



**Technical Service Bulletin**

**Cardio Products**

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**SAP DIR #: 20013220**

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**Subject:** 20013220A TSB-CP100\_200 LI-ION BATTERY, 2.6 SW

**CAR Number:** N/A

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

**Product(s) Referenced:** CP100 & CP200 Electrocardiographs  
Li-Ion Battery, 2.6 SW Upgrade Kit P/N: 105204

**SW Version:** All previously released software versions

**Serial No. / Lot Code:** The Li-Ion battery and 2.6 software will be introduced into manufacturing approximately in early to mid-January, 2013. The starting serial numbers for each device will be communicated once that happens.

CP 100 serial number start: 10020828.

CP 200 serial number start: 20020712.

**NOTE: All devices containing the Li-Ion battery, including new units, loaners and repaired units, will ship with the battery disconnected.**

**This is a change to our installation procedures for our customers. Refer to the revised CP100/CP200 QUICK START GUIDE (WA material # 719446) included with product shipments for connection details.**

## Summary:

The Welch Allyn Diagnostic Cardiology Team is pleased to announce a new version of software and a new Li-Ion battery for the CP100 and CP200 electrocardiographs. The 2.6 software and Li-Ion battery will be provided in newly manufactured devices, and is available as an upgrade kit (WA material # 105204) that can be installed by the customer in the field. The 2.6 software for the upgrade kit is provided on an SD Card for direct installation using the device SD Card slot and software update menu selection, as with previous software upgrade kits.

### Software Enhancements

- Improved connectivity to CardioPerfect Workstation (CPWS) with updated USB drivers for Windows 7/32-bit and Windows 7/64-bit compatibility.
- Support for optional Lithium-Ion battery.
- 3<sup>rd</sup> harmonic mains filtering for cleaner ECGs, both viewed and printed.
- Real Time Clock (RTC) support when used in conjunction with the Pattern 10 Main PCBA (planned to be released 1Q2013).

NOTE: This software release includes all of the previous software improvements.

### Hardware Enhancements

- Lithium-Ion (Li-Ion) Battery –Chemical makeup: (Lithium Iron Phosphate)

For additional details, review and refer to the updated instructions provided with newly manufactured devices WA material # 719446 LIT CP100/CP200 QUICK START GUIDE), provided with the upgrade kit (WA material # 718845 DFU CUSTOMER LETTER APP V2.6 CP100/200), as well as the updated Directions For Use CDs (WA material # 401150 CP100 PRODUCT INFORMATION CD and 401151 CP200 PRODUCT INFORMATION CD) provided with both.

## Issue:

### Windows 7 Operating System Compatibility:

Previous versions of the CP-200 software did not support direct USB communication between the device and the CPWS software installed on computers running Windows 7 operating systems. The updated USB drivers provide Windows 7/32-bit and Windows 7/64-bit compatibility. This will allow the CP-200 to communicate directly, via USB cable, with the CPWS installed on Windows 7 systems.

**NOTE: The CP200 needs to be plugged into, and running on, A/C power in order to successfully install the updated drivers onto the computer.**

NOTE: The new USB drivers were not validated for use on Windows Vista 64-bit or Windows 8 operating systems.

### Lithium-Ion Battery Support:

The 2.6 software, when used with the new Li-Ion battery, addresses complaints surrounding the performance of the Sealed Lead-Acid battery. The software

changes to support the Li-Ion battery include:

- Battery charge level indicator to accommodate the different charging and discharging characteristics of the Lithium vs. SLA battery. Battery charge level indicator accuracy improved for SLA battery as well.
- Low battery indication at ~10% remaining capacity, as well as a “last test” warning that there is sufficient energy for just one more test before the device will automatically shut down when using the Lithium battery (not provided for the SLA battery).
- Prevents operation on low battery (both Lithium and SLA) until the battery is recharged to a minimum level to help prevent the electrocardiograph from becoming unstable and locking-up.

