Technical Service Bulletin

Monitoring Products

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Date: 2011-06-14 SAP DIR #: 20012371

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Subject: TSB-Flexnet Radio 2.30.01 and Cisco Integration

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: Propaq LT, Micropaq, and Propaq CS devices with Flexnet radio

Summary:
A new software version for the Flexnet radio card, 2.30.01, has been released for production for Micropaq and Propaq CS devices. This radio card software implements connectivity with Cisco network infrastructure. To support this version of radio card, new versions of software for the Propaq LT, 1.60.05, and Micropaq, 1.80.00, have also been released. The minimum software levels for the radio and devices referenced in this bulletin are being updated due to this change.

Issue:
Updates were required to the Flexnet radio software to achieve compatibility with Cisco network infrastructure. Additionally, the current Flexnet install base is configured for the extensible authentication protocol (EAP); however, Cisco integration requires pre-shared key (PSK) authentication. This issue required device updates to allow configuration to the PSK authentication protocol.
Action: Flexnet radio software 2.30.01 will become the minimum radio software level for the devices referenced in this bulletin.

Due to this change, the minimum device software level for Propaq LT and Micropaq devices with Flexnet radio will be updated to 1.60.05 and 1.80.00 respectively. The new software versions for the Propaq LT and Micropaq added a new radio configuration menu that allows the user to configure each device for EAP or PSK authentication. As such, all Propaq LT and Micropaq devices with Flexnet radio software 2.30.01 and the corresponding device software installed will be compatible with Aruba and Cisco networks, based on user configuration.

For the Propaq CS, new top level assemblies (TLAs) have been created that are pre-configured for either EAP or PSK authentication. Existing Flexnet Propaq CS (EAP) devices will continue to work with Aruba infrastructure only. Customers who want to integrate the Propaq CS with Cisco networks will have to either purchase new devices or upgrade their existing devices to a Flexnet PSK model. The Flexnet radio configuration for the Propaq CS can be identified by the radio label applied to the SpO2 module or expansion module, as shown here:

- **Flexnet icon**
- **Flexnet PSK icon**

A radio configuration guide, material 408243 / DIR 80016835, has been created to detail the radio configuration process for the Propaq LT, Micropaq and Propaq CS. Each device allows the user to select from a list of preset ESSIDs. Additionally, the Propaq LT and Micropaq allow the user to select the authentication protocol: EAP, PSK, or Open. Further customization of radio security settings is possible by utilizing a provisioning network to directly access the radio card. The Work Definition Statement template, DIR 20011716, has been updated to include details on setting up a provisioning network.

The Cisco Best Practices Guide, DIR 20012147, has been updated to include requirements for Acuity deployments on Cisco infrastructure. Acuity version 7.01.00 or higher is required for deployment on Cisco infrastructure.

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

**Updates:**
- Technical Manual ☑️
- Repair Tool ☑️
- Service Plan ☑️
- Internet/Intranet ☑️
- Procedures ☑️
- Price List ☑️
- Training Material ☑️
- Other ☑️
Service Strategy:

Due to an increased level of radio configurability at the customer’s site, it is now service procedure to ship the devices referenced in this bulletin at the default radio configuration. Prior to starting the functional test for each of these devices, perform the Radio Reset function as described in the applicable Service Manual. Note that due to configuration of radio settings at the customer’s site, the radio reset may need to be performed upon receipt of the device at a service center to allow communication with the Acuity test network.

Additionally, the Acuity test networks installed at service centers need to be updated to allow for connections from the PSK configured Propaq CS devices. See DIR 810-2782-00 for details on required updates to the Acuity test system.

Propaq LT and Micropaq:

Flexnet radio software updates for the Propaq LT and Micropaq will continue to be performed via the wireless update. See the Procedure section below for details.

Propaq CS:

Propaq CS wireless updates cannot be supported at this time. As such, existing Flexnet radio cards that require update to version 2.30.01 will either need to be re-provisioned or replaced. When re-provisioning a radio card for the Propaq CS, ensure the provisioning profile used matches the radio configuration indicated by the device labeling.

To provide loaner support for the new Propaq CS TLAs, 4 new loaner materials have been created. These materials can be used to track loaner movements in SAP. Each loaner material represents a fully configured Propaq CS device with expansion module, and options as shown in the table below:

<table>
<thead>
<tr>
<th>Material</th>
<th>Connector Type</th>
<th>SpO2</th>
<th>Auth. Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>246NDHPRAWC-L</td>
<td>HP</td>
<td>Nellcor</td>
<td>PSK</td>
</tr>
<tr>
<td>246NDAMRAWC-L</td>
<td>AAMI</td>
<td>Nellcor</td>
<td>PSK</td>
</tr>
<tr>
<td>246SDHPRAWC-L</td>
<td>HP</td>
<td>Masimo</td>
<td>PSK</td>
</tr>
<tr>
<td>246SDAMRAWC-L</td>
<td>AAMI</td>
<td>Masimo</td>
<td>PSK</td>
</tr>
</tbody>
</table>

Each service center will be responsible for seeding a PSK configured loaner pool, as necessary based on sales forecasts for their region.
To support repair of PSK configured Propaq CS devices, a new radio card service kit has been created, material 104179. This service kit consists of a Flexnet radio card, provisioned with Flexnet software 2.30.01 and configured for PSK authentication, with an antenna. The 020-0691-00 service kit should still be used for repair of EAP configured devices, as identified by the wireless radio label.

New safety and radio labels have been created for the Propaq Encore and CS. The radio identification section has been removed from the safety label and placed on a separate label as shown below, and IPX references have been removed from the labels. The safety label (p/n 717383) will be installed on each newly manufactured expansion module or SpO2 module, and the radio label will be applied as applicable based on the device configuration.

<table>
<thead>
<tr>
<th>Material Number</th>
<th>Description</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>717383</td>
<td>Safety Label</td>
<td><img src="image" alt="Safety Label" /></td>
</tr>
<tr>
<td>717384</td>
<td>Flexnet Label</td>
<td><img src="image" alt="Flexnet Label" /></td>
</tr>
<tr>
<td>717385</td>
<td>Flexnet PSK Label</td>
<td><img src="image" alt="Flexnet PSK Label" /></td>
</tr>
</tbody>
</table>
The following labels are being replaced by the above and will be discontinued:

- 640-0331-09, LABEL,2XX MONITOR/BAQPAQ,SAFETY,IPX1
- 640-0385-08, LABEL,2XX EM/EMP SAFETY AGENCY,W/O IPX1
- 640-1188-00, LABEL, WIRELESS CS 802.11A, SAFETY, IPX1
- 640-1189-00, LABEL, WIRELESS CS 802.11A, SAFETY, W/O IPX1

Existing stock of these labels may be consumed until depleted. Symbol radio labels 640-0535-02 and 640-0537-02 are unaffected by this change and should be used as applicable. Reference DIR 824-0317-02 for label placement.

The Flexnet radio conversion process has been updated to allow customers with non-wireless or Symbol wireless Propaq CS devices to convert to Flexnet PSK. Reference DIR 832-0144-00 for instructions on performing this update.

**Required Training:**
Ensure training records for the following documents are updated, as applicable, for employees engaged in service and repair of the products referenced in this bulletin.

- 20012371 ver C, TSB-Flexnet 2.30.01, Cisco Integration
- 820-0155-00 ver R, WI, PROD SVC, MICROPAQ EXCH, MIN HW/SW
- 820-0172-00 ver K, WI, SERVICE, PROPAQ 2XX MIN HW/SW LEVELS
- 820-0175-00 ver F, WI, Svc, Propaq LT Minimum HW/SW Levels
- 832-0144-00 ver B, W/I, PROD SERVICE, 24X, 802.11A CONVERSION

**Required Tools:**
- Acuity test system configured per 810-2782-00 ver B or above
- PC w/web browser connected to Acuity test system, Proset32 (840-0511-XX) and OCDemon Flash Memory Programmer installed
- Micropaq Programmer fixture, 850-0515-02
- Propaq LT USB cradle and USB cable
- Printer, Parallel Cable, RS232 Serial Cable

**Required Materials:**
- 810-2226-14 CD, SW, SVC UTIL+SW, SC, 802LT, V1.60.05
Procedure: Radio software update:

To wirelessly update the Flexnet radio software to version 2.30.01 on Propaq LT and Micropaq devices, follow the instructions in the 802.11a Radio Software Update Procedure, 810-2744-00. This instruction, along with the necessary files to complete the update, is available in SAP. The necessary files to perform this update are in the latest versions of the SAP DIRs shown below. Service centers with a validated provisioning station may use the applicable provisioning procedures to update radio cards instead of performing the wireless update.

<table>
<thead>
<tr>
<th>File description</th>
<th>SAP DIR number and file name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Password Generator</td>
<td>855-0233-00, 855-0233-00.exe</td>
</tr>
<tr>
<td>Propaq LT &amp; Micropaq HD radio update files</td>
<td>50010591, webupgrade_Lamarr_PCMCIA.zip</td>
</tr>
</tbody>
</table>

Note: The radio card software update must be performed prior to the corresponding device software update.

Propaq LT software update:

The Propaq LT requires a minimum device software level of 1.60.05 to achieve compatibility with Flexnet radio software 2.30.01. A new Propaq LT service utility CD, part number 810-2226-14, has been released to allow software updates to version 1.60.05.

Micropaq software update:

The Micropaq HD requires a minimum device software level of 1.80.00 to achieve compatibility with Flexnet radio software 2.30.01. The files for Micropaq software version 1.80.00 are located in SAP DIR 50010648.

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.

All Welch Allyn employees and contractors engaged in service and repair of the products referenced in this bulletin shall complete a Read & Sign training record indicating they have read and understand this document, as well as applicable documents listed in the Required Training section.
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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
<th>Change #</th>
<th>Init</th>
<th>Release Date</th>
<th>Appr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Initial Release</td>
<td>D*</td>
<td>CB</td>
<td>D*</td>
<td>D*</td>
</tr>
<tr>
<td>B</td>
<td>Removed versions from DIR references</td>
<td>D*</td>
<td>CB</td>
<td>D*</td>
<td>D*</td>
</tr>
<tr>
<td></td>
<td>Added Acuity version compatibility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Added Propaq LT release information</td>
<td>D*</td>
<td>CB</td>
<td>D*</td>
<td>D*</td>
</tr>
</tbody>
</table>

D* - Refer to SAP DIR digital signature log for approval details.