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

USER MANUAL

Doc 125-05

VariaCardio® TF5 Manual

Table of contents:

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

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.

Manufactured by: MIE Medical Research, Ltd. for

Advanced Medical Diagnostics Group, Ltd.
6, Wortley Moor Road, Leeds, LS12 4JF
United Kingdom
Phone: +44 (0)113 279 1010
Fax: +44 (0)113 2310 820
Website: http://www.amdgmedical.com
E-Mail: TF5@amdgmedical.com

Your VariaCardio TF5 system Serial Number: _____

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.
- 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.

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

MIE Medical Research Ltd
6 Wortley Moor Road,
Leeds, **Tel: +44 113 2793 710**
LS12 4JF. **Fax: +44 113 2310 820**
United Kingdom. **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%.

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.

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 all 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 spectral 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.

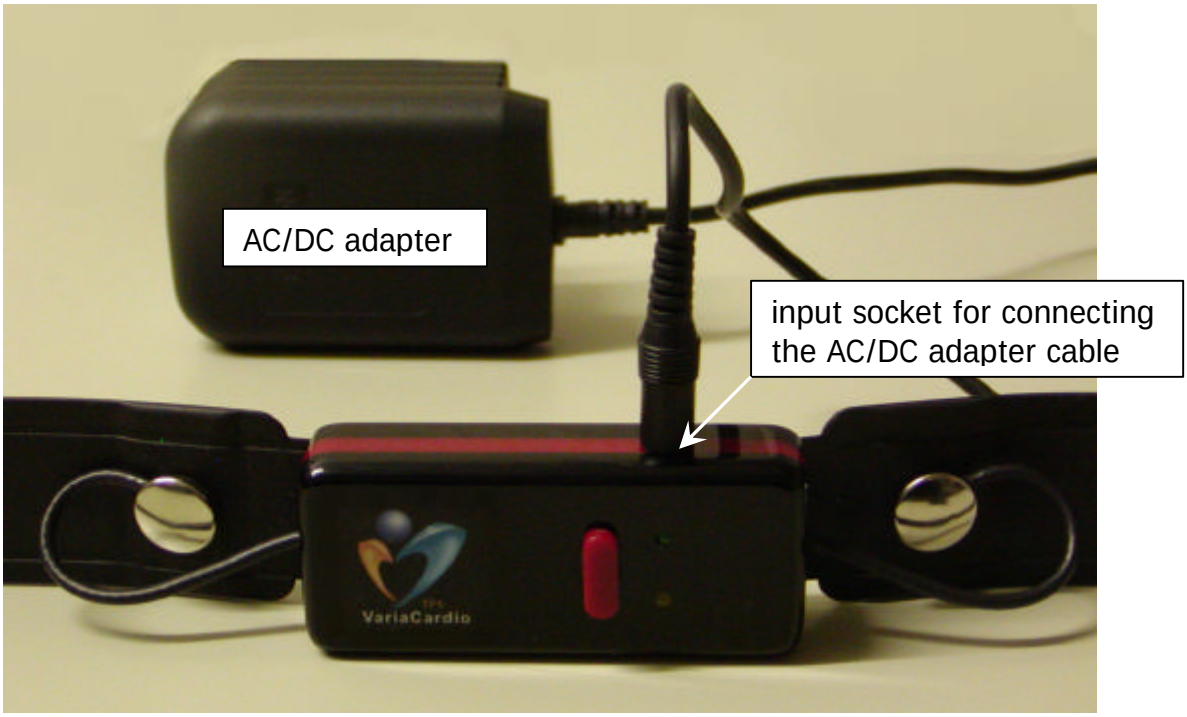
It is possible -- due to the UHF-radio telemetric data transfer -- to perform the examination from a distance of 20-30 metres or longer, e.g., in a separate examination room.

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.

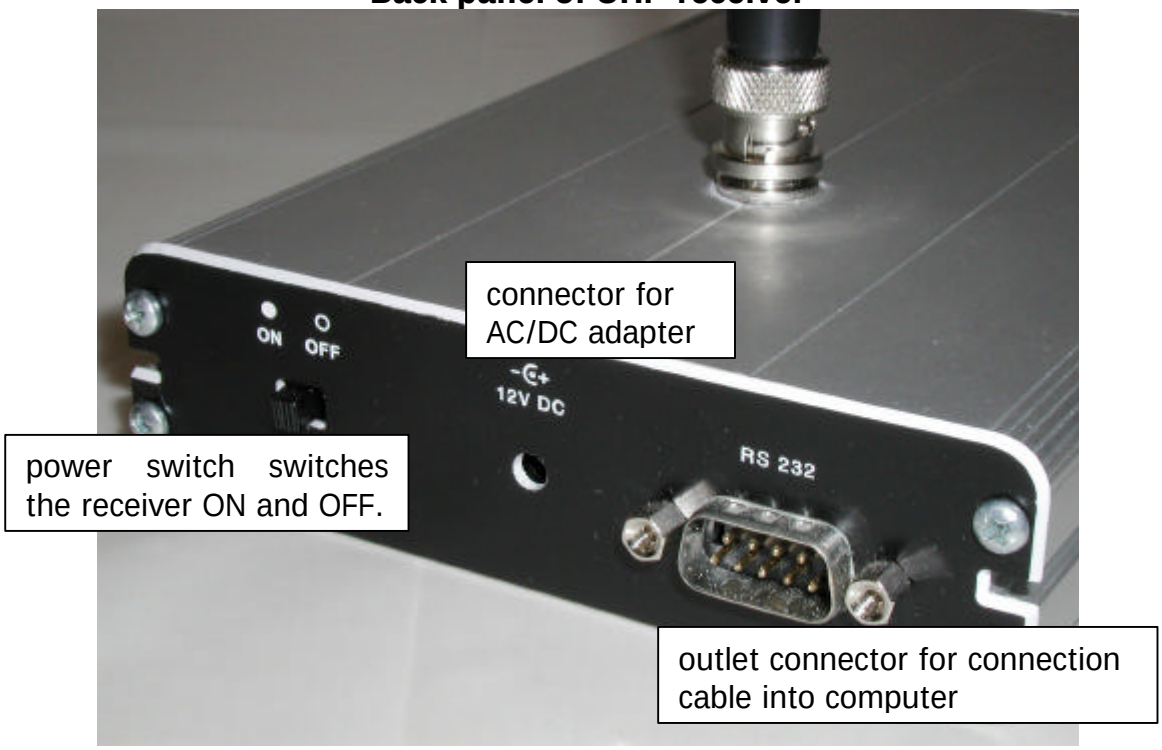
b) Front panel - Contains two LED-diodes (*yellow* one signalling power is ON, *green* one for checking of functional data transfer)

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

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.