### **Artifact Reduction:**

The introduction of a 3<sup>rd</sup> harmonic mains filter further reduces A/C artifact that appears during the viewing or printing of ECGs in electronically noisy environments. Measurements performed by the optional interpretation algorithm are unaffected by the application of this filter.

### **Lithium-Ion Battery:**

The new Lithium battery addresses complaints surrounding the performance of the Sealed Lead-Acid battery. Compared with the SLA battery, the Lithium battery used with the V2.6 software provides:

- Up to 30% faster charge time (less than 8 hours from fully discharged to full capacity).
- Increased battery operating capacity per full charge (~10%).
- Longer battery life (~10x). Because of the Lithium Ion Iron Phosphate chemistry and smart charging technology employed in the Lithium battery, there is virtually no damage to the Lithium battery, and very slow battery capacity degradation over time, when the battery is repeatedly allowed to fully discharge before recharging.

***THE LITHIUM-ION BATTERY HAS A 3-YEAR WARRANTY!!!!***

### **Real Time Clock (RTC):**

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 real time clock SW (V2.6) and HW (Pattern 10 Main Board) provide a non-volatile system date and time that persists when the device is reset, including when the battery is removed. See Table 1 in Action section below for details.

**Action:**

**Windows Drivers:**

**NOTE: The CP200 needs to be plugged into, and running on, A/C power in order to successfully install the updated drivers onto the computer. Please make sure that the unit is plugged into A/C power for either of the following driver installation processes. After the successful installation of the drivers, the device will communicate with the computer while running on battery or A/C power.**

With the 2.6 software installed, both Windows XP and Windows 7 device drivers will be available through Microsoft driver updates. Please refer to the following procedure for the appropriate operating system if the drivers are not automatically downloaded onto the computer when the device is attached to the PC.

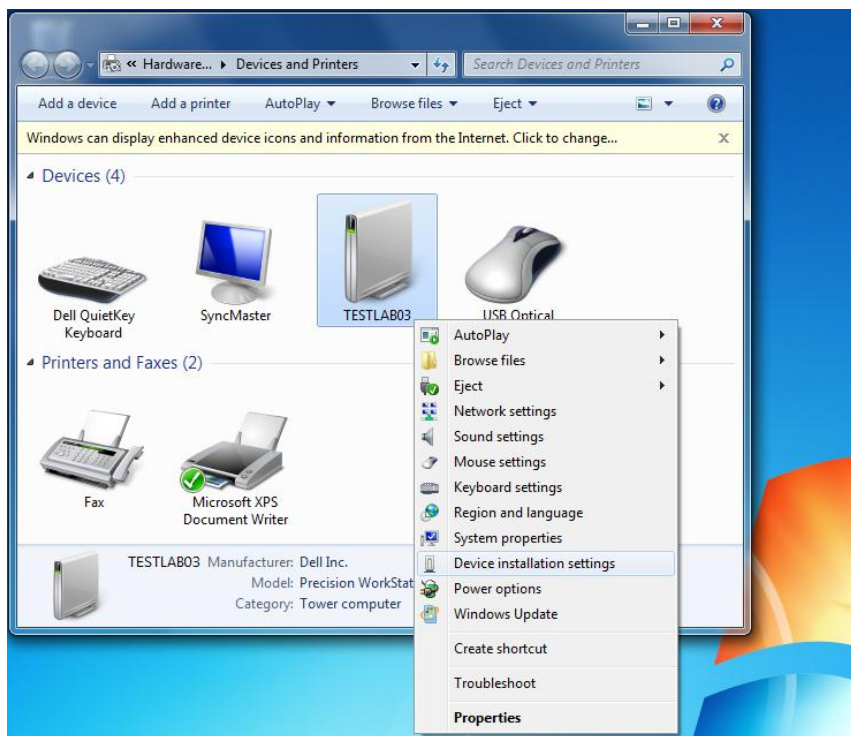
**For Windows 7 Drivers:**

The drivers will likely install automatically, and user will see notifications at lower right of screen confirming that the device drivers were installed successfully and the device is ready to use. If there is an error, the notification at lower right will tell them the driver installation was unsuccessful.

