

User Manual

MetaMax[®] 3B



mie
Medical Research
Limited

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Dear User

Welcome to CORTEX Biophysik.

Thank you for purchasing the

“CORTEX Biophysik MetaMax[®] 3B portable CPX system”
“CORTEX Biophysik MetaSoft metabolic stress test software”.

We hope you will enjoy using your MetaMax[®] 3B as much as we enjoyed developing it for you!

To help us provide the product and service excellence you expect now and in the future, CORTEX Biophysik welcomes your comments and suggestions.

Please complete your registration form and send it back to us to be eligible for customer support, new product information and information on special offers and events sponsored or organized by CORTEX Biophysik. Forms are included in the “Contact” menu of the “Support” module of the MetaSoft software.

We look forward to sharing your experience using MetaMax[®] 3B.

Sincerely



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I. Before you start

Introduction

This User Manual refers to

MetaMax[®] 3B, Version 1.0
MetaSoft, Version 1.3.

It is designed to help you getting started performing cardiopulmonary stress tests with your new MetaMax[®] 3B, answering basic questions about how to assemble the parts and to operate mobile MetaMax[®] 3B. In addition, it gives a short introduction into MetaSoft, the metabolic stress test software supplied with your MetaMax[®] 3B which is needed to measure, display and evaluate the data recorded. A context-sensitive software online help is available for further tips and technical assistance. Please also contact your local CORTEX sales partner for hotline support and/or preventive maintenance and service agreements.

Please read the following instructions and safety regulations carefully before first use, to obtain the best performance from your MetaMax[®] 3B diagnostic system. Keep these instructions in a safe place for future reference.

Intended Use

The MetaMax[®] 3B is a portable cardiopulmonary exercise system (short: CPX system) for pulmonary gas exchange measurements under real conditions. As a truly portable system, it is carried by the patient/test person throughout the entire exercise session, making it suitable for any kind of CPX test - in the field, at the work-site, during treadmill or ergometer exercise in the stress lab. Direct measures of gas exchange include O₂ and CO₂ concentration of the expired/inspired air, heart rate, ventilation, ambient temperature and pressure. In addition, other valuable physiological variables can be obtained (e.g. AT, VO_{2max}), allowing the physician to completely assess a patient's or an athlete's cardiopulmonary status. This device may be used with adults and children over the age of 14 years.

During a CPX test with MetaMax[®] 3B, the patient/test person is wearing a small face mask, breathing out through a volume transducer fixed to the face mask. The gas samples are collected while the patient/test person exercises in the field (e.g. walking, jogging) or on a bicycle ergometer or treadmill. The integrated 3-channel, 5-lead ECG enables the physician to record the ECG of his/her patient/test person and to monitor his/her heart function throughout the test. Selected ECG waveforms, breaths and/or breath sequences can be saved during any kind of exercise for online display and a detailed analysis after the test. In addition, other external diagnostic devices (e.g. blood pressure device) can be connected and directly controlled via the MetaSoft software. An integrated speech module allows physicians/trainers to send predefined phrases of encouragement and instructions from their PC to the MetaMax[®] 3B system using telemetry data transfer. Patients/test persons will hear the phrase selected via earphone which is connected to the base system.

As a breath-by-breath system the MetaMax[®] 3B measures volume continuously and simultaneously determines expired CO₂ and O₂ concentration. The CO₂ output and O₂ uptake during each breath are calculated, and data sampled is transferred breath-by-breath to a PC for immediate display. Breath-by-Breath systems allow very accurate measurements under non-steady-state and changing ambient air conditions. They are considered appropriate for extended CPX testing requirements aimed to accurately follow up the physiological responses during exercise tests in which work rates change more frequently.

The MetaMax[®] 3B is battery-operated. It is used as a self-contained measurement device carried by the patient/test person throughout the test. To provide a secure fit, MetaMax[®] 3B is fixed to "MaxBelt", a comfortable Velcro scarf which is slipped over the patient's / test person's shoulder.

All data collected during measurement is either transferred online to a PC using telemetry data transfer and/or stored in the internal datalogger for later downloading into a PC. In addition, the datalogger ensures utmost data safety in case of transmission failures.

During telemetry data transfer the data collected can be observed in real-time on a PC using MetaSoft software. The MetaSoft database stores the data for a profound analysis and print out after the test using predefined reports.

The MetaMax[®] 3B has to be operated by appropriately trained physicians, properly trained nurses, exercise physiologists, or medical technicians working directly under the supervision of a physician who should be in the immediate vicinity and available for emergencies. The MetaMax[®] 3B must not be used in intensive care environments or for monitoring vital body functions. The ultimate judgement as to which patients/test persons should undergo a metabolic stress test and as to which protocols are selected and/or adapted must be made by the physician based on the limitations of the individual and in light of his medical history and of all of the circumstances presented by that patient/test person.

Neither CORTEX Biophysik nor its sales partners assume any responsibility for the final use of its equipment.

For further information on cardiopulmonary exercise testing please refer to chapter "Indications and contraindications for metabolic stress testing" in your online help of the MetaSoft software or contact your local CORTEX sales partner.

Note: For medical use, federal law restricts this device to sale by or on the order of a physician.

Test settings



As a lightweight, mobile (portable) system, MetaMax[®] 3B allows you

- to test any kind of test person – from patients to elite athletes, from adult to pediatric patients. With its Triple[®] V volume transducer and a special-design *MaxBelt* harness, the MetaMax[®] 3B Ultra model is the ideal system for sports research and sports medicine applications. Pediatric face masks are optionally available to optimize tests with pediatric patients. The integrated speech module allows physicians to safely monitor their patients during field tests, interfering in case of critical events.
- to test patients who, for psychological or physical reasons, (e.g. after a hip operation) are unable to perform ergometer or treadmill tests.
- to select any kind of exercise program, testing patients/test persons during any kind of activity (e.g. daily activities, e.g. walking, climbing stairs, at the work-site, during a training on the track) and within any testing environment (e.g. indoor and outdoor).
- to use the system as a stationary system, performing ergo-meter or treadmill tests in your stress lab and viewing the test online on your PC. Your ergometer or treadmill can be controlled via MetaSoft (optional).

Safety Regulations

For safety reasons the MetaMax[®] 3B must not be operated or used with accessories, disposables, optional modules or analyzers other than offered and/or authorized by the manufacturer. Ergometers and treadmills (digital) which are to be controlled via MetaSoft must meet the legal requirements for medical equipment and may be used with the appropriate MetaMax[®] 3B option only. Computers which are connected to the MetaMax[®] 3B to configure MetaSoft and/or retrieve logged data from the data logger and which were not supplied by the manufacturer, must comply with the technical standards for electronic equipment. They must meet the minimum requirements recommended by CORTEX Biophysik for use with MetaSoft metabolic stress test software to ensure a proper function of the MetaMax[®] 3B.

Do not use or connect any defective, broken or non-genuine parts or accessories. Do not use or repair defective power supplies. Defective power supplies must be replaced prior to use. If in doubt, always contact an authorized CORTEX sales partner or CORTEX Biophysik to check the system before use.

Do not open the system. For repairs return the system to your local CORTEX sales partner or to CORTEX Biophysik. The MetaMax[®] 3B and/or its parts may be repaired by an authorized CORTEX sales partner or by CORTEX technical support staff only. Repairs undertaken by non-authorized personnel may cause severe risk for the user and patient/test person. The CORTEX warranty expires in case of non-authorized repair.

Do not use power supplies with open or defective housings. Always use the power supply and battery charging device within closed and dry rooms. The MetaMax[®] 3B must not be used with anaesthesia gas in combination with oxygen or nitrous oxide (it is not a device of class AP or APG).

Neither CORTEX Biophysik nor its sales partners assume any liability for defects, damages or any injuries caused due to improper use of the MetaMax[®] 3B or due to a violation of its safety regulations and maintenance instructions.

During intended use of the MetaMax[®] 3B, no waste is produced or compounds are generated which need to be disposed. At the end of their life cycle, please discard the device and its accessories according to your local environmental regulations.

For cleaning and maintenance instructions please see chapter "Maintenance, Cleaning & Battery Care" to ensure a proper and long-time performance of your MetaMax[®] 3B.

Interference with other devices

The MetaMax® 3B has been tested for electromagnetic tolerance and meets the required standards. There may be minimum risks, however, of the MetaMax® 3B to interfere with other electronic devices.

These risks are:

There are very strong electromagnetic transmitters (e.g. devices not built to required standards) in the vicinity, which may cause interference of the measurement since the MetaMax® 3B transfers data via telemetry.

Should this occur, please contact your local CORTEX sales partner or CORTEX technical support for assistance.

For further information on the operation of the MetaMax® 3B, technical details and optional modules available, please contact your local CORTEX sales partner or CORTEX Biophysik. Please also see chapter "Technical Data" and back page of this manual for contact details of CORTEX Biophysik.

II. Technical Data

Measurement Device

The MetaMax[®] 3B is a lightweight mobile cardiopulmonary stress test system for pulmonary gas exchange measurements under real conditions during any kind of field or lab exercise, based on breath-by-breath technology.

Parameters

The following parameters are measured and/or calculated during a measurement with MetaMax[®] 3B:

Parameter	S = Standard O = Option
Circulation	
- HR (Heart Rate)	S
- HR _{max} (Maximum Heart Rate)	S
- Blood Pressure (systolic, diastolic, mmHg)	O
- Workload:	
Level (rest, load, recovery), work rate (watts), grade (watts/min., grade/min.), speed (m/sec., km/h, m/h), elevation	O
- 3-channel ECG (5, 10, 20 mm/mV, 15, 25, 75 mm/sec., Einthoven I-III, Wilson V, Nehb, Goldberger aVR, aVF, aVL, ST segment elevation)	S
- 12-channel ECG (Einthoven, Wilson, Goldberger)	O
Gas Exchange	
- FIO ₂ , FEO ₂ (O ₂ Concentration in inspired / expired gas, Vol. %)	S
- FICO ₂ , FECO ₂ (CO ₂ Concentration in inspired / expired gas, Vol. %)	S
- FetO ₂ , FetCO ₂ (End-tidal O ₂ /CO ₂ Concentration in expired gas, Vol. %)	S
- VO ₂ BTPS (Oxygen Uptake BTPS, l/min)	S
- VCO ₂ BTPS (Carbon Dioxide Output BTPS, l/min)	S
- VO ₂ STPD (Absolute O ₂ Uptake STPD, l/min)	S
- VCO ₂ STPD (Absolute CO ₂ Output STPD, l/min)	S
- spec. VO ₂ (Relative O ₂ Uptake, l/min/kg)	S
- spec. VCO ₂ (Relative CO ₂ Output, l/min/kg)	S
- VO _{2max} (Maximum O ₂ Uptake, l/min/kg)	S
- METS (Metabolic Equivalent)	S
- R (Respiratory Exchange Ratio VCO ₂ /VO ₂)	S
- AT (Anaerobic Threshold)	S
- VO ₂ /HR (Oxygen Pulse)	S
- VO ₂ /HR _{max} (Maximum Oxygen Pulse)	S
- VO ₂ / WR (Aerobic Capacity, l/min./W)	S
- O ₂ kinetics (Oxygen Deficit/Redemption, l/min.)	S

Parameter	S = Standard O = Option
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Ventilation

- RR (Respiratory Frequency or Respiratory Rate, Breath/min.) S
- V_T (Tidal Volume, l/Breath) S
- V_E ATPS (Minute Ventilation, l/min.) S
- V_E / VO_2 (Ventilatory Equivalent for O_2) S
- V_E / VCO_2 (Ventilatory Equivalent for CO_2) S
- $PETO_2$ (End-tidal O_2 Partial Pressure, mmHg) S
- $PETCO_2$ (End-tidal CO_2 Partial Pressure, mmHg) S
- $PACO_2$ (Arterial CO_2 Partial Pressure, mmHg) S

Spirometry

Volume-Time Graph

- VC (Vital Capacity, l) O
- FVC (Forced Vital Capacity, l) O
- FEV_1 (Forced Expiratory Volume in the 1st second of a forced expiration, l/sec.) O
- FEV_1/VC (Forced Expiratory Rate, %) O

Flow-Volume-Loop

- PEF (Peak Expiratory Flow, l/sec. or l/min.) S
- MEF_{25} (Expiratory Flow (l/sec) when 25% of FVC remains, also called F_{25}) O
- MEF_{50} (Expiratory Flow (l/sec) when 50% of FVC remains, also called F_{50}) O
- MEF_{75} (Expiratory Flow (l/sec) when 75% of FVC remains, also called F_{75}) O
- MEF (Average Expiratory Flow, l/sec, also called $FEF_{25-75\%}$) O
- PIF (Peak Inspiratory Flow (l/sec or l/min) during forced inspiration) S
- I_{50} (Inspiratory Flow (l/sec) when 50% of FVC remains) O
- R_{50} (Ratio F_{50} / I_{50} in %) O

Indirect Calorimetry

- EE (Energy Expenditure, kcal/min., kcal/h., kcal/day) O
- EE/kg (Energy Expenditure/weight, kcal/kg) O
- Protein, Fat, Carbon Hydrate (% , kcal/day, g/day) O

Technical Specifications

MetaMax[®] 3B Base System

Dimension (L/W/H)	Two housings, 120x110x45mm each
Weight	570g, excluding battery
CPU	16bit processor, 20 MHz, flash memory
Data logger	8 MB data

Analyzers

Volume transducer	<i>Standard model:</i>	
	Type:	DVT, turbine, digital
	Range:	0.1 – 12 l/s
	Resolution:	7 ml
	Accuracy:	2 %
	<i>Ultra model:</i>	
Type:	Triple-V [®] turbine, digital	
Range:	0.05 - 20 l/s	
Resolution:	7 ml	
Accuracy:	2 %	
Resistance:	>0,1 kPA/l/s at 16 l/s	
O ₂ analyzer	Type:	electro-chemical cell
	Range:	0 – 35 % O ₂
	Response time (t ₉₀):	100 ms
	Accuracy:	0.1 Vol. %
CO ₂ analyzer	Type:	ND infrared
	Range:	0 - 13 % CO ₂
	Response time (t ₉₀):	100 ms
	Accuracy:	0.1 Vol. %
Temperature sensor	Type:	NTC Thermistor
	Range:	-55°C - +155°C
	Accuracy:	1°C
Pressure sensor	Type:	Silicon
	Range:	200-1050 mbar
	Accuracy:	1.8%
Heart Rate	POLAR [®] or integrated 3-channel ECG	
Battery	Size (L/W/H):	70 x 38 x 20mm
	Weight:	80g
	Type:	Lithium ion
	Power:	1350 mA
	Voltage:	7.2 V nominal
	Capacity:	approx. 2 hours (SPRINT)
Telemetry	Type:	bidirectional, 19.2 kBaud
	Frequency:	433-434 MHz, manual or automatic selection of frequency (Japan: fixed)
	Range:	up to 1,000m
ECG	Channel:	3
	Leads:	Einthoven, Wilson, Nehb, Goldberger
	Frequency:	100 Hz
	Amplifier:	5, 10, 20 mm/mV

Telemetry Receiver

Dimension (L/W/H)	150x 80x 45 mm
Weight	200g
Frequency	433 – 434 MHz, manual or automatic selection of frequency (Japan: fixed)
Interface	RS232 to connect to PC or notebook computer

Environmental Conditions

During intended use:

Temperature	-20°C - +40° C
Humidity	30 – 99 %
Pressure	500 - 1200 mbar

During transport:

Temperature	-50°C - +70°C
Humidity	5 – 99 %
Pressure	500 - 1200 mbar

During storage:

Temperature	+2° - +25°C
Humidity	30 – 60 %
Pressure	500 – 1200 mbar

MetaMax[®] 3B Standard package includes

- MetaMax[®] 3B portable CPX system with integrated data logger, acoustic speech module, telemetry transmitter, 3-channel ECG module, heart rate receiver and battery compartment
- MaxBelt shoulder mount („scarf“) in three sizes (S, M, L)
- DVT volume transducer with cable, plug-in and integrated temperature sensor for standard applications
- Sample line (Nafion[®]) for gas sampling
- Adult face mask set (sizes: S, M, L)
- Adult head cap
- Polar[®] heart rate transmitter belt with elastic strap
- 5-lead ECG patient cable with self-adhesive disposable ECG electrodes
- Telemetry receiver with antenna, power supply, 9V lithium ion battery and serial link cable for PC/notebook computer
- 2 Lithium ion batteries, SPRINT version
- Battery charger for internal Lithium ion batteries (type SPRINT)
- Earphone for acoustic speech module
- PC connection cable to retrieve logged data from the datalogger
- MetaSoft metabolic stress test software under Windows[®] 95/98, Windows[®] NT
- User manual
- Carrying case

Models

- **MetaMax[®] 3B Standard** with DVT volume transducer suitable for any standard application in cardiology, pulmonology, occupational health and rehabilitation.
- **MetaMax[®] 3B Ultra** with Triple V[®] volume transducer suitable for sports research and sports medicine applications.

Options

Hardware

- CardioLyzer 12 for bike or treadmill testing in the lab with optional modules:
 - PC-based 12-channel, 10-lead rest and stress test ECG
 - Motion-tolerant NIBP
 - Pulse Oximetry
 - Suction electrode system for 12-channel ECG
- CBP 2000 Portable NIBP System

Software

- Ergometer control
- Treadmill control
- Spirometry
- Indirect calorimetry
- Non-invasive cardiac output

Accessories

- MaxBelt Ultra Pack to upgrade MetaMax[®] 3B Standard model for sports research/ sports medicine applications
- Pediatric face mask sets (small, large) for measurements with pediatric patients/athletes
- Calibration Kit
- Computer
- Notebook
- Color printer
- Multi-function trolley/cart

Peripheral Equipment

The MetaMax[®] 3B device has been successfully tested with the following peripheral equipment:

Ergometers

- LODE Corival 400
- LODE Excalibur WLP
- Ergoline 800 s

Treadmills

- Woodway pps 55 med

MetaSoft Metabolic Stress Test Software

Software MetaSoft 1.3
 Operating system Microsoft Windows® 95/98 or Windows NT® 4.0

PC / Notebook Minimum Requirements for MetaSoft

Processor: Pentium II 266 MHz
 RAM: 32 MB
 Hard Drive: 2.1 GB, min. 100 MB free memory
 Floppy Drive: 3.5"
 CD ROM Drive: 2x
 Interface: RS232, Sub-D, 9 pins, male
 Monitor: 15", 17" or LCD color monitor (SVGA 800 x 600 required)
 User interface: Keyboard, mouse or trackball, PS/2 version
 Operating system: Microsoft Windows® 95/98, NT® 3.5/4.0

Safety

Safety Standards EN 60601-1 (1996)
 EN 60601-1-1 (1994)
 EN 60601-1-1/A1 (1996)
 Class Class II, Type BF
 Protection Class IP 31
 EMC EN 60601-1-2 (1994)
 Conformity Class II a
 (according to 93/42/EEC; Appendix IX)

Disinfection instructions see chapter "Maintenance, Cleaning & Battery Care" of this manual.
 No device of class AP/APG.
 Suitable for continuous use.

Certified Quality

CORTEX Biophysik has successfully implemented a Quality Management System satisfying Quality System Standards ISO 9001 and EN 46001.

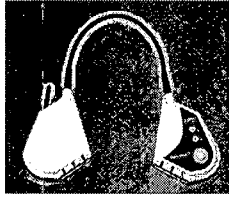
The MetaMax® 3B complies with the Medical Device Directives, MDD 93/42/EEC, and has been approved to carry the CE Mark as shown below:



III. Extent of Supply

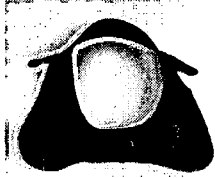
Main Parts	Description
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MetaMax[®] 3B Standard



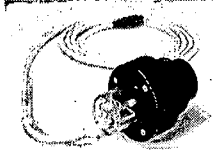
MetaMax[®] 3B base system ✓

Portable cardiopulmonary exercise system for pulmonary gas exchange measurements during any kind of lab or field exercise based on breath-by-breath technology. Base system consists of two housing connected via cable. Key functionalities fully integrated in base system: battery compartment, marker, datalogger (memory system to store test data), telemetry transmitter, Polar[®] heart rate receiver, acoustic output, 3-channel ECG.



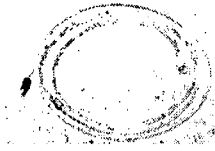
MaxBelt shoulder mount ✓

Comfortable, easy-to-fix harness in scarf form, using a breathable Velcro material. Designed to fix the MetaMax[®] 3B base system to the patient/test person during exercise, using plastic sliders. The standard supply includes MaxBelts in three different sizes (S, M, L) and two sets sliders.



DVT volume transducer

Sensor for volume/flow measurement, with cable, plug-in and integrated temperature sensor. To be inserted into the face mask and connected to the MetaMax[®] 3B base system. The sample line is inserted into the small hole on top of the volume transducer. The hole is fitted with a plug-in which needs to be inserted for volume calibration. Keep it in a safe place.



Sample line

To be plugged into the gas outlet on top of the volume transducer and connected to the MetaMax[®] 3B base system for gas sampling.



Adult Face Mask Set with Adult Head Cap

Breathing mask for the adult patient/test person, supplied in three different mask sizes (S, M, L) and adult head cap to fix face mask.



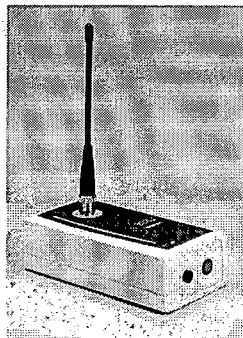
3-channel ECG module

For on-line monitoring of an ECG and the heart rate during a CPX test with MetaMax[®] 3B base system. Supply including:

- Built-in 3-channel ECG module
- 5-lead ECG patient cable
- Disposable self-adhesive ECG electrodes

Main Parts Description

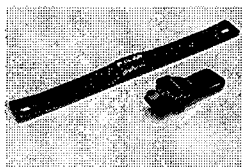
MetaMax® 3B Standard



Telemetry receiver unit

To transfer the data collected to a remote laptop or PC for real-time display of the measurement. Unit including:

- Antenna
- Telemetry receiver with PC connection cable
- Power supply for operation during stationary use
- 9 V Lithium ion battery for operation during field use

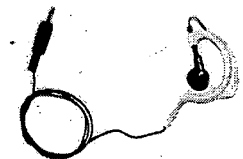


Polar® heart rate transmitter

Heart rate transmitter belt to measure the heart rate simultaneously with the gas exchange, including

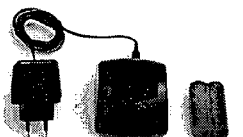
- Transmitter belt to be worn by the patient/test person
- Elastic strap to fix the transmitter belt to the patient/test person

The receiver is already integrated in the MetaMax® 3B base system.



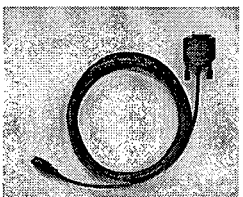
Earphone

Acoustic output of preprogrammed phrases (operator instructions, phrases of encouragement) to optimize operation and/or patient/test person control during mobile exercise.



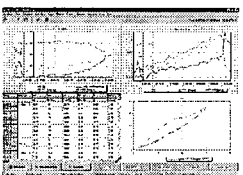
Batteries / battery charger

The MetaMax® 3B is battery-operated. The standard supply includes two Lithium ion batteries (rechargeable) and a battery charger. One battery is inserted into the battery compartment of the base system.



PC connection cable

Interface cable to connect the MetaMax® 3B base system to a PC to configure MetaSoft (e.g. selection of telemetry channel, calibration) and to retrieve logged data from the data logger.

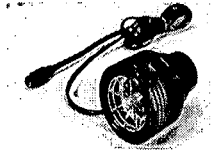


MetaSoft software

User-friendly applicational software for Microsoft® Windows® 95/98 or NT for online measurement, display and analysis of the exercise data recorded during a test with any CORTEX CPX system, including a context-sensitive online help.

Main Parts Description

MetaMax[®] 3B Ultra



Volume Transducer (Triple[®] V)

Volume transducer with extremely low breathing resistance, optimized for high-flow measurements. Ideal for sports research and/or sports medicine. Comes complete with cable, plug-in and integrated temperature sensor.



Windshield for Triple V[®] volume transducer

To be screwn onto the volume transducer whenever the MetaMax[®] 3B is used outside, in case of high air resistance or light radiation.

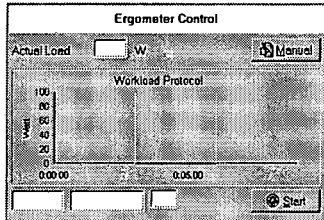


MaxBelt Ultra Harnesses

Special MaxBelt harness optimized for tests with athletes. The extended Velcro strap which is closed on the back provides a better fit during heavy body movements.

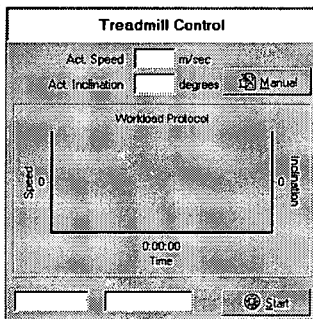
Main Parts Description

Selected Options



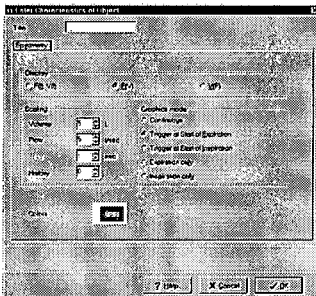
Ergometer control

Software code and interface cable to any commonly used bicycle ergometer for automatic control of the ergometer via MetaSoft during stationary use of MetaMax® 3B.



