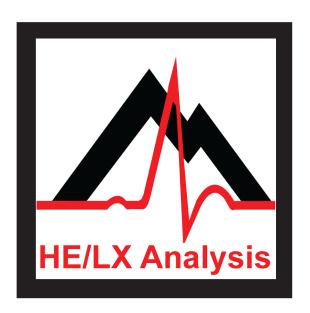
HE/LX Holter Analysis User Manual

Updated: Software version: 6.1b









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1. Introduction

Welcome to NorthEast Monitoring's HE/LX Analysis Software. Used in conjunction with a NorthEast Monitoring Holter recorder, HE/LX Analysis allows you to fully review all of the ECG recorded during the Holter test, including all normal, ventricular, supraventricular, and paced beats.

You can quickly review and edit morphology types, significant arrhythmic events, strips saved for the printed report, data trends, and tables. You can also review and edit report information before it's printed, and then print whatever pages are required to document each patient's Holter test. In addition, HE/LX Analysis automatically reads recording data from the recorder's flashcard - including entries made using the Event button - and saves sample strips of event markers.

Archiving, Remote Reporting and Spectral Analysis are also included.

Intended Use

The Holter Analysis software is intended to provide Holter analysis (arrhythmia and trend data) to physicians on their personal computers, on an off-line basis.

Indications for Use

The HE/LX Analysis software is to be used to analyze the data recorded by Holter recorders such as the NorthEast Monitoring, Inc. DR200/HE and DR400.

- 1. Detection of Arrhythmias: The Holter Analysis Software assists in the evaluation of ECG recordings of cardiac rhythm when intermittent arrhythmias are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.
- 2. Efficacy of Treatment: The Holter Analysis Software assists in documenting the effect of pharmacological treatment of known arrhythmias is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.
- 3. Pacemaker Evaluation: The Holter Analysis Software assists in the evaluation of the function of implanted pacemakers to ensure that the pacemaker is functioning within prescribed limits.
- 4. The Holter Analysis Software is to be used only on the order of a physician.

Clinical benefits

The Holter Analysis software is used to analyze NorthEast Monitoring Holter recordings that are used to assist in the diagnosis of heart issues that do not show up on an electrocardiogram. Holter monitoring is not intended to replace real-time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

Software Package includes:

- · Software-key
- · Memory card reader

The HE/LX Analysis software must be installed on your hard drive to run. The software can be found and downloaded from www.nemon.com under the Support > Downloads and Documents page. A license file, provided separately, and the HASP key must also be installed to run the software. A demo patient has been provided with your software. Otherwise, you will need a flash.dat file from a Holter recorder to begin analysis.

System requirements

The HE/LX Analysis software is to be used to analyze the data recorded by a NorthEast Monitoring Holter recorder. To run the software, your personal computer must include:

- Microsoft Windows 10 or 11 Operating System
- a processor with a speed of 1 GHz or faster
- at least 2 GB of memory
- at least 10 GB of free space on hard drive
- a monitor with a resolution of at least 1280 by 1024
- a memory card reader (included) or a laptop PC card slot (for DR200)
- a laser printer is recommended.

Operator knowledge

To use HE/LX Analysis software, you must have extensive Holter knowledge that allows you to properly identify sinus and paced rhythms, abnormal rhythms, supraventricular and ventricular arrhythmias, artifact, ST segment changes, and pacemaker failures. In addition, all instructions assume a working knowledge of computers and, specifically a Windows operating system.

Software Specifications

User Specifications:

The software is designed to be used by a trained operator under the supervision of a licensed clinician for the purpose of evaluating the severity of arrhythmia as part of the patient's medical evaluation for treatment.

Performance and Specifications:

Arrhythmia Detection:

- Ventricular Premature Beats (VPBs)
- Supraventricular Premature Beats (SVPBs)

Maximum time analyzed:

• A Holter recording up to 14 days

Presentation of data:

• Calibration indication can be provided in reports

ST Segment slope:

 Positive or negative slope indicated based on manual setting of cursors by trained operator

LAN Capability:

• Multiple users can access the same patient data base at the same time

Pacemaker detection:

• Displayed and annotated for operator

Reports:

- Capability of labeling all arrhythmias with the operators input
- Modular with ability for operator to select modules to be included

- All reportable values and labels are editable by the operator
- Ability to remove and/or add sample ECG strips.

Using a DR200/HE

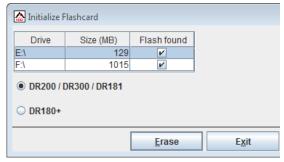
The DR200/HE Holter recorder uses a removable SD flashcard. To input the data from the recorder to the computer system, remove the flashcard from the recorder and insert it into your computer's card reader.

Depending on your computer and your card reader, a window may appear acknowledging that a card has been newly inserted and listing what files are present on the card. A recording saved by a NorthEast Monitoring recorder is named "flash.dat." If the window appears, close it.

Initializing a flashcard

Before using a new card for the first time, or between recordings, you may want to initialize your flashcard with a clean flash.data file.

Using the HE/LX software, select File > Flashcard > Initialize. If a drive is found, the Initialize Flashcard window opens.



Initialize Flashcard Window

First determine that the correct drive has been selected for your card. The drive that will be updated should be highlighted in blue, and if there is already a flash.dat file on it, the check box will be populated.

If a drive has not been found, check to be sure that a card is in the slot and the reader is attached to the computer. You may need to Exit and return to this screen to refresh the Drive list.

Introduction: Using a DR200/HE

Next, check to make sure that the correct card format option is selected for your recorder and then press Erase and your card will be initialized for its next use.

Note: If you insert a card into the recorder and get a message that the "Flashcard is missing," the card is not formatted or erased properly.

Using a DR400

For DR400 recordings, ECG data is saved on a non-removable flashcard. Use the Copy flashcard button from the new Patient Information window to copy the file. Refer to the DR400 User Manual for more information on copying patient files.

Legacy recorders

While they remain in the field, the HE/LX Analysis Software can be used to analyze Holter data recorded on NorthEast Monitoring, Inc. legacy recorders such as the NorthEast Monitoring, Inc. DR180+, DR181 and the DR300. The only limitation is that as of version 6.1 of the software, 12-lead and oximetry features are no longer supported.

The Holter Procedure

The Holter procedure typically includes the following steps:

- Hook-up the patient using a NorthEast Holter recorder.
- Remove the recorder from the patient, remove the flashcard from the recorder and insert the flashcard into the computer's card reader; or for DR400s, attach the recorder to the PC.
- Start the HE/LX Analysis software.
- Create a New patient and copy the flash file to an empty patient directory.
- Enter/review the Patient Information.
- Click Start to allow software to process the Holter data.
- In Bins, review the Templates for each morphology (optional)
- Review what Critical Events and update as required.
- While reviewing, click "Save" to save additional strips with significant events for the final report.
- Review the Saved Strips, making sure that all significant events are documented and labeled properly.
- Create and print the final report to be reviewed by a physician.

Detailed information about the steps outlined above appears in subsequent chapters in this manual.

Report Serious Incident

The user and/or patient must report any serious incident that has occurred in relation to the Holter Monitor should be reported to North East Monitoring and the applicable competent authority / government agency in the country where the incident occurred.

Online help

In addition to the information in this manual and the on-screen help messages that appear within the HE/LX Analysis software, more information and help is available at our web site www.nemon.com or

Introduction: The Holter Procedure

• Toll Free in USA: 866-346-5837

• Phone: [+1] 978-461-3992

• Fax: [+1] 978-461-5991

• email: support@nemon.com

• The "Support" page on the web-site includes software downloads and user guides.

2. PATIENT INFORMATION

The HE/LX Analysis software automatically retrieves the Holter signal, patient identification number, recorder number, date and time the recording started, and any events that the patient saved using the EVENT button on the recorder. All of this information is carried forward onto the Patient Information screen when the flashcard is read. You then, may enter any additional data that you want to save on the Patient Information screen.

While running the HE/LX Analysis software, you have the choice of opening the Patient Information window for (1) the last patient whose Holter test was accessed (that is, the "current" patient), (2) a previous patient whose Holter test has already been analyzed, or (3) a new patient whose Holter test has not yet been analyzed. In the first two cases, a patient record has already been created for the patient and the Holter data for the patient has already been downloaded from the flashcard onto the hard drive of your computer.

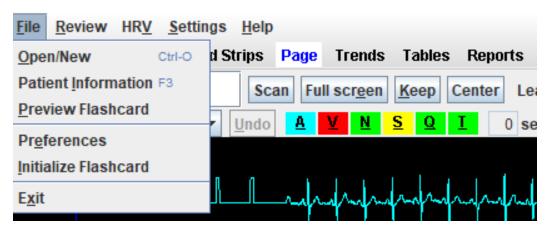
The software has two toolbars that allow you to switch between views for the patient that is currently opened. In this example, "Demo Patient" is the patient who is currently open and whose data you are able to view.



Standard Holter toolbars

In the case of a new patient, a new Patient Information record must be created and the Holter information downloaded from the flashcard. This chapter covers creating a new patient record first.

To enter information about a new patient's Holter recording, the HE/LX Analysis software must be running. When the program appears, it displays a blank screen with the standard toolbars.



File drop-down options

Enter a new patient

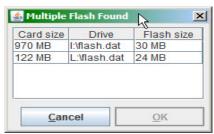
To create a new patient, do the following:

- 1. Insert the patient's flashcard into the card reader or plug DR400 into PC, and click File > Open/New from the toolbar. The Patient List will now appear.
- 2. From the Patient List, select an empty directory (row) and double-click on it or click the New button at the bottom of the window.
- 3. A Patient Information window will open, and click on the Copy Flashcard or Start button to read the flashcard.
- 4. Now press the Start button for analysis to begin.

Some things to be aware of:

- If you press the Copy Flashcard or the Start button before inserting a card, you will see a window that explains that there is no flashcard in the drive. If this happens, insert the flashcard into the drive and click Retry.
- If you see a window that shows that more than one flash.dat file has been found, you will need to determine which file to use before creating your new patient. Once you determine which is correct, click on and highlight

the file that you want to use at this time.



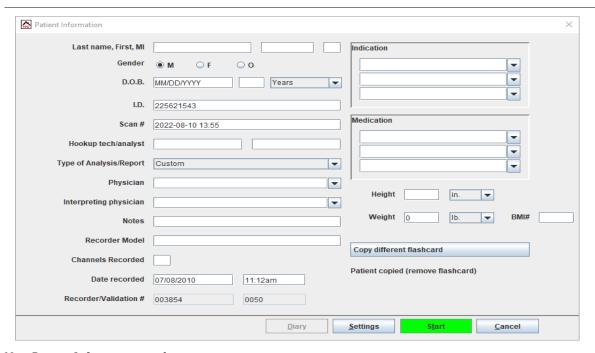
Multiple Flash found

If you are not sure which file to use, you can use File > Preview Flashcard to see recording information about the file that was saved on each card. More information on Preview Flashcard can be found at the end of this chapter.

Patient Information window

As the Holter data from the card loads onto your computer hard drive, you can enter the patient information. Hover your cursor over the title of a field to get more information, when available.

Note: Once the flash.dat has loaded, the "Copy flashcard" button in the Patient Information window changes to "Copy different flashcard." If the ID from the recorder does not match the patient, remove the card, insert the correct one and click "Copy different flashcard."

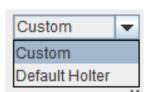


New Patient Information window

DOB and Age

The D.O.B. and Age fields work together. If you know the patient's date of birth, enter it, and the software automatically calculates the patient's age based on the D.O.B. and the recording date. If you do not know the date of birth, but know the age, type a numeric entry in the Age field, and select the appropriate unit (e.g., years) in the Age Unit field.

Type of Analysis/Report



Your system has been set up with a Default Holter configuration or Type of Analysis/Reports to get you started.

The Custom configuration is identical to the Holter configuration, except that it includes the Report header that you entered in the Setup screen, although it is editable, if you so choose.

The Type selected will load a set of default settings for the patient. Once assigned, you can override any of the settings by clicking on Settings and updating where you choose. After you save a patient with one type of analysis / report, you can change it, but all data that you edited, except for patient information, will be lost.

Note: For more information about Types of Analysis/Report, see Chapter 9: Configurations.

Notes

The Notes field allows an alphanumeric entry that can be used to record information that might be helpful about the Holter test or the patient. Notes are not printed on the final report.

Recorder Model and Channels Recorded

User can enter the information from the recording. If always the same, these values can be set up in a configuration for ease of entry.

BMI

HE/LX Analysis will calculate your patient's Body Mass Index (BMI) if you enter the patient's height and weight and the appropriate units. A patient's weight status can be determined from the BMI as follows:

- Below 18.5 Underweight
- 18.5 -24.9 Normal
- 25 29.9 Overweight
- 30 & Above Obese



BMI on Patient Information Screen

Diary Information

While wearing a NorthEast Monitoring Holter recorder, a patient can identify symptoms and activities in two ways:

- (1) by pressing the Event/Diary button on the recorder and, possibly, entering a precoded symptom or activity, or
- (2) by keeping a written record of times and symptoms or activities.

When analysis takes place, the software reads the Event/Diary button information directly from the flashcard and enters it automatically. You must type any significant information from the written record manually into the Diary window from the Patient Information Screen.

To open the Diary Symptoms window, click the Diary button in the Patient Information window. If any entries are present initially, those are the diary entries that were automatically read from the flashcard. You can now add any additional diary entries at this time.

Note: Whether the software uses a 12-or 24-hour clock is determined by your computer's setting in the Control Panel.

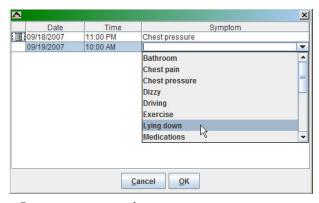
Date -. The date and time will initially be populated by the previous entry or the date recorded. If you need to edit the date, you can either do it manually by clicking on it or double-click on it to open the calendar edit screen

Time -. You should edit the time by double-clicking on the box. Since no two diary entries can contain the same date/time, be sure that you edit the time so that is not the same as what is entered above or below it. If two entries appear at the same date/time, you can edit the symptom to include both.

Symptom -. To enter a symptom, first click on the Symptom field next to the Date. Then enter the text either by typing a freeform entry or by clicking on the arrow to display a scrolling list of pre-typed entries. To enter a selection from the list, click on it; you can now edit the entry or move to the next field by clicking on it. Once a symptom is entered, the diary entry now exists. If there is no symptom, the diary entry does not exist.

When you have finished entering all written diary events, click the OK button to save your entries and return to the Patient Information window.

Delete -. To delete a diary entry, click on the trash can icon to the left of entry.



Dairy symptoms window

Editing -. If you add or modify diaries after analysis, the system will force an update and some of your editing of the ECG may be lost. For this reason, it is best to enter diaries before the analysis is started.

To Change Settings

During Holter analysis, the HE/LX Analysis software makes decisions about the Holter signal based on a variety of predefined settings from the Type of Analysis/Report or Configuration you have chosen for your patient. After selecting a configuration, you can change any of the analysis criteria in the Settings windows, which are accessible from the menu displayed by clicking the Settings button in the Patient Information window or by clicking the Settings menu item in the main toolbar.

Adjustments that can be made in the Settings windows are detailed in Chapter 3: Holter Analysis.

Starting Analysis



To start analysis after entering patient data, click the Start button at the bottom of the

Patient Information window. The Analysis window may appear or you may see Analysis in the lower left-side of the screen. You cannot stop or cancel the initial analysis, and once analysis is complete, the Patient Information will be changed.

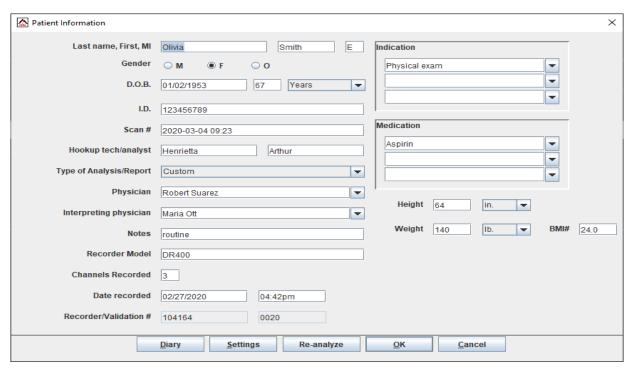
The Current Patient

At any one time, only one patient is the current patient - the patient whose information appears at the top of the screen,



the patient you see when you select File > Patient Information, the patient whose ECG appears in the screen displays, the patient whose report prints when you make the request. To change the current patient to a different one, either click on the appropriate name on the Patient List and click Open, or double-click on the appropriate line.

Also, you can change the current patient using the << and >> buttons in the bottom of the Holter LX window. << changes the current patient to the previous one on the Patient List and >> changes the current patient to the next one on the Patient List. Click each button repeatedly to move backward or forward through the list. To display a combo box listing all patients on the system, click the arrow to the left of the << and >> buttons.



Current Patient Information after analysis

Edit patient information for the "current" patient

Once analysis is complete for a patient's Holter data, you can reopen the Patient Information window and edit the information. To open the Patient Information window, select File > Patient Information.

While most of the Patient Information window is the same as when new, there are significant differences:

- The Re-analyze button replaces the Start button because the Holter signal has already been analyzed. (See Chapter 3: Holter Analysis, for information about using the Re-analyze button.) If you choose to change the Type of Analysis/Report at this time, you will be forced to redo analysis and all edited ECG data will be lost.
- The absence of the Copy different flashcard button.

To save your data and close the Patient Information window without starting analysis, click OK. To close it without saving any changes, click Cancel.

D.O.B.

Recorder#

120003

016598

015403

007277

007277

30363

120003

264959

016598

016598

329374

Name

2 Sample SVT 5.4a

5 TEST01 English set

6 TEST01 French set

11 Crabdac1, Sleep

12 14-day new dll

13 14-day new dll 14 paced, I think

Archive

3 14-day new dll

4 14-day on x

7 DR181

A Patient List

No.

V

Open

Cancel

An example of the Patient List window

Remote Receive

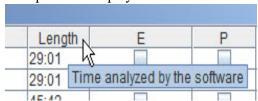
The Patient List

All of the patients saved in the software appear in the Patient List. Select File > Open/New from the toolbar to view.

From the Patient List you can choose to open a patient's record by clicking and highlighting it and pressing "OK" or by double-clicking anywhere on the patient line.

From the Patient List, you also can create a new patient by clicking on an empty directory (row) and clicking the New button at the bottom of the screen. The New button is only available when a directory is empty.

On the Patient List, if you don't know the meaning of a specific column, you can hover your cursor over the heading for that column and help will be displayed if it exists.



Hover for Help on Patient List window

Customize the Patient List View

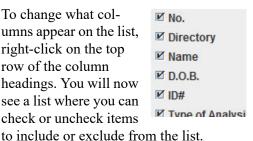
HIS Export

You can customize the Patient List for your specific needs in the following ways:

Delete

New

• To change what columns appear on the list, right-click on the top row of the column headings. You will now see a list where you can check or uncheck items



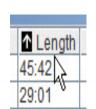
• Once you have decided what columns you want to see, you can change the position of the column by clicking on it and drag-

ging it to a new location.



Grab the column divider to increase or decrease the size of any column.





 Sort on any column by doubleclicking on the header for

Search Patients

03/29/2016

03/16/2016

03/16/2016

03/07/2016

03/07/2016

11/19/2014

03/28/2016

04/07/2016

03/16/2016

03/16/2016

03/29/2016

Analyzed

Length

24:01

333:58

310:09

23:59

23:59

23:56

24:01

8:19

333:58

333:58

11:16

Send Report Remote

Date recorded

09/07/2007

12/05/2013

07/25/2013

07/13/2010

07/13/2010

06/19/2012

09/07/2007

01/07/2007

12/05/2013

12/05/2013

07/06/2009

that column. An arrow will appear to show you which column is sorted.

Search Patients

The Search Patients box will search all visible columns for a match, and only show patients who meet the search criteria.

Archive button

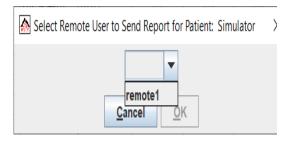
The Archive button at the bottom of the screen will take you to the Archive screen where you can select one or more patients to save in the Archive directory. You can also copy previously deleted records using the Restore tab. More information is provided later in this manual.

Remote Receive button

If the Plugin is installed, the HE/LX Analysis software is able to receive files from the LX Remote web-based system.

Send Report Remote button

The NARP program must be running on your computer for this to work, and the Remote User must be running LX Remote to receive the report. When you select a patient with a report, this button will be enabled.



HIS Export button

If a patient has a PDF report and you see this button, you are able to export records for your Hospital Information System (HIS).

This is done by selecting a patient and pressing the HIS Export button.

By doing this a record and the final report will be written to the directory c:\HIS Transfer.

Delete button

This will allow you to delete one or more patients. This data will be lost forever unless saved elsewhere or Archived.

New button

When you select an empty patient directory, this button is enabled.

Open button

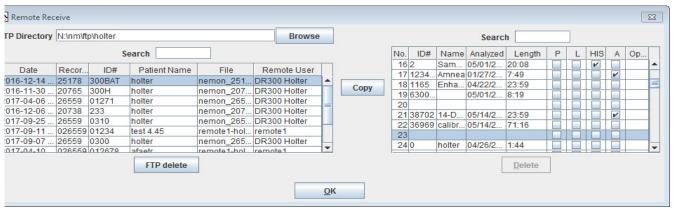
Enables you to open a different patient than is currently opened.

