

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: 4/2/2007**SAP DIR #: 20010869**

Subject: TSB - PCH100-PCH200 Release Ver 1.2.6**Bulletin Type: Software update****Product Family: Holter****Originator: SS / JR Service Engineering Department****Author: Chris Thompson**

Issue: New version of Software for PCH100 and PCH200 Holter System to correct errors, allow for better updates between version and Data Recovery Backup/Restore capability (used for service only) and the upgrade CD can be ordered using P/N 705921. This release also includes a firmware (v022) update for the HR300 recorders.

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 list of what is incorporated in this release. Some are explained in more detail under Enhancements and noted with an asterisk (*).

Application Functional Changes:

- LAN Release contains
 - PCH100 LAN x3 user
 - PCH200 LAN x3 user
- LAN Additional license release
 - PCH100 x5L
 - PCH200 x5L
- Markers duration measured include MSEC interval.
- * System Backup/Restore: Allows backup/restore of database and all data files associated with the system. The system also allows restoring from an older version database. Can be used to also move installation from one computer to another.
- Gain Setting for Full Disclosure: The system allows the user to apply gain settings to Full Disclosure within Forms Review, Arrhythmia Review and Full Disclosure.
- Scroll Full Disclosure using Mouse Wheel: The system allows the user to scroll through Full Disclosure using the mouse wheel.
- Delete Medications and Indications: The system allows the user to remove medications and indications from the system.
- Support for Russian language including new operator manual and quicksteps (on CD)

- * New HR300 Firmware: Support extending LCD display time and Bluetooth preview time from 5 minutes to 20 minutes.

Application Corrections:

- Updated turning point compression algorithm to preserve peaks.
- Correction with drawing pacer markers for compressed data.
- Updated to make Bluetooth communication robust. Multiple devices listing problem corrected.
- Correction with use of special characters within facility information.
- Corrected crash with using navigation keys within forms review when no forms are available.
- Corrected translation string lengths to make them fit within user interface components.
- PCH100 model will not support marker mode.
- Removed display of Full Disclosure flip context menu on PCH100 model.
- * New Firmware release for HR300 to resolve 580 msec gap of data ~ 28 minutes in recording in 48 hour mode.
- EMR Export – Exports using HOLTER as part of base file name
- EMR Export – Report Date time reflects actual Hookup Date/Time and not time of last report edit.
- Dot Net garbage collection improvements – memory consumption mitigated such that long term usage of application without application re-start does not use large amount of memory. Note: we have determined that this can be further mitigated by having user click on Minimize Button.
- Update string translations for all languages
- User can insert comments for each strip
- After SD card upload previous report highlighted in Inbox will open instead a new selected report.
- User Admin password never expires – resolves issue if user administration enabled and admin user password changed, then user administration turned off.
- DOB entry example reflects current selected Date/Time format

Installer Functional Changes: (more under Enhancements)

- * Uninstall will de-activate license file for Standalone and if PC connected to internet.
- * Installation program will use existing Database file and ECG file on PC system
- * Installation program install for all users even if upgrade from pervious version
- * Installation program is isolated from previous versions of software including 1.0.0.2 and 1.1.1.0
- * New MSDE instance for WAHolter01 can be removed using Control Panel Add/Remove Programs
- * Upgrade Install image will not overwrite license file

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	3573 & higher (possibly below if reworked)
HR300	HR300-01065 HR300-01069 HR300-01071 HR300-01073
HR300	HR300-01195

	HR300-01204 HR300-01208 HR300-01217 HR300-01219 HR300-01220 HR300-01225 & 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
 SB-000-0009 LAN Installation Guide

- **Enhancements:**

Improved Installer (PCH100, PCH200)

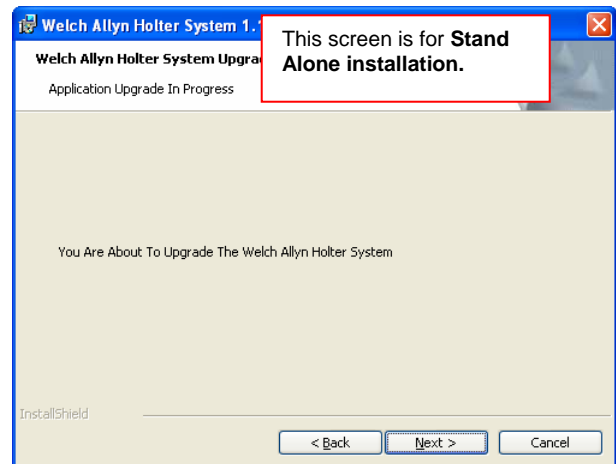
This new installer has incorporated steps to preserve data, remove residual registry keys, remove and update the SQL instance and install the application and data into a new folder when performing an update. In the images below I will first show the installation screens. Then, in a side-by-side, show the system before and after installation. On a new installation you will not see information relevant to the 1.0 folder Installation.

