

GALIX ECG Professional Station

ERGO-PS

COMPUTERIZED STRESS TEST



FDA – Section 6
Operation Manual

Version 2.2
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INDEX

1. INTRODUCTION	3
2. ECG PROFESSIONAL STATION	6
3. ASIGNMENT OF THE CONTROL KEYS	32
4. TECHNICAL SPECIFICATIONS	32
5. WARRANTY	36

1. INTRODUCTION

WARNING:

The USB-DAM acquisition module of the ERGO-PS system provides complete electric insulation of the patient conform to the IEC 60601 standard. Anyway, some personal computers and printers have a strong current discharge to ground. If the connection to ground of the computer opens accidentally and the attendant is in simultaneous contact with the patient and with the metallic parts of the computer, it exists the possibility that the patient receive a discharge through the attendant. This situation is highly improbable. Even though, if the stretcher and computer distribution make this possible, it is an obligation to have a security insulation transformer between the power line and the Computer/Printer equipment.

The ***GALIX ERGO-PS*** is a 12 lead real time, PC Driven Electrocardiograph and Stress Test system, capable to monitoring, analyzing storing and printing ECG patient records. The system meets most of the present and future needs of the cardiology clinician.

The ***GALIX ERGO-PS*** will present high-resolution images of a patient's ECG study and stores the study in the memory for future reference or analysis. The attendant can change leads displayed, gain, time, etc. All essential commands are available through menus, buttons or keystrokes.

The ***GALIX ERGO-PS*** measures cardiac rate and other basic parameters, indicates bradycardia and tachycardia events by visual and audible means. All relevant information, date, time, etc, is presented in the screen

The ***GALIX ERGO-PS*** system is based on a hand held Data Acquisition Module (USB-DAC) with a computer USB interface that acquires high resolution ECG. Patient cables are connected directly to this module. The USB connector can be connected to any USB port in a Lap Top or Desk PC. The module is powered through the USB port eliminating the need for an additional supply.

The ***GALIX ERGO-PS*** software will show computerized ECG and Stress Test studies. The ***GALIX ERGO-PS*** will operate under Windows 98 or greater. These are some of the characteristics of the program:

- Simultaneous monitoring and printing of standard 12 lead ECG or pre selected lead combinations
- Different selectable presentation formats
- Selectable Amplitude Scales (5, 10 or 20 mm/mV)
- Selectable Scan Rates (25, 50 or 100mm/s)
- Heart Rate measurements in the 30 -240 bpm range
- Manual and automatic selection of J Point and ST

- Standard and programmable stress test protocols
- Able to control peripheral equipment (treadmill, bicycle, etc)
- Time and amplitude measurements by screen cursors

1.1. ELECTROCARDIOGRAPHY

The Galix ECG –PS offers different Print forms including different Number of leads per page (1, 2, 3, 6, or 12) and gain (x1, x1.5 or x2). The printouts includes name of patient, date, hour, etc, for ease identification.

All ECG registries may be stored in a PC hard disk for further analysis or revision. These studies stored in a database that includes some handling commands (Add, Delete, Search, etc).

Due to the high detailed resolution, the system will allow full morphological analysis. The clinician is able to obtain time periods, amplitudes with cursors and the automatic measurement tools of the software.

1.2. STRESS TEST

The *GALIX ERGO-PS* allows patient a Stress Test to be conducted using anywhere from 3 to 12 leads with standard preprogrammed protocols (Bruce, Bruce Modified, Naughton, Astrand, etc) or protocols defined by the user.

The GALIX ERGO-PS system can work with treadmills and ergometric bicycles in manual mode. In addition to this the GALIX ERGO-PS can work in automatic mode with some remote-controlled treadmills available in the market. In this case, the treadmills are commanded through a serial RS-232 link. **GALIX Biomedical Instrumentation provides neither treadmills nor ergometric bicycle.**

WARNING:

In case of using a supported remote-controlled treadmill, the control panel of this device must have a display to present the actual speed and the slope. If these values differ from those programmed, the user should consider the treadmill panel indication as valid.

GALIX Biomedical Instrumentation assumes no responsibility for malfunctioning in case the treadmill lack this facility. Likewise, it assumes no responsibility if the customer uses a remote-controlled treadmill other than the supported one.

The *GALIX ERGO-PS* displays the different stages (speed, elevation or load), elapsed time, and messages to guide the attendant during the study.

The final Exam printout will include the following information:

- Demographic Patient information
- Table presenting for each stage: duration, load, heart rate, systolic pressure, diastolic pressure, mean pressure, time, index and commentary.
- ECG strips.

The Stress Test study may be stored in the PC Hard disk, in the database. Individually these are identified for future retrieval and further analysis. The number of studies stored is limited only by the capacity of the PC's hard disk.

2. ECG PROFESSIONAL STATION

The main program of very high resolution electrocardiographic signal acquisition is described below.

2.1. STARTING AND ENDING AN EXAM

Initiating a study:

To begin the electrocardiogram the user must:

1. Double click the “**ERGO-PS**” icon in the desktop and Figure 1 will appear:

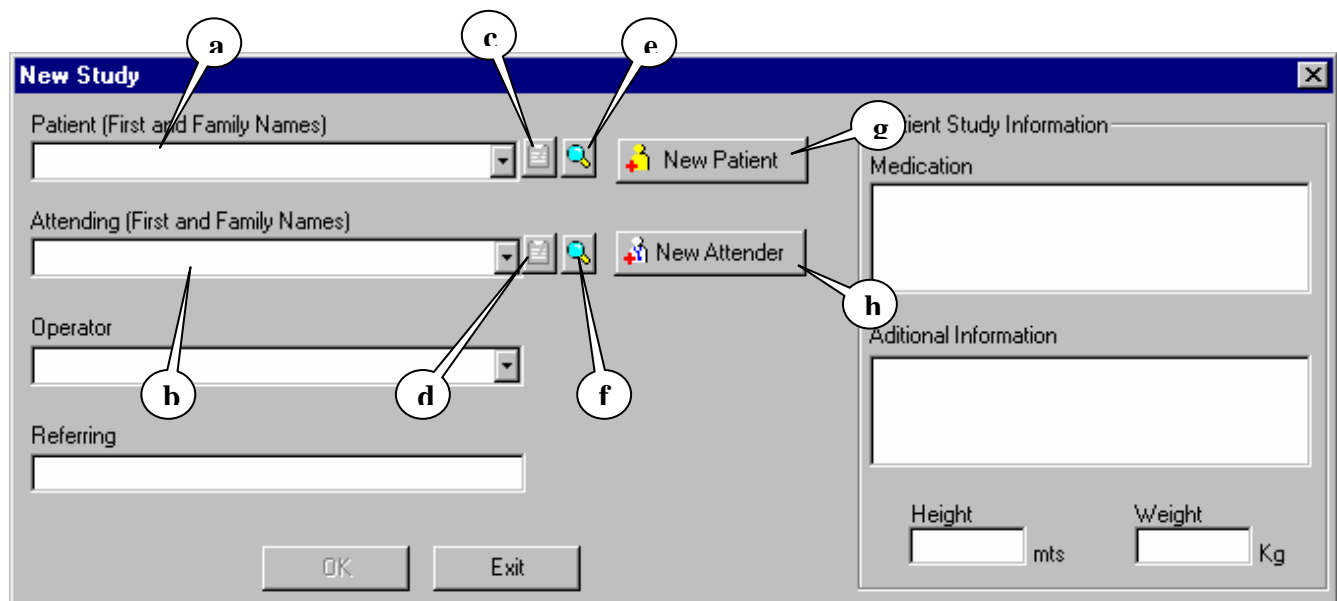




Figure 01

2. In the **Patient** text box (Figure 01-a) type the name of the patient. While writing, the name will be automatically completed with the existing patients from the database. To add a patient click on “New Patient” button (Figure 01-g) and complete the data. (See Section 2.1.4).
3. In the Attendant text box (Figure 01-b) type the name of the physician. The attendant’s name will be automatically completed with the names in the attendant s database. If the attendant is a new one you must click on “New attendant” button (Figure 01-h) and complete the data (See Section 2.1.4).
4. Once selected the patient and attendant you can access to the application by clicking on **OK** to open the monitoring screen that is shown in Figure 06. The OK button will be activated only when the patient and the attendant had been selected.
5. Click on  button from de “monitoring control” (Figure 07-e) to start the ECG acquisition.

Ending a study:

To stop the ECG acquisition:

1. Open on **SCAN** menu from the **Options Menu (Figure 07-h)** and then click **STOP** option. Answer **YES** to the question. This operation can also be called by clicking on the  button (**Figure 07-e**) from the monitoring control toolbar.
2. Click on the “diskette” icon from the toolbar (**Figure 07-g**) to save the study.
3. If the study is successfully saved the message “Data Saved” will appear.

NOTE: This process lasts a few seconds, depending of the extension of the stored study.

2.1.2. ADVANCED PATIENT AND ATTENDANT SEARCH

In this dialog the user can search a patient or an attendant. The search can be done by ID, name or both.

To make a search:

- a) Click the advanced search button (see **Figure 01-e and f**). The Advanced Search dialog will appear (see **Figure 02**).
- b) Type the ID and patient name in the corresponding fields (**Figure 02-a and b**). For a broader search leave some of the fields empty.
- c) Click the Search button (**Figure 02-c**).
- d) The results will be displayed in the Results Grid.
- e) If the Patient or the Attendant is in the list of the Result Grid, select it by clicking on that row.
- f) To use the selected Patient or Attendant in the study, click the Select Patient button. (**Figure 02-d**).
- g) To cancel the search simply press the Cancel button (**Figure 02-e**).

