Subject: VSM6000 MASIMO MX UPGRADE

Distribution Scope: WA Internal

WA Technical Support, Product Service, & International Service Center

Product Referenced: CVSM (VSM 6000) with Masimo SpO2; Material number 713654
Models: 63MXXX, 63MTXX, 63MXPX, 63MTPX, 64MXXX, 64MTXX, 64MXPX, 64MTPX, 65MXXX, 65MTXX, 65MXPX, 65MTPX.

SW Version: Masimo SpO2 V 1.0.1.X and earlier

Serial No. / Lot Code: Serial numbers 1XXXXXXXXX09 to 1XXXXXXXXXX10

Summary: Re-installing or updating software to the Masimo MX module through the host device (using bypass mode) may fail due to a timing issue between the Masimo module and the Medium Compute Engine (MCE). Follow the procedure in this service bulletin to complete a failed installation.

Issue: Due to a timing issue between Masimo MX module and the Medium Compute Engine (MCE), there is a possibility for an error to occur when loading the Masimo software. This only affects the ability to load software to the Masimo MX module when connecting through the CVSM using the bypass mode.

Action: Use the procedure described below to successfully update the Masimo MX device, when updating from Masimo software version 1.0.1.X and earlier.

Reference to Standards: 21 CFR Part 820, ISO 13485, MPD SOP-0002
**Service Strategy:**

Use this procedure when updating the Masimo SpO2 module from version 1.0.1.X and earlier versions, if the software install fails. The timing issue is due to be corrected in Masimo SpO2 software version 1.0.2.0. Version 1.0.2.0 is to be released with Material 716603, “MODULE ASSY SPO2 MASIMO MX”.

**Required Training:**

Follow this TSB process to upgrade devices as needed.

**Required Tools:**

Welch Allyn Service Tool version 1.0.1.0 or later

**Required Materials:**

Masimo SpO2 software update –Available from RSDS

**Procedure:**

1. Connect the CVSM to a PC with internet access running the Welch Allyn Service Tool
2. Select the CVSM (PMP) from the Device List
3. Select the Upgrade heading
   a. If an update is available it will be shown in the Available firmware column
   b. If the update is unavailable contact Welch Allyn Technical Support to have the update setup in RSDS
4. Select the SpO2 Module – Masimo and click the upgrade button
   a. The device is put into bypass mode and the bootloader image is sent to the module to write
   b. When the image is fully written to the module, a command is sent to reboot the module
   c. After the module reboots the MCE will attempt to recognize the module, switch to bypass mode and resume the upgrade process.
      If the progress indicator stalls at 49% as shown below for more than 5 minutes, the host device was unable to recognize the Masimo module after the reboot. Restart the device and re-run the upgrade from the service tool. Since the update did not complete the image file (*.PIM) will still be available to write to the Masimo module.
   d. The main software image is sent to the device
   e. When the image is fully written to the module a command is sent to reboot the module
   f. After the Masimo module reboots the MCE will attempt to recognize the module, run the POST and delete the image

![Upgrading Host Controller](image)
file (*.PIM) from the PC.
If the progress indicator stalls at 99% as shown below for more than 5 minutes, the host device was unable to recognize the Masimo module after the reboot. Cycle the power on the CVSM and it should boot with no POST failures.

Quality Documents: All service centers using SAP to record service transactions: For each monitor serviced, record the service activity in SAP.

All other service centers and Field Service: For each monitor serviced, complete and file a service report and attach to the service DHR.

Notes:
1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

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