GBi GALIX
BIOMEDICAL INSTRUMENTATION, INC.

POLYGRAPH PHYSIO 28

Operation Manual

Version 1.0
May/1/2001

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1. INTRODUCTION

The GALIX PHYSIO-28 POLYGRAPH is a device specifically designed to perform cardiac electrophysiologic studies. The hardware and software design specifications were optimized to achieve the system's high precision and ease of use.

The PHYSIO-28 runs under Windows 2000. This platform provides robustness and reliability in all the control processes. It also allows simultaneous tasks, such as, protocol modification, report generation, graphic visualization, and review of previous studies during the EP study.

The whole study can be stored for further analysis. During the data retrieval process, all the scanning controls are available, allowing the visualization of all the stored channels; even those not visible during the study.

It is important that the user be well acquainted with the basic Windows screens and commands in order to achieve maximum performance with the PHYSIO-28.

The electrophysiology PHYSIO-28 software system comprises three programs:

I) PHYSIO CONFIGURATION
          System Configuration Program..

II) PHYSIO SCANNER
          Monitoring Main Program.

III) PHYSIO REVIEW
          Stored Studies Review Program.

2. *PHYSIO* CONFIGURATION

This module allows the user to configure the PHYSIO-28 for each EP study. This procedure is performed only once, but may be repeated as many times as necessary.

HOW TO CONFIGURE:

1. Turn on the computer.
2. The Windows screen "DESK" will appear.
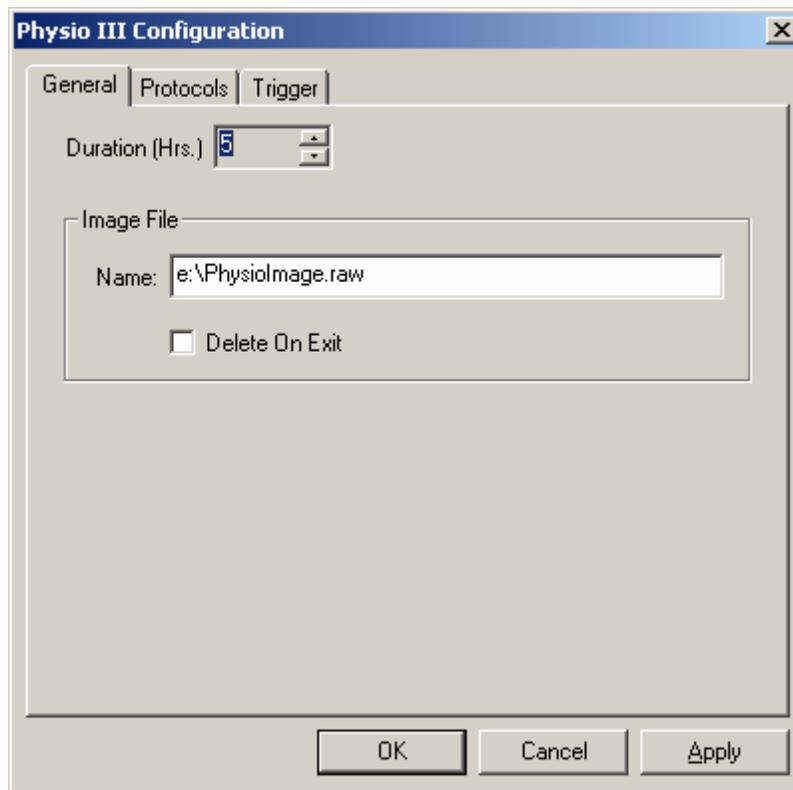3. Double-Click on "PHYSIO III CONFIGURATION". The next screen will appear (**Figure 01**):

Figure 01

This window allows the selection of the expected maximum E.P. study time. The default value is 5 hours, and the maximum time allowed is 8 hours. The polygraph will check if there is enough memory space in the hard disk regardless of the duration of the study selected. If not, the Polygraph program will emit an acoustic warning message and will not run. Under this condition, the user should either diminish the study duration value or delete previous studies stored.

It is important to take into account that the Physio Scanner will occupy 240Mbyte per study hour. For instance, if the study duration value of 5 hours is selected, up to 1.2Gbytes of hard disk memory will be used by this program during the study. Nevertheless, after ending, the stored record will consume 120Mbyte per acquired hour.

Image File is an internal file, which must NOT be modified.
Delete On Exit must be disabled (no check symbol)

2.1. Protocols

It is convenient to click on "PROTOCOLS", to access the following protocol screen:
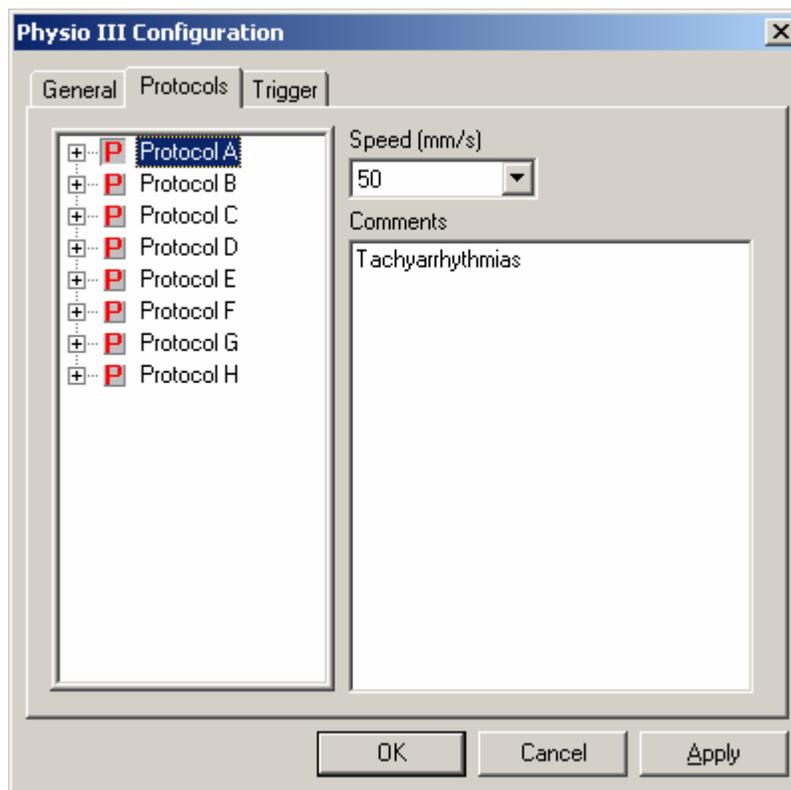

Figure 02

This window shows the 8 protocols that are available, identified with the letters A to H. By clicking on the option "Speed", it is possible to assign an appropriate sweeping speed to every protocol.

Likewise, the operator may associate a name to every protocol by typing it in the area labeled "COMMENTS".

Clicking on the ⎡+⎤ sign of a particular protocol (for instance **Protocol A**), the protocol will open to show the 16 channels identified with the letters A to P.
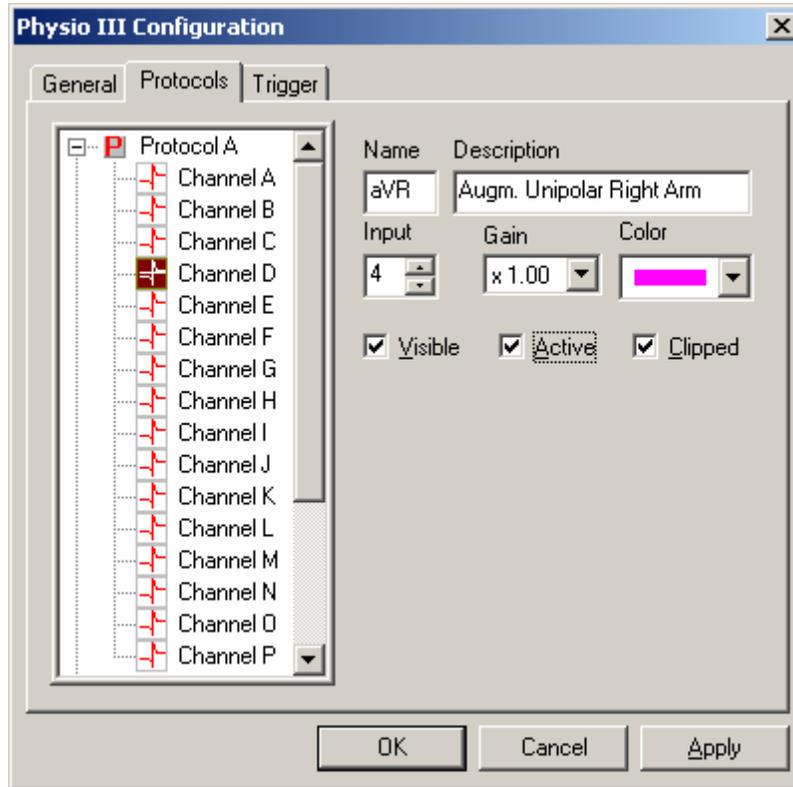

Figure 03

By clicking on any channel of the protocol submenu, one can set up the following parameters related to the channel:

a) **"Name"**: assigns a name to the channel (e.g.: **aVR**). The typed name will identify the displayed channel and will appear on the Physio Scanner screen (**Figure 05**) and the record printout (**Figure 18**).

b) **"Description"**: describes the name assigned to the channel (e.g.: **Augmented Right Lead**).

c) **"Input"**: indicates the physical position at the system input (**this value must be equal** to the channel position in accordance with the letter (e.g.: A=1; B=2; C=3; ...J=10; P=16).

d) **"Gain"**: defines the signal gain.

e) **"Color"**: Assigns a color to the channel. Clicking this line will show the available color palette. The desired color is selected by clicking the corresponding option.

f) **"Visible":** determines if the channel will be shown or not.

f) "**Active":** determines if the channel will be active or inactive. When a channel is ACTIVE its amplitude can be changed with the general gain keys (x0.00, x1.00, x2.00, x4.00, x8.00 and x16.00) of the PHYSIO-28 **Control Panel**.
These keys do not work with INACTIVE channels. This operation mode is useful when it is necessary to produce a fast change in the amplitude of the intracavitary signals only; in such a case the ECG channels should be kept inactive.

h) "**Clipped":** the signal in a clipped channel will never invade the screen strips assigned to the neighboring upper and lower channels, regardless of its amplitude (signal peaks are clipped). The signal of a channel **without CLIPPING** could superimpose other channel signals when the channel gain is increased.

After selecting the required configuration it is necessary to click on APPLY.

Finally, it is necessary to click on OK to confirm or CANCEL to quit the Physio Configuration module.

NOTE: Take into account that the selected configuration is the one present at the beginning of the scanning procedure. During the EP study it is possible to perform any change in the parameters. These modifications will affect the study in progress, but will not affect the start-up configuration of the next study.

3. PHYSIO SCANNER

This is the main program for performing the electrophysiologic study.

3.1. Physio Scanner Start and Stop

To Begin:

a) Turn on the computer. After automatic booting, the Windows screen "DESK", will appear with all the control icons
b) Double-Click on "**PHYSIO III SCANNER"**. The following screen will appear:

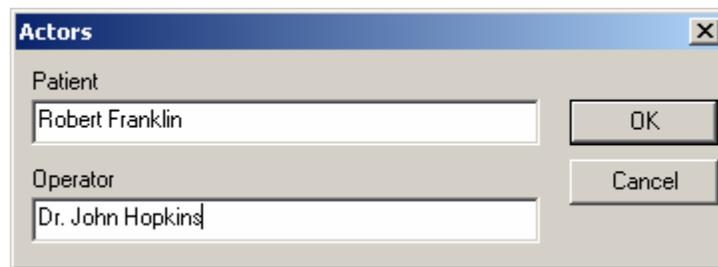**Figure 04**

c) Click on the upper line and type the patient's name.
d) Click on the lower line (OPERATOR) (moving between lines and options is also possible with the ¨TAB¨ key) and type the physician's name.
e) Press ENTER or click on OK to open the Scanning (monitoring) Screen shown on **Figure 05**.
f) Click the button ▶ on the "**Scanning Control**" bar [(d) in **Figure 06**] to begin the study.

To End:
After finishing the EP Study,
a) Click on the SCAN button in the **Option Menu** [(g) in **Figure 06**] and then click on the STOP button. Click on YES to answer the question and then press Accept**.**
b) Click on the Icon with "diskette shape" in the **Record Control** bar [(f) in **Figure 06**]).
c) Type the patient's name.
d) Finally, press the "SAVE" button. NOTE: this process lasts several minutes, depending on the length of the study stored.
e) Click on OK .
f) To quit the PHYSIO SCANNER program after performing the former procedure click on the X button on the upper right corner of the screen as done in any Windows program. A screen asking "**Save the Changes?**" will appear.
g) Click on YES to save the changes and then click on OK .

3.2. Screen Tools
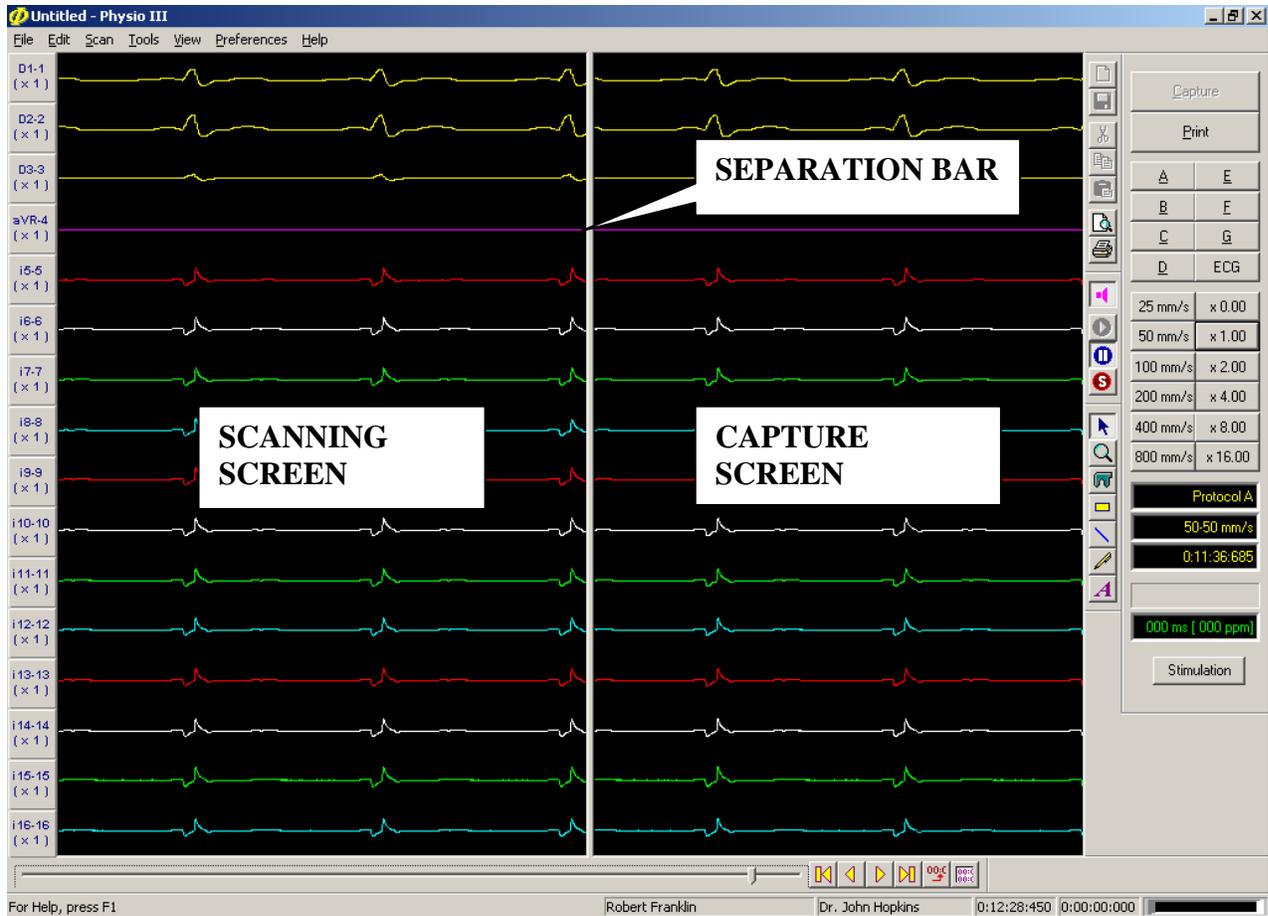
Figure 05

SCANNING SCREEN (left frame):
> Displays signals in Real-Time.

CAPTURE SCREEN (right frame):
> Captures or freezes images displayed on the scanning screen.

SEPARATION BAR:
> This bar Splits the screen into two frames (scanning and capture). The size of both screens can be modified by dragging the Separation Bar with the mouse (clicking on the bar with the left mouse button and moving the mouse while keeping the key pressed).

IMPORTANT: do NOT move the separation bar to the rightmost position (no capture screen); keep at least a narrow capture screen.

The controls available during the EP study are arranged in the following way:
a) *CONTROL PANEL*
b) *POSITION Control*
c) *CHANNEL Control*
d) *SCANNING Control*
e) *TOOL Selection*
f) *RECORD Control*
g) *OPTION Menu*
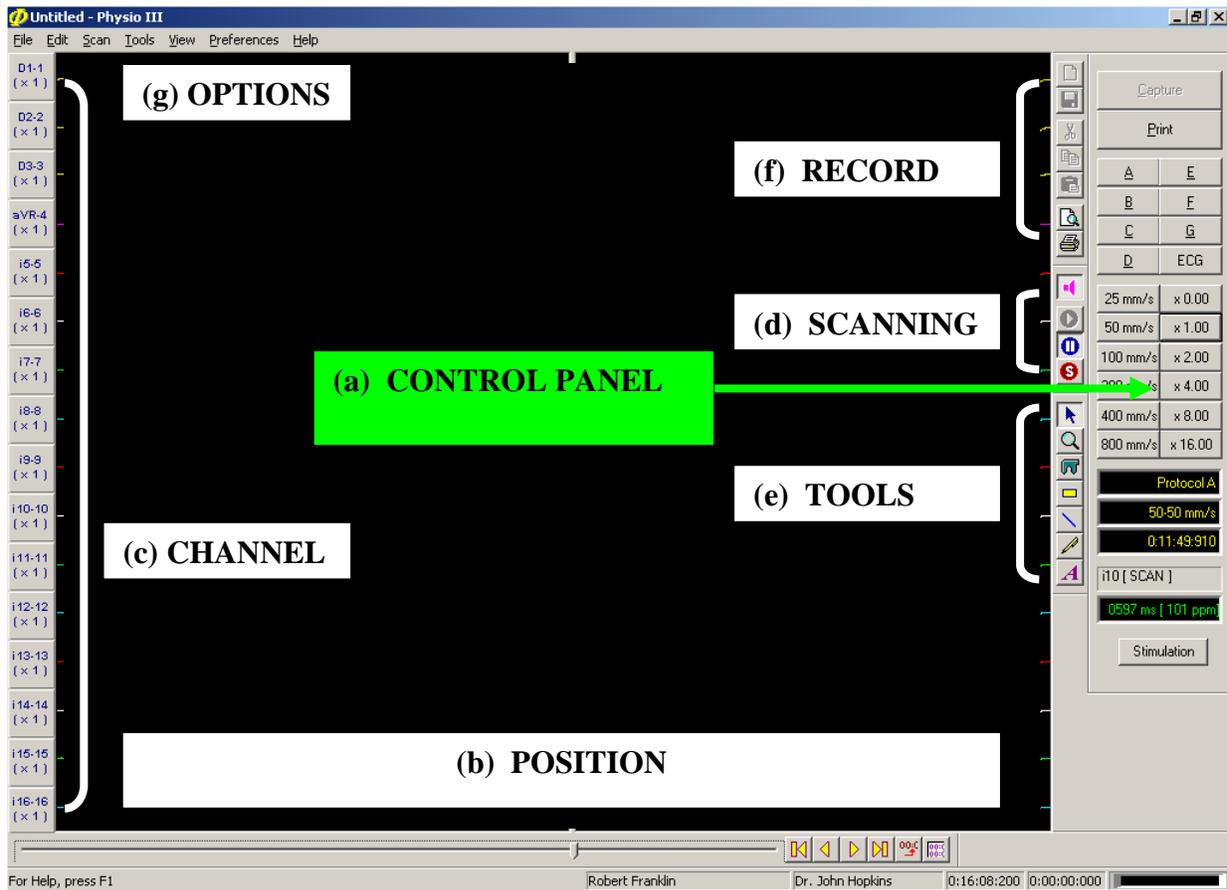
Figure 06

Process Indicators

Figure 07

3.3 Control Panel

Transfer the image from scanning screen to capture screen

Initiate Printing

Preconfigured Protocols

Speed Selectors in both screens

Gain Selectors of Active Channels in both screens

Screen Protocol

Scanning Screen Speed

Identification

Capture Screen Speed

Trigger Channel

Capture Screen Time

RR or S1S1 Interval

Active Mode Indication

Stimulation Channel Slection

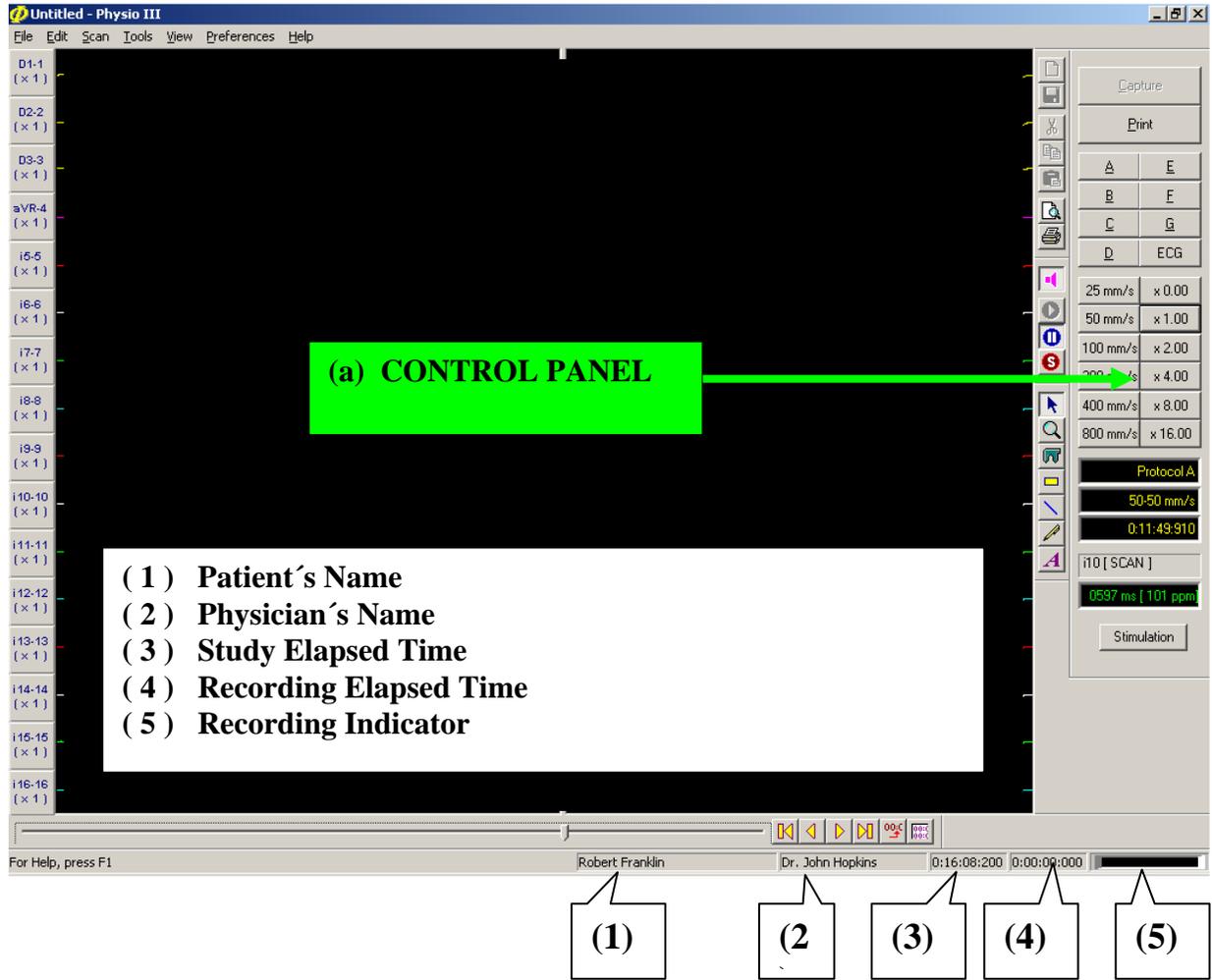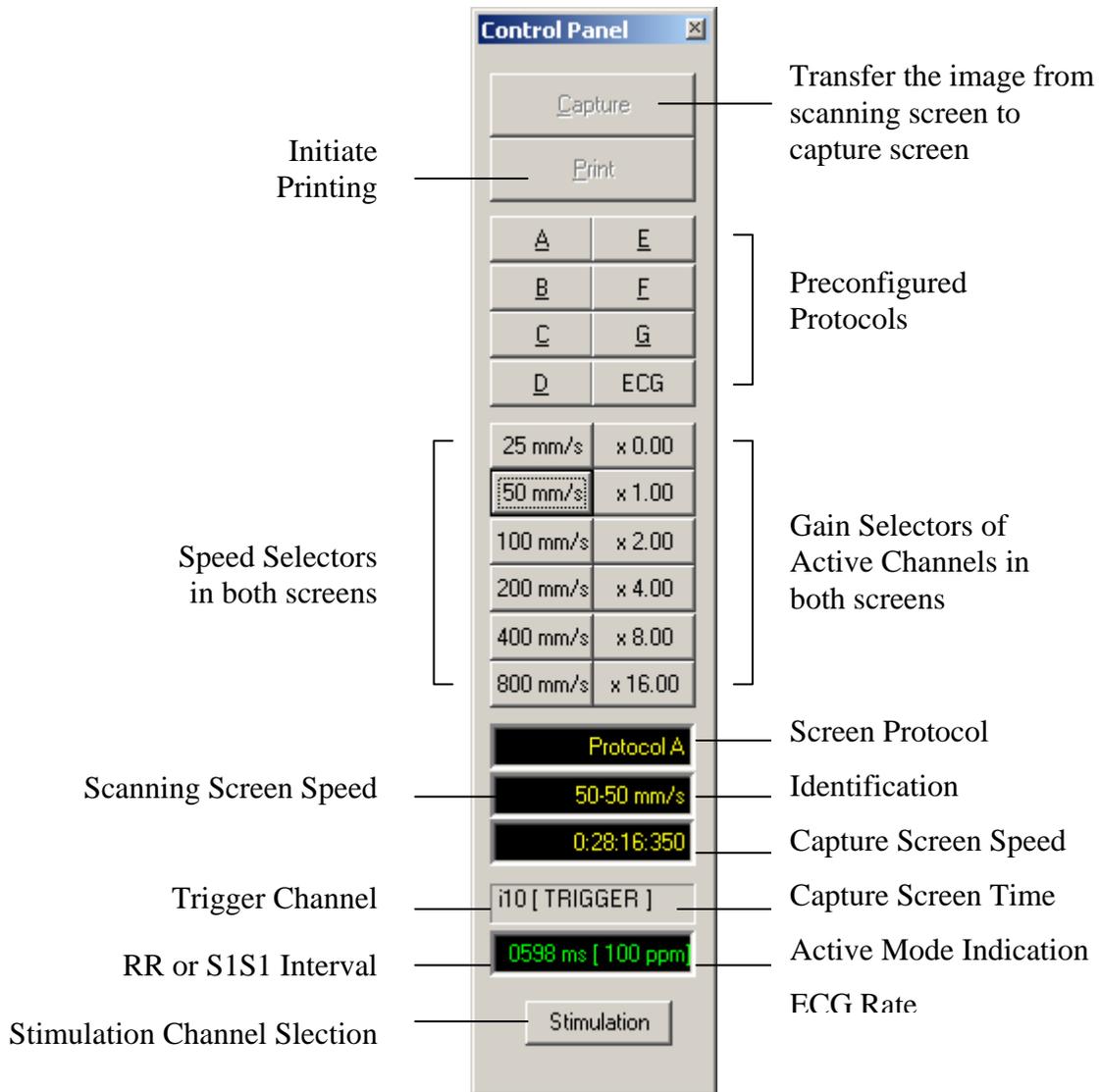ECG Rate

Figure 08

These commands control the format of both screens.

CAPTURE:
Clicking on this button transfers the image from the scanning screen to the capture screen.

PRINT:
Clicking on this button starts printing of the ECG signals shown on the display.
IMPORTANT: the scanning screen must be in PAUSE condition.

PROTOCOLS
There are 8 pre-configured protocols: A - B - C - D - E - F - G - H. Clicking on any letter will setup the corresponding protocol in both screens.

SPEED
25- 50- 100- 200- 400- 800 : Speed in mm/sec (both scanning and capture screens).

