



Technical Service Bulletin

PATIENT MONITORS SYSTEMS

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Subject: TSB-CCSS EPISODIC ONLY WORKFLOW

Distribution Scope: Welch Allyn Global Technical Support, Product, Field & Customer Service.

Product(s) Referenced: Connex Clinical Surveillance System

Summary:

Connex CS 1.6 offers a replacement for Connex VM by utilizing a Connex CS Server with an Episodic Only workflow. In this workflow, Connex CS does not utilize a Connex Central Station.

A key difference between Connex CS and Connex VM is that Connex CS requires a Master Bed List and Covered Area to be defined and configured. Connex VM did not have this requirement.

It was discovered during a customer deployment that the requirements to support the Connex CS – Episodic Only workflow were not clearly defined and documented.

Service requested a Connex CS – Episodic Only workflow has been setup and verified to understand the requirements and characteristics of this configuration in Connex CS.

This TSB will cover the changes to support this Episodic Only Workflow while the appropriate documents are updated.

Issue: Connex CS – Episodic Only Workflow requires:

- For a CS Server, a single Covered Area is created
- For the CS Server Covered Area, any number of UNITS (as seen in ADT message segment PV1-3-1) can be defined
- For each UNIT in the Covered Area, a Unique Integer is configured in the ROOM Value and a hyphen "-" is configured in the BED value of the Master Bed List

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Example:

<u>UNIT</u>	<u>ROOM</u>	<u>BED</u>
UNIT1	1	-
UNIT2	2	-
UNIT"N"	N	-

*Unitname can be any name found in PV1-3-1 while the ROOM Integer increases by 1 for each unit. BED is always “-“

- CVSM can be configured to either
 - Configure Location ID to retrieve Patient List (Input UNIT NAME)
 - Not retrieve a Patient List by programming in the Location ID to be a name not in the Covered Area –OR- leaving the Location ID blank
- Ensure that the Connex CS licensing for each UNIT in Connex CS license pool is identified -AND- matches the UNITS identified in the Covered Area. If these do not match, then the Retrieve Patient List function at the CVSM may be unpredictable.

Action: Standard TSB distribution.

Reference to Standards:

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

Updates:

Technical Manual	<input type="checkbox"/>	Repair Tool	<input type="checkbox"/>
Service Plan	<input type="checkbox"/>	Internet/Intranet	<input type="checkbox"/>
Procedures	<input checked="" type="checkbox"/>	Price List	<input type="checkbox"/>
Training Material	<input type="checkbox"/>	Other	

Procedure:

Step 1: Information Gathering

1. Complete the 80017306 CONNEX CS CUSTOMER PROJECT REQ FORM as normal except Appendix B2
2. In Appendix B2, on page 8 there is a table named “*EPISODIC / HYBRID Non-Central Station Covered Area Information*”. In this table field named “Unit Name (PV1-3-1), input “See Below”
3. In the *Room/Bed* columns, do not add Room numbers or Bed Numbers. Instead, enter every UNIT NAME (PV1-3-1) the customer wants to support.
4. The UNITS in this Table will be used to License Connex CS and be used to configure the Covered Area and Master Bed List

Step 2: Manufacturing

1. Manufacturing will follow their normal process except when licensing Connex CS and configuring the Covered Area and Master Bed List.
2. Manufacturing will be notified the project is a Server with Episodic only Workflow in either the 80017306 CONNEX CS CUSTOMER PROJECT REQ FORM – OR – by the Project Manager
3. Manufacturing will refer to 80017306 CONNEX CS CUSTOMER PROJECT REQ FORM Appendix B2 page 8, to:

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- a. License Connex CS for Each UNIT identified in the “*EPISODIC / HYBRID Non-Central Station Covered Area Information*” UNIT table
- b. Configure the Covered Area and Master Bed List to reflect the following:
 - i. UNIT equals the Name provided in the Table
 - ii. ROOM will equal 1, for the first UNIT, 2, for the second UNIT, and so on until all UNITS have a unique ROOM Value (incremented by 1)
 - iii. All BED values, for all UNIT’s will be a hyphen “-“

Step 3: Installation

1. During Installation Testing and verification of the Connex CS system, the Field Engineer will configure a CVSM to connect to the network.
2. Once connected, the Field Engineer will configure the CVSM location ID to match one of the identified UNITS in 80017306 CONNEX CS CUSTOMER PROJECT REQ FORM Appendix B2 page 8.
3. The Field Engineer will verify an ADT message for a sample UNIT.
4. The Field Engineer will configure the CVSM-Location ID to match a received ADT message for the target UNIT.
5. On the CVSM, the Field Engineer will verify a Patient List is populated with patients from sample UNIT.
6. Remove Location ID info and all patients in Patient List. Power down and retrieve new Patient List. List should not be populated.

Step 4: Verification

1. Reconfigure CVSM to connect and retrieve a Patient List from a UNIT. Then take measurements.
2. OB ORU message should return ROOM/BED info from ADT messages (PV1-3-2 and PV1-3-3).

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*	DLL	D*	D*

D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL

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