Customer Service Bulletin

Product:	Welch Allyn® Connex® Spot Monitor (CSM)	**Date:**	2020-12-08
Subject:	CSM 1.52.00-A0002 SWF Release Notes		
HW Version(s) Affected:	All	**SW Version(s) Affected:**	ALL
Serial Numbers Affected:	All	**Lot or Date Code Affected:**	N/A

Classification:	As Needed		
Distribution:	☒ Customer Care	☐ Product Service	☐ Field Service
	☒ ASPs ☒ Distributors	☒ Customers	☐ Company Confidential

Release Details

This is a CSM sustaining release. The previous release version was 1.51.00. This update enables the below features and additions. The configuration tool was updated to Version 1.90 as well to support the below features and additions. The main features of this release are below.

- BLE licensing now requires an order number within the config tool for software version 1.52.
- Created field in the Advanced service menu to display the Radio Certificate Expiration Date Information and added Technical Alarm to notify certificate is about to expire
- Expanded NEWS2 logic
- Ability to send more precise BMI data to EMR
- Additional BLE pairing process to pair once and then connect automatically
- When DOB is provided by ADT device will auto set patient type and auto set alarm limits and cuff inflation targets
- Traditional Chinese support
- Service Monitor connectivity with HL7 enabled
- The ability to share a config file from one account to another on Service Hub

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The Following Changes have been applied to the 1.52.00 Release:

1. Date of Birth pulled back from EMR changes settings on the device. Utilizing DoB provided by ADT will autoset clinical settings for the below settings and it is based on what is programmed as defaults in the config file. Example: If the patient is age 10 the patient type would be set to Pediatric patient type as well as the alarm limits and other associated settings.
    - patient type (Adult, ped, neonate)
    - Autoset alarm limits
    - Cuff inflation targets
2. HL7 setup and service monitor/dashboard compatibility
    - Adds the ability to push configurations to many devices from a single point while in an HL7 deployment.
    - Add ability when "HL7 is enabled" for the CSM software to determine which server to connect by using either DNS or NRS. If using NRS, DCP will be installed on the server running Service Monitor and PartnerConnect.
    - When using HL7 with NRS, DCP would be configured as follows:

Ordinal	**Description**	**Address**
8	Spot Readings	IPv4 address of the WACP server
OR		
14	TLS Spot Readings	IPv4 address of the WACP server - Secure
AND		
10	Remote Services	IPv4 address of the Service Monitor server

3. Adds ability for the device to support remote service features when using HL7 Direct
    - support the following when configured to use HL7 direct.
        - Remotely load configuration files
        - Remotely load certificates
        - Remotely update software
        - Remotely acquire device log files

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4. Adds ability to send more precise BMI data to EMR .

   Note: NCE Transforms will need to update for Cerner & HL7 customers if they want to use this new feature for BMI

   - Added a new member at the end of the object definition:

     <MEMBER type="float" name="BodyMassIndex-ext" minversion="102" maxversion="CURRENT_VERSION" comment="BMI = weight/(height**2) in kg/m**2"/>

   - Send BMI object out of the CSM device with both members filled in (for backward compatibility).
   - Host software (Connex CS, NCE, etc.) will use BodyMassIndexExt, if non-zero or BodyMassIndex when BodyMassIndexExt is zero.

   Device:

   - Device will continue to use send the integer value in BodyMassIndex member.
   - Device will add the floating point value of BMI in the BodyMassIndexExt member.
   - Device will need to update the version of the CSESDVitalsRRecord so NCE will force a BDD upload.

   NCE:

   - On next NCE transform update, NCE will pick up the BodyMassIndexExt member instead of BodyMassIndex.
   - There are no backward compatibility issues provided versioning is incremented correctly.

   Connex CS:

   - On next Connex CS version, Connex CS will pick up the BodyMassIndexExt member instead of BodyMassIndex.
   - There are no backward compatibility issues provided versioning is incremented correctly.

5. Prevents "New patient" entry when EMR connected
   - "New patient" selection when indications are EMR connected.
6. Removed the ‘Save’ button on device home screen while actively connected via BLE

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7. HL7 Patient Query – Added a method for identifying the device & location (e.g. Location ID and S/N)

   Note: Transforms will need to updated, Cerner & HL7 customers if they want to use this feature.