Preview data

If you would like to review the clerical information on a flashcard or recorder before creating a new patient record, you can insert the card into the drive and then select File > Preview from the main toolbar. This opens the Preview window, which displays the patient ID, Date and time recording was started and Recorder# off the inserted flash.dat file on the card or recorder. Data is not loaded onto your computer's hard drive.



After verifying that the file is correct, click OK to close the window, select File > Open/



Remote Receive window

New and follow the normal process to create a new patient.

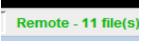
If the information in the Preview window does not match the information you have, do not proceed without clearing up the discrepancy.

Remote Receive

The HE/LX Analysis software is able to receive files from the LX Remote webbased system.

Note: Please ask your technical professional for assistance in setting this up. Refer to Chapter 10 for information on setting up Remote Receive.

If enabled, there is a window at the bottom of the screen that tells



you whether remote files are available, or if your remote process is not running.

Remote Receive Screen

Use Remote Receive to receive and import flash.dat files sent from other facilities. In order to enter patient files into HE/LX Analysis that you receive remotely, you will need to go to File > Open/New and

press the Remote Receive button at the bottom of the Patient List window. You will now see the Remote Receive patient window.

The Remote Receive window has two sides. On the left, is a list all of the patients who are received remotely and currently exist in the FTP directory. If your remotely received patient files are in another directory, use Browse to <u>find</u> your records.

On the right, is a copy of your Patient List and shows your where you have open directories for placing your remote records.

You can copy a patient file onto your desktop by doing the following:

- 1. Select a single record from the Remote/left-side of the screen.
- 2. Select an empty directory on the rightside of the screen. Both should now be highlighted and the **Copy** button should now be available.
- 3. Press the **Copy** button in the middle of the screen. The patient should now be copied to the Patient List on the left.
- 4. Close the screen and you will return to the Patient List where you can begin analysis on your new patients.

Other buttons on the screen are:

- The **FTP delete** button is used to delete FTP records that you do not want to copy to your desktop.
- The **Delete** button is used to delete patient records from the desktop. Only do this if the patient has already been archived or you no longer need this patient information.
- The **OK** button will return you to the previous screen.

As with the Patient List, both sides of the screen can be customized for what columns appear, column width and column order.

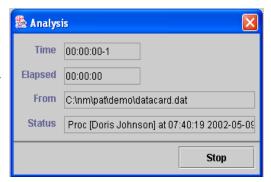
3. HOLTER ANALYSIS

This chapter addresses the features that you have control over during analysis, re-analysis and updating. During analysis, the HE/LX Analysis software detects each R-wave; determines the patient's normal morphology; establishes normal, ventricular and paced templates; matches every beat to a template; counts normal, supraventricular, ventricular and paced beats, including any pairs and runs; measures RR intervals and calculates heart rates; does ST segment and AF analysis; counts other abnormalities as defined in the Scanning Criteria; and saves sample strips for the final report. You can review and edit decisions made by the software; the information is then either re-analyzed or updated to include your changes.

Starting Holter Analysis

After entering patient information, click the green Start button at the bottom of the Patient Information window to start Holter analysis. The Analysis window appears. When analysis is complete, the Analysis window closes automatically.

To interrupt analysis, click the Stop button. The analysis ends immediately, with data only for the portion that was analyzed by the time of the interruption. The unanalyzed ECG can



Analysis window

be reviewed in Page and printed in full disclosure.

All data must be reviewed carefully to ensure that you agree with the beat labels the software has selected; if you do not agree, you can change them and their color will change appropriately. To begin, you will want to fine tune the results by changing the Scanning Criteria, once that is set as you like, you will then be able to edit individual or groups of beats as discussed in the next Chapter - Review Methods.

Color coded beat morphologies

Throughout the HE/LX Analysis software, the ECG is color-coded based on how the system has labeled each beat morphology:

- Light blue (cyan): Signal that appears to be contaminated by artifact.
- **Red:** Beats identified as ventricular premature beats (VPBs). They differ significantly from the normal; they are not necessarily premature.
- Green: Beats the software has identified as normal.
- **Yellow:** Beats identified as supraventricular premature beats (SVPBs). They have a normal morphology, but fall early.

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- **Orange:** Beats identified as part of an AF event.
- Cobalt blue: Beats identified as paced.
- White: Beats identified as pauses, based on the definition in the Scanning Criteria window. The white overrides any other color that the beat may also qualify for (e.g., red because it's a VPB).

In addition to the labels the software can provide for each beat, there are some labels only you can use to relabel beats. These are:

- Questionable (Unknown): Use this label to separate out beats you cannot identify and keep them from being included in another category. They are colored green, like normals. This can be used as a template or a beat label.
- T-wave: Use this label if the software has identified a portion of the signal as a QRS, but it is not. This will remove the beat from the counts and will merge its RR interval with the preceding RR interval. The signal will take the color of whatever beat precedes it. This can only be a beat label.

Beat Labeling

Once the beat morphologies are established, arrhythmia analysis starts by labeling each beat. The beat labels that are automatically assigned by the analysis process are assigned in the following order:

- 1. Event the time-of-day when either (1) the event button was pushed or (2) an entry was manually typed into the Diary Symptoms window
- 2. Artifact ECG Signal that appears to be contaminated by artifact
- 3. VTAC three or more VPBs in a row, regardless of heart rate
- 4. Failure to Sense the occurrence of a paced beat too soon following another beat; that is, too short an RR interval

- 5. Failure to Capture- the presence of a pacemaker spike without a following R-wave
- 6. Inhibition the absence of a paced beat when it should occur; that is, too long an RR interval
- 7. VPB Pair two VPBs in a row
- 8. Bigeminy an alternating pattern of single VPBs and normal beats, with at least three VPBs in the series; that is NVNVNVN
- 9. Trigeminy a pattern of single VPBs every third beat, with normals in between, with at least three VPBs in the series; that is **VNNVNNVN**
- 10. Quadrigeminy a pattern of single VPBs every fourth beat, with normals in between, with at least three VPBs in the series; that is VNNNVNNVN
- 11. VPB- a single beat that matches a ventricular template, regardless of prematurity
- 12. SVT three or more SVPBs in a row, the first 3 beats must meet the SVT Heart rate
- 13. SVPB Pair two SVPBs in a row that meet the SVT Heart rate
- 14. SVPB- a beat that matches a normal template, but occurs at least as early as the SVPB prematurity setting in the Scanning Criteria window
- 15. Missed beat
- 16. PAT (paroxysmal atrial tachycardia) a sudden rate increase, 2x the normal rate, stable before and stable after
- 17. Tachycardia a heart rate at least as fast as the Tachycardia setting in the Scanning Criteria window
- 18. Bradycardia a heart rate at or below the Bradycardia setting in the Scanning Criteria window
- 19. Unknown or Questionable
- 20. AF (Event) AF consists of Atrial Fibrillation and/or Atrial Flutter. To be labeled as AF, beats must meet both Minimum AF Peak HR and Minimum AF Time requirements in the Scanning Criteria. VPB and artifact beats can occur within an AF event. VPB and artifact that falls within an AF

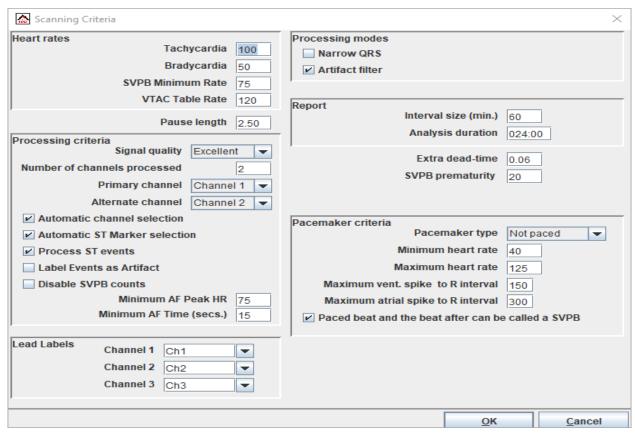
- event, will be included in the AF time, but the beats will not be counted as AF beats, but as VPB or artifact, respectively.
- 21. Irregular HR (Sinus Arrhythmia) a variability in sequential R-R interval
- 22. AV Paced both atrial and ventricular
- 23. A. Paced Atrial only
- 24. V. Paced Ventricular only
- 25. Normal None of the above

Scanning Criteria

The Scanning Criteria are used during Holter analysis to define some of the arrhythmias labeled by the software, along with settings that control the amount of information processed.

The adjustable criteria include:

- Tachycardia defines at least how fast a heart rate must be for the Tachycardia label to appear. All beats that occur at that heart rate or above are included in the tachycardia beat count in the Tachy/Brady table in the Tables window.
- **Bradycardia** defines how low the heart rate must be for the Bradycardia label to appear. All beats that occur at that heart rate or below are included in the bradycardia beat count in the Tachy/Brady table in the Tables window.
- **SVPB Minimum Rate** is the minimum heart rate required for a beat to be labeled SVPB. If not listed in Scanning Criteria, 75 bpm is used. Reanalysis required if changed.
- VTAC Table Rate separates fast and slow runs of VPBs that appear in the Ventricular Runs table of the Tables window and in the



Scanning Criteria window in Settings menu

- Report Summary. In all other areas of the software, slow and fast ventricular runs are combined in the VTAC counts.
- Pause length (sec.) defines how long an RR interval must be for the beat at its onset to be called a Pause and appear white on the colored display. This RR interval can be initiated by any type of beat except artifact.

Processing Criteria will all require reanalysis if updated:

- Signal quality has three settings that control the amount of artifact that is tolerated before the signal is thrown out because of too much artifact:
 - 1. **Research** turns off the artifact detector so that none of the signal except the first minute and the last minute of the recording is called artifact. This results in the analysis of all the signal, including any artifact.
 - 2. *Excellent* allows the software to detect and reject a moderate amount of artifact. Any signal that is determined to be contaminated with artifact appears light blue and is not analyzed. Anything that occurs during periods of artifact is not counted.
 - Normal allows the software to discard any signal that it considers contaminated by artifact. Anything that occurs during periods of artifact is not counted.
- Number of channels processed determines whether the software uses one or two channels to determine the location of an R-wave and what template each matches. Single-channel analysis uses just the channel set in the Primary channel field. Dual-channel analysis uses the Primary channel to locate R-waves first, then refers to the Alternate channel as a back-up channel to locate R-waves, and both primary and alternate to do template-matching.
- **Primary channel** determines which channel is used during analysis. For single-channel analysis, the primary one is the only one used to locate R-waves and do template-matching. For dual-channel analysis, the primary chan-

- nel is used first to locate R-waves, but if an R-wave cannot be located, the software refers to the alternate channel to locate the beat, if one is present.
- Alternate channel is used only in two-channel processing. It determines which channel is used in case an R-wave is not found in the primary channel, and it controls which channel is used as a second channel for template-matching.
- Automatic channel selection allows the software to switch primary and alternate channels if it determines that signal has been lost in the primary channel. Turn this off to force the software to use a particular primary or alternate channel. If you change the Number of channels processed field to 1, this setting is turned off automatically.
- Automatic ST Marker selection allows the software to detect the j-point and set up the ST markers appropriately. If you manually change the ST marker locations in the Calibration window, this setting will turn off automatically.
- Process ST events lets you turn ST segment analysis on or off, depending on your preference.
- Label events as artifact lets you to include or exclude events from the recorder from being labeled as artifact. Sometimes events are inappropriately labeled as arrhythmia because of the calibration mark that is saved at the time the button is pressed.
- **Disable SVPB Counts** prevents the system from label beats as SVPBs. SVPB beats can be labeled manually.
- Minimum AF Peak HR is the minimum HR which at least any 2 beats of the previous 20 must reach. AF includes both Atrial Fibrillation and Atrial flutter. Valid entries are 30-250. Enter 0 in this field to turn both Irregular RR and AF Off. For this to occur, Minimum AF Seconds must also be set to zero.
- Minimum AF Time in Seconds is the minimum amount of time In seconds required to

- label irregular HR as AF. AF can consist of both Atrial Fibrillation and Atrial Flutter. Valid entries are 15-300 seconds. Enter 0 in this field to turn AF Off.
- Lead Labels allows you to change the label for each channel. You can also enter a label of your own by typing in a new entry.
- Narrow QRS permits the software to identify narrower-than-normal QRS complexes, like those seen in pediatric patients, as normal beats. Turn this on routinely for pediatric patients.
- Artifact filter works in conjunction with the Signal quality setting. If it is turned on and Signal quality is set to Normal, the filter limits the response to 20 Hz, instead of 70. If it is on and the Signal quality is set to Excellent or Research, the filter limits the response to 30 Hz instead of 70.
- Interval size (min.) determines how many minutes are including in each interval in the interval tables of the Tables window.
- Analysis duration determines how many hours of data are analyzed. All the ECG loads in from the memory/flash-card during analysis, but analysis stops after the amount of time indicated here. It uses the HHH:MM format, with the first three digits indicating how many hours and the second two indicating how many minutes. A maximum of 336 hours (14 days) may be entered.
- Extra dead-time controls the tail end of the dead-time period following an R-wave during which another QRS complex cannot be detected, allowing for the presence of a T-wave. Increase the time (in seconds) if large T-waves are being identified as R-waves. See details in Appendix A.

- SVPB prematurity (percent) sets the requirement for how early a beat that matches a normal template must be for it to be identified as an SVPB. For example, at a heart rate of 60 bpm, a normal RR interval is 1 second long, and a beat that is 10 percent premature would fall at 0.9 seconds after the preceding beat. The SVPB Minimum Heart Rate must also be met.
- Pacemaker type contains four settings that allow the software to expect certain behavior:
 - 1.*Not paced* means that the software will not identify any pacemaker spikes, beats or failures.
 - 2. *VVI* means that each paced beat will be preceded by a single spike. All paced beats are counted as ventricular paced.
 - 3. *AV sequential* means that paced beats will be preceded by two pacemaker spikes, one atrial and one ventricular. All paced beats are counted as AV paced.
 - 4. *DDD* means that paced beats can be preceded by either one or two pacemaker spikes. Depending on the spike's location relative to the following R-wave, a beat preceded by a single spike can be called either atrial paced or ventricular paced, while a beat preceded by two spikes can be counted as AV paced.
- Minimum heart rate refers to the minimum rate allowed by the pacemaker. If the pacemaker does not fire appropriately and there is an RR interval longer than the patient should experience, the Inhibition label appears.
- Maximum heart rate refers to the maximum rate initiated by the pacemaker. If the pacemaker fires early, typically because it did not sense the previous

beat, it would result in a faster rate, the Sense failure label appears.

- Maximum vent. spike to R interval sets the maximum time between the firing of the second pacemaker spike and the following R-wave. If the second spike appears and is not followed by an R-wave in this amount of time, the Capture failure label appears.
- Maximum atrial spike to R interval sets the limit for how long is allowed between a single spike and the subsequent R-wave. If a single spike occurs and the following R-wave is not within this amount of time, the Capture failure label appears.
- Paced beat and the beat after can be called a SVPB is a setting that allows you to identify early beats following a paced beat as SVPBs because they are premature.

Note: Refer to the section "Pacemaker analysis" in this chapter for more information about the pacemaker settings.

Reanalysis

If you have already analyzed the patient's Holter, changes that you make to many of the settings will force the software to reanalyze the patient's data. When re-analysis takes place, the patient will be newly analyzed and all editing changes you have made previously will be lost.

Re-analysis is required after changing any of the settings in the Processing criteria, Pacemaker criteria and Processing modes. Additionally, Analysis duration, Extra dead-time SVPB Prematurity and SVPB Minimum Heart Rate settings require reanalysis.

After changing settings and clicking OK to save, the software asks you to confirm that

you want to reanalyze or not. If you want the change to take effect, click Yes. If not, click No, and your changes will not be saved.

Update

Some changes in the Settings require an update afterward. The update incorporates simple changes into all other aspects of the report. For example, a change in all matches to a beat with 12 matches from ventricular to aberrant will affect other aspects of the report: the total count of VPBs will decrease by 12 and SVPBs will increase by 12 in Tables, Critical Events, Trends, and Report Summary. In addition, different Saved Strips will be selected.

Those changes in Settings that require an update are all those in the What Strips to Auto Save and How Often Strips Auto Save windows, along with these settings in the Scanning Criteria window - Tachycardia, Bradycardia, VTAC rates, Pause length and Interval size.

If the "Automatically Update feature" is turned on in the Preferences window, the update will occur automatically when you close the Settings window or go to any other window while using the software.



Update required

If the Automatic Update feature is turned off in the Preferences window, that

means that after some editing changes, you must click the Update button to incorporate your changes. After you make changes that require an update, the Update button will become enabled and will blink red as a reminder that you must at some point click it.

What Strips to Auto Save

All the different types of strip labels the software uses appear in this window. The software uses these labels to identify one particular beat or event (for example, the "current" beat or the beat centered in a Saved Strip). Each label can be turned off or on to indicate whether sample strips of that type should be saved for the final report. A check mark indicates that sample strips with that label will be saved.

Click on a label or its check box to turn it off or on. Click on the button Select/Deselect All to turn all labels on or off. Click OK to save changes.

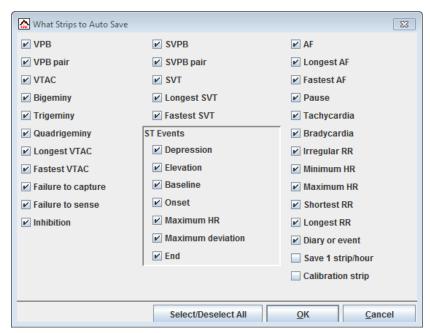
The strip labels in the What Strips to Auto Save window are as follows:

- VPB
- VPB pair
- VTAC

- Bigeminy
- Trigeminy
- Quadrigeminy
- Longest VTAC the longest run of three or more VPBs, regardless of rate
- Fastest VTAC the run of three or more VPBs with the fastest heart rate

Pacemaker Analysis - For more information, refer to the section "Pacemaker Analysis" in this chapter.

- Failure to capture Pacemaker only
- Failure to sense Pacemaker only
- Inhibition Pacemaker only
- SVPB
- SVPB pair
- SVT
- **Longest SVT** the longest run of three or more SVPBs, regardless of rate
- **Fastest SVT** the run of three or more SVPBs with the fastest heart rate



What Strips to Auto Save window in Settings menu

ST Segment Analysis - For more information on ST Analysis, refer to the section "ST Segment Analysis" in this chapter. The Depression and Elevation checkboxes are NOT strip labels. Instead, they determine whether strips of the following types are saved for each episode of ST Depression or Elevation detected by

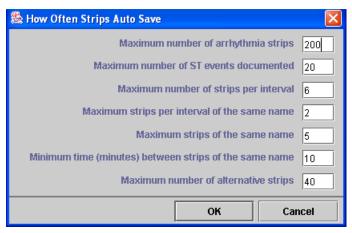
the software.

- **Depression** at least a 1 millimeter depression in the ST segment compared to the patient's normal
- Elevation at least a 1 millimeter elevation in the ST segment compared to the patient's normal
- **Baseline** a sample of the patient's normal ST segment preceding a detected event
- **Onset** near the beginning of a detected event, at the time the change is 0.5 mm.
- **Maximum HR** the ECG when the maximum heart rate occurred during the event
- **Maximum deviation** the ECG at the point of maximum change from the normal
- **End** the ECG after the patient has reestablished normal

More options:

- AF AF events
- Longest AF the longest period of AF
- Fastest AF the fastest period of AF based on AF HR
- Pause an RR interval at least as long as the Pause length in the Scanning Criteria window
- Tachycardia
- Bradycardia
- Irregular RR
- Minimum HR the minimum heart rate calculated using the heart rate algorithm described in Appendix A, generally a fourbeat running average
- Maximum HR the maximum heart rate calculated using the heart rate algorithm described in Appendix A, generally a four-beat running average
- Shortest RR the shortest RR interval measured during the Holter period, excluding those before or after artifact
- Longest RR the longest RR interval measured during the Holter period, excluding those before or after artifact

- Diary or event
- Save 1 strip/hour a strip at the onset of each new hour
- Calibration strip the calibration signal at the onset of the Holter recording



Iow Often Strips Auto Save window in Settings menu

How Often Strips Auto Save

These settings control the distribution of strips that are saved for the report. They have the following uses:

- Maximum number of arrhythmia strips: Saved strips fall into two types arrhythmia and ST. Limit how many arrhythmia strips are saved for the final report by adjusting this field.
- Maximum number of ST events documented: Each ST event, regardless of whether it is depression or elevation, can have five strips saved to document it. To reduce the number of events for which strips are saved, enter a smaller number in this field. To change how many strips are saved per ST event, make the change in the What Strips to Auto Save window.
- Maximum number of strips per interval: Interval length within the Holter period is defined in the Scanning Criteria window, but here you can control the upper limit of how many arrhythmia strips are saved within each interval.
- Maximum strips per interval of the same name: Limit the number of arrhythmia strips of the same label that are saved within an interval.

