

Welch Allyn, Inc.®

Medical Products

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DATE: 10/15/2007

SAP DIR #: 20010975

Subject: TSB - PCH100-PCH200 Release Ver 1.3.0

Bulletin Type: Software update

Product Family: Holter

Originator: SS / JR Service Engineering Department

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Issue: New version of Software for PCH100 and PCH200 Holter System to add Analysis enhancements, correct errors, allow for installation on Windows Vista OS and HR100 firmware update. The update CD can be ordered using P/N 705921.

Distribution Key:

- Internal Welch Allyn distribution only
- External Welch Allyn distribution

Reference: Change Number: N/A

CAR: N/A

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

General:

- Support for installation of the standalone or LAN client on Windows Vista Home Premium, Business and Enterprise version.
- Windows Vista uses SQL Server 2005 Express database instead of MSDE.
- Installation instruction have been changed to include Vista Installations
- Installation instructions have been changed to force installation of Belkin software.
- The Widcomm stack is now enabled by default. New installs are required to also install the Belkin drivers and use the Widcomm stack for Bluetooth operations. (*refer to Global Instruments SB-0011-Belkin Bluetooth Dongle F8T012xx1*).
- A new System Setting option has been added to allow disabling the battery check on the HR100 recorder. Reports uploaded with this option enabled will show an indication in the footer of the printed report that the battery test was disabled. This requires HR100 firmware version 19.
- File cabinet will display recorder information including serial number and firmware version.
- In the Forms category, the checkbox for "View Unmatched Beats" is now enabled by default to show all forms in the category.
- ECG Preview contains a solid line grid pattern.

Analysis:

- Form count reduction.
- Improved Artifact Rejection
- Improved Max HR determination.
- Additional classification improvements.

Bluetooth:

- Retry logic added to help initial connection to the recorder.

HR100 Firmware – Version 19:

- Support for 1GByte SD cards.
- Battery test can be disabled.

Error corrections:

- Paced beat totals are properly shown for narrative summary printout on PCH100 and the narrative summary UI for both PCH100 and PCH200.
- Ventricular titles are no longer showing Supraventricular when Spanish is the selected language.
- HR was incorrectly displaying -1 or 65535 for unknown values on the strips. “---“ is now being shown like all other areas.

Known Issues:

- While transferring configuration file to the recorder using Widcomm driver the user may be prompted with message indicating “configuration could not be transferred” followed by exit application and then restart. This situation is caused by a problem within the Widcomm Bluetooth stack that requires the application to exit in order to clear situation.
- 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.
- Using the newest 6.1 Belkin drivers for the Bluetooth dongle will not work with the application. The 5.1 drivers provided with the currently shipped dongles should be used instead. Note: The Belkin version 6.1 version software will only install on Vista operating system and can only be obtained from the Belkin website.
- 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 also provide on the firmware folder of the CD. *(Refer to Global Instruments SB-0014 - SD Card Reader SDDR-99 V3 May Fail to Read SD Card)*
- 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.
- Firmware Upgrade is not supported on Vista. User will be prompted that firmware upgrade is not available and to contact customer service.
- Report lock information displayed may be inaccurate on LAN systems. This problem may be seen when working with multiple reports assigned to the same patient.

- The application may appear hung when trying to perform PDF printing operations. In case of a failed PDF printing operation, the user is advised to restart the application.
- A “User” may not get added to the system occasionally. The operator in such situation must restart the application and try again.
- 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. *(TSB 20010819 – Release of 1.1.1 explains the update procedure)*

PRODUCT IDENTIFIERS: The table below lists the S/N of product shipping with this software/firmware version.

Product Number	Serial Numbers
PCH100/PCH200 including LAN	4197 & higher (possibly below if reworked)
HR100	HR100-01819 and higher

Classification of Action:

- Mandatory
- Optional
- Does Not Apply

When:

- Immediate
- On Next Service
- At Agreed Upon Time

Service Information and/or Requirements:

- **Documentation required:**
706063 Installation Guide (updated to version 006-700-0075-E)
- **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

VERSION	DESCRIPTION	CHANGE #	INIT	DATE	APPR
A	Review	1010131	CJT	10/26/07	MEB
B	Release to Production	1012881	CJT	12/5/07	KJS

End of Bulletin