



**Welch Allyn Inc.
Medical Products**

Technical Service Bulletin

7 January 2007

Number: M070102P

Subjects addressed in this document: Revised Software Update P/N **705921** (App. 1.1.1) for PCH100 and PCH200 Holter Systems.

Author: Chris Thompson in conjunction with Diagnostic Cardiology Team

FOR COMPANY DISTRIBUTION ONLY (if applicable)

SAP DIR: 20010819

Distribution Key:

- Welch Allyn, Inc. Only
(All Welch Allyn, Inc. Global Service Centers; Internal Departments: R&D, PE, Manufacturing, Marketing, Sales, "Get Smart" publisher, Customer Service, Technical Service, Shared Services)
- Welch Allyn, Inc. and Authorized Service Providers
- Public (No Restrictions)

Reference:

Change Number: _____

Corrective Action Number: N/A

Applies to: All models of PCH100 and PCH200 Holter Systems.

Supporting Documents:

706063 - WELCH ALLYN PCH100 & PCH200 INSTALLATION GUIDE
704556 - DFU, HOLTER HR100/300/1200
705873 - DFU PCH100 SOFTWARE
705874 - DFU PCH200 SOFTWARE

Software Release History:

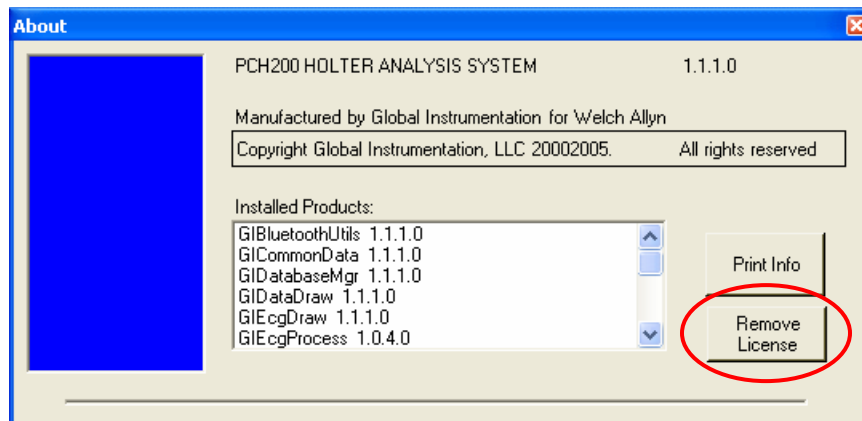
Version 1.0.2 – Domestic launch released June 2006
Version 1.1.1 – International launch released January 2007

Service and Installation Changes

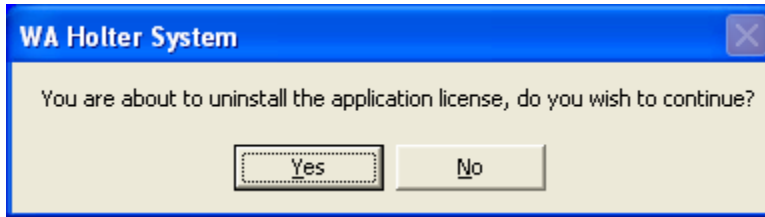
1. **Service Pack 2 on Windows XP**- No longer required for Bluetooth operation. Belkin Bluetooth installation is required per Installation instructions (P/N 706063).
2. **Software License** - Mechanism to move the software license to another computer due to a computer problem or transfer to a new computer. Requires PC to have internet access and user to initiate transfer license from within the application.
 - a. From the initial screen. Click “About”.



- b. Click “Remove License”



- c. Confirm Removal by Clicking “Yes”



- d. Message returned stating whether it was successful or not.

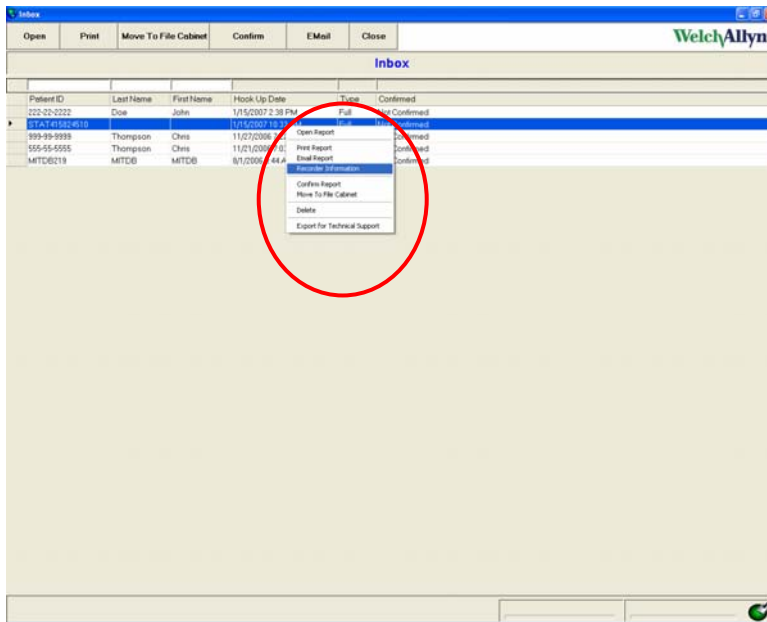


- 3. **Recorder Firmware Update** - is a new service function to update the firmware in the recorder to take advantage of new features or reliability improvements (e.g. update old HR100's to support 48 hour recording). HR100 recorders S/N HR100-1278 and above will not require this update. When performing this update it takes approx. 40 min. to complete and the system cannot be used during this time.

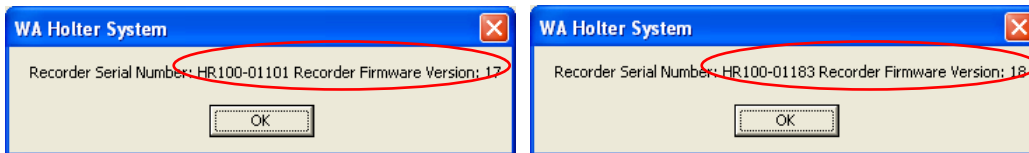
- a. To determine the version of Firmware on a recorder.
 - i. From the initial screen. Click "Inbox".



- ii. Right click on a previous recording.
 - iii. Click "Recorder Information"



iv. Verify correct S/N of recorder and note Firmware version.

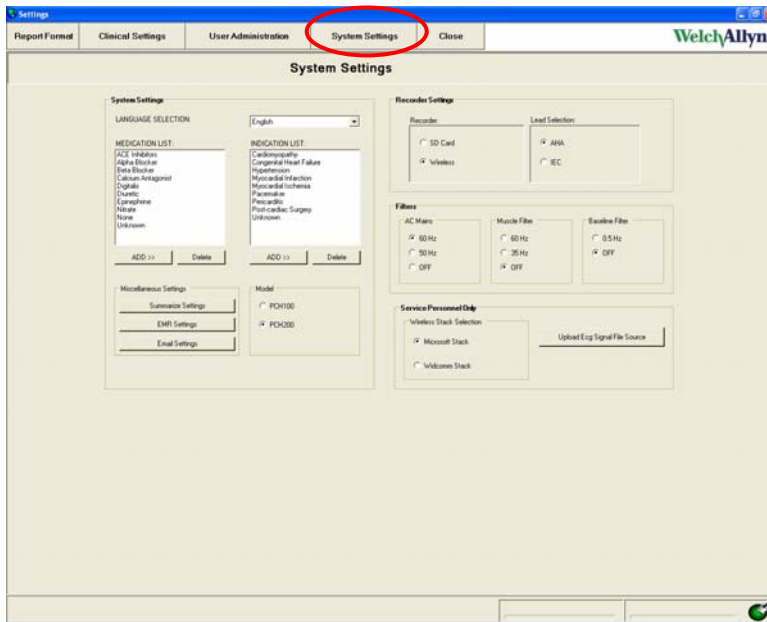


b. To update the Firmware on a recorder.

