



Technical Service Bulletin

Monitoring Products

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Bulletin Type: As Needed

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- Subject:** TSB - CVSM_CIWS, 1.70.04, Update
- 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:** CVSM/CIWS Host SW version 1.70.03 and earlier
Note: This release does not support using patient query with Connex VM version 1.x. Connex VM 1.x customers using patient query will need to upgrade to Connex VM 2.0 before installing this update.
- Serial No. / Lot Code:** All
- Summary:** CVSM/CIWS host software version 1.70.04, has been released to resolve initial power up NIBP start button functional issues, and "NIBP not functional. Call for service." Error message due to a kinked or pinched hose.

Issues:

1. **Initial Power Up NIBP Start Button (1.70.0x).** Upon initial power up the NIBP start button is available to the user prior to NIBP being functional. Early selection of the NIBP start button may result in the NIBP not being responsive or; a technical alarm being displayed “NIBP Not Functional, Call for Service”. Subsequent clearing of the technical alarm causes the NIBP to be grayed out. This can be identified by error code state [4], proxy error [7] in the error log.

Host SW version 1.70.04 will not allow selection of the NIBP start button until after the NIBP module (ModPG) has completed POST (Power on Self-Test) and is ready for use. A spinner icon will be presented in the UI (User Interface) in place of the NIBP start button, until the NIBP has completed initializing.

2. **NIBP Not Functional. Call For Service (1.70.0x).** The NIBP error code, species 6 code 10, is mapped to display a technical error “NIBP not functional. Call for service.” error. The species 6 code 10 is detected when the pressure difference between the primary and safety transducers is 40 mmHg or greater. The different pressure reading between the transducers may be caused by any of the following: a pinched or kinked hose (most likely), an open dump valve, or one or both of the transducers may be out of calibration.

Host SW version 1.70.04 changes the status message, for above described conditions, and allows the NIBP to be retried. A device with a kinked hose will display message, “**Unable to determine NIBP, check connections and tubing for kinks**”. In addition, Autozero failures will now be logged into the device log file.

Action:

Customers experiencing either of the issues addressed in this release will be offered the option of updating their devices to version 1.70.04. Inform customers that this update will also be part of a major upgrade planned this fall.

To deliver the software update, locate the customers PC in PartnerConnect and select the action to download the 1.70.04 from the WA ServiceTool dashboard actions pane. The action is named: *Download CVSM/CISW 1.70.04 Package*.

Some customers may not want software updates. Verify with customer that the software update(s) are acceptable to use in their facility. Examples of reasons customers may not want update; keep all devices at same version, internal evaluation required, prefer to wait for next major software update. If the customer indicates they do not want software update(s), Tech Support is to note on the RMA: “DO NOT UPGRADE SOFTWARE”. Add additional supporting information as needed.

Reference to Standards:

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

References:

20013147 TSB-CVSM_CISW, NIBP Not Functional, Call for Service
20013149 TSB-CVSM_CIWS, NIBP Start Timing
20013154 TSB – WAST, Restoring Bootloader Devices

Updates:	Technical Manual	<input type="checkbox"/>	Repair Tool	<input type="checkbox"/>
	Service Plan	<input type="checkbox"/>	Internet/Intranet	<input checked="" type="checkbox"/>
	Procedures	<input type="checkbox"/>	Price List	<input type="checkbox"/>
	Training Material	<input type="checkbox"/>	Other	

Service Strategy:

The Technical Support group will push the 1.70.04 update to customers identified by marketing and others requesting this update.

Customers shall be informed that this update will be included as part of a major upgrade planned for release in October if they wish to avoid having to perform another upgrade in a few months.

The upgrade package includes the latest updates for all subsystems (with available updates; SpO2 and NIBP) and should be installed by selecting the “upgrade all” button in WAST to ensure all software is updated to current levels. Updates for the subsystems will not appear if the current software was previously installed.

The update package is made available to the WA ServiceTool model to avoid having to download the package for each device.

The CVSM/CIWS Minimum Hardware/Software Level Requirement (DIR 20012631) will be revised to make 1.70.04 the new minimum software level for devices returned for service. Customers returning devices for service may choose to opt out of receiving software updates. The customer’s choice to opt out will be noted on the RMA.

Required Training:

All Welch Allyn employees and contractors engaged in service and repair of CVSM/CISW shall complete a MPD FCD-1493 Individual Employee Compliance Training Record indicating they have read and understand this document. The MPD FCD-1493 is to be filed locally.

