



Technical Service Bulletin

Monitoring Products

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Subject: TSB - CVSM_CIWS, 1.71.02, Release

Note: This document was revised to version C to add Canada to the list of countries approved for Office Profile. CVSM/CIWS version 1.71.02 has been superseded by version 1.71.03 reference DIR 20013291 for additional information. Reference DIR 20012631 CVSM/CIWS Minimum HW/SW levels for current requirements.

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: Applies to CVSM/CIWS with Host SW version 1.70.04 and earlier

Serial No. / Lot Code: All CVSM before 103001754012
All CIWS before 100012444112

Summary: CVSM/CIWS host software version 1.71.02, has been released to add Office Profile with NIBP averaging, resolve issues discovered in previous releases, modify time sync, and add the Match to Save feature. The Office Profile feature is controlled by a device license and is restricted for use in the United States and Canada only at this time. The Office Profile license will be activated on all new CVSM model 63-XXXX-B and CIWS model 84-XXXX-B for distribution in the United States and Canada. Activation of this license on existing devices will be a free upgrade, by request, for customers in the Office Profile approved countries.

Note: Registration has been completed for Canada and the DC status for

plant 1250 has been removed in SAP

Note: The Office Profile license check box will not appear in the devices advanced settings Licensing tab until the license is installed.

Issues resolved:

TFS #8565 USB Flash drive leads to wrench error on quick insert and removal – It was possible to cause the CVSM to wrench by quickly inserting and removing a USB flash drive

TFS #9110 PMP does not close WACP connection correctly on shutdown – It was possible to cause a PC host to have an Ethernet connection to the CVSM remain open if the CVSM was powered down while communicating with a host

TFS #9531 Patient query does not work with PMP 1.7 and Connex VM 1.1 – The CVSM will process a patient query response from Connex VM 1.1 and 2.0 correctly.

TFS #9695 PMP should not delete the thread when closing a WACP connection – It was possible to cause the CVSM to crash by scanning a patient barcode rapidly, initiating many patient queries, or by repeatedly pressing the Network Test button in the Advanced Settings, Network, Server menu.

TFS #9770 'Unable to retrieve list.' message displayed after successful patient list retrieval – The CVSM will not show an incorrect message when scanning a patient, clinician, or when retrieving a patient list.

TFS #10051 Touch screen calibration messages do not appear – The on-screen text messages associated with the touch screen calibration have been restored.

TFS #11592 PMP intermittently loses network connectivity – On very busy networks, the wired Ethernet connection could become non-operational. This has been fixed with improved robustness of the Ethernet connection.

TFS #12467 CVSM loses wired Ethernet connectivity if there is lots of ARP broadcast on the network – This is similar to above.

TFS #12657 Error and event log improvements – A few small changes have been made to the content of the log files.

TFS#13062 Radio Abort causes CVSM wrench while sending records – The interface to the radio has been improved to minimize device assertions (wrenches), and to allow the CVSM to better recover when it experiences problems communicating with the radio.

TFS #16613 Radio configuration parameters do not restore correctly

after being set to default values – This fixes a case where the EAP type is incorrectly imported from a USB flash drive.

TFS #24291 Unable to restore radio settings – The CVSM did not wait long enough in all cases for a radio to reboot after its configuration was changed (via UI, or USB flash drive import). The wait has been extended. This is also a preventive measure for the introduction of the FIPS version of the radio, which takes longer to boot.

TFS #26408 CVSM will wrench on clinician query response handling– It was possible to cause the CVSM to wrench by sending a clinician (from a host, as the result of a query or authentication) with a NULL first, last, middle name, or a NULL ID. See *Compatibility support and system software section below*.