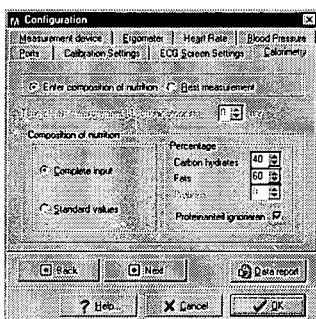
Treadmill control

Software code and interface cable to any commonly used treadmill for automatic control of the treadmill via MetaSoft during stationary use of MetaMax® 3B.



Spirometry

Software to measure, display and store spirometry parameters (e.g. VC, FVC, FEV₁, FEV₁/VC, PEF, MEF₂₅, MEF₅₀, MEF₇₅, PIF) via MetaSoft prior to, during or after a CPX test with MetaMax® 3B. CECA norm values.



Indirect Calorimetry

Software for automatic determination of energy expenditure and metabolism at rest and during exercise based on indirect calorimetry, using MetaSoft.

IV. MetaSoft

MetaSoft is a versatile metabolic stress test software under Microsoft[®] Windows[®] required to measure, analyze and efficiently manage the metabolic data recorded during a CPX test with any CORTEX CPX system.

MetaSoft offers a broad spectrum for evaluation and analysis of key exercise data collected. Developed for users with different testing needs and backgrounds, it carefully balances levels of basic and profound test information, offering an intelligent assistant function and three different user profiles for specific users to perform specific tasks. As an easy-to-use tool, MetaSoft assists you to improve accuracy and consistency in your tests.

To optimize the use of MetaSoft, CORTEX Biophysik and its sales partners are committed to provide individual software training for MetaMax[®] 3B users prior to first-time operation.

Install MetaSoft

MetaSoft is delivered on a CD ROM which is included in your user manual.

This section describes how to install MetaSoft for Windows[®] 95, 98 and Windows[®] NT operating systems.

- Before installing MetaSoft, make sure all programs are closed during the installation process.

Note

If you do not purchase a computer with your MetaMax[®] 3B, check if your PC or notebook on which you intend to install MetaSoft meets the **minimum requirements for operating the software as recommended by CORTEX Biophysik**. For technical details see chapter "Technical Data" of this user manual.

If you purchase your MetaMax[®] 3B with a computer directly from CORTEX Biophysik or from a CORTEX sales partner, MetaSoft is already installed on the PC/notebook upon delivery, offering true plug'n play comfort.

- If you are using Windows[®] NT, log in as „Administrator“ to install MetaSoft in the “Start” menu of Windows[®].
- Insert the MetaSoft CD ROM into the CD ROM drive of your PC/notebook. The installation program automatically starts. If the installation program does not start, open the Windows Explorer, select the CD ROM drive and double-click on **setup.exe** to start the file transfer.

- Follow the on-screen instructions to complete the installation. We strongly recommend to install MetaSoft under the paths suggested by the installation program. The installation program automatically installs MetaSoft in the "Start" menu of Windows[®]/Programs.

Keep the installation CD ROM in a safe place.

- To start MetaSoft, click the "Start" button of Windows[®] to display the "Start" menu. Select the "Programs" folder and select the 'MetaSoft' programs folder. The folder opens a pull-down menu.

Note

MetaSoft has been designed to provide local language support.

The installation program automatically installs the MetaSoft **language version used by your Windows[®] operating system**. To install a language version of MetaSoft different from that of your operating system, click the "Start" button of Windows, select "Settings" – "Control Panel" – "Regional Settings" and select the language you want to use from the selection list.

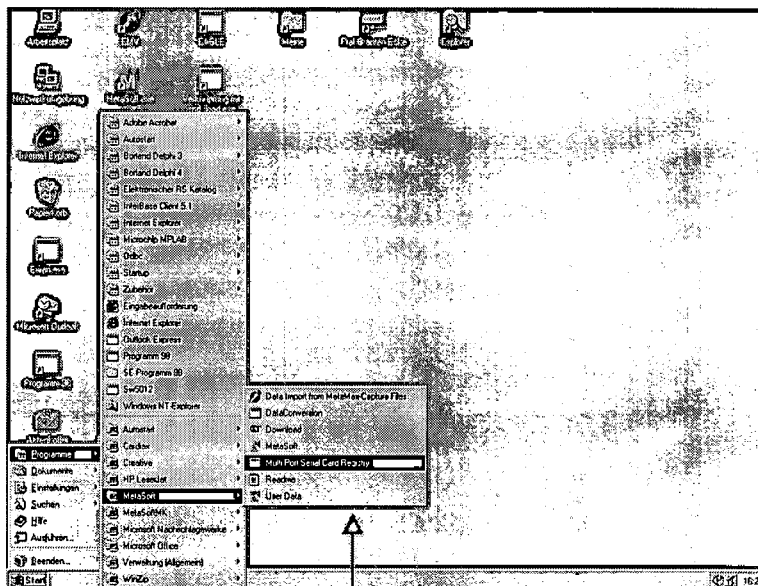
Currently, two language versions, German and English, are available.

MetaSoft Programs Folder

The following programs are selectable from the MetaSoft programs folder:

- **User Data**

Enter your address and select all CORTEX devices used at your institution from the „User Data“ Program (see „MetaSoft basic settings“).



MetaSoft programs

- **Data Import from Capture Files**

Import files recorded via MetaMax software to MetaSoft from the „Data Import from Capture Files“ Program. The files will be stored in the MetaSoft database, allowing you to access all tests recorded with any CORTEX system from one database.

- **MetaSoft**

Perform measurements, evaluate and compare test results or print reports from the “MetaSoft” Program.

- **Download**

Program to update device firmware using the download button of the CORTEX CPX base system. For a description of MetaSoft update installation and download procedures please refer to the *Update Installation/Download Instructions* which accompany each update/download dispatch.

- **Multi Port Serial Card Registry**

Install a multi-port serial card which you may require to connect external devices to your PC for an automatic control via the MetaSoft software, from the „Multi Port Serial Card Install“ Program. Follow the installation instructions of the multi-port serial card manufacturer, then start the „Multi-Port Serial Card Install“ Program of MetaSoft.

- **Readme**

Help file providing start-up instructions on how to install MetaSoft.

MetaSoft Menus or Modules

When you start „MetaSoft“, the blue CORTEX screen will appear, displaying the **main menus**, referred to as **modules**, at the bottom of the screen.

The MetaSoft menus or modules are started by clicking their respective button at the bottom of the CORTEX main screen.

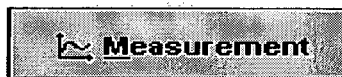
The following modules are selectable:

Menu or module buttons →



Module

Module Functions



- Enter, edit or delete patient/test person information (e.g. age, weight, height, sex etc.).
- View, edit or delete test data of a patient/test person.
- Retrieve data collected during field use from the data logger for performance analysis after the test.
- Perform a one-point calibration measurement (against ambient air) prior to test start.
- Perform a CPX measurement, observing the measurement online on the screen using telemetry data transmission.
- Select and/or customize the default measurement screen (e.g. graphic, numeric display of the parameters on the screen) to your specific testing needs prior to test start.
- Select the kind of exercise (field, bike or treadmill exercise) and/or the exercise program you would like to use for the current test.
- Set markers during the test to mark specific events, e.g. beginning, change of workload, events occurred etc.
- Send off preprogrammed phrases of encouragement/instructions to your patient/test person during mobile exercise using telemetry data transfer, for increased patient comfort/control throughout the test.
- Display predicted/normal values (e.g. oxygen uptake, heart rate etc.) for comparison against measured values.
- View and save single breaths and/or breath sequences during lab and field exercise.
- View and save selected ECG waveforms using the integrated 3-channel ECG module.

Module

Module Functions



- View and evaluate the test data after the test for a more profound performance analysis.
- Download breath cycles, breath sequences and/or ECG waveforms saved during measurement for further evaluation.
- Compare the current test results with a previous test performed with the same patient/test person (intraindividual comparison) or compare the test results of two patients (interindividual comparison).
- Determine additional exercise parameters (AT, VO_{2max} , O_2 kinetics).
- Display predicted against measured values.
- Export the data collected in ASCII or Excel format, e.g. for statistical analysis.
- Print the test data collected, using predefined (e.g. Wasserman report) or user-defined reports.



- Calibrate the volume transducer, the pressure sensor and the gas analyzers via MetaSoft.
- Perform a test measurement for a complete check-up of the sensors and the system.



- Define basic settings to efficiently operate your MetaMax[®] 3B.
- Select the measurement device to be used for the current test if other CORTEX systems are installed and regularly used at your institution.
- Enable ("Actualize" command) system operation and connection prior to test start if you use different CORTEX systems.
- Select the telemetry channel (manually or automatically) and transfer channel data to base system prior to operation.
- Enable options ("Serialize" command) purchased after first-time installation of your MetaMax[®] 3B.
- Enter new or edit existing parameters („channel“).
- Select the PC port(s) to which the MetaMax[®] 3B and/or external devices (e.g. blood pressure module) are to be connected.
- Define user profiles (Standard, Expert, Administrator).
- Assign a user profile to a user.
- Configure the MetaSoft „Wizard“, an automatic assistant function.

Module

Module Functions



- Check if your MetaMax® 3B has been properly connected to your PC to download data from the datalogger and/or can receive data during online measurements using telemetry data transfer.
- Perform a test measurement to check major functions prior to test start.
- Complete and print your registration form required to be eligible for customer support.
- Complete support request forms to be sent to CORTEX Biophysik for further technical assistance.

The "Wizard" is an automatic assistant function. It enables less experienced MetaSoft users to perform a measurement and to print a report after the test, following clear and simple on-screen instructions.

To customize the **Wizard** (e.g. measurement screen, report, ergometer or workload protocol to be used), select "Wizard" from the **Configuration** Menu in MetaSoft Setup.

If you have *Administrator* status, MetaSoft allows you to disable functions, making operation for routine users as easy as possible.

Three different **User Profiles** are selectable: **Standard, Expert or Administrator**. An *Administrator* has full access to all functions/features provided by MetaSoft, defining the user profiles for a *Standard* and *Expert* user and assigning a user profile to each MetaSoft user. *Standard* or *Expert* users have limited access rights. They cannot use all functions/features offered by MetaSoft.

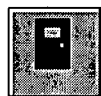
Example: A user with *Standard* user status may have the right to perform a measurement, but may not be allowed to edit or to delete test data. These functions are disabled.

A MetaSoft user can either be an *Administrator, Expert* or *Standard* user. Tasks or functions assigned to a *Standard* and *Expert* user are defined via the **User Profile** command from the **User Menu** in MetaSoft **Setup** (see chapter „MetaSoft basic settings“).

The Standard user mode is the default screen brought up when you start MetaSoft from the MetaSoft programs folder. *Standard* users do not have to log in to perform tasks defined in the *Standard* user profile. Menus or buttons required to perform tasks or to use functions which only an *Administrator* or *Expert* user is allowed to do, are not displayed in the default MetaSoft configuration. These buttons are disabled. *Administrators* or *Expert* users who intend to perform tasks exceeding the *Standard* user status **must log in via the Login Module**. The Login button at the bottom of the CORTEX main screen will change to **Logout**. Users who log out via the **Logout button** automatically return to the *Standard* user mode.

Key Icons

Icon **Function**

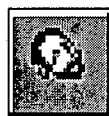


Leave module

Prepare measurements



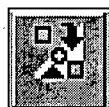
Check connection



Enter new patient / test person



Select patient / test person



Enter new parameter (channel)

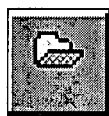


Prepare measurement



Select workload protocol

After the test

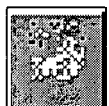


Load single test



Download data from the datalogger

Calibration



Calibrate gas analyzers



Calibrate pressure sensor

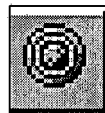
Perform measurements



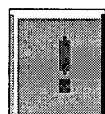
Start one-point calibration
(against ambient air)



Stop one-point calibration
(against ambient air)



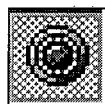
Start measurement
(green)



Add markers



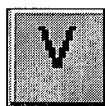
Add markers with comment



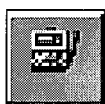
Stop measurement
(red)



Print report



Calibrate volume sensor

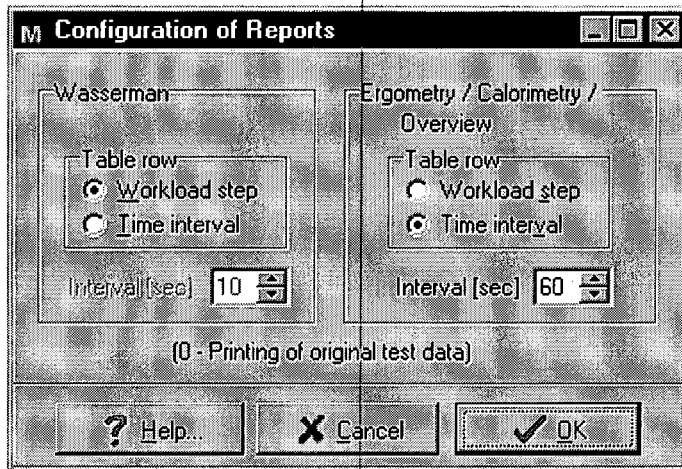


View calibration values

Online Help

CORTEX Biophysik offers additional documentation in Help files and readme files.

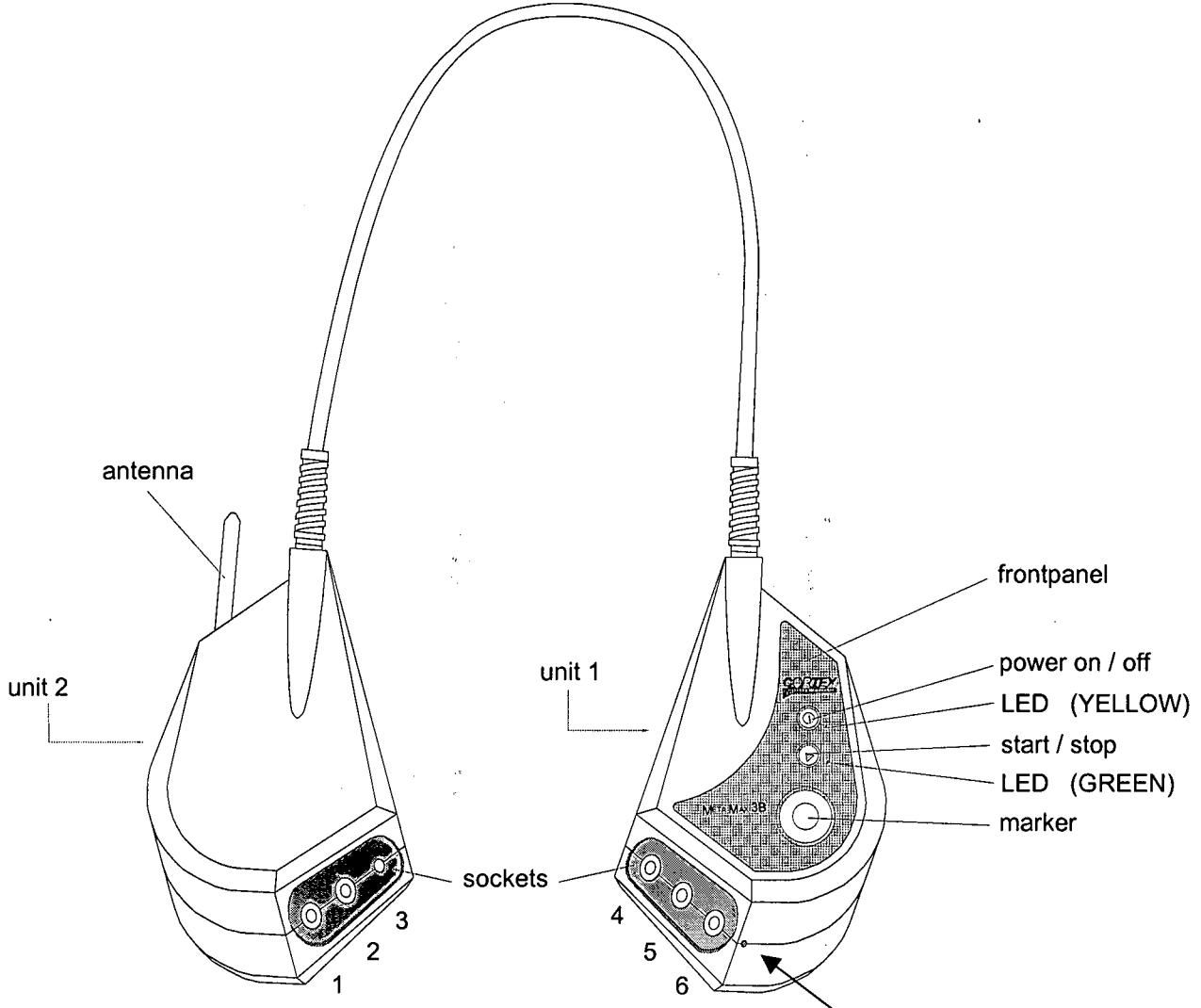
MetaSoft offers an integrated online help intended to provide full details on how to optimize the use of MetaSoft, increasing your efficiency with each test. For context-sensitive Help where available, click the **question mark** icon in the title bar or the **HELP** button in the respective menu, then click the item you want assistance on. Help topics can be printed for future reference.



Click Help button for context-sensitive assistance.

V. MetaMax[®] 3B Base System

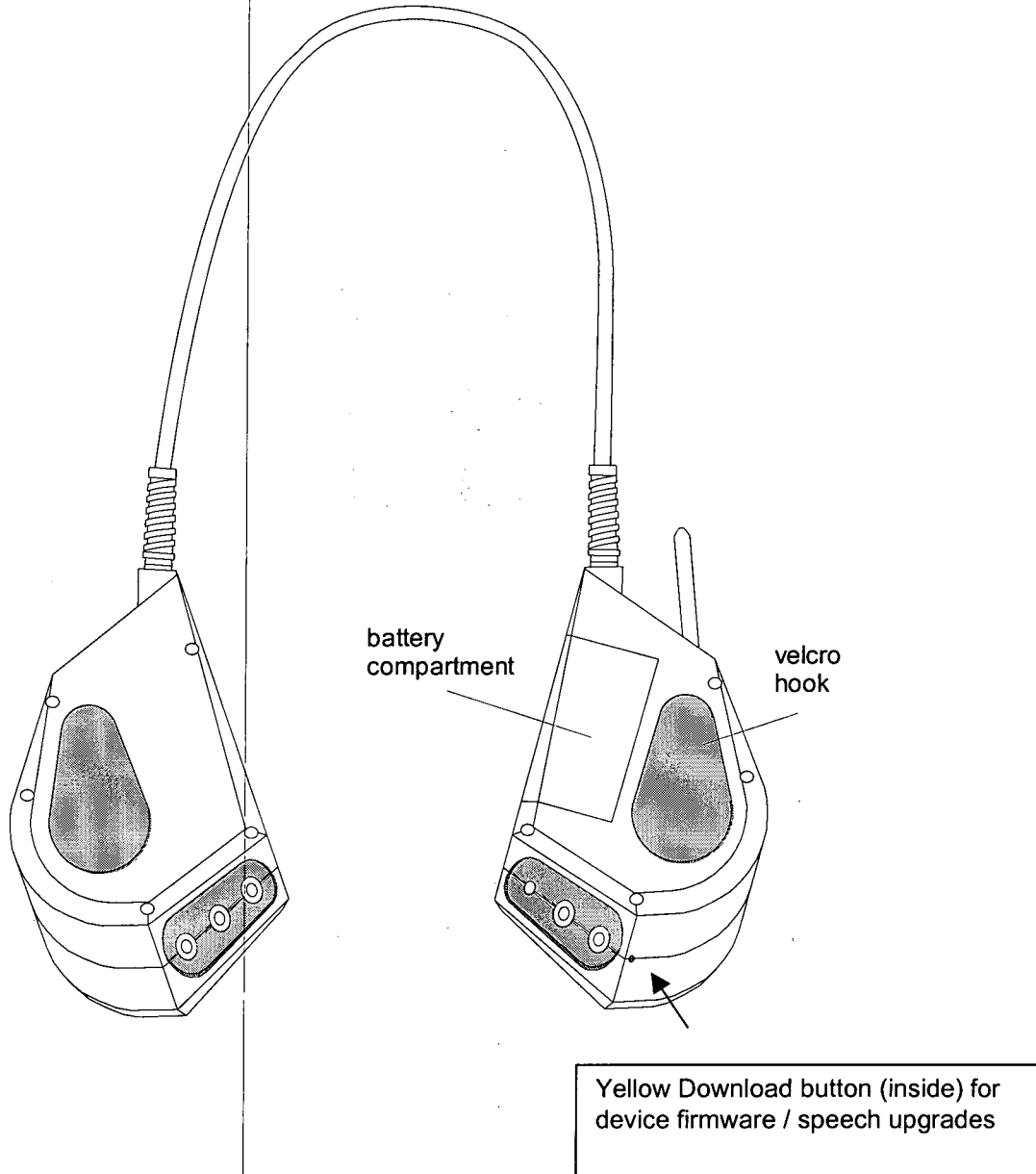
Base System Front View



Yellow Download button (inside) for device firmware / speech upgrades

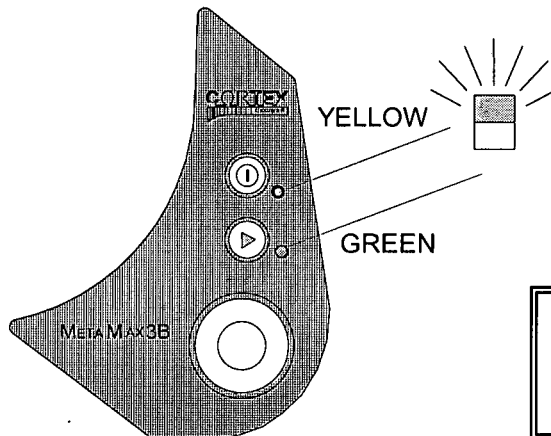
Pos.	Sockets	Marking	Colour
1	External battery		red
2	ECG		white
3	Earphone		black
4	Digital input/ output		brown
5	Volume sensor		violet
6	Sample line		white

Base System Back View



LED / Acoustic Signals

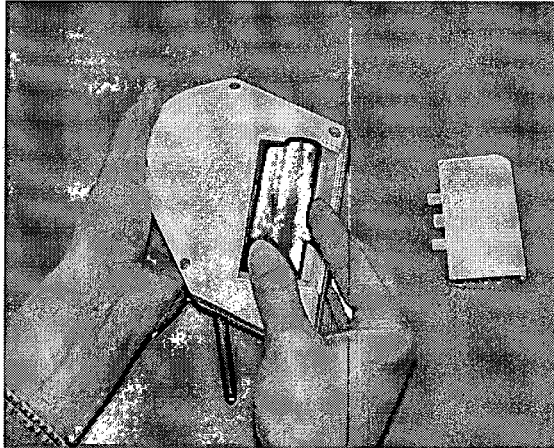
LED / Acoustic Signal	Status Indication
LEDs flashing up.	Base system switched on. A memory test is being performed.
Yellow LED flashing, green LED off.	Self-test running.
Yellow LED lighting	Self-test stopped. Base system ready to perform one-point calibration measurement (ambient air).
Yellow LED lighting, green LED flashing.	One-point calibration measurement running.
Green LED lighting, yellow LED off.	One-point calibration measurement stopped. Base system ready for measurement.
Green LED flashing, yellow LED off.	Measurement running.
Yellow LED lighting.	Measurement stopped. Base system ready to perform one-point calibration measurement (ambient air) prior to next test.
Base system beeping.	Only 1 % of battery capacity left. Please change battery.



Green and yellow LEDs on control panel of base system indicating current device status

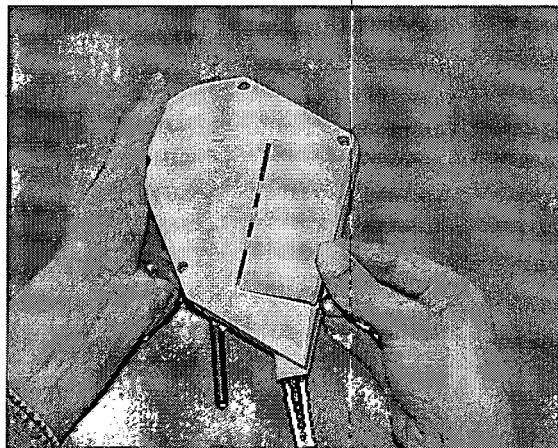
VI. Steps prior to first use

Power system and run it for a warm-up period



To configure your system prior to first operation, your MetaMax[®] 3B base system must be powered and connected to a PC/notebook. A warm-up time of 10 minutes should be sufficient although more time may be needed for system warm-up in colder climates.

- The MetaMax[®] 3B is battery-operated. Open the battery compartment on the back of the MetaMax[®] 3B base system, and insert one fully charged battery from your MetaMax[®] 3B accessory package. Close the battery compartment.

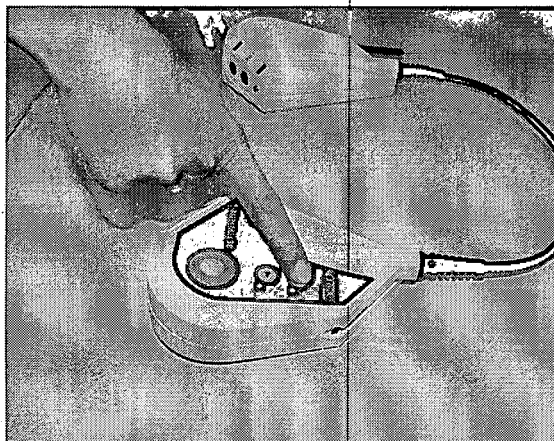


One battery allows you to operate the system for approx. **two hours**. The system will beep repeatedly if the battery is running low.