That is probably due to:

- The computer may not have an internet connection.
- The computer may have automatic driver update turned off. The following procedures detail the steps necessary for enabling the ability for automatically updating drivers in each operating system.

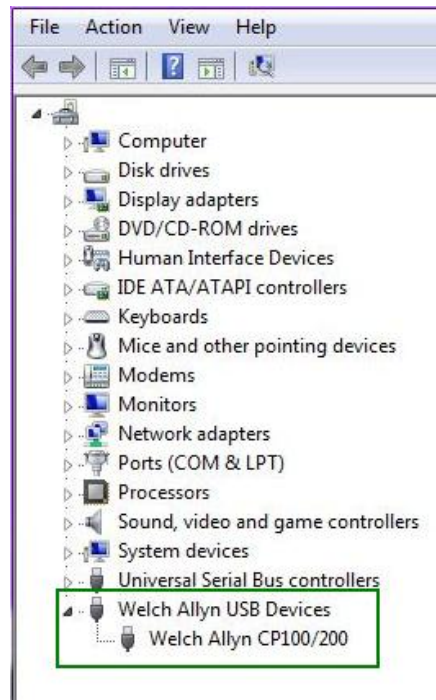
- 1) Disconnect CP200 from PC
- 2) In Start menu, select the Devices and Printers.
- 3) On pop up window, right click the icon with the computer name. On the popup menu, select Device installation settings. Example shows computer name of TESTLAB03.



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- 4) On Device Installation Settings window, choose- Yes, do this automatically.
- 5) Click on Save Changes.
- 6) Reconnect CP200 to PC

Properly installed driver in Windows 7 device manager:



#### For Windows XP Drivers:

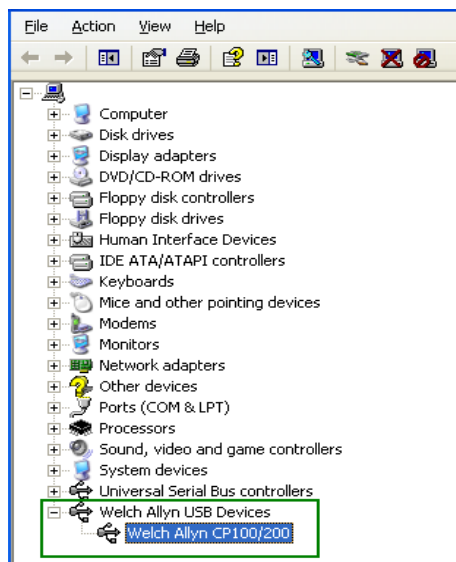
When the CP200 device is plugged into the computer, a Found New Hardware Wizard window should appear, asking if the user wants to search Windows Update.

- 1) The user should select "Yes, this time only".
- 2) Then on the next window, choose Install the software automatically.
- 3) Click Next.

If the wizard does not ask the user to search Windows Update, but instead goes directly to the query for automatic install, then the user will need to turn on Windows Update.

- 4) Disconnect CP200 from PC
- 5) Go to Control Panel, and select Windows Update on the left side of window. On the Windows Update window, select "Turn on Automatic updates".
- 6) Reconnect CP200 to PC
- 7) Answer Yes to search Windows Update
- 8) Choose install automatically

Properly installed driver in Windows XP device manager:



### **Lithium-Ion Battery Support:**

The Lithium-Ion battery and the 2.6 software upgrade will only be available to our customers in the form of a kit: P/N: 105204. Neither the battery nor the software will be available as a separate, customer orderable part. The kit will not be available through distribution and can only be ordered through Welch Allyn. It is strongly recommended that this battery is only used in conjunction with the version 2.6 software so the battery capacity indication is calculated correctly for the new battery type.

The new Li-Ion battery is a direct replacement part for the existing SLA battery and requires no new tools, parts or accessories to install, only a Phillips head screwdriver to open and secure the battery compartment door to connect the positive battery lead. Replacement instructions are provided in the kit, see: WA material #718845 DFU CUSTOMER LETTER APP V2.6 CP100/200.

