



**Technical Service Bulletin**

*Cardio Products*

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**Bulletin Type: As Needed**

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**Date: 2010-09-16**

**SAP DIR #: 20011908**

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**Subject:** TSB – CP50 & CP50 Plus V01.00.01 SOFTWARE RELEASE

**CAR Number:** N/A

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

**Product(s) Referenced:** CP50 and CP50 Plus Electrocardiographs

**SW Version:** ALL

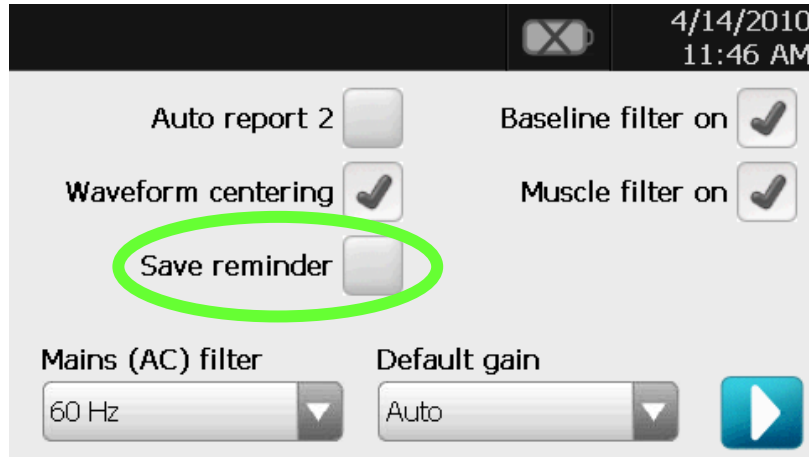
**Starting Serial No.:** All manufactured devices starting with Serial number 109200011310

**Summary:** The Welch Allyn Diagnostic Cardiology Team is pleased to announce a new version of software for the CP50 and CP50 Plus electrocardiographs. This version 01.00.01 software is a general maintenance release that incorporates several improvements outlined below.

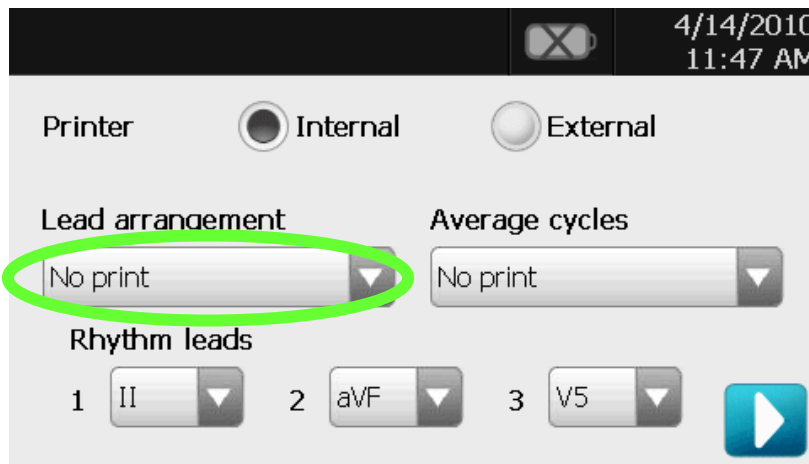
**Issue:** Based on MPD SOP-20211, the software update is classified as continuing engineering project, which is governed by SOP-20213.

**Software Improvements:**

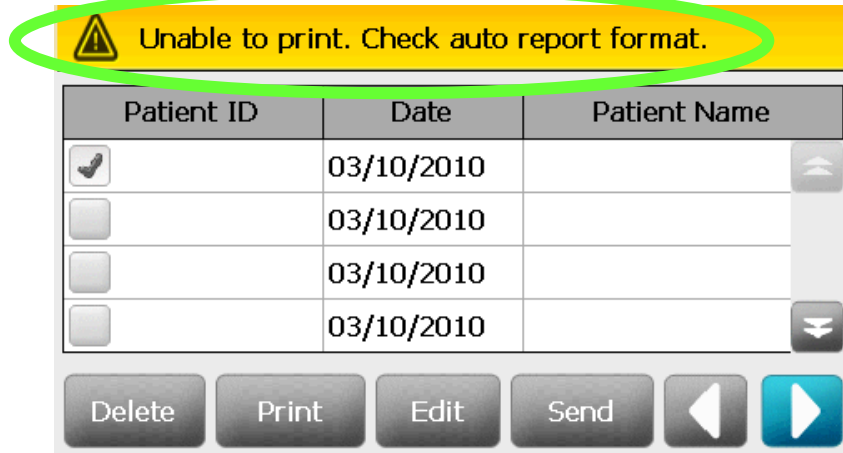
- **Corrected USB to PC connectivity issues when powering from cold boot or returning from standby mode.**
- **ECG “Save Reminder” option added.**  
With the Auto Save feature disabled; when exiting the POST ECG view, the user will have the option be reminded that the ECG test has not been saved and given the option to do so if desired. This option may be enabled or disabled in: *Menu>Settings>ECG Configuration*.



- **“No Print” option added to Auto report 1 and 2 lead arrangement configuration. *Menu>Settings>Auto Report 1 (2)*.**  
When enabled, Auto ECG will proceed from Patient Demographic to Acquisition to Analysis and straight to Post Auto ECG without printing. For STAT Auto ECG, the device will proceed from Acquisition to Analysis and straight to Post Auto ECG without printing if the Auto Report’s Lead configuration is set to “No print”.



When printing ECG test records from the ECG Test folder, if the selected Auto Report Format's lead configuration is set to "No Print", the device will display "Unable to print. Check auto report format" at the top of the screen.



