EKG Master USB

USER MANUAL

WinEKG Pro *Ver 5.0.08*

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SİPARİŞ BİLGİSİ	Sipariş
EKG Master USB-Mini Kit	700170
EKG Hasta Kablosu, Klemp uçlu	600322
EKG Hasta Kablosu, Banana	600310

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CAUTION

You must read before use

Class II- CF Type Defibrillator Protected Medical Device

CE 2797

Power supply: 5VDC / 240mA max from the USB Port of the PC.
Operating / Storage Conditions: Temperature: +5°C +45° Humidity: 95% max.

Before Use, Please Read this User Manual Carefully

The device is ECG System to use with a Personal Computer complying with the safety standard EN 60950.
There is no side effect of the device.
Device is to be used only by/or under supervision of dedicated medical personnel.
Please take care that electrodes, cables and other conductive parts of the device should not contact other conductive parts including earth.
Do not use PC-USB interface cable and patient cable other than supplied by the manufacturer
Possible explosion hazard if used in the presence of flammable anaesthetics.
Check the ground connection of your PC if it is mains powered, please ask authorized technician
Do not use the device in dusty environment, please keep liquids away. Never use solvents to clean the ECG and the accessories. Never use high temperature and radiation sterilisation techniques. (Class IP20 device)
Check all the connections of the equipment before use.
Let the authorized technician inspect the device at least once a year for maintenance.
This ECG device is not intended to use for direct (invasive) cardiac applications.
Please dispose according to Environmental and National guidelines.
Lifetime of the USB ECG Module 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 whether the device functions properly, please contact our Technical Service by phone, fax or e-mail.
There is no danger to use the EKG Master USB for pacemaker patients. Please take care to use and apply any stimulation equipment and signals including pacemakers at a sufficient distance from the ECG electrodes. In case of doubt, please disconnect the ECG and consult Kardinero.
The device is defibrillator protected. However it should be used only with Kardinero patient cable (600322 or 600310) otherwise defibrillator protection will not be effective and functional problems may occur. Please see Chapter 3.3. for the precautions regarding defibrillator use.
Intended use does not include use by the patient, it is not intended for home care use.
This device is not intended to use on patients under surgical environment and during the use of high frequency surgical equipment. If it has to be used for this purpose, the ECG electrodes should be located far enough from the neutral electrode of the ESU and from the operation site to avoid high frequency burns.
Kardinero has the right to make modifications in the software to increase the performance of the product. Please consult Kardinero or your dealer for your questions about the differences between this User Manual and the program version you use.
The ECG device complies with the requirements of EMC regulations. (See Annex C: EMC Declaration)

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1. Introduction

1.1. About Kardinero, Kardiosis and Tepa

Since 1986, our predecessor Kardiosis is one of the world's first PC based ECG manufacturers. With dealers in overseas, Kardinero is striving to achieve a high customer satisfaction. Tepa is also our brand, well known for a long period in the same field. Our R&D division is working to find solutions to the ever changing demands of the medical sector.
Thank you for choosing Kardinero products.

1.2. About the User Manual

This user manual describes the basic installation and use of EKG Master USB - Personal Computer Based Electrocardiography System. This manual also contains "Technical Manual" according to the basic standard IEC/EN 60601-1:2006; Medical electrical equipment- Part 1: General requirements for basic safety and essential performance, Clause: 7.9.3.
You can also access the user manual in the help part of your WinEKG Pro software as WinEKG Pro Help files.
As a PC based device, you need to install necessary software and then plug your EKG Master USB device to the computer's USB port. It can be used with any computer that is compatible with the basic requirements explained in the relevant chapter below.
Please read carefully the **"CAUTION"** page to learn some basic and important points about your device. Please do not attempt to install and use your system before reading this page. Contact addresses for product support are shown also in this page.

Important: Kardinero has the right to make modifications in the software to increase the performance of the product. Certain features described in this manual may not be present in your product depending on the version of your hardware and software. Please consult Kardinero or your dealer for your questions about the differences between this User Manual and the program version you use.

Basic system description, technical specs, accessories and the use of the accessories are explained in the first chapter. Please make sure to use recommended accessories as explained in this chapter.
In the second chapter, requirements for PC, software and printer are explained. Please consult Kardinero if you have any questions regarding your PC configuration; Kardinero technical personnel is ready to reply your questions to make sure that you will install and use your device in a proper way.
IMPORTANT: In this manual, the pictures for some of the monitor screens are printed with a suitable colour pattern instead of the recommended default in the program, to get a better and clearer printing.
Third chapter contains the information on 'how to install your device', for both hardware and software installation. You will be able to install your software and hardware step by step following the instructions given there. Thanks to its flexible and user friendly hardware and software structure, the installation of EKG Master USB will be performed and completed easily in a couple of minutes. Once you have installed your software, your device will be identified automatically every time you plug it in and will be ready to run the WinEKG Pro software.
In the fourth chapter you will find the explanations for your ECG software. The setup of the parameters according to your preferences; the use of the menus, buttons and software tools are included in this chapter.
When you are in the fifth chapter, this means that you are ready to perform ECG recordings and to review previously recorded ECG data. The information on how to make the connection of the electrodes, the placement of the electrodes and the steps of getting a proper ECG report can also be found in this chapter.
In the chapter six, you will find some troubleshooting hints. Problems you can encounter during the use of your EKG Master USB and how to fix them are explained. The problems that you cannot solve alone have

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to be handled by an authorized service technician. Please consult your dealer or Kardinero directly in case of any difficulty.
Chapter seven contains the information for “Technical Manual”. This is according to the basic standard IEC/EN 60601-1:2006; Medical electrical equipment- Part 1: General requirements for basic safety and essential performance, Clause: 7.9.3. The replaceable parts of your product are described in this chapter. The ECG module inside does not contain any serviceable parts which can be replaced by the client or by any technician. Only patient cable can be replaced in case of any defect. Please contact Kardinero service department for your service needs.

2. EKG Master USB

Your EKG Master USB Electrocardiography kit contains following items. The view of the device with patient cable and USB connection cable connected is shown in Figure 1. Please check first that all of the necessary parts listed here are included in the kit:

- EKG Master USB acquisition device with PC- USB connection cable
- Installation Software CD (Standard 12 leads)
- 10 lead “defibrillator protected” patient cable
- User manual
- Set of disposable ECG electrodes
- Optional item: Banana cable with reusable electrodes instead of clamp type patient cable and disposable electrodes

Please read carefully how to install and use your ECG hardware and software for proper operation of your ECG. Please contact your dealer or ask Kardinero through the addresses given in this manual for the nearest service centre.

Figure 1. EKG Master USB mini device

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2.1. PC System Requirements and Adjustments

EKG Master USB is a PC based ECG device, operating through the standard USB (*U*niversal *S*erial *B*us) port of a personal computer. The computer can be any type of personal computer (PC), either desktop or notebook with Windows operating system, it only has to have a suitable USB port for the connection of the device, and it has to meet some basic hardware and software specifications which are typically common for today's PC's. The connection of the device to the USB port is very simple and this connection is performed with full speed USB cable on your ECG acquisition module. The recommended minimum specifications for the PC hardware and software are described in the second chapter.

As the ECG device is used through the connection to the PC, and through running a special software, the user needs to have a basic approach by means of personal computer use and literacy. Using the ECG Software is as simple as using any other commercial software like word processors or PC games. On the other hand, the user must have sufficient clinical experience of using ECG machines.

Technical specifications of your ECG device are given below:

EKG Master USB Mini Device Hardware:

- Class II- BF Type Medical Device
- PC USB (2.0) Compatible
- Power supply requirement: uses 5V from USB port at 240 mA ± 10% maximum current.
- Suspend current less than 500 µA (±10%)
- 12 channels online acquisition,
- Standard 12 leads: DI, DII, DIII, aVR, aVL, aVF, V1-V6.
- Dimensions: 113x80x30 (mm) (±3%)
- Sampling rate: 4000 sample per second max per each channel, software controlled
- Frequency response: 0.05 (time constant: 3.2sec) - 300 Hz (3 dB cut-off)
- Common mode rejection ratio (CMRR): 120 dB
- Sampling sensitivity: better than 0.4 µV
- 16 bits A/D conversion over full dynamic range
- Defibrillator protected input circuits together with accompanying Tepa/Kardinero "special" patient cables
- High level power isolation: leakage currents less than 10 µA
- Designed and produced according to the EN60601-1 patient safety standards when used with the Tepa accessories and with a PC complying with the safety standard EN60950

2.1.1. Hardware Requirements

Your EKG Master USB device should normally run together with any personal computer which has a standard USB port and which is complying with the safety standard **EN 60950**. We recommend for the maximum satisfaction of your product, to have one of the newest generations of the computers, which also has a high speed processor, a large capacity - higher speed hard disk, high capacity of RAM, a good graphics adapter supporting high resolution screens like 1280x1024. Other devices like modem, sound card, network card etc. are not essential for ECG acquisition.

Minimum PC configuration to use the ECG system in a proper way is listed below. Your device may operate also in some systems below the given characteristics, but you may have problems to view the signals in a proper way and to run the program safely. The minimum requirements may differ according to your PC's other hardware and software. If you have questions regarding this subject, please contact your computer consultant or Kardinero.

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- Compatibility to the EN 60950 standard
- Minimum one empty USB standard port
- Minimum processor speed: 1.6 GHz
- Minimum HDD capacity: We recommend to have a HDD reserved for ECG of minimum 40 GByte.
- Minimum RAM capacity: 2 Gbytes
- Minimum graphics resolution: 800x600 is the minimum. Best operation will be in 1280x1024. Minimum 16-bit colour is recommended.
- Monitor: For desktops 15" will work. Larger screens are recommended. For convenient use, colour monitor is necessary. For the notebooks, 14" will be sufficient, larger screens are recommended. Netbooks: 12" can be used.
- Installation files can be copied via CD drive or flash memory. Internal or external CD/DVD writer is recommended for archiving.
- Internet connection via LAN is recommended for ECG data transfer and other remote support options.

Important: We recommend using an "uninterruptible power supply (UPS)" for desktop PC's to prevent data loss in case of power interruption.

There is no need to keep your EKG Master USB always connected to your computer. You may plug the USB connection cable whenever you want to use your device, even when the PC's power is on. You only have to care to run the software after you have plugged the device.

2.1.2. Software Requirements

Similar approach for the hardware explained above also applies for the software requirements. We recommend using one of the most recent and up to date version of Microsoft Windows operating systems. There are no limitations to use other software in the computer you are using for the EKG Master USB.

You only have to take care not to run the programs at the same time you are running ECG. Although there are no specific situations, this may create delays and improper operation of the software. We recommend you to close all the other programs when you run WinEKG Pro software. The software may prompt warning messages in such cases.

****NOTE:** EKG Master USB device and WinEKG Pro software are not compatible with MacOS, UNIX or Linux or other open operating systems. It is designed to run under Windows XP/ Vista/ Windows 7 operating systems.

2.1.3. Power Requirement

For your EKG Master USB device the power supply requirement is 5V from USB port at a maximum current of 240 mA ± 10%.

PC and printer to be used should be supplied according to your requirements.

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2.2. Recommended Accessories

2.2.1. ECG Patient Cable

EKG Master USB device must only be used with the patient cable supplied in the kit. This cable is specially designed and manufactured to meet the requirements of the safety standards by means of defibrillator protection, low patient leakage currents and a proper signal quality. Using other cables and/ or modifying or repairing cables by unauthorized personnel may cause improper operation and violates safety measures.

2.2.2. ECG Electrodes

EKG Master USB device must be used with good quality electrodes, meeting the requirements of standards and having CE mark, to assure a high signal quality. Kardinero strongly recommends using standard snap type disposable electrodes for a better signal quality and hygiene. A sample set of the electrodes is included in the kit. The user may select any brand of the similar type electrodes among several suppliers, considering the price, quality, performance and the availability.

Kardinero optionally supplies also set of reusable electrodes: metal clamp electrodes for the extremities and suction - bulb electrodes for chest leads. Experienced users can use these electrodes, but they must pay special attention to keep them clean to avoid transfer of skin contamination among the patients. For such reusable electrodes, Tepa has the patient cable- with banana plug tips option, which is suitable to use the ECG (also compatible to use together with defibrillators).

