

The HOLTER REPORTER™ OPERATOR'S MANUAL for THE MASTER SERIES and LAB SOFTWARE

NOTICE:

The HOLTER REPORTER[™] MASTER SERIES and associated software is to be sold to and operated by qualified medical personnel. It is the intent of **APPLIED CARDIAC SYSTEMS, INC**. that diagnostic decisions be made by a Professional Overview of Full Disclosure and Selected ECG Samples. Non-edited instrument calculations are not intended to diagnose and should not be used as such without a Professional ECG Overview.

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Preface

In writing this manual, great care was taken in making the information comprehensive and easy to reference. The information contained is organized in such a manner as to aid users with varying levels of expertise to quickly become familiar and well versed in the operation of the instrument. In reading this manual, please feel free to contact **ACS** Applications department and share your suggestions or improvements. We welcome your feedback!

Section I provides an introduction to **Applied Cardiac Systems**, **Inc.**, the product line and philosophy. This section also describes the notation used throughout the manual.

Section II describes the complete system installation; refer to this chapter if the system is being installed for the first time, or is being re-installed after relocation. Read this chapter carefully.

Section III provides instructions on how to properly turn the system power ON and OFF to avoid loss of data or damage to the software.

Section IV is an introduction to the system initialization and operation.

Section V provides detailed information about operating the system, including the various reports printed by the Holter Reporter system.

Section VI includes the suggested step-by-step operation procedure for the Analyzer as a quick operating reference.

Section VII provides information on ordering supplies for the system and recorders

Section VIII provides information on maintenance of the system.

Section IX describes the function of the various hardware components of the system

Section X provides information to help solve any problems encountered.

Section XI provides information to help with using the Lab/ACSD software and properly ejecting USB devices.

Appendix A provides a glossary of terms and a reference guide to the manual.

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SECTION 1.0 INTRODUCTION

1.1 Applied Cardiac Systems - The Company

Since its inception in 1981, **ACS** has specialized in the design and distribution of our Holter products.

1.1.1 The Philosophy

Build the highest quality and most dependable Holter instruments in the medical industry and stand behind them. ACS believes in providing tools for the medical specialist which enhances his/her ability to make accurate diagnostic decisions. There is no substitute for the professional overview of a machine generated report.

1.1.2 The Products

Applied Cardiac Systems has earned the reputation for building the most durable, dependable, feature rich and affordable products in the Holter industry. ACS customers demand quality, longevity and affordability; ACS delivers.

1.1.3 Customer Support

The customer is the most valued asset of Applied Cardiac Systems. Customer support begins with initial training upon installation, and subsequent training is provided as necessary. This support is supplemented with free technical support via telephone by a dedicated staff.

Furthermore, customers receive prompt attention regardless of the nature of their request.

A modular exchange program has been implemented to expedite and facilitate the servicing of the **ACS** HOLTER REPORTER and minimize down time. This program has proven to be the most effective and efficient for our customers.

1.2 The MASTER SERIES

The MASTER SERIES is a powerful Holter diagnostic tool that specializes in processing ECG data from Digital Data and or Flash Card Recorders. The MASTER SERIES combines the latest in technology and dependability, including networking and Internet capabilities. The MASTER SERIES is offered by **ACS** as a Multi-Tasking Holter reporting device that is designed for the sole purpose of generating high quality Holter reports in an easy to read, high resolution ECG format. Full utilization of the Multi-Tasking capabilities by the user will result in the generation of a complete report in the shortest period of time.

Operation of the MASTER SERIES is made simple through extensive hardware and software design considerations. All important operating instructions are essentially provided on the display screens.

The MASTER SERIES incorporates the finest components available for your Holter system. The amount of research and development time dedicated to this product as well as our exhaustive testing and quality assurance procedures ensures the delivery of a reliable and easily maintained medical instrument.

1.3 Typing Convention Used In This Manual

- Bold Used to designate menu options
- " " (Quotes) Used to designate screen titles and messages displayed on screen

KEYBOARD KEY> Designates a key exactly as it is labeled on the keyboard

Left-click Refers to a single click of the left mouse button.

Right-click Refers to a single click of the right mouse button.

Double-click Refers to two successive clicks of the left mouse button

1.3.1 Commonly Referred to Function Keys

- **Page Up:** same as the <9> key on the numeric key pad and active when <Num Lock> is off. This key functions the same as the <Page Up> key in the center keypad of the keyboard.
- **Page Down:** same as the <3> key on the numeric key pad and active when <Num Lock> is off. This key functions the same as the <Page Down> key in the center keypad of the keyboard.
- **<ENTER>** Enter: located in the center-right of the keyboard and generally used to access the next screen.
- <ESC> Escape: located in the top left corner of the keyboard and generally used to end current mode and display a menu.
- $\langle \leftarrow \uparrow \rightarrow \downarrow \rangle$ Arrow keys: located at the lower left of the numeric key pad and generally used to navigate the cursor or selection bar.
- <->, <+> Minus and Plus: located on the far right edge of the keyboard and generally used to adjust the ECG gain.
- **F1-F12>** Function key: located along the top of the keyboard and generally used to perform a designated function on the current screen.

SECTION 2.0 INSTALLATION

2.1 Choosing a Location

The system should be installed in a well ventilated area where the temperature is between 50 and 90 degrees Fahrenheit and the relative humidity is between 20% and 80% non-condensing.

Place the components of the system so that at least six inches are provided between the rear of the module(s) and the wall. This will minimize cable bending and provide for adequate ventilation.

Install the system in a dust and static free environment.

Do not install the system where line voltages fluctuate more than +/-10% from the specified voltage(s) on module nameplates.

Do not install near water faucets, boilers, humidifiers, refrigerators, etc. In order to avoid accidental bumping and damage do not install in high traffic areas.

Note: Never move the system without first disconnecting power from wall outlet. After moving the system, secure all interconnect cabling with locking screws where provided.

2.2 Unpacking The Modules (complete hardware packages only)

The entire system is carefully packaged and shipped from ACS as follows: Report Stand: 1 box, approximate weight 40 lbs.

Analyzer Module, Keyboard, & Mouse: 1 box, approximate weight 45 lbs. Printer Module: 1 box, approximate weight 30 lbs.

Display Monitor: 1 box, approximate weight 15 lbs.

These modules may be shipped with additional hardware and manuals. Carefully remove all modules and other items from the original package and save the original packing material for future use.

Call ACS immediately if any module appears to have been damaged in shipping.

2.3 System Components

The Master SERIES (hardware) system is comprised of several modules, some of which can be recognized as standard personal computer peripherals and accessories (e.g. laser printer, keyboard, and mouse). These components have been modified and integrated into the Master SERIES system. All the hardware, software, and manuals necessary to install and operate the Master SERIES have been included in the original system packages (when complete hardware packages are purchased). Please verify that these items are present and not damaged in shipping.

2.3.1 Components list/ System Components

Analyzer Module

Laser Printer Display Monitor Keyboard/Mouse Report Stand **System Accessories** Software Package Smart Dock/ Docking Station w/ cable Analyzer, Printer, & Display Power Cords (optional) Printer Cables (optional) Power Surge Protector (optional) Mouse Pad **Manuals** Laser Printer Manual(s) (optional) Display Monitor Manual(s) (optional) Windows 7 Professional ™ Manual (s)

2.4 Assembling The Report Stand (Optional)

2.4.1 The Report Stand has been pre-assembled prior to shipment.

2.5 Assembling The System

2.5.1 Module Assembly on the Report Stand (optional)

It is easier to assemble all the components of the system in an area where you can easily move around the stand and do not feel cramped for space before rolling the stand to its final destination.

- 1. Place the Analyzer on the bottom shelf of the Report Stand, as far to the right side as possible.
- 2. On the same bottom shelf place the Printer next to the Analyzer. Performing this step ensures stability of the cart.
- 3 Place the Display Monitor on top of the Report Stand.
- 4. Place the Keyboard on the sliding shelf below the Display Monitor.
- 5. Place the Mouse in a convenient location, most likely to the right of the Keyboard or Display Monitor.

2.5.2 Power Connections

The Analyzer, Laser Printer, and the Display Monitor all have their own individual power supplies and require direct connection to a power outlet via these power cords provided. For each module, connect the female end of the power cord to the designated plug on the module, and plug the male end into the power outlet. It is highly recommended to plug all modules into the high quality line isolator/power surge suppressor you received with the system.

NOTE: The above modules have individual power on/off switches and are set to the off position at the factory. The power switches to these modules should be turned on before the Analyzer module is turned on.

2.5.3 Keyboard Installation

The keyboard is attached to the back of the Analyzer module. The keyboard connector is either USB or color-keyed (purple) in order to easily identify its connector port in the back of the Analyzer module.

2.5.4 Mouse Installation

The Mouse is attached to the back of the Analyzer module. The mouse connector is either USB or color-keyed (green) in order to easily identify its connector port in the back of the Analyzer module.

2.5.5 Display Monitor Installation (optional)

The Display Monitor is attached to the back of the Analyzer module. The display monitor connector is color-keyed either (blue or white) in order to easily identify its connector port in the back of the Analyzer module.

2.5.6 Printer Installation (optional)

2.5.6.1 Activating the Laser Printer

The Laser Printer is connected to the Analyzer module via the USB cable. The USB Printer cable is six feet in length, but it has different connectors at each end. Connect one end of the USB cable to the back of the printer opposite side of the power cable, and the other end to the back of the Analyzer; only one connector will match.

2.5.6.2 Installing the Toner Cartridge

- 1. From the front, open the top of the printer. Remove the toner cartridge from the box and the protective packet.
- 2. Shake the toner cartridge to evenly distribute the toner inside while keeping the cartridge as horizontal as possible.
- 3. Activate the toner cartridge by removing the activation tab; refer to the instructions included with the toner cartridge. After activating the toner cartridge, make sure the cartridge is kept horizontal to avoid leaking toner.
- 4. Place the toner cartridge in the printer; arrows on the toner indicate how the cartridge should slide inside. The toner cartridge should slide all the way in, and click in place.
- 5. Close the top of the printer.
- 6. Make sure the printer is "ON LINE" or the green light is on after the power is turned on.

2.5.6.3 Filling the Paper Tray

- 1. Remove the paper tray from the front of the printer by sliding it out.
- 2. Remove new paper from the ream and "fan" the paper to ensure all the sheets are separated. This procedure reduces the possibility of a paper jam when two sheets of paper are processed simultaneously by the printer instead of one.

- 3. Place the paper in the tray, making sure it is not wrinkled, not over filled, and secured in the corner.
- 4. Slide the paper tray back in to the printer.
- 5. Make sure the printer is "ON LINE" or the green light is on after the power is turned on.

2.5.7 System Installation Complete (optional)

The physical installation is complete when all the modules have been assembled on the stand, connected to the Analyzer module, and power cords are installed as described above.

2.6 Saving the Packing Material (Only when a complete hardware package is purchased) After all the modules and other items have been installed, the boxes and the original packing material should be stored in a convenient place for future use. Any module returned to ACS for service should be packed in the original box with the original packing material to avoid accidental shipping damage.

SECTION 3.0 TURNING ON/OFF

3.1 Power ON

3.1.1 The First Time

3.1.1.1 Use a Surge Suppressor (optional)

It is highly recommended that the MASTER SERIES system be connected to the surge suppressing and noise filtering power strip provided with the system. The strip should prevent noise from interfering with normal system function. It should also prevent possible damage as a result of a power surge.

3.1.1.2 Power ON - Module Power Switch vs. Main Strip Switch

The following modules have individual and separate power switches: Module: Power switch location

- (1) Laser printer: Lower right or left side
- (2) Display screen: Right front side
- (3) Holter Reporter[™] Analyzer: Front right side lower (blue band button)

The power to **all** of the above must be in the "ON" position before the system will function as one unit. If all the power cords are plugged into a main power strip, first turn on the main strip switch; an indicator light should turn on indicating that the individual outlets now have power. Proceed to turn on the power to each module in the sequence listed above.

The order is important because it:

- a. Allows the operator to observe the power ON indicator on each module separately, verifying that it is receiving power and make sure power cords are installed for each module.
- b. Allows certain modules that require more time, such as the laser printer, to warm up before the rest of the modules are turned on.

3.1.1.3 After the First Time

After the installation has been completed the first time, the entire system is turned on and off by using the main surge suppressing power strip switch to which all system modules are connected instead of individually turning each module on and off. If a strip is not used, then the individual module power switches are turned on separately.

3.1.2 When it is Time to Update Software (optional)

The ACS Holter Reporter[™] is shipped with the software pre-installed on the drive (hardware packages Only). Re-installation or update of the Holter Software on the drive occurs only when necessary. Proceed as follows.

3.1.2.1 Update/Install Software

1. Insert the software update/install CD in the CD-ROM drive.

- 2. After CD is inserted, the Install Wizard program should initialize. It may take a few seconds
- 3. From there simply follow the instructions of the Install Wizard.

If Install Wizard Does Not Appear

- 1. After CD is inserted, on the Windows Desktop, Double-click on the "My Computer" icon
- 2. Then Left-click on the "Control Panel" hotlink under "Other Places" on the left side.
- 3. From there Double-click on the "Add or Remove Programs" icon.
- 4. On the far left Left-click on the "Add New Programs" icon.
- 5. Then select "CD or Floppy."
- 6. The Install Wizard should now initialize.
- 7. After the software is updated/installed remove the software update/install CD from the CD-ROM drive and restart the system.

3.2 Power OFF

- **3.2.1** Make sure the Main Menu is displayed on screen. There are two ways to exit the ACS Master SERIES Holter program:
 - 1. With the mouse, click on the "X" in the far upper, RIGHT corner, to exit to Windows.
 - 2. With the mouse, click on the little heart in the far upper, LEFT corner, and select "Close" from the menu that appears, to exit to Windows.
 - 3. If you want to turn the analyzer off, first be sure to exit all programs in Windows, including the Holter program
 - 4. Next, click on the "Start"
 - 5. Click on the red "Turn Off Computer" icon in the right corner.
 - 6. Click on the red "Turn Off" icon again to turn the system off, or the green "Restart" icon to reboot the system.
- **Note:** <u>The minimize button has been disabled</u> because printouts are affected and disrupted if the program is minimized.
- **3.2.2** If all the modules are connected to a main power strip, simply turn off the main power switch when computer is powered down.

Otherwise turn off the power to the individual modules, starting with the Analyzer.

Note: The system may be left on overnight without adverse effects; turn off the display screen only in order to conserve power.

SECTION 4.0 GETTING ACQUAINTED

4.1 The Perfect Match

The MASTER SERIES offers a multitude of scanning and editing features that should satisfy a variety of users' needs. Due to the flexibility built into the MASTER SERIES, the ECG data on a Digital Data Recorder 2003/2010 and the HPP monitors can be easily downloaded and desired reports can be generated in a number of ways depending on user preference and experience.

4.2 Operator Preference and Experience

The intuitive and simple menus of the MASTER SERIES allow both new and experienced users to quickly learn how to operate the system and produce quality reports. The MASTER SERIES provides three primary Holter scanning and editing modes.

Since each mode provides a unique set of features, it is recommended that the user experiments with all modes and discovers his/her own preference.

4.2.1 SUPERIMPOSITION & PREVIEW-PAGING / FULL DISCLOSURE

This mode provides the operator with the ECG superimposed on the left side of the display screen, and previewed five minutes at a time (Preview Paging) or ectopic and ST trend data for each hour (Full Disclosure) on the right side. This mode also provides the following interactive features:

PREVIEW-PAGING

- 1) Highlight and save selected 5-minute pages of ECG data
- 2) Adjust ECG signal amplitude
- 3) Select or change the channel being disclosed
- 4) Select or change the channel being triggered
- 5) Stop the process at any time
- 6) Adjust the speed at which the ECG is being processed.

FULL DISCLOSURE

- 1) Enter Selected Strip times
- 2) Edit hourly ectopic and BPM counts

4.2.2 PAGE FULL DISCLOSURE FROM DISK

This mode is tailored to fit any operator's needs in terms of viewing, editing, printing and even processing speed. Some of the interactive features provided include:

- 1) View, save, and print random or consecutive ECG five minute pages
- 2) Automatically scroll five-minute pages at operator selected speed
- 3) Automatically scroll thirty-minute pages at operator selected speed
- 4) Edit tabulated counts on a five-minute page
- 5) View, save, and print enlarged strips
- 6) Adjust ECG signal amplitudes

- 7) Print complete Full Disclosure
- 8) Select or change the channel being displayed
- 9) Select an appropriate baseline filter to help read the ECG

4.3 System Operation Overview

It is important to start the scanning process with the desired end result in mind. This means producing a final report consisting of an edited summary report (if required) with selected ECG strips, patient data profile, and medical commentary/impressions. In order to produce the final report, the patient profile must be entered into the system using the keyboard. Next, the Analyzer must calibrate itself to the specific patient's ECG recording. This is accomplished by the Preview and Auto-Gain function. The Preview Auto Gain feature is used to select the best ECG channel for disclosing and determining ST Level criteria. The analysis criteria is also chosen during SET-CRITERIA, i.e. what measurements should be taken and reported by the instrument. After setting the analysis criteria, the entire ECG data is scanned in the Superimposition Mode. During or upon completion of the Superimposition process, the Analyzer computations are verified and edited if necessary. Selected strip times are then chosen and annotated. The final report may also be saved on the hard drive or on a CD-R disk (compact disk) for future reference.

4.4 System Software

The software used by the ACS HOLTER REPORTER[™] series is proprietary and is preloaded on the drive. The software initializes and controls the hardware functions. A combination of proprietary hardware and software detect ectopic ECG beats on the data. A removable software storage media in the form of a CD-ROM is used to facilitate periodic updates.

4.5 System Initialization Process

Prior to turning on the power to the Analyzer module, make sure the power switch for all other modules (including the Laser Printer and the Display Monitor) are in the "ON" position. In addition, make sure the Laser Printer display if applicable reads "READY" and is "ON LINE," or the green light is on. When the power to the Analyzer module is turned on, it checks to make sure a keyboard is present and responding. The microprocessor acts as the general administrator of all system functions. When the microprocessor has been initialized, the system checks each external system modules to verify that the power is turned on, all connections have been made, and the modules are ready. When all these conditions have been met, the initialization is complete. The system will then prompt the user to the Windows 7 Professional[™] desktop. From there, simply Double-click on the MASTER SERIES icon to enter the HOLTER REPORTER[™] program.

4.6 Menu Structure

All the MASTER SERIES operations are selected through menu screens which are easy to understand. Each Menu consists of several selections. It may also display options which alter the menu selections or modes of operation. The Menu flow:

The Main Entry Menu, this is where you select

- 1. Download (when a patient returns with a monitor)
- 2. Recall (when you want to "recall" a previously scanned a report).
- 3. Set-Up (this is for setting up the HPP monitor Only).

The next Menu is The MAIN MENU which in turn may lead to lower sub-menu levels. The menu selections are self explanatory and helpful instructions are displayed to facilitate the operation of the MASTER VIII SERIES. The ability to perform the same operation from more than one sub-menu has been added for greater flexibility and operation ease.

4.6.1 Main Menu

The MAIN OPERATING MENU is the hub of all system operations. Each of the options presented on the MAIN MENU is a unique operation. The Main Menu provides the entrance to all system operations.

4.6.2 Sub-Menus

Sub-menu windows are provided on all displays by pressing or clicking on **<ESC**>. These sub-menus include options for returning to the MAIN MENU or other sub-menus, various printing options, or re-entering the current mode.

4.6.3 Menu Selections

Menu selections are made by Double-clicking with the left mouse button, pressing the selection number, or using the up/down arrow keys and pressing **<ENTER>**. Once within any of the system options, you may enter data, move around within that option, and/or correct any data entered. Upon leaving any option, entries are retained in memory by the system for review, editing, or printing at a later time.

SYSTEM MENU OUTLINE

The Main Menu

Patient/Process Data:

- 1. Patient and Facility Data
- 2. Patient Diary
- 3. Preview Auto Gain
- M Return to Entry Menu

Edit:

- 4. Tabular Events
- 5. Full Disclosure

- 6. Selected ECG Strips
- 7. Saved 5 Minute Pages

Review Report:

- 8. Tabular Summary
- 9. Selected Hours
- A BPM / ST Trend
- M Return to Entry Menu

SECTION 5.0

MAIN MENU OPTIONS - SYSTEM OPERATIONS

This section contains detailed information on system options, features, and operation. This section is organized similarly to the system main menu options for quick and logical access to the desired information. Users who are still learning how to use the system and who are not completely familiar with all the system features should follow the suggested step-by-step procedure in the next section and refer to this section for more detail if necessary. Advanced users will find this section useful as a reference.

Note: Certain menu options may not be available during processing. These options are "grayed out" to prevent the user from performing certain functions out of sequence. Active options are in Yellow.

5.1 OPTION HEADER: The ENTRY MENU PURPOSE:

- 1. Download New Patient From Flash (all models)
- 2. Recall Patient From Disk
- 3. Set-Up Holter Performer Plus (HPP monitor only)
- 5.1.1 How to Download a monitor (2003/2010/HPP) SUB-OPTIONS:

OPERATION:

Select **Batch Processing & Change Patient** from the Main Menu. Proceed with the operation as follows:

5.1.2 HOW TO PROCESS / DOWNLOAD ECG FROM A DIGITAL DATA RECORDER (2003/2010)

- 1. Remove the leads cable from the recorder.
- 2. Attach the USB cable to the recorder. Make sure it shows the ACS logo on the recorder.
- 3. Select **Download ECG** from the menu, press **<ENTER>** or Double-click.
- 4. The ECG and Patient data (including time and date) will download into the system. Use **<F10>** to add any additional commentary.
- Press or Left-click on <ESC> when finished to go directly to Preview / Auto Gain Download Instructions can also be found at the top of the Batch Processing Menu screen.

5.1.3 HOW TO PROCESS / DOWNLOAD ECG FROM A HPP MONITOR

- 1. Remove the leads from the HPP monitor and insert monitor into the Smart Dock/Docking Station.
- 2. Select option 1. "Downloading New Patient From Flash"
- 3. The "Downloading Data" screen will appear and show a progress bar.

Warning! Never remove the Smart Dock or Monitor when downloading.

Note: Refer to Section 11 - Extras, for detailed instructions on Ejecting USB devices.

- 4. When the data is finished downloading a red box will appear that says "Data has been processed. Press OK to continue."
- 5. When "OK" is selected you will be directed to the "Patient & Facility Data" screen.
- 6. Type in patient, facility, hook-up, and all other relevant information.
- 7. Press **<ESC>** when finished.
- 8. Select **Diary Entries Mode** from the options menu. Fill in all diary notes then select **<ESC**>.
- 9. Select **Superimposition and Preview Paging** from the options menu.
- 10. You will now be at the **Preview / Auto Gain** screen.

5.1.4 PREPARING A 2003/2010 RECORDER FOR RECORDING

- 1. Insert the leads set into the recorder.
- 2. Remove the battery cover, then insert the SD or compactflash card into the recorder. The flash card slot is next to the battery compartment. Make sure the end with the pinholes goes in first. While inserting a compactflash card, the eject button should pop out.
- 3. Hook up the patient to the recorder via the leads set.
- 4. Install 1 or 2 fresh, AA batteries.
- The recorder will initialize and the LCD will briefly display information about the unit then show the Set-Up Unit menu.
 Enter patient ID, date of birth, date, time, and all relevant information into the recorder. Refer to the Recorder manual for more information.
- 6. At the ECG Data screen on the recorder start the 24 hour recording.

5.1.5 HOW TO PROCESS / DOWNLOAD ECG FROM A 2003/2010 RECORDER

- 1. When finished recording, the recorder will automatically turn off.
- 2. Remove the batteries first, then the SD or compactflash card.
- 3. Insert the SD or compactflash card into the flash card reader.
- 4. Plug the flash card reader into the USB connector.
- 5. From Main Menu select option 1. **Download ECG.**
- 6. The "Downloading Data" screen will appear and show a progress bar.

Warning!

Never remove the Smart Dock or Monitor when downloading.

Note:

- Refer to Section 11 Extras, for detailed instructions on Ejecting USB devices.
- 7. When the data is finished downloading a red box will appear that says "Data has been processed. Press OK to continue."
- 8. When "OK" is selected you will be directed to the "Patient & Facility Data" screen.
- 9. Type in patient, facility, hook-up, and all other relevant information.
- 10. Press **<ESC>** when finished.
- 11. Select **Diary Entries Mode** from the options menu. Fill in all diary notes then select **<ESC**>.
- 12. Select Superimposition and Preview Paging from the options menu.

13. You will now be at the **Preview / Auto Gain** screen. Download Instructions can also be found at the bottom of the Batch Processing Menu screen.

5.1.6 HOW TO PROCESS / DOWNLOAD A MULTIPLE-DAY 2003/2010/HPP RECORDER Downloading a multiple-day recorder is the same as downloading a 24-hour recorder except for these differences:

- 1. At the "Downloading New Patient From Flash" screen the day that is being downloaded will be displayed. All days will be downloaded in one session.
- 2. When typing in the hook-up date at the "Patient & Facility Data" screen remember, the hook-up date needs to be the first day of recording, not when the recording will be finished.
- 3. At the Preview / Auto Gain screen, when you analyze this record it will only be for the first 24 hours. To analyze the other days you must go into "Recall Patient From Disk", then recall and analyze them. There will be a record for each day. Each day is treated like its own 24-hour record. The difference between the records is the hook-up date.

5.1.7 PREVIEW / AUTO GAIN

See Section 5.4 on Superimposition & Preview Paging

5.1.8 Recall Patient From Disk

This screen enables the user to recall, delete, or archive any patient files that have been processed (Processed = Superimposition and Preview Paging / Full Disclosure have been performed).

If a patient record has a gray background then the data source for this record is the local drive.

If a patient record has a blue background then this record has a remote data source, such as a CD, another computer on a network, or another directory on the current computer.

ACTIVE KEYS: During Batch / Library Patients

- <**^>** Back to the previous selection
- Forward to the next selection
- <F6> Toggles between sorting the Patient Files by name and by date
- <F7> Recalls highlighted Patient File
- <F8> Archives highlighted Patient File
- **<F9>** Deletes highlighted Patient File
- **<Print List>** Prints a list of Patient Names

<Data Sources>

Allows the user to select which data source(s) will display the patient files contained within it/them.

<Double-click>

Recalls Patient File

<Right-click> Displays all of the patient record data

<ESC> Exit back to Batch Processing / Change Patient menu

5.2 OPTION: PATIENT DATA & COMMENTARY PURPOSE:

Enter new patient, facility and commentary information into the **ACS** Analyzer, or change previously entered information. Various reports can also be printed.

ACTIVE KEYS:

<Page Up> Back to the previous field entry

<Page Down> <ENTER>

- Forward to the next field entry
- **** Deletes character to the right of the cursor
- <BACKSPACE> Moves the cursor to the left and erases that character
- **<ESC>** Complete current field entry, display menu options
- <F10> Enter Commentary / Impressions field
- <Left-click> Places cursor in desired field

<ALT>+<F9> or <Right click>

Brings up Speed Editor

ACTIVE KEYS: During Commentary / Impressions <F10>

- **** Deletes character to the right of the cursor
- <SPACE> Moves cursor to desired typing area
- **<HOME>** Go to the beginning of current line
- <END> Go to the end of the current line
- <F1> Clear the entire Commentary section
- <ESC> Complete commentary and return to patient profile entry mode
- <**^>** Move the cursor up one line
- $\langle \rightarrow \rangle$ Move the cursor to the right one character
- Move the cursor down one line
- <-> Move the cursor to the left one character

OPERATION:

Select **Patient Data & Commentary** from the Main Menu. Proceed with the operation as follows:

5.2.1 ENTERING THE PATIENT INFORMATION

- 1. a. Enter the patient's LAST name then push "Enter".
 - b. Enter middle initial push "Enter"
 - c. Move on to FIRST name by pressing "Enter"
- 2. The start time, hook-up date, Patient I.D. will be automatically entered.
- 3. Enter the primary medical test indications for the patient, followed by the patient's current relevant medications.
- **Important:** The patient name cannot be edited after you exit the page.

5.2.2 ENTERING THE FACILITY INFORMATION

Note: This is completed during the "Download" section/ Option 1 in the Entry Menu.

- 1. Type the facility name and department (if applicable); press <**ENTER**>.
- 2. Type the last and first name of the physician who ordered the Holter test; press **<ENTER>**.
- 3. Type the last and first name of the physician who will interpret the Holter test results; press **<ENTER**>.
- 4. Type the name of the person who prepared the patient and completed the hookup procedure; press **<ENTER**>.
- 5. Type your name; press <**ENTER**>.
- Type the serial or identification number of the Holter recorder used in the hookup procedure, and the number of ECG channels (either two or three channels); press <ENTER>.

5.2.3 ENTERING THE COMMENTARY IMPRESSIONS

- Press <F10> to access Commentary / Impressions (ONLY when *Supervisor mode* is activated).
- Start typing your comments. <SPACE> moves the cursor one character space. If you want to be able to type on the next line, press or hold the <SPACE> bar until the cursor is where you want to start typing.
- 3. When on the last line of the commentary entry section, hold <SPACE> to proceed to the next line even though it is not visible. There are approximately 25 lines available for typing the commentary impressions but only about ten lines are visible at any one time. Use the arrow keys or mouse to move the cursor and view all the commentary impressions. When printed on paper, all 25 lines of commentary impressions will be present.
- 4. When done with Commentary / Impressions, press or click on <ESC>. This will exit the Commentary / Impressions mode and place the cursor in the field where it was before you entered the Commentary / Impressions field. Press or click <ESC> again to access the options menu.

5.2.4 PRINTING THE PATIENT PROFILE / FINAL REPORT

Press **<ESC**> to see the sub-menu options after entering patient, facility & commentary information.

The Patient Profile and Commentary / Impressions can be printed with or without the narrative. The narrative summarizes the results of the Holter test after the ECG downloaded from the DDR Recorder has been processed. From the options menu pick **Select Report Page Options**, choose all of the desired settings, then click on "OK". Then press or click on **<ESC>**. To print, Double-click on **Print Complete Final Report**. Make sure there is a sufficient amount of paper in the printer.

Optional: A "Report Cover Page" with patient and facility information may be printed on a personalized letterhead paper by loading the paper with your logo on top, face up, into the printer before choosing the print option.

5.2.5 TRANSFERRING TO THE DIARY ENTRIES MENU

The Diary Entry screen can be directly entered by selecting this option. This is a shortcut to selecting the option from the Main menu.

5.2.6 EDIT CUSTOM REPORT

Allows user to enter the "Report Summary" screen and manually edit the Report Summary data.

5.2.7 SPECIAL FEATURES

There are some special features in the "Patient and Facility Data" screen under the **Patient Data and Commentary** section.

5.2.7.1 The Speed Annotate feature works in the following fields:

Indications Medications Facility Department Ordering Physician Interpreting Physician Hook-up By Scanned By Recorder # <**Right Click**> in any of these fields and a box with a list of pre-defined choices will appear. If you want to select one or more of these choices simply **Double-click** on the desired choice. Once you are finished click on "Finished" and your choices will be saved to that field. There are more functions that can be performed in the Speed Annotate box.

5.2.7.2 Speed Annotate Functions:

| Move Up | Moves the blue highlight bar up to the previous selection. |
|-----------------|--|
| Move Down | Moves the blue highlight bar down to the next selection. |
| Add Entry | Press this to add the entry in the primary field to the list field. |
| Delete Entry | Deletes the entry the blue highlight bar is on from the list field. |
| Modify Entry | User can modify or edit the entry the blue highlight bar is on in the list |
| | field. |
| Sort Entries | Rearranges the entries in the list field into alphabetical order |
| Default Entries | Reverts the field list back to the original, default entries. |
| Clear Field | Deletes the entry in the primary field |
| Finished | Sends user back to "Patient and Facility Data" screen and saves all work |
| | done in Speed Annotation box. |

5.2.7.3 SAVE and LOAD buttons

- **SAVE** To save all FACILITY data entered on the "Patient and Facility Data" screen as the default.
- **LOAD** To load FACILITY data saved as the default information.

5.3 OPTION: PATIENT DIARY MODE

PURPOSE: Enter a list of the approximate times corresponding to patient reported symptoms for later viewing.

ACTIVE KEYS:

<**^>** Back to the previous field entry

<↓> or <ENTER>

Forward to the next field entry

- $\langle \rightarrow \rangle$ Move the cursor to the right one character
- <-> Move the cursor to the left one character
- **<BACKSPACE>** Move the cursor to the left and erase that character
- **** Deletes character to the right of the cursor
- <ALT>+<F1> Clear all diary times and events

Right-click on any Event Field

Bring up "Speed Diary Entries" box

<ESC> Complete current field entry, sort entries by the time field, display menu options

Left-click on Desired Event Field

Places cursor in that field

OPERATION:

Patient diary correlation is part of performing a complete Holter study. The patient diary is provided for the MASTER SERIES operator so that symptoms recorded by the patient may be either verified as being related or not to ECG changes.

The MASTER SERIES identifies diary entries in a number of ways. The diary is reviewed by the operator, then valid times and symptoms are entered in the Diary Entries screen.

When Disclosure pages are printed, a "D" is printed in the identifier column to the left of the disclosed ECG. The "D" will assist in validating an individual diary entry. It is important to note that cardiac activity preceding and following a diary symptom can be very important and is easily reviewed on the Disclosure page. An arrow is also printed on the BPM time axis of the Minute by Minute Summary Report to indicate the presence of a diary entry.

The following operations can be performed when in Patient Diary mode:

- A. Enter new patient diary information
- B. Modify patient diary information
- C. Delete patient diary information
- D. Print patient diary information
- E. Go to the Superimposition & Full Disclosure menu
- F. Edit the default diary Speed Annotate entries

5.3.1 ENTERING NEW PATIENT DIARY INFORMATION

Select **Patient Diary Mode** from the **Main Menu**. Proceed with the operation as follows:

- 1. Begin by typing the time for an event corresponding to the patient diary and pressing **<ENTER>**. It is not necessary to type in the start time even though it may be the patient's first diary entry; it is simply understood. Times should be entered in international format, e.g. 13:00 for 1:00 P.M., when applicable. The times may be entered in any order; they will automatically be sorted in chronological order when **<ESC**> is pressed.
- 2. Type in the symptom or event corresponding to the patient's diary and press <ENTER>, or Right-click in the desired field, a list of entries will appear, then Double-click on the desired entry(s) for that field. Function keys <F1> through <F12> may be used to quickly enter in common symptoms or events. Another quick and easy way to enter one of the <F1> through <F12> entries into an event field, is to simply Left-click on the desired field, and then Left-click on the number (<F1>-<F12>) of the entry you want in that field.
 - The following is a list of the quick entry function keys:
 - F1 BOWEL MOVEMENT
 - F2 CHEST PAIN
 - F3 DIZZINESS
 - F4 EXERCISE
 - F5 HEADACHE
 - F6 INDIGESTION
 - F7 LEG PAIN
 - F8 LIGHT HEADED
 - F9 MEAL TIME
 - F10 OUT OF BED
 - F11 PALPITATIONS
 - F12 READING
- 3. Repeat the above steps for the remaining patient diary information.
- 4. When all the patient diary entries have been entered, press or click on the <ESC> key. This will sort the diary entries in chronological order and display the options menu.

5.3.2 MODIFYING PATIENT DIARY INFORMATION

- 1. From the Patient Diary menu, select the option **Return to this Screen** and press **<ENTER>**.
- 2. Move to the entry to be modified by using the appropriate active keys listed above.
- 3. Type over the previous entry to make corrections.
- 4. When all modifications have been made, press the **<ESC>** key. This will again sort the diary entries in chronological order and display the options menu.

5.3.3 DELETING PATIENT DIARY INFORMATION

- 1. From the Patient Diary menu, select the option **Return to this Screen** and press **<ENTER>**.
- 2. Move to the entry to be deleted by Left-clicking and placing the cursor in that field.
- 3. Move the cursor to the very beginning or very end of the text in that field, then click and drag with the Left mouse button until the text is highlighted with the blue bar. After the text is highlighted, press to delete that particular entry, or <ALT>+<F1> to clear all the entries.
- 4. When all desired entries have been deleted, press the **<ESC>** key. This will again sort the remaining diary entries in chronological order and display the options menu.

5.3.4 PRINTING THE PATIENT DIARY REPORT

From the Patient Diary menu Double-click, or press **<ENTER>** on the option **Print Patient Diary Report**. Make sure there is paper in the printer paper tray.

5.3.5 TRANSFERRING TO SUPERIMPOSITION & PREVIEW PAGING

The **Superimposition & Preview Paging** menu can be entered directly by selecting it from the **Patient Diary** menu. This is a shortcut to selecting the option from the **Main Menu**.

5.3.6 EDITING THE DEFAULT SPEED ANNOTATE ENTRIES

The most commonly used diary annotations have been assigned to **<F1>** through **<F12**> function keys for speed annotation. However these default entries can be changed as follows if desired:

- 1. First, bring up the "Speed Diary Entries" box by going to any event field and right-clicking with the mouse.
- 2. Next, select the symptom you wish to be on the common symptoms list, by clicking on it once with the Left mouse button.
- 3. Once it is highlighted with the blue bar, click on the "Move Up" key until it is one of the top 12 entries in the "Speed Diary Entries" box. Click on "Finished".
- 4. Now, whatever the top 12 entries in the "Speed Diary Entries" box are, those will be the entries for the common symptoms list on the right.
- 5. If for any reason you want to revert back to the default (how the list was when you received the system) common symptoms list, bring up the "Speed Diary Entries" box, click on the "Default Entries" button, then click on the "Finished" button. The common symptoms list will now be restored to how it was when you received the system; otherwise, any changes you make to that list will automatically be saved.

"Speed Diary Entries" box Functions:

Enter (Keyboard Only)--Adds highlighted selection to primary field

Esc (Keyboard Only)--Closes "Speed Diary Entries" box and adds changes to current screen

Clear Field--deletes the entry in the primary field

Finished--sends user back to "Patient Diary Report" screen and saves all work done in "Speed Diary Entries" box.

5.4 OPTION: SUPERIMPOSITION & PREVIEW PAGING / FULL DISCLOSURE

PURPOSE: Provide a mode to process ECG received from a Holter Recorder. This mode will generate a Full Disclosure report, provide simultaneous Superimposition display with Full Disclosure or Preview Paging, allow for editing of Tabular Summary, and entry of Selected Strip times.

ACTIVE KEYS: During Superimposition & Preview Paging / Full Disclosure

<F1>-<F3> Function keys used to select which Preview Paging channel is being displayed

<CTRL>+<F1-F3>

Change Trigger channel

<SPACE BAR> (when viewing Superimposition)

- Mark event and save page when analyzing Superimposition (left side of screen)
- **<ESC>** Stop Superimposition and Full Disclosure process
- **F5>** Toggle between Waveform view (Preview Paging) and Tabular view (Full Disclosure)

<F5> then <F11>

View Tabular Summary

<F5> then<F12>

View Strips

 Clear current Selected Strip time entry

- <ENTER>(when viewing Preview Paging)
 - Save Current Page when analyzing Preview Paging (right side of screen)
- <F4> (when viewing Preview paging)

Save Previous 5-minute Page,

<**←**><**↑**><**↓**>Left-click

Move between fields during Tabular Summary edit

- <+>, <-> Increase and Decrease gain/amplitude of ECG
- </>
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OPERATION:

Select **Superimposition & Preview Paging** from the Main Menu. The following operations can be performed when in **Superimposition & Preview Paging / Full Disclosure** mode:

- A. Adjust the analyzer gain settings to maximize the report quality and the accuracy of data.
- B. Set various system analysis modes including ST-Level measurement criteria
- C. Produce a 24-hour Full Disclosure report
- D. Provide a Superimposition display during report generation

- E. Provide an hour by hour Tabular Summary during report generation and allow editing of data.
- F. Allow entry or editing of Selected Strip times.
- G. Transfer to Selected Strip mode.
- H. Print Tabular Summary and Minute by Minute Summary Reports.
- I. Re-print selected, edited Full Disclosure hours.
- J. Transfer to Paging mode.

Important: If you plan on printing Full Disclosure during the Superimposition analysis it is imperative that you select the desired settings for the Full Disclosure printouts from the "Specify Full Disclosure Style" selection under the "Printouts" menu on the Windows Toolbar. Otherwise the Full Disclosure printouts may not be in the desired format and you will have to start "Superimposition & Preview Paging" all over again. A complete full disclosure should be printed for each patient and provided to the ordering physician for finial quality review. ACS provides no assurances that the automatic analyzed report accurately reflects the patient's arrhythmias.

5.4.1 PREVIEW / AUTO-GAIN

After selecting the **Process / Download ECG Data from Recorder** option and the ECG has been downloaded into the system, selecting **<ESC**> will automatically take you to the "Preview Auto-Gain" screen. The intention of this page is to find the *optimal* channel of ECG to analyze. Use the **(+/-)** keys to adjust ECG gain.

In case you decide to process a patient (run Superimposition & Preview Paging) at a different time, "Preview Auto-Gain" can be run by selecting it from the **Batch Processing & Change Patient** menu or by Double-clicking on **Superimposition & Preview Paging** from the Main Menu, which will automatically bring you to the "Preview/Auto Gain" page.

Press **<F1>**, **<F2>** or **<F3>** to find the cleanest channel. Use the **<Arrow Keys>** to move the cursor box to the region of the cleanest waveform **<Page Up>** or **<Page Down>** to select previous or next page and then press **<ENTER>** when you are finished with the current screen.

5.4.2 SET CRITERIA

- 1. From the Preview/Auto-Gain page, select the option for SET CRITERIA <**F11**>. Proceed to the next step if the SET CRITERIA screen is displayed.
- 2. Select desired report criteria. Use the mouse to change/toggle the current report criteria. For each option a check mark means ON, an empty box means OFF. Click on "OK" when done with report criteria.
- 3. During SET CRITERIA:

HEART RATE ANALYSIS ON / OFF

The automatic setting for this selection is "ON" indicating that heart rates are reported during processing. When "OFF", heart rates and heart rate variability will not be analyzed and reported. This option is independent of TABULATOR ANALYSIS and ST-SEGMENT ANALYSIS options; therefore it is possible for the system to report ectopic beat counts and ST-level measurements without reporting heart rates.

ST-SEGMENT ANALYSIS ON / OFF

The automatic setting for this selection is "ON". When "ON", the system will calculate and report the difference between the ST-segment and the Isoelectric line. The ST-level measurements are taken on individual recorded channels. Therefore the I, J and C cursors are adjusted individually.

TABULATOR ANALYSIS ON / OFF

The automatic setting for this selection is "ON". When "ON", the system will analyze, count and report on the ectopic beats.

ECTOPIC IDENTIFIERS ON / OFF

The automatic setting for this selection is "ON". If ectopic identifiers are not desired on the Disclosure pages click on the check-mark box to toggle identifiers "OFF". All identifiers will be turned off with the exception of ">" for event marker and "**D**" for diary entry. Identifiers are usually a matter of preference as they are mainly an operator tool to aid in editing of the report. The identifiers assist the operator in locating difficult to find arrhythmias when viewing the Disclosure pages as well as recognize how well the Tabulator is analyzing the data.

HEART RATE VARIABILITY ON / OFF

The automatic setting for this selection is "ON". When "ON", the system will analyze "normal" ECG data in blocks of five minutes and report heart rate variability.

LHRV IDENTIFIERS ON / OFF

The automatic setting for this selection is "OFF". If LHRV identifiers are desired click on the check-mark box to toggle the identifiers "ON". The HRV identifiers provide visual validation of the Heart Rate Variability Report.

AUTO STRIP TIMES ON / OFF

The automatic setting for this selection is "ON". When "ON", the system will automatically select a time from the report corresponding to the:

- 1. Minimum heart rate
- 2. Maximum heart rate
- 3. Maximum ST depression
- 4. Any diary entries input by technician

The above selected times will appear in the list of selected strip times. The times corresponding to minimum and maximum heart rates will be absent if HEART RATE ANALYSIS option is "OFF".

PEDIATRIC MODE ON / OFF

The automatic setting for this selection is "OFF". If the patient is in the pediatric classification with suspected high heart rates, it is wise to set this selection to "ON" by clicking on the check-mark box prior to processing.

5.4.3 TRIGGER SET-LEVEL

- 1. Press or click on **<F>** to select waveform type.
 - a) Normal
 - b) Pacer
 - c) High Artifact
 - d) Low Amplitude

- e) High Heart Rate
- f) Normal 2
- g) Custom 1
- h) Custom 2
- i) Custom 3
- j) Custom 4
- k) Custom 5
- I) Custom 6
- 2. Press or click on **<T>** to select Trigger Mark Gain.
 - a.) Low
 - b.) Medium
 - c.) High

Use the (+/-) keys to adjust ECG Gain. Use the $\langle \uparrow \rangle$ and $\langle \downarrow \rangle$ keys for fine Trigger Level Setting and $\langle Page \ Up \rangle$ or $\langle Page \ Down \rangle$ keys for coarse Trigger Level Setting. Press $\langle Enter \rangle$ when you are finished with the "Trigger Template" screen. Repeat this process for channels 2 and 3.

Note: It is recommended that you use the keyboard keys as opposed to the mouse when adjusting the Trigger Level Settings.

5.4.3.1 FUNCTION OF TRIGGER MARKS

The trigger marks are important in getting a good and accurate report regarding the BPMs and STs. Basically, the trigger marks make sure the system has correctly identified every R-wave in a given minute. On the Trigger Template page for each channel, you want to make sure that there are white trigger marks under each of the yellow ECG beats.

Also, when you are running Superimposition & Preview Paging, and the channel you've chosen to disclose ends up having a lot of artifact you can change channels so that the BPM and ST counts are accurate. First, press <F1>, <F2>, or <F3> to see which other channel has clearer ECG. Once you've decided on a channel press or click on <CTRL> plus the corresponding channel (<F1> for Channel 1 etc...) so that the trigger marks start tracking the R-waves on that channel instead of the one with artifact on it.

5.4.4 SPECIFY ANALYSIS PARAMETERS

- Adjust the ST-Level Measurement cursors. Since no two patient ECG complexes are alike, the MASTER SERIES provides the ability to adjust the measurement points individually for each channel. Use (+/-) keys to adjust ECG gain. Press <Shift>+ <<-> or <Shift>+<-> arrow keys to select the cleanest, normal waveform. Press <I>, <J> or <C> (calculation) to select the cursor for the particular channel(s). When "L" is selected, the selected cursor, either "I", "J", or "C" will move simultaneously for All Cursors, Active Cursor + Right or Active Cursor + Left.
- Use the <←> or <→> keys to adjust the position of the desired cursor(s). The proper placement of the "I", or Isoelectric cursor is midway between the end of the P-wave and the start of the Q-wave. The "J" cursor should be set on the J-

point. Finally, set the computation point. Keep in mind that the "C" cursor moves automatically with the "J" cursor, initially about 80 milliseconds to the right of the "J" cursor.

This setting is acceptable in many scanning situations. The interval between the J-point to the "C" cursor (computation point) is displayed below the cursors for operator convenience. Fine adjustments can be made in five millisecond increments each time the arrow keys are pressed.

It is important to note that all measurements are taken from the "I" cursor set on the Isoelectric line and the "C" calculation cursor. The "J" cursor is used merely as a reference point for setting the "C" cursor a specified number of milliseconds (usually 80) from the "J" cursor set on the J-point.

3. Press or click on **<ENTER>** when settings are complete.

5.4.5 SUPERIMPOSITION & PREVIEW PAGING / FULL DISCLOSURE

The Superimposition display is used to view ECG signals and save the analyzed Full Disclosure. The Full Disclosure (Tabular View) printed or viewed simultaneously with the Superimposition is then used to verify or edit the final report and select specific strips of ECG data for enlargement, annotation and printing. There are different circumstances and different desires when running Superimposition & Preview Paging. Read any and all of the following categories that apply to your circumstance or desire.

A. RUNNING SUPERIMPOSITION IMMEDIATELY AFTER DOWNLOADING ECG FROM A RECORDER

(Running Superimposition for the 1st time on that patient)

- After selecting option 1. Download New Patient From Flash and the ECG has been downloaded into the system, selecting <ESC> will automatically take you to the "Preview Auto-Gain" screen.
- 2. Press **<F1>**, **<F2>** or **<F3**> to find the cleanest channel and press **<ENTER**> when finished with the current screen.
- 3. Press **<F11>** to select desired report criteria.
- 4. Set the Trigger marks for each channel.
- 5. Set ST-Level Measurement cursors for each channel. Press **<ENTER>** when finished. (See Sections 5.4.1 through 5.4.4 for more detail on each step).
- When finished verifying the I, J, and C cursors at the "Set Level Summary" screen you will be prompted to the Superimposition screen by selecting <ENTER>. There you will be asked, "Do you want to print full disclosure during analysis?".
- **B.** RUNNING SUPERIMPOSITION FROM MAIN MENU or "PREVIEW / AUTO-GAIN" after download.

(Running Superimposition after it's already been run at least once)

Note: There are one of two modes you can be in when running Superimposition and
 Preview Paging for a second time. These two modes, Auto Analyze or Advanced
 Mode, are found in the Settings menu of the gray Windows Toolbar. These
 modes can only be changed when in Supervisor mode.
 If in Auto Analyze mode:
1. The Preview / Auto Gain settings will be pre-determined by the system and Superimposition analysis will begin immediately. Also, Full Disclosure will automatically begin to print according to the "Specify Full Disclosure Style" settings.

If in Advanced Mode:

- If you decide to run Superimposition after it's already been run at least once select Superimposition and Preview Paging from the Main Menu or "Preview / Auto-Gain" from the option 2. Recall Patient From Disk menu.
- A red box will appear saying, "Preview / Auto-Gain has already been performed for this dataset. If you continue you will erase all analysis results from that session. Do you want to continue?" If you select "No" you will return to the previous menu screen and the analysis results will still be unchanged. If you select "Yes";
- 3. A red box will appear saying, "Do you want to use the same analysis parameters as last time?" If you'd like to adjust the cleanest channel, report criteria, Trigger marks, or ST-Level Measurement cursors, click on "No". If the previous Preview / Auto-Gain settings for this patient are OK, click on "Yes". If you're not sure what the previous Preview / Auto-Gain settings are it is safer to click on "No" so you can make sure they are appropriately set.
- 4. When "No" is selected you will be prompted to the Preview / Auto-Gain screen. When "Yes" is selected you will be prompted to the Superimposition screen.
- 5. *Note:* When "Yes" is selected at the screen that says, "Preview / Auto-Gain has already been performed for this dataset. If you continue you will erase all analysis results from that session. Do you want to continue," All Previous Analysis Information Will Be Erased.
- C. IF PRINTING FULL DISCLOSURE

Before Recorder is hooked up to the USB /Smart Dock cable for downloading, do the following:

- 1. From main menu click on "Printouts" on the Windows Toolbar and select "Specify Full Disclosure Style"
- 2. Change the settings to how you would like Full Disclosure to be printed out.
- 3. Proceed to insert the Recorder to USB/Smart Dock cable and download ECG.
- D. IF NOT PRINTING FULL DISCLOSURE

Proceed Normally.

During the Superimposition process all of the recorded ECG channels will be displayed simultaneously even if only a single channel is being disclosed. Also, during Superimposition select **F5**> to toggle between Tabular Summary and Preview Paging. When Superimposition and/or printing are complete, the options menu will automatically appear. Select the next desired option from there

5.4.6 INTERACTIVE SUPERIMPOSITION OPTIONS

5.4.6.1 Before Superimposition (Print Options)

SELECT CHANNEL FOR DISCLOSURE

From Main Menu click on "Printouts" on the Windows Toolbar and select "Specify Full Disclosure Style". Change the settings to how you would like Full Disclosure to be printed out.

5.4.6.2 During Superimposition & Preview Paging

<F1>, <F2>, <F3> DISPLAY CHANNEL

The system will change what channel is being displayed during Preview Paging.

<CTRL>+<F1>,<CTRL>+ <F2>,<CTRL>+<F3> TRIGGER CHANNEL

The system will change the Trigger channel.

<+>, <-> INCREASE AND DECREASE GAIN

The amplitude of the ECG waveforms viewed during Preview Paging will be lowered or increased (+/-).

</>, <*> SUPERIMPOSITION SPEED

The speed at which Superimposition and Preview Paging are run can be changed. (1) is slowest and (5) is fastest.

<SPACE BAR> MARK EVENT ON FULL DISCLOSURE REPORT

The **<SPACE BAR>** key can be pressed while viewing the Superimposition on the screen when a beat of interest is observed. This action causes a simultaneous "*" marker to be placed on the left side of the printed Full Disclosure page next to the corresponding minute. This "*" marker is used to assist the operator in finding that minute on the Full Disclosure page.

<F4> SAVE PREVIOUS PAGE

Pressing **<F4>** will mark and save the previous 5-minute page during Preview Paging **<ENTER> SAVE 5-MINUTE PAGE**

Pressing **<ENTER>** will mark and save the current 5-minute page being displayed during Preview Paging.

<ESC> STOP PROCESSING

The **<ESC>** key can be pressed to stop scanning and printing the Full Disclosure report. The system will finish analyzing the current hour of data and return to the menu.

5.4.6.3 During Superimposition & Full Disclosure

<F5> TOGGLES BETWEEN PREVIEW PAGING AND TABULAR VIEW (FULL DISCLOSURE) <F11> EDIT TABULAR SUMMARY

Allows the user to edit the Tabular Summary count that appears on screen **<F12> EDIT STRIPS**

Allows the user to edit and enter selected strip times

<SPACE BAR> MARK EVENT ON FULL DISCLOSURE REPORT

The **<SPACE BAR>** key can be pressed while viewing the Superimposition on the screen when a beat of interest is observed. This action causes a simultaneous "*" marker to be placed on the left side of the printed Full Disclosure page next to the corresponding minute. This "*" marker is used to assist the operator in finding that minute on the Full Disclosure page.

5.4.7 FULL DISCLOSURE PRINTED PAGE

A complete full disclosure should be printed for each patient and provided to the ordering physician for finial quality review. ACS provides no assurances that the automatic analyzed report accurately reflects the patient's arrhythmias.

A single channel Full Disclosure page can contain anywhere from 15 minutes to 6 hours of ECG data. 60 minutes per page is the most common format. The time corresponding to each line of data is shown immediately to the left of that line.

a. Ectopic Identifiers will be printed if they have been requested. Ectopic Identifiers may be turned off, see earlier section (5.4.2) for SET CRITERIA. Identifiers are printed on the FULL or AUTO DISCLOSURE pages immediately to the left of each minute's time stamp. Identifiers are provided to assist the operator in determining how well the Tabulator is analyzing the ECG. Typically the operator will use the identifiers and the associated disclosed ECG to assist in the verification of the Tabular Summary Report results. Ectopic Identifier codes are used by The MASTER SERIES as shown in the priority table below. These codes are used when the identifier option is "ON". One identifier is printed for each minute of ECG. Identifiers are printed in the priorities indicated by the table below:

| CODE | ECTOPY ENCOUNTERED | PRIORITY |
|------|--------------------|----------|
| * | OPERATOR EVENT | #1 |
| D | DIARY TIME | #2 |
| R | WIDE RUN | #3 |
| Р | 2 SEC PAUSES | #4 |
| С | WIDE COUPLET | #5 |
| Ν | NARROW RUN | #6 |
| W | WIDE BEAT | #7 |
| Е | EARLY NARROW | #8 |

For example, if the 09:34 minute contained wide beats and at the 09:34 minute the operator event button was also pressed, the resulting printed identifier would be "*" indicating the operator event. This is because the operator event has priority over "W" for wide beats. Tabulator results are not affected by the identifiers and wide beats are still counted.

b. **Beats per Minute** values are printed in the first column to the right of each DISCLOSURE minute.

- c. **ST-Level Measurements** for channel one are printed in the column to the right of Beats per Minute for each disclosed minute. ST-Level Measurements for channel two are printed in the third column and ST-Level Measurements for channel three are printed in the fourth column. ST-Level Measurements are not printed during the first eight minutes of FULL or AUTO DISCLOSURE. The first eight minutes are dedicated to system calibration data and the columns will appear blank.
- d. **High and Low BPM and ST-Level Indicators** are provided on each disclosure page to assist the operator in easily identifying the highest and lowest heart rates or ST Levels. Each page of data is reviewed by the computer just prior to printing the disclosure page. A box is then placed around the highest and lowest value in that column of numbers. In cases where more than one minute on each disclosure page has the same value for a high or low, the system will indicate the first occurrence of that value.
- e. **Page totals** for ectopic categories are printed at the bottom of each disclosure page. These totals assist in fast and easy editing of the Tabular Summary Report.

Note: Page totals are compiled for the ectopic beats counted on each page.

- f. **Blank BPM and ST-Level Measurements** indicate the minutes that were not analyzed. When the Tabulator does not have enough good data due to the intrusion of artifact or inadequate R-wave recognition, counting will cease and no data will be printed in the BPM or ST columns for these minutes.
- g. LHRV Identifiers are provided by a box around the five minute segment which contained an episode of low heart rate variability. See section on Tabular Summary Reports for more detail.

5.4.8 TABULAR SUMMARY REPORT & EDITING

The tabulated ectopic counts and ST measurements can be edited as they become available during the Superimposition and Full Disclosure process. The new edited values must be greater than or equal to the MINimum value and less than or equal to the MAXimum value calculated by the system.

- 1. Make sure you are in Tabular View <F5>
- 2. Press the **<F11**> key to start edit mode.
- 3. Use the arrow keys or mouse to move to the field value to be edited.
- 4. Type over the existing value and press **<ENTER>**. A new value can be entered to replace "0", but not if the field is blank. A field will only be blank if there is no data detected during that time i.e. a recording that is stopped prior to a 24-hour procedure. A new value can be entered only if it replaces an existing value.
- **Note**: When a new value has been entered and accepted by the system, the word "**Edited**" appears on the Tabular Summary Report, and edited fields become "<u>red</u>".

5.4.9 SELECTED STRIP TIME ENTRY / EDITING

New selected strip times can be entered or existing entries modified during Superimposition and Full Disclosure. Select strip times from any of the Disclosure pages while the system is processing the data and enter them on this screen. Strip times do not need to be entered in sequence; they will be automatically sorted in chronological order prior to search in the Selected Strip Mode. The times entered on this screen will be held in memory until the Selected Strip Mode is entered at a later time.

- 1. Press the **<F12**> key as the Full Disclosure pages are being printed and reviewed.
- 2. Enter strip times in the space provided by entering the HOUR, MINUTE, SECOND and DURATION. If no duration code is entered, the system will assume a duration code of one (for eight seconds). The maximum duration that you may enter is six for a total of six eight-second strips (48 seconds of continuous strips). Press **<ENTER>** after each time entry.
- Previously entered strip times may be viewed, changed or cleared by using the
 <↑> or <↓> arrow keys. Select any time entry which is in error, and re-type that entry. Select a strip time entry and press key to clear it if necessary.

5.4.10 TRANSFERRING TO SELECTED STRIP MODE

Select strip mode can be entered directly by selecting the "Selected Strip Mode" option when Disclosure has stopped and options menu displayed. This is a shortcut to selecting the option from the Main Menu.

5.4.11 PRINT TABULAR SUMMARY & TRENDS REPORTS

The Tabular and Minute By Minute summary reports can be printed at the end of each Disclosure; they can be edited or non-edited. The Summary reports printed at this point provide an overall analysis report. They also allow identification of important occurrences such as High / Low heart rates and significant ST episodes to assist in choosing Selected Strips. To print these reports go to the Main Menu and click on the "Printouts" menu from the Windows Toolbar.

The reports can be edited and printed again if desired. For more information on editing and printing the summary reports, please refer to Section 5.8 on *Tabular Summary Report* in this manual.

To print the Tabular Summary page and the BPM/ST Trend page from the options menu at the end of Superimposition and Preview Paging select "Print Tabular and Trends."

5.4.12 RE-PRINT EDITED PAGES

This option is only available after a single channel Full Disclosure has been performed. There may be occasions after Full Disclosure has been performed or printed and Tabular Summary data edited when the operator wishes to re-print edited Full Disclosure pages. This option allows the operator to select any one hour, or a number of hours, and re-print the corresponding Full Disclosure pages with the edited information. The edited pages will be re-printed with new ectopic beat totals at the bottom, new minimum/maximum values for heart rates and ST-Level Measurements on the right columns of the page. All ectopic identifiers will be removed from the left side of the page.

- 1. Select "Re-print Edited Pages" from the options menu at the end of Superimposition. A new window will appear on screen.
- 2. Now select the hours to be re-printed. Use the mouse to mark (X) the desired hours. Remember, only the hours which were disclosed earlier may be selected for reprinting. This window displays 24 hours, some of which may be disabled if 24hrs of data was not recorded. An "X" will automatically appear next to any hour that was manually edited.

The following keys can be used to interact in this window:

Use <**F8**> to mark (X) all of the previously disclosed hours for re-printing if so desired.

Use **<DEL**> key to un-mark (remove x from) all of the hours to start the selection over again if necessary.

Use **<F5>** to re-print a channel from the selected hours.

Select either Channel one, two or three from the menu to be printed. Use **<ESC>** to return to the Main Operating Menu when all the selected hours have been re-printed.

5.4.13 TRANSFERRING TO PAGING MODE

Paging mode can be directly entered by selecting the "Paging Mode" option when disclosure has stopped and options menu displayed. This is a shortcut to selecting the option from the Main Menu.

5.5 OPTION: PAGE FULL DISCLOSURE FROM DISK

PURPOSE: Provide a flexible mode to view, expand, edit and print stored ECG data. The stored ECG data from a 2003/2010/HPP Recorder has to be scanned in **Superimposition & Preview Paging** mode prior to executing this option.

Important:

A complete full disclosure should be printed for each patient and provided to the ordering physician for finial quality review. **ACS provides no assurances that the automatic analyzed report accurately reflects the patient's arrhythmias.**

ACTIVE KEYS: During Paging

- <F1>-<F3> Select channel one, two or three to be displayed on screen
- <F4> Save current five minute page displayed on screen for later reference
- <F5> Print current five minute page displayed on screen
- **F6>** Begin Auto-Paging; display pages in sequence automatically, pausing briefly before displaying the next five minute page on screen

<F7>, Right Click, or Double-click

View the expanded ECG strip in the rectangular (strip) cursor on screen

- **F8>** Save the expanded ECG strip within the rectangular (strip) cursor on the screen for later reference
- <F9> View a 30-minute page of ECG instead of a 5-minute page
- **** Delete Strip, Rectangular cursor must be placed EXACTLY over the saved strip to delete

Left Click in designated field

Edit the heart rate, ST Level Measurements, and ectopic beat counts for the current five minute page displayed on screen

- <**F10**> Special print features when printing a five-minute page
- <F11> "Auxiliary Functions" lists additional software features
- <F12> Change the Baseline Filter

$< <> < \uparrow > < \rightarrow > < \downarrow >$ or Left-Click in the ECG field

Move the rectangular (strip) cursor on displayed page. (Can also hold and drag left mouse button)

- **SPACE>** Change the length of the rectangular (strip) cursor; the cursor length is measured in seconds, and changes from 8 to 16 to 24 and then back to 8 seconds with repeated pressing of the **SPACE BAR**>
- <+>,<-> Increase or decrease the amplitude of the ECG displayed on screen by a factor of two, maximum four
- **<Page Up>** Display the previous five minute page in the sequence

<Page Down> or <ENTER>

Display the next five minute page in the sequence

- **HOME**> (Keyboard Only) Moves rectangular cursor to the first page
- <END> (Keyboard Only)

Moves rectangular cursor to the last page

- **<ESC>** a) Exit ST and Ectopic edit mode *or*
 - b) Display Paging options menu

OPERATION:

The Paging option which can be performed in any of the following modes is designed to provide the operator with a completely flexible method of reviewing, editing or printing of Holter ECG data. All the Paging modes provide similar menu options and interactive functions listed under **Common Menu options** and **Common Paging Functions**.

Select one of the following Paging options from the **Main Paging Options** menu, then press **<ENTER>**.

- 1. REVIEW SAVED PAGES
- 2. PAGE TABULAR EVENTS
- 3. PAGE FULL DISCLOSURE
- 4. PAGE SELECTED HOUR
- 5. VIEW SAVED STRIPS

5.5.1 REVIEW SAVED PAGES

In Paging mode and in Preview-Paging mode the operator can "save" certain five minute blocks of ECG data to be referenced and analyzed at a later time. In reality, only an index of the "saved" pages is maintained, allowing instant and random access to any "saved page" on the drive. Hence this mode provides the means to review and

edit all the "saved pages" of interest in chronological sequence, skipping all other "pages" in between.

NOTE: Please see "Common Paging Functions" later in this section for more detail on available interactive paging options.

5.5.2 PAGE TABULAR EVENTS

With certain patients, it would be beneficial to have the ability to skip pages of inactivity and go directly to the desired pages with ectopic and ischemic activity. This mode allows the operator to review and edit on screen only those "pages" selected from the following criteria:

Note: Ventricular ectopic beats will be displayed in "Red". Supra-Ventricular ectopic beats will be in "Green". Diary entries in "Blue".

```
Wide Beats (W)
Wide Pairs (C)
Wide Runs (R)
Early Narrows (E)
Two Second Pauses (P)
Narrow Runs (N)
Strips
Marked Events (D)
Diary (D)
Significant Events
```

NOTE: Please see "Common Paging Functions" later in this section for more detail on available interactive paging options.

5.5.3 PAGE FULL DISCLOSURE

During **Superimposition and Preview Paging**, all of the ECG data on the DDR Recorder is stored on the hard drive. The **Page Full Disclosure** mode allows reviewing and editing of all Full-Disclosure data stored on disk in five minute ECG "pages" displayed on screen.

5.5.3.1 30-MINUTE PAGE

One of the features of the MASTER SERIES is the "30-minute Page" option. To view a 30-minute Page, simply select the **Page Full Disclosure From Disk** option from the Main Menu, and then select the **Page Full Disclosure** option. This will bring you to the "Page 5-Min Full Disclosure" screen. From that screen select **<F9>** to bring up a 30-minute page.

ACTIVE KEYS: For 30-minute Page

- <F1>-<F3> Select channel one, two or three to be displayed on screen
- <F6> Begin Auto-Paging; display pages in sequence automatically
- <+>,<-> Increase or decrease the amplitude of the ECG displayed on screen by a factor of two, maximum four

<Page Up> Moves the screen up 5 minutes, but the rectangular cursor does not move <Page Down> Moves the screen down 5 minutes, but the rectangular cursor does not move

Moves the screen up 1 minute, but the rectangular cursor does not move Moves the screen down 1 minute, but the rectangular cursor does not move

<SHIFT>+ Moves rectangular cursor up one 5-minute block of time

<SHIFT>+ Moves rectangular cursor down one 5-minute block of time

Left-click on ECG

Moves rectangular cursor to that 5-minute block of time

<HOME> Moves rectangular cursor to the first page

<END> Moves rectangular cursor to the last page

Double-click on 5-minute block without a saved strip

Brings you back to the 5-minute page within the rectangular cursor

Double-click on 5-minute block with a saved strip

Brings you to expanded view of the saved strip (25mm display)

<ESC> or <ENTER> (Keyboard Only)

Return back to "Page 5-Min Full Disclosure" screen

NOTE: Please see "Common Paging Functions" later in this section for more detail on available interactive paging options.

5.5.4 PAGE SELECTED HOUR

A 24-hour ECG recording can be divided into 288 five minute blocks of ECG data, called Pages. Paging in sequence through the ECG data in order to review or edit a page corresponding to a time in the middle of Full Disclosure may be time consuming and inefficient. This mode allows the operator to select any hour of Full Disclosure data and review or edit it, at random.

- 1. Select the **Page Selected Hour** option from the Paging Mode options menu.
- Select the desired hours for paging by moving the cursor to that hour and pressing <SPACE>. An "X" will appear next to the selected hour. Use the arrow keys to move the cursor to the desired hour(s). Only the processed hours may be selected.
- 3. Press **<SPACE**> again to unselect an hour.
- 4. Press **<F8**> to select all the analyzed hours; press **<DEL**> to unselect all the hours.
- 5. Press **<F5**> to print the selected hours.
- 6. Press **<ESC**> when finished selecting the hours. The first five minute block of ECG in the first selected hour will be displayed on the Paging screen.
- Press <ENTER> to advance to the next Page in the selected sequence; press
 <PgUp> to return to a previous page. Only the selected hours may be viewed in chronological order.
- 8. Press **<ESC**> in Paging mode when done to display menu options.
- **NOTE:** Please see "Common Paging Functions" later in this section for more detail on available interactive Paging options.

5.5.5 VIEW SAVED STRIPS

This mode allows viewing and editing of previously saved expanded ECG strips.

- 1. Select the **View Saved Strips** option from the Paging options menu.
- 2. Use the active keys listed below to view and edit the saved strips. For more detail, please refer to section 5.6 Selected Strip Mode.

ACTIVE KEYS - During Strip View

- <F1> Begin strip annotation
- <F5> Print currently displayed strip
- **F7>** Use caliper cursors to measure heart rates on displayed strip
- <F8> Use caliper cursors to display mSec. measurements on Selected Strip
- <F9> Toggles between 25mm and 50mm strips
- **** Delete currently displayed strip- deleted strips will not print
- <Page Up> Display previous strip time

<Page Down>, <ENTER>

- Advance to the next strip time
- <**↑**><**↓**> Select between channels
- <+>,<-> Increase or decrease the amplitude of the ECG strip displayed on screen by a factor of 1/2, 1 or 2 times standard.

<←><→> or Rotate Mouse Wheel

Scroll/move the ECG data in the strip display window

<ESC> Finished with strip view; display options menu

5.5.6 COMMON PAGING FUNCTIONS

Paging allows the operator to view a five minute block of ECG data for a single ECG channel. The data on screen is referred to as a Page. Along with ECG, the corresponding heart rates and ST-Level Measurements are located on the right side of the screen for each minute. Total ectopic beat counts for the five minute blocks are displayed below the ECG. A number of interactive functions can be performed in Paging mode; most of these functions require only a single key stroke and the results are immediate. The functions are as follows:

- (1) Select any channel for viewing, editing or printing,
- (2) Save a page (five minute block of ECG data),
- (3) Print a page,
- (4) Automatically advance between pages,
- (5) View an expanded strip of ECG data
- (6) Save and label an expanded strip of ECG data,
- (7) Delete an expanded strip of ECG data,
- (8) Edit BPM counts (beat-per-minute), ST-Level Measurements, and ectopic beat counts,
- (9) Speed edit and speed page using auxiliary features,
- (10) Move the rectangular strip cursor to select a different time,
- (11) Change the length of the rectangular strip cursor to view single or continuous eight second strips,
- (12) Adjust the ECG amplitude up or down,

- (13) View the previous Page,
- (14) View the next Page,
- (15) End tabulated data edit.

