



**Technical Service Bulletin**

**CARDIOPULMONARY**

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**Bulletin Type: AS NEEDED**

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**Manufacturer: Welch Allyn**

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**SAP DIR #: 20012463**

**THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**

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**Subject:** TSB-CP100\_200 PATTERN 10 PCBA RELEASE

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

**Product(s) Referenced:** CP100 and CP200 Electrocardiographs, Pattern 10 PCBA 408515, Pattern 9 PCBA 405559, CP100/CP200 Software Version 2.6.

**Serial No. / Lot Code:** Welch Allyn Production began using PCBA 408515 starting with units:  
CP100: 10021421  
CP200: 20021350

**Summary:** The Pattern 10 PCBA, used in conjunction with software version 2.6, introduces the functionality of a Real Time Clock (RTC).

**Issue:** When the device is reset or the battery is removed, the system date and time is lost and cannot be automatically recovered. It must be entered by the operator to insure the system date and time is correct.  
The combination of the real time clock (RTC) SW (V2.6), and HW (Pattern 10 Main Board) will provide a non-volatile system date and time that persists for up to 4 days when the device is reset, including when the battery is removed.

**Action: See Service Strategy**

**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 checked="" type="checkbox"/> |
| Procedures        | <input type="checkbox"/> | Price List        | <input type="checkbox"/>            |
| Training Material | <input type="checkbox"/> | Other             |                                     |

**Service Strategy:**

Current stock of Pattern 9 PCBA 405559 shall be exhausted prior to using the Pattern 10 PCBA 408515 for repairs.

Pattern 10 boards are received with a previous version of software. The RTC available for use with the new Pattern 10 PCBA is only available when used with software version 2.6. When used with software versions previous to 2.6, the Pattern 10 PCBA will perform as expected, but will not provide the added functionality of the RTC. Therefore, Repair Centers will need to continue to install the version 2.6 software onto systems repaired with the new Pattern 10 boards.

For now, customers will be required to send their unit in for service if they believe that the main board needs to be replaced. We are currently working toward a possible solution for the customer that will not require them to send the unit in for repair. This TSB will be updated should a process and documentation become available which would allow customers to order the Pattern 10 board.

**Required Materials:**

- 408515 (PCBA, CP100/200 MAIN PATTERN 10)
- 409255 (VERSION 2.6 CP100/200 SOFTWARE)

**Procedure:**

After the initial setting of the date and time on the device, the Time/Date screen will be bypassed upon reset of the unit. If the battery is removed, the device retains the date and time for a period of at least 4 days. Beyond 4 days, the date and time may need to be re-entered upon applying A/C power, or a charged battery, to the device.

**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 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**

<b>Revision History</b>					
<b>Version</b>	<b>Description</b>	<b>Change #</b>	<b>Init</b>	<b>Release Date</b>	<b>Appr</b>
A	Initial Release	D*	SMB	D*	D*
<b>D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL</b>					