



Technical Service Bulletin

Cardio Products

Welch Allyn, Inc.®
4341 State Street Road
Skaneateles Falls, New York 13153-0220 USA

Bulletin Type: As Needed

Tel: 1-315-685-4100 Fax: 1-315-685-4653
www.WelchAllyn.com

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SAP DIR #: 20012943

Subject: TSB - PCH Holter 1.6.4 SW Release

CAR Number: N/A

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

Product(s) Referenced:

| | |
|--------|--|
| 100710 | PCH100 OFFICE HOLTER SOFTWARE KIT |
| 100711 | PCH100 OFFICE HOLTER SYSTEM |
| 100713 | PCH200 EXPERT HOLTER SYSTEM |
| 101510 | PCH100 STANDALONE HOLTER S/W W/O REC |
| 101511 | PCH100 LAN - 3 USER HOLTER S/W W/O REC |
| 704525 | PCH100 STANDALONE SOFTWARE |
| 704526 | PCH100 LAN - 3 USER LICENSE |
| 704527 | PCH200 STANDALONE SOFTWARE |
| 704528 | PCH200 LAN - 3 USER LICENSE |

SW Version: v1.6.4.0 PCHx00 and v101 HR100 Recorder

Summary: Release Notes for Welch Allyn Holter System Software Release 1.6.4.0.
Upgrade can be performed on all versions of software, including patches

This bulletin (20012943) is based on Service Bulletin "SB-0052" issued by GI Medical to Welch Allyn.

Issue: The following issues have been resolved:

- Application would crash in the event that a user ran EMR Export on the same report twice during the same application session.
- Ventricular patterns displays on ECG strip would start at previous Normal beat, which could have been far enough ahead of the Ventricular event that no Ventricular beat is shown on screen.
- Application would fail to install on systems where the model database for SQL instance WAHolter01 was larger than 2 MB in

size. TSB 20012781 should be disregarded with the installation of this software. [Cancels out GI SB-0046]

- Application would crash if computer's Date/Time format was not the US Date/Time format. TSB 20012804 should be disregarded with the installation of this software. [Cancels out GI SB-0047]
- If both EMR Export and Summarize were set to be performed on Confirmation of report, Summarization would take place, but the EMR Export would not.
- Merge of a Standalone database to LAN database would crash on merge attempt.
- CPWS would display a WA Holter System crash if the folder selected in the EMR Export configuration did not have permission to write to. Message will indicate that folder does not have adequate permissions.
- Printed report that contained the narrative summary and not the tabulated data would not display beat percentage for Ventricular, Supraventricular and Paced beats. Narrative summary now displays the percentage of beats for the categories listed.
- Arrhythmia Review pause view showed pauses in time sorted order and not ordered by length of pause per duration grouping.
- Application would print an infinite number of pages in rare occurrence of form classifications.
- Extremely long words in the physician's interpretation would cause an error to occur during printing of a report.
- Application could not find the LAN SQL instance on client when WA Holter System LAN server had an instance of SQL 2005 installed prior to the install of the LAN server. SQL Express 2005 will be installed with all systems that require a database instance on fresh installs and on upgrades or repairs that require database instances. Previous installs will continue to use whichever database instance was installed at original install.
- Users could enter unlimited characters into the Physician, Hookup Technician, and Ordering Physician field and if the number of characters exceeded the max, the system would crash on save of patient data.

Recorder Firmware Changes (version 101)

- This is applicable for recorders serial number HR100- 02750 or higher.
- If the Secure Digital (SD) Card is removed during a Holter Procedure, recorder will report an error "E8" (8 Beeps).
- Bluetooth radio remains on when recorder is in wireless initialization mode "E2".
- Recorder will not power-up if battery measures $\leq 1.20V$.

Action:

In order to resolve the above issues the application and recorder software must be upgraded.

The following issues are not resolved:

Known Issues:

- Application fails to activate on first attempt on Windows 7. User must restart application and try again. Every Windows 7 installation will take two attempts to activate.
- 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 and Windows 7 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.
- When programming for 48-hour mode while using HR100 recorders with Firmware version 17, the operator will see noise for ECG traces in the ECG preview. The data recorded will also contain noise ECG traces. Recorders with serial numbers HR100-01100 through HR100-01277 shipped with firmware version 17. The ability to upgrade the device firmware to the latest version via BlueTooth communication is included as an additional process in the software and resolves this issue.
- 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 cannot be restored on systems using MSDE for the database client.
- Application will not run under any Windows Compatibility Modes (ie Windows 95, 98, NT 4.0, 2000)
- In the majority of Windows 7 installations, the application may show inactive recorder(s) in the recorder list. Un-pair the device from the Bluetooth and attempt to program again. If the device is not found by the software while searching for devices in range, troubleshoot accordingly. This issue will be addressed in the next release of the software.
- Adding of Physicians, Technicians, and Over-reading Physicians may not show in appropriate list. (Note: To resolve just re-enter the same information)
- Recorders with older SD cards may run for less time than configured.
- Application does not reposition R-R graph plot lines when user navigates beat to beat.
- Windows Vista and 7 x64 bit do not install easyPDF6 during the installation process.. Choosing the EasyPDF6 option in any of the

- application features that use it will initiate and install this program.
- Upgrading from version 1.0.0.2 may prompt the user to re-activate the software.
- Re-installing a LAN system after uninstalling will require the registry for WAHolter be removed. (Note: Contact GI Service support for assistance.)
- Application crashes on startup on Windows 2000. (Application no longer supported on Windows 2000).

Reference to Standards:

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

Service Strategy:

Standard TSB Distribution

Required Training:

N/A.

Required Tools:

N/A

Required Materials:

N/A

Quality Process for failed units or components:

N/A

Procedure:

All Customer Upgrades:

- Customers may upgrade to the new version PCHx00 software at no charge by using p/n: 705921 to obtain the software upgrade installation CD

Sales Reps only:

- For sales reps that do not already have the PCH Demonstration Software installed on their computer, contact your Connected Device Manager (US) or Regional Product Manager for approval and ordering instructions
- For sales reps that have already installed the PCH Demonstration Software:

Important NOTES --- Before starting upgrade ---

- Start-up WA application and make sure it is operational – If not, contact Technical Support
- Check software version to make sure the current version is at least 1.4.0.2 before proceeding – PCH Demo Upgrade Utility will not work on previous versions. They will need to order the current upgrade disk
- Make sure to exit WAHolter application before starting upgrade

- Go to GI Software Website:

<http://globalinstrumentation.com/WAHolterSystem/UpgradeUtility/publish.htm>

- Follow the instructions for steps 1, 2 and 3 on this website. Each step includes a link with detailed instructions.

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 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 | ReleaseDate | Appr |
| A | Initial Release | D* | SMB | D* | D* |
| D* - See SAP DIR for Change number, Approver Name and Date of Approval | | | | | |