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

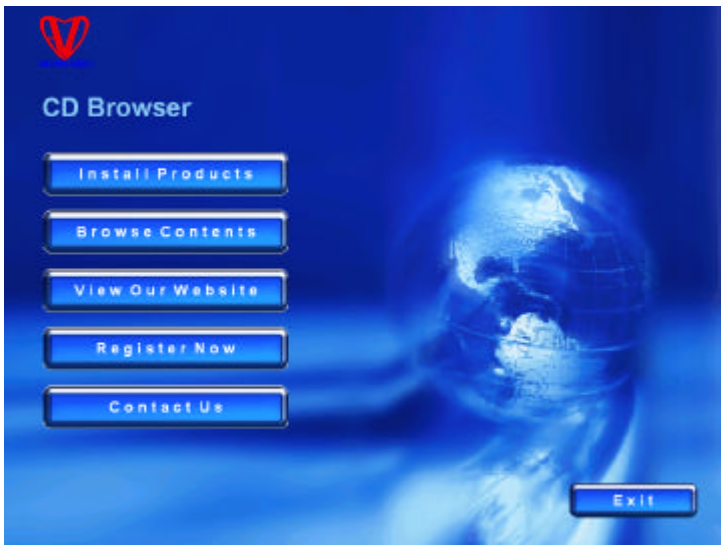
Note: Your VariaCardio TF5 system is usually installed & configured by an experienced manufacturer's technician or by one of authorised distributors so that it is ready for use. In this case you can skip this section and proceed directly to next Chapter **4.2. How to launch the application.**

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.

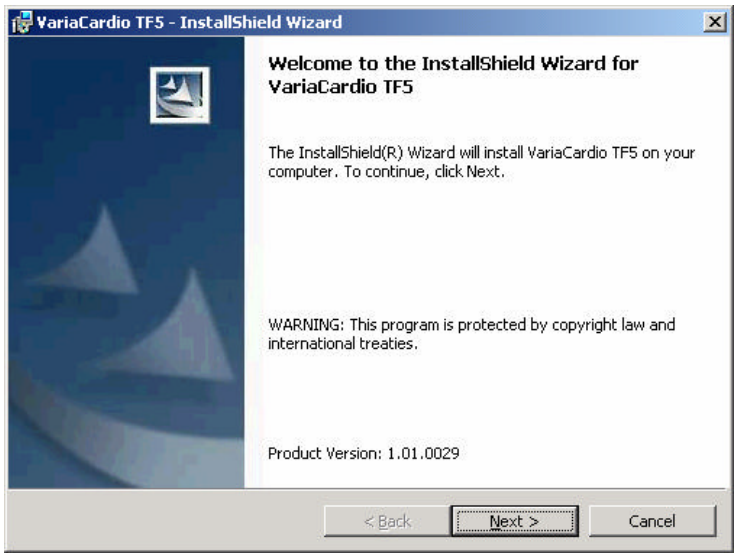
Once the installation process is complete you must click 'Menu' to return the opening page. Here you may choose to review our website or register the software.

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:



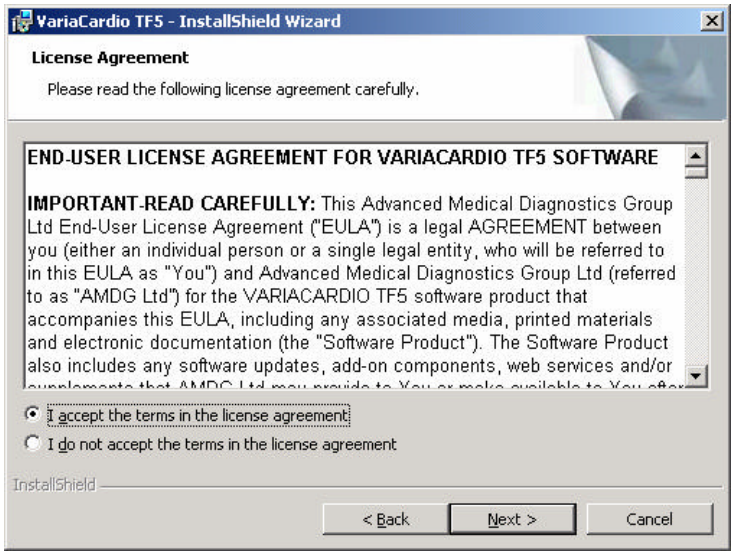
1. After some internal preparation, the installation wizard welcomes you and confirms the application to be installed. Click 'Next' to proceed with the installation.

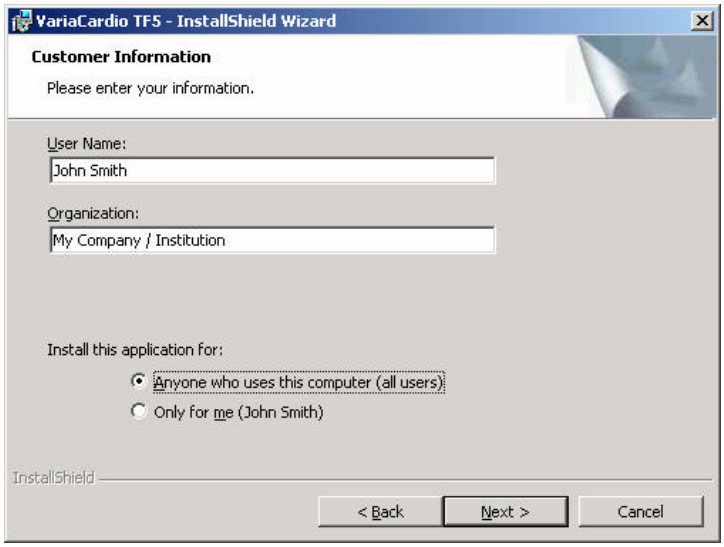
Important: On some systems, the Microsoft Installer may need to update critical system components before the installation wizard can proceed. You may be prompted to restart your computer, after which the installation wizard will automatically resume and proceed as normal. In extreme cases

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.