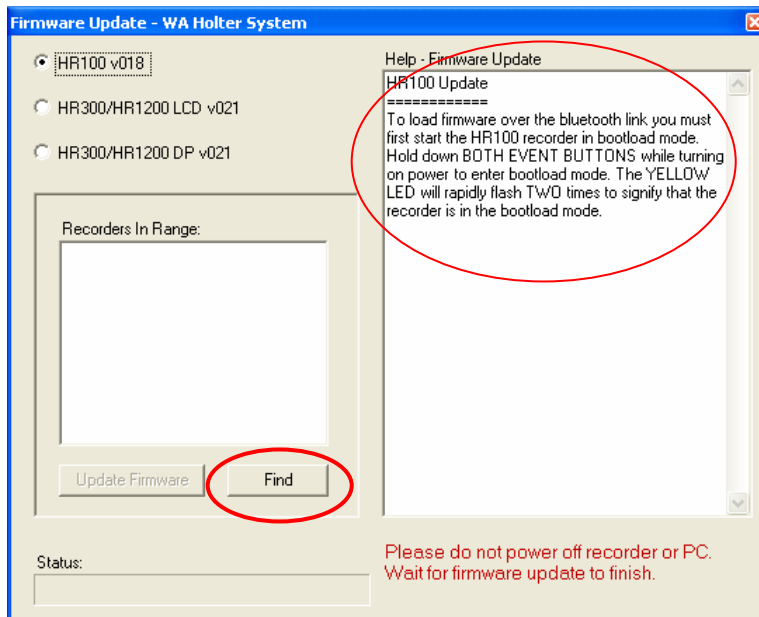
i. From the initial screen. Click "Settings".



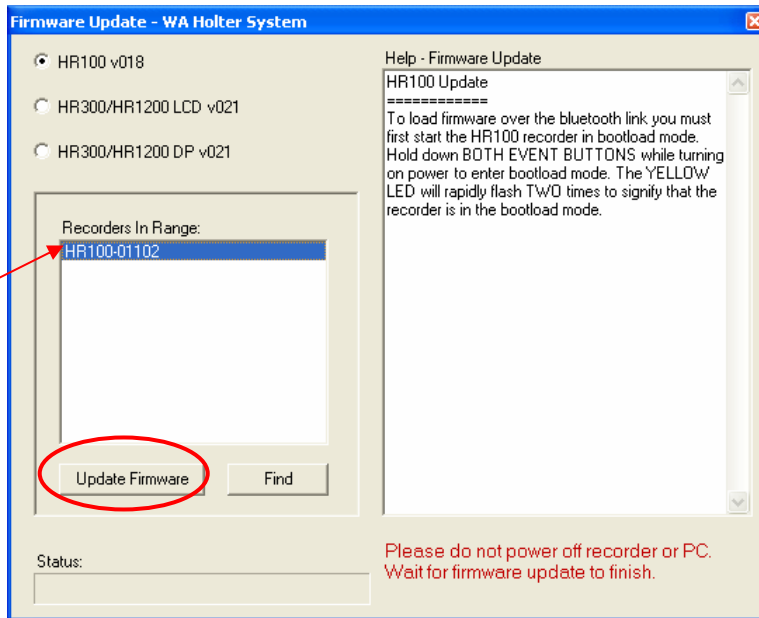
ii. Click "System Settings"



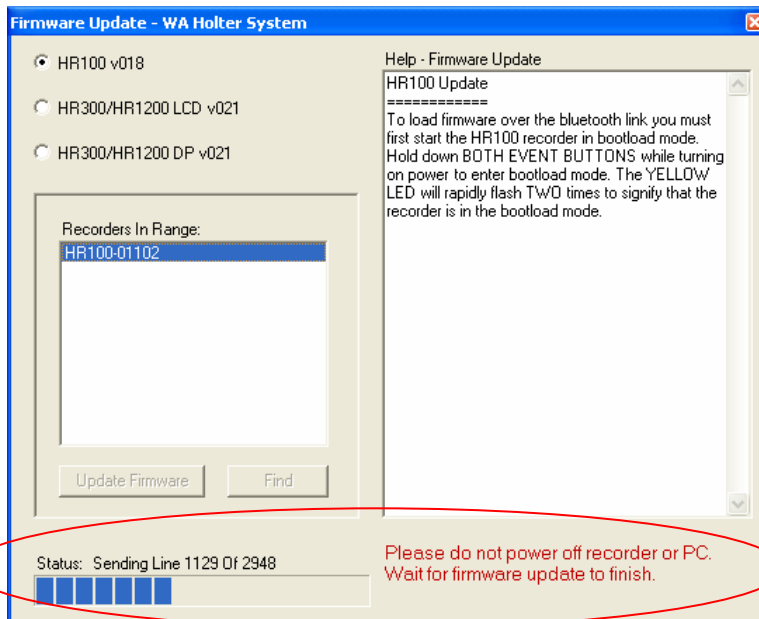
- iii. Press “CTRL” “F” on the keyboard. This will present the “Firmware update” screen.
- iv. Follow direction on screen to power recorder into bootload mode. (Note: The Yellow rapid flash of the LED happens almost immediately after inserting the battery). It is very important to use a NEW battery when doing this update.
- v. Click “Find” button



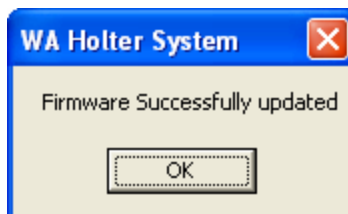
- vi. Recorders in range will be listed in the window.
- vii. Highlight the recorder that needs updating (only one recorder at a time) and click “Update Firmware” (Note: This takes approx 40 min to complete and can not be interrupted.)