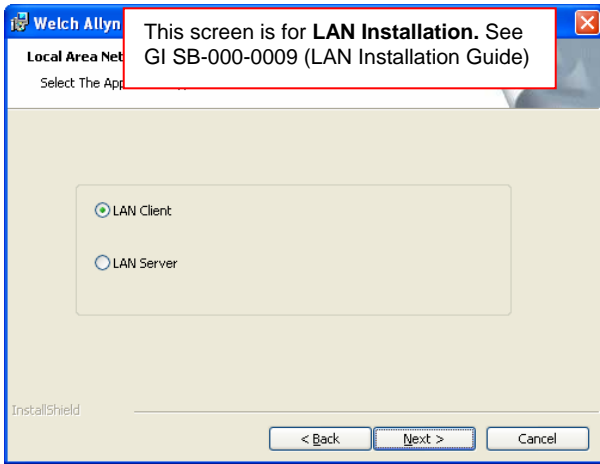
Installation

1.

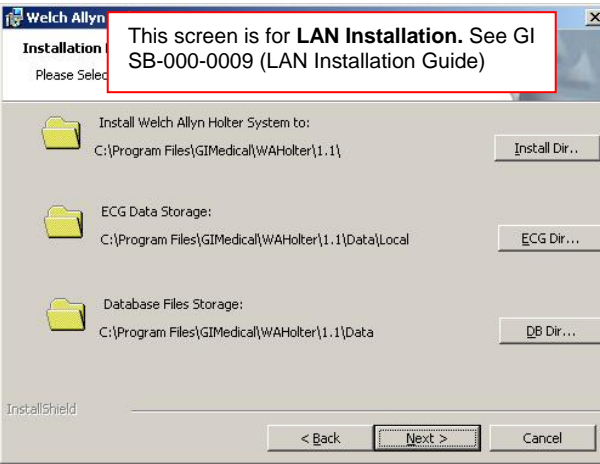
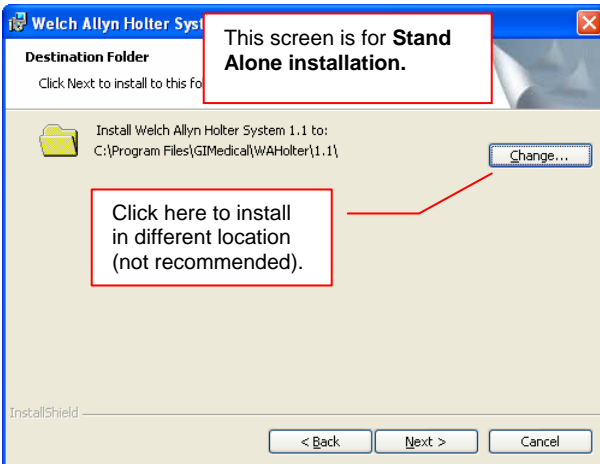


2.

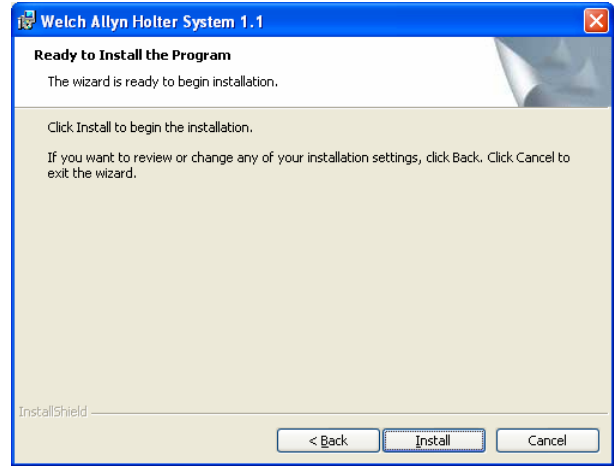




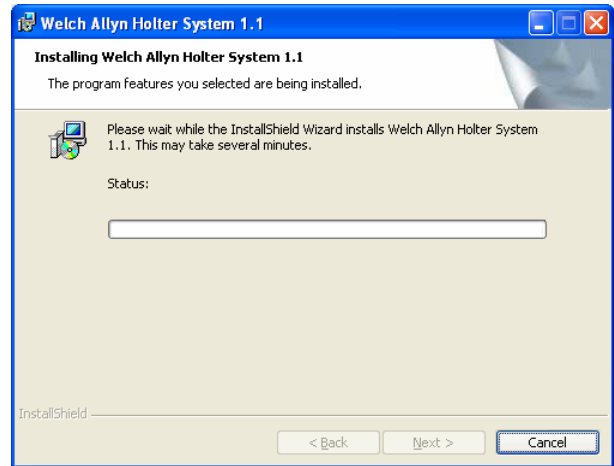
3.



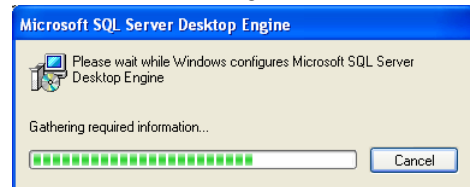
4.