Required Tools:

The customer will need: Welch Allyn Service Tool version 1.5.0. or later

Required Materials:

Software available from PartnerConnect:

Download CVSM/CIWS 1.70.04 Package

Quality Process for failed units or components:

For customer device’s that fail to update properly create an RMA. Where ever possible download device error and event logs and the PTSS log. The PTSS log is stored in:

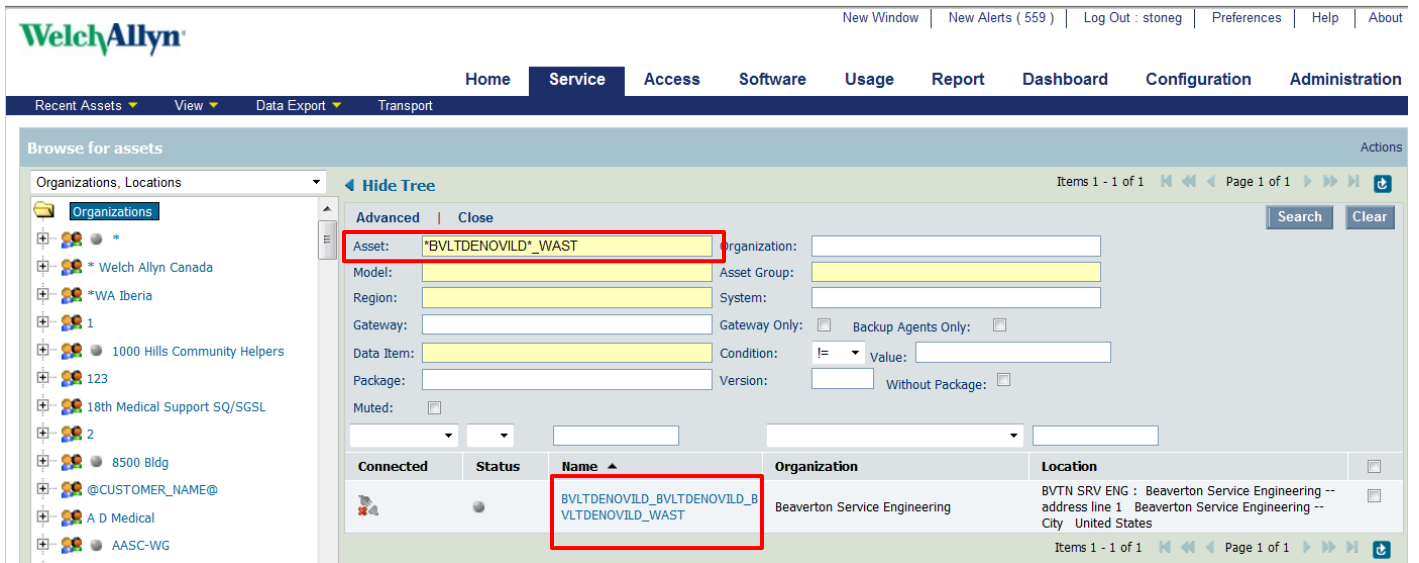
- **Windows XP:** C: Documents and Settings\All Users\Application data\Welch Allyn Service Tool
- **Windows 7:** C:\ProgramData\Welch Allyn Service Tool

Attach the log files to the RMA and email Service Engineering with the SAP notification.

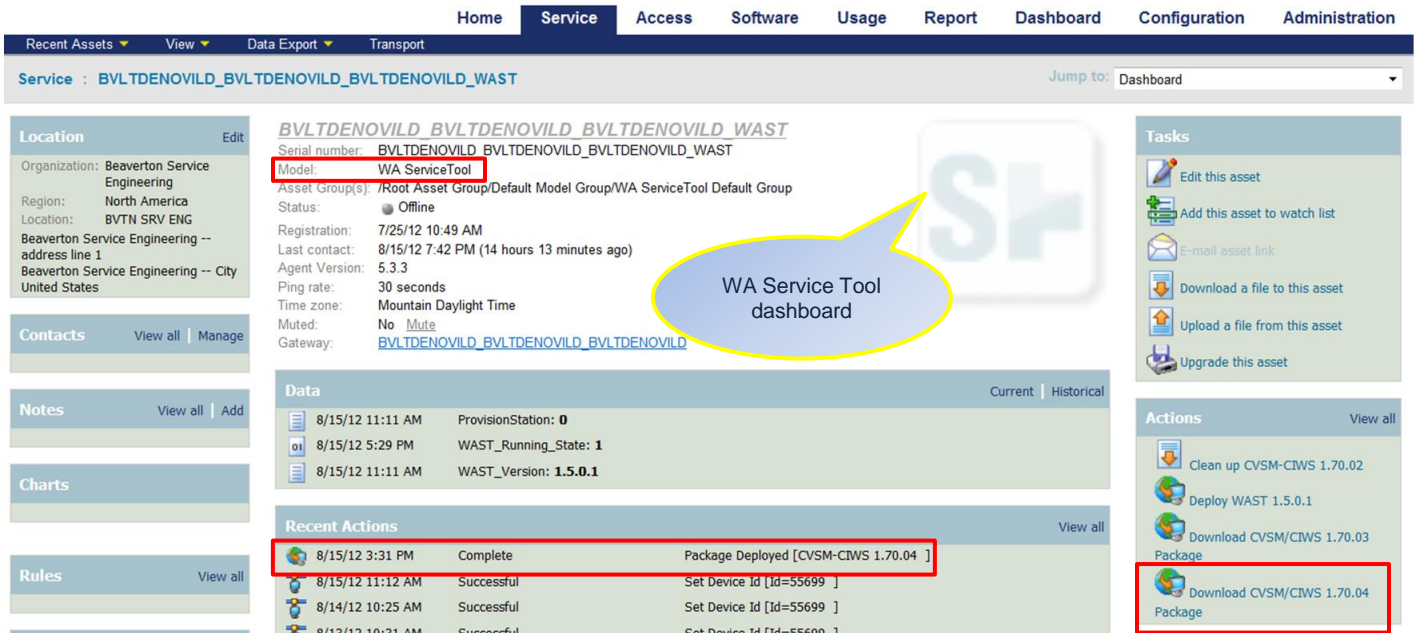
Refer to DIR 60027700, Portable Monitor Platform Repair and Service Plan, section 5 Repair Part Retention.