- Maximum strips of the same name: Limit the number of arrhythmia strips of the same label that are saved during the entire Holter recording.
- Minimum time (minutes) between strips of the same name: Distribute the arrhythmia strips saved by requiring more or less time between those with the same label.
- Maximum number of alternative strips: Control

how many alternatives are available for the following: Minimum HR, Maximum HR, Shortest RR, Longest RR, Longest VTAC, Fastest VTAC, Longest SVT, Fastest SVT, Longest AF and Fastest AF.

To make changes, select the current entry and type over it. Click on OK to save changes and exit.

ST segment analysis

ST segment analysis includes these steps (which are each explained in depth in the following pages):

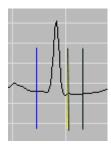
- 1.**Setting ST markers.** This is done automatically by the software, but you can adjust the markers for any patient.
- 2. **Measuring the ST segment** on all three channels of every normal beat. This is done automatically. If you relabel normal beats to some other label, the ST segment analysis will be redone automatically.
- 3. **Plotting ST data** in 30-second increments. All normal beats within each 30-second time period are averaged.
- 4. **Establishing ST baseline** for the patient throughout the Holter period. The software does this automatically and plots it in blue on the ST trends in the Trends window.
- 5. Comparing the 30-second ST segment data measured with the baseline at the same time. A difference of at least 1 millimeter in any channel is considered to be an event. Again, the software does this automatically.
- 6. **Identifying ST events.** ST events are listed in the ST event table in the Tables window. This is automatically compiled for you, but you can edit any of the fields within the table.
- 7. **Documenting ST events.** You determine which strips are saved to document each event, based on the settings in the What Strips to Auto Save window. How many ST events are documented is determined in the How Often to Auto Save window.

Note: The procedure does not include calibrating the signal because the data is recorded at 1 centimeter per millivolt, the standard for ST segment analysis.

Setting ST markers

To review the locations of the ST markers used during analysis:

- 1. Select Review > Calibration. The Calibration window opens displaying the calibration pulse, a series of eight 1-millivolt square waves.
- 2. Click the button to the left of "ST Marker" to change the display to ECG and three colored, vertical markers, which include:



3 ST Markers

- the left-hand marker (cobalt blue) indicates where iso-electric is in the baseline preceding the QRS complex;
- the middle marker (yellow) is located at or just following the j-point (where the QRS ends and the ST segment begins); and
- the right-hand marker (light blue) is located during the ST segment.

Note: If the ECG displayed is not clean and representative of the patient's normal, click the down arrow of the scroll bar to jump forward to different ECG

3. If the markers are not located where you want them, drag them to move them to the appropriate locations. The ST segment measurement can be made at the location of either the j-point or the ST segment marker, while the other of the two is used to indicate the slope of the ST segment. The time between those two markers is listed in the field labeled "ST Segment (ms)." Be sure to locate each marker based on your facility's protocol.

Note: Each marker for each channel moves independently so that you can precisely position the markers based on each channel's morphology.

- 4. Once each marker is in the appropriate location, click the button next to Done. If you have made changes to either the Gain or the ST Marker window, a window opens to ask whether it's okay to continue. Click on Yes to make the change and continue. Click No to cancel your changes and retain the previous information
- 5. To exit from the ST Marker window without saving your changes, click the button next to Cancel.

Measuring the ST segment

This is performed automatically for all three channels of ECG. Whether the ST segment measurement is done at the position of the j-point or the ST segment marker is determined by the setting "ST measurement" in the Preferences window. See Chapter 8 for details of the Preferences settings and their use.

The ST segment measurement is averaged in 30-second increments throughout the Holter period. Only normals not contaminated by artifact are included in each average. At least eight valid measurements must be made within a 30-second period for it to be included; if there are fewer than eight clean normal beats, the 30-second increment is considered artifact.

For any particular beat, you can

mea-

sure the ST segment manually by going to the Page display and selecting the beat as the current beat. In the Expanded display, drag the left marker to define iso-electric and the right marker to the appropriate location of the ST segment. The vertical difference between where the two markers intersect each channel of ECG is listed in the ST 1, 2 and 3 fields in the Expanded toolbar.

Plotting ST segment data

The data for all three channels is plotted in the ST level display of the Trends window. To display it, select Trends from the Review toolbar and then select ST level in the Type field.

The top trend is minute-by-minute heart rate. Immediately below that is the ST trend for channel 1, then channel 2, with channel 3 on the bottom. Each trend shows the patient's calculated baseline as a cobalt blue trend, with the patient's ST measurement plotted in green and the slope of the ST segment indicated by a red vertical line.

The software calculates the patient's ST baseline from the patient's normal ST segment measurements as the Holtered period progresses. ST segment changes that are caused by positional changes result in changes in the patient's baseline, and are not usually considered ST events themselves. The patient's baseline during what ends up being an ST event is interpolated from the baseline before and after the event.

The significance of establishing a patient's baseline is that it means that normal is not always defined as iso-electric (that is, with no voltage) and that significant changes are relative to the patient's baseline, not to iso-electric.

Identifying ST events

The ST analysis software looks through the ST level trends, comparing the ST trends to the patient's baseline trends, to find episodes of significant ST segment changes.

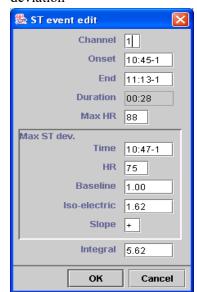
For an incident to be called an ST event, at least one 30-second ST segment data point must be at least 1 millimeter different than the patient's baseline for that channel at that time-of-day. A depression is a change of at least 1 millimeter in the negative direction, while an elevation is a change of at least 1 millimeter in the positive direction.

In the ST level trends, incidents that are flagged as ST segment events are indicated by a light blue horizontal line above the appropriate channel and lasting as long as the event.

The events are listed in the ST event table in the Tables window. To display it, click Tables in the Review toolbar, then click on ST event in the Tables list at the right of the Tables window. In that table, the description for each event includes:

- **Channel** the channel in which the event was detected
- Onset the time-of-day at the start of the event (defined as when the change in ST segment passes through the point 0.5-millimeter different from the patient's baseline)
- End the time-of-day at the end of the event (defined as when the change in ST segment returns to within 0.5-millimeters different from the patient's baseline)
- **Duration** the difference between the end and the onset times
- Max HR the maximum heart rate calculated during the duration of the event

- Max ST deviation Time the time-ofday at the event's maximum deviation from the patient's baseline
- Max ST deviation HR the heart rate during the event's maximum deviation from the patient's baseline
- Max ST deviation Baseline the ST segment measurement's deviation from the patient's baseline at the point of maximum deviation
- Max ST deviation Iso-electric the ST segment measurement's deviation from iso-electric at the point of maximum deviation



ST Event Edit window

- Max ST deviation Slope the slope of the ST segment event at the point of maximum deviation (+ indicates upsloping; - indicates downsloping; 0 indicates horizontal)
- Integral the calculation that reflects the area under the slope between the ST trend and the patient's baseline during the event

Note: If an event includes both a positive component and a negative one, the integral is actually less than the true area.

Although we report the absolute value, the integral calculation can result in a "negative" area, which when added to a positive area can cancel some or all of it.

All of the information listed in the ST event table can be edited by clicking the Edit button to open the ST Event Edit window and making the changes you desire. To edit an entry, drag across the existing entry and type the information to replace it. When finished, click OK to save your changes and exit.

To add an ST event, click the Add button. The ST Event Edit window opens with blank fields. Type the appropriate information in each of the fields. Click OK to save the event.

To delete an ST event from the table, click on the event to be deleted, then click the Delete button. The event disappears.

Documenting ST events

You control what strips are saved to document ST segment events using a combination of settings in the What Strips to Auto Save and How Often Strips Auto Save windows.

Pacemaker analysis

Pacemaker activity is recorded on North-East Monitoring Holter Recorders without distorting the patient's ECG, by removing the effects of the pacemaker spike and replacing it with a pacemaker marker. That marker, when re-introduced to the ECG when the flashcard is read by the analysis software, appears as a vertical spike in the precise location of the original pacemaker spike.

For the software to do a proper analysis of the pacemaker activity during the Holter period, the pacemaker settings in the Scanning Criteria window must be set properly. They include:

- Pacemaker type, which contains four settings that allow the software to expect certain behavior:
 - 1.*Not paced* means that the software will not identify any pacemaker spikes, beats or failures.
 - 2. *VVI* means that each paced beat will be preceded by a single spike. All paced beats are counted as ventricular paced.
 - 3. *AV sequential* means that paced beats should be preceded by two pacemaker spikes, one atrial and one ventricular.
 - 4. *DDD* means that paced beats can be preceded by either a one or two pacemaker spikes. Depending on the spike's location relative to the following R-wave, a beat preceded by a single spike will be called either atrial paced or ventricular paced, while a beat preceded by two spikes will be counted as AV paced.
- Minimum heart rate refers to the minimum rate allowed by the pacemaker. If the pacemaker does not fire appropriately and there is a RR interval longer than the patient should experience, the Inhibition label appears.

- Maximum heart rate refers to the maximum rate initiated by the pacemaker. If the pacemaker fires early, typically because it did not sense the previous beat, it would result in a faster rate, the Sense failure label appears.
- Maximum vent. spike to R interval sets the maximum time between the firing of the second pacemaker spike and the following R-wave. If the second spike appears and is not followed by an R-wave in this amount of time, the Capture failure label appears.
- Maximum atrial spike to R interval sets the limit for how long is allowed between a single spike and the subsequent R-wave. If a single spike occurs and the following R-wave is not within this amount of time, the Capture failure label appears.
- Paced beat and the beat after can be called a SVPB is a setting that allows you to identify early beats following a paced beat as SVPBs because they were premature, even if they themselves are paced beats. Click on the check box to turn it off and on.

Pacemaker labels

Beats can be identified and counted with the following labels (refer to the diagram on the previous page):

- A paced for a beat that is paced just in the atrium. The atrial spike is determined to be the one that occurs well before the QRS, falling before the "Maximum ventricular spike to R interval," but within the "Maximum atrial spike to R interval."
- V paced for a beat that is paced just in the ventricle. With pacemaker type set to DDD or AV Sequential, the ventricular spike is determined to be the one that occurs during the "Maximum ventricular spike to R interval." This label also

- includes all paced beats with the pacemaker type set to VVI and all beats without pacemaker spikes that are manually labeled "Paced."
- AV paced for a beat that is paced in both the atrium and the ventricle, with the atrial and ventricular spikes identified in the same way as described above.
- Sense failure means that the pacemaker (1) did not sense a QRS that occurred and (2) fired, resulting in a shorter-than-programmed R-to-spike interval. The label can happen under three scenarios:
 - 1.Pacemaker type is set to DDD and two pacemaker spikes occur, with less than the "Maximum atrial spike to R interval" between them, and with the second spike more than 20 milliseconds after the QRS.
 - 2. A single spike is more than 20 milliseconds after the QRS.
 - 3. The time between the preceding QRS and the next pacemaker spike is less than 60 divided by the "Maximum heart rate;" that is, the pacemaker fired early.
- **Inhibition** refers to inappropriate inhibition of the pacemaker, resulting in a longer-than-programmed RR interval. This label appears if the time between

- the preceding QRS and the next pacemaker spike is greater than 60 divided by the "Minimum heart rate" setting; that is, the pacemaker fired late.
- Capture failure means that the pacemaker has fired, but there is no subsequent QRS within the allotted interval. The label, which falls on the detected QRS after the missing QRS, appears in four scenarios:
 - 1. The pacemaker type is DDD or AV Sequential and there are two pacemaker spikes, with the time between them less than "Maximum atrial spike to R interval" and the time between the second spike to the QRS greater than the "Maximum ventricular spike to R interval" setting.
 - 2. The pacemaker type is DDD or AV Sequential and there is only one pacemaker spike, with the time between the spike and the following QRS greater than the "Maximum atrial spike to R interval" setting.
 - 3. The pacemaker type is VVI and the time between the pacemaker spike and the following QRS is greater than the "Maximum ventricular spike to R interval" setting.
 - 4. There are two pacemaker spikes that are more than the "Maximum atrial"

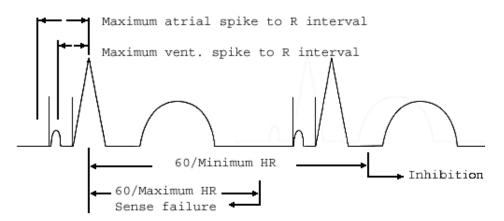


Diagram of pacemaker interval settings

spike to R interval" apart and the time from the first pacemaker spike to the following QRS is greater than the "Maximum ventricular spike to R interval" setting.

Pacemaker table

Pacemaker counts are itemized in the Paced table in the Tables window. To display it, click Tables in the Review toolbar, then click on Paced in the Tables list at the right of the Tables window. The Paced table is an interval table and the reported data includes:

- **Time-of-day** the time-of-day at the start of the interval;
- **Total Beats** the total number of beats identified and counted within the interval, not including artifact;
- Time Analyzed the total amount of time analyzed during the interval; this does not including periods that are considered to be artifact;
- **Total Paced** total of the following 3 fields:
- Atrial Only paced beats that were determined to be paced only in the atrium, not the ventricle;
- Vent(ricular) Only paced beats that were determined to be paced only in the ventricle, not the atrium;
- AV paced beats that were determined to be paced in both atrial and ventricular chambers;
- Sense Failure the number of times sense failures occurred (these are defined in the previous section);
- Capture Failure the number of times capture failures occurred (these are defined in the previous section);
- Inhibit(ion) the number of times the pacemaker was inappropriately inhib-

- ited from firing (this is defined in the previous section).
- Paced% the percentage of paced beats out of all beats in that interval.

The fields in this table can be edited as described in the "Editing table entries" section of the following chapter.

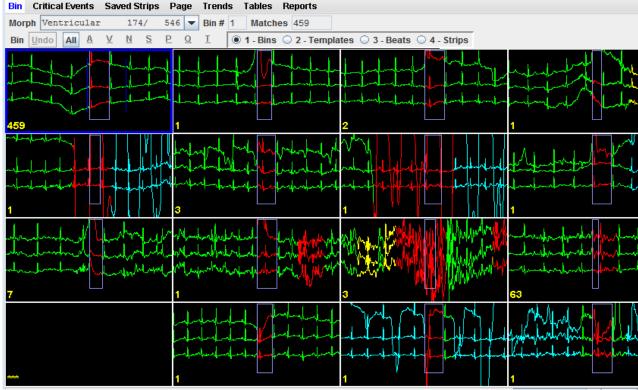
4. REVIEW METHODS

The Holter signal can be reviewed within HE/LX Analysis software in several ways: (1) Templates established during analysis, (2) Critical Events where beats are placed in categories based on the most significant events, (3) Saved strips which will appear on final report, (4) the Page screen which has on-screen full disclosure of all the ECG recording, (5) the Trend graph that charts the heart rate and RR (6) Tables which also can be included on the report, and (7) Superimposition and Calibration.

1. Bins/Templates

During analysis, the HE/LX software first determines what the patient's normal QRS complex looks like and establishes a template called "normal." Each beat after that is compared to the normal template; matches to that template are also called normal, while a similar but slightly different morphology will establish a new template, also called normal. A QRS complex that differs more significantly from the normal template will establish a template called "ventricular." A new template is established for each different morphology identified by the software. Subsequent matches to a template get labeled based on the template label, the timing of the beat, and other criteria.

After analysis, the templates that generally look alike are grouped together in "bins." You can review these bins by morphology, that is, all normal bins or all ventricular bins. Within the Bin window, you can also review by template, displaying all the templates within each bin, one bin



Ventricular bins in Bin window

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after the other. You can also review all matches to each template, displaying them one template after another.

Description of the Bin window

The Bin window opens with all templates of a particular morphology (normal, ventricular, paced, artifact or questionable) displayed, up to a maximum of 16 bins. The morphology drop-down lists how many templates of that type were established for this patient and how many total beats were counted as this type. For example, in the figure on the previous page, there are 9 ventricular bins made up of 12 templates, and a total of 7,855 beats matched the templates in those bins.

To change the morphology displayed, click on the drop-down arrow to display your choices, then click on the type you want displayed.

In each bin display, the three channels of the center beat are surrounded by an outlined box. That beat is the one that is in the bin; the surrounding ECG is displayed to show how the beat occurred, but is not included in the bin. The number in the left corner of each bin indicates how many total beats matched the templates within that bin.

To select a particular bin, click on it. The time-of-day becomes outlined and the Bin # and Matches fields now display data for that particular bin.

Relabeling a bin

To relabel a bin and all of its contents (all templates and matches), click on the bin to select it, then click on one of the label buttons under the Morphology field. The relabel buttons are not active unless one or more bins are selected.

The relabel buttons include:

- A for artifact
- V for ventricular
- N for normal
- **P** for paced. (appears only if Pacemaker mode is on in Scanning Criteria)
- **Q** for questionable/unknown

Note: No S label buttons appears here because an SVPB matches a normal template, but is early.

To relabel multiple bins, click on each of the bins you want to relabel and then click on the appropriate relabel button. To relabel all of the displayed bins, click the All button to select all the displayed bins and then click the appropriate relabel button.

Undo

Before leaving one of the Bin views, you can undo one or more relabels by clicking Undo. Undo will restore all of the beats to their state before the last relabel.

Single mode

Single mode button appears for Artifact and any other morphology that has a beat that has been relabeled. This is because these beats are not assigned to a template. Click the Single mode button to go to the Beats screen where you can view and relabel single beats.

Changing levels in Bin window

To display the templates within a particular bin, click on the bin and then click on the Templates button.

Moving from one level of the Bin window to the next can also be done by double-clicking on the ECG in the bin, template, or beats display. Each double-click changes the button position one button to the right.

When a scroll bar appears to the right of a field or window, you have the option of using it or using the scroll button on your mouse, if you have one.

Template display

The individual templates are presented with two additional pieces of information just underneath each template - the number of matches to the template and the time-of-day the template was established, that is, the first occurrence of that template.

When you click to highlight a particular template, the Strip # and Matches fields update to reflect information about the current template.

The template display contains up to 12 templates that matched the current bin. If more than 12 templates fell into that bin, you can access additional pages of templates by using the PageDown key, the scroll bar or the Scan button. If you use the PageDown key, once you reach the last page of templates in the current bin, PageDown will display the templates that matched the next sequential bin of the same morphology type.

To display the templates in a different bin, click the up and down arrows of the Bin # field.

Relabeling a template

To relabel a template and all matches to it, click on the template to select it (the time-of-day of a selected template is surrounded by a yellow box), then click on a label button under the Morphology field.

To relabel multiple templates, click on each of the templates you want to relabel and then click on the appropriate relabel button. To relabel all of the displayed templates, click the All button to select all the displayed templates and then click the appropriate relabel button.

Note: If there are multiple pages of templates within a bin and you relabel one or more of them, blank spaces are temporarily left where the template(s) originally appeared. After paging up or down and returning, the blank spaces are gone.

Beats display

Clicking the Beats button displays up to 24 of the beats that matched the current template. Use the PageDown, the Scan button, or the scroll bar to display additional matches to the template. The display includes the time-of-day each beat occurred, the template number the beats matched (in the Template field), and the total matches to the template (Strip #).

For the current beat, two blue vertical markers appear. The markers can be used to make measurements, which appear in the data fields below the large time-of-day field.

Drag the blue markers to appropriate locations to have the data fields display:

- **HR** (2**RR**) field shows the heart rate calculation based on the blue markers being two **RR** intervals apart.
- **Time** field indicates the time (in seconds) between the blue markers.
- ST 1 field displays the vertical difference between where the markers intersect channel 1. The left marker should define iso-electric and the right marker should be located where you want the ST measurement made.
- ST 2 field displays the vertical difference between where the markers intersect channel 2. They should be positioned as indicated for channel 1.

• ST 3 field displays the vertical difference between where the markers intersect channel 3. They should be positioned as indicated for channel 1.

Click the Both check box to drag the markers keeping them the same distance apart. Click the Both box again to move the markers separately.

To keep the calipers in the same locations as you move through different screens of ECG, click the check box next to Lock; the calipers will stay in the indicated locations unless you move them again. Click again to turn off.

Relabeling a beat

The Beats window in Bin allows only single-beat editing, which removes a beat from its template and relabels just that beat. To relabel a beat this way, click on the beat to select it, then click on one of the relabel buttons under the Morphology field.



Relabel buttons for beats and strips

In addition to the relabel buttons defined in the "Relabeling a bin" section earlier in this chapter, the relabel buttons for beats and strips include:

- S for supraventricular
- T for T-wave

To relabel multiple beats, click on each of them and then click on the correct relabel button.

Saving sample strips for report

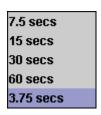
As you review the ECG, you can choose to manually save sample strips for the report. The 7.5-second sample strips are printed as full-sized, 25-mm/second ECG on a background grid. To save a strip containing one

of the displayed beats, click on the beat you want at the center of the strip to make it the current beat, and then click Keep; the Keep window opens. To label the strip, either type the label in the Description field or select a label from the scrolling list; then click OK to save the strip.

For more information about the Keep window, see "Saving sample strips for the report" in the Page window section of this chapter.

