Technical Service Bulletin

Monitoring Products

Bulletin Type: Information Only

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Date: 2009-07-10
SAP DIR #: 20011510

Subject: TSB-Propaq SCP Service Kit 020-0476-00 Obsolescence

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

Product(s) Referenced: Propaq 2XX Series Monitors equipped with the Pulse Oximeter Option

Summary: \( \text{SpO}_2 \) Control Processor (SCP) Printed Circuit Board Assembly (PCBA) 031-0010-04 has been discontinued and as a result service kit 020-0476-00 will become unavailable when current inventories are depleted.

Issue: Demand for SCP PCBA 031-0010-04 is no longer sufficient to justify cost of continued production.

Action: SCP PCBA 031-0133-XX will become the default replacement for all SCP failures when stock of SCP service kit 020-0476-00 is depleted.

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

Other Documents:
- 820-0172-XX, W/I Factory Service Propaq Process Min HW/SW Levels
- 810-1084-XX, Service Manual, Propaq Encore, 20X Series, CD
- 810-1316-XX, Service Manual, Propaq Encore, 20X Series, Hardcopy
- 810-1657-XX, Service Manual, Propaq CS, 24X Series, CD
- 810-1315-XX, Service Manual, Propaq CS, 24X Series, Hardcopy
- 810-2737-XX, Service Manual, Propaq CS 24X Series, V3.7X, Hardcopy
Service Strategy:

- Replace failed legacy SCP PCBA 031-0010-XX with SCP PCBA 031-0133-XX when inventory of SCP service kit 020-0476-XX is depleted.
- Update balance of monitor hardware and/or software as required per 820-0172-00.
- Replace chassis plastic if required clearance cutouts for PCBA 031-0133-XX are not present. See Figure 1, Expansion Module (EM) and Figure 2, SPO2 Only for indication of required PCBA clearance cutouts. The following chassis service kits are compatible with PCBA 031-0133-XX:
  - 020-0122-01, Front Chassis, SPO2 Only
  - 020-0581-00, Main Chassis, EM With Printer For CO2 Conn., W/O Bracket
  - 020-0583-00, Main Chassis, EM W/O Printer For CO2 Conn., W/O Bracket
  - 020-0599-00, Main Chassis, EM With Printer, ESD
  - 020-0600-00, Main Chassis, EM W/O Printer, ESD

Figure 1

SCP PCBA Clearance Cutouts

Figure 2
**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.

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**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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**End of Bulletin**

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**Revision History**

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