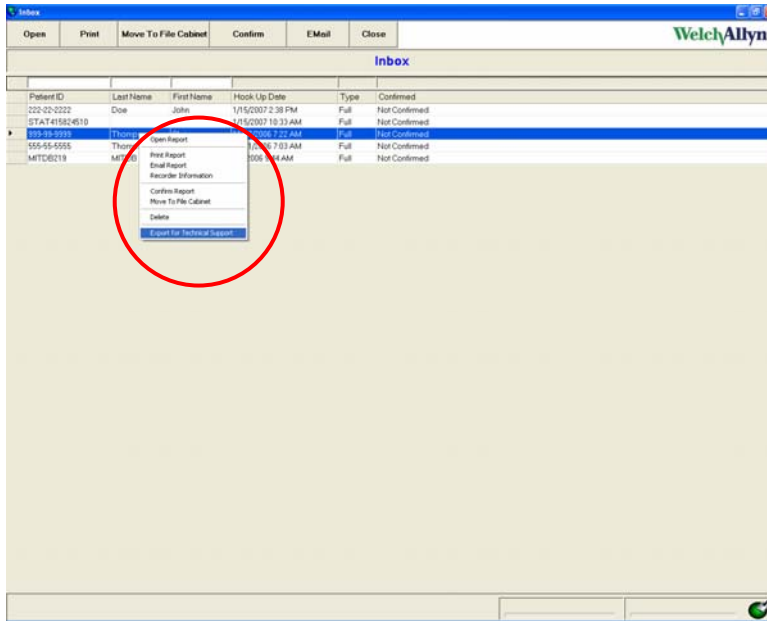
- viii. It is important that the PC or Recorder is not shut down during the update process. This can cause damage to the recorder.



- ix. You will receive a message when the update is complete. Click "OK"



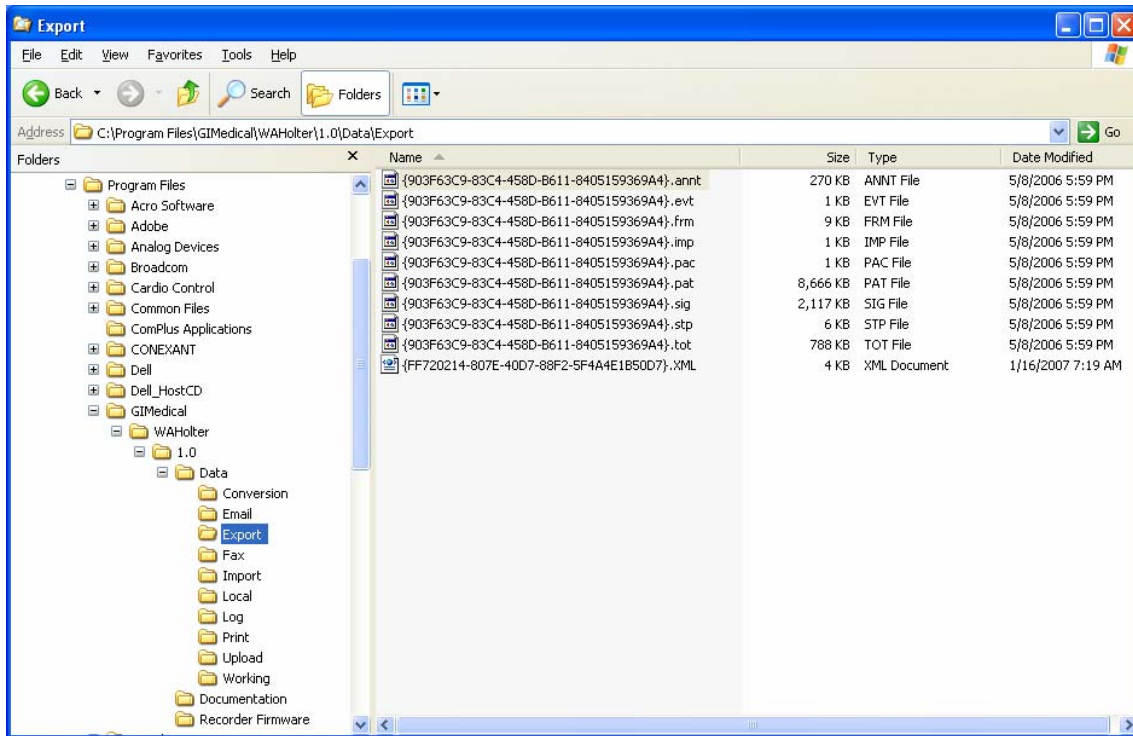
- 4. **Logo file types** - We now support the use of .bmp image types as well as .jpg.
- 5. **Renamed the Export function** - for patient tests (available from context sensitive menu found in “Inbox”, and “File Cabinet”) to “Export for Technical Support Only”.
 - a. From initial screen. Click “Inbox” and Right Click on report to export. Select “Export for Technical Support”



- b. A message stating report exported will appear.



- c. To locate the files. Open Windows Explorer and browse to “C:\Program Files\GIMedical\WAHolter\1.0\Data\Export”

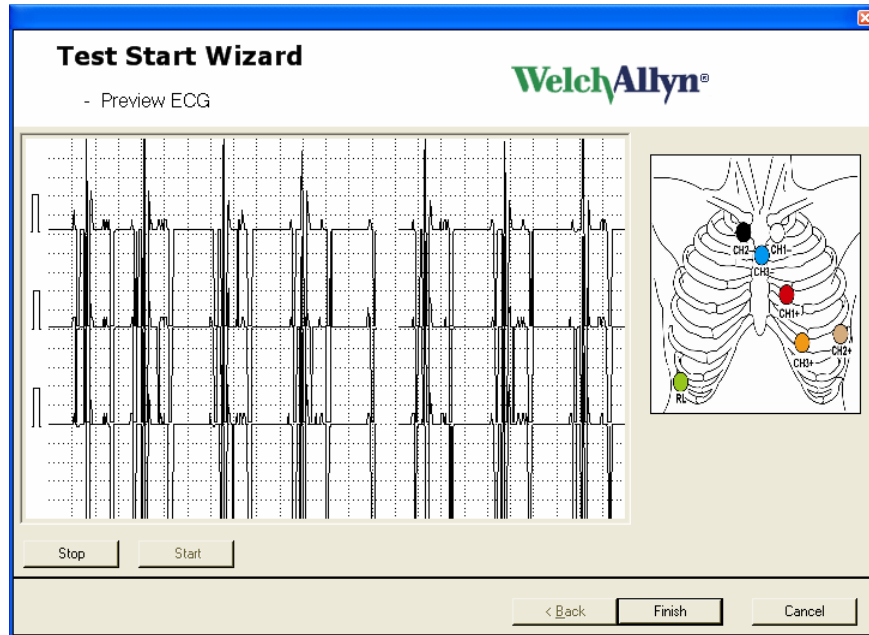


6. **Installs for all users** - Previously released installation version (1.0.2) only installed for Admin user not all users. The new version will install for all users on system. SB-0002 (Application Is Not Available for All Users) will not be required with this new release.
7. **Microsoft SQL Server Desktop Engine (WAHOLTER) “Remove”** – is now available from “Add or Remove Programs” when a new installation is performed. Systems updating from version 1.0.2 this will not be available.
8. **Part Number changes**

