



# Technical Service Bulletin

## CARDIOPULMONARY

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**Bulletin Type:**  
**NEXT SERVICE ACTIVITY**

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**Manufacturer: Welch Allyn**

<b>Date: 2014-01-20</b>		<b>SAP DIR #: 20013941</b>	
<b><u>THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION</u></b>			
It can be distributed or made available to only those individuals, companies, and organizations which have current Welch Allyn Confidentiality Agreements, and have a need to know.			
<b>Subject:</b>	TSB-CP150 V2.00.03 SOFTWARE RELEASE		
<b>Distribution Scope:</b>	Welch Allyn Global Technical Support, Product , Field & Customer Service and WA ASP's		
<b>Product(s) Referenced:</b>	<ul style="list-style-type: none"> <li>• All CP150 Electrocardiographs</li> <li>• Spirometer Flow Transducer: Lot Codes: 2014 &amp; above</li> <li>• CP150-0030 / SERV KIT, SOFTWARE UPDATE V2.00.03 (with power switch)</li> <li>• CP150-0031 / SERV KIT, SOFTWARE UPDATE ONLY V2.00.03</li> <li>• 20013803 TSB-CP150 V1.00.03 SOFTWARE RELEASE</li> </ul>		
<b>SW Version:</b>	All		
<b>Lot Code:</b>	Spirometer Flow Transducers with Lot Code: 2015 and higher		
<b>Summary:</b>	<p>The Welch Allyn Diagnostic Cardiology Team is releasing a new version of software for the CP150 electrocardiograph. This version improves the functionality of the electrocardiograph and incorporates the software solution detailed below.</p> <p>This update incorporates all prior updates.</p> <p><u>NOTE:</u> This software update is not applicable for China CP150 units until registration of version 2.00.XX is complete.</p>		
<b>Issue:</b>	<p>The new software addresses the following:</p> <ul style="list-style-type: none"> <li>• Correction of the “bpm” translation in Danish, Finnish, French and Dutch.</li> <li>• Calibration support for a new transducer design.</li> </ul> <p>CP150 electrocardiographs with software V2.00.02 and below will not recognize the new Spirometer transducers with Lot Codes: 2015 and above. An error message “Invalid transducer calibration code” will appear on the screen.</p>		
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**Action:**

A new Spirometry transducer (Lot Code: 2015 and above) will be replacing the current transducer (Lot Code: 2014). In order for the CP150 to recognize lot codes of 2015 and above as valid lot codes, the CP150 will need to be updated with software V2.00.03 or higher; V2.00.03 can accept both the old and new transducers.

All existing flow-transducer stock will be replaced with the new transducer, however, customers' flow-transducers that have Lot Code 2014 and that are in working order need not be replaced, i.e., may be used until depleted.

**Hardware component updates:**

The following hardware components will be installed into devices that are returned for repair and have serial numbers prior to 100012672614. (See **Service Strategy** section / **Service Centers and ASPs** below for details.)

- Switch Power ESD
- CP150 ESD Switch Tape
- Pro Gaff Tape

**Supporting document updates to support CP150 V2.00.XX:**

- DFU CD Material 105755
- Service Manual DIR 80018104
- DFU DIR 80018007

**Service Strategy:**

**Customer Care / Technical Support:** Customers with devices that have a previous version of software and desire the ability to use the spirometry option may order part number:

CP150-0031 / SERV KIT, SOFTWARE UPDATE ONLY V2.00.03

NOTE: This software update is not applicable for China CP150 units until registration of version 2.00.XX is complete. This TSB will be updated as China completes registration.

For China customers, refer to:

20013803 TSB-CP150 V1.00.03 SOFTWARE RELEASE

**Service Centers and ASPs:** will perform the following updates on units that come in for repair, have not done hardware changes stated below, and have serial numbers before 100012672614.

Order part number: CP150-0030 SERV KIT, SOFTWARE UPDATE V2.00.03 (with power switch)

1. Update the software to V2.00.03, (for devices that do not already have 2.00.03 installed), by following CP150 CUSTOMER LETTER (723177);
2. Change out the CP150 SWITCH POWER ESD (410182);
3. Install CP150\_ESD\_SWITCH\_TAPE (721364) and TAPE, PRO-GAFF, BLK 3/4" WD (M11580).