Procedure:

1. Log on to PartnerConnect: <https://welchallynsolutions.com>
2. Go to the Service tab.
3. In the asset field enter the customer’s computer name or registered serial number enclosed with asterisks, followed by “_WAST”, click **Search**.
4. Select the customer’s computer by clicking on the customers computer name in the list, with the “_WAST” ending, to open the WA ServiceTool dashboard screen.



5. On the right side of the dashboard, in the actions pane, select, “Download CVSM/CIWS 1.70.04 package”.



6. Confirm that you want to execute the action by clicking **Execute**.

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7. Confirm the package appears in the recent actions pane (center screen). The initial status will be; waiting to deliver. After a minute the status will change to: started, and finally to complete.

Trouble shooting: PartnerConnect

If the package download fails to complete, verify the computer is connected and restart the download.

To verify the customer's computer is still connected, check the last contact time, it should be less than 30 seconds ago.

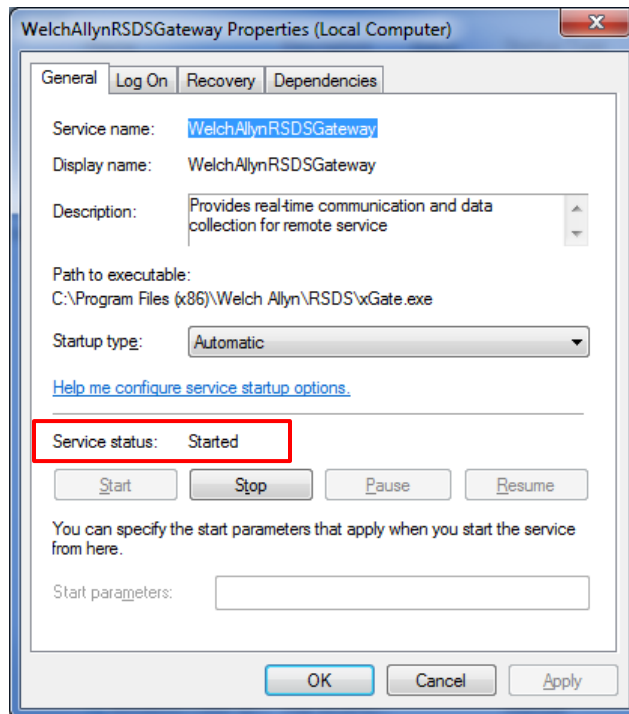
20110400040_PDXPFACTSVC13_WAST

Serial number: 20110400040_PDXPFACTSVC13_WAST
Model: WA ServiceTool
Asset Group(s): /Root Asset Group/Default Model Group/WA ServiceTool Default Group
Status: ● Good
Registration: 7/25/12 2:34 AM
Last contact: 8/16/12 9:58 AM (29 seconds ago)
Agent version: 5.3.3
Ping rate: 30 seconds
Time zone: Atlantic Daylight Time
Muted: No [Mute](#)
Gateway: [20110400040_PDXPFACTSVC13](#)



If the computer disconnected check the status of the WelchAllyn RSDS Gateway service and verify it is started. Verify the PC has an internet connection.

1. From the Start menu open the control panel
2. Open Administrative tools
3. From the list of administrative tools select Services
4. From the list of services select WelchAllyn RSDS Gateway



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WAST

If upgrade fails and the device is still available in the service tool, retry the upgrade process several times.

If the main software does not install correctly the device may appear in the service tool as a Bootloader device. Refer to TSB 20013154, “TSB- WAST, Restoring Bootloader Devices”

After completing a successful SpO2 upgrade, Masimo or Nellcor, the WAST upgrade screen will continue to show an available SpO2 upgrade. It is not necessary to repeat the upgrade process.

If the upgrade cannot be completed successfully, RMA device to product service. Save the device error log, event log, PTSS log and attach to the RMA.

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

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	DD	D*	D*
B	Replace WA-Gateway deployment with, WA ServiceTool deployment. Add PartnerConnect screen shots in procedure. Update Required Training section.	D*	DD	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					