



Technical Service Bulletin

Cardio Products

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Bulletin Type: As Needed *

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Date: 2012-07-19 **SAP DIR #: 20012762**

Subject: TSB -CP100-200 PATTERN 9 PCBA and GATE 7

CAR Number: N/A

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

Product(s) Referenced: CP100 and CP200 Electrocardiographs

SW Version: N/A

Serial No. / Lot Code: Welch Allyn Production began using PCBA 405559 starting with units:
CP100: 10012480
CP200: 20014545
Welch Allyn Production began using all of the significant changes mentioned in this TSB starting with:
CP100: 10020000
CP200: 20020000
NIEUWPOORT: Visible changes (detailed below) make the new design easy to identify.

The individual changes were phased into production at different times to use up the individual component inventory to minimize scrap costs.

Summary:

These topics are discussed briefly in the “Summary” section, then covered again in detail in the “Summary Details” section: *New CP100/CP200 Main PCBA (PATTERN 9), Keyboards, Nieuwpoort (a.k.a. Patient Cable ECG front end including updated patient leads banana contacts), Quick Start Guide & Directions For Use CDs*

- New Main PCBA 405559 (PCA, CP100/200 MAIN PATTERN 9) replaces PCBA 407737 (ASSY, MAIN PCA, CP100/200 PATTERN 8R).

New Main PCBA Key Features:

- Allows a system reset by holding the power button for ~7 seconds in addition to the existing system reset method.
- Automatically performs a watchdog timer system reset if a key HW timing signal is not running.
- Reduction of battery degradation and avoid potential lock up conditions.

The CP100 and CP200 changes listed above are expected to reduce battery degradation and improve battery life. The Main PCBA changes may further reduce ESD induced lockup events and will improve recovery when lockup events occur.

- New CP100 Keyboard assembly 405006 replaces 405641.

New CP200 Keyboard assembly 405028 replaces 403312.

- Keyboard power LED turns YELLOW when battery needs to be charged when used with new Main PCBA (Pattern 9 only).
- Nieuwpoort module (a.k.a. ECG Patient Cable) redesign plus lead wire comb (rake). No customer part number changes.
 - RL and LL lead wire attachment ports are brought to the front of the module to reduce ambient noise susceptibility.
 - Welch Allyn Manufacturing will insert the lead wires into the Nieuwpoort so that the end customer will not need to perform this assembly.
 - Additional 10 position lead wire comb (rake) added close to the Nieuwpoort to reduce ambient noise susceptibility.
 - Banana plug lead wire contact design improvement – new helical design to improve spring contact reliability.
- The revised printed CP100/CP200 Quick Start Guide (718376) is now included with all customer orders.
- There is a new revision to the CP Series Electrocardiographs Update to Directions for Use. The document is now supplied on the product CD and will be in electronic format only. The printed DFUs are removed from all customer orders including SW upgrade kits. The updated CD set must be provided to the Customer upon device update(s). CD sets are listed below:
 - 401150 CP100 PRODUCT INFORMATION CD (uses updated 408730 ASSY, CP100 PROD INFO CD 1&2 PURCHASED)
 - 401151 CP200 PRODUCT INFORMATION CD (uses updated 408731 ASSY, CP200 PROD INFO CD 1&2 PURCHASED)

**Summary
Detail:**

MAIN PCBA 405559 features:

System Reset (Power button push and hold reset):

Push and hold the power button to force a system reset. Push and hold reset provides another way for the user to reset the CP100-200 device. The CP100-200 device will reset if the user presses and holds the power button (On/Off key) for about **7 seconds**.



The previous method of resetting the electrocardiograph is still available as documented in the DFU.

Watchdog timer (to initiate Automatic Reset):

The watchdog timer will force a system reset when the System Clock (*not related to date & time clock*) stops responding. The watchdog timer triggers a system reset within 30 seconds after the system clock becomes inactive. The CP100-200 device will reset to the time/date screen after a complete boot cycle of ~60 seconds. A reset from the watchdog timer cannot be initiated by the user.

Reduce battery degradation & avoid potential lockup conditions:

- **Increased charge current +100mA**

The device charge current has been increased by ~100mA. The increase in current allows more energy to be delivered to the battery in less time.