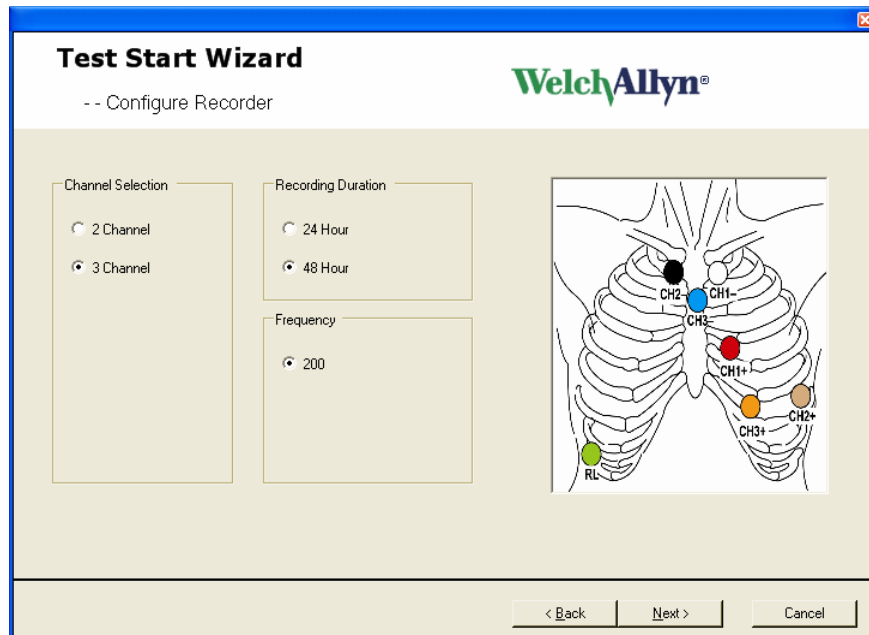
Old Number	New Number
704525	101510 (PCH100 Stand-alone Holter S/W w/o Rec)
704526	101511 (PCH100 LAN - 3 USER Holter S/W w/o Rec)
704527	101512 (PCH200 STANDALONE Holter S/W w/o Rec)
704528	101513 (PCH200 LAN - 3 USER Holter S/W w/o Rec)

New Features

1. **HR100 Holter recorder** - can be programmed to record 24 or 48 hrs, at 200 samples per second.
 - a. **Recorders not updated to firmware 018** will exhibit the following on the Preview ECG screen when attempting to start a recording.



- b. To verify that this is the issue you should "Cancel" and Run "Test Start up" again. This time select only a 24 hr recording.



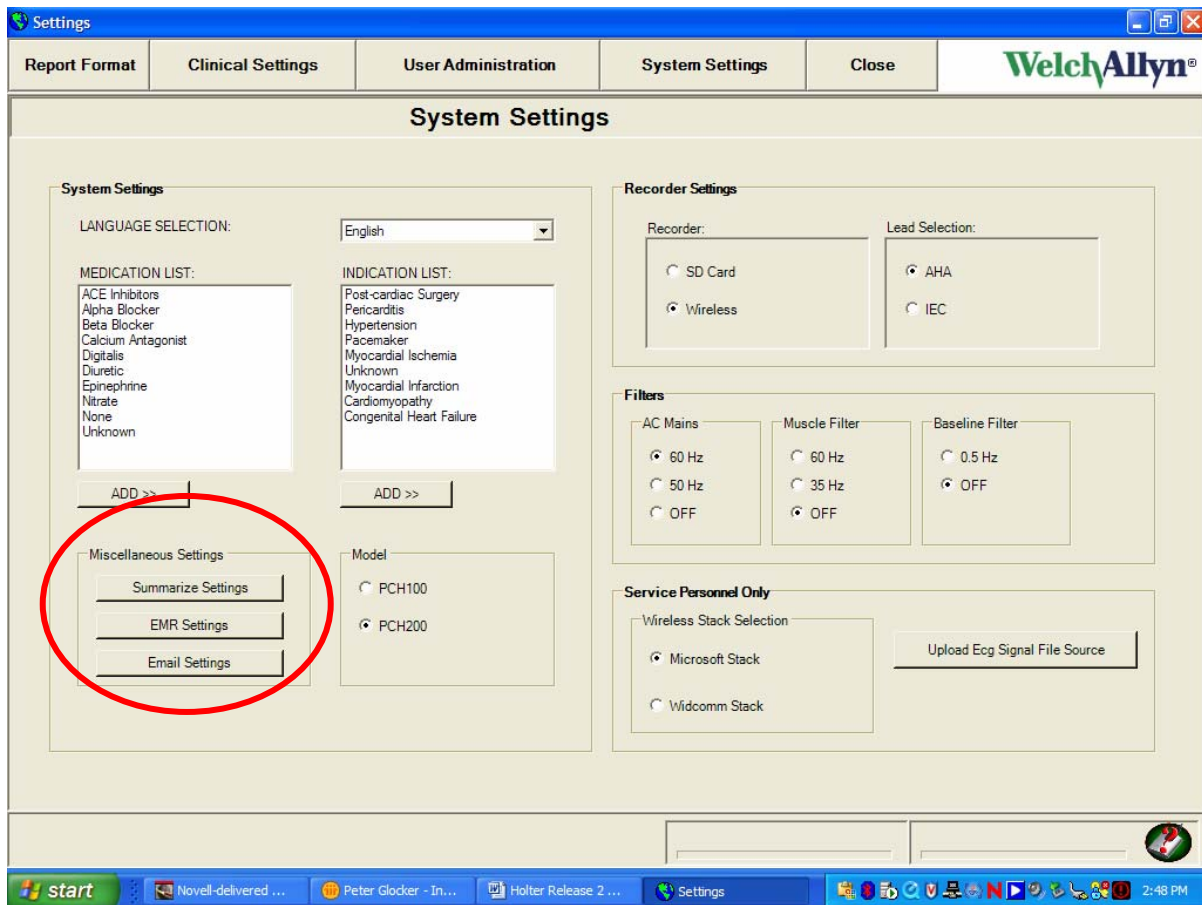
- c. If this works fine and the customer wishes to perform 48 hr recordings they need to update the Firmware as described above.

2. HR300 Holter recorder

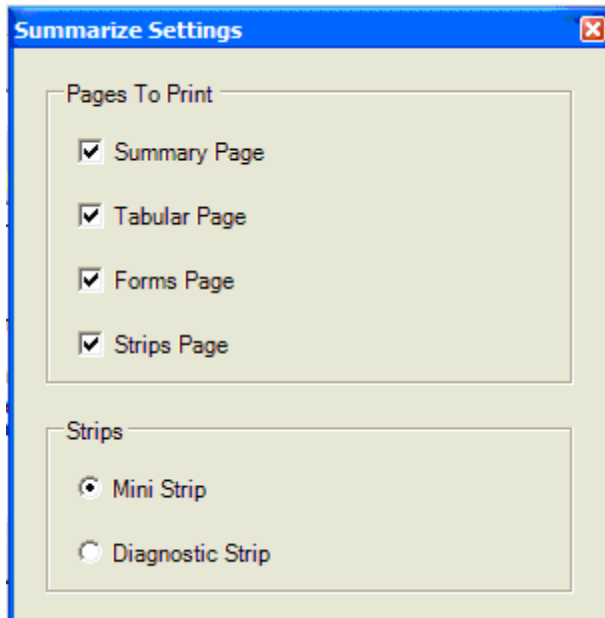
- a. Program options - 24 or 48 hours at 200 samples per second
- b. Higher sample rates of 500 and 1,000 sample per second can be selected but the recording times are limited to 24 hours and will require a higher capacity storage SD card of 1 GB.