AMPLITUDE
0 – 1 – 2 – 4 – 8 – 16 : Gain of all ACTIVE channels.

DISPLAYS
The displays show:
(1) Selected protocol.
(2) Sweeping speed in both scanning and capture screens.
(3) Image time in "hours:minutes:seconds" format on the capture screen.
(4) Trigger channel and Active Mode (TRIGGER / SCAN).
(5) RR interval (in msec) and heart Rate (in bpm).

STIMULATION
Clicking on this button opens the Stimulation Channel Selection Window.
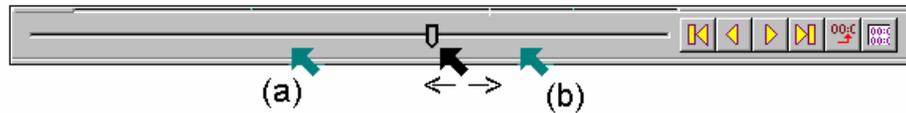
3.4 Time Position Control

Figure 09

The Time Position control in the **Capture Screen** allows easy access to a particular time of the whole study.

The key slides the **Capture Screen** through the study. The process consists of positioning the mouse arrow on the cursor, and further clicking (left button) and dragging the mouse. The screen time (data position in the study) appears in the lower window of the **CONTROL PANEL** (See **Figure 08**).

Controls available with a click (left button) of the mouse:
- At the left of the cursor: moves time position backward 4 seconds (a).
- At the right of the cursor: moves time position forward 4 seconds (b).
- ⏮ : Moves to the beginning of the study.
- ⏭ : Moves to the end of the study.
- ◀ : Moves backward 250 msec.
- ▶ : Moves forward 250 msec.
- ⊞ : Opens the time/position window (See **Figure 10**)
- ▦ : Opens the capture window [CAPTURES] (See **Figure 11**)

The time/position and captures windows operation are explained below:

3.4.1. Time/Position Window

This window provides fast access to any point in time, or data position in the study by providing its corresponding hour, minute and second values. The signal data corresponding to the selected time is displayed on the Capture Screen. Furthermore, the user may move backward or forward using the above explained commands.

The Time/Position window is accessed by clicking the ⊞ button (see **Figure 10**).
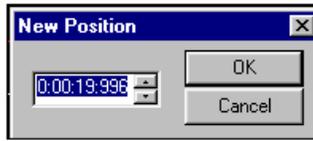
Figure 10

IMPORTANT: enter the time/position value properly in accordance with the fields assigned

HOUR : **MINUTES** : **SECONDS** : **MILLISECONDS**			
one digit	two digits	two digits	three digits

The entered time data is validated by pressing OK. The Capture Screen will show the signals present at the selected time.

3.4.2. Image Capture Window

This window allows the capture of the image time for further fast retrieval during the study. The captured image time/position will be stored and can be retrieved later during study review with the PHYSIO III REVIEW module.

To Capture an image with the "CAPTURE" option:

IMPORTANT: to capture an image the save mode must be enabled. This is done by pressing the **S** button in the Scanning Control bar [see (d) in **Figure 06**].

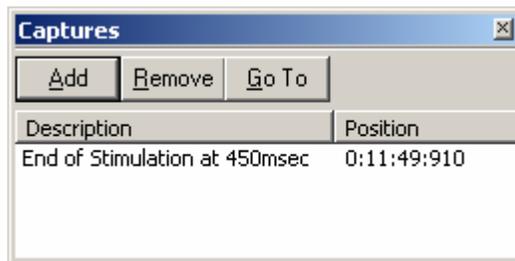• Click on ▦ (Figure 09). The following screen will appear:

Figure 11

• Click on Add. It will show the **New Capture Window** with an empty Description Field.

- Type text to label the selected image. For instance:

Figure 12

- Confirm the entered text by pressing OK. This adds the labeled image to the capture list. All the captured images will be easily accessed by means of the "Review Procedure" described below.

The capture list is automatically stored upon finishing the study (save mode active). Therefore, the labeled images are accessed in the PHYSIO REVIEW module with the same procedure.

To Find the labeled images:

- Click on the button ⊞ (**Figure 09**). The capture window will appear.
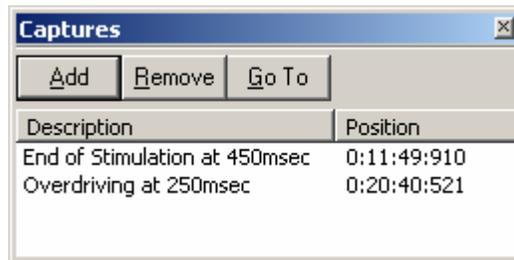
- Select the label corresponding to the captured image to display.
- Click on GO TO. The Capture Screen will show the image selected.

Procedure to delete captured images from the capture list:

1) Click on the button ⊞ (**Figure 09**). The capture window (**Figure 11**) will appear.
2) Select the label corresponding to the captured image to delete.
3) Click on REMOVE. The label and corresponding time/position image is deleted from the list.

3.5. Channel Control

The channel control bar is on the left side of the Scanning Screen. For each channel, the space indicated by the a, b, and c labels correspond to:
(a) Channel Signal Identification.
(b) Channel Order within the set of the 16 channels that could be displayed simultaneously.
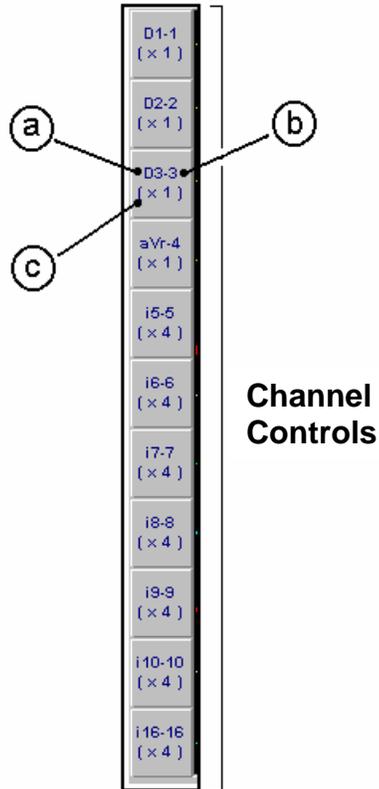(c) Channel Gain (amplitude).

Figure 13

Every channel has an <u>independent</u> setup format. Clicking on any box of the channel control bar will open the CHANNEL CONTROL window (**Figure 14**) corresponding to the selected channel.

The CHANNEL CONTROL window has the following commands and options:

(1) Channel:
- Clicking on this line will display all the available channels in the current protocol
- Clicking on one of these channels will select it for format modification. The selected channel will appear in the corresponding box

(2) TRIGGER:
- Enables the TRIGGER Scanning Mode. See the corresponding section in the manual.

(4) Color:
- Changes the channel color.
- Clicking on this box will show the color palette.

(5) Gain:
- Click on the cursor and drag right/left to increase/decrease the gain respectively.
- The updated gain is also shown in digital format.

(6) ATTRIBUTES

VISIBLE:
- Click on this option to make the channel appear or disappear on the screen. The remaining channels are repositioned automatically.
- **<u>IMPORTANT</u>: even though the channel is NOT visible, its corresponding signal is still being processed. In other words, the skipped channel representation can be recovered by making the channel visible and moving backwards in the study.**

ACTIVE:
- <u>Active</u>:   the channel is sensitive to the overall gain of the CONTROL PANEL.
- <u>Inactive</u>:   the channel is not sensitive to the overall gain of the CONTROL PANEL.

CLIPPED:
- <u>Yes</u>: signal peaks will never invade screen strips assigned to neighbor channels.
- <u>No</u>: signal peaks may invade screen strips assigned to neighbor channels, depending on the peak amplitude.
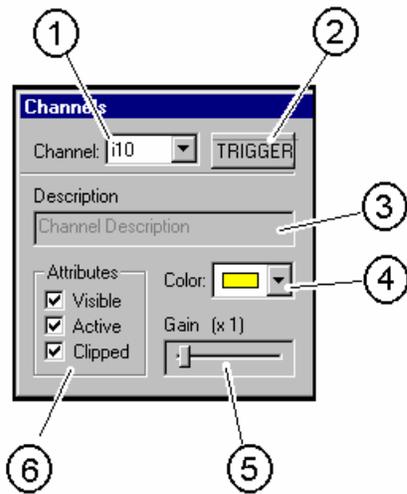
(1) Channel selected for modification

(2) TRIGGER function enabling/disabling

(3) Channel Description assigned during "PHYSIO CONFIGURATION"

(4) Channel Color selection

(5) Channel Gain (Signal Amplitude) selection

(6) Channel Attributes setup

Figure 14

3.6. Scanning Control

This bar placed at the right of the screen (see **Figure 6**) provides de following controls:
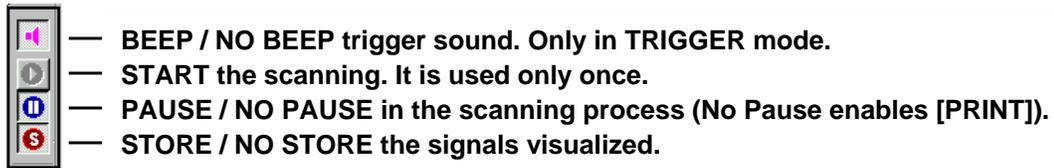
— **BEEP / NO BEEP trigger sound. Only in TRIGGER mode.**
— **START the scanning. It is used only once.**
— **PAUSE / NO PAUSE in the scanning process (No Pause enables [PRINT]).**
— **STORE / NO STORE the signals visualized.**

Figure 15

SAVE / NO SAVE:

If the $\boxed{S}$ button is depressed, the information is stored in the hard disk and the corresponding red indicator flashes (indicator (5) of **Figure 07**).

Every time that the $\boxed{S}$ button is clicked, the cumulated recording time is updated. This value is displayed by the indicator (4) of **figure 07**.

IMPORTANT: We recommended saving only the parts of the study that are of interest to the physician.. The maximum recording time is 8 hours. Every stored hour of data consumes 120 Mbytes of hard disk memory space. If the storage option is not activated, the physician can nevertheless retrieve any image of the study by means of the position control (Figure 09) while the study is running. After finishing the session, only the stored data is retrievable.

3.7. Tool Icons

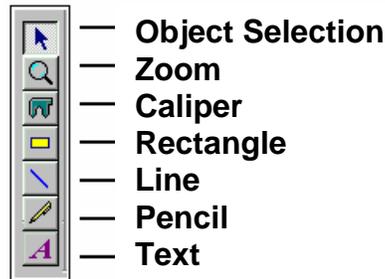The following tools are available upon clicking on the corresponding buttons:

— Object Selection
— Zoom
— Caliper
— Rectangle
— Line
— Pencil
— Text

Figure 16

⬚ SELECT SCREEN/OBJECT TO ACTIVATE/MODIFY
- Click on ⬚ .
- Place the arrow on the object to control and click with the mouse right button.
- Place the arrow on the tool to use and click with the mouse left button.
- Place the arrow on the object to work with.

⬚ ZOOM
This option changes the sweeping speed on the Capture Screen only.
- Click on ⬚ .
- Place the mouse arrow on the Scanning Screen (the arrow turns into a magnifier).
- Click with the mouse left button to increase the sweeping speed of the Capture Screen.
- Click with the mouse right button to decrease the sweeping speed of the Capture Screen.
The speed of the Scanning Screen does NOT change.

⬚ CALIPER (see CALIPER section)

⬚ RECTANGLE
- Click on ⬚ .
- Place the mouse arrow on either screen. The arrow will turn into ⬚ .
- Click the mouse left button. Draw the rectangle figure and release the mouse button.

⬚ STRAIGHT LINES
- Click on ⬚ .
- Place the mouse arrow on either screen. The arrow will turn into a straight line.
- Click the mouse left button. Draw the line and release the mouse button.

☑ PENCIL
- Click on ☑ .
- Place the mouse arrow on either screen. The arrow will turn into a pencil.
- Click the mouse left button. Draw the line and release the mouse button.

Ⓐ TEXT
This option allows the insertion of text.
- Click on Ⓐ .
- Place the mouse arrow on either screen. The arrow will turn into a letter "A".
- Click the mouse left button and drag it to depict a rectangular shape.
- Release the mouse button. A Text window will appear. Type the desired text.
- Click on OK when finished.

3.8. Recording Control

The following icons activate the corresponding functions.
NOTE: The operator should be familiar with the basic MS Windows commands in order to achieve the best performance.


```
(C)  ┌─ — Open New Program
     ├─ — Store Study
     ├─ — Cut Selected Object
     ├─ — Copy Selected Object
     ├─ — Paste Cut/Selected Object
(a)  ├─ — Print Preview
(b)  └─ — Print
```
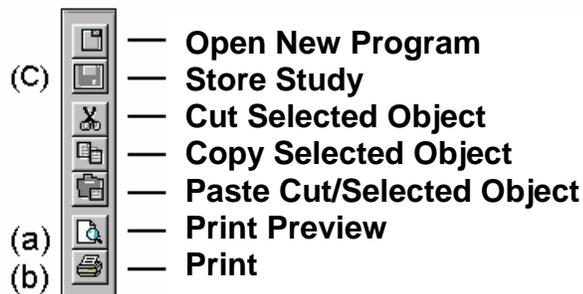
Figure 17

(a) PRINT PREVIEW
(b) PRINT during scanning it is possible to print the image with this button. To do this, the user must PAUSE the scanning (**Figure 15**).

REMINDER: Data is never lost regardless of the process being executed.

Page Preview before printing

After clicking on the item "PRINT PREVIEW" (item (a) in the **Figure 17**), the screen will show the page to be printed:
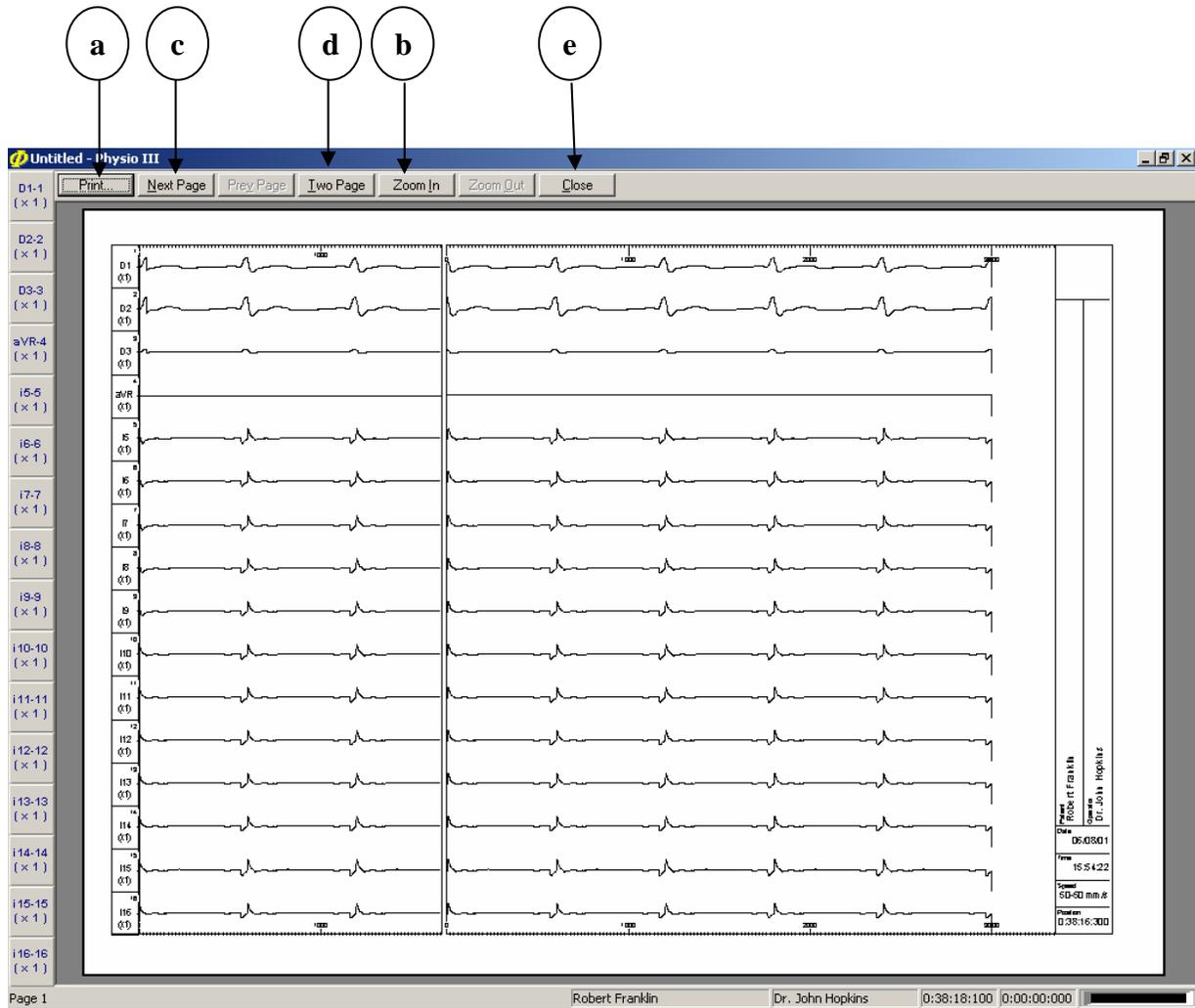
Figure 18

(a) Press Print to **Print** the screen shown.
(b) Press Zoom In to magnify the image. The mouse arrow will turn into a magnifier icon. Point the area to magnify. Press ZOOM again to disable this function.
(c) When Zoom is active the image occupies more than one screen. Press Next Page to switch between screen pages.
(d) Press Two Pages to visualize two pages simultaneously.
(e) Press Close to close the Print Preview Screen.

3.9. Caliper

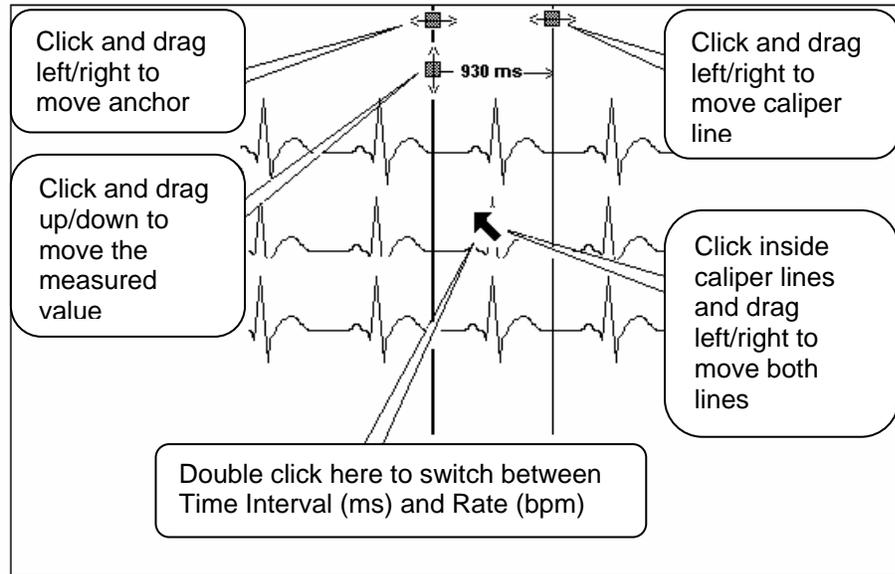**Figure 19**

It is possible to place an unlimited number of CALIPERS on both screens.