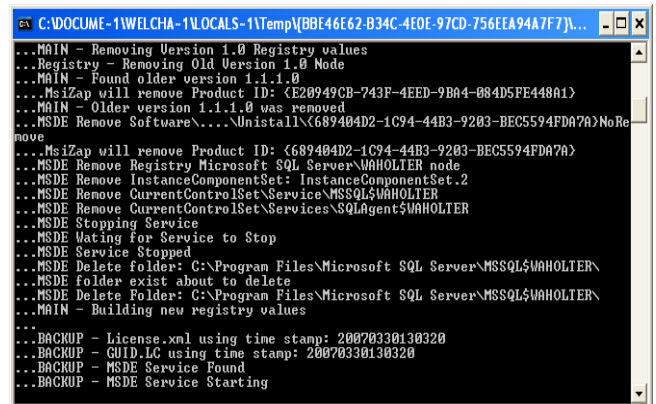
5.



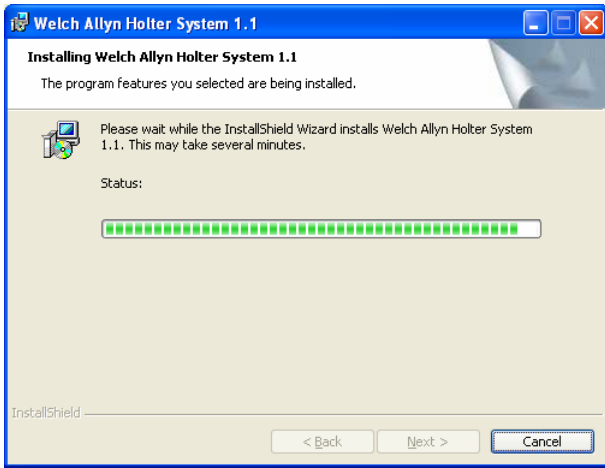
6.



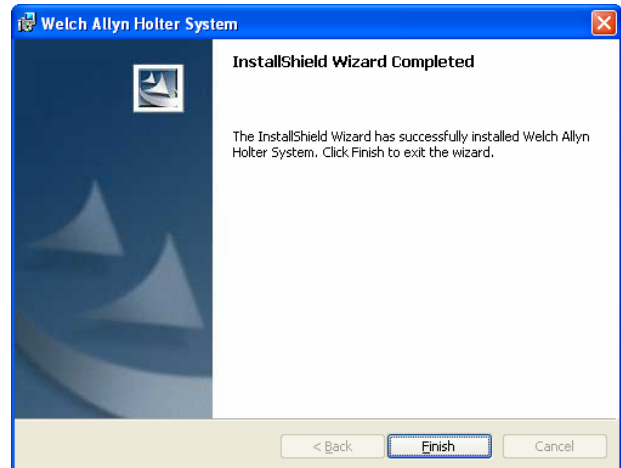
7.



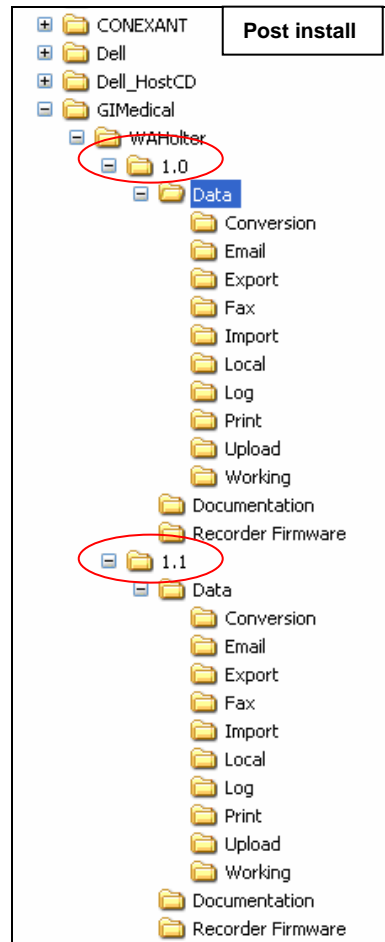
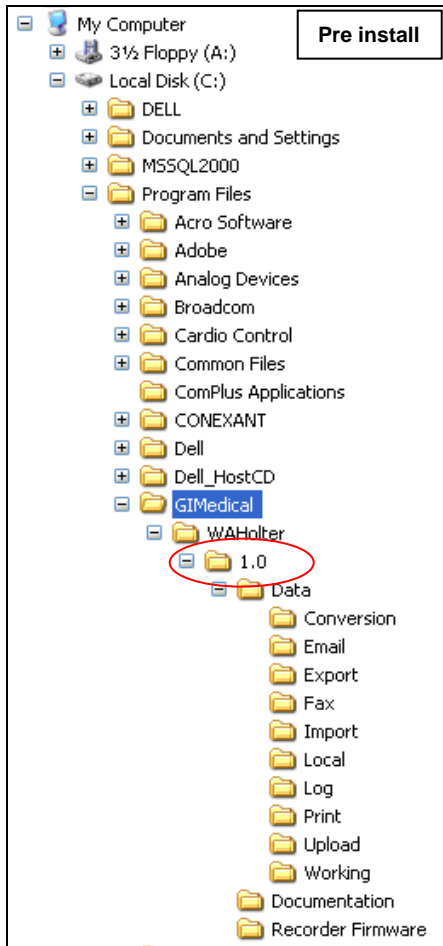
8.



