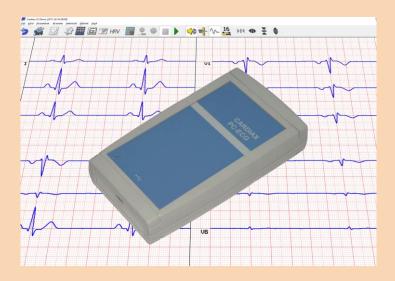
# Cardiax PC ECG USER MANUAL

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### **1. Introduction**

Cardiax 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 Cardiax 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 Cardiax 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 Cardiax 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 Cardiax system can also be interfaced with medical database systems.

#### **1.2 Main system components**

- Cardiax ECG recorder (USB only connection or both USB and WiFi connection)
- USB cable for connection to PC (A-mini B)
- Cardiax software

Together, these cooperating components are referred to as the Cardiax 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 7, Windows 8/8.1, Windows 10.

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

The *Windows XP* system is not recommended at all, even its manufacturer stopped its support and updates. The flawless usage of the <u>WiFi ECG</u> and the synchronization feature with <u>Android devices</u> are not possible on XP systems!

#### 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 Cardiax system is used according to this User's Manual.

Only IMED Ltd. approved accessories should be used with the equipment.

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.

Cardiax 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 Cardiax. However, equipment operators and supervising physicians should be aware of the presence of pacemakers or other devices.

The Cardiax 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.

#### 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.
- Cables should be stored after forming them into a loose loop avoiding cable breaks.

#### 2. Using a defibrillator

- Although the ECG input is protected against electric discharge, this way enabling the use of cables without defibrillator protection as well, 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 Cardiax 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, which are not part of the system must not be integrated into it.
- When operating the Cardiax 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!
- To prevent any damage to the touch-key on the device, only use fingertips. Avoid using hard or sharp objects to depress the key!

#### 5. During usage, in operation

- 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. Cleaning and disinfecting

- Do not immerse the device and the cables in any liquid in order to perform cleaning! For cleaning exterior surfaces and cables, use mild detergent or soap diluted in water with a soft, lint-free cloth.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces!
- Do not try to apply high temperature sterilization processes, like autoclaving or stem cleaning!
- For disinfecting the cables and lead wires, wipe exterior with a soft, lintfree cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution.
- After moist cleaning, dry surfaces with a clean cloth, especially the metal contact plates of the patient cable to prevent corrosion!

#### 8. Maintenance and checking

- The Cardiax 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 Cardiax 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.
- In case of the WiFi model, the lifetime of the built in battery depends primarily on the number of charge-discharge cycles, but environmental circumstances (temperature, humidity) are also influential. End of lifetime can be concluded most appropriately by recognizing the following scenario in the routine use of the device: the charge indicator (LED on device or indicator in the <u>status line</u> of the program) signals low charge state more often than ordinary was normal (nevertheless no significant change in WiFi propagation is encountered). In this case it is recommended to get in contact with the manufacturer for having the battery replaced!

#### 8. Disposal

 Should the ECG device get any non-repairable failure or damage, or for any other reason the user opts for disposition, the device should be qualified as hazardous electronic waste equipment and at must exclusively be disposed at designated collection facilities.

#### **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 Cardiax 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 Cardiax 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 Cardiax PC ECG.

Electromagnetic Emissions The Cardiax PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardiax PC ECG should assure that it is used in such an environment.					
Emissions test	Compliance	Electromagnetic environment – guidance			
RF emissions CISPR 11	Group 1	The Cardiax 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 Cardiax PC ECG is suitable for use in			
Harmonic emissions IEC 61000-3-2	Not Applicable	all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used			
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	for domestic purposes.			

Electromagnetic Immunity The Cardiax PC ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardiax PC ECG should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2:2008 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD)	±4 kV contact	±4 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with
IEC 61000-4-2	±8 kV air	±8 kV air	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 % Uτ (>95 % dip in Uτ) for 0,5 cycle 40 % Uτ (60 % dip in Uτ) for 5 cycles 70 % Uτ (30 % dip in Uτ) for 25 cycles <5 % Uτ (>95 % dip in Uτ) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cardiax PC ECG requires continued operation during power mains interruptions, it is recommended that the Cardiax 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.

	Electromagnetic Immunity					
	G is intended for use in the el- iax PC ECG should assure th		ronment specified below. The customer or an environment.			
Immunity test	IEC 60601-1-2:2008 test level	Compliance	Electromagnetic environment– guidance			
	level	level				
Radiated RF	3 V/m	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Cardiax PC ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter			
Raulaleu Ri	5 V/III	0 1/11	Recommended separation distance			
IEC 61000-4-3	80 MHz to 1 GHz					
			d =1.2 √P 80 to 800 MHz			
			$d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) and <i>d</i> is the recommended separation distance in meters (m).			
NOTE 2 These g	Hz and 800 MHz, the higher guidelines may not apply in al	I situations. Electror				
by absorption and re	eflection from structures, obje	cts and people.				

#### Recommended separation distances between portable and mobile RF communications equipment and the Cardiax PC ECG

The Cardiax PC ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardiax PC ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardiax PC ECG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of	Separation distance according to frequency of transmitter (m)				
transmitter (W)	<b>150 KHz to 80 MHz</b> $d$ =1.2 $\sqrt{P}$	<b>80 MHz to 800 MHz</b> <i>d</i> =1.2 $\sqrt{P}$	<b>800 MHz to 2.5 GHz</b> <i>d</i> =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 FCC Compliance Statement**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Contains component with FCC ID: W7OMRF24WG0MAMB

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

### 1.7 Technical parameters

Patient protection:	floating common (IEC-601, CF type)
	Isolation: DC/DC converter, USB isolator
Shock protection:	Class II.
Defibrillator protection:	5 kV (max. 1 kV/ms)
Resolution:	0.05 µV/bit (24 bit A/D)
Sample rate:	2000 Hz
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 supply:	
both models, used	
on USB port:	+ 5 V , 100 mA
WiFi model using	
embedded battery:	+3,7 V Li-Po , 2000 mAh
Battery performance:	10hrs of normal monitoring use
(WiFi model only)	(started fully-charged)
Battery recharging time: (WiFi model only)	5hrs from depleted to 90% performance
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: yellow LED
	slow blinking: USB connected
	solid light: ECG monitoring
	WiFi enabled model: blue LED:
	solid light: active WiFi connection
	blinking: searching WiFi network
	green LED:
	battery charge level status
Computer requirement	Windows XP, Vista, Windows 7, 8/8.1, 10
	(32 or 64 bit) operating systems
Controls	WiFi enabled model:
	power-on button (touch)

	Everything else from Cardiax software
Accessories:	Standard 10 wire ECG cable,
	Standard limb and precordial ECG electrodes
	(optional)
	Standard USB cable A-mini B
Operation	Continuous operation
Operating temperature:	0 °C +50 °C
Storage temperature:	-40 °C +70 °C
Operating and storage humidity:	25% 95%
Operating and storage pressure	750 … 1060 hPa
range:	

### **1.8 Explanation of symbols on machine**

⊣♥	System is CF-type, protected against defibrillator.	
	This device has Class II shock protection.	
$\triangle$	Consult the Manual for proper and effective usage!	
CD-ROM	User's Manual in electronic form.	
	Manufacturer	
	Date of manufacture	
((:-	Device is equipped with WiFi module.	

### 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, Windows 8 / 8.1, Windows 10

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 Cardiax 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 <u>appendix 13.2 B</u>)

#### 2.2 Software installation

- Turn on the computer.
- After starting Windows, place the installation CD labeled Cardiax into the CD drive.
- If the automatic insert notification is enabled, the Cardiax 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 Cardiax can be started by clicking on the following icon on the desktop, or by launching "wincrx32.exe".



### 3. Setting the default parameters

Menu: Setup

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

#### 3.1 ECG device

The user selects the source for the incoming ECG data:

Preferences		- 🗆 X
Categories	ECG device ECG on USB Demo, simulated ECG ECG on USB ECG on WFi TCP/IP ECG device	Serial number (SN): Assign
☐ Blood pressure ☐ User ☐ Options ⊕ Advanced	Only establish direct WiFi ECG connection     Computer's WiFi connection:	n while recording  Use specific WiFi interface  Allow remote monitoring
	Ok <u>C</u> ancel	Дррју

- '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, detailed in the <u>Appendix</u>.
- 'TCP/IP ECG device': Controlling a remote device through TCP/IP network. Detailed in the <u>Netdevice section</u>.

The remote monitoring function is detailed in a separate section!

#### 3.2 ECG

#### Settings for the ECG recording:

Preferences				- 0	×
Categories ECG device ECG	✓ Sound     □ J 60/80	✓ Speaker		Spee <u>d</u> 25 mm/sec	•
Print     Batch, ergometry     Display settings     Ergometry     Ergometry     Fradmill program     Blood pressure     -User     -Options	F Enable automatic dia     F Possible     F Unspec     SHz     F 50Hz	agnosis ⊏ Baseline filter		Amplitude 10 mm/mV Record length 16 sec QTc: Bazett	•
Advanced	60Hz     Electrode placement		Dropperfiel		
			2x6 leads		•
	<u>R</u> hythm		I		•
	Free selected 3		II,V2,V5		•
	Free selected 6	atic diagnosis          Baseline filter         Precordial         2x6 leads         II         II,V2,V5         I,II,aVF,V2,V4,V5		•	
	3D reconstruction		Inverse Dower		•
	Ok	<u>C</u> ancel	Apply		

- 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 <u>automatic diagnosis</u> function can be accessed; otherwise it is disabled. The categories can be enabled selectively
- **Filters**: 35Hz: muscle-noise filter, 50Hz or 60Hz mains filter (it is advisable to have these turned on), 0.1Hz baseline fluctuation reduction filter
- 'QTc': the method used to calculate the heart rate corrected QT interval can be selected (<u>Bazett, Fridericia, Framingham, Hodges, Nomogram,</u> <u>Bazett+Fridericia</u>)
- 'Sound': state of QRS-complex detection signaling
- 'Speaker': use the system speaker for QRS signaling
- '*Recording length'*: the default length of the stored ECG snapshot, 8, 16 or 32 sec
- **'J+60/80'**: the method of calculating the end of the ST segment; for more information, see the <u>ECG interpretation</u>

- '*Electrode placement':* the actual <u>placement</u> of electrodes. Important for storing and evaluating 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. (*Inverse Dower, Regression, Quasi orthogonal*)

#### 3.3 Print

General ECG printout setting can be modified in this *Setup*-category. Printing is possible from the monitor window that displays the ECG curve, in this case the displayed Leads are printed.

Furthermore, initiated from the <u>findings view</u> of a patient –that lists the recordings– several selected pages can be printed regarding the selected ECG(s). This is called **batch printing**.

The setting under the main *Print* options category control general and quality parameters for both types of printings.

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 cannot be modified it will be always white.

Preferences			- 0	×
Categories	Printer colors			
ECG device	Background		Default schemes	
ECG Print Batch, rest ECG	Grid		r Blue	
Batch, ergometry	Curve			
<ul> <li>Display settings</li> <li>Ergometry</li> <li>Ergometer program</li> </ul>	<u>L</u> ine		⊂ Black	
Treadmill program Blood pressure	Text			
User	Grid			_
Options     Advanced	<ul> <li>New style</li> </ul>		☑ Draw grid first	
	Step	1 •	ECG curve thickness	
	<ul> <li>Old style</li> </ul>			
	Point size	6 -	Default	
	Print 3x4 leads from		Diagnosis in header	
	Print parameters fr	om diagnosis window		
	Picture export			
	Picture size	6976 X 5000	✓ Portrait pic. export	
	Ok	<u>C</u> ancel	Apply	

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.

The '*Default*' gives the optimum settings for the most common, recent printers.

Checking the '*Print 3x4 leads*' defaults to force printing in lead format <u>3x4 always</u> if printing from the monitor window, <u>regardless of the displayed</u>

#### lead selections.

On pages containing any ECG curve, the **diagnosis** can be printed **in the header** by checking the specific box.

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

The Diagnosis window, awoke from the ECG display- gives the possibility to print the diagnoses text and the parameter table on separate tabs. By checking '*Print parameters from diagnoses window*' makes the parameter table be automatically printed with the diagnosis.

The 'Batch' subcategories provide the possibility to select the pages for printing form the <u>Findings window</u> and Ergometry <u>phase list</u>, respectively

Preferences					$\times$
Categories	Leads				
ECG device ECG Print <u>Batch, rest ECG</u> Batch, ergometry	Standard Unipolar precordial 1-3 precordial 4-6 12 leads	^	Speed 25 mm/sec 50 mm/sec 100 mm/sec		
<ul> <li>Display settings</li> <li>Ergometry</li> <li>Ergometer program</li> <li>Treadmill program</li> <li>Blood pressure</li> <li>User</li> </ul>	2x6 leads Cabr. & Precord. 2x6 Cabr. & Precord. Free selected 3 Free selected 6 3x4 leads	Ţ	Amplitude 5 mm/mV 10 mm/mV 20 mm/mV		
Options     Advanced	At given seconds (eg:300,60	00,)	☑ Online comment list		
	r ECG		With 12 Leads ECG		
	□ <u>M</u> edian		Vector		
	Diagnosis		□ HRV		
	✓ Extra beat		□ Parameters		
	□ Single lead				
	Lead:	Spee <u>d</u> ▼ 50 mm/s	Amplitude	 	<b>~</b>
	Ok	<u>C</u> ancel	Apply		

*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 ... marking (three dots) periodicity can be defined (e.g.:100,... means every 100<sup>th</sup> second).

Items from the interpretation can also be selected ('Median', 'Diagnosis').

The '*Extra beat*' prints the recording's extra beats in a table form along all 12 leads.

The list of <u>online comments</u> associated with given moments of the record can be printed with time information and optionally with the 12 Leads printout of the events.

The '**Single lead**' box gives additional printout of the whole record with the corresponding *speed* and *amplitude* settings.

The 'Batch, 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 the rest ECG batch settings in the previous sub-category. Likewise the *lead selections, speed, amplitude* settings and *single lead* parameters are also independent of the rest ECG batch settings.

Preferences						$\times$
Preferences Categories Categorie	Leads Extremal Precordial Frank Nebb Inverse Dower Regression Quasi orthogonal Cabrera Standard Unipolar precordial 1-3		v	Speed 25 mm/sec 50 mm/sec 100 mm/sec Amplitude 5 mm/mV 10 mm/mV 20 mm/mV		
User Options ⊕ Advanced	I⊽ ECG I⊂ <u>M</u> edian I⊂ Diagnosis I⊂ Extra beat	ECG		<ul> <li>✓ Ergometry</li> <li>✓ Online comment list</li> <li>✓ With 12 Leads ECG</li> <li>✓ Vector</li> <li>✓ HRV</li> <li>✓ Parameters</li> </ul>		
	Single lead Lead:	Speed 50 mm/s		Amplitude		Ţ

	ECG	Ergometry
List of phases		I S <u>T</u> -level
Graphs		🔽 Conconi
☑ ST-trend		✓ Median of phases

#### 3.4 Display settings

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

Preferences						Х
Categories	Colors		- Dofault c	schemes		
ECG device	Background					
	Grid		C	Blue		
Batch, ergometry	Curve		¢	White		
Ergometry	Line					
<ul> <li>Ergometer program</li> <li>Treadmill program</li> <li>Blood pressure</li> </ul>	Text		C	Black		
User Options	C Shrink height			-Language English (UK date D-M-Y)		•
	E Medians in longtime monitor window					
	□ Always on top			- Fontsize Automatic (12)		•
	Multiple ECG windows					
	ECG curve thickness			Toolbar icon size		
		1	<b>_</b>	Medium		-
	User interface timeout (min):	0		🔽 English units (height, weig	jht)	
	Ok <u>C</u> ancel		<u>A</u> pply			

Colors 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 schemes*').

By selecting '**Shrink height**', 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.

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

And in case an ECG window is opened (either for recording or viewing), going a level higher into the Filer view (by closing the current list of recordings for the patient), can only be accomplished, when this feature is checked.

'*Language*' can be selected for the program interface, if changed, the program will restart. There are several 'English' items with different date forms (UK, US, Islamic, Persian).

**'Fontsize**' determines the used font size in all Cardiax windows. Note, that other, operating system dependent fonts, like in menus and on systemmessage boxes cannot be changed here. It is advised to choose the maximum size that fits your display resolution.

**'Toolbar icon size**' provides three possibilities (small, medium, big) to select the most ergonomic appearance on any modern display platform.

**'User interface timeout**' if greater than 0, the monitor window will close after the specified inactivity time as well as it steps back from any opened findings list or ergometry phase list windows to the Filer window. This behavior can prove useful if a network database is used, and a user happens to leave the monitor window open for a long time (e.g. lunch break), that would disable others to access the database.

**'English units**' is for entering and displaying patient height and weight in foot, inch and pound. However, this setting does not affect any treadmill speed setting, those are dependent only on the <u>device type set</u>.

#### 3.5 Stress test setup

See the <u>chapter 9. Settings for the Stress test</u> 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 (max 255 characters). Initials are used on the *Patient Card*, to indicate which doctor the patient belongs to. In printing only the full name appears. Also, for <u>diagnosis locking</u> at least one user must be given here! A maximum of 100 doctors can be defined.

#### 3.7 Upgrade options

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

Options are the following:

- **'Network database'**: enables the <u>use</u> of the software over a local area network. Recording is possible using the server software running on an other computer with the ECG device connected. The database on the server 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'*: <u>online observation</u> 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.
- *'Pulse oximeter'*: enables the storage and display of the data from the <u>compatible pulsoximeter</u> devices simultaneously with the ECG recording.
- *'NetCenter'*: enables to use the Cardiax as a <u>central database service</u>, that aggregates the users' patients and records. Other authenticated Cardiax users can synchronize their local database with it.

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

Send the device number of your system and the list of requested options to your Cardiax distributor. You will receive a new password. Enter this password by clicking the '*Change*' button, then the new options will be available.

In the following chapters the settings under the 'Advanced' category will be described:

Preferences					×
Categories	Old password New password Confirm new password	Entry pass	password		
Treadmill program     Blood pressure     User     Options     WiFi     Pulse oximeter     Mail     Auto backup     Auto export	Password for delete       Old password       New password       Confirm new password       Delete password				
NetCenter Security groups	Backup on exit     Automatic patient code generation	1	Toolbar icons       Image: Emergency ECG       Image: Folder of documents       Image: Android		
	Ok <u>C</u> ancel		Apply		

#### 3.8 Program elements and possibilities

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. It is an automation of always selecting the <u>Backup</u> function from the *Transfer* menu at program exit.

'Automatic code generation' is suited for hospital application and information technology: it automatically generates a unique random code for every new patient created. (The code can be refined later on).

Under the '**Toolbar icons**' the following functions can be enabled as toolbar icons:

- Emergency ECG recording with generated patient data that can be later specified,
- Opening the storage place of <u>External documents</u> stored in the Cardiax database,
- Start data exchange with mobile devices.

#### 3.9 WiFi device settings

Settings for the ECG device with WiFi connection.

See the section <u>Setup the WiFi connection mode of the ECG device</u> of appendix D. for details.

#### 3.10 Pulse oximeter

Settings for the optional pulse oximeter device. Detailed in Appendix E.

#### 3.11 Mail settings

See in the chapter 8. Transfer functions for details.

#### 3.12 Auto backup and export

Hospital specific application.

#### 3.13 NetCenter

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

#### 3.14 Security groups

Hospital specific application in the first place, see in Appendix F.



### 4. Using the Card File in Cardiax

<b>F</b> 🖵	<u></u> 🖉 🖉 🚦	<b>34 =</b>			
Name: 03 Der		✓ Name:	Code:	Born:	Last ECG:
vame. j03 Der	10	• 01 Demo	000 000 001	23-11-1979	04-02-2011
ode: 000 00	0.003	O2 Demo     O3 Demo     O	000 000 002	13-09-1946	24-01-2011 26-09-2011
1000 00	0000	03 Demo     04 Demo	000 000 003	20-09-1960	10-11-2006
orn:	20-09-1960	04 Demo     05 Demo	000 000 004	07-02-1927	23-04-2007
	,		000 000 005	09-04-1945	20-12-2010
Sex:	Male	07 Demo	000 000 000	09-02-1926	27-06-2011
	,		000 000 007	15-12-1958	07-09-2010
leight(ft-in):	5' 11"	09 Demo	000 000 009	31-01-1930	04-03-2009
	181		000 000 010	06-01-1923	13-01-2011
Veight(lb):	101	11 Demo	000 000 011	11-06-1940	15-05-2009
octor:		12 Demo Compare	000 000 012	25-11-1947	25-03-2011
	1	13 Demo Ergometria	000 000 013	16-11-1964	27-11-2006
Diagnosis:		14 Demo Frank	000 000 014	27-09-1980	16-10-2007
ECG: R	est: 1				

When you start the program, the Cardiax 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), or can be selected from the 'Sort' menu. The current sort mode is reflected by a tick mark in the corresponding header.

The easiest way to <u>find a patient</u> is to enter the starting letters of the **patient's name** in name sorting mode. The cursor jumps automatically to the first line where letters are identical with the entered letters.

If sort mode is set to code, the **code** can be entered for **searching**, navigating in the list.

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

In case the folder icon in front of the name is orange, a new recording is made for the patient, or an existing recording was opened or printed. This eases the <u>daily tracking</u> of the program usage.

The little **plus sign** in the icon indicates that the patient already has some recordings.

#### 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 label of the diagnosis field can be edited here.

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

#### 4.2 Editing a patient card



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

The patient card can be modified any time.

The last line of the patient card contains read-only information about the number of stored rest or stress test ECG recordings.

#### 4.3 Deleting from the patient list



Menu: Patient / Delete, Hotkey: [Del]

All data for the patient will be deleted after confirmation.

*IMPORTANT:* the deleted cards cannot be undeleted! All patient data including ECG records will be lost!

#### 4.4 Attached documents



#### Menu: Patient / Folder of documents

Other, non-Cardiax specific documents (pictures, texts, files from other applications) can be attached to a patient, that are stored in the database of Cardiax. This command opens a folder inside the database, and that folder is assigned exclusively to the given patient. Documents here can be manipulated (copied, moved, opened, deleted...) just like in the Explorer. Adding new documents can be achieved by dragging them here with the mouse, or by pasting previously copied files. Another Explorer window can be opened by selecting any location in the left directory pane of the patient's attachments folder. If a patient has anything in his/her folder, the paperclip icon will appear as non-empty.

#### Menu: Patient /Add to documents

Opens a file browsing window, where a single file can be selected to **add to** the patient's database.

#### 4.5 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. Furthermore, holding the [Ctrl] key and moving the cursor up or down, the selection sate of the new line is toggled.

SELECT GROUP

Use the 'Select Group' window to indicate the aspects of the selecting selection or deselection. If the data are indicated with (min) or (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 searchcriteria) 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 [\*].

Code:	
Age: (min - max):	-
Sex	⊂ Male ⊂ Female
Height: (min - max):	-
Weight: (min - max):	-
Doctor:	
Diagnosis:	
Date (min):	
Date (max):	
<ul> <li>□ Non edited diagnosis</li> <li>□ Edited diagnosis</li> <li>□ ECG</li> <li>□ Frank</li> <li>□ Ergometry</li> </ul>	
External	
Ok	<u>C</u> ancel

Moving directly between selected lines is possible by holding the [Shift] key while using the [Up] and [Down] arrows.

The last line of the *Select* menu saves the selection list to a text file with the data visible in the card-list (name, code, born date, last ECG date).

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

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

<u> Cardiax</u>			-	×
Patient Record Sg	ort Select Transfer Setup He	*		
	🧾 🌇 🥢 📖			
Name: 12 Dem	no Compare	List of records Comment:  I 11-12-2007 10:56 Precordial [16s]		
Code: 000 000	0 012	<ul> <li>17-04-2008 09:54 Precordial [16s]</li> <li>09-05-2008 09:18 Precordial [16s]</li> </ul>		
Born:	25-11-1947	<ul> <li>29-07-2008 11:31 Precordial [16s]</li> <li>01-08-2008 12:10 Precordial [16s]</li> </ul>		 
Sex:	Female	25-03-2011 08:03 Precordial [16s]		
Height(ft-in):	5' 3"			
Weight(lb):	172			
Doctor:				
Diagnosis:				
ECG: Re	st 6			
List of records		c:\crx	6/0	

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, time, and the lead system of the recording and the record comment.

The green tick mark on the record's icon indicate the presence of edited diagnoses regarding that specific record.

Stress test ECG records have cyan folder icons, referring to the collection of the test phases.

The *SpO2* text after the type of the recording indicates, that the record has simultaneous <u>pulsoximetry</u> curve (plethysmograph) and saturation data along the ECG.

When clicking with the **right mouse button** on a recording, a list of common tasks will appear. The middle row is for changing the state of the recording. This state is automatically set for an ECG every time, when the <u>edited diagnosis</u> is saved. This so called checked state of the recording can be toggled here without effecting the presence of the edited diagnoses.

In the checked state the icon of the recording will have a green tick on it.

ECG ruler/ <u>F</u> inal report	Enter
Comment to recording Delete record	F4 Del
Select/Deselect	F3
Checked recording	
ECG- <u>c</u> opy	Ctrl+C
ECG-i <u>n</u> sert	Ctrl+V
<u>E</u> xport	•
Send by mail	F11

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, Hotkey: [Ctrl-c]

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, Hotkey: [Ctrl+v]

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

#### 4.7 Comment handling

Record comment

Menu: Record / Comment to recording, Hotkey: [F4]

Any item in the <u>list of the **ECG recordings**</u>, can have a short comment (up to 20 characters). This will appear in the header of the print too.

• Patient comment

#### Menu: Patient / Comment block, Hotkey: [F2]

You can attach a comment block to **each patient** (up to 30000 characters). It can also be printed out from its edit window.

• Further comments can be attached to the <u>stress tests</u> as a whole (in addition to the Record comment) and to its <u>each phases</u> separately.

• In case of long recordings (**not in case of 8/16/32s snapshots!**) so called <u>online comments</u> can be attached to specific moments of the record, during the recording process or later, when re-viewing the ECG curve.

# 5. ECG recording (monitoring)

You can monitor the ECG with the Cardiax system if you have a connected and enabled Cardiax device. During monitoring, the ECG curve is displayed on the screen and you can save selected temporal segments of data. The parameters and features of the display can be altered with the controls detailed in the followings. If the device selected in the Setup is not available, the followings are displayed:

Cardiax	
$\otimes$	ECG driver: ECG device not found!
	ОК

Cardiax	<b>—</b>
<u> </u>	Change device: 'Setup/Ecg/Ecg device'
	ОК

In the <u>'Setup – ECG device'</u> menu, the proper device must be selected. By using the '*Demo ECG*', possibility, a simulated ECG source is attached internally for easing and speeding up the learning process of the program, without the requirement of a hardware device.

# 5.1 Start the monitoring



## Emergency start

Only available in the Patient list view, it starts immediately the ECG monitoring window for an automatically added new patient. All data of the patient can be entered afterwards. If the patient turns out to already have been added, the new record can be <u>moved</u> into that card.

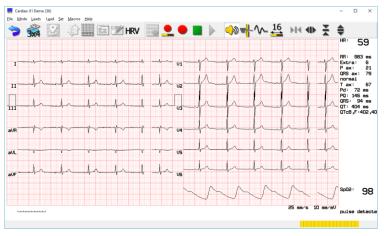


Menu: Record / ECG record, Hotkey: [F9]

Monitoring can be started both from the <u>Filer view</u> and the <u>Findings view</u> of a patient using the <u>predefined lead settings</u>.

The '*Record*' menu provides the possibility to start a monitoring session with other lead-placement, than the actually set one. The following menu items can be used:

Record / ECG record, extremal Record / ECG record, precordial Record / ECG record, Frank Record / ECG record, Nehb



# 5.2 Display control

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

Time resolution:



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

Paper speed can be 25, 50, 100 or 200 mm/s. **Amplitude:** 



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

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

# Sound:



Menu: Set / Sound, Hotkey: [F6]

It is possible to toggle on/off the beat detection sound.

### Filters:

These enhance the evaluability of the signal both in stored and in real-time cases. In the later, 2.5 second delay is introduced in the displayed signal!



Menu: Set / Filter (35Hz), Hotkey: [F7] Toggles the 35 Hz tremor filter.



Menu: Set / Baseline filter

Spline-filter for reducing the baseline wander. Only switchable in case of displaying online ECG curves coming right from the patient, since its use introduces some delay in the order of a second that can be disturbing in some examinations. This filter cannot be switched off when reviewing recordings!

Other filters (for reducing the hum disturbance from the mains) can be controlled from the <u>Setup / ECG</u> 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

#### Menu: Leads

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

## 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, and in addition:

- Precordial: V1, V2, V3, V4, V5, V6
- Precordial 1-3: V1, V2, V3
- Precordial 4-6: V4, V5, V6
- Free selected 3 leads (can be set in <u>'Setup / ECG'</u>)
- Free selected 6 leads (can be set in <u>'Setup / ECG'</u>)
- 12 leads: I, II, II, 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, and in addition:
- Frank: X, Y,Z

The stored recording is indicated as 'Frank'.

## 4. Placing 3 extremal electrodes in the Nehb arrangement:

• Nehb: D, A, J

The stored recording is indicated as 'Nehb'.

# 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 (snapshot). The ECG curves are always stored without the 35 Hz filtration. There is a yellow progress-bar in the lower right corner of the status line that informs about the available signal length.

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



# Menu: Set / Record length = 8 | 16 | 32 sec, Hotkey: [F8]

Pressing [F8] repeatedly will cycle through the three options. The default can be set in the <u>'Setup'</u>.

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 () button or by exiting the monitoring window.

#### Online comments:



#### Menu: Mode / Insert comment, Hotkey: [F4]

During the saving of the ECG signal or later at reviewing it, there is the possibility to attach comments to specific moments of the ECG curve. These are the online comments (max.390 characters each).

Online comments	
00:04: alcoholic smell	Predefined texts
0 : 4 [m:s] alcoholic smell	Insert Edit •
Ok Return Delete Print	

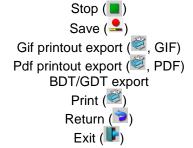
On the left side the listing of all the comments attached to this record can be seen, in the edit field below the new one can be entered. On the right, there are the predefined texts, easy to insert. New ones can also be defined (max. 345 characters), but it is recommended to prepare them beforehand; opening any long time recording it is possible to open this window for editing the global predefined texts.

In the list of predefined texts a row can be positioned to adapt to the usage frequency with the help of the arrow-buttons or with the [Up]/[Down] cursor keys while holding down the [*Ctrl*].

While recording, the list of the comments can be printed using the '*Print*' button. When re-viewing stored ECG records, the '*Print with ECG curve*' checkbox enables to print the 12-lead curve around the given moments the comment belongs to.

## 5.5 Common task automation – Macros

There is a 'Macro' menu in the monitor window that enables to select specific tasks related to the monitor window that can be executed one after the other to speed up the workflow. The key [F2] can be used to start the selected tasks. Those can be the following (the list reflects the order of execution):



# 6. Stored ECG recordings

## 6.1 ECG ruler, manual measuring

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:

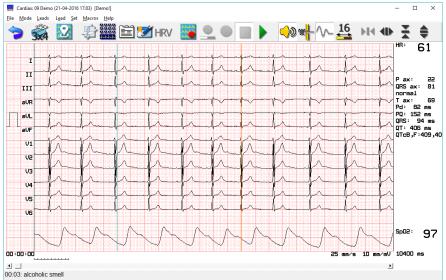
#### "Baseline correction failed"

You can perform measurements on the curve displayed in the ECG rulers with the help of **markers** (black). Approaching any with the mouse pointer, the pointer will display three arrows ( $\ddagger$  or  $\ddagger$ ) and while holding the left mouse button the marker can be individually moved. Holding the right mouse button enables to move them together keeping their set distance.

Keyboard shortcuts can also be used to select and position the markers:

[Shift+Right, Left] : selection

[Ctrl+ Right, Left] : positioning



The top right hand side of the window displays the average heart rate (HR) and parameters regarding the whole record, when the **selection markers** (black) are at the edges of the curve. On the bottom the distance of the markers are displayed in *milliseconds*, with possible oximetry data above. If the markers are moved, the amplitude values and their difference will be

displayed on the right, as read by the markers intersecting the ECG curves. Below the distance of the markers a heart rate will appear, calculated from that distance as an RR.

Using Frank placement, 2D and 3D <u>vector-graphs</u> are also available. In case of precordial placement a reconstruction algorithm can be used to also display the vector-graphs.

Two other marker types can appear on the window:

- places of extra/irregular beats (orange marker)
- only for longtime recordings <u>online comments</u> (cyan marker)

Moving the mouse pointer over these kinds of markers, the status bar will show the information regarding that marker.

#### Longtime recordings:

**Right mouse-clicking** on the screen enables to place new ones or to edit/delete existing ones. Also, the displayed curve position can be moved to the next/previous markers easily.

Inserting or editing extras, the following qualifications are available:

Premature complexes:

Sinus Atrial

Ventricular

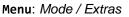
Junctional

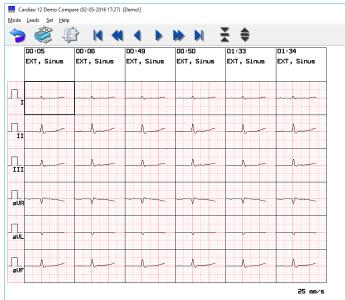
Escape:

- Ventricular
- Sinus
- Atrial
- Junctional

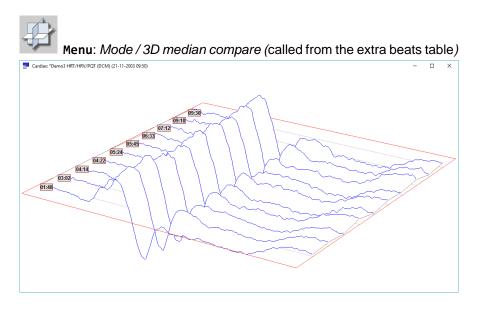
- Aberrantly conducted
- Other form

All extra beats in a longtime recording can be displayed in a table form sideby-side:





Each individual extra beat has a column, (both automatically recognized and manually inserted ones) with time and type. If all extras cannot fit the window at a time, the blue horizontal arrows can be used for scrolling, as well as the [Left], [Right], [PageUp], [PageDown], [Home] and [End] keys. Clicking on an extra opens a detailed view of it. Additionally, the time consecutive of extras in time can be displayed in 3D for comparison:



The spatial view can be zoomed using the slide on this window. The cross-hair provides a way for rotating the diagram. Time labelling can be used for better identification. In the listbox the displayed lead can be selected. The 35Hz tremor filter can be applied to the displayed signal

3D Buttons			
	- 3D	+	Filter (35Hz) on/off 🔽
		_	V1 lead -
	Show labels Auto zoom	হ	
	7440 20011		
	Print	R	eturn

Also from the ECG ruler (where the ECG curve is displayed) it is possible to analyze the ST segment of the signal, <u>like in the ergometric tests</u>:

Menu: Mode / ST Trend

The characteristic point (STJ, STM, STE, SLP) can be selected in the toolbar, it's data will be displayed. When the '*ST Trend*' tab is active, the individual lead buttons in the toolbar open up the corresponding graph in greater detail. The '*ST List*' tab shows the exact values of the selected point.