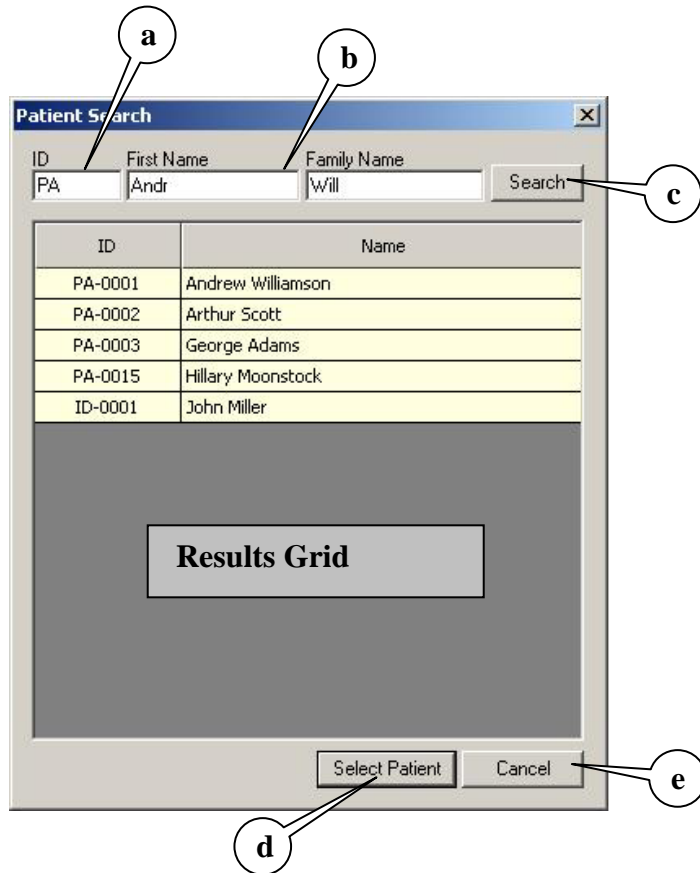


Figure 02

2.1.3. PATIENT AND ATTENDANT DETAILED VIEW

Once selected the Patient or the attendant, the user can click the View Details button (see **Figure 01-c and d**). This button will open a dialog with the Patient or Attendant information stored in the database (see **Figure 03**).

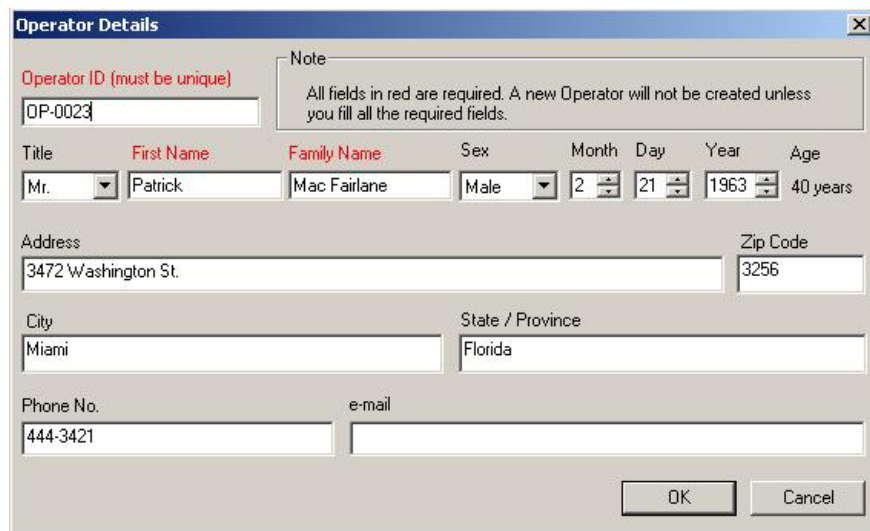


Figure 03

2.1.4. ADD A PATIENT OR AN ATTENDANT TO THE DATABASE

If the Patient or the Attendant is not in the database, the user can add them by clicking on the New Patient or New Attendant Button (**Figure 01-g and h**).

To add a Patient:

- Click on the New Patient button. The New Patient dialog will be displayed (see **Figure 04**). If the button is disabled, the selection must be deleted in the Patient field (**Figure 01-a**).
- In this dialog the fields with red title must be completed to add the patient to the database. The ones titled in black are optional.
- Click on the OK button. The dialog will be closed, the Patient will be added to the database, and selected in the Actors dialog.
- To cancel the operation click on the Cancel button.

The screenshot shows a 'New Patient' dialog box with the following fields and values:

- Patient ID (must be unique):** ID-0001
- Note:** All fields in red are required. A new Patient will not be created unless you fill all the required fields.
- First Name:** John
- Family Name:** Miller
- Sex:** Male
- Month:** 2
- Day:** 14
- Year:** 1971
- Age:** 32 years
- Nationality:** (empty)
- Profession:** (empty)
- Address:** 2555 Collins Avenue
- Zip Code:** 33456
- City:** Miami
- State / Province:** Florida
- Phone No.:** 555-5643
- Fax:** 555-5644
- e-mail:** (empty)

Buttons: OK, Cancel

Figure 04

To add an Attendant:

- Click on the New Attendant button. The New Attendant dialog will be displayed (see **Figure 04**). If the button is disabled, the selection must be deleted in the Attendant field (**Figure 01-b**).
- In this dialog the fields with red labels must be completed to add the Attendant to the database. The ones titled in black are optional.
- Click on the OK button. The dialog will be closed, the Attendant will be added to the database, and selected in the New Study dialog.
- To cancel the operation click on the Cancel button.

New Operator

Operator ID (must be unique)
 OP-0003

Note
 All fields in red are required. A new Operator will not be created unless you fill all the required fields.

Title: Dr. First Name: Jonas Family Name: Auchtung Sex: Male Month: 11 Day: 7 Year: 1961 Age: 41 years

Address: 3417 Lincoln Avenue Zip Code: 4456

City: Miami State / Province: Florida

Phone No.: 444-6734 e-mail:

OK Cancel

Figure 05

2.2. ERGO SCREEN ELEMENTS

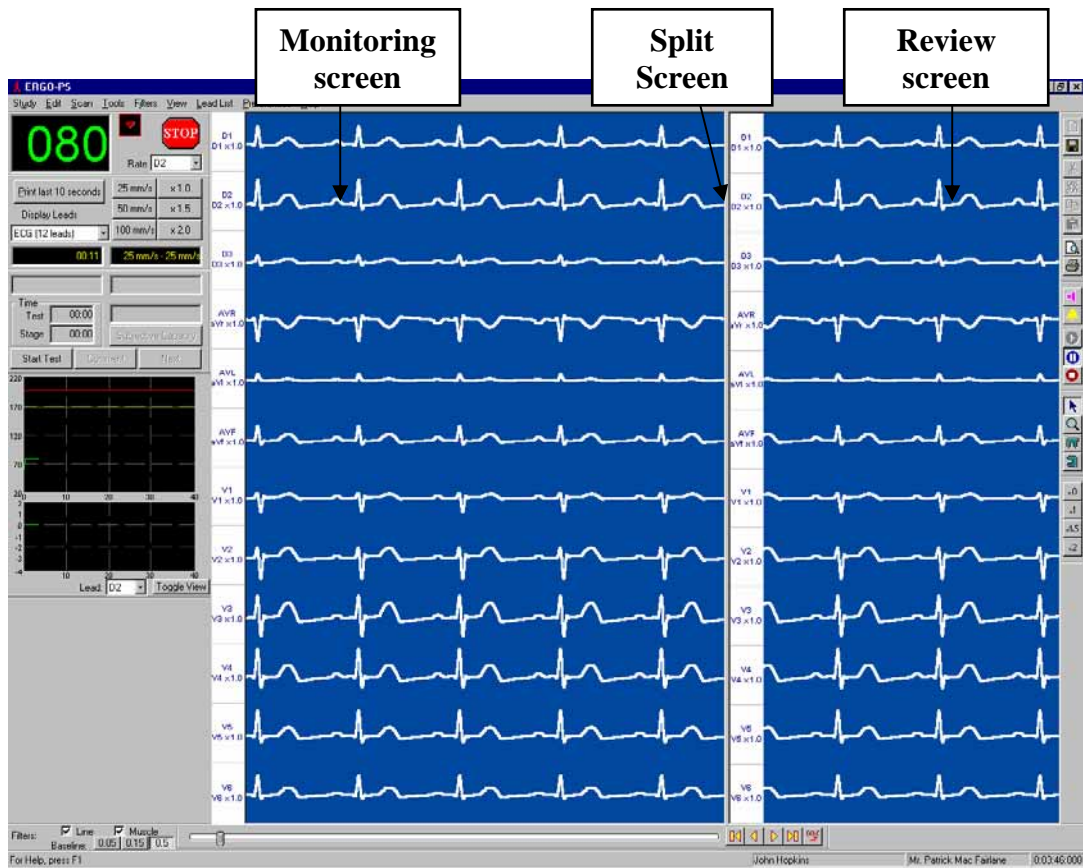


Figure 06

MONITORING SCREEN (Left Side):

Exhibit real time ECG signals.

Review SCREEN (Right Side):

Allows a complete study review on the study

SPLIT SCREEN BAR

Divides the screen into 2; monitoring and review screens. The size of each screen can be changed by the attendant by clicking on the bar with the mouse and moving the line.

