Subject: TSB – CVSM/CIWS, MODPG NIBP 2.03 Update

CAR Number: SKF CAR 1180

Distribution Scope: WA ASP's and Distributors
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: CVSM (Connex Vital Signs Monitor) - All Models
CIWS (Connex Integrated Wall System) - All Models

SW Version: NIBP module SW version 2.0.2 and earlier

Serial No. / Lot Code: All

Summary: ModPG (NIBP) version 2.03 has been released to resolve ModPG ATE failures. Version 2.03 also includes updates from version 2.02 which resolved intermittent NIBP not functional issues associated with version 2.0.

Issue: ModPG ATE failures. Errors may occur during power-up and may be logged in prior to the operating system of Mod PG being up and running. A resulting watchdog reset may occur on power-up before a successful completion of POST. The ATE may then time out resulting in a ModPG failure.

Issues resolved in version 2.02

NIBP not functional. When this Error is present, it will present itself visually and audibly each time the device is turned on as follows:

- The message “NIBP Not Functional. Call for service.” Appears on the
device home tab.

- The NIBP pane in the home tab appears grey to indicate that NIBP is not available.
- The device error log will contain the following:

  
  
  (User EEPROM checksum error. Configuration data which can be set in the user's configuration menu was damaged or lost)

  or

  
  (Failed to load safety processors calibration record from EEPROM)

Notes:

- Installation of NIBP module software will clear existing “NIBP Not Functional” error, for the WACP sp[5], code[4].
- Devices with the WACP sp[6] code[1], will need to have the NIBP module recalibrated by either using the Service Tool Gold license or sending the device to Product Service.

Action

Use the Welch Allyn Service Tool, silver or gold license, to install NIBP module software version 2.0.3. If ModPG (NIBP) version 2.02 has been previously installed, upgrade to version 2.03 is optional.

- If you have the Welch Allyn Service Tool installed proceed to the section titled, “Procedure.”
- If you have not installed the service tool proceed to the section titled, “Installing the Welch Allyn Service Tool.”
- If you want to verify the version of the Service tool, proceed to the section titled, “Verify version of the Service.”

Reference to Standards

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates

- Technical Manual ☐ Repair Tool ☒
- Service Plan ☐ Internet/Intranet ☒
- Procedures ☐ Price List ☐
- Training Material ☐ Other

Service Strategy

CVSM or CIWS devices will be updated to ModPG (NIBP) version 2.03. If ModPG (NIBP) has been previously updated to version 2.02, it is not necessary to update to version 2.03. ModPG (NIBP) version 2.03 software is compatible with all previous versions of CVSM/CIWS host software versions.

Software package ModPG (NIBP) version 2.03, shall be automatically distributed through PartnerConnect to all PMP models. The update will be installed using the Welch Allyn service tool.

Customer devices requiring an upgrade that are not available remotely will need to be returned to Welch Allyn. Loaners if available will be provided, normal charges apply.
Customers calling Technical Support with the NIBP EPROM issue sp5 error code 4, will have the option of:

- Using the service tool to update the NIBP software.
- Returning the device to Welch Allyn for repair. Loaners, if available, will be provided free of charge for device with ModPG (NIBP) v2.00.

The software update package listed below has been created on PartnerConnect and is automatically pushed out to CVSM/CIW when the device is connected to the service tool:

- NIBP Upgrade v2.03

Required Training

All Welch Allyn employees and contractors engaged in the service and repair of the CVSM / CIWS shall complete a training record indicating they have read and understand this document. The local service center shall maintain a file of training records for their service personnel.

Required Tools

Welch Allyn Service Tool version 1.5.0. or later:

- Order the CD, REF 103521
  Download from Welch Allyn: http://www.welchallyn.com/promotions/services/serviceTool.htm

Required Materials


NIBP Software version 2.03 (automatically distributed via PartnerConnect)
  Also available from:
  Partner Connect SW package: NIBP Upgrade v2.03
  SAP DIR 50010827 version A, SWF: MOD PG v2.03

Quality Process for failed units or components

NA

Procedure

Perform software upgrades

1.) Install the Welch Allyn Service Tool on a PC.
2.) Connect the device to AC power.
3.) Connect the USB type A-to-mini-B cable, connecting the A end to the PC and the mini-B end to the client USB port on the device.
4.) Start the PC and launch the service tool, if the simple user interface screen opens, click Service.
5.) Log on using the default user ID ADMIN and no password, click Log on; or using your facility account ID and password.
6.) Turn the device on. The device appears on the service-tool Device list tab.
7.) Highlight the device on the Device list tab and click Select.
8.) From the device tab, click the Upgrade tab.
9.) Select NIBP Sensor from Device table.
10.) Click, Upgrade, Yes.

**Note:** The upgrade indicator pauses while the device reboots. If the device fails to reboot it may be necessary to manually reboot the device. In the event the device failed to reboot at least 99% it will show up as a boot loader. If the upgrade will not proceed from this point it will be necessary to return the device to product service.

11.) Wait for the upgrade to complete. The total upgrade process should take approximately 3-5 minutes.

12.) Once the upgrade is complete the service tool will return to the Welch Allyn Connex Device tab. Verify device firmware version in the table:

   NIBP Sensor – 2.0.3

13.) Close Welch Allyn Connex Device tab. **Wait for tab to close before disconnecting device** (this allows upgrade information to be sent to PartnerConnect).

### Installing the Welch Allyn Service Tool

Follow the instructions in the Welch Allyn Service Tool Installation and Configuration Guide to install the service tool.

[http://www.welchallyn.com/promotions/services/serviceTool.htm](http://www.welchallyn.com/promotions/services/serviceTool.htm)

### Verify version of the Service Tool

1. Launch the service tool.
2. Click Service.
3. Login.
4. Click Help, About Service Tool.
5. Verify the version of service tool is 1.5.0.0

### 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.

### Trouble shooting

If upgrade fails and the device is still available in the service tool, retry the upgrade process several times. If the upgrade cannot be completed successfully, RMA device to product service.

**Note:** If there is a failure of the upgrade process, it is acceptable to attempt the upgrade process again. This is acceptable because a failure of the upgrade process is not a failure of the NIBP module.

Devices with the WACP sp[6] code[1], will need to have the NIBP module recalibrated by either using the Service Tool Gold license or sending the device to Product Service.
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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D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL.