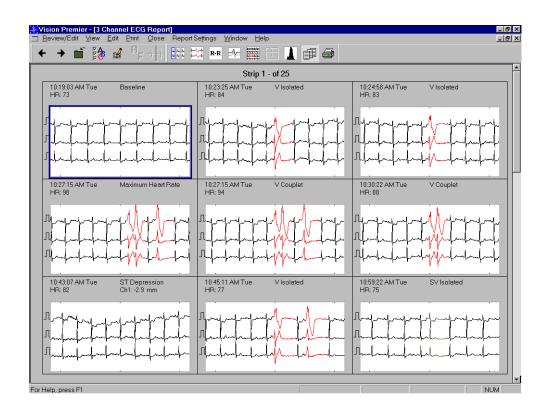
Operating Instructions



Vision™ Holter Analysis System

Software Version 3.5

Part No. 70-01234-01 Rev. A

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Intended Use

NOTICE: This device is intended to be used as a Holter Monitor Analysis System for the purpose of screening for ECG rhythm disturbances. It should be used by or under the supervision of those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

This device is intended to be used under the supervision of a qualified physician. The Vision™ Holter analysis system may be used in conjunction with standard 12-lead ECG analysis as an additional means for identifying heart disease. The extended recording period for Holter data provides a great deal more data than the standard 10second ECG recording. A Holter recording captures abnormalities which may be infrequent or provoked by specific activities.

Suggested indications for conducting Holter analysis include:

- ✓ Arrhythmias
- ✓ Chest pain
- Unexplained syncope
- ✓ Shortness of breath
- ✔ Palpitations
- ✓ Evaluation of a pacemaker
- ✔ Regulation of antiarrhythmic drugs
- ✓ Evaluation of a patient after myocardial infarction
- ✓ Family history of heart disease

The VisionTM system uses a sophisticated algorithm to detect, measure and classify QRS complexes. Each beat is classified and grouped into classifications called forms.

After the VisionTM system has performed its analysis of the data, you may then review and change the system's classification.

When editing has been completed, the VisionTM system automatically recompiles the report and incorporates your changes into the final results. All aspects of the report are affected; hourly totals and beat totals.

NOTICE: Computer assisted analysis is a valuable tool when used properly. However, no automated analysis is completely reliable and the results should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

Software Version

This manual contains instructions for using Version 3.5 of the Vision[™] software. To check the version of the software you have installed on your system, perform the following steps:

- 1. From the Windows[®] desktop, start the VisionTM application as described in the setup manual.
- **2.** Under Help on the menu bar, select About Vision... The software version is indicated in the window that appears.

Electronic Manuals

VisionTM software includes electronic manuals, if this optional feature has been installed. To access electronic manuals, including the VisionTM Series Setup Guide, VisionTM Operating Instructions, perform the following steps:

- 1. From the Windows® desktop, double-click the program icon. This will start the program.
- 2. Under Help on the menu bar, select Setup Guide or one of the other manuals that are listed.

NOTE: The Operating Instructions is listed as Main Manual.

Warnings, Cautions & Notices



Warnings

WARNING: Most waveform displays are not diagnostic quality. Due to monitor video resolution, waveforms displayed on the monitor are for viewing purposes only. To view data that is diagnostic quality, use the report strip view or print the record.

WARNING: Remove all Holter sensors from the patient before defibrillation. There is a risk of defibrillation failure, burns and equipment damage if defibrillator paddles contact sensors or cables. In the special case where the patient has a defibrillator at home, family members and in-home caregivers who could be responsible for attempting defibrillation must be advised of this hazard.

WARNING: Explosion hazard. Do NOT use in the presence of flammable anesthetics

Cautions

CAUTION: Edits made directly to Holter report e-mail attachments cannot be saved. To edit Holter reports received via e-mail, first save the attached report to a secure file location (requires an .rps file extension).

CAUTION: Do NOT use acetone, ether, freon, petroleum derivatives or other solvents to clean the recorder

CAUTION: Although Burdick recorders are designed to meet IEC 60601-1-2 EMC immunity requirements, the presence of strong EMI fields generated by electronic, surgical or diathermy instruments in close proximity to the unit may cause trace noise or input overload conditions.

CAUTION: To avoid operator injury refer to you PC owners manual for proper ergometric use.

Notices

NOTICE: U.S Federal law restricts this device to use by or on the order of a physician.

NOTICE: Computer assisted analysis is a valuable tool when used properly. However, no automated analysis is completely reliable and results should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

NOTICE: Because the Holter system offers different lead configurations, always ensure that the appropriate sensor placement is employed for the lead configuration selected.

NOTICE: This device is intended to be used as a Holter Monitor Analysis System for the purpose of screening for ECG rhythm disturbances. It should be used by or under the supervision of those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

Chapter

1

Introduction to VisionTM

Inspection Upon Delivery

Your new VisionTM Holter Analysis system was carefully inspected before shipment. Please inspect all components upon delivery for any damage which may have occurred in transit. If you notice any damage, please contact your shipping agent. If items are missing, contact your local representative or call VisionTM Customer Service at (800) 426-0337 or (262) 953-3500.

NOTE: Your Vision[™] system is intended for use with approved supplies; its reliability and performance are directly affected by the supplies you use.

All functions of the VisionTM system are designed to be user-friendly and easy to understand. If questions arise or you would like additional information, contact your local representative or VisionTM Technical Support Department at (800) 426-0337 or (262) 953-3500.



Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIa.



Complies with the EMC/Radiocommunications requirements set out by the Australian Communication Authority under Radiocommunications Act, 1992.

System Requirements

In order to run the VisionTM program your computer system will need to meet minimum requirements. For more information, refer to Chapter 1 of the VisionTM Series Setup Guide.

Starting the Program

NOTE: Reference your PC/ peripheral manual for hardware installation.

Starting from the Icon on the Desktop

- **1.** Turn on your computer.
- 2. Double click on the VisionTM Series Holter System icon to start the program.



3. The VisionTM program is started and the *Report Manager* window is displayed.

Exiting the Program

To exit, click on Procedure then select Exit in the Vision™ *Report Manager* window. The Windows[®] desktop is displayed.

Removing the PC Card

If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer.

NOTE: The following procedure applies for internal PC Card drives only. Disregard the following if you are using an external PC Card drive.

- 1. To deactivate the PC Card drive, click on the PC Card symbol in the lower right corner of the desktop.
- **2.** Safely remove hardware.

NOTE: "Safely removing hardware" is done in two ways. The system may ask to safely remove the hardware, then stop the media, or may request the user to eject the media. Either way, the media must be stopped or ejected using a mouse click on the media message.

3. When the PC Card is deactivated, Windows[®] will display a confirmation message. Click [OK] and remove the PC Card from the computer.

Search by Time

You can search for specific times in the Holter report using the graphic summary view (see "Graphic Summary" on pg. 5-9). Time is indicated near the bottom of the window. Locate the desired time and double click to view the beats.

You can also search for specific times in the full disclosure view. For more information, see "Search by Time" on pg. 8-3.

Running Vision™ Remotely

Windows[®] remote operations are built into Windows® XP and Windows® 7 but are not part of Vision.

Getting Around

The VisionTM system follows Microsoft[®] Windows[®] conventions for manipulating files and issuing commands. When you start the program, two windows are displayed, one for the application and one for the report manager. The application window includes the title and menu bars, toolbar, control-menu box, minimize and maximize/restore buttons and, when necessary, vertical and horizontal scroll bars. The **Report Manager** window has only its own title bar and window controls.

You can move around within each window by dragging or clicking the scroll bars, and can resize each window by clicking and dragging the borders and corners. Click and drag the title bar to move the window itself about. To reduce the active window to an icon, select Minimize from the control-menu box or the Minimize button. To have the window fill the screen, click on the Maximize button. (*Report* windows are always maximized when they are first opened.)

The program will display multiple, independent windows, so you can have several different reports open at once. Each report will have its own window and can be separately moved, resized, opened and closed, and printed. To make a window active, just click on it, or press F-T to cycle through the open windows.

Objects are special items displayed on the screen. You can use these items to interact with the system:

- Menu Bars
- **Toolbars**
- Context Menus
- Dialog Boxes
- **Confirmation Boxes**

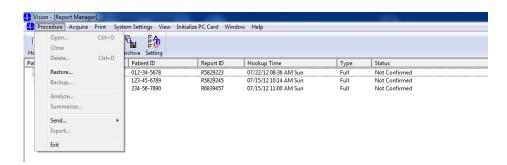
NOTE: When an object appears lighter than the rest, or grayed-out, this means that the object is not available. An object may be unavailable if:

- VisionTM is not in the appropriate mode to utilize that object.
- ✓ Your version of VisionTM does not support the object's function.

Menu Bars

Menu bars may be used to select an item such as a new window or to select a function such as acquiring a new record from the Holter recorder.

Figure 1-1 Menu Bar



Menu bars contain two basic types of commands. "Executing" commands carry out tasks immediately when selected and "Dialog box" commands, followed by an ellipsis (...), bring up dialog boxes.

You can use either the mouse or the keyboard to activate and use menu commands.

Using the Mouse

- 1. Position the pointer over the menu bar item and click. More choices become available.
- 2. Click on one of these items to select it or click anywhere outside the menu bar to cancel.

Using the Keyboard

- 1. To activate a menu bar item, hold down the A key and press the appropriate "hot key."
 - A hot key is a key on the keyboard which is temporarily specialized to perform a function. To indicate which key will perform this function, a letter is underlined. For example, r is the hot key which activates the Procedure menu bar item.
- 2. To select an item from the pull down menu that appears, press the appropriate hot key. (A is not needed once the pull down menu is activated.)
 - Instead of hot keys, you may use the Z and Y keys on the right side of the keyboard. With these keys, highlight the desired item and press E to select it.
- 3. You may deactivate pull down menus by pressing A or moving to other menus with the Q or R key on the right side of the keyboard.

Toolbars

Toolbars are a row (or rows) of icons located just below the menu bar. Toolbar icons are provided to allow you to initiate a function or to advance to another window with just a single click of the mouse. All of the icons have a corresponding menu bar and/or drop down menu which will perform the same function.

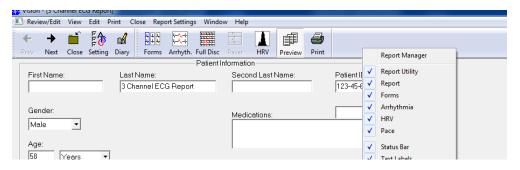
Figure 1-2
Toolbar



The icons presented in the Vision[™] system toolbar change according to what is shown in the active window. For example, if you are currently reviewing forms, you are presented with additional icons to enable you to quickly switch to another type of form.

You have the option of choosing which toolbars are displayed and whether or not the text labels are on or off. To change these options, point the mouse anywhere in the toolbar area and right click. A context menu will appear. Options are active when they have a check mark next to the name. If you make any changes to these options, your selections will become active after the program has been restarted.

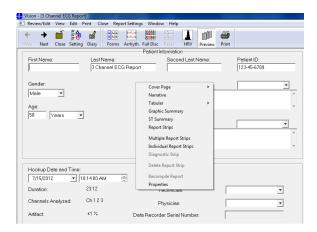
Figure 1-3Toolbar Options



Context Menus

A context menu is a list of functions available to you in context to whatever you are pointing the mouse at when you activate the menu. You can activate a context menu by right clicking within a window. Not all windows have context menus.

Figure 1-4 Context Menu



Dialog Boxes

Dialog boxes are used to enter information by typing in edit fields, picking from pulldown menus, or selecting check boxes or radio buttons. Dialog boxes also include buttons for indicating you are finished and want the program to accept the new settings or to escape without making any changes.

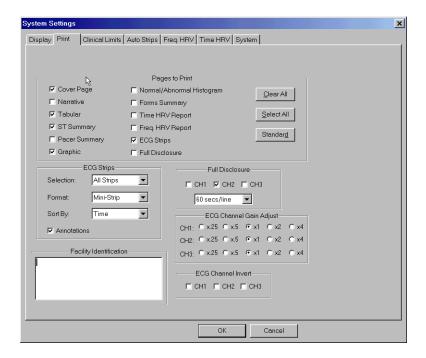
Dialog boxes may include any or all of the following objects:

- ●Edit Fields
- List Boxes
- Check Boxes
- Radio Buttons
- ●Tabs

Edit Fields

An edit field is a box where you can enter text from the keyboard. To view a window with edit fields, click on the System Settings icon in the toolbar of the *Report Manager* window.

