Question or Item	Answer
Did you verify that you are using the most recent version of this form?	☒ Yes ☐ No
Date	December 07, 2023
Individual creating the CSB	Matthew Bell
Customer	All
Product(s) affected:	**Connex Spot Monitor (CSM)** **Welch Allyn Configuration Tool**
Hardware Version(s) affected:	All
Software Version(s):	All versions
Serial Number(s):	All
Lot or Date Code Affected:	N/A
Subject:	CSM 1.53.00-A0005 and Configuration Tool 1.94 Release Notes

Issue details

Baxter is releasing a software update to CSM software version 1.53.00-A0005 with software and security enhancements. In addition, the Configuration Tool is updating to software version 1.9.4

Definitions:

Acronym	Description/ Definition
APM	Accessory Power Management
BLE	Bluetooth Low Energy
BR/EDR	Bluetooth Basic Rate/Enhanced Data Rate
CSM	Connex Spot Monitor
CVC	Connex Vitals Core. Renamed to CSM.
NIBP	Non-Invasive Blood Pressure
NCE	Network Connectivity Engine Software
PCA	Printed Circuit Assembly
PDM	Product Data Management
APM PIC	A PIC16F1518 that manages the APM's rechargeable battery, its work light, the battery life indicator LED string, the printer print head power, and the CVC accelerometer
CVC PIC	A PIC16F1518 that manages the CVC's rechargeable battery (if one is installed), the front panel LEDs, and the connection with the APM processor (if required)
HIS_ID	Hospital Information System
IP	Internet Protocol
VID	Vendor ID
OKC	Opportunistic Key Caching
NEWS2 SCAL2	National Early Warning Score Scale 2
PID	Product ID
PHI	Personal Health Information
PKI	Public Key Infrastructure
RRp	Masimo Respiration Rate from the Pleth. Respiration rate is measured based on changes in the plethysmographic waveform.
SCRM	SmartCare Remote Management
SDK	Welch Allyn Connectivity SDK Development
SpO2	Oxygen Saturation Percentage of oxygenated hemoglobin in the blood
SRS	Software Requirements Specification
SW	Software
SWF	Software File
TFS	Team Foundation Server
TLS	a widely adopted security protocol designed to facilitate privacy and data security for communications over the Internet
UI	User Interface
WA	Welch Allyn
WACP	Welch Allyn Communication Protocol
WAST	Welch Allyn Service Tool
WEP	WEP (Wired Equivalent Privacy) is the oldest and most common Wi-Fi security protocol. It was the privacy component established in the IEEE 802.11, a set of technical standards that aimed to provide a wireless local area network (WLAN) with a comparable level of security to a wired local area network (LAN).
WPA	The WPA protocol implements the Temporal Key Integrity Protocol (TKIP). WEP used a 64-bit or 128-bit encryption key
WPA2	WPA2 (Wi-Fi Protected Access 2) is the second generation of the Wi-Fi Protected Access wireless security protocol. Like its predecessor, WPA2 was designed to secure and protect Wi-Fi networks.

Solution/Action:

Baxter Inc. is pleased to announce the release of a new firmware package for the Welch Allyn Connex Spot Monitor. This release (CSM firmware version 1.53.00-A0005*****) incorporates new Software and security enhancements.

The following enhancements have been incorporated into this firmware release:
- Prevented the downgrade or rollback to an older host (lower number) software version when operating with host version 1.53.00.
- Removed WEP, WPA, and Open from a set of wireless Authentication/Encryption options.
- Included Newmar radio 2.00.04 in the build package for CSM 1.53.00.
- Updated asset tag and location usage, so if they are not set in the config file, they are not cleared in the device.
- An advanced settings password is required for configuration updates.
- Security: Added Client authentication support.
- Added Support to Encrypt Device Service Data to Service Monitor.
- Added configurable option to protect PHI Data when a Priority Alarm Occurs on the Lock Screen.
- Chinese Translation Fixes/Edits.
- Added support for IP addresses for service monitoring when the network connectivity method is Host IP.
- Added support for TLS 1.3.
- Removed the "Pair Every Time" BLE workflow.
- Required complex password entry for access to the debug menu.
- Removed the creation of Core files from CSM.
- Added a new VID/PID to allow a new APM USB host controller.
- Added logging of alarm related settings and changes made to those settings to comply with 60601-1-8:2006/AMD2:2020.
- Ensured all setting changes possible through the UI have corresponding log entries.