9.



Pre and Post Installation



The images above are to show that before installation there was a folder named 1.0 under Program Files/GIMedical/WAHolter and after installation there is still a folder called 1.0 with the addition of a 1.1 folder. Starting with this version of software the application will be installed and launch from the 1.1 folder and not the 1.0 folder. The 1.0 folder can be removed once the customer has operated on the new version for some time and everything is running OK.

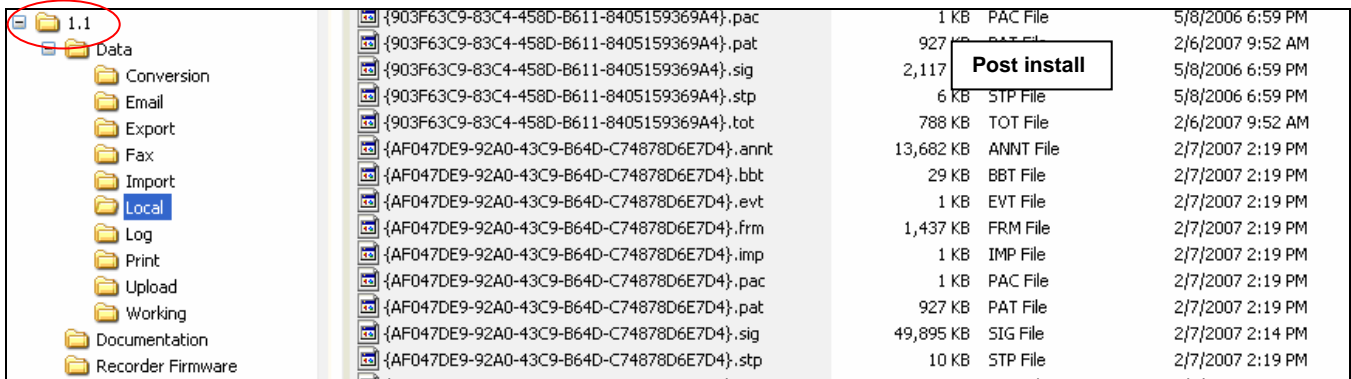
		Pre install	Size
Keyspan USB Serial Adapter			0.95MB
Microsoft .NET Framework 1.1			
Microsoft .NET Framework 1.1 Hotfix (KB886903)			
Microsoft SQL Server Desktop Engine			Size 59.08MB
Microsoft SQL Server Desktop Engine (WAHOLTER)			Size 59.08MB
SoundMAX			Size 0.86MB
USB Serial Converter Drivers for USB Spirometer			

		Post install	Size
Keyspan USB Serial Adapter			0.95MB
Microsoft .NET Framework 1.1			
Microsoft .NET Framework 1.1 Hotfix (KB886903)			
Microsoft SQL Server Desktop Engine			Size 59.08MB
Microsoft SQL Server Desktop Engine (WAHOLTER01)			Size 65.99MB
SoundMAX			Size 0.86MB
USB Serial Converter Drivers for USB Spirometer			

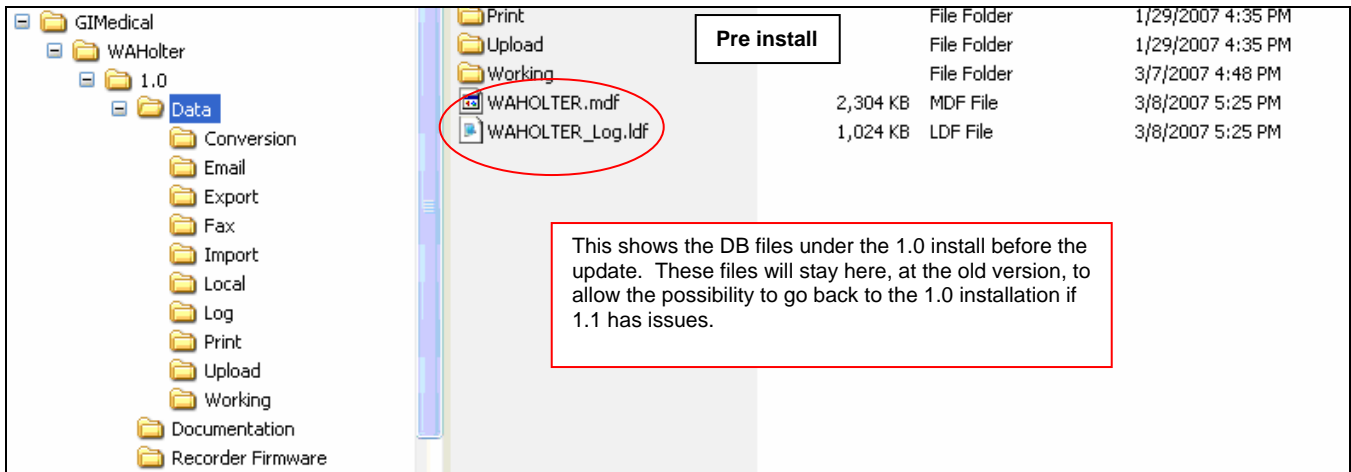
The images above are to show the removal and installation of a new SQL instance (WAHOLTER01) from Add/Remove programs under Control Panel.

		Pre install	Size	Type
{58B86D9F-DFC5-4F9F-A5A3-182CC51B4A6F}.frm			16 KB	FRM File
{322B9246-D34D-4C06-9648-E5C1FD719A2C}.frm			580 KB	FRM File
{903F63C9-83C4-458D-B611-8405159369A4}.frm			9 KB	FRM File
{AF047DE9-92A0-43C9-B64D-C74878D6E7D4}.frm			1,427 KB	FRM File
{58B86D9F-DFC5-4F9F-A5A3-182CC51B4A6F}.imp			1 KB	IMP File
{322B9246-D34D-4C06-9648-E5C1FD719A2C}.imp			1 KB	IMP File
{903F63C9-83C4-458D-B611-8405159369A4}.imp			1 KB	IMP File
{AF047DE9-92A0-43C9-B64D-C74878D6E7D4}.imp			1 KB	IMP File
{58B86D9F-DFC5-4F9F-A5A3-182CC51B4A6F}.pac			1 KB	PAC File
{322B9246-D34D-4C06-9648-E5C1FD719A2C}.pac			3 KB	PAC File
{903F63C9-83C4-458D-B611-8405159369A4}.pac			1 KB	PAC File
{AF047DE9-92A0-43C9-B64D-C74878D6E7D4}.pac			1 KB	PAC File
{58B86D9F-DFC5-4F9F-A5A3-182CC51B4A6F}.pat			927 KB	PAT File
{322B9246-D34D-4C06-9648-E5C1FD719A2C}.pat			927 KB	PAT File
{903F63C9-83C4-458D-B611-8405159369A4}.pat			927 KB	PAT File
{AF047DE9-92A0-43C9-B64D-C74878D6E7D4}.pat			927 KB	PAT File

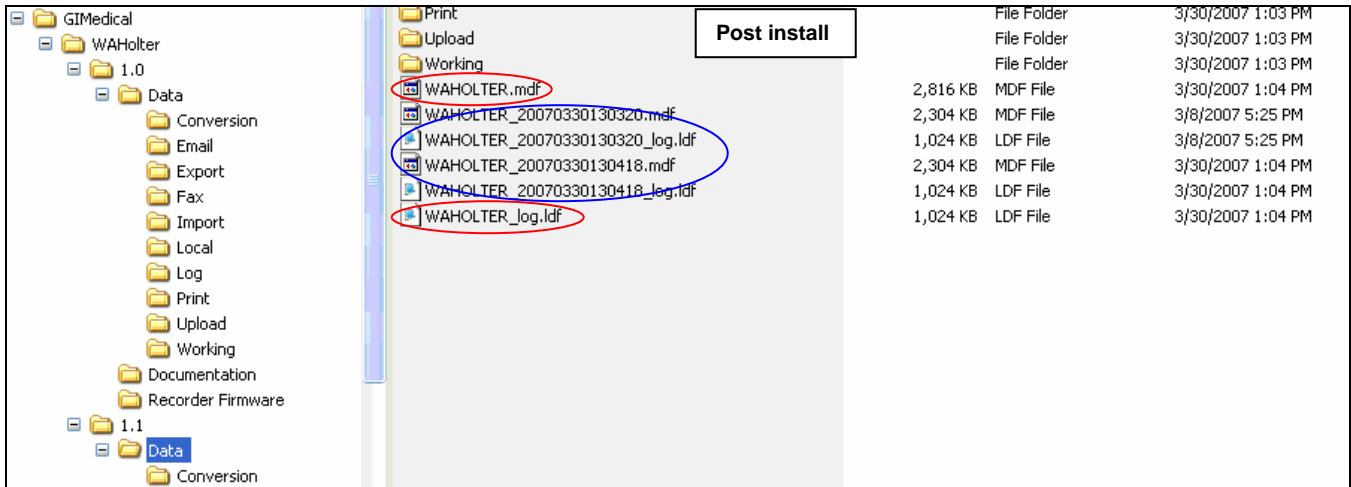
		Post install
<p>Note: all the Data has been <u>moved</u> to the Local folder under the 1.1 install. See image below.</p>		



These images show that after the installation the Data in the Local folder is moved to the Local folder under the new 1.1 folder.



This shows the DB files under the 1.0 install before the update. These files will stay here, at the old version, to allow the possibility to go back to the 1.0 installation if 1.1 has issues.