2.2.3. USB Interface Cable

The cable to use between EKG Master USB and your personal computer is tied and soldered internally to the ECG Device. This cable is a full speed PC - USB interface cable with a length of minimum 4,8 meters, with a ferrite filter located close to the device, and it has extra thick power supply wires. In case of any problem with your cable, (i.e. broken cable) please contact your EKG Master USB supplier or nearest Kardinero service station.

Important: In case of service need, the cable can only be replaced with a cable with the same specifications stated here and by an authorized service station. The cable specification shall be: the length between 4 to 5 meters; wire diameters at least AWG24 for the power supply section and AWG28 for the data signal section, and with an EMC filter.

2.3. WinEKG Pro Software Specifications

- Windows 7/8/10 compatible
- 12 leads real time and simultaneous acquisition and monitoring of ECG signals
- User selectable and configurable signal display and printout formats: 6x2, 3x4, 12x1, 6x1, 3x1 and 1x1.
- Long term recording up to 1 hour
- Continuous monitoring
- Software filters: EMG Filter (low pass); Base-line Filter (0,5 Hz high pass); Line Interference Filter (50 or 60 Hz Notch)
- Display signal gain: 5, 10, 20, 40, 80 mm/mV (±5%) (According to the grid)
- Display time scale: 6.25, 12.5, 25, 50, 100 mm/sec (±5%) (According to the grid)
- Selectable display colours for background, signal and grid
- ECG print-out on normal A4 paper (also possible on normal millimetre grid paper)
- ECG data archiving (in SCP-ECG, JPEG and PDF formats), reviewing and re-reporting

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- Memory need for archive: approximately 320 Kbytes for 20 seconds of 12 lead ECG record at 1000 sample/sec. (2000 records per 1GB hard disc capacity)

2.4 Using a Printer

Any Windows compatible printer can be used to get an ECG print out. You can use the EKG Master USB for monitoring and archiving, without having any print out. You can connect your printer any time you want and get your printouts.

We recommend using laser printers. Recommended minimum resolution is 600 dpi or higher. Dot matrix printers are no more recommended. Please also check that your printer software is installed properly and selected as the default printer. You can find detailed instructions for the installation of the printer in your "Operating System's Manual" and your printer's "User Manual". In case of any doubt, please contact your computer and/or printer supplier or nearest Kardinero office.

Using a virtual printer or pdf printer on your computer, you may save your ECG records in picture or pdf formats. We recommend pdf printers' records archival for a convenient record platform.

3. EKG Master USB DEVICE INSTALLATION

Important: If you are installing your device for the first time on this PC, please perform the software installation first!

3.1. Software Installation

Software installation will be performed using the installation software CD included in your EKG Master USB kit or downloaded from a reference link. The installation process is a simple process like any other commercial software installation, easily performed through following the instructions on the PC screen. Please place the CD in the tray of the CD drive of your PC first. Normally, the CD will automatically run the setup program.

****NOTE:** If your PC's CD drive is not set to run programs automatically (Autorun enabled), installation will not start automatically. If the setup program does not start automatically, please "Open" the CD drive under "My Computer". The installation program is located under the root directory of the CD drive, and the name of the program is "Setup.exe". Please "execute" this program and follow the commands on the screen.

****NOTE:** If your PC's USB Disk drive is not set to run programs automatically (Autorun enabled), installation will not start automatically. . If the setup program does not start automatically, please "Open" the USB Disk drive under "My Computer". The installation program is located under the root directory of the USB Disk drive, and the name of the program is "Setup.exe". Please "execute" this program and follow the commands on the screen.

IMPORTANT: WinEKG Pro software installation wizard checks your system for .NET Framework. If your computer does not have .NET Framework package, this wizard installs it into your system. .NET Framework enables you to operate software developed on Microsoft .NET. For you do not need to install .NET, it is already configured in the operating system. Please ask your dealer or PC consultant for your questions and problems.

- The first window after beginning the installation is the "Welcome" screen as shown in Figure 2. Please proceed with the selection "Next > ". Following screens are briefly described below.

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Figure 2. Beginning with Installation

After pressing the tir Next usu button, the ık Setup Wizard göster box will be displayed. Click '' Next > "to continue the installation. (Figure 3)

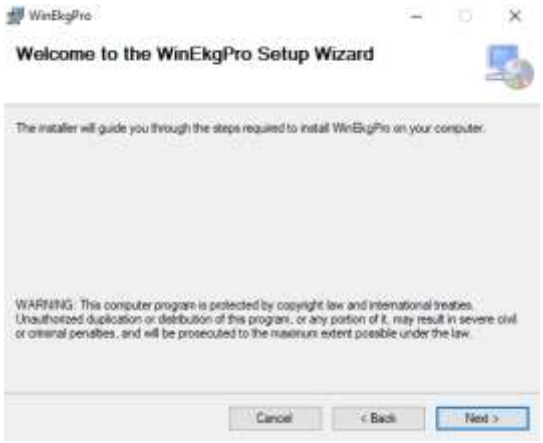

Figure 3. WinEkgPro Setup Wizard Window

You will then be asked which directory (folder) you want the program to install. The default value for this directory is C: \ Program Files \ Kardinero \ WinEkgPro \. You can change the name of this directory or you can accept the default value. Select "Just me'' if you want to use the program only and select " Everyone'' if it is to be used by other users. Press basın NEXT İşlem when you are finished. (Figure 4)

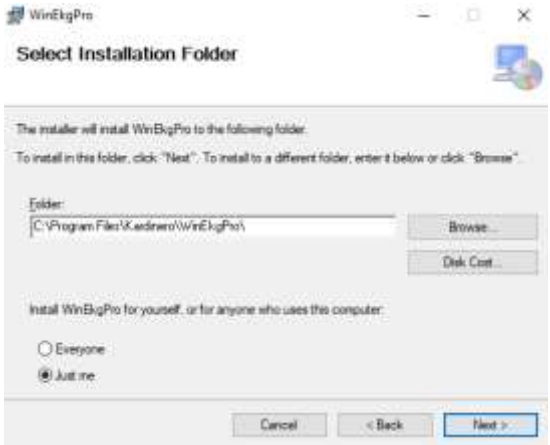

Figure 4. Installation Index Locator Window

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The on-screen window indicates that the installation wizard is ready to install WinEkg Pro on the computer you are currently installing. Click ‘’Next>’’ to start the installation. (Figure 5)

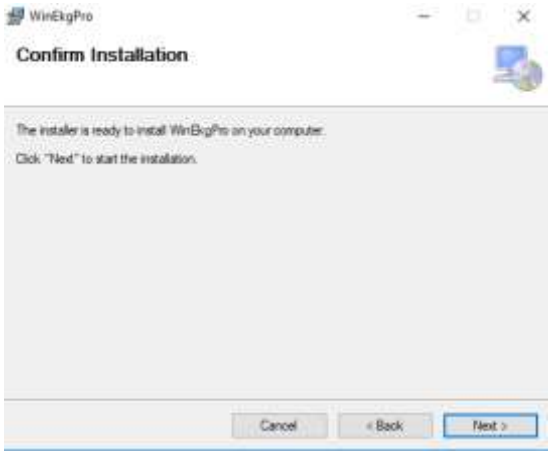

Figure 5. Setup Verification Window

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’’ to cancel the installation. Contact your authorized dealer. If you agree and agree, click ”I Agree“ and click ” Next > “. (Figure 6)

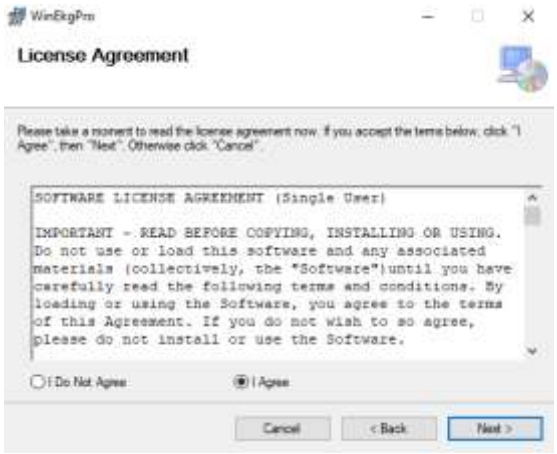

Figure 6. License Agreement Approval Window

After this process, WinEkg Pro program installation and copying the files of the program to the computer is in progress. Please wait until copying is complete. (Figure 7)

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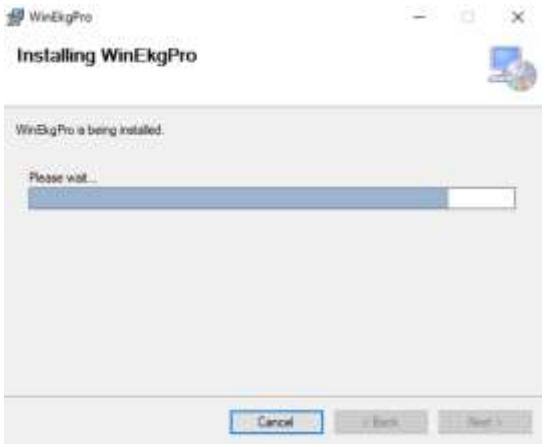

Figure 7. Installation Progress Window

On the screen to complete the installation process, the following window with "Close" button. (Figure 8)

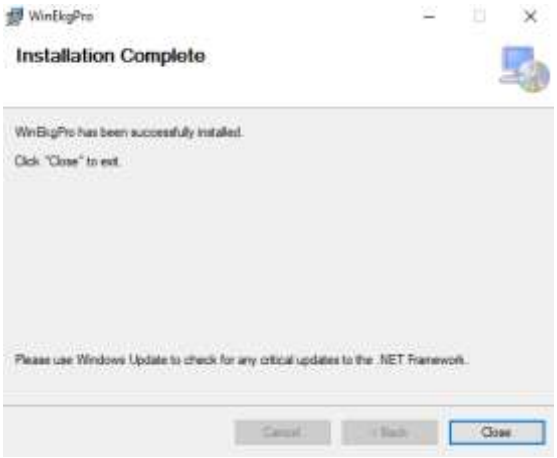

Figure 8. Installation Completion Window

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

3.1.1. The Removal (Uninstall) of the WinEKG Pro Software from your Computer

If you try to perform the installation once again after the WinEKG Pro is already installed, it will automatically ask you to confirm the “removal of the program”. If you select “Yes”, WinEKG Pro software will be removed from your PC. You can repeat the installation again to re-install the ECG software. You can uninstall the software using “Control Panel- Add or remove Programs”. (Figure 9)

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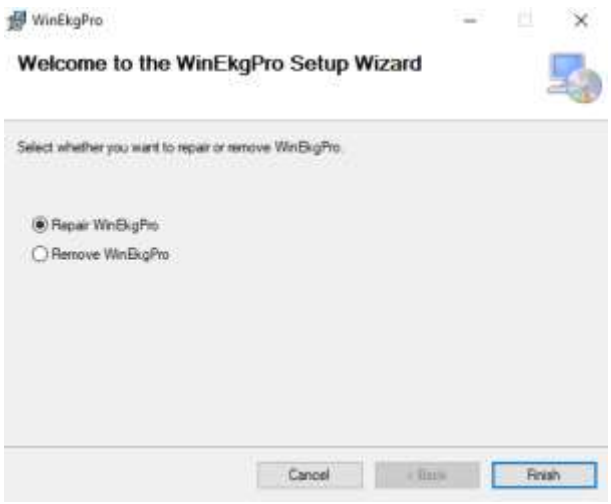

Figure 9

3.2. Hardware Installation

Hardware installation of the EKG Master USB is straightforward, like any other well-known USB port connectable PC peripheral devices. The USB connection cable is already hardware - mounted on your ECG device. Depending on the type of the computer you are using, USB port connector is located on the rear panel or on one of the side panels of the PC. There may be more than one USB connectors on your computer; you can easily identify the USB port connector, looking at the tip of the USB connection cable of your device.

For the computer connection, you also can use a standard USB hub, if you have other USB devices more than the number of built-in-connectors on your computer. In this case, you can plug your EKG device's USB cable to the socket on the hub, which has a similar connection to the computer.