   See **CSB 80027235 as reference**

   Applications receiving a patient query can differentiate between < 1.51 and >= 1.51 and process messages as follows:

   1. < 1.51
      a. QRD-7 = 1
      b. QRD-8 = ^RD
      c. QRD-9 = Patient ID search ID
      d. QRD-10 = DEM
   2. >= 1.51
      a. QRD-7 = 1^RD
      b. QRD-8 = Patient ID search ID
      c. QRD-9 = DEM
      d. QRD-10 = Device Location ID
      e. QRD-13 = Device Serial Number

   Based on these values the receiving application can determine where the patient ID is located and can adjust capturing the fields needed to execute the query.

8. Optionally, removes the pairing confirmation when connecting via BLE
9. Adds Radio Certificate Information and Related Technical Alarm to CSM.
   - Device now shows radio cert expiration date in Advanced menu
   - Device has a technical alarm when date is exceeded
10. Translates the device UI Into Traditional Chinese (keyboard not included)
11. Removes out of range Values from EWS Calculation
    - CSAS: Temp reading received from device but missing in Outbound ORU, when a value is out of range on the device, be it -- or ++, that value should not be used in EWS calculations.

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- If the Parameter is deemed out of range, it should not be used to calculate score. Clinician should be looking for a second source of the vital if out of range and can manually input which would be included in the score.

12. Populates HISId for the parameter/modifier that are part of the scoring system.
    - CSM with options for two or more scoring systems has a user entered parameter/modifier value for one scoring system but a different scoring system is selected which does not include the entered parameter/modifier. This entered parameter/modifier would not be sent to the host when a vitals record is sent. The change will make it so any user entered parameter will be sent to the host, independent as to whether the parameter is part of the selected scoring system or not.
        - **Scenario:**
            - CSM uses MEWS and FRAT scoring systems.
            - HOFF parameter is part of FRAT scoring system.
            - User selects MEWS scoring system.
            - User enters value for HOFF parameter.
            - CSM and NCE will not send HOFF parameter value in vitals record even if the user enters the value because HOFF is NOT part of MEWS scoring system.
    - The change will send all parameters with entered values in vitals record even if they are not part of the selected scoring system.

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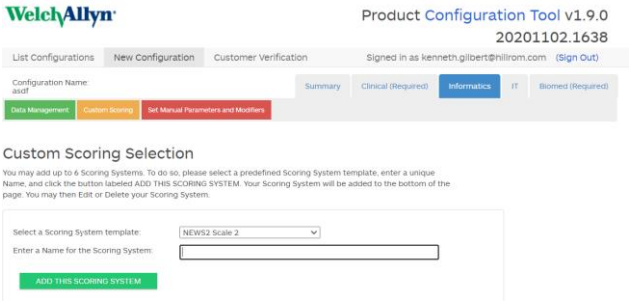
13. AddsNEWS2 2 Scale Option Based on O2
    - For NEWS2 Scale2, it is subdivided based upon patients with good or compromised lungs. Patients with compromised lungs are Scale2. The scoring is different based upon whether the patient is on Oxygen or not. The configuration tool now has a configuration option and outputs a custom score file that can select different scoring values based upon oxygen begin available or not for a NEWS2 Scale 2 patient. This feature will add support to dynamically select the correct algorithm based upon the oxygen setting. The Configuration Tool the Filter By column allows dynamic selection of different algorithm methods for SPO2.



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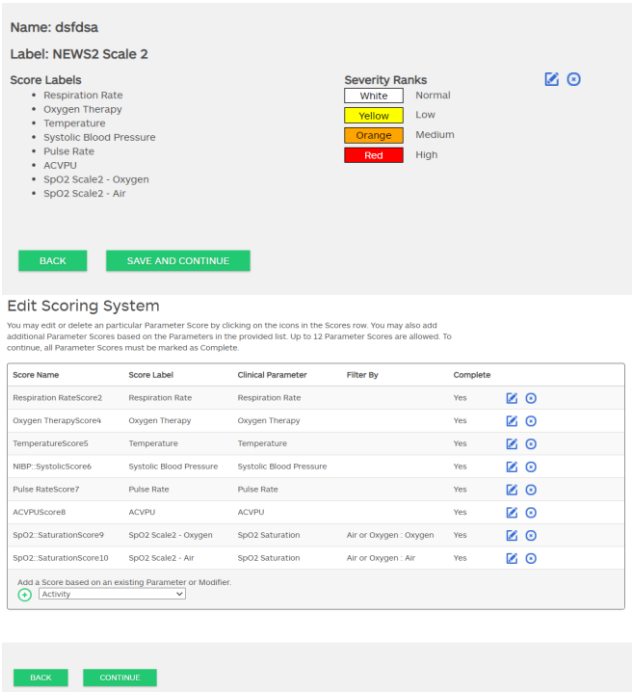