These images show the DB files that are used by the software to keep track of the recordings. The 1.0\Data folder DB files are kept in the 1.0\Data folder to allow (if needed) to copy all the Data Files from the 1.1\Local folder to the 1.0\Local folder and return back to 1.0 folder installation. **Note:** If this is done the recording shown will only be those that were done with the 1.0 folder Installation. Any recording done with the 1.1 folder installation will not be visible in 1.0.

A copy of the DB files is also written to the 1.1\Data folder installation and a couple of back up copies (circled in Blue) are kept as redundant backups of the DB files. Depending on the number of updates that have been performed on the system there may be more files.

Local Disk (C:)	Temp	File Folder	12/1/2006 8:21 AM
DELL	WINDOWS	File Folder	4/12/2007 3:07 AM
Documents and Settings	Backup.bak	5,344 KB BAK File	2/13/2006 3:52 PM
MSSQL2000	dkab.log	1 KB Text Document	7/13/2006 1:16 PM
Data	INSTALL.LOG	8 KB Text Document	11/15/2006 8:04 AM
MSSQL	IntallWAHolter.log	2,225 KB Text Document	4/3/2007 7:42 AM
Program Files	MSDE2kLog.txt	1,959 KB Text Document	2/17/2006 12:43 PM
Acro Software	WAHolter01MSDELog.log	2,327 KB Text Document	3/30/2007 1:02 PM
Adobe	WAHolterInstallation.log	18 KB Text Document	4/3/2007 7:41 AM
Analog Devices	WAHolterMasterLog.log	1 KB Text Document	4/3/2007 7:41 AM

This image shows that off the root of C drive the installation creates several installation logs. These logs can be helpful if ANYTHING goes astray with the installation.

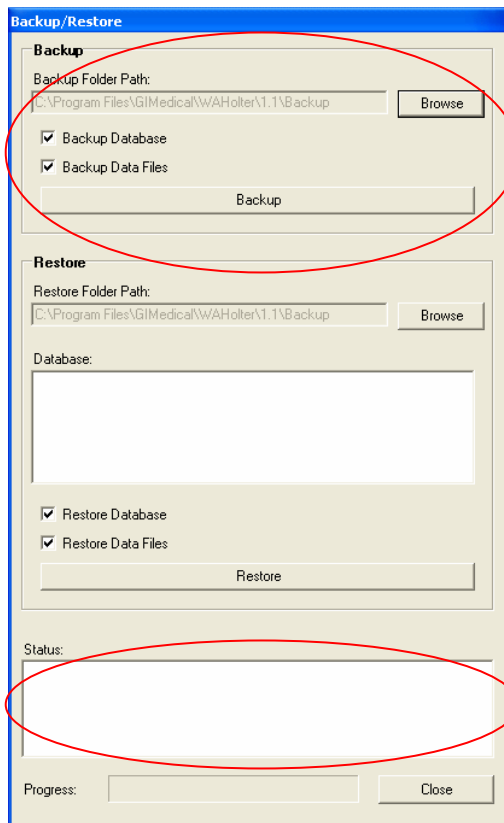
Data Recovery Backup/Restore (not an Archive)

The Data Recovery Backup/Restore capability in this version is intended for use by qualified IT Administrators or WA Tech Support to make a complete Backup of the DB and the Data files prior to work being done on the computer. This will allow for a Restore of the original data if something happens while the system is being worked on. Below are bullets on when this tool may be useful.

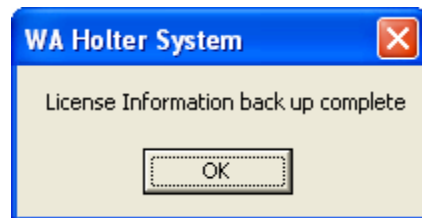
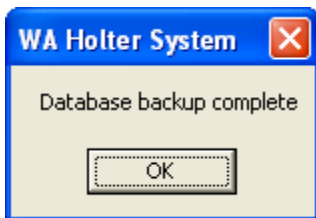
- Customer wishes to move their Software to another computer (remembering to deactivate the software on the current system) they could use this to move the data from the old computer to the new one.
- IT Professional would use this to make a complete backup to a network drive that can be then backed up by the backup routine on their network.
- If during a trouble call it is determined the software needs to be repaired/reinstalled.

About Backup and Recovery

It can be found under the “Service Personnel Only” block in the “System Settings” Screen.

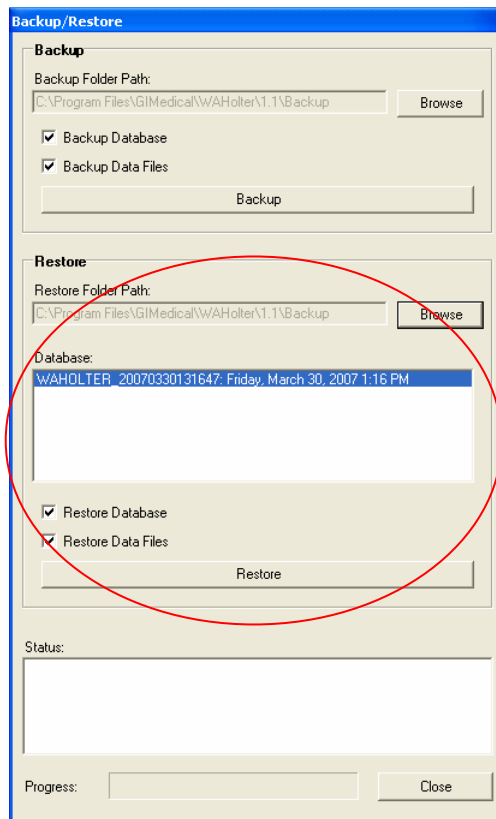


When backing up it is recommended that you backup the Database and Data Files. Using the Browse button you can direct the backup to write to anywhere on the local drive or map drive on a network. The Status windows will show status as it goes through the backup and restore functions.