FILTERS:

The attendant can introduce the following filter at any time during the exam.

- **Line:** To minimize the interference generated by the power line (50 or 60 Hz, specified in the system configuration).
- **Muscular:** To minimize the interference generated to the ECG by myoelectric potentials noise.
- **Baseline:** To minimize the interference generated by skin-electrode interface to the ECG Baseline.

The following controls are available during the ERGO exam:

- a) *Control Panel*
- b) *Position Control*
- c) *Channel bar in the Monitoring Screen*
- d) *Channel bar in the Review Screen*
- e) *Monitoring Control*
- f) *Tool Icons*
- g) *Print Control*
- h) *Option menu*
- i) *Filters*
- j) *Heart Rate Meter*
- k) *Position Bar*
- l) *Gain Control in the Revision Screen*

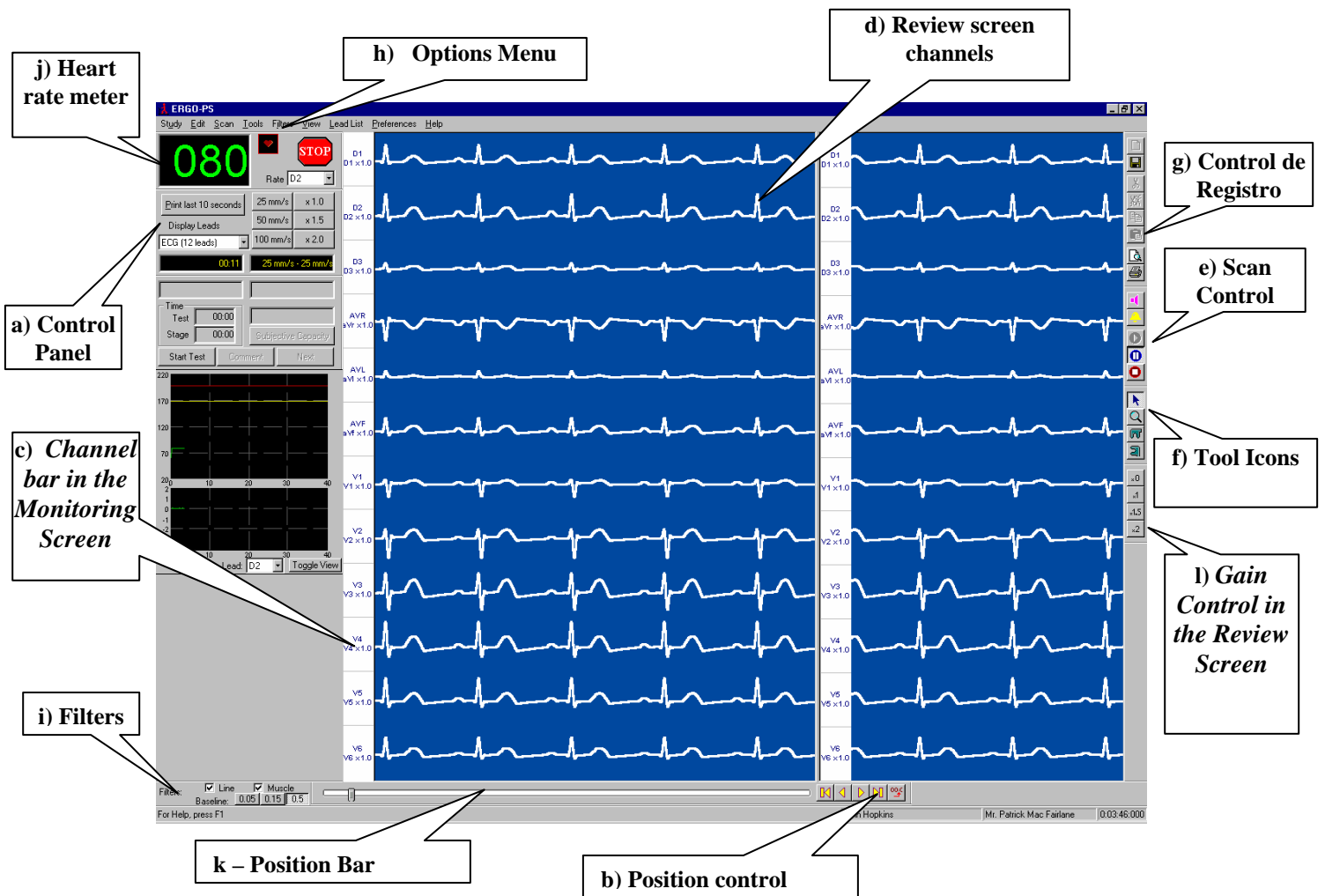


Figure 07

2.2.1 OPTIONS MENU: VIEW

Within the Options Menu (Figure 07-h), a “View” icon is available, allowing to the attendant the following options:

- **Tool Bars:** Makes the toolbar visible
- **Status Bar:** Makes the status bar visible
- **Scan Window Channel Bar:** Makes the channel bars visible in the scan screen
- **Review Window Channel Bar:** Makes the channel bars visible in the review screen
- **Scan Window Grid:** Makes the grid lines in the scan screen visible
- **Review Window Grid:** Makes the grid lines in the review screen visible
- **Tag List:** Presents a list of all events captured during the exam
- **Black Background:** Changes the background color.
- **Line Thickness:** Permits a change of line thickness. This option is useful for making slides.

2.2.2 PROCESS INDICATORS

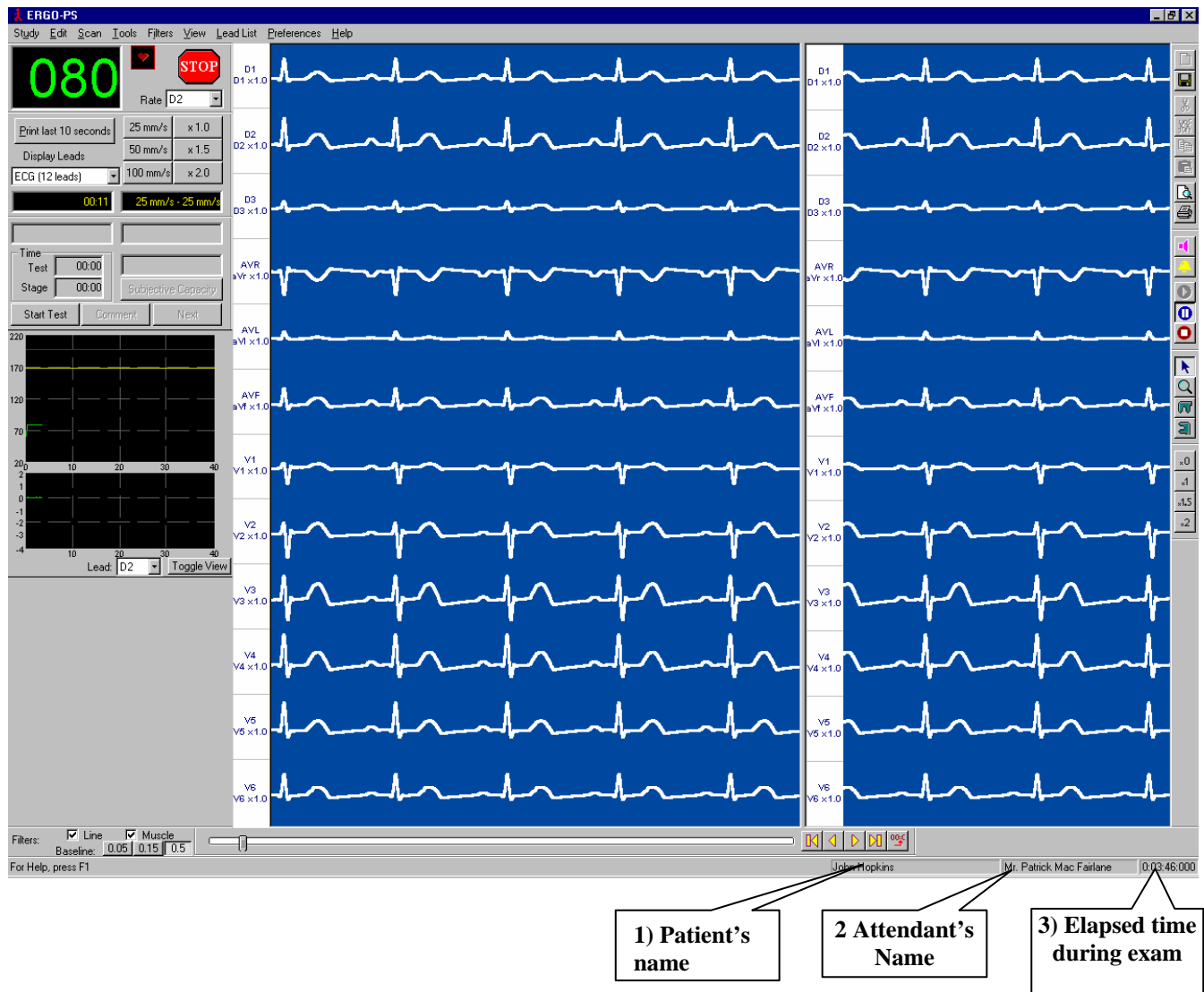


Figure 08

2.3 CONTROL PANEL

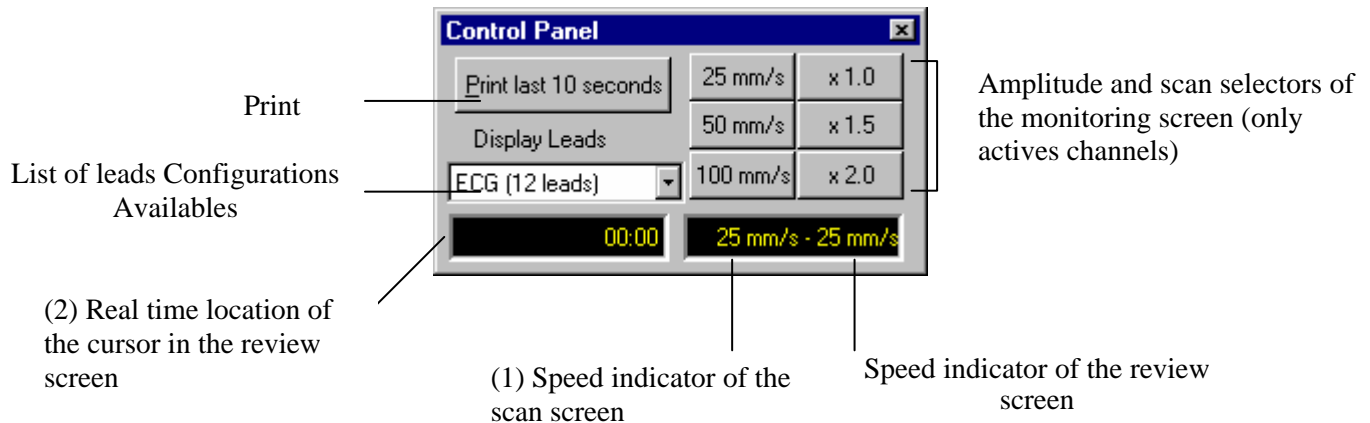


Figure 09

PRINT (See **Figure 07-g**)

This button prints the ECG signals shown in the review screen.

PRINT LAST 10 SECONDS:

Prints the last ten seconds of ECG acquired.

CONFIGURATIONS

List of leads configurations available.

SPEED

25- 50- 100: The scanning speed in mm/sec.

AMPLITUDE

1 – 1.5 – 2: Sets the gain of every ACTIVE channel.

DISPLAYS

(1) Indicates the scanning speed in the scan and review screens.

(2) Present position in minutes and seconds of the review screen. The position can be modified with the cursor of the position control. (**Figure 10**).

2.4 POSITION CONTROL IN THE REVIEW SCREEN




(a)







Figure 10

(b)

The position control of the **Review Screen** allows locating quickly any moment of a study.

The cursor  is use to display the study ECG of the **Review Screen**. Simply drag with the mouse the position cursor. The corresponding time of the cursor in minutes and seconds is indicated in the CONTROL PANEL. (**Figure 09-2**).


Additional possibilities to review the ECG on the review screen (See Figure 10):

- : Displays the initial portion of the study
- : Displays the end portion of the study
- : Rewinds the ECG shown 250 msec.
- : Forwards the ECG shown 250 msec
- : Opens the New Position window (See **Figure 11**)
- : Opens Tag List window (**Figure 07**)

The New position and Capture windows are explained below.

2.4.1. NEW POSITION WINDOW

This window provides a quick access to any moment in the study. Just introduce the values in minutes and seconds. The signals corresponding to the time selected will be displayed in the review screen.

The New Position window is shown by clicking on the button  of **Figure 07**.

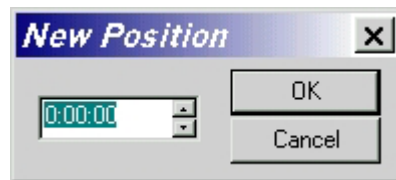



Figure 11

IMPORTANT: Fill the values of New Position according to the assigned digits.

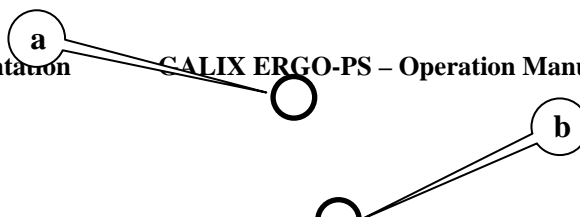
<u>MINUTES:</u> two digits	<u>SECONDS</u> two digits
--------------------------------------	-------------------------------------

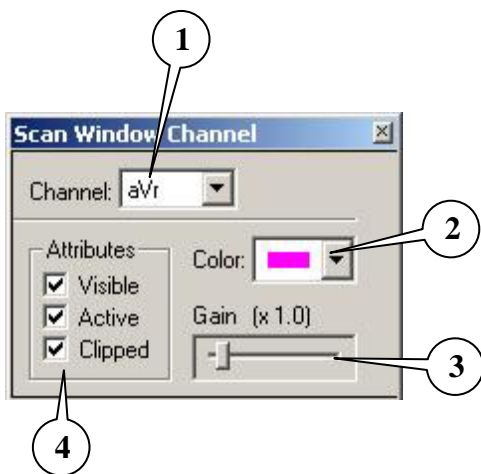
The time entered is applied after clicking the  button. The review screen will show the ECG corresponding to the selected time.

2.5. CHANNEL CONTROL BARS

The channel control bars are located to the left of the scan and review windows. (**Figure 15**). They can be hidden independently with the corresponding options in the View menu.

- (a) Channel signal identification.
- (b) Channel Gain (amplitude).
- (c) Selected Channel. By clicking on a channel a dialog box is displayed with its properties (see **Figure 16**). The background of the selected channel will be shown in orange.





- (1) Identification of the selected lead
- (2) Displays to choose the color of the selected lead
- (3) Modifies the gain of the selected lead
- (4) Attributes of the selected lead

Figure 16

The CONTROL CHANNEL window options:

- (1) **CHANNEL:**
- Leads available for the selected configuration.
 - Select a lead to configure it.

(2) **COLOR:**

- It is use to change the color of the lead.
- Shows the color pallet available.

(3) GAIN:

- Move the cursor to the right or left to increase or decrease the amplitude of the selected lead.
- The new gain is also shown in the bar.

(4) ATTRIBUTES

VISIBLE:

- Makes the derivation visible in the screen. The other leads will tile automatically.
- **IMPORTANT: even though the lead is NOT visible, the signal is acquired and processed.**

ACTIVE:

- Active: The lead gain is modified when the general gain of the CONTROL PANEL is changed.
- Inactive: The lead gain is not modified when the gain of the CONTROL PANEL is changed.

CLIPPED:

- Yes: the signal of the lead is restricted to the width of its channel.
- No: the signal of the lead is not restricted to the width of its channel

2.6. MONITORING CONTROL

This toolbar is located on the right of the screen (See **Figure 07-e**), has the following buttons:

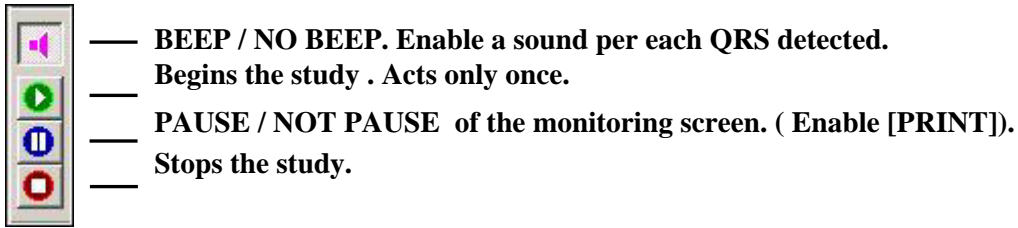


Figure 17

2.7. TOOLS ICONS

The following tools are available in the tools toolbar:

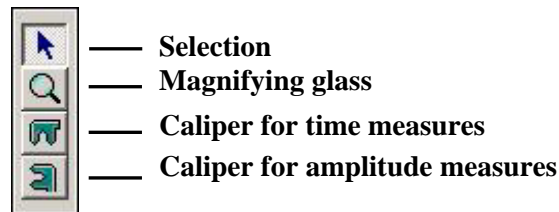




Figure 18

Selection tool

- Click on .
- Select with the mouse the object you want to control and click it with the right button.
- Select with the mouse the tool you want to use and click it with the left button.

Zoom tool

This tool changes the speed of the view clicked.

- Click on .
- Move the mouse cursor on the scan or review screen.
- Click on with the left button of the mouse to increase the speed in the selected view.
- Click on with the right button of the mouse to decrease the speed on the selected view.

CALIPER:

To activate the caliper you must click with right button on the screen that you want to work . (See section **2.9 CALIPER**)

2.8. REGISTER CONTROL

NOTE: It is recommended that the user get used with the basic commands of MS Windows in order to obtain maximum efficiency in the use of the following functions.

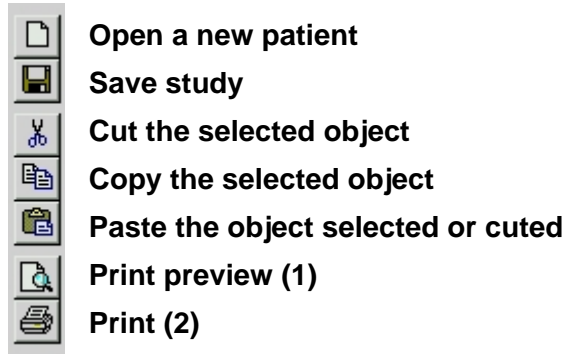


Figure 19

Print

Prints the ECG shown in the review screen.

Print Preview

Prints preview of the ECG shown in the review screen (See **Figure 20**).

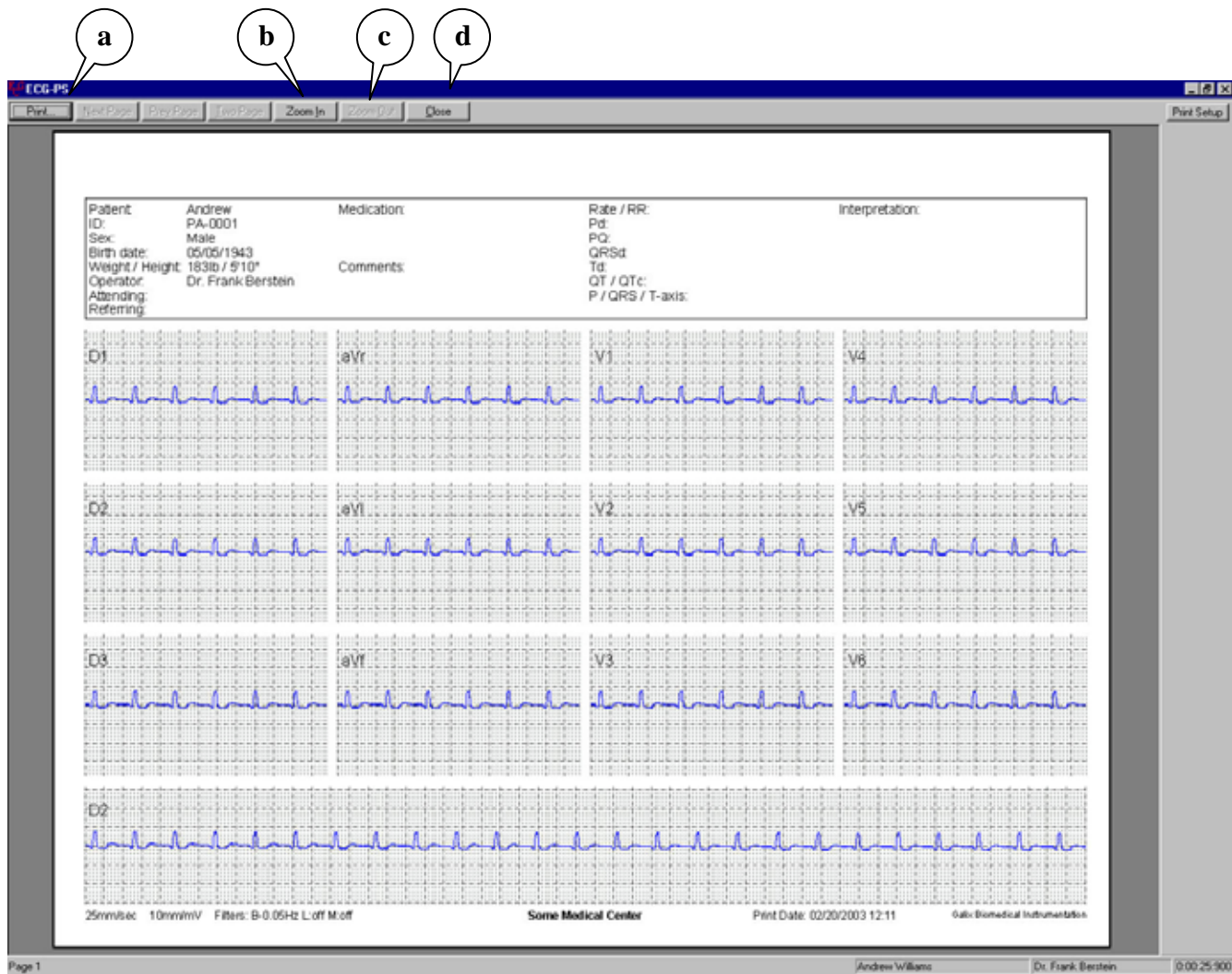


Figure 20

- (a) Click on **Print** to print the shown page.
- (b) Click on **Zoom In** to enlarge the image. The arrow of the mouse will change to a magnifying glass. Point and click the area to enlarge.
- (c) Press **Close** in order to close the Print Preview window without printing.

Note: In a color printer, all the objects and signals will appear with their correspondent colors.

2.9. CALIPER

The program allows to insert calipers to measure time periods (msec) and amplitudes (mvolts) .

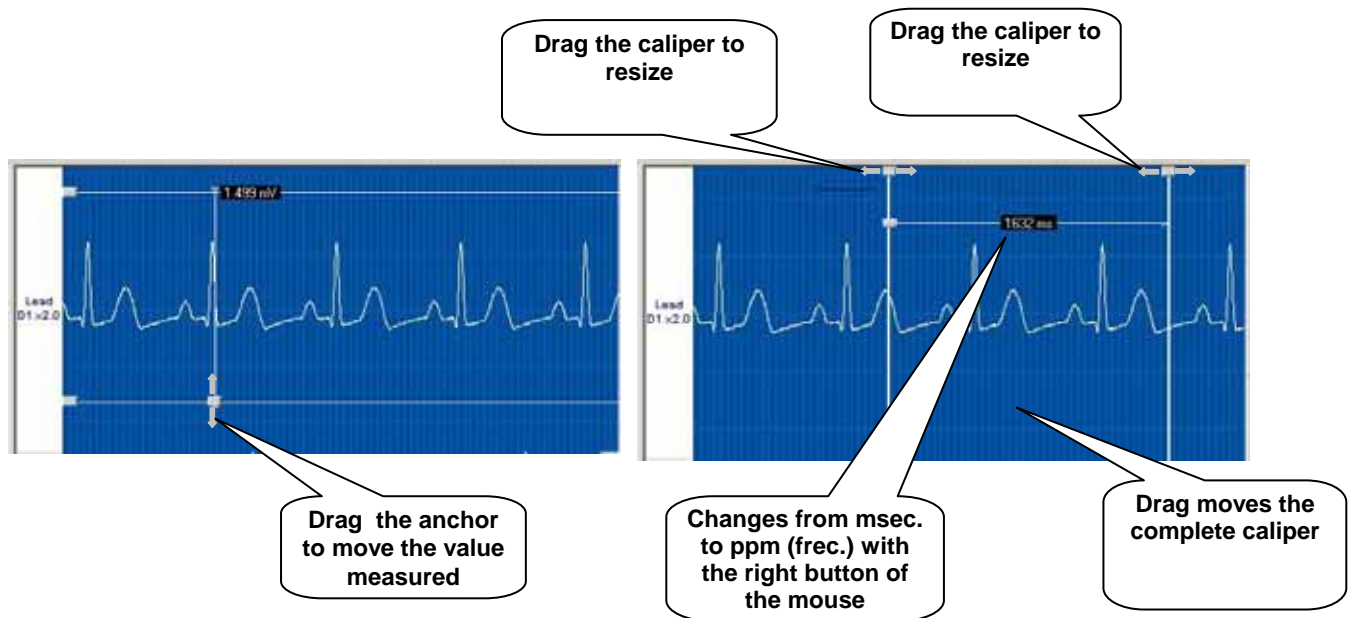


Figure 21

Procedure to activate the calipers:

- Click on .
- Click on  with the left button of the mouse.


Measurement:

The arrow of the mouse is .



- Click on the first point of the measurement and drag the mouse (maintaining the button pressed) to the second point of the measurement, then release the mouse button.

IMPORTANT: Observe that pressing the right button of the mouse transforms the measurement indicated in milliseconds (msec) into beats per minutes (bpm)

Insert a new caliper:

The  tool will maintain active after inserting a caliper. To add another one follow the steps detailed above.

Erasing calipers:

- Select the caliper you want to erase with the  tool.
- Click on  button.
- If there is only one caliper it will be erased.
- If there were more than one caliper the following question will appear: Do you want to cut them all?
 - "YES" Will erase all calipers from the screen.
 - "NO" Will erase only the selected caliper.

Note: Clicking the Paste button will recover the last caliper erased. (Figure 19).

Changing caliper color:

Select the caliper (square in the upper part of the caliper)

- Select VIEW from the OPTIONS menu (Figure 07).
- Select COLORS. The color dialog box will appear. (Figure 22).
- Click the desired color.



Figure 22

2.10. CHANNEL LIST

The properties of the channels of the review screen can be directly modified. The second option allows to quickly modify several channels without going one by one.

2.10.1 CHANNEL LIST IN THE MONITORING SCREEN

Select Scan Window Channel List in the Channel List item from the Options menu. The Scan Window Lead List dialog will appear (see **Figure 23** and **Figure 24**).

#	Lead	Label	Gain	Visible	Active	Clipped	Color
1	D1	Lead	1.0	✗	✗	✓	Red
2	D2	Lead	1.0	✗	✗	✓	Red
3	D3	Lead	1.0	✗	✗	✓	Red
4	aVr	Lead	1.0	✗	✗	✓	Magenta
5	aVl	Lead	1.0	✗	✗	✓	Magenta
6	aVf	Lead	1.0	✗	✗	✓	Magenta
7	X	Lead	1.0	✓	✓	✓	Yellow
8	Y	Lead	1.0	✓	✓	✓	Yellow
9	Z	Lead	1.0	✓	✓	✓	Yellow

Buttons: Apply, Discard

Figure 23 - Vectorials

#	Lead	Label	Gain	Visible	Active	Clipped	Color
1	D1	Lead	1.0	✗	✓	✓	Red
2	D2	Lead	1.0	✓	✓	✓	Red
3	D3	Lead	1.0	✗	✓	✓	Red
4	aVr	Lead	1.0	✗	✓	✓	Magenta
5	aVl	Lead	1.0	✗	✓	✓	Magenta
6	aVf	Lead	1.0	✗	✓	✓	Magenta
7	V1	Lead	1.0	✗	✓	✓	Green
8	V2	Lead	1.0	✓	✓	✓	Green
9	V3	Lead	1.0	✗	✓	✓	Green
10	V4	Lead	1.0	✗	✓	✓	Green
11	V5	Lead	1.0	✓	✓	✓	Green
12	V6	Lead	1.0	✗	✓	✓	Green

Buttons: Apply, Discard

Figure 24 - Not Vectorials

The Scan Window Lead List dialog allows the physician to modify all the properties of the channels that are being acquired.