14. Upon close of WACP connection, if in service state, force device state out of Service State. This fixes an issue with Service Hub not being able to show device after connected to WAST.

15. Expands HIS ID(s) beyond 31 characters to 64 characters

    - This is internal to HL7 and relates to the communications with an HL7 host system. HIS ID(s) was limited to 31 characters. For scoring parameter mapping, more than 31 characters are required in the HIS ID so the mapping in the configuration can traverse the entire device and through the entire system through

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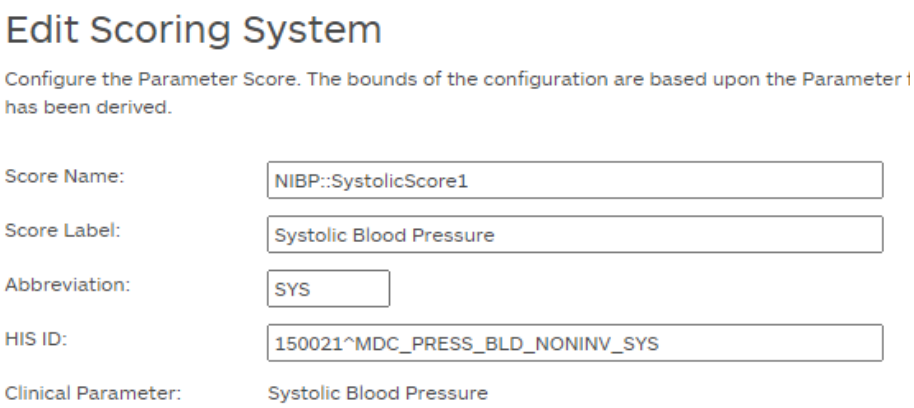
WACP and HL7 interfaces.



16. Adds licensing capability for BLE using the Config Tool with Sales Order and device Serial Numbers
17. Updates Swedish Translations
18. Uses CRespDStd for Manual Resp Rate

    Note: Transforms on 1.51 upgrade transforms or go to 1.52
19. Changes the alarm (bell) icons when the Simplified Chinese language is selected

Configuration Tool Changes:

1. Adds configuration to enable/disable BLE pairing for each time you connect with default set to Enable
2. Bluetooth BLE UI License Activation with Sales Order and Device Serial Number
3. Adds Configuration to Enable/Disable Autoset of Patient Type when available with Patient List or Query

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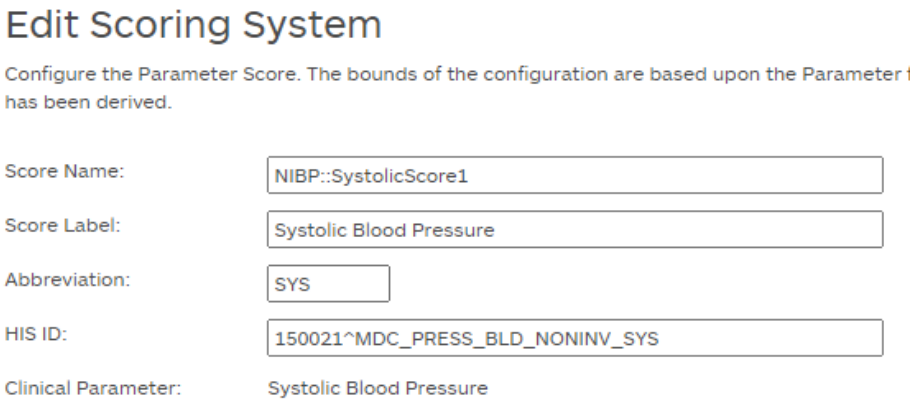
4. Expands HIS ID(s) beyond 31 characters to 64 characters
    - For scoring parameter mapping, more than 31 characters are required in the HIS ID so the mapping in the configuration can traverse the entire device and through the entire system through WACP and HL7 interfaces.