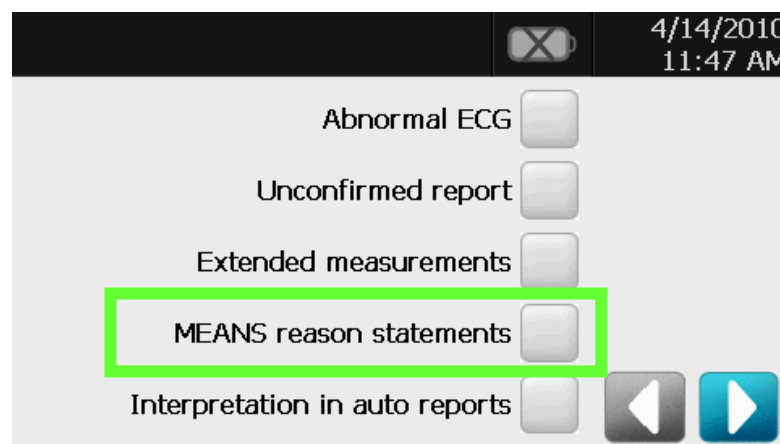
➤ **Patient data checkers added for Denmark, Sweden and Norway.**

CP50 V01.00.00 software does not check for any particular format of patient IDs entered by the user.

CP50 V01.00.01 software will check for the ID formats for Denmark, Sweden and Norway. These countries' IDs follow some special formats, which DOB and gender are embedded in. If the data checkers detect that the entered patient ID is within any of these special formats, the patient's DOB and gender will be automatically extracted.

➤ **Option added for turning on/off MEANS reason statements on printout.** This option will be disabled (will not print) by default.

*Menu>Settings>Auto Report 1 (2).*



➤ **Corrected issue: Touch Screen calibration values were not used while device is in Maintenance Mode.**

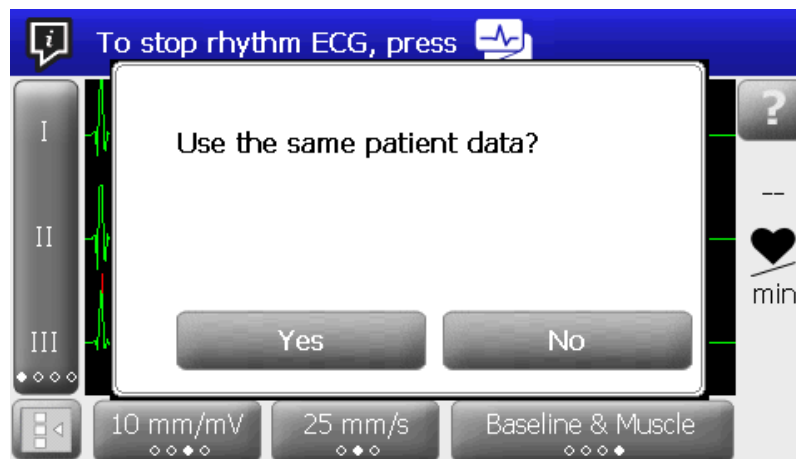
The CP50 Touch Screen is calibrated during production however these values did not carry over when entering Maintenance Mode. The values will now be collected from memory.

➤ **Corrected issue: Additional page is being printed that contains 1mm of data when printing an Auto ECG report to an external printer.**

Acquired Auto ECG report data has been corrected to fit one page so that the last 1mm of data will not cause a second page to print when using an external printer.

➤ **Additional prompt added to allow users to use the previous patient information for a Rhythm ECG.**

When a Rhythm ECG is started, the user will be prompted whether to reuse the last patient demographic, if available or none if no previous patient information exists. The dialogue "Use the same patient data?" will be displayed.



➤ **Corrected: Empty worklist download error.**

CP50 V01.00.00 software: When downloading an empty worklist from remote, the device did not correctly reflect the empty list in the user interface even when it had cleared its internal cache.

When a user selects any entry in the currently displayed list and tries to delete the entry, it caused the device to reboot. Corrected in CP50 V01.00.01 software

➤ **Corrected: Pacer Confirmation did not take effect.**

CP50 V01.00.00 software: The device would detect and prompt for the confirmation of an existing artificial pacemaker. If confirmed, the device may not acknowledge the confirmation and proceed with interpretation analysis. Corrected in CP50 V01.00.01 software.

**Action:**

Apply the update as needed using Software Update kit (P/N CP50-016). All CP50 devices returned for repair or evaluation should always be updated to the latest software version before being returned to the customer.

**Reference to Standards:**

- 21 CFR Part 820 & ISO 13485

**Updates:**

|                   |                                     |                   |                          |
|-------------------|-------------------------------------|-------------------|--------------------------|
| DFU               | <input checked="" 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             |                          |

**Service Strategy:**

Standard TSB distribution

**Required Training:**

N/A

**Required Tools:**

N/A

**Required Materials:**

Software Update kit (P/N CP50-016)

**Quality Process for failed units or components:**

N/A

**Procedure:**

The Software will be updated via supplied USB thumb drive.

Refer to Customer letter 715751 (Also shipped with Software Update kit (P/N CP50-016) for detailed software update instructions.

**Important note:** This particular software update will require the device to boot into Maintenance mode as described in Customer letter 71575. This extra process will be the exception and not the norm regarding most future CP50 and CP50 Plus software updates.

**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**

| <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*              | D*          | D*                  | D*          |
| D* - See SAP DIR for Change number, Approver Name and Date of Approval |                    |                 |             |                     |             |