- #: Number of the channel (de 1 a 12)
- Input Channel: Indicates which lead will be used. Making a double click on any cell of this column will display a list box containing the leads available.
- Label: Description of the lead. This description can be modified at any time along the study, recording all the changes and the moment when it happened. To modify it, just do double click on the cell and insert the new description.
- Gain: Modifies the gain of the lead signal. To modify the value double click on it.
- Visible: Shows or hides the lead on the review screen. Double click on the cell inverts its value.
- Active: All the active leads will change when changed from the Control Panel (See **Figure 16**). Double click on the cell change its value.
- Clipped: Indicates if the lead will be drawn clipped or not. Double click on the cell change its value.
- Color: Displays the colors of each lead.

Once the changes are done the physician can:

- a. Apply the changes: Click the Apply button.
- b. Cancel changes: Click the Cancel button.

2.11 ADD OR MODIFY A PROTOCOL FOR AN ERGO STUDY

To add or modify a protocol for a stress test study, the user must select from the Preferences Menu the Ergo Protocol Setup Option. The Ergo Protocol Setup dialog will appear (See **Figure 25**).

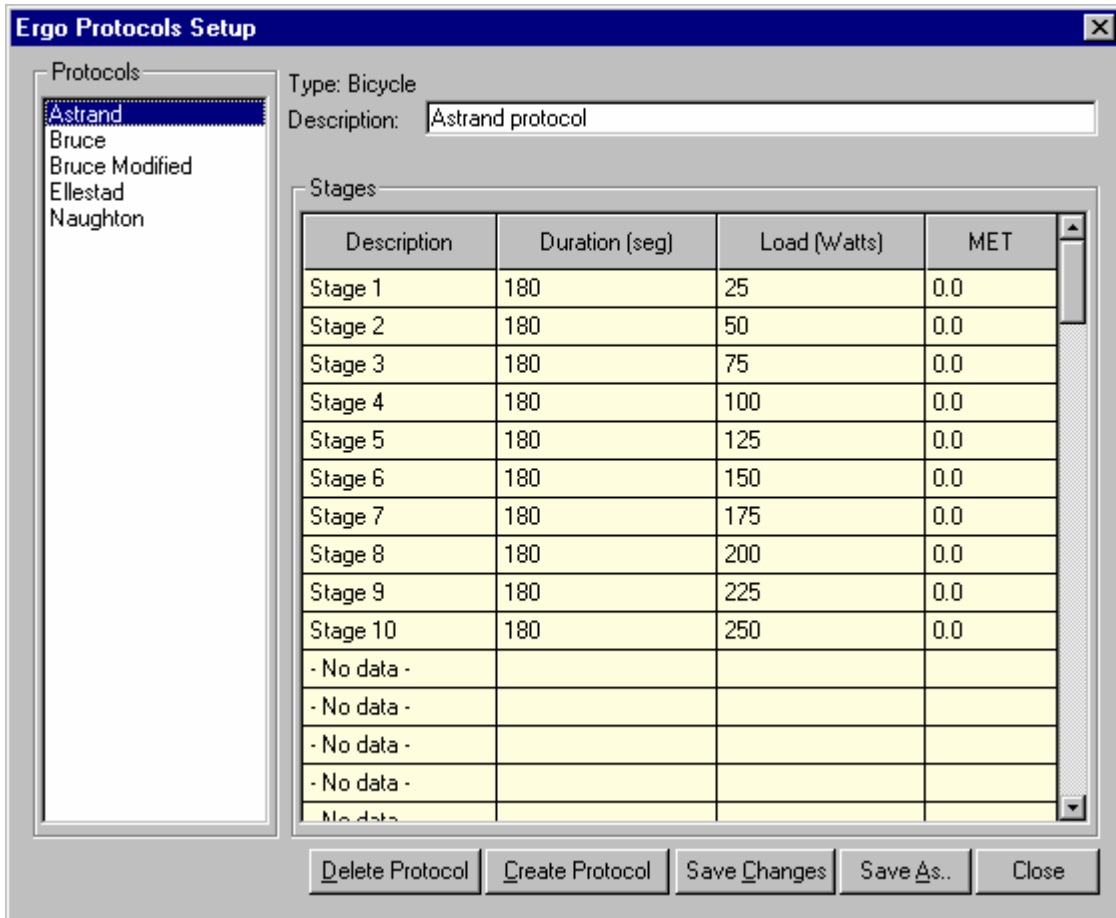


Figure 25 –Ergo Protocols Setup dialog

To modify a protocol, select it from the list on the left. Then modify the values desired in the grid that describes each of the stages and click on “Save Changes” button.

To add a new protocol click on “Create Protocol” button. The New Protocol dialog will appear, specify the name, description and type (Treadmill or Bicycle) of protocol to create. Define each stage. The definition of each stage must not have empty spaces, otherwise the stage will not be saved. To save the protocol you must click on “Save Changes” button.

2.12 SISTEM CONFIGURATION

To configure the system choose Configuration from the Preferences menu and the configuration system dialog will appear. In this dialog the system options are separated in tabs.

Filters

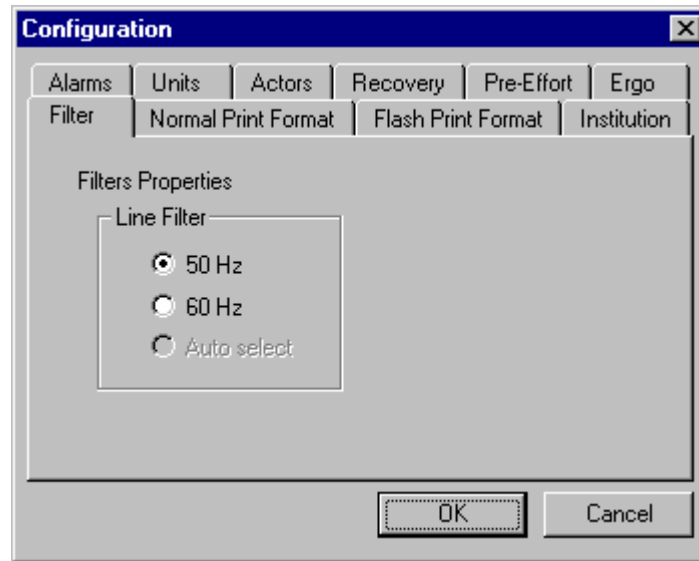


Figure 26 – Filters configuration dialog

Select the frequency of the line filter according to the country were the system is used.

Print Format

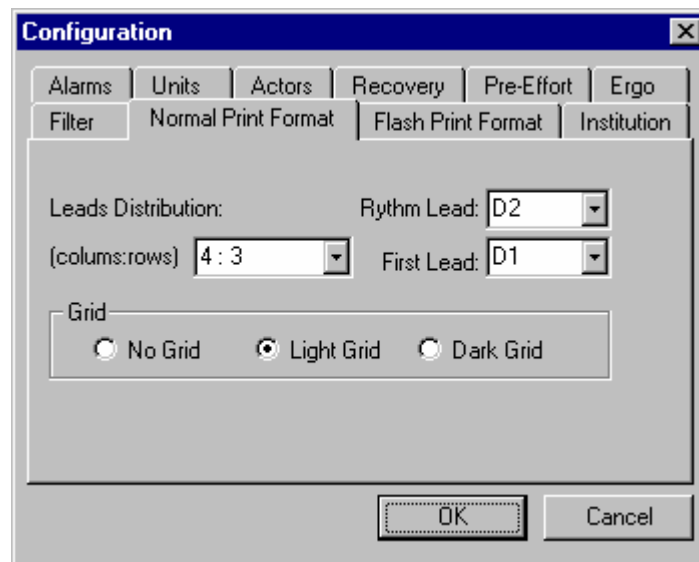
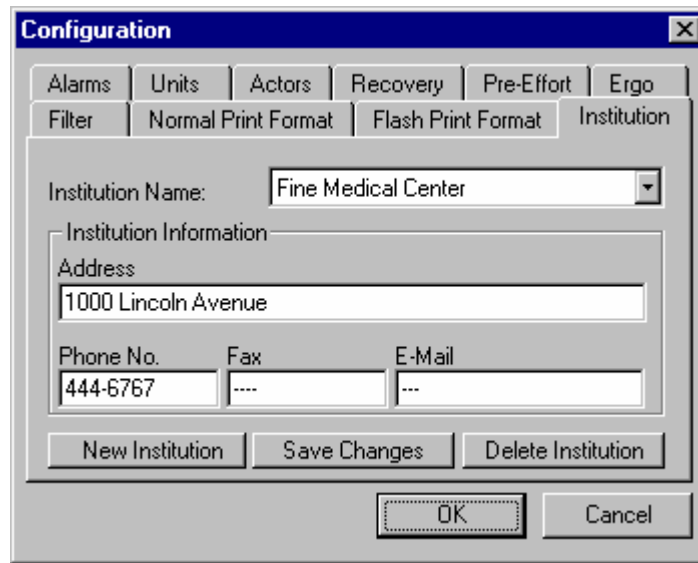


Figure 27 – Print Format configuration dialog

The format established in Normal Print Format and Flash Print Format, will be used when printing form the review screen and the last 10 seconds of signal respectively.