5. Adds support for dynamic selection of NEWS2 Scale 2 Option values Based on O2
    - For NEWS2 Scale2, it is subdivided based upon patients with good or compromised lungs. Patients with compromised lungs are Scale2. The scoring is different based upon whether the patient is on Oxygen or not. The support needed is for the configuration tool to be able to present a configuration option and output a custom score file that can select different scoring values based upon oxygen begin available or not for a NEWS2 Scale 2 patient.
6. Prevents new patient entry and only allow patient selection from list
    - This is the addition of "Prevent New Patient Entry" selection in the configuration tool to enable or disable the ability to only allow selection of a patient from a patient list.
7. HL7 setup and service monitor/dashboard compatibility
    - allow to use Host IP if "Enable HL7" is selected. In order to support the connection to service monitor / dashboard, the additional connectivity method should be allow with HL7, ie: DNS, DHCP and NRS. This change allow to connect to service monitor / dashboard and remote service while configure to send the HL7 message directly to EMR.
8. Adds Traditional Chinese Language option (UI only, not keyboard)
9. Updates Configurator Tools to NOT return the default configuration if part number is not available in the database and return the error message.

10. Adds the ability to share/copy a config file from one user account to another user account
    - The Config Tool does not support standardization efforts in the way configuration files are distributed. If a Biomed want to create a file for his/her facility, there is no way for us to allow their IT or Biomed Admin to get a file to them, they must create from scratch. This is now available.

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11. Bluetooth BLE UI License Activation with Sales Order and Device Serial Number

Hardware/Software Compatibility:

It is expected that the CSM 1.52.00-A0002 software is 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 Pattern F Pattern H Pattern H	409703-12; PCA, CVC Main Board, NOTE: The board version read by SW is E. 409703-16; PCA, CVC Main Board, 3rd Edition, NOTE: The board version read by SW is F. 409703-18; PCA, CVC Main Board, 4th Edition, NOTE: The board version read by SW is G. 409703-20; PCA, CVC Main Board, 4th Edition, NOTE: The board version read by SW is G.
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	SWF: NGLAV SureTemp v1.00.00.00006
Braun Pro 6000 Software	3.85	Vendor firmware
Newmar Radio Software	2.00.02	50012632 B SWF, Newmar 2.00.02 A0001
Bluetooth BR/EDR	Bluetopia Stack version 4.0.1.1 which minimally support the Bluetooth Core Specification	Also known as Basic Rate/Enhanced Data Rate (BR/EDR).

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	Version 2.1 for Bluetooth BR/EDR	
Bluetooth Low Energy	Bluetopia Stack version 4.0.1.1 which minimally support the Bluetooth Core Specification Version 4.0 for BLE	SEE NOTE 1
Scale Software	N/A	Various manufacturers – must be WACP compatible.
WA Connectivity SDK	3.0.0.19	50011345 M; SWF: SDK 3.0.0.19
NCE	NCE 5.1.0.16 SEE NOTE 2	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
CSM Configuration Tool	1.9.0	50013510 A; SWF Config Tool v1.9.0
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:

- CSM 1.52.00 adds an additional Bluetooth pairing method of only pairing once and then automatically connecting in contrast to its original method of requiring pairing every time. This is configurable through the configuration tool. The pair ever time configuration approach was modified to follow proper Bluetooth sequencing of messages and, as a result, some phones may be required to clear the

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bonding information (forget) with CSM each time they want to connect to it. If you want pairing confirmation each time the CSM connects with a mobile device, you must first 'Forget the Device' on the mobile device before each connection. This is because of an iOS security change and did not need to be done before.

Note 2:

CSM 1.52.00 changed the manual resp rate back to using CRespDStd from CRespDData. The maximum HIS IDs length has been increased from 31 to 64 characters. The values for QRD-7 through QRD-10 and QRD-13 were changed in 1.51.00 and now verified in 1.52.00.

Note 3:

The Config Tool outputs 2 types of Config Files: 1) Device Settings 2) Device Licenses

A 1.51 Device Settings Config File will work on a 1.52 device, but with the limitations set by the 1.51 Config settings.