Note

To save the battery during prep-up time or calibration, external batteries are optionally available (Sprint: = 2 hrs., Medium = approx. 4 hours). They are connected to the MetaMax[®] 3B base system via cable which is to be plugged into the red marked **bat** socket at the front of the MetaMax[®] 3B base system. External batteries are charged using a special battery charger.

Ask your local CORTEX Biophysik sales partner or CORTEX Biophysik for optional battery packs.



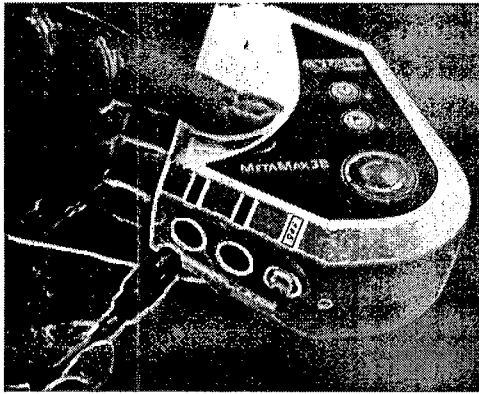
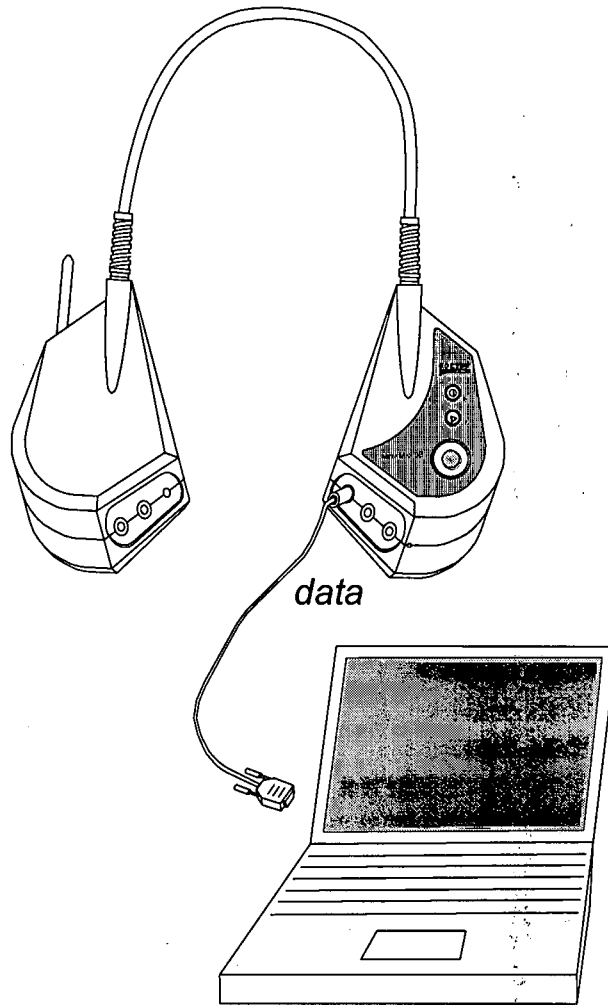
- Turn on MetaMax[®] 3B by pressing the **⏻ on/off button** (first button on front panel of base system) for a second.

A short beep indicates that the system is now powered.

Connect base system to PC / Notebook

To connect the MetaMax[®] 3B base system to your PC/notebook, use the PC connection cable from your supply package.

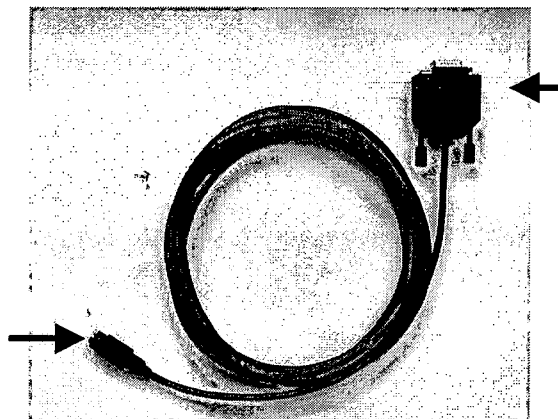
Connect the **brown-marked** cable connector to the brown **data** socket at the front of the MetaMax[®] 3B base system. Turn its shaft to the right to fasten it. Plug the serial connector of the cable into the respective port of your PC/notebook.



PC connection cable

Serial plug-in to be inserted into PC/notebook

Brown marked cable connector to be inserted into MetaMax[®] 3B base system



MetaSoft Basic Settings

Perform the following tasks to configure MetaSoft prior to first use of your MetaMax[®] 3B:

1. Start *User Data* from MetaSoft programs folder

User Menu

If this is a first-time installation, please enter the name and address of your institution via the **User Menu** from the *User Data* program to have them printed on reports generated by MetaSoft.

To replace the CORTEX company logo by your own logo, change to the directory which contains a bitmap file of your logo or type the full path in the „Logo file“ text box.

Cortex device Menu

Select all **CORTEX system(s)** used at your facility via the „Cortex device“ Menu from the „User Data“ program.

MetaSoft is a universal software which can be used with any CORTEX CPX system.

2. Start *MetaSoft* from MetaSoft programs folder

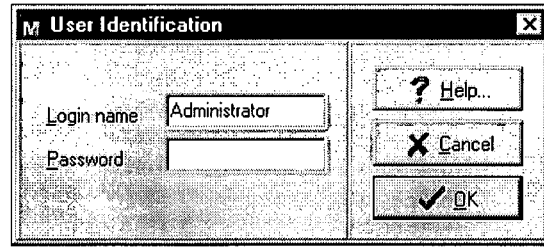
When you start „MetaSoft“, the blue CORTEX screen will appear, displaying the **main menu**, referred to as **modules**, at the bottom of the screen (see chapter “MetaSoft Menu / Modules”).

Menu or module buttons

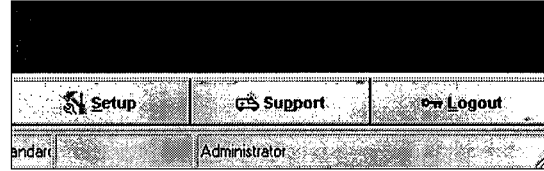


3. Log in as “Administrator”

Click the **Login** button at the bottom of the CORTEX main screen, and the **User Identification** window will appear. Type **Administrator** in the **Login name** text field. No password is required. Click **OK** to proceed with configuration.



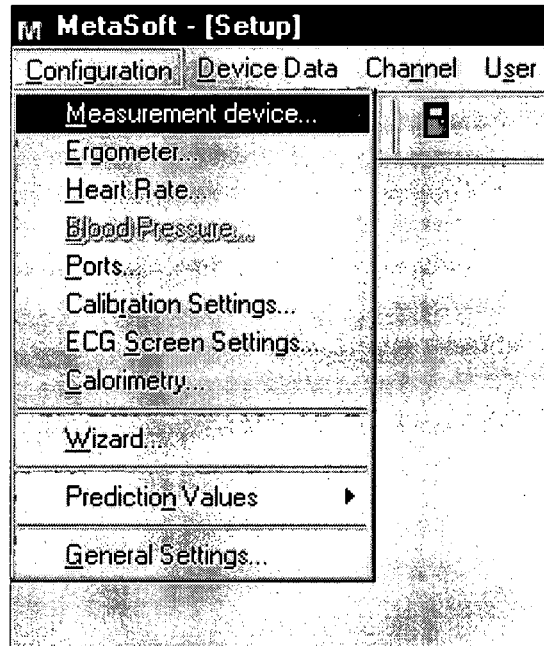
The Login button turns into a **Logout** button.



4. Select measurement device

Start MetaSoft Setup from the main screen.

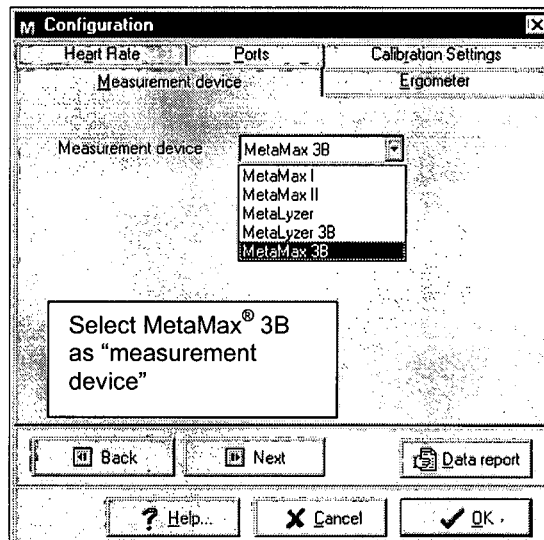
Select the **Configuration** Menu from MetaSoft **Setup**.



The **Configuration** window will appear. Select „MetaMax[®] 3B“ from the **Measurement device** selection box of the **Measurement device** Menu.

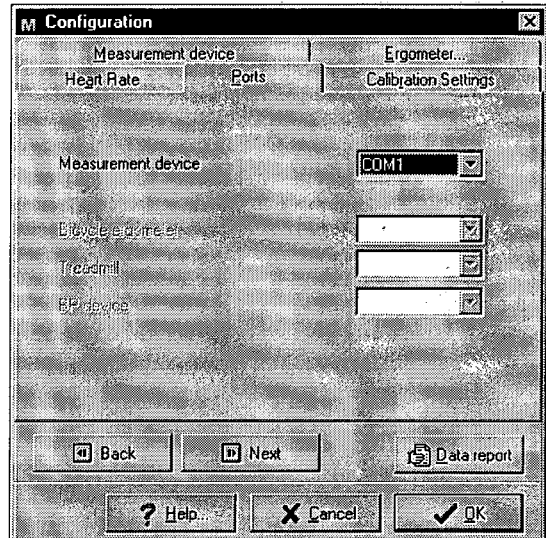
Note

If you use other CORTEX CPX systems at your facility, choose the system to be used for the current test.



5. Select PC port

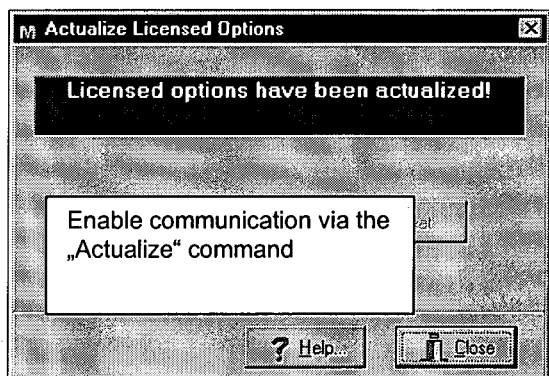
Select **Ports** from the **Configuration** Menu to choose the serial port of your PC to which your MetaMax® 3B is to be connected.



6. Enable Communication

To enable communication select the **Actualize** command from the **Device data** Menu of MetaSoft Setup.

The message **Licensed options have been actualized** will appear in the *Actualize Licensed Options* window if device data is received. All pre-installed options (e.g. ergometer control etc.) are now enabled.



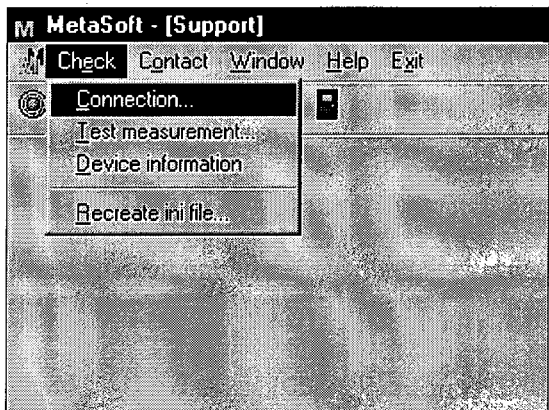
7. Check PC connection

Start MetaSoft **Support** from the main screen.

Click in the "Connection" icon

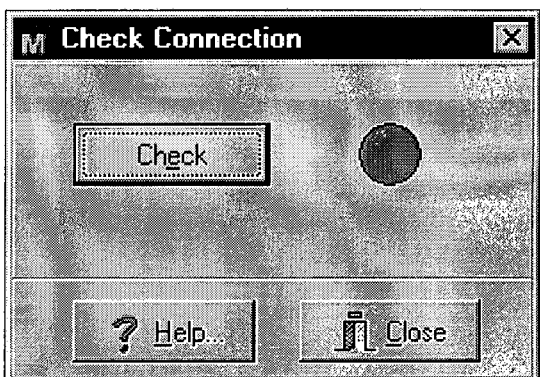


on the ICON toolbar at the top or select **Connection** from the **Check** Menu.



The *Check Connection* window will appear. Click in the **Check** button.

A **green circle** indicates that the system is connected and can receive/transfer data.

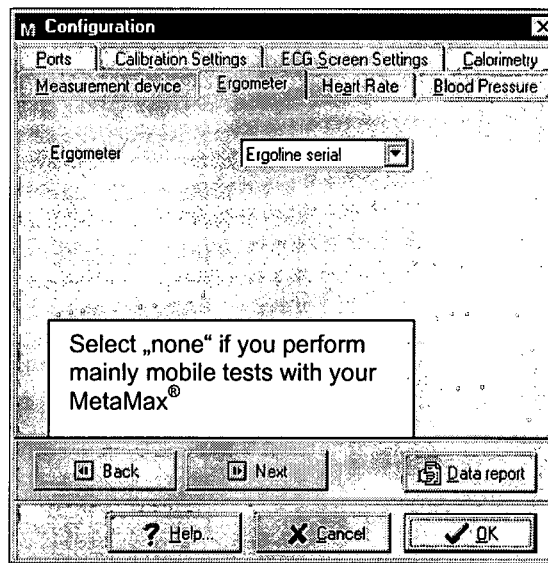


8. Select ergometer

Return to the **Configuration Menu** of MetaSoft **Setup**. Select the **default ergometer (bicycle or treadmill)** to be used for **stationary tests** with MetaMax[®] 3B from the **Ergometer Menu** in the **Configuration** window. By default, the entry is **none** since your MetaMax[®] 3B is a portable device designed for field tests.

If you have purchased the ergometer/treadmill control option, a selection list of ergometers and treadmills (digital only) which can be controlled via the ergometer or treadmill control option of MetaSoft will appear. Once an ergometer/treadmill has been selected, a workload protocol window will appear allowing you to select a default workload program for your tests.

Select „none“ if you use your MetaMax[®] 3B for field tests only or if you do not use the ergometer/ treadmill control option.

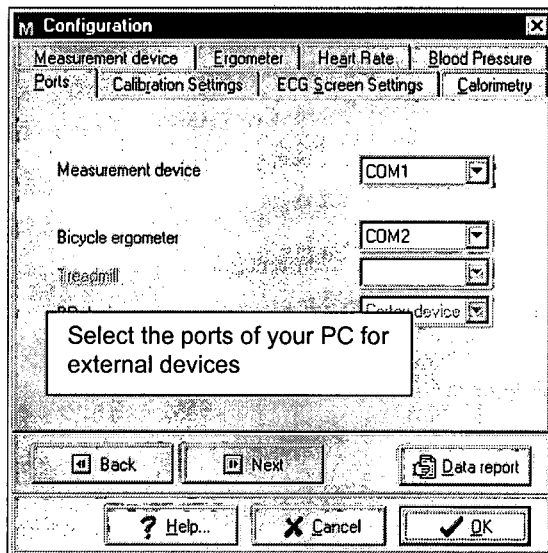


9. Choose ports of PC for external devices connected

To choose the serial port(s) of your PC to which external devices, e.g. ergometers, are to be connected, which you want to use with your MetaMax[®] 3B, select **Ports** from the **Configuration Menu** in MetaSoft **Setup**.

Note

Any option (e.g. blood pressure) installed has its own menu. If you have purchased options after first-time installation of your MetaMax[®] 3B, these options must be enabled via the **Serialize** command from the **Device data Menu** in MetaSoft **Setup** prior to first use.

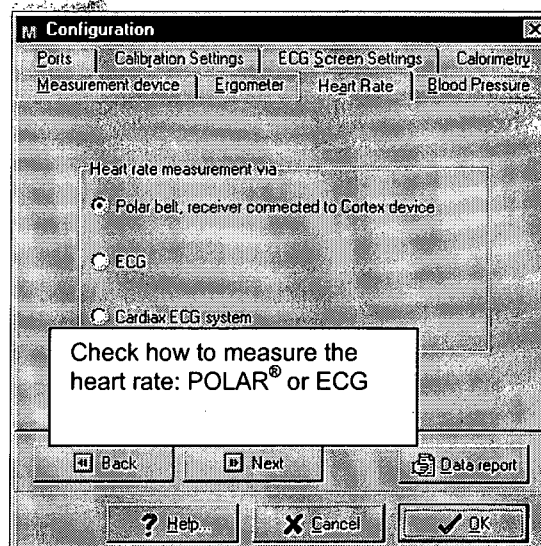


10. Select heart rate source

The heart rate can be measured using the POLAR® heart rate monitor or the integrated 3-channel ECG module (optionally using CARDIAX 12-channel PC ECG during stationary use).

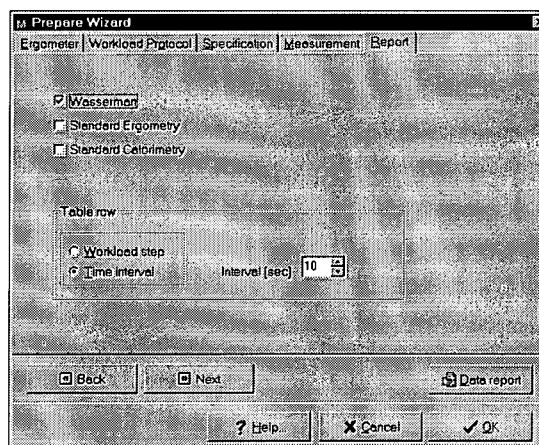
By default, the heart rate is measured using POLAR®. To change the default entry, select the **Heart Rate** Menu from the *Configuration* screen and tick the appropriate option.

It is recommended to measure the heart rate using Polar® in case ECG signal transfer may fail due to motion artefacts and/or transmission failure during field tests.



11. Customize Wizard

To customize the „Wizard“, select **Wizard** from the **Configuration** Menu and check the appropriate functions (e.g. measurement screen, report, workload program to be used).

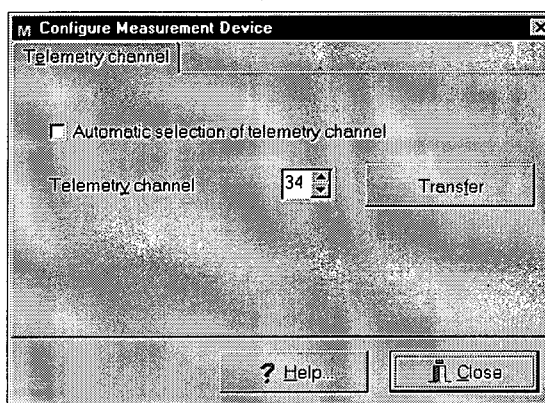


12. Select telemetry channel

The MetaMax® 3B transfers data via telemetry. The integrated telemetry of the MetaMax® 3B provides for a manual or automatic selection of the frequency.

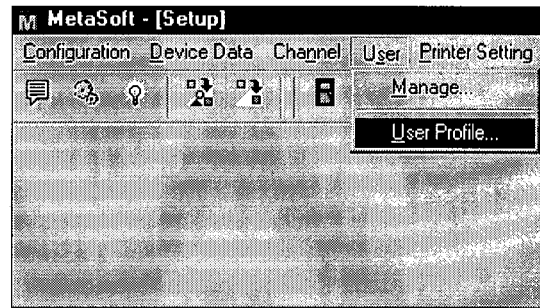
To enable data transfer, select **Telemetry Channel** from the **Device Data** Menu. The *Configure Measurement Device* screen will appear. Enter a frequency (For Japan: **Enter „O“ as telemetry channel**) or check „Automatic selection of telemetry channel“. Click in the **Transfer** button to enable telemetry data transfer from your device to your PC. A beep indicates that the frequency data has been successfully transferred to the MetaMax® 3B base system.

Note: The Japanese version of MetaMax® 3B does not provide for an automatic frequency selection. The selection box „Automatic selection of telemetry channel“ is disabled.



13. Customize User Profiles

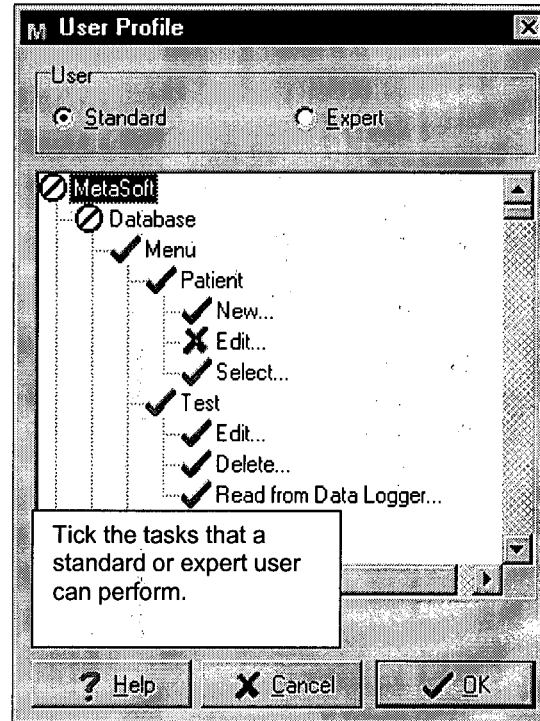
To customize the default „Standard“ and „Expert“ user profiles, select **User profile** from the **User Menu** in **MetaSoft Setup**. The *User profile* screen will appear.



Check the profile that you want to customize: Standard or Expert, then double-click those tasks/functions that you wish to assign to the user profile checked.

A green checkmark indicates that the function has been enabled, a red cross indicates that the function has been disabled.

A „Standard“ user as defined by the right-hand profile can enter and select patients, but is not allowed to edit patient data. The command/task *“Edit patient data”* is disabled. It will not be displayed in the Standard configuration which is automatically brought up when MetaSoft is started from the MetaSoft programs folder.



14. Enter users and assign user profiles

To assign a user profile to a MetaSoft user, select **Manage** from the **User Menu** in **MetaSoft Setup**. Enter the name and a password for the user and choose the user profile that you want to assign to this user from the **“Status”** selection list.



VII. Calibration

General

To maintain the highest possible accuracy, periodic calibration of the MetaMax[®] 3B analyzers with certified calibration equipment and in accordance with the instructions described in the MetaMax[®] 3B Calibration Manual is strongly recommended.

For a description of the calibration procedures and practices please refer to your MetaMax[®] 3B Calibration Manual which is part of your MetaMax[®] 3B accessory. Please read the calibration instructions thoroughly prior to performing a calibration measurement. Calibration procedures should be performed by trained personnel only to ensure utmost operator safety and to maintain a proper function of your MetaMax[®] 3B system.

Each analyzer of the MetaMax[®] 3B is individually pre-calibrated on delivery of the system, enabling users to operate their MetaMax[®] 3B immediately upon installation. A calibration report is included in the extent of supply, specifying the calibration factors and the barometric pressure at the time of calibration.

Depending on the prevailing altitude level of your area or the operating conditions in which you intend to use your MetaMax[®] 3B upon installation, it may be necessary to recalibrate its gas analyzers prior to first use. It should be noted that the MetaMax[®] 3B is calibrated based on a barometric pressure level of approximately 1000 mbar when delivered. Should the mean level of barometric pressure in your area be lower than 900 mbar, a gas calibration measurement should be performed prior to first use of the MetaMax[®] 3B system.

Calibration Procedures

The following calibration procedures are available:

- Gas calibration of the O₂ and CO₂ analyzers (2-point calibration, 1-point calibration),
- Volume calibration of the volume transducer,
- Calibration of the pressure analyzer.

A proper calibration compensates for differences due to

- special make of analyzer,
- age,
- changing operating conditions.

Important

To ensure the highest possible accuracy, the MetaMax[®] 3B analyzers should be calibrated under conditions (temperature, pressure, humidity) similar to the environmental conditions in which the system is operated.

If the MetaMax[®] 3B is usually operated at normal barometric pressure, it is strongly recommended to recalibrate its analyzers if a test is to be performed at high altitude.

Calibration Practices

If the MetaMax[®] 3B is operated in **stable environmental conditions**, i.e. if it is used in the same environmental conditions or if environmental conditions in which it is used, do not change significantly between the measurements, the following calibration practices are recommended to verify and maintain accuracy of its analyzers:

Gas analyzers

A two-point gas calibration should be executed **prior to a test series** (e.g. tests exceeding one day), **at least every 30 days**. A one-point calibration (against ambient air) must be performed prior to each measurement/test. For instructions on how to perform a one-point calibration measurement please refer to chapter VIII „Perform one-point calibration measurement“ of this user manual.

Volume transducer

The volume transducer should be calibrated at least **every 30 days**.

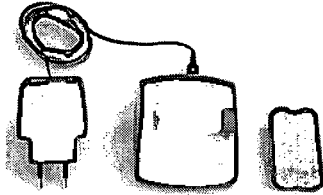
Pressure analyzer

It is not necessary to recalibrate the pressure analyzer unless barometric pressure changes significantly. It is recommended, however, to check the barometric pressure from time to time (e.g. every six months) with a reference barometer, and compare the barometric pressure of the device to the actual barometric pressure. If the values measured differ from the previous calibration values by more than 10 mbar, the pressure analyzer should be recalibrated.

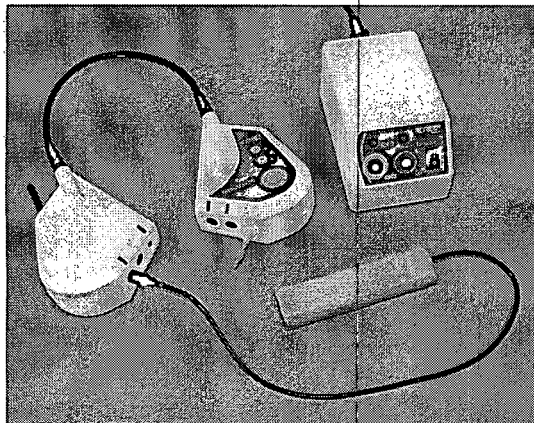
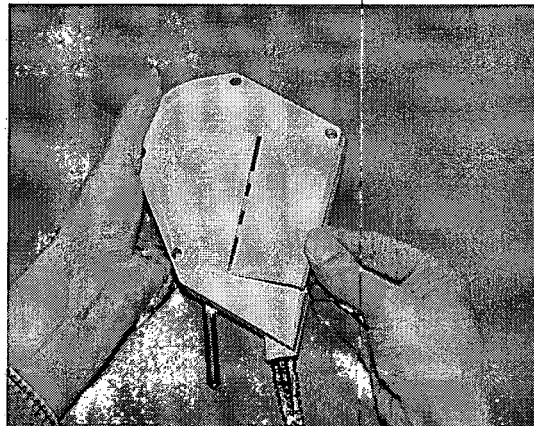
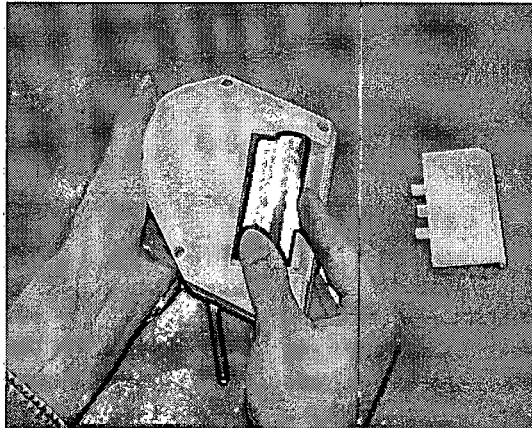
Important

Remember to execute a two-point gas calibration after the pressure analyzer has been recalibrated.

VIII. Performing tests



Battery charger for internal batteries



Prepare device and parts

Charge and insert battery

The MetaMax® 3B is operated on **rechargeable Lithium ion batteries**.

Please make sure that your batteries are **fully charged** before starting your test.

To charge the batteries, connect the battery charger from your supply package to the mains supply, using the supplied mains adapter. **A green LED** indicates that the **battery is fully charged (100%)**. A red LED indicates that the battery is still being charged (0 – 99.9%). It takes approx. 4 – 5 hours to recharge a battery for full capacity.

To power the system, open the battery compartment on the back and insert one of the two batteries from your supply package. Close the battery compartment.

Important

Your basic supply package includes two batteries ("sprint" type) with a minimum capacity of two hours each. They are inserted into the battery compartment of the base system. The base system will beep if the battery is running low.

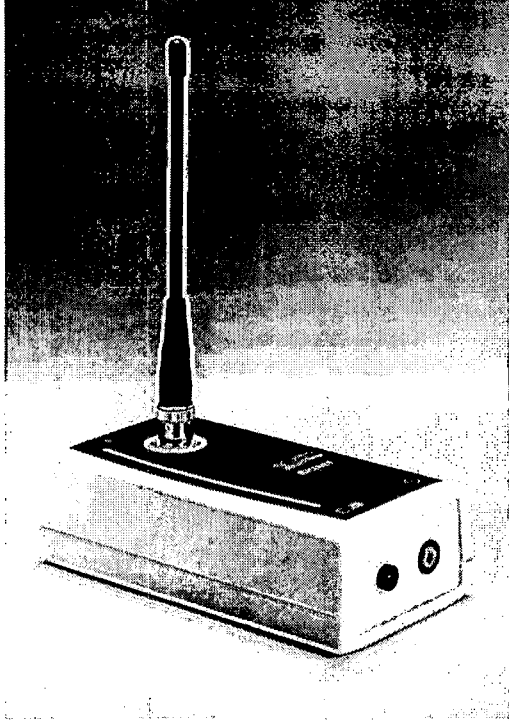
To change an internal battery during the test, either connect an external battery prior to opening the battery compartment or stop measurement.

To save the internal battery during the prep-up time, external batteries are optionally available (Sprint = approx. 2 hrs., Medium = approx. 4 hours).

External batteries are charged using a special battery charger as shown on the left photo.

Connect telemetry receiver

To view the data online on your PC/notebook throughout the test, connect the telemetry receiver to your PC.

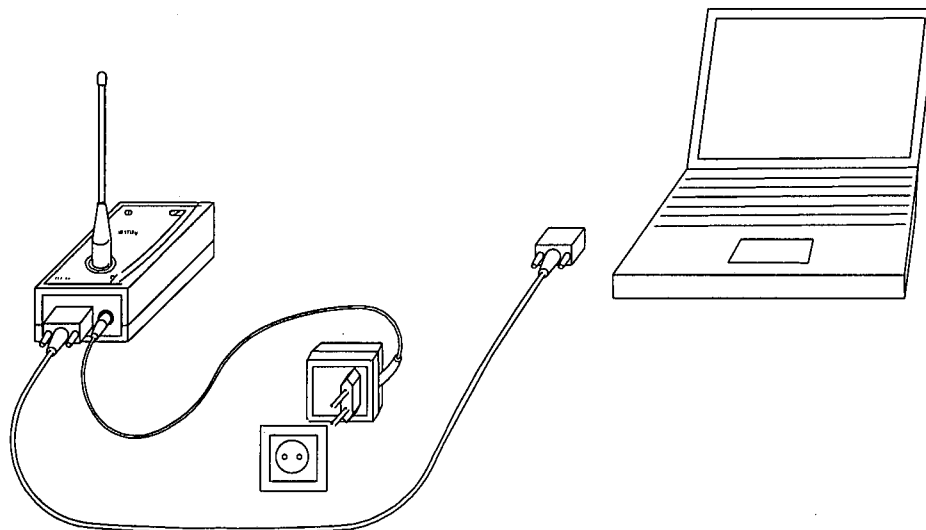


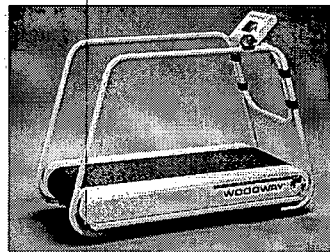
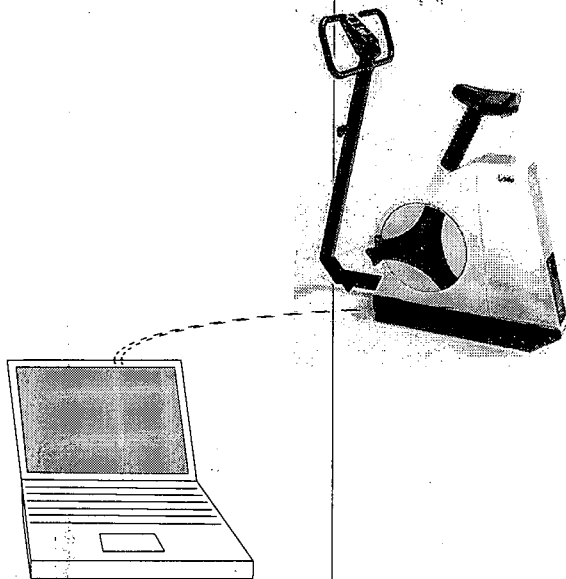
- Screw the antenna on top of the telemetry receiver.
- Connect the telemetry receiver to your PC/ notebook using the serial link cable provided in your supply package. Connect it to the serial port selected during setup.
- To power the telemetry receiver, either connect it to the mains supply, using the power supply from your supply package, or insert a 9V Lithium ion battery into the battery compartment at the bottom of the telemetry receiver.
- Turn the telemetry receiver on. The green LED on the on/off switch is lighting.

*Fig. below:
Hardware setup for telemetry data transfer*

Important

Be careful to first connect the telemetry receiver, then switch it on and transfer the telemetry channel to the base system prior to starting MetaSoft Measurement.





Connect ergometer or treadmill (optional)

The ergometer/treadmill control option provides for an automatic and/or manual control of an ergometer/treadmill connected during stationary use of the MetaMax® 3B base system using MetaSoft.

If you use a digital bicycle ergometer / treadmill, connect the ergometer / treadmill to the serial port of your PC using the interface cable included in the optional ergometer / treadmill control package.

Important

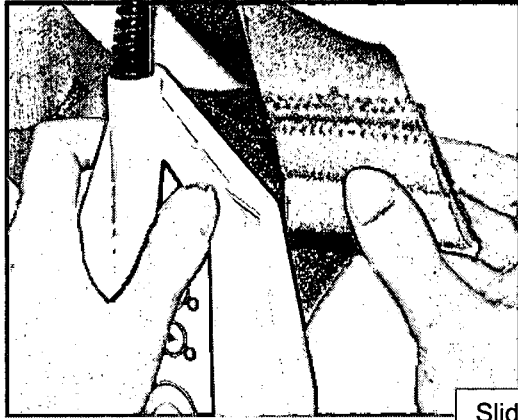
The ergometer/treadmill control option can be used with **digital ergometers / treadmills only**.

As an option it is not included in the basic supply package. The optional package includes the control software and an ergometer cable for your ergometer/treadmill. Cables for other ergometers/treadmills supported by MetaSoft are available on order.

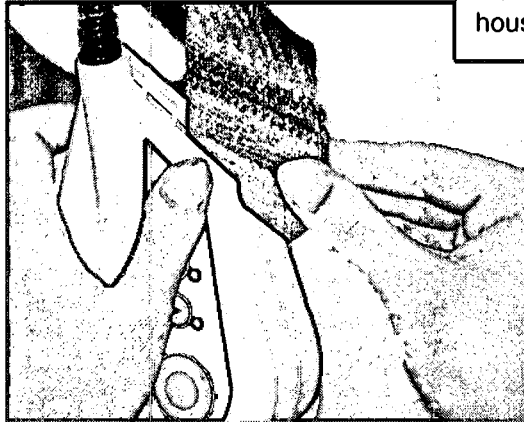
If you have purchased the ergometer and/or treadmill control option **after first-time installation** of your MetaMax® 3B, select **Serialize** from the **Device data** Menu in MetaSoft **Setup** to enable the option prior to first use.

Fix MetaMax[®] 3B base system to MaxBelt

Select an appropriately sized MaxBelt (sizes: S, M, L) or MaxBelt Ultra (sizes: S, M) and fix the MetaMax[®] 3B base system to a MaxBelt shoulder mount or MaxBelt Ultra harness (Ultra model) prior to connecting the tubes and cables.

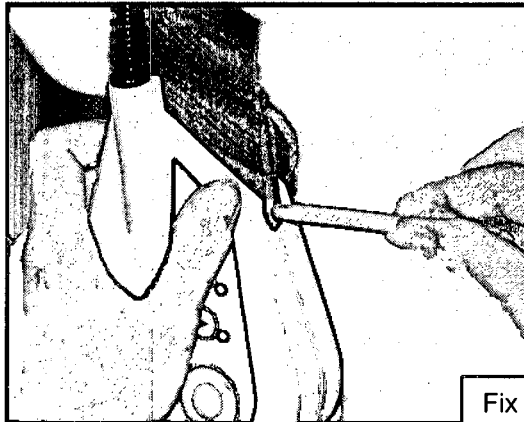


Slide Velcro loop of MaxBelt into housing



- There is a Velcro loop patch sewn on each side of MaxBelt (or MaxBelt Ultra) which fits the Velcro hook patch on the back side of each housing.

- Slide one MaxBelt loop each into the opening on top of each housing.



Fix loop with slider

- Insert a slider through each loop to fix the housing to MaxBelt. Adjust the position of each housing on MaxBelt.

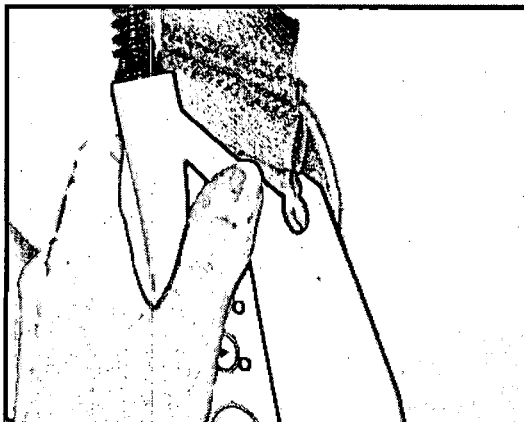
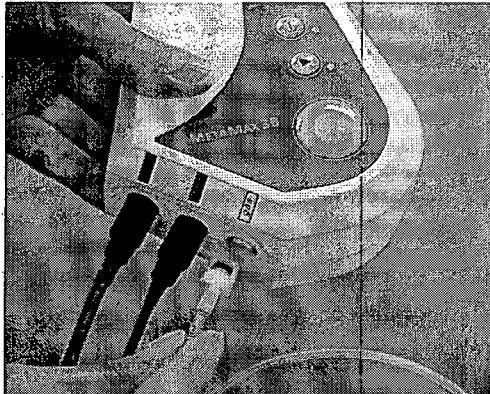
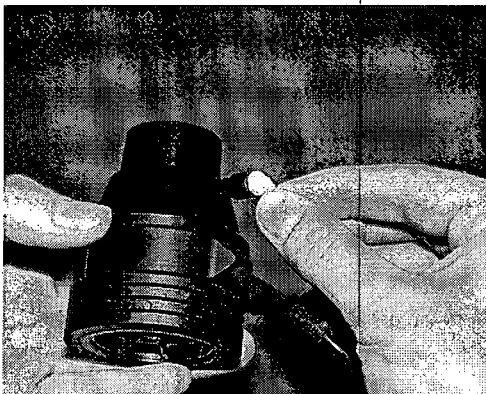


Fig. : MetaMax[®] 3B base system fixed to MaxBelt/MaxBelt Ultra harness.

Connect cables / tubes

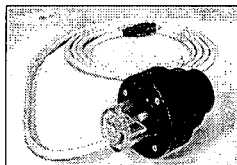


- Plug the connector of the violet marked **volume transducer cable** (DVT or Triple® V) into the violet **vol** socket of the MetaMax® 3B base system. Turn its shaft to the right to fasten it.
- Plug the plastic plug-in of the **sample line** into the **gas** socket of the base system.

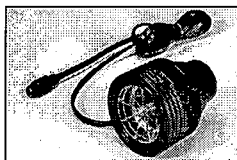


- Plug the **black plug-in of the sample line** into the **gas outlet on top of the volume transducer**.

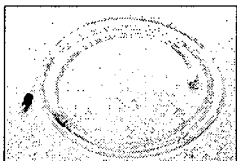
Volume transducer and sample line are now completely connected to the base system.



DVT
volume transducer
(MetaMax® 3B Standard)



Triple® V
volume transducer
(MetaMax® 3B Ultra)



Sample line



Fig: MetaMax® 3B Standard with DVT volume transducer

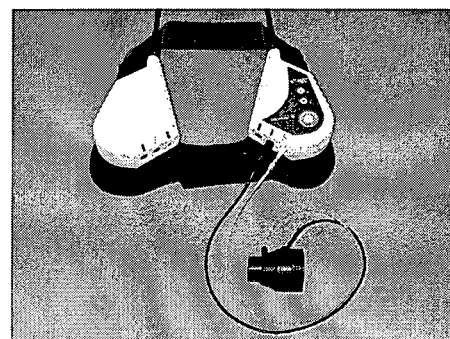
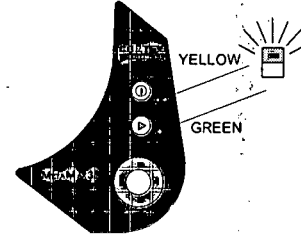
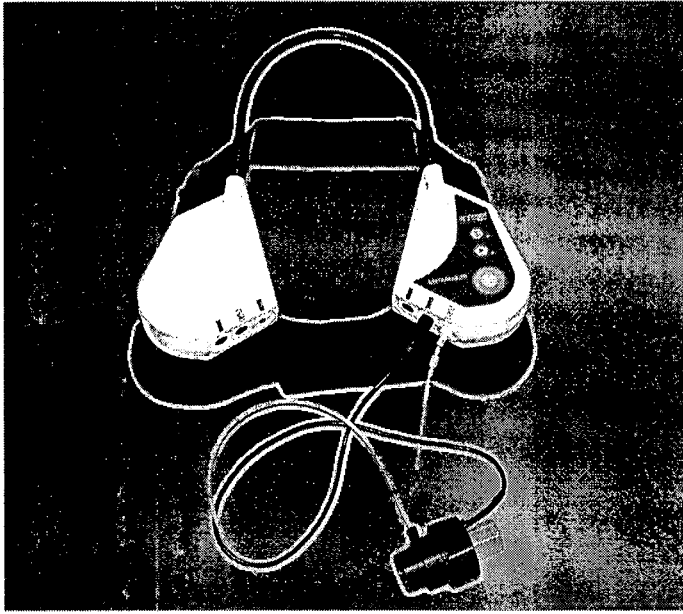


Fig: MetaMax® 3B Ultra with Triple® V volume transducer

Turn on MetaMax[®] 3B

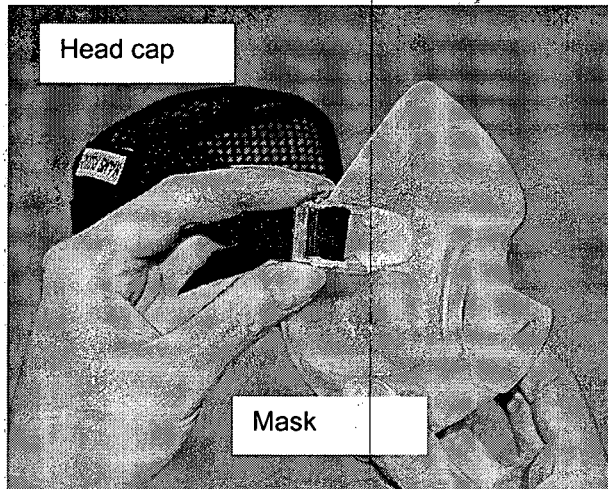
Turn on your MetaMax[®] 3B by pressing the **① on/off button** (first button on control panel of base system) for a second.



Both LEDs are lighting, indicating that a memory test is being performed.

Important

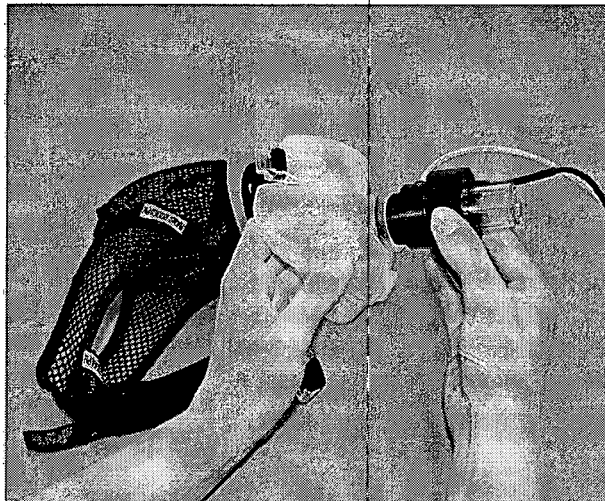
Your MetaMax[®] 3B needs at least ten minutes for its analyzers to warm up prior to starting a measurement.



Select mask and fix head cap

Select an appropriate face mask and fix it to the head cap as shown on the left. Only the top clips of the head cap are fixed to the head cap assembly.

Your MetaMax[®] 3B comes complete with adult face masks in three different sizes: S, M, L. Pediatric face masks and head caps are optionally available.



Connect volume transducer and sample line to mask

Insert the volume transducer with the sample line connected into the **face mask**. Please make sure that the sample line is properly connected.

Fig. DVT volume transducer (MetaMax[®] 3B Standard) and sample line connected to face mask.

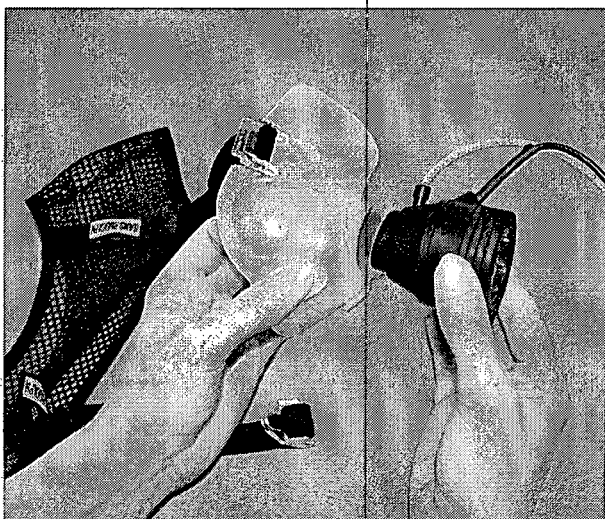


Fig. Triple[®] V volume transducer (MetaMax[®] 3B Ultra) and sample line connected to face mask.

Note

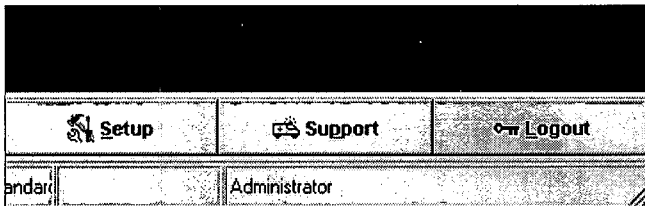
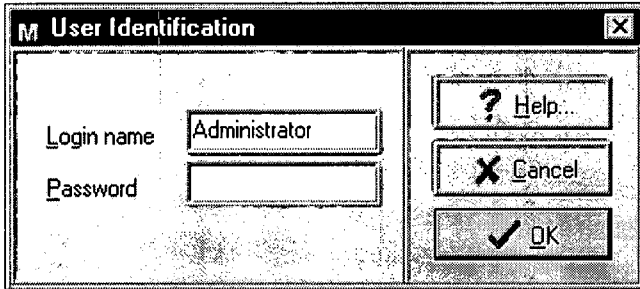
Screw the wind shield onto the Triple[®] V volume transducer **when performing outdoor tests using MetaMax[®] 3B Ultra.**

Perform basic settings

Start MetaSoft

Start **MetaSoft** from the MetaSoft programs folder.

When you start **MetaSoft**, the CORTEX Biophysik screen will appear, displaying the **main menus** (also referred to as “modules”) **at the bottom**.



Important

The “**Standard**” user mode is the default screen brought up when you start MetaSoft.

The „Standard“ user profile is configured and assigned to each MetaSoft user from the *Setup Menu/Module*.

Should you find any functions described in this manual missing or disabled, e.g. you cannot add parameters to a screen, or retrieve data from the data logger, these functions may have been disabled in the „Standard“ user profile.

To perform a function disabled in the Standard user mode, click in the



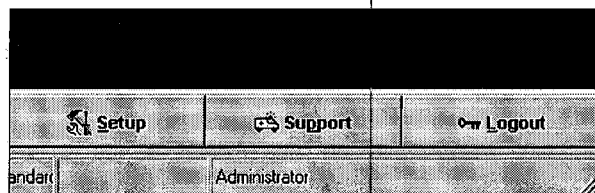
button at the bottom of the MetaSoft main screen, and the **User Identification** window will appear.

Enter **Administrator** in the **Login name** text box and click in the **OK** button. The Login button turns into a **Logout** button.

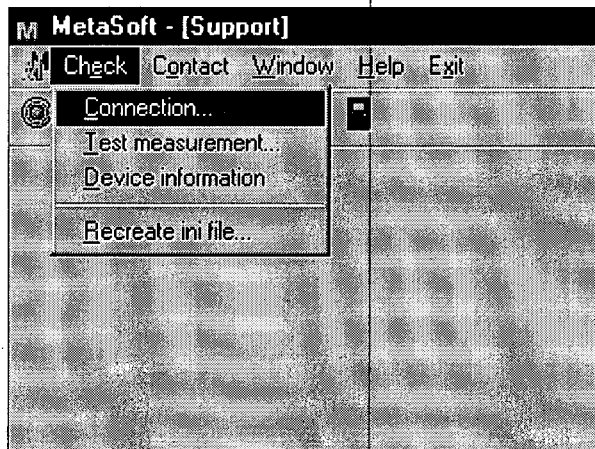
If you have been assigned a *Login name* and *Password*, enter your login name and/or password. The login name and password are assigned by a user at your site with “Administrator“ user rights.

Check connection

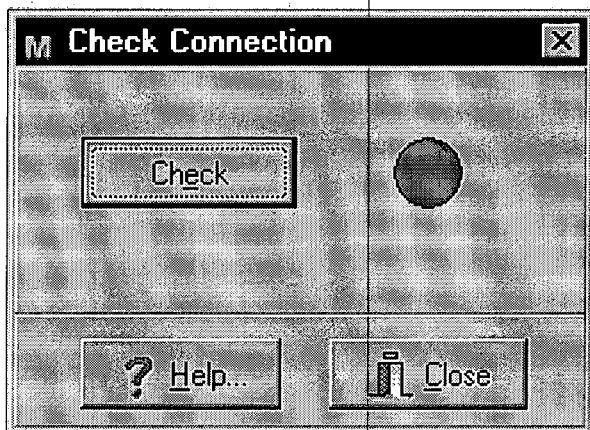
To check if your MetaMax[®] 3B base system is properly connected to your PC/notebook, select **Support** from the MetaSoft main screen to start the *Support* Menu.



Click the **Connection** icon



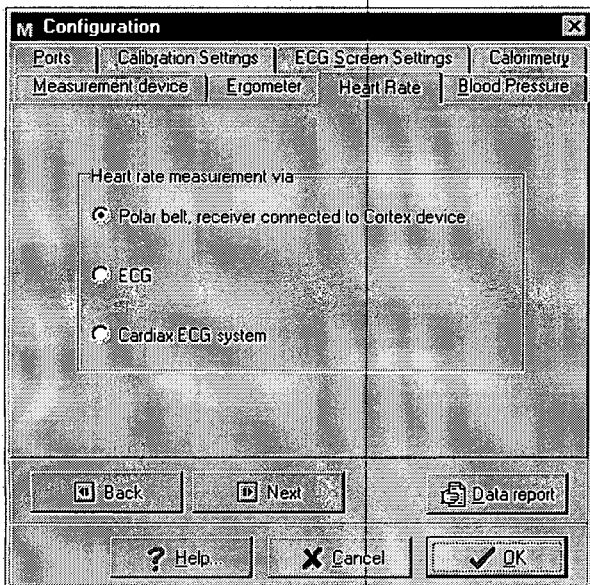
on the **ICON** toolbar at the top of MetaSoft Support or select **Connection** from the **Check** Menu of MetaSoft **Support**.



The *Check Connection* window will appear.

Click the **Check** button.

The circle will turn green if the system is connected and can receive and/or transfer data.



Select HR measurement

Decide **prior to test start** how you want to measure the heart rate.

The following options are selectable:

- Polar[®] connected to PC
- ECG module (= 3-channel ECG)
- CARDIAX ECG (optional)

Select **Heart rate** from the **Configuration** Menu in MetaSoft **Setup**. Tick the appropriate heart rate source. Measure the heart rate using Polar[®] to make sure it is properly recorded in case ECG signal transfer fails due to motion artefacts or telemetry transmission failure.

Enter new patient into MetaSoft Database

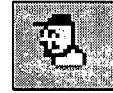
Click in the **Measurement** button to start **MetaSoft Measurement**.

- To enter a **new patient/test person** prior to measurement, select **Test Person (or Patient)** from MetaSoft Measurement.

Click the **“New”** button from the **Select test person/patient** screen.

or

click the **“patient/test person”** icon



on the **ICON** toolbar in **MetaSoft Measurement**.

The **“Enter Test Person Data”** screen will appear. Enter basic patient data (sex, height, weight) into the respective text fields of the **Personal Data** Menu.

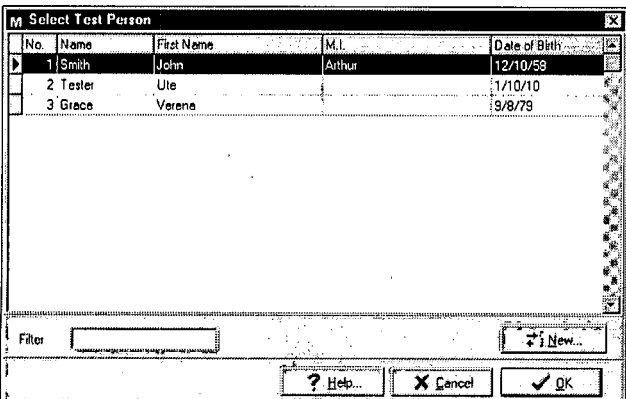
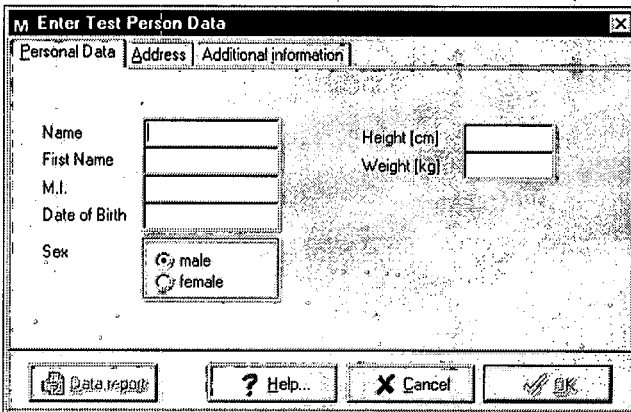
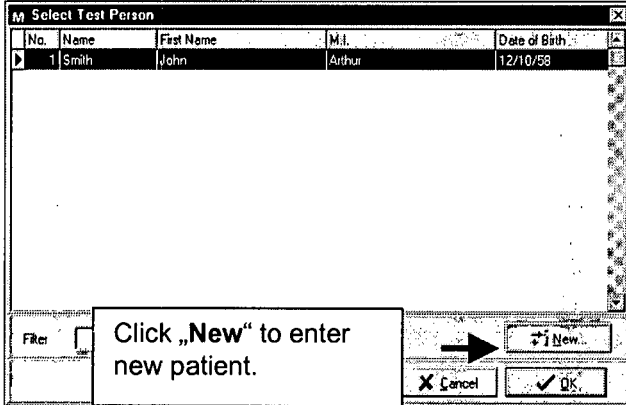
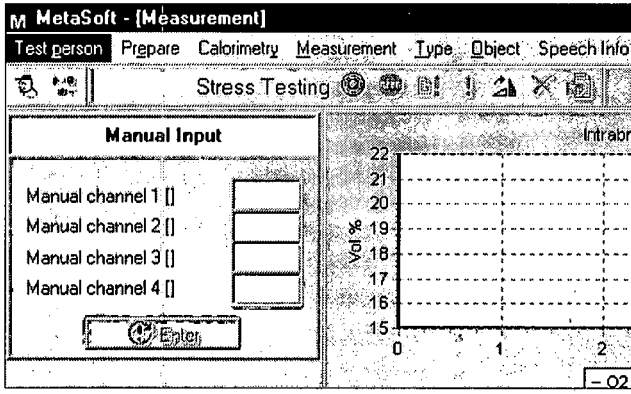
Alternatively, patient/test person data can be entered and also edited from the **“Test person/Patient”** Menu in **MetaSoft Database**. Use **MetaSoft Database** if you have to enter several patients/test persons or if you want to edit and/or delete patients/test persons.

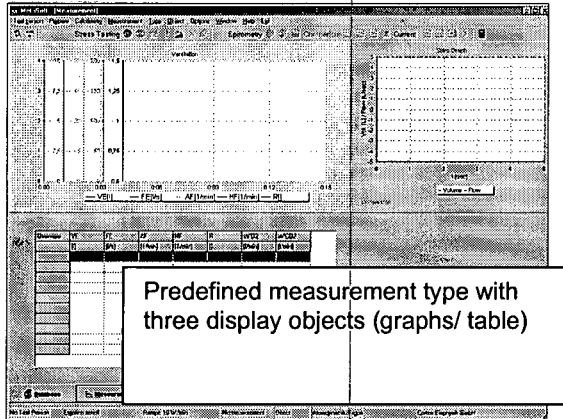
Important!

A 4-digit year is required for date entry (Year 2000 compliance).

Select patient/test person from MetaSoft Database

Select the name of the patient/test person who is going to perform the current test from the selection list of the **“Test person/Patient”** Menu in **MetaSoft Measurement**.





Select and/or customize measurement screen

When you start MetaSoft Measurement, the **measurement screen** (referred to as **type**) last used will be displayed.

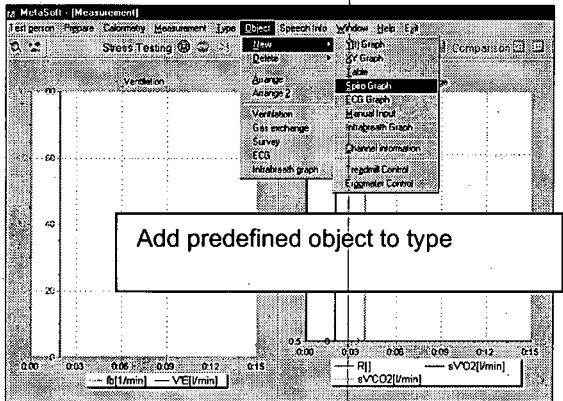
The measurement type displays a predefined configuration of graphs and tables, referred to as **display objects**.

Basic commands to customize the screen

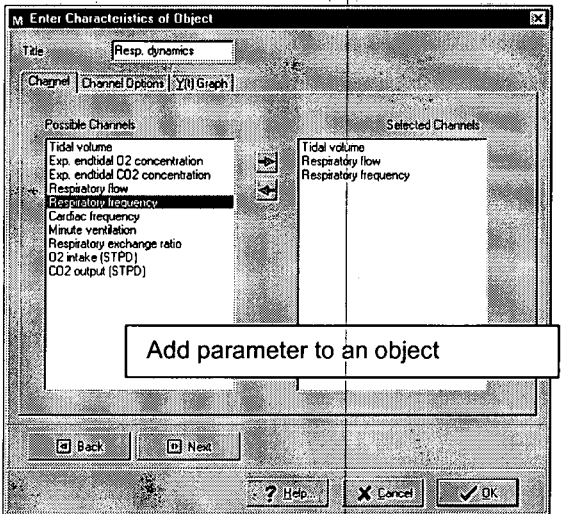
To use a predefined measurement type, select **Select** from the **Type Menu**.

To add a predefined display object, e.g. ECG graph, to the current type (screen), select the appropriate display object via the **Object – New command** from the **Object Menu**.

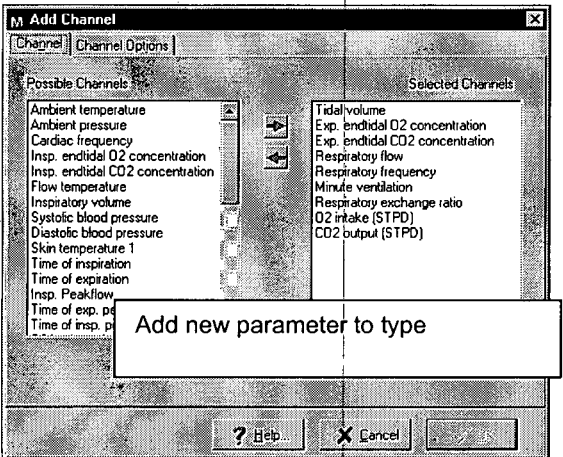
To configure a new display object (**graph/table**) and add it to the screen, select **New** from the **Object Menu**. Choose the type of object you want to format: graph or table.



To add parameters to a display object (table/graph) of a type (screen) which already includes these parameters, right-click into the display object. Select **Properties** from the context menu. The **Enter Characteristics of Object** screen will appear. Click the parameter to be added to the active object. If you do not find the parameter in the context menu, first add the parameter to the type (screen), then add it to the display object.



To add parameters to a type (screen), which are not yet defined in this screen, select **Add channel** from the **Type Menu** in MetaSoft Measurement. Select all parameters (referred to as **channels**) you would like to add to the current measurement type (screen). Right-click into the display object to add the new parameters to the display object as described above.



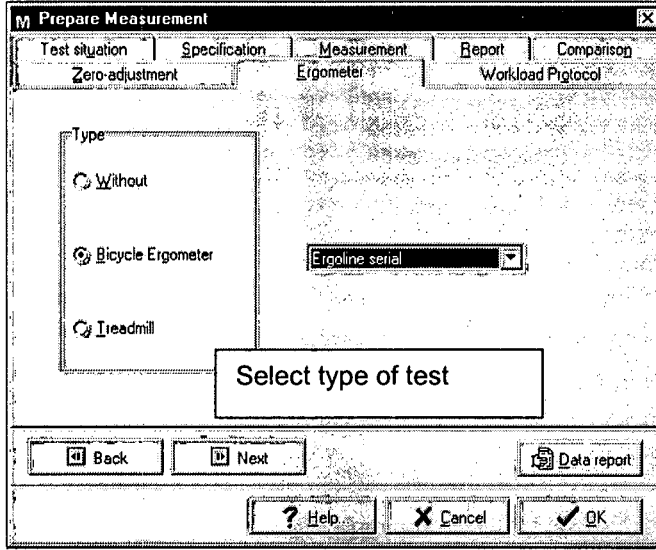
A graphic display object can display up to five different parameters, a table display object up to ten different parameters

Select test and workload protocol

Click the **Prepare** icon



on the icon toolbar at the top, or select the **Prepare Menu**. The *Prepare measurement* window will be displayed.

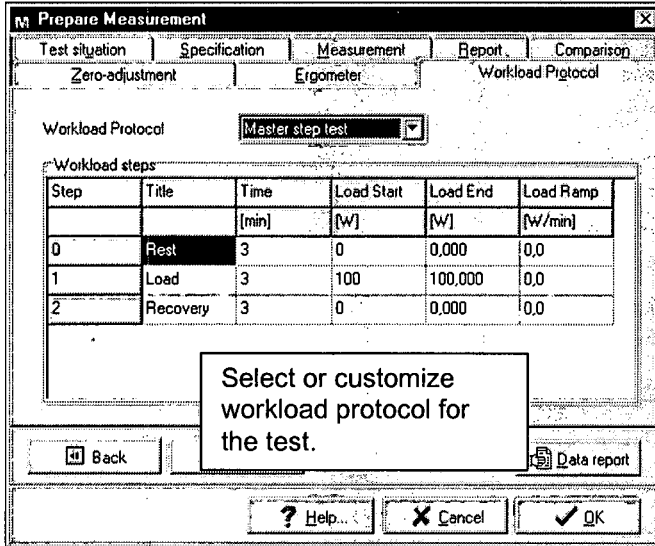


Field exercise

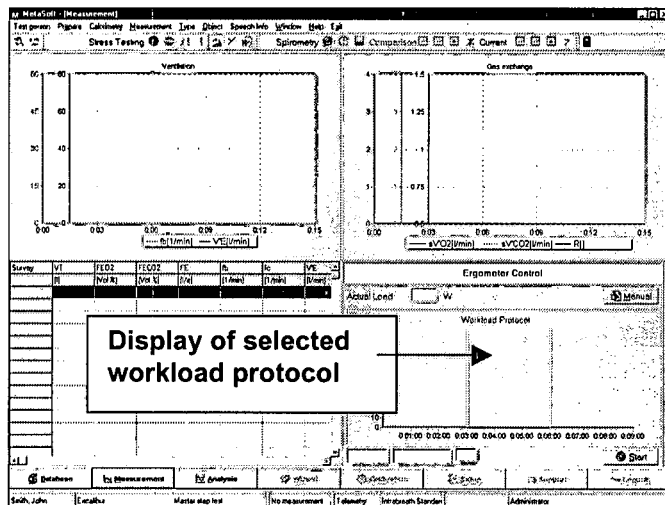
Select **“without”** from the **Ergometer** Menu in the *Prepare Measurement* screen if you want to perform a field test.

Ergometer / treadmill exercise

If you have purchased the ergometer/ treadmill control option, your ergometer/ treadmill (digital types only) can be automatically controlled via MetaSoft.



- Select **„Ergometer“** from the **„Prepare“** Menu in MetaSoft Measurement. Check the kind of ergometer to be used for the test: bicycle ergometer or treadmill. Select the ergometer/treadmill type from the selection list.
- Select **“Workload protocol”** from the **„Prepare Measurement“** Menu to choose a predefined workload protocol for the test or to customize the workload protocol to your specific testing needs.
- The workload protocol will be displayed as a new display object headed **“Ergometer or Treadmill Control”** in the measurement screen selected.



The workload protocol starts automatically when you start your CPX test. To change the workload, simply click in the **“Manual”** button in the **„Ergometer Control“** display object, then enter the new workload.

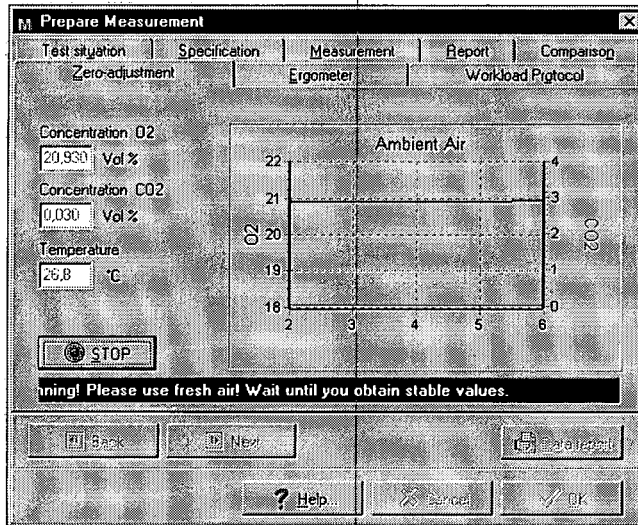
Perform one-point calibration measurement

Perform a one-point calibration measurement (ambient air measurement) **shortly** before you start with your CPX test.

A dialog window will remind you to execute a one-point calibration (referred to as zero adjustment) prior to starting with a measurement.

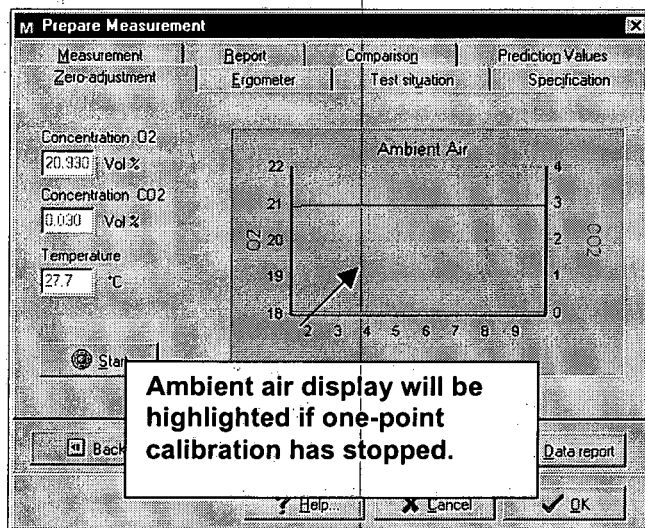
- Select „Zero adjustment“ from the „Prepare Measurement“ Menu. The Zero adjustment window will appear.

- Click in the **Start** button



to start one-point calibration. The **Start** button will turn into a **Stop** button.

The one-point calibration measurement will automatically stop once stable values have been reached, highlighting the **Ambient Air** graphic display in the “Zero adjustment” screen.



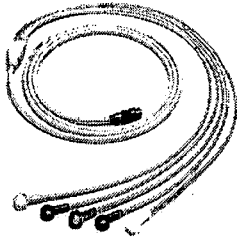
During one-point calibration, the yellow LED of the base system is lighting and the green LED is flashing.

Important

Make sure your patient/test person does not put on the face mask until a one-point calibration measurement has been performed.

During one-point calibration the sample line and volume transducer must be exposed to ambient air. Take care no one exhales into the volume transducer and sample line.

Prepare your patient / test person for the test



5-lead color-coded
ECG patient cable

Place electrodes and attach 5-lead ECG patient cable

The built-in 3-channel, 5-lead ECG module is a **monitoring ECG** allowing you to view, record and save selected ECG waveforms during a CPX test with your MetaMax[®] 3B.

To monitor the ECG of your patient / test person throughout the CPX test,

- place five self-adhesive electrodes on your patient's/test person's skin,
- then attach the leads of the 5-lead patient cable provided.

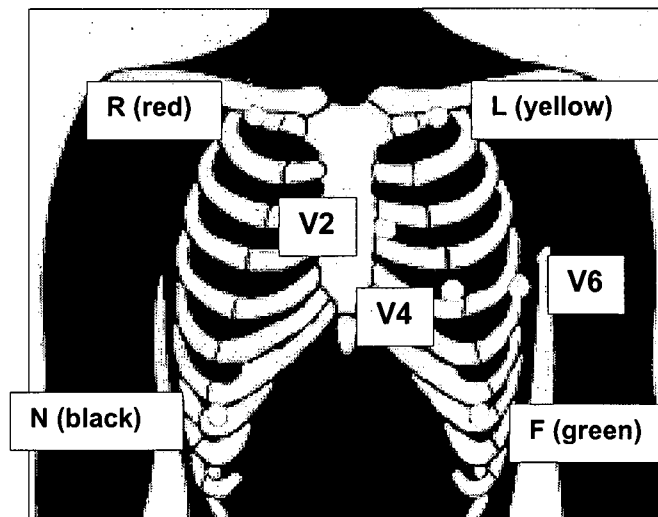
The built-in ECG allows you to record the ECG after Wilson, Einthoven and Goldberger.

For a proper placement of the chest electrodes, please refer to the below lead placement diagram.

Recommended lead placement for tests with MetaMax[®] 3B after Wilson:

The white electrode can be placed on V1 to V6.

To improve trace quality, however, place the white electrode on either V2, V4 or V6 as shown on the right figure.

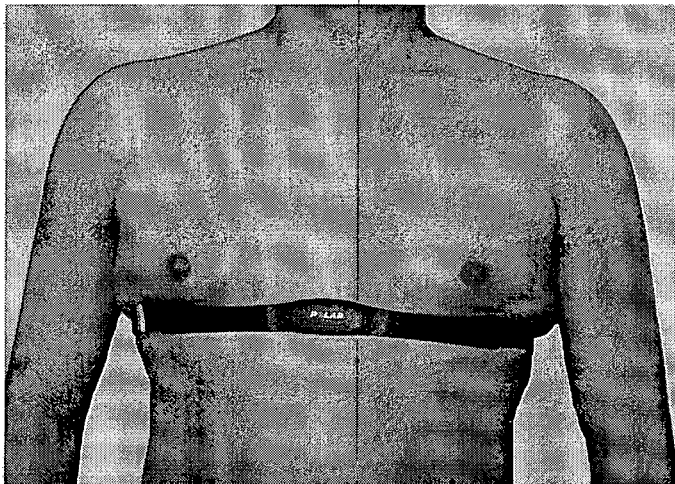
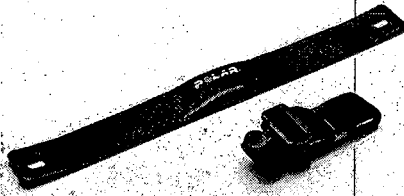


Note

Use the Polar[®] belt provided to measure the heart rate while recording the ECG.

Fix Polar® HR Transmitter Belt

The heart rate can be measured using POLAR® or the integrated 3-channel ECG module.



- Fix the POLAR® transmitter belt to the thorax of your patient/test person, using the elastic strap included in the Polar® set.

The POLAR® receiver is integrated in the base system.

- Check if Polar® has been selected as heart rate source in the **Configuration Menu** in **MetaSoft Setup**.

Attention

We recommend to measure the heart rate using Polar® to make sure it is properly recorded in case ECG signal transfer fails due to motion artefacts or telemetry transmission failures.



MetaMax[®] 3B
fixed to MaxBelt

Fix MetaMax[®] 3B to patient/test person

If the MetaMax[®] 3B base system is fixed to MaxBelt (shoulder mount)

ask your patient/test person to slip it around his/her shoulder like a **scarf**. Close the shoulder mount in front. Adjust the position of its housing on MaxBelt.

If the shoulder mount does not fit properly, remove your MetaMax[®] 3B and select a different shoulder mount size (available in sizes S, M, L).

If the MetaMax[®] 3B base system is fixed to MaxBelt Ultra (harness),

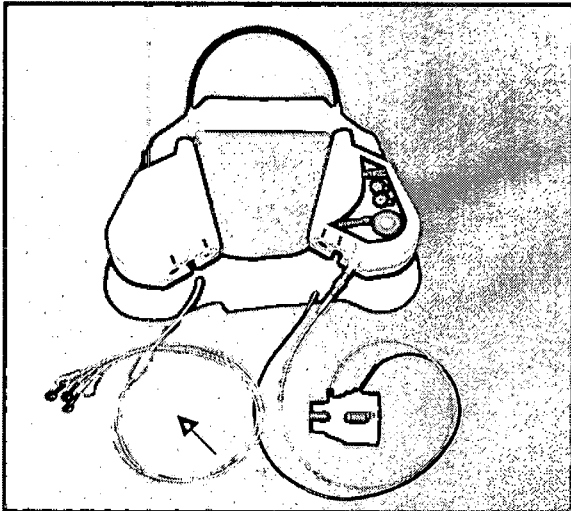
ask your patient/test person to slip the pre-assembled „scarf“ around his/her shoulder and fix the long Velcro straps on the back. Adjust the position of its housing on MaxBelt Ultra.

If the harness does not fit properly, remove your **MetaMax[®] 3B** and select a different harness size (available in sizes S, L).

Connect ECG patient cable to base system

To monitor the ECG using the built-in 3-channel ECG module,

connect the 5-lead ECG patient cable to the base system, inserting the plug-in of the **white**-marked patient cable into the **white ecg socket** of the base system. Turn its shaft to the right to fasten it.



Connect patient cable to **ecg**
socket of base system

Fix mask



Pull the head cap with the face mask over the head of your patient / test person **after you have performed a one-point calibration measurement against ambient air**. Fasten the two Velcro straps of the head cap not yet connected to the face mask.



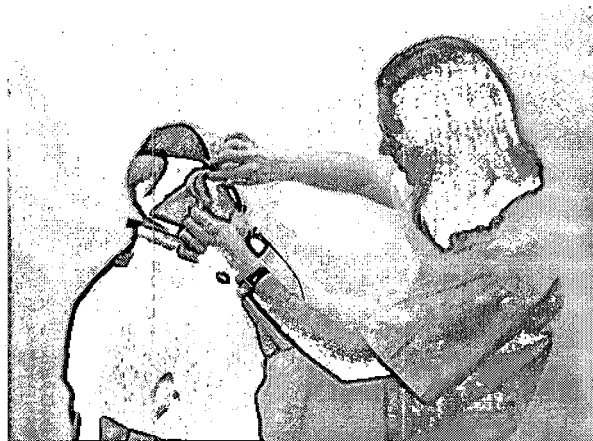
Adjust mask

Use the Velcro straps of the head cap to fit the face mask to your patient's/test person's face.



Important

To make sure that no air is escaping from under the face mask, ask your patient/test person to keep a flat hand to the volume transducer while breathing through it. If no air escapes at the sides, the mask fits correctly. Otherwise try a different face mask size or tighten the straps of the head cap.



Important

The system is beeping repeatedly if the battery is running low. To check the battery status prior to test start, select „Device Information“ from the „Measurement“ Menu in MetaSoft Measurement.

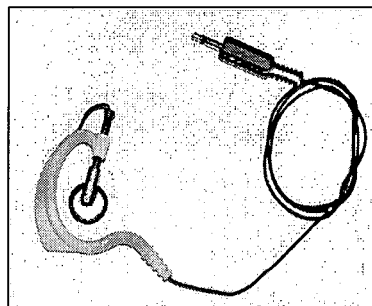
Connect earphone

The MetaMax[®] 3B base system integrates a speech module.

Phrases of encouragement or short instructions can be selected from the **Speech Info** Menu in MetaSoft Measurement and sent off to the patient/test person using telemetry data transfer.

Connect the earphone from your supply package to the **black audio** socket of the MetaMax[®] 3B base system. The audio socket is marked with a small headphone symbol.

Ask your patient/test person to put on the earphone.



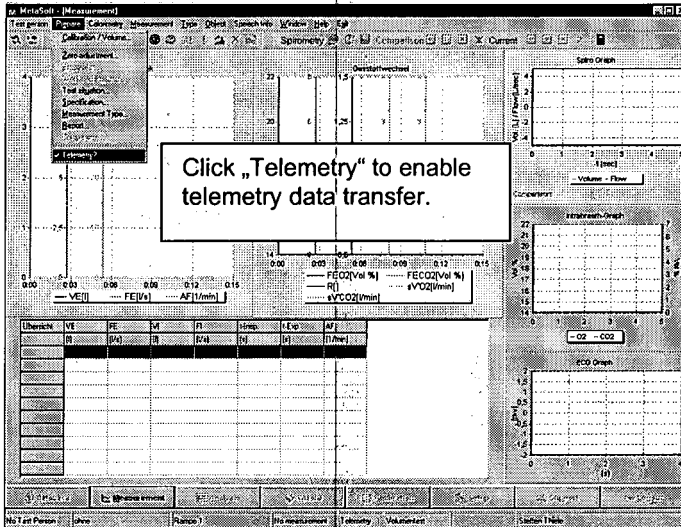
Earphone with cable for acoustic commands

Ready for the test

Start with your CPX test if your MetaMax[®] 3B is ready for measurement.

The green LED is lighting if MetaMax[®] 3B is ready to start measurement.

Perform measurement



Select telemetry measurement mode

Select "Telemetry?" from the "Prepare" Menu in MetaSoft Measurement.

A check mark indicates that the telemetry mode has been enabled.

Note

The data collected will be automatically stored in the internal datalogger of the base system to ensure data safety in case of transmission failure.

Important

To ensure a proper transfer of data via telemetry, please check the following prior to starting MetaSoft Measurement:

- a. Check if you have selected a **telemetry channel** and transferred the channel to the base system (see chapter „Steps prior to first use“).
- b. Check if the telemetry receiver has been switched on.
- c. Make sure the PC connection cable required to retrieve logged data from the datalogger or to perform basic settings in MetaSoft (see chapter „Steps prior to first use“) has been **disconnected**. It **must not** be connected to the base system during measurement.
- d. Check if the telemetry receiver has been connected to your PC.
- e. Make sure that the telemetry receiver is placed not too close to the PC. (recommended distance: up to 1.5 m).

Start / stop measurement

Via base system

Press the **start/stop** button of the MetaMax[®] 3B base system (second button from the top on control panel) to start/stop the measurement if you are on the spot to start measurement.



Start/stop measurement via **start/stop** button of base system

Via MetaSoft

MetaMax[®] 3B uses a bidirectional telemetry, allowing you to operate the system from a remote location.

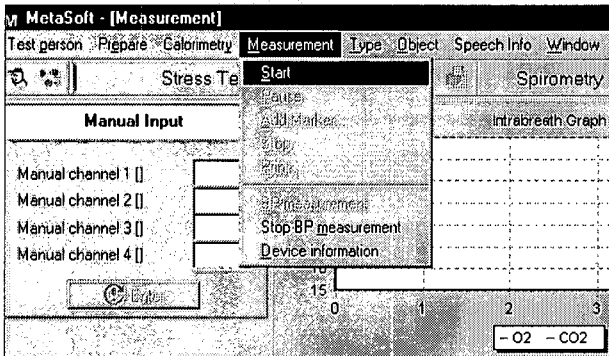
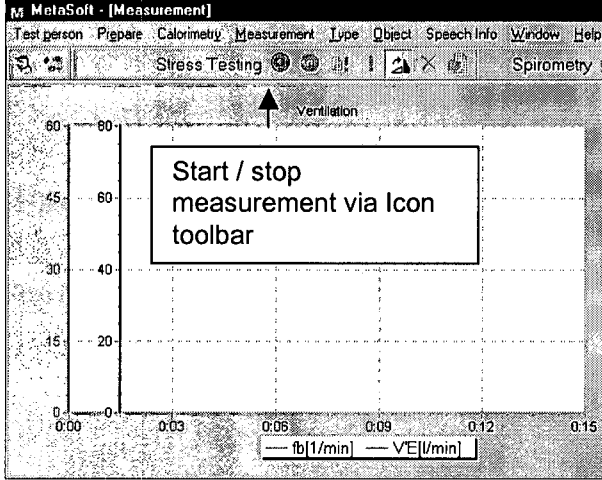
- To start/stop measurement, click the **Start/Stop** icon



on the Icon toolbar or select "Start" or "Stop" from the **Measurement** Menu in MetaSoft Measurement.

Once measurement has been started, the Start button will be disabled, and the **Stop** button enabled.

- To stop measurement and resume it later on, select **Pause** from the **Measurement** Menu.



Add markers

Markers set by the patient or test person

Depending on testing needs you can ask your patient/test person to set markers at agreed-time intervals during the test by pressing the **orange-coloured marker button** on the MetaMax® 3B base system



Set markers via marker button on MetaMax® 3B base system.



Set marker



Set marker and add comment

Set markers and add comments via MetaSoft directly from your PC

Markers set by the operator

To mark specific events (e.g. abnormalities occurred, change of workload, etc.) directly from your PC, select **“Add Marker”** from the **“Measurement”** Menu.

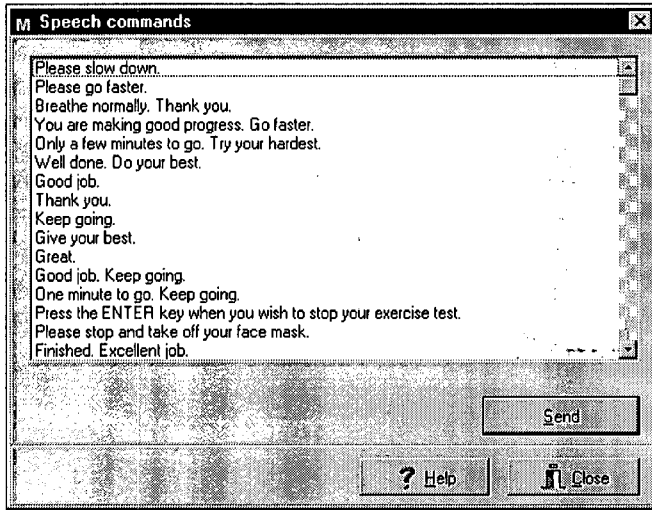
Click **OK** to enter a comment in the *Comment* field. The marker will be displayed as a vertical line in the graphic display object of your measurement screen.

Markers set during measurement will be stored in the test data file for later downloading into the analysis screen and/or test print outs after the test.

Motivate and/or instruct your patient via earphone

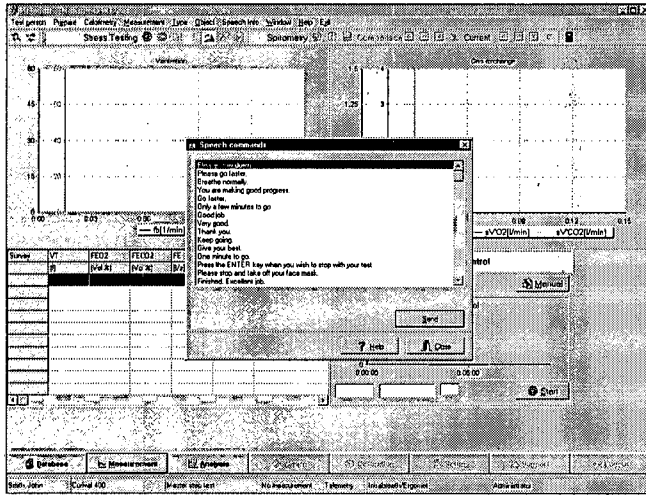
The MetaMax[®] 3B base system stores preprogrammed phrases of encouragement or instructions (e.g. Please slow down.) for acoustic output.

To display a list of the instructions selectable, click the **Speech Info** Menu in MetaSoft **Measurement**.



To send off an instruction to your patient/test person during the test (e.g. to ask him to slow down in case of an event occurred or alarm limit reached) select an appropriate phrase from the selection list in the **Speech commands** screen and click OK.

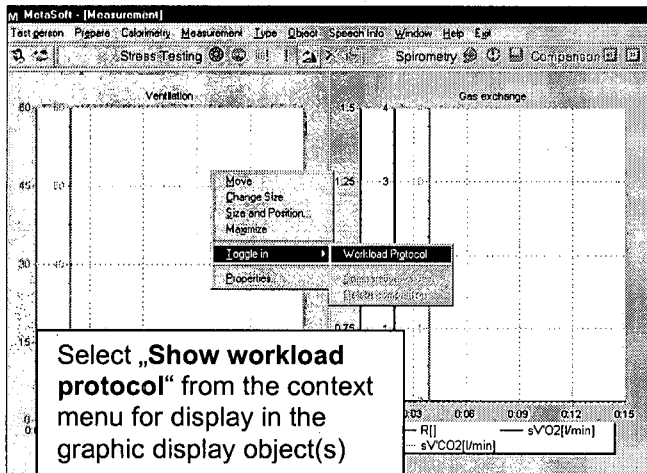
The command will be transferred using telemetry to the MetaMax[®] 3B base system and communicated via earphone to your patient/test person.



Display workload protocol

To display the workload protocol in the graphic display window during an ergometer or treadmill exercise controlled via the ergometer/treadmill control option of MetaSoft, right-click into the graphic display object. The object context menu appears.

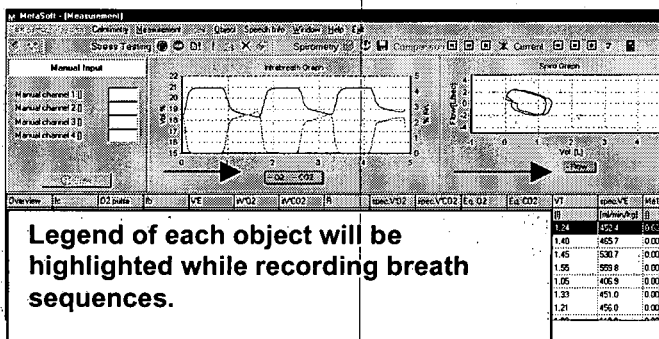
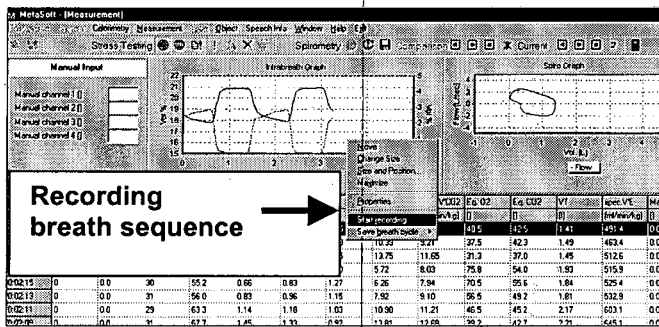
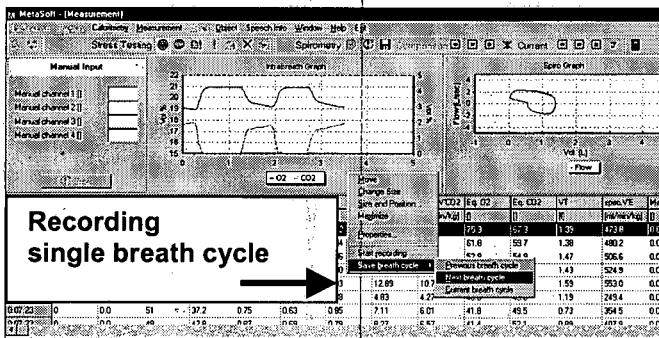
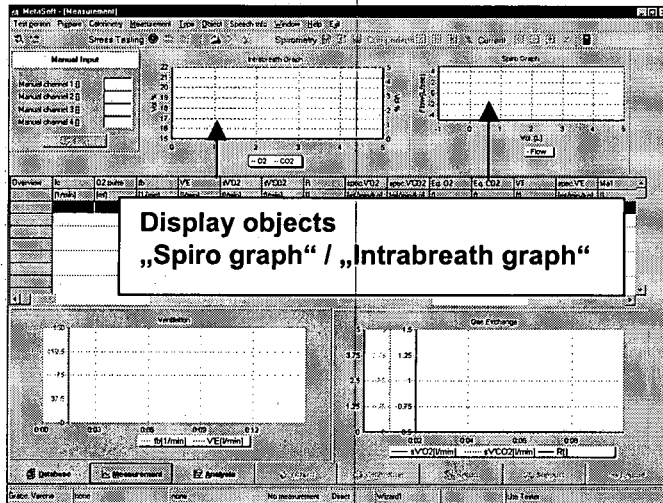
Select **"Toggle in"**. Select **"Workload protocol"** from the object context menu to view the workload protocol as a graph (grey).



View / record breaths or breath sequences

To view and/or save single breaths or breath sequences during field or lab exercise,

- select the „Spiro graph“ (flow) and/or „Intrabreath graph“ (O₂/CO₂ concentrations) object(s) from the **Object Menu** in MetaSoft Measurement to add it / them to your measurement screen. Alternatively, select a measurement type which displays either of these objects from the **Type Menu**.



- To start recording, right-click into either of these two display objects to bring up their **Context Menu**. The object context window will appear.
- To record a **single breath cycle**, select „**Save breath cycle**“ from the Context Menu. Select the breath cycle to be stored (previous, next, current breath cycle).
- Select „**Start recording**“ from the Context menu if you want to save a **breath sequence** (several subsequent breath cycles). Once you have started recording, the command „**Stop recording**“ will be enabled, displaying a checkmark.

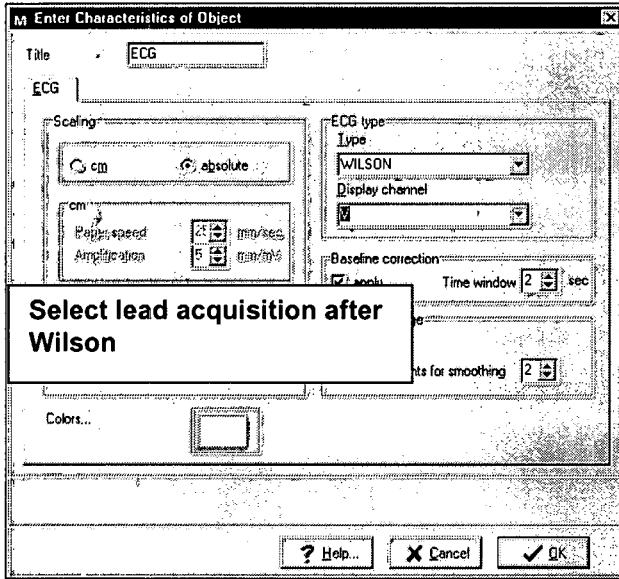
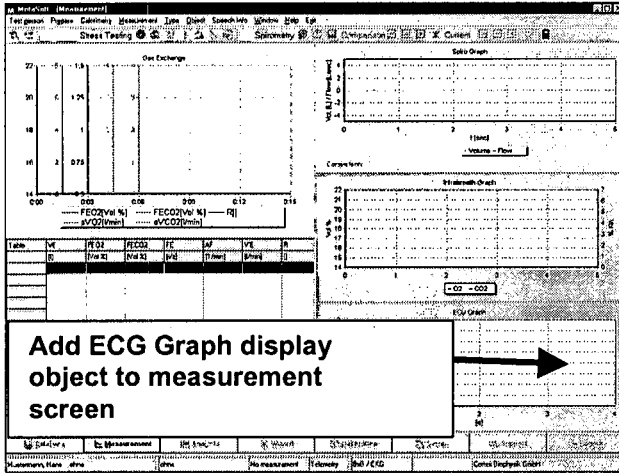
To stop recording, select „**Stop recording**“ from the Context Menu. Recording stops automatically after five minutes.

- The legend of the display object(s) „Spiro Graph“ and/or „Intrabreath Graph“ will be highlighted while recording.

View and record ECGs

To view and record an ECG during the CPX test using the integrated 3-channel ECG,

- add the **ECG Graph** display object from the **Object Menu** in MetaSoft Measurement or select a measurement screen with an ECG display object from the **"Type"** Menu.
- Select the lead (Wilson etc.) prior to test start. Use the ECG acquisition after Wilson to record the ECG during a test with MetaMax[®] 3B for optimum trace quality (also see chapter "Place ECG electrodes and fix ECG cable" on page 48).



Right-click into the **ECG Graph** display object. The context menu will appear.

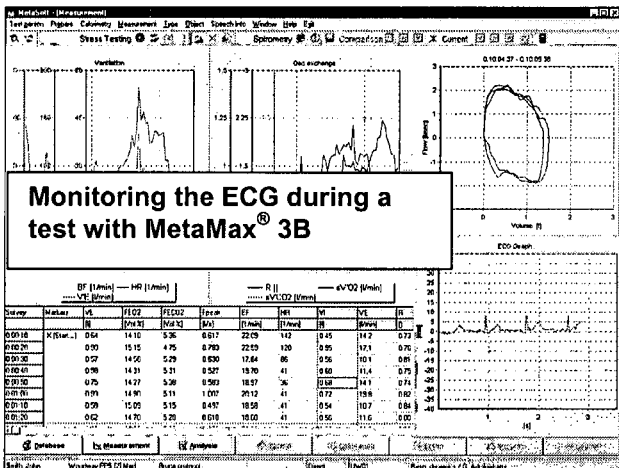
Select **"Properties"** from the Context Menu. The *Enter Characteristics of Object* screen of the ECG display object will appear. Select the lead acquisition after Wilson from the **"Type"** selection box. Please note that the Wilson lead acquisition provides for a **one-channel display only (V)**. One channel is selectable for display during the test.

To view either of the **three channels** during measurement, e.g. if the ECG is recorded after Einthoven or Goldberger, select **"Display channel"** from the object context menu during measurement and choose the channel you would like to be displayed.

- To record **ECG waveforms** during the test, select **"Start recording"** from the context Menu of the ECG display object.

The ECG data of the channel selected for display will be recorded. Once you have started recording, the command „Stop recording" will be enabled, displaying a checkmark.

To stop recording, select **Stop recording** from the Context Menu. Recording stops automatically after five minutes.



Using the datalogger (offline measurement)

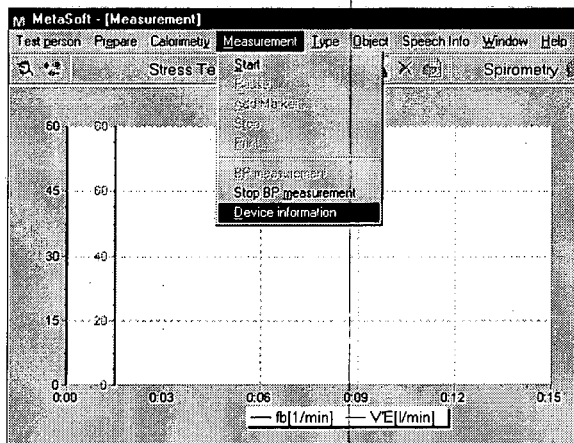
As a truly portable (mobile) system, the MetaMax[®] 3B integrates a data logger (internal memory system) allowing you

- to store test data (e.g. during outdoor use) and evaluate it after the test. The data logger automatically stores any CPX data collected during any kind of measurement. Breath cycles and/or breath or ECG sequences, however, can be selected and stored during online measurement only.
- to download the ECG waveforms of all three channels of an ECG lead if an ECG has been recorded simultaneously with the CPX test using the 3-channel ECG module.
- to optimize data safety in case of transmission failure due to radio interference since data is transferred via telemetry during routine tests.

During tests with the data logger („offline“ measurement), the data cannot be viewed online. The telemetry data transfer of your MetaMax[®] 3B is disabled.

The MetaMax[®] 3B base system is used as a self-contained measurement device which is not operated from a PC. The integrated speech module guides the operator step-by-step through the test, giving acoustic instructions and/or indicating the current device and measurement status.

To evaluate the data collected, the MetaMax[®] 3B base system is to be connected to your PC to download the stored data into MetaSoft Database.

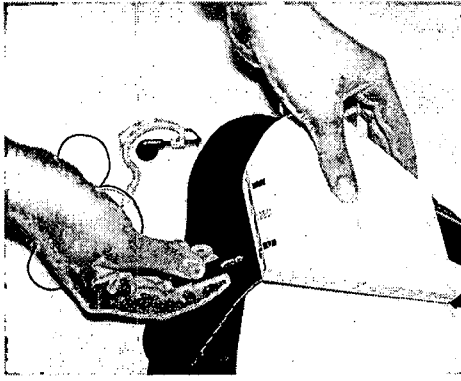


Important

Take care to check the datalogger prior to starting an offline measurement. Clear it if necessary since the data logger does not overwrite data.

To view the current logger status, select „Device Information“ from the Measurement Menu in MetaSoft Measurement.

The „Device Info“ window will appear displaying the current status of the data logger and the internal battery.



Follow acoustic instructions and LED signals

Offline tests

The speech module assists you to safely prepare and to perform an *offline* test if telemetry data transfer is inactive.

- Turn on MetaMax[®] 3B and prepare the device and your patient/test person for measurement as described in the previous chapters.
- Plug the earphone cable into the **audio socket** of the MetaMax[®] 3B base system und put on the earphone. **Follow the acoustic instructions.**

After you have turned on the base system, both LEDs are lighting, indicating that a memory test is being performed. After the memory test, the yellow LED is flashing.

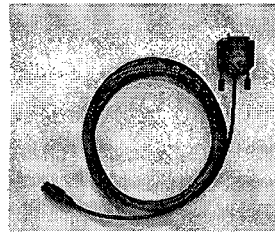
The yellow LED will be lighting if your MetaMax[®] 3B is ready for operation. You are asked to perform a one-point calibration measurement (ambient air measurement) prior to your test.

Press the **▶ start / stop** button (second button on panel) of the MetaMax[®] 3B base system to start calibration. Take care no one exhales into the volume transducer/sample line during ambient air measurement. The green LED is lighting, indicating that calibration has stopped and the system is now ready to start measurement. You are asked to proceed with your test.

- Start measurement after one-point calibration by pressing the **▶ start / stop** button. During measurement, the green LED is flashing, the yellow LED is off.

Once measurement has started, you can hear the parameters via earphone, allowing you to check if the values are properly received. Disconnect the earphone before your patient/test person starts with his/her test.

- Stop measurement by pressing once again on the **▶ start / stop** button or by asking your patient/test person to do so. Once measurement has been stopped, the yellow LED is lighting, indicating that the system is ready to perform a one-point calibration prior to the next test.



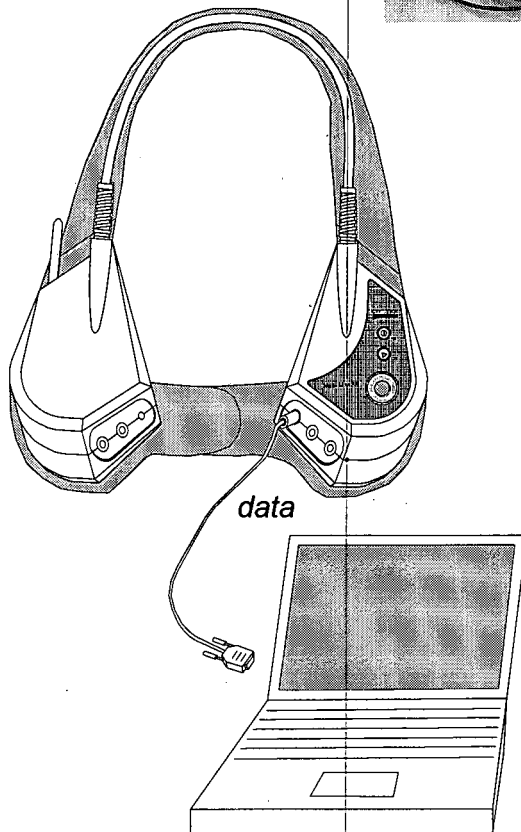
Download data from the datalogger

Connect MetaMax® 3B base system to PC

After the test, all stored measurement data can be downloaded into your PC for evaluation using MetaSoft.

To retrieve logged data from the datalogger

- connect the MetaMax® 3B base system to your PC using the provided PC connection cable. Plug the connector of the brown-marked connection cable into the brown **data** socket of the base system, the serial plug-in of the cable into your PC.
- turn the device on.



Start MetaSoft

When you start MetaSoft, the blue CORTEX screen will appear, displaying the **main menu or modules** at the bottom of the screen.

Important

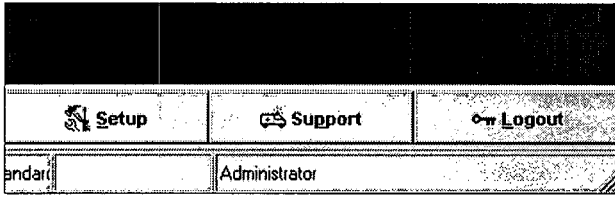
The **“Standard” user mode** is the default screen brought up when you start MetaSoft. To perform tasks exceeding Standard user status, access MetaSoft via the Login module. The Login button turns into a Logout button.

(See chapters „MetaSoft Modules - Login“ and „Steps prior to first use“)



Check connection

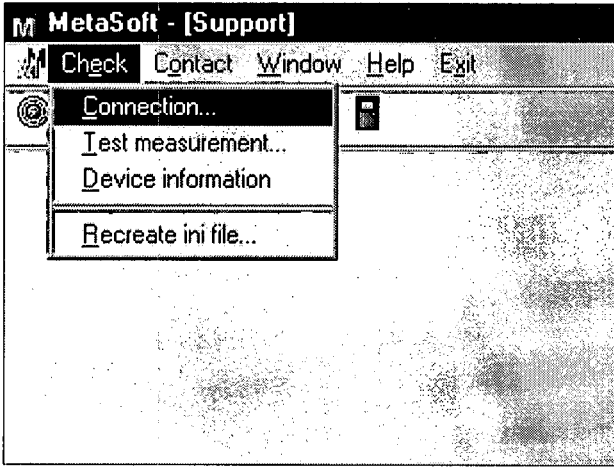
To check if your MetaMax[®] 3B base system is properly connected to your PC/notebook, select **Support** from the MetaSoft main screen to start the *Support* module.



Click the **Connection** icon



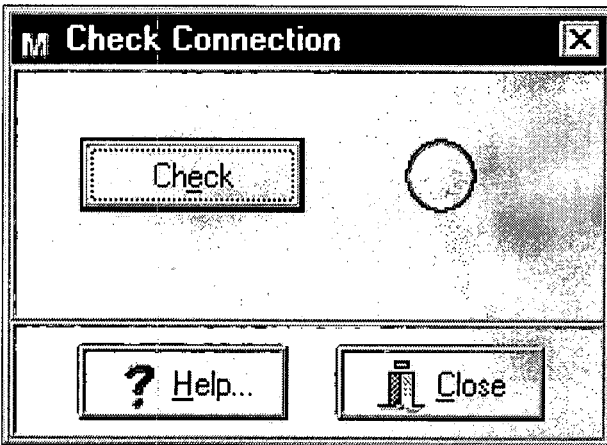
on the ICON toolbar at the top of MetaSoft Support or select **Connection** from the **Check Menu** of MetaSoft Support.



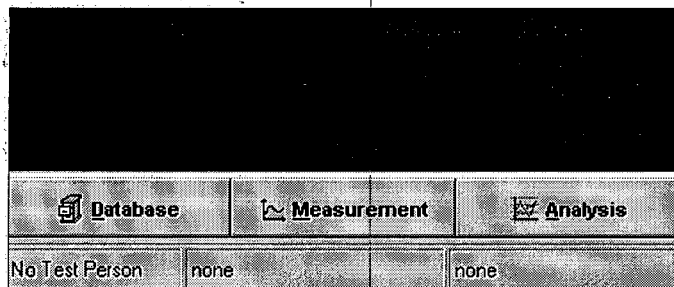
The *Check Connection* window will appear.

Click the **Check** button.

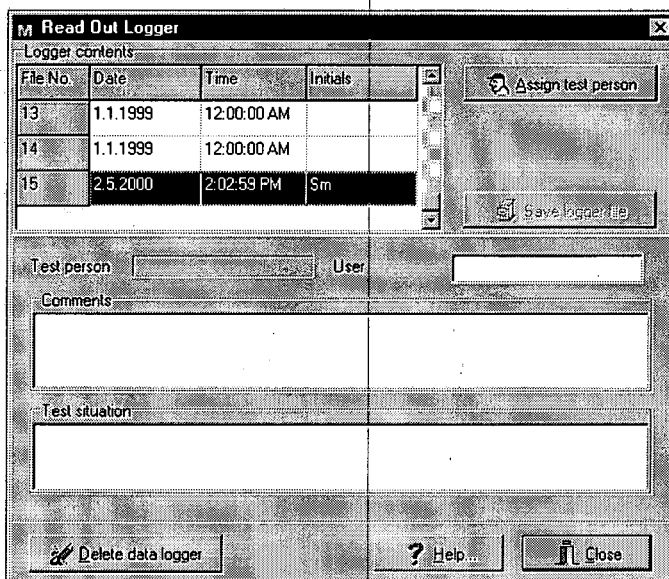
The circle will turn green if the system is connected and can receive and/or transfer data.



Retrieve data via MetaSoft Database



- Click the **Database** button on the main screen.

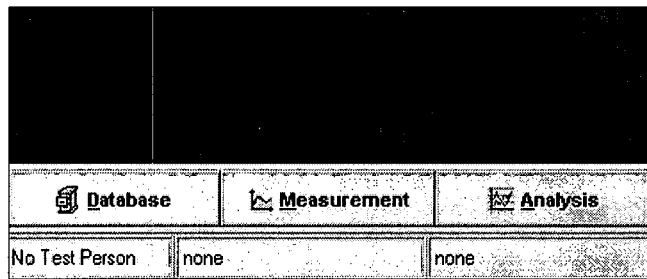


- Select **Read out logger** from the **"Test"** Menu of MetaSoft Database. The **Read Out Logger** screen will appear.

A list of tests stored in the data logger will be displayed in the **Read Out Logger** screen. Choose the test you want to download.

- To assign the name of your patient/test person to the test selected, click the **Assign patient/test person** button.
- Select your patient/test person from the selection list or enter a new patient via the **New** button.
- If applicable, you can type additional information on the test into the "Comments" and "Test situation" text fields displayed.
 - To retrieve the test and store it in the database for evaluation, click the **Save logger file** button. The **Save logger file** button will be enabled once a patient/test person has been assigned to a test.

IX. After the test

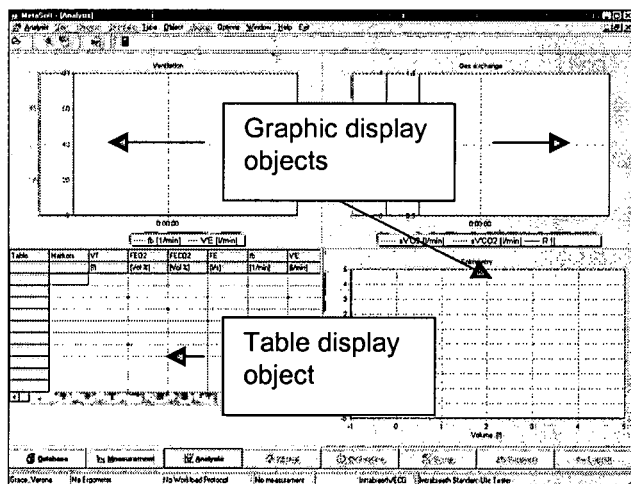


Start MetaSoft Analysis

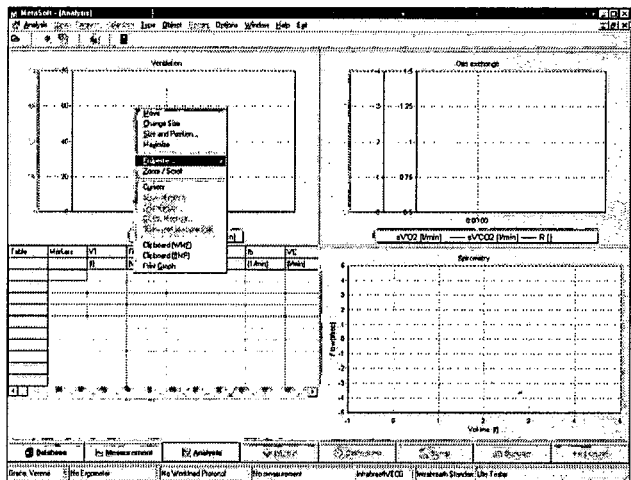
Click in the **Analysis** button at the bottom of the CORTEX screen to start the evaluation program **MetaSoft Analysis**. **MetaSoft Analysis** allows you to evaluate the test data, to determine additional parameters (e.g. AT, VO_{2max}) or to print test reports.

Select/customize screen

The **analysis screen** (or type) displays a predefined configuration of graphs and tables, referred to as “**display objects**”.



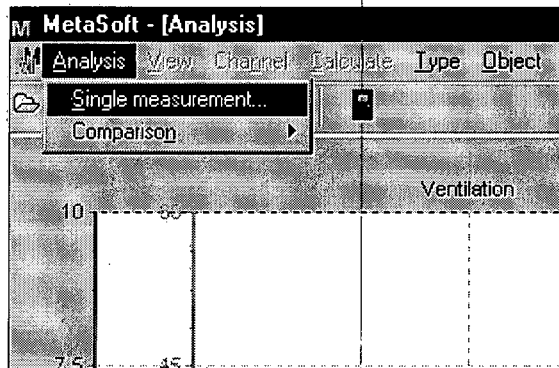
- To use a predefined screen configuration (“**type**”), choose **Select** from the **Type Menu** of MetaSoft Analysis.
- To add an existing display object to the screen (e.g. ECG), select the display object from the **Object Menu** in MetaSoft Analysis via the **Object – New command**. To configure a new or remove a display object from the screen, select “**New**” or “**Remove**” from the “**Object**” menu.



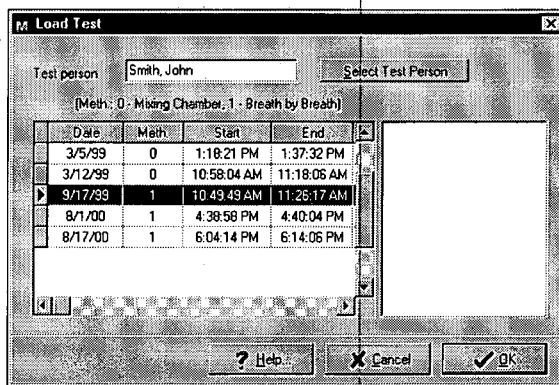
- To add parameters to a display object of a configuration screen which includes these parameters, first right-click into the appropriate display object, then select **Properties** from the object context menu. Select the parameter to be added from the **Enter Characteristics of Object** screen (see fig. 2).
- To add parameters to a display object of an analysis screen, which are not yet defined in this screen, first select “**Add channel**” from the “**Type**” Menu in MetaSoft Analysis. Select all parameters („channels“) you would like to add to the current analysis type (screen). Then right-click into the appropriate display object to add the new parameters to the display object as described above.

A graphic display object can display up to five different parameters, a table display object up to ten different parameters.

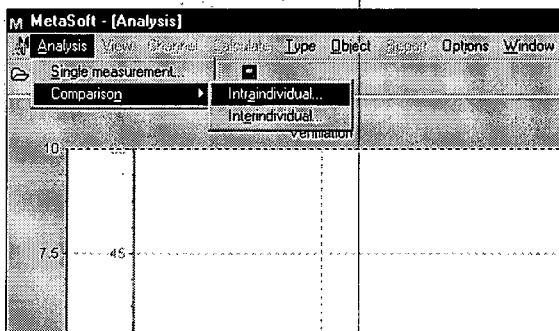
Load test for evaluation and/or comparison



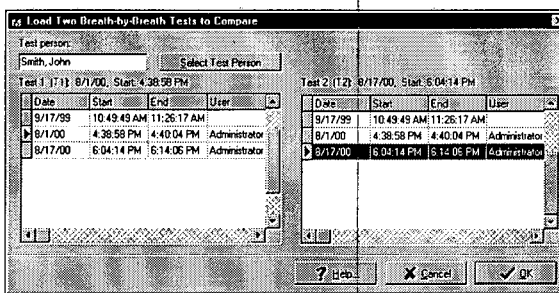
- To select a test for evaluation on the screen, first click the **Open File** icon on the icon toolbar, or select **Single Measurement** from the **Analysis** Menu in MetaSoft Analysis.



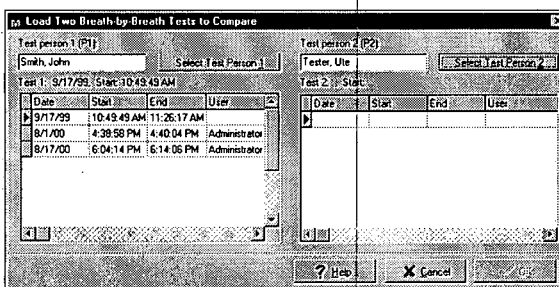
The **Load Test** screen will appear. Double-click the test you want to view, and it will be loaded into your screen.



- To compare the test with a previous test of the same test person, select **Comparison - Intra-individual** from the **Analysis** Menu.

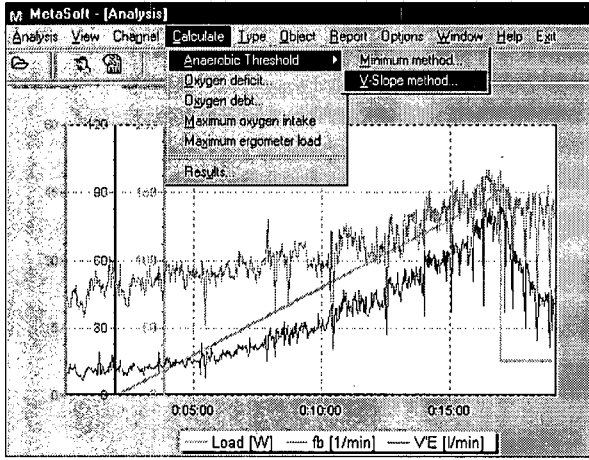


The "Load Two Breath-by-Breath Tests to Compare" screen will appear. Select **Test 1** and **Test 2**, and click **OK** to load both tests into your screen.



- To compare the test with a test of a different test person, select **Comparison - Interindividual** from the **Analysis** Menu. Select **Test 1** and **Test 2** from the "Load Two Breath-by-Breath Tests to Compare" screen, and click **OK**.

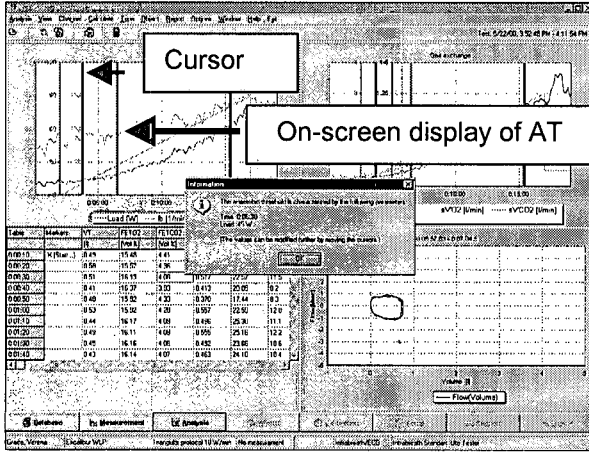
Determine Anaerobic Threshold



MetaSoft provides for an automatic determination of the anaerobic threshold using two popular methods – V-Slope or ventilatory equation. Additionally, O₂ kinetics can be calculated.

Anaerobic Threshold

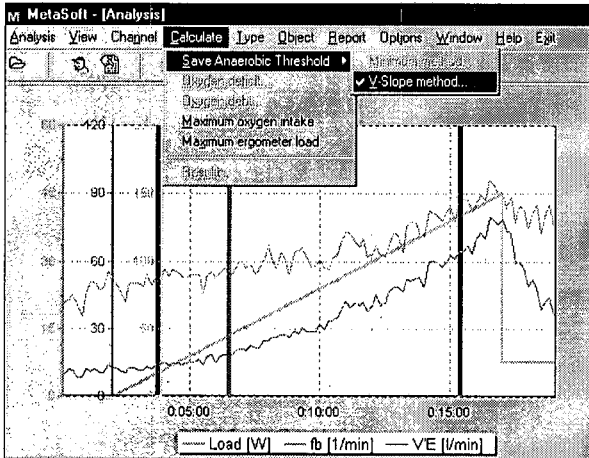
Select „V-Slope“ or „Minimum method“ via the „Anaerobic Threshold“ command from the **Calculate** Menu. The anaerobic threshold will be automatically calculated based on a fixed time interval of ten seconds between the measurement values. An information window will pop up specifying time and exercise level (work rate).



Note: Select „Change to equidistant channels“ from the „Channel“ Menu in MetaSoft Analysis to calculate the AT based on a fixed time interval of over 10 seconds, e.g. 30 seconds, prior to selecting the calculation method.

The AT calculated will be displayed as a vertical line (pink) in the graphic display objects. If necessary, it can be modified by moving the cursors.

Tip: The AT can be more accurately determined when using ramp protocols.



Select „Change to original data“ from the „Channel“ Menu to restore the original data.

To save the calculated AT in the database for report print-outs, select **Save Anaerobic Threshold – V-slope method** from the **Calculate** Menu.

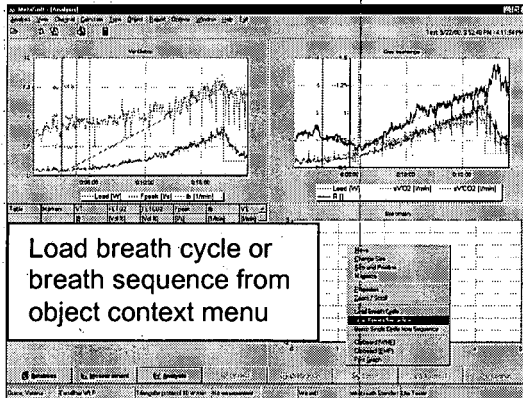
Name of Parameter	1st feature	2nd feature
Anaerobic threshold (V-Slope method)	Time 0:06:30	Load 45.000 [W]

To view all results, select „Results“ from the **Calculate** Menu. The „Calculated Parameters“ window will appear listing all parameters calculated.

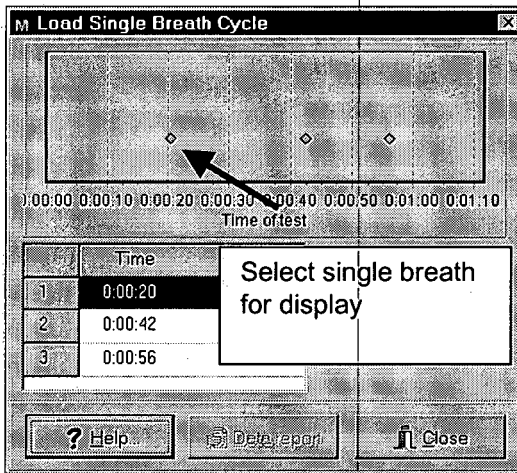
Retrieve stored breaths/ breath sequences

To evaluate the breaths or breath sequences recorded during measurement,

- either of the two display objects „Spiro Graph“ (Flow) and/or „Intrabreath“ (O_2/CO_2) must be displayed in your analysis screen. Add the appropriate object to the screen via the **Object – New** command from the **Object Menu**, or **select an analysis type** which displays either of these two objects from the „Type“ Menu in MetaSoft Analysis.

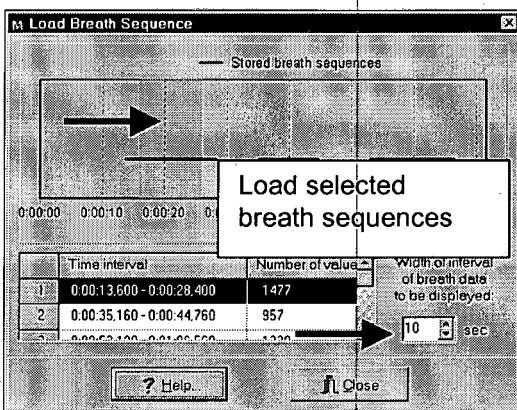


- Right-click into either of the two display objects to bring up their context menu.
- Select „ **Load breath cycle**“ from the Context Menu to evaluate a single breath or „**Load Breath Sequence**“ to evaluate breath sequences recorded.

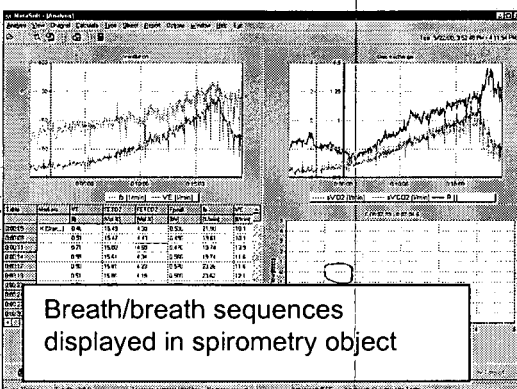


The **Load Single Breath Cycle** or **Load Breath Sequence** screen will appear, showing all breath cycles or breath sequences recorded. Single breaths are displayed as green dots; breath sequences are displayed as red horizontal lines.

- To display a single breath, click the appropriate green dot or time.
- To display a breath sequence, move the green vertical bar of the **Load Breath Sequence** screen to highlight those areas you would like to view on the screen or select the time interval from the “Width of interval of breath data” selection box.



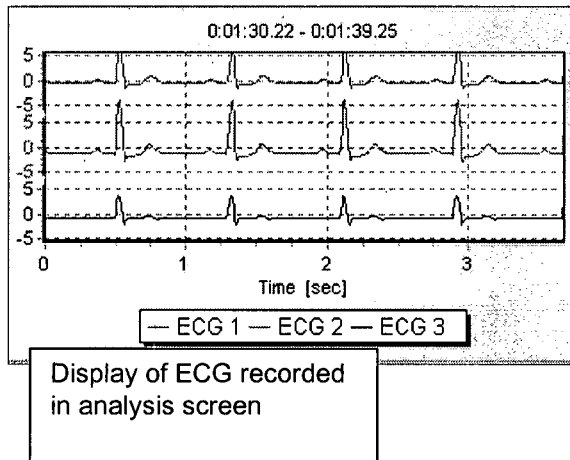
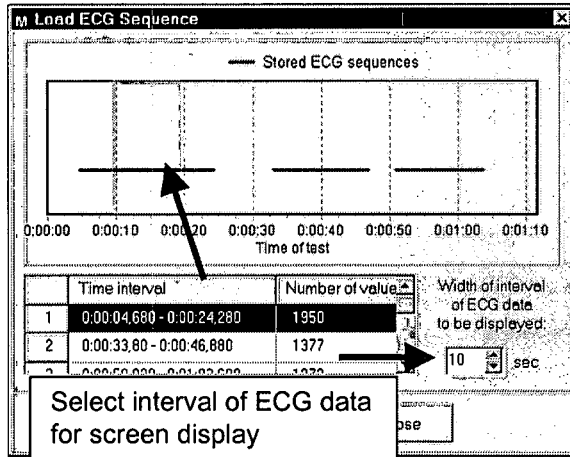
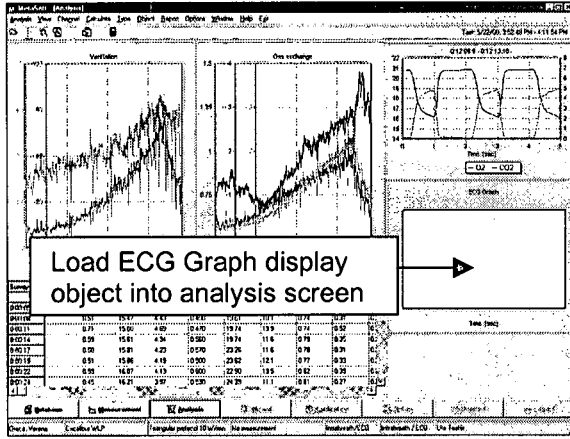
- To display a single breath from a breath sequence recorded, load the appropriate breath sequence: Select **F(t), V(t)** as display mode via the **Properties** command from the object context menu. Right-click into the object, and select “**Grasp single breath cycle from sequence**” from the context menu which is now enabled. If you click the highlighted breath you want to view, a report will be displayed. Select **Print** to print the report or **Close** to return to your screen. The highlighted breath will be saved in the database and can be loaded into the screen via the **Load Breath Cycle** command from the object context menu.



Retrieve stored ECG data

To view the ECG data recorded using the built-in 3-channel ECG,

- the „ECG Graph“ display object must be displayed in the analysis screen. Add it to your screen via the **Object – New** command from the **Object Menu**, or select an analysis type displaying the ECG Graph object from the „Type“ Menu in MetaSoft Analysis.
- Right-click into the *ECG Graph* display object to bring up the object context menu. Select „Load ECG sequence“ from the Context Menu.



The **Load ECG Sequence** screen will appear, displaying all ECG sequences recorded as red horizontal lines.

Move the green vertical bar of the *Load ECG Sequence* screen to highlight those areas you would like to view on the screen or select the appropriate time interval from the “Width of interval of ECG data” selection box.