- 3. **Report summarization into pdf** - With this release of software, the file size of a 24-hour study will be reduced to 64 MB and a 48-hour study will be 128 MB. Since these are very large files, the summarization feature will convert an existing report (not including full disclosure) to a pdf file without the need of a PDF writer. *Note: Summarization deletes the raw data, with only the .pdf file of the report remaining and there is no undo!* Typical file sizes for the .pdf files will be ~4 MB.

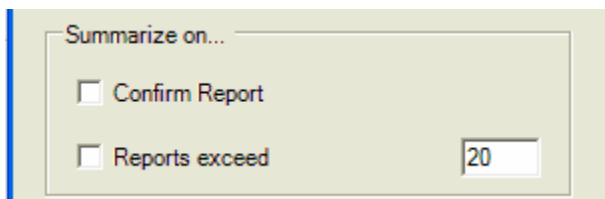
To configure this option a “Summarize Settings button” has been added under the Miscellaneous Settings group in System Settings.



- a. The customer can:
 - i. Select which items to include in the summary.

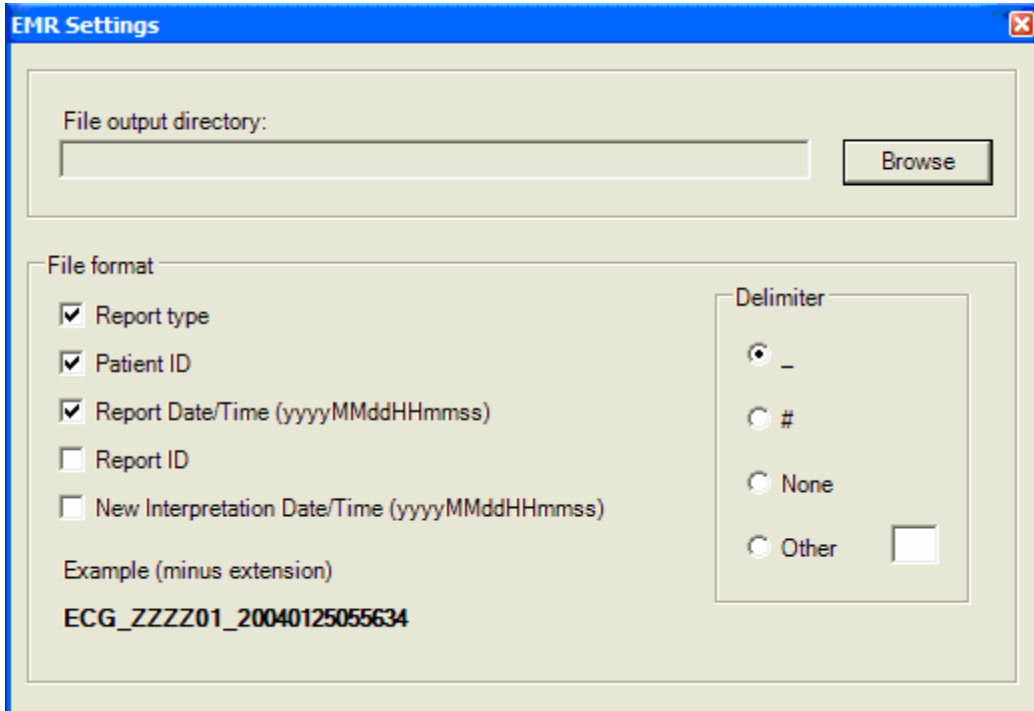


- ii. Select option for summarizing the report.
 1. Customer Initiated (default) – The option to manually summarize a report is available from the Inbox in the PCH100, and from the File Cabinet in the PCH200.
 2. Automatically - when the test is confirmed.
 3. Automatically - at some report count threshold set by the user, e.g. 20 tests. Summarizes the oldest test and deletes the raw data. *NOTE: The user is provided no warning.*

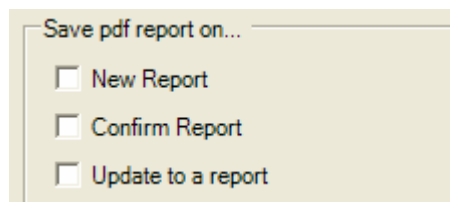


- b. Upon summarization - the full report (the raw data) will be deleted.
 - c. Summarized reports - are listed in the inbox (PCH100) or the File Cabinet (PCH200), with a status indicating they have been summarized.
4. **EMR Settings** - “File Link” functionality has been added to export tests for patient electronic records. As part of the Export process the reports are converted into a .pdf for export. To configure this option an “EMR Settings button” has been added under the Miscellaneous Settings group in System Settings. (see first image under Report Summarization above)
- a. The customer can:
 - i. Define the output directory.

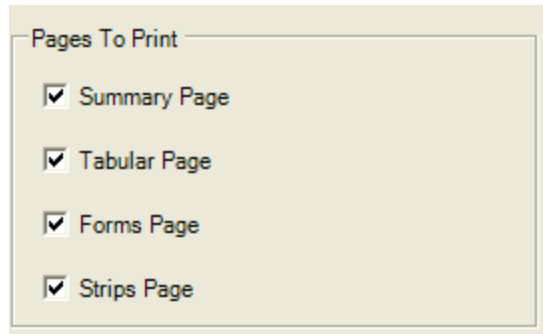
- ii. Define File Format - The substrings used to build the exported file name is configured by selecting which items from the list under file format. The delimiter used to separate each substring can also be configured. The exported file name is a concatenation of substrings, where each substring is separated by a delimiter.



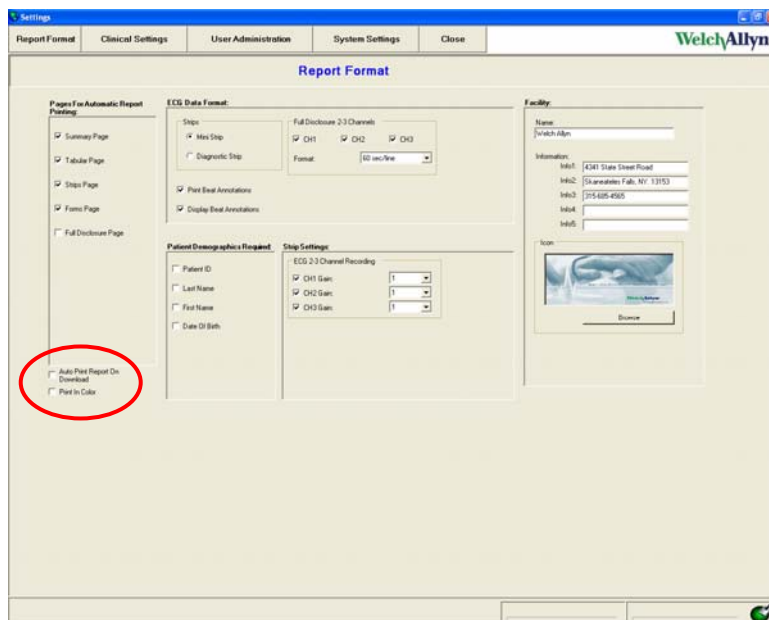
- b. Send pdf report on... – Triggers for Exporting will consist of the following (any combination of the three triggers is possible).
 - i. Initial report upload
 - ii. Automatically when confirmed
 - iii. Update to Report - Automatically if the report has been changed or interpretation modified



- c. Pages to Print: - This list of check boxes is available to select the pages to include in the export of the .pdf file to the EMR.



