



**Technical Service
Bulletin**

Cardio Products

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Bulletin Type: As Needed

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Date: 2010-08-12 **SAP DIR #: 20012608**

Subject: TSB – CP50 & CP50 Plus V01.20.01 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

**Serial No. / Lot
Code:** N/A

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 01.20.01 software is a general maintenance release that incorporates several improvements outlined below. This update incorporates all prior updates.

Issue: Release of new Software addressing the following:

- Auto ECG Test Assignment
- Saving ECG Test as PDF file
- Report Printing Option
- Download worklist using filter
- Static DataCatcher IP Address
- Clearing of Patient Demographic
- Downgrading Software
- Multiple ECG test print using External Printer
- PTSS Support

Software Improvements:

➤ Workflow improvement: Auto ECG Test Assignment

This feature is only available for the Plus version.

During an Auto ECG procedure, the patient information is requested.

User can choose the following actions:

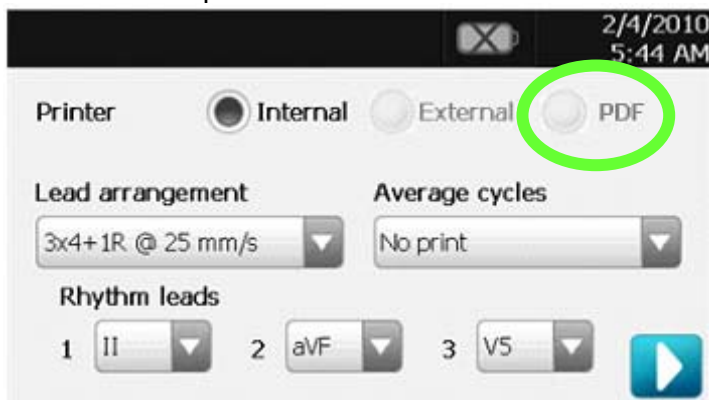
- Enter the patient information manually
- Select a patient from a search
- Select a patient from the worklist
- Skip this step
- No change to the patient information of this test is permitted beyond this step. The improved workflow permits a test to be assigned if no patient information has been provided during the Auto ECG procedure.
- An “Assign” button will be visible in the Post ECG screen when the “Test Assignment” option is enabled in the ECG Configuration. This button will be enabled only if no patient information has been provided. Users can select patient from the local worklist. Once the test has been assigned to a patient in the Post ECG screen, the “Assign” button will be disabled.
- The above applies to STAT ECG procedure.

➤ Workflow improvement: Saving ECG Test as PDF file

This feature is only available for the Plus version.

Currently the device supports saving of ECG test internally in a proprietary format. The improved workflow adds a new option to save the ECG test as a PDF file to an attached USB Mass Storage only.

- The saved PDF file will be labeled as YYYYMMDDHHMMSS_PatientID.pdf when patient ID is available or YYYYMMDDHHMMSS.pdf if not.
- To enable this feature, configure the printer option to PDF in the Auto Report 1 or 2 screen.



- This feature is similar to a PC method of generating PDF, i.e. we specify the printer to be a PDF writer instead.
- PDF option is available in both Auto Report 1 and 2.

- Supported are all the Lead Configurations, Average Complexes, and Extended Measurements (format identical to that of the External Printer Formats).
- Existing files in the USB Mass Storage sharing the same filename will be overwritten.
- Limited to Auto Report printing. Rhythm printing as PDF is not supported.
- PDF output is black and white only.

➤ **Usability Improvement: Report Printing Option**

Previously, a user could disable printing of STAT and Auto ECG Test Report Printing by selecting “No Print” in the *Lead Arrangement option*. To avoid confusion, this functionality is now shifted to the *ECG Settings*. The “No Print” feature is only available for the Plus version.

- To enable, simply go to Menu>Settings>ECG (tab)>ECG configuration and check “Print reports”.
- The “No Print” has been removed from Lead arrangement.
- When disabled, CP50 will print the Auto or STAT ECG test report after interpretation based on either Auto Report 1 or Auto Report 2 formats selected during the start of the test.
- When enabled, CP50 will skip the printing and proceed to Post ECG once interpretation is completed.

➤ **Usability Improvement: Download worklist using filter**

Previously, when downloading worklist from remote workstation, any found work order will be downloaded.

The improved usability allows the downloading of worklist to be filtered by Practice ID.

➤ **Usability Improvement: Static DataCatcher IP Address**

Added the option to specify the DataCatcher IP Address instead of searching the network. In some cases this may improve the connection time between CP50 and CPWS.

➤ **Usability Improvement: Clearing of Patient Demographic**

During an Auto ECG procedure, patient demographic is requested. When the test ends and another test (Auto or Rhythm) is started, CP50 will prompt the reuse of the last patient demographic for the new test.

To avoid any confusion the current release forces the patient demographic to be cleared once the Auto ECG Test procedure has ended.

➤ **Corrected Issue: Downgrading Software**

User can now choose to downgrade the device to a lower functionality version.

➤ **Corrected issue: Multiple ECG test print using External Printer**

When more than 1 Stored ECG Test has been selected to be printed using the external printer, this caused the device to stop working.

Resolution: Software is modified to ensure that the device is capable of handling multiple external print jobs.

➤ **Service Improvement: PTSS (Service tool) Support**

Note: This change readies the CP50 for PTSS support. PTSS will support CP50 at a future date.

The CP50 01.20.01 software release supports the following features:

- POST reporting
- Software versions reporting
- Serial number reporting
- Battery information
- Software update
- Network information
- Touch screen calibration
- Printer pattern test
- Printer speed test
- USB host port test
- Audio test
- BDDS Data Transfer

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	<input type="checkbox"/>	Other	
Material			

Service Strategy:

Standard TSB distribution

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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 716621 (Also shipped with Software Update kit (P/N CP50-016) for detailed software update instructions.
Important note: This software update will not require the device to boot into Maintenance mode as required in previous 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

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	DCS	D*	D*
B	<ul style="list-style-type: none"> Added <i>Plus version only</i> to PDF print section Description added to document footer 	D*	DCS	D*	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					