



Technical Service Bulletin

PATIENT MONITORS SYS

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- Subject:** TSB-CVSM/CIWS 1.71.03 RELEASE
- Distribution Scope:** Welch Allyn Global Technical Support, Product, Field & Customer Service. WA ASP's and Distributors
- Product(s) Referenced:** CVSM (Connex Vital Signs Monitor) – Models 6300, 6400, 6500
CIWS (Connex Integrated Wall System) - All Models
- Summary:** CVSM/CIWS host software version 1.71.03 and updated FSS module software has been released to improve device stability. This release contains the following improvements and feature enhancements:
- Corrects an issue where patient queries failed due to truncated data or case sensitivity introduced in Host version 1.71.02. This corrects the Cerner EMR compatibility issue discussed in CSB 20013341, CVSM/CIWS 1.71.02 Patient Query Impact
 - Prevents a wrench 01 error when over 300 patient records are stored on the device
 - Prevents a wrench 01 or 06 error during boot, software update, or shut down
 - Prevents a wrench 14 error when updating FSS module software
 - Prevents a “NIBP Not Functional, Call for Service” error at high temperatures. This error would be recorded in the error log as follows:
BUF:Nibp Error: WACP sp[6], code [18]
 - Prevents errors when loading a configuration file that was exported from a device with a different version of host software

- Improves MAP calculation when heart rate is greater than 100 BPM on non-Neonate cycles
- Resolves issues where the device displayed the incorrect date and implements a time sync request every 15 minutes
- Adds ability to export device error and event logs to an external USB drive. To export the logs, connect an external USB drive to the CVSM, navigate to the Advanced > Service > Logs menu, and touch “Save to USB.”
- Enhances feature set for the clinician password. When entering the password, characters are now displayed as asterisks. The following characters are now accepted:
}] | \ ~ ` \$ % ^ + = { [
- Wireless authentication parameters are now obfuscated when entering into the device UI or exporting the configuration file to an external USB drive.
- Adds support for additional barcode scanners available from Welch Allyn:
Xenon 1900 – Part Number: 6000-916
JADAK HS1M – Part Number: 6000-916HS
- The comms module hardware and NIBP safety software versions are now displayed in the Advanced > Service > Device menu.

Note: Improvements for stability of software updates will not be in effect until after the device has been successfully updated to this version.

Issue: See Appendix A for a list of resolved issues and new features.

Action:

CVSM/CIWS software version 1.71.03 package will be **Auto-deployed** via PartnerConnect.

Technical Support:

Customers experiencing any of the issues addressed in this release should be advised to upgrade their devices to version 1.71.03 via the **Upgrade all** button in the WAST. Individual FSS or host updates are not recommended.

If required, manually push software updates using PartnerConnect; see the **Download CVSM/CIWS 1.71.03 Package** in the Procedure section of this document for instructions on this process.

If creating an RMA for CVSM or CIWS, always ask the customer if there is any reason they might not want the software updated. Some customers may not want software updates. Examples of reasons customers may not want an update: keep all devices at same version, internal evaluation is required, preference to wait for the next 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.

Product Service Centers:

The CVSM/CIWS Minimum Hardware/Software Level requirement document 20012631 has been updated to make the CVSM/CIWS host software version 1.71.03 the minimum software level.

Before upgrading the software verify the RMA does not indicate the device should not be updated.

Software Compatibility:

The following table depicts the software compatibility between the host and subsystems. New software versions included in this release are **bold**.

To promote use of the most recent configuration, host version 1.71.03 is not backwards-compatible with older versions of FSS software included in this release. All modules should be updated simultaneously.

Note: Braun dock main and boot software have been included in the 1.71.03 software distribution package, even though they have not been revised as part of the 1.71.03 release.

Host (Boot)	Comms	Radio Server (Kernel)	Sure Temp Plus (Boot)	Masimo WUI SpO2 (Boot) [MX]	Nellcor WUI SpO2 (Boot)	NIBP Core (Boot) [Safety]	Braun dock (Boot)	Weight Scale Adapter (Boot)
1.71.03 (1.71.03)	1.00.00 A0003	2.30.00 (4.1.26)	2.02 (1.02)	2.09 (1.04) [7.5.1.3]	1.00.14 (1.00.14)	2.05 (1.02) [1.03]	1.00.03 (1.00.01)	1.0.26 (1.0.2)
		2.30.02 (4.1.30)						
		2.30.03 (4.1.31)						
		3.00.00 (5.0.0)						
		3.00.01 (5.0.1)						

The following table depicts software compatibility between this release and supporting software systems:

	CVSM/CIWS 1.71.03
WAST 1.5.0.0	Fully Compatible
WAST 1.5.0.2	Fully Compatible
WAST 1.6.0.0	Fully Compatible
Connex VM 1.1	Compatible, except for Match to Save Features. When querying on the device with match-to-save enabled, the user will get an “Unable to identify Patient. Touch Clear to delete all data” information message.
Connex VM 2.0 with WelchAllyn.IO.DLL 2.6.3	Fully Compatible
Connex VM 2.0 with WACP.DLL 2.7.0.0 & WelchAllyn.IO.DLL 2.8.0.26651	Device displays '???' for NULL clinician fields returned from a query
Connex VM 2.0.1	Fully Compatible
DataCatcher 4.00.0.00020	Fully Compatible
Connectivity SDK 2.3	Fully Compatible

Reference to Standards:

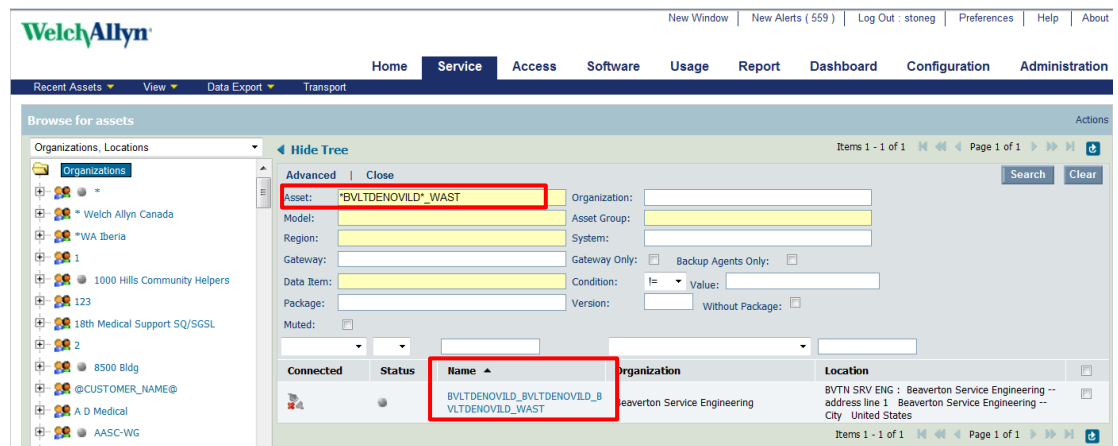
- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Required Training: Ensure training records are updated, as applicable, for personnel engaged in the service and repair of products referenced in this bulletin for the following documents:

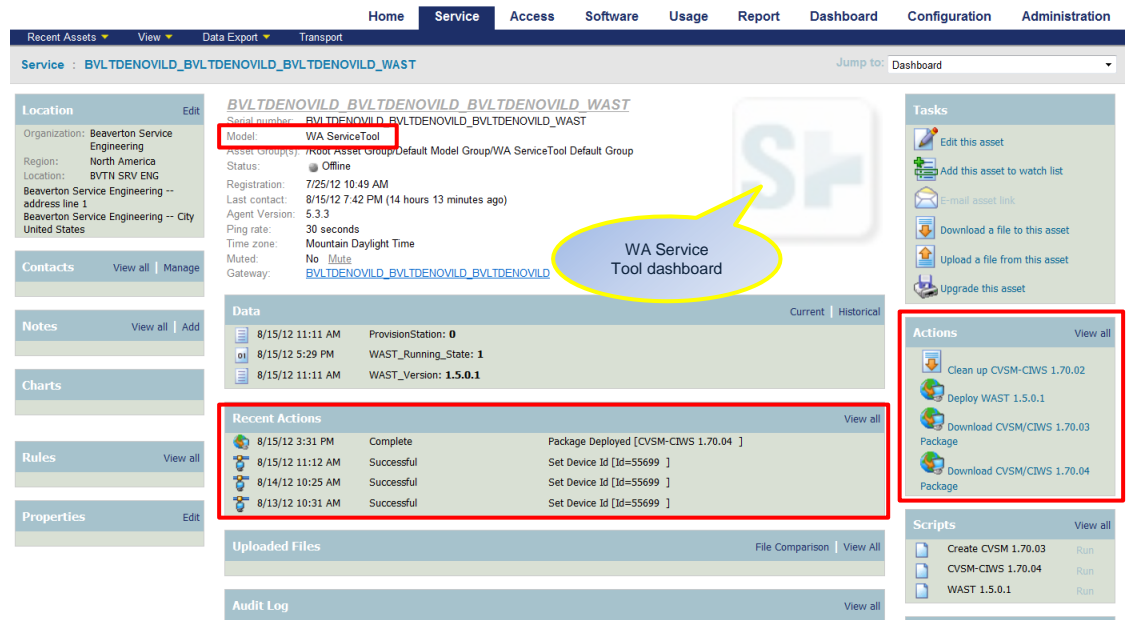
- 20013291 ver A, TSB-CVSM_CIWS 1.71.03 RELEASE (this document)
- 20012631 ver N, CVSM MIN HW/SW REQUIREMENTS

