

ars-Efor

ECG STRESS TEST SYSTEM WITH TREADMILL

USER MANUAL

Rev. 4- May- 2021- With StressWin Pro V4.2.10

healthy innovation

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ORDER INFO	Order No
ars-EFOR ECG Stress Test System with	700130
ars-EFOR ECG Stress Test System Kit	700120
TM-Pro 2000 Treadmill	700180
ECG Patient Cable. clamp	600322

CAUTION
Read Instructions Carefully Before Use!



- This device is a stress test ECG system intended to be used with a personal PC that complies with the EN60950 standard. The device has the CE mark.
- There are no side effects of the device
- Treadmill comprises moving parts. Keep the children away while the moving parts are on
- Device is to be used only by/or under supervision of dedicated medical personnel who have been trained specifically in the ECG Stress Technique and in the evaluation of ECG data under stress.
- Make sure that ECG cable/electrodes and other parts of the system do not touch the surrounding conductors and ground in the environment.
- Only use the ECG cable and USB cable provided by the manufacturer to guarantee safe operation during defibrillator use.
- To avoid a possible explosion, do not use the electrocardiograph in the presence of flammable anesthetics
- Check if the device is properly grounded, please ask authorized technician.
- Do not use the device in dusty environment, please keep liquids and solvents away. Do not use solvents for cleaning this system and its accessories. Do not use high temperature or radiation sterilization techniques.
- Check that all cable connections are safe and secured before use
- The accuracy of the measurements made by the device is defined under normal and high quality signal acquisition conditions. If there are disturbances on the signals, the accuracy of the measurements can be affected. For such situations, the operator should interpret the signals using his/her experience on the view of the obtained ECG signals.
- Check the integrity of the system and its parts every day before use. Let the authorized technician inspect the device at least once a year for maintenance and calibration.
- This device is not suitable for direct cardiac applications.
- Please comply with national and international regulations in use of disposable materials.
- Proposed lifetime of the system and ECG card is 5 years. Manufacturing date is stated in the serial number, first part as XXYY shows the year of manufacture XX and the week of the year YY. Disposal of the device shall be made for each part separately by experts.
- If you are unsure that device is functioning properly, please contact our technical service via phone number, fax or e-mail. If there is not any signal or only a straight line on one of the channels or any lead contact warning on the screen, the device is inoperable.
- Device can be used safely in patients with pacemakers. Make sure external pacemaker and stimulator connections are at a sufficient distance from ECG electrodes. In case of ambiguity, contact Kardinero.
- Use only parts and accessories supplied with the device and available through Kardinero. (ECG patient cables order no:600322) The use of accessories other than those specified may result in degraded performance or unsafe use of this device.
- Device is not intended for home use or patient self-use.
- This device is not intended to be used in Operating Rooms (OR) or with high frequency surgical devices. If it must be used, then to prevent high frequency burns, keep ECG electrodes and cables away from the neutral electrode of the high frequency surgical device and also the operated area of the patient.
- Kardinero has every right to modify software to improve product performance. For differences between this user manual and your software version, contact Kardinero or reseller.
- This ECG device complies with EMC regulations. Details are given in Annex-C
- Transportation of the device: Device must be transported by Kardinero or using the pallet and crating which are approved by Kardinero.

Class I– CF Type Defibrillator Protected Medical Device

Mains: 220V±10%/ 50Hz±5%/ 2500VA

Operating / Storage Conditions

Temperature: +5°C +45°C Humidity: 95% max.

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1. INTRODUCTION

1.1. About Kardinero

Since 1988, Kardiosis and its successor Kardinero are one of the world's first PC based ECG manufacturers. With representatives across continents, Kardinero is striving to achieve a high customer satisfaction. Our R&D division is working to find solutions to the ever-changing demands of the medical sector. Thank you for choosing Kardiosis products.

1.2. About User Manual

This manual covers settings and installation for ECG Stress System and system configuration of its special software StressWin Pro, printer installation and settings, and troubleshooting some problems that may be encountered during system setup and usage.

- When you encounter any problems, consult to the chapter titled 'Maintenance and Repair'.
- If you can't troubleshoot the problem, call Kardinero Technical Service Department for help.
- Information is provided for using StressWin Pro software in Chapter 7. You can use StressWin Pro efficiently by reading this chapter carefully.

2. ABOUT ARS-EFOR ECG STRESS TEST SYSTEM WITH TREADMILL

This system has been designed and manufactured for electrocardiography recording and reporting during exercise in order to use in diagnosing cardiac diseases on adults or children of suitable body size, according to the doctor's decision. System must be used under the supervision of an authorized doctor. Patients, to be tested must be able walk on the treadmill. Before testing patients who may encounter difficulties while walking, it is advised to let them try it manually and slowly and get used to walk on the treadmill. With this manual prepared by Kardinero Inc., it is aimed to provide users with the basic information such as usage, simple maintenance, problems that may be encountered and solutions for them, and technical specifications. Consult our company for the subjects that are not covered in this manual.

System is PC-based and consists of the following units:

- Treadmill
- ECG Module (ECG Master USB Module)
- Main computer unit, monitor, keyboard, mouse
- Patient cable with clamp end (EKG patient cable of Kardinero with defibrillator protection, suitable for ECG module used),
- Connection and power cables
- Clamp type defibrillator protected ECG patient cable
- Software and documentation (StressWin PRO) package including software for system, operating system and driver software, documentation and manuals
- System trolley
- Automatic Blood Pressure Monitor (optional)

If you have purchased ars-Efor as a kit only, you need to provide your own PC, printer and trolley.

System must be setup by Kardinero Service personnel or others authorized by Kardinero. A simple setup diagram of the system is shown in user manual. System is delivered with software already installed by Kardinero during manufacturing. The user is responsible for any problems encountered because of the use of any other software unless permitted by Kardinero.

Kardinero disclaims any responsibility for the problems that may occur due to the failures or conflicts during the installation of other software and/or hardware.

Software set shipped with the system is provided to use for servicing when needed later. Since all of them are licensed, it's forbidden to install them on different computers. User will be responsible for violations on this subject. Setup and setting instructions provided in followed chapters are for general information. Under normal conditions it's advised to carry out these settings by Kardinero authorized personnel.

2.1. Introducing Stress System

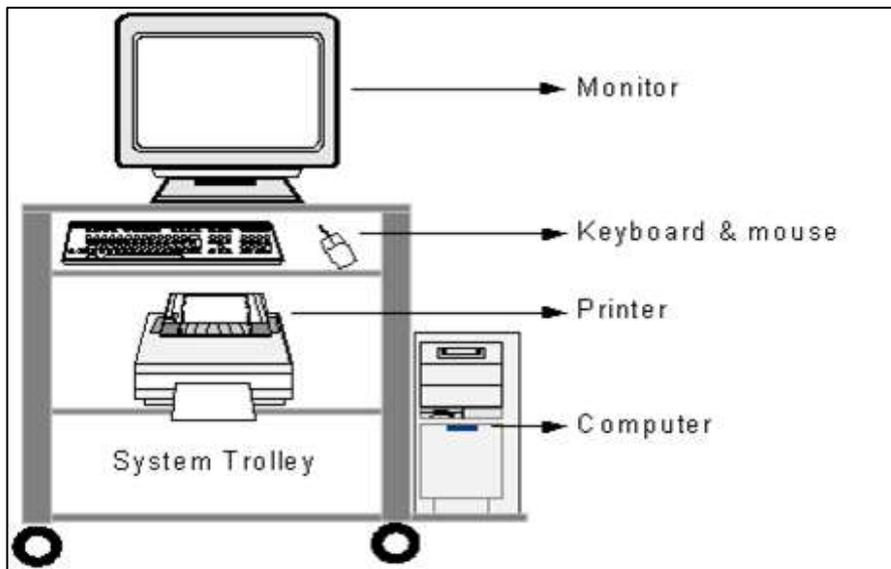


Figure 1. System Trolley (Console)

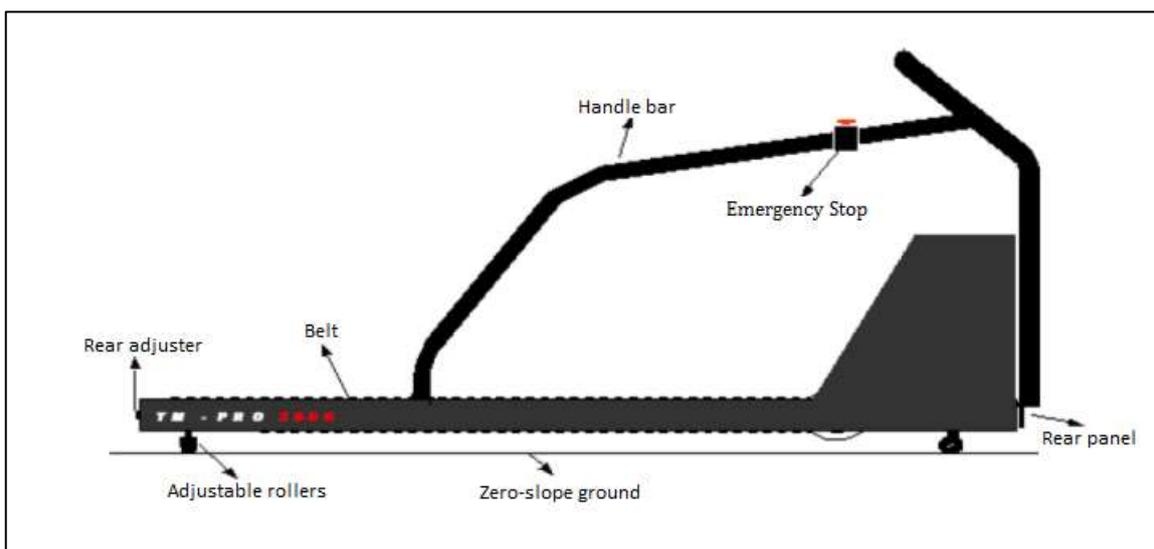


Figure 2. Treadmill

2.1.1. Hardware Requirements

PC

- The microprocessor should have mid-to-top speed and processing capability.
- The ECG Master must have at least one USB port for the USB device.
- Master Memory (RAM) must be at least 8 GB.
- On the motherboard, at least one RS 232 Serial Port connector must be provided for the treadmill control.
- If an automatic blood pressure measuring device is to be found; 2 more RS232 outputs (for Tango+) or 1 RS232 and USB outputs (Tango M2) are required.
- The hard drive must be at least 500 GB. Larger disk capacity is recommended.
- Minimum 4 GB of display memory. The corresponding video card must support 1920x1080 and 32Bit color resolution.
- The monitor must support 1920x1080 or higher resolution.
- Must be a PS / 2 or USB mouse.
- DVD-RW is recommended for data recording and storage.

ECG

- ECG Master USB Module with 10 lead patient cable

Printer

- Laser printer: Minimum 600 dpi resolution for black and white prints

Treadmill

- TM-Pro Series
- Optionally:
 - Suntech TANGO automatic blood pressure monitor,
 - Kardinero USB ECG compatible vacuum-electrode system,
 - Ergonomic bicycle, Ergoline compatible,
 - For computer hardware and accessories installations, you can refer to hardware units' booklets.

2.1.2. Software Requirements

- Windows 7, 8 or 10 operating system,
- StressWin Pro software installation program,
- ECG Master USB Module device drivers (these drivers are automatically installed during StressWin Pro software installation),
- Printer device driver,
- Video card device driver,
- Monitor device driver,
- Optional: Resting ECG interpretation software,
- Drivers for other hardware, software requirements are required.

2.2. SYSTEM PROPERTIES

2.2.1. About StressWin Pro

StressWin Pro is the software of ECG exercise test system for monitoring, recording, control and reporting of stress ECG. This software has been designed and developed completely by software programming staff of Kardinero R&D Department.

StressWin Pro, 12-lead ECG Stress Test software, is real-time and compatible with Windows 7/8/10; and has following properties:

- Receive real-time ECG data,
- Display of ECG signals on the monitor (6x2, 3x4, 12, 6, 3, 1, Average),
- Recording of ECG signals,
- Detection of QRS complexes and averaging of signals,
- Receiving reports from the printer after rest, exercise, relaxation and testing,
- Reports during rest (pre-test: pre-test),
- Reports during testing (in Exercise and Relaxation),
- Averages and 12 channel Records (Raw Data – RawData),
- Averages and 12 channels Linked Median,
- Post-test (recovery) reports,
- Slope, ST, ST-Heart Rate Trend Charts,
- Summary page (Blood Pressure, Pulse Graph),
- Event recording output,
- Review output (Doctor's reviews),
- Saving the entire report in JPEG format,
- Saving the entire report as a complete PDF file,
- Saving report pages in JPEG format,
- Dicom integration,
- Health institution and patient information output,
- Frozen 10 second ECG recording output,
- Automatic control of treadmill slope and speed by the software,
- Control and monitoring of the applied values (speed, slope) for the treadmill
- Optional ergometer bicycle power control (Watts) and monitoring of the value,
- Protocol selection (Bruce, Naughton, Ergo etc.) and protocol creation as desired,
- Amplitude and speed indicators for the ST measuring point, display and outputs,
- Filter application possibilities,
- 50 Hz or 60 Hz line filter,
- EMG filter,
- Baseline filter,
- Freeze and review of 10 seconds of ECG signals features.

2.2.2. Technical Specifications

Standard Exercise ECG Testing

- MS Windows based exercise ECG testing software: *StressWinPro* 12 channel real time simultaneous ECG monitoring
- Automatic control of Treadmill with the software**
- Bruce, Naughton and many other protocols with possibility of adding unlimited user defined protocols.
- Also suitable for 'Ergometric Bicycle'
- Real time continuous ST level and slope trends
- Real time ECG averaging and displaying
- Average (average) calculation and representation of ECG signals in real time
- Blood Pressure and Pulse Trend Charts
- Target and maximum target pulse values
- Heart Rate
- METS display
- Freezing of screen and print-outs of frozen sections.
- Selectable Full Disclosure ECG recording
- Step forward-backward during testing
- Manual treadmill control during stress testing
- Display of step related information
- Full disclosure storage of ECG data on
- Audible warning before step changes for the patient and the clinician
- 1000 patient records require approximately 15 GB disk space.

Reports

- User selectable report options
- Drawing options for averaged and raw data signals**
- ST-level trend with point-J
- Reports of averages and ECG signals
- ST level/slope values at each step
- ST level/slope, heart rate and blood pressure trends
- Patient data
- Doctor's remarks
- Event reports
- Print outs of frozen screen sections

ECG Signal

- 12 channel recording
- Derivations: Standard: DI, DII, DIII, aVR, aVL, aVF, V1-V6
- Maximum sampling rate for signal processing: 4000 sps per channel
- Frequency response: 0.05 – 300 Hz (3dB)
- Time constant: 3.2 s (min)

- CMRR: 120 dB
- Sampling resolution: 0.3 μ V (\pm 2 bit) at 16 bits sampling
- Defibrillator protected patient cable and input circuitry
- Software digital filtering: EMG, baseline and line filters
- Amplitude scale (screen and print-outs) 2.5, 5,10,20,40 mm/mv
- Time scale (screen and print-outs) 12.5,25,50,100 mm/sec
- Design and production comply with EN60601-1 (IEC 601-1) Electrical Safety Standards.

Treadmill

- Automatic speed and slope control
- Speed: 0- 17.0 km/h (\pm 0.1) (Optional: 25 km/h)
- Slope: 0-25 % (\pm 0.1)
- Internal dimensions: 55 cm x150 cm
- External dimensions: 70.5 X 209 x 132
- Load capacity: 180 kg
- Safety: Emergency stop button
- Speed motor power: 2.2 kW

Control Unit

- Minimum Pentium IV based PC
- Windows XP® operating system
- System trolley
- Laser printer
- Modem interface
- 21" color monitor

Optional

- Automatic dynamic blood pressure monitor
- Ergometric Bicycle
- Uninterruptible power supply (UPS)
- Vacuum electrode system

NOTE: Tolerances for the measured parameters above are 5%, which corresponds to hardware's amplitude and time scale accuracy. High noise on the acquired signals may affect the calculations performed by the SW, and may result to exceed these tolerances. Heart Rate calculation performed during exercise is sensitive to some parameters and the tolerance margin for heart rate is 10%.

3. Installing StressWinPro Software

WARNING: Connect ECG Master USB Module after installation

3.1. Installation

Insert the StressWinPro installation CD in the CD/DVD driver. Installation will start automatically. Or; copy the “StressWinPro_Install....” File to your computer and run it.