Figure 1-5
Edit Field



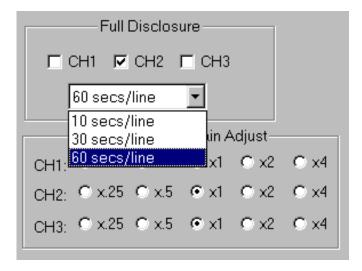
The Facility Identification field is an Edit field. Move the mouse pointer into this field and click to activate the field. Notice that the pointer turns into an I-beam ($\boxed{}$) in these fields. Edit fields accept text from the keyboard when they are active. This is indicated by a blinking cursor at the insertion point. Start typing and the characters you type are placed into the box.

Space in edit fields is limited. Each edit field accepts a specific type of information. For example, some accept only numbers within a preset range. If you type invalid information, a dialog box will inform you of the problem.

List Boxes

A list box is a box with a list of available choices. An example of a list box is shown for the Full Disclosure option in the Print tab of the *System Settings* window.

Figure 1-6
List Box



List boxes are not fully displayed until activated by clicking the expand button (). To select an item from a list, position the pointer over the item and click. Click outside the list to deactivate it.

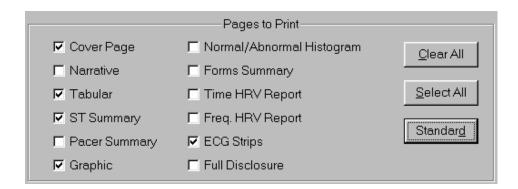
You can create or add to some of the lists that are available on the VisionTMsystem. Most of these user-editable lists are found in the *Patient Demographic Information* and the *Miscellaneous Data* windows. These lists are identified by a special expand button (...). Click this button to access the window where the list can be edited.

Check Boxes

A check box is a small square object.

Check boxes are either selected or unselected. A selected check box is indicated by a check mark. Click in the check box to select or deselect that item. Any number of check boxes may be selected.

Figure 1-7 Check Boxes

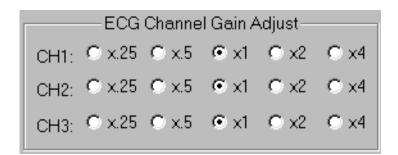


Radio Buttons

A radio button is a small round object that is always displayed in a group of two or more, mutually exclusive buttons.

Like check boxes, radio buttons are either selected or unselected. A selected radio button is indicated by a filled-in dot. Unlike check boxes, selecting one radio button in a group causes any other radio button in that group to become unselected. Click on the radio button to select the desired item.

Figure 1-8 Radio Buttons

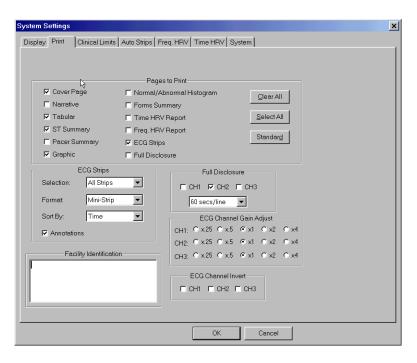


Tabs

Some windows have more information in them than can be displayed at one time. The problem of displaying all the information is handled by using tabs.

Windows with tabs have multiple "pages" that are overlapping. A tab from each page is visible at all times. You can click on the tab to display the corresponding page.

Figure 1-9 Tabs



Confirmation Boxes

A confirmation box is a small window with just one or two buttons, usually [OK] alone or both [OK] and [Cancel] together. These boxes provide you with information or ask you to verify an action. They disappear after you select a button.

An example of a confirmation box is displayed if you try to delete a record in the *Report Manager* window.

Figure 1-10
Dialog Box



You must respond to a confirmation box in order to continue working. In the above example you must click [OK] or [Cancel] to acknowledge the message.

PC Card Recording Preparation

To prepare for a patient recording, you must prepare the recorder and connect the recorder to the patient. Please refer to the Operating Instructions that came with your recorder for further information. If you are using a PC Card recorder, the PC Card must be initialized prior to being inserted into the recorder.

The Vision[™] system provides two methods for initializing the PC Card. If you are experienced with patient hookup and PC Card initialization, follow the instructions given in "Initializing the PC Card" below. The Vision™ system also offers a "Hookup Wizard" to guide you through all of the steps necessary to ensure accurate recording results. (For more information, see "Hookup Wizard - Digital Recorder" on pg. 2-4.)

Initializing the PC Card

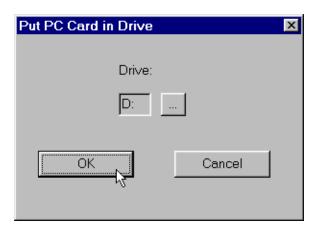
To record data from a patient you must first prepare the PC Card. This process is called Initialization.

NOTE: If, at any time, you are unable to proceed to the next step refer to "Maintenance & Troubleshooting" on pg. 11-1.

- 1. Remove the PC Card from the recorder and place it in the PC Card slot in your computer.
- 2. Start the VisionTM program. The *Report Manager* window is displayed.
- Select Initialize PC Card from the Menu bar.

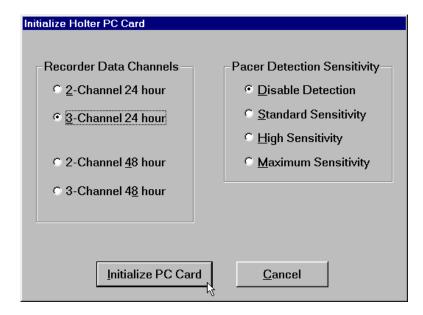
NOTE: If a PC Card is not inserted into PC Card drive, a dialog will appear requesting you to insert a PC Card. This dialog will also allow you to browse for the PC Card in case it is located in a different drive.

Figure 2-1 Insert PC Card Dialog Box



The *Initialize Holter PC Card* window is displayed.

Figure 2-2
PC Card Initialization
Options



NOTE: Your Vision™ system automatically recognizes the size of the PC Card being initialized and will grey out options not available to that specific card.

- **4.** Select the appropriate number of recorder data channels and time duration to record by clicking the corresponding radio button.
- **5.** If you have the optional Pacer software installed on your system, select the appropriate detection sensitivity. Refer to the Pacer Operating Instructions for more information.

NOTE: If you are using a Burdick 4250 digital recorder, the hardware supports two levels of sensitivity, ON or OFF instead of the four listed on the screen. Disable on the screen will set the recorder sensitivity off. All other selections will turn sensitivity on.

6. Click [Initialize PC Card] to begin initialization. The *Enter Patient Information* window is presented.

NOTE: The *Enter Patient Information* window will not appear if this feature has been disabled. If the window does not appear, proceed directly to step 7.

Enter the patient's information into the window. When you are finished, click [OK]. For more information, see "The Enter Patient Information Window" on pg. 2-3.

7. When initialization is complete, a confirmation dialog box is displayed.

Figure 2-3 PC Card Initialization Confirmation

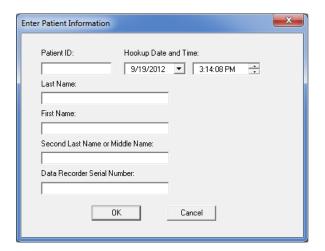


8. Click [OK].

NOTE: If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer. See "Removing the PC Card" on pg. 1-2 for more information.

The Enter Patient Information Window

Figure 2-4 Enter Patient Information



NOTE: Patient information entry is optional during initialization. You will also have the opportunity to enter patient information during record acquisition. If you prefer to enter patient information at a later time, click [Cancel].

Use the keyboard to enter information.

1. Enter the Patient ID (identification number).

NOTE: If you do not enter a patient ID, VisionTM automatically generates a patient ID that begins with STAT#. Patient ID, as well as other patient information fields, can also be edited when acquiring the patient record from the PC Card.

- 2. Click in the Last Name field and enter the patient's Last Name.
- 3. Click in the First Name field and enter the patient's First Name.
- 4. Click in the Second Last name or Middle Name field and enter the patient's second last name or middle name.

- 5. Click in the Data Recorder Serial Number field and enter the recorder serial number (this is located on the back or inside of the recorder).
- 6. The Hookup Date and Hookup Time are automatically filled in with the current date and time. Change this information if necessary.
- 7. When you are finished entering information, click [OK].

Hookup Wizard - Digital Recorder

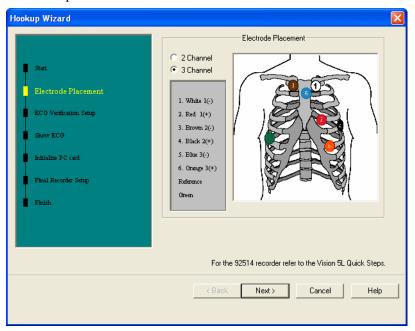
The Hookup Wizard includes three tiers of information:

- ✓ an outline of all the necessary steps
- ✓ detailed instructions in for each step (text and/or graphics)

The Hookup Wizard guides you through all of the steps necessary to ensure accurate recording results. The wizard also initializes the PC Card for you. As the wizard guides you through the appropriate steps, you may press [Back] at anytime to review the previous steps and any choices you have made.

- 1. Start the VisionTM program. The **Report Manager** window is displayed.
- **2.** Insert a PC Card into the PC Card slot in the computer.
- 3. Click on the Hookup Wizard icon () in the toolbar. The *Hookup Wizard* is presented.

Figure 2-5 Hookup Wizard -Electrode Placement

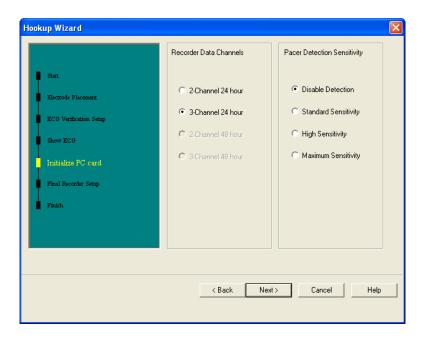


- **4.** Click on the appropriate radio button for either a 2-channel or a 3channel hookup.
- 5. Attach the electrodes on the patient as indicated on the screen.

NOTE: Welsh cups may be used at this point to eliminate waste of sensors during signal verification. The Welsh cup will leave a red mark on the chest to aid in final placement of the sensor.

6. When you are satisfied that the electrodes are properly placed on the patient, click [Next]. The *Initialize PC Card* screen is presented.

Figure 2-6 Hookup Wizard -Initialize PC Card



NOTE: Your VisionTM system automatically recognizes the size of the PC Card being initialized and will grey out options not available to that specific card.

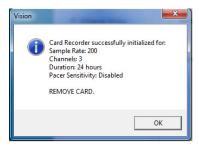
- 7. Select the appropriate number of recorder data channels and time duration to record by clicking the corresponding radio button.
- **8.** If you have the optional Pacer software installed on your system, select the appropriate detection sensitivity.
- 9. Click [Next]. The *Enter Patient Information* window is presented.

NOTE: The *Enter Patient Information* window will not appear if this feature has been disabled. If the window does not appear, proceed directly to step 10.

Enter the patient's information into the window. When you are finished, click [OK]. For more information, see "The Enter Patient Information Window" on pg. 2-3.

10. When initialization is complete, a confirmation dialog box is displayed.

Figure 2-7
PC Card Initialization
Confirmation



NOTE: If you are using an internal PC Card to acquire patient records, you must deactivate the PC Card drive before removing the PC Card from the computer. See "Removing the PC Card" on pg. 1-2 for more information.

11. Remove the PC Card and click [OK] to continue. The *Final Recorder Setup* screen is displayed.

Figure 2-8 Hookup Wizard – Final Recorder Setup



12. Follow the on-screen instructions for final recorder setup and click [Finish].

3

Acquiring & Analyzing Patient Data

After you have recorded data from a patient, you must copy the data to your computer for analysis.

VisionTM 3.5 is capable of copying recorded data from a PC card using either an external card reader, an integral card reader or through a Burdick 4250 recorder using a Burdick 4250 recorder connection cable. In all cases, Windows[®] will attach an unused drive letter to the PC card once connected regardless of whether inserted in a reader or located in the Burdick 4250 recorder. Steps to copy the data using VisionTM 3.5 will be the same for each type.

If you are using a card reader, remove the PC Card from the recorder and insert it into the PC Card bay on your computer.

NOTE: It may be necessary to shut the recorder down manually prior to removing the PC Card. For more information, refer to the instructions that came with the recorder.

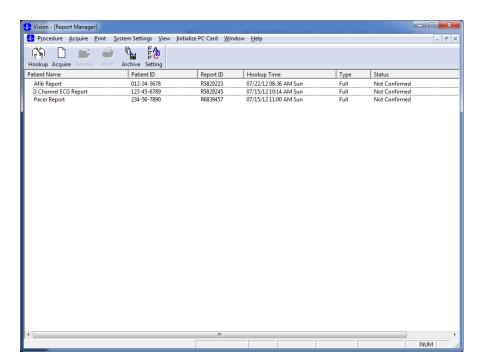
If you are using a Burdick 4250 recorder connection cable, ensure the PC card is inserted correctly in the recorder, then plug the cable into the recorder and plug the other end of the cable into the computer.

To acquire and analyze data:

NOTE: If, at any time, you are unable to proceed to the next step refer to "Maintenance & Troubleshooting" on pg. 11-1.

1. Start the VisionTM program. The *Report Manager* window is displayed.

Figure 3-1 Report Manager

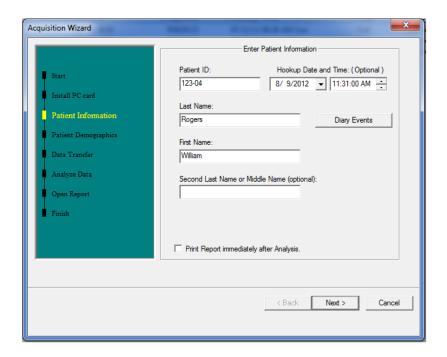


2. Select Acquire from the menu bar or click on the Acquire New Report icon (). The Acquisition Wizard is presented to guide you through the steps necessary to acquire the patient record from the recording media.

The *Enter Patient Information* screen is displayed.

NOTE: If patient information was entered during PC Card initialization, then this information will appear automatically in the Enter Patient Information window. Continue to step 14 on page 3-3.

Figure 3-2 Acquisition Wizard -**Enter Patient Information**



NOTE: Although it is possible to enter a total of 64 characters in each name field, VisionTM will display only the first 52 characters of the combined name fields in the **Report Manager** window. The name and patient ID may also be truncated to fit on the printouts.

- 3. Enter the Patient ID (identification number) [32 characters maximum].
- 4. Click in the Last Name field and enter the patient's Last Name [64] characters maximum].
- 5. Click in the First Name field and enter the patient's First Name [64] characters maximum].

NOTE: These are the only fields which are required in order to acquire the record from the PC Card. You may skip to step 11, if desired.

6. Click in the Second Last name or Middle Name field and enter the patient's second last name or middle name [64 characters maximum].

- 7. To apply preset clinical limits to the patient data, select one of the five options from the Clinical Limits Configuration pull down menu. See "Clinical Limits" on pg. 9-4 for information on the Clinical Limits settings.
- **8.** The Hookup Date may be automatically filled in with the date entered during initialization

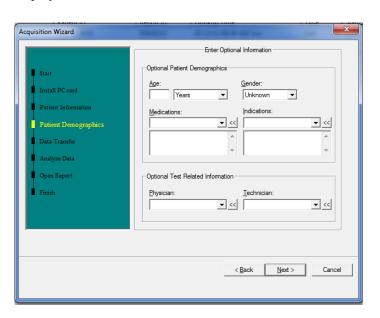
Use the patient diary to verify this information. Change the date if necessary.

- **9.** The Hookup Time is automatically filled in with:
 - ✓ the time entered during initialization, or
 - ✓ the current time

Use the patient diary to verify this information. Change the time if necessary.

- **10.** To add comments to the patient event list or to insert patient diary time and comments, see "Diary Event Entry" on pg. 3-5.
- **11.** Click [Next]. The *Enter Patient Demographic Information* screen is displayed.

Figure 3-3 Acquisition Wizard – Enter Patient Demographic Information



NOTE: All of the fields in this screen are optional. You may skip to step 17 if you do not wish to include any of this information in the patient's report.

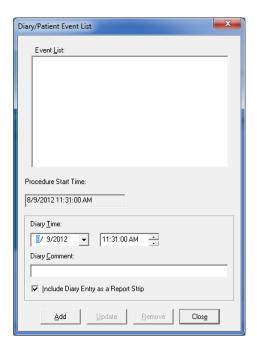
- **12.** Enter the patient's **Age** and select the proper age units from the drop down menu
- 13. Select the patient's Race from the pull down menu.
- **14.** Select the patient's **Gender** from the pull down menu.

- 15. Enter the patient's Height and Weight and select the appropriate units from the pull down menus.
 - **NOTE:** The lists that appear in the Medications and Indications fields may be edited. Click on the expand button (<) and you are presented with a new window where you can add, delete or edit the available selections.
- **16.** Select any Medications that the patient is taking from the pull down menu or, if the medications are not listed, type them in the text entry field.
- 17. Select any Indications that the patient exhibits from the pull down menu or, if the indications are not listed, type them in the text entry field.
- **18.** Click [Next] when you are finished editing the information in this screen. The record is copied to your computer and analysis is performed.
- **19.** The new record is listed in the *Report Manager* window. The complete, unedited report and full disclosure is now ready for you to review, edit and print.

Diary Event Entry

To add comments to the patient event list or to insert patient diary time and comments, click [Diary Events] in the *Enter Patient Information* window. The *Diary/Patient Event List* window is displayed.

Figure 3-4 Acquisition Wizard – Diary/Patient Event List



Using the patient's diary, enter information as necessary. If you want the diary entries included as a report strip in the final report, ensure this option is checked.

- To enter a diary event, enter the date and time under Diary Time. Use the keyboard to enter information under Diary Comment. Click Add to add the entry to the Event List. Repeat these steps as necessary to enter all of the diary events.
- To update an entry, select the entry in the Event List. Make changes as necessary in the Diary Time and Diary Comment boxes. Click [Update].
- To remove an entry, select the entry in the Event List and click [Remove].

When you are finished editing, press [Close]. You are returned to the *Acquisition Wizard-Patient Information* window.

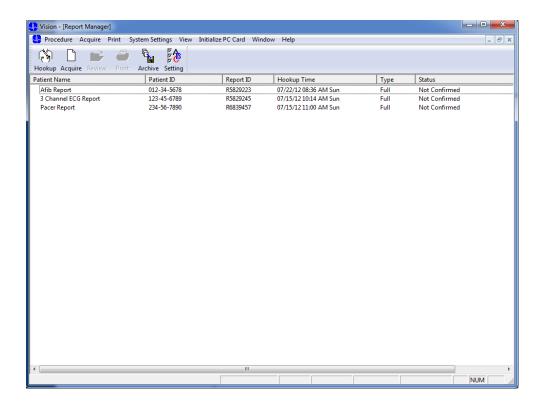
Chapter

4

Managing Reports

When you first start the VisionTM program, the first thing that is displayed is the *Report Manager* window.

Figure 4-1 Report Manager



This window is your starting point for accessing and organizing all of your patient records.

Sharing Records over the Network

NOTE: In order to share records over the network with other users, you must install multiple licenses of VisionTM. Additionally, you must configure the system for network use; for more information, see the VisionTM Series Setup Guide.

If another user on the network opens a record, then VisionTM locks the record to everyone but the user until the user closes the record. The record is unavailable to other users and shows a status of Opened Review/Edit in the *Report Manager* window.

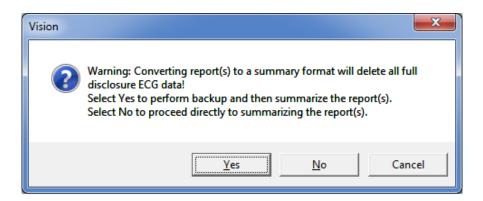
Sorting Patient Reports

At the top of the *Report Manager* window, below the toolbar, is a special kind of menu. This menu displays titles for the columns of information which are displayed for each report such as Patient ID. Click on a title in this menu to sort all the displayed records according to the information in that column into descending or ascending order.

Analyzing Patient Records

To eliminate any editing that may have been done on a patient's report and generate a new report based on the original data, you may re-analyze the report. To re-analyze a patient's record, highlight the record and click on **Procedure** in the menu bar then select **Analyze** from the pull down menu. The Select Channels to Analyze window is displayed.

Figure 4-2 Select Channels to Analyze



Select each of the channels you wish to re-analyze, and click [OK].

Changing Reports to be Displayed

You may determine which types of reports are displayed in the *Report Manager* window. The options are:

- ✓ All Reports
- ✓ Full Disclosure Reports only
- ✓ Summary Reports only
- Nonconfirmed Reports only
- Confirmed Reports only

These options make it easier for you to select the reports you wish to work with during a particular session.

Click on View in the menu bar and select the type of reports you wish to see displayed. The Refresh option updates the screen.

Tracking Open Windows

Another item in the *Report Manager* menu bar is the Window option. Select from the pull down menu under Window to manage how you want to view open windows. The Cascade option allows windows to appear over one another while the Tile option makes every window fit so that no window is obscured by any other.

Each open window is listed at the bottom of the pull down menu. The window which is currently active is indicated by a check mark.

Backup and Restore of Reports

The Vision™ system allows you to backup or store your patient records to any digital storage device that is accessible to your computer. You can then restore those reports in the toolbar. Select Backup or Restore from the options presented.

NOTE: The Full Disclosure, Final Report and summary reports may be archived.

NOTE: Roxio software is required to backup or restore using a CDR or CDRW driveon Windows® XP systems.

Backup Reports

This option allows you to backup a report to a local, network, optical, CDR or CDRW drive.

Select the Backup option and the *Backup Wizard* window is displayed.

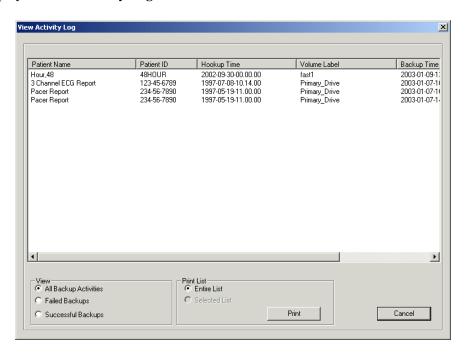
Figure 4-3 Backup Wizard



- 2. Under **Where**, enter the destination folder where you want the backup file to go. If you want to change the destination folder, click the [Browse] button to locate and select the new drive or folder you wish to use.
- 3. Click the [Finish] button to start the backup process. If an error occurs during the backup process, a message is displayed in the *Report Manager Status* column.

You may also select the [View Activity Log] button on the *Backup Wizard* window to display the *View Activity Log* window.

Figure 4-4 View Activity Log



This window automatically sorts reports according to the time of backup (the last report backed up is at the top of the list). The list can also be sorted into ascending or descending order by column title, such as Patient ID.

In the *View Activity Log* window, two additional group boxes are shown: the *View* group box and the *Print List* group box. Selecting a radio button in the *View* group box will automatically display the corresponding backup reports for the view selected. Selecting a radio button in the *Print List* group box will select the Entire List of reports or the Selected List of highlighted reports for printing. Click on a report to highlight it. To select more than one report, press and hold the C key while clicking on the reports.

NOTE: The **Selected** List option becomes active after a report is highlighted.