See below for a more detailed description of the above functions.

1. Select Another ECG Channel for Viewing

Press **<F1>**, **<F2>** or **<F3>** to view channel one, channel two or channel three. These keys perform the same function in Auto Page mode.

2. Save a Page

Press **<F4>** to save the current page displayed on screen. Saved pages can later be viewed separately by entering **Review Saved Pages**.

3. Print a Page

Press **<F5>** to print the current five minute block of ECG data. The ECG on the printed page will be larger than the printed Full Disclosure, but smaller than the selected (expanded ECG) strips.

4. Auto Page

Press **<F6>** to turn on the Auto Paging mode. When on, the pages will be displayed automatically in sequence after a brief pause in between the pages. Auto Paging can be performed in SLOW, MEDIUM, FAST or TURBO speeds where the duration for the pause in between pages is reduced, respectively. Use **<^**> or **<**> to change Auto Paging speed. Auto Paging can also be used for saved pages; here only the saved page sequence will be displayed. Auto Paging is stopped automatically when any ectopic or other activity of interest is detected, or use **<SPACE**> to manually stop it. Press **<ESC>** to turn off Auto Paging. It will also turn off automatically when the last page in the sequence is displayed on screen.

5. View a Strip

Press **<F7>**, Right-click, or Double-click to view the ECG within the strip cursor box. The ECG will be expanded and displayed on screen, eight seconds at a time. If the strip cursor length is greater than eight seconds, then the first eight seconds will be expanded and displayed; the remaining continuous seconds can be viewed by pressing the **<ENTER**> key. For more information on expanded ECG strips please refer to section **5.6** Selected Strip Mode.

6. Save and label a Strip

Press **<F8>** to save the expanded ECG strip within the strip cursor box, it will be highlighted to indicate that the strip has been saved. If the strip cursor box length is greater than eight seconds, then the strip will be saved in "continuous" fashion. Saved selected strips can be later reviewed by choosing VIEW SAVED STRIPS option from one of the Paging menus. To annotate from the expanded ECG strip view, select **<F1>** or Left-click on the Annotation box right under where it says VIEW STRIP in yellow. If the strip was just saved then the Annotation box will likely be empty.

7. Delete a Saved Strip

Saved strips can be deleted (un-saved) using this option.

- 1. Position the strip cursor box directly over the saved (highlighted) strip. Make sure the starting time matches perfectly.
- Press ; the strip will be un-saved and the highlight removed. Continuous strips are deleted in the same manner.
- 3. Proceed with other options.

8. Edit Tabulated Data

Left-click in the desired ectopic beat field to start editing the ectopic beat counts, heart rates and ST-Level Measurements. The ectopic beat totals are found at the bottom of the 5-minute page above the hotkey menu. If necessary, change the total by typing in the correct number. Press **<ENTER**>, **<PgDn**>, or **<Left-click**> in desired field to advance to the next ectopic beat total. Press **<PgUp**> to go to the previous entry. After the last ectopic beat total, the heart rate for the first minute of the page will be highlighted. Again the beats-per-minute (BPM) count can be edited by typing the correct number. Next, the ST- level calculations for each channel for the first minute on the page can be edited, starting with channel one. When done with the first minute, follow the same procedure for the remaining minutes on screen. After the last minute has been edited, the WIDE ectopic beat total will be highlighted again.

Note: The <↑> and <↓> arrows can be used as well as the <**PgUp**> and <**PgDn**> keys to move the cursor while editing the BPM and ST counts. Press <**ESC**> when done editing.

9. Auxiliary Features Menu

Paging mode offers a number of editing and direct page access features, some of which are not listed on the display screen. Press **<F11>** to display a list of features and their corresponding "speed keys" while in Paging Mode. While in Paging mode:

Press In order to...

Speed Edit Keys

| Ŵ | Edit "Wide" counts |
|--------------|--|
| С | Edit "Wide Couplet" counts |
| R | Edit "Wide Run" counts |
| E | Edit "Early Narrow" counts |
| Р | Edit "Pause" counts |
| Ν | Edit "Narrow Run" counts |
| Ctrl+Enter | Go to next page while editing |
| Shift+Enter | Go to previous page while editing |
| V | Begin Ectopic Edit Session |
| Ctrl+Space | Specify Ectopic Count Display |
| Speed Paging | Keys |
| Home | Go to the First page |
| End | Go to Last page |
| PgUp | Go to Previous page |
| PgDn | Go to Next page |
| (/, *) | Go to previous or next selected strip (Page 5 Min FD only) |

Ctrl-F1..F12 Go to Hour 1; Ctrl-F2 Go to Hour 2, ... Ctrl-F12 Go to Hour 12 (Page 5 Min FD only)

Ctrl+Shift-F1..F12 Go to Hour 13; **Ctrl+Shift-F2** Go to Hour 14, ... **Ctrl+Shift-F12** Go to Hour 24 (Page 5 Min FD only)

Shift-F8 Save Strip and Automatic Annotation

Ctrl T Trigger mark display on/off

Ctrl C Ectopic beat coloring on/off

10. Move Strip Cursor Box

Use the arrow keys or Mouse to move the strip cursor box to any desired location on the page to expand or save an ECG strip of data. The cursor box will wrap around the minute boundaries, at the end of the current minute and the beginning of the next; this is normal.

11. Change Strip Cursor Box Length

Press **<SPACE>** to increase the length of the strip cursor box by eight seconds, to a maximum of twenty four (24) seconds. Pressing **<SPACE>** repeatedly will change the box length back to eight seconds.

12. Adjust ECG Gain

Press either <+> or <-> keys to increase or decrease the amplitude of ECG displayed on the page. The amplitude is adjusted by a factor of two each time one of the above keys is pressed, for a maximum factor of four. That is, if the normal amplitude is considered to be 1, then the ECG can be displayed in the range ¼, ½, 1, 2, and 4.

13. View Previous Page

Press **<PgUp>** to view the previous page in the sequence. When viewing "saved" pages, the previous saved page in the chronological sequence will be displayed. **<PgUp>** also works in Auto Paging mode.

14. View Next Page

Press **<ENTER>**or **<PgDn**> to view the next page in the sequence. When viewing "saved" pages, the next saved page in the chronological sequence will be displayed.

15. End Tabulated Data Edit

Press **<ESC>** to finish editing. Pressing the **<ESC**> key again will cause a Paging menu to be displayed on screen.

5.5.7 COMMON MENU OPTIONS

Press **<ESC>** in any Paging mode until an OPTIONS sub-menu is displayed, usually at the center of the display screen.

See below for a more detailed discussion of the above menu options.

1. Return to Main Menu

Select this option to exit Paging Mode and return to the Main Operating Menu.

2. View Saved Strips

Selected expanded ECG strips saved in Paging Mode can be viewed in sequence by choosing this option. In "strip" mode a number of options for annotating and

printing are available; for more information on expanded ECG strips see section 5.6 Selected Strip Mode.

3. Page Tabular Events

See section 5.5.2 Page Tabular Events.

4. Print Selected Strips

Select this option by pressing **<ESC**> or by clicking on the "Printouts" menu on the Windows Toolbar. Once "Print Selected Strips" is selected the Print Preview Page will appear. From there use "Prev Page" and "Next Page" to see what will be printed. When ready to print all the saved ECG strips click on "Print". The list of strip times can be viewed by selecting **Selected Strip Mode** option from the Main Menu. Strip times can be added, deleted or changed when in **Selected Strip Mode**. Strip times can be added by using the "Save Strip" function <F8> in Paging mode. For more information on expanded ECG strips see the section on **Selected Strip Mode**.

5. Print Full Disclosure

Full Disclosure can be printed during or after the Superimposition & Preview Paging mode. The tabulated results from running Full Disclosure can be edited in Paging mode and the entire Full Disclosure can be printed with the edited tabulated data. To "Print Full Disclosure" press **<ESC>** and select it from the options menu or click the "Printouts" menu on the Windows Toolbar. Once "Print Full Disclosure" is selected the Print Preview Page will appear. From there use "Prev-Page" and "Next Page" to see what will be printed. To change the Full Disclosure format, click on "Close" and select "Specify Full Disclosure Style" from the "Printouts" menu on the Windows Toolbar. Once desired format is selected, click on "Print Full Disclosure" then click on "Print".

6. Print Saved 5 Minute Pages

Select "Print Saved 5 Min Pages" from the Options or "Printouts" menu to print all the previously saved 5 minute pages in Paging or Preview Paging modes. This option will be grayed out if no 5 minute pages are saved.

7. Print Complete Final Report

The "COMPLETE FINAL REPORT" consists of the following pages. The user must specify which pages to include/exclude in his/her Complete Final Report by going to the **Printouts** drop-down menu and choosing **Specify Page Report Options**. Default Report Cover Custom Report Cover Commentary with Narrative Commentary without Narrative Patient Diary Tabular Summary BPM ST Trend Ectopic Trend HRV Trend Selected Strips Saved 5-minute Pages

Full Disclosure

The Complete Final Report is usually printed after the ECG has been analyzed, expanded ECG strips selected, and results edited. It is one of the last steps prior to processing another DDR, 2000/2001, 2002/2003 or HPP Recorder. Select **Print Complete Final Report** from the options or "Printouts" menu to print the above reports. Select "Specify Page Report Options" from the "Printouts" menu on the Windows Toolbar to specify which pages are to be printed as a part of the Complete Final Report. Click on "Save Options" to save the currently selected pages as the default pages printed in the Complete Final Report. **Special Option:** If desired, you can send **ACS** a piece of paper with your company/office letterhead and for a small fee we'll convert it to an electronic format, send it back, then you can install it on your system and your letterhead will appear on printed reports. Be sure to call **ACS** and make shipping arrangements before sending. Otherwise, we cannot guarantee it will be done.

8. Main Paging Options

Select this option to display the Paging mode menu. A Paging mode can then be selected from the options menu.

9. Return To This Screen

Select this option to remove the menu from the screen and view the current Page displayed in the background. The Paging mode will remain as it was before.

5.6 OPTION: SELECTED STRIP MODE

PURPOSE: Expand selected ECG data for viewing, analysis, and printing in a similar format to EKG machine output: 25-mm/sec, or 50 mm/sec 10-mm/mV.

ACTIVE KEYS: During Time Entry

- <F1>-<F3> Select Channel
- <F4> (Keyboard Only)

Edit Annotation

| <f5></f5> | Delete CALibration strip - CALibration pulses are missing |
|-----------------------|--|
| <f6></f6> | Automatically enter or remove Diary times |
| <f7></f7> | Automatically enter or remove the MIN and MAX BPM times |
| <f8></f8> | Automatically enter or remove the MAX ST time |
| <f12></f12> | Select from among several baseline filters |
| <↑><↓> | Advance to the next strip time entry |
| <+>,< -> | Increase or decrease the amplitude of the ECG strip displayed on screen by a |
| | factor of ½, 1 or 2 times standard. |
| <space></space> | View next 8 second section when viewing a continuous strip During Strip View |
| | During Strip Calipers BPM Display |
| <enter></enter> | View Strip mode on displayed strip time entry |
| | Clear current strip time entry |
| <alt>+<f1></f1></alt> | Clear all strip time entries |
| <esc></esc> | Display options menu |

ACTIVE KEYS: During Strip View

- **<F1>** Begin strip annotation
- <F4> Save Strip
- **<F5>** Print strip currently displayed
- <F6> View next saved strip
- **F7>** Use caliper cursors to measure heart rate on displayed strip
- **F8>** Use caliper cursors to display mSec on displayed strip
- <F9> Toggle between 25mm and 50mm display of current strip
- **SHIFT>+<F3>** Jump to 5 Minute page that contains this ECG strip. (If this option is used, user must go back through Main Menu to access **Selected Strips** Time Entry screen.)
- **** Delete strip currently displayed deleted strips will not print
- <PgUp> View previous strip time
- **<ENTER>** View next strip time
- <**↑**><**↓**> Select between channels
- <+>,< -> Increase or decrease the amplitude of the ECG strip displayed on screen by a factor of ½, 1 or 2 times standard.
- $<\leftrightarrow>>>$ Scroll/move the ECG data in the strip display window in 1 second increments

<ESC>, <Right-click>

Finished with strip view; go back to Selected Strips Time Entry screen

ACTIVE KEYS: During Strip Calipers BPM Display

- **F7>** Activate caliper cursors on Selected Strip
- <L> Select left edge of caliper cursors for adjustment
- <R> Select right edge of caliper cursors for adjustment
- Select both edges of caliper cursors for adjustment
- $<\leftrightarrow>>\rightarrow>$ Move selected edge(s) of caliper cursors

<SHIFT>+<←> or <SHIFT>+<→>

- Move both caliper cursors,
- <**↑**><**↓**> Select between channels
- **<ENTER>** Calculate and display the heart rate for the current caliper setting

<ESC>, <Right-click>

Remove caliper cursors from screen; finished with heart rate measurements

NOTE: User can Left-click, hold, and drag desired caliper cursor instead of using arrow keys. User can also Left-click on desired Channel or Gain field on left side of screen.

ACTIVE KEYS: During Strip Calipers mSec Display

- <F8> Activate mSec measurements using caliper cursors on Selected Strip
- <L> Select left edge of caliper cursors for adjustment
- <R> Select right edge of caliper cursors for adjustment
- Select both edges of caliper cursors for adjustment
- $<\leftrightarrow>>>$ Move selected edge(s) of caliper cursors

<SHIFT>+<←> or <SHIFT>+<→>

Move both caliper cursors

- <**↑**><**↓**> Select between channels
- **<ENTER>** Calculate and display mSec measurements
- **<ESC>** Remove caliper cursors from screen; finish with mSec measurements
- NOTE: User can Left-click, hold, and drag desired caliper cursor instead of using arrow keys. User can also Left-click on desired Channel or Gain field on left side of screen.

5.6.1 BACKGROUND

Selected Strips are diagnostic quality examples of the selected ECG overlaid upon 25 millimeter per second grids. Each strip contains eight seconds of three ECG channels at the time selected by the operator. When displayed or printed, the time selected is the beginning of the eight second strip.

The ECG data can be selected for expansion by:

- A. Saving the ECG data time on display screen during Paging Mode
- B. Entering Selected Strip times during Full Disclosure (Tabular View)
- C. Entering Selected Strip times in the Selected Strip Mode

In Selected Strip Mode, the operator may select any of the following options from the menu:

- (1) Return to Main Operating Menu
- (2) Display and Annotate Selected Strips
- (3) Print Selected Strips
- (4) Print Complete Final Report
- (5) Return To This Screen

When Displaying and Annotating Selected Strips on screen, the following interactive functions can be performed:

- (A) Annotate strips
- (B) Print a strip
- (C) Measure heart rate with caliper cursors
- (D) Calculate mSec measurements with caliper cursors
- (E) Delete a (saved) strip
- (F) View strips sequentially forward or backward
- (G) Select a channel
- (H) Adjust gain/amplitude
- (I) Scroll (move ECG) right or left when searching for a beat
- (J) See a strip in 25mm or 50 mm format
- (K) See 5-minute page that contains the current strip
- (L) Return to selected strip menu options

OPERATION:

Although selected expanded ECG strips can be viewed in the **Page Full Disclosure from Disk** mode, all capabilities become available in **Selected Strip Mode**.

Choose the **Selected Strip Mode** option from the Main Menu. The following steps are usually performed, in this order, when processing expanded ECG strips. The

remainder of this section will describe these steps.

* Enter / Select the strip times

- * View & annotate ECG strips
- * Measure heart rates
- * Calculate the mSec on Selected Strips
- * Save or delete strips
- * Print strips

5.6.2 ENTERING / SELECTING THE STRIP TIMES

Strips can be selected in the following ways:

- (1) Indirect time entry Saving Strips in Paging Mode
 - Press <F8> to save the ECG within the strip cursor box while in Paging Mode. A brief message on screen will acknowledge the strip has been saved. The strip of saved ECG will also be highlighted. For more detail on Paging options refer to Section 5.5 Page Full Disclosure From Disk.
 - 2. Press <**F4**> to save the expanded strip when in View Strip Mode. A brief message on screen will acknowledge the strip has been saved. For more detail on Paging options, refer to that section.
- (2) Direct time entry Typing Desired Time During Full Disclosure and in Selected Strip Mode During Full Disclosure
 - While Full Disclosure is being printed and looked over, if a section of ECG of interest is observed press <F5> to enter Tabular View (if not already in it) then <F12> to begin entering strip times. Remember to use the international time standard when entering strip times. A one-digit DURATION CODE follows at the end of the six digit time entry e.g. 09:05:10 1. The DURATION CODE is the number of eight second expanded strips starting from the time entry. A DURATION CODE of two means two eight second continuous strips, for a total of 16 seconds. Press <↓> after each time entry to advance to the next.
 - 2. These strip times will be saved and will appear when **Selected Strip Mode** is entered. **In Selected Strip Mode**
 - 1. In **Selected Strip Mode** the Time Entry screen has four columns and thirteen rows of fields, all for strip time entry.
 - If desired, press <F6> to automatically enter the patient diary times. All the times entered in Patient Diary Mode will automatically be copied to this screen. Duplicate time entries will be eliminated.
 - If desired, press <F7> to automatically enter the two time entries corresponding to the minutes with minimum and maximum heart rates for the entire recording. Duplicate time entries will be eliminated.
 - If desired, press <F8> to automatically enter one time entry corresponding to the minute with maximum ST depression in the entire recording. Duplicate times will be eliminated.
 - 5. If desired, use the arrow keys to highlight any time entry and press **<DEL**> to clear that entry.
 - 6. If desired, press **<ALT><F1>** to clear all strip time entries.

- 7. If desired, use the arrow keys to highlight any time entry, and edit it by typing a new entry over that entry.
- 8. Press **<ESC>** when finished with all time entries. The options menu will be displayed on screen.

5.6.3 VIEWING AND ANNOTATING SELECTED STRIPS

Selected expanded ECG strips can be viewed either in Paging Mode or Selected Strip Mode as follows:

Viewing and Annotating Strips in Paging Mode

- 1. Press **<F7**> to view the expanded ECG strip within the strip cursor box.
- Once in View Strip mode, the expanded ECG strips may be examined and annotated the same as in Selected Strip Mode. Please refer to instructions in Strip Mode below. Remember, annotations will appear on Selected Strips when printed.

Viewing and Annotating in Selected Strip Mode

- 1. After entering the strip times, press **<ESC>** and select the **Display and Annotate Selected Strips** option from the options menu.
- Press <F1> or Left-click on annotation field to Annotate the expanded strip. Annotation is the process of identification and labeling of individual expanded strips before printing.
- 3. If desired, press <**PgUp**> to view the previous expanded strip. Press <**ENTER**> to view the next strip.
- 4. If desired, increase or decrease the gain/amplitude of an ECG channel by pressing the <+> and <-> keys. The gain of each ECG channel is adjusted separately by using the <↑> or <↓> keys to select the channel first. The active channel and its gain will be highlighted on the left side of display.
- If desired, press <←> or <→> to view ECG one second after or before the current ECG displayed. This action is referred to as scrolling and is useful when trying to find or center a particular ECG beat.
- 6. Press **<ESC**> when done. You will be reverted back to the Time Entry screen in **Selected Strip Mode**.
- 7. Refer to the **During Strip View** chart at the top of this section to see all of the features that can be performed in "View Strip" mode.

5.6.4 MEASURING HEART RATES AND mSec's USING CALIPER CURSORS

Instant heart rate calculations can be obtained for expanded ECG strips displayed on screen in the "View Strip" mode. Two purple cursors displayed as vertical lines are used to designate right and left edges of the measurement calipers.

- 1. In "View Strip" mode, press <**F7**> to turn on the caliper cursors to calculate Heart Rate and <**F8**> to calculate mSec's.
- 2. Inspect the expanded strip display. Look for an area of ECG in a channel with the most distinguishable QRS complex.
- 3. Use the $\langle \uparrow \rangle$ or $\langle \downarrow \rangle$ key, or Left-click to select the channel.
- 4. Press <L> to select the left caliper cursor (left edge of caliper cursor).

- 5. Use the <←> or <→> keys, or Left-click to move the left caliper cursor, and place directly over the crest of an R-wave.
- 6. Press <**R**> to select the right cursor (right edge of caliper cursors).
- 7. Use the <←> or <→> keys, or Left-click to move the right caliper cursor and place directly over the crest of an R-wave two beats to the right of the left caliper cursor.
- If necessary, press to select and move both caliper cursors simultaneously, or press <SHIFT>+<←> or <SHIFT>+<→>. Then select the individual caliper cursors for fine adjustments.
- 9. After both left and right caliper cursors are in place, press <**ENTER**>. The heart rate will be measured and displayed on the upper right hand corner of the screen.
- 10. Press <**ESC**> if no more heart rate measurements are desired. You will return to the "View Strip" screen.

NOTE: Caliper Cursors may be moved more quickly by pressing the **<SHIFT**> key simultaneously when using the arrow keys.

REMEMBER: The caliper cursors must span across **TWO** beats in order to calculate the proper heart rate.

5.6.5 SAVING OR DELETING STRIPS

Certain desired expanded strips can be saved for the purpose of viewing or printing at a later time. The "saving" action merely causes a reference to be made to the time of the ECG strip on the Full Disclosure page. Expanded ECG strip times may be selected to be saved in **Superimposition & Full Disclosure** mode, **Page Full Disclosure from Disk** mode or in **Selected Strip** mode. To avoid confusion, a strip can only be saved or deleted when it is being viewed on the display screen and its boundaries are clearly visible. Saved strips which are no longer needed may be deleted while viewing those strips. A strip which has been deleted is not removed from the Full Disclosure page; rather the reference to the time of that strip is removed. Therefore the same strip may be saved and deleted many times.

Saving Strips in Superimposition & Full Disclosure Mode

- 1. Press **<F5**> to get into Tabular View during Superimposition.
- 2. In Tabular View press <**F12**> as Full Disclosure pages are being printed and reviewed.
- Enter strip times in the space provided by entering the HOUR, MINUTE, SECOND and DURATION. If no duration code is entered, the system will assume a duration code of one (for eight seconds). The maximum duration that you may enter is six for a total of six eight second strips (48 seconds of continuous strips). Press <ENTER> after each time entry.
- Strip times may be changed or cleared by using the <↑> or <↓> arrow keys. Select any time entry which is in error, and re-type that entry. Select a strip time entry and press <**DEL**> to clear it if necessary.

Saving strips in Paging Mode

- 1. Inspect the Full Disclosure page on screen and identify the strip you wish to save.
- 2. Use the arrow keys or mouse to move the strip cursor box to the desired area.

- 3. If necessary, press the **<SPACE**> bar to select a larger continuous ECG area for expansion (refer to Paging options).
- 4. Press **<F8>** to save the ECG strip within the strip cursor box.
- 5. To delete a saved strip, press **** when viewing the expanded strip on the display screen.

Saving strips in Selected Strips Mode

- 1. Press **<F4>** to save an expanded ECG strip while viewing it on the display screen.
- 2. To delete a saved strip, press **** when viewing the expanded strip on the display screen.

5.6.6 PRINTING STRIPS

Selected expanded ECG strips can be printed in either eight-second 25mm strip length or four-second 50mm strip length. The strips are usually calibrated to ensure accurate ECG amplitude reporting. Therefore the standard calibration pulses will be adjusted to a height of 10mm or 1mv. The expanded strips can be printed while in Selected Strip mode or Paging mode. To help make printing easier and more efficient there is a "Printouts" menu located on the gray Windows Toolbar in the upper left-hand corner in between the two places where the patient name is shown.

