System for Telemetric, Non-invasive, Computer-aided Evaluation of Heart Rate Variability

USER MANUAL

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Doc 125-05

VariaCardio® TF5 Manual

Table of contents:

1.BEFORE YOU BEGIN 3

1.1 WARNINGS 4
DISCLAIMER OF WARRANTY 6
1.2. VARIACARDIO TF5 HELP LINE 6
1.3. CARING FOR THE VARIACARDIO TF5 SYSTEM 6
1.4. TECHNICAL AND SAFETY NOTES 8

2. GENERAL DESCRIPTION 9

2.1. PARTS OF THE VARIACARDIO TF5 9
2.1.1. CHEST BELT WITH UHF-TRANSMITTER 10
2.1.2. UHF-RECEIVER 12
2.2. OTHER COMPONENTS / PRINTER 13
2.3. AC/DC ADAPTER FOR A TRANSMITTER BATTERY AND GUIDELINES FOR ITS CHARGING 14
2.4. PRODUCTION, TESTING, WARRANTY AND TECHNICAL SUPPORT 14

3. VARIACARDIO TF5 PROGRAM PRINCIPLES & CONTROL 16

3.1. WHAT THE SWITCH BUTTONS MEAN 16
3.2. WHAT THE LED DIODES MEAN 16
3.3. WHAT IS THE NORMAL OPERATION SETTING 16

4. OPERATING THE VARIACARDIO TF5 17

4.1. HOW TO INSTALL THE SOFTWARE 17
INSTALLATION WIZARD 18
4.2. HOW TO LAUNCH THE APPLICATION 21
4.3. HOW TO ADJUST THE BELT 22
4.4. HOW TO ADJUST THE COMMUNICATION RECEIVER/COMPUTER: 22
4.5. HOW TO ENTER THE DATA AND/OR TO CONTROL THE SYSTEM 23

5. CLINICAL USE OF THE SYSTEM: DATABASE 24

5.1. BEFORE WE START 24
5.2. HOW TO START THE PROGRAM 24
5.3. THE BASIC OPERATION SCREEN 25
5.4. DATABASE: HOW TO FIND A SUBJECT 27
5.5. DATABASE: HOW TO ADD A NEW SUBJECT RECORD 27
5.6. DATABASE: HOW TO DELETE A RECORD / SUBJECT 29
5.7. DATABASE: HOW TO CHANGE THE DATABASE / CREATE A NEW DATABASE 29

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5.8. DATABASE: HOW TO SET THE DATABASE AS DEFAULT 30
5.9. DATABASE: HOW TO IMPORT DATA OBTAINED BY PREVIOUS MODELS 30
5.10. DATABASE: HOW TO COMPACT THE DATABASE 30
5.11. LICENSE, HARDLOCK, DATA PROTECTION & BUSINESS ISSUES 31
5.12. HOW TO SEND RECORDS AND PROTOCOLS VIA E-MAIL 31
5.13. HOW TO EXPORT AND IMPORT HRV RECORDS 32
6. CLINICAL USE OF THE SYSTEM: MEASUREMENTS 33
6.1. MEASUREMENTS: SPECTRAL TEST MEASURING SCREEN 33
6.2. MEASUREMENTS: HOW TO PERFORM MEASUREMENT 34
6.3. HOW TO BROWSE/EDIT THE DATA 38
6.3.1. ECG BROWSER 41

7. CLINICAL USE OF THE SYSTEM: ANALYSIS 43

7.1. HRV BASICS. HOW TO UNDERSTAND THE PRINCIPLES OF ANALYSIS 43
7.2. HRV BASICS. HOW THE R-R INTERVALS MEASUREMENT WORKS 45
7.3. HRV BASICS. HOW TO UNDERSTAND THE 3D RESULTS 46
7.4. ANALYSIS. HOW TO PERFORM THE ANALYSIS 48
7.4.1. BASIC ANALYSIS SCREEN. 3D RUNNING SPECTRA GRAPH 48
7.4.2. BASIC ANALYSIS SCREEN. STATISTICAL TABLE 50
7.4.3. BASIC ANALYSIS SCREEN. GRAPHICAL TABLE 50
7.4.4. BASIC ANALYSIS SCREEN. RESUME 51
7.4.5. BASIC ANALYSIS SCREEN. EXPORT OF NUMERICAL RESULTS 51
7.5. ANALYSIS. MEDICAL REPORT AND HOW TO OBTAIN IT 52

8. BATTERY OF SHORT CARDIOVASCULAR REFLEX TESTS AS PROPOSED BY EWING (SO-CALLED 'EWING BATTERY') 53

8.1. EWING BATTERY: INTRODUCTION 53
8.2. HOW TO PERFORM THE EWING'S TEST BATTERY 53
8.2.1. EWING BATTERY: HOW TO PERFORM THE DEEP BREATHING TEST 55
8.2.2. EWING BATTERY: HOW TO PERFORM THE VALSALVA MANEUVER 57
8.2.2. EWING BATTERY: HOW TO PERFORM THE ORTHOSTATIC TEST 58
9.1. SOME PRACTICAL EXAMPLES 60
9.2. APPLICATION NOTES 61
YOUR NOTES 63

The VariaCardio TF5 system is manufactured and distributed exclusively by Advanced Medical Diagnostics Group, Ltd, UK and its partners.

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1. Before You Begin

Thank you for purchasing this VariaCardio TF5 system.
The operating instructions that are found in this manual should be followed carefully to ensure many years of reliable service. Please read these instructions thoroughly before using the VariaCardio TF5 system.
The operating instructions should allow the average user to become familiar and proficient in the review and editing of patient records generated by the VariaCardio TF5 system. This manual does not teach the operator to recognise or to interpret the records. That information is beyond the scope of this manual. An overview is described later in this document.

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Your VariaCardio TF5 system Serial Number: _____

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1.1 Warnings

- Do not operate the VariaCardio TF5 system on a patient with a heart pacemaker or any other telemetrically (UHF range) programmable/controllable device.
- If a patient connected to the VariaCardio TF5 system is to be defibrillated, the leads must be removed from the patient before defibrillation.
- There are no user serviceable parts.
- FCC Part 15 requirement:- This device requires a shielded interface cable (RS232) to ensure compliance.
- The operating UHF frequency range of 869.7 MHz (914.5 MHz USA only) used for wireless ECG/RR data transfer is considered for general industrial, scientific and medical use ('ISM band'). Therefore, it might casually be possible that disturbance caused by another wireless device working on the same operating frequency occurs. This situation means in no way any hazard for patient. However, it might be necessary to use another operating frequency for your VariaCardio TF5 to work correctly.
- User changes or modifications not expressly approved by AMDG/MIE could void the user's authority to operate the VariaCardio TF5.

Exclusions:

- Do not store or operate the VariaCardio TF5 system in a sterile, wet, damp or dusty environment.
- Do not use the system in areas with explosive and / or inflammable gases.
- Do not store or operate the system in direct sunlight
- Only use antennae provided with the VariaVardio TF5 system.

Regulatory:

- FDA: This instrument is a Class II, Type B Applied Part device.
- CE: This device is a class 2a device with a measuring function.
- Accuracy is ± 1ms R-R interval measurement (equivalent to ± 0.1%)
- Suitable for continuous use.
- Use only battery charger supplied.
- This Product complies with:
    - Electromagnetic compatibility FCC CFR 47, parts 15.249 for intentional radiators
    - Electromagnetic compatibility FCC CFR47, parts 15.109 for unintentional radiators
    - Electrical safety EN 60601-1:1993
    - Electromagnetic compatibility EN 60601-1-2:1993, EN 61000-3-2:1995, EN 61000-3-3:1995, ETSI EN 300 220-3 V.1.1.1. (2000-09), ETSI EN 301 489-3 V1.2.1 (2000-08)
- Use only AMDG/MIE approved accessories to maintain integrity.

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Symbols:

Warning – read instructions before use

MM.YY Date of manufacture – MM.YY

Type B Applied Part

TX FCC ID: HH4TF5-TX Transmitter Federal Communications Commission Identification number
RX FCC ID: HH4TF5-RX Receiver Federal Communications Commission Identification number

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.

CE 0120 This product is CE certified with notified body 0120

230V~50Hz Suitable for use on mains power supply of 220V to 240V.

110V~60Hz Suitable for use on mains power supply of 100 to 120V 60Hz

12V⎓ 12V dc input for charging internal battery

NOTE: NO USER SERVICEABLE PARTS.
FOR SERVICE CONTACT

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6 Wortley Moor Road,
Leeds,
LS12 4JF.
United Kingdom.

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e-mail service@mie-uk.com

DISCLAIMER OF WARRANTY

The VariaCardio TF5 is manufactured by MIE Medical Research Limited for Advanced Medical Diagnostics Group Ltd (AMDG). AMDG warrants only that the product is free from defects in the materials and workmanship under normal usage, for a period of 12 months after receipt, and any implied warranty is also limited to 12 months.

The warranty for the TF5 is based on following the instructions indicated in the "instruction and technical manuals". However in no event shall MIE Medical Research Limited be liable for any damages whatsoever arising out deviation from these instructions.

This manual provides information for the operation, set-up and care of the VariaCardio TF5 system. The system does not require a trained technician to determine fiducial points and/or pattern recognition to achieve its specific performance. All analysis is performed automatically within the unit using the parameters set at the beginning of the procedure. The physician or the operator may perform editing of the obtained data immediately at the end of the recording session or any time later.

1.2. VariaCardio TF5 Help Line

Advanced Medical Diagnostics Group provides a help line for all your technical and other questions Mon-Fri between 9:00 AM and 5:00 PM of UK time:

Phone: +44 (0)113 279 1010
Fax: +44 (0)113 2310 820
Website: http://www.amdgmedical.com
http://www.mie-uk.com
E-Mail: TF5@amdgmedical.com

1.3. Caring for the VariaCardio TF5 System

Cleaning instructions:
The system may be cleaned with any non-corrosive disinfectant commonly used for superficial skin disinfection purposes. Use a damp cloth to clean the instrument.
Do not expose the system to steam, corrosive liquids, high temperatures or any kind of radiation/sterilisation. This equipment is not protected for the ingress of liquids.

Shipment/transportation and long-term storage:
The system has been thoroughly checked in standard transportation environments e.g. air, road, rail & sea. There was no deterioration in its safety or function recorded. The instrument should be stored in temperatures of between +5 and +35 °C and humidity up to 75%.

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Inspection and service:
The manufacturer recommends the system to be thoroughly checked once every 2-years. This check will be performed exclusively by the manufacturer or its local authorised service centre. Please contact your distributor for more details. Unauthorised servicing of this equipment voids any guarantees and the manufacturer or distributor cannot accept any liability as to its proper functioning or safety.

Environmental information:
The system includes a Lithium ion battery, which is to be replaced exclusively by authorised facility. If the system is to be inactive for long periods of time, please contact your distributor to ensure all local environmental laws are met.

Technical information:
There are no serviceable parts inside. Exchange of internal battery will be provided only by your authorised service centre. Please contact your distributor's office.

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1.4. Technical and Safety Notes

Safety:

The system must be connected only to computer complying to EN 60950. Use only the connecting cables supplied with the system (<3m).

Installation requirements: The system must be installed at a minimum distance of 1.5 m from the patient, or the computer must be connected to a separating transformer. Take care of possible hazards caused by the summation of leakage currents when several electronic instruments are interconnected.

Use only the AC/DC adapter delivered with the system. Check if the voltage of the power supply matches your local mains supply (110/220/240 V).

The chest belt with flat electrodes used in the VariaCardio TF5 is manufactured to conform with the MDD 93/42/EEC (AUT76 1032-029-98). Additionally, during the 5-years practical experience - no side-effects or bio-incompatibility effects related to the use of this chest belt have been reported.

If the ECG amplifier is inoperable due to an overload or saturation, the yellow LED on the transmitter stops blinking (according to EN 601-2-25, clause 6.8.2).

The VariaCardio TF5 complies with Medical Device Directive 93/42/EEC, including the international standards of electrical safety and electromagnetic compatibility.

Physicians' review:

The ability of trained people to recognise certain patterns can be better than machines in certain circumstances. Therefore the user should be aware of the fallibility of such equipment in performing these tasks. This caveat applies to the various artefact/pattern recognition tasks performed by <u>all</u> ECG analysis systems including the TF5 system. Therefore, no *significant* diagnostic/treatment decisions should be made solely based on the results of the equipment's analysis. In such cases, users should satisfy themselves with the accuracy of the equipment's analysis by confirming it with the underlying heart beat/ECG data as contained in the obtained records.

Recommended PC equipment:

For problem-free use of the VariaCardio TF5 system, you should use a dedicated IBM PC-compatible computer with the following

(a) *minimum* specifications: CPU Pentium 200 MHz, 32 MB RAM and 10 MB of available hard disk space (optionally, a notebook with identical features), 1 free serial port, with MS-Windows version 98, Second Edition and any commonly used printer, or

(b) *optimum* specifications: CPU Pentium III 500 MHz and higher, 64 MB RAM and 20 MB of available hard disk space (optionally, a notebook with identical features), 1 free serial port, with MS-Windows version 98, Second Edition /2000, and laser (colour) printer.

Notice:

In accordance with an ongoing development and improvement of the technology, the manufacturer reserves the right to change/adapt any procedure used in the system.

2. General Description

VariaCardio TF5 is a telemetric, on-line, computer-aided system for the examination of heart rate variability, based on its *time-domain* and *frequency-domain* (spectral) analysis. The system can be used in any clinical or research environment.

The system telemetrically collects and stores data derived from one-channel ECG (both, intervals between consecutive normal R waves, and ECG signal separately) obtained during a standardised modified orthostatic test (within positions supine/standing/supine, each of them being 5 minutes long) or during a battery of cardiovascular reflex tests. Such a test is performed under strictly standardised conditions excluding any external disturbance. An option to evaluate the test is then immediately available, this enables the user to get a quick, accurate, quantitative, highly standardised and evidence-based information on the current state of a examined subject that can be used in the further decision making process.

Analysis of heart rate variability has been accepted by the medical community to assess cardiac autonomic function fully non-invasively, to explore the pathophysiological mechanisms of heart diseases, to evaluate effects of therapy and/or to predict long-term prognosis.

2.1. Parts of the VariaCardio TF5

Hardware:

(1) An adjustable **chest belt** with two flat electrodes and an on-board MCU-based signal-analysis unit combined with built-in battery-powered UHF-transmitter,

(2) An UHF-**receiver** connected directly to an IBM-PC compatible computer via the serial port via an RS-232 connection,

(3) AC/DC adapter, cables, accessories.

Software:
A data collection, digital encoding, transmission and analysis software package enables the transmitted data to be displayed, stored and edited. The patient heart rate variability data and ECG can be displayed online and analysed offline in different graphical forms and can be printed out together with standardised statistical reports on any commonly used printer.

The system offers the following examination features:

- A short-term **spectral analysis** of the heart rate variability using a Fast Fourier Transform permitting a quantification of the influence that individual components of the autonomic nervous system have on the heart rate. The variability is evaluated by following indices: (a) in "*frequency domain"* - absolute and relative *s*pectral power in two or three frequency bands, their ratios, total and cumulative total power, power spectral density, average frequency, (b) in "*time domain"* - averaged R-R interval, its standard deviation and MSSD, usually in 3 examination intervals (of 300 seconds each). The system offers the possibility to monitor the instantaneous heart rate (time resolution 1 ms) and spectral curve in real time on the computer monitor.
- Commonly used 'gold-standard' **Ewing's battery** of cardiovascular autonomic function reflex tests, including a registration of changes in the heart rate during relaxed and deep breathing, Valsalva maneuver and orthostatic load. System enables an immediate statistical evaluation of all commonly used indices and offers a possibility to store, print and/or process patient data.
- Single channel **ECG** with a time resolution of 2 ms, with a possibility to continuously monitor, store, print and/or process patient data.

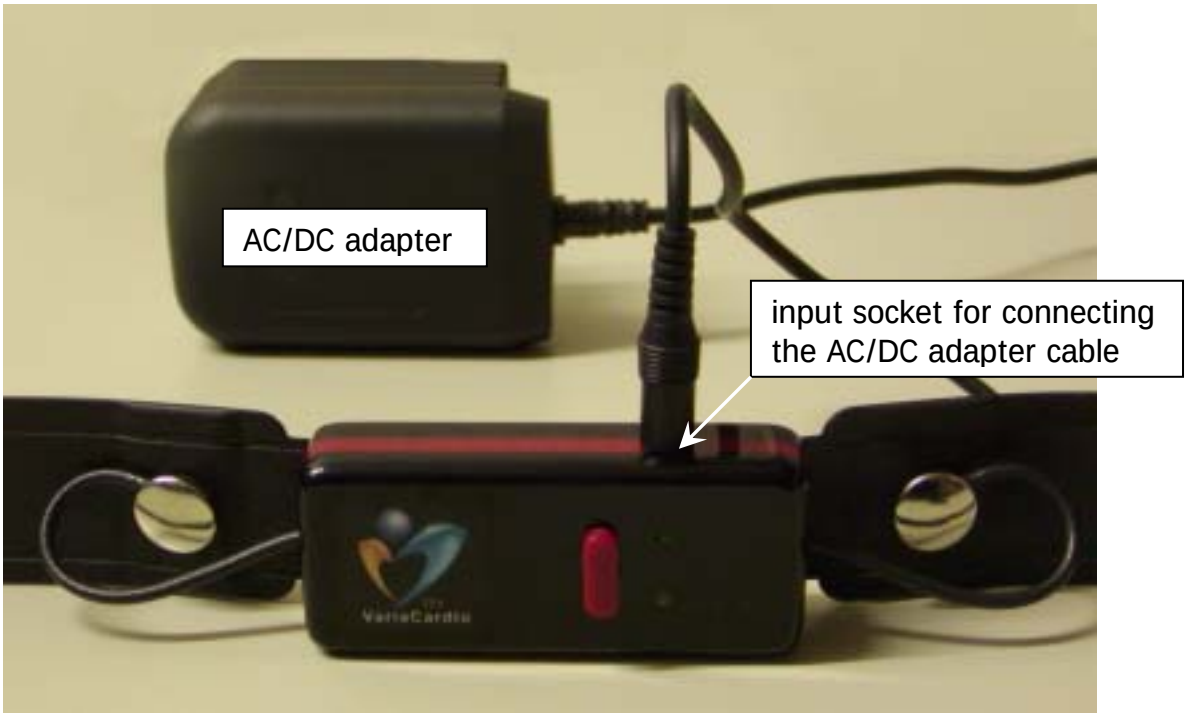
It is possible -- due to the UHF-radio telemetric data transfer -- to perform the examination from a distance of 20-30 metres or longer, e.g., in a separate examination room.

2.1.1. Chest Belt with UHF-Transmitter

a) **Overview** - The UHF-transmitter consists of an adjustable chest belt with two integrated flat rubber electrodes. The single channel ECG and R-R interval is sent to an on-board signal-conditioning unit incorporating a central processing unit microchip. The data is analysed prior to transmission. The ECG signals are sampled at 500 Hz whereas the R-R intervals are sampled at 1000 Hz. Another data channel is used for checking the transmitter battery voltage level.

b) **Front panel** – The front panel has two Light Emitting Diodes (LED's). The *yellow* one indicates that data transfer is functioning. The *green* one is used for indicating the charging procedure. A miniature power switch switches the telemetric unit on and off.

c) **Bottom panel** - contains an input socket for connecting the AC/DC adapter cable (for the transmitter battery charging).



Technical data:

Data acquisition:

Two flat rubber electrodes

- sampling rate for ECG signal 500 Hz
- sampling rate for R-R intervals 1000 Hz

Transmission:

- output power 10 mW
- operating frequency range 869.7 MHz (914.5 MHz USA only) (ISM Band; for local radio frequency approval check the Technical files or contact your distributor)
- supply voltage (integral rechargeable Li-Ion battery) 3.7 V DC
- operating time (continual transmission) more than 10 hours
- dimensions (LxBxH) 80x40x30 mm
- weight including battery (without chest belt) 160 g

2.1.2. UHF-Receiver

a) **Overview** - The UHF-receiver is housed in a metal case with two BNC connectors for the antennae on the top. The received data is transferred via the RS232 port to a computer.

b) **Front panel** - Contains two LED-diodes (*yellow* one signalling power is ON, *green* one for checking of functional data transfer)

c) **Back panel** - Contains one outlet connector CANON for the connection cable into the computer (via COM1 or COM2 port) and one connector for the AC/DC adapter. A power switch switches the receiver ON and OFF.

Technical data:

• operating frequency range	869.7 MHz (914.5MHz USA only ISM Band)
• sensitivity	0.3 μV
• antennae	lambda/4 type
• communication protocol	RS 232 (IBM-PC)
• supply voltage	9-12 V
• dimensions (LxBxH)	170x115x30mm
• weight	390 g

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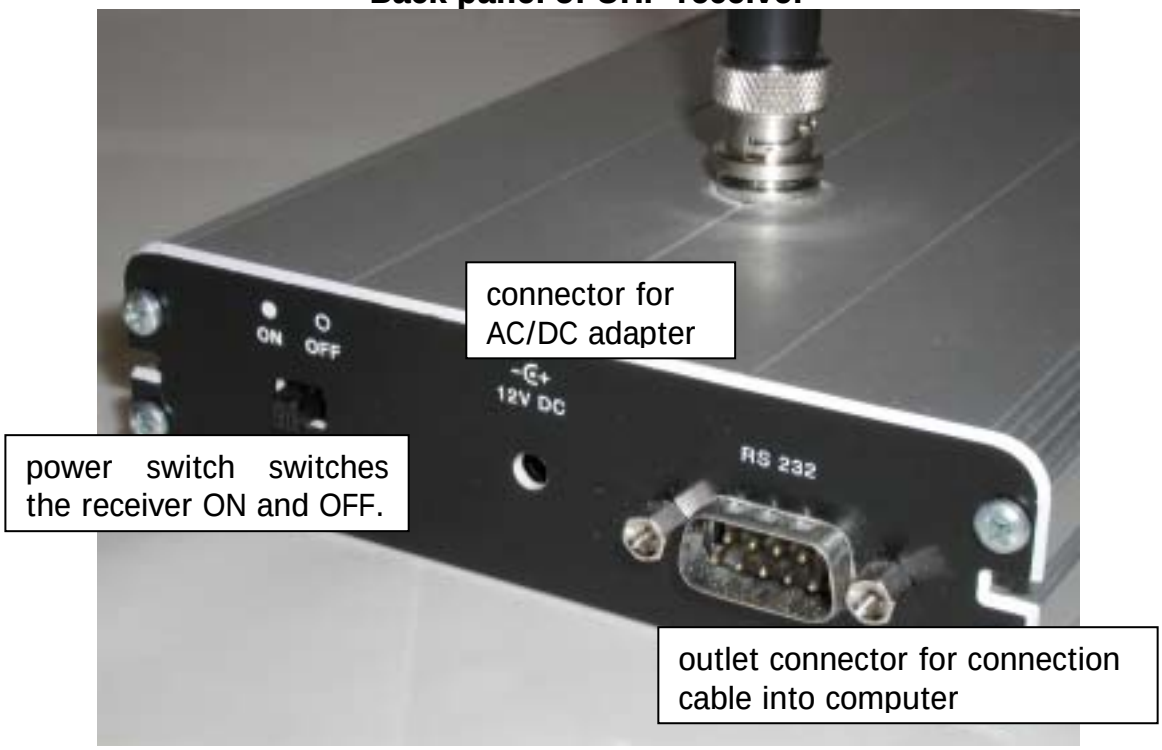
Back panel of UHF-receiver



AC/DC adapter: (complies with IEC 60-601).