Institution

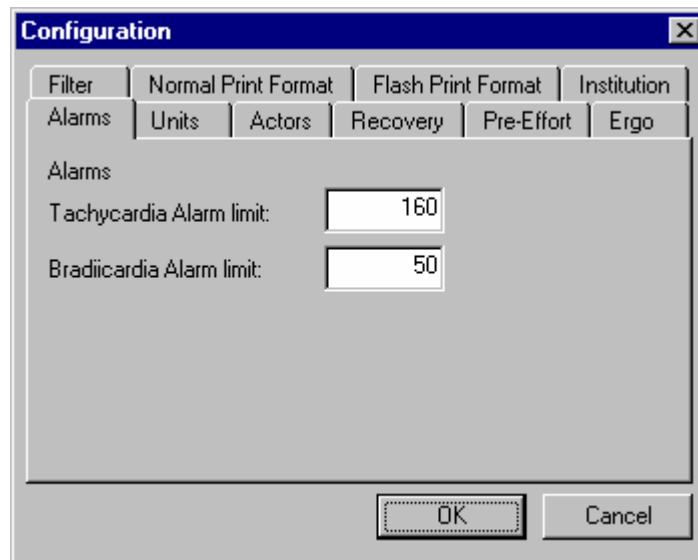


The image shows a 'Configuration' dialog box with a blue title bar and a close button. It features a tabbed interface with tabs for 'Alarms', 'Units', 'Actors', 'Recovery', 'Pre-Effort', 'Ergo', 'Filter', 'Normal Print Format', 'Flash Print Format', and 'Institution'. The 'Institution' tab is selected. The 'Institution Name' is set to 'Fine Medical Center'. Below this, there is a section for 'Institution Information' containing an 'Address' field with '1000 Lincoln Avenue', and three fields for 'Phone No.' (444-6767), 'Fax' (---), and 'E-Mail' (---). At the bottom, there are buttons for 'New Institution', 'Save Changes', 'Delete Institution', 'OK', and 'Cancel'.

Figure 28 –Institution configuration dialog

Configuration of the institution where the studies are done. The name of the institution is printed in the title of the ECG prints.

Alarms



The image shows a 'Configuration' dialog box with a blue title bar and a close button. It features a tabbed interface with tabs for 'Filter', 'Normal Print Format', 'Flash Print Format', 'Institution', 'Alarms', 'Units', 'Actors', 'Recovery', 'Pre-Effort', and 'Ergo'. The 'Alarms' tab is selected. The 'Alarms' section contains two fields: 'Tachycardia Alarm limit' set to 160 and 'Bradycardia Alarm limit' set to 50. At the bottom, there are buttons for 'OK' and 'Cancel'.

Figure 29 – Alarms configuration dialog

A tachycardia alarm will trigger when the heart beat rate is greater than the value of the limit established. In the same way a bradycardia alarm will trigger when the heart beat rate is lower than the value of the limit established. In order to be able to listen to the alarms the PC must have a sound card and speakers, otherwise you will only see the visual alarm.

Preferred units

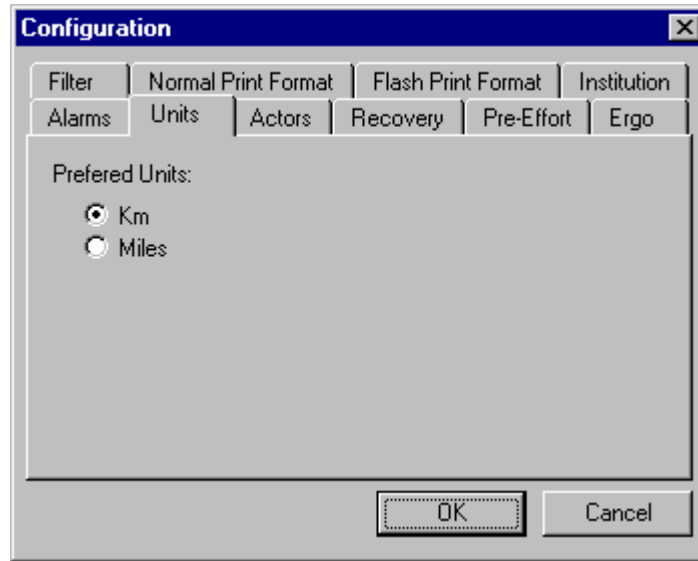


Figure 30 – Units configuration dialog

Preferred units, Km or Miles. For example the treadmill speed in Km/h or Mi/h.

Actors

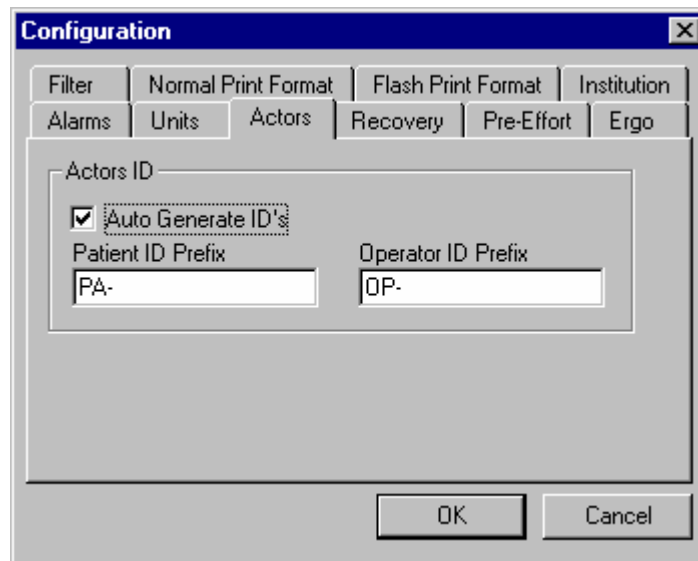


Figure 31 – Actors configuration dialog

If patient and attendant codes are auto generated, is it possible to configure the prefix for each one of them.

Recovery Stage

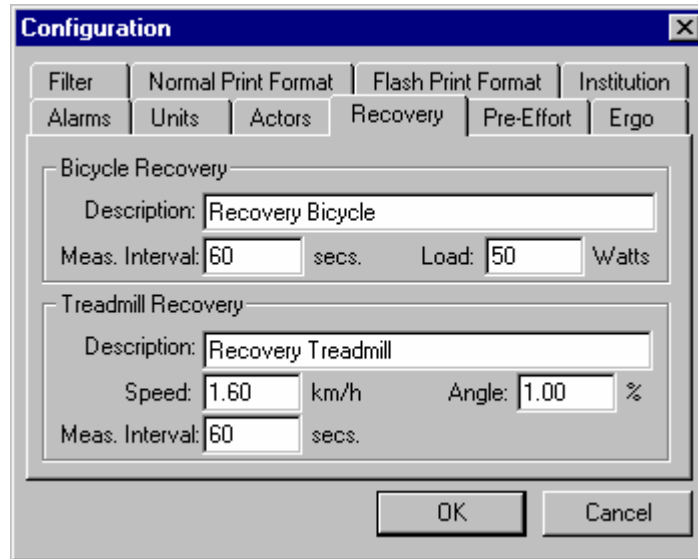


Figure 32 – Recovery Stage configuration dialog

Recovery stage configuration. This stage is common to all the Stress Test protocols, but of course, it is different for treadmill and bicycle protocols. When this stage is concluded, the blood pressure is measured and the stage is restarted.

Pre-effort Stage

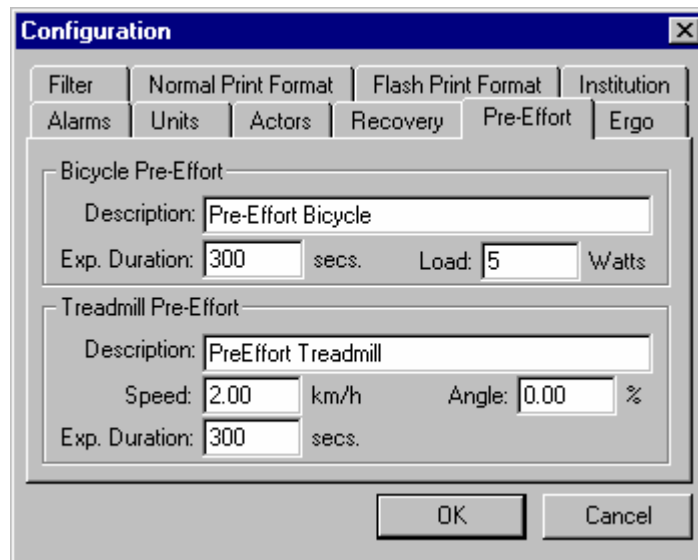


Figure 33 – Pre-Effort Stage configuration dialog

Pre-effort stage configuration. This stage is common to all protocols, differentiated by the type. When the stage is concluded, the first stage of the Stress Test protocol is started.