Procedure to activate the calipers:
- Press ⬉.
- Place the mouse arrow on either screen and click the mouse right button.
- Place the mouse arrow on 🖩 and click the mouse left button.
- Place the mouse arrow on the screen. The arrow will turn into a 🖩.

To measure:
Mouse pointer is 🖩 .
- Click on the first measuring point and drag (keeping the mouse button pressed) the mouse to the second measuring point. Release the mouse button.

Note that the digital value is updated while the mouse is moving. Moving to the left will produce negative values.

To add another caliper:
The tool 🖩 remains active after placing the caliper. To place another caliper, proceed as explained previously.

To delete calipers:

- Point the Caliper to delete with the tool ◤
- Click ⊠ .
- If there is only one Caliper, it will be erased.
- If there are more than one Calipers, a box "asking to erase all the Calipers" will appear. The answer:
    - "YES" will delete all the Calipers in the screen.
    - "NO" will erase only the pointed Caliper.

To change the caliper color:

Assuming that the caliper has been pointed (small squares at the top of the caliper lines)

- Click on VIEW of the OPTION Menu (**Figure 5**).
- Click on COLORS. A color dialog box will appear (**Figure 20**).
- Click **the mouse right button** on the selected color.

Figure 20

NOTE: A cut Caliper can be pasted on the screen using the corresponding icons described in the Windows Operating System. Refer to the **Figure 17** (Recording Control). Likewise, it can be copied and pasted on the same window or on another ..

3.10. Trigger

To activate the Trigger Mode:

- Select the trigger source channel by clicking the channel box in the **Channel Control** (see **Figure 13**). The following dialog window will appear:
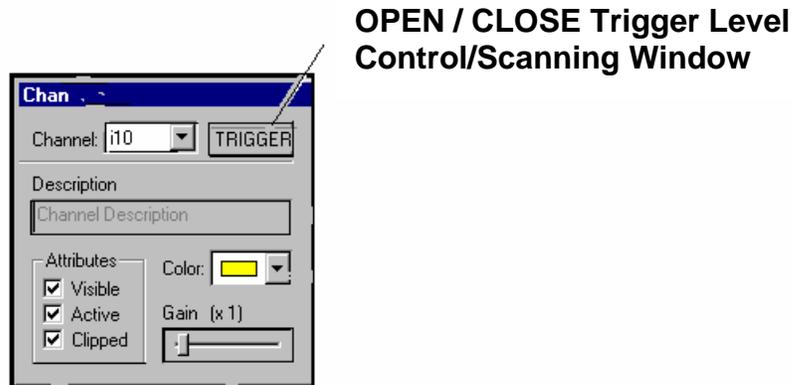

OPEN / CLOSE Trigger Level Control/Scanning Window

Figure 21

- Click on [TRIGGER]. The following dialog window will appear:
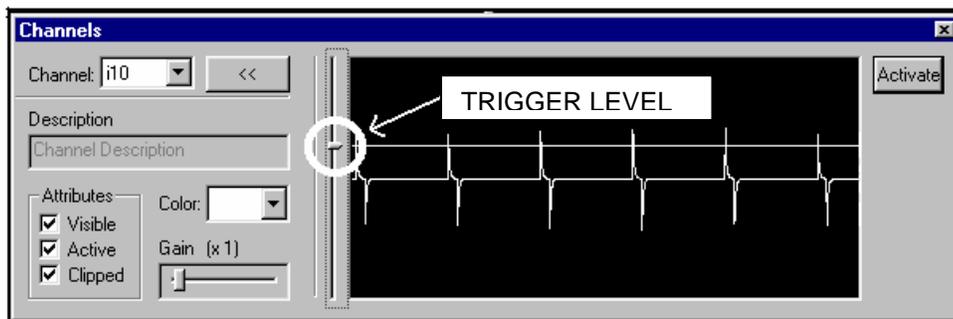
TRIGGER LEVEL

Figure 22

- Place the mouse arrow on the TRIGGER LEVEL cursor. Click and drag the mouse vertically so that the horizontal line crosses the peaks of the signal with which to synchronize.
- Click on the [ACTIVATE] button located at upper-right portion of the window (**Figure 22**).
- Move the mouse cursor to the Option Menu (**Figure 5**) and click on [VIEW] to access the VIEW options.
- Click on option [TRIGGER]. The monitoring will start under the TRIGGER mode, synchronizing the signal at the beginning of the scanning screen.

- The time interval between trigger events and the corresponding rate are displayed at the bottom of the CONTROL PANEL (**Figure 8**).
- After finishing every sweep on the scanning screen, the depicted screen is transferred to the capture screen.
- To perform measurements it is necessary to PAUSE the scanning screen beforehand.
- Every trigger event elicits an acoustic "BEEP". The BEEP generation is enabled/disabled by clicking on the "loudspeaker" button of the Scanning Control bar (see **Figure 15**). The BEEP only operates in TRIGGER mode.

To resume to the SCAN mode (No synchronization)

- Move the mouse arrow to the Option Menu (**Figure 5**) and click on [VIEW]. Several options will be presented.
- Click on [SCAN] to disable signal synchronization.

3.11. Selection of Stimulation Channel

The Physio-Stim electrophysiologic stimulator can be internally connected to any intracavitary channel. This is performed in the following way:

- Click on the STIMULATION button placed below the CONTROL PANEL. The Stimulation Channel Selection window will be opened.

Figure 23

- Click on the ENABLE box to enable the stimulation channel.

- Select the stimulation channel from the list by clicking on the desired channel.
- Quit the Stimulation Channel Selection window. Once the user exits this window, the Physio-Stim electrical terminals will be internally connected to the jacks (+ and -) of the connection box corresponding to the selected channel.

The Physio-Stim is now ready to deliver pacing or extrastimuli to the patient during the EP study.

3.12. Cardiac Recovery Time Measurement

- Connect the Physio-Stim to a visible channel. The stimulator pulse looks large and distorted due to its large amplitude. Select the channel gain so that when stimulation pulses are not present, the intra-cardiac signal appears clearly but with a much smaller amplitude.
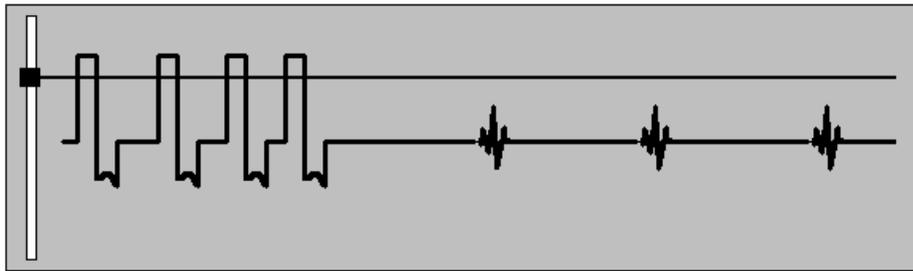- Setup the trigger level to cross the stimulating pulses, but not the intra-cardiac signal.

Figure 24

This procedure will ensure that the scanning screen depicted after a stimulation burst will be transferred to the Capture Screen. The image on the Capture Screen will be frozen until the next stimulation pulse, which triggers the scanning. Pressing PAUSE after a stimulation burst is recommended, in order to perform measurements.

3.13. Auxiliary Monitor Screen
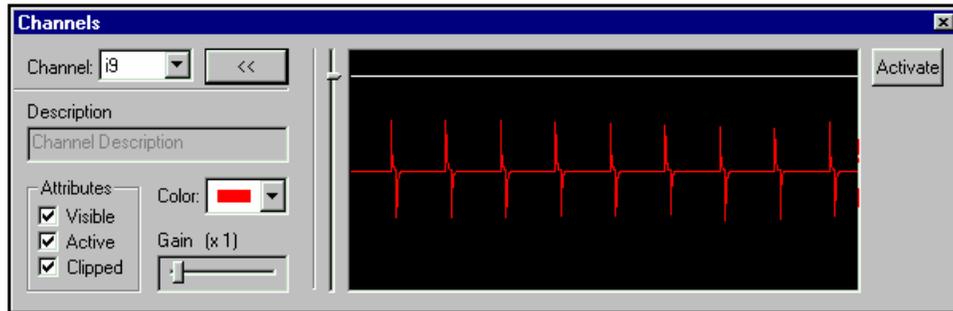
Figure 25

The TRIGGER screen described above can also serve as an auxiliary monitor screen. The characteristics of this screen are the following:

- Available in SCAN or TRIGGER mode.
- The signal always runs at 25 mm/sec even in the case of frozen Scanning and Capture screens.
- It is useful for continuously monitoring the cardiac rhythm while other processes are in progress.
- Any channel may be displayed independently of the channel selected for Trigger Synchronization.
- The displayed signal becomes synchronized by clicking on [ACTIVATE]

4. PHYSIO REVIEW

The Physio-Review module provides the tools for reviewing and analyzing the stored studies.