New Features:

TFS #17751 Time Sync: Automatic Management of Device Time Sync – This change will cause the CVSM to sync just after 2 AM each day, to minimize the time that the device is one hour behind/ahead on the days that daylight saving time starts/ends. The CVSM will still sync five minutes after it is turned on, but instead of syncing again 24 hours later, it will sync at 2:05 AM (+/- random offset) every morning. Once the time sync completes an algorithm calculates the amount of time from the current time until 2:05 AM and creates a timer based on that difference +/- a random offset to prevent all CVSMs from requesting time sync at the same time.

TFS #18736 Support NIBP averaging algorithm – This is an NIBP program mode, available only in Office Profile. The user can configure a series of NIBP cycles, and at the end of the program, the CVSM will display an average of the readings. See the DFU addendum for Office Profile (P/N 105010) for more information.

TFS #18875 Add Office Profile to PMP – This is a new profile, designed for ambulatory care. It allows the user to do more from the home screen, such as enter height and weight. This profile supports the NIBP averaging program. See the DFU addendum for Office Profile (P/N 105010) for more information.

TFS #22156 Provide capability to require a successful patient/clinician query before a test can be saved – Adds the “Match to Save” configuration options needed to require the user to successfully query a patient and/or clinician from Connex before the user is allowed to save a test. See the DFU addendum (P/N 105218) for more information.

Open Known Issues:

TFS #7662 PMP shuts down without AC connected unless charged passed 20%.

TFS #7695 CVSM USB hub crashes when plugging in USB device

TFS #15582 Resolved in version 1.71.03.
Wrench 1 if 400 patient records are becoming too old simultaneously

TFS #23255 Device assertion during software upgrade.

TFS #24158 Resolved in version 1.71.03

Device crash when unable to clear some NIBP sensor errors

TFS #24306 Resolved in version 1.71.03

Device will wrench (00000014) when upgrading module software

TFS #27228 Resolved in version 1.71.03.

CVSM is case sensitive to patient ID while Connex VM is not. When the *Search by patient ID* advanced setting is checked, the patient query will fail if the patient ID case is different from the patient ID case on the server. The failure mode is dependent on the *Require patient ID match to save measurements* setting as follows:

- If the *Require patient ID match to save measurements* setting is **not checked** no patient information is returned and the user may continue to save the patient's readings with the unmatched patient ID. If user sends saved data, Connex VM will accept the data into the patient ID that exists regardless of case sensitivity.
- If the *Require patient ID match to save measurements* setting is **checked** the user will be unable to save the patient's readings.

Compatibility with subsystem software:

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)
1.71.02 (1.71.02)	1.00.00 A0003	2.20.00 (4.1.22)		1.0.2.0 (1.0.2) [7.5.1.3]		2.00 (1.00) [1.00]		
		2.30.00 (4.1.26)		1.7.3 (1.0.2) [7.5.1.3]	1.00.12 1815 (1.00.01 0528)	2.02 (1.00) [1.01]	1.00.02 (1.00.00)	1.0.25 (1.0.1)
		2.30.02 (4.1.30)	2.00 (1.00)	2.0.7 (1.0.3) [7.5.1.3]	1.00.13 (1.00.01 0528)	2.03 (1.00) [1.02]	1.00.03 (1.00.01)	1.0.26 (1.0.2)
		2.30.03 (4.1.31)	2.02 (1.02)	2.0.7 (1.0.3) [7.8.0.5]	1.00.14 (1.00.14)	2.05 (1.02) [1.0.3]		
		3.00.00 (5.0.0)		2.0.9 (1.04) [7.8.0.5]				
		3.00.01 5.0.1						

Compatibility support and system software:

Host Software	Host Notes	CVSM/CIWS 1.71.02
WAST 1.5.0.0	Original WACP 2.0	Fully Compatible
WAST 1.5.0.2	New NIBP and PMP plug-ins WACP 2.0	Fully Compatible
WAST 1.6.0.0	See TSB-Welch Allyn Service Tool- WAST v1.6.0.0 DIR 20013381	Fully Compatible
Connex VM 1.1, WelchAllyn.IO.DLL 2.3.3.19218	"1.1" is the version the user sees, not the build number The WelchAllyn.IO.DLL includes the WACP.DLL functionality WACP 2.0	Fully Compatible
Connex VM 2.0, WelchAllyn.IO.DLL 2.6.3	"2.0" is the version the user sees, not the build number The WelchAllyn.IO.DLL includes the WACP.DLL functionality WACP 2.0	Fully Compatible
Connex VM 2.0, WACP.DLL 2.7.0.0, WelchAllyn.IO.DLL 2.8.0.26651	No change to Connex Exeter Patch WACP stack is now its own DLL WACP 2.1	Device displays "???" for NULL clinician fields returned from a query
Connex VM 2.0.1, WACP.DLL 2.8.3.0, WelchAllyn.IO.DLL 2.9.0.14850	"2.0.1" is the version the user sees, not the build number WACP 2.2 that is backwards compatible with WACP 2.0, 2.1	Fully Compatible
DataCatcher 4.00.0.00020	WACP 2.0 is embedded in DataCatcher.	Fully Compatible

New Materials:

105294 Office Profile license

105218 Addendum, Connex Device 1.7X DFU, ML (Multi-language) (P/N 719211)

105010 Addendum, Office Profile, PDF, ML (P/N 718680)

Action:

Technical Support action:

See DIR 20013291 TSB-CVSM/CIWS 1.71.03 RELEASE

Technical Support action to deliver authorization code for Office Profile license:

Tech support will receive service notifications created by Customer Care to provide the Office Profile license and this software upgrade to select US and Canadian customers. In order to execute the service notification it must include the name of the computer to push the software and license to and customer contact information. If this information is missing from the service notification contact the Customer Care representative that created it and ask them to properly complete the notification.

Office Profile is only approved for use in the United States and Canada. Before deploying the Office Profile package verify the customers registered location information in the PartnerConnect.

To deliver the authorization code using PartnerConnect see the **Download Office Profile Authorization Code** in the Procedure section of this document.

Product Service action:

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

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

When replacing the MCE on a device that had the Office Profile license installed download the authorization code from PartnerConnect to activate the Office Profile license. See **Download Office Profile Authorization Code**.

Reference to Standards:

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

References:

- 20013291 TSB-CVSM/CIWS 1.71.03 RELEASE
- 20012631 CVSM/CIWS Minimum Hardware/Software Level Requirement
- 105218 Addendum, Connex Device 1.7X DFU, ML (P/N 719211)
- 105010 Addendum, Office Profile, PDF, ML (P/N 718680)
- 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:

CVSM/CIWS software version 1.71.02 has been superseded by version 1.71.03 refer to DIR 20013291 for additional information. Version 1.71.03 fully supports Office Profile.

Technical Support will assist Customer Care in delivering the Office Profile authorization code to US & Canadian customers requesting it. The Office Profile license is offered to customers free of charge. To minimize the expense of delivering the software and Office Profile license PartnerConnect will be utilized to push the necessary files to the customer’s computer running the Welch Allyn Service Tool.

The Office Profile authorization code package is made available in PartnerConnect to the WA ServiceTool model. The update script will create a shortcut to the Office Profile Docs folder on the remote computers desktop.

Required Training:

All Welch Allyn employees and contractors engaged in service and repair of CVSM/CIWS 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:**

Download Office Profile Authorization Code

Package includes:

Authorization code with install instruction PDF*

ADDENDUM, OFFICE PROFILE, PDF, ML (Material number 718680) PDF

QRC, OFFICE PROFILE, ENGLISH (Material number 718832)

QRC, OFFICE PROFILE, EUR FRENCH (Material number 719360)

QRC, OFFICE PROFILE, NEUTRAL SPANISH (Material number 719361)

*The Office Profile authorization code included in the download package is good for an unlimited number of licenses.