Strips display

The Strips display provides a full-screen display of the current beat. All buttons, fields, and markers work as described in the previous section,



Display field choices

"Beats display," with one addition - the Display field. This controls the amount of time that appears in the full-screen display. Click on the arrow in the field to show your choices, and click on your choice to change the amount of time.

Move between Review Windows

All Review windows are linked by time-of-day. In addition, the Page window is linked to all other Review windows through the right-hand button on the mouse. From any other Review window, a right-click will jump to the Page display, retaining the current beat. After that, a right-click in Page will then take you back to where you originally were, regardless of whether you change the current beat in the Page window.

2. Critical Events.

Every beat appears in a category in Critical Events. For more information and an explanation of how beats are labeled and hierarchy, refer to the section entitled "Beat Labeling" in Chapter 3.

Categories and Counts

The Critical Event categories and the count in each is listed on the left-side of the screen. If required, use the scroll bar to view the complete list, and then select a Critical Event category to display by clicking on it.

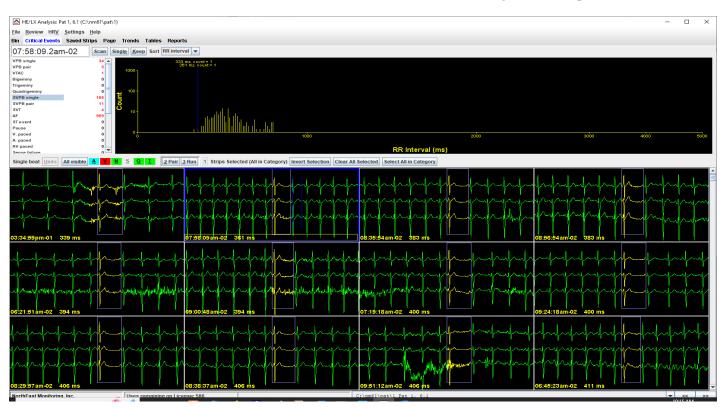
Note: Because of the way beats are assigned into Critical Event categories, the number of beats on this list will not necessarily match totals on the Tables or reports. As a beat that appears in one category of Critical Events does not appear in all other applicable categories. For example, if a VPB appears in

Bigeminy, it does not appear in VPB; if a paced beat appears in Sense Failure, it does not appear in any other category. Therefore, do not rely on the counts in Critical Events to provide comprehensive totals like the tables do.

To move through the displayed episodes, use the Page Up (PgUp) and Page Down (PgDn) keys, the scroll bar, the scroll button on your mouse, or click Scan to automatically move from one display to the next. Click the Scan button again to stop the display.

Single/Multiple views

When a single episode is displayed, click the Multiple button to display 12 at a time. When multiple episodes are displayed, the button label changes to "Single;" click that to display just one episode. You can also double-click on a strip to toggle back and forth between the single and multiple dis-



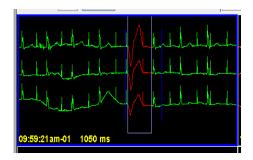
Critical Events window - multiple display

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plays. Each event is labeled with time-of-day and RR interval. In addition, if the ECG appears in a strip saved for the printed report, the word "saved" appears to the right of the RR interval.



Current episode denoted by blue box

ST events

ST events are in the Critical Events list. If you click ST Events, the strips showing the maximum ST deviation during each event are displayed. In addition, an ST event table button is available to view tables directly from this screen.

HR strips

Critical Events includes this display of all the ECG recorded during the Holter period, in 7.5-second strips. While some beats may appear more than once in other categories (because they are adjacent to the current beat being displayed), this category displays each beat in one strip only. The heart rate listed is based on all beats present in the displayed strip.

Saved strips

Saved strips are in the Critical Events list so that you can review the strips saved for the final report without leaving the Critical Events window.

Sorting episodes within a category

The Sort field lets you change the order of the episodes within each type. You can choose "RR interval" to put them in order based on the RR interval, from shortest to longest, starting with the current beat. Unlike RR interval labeling elsewhere in the software, which labels the interval length from the current beat to the following beat, sorting by RR interval in Critical Events sorts based on the RR interval preceding the current beat; in that way, you can review the most premature beats of a type or the latest beats of a type.

The "Time" setting orders the episodes based on the time-of-day of the event, from earliest to latest.

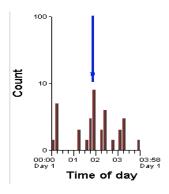
The "24 hours" setting also orders them by time-of-day, but the histogram at the top of the window is divided into hourly intervals. See the "Histograms" section below for details.

Histograms

The top portion of the Critical Events window presents a histogram showing the distribution of the events within the type displayed - either an RR histogram or a 24-hour histogram.

The RR histogram plots the length of the RR interval preceding each episode of the displayed type. The number of events is on the vertical axis (with a log scale) and RR interval (in milliseconds) is on the horizontal axis. The blue marker is located at the position of the current event. To display the event associated with an alternate RR interval, click on the RR interval in the histogram; the appropriate event will appear as the active event in the bottom portion of the window.

The 24-hour histogram shows how many episodes of the displayed type occurred during each 10-minute interval of the recording. The blue arrow is located at the position of the current event. To display the events associated with a different time-of-day, click on the histogram at that time; the appropriate event will appear as the active event in the bottom portion of the window.

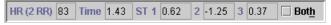


24-hour histogram

Which histogram displays is based on the setting in the Sort field. The settings "RR interval" and "Time" display the RR histogram; the setting "24 hours" displays the time-of-day histogram shown above.

Data fields

In multiple view, the active episode is denoted by a blue box. In single or multiple view, the current episode has two blue vertical markers (calipers) appear and can



Data fields in Beats and Strips displays

be used to measure the beats. Drag the blue markers to appropriate locations to have the data fields display:

- **HR (2RR)** field shows the heart rate calculation based on the blue markers being two RR intervals apart.
- The **Time** field indicates the time (in seconds) between the blue markers.

- The ST 1 field displays the vertical difference between where the markers intersect channel 1. The left marker should define iso-electric and the right marker should be located where you want the ST measurement made.
- The **ST 2** field displays the vertical difference between where the markers intersect channel 2. They should be positioned as indicated for channel 1.
- The **ST 3** field displays the vertical difference between where the markers intersect channel 3. They should be positioned as indicated for channel 1.

Click the Both check box to drag the markers keeping them the same distance apart. Click the Both box again to move the markers separately.

To keep the calipers in the same locations as you move through different screens of ECG, click the check box next to Lock; the calipers will stay in the indicated locations unless you move them again. Click to turn off.

Relabeling in Critical Events



Relabel button options

To relabel a beat within the Critical Events window, click on the event to select it. When selected, the beat label will have a yellow box around it. Once selected, choose the beat label that you want to change it to. Such as:

- A for artifact
- V for ventricular
- N for normal
- S for supraventricular
- **P** for paced (appears only if Pacemaker mode is on in Scanning Criteria)

- **Q** for questionable/unknown
- T for T-wave

To relabel multiple beats, click on several, then click the relabel button.

To relabel all beats displayed on the current page, click the All visible button, then the relabel button.

The Histogram can also be used to select beats to relabel. Click and drag to select a range of beats using Histogram.

Multiple Page Relabeling

When a Critical Event category appears on more than one screen (there are 12 per screen), you can use the Invert Selection, Clear All Selected and Select All in Category buttons to pick and choose all of the events prior to relabeling. As beats are selected, the yellow box around the beat will denote that it is included. Additionally, the box will show how many beats have been selected before doing the relabel.

If need be, the Undo button can be used to undo the relabeling over multiple pages.

VPB and SVPB relabeling

In addition, these relabel buttons appear whenever the type displayed is an ectopic event of either ventricular or supraventricular origin:

• 1 Single - This will change all beat labels to normal except for the current beat, which will be called a single SVPB or VPB, depending on its present label. If the present type is SVT, this button will remove the run that was counted and replace it with an SVPB. If the present type is VPB Pair, this button

- will subtract the pair and replace it with a VPB.
- 2 Pair This will change beat labels so that two sequential beats are called a pair, either an SVPB Pair or a VPB Pair, depending on its present label. If the present type is VPB, this button will change the selected event to be labeled and counted as a VPB Pair. If the present type is SVT, the selected run will be relabeled and counted as an SVPB Pair.
- 3 Run This will change beat labels so that three sequential beats are called a run, either SVT or VTAC, depending on its present label. If the present type is SVPB, a three-beat run of SVT will replace the SVPB. If the present type is VPB Pair, a three-beat run of VTAC will replace the pair.

Save Strips for report

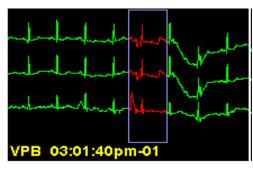
To save a strip containing one of the displayed beats, click on the beat you want at the center of the strip to make it the current beat, and then click Keep; the Keep window opens. To keep it with the current label, click OK. To relabel the strip, type the label in the Description field or select a label from the scrolling list; then click OK to save the strip.

To save multiple strips all with the same label, click on each one to be saved, then click the Keep button and click on the button that indicates multiple strips - it will read "x strips," with x equal to the number of strips you selected before clicking Keep.

3. Saved Strips

The report includes full-size, 7.5-second, 25-mm/sec strips on a background grid. Some strips are automatically saved based on the settings in the What Strips to Auto Save window. You can also use the Keep button to manually save strips while reviewing the Holter recording.

To review the saved strips, click Saved Strips in the Holter menu. The Saved Strips window displays a miniature version of the strips 12 at a time. Each is labeled with its strip label and the time-of-day at which it occurred. Page through them using either the PageUp and PageDown keys, clicking on the up and down arrows of the scroll bar, or using the scroll button on your mouse.



A Saved Strip

The strips are initially sorted by strip label. To review them ordered by time-of-day, select Time from the choices in the Sort field.

Note: ST event labels include the channel in which the ST segment change occurred.

Changing the active strip

At any time, there is only one active strip, the strip outlined in blue. Four fields above the strips refer specifically to the active strip. Those fields include time-of-day, a strip number, HR (heart rate) and HR2 (the second heart rate, that is, the heart rate of a run of VTAC or SVT in the strip).

To change the active strip, click on the one you want so that the outline surrounds it. You can also change the active strip by clicking the List button in the toolbar to open the List window. The List window lists each strip label and corresponding heart rate in order of time-of-day. To display a particular strip from the list, click on the appropriate entry on the list and click OK, or double-click on the entry.

Editing a strip label

To change the label of the active strip, click on Edit in the toolbar. The Edit window opens; it includes a field with the current label of the strip and the heart rate of the ECG in the strip, along with the second heart rate, the rate of either SVT or VTAC if it is present. (A second heart rate of 0 indicates that there is no run on the strip.)



Edit window

You can either type over the existing strip label in the Description field or select an alternate label by clicking on the arrow at the right end of the Description field and selecting a label from the displayed list.

If you type the entry, the auto-fill feature appears - as you type, the characters are matched to the preset list and will automatically fill in; if the text that appears is not what you want, continue typing the entry until it displays appropriately. If the label

you want is not already on the preset list, you must type the entire entry. Once the correct label appears, press Enter.

To change the heart rate on the strip, click on the HR field and type over the existing entry. When you have completed your changes, click OK to save.

Deleting strips

If you decide to delete one or more of the strips from the final report, you can do that in the Saved Strips window. To delete one strip in the Multiple strip display, click on it to make that strip the active one, then click Delete in the toolbar. To delete more than one strip, click on the first strip to make it the active strip; in addition to the blue highlight around the strip, there is also a yellow highlight around the time-of-day, indicating that the strip is selected. Click on any additional strips you want to delete, then click Delete in the toolbar. All of the selected strips (as indicated by the yellow highlight) are now deleted.

When you delete a strip, its label becomes red; strips with red labels are not included in the printed report. To retrieve a deleted strip, click on it and then click Delete in the toolbar again; the label text changes back to yellow.

To delete all of the strips displayed, click the button labeled Del/Undel All. To retrieve all of the strips displayed, click the button again.

Deleting channels from a strip

To delete one or more channels of a strip, but not the entire strip, click on a strip to make it active. Then, click on one of the check boxes labeled Channel 1, 2 and 3. For a particular strip, if a check is present, the channel will be included; if a box is not checked, the channel will be deleted. To

delete a channel from all strips, delete the channel from the active strip, then click on All.

When the Confirm window appears, click Yes to delete the channel(s) from all strips.

Replacing strip with alternative

Some strips can be replaced by an alternative: maximum and minimum heart rates, shortest and longest RR intervals, and fastest and longest runs of VTAC and SVT. The software selects sample strips for those types automatically. If you would prefer to select a different one (perhaps because the selected one contains artifact), click on the strip to make it active; the Alternatives button appears.

When you click Alternatives, the Alternatives window opens, displaying other choices for that label. All categories except the longest runs are sorted by heart rate, with the worst case first; the longest runs of SVT and VTAC are sorted by length, longest first. The current selection is the first one, in the upper left corner.

To select a different strip, click on the strip and then the Select new Alternative button. The window closes and the new strip appears in the Saved Strips window. To exit from the Alternatives window without changing the strip, click the Back to Saved Strips button.

Measuring

The data fields in the center of the toolbar-HR (2 RR), Time, and the ST indicators for each channel - contain data calculated based on the two blue calipers in the active strip. As you drag the blue calipers, those fields change, reflecting the new caliper positions.

To measure a two-beat heart rate, place the calipers two RR intervals apart; the measurement appears in the HR (2 RR) field. To measure ST in any of the channels, position the left caliper in the isoelectric area of the PR interval and the right caliper where you want to make the ST measurement; the measurements for each channel appear in the appropriate fields.

To move the calipers keeping them the same distance apart, click the check box next to Both and then drag the calipers. Click again to remove the mark and move them separately.

To keep the calipers in the same locations as you move through different screens of ECG, click the check box next to Lock; the calipers will stay in the indicated locations unless you move them again. Click again to turn off.

All other buttons and fields work in the Expanded display just as they do in the Multiple strip display. Use PageUp and PageDown to display the other strips. To return to the Multiple strip display, click Multiple in the toolbar.



Confirm window for deleting channel in All strips

Expanding the active strip

To view a strip more closely, either click Single in the toolbar or double-click on the strip. It then fills the Saved Strips window. Each beat is labeled with either the heart rate (BPM) or the length (in milliseconds) of the RR interval following the beat.

The blue measurement calipers and the related data fields work in this window exactly as those described in the previous section, "Measuring."

4. Page screen

The Page window allows you to review all of the ECG stored during the recording, like an electronic full disclosure. To open it, click on Page in the Review toolbar.

Full screen/Expand button

Using the Full screen/Expand button, you can toggle the window format back and forth between (1) only a single-channel display and (2) a combination screen with a single-channel display on the top half and an expanded strip on the bottom.

The single-channel page display contains a blue highlight box surrounding one of the QRS complexes, the "current" beat. The time-of-day at that beat is displayed in the time field in the upper left corner of the window. To move the highlight box to a

12:10:44.3pm-01

different beat, click on the beat you want to view and the new beat will now have a blue box around it.

Other Page buttons

Scan. In the single-channel display, you can visually review pages of ECG by using the PageUp and PageDown keys, by clicking on the down arrow of the scroll bar, by using the scroll button on your mouse, or by clicking the Scan button. Turn the Scan button off by clicking it again. Control the speed of the scan by pressing + to make it faster and - to slow it down.

Keep. The Keep button allows you to save one or more strips. Saving strips is covered later in this chapter.

Center. To adjust the ECG so that the highlighted beat appears in the center of the page, click Center.

Lead. To change the channel displayed, click on the Lead field and select a different channel from the list.

Gain. To change the amplitude of the displayed signal, click on the Gain field and select a different size from the list.



Zoom. To change the amount of time dis-

Gain choices

played on each page, click on the Zoom field and select a different amount of time.

Display. To change the amount of time that appears in the expanded mode, click in the Display field in the toolbar at the center of the window and select the amount of time to be displayed.

Print. To obtain a single-page printout of the ECG on the screen, click Print in the toolbar at the top of the Page window.

Invert/Hide. To invert the signal in a channel or to hide it from view (because the signal in one channel interferes with your visual review of another channel) go to Review > Invert/Hide to open the Invert/Hide window. Click on the check box for each channel to be inverted; click on it again to return the signal to normal. Click on the check box for each channel to be hidden; click again to return it to normal. Click OK to save any changes.



Invert/Hide window

Relabeling

To relabel in the Page window, click on the beat to be relabeled, select the appropriate setting for the Mode field, and then click the appropriate relabel button.



The relabel buttons include:

- A for artifact
- V for ventricular
- N for normal
- S for supraventricular
- P for paced (appears only when Paced mode is on in Scanning Criteria window)
- **Q** for questionable or unknown
- T for T-wave

Single vs. All Matches

The type of relabeling performed is determined by the setting in the Mode field. Choices are:

• All matches relabels the template to whatever label you choose. It is



Relabel Modes

removed from its present bin and established as a template in its new morphology; all matches to that template have the new label.

• **Single beat** relabels just the current, highlighted beat to whatever label you choose, removing the beat from whatever template and bin it was in and installing it in a new template in its new morphology.

Note: Although the S and T labels are available on Page, only a single beat at a time can be relabeled to S or T. Even if Mode is set to All matches, only a single-beat edit will be performed.

Relabel Multiple Beats

To relabel multiple single beats to the same label, click on the first beat, then press the Shift key and click on each additional beat. A blue highlight box surrounds each of the beats to be relabeled; click the appropriate relabel button. This method does single-beat relabeling only.

To relabel a string of beats to the same label, click on the first beat and then drag across to the last beat; the beats turn magenta. Then click the appropriate relabel button. This method does single-beat relabeling only.

Note: Whenever you use a relabel button, a message appears in the bottom strip of the window indicating what label was given to the beat and how many beats were relabeled. In addition, error messages appear there whenever you try to relabel inappropriately.

To undo a relabel, click the Undo button. The labeling reverts to just before the last relabel.

Turning AF On/Off

If a patient is in intermittent atrial fibrillation or flutter and you want to create a single AF event, click on the first beat and then drag across to the last beat. The time period turns magenta. Now click the AF On button. No SVPBs will be counted during that time period and will instead be counted as AF.

To change a period of AF to Normal, repeat the process, but click the AF Off button instead.



AF On/Off buttons

Inserting a beat

If while you are reviewing the ECG in the Page window, you see that a particular beat is included in the highlight box of the preceding beat, it means that the beat was missed. This is usually because of very low amplitude, but sometimes because of low slope. To force the system to count the beat, you can use the Insert button in the Expanded Page toolbar.



Insert window

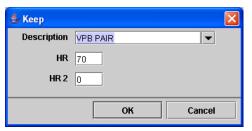
To insert a beat, first click near the beat so that it appears in the Expanded Page display, then drag or click the left-hand caliper to the location of the missed QRS complex. Click the Insert button in the toolbar in the middle of the window. The Insert window opens, with the time-of-day of the new beat listed in the first field and a beat label in the Morphology field. Click on the arrow in the Morphology field to display the list of label choices and make your selection. Then click OK to insert that type of beat where the left-hand caliper is.

Saving strips for the report

As you review the ECG, you can choose to manually save sample strips for the report.

The 7.5-second sample strips are printed as full-sized, 25 mm/second ECG on a background grid.

To save a strip, click on the beat you want at the center of the strip to move the highlight box there, and then click the Keep button; the Keep window opens. The Description field contains the current beat label; to keep that label, leave the field as is. To relabel the strip, either type the label in the Description field or select a label from the scrolling list; then click OK to save the strip.

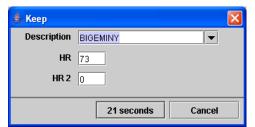


Keep window with OK button

The Keep window also includes two heart rate fields: HR, which equals the heart rate of the background rhythm of the strip, and HR 2, which is the rate of the run (VTAC or SVT) on the strip, if there is one. HR 2 equal to 0 means that there is no run on the strip. Both fields can be edited if you choose to. Be sure to make any measurements before you click Keep because the calipers are not accessible when the Keep window is open. Once the label and the heart rate fields contain the information you want, click OK.

To save strips of an event longer than 7.5 seconds, drag the cursor across the ECG to be saved (the selected ECG turns magenta) and then click Keep. In the Keep window, you can enter the label of the first strip in the series and then click the left button, which indicates how long a time period to be saved. Subsequent strips in the series will be labeled "Continuous (x/n)" (mean-

ing strip number x out of a total of n strips in the series).



Keep window with time button

To save multiple strips, all with the same label, click on a beat at the center of the ECG to be saved, then hold the Shift key down and click on another beat. Then click Keep. In the Keep window, click the button labeled "n strips" to save all the selected examples; click the button labeled "1 strip" to save just the last beat selected. All saved strips will have the label in the Description field; change it when appropriate. Because the strips are likely to have different heart rates, no heart rate fields are presented.



Keep window with multiple strip button

Measuring in Expanded Page

The two blue vertical calipers that appear in the Expanded strip in Page can be used to make a variety of measurements. To measure, drag the calipers to specific locations on the ECG; or click on the ECG to move the closer caliper to that location. To move both calipers while keeping them the same distance apart, click on the Both check box in the center toolbar and then drag or click them to a new position; click the Both check box again to move each caliper separately.