The following bug fixes have been addressed:
- When the device is in intervals, the profile active intervals program is running, and the config file is loaded with clinician authentication required for saving; the intervals program is still running after the config change.
- Roaming dropdown is still available after re-enabling the Radio setting.
- Temp default units are not applied on Braun.
- Security: Update the kernel version to fix the USB subsystem.
- CSM NEWS2 Scale2 on Air send the incorrect HIS_ID.
- Software resets Custom Score algorithm when establishing patient context.
- Barcode scanning incorrectly changes the Patient ID on the Review Screen.
- PDM incorrectly causes context switch.
- Exiting Advanced Settings prevents patient barcode scan.
- Radio configuration screen allows non-working configuration.
- Multiple alarm messages, delay in scrolling.
- Roaming is set to "OKC," but the field was not grayed out.

*PLEASE NOTE: Once a CSM has updated to 1.53.00 A0005, it **CANNOT** be rolled back to a previous version of the device firmware.

The Welch Allyn Configuration Tool has been updated to version 1.94, which includes the following Software and Security Enhancements:
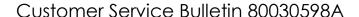
- Corrected Weak security questions.
- Corrected ability to Change passwords without notifying the user.
- Corrected Inadequate account lockout protocols.
- Prevented User account harvesting from insecure password reset methods.
- Corrected Cross-site scripting (XSS).
- Corrected insecure HTTP header configuration, specifically the X-Frame-Options header not being set.
- Corrected Password field with autocomplete enabled.
- Corrected Lack of timely idle session timeout.
- Added configurable option to protect PHI data when low priority alarm occurs in lock screen.
- Added Configuration options encrypting data to service monitor.
- Added IP address and port settings when selecting Host IP for network connectivity method.
- Added Client authentication enable/disable options.
- Removed configuration option for ConfirmBLEPairing.
- Required Admin Access Code to be changed by the user prior to saving a configuration.
- Removed WEP, WPA, and Open from the set of wireless authentication/encryption options.
- Corrected problem that when Server authentication and client authentication should not be set-able when data encryption is disabled.
- Removed the configuration option to disable/enable advanced settings password.

CSM Hardware/Software Compatibility:

The CSM 1.53.00-A0005 software is expected to be compatible with the below listed **or newer** versions until superseded by a future CSM software update.

Compatible Versions		
Subsystem Description	**Version**	**Notes**
CSM Main Board	Pattern E	409703-12; PCA, CVC Main Board, NOTE: The board version read by SW is E.
	Pattern F	409703-16; PCA, CVC Main Board, 3rd Edition, NOTE: The board version read by SW is F.
	Pattern H	409703-18; PCA, CVC Main Board, 4th Edition, NOTE: The board version read by SW is G.
	Pattern H	409703-20; PCA, CVC Main Board, 4th Edition, NOTE: The board version read by SW is G.
APM PIC Software	2.00	50011599 B; CSM, APM PIC, V2.00
CSM PIC Software	3.01	50012000 A; CSM, CVC PIC, 3.01
NIBP Software	1.00.00.00009 - Main 1.00.00.00002 – Boot 1.00.00.00007 - Safety	50012391 A; PIM SWF: NGLAV ModPG v1.00.00.00009 50011590 A; PCA SWF: NGLAV ModPG Safety v1.00.00.00007
Masimo MX SpO2 Software	7.10.7.0 7.14.6.2	Vendor firmware – Non-RRp With RRp support
Nellcor SpO2 Software	HW 1.2.1.0 DSP GR101357E00 FE 1.1.0.0	Vendor firmware
Nonin SpO2 Software	45 (0x2d)	Vendor firmware
SureTemp Software	1.00.00 00006	50012488 B; PIM SWF: NGLAV SureTemp v1.00.00.00006
Braun Pro 6000 Software	3.85	Vendor firmware
Newmar Radio Software	2.00.04 SEE NOTE 1	50014478 B SWF, Newmar 2.00.04 A0002
Bluetooth BR/EDR	Bluetopia Stack version 4.0.1.1 which minimally support the Bluetooth Core Specification Version 2.1 for Bluetooth BR/EDR	Also known as Basic Rate/Enhanced Data Rate (BR/EDR).
Bluetooth Low Energy	Bluetopia Stack version 4.0.1.1 which minimally support the Bluetooth Core Specification Version 4.0 for BLE	N/A
Scale Software	N/A	Various manufacturers – must be WACP compatible.
WACP	2.4.0	N/A
WA Connectivity SDK	3.0.0.19	50011345 M; SWF: SDK 3.0.0.19

