



**Technical Service Bulletin**

**Cardio Products**

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**Bulletin Type: As Needed**

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**Date: 2009-10-15**

**SAP DIR #: 20011603**

**Subject:** TSB - CP100 & CP200 V2.5 SOFTWARE RELEASE

**CAR Number:** N/A

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

**Product(s) Referenced:** CP100 & CP200 Electrocardiographs

**SW Version:** ALL

**Serial No. / Lot Code:** CP100: S/N 10008271 and higher starting 2009-10-15  
CP200: S/N 20009392 and higher starting 2009-10-15

**Summary:** The Welch Allyn Diagnostic Cardiology Team is pleased to announce a new version of software for the CP100 and CP200 electrocardiographs. This version 2.5 software is a general maintenance release that incorporates several improvements outlined below. *This software update does not include any specific improvements to reduce lock up issues.*

The CP100/CP200 SOFTWARE UPDATE KIT (P/N 100942) contains the revised:

- DFU CUSTOMER LETTER APP V2.5 CP100/200 (P/N 714531),
- DFU SW UPDATE APP V2.5 CP100/200 (P/N 714530),
- CP100 PRODUCT INFORMATION CD (P/N 401150),
- CP200 PRODUCT INFORMATION CD (P/N 401151) and
- ASSY, SD CARD, APP V2.5.0 BOOT V2.1.0 (P/N 406480).

When an update is performed in the field by a Welch Allyn employee or authorized representative, the revised Customer Letter, DFU Update and DFU CDs must be left with the customer after the update is performed. The SD card may be left with the customer but is not required.

## **Improvements with Software Version 2.5:**

- **Location of printed date and time changed**  
The date and time on the ECG printout has been moved from the footer to the header on the ECG printout to make it easier to see and prevent confusion with other information printed in the footer.
- **Support of external memory devices**  
Drivers have been updated to support USB storage device with memory sizes greater than 2 GB.

**Note:** The CP100 and CP200 do not support SD card capacities greater than 2 GB including SDHC and SDXC high capacity SD card formats, or other USB storage devices that have software applications pre-installed such as SanDisk U3 Smart technology.

**Note:** The larger the capacity of the USB storage device, the more time is needed to transfer files. Several minutes may be required to transfer files using large capacity USB storage devices. Please be patient.

- **Work flow changes to limit misidentified ECGs**
  - For STAT or Auto ECGs without patient ID or name, the report Print Copy option will not be available - this is intended to prevent multiple copies of printed ECG reports without patient identification.
  - The Post ECG screen now times out at 2 minutes and automatically returns to Preview ECG display.
- **Print Quality**  
The light printing sometimes observed with V2.4 software has been eliminated.
- **Enhanced Error Logging (Engineering Use only)**  
Enhanced error logging may be enabled or disabled from the keyboard to support engineering investigations as needed. When shipped to customers this feature is disabled by default.

**Note:** Wireless connectivity support is not available with this SW release and remains a potential future option.

**Existing CP200 Customer Software Update:**

- **Software Version 2.5 CP100/CP200 SOFTWARE UPDATE KIT is being sent to all existing CP200 customers**

A complementary V2.5 software update kit (P/N 102984 for USA, 100942 for International) along with a CP200 USER REMINDER Letter (SAP DIR 80015670 for USA, 80015689 for International) are being sent to all existing CP200 customers as an outcome of the Health Risk Evaluation (SAP DIR 60030087) of CP 200 “Print Copy” complaints. The customer is not required to perform the software upgrade. Refer to the CP200 FAQ link on The Pulse at:

[http://thepulse/intranet/product\\_support/support\\_faqs/default.jsp](http://thepulse/intranet/product_support/support_faqs/default.jsp) for more information.

**Reference to Standards:**

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

**Updates:** If required

- |                   |                          |                   |                          |
|-------------------|--------------------------|-------------------|--------------------------|
| Technical Manual  | <input type="checkbox"/> | Repair Tool       | <input type="checkbox"/> |
| Service Plan      | <input type="checkbox"/> | Internet/Intranet | <input type="checkbox"/> |
| Procedures        | <input type="checkbox"/> | Price List        | <input type="checkbox"/> |
| Training Material | <input type="checkbox"/> | Other             |                          |

**Required Training:**

No training required. Refer to this distributed TSB.

**Required Tools:**

None

**Required Materials:**

Software Update kit (P/N 100942)

**Quality Documents:**

**All service centers using SAP to record service transactions:** For each device serviced, record the service activity in SAP.

**All other service centers and Field Service:** For each device 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**

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Release to production	D*	D*	D*	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					

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