Important notice:

- Testing of functionality is **only** possible when the **whole system is in operation**, i.e., the *transmitter* broadcasts regular signals -- the yellow LED diode is regularly blinking according to the current patient's heart rate, the *receiver* is on /yellow diode/ and receives data /green diode/, and it is connected to a computer on which the respective program is running.

2.2. Other Components / Printer

By arrangement, the systems can be delivered with an IBM-PC compatible computer and monitor. Minimum operation system requirement is a MS-Windows version 98 or higher.

When installing the program on to a PC, it is highly recommended to dedicate this computer only to measurements of the autonomic nervous system. If the system is installed on a computer that is used for another purposes, there is a risk that software conflict may occur. In this case the manufacturer of VariaCardio TF5 cannot be held responsible for any damage incurred to the system and its use.

The system runs with any standard (commonly available) printer. For better documentation results it is recommended to use an ink-jet or a laser printer. For professional presentations it is highly recommended to use a colour printer (ink-jet/laser). After software installation check the appropriate printer installation (see Chapter Options/Adjustment).

2.3. AC/DC Adapter for a Transmitter Battery and Guidelines for its Charging

The transmitter contains a battery (3.7V Li-Ion), which provides a minimum of 24 hours continuous operation. For charging, use exclusively the AC/DC adapter supplied.

Charging:

- Plug in the AC/DC adapter's connecting cable into the input socket located in the bottom panel of the transmitter.
- Plug in the mains cable of AC/DC adapter into the mains supply: the control green diode on the adapter turns ON and the charging LED-diode on transmitter also turns to green. After the battery is fully charged, the green diode turns off and another LED-diode on the front panel of the transmitter turns to yellow.
- The charging process is controlled by electronics in the transmitter; there is no risk of damage to the battery.

IMPORTANT NOTICE: While charging, the transmitter must *not* be used on a patient!

2.4. Production, Testing, Warranty and Technical Support

The electronic components in the transmitter use surface mount technology. Prior to final assembly, the circuits are checked and the whole system undergoes an 8-day uninterrupted burn-in test with all functions tested.

Warranty:

Advanced Medical Diagnostics Group (AMDG) guarantees the VariaCardio TF5 when new, to be free of defects in material and workmanship and to perform according to the manufacturer's specifications for a period of one year from the date of purchase from AMDG or its authorised distributors or agents. AMDG will replace any components found to be defective or at variance from manufacturer's specifications within this time. It shall be the purchaser's responsibility to return the instrument directly to AMDG or its agents, post-paid.

This warranty does *not* include cables, batteries and other accessories that are not products of AMDG. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is void if the system is not used in accordance with the manufacturer's recommendations. This warranty is void if unauthorised or unqualified persons attempt to make repairs. The warranty entitles the owner of the equipment to replacement of the part(s) or unit at AMDG's discretion. Purchase date determines warranty requirements. In the case of a defect or other warranty service, please call the authorised distributor AMDG for a Return Material Authorisation Form and return the unit post-paid directly.

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The software is not guaranteed to function in every application or with non-standard hardware and software. The warranty does not extend to damage to equipment resulting from alteration, misuse, negligence, abuse, accident, unauthorised service, vandalism or acts of God. A yearly check-up in AMDG or its authorised centres is recommended; check of the system once in 2-years period is requested. Please contact an AMDG representative for more details.

Technical support:
Is provided Monday to Friday (9am – 5pm UK time). Repairs are normally made within 72 h (excluding shipping and other relevant operations), by replacing the defective part/or the whole device, during the warranty period free. After the warranty period, repairs will be billed according to the current company pricing policy. The above mentioned technical support is exclusively provided by AMDG or its authorised partners.

Helpline:
Advanced Medical Diagnostics Group provides a **help line** for all your technical and other questions Mon-Fri between 9:00 AM and 5:00 PM of UK time:

Phone:	+44 (0)113 279 1010
Fax:	+44 (0)113 2310 820
Website:	http://www.amdgmedical.com
	http://www.mie-uk.com
E-Mail:	TF5@amdgmedical.com

3. VariaCardio TF5 Program Principles & Control

The VariaCardio TF5 *(a) hardware* is operated by using the power switch buttons located on the transmitter and receiver and *(b) software* by program commands, see below. Switch each button slowly and firmly, then release and check the corresponding LED diode is on/off.

3.1. What the Switch Buttons Mean

(1) On **transmitter**: Turns the transmitter on and off (please be sure that the transmitter is switched off after the examination)
(2) On **receiver**: Turns the receiver on and off

3.2. What the LED Diodes Mean

(1) **Yellow LED diode on transmitter.** After switching on, the transmitter informs on occurrence of every detected R wave (heart beat) by short blinking of yellow LED diode. Usually, the diode blinks in *regular* intervals around 1 second.
If an artifact / ectopic beat is detected, *irregular* blinking occurs. Typically, this might happen when changing the examination position. In an extremely rare case, a quick irregular blinking might mean a severe cardiac arrhythmia. Therefore, in such cases immediately check the ECG signal and provide appropriate diagnostic/therapeutic steps.
Green LED diode on transmitter is activated when the battery in the transmitter is charged. When the charging process is finished, the green LED diode turns off and the yellow LED diode constantly lights instead.
It is acceptable to leave the AC/DC adapter connected to the transmitter after the charging is finished as the electronics within the transmitter prevents any overcharging automatically.
(2) **Yellow LED diode on receiver** shows the receiver is on.
Green LED diode on receiver displays transmission/reception of data.

3.3. What is the Normal Operation Setting

- **Chest belt** is positioned on the patient (for details, see the How to adjust the belt chapter) and UHF-transmitter is switched on.
- **UHF-receiver** is switched on, antenna is mounted on the top.
- There is a **connection cable** between back panel of UHF-receiver and COM1/COM2 port on the back of PC.
- AC/DC adapter is plugged-in, **adapter cable** is plugged into the back of UHF-receiver.
- Heart rate variability **program** runs on a dedicated computer with appropriate operation system.

During the normal operation the system shows regular short blinking of *yellow* LED-diode on transmitter with *green and yellow* LED diodes on receiver constantly being

on, while on the PC screen one-channel ECG signal with corresponding R-R intervals and on-line spectral curve are being constantly refreshed.

4. Operating the VariaCardio TF5

4.1. How to Install the Software

Note: Your VariaCardio TF5 system is usually installed & configured by an experienced manufacturer's technician or by one of authorised distributors so that it is ready for use. In this case you can skip this section and proceed directly to next Chapter **4.2. How to launch the application.**

Important note:
It is strongly recommended that a dedicated computer be used for measurements of the autonomic nervous system as a conflict with other software installations may occur. In this case the manufacturer cannot be held responsible for any possible problems.

Installation details:

The VariaCardio TF5 software must be installed onto your PC before it can be used. Launching the installation wizard from our CD-Browser is extremely straightforward.
Note: To avoid any potential conflicts during installation, before launching the installation wizard, it is recommended that you close any applications you are working in. It is also good practice to make a complete backup of your system and your critical documents/data/files to guard against any possible damage/loss.

1. Insert the supplied CD-ROM into the CD-ROM drive of your computer.

Within a few moments you should be presented with the CD-Browser pictured opposite.

Should the CD-Browser fail to launch automatically it is possible the 'AutoPlay' facility has been disabled on your computer. In this case you must launch the CD-Browser manually:

Browse the CD contents by double-clicking on the 'My Computer' icon of your desktop followed by your CD-ROM icon. Then locate and double-click on the file 'Menu.exe' (may simply be displayed as 'Menu').

2. Clicking 'Install Products' will display a list of programs supplied on the CD for installation:

To begin the installation process, click 'VariaCardio TF5', launching the Installation Wizard. Refer to the Installation Wizard section of this manual for details on the installation process.

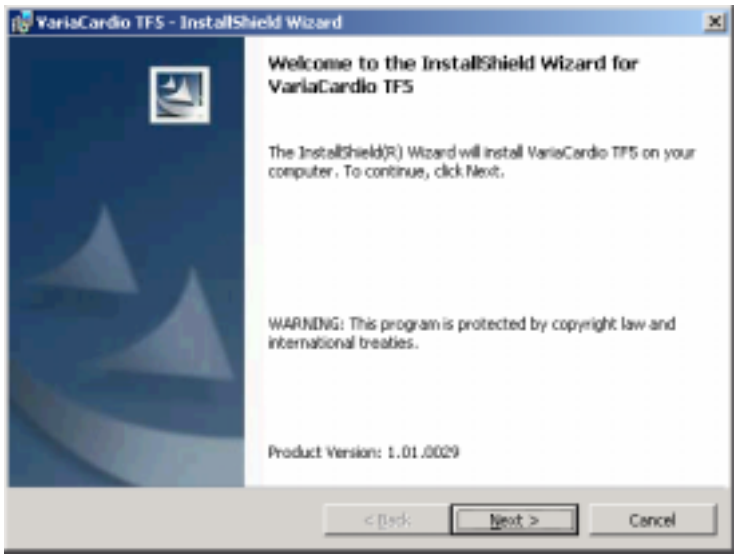
Once the installation process is complete you must click 'Menu' to return the opening page. Here you may choose to review our website or register the software.

3. Finally, click 'Exit' to close the CD-Browser.

Installation Wizard

The VariaCardio TF5 software must be installed onto your PC before it can be used. Once installed you may use the software without needing the CD-ROM. You must ensure your PC meets the minimum requirements and provides the necessary ports (see the 'Requirements' section for more information).
The installation wizard is supplied on your CD-ROM and may be launched from the CD-Browser. Alternatively, updates may be downloaded via the internet or emailed from our support team; these are simply launched directly from where you saved them.
Note: To avoid any potential conflicts during installation, before launching the installation wizard, it is recommended that you close any applications you are working in. It is also good practice to make a complete backup of your system and your critical documents/data/files to guard against any possible damage/loss.

Having launched the installation wizard, proceed as follows:



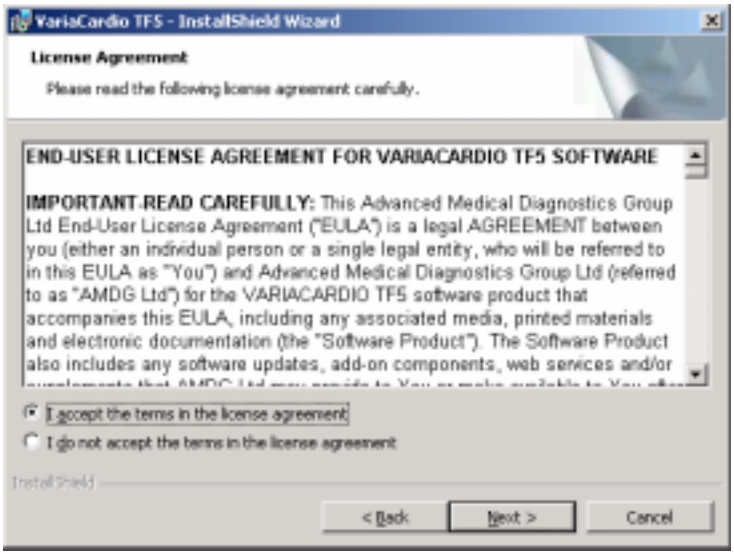
1. After some internal preparation, the installation wizard welcomes you and confirms the application to be installed. Click 'Next' to proceed with the installation.

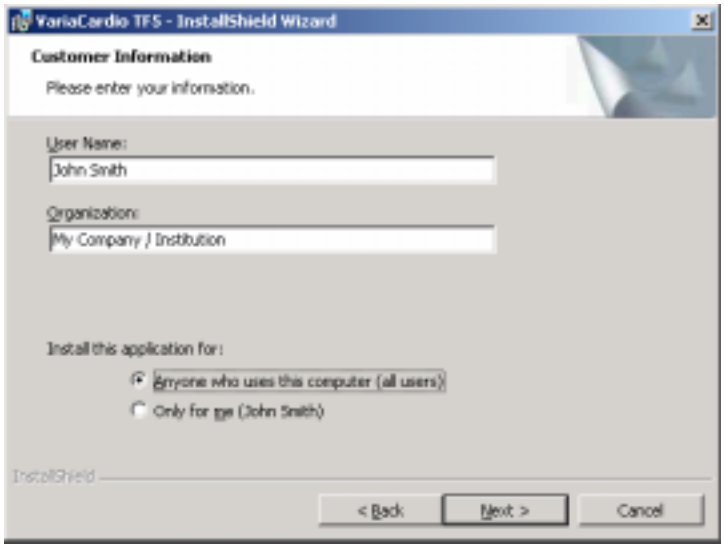
   Important: On some systems, the Microsoft Installer may need to update critical system components before the installation wizard can proceed. You may be prompted to restart your computer, after which the installation wizard will automatically resume and proceed as normal. In extreme cases

multiple restarts may be required.

2. You will be presented with the end-user license agreement which you should read carefully. Use the scrollbar and arrows at the right hand side to scroll down the document.

   In order to use our software you must accept the terms in this agreement. Click the button noting your acceptance ('I accept…'), then click 'Next'.





3. Please complete the fields prompting for your customer information for registration.

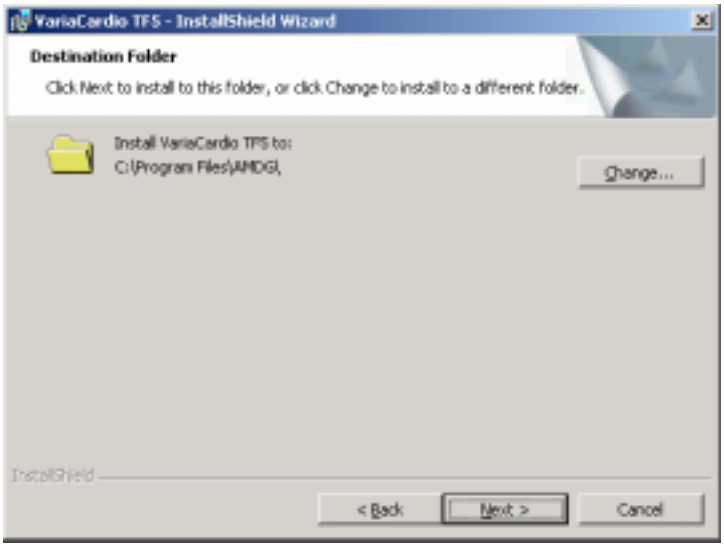
4. You may select which users the application is made available to (useful for corporate or institution users). Selecting 'Only for me' avoids the software being placed in other users' start menus, but does not prevent them manually launching the software directly. If you are uncertain, you should accept the default selection. Note: *'All users'* may require you to be logged in with administration privileges (consult your administrator).

5. Once you are happy with the information entered, click 'Next' to proceed.

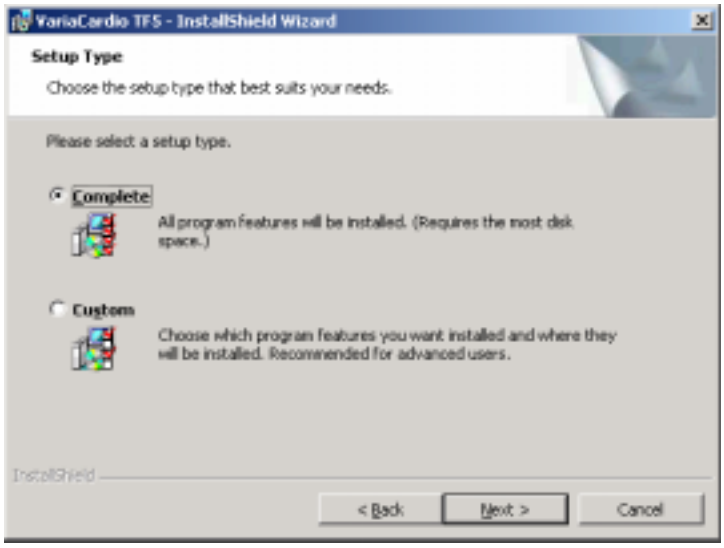
6. You may choose where the application should be installed:

   Should you wish to install to a location other than the default, click 'Change' to select an alternative location.
   Note: If installing for *'All Users'* you must select a location available to every user bearing in mind their privileges.

   Once you are happy with the install location, click 'Next' to proceed.



7. You may select the type of installation to be performed, then click 'Next' to proceed.

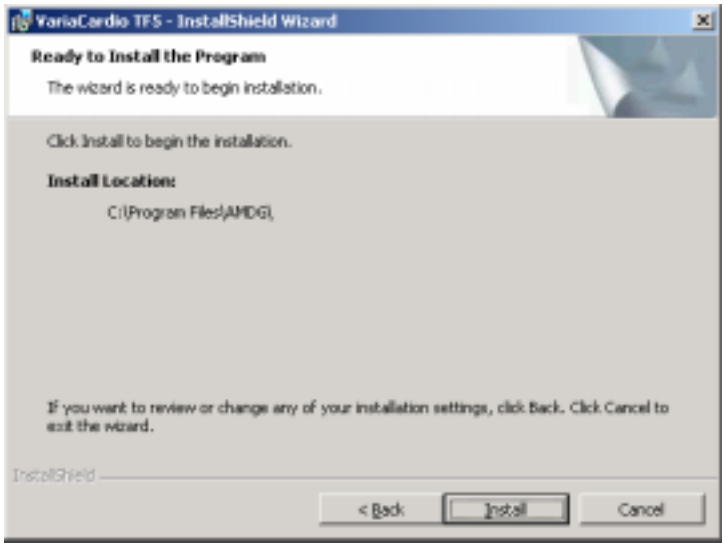


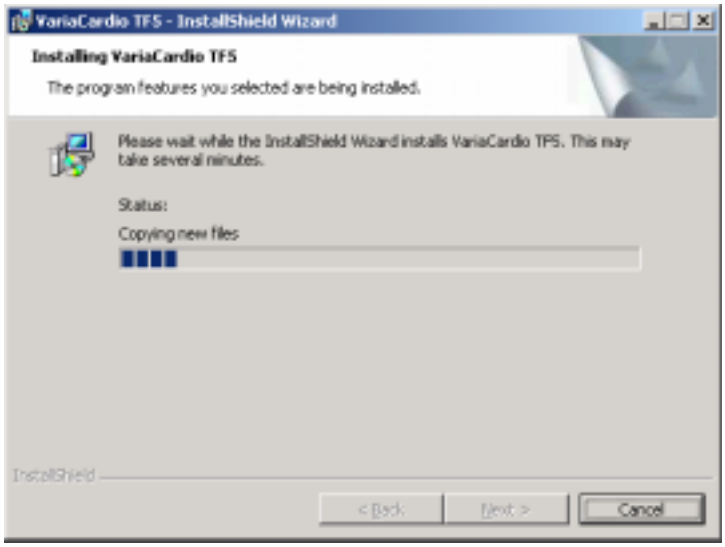
Complete installation installs the full application with all features, help, manuals & tutorials.

Custom installation allows you to select exactly which features are to be installed and the individual install location of each component. Note: Custom installation is only recommended for advanced users and is not documented here.

8. The wizard has ascertained all the necessary details to begin installation. This is your final chance to review the summary of the options you have selected.

   Click 'Install' to begin the physical installation process. Alternatively, if you would like to review/change any of the options use the 'Back' button to backtrack through the selection process.

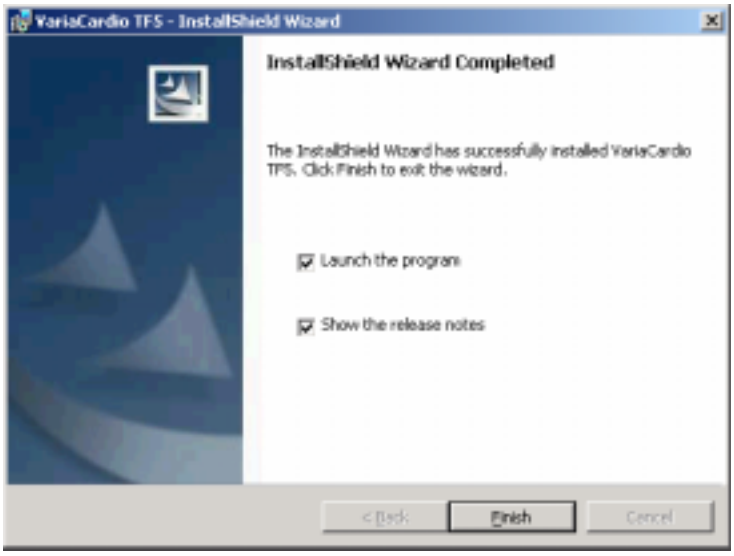




9. The features you selected will now be installed. Please wait while the process completes. This task may several moments.

Once complete, the wizard will inform you as to the success of the operation.

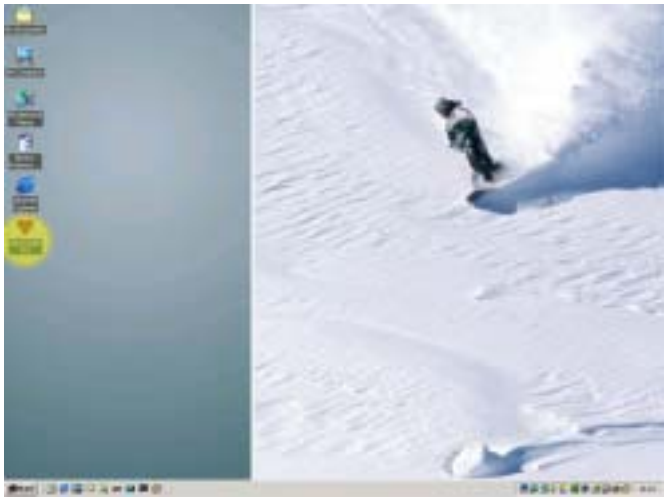
10. Typically you can click 'Finish' to exit the installation wizard. Note, however, if some files in need of updating were in use, you may be prompted to restart your computer. These files will then be updated during the restart and the wizard will exit automatically.



The checkboxes allow you to launch the application upon exiting the wizard and give you the opportunity to review the release notes which outline any last minute addendums to the manual and provide information on any fixes, enhancements or known problems with the release.

4.2. How to Launch the Application

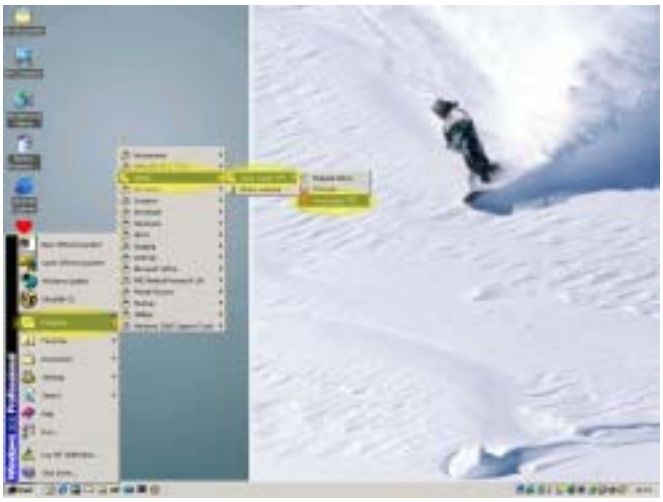
Once installed, the VariaCardio TF5 software can be launched from your desktop or start menu.