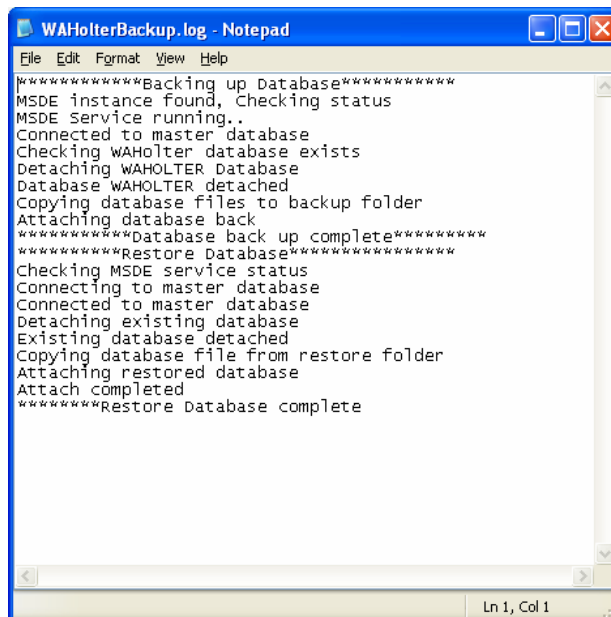


After clicking Backup you will receive a prompt for each part of the backup. Above are the messages you will receive in order from left to right.

Note: The Backup also backs up the License file in case it is needed.



When doing a Restore you will need to use the “Browse” button to tell the software where the backup is located. This is true even when you kept the default and it is in the window. When you have selected a valid folder the Backup will show in the Database window.



The Backup and Restore function also creates/updates a log file in the folder the backup is sent to.

Network Capability

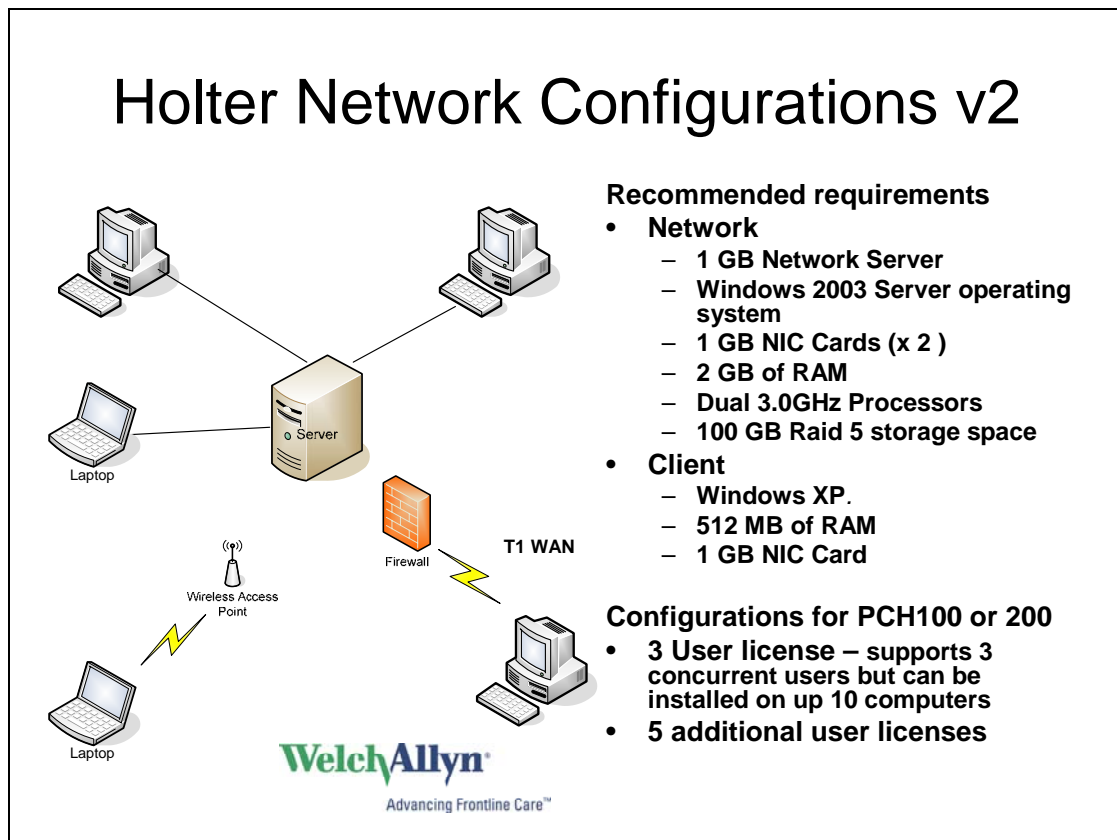
This version of the software is now available with Network capability and includes PCH100 and PCH200 Systems. Some points to note.