A) Check the software version of the device. If at a prior version, update the

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software to V2.00.03. Refer to CP150 CUSTOMER LETTER (723177) for detailed software update instructions.

B) Replace the hardware components:

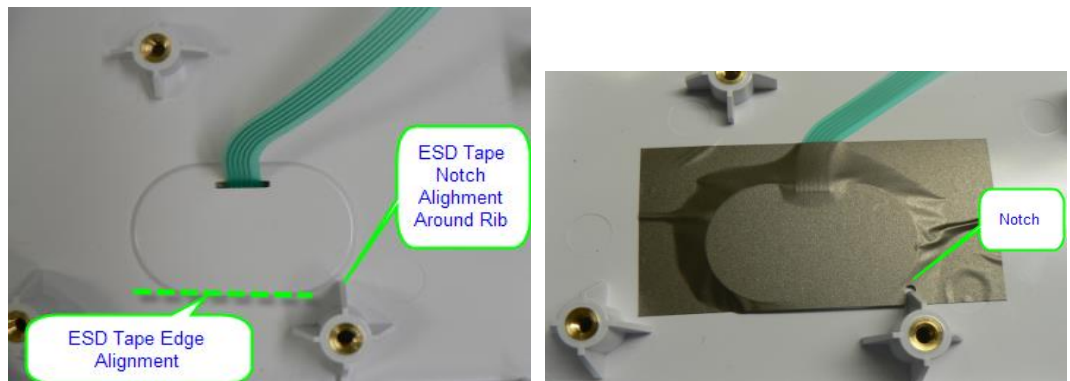
- I. Remove Top Housing assembly from the unit.
- II. Using tweezers, carefully peel the Power Switch Membrane from the Top Housing and remove the Flex cable.



- III. Insert the new Flex cable through the slit in the Top Housing. Remove the adhesive liner from the Power Switch Membrane. Make sure that the liner next to the flex is also removed. Press and secure the Switch Membrane into the recessed area.

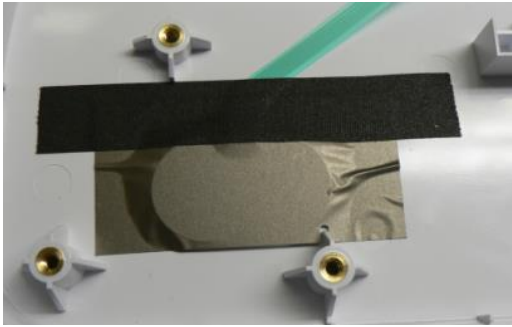
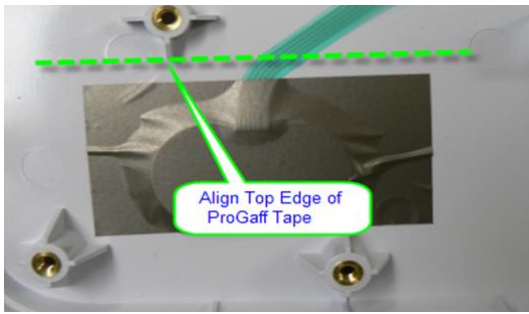


- IV. Affix ESD Tape over the underside of the Power Switch and the protruding flex circuit. Align the notch on the screw post rib as shown. Align the edge of the tape around the edge of the indentation for the Power Switch as shown.



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V. Add Pro Gaff tape over the EMC Tape. The Pro Gaff Tape should overlap over the length of the ESD Tape. The Pro Gaff Tape top edge should be aligned just under the screw post rib as shown.



- Reassemble the Top Housing assembly onto the unit. Perform all necessary tests and functional checks.

**Reference to Standards:**

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

**Required Materials:**

- CP150-0030 SERV KIT, SOFTWARE UPDATE V2.00.03 (with power switch)
- CP150-0031 SERV KIT, SOFTWARE UPDATE ONLY V2.00.03

**Procedure:**

The Software can be updated via supplied USB thumb drive or Welch Allyn Service Tools.  
 Refer to Customer Letter 723177 shipped with the Software Update Kit for detailed software update instructions.  
 The release of this TSB will obsolete the use of 20013723A TSB-CP150 V2.00.02 SOFTWARE RELEASE.

**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.

**Notes:**

1. Contact Welch Allyn regarding any questions or concerns 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*	AO	D*	D*

D\* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL

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