55112
USA
www.medtronic.com

URGENT MEDICAL DEVICE COMMUNICATION

Medtronic HeartWare™ HVAD™ Monitor Autologs

September 2023

Dear Healthcare Professional,

This letter is a follow-up to the May 2023 Urgent Medical Device Communication titled "Medtronic HeartWare™ HVAD™ Monitor Autologs" which informed you of an issue with the HVAD™ System Autologs web portal. Specifically, Medtronic had identified that the logfiles downloaded from the recently updated Model 1521 monitors (Serial Numbers: MON4xxxxxx for OUS and MON5xxxxxx for US) were unable to be processed by the web portal. **This communication is to notify you that this issue has now been resolved, and you may resume submitting logfiles for all models of monitors to the Autologs web portal.**

Customer Actions:

- Resume submitting logfiles for all models of monitors to autologs.medtronic.com. If you need assistance in submitting HVAD 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

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

Medtronic

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Gail Schroeder".

Gail Schroeder

Vice President, Quality and Regulatory

Medtronic Mechanical Circulatory Support (MCS)