From your desktop:

1. Locate and double-click on the 'VariaCardio TF5' program icon on your desktop (here highlighted in yellow).

   N.B. Depending on your settings, it may only be necessary to single-click the icon in order to launch the application.



Alternatively, from the start menu:

1. Click on the 'Start' button.
2. Click on the 'Programs' folder from the list.
3. Click on the 'AMDG' folder.

N.B. Depending on your settings, this entry may appear at the foot of your list rather than in alphabetical order.

4. Click on the 'VariaCardio TF5' folder.
5. Click on the 'VariaCardio TF5' program icon.

4.3. How to Adjust the Belt

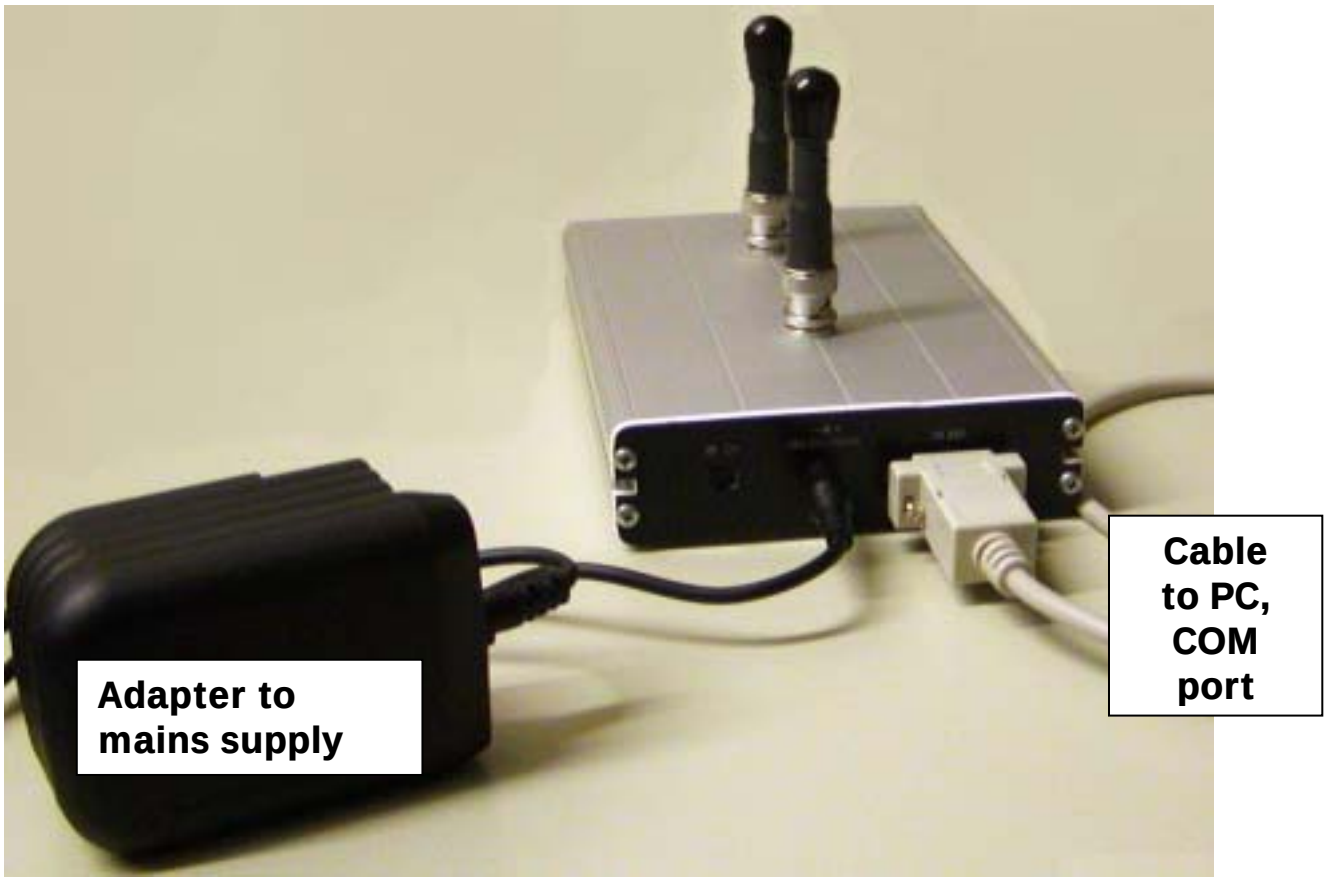
It is important to adjust the belt on the patient's chest so that the transmitter is located exactly in the middle of the thorax. If the original signal is not obtained correctly, the LED diode on the transmitter blinks irregularly or not at all. If this happens (assuming that there is NO cardiac arrhythmia), the reason could be that the electrical heart axis is shifted. In this case, it is recommended to shift the whole transmitter belt to the left so that a signal is regularly transmitted again. Rarely, in some cases, it may be necessary to turn the whole thorax belt upside-down so that the red electrode is on the right side. You can check the general quality of the signal on the monitor in the option/display "Hardware info" in the basic screen. Usually, an optimal ECG signal should have a high, dominant, positive R-wave.

☞ Summary:

1. Adjust the chest belt on the patient's chest (as described above, see the photo)
2. Switch the power on the transmitter
3. Check the regularity of the yellow LED-diode signal on the transmitter and adjust the position of chest belt if necessary
4. Switch the power on the receiver
5. Start the program and check the ECG/heart rate display on the monitor in the "Hardware info" option. Afterwards, start measuring.

4.4. How to Adjust the Communication Receiver/Computer:

The most commonly used communication port is COM1. The default is set to COM1. The program automatically checks for available communication ports and shows them in the "Engineering" option, should you wish to manually adjust.



4.5. How to Enter the Data and/or to Control the System

Using the keyboard: simply press the key with number or letter as indicated, or use the arrow /Tab keys to change the position on the screen and press ENTER afterwards.

Using the PC mouse makes some tasks easier: where available, simply click with the left mouse button on the symbols/icons on the screen as displayed. While browsing the heart rate record, simply click on an appropriate heartbeat in order to mark or select it.

"CTRL" + "KEY"

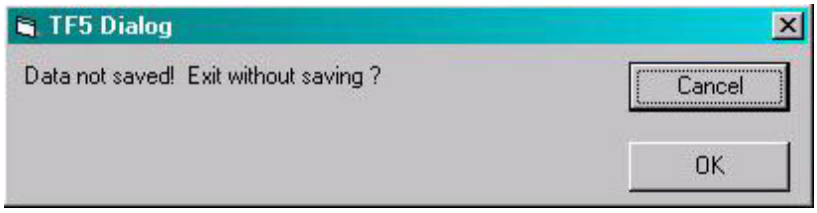
Using the 'hot keys' enables by pressing a certain combination of two keys (mostly CTRL or ALT + letter/number, see the underlined letters in various program menu options) to activate a certain procedure. Where possible, for experienced users this allows more fluent program operation while avoiding time-consuming positioning of mouse on the PC screen or using arrow keys.

5. Clinical Use of the System: Database

5.1. Before We Start

Generally, within the program, you can move using the standard **keyboard** keys *⇧, ⇩, PgUp, PgDn, Home* and *End*, **or** using the left button of the **mouse** (by clicking directly on selected record **or** by clicking on icons on the screen).

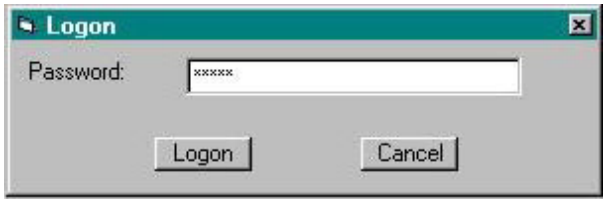
Also other **standard Windows icons and commands** work as usual, like icons for manipulation with active window (e.g., close, minimize, restore window) etc.

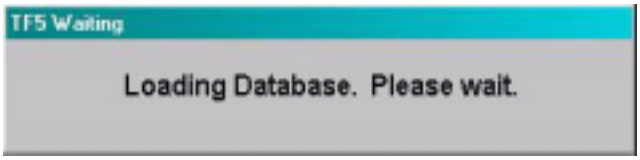


Important program steps are 'guarded' by **alerts/warnings**. These short hints help the user to prevent mistakes and/or errors in data handling like e.g., cancelling the data recording too early, omitting data saving, exiting the program inappropriately etc.

5.2. How to Start the Program

Double click on the "TF5" icon on the desktop. A "**Welcome window**" appears and you are prompted to enter the password that protects the program and data against unauthorised use (if function activated in 'Engineering' menu).



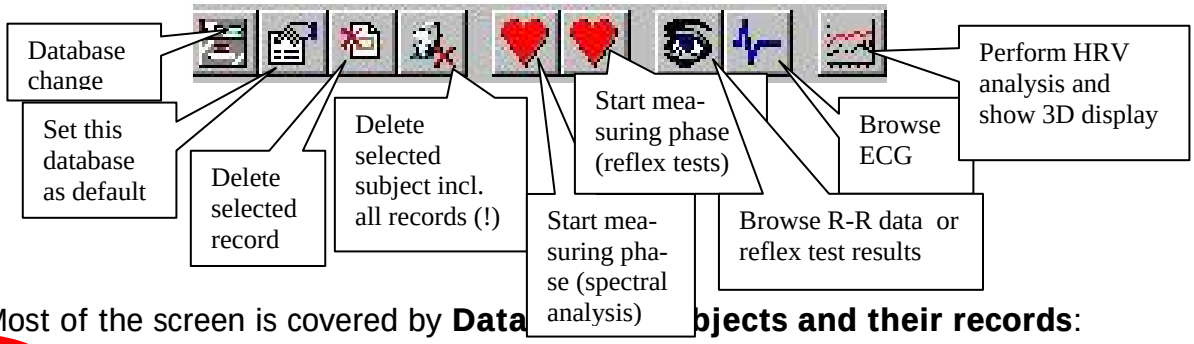


After entering the password, click on "**Logon**" button; that is followed by the message "**Loading Database, Please wait**" (this might take several seconds accordingly to the size of database). Finally, a basic operation screen appears. The usual way to get started with the program is to create or select an existing subject record in the **Database**. In this program option, you can *add, search, read, change* or *delete* any information relevant (for further information see next chapter).

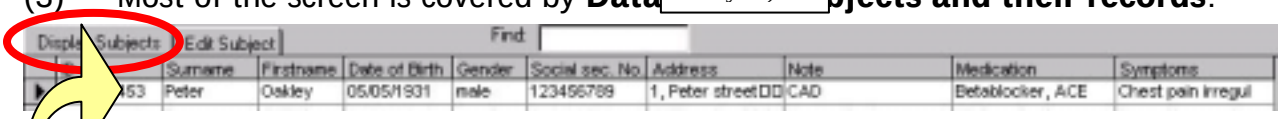
5.3. The Basic Operation Screen

(1) The first line displays **main program options** – *Database* processing, HRV *Measuring*, *Browsing* and *Analysis* sections, *Engineering*/program adjustments and *Help* files. Using hot keys "ALT" + appropriate letter (as underlined) **or** clicking on the option allows you to activate the submenu. You can also use the program icons, see description below.

(2) The second part below this menu includes **program icons** that generally correspond with the main program menu in the first line. Whilst the basic screen shows the database of subjects, some additional icons/options for *database handling* can be found in this menu (Database change, Setting database as default, Deletion of current/selected record and Deletion of current/selected subject). Further, all icons for *data processing* (Data recording, Data browsing and HRV analysis/3D Display) are located there, as well.



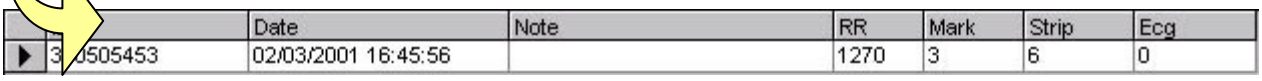
(3) Most of the screen is covered by **Data** [illegible] **bjects and their records**:



Program option "**Display Subjects**" allows the display of all subjects found in a selected database, these may be sorted into order by clicking on/highlighting the relevant item column. Each **database subject record** consists of

(a) **personal data**/items (see above – ID, Surname and first name, Date of birth, Gender, Social insurance No, Address and three user-adjustable free text fields) and

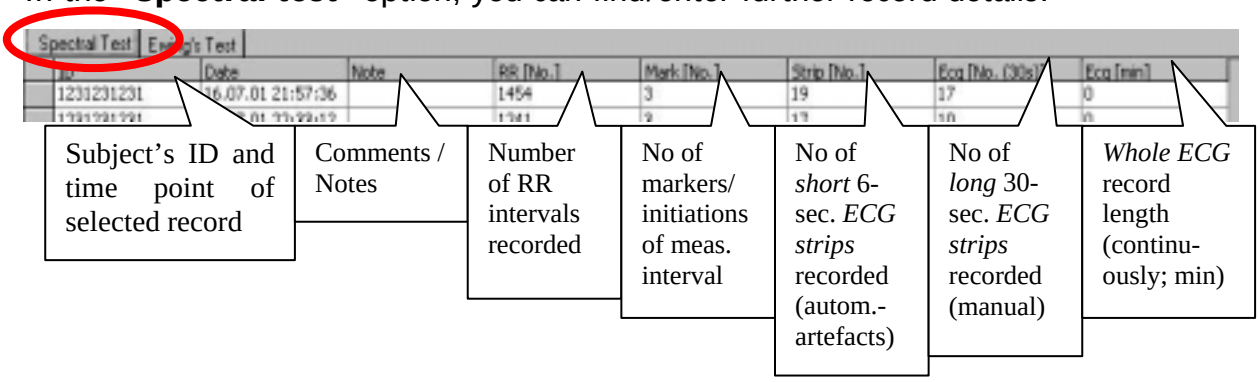
(b) **test data - heart rate variability and/or one-channel ECG record** (see below). Record details relating to the selected subject are shown in a separate window *below* the main database window.



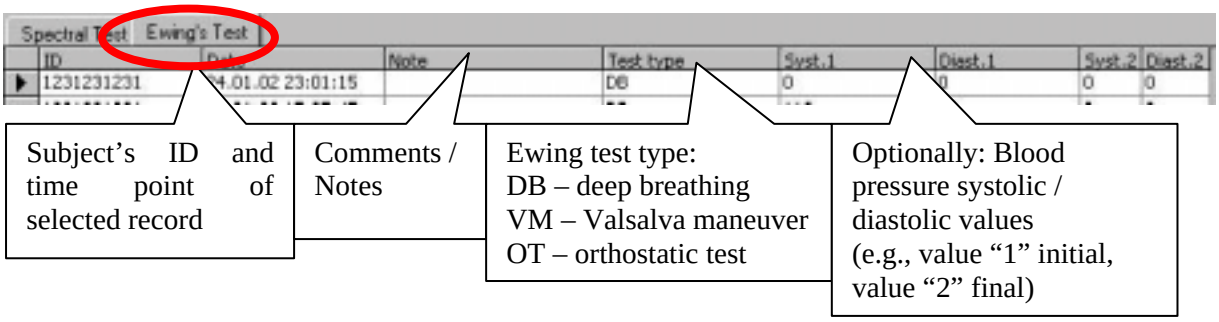
In accordance with used test category, it is possible to process **spectral analysis** /frequency-domain/ -- as obtained during modified orthostatic load -- or a battery of short cardiovascular reflex /time-domain/ tests (so called **Ewing battery**, named after its author, DJ Ewing). To choose one, just click on the test type option -- "Spectral Test" or "Ewing's Test".

(c) 2001-2003 Advanced Medical Diagnostics Group, Ltd

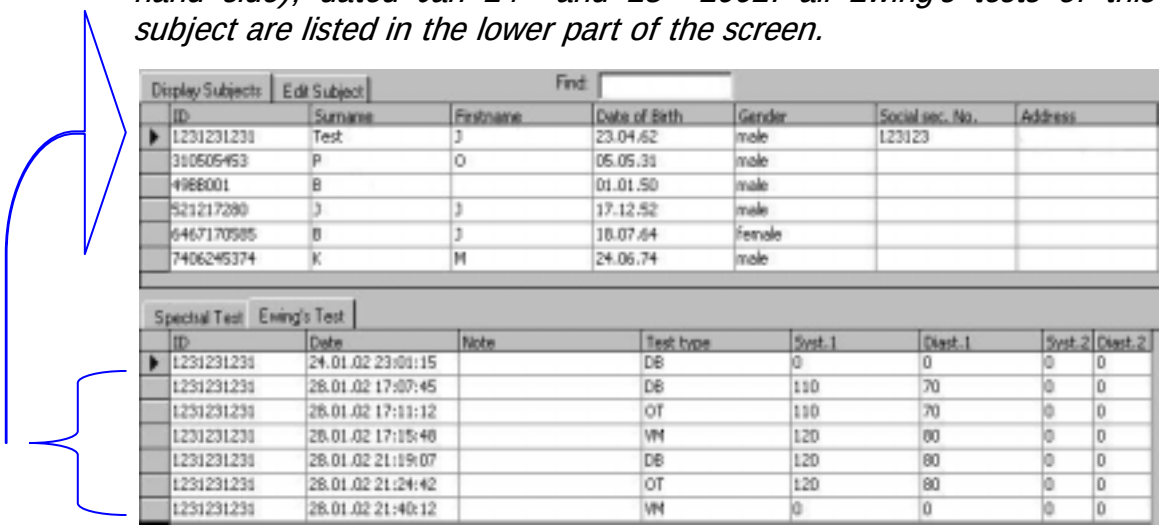
In the **"Spectral test"** option, you can find/enter further record details:



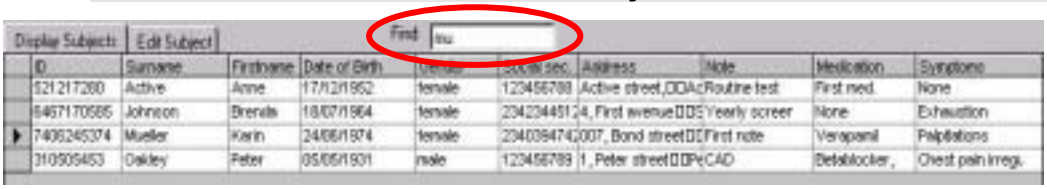
In the **"Ewing's test"** option, following record details can be found/entered:



Practical example: *The following screen shows an example of reflex tests (Ewing's) battery recorded in subject Test J (for subject's details see the upper panel of the screen with a small black arrow at the left-hand side), dated Jan 24th and 28th 2002: all Ewing's tests of this subject are listed in the lower part of the screen.*

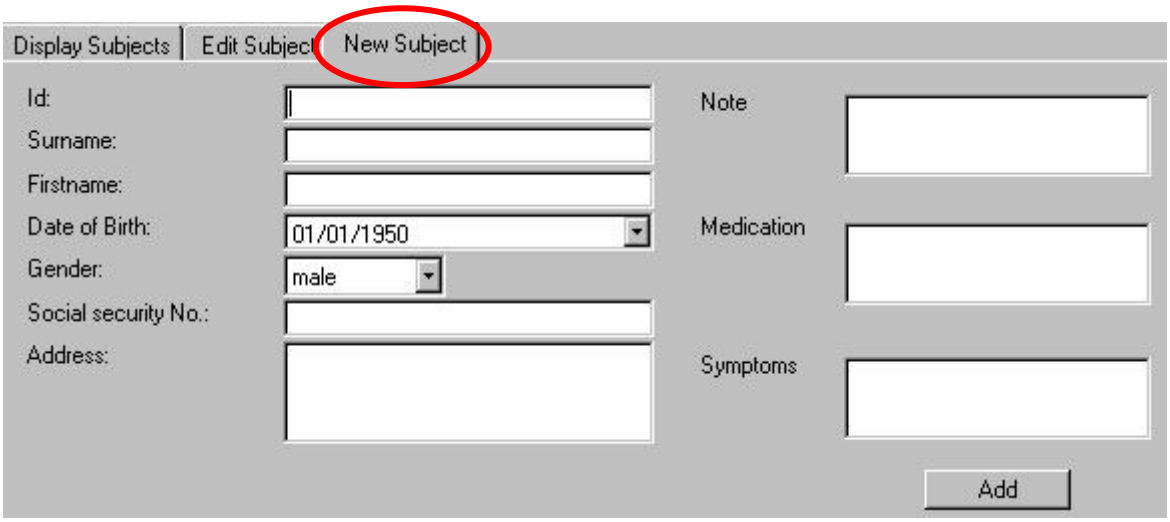


5.4. Database: How to Find a Subject

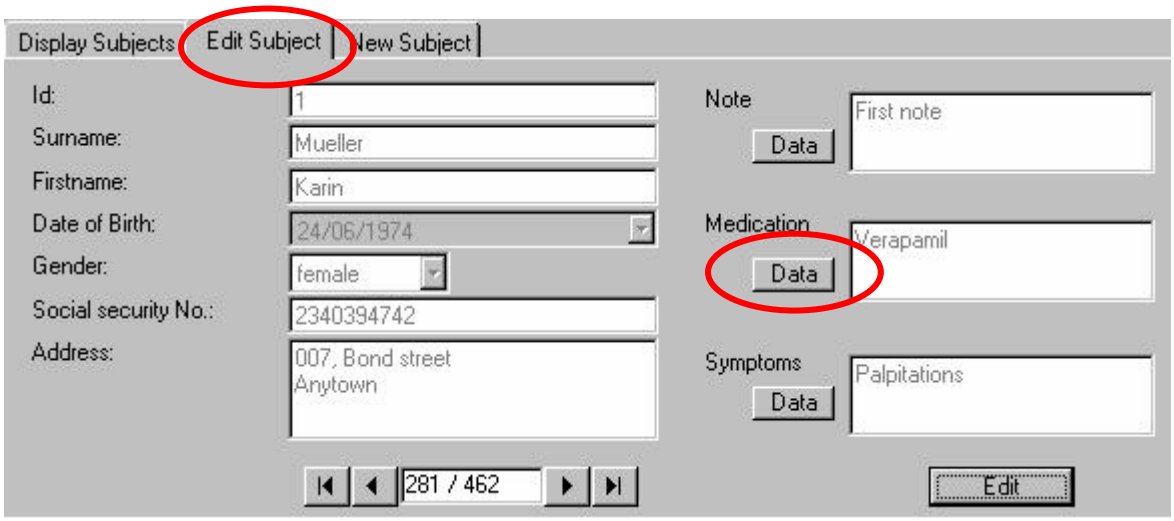


By entering the first digits of ID or surname letters into the field "**Find**" located just above the Database headings it is possible to find quickly the requested subject. The corresponding subject's personal record is indicated by a small black arrow on the left-hand side in the Database window. Below the Database window, in the Records section, the subject's first recorded HRV data is marked, as well. In further data processing, it is possible to *browse personal data, HRV data* or to *analyse and display the HRV data* of selected subject's record.

5.5. Database: How to Add a New Subject Record

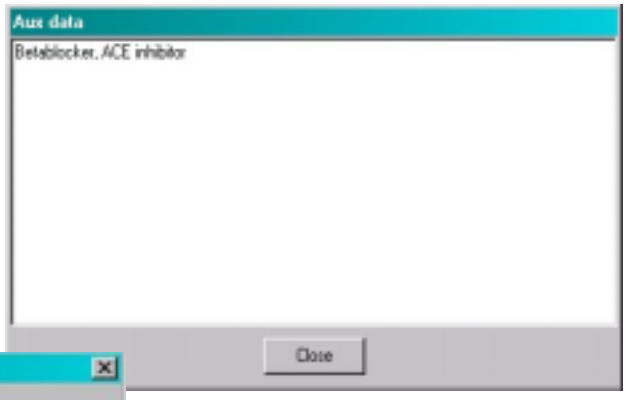


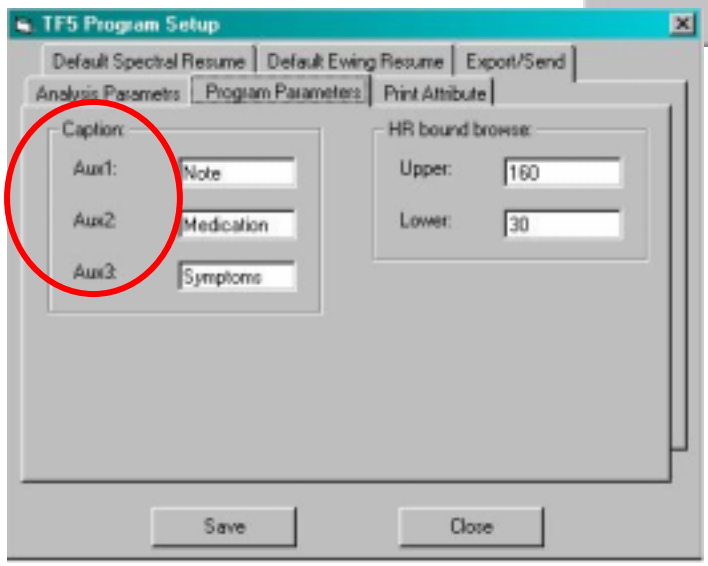
- Click on **New Subject** sheet: a single screen with personal data of the selected subject is displayed, see above. Here it is possible to enter data of a new subject. On completion, various standard fields (see above) can be entered while the ID No, Surname, Date of birth and Gender are requested items. ID checker prevents entering identical ID or omitting to enter the ID at all. Date of birth can be selected in a calendar that becomes available by clicking on the arrow in this field, or it can be entered in format dd / mm / yyyy. Gender options can be selected by clicking the arrow in the Gender field, as well. When finished, click on **Add** button to store the data.



- **Edit** option: Allows you to edit the already entered data. Click on **Edit** button opens access to all information with exception of ID. When finished, the new information on subject can be **Cancel**ed or **Update**d using the corresponding buttons.

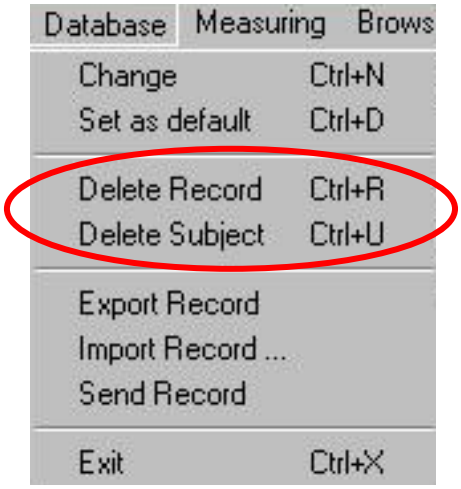
By clicking the **Data** button at the right-hand side, you can open an auxiliary data window where free text information can be entered. Three Aux data windows are provided for each subject. In the main program menu **Engineering**-> submenu **Program Setup**-> option **Aux Caption** it is possible to adjust titles/headings of these auxiliary data windows.





Bear in mind, please, that the newly added / edited subject's data must be **always saved** = "updated" before any further processing is done: use the **Update** button on the screen. If you want to cancel the editing, simply by pressing the **Cancel** button.

5.6. Database: How to Delete a Record / Subject



Mark subject's **record** to be deleted by clicking on the record with left mouse button. A small arrow at the left-hand side of database records listing appears. This arrow identifies the record to be deleted by

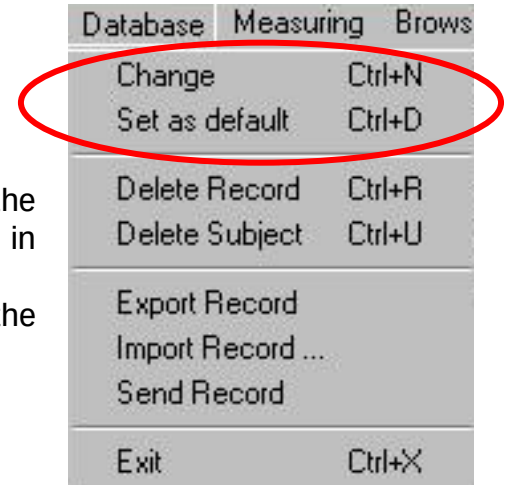
- Clicking on Delete Record icon **or**
- Selecting in main program menu: Database -> Delete Record **or**
- Pressing CTRL + R keys together.

Similarly, the database **subject** can be deleted completely -- including all records -- by

- Clicking on Delete Subject icon **or**
- Selecting in main program menu: Database -> Delete Subject **or**
- Pressing CTRL + U keys together.

In both cases, a security alert appears in order to guard such (sometimes unintended) action – see below. Just confirm, please, your decision.

5.7. Database: How to Change the Database / Create a New Database



- Click on Change Database icon **or**
- Open the Database menu, here click on -> Change **or**
- Press CTRL + N keys together

Then -- in the **Open database** window – either enter the file name of the database to get opened or highlight it in a listing and click on **Open** command.
Similarly, if creating a **new** database, enter simply the name for the new database and click **Open** command.

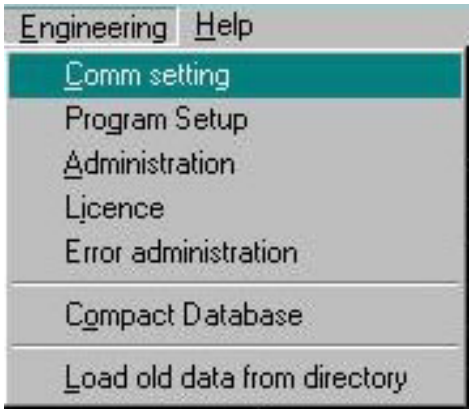
5.8. Database: How to Set the Database as Default

- Click on Set as default database icon **or**
- Open the Database menu, click on -> Set as default option **or**
- Press CTRL + D keys together

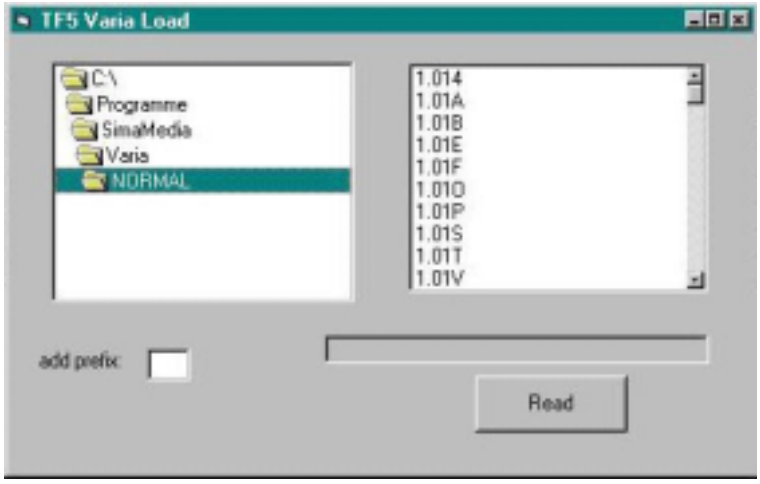
During starting procedure, program will automatically call this default database.

5.9. Database: How to Import Data Obtained by Previous Models

It is possible to import data obtained by previous generations of VariaPulse® TF3 and VariaCardio® TF4 systems so that you can individually compare progress of findings over years. To do this, open **Engineering** submenu in the Main program menu. Here, highlight the last option **Load old data from directory**. Alternatively, press CTRL + L.



Then, in the "Varia load" window select the subdirectory and/or files to be downloaded and press **Read** button. Progress in data downloading is shown graphically. When finished, close the window. Newly downloaded files are displayed in the currently selected database. Be aware, please, that older files obtained by TF3 and TF4 systems are formatted differently from the present database. It might be necessary to edit the subject personal data (surname, date of birth etc.) before the downloaded files can be processed.

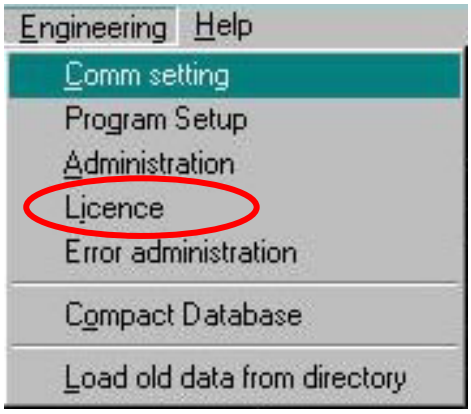


5.10. Database: How to Compact the Database

From time to time it is useful to compact the database so that the data access is quicker and database size gets smaller. To do this, click on Engineering and select **Compact database** option (**or** press CTRL + O keys, see the figure above). The process can take several minutes if the database is big, so please be patient.
We strongly suggest you to store a database copy separately from your computer.

5.11. License, Hardlock, Data Protection & Business Issues

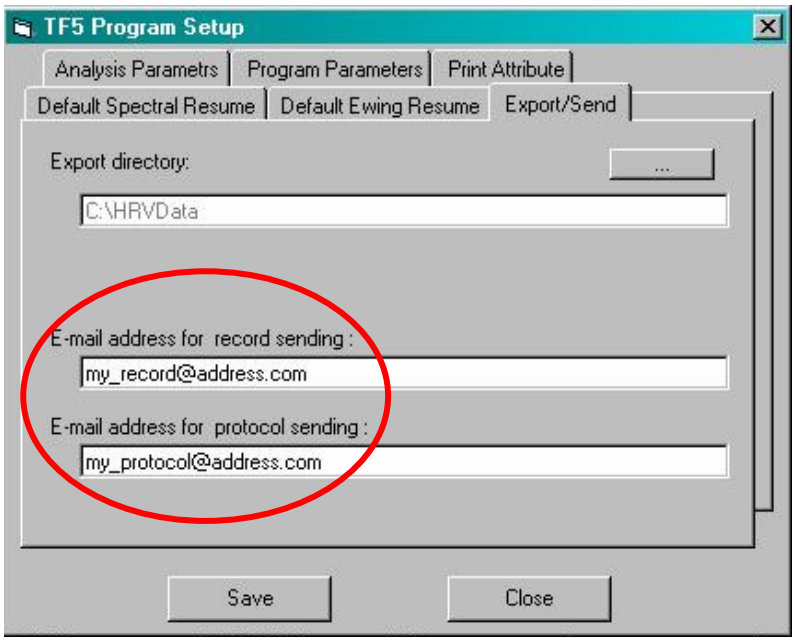
In order to maximally protect your sensitive data and the know-how of the system, a special programmable, hi-tech hardlock is to be connected when using the system VariaCardio TF5. This hardlock is connected with the PC via standard printer port that can be found on the back of the computer. A "free" version of the TF5 program – that does *not* require use of the hardlock -- allows browsing the pre-recorded demo data and its 3-D display & analysis only. All other practical steps in clinical use of TF5 require connection with the hardlock that includes license data specially pre-programmed for the individual user in order to allow her/him to make a maximum use of the system in accordance with her/his business model. Some relevant user-specific data (see below) are downloadable from the connected hardlock in the main menu section **Engineering → License**.

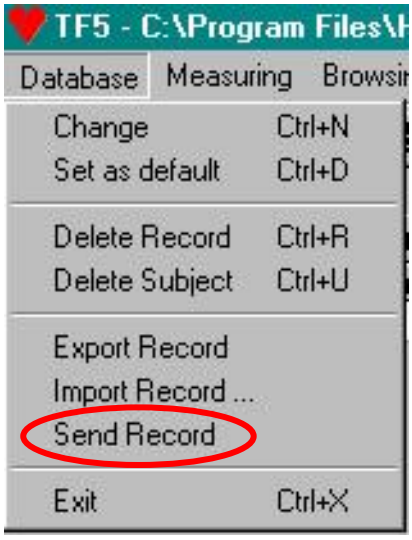


Important notice: Bear in mind, please, that programming the hardlock as well as adjustment of your TF5 system license conditions require – at least initially -- **presence of AMDG or its authorised representative**. Therefore, we **strongly suggest you to consult** any step regarding such license manipulations in advance. Otherwise, AMDG or its partners *can not* be held responsible for any direct in indirect damage potentially occurring in this respect.

5.12. How to Send Records and Protocols via E-mail

Separate HRV records and/or complete examination protocols with comments can be sent in encrypted form in order to enable consulting the data with the Remote Analysis Centre and/or to facilitate delivery of the complete examination protocols to related subjects. To do this, it is necessary first to adjust the e-mail addresses for data exchange in the **Engineering** -> **Program Setup** -> **Export/Send** option:

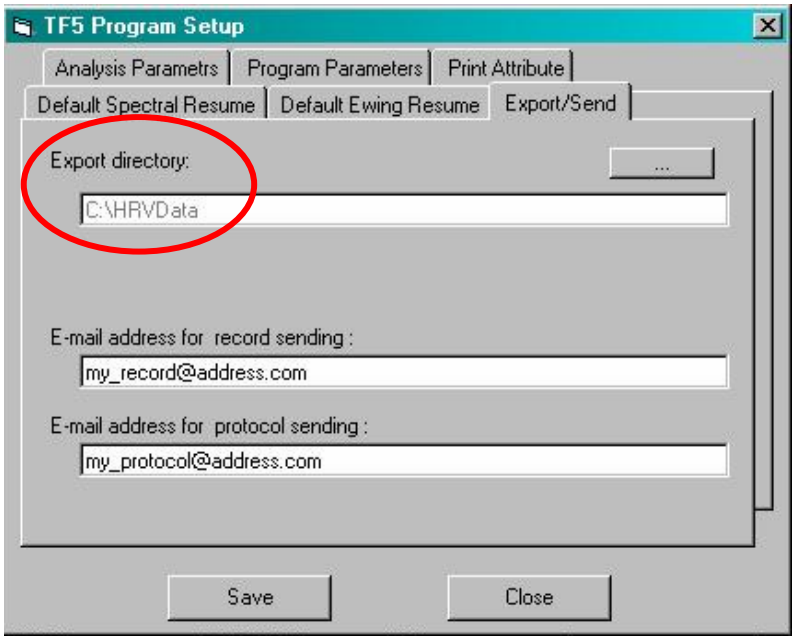




Then, select/mark the record to be sent - simply by moving the arrow at the left/hand side of the basic database screen (name of the subject in the upper part of the screen, individual record/s in the lower part). Afterwards, selected HRV data can be sent via a standard e-mail program (MS Outlook) by choosing option **Database -> Send Record**. Whenever connected to Internet, the data will be automatically sent to the address indicated in the Setup.

5.13. How to Export and Import HRV Records

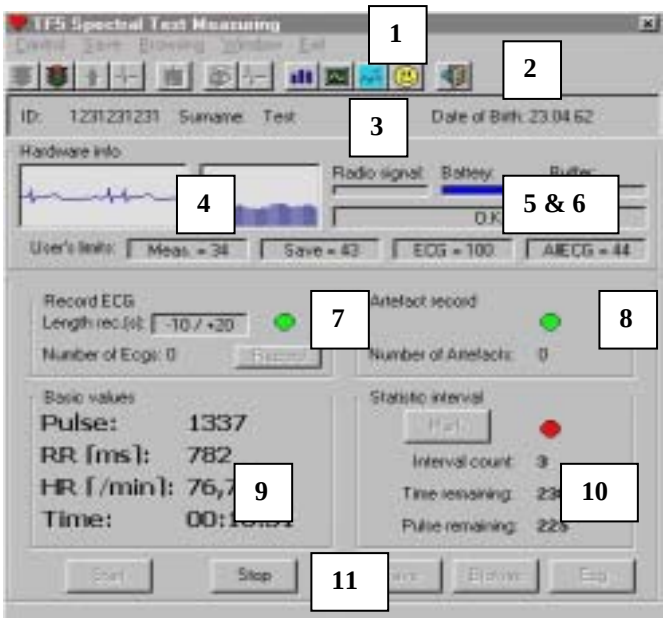
Using **Database->Export Record** or **Import Record** option it is possible to manipulate the selected record of chosen subject. This is typically done e.g. when the HRV record is to be further processed separately (export) or a record from a different database is to be imported into another one (import). The newly generated file can be found in the export directory as adjusted in the **Engineering -> Program Setup -> Export/Send** option.



6. Clinical Use of the System: Measurements

6.1. Measurements: Spectral Test Measuring Screen

In the basic operation screen, click on icon Measuring (**or** press CTRL + S **or** open Measuring option in the main program menu and select 'Spectral test').
New screen **Spectral test measuring** is displayed with following main sessions:



(1) **Commands menu** including submenu items Control, Save, Browse, Window and Exit.
(2) **Icons menu** corresponding with the above, including additionally Start and Stop, Interval marking, Record ECG icons etc., for details see below.
(3) **Subject identification** with ID, Surname and Date of birth items.
(4) **Hardware info** shows the current quality of data transfer/ECG in *left* window and progress of heart rate over recent time in the *right* window.
(5) **Radio signal** quality indicator, and **Battery** status show current state of these items.
(6) **Alert window** below the radio signal and battery status indicators informs you of system configuration and of possible errors (e.g., alert 'Receiver switched off...'). A strip with information "OK" shows normal setting, strip blinking in orange warns of errors and possible cause of the problem encountered is displayed. Furthermore, pre-defined user's limits – in accordance with pre-set/prepaid service – and currently available number of TF5 test actions are shown.
(7) **Record ECG** section contains data on ECG record length from pressing the CTRL + E hot keys **or** clicking on ECG record icon **or** pressing Record button, and information on total number of ECG records in this measuring session. The default setting '–10 / +20' shows that from the event the previous 10 seconds and following 20 seconds are recorded (=30 seconds for each ECG record). The red button in this section shows ECG strip recording.
(8) **Artefact record** section displays the number of artefacts and automatic artefact recognition state. The button when green indicates normal heart rate data, when red informs of automatically recognised and corrected artefacts (cardiac arrhythmia, movement artefacts e.g., while changing position from supine to standing).
(9) **Basic values** window delivers exact numeric information on instantaneous R-R data: Pulse number, Length of R-R interval in [ms], Heart rate in [beats per minute] and Time elapsed since pressing Start button in [hrs:min:sec] (Note, please, that this total time differs from the "Time remaining" information in the section 10).
(10) **Statistic interval** section is only active during recording the data for HRV analysis. Once Mark button is pressed, analysis interval count number is shown (normally 1 – 3, corresponding with examination procedure in 1-supine/2-standing/3-supine). Paralelly, countdown for Time and number of Pulses remaining starts from 300 downwards.
(11) **Measuring control buttons** at the bottom of the window control program functions such as Start, Stop, Save, Browse (R-R data) and (Browse) ECG.

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6.2. Measurements: How to Perform Measurement

6.2.1. Measurements: What to Do *Before* the Examination

Examined subject:
It should be noted that autonomic nervous system response depends on numerous factors that influence the result of the examination:

- It is recommended to refrain from smoking or drinking coffee, tea, alcohol and/or other sympathomimetic substances for 8-12 hours prior to examination.
- In patients with chronic medication, it is recommended to continue with their usual medication and nutrition, with the exception of those using beta-blockers, which have been shown to substantially increase the vagal tone (diagnostic purposes!). In such case, consider an interim exchange with other pharmaceuticals.
- Subjects with insulin treated diabetes should avoid hypoglycaemia within the last 12 hours.

Medical personnel:
Be sure that examination conditions meet the standards necessary to obtain reliable and reproducible data:

- The examination should be performed in a quiet, gently illuminated room of a constant temperature and optimally between 8:00 AM and 2:00 PM.
- Patients should be requested to lie down quietly for a preparatory phase of 10-15 min to exclude relevant emotional or external influences on the autonomic regulation.
- In general, during the examination, speaking or physical activities that are not related to the testing procedure should be avoided.
- It is recommended not to make any telephone calls or undertake any other activities that may influence the steady state of autonomic regulations during the examination period.
- Ideally the examiner instructs the subject on the measurement procedure, enters personal and other relevant data and leaves the examination room leaving the examined subject alone.
- Check there is no conflict with the chapter 1.1. Cautionary Information in the Manual.

6.2.2.Measurements: What to Do *During* the Examination

(a) Start the program, Select / Add the new subject in **Database**

(b) Adjust the **chest belt** and **switch** the transmitter **on**.

(c) Check if the yellow **LED diode** on transmitter is regularly blinking. Switch on the receiver and check if its both **LED diodes** are on.

(d) Click on **Spectrum Measuring** section icon (**or** press CTRL + P **or** open Measuring option in the main program menu and select Spectrum).

(e) **Spectral test measuring** screen is displayed. **Hardware info** section (object No 4, see chapter 6.1. Spectral test measuring screen) is activated immediately. Check quality of transmitted & displayed signals (ECG and heart rate course) in separated windows. Change the position or adjust the length of the chest belt if necessary.

(f) If OK, Start the examination by clicking on **Start icon** (**or** open Control submenu and select Start **or** press CTRL + S **or** click the Start control button at the bottom).

Important notice: If for any reason it is necessary to record full-time ECG record throughout the whole examination, please choose this special option in the **Control** submenu -> **Start with whole ECG**, instead of clicking the Start icon shown above.

(g) Note that -- when properly started -- **Icons setting** changes consistently, i.e., Start icon is disabled and Stop icon along with other icons related to current program step are enabled. The same is valid for **Measuring Control buttons** at the window bottom (Start, Stop, Save, Browse and ECG).

(h) Additionally, in **Basic values** section (object No 9, see chapter 6.1. Spectral test measuring screen) information is displayed on: instantaneous Pulse number, Length of R-R interval, Heart rate and Time elapsed since pressing the Start button.

(i) Also, information on the **transmitter battery status** and on **system functions** are displayed (objects No 5 & 6). Automatic artefact recognition and data correction procedure starts now, as well, showing continuously updated number of processed artefacts in **Artefact record** session. If possible, leave the examination room now and perform the further examination control / program steps from a separate room.

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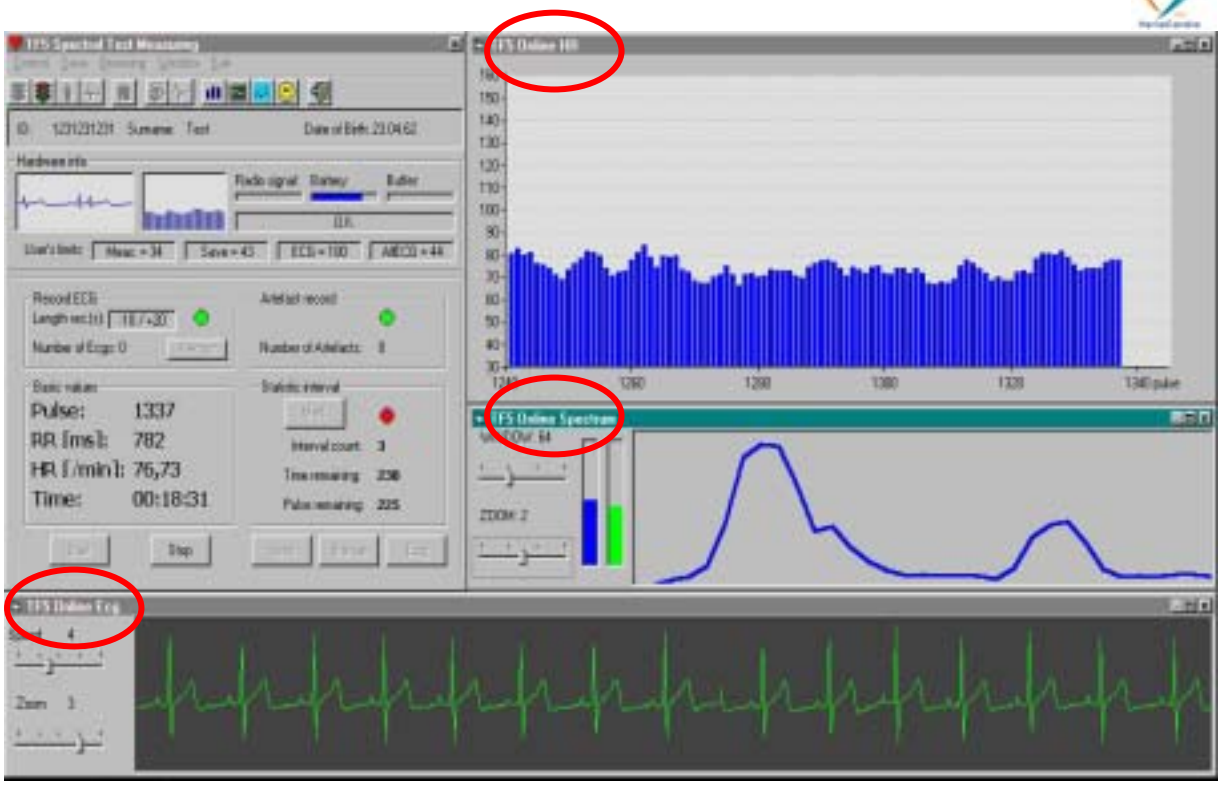


(j) At the right-hand side & bottom of the screen, 3 new 'on-line' windows display:

- Window '**TF5 Online HR**' displays the course of heart rate against time within the recent approx 100 pulses (accordingly to the currently adjusted window size)
- Window '**TF5 Online ECG**' displays single-channel ECG (time resolution 500 Hz). It is possible to adjust the signal displaying speed and zooming by 'drag-and-drop' with PC mouse (like in most other windows in the program).
- Window '**TF5 Online Spectrum**' displays the instantaneous spectral curve based on recent 32 / 64 / 128 or 256 heart beats. This option has no influence on the performance of the statistics after the examination is finished and serves only for displaying the spectral curve *during* the measurement. Also here, it is possible to adjust the spectral curve window and zooming by 'drag-and-drop' with PC mouse. Additionally, two - blue and green - columns showing the instantaneous **'sympathovagal' balance** / spectral power distribution between low (0.05-0.15 Hz) and high (0.15-0.40 Hz) frequency bands can be found here.
- ***Note:*** *The first on-line spectral curve and sympathovagal balance graphics appear on the monitor only after the chosen number of pulses is reached (32 pulses being the minimum). In the case above a 64 pulses-window is chosen.*

All these 'online windows' can be switched off/on (see the icons) and are fully resizable to allow the user full flexibility to adjust the screen accordingly to her/his needs. Default positions can be quickly adjusted by clicking the icon **Default** windows display or pressing CTRL + D.

(k) When the subject's preparatory phase is finished, **Mark** beginning of the first examination interval (**or** press CTRL + M **or** open submenu

Control -> Mark **or** click the Mark button in the Statistic interval session). Only at this point +300 seconds/+300 pulses -- whichever takes longer -- the data will be included in the final statistical analysis (see also Statistic interval session No 10). Data obtained *before* and *after* this examination interval are displayed in the 3-D graphics but *not included* in the statistical analysis.

(l) **Statistic interval** section (No 10, for details see chapter 6.1. Spectrum measuring screen) is now activated, additionally: examination interval number is shown (normally 1 – 3, corresponding with examination procedure in 1-supine /2-standing /3-supine), and countdown for Time and number of Pulses remaining -- both starting from 300 downwards -- run.

(m) It is possible to record single-channel **ECG** strips as necessary, within the whole examination process. By pressing ECG record icon (**or** clicking the Record button within the session /Record ECG session No 7/ **or** pressing CTRL + E **or** through program submenu Control -> ECG Record) a 30 second strip is recorded (–10 sec / +20 sec from the event). Red button in this section shows ECG strip recording, green button ECG recording not operating at present. In case of choosing the whole examination ECG record (see step /f/ in this chapter) this option is disabled.

(n) Once the 1st interval countdown is finished by reaching 0, **Interval count '1'** appears in the Statistic interval session and time/pulse countdowns disappear. In this moment you can request subject for active change of position – from supine to standing. Be aware that some seniors might need a help at this moment.

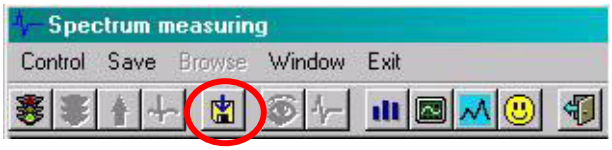
(o) Once subject is stable and his heart rate does not display artefacts or extreme changes related to the position change, **Mark** the beginning of the second examination interval (return to step /j/ and follow the above listed procedure). Please be aware that one of the most relevant conditions for successful HRV data analysis is its stability (data 'stationarity'). Therefore, wait for a while after position change before you mark the next interval.

(p) Once the 2nd interval countdown is finished by reaching 0, **Interval count '2'** appears in the Statistic interval section and time/pulse countdowns disappear. Again the subject can be requested to change position – from standing back to supine again. Afterwards, **mark** the third examination interval.

(r) After successful data collection **Stop** the measuring phase by clicking on Stop icon **or** open submenu Control -> Stop **or** press CTRL + P **or** click the Stop control button at the window bottom.

(p) Remember, please, to **immediately save the collected data** (click Save icon **or** Save control button **or** Save command in main menu).

6.2.3. Measurements: What to Do *After* the Examination



Ensure that you have finished the recording correctly, i.e., after the 3rd examination interval (Statistic interval count = 3), by clicking Stop icon **or** via submenu Control -> Stop **or** pressing CTRL + P **or** clicking the Stop control button at the bottom. **Save** the record immediately (click Save icon **or** Save control button **or** Save command in main menu)! Further steps lead to browsing the record and to analysis.

6.3. How to Browse/Edit the Data

Before considering the results, check the integrity of the recorded data and remove any artefacts as necessary (by accepting/rejecting automatic recognition procedures and/or manually). Records that contain non-processable artefacts should be deemed as invalid and in these cases, the examination should be repeated. The same pertains in the final statistics table if excessive non-stationary parameters are found (i.e., statistical relative deviation exceeds approx. 20-30% in older population or approx. 30-40% in younger subjects).

Click the Browse icon **or** open Browse option -> select Browse spectrum **or** press CTRL+B keys together. A new window (**Browser**) opens that consists of several sections:

6.3.1. Browser Structure

(1) Browser commands **menu**
(2) Browser commands **icons**
(3) **Overview** display of whole examination **heart rate time course**
(4) **Heart rate detailed window** corresponding with the selection as in above window. Clicking on a selected bar in the HR detail window shows at the bottom information on the instantaneous pulse number, pulse rate and time relapsed since the beginning of examination.
(5) Optional window displays **ECG strip** related to the event (artefact). This window displays the short ECG strip only if it is automatically recorded. A standard ECG browser can be activated in other program sessions.
(6) **Artefacts processing** optional window

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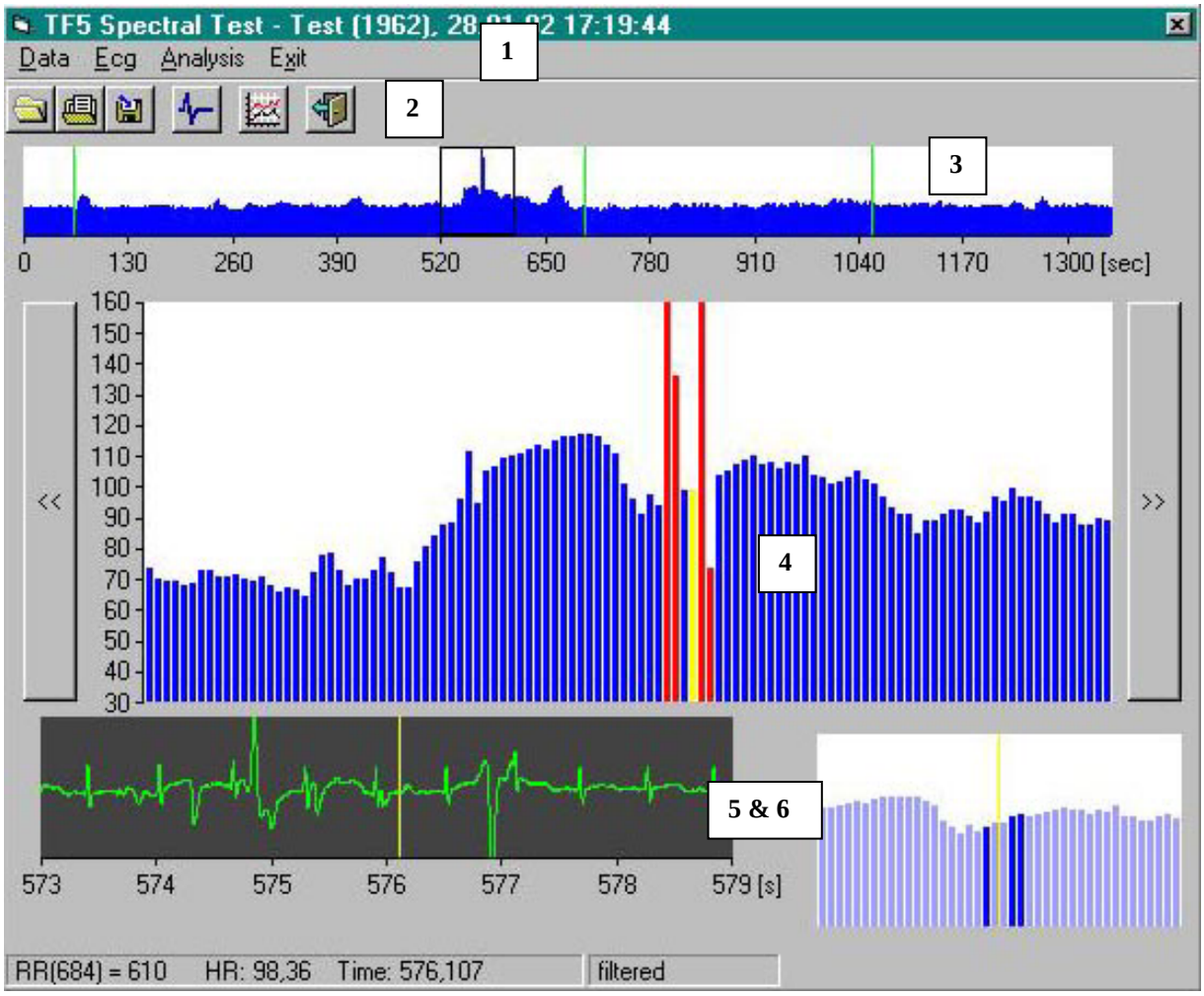
When **browsing** the heart rate record you can

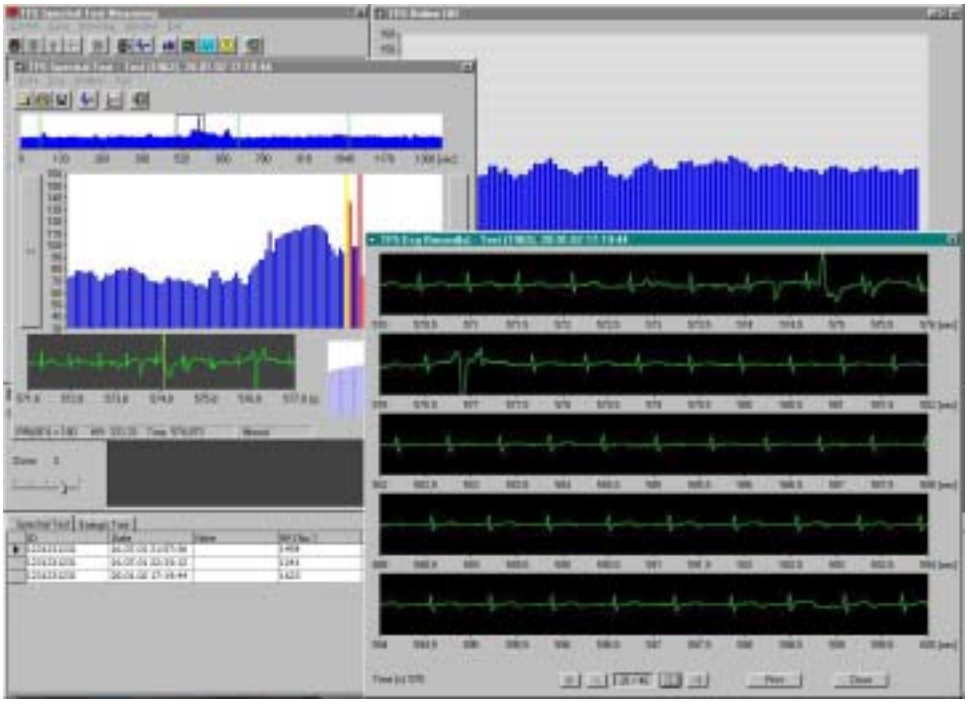
- either move the selection window within the examination overview – using left mouse button and 'drag-and-drop' method in the window examination overview (section 3), whilst the selected heart rate part displays "zoomed" in more detail in the window below (section 4)
- or click on the sliders at the left or right-hand side of the detailed window (section 4) to scroll the HR data. This enables one to check the record thoroughly, however, it takes slightly more time.



Additionally, in the heart rate **overview** (section 3) or **detailed** (section 4) **windows** the following markers of various colours can be found:

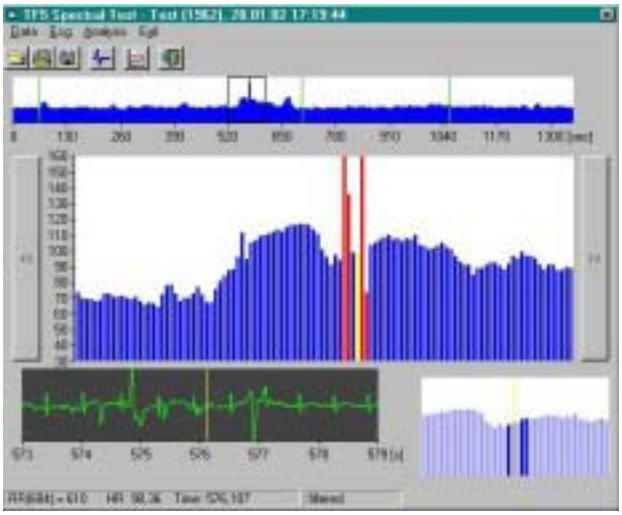
- **Green marker** – shows the beginning of each examination interval that is included into the final statistical analysis
- **Red marker** – indicates artefacts automatically recognised and recorded with corresponding 6-second ECG strip during the data collection. Artefact in form of red heart beat vertical bar(s) is displayed in the HR detailed window (section 4) and corresponding ECG strip -- as stored *automatically* during the examination -- in the window below (section 5).
- **Violet marker** – corresponds with 30-seconds ECG record as obtained during the examination. This data can be browsed simultaneously in a separate standard ECG Browser, for example see below:

Practical example: *HR browser showing automatically recorded artefact caused by ectopic beat (check section 5), proposed data correction (section 6) and ECG browser located over the HR browser window showing the long ECG strip (whole examination). You can switch between both browsers to view details, as well.*



6.3.2. How to Find and Process Artefacts

- Window HR **overview** (section 3): Find the automatically recorded artefact (red marker) in the HR overview. Move the selection window onto the red marker ('drag-and-drop' the window with left mouse button).
- Window HR **detail** (section 4): Selected HR course is displayed. Click the *left* mouse button and/or 'drag' over the artefacts to the right or left to mark them if necessary = if not completely detected/marked by program yet (red colour bar). The same procedure with *right* mouse button unmarks them (blue colour, again).
- Window **ECG strip** (section 5) shows corresponding ECG data while
- Window **Artefacts processing** (section 6) shows generated corrections in heart rate in dark blue colour based on calculations algorithm over surrounding normal heart beats. Check the proposed artefact correction and mark/unmark the artefact portion in the section 4 if necessary. In general, the heart rate course should be smooth (we suggest the exclusion of ectopic beats, as well, see the figure).



- Progress to other artefacts and use the same procedure. Once satisfied with artefacts processing, press the **Save** icon **or** Save command in the menu. For the final analysis, **only 'edited/filtered' data** can be used. Be aware, please, that even *one single artefact* can totally destroy the quality of the results.

- However, it is still possible to view the **original file**, as well. Click the 'Load original data' icon (**or** open 'Load' command and select Original data or press CTRL+O together). Similarly, you can return to the 'filtered' file – click on icon 'Load filtered data' (**or** open 'Load' command and select Filtered data or press CTRL+F together). The computer stores separately the latest processed file as a 'filtered' one while the 'original' file remains unchanged. Date (time point) of current file editing/filtering along with the date of original record are stored, and this data is available in the Report.

6.3.1. ECG Browser

It is possible to view either the 30-seconds long single-channel ECG strip(s) or the whole examination ECG record as recorded during the examination session, in a separate window. You can **open it** in

(a) **Spectral test measuring** session: click the ECG browse icon that is available immediately after the HR record has been saved (**or** open the Browse menu and select Browse ECG command **or** press CTRL + C together), or

(b) **HR Browser** session: click the ECG browse icon (**or** command), or

(c) **Basic operation screen:** select the subject and record (small arrow at the left-hand side), click the ECG browse icon (**or** Browsing main menu, command ECG **or** CTRL + E together)

Structure of the ECG browser is simple:

- **Window heading** shows personal data, date & time of ECG recording
- **Five strips** displaying ECG course from –10 until +20 seconds from pressing the ECG record button (time 0, violet marker)
- **Bottom line** includes information on number of R-R interval, marker time location on the heart rate course axis, present number and total number of recorded ECG files, and 'Close' button.

Its **main function** is to enable viewing the ECG record and to support decision making processes while browsing the heart rate course record and considering possible artefacts.

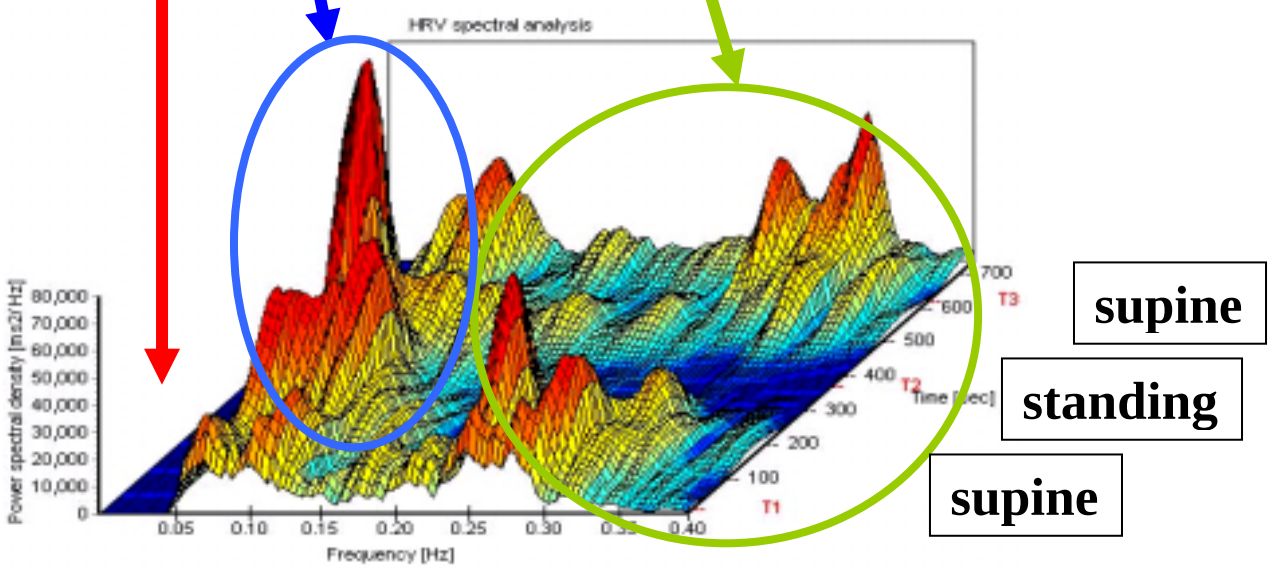
7. Clinical Use of the System: Analysis

7.1. HRV Basics. How to Understand the Principles of Analysis

In general, it is recommended to perform (and to understand) the examination as a view on **cardiovascular autonomic regulations during a modified orthostatic load**. This scheme allows assessment not only of the energy contents of the **autonomic control** during well-defined examination positions, but also disturbances in its **dynamics**. Therefore, both the absolute numbers in the statistics table and the changes/behaviour in autonomic control as displayed in the three-dimensional graphics are relevant for diagnostic resumes.

Spontaneous beat-to-beat fluctuations in heart rate reflect ongoing modulation of sinus node activity through several cardiovascular control mechanisms. In addition to the respiratory sinus arrhythmia (0.2 – 0.3 Hz), the heart rate typically oscillates at specific lower frequencies, most commonly at about 0.05 - 0.15 Hz and lower, as well. All these heart rate fluctuations can be quantified by the technique of **power spectrum analysis**, which calculates the frequency content of time-varying signals. Power spectra are quantified by measuring the area under the spectral curve (*Spectral Power*) and its density/amplitude (*Power Spectrum Density*) in two/three frequency bands (see the figure below; frequency axis 0.00 - 0.40 Hz, displayed spectrum range 0.05 - 0.40 Hz):

- **Very-Low Frequency** (VLF; 0.02 – 0.05 Hz) /*not included in this fig.*/ and/or
  - **Low Frequency** (LF; 0.05 – 0.15 Hz) components of spectral energy reflect sympathetic-thermo-regulation influence with a certain parasympathetic modulation, and
    - **High Frequency** (HF; usually 0.15-0.40 Hz) component reflects parasympathetic influence. The ratio of LF to HF is mostly considered to be an indicator of sympathovagal balance.



In the VariaCardio TF5, power spectra are calculated by computing the magnitude squared of the **fast Fourier transform** based on data points obtained from **300 seconds' tachometer** signal. As in any biological process, the data contain both harmonic and non-harmonic information, therefore no filtration of specific ('chaotic') parts of the information is used. The total power is then obtained by integrating the power spectrum from 0.02 to 0.40 Hz, the respective components of spectrum (VLF, LF & HF) represent then in the above mentioned frequency bands. Power at frequencies below 0.02 Hz should be probably not considered because it may not be reliably measured within data records 300 seconds long. (e.g., in case of less than 0.01 Hz the wave length is then more than 100 sec., i.e. energy of only a couple of cycles during one position recording is quantified).

Based on the length of record analysed, this kind of spectral analysis is also called a **"short--term" analysis**; the spectral power can be viewed as the variance in heart rate during the 300 seconds periods. The "long--term" spectral analyses are represented by analyses using 24h Holter recordings. However, to our current knowledge, none of the standard 24-hour Holter monitors does have a sampling frequency high enough to offer adequate analysis.

Short-term spectral analysis of HRV is **practical and easily applied** in the clinic. It was found that the immediate variability of short-term spectral measures of HRV was low, and short, 2- to 15-minute samples were found to be excellent predictors of mortality and correlated with prognostically important data from sustained recording periods. Due to this simplification, patients could accept more consecutive measurement series during longitudinal studies, as well. The method takes only a short time and is quite independent of the patient's compliance during the examination. In contrast to the less sensitive total Ewing standard score of cardiovascular reflex battery, the selected cumulative indices over more than one time segments (e.g., in positions supine-standing-supine) proved to be able to assess even small changes in cardiac autonomic supply.

The current methods most commonly used for analysis of HRV in frequency domain are based either on fast Fourier transform or on auto-regressive model. Under various conditions, both analytical approaches deliver similar results. As the examinations are commonly performed under routine clinical conditions requiring immediate results, system using **fast Fourier transform** analysis has the **advantage** of sufficient simplicity of well defined algorithms, high processing speed and on-line graphic display modality. Although the information given by the spectral indices corresponds to that given by indices of time-domain analysis, it was shown that **cumulative index** is more representative of the actual global state of autonomic regulation and reflects the total instantaneous sympathetic and parasympathetic effects.

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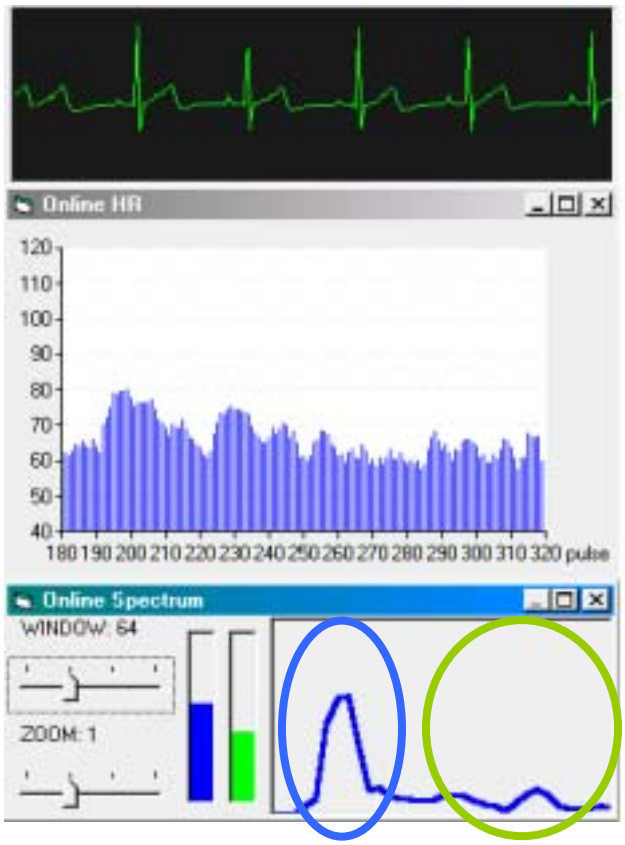
7.2. HRV Basics. How the R-R Intervals Measurement Works



Surface **ECG** is continuously monitored and R-R intervals are measured with a time resolution of 1 ms and further processed by microprocessor in the transmitter unit. The ECG and R-R data are telemetrically transferred to a receiver connected to a PC-compatible computer.

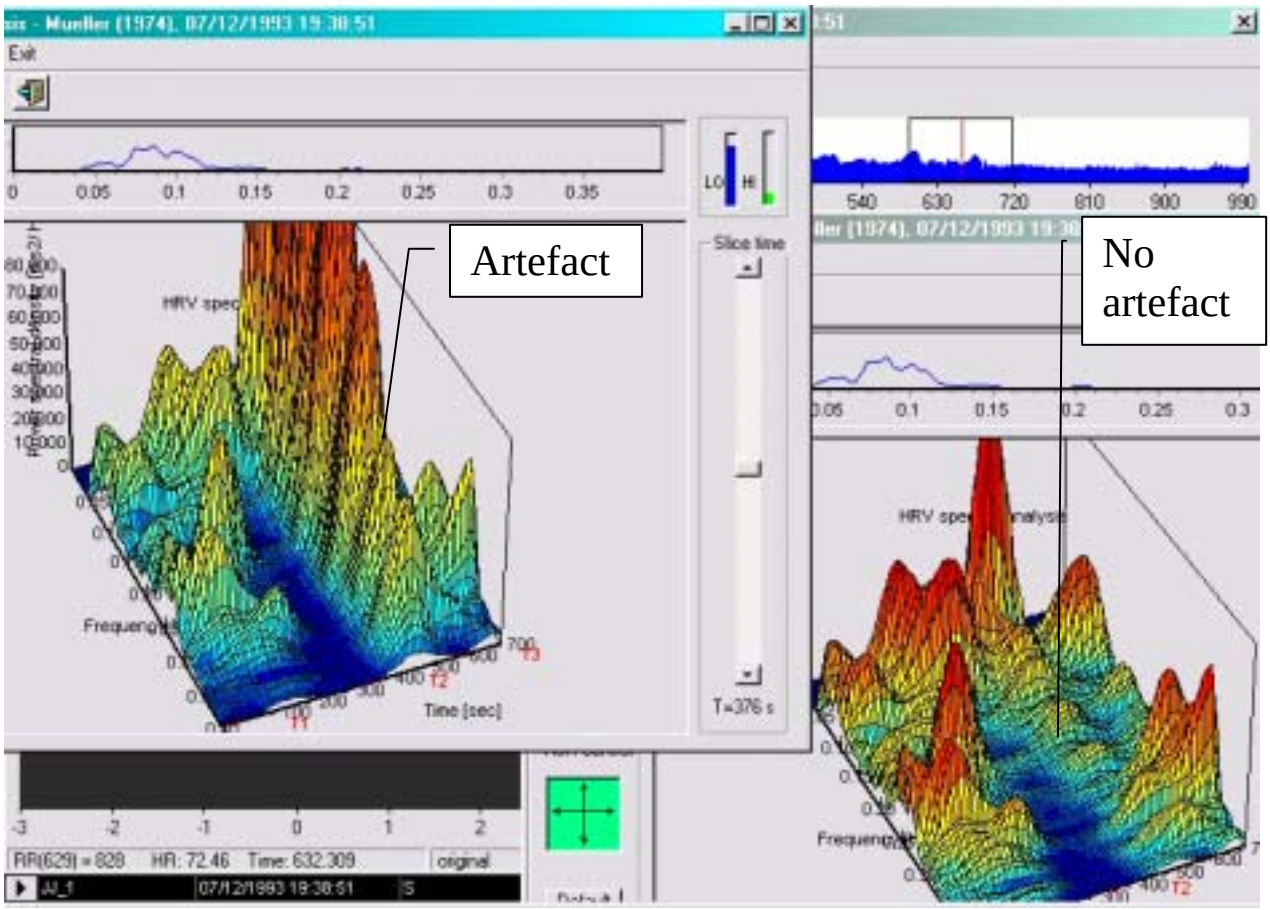
The ECG signal and computed **heart rate** is displayed after each heart beat on the monitor in form of a vertical bar graph with numerical information on current heart rate, R-R interval length and time elapsed since the beginning of measurement in a separate window.

Instantaneous (online) **spectral curve** based on the last 32, *64 (see the figure),* 128 or 256 beats is displayed as well. The figure shows two typical peaks of LF and HF bands.

The automatic **artefact recognition** of the received data is processed on a **real-time basis** and displayed on the monitor. When recording has finished, the original data set is stored and then automatically filtered, excluding the recorded artefacts using a special recognition algorithm. Finally, there is a possibility to filter the file manually as well. Therefore, there are two files stored (**'original'** and **'filtered'** ones) related to one data set.

For better understanding **why the artefact processing is that important**, see the figures below:

- The *left* figure shows the spectrum created on data including one single artefact around the time point 640 seconds (see the Browser -- upper right window).
- The *right* figure shows spectrum based on the same dataset, however, with the artefact rejected and substituted by a computed data hat is consistent with the current data time series.



7.3. HRV Basics. How to Understand the 3D Results

The computational method of spectral analysis is based on a fast Fourier transform. The final results are immediately displayed on the monitor as a three-dimensional running spectrum, permitting a **general overview of the dynamics and of the absolute energy** content of the system. All parameters are computed for each time segment: within the high frequency band (0,15-0,40 Hz, attributed exclusively to parasympathetic tone), the low-frequency band (0,05-0,15 Hz) and very-low frequency band (0,02-0,05 Hz, shown to represent a combination of sympathetic and parasympathetic effects and others like thermoregulation etc. on cardiac autonomic tone). The autonomic control varies under different physiological states, typically during a modified orthostatic load: the *parasympathetic* component is predominant in supine position, while the *sympathetic* one during active standing.

The main outcome variables in ***frequency domain*** are:

- Absolute **spectral power** (units [ms^2]) and
- **Power spectral density** (units [ms^2/Hz]) in two or three frequency bands and their
- **Ratios** VLF/LF and LF/HF bands
- **Mean frequency** (units [mHz]) for each frequency band
- **Cumulative spectral power:** to increase the reliability of the short-term measurements and to assess even small intra-individual differences in global autonomic tone, the **cumulative index** (spectral power of the total

frequency band with its very-low, low and high frequency over all recorded positions; units [ms^2]) representing the total averaged area under all consecutive spectral curves within the short-term recording is calculated

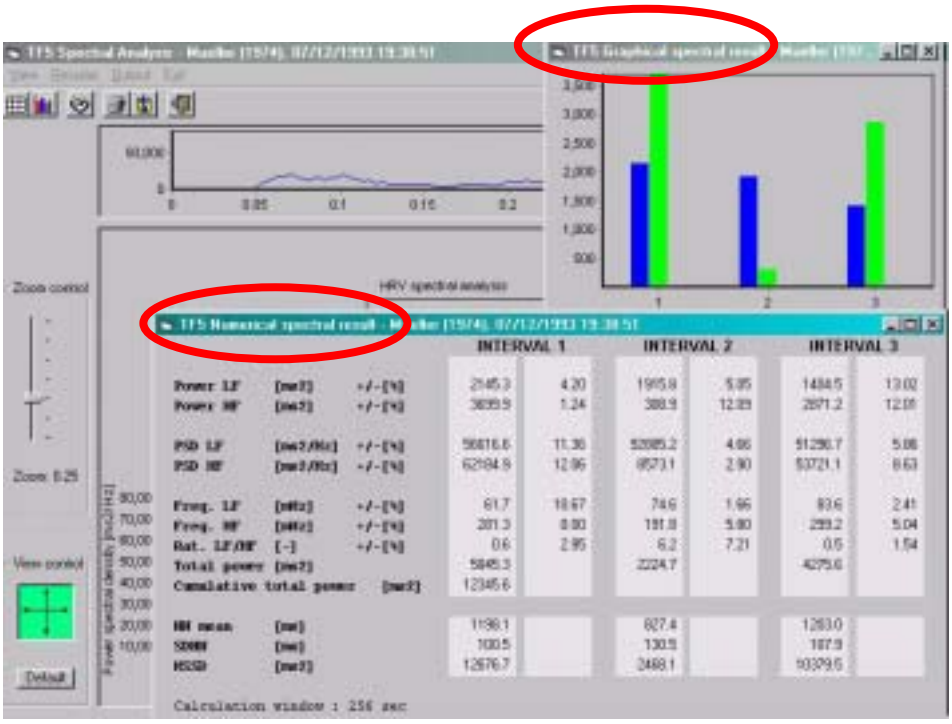
- **Standard deviations** (units [%]): calculated for each parameter, as this information is necessary for assessment of the **'stationarity'** of the examination. We recommend excluding any findings having more than 20-30% relative deviation in any of the time segments recorded. In those cases, the examinations should be repeated

Additionally, calculations of ***time-domain*** parameters are made, as well:

- **Mean R-R** interval (NN mean)
- **Standard deviation** of mean R-R interval (SDNN)
- **MSSD** (Mean of the squared differences between two adjacent normal R-R intervals over given recording period)

It is possible to display the **results in three different display options**, as:

(1) Three-dimensional running spectra graph (see Chapter 7.4. How to Perform the Analysis)
(2) Statistical table ('*Numerical spectral results*')
(3) Graphical form ('*Graphical spectral results*').



Practical example: *The figure above shows results options (2) and (3), based on normal cardiac autonomic control as obtained during modified orthostatic load: the numerical data displayed correspond with the above listed main outcome variables, the graphical output displays absolute values of spectral powers LF & HF in (three) examination intervals. It documents predominance of HF band (right column, in green) in supine -- intervals 1 and 3 -- and predominance of LF band (left column, in blue) in standing positions -- interval 2.*

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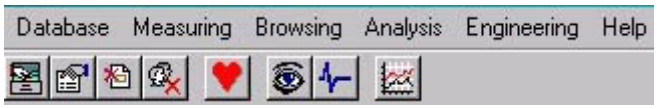
7.4. Analysis. How to Perform the Analysis

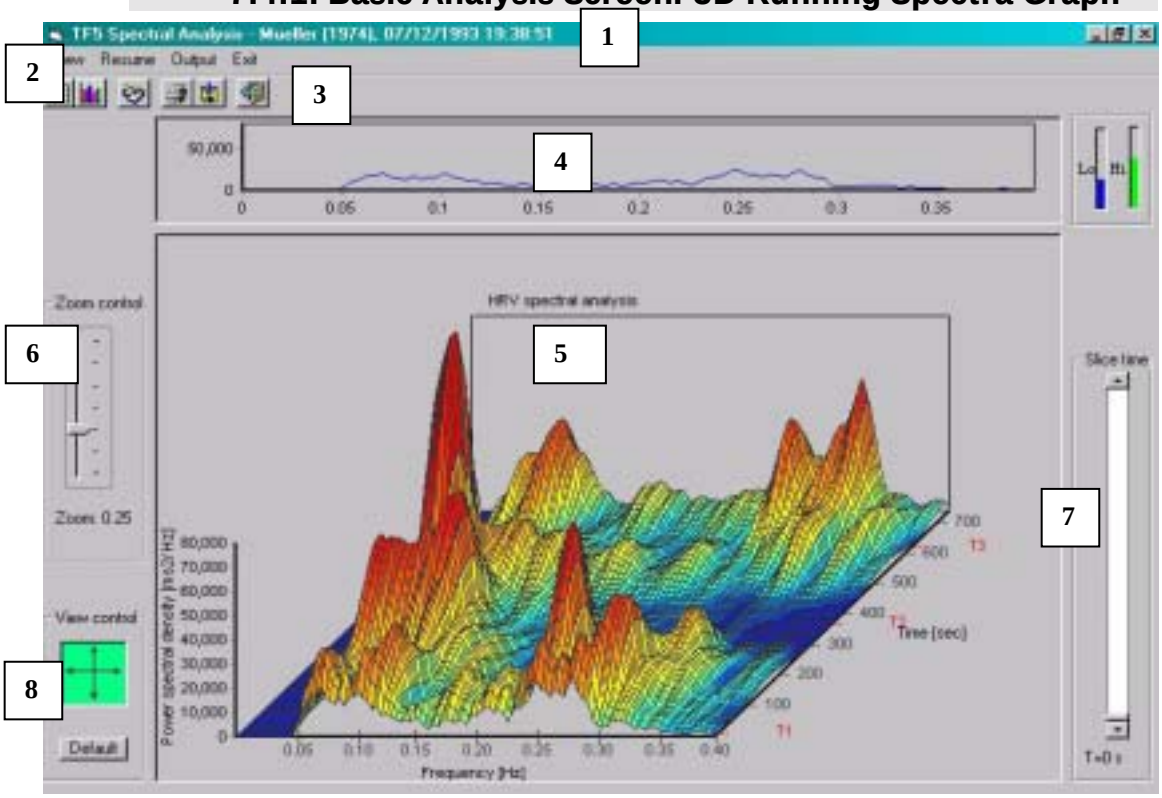


First select the subject for the analysis from the **Subjects listing** in the basic operation screen (see Chapter 5.4. Database: How to Find a Subject).

Optionally, then open the **Browser** – click on icon -- and check the consistency of the R-R data, particularly with respect to artefacts. If artefact found, process it properly – see the Chapter 6.3.2. How to find and process artefacts. Bear in mind, please, that even one artefact might totally destroy the quality of information received over the total 15 minutes measurement.

However, you can also directly progress to the 3D analysis: click on icon Frequency domain analysis **or** press CTRL + F together **or** in the main program menu open Analysis -> Frequency domain. Following **Basic analysis screen** is opened:

7.4.1. Basic Analysis Screen. 3D Running Spectra Graph



Practical example *shows a typical pattern obtained in a subject with no detected disturbances in cardiovascular autonomic control during a modified orthostatic test (lying down [T1] - standing up [T2] - lying down [T3], calculation for every position is based on 256 artefact-free data points; note that this display includes only low and high-frequency bands /range adjustable in the Engineering->Program Setup/). The graphics shows clearly a predominance of HF band (0.15-0.40 Hz) during supine positions (marked as T1 and T3) while LF band (0.05-0.15 Hz) gets 'activated' during standing-up (marked as T2). The numbers 1-8 are related to its detailed description, see below.*

The standard **Basic analysis screen** of the measurements includes:

(1) Windows heading includes subject's last name, year of birth and recording time details of the record analysed.

(2) Below, a line with Program sub-menu commands include options **View** (Statistical table or Graphical output), **Resume** (allows to write comments on the results), **Output** (Printing or Export of the results in text format) and **Exit**.

(3) **Icons** enabling quick access to the most of above functions.

(4) **Two-dimensional spectral graph** that shows single spectral curve created at specific time point – see the 'slider' at the right-hand side of the output screen. An instantaneous sympathovagal balance 'online' chart (is displayed right along the 2D spectral curve (blue & green bars).

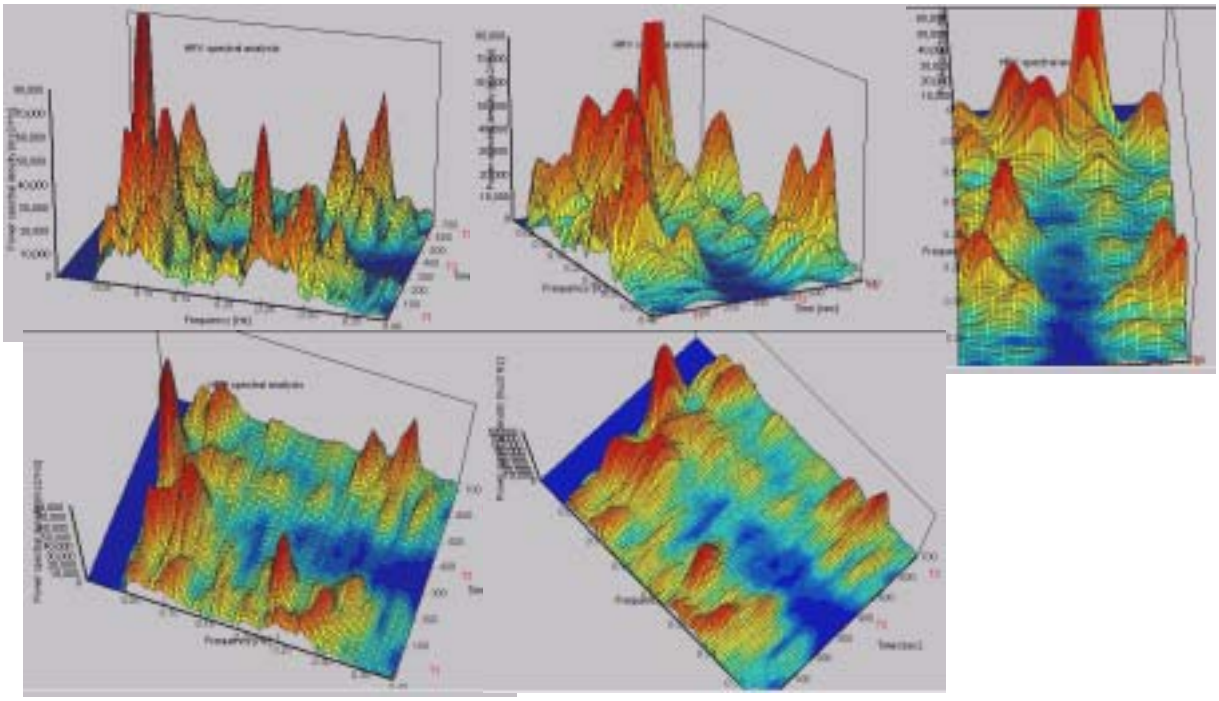
(5) The biggest part of the screen covers **three-dimensional running spectra graph** showing the behaviour of the autonomic cardiac control system during the whole examination. Note, please, that while this display shows the complete record including the changes of position etc., the final statistical results are based only on 0 - 300 seconds periods from pressing the marker in each position (see markers T1, T2 and T3).

(6) **Zoom control** slider allows to adjust the size of the displayed graph.

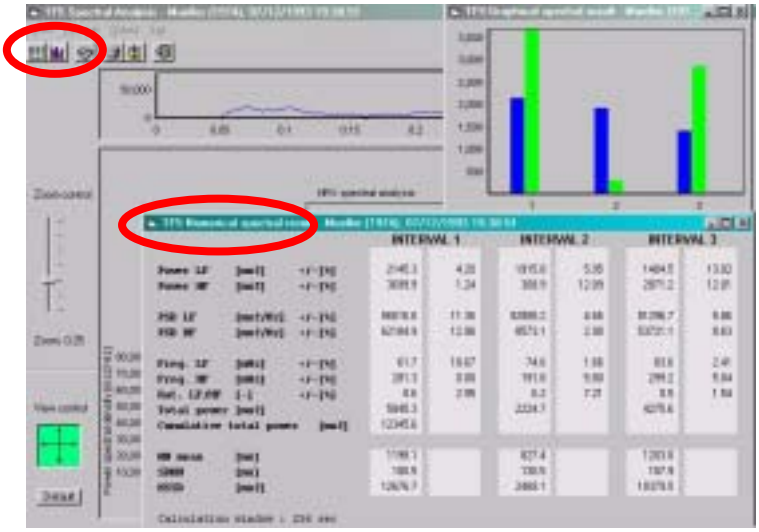
(7) **Time control** slider allows to 'slide' the graph while showing instantaneous spectral curve at specific time point ('slice time'). This interval is displayed in [seconds] from the start of measurements (and *not* from pressing any of the markers!) below the slider.

(8) **View control** pointer at the left lower corner below allows to adjust the view angle of the 3D graph in order to enable better overview over the results.

Practical example: *Below you can find some examples of 3D display manipulation using the '**View control**' option, in order to obtain an optimum graphical overview of the autonomic control during the modified orthostatic test.*



7.4.2. Basic Analysis Screen. Statistical Table



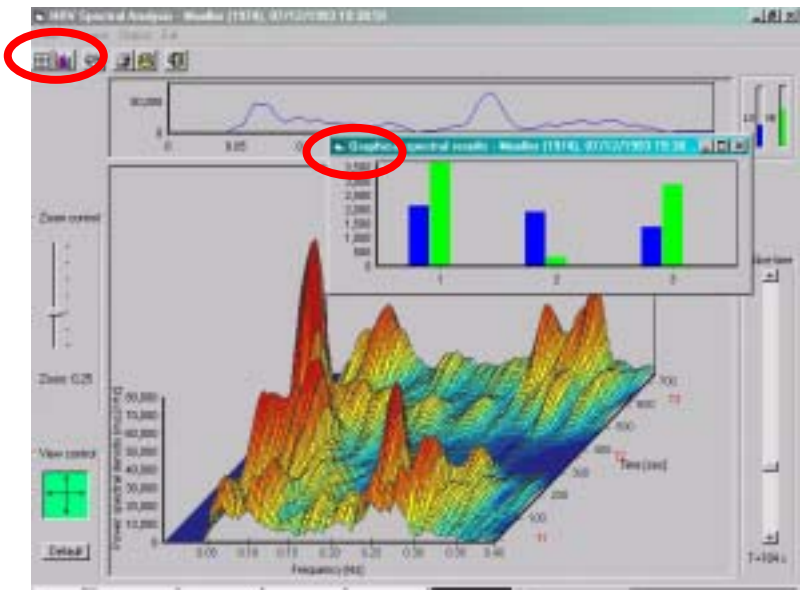
The results can be obtained in form of the **Numerical spectral results** table that is reached by clicking on the first icon in the Submenu commands line.

The table is *vertically* divided into three sections covering 3 measurement intervals (supine/ standing/ supine). *Horizontally,* groups of parameters are shown where the most important information includes the (**Spectral**) **Power** variable, displaying power within specific frequency bands.

Above in the **Statistical table** you can see results of short-term HRV spectral analysis as obtained in a normal subject (see also Chapter 7.3. HRV Basics):

- Variables **Power LF** and **HF** represent low and high frequency bands here.
- Variables **PSD** mean **Power Spectral Density**, in both frequency bands.
- **Freq.** shows the mean frequency within the specific bands.
- **Rat. LF/HF** displays interconnections between low and high frequency band spectra in all positions separately. Some authors declare this variable as 'sympathovagal balance'.
- **Total power** sums the LF and HF powers.
- **Cumulative total power** shows sum of three total power variables above.
- **NN mean** shows a mean value of R-R intervals within the position.
- **SDNN** standard deviation of mean R-R interval.
- **MSSD** shows Mean of the squared differences between two adjacent normal R-R intervals over recording position.

7.4.3. Basic Analysis Screen. Graphical Table

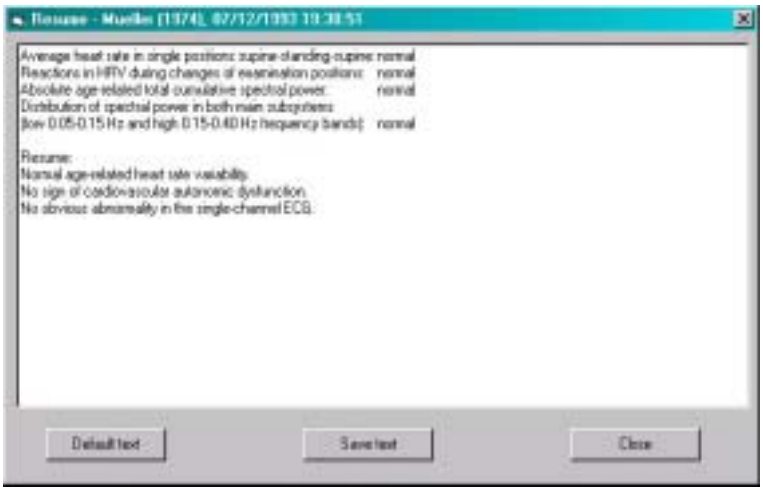


Also, there is a possibility to obtain a quick overview of the results in a graphical form (**Graphical spectral results** table), by clicking on the first icon in the Submenu commands line.

The chart shows distribution of LF and HF spectral powers related to each examination interval, here shown as 1, 2, 3. On the left-hand axis absolute value of the parameters can be found (unit [ms^2]).

Important notice:
Please note that for the statistics, only those 300 seconds' time intervals marked previously in the measurement session are included. Check the Browser, please, where the start of *statistical* intervals is marked in green. This can sometimes 'optically' diverge from the *graphically* displayed results.

7.4.4. Basic Analysis Screen. Resume



For reporting, comments on the HRV analysis results prepared by medical professional might be necessary. For this reason, an option **Resume** allows to enter and store record-specific texts related to any part of the examination procedure.
Click on icon or in the program submenu open the Resume option. In the window, type in your texts. Alternatively, you can use pre-defined text patterns as prepared in the Main program menu, **Engineering** -> **Program setup** menu -> **Default resume** option.
When finished, please be sure to save the created texts and close the window. This Resume text appears in the printed Report, as described below.

7.4.5. Basic Analysis Screen. Export of Numerical Results

For various reasons, the export of results in digital form might be necessary. In such case click, please, on the icon **or** open in the Program submenu the option **Output** -> **Data export**. A text table 'export.txt' (located in the TF5 program directory or as adjusted in the **Engineering** -> **Program Setup** -> **Export/Send** menu) is then created which includes consecutively listed following variables as originally displayed in the **Numerical spectral results** table, separated by ';':

*id; name; date; Power LF **1** [ms2]; Power LF 1 variance [%]; Power HF 1 [ms2]; Power HF 1 variance [%]; PSD LF 1 [ms2/Hz]; PSD LF 1 variance [%]; PSD HF 1 [ms2/Hz]; PSD HF 1 variance [%]; Freq. LF 1 [mHz]; Freq. LF 1 variance [%]; Freq. HF 1 [mHz]; Freq. HF 1 variance [%]; Rat. LF/HF 1 [-]; Rat. LF/HF 1 variance [%]; R-R inter. 1 [ms]; R-R inter. 1 variance [%]; Total power 1 [ms2]; Cumulative total power [ms2];*

*Power LF **2** [ms2]; Power LF 2 variance [%]; Power HF 2 [ms2]; Power HF 2 variance [%]; PSD LF 2 [ms2/Hz]; PSD LF 2 variance [%]; PSD HF 2 [ms2/Hz]; PSD HF 2 variance [%]; Freq. LF 2 [mHz]; Freq. LF 2 variance [%]; Freq. HF 2 [mHz]; Freq. HF 2 variance [%]; Rat. LF/HF 2 [-]; Rat. LF/HF 2 variance [%]; R-R inter. 2 [ms]; R-R inter. 2 variance [%]; Total power 2 [ms2];*

*Power LF **3** [ms2]; Power LF 3 variance [%]; Power HF 3 [ms2]; Power HF 3 variance [%]; PSD LF 3 [ms2/Hz]; PSD LF 3 variance [%]; PSD HF 3 [ms2/Hz]; PSD*

HF 3 variance [%]; Freq. LF 3 [mHz]; Freq. LF 3 variance [%]; Freq. HF 3 [mHz]; Freq. HF 3 variance [%]; Rat. LF/HF 3 [-]; Rat. LF/HF 3 variance [%]; R-R inter. 3 [ms]; R-R inter. 3 variance [%]; Total power 3 [ms2];

The recently edited results are consecutively added to the previous one into one text file, line by line. I.e., whenever numerical results data of any subject are exported, these numbers appear in the 'export.txt' file, in the next line.

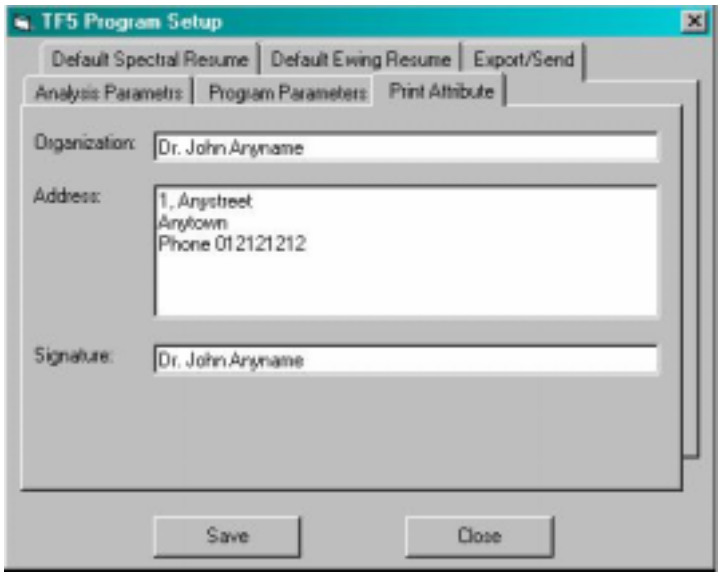
7.5. Analysis. Medical Report and How to Obtain It

Detailed medical reports including the graphical and numerical information obtained during the HRV measurements, completed by personal data details and summary prepared by the examiner/reviewer can be printed from the Basic analysis screen session after pressing the Print icon **or** by following in the Program submenu the option Output -> Print protocol **or** by pressing CTRL + P.

Medical report includes following main sections:

Page 1 of the Report

(1) Organisation / Reporting physician details (adjustable in the Main program menu -> **Engineering** -> **Program Setup** -> **Print Attribute**)



(2) Subject's personal data

(3) Record technical information including number of artefacts and ECG records

(4) Written resume – as/if prepared by reporting physician (text can be entered in the Basic analysis screen -> **Resume**) -- followed by the date of analysis, printing and name of reporting physician.

(5) Below, at the bottom line technical data on current system installation are included.

Page 2 of the Report

(6) Graphical 3D running spectra output including the last name, year of birth and recording details in the figure heading. Note that the printout is 'interactive' as it corresponds with the current view angle of 3D graphical output as just adjusted.

(7) Statistical table including all variables originally displayed in the Numerical spectral results

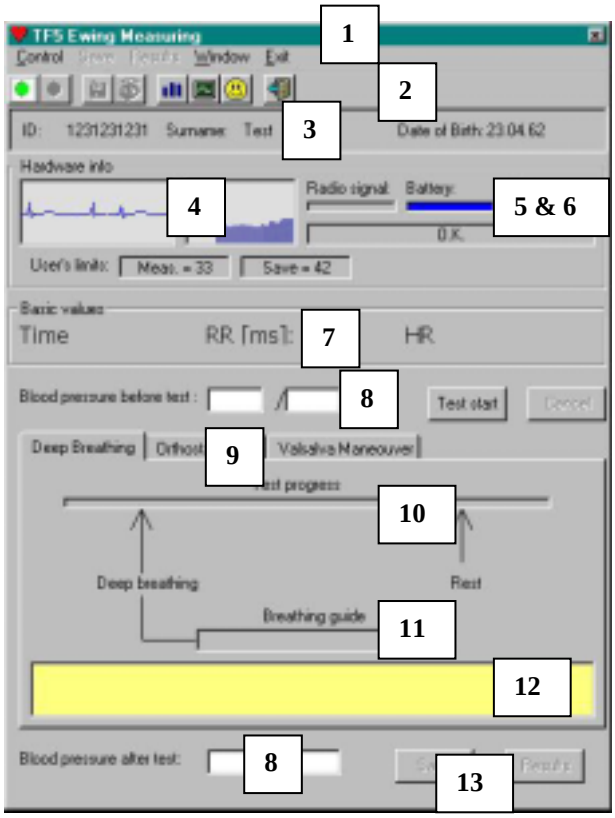
8. Battery of Short Cardiovascular Reflex Tests as Proposed by Ewing (so-called 'Ewing battery')

8.1. Ewing Battery: Introduction

This battery of cardiovascular bedside reflex tests consists of three/four functional tests of heart rate variability, for details see below. The obtained results are then analysed in time-domain as proposed by DJ Ewing *(e.g., see DJ Ewing et al: The Value of Cardiovascular Autonomic Function Tests: 10 Years Experience in Diabetes. Diabetes Care 1985, Vol.8, No.5; 491-498)*. The tests have been suggested to be suitable for a clinical routine screening ('gold standard'), although they predominantly represent vagal function information, are semi-quantitative only, and probably do not detect sufficiently those early stages of autonomic dysfunction that usually are modifiable by various interventions.

8.2. How to Perform the Ewing's Test Battery

In the basic operation screen, click on icon Measuring (**or** press CTRL + E **or** open Measuring option in the main program menu and select Ewing's Test).
New screen **Ewing's test measuring** is displayed with following main sessions:



1. **Commands menu** including submenu items Control, Save, Results, Window and Exit.
2. **Icons menu** corresponding with the above, including additionally Start and Stop, Save, Browse the results, Display/Hide specific windows, for details see below.
3. **Subject identification** with ID, Surname and Date of birth items.
4. **Hardware info** shows the current quality of data transfer/ECG in *left* window and progress of heart rate over recent time in the *right* window.
5. **Radio signal** quality indicator, and **Battery** status show current state of these items.
6. **Alert window** below the radio signal and battery status indicators informs you of system configuration and of possible errors (e.g., alert 'Receiver switched off...'). A strip with information "OK" shows normal setting, strip blinking in orange warns of errors and possible cause of the problem encountered is displayed. Furthermore, pre-defined user's limits – in accordance with pre-set/prepaid service – and currently available number of TF5 test actions are shown.

7. **Blood pressure** values can be *optionally* entered before and after the Valsalva maneuver and Deep breathing tests. These BP values are, however, *required* for correct consideration of results during the orthostatic test.
8. **Basic values** window delivers exact numeric information on instantaneous R-R data: Time elapsed since pressing 'Test start' button in [min:sec], Length of R-R interval in [ms] and Heart rate in [beats per minute].
9. **Test selection menu** enables to choose among the tests: deep breathing, Valsalva or orthostatic load.
10. **Test progress bar** is an optical hint showing progress of the test in form of constantly growing 'line' / small squares.
11. **Breathing guide bar** is used for guiding/support of correct & reproducible deep breathing pattern.
12. **Help alerts** can be seen in well readable big letters in a yellow bar as indicated above. Commands shown here can be used as guides for correct/standardised performing the tests. Additionally, corresponding voice commands can be heard paralelly.
13. **Measuring control buttons** at the bottom of the window control program functions such as Save and Results. Compared to the spectral analysis section, here is no need to use Stop buttons as the test ends automatically in accordance with standardised test protocol. An alert/help & voice messages inform about the end of each test.

In the Test selection menu (section 9, see above) in the measuring screen click on appropriate button, that allows you to perform one of the three reflex tests:

(1) **Deep breathing** - heart rate changes during four deep breathing cycles are recorded, each of them consisting of 5 sec. inspiration and 5 sec. expiration. After four breathing cycles are completed, test ends automatically.

(2) **Valsalva manoeuvre** - tests heart rate changes following a deep inspiration and 15-seconds expiration against 40 mmHg pressure. As reported, it is recommended to perform this test three times in one measurement session (or to perform one "test" measurement at least before the recording, in order to demonstrate the exact test procedure for the patient).

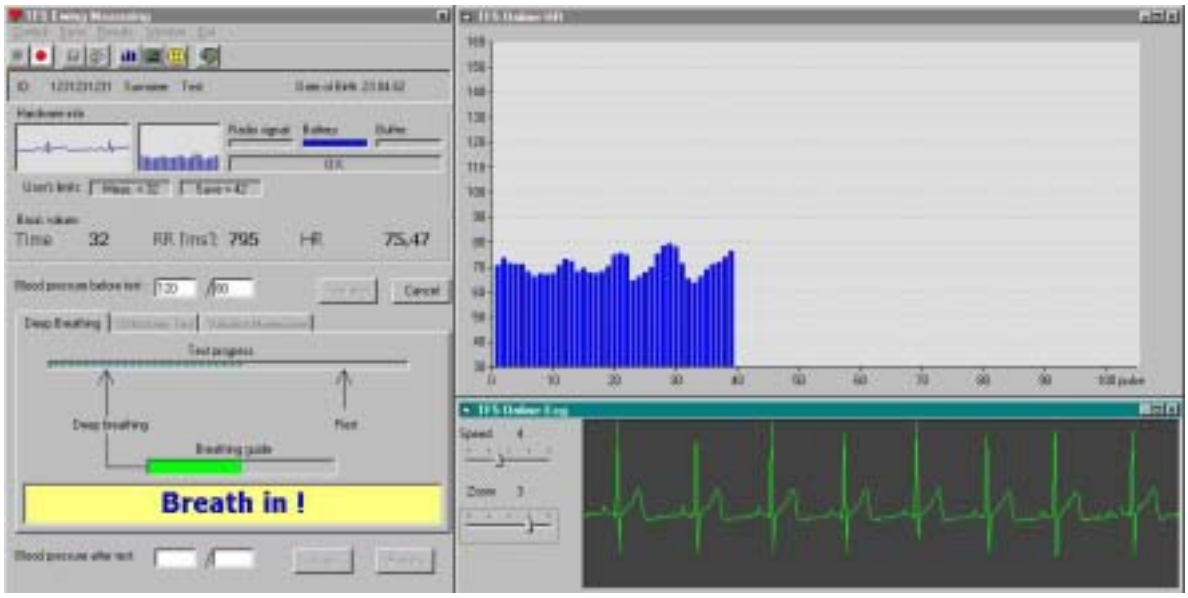
(3) **Orthostatic test** - changes of heart rate and blood pressure (separately, using a common BP measurement device) during supine position, and, during the first 30 seconds, HR changes and/or some 2 - 5 minutes BP changes after standing up are recorded.

To perform any of the individual tests, see the following description. The help function at the bottom of the screen offers information and hints as to how to proceed. After starting the test, the elapsed time interval since the beginning of the test, R-R interval length and the instantaneous heart rate are displayed.

Generally, before starting the first test, you have to **choose / add a new test subject** in the program database. For details, refer to the Chapter 'How to find a subject' or 'How to add a new subject', please. Afterwards, in the **Main menu** progress to **Measuring -> Ewing's Test** (alternatively press CTRL+E together or click on the icon). If the transmitter is already correctly positioned on the subjects's chest and it is switched 'on', you will already have an option to check the quality of transmitted data in the hardware info windows (section 4, see above). This option is identical with the function in the spectrum measuring screen. If the displays are satisfactory, progress to the first Ewing's test:

8.2.1. Ewing Battery: How to Perform the Deep Breathing Test

The subject sits quietly on the examination bed, the thorax belt with integral electrodes is correctly positioned on the chest and the transmitter switched on (regular signals as indicated by the LED-diode are detected).
Click on the Deep breathing test button (section 9 in the measuring screen). Enter the blood pressure value, if needed (optional). Then click on the '**Test start**' button -- see below, the screen shows effect of a cyclical breathing on the heart rate course while voice and written / graphical commands help to guide the test appropriately:



After an initial phase (10 seconds) that is necessary for obtaining basic data for statistics, a voice and written command "**Breath in**" appears, followed after 5 seconds by "**Breath out**" command. Paralelly, a breathing guide bar slowly increases and decreases in green so that the subject's cyclical breathing excursions are maximally standardised, each of them 5 seconds (four inspirations and four exspirations). When finished (after 40 seconds), a message appears on the screen: "**Breath normally**". Another 10 seconds of data are then recorded for computational purposes, a final longer beep and messages "**Test is finished**" indicate that the test is finished automatically.

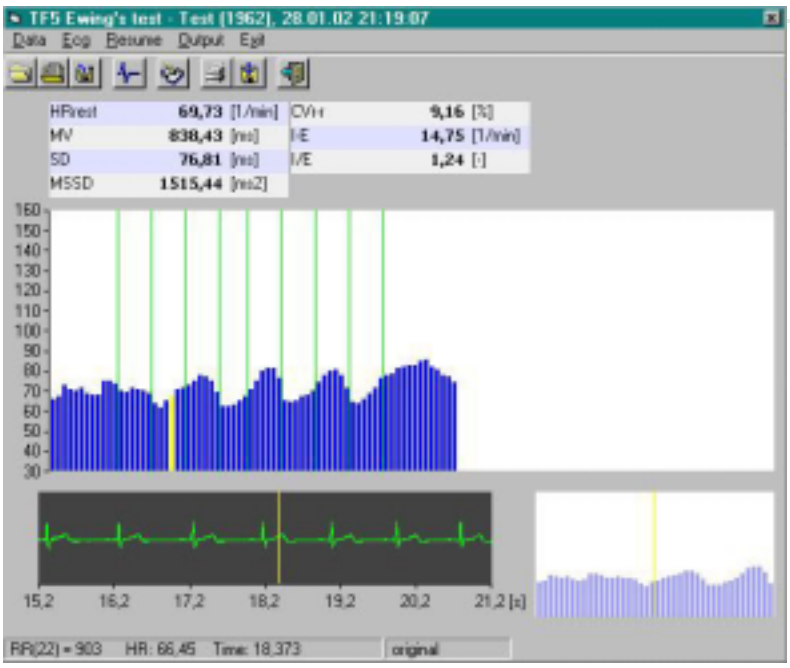
***Important notice**: the record must be absolutely artefact-free in order to ensure reliable test results.* (See "Filtration" procedure)

After the measurement is *finished*, the following procedures/keys can be used:
After any of the Ewing's tests is finished, **save**, please, (by clicking on the '**Save**' button below) the recorded data immediately. Afterwards, the patient's record and identification information is displayed, as well as graphics displaying the heart rate course during the whole test and all relevant statistical results – click on the '**Results**' button below.

Relevant parameters: Deep breathing test

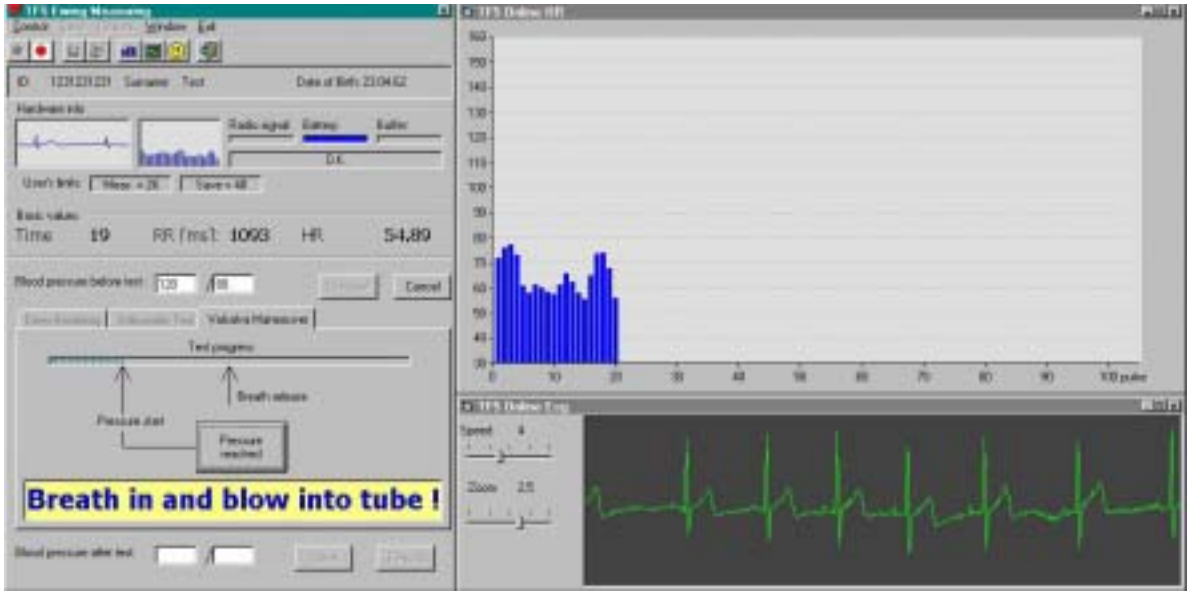
HRrest :	Resting heart rate
MV:	Average R-R interval
SD:	Standard deviation
MSSD:	Mean Square of Differences of Successive R-R Intervals
CVr-r :	Component Variance of R-R Intervals
I-E:	Difference Inspirium and Expirium heart rate
I/E:	Ratio maximum vers. minimum heart rate during Inspirium and Expirium

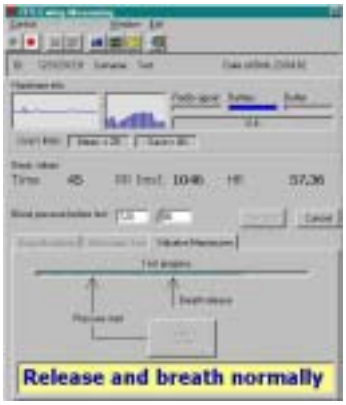
Practical example: *Typical results screen with apparently normal heart rate variability during the deep breathing test. For parameters description, see above. The green lines in the main screen show time course of test commands (5-seconds cycles), ECG below, position of the browser of heart rate course and numbers shown at the bottom line are related to the marked HR value – in yellow, see the main screen. In order to remove artefacts, the marking can be changed by moving the mouse and clicking the left (mark) or right (unmark) buttons. This procedure is identical with that used in spectral analysis processing, as described earlier.*



8.2.2. Ewing Battery: How to Perform the Valsalva Maneuver

Choose the '**Valsalva maneuver**' option by clicking the button. Optionally, enter the blood pressure values and start the measurement by clicking the '**Test start**' button. After starting you have to wait for 10 seconds, after which a message '**Breath in and blow into tube**' appears. Identical voice command is heard, as well. The patient has to inhale deeply, and when starting the exhalation (while reaching 40 mmHg on the manometer), the examiner has to press the '**Pressure reached**' key. Under constant resistance of 40 mmHg during the expiration, the heart rate course is recorded for 15 seconds.





Afterwards a short signal beeps, and a message '**Release and breath normally**' appears, paralleled by a voice command. The subject returns to normal breathing and has to wait until the end of the test (some 20 seconds again). Finally, a message '**Test is finished**' closes the examination. Please save the recorded data immediately, again, by clicking the '**Save**' button below. Results of the test are available by clicking the '**Results**' button below on the screen.

Relevant parameters: Valsalva maneuver

VR	Valsalva-Ratio
t max	Timepoint of maximal heart rate
t min	Timepoint of minimal heart rate
HRrest	Resting heart rate
HR max	Maximal heart rate
HR min	Minimal heart rate
HR max / HR rest	Ratio maximal heart rate vers. rest
HR max - HR rest	Difference maximal heart rate minus rest
HR min / HR rest	Ratio minimal heart rate vers. rest

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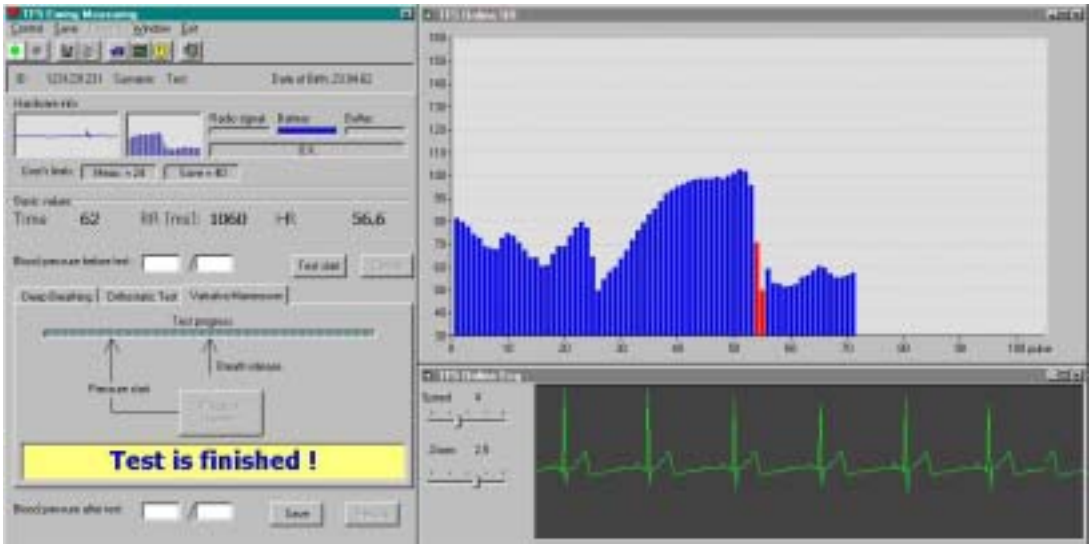
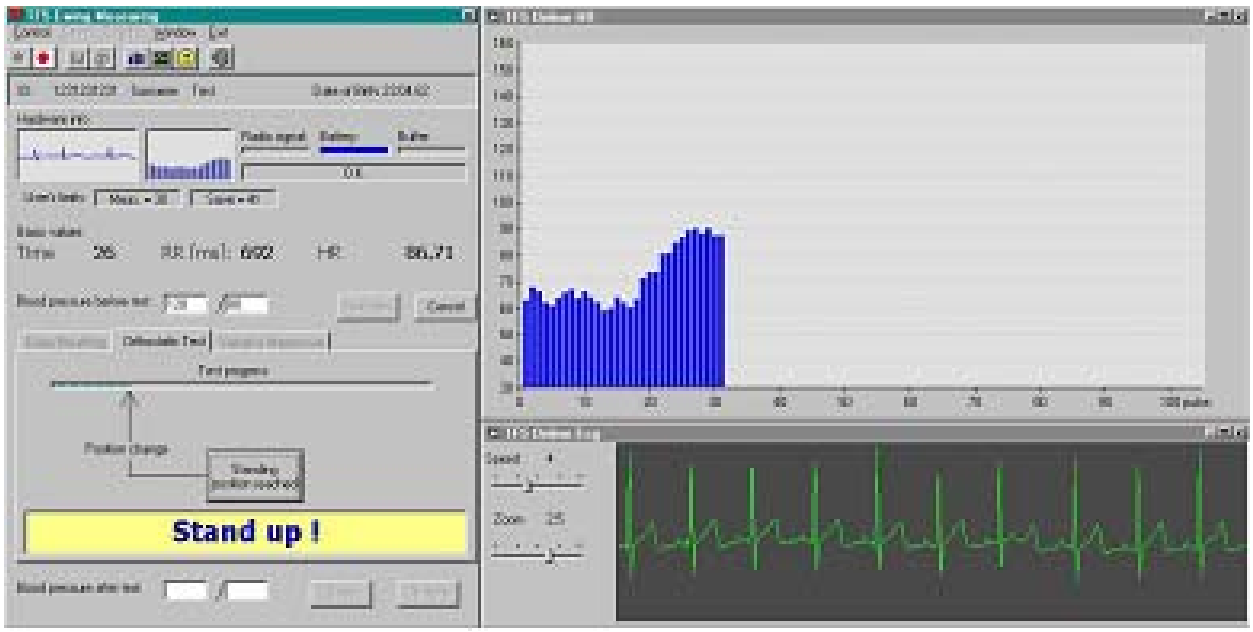


Practical example: *Above you can see a typical course of normal reaction of heart rate during the Valsalva maneuver (blue bars) as seen during the examination. Just a note,* ***save*** *always the obtained data as soon as possible to avoid unnecessary data loss etc.*

Notice: *From experience, it is recommended to make three Valsalva tests, and to express the result (the Valsalva ratio) as the mean ratio from the three successive tests (for more details see also Ewing DJ: The Value of Cardiovascular Autonomic Function Tests: 10 Years of Experience in Diabetes; Diabetes Care, 1985, 5: 491-498).*

8.2.2. Ewing Battery: How to Perform the Orthostatic Test

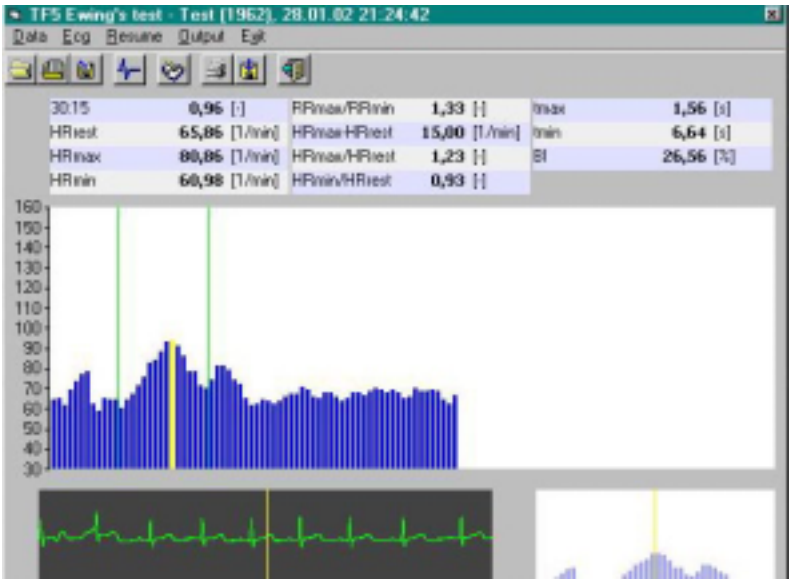
Whilst the subject is lying on the bed, measure his BP and – after choosing the '**Orthostatic test'** option -- enter the values into the fields '**Blood pressure before the test**'. Click the '**Start**' button and wait for 10 sec (see the description above).



After this preparatory phase, a message '**Stand up**' appears, paralleled by a voice command. After the subject finished the change of his position and is quietly standing, click the button '**Standing position reached**'. The subject stands until the automatic ending of the test. The examiner (repeatedly) measures the blood pressure throughout the test. It is highly recommended to enter the blood pressure values into the program at the beginning and end of the test, as indicated on the screen. Finally, a confirmation '**Test is finished**' appears/is heard, while you save the data immediately, by clicking the '**Save**' button to be found below on the screen left.

Relevant parameters: Orthostatic test

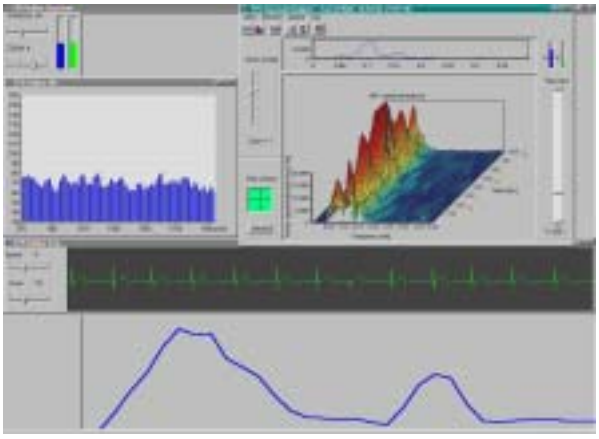
30:15 Ratio	Ratio of heart rates around the 30th & 15th beat
HR rest	Rest heart rate
HR max	Maximal heart rate
HR min	Minimal heart rate
HR max / HR min	Ratio maximal heart rate vers. minimal one
HR max - HR rest	Difference maximal heart rate minus rest
HR max / HR rest	Ratio maximal heart rate vers. rest
HR min / HR rest	Ratio minimal heart rate vers. rest
BP pre	Blood pressure value during lying down
t max	Timepoint of maximal heart rate
t min	Timepoint of minimal heart rate
BI	Brake Index
BP post:	Blood pressure value after standing up



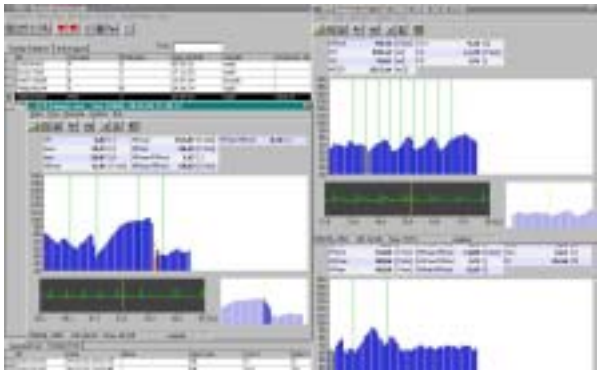
9.1. Some Practical Examples

Below you can find some examples to show the versatility of applications and use of the TF5 program just to help you in finding appropriate use of the system:

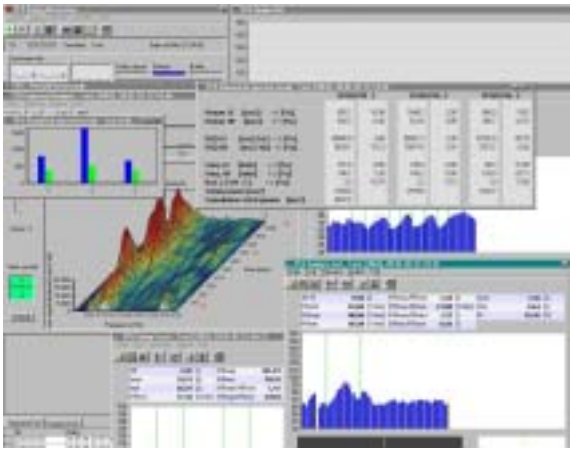
- E.g., it is possible to revise the previous results, while another examination is running, and to show both paralelly on the screen.



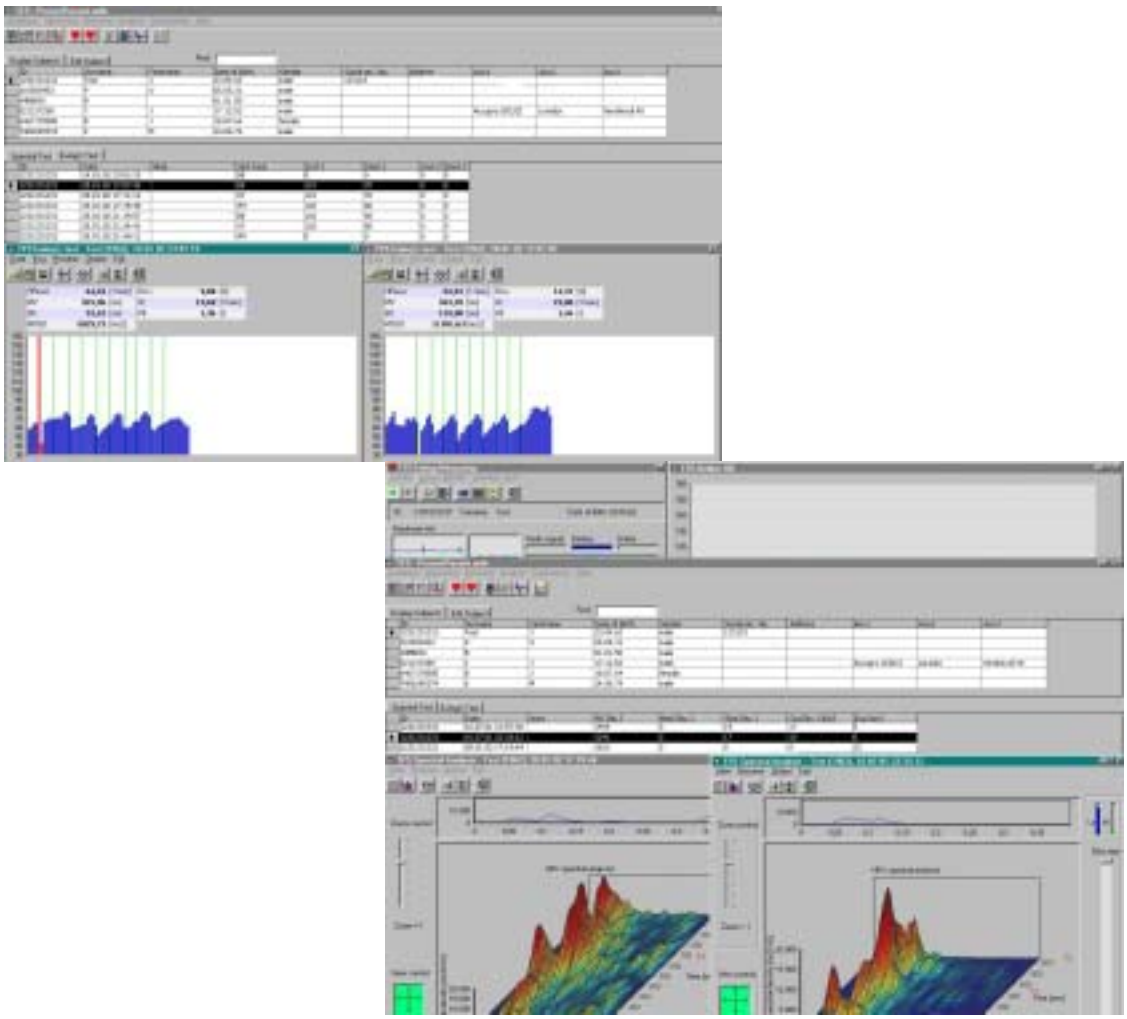
- You can display all results of short reflex test (Ewing) battery on one screen, and resize/manipulate the results windows to obtain the best overview.



- Also results of both analysis types – Ewing battery and spectral analysis – can be displayed in one screen for better and instant overview of the subject's results.



- Progress of the individual test results overt longer time period can be shown e.g., as follows.



9.2. Application Notes

Examination of heart rate variability has considerable potential to assess the role of autonomic nervous system fluctuations in normal healthy individuals and in those with various cardiovascular and non-cardiovascular disorders. Population based clinical trials show that the short-term examination of HRV, particularly in frequency domain, offers relevant prognostic information independent of and beyond that provided by traditional risk factors. Depressed HRV is a predictor of mortality and arrhythmic complications, however, like in any other method, to improve the predictive value HRV can be combined with other factors, e.g. LV ejection fraction in post-myocardial infarction risk stratification etc.

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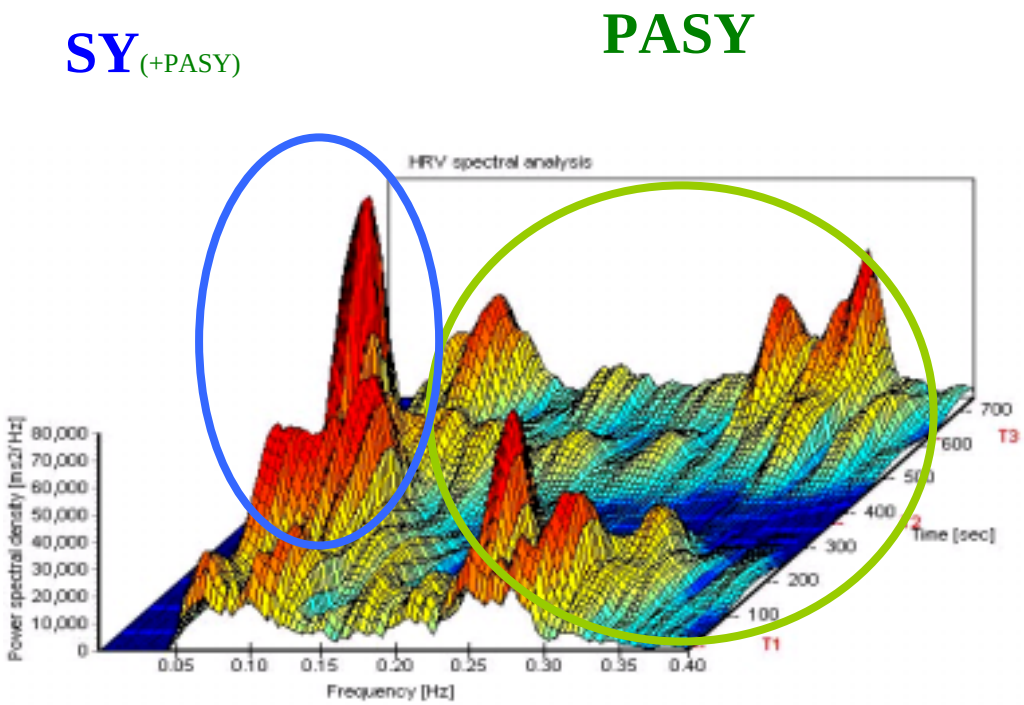
General Picture:

During the modified orthostatic load (provided it is performed as recommended in the user manual) the following characteristics are of particular interest:

(a) Three-dimensional graphics:

- Total energy contents (fluctuations) of the low and high frequency bands
- Physiological predominance of both control sub-systems during different positions
- Reactivity/reflexivity of the system during the standing up and after lying down.



Principally, the area under the fluctuations to the left from 0.15 Hz on the x-axis represents the *sympathetic* activity including probably a certain amount of parasympathetic influence. Fluctuations to the right from the arbitrary limit 0.15 Hz on the frequency axis reflect solely the *parasympathetic* cardiovascular control.

(b) Statistical table:

It is often helpful to compare the visual results with the numerical values as listed in the statistical table (see user manual). Please note that there is a strong relationship between age and normal reference range which considerable diminishes with severity of disturbance (described later in this chapter).

Normally, during supine positions (the first and third time intervals, labelled T1 and T3 on the z-axis) there is a predominance of a parasympathetic tone, as indicated in the above graph labelled “PASY“. During standing (position T2), activation of the sympathetic tone can be detected (labelled “SY“).

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Your Notes:

In case of any comments and/or questions, please feel free to contact your distributor, or the manufacturer directly:

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Thank you.

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