To Begin:

- Turn on the computer and access the Windows "DESK" screen.
- Click on "PHYSIO REVIEW". The following screen will appear.
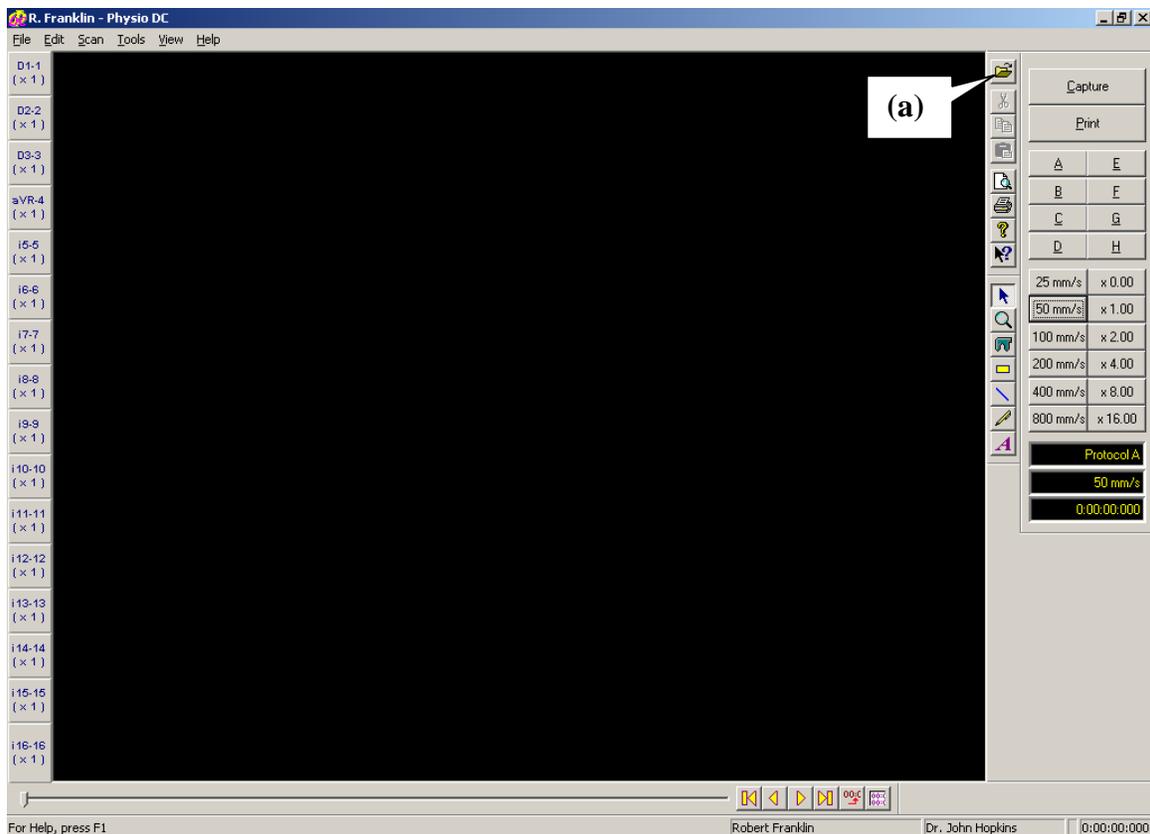
Figure 26

- Click on item (a) of **Figure 26** to access a box entitled "PATIENTS" that has the list of all stored studies.
- Double click on the study you are interested in. The following screen will be opened:

Figure 27

- **The PHYSIO REVIEW module utilizes the same commands as PHYSIO SCANNER commands explained before. The only difference is that the former lacks the Separation Bar.**

To End:

a) Press the ⊠ button on the upper right side of **Figure 27**. A dialog box appears asking "**Save Changes?**"
b) Press "NO".

5. KEY ASSIGNMENT

When the Scanning Screen is open some keyboard keys have the special functions described below. If another window is opened the key assignment may be different.

$\boxed{>}$ (RIGHT Arrow): Increases the speed of the Scanning and Capture Screens.

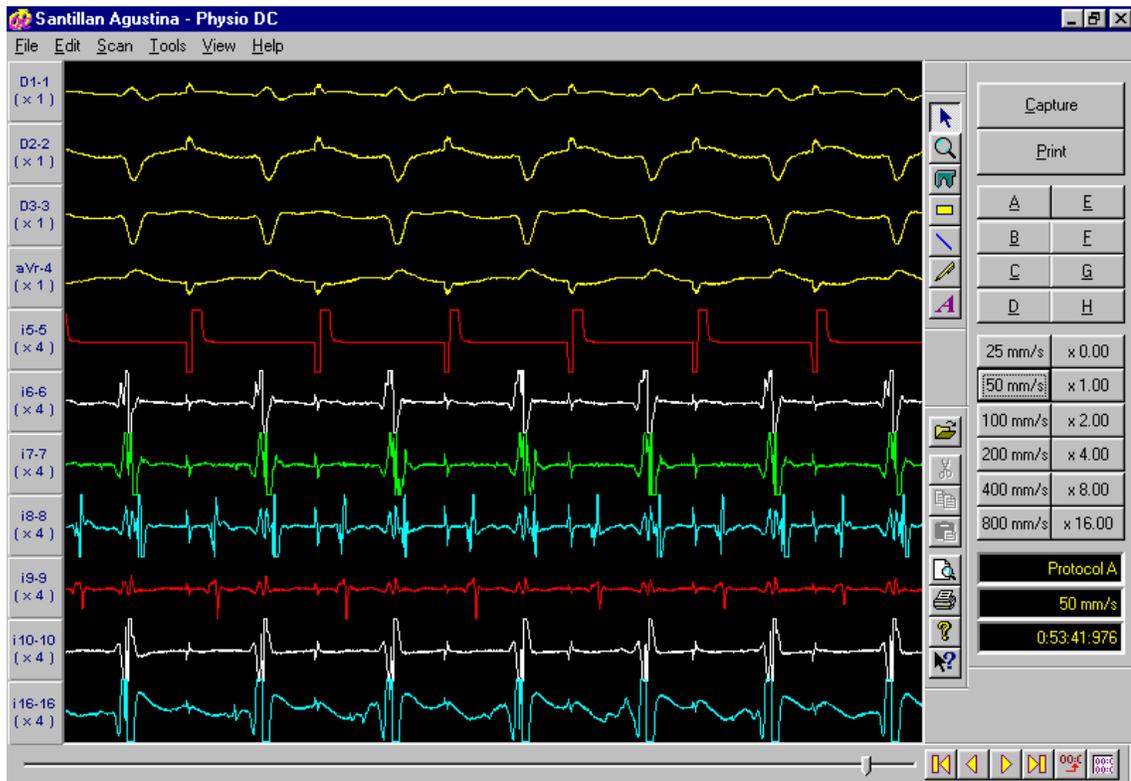$\boxed{<}$ (LEFT Arrow): Decreases the speed in both screens.

$\boxed{\uparrow}$ (UP Arrow): Increases the amplitude of all channels.

$\boxed{\downarrow}$ (DOWN Arrow): Decreases the amplitude of all channels.

$\boxed{\text{HOME}}$: Moves the Capture Screen to the beginning of the study.

$\boxed{\text{END}}$: Moves the Capture Screen to the end of the study.

$\boxed{\text{PAGE UP}}$: Moves the Capture Screen 250 msec backwards.

$\boxed{\text{PAGE DOWN}}$: Moves the Capture Screen 250 msec forward.

$\boxed{\text{SPACE BAR}}$: Freezes / Unfreezes the signals on the Scanning Screen.

$\boxed{\text{Control} + \text{B}}$: Enables / Disables the acoustic Trigger "BEEP".

$\boxed{\text{Control} + \text{T}}$: Enables / Disables the TRIGGER mode.

$\boxed{\text{PAUSE}}$: Transfers the image from the Scanning Screen to the Capture Screen.

6. INTERFACE MODULE–CHANNEL SELECTION

The PHYSIO-28 Polygraph has 28 preamplifier channels (12 Surface ECG channels and 16 Intra-cardiac Channels), but only 16 channels can be acquired and visualized. All the 28 signal preamplifiers are placed in the Interface Module, which shares the same cabinet with the Physio-Stim EP Stimulator. The hardware interconnection diagram is shown in the **Figure 29**.

The physician first has to configure the protocol in order to select those channels required for the EP study. For instance, the physician may configure the following three protocols from the available eight protocols:

(A):   **4 ECG** (D1, D2, D3, aVR)   + **12 INTRACARDIAC** (IC-1 to IC-12)
(B):   **8 ECG** (D1-3, aVR, aVF, aVL, V1, V5)   + **8 INTRACARDIAC** (IC-9 to IC-16)
(C):   **12 ECG** (bipolar, augmented, precordial)   + **4 INTRACARDIAC** (IC-5 to IC-8)

The position of the channels on the screen could be the following:
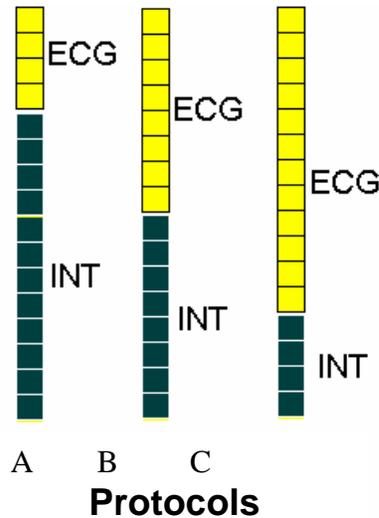