Procedure: **Download CVSM/CIWS 1.71.03 Package** (If required, manual push)

1. Log on to PartnerConnect: <https://welchallynsolutions.com>
2. Go to the Service tab.
3. In the asset field enter the customer's computer enclosed with asterisks, followed by "_WAST", click **Search**. Example: *acmecomputer*_WAST.



4. Select the customer's computer by clicking on the customer's computer name in the list, with the "_WAST" ending, to open the WA ServiceTool dashboard screen.
5. In the *Actions* section on the right side of the dashboard, select **"Download CVSM/CIWS 1.71.03 package"**.



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

The package will be downloaded to:

Windows XP: C:\Program Files\Welch Allyn\RSDS\DefaultProject\WA ServiceTool\Downloads\PMP1.71.03

Windows 7: C:\Program Files (x86)\Welch Allyn\RSDS\DefaultProject\WA ServiceTool\Downloads\PMP1.71.03

Quality Documents: **All service centers using SAP to record service transactions:** For each product serviced, record the service activity in SAP.
All other service centers and Field Service: For each product 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*	CB	D*	D*
D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL					

Appendix A: Issues Resolved & New Features

Issues Resolved:

- TFS 27152** Nellcor - Fix the USB power disconnect/delay before coming off the USB bus to prevent a wrench 14 when upgrading the module software.
- TFS 27177** ModPG (NIBP) – Switch to the internal oscillator to prevent module errors at high temperatures: "NIBP Not Functional, Call for Service" - Species 6 Error Code 18.
- TFS 27179** ModPG (NIBP) – Fix the USB power disconnect/delay before coming off the USB bus to prevent a wrench 14 when upgrading the module software.
- TFS 27182** ModPG (NIBP) – Added code to recalculate the MAP value after the diastolic is updated if the heart rate is greater than 100 and this is not a neonate cycle.
- TFS 27189** SureTemp – Fix the USB power disconnect/delay before coming off the USB bus to prevent a wrench 14 when upgrading the module software.
- TFS 27194** Prevent wrench 01 error during NIBP upgrade

New Features:

- TFS 9917** Allow time to be set on production ATE, so that the log entries are unique. Preserve current behavior that the "Set Time and Date" message appears until the customer sets the time and date.
- TFS 11491** Hide the Clinician password during entry by displaying asterisks instead of the actual characters.
- TFS 11545** Support additional special characters for the clinician password. }] | \ ~ ` \$ % ^ + = { [
- TFS 14907** Add the ability to export the Error and Event logs to a USB flash drive.
- TFS 17485** Adds support for new Barcode scanners: Xenon 1900 and new HS-1.
- TFS 21381** Protect the wireless authentication parameters when exporting the CVSM configuration file by obfuscating the displayed text in the exported configuration file; specifically the network passkey, and the EAP username and password.
- TFS 23010** Show Communication module hardware version on Service, Device table.
- TFS 23098** Prevent wrench error with configurations transfers between different software versions. Automatically revert to factory default configuration, if importing a configuration item that is newer than the software understands.
- TFS 23445** Add NIBP safety processor software version to the Device table.

- TFS 24194** Fix NIBP proxy to send the clear safety status commands less frequently. Corrects an issue in which the device is sending too many clear requests to the NIBP sensor which can cause a wrench error.
- TFS 24307** Prevent race condition between the USB Hub checker Thread and USBX Enumeration Thread to prevent a wrench 14 when upgrading FSS module software.
- TFS 25802** Add information messages, for the Braun thermometer to address when:
- Braun handle is not docked properly.
 - Braun handle is docked properly but does not contain a new temperature to transfer to the device.
- In each case, the device would display "Temperature not functional. Call for service". New messages for noted conditions are ""Thermometer docked improperly. Check contacts and connections," and, "Unable to detect temperature. Retry Measurement."
- TFS 26485** Allows device to set the time on the radio card.
- TFS 27156** Hide wireless authentication parameters when they are being entered on front panel of device by replacing characters with asterisks. Affects PSK passphrase and network key, EAP password, and WEP keys.
- TFS 27539** Modify software to restore backwards compatibility of patient query interface. Patient query behavior has been rolled back to host version 1.70.04 functionality. The match-to-save feature now compares the GUID of the response to the GUID of the query. This change prevents failures of match-to-save due to case sensitivity or data that is truncated by the EMR.
- TFS 27574** Prevent a wrench 01 error when over 300 patient records are stored on the device.
- TFS 27607** Update the boot loader so BOOT mode cleanly gets off the USB Bus, to prevent errors during software updates.
- TFS 27609** Address Real Time Clock drift. Resolve issues where the device displayed the incorrect date (e.g. year 1970 or 2086). Implement a time sync request every 15 minutes.
- TFS 27619** Prevent a wrench 01 or 06 during boot, software update or shutdown due to issue with BOOT NFC Bad Block Management Code.

