Customer Service Bulletin

Monitoring Products

Bulletin Type: As Needed

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Subject: CSB-Propaq 2XX Service Manual Defib Sync Verification Update

Distribution Scope: WA Customers

Product(s) Referenced: Propaq Encore, Propaq CS

This bulletin applies to all Propaq Encore and Propaq CS service manuals that reference use of the Lifepak 5 or Lifepak 6s to complete the functional verification.

Summary: An alternate procedure to test the Defib Sync functionality of the Propaq Encore and Propaq CS devices is being released to support customers who are unable to perform the original test as documented in the service manuals.

Issue: Welch Allyn accessories to allow interface between the referenced products and a Lifepak 5 or Lifepak 6s defibrillator have been discontinued. Discontinuation of these accessories prevents successful completion of one section of the functional verification described in the Propaq Encore and Propaq CS service manuals.

Action: An alternate procedure to test the Defib Sync functionality of the Propaq Encore and Propaq CS devices is being released to address this issue. Customers who cannot complete the functional verification described in the affected service manuals due to parts availability may perform the procedure in this Customer Service Bulletin to satisfy the requirement to test the Defib Sync functionality of the Propaq Encore and Propaq CS devices.

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

Required Tools:
- Pulse Generator capable of supplying a 0 to 3 volt square wave pulse with a pulse width of 10 milliseconds and a 1 hertz frequency.
- Wire, 26 AWG.
**Procedure:**

In the “Functional Verification” chapter of the service manual, section “ECG/RESP Channel and Alarm Indicators,” locate the steps shown below (step numbers may vary based on manual revision):

12. Using either a LifePak 5 or LifePak 6s and appropriate Welch Allyn adapter, set up the monitor and defibrillator according to instructions provided in the Defib Sync User’s Guide.

13. Check the monitor display for sync markers on the ECG waveform.

14. Disconnect the defibrillator from the monitor.

Substitute the following steps for the steps shown above:

1. Adjust the pulse generator to provide a baseline of zero volts with +3 volt pulses of 10 millisecond duration and a repetition rate of 1 hertz.

2. Using the diagram below, insert the conductive wires into the Ground and Marker In pins of the Defib Sync connector. Connect the pulse generator output and ground to the wires.

3. Turn off the patient simulator. If the respiration rate reaches zero while the patient simulator is off, an apnea alarm may occur. If this occurs, press the suspend key and continue the test.

4. Verify the monitor displays marker pulses (vertical dotted line segments above and below the ECG trace).

Note: If the ECG simulator is producing an ECG signal, the timing of the marker signals may eventually drift through the timing of the simulator’s QRSs. Because the monitor does several fault-detection tests on this interface, such timing coincidence may result in an equipment alert and/or preventing the marker indicators from being displayed.

5. Disconnect the pulse generator and verify the marker pulses are no longer inserted in the monitor’s ECG trace.

6. Remove the conductive wires from the Defib Sync connector.
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.

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