5. **Print in color** – A selection to print reports in color has been added under Settings, Report Format. If this box is checked, the reports will print in color if a color printer is used and the pdf documents will also be in color.

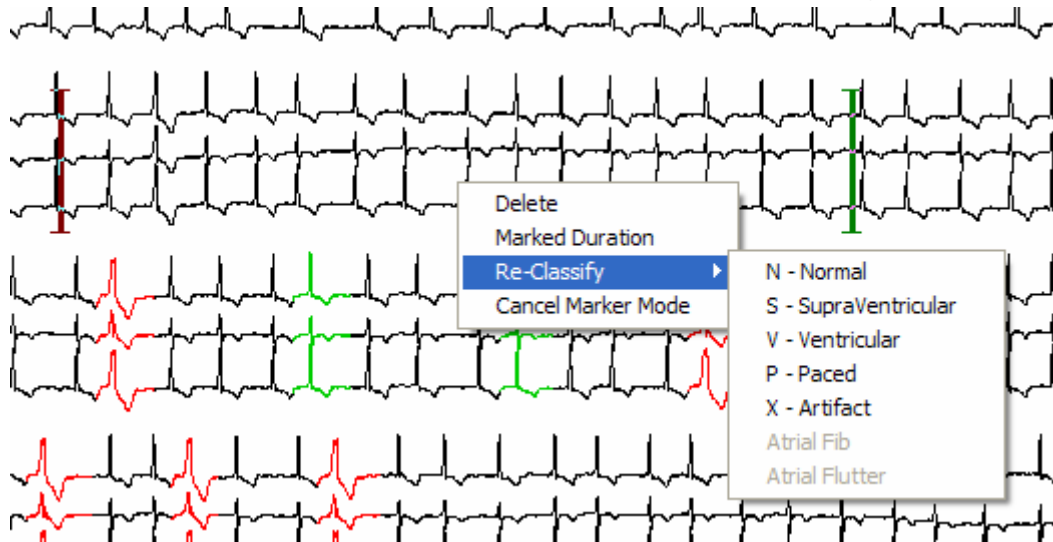


6. **Algorithm update** - improved beat detection in regions of low amplitude and better noise rejection capability.

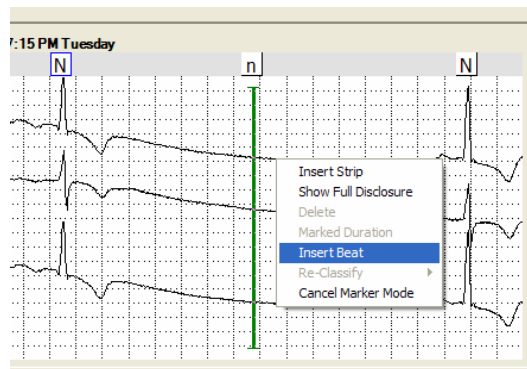
Changes for the PCH200 Only

1. **Relabel beats in a selected region** - In the RR tab under Arrhythmia Review or Full Disclosure, mark off regions to relabel the beats in regions of data, mark regions of afib and flutter or delete artifact. Identify regions by placing the cursor at the start of the region and pressing the “Enter” key. A second green bar appears, position at the end of the region (even across multiple pages). For precise control, use the Ctrl key and left or right arrow. Select right mouse for the options.
 - a. Relabel beats in the marked region, Normal (N), Supraventricular (S), Ventricular (V), Paced (P), Artifact (X)

- b. Automatic SVE's will be relabeled in Afib marked regions
- c. The printed report will list total number of Afib Episodes and total duration. Statement would be "There were X Afib episodes with total duration xxxx minutes."
- d. Summary Preview will display the additional Afib information only in the Narrative Summary view. Statement "There were X Afib episodes with total duration xxxx minutes."
- e. Marked Duration – provides the time interval in the selected region



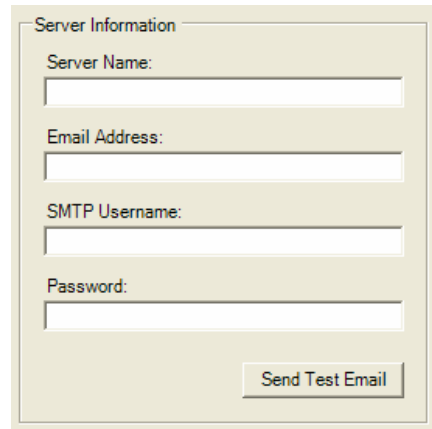
- 2. **Insert beat capability** - for missed QRS detections generally due to low amplitude recordings – available in Arrhythmia mode.
 - a. Point cursor to missed QRS detection
 - b. For precise control, use the Ctrl key and left or right arrow.
 - c. Select right mouse control and Insert Beat – a neat label, lower case n is added. Highlight using the right mouse control to change as necessary, e.g. S or V.



- 3. **Email reports** – Automatically converts the selected report into a .pdf.

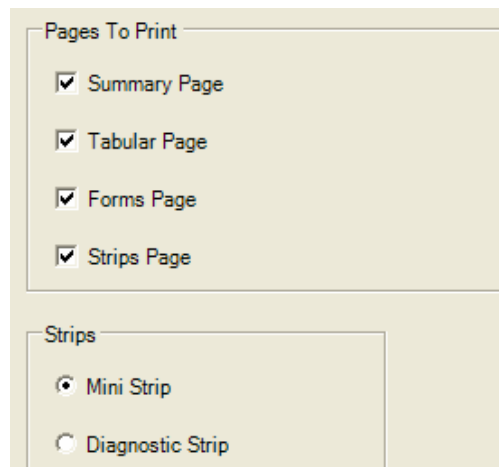
To configure this option a button, “Email Settings”, has been added to the System Settings tab (see first image above). Options include:

- a. Server Information
 - i. Server Name - This is the SMTP server name for the customer’s email service. Example would be “smtp.twcny.rr.com”.
 - ii. Email address – sender’s email address which is entered into the “From” field on the email
 - iii. SMTP Username and Password are optional



The screenshot shows a form titled "Server Information" with four input fields: "Server Name:", "Email Address:", "SMTP Username:", and "Password:". A "Send Test Email" button is located at the bottom right of the form.

- b. Report Format for email
 - i. Pages to print and strips



The screenshot shows a form titled "Pages To Print" with four checked checkboxes: "Summary Page", "Tabular Page", "Forms Page", and "Strips Page". Below this is a section titled "Strips" with two radio button options: "Mini Strip" (selected) and "Diagnostic Strip".

