



**Technical Service
Bulletin**

Cardio Products

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Bulletin Type: As Needed

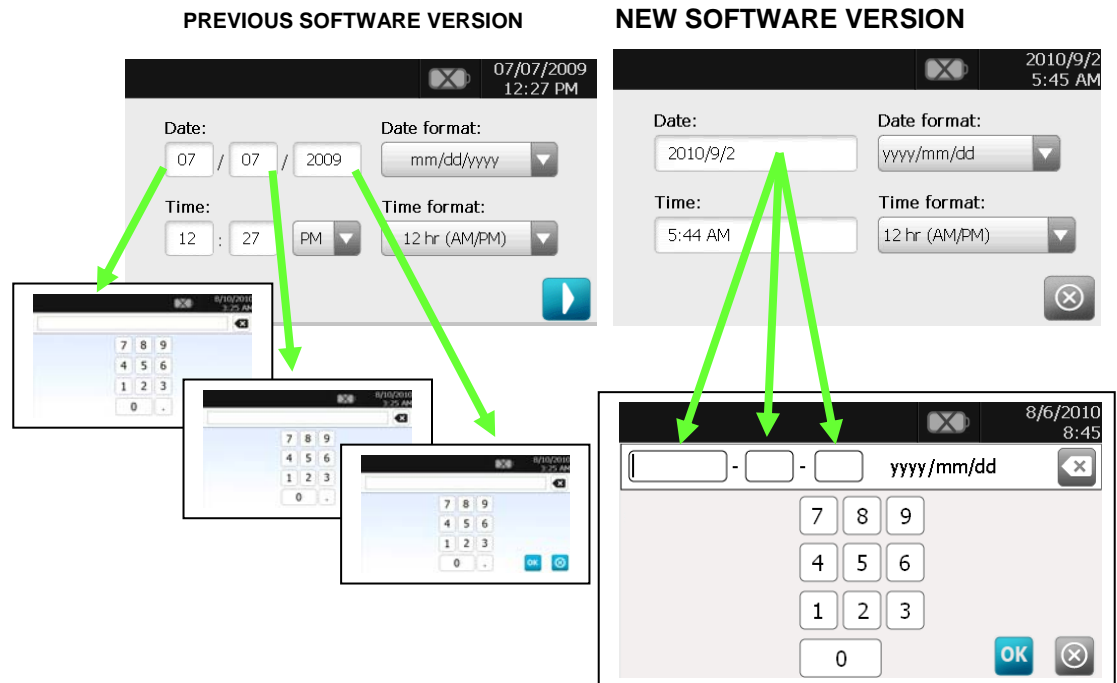
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Date: 2010-12-10	SAP DIR #: 20012096
Subject:	TSB – CP50 & CP50 Plus V01.10.01 SOFTWARE RELEASE
CAR Number:	N/A
Distribution Scope:	WA Internal WA Technical Support, Product Service, & International Service Centers
Product(s) Referenced:	CP50 and CP50 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 01.10.01 software is a general maintenance release that incorporates several improvements outlined below. This update incorporates all prior updates.
Issue:	Based on MPD SOP-20211, the software update is classified as continuing engineering project, which is governed by SOP-20213.

Software Improvements:

➤ **User interface improvement: Date & Time entry**

During an Auto ECG procedure, the age or date of birth of the patient is requested. Previously, we needed to tap on fields individually such as day, month, and year to enter the date (multiple tapping). The improved interface will allow for these fields to be filled from a single screen. This change applies to the system's regional date settings as well. Similarly, the clock setting will allow the hour and minute fields to be filled from a single screen. Samples of the new user interface are shown in the images below.



➤ **Chinese MEANS**

Chinese MEANS interpretation algorithm has been added to accommodate the Chinese market.

➤ **Vietnamese language and MEANS:**

The CP50 device and associated documentation has added the Vietnamese language. Vietnamese MEANS interpretation algorithm has been added to accommodate the Vietnamese market.

➤ **Additional print formats**

The following additional print formats are available for internal and external printing:

3 x 4 - 5.0 seconds of each lead @ 25 mm/sec

3 x 4 - 2.5 seconds of each lead @ 50 mm/sec

3 x 4 - 5.0 seconds of each lead @ 50 mm/sec

➤ **Software Update process improvement**

Software updates post V01.10.01 will now be able to update all software images, with the exception of Main Fonts, through the main user interface. Previous to and including this update, the user needs to enter maintenance mode to update any image other than Main Applications. This process requires the user to press and hold both the **Auto** and **Rhythm** buttons, and then press and release the **Power** button as described in the accompanying customer letter.

All future software updates will update all images (except Main Fonts) by simply going to Menu>Settings>System (tab)> Updates.

➤ **Corrected issue: Fast tapping in Printer Error Dialog causes application to be inactive**

When a print error is encountered, the device would display a print retry dialog. Fast tapping on the retry button caused the application to become inactive. This has been corrected in software version 01.10.01.

➤ **Corrected issue: Intermittent Ethernet connection failure when connecting to Connex CSK.**

It has been determined that having a USB and Ethernet channel simultaneously opened caused a race condition to specific events. The events do not reflect the actual condition thus causing the device to stop connection attempts via Ethernet. The displayed alert will state "Destination unreachable or full".

This issue has been corrected with a software change to ensure that only 1 channel is available at any instance.

➤ **Setting of device language during out-of-box bootup**

An issue has been identified where during initial device setup, if a language is selected inadvertently or otherwise the user interface will continue to the device activation screen without delay. This potential issue has been resolved in software version 01.10.01 by changing the logic to ensure that the language selection is only completed after the user touches the "Next" button.

➤ **Corrected issue: CPWS communication - OrderID is not populated in ECG Test record**

Using a patient demographic selected from the worklist downloaded from CPWS, when an ECG test is completed, the OrderID was not populated. The result is the inability to reflect that the work order is completed.

Software has been modified to ensure that the OrderID is encapsulated for a selected Patient Order from the downloaded worklist. This action is transparent to the user.

Additionally, the Patient ID field will be set to *read only* when a patient order is selected from the Worklist during an Auto ECG, thus protecting the Patient from being modified. The user will be able to modify all information other than the Patient ID.

➤ **Heart rate symbol update on the Chinese user interface**

According to the Chinese national standard, heart rate should be expressed by "HR/分钟". The CP50 device and associated documentation have been updated.

➤ **Corrected issue: Patient Order not deleting after midnight**

When a patient order is created on the device, the file creation date is actually GMT-8 behind the system time. As a result, when the system time passes midnight, the patient order is not deleted as intended. The Window CE registry has been updated to ensure that the system time zone is set to GMT. In this case, all the file creation times shall be set to GMT.

➤ **Corrected issue: USB Host Port may become unstable**

When the device is entering and exiting sleep mode, the USB Host port that is used for USB Mass Storage device does not power down and power up properly. This has been corrected with version 01.10.01.

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)

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 particular software update will require the device to boot into Maintenance mode as described in Customer letter 716621.

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