***Note:** If CD/DVD driver has not been set to automatic execution mode, installation will not start automatically. In this case, open the files in the CD, then find and click the “**Setup.exe**” file for installation.

IMPORTANT: The StressWin PRO program requires Microsoft’s .NET (dot net) framework to work. The StressWin PRO program checks whether the .NET Framework is installed on your computer during installation. If the program is not installed, install the .NET Framework program named .exe dotnetfx.exe .NET on the installation CD. Or; visit Microsoft support web site for installation of actual .NET Framework. If you are experiencing a .NET Framework problem with older versions of Windows, contact your computer service support or Kardinero.

Then, you will see the “StressWin Pro Installation” window below. Click ‘Next >’ (Figure 3)



Figure 3. StressWin Pro Installation Opening Window

After pressing the “Next” button, the “Setup Wizard” box shown below will appear. Click “**Next >**” to continue the installation. (Figure 4)

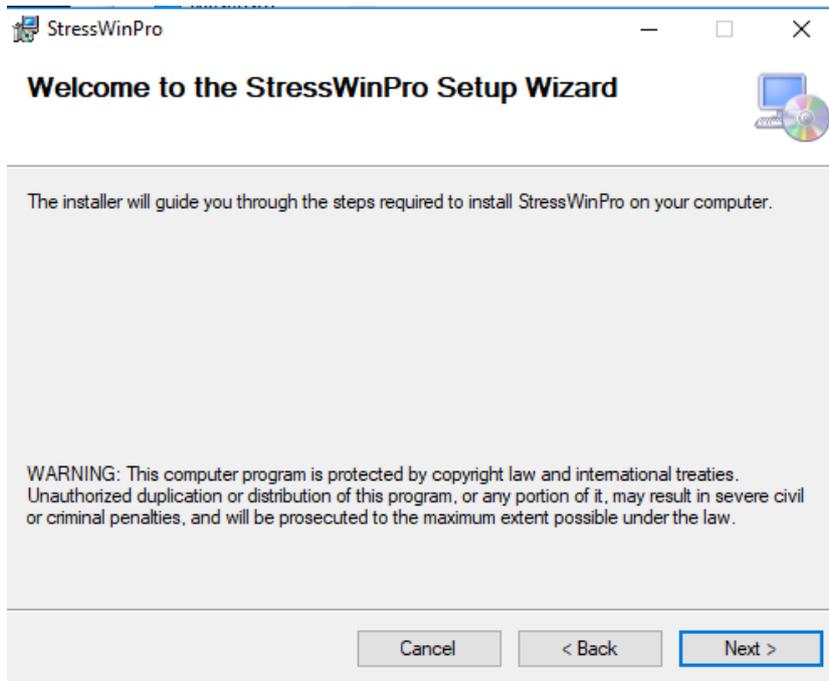


Figure 4. StressWin Pro Setup Wizard Window

You will then be asked which directory (folder) you want the program to install. The default value for this directory is **C:\Program Files\Kardinerer\StressWinPro**. You can change the name of this directory or you can accept the default value. **“Just Me”** select the option if you are going to use the program and select **“Everyone”** if it is to be used by other users. Press ‘Next >’ after you have finished. (Figure 5)

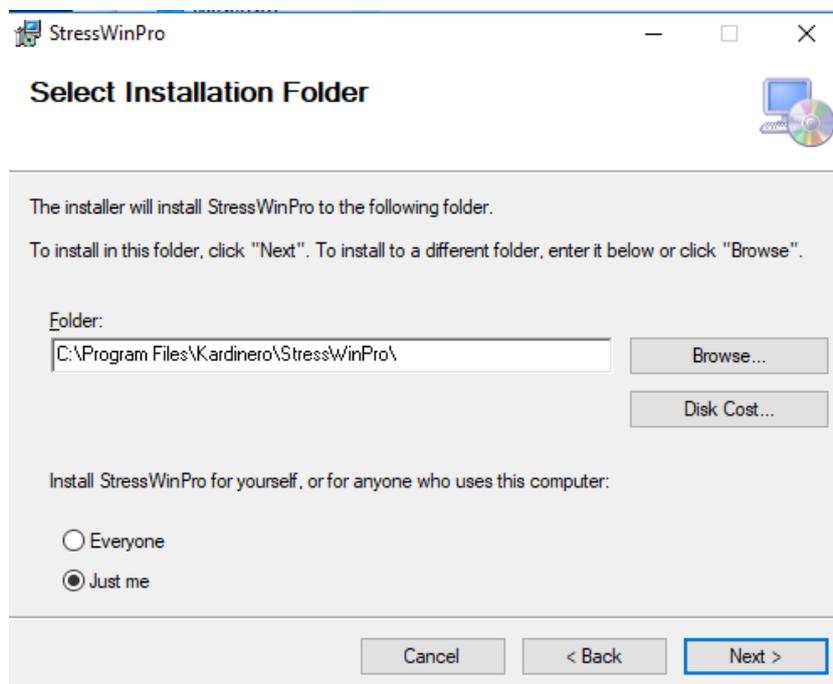


Figure 5. Select Installation Folder Window

The appearing window indicates that the setup wizard is ready to install the StresWin Pro software on the computer. Click **“Next >”** to start the installation. (Figure 6)

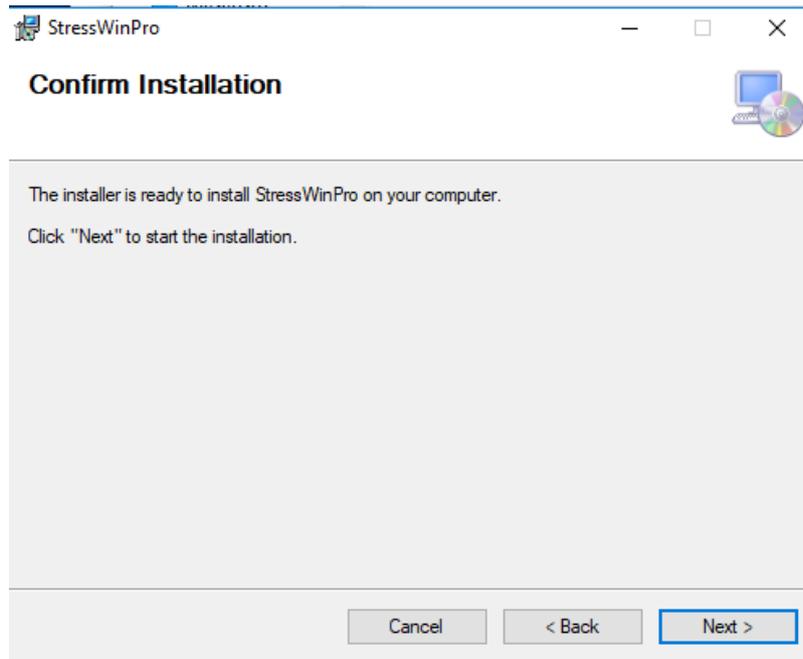


Figure 6. Confirm Installation Window

During the installation, the screen you received at this stage is the approval of the license agreement. The system software may only be installed and used by licensed users who have purchased the software and or hardware.

Read this license text and if you feel that you do not agree with the terms you do not agree with, select **“I Do Not Agree”** and click Cancel to cancel the installation. Contact your authorized dealer. If you agree, click **“I Agree”** and click **“Next >”** to proceed. (Figure 7)

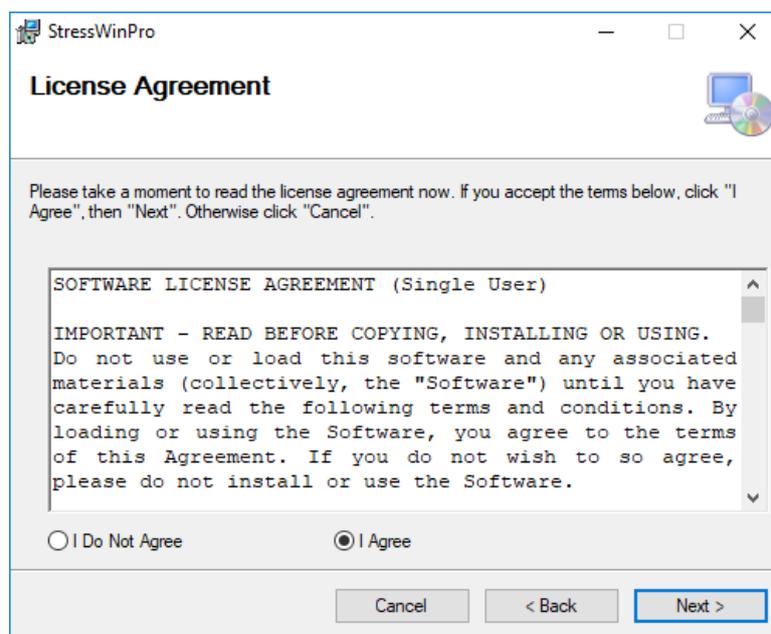


Figure 7. License Agreement Confirmation Window

After this step, the installation of the Stress Win Pro program and copying the files of the program to the computer is in progress. Please wait until copying is complete. (Figure 8)

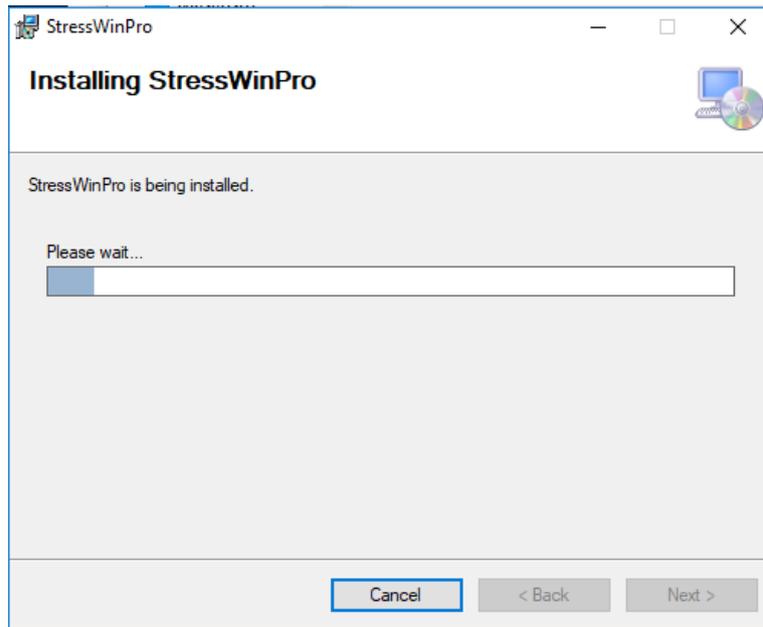


Figure 8. Installation Progress Window

Press the Close button to complete the installation process with the window below. (Figure 9)

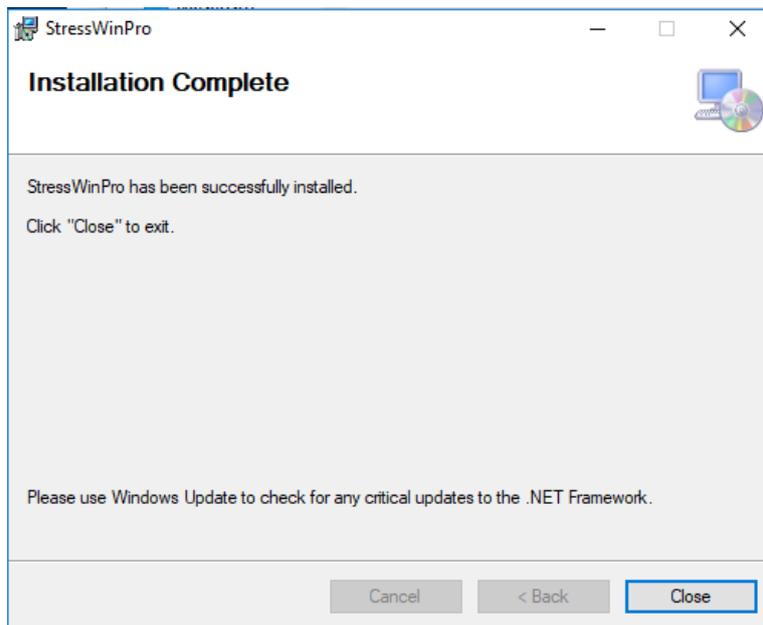


Figure 9. Installation Completion Window

Important: Keep your installation CD/ or files in another platform in a safe and convenient place, considering that you may need it in the future.

3.1.1. Uninstalling StressWin Pro

You can uninstall StressWin Pro in two ways. As shown in Figure 10, first option is to use the installation CD itself. Select “**Remove StressWin Pro**” button and then click “**Finish**” button.

Second option is to use “**Start – Control Panel – Add or Remove programs**”. Select “**StressWinPro**” and then click “**Remove**” button.

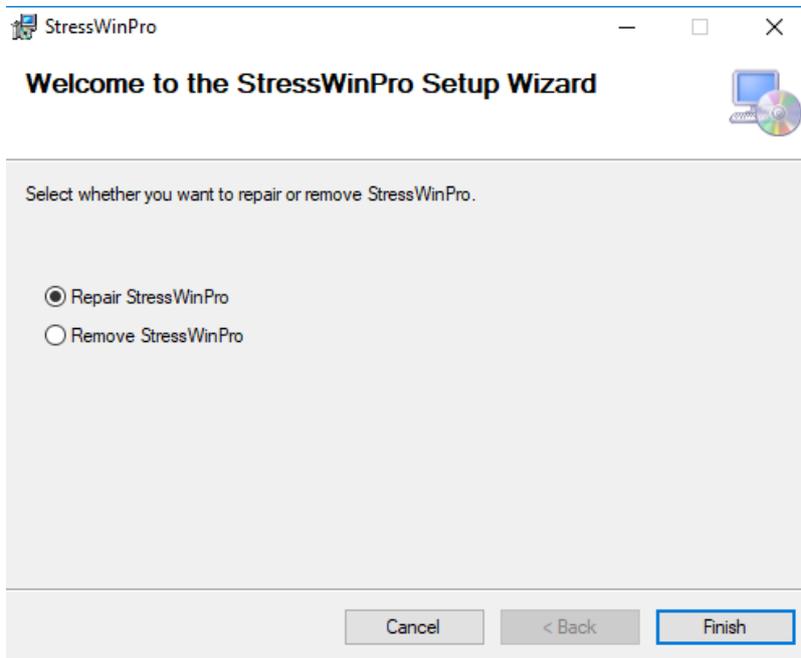


Figure 10

3.2. Installing ECG Master USB Device

The installation of your ECG Master USB device is done directly by other means such as well-known USB-connected devices. Depending on the computer you are using, the USB port connection may be on the rear, front, or side of the computer chassis. There may be more than one USB port on desktop computers. You can easily identify a USB port by looking at your device’s USB connection cable.

If you are using more than one USB connected device, you can also use a standard USB hub for connection. In this case, insert the USB cable of your ECG in the same way as in the socket.

If you are not familiar with the USB connection, follow the instructions for your computer’s user manual. You can also call the service for help.

It is important to have the power connections and grounding of your computer properly to get a good ECG signal. If you have problems with grounding, ask an experienced electrician for help.

Important: Your ECG Master USB device does not need to stay connected to your computer always. When you want to use your device, you can connect your USB cable to your computer. The point is that you should run the software after connecting the device to the computer.

The green LED on the ECG Master device is the indicator that your USB device is working and is shown in Figure 11. This green LED flashes once when you connect your device to your computer. When you run the program, the LED is lit continuously. When you exit the program, the LED goes off.



Figure 11. EKG Master USB Module

After the ECG Master USB Module is installed, and when the Module is connected to the computer, the device is shown under Control Panel > Device Manager under Universal Serial Bus Controllers (USB) displayed as the **Kardinerio ECG Master USB** or **TEPA USB DEVICE**. (Figure 12)

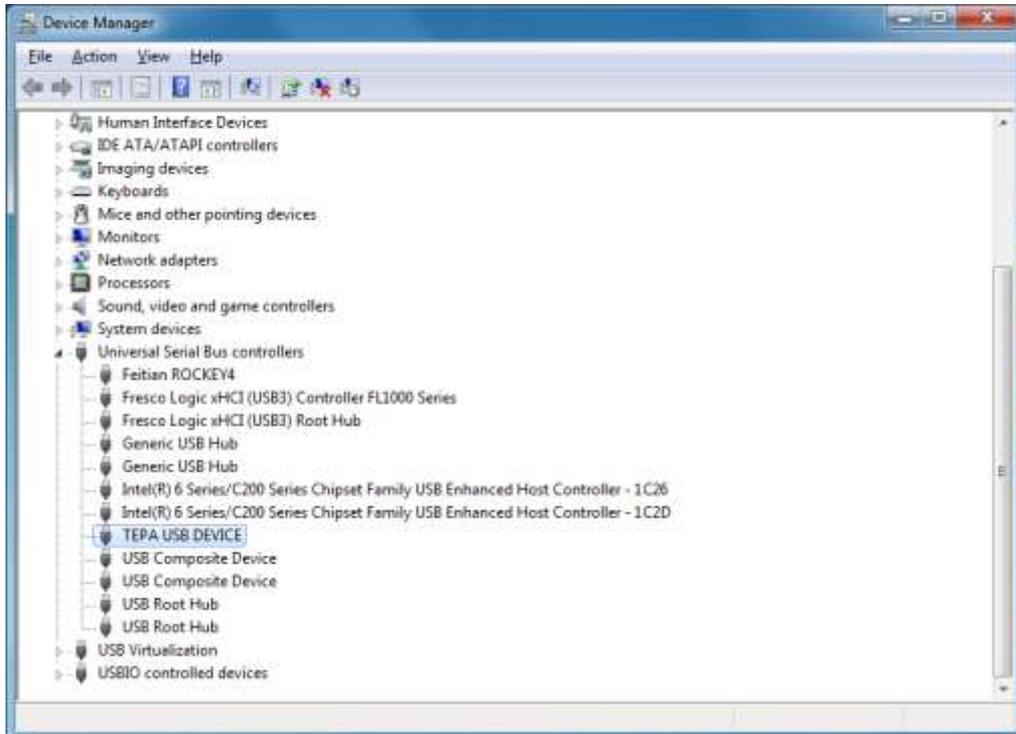


Figure 12. System Recognition of ECG Master USB Module

3.3. Entering Module Password

After the installing the software (see 3.1.), please run the program once to enter ECG USB Module password. This will open the entry screen. (see Figure 13)

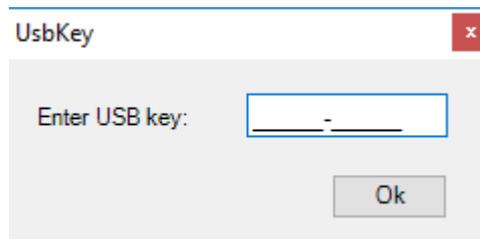


Figure 13. USB Key Window

After the USB Key Window opens, enter the password given to you by the Kardinero Authority as shown (see Figure 14).

NOTE: Be careful for upper case and lower case when entering the password!

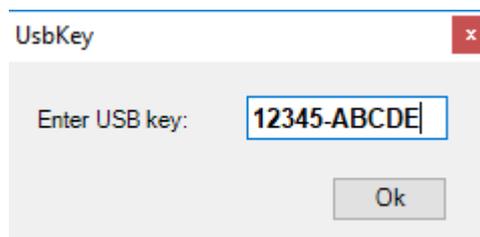


Figure 14. USB Key Window

4. INSTALLATION OF STRESS TEST SYSTEM

4.1. Mechanical Setup

Treadmill must be located on a pure and plain horizontal surface having zero slope. Trolley must be placed somewhere near the treadmill. Thus, the patient cable and data cable are guaranteed to be in appropriate distance. These cables should not be squeezed and damaged because of the movement of the treadmill.

4.2. Electrical Setup (ECG Master USB)

USB and patient cable must be laid with precaution to avoid them getting squeezed and damaged under the treadmill. The treadmill must be connected to an outlet with protective ground, as indicated in Figure 15. EKG Master USB module has to be connected to a USB port of the PC and patient cable should be connected to the ECG module.

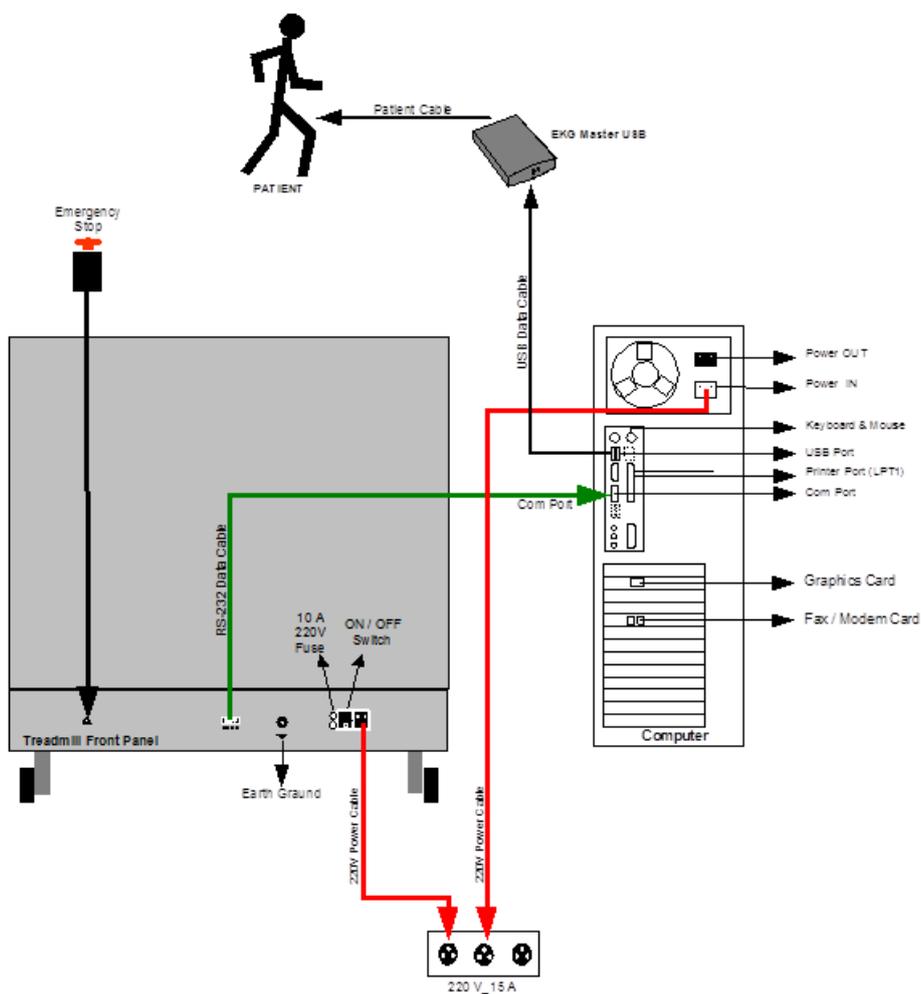


Figure 15. Patient, ECG Master USB and Treadmill Electrical Connections

4.3. SunTech TANGO Dynamic Blood Pressure Monitor Setup

Suntech Tango automatic blood pressure device, which works in real time with the ECG Stress Test system, has two different models, Tango Plus and Tango M2. There are differences between these 2 different models' computer setups. Follow the appropriate Suntech Tango computer installation information from the following Suntech Tango computer installation information.

For the Suntech Tango M2 automatic blood pressure device to be included in the exercise system, the computer is installed as follows:

If you want to monitor blood pressure automatically during exercise, you should add your Suntech Tango M2 Model dynamic blood pressure monitor to our system. Note: The two sided 9-PIN RS232 cable used in the previous model has been replaced. The replaced connection will be made via a USB A-B cable. Hardware installations must be started first. The Tango M2 Patient ECG trigger cable's (green cable) BNC end is plugged into the device and the relevant RS-232 Port of the computer appropriately. USB A-B cable's device part should be connected to the matching socket on the Tango M2 and the other side should be connected to the one of the PC's USB ports. Please copy the required Driver File to the desktop for installation. Click on Control Panel and open Device Manager. In Device Manager, there will be a connection in the Ports section to the TANGO M2 Serial Over USB Connection (COM ...). Right-click on the TANGO M2 Serial Over USB Connection and select Update My Computer in the window that appears after you click "Scan My Computer" for Driver Software. Click on the window in the new window that opens, select the file on the desktop we have given for installation, click Next and then click Close. To check at the end of the installation, see the Tango M2 Serial Over USB (COM ...) connection in Device Manager. Open the settings in the StressWin Pro program. (Figure 17) On the Devices tab, select the Port selection (COM ...) in the Blood Pressure as you set Tango M2 in the Device manager. For the ECG Trigger, select the PC's port number, as you connected ECG trigger cable to the RS 232 port. This is necessary to receive the ECG-R wave synchronization signals from the system. Finally, set up your settings as shown in Figure 16 from the Monitor Setup on your TANGO M2 automatic blood pressure monitor. After these selections, the installation is completed and ready for processing. If necessary, these settings can be changed in Settings. All of these settings will be made at the initial installation of the system. Contact Kardinero if you have a problem with the setting and communication ports.



Figure 16. Suntech Tango Main Menu Setup

Finally, set your settings as shown in Figure 16 in the Monitor Setup on your TANGO M2 automatic blood pressure device.

Another model is Tango Plus and its installation on the computer for inclusion in the exercise system:

You need to add the Suntech Tango Plus model dynamic blood pressure monitor to your system. The monitor needs three serial ports that are open on the computer in your exercise system. Desktop computers are usually available in two and the third port is used for serial port multiplexer. In the Port section of the Blood pressure section of Figure 17, the COM port should be selected in the Port section where the standard RS-232 serial port cable is connected to provide communication between the dynamic blood pressure monitor and the computer, and to receive the ECG-R wave synchronization signals from the system in the ECG timing port, the COM port with which the used cable is connected must be selected. A cable ECG synchronization cable with one end BNC connector and the other end with 9-PIN RS-232. If necessary, these settings can be changed in Settings. All of these settings will be made at the initial installation of the system.

Contact Kardinero if you have a problem with communication ports.

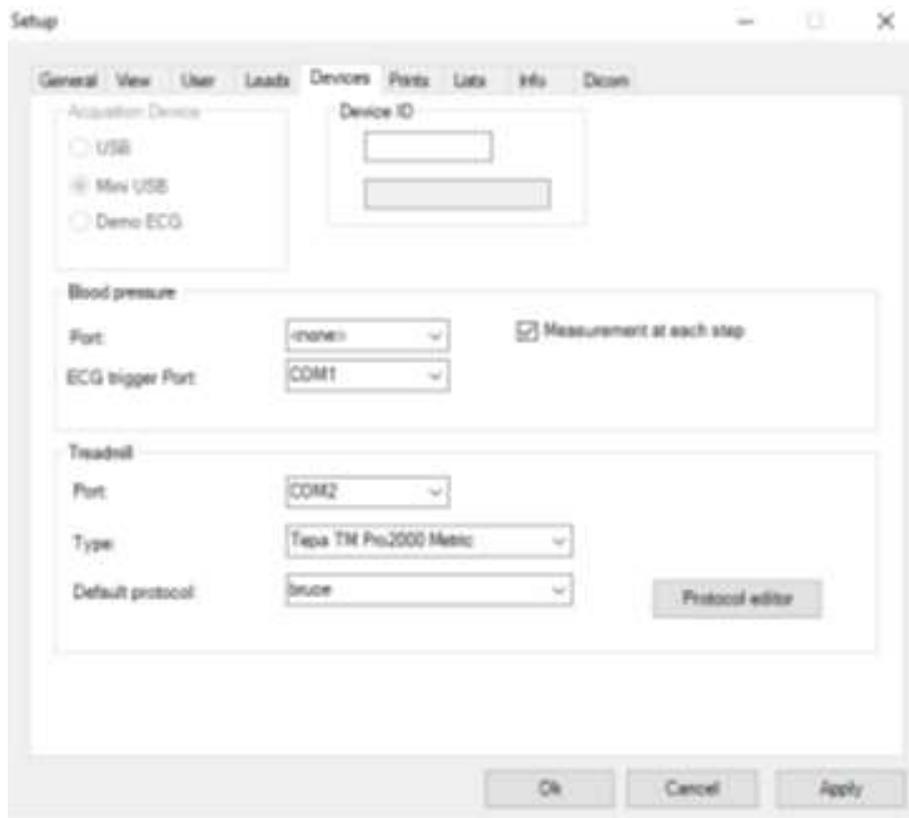


Figure 17. Setup Screen

On the SunTech side, protocol should be selected as **SunTech** and ECG Trigger as **Digital↑ (Digital up)**.

*** NOTE: Since the previous TANGO Plus model does not have a USB connection, a two-sided RS-232 cable will be used; its connection is described above.**

5. Printer Installation

In some printers, the installation programs in their installation CDs automatically detect and install the software as soon as you insert the CD. If you have a printer connected to your computer via a USB port, the Windows operating system usually installs the driver software for this printer on your computer automatically. If it cannot perform the installation in full, he will ask you to insert the CD of that printer into the drive.

One way to install a printer is to enter it in Start-> Printers and Faxes; Click Add Printer. In this case, the computer will ask you questions about the location and installation information of the printer you want to install. You may also need to use the installation CD or diskette that came with your printer. If you have any difficulty, please consult your computer specialist.

6. SETTINGS

Settings discussed in this chapter have to be adjusted by Kardinero's authorized personnel during first setup. The instructions below are provided as general information. In case of a need for re-adjustment, especially because of changing location, carrying out these instructions by experienced staff that has the knowledge of computer hardware and software is favorable. If you encounter setup problems related to your system, apply Kardinero Inc. authorized service personnel.

6.1 Treadmill Settings

6.1.1. Treadmill Foot Settings

Treadmill includes 4 feet: 2 front wheels and 2 rear-setting feet. When the treadmill is set to run, if there is vibration/oscillation, this can be corrected by rotating rear setting feet in "E" and/or "G" directions to level the treadmill on uneven surfaces. (Figure 18)

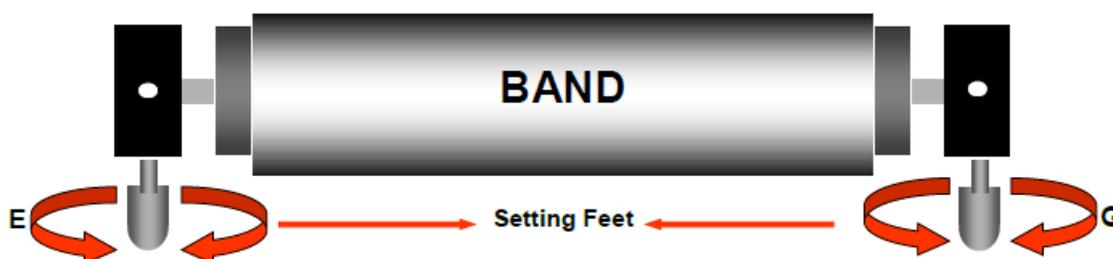


Figure 18. Treadmill Foot Settings

6.1.2. Treadmill Band Settings

Band setting is the adjustment that must be done when the band slips to the sides. During the adjustment, adjusting screw is squeezed in A-B-C-D directions while the band's speed is at 3 km/h and tension is kept constant. If **Band** slipped to the **right**, screw is squeezed in **A** or **B** direction while being sure not to change the band's tension. If **Band** slipped to the **left**, screw is squeezed in **C** or **D** direction while being sure not to change the band's tension, see Figure 19.

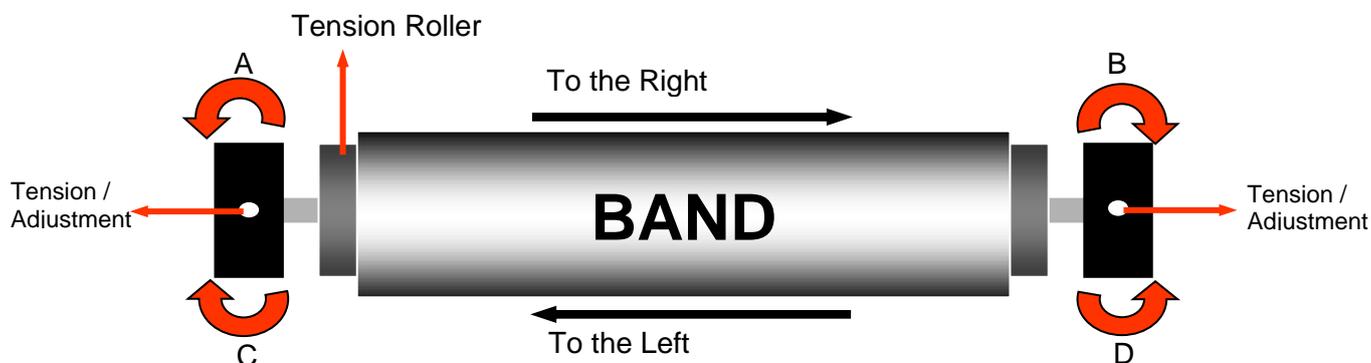


Figure 19. Treadmill Band Settings

6.2. Screen and Display Settings

We recommend StressWin Pro software to be used on 1920 x 1080 (HD) screen resolution. Display properties are needed to be adjusted accordingly. To do this, right-click a blank spot on the Desktop and select “Screen Resolution” from the shortcut menu. You’ll see the dialog box related to display settings shown Figure 20 below. Adjust the resolution to 1920 x 1080 pixels.

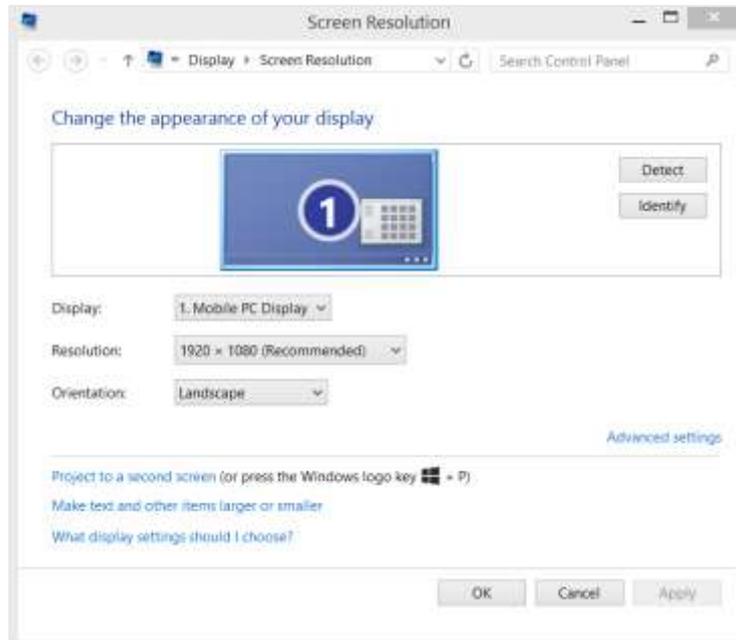


Figure 20. Screen and Display Settings

6.3. Setting the Program Language

StressWin Pro program language can be set by changing the language of the Windows. To do this, use **Start -> Control Panel -> Date, Time, Language and Regional Options -> Regional and Language Options** and select the language of your choice from the list as shown in Figure 6.4. If selected language is not supported by StressWin Pro, English will be used as default.



IMPORTANT: If your operating system is in English and the program is running in English, make sure that the language option in the taskbar is in English. If you are not in Turkish, click on it to try Turkish (TR). If such an option does not appear; For the region; Start -> Settings -> Control Panel -> Regional portion of Turkey (Figure 21) by selecting, for Languages; You can select English (Figure 21) in Start -> Settings -> Control Panel -> Language Options. During this process, Windows may prompt you to install the Microsoft Windows installation CD. If you are having problems with this selection, contact your computer provider or Kardinero.

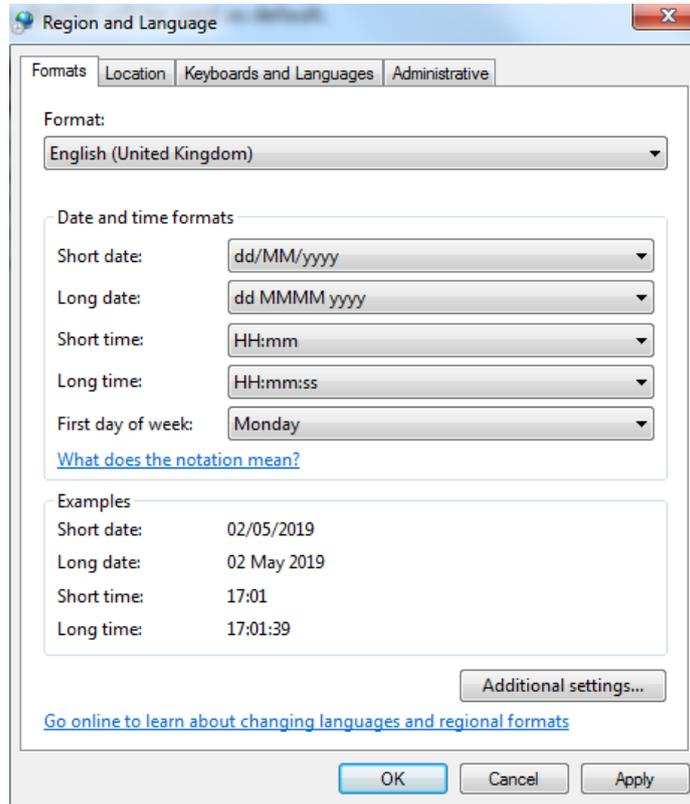


Figure 21. Regional and Language Settings

7. USING STRESSWIN PRO

This chapter gives the instructions for using Kardinero Stress Test system. Turn on the power to the treadmill and the computer. Treadmill On/Off button is located at the rear of the treadmill.

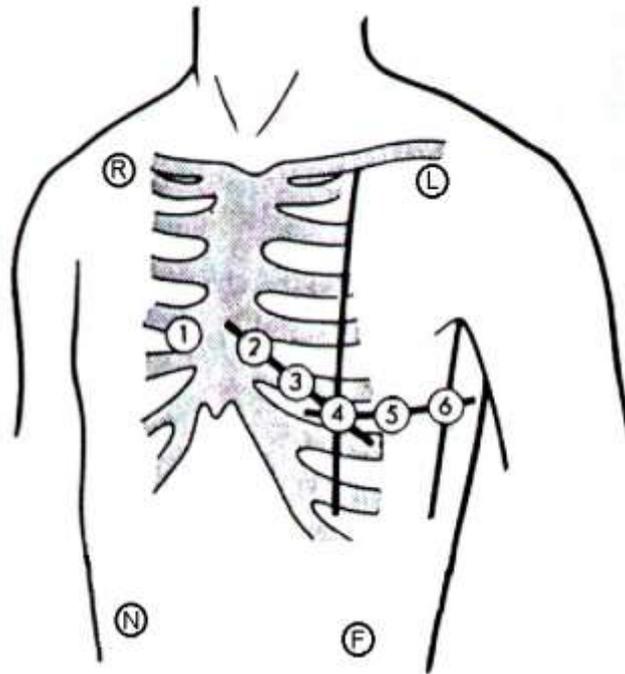


Figure 22. ECG Electrodes Layout

ECG Electrodes' Layout

R (RA)	Red	Right arm
L (LA)	Yellow	Left arm
F (LL)	Green	Left leg
N (RL)	Black	Right leg
C1	Red	Intercostal gap at the right of sternum
C2	Yellow	intercostal gap at the left of sternum
C3	Green	At the mid-level of C2 and C4, on 5 th costal bone
C4	Brown	Mid-front armpit line of left collar bone
C5	Black	Left-front collar bone line on C4 horizontal level
C6	Purple	Left-mid collar bone line on C4 horizontal level

After system is ready to use, cables are placed on patient's body (Figure 22) and the patient is prepared for the test. Patient and system must be prepared by personnel experienced in ECG stress test. You must be sure that electrodes are attached firmly, electrodes and ends of patient cables attached to electrodes are fixed by net bandage and they do not move during the test. Please use high quality electrodes which are suitable and recommended for ECG stress testing. Make sure that ECG cable/electrodes and other parts of the system do not touch the surrounding conductors and ground in the environment.

Electrode layout configuration used is standard 12 leads (6 extremity, 6 chest). 10-lead patient cable connection points to acquire standard 12 derivations are shown in Fig. 22. Patient must walk on treadmill with comfortable socks and must not use shoes. This is required to avoid static electricity due to different shoe types.

To start the program, follow the menu commands “**Start -> All Programs -> StressWinPro**”. You may also start the program by clicking/double clicking the StressWinPro shortcut icon on the Desktop.

7.1. Startup Screen

Using the toolbar buttons, Startup Screen enables you to start a new test, open an existing test, change settings and access program info, as shown in Figure 23. You can also reprint previous tests using the “Reprints” menu item under the “file” tab.

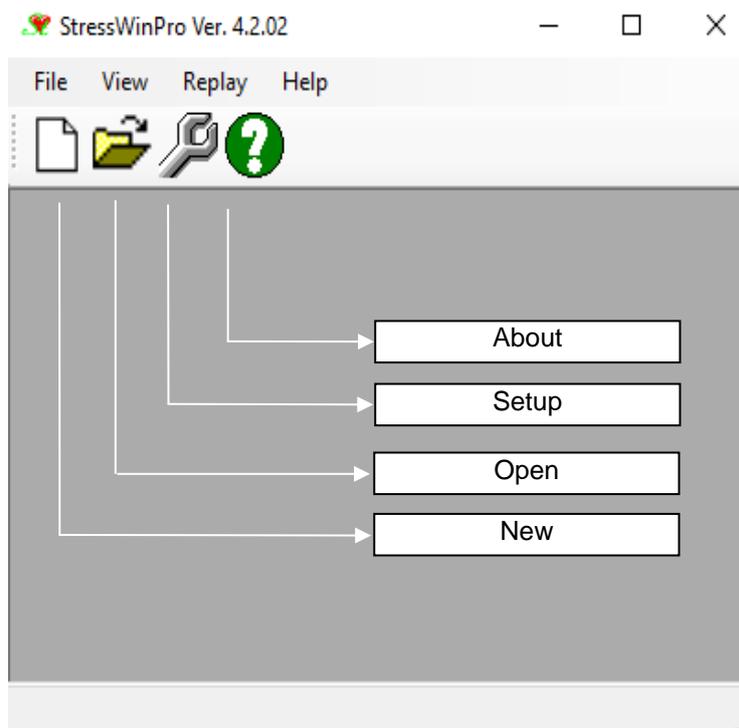


Figure 23. StressWinPro Startup Screen

Menu Bar: As indicated on Figure 23, all program functions can be accessed using the mouse or keyboard. To access menu items via keyboard, first press “**Alt**” key and then use arrow keys to select the menu item. Shortcut keys for some menu items are also available using function keys “**F1, F2, etc.**”

Tool Bar: Buttons and combo boxes are placed on the toolbar. Frequently used menu items have their corresponding buttons. Use mouse to select desired button functions.

Status Bar: Lower most bars on the screen. Status messages and other information are displayed on this bar.

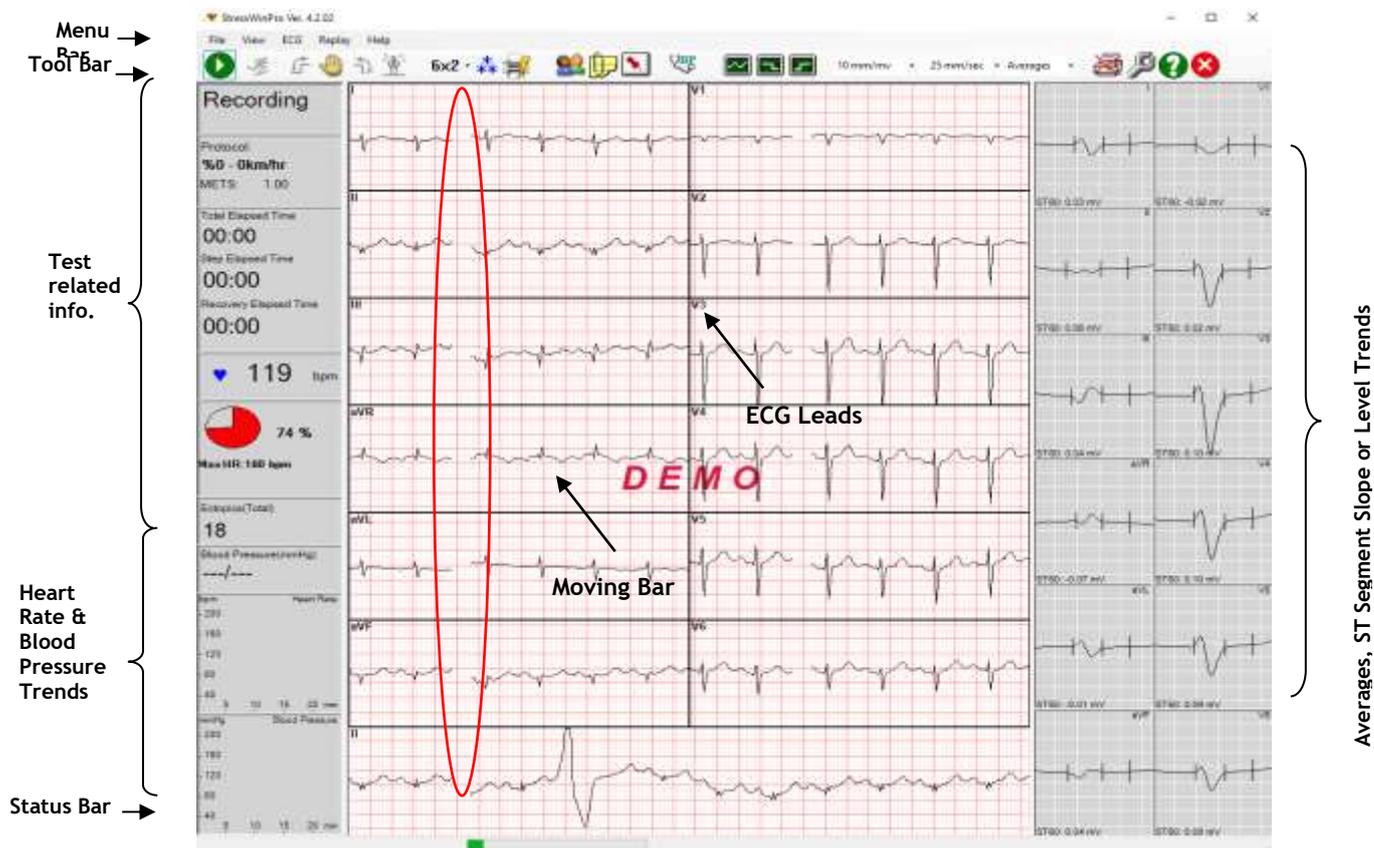


Figure 24. StressWinPro Test Screen

Heart Rate Calculation:

Karvonen formula:
 Maximum number of heart beats – % intensity of Rested heart rate + Number of resting heart rate

7.2 How to perform a test?

Before explaining all functions in detail, it's useful to discuss, in general terms, how to perform a stress test and the steps it includes. During stress testing, a patient is allowed to run on a treadmill. Stress test consists of three steps: Rest, Exercise and Recovery. As it can be understood from their names easily, rest ECG recording is done while patient is inactive, or resting. This recording forms a reference for the signal base at later stages of the test. Therefore, it is recommended to do this recording while the patient is standing. During exercise recording, patient runs on the treadmill according to a particular protocol until patient's heart rate reaches to a predefined target heart rate. *Alternatively*, maximum heart rate can be used, if desired. Choosing between "target heart rate" and "maximum heart rate" is found at "Setup->General" tab page. According to the heart rate chosen by the user, the GUI on the right updates the chart and the selected heart rate is written in bold characters. Patient may have difficulties with running on the treadmill or suffer from some health conditions during this process. In such a case, test must be finished and patient's complaints must be recorded. After peak exercise step, patient enters rest (or recovery) stage and ECG signals are recorded. This last step is the recovery phase. ECG signals recorded during all phases are then assessed by the doctor.

Throughout the following sections, stress testing is explained in detail.

7.3 StressWin Pro Commands and Functions

Commands and functions accessible through the toolbar buttons are shown in Figure 25.



Figure 25. Toolbar

7.3.1. New Patient Recording (NEW)



You can start a new test by clicking on the “New” button on the toolbar or “File -> New” menu item on the menu bar. A dialog box to enter patient data is displayed in Figure 26.

