

**Cardio M-PC**

**User Manual**

**CE0123**

# Contents

## 1. Introduction

- 1.1 Features:
- 1.2 Main system components
- 1.3 General instructions
- 1.4 Security instructions
- 1.5 Electromagnetic Compatibility
- 1.7 Explanation of symbols on machine

## 2. Installation

- 2.1 Hardware installation
- 2.2 Software installation

## 3. Setting the default parameters

- 3.1 ECG device
- 3.2 ECG
- 3.3 Print
- 3.4 Setting the size and color of the Monitor window
- 3.5 Stress test setup
- 3.6 User
- 3.7 Upgrade options
- 3.8 Password protection for using Cardio M PC
- 3.9 Mail settings
- 3.10 NetCenter
- 3.11 Auto backup
- 3.12 Security groups

## 4. Using the Card File in Cardio M PC

- 4.1 Adding a new patient
- 4.2 Editing a patient card
- 4.3 Deleting from the patient list
- 4.4 Selecting card files
- 4.5 Findings (list of stored ECG recordings)
- 4.6 Comment block operations

## 5. ECG recording

- 5.1 Monitoring
- 5.2 Time resolution, amplitude gain, QRS-sound and filter
- 5.3 Selecting a lead system
- 5.4 Storing the ECG recording

## 6. Stored ECG recordings

- 6.1 Recording display in the 'ECG ruler'
- 6.2 Comparison of recordings, medians
- 6.3 The Frank ECG vector
- 6.4 Replay of recordings
- 6.5 Data export to MS-Excel 
- 6.6 Longtime recordings

## 7. Evaluation of the ECG recordings

- 7.1 Manual evaluation in the 'ECG ruler'
- 7.2 Median calculation
- 7.3 Parameters

## 8. Data transfer functions

- 8.1 Copying patient card
- 8.2 Backup
- 8.3 Copying and inserting ECG recordings
- 8.4 Exporting and importing files
- 8.5 Send / receive by mail

## 9. Settings for the stress test

- 9.1 Ergometer/bicycle, blood pressure measurement and RS232 control
- 9.2 Load program (Ergometer/Treadmill)

## 10. Stress test

- 10.1 Recording the stress test
- 10.2 Recovery phase
- 10.3 Blood pressure measurement
- 10.4 Manual change of workload

## 11. Evaluation of the Final report

- 11.1 Calculation of maximum exercise performance
-

- 11.2 Stress test graphs
- 11.3 ST evaluation

## **12. Network operation, multi-user features**

- 12.1 Local network operation
- 12.2 Remote monitoring
- 12.3 Remote device (netdevice) operation
- 12.4 Server/Client (remote database) operation
- 12.5 Cardio M PC NetCenter

## **13. Appendix**

- 13.1 Appendix A: Diagnosis
- 13.2 Appendix B: Electrode placements and lead calculations

# 1. Introduction

**Cardio M PC** is a complete 12-lead electrocardiogram (ECG) system that is personal computer (PC) based. It provides a full-featured, portable ECG that has important advantages compared to traditional ECG machines.

## 1.1 Features:

- ECG data is easily collected and stored using the standard 12-lead configuration, or using the Frank lead configuration. In the Frank lead configuration, a vector ECG is automatically stored.
- Real-time or stored ECG tracings are clearly displayed on a computer monitor, and may be printed whenever desired on inexpensive standard printer paper. Costly ECG paper is no longer needed.
- Stored ECG data can be accessed at any time. Multiple recordings from a single patient can be easily evaluated and compared.
- The Cardio M PC database provides a user-friendly interface that can accommodate even the largest clinical and research needs. The system is capable of handling 2 million patients each with a maximum of 1000 ECG tracings.
- ECG recordings can be stored and categorized in patient folders or by common features. Stored recordings can also be easily copied, archived, or re-analyzed.
- Context-sensitive help messages make the system easy to use.
- A built-in text editor can be used to create, edit, store and print notes and comments.
- Automatic evaluation and diagnostics facilitate the physician's diagnoses.
- The Cardio M PC system is also designed to readily interface with commonly used peripheral devices in the Exercise Stress Testing or physiology laboratory. The system can automatically control a treadmill or cycle ergometer/bicycle while recording the 12-lead ECG.
- The Cardio M PC system can be easily installed on any appropriate PC with a USB interface. It can be used in local networks, or can be installed on a portable computer (notebook) for mobile use. The Cardio M PC system can also be interfaced with medical database systems.

## 1.2 Main system components

The main parts of the system are:

- CARDIO M ECG recorder (CARDIO M -U: USB, Cardio M PC -W: both USB WiFiconnection)
- USB cable for connection to PC (A-mini B)
- **Cardio M PC** software

Together, these cooperating components are referred to as the Cardio M PC **PC** system.

## Minimal computer requirements :

*A personal computer configuration (desktop or notebook or netbook optionally equipped with inkjet or laser printer) with installed and working operating system from the following list:*

*Windows XP, Windows Vista, Windows 7.*

Note: the computer has to meet the requirements of the standard for business machines (EN 60950).

## 1.3 General instructions

The equipment is designed for use by qualified medical personnel only.

Please read this User's Manual thoroughly before using the equipment.

Safe operation and accurate results can be achieved only when the Cardio M PC system is used according to this User's Manual.

Only Medical Econet GmbH approved accessories should be used with the equipment.

### 1. Instructions for storing and transporting

- Do not operate or store this equipment in places with high humidity, in places with extreme atmospheric pressures or temperatures, in any place where it can contact water, or where poor ventilation, dust or any chemical pollution or industrial gas is present.
- This equipment must be stored on a flat surface. It should be protected against dropping, vibration, shaking and extreme mechanical forces both during storage and transportation.
- This equipment complies with IEC 601-1 type class II shock protection; therefore the computer must always be operated with its supplied shock protected voltage connector. Connect the computer's

voltage connector as specified, taking care to match the voltage and frequency of the network with the voltage and frequency of the device. Grounding the equipment is achieved through the network shock protection connector.

- **Cardio M** may be used safely in patients with pacemakers or other implanted devices. Like any ECG, the pacemaker or other device will not disrupt or be influenced by the operation of Cardio M PC. However, equipment operators and supervising physicians should be aware of the presence of pacemakers or other devices.
- The Cardio M PC system is designed for external, skin-surface ECG recordings only. It must not be used for intracardiac recordings and must never be directly connected to the pericardium with internal electrodes.

## **2. Using a defibrillator**

- Although the ECG input is protected against electric discharge, the electrodes must not connect with or otherwise contact the defibrillator pads or paddles.
- To avoid injury, the patient's bed, the patient, and all equipment or devices being used on the patient must not be touched by any personnel during defibrillation.

## **3. Using a high frequency device during surgical procedures**

- When the Cardio M PC system is used simultaneously with a high frequency device such as electrocautery, make sure that the ECG electrodes are placed as far as possible away from the surgical field, to prevent skin injuries that might result from malfunction of the neutral electrodes of the high frequency device. Only experienced personnel should place these neutral electrodes and special care must be taken.

## **4. Before using the device**

- Check that the device is in its usual state. Verify the correct connection of cables, especially the patient electrodes and lead wires.
- Check, that the computer must be placed at least 1.5m far away from the patient. A mains adapter or an extension cable must not be used.
- Other devices, that are not part of the system must not be integrated into it.
- When operating Cardio M PC with other electric devices, care must be taken that the devices do not disturb each other, and that possibly all devices are connected to the same potential equalizer, thus

reducing the risk of current infiltrating through to other devices.

- To avoid polarization voltage, and possible baseline fluctuation, all ECG electrodes applied on the skin surface should be of similar type. Avoid reusing disposable electrodes or using mixed types of electrodes.

### **5. During usage**

- Do not touch the electrodes and take care that neither the patient nor the electrodes connect with conducting objects (e.g.: metal parts of the examining bed, equipment holding tripods, etc).
- If one or more electrodes become loose, disconnected or are inexpertly placed, an error message will occur on the computer monitor during ECG recording. Replace these electrodes.
- If required for patient safety, switch off the device and disconnect the electrodes.

### **6. After using the device**

- Immediately after use, disconnect the lead wires from the electrodes, then remove and dispose the electrodes.
- Non-disposable electrodes, if used, should be properly cleaned after each use with alcohol of appropriate clearing materials. If needed, the lead wires may also be cleaned as appropriate.

### **7. Maintenance and checking**

- The Cardio M PC system and any accessories should be checked regularly (monthly) by visual inspection. If the system has been stored or not used for a long period of time (6 month), all components accessories must be checked carefully before using it again. The device must be powered off before cleaning and disinfection. The device must not be modified or altered any way.
- The Cardio M PC system is calibrated by the manufacturer prior to delivery. No additional calibration or scheduled maintenance needed under normal operation. In case of malfunction, manufacturer or distributor should be informed and the system should be taken out of service and labeled with visually prominent notice to prevent continued use. Repair must be carried out by the manufacturer or a qualified agent of the manufacturer.

## 1.4 Security instructions

This device complies with IEC601-1-2 international standards for electric medical devices and electromagnetic tolerance of devices.

If the electromagnetic environment exceeds limits specified in IEC601-1-2, the device could be disturbed such that malfunction or failure could occur.

Therefore to prevent malfunction or failure, nearby interference or noise should be eliminated before operating the device.

Here are some of the common sources of interference and steps to prevent them:

- The device is not grounded, is not connected to a potential equalizer.  
*Remedy:* Connect the potential equalizer switch of the device with the one in the examination room with a potential equalizer cable.
- Strong electromagnetic noise produced by nearby noise source (e.g.: mobile phone or radio station).  
*Remedy:* Eliminate the nearby noise source or, if the source cannot be eliminated, install the Cardio M PC system in another location.
- Radio-frequency noise (produced by another device) through the power supply of the system.  
*Remedy:* Search for the source of the noise and eliminate it if possible. Alternatively, try another power supply.
- Direct or indirect effect of electrostatic discharge.  
*Remedy:* Before operating the system make sure that neither the patient nor the user is electrostatically charged. The danger of electrostatic discharge can be reduced by suitable humidity and antistatic flooring.

### 1.5 Electromagnetic Compatibility

The Cardio M PC ECG needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided.

Portable and mobile RF communications equipment can affect the Cardio M PC ECG.

<b>Electromagnetic Emissions</b>		
The Cardio M PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio M PC ECG should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	The Cardio M PC ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Cardio M PC ECG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

<b>Electromagnetic Immunity</b>			
The Cardio M PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio M PC ECG should assure that it is used in such an environment.			
Immunity test	IEC 60601:1993 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±4 kV contact ±8 kV air	±4 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle  40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles  70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles  <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cardio M PC PC ECG requires continued operation during power mains interruptions, it is recommended that the Cardio M PC PC ECG be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

<b>Electromagnetic Immunity</b>			
The Cardio M PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio M PC ECG should assure that it is used in such an environment.			
Immunity test	IEC 60601:1993 test level	Compliance level	Electromagnetic environment—guidance
Radiated RF  IEC 61000-4-3	3 V/m  80 MHz to 1 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Cardio M PC ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = 1.2 \sqrt{P}$ 80 to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where $P$ is the maximum output power rating of the transmitter in watts (W) and $d$ is the recommended separation distance in meters (m).
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

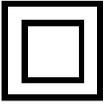
<b>Recommended separation distances between portable and mobile RF communications equipment and the Cardio M PC ECG</b>			
The Cardio M PC ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardio M PC ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardio M PC ECG as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter  m		
	150 KHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			

## 1.6 Technical parameters

Patient protection:	floating common (IEC-601, BF type)
Shock protection:	Class II.
Defibrillator protection:	5 kV (max. 1 kV/msec)
Resolution:	2.44 $\mu$ V/bit (12 bit A/D)
Input impedance:	>10 MOhm
CMRR:	>120 dB
Filters:	524 Hz low pass (hardware, constant)
	50, 100, 200 Hz (software, switchable)
	60, 120 Hz (software, switchable)
	35 Hz (software tremor filter, switchable)
Time constant:	1.6 sec
Linearity error:	<0,5%, < 1/2 LSB
Polarization voltage:	400 mV
Leads:	12 Standard + 3 Frank
Power consumption:	Both models: used on USB port + 5 V - 100 mA, <b>CARDIO M -W:</b> +3,7 V Li-Po embedded battery (2000 mAh)
Printing	To normal paper (A4) with inkjet or laser printer connected to the computer
Display	Using the monitor/video output of the computer
Status indication	Both models: green LED battery charge level status Both models: yellow LED slow blinking: USB connected solid light: ECG monitoring <b>CARDIO M -W:</b> blue LED solid light: active WiFi connection blinking: searching WiFi network
Computer requirement	Windows XP, Vista, Windows 7 (32 or 64 bit) operating systems
Controls	<b>CARDIO M -W:</b> power-on button (touch) Everything else from Cardio M PC softver
Accessories:	Standard 10 wire ECG cable, Standard limb and precordial ECG electrodes (optional) Standard USB cable A-mini B
Operation	Continuous operation

Operating temperature:	+10 °C - +40 °C
Storage temperature:	0 °C - +40 °C
Operating and storage humidity:	25% - 95%
Operating and storage pressure range:	750 – 1060 hPa

### 1.7 Explanation of symbols on machine

	Read User's Manual before operating!
	System is BF-type, protected against defibrillator.
	This device has Class II shock protection.
	Manufacturer.
	Date of manufacturing (YYYY-MM-DD).

## 2. Installation

### 2.1 Hardware installation

The parts of the system:

- ECG sampling device (connected to a USB port or with WiFi connection)
- Standard USB cable (A-mini B max. 3 m)
- Patient cable

**Operating system:** Windows XP, Windows Vista, Windows 7

The ECG device is connected to the computer using a standard USB cable shipped with the device. The cable has two different connectors, one that fits into the device and the other into the computer. The operating system of the computer automatically recognizes the ECG, whereupon the yellow LED on the device lights up and starts blinking. When the online monitoring is started in the Cardio M PC program the LED will light continuously due to the data transmission.

The standard ECG electrodes (can be ordered optionally) must be attached to the patient as regular. (see appendix 13.2 B)

### 2.2 Software installation

- Turn on the computer.
- After starting Windows, place the installation CD labeled Cardio M PC into the CD drive.
- If the automatic insert notification is enabled, the Cardio M PC installer will auto-start. Otherwise browse to the root folder of the CD-ROM and execute the installer shown with the following icon:



- Choose the destination directory. If there is a previous version already installed, we recommend that the new version be installed to the same directory. In this case the new version will automatically use the previous database. Choose the language. After successful installation Cardio M PC can be started by clicking on the following icon on the desktop, or by launching "wincrx32.exe".



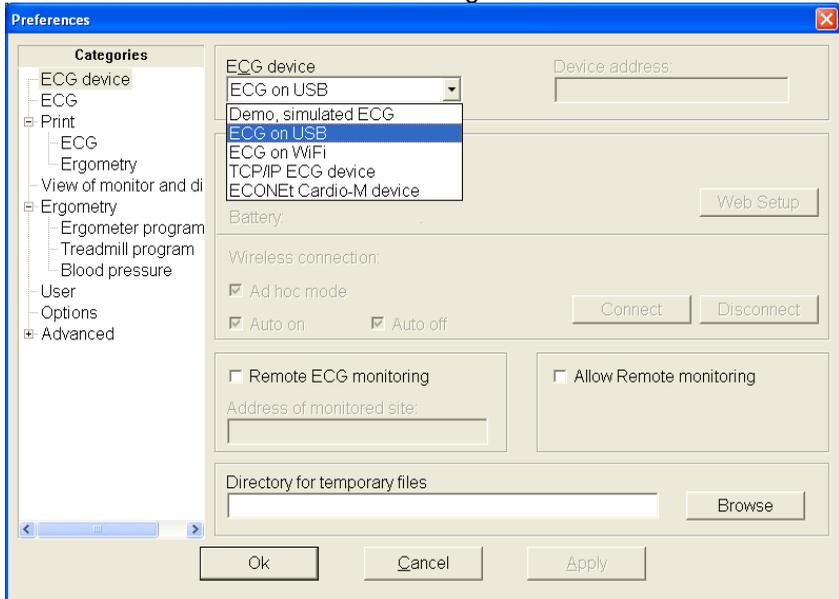
## 3. Setting the default parameters

Default parameters concerning the functions listed on the left can be adjusted here.

Menu: *Setup*

### 3.1 ECG device

The user selects the source for the incoming ECG data:



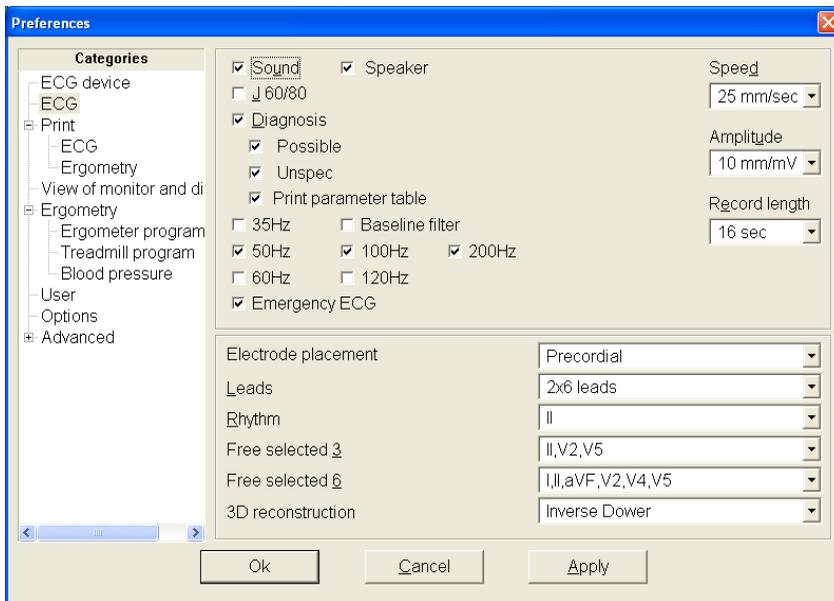
- ◆ *'Demo, simulated ECG'*: there is no connected ECG device, a simulated, not real, stored ECG curve is looped to simulate ECG recording.
- ◆ *'ECG on USB'*: USB-version device is connected to USB port.
- ◆ *'ECG on WiFi'*: Wireless device on WiFi network.
- ◆ *'TCP/IP ECG device'*: Controlling a remote device through TCP/IP network.

For supporting previous, already not manufactured and serviced but still working products, further two types of devices are available by selecting the ECG device category holding the *Ctrl* key pressed:

- ◆ 'ECG on LPT1': (or LPT2, or LPT3) printer port ECG device is connected to the specified printer port.
- ◆ 'Inner ECG Card': Cardio M PC extension card is used, which is built into the computer.

## 3.2 ECG

Settings for the ECG recording:



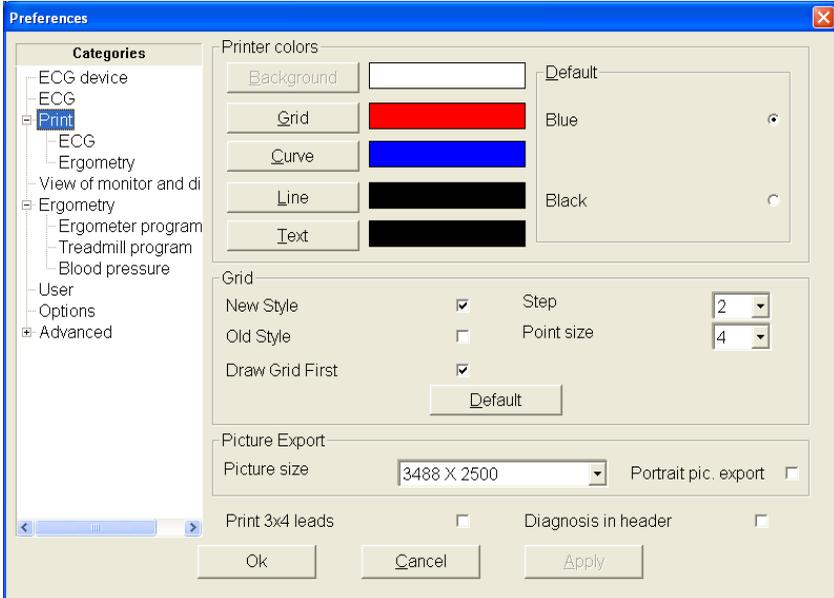
- The 'Leads', monitoring 'Speed' and the 'Amplitude' parameters can also be changed during the recording. With every new recording, the same default values set here will be used, until they are changed by the user.
- 'Diagnosis': when switched on, the automatic diagnosis function can be accessed; otherwise it is disabled. The categories can be enabled selectively
- Filters: 35Hz: muscle-noise filter, 50Hz, 100Hz, 200Hz or 60Hz and 120Hz: mains filter (it is advisable to have these turned on), 0.1Hz baseline fluctuation reduction filter

- '*Sound*': state of QRS-complex detection signaling
- '*Speaker*': use the system speaker for QRS signaling
- '*Recording length*': the length of the stored ECG segment, 8, 16 or 32 sec
- '*J+60/80*': the method of calculating the end of the ST segment; for more information see the Stress test chapter
- '*Electrode placement*': the actual placement of electrodes. Important for storing and evaluation of ECG recordings.
- '*Leads*': the lead combination by which the ECG curves will be represented.
- '*Rhythm*': You can select any of the 12 leads to be the rhythm strip on the median screen.
- '*Free selected*': It is possible to monitor any 3 or 6 channels in the recording. Here you can select which 3 or 6 you want to see.
- '*3D reconstruction*': Conversion method for vector ECG from normal 12 lead ECG.

### 3.3 Print

General ECG printout setting can be modified in this *Setup*-category.

In case of color printers, the color of the curves, the grid, the lines and the texts can be selected separately or well established default schemes can be selected. The background can not be modified it will be always white.



In some cases (especially with high resolution laser printers) the grid is too light, for this the printing style can be adjusted. The 'Old style' setting uses dots for the grid with the given *point size*, while the 'New style' draws lines as the grid using the *step size*.

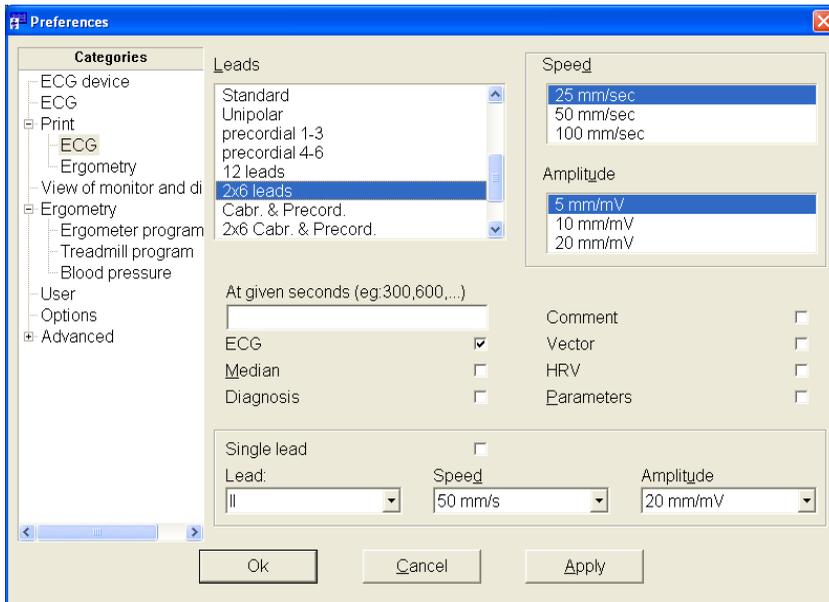
Toggling 'Draw grid first' may help in cases when grid is not printed correctly due to printer driver issues.

Checking the 'Print 3x4 leads' forces printing in 3x4 lead format always if printing from the monitor regardless of the selected lead selections.

The selectable 'Picture size' and the orientation is used for GIF and DICOM file exports from the print dialog.

Different prints can be created from the same ECG record.

The 'ECG' sub-category allows the predefinition of print-types which can be used at later time printing from the record list view of a patient (not from monitor view).



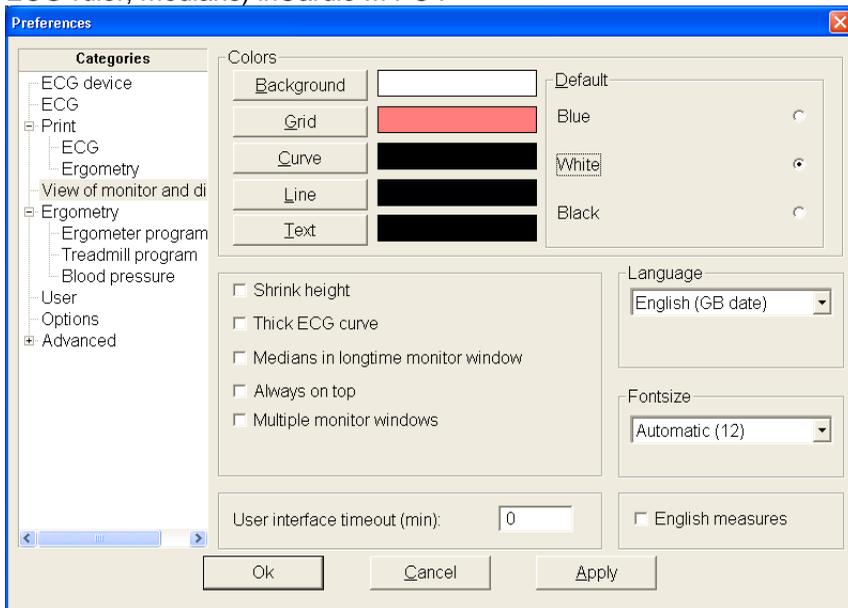
Lead combinations (multiple selection possible), speed and amplitude of the recording can be selected. Specifying given seconds results one page of ECG-curve printout at each given time points. With the special ... sign (three dots) periodicity can be defined (e.g.:100,... means every 100<sup>th</sup> second). Parts of the interpretation can also be separately included in the printing. The 'Single lead' box gives additional printout of the whole record with the corresponding speed and amplitude settings.

The 'Ergometry' sub-category allows the following report items of the stress test to be printed besides the ECG properties (on the ECG tab) that are also available independently from rest ECG settings in the previous sub-category. Likewise the *lead selections*, *speed*, *amplitude* settings and *single lead* parameters are also independent of the rest ECG settings.

ECG		Ergometry	
List of records	<input type="checkbox"/>	ST Level	<input type="checkbox"/>
Graphs	<input type="checkbox"/>	Conconi	<input type="checkbox"/>
ST Trend	<input type="checkbox"/>	Median of phases	<input type="checkbox"/>

### 3.4 Setting the size and color of the Monitor window

You can customize here the general appearance of the windows (monitor, ECG-ruler, medians) in Cardio M PC .



Colours can be set separately for the elements of graphs by clicking its button and selecting from the upcoming dialog, or you can choose from three presets (Default).

By selecting '*Shrink heigh*', the monitor window's height will change proportionally to the number of channels displayed. It can be useful, when other running programs also need to be seen on the display.

'*Thick ECG curve*' provides better visibility on the screen.

'*Medians in longtime monitor window*' displays the online calculated medians together with the curves.

'*Always on top*' ensures that the monitor window is always seen above other running applications.

When '*Multiple monitor windows*' is checked, each ECG record appears in its own individual window (e.g. for comparison).

'*Language*' can be selected for the program interface, if changed, the program restarts.

'*Fontsize*' determines the used font size in all Cardio M PC windows. Note

that other, operating system dependent fonts, like in menus and on system-messageboxes cannot be changed here. It is advised to choose the maximum size that fits your display resolution.

### 3.5 Stress test setup

See the chapter 9. *Settings for the Stress test* for details.

### 3.6 User

*'Institute'*: Set the data of the institute. This will appear in the header of every printed page.

*'Doctors'*: The first column of the table is for the doctor's initials, the second for his/her full name. Initials are used on the *Patient Card*, to indicate which doctor the patient belongs to. In printing only the full name appears.

### 3.7 Upgrade options

You can see information about the version numbers (ECG device, Software) and the list of possible options. An option is *enabled* if it is checked in the list

Options are the following:

- *'Network database'*: to use the software over a local area network. Recording is possible using the server software running on the computer with the ECG device connected. The created database can be viewed on all workstations.
- *'Stress test'*: if the stress test option is enabled, then the device can automatically control the ergometer/bicycle as well as save and store stress test 12-lead ECGs.
- *'Remote monitoring'*: online observation of ECG monitoring over a network. This function is useful, for example during stress tests, when an observing doctor is able to view the ECG curves on another computer.

#### **If you want to purchase a new option:**

Send the device number of your system and the list of requested options to your Cardio M PC distributor. You will receive a new password. Enter this password in the *Password* field then the new options will be available.

### 3.8 Password protection for using Cardio M PC

In the settings of the *'Advanced'* main category, you can prevent the unauthorized usage of the program by creating an optional entry password. After giving the new password, you have to re-type it to

confirm. If the new password and the confirmed password are not identical, a warning message appears and the password is not changed. When you next start the program, the system will ask for the new password.

Checking '*Backup on exit*' ensures a backup process to happen at program termination for saving any new data into a given directory.

### **3.9 Mail settings**

See in the chapter 8. *Transfer functions* for details.

### **3.10 NetCenter**

See in the chapter 12. *Network operation, multi-user features* for details.

### **3.11 Auto backup**

Hospital specific application.

### **3.12 Security groups**

Hospital specific application.

## 4. Using the Card File in Cardio M PC

When you start the program, the Cardio M PC system displays the **Card File** window. The right hand side of the window contains the **Patient List**, the left hand side of the window shows the **Patient Card** of the patient selected from the list. The Patient List contains the name, code, birth date, and the date of the last ECG record. The width of the columns can be adjusted (or even hidden) with the mouse by grabbing the delimiter in the table header.

The default order of the patients is alphabetical which can be changed by clicking on the header of the desired column (code, born, last ECG).

The easiest way to find a patient is to enter the starting letters of the patient's name. The cursor jumps automatically to the first line where letters are identical with the entered letters.

You can move in the patient list with the [Up] and [Down] keys, [PgUp] and [PgDn] are for the bigger jumps (pages). Jumping to the beginning/end of list: [Home], [End].

### 4.1 Adding a new patient



Menu: *Patient / New patient* Hotkey: [Insert]

You can start to start fill out the patient card. The patient card includes the following fields: *name, code, birth date, sex, height, weight, doctor, diagnosis*.

The entered dates can be stored by pressing [Enter] or by clicking on *OK*.

### 4.2 Editing a patient card

The patient card can be modified any time.



Menu: *Patient / Patient card* Hotkey: [Tab]

The last three lines of the patient card contain read-only information:

- number of stored rest or stress test ECG recordings,
- indicator of the patient's comment block
- date of the last ECG recording.

### 4.3 Deleting from the patient list



Menu: *Patient / Delete* Hotkey: [Del]

All data for the patient (including ECG recordings) will be deleted. **Important: the deleted cards cannot be undeleted! All patient data including ECG records will be lost!**

### 4.4 Selecting card files

Menu: *Select*

In the *Select* menu item you have the option to select only specific cards from the card file. You can select names one by one by pressing the [F3] key, or by groups, according to some common feature.

Use the *Select Group* window to indicate the aspects of the selecting - selection or deselection. If the data are indicated with [min] - [max], the two limit values are also included in the selection. In the '*Code*' and the '*Diagnosis*' field you can search for character strings, the '*Doctor*' field can be used to search by the initials of the doctor.

The number of the cards that have been found (i.e., that meet the search criteria) appears under the **Patient list**, with the names of the appropriate patients highlighted. You can select according to one or more criteria at a time, and by specifying another criterion you can extend or reduce the number of the selected cards. You can also create the inverse of the selection.

### 4.5 Findings (list of stored ECG recordings)

Entry: from the **Patient List** with [Enter] or double-click.

The left hand side of the **Findings** screen shows the card of the selected patient, the right hand side displays the list of the stored ECG recordings sorted by date.

The list of the recordings shows the date, and the lead system of the recording. Stress test ECG recordings appear as *Final report*.

**Cardio M** allows you to collect an unlimited number of ECG recordings from a patient and store up to 99 resting ECG recordings and 30 stress test ECG recordings in one patient card.

Select the appropriate field in the *Record* menu item to make a new ECG recording, to replay, evaluate, delete or copy a stored ECG recording, or to compare the ECG recordings and the medians.

## Deleting an ECG recording



Menu: *Record / Delete* Hotkey: [Del]

After selecting this function you have to confirm your decision. **The deleted recordings cannot be recovered!**

## Selecting ECG

You can select one or more recordings by [F3] from the stored ECG curves. Select a recording in order to replay or evaluate it, or select several recordings to compare the ECGs and/or their medians, or to copy or print the ECGs. You can also create the inverse of the selection. The selection is valid until you cancel it or until you quit the patient card.

## Copying ECG

Menu: *Record / ECG-Copy*

Patient records can be copied to other patient's records. This could be useful if you are trying to merge the mistakenly twice registered patient's distinct records into one or if you just want to see records of different patients in one listing.

After selecting the records to copy you have to select the target patient in the patient list and enter his/her records.

Menu: *Record / ECG-insert*

After you have confirmed your operation the records will be inserted into the list in the correct chronological order.

## 4.6 Comment block operations

Besides this, you can edit a comment line for **each ECG recording**, which can be up to 20 characters in length.

Menu: *Record / Comment to recording*

Hotkey: [F4]

You can attach a comment block for **each patient**.

Menu: *Patient / Comment block*

Hotkey: [F2]



## 5. ECG recording

### 5.1 Monitoring

You can monitor the ECG with the Cardio M PC system if you have a connected and enabled Cardio M PC device. During monitoring, the ECG curve is displayed on the screen and you can save selected temporal segments of data. You can turn on/off the tremor filter, the sound of the QRS detector or change the lead system, the number of the displayed channels, paper speed, time resolution, amplitude gain, and the length of the recording to be stored. If the device selected in the Setup is not available, the following is displayed:



#### Start the monitoring



Menu: *Record / ECG record* Hotkey: [F9]

Note: First you should select your device in the *Setup / ECG* menu. If the default '*Demo no ECG*', is selected, you will get a simulated recording.

### 5.2 Time resolution, amplitude gain, QRS-sound and filter

The time and amplitude resolution of the ECG recording starts with the parameters selected in the *Setup*, but these can be changed during the recording.

#### Time resolution:



Menu: *Set / Time resolution* Hotkeys: [-], [+]

Speed can be 25, 50, 100 or 200 mm/s.

#### Amplitude:



Menu: *Set / Amplitude* Hotkeys: [Up], [Down]

Amplitude can be 5, 10, or 20 mm/mV.

It is possible to toggle on/off the beat detection sound, the 35 Hz tremor filter, and the baseline wander (spline) filter.

**Sound:**

Menu: *Set / Sound* Hotkey: [F6]

**Filter:**

Menu: *Set / Filter* Hotkey: [F7]

Besides the 35Hz tremor and baseline wander (spline) filters, there are also other filters available. Enabling and disabling these is done through the Setup - ECG menu.

The average pulse (HR, beats per minute) and the time between the last two R waves (RR, msec) can be seen in the top-right corner of the screen.

### 5.3 Selecting a lead system

The system supports three types of electrode placement, from which the following lead combinations can be displayed (see also Appendix C.):

#### 1. Placing only the limb electrodes:

- *Limb: I, II, III, aVR, aVL, aVF*
- *Cabrera: aVL, I, -aVR, II, aVF, III*
- *Standard: I, II, III*
- *Unipolar: aVR, aVL, aVF*

The stored recording is indicated as '**Extremal**' .

#### 2. Standard placement of all 10 electrodes:

- the previous four, plus:

- *Precordial: V1, V2, V3, V4, V5, V6*
- *Precordial 1-3: V1, V2, V3*
- *Precordial 4-6: V4, V5, V6*
- *Free select 3 leads (can be set in the 'ECG' window of the 'Setup')*
- *Free select 6 leads (can be set in the 'ECG' window of the 'Setup')*
- *12 leads: I, II, III, aVR, aVL, aVF, V1...V6*
- *Cabrera+Precordial: aVL, I, -aVR, II, aVF, III, V1...V6*

The indication of the stored recording is '**Precordial**'

#### 3. Frank placement of 10 electrodes:

- the first four, plus:

- *Frank: X, Y, Z*

The stored recording is indicated as '**Frank**' .

## 5.4 Storing the ECG recording



Menu: *Mode / Save* Hotkey: [F9]

You can use this function to save the immediately preceding 8, 16 or 32 sec of ECG tracing that you have been monitoring. The ECG curves are always stored without the 35 Hz filtration.

The length of the ECG to be stored can be specified by:



Menu: *Set / Record length = 8/16/32* Hotkey: [F8]

Pressing [F8] repeatedly will cycle through the three options.

It is also possible to continuously save the whole ECG curve forward in time. To activate:



Menu: *Mode / Continuous save*

This will cause the actually displayed curves to be stored continuously on the storage device. The timer on the right side of the screen shows the length of the ECG recording that has already been saved by the program. Saving can be terminated any time by pressing the Stop (green square) button or by exiting the monitoring window. The ECG records saved in this fashion will have the name "Longtime" in the list of ECG recordings, regardless of the lead configuration you are using.

## 6. Stored ECG recordings

### 6.1 Recording display in the 'ECG ruler'

The curves are displayed with baseline correction. If the baseline correction could not be performed, for example because the recording was too noisy, incomplete, or possibly because the patient had a pacemaker, and an error message will appear:

*"Baseline correction failed"*

You can perform measurements on the curve displayed in the ECG rulers with the help of the markers. The top right hand side of the window displays the average heart rate (HR), below it the time interval between the markers in msec, and the heart rate that you would get if you regard this time interval as the RR distance.

Using Frank placement, 2D and 3D vectorgraphs are also available.

#### Filter



Menu: *Set / Filter* Hotkey: [F7]

The filter of the ECG can be turned on/off. (see also *Monitoring*).

### 6.2 Comparison of recordings, medians

To compare recordings select from the list with the key [F3]. There are two possible ways of comparison:

#### 1. Compare of ECG curves



Menu: *Record / Compare*

You can compare the specific leads of up to 6 rest or stress test recordings. If there are more recordings selected, only the first 6 will appear in the comparison. The program displays the same lead of the selected records. Select another type of lead from the *Leads* menu.

#### 2. Median comparison



Menu: *Record / Compare*

The program displays, in the case of a 6 channel recording a maximum of 7, and in the case of a 3 channel lead a maximum of 4, median recordings at a time. If you have selected several recordings, use the [PgUp] and [PgDown] keys to scroll forward or backward. The median cells display

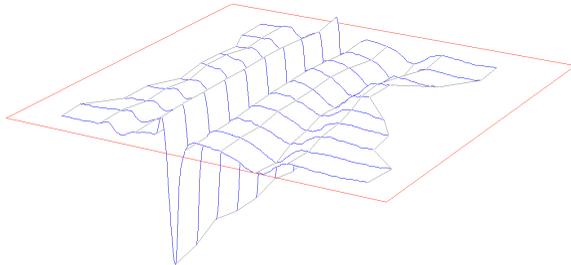
the average beat of the recordings. The header of the columns contains the heart rate (HR) calculated from the given curve, the date of the recording and, for stress tests, the serial information related to load phases and time values. You can magnify the median cells with the mouse-click. Above the magnified picture the program displays the global parameters and besides those the parameters characteristic to the individual lead.

You can analyze and compare the medians in a much more vividly descriptive way by viewing them all together: Cardio M PC can put together the related medians in a 3D-figure. Medians from different recordings appear one after another. It is easy to see the differences in the length of the QRS-complex, the T-wave, etc. Medians from every lead can be examined this way.



Menu: *Mode / 3D-median compare*

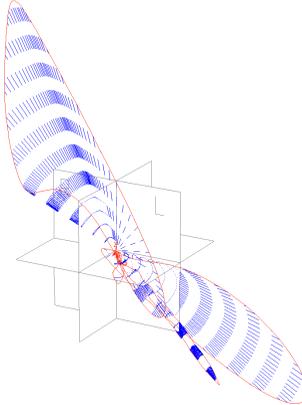
The picture below illustrates a 3D-median from the V1 lead:



## 6.3 The Frank ECG vector



Menu: *Mode / Vector*



The Cardio M PC program can display the vector ECG from the 'Frank' ECG recording. You need the special placement of the precordial electrodes in order to make a 'Frank' ECG recording (see Appendix B.)

The 'Frank' recording displays the orthographic projection of the ECG vector in the X, Y and Z planes (leads). The program creates and displays the vector diagram from the segment marked out in the ECG ruler by the markers.

The left window shows the frontal, horizontal and sagittal projection, the right window shows the 3-D curve. You can rotate the 3D diagram in any direction and toggle on/off the 35 Hz filter.

## 6.4 Replay of recordings

*Mode / Playback* displays the stored recordings in a form that simulates the monitoring mode. All functions valid during monitoring are also valid here, except the recording length.

## 6.5 Data export to MS-Excel

Menu: *Mode / File export*

Thanks to the file export feature you can display data from your recordings using Microsoft Excel, allowing you to make presentations, perform statistical analyses, etc. The exported file is a plain text file, with the data cells in the table separated by semicolons. You can export all of the following:

- the recording itself - every point of the curve is represented by an

integer number,

- medians, counted from the curve
- result of the diagnostics and the parameter table

File export can be started by *Mode / File export* from **Ruler** and from the window of the **Medians** or by pressing the *Export* button in the **Diagnosis** window.

### 6.6 Longtime recordings

With saved "Longtime" ECG curves, besides the previously mentioned measurement and other functions, it is also possible to obtain a view of the whole recording. This can be done within the *Navigation window*.

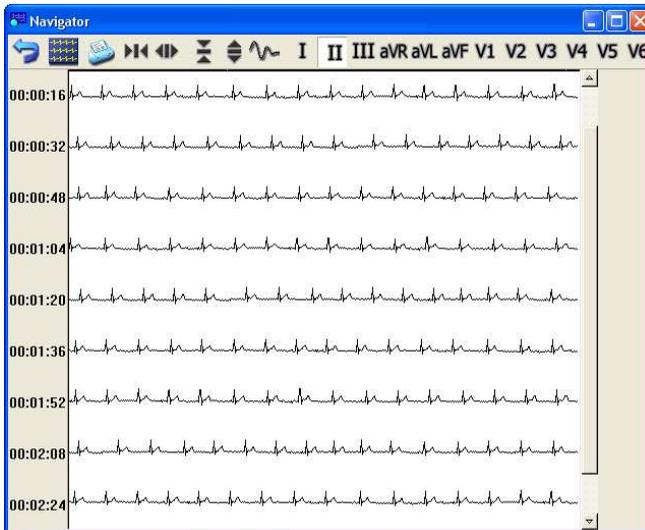


Menu: *Mode / Navigation window*

The *Navigation window* will display a single channel ECG picture that the user, can scroll through. Orientation is made easier by the time stamps on the left.



Using the lead-specific icons at the top, it is possible to individually view information from any of 12 leads. The arrow symbols control the time and amplitude sampling rate while the lead buttons change the lead to be displayed in the previously mentioned way.



## 7. Evaluation of the ECG recordings

The Cardio M PC system allows you to evaluate and analyze your stored ECG recordings in an offline fashion, subsequent to data collection itself.

The 12 lead ECG recordings indicated as '*Precordial*' can be automatically evaluated. The automatic evaluation (*ECG ruler / Interpretation*) produces the averaged (median) beats from the recording, performs the rhythm and contour analysis, and prepares a table of the related parameters.

If the selected recording is incomplete (the ECG sign does not appear on a channel) or one of the leads is too noisy, an error message appears, and the program does not perform the automatic evaluation.

### 7.1 Manual evaluation in the 'ECG ruler'



Menu: *Mode / Interpretation* Hotkey: [F8]

The median calculation determines the most characteristic beat in each lead and displays these median beats for all 12 leads. It also calculates the time and amplitude values necessary for the rhythm and contour analysis, draws the rhythm curve and displays a table of the diagnostically important parameters.

### 7.2 Median calculation

The Interpretation window displays the most characteristic (averaged or median) beat for each lead. The bottom part of the screen shows the rhythm curve. Select one lead as the rhythm curve in the *Setup / ECG* menu. The medians appear in 50 mm/sec time resolution and with 10 mm/mV amplitude. The parameters of the rhythm curve: 8 sec, 25 mm/sec and 5 mm/mV.

The upper table (on the right) shows the global parameters relating to the whole of the analyzed curve, whereas the lower table displays the more specific parameters relating to the selected lead. You can click with the mouse on any selected median cell in order to enlarge it. The corresponding median curve will appear in the graphic part of the screen in magnification, with 20 mm/mV amplitude and 200 mm/sec time resolution.

On the magnified median, markers show the interval-related calculation points for all of the usual projection points on the ECG curve: These points are the same for every lead, as shown in the table above and to the right of the medians.

- PB, PE - beginning, end of the P wave;

- B, J - beginning, end of the QRS complex;
- STE - end of the ST segment;
- TE - end of the T wave.

The parameters within the table beneath and to the right of the medians are calculated on a lead-by-lead basis. The calculation of the ST attributes can be done in two different ways, press F5 to toggle it. The calculation of the end of the ST segment is different:

- STE - the middle point of the interval between the global cusp of the T wave and the J point
- J80 (J60) - 80 msec from the J point or in case of HR > 100, 60 msec from the J point.

### 7.3 Parameters



Menu: *Mode / Diagnosis*

The *Parameters* item displays the parameters of every lead system in a comprehensive table. The upper part of the table contains the global parameters relating to the whole of the recording, the lower part contains the specific parameters of each lead system.

The *Automatic diagnosis* provides a suggested rhythm and clinical diagnosis based on the evaluation of the morphology of the recorded ECG, to assist in interpretation by the physician. **ANY FINAL DIAGNOSIS MUST ALWAYS BE MADE BY A QUALIFIED PHYSICIAN.** The physician's diagnosis can be added by opening the *Edit diagnosis* item, where the suggested *Automatic diagnosis* text will be displayed.

Patient AGE must be entered by the user for the *Automatic diagnosis* function to operate: (children 1-15 years, adults 16+ years). Without an entry for patient AGE in the patient card, a warning appears.

The first statement of the diagnosis contains the length of the ECG recording used for analysis, the total number of the beats analyzed, and statements that refer to the normal (non-pathological) attributes of the ECG. Following this is a list of ECG alterations classified as pathological. This list also includes findings in which pathological ECG findings are present but in which ECG parameters do not reach threshold values to make a diagnosis. The diagnosis also lists non-characteristic deviations that cannot be clearly related to a pathological ECG alteration but which should be further evaluated.

## 8. Data transfer functions

### 8.1 Copying patient card

Menu: *Transfer / Open 2nd card file*

This function can be used for copying all patient data to another subdirectory or another drive.

The target drive and subdirectory where the data should be copied should be specified. If a nonexistent directory is specified, the program will offer to create it. After pressing OK, the patient list is divided into two parts. The upper panel shows the previous database and the lower panel shows the newly opened database. If there is already patient data it will be displayed.

To change to the new database:

Menu: *Transfer / Toggle card files* - Hotkey:[F6]

To copy from one to the other:

Menu: *Transfer / Copy* - Hotkey:[F5]

Patient records that have been selected will be copied. If no records are highlighted as selections, the single record at the cursor will be copied. All data, including ECG recordings, is copied.

### Re-archive

Menu: *Transfer / Re-archive*

Previous versions of Cardio M PC allowed a group of patients to be archived to smaller capacity media (floppy disc) for backup. This feature is dismissed due to the great increase in disk capacities, though the re-archiving of previously archived data is supported through this command.

### 8.2 Backup

Menu: *Transfer / Backup*

*Backup* can easily be done with this function to create a duplicate (mirror) database. When *Backup* is invoked the program will automatically select and copy patient records that do not already exist in the duplicate (mirror) database (or that are newer than existing records).

### 8.3 Copying and inserting ECG recordings

Menu: *Record / ECG-copy*, *Record / ECG-insert*

It is easy to copy individual ECG recordings as follows:

- Select the recordings to be copied on the **Findings** screen [F3]

- Use the *Record / ECG-copy* function to copy the selected recordings. The program will store which recordings have been selected.
- Select the patient's card file where the selected ECG recordings are to be copied, then use the *Record / ECG-insert* function to insert them in the list.

Examples of using this function:

- If a patient's ECG is mistakenly recorded twice, it is possible, to unite the two recordings into one, and delete the unnecessary record.
- If recordings of a common type are to be examined, for example myocardial infarction patients, it is possible to create a record called "Myocardial Infarction", and collect the recordings in that card.

## 8.4 Exporting and importing files

Cardio M can export the measurements in several file formats, most of them are commonly used in the medical industry, like SCP, HL7 or DICOM.

Menu: *'Transfer'* /

From the patient list or from the record list, the selected items or the actual item can be **exported** using the *'Transfer'* menu in the following formats:

- SCP: With the *'File export (SCP)'* function a directory browsing dialog opens and after selecting or creating the desired destination directory, the concerned recordings are written as SCP files, containing patient data too. **Concerned recordings** are all the rest or stress ECG records of the selected patients, or if none is selected only of the actual one. If the function is selected in the record list of a patient, concerned recordings are the selected / actual rest or stress ECG records. File names are generated from the creation time of the recordings and have the extension **.scp**.
- HL7: With the *'HL7 export'* function a confirmation window pops up and after selecting *'OK'* the concerned recordings (see above) are written in HL7 format files into the **EXPORT** directory of Cardio M PC (default is C:\Crx\EXPORT). There is a setting in the initialization file (default is Cardio M PC *.ini*) that enables the ECG curve data to be written into the HL7 file as well. The setting is under the [hl7] section as *wave=1*. File names are generated from the creation time of the recordings and have the extension **.rep**.
- DICOM: With the *'DICOM wave export'* function a directory browsing dialog opens and after selecting or creating the desired

destination directory, the concerned recordings (see above) are written as DICOM files with waveform data, containing patient data too. File names are generated from the creation time of the recordings and have the extension **.dcm**.

- **CRC**: It can be created with the '*File export (CRC)*' function. It is a *proprietary format* and can contain the records of a patient, so when more patients are selected when exporting, a directory browser opens for selecting the destination of multiple files (one for each patient), while if a record or selected records from a single patient are involved, a file selection dialog opens, where the name can be specified too. Else a random name is used. Extension of the file is **.crc**. (additional files may be created with the same name but with random extension, the crc file needs them)
- **CRN**: It can be created with the '*Patient name export (CRN)*' function. Also proprietary for informational purposes, contains patient data only. A file selection dialog opens and the destination file will contain the data of the actual patient, regardless of any selection if invoked from the patient list view. Extension of the file is **.crn**.

These export functions are also available in the popup menu of the list views invoked by right mouse clicking on an item or selected items.

File exporting can be initiated from the monitor window as well. Under the '*Mode*' menu there is a '*File export (CSV/SCP/DCM)*' function that opens a file selection dialog to define the destination file and also the export format for the ECG record being viewed. For CSV type selection the curve data is not exported, see chapter 6.5 *Data export to MS-Excel* for details. When initiated from the median view, the SCP or DICOM file will contain the medians as the wave data.

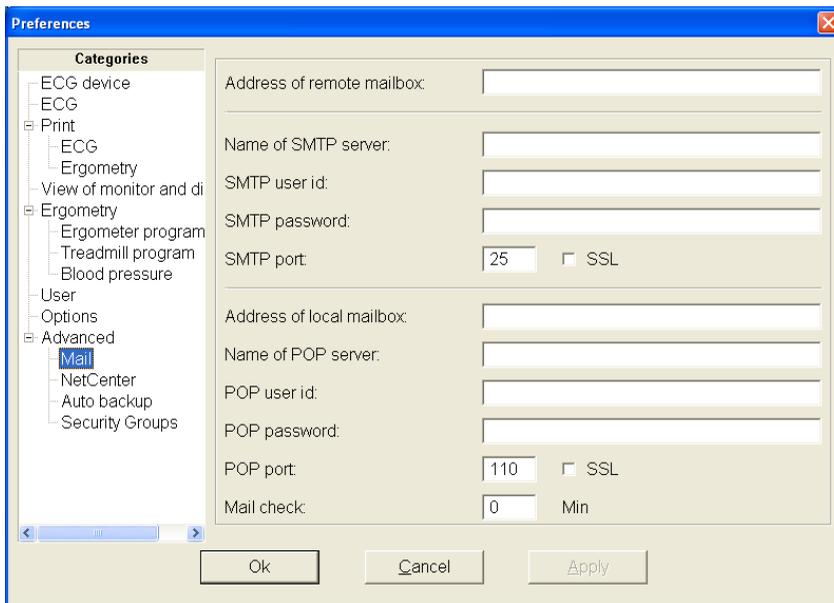
Raster based DICOM files can also be created with Cardio M PC . Everything that can be sent to the printer in Cardio M PC can also be exported as DICOM encapsulated Jpeg images. In the lower right corner of the Printing dialog in Cardio M PC there are two buttons for picture exporting. One is for DICOM, the other is for GIF format. The DICOM file will contain patient data too, while the GIF will have a text file created with **.ini** extension holding the patient and other metadata. For available picture settings see chapter 3.3 *Print*.

Cardio M can **import** files in its own CRC format. The function can be invoked by selecting *'Import from file (CRC)'* under the *'Transfer'* menu. Then a directory browser opens for selecting the place where the files to be imported are located. All the patient cards and ECG recordings in the directory will be imported. Upon successful import, the files are deleted. This function is only accessible in the patient list window.

## 8.5 Send / receive by mail

Patient cards and ECG recordings can be transmitted by e-mail with an appropriate Internet connection. Required settings must be given previously in the *'Setup'* menu under the *'Advanced / Mail'* category. The address of the remote and local mailboxes are to be filled implicitly.

The SMTP and POP server names can be obtained from the mailer client if set, or from the Internet provider. Some servers may require secure connection, this can be set by checking SSL. The ports are also need to be obtained from the service provider.



A non-zero value for the *'Mail check'* field provides automatic checking of inbound mails into the local inbox.

The sending procedure:

- select the patient cards / ECG recordings to be send [F3]
  - select the '*Transfer / Send by mail*' function [F11]
  - input or select previous recipient address in the pop-up window
- Mail sending can be initiated from 'inside' an ECG recording while viewing in the monitor window by pressing key F11.