"PRINTOUTS" MENU FROM THE TOOLBAR

- View Print Preview--If this selection is check-marked a Print Preview screen will appear when the Print Selected Strips and Print Complete Final Report options are selected. If this selection is unchecked, when the Print Selected Strips and Print Complete Final Report options are selected the pages will automatically start printing.
- 2. **Print in Color**--Pages will be printed in color.
- 3. **Print Complete Final Report**--Use this selection to print the Complete Final Report from this menu instead of the options menu accessed by pressing **<ESC**>.
- 4. **Specify Page Report Options**--Use this selection to determine which pages will be printed in the Complete Final Report. Left-click on "Save Options" to save the currently selected pages as the default pages printed when **Print Complete Final Report** is chosen.
- 5. **Print Tabular Summary**-- Prints the Tabular Summary Report. The Standard Page will always be printed. There is the option to print Aux Ectopic Pages 1 and 2 if so desired.
- 6. **Print Patient Profile**
- 7. Print Diary
- 8. Print BPM/ST
- 9. Print Narrative
- 10. **Print Hear Rate Variability**
- 11. Print Selected Strips
- 12. Print Saved 5 Min Pages
- 13. Print Ectopic Summary

5.6.6.1 PRINTING STRIPS IN SELECTED STRIP MODE

Selected expanded strips can be printed in several ways, depending on the operator's preference or need as follows:

From Selected Strips Options Menu

Print Selected Strips

- Make sure all the desired times corresponding to the ECG Full Disclosure have been entered. Use <F5>, <F6>, <F7> and <F8>, to automatically enter the CALibration strip, Diary times, Min/Max BPM strips, and Max ST strip, respectively.
- 2. Press **<ESC**> to bring up the options menu.
- 3. Double-click on **Print Selected Strips**
- 4. On the Print Preview screen use "Next Page" and "Prev Page" to see what will be printed. Left-click on "Print" to print selected strips. Left-click on "Close" to exit the Print Preview screen and return to the "Selected Strips" screen.

Print Complete Final Report

- Make sure all the desired times corresponding to the ECG Full Disclosure have been entered. Use <F5>, <F6>, <F7> and <F8>, to automatically enter the CALibration strip, Diary times, Min/Max BPM strips, and Max ST strip, respectively.
- 2. Press **<ESC**> to bring up the options menu.
- 3. Double-click on Print Complete Final Report
- 4. On the Print Preview screen use "Next Page" and "Prev-Page" to see what will be printed. Left-click on "Print" to print selected strips. Left-click on "Close" to exit the Print Preview screen and return to the "Selected Strips" screen.

From Selected Strips View Mode

- Make sure the desired expanded ECG strip is displayed on screen. This can be accomplished by choosing the **Display and Annotate Strips** from the options menu or pressing <**ENTER**> when the desired strip time is highlighted at the "Selected Strips" screen.
- 2. Press **<F5**> to print the individual strip displayed on the screen.
- 3. If the Print Preview screen appears select "Print".

5.6.6.2 PRINTING STRIPS IN PAGING MODE

- 1. When viewing a five-minute page, press <**F7**> to expand and view the ECG within the strip cursor box, then press <**F5**> to print that individual strip.
- 2. To print all selected strips, press <**ESC**> to bring up the options menu. Then select **Print Selected Strips** to print all of the saved strips.

5.7 OPTION: BPM/ST TREND

PURPOSE: Give the user a way to view the ECG and Report data in a graphical form and use as a shortcut to "Page 5-Min Full Disclosure" screen.

ACTIVE KEYS: (During Both Simple and Advanced Mode) On BPM/ST Trend Screen <ENTER>, <Double-click>

Wherever the vertical cursor is, or wherever user double-clicks, the 5-Min Page corresponding to that time will be shown.

- **<G>** Toggles between a filled in/highlighted graph and an outlined graph
- <V> Gives the option of seeing:
 - 1) BPM/ST Trend for Each Channel
 - 2) 5 minute Ectopic Trend Report for: Wide Beats, Wide Pairs, Wide Runs
 - 3) 5 minute Ectopic Trend Report for: Early Narrows, 2-second Pauses, Narrow Runs
 - 4) 1 hour Ectopic Trend Report for: Wide Beats, Wide Pairs, Wide Runs
- 5) 1 hour Ectopic Trend Report for: Early Narrows, 2-second Pauses, Narrow Runs < < > > Move vertical cursor 1 minute to the left or right.

Highest (located to the left of the BPM graph)

Moves the cursor to the time with the maximum BPM

Lowest (located to the left of the BPM graph)

Moves the cursor to the time with the minimum BPM

<ESC> Bring up the options sub-menu

5.7.1 READING THE BPM GRAPH

The length of the graph (horizontal axis) represents the 24 hr. period of time when ECG was recorded. Just beneath the "BPM" graph is an hourly scale, in green and blue, of the 24 hr. Period. On the 5-Min Page: In the case of selected strips or a diary time entry, a rectangular highlighted box will appear instead of colored ECG. If looking for an "Event Mark" the ECG will be light blue.

If looking for an ectopic beat, the ECG should be colored according to which kind of ectopic beat it is.

On the left and right side of the BPM graph there is a scale 0-300 in increments of 50. These numbers represent the Beats Per Minute. The gray graph line is there to show you approximately how many BPMs there were at that particular time in the recording. To know the exact time and count, place the vertical cursor over the spot you'd like to know, and on the far left, just above the graph (not at the top of the screen, but above the lowest graph, the BPM graph) it shows in yellow the exact time and BPM count for that minute. On the right side just above the graph, in light blue, it will show the average Beats Per Minute for the 24hr. period.

5.7.2 READING THE ST GRAPHS

The three top graphs are of the ST trends on all 3 channels. The hourly scale at the bottom still applies to these graphs. On the left and right of each of these graphs is a scale ranging from -5.0 to +5.0. These numbers represent the ST values. The yellow graph line shows the approximate ST value at that point in time.

To know the exact time and ST count, place the vertical cursor over the spot you'd like to know and look for the exact time and ST count on the left, just above the graph. On the right side just above all three of the graphs, in blue, it will show the average ST values of each channel for the 24hr. period.

5.7.3 READING THE ECTOPIC TREND REPORT (5 Minutes) GRAPHS

When **V** is pressed, the next set of graphs displayed after the ST Trend graphs are the Ectopic Trend Report (5 minute) graphs featuring Wide Beats, Wide Pairs, and Wide Runs. The hourly scale at the bottom still applies to these graphs. On the left and right of each of these graphs is a scale ranging from 0 to 320 in increments of 80. These numbers represent the number of ectopic beats.

The graph line for each graph is shown in the color that represents that particular ectopic beat. The graph proceeds along the 24hr period in increments of 5 minutes, each "squared increment" representing a 5-min page. Use the mouse to place the vertical cursor anywhere on the graph. In the left corner above each graph in yellow it shows the exact time, and the exact amount of that particular kind of ectopic beat to occur within that 5 minute period of time.

Use the left and right arrow keys to move the vertical cursor 1 minute at a time. The ectopic count will be the same for any five consecutive minutes from 00:01 to 00:05 and 00:06 to 00:00. The basic purpose of this graph is to measure the number of ectopic beats that occur in a 5-minute period.

Press **<G>** to fill in the graph with color.

Press <**V**> again to access the Ectopic Trend Report (5 minute) graphs featuring: Early Narrows, 2 Second Pauses, and Narrow Runs.

5.7.4 READING THE ECTOPIC TREND REPORT (Hour) GRAPHS

When **<V>** is pressed, the next set of graphs displayed after the Ectopic Trend Report (5 minutes) are the Ectopic Trend Report (Hour) graphs featuring Wide Beats, Wide Pairs, and Wide Runs. The hourly scale at the bottom still applies to these graphs. On the left and right of each of these graphs is a scale ranging from 0 to 3000. These numbers represent the number of ectopic beats.

The graph line for each graph is shown in the color that represents that particular ectopic beat. The graph proceeds along the 24hr period in increments of 1 hour, each "squared increment" representing a 1-hour page. However, if you Double-click within that hour the 5-min page corresponding to that minute will be displayed NOT the 1-hour page. Use the mouse to place the vertical cursor anywhere on the graph. In the left corner above each graph in yellow it shows the exact time, and the exact amount of that particular kind of ectopic beat that occurred in that 1 hour period of time. Use the left and right arrow keys to move the vertical cursor 1 minute at a time. The ectopic count will be the same for any minute within that hour. The basic purpose of this graph is to measure the number of ectopic beats that occur in a 1-hour period.

Press **<G>** to fill in the graph with color.

Press <**V**> again to access the Ectopic Trend Report (Hour) graphs featuring: Early Narrows, 2 Second Pauses, and Narrow Runs.

5.8 OPTION: TABULAR SUMMARY REPORT

PURPOSE: Provide the means to edit and customize the tabulated summary of ECG data before printing.

AUTOMATIC MULTI-PROCESSING:

The ECG data tabulation in the Analyzer is performed by the TABULATOR, a 32-bit micro-processor during Disclosure modes. The TABULATOR is controlled by proprietary software algorithms. It monitors and reports on significant abnormal categories. Clinical verification of the Tabular Summary Reports is achieved through operator interface with the Analyzer via the Tabulator editor. The Tabular Summary Report is the organized presentation of the results obtained while performing Full Disclosure.

The Tabular Summary Editor option from the Main Menu provides a sub-menu with the following options:

ACTIVE KEYS: During the Editing Process

$< \land \uparrow \rightarrow \downarrow >, < Left-click>$

- Position the cursor on another entry
- **<ENTER>** Accept the current entry and advance to the next.
- **** Delete character to the left of the cursor
- <BACKSPACE> Delete character to the left of the cursor
- <F3> Enter new headings for the ectopic beat columns
- <F4> Decide whether or not to report a particular ectopic column
- **<F5>** Globally edit the data on the Tabular Summary
- <AuxEct> Changes default ectopic beat columns to auxiliary ectopic beats
- <Right-click> (Advanced Mode Only)

Bring up minute-by-minute chart of selected hour

- <CTRL>+Delete the last hour of the report (usually when the patient is disconnected. Excessive artifact may affect tabular results).
- **<ESC>** End a function, or display Tabular Summary Editor menu

EDIT SCREEN INDICATORS:

EDITED / NON-EDITED

Located in the upper right screen corner in a red box, it indicates whether the computer tabulated results have been reviewed and changed by the operator. Any field that is edited will also become a red box.

PATIENT NAME

Located in the upper left screen corner (yellow).

HOOK-UP DATE

Located in the upper left screen corner, directly below the patient name (yellow)

BPM MIN / BPM MAX

The minimum and the maximum BPM for the whole report is located next to Global Edit. The minimum and the maximum BPM for each hour is to the right of the hour listing.

ST MIN / ST MAX

The minimum and the maximum for each channel are next to the hourly BPM MIN/MAX columns.

ECTOPIC MIN / MAX

The minimum and the maximum for each ectopic category are located on the right half of the screen.

CURRENT EDIT

Field will be highlighted by a white box with a blinking cursor. Left-click within the field to position the cursor at the desired location.

OPERATION:

The Tabular Summary Editor option allows the operator to:

- 1. Edit the tabulated ECG data either a single hour at a time or globally (entire report).
- 2. Customize the tabulated data report format before printing by changing report column headings, and/or choosing the report columns to be printed.
- Print various summary reports such as: 3.
 - * Tabular Summary Report
 - * Minute by Minute Summary Report
 - * Hourly Summary Report
 - * Heart Rate Variability Report

EDITING THE TABULATED ECG DATA 5.8.1

The TABULATOR editor was designed to enable fast and friendly editing of the final report. This section, in conjunction with the instructions displayed on the screen, explain the broad capability of the editing features available.

START:

From the Main Operating Menu, select the Tabular Summary Report option. Next, the tabulated ECG data will appear on the display screen. The data may be "Edited" or "Non-Edited" as indicated in the red box in the upper right-hand corner of the screen. A white box with a blinking cursor indicates the current field being edited. A red box indicates that field has been edited by the operator.

5.8.1.1 SINGLE ENTRY EDITING

- 1. Press the arrow keys or Left-click to select the field to be edited.
- 2. Type over the data within the field by using the numeric keys.
- 3. Press the **<BACKSPACE>** and **<DELETE>** keys to correct typing errors or clear the field.
- Press <ENTER> to complete editing the current field and advance to the next 4. entry.
- Repeat the same steps for other fields to be edited. 5.
- 6. Press **<ESC**> to display a menu when all editing is complete.

5.8.1.2 GLOBAL EDITING

Global edit is a feature which allows the editing of the maximum and minimum heart rates for the entire 24 hours, thereby limiting the range of calculated values. It also allows the ectopic beat counts for entire columns to be changed to zero.

- 1. Press **<F5**> to begin Global Edit Mode.
- 2. Near the top of the display screen, you will be prompted to BPM Min and BPM Max.
- 3. **BPM Min**: Use the numeric keys to enter the absolute minimum heart rate for the 24-hour patient data being analyzed, then press **<ENTER**>. If the Tabulator has reported values for the minimum heart rate that are lower than your calculations, then enter your calculation for the minimum heart rate as BPM Min value. All heart rate values below BPM Min value will be increased to the new minimum at the completion of Global Edit.
- 4. **BPM Max**: Use the numeric keys to enter the absolute maximum heart rate for the 24-hour patient data being analyzed, then press **<ENTER**>. If the Tabulator has reported values for the maximum heart rate that are higher than your calculations, then enter your calculation for the maximum heart rate as BPM Max value. All heart rate values above BPM Max value will be decreased to the new maximum at the completion of Global Edit.
- 5. ZERO DATA: After entering the BPM Min and BPM Max values, you may choose to change all of the values in an ectopic beat column to zero (0). To accomplish this, either press <F5> to enter Global Edit and use the arrow keys, or simply Left-click to enter the desired ZERO DATA field.
- Press <ESC> to end Global Edit options. The Tabulator editor will ask you to confirm the changes. Select "Y" (Yes) to make the changes effective (permanent), or "N" (No) to cancel and exit Global Edit mode.
- 7. The Global Edit options can be accessed as many times as desired by following the above procedure. Please be aware that the Minute by Minute Summary Report graph may change significantly as a result of a Global Edit.

5.8.2 CUSTOMIZING THE TABULATED DATA REPORT FORMAT

5.8.2.1 EDITING ECTOPIC COLUMN HEADINGS

- 1. A total of ten characters are available for each ectopic beat column heading if changes of the standard headings are desired. The ten character headings are divided into two lines of five characters each.
- 2. Press the **<F3>** key to begin changing ectopic column headings.
- 3. Press the arrow keys, <**ENTER**>, or Left-click to advance to the desired column heading.
- 4. Press **** or **<BACKSPACE>** to delete characters in the field, or simply start typing the new heading.
- 5. Press **<F1**> to load default ectopic headings.
- 6. Press <**ESC**> to resume previous data editing when all new column headings have been entered. New headings will remain in effect until changed again by the operator or a new patient is downloaded.

Special Feature: When an ectopic column heading is changed on the Tabular Summary Report screen, the heading is also changed in the "Page 5-Min Full Disclosure" screen in the Page Full Disclosure from Disk mode.

5.8.2.2 SELECTING COLUMNS TO BE PRINTED (REPORT MODE)

- 1. The Report mode, beneath the Global Edit mode, allows only the desired tabulated data columns to be printed by indicating a "Yes" or "No" above the column heading. The automatic setting is for all tabulated data columns to be reported.
- 2. Press **<F4>** to enter Report mode.
- 3. Press the arrow keys, <**ENTER**>, or Left-click to advance to the desired column heading.
- 4. All Report column headings are automatically defaulted to "Yes". Double-click on the desired column heading to change it to "No."
- 5. Press <**ESC**> when all desired columns have been selected. The new settings will remain in effect until changed again by the operator or a new patient is downloaded.

5.8.3 PRINTING VARIOUS SUMMARY REPORTS

The summary reports allow the operator to print the current data stored in memory or displayed on screen. The following summary reports can be printed any time after Superimposition has been completed:

- * Tabular Summary Report
- * Minute by Minute Summary Report
- * Hourly Summary Report
- * Heart Rate Variability Report

Great flexibility in summary report printing is provided to the operator. The Summary reports can be printed, partially or completely, before or after editing, and with or without narrative.

PRINTING THE DESIRED REPORT

- 1. From the Main Menu, select the **Tabular Summary Report** option.
- 2. Press <**ESC**> to display the options menu.
- 3. From the **Tabular Summary Report** menu, select one of the following options:

5.8.3.1 Select Report Page Options

This option allows the user to determine which reports are printed in the Complete Final Report. Check-mark the desired pages then click on "Save Options" to save the currently selected pages to be the default pages printed every time **Print Complete Final Report** is chosen. This option can also be chosen by selecting **Specify Page Report Options** from the "Printouts" menu on the Windows Toolbar.

5.8.3.2 Edit Custom Report

The Edit Custom Report option is a report summary of the entire 24 hours of data. This report provides the user with an overall summary of what happened during the 24 hour recording.

Edit field Color Legend

A **black/dark gray** edit field is a field that can be edited by the user but is currently unedited.

A **red** edit field is a field that has been edited by the user.

A **blue** edit field is a reference field for this screen. These are totals that were tabulated by the system and cannot be changed at this screen. These values can however be changed at the "Tabular Summary Report" screen.

A **green** edit field is a calculated field. These values were calculated by the system and cannot be changed at all.

Press <F10> to Print Complete Final Report from this screen.

The **Edit Custom Report** option that brings you to the "Report Summary" screen is called the **Custom Report Cover** when selecting the Page Report Options.

5.8.3.3 Print Full Featured Tabular includes:

- * Tabular Summary Report
- * BPM / ST Trend Report
- * Ectopic Trend Report
- * Full Disclosure

These reports will be printed if they are check-marked.

5.8.3.4 Print Tabular Summary Report Only includes:

* Tabular Summary Report

5.8.3.5 Print HRV Report

This option will print the Heart Rate Variability (HRV) report which contains data for both commonly used methods of HRV analysis: MAGID and SDANN.

HEART RATE VARIABILITY - DESCRIPTION: Heart Rate variability (HRV) is a calculation that is extremely well suited to Holter monitoring because the entire 24-hours of continuous ECG data is available for analysis. The Analyzer performs the HRV study in parallel with performing Disclosure, Superimposition, ST analysis and Arrhythmia counting.

HRV METHODS: N-N (normal to normal) interval variability is measured and calculated in 5-minute blocks. The N-N intervals are compared in a running average in each minute within 5-minute blocks. All N-N intervals less than or greater than the average N-N interval by more than 20 % are excluded from further calculations. The entire minute is then re-scanned by the Tabulator computer with the Tabulator algorithm to identify abnormal beats and/or artifact. These beats and their adjacent N-N intervals are then classified, tabulated and excluded from N-N interval calculations. The remaining intervals are logged and raw data for this minute is stored in an array in the Tabulator. Each additional minute in the 5-minute block is reviewed as described

above. Upon reaching the end of the 5-minute block the Tabulator computer then reviews the raw data from each of the 5 minutes in the block to determine if at least 100 good intervals between normal were retained in the N-N analysis process. If more than 100 good intervals were recognized in the 5-minute block then the raw N-N interval data is processed for the Mean of the normal intervals and then processed for Standard Deviation of the normal intervals. If there are at least 100 normal intervals the five minute Standard Deviation and Mean values are stored for printing at the end of the study.

If a Standard Deviation result of less than 30 mSec is determined then a box is printed around that 5-minute segment on the Full Disclosure page containing the detected LHRV for visual verification.

5.8.3.6 Print Complete Final Report

This option will cause the summary reports for the current patient file to be printed. The **Complete Final Report** includes:

- * Default Report Cover
- * Custom Report Cover
- * Commentary w/ Narrative
- * Commentary w/o Narrative
- * Patient Diary Report
- * Tabular Summary Report
- * BPM / ST Trend Report
- * Ectopic Trend Report
- * Heart Rate Variability Trend Report
- * Selected Strips
- * Saved 5-min Pages
- * Full Disclosure
- Note: However, from the Page Report Options menu (Accessed by pressing <ESC> and selecting Select Report Page Options or by selecting Specify Page Report Options from the "Printouts" menu on the Windows Toolbar) you can choose exactly what reports will be printed in the Complete Final Report.

5.8.4 EDITED vs. NON-EDITED REPORTS

All reports printed will be marked "Non-Edited" unless at least one unit of data or value in the Tabular Summary Editor is modified by the operator. Reports will indicate "Edited" when the operator selects the Tabular Summary Report option from the Main Menu and modifies at least one value.

Note: Once a value has been modified, the reports will remain "Edited" even if the original value is typed. Custom Report Cover Page has to be manually changed to be considered Edited.

5.8.5 UPDATED TABULAR SUMMARY

5.8.5.1 Ectopic Message

Wide Beat field is a Total Wide count not an Isolated Wide Count! Minimum value for an hour must be 2* Wide Pairs + 3* Wide Runs. This value will be inserted for you automatically.

Make sure to edit the total number of beats to include all Wide beats in the Runs and all isolated Wide beats.

You will see this message when editing Wide Pairs, Wide Runs, and Narrow Runs.

When editing Wide Pairs, Wide Runs, and Narrow Runs this message will appear. This message can be turned off by going to the Settings menu and unchecking Ectopic Message.

Explanation of Message: When editing Wide Pairs, Wide Runs, and Narrow Runs, the Wide Beats and Early Narrows will automatically get updated.

Example: Let's say you are editing an hour with 0 Wide Beats, 0 Wide Pairs, and 0 Wide Runs. A Wide Pair by definition contains two beats. A Wide Run by definition contains three beats. So if a user changes Wide Pairs from 0 to 1, then the Wide Beats field (since it's a total) will automatically be updated from 0 to 2. If a user then changes the Wide Runs from 0 to 3 then the Wide Beats field (already contains 2 beats because of the 1 Wide Pair) will automatically be updated from 2 to 11.

1 Wide Pair = 2 Wide Beats

3 Wide Runs = 9 Wide Beats (2 + 9 = 11 Wide Beats)

The system will only ever attribute three beats to a run. If a run is longer than three beats, then the user needs to update the Wide Beats to account for the extra beats in a run.

Wide Beat field is a Total Wide count not an Isolated Wide Count! Wide Beats include all Wides in Pairs and Wide Runs. Since you have entered a ZERO for the total, the Pairs field will be cleared for you automatically.

You will see this message when editing Wide Beats and Early Narrows.

When editing Wide Beats and Early Narrows this message will appear. This message can be turned off by going to the Settings menu and un-checking Ectopic Message. *Explanation of Message:* When editing Wide Beats or Early Narrows, if a value gets changed to 0, (since Wide Beats and Early Narrows are totals) then the Wide Pairs and Wide Runs, or Narrow Runs will also be zeroed.

Also, the Wide Beats total cannot be less than the logical total if there are Wide Pairs and Wide Runs. The Early Narrows total cannot be less than the logical total if there are Narrow Runs.

Example: Let's say you are editing an hour with 0 Wide Beats, 0 Wide Pairs, and 0 Wide Runs. You then change Wide Pairs from 0 to 2. This will update Wide Beats to 4.

Then you change Wide Runs from 0 to 2. This will update Wide Beats to 10. Then you decide to change Wide Beats from 10 to 8. The system will not allow this (it will keep the 10) because if you have 2 Wide Pairs and 2 Wide Runs the logical total cannot be less than 10. If you want to lower Wide Beats you will have to first lower Wide Pairs or Wide Runs.

5.8.5.2 Tool Tips

The program now shows Tool Tips near the top of the screen. Different Tool Tips will be shown depending on whether the mouse is hovering over a BPM, ST, or Ectopy column. Tool Tips cannot be turned off.

Editing Ectopy from Tabular Summary now clears affected values on 5-minute pages. *Example:* Let's say a user decides to change the Wide Beats for hour 13:00 from 56 to 46 on Tabular Summary. This will clear the values for Wide Beats on all 5-minute Pages (Full Disclosure) in hour 13:00. On the 5-minute Page, the affected fields will be red and display "N/A". Since these fields were edited from Tabular Summary, the system can't know which values to keep or edit on the 5-minute Pages so it clears them all. Let's say the user then changes the Wide Beats field on a 5-minute Page from "N/A" to 15. This 15 will now overwrite the 46 on Tabular Summary and the field (on Tabular Summary) will be colored maroon.

Remember: N/A means "Not Applicable" or in this case "Unknown". N/A does not mean 0, it just means the system doesn't know what the values are.

5.8.5.3 Editing BPM (Hourly)

There are four ways to edit BPM. The Min BPM can be raised or lowered, and the Max BPM can be raised or lowered.

Min BPM Lowered –At the 5-min Page the minute with the lowest BPM for the edited hour will be lowered to the new value (entered on Tabular Summary)

Min BPM Raised – All BPMs below the new value will be raised to that value on the 5min Pages for that hour. All BPMs that are raised will be in a red box on the 5-min Page.

Max BPM Lowered - All BPMs above the new value will be lowered to that value on the 5-min Pages for that hour. All BPMs that are lowered will be in a red box on the 5-min Page.

Max BPM Raised - At the 5-min Page the minute with the highest BPM for the edited hour will be raised to the new value (entered on Tabular Summary)

5.8.5.4 Editing BPM (Global)

There are four ways to Globally edit BPM. The Min BPM can be raised or lowered, and the Max BPM can be raised or lowered. Global editing affects the entire report not just an hour.

Min BPM Lowered – At Tabular Summary every hour with the lowest BPM (e.g. 30) will be changed to the new low BPM (e.g. 25). At the 5-min Pages all minutes with the lowest BPM (30) will be changed to the new low BPM (25) entered on Tabular Summary. All edited BPM fields will be red.

Min BPM Raised – All BPMs below the new value will be raised to the new value on Tabular Summary. All BPMs below the new value will also be raised on all 5-min Pages. All BPMs that are raised will be in a red box.

Example: Let's say the Min BPM was 30 and a user globally edited to change it to 35. Every hour on Tabular Summary with 30 as the low BPM will be changed to 35, and the field turned red. Every minute in 5-min Pages with 30 as the Min BPM will be changed to 35, and the fields turned red.

Max BPM Raised - At Tabular Summary every hour with the highest BPM (e.g. 120) will be changed to the new high BPM (e.g. 125). At the 5-min Pages all minutes with the highest BPM (120) will be changed to the new high BPM (125) entered on Tabular Summary. All edited BPM fields will be red.

Max BPM Lowered - All BPMs above the new value will be lowered to the new value on Tabular Summary. All BPMs above the new value will also be lowered on all 5-min Pages. All BPMs that are lowered will be in a red box.

Example: Let's say the Max BPM was 120 and a user globally edited to change it to 110. Every hour on Tabular Summary with 120 as the high BPM will be changed to 110, and the field turned red. Every minute in 5-min Pages with 120 as the Max BPM will be changed to 110, and the fields turned red.

5.8.5.5 Minute Chart (Delete Hours)

Users no longer need to be in Advanced Mode to access the Minute Chart. To access the Minute Chart, right-click on the active field in Tabular Summary.

Delete Hours: Users can now delete any hour except the first. To delete an hour, right click on the active field in the hour you wish to delete, and choose <Del Hour>. Then hit <Esc> to leave the Minute Chart. The BPMs, STs, and Ectopy for that hour should be blank.

5.8.5.6 Custom Report

Turn On/Off at Settings Menu

The Custom Report screen is now turned off (not accessible) by default. Custom Report can be turned on by going to the Settings Menu and choosing Custom Report. **Heart Rate Data** Section of Holter Study

Total Beats = This field is now Read Only.

Min BPM = The Min BPM field is now Read Only. But the time is still editable. The time can be changed to a minute that contains the Min BPM. If the user attempts to enter a time that does not contain the Min BPM then an error message will be displayed.

Max BPM = The Max BPM field is now Read Only. But the time is still editable. The time can be changed to a minute that contains the Max BPM. If the user attempts to enter a time that does not contain the Max BPM then an error message will be displayed.

Ventricular (Wides)

Beats = This field displays the number of beats in all Wide Runs

Longest = This field displays the number of beats in the longest run and the time the run occurred.

Fastest = This field displays the BPM of the fastest run and the time the run occurred.

Supraventricular (Earlies)

Beats = This field displays the number of beats in all Narrow Runs Longest = This field displays the number of beats in the longest run and the time the run occurred.

Fastest = This field displays the BPM of the fastest run and the time the run occurred. Longest Pause = This field displays the length of the longest Pause, also displayed is (in mSec) and the time the Pause occurred.

5-minute Pages

5.8.5.7 Editing BPM

If a BPM is edited and becomes the Min or Max BPM for that hour, it will update the Min or Max on Tabular Summary. That field will be colored maroon.

Min Strip

If the BPM for the Min BPM Strip is raised, the system will automatically find the new low BPM and save a new Min Strip.

Max Strip

If the BPM for the Max BPM Strip is lowered, the system will automatically find the new high BPM and save a new Min Strip.

Find a New Min/Max Strip

To have the system find a new Min or Max Strip simply delete the BPM (enter 255) and a new strip will be found.

5.8.5.8 Editing Ectopy

When editing Ectopy at 5-minute Pages the ectopic totals are added up to combine for the hourly total.

Example: Let's say before any editing occurs the Wide Beats total for an hour on Tabular Summary is 55. Then the user goes to that hour in 5-minute Paging and sees the Wide Beats for first 5-min page is 25, for the second 5-min page it's 30, and the rest of the 5-min pages it's 0. Then the user changes the 0 on the third 5-min page to 15. The new Wide Beat total in Tabular Summary will now be 70, and that field will be colored maroon.

N/A's - If there are edited (red) fields displaying "N/A" this means that ectopic category was edited from Tabular Summary. Any time Ectopy is edited from Tabular Summary the 5-min Pages will display N/A. However, these fields can still be edited from the 5-min page.

Editing STs

Changing an ST to a Min or Max for that hour will update Tabular Summary. The Tabular Summary field will be colored maroon.

5.8.5.9 Clearing Fields

Below the BPM and ST Headings, and next to the Ectopy Headings are Red X buttons. These buttons clear the associated column. This gives users the option of quickly clearing data on a 5-minute Page instead of having to clear one field at a time or clearing the whole hour from Tabular Summary. If a user clears an ST column that contains the Min or Max ST for that hour, Tabular Summary will automatically be updated to display the new Min/Max ST. If a user clears a BPM column that contains the Min or Max BPM for that hour, Tabular Summary will automatically be updated to display the new Min/Max BPM. If it is the Min/Max BPM for the entire report, Tabular Summary will be updated with the new BPM(s) and a new Min/Max strip will be found on 5-min pages. When a user clears any Ectopic row, the values will be replaced with "N/A." However, Tabular Summary and Custom Report will not be changed because the system does not know the exact values.

5.8.6 Restore Points



You will see this message when leaving the Full Disclosure (5-Min Page) and Tabular

This feature was added to the program to help users save data in case it inadvertently gets changed or deleted. When a user leaves the Page 5-Min Full Disclosure or Tabular Summary screens a message will be displayed, "Would you like to save a restore point?". Click Yes to save the current data and settings for both pages. Click No to not save the current data and settings.

To retrieve a saved restore point, go to the User Actions drop-down menu and choose Recall Restore Point. This will restore your last saved configuration.

5.8.7 Settings Menu

Advanced Mode

The setting for Advanced Mode can now be saved. When you click Advanced Mode to turn it On or Off, you will be asked if you want to save the setting. Choosing Yes will keep the current setting, even when the program is closed. Choosing No will not keep the current setting when the program is closed.

Automatic Strips

The setting for Automatic Strips can now be saved. When you click Automatic Strips to turn it On or Off, you will be asked if you want to save the setting. Choosing Yes will keep the current setting, even when the program is closed. Choosing No will not keep the current setting when the program is closed.

Ectopic Message

This option allows users to turn off the Ectopic Message displayed on Tabular Summary when editing Ectopy.

Custom Report

This option allows users to turn on the Custom Report screen. By default the Custom Report will be turned off (not accessible). To use the Custom Report verify this option is turned on. Custom Report can be accessed through the Tabular Summary and BPM/ST Trend options (Esc) menus.

User Actions Menu

Restore Point Reminder

This option allows users to turn off the Restore Point Message that is displayed when leaving the Tabular Summary and 5-minute Page (Full-Disclosure) screens.

Set Restore Point

This option allows the user to save the current data on Tabular Summary and Full Disclosure. In case information is inadvertently changed or deleted this restore point can be recalled and the data restored.

Recall Restore Point

This option allows the user to restore the last saved configuration of data on Tabular Summary and Full Disclosure.

Set Criteria

This option allows the user to choose which types of data are displayed in the report. The user can choose to display data types such as BPM, ST, Ectopy, etc... When a data type is unchecked, that data will not be displayed on relevant screens and printouts. *Example:* If Heart Rate Analysis is unchecked, then BPM data will not be shown on Tabular Summary, 5-min Pages, Full Disclosure, and Custom report screen and printouts. In some earlier versions, the Set Criteria option was only accessible at the Preview Paging and Trigger Template screens. But entering Preview Paging would erase the current analysis results. We added the Set Criteria options to the Setting menu so users could access it without erasing their analysis results.

5.8.8 24 Hour -> AM/PM Chart

| 12:00 AH -> 0 | :00 | 12:00 | PH | -> | 12:00 |
|----------------|-----|-------|----|----|-------|
| 1:00 AH -> 1 | :00 | 1:00 | PH | -> | 13:00 |
| 2:00 AH -> 2 | :00 | 2:00 | PM | -> | 14:00 |
| 3:00 AH -> 3 | :00 | 3:00 | PH | -> | 15:00 |
| 4:00 AH -> 4 | :00 | 4:00 | PH | -> | 16:00 |
| 5:00 AM -> 5 | :00 | 5:00 | PH | -> | 17:00 |
| 6:00 AH -> 6 | :00 | 6:00 | PH | -> | 18:00 |
| 7:00 AH -> 7 | :00 | 7:00 | PH | -> | 19:00 |
| 8:00 AH -> 8 | :00 | 8:00 | PH | -> | 20:00 |
| 9:00 AH -> 9 | :00 | 9:00 | EH | -> | 21:00 |
| LO:00 AH -> 10 | :00 | 10:00 | PH | -> | 22:00 |
| 11:00 AH -> 11 | :00 | 11:00 | PH | -> | 23:00 |

This chart shows Standard to Military time conversion. This should help users enter the correct hook-up time.

5.9 OPTION: ALTERNATE FUNCTIONS

PURPOSE: Provide the user with the ability to e-mail, back-up, archive, export and FTP patient files.

ALTERNATE FUNCTIONS MENU:

5.9.1 RETURN TO MAIN MENU
Select this option to leave the Alternate Functions Menu and return to the Main Menu.

5.9.2 SEND RECORDS VIA EMAIL

ACTIVE KEYS: During Send Records via Email

Double-click on Patient File

Selects a file to be emailed. Without first selecting a file(s) the "Review Selections" **<F7**> function will not work

<F6> Toggles between sorting the patient records by Name or Date

<F6> (Advanced Mode)

Displays specific patient records based on filtering criteria entered on top half of screen.

<F7> After selecting the files to email, select this to review files and be able to email them.

<F2> (Advanced Mode)

Clears/Resets all of the information in Search Criteria.

<**F9>** In the "Review List of Selected Records to Email" screen you can unmark or uncheck any files you've selected to email.

<F10> (Advanced Mode)

Gives a full-screen view of all the patient files and allows user to select which files to email by Double-clicking.

<F11> (Advanced Mode)

Toggles between the patient files being listed with or without details.

<ESC> Exit current screen and go back to the Alternate Functions menu.

<Print List>

Allows the user to print the list of patients with or without details.

<Data Sources>

Allows the user to select which data source(s) will display the patient files contained within it/them.

Email prerequisites and descriptions:

Emailing **only** works with the **Microsoft Outlook Express** application, not with Microsoft Outlook, not with Internet based email services such as Yahoo, Hotmail, AOL etc..., only Outlook Express.

When you choose to email using the **ACS Proprietary** method the system makes a copy of the patient files and archives the copied files. It then adds the archived files as an attachment to your email message. By emailing you are not archiving the original patient record. You will still have full ability to edit, save strips, re-analyze, etc... When you choose to email using the **PDF** method the system creates a .pdf file. The report pages included in that .pdf file are the ones currently selected at **Specify Page Report Options** on the **Printouts** drop-down menu. The title of the .pdf file is this format:

"LastName_FirstName_Month_Day_Year.pdf". The date included in the title is the Hook-up date. The .pdf file is saved in the C:\pdf folder unless otherwise specified by you.

To Email a file:

- 1. From the Main Menu go to **9. Alternate Functions** then **2. Send Records via Email**.
- The "Select Archived Records to Email" screen will now be displayed. It looks very similar to the "Batch Recall or Delete" screen. From there press or Left-click on <F10> to bring up a full-screen view of the patient files.
- 3. From the full-screen view, Double-click on all of the files you wish to email. A white check-mark will appear next to the patient's name to signify that it has been selected.
- After you've selected the files you wish to email press or Left-click on <F7>
 "Review Selections and Email Records." Now you should only see the files you've selected to email.
- 5. Press or Left-click on **<F7>** again. This will prompt the "Email Attachment Selection" window:

If you choose **ACS proprietary**, your **Outlook Express Email account** will be prompted with archived copies of the patient files included as attachments. Type in the email address you're sending to and send your message. After the .pdf file is created your **Outlook Express Email account** will be prompted with the .pdf file attached.

5.9.3 GET RECORDS FROM EMAIL

ACS Proprietary

When you receive an email through your **Outlook Express account**, save the attachments in the C:\acs\Inbox folder.

Open the MASTER SERIES program. From the Main Menu select **9. Alternate** Functions then **3. Get Records From Email**.

If there are records in your email inbox (C:\acs\Inbox folder) they will automatically be downloaded into the batch bin and a message will appear:



To access the emailed records go to **1. Batch Processing and Change Patient** from the Main Menu, then **8. Batch Recall or Delete**. The emailed files should be listed with the other patient records. (If you are in **Advanced Mode** and **<F11> Show Details** is On, the emailed record should have a check mark next to the "From Email" description.) If there are no records in your email inbox a message will appear that says:



PDF

When you receive an email through your **Outlook Express account**, save the .pdf attachment anywhere on the computer, and open it by double-clicking. If you are going to view a .pdf file on a **non-ACS** system you will need pdf viewing software, such as **Adobe Reader**.

5.9.4 SEND RECORDS VIA FILE TRANSFER (Special Feature by Request Only)

ACTIVE KEYS: During Select Records to Transfer

Double-click on Patient File

Selects a file to be Transferred. Without first selecting a file(s) the "Review List of Records to Transfer" **<F7>** function will not work.

<F6> Toggles between sorting the patient records by Name or Date

<F6> (Advanced Mode)

Displays specific patient records based on filtering criteria entered on top half of screen.

F7> After selecting the files to Transfer, select this to review files and be able to Transfer them.

<F2> (Advanced Mode)

Clears/Resets all of the information in Search Criteria.

F9> At the "Review List of Records to Transfer" screen you can unmark or uncheck any files you've selected to Transfer.

<F10> (Advanced Mode)

Gives a full-screen view of all the patient files and allows you to select which files you want to Transfer by Double-clicking.

<F11> (Advanced Mode)

Toggles between the patient files being listed with or without details.

<Esc> Exit current screen and go back to the Alternate Functions menu.

<Print List> Allows the user to print the list of patients with or without details.

Some Information About FTP:

The ability to FTP patient records is a special feature that requires an additional cost The FTP ability must first be set up in coordination with the **ACS** Engineering department.

ACS uses *Ipswitch's* **WS_FTP Professional** and **WS_FTP Server** programs to execute our FTP functions.

To Transfer a File:

From the Main Menu go to **9. Alternate Functions** then **4. Send Records via File Transfer**.

You may receive this message:



Always select **Yes**, or you may risk sending files that have already been sent. The "Select Records to Transfer" screen will now be displayed. It looks very similar to the "Batch Recall or Delete" screen. From there press or Left-click on **<F10> (Advanced Mode)** to bring up a full-screen view of the patient files.

From the full-screen view, Double-click on all of the files you wish to transfer. A white check-mark will appear next to the patient's name to signify that it has been selected. After you've selected the files you wish to transfer, press or Left-click on **<F7>** "Review List of Records to Transfer". Now you should only see the files you've selected to transfer.

Press or Left-click on **<F7>** again. This will prompt red message boxes informing you of the system's actions, with messages stating:

Copying LastName, FirstName, files.

Please wait...copying...file.

There are approximately 5 of these messages.

When the system is finished copying the necessary files to the C:\acs\Outbox

subdirectory, the Ipswitch WS_FTP Professional program will be prompted.

The Local computer (computer you're currently at and will be sending files from) is represented in the left window pane.

The Remote computer (computer you're sending the files to) is represented in the right window pane.

There should be about 5 files per patient (plus 1 package file) in the Local Computer window pane (probably labeled **My Computer**). The right window pane (Remote computer) should be blank.

Left-click on a file in the left window pane (**My Computer**) then press **<Ctrl>+<A>** on the keyboard to select all the files.

Click on the green right arrow to upload/transfer the files.

At the bottom of the window you can see the transfer process.

When the transfer is complete, the files will appear in the right window pane. Close the FTP program and return to the Main Menu.

5.9.5 GET RECORDS FROM FILE TRANSFER (Special Feature by Request Only)

To Get Records from a File Transfer:

From the Main Menu go to **9. Alternate Functions** then **5. Get Records from File Transfer**.

If there are files to get, this message box will appear after you access the **Alternate Functions** menu:

You have patient files on your FTP inbox. 1 patient(s) received

After selecting 5. Get Records from File Transfer you should receive this message:

Process Complete.

If there aren't any files to get then this message box will appear:



To access the received file, from the Main Menu go to **1. Batch Processing & Change Patient** then **8. Batch Recall or Delete**.

5.9.6 BACKUP RECORDS

ACTIVE KEYS: During Backup Records

Double-click on Patient File

Selects a file to be Backed up. Without first selecting a file(s) the "Review Selections and Backup Records" **<F7>** function will not work.

<F6> Toggles between sorting the patient records by Name or Date

<F6> (Advanced Mode)

Displays specific patient records based on filtering criteria entered on top half of screen.

F7> After selecting the files to Backup, select this to review files and be able to Back them up.

<F2> (Advanced Mode)

Clears/Resets all of the information in Search Criteria.

F9> At the "Review Selections and Backup Records" screen you can unmark or uncheck any files you've selected to Backup.

<F10> (Advanced Mode)

Gives a full-screen view of all the patient files and allows you to select which files you want to Backup by Double-clicking.

<F11> (Advanced Mode)

Toggles between the patient files being listed with or without details.

<Esc> Exit current screen and go back to the Alternate Functions menu.

<Print List> Allows the user to print the list of patients with or without details.

To Backup a file:

- 1. Insert an ACS pre-formatted Backup CD into the CD-ROM drive. (Any other CD will not work)
- 2. From the Main Menu go to **9. Alternate Functions** then **6. Backup Records**.
- 3. You will now be at a screen called "Select Records to Backup" that looks similar to the "Batch Recall or Delete" screen. From there select **<F10>** to bring up a full-screen view of the patient files.
- 4. From the full-screen view, Double-click on all of the files you wish to Backup. A white check-mark will appear next to the patient's name to signify that it has been selected.
- After you've selected the files you wish to Backup press or left-click on <F7>
 "Review Selections and Backup Records". Now you should only see the files
 you've selected to Back up.
- 6. Press **<F7**> to Backup all selected files.
- When you choose to eject the Backup CD a window might appear in the bottom right corner of your screen.
 Be sure to un-check the "Make disc readable on any CD or DVD drive..." box. If you leave this box checked and eject the CD it will be closed and will not properly work with the MASTER SERIES program. The Backup CD needs to be open for it to work properly.

5.9.7 ARCHIVE RECORDS

The purpose of archiving records is to condense the patient file size from about 70 Megabytes to 150 Kilobytes. An archived record contains the Complete Final Report and Saved Strips.

Note: However, you will lose the ability to Re-analyze, Page Full Disclosure, and save additional strips after a patient record is archived.

ACTIVE KEYS: During Archive Records

Double-click on Patient File

Selects a file to be archived. Without first selecting a file(s) the "Review List of Records to Archive" **<F7>** function will not work.

<F6> Toggles between sorting the patient records by Name or Date

<F6> (Advanced Mode)

Displays specific patient records based on filtering criteria entered on top half of screen.

F7> After selecting the files to archive, select this to review files and be able to archive them.

<F2> (Advanced Mode)

Clears/Resets all of the information in Search Criteria.

F9> At the "Review List of Records to Archive" screen you can unmark or uncheck any files you've selected to archive.

<F10> (Advanced Mode)

Gives a full-screen view of all the patient files and allows you to select which files you want to archive by Double-clicking.

<F11> (Advanced Mode)

Toggles between the patient files being listed with or without details.

<Esc> Exit current screen and go back to the **Alternate Functions** menu.

<Print List> Allows the user to print the list of patients with or without details.

<Data Sources>

Allows the user to select which data source(s) will display the patient files contained within it/them.

To Archive a file:

- 1. From the Main Menu go to **9. Alternate Functions** then **7. Archive Records**.
- The "Select Records to Archive" screen will now be displayed. It looks very similar to the "Batch Recall or Delete" screen. From there press or Left-click on <F10> to bring up a full-screen view of the patient files.
- 3. From the full-screen view, Double-click on all of the files you wish to archive. A white check-mark will appear next to the patient's name to signify that it has been selected.
- 4. After you've selected the files you wish to archive, press or Left-click on **<F7>** "Review List of Records to Archive". Now you should only see the files you've selected to archive.
- 5. Press or Left-click on **<F7>** again. This will prompt a message box:



If you select **No** the files will not be archived.

If you select **Yes**, the selected file(s) will be archived and appear in **red**.

5.9.8 EXPORT

Patient records can be exported in 3 different formats: ASCII, XML, and CDS.

- **ASCII** This allows the user to export Complete Final Report and Selected Strip data in text format to review in a database analysis program such as Excel or Access.
- **XML** XML is similar to HTML (web-based) format. An XML exported report can be viewed with Internet Explorer.
- **CDS** CDS is a custom format that cannot be used by most facilities.

To Export a file:

- 1. From the Main menu go to **1. Batch Processing & Change Patient** then **8. Batch Recall or Delete**.
- 2. Recall the patient you want to export.
- 3. Return to the Main Menu and select **9. Alternate Functions** then **8. Export.**

- 4. Click the **Browse** button to change the name (if desired) and storage location of the file.
- 5. Click **OK** to export the patient record into the chosen format.
- 6. The default location for exported files is: C:\ASCII_Export.

5.9.9 SERIAL ANALYSIS

Not Available at this Time

5.10 OPTION: WINDOWS DROP-DOWN MENUS

PURPOSE: To give the user navigation and printing shortcuts as well as editing and customization options.

5.10.1 NAVIGATE (upper left)

The **Navigate** menu provides a way for the user to access any of the Main Menu options from the current screen without having to go back to the Main Menu. The page that is currently being displayed will be grayed out. Screens that are listed also have shortcut keys listed next to them for even faster navigation.

5.10.2 **PRINTOUTS** (upper left)

The **Printouts** menu provides the user with a way to easily print selected strips, a report, or pages of a report, without having to access the designated screen. After a patient file has been processed use this menu to:

- 1. View Print Preview -- If this selection is check-marked a Print Preview screen will appear when any printing option is selected. If this selection is unchecked, when a printing option is selected, the pages will start printing without a Print Preview.
- 2. Print in Color -- Pages will be printed in color if a color printer is attached.
- 3. **Print Complete Final Report** -- Use this selection to print the Complete Final Report from this menu instead of the options menu accessed by pressing **<ESC**>.
- 4. **Specify Page Report Options** -- Use this selection to determine which pages will be printed in the Complete Final Report. Left-click on "Save Options" to save the currently selected pages as the default pages printed when Print Complete Final Report is chosen.
- 5. **Print Full Disclosure** -- Use this selection to print Full Disclosure from this menu instead of the options menu accessed by pressing **<ESC**>.
- Specify Full Disclosure Style -- Use this selection to determine what format Full Disclosure will be printed in. The Full Disclosure printing format ranges from 15 minutes per page to 6 hours per page. One, two, or three channels can be printed at a time.
- 7. **Print Tabular Summary** -- Prints the Tabular Summary Report. The Standard Page will always be printed. The feature to allow Auxiliary Ectopic pages to be printed is not available at this time.
- 8. Print Patient Profile
- 9. Print Diary
- 10. Print BPM/ST

- 11. Print Narrative
- 12. Print Heart Rate Variability
- 13. Print Selected Strips
- 14. Print Saved 5 min Pages
- 15. Print Ectopic Summary
- 16. **Print to PDF** -- Turning this feature on will allow the user to print the Complete Final Report in .pdf format.

Edit Filename -- Allows the user to change the name and storage location of the file. The default filename is:

"LastName_FirstName_Month_Date_Year_F#.pdf". The Date in the filename is the hook-up date. The F# is how many times you've made a .pdf file for this patient. F1 = First time.

- Make PDF File -- Creates the pdf file containing the pages currently selected in Specify Page Report Option. The default storage location for the .pdf files is: C:\pdf.
- Add Full Disclosure pages to file -- Allows the user to include the Full Disclosure in the .pdf file.

Cancel -- This closes the 'Make PDF File' window without making a .pdf file.

5.10.3 SETTINGS (upper right)

The **Settings** menu allows for the MASTER SERIES to be run in certain modes according to the doctor's preference. Some of the options on this menu can only be accessed while at the Main Operating Menu.

Supervisor -- Supervisor Mode controls what other options in the **Settings** menu are enabled. When in Supervisor Mode the user can access **Settings** menu options such as, Advanced Mode, DataSource Admin, Read Only, Reverse Channels, Software License and Recorder Information.

To enable Supervisor Mode once it has been disabled, the appropriate password must be entered in the Supervisor Password box. This box is accessed by clicking on **Supervisor** when it is disabled.

In prior versions the system would automatically turn Supervisor Mode off when the program was closed. Now you have the option of keeping Supervisor Mode On (or Off) all the time, even if the program is closed.

When you click on the **Supervisor** option you will get the option to keep the change. Settings menu options available based on Supervisor Mode status.

Supervisor ON All options available. Supervisor OFF Only these options available: Auto Analyze Automatic Strips Automatic HR added to Strips

- **5.10.3.1** Advanced Mode -- The user must be in Supervisor Mode to turn Advanced Mode On and Off. When Advanced Mode is on, the following features are available in the program:
 - 1. Batch Recall screen with More Options

ACTIVE KEYS: During Batch/Library Patients (Advanced Mode)

<**^**> (Keyboard)

Back to the previous selection

- $<\downarrow>$ (Keyboard)
 - Forward to the next selection
- <F1> Refresh/Update patient record list
- <F2> Clears/Deletes all information in "Search Criteria" fields
- <F3> Toggles between Male/Female in Search Criteria section
- <F4> Toggles between Contains/Does not Contain in "Indications" field of Search Criteria section
- <F5> Toggles between Contains/Does not Contain in "Medications" field of Search Criteria section
- <F6> Sort patients by any of these categories
- **<F7>** Recall the highlighted patient record.
- **<F8>** Archive the highlighted patient record.
- **<F9>** Delete the highlighted patient record.
- <F10> Full screen view of patient records
- <F11> Toggles between the patient records being listed with or without details
- **<ESC>** Finished with screen, display menu options

<Double Left-click>

Recall the highlighted patient record.

There are 3 additional sections of the screen, **Search Criteria**, **Sort Records By** and **List of Reports**.

Search Criteria

Use this feature to specify which patient records are shown according to the criteria entered. When all relevant criteria is entered press or left-click on **<F1>** to update the patients listed according to the search criteria.

Press or left-click on <**F2**> to Erase/Reset all fields in the Search Criteria section. **Sort Records By**

Use this feature to list all of the patient records according to one of the following criteria: Patient Name, Exam Date (Hook up Date)-Ascending order, Exam Date (Hook up Date)-Descending order, Age, Ordering Physician, Interpreting Physician, Indications, Medications, Facility, Department, Hooked up By, Scanned By, Recorder #.

List of Reports

This feature allows the user to choose which patient records are displayed using 5 criteria. The five criteria are Processed, Archived, Backed Up, Received via Email and Email Sent.

Processed - means the patient record has been analyzed.

Archived - means the patient record has been archived (name appears in red). **Backed Up** - means the patient record was backed up to a CD, or other storage device.

Received via Email - means this file was received through an email from another MASTER SERIES.

Email Sent - means this file was sent via email from your MASTER SERIES to another MASTER SERIES.

How it Works

Next to each of these five categories is a **Y**, **N**, and **Both**. Click on Y, N, or Both in order to view patient records of that type.

For example: For the Processed category...

If **Y** is selected, then only patient records/batch files that have been processed will be shown.

If **N** is selected, then only patient records/batch files that have NOT been processed will be shown.

If **Both** is selected, then both Processed and non-Processed patient records/batch files will be shown.

However, each category is independent of each other. If **Y** by *Processed* is selected, then all files that have been processed will be shown regardless if these files have been backed up or not, archived or not, sent via email or not, or received via email or not. The search can be narrowed more specifically by selecting **Y**, **N**, or **Both** for each of the five categories.

2. Tabular Summary Minute by Minute viewer

ACTIVE KEYS: During Tabular Summary Minute by Minute Viewer (Advanced Mode)

| <previous hour=""></previous> | Displays data of previous hour |
|--------------------------------|--|
| <next hour=""></next> | Displays data of next hour |
| <ectopic display=""></ectopic> | Displays a different list of ectopic beats |
| <esc></esc> | Closes Minute by Minute viewer |

This window allows the user to review ectopic and ST data on a minute by minute basis.

Auto Analyze -- Advanced Mode must be disabled in order for Auto Analyze mode to work. Auto Analyze mode allows for the ECG to be downloaded into the system and initialize Superimposition & Preview Paging without having to manually go through the Diary Entry, Preview/Auto- Gain, Trigger Template, and Specify Analysis Parameters screens. These screens are bypassed in Auto Analyze mode.

How to use Auto Analyze Mode:

- 1. Disable Advanced Mode
- 2. Enable Auto Analyze Mode

- 3. Hook up a 2003/2010/HPP Recorder that has ECG ready to be downloaded to the system
- 4. Select **"1. Download New Patient From Flash"** (Or the appropriate Recorder model) on **The Entry Menu option.**

5.10.3.2 Color Assignments

This selection allows the user to change the colors displayed on the waveforms, graphs, printouts, and screens in general.

The **Color Assignments** box is divided up into two main sections.

1) The top section is called Screen Colors.

Under that is a sub-section called **Waveforms**. To the right of **Waveforms** is another sub-section called **Minute Identifiers**. These two sub-sections are used to change the colors of the Markers on the BPM/ST Trend screen and Page Full Disclosure screen. The section to the far right is **Page Colors**.

 The bottom section is called Printer Colors. Under that are sub-sections called Graphs, Waveforms, and Minute Identifiers. Next to the descriptions are the colors that will appear on the printouts.

Changing the Colors:

- Remember to differentiate between the Screen Colors and the Printer Colors. Left-click on the desired color to be changed. A Color box will appear. Left-click on a color then click on "OK" to change it.
- 2) or Create a Color:

Click on **Define Custom Colors.** Click in the rainbow color box. Use the vertical bar and black arrow to the right to specify the shade of the color. Click on **Add to Custom Colors** (bottom right) to save this color, or click on "OK" to change to this color without saving it.

5.10.3.3 Data Source Admin.

Supervisor mode must be on for this option to be available. This option allows the user to add or delete data sources from which patient records can be recalled from or saved to.

Read Only

When the Read Only Mode is enabled there can be no inserting, editing, or deleting of data in any screen. This mode is for viewing and printing purposes only.

5.10.3.4 Reverse Channels

This option allows the user to invert channels in case the leads were accidentally switched when the patient was hooked up. Select **Reverse Channels**, then pick which channel(s) need(s) to be inverted. Check each channel in Page Full Disclosure mode to make sure they are all right-side up. An easy way to tell if they are right-side up is too look at the Cal pulses. Once all of the channels are right-side up re-analyze by choosing **4. Preview Auto Gain**, **Superimposition & Preview Paging**.

5.10.3.5 Software License

This option will bring up a window that displays the ACS Code and ACS Key of that particular software product (MASTER SERIES). The ACS address and phone number are also shown to help the customer acquire his/her ACS Key. An ACS Key is required for the software to work properly.

5.10.3.6 Automatic Strips

There are 2 parts to this feature.

- If Automatic Strips is on when analysis is performed, the system will automatically save ECG strips that contain: the min and max BPM, the Max ST, the first three occurrences of (if applicable) a Wide, Early, Narrow, Pause, Pair, and Run. These strips can be found at the Selected Strips screen.
- 2) If the minute that contains an Automatic Strip is edited in Page Full Disclosure mode, the system will automatically find another auto strip. For example, if you find the minute of the Max BPM and change the BPM from 120 to 100, the system will look for the minute with the next highest BPM, say it's 118. That will become the new Max BPM Strip. If Automatic Strips is off and a minute is edited while Paging Full Disclosure, the system will not find a new automatic strip. If a strip is deleted in Page Full Disclosure mode, another automatic strip will not be found whether Automatic Strips is on or off. Remember: Automatic Strips must be enabled before Analysis is performed for these strips to be saved.
- 5.10.3.7 Automatic HR added to Strips -- If this option is enabled, Strips that are selected in Page Full Disclosure mode will display the Heart Rate on screen and on printouts. Any Auto Strips, Diary Strips, or strips that are selected by entering a time (either while analyzing or on the Selected Strips screen) will **never** display the Heart Rate, only strips selected in Page Full Disclosure mode.
- **5.10.3.8 Recorder Information** -- This purpose of this option is to give detailed information about the Recorder for troubleshooting purposes. This information can be printed if desired. A patient must be recalled for this option to be available.

| Unit Serial #: | This is the specific serial number for this individual recorder. |
|----------------|--|
| Company: | This is the company model number for this recorder. |
| Version: | This is the firmware version of this individual recorder. |
| Date: | This is the hook-up date entered into the recorder for this |
| | particular patient. |
| Time: | This is the start time entered into the recorder for this |
| | particular patient. |
| Patient ID: | This is the Patient ID number entered into the recorder for this |
| | particular patient. |
| Date of Birth: | This is the DOB entered into the recorder for this particular |
| | patient. |
| | |

5.10.3.9 Export ECG (Special Feature by Request Only)

This option allows the user to export the ECG data into a 1,2,3 binary format. The ACS ECG Export Viewer program is needed to view the ECG in the binary format. A patient must be recalled for this option to be available. Click the **Browse** button to name and save the file. **Do not** use / or \ in the file name. The default folder the file is saved to is C:\ASCII_Export Click **Translate** to export the patient file. The file is saved in .DAT format. Use the ACS ECG Export Viewer to view the exported data.

5.10.4 HELP (upper right)

The **Help** menu provides general and specific information about the program. **About** -- Shows the Model of the Product, Software Version, Copyright, and Company Name. Inside the dialog box, it shows whether certain features are On or Off. Also shown is the date the license was issued and how long the license is registered. **Manual** -- This is the MASTER SERIES manual. The manual is in .pdf format and best viewed with the window maximized to full-screen.

SECTION 6.0 REPORT GENERATION

- 6.1 Step-by-Step Report Generation for all Recorder Models (via USB)
 - **Step 1.** When run is over, disconnect leads cable from recorder and attach/ insert into Smart Dock or insert USB cable.
 - **Step 2.** Attach the USB/Smart Dock cable that is connected to the back of the MASTER SERIES
 - Step 3. From the ENTRY MENU select option 1. Download New Patient From Flash
 - Step 4. Verify Recorded data displayed
 - **Step 5.** Follow instructions and enter all relevant data.
 - Step 6. Verify data and follow instructions displayed
 - Step 7. Select Download New Patient From Flash under The ENTRY MENU.
 - **Step 8.** ECG and Patient data will download from recorder into the MASTER SERIES. When downloading has finished press **<OK>** to continue.
 - Step 9. The "Patient & Facility Data" screen will now appear. Verify the data on the "Patient & Facility Data" screen is accurate and complete. Select <ESC> and a message box will appear. (Please double check Patients Last Name, Start Time and Hook-up Date, You will not be allowed to edit these fields in the future. Press YES to save this new patient or NO to continue editing.) Do you wish to go to Diary YES or NO (LAB option only, Do you wish to enter patients insurance Information YES or NO?)
 - **Step 10.** Preview/Auto Gain will now start. The intention of this page is to find the *optimal* channel of ECG to analyze. Use the **(+/-)** keys to adjust ECG Gain.
 - Step 11. Press <F1>, <F2. or <F3> to find the cleanest channel. Use Arrow Keys or Mouse to move the cursor box to the region of the cleanest waveform and then press <ENTER> when finished with the current page.
 - Step 12. You are now on the TRIGGER SET-LEVEL page for Channel 1. The intention of this page is to align one vertical trigger mark to each R-wave. Use the (+/-) keys to adjust ECG gain. Press the <F> key to select the waveform type (Normal 1 or 2, Pacer, High Artifact, Low Amplitude, High Heart Rate, and Custom 1-6).
 - Step 13. Press the <T> key to select Trigger Mark Gain (Low, Medium, High). Press
 <PgUp> and <PgDn> for Coarse Trigger Level Settings and the Up and Down
 Arrow Keys for Fine Trigger Settings. This is done to assist the trigger set-up.
 Press <ENTER> to continue.
 - **Step 14.** Repeat steps 12 and 13 to properly adjust the TRIGGER SET-LEVEL for Channels 2 and 3.
 - Step 15. On the SPECIFY ANALYSIS PARAMETERS page, follow INSTRUCTIONS 1 through 6 on the right side of the screen. The intention of this page is to fine-tune adjustments of the Iso Cursor, J Point and Calculation Point cursor, for ST-Segment measurements. Repeat this step for Channels 2 and 3. When finished press <ENTER>..

- **Step 16.** Press **<ENTER>** to select Preview-Page Mode and **(Y or N)** to Print Full Disclosure during Preview Paging.
- Step 17. During Superimposition press <ENTER> to save the current page, or <F4> to save the previous page. If you wish to save an ECG segment observed though Superimposition, press <SPACE> to highlight and save the corresponding page.
- Step 18. After Superimposition and Preview Paging is finished, the Options menu will automatically appear. Select Paging Mode and then select Review Saved Pages. Use arrow keys to move the cursor on desired ECG segments. Press <F7> to View Strip or <F8> to Save Strip and label it. Press <F5> in any paging mode to print a 5 minute page. When finished saving strips from saved pages, press <ESC>.
- **Step 19.** Select **Page Tabular Events** from Options Menu to verify and edit tabulator judgments, if necessary. Select each permissible event category; Proceed as with Step 17.
- Step 20. After all events have been reviewed, & strips stored, select Main Paging Options then select View Saved Strips.
- **Step 21.** View and annotate strips as desired. When finished press **<ESC>**.
- **Step 22.** Insert a sheet of your letterhead face up into the printer's fold out tray. From the **Printouts** Drop-down menu select **Print Complete Final Report**.
- **Step 21.** Insert a sheet of your letterhead face up into the printer's fold out tray. From the **Printouts** Drop-down menu select **Print Complete Final Report**.
- Step 22. Return to the Main Operating Menu.
- Step 24. Repeat this process for next patient.
- **Note:** Optional External Backup drives may be purchased from ACS for backup and archiving of patient records (By archiving a patient file, the ability to run Superimposition and Page Full Disclosure is gone)

6.2 Step-by-Step Report Generation for a 2003/2010/HPP Recorder (HPP via Smart Dock only)

- **Step 1.** After patient has finished his/her 24 hr. recording, remove flashcard (HPP only remove lead set and insert into Smart Dock) from recorder and insert into MASTER SERIES.
- Step 2. From the ENTRY MENU select option 1. Download New Patient From Flash
- Step 3. Select Process / Download ECG from Flash
- Step 4. The "Downloading Data" screen will appear and show a progress bar. When the data is finished downloading a red box will appear that says "Data has been processed. Press OK to continue." When <OK> is selected you will be directed to the "Patient & Facility Data" screen.
- **Step 5.** Type in patient, facility, hook-up, and all other relevant information. Press Shift+F1> when finished to access the "Patient Diary Report" screen
- Step 6. At the "Patient Diary Report" screen fill in all diary notes then select <Shift+F1> to go back to the "Patient & Facility Data" screen.

- **Step 7.** At the "Patient & Facility Data" screen press <**ESC**> to enter Preview/Auto Gain.
- **Step 8.** You will now be at the "Preview / Auto Gain" screen. The intention of this page is to find the *optimal* channel of ECG to analyze. Use the **(+/-)** keys to adjust ECG Gain.
- Step 9. Press <F1>, <F2. or <F3> to find the cleanest channel. Use Arrow Keys or
 Mouse to move the cursor box to the region of the cleanest waveform and then press <ENTER> when finished with the current page.
- Step 10. You are now on the TRIGGER SET-LEVEL page for Channel 1. The intention of this page is to align *one* vertical trigger mark to each R-wave.
 Use the (+/-) keys to adjust ECG gain. Press the <F> key to select the waveform type (Normal 1 or 2, Pacer, High Artifact, Low Amplitude, High Heart Rate, and Custom 1-6).
- Step 11. Press the <T> key to select Trigger Mark Gain (Low, Medium, High). Press
 <PgUp> and <PgDn> for Coarse Trigger Level Settings and the Up and Down
 Arrow Keys for Fine Trigger Settings. This is done to assist the trigger set-up.
 Press <ENTER> to continue.
- **Step 12.** Repeat steps 11 and 12 to properly adjust the TRIGGER SET-LEVEL for Channels 2 and 3.
- Step 13. On the SPECIFY ANALYSIS PARAMETERS page, follow INSTRUCTIONS 1 through 6 on the right side of the screen. The intention of this page is to fine-tune adjustments of the Iso Cursor, J Point and Calculation Point cursor, for ST-Segment measurements. Repeat this step for Channels 2 and 3. When finished press <ENTER>..
- **Step 14.** Press **<ENTER>** to select Preview-Page Mode and **(Y or N)** to Print Full Disclosure during Preview Paging.
- Step 15. During Superimposition press <ENTER> to save the current page, or <F4> to save the previous page. If you wish to save an ECG segment observed though Superimposition, press <SPACE> to highlight and save the corresponding page.
- Step 16. After Superimposition and Preview Paging is finished, the Options menu will automatically appear. Select Paging Mode and then select Review Saved Pages. Use arrow keys to move the cursor on desired ECG segments. Press <F7> to View Strip or <F8> to Save Strip and label it. Press <F5> in any paging mode to print a 5 minute page. When finished saving strips from saved pages, press <ESC>.
- **Step 17.** Select **Page Tabular Events** from Options Menu to verify and edit tabulator judgments, if necessary. Select each permissible event category; Proceed as with Step 17.
- Step 18. After all events have been reviewed, & strips stored, select Main Paging Options then select View Saved Strips.
- Step 19. View and annotate strips as desired. When finished press <ESC>.
- **Step 20.** Insert a sheet of your letterhead face up into the printer's fold out tray. From the **Printouts** Drop-down menu select **Print Complete Final Report**.

Step 21. Insert a sheet of your letterhead face up into the printer's fold out tray. From the **Printouts** Drop-down menu select **Print Complete Final Report**.

Step 22. Return to the Main Operating Menu.

- Step 24. Repeat this process for next patient.
- **Note:** Optional External Backup drives may be purchased from ACS for backup and archiving of patient records (By archiving a patient file, the ability to run Superimposition and Page Full Disclosure is gone)

6.3 Step-by-Step Report Generation for a 2003/2010 Recorder (SD/Compactflash Card via USB)

- **Step 1.** After patient has finished his/her 24 hr. recording, remove the batteries from the recorder first, then the SD or compactflash card.
- **Step 2.** Insert the SD or compactflash card into the flash card reader.
- Step 3. Plug the flash card reader into the USB port on the computer
- Step 4. Select option 1. Download New Patient From Flash
- Step 5. The "Downloading Data" screen will appear and show a progress bar. When the data is finished downloading a red box will appear that says "Data has been processed. Press OK to continue." When <OK> is selected you will be directed to the "Patient & Facility Data" screen.
- Warning! Do Not Disconnect the SD/Compactflash Card Reader from the USB Connector without Referring to this page: 5.14 Protecting Compactflash Card Format
- Step 6. Type in patient, facility, hook-up, and all other relevant information. Press
 <Shift+F1> when finished to access the "Patient Diary Report" screen.
- Step 7. At the "Patient Diary Report" screen fill in all diary notes then select <Shift+F1> to go back to the "Patient & Facility Data" screen.
- **Step 8.** At the "Patient & Facility Data" screen press <**ESC**> to enter Preview/Auto Gain.
- **Step 9.** You will now be at the **Preview / Auto Gain** screen. The intention of this page is to find the *optimal* channel of ECG to analyze. Use the **(+/-)** keys to adjust ECG Gain.
- Step 10. Press <F1>, <F2. or <F3> to find the cleanest channel. Use Arrow Keys or Mouse to move the cursor box to the region of the cleanest waveform and then press <ENTER> when finished with the current page.
- Step 11. You are now on the TRIGGER SET-LEVEL page for Channel 1. The intention of this page is to align *one* vertical trigger mark to each R-wave. Use the (+/-) keys to adjust ECG gain. Press the <F> key to select the waveform type (Normal 1 or 2, Pacer, High Artifact, Low Amplitude, High Heart Rate, and Custom 1-6).
- Step 12. Press the <T> key to select Trigger Mark Gain (Low, Medium, High). Press
 <PgUp> and <PgDn> for Coarse Trigger Level Settings and the Up and Down
 Arrow Keys for Fine Trigger Settings. This is done to assist the trigger set-up.
 Press <ENTER> to continue.

- **Step 13.** Repeat steps 12 and 13 to properly adjust the TRIGGER SET-LEVEL for Channels 2 and 3.
- Step 14. On the SPECIFY ANALYSIS PARAMETERS page, follow INSTRUCTIONS 1 through 6 on the right side of the screen. The intention of this page is to finetune adjustments of the Iso Cursor, J Point and Calculation Point cursor, for ST-Segment measurements. Repeat this step for Channels 2 and 3. When finished press <ENTER>.
- **Step 15.** Press **<ENTER>** to select Preview-Page Mode and **(Y or N)** to Print Full Disclosure during Preview Paging.
- Step 16. During Superimposition press <ENTER> to save the current page, or <F4> to save the previous page. If you wish to save an ECG segment observed though Superimposition, press <SPACE> to highlight and save the corresponding page.
- Step 17. After Superimposition and Preview Paging is finished, the Options menu will automatically appear. Select Paging Mode and then select Review Saved Pages. Use arrow keys to move the cursor on desired ECG segments. Press <F7> to View Strip or <F8> to Save Strip and label it. Press <F5> in any paging mode to print a 5 minute page. When finished saving strips from saved pages, press <ESC>.
- **Step 18.** Select **Page Tabular Events** from Options Menu to verify and edit tabulator judgments, if necessary. Select each permissible event category; Proceed as with Step 17.
- Step 19. After all events have been reviewed, & strips stored, select Main Paging Options then select View Saved Strips.
- Step 20. View and annotate strips as desired. When finished press <ESC>.
- **Step 21.** Insert a sheet of your letterhead face up into the printer's fold out tray. From the **Printouts** Drop-down menu select **Print Complete Final Report**.

Step 22. Return to the Main Operating Menu.

Step 24. Repeat this process for next patient.

Note: Optional External Backup drives may be purchased from ACS for backup and archiving of patient records (By archiving a patient file, the ability to run Superimposition and Page Full Disclosure is gone)

SECTION 7.0 ORDERING SUPPLIES & ACCESSORIES

ORDERING SUPPLIES & ACCESSORIES

In this Holter industry, poor product performance is often traced to poor performing supplies. In a continued effort to guarantee you the very best results with our **ACS** Holter Instrumentation, we recommend only the highest quality accessories. All **ACS** supplies have been carefully selected to provide optimum performance.

7.1 RECORDER SUPPLIES

TO PLACE AN ORDER CALL TOLL FREE (800) 423-2929, ASK FOR THE ACCESSORIES DEPARTMENT.

| HPP RECORDER SUPPLIES | ACS Part Number | | | |
|---|-----------------|--|--|--|
| 3 Channel Hook-Up Kit w/ Bic razors (HPP) | 4136HKP1 | | | |
| 3 Channel Hook-Up Kit w/o razors (HPP) | 4136HKPD | | | |
| Event Hook-Up Kit (HPP) | 4136HKP2 | | | |
| Lanyard | 22091212 | | | |
| 3 Wire, 2 Channel 20" Lead set | 22091214 | | | |
| 3 Wire, 2 Channel 39" Lead set | 22091222 | | | |
| 5 Wire, 3 Channel 20" Lead set (Holter only) | 22091223 | | | |
| 5 Wire, 3 Channel 39" Lead set (Holter only) | 22091224 | | | |
| USB Charging Cable | 22091215 | | | |
| AC Charging Adapter | 22091231 | | | |
| Power Off Plug | 22091217 | | | |
| For all HPP supplies see HPP Manual | 4444HPPM | | | |
| * Custom hook-up kits are available upon request. | | | | |
| 2003/2010 RECORDER SUPPLIES | ACS Part Number | | | |

| 2003/2010 RECORDER SUPPLIES | ACS Part Number |
|---|---------------------------------|
| *3 Channel Hook-Up Kit w/ surgical razors (2003/2010) | 4136DDRA |
| *3 Channel Hook-Up Kit w/ Bic razors (2003/2010) | 4136DDRI |
| *3 Channel Hook-Up Kit w/o razors (2003/2010) | 4136DDRD |
| ACS Holter/Stress Electrodes (5 per pkg) | 4103DISP |
| ACS Holter/Stress Electrodes (7 per pkg) | 4103DISP-3 |
| Skin Prep Scrubbies | 42030001 |
| Batteries (AA) Alkaline | 444xAABT (x=Brand availability) |
| 3 Channel, 7-Wire Lead Set (2003/2010) | 41032204 |
| Carrying Case (2003/2010) | 41032245 |
| Shoulder Strap / Belt (2003/2010) | 41032250 |
| SD Flash Card 2GB (2010) | 120725GB |
| | |

| Flash Card 48hr 256MB (2003) | 12072256 |
|------------------------------|----------|
| Flash Card 24hr 128MB (2003) | 12072128 |
| User Manual (2010) | 44442010 |
| User Manual (2003) | 44442003 |
| | |

* Custom hook-up kits are available upon request.

ACS reserves the right to void the product warranty, either in whole or in part, if it is determined that inferior quality supplies are the cause of specification degradation or damage to the instrument.

7.2 SCANNER / ANALYZER SUPPLIES

TO PLACE AN ORDER CALL TOLL FREE (800) 423-2929, ASK FOR THE ACCESSORY DEPARTMENT.

SCANNER / ANALYZER SUPPLIES

| Smart Dock (HPP Only) | 22091219 |
|-------------------------------------|----------|
| USB Cable for Smart Dock (HPP Only) | 22091220 |
| USB Flash Card Reader | 1336USBR |
| Toner Cartridge (Brother HL5340) | 42035112 |
| Toner Cartridge (Brother HL5440) | 42035115 |
| Toner Cartridge (HP4000 & 4050) | 42035107 |
| Toner Cartridge (HP2100 & 2200) | 42035102 |
| Toner Cartridge (HP 6) | 42035106 |
| Toner Cartridge (HP 4, 4+ & 5) | 42035104 |

ACS reserves the right to void the product warranty, either in whole or in part, if it is determined that inferior quality supplies are the cause of specification degradation or damage to the instrument.

SECTION 8.0 MAINTENANCE

REGULAR MAINTENANCE

The Holter Reporter[™] system requires minimal regular preventive maintenance and service. This section describes the recommended maintenance schedule. Please call ACS Applications or Technical Support if you have any questions, or suspect a

Please call ACS Applications or Technical Support if you have any questions, or suspect a problem.

8.1 Laser Printer

| USAGE PREVENTATIVE MAINTENANCE (P.M.) | | P.M. TIME |
|---|--|--------------|
| Every 50-75 Check the print darkness quality; order and | | Approx. five |
| reports printed replace toner cartridge if necessary. | | minutes |
| Every 100 | Open the top lid of the printer, remove toner | Approx. Five |
| reports printed cartridge, and wipe excess paper and toner dust | | minutes |
| | from inside using a slightly damp white cloth. | |
| Every 1000 | Check the rubber paper pick-up roller if worn or | Approx. five |
| reports printed | if the printer is not picking up the paper. | minutes |

8.2 Display Screen

| USAGE | PREVENTATIVE MAINTENANCE (P.M.) | P.M. TIME |
|-------------|---------------------------------------|-------------|
| Every month | Clean screen using a DRY, SOFT CLOTH. | Approx. One |
| | NO PAPER TOWELS. | minute |

8.3 Keyboard

| USAGE PREVENTATIVE MAINTENANCE (P.M.) | | P.M. TIME |
|--|------------------|-------------|
| Every month Clean the keyboard using a soft brush to | | Approx. One |
| | remove the dust. | minute |
| | | |

SECTION 9.0 MODULE FUNCTION

The MASTER SERIES incorporates several independent electronic modules which have been carefully integrated to function as one complete system. To better understand the operation of the system as a whole, it is useful to become familiar with the function of the individual modules.

- **9.1 ANALYZER MODULE** The Analyzer Module is the heart of the MASTER SERIES. Located within the analyzer module are the CD-ROM, hard drive(s), power supply, video card, network card, modem, USB port, and the computer motherboard.
- **9.2 LASER PRINTER** The laser printers offered with the MASTER SERIES can be used with any compatible computer system via the USB or parallel port.
- **9.3 DISPLAY MONITOR** The display monitor is a standard computer peripheral item. **ACS** provides monitors which meet FCC requirements. The LCD color monitor was chosen on the basis of reliability, readability, resolution and aesthetic appearance.
- **9.4 KEYBOARD** The keyboard, like the monitor, is a standard computer peripheral item. Our criteria for selection was based upon manufacturer reputation and sturdy, reliable construction.
- **9.5 MOUSE** The mouse, like the monitor, is a standard computer peripheral item. Our criteria for selection was based upon manufacturer reputation and sturdy, reliable construction.

SECTION 10.0

HELP

10.1 PROBLEMS

Most problems experienced are not due to system failure, but related to improper operation, cable connections or other external factors such as recording problems. Call ACS Technical Support at (800) 423-2929 ext 325.

10.2 SUPPORT

10.2.1 TECHNICAL

Technical support refers to expert assistance provided when the operator suspects equipment malfunction. **Free** expert technical support is provided during standard business hours to all **ACS** customers whose equipment is covered under original or extended warranty at:

Phone: (949) 855-9366

Phone: (800) 423-2929 ext 325/330 (Toll free in the U.S.A.)

10.2.2 APPLICATIONS

ACS has full time personnel in the Applications department, dedicated to answer any question related to the operation of the system. An **in-service call** may also be requested from the Applications department. For Applications assistance please call **ACS** at:

Phone: (949) 855-9366 Phone: (800) 423-2929 Toll free in the U.S.A. Fax: (949) 855-9166

10.2.3 SALES

Sales assistance is provided by both internal and field sales representatives. Call ACS headquarters to obtain sales assistance or a list of representatives in your area at: Phone: (949) 855-9366 Phone: (800) 423-2929 Toll free in the U.S.A. Fax: (949) 581-1009 Fax: (949) 855-1005 Customer Support

SECTION 11.0 EXTRAS

11.1 Downloading a monitor (Models HPP, 2003, 2010) using the Lab/ACSD software.

This section contains detailed information on "How to Upload" to the Lab through the Lab/ACSD software, features, and operation. This section is organized similarly to the system main menu options for quick and logical access to the desired information. Users who are still learning how to use the system and who are not completely familiar with all the system features should follow the suggested step-by-step procedure in the next section and refer to this section for more detail if necessary. Advanced users will find this section useful as a reference.

Note: Certain menu options may not be available prior to uploading/processing. These options are "grayed out" to prevent the user from performing certain functions out of sequence. Active options are in Yellow.

11.1.1 When a PATIENT Monitor is returned:

- 1. Remove the Lead-Set cable (pinch the two buttons to release the Lead-Set from the HPP monitor (HPP Only).
- 2. Insert HPP monitor into the Smart Dock / Docking Station (2003/2010 Models: attach the USB cable or remove memory card from device and insert into a card reader).
- Launch the Lab/ACSD Software (Click the icon on your desktop/computer screen). Press any key to continue.

From the Entry Menu:

- 4. Click On Option 1. "Download" from the Entry Menu,
- 5. The START TIME, START DATE, AND Patient ID will be automatically pulled in. All boxes with "Red Stars" must be filled in. When complete, press the **ESC** key.
- 6. The RED Warning Box will be displayed: "Be sure to check that all data in this section is entered correctly. You will not be able to go back to correct it again." Click on the "Yes" or "No" button when finished with your review.
- The "RED" warning box will be displayed: "Do YOU need to enter patient insurance info? Yes or No?" (Click "NO" if your practice does own billing. Click "YES" if not).
- 8. The RED warning box will display: "Do you want to enter Diary Events?" Yes if patient returned a Diary, NO if the patient did not.

9. The RED warning box will ask: "Do you want to send files to ACS Diagnostics now?"

Click "YES". The Select Recorders to Transfer list will show all the stored patients. Click on the patient name you want to send. A White Check Mark will appear to the left of the selected patient's name. Then press the "F7" button on the top of your keyboard. A second List will appear: "Review List of Records to Transfer". Verify that the right patient has the "White Checkmark" next to it, then press the "F7" key again to send. The Log-In box will appear: "Enter your **FTP Username**": (once you enter this, the system will save it)

FTP Password: (once you enter this, the system will save it)

Contact: (Your name goes here)

Phone: (Your phone number)

Then Click "OK". A few "RED" status boxes will flash on the screen. Allow the process to continue without interruption. "Upload Complete" message will appear when the upload process is finished. Click "OK".

11.1.2 HOW TO RETRIEVE REPORTS FROM THE Lab/ACSD SOFTWARE (Download from LAB)

- 1. From computer desktop. Click on the Lab/ACSD icon to launch the software.
- 2. Press any key to start program.
- At the top left of the screen, in the tool bar area section, click on ACS Diagnostics. The dropdown menu will appear, click on **Download FROM ACS** Diagnostics.
- 4. A "RED" status box will appear with the processed reports. Do not interrupt this process. You will get a "Download Complete" message when done.
- 5. From "the Entry Menu" select Option 2. Recall Patient Data. Double click on the desired patient.

11.1.2.1 <u>Printing out Patient Reports:</u>

- 1. From the Main Menu, go to the top of the menu screen, in the tool bar section, Click on the Printout button, dropdown options will appear.
- 2. Select Print Complete Finial Report

11.2 Properly Ejecting USB Devices from Windows

After downloading data from an SD or Compactflash card, it is important to notify the Operating System (Windows 7 or XP) of your intention to remove (unplug) the hardware device (USB Compactflash Card reader) before actually removing the Compactflash card reader from the USB connector.

Note: Failure to follow these instructions may result in the corruption of the file system formatting on the Compactflash card, rendering it unusable for further recording.

11.2.1 Disabling Hardware Device

- 1. In the bottom right corner of the screen, next to the time display, there are miniicons and an arrow pointing left. **Left-click** on the arrow to see the rest of the mini-icons.
- 2. Left-click on the mini-icon with the green mark above a gray card. A selection titled "Safely remove USB Mass Storage Device" will appear. Left-click on it.
- 3. A message will appear in the bottom right corner of the screen notifying you that it is now safe to remove the hardware, in this case, the Compactflash card reader from the USB connector.

11.2.2 Physically Removing USB Compactflash Card Reader

- Remove the Compactflash card reader, with the SD or Compactflash card still in it, from the USB connector. Once disconnected, you can remove the SD or Compactflash card from the reader.
- 2. **Do Not** remove the SD or Compactflash card from the card reader **before** you disconnect the card reader from the USB slot.

APPENDIX A GLOSSARY OF TERMS APPENDIX A - ALPHABETICAL GLOSSARY OF TERMS

TERM DEFINITION / DESCRIPTION

ANALYZER The computer/microprocessor which performs the analysis on ECG data.

ANNOTATE Type comments or remarks to compliment ECG data; label.

Recall Patient From Disk One of multiple locations on the batch process cartridge available for storing a patient's information. A batch bin is re-usable and must be selected before batch processing.

The ENTRY MENU Process multiple patient, saving the ECG data information in a batch bin before proceeding to the next.

BPM Beats Per Minute or heart rate.

CAL PULSE Calibration/square signal, usually recorded at the beginning of the Holter recording. This pulse (signal) is used for reference, and to "normalize" the patient ECG data.

CALIPER CURSOR An edge of a "heart rate ruler" used to measure the heart rate for the ECG data displayed on screen.

CURSOR A flashing or solid position indicator on screen. The cursor is the computer counterpart of the print head on the manual typewriter, indicating the next typing position.

HPP RECORDER (Holter Performer Plus) A digital data recorder used exclusively with the MASTER SERIES Analyzer

ECTOPIC Related to abnormal ECG rhythms.

EVENT An ECG occurrence/symptom of concern or interest for the patient or the operator.

EVENT INDICATOR An indicator on display screen or printed report which helps identify an event.

FULL DISCLOSURE A reporting technique whereby every and all ECG activity is disclosed for a specific period of time, e.g. twenty-four hour Full Disclosure.

HRV ANALYSIS Heart Rate Variability - Analysis of heart rate variations as a method of predicting potential cardiac complications. This term is used interchangeably with LHRV analysis.

ISCHEMIC Related to abnormal ECG ST-Segment levels.

KEYBOARD In general, a keyboard is an input device which allows data or commands to be entered; it provides the mechanism for communication with a machine. The keyboard for the Holter Reporter[™] is the typewriter-like key pad.

LHRV ANALYSIS Low Heart Rate Variability - Analysis of possible correlations between low heart rate variations and potential cardiac complications. This term is used interchangeably with HRV analysis.

LIBRARY A collection of stored individual patient information including selected ECG data.

LIBRARY CD The Compact Disk used to store individual patient information and ECG data.

MONITOR A term used when referring to a display screen (display monitor). A monitor is also sometimes used when referring to a Holter monitor recorder.

PAGING An ECG analysis method where stored Full Disclosure ECG data is retrieved and displayed on screen for viewing and editing.

PREVIEW / AUTOGAIN An operation performed by the Analyzer where the gain/amplitude of the ECG data is automatically adjusted.

PREVIEW-PAGE An analyzer operation where ECG data is read and displayed on screen.

PRINTER Laser printer, used to produce high speed and high quality reports. The print method is non-impact, using special toner contained in a toner cartridge for printing.

RECALL Retrieve previously saved information.

SAVE / STORE Store desired data/information in memory or on disk. If stored on the hard disk, the information is usually saved permanently until deleted or overwritten.

SCANNER Refers to the specialized Analyzer used to read/scan ECG data.

SELECTED STRIP A section of ECG data to be expanded for viewing or printing.

SOFTWARE Computer program(s) which instruct the electronic machine to operate in a certain fashion.

ST-LEVEL Measurement taken on the ST-Segment of a "normal" ECG complex, using the Isoelectric line as reference.

SUPERIMPOSITION ECG data displayed on screen directly from the DDR Recorder.

TABULAR SUMMARY A summary of the analysis performed on a Holter recording represented in a columnar fashion for quick viewing and editing.

APPENDIX B

PRINTER SETUP

APPENDIX B - PRINTER SETUP (optional)

The Laser Printer is shipped with default settings to work with the MASTER SERIES Holter Reporter™. These settings can be verified or reset with Printer Setup option as follows.

- 1. Turn on the system
- 2. From the Windows 7[™] or XP desktop double-click on the "My Computer" icon.
- 3. On the left side under "Other Places" left-click on the "Control Panel" hot link.
- 4. Under the "Pick a Category" click on "Printers and Other Hardware."
- 5. Under "or pick a Control Panel icon" click on "Printers and Faxes."
- 6. Verify that a Printer icon that is the make and model of the Laser Printer connected to your computer has a black checkmark next to it.

APPENDIX C SAMPLE FORMS AND REFERENCE DOCUMENTS

Document Title

ACS Doc # / Part Number

| HPP Monitor Step-by-Step Procedure | 51440049 |
|---|---------------------|
| Recorder Log | 34890794 |
| 2010 Holter Performer Recorder Step-by-Step Guide | 51440028 |
| 2003 Holter Performer Recorder Step-by-Step Guide | 34890797 / 4441SS03 |



Doc. 51440049 Rev, Original

RECORDER LOG

| | Hook-Up Date | PATIENT NAME | RECORDER NUMBER | Hook-up Tech | Download Yes/No | Comments |
|----|-----------------|--------------|-----------------|-----------------|--------------------|----------|
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
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| 6 | | | | | | |
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APPLIED CARDIAC SYSTEMS, INC.

Phone: (800) 423-2929 ACSD LAB: (855)-423-2191

22912 El Pacifico Drive, Laguna Hills, CA 92653



The Holter Performer 2010 STEP-by-STEP Guide

BEGIN THE RECORDING

STEP 1: Insert the lead set into the recorder. The lead set will align with the outer case of the recorder and snap into place.

STEP 2: Place the electrodes on the patient. Follow the ACS diagram for protocol and proper lead placement.

STEP 3: Remove the battery cover. The flashcard should be inserted into the recorder.

STEP 4: Install one new or rechargeable AA battery in the Holter Performer 2010. Observe the correct battery polarity and replace battery cover.

STEP 5: The recorder will initialize and the LCD will display the Patient Info Screen. Press the down arrow until it is next to ID Style. ENTER to select the highlighted entry. Use the DOWN arrow button to toggle between NUMERIC and ALPHA/NUMERIC. Numeric allows only numbers to be entered in Patient ID. Alpha/Numeric allows both numbers and letters to be used. Use the ENTER key to accept ID style.

STEP 6: Use the UP arrow to move to Patient (ID). ENTER to select the highlighted entry. Use the UP and DOWN arrow buttons to change the values. Use the RIGHT and LEFT arrows to move places. Use the ENTER key to accept ID

STEP 7: The Patient Info Screen appears. Use the DOWN arrow until the DOB is highlighted. Press ENTER to select highlighted entry. Use the UP and DOWN arrows to change the numerical value and the RIGHT and LEFT arrows to move places. Use the ENTER key to accept the DOB.

STEP 8: The Patient Info Screen appears. If you are performing a 48 hour Holter use the left arrow to move to the ECG Settings screen. An arrow appears next to Duration. Press ENTER to select highlighted entry. Use the UP arrow to change the time. Press ENTER to select. Use the right arrow to move to the Patient Info screen.

STEP 9: Use the right arrow to move from the Patient Info Screen to the Review and Start Menu. The arrow appears next to Review Leads. Press ENTER to select highlighted entry. The EKG for Channel 1 appears. Verify proper hook-up and prep by tapping electrode sites. To review Channel 2, use the right arrow. To review Channel 3, use the right arrow. Remember to tap each electrode site and reposition electrodes as necessary. Use the ENTER key when all channels have been reviewed.

STEP 10: Use the DOWN arrow to move to Start Recording. Press ENTER to select highlighted entry. The LCD screen will display various messages including: Formatting SD Card, Allocating Files and Calibrating. The LCD will then display Recording Time Left.

DOWNLOAD THE RECORDING

STEP 1: After the 24 hour recording is complete, note the "Insert USB Cable" message on the LCD. To stop the recording before the 24 hours is complete, press the RIGHT ARROW button and the ENTER key simultaneously. To confirm early shut down, push the EVENT button. The "Insert USB Cable" message appears. If the screen is blank, insert a new set of batteries.

STEP 2: Check the battery status by removing and reinserting a battery. "GOOD" battery status is necessary for ECG download. Replace batteries if necessary.

STEP 3: Remove the patient cable from the recorder. Attach the recorder to the USB cable; this cable is connected to the Holter Reporter Analyzer. The LCD will display Connected-HS. Continue with the Master Series Report Generation Step-by-Step Guide.



The Holter Performer 2003

STEP-by-STEP Guide

BEGIN THE RECORDING

STEP 1: Insert the lead set into the Recorder. The lead set will align with the outer case of the recorder and snap in place.

STEP 2: Place the electrodes on the patient.

STEP 3: Remove battery cover. The CompactFlash card should be inserted into the recorder. If you wish to record multi-days, remove the 24 hour flash card and insert the multi-day flashcard

STEP 4: Install two fresh batteries in the Holter Performer 2003. Observe the correct battery polarity and replace battery cover.

STEP 5: The recorder will initialize and the LCD will show the Set-Up Unit menu. Press ENTER to select the highlighted entry. Use the UP and DOWN ARROW buttons to input the PATIENT ID and DATE of BIRTH, DATE and TIME. Select ENTER to accept.

STEP 6: When complete, use the RIGHT ARROW button to enter the HOOK-UP REVIEW screen.

STEP 7: Select the ENTER review each Channel's signal trace in real time. Use the RIGHT and LEFT ARROW keys to adjust the signal gain. Select ENTER to accept.

STEP 8: Select the RIGHT ARROW to advance to the ECG DATA screen. Select the ENTER button to continue.

STEP 9: The recorder is now erasing the previously recorded data. During the recording, the time remaining, patient ID, and date will be displayed.

STEP 10: Instruct the patient on proper use of the EVENT BUTTON and DIARY.

DOWNLOAD THE RECORDING

STEP 1: After the 24 hour recording is complete, remove batteries. To stop the recording before the 24 hours is complete, press the RIGHT ARROW button and the ENTER key <u>simultaneously</u> until the "Insert USB Cable" message appears.

STEP 2: Remove the patient cable from the recorder. Attach the USB download cable recorder to the recorder; this cable is connected to the Holter Reporter Analyzer. Insert fresh batteries. The LCD will display Connected – HS.

STEP 3: Check the battery status. "GOOD" battery status is necessary for ECG download. Replace batteries if necessary. If the screen is blank, insert a new set of batteries.

STEP 4: Continue with the Master Series Report Generation Step-by-Step Guide.

DISCONNECT THE RECORDER FROM THE ANALYZER

STEP 1: Use the mouse pointer to select the "Safely Remove 'USB CompactFlash reader/writer' icon" on the task bar located on the bottom right corner of the screen. Left click the pop-up icon once. It will state, "The 'USB CompactFlash reader/writer' device can now be safely removed from the system." Unplug the recorder from the USB cable.

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