The package is down loaded to:

- *Windows XP: C:\Program Files (x86)\Welch Allyn\RSDS\DefaultProject\WA ServiceTool\Downloads\OfficeProfile Docs*
- *Windows 7: C:\Program Files (x86)\Welch Allyn\RSDS\DefaultProject\WA ServiceTool\Downloads\OfficeProfile Docs*

**Quality
Process for
failed units or
components:**

For customer devices 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:

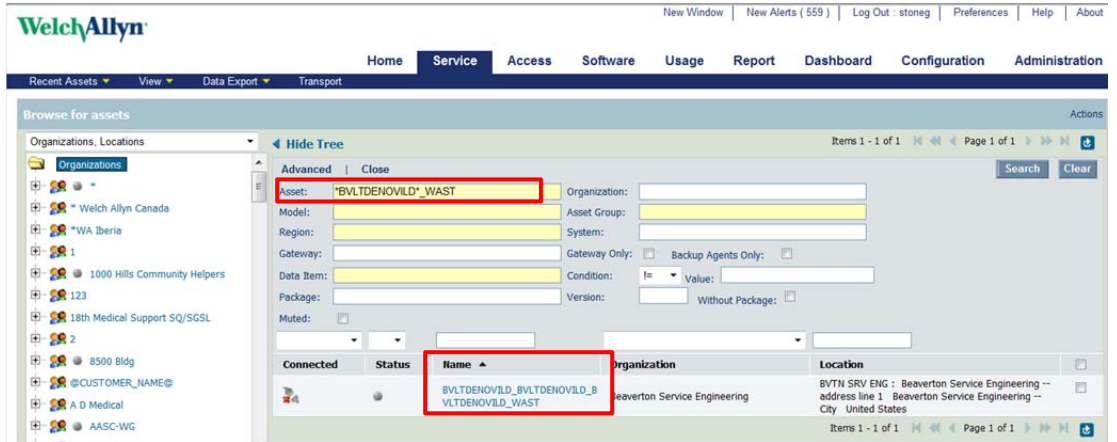
- **Windows XP:** C:\Documents and Settings\All Users\Application data\Welch Allyn Service Tool
- **Windows 7:** C:\ProgramData\Welch Allyn Service Tool

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

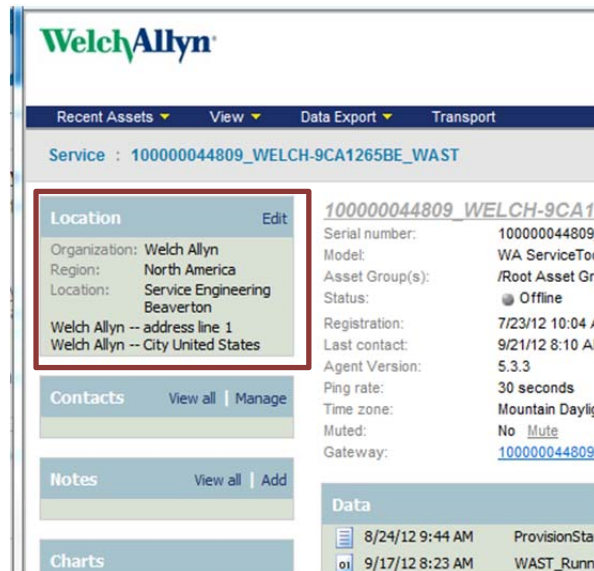
Procedure:

Download Office Profile Authorization Code

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. For customers requesting the Office Profile license, confirm the computer's registered location is in the United States or Canada by checking the Location pane in the upper left hand corner of the dashboard screen. **The Office Profile license may only be sent to computer's registered as being located in the United States or Canada.** If the location is not within the United States or Canada confirm the customer's information with Customer Care.



On the right side of the dashboard, in the actions pane, select, **"Download Office Profile Authorization Code"**.

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. If the package fails to download see trouble shooting below.

The windows script will run on the remote computer and place a shortcut to the Office Profile Docs folder containing the Authorization code and DFU addendum on the computers desktop. Customers must use authorization code with the Welch Allyn Service Tool to activate the license.