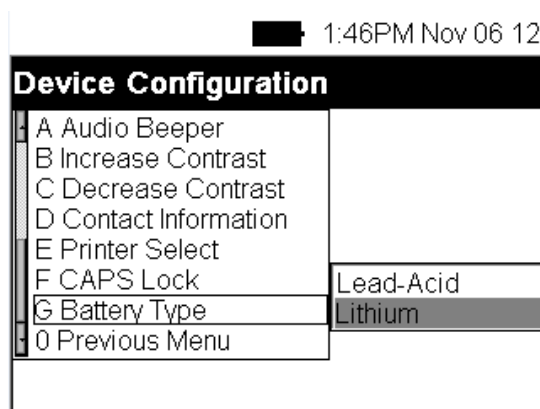
Note: A new fuse is provided with the Lithium battery upgrade kit. The old fuse should be replaced and discarded whenever a battery is replaced.

In addition to battery charge level indicator changes to accommodate the different charging and discharging characteristics of the Lithium vs. SLA battery, the 2.6 software provides low battery indications at approximately 10% remaining capacity, as well as a "last test" warning that there is sufficient energy for just one more test before the device will automatically shut down when using the new Lithium battery (The "Last test" warning is not provided for the SLA battery). This assists the customer in recognizing when the battery is depleted and the device needs to be plugged in to continue using the device. The 2.6 software also prevents operation on low battery (both Lithium and SLA) until the battery is recharged to a minimum level to help prevent the electrocardiograph from becoming unstable and locking-up.

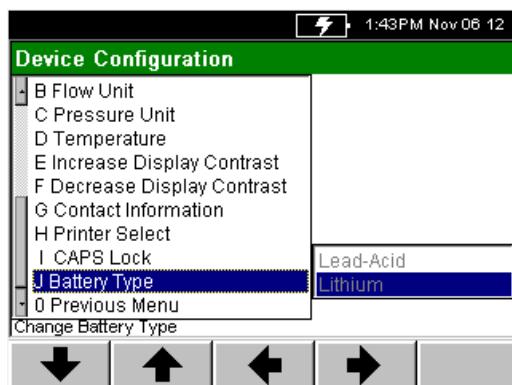
Support for the Li-Ion battery is set by default with the installation of the 2.6 software. If the software is installed into a device that has a Sealed Lead Acid (SLA) battery installed, the battery type will need to be changed manually so that the battery type is correctly selected in the device menu. The software also provides a more accurately displayed battery capacity gauge for the SLA than previous software versions.

To access the battery type selection in the device menu:

- CP-100 Menu:
  1. Press the Menu button
  2. Press “2” for System Settings
  3. Press “1” for Device Configuration
  4. Press “G” for Battery Type
    - NOTE: Example shows software install default choice of Lithium.



- CP-200 Menu:
  1. Press the Menu button
  2. Press “5” for System Settings
  3. Press “1” for Device Configuration
  4. Press “J” for Battery Type
    - NOTE: Example shows software install default choice of Lithium.



**Real Time Clock:**

Note: The Pattern 10 Main PCBA, referenced in Table 1 below, is an expected future release. As of the release date of this TSB, the Pattern 10 PCBA is not yet available.