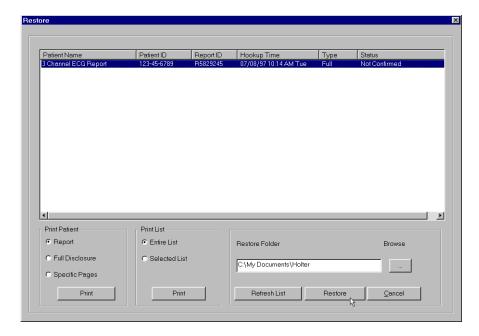
After making your selections from the *View* and *Print List* group boxes, click the [Print] button in the *Print List* group box to print your selection(s) from the *View Activity Log* window to your printer. To cancel any actions in the *View Activity Log* window and return to the *Backup Wizard* window click the [Cancel] button.

Restore Reports

This option allows you to restore a report from a local, network, optical, CDR or CDRW drive.

1. Select the **Restore** option and the **Restore** window is displayed.

Figure 4-5 Restore



- 2. Enter the *Restore Folder* where you want to get the report from. If you want to change the *Restore Folder*, click the [Browse] button to locate and select the new drive or folder you wish to use. The records available in the location you have selected will be listed.
- 3. If a folder is manually selected, click the [Refresh List] button to update the list according to what reports are available for restoring. Select the report to be restored by clicking once on it and tagging it. The *Print Patient* group box and the *Print List* group box options are now available. To select more than one report, press and hold the C key while clicking on the reports.

The **Print Patient** group box allows you to print specific components of an individual report without actually opening or restoring the report. Select the Report option to print the entire Final Report at the time the report was active in the system. Select the Full Disclosure option to print the entire procedure or portions of patient data as defined in the *System Settings* window (see "Print" on pg. 9-2.) Select the Specific Pages option to print only the Final Report pages that you select. A window similar to the **System Settings** window (see "Print" on pg. 9-2) is displayed allowing you to make selections that affect only the current printout.

The **Print List** group box allows you to print the Entire List of restorable reports or the Selected List of tagged reports as shown in the *Restore* window. Printing this list would be recommended in order to have a printed copy of a patient reports backed up on this logical drive.

4. Click the [Restore] button to start the restore process or click the [Cancel] button if you do not want to restore a report at this time.

Summarizing Reports

Once a Holter report has been reviewed by a doctor, and further actions have been taken (if necessary), full disclosure data may not need to be saved on VisionTM any longer. Full disclosure reports can be converted to summary reports using the Summarize procedure. When a report is summarized, full disclosure data is discarded. The summary reports consists of a cover page, VE tabular, SVE tabular, pacer tabular, narrative, graphic summary, ST summary and strips.

Summary reports require very little space compared to full reports, and therefore potentially can be saved longer than full reports (for more information, see "Maximum Reports" on pg. 9-6).

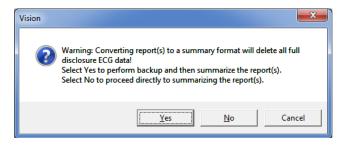
To convert a full disclosure report to a summary report:

1. Highlight the desired record in the *Report Manager* window.

NOTE: To select more than one report, hold down the Control key.

- 2. Select Procedure from the menu bar.
- **3.** From the pull down menu, select Summarize.
- **4.** The following message box appears.

Figure 4-6Summarize warning



To backup the full report before proceeding, select [Yes]. The *Backup Wizard* window is displayed. Enter the destination folder and select [Finish].

To proceed without backing up, select [No].

NOTE: Full disclosure data will be lost if the full report is not backed up prior to summarizing.

To exit without performing any action, select [Cancel].

Once a report has been converted a summary report, the Type as shown in the *Report Manager* window changes to Summary.

Chapter

Reviewing the Report

The VisionTM system provides a comprehensive and detailed report of a patient's ambulatory cardiac procedure.

NOTICE: Computer assisted interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable and interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

NOTICE: Waveform detection performance will exceed a combined score of 190 out of 200 based on the Publication titled "A model for Performance Evaluation of Ventricular Arrhythmia Detectors" presented in Computer In Cardiology, IEEE Computer Society, 1982 and in document "Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms." published by AAMI approved 27 April 1987.

Beat Classification

During analysis, the VisionTM Holter analysis system uses a technique known as feature extraction to group, based on their features, the individual QRS complexes into forms. These formal and heuristic features include QRS morphology, QRS width, QRS absolute area, QRS offset, QRS peak-to-peak amplitude and prematurity.

After the individual ORS complexes have been consolidated into forms, the forms are classified into one of the following categories: Normal (N), Ventricular (V), Paced (P), Other (?) or Artifact (A). Paced beats are identified only if you are using the optional pacer software.

Identification of ventricular and supraventricular arrhythmias takes place. These are then classified as runs, couplets, isolated or SV episodes.

Rate-dependent arrhythmias, tachycardia and bradycardia, are calculated on the basis of the RR intervals measured in an eight-beat sliding window.

Pauses are identified when an RR interval exceeds preset criteria.

ST changes, both negative (depression) and positive (elevation), that satisfy the criteria for amplitude, duration, and separation from prior episodes are identified as ST episodes.

Prior to printing the report, the classification of all arrhythmia and ischemic episodes can be reviewed and edited.

NOTE: The VisionTM system locks out the first five minutes of ECG data which is used for calibration. These beats are labeled U (Uneditable) in graphic displays.

Viewing and Editing

There are several ways to advance through the pages of the final report; use the method that is most comfortable for you:

- ✓ Select View in the Menu bar. From the pull down menu, select the page you wish to view.
- ✓ Press O/N.
- ✓ Click on the Next/Previous page icons (←/→) to move forward or back through the pages.

The Holter data and/or analysis information contained in some of the report pages is editable. If the information on such a page has been edited, then the lower left corner of the window will show * Modified by user. Refer to the graphic under "Narrative Summary" on pg. 5-6 for an example.

NOTE: The * **Modified by user** message appears only on the page that has been edited, and is limited to the following pages only: Narrative Summary, Ventricular Tabular, Supraventricular Tabular, Pacer Tabular, and ST Tabular.

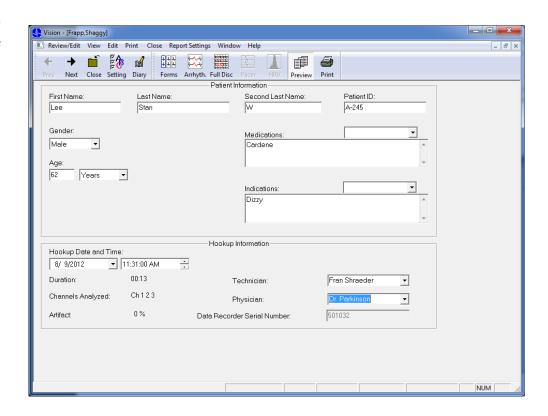
Following is a description of the pages that can be selectively included in the report.

Cover Page

Start from the Report Manager window. Double click the record you wish to review or edit. The *Patient Information* window is displayed. This is the first page of the Final Report Cover Page.

Patient Information

Figure 5-1 Patient Information

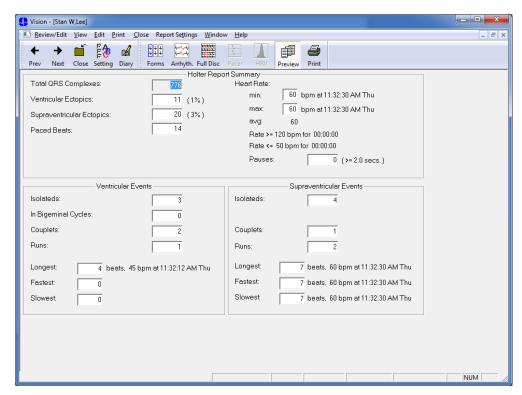


This window includes the patient demographics, medications and clinical indications. Enter the appropriate information using the keyboard.

NOTE: The entries for hookup time, recording duration and channels analyzed are entered during acquisition. You should verify that this information is correct.

Holter Report Summary

Figure 5-2 Holter Report Summary



This section draws the physician's attention to highest and lowest heart rate, total number of QRS, ventricular and supraventricular beats, severity of pauses and the time of occurrence, duration and rate of the longest, fastest, and slowest runs - both ventricular and supraventricular.

Any area that can be highlighted with the cursor can be edited. Before editing, however, you should be aware of the following:

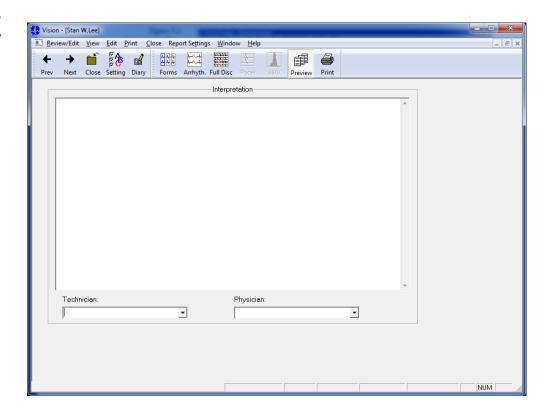
- This is the only place that Bigeminals are reported.
- Heart Rate (minimum and maximum) values must be between 0 and 250.
- The only change that you can make to the rest of the values displayed in this window is to change a value to zero. You can do this if you disagree with the calculated value and wish to have nothing printed on the Final Report. To edit these values to something besides zero, you should edit forms and arrhythmias so that the Vision™ system recalculates the results.

NOTE: Paced beats can be edited on the pace tabular summary page.

NOTE: The number of isolated ventricular beats indicated in the Summary section of the cover page is different from that indicated in the Review Arrhythmias display. This is because on the cover page every ventricular ectopic on the record is counted, however, in the Review Arrhythmias display, the last ventricular ectopic of every bigeminal cycle is not displayed.

Interpretation

Figure 5-3 Interpretation Page



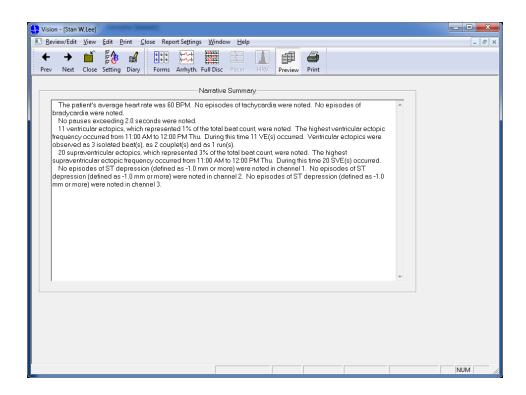
This section provides a place for the reviewing physician to type in the interpretation. Blank lines are omitted in order to save space on the printouts.

If you enter a name (or select one from the drop down menu) in the Transcribed By and Overreading Physician fields, the record report status will be changed to "Confirmed."

When the Cover Page is printed, there is a place for the reviewing physician to sign and date the interpretation.

Narrative Summary

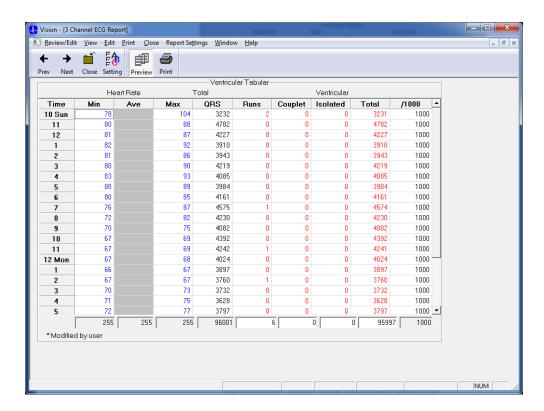
Figure 5-4
Narrative Summary



This page presents a concise statement of the results in an easy-to-read narrative style. It can be used as a preliminary guide for the physician's review of the report or be included in the report as the physician's interpretation.

Tabular Summary

Figure 5-5 Ventricular Tabular Summary



The Tabular Summary pages provide an hourly summary of the results. Variations in heart rate or frequency of arrhythmias during periods of activity or sleep can be easily identified.

1. Use the arrow keys to move through the columns and rows of each table.

You may edit any areas that can be highlighted by the cursor, however, if you change the quantity in the Total QRS column, even inadvertently, the system requires that it be changed to 0. You can do this if you disagree with the calculated value and wish to have nothing printed on the Final Report. To edit these values to something besides zero, you should edit forms and arrhythmias so that the VisionTM system recalculates the results.

2. After reviewing the Ventricular Tabular summary, advance to the Supraventricular Tabular screen. This screen is similar to the *Ventricular Tabular* screen.

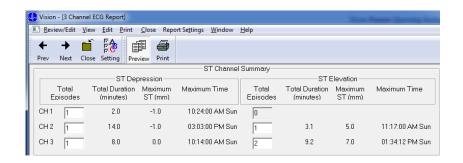
ST Summary

This page provides a detailed summary of all ST episodes that satisfy the clinical criteria for amplitude, duration and separation. It is divided into two sections.

NOTE: The printout of the ST Episode Summary will include a subset of all ST episodes displayed.

ST Channel Summary

Figure 5-6 ST Channel Summary

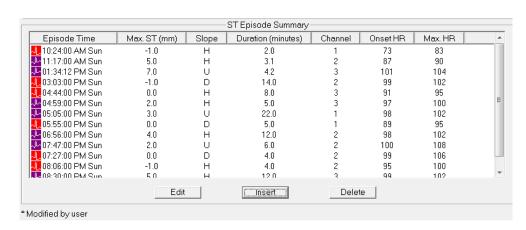


The ST Channel Summary provides:

- The number of episodes of depression or elevation.
- The duration of all episodes.
- The time and maximum depression/elevation of the episodes for each channel of data.

ST Episode Summary

Figure 5-7
ST Episode Summary



The ST Episode Summary provides the following information for each significant episode:

- Onset time and date
- Peak ST change (identified as elevation or depression)

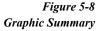
- Slope (downsloping, upsloping or horizontal)
- Duration
- Channel
- Heart rate at onset
- Heart rate at maximum ST change

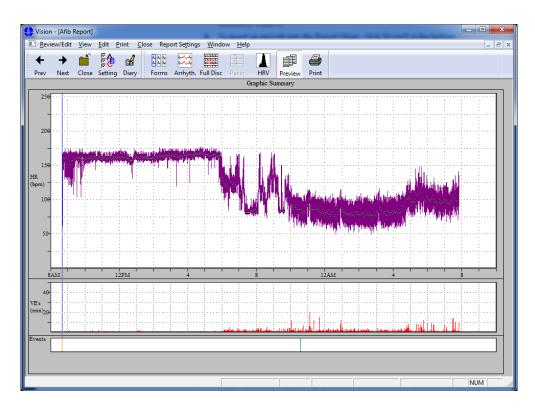
Each entry listed may be edited, inserted into the Report Strips or deleted.

- 1. Click the episode you wish to review or edit. The episode becomes highlighted.
- 2. To edit an episode, click [Edit] at the bottom of the screen. The ST Episode Edit window is displayed.
- 3. When all changes have been made, click [OK] to return to the ST Summary window.
- 4. To insert an episode into the Report Strips, click [Insert] at the bottom of the screen. The ST Episode Edit window is displayed.
- 5. Verify that all the information is correct and click [OK].

To delete an episode, click [Delete]. The episode is removed from the list.

Graphic Summary





This display shows trends in ST level, heart rate and ventricular frequency for a 24hour period.

Average ST level is graphed for each channel with 1-minute resolution.

Breaks in the graph indicate that ST measurements were interrupted because of ectopics, wide QRSs or excessive noise/artifacts.

Maximum, average, and minimum heart rates are graphed with 1-minute resolution. Note that the time and rate of maximum and minimum heart rates are also on the report cover page and are included automatically in the selected ECG strips.

Frequency of ventricular beats is graphed with 1-minute resolution.

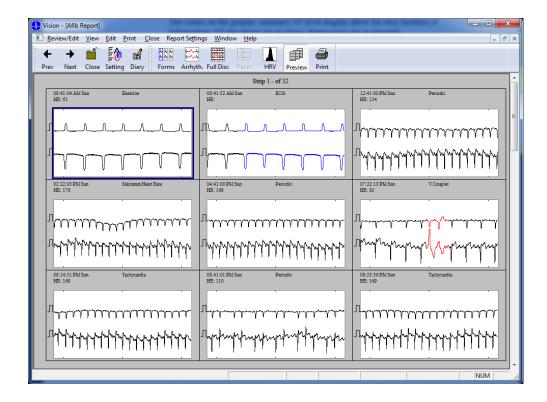
Tic marks (|) denoting the times at which the patient pressed the event button on the recorder are printed below the ectopic ventricular trends.

The colors on the graphic summary ST level display allow for easy location of information: ST elevations are in green; depressions are in magenta.

The HR graph is divided into two colors: green indicates the average; magenta indicates the high and low rate for each 1-minute interval.

Report Strips

Figure 5-9 Report Strips



The final report pages show some of the strips selected by the system to represent the arrhythmias noted in the report.

Each ECG strip shows the designation of the strip, the time and the heart rate. For some arrhythmias (such as runs, pauses and bigeminy) additional information is also included.

For clarity of presentation, the arrhythmia of interest is centered in the strip or, as in the case of runs, tachycardia, bradycardia, bigeminy or pauses, the onset of the arrhythmia is centered

The ECG strips will vary from report to report depending upon system configuration and the data being analyzed. The strips are presented either by time or by category, depending on the report configuration. If they are grouped by time, the strips are printed in chronological order starting at the beginning of the recording. If they are grouped by category, all strips of the same type (isolated, couplets, runs, etc.) are printed together.

To review the remaining report strips, press N or select the left or right arrow keys or click in the scroll bar located on the right side of the window. The strips are displayed one after another until the last strip.

The Report Strips may be edited and deleted.

1. To edit a Report Strip, click on the strip to highlight it and press E. A window similar to a diagnostic strip is displayed.

Figure 5-10
Report Strip editing



- 2. You may edit any of the fields which can be highlighted by the cursor. You can also select a strip label from the drop down menu.
- 3. When you have finished editing the report strip, press X.
- 4. To delete a Report Strip, click on the strip, in the Report Strip view, to highlight it and press the = key.

Chapter

6

Reviewing & Editing Forms

The Vision[™] system uses a sophisticated algorithm to detect, measure and classify QRS complexes as types of forms.

A form is a group of beats that have similar characteristics. Forms are broken down into five different categories: Normal, Ventricular, Other, Paced and Artifact.

Normal forms (N) contain normal beats and SVE beats.

Ventricular forms (V) contain ventricular, fusion, escape and idioventricular beats.

The Other forms (?) contain questionable normal beats that the system could not identify with 100% confidence. They are placed here for review and editing by you.

Paced forms (P) contain beats that were generated by a pacemaker (detected only when the pacer analysis software option is installed or when manually labelled by you).

Artifact forms (X) contain all detected events that were determined to be noise or artifact. T-waves, P-waves and noise are examples of Artifact forms and beats.

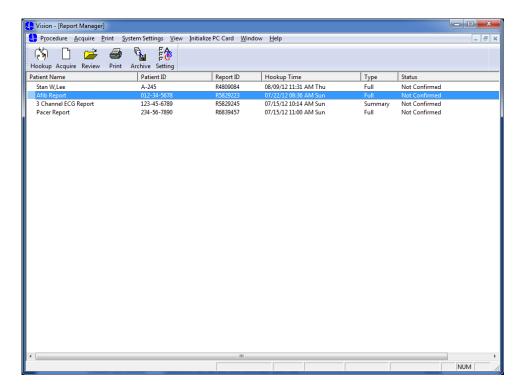
The Vision™ system offers many powerful editing capabilities that allow you to change the system's original classification. These editing capabilities allow you to override the form or beat classification assigned by the system.

When form editing has been completed, the VisionTM system automatically recompiles the report and incorporates your changes into the final results. All aspects of the report are affected; hourly totals and beat totals. Even strips selected for the report may be changed.

Reviewing Forms

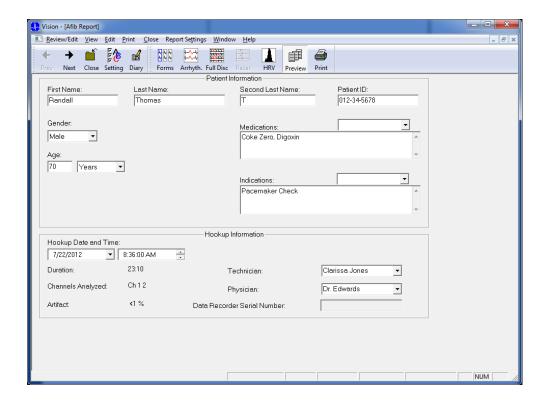
1. Start from the *Report Manager* window.

Figure 6-1 Report Manager



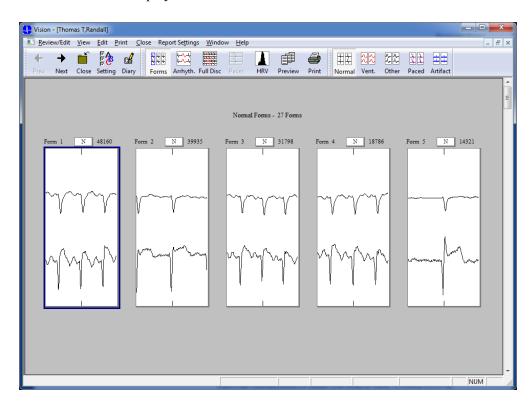
2. Double click the record you wish to review or edit. The *Patient Information* window is displayed.

Figure 6-2
Patient Information



- 3. Verify that the information displayed in the window is correct.
- **4.** Click the Forms icon () in the toolbar. The *Normal Category* forms window is displayed.

Figure 6-3 Normal Forms



NOTE: There are several ways to advance through the various sets of forms: 1.) Click on the icon for the classification of forms you wish to view. 2.) Select View in the Menu bar. From the pull down menu, select the classification of forms you wish to view. 3.) Press O/N or click on the Next/Previous page icons (\leftarrow/\rightarrow) to move forward or back through the pages. Use the method that is most comfortable for you.

NOTE: If there are more than 21 forms in the category, more than one screen may be displayed for that category and you will need to press N to move to the next set of forms or use the scroll bar to the right.

The Form Display

The forms are displayed in groups of up to 21 per screen. Each screen gives the following information:

- ✓ Category
- ✓ Number of forms in the category
- ✓ Each form's number and population
- ✓ Letter used to designate the form (for example, N for Normal)

Form Numbers

Form numbers are assigned based on the number of beats in the form (and does not depend on the beat category). Form 1 always has the largest number of beats.

Prime Forms

While reviewing forms you may notice that one form in a category does not display any waveform in the viewing window. This indicates that this is the prime form. The prime forms are also indicated by a small tic mark next to the form designation (\mathbb{N}).

The beats grouped in the prime form do not fit any other form. At least five beats that share the same morphology are required to create a form. If there are not enough beats to create a form, the beats are placed in the prime form for that category.

Displayed Channels

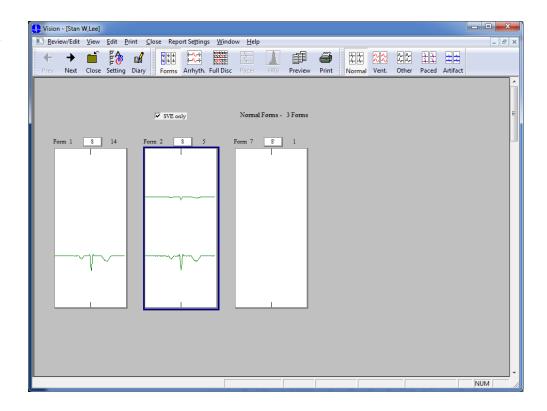
A form that does not display a waveform for channel 1 or channel 2, indicates that those beats within that group may have had a low amplitude signal in the other channel or artifact. Typically, the unused channel contains data with too much artifact or with a wandering baseline.

SVE Only

The SVE Only checkbox appears on the Normal Forms display. When this box is checked, if there are any SVE beats within the currently highlighted form, a representative SVE beat and the count of SVE beats within that form are displayed.

Using the SVE Only option provides a more detailed view of the SVE morphology. It provides a useful tool to edit false positives, i.e. artifact, from the report. SVE false positives are typically recorded as single channel forms.

