

HemoSphere Advanced Monitoring Platform Technical Bulletin –CC003

Description

For HemoSphere monitor with software V02.03.000.103, in rare instances the monitor may experience a “Fatal Exception Error” indicating that a file is currently in use and cannot be accessed. This is caused when the monitor is attempting to delete an active log file as part of the data purge process to free up storage space. There is no mechanism to prevent deletion of log files that are currently being written to.

Model	Software
HEM1	02.03.000.103

Suggested Actions

1. Turn the monitor off and then on again.
2. When the monitor is not in use, perform a data wipe to free up storage space and enhance the monitor’s performance.
 - a. Touch the Settings tab → Advanced Setup button → Enter the 8-digit password (Secure user password) → System Reset button → Data Wipe button → Select Wipe Data
 - b. Follow the on-screen instructions to complete the data wipe process.

Note: If you need help with the 8-digit password, please contact Edwards Technical Support.

It is recommended to periodically check the available storage space on the monitor and perform a data wipe when the remaining space is below 15GB (15,000,000,000 bytes).

To verify the available storage space:

1. Touch the Settings tab → Advanced Setup button → Enter the 8-digit password (Secure user password) → Service button → System Status button
2. A displayed warning message will indicate a shutdown is required to proceed. → Touch Continue.
3. Check the available space on the D drive (D: Drive Space Available, value shown in bytes) and power cycle the monitor as required (touch Shutdown button).

For additional details, please see HemoSphere monitor release notes for software release version 02.03.000.103 at <https://eifu.edwards.com>. This issue will be resolved in the next software update, when available.

If you would like to learn more, please contact your Edwards Sales Representative or Edwards Technical Support. Thank you for choosing Edwards Lifesciences to meet your patient monitoring and management needs.

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Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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