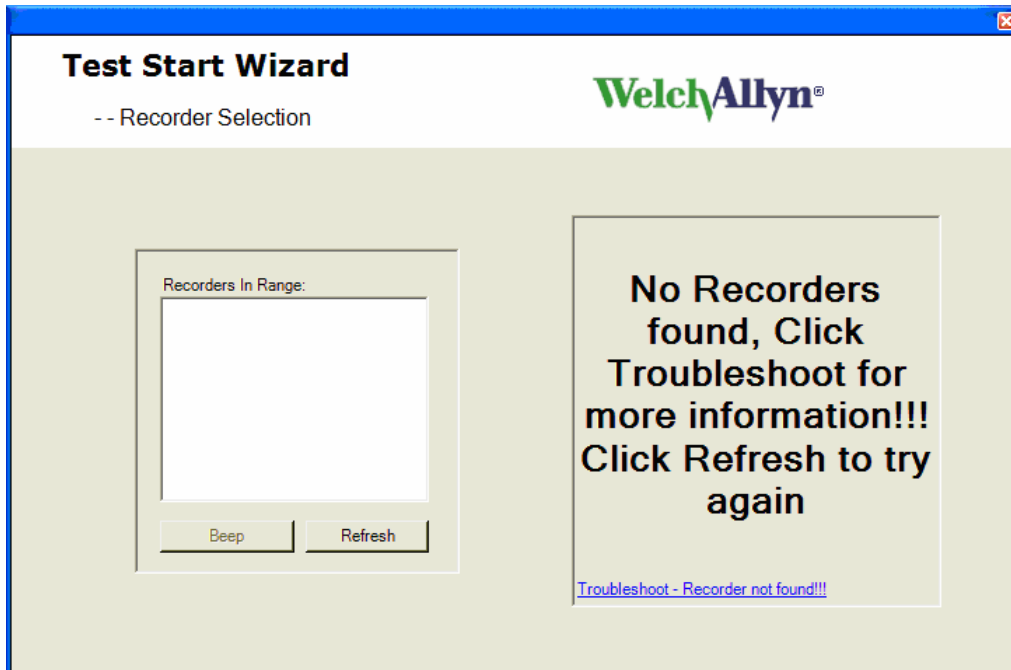
User Interface Improvements (PCH100 and PCH200)

1. **Acquisition Wizard** – only the “Next” or “Finish” button will be available at one time, eliminating the potential confusion between using both buttons on the same screen. The Next or Finish button will be in the same screen location.

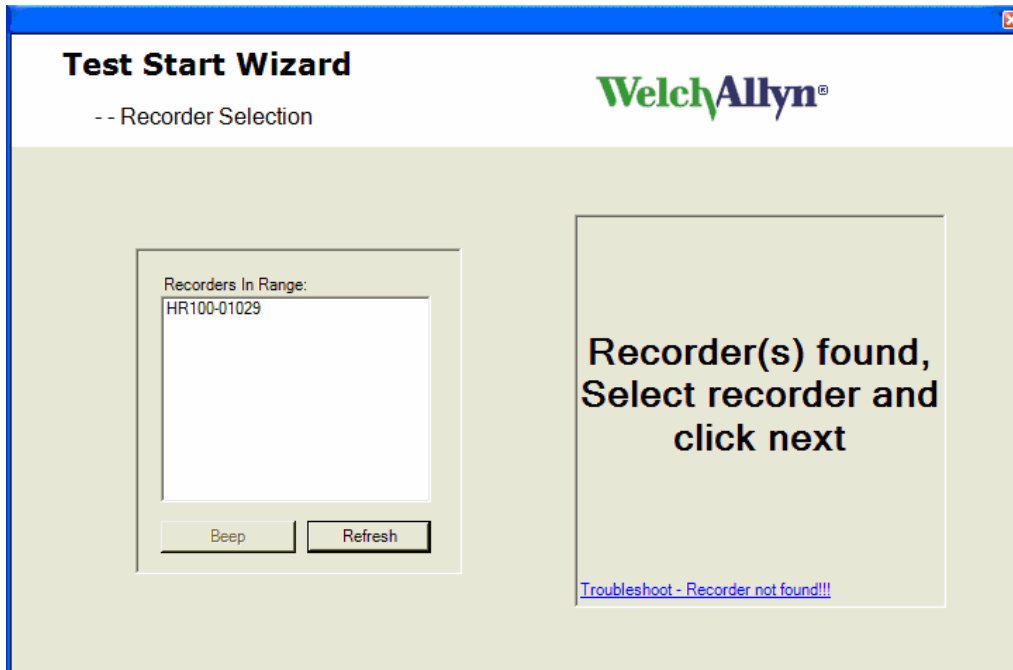
- 2. **Print dialog box** - When printing a Report, the “Print in progress” dialog box does not appear until after the user selects the printer to be used from the “Print” Common Dialog box. Sometimes this dialog box would block the ability to select the printer.
- 3. **Test Startup Wizard**, in Wireless mode – New screens have been added to simplify the workflow. Changes include:
 - a. To reduce the time it takes to start a test, the wireless search for the recorder starts while the user is entering patient data
 - b. Recorder Selection Page has been changed
 - i. “Change help-Find Recorder” to “Troubleshoot - Recorder Not Found !!!”
 - ii. Added a panel on the right side of the screen that show progress.
 - 1. Initially it displays “Searching for recorder, please wait”. This message keeps flashing until it finds the recorder or no recorder is found



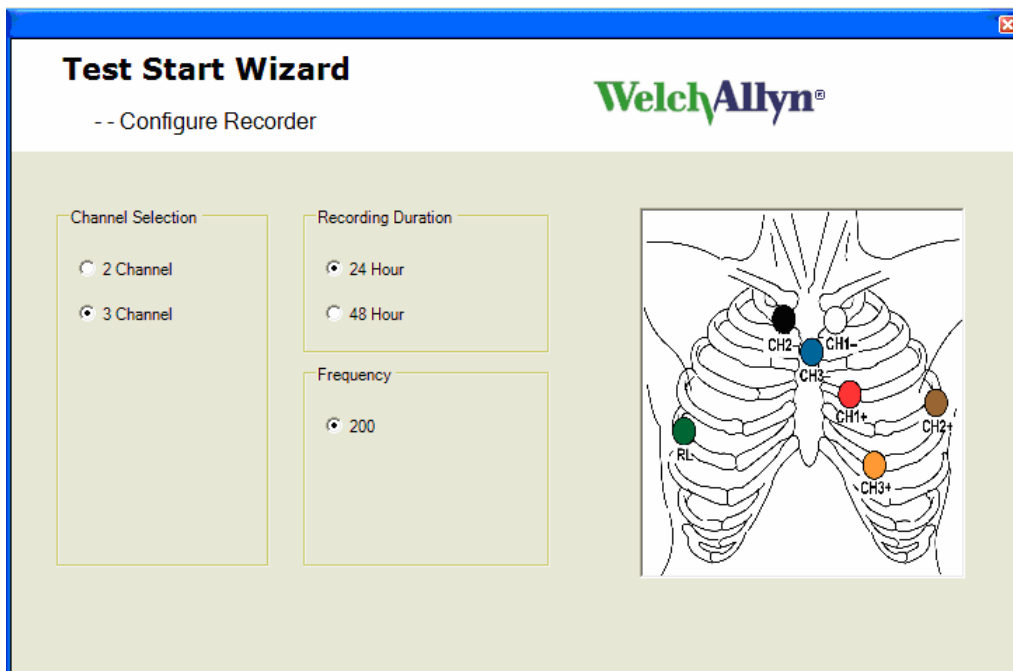
- 2. If the recorder wireless is not available, the screen displays “No Recorders found, Click Troubleshoot for more information !!! Click Refresh to try again.”