To measure the heart rate on the strip, place the calipers two RR intervals apart; the heart rate appears in the HR (2 RR) field. To measure an RR or a PR interval, place the left caliper at the start of the interval and the right caliper at the end of the interval; the time between them appears in the Time field.

To keep the calipers in the same locations as you move through different screens of ECG, click the check box next to Lock; the calipers will stay in the indicated locations unless you move them again. Click again to turn off.



ST segment and slope measurement data boxes

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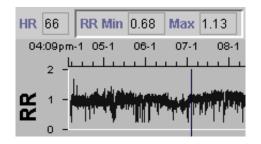
o make ST measurements, place the left caliper in the isoelectric portion of the PR interval, and place the right caliper where you want the ST segment measurement to be made; the vertical distance between where the left caliper intersects the ECG and where the right caliper intersects the ECG will appear in the ST field for each channel (labeled ST 1, 2, 3).

5. Trends window

Open the trends window by clicking on Trends in the Review toolbar or by selecting Review > Trends in the primary Holter toolbar.

General Trend

The General trend screen presents data in one-minute increments throughout the Holter period, including the RR trend showing the range of RR interval measurements; the heart rate trend showing the average heart rate; total VPB and VTAC trends; and total SVPB and SVT trends



RR trend with min and max indicated

On all of the trends, time-of-day appears on the horizontal axis. RR intervals are plotted so that the range within each minute appears as a vertical line; the top end of the line indicates the longest RR interval within that minute, and the bottom of the line indicates the shortest RR interval within it.

ST Trend

The ST trend screen presents the ST segment analysis data in 30-second increments throughout the Holtered period for all channels of ECG data. The placement of the ST calipers is automatic unless you re-set them in the Calibration window. See the section "ST segment analysis" in the previous chapter for more detailed information about ST segment analysis.

The ST trends include three components for each channel: (1) the patient's baseline ST measurement, that is, the patient's normal ST; (2) the actual measurement made for each 30-second increment; and (3) the slope indicator for each 30-second indicator. The baseline measurement is trended as a blue line, the actual measurement is green, and the slope indicator is a vertical red line drawn from the actual measurement to the measured value at the slope caliper.

The blue marker

The blue vertical marker is located at the time-of-day of a particular 30-second segment. Click on either trend to move the marker to a different time-of-day. The time-of-day that appears in the large data box indicates the time-of-day at the marker. The data boxes at the top of the display indicate the data collected for the minute where the marker is located, including heart rate (HR), the shortest RR interval (RR Min), the longest RR interval (Max), the total number of VPBs and SVPBs, and the total number of VPBs and SVPBs that occurred during runs of VTAC and SVT. In addition, the ST data boxes include data collected for the 30-second interval where the marker is located. including the ST segment measurement for each channel in ST 1, 2 and 3, and the ST slope measurement for each channel in Slope 1, 2 and 3.

Asterisks indicate that there is no data for that time period, usually because of artifact.

Relabeling to artifact

If entire periods are contaminated by artifact or if the electrodes were removed early (which generates lots of high frequency noise without ECG at the end of

the Holter data), you can relabel continuous periods of data artifact.

In the Trends window, to relabel a continuous period as artifact, click at the time-of-day you want to start rejecting and then drag until the end time. The time period turns magenta. Now click the Artifact button. A message will appear asking whether you mean to relabel the period as artifact. Click Yes to do so. All of the data within that time period is now called artifact, colored light blue, and not included in any of the totals.

Shorten analysis time

If the Holter period ends prematurely, you can either throw out the information as artifact, as described in the section above or you can shorten the analysis time.

To shorten the analysis time, in the Trends window, click to move the marker to the time-of-day at which you would like to end analysis, then select Review > Shorten analysis time. When the window opens to confirm the command, click Yes to re-analyze the data, stopping at the time indi-

cated. To close without re-analyzing, click No.

Turning AF On/Off

If a patient is in intermittent atrial fibrillation or flutter and you want to create a single AF event, click on the trend on the begin time and then drag across to the end of the AF time. The time period turns magenta. Now click the AF On button. No SVPBs will be counted during that time period and will instead be counted as AF.

To change a period of AF to Normal, repeat the process, but click the AF Off button instead.



AF On/Off buttons

Amount of time displayed

You can expand the trends by decreasing the amount of time displayed across a single page. To change the amount of time displayed, click on the arrow in the Hours



Calipers placed two RR intervals apart to measure heart rate

field and select the number of hours you want displayed per page.

When Hours is set to less than 24 for a 24-hour recording, there are multiple pages of data. To move from one page of data to the next, use either the PageUp and PageDown keys on your keyboard, or the scroll bar.

6. Tables

Tables to be included in the final report include interval tables of general, ventricular, supraventricular, ventricular runs, supraventricular runs, pacemaker data, bigeminy, and tachycardia and bradycardia data, along with a table listing episodes of significant ST segment change.

To review the tables compiled for a patient, click Tables in the Review toolbar. The listing of what tables are available appears at the right of the screen. The displayed table is highlighted in blue. To display a different table instead, click on its name in the list.

The tables and their fields include:

- General This is an interval table that lists the time-of-day at the start of the interval; the low, mean and high heart rate calculated during the interval (see appendix A for details of heart rate calculations); the total number of beats identified and counted in the interval (this excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the total number of SVPB beats; the total number of VPB beats; the number of pauses; and a field for manually-entered rhythm comments.
- Supraventricular This is an interval table that lists the time-of-day at the start of the interval; the total number of beats identified and counted in the interval (this excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the total number of SVPBs counted; the number of single SVPBs; the number of SVPB pairs; the number of runs of SVPB; and the number of SVPBs that occurred in runs.
- **Ventricular** An interval table that lists the time-of-day at the start of the

interval; the total number of beats identified and counted in the interval (this excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the total number of VPBs counted; the number of single VPBs; the number of VPB pairs; the number of runs of VTAC; and the number of VTAC beats that occurred in runs.

• ST Event - This table lists the ST segment events that were detected during the Holter test. Data in this table includes the channel in which the event was detected; the time-of-day at the start of the event; the time-of-day at the end of the event; the duration of the event; the maximum heart rate calculated during the event; the time-of-day at the event's maximum deviation from the patient's baseline; the heart rate during the event's maximum deviation from the patient's baseline; the ST segment measurement's deviation from the patient's baseline; the ST segment measurement's deviation from iso-electric; the slope of the ST segment event at the point of maximum deviation; and the integral of the event.

Note: Details of ST segment analysis and labels are provided in the "ST segment analysis" section of the previous chapter.

• Paced - An interval table that lists the time-of-day at the start of the interval; the total number of beats identified and counted in the interval (this excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the total number of beats counted as paced; the number that were atrial-paced only; the number that were ventricular-paced only; the number that were paced in both chambers; the number of sense failures; the number of occur-

rences of inappropriate inhibition; and the percentage of paced beats.

Note: Details of the pacemaker analysis and labels are provided in the "Pacemaker analysis" section of the previous chapter.

- Supraventricular runs An interval table that lists the time-of-day at the start of the interval; then the number of 3-beat, 4-beat, 5-beat, 6-to-9-beat, and 10+-beat SVT runs. It also includes number of beats included in AF events, the number of AF events, and total AF time.
- Ventricular runs An interval table that lists the time-of-day at the start of the interval; then the number of 3-beat, 4-beat, 5-beat, 6-to-9-beat, and 10+beat VPB runs that occurred at a rate less than the VTAC heart rate setting in Scanning Criteria; then the number of 3-beat, 4-beat, 5-beat, 6-to-9-beat, and 10+-beat VPB runs that occurred at a rate equal to or more than the VTAC heart rate setting in Scanning Criteria.
- **Bigeminy** An interval table that lists the time-of-day at the start of the interval; the total number of beats identified and counted in the interval (this excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the total number of VPBs that occurred in bigeminy; the number of 3-VPB episodes of bigeminy; the number of episodes of bigeminy that included 4 through 9 VPBs; the number of episodes of bigeminy that included 10 through 24 VPBs; and the number of episodes of bigeminy that included 25 or more VPBs.
- Tachy/Brady An interval table that lists the time-of-day at the start of the interval; the total number of beats identified and counted in the interval (this



ST segment and slope measurement data boxes

excludes periods of artifact); the amount of time analyzed (this also excludes artifact); the number of beats of bradycardia that occurred as defined by the Bradycardia setting in Scanning Criteria; the amount of time spent in bradycardia; the number of beats of tachycardia that occurred as defined by the Tachycardia setting in Scanning Criteria; and the amount of time spent in tachycardia.

Printing tables

To print a displayed table, click Print to open the Print window, then click OK to print.

Editing table entries

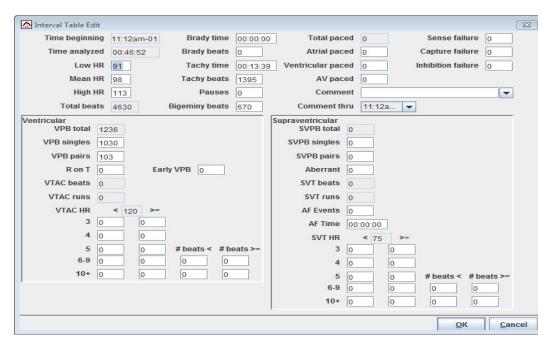
To edit information that appears in the tables, you can either use the Edit or the Zero button. In the interval tables (all but

the ST event) the Edit button opens the Interval Table Edit window that allows you to change information within the data fields for a particular interval. To use the Edit button, first click on a particular interval in a table to highlight it, then click Edit.

Note: If you choose to edit tables, this should be the last thing you do before creating the report, as calculated values are recalculated every time you do an Update or Reanalyze the data.

Note: If you have already created a front page, you will need to do a View Summary > Reset to ensure that table changes are incorporated on the front page of the report.

Editable fields appear with data against a white background. Fields that you cannot edit have a blue background. For example, total beat counts are not editable because they are calculated from other field data present in the table; as you make changes



Interval Table Edit window

to the other fields, the total counts change appropriately.

To completely eliminate all information within an interval, use the Zero button, which opens the Interval Table Zero window.Click on as many data fields as you want zeroed out in the interval tables, then click OK.

Select/deselect all buttons are available for each section. Use them to turn on or off all data fields within each specified section general information, ventricular, or supraventricular.

6. Additional features

Superimposition

HE/LX Analysis software allows you to review the patient's ECG in superimposition mode. In superimposition, each beat is quickly superimposed upon the preceding one in a continuous stream, which allows you to easily identify rhythm changes. Normal beats, VPBs and artifact are superimposed in separate locations in the Superimposition window so that you can also verify beat identification.



Superimposition

To open the Superimposition window, select Superimposition from the dropdown Review menu. Click on Scan to start

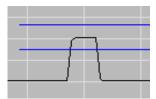
and stop the superimposition display.

In the display, channel 1 appears on top, channel 2 in the middle, and channel 3 at the bottom. Beats that match normal and paced templates are superimposed at the left side of the window, while beats that match ventricular templates appear in the center, and signal that is considered artifact appears to the right of the window.

Control the speed of the scan by repeatedly pressing + to make it faster and - to slow it down.

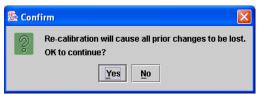
Calibration

Although the NorthEast Monitoring Holter Recorders save the patient's Holter signal at standard calibration, you can display the calibration signal at the start of the recording and adjust the height.



Calibration signal with markers

To open the Calibration window, select Calibration from the drop-down Review menu. Three channels of calibration signal are displayed. The two horizontal lines for each channel should be lined up so that one is level with the top of the square wave and one is level with baseline. Drag the lines to move them.



Confirm window after changes in Calibration

When finished, click on Done to save the new positions. A Confirm window will appear, asking you whether you really want to re-analyze using the new marker positions. Click on Yes to continue, and click on No to retain the previous marker locations.

Note: Whenever you make changes in the Calibration window, the signal must be re-analyzed when you exit. If you choose to not re-analyze, the changes are not saved. To close the Calibration window without saving new marker locations, click Cancel.

In addition, you can use the Calibration window to increase the size of a very low-voltage ECG signal or decrease the size of a very high-voltage signal, if the size causes problems during analysis. To increase the size of the signal for analysis, set the horizontal gain markers close together. To decrease the size of the signal for analysis, set the horizontal gain markers far apart.

Note: If you use the gain markers in this way, the signal is no longer calibrated and no ST measurements are correct.

ST Markers

The Calibration window is also used to access and adjust the ST markers used during ST segment analysis.

Details of adjusting the markers and all other aspects of ST segment analysis are provided in the "ST segment analysis" section of the previous chapter

5. HRV ANALYSIS

Heart Rate Variability (HRV) software allows you to review information about a patient's normal-to-normal RR interval data in a wide variety of ways, including Lorenz, 3-dimensional, circadian and time-domain plots. In addition, HRV information is reported in tabular formats of both time and frequency domain. Tables include calculations standard for HRV analysis, including SDNN, SDSD, RMSSD, NN50 count, pNN50, and a variety of indices - HRV triangular, differential and logarithmic.

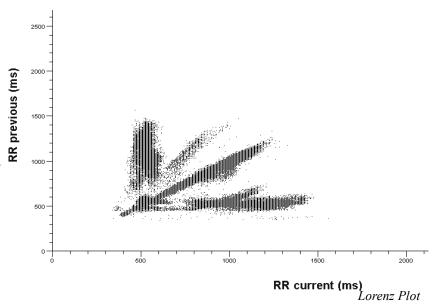
Reviewing HRV data

Review the HRV data by selecting one of the items from the HRV drop-down menu in the main Holter menu bar.

Note: HRV Analysis can only be performed when the Analysis time is 24 hours or less. For this reason, the HRV menu option from the toolbar will be disabled when the Analysis duration is greater than 28 hours.

Lorenz Plot

These are scatter diagrams comparing the RR interval following the current beat to the RR interval prior to the current beat. You can choose to display all RR intervals, only normalto-normal RR intervals, only RR intervals on either side of a ventricular ectopic, or only RR intervals on either side of a supraventricular ectopic. Make your selection in the Morph field by clicking on the arrow and then clicking on your choice. You can



change the range on the two axes by making a different selection in the Scale (ms) field. Your choices are 1000, 2000, 3000, 4000, or 5000. Click on the arrow in the field and then click on your choice to change the setting.

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In addition, the number of beats plotted on a particular Lorenz scatter diagram is indicated in the Matches field.

Time Domain Plots

Access these by selecting HRV > Time Domain Plots. If spectral analysis has not yet been run for this patient, a query box appears asking whether to run it. In order to view the time domain plots, spectral analysis must have been run for the patient.



Confirmation query

Click Yes to run spectral analysis and then display the requested data; click No to close the window without running spectral analysis or displaying the data.

The time domain plots contain separate trends of these different measurements and calculations over time for each interval:

- **SDNN** the standard deviation of the normal-to-normal RR intervals;
- RMS the root mean square of the differences between sequential RR intervals;
- **SDSD** the standard deviation of the differences between sequential RR intervals;
- NN50 the number of normal-to-normal RR intervals that were more than 50 milliseconds different from the preceding RR interval;
- PNN50 the percentage of normal-tonormal RR intervals that were more

- than 50 milliseconds different from the preceding RR interval;
- **MeanRR** the average RR interval within the specified time period; and
- **ProcTime** the amount of time (in seconds) processed within the interval.

To read specific data from the trends, click on the time-of-day of interest and a blue marker appears. The data fields at the top of the window indicate the specific reading for each calculation at the time-of-day of the blue marker.

To change the number of hours displayed, make your selection from the list of choices in the Hours field. To display the choices, click on the arrow to the right of the field. Click on your choice to select it.

Tables

Three different tables are available for review. Please note that these are accessible using the HRV menu, not the Holter Tables window.

Summary of Time Domain

This tabulates this information for the entire Holter period:

- **SDNN** the standard deviation of the normal-to-normal RR intervals:
- **SDANN** -the standard deviation of the normal-to-normal RR intervals for each 5-minute period of the 24-hour recording;
- RMSSD the root mean square of the differences between sequential RR intervals;
- **SDNN index** the mean of the standard deviation of all normal-to-normal RR intervals for all 5-minute segments of a 24-hour recording;

- **SDSD** the standard deviation of the differences between sequential RR intervals;
- **NN50 count** the number of normal-tonormal RR intervals that were more than 50 milliseconds different from the preceding RR interval;
- pNN50 the percentage of normal-tonormal RR intervals that were more than 50 milliseconds different from the preceding RR interval;
- HRV triangular index an index calculated by first determining the density of beats vs. RR intervals (scaled to a sampling rate of 128 per second), then dividing the total number of beats by the peak density.
- TINN a variation of the triangular index described above.
- **Differential index** an index describing the differences between the widths of the histogram of differences between adjacent RR intervals measured at the of 1,000 and 10,000 beats.
- Logarithmic index coefficient φ of the negative exponential Ke^{-φt} that is the best approximation of the histogram of absolute differences between adjacent RR intervals.
- Spectrum slope on log-log plot slope of the linear interpolation of the long-term (24-hour) spectrum in a log-log scale. This is the value β of the function $(\log(f)-\alpha)/\beta$ that gives the best estimation of the function $\log(P(f))$ where P(f) is the power density of the spectrum.
- Ranges values of entire 24 hours the values defining each frequency range for this patient.
- **Interval length** the amount of time (in seconds) included in each interval.
- **Number of intervals** the number of intervals included in the 24-hour recording;

- Values per interval the RR tachogram is sampled every (interval length)/ (values per interval) seconds to calculate the long-term (24-hour or procedure length) spectrum.
- Frequency resolution of short-term spectrums this is the size of the step in frequency used to make all calculations for each interval (100 or 300 seconds).
- Frequency resolution of 24-hour spectrum this is the size of the step in frequency used to make all calculations for the long-term spectrum (24-hour or procedure length).

Time Domain

This reports the time domain information for the included data. The table includes:

- # the data number;
- **Time** the time-of-day of the data;
- **SDNN** the standard deviation of the normal-to-normal RR intervals;
- RMS the root mean square of the differences between sequential RR intervals:
- SDSD the standard deviation of the differences between sequential RR intervals;
- NN50 the number of normal-to-normal RR intervals that were more than 50 milliseconds different from the preceding RR interval;
- **pNN50** the percentage of normal-tonormal RR intervals that were more than 50 milliseconds different from the preceding RR interval;
- Mean RR the average RR interval;
- **Proc. Time** the amount of time included;
- # **Beats** the total number of beats used for the calculations.

Frequency Domain

This reports the frequency domain information for the included data. The table includes:

- # the data number:
- Time the time-of-day of the data;
- Regular VLF (very low frequency), LF (low frequency), HF (high frequency) and Total - the actual calculations made for the data indicated:
- Normalized LF (low frequency) and HF (high frequency) - the relative amount of high versus low frequency data expressed as a percentage of the total.

Note: For a valid interval for the calculation of HRV time domain variables, the number of valid beats must be at least greater than the "minimum percentage of an interval which is valid" which defaults to 90%. Invalid beats are paced, pauses, AF, VPBs, SVPBs and artifact. Additionally there must be at least one 100 second period in the interval free of repeating arrhythmia such as bigeminy and trigeminy, as well as multiple VPBs or SVPBs in a row.

HRV Analysis

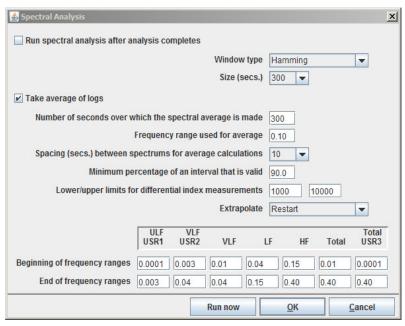
To perform HRV analysis, the software considers only normal-to-normal RR intervals and performs the analysis based on the settings available in Settings > Spectral Analysis.

Spectral Analysis settings

The following settings are available in the Spectral Analysis window:

• Run spectral analysis after analysis completes. This setting determines whether HRV analysis will be done

- automatically at the end of Holter analysis. A check mark in the check box indicates that the HRV program will run automatically upon completion of Holter analysis. No check mark indicates that HRV analysis will not be performed automatically. If the HRV analysis has not been done and you ask to review HRV data, the software will ask whether you want to run it at that time.
- Window type. This field indicates what type of sliding window is used for HRV analysis and what type of window to use. The choices are None (simple sliding window), Hamming, Hann, and Triangle. Click on the arrow in the field to list the choices and click on your selection.
- Size (secs.). This setting determines whether the sliding window is 100 or 300 seconds long. Click on the arrow in the field to list the choices and click on your selection. A setting of 100 limits the minimum frequency to 0.01 Hz., while 300 limits the minimum frequency to 0.0033.
- Take average of logs. As HRV analysis is done, you can choose to have the magnitude of spectral values first converted to a log form before averaging. A check mark in the check box indicates that the data will be converted; no check mark indicates that the average is performed on the magnitude of the spectral values directly and the log, if any, is taken after the average.
- Number of seconds over which the spectral average is made. The average of the spectrum is a two-dimensional calculation made using a sliding window. The window is the "Size" described above; it moves "Spacing between averages" described below between each spectrum calculation.



Spectral Analysis Settings window

This setting is the total number of seconds the window must move to calculate one point in the result. The range allowed is from 0 to 3600. Click on the field and type your entry to change the setting.

- Frequency range used for average.