- **Deep discharge disconnect added**

The deep discharge disconnect circuit is intended to reduce the likelihood that a CP100-200 will be operated on a deeply discharged battery. The deep discharge disconnect circuit is functional when the device is in sleep mode, not connected to AC mains and the voltage falls below ~5.3V. Once enabled, the deep discharge disconnect circuit is functional until the battery voltage exceeds ~6.2V. This circuit is disabled during normal operation on battery to prevent nuisance disconnects while using the device.

The deep discharge disconnect circuit:

- Disconnects the battery at very low battery voltage (below ~5.3V) to protect it from permanent performance degradation due to deep discharge.
- Prevents operation at very low battery voltage (below ~5.3V) to reduce

- potential lockup events due to loss of power supply voltage regulation.
 - Requires the user to connect AC mains to operate the unit at very low battery voltage until the battery is adequately charged to a sufficient level (above ~6.2V) once the deep discharge disconnect has occurred.
 - Prevents the device from operating on a poor performing battery that cannot be adequately charged (above ~6.2V).
- **Reduced the standby current to less than 3mA total**

The new Main PCBA reduces the standby current from ~5mA to ~3mA further reducing the load on the battery. This is expected to improve battery life.
 - **CP Series Electrocardiographs Update to Directions for Use**

Refer to the revised **Update to Directions for Use** for additional information regarding these changes. Also refer to the Welch Allyn or the internal Pulse websites for additional product specific information.

Keyboards:

- New CP100 Keyboard assembly 405006 replaces 405641.
- New CP200 Keyboard assembly 405028 replaces 403312.

➤ What to expect with the Pattern 9 and new keyboard combination:

There are three states of the LED: GREEN, YELLOW and not illuminated. The LED is GREEN to indicate AC mains power is connected. The LED is YELLOW to indicate the battery needs to be charged or replaced. The GREEN LED takes precedence over the YELLOW LED. The LED will be GREEN when connected to a live mains voltage source. The LED can only be YELLOW or not illuminated when operating from the battery.

The LED will be YELLOW when the CP100-200 is operating on battery power and the cell voltage decreases to ~5.6V. Once initiated, the LED shall remain YELLOW until the cell voltage increases to ~6.3V (indicates a charge condition) or returns to green any time AC mains is connected. The LED will revert to YELLOW if AC mains is disconnected before the battery voltage increases to ~6.3V (indicates a sufficient charge has not taken place).

The Yellow LED will only be visible with this combination: The Pattern 9 PCBA and new Keyboards 405641 or 403312.

Note: This circuit is independent of the software indications for "Low Battery Warning" and "Critically Low", and of the battery status icon on the LCD.

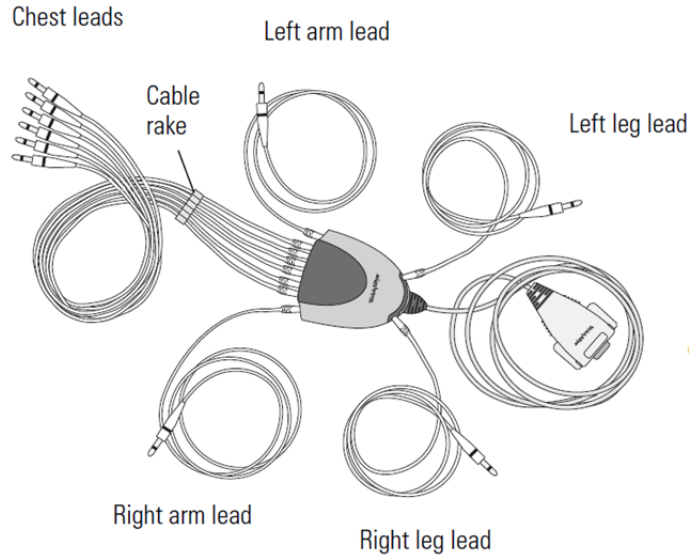
Note: When the device begins to print it will cause a sudden drop in measured voltage below ~5.6V but then rebound back to its previous level. This sudden drop and rebound will cause a brief flash of the LED (yellow) if the device is on battery power.

