



Technical Service Bulletin

Monitoring Products

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- Subject:** TSB - Flexnet Radio FIPS 3.00.00 CVSM/CIWS
- Distribution Scope:** WA ASP's and Distributors
WA Technical Support, Product Service, & International Service Centers
- Product(s) Referenced:** Connex Vital Signs Monitor (CVSM) and Connex Integrated Wall System (CIWS) with the radio option; **406187** PLAT. RADIO, PROV. SPI,802.11A/B/G or **408472** PLAT. RADIO 2.30, PROV. SPI,802.11A/B/G.
- Serial No. / Lot Code:** Radio software version 3.00.00 was added to the CVSM model 65-XXXX starting with serial number **103001243812**.
- Summary:** The platform radio **408472** PLATS RADIO 2.30, PROV. SPI,802.11A/B/G is being replaced with **409115** PLAT. RADIO 3.00,PROV. SPI,802.11A/B/G to add FIPS 140-2 functionality, and address a TCP connection issue with Connex VM to properly close the socket.
- Issue:**
- Adds Federal Information Processing Standard (FIPS 140-2) FIPS compliant algorithm. Add FIPS 140-2 functionality in Lamarr2 which involves the addition of the Open SSL FIPS Canister Module v2.0 and updated version of Open SSL v1.0.1, modifications to the supplicant, modifications to the Prism driver LMAC/UMAC and Host interface to use SW AES Encryption/Decryption to the platform.
 - The radio did not properly close the TCP connection with Connex VM 2.0 before allowing the port numbers to be reused, ultimately resulting in a connection failure. Although this issue was addressed in Connex VM 2.0 (see TSB 20012817) it was corrected in this release to properly close the sockets.

Action: Use the procedure described in the Radio configuration guide, Connex® Vital Signs Monitor 6000 Series and Connex® Integrated Wall System DIR# 80018044 to update either **406187** or **408472** as necessary.

Note on FIPS Compliance – To meet the Federal Information Processing Standard the customer’s network must also support compliance and be used in a manner that is compliant with the standard. To be compliant with FIPS, customers will need to use HTTPS when accessing the radio’s web interface to add certificates.

The radio is running in FIPS mode when the authentication type is set to WPA2-PSK or WPA2-AES with EAP type TLS and Security protocol set to CCMP. All other authentications are run in NON-FIPS mode.

Note on host compatibility – CVSM and CIWS with host SW version 1.50.02 or older will need to be upgraded to host version 1.70.03 or later to fully support the radio 3.00.00 SW. The CVSM host SW version 1.50.02 and earlier UI does not support the WEP authentication type. The 3.00.00 radio software was only tested with CVSM/CIWS host software versions 1.70.03 and 1.71.00.

Note on Connex VM 1.x compatibility – CVSM/CIWS host software version 1.70.xx does not support the patient query function when used with Connex VM 1.x. Support for patient query is restored in CVSM/CIWS 1.71.02. Connex VM 1.x customers upgrading to radio software version 3.00.00 should upgrade the CVSM/CIWS software to version 1.71.02.

Note on configuration – Configuring the radio through its web interface may cause the host to lose communication with the radio and display the Radio card inoperable technical alarm. If this happens reboot the CVSM/CIWS and configure the radio through the CVSM/CIWS user interface. The web interface should only be used to update the software or load certificates.

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002If the service

Reference

- 80018044 Radio configuration guide, Connex® Vital Signs Monitor 6000 Series and Connex® Integrated Wall System
- 60048306 SRN 802.11a/b/g SW version 3.00.00
- 20012817 TSB-Connex VM WACP defect
- FIPS 140-2 Consolidated Validation Certificate No.0018 See ECM in SAP 90095690

Service Strategy:

The original platform radio service kit **103356** containing **406187** PLATS RADIO,PROV. SPI,802.11A/B/G (SW version 2.20.00) will remain available to replace failed radios in CVSM’s that cannot be upgraded to host software version 1.70.00 or later.

The BOM for newer platform radio service kit **104560** SERV KIT,PLFM RADIO 2.30 will be updated to replace **408472** PLAT. RADIO 2.30,PROV. SPI,802.11A/B/G with **409115** PLAT. RADIO 3.00,PROV. SPI,802.11A/B/G.