 The average is made over this range of frequencies. Click on the field and type your entry to change the setting.
- Spacing (secs.) between spectrums for average calculations. The number of seconds the window is moved for each spectrum calculation used to calculate the average spectrum. When this is set to the typical value of 10 seconds and the average is set to 300 seconds, then 30 spectrums are calculated for each value in the resulting average spectrum. Click on the arrow in the field to list the choices.
- Minimum percentage of an interval that is valid. At least this percentage of beats within an interval must be used for the interval to be included. Too

- much artifact or ectopy within an interval will prevent it from being included. Click on the field and type your entry to change the setting.
- Lower/upper limits for differential index measurements. The differential index measurement is defined as the difference between the widths of the histogram of differences between
- adjacent RR intervals measured as selected heights. the upper and lower limits are the selected heights for this measurement. Click on each field and type your entry to change the settings.
- Extrapolate. This field determines what happens to the calculations when an ectopic beat occurs. The Restart setting indicates that the calculation ends there and starts again on the next normal-to-normal RR interval. The Interpolation setting indicates that the RR intervals on either side of the ectopic will be

3D Plot

This plot presents the data from the eight different frequency ranges (as defined in the Spectral Analysis settings window) on three axes: (1) Frequency, (2) Spectral Power Density and (3) Time.

To change the amount of time displayed on the graph, type an entry in the Hours field and then click the Go button. To change the settings for Mesh X, Mesh Y, Shaded, Contour, Hidden Lines or Zones, click on the check box to the left of the label, then click the Go button. A check mark in the check box indicates that the setting is on; no check mark indicates that the setting is off. After you click Go, the graph will redraw using the new settings.

To customize the axes, select Custom from the field above the Go button. This activates the X, Y, and Z fields to the right of it. Type the new orientation for whichever axis you choose and then click the Go button. To return the graph to its original settings, click on the arrow and select Default from the list of choices, then click Go.

Circadian Plots

This shows the power level of each frequency over time, in both absolute terms (seconds squared) and normalized as a percentage. The color key for each frequency is indicated at the top of the plot, underneath the data field of the frequency the color represents.

A check mark to the left of the frequency indicates that the frequency is plotted. No check mark indicates that the frequency is not plotted. To change the setting for a frequency, click on the check box.

To read specific data from the plot, click on the time-of-day of interest and a blue marker appears. The data fields at the top of the plot now indicate the specific reading for each plotted frequency at the timeof-day of the blue marker.

To change the number of hours displayed, make your selection from the list of choices in the Hours field. To display the choices, click on the arrow to the right of the field. Click on your choice to select it.

- merged and the location of a normal beat interpolated from the surrounding RR intervals.
- Beginning/End of frequency ranges. Each of the frequency ranges indicated are used to calculate the total energy in the indicated portion of the spectrum. This is used for all spectrum calculations. The calculated energy in each range is calculated every 5 minutes. The results appear in the Circadian Plots. Note that some columns such as the ULF may have no valid spectral values for a 5-minute spectrum if the default values are used. If alternate values are supplied, the resulting trend could be valid. These values are also used in the same manner to calculate the range values in the spectrum summary.

The frequency ranges are abbreviated:

- ULF USR1 stands for ultra low frequency, with the range defined by the user;
- VLF USR2 stands for very low frequency, with the range defined by the user;
- VLF stands for very low frequency;
- LF stands for low frequency;
- **HF** stands for high frequency;
- Total stands for the total; and
- **Total USR3** stands for the total, with the range defined by the user.

24 Hour Plot

This plots power (milliseconds squared) versus frequency (Hz), showing the delineation of each frequency range. It can be presented on either a linear or a log scale.

Printing HRV data

Report modules

- Frequency Domain Table. Lists the very low, low, and high frequency data for each interval. Each frequency is reported as a percentage, for a total of 1.0 for each type of frequency.
- Normalized Frequency Domain. lists the low (LF) and high frequency (HF) data normalized by dividing each by the total for that frequency.
- Time Domain Table. For each interval, this lists the total number of normal beats along with heart rate variability calculations, including the standard deviation of normal-normal intervals (SDNN), the root mean square of the standard deviation (RMSSD), the standard deviation of the standard deviations (SDSD), the number of normalnormal intervals that were greater than 50 milliseconds different from the preceding normal-normal interval (NN50), the percentage of normal-normal intervals that were greater than 50 milliseconds different from the preceding normal-normal interval (PNN50), the average normal-normal interval (RR Mean), and the time included in the interval.
- HRV Time Summary. A summary of the time domain calculations, as described for the "Time Domain Table" above, plus the maximum standard deviation of normal-normal intervals (Max SDNN), the SDANN, the SDNN index, the HRV triangular index, the Differential index and the Logarithmic index. In addition, the time domain data is plotted across the Holter period, along with two histograms, one showing the RR interval distribution of nor-

mal beats and the other showing the RR interval distribution of all beats.

To include a module in the report, the check box next to the module name in the Reports window must contain a check mark. Click on an empty box to add a check mark, and click on a check mark to remove it. To turn all of the modules on or off, click on the All On/Off check box under the report module list; to change them all again, click on the All On/Off check box again.

6. REPORTING

The software generates printed reports composed of a variety of report modules that can be included or excluded. Each module can be selected individually, depending on your documentation requirements. Modules range from those with clerical information and Scanning Criteria settings to those with tables of ventricular runs and detailed trends. Sample strips documenting events can be printed in standard 25 mm/ second format. Full disclosure of any interval can also be included. Some report modules are not appropriate for particular patients and are not included in the list of selectable modules when you go to print the report.

Note: All data printed on the patient report should be reviewed by a qualified physician.

Steps to create a report

The steps to create a report for the current patient are as follows:

- 1. Open the Report Screen and choose the List of reports that you want to include.
- 2. Click on "Create Report" button in lower-left. Report will be created and LibreOffice Writer will open
- 3. Within LibreOffice, review report. Edit the front page, add Comments into the comment box on first page. Save the report before closing.
- 4. If report is final, save a PDF with LibreOffice or using the Create PDF button. Once the report

Report modules

To access the report modules that can be included in the final printed report, open the Reports window. The report modules that are available for the current patient are listed in the right half of the Reports window. They may include:

- **Patient Information.** The front page of report as determined by the Report Summary selection. It includes the Patient Information, a Summary, and the Summary text entered by user on the View Summary window.
- **List of Diary Events.** Lists the time-of-day and symptom for each entry in the Diary Symptoms window accessible from the Patient Information window.
- **Hourly Rhythm Page.** Lists the rhythm type manually entered in the General table in Tables window, using the Edit window.
- **Settings Page.** Includes entries from the Scanning Criteria window and their settings for the patient.
- General Profile. An overview of the patient's Holter data. The table includes interval data: the time-of-day at the start of the interval; the low, mean and high heart rates within the interval; the total number of beats; the total number of VPBs, VPB pairs, runs of VTAC, SVPBs, SVPB pairs, runs of SVT, and pauses; and the amount of time analyzed in the interval.
- Trends. Include minute-by-minute heart rate, VPBs, VTAC beats, SVPBs, and SVT beats.

- Supraventricular / AF Summary.
 - Tabulates the patient's supraventricular ectopy, including SVPB totals, singles, pairs, and runs for each interval. Also displays a detailed summary of supraventricular run information, described by run length and by the heart rate during the run. AF beats, events and time also included when it exists.
- Ventricular Summary. Tabulates the patient's ventricular ectopy, including VPB totals, singles, pairs, and runs for each interval. In addition, it displays a detailed summary of ventricular run information, described by run length and by the heart rate during the run.
- **Bigeminy.** An interval table that lists the number of runs of bigeminy by length (in beats).
- ST Episodes. List describing the detected ST segment events during the Holter test, along with a trend of the ST segment measurements for each of the three channels and the marker locations that were used for ST segment analysis. Each description includes:
 - 5. **Ch** the channel in which the event occurred;
 - 6. **Onset** the time-of-day the event started:
 - 7. **End** the time-of-day the event ended:
 - 8. **Duration** the duration of the event in HH:MM:SS; Note, the total duration may not equal the sum of the column as some times may overlap and will not be counted more than once in the total.
 - 9. **Max HR** the maximum heart rate during the event;
 - 10. **Time** the time-of-day of the maximum ST change during the event;
 - 11. **HR** the heart rate at the time-of-day of the maximum ST change during the event;

Reports	
Front Page	L
List of Diary Events	
Hourly Rhythm Page	
Settings Page	
General Profile	
Trends	Г
Supraventricular/AF Summary	
Ventricular Summary	
Bigeminy	
ST Episodes	
Expanded Heart rate + ST trend	
Critical Events	
Brady/Tachy Table and HR Trend	
Full-Sized Strips	
Half-Sized Strips	
Full Disclosure Strips	
Paced Data Information	
Paced Interval Histogram	
Paced Summary Information	
Frequency Domain Table	
Time Domain Table	
HRV Time Summary	
Full Disclosure 30 min/page	
Full Disclosure 60 min/page	

Report modules in Reports window

- 12. **mm from baseline** the maximum change (in millimeters) from baseline during the event;
- 13. **mm from iso-electric** the maximum change (in millimeters) from iso-electric during the event;
- 14. **Slope** the slope of the ST segment during the event; and
- 15. **Integral** the integral (considered to be the area between the curves) between the ST segment trend and the patient's baseline trend during the event.
- Expanded Heart rate + ST trend.

Presents 8 hours of minute heart rates and 30-second ST data (for each channel) per page.

• **Critical Events.** A bar graph that includes interval data and a representa-

tive example for each of these significant types of event: VPBs, VPB pairs, VTAC, SVPBs, SVPB pairs, SVT and pauses.

- Brady/Tachy Table and HR Trend. An interval table that lists the number of beats of bradycardia that occurred and the time spent in bradycardia, along with the number of beats of tachycardia that occurred and the time spent in tachycardia. Below the table is a 48-hour heart-rate trend.
- **Full-Size Strips.** Presents the saved strips in a 25 mm/second format, with three strips per page.
- Half-Size Strips. Presents up to 14 strips per page in a non-standard format.
- **Full Disclosure Strips.** Full-sized strip at the top with 6 minutes of full disclosure below.

Paced Reports are only listed when Paced is turned on.

- Paced Data Information. An interval table that describes the pacemaker activity during the Holter period. This includes the total number of paced beats, the percentage of paced beats, the number of beats that were atrial-paced only, the number that were ventricular-paced only, and the number that were paced in both the atrium and the ventricle, along with capture failures, sense failures, and inappropriate inhibition.
- Paced Interval Histogram. This includes four histograms plotting the number of beats versus the RR interval following the current beat. The four include total paced beats, sense failures, capture failures, and inappropriate inhibition. This module also includes a heart rate trend for the Holter period, and the definitions of the LX software's pacemaker labels.

• Paced Summary Information. This interval table details the number of paced beats and percentages for all paced beats, atrial-paced only, ventricular-paced only and dual-chambered paced beats. The information also includes the pacemaker settings used during analysis, as defined in the Scanning Criteria window.

The following reports are only listed when available:

- Frequency Domain Table. *This lists the very low, low, and high frequency data for each interval. Each frequency is reported as a percentage, for a total of 1.0 for each type of frequency.
- Normalized Frequency Domain. This lists the low (LF) and high frequency (HF) data normalized by dividing each by the total for that frequency.
- Time Domain Table.* For each interval, this lists the total number of normal beats along with heart rate variability calculations, including the standard deviation of normal-normal intervals (SDNN), the root mean square of the standard deviation (RMSSD), the standard deviation of the standard deviations (SDSD), the number of normalnormal intervals that were greater than 50 milliseconds different from the preceding normal-normal interval (NN50), the percentage of normal-normal intervals that were greater than 50 milliseconds different from the preceding normal-normal interval (PNN50), the average normal-normal interval (RR Mean), and the time included in the interval.

*Note: The Summary/Overall line at the bottom of these reports is calculated for the entire analysis period. Since some of the columns represent non-linear calculations, such as standard deviations, there is no linear operation (like average, min,

max or median) one can do on the column to produce the value in the summary/overall line. For example, for the SDNN column, the value in the summary line will be calculated for the entire recording, and in general, will not be a simple average of the values calculated at each interval in the table above.

• HRV Time Summary. This prints a summary of the time domain calculations, as described for the "Time Domain Table" above, plus the maximum standard deviation of normal-normal intervals (Max SDNN), the SDANN, the SDNN index, the HRV triangular index, the Differential index and the Logarithmic index. In addition, the time domain data is plotted across the Holter period, along with two histograms, one showing the RR interval distribution of normal beats and the other showing the RR interval distribution of all beats.

Full Disclosure:

• Full Disclosure. For either full disclosure report, select Channels and Intervals on the left-side of the reports screen. To turn all of the Intervals on or off, click on the All On/Off check box under the list of applicable intervals.

Strip annotation

Strips printed in the report can include a beat-by-beat annotation of the ECG. In the Reports window, set the Strip annotation field to indicate how you would like the beats annotated. Your choices are Labels, which are beat labels; Heart Rate, which is a beat-by-beat heart rate calculation based on the current-beat-to-following-beat RR interval; RR, shows the RR interval (in

milliseconds) from the current beat to the following one; and none - no labels.



Choices for Strip annotation

The beat labels consist of:

- N for normal
- S for SVPB
- V for VPB
- A for artifact
- **P** for paced (A, V, or AV)
- F for AF
- **D** for event marker
- ? for questionable/unknown

Report heading

The Patient Information module of the report includes a report heading so that you can customize the report for your facility. The heading consists of five lines of free form text, with up to 34 characters per line. To enter text in a line, click on the field and type your entry. Click on each field in turn and type. You can leave any line blank.



Report heading in Reports window

If your address comes up automatically, but you would like to change it for a particular patient, you can either make your selection from the addresses you have associated with different report configurations (see Chapter 9: Configurations for

details) or you can use the Delete/Backspace keys to clear what is there, and then type your entry.

To select an address from a different configuration, click the List button. That opens the Report Headings window listing your options. Click your choice to highlight it, then click Copy to close the window and replace the address.

Full disclosure

Full disclosure is a printout of all the ECG recorded during the Holter monitoring period, in a miniaturized format. Each page is annotated with time-of-day along the left margin.

You can print full disclosure in a variety of formats based on the channels printed and the amount of time printed on each page. Full disclosure can be printed for a single channel or for two channels together on a page (channels 1 and 2, or channels 1 and 3, or channels 2 and 3). It can be printed with 30 minutes of ECG per page or 60 minutes.

Determining what to print in full disclosure

To request a full disclosure printout, select Reports from the Review toolbar. In the Reports window, there is a section with settings that control full disclosure. It includes three fields:

• Time per page check boxes. At the top of the section are two check boxes labeled 30 min/page and 60 min/page. To print full disclosure, there must be a check mark in one of these check boxes. Click on the check box to make a check mark appear in it; click on the other check box to put the check mark there and remove it from the first check box. To eliminate a check mark, click again

on the check box.

- Channel(s) field. To indicate what channel(s) to print in full disclosure, select an entry from the Channel field. Click on the arrow to display your choices, and then click on your selection.
- Intervals to include. Full disclosure can be printed for each hourly interval, all of the hourly intervals, or whatever combination you select. For each Holter test, the Intervals field lists all hourly intervals in the recording. To include an interval in the full disclosure printout, click on the check box next to the timeof-day at the beginning of the interval. Click on as many intervals as you would like to print. To eliminate an interval from the printout, click on the check box to get rid of the check mark. To check all intervals on or off, click on the All On/Off check box below the interval list.

Note: The time per page check boxes control how much total ECG is printed per page. If you choose to print two channels of ECG, the 30 min/page setting will print both channels during a 15-minute time period, and the 60 min/page setting will print both channels of a 30-minute time period.

Create/Open Report

Click on Create Report to open an editable report in LibreOffice. If the report already exists, the button will read Open Report and clicking on it will open the current report for that patient. Once open, you can edit the report and Save it before closing.

Comments

You can add comments and edit the report once opened in LibreOffice. The AutoText feature in LibreOffice Writer can be used to create and input comment text that you frequently use on the reports. If comments are added, be sure to Save your report to save the comments.

Create/Open PDF

You will need to save a PDF to transfer the file via LX Remote or to save it in Archive. If a PDF file exists for this patient the button will be labeled Open PDF. If the patient does not have a PDF version of their report, you can create a PDF by clicking on the Create PDF button from the report screen.

You can also create a PDF from within LibreOffice
Writer. You can do this by clicking on the create PDF button on the top toolbar.
Alternatively, you can save the document in another location by going to File > Export as > Export as PDF.

Open Acrobat

from the PDF Options window that opens during Export as PDF and the setting will be saved.

Print Report

You can either print from LibreOffice or Adobe Reader. In order to print from Adobe, you may need to adjust the Adobe Settings to ensure that they are correct for the report, such as Print from File and other Advance settings.

More about Reports

Status indicators

Click on appropriate box to keep track of whether a patient's Holter has been edited, printed, and/or verified. Once the report is final, you can Lock the patient so that no edits can be made to their report or information, without first unlocking it.

Report default set

You can modify which report modules are selected initially by creating configurations that include the report set that you desire. You can do this under the "Report" tab in Configurations.

Adding Logo to report

Your logo jpg, should be square and fit into a 3x3 cm. box on the top-left of front page. The jpg file should be named logo.jpg and must be placed into the bin\logo directory.

Closing the Reports window

At any time, you can save changes to the Reports window settings, but exit without printing the report, by clicking OK. Or, to exit without saving any changes to the set.

Customizing Reports

The software uses LibreOffice Write templates to produce the reports. If the user modifies any of these templates for any reason, NorthEast Monitoring will not be responsible. A clean set of report templates can be found on our web-site.

Extensive knowledge of LibreOffice Writer and its layout capabilities is required to make minor changes to the templates.

For substantive adjustments, knowledge of Python, Python appy package and xml is required.

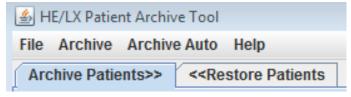
7. ARCHIVE PATIENTS

Before the Patient List directory is full, you will want to archive and delete patient records to make room for new ones. You can choose to do this manually or it can be automated to run on a regular basis.

Installing the Archive Utility

Effective with release 6.1 of HE/LX Analysis, the Archive Utility has a separate install. The install can be found under the Holter Software on the Support >Downloads & Document page at www.nemon.com.

HE/LX Patient Archive is accessible by going to the File > Open/New > Patient List and clicking the Archive button at the bottom of the screen. The Archive tool has two tabs -



Archive Patient Tab selected

Archive Patients and Restore Patients.

Archiving a patient consists of two steps: 1) copy the patient to the Archive folder and 2) delete the patient from the Patient List. Once archived, if you need to go back to a patient who has been Archived and deleted from the Patient List, you can go to the Archive folder and restore the patient back to the Patient List.

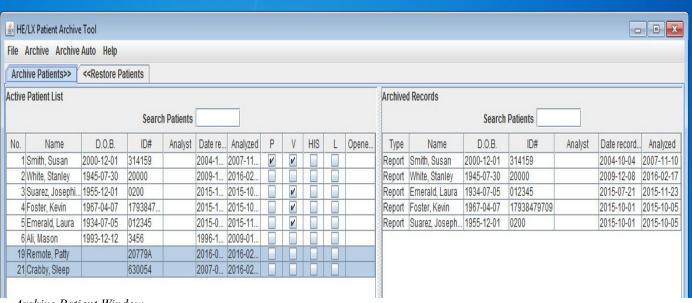
Archive Type

From the toolbar, you can select an Archive Type. Archive Type "Full", will copy all patient data, including the entire Holter recording and report; and Archive Type "Report only"



Change Archive Type and Compression from toolbar

will save an electronic version of the patient's Holter report, including ECG strips, but not the recording. Only by doing an "Full" Archive, can the patient's Holter data be restored and reanalyzed.



Archive Patient Window

Compression Level

Increase the compression level to save disk space when archiving. The more compressed the file, the longer archiving will take.

Archive Patients Tab

The HE/LX Patient Archive Tool will initially open with the "Archive Patients" tab selected. Once opened, all patients who can be archived will be highlighted in blue. A patient is highlighted in blue when:

- 1. They have been analyzed
- 2. They have a PDF report
- 3. They have never been archived previously, or their information has been updated since they were last archived.

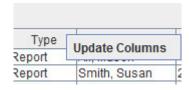
If you want to override the highlighted patients, you can hold the Shift-key and click on any directory in order to manually select or deselect it. When finished, click the "Archived Selected Patients" button at the bottom of the screen and the selected patients will be copied to the Archive folder.

Note: If a Patient is opened and viewed, but not updated, the system will perceive this patient as being updated and show that the patient needs to be archived again. To ensure that this does not become a problem for you, be sure to wait to archive a patient until you are sure that they will most likely not be viewed or reviewed again.

Delete Patient Records

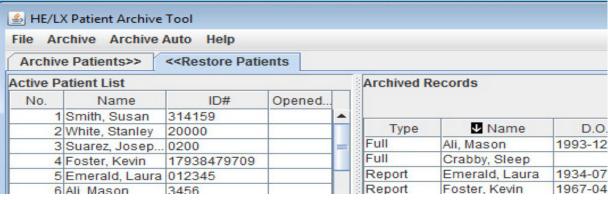
Once archived, you will want to delete the patients from the Patient List in order to make room for new patients. The Archived check box, labeled "A" on the Patient List, will show you which patients have been archived and can be deleted at this time.