- The LAN software is designed to share data across a network, it does not provide multiple licenses for locations not connected to a server (i.e. one database)
- 101511 and 101513 includes software to load on up to 10 computers but only 3 users can be actively using the software at the same time
- Additional licenses can be purchased in bundles of 5 using P/N's 704529 and 704540

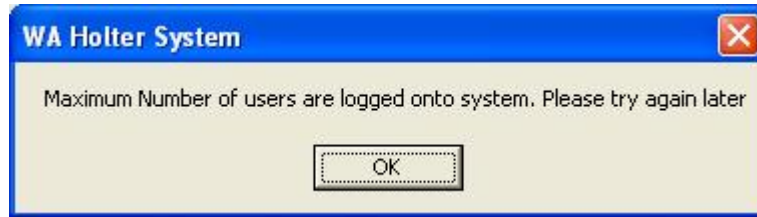
Below is a list of the P/N's for the LAN configurations that can be ordered.

P/N	Description
101511	PCH100 LAN - 3 USER HOLTER S/W W/O REC
101513	PCH200 LAN - 3 USER HOLTER S/W W/O REC
704529	PCH100 LAN - 5 ADDITIONAL USER LICENSES
704540	PCH200 LAN - 5 ADDITIONAL USER LICENSES
705921	WELCH ALLYN HOLTER SYSTEM UPGRADE CD

The image below is visual for a Network configuration along with Recommended Specification for the Server and Client station.



Some Messages that may be encountered during LAN use



Issue:

1. This message may occur when a user tries to log on to the Holter software and the maximum number of users (based on the number of licenses purchased) is reached.
2. Or this may occur if a user loses the network connection without logging off.

Solution

1. Another user must log off.
2. The user that was disconnected must log on the same computer and log off or log in will automatically reset after 24 hours.



Issue:

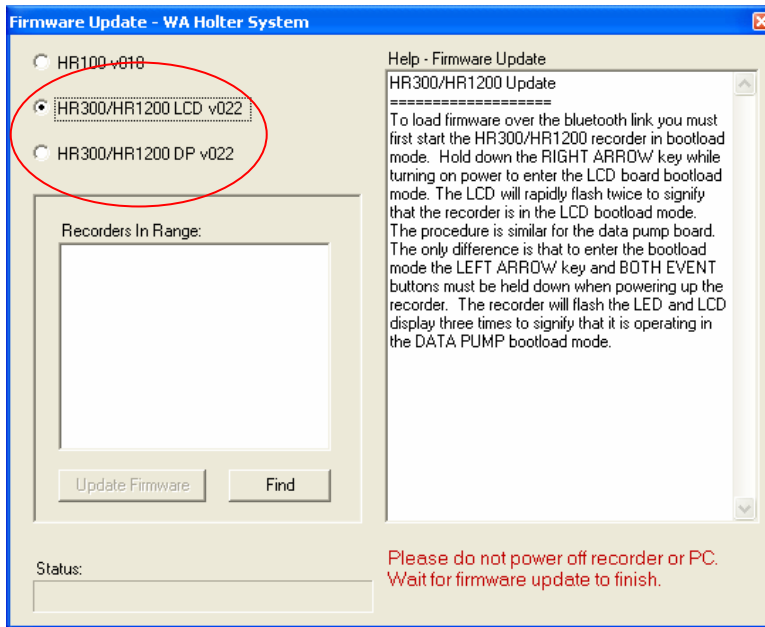
1. Another user has this patient record open.

Solution:

1. The site named in the error dialog box must Close the patient record. In the example above the log in ID is "Test User" and the computer name is D2C35GB1.

HR300 Firmware Update

The HR300 has a new firmware (v022) that can be updated through this version of software. To update the system you must get to System Settings and "CTRL" & "F" to bring up the update screen.



When updating the HR300 allow for approx 40 min per update and you must update both the LCD and DP (Approx. 80 min total). The box under “Help – Firmware Update” explains how to put the recorder into the correct mode to perform the update. A list of recorders that will ship with this update are included in the beginning of this bulletin. The list below identifies the S/N’s that will need this update.

HR300-01015	HR300-01039	HR300-01042
HR300-01056	HR300-01059	HR300-01064
HR300-01070	HR300-01072	HR300-01100
HR300-01123	HR300-01126	HR300-01155
HR300-01158	HR300-01177	HR300-01180
HR300-01194	HR300-01207	HR300-01221
HR300-01222	-	-

- **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	5/7/07	RJS
B	Release to Production	1011256	CJT	5/24/07	MEB

End of Bulletin