Figure 6-4 Normal Forms -SVE Only



Editing Forms

While reviewing forms, the first form is highlighted. The highlight cursor can be moved with the arrow keys or by clicking twice on the desired form. The highlighted form is the one that can be edited.

To edit a form designation (and the designation of all the beats in that form):

- 1. Highlight the desired form.
- 2. Click Edit in the menu bar or click on the form with the right mouse button and select the desired form label from the list. The form is automatically moved to the correct category and the label is changed. All the beats included in the form are relabeled.

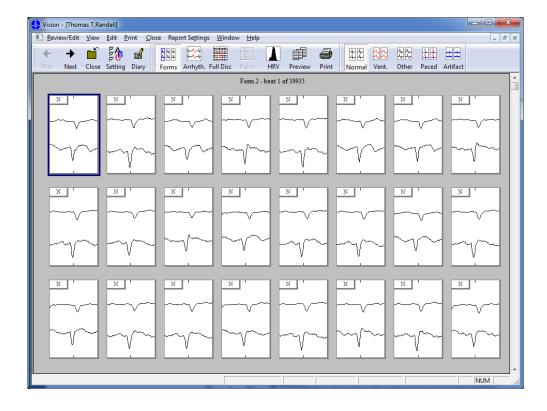
Editing Beats

When viewing forms, you may edit not only the form designation but you may also review and edit individual beats.

The Multi-Beat Display

1. Click on the desired form and select Multi Beat from the View menu. The multi-beat view of the form is displayed.

Figure 6-5 Multi-Beat Display



Every beat that is incorporated into the form is displayed in a series of screens with up to 60 beats per screen.

NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-6).

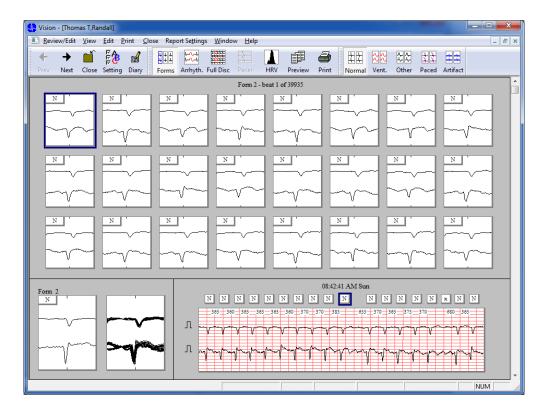
Press O and N to move through each screen or select the left and right arrows or click in the scroll bar located on the right side of the window.

- To view a beat within the context of Full Disclosure data, click on the beat to highlight it and then select Full Disclosure from the View menu.
- **3.** To edit the beat label, right click on the beat and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

The Multi Beat with Superimposition Display

If, during the beat review, you need to see more detail of the selected beat, select Multi Beat with Superimposition from the View menu or double click on the Form.

Figure 6-6 Multi-Beat with Superimposition Display



This screen displays up to 40 beats rather than 60. In the lower left of the screen is a waveform that represents the basic appearance of the beats in the form. Next to this is a composite picture of the displayed beats superimposed on one another. In the lower right corner of the screen is a diagnostic strip. There are two tic marks, one at the top and one at the bottom of this box. The beat in line with these two marks is the currently highlighted beat.

As in the Multi Beat display, you can edit the designation of an individual beat:

Right click on the beat and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

NOTE: Tagged beat selections are not preserved from page to page.

The Diagnostic Strip Display

NOTICE: A warning message may appear at the bottom of the strip if the system was unable to identify and automatically calibrate your monitor for diagnostic quality. If this warning appears and you require diagnostic quality images, try an alternative monitor.

Double click on a specific beat to view the beat in more detail. The Diagnostic Strip is displayed.

Figure 6-7
Diagnostic Strip Display



This screen shows a 7-second diagnostic strip. The waveform in line with the two center marks is the currently selected beat. Along the bottom of the screen is a 30-second Full Disclosure strip with the contextual viewing box centered over the same data as that displayed in the 7-second Diagnostic Strip.

To edit the beats in this screen, right click on the beat label and select the desired label from the list. The beat is automatically moved to the prime form of the correct category and the label is changed.

Chapter

Reviewing & Editing Arrhythmias

The VisionTM system detects arrhythmias and annotates events indicated each time the patient presses the Event button on the recorder. These episodes are then separated into five classifications:

- Pause Episodes
- Ventricular Episodes
- Supraventricular Episodes
- Tachycardia/Bradycardia Episodes
- ST Episodes

Reviewing Arrhythmias

- Start from the *Report Manager* window.
- Double click the record you wish to review or edit. The *Patient Information* window is displayed.
- 3. Verify that the information displayed in the window is correct.
- Click the Arrhythmias icon (in the toolbar. The *Pattern Strip* window is displayed.

Figure 7-1 Pattern Strip



NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-6).

Most of the arrhythmia windows are very similar. These windows are all divided into two sections:

- ✓ The Histogram Distribution display
- ✓ The Diagnostic Strip and Form displays

The Histogram Distribution Display

With the exception of the *Min/Max Heart Rate* window, the top right portion displays the histogram distribution for the category with the following features:

- Each column represents a subcategory for the arrhythmia. The first column represents the number of single beats containing the arrhythmia. The second column represents the number of instances with 2 consecutive beats containing the arrhythmia. This pattern continues to the far right column, which represents the number of instances with 10 consecutive beats containing the arrhythmia.
- The height of each column represents the number of episodes that are included for each subcategory. This number also appears at the top of each column.
- The columns are proportional in height. The maximum height for specific episodes is as follows:

Isolated Ventricular and Supraventricular = 500

Ventricular and Supraventricular Couplets = 400

Ventricular and Supraventricular Runs = 400

Ventricular Bigeminy = 200

Pauses = 400

Tachycardia and Bradycardia = 200

If the number of episodes exceeds the maximum height, then the total episode count appears in brackets in the title window (to the left of the histogram display).

- The column that includes the most severe episodes is automatically highlighted when this window is opened.
- The top, left portion of this window displays the total number of episodes for the current subcategory of arrhythmia and which of these episodes is currently displayed.

The Diagnostic Strip

This section contains a 7-second diagnostic strip. The onset of the current episode is centered in this box. Above the 7-second strip is information about the episode such as a description of the subcategory and the heart rate. Also displayed is more detailed information when applicable. For example, a Pause episode will have the pause duration displayed here.

Editing Arrhythmias

Selecting Arrhythmias to Edit

VisionTM includes a certain number of representative arrhythmia strips in the Final Report. The number of strips included is determined by the System Settings. (See "System Setup" on pg. 9-1.) Vision™ selects what it considers to be the worst-case examples of each type of arrhythmia. You may, however, wish to edit or include additional strips that you feel are representative or delete those that you believe are not significant.

- 1. Click on the column of the subcategory you wish to review in order to view the Diagnostic Strips.
- 2. To view the next Pattern Strip for the current arrhythmia subcategory, press N or the right arrow. Press O or the left arrow to go to the previous Pattern Strip at any time.
- 3. To view another arrhythmia category, click the icon in the toolbar that corresponds to the category you wish to review such as SVE Episodes ().

Editing an Episode

NOTE: Beats labeled as SVE may be reclassified as Normal if beats within the SVE run are manually edited. It takes two beats in a row to trigger the labelling of an SVE run. Relabelling one of these beats results in a different call by the VisionTM software.

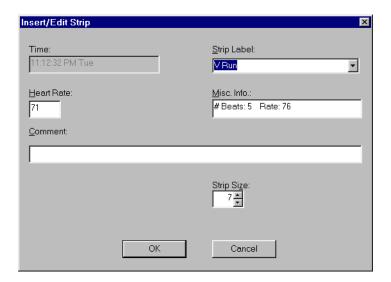
Editing the Beat Classification

Right click on the beat label above the desired beat in the 7-second strip display and select the appropriate classification for the beat from the context menu.

Including the Strip in the Final Report

- 1. Select Strip Included from the Context menu of the 7-second strip display. The *Insert/Edit Strip* window is displayed.
- **2.** Fill in the information as needed.

Figure 7-2 Insert/Edit Strip



3. Click [OK] to save your changes and insert the strip.

Deleting a Strip

1. When the strip you wish to delete is showing in the diagnostic strip section, press the = key or right click the mouse and select Delete ECG Data from the context menu. All of the beats in that strip will turn blue to indicate that they will not be used when the report is recompiled.

NOTE: The data is not actually deleted. If you re-analyze the report, the data will be returned to it's original state.

Chapter

Viewing the ECG

The Vision[™] system allows you to review and verify every beat recorded during the monitoring period. You may edit the classifications made by the system during analysis.

Full Disclosure

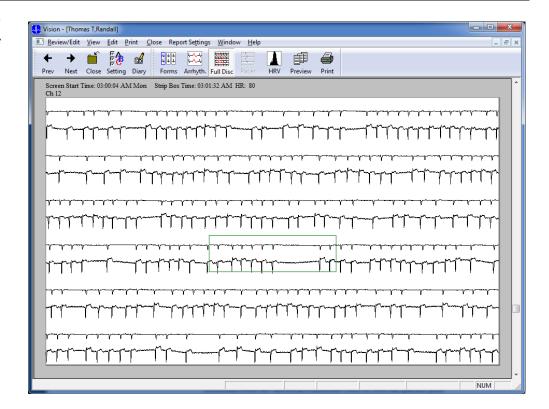
This method of reviewing the recorded ECG data is page-by-page. Each screen displays from 20 seconds of ECG data to up to 10 minutes depending on the number of channels displayed and the number of seconds displayed per line.

The display format for this window may be edited in the **System Settings** window (see "Display" on pg. 9-3). To change the display format for the current report only, click the Report Settings icon () in the toolbar.

Displaying the Full Disclosure

- 1. Start from the *Report Manager* window.
- 2. Double click on the record you wish to review to open it.
- 3. Click the Full Disclosure Review icon () in the toolbar. Full-Disclosure data is displayed.

Figure 8-1Full Disclosure



NOTE: Some frequently used functions can be accessed quickly by right clicking within this window. This will activate a context menu (see "Context Menus" on pg. 1-6).

This window shows all hours of the recording.

Abnormal beats are shown in a different color so you can quickly pick out the abnormal beats.

- ✓ Normal beats are black
- ✔ Ventricular beats are red
- ✓ SVEs are green
- Paced beats are magenta
- ✓ Artifact beats that are labelled asterisk or period are blue. Artifact beats that are labelled x, X, t, or p are the same color as the previous beat.
- **4.** To view the data at different times, use the scroll bar to the right of the screen.

NOTE: The first five minutes of the ECG data is blue. This indicates that this data was not used to generate the report. The VisionTM system locks out the first five minutes of ECG data which is used for calibration. These beats are labeled U (Uneditable) in other graphic displays.

Search by Time

You can search by time in the Full Disclosure view.

- 1. Press the t key.
- 2. Enter the date and time in the window that displays and click [OK].
- **3.** The view changes to display the selected time.

Selecting Data to Edit or Delete

To select Full Disclosure data, you can position the cursor box over the data you wish to edit or delete, or you can use two I-beam shaped cursors to mark off specific regions.

To position the Cursor box, move your mouse cursor over the data you want to select and left click your mouse.

To use the I-beam cursors:

- 1. Hold down the CTRL key.
- 2. Click at the beginning of the section you wish to select.
- 3. Continue to hold the CTRL key and click again at the end of the data you wish to select.

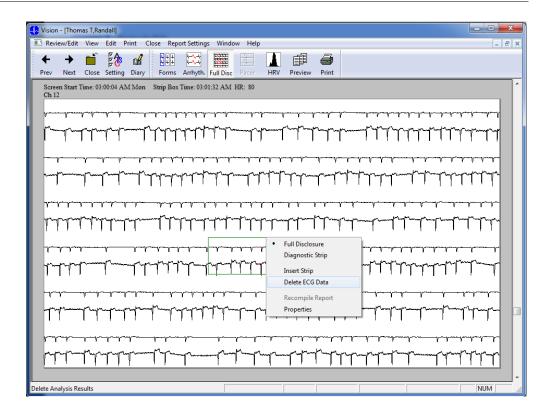
You can view and edit the selected data more closely by right-clicking within the area you have selected and choosing Diagnostic Strip from the context menu.