Customizing Screens



Just like the primary Patient List, you can customize any of the archive lists

by changing, moving and resizing columns.



Restore Patient Tab

Select columns by right-clicking on any of the column headings and then on "Update Columns." You can also search on each list by typing into the Search box at top of the screen.

Restore Patients Tab

You can only restore patients when a Full Archive type has been performed.

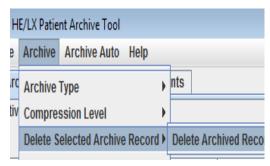
To restore a patient that has been archived and deleted from the Patient List, select the Restore Patients tab on the HE/LX Patient Archive Tool. When selected, it will be blue. You will now see a searchable list of all archived records on the right. Select the archived patient you want to restore on the right, and an empty patient directory on the left. Then click the Restore Selected Record at the bottom of the screen to copy the patient back to the Active Patient List.



Restore "Full" Archived Records

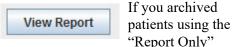
Delete record after Restore

At this time, if you want to delete the Archived record of the patient you just restored, you can go to the toolbar and select Archive > Delete Selected Archive Record.



Restore Patient Tab

Report only Archive



option, you will not be able to restore those patients as they no longer have the ECG file. Instead, you can View the patient's report by clicking on the View button at the bottom of the screen.

Auto Archive

The Archive process consists of two actions, both of which can be run automatically on a schedule or initiated by you by clicking the Auto Archive button from the Archive Window. The two pieces to archiving are:

- Copy a patient from the Patient List to Archive after a defined number of days that the patient has a report created or modified
- 2. Delete the patient from the Patient List after a defined number of days after the patient has been Archived and no subsequent changes to the patient have been made.

Scheduling Auto Archive

You can schedule the Archive program to run in the background. You can do this by setting up a Scheduled Task from Control Panel > Administrative Tools. The command that should be entered where "c:nm" is the location where the HE/LX Analysis is installed:

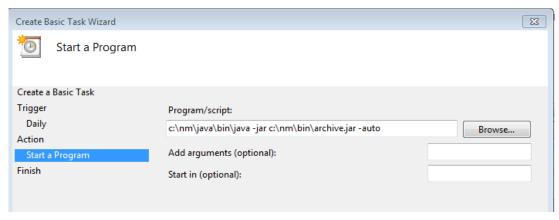
Auto Archive and Archive.ini

An Archive.ini file is included in the installation in the bin directory. The directory where the archived files are saved can be changed here. Additionally, the number of days criteria used to Archive and/or Delete patients can be found and edited in this file. They are:

- AutoArchiveDays the number of days after a patient has a report created that the patient will be copied to the archive directory. Make -1 to turn this feature off.
- AutoDeleteDays The number of days after a patient is archived that the record will be deleted from the Patient List, Make -1 to turn this feature off.

c:\nm\java\jdk-14.0.1\bin\java.exe -jar c:\nm\bin\archive.jar -auto

Optionally, you can use the Archive.ini file in the bin directory to modify the auto archive criteria.



Scheduled Task Example

8. PREFERENCES

You can customize certain parts of the HE/LX Analysis software to better suit the needs of your facility. The options range from entering the names of physicians who order Holter tests - so that you don't have to type them in each time - to which Review window you want to come up automatically at the end of analysis.

Preferences window

To open the Preferences window, select File > Preferences.

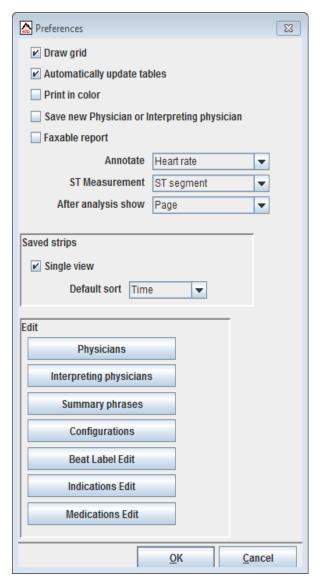
Draw grid

You can choose whether or not there is a background grid behind the Expanded strip displayed in the Page window. Click on the Draw grid check box to change the setting. A check mark indicates that a light grid will appear. No check mark means that the grid will not appear.

Automatically update tables

A check mark should appear in the check box so that the software automatically updates counts, tables and strip labels after you relabel a beat, template or bin in any of the Review windows. If it does not automatically update, you must manually run an update after making changes.

Note: If this setting is off you must have the toolbar turned on, as a blinking red Update button will appear in the lower toolbar when an update is required. To manually run an update after making changes, click on the blinking red button or select Review > Update.



Preferences window

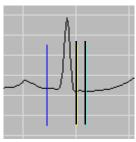
Save new Physician or Interpreting physician

Allows the software to ask you whether to add a new or interpreting physician name to the appropriate list when you close the Patient Information window after typing a new name in either field.

Annotation

Select how the beats in any on-screen, expanded strip should be labeled with a beat-by-beat heart rate calculation or RR interval length. The annotation refers to the RR interval starting at the R-wave under the label. Click on the arrow in the field to display your choices. Click on your choice to select it.

ST measurement



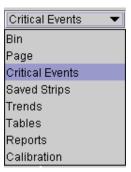
Positions of ST markers

ST segment analysis can be performed with the ST segment measurement made at the position of either of the two right-most ST markers.

The middle marker identifies the J-point and the one at the far right is the ST segment marker. Indicate in this field which marker should be used for ST segment analysis. Click the arrow in the field to display your choices, then click your choice.

After analysis show

Allows you to determine which window is displayed upon the completion of analysis. Your choices include any of the Review windows and the Reports window.



Choices for display

To change the

setting, click on the arrow in the field to display the list of choices, then click on your selection.

Saved Strips Default View

Saved Strips Default View allows you to set up how the Saved Strips screen will look initially after analysis. If "Single View" is checked, you will see a single strip; uncheck it to see multiple strips initially. Once you open the screen, you can modify these settings for each patient as you choose.

Physicians and Interpreting Physicians windows

Physician and Interpreting physician entries can be entered, edited and deleted here, allowing you to make a selection from a list instead of typing the physician names for each patient in Patient Information. Additionally, if you turn on the Save new Physician or Interpreting physician Preference setting described earlier in this chapter, you can add new names to the list automatically when entering new physicians in the Patient Information window.

To create an entry, click on the "Add new item" button, go to the new line and enter the item. Hit the Enter button on the keyboard to save and add more if you like.

To exit without saving changes, click Cancel. To edit just click on a line and then update, and to delete an entry, click on the trash can next to line you want to remove. Click OK to exit the screen when finished.

Beat Label Edit

This screen allows you to customize the list of labels that appear on Strip Labels, Saved Strips and the final report. Double-click on the No. of the label that you want to edit on the column labeled "Editable custom label," edit and press Enter.

Note: Changes to labels must be made carefully because the meaning of the label MUST NOT change. For example, when the system calls a beat ventricular, it uses the VPB label when saving strips for the report; you can change the text to read VE instead, but not SVPB or BBB, or your report will be incorrect.

Indications and Medications Edit

This window is for customizing the indication and medication lists on the Patient Information screen.

Configurations

Click this button to launch the Configuration program that allows further customize the HE/LX Analysis software settings. Details appear in Chapter 10: Configurations.

Updating Software

If you are upgrading from an older version of the software, LX Analysis (5.2 or later), you should be able to copy and paste the old info.ini file into your new location. (See above) The old info.ini file will either be found in the directory of the old install, if you installed to a new directory; or in bin_backup if you installed your software in the same directory.

9. CONFIGURATIONS

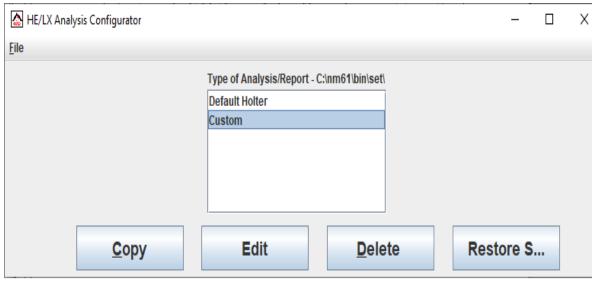
The Configuration program (also called the Configurator) allows you to customize certain aspects of the screen displays, analysis and reports. With careful attention to detail, you can establish report formats that are specific to a physician or automatically change dozens of analysis settings for a particular patient type (e.g., patients with pacemakers). Each separate customized format is called a configuration.

You access the Configurator with the HE/LX Analysis program running via the File > Preferences Screen. At the bottom of the Preferences window, click the Configurations button. The main Configurations window opens.

Configuration window

The main Configuration window opens with a listing of all current configurations of your software. Each should have a unique name. To start, you have been supplied with a Default Holter configuration and it cannot be edited, but it can be used during analysis, or as a starting point for a new configuration. You can delete all but the "Holter Default" configuration if you want to do so. If you want to bring back default configuration after it has been deleted, you can press the "Restore" button.

To edit the Custom or another configuration, click on the name associated with the configuration you want to change, and then click the Edit button.



Main Configuration window

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To create a new configuration, click on the name associated with a configuration similar to the one you want to create, and then click the Copy button.

To delete a configuration, click on the name associated with the configuration you want to eliminate, and then click the Delete button.

To restore the default configurations, click on the Restore button. Use this cautiously as any configurations you created will be lost.

Configuration folders

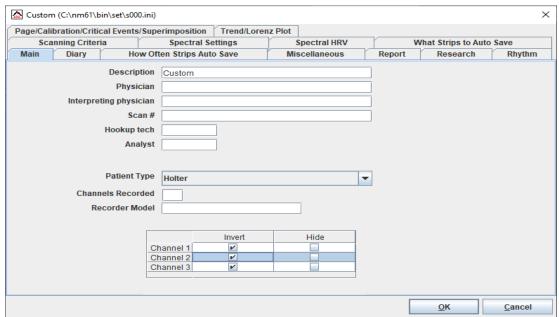
A configuration consists of a series of folders with tabs. Each folder contains the controls for a particular window or portion of the HE/LX Analysis software. Within the folders for a configuration, an entry in a field automatically populates that field for a patient when you select the configuration or "Type of Analysis/Report".

To display the fields in a particular folder, click on each of the tabs for that folder:

Main - Includes the name or description of the configuration, which appears in the Type of Analysis/Report list; the physician's and interpreting physician's names associated with the configuration; the scan number; hookup technician; and analyst.

When you create a new configuration by using the Copy button, the Description field in the Main folder reads
New Type. Be sure to type a new name for the configuration in the Description field to differentiate it from others you create. This is the name that will be visible on the Patient Information as Type of Analysis/Report.

The Main folder contains the Scan # field which controls the auto-sequencing of the Scan number in the Patient Information window. To have the system automatically increment the scan number for each patient, enter \$seq in



Configuration folders

the Scan # field; to include the date and/ or time-of-day in the Scan # field, enter \$date or \$time, respectively. Use whatever order you want the scan number to follow. Also, be sure to turn on the "Assign date and time to Scan #" feature in the Preferences window.

The Main folder includes a field called Patient Type. At this point, only "Holter" is supported.

The rest of the folders are:

- Diary Different diary entries can be added, and diary entries can be replaced with other text or deleted singly or all together. The diary entries appear in the drop-down list of choices in the Symptom field in File > Patient Information > Diary.
- How Often Strips Auto Save This controls the settings that come up automatically in this window in Settings > How Often Strips Auto Save.
- Miscellaneous This controls the beatby-beat annotation, the ST segment analysis location in the Preferences window, and some advanced file naming fields.
- Report This controls the default report set for the configuration. Additionally, you can customize the default report heading, front page, strip annotation, full disclosure, report summary, and saved strips fields in the Reports window. You can also change the company's name and address.
- Rhythm Different rhythm types can be added, and rhythm types can be replaced with other text or deleted. Rhythm types appear in the Comment field in Tables > Edit. They do not appear in the printed report.

- Scanning Criteria This controls the automatic settings that appear in the Scanning Criteria window. The window is accessible from the Patient Information window by clicking Settings > Scanning Criteria or from the main Holter menu under Settings > Scanning Criteria.
- Spectral Settings This controls the automatic settings that appear in the Spectral Analysis window. The window appears when you select Settings > Spectral Analysis.
- Spectral HRV This controls the the heart rate variability plots in the HRV menu.
- What Strips to Auto Save This controls the settings that come up automatically in this window in Settings > What Strips to Auto Save.
- Page/Saved Strips/Critical Events/ Superimposition/Calibration - This controls the appearance of some of the Review windows, the settings in some fields, and whether the window initially appears in Expanded mode.
- **Trend/Lorenz Plot** This controls the Type that is initially displayed.

Saving a configuration

For each configuration you create or edit, make changes in as many folders as you need to. When all folders reflect what you want to associate with that configuration, click the OK button at the bottom of the window. Your new configuration will be saved and the window closed; the main Configurator window then appears.

Exiting from the Configuration program

To exit from the Configuration program, click on the red Close button in the upper right corner of the window.

Using a configuration

The configuration is used when you start a new Holter test. When creating a new patient, the list of Configurations appears in the Type of Analysis/Report field on the Patient Information window.

By choosing a configuration, all of the items that were defined in the configurator will be applied automatically to your patient. Any of these settings can then be updated for your patient if you choose to do so, before or after analysis.

At any time you can go back and change the Type of Analysis/Report for a patient, but keep in mind that all settings will be reset to the new configuration and any editing you have already done to the patient will be lost.

10.LICENSING, UTILITIES & SET UP

Licensing

There are two options for licensing the software: 1)a permanent license that allows for unlimited number of uses of the software and 2)Pay-per-Use (PPU) license that counts and monitors the number of Holter files that have been analyzed by a user. All installations, regardless of license type, must include a license.ini file in the bin directory. When the software is running, the type of license or Uses Remaining (for PPU), is displayed at the bottom of the main screen.

For Permanent licensing, a physical HASP software key must be plugged into your PC or your network. When licensed to do so, a key can be shared by many users. The license file, license.ini, must be installed in the bin directory on each PC where HE/LX has been installed.



Sentinel HASP key

For Pay-per-use (PPU) licensing, Contact NorthEast Monitoring Technical Support for information on our PPU licensing program. Email to support@nemon.com or call [+1] 978-461-3992 option 1.

See Appendix B for more information on Network installations as additional setup is required for all license types.

Utilities

When installing the software, two additional utilities have been installed with the HE/LX Analysis Software: 1) HASPFinder and 2) Settings. Both utilities have been installed under "NorthEast Monitoring" programs list.

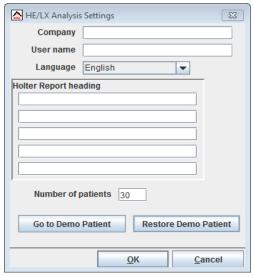
The HASPFinder Utility.

- The HASPFinder utility will look up and show you any NorthEast Monitoring HASP key that is visible to the computer. The utility will also show you the license.ini file and if the license.ini file matches any of the HASP keys plus:
- For PPU licensing, the HASPFinder utility will also show you the Use Count and Limit for you license.
- If your software has a Customer Code that can also be seen via the HASPFinder utility.

```
HASPFinder test program
                                 version:
     NorthEast Monitoring Keys Found:
    Serial
               Network
                            Use
                                      Use
    Number
               Licenses
                           Count
                                     Limit
    752b1fa6
                     0
                             58
                                       60
                     4
                            135
                                      500
License found - Pay-per-Use
HASP key
           Customer Code
    0004
```

The Settings Utility

In Settings, you can enter the names of both your facility and the primary user of your Holter software, along with five lines for the name and address that appear in the Reports window when you print a Holter report.



Settings window

Changing Language

The drop-down box will show the list of languages that are currently supported in the software. To change the language used throughout HE/LX Analysis, make your selection from the drop-down menu.

Number of Patients

To change the number of directories stored on the Patient List, you can enter a different number here. If you choose to increase the number, additional directories will be created, but if you need to decrease the number of directories, you will need Windows Explorer to do so, but be sure that the directories you are deleting are either empty or the patient data has already been archived.

NorthEast Monitoring recommends that you have no more than 500 patient directories, as when more than 500 exist, the speed of the system may be compromised. See Chapter 8 for more information on Archiving patient directories.

Go to and Restore Demo Patient buttons

If there is ever a time that you are unable to start the software because of a problematic patient record, you can use the Go to Demo Patient button to open the software. If for some reason the demo patient has been deleted, you can first restore it using the Restore Demo Patient button.

Patient Directories

Starting with Holter LX Analysis 5.4e, all patient files must exist in a single directory. The [PatientParentDir] denotes the directory location and size and can be found at the top of the h4w.ini file. By default, the pat directory will be created in the local application directory. You can modify it to meet your needs. Below are some examples of how it can appear:

[PatientParentDir] c:\nm\pat, 100 ;default example

[PatientParentDir]
e:\nm60\pat, 30
;default when software installed in other than nm directory, for example, nm60

[PatientParentDir] \\shared_dir\nm\pat, 30 ;\Network example

Permanently Delete Patient Directories

If for some reason you would like to reduce the number of patient directories, you must first delete the patient records in the directories you will delete. You can do this by going to the Patient List, selecting the patients, and then clicking the Delete button. You will then need to go to the Settings Utility window to reduce the number of patient directories, and then use Windows Explorer to delete unwanted directories permanently. Use the Archive function to save patient directory prior to deleting directories.

LX Remote Interface

The HE/LX Analysis software is able to receive Holter files and send report files through the LX Remote web-based system.

Note: Please ask your technical professional for assistance in setting this up. Also refer to the LX Remote manual for more information. All manuals can be found at www.nemon.com.

Plugins

The HE/LX Analysis software comes with plugins that enable the HE/LX Analysis and the LX Remote systems to work together. In order for these plugins to function, they must be copied from c:\nm\bin\Plugins_Available to c:\nm\bin\plugins, or wherever your HE/LX software is installed.

The plugins for Remote are:

- remotereceiveplugin.jar
- reportsendplugin.jar
- narpstatusbarplugin.jar

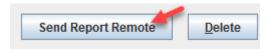
remotereceinveplugin.jar

This plugin enables the Remote Receive screen, which can be found from the Patient List.



reportsendplugin.jar

This plugin enables a button which allows you to send reports back to your remote users automatically. This button will be visible at the bottom of the Patient List.



narpstatusbarplugin.jar



This plugin enables NARP messaging which tells you if the NARP program has

stopped running, and when it is running, how many new files are available.

h4w.ini file

In addition to the plugin being installed in the proper directory, the following variables must be correctly set up in the h4w.ini file. If any of the plugins are not working as expected, you may one to check these:

The report upload directory. The location where the Reports directory is located for sending reports back to your users via the NARP. This should appear under the [NARP] section:

uploadDir = c:\nm\reports

The NARP status file. The name and location of the NARP status file that indicates that the NARP is running. In the [Settings] section:

narpstatusfile =
 c:\nm\narp\NARP_Status.ini

Interface for Foreign (not NorthEast Monitoring) Data Formats

The HE/LX software can be used to process ECG data from foreign recorders that use their own unique file formats. To accomplish this one converts the foreign data into an intermediate binary format (IBF) which can then be processed by HE/LX Analysis.

The license for the HE/LX Analysis system must include the "Data" option. Note that this requires the PPU (Pay-per-use) license option.

The following steps are necessary to enable a foreign recorder interface:

- 1. The plugin must be enabled. The plugin foreignrecorderimportplugin.jar must be copied from c:\nm\bin\Plugins_Available to c:\nm\bin\plugins.
- 2. The foreign data must be converted to the IBF format. This conversion utility is the responsibility of the vendor supplying the foreign data. The IBF data format is defined as follows:
 - 2.1 Up to three (3) channels of Holter data are supported. For each channel a separate binary file must be supplied. The files are to be named flashc0.dat, flashc1.dat and flashc2.dat for channels 1, 2, and 3 respectively. If fewer channels are to be processed, only generate the first N files as required. These files are to be placed in the \<nm>\bin\tmp directory (replacing <nm> with the actual installed location). The data must be in the form of 16-bit binary values with the least significant byte first (little endian).
 - 2.2 The least significant bit must be equivalent to a voltage at the electrodes of 12.5 microvolts.
 - 2.3 The sampling rate must be 180 samples per second.