A   B   C
Protocols

Figure 28

IMPORTANT:
Only the selected channels are processed and stored. The channels not present in the protocol are NOT acquired and can NOT be retrieved.
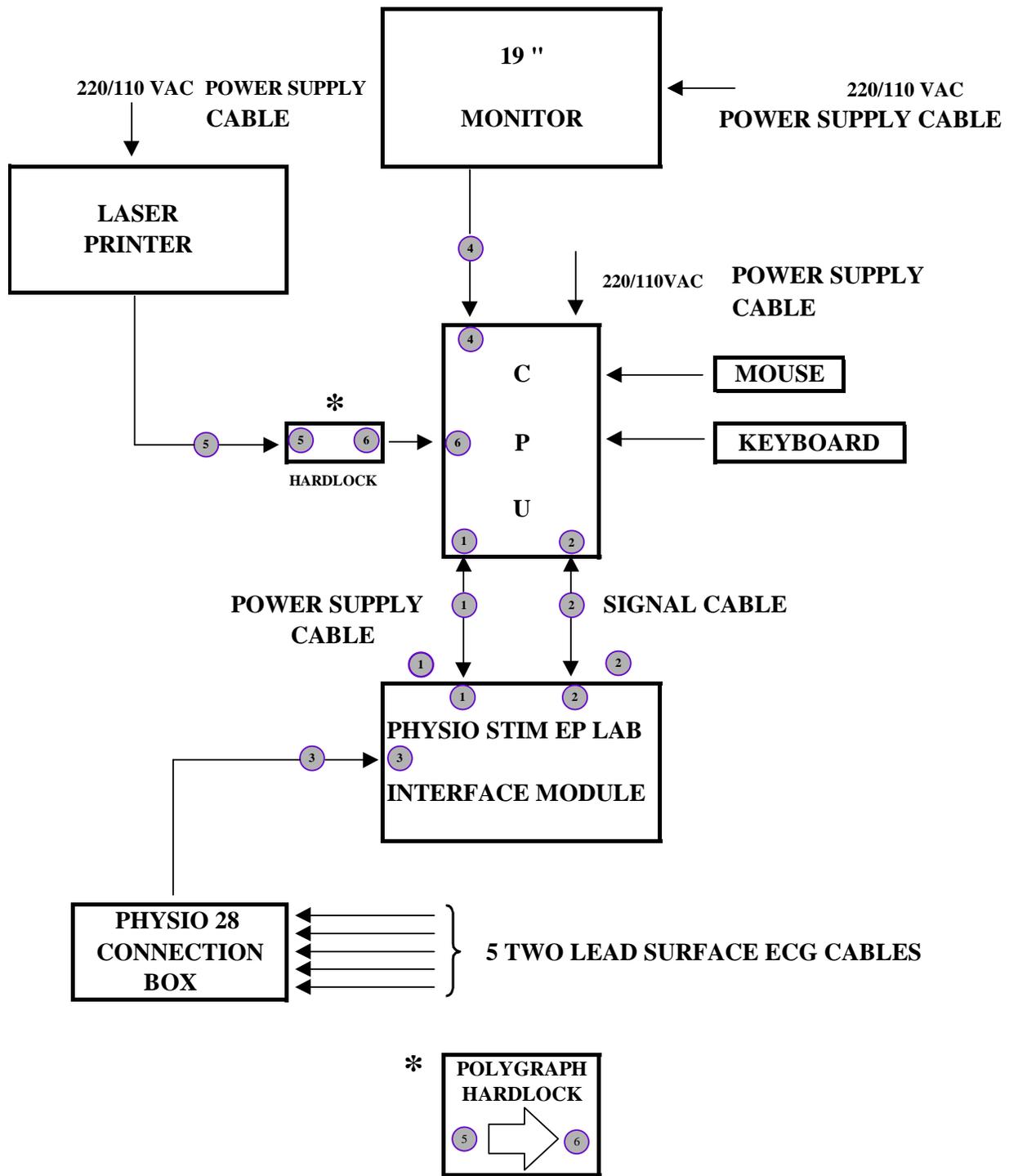

HARDWARE INTERCONNECTION DIAGRAM

Figure 29

7. TECHNICAL SPECIFICATIONS

PHYSIO–28 High Resolution Polygraph for Cardiac Electrophysiology

GENERAL DESCRIPTION

The GALIX PHYSIO-28 is a device developed with the latest Hardware and Software technologies to perform comprehensive cardiac electrophysiologic studies.

The system runs under the Windows 2000 operating system. This platform provides robustness and safety to all the control processes. It also supports concurrent tasks such as, protocol selection, report generation, graphic representations, review of previous studies, during the EP study.

The whole study can be stored for further retrieval. The study review is fully functional, including the visualization of channels not present on the screen during the study. The physician can also review other patient studies stored in the database of the system.

The PHYSIO-28 has a robust text editor to generate and print reports at will. In addition, the physician can generate graphics and drawings, and optimize the quality of the images for slide preparation.

Since the system comes with the Microsoft Windows 2000 operating system, the operator can make use of all the features associated with this software environment.

The PHYSIO-28 system comprises:

- **CENTRAL PROCESSING UNIT (CPU)**
  - Personal Computer (Pentium III, with Hard Disk, Diskette Driver and Parallel Port)
  - SVGA Color Monitor
  - Keyboard + Mouse
  - Laser Printer (600 dpi – 8 ppm)
- **INTERFACE MODULE / PHYSIO-STIM:**
  - Surface ECG Module: 12 surface ECG channels with all standard leads (D1, D2, D3, aVF, aVL, aVR, V1, V2, V3, V4, V5, V6)
  - Intra-cardiac Module: 16 Intra-cardiac Channels (I1 to I16)
  - Physio-Stim: cardiac electrophysiologic stimulator with up to three extrastimuli
- **CONNECTION BOX**
  - Catheters: 32 female terminals for 2mm-pin connectors
  - Surface ECG: Five 2-wire conductor connectors
                    (RL, LL ; RA, LA ; V1, V2 ; V3, V4 ; V5, V6)

SOFTWARE FEATURES:

- Channels:
  - 28 channels available for monitoring
    (12 standard Surface ECG Leads and 16 Intra-cardiac Channels)
  - 16 channels depicted simultaneously on screen, with channel selection through the keyboard.
- Windows:
  - 2 Monitoring windows available (Real Time + Capture)
  - In one window the screen can be frozen in order to perform measurements and comparisons, while in the remaining screen, 16 channels are running continuously in real time.
  - Both windows can be frozen and are of variable size.
  - During the study, one of the windows can be used to review the whole study while the actual ECG is displayed in the other one.
- Visualization:
  - The color and the amplitude scale of each channel can be changed independently, and the "clip function" can be enabled/disabled without freezing the screen.
  - The scanning speed ranges from 25 to 800 mm/sec.
  - It is possible to superimpose measurement values and texts, and add or remove channels without freezing the screen.
- Storage:
  - Up to eight hours of ECG data can be stored.
  - Time marks can be inserted to speed up a particular search of ECG complex during the study review.
- Calipers:
  - Calipers are used to measure time intervals with 1msec resolution. The heart rate measured is shown in beats per minute.
  - Calipers are unlimited and each one can be shifted and copied from one window to the other.
- Protocols:
  - There are 8 pre-configured protocols, each one including: number of channels, color, scan speed and amplitude of each channel previously defined.
  - The operator can choose the channels presented at any time.
- Printing:
  - The contents of both windows may be printed at any time. The printing delay of a frozen screen is less than 3 sec.
- Triggering System:
  - Trigger performed by any channel and synchronized with the stimulator.
  - Automatic visualization of the recovery time.
  - Auxiliary dynamic window to control the cardiac rhythm in any channel when both screens are frozen.

TECHNICAL SPECIFICATIONS:

SCREEEN:
Monitor: SVGA Color, 19" (Optional: 21")
Resolution: 1268 x 1024 / 1024 x 768 pixels, Non-interlaced, Color: 16 bits

PRINTER:
Method: LASER printing
Speed :   3 sec delay time (typical)
Resolution: 600 dpi (Optional: 1200 dpi)

COMPUTER:
Processor: PENTIUM III 700 MHz (or better)
Hard Drive: 30 Gbytes (o better)
RAM: 128 Mb
ACCESORIES: Keyboard and Mouse
BACK-UP: Massive Storage with CD Recorder

POWER SUPPLY:
Mains: 220V-50Hz / 110V-60Hz

VISUALIZATION:
Available channels: 28 (maximum)
Visible channels: 16 (maximum)
Visible Windows: 2 (Real-Time + Capture)
Caliper number: unlimited
Resolution
    Vertical: 12 bits per channel
    Horizontal: 1 msec
    caliper: 1 msec
    ECG Frequency: 1 bpm
Presentation Speed: 25 - 800 mm/sec
Vertical Scale: 1 – 32mm/mV

ECG MODULE:

Channels: 12 Leads (D1, D2, D3, aVR, aVL, aVF, V1 - V6)
Bandwidth: 001 - 100 Hz
Input Impedance: 10 Mohm @ 30 Hz
Notch Filter: 50Hz / 60Hz Central Frequency

INTRACARDIAC MODULE

Channels: 16 bipolar
Bandwidth: 10 - 400 Hz
Input Impedance: 10 Mohm @ 30 Hz

PRESENTATION:

The PHYSIO-28 system includes the following parts:
- **1 – CPU**
- **1 – Monitor**
- **1 – Keyboard**
- **1 – Optical mouse**
- **1 – Laser Printer**
- **1 – Interface Module Signal Cable**
- **1 – Interface Module Power Supply Cable**
- **1 – Hardlock**
- **1 – Physio Stim / Interface Module**
- **1 – Physio 28 Connection Box**
- **5 -Two Lead Surface ECG Patient Cables.**
- **1 --I.V. Mounting Pole for Connection Box**
- **1 – Operation Manual**
- **1 – CD with Installation Software and Documentation**

OPTIONS:
- 21" High Resolution Color Monitor
- Monochromatic Laser, 1200 DPI, 17 pages per minute
- Transport Cart: robust wheels and special wire bundle connection for the polygraph
- Uninterruptible Power Supply (UPS) (to continue the study during power supply black-outs).
  <u>NOTE:</u> it is recommended to install an UPS if the mains are not supported by a general Power Supply Backup.

8. WARRANTY

Each GALIX PHYSIO-28 Polygraph for Electrophysiologic Studies is warranted against all manufacturing defects for a period of 12 months from date of delivery.

GALIX BIOMEDICAL INSTRUMENTATION warrants to the original purchaser that the PHYSIO-28 Polygraph, of its exclusive manufacture, does not present any defect which might impede its normal use.

The present warranty does not cover defects due to transport by whatever means, inappropriate operation, negligence, rough handling, servicing not authorized by GALIX, violent acts or accidental damage.

GALIX BIOMEDICAL INSTRUMENTATION shall not be liable for any damage or medical charge resulting from or caused by any failure or malfunction.

GALIX INSTRUMENTACION BIOMEDICA S.R.L. reserves the right to make improvements or to change specifications in its products at any time and without notice.