Table 1

	CP100-200 SW Versions 2.3.0 through 2.5.0	CP100-200 SW Version 2.6.0 and greater
<b>Old Hardware (Pattern 9 and earlier)</b>	<p>Date/time entry is manual; if device loses power or is reset, user is prompted to enter the date and time. There is no battery backup on device to retain date/time information.</p> <p>SW upgrades (Ver 2.3.0 through Ver 2.5.0) allow for backup date/time stamp method; device writes date/time to nonvolatile memory at "midnight". Recalled time/date may be inaccurate for up to the period between the actual current time/date and the time/date saved.</p>	<p>Date/time entry is manual; if device loses power or is reset, user is prompted to enter the date and time. There is no battery backup on device to retain date/time information.</p> <p>SW upgrades (Ver 2.6.0 and greater), no previous time date settings are stored. If the device loses power or is reset, time/date default to: Midnight/June 1, 1999.</p>
<b>New hardware (Pattern 10 and later)</b>	<p>N/A - The new hardware ships with new software (Ver 2.6.0 and greater). If new hardware is used with software (Ver 2.3.0 through Ver 2.5.0) then "Date/time entry is manual; if device loses power or is reset, user is prompted to enter the date and time. There is no software to enable real time clock functionality.</p> <p>SW upgrades (Ver 2.3.0 through Ver 2.5.0) allow for backup date/time stamp method; device writes date/time to nonvolatile memory at "midnight". Recalled time/date may be inaccurate for up to the period between the actual current time/date and the time/date saved."</p>	<p>SW upgrades (Ver 2.6.0 and greater) initial Date/time entry is manual; if device loses power or is reset, user is prompted with the date/time entry screen. There is battery backup on device to retain date/time information for up to 96 hours when power is removed from the device.</p> <p>Time/date information is maintained by the real time clock. The accumulated time/date is accurate. Absolute time/date accuracy determined by user input accuracy. If the device is reset or the backup battery is discharged (&gt;96hr power loss) then the time/date default to: Midnight/June 1, 1999.</p>

**Reference to Standards:**

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

**Service Strategy:**

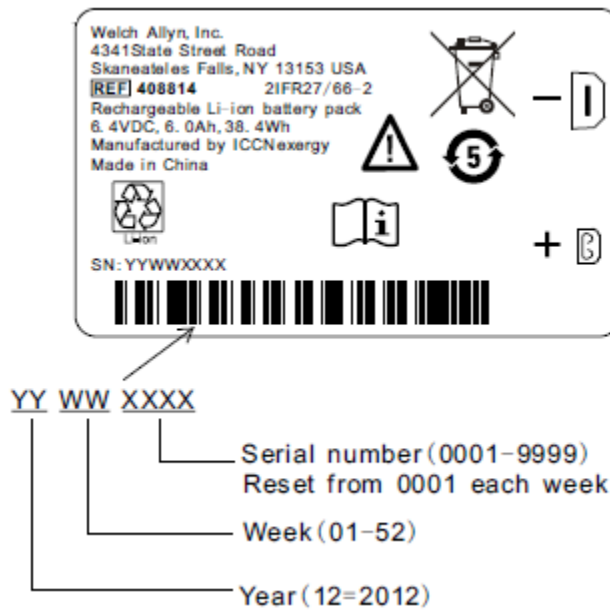
NOTE: Neither the Lithium-Ion Battery nor the 2.6 software are required upgrades.

Customer Service and Technical Support:

- Customers may only order the Li-Ion Battery / 2.6 Software Upgrade Kit, part number: **105204**, through Welch Allyn and its Service Centers. This kit will not be available through distributors. Customers will not be able to order the battery or the software separately.
- Customers will be charged the list price that is posted in SAP at the time of the transaction. Exceptions to this charge will be handled on a case-by-case basis through the appropriate regional manager.
- If a battery is found to have failed under warranty, the customer will receive another 105204 battery/software upgrade kit.



Note: The age of the battery may be determined using the serial number printed on the battery label as shown below. In certain cases, an invoice may be requested from the customer to confirm warranty status.



- Upgrades will be provided at no charge for customers covered by an appropriate PIC agreement.
- In-warranty customers not experiencing issues may be offered the Li-Ion Battery / 2.6 SW Upgrade Kit at a discount of 50%.
- Distributors can purchase the Li-Ion Battery / 2.6 SW Upgrade Kit for their demo units at a discount of 50%.
- Free Li-Ion Battery / 2.6 SW Upgrade Kits will be available for Welch Allyn sales reps.

