Subject: TSB-CVSM/CIWS 32 GB FLASH DRIVE

Distribution Scope: Welch Allyn Global Technical Support, Product, Field & Customer Service. WA ASP's and Distributors

Product(s) Referenced: CVSM – Connex Vital Sign Monitor
CIWS – Connex Integrated Wall System

SW Version: 1.71.03 and 2.20.00

Summary: The current qualified 2Gb Sandisk (WA PN 715804) is no longer available It will be replaced with a 32Gb flash drive (WA PN 720817) already qualified for use with CS.

Issue: The USB flash drive previously used with CVSM and CIWS (WA PN 715804) to transfer files between the devices and the PC has gone obsolete and is no longer available. A newer 32 GB flash drive already used with Connex CS has been qualified for use with CVSM and CIWS host version 1.71.03 and 2.20.00.

The 32 GB drive may be used to transfer configuration files, log files and custom data files to and from the devices.

The 32 GB flash drive has the following limitations:

- The drive needs to be empty before use.
- The drive should not be left plugged in for extended periods of time in devices used with CVSM version 2.20.00 (it will wrench if a call home occurs while connected).

The older 2GB Sandisk (WA PN 715804) drive is no longer available but may continue to be used.
Action: Use the 32 GB flash drive as needed to transfer configuration files, log files and custom data files to and from the devices.

Reference to Standards: • 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates: Technical Manual

Service Stagey: Service may continue to use the older 2GB Sandisk (WA PN 715804) drive. When additional or replacement flash drives are required purchase WA PN 720817. The service manual and any service documentation referencing the older Sandisk 2 GB drive will be updated at the next revision to list the new material. The New material will receive a customer facing material number and be set up for sale.

New Material: 720817 MEDIA 32 GB USB FLASH DRIVE

Quality Documents: All service centers using SAP to record service transactions: For each product serviced, record the service activity in SAP.

All other service centers and Field Service: For each product serviced, complete and file a service report and attach to the service DHR.

Notes:
1. Contact Welch Allyn regarding any questions or concerns 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

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