

Welch Allyn, Inc.®

Medical Products
4341 State Street Road
Skaneateles Falls, New York 13153-0220 USA
Tel: (315) 685- 4100 Fax: (315) 685-4653
Copyright 2007 Welch Allyn, Inc. All rights reserved.

DATE: 2008-12-02**SAP DIR #: 20011220**

Subject: TSB - CP100-CP200 2.4 Software Release**Bulletin Type: Software update****Product Family: CP100 - CP200****Originator: SS / JR Service Engineering Department****Author: Kirk Stevenson**

Issue: Revised Software Update P/N 100942 (App. 2.4.0 and Boot 2.1.0) for CP100-CP200 Electrocardiographs.

Distribution Key:

- Internal Welch Allyn distribution only
- External Welch Allyn distribution

Reference: 5003662 CAR: N/A

Solution Statement: The Welch Allyn Diagnostic Cardiology Team is pleased to announce a new version of software for the CP100 and CP200 electrocardiographs. This version (2.4) of the software incorporates several new enhancements that are outlined below. There is a customer letter (P/N 711252) provided with the update kit (P/N 100942) that each customer will receive when ordering. There is also an updated (P/N 711213) DFU, Software Update V2.4. When an update is performed in the field, by a Welch Allyn employee or authorized representative, the customer letter and the updated DFU must be left with the customer after the update is performed.

PRODUCT IDENTIFIERS:

The starting S/N of each device shipped with this version is listed below

Product Number	Serial Numbers
CP100	10005872
CP200	20006921

Classification of Action:

- Mandatory
- Optional
- Does Not Apply

When:

- Immediate
- On Next Service
- At Agreed Upon Time

Documentation required:

- 711252 - DFU CUSTOMER LETTER APP V2.4 CP100/200
- 711213 - DFU, Software Update V2.4
- 405181 - ASSY, CP100 PROD INFO CD 1 & 2 PURCHASED
- 405182 - ASSY, CP200 PROD INFO CD 1 & 2 PURCHASED

Caution: CP100 and CP200 customers transferring ECG and spirometry tests to CPWS must also upgrade to the latest connectivity kit – part number 100942. See table below.

Compatibility Matrix:

	2.3 & earlier	2.4 & beyond	<p>Key message: - Existing units in the field that use File Importer and wish to be updated to 2.4 will require the newest version of File Importer!</p>
File Importer version 2.0.0 and earlier	YES	NO	
File Importer 2.1.0 & later	YES	YES	

Capabilities	Ped MEANS	Wireless	File Importer version 2.0.0 or earlier	File Importer 2.1.0 and later
2.4 Firmware	yes	yes	No	yes
2.3 Firmware	no	no	Yes	yes

2.4 Board Patterns Matrix	Wireless & Barcode	Wireless Only	Barcode Only	Ped MEANS	Memory Storage
Pattern 6 (32 MB RAM) Pattern 7 (32MB RAM)	no	no menu grayed out	no	yes	70 adult/35 PED ECG tests*
Pattern 7 plus (64MB RAM)	no	yes	yes	yes	100+ mix of adult and PEDS

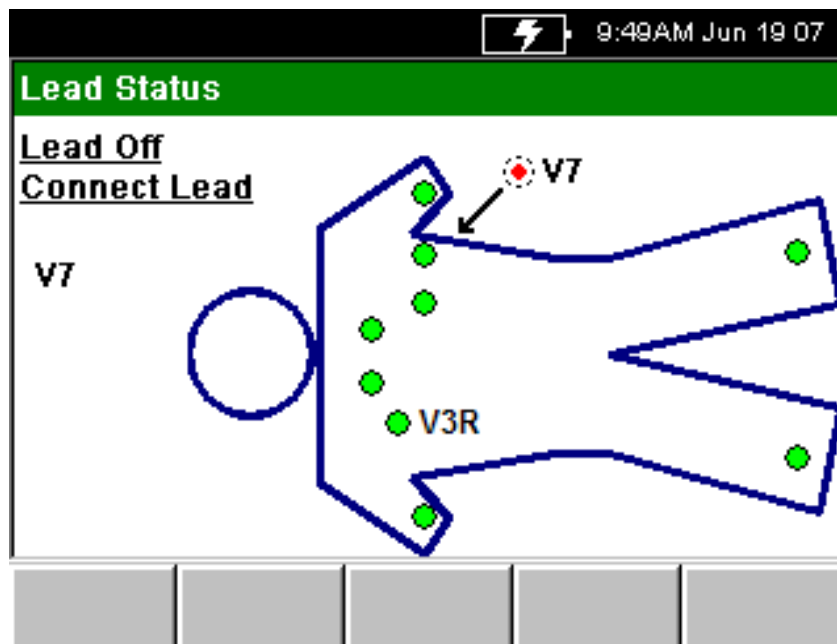
*An adult ECG test generally uses a little over 100 KB of storage space. A Ped test generally uses a little over 200 KB of storage space. Ped ECG's will use up twice the storage space on the device.