Time (m, s) 0022 0032 0142 0150 0142 02230 0142 02230 02230 02257 00251 0420 0230 02551 0420 0230 04100 0400000000	HR 1000 00000000000000000000000000000000	51 mm	- MV 00000000000000000000000000000000000	1		*VR #M 0.0000 0.00000 0.00000 0.000000	8VI, VIII 000 000 000 000 000 000 000 000	#VF [eV] 0.03 0.04 0.04 0.04 0.04 0.04 0.04	5 H 00000000000000000000000000000000000	V2 m/ 0.0777 0.0777 0.0777 0.0777 0.0777 0.0777 0.0777 0.0777	55 aread 50 100 100 100 100 100 100 100	V4 (mV) 0.0200 0.0200 0.0200 0.02000 0.02000 0.02000 0.0200000000	V5 B02 0.02 0.03 0.03 0.03 0.03 0.03 0.03 0.	WI (IIIV) 0002 002 002 002 002 003 003 003
00 30 00 45 01 06 01 15 01 33 01 42 02 00	00000000000000000000000000000000000000	001 002 001 002 001 002 001 002 001 002 002		1	0.03	-0.02	10.0 10.0 10.0 10.0 10.0 00.0	0.03 0.03 0.04 0.04 0.04 0.04 0.04 0.04	0.04 0.04 0.04 0.04 0.04 0.04 0.03	0.07	004 004 004 004 004 004 004 004	0.02 0.02 0.02 0.02 0.02 0.02 0.02	0.02	0.07
02/3/04 02/2/02/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2	8984596884895688888888888888888888888888	800 800 800 800 800 800 800 800 800 800	00 00 00 00	4554554545445445445445445544		04040404040404040404040404040404040404	000 000 000 000 000 000 000 000 000 00	004 005 004 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004 005 004	004 004 000 004 004 004 004 004 004 004	000000000000000000000000000000000000000			200 900 900 900 900 900 900 900 900 900	002 002 002 003 002 003 003 003 003 003
	06:30 07:01 07:01 07:36 07:48 01:00 08:15 08:27 08:45	07.36 62 07.48 60 00.00 59 00.15 61 08.27 60	07.36 62 0.01	07.56 62 0.01 0.0	00:00         56         002         0.01           00:01         002         0.01         0.04           01:01         000         0.01         0.04           01:01         000         0.01         0.04           01:01         000         0.01         0.04           01:03         000         0.01         0.04           01:04         000         0.01         0.04           01:05         000         0.01         0.04           01:00         0.01         0.04         0.05           01:00         0.01         0.05         0.05         0.05           01:01         0.01         0.05         0.05         0.05           01:01         0.01         0.05         0.02         0.05           01:01         0.01         0.02         0.05         0.05	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	0011         0112         0114         0113 <th< td=""><td><math display="block"> \begin{array}{cccccccccccccccccccccccccccccccccccc</math></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$						

# 6.2 Comparison of recordings, medians

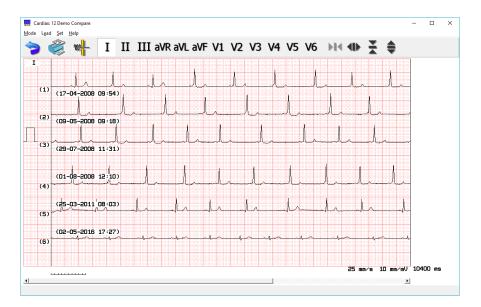
To compare recordings, first select from the list of the <u>Findings</u> with the [F3] key, the [\*] key inverts the actual selection. There are two possible ways of comparison:

## 1. Comparision 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 or using the toolbar icons. The 35Hz filter is selectable.



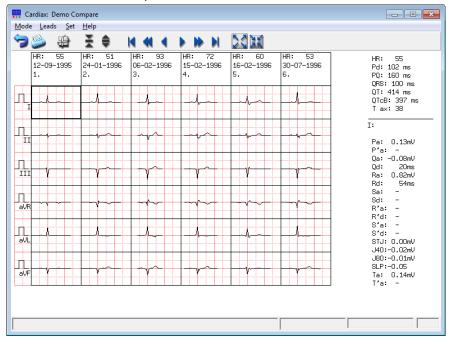
#### 2. Median comparison



### Menu: Record / Median-compare

The program displays, in the case of a 6 channel recording a maximum of 6, 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. (see Medians).

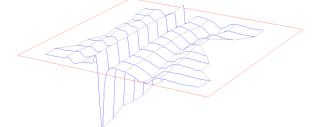
Above the magnified picture the program displays the global parameters and besides those, the parameters characteristic to the individual lead.



You can analyze and compare the medians in a much more vividly descriptive way by viewing them all together: Cardiax 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:



The spatial view can be zoomed using the slide on this window. The cross-hair provides a way for rotating the diagram. Time labelling (time of recording) can be used for better identification. In the listbox the displayed lead can be selected. The 35Hz tremor filter can be applied to the displayed signal.

3D Buttons			
	- 3D	+	Filter (35Hz) on/off □
			I lead 🔹
	Show labels		
	Auto zoom	◄	
	Print	R	eturn

# 6.3 Vector ECG (precordial, Frank)

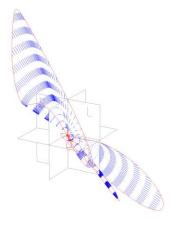


Menu: Mode / Vector

The Cardiax program can display the vector ECG from 'precordial' or 'Frank' ECG recording. You need the special placement of the precordial electrodes in order to make a 'Frank' ECG recording (see <u>Appendix B</u>.)

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 actual <u>selection</u> in the ECG ruler defined by the markers, or when markers are both on the edges (no selection), the median beat is displayed.





The left window shows the frontal, horizontal and sagittal projection, the right window shows the 3-D curve. Clicking any of the 2D projections shows it on the right in more details. Clicking on it again restores the 3D view.

The list box of the control window can also select the displayed content (3D, 2D). The 3D graph can be rotated using the cross hair, and the both the 2D and 3D sizes can be changed with the sliders independently. The endpoint of the

	- 3D +	Filter (35Hz) on/off				
/	- 2D +	Inverse Dower 🧿				
		Regression C				
	- +	Quasi orthogonal				
	Auto zoom	3D •				
Slow Print Return						

selection that is displayed can be trimmed with the lowest slider, so the progress of the curve in time can be examined. The '*Slow*' button serves a similar purpose: it redraws the curve in slow motion. When '*Auto zoom*' is checked, the graph always fits the window.

The tremor filter is optional on the displayed curve.

In case of precordial recordings the applied 3D-reconstruction method can also be selected. (inverse-Dower, regression, quasi orthogonal).

The following control movements can be done also by using the keyboard:

[Cursor up], [down], [left], [right]: rotate the 3D figure

[Shift] + [Cursor up], [down], [left], [right]: move the 3D figure

[Ctrl] + [Cursor up], [down], [left], [right]: move the 2D figures

[+], [-]: zoom the 3D figure

*[Ctrl]* + *[*+*]*, *[*-*]*: zoom the 2D figures

Rotating can also be controlled by the wheel of the mouse: the cross-hair can be moved on the associated control, the direction of the movement can be altered by pressing [*Ctrl*] of [*Shift*] or both

## 6.4 Replay of recordings

## Menu: 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.



Menu: Set / Baseline filter

During **playback of longtime recording**, it is possible to view the original signal without applying the baseline filter. The tremor filter can also be switched off.

The <u>HRV analysis</u> is available at this time too, and the <u>navigator window</u> can also be opened, where the <u>markers</u> follow the playback position. Both extra beats and online comments can be inserted or edited.

## 6.5 Data export

### Menu: File / File export

It is possible to use the data of the displayed record in other applications, as well. The output file format can be chosen (csv, scp, dcm, xml, hl7). More about the formats in <u>chapter 8.4</u>.

In case of the CSV format the signal amplitude values as integer numbers will be stored in text form, separated by commas. This provides an easy way for making Microsoft Excel Presentations as well as for custom scale statistical and signal analytical computations.

This '*File export*' can be started from the **Ruler** and from the window of the **Medians** too. In the latter case the median curve values will be exported in the selected form.

#### Menu: File / Picture export

In the chapter about printing possibilities the picture file export feature of the printing is also <u>introduced</u>. The current menu item is essentially a shortcut to this function, bypassing the print-dialog. The type of the export (*gif, pdf, dcm*) can be selected on the file save dialog.

In the **<u>Diagnoses window</u>** the export button allows to save the edited diagnoses and the parameter table values in *csv* format.

Export functionality is also available in the median view:

### Menu: Mode / File export

In this case, the median curves will be written in the selected format (*csv, scp, dcm, hl7*)

# 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. Baseline correction is optional in this view, but using it may slow down the display response with several seconds when the record is long.

👼 Navigator	-		×
🐤 飂 📑 🗺 HRV//- I II III aVR aVL aVF V1 V2 V3 V4 V5 V6 🙌 ╉			
00:000 ph h h h h h h h h h h h h h h h h h	5 mm/s	5 mm/m ~/`~^	<u>×</u> -
00:00:45 Ar har har har har har har har har har ha	upup	.h.h	<b>L</b>
00:01:30 hhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhh	uhh	-h-h	L
00:02:15 hhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhh	uhuh	huh	L
00:03:00/white hit had a fragman fragmatic fra	white	.h.h	1
00:03:05 ph h h h h h h h h h h h h h h h <mark>Start of ECG rule: 00:03:18</mark> h h h h h h h h h h h h h h h h h h h	nhih	hhr	4
00:00:00 hhhhhhhhhhhhhhhhhhhhhhhhhhhhhh	uhuh	.h.h.	4
00:05:15 h h h h h h h h h h h h h h h h h h h	upup.	hh	4-
00:0000 hhhhhhhhhhhhhhhhhhhhhhhhhhhhhhh	which	.h.h	4
00:06:45 hhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhhh	i.h.h.	.h.h	l
0007.30 h h h h h h h h h h h h h h h h h h h	hh	hap	

The scaling arrows control the time (1...50 mm/s) and amplitude (2,5...20 mm/mV) resolution of the displayed signal, selected by the lead buttons of the toolbar.

Resolution can be set also by keyboard: [+],[-] for the time, cursor [up], [down] for the amplitude. Keys for navigation are: cursor [left], [right] (or [PageUp], [PageDown]) and [Home], [End]



Using the **section** icon, the monitor window can be re-activated, but this navigator stays open. The two windows work in synch; if the selection markers on the navigator are moved, the monitor window will display that selection and vice-versa.

The printer icon will print the selected lead from beginning to end. The scale of the printing can be selected (*mm/s, mm/mV*) and the number of pages used are also displayed for information.

Printing	
Length of recording:	Number of pages: 1
○ 50 mm/s	
© 25 mm/s	20 mm/mV
• 10 mm/s	10 mm/mV
⊂ 5 mm/s	○ 5 mm/mV
O 2 mm/s	○ 2.5 mm/mV
○ 1 mm/s	© 2.5 min/mv
ОК	<u>C</u> ancel

In the navigator window several markers are displayed on the ECG signal:

The two tallest, black ones enclose the section of the curve that is currently disoplayed in the monitor window. Their middlepoint will be positioned to the mouse pointer, in case a left click has happened. The shorter, orange marker indicates the extra beats. The cyan markers denote online comments attached to the curve.

A **right mouse click** opens a pop-up menu with the possibility to edit, delete or insert new extras at the detected beats, as well as comments anywhere.

In this menu the signal section for <u>HRV analisys</u> can also be set; light green markers will be placed at the ends of the selected signal section.

In case of stress test recordings, the phase-changes are also visible as purple markers.

Positioning the mouse cursor over any marker will pop up a tip-box with the information about the marker type, time, as seen on the montage above.

# 7. Evaluation of the ECG recordings

The Cardiax system allows you to evaluate and analyze the stored ECG recordings in an offline fashion, subsequent to data collection.

The automatic evaluation (*Interpretation* and *Diagnose* from the ECG ruler) produces the averaged (median) beats from the recording, performs the rhythm and contour analysis, and prepares a table of the related parameters, with a proposed diagnose text.

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.

These features are only available in case of recordings the precordial leads were in use (the Precordial- or Frank system, proposed diagnosis only for Precordial)!

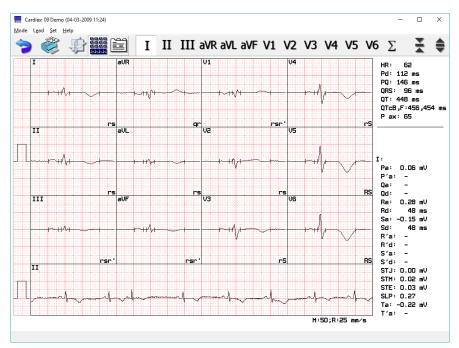
# 7.1 Manual evaluation in the 'ECG ruler'

A A A A
hhh

## 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. As a result of rhythm and morphological analysis for adults at least 15 years old and for children between 2 and 14 years the Cardiax proposes a diagnosis.

### IMED Ltd.



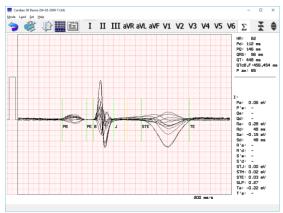
The upper graph contains the medians, the averaged beats corresponding to the selected lead system. The rhythm curve can be seen on the bottom, it's lead type can be <u>selected</u> in the '*Setup*' menu. The medians are displayed in 50 mm/sec time- and in 5 or 10 or 20 mm/mV amplitude resolution. Parameters of the rhythm curve are 8 seconds length, 25 mm/sec time and the selected amplitude resolution. The upper list on the right side contains global parameters of the analyzed ECG curve, the lower list displays the detailed parameters of the actually selected median.

# 7.2 Interpretation, median calculation

You can click with the mouse on any selected median cell or click the corresponding lead-icon on the toolbar in order to select and enlarge it. The

enlarged median curve will appear in the graphic part of the screen in magnification, with 20 mm/mV amplitude and 200 mm/sec time resolution. The toolbar icons change the leads in this magnified view too.

On the magnified median, green markers show the global characteristic points. These are the



characteristic points of the three dimensional QRS electrical phenomenon and are calculated from its projections (the leads). These global points are at the same position in case of every lead, by default. The following points are in question:

- PB, PE: the beginning and end of the P wave
- B, J: the beginning and end of the QRS complex
- TE: the end of the T wave

and according to the method for determining the end of the ST section:

- STM: the midpoint between J and STE (yellow marker)
- STE: end of ST section
- or
- J40/J30: 40/30 *ms* right from the J point, (yellow marker)
- J80/J60: 80/60 *ms* right from the J point (yellow marker)

The yellow, derived points are determined by other points and cannot be positioned directly in the way <u>described below</u>!

The calculation of the ST attributes can be done in two different ways, set in the <u>'Setup/ECG'</u> menu. The calculation of the end of the ST segment is different:

- STE: the midpoint of the interval between the global top of the T wave and the J point.;
- J80 (J60): 80 ms right from the J point or 60 ms, if HR > 100.

In the lower right corner of the individual lead-medians letters indicate the type (Q,R,S,T) of the identified waves, their amplitude magnitude (UPPER/lower case: Q,q) and the possible multiplicity is indicated by apostrophe (r,r').

The lower list on the right of the median graphs contains parameters calculated for the selected lead, the lead name is under the horizontal line. These parameters for all leads are collected in the <u>Parameter</u> table.

The positions of the markers can be modified; vertically lining up the mouse pointer with a marker changes the pointer to arrows pointing toward each other (‡‡), now holding the mouse button down enables to drag the marker.

The modified marker will become red.

Only modifying the markers in the **summed** view ( $\Sigma$ ) has influence on the diagnosis, since in this case the global points are altered. This is noted in the *'Automatic diagnosis'* and in the status line as well with the text *"Interpretation with modified base points"*.

In case of the medians of the individual leads the green markers are placed at the actual position of the global points, which can be already modified as well (markers in the summed view). Moving the markers in the individual view also changes them to red. Likewise, the <u>Parameter table</u> will also contain these values.

Any base point modification on any view results displaying an additional line in the list of parameters containing the QT regarding the given lead.

The modified point can be restored to the default positions of every median view by the right mouse click: on a specific lead it restores the actual global positions, on the summed view all markers are restored to the system computed positions.

The modified markers are only stored in case of short-time, snapshot recordings (8 / 16 / 32 sec), for long-time rest or stress recording modifications are not stored!

# 7.3 Diagnosis and parameters

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### Menu: Mode / Diagnosis

Diagnosis		
Name: Demo 09 Code:RRGSDR65B06E704R		
Automatic diagnosis	<u>E</u> dit diagnosis	P <u>a</u> rameters
The analyzed part of the ECG (16 se abnormalities given the patient's		Predefined texts
Penis infortunatus lateris sinistri		
		Insert
		Edit •
<u>Save</u> Diagnosis <u>r</u> ese	t Lock Send	New Delete •
Print	Export To clipboard	Return

The *Automatic diagnosis* –<u>if enabled</u>– 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. The text can be restored to the automatic suggestion or it can be password-locked by a doctor registered in the Cardiax program, to prevent modification. After the edited text is saved the recording will have a green tick on its icon in the recordings list, where it can be <u>manually set on or off</u> independently of the presence of the edited diagnosis.

To prevent editing by unauthorized persons, the diagnosis can be password locked by a <u>given doctor</u>.

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.

The '*Parameters*' tab displays the parameters of every lead system in a comprehensive table.

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Co	ode:000 (	000 009											
				1		Edit dia	agnosis				Parame	tore	
_	Automa	inc ulayin		157							Falame	aers	
	65 QRS					· · ·							
HR: 62	Pd: 112	ms PQ	146 ms	QRS: 9	6 ms QT	: 448 ms	QTcB,F	:456,454	ms QT	d: 70 ms	ST: 128	ms Td:	224 m
	1		III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	
Pa:	0.06	0.12	0.09	-0.08	-0.03	0.10	-0.07	0.05	0.09	0.07	0.07	0.07	mV
P'a:	-	-	-	-	-	-	-	-	-	-	-	-	mV
Qa:	-	-	-	-0.33	-	-	-	-	-	-	-	-	mV
Qd:	-	-	-	52	-	-	-	-	-	-	-	-	ms
Ra:	0.28	0.41	0.23	0.17	0.13	0.29	0.04	0.16	0.29	0.47	0.85	0.90	mV
Rd:	48	36	26	44	42	38	22	34	40	44	46	46	ms
Sa:	-0.15	-0.20	-0.05	-	-0.15	-0.13	-0.23	-0.37	-0.54	-0.61	-0.64	-0.52	mV
Sd:	48	24	10	-	54	18	32	32	52	52	50	50	ms
R'a:	-	-	0.06	-	-	0.04	0.18	-	-	-	-	-	mV
R'd:	-	-	26	-	-	20	40	-	-	-	-	-	ms
S'a:	-	-	-	-	-	-	-	-	-	-	-	-	mV
S'd:	-	-	-	-	-	-	-	-	-	-	-	-	ms
STJ:	0.00	0.00	0.01	0.00	-0.01	0.01	0.02	0.03	0.01	-0.01	-0.04	-0.03	mV
STM:	0.02	0.01	0.00	-0.02	0.01	0.00	0.01	0.05	0.05	0.03	0.00	0.00	mV
STE:	0.03	0.00	-0.03	-0.02	0.03	-0.01	0.01	0.08	0.07	0.04	0.00	0.00	mV
SLP:	0.27	-0.01	-0.33	-0.13	0.30	-0.16	-0.09	0.39	0.48	0.38	0.30	0.23	
Fa:	-0.22	-0.16	-0.06	0.18	-0.13	-0.07	0.13	0.12	-0.14	-0.34	-0.63	-0.61	mV
l'a:	-	-	0.05	-	-	-	-	-	-	-	-	-	mV
QT:	518	448	448	448	448	448	448	448	448	448	448	448	ms
				,		,					,		
			Pr	int	Exp	ort	To clin	board	Re	turn			

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 upper table contains the QTd (QT dispersion) among the global parameters and the lead specific QT values in the last line of the parameter table. These items are only displayed if <u>any base point</u> <u>was modified</u> on any median-view. QTd also has only sense in this case, since that is the greatest absolute difference of the individual (modified) QT values regarding all the leads (on the picture QTd=70 ms=QT<sub>1</sub>-QT<sub>aVR</sub>).

## All global parameters:

P ax [deg]	P axis	QRS ax [deg]	QRS axis
T ax [deg]	T axis	QRS-T ax <sup>[deg]</sup>	QRS-T angle
Pd [ms]	length of P wave ( <u>PB – PE</u> )	PQ [ms]	length of PQ (PR) section ( <u>PB – B</u> )
QT [ms]	length of QT section ( <u>B –TE</u> )	QRS [ms]	length of the QRS complex ( $B - J$ )
QTc [ms]	heart rate corrected QT length, the parameter is completed with the name of the <u>applied</u> method	QTd [ms]	QT dispersion (only by modified basepoints!)
ST [ms]	length of ST section	Td [ms]	length of T wave

Parameters for individual leads:

Pa [mV]	amplitude of P wave	STJ [mV]	amplitude of the J point
P'a [mV]			on the <u>method set</u> to determine the end of the ST section:
Qa [mV]	amplitude of Q wave	STM [mV]	amplitude of the <u>STM</u> point
Qd [ms]	length of Q wave	STE [mV]	amplitude of the <u>STE</u> point
Ra [mV]	amplitude of R wave		or:
Rd [ms]	length of R wave	J40/J30 [mV]	amplitude of the <u>J40/J30</u> point
Sa [mV]	amplitude of S wave	J80/J60 [mV]	amplitude of the <u>J80/J60</u> point
Sd [ms]	length of S wave		
R'a [mV]	amplitude of 2 <sup>nd</sup> R wave	SLP [-]	slope of the SL section
R'd [ms]	length of 2 <sup>nd</sup> R wave	Ta [mV]	amplitude of T wave
S'a [mV]	amplitude of 2 <sup>nd</sup> S wave	T'a [mV]	amplitude of 2 <sup>nd</sup> T wave
S'd [ms]	length of 2 <sup>nd</sup> S wave	QT [ms]	length of QT section (only if basepoints are modified!)

# 7.3 Heart Rate Variability



Menu: Mode / HRV

This function can be used for recordings longer than 2 minutes in case of stored ones, and after the 2<sup>nd</sup> minute of the actual online recording. In this latter case analysis is done on the data gathered until the function call without interrupting the recording process. The analysis method and parameters are described in <u>appendix 13.3.C</u>.

# 8. Data transfer functions

Data export possibilities during the interpretation and review of the ECG signal is collected in <u>chapter 6.5</u>.

The <u>Card file screen</u> also provides means for transferring patient data and findings in several formats common in healthcare information systems.

# 8.1 Copying patient cards

## Menu: Transfer / Open 2nd card file

This function can be used for copying all patient data into another database located in other 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/created database. If there is already patient data in this database, 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.

# 8.2 Backup, synchronization

Menu: Transfer / Backup, Synchronization

*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). The selection of the place of the mirror database is done in a directory selection dialog, if there is no Cardiax database at the selected place, a new one will be created. More than one different databases can be backed up to the same mirror, this way serving as a central collection of ECG data. Following the backup process the mirror database stays open as a second database in the Cardiax window and the selection reflects the patients concerned in the

backup. If there is any selection remained in the original (upper) database it indicates that some records could not be copied.

Synchronization also starts by selecting the target database. If there is currently no Cardiax



<-new items---



database, then a new one will be created. The synchronization process is a two steps operation; first the local database will be searched for newer recordings (and patients) and after confirmation will be copied into the other database. Next the other database will be searched for new items, what are not present in the local database. Those will be copied into the local database. The other database will remain open as second database, this case as well.

## None of the above operations delete any data!

In both cases the selections can be ended using the [/] key, and the second database can be closed from the menu '*Transfer / Close 2nd database*'.

# 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

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

```
Menu: 'Transfer' / Export / ...
```

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:

- <u>SCP</u>: 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.
- <u>HL7</u>: 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 Cardiax (default is C:\Crx\EXPORT). There is a setting in the initialization file (default is *cardiax.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**.
- **<u>DICOM</u>**: 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.
- <u>XML</u>: The files containing both waveform and patient data are placed into the selected directory, like in the above cases. The format is compatible with the MUSE(R) cardiology information system. File names are generated from the creation time of the recordings and have the extension **.xml**.
- <u>CRM</u>: It can be created with the '*File export (CRM)*' 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 **.crm** 

• **<u>CRN</u>**: 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/.XML/.HL7)'* function that opens a file selection dialog to define the destination file and also the export format for the ECG record being viewed. See <u>chapter 6.5 Data</u> <u>export</u> for details.

Menu: 'Transfer' / Import from file (.crc/.crm)

The function invokes a directory browser 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.

The program can also import crc files from earlier versions.

This function is only accessible in the patient list window.

## 8.5 Send / receive by mail

Menu: Transfer / Mail send, Mail receive, Hotkey: [F11 / F12] Patient cards and ECG recordings can be transmitted by e-mail with an appropriate Internet connection.

If records are received in a routine fashion by e-mail, not only casual, it is strongly recommended to set up a **dedicated mailbox** merely for receiving Cardiax ECG data. It ensures that the receiver process of Cardiax is not slowed down by parsing other, non ECG mails.

Required settings must be given previously in the 'Setup' menu under the 'Advanced / Mail' category. The addresses of the remote and local mailboxes are obvious.

The SMTP and POP server names can be obtained from the mailer client if set, or from the IT professional of the Institute / Internet provider. Some servers may require secure connection, which can be set by checking the SSL box. The ports are also need to be obtained from the IT professional, if different from the standard ones.

If Internet access is only available through a corporate-proxy, the relating parameters can also be set manually here for the mail sending/receiving.

Preferences		- D X	_
Categories	Address of remote mailbox:		٦
ECG device	ecgexpert@heartrate.hosp.org		
p Print	Name of SMTP server:	smtp.cardiax_hospital_1.org	
-Batch, rest ECG	SMTP port:	25	
- Batch, ergometry Display settings	SMTP user id:	cardiaxuser125	-
Ergometry Ergometer program	SMTP password:	*******	
- Treadmill program Blood pressure	Address of local mailbox:	Mail check:	
User	dr.memyself@cardiax_hospital_1.org	0 Min	
- Options - Advanced	Name of POP server:	pop.cardiax_hospital_1.org	
WiFi	POP port:	110	
-Pulse oximeter	POP user id:	dr.memyself	-
- Mail - Auto backup	POP password:	*****	-
Auto export		1	
- NetCenter Security groups	Use proxy server:	squid.cardiax_hospital_1.org	
occurry groups	Proxy port:	3128	
	Proxy user:	squid_user124	-
	Proxy password:	******	
	Ok <u>C</u> ancel	Apply	

The 'Send to mobile device' option ensures that the sent mail can be imported by the Android version of Cardiax, running on a mobile device. According to the characteristics of the Cardiax Mobile software, only 8, 16 and 32 seconds long recordings (snapshots) are sent in this case. This option can also be changed at the time of mailing as shown on the next figure. However, if other type of recording is tried to be mailed in mobile format, only the patient data will be included.

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

Send patient data by e-mail; key:[F11]		
Send 1 patient(s) data file to:		
ecg.expert@heartrate.hosp.org		•
Ok	<u>C</u> ancel	

Mail sending can also 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 Cardiax 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.

## 8.6 Data exchange with mobile (Android) device

Not available on Windows XP systems!



## Menu: Transfer / Mobil device

With the advent of the Cardiax Mobile <u>application</u> under the Android system, this dialog provides the possibility to synchronize, move the ECG database between the desktop computer and the mobile device (tablet, smartphone).

The Android systems from version 3.0 (Honeycomb) on prefer the MTP protocol for file transfer, while in previous versions the Mass Storage protocol, well known on USB drives, is used. In the list, all devices connected in either way will appear (including simple USB drives, not only the tablets and smartphones!), according to the operating system. MTP support is included in the Windows operating system from the Vista version by default, on previous versions the support can be installed.

A line in the list refers to a device, beginning with the name of the device and at the end there will be:

crx_mobile	if the device contains Cardiax Mobile database, and
	if the database is not found

Cardiax
Windows Portable Devices
LGE:Nexus 4: crx_mobile Generic:STORAGE DEVICE: Qualcomm: IncorporatedMas: crx_mobile
Import recordings
Export patient cards
Export recordings
Copy anyway
Ok <u>C</u> ancel Android

The following tasks can be accomplished (one at a time):

**Import recordings**: read all recordings from the mobile device and insert them into the Cardiax database.

**Export patient cards**: copy the selected (or all) patient cards without the recordings to the mobile device.

**Export recordings**: copy the selected (or all) patient cards and the recordings to the mobile device. The 'Copy anyway' option ensures to copy the data regardless of the synchronization state of the device.

According to the characteristics of the Cardiax Mobile software, only 8, 16 and 32 seconds long recordings are sent to the mobile device.

The Cardiax program keeps a registry of the synchronization data movements between it's database and the individual Android devices in order to speed up the synchronization process. It proves to be beneficial in case of certain devices, where the speed of the data transfer tends to be rather slow – this registry helps to transfer only the missing data.

By checking the **Copy anyway** option, this registry can be ignored in the selected direction. This provides the possibility to restore data that has been previously synchronized, but got lost meanwhile. The process may take longer to complete in this case – depending on the number of recordings, cards.

### 8.7 Printing, exporting pictures

Many views of the program can be used for printing. All start with the following dialog, where printing-related setting can be made.

The 'Setup...' can be used to select from the system's installed printers.

**'Pages'** are only available in case of batch printing (in the <u>Findings</u>, in ergometry's <u>list of phases</u>) and provides a possibility to alter the set of pages to print by opening the appropriate <u>Setup</u> category.

The **'Preview'** invokes a web browser with the expected result of the print process.

Pri	nting		×
	06 Demo		Ok
		0/1	<u>C</u> ancel
	Selected		Setup
	Canon iP7200 series WS		<u>P</u> ages
	Language of printing		Preview
	English (UK date D-M-Y)	•	Pic. export
			DICOM
			PDF

In the lower right corner of the Printing dialog in Cardiax there are buttons providing picture-file creation. Everything that can be sent to the printer in Cardiax can also be exported as **GIF** pictures or **raster based DICOM** files, namely DICOM encapsulated Jpeg images. 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 size and orientation of the picture see, chapter 3.3 Print.

Further, printing into pdf files is natively available, there is no need to additionally install special printer drivers (pdf printers).

The language of labels and texts in the printouts can be selected independently of the language of Cardiax.

# 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 Controlled ergometer devices

Before beginning the stress test, select the type (name) of the connected device from the right hand site list. Bicycles are on the top, followed by the treadmills, both groups are in alphabetical order individually.

Preferences		— 🗆 X
Categories ECG device	Controlled devices Lode; Corival	
<ul> <li>ECG</li> <li>Print</li> <li>Batch, rest ECG</li> <li>Batch, ergometry</li> <li>Display settings</li> <li>Ergometry</li> <li>Ergometry</li> <li>Ergometry</li> <li>Blood pressure</li> <li>User</li> <li>Options</li> <li>Advanced</li> </ul>	Port COM 1 (Kommunikációs port) COM 7 (Virtual Serial Port 8 (Eltima Software)) COM 17 (Virtual Serial Port 8 (Eltima Software))	Device Ergoline; Variobike 500 Ergosana; Sana Bike 120F/150F Ergosana; Sana Bike 250F/450F Ergosana; Sana Couch/Cardio 350L/350SE Ergosana; Sana Couch/Cardio 450L/450SE Ergosana; Sana Couch/Cardio 450L/450SE Ergosan; Sana Couch/Cardio 450L/450S
	Detect connection of device	Seca Seca; Cardiotest 100 Siemens; EM 840 Tunturi F60R
	Check Command test	Treadmill (km/h) without PC communication
	Ok <u>C</u> ancel	Apply

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*, take care to select the proper speed unit (in brackets) used by the device: *km/h* or *mph*. This is independent of the <u>units</u> set for patient data. This unit will be used in the settings for treadmill program. In the case of ergometers, the *"(with BP)*" denotes that the device has controllable, built in blood pressure meter.

On the *Blood pressure* sub-category, the separate blood pressure measuring device and its connection port can be given. The selected device is only controlled during the test, if it is enabled here!

Preferences		- 🗆 X
Categories	Controlled devices Lode; Corival Bosotron 2	Device ASM 1000/2000 BP Meter Bosotron 2d Cardiolyzer 1.2 Dimeq EBM 503 Dimeq EBM 503 D BP 200 Plus METRONIK BL-6M
	Detect connection of device	
	Ok <u>C</u> ancel	Apply

For both devices above, the connection port (serial port) must also be given next to selection; if known, just select the line from the available ports. With the help of the **'Detect connection of device'** button, the program tries to initiate connection to the device by trying the available ports one-by-one. The result of the probe will be displayed in the *Controlled devices* box on the top of the page. On success '*RS-232 control*' message will appear. If, on the other hand, '*No RS-232 connection*' is displayed, the program is unable to control the device. There are several possible reasons for this warning message:

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, or external control is disabled on it
- the selected device is not identical with the connected device
- the serial cable is not appropriate or it is broken

Use the '**Check**' button to test the connection using the actually selected port. The result is displayed as described above.

The '**Command test'** button enters a service dialog, where the control commands can be individually checked in case both stress and blood pressure devices.

### 9.2 Load program

The workload scheduling can be given here.

The selected stress and blood pressure device is displayed on the top.

Below, parameters valid in case of any protocols (global settings) can be seen, like online curve printouts at phase ends and manual load alteration.

The next box contains the protocol related settings.

The empty place on the bottom will contain the data related to an actual patient when starting the stress procedure along with break conditions for the test. Those are not stored, the doctor must set them individually for every test, taking the patient's condition into account!

New protocols can be defined for later use.

The parameters of the built in protocols cannot be changed!

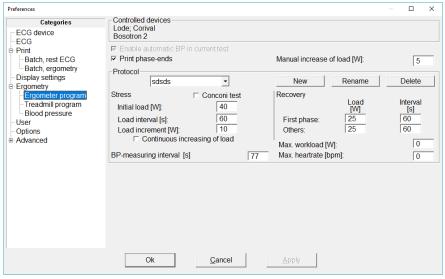
Pressing '**New'** button will initiate the new protocol with the currently visible parameter values.

The interval values are not allowed to be shorter than 60 second.

#### Ergometer

The '*Manual increase of load*' is protocol independent and used when pressing the <u>specific</u> buttons during stress test.

Stress and recovery related values are separated by the vertical line on the middle.



Beside the three stress parameters, one of two options can be selected:

**'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 for athletes, frequent in Switzerland.

After the stress phase, it is possible to define different load value and interval for the first recovery phase (using the **First phase** and **Others** lines). This can be useful when the patient reached high load (e.g. sportsmen) and the doctor intends to introduce recovery phase (usually 25 W) gradually.

**'BP-measuring interval'** – applies to blood pressure measurement frequency. This determines the start of the notification bar and the start of pumping, in case of automatic blood pressure <u>measurement</u> is enabled.

For the protocol, specific stop conditions, '*Max workload*', '*Max heartrate*' can be defined. These are automatically offered for breakpoint values when starting the test.

### **Treadmill**

A '**Warm up speed**' can be given to immediately start the treadmill at this speed, when opening the monitor window of a new ergometry test.

The '*Manual speed/gradient step*' is used when pressing the V+ / V- and G+ / G- buttons respectively, during stress test <u>to modify</u> the ergometry device parameters.

The 'Do not repeat last recovery phase' setting ensures to stop the treadmill after the last recovery phase is completed.

In the protocol field, the stress and the recovery phases can be programmed by defining the *time*, *speed* and *grade* values for the phases. The stress and recovery programs have individual tables switched by the tabs. The maximum number of phases can be 12.

The following common protocols are predefined:

- BALKE
- BRUCE
- BALKE MOD
- BRUCE MOD
- ACIP
- NAUGHTON
- ELLESTAD I
- CORNELL
- ELLESTAD II

#### IMED Ltd.

Preferences							-		×				
Categories	Controlled de												
ECG device	Bosotron 2												
<ul> <li>ECG</li> <li>Print</li> <li>Batch, rest ECG</li> <li>Batch, ergometry</li> <li>Display settings</li> </ul>	<ul><li>✓ Enable auto</li><li>✓ Print phase</li><li>✓ Warm up speet</li></ul>	-ends	urrent test	0.0	Manual speed step [km/h]:           0.0         Manual gradient step [%]:           Image: Do not repeat last recovery phase								
Ergometer program	Protocol	BRUCE MOD	•		New		ame	Delete	1				
<ul> <li>Treadmill program</li> <li>Blood pressure</li> </ul>		Stress pr	ogram		1	Recovery	program						
– User – Options ⊕ Advanced	Stress program           Phase         Time         Speed           [s]         [km/h]           1.         180         2.7           2.         180         2.7           3.         180         2.7           4.         180         4.0           5.         180         5.4           6.         180         6.7	Grade [%] 0.0 5.0 10.0 12.0 14.0 16.0	Phase 7. 8. 9. 10. 11. 12.	Time [s] 180 180 180 180 180 180 180	Speed [km/h] 8.0 8.8 9.6 9.6 9.6 9.6 9.6	Grade [%] 18.0 22.0 22.0 22.0 22.0 22.0							
	Ok		<u>C</u> ancel		<u>A</u> pply								

For this kind of stress devices the blood pressure intervals are tied to the phases, no independent intervals can be given for it.

# **10. Stress test**

#### Menu: Record / Stress test

First, the **Settings window** appears, and the device connection will be checked, if controllable device was selected. In case connection is fine '*RS-232 control*' message appears next to the device name, otherwise 'No RS-232 connection!' This requires checking the setting according to the previous chapter.

Any automatic **blood pressure** measurement can be disabled for the current session, temporarily (the upper checkbox).

In case the **curve printing for phase ends** is set, it is highlighted in order to rise attention. It can be disabled for the current session, but there is a possibility to toggle it anytime during the test in the *File menu*.

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

Below are the procedures for starting ergometer and treadmill tests are detailed. In both cases a protocol must be selected and the values are updated.

### **Ergometer**

According to the patient data, the maximal heatbeat rate and the expected load values are calculated and shown on the bottom of the window.

Preferences	Controlled devices			X
Categories ECG device ECG	Lode; Corival Bosotron 2			
■ Print Batch, rest ECG	<ul> <li>✓ Enable automatic BP in current test</li> <li>✓ Print phase-ends</li> </ul>	Manual increase of load [W]:	5	
Batch, ergometry     Display settings     Ergometry     Treadmill program     Blood pressure     User     Options     Advanced	Protocol Default protokol Stress Conconi test Initial load [W]: Load interval [s]: Continuous increasing of load BP-measuring interval [s] Values calculated for the patient Max. expected workload [W]: by weight by body surface by age (G26/III)	60 179 174 193 137	New         Rename           Recovery         Load           [W]         25           Others:         25           Max. workload [W];         Max. heartrate [bpm];           Test breakpoints         Max. workload [W];           Max. workload [W];         Max. workload [W];           Max. workload [W];         Max. systole [mmHg];           Max. diastole [mmHg];         Max. diastole [mmHg];	Delete Interval [S] 60 0 0 179 0 0 0 0 179 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

Regarding the test break threshold values, the blood pressure and SpO2 values are not used by default, can be filled out considering patient under test. The *Maximal heartrate* value is taken from the *values calculated for the patient* (179 bpm on the figure above). When the selected protocol has a given value (not zero) for a maximal threshold, then that will be set for the corresponding breakpoint field.

Any threshold in the Test breakpoint section can be modified independent of its initial value according to the opinion of the competent doctor. The **value zero** means excluding the measured quantity from the breakpoint conditions.

# <u>Treadmill</u>

Below the protocol fields, the Test breakpoint thresholds can be given, by default there is none set.

Preferences				– 🗆 X
Categories	Controlled devices			
ECG device ECG	Bosotron 2			
Print     Batch, rest ECG     Batch, ergometry	Enable automatic BP in current test     Print phase-ends     Protocol		Manual increase of load [W]:	5
<ul> <li>Display settings</li> <li>Ergometry</li> </ul>	Default protokol		New Rename	Delete
Ergometer program     Treadmill program     Blood pressure     User     Options     Advanced	Stress Conconi test Initial load [W]: 40 Load interval [s]: 60 Load increment [W]: 10 □ Continuous increasing of load BP-measuring interval [s] Values calculated for the patient Max. expected heart rate [bpm]: Expected workload [W]: by weight by body surface by age (G26/III)	60 179 174 193 137	Recovery     Load [W]       First phase:     25       Others:     25       Max. workload [W]:     Max. heartrate [bpm]:       Test breakpoints     Max. workload [W]:       Max. workload [W]:     Max. heartrate [bpm]:       Max. workload [W]:     Max. deatrate [bpm]:       Max. systole [mmHg]:     Max. diastole [mmHg]:       Min. SpO2 [%]:     Max. diastole [mmHg]:	Interval [5] 60 60 0 0 179 0 0 0 0 0
	Start <u>C</u> ancel		Apply	

After all set as required, the test can be started by the *Start* button.

### **10.1 Recording the stress test**

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

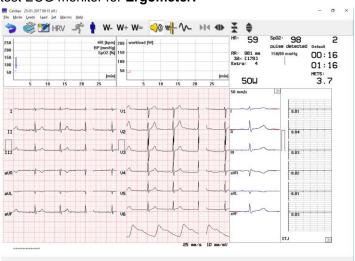


### Menu: Stress test / Start

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 what was chosen in the <u>Settings</u> menu. At the end of each stage the workload will be increased for the next stage.

The monitor window displays the following data:

- blood pressure input field (also display, in case of automatic measuring)
- time of blood pressure measurement due
- stage time and total test time in sec
- actual load measured in W (or, in case of a treadmill: speed and gradient too)



#### Stress test ECG monitor for Ergometer:

#### Stress test ECG monitor for Treadmill:



Above the online ECG curves heart rate, blood pressure, SpO2 and load graphs can be seen. Heart rate and SpO2 are curves, while blood pressure is displayed as horizontal bars (systole and diastole at a time).

On the left of the ECG curves the medians and ST amplitudes can be seen. The displayed values are updated every 4 seconds computed from the last 16 seconds of the curves. The initial median (resting state) is always displayed as reference in a different color, enabling the tracking of the shape of the beats.

The double arrowheads in the lower right corner of the ST graphs functions as a button for changing the displayed ST amplitude type (STJ, STM, STE, SLP).

If 2x6 leads are displayed, the median window also has a double arrowhead in the upper right corner. It can be used to change the displayed 6 leads for what median and ST is displayed.

#### Menu: Record / Ergometrie up-to-now

It is possible to view the ECG curve of the actual running ergometry session. It opens up a new window with a temporal copy of the ECG curve stored so far for examination, but no online comments or edited diagnosis can be attached during the review.

#### Menu: Record / Print phase ends on/off

Automatic printing can be scheduled or disabled at the end of each phasechange in stress test.

#### Test breakpoints

Can be given or confirmed in the <u>Settings window</u> appearing at starting the test. If any one of the test breakpoints, is reached (heart rate, load, systole, diastole), the program gives a warning. However, you can choose to continue the test at the current workload, by pressing [F3] within 15 seconds. If not, the recovery phase will be initiated.

Stress can be discontinued either by reaching any of the break conditions or by the decision of the supervising doctor.

## 10.2 Recovery phase, end of stress testing

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

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. Automatic blood pressure measurement will continue in the set intervals and will be stored together with ECG measurements in the recovery phases too.

Terminating the stress test is possible by:



## 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.

40 seconds before the end of each workload stage, the program displays a yellow progress bar under the input field of the input field of the pressure value.

The blood pressure measurements can be done in two ways:

In <u>manual</u> BP mode, the user types the BP measurements into the input field using the following form: *systole/diastole*. Basically, two, separated (by *space* or *'*/') numeric values are expected.

With an <u>automated</u> BP measurement device connected and enabled, the computer reads and stores the data. The program displays the last measured BP values.

The frequency (interval) of BP measurements can be set at the protocol setup. The above mentioned 40 seconds are true for equal phase length and BP measure intervals.

The result of a measurement is stored under the phase the in which it was started in.

Hotkey: [Ctrl+F4]

It is possible to start additional measurements by pressing the *Ctrl-F4* key combination. The time-stripe appears, and the controlled device starts pumping.

# 10.4 Manual change of workload

It is possible to increase or decrease the pre-programmed workload with the value set as the <u>'Manual increase of the load'</u> in the ergometry program settings.



increase/decrease by the set amount.

Each push of the button changes the load by the set amount. The new load value will be sent to the device within 5 seconds

W=It is also possible to hold the workload constant and cancel the preprogrammed increases in workload. In this case the workload will remain constant until it is cancelled. With this choice, the displayed workload value (watts) blinks, and the workload remains constant until this choice is again selected to cancel.

In case a treadmill is used for the stress test the following manual load (speed, gradient) manipulation buttons will appear:



These will change the respective parameter of the test device by the amount set up in the <u>Preferences</u> of the program.

# **11. Evaluation of the Final report**

The final protocol of a stress test is displayed in the <u>list of recordings</u> with a cyan folder icon and identified as *Stress test*. Press [Enter] or doubleclick to open the **Final report** for evaluation.

List of records		Comment:
27-11-2006 16:15	Stress test	TrackMaster
11 12 2007 10.56	Drocordial [16c]	

The **Final report** consists of 4 main information categories: *List, Graphs, ST Trend, ST List* and an additional *Conconi* tab, if the protocol was set so.

In each tab, the comment regarding the whole stress test is available for editing or printing (max.of 30000 characters):

```
Menu: ECG / Ergometry comment , Hotkey: [F2]
```

This text is essentially the <u>edited diagnosis</u> of the whole recording, this way can be accessed without opening the recording. (For stress test recordings, no automatic diagnosis is proposed.)

## List of workload phases

The list provides information about the ECG recording and characteristic values of the test phases.

In case of **bicycle ergometry**, the time, load, heart rate(HR), blood pressure (BP), double product (max HR \* max systolic BP) (DP), revolutions per minute (rpm) and selected ST amplitude are shown.

> 🥪	S 🛯		נדא 🔁	STM S	te SLP	Ι	II II	I aV	R aVL aVF V1	V2	V3 V4	V5 V6	
	<u>L</u> ist		1	<u>G</u> rap	hs		1	S	T-trend	1	SI	-level	
Phase	Time [m:s]	Wload [W]	BP [mmHg]	HR [bpm]	DP	rpm	STE/V2 [mV]		Max HR predicted:			178	
Rest St 1 St 2 St 2 St 4 IRI 1 IRI 2 IRI 3	00:00 03:00 09:00 11:00 01:00 03:00 05:00	0 75 125 125 175 25 25 25 25	140/85 150/80 150/80 170/80 155/80 155/90	99 108 108 141 165 143 104 92	15120 16200 21150 24310 16120 13800	0 0 0 0 0 0	0.16 0.18 0.16 0.21 0.21 0.34 0.16 0.20		Max.HR: Max.BP: Workload attained [\ Max.load [\V]: METS: Extra beat by weight (92 kg)— Expected workload [ Ability [%]:			165 (92 % 170/80 158 175 7.7 2 243 65	0
PWC 130: 150: 170:		[W] [W/kg] 125 1.36 143 1.55 			Norm. 1.50 2.00 2.50	_	-by body surface (2. Expected workload [ Ability [%]:		223 70				

For **treadmill** tests speed and gradient values are displayed too, and the METS values are shown in each phase.

		ST ST	STM STE SL	D T	II III aV	R aVL aVF	V1 V2	V3 V4 V5	V6
			SILL SIL SIL	-			11 12		••
<u>L</u> ist		1	Graphs		<u>S</u>	T-trend	1	S <u>T</u> -level	
Phase	Time [m:s]	Speed [km/h]	Grade [%]	BP [mmHg]	HR [bpm]	DP	METS	WATT [W]	STE/V2 [mV]
Rest	00:00	0.0	0.0		89	-	-	-	0.15
St 1 St 2 St 3	03:00 06:00 07:24	2.7 4.0 5.4	10.0 12.0 14.0	110/70 120/80	118 133 133	12980 15960	4.0 6.6 9.9	36 65 101	0.16 -0.11 0.08
RI 1	02:19	5.4	14.0		111	-	9.9	101	0.08
Max HR predicted: Max.BP:	181 120/80		Max.HR:		150 (82 %)		2 [ml/kg/min]: uble prod:		34.5 15960
Comment of ergome	try phase						TS:		9.9
klsdjfhsjkldfsadf									

In the last column choose the symbol or press [F5] to toggle between the STE, STM and STJ amplitudes and the slope of the ST segment , 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) *milliseconds* to determine the end of the ST segment (menu: 'Setup' / 'ECG' / 'J + 60/80' / 'ON').

For each phase, an individual short comment can be attached (max.59 characters).

Menu: ECG / Phase comment, Hotkey: [F4]

The BP and HR displayed for the phases can be altered, if required.

Menu: ECG / Edit ...

These options can also be accessed using the **local menu**, invoked by right clicking a phase.

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 (neither in the <u>exported</u> data)
- 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.

# **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.

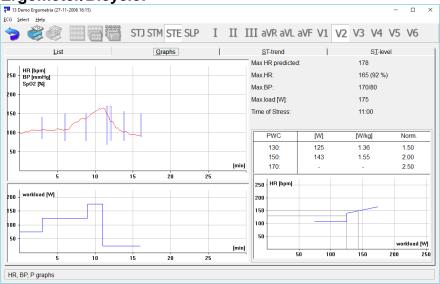
For an <u>ergometer/bicycle</u> stress test, the right hand side of the screen display shows an evaluation of exercise performance. The maximum expected performance from the patient can be calculated according to the weight and the body surface area, by the method of DuBois. The display also shows achieved performance as a percentage of maximum predicted. If the HR during the stress test has reached the limits defined for the PWC (physical working capacity) 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 <u>treadmill</u> stress test the program displays (to the right of the table) the calculated oxygen consumption (VO2), 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 SpO2 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:

<u>S</u> elect <u>H</u> elp	tria (18-10-200										_		
) 🍣	<b>8</b> [		רצ נדצ	TM STE SLP	Ι	II	III aVR aVL aV	F V1	V2	V3 V4	V5	V6	
	List			Graphs	1		ST-trend	1		S <u>T</u> -le	evel		
0 - HR (bpm) BP (mmH Sp02 (%) 0 -		<b>^</b>					Max HR predicted: Max.HR: Max.BP: VO2 [ml/kg/min]: Double prod: Time of Stress:		1	181 150 (82 9 120/80 34.5 15960 7:24	6)		
0	5	10	15	20	25	[min]	40						
VO2 (ml/kg							30						
						(min)	10				V02	[ml/kg/	m
	5	10	15	20	25		20		40	6		9	30

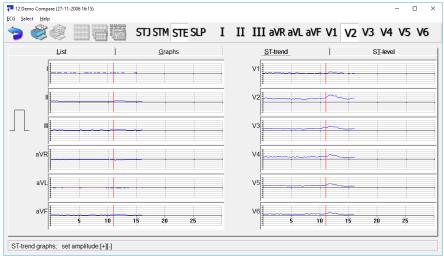
The first two diagrams show the same measurements as in the case of the ergometer/bicycle. The third figure is the diagram of the calculated oxygen consumption as a function of time.

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, STE or SLP values. With [Up] and [Down] keys can you change the amplitude gain. By pushing a lead button on the toolbar or double clicking a small graph, the corresponding curve opens in a separate window for scalable display.



#### 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, STE or SLP values.

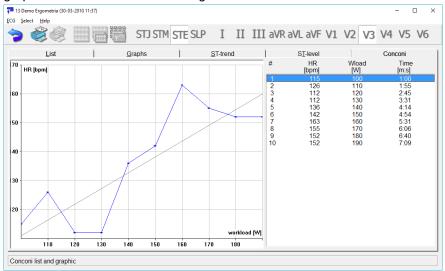
The STE, STM and STJ values are replaced with J80/J60, J40/J30 STJ values if the program used the J+80(60) *milliseconds* method to determine the end of the ST segment. (<u>menu</u>: 'Setup' / 'ECG' / 'J60/80' / 'ON'). This is reflected in the header of the first column of the list.

Hitting [Enter] or double-clicking on a row of phase opens the ECG curve at the appropriate time position.

	Help	har and a		СТ		TE SLP	т	TT TI	IaVR	->// ->//		10 1	2 1/4		6
2 🔍	200	destandaria. Sestandaria		51.	SIMS	SIE SLP	1	11 11	I avk	dvL dv	L AT	VZ V	3 V4	V5 V	0
	<u>L</u> ist		1		Graph	s	1		ST-trend				ST-level		
	Time	HR	1		III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	
TE	[m:s]	[bpm]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	[mV]	
	06:45	117	0.01	0.04	0.03	-0.02	-0.01	0.03	0.02	0.14	0.07	0.07	0.07	0.05	
	07:00	123	0.02	0.04	0.03	-0.02	0.00	0.03	0.01	0.14	0.07	0.06	0.06	0.07	
	07:15	127	0.01	0.04	0.04	-0.02	-0.01	0.05	0.02	0.13	0.09	0.12	0.09	0.07	
	07:30	128	0.01	0.04	0.03	-0.02	0.00	0.03	0.01	0.13	0.09	0.08	0.10	0.11	
	07:45	129	0.02	0.05	0.03	-0.03	0.00	0.04	0.02	0.15	0.11	0.11	0.12	0.09	
	08:00	135	0.01	0.03	0.01	-0.02	0.00	0.02	0.02	0.15	0.10	0.09	0.09	0.09	
	08:15	137	0.01	0.03	0.03	-0.02	0.00	0.03	0.02	0.18	0.11	0.11	0.11	0.09	
	08:30	137	0.01	0.03	0.02	-0.02	0.00	0.03	0.02	0.20	0.11	0.11	0.11	0.13	
	08:45	136	0.01	0.04	0.03	-0.02	0.00	0.04	0.02	0.18	0.12	0.15	0.12	0.09	
	09:00	141	0.01	0.04	0.03	-0.02	-0.01	0.04	0.01	0.15	0.10	0.11	0.12	0.11	
	09:15	145	0.02	0.04	0.01	-0.03	0.01	0.02	0.03	0.17	0.10	0.10	0.09	0.07	
	09:30	149	0.01	0.04	0.02	-0.02	-0.01	0.04	0.02	0.18	0.11	0.11	0.11	0.11	
	09:45	153	0.01	0.03	0.03	-0.01	-0.01	0.03	0.02	0.19	0.11	0.13	0.12	0.09	
	10:00	155	0.01	0.04	0.03	-0.02	-0.01	0.04	0.03	0.18	0.12	0.11	0.09	0.07	
	10:15	159	0.01	0.02	0.02	-0.01 -0.03	-0.01	0.02	0.03	0.18	0.12	0.13	0.12	0.09	
	10:30	163	0.01	0.05	0.04		-0.01 -0.02	0.04	0.01	0.19	0.14	0.14	0.13		
BREAK	10:45 11:00	162 165	0.01 0.01	0.04	0.04	-0.02	-0.02	0.04 0.04	0.02	0.21 0.21	0.14 0.15	0.14 0.14	0.12 0.13	0.09	
REAN	00:00	165	0.01	0.04	0.03	-0.02	-0.01	0.04	0.02	0.21	0.15	0.14	0.13	0.10	
	00:00	163	0.01	0.05	0.03	-0.05	-0.01	0.04	0.02	0.21	0.15	0.15	0.13	0.10	
	00:30	150	0.03	0.00	0.04	-0.05	-0.01	0.05	0.03	0.29	0.15	0.15	0.13	0.11	
	00:45	143	0.01	0.07	0.06	-0.04	-0.02	0.00	0.07	0.32	0.21	0.21	0.19	0.15	
	01:00	130	0.02	0.06	0.05	-0.04	-0.02	0.07	0.07	0.34	0.22	0.22	0.18	0.10	

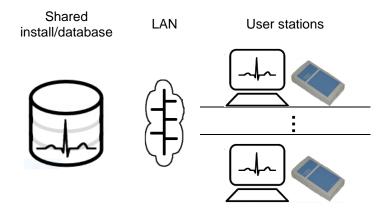
# 11.4 Conconi

Evaluation of the special test type in graphical and table form. Clicking the graph zooms on the curve to the greatest visible extent.



# 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.

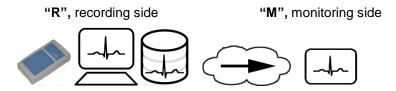
In network operation ECG recording on a workstation is possible only after enabling the option with a password. For these workstations the *'Network database'* option must be bought as well as other options that are needed on the workstation (see <u>chapter 3.7 Options</u>).

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 Cardiax to monitor the ECG recording process running simultaneously on another workstation in the local network or on another properly configured place through the Internet using TCP/IP. It makes possible to supervise a long time ECG recording, typically a stress test.

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

Preferences		— 🗆 X
Categories ECG device -ECG Print -Batch, rest ECG	ECG device ECG on USB	Serial number (SN): 0605120535
<ul> <li>Batch, ergometry</li> <li>Display settings</li> <li>Ergometry</li> <li>Ergometer program</li> <li>Treadmill program</li> </ul>	<	Assign
Blood pressure User Options ⊕ Advanced	Only establish direct WIFI ECG connection     Computer's WIFI connection:	☐ Use specific WiFi interface
	Remote ECG monitoring         Automotion         Automotion         at the "monitoring" side	Allow remote monitoring at the "recording" side
	Ok <u>C</u> ancel	Apply

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

"R" starts monitoring and optionally the long-time recording (or the stress

test, where long-time recording is automatic). "M" also starts monitoring and the curve on "R" is displayed. "M" cannot record this curve, only "R" can, so no data of the actual patient of "M" will be altered.

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

On the Windows firewall of "R" 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 "R" is 7777, "M" 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 "R", the inbound port number can be modified in the *cardiax.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 "**P**" be the location where ECG is measured and place "**E**" where it is coordinated from. Both places run a normal installation of Cardiax. At "**P**", the user sets up the Cardiax program for normal recording (e.g.: Setup / ECG device / ECG on USB).

If **"P**" can surly access the ECG device locally then the program must be started/restarted with the parameter **-netdevice** for behaving as a "*netdevice*". (For frequent use, a shortcut with the modified command line is recommended to be created.) This way Cardiax at **"P**" starts monitoring immediately, and opens a TCP port for listening for incoming "Expert side" connections. No data is stored at location **"P**"!

From now on, the user at "**P**" has nothing to do, expect for supplying the IP address of "**P**" computer to "**E**", in case not already known. This address appears on the lower side of the monitoring window. Practically a communication channel should be established between "**P**" and "**E**" (chat, skype, telephone) since operations must be synchronised and patient data is also entered by "**E**".

At place "**E**" in the *Setup, ECG device* must be selected as *TCP/IP ECG device* and the IP address of "**P**" must be supplied. Afterwards, the Cardiax program can be used as regularly for recording the signal coming from of "**P**".

Firewalls must be set to enable the listening port on "**P**" and the connection establishment on "**E**" too! If "**P**" is connected to the internet from behind a NAT, a proper port forwarding must also be set up on the NAT-router. The default TCP port used is the 7778, but can be modified; at "**P**" the **cardiax.ini** file has the following entry for overriding:

[ecg]

iNetDevicePort=xxxx

and at "**E**", the *Device address* field can have the port number after the address, separated by a colon (e.g.: fire2.fs.org:xxxx).

### 12.4 Server/Client (remote database) operation

In this operational mode the Cardiax program running on a local computer (Client) connects to the database of a Cardiax 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.

Cnx Server	
TCP IP	
Received Command	OFFLINE
Command Status	
Listen Password	Exit

#### Starting the Client program:

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

#### a) 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.

Choose communication device			×
TCP IP			
Connect	Setup	<u>C</u> ancel	

#### b) 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.

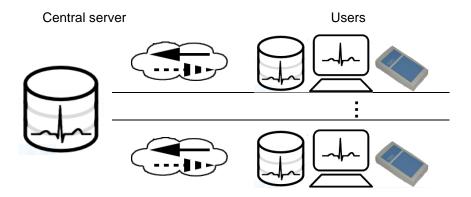
This function is useful for copying and comparing data between two databases.

#### c) 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 Cardiax NetCenter



#### **Operation:**

Users run the Cardiax program on local workstations (or laptops) in client mode. These workstations connect to the central database using TCP/IP network protocol. Connection can be made on a LAN, Intranet or on the Internet. The locally stored recordings (and attached documents) 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 them with its local database. The short recordings (snapshots) 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.

#### Security:

On the central machine name/password pairs must be defined. When starting Cardiax in client mode on the workstations, 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. At restart, the username and the password must be given again.

#### User side (client):

For accessing the central server, the address and optional port number of it must be set beforehand by starting Cardiax normally. The required settings are in the '*Setup*' menu under the '*Advanced* / *NetCenter*' category. The default port 3920 is used, if the field is left blank.

Preferences		
Categories		
ECG device	Server:	surg2.hosp1.hu
ECG		
B Print Batch, rest ECG	Port:	
Batch, ergometry		
- View of monitor and dialogs		
Ergometry		
Ergometer program		
- Treadmill program - Blood pressure		
User		
- Options		
Advanced		
WiFi		
- Pulse oximeter - Mail		
- Auto backup		
- Auto export		
NetCenter		
- Security groups		
<		
	Ok Cancel	Apply

For NetCenter functionality, Cardiax must be started with the parameter **-netclient** on the client side. At start, the program asks for the user name and password to the server. Cardiax then loads the "*Crx Client Agent*" background process. 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 (with up-arrow) is placed onto the system tray:



The client agent may stay loaded for a while, after the main program is terminated until it finishes any ongoing synchronization with the server. Finally it terminates automatically.

The process of adding a new patient is a slightly different: the *code* field is activated as the dialog opens and only the code need to be entered. By hitting enter, the server is asked for the other patient parameters from the server. If the server could not provide them, the dialog opens again and registration can be completed. The new patient will immediately appear on the server too.

Double-clicking the agent's tray icon a window opens that contains a listing with the technical details of the requests sent to the server:

× 📴			
request	read	write	status
20150323_092818_119_CE985864_NQVC34BP.CRZ	40 + 371	104 + 401	Ok
20150323_092756_461_81150341_TS6FSNOT.CRZ.UP	40 + 371	107 + 371	Ok
request	read	write	status
20150323_092522_284_616AB20D_NVMPGMQR.CRZ	40 + 273	104 + 273	Ok
20150323_092537_323_D036DC41_9D862HGU.CRZ	40 + 371	104 + 409	Ok
20150323_092549_619_8AC18DBC_08R49DF4.CRZ	40 + 371	104 + 401	Ok
20150323_092619_948_2EAE1291_08R49DF4.CRZ.UP	40 + 371	107 + 371	Ok
20150323_092630_502_E74D689D_08R49DF4.CRZ	40 + 371	104 + 401	Ok
20150323_092720_747_DEB4C1D1_08R49DF4.CRZ	40 + 371	104 + 401	Ok
20150323_092729_833_BE825C37_08R49DF4.CRZ	40 + 371	104 + 401	Ok
20150323_092748_274_D78C49EA_T56FSNOT.CRZ	40 + 371	104 + 401	Ok
20150323_092756_461_81150341_TS6FSNOT.CRZ.UP	40 + 371	107 + 371	Ok
20150323_092818_119_CE985864_NQVC34BP.CRZ	40 + 371	104 + 401	Ok

There are two buttons: the first terminates the agent (the upper right only minimizes to the tray), and the second enables auto-scrolling the list.

#### Central side (server):

On the central computer the program must be started with the parameter – **netserver**. Cardiax starts the "*Crx Server Agent*" background process. 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 (with down-arrow) represents the server agent on the system tray:



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

SERVER/20150320 14/20150320 144552 250 5BF2B4C	
ielo	
0k .\SERVER!20150320_14!20150320_143341_152_19F47CA2_GQ72H3DS.CRZ.20150320_143346_833.REC.(Ok): [/] hello	
SERVER20150320 1400150320 143643 183 2854472A 30278403 CR22150320 143649 831 REC (Dk) [03 Demo. SERVER20150320 1420150320 143710 089 C-206024 G072H030 CR21 P2 030502 14376 38 REC (Dk) [03 Demo. SERVER20150320 1420150320 143710 851 DECAE73 TK671GH1 CR220150320 14375 5517 REC (Dk) [Dhi Toe SERVER20150320 1420150320 14372 4851 DECAE73 TK671GH1 CR220150320 14376 5517 REC (Dk) [Dhi Toe SERVER20150320 1420150320 14382 914 4 EC28327 214K1M0K RC220150320 14376 5517 REC (Dk) [Dhi Toe	mo / 000 000 003) up single
SERVER20150320 1420150320 143825 914 37FFE20D TatkJK0KB CR2 20150320 143823 350 REC (0ki) 10 Demoi SERVER20150330 1420150320 143828 914 05962201 1 VH00VXC CR2 20150320 143835 438 REC (0ki) [05 Demoi SERVER20150330 1420150320 14388 914 D4962201 VH00VXC CR2 20150320 14389 424 REC (0ki) [10 Demoi SERVER20150330 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14389 424 REC (0ki) [11 Demoi SERVER20150330 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14389 424 REC (0ki) [12 Demoi SERVER2015030 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14389 424 REC (0ki) [12 Demoi SERVER2015030 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14389 44 REC (0ki) [12 Demoi SERVER2015030 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14389 544 REC (0ki) [12 Demoi SERVER2015030 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14388 164 PCC [14 Demoi SERVER2015030 1420150320 14388 164 D452PCD55 4MxP53L CR2 20150320 14388 164 PCC [14 Demoi SERVER2015030 1420150320 14388 164 PCC [15 D452] [15 D4530 14388 164 PCC [15 D454] [15 D455 [15 D452] [15 D452] [15 D452] [15 D4552] [15 D455	/ 000 000 005] down Frank / 000 000 014] down
.SERVER20160320_1420150320_143838_539_BCCA9210_LHRY8150_CR2.20150320_143845_059.REC (A) [13 Demo 1 .SERVER20150320_1420150320_143552_250_5BF2B4C5_14K,K0KB_CR2.20150320_144601_036_REC (A) [1] Demo 1	

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

The agent window can also be activated by clicking on its tray icon, and the technical details of the received request are listed:

×	3 <b>6</b> 7						
user	request			read	write	status	
				0		*** unathorized: 94	
user	request	read	write	status			
drCarter	20150320_143341_152_19F47CA2	104 + 273	39 + 273	Ok			
drCarter	20150320_143643_183_6B54472A	104 + 409	39 + 371	Ok	Ok		
drCarter	20150320_143710_098_FCE40624	109 + 32950	39 + 371	Ok	Ok		
drCarter	20150320_143748_851_0EEA8E73	104 + 401	39 + 371	Ok	Ok		
profJoe	20150320_143822_914_4E6283F2	104 + 273	39 + 273	Ok	Ok		
profJoe	20150320_143825_914_37FFE20D	104 + 425	39 + 371	Ok			
profJoe	20150320_143828_914_D96292D1	104 + 409	39 + 371	Ok			
profJoe	20150320_143832_945_1CFDFBC	104 + 409	39 + 371	Ok			
profJoe	20150320_143836_164_B42FDCB5	104 + 449	39 + 371	Ok			
profJoe	20150320_143838_539_BCCA921	104 + 417	39 + 371	Ok			
		0		*** una	thorized: 941		
drCarter	20150320_144552_250_5BF2B4C5	104 + 273	39 + 273	Ok			
		0		*** una	thorized: 941		

There are three buttons: the first terminates the agent (the upper right only minimizes to the tray), the second enables auto-scrolling the list, and the third is for adding a new user, described below.

#### User management

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

icon on the tray, a local menu pops up, where selecting the 'Add new user' opens a dialog for entering a new name/password pair to have access to the server. The same dialog opens if the key symbol is pressed on the opened agent window. The usernames with password are case sensitive and are stored in the **pass.dat** file at the same directory Cardiax 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 *cardiax.ini* file in the [NetCenter] section by specifying listening\_port=1234, where 1234 is the desired port number.

## **12.6 External requests**

詚

Menu: Transfer / External requests

Used in hospital, surgery information systems for tracking and handling referrals for ECG examination.

### **12.7 Calling Cardiax from other applications**

The program can be used by other applications for making ECG recordings and viewing them later on. The application can refer to a specific recording by a unique identification method. The recording and all adherent data is stored in the database of Cardiax, the calling application only needs to store the identifier.

There are two ways for invoking Cardiax; the first results a single session, that closes the program after the ECG is done, the other leaves the program running, ready for accepting further calls from applications.

- wincrx32 /Qxxx.ini
- wcrxcl32 /Qxxx.ini

In both cases a /**Q** switch followed a filename *xxx.ini* must be supplied, where *xxx.ini* is the name of the configuration file. This name can contain a full path, e.g.:

#### /Q"D:\Some\Common Place\crx\_caller.ini"

Pay attention to using quote marks in case the path contains space, like in this example! The *ini* file should contain data required for patient identification and intended operation.

For identification of an existing record, several options are available, as discussed below.

In case new recording is to be taken, the folder of the specified patient is opened and monitoring can be started by user interaction (pushing the rest or the stress ECG button). The possible fields for the *ini* file can be seen below. The possible values are also given as remarks following the semicolons.

The name and date field can be given in component-wise form using individual fields.

#### IMED Ltd.

```
[Patient]
  Readonly=0
                                  ; (default)
  ;1-new patient is not created, if not already exists in database
 Name=Joe Smith
  ;can be given as divided into parts:
  ; Lastname=Smith
  ; Firstname=Joe
  ; CrxId=
                                 ; existing patient can referenced with
this,
  ;will be written back into the processed file
  ; Crx0k=
                                 ; 1-processed file
 Id=123-456-789
 Sex=1
                                 ; 1-male, 2-female
 Weight=70
                                 ; in kg
 Height=170
                                 : in cm
 Dateform=ymd
                                  ; year/month/day (default)
                                 ; mdy-month/day/year
                                 ; dmy-day /month/year
                                 ; in Dateform format
 Born=1930/12/30
  ;can be given as divided into parts:
  ; Birthyear=1930
  ; Birthmonth=12
  ; Birthday=30
 Diagn=Seduxen wificus
 Doctor=Dr Walter Brown
 OFM=0
                                  ; 0-ANSI(1251) (default)
                                 ; 1-OEM(852)
[Institute]
 Inst=Federal lunatic asylum.
[Files]
  : New=newrecordIDs.txt
  ; Old=viewrecorID.txt
  ; Record=patientandrecordIDs.txt
[Record]
 Date=2013/12/30-12:30
                                  ; date in Dateform format
                                 ; time as hours:minutes:seconds
  ; can be given as divided into parts:
  : RecordStartYear=2013
  ; RecordStartMonth=12
  ; RecordStartDay=30
  ; RecordStartHour=12
  ; RecordStartMin=30
  ; RecordStartSec=
```

The calling application has the responsibility to generate unique names for the *xxx.ini* file, if needed (e.g. in network usage scenario).

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Values marked as default are used in case the specific field is missing.

The *Id* field is used to identify the patient. The calling application should provide unique identifiers (e.g. a social security ID). All the other fields are optional but recommended, and stored in the Cardiax database. If a patient with the given *Id* exists in the database, his/her list of recordings will be shown. Otherwise it will be treated as a new patient and his/her data will be inserted into the database.

In case the caller cannot provide unique identifiers, the Cardiax generated inner ID can also be used. It is returned after the first call with a new patient, when it is inserted into the database, and can be used in subsequent calls for identification. However, if used for existing patient identification, this id must be supplied in the *CrxId* field, not in the *Id* field!

After the call, Cardiax does not delete the *xxx.ini* file, but appends the following two lines to the [Patient] section:

CrxOk=1 CrxId=*yyyyyyyy* 

The CrxOk=1 item is used to ensure that the file was processed by Cardiax and will not be read at subsequent calls. The CrxId field is an 8 character long (alphanumeric) inner identification string. This can be used in later calls to identify the patient. It will be written back into the processed *ini* file (even if a valid *Id* field was used).

The name of the patient is given in the *Name* field or in the *Lastname*, *Firstname* fields in divided form. The name in the *Doctor* field is inserted into the users of Cardiax and assigned to the patient. A temporal institute name can be defined in the [Institute] section that will be used in printing and exporting during only the calling session, instead of the one set up in the program previously.

A *Diagn* field can be used to supply information about the patient, it will be stored on the patient's card.

Accented characters can be used in the fields if needed, using either the 1250 (Windows, Ansi) character set or the 852 character page (DOS, OEM). In the 852 case the OEM field should be set to 1.

The *ini* file can also be in Unicode format (with valid byte order marking /BOM/), this way the characters in the fields are also Unicode encoded enabling a wider range of characters to use.

The *Born* field contains the date in *year-month-day* format by default, but other formats can be applied using the *Dateform* field. Additionally, it is possible to define each number in the date individually (*Birthyear*, *Birthmonth*, *Birthday*).

The Weight, Height fields are interpreted as kg and cm respectively, independent of the unit-system used in the program.

Case of new recording:

In the *New* filed of the [Files] section the caller can supply the name of a file (newrecordIDs.txt in the example), where the time and type of the recordings of the given patient will be written.

Attention! The date format for the selected language in the program will be used here! For example in case of two recordings (a continuous recording and a snapshot record) the file will contain the followings:

```
18-04-2017 11:04 Precordial [3m52s] Sp02
18-04-2017 11:24 Precordial
```

Also, a *Record* field with a filename (patientandrecordIDs.txt) can also be defined: the patient ID together with the record ID will be stored in it, like:

```
PatienId:123-456-789
ECGrecordingID:18-04-2017 10:26 Precordial
```

#### Case of viewing an existing record:

The *OLd* filed in the [Files] section may be used to define the name of an existing file (viewrecorID.txt in the example). If this file contains the time of a recording, like:

```
2017-04-18-11:23
```

For the interpretation of the date, the format defined in the *ini* file (by the *Dateform* field or the default *year-month-day*) is used.

During the call Cardiax will automatically display the given recording.

In the [Record] section the recording to be displayed can be given directly (not by the means of using any *OLd* file) under the *Date* field. For the format interpretation, the *Dateform* is used, as above. It is possible here also to specify each component of the date individually using independent fields (*RecordStartYear*, *RecordStartMonth*, *RecordStartDay*, *RecordStartHour*, *RecordStartMin*, *RecordStartSec*).

The referenced files are searched for or created in the same directory as the *xxx.ini* calling file.

## 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

Taun	anological abnormanties			
	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, &linferior, ) location
	prolonged QT
Poss	ible 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, &linferior) location
	ST abnormality probably digitalis effect
	prolonged QT

#### Unspecified, undetermined variations

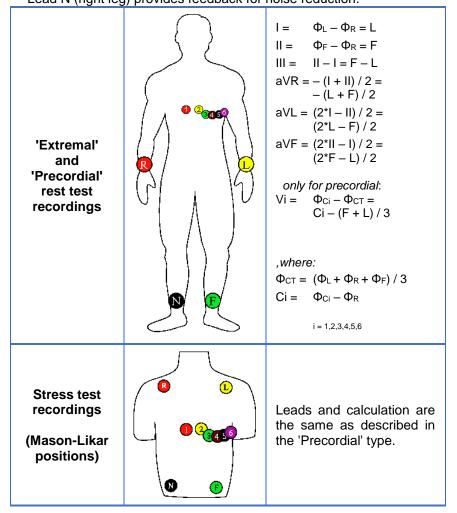
	QRS left axis deviation
**	QRS superior axis deviation
	QRS right axis deviation
	QRS right superior axis deviation
	abnormal QRS-T angle
	nonspecific intraventricular block
	ST elevation
	ST elevation because of early repolarization
	ST depression [ probably digitalis effect ]
	junctional ST depression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

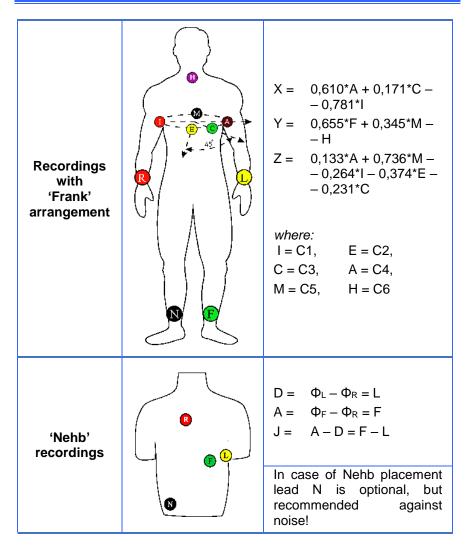
\* - only in pediatric diagnose | - or, & - and

\*\* - only in adult diagnose

# 13.2 Appendix B: Electrode placements and lead calculations, applied equations

In the following equations,  $\Phi_R$ ,  $\Phi_L$ ,  $\Phi_F$ ,  $\Phi_{C1}$ ,  $\Phi_{C2}$ ,  $\Phi_{C3}$ ,  $\Phi_{C4}$ ,  $\Phi_{C5}$ ,  $\Phi_{C6}$ , are the potential values of the applied lead electrodes at the places indicated in the lower index and shown on the graphs. In the equations, the L, F, C1, C2, C3, C4, C5, C6 are the digitalized signals provided by the ECG device, representing the potential differences of the electrodes with respect to  $\Phi_R$ . Lead N (right leg) provides feedback for noise reduction.





#### QT correction Methods

- Bazett: QTcB = QT / (RR/1000)^1/2
- Fridericia:  $QTcFri = QT / (RR/1000)^{1/3}$
- Framingham:  $QTcFra = QT + 0.154^{*}(1000-RR)$
- Hodges: QTcH = QT+1.75\*(HR-60)
- Nomogram: QTcN = QT + 0.116\*(1000-RR), if RR>1000
  - = QT + 0.156\*(1000-RR), if 600<RR<1000
  - = QT + 0.384\* (1000-RR), if RR<600

where HR is the heart rate and RR = 60000/HR [ms]

#### Vector ECG reconstruction methods

• Inverz Dower:

iDx = -0.172\*V1 -0.074\*V2 +0.122\*V3 +0.231\*V4 +0.239\*V5 +0.194\*V6 + + 0.156\*I - 0.010\*II iDy = +0.057\*V1 -0.019\*V2 -0.106\*V3 -0.022\*V4 +0.041\*V5 +0.048\*V6 -- 0.227\*I +0.887\*II iDz = -0.229\*V1 -0.310\*V2 -0.246\*V3 -0.063\*V4 +0.055\*V5 +0.108\*V6 + + 0.022\*I +0.102\*II

• Regression:

Rx = -0.130\*V1 +0.050\*V2 -0.010\*V3 +0.140\*V4 +0.060\*V5 +0.540\*V6 + + 0.380\*I -0.070\*II Ry = +0.060\*V1 -0.020\*V2 -0.050\*V3 +0.060\*V4 -0.170\*V5 +0.130\*V6 -

$$Ry = +0.060^{\circ}V1 - 0.020^{\circ}V2 - 0.050^{\circ}V3 + 0.060^{\circ}V4 - 0.170^{\circ}V5 + 0.130^{\circ}V6 - 0.070^{\circ}I + 0.930^{\circ}II = 0.000^{\circ}II + 0.000^{\circ}II = 0.000^{\circ}$$

- $\label{eq:rescaled} \begin{array}{l} {\sf Rz} = -0.430^* {\sf V1} \ -0.060^* {\sf V2} \ -0.140^* {\sf V3} \ -0.200^* {\sf V4} \ -0.110^* {\sf V5} \ +0.310^* {\sf V6} \ + \\ + \ 0.110^* {\sf I} \ -0.230^* {\sf II} \end{array}$
- Quasi orthogonal:
  - $\begin{array}{l} Qx = V6\\ Qy = II\\ Qz = -0.5^*V2 \end{array}$

## 13.3 Appendix C: Heart Rate Variability

Heart rate variability (**HRV**) is a measure of the beat-to-beat changes in heart rate.

Variations in circulation may be evaluated by a number of methods including heart rate variability, variability of pulse, blood pressure, stroke volume, maximal volume and linear speed of the bloodstream in aorta and other vessels. Other periodic processes occurring in the cardiovascular system may also be analysed.

Methods of obtaining the HRV parameters:

- 1) Time domain methods
- 2) Frequency domain methods

#### 1. Time Domain Methods

The basis of these methods is either the heart rate at any point in time or the intervals between successive complexes. In a continuous electrocardiographic (ECG) record each QRS complex is detected, and the so-called normal-to-normal (NN) intervals (i.e. intervals between adjacent QRS complexes resulting from sinus node depolarisation), or the instantaneous heart rate is determined.

#### Statistical Methods

The measures obtained after analyses of a series of instantaneous heart rates or NN intervals can be divided into 2 classes:

- those derived from direct measurements of the instantaneous heart rate or NN intervals
- those derived from the differences between NN intervals

The variables to be obtained are the following:

- Mean heart rate (HR, [*int/min*])
- Mean NN interval (mNN or mRR, [ms])
- Standard deviation of the NN interval (SDNN, [ms]) the square root of variance between the NN intervals. Since variance is mathematically equal to total power of spectral analysis, SDNN reflects all the cyclic components responsible for variability in the period of recording.

- Standard deviation of the average NN interval calculated over 5min periods within the duration of the recording (**SDANN**, [*ms*]). This parameter is an estimate of the changes in heart rate due to cycles longer than 5 minutes
- The square root of the mean squared differences of successive NN intervals (**RMSSD**, [*ms*]).
- The number of pairs of adjacent NN intervals differing by more than 50 ms in the entire recording (**NN50**)
- NN50 count divided by the total number of all NN intervals (pNN50, [%])

The last three measurements reflect high frequency variations in the structure of HRV and thus are highly correlated.

#### Geometrical Methods

The series of NN intervals can also be converted into several geometric patterns:

- tachogram is a graph of HR [*BPM*] and time [s].
- Poincaré, plot looks like a "cloud" which consists of a number of points. Abscissa of the point is the length of the previous NN interval. Ordinate of the point it the length of the subsequent NN interval. The decreased HRV is reflected in a greater density and smaller size of the cloud. The type of the point distribution is determined by origin of QRS complexes. SD1 and SD2 are two standard Poincaré, plot descriptors. SD2 is defined as the standard deviation of the projection of the Poincaré, plot on the line of identity (y = x), and SD1 is the standard deviation of projection of the PP on the line perpendicular to the line of identity (y = -x). s is the area of the ellipse determined by SD1 and SD2.
- Histogram of NN intervals
- The triangular index (HRV index) is the integral of the density distribution divided by the maximum of the density distribution. The index reflects total heart rate variability measured over the recording and is more influenced by the lower than by the higher frequencies.

#### 2. Frequency Domain Methods

Methods for calculation of power spectral density may be classified as parametric and non-parametric; in most instances both methods provide comparable results. The important characteristics of the spectrum are the power of the spectrum and the powers of its separate zones. Four main spectral components are distinguished.

- Non-parametric method
   Fast Fourier Transformation (FFT)
- Parametric method
   Autoregressive model

#### Analysis of the short-term recordings/interval (5 min)

- Total Power [ms\*ms] Variance of all NN intervals
- VLF [*ms\*ms*] power in the very low frequency range (0,01-0,04)
- LF [*ms\*ms*] power in the low frequency (0,04 0,15 Hz)
- LF norm [-]- LF power in normalized units: LF/(Total Power - VLF)\*100
- **HF** [*ms\*ms*] **power in the high frequency range** (0,15 0,4 Hz)
- **HF norm** [-] **HF power in normalized units:** HF/(Total Power - VLF)\*100
- LF/HF ratio LF[ms\*ms] / HF[ms\*ms]

## 13.4 Appendix D: WiFi ECG device usage guide

Cardiax version 4.20.0 and ECG device firmware version 4.09 or higher

The Cardiax ECG program has two different kinds of modes for connecting WiFi ECG devices to fit different usage scenarios common in practice. These modes are:

 the direct wireless connection, when the ECG device acts as a WiFi access point (AP mode) that can be connected by the computer equipped with WiFi interface,



For direct connection **at least Windows Vista** operating system is recommended for reliable connection and signal transfer.

On the not supported nor recommended Windows **XP** SP2 or SP3 systems connection initialization can be **uncertain** due to the OS architecture.

and the indirect connection in the so called Infrastructure mode. In this
mode the ECG device connects wirelessly to an existing WLAN router
(acting as a WiFi access point). Host computers, that connect the local
network through a wired or wireless link, can reach the ECG device.



Previous, first generation devices establish direct connection in a different approach (**Ad-hoc** mode) then the present models. The differences in the operation are collected under a <u>separate section</u>.

The second generation WiFi ECG devices are labeled on the back side with **WiFi-g** marking on the upper right side of the label.



In case of both generations, pay attention to the fact, that using direct modes will reserve the WiFi interface exclusively for the time the ECG device is connected, disabling any other services, if any (for example Internet or LAN) provided on that same interface!

With additional WiFi adapters installed on the system, it is <u>possible</u> though, to keep existing network connections alive during ECG device access. This can increase efficiency on notebook computers if email transaction is required, and can be a requirement in sessions, where network ECG database is accessed.

In direct connection mode the ECG device acts as a WiFi access point (*AP*, with an individual SSID name like, for example ECG-0613032801) that can be connected by the computer equipped with WiFi interface.

In *Infrastructure* mode the ECG device connects wirelessly to an existing WLAN router (acting as a WiFi access point). Host computers, that are connected the local network through a wired or wireless link, can reach the ECG device.

#### Device assignment to the Cardiax application

For using the wireless ECG, the device must be assigned to the Cardiax program. Select "Setup" from the main menu to open the preferences dialog. The following figure summarizes the procedure of the device assignment, true for both direct modes and for the indirect mode independent of device generation:

Preferences	<b>2.</b> +Apply <b>3</b> .	
Categories	ECG device Mode of connection ECG on WiFi Direct, (AP)	Assigned device
Print     Batch, rest ECG     Batch, ergometry     View of monitor and dialogs     Ergometry     Ergometry     Frgometer program     Treadmill program	WiFi Device numb   Device at address: 0613032801 ECG access point (AP)	Battery: Assign 4.
- Blood pressure - User - Options B- Advanced	Only establish direct WiFi ECG connection while re- Computer's WiFi connection:     Obsconnection:     Obsconnection:	Use specific WiFi interface
	Remote ECG monitoring       Address of monitored site:	Allow remote monitoring
۲. m. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲. ۲.	Ok <u>C</u> ancel	<b>5</b> .

- 1. Select 'ECG device' category.
- 2. Select 'ECG on WiFi' from the 'ECG device' drop-down list, and press the 'Apply' button. The controls related to Cardiax's WLAN settings and the list displaying the enumerated WiFi devices get enabled.

From this point, all modifications related to WiFi ECG devices will apply automatically, to ease the flow of setup, but can be cancelled to revert back to the original state unless no explicit push of the '*Apply*' button happened. The restoration true for the assigned serial and the interface selection also.

**3.** The default operating mode of a newly purchased WiFi ECG device is *ECG access point*, and the drop-down list of modes also defaults to it on fresh installs. Other modes should be selected in this step if needed. Press the '*Apply*' button to commit the mode change.

After mode change, the list of the enumerated devices and the current assigned device number will be cleared and new assignment must be done from the enumeration result in the new mode.

**ATTENTION!** The desired WiFi mode in the device must also be set **beforehand**, otherwise it won't be detectable for the Cardiax program! This process is described in the section <u>Setup the WiFi connection</u> <u>mode of the ECG device</u>.

For proceeding to update the available device list:

- Touch the on/off button (①) to turn the ECG device on.
   The blue LED starts blinking.
- Soon, the *WiFi list* in the *Preferences* window will be filled with data of the devices enumerated, like: the serial number (SN), and the IP address with battery information of connected devices.

The enumeration process is automatic and continuous while the ECG device is set to WiFi type; the results will follow the presence and on/off state of available ECG devices.

**4.** With the help of the Device number (SN), select the device. Assign the selected device by pressing the '*Assign*' button or double clicking the selected line.

The Assigned device field will display the serial number of the selection.

**5.** Press the 'OK' button to save settings and close the dialog or press the 'Apply' button to continue setup with the assigned device.

After set up an assigned device, the communication with it can be checked by selecting the Options category in the Preferences dialog or by starting

the ECG monitor from the main window (

If the device becomes unavailable (turned off, moved out of WiFi range), a window will inform about *the current* state of the connection than can also be cancelled.

Connecting WiFi ECG device
SN: 0613032801; ECG access point, (AP)
Waiting for WiFi device
Cancel

#### WiFi Interface selection

In case more than one WiFi interface are available on the computer, Cardiax selects the one with no active connection ('free' interface) for

communicating with the ECG device, by default. In case no free is available, an interface is chosen and will be used to connect the ECG device by all means. It is possible though to select a specific WiFi interface for Cardiax exclusively use without modifying the connection state of any other interfaces.

On the previously discussed WiFi device setup dialog a checkbox with the title 'Use specific WiFi interface' can be found. When clicked, it opens the selection dialog, what informs about the current interface used by Cardiax and lists the available WiFi interfaces in the system. If a specific interface is selected (non automatic selection), then the checkbox will be checked on the setup dialog.

Wifi interface			
Currently used for ECG device connection: 802.11n USB Wireless LAN Card #2			
Specific for ECG device connection:			
Automatic (prefer free one, if available) TP-LINK 300Mbps Mini Wireless N USB Adapter #4 802.11n USB Wireless LAN Card #2			
Refresh list			
Ok <u>C</u> ancel			

In those cases, where **only one interface** is available in the system and internet access if required for Cardiax (e.g. mailing) or for other activity a solution is provided to allocate the WiFi interface for direct connection to the ECG device **only for the time of recording**. This can be achieved by checking the 'Only establish direct WiFi connection while recording' option.

As a result connection to the ECG device only begins by starting the recording, and it restores the original as soon as the process is stopped (no need to exit the monitor window).

Running the Cardiax from a server installation is not possible this way, since that requires continual network connection with the server!

#### WiFi items on the toolbar

When selecting WiFi ECG for device, a WiFi icon appears on the right most side of the toolbar line indicating the state of connection to or the availability of the assigned ECG device. If the connection mode is selected as **direct** (AP or Ad hoc) a button with blue WiFi icon appears on the toolbar main menu line for controlling connection initiation or disconnection.

WiFi button	WiFi state
Cardiax	- 🗆 X
Extint Becord Sgnt Select Iransfer Setup Help	e))
✓         Name:         Code:         Born:           Di 01 Domo         000.000.001         23.11.1070         23.11.1070	Last ECG:

After successfully establishing direct connection (AP or Ad hoc) to the device, the connection is not broken automatically while the program is running. The pushed state of the WiFi button also reflects this. Switching the WiFi button off, the connection can be broken and the WiFi interface can be **restored** to its previous **state**. So it can be used for serving other simultaneously arising needs using the program (e.g. **need of Internet or LAN access for transferring ECG records**)

Pushing the WiFi button initiates the direct mode connection to the assigned ECG device in the background, for the device to be immediately available at the time of starting a new recording process. If no device assignment exists and the mode is set to direct (Access point or Ad hoc), the *Preferences* dialog opens automatically to select and assign an ECG device. Automatic control of this button can be selected to provide the optimal behavior in certain usage scenarios (e.g. mailing, synchronization); the previously <u>described option</u> ensures this.

The battery state of the connected device is showed on the status line both in the Card File and in the Monitor windows, a black flash icon indicates if charger is connected. The color follows the <u>power LED</u> of the device, while the fill ratio is proportional to the charge level.

L	🛯 🗈 14 Demo Frank	000 000 014 27-09-1980 16-10-2007		~
Start ECG monitor for recording		C:/CIX	30 / 0	1
			Battery	state

The following table summarizes the possible effects and meanings of the WiFi control items on the toolbar:

	<b>Direct</b> mode, EKG access point (AP)	Indirect mode, Infrastructure (LAN)	
WiFi button:			
(released)	WiFi interface is available, but <b>not</b> <b>used for direct connection</b> to the assigned ECG device		
(pushed)	<b>Direct connection</b> to the assigned ECG device has been <b>initiated</b>	The button is not displayed in this mode	
(grayed)	<b>No WiFi</b> interface is <b>available</b> for direct connection		
WiFi status icon:			
(î)	The assigned ECG <b>device is being</b> <b>connected</b> directly on the WiFi interface	Pictogram not used	
J)	<b>Direct connection</b> to the assigned ECG device has been <b>established</b>	in this mode	
()	WiFi interface is available, but not used for direct connection to the ECG device	Assigned ECG device is <b>not</b> <b>found</b> on any available network	
<)	Pictogram not used in this mode	Assigned ECG device is <b>found</b> on one of the available networks	
(grayed)	<b>No WiFi</b> interface is <b>available</b> on the computer	No network adapter available on the computer	

#### Setup the WiFi connection mode of the ECG device

Both generations of WiFi ECG devices can be configured to automatically connect to specific wireless networks (WLAN), defined by the user, with the use of profiles

Only in the case of first generation devices two built-in profiles are also available, their description is given in the referring section.

Preferences		• •
Categories	2nd generation device (WiFi-g)	
ECG device ECG Print	Directly connectable as an access point (AP)	channel:
ECG	1st generation device, default connection points	
Ergometry View of monitor and dialogs	Active Ad hoc network by Computer, SSID:	
Ergometry Ergometer program	Active Hotspot by Android device, SSID:	
- Treadmill program	Local networks (LAN) the ECG device can connect to	
Blood pressure	Network name (SSID):	
- Options	Password:	*
- Pulse oximeter - Mail - Auto backup	Active     Active     Active     Active	<b></b>
- Auto backup - Auto export - NetCenter - Security groups	Active     Network name (SSID):     Password:	<b></b>
	Active     Active     Active     Active	*
	by USB   Read profiles  Device number:  Device number:	
	Ok <u>Cancel</u> Apply	

Initially, all variable fields are grayed and become only available after reading the profile of a device, according to its type. Follow the next steps to setup mode of operation and connection points of the WiFi ECG device:

- Touch the on/off button  $(\bigcirc)$  to turn the ECG device on.
- Connect the ECG device to the host computer running Cardiax by a USB cable.

The yellow LED starts blinking.

- Select 'Setup' from the main menu and choose the 'Advanced / WiFi' category.
- Press the '*Read profiles*' button to download the profiles stored on the device. (Leave the drop-down list on '*by USB*').

The profiles with the "Active" checkboxes determine the WiFi networks the

device attempts to connect to. The order of the list determines the priority of connection in case more than one are available at the same time and each are signed active. The topmost of the available active networks will be connected.

Categories 2nd generation device (WiFi-g)	
	WiFi channel:
ECG device V Directly connectable as an access point (AP)	2
-1st generation device, default connection points	
ECG	
Ergometry	,
Ergometer program	
Treadmill program     Active     Password:     Active	*
-User Network name (SSID): Home, office	
	*
WiFi	
Mail Cartine (SSD).	*
- Auto backup	
Auto export Active NetWork name (SSID):	*
- Security groups	Device number:
by USB  Read profiles Send profiles	0613090945
	1
Ok <u>C</u> ancel <u>Apply</u>	

Setup as ECG access point

The 'Directly connectable as an access point (AP)' checkbox determines the mode of operation of the device: it can be directly connected or it connects one of the given local wireless networks. The two behaviors are exclusive; changing the checkboxes can implicitly alter the other mode's checkboxes too.

For devices with most recent firmware version (greater than and including v4.41), the WiFi channel number the device uses can also be selected to best fit specific RF (radio frequency) environments. This can be useful in case other WiFi network coexistence and interference is experienced.

Channels 1 to 11 are supported with the additional possibility (*Auto*) to have the device always select a channel when switching the device on, according to the then present WiFi channel usage the device can determine.

For devices with older firmware not supporting this settings the used channel is displayed but can not be changed (the control is grayed).

All WiFi-g devices can be firmware upgraded for this function to be

available!

#### Setup for connecting wireless LANs

Four WLAN networks can be given to the device for automatic connection both for first and second generation ones. This eases the usage of the ECG device at multiple places (hospital, office, surgery, ...), the device automatically connects the one that is available.

- Type the name (SSID) and password of the WLAN to be automatically connected into the topmost available place.
- The unchecked '*Active*' mark can temporarily disable connection attempts to the specific network without deleting its parameters.

The password fields of the user defined WLAN networks can individually be displayed visible using the asterisk button on the right side of the specific field.

After the settings are done, press the 'Send profiles' button to set WLAN parameters of the device. The device will restart to apply the received settings.

If USB cable is not available (e.g. forgot to bring with the laptop), one can set profiles by an established WiFi connection to the device too. The procedure is the same as with the cable, only the WiFi availability of the device must be previously ensured; this is shown by the green checkmark of the WiFi status icon on the toolbar.

If fulfilled, meaning the assigned ECG device can be reached, one just has to select the '*by WiFi*' option at the bottom of the 'Setup / Advanced / WiFi' dialog before submitting the read operation.

**ATTENTION!** If the current connection to the device can not be restored after applying the new settings (due to switching to other mode or profile modification), then under '*Settings / ECG device*' the device must be reassigned in order to further use it.

#### LEDs on the ECG device

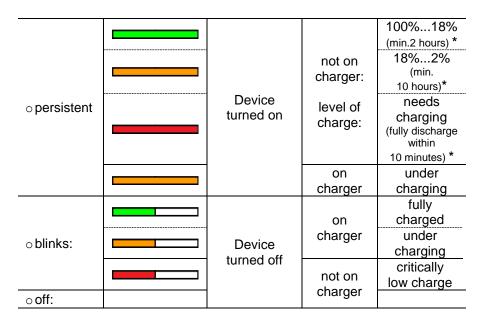
The device also has an indication of its current WiFi state. In the lack of WiFi connection the blue LED blinks faster, in connected state is blinks slower. Details of the visual feedback are given in the next tables by the means of the rhythm of LED blinking.

(Blink patterns correspond to 2 seconds long interval)

## Power LED (green / orange / red):

The time values in the table are for reference only!

Those depend on the age, usage and storage/operation environment of the specific battery. The given values are assumed for newly manufactured, previously not used batteries, that if fully charged, can provide typically 10 hours of continuous ECG recording without recharging. The quality and power demand of the WiFi signal propagation (channel-interference, spatial distance) can greatly influence this time.



•)) WiFi LED	(blue):			
For first generation devices other explanation applies!				
o persistent     ECG recording through WiFi     connection			through WiFi	
o blinks:	fast:	Waiting for connection	in ECG access	
	slow:	Connected	point (AP) mode	
	fast double :	Attempting connection	in <i>Infrastructure</i> mode to an	
	slow double:	Connected, has valid IP address (DHCP)	available WiFi network in the profile list	
o blinks very fast:		Parameter con	figuration phase	

• USB LED (yellow):

o persistent		ECG recording through USB connection
o blinks:	slow:	USB connection established
○ off		No USB connection

#### Reset connection mode of the device

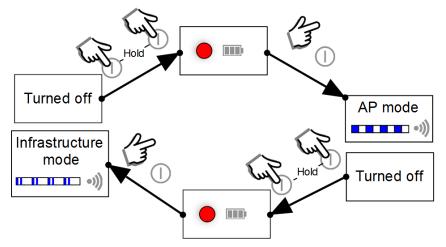
The device can be reset to the default connection mode without connecting to a computer, so it can be surely connected by a computer.

When turning the device on, keep the on/off button  $(\bigcirc)$  touched until the power LED turns into red. Releasing the button starts the device with the restored settings.

The fast blinking of the blue LED shows the device is accessible in AP mode. Any wireless local network parameters set up will remain intact, only become inactive.

For first generation devices reset, see the relating section.

From firmware version v4.42, the reset function can serve as a quick switch between operation modes between direct and indirect (if any given) without the need of a computer. This can be beneficial in cases when the doctor uses the device at surgery on the local LAN and visits the patient with a mobile device (laptop, tablet) using direct connection to the ECG device. From the given version on, the firmware activates all of it's given wireless local network profiles in the case the reset is committed in being in direct connection (AP) mode. The fast double blinking blue LED pattern informs the user about using the WLAN profiles. At least one WLAN parameters are required to be already set up in the device. The blue LED blinks regular fast if connection mode is reset to direct AP.



All **WiFi-g** devices can be firmware upgraded for this mode switching function to be available!

#### Specific settings for first generation (Ad Hoc mode) devices

These devices differ in the realization of the direct connection from the currently produced ones due to their WiFi module with older technology. Those modules can only connect to available WiFi networks and are incapable of creating one for others to connect to.

The indirect connection mode (infrastructure) and the related settings are the same as <u>previously described</u>.

Direct connection to these devices is realized in *ad hoc* mode, in which the computer (with WiFi interface) and the ECG device forms an Ad-hoc WLAN network using the predefined name (SSID) "Mobile-ECG". Creating the network is the task of the computer, the ECG device in range can then connect to it.

#### Toolbar WiFi items on first generation devices

The toolbar WiFi button and the status icon practically provide the same functionality and visual feedback as in the case of current devices; the button initiates or breaks direct connection while established connection is reflected as a green checkmark on the status icon. In the following tables the differences are emphasized to ease orientation:

#### WiFi button function on first generation devices:

	Direct mode, Ad hoc	Indirect mode, Infrastructure(LAN)	
(released)	WiFi interface on the computer is available, <b>not used for direct</b> <b>connection</b> to the assigned ECG device		
(pushed)	The computer is directed to create ad hoc WiFi network accepting direct ECG device connections	The button is not displayed in this mode	
(grayed)	<b>No WiFi</b> interface is <b>available</b> for direct connection		

## WiFi icon (status) meaning on first generation devices:

	Direct mode, Ad hoc	Indirect mode, Infrastructure(LAN)		
(îr.	Ad hoc network is created by the computer and waiting for direct connection of ECG devices	Pictogram not used		
<b></b>	Direct connection to the assigned ECG device has been established	in this mode		
<b>?</b>	WiFi interface on the computer is available, not used for direct connection to the ECG device	Assigned ECG device is <b>not</b> found on available networks		
<b>?</b>	Pictogram not used in this mode	Assigned ECG device is <b>found</b> on one of the available networks		
(grayed)	No WiFi interface is available on the computer	No network adapter on the computer		

#### Setup the WiFi connection mode of the first generation ECG device

In case of the first generation devices, above the local network profiles there are two built-in connection profiles listed. Both are responsible for directly connecting the device, one with the computer ('*Mobile-ECG*') and the other with the Android application running on a mobile device and <u>available on Google Play</u>. In these two cases the name of the networks are fixed and displayed only for information.

Preferences					X
Categories		tion device (WiFi-g)		WiFi cha	nnel:
ECG device	Directly connectable as an access point (AP)			-	
Print ECG	<ul> <li>Section 1 to the section of the secti</li></ul>		Mobile-ECG		
Ergometry	C Active	□ Active Hotspot by Android device, SSID:		Mobile-ECG-AP	
Ergometry	Local networks (LAN) the ECG device can connect to				
- Ergometer program	Active	Network name (SSID):	Workplace_surgery		
Blood pressure	/ / terve	Password:	*****		*
User	C Active	Network name (SSID):	School_surgery		
Options Options Advanced WiFi Pulsoxi Mail Auto backup Auto backup Auto export NetCenter Security groups		Password:	******		*
	C Active	Network name (SSID):			_
	Active	Password:			*
	Active	Network name (SSID):			
	Active	Password:			*
	by USB 💌	Read profiles	Send profiles	Device number: 0612061116	
	Ok	Cancel	Apply	]	

The order of the list in this case also determines the priority of connection in case more than one are available at the same time and each are signed active. The topmost of the available active networks will be connected.

#### LEDs on the first generation ECG device

First generation devices report only the state of their connection with faster (if unconnected) or slower blinking (if connected), regardless of the type of the connected WiFi network.

(Blink patterns correspond to 2 seconds long interval)



o persistent		ECG recording through WiFi connection		
o blinks:	fast:	Attempting connection	to an available WiFi network listed in the profile list, ( <i>Ad hoc, Android</i>	
	slow:	Connected	<i>hotspot,</i> <i>Infrastructure</i> ), not specified	
o blinks very fast:		Parameter cor	nfiguration phase	

#### Reset connection mode of the first generation device

First generation devices reset to their direct connection mode (Ad hoc), for surely being accessible wirelessly by the computer. After the reset operation the first start will begin with a very quick blinking of the blue LED (parameter configuration). Any wireless local network profiles set up are left intact, only the two built-in profiles are ensured to be set into active state.

## 13.5 Appendix E: Pulse Oximeter setup

Recent versions of Cardiax can display the online SpO2 curve acquired from the Meditech wireless (bluetooth) pulse oximeter unit (OxyT). The Cardiax program must be set up to communicate with the Meditech pulse oximeter device. In the *Setup* menu, under the *Advanced* category the *Pulse oximeter* sub-category must be selected. On the right-hand side of the dialog, after setting the device to *MeditechOxyT*, the bluetooth settings become available.

There are three other possibilities for the *Pulse oximeter device* dropdown: *None* 

for not displaying any SpO2 data. It keeps the settings already set up, only disables the usage of the pulse oximeter device, if it is temporarily unavailable to speed up the initialization of an ECG session.

#### EnviteC

for previous versions of Cardiax USB devices, up to SN0611100750 with a piggybacked pulse oximeter solution.

#### ChoiceMMed

already not traded, Bluetooth pulse oximeter.

This additional online SpO2 curve operation needs the feature password to be given for the ECG device in the Options preference category!

Preferences		— 🗆 X
Categories ECG device ECG	Pulse oximeter device MeditechOxyT	
Print     Batch, rest ECG     Batch, ergometry     Display settings     Ergometry     Ergometry     Ergometer program     Blood pressure     User     Options     Advanced     WiFi     Pulse oximeter     Mail     Auto backup     Auto backup     Auto export     NetCenter     Security groups		C User connected COM port:
	Ok <u>C</u> ancel	Apply

In case of the bluetooth pulse oximeter devices (Meditech, ChoiceMMed), the two radio button choices enable all kinds of Bluetooth adapter and software configurations to work with Cardiax:

If the operating system has a Bluetooth radio device (external usb dongle or built-in for notebooks), that required no software component to be installed, that means it uses the native Bluetooth capabilities of the operating system (the so called Microsoft Bluetooth stack). In this case a search must be initiated in order to assign the pulse oximeter device to Cardiax. The pulse oximeter device must be turned on with the probe plugged in. Pushing the *Search* button starts the process. If the pulse oximeter device is found, the Bluetooth name if automatically filled into the *Assigned device* field. This means the Cardiax registered the device parameters for future connections. If the search was invalid (---), try once more. If still nothing was found, check the operation of the pulse oximeter devices are available at the same time, one must be chosen in a selection dialog.

In case the pulse oximetry operation is not needed temporarily, simply choose *None* under the Pulse oximeter device. Later, simply restoring any b*luetooth oximeter* selection will revert to the registered device settings, that can be immediately used, without searching again.

 If the operating system uses other, non Microsoft Bluetooth implementation (mainly in older, Windows XP versions, like the Widcomm or the BlueSoleil stacks), then the connection to the device needs user assistance. The pulse oximeter device must be connected with the help of the used Bluetooth stack, and a COM port will be assigned to it (if a PIN code is required, then supply 0000 as the answer). The number of this port created must be supplied for Cardiax into the "user connected" field.

## 13.6 Appendix F: User rights in the Cardiax system

The various operations in Cardiax can be controlled on a user basis. This feature is **primarily implemented for network usage in institutional environments** (e.g. doctor vs. nurse tasks, competences).

The identity of the user is determined using the operating system by getting the user and group names of the actual login-session from Windows. The rights for the ID-s obtained this way is handled by Cardiax by means of the so called **"Security groups"** coupled to the actually active database. Its presence is always checked at the time of opening it.

Top be able to use the security features with a database, the filesystem of the database server/workstation is required to support read/write access control for groups and users on files and directories. This requires NTFS filesystems.

The clients, in a server hosted installation, also need to run NT based operating system to use the secured database with the defined rights.

The file describing the rights for the database is stored on the computer that contains the opened database (for example *\\CRXSERVER*, that can be the localhost or in a network environment a remote computer as well). This computer has a **shared** *CrxRights* **directory** with the same, CrxRights share name (like *\\CRXSERVER\CrxRights*).

On XP Professional systems, defining rights for shared folders is possible if "Use simple file sharing" is turned off (in *My Computer/Tools/Folder options/View/* window).

The system Administrator needs to create it with the proper access rights. Typical place for this is the *C*:\*CrxRights*, but with advanced administration practice it can be placed inside the database as well (e.g. *C*:\*Crx\CrxRights*), paying special attention for the proper separation from the inheritable rights of the database! The *CrxRights* directory should be only readable (but must be readable) for all users, so only authorized modification is allowed on the rights. Otherwise, all those groups/users are allowed to modify it, who have read/write access to *CrxRights* directory on the containing computer.

The **directory of the database must also be shared**. This is the directory (by default the *C*:\*Crx*), where –among others– the following subdirectories reside: *data, text, doq, lock*. A dedicated share-name for the database is not a requirement; it can also be inside of a shared upper directory. e.g.:\\*CRXSERVER\UpperShared*\Crx and \\*CRXSERVER\Crx* are both applicable.

For administrators, full access is recommended for both above shares.

After this, setting the rights is possible in the program in the list of Setup/Security groups.

Preferences		
Categories	superuser	
ECG device ECG device ECG Print -ECG -Ergometry -View of monitor and dialogs Ergometry - Treadmill program - Treadmill program - Blood pressure - User - Options Advanced - WiFi - Pulse oximeter - Mail	Doctors Assistants john sarah	<ul> <li>✓ New patient card</li> <li>✓ Edit patient data</li> <li>✓ Delete patient card</li> <li>✓ Start new recording</li> <li>Modify comment/diagnosis</li> <li>✓ Delete recordings</li> <li>✓ Data export</li> <li>✓ Data import</li> <li>✓ Send e-mail</li> <li>✓ Send direct to remote database</li> <li>✓ 2. database</li> </ul>
- Auto export NetCenter	Delete	Change preferences
-Security groups	Group/User:	Add Add

The names in the list correspond to users or groups that have rights defined in Cardiax.

The required identifiers can be added "manually" by a competent administrator with proper understanding of the system / multi-user network environment of interest.

The current state of the rights for a specific identifier can be seen in the right-hand side column, when selected. Modification is possible only for administrators.

The identifier of the current user can be seen in the middle, above the userlist. Any error prohibiting the use of the security groups is also displayed here.

In case a second database (card file) is also opened, the setup is done on the database that has the focus in the user interface of the program. Regarding a network database (in a server-client model), only the user with write permission to the server's *CrxRights* directory can commit changes.

A database becomes secured if at least one user/group is listed on the menu in the Setup. Security features of the database are gone if all users/groups are deleted from that list.

Attention! If rights have been defined to a database and someone's user name or his group is not listed in Setup, and cannot write the *CrxRights* directory for that database, that user is not allowed to use the database. If

this database is given as the first one, the program will not start.

Summary of typical setup:

- Make directory C:\CrxRights and share it under the name CrxRights. Ensure read only access (both file level and share level) for all users of Cardiax.
- Share the database directory (*C*:\*Crx*) of the program.
- Open the program with the database and add the user/group identifiers and desired rights in *Setup/Advanced/Security groups*.