Subsystem Description	Version	Notes
NCE	NCE 5.1.0.16	50011826 R; SWF NCE 5.1.0.16 NCE Server Configuration for SSO (Single Sign On) (DIR 60072721) TransformSheets and Config from IDS-CFG - CDIS-NCE HL7 TCP EMR Interface (DIR 60059617)
Connex	CS 1.7.1	50012204 B SWF: Connex CS 1.7.1 CSAD INSTALLER DBNameBL1
PDM Database Schema	16	Current schema version is logged at device power-up.
CSM Configuration Tool	1.9.4	50014747 B; SWF Config Tool v1.9.4
CSM Configuration Schema	60064014 J	IDS, CSM CONFIGURATION
SRS-Device Configuration Specification	60060648 AG	SRS - Device Configuration Specification
WAST	1.9.0.0	50013091 C, SWF: WAST 1.9 Installer
SWF: WAST CSM plugin v .1.2.0.0	V1.2.0.0	Necessary for support for loading radio certificates and updating first time boot flag when replacing main boards.
Service Monitor	1.6.0.1	50012786 B SWF: Service Monitor 1.6.0.1

NOTE 1: The Newmar Radio Software 2.00.04 associated with this release is not backward compatible with prior versions of the Newmar Radio Software. Downgrading a CSM to a version prior to 1.53.00 is not supported and should not be attempted once a CSM has been upgraded to 1.53.00.

NOTE 2: The user can access the CSM Configurator tool to determine the passcode.

Update Instructions

The 1.53.00-A0005 software will be manually deployed to the Welch Allyn Service Tool (WAST). During the initial release of this software, 1.53.00 will only be available over WAST. Customers who wish to update their devices must request that Baxter give them access. All customers should be made aware of the design change that once CSM is upgraded to 1.53.00, it **CANNOT** be rolled back to a previous version of the device firmware.

Instructions on Software upgrades are covered in the Service Manual located on the Hillrom Patient Monitoring CSM website shown in the link below. Select the appropriate service manual for your device by selecting the **EDUCATION AND DOCUMENTATION → SERVICE MANUAL** tab.

Hillrom Patient Monitoring CSM webpage link:
https://www.hillrom.com/en/products/connex-spot-monitor/

During the initial release period, the software will only be available by request over WAST. 1.53.00 will not be made available to customers on SmartCare Remote Management (SCRM) or put on the manufacturing line during the initial release period. More communication on the 1.53 release for SCRM and production will be distributed in the second half of 2024.

The following will be needed for the customer to request an upgrade to 1.53.00 when contacting Technical Support via Emails provided in Figure 1 for contact information:

- Customer Contact Info Name/Phone Number
- Facility Name
- PC Name that WAST is located
- Serial Number of the device.

Customer care will reach out with a confirmation e-mail once they process the upgrade request. 1.53 IFU (all languages), RRp Addendum and Quick Start Guide will be included in the download location (C:\Program Files (x86)\Welch Allyn\PartnerConnect\Firmware\manual_ST_csm\1.53.00\1.53.00-A0005\Literature\) for CSM 1.53.00.

United States	HRC_Customer_Service_WelchAllyn@baxter.com
Asia	HRC_ASEANNA_Services@baxter.com
India	HRC_ISC_WelchAllyn@baxter.com
Australia	HRC_TechSupport_AU_WelchAllyn@baxter.com

Figure 1

Please contact your local Baxter Tech Support E-mail for access.

Reference Documents:
20017634A – TSB 1.53.00-A0005

END OF BULLETIN

Version	Sec, Pg, Para Changed	Change Made	Date Version Created	Version Created By (initials)
A	N/A	Initial Release	2023-12-07	MDB