Enhancements:

Pediatric support

A pediatric algorithm (Ped MEANS) has been added to provide a computer assisted interpretation for patients from 1 day to 18 years of age. When entering a patient's age below 18 years, the CP100 and 200 will automatically use the pediatric algorithm. In addition; the user has the option to use an augmented lead set. The augmented lead set supports an alternate placement (V3 > V3R and V5 > V7). This lead placement is easier to use on the small chests of infants and young children. Use of the augmented lead set is selected in the

menu settings (Option 3 then 5). When enabled, the user will be prompted to choose *Standard* or *Augmented*. If augmented is selected, the lead status screen will look like this.



Programming of the augmented lead set

- Available under *Menu > ECG Setup*.
- If age instead of date of birth is selected for the report header, the user can enter the age in years and months. If greater accuracy is required, e.g. less than 30 days old, the user should switch to date of birth.
- The ECG analysis process may take slightly longer to complete than an adult.

Practice ID setting

You can now enter the name (ID) of your practice, clinic, or hospital. This ID prints on the bottom margin of the ECG report. Up to 40 characters can be added

New report format

There is a new auto ECG report format: 6x2 + 1R (6 rows x 2 columns + 1 rhythm lead).

Choice of QTc computation method

The computation method of correcting the waveform's QT interval, based on the heart rate, is called the QTc interval. The corrected number is expressed in milliseconds. The only QTc interval displayed in the ECG measurements portion of the report is the corrected number. You can now choose the computation method of either:

- Bazett - $QTc = Q * \sqrt{HR/60}$
- Hodges - $QTc = 1.75*(HR-60)$

Spirometry module

The optional CP 200 spirometry module, which previously supported patients as young as six, now supports patients as young as three.

More races added

Four more races are now available for entering patient data: Polynesian, Indian, Aboriginal, and Native American.

- These do not affect the ECG interpretation.
- If any of the new races are selected, then spirometry will use a 94% adjustment for FVC and FEV1 per NIOSH recommendations.

Configurable rhythm leads

- You can now configure the order in which leads appear during rhythm printing, e.g. customize a 3 lead grouping with lead II, aVF and V5.
- This can be programmed under *Menu > ECG Settings > Rhythm Report Settings*

ECG Display Scaling

In response to customers that wanted the low amplitudes displayed during preview to be more representative of the printed ECG, we have increased the scaling of the data approximately 28%. This should make the limb leads larger on the display for better assessment of signal quality. Correspondingly for patients with very large amplitude signals, the tops of the QR wave may be clipped.

Other Corrections (CP100 & CP200)

- Spiro calibration file fixed.
- Spirometry flow unit measurements now print on the report correctly.
- 'Obstructive interpretation' definition has been corrected on the spirometry help page.
- Spirometry post test times print correctly.
- Printout of ECG *copy* or *repeat* test interpretation no longer displays "warning: age not available, assumed 35 years".
- Corrected some incorrectly translated MEANS diagnostic statements for French and Danish
- New translations for Finnish

Please Note: The 2.4 version includes new CP200 functionality to support the use of wireless connectivity and bar code reader. Although the software has been enabled, additional hardware changes are required to the CP200. This capability is not backward compatible.

Compatibility Matrix:

- **Components Required:**

N/A

- **Materials Required:**

N/A

• **Technician Qualifications:**

N/A

• **Tools and Test Equipment Required:**

N/A

• **Reporting / Recording of Findings:**

N/A (Attach inspection and service report, if applicable)

• **Contact(s):**

N/A

• **Parts Disposition:**

• **In-Stock:** N/A

• **Failed parts:** N/A

• **Date or Lot Code and Location:**

N/A

• **TechView CD:** N/A

COMPLAINTS: Welch Allyn, Inc. Medical Customer Complaint process must be followed for any complaint activity resulting from this or other issues.

Note:

Drawings and/or illustrations and/or part numbers in this document are for reference purposes only and current to the date of this bulletin. Contact the Welch Allyn Service Engineering Department at Skaneateles Falls NY, USA if you have any questions about this bulletin, or to verify that you have the most current service information.

Revision History

VER	DESCRIPTION	ECR #	INIT	DATE	APPR
A	Release to Production	5003662	KJS	D*	D*

D* SEE SAP DIR DIGITAL SIGNATURE LOG FOR APPROVAL DETAILS

End of Bulletin