The receiving procedure:

The program checks automatically in the specified intervals for inbound mails. New ones are downloaded and added to the Cardio M PC database automatically, accompanied by a notification window. Checking for new mail can be initiated anytime using the menu '*Transfer / Receive by mail*' or by pressing key F12.

---

## 9. Settings for the stress test

Menu: *Setup / Ergometry*

In the main category (*Ergometry*) the device can be selected, while in the following two subcategories the workload parameters can be set. In the third subcategory the blood pressure device can be selected and enabled.

### 9.1 Ergometer/bicycle, blood pressure measurement and RS232 control

Before beginning the stress test, select the serial port (*Port* item) and the type (name) of the connected device. If the type of bicycle or treadmill used for the stress test is not listed, or if it cannot be controlled by a computer, then choose *Ergometer* or *Treadmill without PC connection* . When using the *Treadmill* you have the option to choose the units of speed measurement: km/h or mph.

Use the '*Check*' button to test the connection. If successfully connected, then a '*RS-232 control*' message appears. If the program is unable to control the device, the warning message '*No RS-232 connection*' appears. There are several possible reasons for this warning message:

- the device is not connected properly
- the device is turned off
- the selected device is not identical with the connected device
- the appropriate COM port has not been chosen
- the COM port is not set up correctly
- the serial cable is not appropriate or it is broken

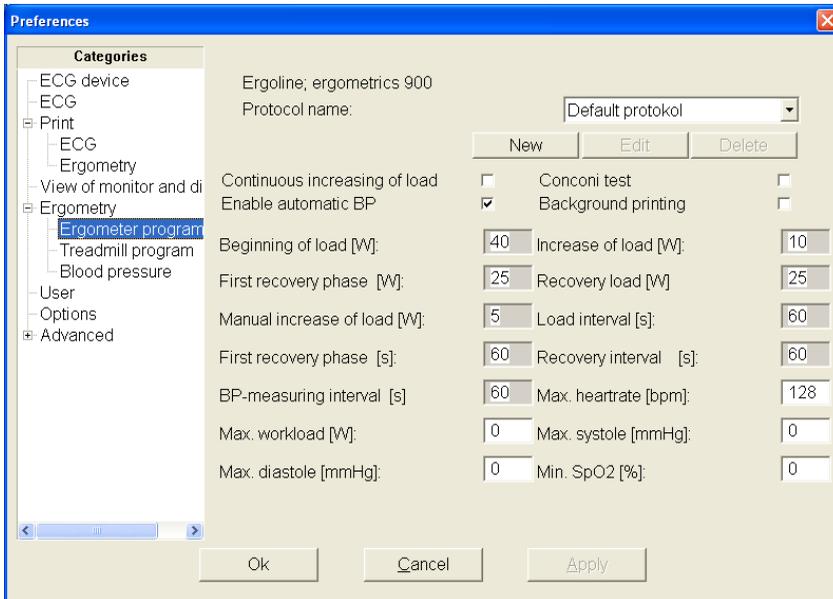
With the *Command test* button the individual control commands can be tested.

### 9.2 Load program (Ergometer/Treadmill)

The workload scheduling can be given here.

When using a **cycle ergometer/bicycle**, you can select a protocol or define a new one by giving a name and pressing '*New*' button. The parameters '*Beginning of load*', '*Increase of load*' and '*Load interval*' are self explanatory. The '*First recovery phase*' can be differentiated by

assigning specific load and interval values to it. This can be useful when the patient reached high load (e.g. sportsmen) and the doctor intends to introduce recovery phase gradually. Subsequent recovery phase setting are given at '*Recovery load*' (usually 25W) and '*Recovery interval*'. The '*Manual increase of load*' is used when pressing the W- / W+ buttons during stress test.



'*BP-measuring interval*' – applies to blood pressure measurement frequency if no extra BP is given. This duration cannot be shorter than 60 sec.

'*Continuous increasing of load*' – by selecting this option, the load will increase linearly during the given interval, not abruptly at the end of each one.

'*Conconi test*' – special load type, frequent in Switzerland.

By setting any of the stop conditions '*Max heartrate*', '*Max workload*', '*Max systole/diastole*', '*Min SpO2*' the program alerts when a specific value is reached.

When using a **treadmill**, first a protocol must be selected or a new one can be created. The tables contain the time, speed and grade parameters for the phases of the program. The stress and recovery programs have individual tables. The maximum number of phases can be 12.

The following common protocols are predefined:

0 = BRUCE	1 = MODIFIED BRUCE
2 = NAUGHTON	3 = CORNELL
4 = BALKE	5 = MODIFIED BALKE
6 = ACIP	7 = ELLESTAD I
8 = ELLESTAD II	

The following stop conditions can be set: *'Max heartrate'*, *'Max systole/diastole'*, *'Min SpO2'*. The program alerts when a specific value is reached.

## 10. Stress test

Menu: *Record / Stress test*

First, in the setting window, make sure there is a checkbox next to “RS232 connecting”

If the necessary patient information (date of birth, sex, height, weight) is not specified on the patient card, a warning appears. You can continue without supplying the data or return to the PATIENT CARD, enter the necessary data and restart the stress test.

After choosing the appropriate stress program, begin monitoring by pressing (*START*, or [F9]).



### 10.1 Recording the stress test

Monitoring begins with a resting ECG recording. You can begin the workload stages as following:



Menu: *Stress test / Start*

Hotkey: [F9]

The ergometer/bicycle will begin with the initial workload and the storing of the full 12 channel ECG recording will also start. The duration of workload stages will be that chosen in the *Settings* menu. At the end of each stage, an ECG is stored, and the workload will be increased for the next stage.

The monitor window displays the following data:

- blood pressure (or, in case of automatic measuring: the word “display”)
- time of blood pressure measurement
- stage time and total test time in sec
- actual load measured in W (or, in case of a treadmill: speed and rise)

### Test breakpoints

If any one of the test breakpoints is reached, the program enters the recovery phase. However, you can choose to continue the test at the current workload, by pressing [F3] within 15 seconds.

On the screen display, below the test time indicators, you can see the actual value of the workload, measured in watts for the ergometer/bicycle and as speed and grade for the treadmill.

## 10.2 Recovery phase

At the end of the last workload stage, or when any test endpoint is reached, the program automatically switches to the recovery phase.



Menu: *Stress test / Recovery*

If a limit value is reached, the workload can be continued by pressing [F3] within 15 seconds and the recovery phase will not begin

In the recovery phase the workload is set to zero or to a minimum value, and blood pressure measurements continue. With ergometer/bicycles controlled by the computer, the workload is set to a minimum value automatically. With ergometer/bicycles that are not computer controlled, the minimum workload must be set manually.



Menu: *Mode / Return*

Hotkey:[ESC]

Quits the program. Be sure to the test is completed and saved before quitting.

### 10.3 Blood pressure measurement

Blood pressure (BP) measurements start automatically at the end of the rest, load and recovery phases. The blood pressure measurements can be done in two ways:

In manual BP mode, the user types in BP measurements in the following form: BP[mmHg] = systole/diastole. Before the end of each workload stage, the program provides a beep signal and a schematic figure of a sphygmomanometer appears under the pulse values. The BP measurements are to be entered 40 seconds after the beep tone - a white stripe in the schematic figure indicates the time remaining.

With an automated BP measurement device connected, the computer acquired and stores the data. The program displays the last measured BP values.

It's also possible to take BP measurements more than once in each stage or phase, or to leave out BP measurements. This option is set in *Extra BP-measurement*. If this field is empty or 0, then each stage or phase will have one BP measurement performed.

If this field is set to :

1, 2, 3, 4            then there will be            2, 3, 4 or 5 measuring per phase.  
-1, -2, -3, -4       then the 1st, 2nd, 3rd and 4th phases will not have BP measurements taken.

#### Examples:

- Interval = 180
- Extra BP measuring = 2
- Time interval for BP-measuring:  $180/(1+2) = 60$ .
- Interval = 90
- Extra BP measuring = -1
- Time interval for BP-measuring:  $= 90*(1+1) = 180$ .

At the end of extra BP-measurements (40 sec after the beep) there will also be an additional ECG saved. The measured BP values will be added to this ECG recording.

### 10.4 Manual change of workload

It is possible to increase or decrease the pre-programmed workload with the value set as the '*Manual increase of the load*' in the ergometry

program settings.

**W+**

increase by the set amount.

**W-**

decrease by the set amount.

Once the desired change in workload set, it should be saved by pressing ([F9]) within 10 seconds to store the new workload value.

It is also possible to hold the workload constant and cancel the pre-programmed increases in workload. In this case the workload will remain constant until it is cancelled.

**W=**

With this choice, the displayed workload value (watts) blinks, and the workload remains constant until this choice is again selected to cancel.

## 11. Evaluation of the Final report

The final protocol of a stress test is displayed in the list of recordings and identified as **Final report**. Press [Enter] or double-click to open a **Final report** for evaluation.

The **Final report** consists of 4 main parts: *List, Graphs, ST Trend, ST List*.

### List of workload stages

The recording list shows the ECG recordings made during the stress test and parameters of each stage.

The ECG list of an **ergometer/bicycle** stress test contains the time, load, blood pressure (BP), heart rate (HR), revolutions per minute and ST values of the phases. In case of a **treadmill** stress test, the fields for load and the revolutions per minute are replaced with data relating to the speed, grade, MET values and the Double-Product or Cross-Product (Max HR X Max systolic BP).

In the last column choose the symbol or press [F5] to toggle between the STE, STM and STJ amplitudes, and press the [+] and [-] keys to toggle between the lead systems. The STE, STM and STJ values are replaced with J80/J60, J40/J30 ST J values if the program used the option for J+80(60) msec to determine the end of the ST segment ('Setup' 'ECG' 'J + 60/80' 'ON').

Select the *ECG* menu item to replay, measure, evaluate, compare and delete a recording in the same way as for resting ECG recording. Press [F3] to select recordings for comparison.

The evaluation of ECG intervals and segments of the stress test ECG is performed in an identical manner as the evaluation of resting ECG recordings. However, the automatic interpretation function in the stress test ECG differs in a few ways:

- the parameters of the P wave do not occur in the parameter tables
- if a lead is noisy or cannot be evaluated, the program does not calculate the median of this lead, but the other medians and their parameter tables are calculated
- the program does not propose a diagnosis, but you can ask for the reports of the evaluation

### 11.1 Calculation of maximum exercise performance

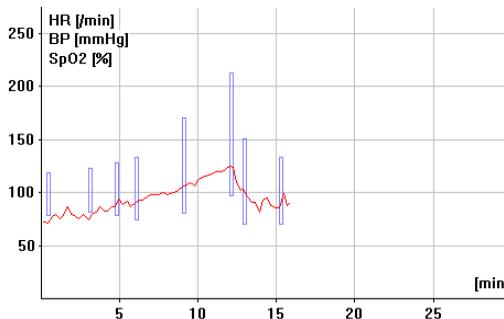
Maximal HR, predicted HR (220 minus age), maximal BP and the maximal

workload achieved are displayed just below the recording list.

For a ergometer/bicycle stress test, the right hand side of the screen display shows an evaluation of exercise performance. The maximum expected performance from the patient can be calculated according to the weight and the body surface area, by the method of DuBois. The display also shows achieved performance as a percentage of maximum predicted. If the HR during the stress test has reached the limits defined for the PWC calculation (130, 150, 170 /min), the program gives the absolute and relative PWC values as well as the "normal" PWC values according to age and sex in a table.

For a treadmill stress test the program displays (to the right of the table) the calculated oxygen consumption (VO<sub>2</sub>), the Double-product (product of the maximal HR and the maximal systolic BP) and MET values.

### 11.2 Stress test graphs



You can view the diagrams and tables giving a comprehensive evaluation of the stress test.

#### *Ergometer/Bicycle:*

On the left hand side of the screen the first graph displays the heart rate and if available, the SpO<sub>2</sub> percentage as a function of time and the blood pressure measurements. Predicted HR, maximum HR and the maximum GP values, shown in the top right corner. Beneath this graph, the workload is displayed as a function of time.

On the right you can see the table of the PWC. The third graph displays the trend of heart rate as a function of exercise performance, with the PWC values marked.

#### *Treadmill:*

The first two diagrams show the same measurements as in the case of the ergometer/bicycle. The third figure is the diagram of the calculated

oxygen consumption as a function of time.

The right hand side of the screen displays the calculated oxygen consumption and the Double-product values. Beneath that, there is diagram displaying the trend of the Double-product / 1000 as a function of oxygen consumption.

### **11.3 ST evaluation**

#### **ST Trend:**

The screen displays the ST diagrams of the 12 standard leads as a function of time. Press [F5] to toggle the STJ, STM and STE values. With [Up] and [Down] keys can you change the amplitude gain.

#### **ST List:**

The ST-list is a comprehensive table of heart rates and ST values of the standard 12 leads. Press F5 to toggle the STJ, STM and STE values.

The STE, STM and STJ values are replaced with J80/J60, J40/J30 STJ values if the program used the J+80(60) msec to determine the end of the ST segment. ('Setup' / 'ECG' / 'J + 60/80' 'ON').

## 12. Network operation, multi-user features

### 12.1 Local network operation

In case of using the program in a network configuration the software must be installed only to the server computer. It can be executed on each workstation that uses the common database located on the server. A patient's card can be accessed from several places this way and possible changes can be tracked from those places without intervention.

The parameters set in the 'Setup' menu are valid for each workstation. When a user wishes to use custom configuration, the program can be started with the `-i` option and the name (e.g. station01) of the .INI file containing the custom settings:

**wincrx32.exe -istation01**

If the given file does not exist, the program will create one, but a unique name selection is important in the network environment.

In network operation ECG recording on a workstation is possible only after enabling the option with a password. For these workstations the '*Network database*' option must be bought as well as other options that are needed on the workstation (see chapter 3.7 Options).

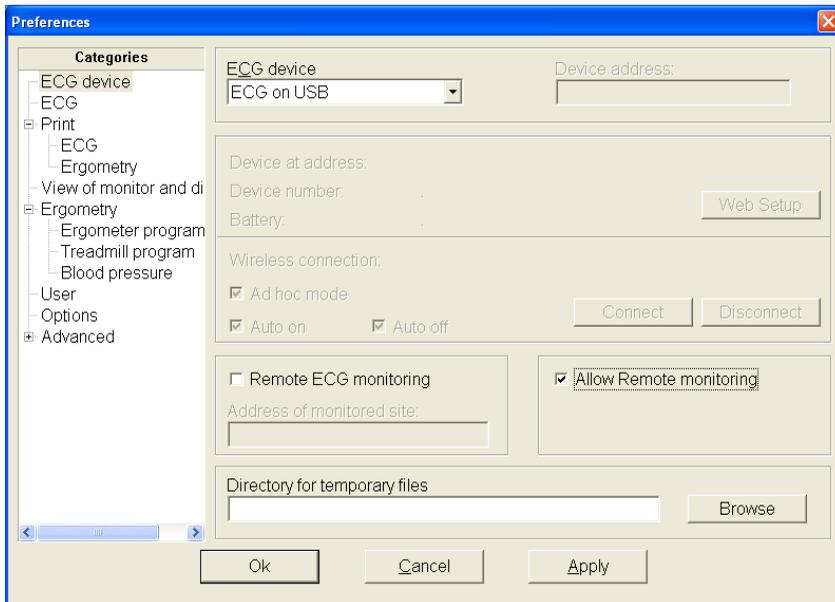
Network operation introduces some limits: only one user can access a patient's card at a time and a card cannot be deleted when more than one user is accessing the database.

This kind of operation is available not only on Local Area Network but also on other compatible remote networks (e.g. Virtual Private Network).

### 12.2 Remote monitoring

Remote monitoring is a feature that allows a workstation running Cardio M PC to monitor the ECG recording process running simultaneously on another workstation in the local network.

The ECG recording is done on workstation "A", while workstation "B" wants to monitor the curve being recorded. In the *Setup* menu under the '*ECG device*' category of "A", the '*Allow remote monitoring*' must be checked.



On the monitoring side, the Remote ECG monitoring has to be checked in the same Setup category as above and the IP name or address must be supplied in address field below

“A” starts monitoring and optionally the long-time recording (or the stress test, where long-time recording is automatic). “B” also starts monitoring and the curve on “A” is displayed. “B” can not record this curve, only “A” can.

This function is also an option and therefore requires a password.

On the Windows firewall of “A” the transfer must be enabled and if a router is also involved in the transfer, the necessary port-forwarding and/or firewall settings must be given. The default inbound port on “A” is 7777, “B” uses it also as default, but can be overridden by merging the port number after the address separated by a colon (e.g.: office2.hosp.org:7697). On “A”, the inbound port number can be modified in the Cardio M PC .ini file overriding the following entry in the [ecg] section:

```
[ecg]
RemoteMonitorPort=7697
```

## 12.3 Remote device (netdevice) operation

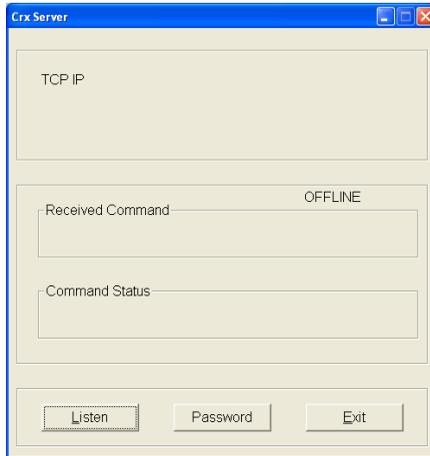
Using this function an ECG expert is able to advise a non-specialist. In another way, the expert makes an ECG recording originating the signal from a distant place. Let place "A" be the location where ECG is measured and place "B" where it is coordinated from. At "A", the user sets up the Cardio M PC program for normal recording (e.g.: Setup / ECG device / ECG on USB). The program must be started with the parameter **-netdevice**. This way Cardio M PC at "A" starts monitoring immediately, the user has nothing to do expect supplying the IP address of "A" to "B". This address appears on the lower side of the monitoring window. Practically a communication channel should be established between "A" and "B" (chat, skype, telephone) since operations must be synchronised and patient data is also entered by "B".

At place "B" in the *Setup, ECG device* must be selected as *TCP/IP ECG device* and the IP address of "A" must be supplied. Afterwards, the Cardio M PC program can be used as regular for recording the signal coming from of "A".

## 12.4 Server/Client (remote database) operation

In this operational mode the Cardio M PC program running on a local computer (Client) connects to the database of a Cardio M PC running on a remote computer (Server) using TCP/IP protocol.

Starting the server program is possible from the 'Transfer' menu by selecting 'Start server'. When starting for the first time, a password must be given by clicking the 'Password' button on the window just appeared. This button can be used later as well, if the password needs to be changed. This same password given on the server side has to be used on the Client side when connecting.



Next, the *'Listen'* function must be started and the network port can be set if necessary. If the port number is appropriate, the *'Continue'* button places the server program into communication-ready state.

**Starting the Client program:**

We have three possibilities to connect to a remote Server's database.

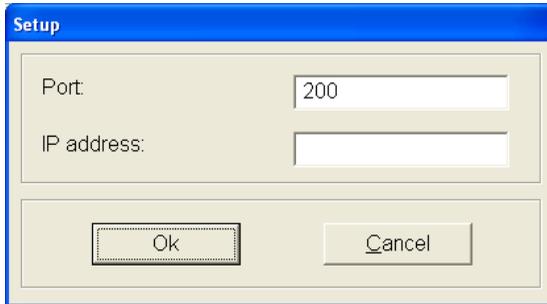
- **The Server holds the whole database (patient-list)**

From the *'Transfer'* menu the *'Remote database'* function must be selected. Then the following window appears:



Using the Setup button the IP address and the listening port of the server can be set. These values are remembered in new sessions after exiting

the program but can be modified if the server changes.



By clicking the *'Connect'* button the program asks the password for accessing the Server. After given the correct password, the Client program connects to the Server and the patient-list of the remote database appears.

- **The Server as the second card file**

From the *'Transfer'* menu the *'Open 2<sup>nd</sup> card file'* function is selected. A window opens and the *'Remote'* button on it's upper side must be clicked that opens the same window mentioned in the previous point. Connection is established as described there. The patient-list splits into two. In the upper part the Client, in the lower the Server database can be seen.

This function is useful for copying and comparing data between two databases.

- **Sending a patient's data to the Server**

The patient to be sent is selected in the patient-list. The *'Send to'* function under *'Transfer'* menu is selected. Connection is established as described previously. The patient file is transferred into the *'IMPORT'* directory on the Server (default is C:\CRX\IMPORT), from there it must be imported into the server program later.

This function is useful only if one patient's data must be transferred and there is no need for the Server's database to appear on the Client (that would take significantly more time).

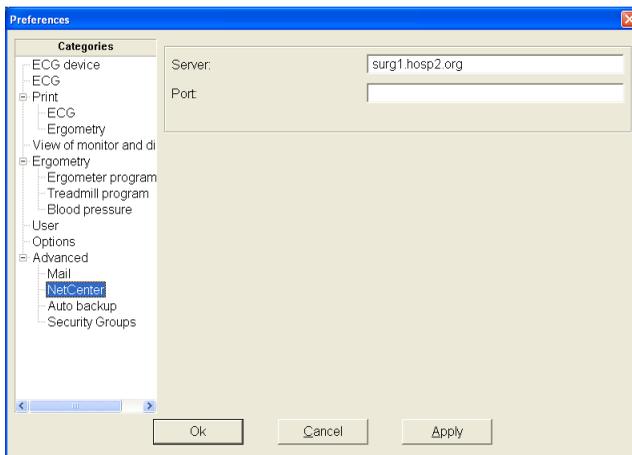
## 12.5 Cardio M PC NetCenter

### Operation:

Users run the Cardio M PC program on local workstations in client mode. These workstations connect to the central database using TCP/IP network protocol. Connection can be made on a LAN or on the Internet. The locally stored recordings are copied onto the database of the specified central server. The workstations connected to the server see only their own local database, while their database is continually synchronizing with the central database. When the user adds a new patient or views the card of an existing one, the client checks if the patient is already available on the server. If so, it asks for the existing recordings from the server and merges with its local database. The short recordings are downloaded instantly. For performance reasons, the long recordings and stress-tests are downloaded only on demand, if viewed. For patient identification the *Code* field is used. In case a new ECG record is made (short-, long-recording, stress-test) the record is placed into an upload queue. Uploading is done in the background, while the user can work with the program normally without interruption.

### User side (client):

For accessing the central server, the address and optional port number of it must be set beforehand by starting Cardio M PC normally. The required settings are in the 'Setup' menu under the 'Advanced / NetCenter' category.



For NetCenter functionality, Cardio M PC must be started with the parameter

**-netclient** on the client side. At start, the program asks for user name and password to the server. Then Cardio M PC loads the "Cardio M Client Agent" background process (agent). This program runs on the tray and is responsible for the TCP/IP data-transfer with the server on the client machine. The following icon is placed onto the system tray:



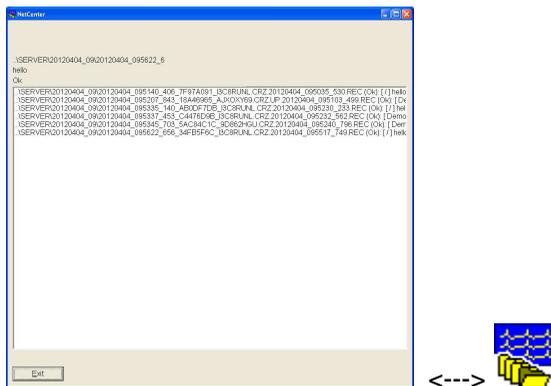
The client agent may stay loaded after the main program is terminated while it finishes any ongoing synchronization with the server.

**Central side (server):**

On the central computer the program must be started with the parameter **-netserver**. The Cardio M PC starts the "Cardio M Server Agent" background process (agent). This program runs on the tray and is responsible for the TCP/IP data-transfer with the clients on the server machine. The following icon represents the server agent on the system tray:



Meanwhile the main program opens a dialog, where the queries, the status and the error messages are displayed. This dialog can be minimized also to the tray and reopened from there:



Terminating the main program by the 'Exit' button also terminates this agent.



**Security:**

On the central machine name/password pairs must be defined. When starting Cardio M PC in client mode, the client agent opens a dialog for entering user name and password to access the server. Then the agent checks the server whether the user has the right to use NetCenter. If so, the given username/password is sent along with all subsequent queries to the server, until the client is stopped. At restart, the username and the password must be given again.

On the server side, having the agent already running and right clicking it's



on the tray, a local menu pops up, where under the 'Set new password' opens a dialog for entering a new name/password pair to have access to the server. The usernames with password are stored in the **pass.dat** file at the same directory Cardio M PC is located. (default place is C:\Crx\EXE)

Administering (deleting users, adding multiple users quickly, changing passwords) can be done by editing this text file, where the syntax is one comma separated `<user_name>,<password>` pair by one line.

The listening TCP port of the server can be modified by editing the Cardio M PC **.ini** file in the [NetCenter] section by specifying `listening_port=1234`, where 1234 is the desired port number.

## 13. Appendix

### 13.1 Appendix A: Diagnosis

#### Normal ECG

The analyzed part of the ECG (..sec,..beats) shows no signs of abnormality (for one of the patient's age).

#### Pathological abnormalities

	short PQ
	sinus ( bradycardia   tachycardia )
	sinus ( bradyarrhythmia   arrhythmia   tachyarrhythmia )
	Mod.: [ with short PQ ]
	sinus origin P-wave ( VR: , AR: )
**	atrial ( bradycardia   rhythm   tachycardia)
**	atrial ( bradyarrhythmia   arrhythmia   tachyarrhythmia )
*	low right atrial ( bradycardia   rhythm   tachycardia )
*	left atrial ( bradycardia   rhythm   tachycardia )
	Mod.: [ with short PQ ]
	atrial origin P-wave ( VR: , AR: )
	unusual P axis, probable accelerated junctional rhythm
	unusual P axis, probable junctional ( bradycardia   tachycardia )
	accelerated junctional rhythm
	junctional ( bradycardia   tachycardia )
	atrial flutter ( with slow ventricular response   with normal ventricular frequency   with rapid ventricular response )
*	irregular atrial function ( with slow ventricular response   with normal ventricular frequency   with rapid ventricular response )
**	atrial fibrillation ( with slow ventricular response   with normal ventricular frequency   with rapid ventricular response )
	accelerated ventricular rhythm
	ventricular ( bradycardia   tachycardia )
	undetermined rhythm
	first degree AV-block ( Long PQ )
	2nd degree AV-block, Wenckebach periodicity
	2nd degree AV-block, Mobitz - II type
	higher degree AV-block
	complete heart block
	( unifocal   multifocal ) premature ventricular complexes
	n [ pair of consecutive   sequence of consecutive ] premature

	Ventricular complex(es)
	n premature ventricular complex(es) or aberrantly conducted
	n premature ( sinus   atrial ) complex(es)
	Mod.: [ with QRS widening ]
	n [ pair of consecutive   sequence of consecutive ] premature
	junctional complex(es)
	Mod.: [ with QRS widening ]
	n aberrantly conducted complex(es)
	n other form complex(es)
	n ventricular escape complex(es)
	n ( sinus   atrial   junctional ) escape complex(es)
	Mod.: [ with QRS widening ]
	bigeminy pattern
*	dextrocardia
	Wolff-Parkinson-White pattern [ type A   type B ]
	low voltage QRS
	( right   left ) atrial enlargement
	biatrial enlargement
	incomplete right bundle branch block [ with repol. abn.   with possible repol. abn. ]
	incomplete right bundle branch block plus right ventricular enlargement [ with repol. abn.   with possible repol. abn. ]
	right bundle branch block [ with repol. abn.   with possible repol. abn. ]
	right bundle branch block plus right ventricular enlargement [ with repol. abn.   with possible repol. abn. ]
	incomplete left bundle branch block
	left bundle branch block
	left anterior fascicular block
	( right   left ) ventricular hypertrophy [ with repol. abn.   with possible repol. abn. ]
	biventricular hypertrophy [ with repol. abn.   with possible repol. abn. ]
	Mod.: [ with QRS widening ]
**	myocardial infarction in ( anterior, & septal, & lateral, & inferior, & posterior ) location
**	myocardial injury in ( anterior, & septal, & lateral, & inferior ) location
	acute pericarditis
**	myocardial ischemia in ( anterior, & septal, & lateral, & inferior, ) location

**	myocardial ischemia or digitalis effect in ( anterior, & septal, & lateral, & inferior, ) location
	prolonged QT

**Possible pathological abnormalities**

	2nd degree AV-block
**	left posterior fascicular block
	Wolff-Parkinson-White pattern [ type A   type B ]
	( right   left ) atrial enlargement
	biatrial enlargement
	( right   left ) ventricular hypertrophy [ with repol. abn.   with possible repol. abn. ]
	biventricular hypertrophy [ with repol. abn.   with possible repol. abn. ]
**	Mod.: [ with QRS widening ]
	myocardial infarction in ( anterior, & septal, & lateral, & inferior, & posterior ) location
	subendocardial injury in ( anterior, & septal, & lateral, & inferior ) location
	acute pericarditis
	myocardial ischemia in ( anterior, & septal, & lateral, & inferior ) location
	myocardial ischemia or digitalis effect in ( anterior, & septal, & lateral, & inferior ) location
	ST abnormality probably digitalis effect
	prolonged QT

**Unspecified, undetermined variations**

	QRS left axis deviation
**	QRS superior axis deviation
	QRS right axis deviation
	QRS right superior axis deviation
	abnormal QRS-T angle
	nonspecific intraventricular block
	ST elevation
	ST elevation because of early repolarization
	ST depression [ probably digitalis effect ]
	junctional ST depression
	T wave abnormality [ probably digitalis effect ]
	ST and T abnormality [ probably digitalis effect ]

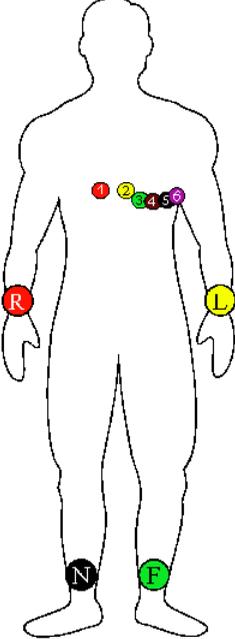
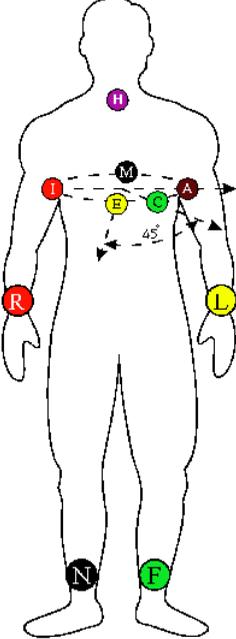
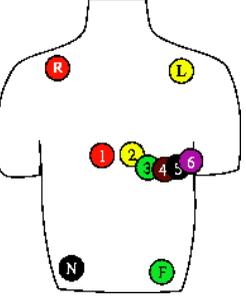
\* - only in pediatric diagnose

\*\* - only in adult diagnose

| - or

& - and

### 13.2 Appendix B: Electrode placements and lead calculations

'Extremal' and 'Precordial' rest test recordings:	Recordings with Frank arrangement	Stress test recordings
		
<p> <math>I = L - R</math>  <math>II = F - R</math>  <math>III = F - L</math>  <math>aVR = R - (F + L) / 2</math>  <math>aVL = L - (F + R) / 2</math>  <math>aVF = F - (L + R) / 2</math>  <math>V1 = C1 - (F + L + R) / 3</math>  <math>V2 = C2 - (F + L + R) / 3</math>  <math>V3 = C3 - (F + L + R) / 3</math>  <math>V4 = C4 - (F + L + R) / 3</math>  <math>V5 = C5 - (F + L + R) / 3</math>  <math>V6 = C6 - (F + L + R) / 3</math> </p>	<p> <math>X = 0.78 * (0.78 * A + 0.22 * C - I)</math>  <math>Y = 0.35 * M + 0.65 * F - H</math>  <math>Z = 0.87 * (0.15 * A + 0.85 * M - 0.30 * I - 0.43 * E - 0.27 * C)</math> </p> <p> <math>I = C1, E = C2,</math>  <math>C = C3, A = C4,</math>  <math>M = C5, H = C6,</math> </p>	<p>Leads and calculation are the same as described in the 'Precordial' type.</p>

## **International Sales & Service**

**Medical Econet GmbH**

**Mainstr. 6 c-d**

**45768 Marl**

**Germany**

[www.medical-econet.com](http://www.medical-econet.com)

# **Medical Econet GmbH**