3. Selecting the trouble shooting dialog at the bottom of the panel will display the following suggestions:
 - a. Verify SD card is inserted into recorder.
 - b. Verify that a new battery has been inserted, wait for the 2 beeps.
 - c. Click on Refresh.
 - d. Verify that a Bluetooth USB device light is active (LED will be blinking or on). If not - Close application, remove and insert Bluetooth USB device into the same port and restart the process.
 - e. If the problem persists, contact technical support.
4. Upon success, one or more recorders will be listed in the left hand pane. Displayed in the right hand pane will be: "Recorder(s) found, Select recorder and click next"

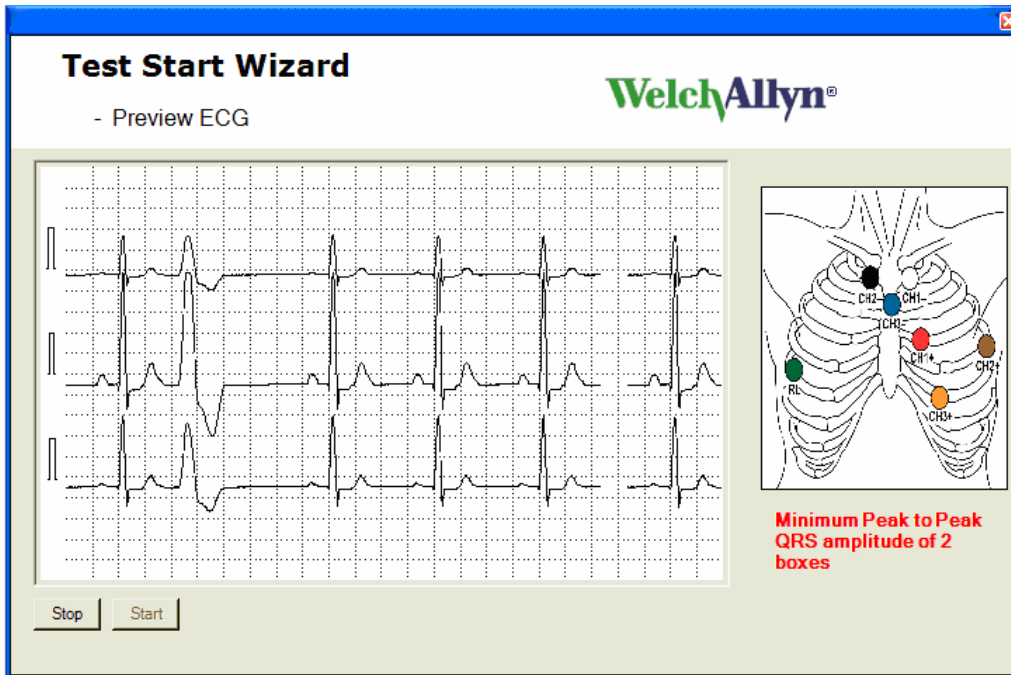


- c. A new Configuration Page includes:
- i. Channel Selection – 2 or 3 channel
 - ii. Recording Duration – 24 or 48 hours
 - iii. Sampling rate – additional selections include 500 and 1,000 for the HR300
 - iv. Lead placement graphic

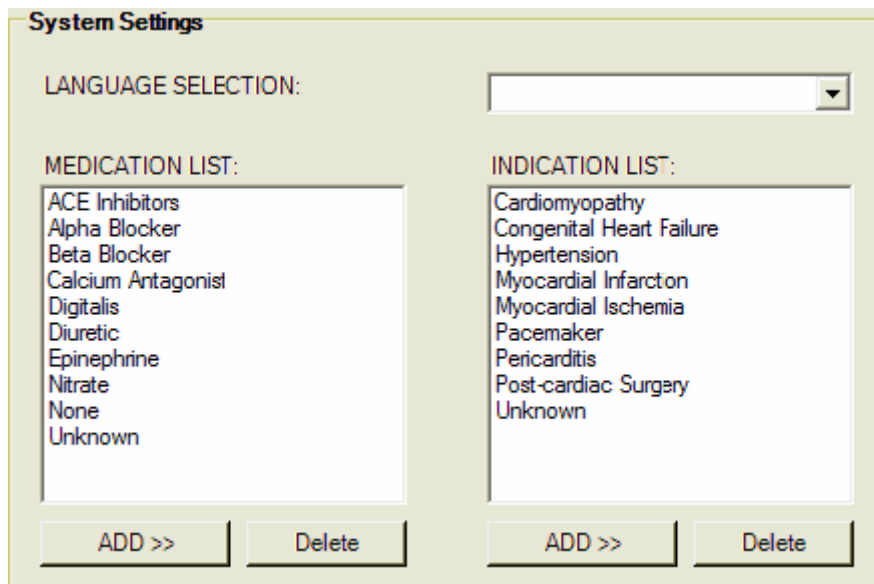


- d. ECG Preview display has the following changes

- i. Grid
- ii. Message flashing to remind operator amplitude requirement “Minimum Peak to Peak QRS amplitude of 2 boxes.”



4. **Medication and Indications** – under System Settings for Medications and Indications
- a. A “Delete” option has been added
 - b. Meds and indications are listed alphabetically



International Specific Changes

1. **System Settings** - will allow the configuration of the Torso image to be displayed. It will allow either the AHA or the IEC to be selected.
2. **International languages supported:** French, German, Danish, Dutch, Finish, Greek, Italian, Norwegian, Polish, Portuguese, Spanish, and Swedish.

Service Strategy:

Updates from 1.0.2 to 1.1.1 – Update CD's may be ordered under P/N 705921 and are free of charge.

Inspection and preventative replacement as applicable:

Classification of Action:

- Mandatory
- Optional
- Does Not Apply

When:

- Immediate
- On Next Service
- At Agreed Upon Time

Note:

Drawings and/or illustrations and/or part numbers in this document are for reference only and current to the date of this bulletin. Contact the Welch Allyn Customer Service department for any questions on this bulletin, or to verify that you have the most current service information.

Complaint Records:

Alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of this product shall be documented, processed and readily available if requested according to the applicable complaint procedures for medical devices. Complaint records shall include:

1. The name of the device;
2. The date the complaint was received;
3. Any device identification(s) and control number(s) used;
4. The name, address and phone number of the complainant;
5. The nature and details of the complaint;
6. The dates and results of the investigation;
7. Any corrective action taken; and
8. Any reply to the complainant.

Service Reports:

Service reports on this product shall be documented and maintained so that they are readily available if requested. Service reports shall include:

1. The name of the device serviced;
2. Any device identifications(s) and control numbers(s) used;
3. The date of service;
4. The individuals(s) servicing the device;
5. The customer's "chief complaint" or "reason for return" and the defect found after inspection;
6. The service performed; and
7. The test and inspection data (after servicing).

Revision History

VERSION	DESCRIPTION	CHANGE #	INIT	DATE	APPR
A	Draft for Internal Reviews	1010131	CJT	1/22/07	KMG
B	RELEASE TO PRODUCTION	1010218	CJT	1/22/07	KMG

End of Bulletin**M070102P**