For instructions on activating the license refer to “*Activate a feature or license*” in the *Welch Allyn Service Tool Installation and Configuration Guide* packaged with the host device or available on Welchallyn.com

Troubleshooting:
PartnerConnect

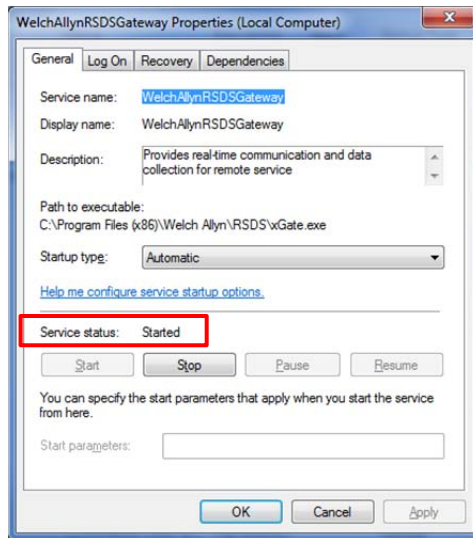
If the package download fails to complete, verify the computer is connected and restart the download.

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

If the customer’s computer 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.



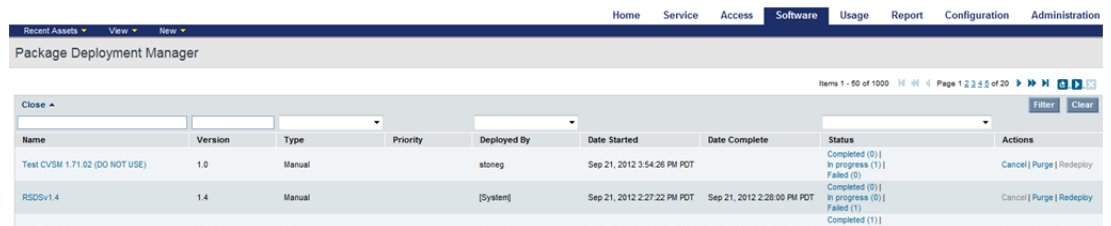
5. If the problem persists verify the PC has an internet connection.

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



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.
6. 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 dash board.

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*	GS	D*	D*
B	Add Serial numbers, Add additional detail to TFS# 17751. Add reference to TFS# 18736, 18875, and 22156. Added TFS#27228. Added option to allow service managers to add the DFU addendum to the box. Add QRC to Download Office Profile Authorization code package. Correct the procedure for downloading the OP authorization code by replacing “right hand” with “left hand” in describing the relative position of the location pane in PartnerConnect. Add additional trouble shooting steps for WAST upgrade failures.	D*	GS	D*	D*
C	Add Note below Subject section. Summary section: Add Canada to the list of countries for which Office Profile is approved. Open known issues section: add comment to those issues resolved in 1.71.03 Compatibility with Subsystem software section: Update table to include subsystem versions released after version B of this document Compatibility support and system software section: Add Compatibility with WAST 1.6.0.0 Action section: Delete action to upgrade customers to 1.71.02 refer to DIR 20013291 TSB-CVSM/CIWS 1.71.03 RELEASE References section: Add DIR 20013291 TSB-CVSM/CIWS 1.71.03 RELEASE Service strategy section: Delete strategy for upgrading customers to 1.71.02 refer to DIR 20013291 TSB-CVSM/CIWS 1.71.03 RELEASE Required materials section: Delete 1.71.02				

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	<p>package and included files.</p> <p>Procedure section: Delete procedure for downloading CVSM/CIWS 1.71.02 package. Edit the download procedure for the Office Profile authorization code to include steps from the deleted procedure for accessing the device in PartnerConnect and include Canada.</p> <p>Troubleshooting section: Delete troubleshooting failed upgrades in WAST.</p>				
D* - Refer to SAP DIR digital signature log for approval details.					