Most noise is removed automatically by the system during analysis, however, you may encounter recordings that contain excessive amounts of artifact that you don't want considered when analyzing a report. To handle these occurrences, the system allows you to manually delete data from analysis. Data can be deleted in amounts as small as seven seconds or as large as the entire procedure.

The deleted data is not removed from the system; it is "marked" and the system ignores the data when building a report. The deleted data appears blue to indicate that it will not be used in analysis when the report is recompiled.

To delete data, use the above procedure to select the data you wish to delete and press the DEL key on the keyboard or right click the mouse and select Delete ECG Data.

Figure 8-2
Delete ECG Data

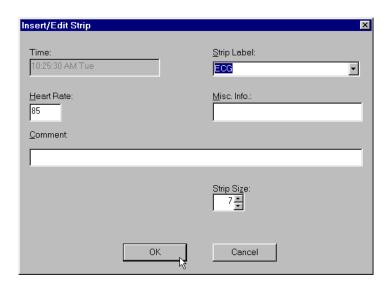


Inserting a Report Strip

Data may be manually inserted into the Final Report (see "Report Strips" on pg. 5-11).

- 1. Select the desired data (see "Selecting Data to Edit or Delete" on pg. 8-3).
- **2.** Right click the mouse and select **Insert Strip** from the context menu. The *Insert/Edit Strip* window is displayed.

Figure 8-3
Insert Strip



The Time field is automatically filled in with the time of the center of the strip.

The Strip Label field is automatically set to ECG but may be changed by selecting a different label from the pull down menu.

The Heart Rate field is automatically filled in with the rate from the time of the beat closest to the center of the strip.

The Strip Size field is set in seven second increments up to 56 seconds. This field will be filled in automatically if you first select the data as described in "Selecting Data to Edit or Delete" on pg. 8-3. You will usually want to include enough data prior to the arrhythmia to aid in evaluating the arrhythmia.

The Comment field allows you to enter a brief note to indicate the reason you have inserted this strip into the final report.

3. Fill in and edit the information in this window as needed then click [OK].

Displaying a Diagnostic Strip

For a more detailed view of a beat, right-click on the selected data in the full disclosure view and select Diagnostic Strip from the context menu.

Figure 8-4 Diagnostic Strip



This screen shows a larger display of the contextual viewing box. The waveform in line with the highlighted label is the selected beat. Along the bottom of the screen is a 30second Full Disclosure strip with the contextual viewing box centered over the same data as that displayed in the 7-second Diagnostic Strip.

Chapter

System Setup

The Vision™ System Settings option allows you to set various parameters of the system setup and report configurations.

To access the System Settings:

- 1. Start from the *Report Manager* window.
- 2. Click on the System Settings icon () in the toolbar or select the System Settings menu. The *System Settings* window is displayed.

There are 7 pages in this window:

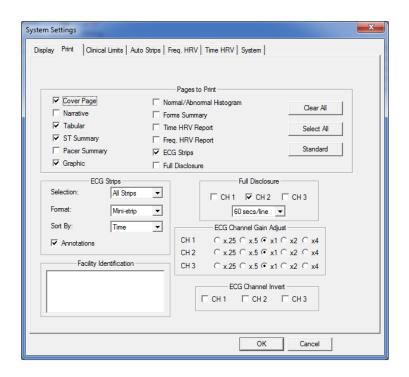
- ✓ Display
- Print
- Clinical Limits
- **Auto Strips**
- Freq. HRV
- Time HRV
- System

To switch to a different page, click on the appropriate tab. The Print page is displayed when this window is first opened.

NOTE: The two tabs, Frequency HRV and Time HRV, are described in your HRV option operating instructions if you have purchased the HRV option.

Print

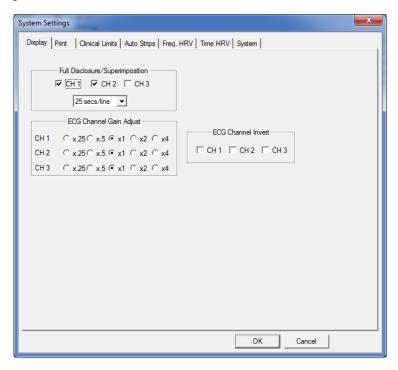
Figure 9-1 System Settings – Print Settings



Print Settings		
Pages to Print	Select which report pages will print when Print Report is selected.	
ECG Strips	Selection	
	All Strips or User Inserted.	
	Format	
	Mini-Strip or Diagnostic.	
	Mini-Strip is a paper-conserving, small print format and Diagnostic is a larger, diagnostic-quality print format.	
	Sort By	
	Time or Category.	
	When sorted by Time, the strips are printed in chronological order. When sorted by Category, like strips are printed together.	
Annotations	Include beat annotations above each strip in the printout.	
Full Disclosure	Select which channels to print and what resolution to use when printing the full disclosure (10, 30 or 60 seconds per line).	
ECG Channel Gain Adjust	Adjust the amplitude for one or more channels only if the patient's signal is consistently weak or strong.	
ECG Channel Invert	Invert the signal from one or more channels.	
Facility Identification	Type the name and address information as desired for your facility. This information will appear on the cover page of report printouts. The first line that you type in this field will appear at the top of every printed page of the report.	

Display

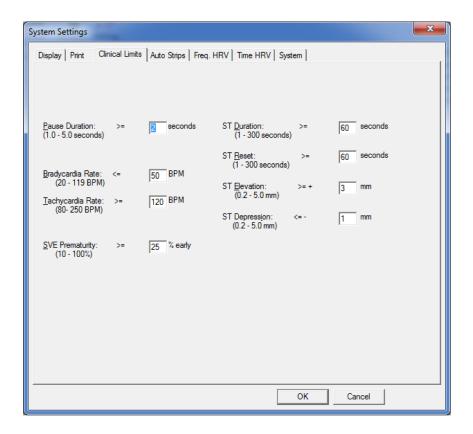
Figure 9-2 System Settings – Display Settings



Display Settings		
Full Disclosure/ Superimposition	Select which channels are displayed and the number of seconds of data are displayed on each line (10, 15, 25, or 30 seconds per line).	
	NOTE: No data is excluded from analysis.	
	NOTE: The display will be larger if there are fewer seconds displayed per line.	
ECG Channel Gain Adjust	If the patient's data is consistently weak or strong in one or more channels, adjust the displayed amplitude for those channels.	
ECG Channel Invert	Invert the display for one or more channels.	
	NOTE: There is no visual indication on the screen or printouts that this inversion has been made.	

Clinical Limits

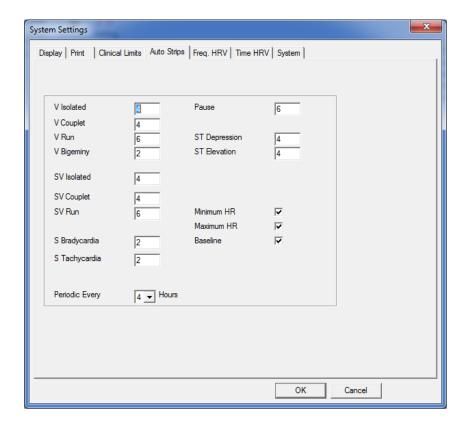
Figure 9-3 System Settings – Clinical Limits Settings



Clinical Limit Settings		
Pause Duration	The amount of time (in seconds) that must elapse with no ECG detected before a pause is declared.	
Bradycardia Rate	The rate the heart rate must fall below before a bradycardia event is declared.	
Tachycardia Rate	The rate the heart rate must exceed before a tachycardia event is declared.	
SVE Prematurity	The percentage that a normal morphology beat must be premature before an SVE event is declared.	
ST Duration	The time (in seconds) an ST episode must exceed the threshold limits before being declared an event.	
ST Reset	The time (in seconds) an ST episode must not exceed the threshold limits to end the declared event.	
ST Elevation	The amplitude threshold (in millimeters) the ST segment must exceed above the baseline before being declared.	
ST Depression	The amplitude threshold (in millimeters) the ST segment must exceed below the baseline before being declared.	

Auto Strips

Figure 9-4 System Settings -Auto Strip Settings



Use this screen to tell the system how many strips of each category you want included in the Final Report. Any combination of these strips may be selected for a maximum of 255 total strips.

Figure 9-5 Freq HRV

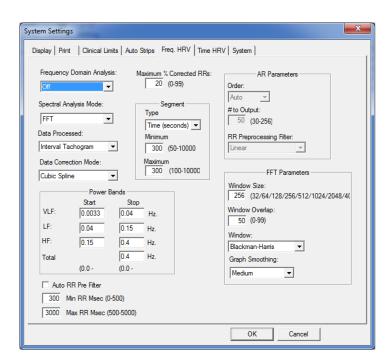
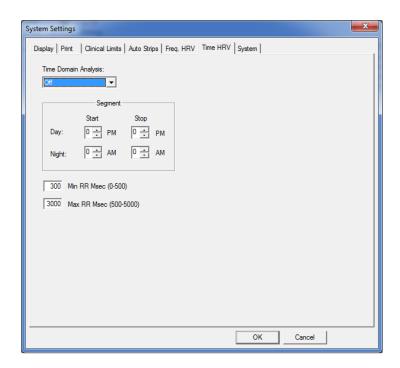
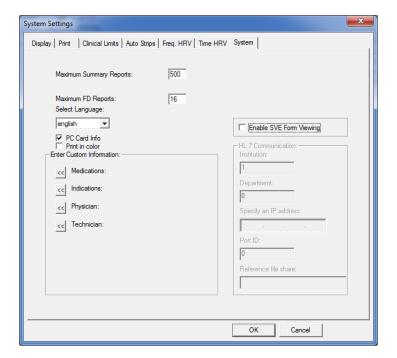


Figure 9-6 Time HRV



System

Figure 9-7 System Settings – System



Maximum Reports

Use the Maximum Summary Reports and Maximum FD Reports fields to set a limit on the number of reports that can be saved in VisionTM. Once the limit is reached, old reports must be deleted before a new report can be acquired.

When setting these values, make sure that you have enough free space on your computer's hard drive to hold the indicated number of reports. As a general rule, one FD (full disclosure) report requires between 20 and 30 Mb of space, depending on whether the recording was 2 channel or 3 channel. One 48-hour FD report will use up to twice these amounts. Summary Reports usually require between 200K and 500 K bytes or more of space, depending on the total number of report strips and the size of each strip.

For additional information on storage requirements, refer to the Setup Guide.

PC Card Info

Use this checkbox to enable or disable patient information entry during PC Card initialization. When the feature is enabled, the user has the option to enter patient demographic as a part of initialization. Any patient information entered during initialization is automatically saved to the record.

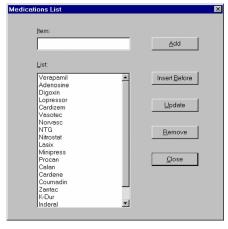
Disable this feature if you do not want the *Enter Patient Information* window to appear during initialization.

Enter Custom Information

Use this area to add, delete or modify the lists for medications, indications, overreading physician, scan technician, referring physician, hookup technician, and data recorder serial number.

Click on the arrows next to the selection to view the list for the selection. For example, to view the list of medications, click on the arrows next to Medications. The *Medications List* window is displayed.

Figure 9-8
The Medications List



To add a new item to the list, type in the desired information and select [Add].

If you want the item to appear in a specific location in the list, highlight the item that will appear just after the new item, type the desired information for the new item, and select [Insert Before].

To delete an item from the list, highlight the item and select [Remove].

To change an existing item, highlight the item, type in the changes and select [Update].

NOTE: All changes are saved automatically.

To exit the window, select [Close].

HL7 Communication

HL7 parameters must be configured in order for VisionTM to communicate with the PYRAMIS[®] ECG Management System (see "Sending HL7 Reports" on pg. 10-5).

- ✓ Enter the IP address of the PYRAMIS machine which will be receiving the exported data.
- ✓ Enter the network location (Reference file share) for holding summary reports that have been sent as part of HL7 communication.