Appendix B: Troubleshooting

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

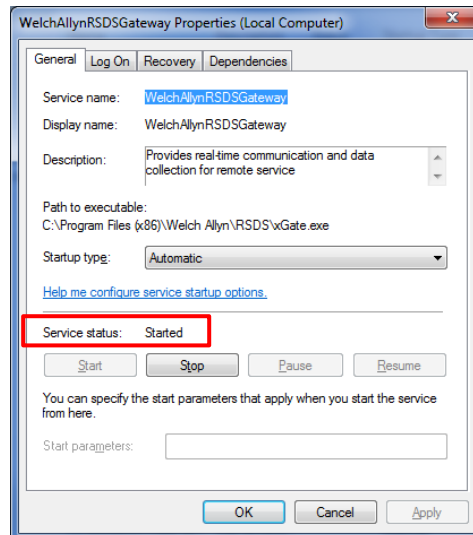
To verify the customer's computer is still connected, check the last contact time, it should be less than 30 seconds ago.

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 customer's computer is disconnected, ask the customer to check the status of the WelchAllyn RSDS Gateway service and verify it is started. From the Start menu, open the control panel

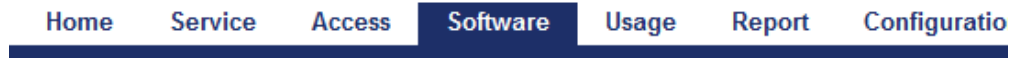
1. Open Administrative tools
2. From the list of administrative tools select Services
3. From the list of services select WelchAllyn RSDS Gateway
4. From the WelchAllyn RSDS Gateway properties dialog box stop the service and restart the service.



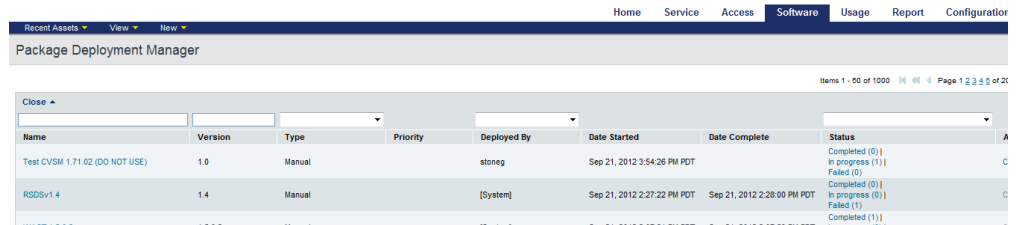
5. If the problem persists verify the PC has an internet connection.

If the customer's computer is connected but the download has not completed, check the status of the download as follows:

1. Select the Software application (tab) in PartnerConnect



2. Select: View packages that are deployed or in progress
3. Filter by your name in the deployed column to see the packages deployed under your account



Name	Version	Type	Priority	Deployed By	Date Started	Date Complete	Status
Test CVSM 1.71.02 (DO NOT USE)	1.0	Manual		stoneg	Sep 21, 2012 3:54:26 PM PDT		Completed (0) In progress (1) Failed (0)
RSDSv1.4	1.4	Manual		[System]	Sep 21, 2012 2:27:22 PM PDT	Sep 21, 2012 2:28:00 PM PDT	Completed (0) In progress (0) Failed (1) Completed (1)

4. Observe the status in the second column from the right
5. If the status is "Failed". Return to the WAST dashboard and restart the Action.

If the status is "In progress" wait up to 30 minutes for the download to complete, before canceling the download and reinitiating the download from the WAST dashboard.

WAST:

If upgrade fails and the device is still available in the service tool, retry the upgrade process several times. You may also try using a different USB port on the PC and/or a different USB cable. Avoid using a USB 3.0 port, these have a blue connector.

After completing a SpO2 upgrade, the WAST upgrade screen will continue to show an available SpO2 upgrade. It is not necessary to repeat the upgrade process if the WAST indicates the most recent version is installed.

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"

If the upgrade cannot be completed successfully, RMA device to Product Service. Where possible, download the device error and event logs and the PTSS log, and attach the log files to the RMA. 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