Stress Test

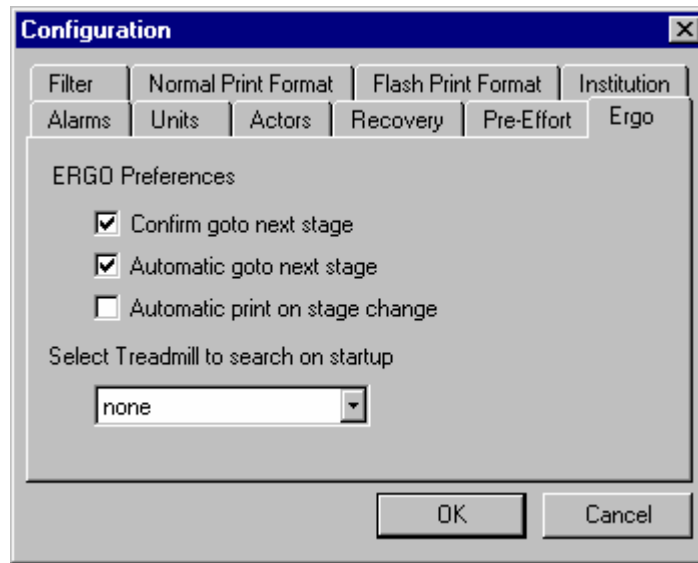




Figure 34 – Stress Test configuration Dialog


General configuration of the Stress Test. Automatic go to next stage, when the stage is concluded the system will automatically pass to the next stage. Confirm go to next stage, 30 seconds before the stage is concluded the attendant is warned of the end of the stage. Automatic print on stage change, prints ECG when the stages changes. Select Treadmill, selects the treadmill to control. If a treadmill is selected the user must close and restart the program.


3. ASSIGNMENT OF THE CONTROL KEYS

When opened the scan window some of the keyboard keys have the following special functions:

 (RIGHT arrow): Increases the speed of the scan and review screens.

 (LEFT arrow): Reduces the speed of both screens.

 (UP arrow): Increases the amplitude of all channels.

 (DOWN arrow): Reduces the amplitude of all channels.

HOME : Moves the signals on the review screen to the beginning of the study.

END : Moves the signals on the review screen to the end of the study.

PAGE UP : Moves the signals on the review screen 250 msec backwards.

PAGE DOWN : Moves the signals, in the review screen 250 msec forwards.

SPACE BAR : Freezes / Defreeze The signals on the scan screen.

Clicking on the image freezes at the end of the scanning. Making a double click freezes the image instantly.

Control + B : Enable / Disable the acoustic “BEEP” of the QRS.

IMPORTANT: The Data Acquisition Module should be cleaned regularly, using a cloth with alcohol.

4. TECHNICAL SPECIFICATIONS

GALIX ECG-PS Data Acquisition Module (DAM-PS)

Input Amplifier

Frequency response:	0.05Hz±11% a 500Hz±5% @ -3dB
CMRR :	100dB min, @ DC to 60Hz
Background added noise:	1.1 μ Vrms max, @ 0.05Hz to 500Hz
Input Signal Span:	16.4mVpp±3% @ 10Hz
Electrode offset Tolerance:	300mV min.
Lead Input Impedance:	> 100 Mohm @ DC to 500Hz
Lead Bias Current:	1nA max
Reference Compensation:	Selectable for Limb or XYZ electrodes
Patient Connection:	10 leads (Limb+Chest) / 7 leads (Limb+XYZ), shielded cables with current limitation

Data Acquisition

Sampling Rate:	3000 samples per second per lead (1000 Sample/sec/lead, normalized)
Sampling Resolution:	0.25mV±3% (1 μ V, normalized) @ 10Hz
Data Resolution:	16 Bits (14 Bits, normalized)
Analog Anti-Alias Filter:	500 Hz±5%, 3 ^o order, Butterworth low pass
Modes:	12 Leads (Limb+Chest) / 9 Leads (Limb+XYZ)

Electrical

PC interface:	Full Speed USB 1.1, 12Mbit/s
Power consumption:	100mA max (supplied by Computer USB Port)
Patient Isolation:	2500V, 50pF max
Patient Leakage Current:	< 5uA (Patient Electrically Isolated)
Defibrillator Protection:	5 KV, 10 ms / 400 Joules

Physical

Size:	5.5" (140mm) x 2.5" (63mm) x 1.2" (31mm)
Weight:	0.5 lbs (230g), USB Interface Cable Included
Enclosure:	Water and Dust Proof, ergonomic design
Interface Cable length:	10ft (3m)
Color:	Off-White
External Material:	ABS (UL 94 HB)

Environmental

Operating Temperature:	50 to 110°F (10 to 45°C)
Storage Temperature:	-4 to 150°F (-20 to 65°C)
Operating Humidity:	5 to 95% relative, non condensing
Storage Humidity:	5 to 95% relative, non condensing
Atmospheric Pressure:	700 to 1060 hPa

GALIX ECG-PS Software (running on PC)

Signal Processing

(Overall digital tolerance less than 0.1%)

Low Pass Filter:	150 Hz, FIR type
High Pass Filter:	0.05Hz / 0.15Hz / 0.5Hz, 3rd Order
Muscle Filter:	35Hz @ -3dB / 72Hz @ -40dB, Chebycheff Inv.
Baseline Drift Filter:	None / 0.5Hz
Line Suppression Filter:	None / 50Hz / 60Hz, 60dB min
Output Data Rate:	1000 Sps
Output Data Resolution:	14 Bits

Signal Analysis

(calculated on the basis of the entire 10-sec recording)

Rate [bpm]:	Heart Rate \pm 2% or 3bpm
ST-L [mV]:	deviation of the ST segment from the isoelectric level in lead "L" \pm 0.1mm
STsL-L [mV/ms]:	slope of the ST segment in lead "L" \pm 15%

Minimum PC requirements

SCREEN:

- Monitor: SVGA Color, 15" (Recommended: 17")
- Resolution: 1268 x 1024 / 1024 x 768 pixels, Non-interlaced, Color: 16 bits

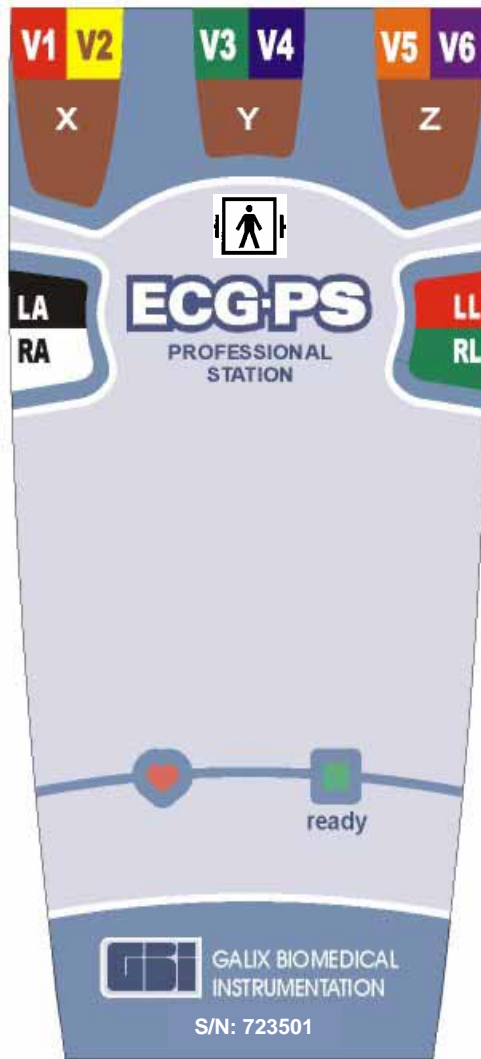
COMPUTER:

- Processor: PENTIUM III 700 MHz (or better)
- Hard Drive: 30 Gbytes (o better)
- RAM: 128 Mb
- I/O: Parallel, USB, Serial
- Accessories: Keyboard and Mouse
- Operating System: Windows98, Windows Me, Windows XP

Standard Accessories

- Five 2-lead fully shielded patient cable
- Four clamp electrodes (limb leads)
- Six suction electrodes (chest leads)
- One Installation CD
- One Hard-Lock protection key
- One Operation Manual

C



Front Label

5. WARRANTY

GALIX BIOMEDICAL INSTRUMENTATION

Limited Warranty

GALIX Biomedical Instrumentation provides to the original purchaser the following limited warranty from date of invoice.

All serialized parts	18 months
Accessories, i.e. patient cables, disposables	90 days

GALIX Biomedical Instrumentation warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instrument when returned from the customer's facility prepaid to the factory. GALIX Biomedical Instrumentation will repair any component(s) or part(s) that is found to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser shall first notify GALIX Biomedical Instrumentation of the suspected defect. The instrument should be carefully packaged and shipped prepaid to:

GALIX BIOMEDICAL INSTRUMENTATION
Service Department
2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.
Tel.: (305) 534-5905 Fax: (305) 534-8222

Your instrument will be repaired in the shortest possible time and returned by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, act of God, or if the instrument has been serviced or modified by any person not authorized by GALIX Biomedical Instrumentation.

Equipment distributed by GALIX Biomedical Instrumentation such as, but not limited to personal computers and printers will carry the original equipment manufacturer's warranty and will not be warranted by GALIX Biomedical Instrumentation.

This limited warranty contains the entire obligation of GALIX Biomedical Instrumentation, and no other warranties expressed, implied or statutory are given. No representative or employee of GALIX Biomedical Instrumentation is authorized to assume any further liability, or grant any further warranties except as set herein.

GALIX BIOMEDICAL INSTRUMENTATION

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