- 2.4 The utility which produces or copies this data must be callable at the command line in a Windows-based system.
- **3.Pat.001 File.** If additional information, such as patient name or patient ID, are to be passed to the HE/LX Analysis program at the same time as the ECG data, a file called pat.001 must be generated.
 - 3.1 This is to be done by using a "blank" pat.001 file from the same version of the HE/LX Analysis system which will be used for analysis.
 - 3.2 To generate this system file, select "File-New" and select an empty patient directory and note the path to this directory but do not select it yet, exit the new/open window.
 - 3.3 Copy a flash.dat file into the empty directory. This can be the file from c:\nm\pat\demo. Again in "File->Open/New" select the patient directory found previously.
 - 3.4 Exit the program and get the pat.001 file which was generated in the directory selected above.
 - 3.5 Edit the line in the pat.001 file: IgnoreFlashFile = 0 to IgnoreFlashFile = 1
 - 3.6 Edit the DateRecorded (start date of recording) and TapeTimeBeg (start time of recording) in the following format:

DateRecorded = 12-Dec-2012 TapeTimeBeg = 12:12:00.000

3.7 You may also want to enter other recording identification into the pat.001 file before analyzing.

PatientNameLast = (optional)
PatientNameFirst = (optional)
ScanNo = (optional)
IdNo = (patient ID)
RecorderNo = (optional)

3.8 If there are diaries for the recording, they can be added to the [Diary] section with the time being the offset from the beginning of the recording. An example:

[Diary]

10:46:06.367 Event

10:53:03.900 Rapid HR

11:33:03.811 Palpitations

- 4. A batch file must be created which does the following:
 - 4.1 Calls the vendor supplied conversion utility to generate the tmp\flashcx.dat (IBF) files.
 - 4.2 Places the pat.001 file in the selected patient directory. The first argument to the batch file, which is accessed as %1, is the path to the current patient directory.
 - 4.3 Places a "dummy" flash.dat file in the selected patient directory. This file must be a valid flash.dat file but will not be used for analysis. The file in \nm\pat\demo can be used.
 - 4.4 Calls the utility unpackdc.exe as follows (missing flashcx.dat files are replaced with):

unpackdc %1\datacard.dat tmp\flashc0.dat tmp\flashc1.dat tmp\flashc2.dat 3

- 4.5 The batch file may be called userimport.bat and must be in the c:\nm\bin directory.
- 5. In the c:\nm\bin\h4w.ini file a line must be added after the [Settings] header and before the next [] section. The line is:

FRIImportCommand=userimport.bat \$PatientDirectory

with the userimport.bat name replaced by the batch file name actually used above.

6. If the sampling rate and/or scaling of the data cannot be provided as specified, then it is possible within a limited range to have the unpackdc.exe utility make some adjustments. This is only recommended if the LSB of the data is less than 12.5

micro volts or the sampling rate is greater than 360 samples/second. Run the unpackdc.exe utility at the command line with no arguments to view the full set of instructions.

- 7. To start processing the data:
 - 7.1 In the HE/LX Analysis program open File->Open/New.
 - 7.2 Select an unused patient data slot and the "Import ECG" button which has been enabled.

Import ECG

7.3 Clicking on the "Import ECG" button will cause the batch file from above to be run and will then open the Patient Information screen to allow processing to be started.

8. Sample / example batch file

Here is a sample of the batch file. It assumes that a recorder manufacturer created a callable executable named TZMM.exe instead of userimport.bat.

TZMM.exe -c 1 -f helx -i tmp\tz -o tmp\flashc0.dat

TZMM.exe -c 2 -f helx -i tmp\tz -o tmp\flashc1.dat

TZMM.exe -c 3 -f helx -i tmp\tz -o tmp\flashc2.dat

unpackdc %1\datacard.dat tmp\flashc0.dat tmp\flashc1.dat tmp\flashc2.dat 3

copy \nm60a\pat\demo\flash.dat %1 /y

copy import pat.001 %1\pat.001

In this case, the h4w.ini file should be modified as follows:

FRIImportCommand=TZMM.bat \$PatientDirectory

Remote Receive for PPU

A special feature allows you to create patient directories in advance so that you can receive recordings remotely and assign them into the patient folders using the Remote feature.

This can be accomplished by:

- 1. Add variable HISRemoteReceive = 1 under [Settings] in h4w.ini.
- 2. Populate empty patient directories with an externally generated pat.001 file.

Then, using Remote Receive, copy the remote files into the populated patient directories.

HIS Import Option

Hospitals can choose to save LX Remote flash.dat files to pre-loaded patient directories, by inserting the following variable into the h4w.in file under [Settings]:

HISRemoteReceive = 1 If this option is chosen, then Remote files can only be saved in pre-populated patient directories that are loaded via an external process.

HIS Export

HE/LX Analysis includes an interface to your hospital information system (HIS). Once a patient is completely analyzed and a PDF report has been saved, the user can save a copy of the patient data and final report in a location for your hospital information system to retrieve.

Once HIS Export is set up, a button can be found at the bottom of the Patient List. The button will be enabled only when a patient has a PDF report to copy.

HIS Export Setup

The HIS export plugin - hisexportplugin.jar - must be copied into the Plugins directory (from Plugins_available) in order for the HIS Export button to be visible on the Patient List.

Additionally, the following variables must exist in your h4w.ini file and need to have the correct paths in order for the HIS Export to function properly:

HISExportCommand = cmd /c rephis.bat "\$HISExportPath" HISExportPath = c:\HIS_Transfer\Pat-\$IDNO-\$DateRecorded-\$CurrentTime-Stamp

The HISExportPath determines where the files are saved. As per above, the files will appear in the user's c:\HIS_Transfer directory. Each file name will begin with the following format, Pat-\$IDNO-\$DateRecorded-\$CurrentTimeStamp, unless you choose to do otherwise.

The HIS Export Process

The user creates the HIS files by going to the Patient List, clicking on one or more patients, and then clicking on the HIS Export button. The HIS Export button will only be enabled if the patients selected have a report to export. Three files are created for each patient during this process:

- 3. cmp the existence of this file tells you that the other files are ready to be retrieved.
- 4. pdf the patient's Holter report
- 5. txt a text file in an xlm format with the patient data.

The File Format

The txt file includes the following data elements:

PATIENT INFORMATION

This information comes from the Patient Information window. Most of this information has been entered by the user.

- PatientName
- PatientNameFirst
- PatientNameMI
- PatientNameLast
- Physician
- DOB
- ScanNo
- IdNo
- Age
- AgeUnit
- Sex
- Gender
- RecorderNo
- Analyst
- HookupTech
- PhysicianInterp
- Indication
- Medication
- height
- heightunit
- weight
- weightunit
- bmi
- Recordermodel
- NoChannelsRecorded

SUMMARY INFORMATION

- DateRecorded
- DateProcessed
- TapeTimeBegin
- Minimum-Heart-Rate
- Mean-Heart-Rate
- Maximum-Heart-Rate
- Total-Time-Analyzed
- Total-Beats
- GP-Total-Time-Recorded
- GP-Heart-Rate-MEAN
- GP-Runs-VT
- GP-Runs-SVT
- GP-Pauses
- GP-Longest-PauseRR
- GP-Notes
- Percent-Artifact

PACED INFORMATION

- Total-Beats-Paced
- Percent-Beats-Paced
- Beats-Atrial-Paced
- Percent-Beats-Atrial-Paced
- Beats-Vent-Paced
- Percent-Beats-Vent-Paced
- Beats-AV-Paced
- Percent-Beats-AV-paced

PACED DATA INFORMATION

- Paced-Capture-Failure
- Paced-Sense-Failure
- Paced-Inhibition

PACEMAKER TYPE SETTINGS

- Pacemaker-Type
- Minimum-Programmed-Heart-Rate
- Maximum-Programmed-Heart-Rate
- Maximum-Ventricular-to-R-interval
- Maximum-atrial-to-R-interval

SUPRAVENTRICULAR SUMMARY

- Total-SVPB
- SVPB-Single
- SVPB-Pairs

- Total-SVT-Events
- Total-Beats-In-SVT
- SVPB-run3-greater
- SVPB-run4-greater
- SVPB-run5-greater
- SVPB-run69-greater
- SVPB-run10-greater
- SVPB-Beats-Greater
- SVPB-long-beats
- SVPB-long-time
- SVPB-long-BPM
- SVPB-fast-beats
- SVPB-fast-time
- SVPB-fast-BPM

A FIB

- AF-Beats
- AF-Events
- AF-Time
- AF-Percent
- AF-long-beats
- AF-long-time
- AF-long-BPM
- AF-fast-beats
- AF-fast-time
- AF-fast-BPM

BRADYCARDIA/TACHYCARDIA TABLE

- Beats-Bradycardia
- Time-in-Bradycardia
- Beats-Tachycardia
- Time-in-Tachycardia
- Perc-Beats-Bradycardia
- Perc-Time-in-Bradycardia
- Perc-Beats-Tachycardia
- Perc-Time-in-Tachycardia

BIGEMINY TABLE

- Bigeminy-Beats
- Bigeminy-3Beats
- Bigeminy-49Beats
- Bigeminy-1024Beats
- Bigeminy-25Beats

VENTRICULAR SUMMARY

- VENT-Runs-VT
- VENT-Beats-VTAC
- VENT-Total-Beats
- VENT-single-vpb
- VENT-Pairs
- VENT-run3-less
- VENT-run4-less
- VENT-run5-less
- VENT-run69-less
- VENT-run10-less
- VENT-beats-less
- VENT-run3-greater
- VENT-run4-greater
- VENT-run5-greater
- VENT-run69-greater
- VENT-run10-greater
- VENT-beats-greater
- VENT-long-beats
- VENT-long-time
- VENT-long-BPM
- VENT-fast-beats
- VENT-fast-time
- VENT-fast-BPM

SETTINGS

- SET-Tachycardia-rates-greater
- SET-Bradycardia-rates-less
- SET-Pauses-greater
- SET-Categorize-SVT-greater
- SET-Categorize-VT-greater
- SET-Signal-Quality
- SET-Number-Channels-Processed
- SET-Primary-Channel
- SET-Alternate-Channel
- SET-Automatic-Channel-Selection
- SET-Automatic-ST-marker-selection
- SET-Process-ST-Events
- SET-Artifact-Filter
- SET-Narrow-QRS
- SET-Extra-Dead-Time
- SET-Label-SVPB-prematurity
- SET-Label-Early-VPB-prematurity
- SET-Minimum-AF-Peak-HR
- SET-Minimum-AF-time

- SET-SVBs-Disabled
- SET-Maximum-Analysis-Duration
- SET-Interval-Size
- SET-Lead-Label-1
- SET-Lead-Label-2
- SET-Lead-Label-3

ST EPISODE TABLE

- ST-EPISODE-Elevation-MM-Baseline
- ST-EPISODE-Elevation-MM-ISO-ELEC
- ST-EPISODE-Elevation-Integral
- ST-EPISODE-Depression-MM-Baseline
- ST-EPISODE-Depression-MM-ISO-ELEC
- ST-EPISODE-Depression-Integral

TIME DOMAIN CALCULATIONS

- SDNN-ms
- Max SDNN-ms
- SDANN-ms
- RMSSD-ms
- SDNN index-ms
- NN50 count
- pNN50-percent
- HRV triangular index
- Differential index-ms
- Logarithmic index

APPENDIX A CALCULATION OF HEART RATE

Types of heart rates

A variety of heart rate calculations are made by HE/LX Analysis. They include:

- Current heart rate
- Minute-by-minute heart rate
- · Beat-by-beat heart rate
- Mean heart rate in intervals
- Mean heart rate for Holtered period
- · Second heart rate
- AF Heart rate
- Heart rate strips

Current heart rate

This is a complex function that takes the current beat and the beats preceding it into account. This weighted average follows these rules:

- 1. If the differences between the adjacent beats of the preceding four RR intervals are no more than 12 percent of the average RR interval for the previous beat and the beats are all normal, then the new average RR interval is the simple average of the previous four RR intervals.
- 2. If the previous four RR intervals were NOT bigeminy, VTAC or SVT AND the current RR interval is within 25 percent of the previous average AND the previous two beats were not ventricular AND the previous 10 beats were not supraventricular, then the new average RR interval is 1/8 of the current RR interval plus 7/8 of the previous average.
- 3. If the previous four RR intervals were NOT bigeminy, VTAC or SVT AND the current RR interval is not within 25 percent of the previous average OR any of the previous two beats were ventricular OR any of the previous 10 beats were supraventricular, then the new average is 1/32 of the current RR interval plus 31/32 of the previous average.
- 4. If the previous four RR intervals were bigeminy, VTAC or SVT, then the average RR interval is changed by 0.000087 seconds. It is increased if the current interval is longer than the previous interval, otherwise it is decreased.

Once the current average RR interval is determined, the current heart rate is calculated as 60 divided by the current average RR interval, that is, current HR = 60/(current RR interval).

The current heart rate is used as the heart rate that appears in the heart rate data field for any displayed strip. This includes the heart rate associated with any strip in the Selected Strips window and in the printed report.

The current heart rate is also used to detect tachycardia and bradycardia. The onset of either is determined to be when the current heart rate reaches the tachycardia or bradycardia settings in the Scanning Criteria window.

The low and high heart rates reported in the Tables window and in the tables of the printed report refer to the lowest and highest current heart rate calculated during the interval.

Heart Rate calculation limits

The absolute limits are 20 and 300 (3 seconds to 0.2 seconds). If the "additional dead time" is not set to zero, then this upper limit can be lowered further. If the "additional dead time" is set to 0.1 or greater, then the HR upper limit is = 30 / (additional dead time).

Minute-by-minute heart rate

The heart rate plotted in the Trends window is a minute-by-minute heart rate. It is calculated as 60 times the number of beats processed in the minute divided by the sum of all RR intervals of beats processed in the minute (in seconds).

Beat-by-beat heart rate

The heart rate associated with each beat in expanded displays whenever the Annotation field in the Preferences window is set to Heart Rate is the beat-by-beat heart rate. It is calculated based on the RR interval following the labeled beat. Beat-by-beat heart rate equals 60 divided by RR interval, that is, HR = 60/(RR).

Mean heart rate in intervals

In the tables (in Tables window and printed report), the mean heart rate within each interval is calculated by dividing the number of beats in that interval by the amount of time processed within the interval.

Mean heart rate for Holtered period

In the Report Summary (in the Report Summary window and printed report), the mean heart rate during the Holter test is the number of beats counted divided by the amount of time processed.

Second heart rate

The second heart rate is the heart rate associated with a run of VTAC or SVT. It is calculated as 120 divided by the sum of the current RR interval and the previous RR interval. The second heart rate appears in strips with VTAC or SVT in Selected Strips, the printed report, and the strip list, labeled HR2.

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The second heart rate is used to determine where in the ventricular and supraventricular run tables a run of VTAC or SVT appears. The heart rate separating fast from slow runs is determined by the VTAC and SVT settings in Scanning Criteria, but the rate of each event is considered to be the second heart rate.

The second heart rate is also used to determine which run is identified as the fastest run of VTAC and SVT.

AF heart rate

The AF heart rate is used to determine the Fastest AF strip and is also the HR that appears on any AF type strip created by the software. The AF heart rate is calculated from the average of the RR intervals that are completely within +- 3.75 seconds of the current beat, which is the same as the standard 7.5 second strip.

Heart rate strips

In the Critical Events window, there is a choice in the Type field called "HR strips." This displays all ECG from the Holter test divided into 7.5-second strips. Each strip includes a time-of-day and a Strip HR. That Strip heart rate is the total number of RR intervals (including partial ones, but excluding artifact) within the strip divided by the sum of the RR intervals.

Defining dead-time

Dead-time is the amount of time (in seconds) after a detected QRS complex during which the software will not look for another QRS complex. Generally, this helps to prevent the mis-identification of tall T-waves as QRS complexes.

The operator can add more time to the tail end of the dead-time using the Extra dead-time setting in the Scanning Criteria window. Because the recovery time (i.e., the width of the T-wave) varies with heart rate, the dead-time built into the software adjusts based on the current heart rate. At higher rates, the dead-time decreases, and at lower rates, the dead-time increases.

The heart rate determines the dead-time as shown in the following table:

TABLE 1. How Heart Rate Determines Dead-time

Heart rate	Dead- time	Heart rate	Dead- time	Heart rate	Dead- time	Heart rate	Dead- time
30 - 45	0.50000	80	0.23812	115	0.22000	150	0.20000
50	0.43500	85	0.22000	120	0.22000	155	0.19354
55	0.38727	90	0.22000	125	0.22000	160	0.18750
60	0.34750	95	0.22000	130	0.22000	165	0.18181
65	0.31384	100	0.22000	135	0.22000	170	0.17647
70	0.28500	105	0.22000	140	0.21428	175	0.17142
75	0.26000	110	0.22000	145	0.20689		

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APPENDIX B NETWORK INSTALLATIONS

Network HASP Key Installation

For Permanent and Timed licenses only.

System Requirements:

- 1. The network HASP key server should be a minimum of a Windows 7, which is visible (can be pinged) from each client computer.
- 2. The network HASP key server must have one USB port available.
- 3. Port 1947 must be available on all computers for use by the Safenet drivers.

Installation:

- 1. Install the HASP User Setup on the network license server. During this installation, the installer will ask for permission to modify the firewall (if any) to allow network access to the Safenet drivers. This must be allowed.
 - The current HASP installer is available at www.nemon.com on the Support page under "Technical Support Files."
- 2. Put the HASP key in an available USB port on the server. Using USB hubs is allowed.
- 3. On each client computer, install the HE/LX Analysis program, and the Adobe Reader if prompted to do so. By default the HASPFinder utility will also be installed.
- 4. Install the license.ini file on each client computer.
- 5. Run the HASPFinder software on each client to verify that the HASP key can be seen from each location. The HASPFinder should also see the local license.ini file and confirm that it matches the HASP key.
- 6. Run the HE/LX Analysis program to confirm installation is successful.

Setting up Shared Network Patient Data

Beware that this will slow down response time, depending on the speed of your network. If you choose to set up network patient data, do the following below.

First, determine the location and number of patient directories.

Then, on each client machine, open the h4w.ini file that is located in the c:\nm\bin directory and do the following:

1. Delete the following lines:

[Current]

LoadedPatient = C:\nm\pat\xx PatDir = C:\nm\pat\xx LastPatient = C:\nm\pat\xx

2. Modify the line that immediately follows [PatientParentDir]:

from: c:\nm\pat, xxx

to the network path for the base of the patient directories followed by a comma and the number of directories that you choose to have created initially.

Next, start the HE/LX Analysis software on a single client machine. It will create the number of directories you specified on the network machine. (The system may fail as there is no demo patient yet.)

Lastly, and very important, copy and paste the "demo" patient directory from the client machine to the patient directory on the network.

PPU Networks - Additional step

In order to count Pay-per-Use (PPU) uses, the program will generate and update a file named procedure history.dat in the bin directory.

If HE/LX Analysis is being run on more than one computer, you will need to create an environment variable called NEM_PROC_HIST. The value of the variable needs to include the a shared network location that all workstations can access and update.

This is done by going to Control Panel->System->Advanced system settings->Environment Variables->System variables->New then enter (the variable value is an example):

Variable name: NEM PROC HIST

Variable value:

\\server name\\share name\\directory name\\procedure history.dat

Once the variable is create, re-boot the computer to make it effective. At command line, you can type "set" and all the settings should show.

Setting up Shared Network Patient Data

Beware that this will slow down response time, depending on the speed of your network. If you choose to set up network patient data, do the following below.

First, determine the location and number of patient directories.

Then, on each client machine, open the h4w.ini file that is located in the c:\nm\bin directory and do the following:

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[Current]

2. Modify the line that immediately follows [PatientParentDir]:

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to the network path for the base of the patient directories followed by a comma and the number of directories that you choose to have created initially.

Next, start the HE/LX Analysis software on a single client machine. It will create the number of directories you specified on the network machine. (The system may fail as there is no demo patient yet.)

Lastly, and very important, copy and paste the "demo" patient directory from the client machine to the patient directory on the network.

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Variable value:

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Once the variable is create, re-boot the computer to make it effective. At command line, you can type "set" and all the settings should show.

Windows 2008 Server Installation

First, each user needs a directory assigned to it in the form of "c:\user\test1" for user test1.

The user name should have no spaces. If there are spaces in the user name, then a logical redefinition will be required as the HE/LX Analysis program will not accept spaces in the path of the patient directories.

Then assuming the user names are of the form testxxx, the following has to be done:

- 1. Make a dummy installation of the HE/LX Analysis onto the C drive in the normal location c:\nm. This installation will not actually be used.
- 2. Copy the license.ini file into the c:\nm\bin directory.
- 3. Copy and paste the full directory (c:\nm) into each user directory c:\user\testxxxx, resulting in a bin path of the form c:\user\test1\nm\bin.
- 4. The file c:\user\test1\nm\bin\h4w.ini must be edited so that each instance of c:\nm\ is changed to c:\user\test1\nm\
- 5. See "Setting up Shared Network Patient Data" to allow for sharing of patient files

Now it should be possible to login to each user with "Remote Desktop Connection" and have all copies running at the same time up to the limit of licenses in the network key (dongle).

Once everything is up and running, if the number of users exceeds the number of licenses allowed, a message "no NEM dongle found" or a "no matching license" will appear.

If the space in user name limitation is a problem, it should be possible to use MKLINK to create a logical name which is acceptable.

It should be possible to create a script to do all this for each new user.

APPENDIX C TEST ISSUES

The following is a list of test issues that have been identified in this version of the software:

- 1. Lead labels don't translate during install. You will have to create new configurations with the translated lead labels that you desire.
- 2. A non-English install may complain that a symbols file is missing, even though it is not.
- 3. Lead labels can be made to be blank, but doing a reanalysis or update may restore the old label. Just be sure that lead labels are changed to blank before running report.
- 4. The new date on the screens does not change with the operating system date format. Always dd mmmm, yyyy.
- 5. HRV screens are available in non-English languages regardless of time analyzed. This data is not considered valid if time analyzed is greater than 24 hours.
- 6. Patient Info: medications and indications do not trigger new report. If you update either, be sure to create a new report in order to update.