Please refer to your PC's user instruction if you are not familiar with the USB port connector. Please call for assistance in case of any doubt.

To have a good quality ECG signal, your PC's power connections and the grounding of your power outlets should be made properly. Please ask a dedicated electrics technician if you have problems with your mains and grounding.

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Important: You do not need to keep your EKG Master USB always connected to your computer. You may plug the USB connection cable whenever you want to use your device. You only have to care to run the software after you plug the device.

If you use a notebook, please make sure whether its battery supply allows you to use your EKG device without mains connection. You can check this by pulling out the power cable while you are running the EKG program with EKG Master USB device connected. If the program fails to continue and gives a warning like “no device found”, it means that PC does not support USB power with its internal battery. In this case, you should use your EKG device while the computer always mains power connected. Please call Kardinero for support if you have any trouble.

The only indicator on the EKG Master USB device is the green LED on the USB cable side. This LED is shown in Figure 1 Whenever the device is plugged in, LED lights **ON** momentarily to indicate that the PC recognizes the device. While the program runs, this LED lights **ON** to indicate that it is being used by the application. When the user exits the program, LED turns off to indicate that the device is not being used.

3.3. Installation of the Accessories

The ECG cable in your kit is to be connected to the ECG cable socket on the EKG Master USB device. This connector is a 15 pin D-sub miniature socket. Fasten the connector using two screws on the edges.

Important: Please only use special Tepa ECG Patient cable what is included in your EKG Master USB Kit. Using other cables may cause improper functioning of the system. It may also result in critical violation of defibrillator pulse protection properties of the device. Consequently this may damage the EKG device and the computer.

Important: Please plug the patient cable firmly into the socket on your EKG Master USB device, and tighten the screws.

Please also decide what type and which brand of disposable ECG electrodes you will use. Normally EKG Master USB device is supplied with snap type disposable ECG electrodes. The tips of the patient cable are suitable to any type of the snap- connected standard electrodes. Please use one of the similar types of the disposable electrodes from your local dealers. Please make the selection considering quality- price- and availability of the electrodes. Please also take care that the electrodes you are using have CE mark, and/ or your local accreditation requirements.

You may use optional reusable metal electrodes. Kardinero also supplies these electrodes as option if requested. These electrodes can also be connected to your snap type ECG cable. You can also order banana type ECG cable from your Tepa products dealer, if you will always use reusable electrodes. Kardinero recommends using disposable electrodes for hygiene.

Please also decide on the type of the printing paper you will use. We recommend you to use suitable millimetre grid A4 size paper, to save printer ink or toner and to have a shorter printout time. Otherwise, you can have also the grid printed together with the signals. Please refer to Chapter 4.4.1 to enable the printing of the grid from your printer.

After these steps, you are ready with the hardware installation of your EKG device. Please check the printer connection of your computer, if you want to have printouts.

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4. WinECG Pro Software

How to use the 12-channel ECG was explained. After the system was installed and operational, the team gave power. To be ready to draw ECG, it must be opened on the computer. The Windows operating system is running on the screen. Any control of WinECG Pro, observing the results etc.

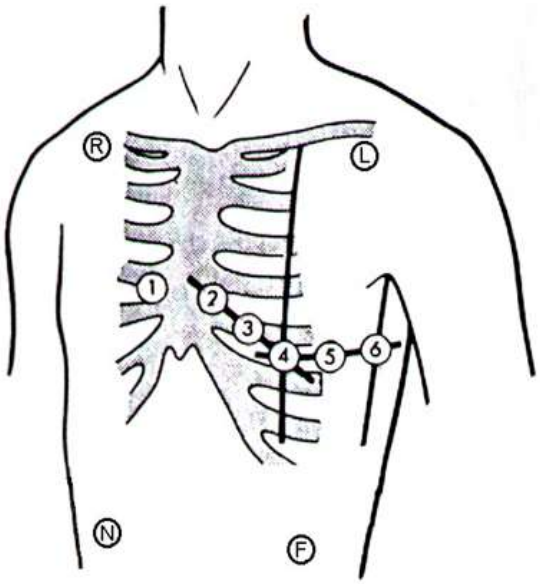

Figure 10. ECG Elektrode Locations

ECG Elektrode Locations

R (RA)	Red	Right arm
L (LA)	Yellow	Left arm
F (LL)	Green	Left leg
N (RL)	Black	Right leg
C1	Red	4th intercostas space to the right of the chest bone,
C2	Yellow	4th intercostals space to the left of the chest bone,
C3	Green	in the middle between C2 and C4, 5th costal bone,
C4	Brown	5th intercostals space, mid line below the left clavicle,
C5	Black	same level like C4, frontal armpit line,
C6	Violet	same level like C4, mid armpit line.

The first step to begin with ECG recording is to have your system ready. Please make the ECG cable and USB cable connections of your EKG Master USB device as explained above in Chapter 3, and plug the USB cable to your PC's USB port. If your device is supplied from the mains, make sure that you are using proper power cables wall outlets, proper grounding connections. If you have excess line noise on the recorded ECG signals, ask a dedicated technician to check your mains and grounding connections.

Important: You cannot perform ECG recording without connecting your device to the USB port of your PC. You can only review previously recorded ECG data. So, please make sure that your EKG Master USB device is connected to your PC via USB cable.

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Important: Please check the physical integrity and the quality of your device and patient cable before performing ECG records. Never use broken cables, damaged devices and accessories, as this may cause several risks for your patient. Please also check that your ECG patient cable connector plug is tightly screwed to the socket on the EKG Master USB device.

Please close all other Windows applications. Run WinEKG Pro program clicking the icon on the desktop or using the shortcut (Start – Program Files - WinEKG Pro) on the Start menu. You will see the ECG screen, without signals but with grid and the buttons and the menus according to your setup configuration. You can change the settings either through the selection of "Setup" or through the toolbars on the screen as explained in Chapter 4.

Important: Due to differences of PC operating systems or different user settings for operating system, there may be small differences of views and shortcuts.

Make the electrode connections for your patient. A dedicated and trained user is well familiar with these placements. The standard 12 lead application and the definition of locations are shown in Figure Arm and leg electrodes can be placed either to the positions shown in Figure or to the wrists and ankles. Please take special care to have the skin of the patient clean and ready for the measurements. To have the best signal quality, please clean the electro, there might be e locations very well and please also shave the hair on the skin of the electrode placement areas.

If you use metal- reusable electrodes, use a suitable amount of electrode gel, but never too much. You have to place the metal clamp extremity electrodes to the wrists and to the ankles of the patient for arms and legs respectively.

If you are using disposable electrodes, check the quality of the material and check the gel on the electrode surface. Always use proper size of electrodes according to your applications.

Keep the patient cables always straight and orderly as possible so that they do not bend, get stretched or twisted and do not easily get broken.

If defibrillator will be used during ECG recording, following points should be considered:

- Do not use excess gel for defibrillator paddles (electrodes) and ECG electrodes
- Do not apply defibrillator electrodes directly to/on ECG electrodes; keep a distance of at least 3-4 cm's
- Take care that the patient's body does not touch any metal or conductive part around the examination site
- Do not touch the body of the patient, especially during defibrillator discharge
- Defibrillation should only be performed by a trained person
- Apply basic safety rules for defibrillator usage

4.1. Determining the Running Language

WinECG Pro software running language is determined by the default language setting of the installed operating system. In order to operate in English mode, your Language settings must be initialized in English. For other languages, please contact Kardinero. For not-supported languages, the default language is English.

IMPORTANT: You must set your regional and language settings to English in order to operate the program in English mode. Else, WinECG Pro software may operate in Turkish. To set your setting into English click on; for region; Start -> Settings -> Control Panel -> Regional Settings choose 'United States' (Figure 11). For language; Start -> Settings -> Control Panel -> Language Settings choose 'Languages' (Figure 12) part from language settings and then change the "Standards and formats" value to "English (United States)" . Your computer may ask for Microsoft Windows Installation CD during this procedure.

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Figure 11. Regional Settings

Figure 12. Language Settings

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4.2. WinEKG Pro Program Commands and Functions

The section on the 'Menu Bar', 'Toolbar', 'Status Bar' and 'ECG Registration' is given in Figure 13.

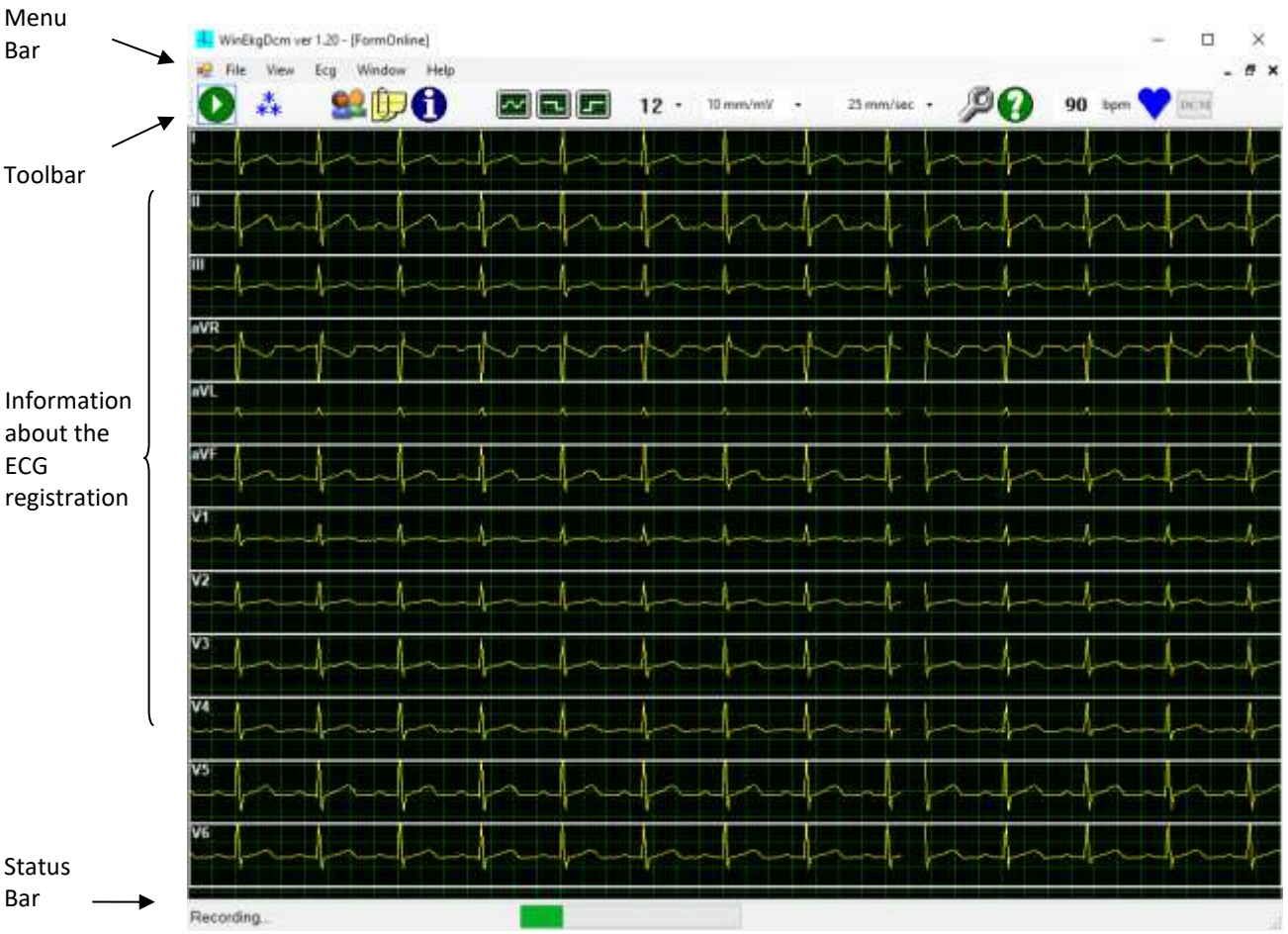

Figure 13. ECG Recording Screen

Menu Bar: As can be seen in Figure 13, the menu is at the top of the program window, where the functions in the program are sorted. Any menu unit can be selected by mouse or keyboard. To access via the keyboard, you must first press the Alt key. It is possible to make a selection by pressing the Alt key and using the arrow keys or by pressing the letters that appear as underlined in the menu.

Toolbar: It is the bar with the buttons and pop-up windows listed under the menu. Use these buttons and units to use the mouse.

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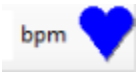
The buttons and the menu bar on the toolbar in your ECG program are shown and explained below. You can easily select buttons and appropriate options using your mouse. When the mouse is moved over a shape, the description of the function can be seen in the small labels that appear. The toolbar shown when ECG signals are received is as in Figure 14. The options that appear after starting the recording are described below. Please see the following commands. Use descriptions through menus are also provided in this section.

Figure 14. Toolbar

Table 1 below describes the function of each button on the screen.

	Start/Stop recording		Line interference filter
	Screen freezing of signals during recording		EMG filter
	Entering patient information		Baseline Filter
	Additional information and notes that the user wants to enter		Introduction to user settings
	Time and some technical information about the ECG		About
	Importing data from Dicom		Yorum
	Save		Yazdır
	Display of ECG channels in row x column format		Patient gives bpm information
	Receive from Dicom		

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Start/Stop Recording

This command starts the ECG recording while normal signal viewing (monitoring) is in progress. (Figure 15)

Figure 15. Start/Stop Recording Function

Freeze

This command is used to monitor the signals displayed on the screen at any time. 12 Channel ECG signals can be instantaneous frozen and ECG recording can be evaluated. (Figure 16)

Figure 16. Freeze Function

Patient Info

If you want to have patient information or want to record some basic information about the patient, along with ECG data, this information allows you to view and enter the simultaneous arrangement and patient

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information before monitoring ECG data. If the ”Enter patient information before recording” option is selected in the options in the “View” section of the Settings screen, this page will open automatically when you start recording. (Figure 17)

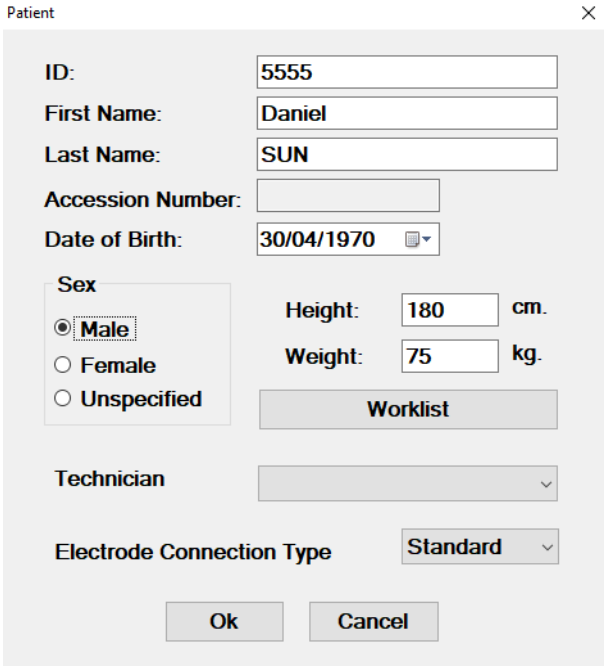

Figure 17. Patient Information Screen

Remarks

It is possible to add the patient's past disease information during or after the ECG recording, or the conditions that can be detected during the recording. (Figure 18)

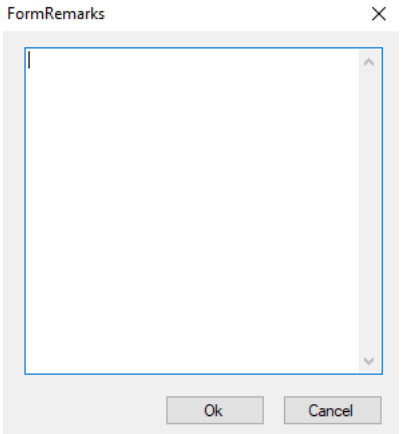

Figure 18. Remarks Screen

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ECG Info

It is a function that contains several information about the recorded ECG data. (Figure 19)

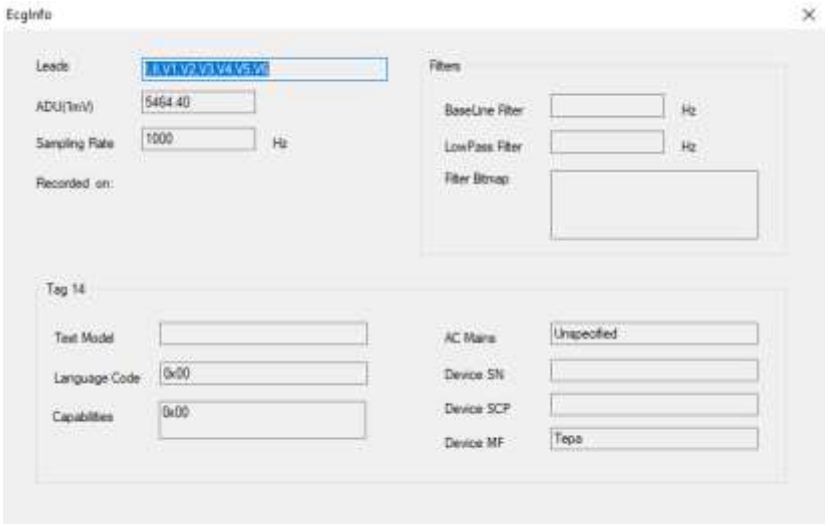

Figure 19. ECG Information Screen

Receive From Dicom

In the Settings> General tab, it is the function that allows access to the patient information registered in the PACS and that the ECG records are stored in the PACS under the relevant patient file, provided that Dicom integration is checked. The screen in Figure 20 below will appear below when you click Dicom.

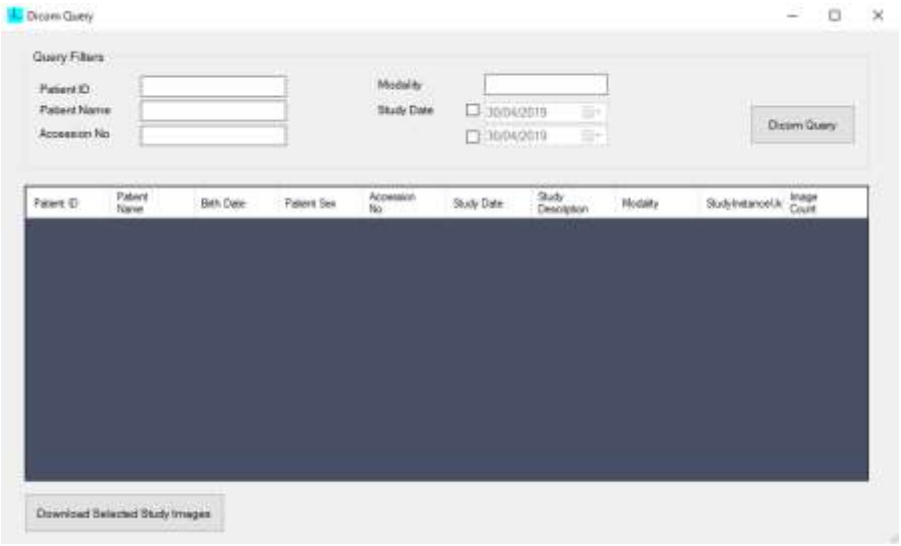

Figure 20. Receive From Dicom Screen

Save

Enables recording of the recorded ECG record.

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Print

It is the function that enables the print- out of the recorded ECG, or of any previously recorded ECG at any time.

View

It is the ECG format selection to view on the screen, number of the rows and columns of ECG leads. 6x2, 3x4, 12, 6, 3 and 1 format options are available. Lead group selection during acquisition for partial viewing modes can be made via F7 key.

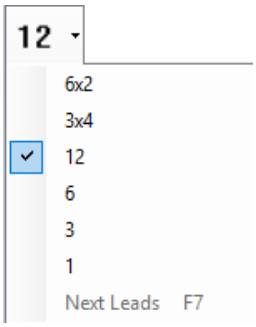
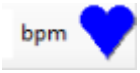


Figure 21. View Options

Heart Rate in bpm 

It shows the heart rate (bpm) of the patient simultaneously during the ECG recording. (Figure 22)

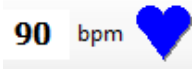


Figure 22. Heart Rate Information

Measurements

In order to use the optional Comment ’feature; You must have selected the ‘Interpret ECG recording’ option on the da General Tab of the Settings menu before you start recording. Otherwise, it is not possible to use the Comment feature.

If the comment option is received, the USB key (USB Dongle) must be connected to the computer. Cardionics's interpretation program is applied. The output of the comment is automatically obtained as shown in Figure 23 below.

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**** IMPORTANT NOTE: The interpretation is a comment that shows a series of measurements made on ECG signals in a table and a margin of error obtained by a series of operations on numerical data. The interpretation must be evaluated by a qualified physician.**

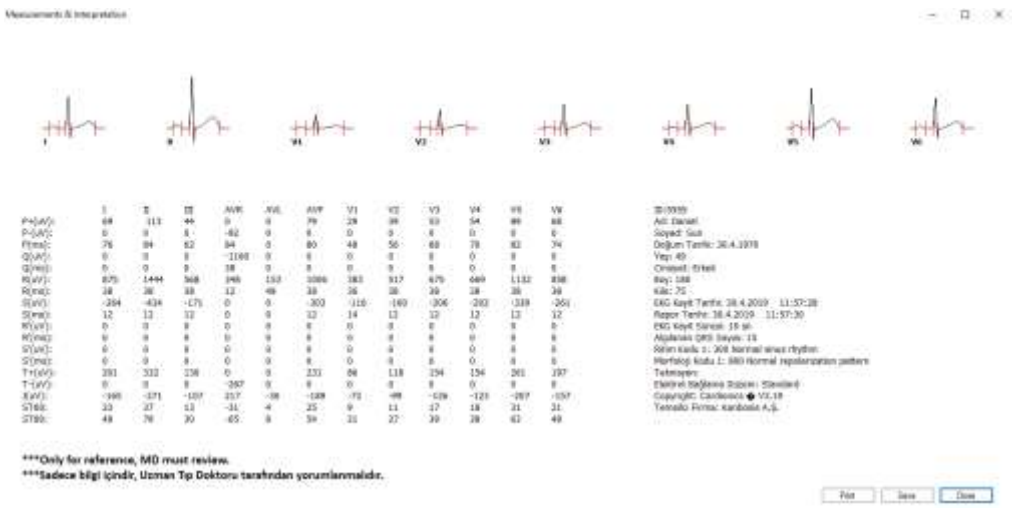

Figure 23. Measurements and comment screen

About

Contains information about our company Kardinero, and information like software and hardware releases. You can get more info on the Menu options.

Setup

Allows you to enter user settings. For detailed explanation see chapter 4.2.1.4.

Filters

These are the filter options you can to apply to the ECG signal. Line interference filter, EMG filter and baseline filter are available. Detailed descriptions can be found in this section.

Status Bar: The bar at the bottom of the window. Here, functional descriptions of the operation of the program are presented.

4.2.1. Opening Screen

When the new patient record button is pressed from the opening screen, you can see the screen in Figure 24. Important sections on this screen are shown roughly. The functions that can be used in the program and the way in which ECG recording is done are explained in detail below.

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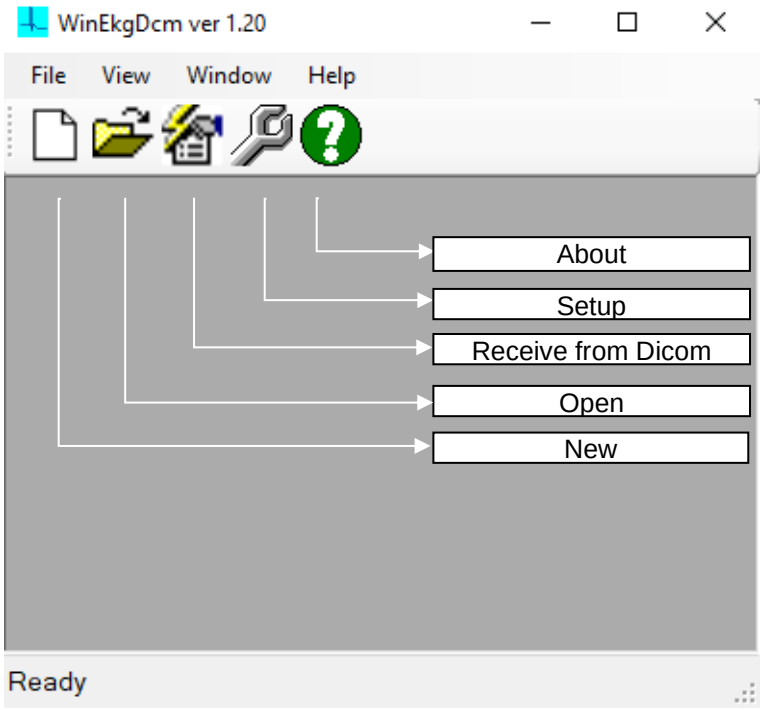

Figure 24. WinEKG Pro Welcome Screen

4.2.1.1. Starting a New Patient Record

Starting the new patient record is done by pressing the New File button on the WinEKG Pro splash screen or by pressing New in the File menu. After pressing this button, the Patient Information window with the patient registration screen is entered. (Figure 25)

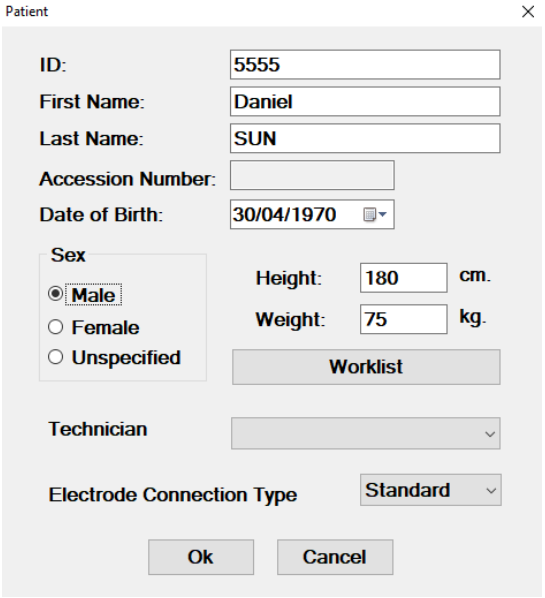

Figure 25. Patient Information

You need to enter at least one character in one of the ID or First Name fields. If this information is not entered, the patient's ECG recording is only done with the actual Date- Time information. After the patient registration is finished, the program is now ready to start ECG recording.

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4.2.1.2. Open

This command allows the system to display the information and data of the patient who has already a record in the system.

4.1.2.3. Send to Dicom

In order to use this tab, you must first select 'Dicom Integration' in General tab in 'Settings' Otherwise, you cannot retrieve patient information from the PACS system.

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.

4.2.1.4. Setup

4.2.1.4.1. General Tab

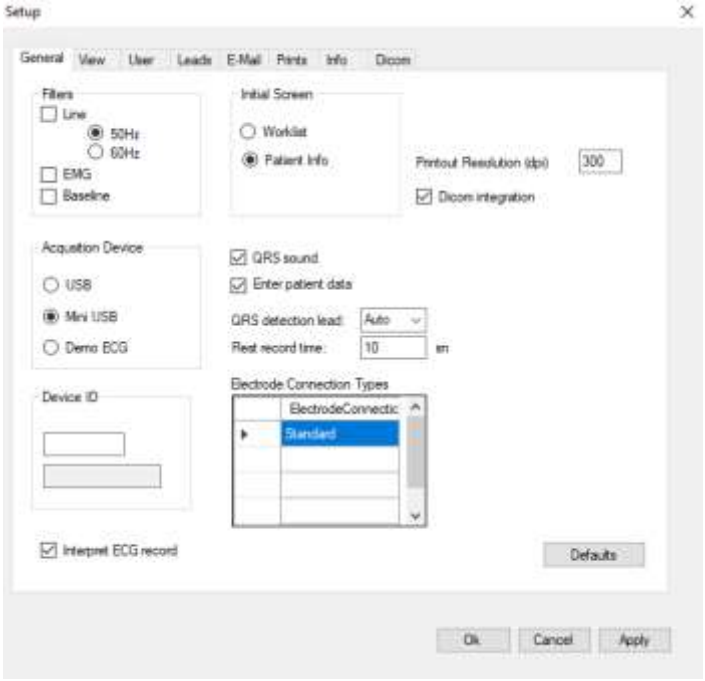

Figure 26. General Tab

This screen shows you these choices: Which type of acquisition device (recording module) you want to use, recording time, if you want to be warned for R-R intervals (QRS sound), etc. Details are as follows (see Figure 26):

Acquisition device: You can only use the software WinEKG Pro with an "EKG Master USB" recording module. If you do not plug in the USB recording module you can only see the previous recorded signals in Demo ECG mode.

Recording Duration: Concerning to your hard-drive's capacity you can make records up to 3600 seconds. Minimum duration to be able to have interpretation is 10 seconds.

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QRS sound: If you would like to be warned for each ECG waveform repetition click on this choice otherwise you are not able to hear any.

Filters: Default selection of filters to be used for monitoring on the screen. You can set the application of the "Mains filter", EMG and the "Baseline filter" by clicking the appropriate boxes here as your defaults. In this case, these software filters will be directly active every time you run the program. You will be able to change these in the program during acquisition.

Enter patient data before recording: You can skip patient data entry by unchecking this option.

QRS detection lead: You can force a specific lead (derivation) for QRS detection.

Device ID: Used for service purposes by service people.

"Default" (just for the current section): When you click on, you will return to manufacturer's defaults.

PrintOut Resolution (dpi): Specifies the dpi value of the output you will receive based on your printer specifications.

Dicom Integration: In order to use the Dicom tab, this integration must be selected.

Interpret ECG recording: When the option to comment ECG recording is active, the comment window is opened during recording or after recording and the desired comment is written.

4.2.1.4.2. View Tab

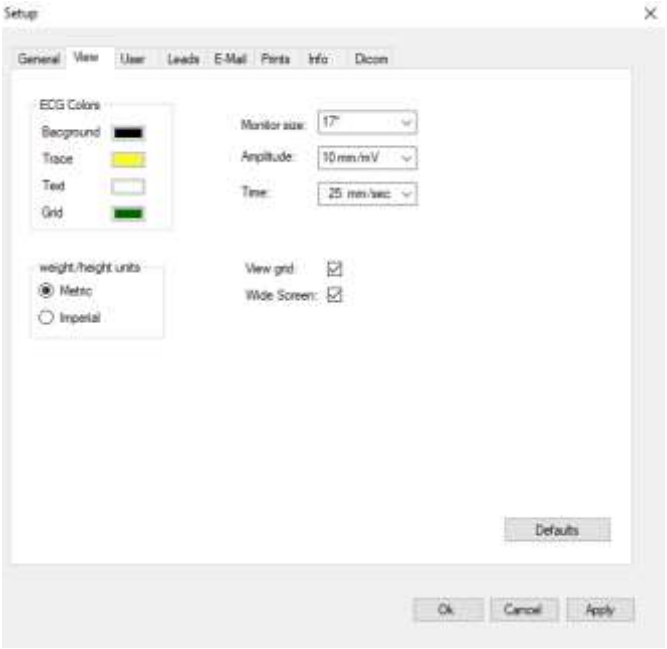

Figure 27. View Tab

The monitor size of the computer on which your WinEKG Pro program is installed, changes in the morphological and aesthetic structures of the ECG signals you see on the screen are made here. With the Filters to be applied, morphological, ECG Colors and Grid settings can be changed with aesthetic arrangements. (Figure 27)

Monitor Size: WinEKG Pro software can be used with 14", 15", 17" and 19" monitors. Recommended monitor size is 17". This selection assures approximate physical compatibility with real sizes.

Amplitude: You can optimise your ECG signal view that appears on the screen by changing the mm/mV ratio of the signal.

Time: Speed of the ECG signal that appears on the screen can be changed in this part. It has no effect on the printed ECG.

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ECG Colours: You can change colour view of the screen. These are: Screen background colour, ECG signal colours, colour of titles appears on the screen and colour of the grid that ECG printed on.

Weight/Height Units: According to what unit system would you like to use you may choose “Metric” unit system or “Imperial (inch)” unit system.

Grid: View Grid allow ECG signal to be seen like on the milimetric paper view.

Widescreen: If the aspect ratio of the monitor you are using is 16: 9, you should activate this option. Otherwise, the grid view on the screen moves away from the squareness.

4.2.1.4.3. Personal Entries

In the third tab (User) of the you can enter some information about your organization. This information will be printed on your ECG reports. You can write the “Name” of your organization, the “Address” and the name of two practitioners, of whom you want to have the names in the ECG reports. (Figure 28)

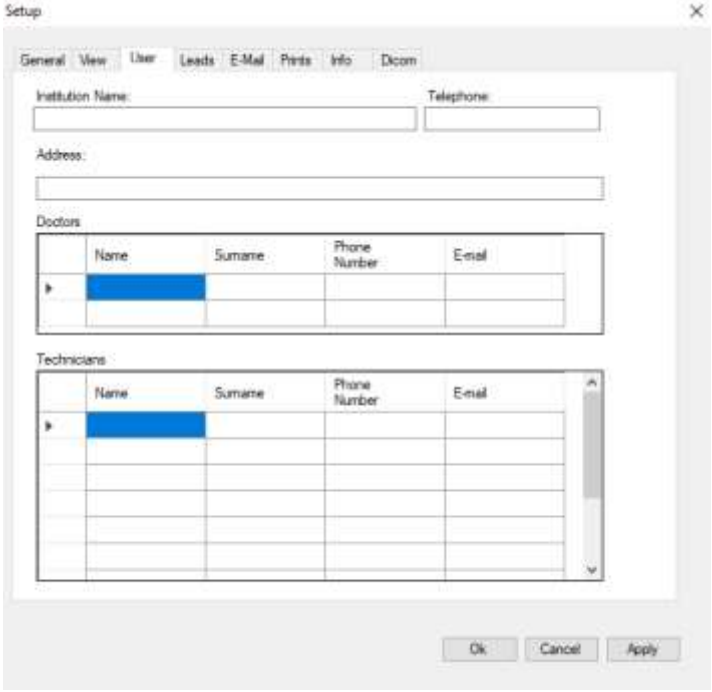

Figure 28. Personal Entries

4.2.1.4.4. Leads Options Tab

This window allows you to choose which ECG lead configuration you would like to see on your screen. You are able to select three and six lead ECG view configurations easily. (Figure 29)

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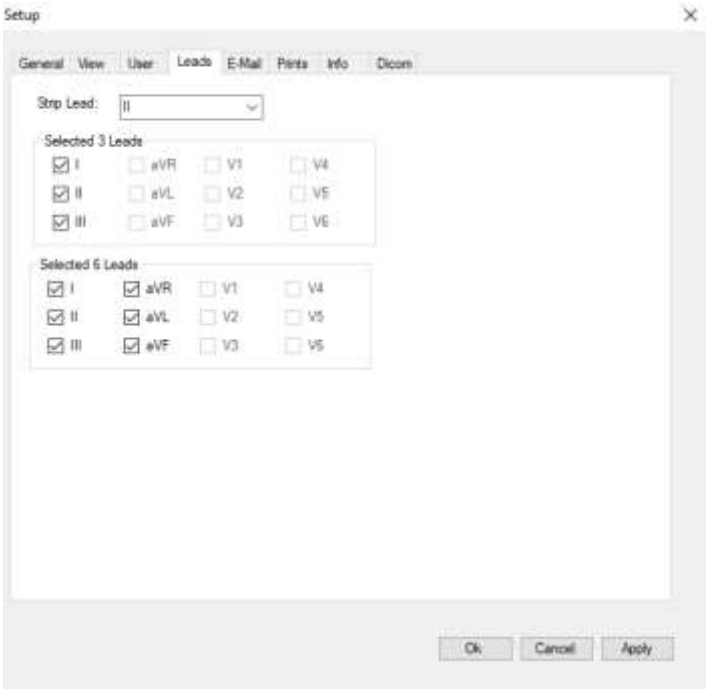

Figure 29. Leads Options

4.2.1.4.5. Printouts Tab

Under this window, the properties of the printouts to be taken from the printer are selected and determined. The view of this screen is shown in Figure 30.
You may want the output filter settings to be the same as the screen you are working on. In this case, which filters are selected on the screen, the output will also be filtered in the same way or it is possible to select different filter patterns for the output. The filters can be selected separately.
The output scale settings can also be selected from the beginning so that they are the same as on the screen. Or, fixed scales can be selected separately for amplitude and duration.
With “Print Grid” selection, you can get the grids printed when printing on plain paper.

This option should be selected if plain white paper is used.
This should not be selected if millimeter- grid paper is used.
It is recommended to save on the printer cartridge using millimeter- grid paper.
Leaving this option blank will extend the life of your printer and printer cartridge.

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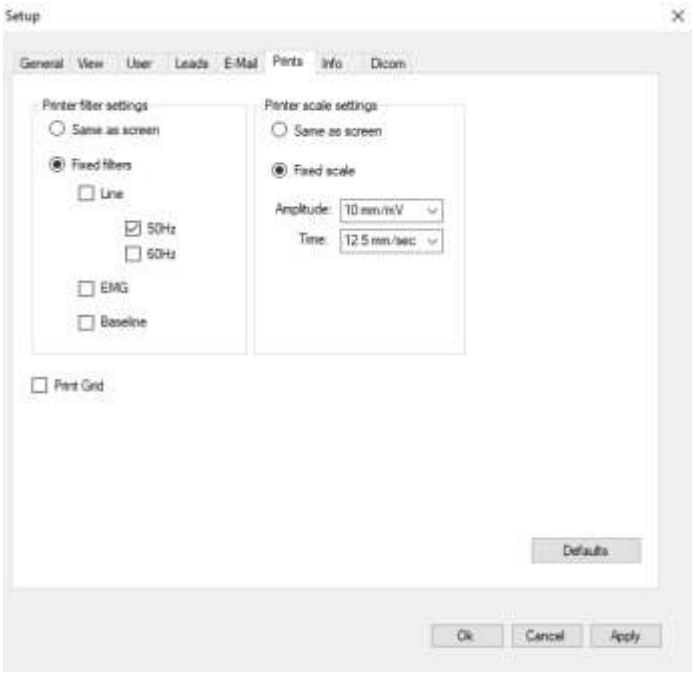

Figure 30. Prints Tab

4.2.1.4.6. Info Tab

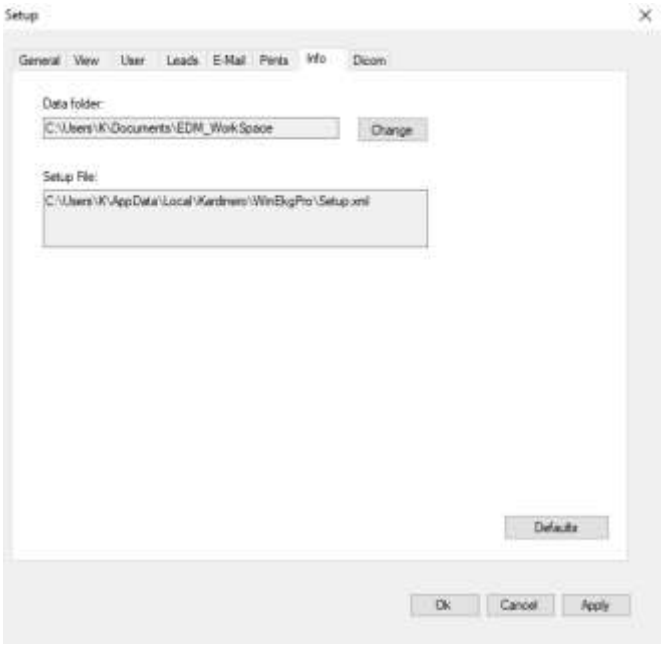

Figure 31. Info Tab

This tab provides information about the location of files obtained as a result of the ECG recordings and of the Setup information file. Optionally, files can be saved to the desired location prior to recording, or you can change them to the desired location after recording. This tab also selects which folder to store data to be stored on the computer disk. (Figure 31)

4.2.1.4.7. Dicom Tab

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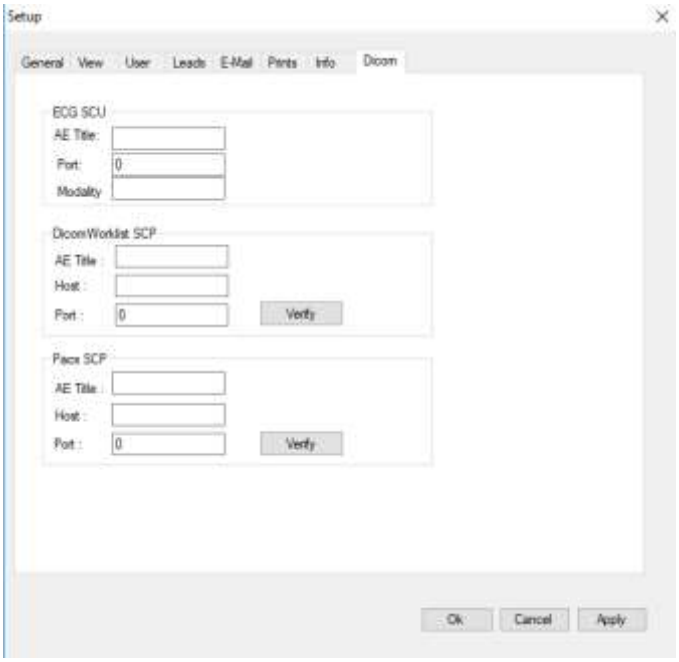

Figure 32. Dicom Tab

In order to use this tab (Figure 32), first the 'Dicom Integration' in the 'General' tab in the should be selected. Otherwise, the Dicom tab is not available.

Dicom tab; provides settings for communication with the PACS system in which the patient information is stored and stored and the DICOM files containing the data from the patients are recorded and stored. The settings in this section must 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 to.

4.2.1.5. About

The contact information for Kardinero, the manufacturer of the WinEKG Pro Program, includes the version information of the software program. (Figure 33)

Figure 33. About

4.3. Menu Options

Like other Windows-based software applications, WinEKG Pro also has consecutive pop-up menus to select program functions and options. Figure 34 shows the selection from ‘ECG’ down to ‘Filters’ (Figure 34)

Figure 34. Menu Options

This menu supports the ease of work done with these menus depending on the user's access to functions.

The list of menu functions and their descriptions are given below.

4.3.1. File Menu

- New: Starts new signal acquisition.
- Open: Opens an existing patient ECG for re-examination.
- Close: This closes the registration process or patient file.
- Save: save the latest ECG signals on the disk.
- Save Picture As: Saves a recorded ECG data in jpeg, bitmap, gif formats.
- Print preview: View the page to be printed before printing.
- Print: Prints ECG signals in the formats as selected from the toolbar or from the Setup.
- Send: Send the saved ECG data in e-mail attachments or save in binary format.
- Exit: Use to exit the program.

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4.3.2. View Menu

- Grid: Grid selection on the screen
- Derivation format: Allows the selection of ECG signals on the screen as 6x2, 3x4, 12x1, 6x1, 3x1 or 1 channel view.
- Patient Information: It is provided to see the personal information of the patient. It is not necessary to fill all the locations given for the information entry.
- ECG Information: Some technical information about the device is displayed. For service purposes only.
- Notes: The notes to be added to the ECG by the user are entered.
- Comment: Automatic measurement and evaluation on ECG signals.

Caution: The minimum recording time required to receive comments from the system is 10 seconds.

- Settings: Select the ECG parameters in section 4.4. edited as described.

Once you have set and selected the screen format, you exit the program and enter the same format again.

4.3.3. ECG Menu

- **Start / Stop Recording:** Starts and stops the ECG recording.
- **Freeze:** Pauses the signal transfer and freezes the signals on the display.
- **Filters:** ECG Filter options are as shown in Figure 35.

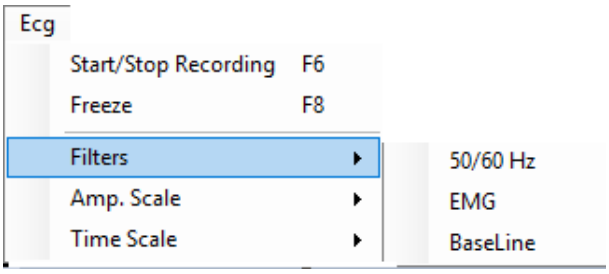

Figure 35. ECG Filters Options

- 50Hz: "Mains (Line Interference) (50 Hz or 60 Hz) Filter", Eliminating Line Interface.

- EMG: "EMG Filter", Eliminating EMG noise from ECG recordings.

- Baseline: "Baseline Filter", 0.5 Hz high-pass filters to eliminate baseline wander.

- **Amplitude:** Changes the amplitude coefficient on the monitor screen. The options are: 5- 10- 20- 40 and 80 mm/mV. The default is selected on the Setup. The monitor amplitude selection is independent from the printout amplitude selection. The amplitude on the print out can only be changed on the Setup. (Figure 36)

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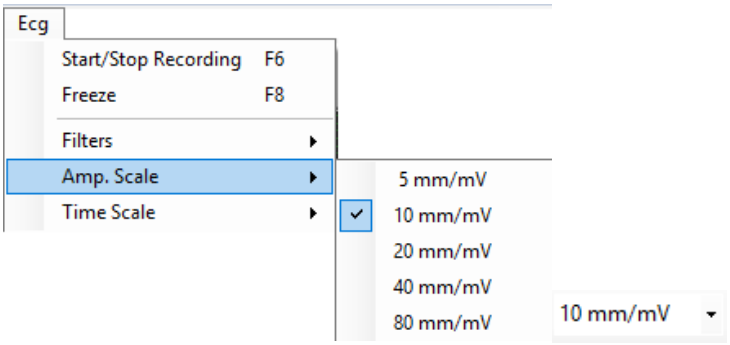

Figure 36. ECG Amplitude Options

- **Time:** Changes the horizontal speed of the ECG signal trace. The options are 6.25-12.5- 25- 50- 100 mm/seconds. The default is selected on the Setup. The monitor speed selection is independent from the printout speed selection. The speed on the print out can only be changed on the Setup. (Figure 37)

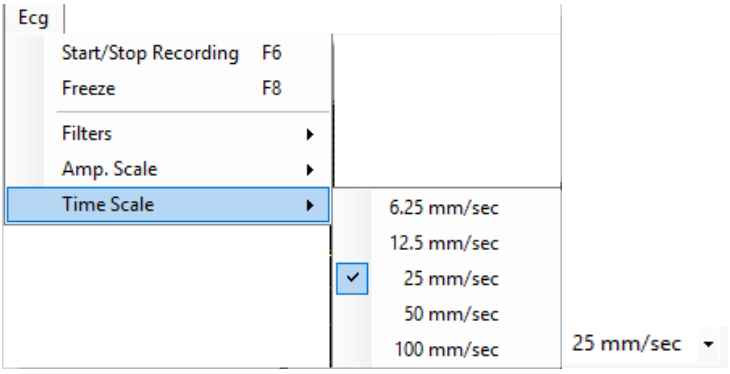

Figure 37. ECG Time Options

4.3.4. Window Menu

WinEKG Pro allows the opening of multiple ECG recording screens for the same patient or other patients. In this case, more than one ECG signal window appears on the screen. (Figure 38) (Figure 39)

- **Cascade:** Places them on the screen if more than one ECG file is opened.
- **Tile Horizontal:** Place multiple opened ECG files horizontally.
- **Tile Vertical:** Place multiple opened ECG files vertically.
- **Arrange Icons:** Edit icons of opened windows in the status bar.

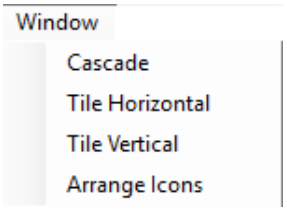

Figure 38. Window Menu Options

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Figure 39. Window Menu

4.3.5. Help Menu

- Contents: Provides access to the contents of the manual.
- About: Information about the program version can be seen.

4.4. Scroll Window

The scroll window is located on the bottom of the screen, as shown in Figure 40. For the use and explanation of the Review mode, please see Chapter 5.2. You can move the button directly by dragging and moving the mouse to see different instants of your ECG record.

Figure 40. Scroll Window

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5. Recording ECGs

5.1. Patient Information

To have the name of the patient on the printout and to save basic information about the patient together with the ECG data, you have to edit and enter them before or during the monitoring. To open the “Patient Information” window, which is shown in Figure 41, you can simply click the button on the vertical- left toolbar, or you can use the menu list from the menu- bar (Please refer to the Chapters 4.2.1.1. Please enter the name, date of birth, weight, height and the sex to their appropriate fields using your PC’s keyboard and mouse.

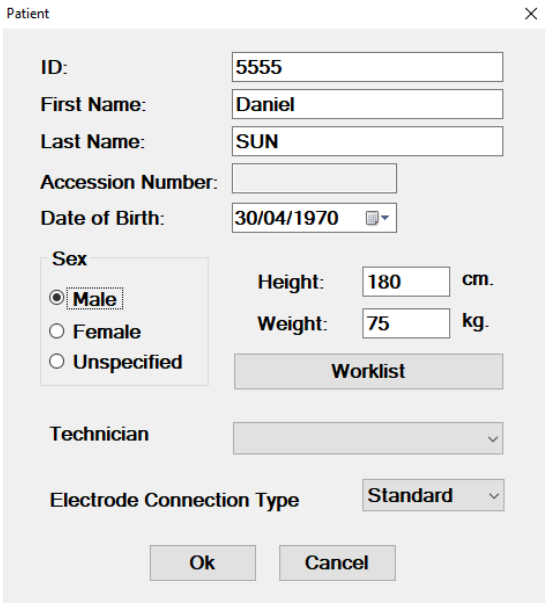

Figure 41. Patient Information Window

Please enter the patient's name, date of birth, weight, height and gender using the keyboard and mouse. You can enter any number as an identification number. This number will be your own number, such as an insurance number or personal identification number. If you press OK, the window will close and you can continue recording.

The ECG data are stored in the SCP-ECG standard, JPEG and PDF format. The information you enter here can be re-examined and used with other SCP-ECG supported ECG software and Windows based system computer and PDF reader program after recording. After the recording, you can access your ECG records with the Acrobat Reader PDF reader under Windows, and you can also print and print using the Windows photo 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.

5.2. ECG Monitoring

Important Note: Please take care that you have to consider the grids on the screen for the measurements. The metric length of your signals may differ according to your monitor’s size. But the length of the signals is always adjusted to the grid on your monitor. Always consider the grids and the scales for the grid when making calculations on the screen.

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Figure 42. ECG Transfer and Recording Window

If you are ready with the connection of the cable and electrodes to the patient, you can begin with the recording and monitoring of the ECG signals. Monitoring of ECG signals begins immediately by clicking the "New" button on the toolbar. If the electrodes and cable are connected properly, you will begin to visualize ECG signals in the format you have selected. A sample acquisition view in 12 channels 4x3 format is shown in Figure 42.

To start recording, click on the "Start" button. You can view the status of the recording through progress and elapsed time indicators on the status bar.

You can change amplitude (gain) and speed scales during the recording, you can change filter settings, grid view and leads format, and you can edit patient information during the recording. But you cannot enter in the "Setup" to adjust or change your settings.

You can end recording any time you want by clicking "Stop" button on the "Setup". You also can use menu lists or hidden menu to end the recording.

5.3. ECG Print Out

You can use "Print" button in the toolbar or "Print" option in the File menu to begin printing. Normally, if you do not change the signal position on the screen, last seconds of the record are printed, where the duration is dependent on the printout format you have selected.

Printed Interpretation page includes the entire channels and chosen rhythm channel in reduced format. Interpretation page may include 2 minutes ECG recording.

You can have the printout of an ECG record any time you want, as long as this data is kept in your archive directory. If you have the ECG data already retrieved, you can select a start point, and you can have a print out simply clicking the "Print" button on the Toolbar.

Important: Before you click the "Print" button, please make sure that your "default" printer is connected to your PC and it is made "ON".

Please contact your computer- printer dealer or contact Kardinero if you have problems with your PC- printer configuration.

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5.4. Archiving ECG data

Immediately after you finish the recording of ECG, “Save ECG File” window appears and you are asked whether you want to save the data. Clicking the “Save” button in this screen, you can save the data. You can change the name of the file like any other Windows application.

The saved data is the raw data. The filters and other selections like monitoring or printing selections are not saved together. You can edit and view this ECG data on any other PC, where EKG Master USB program has been installed.

While saving files, WinEKG Pro software gives a name to your recorded data like “PatientName_RecordDate_RecordTime”. It is recommended you use this type of given name but you may also give a name according to your preference.

All saved ECG data is stored in the directory “C:\Users\[username]\Documents\EDM_Workspace” unless you have selected a different directory during the installation. You can save and organize your data according to your basic computer practice.

You can either use the given folder **“C:\Users\[username]\Documents\EDM_Workspace”** or you may define a new folder to save your data files. You may also define different folders for different patient types by using your Windows Operating system’s file/folder processing tools.

The entries you receive with the WinEKG Pro program are stored in the Program Files \ Kardinero \ Data \. WinEKG Pro program you receive the program after you exit the program as output from your printer. The WinEKG Pro program stores the current ECG signals as a good alternative to Microsoft Windows 64bit resolution graphics (Portable Document Format), JPEG (Joint Photographic Experts Group) and SCP-ECG standard. The files in this format are saved as **[relevantNoteFile] \ [year-month-day_Hour-minute-second].**

For example a patient named Daniel SUN: DanielSUN5555\20190430_153353.PDF is saved as DanielSUN5555\20190430_153353.JPEG and DanielSUN5555\ 20190430_153353.SCP.

The files are saved in the ‘EDM_WorkSpace ’ folder in ‘Documents’ on your computer.

Important: Before clicking Print, make sure your printer is turned on and connected to your computer.

Another important point is the optional comment output. It is contained in the file containing the patient data in JPEG format. After the recording, you can get the output of the comment for the related patient file that is saved.

5.5. Retrieval and Review of ECG Data

You can review ECG signals either just after you have finished the recording or retrieving them any time you want through the “Archive” selection on the Toolbar. Please refer to Chapter 4.2 to use the Toolbar and 4.3 to use the Menu options.

On the ECG signals you are reviewing, you can perform following:

- Change the order of the leads,
- Change screen format,
- Change the grid view,
- Change amplitude and speed scales,
- Print any part of the signals,
- Have different type of printouts,

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- Apply different filters,
- Scroll through the complete record in any screen format,

Please refer to the explanations in Chapter 4.3 for the functions. These changes do not affect the raw data, as the signals are saved in raw format.

5.6. OnScreen Measurement

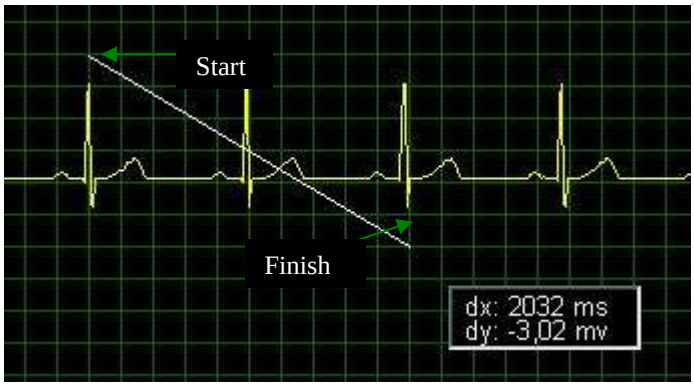

Figure 43. Onscreen Measurement

WinEKG Pro software includes an application to make measurement on the screen during ECG record inspection. To use this application, when your mouse pointer is on the recorded signal first measurement point, click on left mouse button to start calipers and do not release your finger until the end point of measurement. While doing this you will see something like in the Figure 43. As soon as your finger clicked on, you will see the measurement values in the x (horizontal- time in ms) and y (vertical- mV) axes.

5.7. Multiple Windows

Figure 44. Multiple Window View

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WinEKG software provides you to investigate multiple patient records at the same screen. By the way you can compare different signals and you can make measurements. You may put your windows in different styles as mentioned in Chapter 4.3.4.

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5.8. Switching Off

To exit the WinEKG Pro software, click ‘‘x’’ in the upper right corner, as in all Windows applications. The lower selection is used for exiting from the patient record and the upper selection is used for exiting the entire program.

IMPORTANT NOTE: Before you exit the program, be sure to save all the data you need to keep in the computer memory.

As with any other USB device, the USB ECG module can also be removed from the device when the computer is turned on. You can remove the USB module by pulling the cable connector out of the USB socket. You can turn off your computer according to the instruction manual and your application settings. Each time the USB module is plugged into the computer, it will start working by reinstalling its own operating software.

6. Troubleshooting

6.1. Warning and Information Messages

In this chapter, warning and information messages, which may appear on your PC monitor screen during the use of your EKG Master USB device, are given.

“No data from designated acquisition device close the program and retry!”

There is a problem at the input/output side of the program. It may be due to a hardware malfunction or it is a temporary software problem. Restart your program and try again. If persists, call your dealer.

“Enter a number between 10-3600!”

You may take records between 10 to 3600 seconds in the program. Enter a value in this interval when asked.

“Data is delayed by 3 seconds!”

Because of the filter that you selected, your ECG signal comes on the screen with time latency. Be aware of this while taking records from your patients.

“First installation or setup file does not exist. Setup file will be created!”

When you try to use your software for first time, you will see this warning. This is just for your information.

“No QRS or noisy signal!”

Check your patient cables and cable connectors. If you still have this warning, call your dealer and/or Kardinero.

“First save the record in .scp format and retry”

In order to convert your ECG signal in binary format, first of all you should save it in .scp format.

6.2. Error Messages

6.2.1. SCP-ECG Errors

Error and warning messages given below are related with the archived ECG files, which are in SCP-ECG data format. The incompatibilities with this format are stated with the following statements. You will get these messages if you are trying to use an incompatible data from another source, from an old version of ECG data. You will also get these messages with any corrupt data due to a PC problem. In either case,

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please do not use the program with this data. Please note the message you get and contact your dealer for further detailed information:

- “Invalid Length at Tag:”
- “CRC error!”
- “Zero avm or sample interval”
- “Invalid length for section”
- “Huffman tables not supported!”
- “Missing "SCPECG" string in Section 0 ID Header”
- “Record length different from actual file length”
- “File to be converted does not have .scp extension!”

6.2.2. Other Errors

“Invalid Height!”

Height you entered is out of range. Change it with a proper value.

“Display buffer overflow, close other running programs and increase graphics hardware accelerator speed!”

Memory stack overflow because of insufficient hardware sources. Upgrading your hardware required.

“Invalid Weight!”

Weight you entered is out of range. Change it with a proper value.

“Not a valid numeric character!”

Entered value is not suitable for WinEKG Pro software. Please enter proper value.

“Decrease the recording time... Maximum recording seconds for this PC:”

You cannot make that long record because of insufficiency of your hardware memory. Decrease the time length and try again.

“Can not create .bin extension file!”

You see this when you try to save but can not save your signals in binary format.

“Complete Lead selection!”

You see this warning if you don’t choose all necessary leads when you are determining which derivation you are going to use.

“Can not save setup file!”

It means “setup.xml” file could not be saved. Restart program again. If persists, call your dealer and/or Kardinero.

6.3. Solving Problems

In this chapter you can find the solutions for the problems you can solve by yourself. Please contact authorized Kardinero service or PC specialist for the problems which you cannot remedy using this user manual.

- Problem: EKG Master USB device LED does not light momentarily at first plug in.

  Solution: Make sure that your USB interface cable is properly connected to the PC. If the problem still exists, contact your dealer.

- Problem: You cannot run the WinEKG Pro program.

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Solution: Try to locate the program directory and check the existence according to the directory structure of your installation. Refer to Chapter 3 for the installation information. Make a copy of your Archive directory, uninstall and reinstall the program.

- Problem: Your program does not recognize your EKG Master USB device, although the LED is OK:

Solution: Please check the status of USB devices in the "Device Manager" of your computer. If the "Tepa EKG Master USB device" is there with or without a sign of a technical problem, remove the device, uninstall the software and re-install it. Refer to Chapter 3 for the installation information. Make a copy of your Archive directory, and then uninstall and reinstall the program. If the problem still persists contact your dealer.

- Problem: The printer does not print.

Solution: Check your printer's power and signal connections. Also check the print cartridges of your printer. If they are OK and you still have problem, check the printer driver software. Open the "Printers" window of your operating system in the start menu through settings. Refer to the installation manual of your printer and operating system. Please make sure that the printer you are using is set as the default printer.

- Problem: Too much line noise on ECG signals.

Solution: Check whether you can remove this noise by applying line interference filters of your WinEKG software and refer to Chapter 4.3.3. Check your patient cable and electrodes. Replace the electrodes if they are not suitable to use. If you are not sure about the adequacy and integrity of your patient cable, please contact authorized technical service. Please also check your mains outlet and grounding. If they are not appropriate, please call an authorized technician and have them repaired. We recommend in such a case to check your power grounding. Be sure that there is not any high power equipment in a very close area, which may cause excess interference; consult a biomedical technician.

- Problem: Too much line and/or other noise on ECG signals

The ECG device complies with the requirements of EMC regulations. However, please take care that equipment emitting strong electromagnetic waves like mobile phones, X-ray equipment, power generators etc can affect the quality of the ECG signals and therefore you should avoid that such equipment is not placed close to ECG site. Please consult Kardinero in case of any doubt.

- Problem: Too much EMG noise on ECG signals.

Solution: Check, whether you can remove this noise by applying EMG filters of your WinEKG Pro software and refer to Chapter 4.3.3. Check your patient cable and electrodes. Replace the electrodes if they are not suitable to use. Ask your patient to stay still and not to move. Check whether the examination table is comfortable enough and suitable.

- Problem: Too much baseline wanders on ECG signals.

Solution: Similar to EMG noise above. Please try to remedy the problem by selecting the baseline filter through the selection on the "Toolbar", if this problem is patient dependent.

- Problem: Any computer hardware or software problem, causing you not to use your ECG device.

Solution: Consult an authorized PC specialist or your dealer.

6.4. Periodic Maintenance

EKG Master USB does not need any specific periodic maintenance. There are only some simple maintenance and cleaning that have to be done by the user. These are:

Please keep the device and the accessories clean. You can clean the surface of your device and the cables with a soft towel and with a mild detergent. Do never use solvents and strong detergents. Never immerse your device and the cables in the water or any other fluid. Never wet the connectors on your ECG device. If you use reusable electrodes, please separate them from the cable and wash them at least once a week,

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with mild detergent water, and dry them immediately with a soft towel. Never leave the reusable electrodes with gel on it for a long time. Do not let the gel to dry on the electrode surface.

Visually inspect your ECG patient cable and your ECG device for the mechanical integrity as often as you use your device. Do not use damaged or broken devices and accessories. Consult your dealer for service.

There is no need for periodic- electronic calibration of your device. Using an ECG simulator you can check the accuracy of your measurements. Please consult your dealer or an authorized biomedical technician if you are unsure about the measurements you have made.

6.5. Transportation and Storage

The storage conditions for the EKG Master USB device and accessories are similar to other electronic devices. Operation and storage temperature limits are +5°C to +45°C. Maximum relative humidity limit is 95%.

As the device and accessories are portable, we recommend carrying them in a suitable transportation bag.

6.6. 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	CE 2797	Conforming EU Medical Devices Directory, Notified Body BSI's number 2797
	Warning: High Voltage		Defibrillator signal protected inputs
	Manufacturer's address		

7. Technical Description and Service Notes

7.1. Introduction

Technical Manual- or Service Manual- of EKG Master USB is included in the User Manual. No other document has been prepared for this purpose. This document includes details as described in the basic standard ISO/ EN 60601-1 Medical Devices- General Requirements for Safety; clause 7.9 Accompanying Documents- sub-clause 7.9.3 Technical Description.

7.2. General Information and Warnings

EKG Master USB has its (bilingual: English and Turkish) labels as printed on its case according to the requirements of the standards. Further information described in this standard has been stated in this User Manual and Technical Description.

EKG master USB device gets its power from the USB port where it is connected: 5VDC/ 240 mA ±10%.

EKG Master USB is a Class IP20 device.

Operating- storage conditions: +5 / 45˚C max 95% humidity.

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WARNING: This medical device does not contain any replaceable parts inside. The device is not "field repairable". It can only be repaired by the manufacturer, in its premises and under direct control. Therefore, detailed circuit diagrams and internal component part lists are not a subject for this manual. Please contact your authorized dealer or service provider. Trying to repair the device may cause serious **HAZARDS** for the user and for the patient.

WARNING: No modification of this equipment is allowed.

WARNING: Please carefully read this User Manual before using the device for the first time.

WARNING: Please refer to the CAUTIONS on page 3 of this User Manual.

7.3. Brief Functional Description

EKG Master USB is a medical device to record patient's ECG signals, intended to use by a physician or health personnel. EKG Master USB is to be used with a personnel computer, also using specially developed software WinEKG Pro developed by Kardinero. Technical specifications of the EKG Master USB are given on page 9, chapter 1.4 of this manual.

Functional block diagram of the device is given on Figure 7.2.

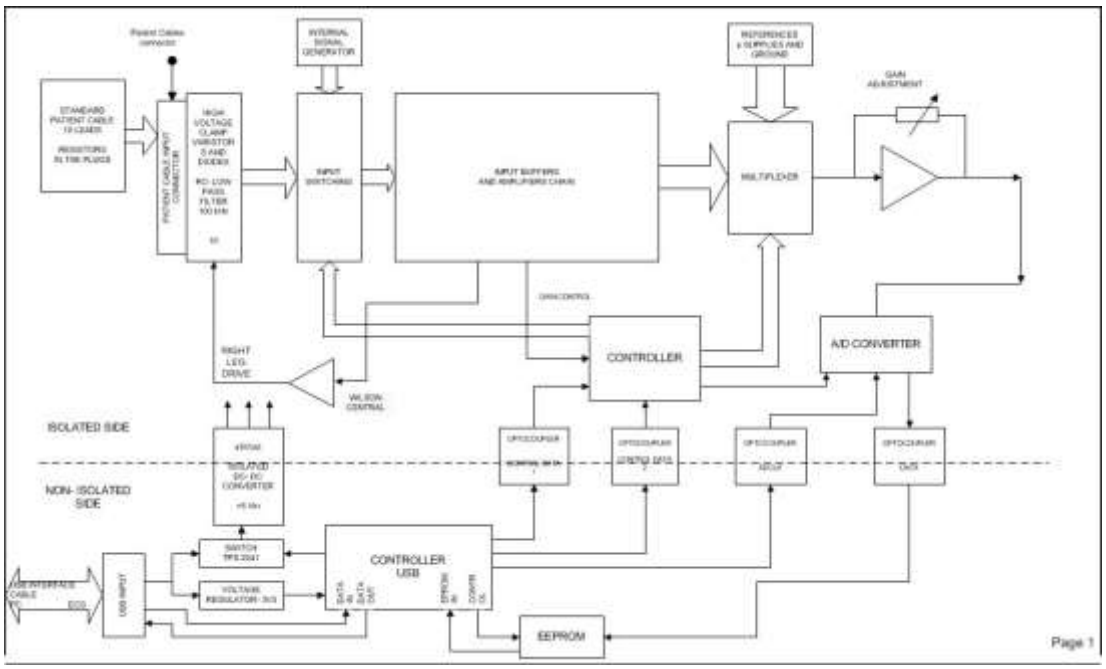

Figure 7.1. Block diagram of EKG Master USB acquisition module.

ECG acquisition circuitry basically consists of two sides: isolated side and non-isolated side. These sides are separated by a DC-DC converter power supply and signal isolating optocouplers. Non-isolated side comprises the circuits for PC connection. Isolated side comprises analog circuits for signal amplification, AD conversion and controls of this part.

ECG cable to be connected to the device contain resistors at the tips, to guarantee defibrillator protected inputs. Cable connector is a D-sub 15 pin connector, with a specially designed configuration.

As there is no connection of the device to the mains, and as there is no use of batteries, there is no other power supply and fuse information for the ECG device. The device is directly supplied by the computer's USB port. The USB cable of the device is also not replaceable in the field; it is a special cable and we strongly recommend to replace it only by manufacturer's service department. In case of urgent need, one should take care:

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The cable to use between EKG Master USB and your personal computer is tied and soldered internally to the ECG Device. This cable is a full speed PC - USB interface cable.

Important: In case of service need, the cable can only be replaced with a cable with the same specifications stated here and by an authorized service station. The cable specification shall be: the length between 4 to 5 meters; wire diameters at least AWG24 for the power supply section and AWG28 for the data signal section, and with an EMC filter.

APPENDIX: A

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APPENDIX: B

TERMS OF LIMITED WARRANTY

This Warranty Agreement applies to any products and services (collectively, "purchase") related with EKG Master USB System purchased from Kardinero, Inc. or any of its subsidiaries or affiliates ("Kardinero") or a Kardinero authorized reseller ("Reseller"), unless you enter into a separate written agreement with Kardinero.

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THIS RETURN POLICY IS NOT A WARRANTY.

NOTE: Kardinero will not accept for return any products you purchased from a Reseller.

2. Technical Support. For 30 days from the date of invoice Kardinero will assist you with (i) installation of your WinEKG program by means of telephone or Internet. The warranty does not cover any on site installations. Technical support for issues beyond the scope of this basic technical support may be available under other service agreements. Kardinero provides technical support via on-line, telephone and other remote methods. Kardinero may change the means through which it provides technical support at any time. Kardinero does not guarantee that software will be completely free from errors or bugs, either in isolation or in combination with hardware. Only significant errors in the software that make it unusable are covered.

3. Product Warranty. Kardinero warrants to the original purchaser or, for products purchased from a Reseller, to the original end-user that Tepa-branded products will be free from defects in materials and workmanship for 1 (one) year from the date of shipment. During the warranty period, Kardinero will, at its option: (1) provide replacement parts necessary to repair the product, (2) replace the product with a new and comparable product.

Kardinero will determine how and where repair services are provided, and you may be required to deliver your product to an authorized service location. Replacement parts or products will be new or serviceably used, comparable in function and performance to the original part or product, and warranted for the remainder of the original warranty period. You authorize Kardinero to send replacement parts and products to an authorized third party service provider. Purchasing additional products from Kardinero does not extend your warranty period. To obtain service under this limited warranty, you must follow Kardinero's warranty procedures. You may be required to return defective items to Kardinero and Kardinero will charge you for replacement parts or products if you fail to do so.

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APPENDIX C:

EMC (Electromagnetic Compatibility) Declaration

This device has been tested according to the IEC 60601-1-2:2007 Electromagnetic Compatibility standard and has been verified that the measurements are within the specified limits. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate energy in radio frequencies. It should be installed and used in accordance with the instructions; otherwise, it may cause interference to other devices in the vicinity. Such situations of interference can be decided by disconnecting-reconnecting this device from the PC, and by observing the following:

- Changing the location of the device,
- Increasing the distance between the devices,
- Changing the mains connection of the used PC and printer,
- Consulting the manufacturer or its authorized service personnel.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Use of accessories and cables other than those specified in this manual may result in increased emissions or decreased immunity of EKG Master USB device.

This device should only be used with other equipment, as specified in this manual.

Relevant Tests and Standards	Compatibility	Electromagnetic environment- manual
Radiated RF emissions EN 55011 (CISPR 11) Class B	ECG Module. 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.
Electrostatic discharge (ESD) EN 61000-4-2	ECG Module; 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 enclosure. 80 MHz to 2700MHz 3V/m – Antenna distance 3 m 80% AM at 1kHz sin Passed the test. Complies.	Such electromagnetic fields should be at low levels in a typical commercial or hospital environment. Wireless communication equipment during their use should be kept out of the room of the system.
Immunity to Power Frequency (50Hz) magnetic field IEC 61000-4-8	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.

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EKG Master USB- Mini Kit	700170
EKG Patient Cable, Clamp Type	600311
EKG Patient Cable, Banana Type	600322
ECG Extremity electrodes, metal clamp	600330
ECG Chest electrodes, metal suction	600340