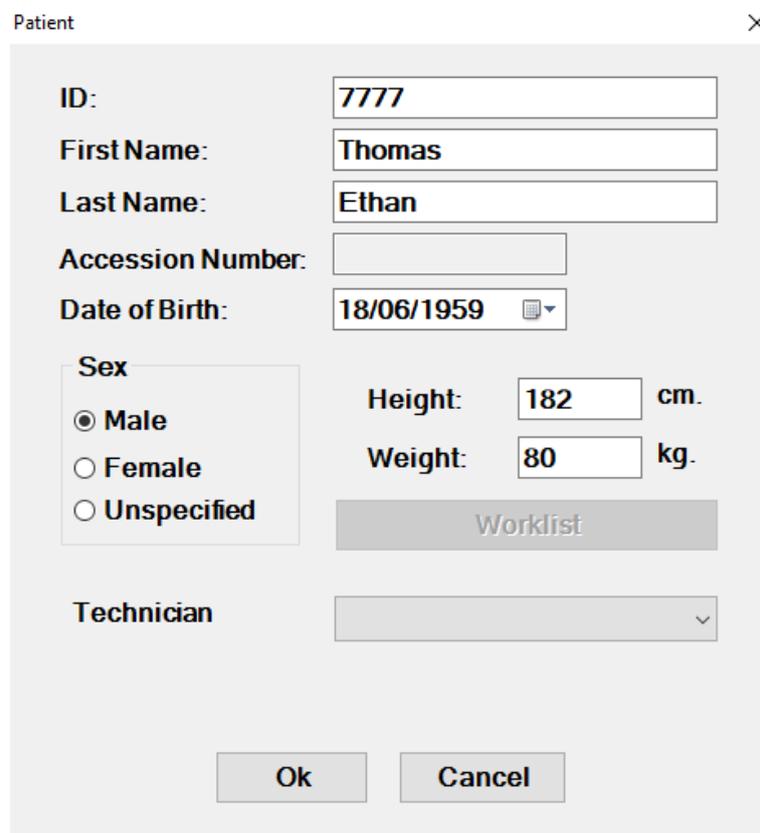
The image shows a 'Patient' information dialog box. It has a title bar with 'Patient' and a close button. The fields are: ID (7777), First Name (Thomas), Last Name (Ethan), Accession Number (empty), Date of Birth (18/06/1959), Sex (radio buttons for Male, Female, Unspecified), Height (182 cm), Weight (80 kg), and Technician (dropdown menu). There is a 'Worklist' button and 'Ok' and 'Cancel' buttons at the bottom.

Figure 26. Patient Information Window

At least one of the fields for ID, last name or first name must be entered. You may also skip entering data at this stage since same window will appear later in rest ECG approval stage.

You are now ready to start the test.

7.3.2. Start/Stop Recording



Rest ECG recording will start at this stage with a default recording duration of 10 seconds. Recording duration can be changed from the “Setup” menu as desired. Before clicking this button make sure ECG signal quality is acceptable at all leads. You may wish to momentarily disable all filters at this stage to monitor the raw signal quality.

After recording is completed, a rest ECG approval window is displayed. Averages and program calculated critical points (Q onset and J points) are displayed on the right. At this stage, you may change the position of critical points by moving the associated bars with the mouse as shown in Figure 27.

If you are not satisfied with the recording, click on “Reject” else click on “Accept” button to proceed with the test. Then, patient information window will appear to give you a chance for entering or modifying patient data. You will not be able to modify or edit patient information after this stage.

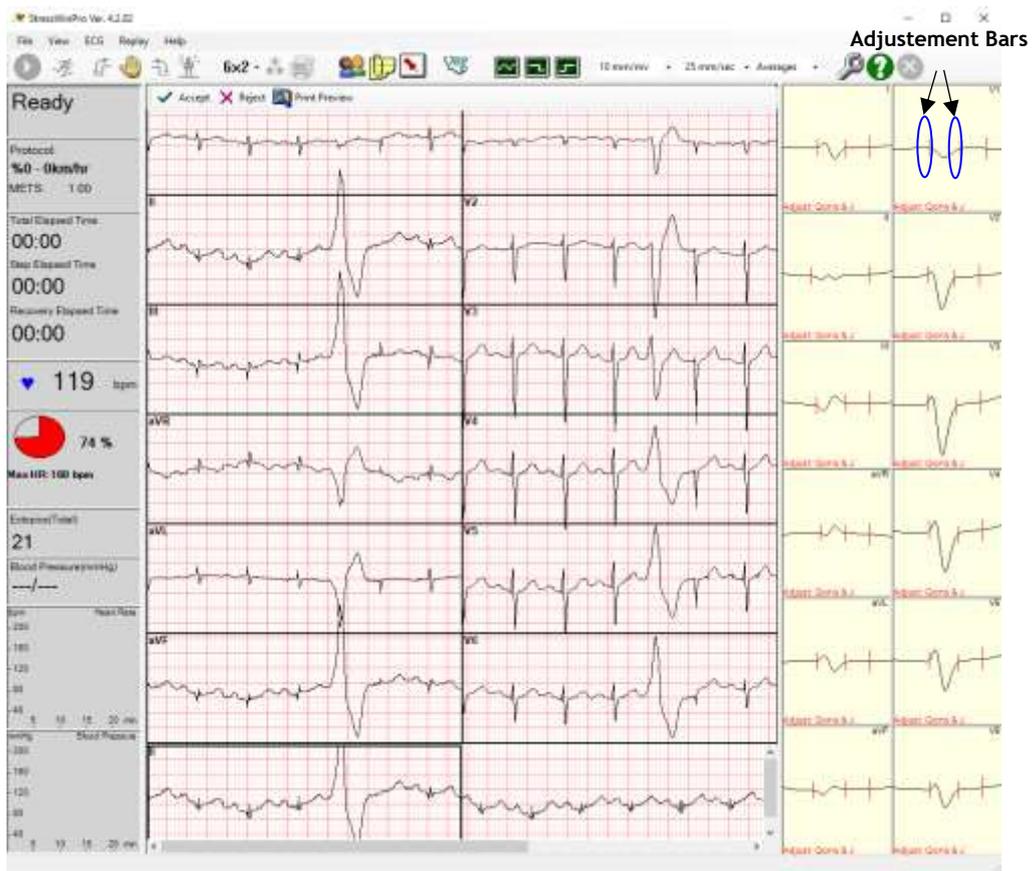


Figure 27. Rest ECG Approval Window

7.3.3. Replay

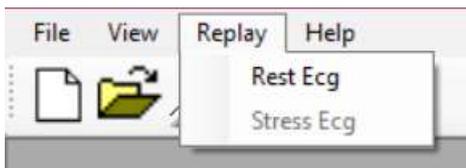


Figure 28. Replay Menu Item



Figure 29. Replay Menu Item after Rest ECG is recorded

This feature enables the user to open ECG data saved in “scp” format for either rest ECG or stress ECG testing. At the start of ECG test, i.e. rest ECG testing, only the “Rest ECG” option is active, please see Figure 28. The user is allowed to select a “scp” file for rest ECG. After ECG data recording is completed, user is allowed to select another “scp” file to run for stress ECG testing, Figure 29. Therefore, “Stress ECG” option becomes active while the user is not allowed to click on “Rest ECG”. For both cases, a dialog box opens for the user to select the ECG data file. The software runs the selected file as if a patient is connected to the device if the selected file is valid.

7.3.4. Start Stress ECG Recording



This control becomes active only after rest ECG recording is done and approved. When clicked, Treadmill will start running according to the selected protocol in the “Setup” menu. During stress testing, ECG averages are formed in real time and test parameters are calculated using the averages.

7.3.5. Recovery Step



When target heart rate (or maximum heart rate, depending on the configuration) is achieved or patient cannot exercise anymore or test is deemed to be sufficient, click on this control to skip to recovery steps of the protocol. If this control is not clicked, recovery steps will be entered after all exercise steps are finished as defined in the protocol.

7.3.6. Stop Stress ECG Testing



Although test will be terminated automatically at the end of the protocol, it is possible to stop the test by this control before all the previous steps of the protocol are done. This control can be clicked at any step of the executed protocol. When clicked ECG recording is stopped and end of test reports are printed. A remarks window pops up to allow doctor to write final remarks and a report. When the test is terminated, Startup screen appears again for a new test.

7.3.7. Step Forward



This control enables you to skip the current step and proceed to the next step.

7.3.8. Manual Control



This command is used to intervene when the treadmill is deemed necessary during effort extraction. Clicking the button in the Figure 30 when this window is opened, the slope of the runner remains there and the speed is 0.0 (zero). The required speed and slope information can be sent here. During these operations, the patient’s signals are displayed, but the effort does not continue. When the window is closed, the exercise continues from where it left off (including Speed and Slope).

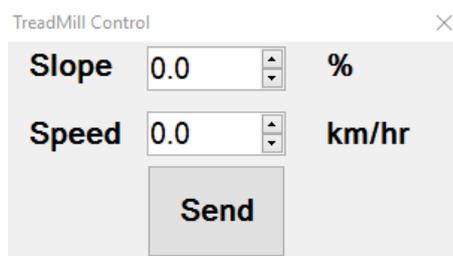


Figure 30

7.3.9. Step Backward



This control enables you to skip the current step and return back to the previous step. This function is disabled during the recovery phase in order to prevent any dangerous situations for the patient by going back to the stress phase.

7.3.10. Views



Different ECG view formats are available to suit user's preferences as shown in Figure 31.

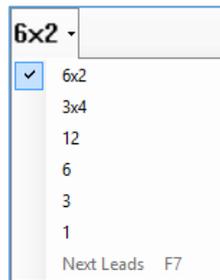


Figure 31

- 6x2** : Channels are organized as six rows by two columns. A rhythm channel selectable by the “Setup” menu is displayed at the very bottom of the screen.
- 3x4** : Channels are organized as three rows by four columns. A rhythm channel selectable by the “Setup” menu is displayed at the very bottom of the screen.
- 12** : All twelve channels are displayed one after the other as twelve rows.
- 6** : Six channels selectable by the “Setup” menu are displayed as rows.
- 3** : Three channels selectable by the “Setup” menu are displayed as rows.
- 1** : One channel selectable by “Setup -> Leads -> Strip Lead” is displayed.

7.3.11. Freeze



This control freezes the last 10 seconds of ECG signals and displays it as shown in Figure 32. Frozen section is displayed in a separate window while real time ECG is continued to be displayed. You can save (📄), print (🖨️) or automatically interpret (🏠) the frozen ECG signal.

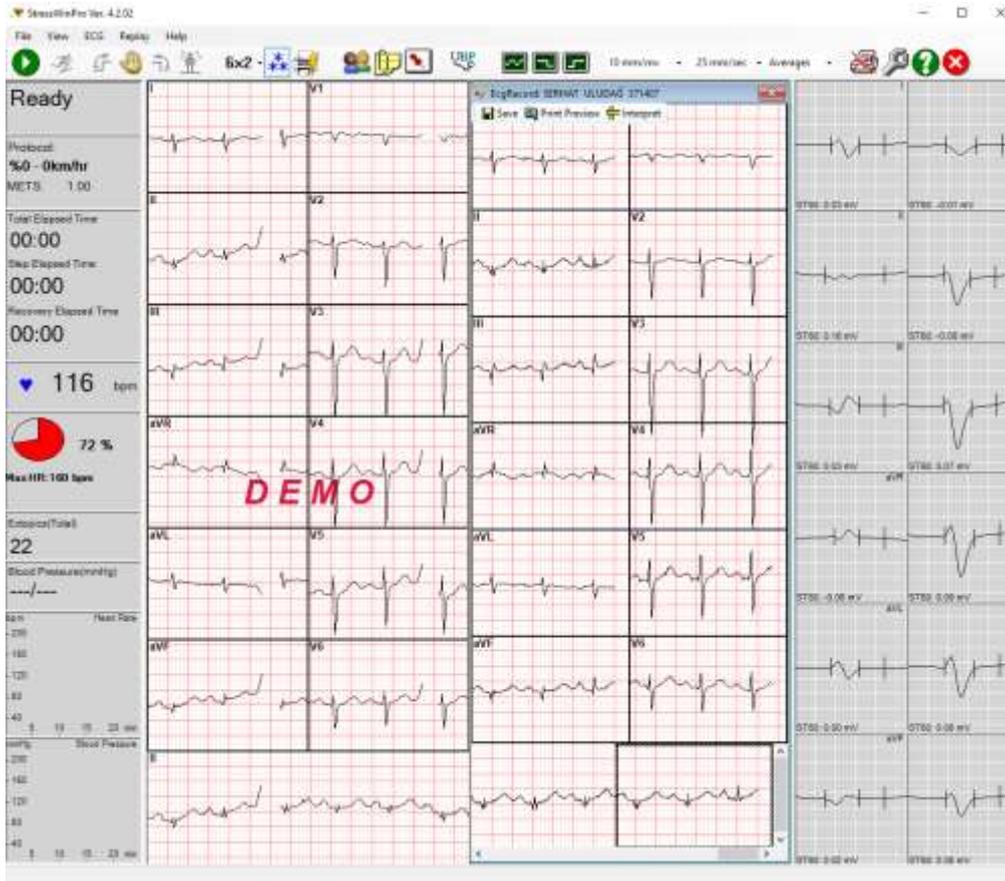


Figure 32. Freezing the ECG signals

ECG is continued to be displayed on the left

10 seconds of frozen ECG is displayed on the right

7.3.12. Quick Print (WIP)



This function is not fully developed yet, as of this version, and it is a work in progress. It is aimed to work similar to “Freeze” function, which is explained in Section 7.3.11, but providing the user with a print-out of the last 10 seconds of ECG data, instead of displaying it on screen.

7.3.13. Patient Info



Patient information can be viewed or edited by this control. At least one of the fields for ID, last name or first name must be entered before rest ECG is approved. You cannot change any of these 3 fields during testing since these fields are combined to form the folder name where test results are stored.

7.3.14. Remarks



Doctor’s remarks can be entered using this function.

7.3.15. Event Record



When this control is activated, an event record window pops up as shown in Figure 33. You can enter various data related to the event observed such as free text, blood pressure, etc. A snapshot ECG is automatically saved at the time when the control is first clicked and printed if print-out of events is selected at the “Setup” menu.

Figure 33. Evet Record Window

7.3.16. Blood Pressure



Blood pressure window is displayed when this control is clicked. If you have a SunTech Blood Pressure Monitor connected to your system, you can initiate a measurement from this window and results would be automatically entered by the system. If you measured the Blood Pressure manually, enter Systolic and Diastolic values in mm Hg units in the appropriate data entry boxes, shown in Figure 34. Once you have completed the blood pressure data entry and clicked “Ok”, trend graphics will also be updated.

Figure 34. Blood Pressure Window

7.3.17. Line Filter



This control applies 50Hz or 60Hz line filter on the ECG signal. Use “Setup” to select 50 or 60Hz option. Since filtering masks the quality of raw ECG signal, it is always a good idea to momentarily disable filters and check the quality of the unfiltered ECG signal.

7.3.18. EMG Filter



If there is excess noise due to muscle tremor, use this control to apply EMG filtering on the ECG signal.

7.3.19. Baseline Filter



This control activates baseline filtering on the ECG signal. Note that baseline filtering delays the ECG signal about 3 seconds.

7.3.20. Time Scale

Speed at which ECG are displayed can be changed by selecting different time scales such as 12.5, 25, 50 or 100 mm/sec. Use the time scale combo box or the related menu item to change ECG time scale. (Figure 35)

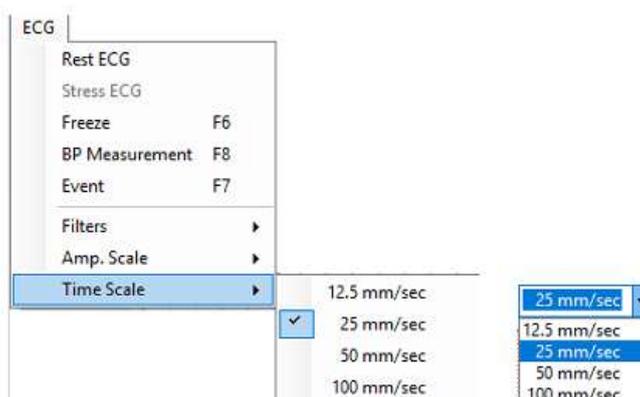


Figure 35. Changing the time scale

7.3.21. Amplitude Scale

Amplitude scale at which ECG signals are displayed can be changed by selecting different amplitude scales such as 2.5, 5, 10, 20 or 40 mm/mV. Use the amplitude scale combo box or the related menu item to change ECG amplitude scale. (Figure 36)

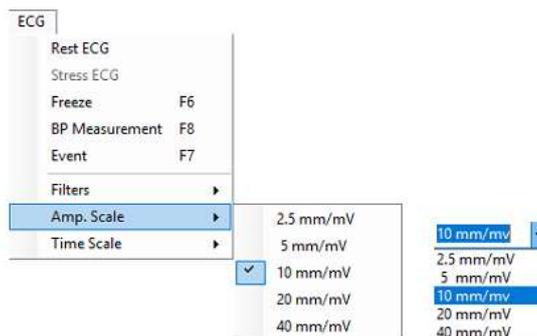


Figure 36. Changing the amplitude scale

7.3.22. Trends Graphics

By using the right bar combo selection control, you can view ST level and slope trends on the right bar instead of averages. (Figure 37)

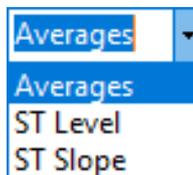


Figure 37. Changing the trends graphics

7.3.23 Enable/Disable Prints



This button enables or disables printing of the selected print-outs depending on the number of clicks.

7.3.24. Setup



Setup enables you to change various user selectable parameters through window shown in Figure 38.

If you open the Setup window during the test mode, some parameters may be locked to prevent changes. In this case open the Setup window on the Startup screen to access all parameters.

In the following section, Setup tab pages will be explained in detail.

7.3.24.1. General Tab Page

The **General tab** is shown in Figure 38.

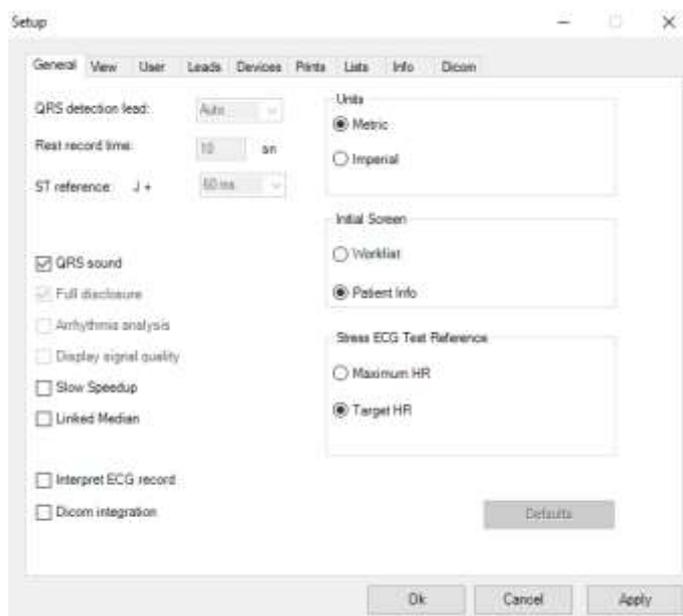


Figure 38. Setup Window General Tab Page

QRS Detection Lead: Auto QRS detection by default is done by majority voting on all channels. If the QRS is detected in more than half of the channels, then QRS is said to be detected. It is also possible to select QRS detection on a single channel.

Rest Record Time: Indicates the duration of rest ECG recording at the start of stress test. Default value is 10 seconds.

ST reference point: ST level is calculated at a selected distance after the J point. This reference point is adjustable between 10 – 80 ms.

QRS Sound: When a heartbeat is detected it is indicated by a beep sound which can be turned on or off using this option

Full Disclosure: All the raw ECG data during testing is recorded and saved if this option is enabled. Due to demand for hard disk and RAM memory space, this option is by default disabled.

Arrhythmia Analysis: Basic arrhythmia statements are indicated on the status bar when this option is enabled.

Display Signal Quality: The signal qualities of the channels are indicated on the status bar if selected. The channels with noisy signals are displayed in red color while the others are shown in green.



Slow Speed Up: It allows the user to speed up the treadmill iteratively if needed. This functionality is generally requested by the users that have difficulties to run on the treadmill.

Weight/Height: Metric or British imperial metric units can be selected.

Default:  This button is used to set all of the above values to default values.

Dicom Integration: To get information from the Dicom tab, it must be activated. The purpose of this structure is to access the structure where the patient information is stored and stored and the file containing the data from the patients is saved and stored.

7.3.24.2. View Tab Page

The **View tab** is shown in Figure 39.

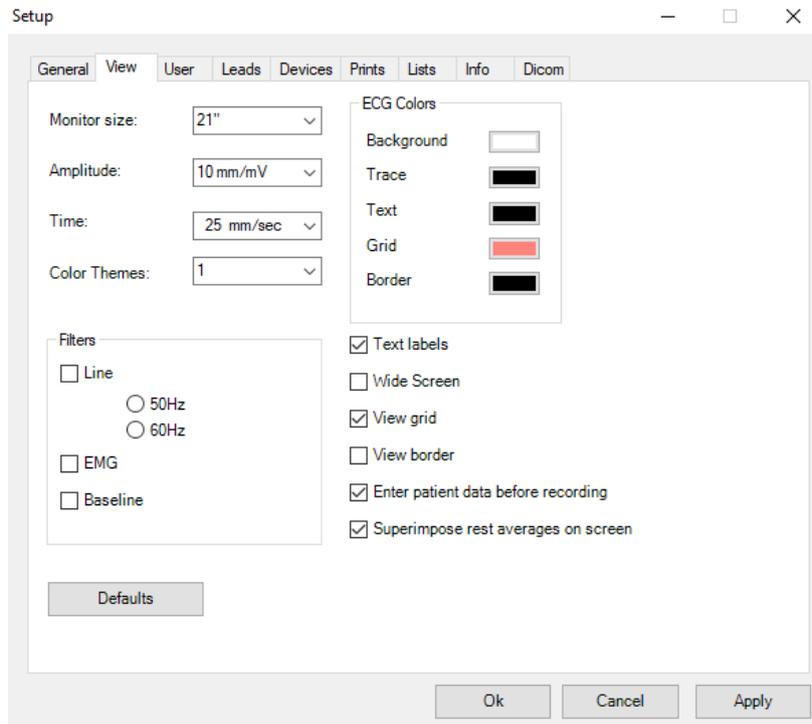


Figure 39. View Tab Page

Monitor Size: When monitor size is entered correctly, ECG amplitude and time scales on the screen will also be reflected more accurately, similar to an ECG on paper. Note that this adjustment is not related to ECG signals on printouts.

Amplitude Scale: 2.5, 5, 10, 20 or 40 mm/mV values can be selected.

Time Scale: 12.5, 25, 50 and 100 mm/sec values can be selected.

Filters: Line filter eliminates 50Hz or 60Hz interference from power line voltage. EMG filter eliminates interference due to muscle tremor. Baseline filter eliminates baseline shift on the signal due to patient and electrode movements. In a good recording none of these filters would be necessary.

ECG Colors: Colors related to displaying ECG signals such as background, trace, text and grid colors can be changed according to the user's preferences.

Wide Screen: Amplitude and scale of the ECG signal displayed on the screen are adjusted to a more approximate view when this option is selected.

View grid: Milimetric grid is superimposed on the ECG signal when this option is enabled.

View border: Border is superimposed on the ECG signal when this option is enabled.

Enter patient data before recording: if this option is enabled, a patient information window is displayed to enter the patient data when a new test is started.

Superimpose rest averages on screen: In rest ECG test, software calculates the average beats for each channel and stores them as a reference for stress ECG testing. If this option is selected, the average beats calculated for stress ECG and the rest ECG tests are drawn on top of each other.

Default: **Defaults**

This button is used to set all of the above values to default values.

7.3.24.3. User Tab Page

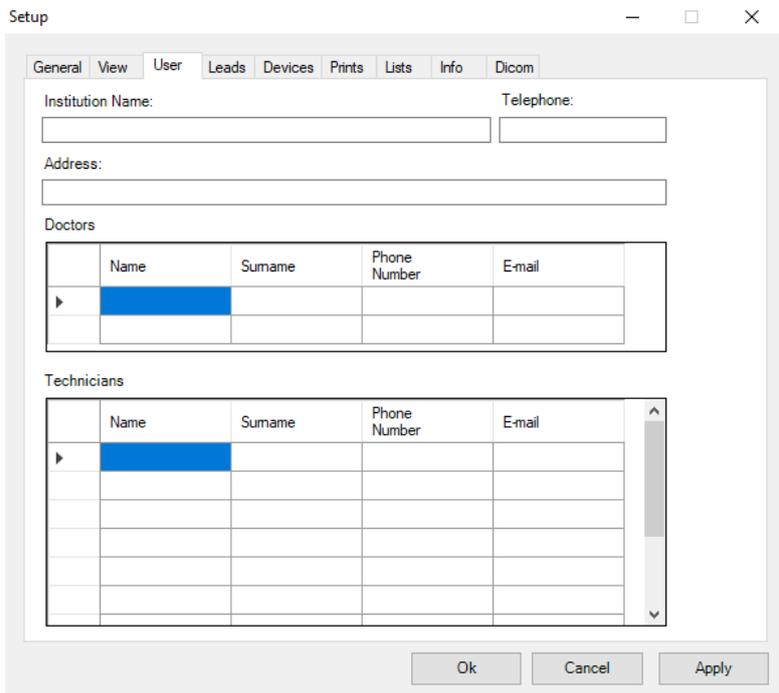


Figure 40. User Tab Page

This setup page enables you to enter information about the user. This information is printed on the cover page of the report. Here you can also change the location of data folder where the test results are saved. (Fig. 40)

7.3.24.4. Leads Tab Page

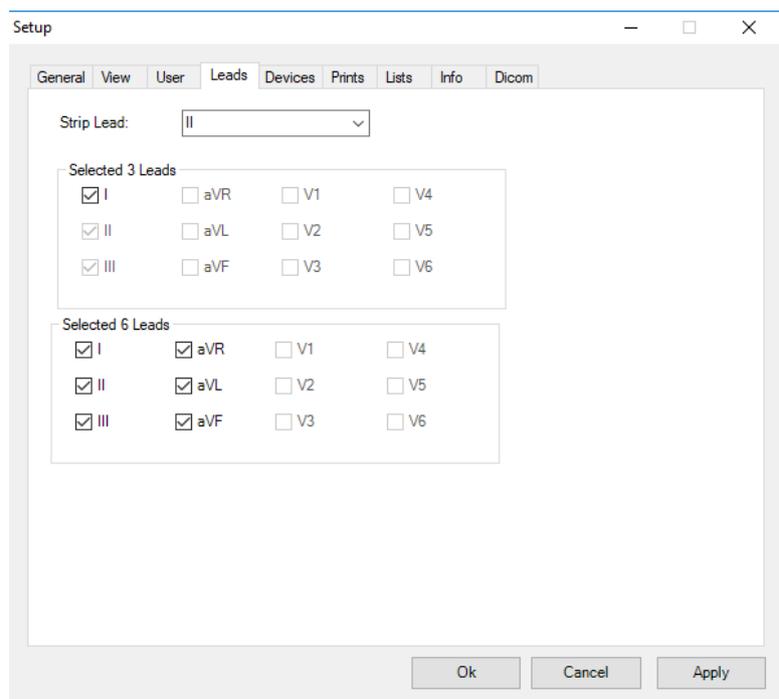


Figure 41. Leads Tab Page

You can select channels of your choice to be displayed in the view formats of 6x2 and 3x4 by using the page in Figure 41. You can also select the desired strip lead to be displayed at the bottom of the display in these view formats.

7.3.24.5. Devices Tab Page

The **Devices tab** is shown in Figure 42.

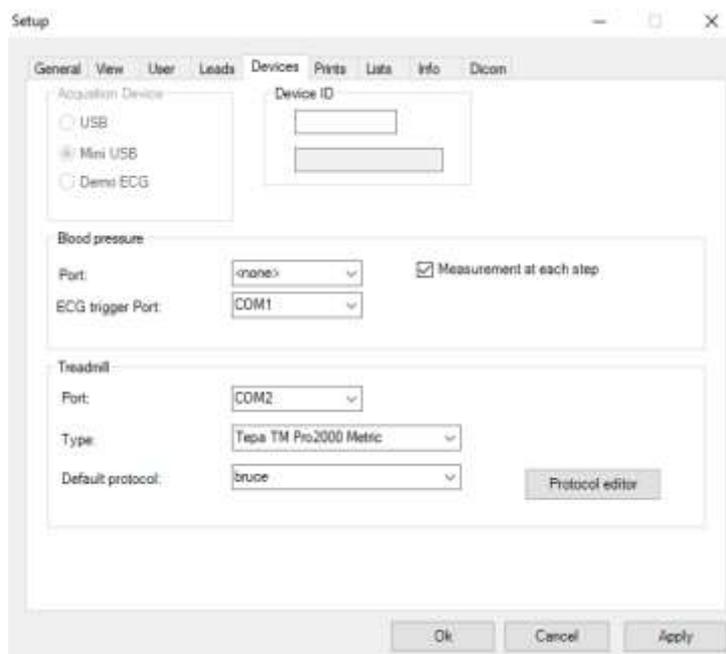


Figure 42. Devices Tab Page

Acquisition Device: You can also use StressWin Pro in demonstration mode without the ECG device. ECG data in “demo.scp” file is displayed as if data is acquired by the ECG device. You can also run your own selected SCP-ECG files in demo mode. For this, just rename your file as “demo.scp”.

Blood Pressure: SunTech dynamic blood pressure monitor adjustments can be done here. Refer to Section 4.3 for details.

Treadmill: You can select the RS232 port connection to treadmill, treadmill type and protocol to be used during the test.

Protocol Editor: There are a number of protocols that comes with the StressWin Pro. You may also create new protocols or modify the existing protocols using the protocol editor or select any of the protocols as the default protocol. Protocol Editor is easy to use and self-explanatory as shown in Figure 43.

Important Note: It should be noted that created protocols **must** be saved with “_ptc.xml” at the end of their name, using “.xml” extension alone is not enough, otherwise you might end up with a corrupt data file or no file at all.

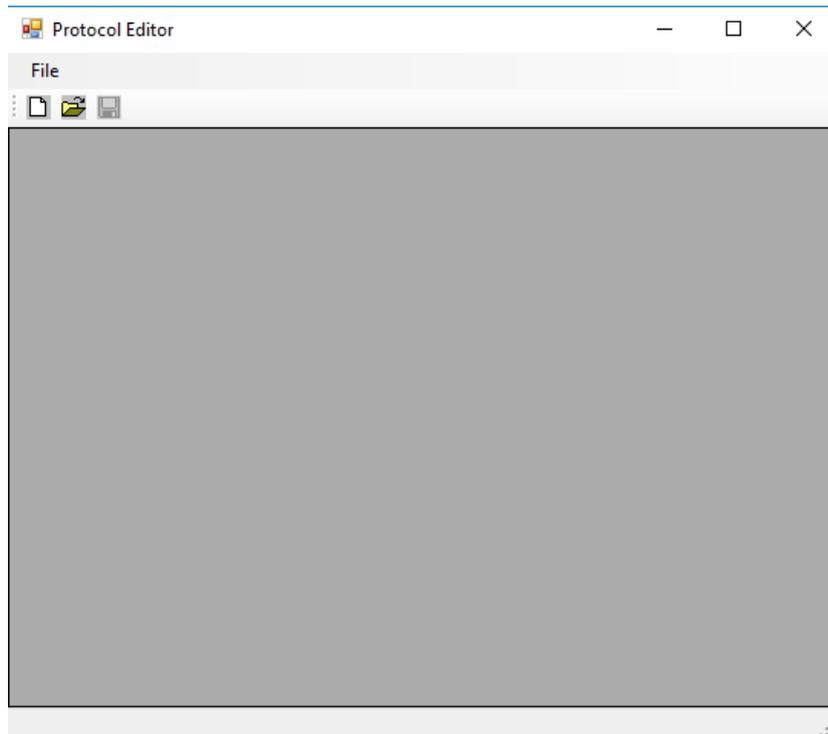


Figure 43. Protocol Editor

7.3.24.6. Prints Tab Page

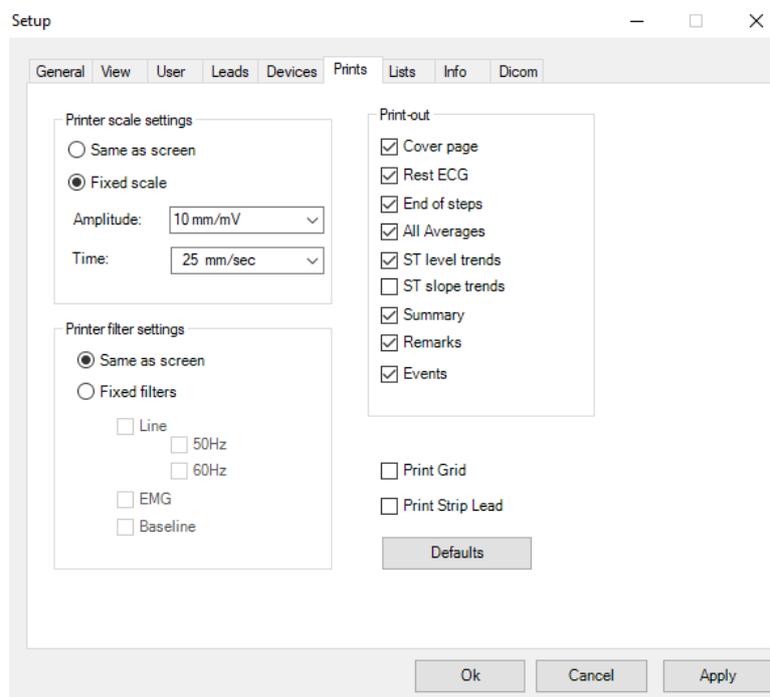


Figure 44. Prints Tab Page

This part of setup enables you to configure print-outs related options. (Figure 44)

Printer Scale Settings: If “Same as screen” is selected, print-outs will have the same time and amplitude scale settings as set on the screen. You can also select fixed time and amplitude scale settings regardless of the screen settings.

Printer Filter Settings: If “Same as screen” is selected, print-outs will have the same filter settings as set on the screen. You can also select fixed filter settings regardless of the screen settings.

Print-outs: Desired print-out pages are selected here. Even if you have not selected a particular page for print-out, you can always print this page later from the “Reprints” menu item.

Print Grid: If selected, millimetric grids will also printed on the paper. Since it slows down printing and consumes ink. It is better to use Kardinero/Tepa ECG paper with grids already on them.

Default:  This button is used to set all of the above values to default values.

7.3.24.7. Lists Tab Page

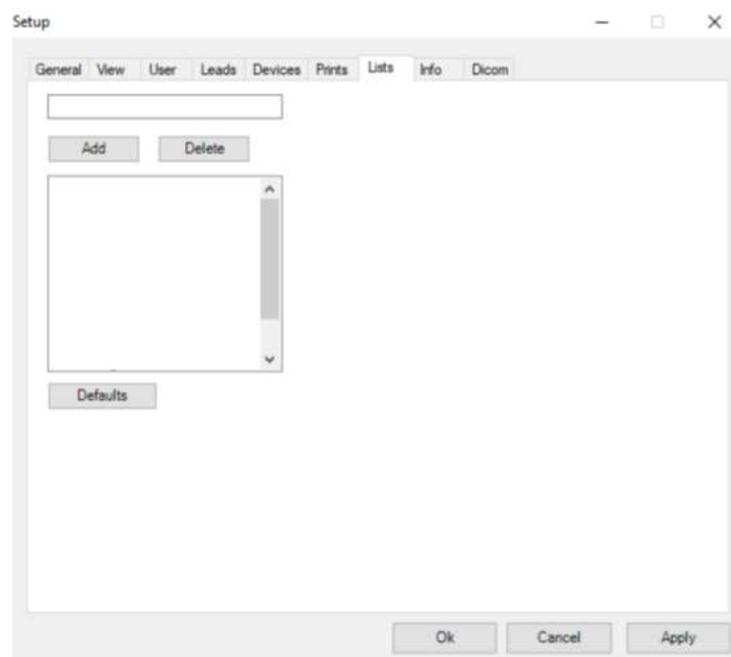


Figure 45. Lists Tab Page

During an event capturing and recording, you can enter free text information to describe the event. For common event descriptions, instead of typing, you can transfer the event description from a list. You can create your event description list from the Lists Tab Page. You can also use the default list provided by StressWin Pro. (Figure 45)

7.3.24.8. Info Tab Page

This tab provides information about the location of files obtained as a result of an effort record. Optionally, files can be saved to the desired location prior to recording, or you can change them to the desired location after recording. (Figure 46)

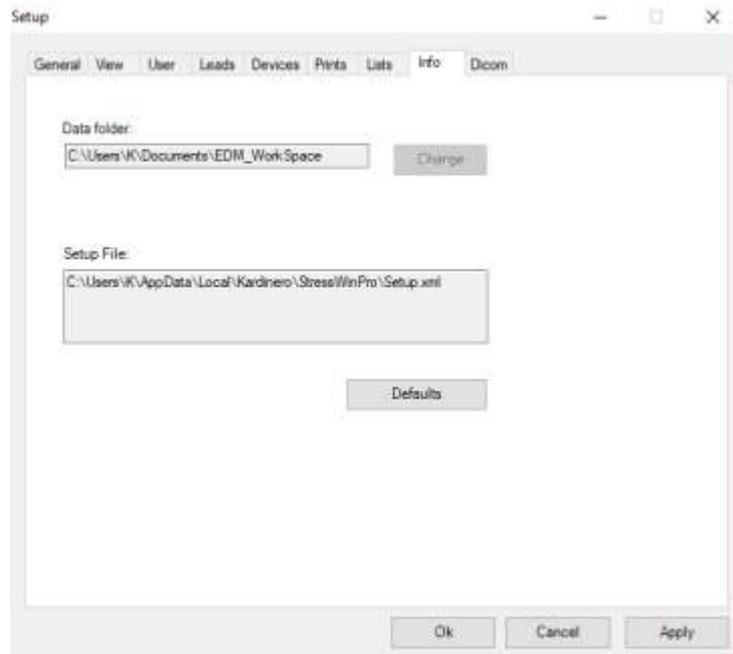


Figure 46. Info Tab Page

7.3.24.9. Dicom Tab Page

Before this tab can be used, 'Dicom Integration' must be marked in the 'General Tab' in the 'Setup' section. Otherwise, you cannot obtain information from the Dicom tab.

Dicom tab; The information in this section should be made according to the information given by the PACS system supervisor. Users can access the patient information and reports via the PACS network where the device is connected. (Figure 47)

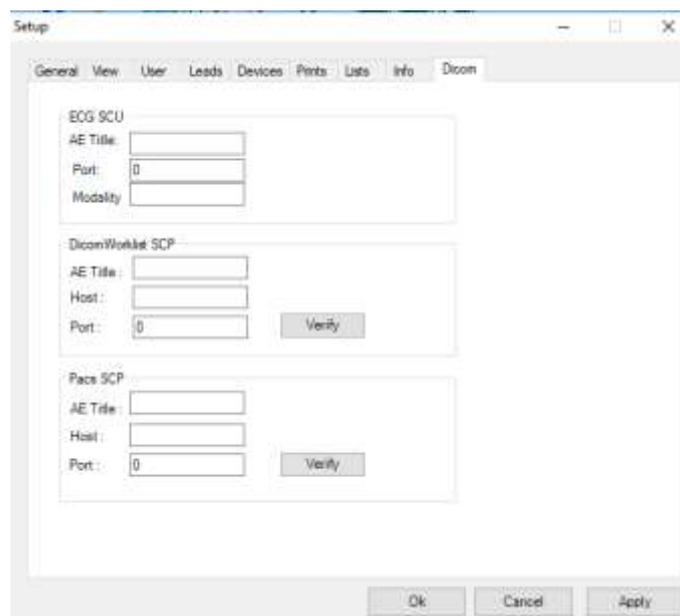


Figure 47. Dicom Tab Page

7.3.25. Averages and ST Trend Graphics

On the right side of the screen, averages or ST Trend graphics are displayed. Click the right bar selection combo box to select your choice of Averages, ST Level or ST Slope trend graphics. If you click any of the 12 regions displayed, that region will be enlarged four times. You can also assign any channel to any region by right mouse click. Averages and trends are updated on the screen in real time. (Figure 48- Figure49- Figure50)

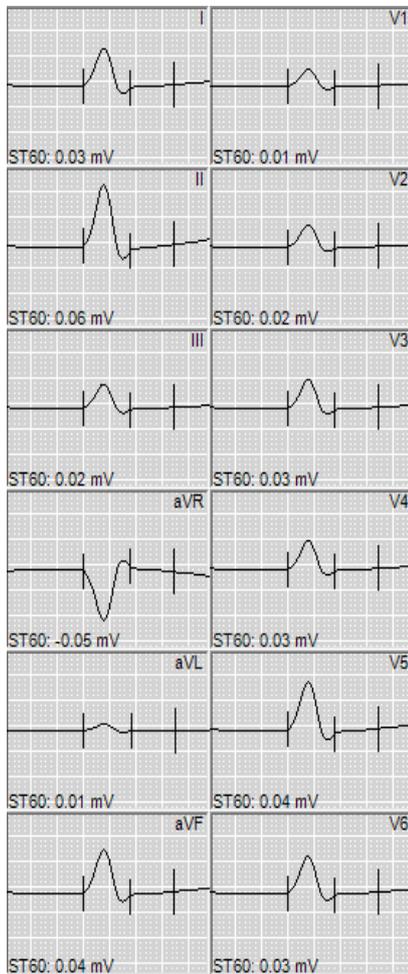


Figure 48. Averages

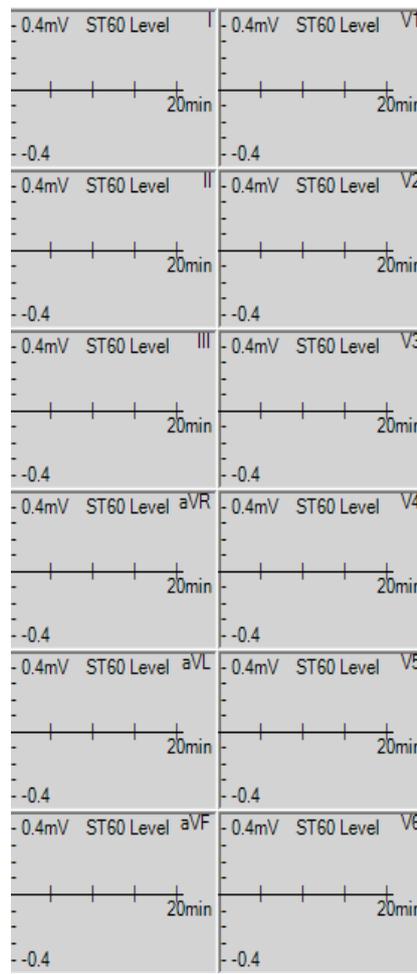


Figure 49. ST Level

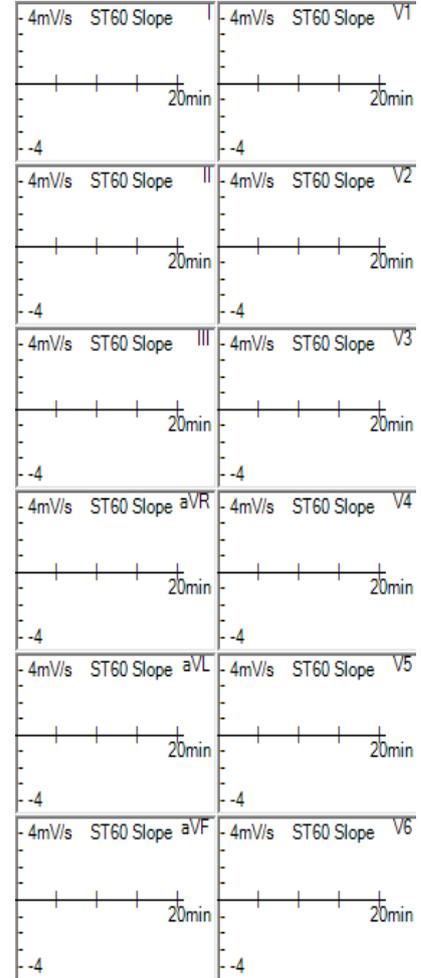


Figure 50. ST Slope

7.3.26. Information Bar

The **Information Bar** is shown in Figure 51.

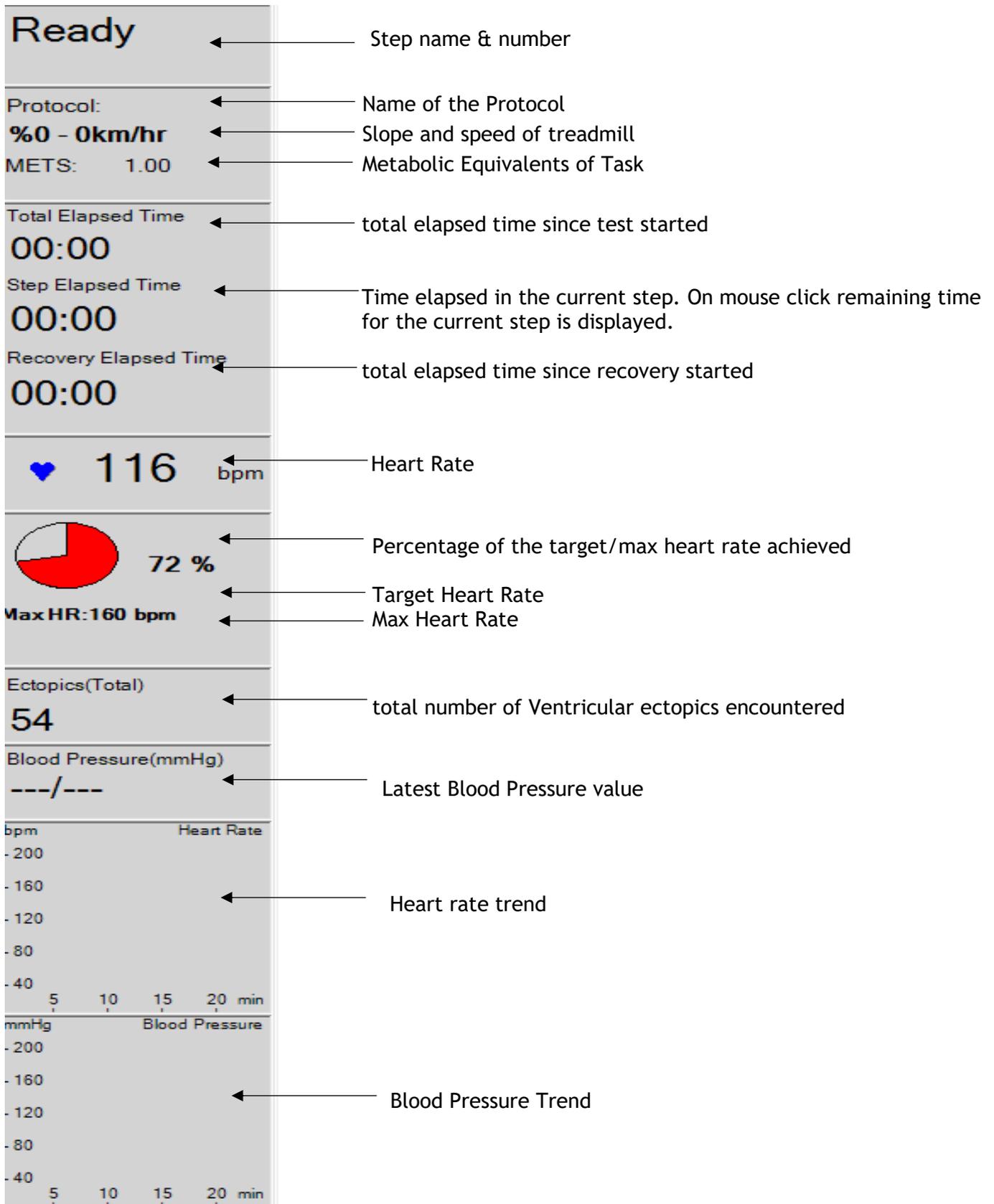


Figure 51. Information View

7.3.27. Close



During monitoring (i.e. before protocol steps have started), click this control to stop monitoring and go back to start up screen.

7.3.28. Stop



This button is similar in function to emergency stop on the treadmill. When pressed treadmill will be stopped. Not for routine use, must only be used in emergency situations.

7.3.29. Reprint

All recordings and test results are saved under the data folder specified in the User Tab Page of the Setup window. You can use the File -> Reprints menu item to print all or selected pages of the test report.

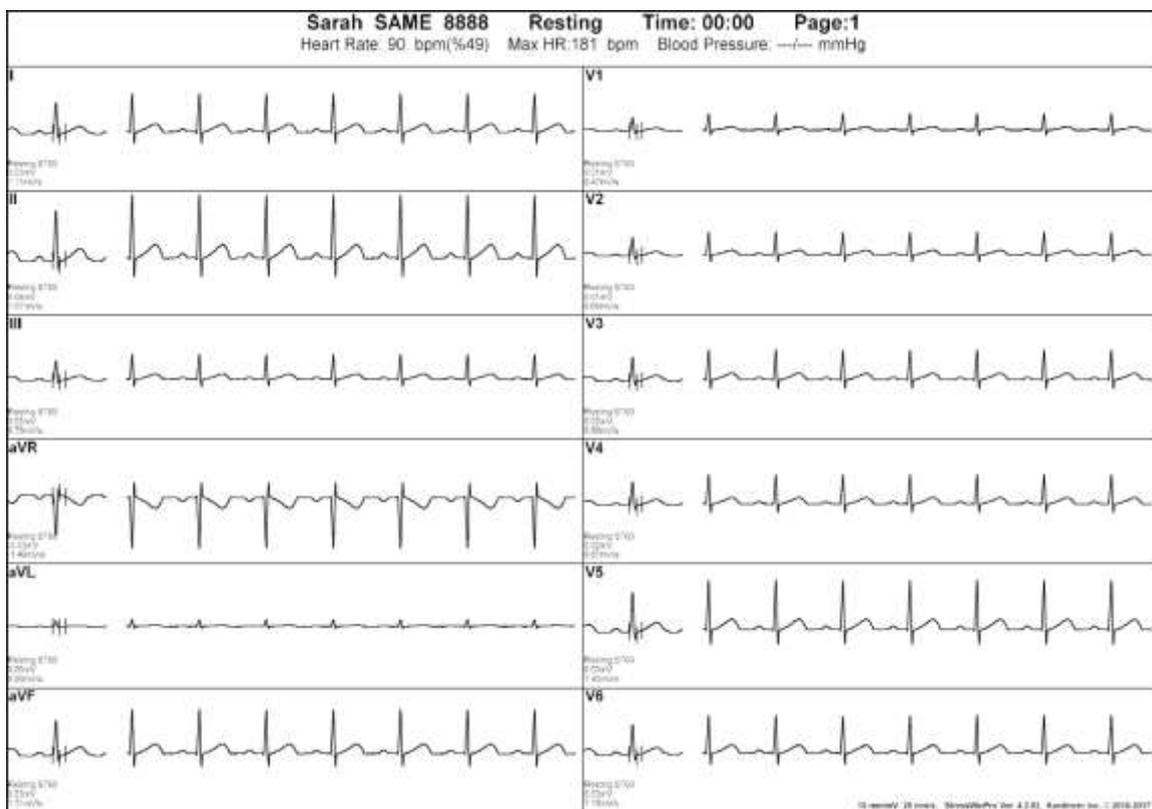


Figure 52. Report Print Page

The entries you receive with the StressWin Pro program are stored in the **Program Files \ Kardinero \ Data \.[RelatedPatientFile]** .StressWin Pro program you receive the program after you exit the program as output from the printer. The StressWin Pro program stores the current ECG signals as a good alternative for Microsoft Windows 64bit resolution graphics (Portable Document Format) and JPEG (Joint Photographic Experts Group). The files in this format are [relatedPatientFile] \ XECG \ [year-month-day_hour-minute-second]. The files are saved in the **“EDM_WorkSpace”** file in the ‘Documents’ section of your computer. You can access these graphics after registration with the Acrobat Reader PDF reader under Windows, you can look and print, or you can still print using Windows photo’s printing wizard. When you click on the JPEG or PDF file that you want to print, the supported PDF reader or Windows Photo Viewer will display your chart the way you want it. (Figure 52)

8. MAINTENANCE – TROUBLESHOOTING

8.1. Periodic Maintenance

Ars-EFOR Treadmill Exercise Test System does not require detailed technical periodic maintenance. But there are some simple maintenance and cleaning processes that have to be done by the user. These are:

- Visual inspection of ECG patient cable once per week in average
- Surface cleaning of system once per week in average

Cleaning of each of the system components should be followed as described below:

- Treadmill

Cleaning the belt (upper and lower surfaces) and platform once per month (according to the usage frequency, this process may need to be occur more frequently). Use a soft moist towel. Clean also the handles touched by the patients with the moist towel and apply a spray- surface disinfectant.

- ECG Module (ECG Master USB Module) and ECG patient cable

Clean the ECG module, carrying holder and belt and ECG cable with the soft moist towel in a gentle way without forcing the cables and grabbers, and apply a spray- surface disinfectant in general.

- Main computer unit, monitor, keyboard, mouse and system trolley

Clean all parts of the system computer and of the trolley using the soft moist towel. Use a “screen and TV cleaner” once a month for PC monitor. Special solutions for PC and monitor cleaning available in the market can be used.

- Connection and power cables

Clean all cables with the soft moist towel.

- Automatic Blood Pressure Monitor (optional)

If you also have an optional BP device, clean the BP device and BP cuff with the soft moist towel in a gentle way without forcing the hoses and cables. Apply a spray- surface disinfectant to the cuff.

8.2. Too Much Noise in ECG Signals

Too much noise in ECG signals is one of the problems frequently encountered in all ECG stress systems in general. Any of the problems mentioned below may have appeared during device usage. Thus, you must know the changes that have been just made before the problem has been appeared and whether a problem has been encountered before or not. Any device that has been connected to the same mains recently and that requires too much power (such as elevator, engine, air-conditioner, etc.) and any grounding related problems must be questioned. Principal reasons for noise in ECG signals are:

1. Defective patient cable: If the cable ends or parts are corrupted, cable must be changed with a new one. Repairing or attempting to repair the cable by the user is not safe. Only service staff authorized by Kardinero can decide whether the cable may be repaired or not.
2. System is not properly grounded; network to which the system is connected has grounding problems. The primary problem in the system grounding is insufficient network grounding. This must be done under the control of an authorized electrician. Poor quality and corrupted extending cables are one of the important problem sources. If necessary, outer grounding cable must be used.
3. Using poor quality electrodes. Many of the electrode manufacturers have special electrode models suitable ECG for stress test. For these models, consult your product provider.
4. Not using a bandage or something similar for fixing the electrodes: During stress ECG testing, it's advised to use net bandage or similar fixing to avoid the noise caused by the movement of cable ends connected to the electrodes on the patient's body and the movement of the electrodes' adhesive surface.

8.3. Image Resolution Troubleshooting

It supports the appropriate resolution of the video card on your computer that is given to you by Kardinero. However, if you need to reconfigure your system for any reason, you may not be able to provide the required

resolution without installing the appropriate video card device driver. Please follow the steps below carefully. Contact an experienced computer service support or Kardinero Technical Service.

8.4. Printer Troubleshooting

Printer Communication Control

If you are unable to print, there may be a communication problem with the printer. In this case, it is useful to check the connection cable. If you cannot solve the communication problem, contact Kardinero Technical Service Department.

8.5. Other Problems

An important majority of the problems you may encounter with your Exercise Test System are those caused by the noises due to the patient and network failures and by the differences in computer configuration or changes made in time. To have maximum efficiency of the system, you must use a well-grounded plug. One must be aware of the electrical parasites caused by power-consuming devices and systems nearby (for example elevator, X-rayed devices, air-conditioner, etc.).

8.6. Descriptions of the Signs- Figures

Descriptions of the signs used in this manual and in the device are below:

	Read the User Manual carefully before using the device		Conforming EU Medical Devices Directory, Notified Body BSI's number 2797
	Warning: High Voltage		Defibrillator signal protected inputs
	Manufacturer's address		

9. STANDARD PROTOCOL VALUES

Steps	Bruce			Bruce		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	2,7	10	3	1,7	10	3
2	4,0	12	3	2,5	12	3
3	5,5	14	3	3,4	14	3
4	6,8	16	3	4,2	16	3
5	8,0	18	3	5,0	18	3
6	8,8	20	3	5,5	20	3
7	9,7	22	3	6,0	22	3
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Modified Bruce			Modified Bruce		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	2,7	0	3	1,7	0	3
2	2,7	5	3	1,7	5	3
3	2,7	10	3	1,7	10	3
4	4,0	12	3	2,5	12	3
5	5,5	14	3	3,4	14	3
6	6,7	16	3	4,2	16	3
7	8,0	18	3	5,0	18	3
8	8,8	20	3	5,5	20	3
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Naughton			Naughton		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	3,2	0,0	2	2,0	0,0	2
2	3,2	3,5	2	2,0	3,5	2
3	3,2	7,0	2	2,0	7,0	2
4	3,2	10,5	2	2,0	10,5	2
5	3,2	14,0	2	2,0	14,0	2
6	3,2	17,5	2	2,0	17,5	2
7	4,8	12,5	2	3,0	12,5	2
8	4,8	15,0	2	3,0	15,0	2
9	4,8	17,5	2	3,0	17,5	2
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Ellestad			Ellestad		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	2,7	10	3	1,7	10	3
2	4,8	10	2	3,0	10	2
3	6,4	10	2	4,0	10	2
4	8,0	10	3	5,0	10	3
5	9,7	15	2	6,0	15	2
6	11,3	15	2	7,0	15	2
7	12,9	15	2	8,0	15	2
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Balke 1			Balke 1		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	5,3	2	1	3,3	2	1
2	5,3	4	1	3,3	4	1
3	5,3	6	1	3,3	6	1
4	5,3	8	1	3,3	8	1
5	5,3	10	1	3,3	10	1
6	5,3	12	1	3,3	12	1
7	5,3	14	1	3,3	14	1
8	5,3	16	1	3,3	16	1
9	5,3	18	1	3,3	18	1
10	5,3	20	1	3,3	20	1
11	5,3	22	1	3,3	22	1
12	5,3	24	1	3,3	24	1
13	5,3	26	1	3,3	26	1
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Balke 2			Balke 2		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	4,8	0,0	1	3,0	0,0	1
2	4,8	2,5	1	3,0	2,5	1
3	4,8	5,0	1	3,0	5,0	1
4	4,8	7,5	1	3,0	7,5	1
5	4,8	10,0	1	3,0	10,0	1
6	4,8	12,5	1	3,0	12,5	1
7	4,8	15,0	1	3,0	15,0	1
8	4,8	17,5	1	3,0	17,5	1
9	4,8	20,0	1	3,0	20,0	1
10	4,8	22,5	1	3,0	22,5	1
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Mc Henry			Mc Henry		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	3,2	3,0	3	2,0	3,0	3
2	5,3	6,0	3	3,3	6,0	3
3	5,3	9,0	3	3,3	9,0	3
4	5,3	12,0	3	3,3	12,0	3
5	5,3	15,0	3	3,3	15,0	3
6	5,3	18,0	3	3,3	18,0	3
7	5,3	21,0	3	3,3	21,0	3
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	ACIP			ACIP		
	Speed	Slope	Duration	Speed	Slope	Duration
	km/h	%	min	mph	%	min
1	3,2	0,0	3	2,0	0,0	3
2	4,0	2,0	3	2,5	2,0	3
3	4,8	3,0	3	3,0	3,0	3
4	4,8	7,0	3	3,0	7,0	3
5	4,8	10,5	3	3,0	10,5	3
6	4,8	14,0	3	3,0	14,0	3
7	4,8	17,5	3	3,0	17,5	3
8	4,8	21,0	3	3,0	21,0	3
9	5,0	24,0	3	3,1	24,0	3
10	5,5	24,0	3	3,4	24,0	3
R1	2,7	0	1	1,7	0	1
R2	0,0	0	1	0,0	0	1
R3	0,0	0	1	0,0	0	1

Steps	Ergo	
	watt	Duration
	Kpm/min	min
1	25	1
2	49	1
3	74	1
4	98	1
5	123	1
6	148	1
7	172	1
8	197	1
9	221	1
10	246	1
R1	25	1
R2	0	1
R3	0	1

Steps	Persantine		
	Speed	Slope	Duration
	mph	%	min
1	0	0	1
2	0	0	1
3	0	0	1
4	0	0	1
R1	0	0	2
R2	0	0	1
R3	0	0	1
R4	0	0	1
R5	0	0	1
R6	0	0	1

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Annex: B

LIMITED INTERNATIONAL WARRANTY

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Annex: C

EMC (Electromagnetic Compatibility) Declaration:

This device has been tested according to the standard IEC60601-1-2: 2016 Electromagnetic Compatibility for Medical Devices and verified that the measured values are within the specified limits. This device generates and uses radio frequencies and its energy, and if not used according to the instructions given in this manual, it may cause undesired effects on some other devices in the vicinity. If it is realized that this device affects other devices in the vicinity, following measures should be taken:

- Change the place of the device,
- Increase the distance between the devices,
- Connect the device to another power socket,
- Ask the manufacturer for support.

Mobile communication devices, wireless phones may affect this device's normal operation.

Using cables and accessories which are not recommended in this manual, may cause improper results.

Tests applied to this device are summarized below:

EMC (Electromagnetic Compatibility)- Electromagnetic Immunity Declaration- and Guidance for Professional Healthcare Facility Environment:

Kardinero Ars-Efor ECG Stress Test System is intended for use in a Professional Healthcare Facility within the electromagnetic environment specified below. It is not intended for home use. It is not designed for use together with HF surgical equipment. This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2.

Emission Tests	Application/ Compliance	Electromagnetic environment- guide
Radiated RF emissions EN 55011 (CISPR 11) Class B	ECG Module and Treadmill. 30- 1000 MHz. 3 m antenna; both V/H polarization. Passed the test. Complies.	The device may radiate high frequency electromagnetic waves in the environment because of the active electronic components- circuits. But the levels of such signals are very low and within the limits defined in the relevant standards.
Conducted emissions EN 55011 (CISPR 11) Class B	NA for ECG Module; treadmill power only. 0.15- 30 MHz Passed the test. Complies.	Kardinero PC based ECG and stress test system with treadmill is suitable to use in in all establishments including those directly connected to the public low-voltage power supply network.
Voltage variations and flicker emissions EN 61000-3-3 and Harmonic emissions 61000-3-2	NA for ECG Module; treadmill power only. Short term flicker 1.00 Long term flicker 0.65 Max. time 500 ms RSSV Change 3.30%; dmax 4% And harmonics measurement Passed the test. Complies.	Kardinero PC based ECG and stress test system with treadmill is suitable to use in in all establishments including those directly connected to the public low-voltage power supply network.

Immunity Tests	Applied to	Test parameters and compliance	Electromagnetic environment- guide
Electrostatic discharge (ESD) EN 61000-4-2	ECG Module and Treadmill; all inputs and insulating surfaces	Contact: 8 kV Air: 2, 4, 8, 15 kV Horizontal and vertical coupling planes 8 kV Disch. Imp.: 330 Ohm/ 150 pF 10 positive/ 10 negative discharges Passed the test. Complies.	Electrostatic discharges caused by any furniture, floor material, static electricity producing cloths etc may affect the quality of the signals acquired during the use of the device and may be harmful for the device. The device complies relevant standards in this respect. Floors of the room should be antistatic. The users and patients should avoid wearing static electricity producing material.
Radiated RF EM fields EN 61000-4-3	ECG Module and Treadmill enclosures	80 MHz to 2700MHz 3V/m – Antenna distance 3 m 80% AM at 1kHz sin	Such electromagnetic fields should be at low levels in a typical commercial or hospital environment. Wireless communication equipment during their

		Passed the test. Complies.	use should be kept out of the room of the system.
Electrical fast transient immunity/ burst EN 61000-4-4	ECG Module to com port N/A; Applied to Treadmill to power line input	Treadmill: 2 kV, 100 kHz, ≥ 60 s Passed the test. Complies.	Mains power quality should be that of a typical commercial or hospital environment- professional healthcare facility.
Surge immunity EN 61000-4-5	ECG Module N/A; Treadmill to power line input and protective gnd.	0.5 and 1 kV line- line; 2 kV line- gnd. o/p impedance: 2 ohm and 12 Ohm respectively; phase 0°, 90°, 180°, 270° Passed the test. Complies.	Mains power quality should be that of a typical commercial or hospital environment- professional healthcare facility.
Immunity to conducted Disturbances induced by RF fields IEC 61000-4-6	ECG Module N/A; Treadmill to power inputs	Field 3 V; 0.15 MHz- 80 MHz; AM 80%- 1 kHz sine; 1 % steps w. 2 s dwell Passed the test. Complies.	Mains power quality should be that of a typical commercial or hospital environment- professional healthcare facility.
Immunity to Power Frequency (50Hz) magnetic field IEC 61000-4-8	Treadmill and ECG Module enclosure	30 A/m; 50- 60 Hz Passed the test. Complies.	As the device makes sensitive measurements, it is not recommended to use this device in the vicinity of disturbing equipment. The device is not affected from the disturbances within the normal limits radiated from such sources (like transformers, motors etc). Such magnetic fields should be at known levels in a typical location of a hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	ECG Module N/A; Treadmill to power line input	Minimum 3 test events 10 s (min) 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, 3 Test cycles Passed the test. Complies.	Mains power quality should be that of a typical commercial or hospital environment- professional healthcare facility. If the users need it during power mains interruption, it is recommended that the system is powered from an uninterruptible power supply (UPS).

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