Nieuwpoort:

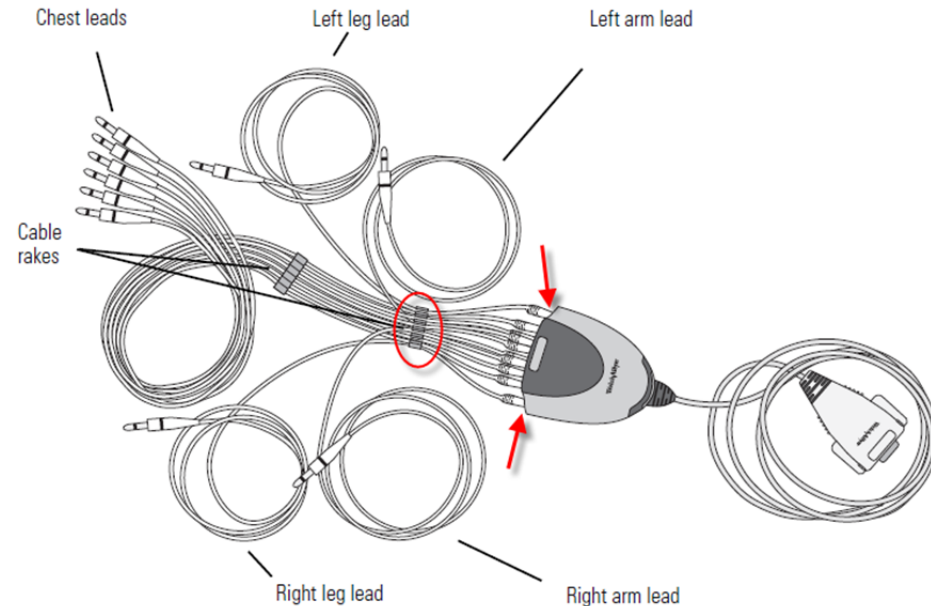
Nieuwpoort module redesign:

- The Nieuwpoort module (a.k.a. Patient Cable) has been redesigned moving the lead wire connections for RL and LL to the front of the module along-side all other lead wires. An additional Cable Rake has been added close to the Nieuwpoort to reduce susceptibility to noise:

Previous configuration:



New Configuration:



- Lead wires now inserted prior to shipment:
Welch Allyn Manufacturing will insert the banana contact lead wires into the Nieuwpoort so that the end customer will not need to perform this assembly.
- Replacement Patient cable to include lead wires already inserted:

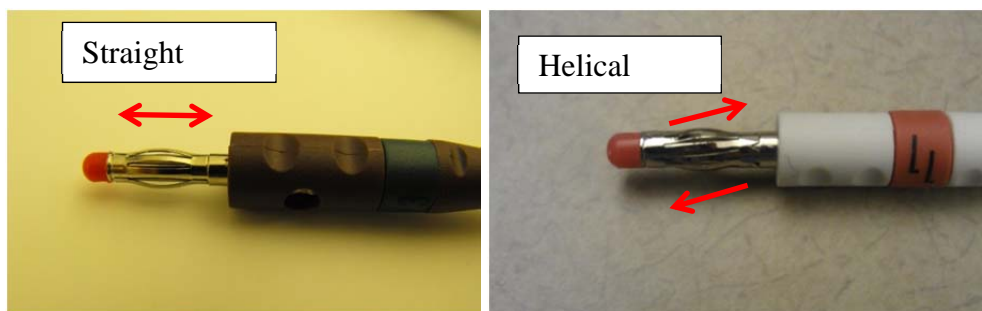
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To ensure that customers will always receive new lead wires whenever replacing the Patient Cable (Nieuwpoort), the existing Bill of Materials has been changed to include the banana contact lead wires which will be pre-assembled as mentioned above.

- The List price of the Patient Cable will not change with the addition of the lead wires.
- The customer facing Patient Cable part numbers (400293 AHA and 400294 IEC) remain the same (WA internal material number 408826 / 408661 replaces 401126 and 408827 / 408662 replaces 401127)
- The customer can still order the 10-lead replaceable lead sets separately if needed.

Banana plug lead wire redesign

- Banana springs have been improved by using a new helical design to improve spring tension.



The new design applies to existing customer facing part numbers:

- 401129 AHA Banana (updated 408634 replaces 401672)
- 401122 IEC Banana (updated 408633 replaces 401671)

NOTE: The effectivity of this running change to the banana spring contacts is pending use up of existing cable inventory (likely during 4Q2012). The change is not linked with the new Nieuwpoort effectivity or with the new serial number ranges.