If a customer requires a radio with software version 2.30.03 as may be the case if the customer does not want the host software updated to 1.70.03 or later, it is acceptable to upgrade a **406187** radio or downgrade a **409115** radio.

Upgrades may be delivered onsite by field service or the customer may be offered the opportunity to perform the upgrade themselves on an as needed basis as determined below. Customers may be charged for any on site upgrades.

Customers who call with radio connectivity issues will be evaluated by Technical Support. If the issue cannot be resolved, it will be escalated to Service Engineering. Service Engineering will work with the radio team to determine if an upgrade will resolve the issue and how it will be deployed.

If an on-site upgrade is needed, Field Service will be requested to assist. In the event Field Service is unable to make an onsite visit within the customer's time frame, the customer will be offered the option of performing the upgrade themselves or returning the device to a service center. Customers opting to perform the upgrade will receive instructions for performing the upgrade along with the upgrade software via PartnerConnect.

Warranty coverage will remain in effect for any damage to the radio resulting from the customers attempt at upgrading the radio software, provided the case was not opened and no modifications were made to the hardware. In the event the customer is unable to complete the upgrade the device may be returned to product service for repair.

Service centers will continue the policy of upgrading device host software to current levels when required. The minimum radio software level will remain 2.30.03, as 3.00.00 does not offer significant improvements to reliability or performance over 2.30.03. CVSM/CIWS host software 1.70.03 or later is required for Flexnet radio software version 3.00.00, as earlier host software versions have not been validated with radio 3.00.00. Therefore devices that cannot be upgraded to the current host software version shall only be upgraded to the highest compatible version. See CVSM Minimum Hardware/Software Level Requirement for current software levels DIR# 20012631. Upgrade the radio SW to the highest compatible version to address any issues corrected in an updated release. The upgrade is provided at no charge for those customers needing the upgrade to address issues corrected in a later release.

When issuing an RMA the service representative will need to ask the customer if the device is being used with Connex VM 1.x. *Inform the customer there is a known issue with the patient query when running SW version 1.70.00 to version 1.71.00 with Connex VM 1.x. Any customer using Connex VM 1.x with patient query should continue to use the host software version 1.50.02. In this case, indicate on the RMA the host SW must not be upgraded above version 1.50.02, and the radio SW must remain at SW version 2.20.00. If the customer understands the issue but wishes to have the device upgraded indicate on the RMA that the customer was informed of the patient query issue, but requested the device be upgraded with the understanding the patient query feature would no longer be available.*

Customers shall be notified the upgrade may return the radio configuration to default settings.

The radio software update process is detailed in the Radio configuration guide, Connex® Vital Signs Monitor 6000 Series and Connex® Integrated Wall

System DIR# 80018044.

Required Tools: See Radio configuration guide, Connex® Vital Signs Monitor 6000 Series and Connex® Integrated Wall System DIR# 80018044.

Required Materials: The radio software files may be downloaded from SAP or PartnerConnect

SAP

DIR 50010899 , SWF: PLFM Radio 3_00_00 FIPS

You will need the following four files from DIR 50010899:

1. NK_5_0_0.bin
2. nk_5_0_0.sha1.txt
3. Lamarr2_SPI_FIPS.cab
4. Lamarr2_SPI_FIPS.sha1.txt

PartnerConnect

From the WAST dashboard select Upgrade this device from the Tasks pane, and deploy Lamar2_Radio_SW_Upgrade_3.00.00

The zip file containing all four files is downloaded to either:

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

Windows XP C:\Program Files\Welch Allyn\RS\DefaultProject\WA ServiceTool\Downloads.

A copy of the radio configuration guide DIR 80018044 is included with the upgrade package.

Procedure: See Radio configuration guide, Connex® Vital Signs Monitor 6000 Series and Connex® Integrated Wall System DIR# 80018044.

Required Training: All Welch Allyn employees and contractors engaged in service and repair of CVSM and 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.

Note: This table cross references the Lamar II radio software Server and Kernel version:

Server version	Kernel version
2.20.00	4.1.22
2.30.00	4.1.26
2.30.02	4.1.30
2.30.03	4.1.31
3.00.00	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.

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*	GCS	D*	D*
B	Changed date. Changed distribution scope to WA ASP's and Distributors Added Serial No. / Lot Code section. Added 80018044 to the PartnerConnect upgrade package Added CIWS to required training Added Note for Radio Server and kernel versions	D*	GCS	D*	D*
D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL					