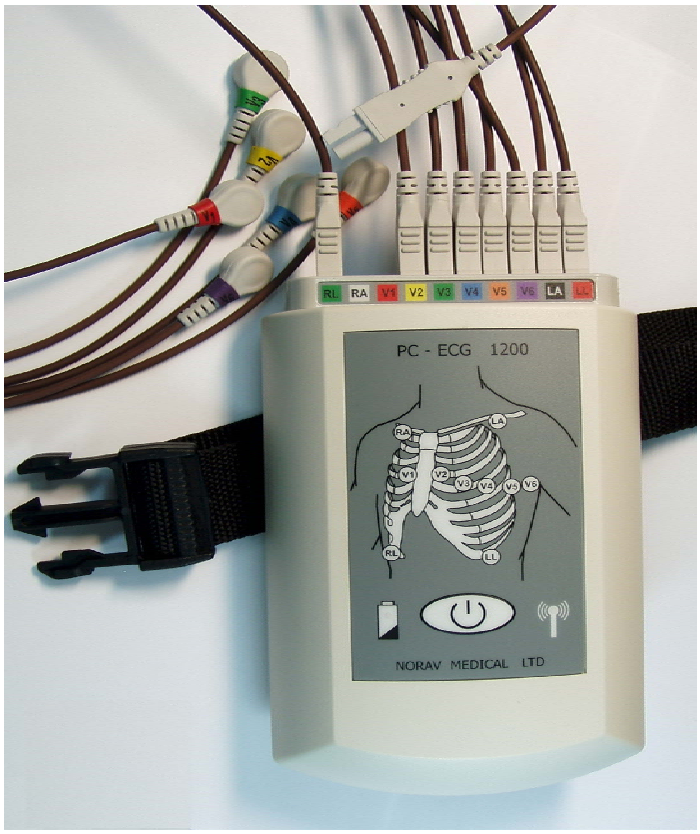
NORAV medical



Instructions for Use and Technical Description

CE

0473

Norav Users Guide

For Models: 1200W recorder; software versions: 5.0 and later

Document Number: NV-54/PCECG1200W

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Standards Compliance

The interference generated by the device was tested according to the EMC 89/336/EEC and found compliant with the standard.

The software complies with *Standards for Analysis of Ventricular Late Potentials Using High Resolution or Signal Averaged Electrocardiography*, published in 1991 by the *Task Force Committee of the European Society of Cardiology*, the *American Heart Association,* and the *American College of Cardiology*.

The PC-ECG conforms to MDD 93/42 EEC Annex II, EC11 and EN 60601-2.

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Caution

US Federal Law restricts this device to sale by, or on the order of, a physician

The PC-ECG 1200W is tested and certified for the following standards:

EN60601/1:	International
EN60601/2/25:	International
EN60601/2/27:	International
EN301 489-1;	International
EN301 489-3;	International
EN300 440;	International
Protection type and class:	CF
Defibrillation protection:	Built in

Disclaimer

This system is intended as a decision support system for persons who have received appropriate medical training, and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any application of medical information from the program, other than the original design or intended use thereof, is not advised and considered a misuse of the software product.

Norav Limited Warranty

Norav products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Norav or the dealer to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav determines has been modified or damaged by the customer.

Except for the express warranties stated above, Norav disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations or liabilities on the part of Norav for damages, including but not limited to, special, indirect, or consequential, arising out of or in connection with the use or performance of Norav products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

For service or technical support contact your local supplier or Norav Medical.

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CHAPTER 1: INTRODUCTION

Manual Organization

This manual explains in detail how to install and use the PC-ECG 1200.

At the beginning of each application chapter, there is a **Quick Start** section, which is a brief explanation of how to carry out a study, including the keyboard short-cuts for the main functions. If you are familiar with ECG procedures, you can use this Quick Start section to get up and running quickly.

The software must be installed before the hardware. See Software Installation, page *7* and Hardware Installation, page *13*.

Document Conventions

Notes and Cautions

Pay particular attention at specific points in a procedure when one of the following messages appears:

WARNING

Warnings call attention to possible hazards involving potential damage or injury to persons.

Caution

Cautions refer to practices necessary to protect against potential damage or loss to equipment. Pay careful attention to instructions.

Note

Notes provide pertinent information to help obtain optimum performance from the software or signify an important step or procedure that requires special attention.

Abbreviations and Acronyms

Abbreviation	Meaning
BP	Blood pressure
ECG	Electrocardiogram
Database	Database application
HRV	Heart Rate Variability
ID	Identification
LP	Late Potential
LQTS	Long QT Syndrome
METS	Metabolic Stress Estimation
SN	Serial Number
USB	Universal Serial Bus

Equipment Symbols

Symbol	Description
	Defibrillated CF type equipment
	Class II equipment
	Complies with the Medical Device Directive of the European Union
	Attention, consult ACCOMPANYING DOCUMENTS
	Non-ionizing radiation.

CHAPTER 2: OVERVIEW

Package Contents

The PC-ECG 1200W package contains the following elements:

- Wireless Acquisition box PCECG1200W (page 15)
- Patient leads
- USB cable
- 1200WR Receiver
- Antenna
- Software CD with the PC-ECG 1200 installation package, including:
  - ◊ Rest
  - ◊ Stress
  - ◊ Monitor
  - ◊ HRV
  - ◊ LP
  - ◊ Database
- Software key (if optional software is included)

Programs

Each program has a specific purpose. The following is a brief description of when to use each one:

Rest	Records and measures short ECG tests on patients in resting position (up to 10 seconds)
Stress	Records and measures ECG tests on patients under stress conditions using a pre-defined test protocol. The stress test includes 3 basic stages: • Rest • Stress • Recovery Each stage may be divided into more than one phase according to the testing protocol used.
Monitor	Works with an ECG device to record, monitor and save a prolonged ECG test in rest condition
HRV	Tests according to time how patient pulse and heart rate varies with load, medication, etc.
LP	Predicts tendency to ventricular tachycardia
Database	ECG Database Management System. Manages patients and ECG tests details.

PC-ECG Models

1200 W	Wireless ECG Recording test during stress and rest condition (attached to patient's body)

Indications for Use of the PC-ECG 1200

ECG Intended Use

ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases:

- ◊ Patients with suspected cardiac abnormalities
- ◊ Populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired.

QT Analysis is useful in the assessment of long QT syndrome (LQTS). In some instances, LQTS can be corrected by pharmacological therapy. QT analysis is also used to measure QT dispersion, the difference between maximal and minimal QT values. QT dispersion is a measure of the inhomogeneity of ventricular repolarization.

The PC ECG 1200 has been tested to measure Heart Rate Variability to within 1 millisecond tolerance. The clinical significance of Heart Rate Variability measures should be determined by a physician.

The PC ECG 1200 has been tested to measure Late Potential to a tolerance of within 1 millisecond, and 1 microvolt. The clinical significance of Late Potential measures should be determined by a physician.

Stress Testing Intended Use

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present. Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thus to coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG during patient exercise. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise loads are determined by predefined protocols. The ECG signals are recorded for the resting, exercise, and recovery phase portions of the exercise protocol. The changes in ECG waveforms are compared to the resting ECG records. Most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol, although this is not essential.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database is used as a tool for performance testing.

The significance of the ST segment changes **must** be determined by a physician.

Contraindications for Use and Adverse Effects

The device has no contraindications or adverse events.

CHAPTER 3: SOFTWARE INSTALLATION

System Requirements and Prerequisites

Hardware

Note

Stress application with real-time printout is resource intensive.

To optimize performance, we recommend that you disable "Start Up" programs to free system resources. For instructions, see Windows help.

Note

The PC should not be set up to work under saving power conditions. Do not enable PC sleep mode (standby), hibernate, or turning off the hard disk while running an ECG test.

PC Minimum Configuration

Application	CPU Speed (MHz)	RAM Memory (MB)	Disk Space (GB)	Number of Free RS232 or USB Ports
Rest	100	32	2	1
Monitoring Application	200	32	4	1
LP	450	128	2	1
HRV	450	128	2	1
Database	200	64	8	1
Stress	1000	128	20	2
Stress + R trigger	1300	128	20	2
Stress + Blood pressure monitor	1500	128	20	3

Table 1: Minimum Computer Configuration

Installing Printers

Application	Technology	RAM Memory (MB)	Driver
Rest	LASER/INK	2	Vendor / MS
Monitoring Application	LASER/INK	2	Vendor / MS
LP	LASER/INK	2	Vendor / MS
HRV	LASER/INK	2	Vendor / MS
Database	LASER/INK	2	Vendor / MS
Stress	Fast LASER	8	MS

Table 2: Printers Installation Requirements

Installing the Thermal Printer

Use a 4 inch or 8 inch thermal printer. The thermal printer driver is installed separately from the PC-ECG 1200 program.

A thermal printer can be supplied by Norav (MP200, 8 inch). This printer requires the purchase of a dongle with P1 license permission. The MP200 driver is available on the PC-ECG 1200 CD at the following path: "<CD>:\MP200\OEMPRINT.inf".

Installing or Updating The PC Software

Note:

Install the software before installing the hardware. If the device is connected to the PC, disconnect the device before installing the software.

The software package works under Windows NT, 98, ME, 2000, and XP operating systems.

To Install PC-ECG 1200

1. Insert the CD in the drive.
   The installation program starts automatically.
2. Follow the instructions on-screen.0 .

After you have completed installation, a group icon called PC-ECG 1200 is added to the desktop. Double-click the group icon to display the following program icons:

Note: Icons are displayed only for those programs for which you have purchased the license

Icon	Explanation
	Heart Rate Variability
	Late Potential Signal Averaging
	Monitoring
	Resting ECG
	Stress Test
	Database application

Table 3: Program Icons

Resting ECG is the basic software package. It does not require a software key.

The following are optional and require software keys:

◊ Measurement and interpretation functions for Resting ECG

- ◊ ECG Database
- ◊ Heart Rate Variability
- ◊ Late Potential
- ◊ Monitoring
- ◊ Stress Test

You can activate optional packages that have no key by selecting **Simulator** in Setup (see Simulator ECG, Page 32).

If you have purchased the **S2** remote viewing, install the **Remote View** program from the **Remote View** directory on the CD. This program enables a remote viewer for an ECG study. The image is displayed in JPEG format.

To Uninstall PC-ECG 1200

New Version Replacing Old Version

There is no need to remove the previous installation. The existing setup will remain for the new version.

If the new software version does not operate properly, remove the old installation (see *Old Version Replacing New Version*, below) and then remove the old existing setup as follows:

Start → Run→ Type `regedit`→ OK→ Choose HKEY_CURRENT_USER → Software→ NORAV MEDICAL→ Edit→ Delete

Old Version Replacing New Version

Uninstall the existing version as follows:

My Computer → Control Panel → Add/Remove Programs → PC-ECG 1200 → Add/Remove → OK

To Free Disk Space and Ensure Smooth Operation

Windows provides utilities to delete superfluous files, and to defragment the disk. Refer to Windows help for instructions on using Disk Cleanup and Defragment.

Backing up and Restoring Setups and Protocols

When you reinstall or upgrade PC-ECG 1200, the program overwrites your existing configurations and protocols.

To save the configuration data for stress application, follow these procedures:

To Save Stress Test Setup

1. Start Stress ECG.
2. Click View**Save Setup (see** Figure 1**).**

Figure 1: Saving Stress Setup

3. Name the file.
4. Provide a location in which to save the file and Click **OK.**

To Load Stress Test Setup

1. Start **Stress ECG.**
2. Click View**Load Setup.**
3. Click **Browse** and find the location in which the file is saved.
4. Select the file (with the name you gave it and the suffix 'STF') and click **OK.**

To Save Stress Protocols

1. Create a new directory in C:\My Documents, with a name like **PcBackup.**
2. Copy file **StWorked.mdb** from the directory where PC-ECG is installed (normally C:\Program Files\PC-ECG).
3. Paste it into a backup directory (e.g., C:\My Documents\PcBackup).

To Load Stress Protocols

1. Copy the file **StWorked.mdb** from the directory where you saved it (e.g., C:\My Documents\PcBackup).
2. Paste it into the directory where PC-ECG is installed (normally C:\Program Files\PC-ECG).
   A window is displayed, asking you if you would like to replace the existing file.
3. Click **Yes**.

To Set Preferences

1. After installing the PC-ECG 1200 package, and prior to operation, click **Setup** to tailor your preferences.
2. Begin with **Environment**, which configures the hardware.
3. Continue with the other tabs in any order.

CHAPTER 4: HARDWARE INSTALLATION

Safety

WARNING

The PC-ECG 1200W transmitter uses battery power supply. PCECG1200WR receiver uses Power supply via USB port. It is also sensitive to electrical interference.

The PC-ECG 1200 controls exercise machines.

To prevent possible injury, read this page carefully prior to installing the device.

- A patient undergoing a test must be at a distance of at least:
  - 1.5 meters from the computer, printer and other peripherals,
- If such conditions cannot be fulfilled, the entire system needs to be connected to the A/C power supply through an Isolation transformer meeting the EN60601/1 standard.
- Use only the recommended battery type as instructed in the technical specifications to operate the PCECG1200W (4 - AA alkaline or NIMH rechargeable).
- Do not use batteries with expired dates.
- Remove batteries form the PCECG1200W when it is not in use.
- Any treadmill used with the PC-ECG 1200 must contain a manual control in order to allow the user to stop the operation of the treadmill in case of emergency.
- In the event of apparent changes in the performance of the device, discontinue use immediately. Do not resume use until the device is approved by the manufacturer or by a representative of the manufacturer.
- If audio is playing on the PC, the ECG shows interference. Do not run an audio CD on the PC while running an ECG test via the USB connection.
- Defibrillation protection is built in for Model W.
- Operate the unit only at clinics and hospitals. Do not use at home.
- Operation only by trained medical staff.

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.

Note

The manufacturer is not responsible for any Radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

Note

Install hardware only after software installation.

CLASSIFICATION OF THE EQUIPMENT

- According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT

- According to the degree of protection against electric shock: TYPE CF APPLIED PART

- According to the degree of protection against ingress of water: ORDINARY EQUIPMENT

- According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

- According to the mode of operation: CONTINUOUS OPERATION

Installing Model 1200W

The PC-ECG 1200W kit contains the following items:

- ◊ Acquisition box (see Figure 2, below)
- ◊ Patient leads
- ◊ USB cable (see Figure 3, page 16)
- ◊ Antenna
- ◊ 1200 WR receiver (see Figure 4, page 18)
- ◊ Software CD of PC-ECG 1200 installation package.
- ◊ Software key (if optional software is included)

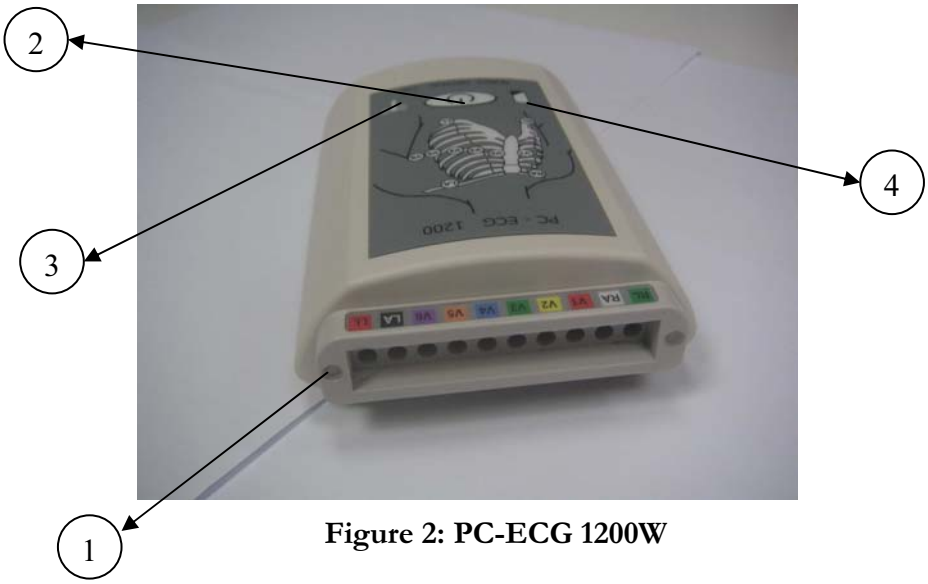

Figure 2: PC-ECG 1200W

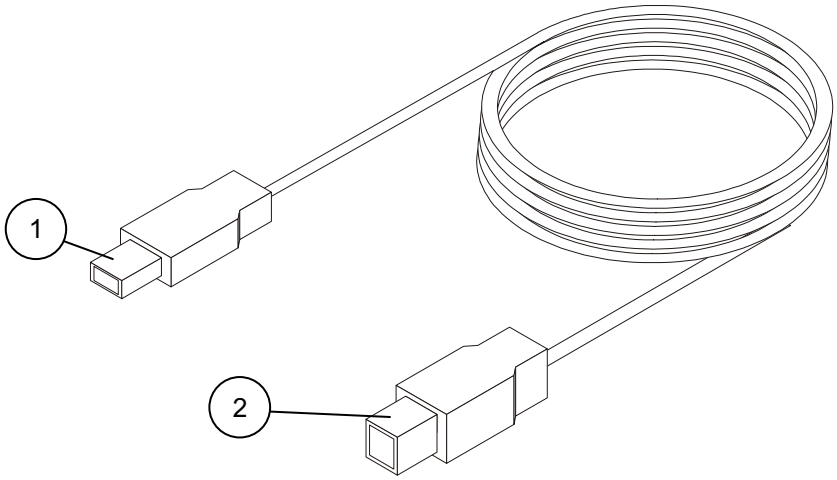

Figure 3: USB Cable

To Connect Via USB

Caution

Make sure the device is switched off Cautions refer to practices necessary to protect against potential damage or loss to equipment.

1. Connect Antenna (Figure 4, Page 18, detail 4) to the connector on 1200WR Receiver (Figure 4, Page 18, detail 2).
2. Connect the A-type connector of the USB cable (Figure 3, Page 16, detail 1) to the PC.
3. Connect the B-type connector of the USB cable (Figure 3, Page 16, detail 2) to the input of the 1200WR Receiver (Figure 4, Page 18, detail 1).
4. A wizard for installing new hardware driver appears. Follow the instructions. If working under Windows XP press "Continue anyway" on message regarding the digital signature (each time it appears). After the driver is installed make sure the green light is illuminated on the 1200 WR Receiver (Figure 4, Page 18, detail 3)
5. Insert 4 - AA alkaline or NIMH rechargeable batteries into the battery compartment of the PCECG1200W unit.
6. Switch on the PC-ECG 1200W (Figure 2, Page 15, detail 2) and verify that the ON light is illuminated Figure 2, Page 15, detail 3).
7. Connect the 10 patient leads according to the lables to the 10 connectors of the PC-ECG 1200W (Figure 2, Page 15, detail 1).
8. If the optional software key is included, connect it to the parallel port of the computer.
9. If a printer is connected via the parallel port, plug the printer cable into the key.

The optional BNC output (Figure 4, Page 18, detail 5) is a trigger control for connecting to an external device, such as an ergometer or the Tango unit.

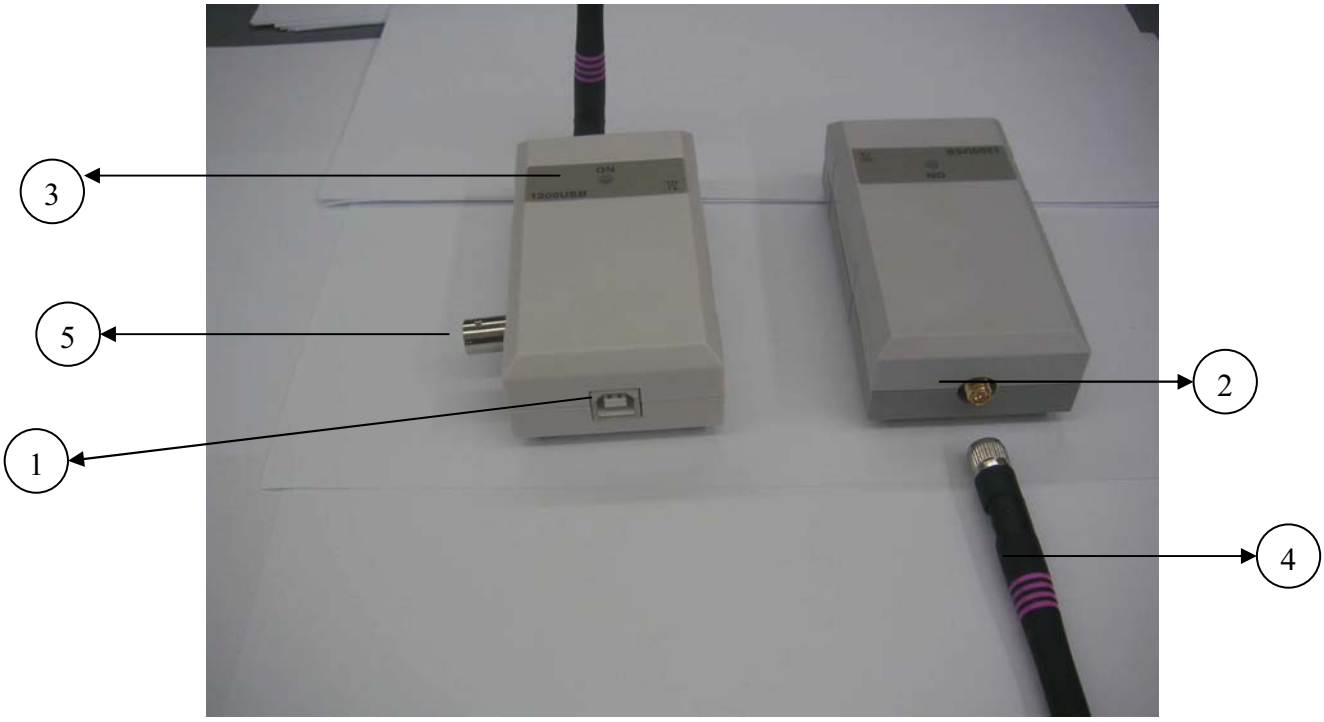

Figure 4: 1200 WR Receiver

To Verify the Connections

1. Connect the PC-ECG 1200W to the patient.
2. Connect the electrode leads to the electrodes, starting with RL.
3. Verify that an ECG is acquired and displayed on the screen.

To Perform Maintenance

! **Caution**	The device is not waterproof. Do not expose the device to water or any kind of liquid. Maintain in a dry place.

1. Use alcohol pads to clean the device of moisture and hairs.
2. Replace the pouch or wash it at 30^0C.

Calibration

The device does not need any calibration.

Connecting an Exercise Device

You can connect a treadmill or ergometer to the computer independently of the PC-ECG 1200W. You can also operate the exercise device without using an ECG recorder by using the software with Simulator option selected.

To Connect an RS232 Controlled Treadmill/Ergometer

Connect the RS232 cable (as specified by the vendor) to COM 2 (if COM 2 is in use, then wait until the software has been installed and use the assigned COM port).

To Connect an Analog Controlled Treadmill/Ergometer

A digital/analog converter (D/A) board converts the digital signal from the computer into an analog signal that the treadmill or ergometer can read.

1. Insert the D/A board into the PC.
2. Connect the cable from the D/A board as specified in the D/A board table.

Cabling

The RS232 cable should contain at least 3 wires: TD, RD using pin 2 and 3 and GROUND using pin 5.

Straight type means that pin 2 on the PC side connects to pin 2 on the exercise device side, pin 3 on the PC side connects to pin 3 on the exercise device side, and pin 5 on the PC side connects to pin 5 on the exercise device side.

Crossed type means that pin 2 on the PC side connects to pin 3 on the exercise device side, pin 3 on the PC side connects to pin 2 on the exercise device side and pin 5 on the PC side connects to pin 5 on the exercise device side.

To Determine Treadmill Cabling

Check which pins are assigned for TD and RD on the exercise device connector.

- If pin 2 is RD and pin 3 is TD, then the exercise device requires a crossed cable
- If pin 2 is TD and pin 3 is RD, then the exercise device requires a straight cable.

Connecting a Blood Pressure Stress Monitor

To Connect a Blood Pressure stress Monitor

1. Insert the D/A board into the PC and connect the cable from the D/A board to the BNC input on the monitor.
2. Connect the RS232 cable (as specified by the monitor vendor) to COM 4. If COM 4 is in use, wait until the software is installed and use the assigned COM.

CHAPTER 5: ACCESSORIES INSTALLATION

D/A Board: Model: CIO-DAC02 for ISA Bus

The software uses a digital signal, but the exercise device (treadmill or ergometer) operates through an analog signal. To make communication possible, the D/A board converts the digital signal into an analog signal.

Jumpers Setting

D/A0=	-5
D/A1=	-5
WAIT STATE=	Off

Settings and Output of the D/A Board for 0-4 Volt Output

Board P/N and Board target	**Board address and address switches**	**Common pin no. on D25 connector**	**Out 1 pin no. on D25 connector**	**Out 2 pin no. on D25 connector**
D1-a Treadmill Analog control	300H. switches 8,9 DOWN the rest UP	1	Speed pin : 24	Grade pin: 18
D1-a Ergometer Analog control	300H. switches 8,9 DOWN the rest UP	1	Power pin : 24	
D1-s Metabolic Interface	304H. switches 8,9,2 DOWN the rest UP	1	Heart Rate pin: 24	Work Load pin: 18
D1-t ECG Trigger	308H. switches 8,9,3 DOWN the rest UP	1	TTL OUT pin: 24	

Table 4: D/A Board 0 to+4 Volt

Settings and Output of the D/A Board for -4 to +4 Volt Output

Board P/N and Board target	Board address and address switches	Common pin no. on D25 connector	Out 1 pin no. on D25 connector	Out 2 pin no. on D25 connector
D1-a Treadmill Analog control	300H. switches 8,9 DOWN the rest UP	1	Speed Pin: 23	Grade pin: 17
D1-a Ergometer Analog control	300H. switches 8,9 DOWN the rest UP	1	Power pin: 23	
D1-s Metabolic Interface	304H. switches 8,9,2 DOWN the rest UP	1	Heart Rate pin: 23	Work Load pin: 17

Table 5: D/A Board –4 to +4 Volt

To Continue Setup (After Installing the ISA Board/s)

1. In **Stress** ECG, click Setup > **Environment**.
2. Select the **Advance** tab.
3. Check the appropriate boxes for R-wave Trigger, USB Connection, and Cards.

PCI Bus Board Functioning as an ECG Trigger

The ECG trigger function can be provided either via the PCI bus board (see immediately below) or by connecting to the 1200 USB through the BNC output. The Stress application can control an analog/trigger signal. The analog/trigger control can be configured in the setup dialog for connection through either the PCI card or the 1200 USB adaptor.

To Set Up an ECG Trigger via PCI Bus Board

Install the board as instructed by the manufacturer.

Note

Install the PCI-DIO24 driver from the CD before connecting the Tango device. If the device was connected before the driver is installed, then cancel the **Add New Hardware** wizard, disconnect the Tango device, and install the software.

To Complete Setup

1. Click Stress Setup > **Environment**.
2. Click the **Advance** tab.
3. Check the appropriate boxes for R-wave Trigger, USB Connection, and Cards.

Cable for PCI board

Connector pin 21 on D37 connector—common

Connector pin 37 on D37 connector—TTL

The target side can be either BNC or PHONO.

Installation of the TANGO Automatic BP Unit

Note

You must install the PCI-DIO24 driver from the CD before connecting the Tango device. If the device was connected before the driver was installed, then cancel the **Add New Hardware** wizard, disconnect the Tango device, and install the software.

1. Insert the PCI-DIO24 card driver CD in the CD driver.
2. Select **Install InstaCall** from the menu displayed.
3. Follow the instructions.

To Verify that the Driver is Installed Correctly

1. Right click **My Computer** on the desktop and select **Properties** from the pop-up menu.
2. Select **Hardware** tab from the dialog box and click **Device Manager**.
3. Locate the icon next to "Das Computers PCI-DIO24".
   If the icon has no accompanying marks, then it is correctly installed.
   If it is checked with **"?"** or **"!"**,update the driver, as explained below.

To Update the Driver

1. Double click the icon and click **Update Driver**.
2. Select **Install the software automatically** and click **Next**.
3. Define the path for the driver as C:\Windows\inf\OEM XX.inf and follow the instructions on screen to complete the installation.

Connecting TANGO Automatic BP Unit

(Requires Option S1 or S2)

The Tango unit connects to the PC by 2 cables:

1. RS232 modem cable both sides female D9 connectors.

   Pin 2 ----------Pin 3

   Pin 3 ----------Pin 2

   Pin 5 ----------Pin 5

2. R-R trigger cable connecting board D1-t (plugged in PC) by D37 (D25 on old boards) connector to the BNC socket of the Tango.

To Set Up PC-ECG Software

1. In **Environment**, assign a COM port for **Automatic Blood Pressure COM Port** and check **R-Wave Trigger**.
2. In Protocols, check **Measure BP by automatic device**

To Set Up Tango Unit

The configuration of the Tango unit for communication should be SUNTECH (as device) and DKA (as technique). Define these as follows:

TEST PARAMETERS, TECHNIQUE = DKA

UTILITIES, DEVICE = SUNTECH

CHAPTER 6: PATIENT PREPARATION

The ECG traces quality depends very much on the stability and conductivity of the electrodes during the test, especially during high stages when the patient movements can cause artifacts. Here are some basic rules to ensure good electrical contact:

- ◊ Shave hair at the electrode contact points
- ◊ Use a special shirt that attaches the electrodes and lead wires to the body
- ◊ Use high quality liquid gel electrodes
- ◊ Make sure that the lead wires do not swing

Attach the leads as shown in Figure 5, below (RA=right arm, LA=left arm, RL=right leg, LL=left leg).

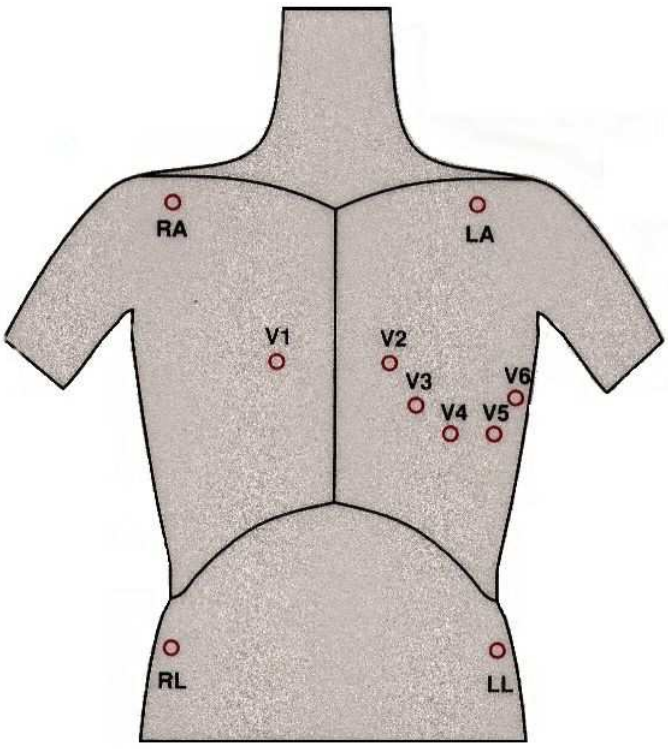

Figure 5: Electrode Placement

CHAPTER 7: RESTING ECG

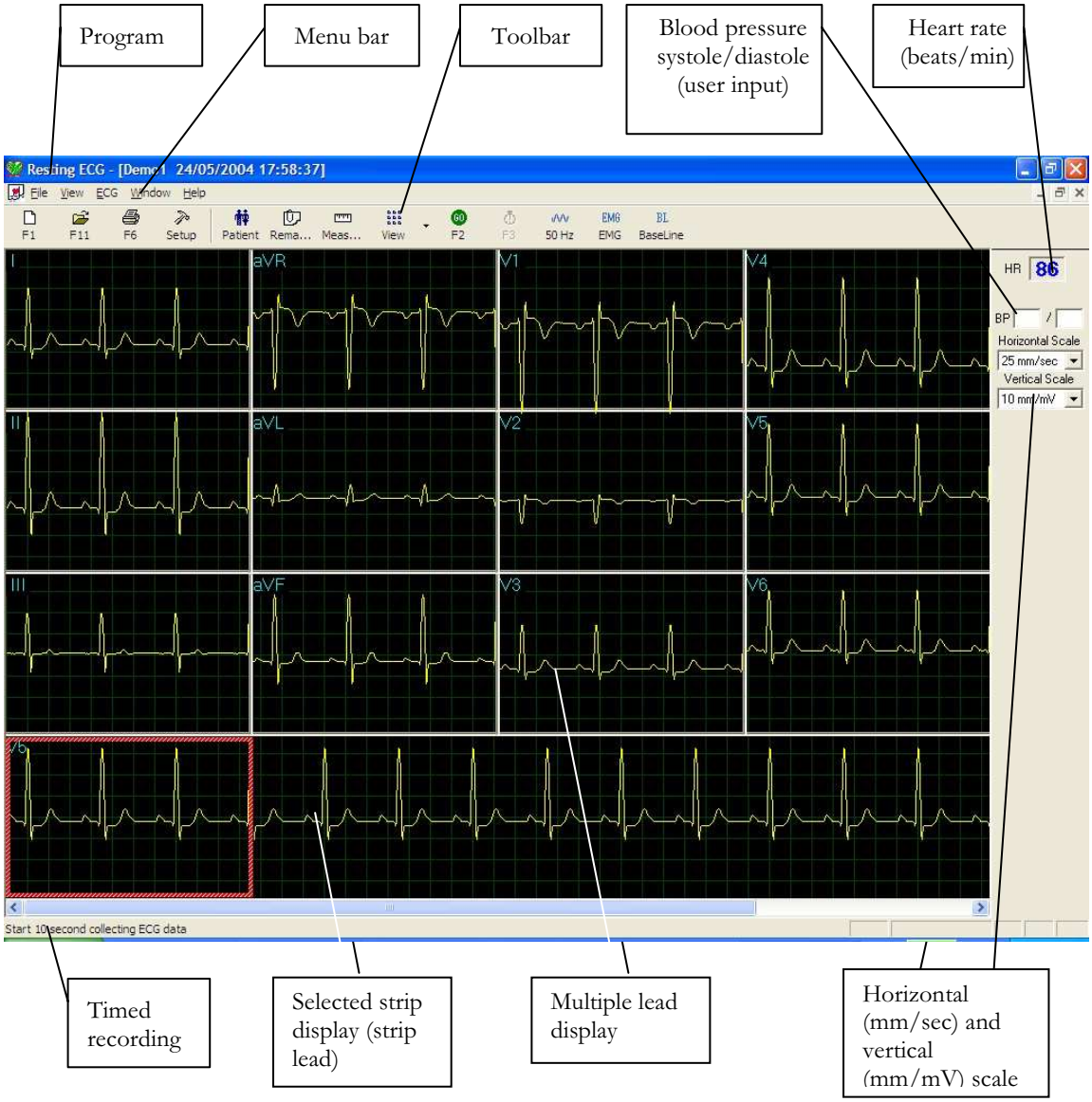

Figure 6: Resting ECG Main Screen

Quick Start

To Perform a New Test

1. Click **F1** (or the **New** button on the tool bar).
2. Insert patient details in the dialog box.
3. Click **OK.**
4. Enter blood pressure.
5. Click **F2** to stop data collection or **F3** to start data collection (10 seconds).

Operation with Function Keys

F1	New Recording
F2	Start/Stop
F3	10 sec. recording
F6	Print
F11	Open Saved Study

Table 6: Operation with Function Keys

For an example of a printed report, see Appendix C:, page 111.

Resting 12 Lead ECG

This application uses the standard 10 contact cables. It contains four limbs (RA, LA, LL, and RL) and six chest (V1-V6) contacts. 12 derivations are recorded and displayed:

- 3 Bipolar derivations: I, II, III
- 3 Augmented derivations: aVR, aVL, aVF
- 6 Unipolar derivations: V1-V6
- You can use a simpler cable with four contacts (only limbs). It produces six derivations only: three Bipolar and three Augmented

Leads Placement

You can place the leads on the patient in various ways. The usual method is to place the leads in the standard positions on the chest (V1-V6). To identify the placement of

the leads, the channels are renamed. Additional options for lead placement are V7-V9, and the Right chest Lead system.

To Define the Lead System

1. Click Setup > **Lead**.
2. Select the lead system to use (Default: Standard).

Toolbar Overview

The Toolbar (Easy Toolbars Mode)

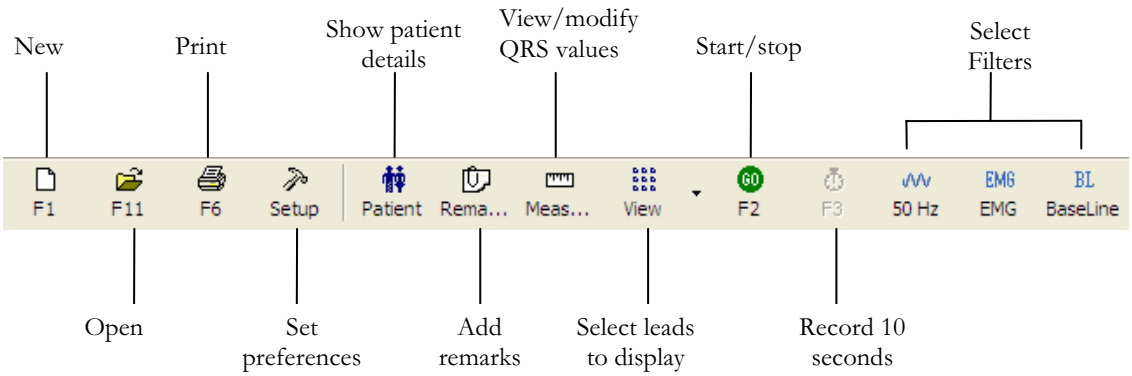

Figure 7: Resting ECG Toolbar

Note

The icons shown on page 35 are from the full toolbar. You can use the view menu to show an abbreviated display with or without captions.

Resting ECG Setup

Click **Setup** on the Toolbar to access the following parameters:

Tab	Option	Description
Leads	Lead Systems	Define the lead system to be used and displayed according to the electrode placement on the patient. Choose between Standard, Cabrera, V7-V9, and V3R-V5R lead systems (default: standard system).
	Default 3 leads	Define the 3 leads that will be displayed as default when using 3x1-view format.
	Default 6 leads	Define the 6 leads that will be displayed as default when using 6x1 or 3x2-view format.
	Strip Lead	10 sec lead to appear in 4x3 and 6x2 formats.
ECG Recording	Filter 50/60Hz	Default is cleared. When checked, the default status of 50/60Hz filter is ON (according to the checked frequency 50 or 60).
	EMG Filter	Default is cleared. When checked, the default status of the EMG filter is ON.
	Baseline Filter	Default is cleared. When checked, the default status of the Baseline filter is ON.
	Save options	If **Auto Save** is ON, the file is stored by last name or by ID. If **Auto Save** is OFF, a dialog box is displayed asking the user to enter a file name.
	Auto stop after 10 sec	If cleared (default), recording runs till stopped by the user. If checked, stops recording automatically after 10 sec.
	Auto Print	Use this option for automatic printing of the test at the end of the Rest test. If more than one printer is defined in the network, select the appropriate one from the list.
	Simulator ECG	If cleared (default), ECG recording is done from the PC-ECG unit. If checked, the ECG recording is done from the demo file included in the software package. In this case, the recording unit is not needed.
	Data Directory	Allows the user to define a directory for saved ECG recordings (if ECG database is not used). Use a secondary hard disk, if one is available.
	Use ECG Database	Select this option to connect to the default ECG database. When this option is selected (checked) the ECG tests are saved in the database.

Tab	Option	Description
	BACKUP Data directory for AutoSave mode	When Auto Save option is selected, this allows the user to define a local path for a backup directory. The backup directory is useful when the data directory or database is not on the same computer. In such a case, ECG file save can fail due to failure in connection.
Diagnosis		Optional. Active only if the measurement option (I1) is installed.
	ST after J	Defines the ST spot relative to the J point.
	Print Options	Allows the user to determine if and when to have automatic results printed. Define if measurements and/or interpretations should be added to printouts. Options are Never, After Confirmation, or Always.
View	Draw over lead borders	If checked (default), does not limit the extreme high amplitude ECG pulses from exceeding the borders. If cleared, chops the pulses at the borders.
	View calibration pulse 1 mV	If cleared (default), the 1-mV pulse will appear only in printing. If checked, the 1-mV pulse will also appear on the screen.
	Leads Base line shift	If cleared (default), the base line of each lead is exactly in the middle of the lead's area. If checked, a special shift is added to each lead to view its maximum. For example: lead V6, being positive pulsed, gets negative shift.
	Separate Leads	If checked, leads are displayed framed and separated from each other. If cleared, leads are not separated. Default is checked.
	Draw Grid	If checked, displays grid lines when the application is opened. If cleared, the application is opened with no grid lines Default is checked.
	Horizontal Scale	Sets the default value for the horizontal scale window on the screen (mm/sec).
	Vertical Scale	Sets the default value for the vertical scale window on the screen (mm/mV).
	Rest ECG color selection	Allows the user to choose colors for the Rest ECG application for background, traces, grid, and text.
	Restore Defaults	When activated, restores the factory default colors: black for background, yellow for traces, green for grid, turquoise for text.
	Easy Toolbar Mode	If checked, allows the user to use the regular Icons. If cleared, allows the user to use the optional Icons
	Text Label	Adds text to the Icons. Enables use by keyboard.

Tab	Option	Description
Installation		Saves users' data (hospital and physician). This data is printed on any print out and sent as email.
	Measurement Standard	Define whether measurements will be calculated according to the metric or the USA standard. Default is metric.
	Magnetic Card Reader	Select this option to use a magnetic card with bar-code to insert patient details. (Select the magnetic card type.)
Environment	Connection	Select the option button (COM port/USB), to choose the port the device should be connected through. If the COM port option is selected, select the serial input for the PC-ECG unit from the COM port selection list. If the USB connection is selected, the COM PC-ECG selection list is disabled. (Default at installation is USB).
	Display Size	Choose between 14/15-inch screen (default) and 17-inch screen. This setting is required in order to display the ECG and grid in the correct scale.
	Graph paper	If set to **On**, prints 1mm and 5 mm squares on printouts. **Regular Grid** is guaranteed to fit any printer. **Improved Grid** shows a fine grid but may not work on some printers.
	Paper Size	Sets paper size. either conventional printer or 4-inch thermal printer.
	Large Remarks Font	Enables large font for user entered free text.
	Color Printout	Select this option for colored printouts.
	Shadow/Frame For Area of Interest	Allows the user to choose between shadow and frame to highlight the interest area.
Picture Format	AutoSave ECG in Picture Format	Select this option to save the test automatically as a JPG image.
	Set File Name By	Set the file names to include Patient Last Name or Patient ID. Check date and/or hour to include them in the file name.
	Picture Format	Select the resolution of the picture (normal or high resolution).
	Picture Directory	Set the directory for saved pictures. The default is C:\Program Files\PCECG\Data.
GDT/BDT Format	Automatic	Setup automatic GDT/BDT format.
	Save test in GDT/BDT	If checked, save test automatically to GDT/BDT format.
	Import from GDT/BDT	If checked, imports tests automatically as GDT/BDT format.

Tab	Option	Description
	File Format	Select the file format: GDT or BDT.
	Import Codepage 437	Check this option to import Code page 437.
	Export Codepage 437	Check this option to export Code page 437.
	Edit Labels	Click this button to open a dialog box with an editable list of the field labels used in the GDT and BDT files.
	GDT/BDT Data Directory	Define the directory path where the GDT/BDT files should be maintained.
	Token for PCECG	Default is PEKG.
	Token for Practice EDP	Default is EDV1.
Text File	Auto Save Test Data in Text file	Select this option to save the test data in a text file automatically at the end of the rest test.
	Set Text file Name by	Set the text file name according to Test File Name or according to the fields Patient ID and/or Patient Last Name.
	Text File Data Directory	Set the directory path to maintain the text files with the ECG data. Default is C:\Program Files\PCECG\Data.

Table 7: Resting ECG Setup Options

Toolbar and Menus

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Start a new study		F1	File > New Rest Test	Starts a new 12 lead recording. The patient data can be entered prior to ECG recording, but this is not mandatory. The recording time is according to the setup for ECG Recording: either continuous or limited to 10 sec. To stop recording, click **GO/STOP**.
Open an existing study		F11	File > Open	Shows recordings that are saved on disk.

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Import Data from SCP Format			File > Import from SCP Format (Select the required file(s) and path from the dialog box and click **OK**)	SCP format is a European format for ECG files. The Rest application can identify these files, import them, and save them as Rest files, either to the database or to the defined folder for the Rest files.
Import demographic data from HIS to PC-ECG			File > GDT/BDT Format For details see **Import from GDT/BDT**, page 105	This file always contains the last patient data.
Export the GDT/BDT file from PC-ECG to HIS			File > GDT/BDT Format For details see **Save Test in GDT/BDT** page 105	This file always contains the last patient data.
Save a recording		Ctrl+S	File > Save	Saves recording on disk (default file name: REST).
Send results via email			File > Send	Sends recording data via email. If the large icons are used the operation must be performed through the FILE menu Prerequisites: e-mail software package, modem, and internet provider (not included in the PC-ECG 1200 package). Once an ECG study is displayed on the screen of the transmitting side, click this icon to attach the ECG file and send an e-mail to a specified address. The receiver must have the PC-ECG 1200 software installed. A regular email is sent with the ECG as an attached file. The receiver can either double click the file to display the ECG on the screen, or save it in the PC-ECG 1200 studies default directory.
Export to MATLAB format		Ctrl+E	File > Export to Matlab Format	Saves ECG results in MATLAB format. (For details see **Using the Matlab Feature within PC-ECG 1200**, page 39).

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Create a text file			File > Create Text File	Saves ECG data in text format.
Save the test as an image			File > Save ECG to Picture Format	Saves ECG test as a JPG image.
Print a miniature printout of results			File > Print Average Mini Card	Prints results as a mini-card that can be carried in the pocket or wallet.
Print results		F6	File > Print	Prints the recordings currently shown on the screen. Note that the 1-mV signal is always printed.
Set preferences			View > Setup	Allows the user to set preferences for Leads, ECG Recording, Diagnosis, View, Installation, Environment, Picture Format, GDT/BDT Format, and Text File. For details see Table 7, page 35.
Display program, hardware, and contact information			Help > About	Displays software version number (which should be quoted on any software inquiry) software key, and permissions; Norav contact information; memory size and free disk space; HASP ID number (ID of existing software keys). This ID number is used for adding software options.
Print patient data		—	View > Patient Data	Can be added to the recording. It will be printed together with ECG traces. If the recording is saved, then the PATIENT DATA will be saved together with the ECG traces. Use the Previous option if the same patient undergoes a second study.
Add remarks		—	View > Remarks\ Interpretation	Allows the user to enter free text during or after the ECG recording. This is printed and saved together with ECG traces. If the Interpretation option is installed, then Interpretation Statements is also displayed.

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
View and modify QRS values		—	View > Measurements	An optional feature that requires a software key (I1 or I2 license). Displays a comprehensive table of measured values. You can alter the values either by editing them in the table or by using Caliper to change the horizontal and vertical markers. When Caliper is activated, a large QRS is shown with the standard markers. Open the Standard Markers window (upper right side) and select the QRS interval of interest for modification. The area changes to blue. Use the mouse to move the markers. (For details see **Measurements/ Interpretation**, page 85).
Display/hide the grid		—	View > Grid	Displays or hides the 5mm raster grid. Print outs are always with 1mm raster.
Display information from different leads (5 options)				
Display 3x4		—	View > Leads Format > 3x4 Windows	Classical format. 12 lead ECG of 2.5sec ECG + 10sec trace.*
Display 6x2		—	View > Leads Format > 6x2 Windows	12 lead ECG of 5sec ECG + 10sec trace.*
Display 12x1		—	View > Leads Format > 12 Leads	12 lead ECG of 10sec ECG.*
Display 6x1		—	View > Leads Format > 6 Leads	6 lead ECG of 10sec ECG.*
Display 3x1		—	View > Leads Format > 3 Leads	3 lead ECG of 10sec ECG.*
View/print averages		—		Produces a typical QRS for every lead from the raw ECG data. The averages can be printed either full size or minimized in a credit card size. To perform a miniature print, enter FILE and then PRINT MINIATURE.