

### Welch Allyn, Inc.®

Medical Products

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**DATE: 2010-05-25**

**SAP DIR #: 20011958**

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**Subject: TSB - WA Holter Release Ver 1.6.0.0**

**Bulletin Type: Software update**

**Product Family: Holter**

**Originator: SS / JR Service Engineering Department**

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**Issue:** Release Notes for Software Release 1.6.0.0. Upgrade can be performed on all versions of software, including patches.

#### Distribution Key:

- Internal Welch Allyn distribution only
- External Welch Allyn distribution

**Solution Statement:** The manufacturer of the PCH100 and PCH200 Holter System has released a new patch of the software. Below is a more detailed list of what is included in this release.

#### New Items

- Windows 7 Compatibility – Windows 7 Home Premium and Professional (32 Bit Only)
- Wireless Recorder Management allows the user to pre-configure the list of recorders in use. This allows the user to skip the process of finding a recorder and allows them to just select the recorder and go.
- Physicians, Technicians, and Ordering Physicians can now be edited and deleted from the list.
- Addition of Continuation Strips to the user interface review and print. Allows the user to print up to 56 seconds of data across 4 strips (14 seconds each). (PCH200 Only)
- Addition of Full Disclosure strips to the user interface review and print. Allows the user to print as much Full Disclosure view as necessary instead of printing out the whole full disclosure report. (PCH200 Only)
- Selectable Preview Report Strips in the Arrhythmia Review screen. Allows the user to select the strip shown in the Preview Report Strip section just by setting the check box on the strip.
- User Selected Summary Events. Users are now able to select the Summary Events (Pause, Ventricular, and Supraventricular) strips by navigating through the events in the Preview Report Strips.
- Normal Forms page now allows the user to view the SVE only. This will show the SVE's found in each form. If none exist the form will be blank. Requires a re-compile for older reports.

- Users can now set the Summary Page view that they would prefer between narrative and tabular summary. Default is narrative.
- Calipers on the Strip presentation in Arrhythmia Review allow the user to measure using the X Caliper (mSec) and Y Caliper ( $\mu$ V).
- Highlighted Arrhythmia Review bar graph lets users know which column is currently being shown.
- Afib Management screen allows the user to see all of the Afib events that were entered in the report. (PCH200 Only)
- New Beat labels: Normal – Junctional, Aberrant, BBB, Questionable and Ventricular – Escape, Fusion, Idioventricular. (PCH200 Only)
- Reports are now compressed upon upload. Report should be compressed to approximately half the size of the older data files. This will vary based on the report.
- Diagnostic strips now allow the user to add RR Values to the print out.
- Setting for number of predefined strip shown in reports. Users can have the report show as many or as few strips as they want.
- Users can define strip labels if no predefined label fits their need.
- Users can sort strips by time instead of by category.
- Customer with multiple sites can now add Site Information into the report.
- Reports can be made offline for saving of storage space. Report can be moved to a backup location to save space on the user's hard drive.
- Secondary Backup allows the user to reconstruct a database without having the original database. Files will contain information to reconstruct on import.
- Application will now inform users if Report on SD card has already been updated.
- SD cards will now contain patient ID, so on upload to a machine that doesn't have the record, the system will import the patient ID.
- User will be alerted if database is approaching max size. Unused database entries are removed.

### **Recorder changes**

- HR100 – firmware version 21 supports SD card sizes from 256 megabyte thru 16 gigabyte. FAT file format recommended for SD Card sizes 2 GB and less.

### **Bug Fixes**

- Firmware upgrade times are improved and are now available on Windows Vista and 7.
- LAN users were shown incorrect locking message when a user had a report with the same patient information locked.
- Report missing a file, now will recompile or reanalyze based on the missing file. Once done, the system will be able to open the report.
- EMR path now no longer crashes on startup if UNC path is used.
- Blank patient event no longer causes error message on printing of strips.

### **Known Issues**

- Removing the Belkin drivers will cause the application to crash on startup. This is due to the removal process deleting the WBTAPI.dll file required by the application to run. If the Belkin drivers are removed, perform a Repair of the WA Holter System to restore the needed file.
- A problem appears where the SanDisk SD card readers may not read certain cards. This is a problem mostly associated with SanDisk SDDR-99 V3 readers and may be resolved by a firmware upgrade provided from SanDisk's website and also provided on the firmware folder of the CD.
- Backup/Restore will not work on Vista without Administrative rights. A User or Admin account trying to access the Backup/Restore feature will be prompted that they do not have

access. They will need to close the application down, right click the shortcut and choose “Run as administrator”. This will require an administrator password and give the application full rights to perform the service.

- Some newer strings within the application have not been translated. Some examples of such strings are:
  - Battery Test Disabled – On System Settings Page as well as printed reports.
  - Test Startup – Messages during Bluetooth initialization.
  - Backup and Restore – Messages during backup and restore operations.
- HR100 Firmware version 17 allows initialization for 48-hour mode. During hookup preview the operator will see noise for ECG traces. The data recorded will contain noise ECG traces. Recorders with serial numbers HR100-01100 through HR100-01277 have firmware version 17.
- Backup functionality does not check the destination for sufficient space or if it is set to read-only status.
- Application fails to start if installed to a non-default directory after removing from default.
- Database Backups made on Systems using SQL Express can not be restored on systems using MSDE for the database client.
- PCH LAN system server installs will not work if SQL 2008 is installed. The PCH LAN system installs Microsoft MSDE which is not compatible with Microsoft SQL 2008. A work around exist. Please contact GI service support for assistance on workaround.
- Application will not run under any Windows Compatibility Modes (ie Windows 95, 98, NT 4.0, 2000)

**Classification of Action:**

- Mandatory
- Optional
- Does Not Apply

**When:**

- Immediate
- On Next Service
- At Agreed Upon Time

**Service Information and/or Requirements:**

- **Documentation required:**  
PCH100/PCH200 LAN INSTALLATION GUIDE (716022)
- **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.

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**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***

VERSION	DESCRIPTION	INIT	DATE	APPR
A	Release to SAP	KJS	2010-05-26	D*

D\* SEE SAP DIR DIGITAL SIGNATURE LOG FOR APPROVAL DETAILS

**End of Bulletin**