A 1.52 Device Settings Config File will work on a 1.51 device, but with the limitations set by the 1.51 SW (new features that are added with 1.52 via the Config Tool will not work such as removing the BLE Pairing Confirmation)

A 1.52 BLE License Config File will not enable BLE on a 1.51 device.

A 1.52 Config File, if put onto a device with BLE previously activated, will not remove the existing BLE license.

Summary of Prior Releases:

1.51.00.A0002 version released 4/24/2020

This is a CSM sustaining release. The previous release version was 1.42.00. This update enables the many features and additions. Adds: Masimo RRp (Respiration-Rate via Pleth); Adds Patient List capability to HL7 OOB; Adds The capability to Disable USB ports; Etc….. The

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configuration tool was updated as well to support the creation of two (2) config files (Standard Config, as well as a License Config) that can be applied to the CSM device in the same manner as before using WAST or a USB stick.

1.42.00.A0001 version released 10/02/2019
This is a CSM sustaining release. The previous release version was 1.41.01. This update provides encryption of PHI data at rest as well as minor improvement of the services for BLE. When the values sent were high systolic BP (>204) and Weight (>327kg) via BLE they would show as a negative number in the EMR application.

1.41.01.A0001 version released 07/09/2019
This is a CSM sustaining release. The previous release version was 1.41.00. This update included a fix for a minor time delay for the manufacturing automated test equipment.

1.41.00.A0005 version released 03/10/2019
This is a CSM sustaining release. The previous release version was 1.40.10. This update provides support for Service Workflow updates, Newmar Radio Updates, as well as an assortment of software anomaly fixes.

Key updates provided in this release are noted below:

- Remote upgrade and configuration from Service Monitor and view only access (VNC).
- New Radio Software Newmar v2.00.02
  - ❖ Added b/g/n Radio Selection mode
  - ❖ Added independent FIPS Enable/Disable functionality to WPA2-Personal and valid WPA2-Enterprise Auth Modes/EAP Types, default FIPS enabled
  - ❖ Newmar certificate installation should encrypt password file information

    Note: Requires the wa-updatecerts script used by WAST to create certificate PIM files be updated to the latest version. If the version of WAST that does not include the updated wa-updatecerts script, certificates **will not** successfully authenticate on Newmar 2.00.02 SW.
- Clear Patient ID in office profile save
- Beirut Time Zone support

1.40.10.A0002 version released 12/10/2018
This is a maintenance release for CSM. The previous shipping production release was 1.40.00-A0002. This update provides support for 4th-Edition compliance. Supports All Device Hardware versions. Upgradeable, and down-grade-able only to 1.32.19 version.

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1.40.00.A0002 version released 09/19/2018
This is a maintenance release for CSM. The previous shipping production release was 1.32.10-A0001. This update provides support for 4th-Edition compliance. Supports All Device Hardware versions. Upgradeable, and down-grade-able only to 1.32.19 version.

1.32.19.A0001 version released 12/10/2018
This is a service maintenance release for CSM. The previous shipping production release was 1.32.10-A0001. This update provides support for new Hardware based on 4th Edition Compliance. Upgradeable with new hardware only (Version G or greater). Supports ALL Device Hardware version. Can't be downgraded to any previous versions.

1.32.10.A0001 version released 8/07/2018
This is a service maintenance release for CSM. The previous shipping production release was 1.32.02-A0002. This update provides support for 4th-Edition compliance, an assortment of software updates (detailed below), and support for the Thai language. CSM Configuration Tool has also been updated to v1.8.3 20180727 located here https://config.welchallyn.com/configurator/

Update Instructions

The 1.52.00 software will be ***auto deployed*** to the Welch Allyn Service Tool (WAST).

Instruction to do Software upgrades is covered in the Service Manual located on our website below.

https://www.welchallyn.com/en/products/categories/patient-monitoring/vital-signs-devices/connex-spot-monitor/documents.html

For information about Welch Allyn product(s) and/or features, contact your Welch Allyn Sales Rep, or our Technical Support Team: www.welchallyn.com/about/company/locations.htm

Version	Sec, Pg, Para Changed	Change Made	Date Version Created	Version Created By (initials)
A	N/A	Initial Release	2020-12-08	KMG

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