Note

The datalogger stores the selected ECG waveforms of **all channels** of a lead during online measurement. To view ECG waveforms of a channel which was not displayed (where applicable) during measurement, download the ECG data from the datalogger.

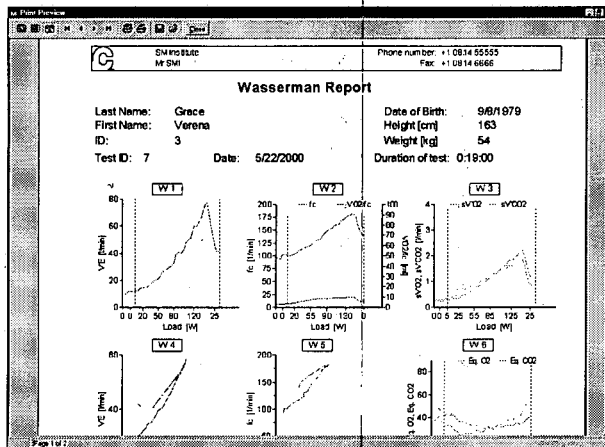
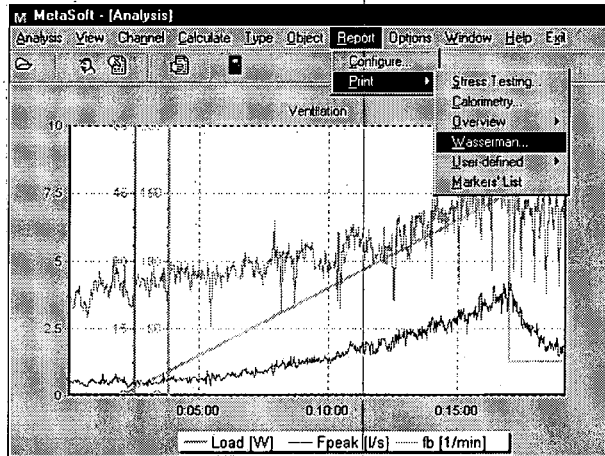
Fig.: 3-channel display of ECG data recorded after Einthoven

Print test report

After the test, all test data collected can be printed in graphic and/or numeric format.

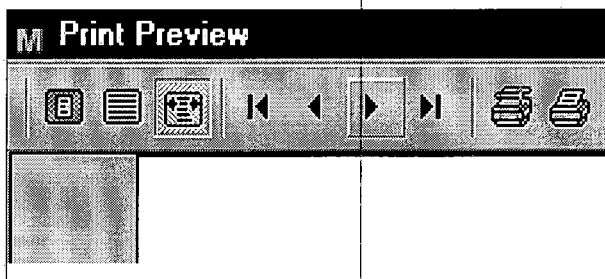
To print a predefined report of the test (tables/ graphs), e.g. Wasserman report, select "Report – Print" from the "Report" Menu in MetaSoft Analysis.

Click the appropriate report from the selection list.

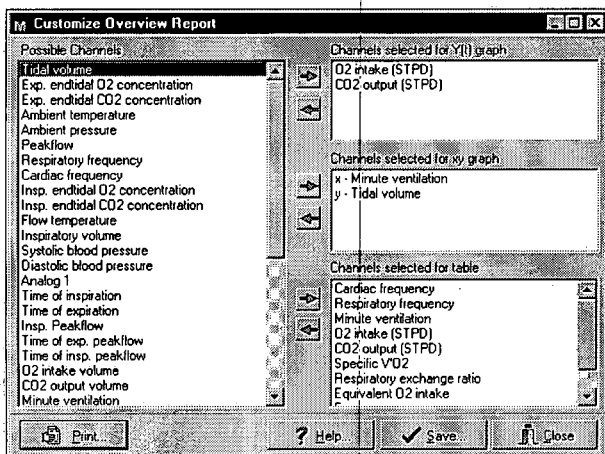


The test data will be displayed in a graphic format.

Fig.: Print preview of predefined report



To view a table display of the test data, click the *arrow* icon on the icon toolbar at the top of the *Print Preview* screen.



To configure your own report, select **Print – Overview** from the **Report** Menu. The Overview report is a two-graph, one-table report. The first page shows the parameters selected as an y/t and/or x/y graph, the second page shows a table display of the parameters selected.

Fig.: Configure your own report

X. Maintenance, Cleaning & Battery Care

General

The maintenance and cleaning instructions described in this manual are intended to provide guidance on routine maintenance of the MetaMax[®] 3B and its accessories to satisfy your internal quality assurance and as a matter of good hygienic practice.

To maintain your MetaMax[®] 3B at peak performance it is strongly recommended to observe these maintenance and cleaning instructions. Non-observance of these instructions may result in a failure to properly operate your MetaMax[®] 3B system and/or in a severe safety risk for the user. The warranty expires in case of non-observance of the maintenance and cleaning instructions.

Please contact your local CORTEX Biophysik sales partner or CORTEX Biophysik for a preventive maintenance agreement.

Cleaning & Maintenance Routines

Cleaning & maintenance procedures to be performed by the user:

Cleaning and disinfection after each test and/or after each patient

- Cleaning and disinfection of the face mask(s);
- Cleaning of the head cap;
- Cleaning of MetaMax[®] 3B housing;
- Cleaning and disinfection of the volume transducer;
- Visual inspection of system and parts prior to next use;
- Recharging of batteries.

Maintenance after six months of use

- Replacement of the sample line,
- Battery care

Maintenance to be undertaken by local CORTEX sales partner or properly trained staff:

Replacement of O₂ Analyzer

The oxygen analyzer (sensor) is an electro-chemical cell (fuel cell) which is used up after six months of use. It should therefore be replaced **every six months**. The MetaMax[®] 3B base system integrates an audio/visual self-test routine. A message will appear on your MetaSoft screen or communicated via earphone prior to measurement in case the oxygen analyzer is used up and needs to be replaced.

The O₂ analyzer should be replaced by your local CORTEX sales partner or properly trained or experienced technical support staff only. To replace the analyzer, refer to the instructions included in your O₂ replacement package.

Replacement parts and consumables can be purchased from your local CORTEX sales partner or CORTEX Biophysik GmbH.

Preventive Maintenance

To maintain a long-time performance of your MetaMax[®] 3B, the system should be thoroughly checked for wear or damage of critical parts (e.g. filter, pneumatic components) every twelve months.

Return the system to your local CORTEX sales partner or CORTEX Biophysik for a preventive maintenance inspection, or contact your CORTEX sales partner or CORTEX Biophysik for a maintenance agreement.

Cleaning & Maintenance Instructions

Cleaning and disinfection of the face mask

The face mask must be removed, soak-cleaned and disinfected after each patient. The cleaning of reusable devices usually begins soon after use.

Note: Protective attire is required of personnel handling contaminated devices. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

Cleaning

- After the test, remove the volume transducer and the head cap from the face mask. Soil is wiped from the device surface with a moist sponge or cloth.
- Inspect the mask and its components for damages at all stages of handling. If damage is detected on any of the components, it should be identified and replaced.
- Soak or rinse the device in water of 20° – 45°C. Use a pH neutral mild detergent. If an enzyme product is required, soak for two minutes. Remove, examine and extend the soak time for components with dried-on matter for up to five minutes. Soaking of components over five minutes may be detrimental, causing damage to the component's surface.
- After soaking, the mask must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components.
- Dry mask thoroughly using a soft clean cloth or disposable paper towels.

Disinfection with liquid solutions

The following disinfectants have been tested and approved:

- Cidex, (Surgicos Inc., Johnson & Johnson Corp.),
- Metricide, (Metrex Research Corp.),
- Glutarex, (3M Company)
- Lysetol med, (Schülke & Mayr GmbH)
- Take care to observe the recommendations of the manufacturer when using specific disinfectants. Use any of these disinfectants as recommended by the manufacturer.
- Determine the required soak temperature and time of the disinfectant and assure that these requirements are met. Activate the solution by mixing the components per manufacturer's instruction. Pour the activated solution into an appropriately-sized basin. Completely immerse the mask in the basin. The disinfectant agent must contact all surfaces to ensure disinfection. Cover the basin.
- Adequate rinsing must follow disinfection to remove all traces of the disinfectant. Rinse for at least one minute with water (sterile water is preferred).
- To prevent the growth of waterborne organism, the mask should be dried thoroughly using a soft cloth or disposable paper towels.
- In case skin irritations occur after use of a specific disinfectant, stop disinfecting with this solution and use any other of the approved solutions. If none of the disinfectant solutions will stop the skin irritation effect, use steam disinfection.

Disinfection with steam

The disinfection of the mask can be achieved with steam disinfection. The maximum temperature of cycle must not exceed 135°C. The cycle time must not exceed 15 minutes.

Cleaning of the head cap assembly

The head cap assembly should be removed and cleaned after each patient. The cleaning of reusable devices usually begins soon after use.

- The head cap assembly, including the clips, can be hand-washed in water of 20° – 45°C, using a non-oily, mild detergent.
- Rinse thoroughly in water. Machine or line dry. Do not iron the head cap.
- Inspect the head cap for damages at all stages of handling. If damage is detected on any of its components (e.g. the clips), it should be identified and replaced.

Cleaning of housing

Before cleaning the MetaMax[®] 3B base system, remove MaxBelt or MaxBelt Ultra and disconnect any tubes and/or cables from the system.

Use a moist cloth to wipe the instrument clean. Liquids must not be allowed to enter the device. Any hospital-grade cleaning agent and disinfectant may be used.

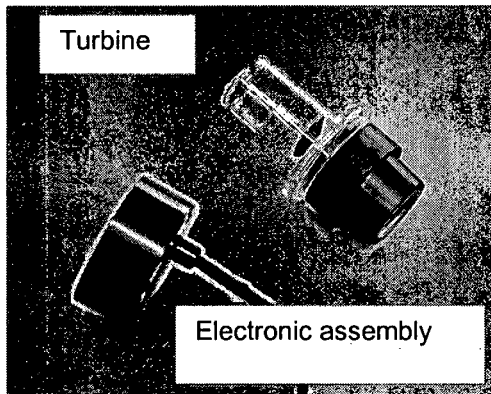
Danger

If liquids have entered the device it must be checked by a service technician before it can be used again.

Cleaning and disinfection of DVT volume transducer (MetaMax[®] 3B Standard)

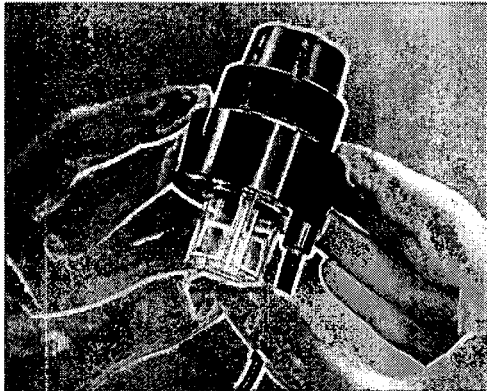
The DVT volume transducer must be cleaned and disinfected **after each patient**. This means one test can be performed while the **contaminated parts** are being cleaned. The standard package includes one volume transducer; exchange units are available on order from your local CORTEX sales partner or the manufacturer.

- Remove the volume transducer from the face mask.
- Disconnect all tubes from the volume transducer.
- Disassemble the volume transducer.

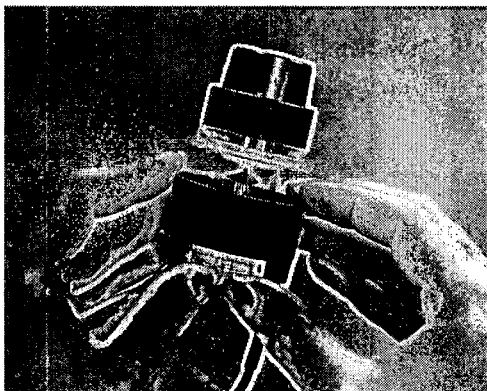


The DVT volume transducer consists of two parts:

- turbine with mask adapter
- electronic assembly with cable.



To disassemble the volume transducer, carefully push turbine out of electronic assembly.

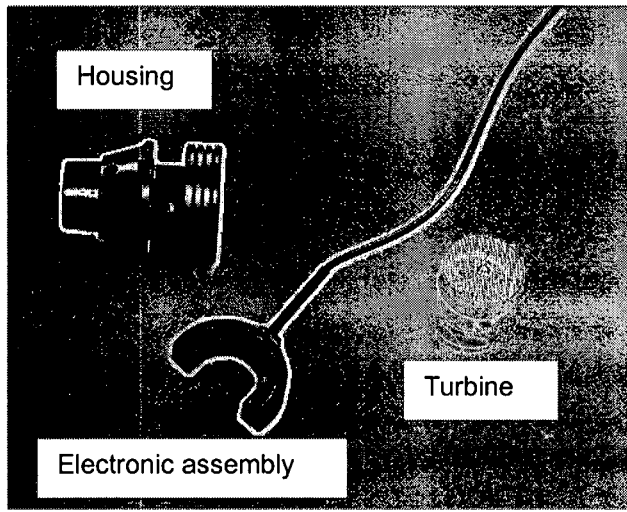


- After disassembly of the volume transducer check its parts for mechanical damages (turbine, sieve, housing of electronic assembly, cable connectors).
- Rinse turbine in warm water (< 50°C). **Do not hold the turbine under running water.** This may damage the turbine.
- Put turbine into a disinfecting solution (see disinfectants recommended for face mask).
- After disinfecting, first rinse the turbine in pure water, then in distilled water to avoid calcification after air drying. Air dry the turbine. **Do not use mechanical dryers, paper or textile for drying** to keep the turbine free from dust and fibre deposits.
- The housing of the electronic assembly may be surface-cleaned, using a fluff-free, weakly moistened cloth. **Moisture must not get into the housing.**
- To reassemble the volume transducer, follow the opposite instructions by pushing turbine back into electronic assembly. **The parts must be thoroughly dried before assembling.**

Cleaning and disinfection of the Triple V[®] volume transducer (MetaMax[®] 3B Ultra)

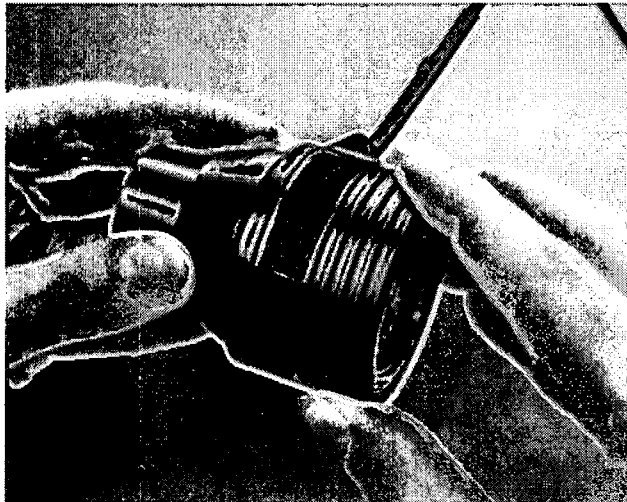
The Triple[®] volume transducer must be cleaned and disinfected **after each patient**. This means one test can be performed while the contaminated parts are being cleaned. The standard package includes one volume transducer; exchange units are available on order from your local CORTEX sales partner or the manufacturer.

1. Remove the volume transducer from the face mask.
2. Disconnect any tubes from the volume transducer.
3. **Disassemble** the volume transducer:



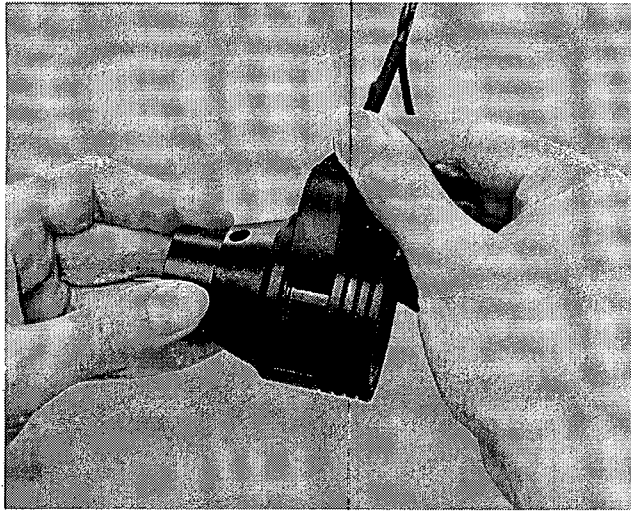
The Triple[®] V volume transducer consists of the following parts:

- housing
- turbine
- electronic assembly with cable

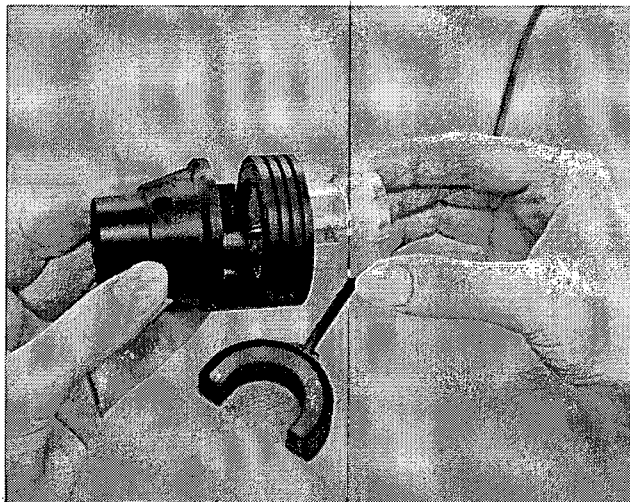
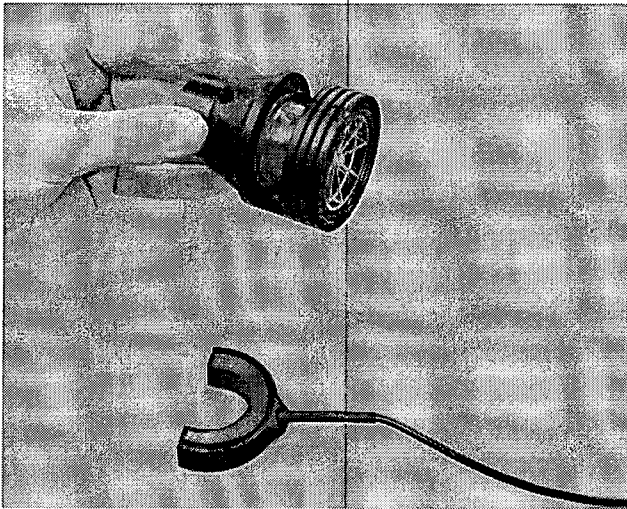


Disassembly of Triple[®] V volume transducer:

1. Turn housing a half turn to the left to unfasten electronic assembly.



2. Remove electronic assembly from housing.



3. Slide turbine out of housing.

4. After disassembly visually check the parts for mechanical damages (turbine, sieve, housing of electronic assembly, cable connectors).

Cleaning

1. Turbine:

- Rinse the turbine/transducer in warm water (< 50°C). **Do not hold the turbine/transducer under running water.** This may damage the turbine/transducer.
- Put the turbine/transducer into a disinfection solution (see disinfectants recommended for face mask).
- After disinfection first rinse the turbine/transducer in pure water, then in distilled water to avoid calcification after air drying. Air-dry the turbine/transducer. **Do not use mechanical dryers, paper or textile for drying** to keep the turbine free from dust and fibre deposits.

2. Electronic Assembly:

The housing must be surface-cleaned, using a fluff-free, weakly moistened cloth only. **Moisture must not get into the housing.**

3. Housing:

The housing can be easily cleaned using a non-oily, mild soap. Rinse thoroughly in running water.

Re-Assembly of Triple[®] V volume transducer

To assemble the parts, follow the opposite instructions. First slide turbine back into housing. Press electronic assembly back into housing and turn housing a half-turn to the right to fasten electronic assembly. The parts must be thoroughly dried before assembling. Take care that the sieve of the turbine shows towards the mask adapter.

Replacement of the sample line

The entire sample line **must be replaced in case of breakage**. It is recommended to replace it **after six months of use**. Defective or worn sample lines may result in inaccurate measurements. They allow water condensate inside the sensor where it could damage the electronic components within the measurement device, causing a severe system failure. Sample lines can be purchased via your local CORTEX sales partner or CORTEX Biophysik GmbH.

Visual inspection of system and parts prior to next use

Visually check each part of the system and its cables for signs of mechanical damage (e.g. broken connectors, crooked pin connections etc.) **prior to each use**. Should you detect damages or impaired device functions which present a hazard to the user, replace the part immediately or return it for a preventive maintenance inspection to your local CORTEX Biophysik sales partner or CORTEX Biophysik before using it again.

Recharging batteries prior to next use

Remove the battery from the battery compartment if it is empty or if the MetaMax[®] 3B is not to be used for a long time. Charge the batteries prior to next use and if the batteries have not been used for a long period. The batteries should be allowed to recharge for 4 to 5 hours for full capacity. The ambient temperature for recharging should be between 0°C - +40°C. Replace batteries when usage time between charges becomes too short (less than 50 %, i.e. reducing the operating time of MetaMax[®] 3B to less than one hour).

Battery Care

The batteries have to be prevented from humidity and high temperatures and checked for mechanical damages after each use. They should be recharged before storage at least every 6 (six) months.

For additional information and warnings read the following handling instructions provided by the manufacturer of the batteries. Please read and follow the handling instructions for the battery before use. Improper use of the battery may cause heat, fire, explosion, damage or capacity deterioration of the battery.



Warnings

- Keep Lithium batteries away from children.
- Lithium batteries are poisonous.
- Important: If batteries are swallowed, immediately contact a physician or your local poison control authority.
- Do not use the battery at high temperatures (see below operating conditions for batteries).
- Do not use any other maker's battery charger. Always use the battery charger from your supply package to recharge the batteries.
- Do not let the battery terminals (+ and -) contact a wire or any metal (like a metal necklace or a hairpin) with which it is carried or stored together.
- Do not throw, drop or attempt to disassemble or alter the battery to avoid mechanical damage.
- Do not put the battery in a microwave oven or a pressure cooker.
- Do not leave the battery in a charger or equipment if it generates an odor and/or heat, changes colour an/or shape, leaks electrolyte, or causes any other abnormality. In such a case, immediately take the battery out of the charger or equipment and keep it away from fire, otherwise, the battery might overheat, explode, or cause fire.
- Do not use the battery in other than the following conditions, otherwise, the battery might cause heat generation, damage, or deterioration of its performance.

Operating environment

- When the battery is recharged: 0°C to +40°C
- When the battery is discharged: -20°C to +40°C
(= when MetaMax[®] 3B is operated)
- The battery was charged before shipment and is ready for use. It may be necessary, however, to recharge the battery after long transport prior to first use to ensure maximum battery performance.
- When the battery is expected not to be used for a long time, remove the battery from its compartment.
- Despite being rechargeable, the battery has a limited life span. Replace when usage time between charges becomes short.
- **Important: Discard batteries according to your local environmental regulations.**

If you have any question regarding the use of the battery which is not specified above, please contact your local sales partner of the MetaMax[®] 3B equipment or CORTEX Biophysik GmbH. Neither CORTEX Biophysik nor its sales partners assume any liability for defects or damages occurred due to non-authorized use of the battery.

XI. Annexes

Operator instructions and audio self-test messages which may be communicated via earphone during the prep-up time:

- 1 Hello! I am your MetaMax Triple B.
- 2 I need a few minutes to perform a self test.
- 3 Please wait a moment.
- 4 Please take note of possible error messages.
- 5 Please check if the sample line has been properly connected.
- 6 The sample line is blocked.
- 7 Please check calibration of C O 2 sensor.
- 8 Please check calibration of O 2 sensor.
- 9 Please check calibration of volume transducer.
- 10 Please check calibration of pressure sensor.
- 11 Volume transducer defective or not connected.
- 12 Error occurred during C O 2 measurement.
- 13 Please contact your local CORTEX sales partner.
- 14 Error occurred during O 2 measurement.
- 15 O 2 sensor used-up.
- 16 Pump defective.
- 17 Error occurred during pressure measurement.
- 18 Error occurred during differential pressure measurement.
- 19 Error occurred during humidity measurement.
- 20 Error occurred during device temperature measurement.
- 21 Memory error.
- 22 Radio transmission failed.
- 23 Radio transmission restored.
- 24 The self test has stopped.
- 25 I need a few minutes to warm up.
- 26 I am ready for operation.
- 27 Please perform a zero adjustment (one-point calibration) shortly before you start with your test.
- 28 Press the ENTER key to start the zero adjustment (one-point calibration).
- 29 I am now starting the zero adjustment (one-point calibration).
- 30 Make sure you sample ambient air.
- 31 I have stopped the zero adjustment (one-point calibration).
- 32 Please start with your test.
- 33 Press the ENTER key.
- 34 Your test has started.
- 35 Press the ENTER key to stop your test.
- 36 The following parameters are repeated regularly:
- 37 Good luck.

XII. Contact CORTEX Biophysik

Via email

Technical support: support@cortex-medical.de
Product information: sales@cortex-medical.de

Via Internet

<http://www.cortex-medical.de>

Via fax or phone

Technical support: Phone +49 341 4 87 49-40
Fax +49 341 4 87 49-50

Product information: Phone +49 341 4 87 49-0
Fax +49 341 4 87 49-50

Via mail

CORTEX Biophysik GmbH
Nonnenstrasse 39
04229 Leipzig
Germany

We look forward to your feedback.

Enjoy using your MetaMax[®] 3B.



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Metricide is a registered trademark of Metrex Research.

Glutorex and 3M is a registered trademark of 3M Company.

Lysetol med is a registered trademark of Schülke & Mayr.

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XIV. Disclaimer

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XV. Personal Notes