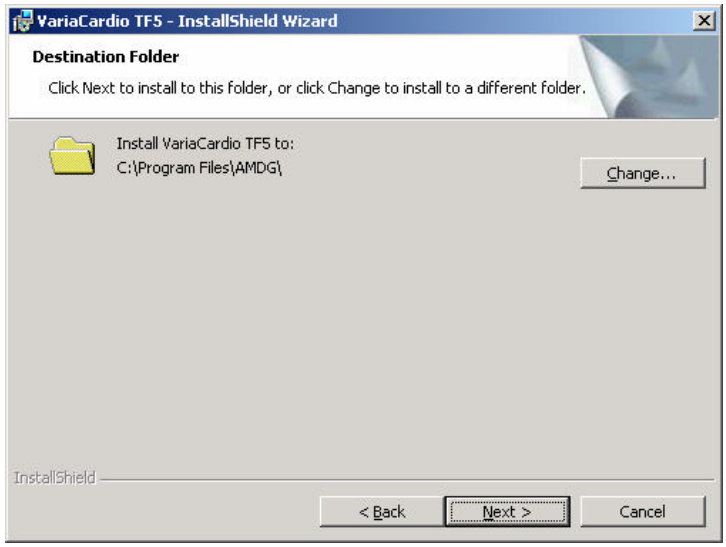
4. You may select which users the application is made available to (useful for corporate or institution users). Selecting 'Only for me' avoids the software being placed in other users' start menus, but does not prevent them manually launching the software directly. If you are uncertain, you should accept 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.

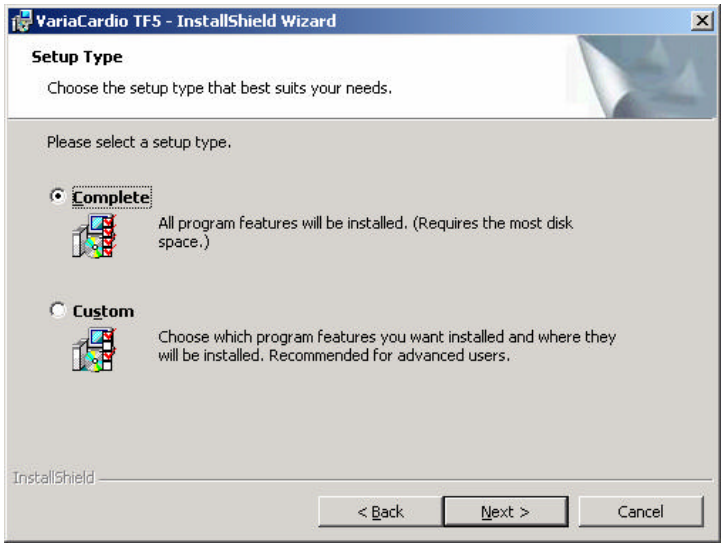
6. You may choose where the application should be installed:

   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.

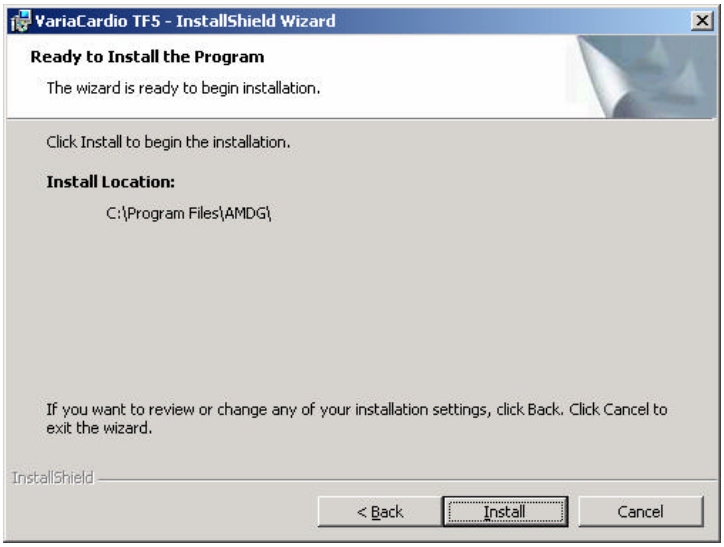


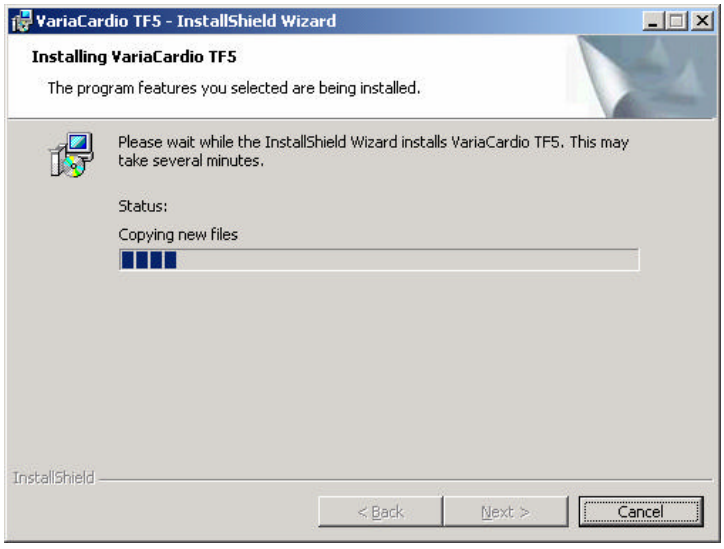
Complete installation installs the full application with all features, help, manuals & tutorials.

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.

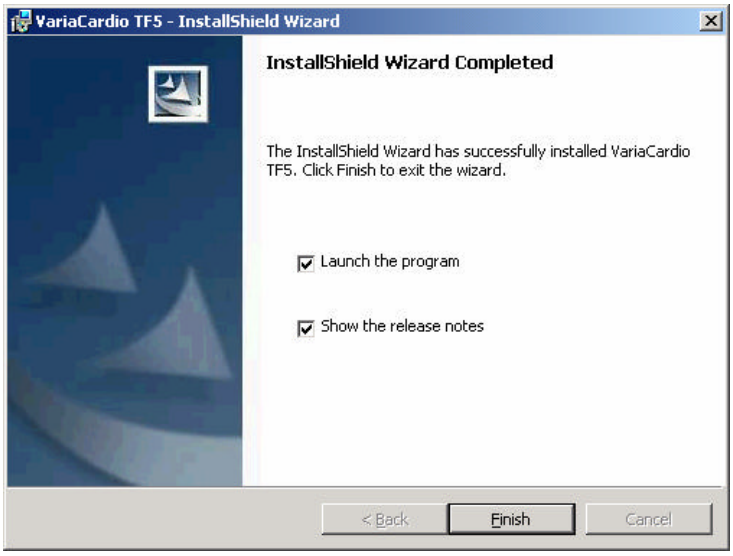




9. The features you selected will now be installed. Please wait while the process completes. This task may several moments.

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

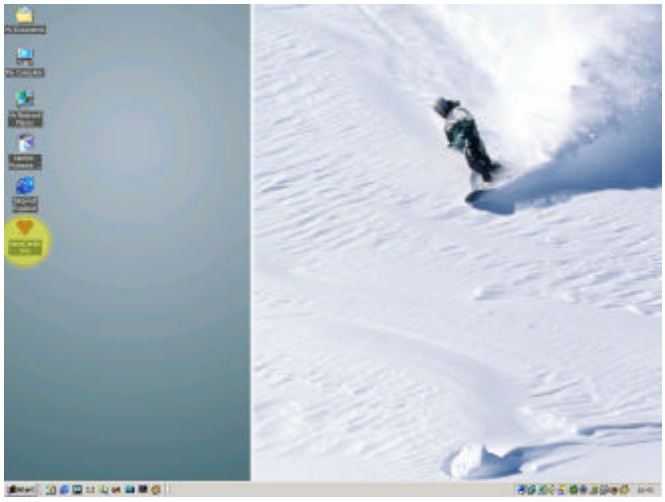
10. Typically you can click 'Finish' to exit the installation wizard. Note, however, if some files in need of updating were in use, you may be prompted to restart your computer. These files will then be updated during the restart and the wizard will exit automatically.



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

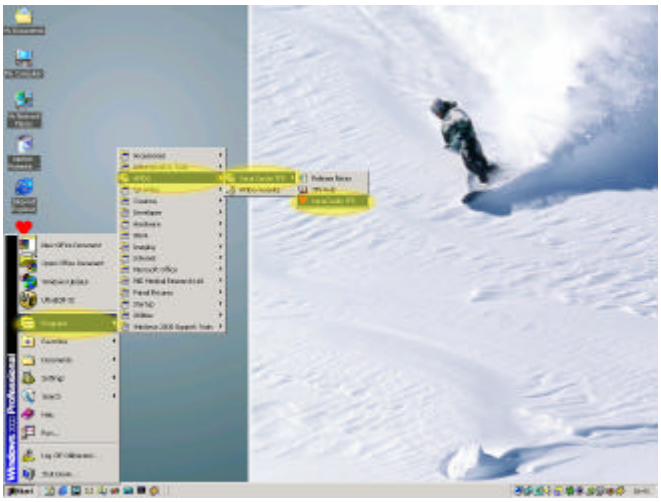
Once installed, the VariaCardio TF5 software can be launched from your desktop or start menu.



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

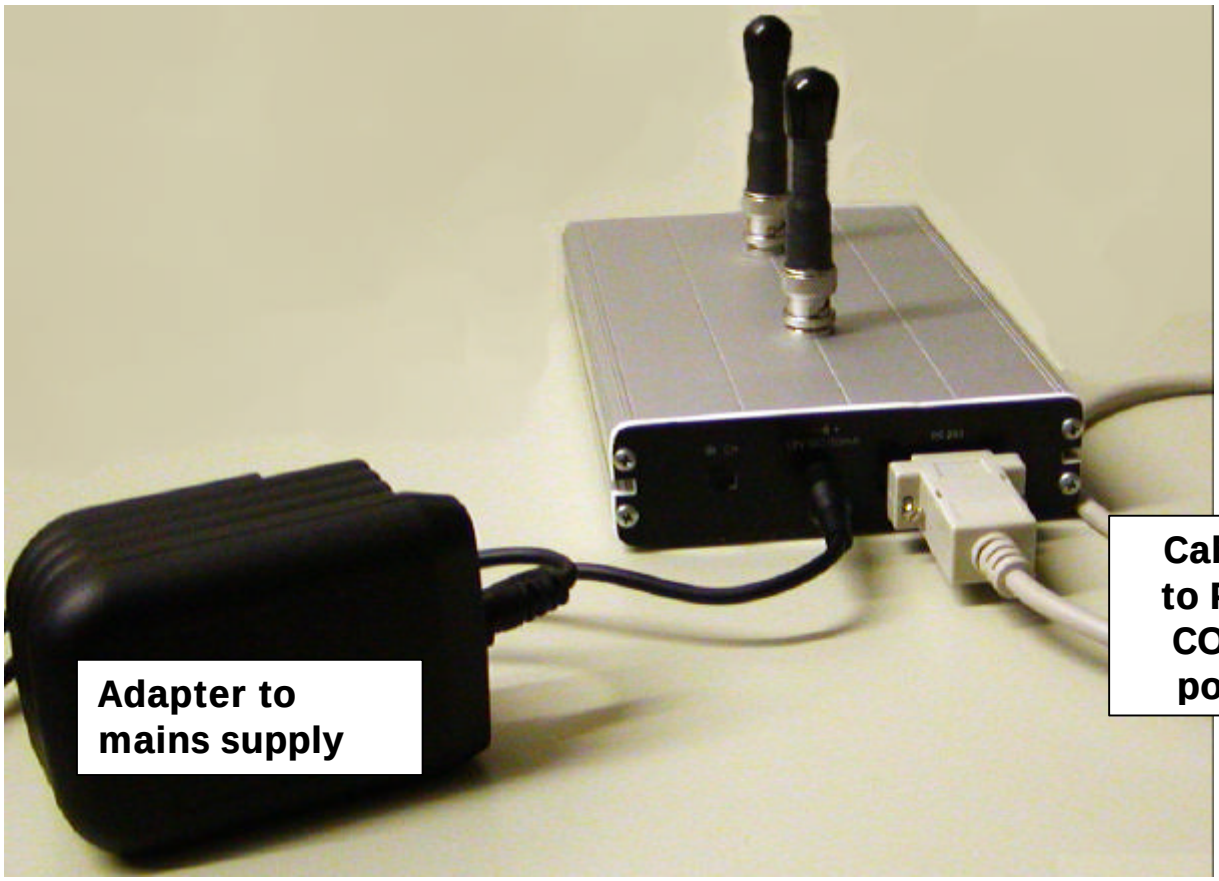
It is important to adjust the belt on the patient's chest so that the transmitter is located exactly in the middle of the thorax. If the original signal is not obtained correctly, the LED diode on the transmitter blinks irregularly or not at all. If this happens (assuming that there is NO cardiac arrhythmia), 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.

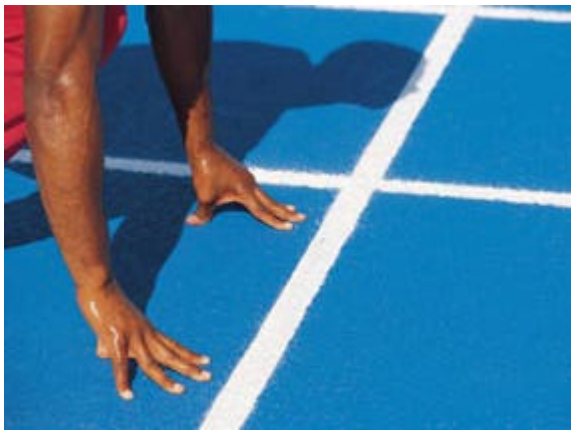
Using the PC mouse makes some tasks easier: where available, simply click with the left mouse button on the symbols/icons on the screen as displayed. While browsing the heart rate record, simply click on an appropriate heartbeat in order to mark or select it.

"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.

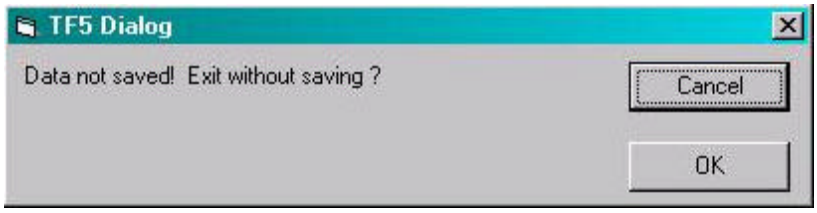
5. Clinical Use of the System: Database

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).

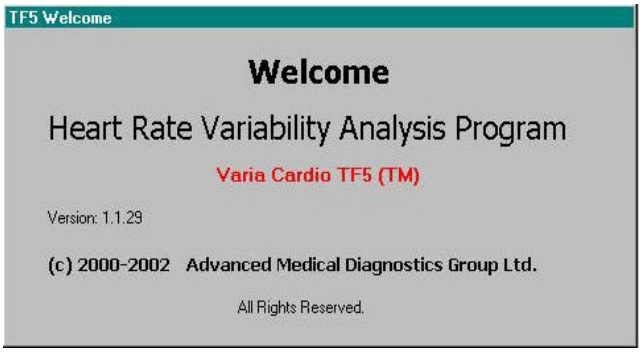
Also other **standard Windows icons and commands** work as usual, like icons for manipulation with active window (e.g., close, minimize, restore window) etc.



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).

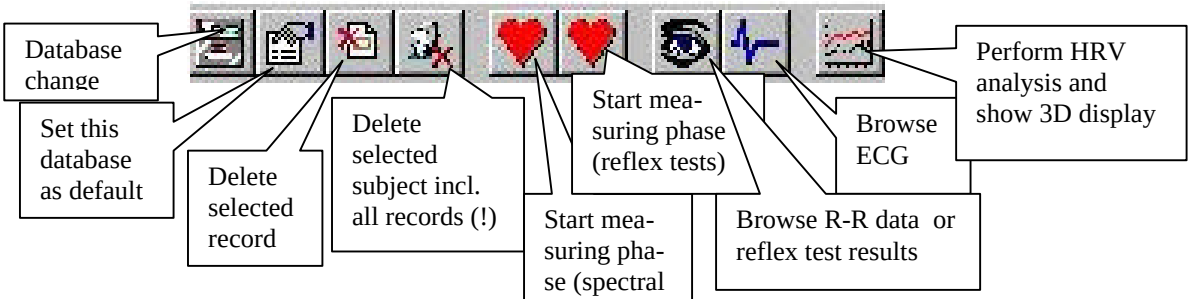


After entering the password, click on "**Logon**" button; that is followed by the message "**Loading Database, Please wait**" (this might take several seconds accordingly to the size of database). Finally, a basic operation screen appears. The usual way to get started with the program is to create or 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).

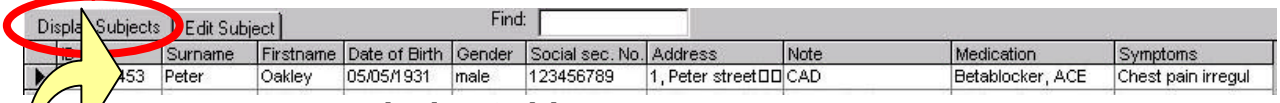
5.3. The Basic Operation Screen

(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 bjects and their records**:



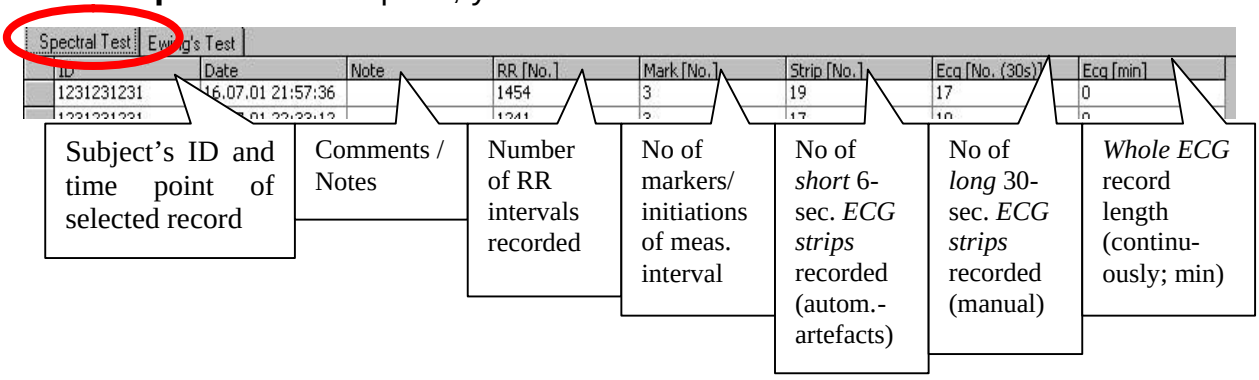
Program option "**Display Subjects**" allows the display of all subjects found in a selected database, these may be sorted into order by clicking on/highlighting the relevant item column. Each **database subject record** consists of

(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

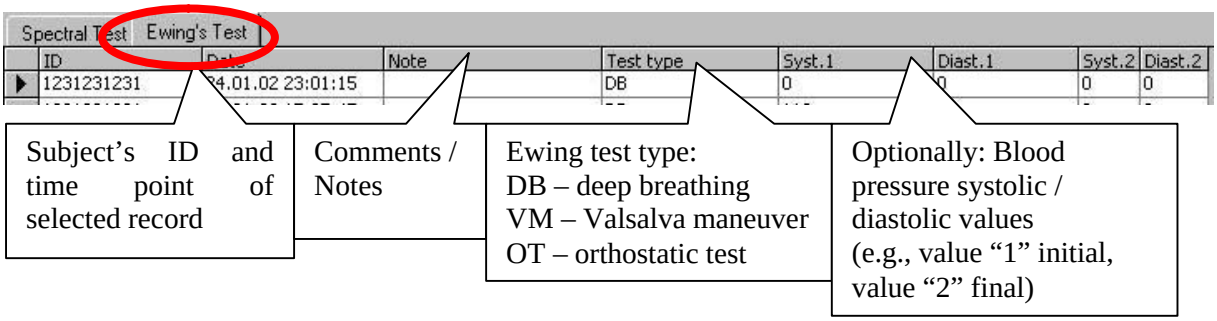
(b) **test data - heart rate variability and/or one-channel ECG record** (see below). Record details relating to the selected subject are shown in a separate window *below* the main database window.

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".

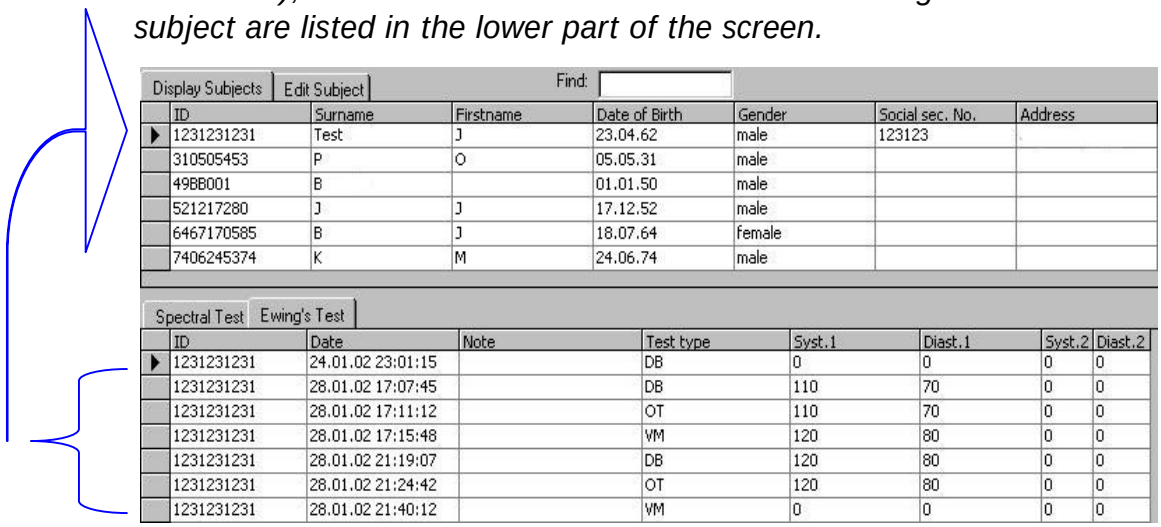
In the **"Spectral test"** option, you can find/enter further record details:



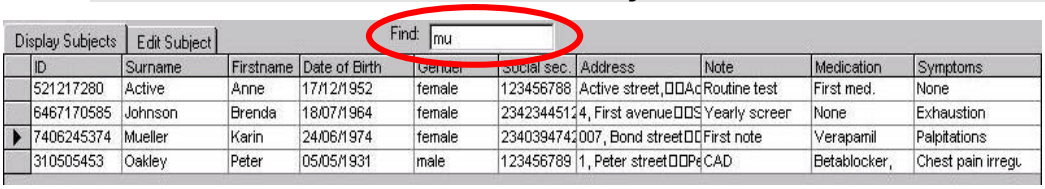
In the **"Ewing's test"** option, following record details can be found/entered:



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.*

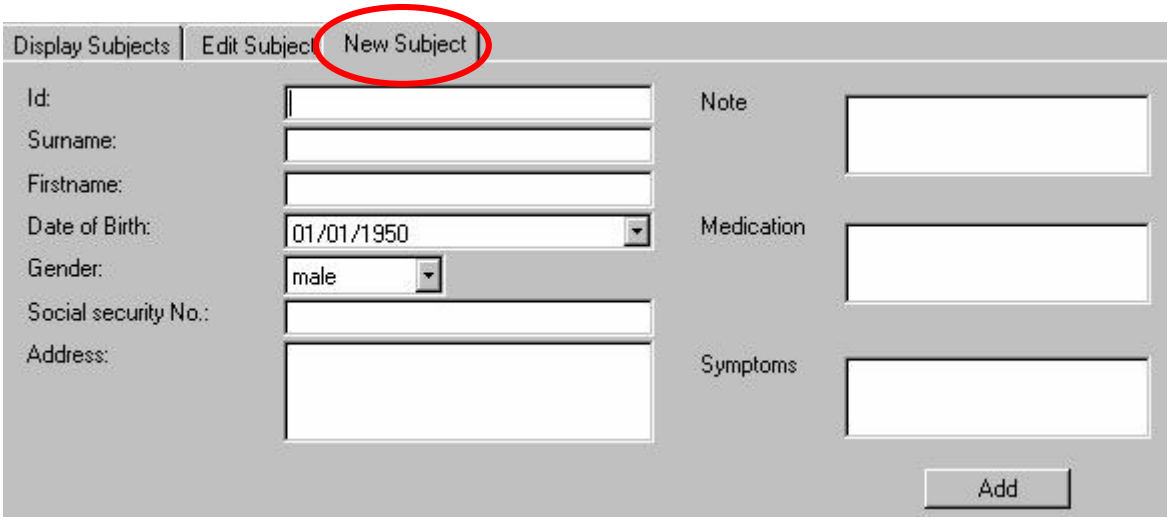


5.4. Database: How to Find a Subject

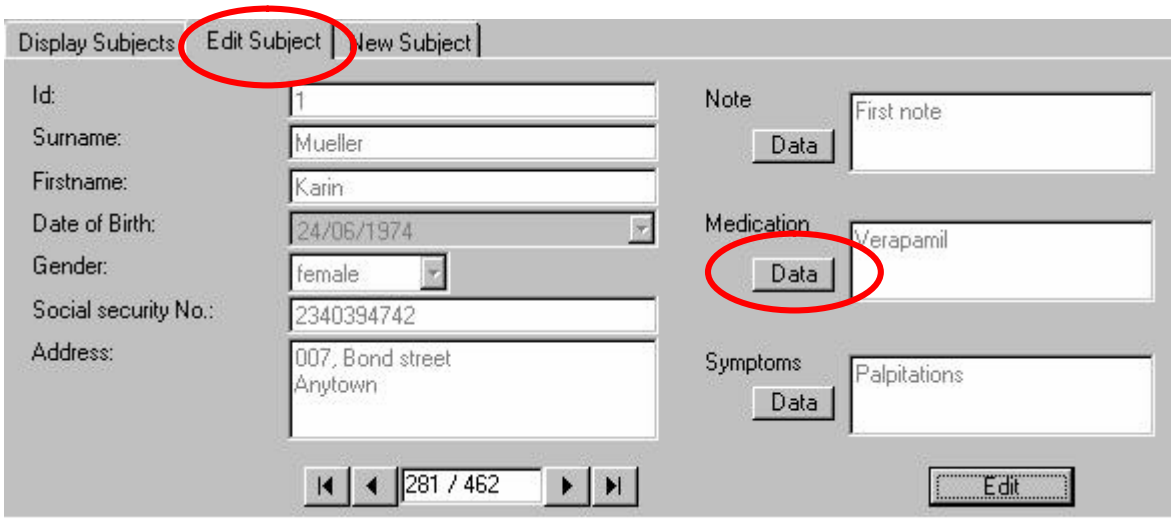


By entering the first digits of ID or surname letters into the field "**Find**" located just above the Database headings it is possible to find quickly the requested subject. The corresponding subject's personal record is indicated by a small black arrow on the left-hand side in the Database window. 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

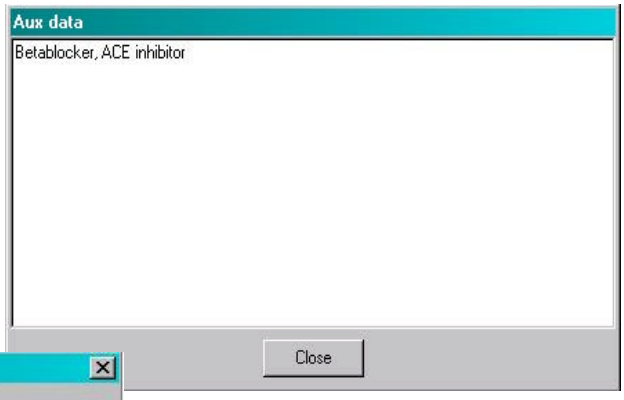


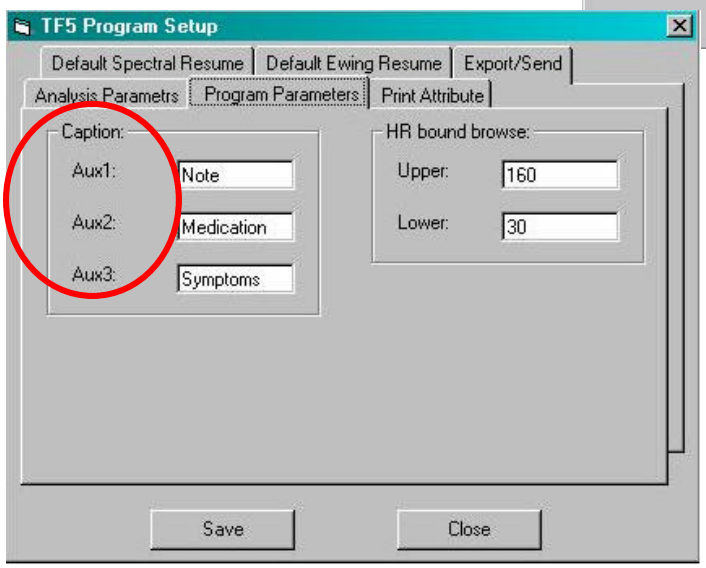
- Click on **New Subject** sheet: a single screen with personal data of the selected subject is displayed, see above. Here it is possible to enter data of a new subject. On completion, various standard fields (see above) can be entered while the ID No, Surname, Date of birth and Gender are requested 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.

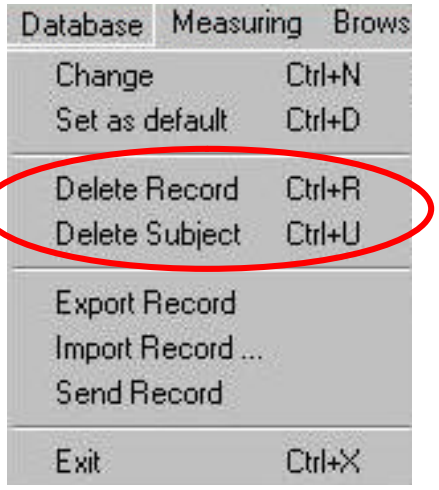
By clicking the **Data** button at the right-hand side, you can open an auxiliary data window where free text information can be entered. Three Aux data windows are provided for each subject. In the main program menu **Engineering**-> submenu **Program Setup**-> option **Aux Caption** it is possible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



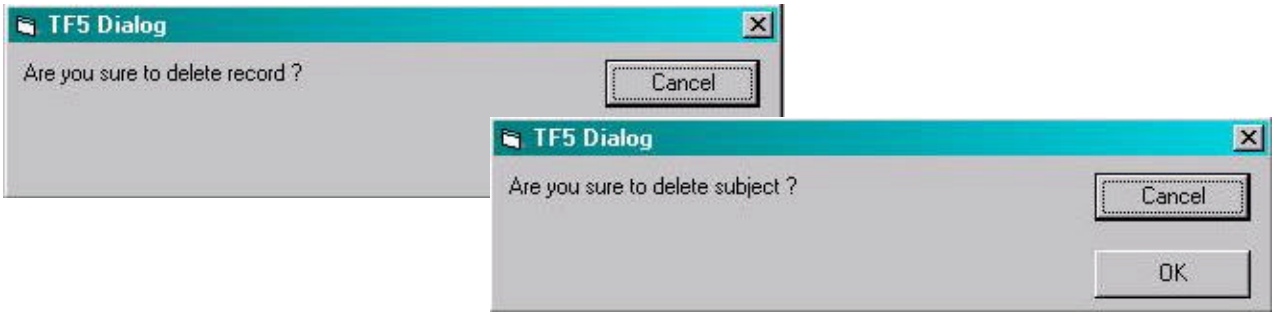
Mark subject's **record** to be deleted by clicking on the record with left mouse button. A small arrow at the left-hand side of database records listing appears. This arrow identifies the record to be deleted by

- 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.

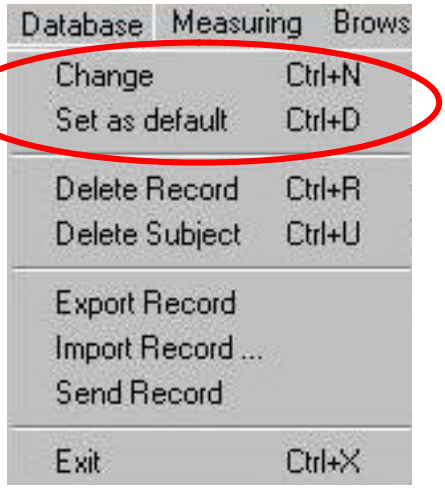
In both cases, a security alert appears in order to guard such (sometimes unintended) action – see below. Just confirm, please, your decision.



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.



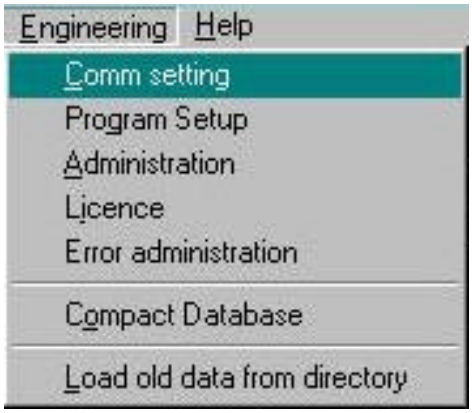
5.8. Database: How to Set the Database as Default

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

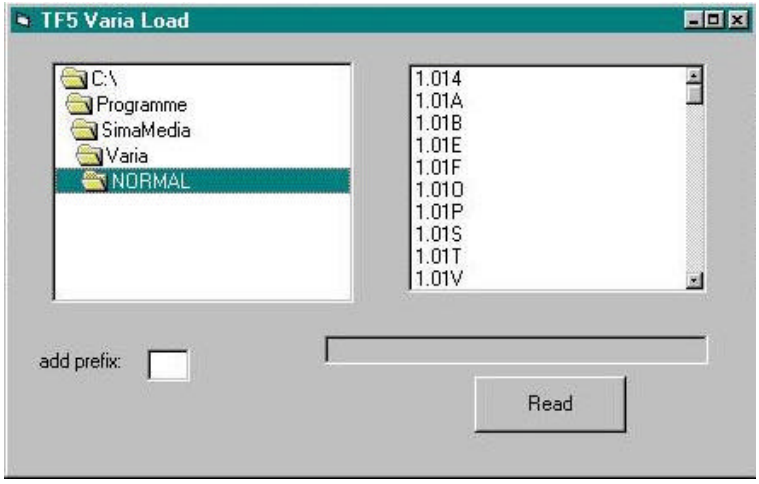
During starting procedure, program will automatically call this default database.

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.