Global Service and Repair Centers:

**NOTE: All devices containing the Li-Ion battery, including new units, loaners and repaired units, will ship with the battery disconnected.**

**All shipping packages containing devices with the Li-Ion Battery installed will need to be updated with the applicable Li-Ion Battery label (WA material # 713033).**

**This is a change to our installation procedures for our customers. Include CP100/CP200 QUICK START GUIDE (WA material # 719446) with loaners and repaired product shipments containing the Li-Ion battery for connection details.**

- The option to upgrade to the Li-Ion battery should be included on all repair estimates for devices that have the SLA installed when received into repair.
- Service Centers will order the Li-Ion Battery / 2.6 Software Upgrade Kit,

part number: **105204** for all devices that are receiving both the battery and software upgrade. All CDs, software and literature included in the upgrade kit will be shipped with the unit back to the customer.

- CP100 and CP200 devices that are returned to the Service Center for repair but are not receiving a Li-Ion battery will be upgraded to the 2.6 version of the software. Repair technicians may keep a copy of the 2.6 software (WA part number 409255), on hand to upgrade the device when the customer has declined the upgrade to the Li-Ion battery. If a customer has a bad SLA battery and declines the upgrade to Li-Ion, the unit will be returned to them with the bad SLA battery and version 2.6 installed on the device and the Battery Type set manually to Lead-Acid.
- If a device is received with a Li-Ion battery that has failed within its warranty period, Global Service Centers may order the Li-Ion battery as a service replacement, part number: **408814**.

NOTE: The Sealed Lead-Acid battery (P/N: 100660) for the CP100 and CP200 will be obsoleted and no longer available shortly after the release of the Li-Ion battery.

**Required Training:** N/A

**Required Tools:** N/A

**Required Materials:** Li-Ion Battery with 2.6 Software Upgrade Kit (P/N: 105204)

**Quality Process for failed units or components:** N/A

**Troubleshooting:** Last test warning: Upon power-up or wake-up, the device requires 6 seconds to properly determine the voltage / charge level of the battery. If the customer initiates an ECG or Spirometry test prior to the end of this 6 second time period, the customer may not receive the "Last test" warning. In these rare situations, the test may not be performed and printed as expected. Because rhythm printing is a continuous operation, the "Last test" warning may not appear or work consistently.

Battery Indicator accuracy: Poor battery capacity indicator performance will be caused by having the wrong battery type selected in the menu for the type of battery installed... i.e. - Lead-Acid chosen in the menu with a Li-Ion installed or vice versa. The use the Li-Ion battery with software versions prior to 2.6 will also cause poor battery capacity indicator performance.

Known Issues:

- Future dates and non-existent dates may be entered into Patient Data fields.
- Units may turn on automatically with no user input or key presses when leaving the charge state.

- A blank page may be printed at the end of a 3-page Spirometry report.
- When printing more than 10 pages of Rhythm ECG at a time, the header and footer of each 'page' will no longer be in alignment with the paper's perforations.
- Rhythm ECG key handling error from LTD Printer Test service screen causes Rhythm Printing to be skipped and user goes to Ready screen. (Repair function only)
- After a Low Battery Power-down, on Power-up, the Low Battery pop-up is displayed and the screen takes a second or so to change to the Lead-Off Torso.
- CP 200 USB Connectivity - CP 200 may say "Failed to send test to Workstation" when the test actually sent.
- When low power message is displayed during a Rhythm print, user cannot stop the Rhythm print. The unit will shut down automatically after 60 seconds.
- Upgrade Software Exit key may appear to be disabled, but works if pressed.
- External printer printout may show waveform with part of the R wave clipped.
- For a patient with a very high heart rate, the artifact warning message may appear and become stuck. The user can start a new test in order to clear the artifact warning.
- International languages will not display some characters marks correctly because the input field is not tall enough.
- Spirometry printout has legend title "Legend" in English regardless of current system language.
- In some languages, when users are performing an upgrade, they may not see some of the status and error messages.
- If incorrect patient DOB leads to very old patient (older than physically possible), it may not be possible to import the test into CPWS.
- FlashFX defect with bad block allocation may cause a programming problem which manifests itself in two ways:

Patient information cannot be stored or patient test records cannot be stored (device info screen shows it has run out of NAND memory)

AND

Device cannot be started from power off (this will only happen after an upgrade, but not in every device).

The user may have a non-functional device and need to send the unit to service for repair.

**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.

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