All other values are automatically entered with default values.

NOTE: The Institution and Department numbers are derived from similar values on PYRAMIS. The Port ID number is the number for communication between VisionTM and PYRAMIS.

Chapter

10

Printing and Sending Files

Printing the Report

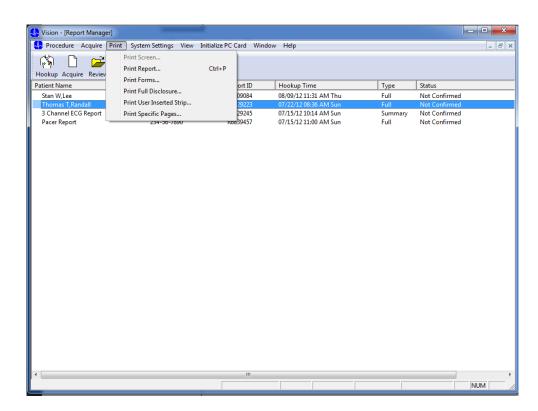
From the *Report Manager* window there are 5 options for printing patient data:

- Print Report
- ✔ Print Forms
- ✔ Print Full Disclosure
- ✔ Print User-Inserted Strip
- ✔ Print Specific Pages

To print patient data:

- 1. Highlight the desired record in the *Report Manager* window.
- 2. Click on Print in the Menu bar.
- 3. From the pull down menu, select the desired print option.

Figure 10-1Print Options



Print Report

Select this option to print the entire Final Report as defined in the *System Settings* window (see "Print" on pg. 9-2).

Print Forms

Select this option to print all the forms as they are displayed for form review (see "Reviewing Forms" on pg. 6-2).

Print Full Disclosure

Select this option to print the entire 24 hours of patient data. The format for this printout is determined in the *System Settings* window (see "Print" on pg. 9-2).

Print User-Inserted Strip

Select this option to print all the strips that have been inserted manually. The format for this printout is determined in the **System Settings** window (see "Print" on pg. 9-2).

Print Specific Pages

Select this option to print only the Final Report pages that you select. A window similar to the **System Settings** window (see "Print" on pg. 9-2 for a description of this window) is displayed where you can make selections that affect only the current printout.

NOTE: If the highlighted record is a summary report, then several of the options under Pages to Print will be grayed out.

Print Strip

NOTE: When a strip is printed as part of a report, the selected strip appears in large scale across the top, and a related section of full disclosure appears along the bottom, as shown in the figure below:

Figure 10-2Print Strip Example



- 1. Related section of the full disclosure display
- 2. Box in the full disclosure display

The box in the center of the full disclosure display does not indicate the printed strip of the full disclosure display; in fact, the box does not have meaning in this context. The box in the center of the full disclosure display has meaning only during on-screen editing. For more information, see Viewing the ECG in the Operating Instructions manual for the Vision Series Holter.

Please be assured that the data displayed is accurate, the printed mini-strip exactly matches what was selected during on-screen editing, and the analysis performed by the system is thorough and complete.

If you have any questions, please contact Cardiac Science Technical Support at 800-426-0337 or Email: techsupport@cardiacscience.com.

Taking Pictures of the Display

With the Vision[™] system you can obtain pictures of the image shown on the display. This option has many uses. For example, if you are experiencing difficulties with your system, having a picture of the display is useful when consulting with Technical Support personnel.

There are several options available with the Print Screen feature:

- Obtain a picture of the entire screen display.
- Obtain a picture of the active window only.
- Obtain a printout from the printer.
- Obtain a picture that can be pasted into a document such as a WordPad document or a graphic program document.

Follow the instructions below to take pictures of the display for printing or pasting into a document.

To take a picture of the display:

✓ Press the <Print Scrn> key to take a picture of the entire screen.

or

- Click within the window that you want to capture. The window becomes active.
- ✓ Hold down the ALT key and simultaneously press the <Print Scrn> key.

Faxing Reports

NOTE: To use the Fax option, you must have a modem and fax software installed. For additional information, see the VisionTM Series Setup Guide.

- 1. Print as you would to a normal printer (see "Printing the Report" on pg. 10-1 and "" on pg. 10-3).
- 2. When the *Print* window is displayed, select Microsoft Fax as the name of the printer.
- 3. Click [OK].

Sending Reports

Sending HL7 Reports

NOTE: This feature is optional on VisionTM.

If the HL7 communication option has been installed on VisionTM, users can send data to compatible management systems, such as PYRAMIS[®] ECG management system. When an HL7 report is sent, the following information is included: cover page, VE tabular, SVE tabular, pacer tabular, narrative, and ST summary.

To send a report in HL7 format:

1. Highlight the desired record in the *Report Manager* window.

NOTE: To select more than one report, hold down the Control key.

- 2. Select Procedure from the menu bar.
- 3. From the pull down menu, select Send and then HL 7 Report.

The report is sent to the IP address and port ID listed in the *System Settings* window (see "HL7 Communication" on pg. 9-8).

Sending Summary Reports Using E-Mail

Users can e-mail summary reports to recipients using the host site's e-mail application (for more information on summary reports, see "Summarizing Reports" on pg. 4-6). Summary reports are included as an attachment on e-mails, and can be viewed on systems installed with the VisionTM Series Holter Report Viewer (for more information, see the VisionTM Series Holter Report Viewer Installation Instructions and Operating Instructions).

To e-mail a summary report:

NOTE: VisionTM automatically generates a summary report if one does not already exist for a record. The summary report is then deleted once the e-mail is sent.

- **1.** Double click the record to open it.
- 2. Select Report Settings from the menu bar to view the print settings for the report.
- **3.** Make changes as necessary. Click [OK].

NOTE: In order for the e-mail recipient to print each page in the summary report, each active checkbox in **Pages to Print** must be selected.

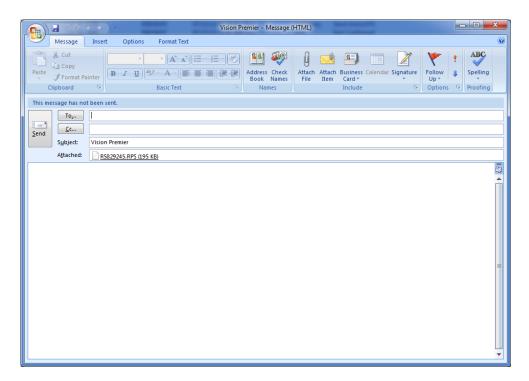
- **4.** Close the report.
- **5.** With the report highlighted in the *Report Manager* window, select Procedure from the menu bar.

NOTE: To select more than one report, hold down the Control key.

- **6.** From the pull down menu, select Send and then Mail Recipient.
- 7. The e-mail form is displayed.

NOTE: The information provided here includes details that are specific to Outlook[®] Express*. This is for illustration purposes only; various e-mail applications can be used.

Figure 10-3 E-Mail form in Outlook Express



- **8.** Enter e-mail addresses as desired.
- 9. Press the send key to e-mail the report.

CAUTION: Edits made directly to Holter report e-mail attachments cannot be saved. To edit Holter reports received via e-mail, first save the attached report to a secure file location (requires an .rps file extension).

^{*}Outlook® Express is a registered trademark of Microsoft® corporation

Exporting Reports

Holter report data can be converted into text format for additional analysis and reporting. Conversion occurs through the process of exporting data. Exported data can be imported into spreadsheets.

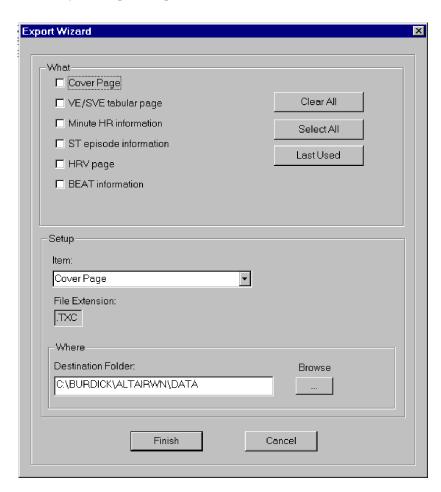
To convert Holter report data to text:

1. Highlight the desired record in the *Report Manager* window.

NOTE: To select more than one message, hold down the Control key.

- 2. Select Procedure from the menu bar.
- 3. From the pull down menu, select Export.
- **4.** The *Export Wizard* window will appear to guide you through the steps necessary to setup the export function.

Figure 10-4
The Export Wizard



- **5.** Select which information you would like to export under What.
- **6.** To change the destination folder, select an item from under **Setup**. Click the [**Browse**] button to locate and select the new drive or folder you wish to use.

You must change the destination for each item individually.

7. Once all information has been configured as desired, click on the [Finish] button.

Accessing Exported Data

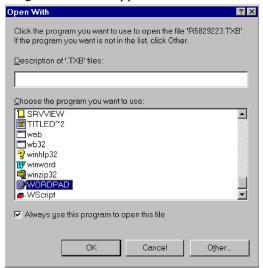
One file is created for each item that is selected under What in the Export Wizard window (items include, for example, cover page, VE/SVE tabular page, etc.). Each exported item has a different file extension—for example, the file extension for a Cover Page is .txc. All files, however, can be opened as text.

To open exported files:

- 1. Open the location where the exported data was saved (the location given for Destination Folder in the *Export Wizard* window).
- 2. Click on the file you wish to open. Use the table below to identify each file.

File Extension	Item	Data Format	
.txc	Cover Page	tab delimited	
.txt	VE/SVE tabular page	tab delimited	
.txm	Minute HR information	comma delimited	
.txs	ST episode information	comma delimited	
.txh	HRV page	tab delimited	
.txb	BEAT information	comma delimited	

3. The following window will appear.



Select a program to open the file. The data can be opened using word processing programs (such as Microsoft® Word), text viewing programs (such as Notepad or Wordpad), and spreadsheets (such as Microsoft[®] Excel).

Chapter

11

Maintenance & Troubleshooting

No calibration is needed for your Vision[™] system. For maintenance and cleaning procedures, consult the documentation that came with your computer.

Contact an authorized service agent immediately if:

- ✓ The equipment is dropped or subjected to some other mechanical stress.
- ✓ Liquid is spilled on the equipment.
- ✓ The equipment is not functioning as described in this manual.
- ✓ Parts of the enclosure are cracked or missing.
- ✓ Any connector shows signs of deterioration such as cracking.

All functions of the VisionTM system are designed to be user-friendly and easy to understand. If a questions arise or you would like additional information, contact your local representative or VisionTM Technical Support Department at (800) 426-0337 or (262) 953-3500.

Computer-to-Recorder Interface Error Codes

NOTE: Please consult the operating instructions that accompanied your recorder for additional information.

The following error codes are displayed on the computer during the PC-Card initialization sequence.

Code	Possible Cause	Type of Problem
1	Wrong number of parameters passed by the host application	software
2	Data-file error.	software
3	Info-file error.	software
4	Pacer-file error.	software
5	Timeout during disk transfer	hardware
6	Disk did not respond to power-up test and/or disk erase procedure failed.	hardware
7	No disk detected.	hardware
8	RTC/NVM write error.	hardware
9	Drive power-down error.	hardware
10	Excessive errors during disk read.	hardware

Code	Possible Cause	Type of Problem
11	Unable to read cylinder index from drive.	hardware
12	Failure to read time from UPLD.DAT info file.	hardware or software
13	Unable to build header file.	software
14	Unable to build event file.	software
15	Initialization failure.	hardware or software
16	Initialization failure (pacer-data area).	hardware or software
17	Initialization failure (time/mode verification failure).	hardware or software
18	Mode information has been corrupted (check connections). Batteries were removed and reinstalled during recording.	hardware
20	Recorder does not contain data for procedure requested.	
23	Requested 2-channel data - recorder contains 3-channel data.	
24	Invalid data request.	
30	Recorder type is not capable of combined-mode operation.	
41	Did not detect flash card.	hardware
48	Did not find disk interface board	hardware
255	Poor or no data on recorder	
1368	Copy protection violation	
1369	Copy protection violation	

Printing Problems

Most printing problems will result in a message displayed on the screen. Consult the operating instructions for your printer to troubleshoot these problems.

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