Action: None of the changes described in this TSB are required service updates. All of the changes covered in this TSB are ongoing improvements to the CP100 and CP200 Electrocardiographs. None of the changes are required to meet the performance specifications of the devices.

- 405559 New Main PCBA (PCA, CP100/200 MAIN PATTERN 9)
 - Use up existing PCBA 407737 (ASSY, MAIN PCA, CP100/200 PATTERN 8R) inventory as part of normal service activities.
 - In situations when a CP100 or CP200 device experiences repeated lock-ups / screen freezes,
 - 1) **and** the battery is less than 90 days old,
 - 2) **and** the ESD shield updates described in TSB 20011611 have already been implemented (check service history & serial #), replacing an older version Main PCBA with a 405559 Pattern 9 PCBA **may** further reduce lockups and **will** improve recovery when lockup events occur.
- 405006 New CP100 Keyboard assembly
 - Use up existing 405641 inventory as part of normal service activities.
- 405028 New CP200 Keyboard assembly
 - Use up existing 403312 inventory as part of normal service activities.
- 400293 AHA (ECG PATIENT LEAD CABLE, AHA, CP100/200) – revised version with AHA banana contact patient leads attached
 - Use up existing 400293 (401126 vs. 408826 / 408661) inventory as part of normal service activities.
- 400294 IEC (ECG PATIENT LEAD CABLE, IEC, CP100/200) – revised version with IEC banana contact patient leads attached
 - Use up existing 400293 (401127 vs. 408827 / 408662) inventory as part of normal service activities.
- 401150 CP100 PRODUCT INFORMATION CD (uses updated 408730 ASSY, CP100 PROD INFO CD 1&2 PURCHASED)
 - Discard existing 406524 CDs set; discard paper DFUs 408794, 714513 no longer needed with new CDs sets and Quick Start Guide 718376.
 - Provide revised CP100 Product Info CDs when the keyboard and/or main PCBA are replaced with the new components during service.
- 401151 CP200 PRODUCT INFORMATION CD (uses updated 408731 ASSY, CP200 PROD INFO CD 1&2 PURCHASED)
 - Discard 406525 CDs set; discard paper DFUs 408793, 408795, 714513 no longer needed with new CDs set and Quick Start Guide 718376.
 - Provide revised CP200 Product Info CDs when the keyboard and/or main PCBA are replaced with the new components during service.

Other Recommendations:

- In situations when maximum battery performance for a CP200 is desired, consider replacing the CP200 LCD per TSB 20012589.

Reference to Standards:

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

Updates:

DFU	<input checked="" type="checkbox"/>	Repair Tool	<input type="checkbox"/>
Service Plan	<input type="checkbox"/>	Internet/Intranet	<input checked="" 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:

The new required materials will be available immediately.

405559 (PCA, CP100/200 MAIN PATTERN 9)

405006 (ASSY KEYBOARD CP100)

405028 (ASSY, QWERTY KEYBOARD, CP200, NORMANDY)

400293 AHA (ECG PATIENT LEAD CABLE, AHA, CP100/200) – revised version with AHA banana contact patient leads attached

400294 IEC (ECG PATIENT LEAD CABLE, IEC, CP100/200) – revised version with IEC banana contact patient leads attached

401150 CP100 PRODUCT INFORMATION CD (uses updated 408730 ASSY, CP100 PROD INFO CD 1&2 PURCHASED)

401151 CP200 PRODUCT INFORMATION CD (uses updated 408731 ASSY, CP200 PROD INFO CD 1&2 PURCHASED)

Quality Process for failed units or components: N/A

Procedure: One for one part replacements.

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	TSB - New CP100/200 Main PCBA & keyboards	D*	DCS	D*	D*
B	<ul style="list-style-type: none"> • TSB - New CP100/200 Main PCBA & keyboards – update to include the additional Gate 7 changes since the initial release • Filename change: 20012762B.TSB.Pattern9.Gate7 	D*	DCS	D*	D*
C	<ul style="list-style-type: none"> • Remove specific Nieuwpoort Serial Number Reference • Subject line and footer description renamed to conform with TSB consistency guidelines 	D*	DCS	D*	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					