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**K4 b$^2$ User manual, XII Edition**
**01/2005**

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# Getting started

# Important notices

## Intended use

The measurement of oxygen uptake during sport or real life activities is of great interest for the development of training programs and the study of their effects on elite athletes or for assessing the efficacy of a rehabilitation therapy.

A common method for assessing the effects of endurance training is the monitoring of various respiratory parameters during submaximal exercise.

One difficulty to achieve this goal during sport that cannot be simulated in the laboratory is to use a reliable and valid portable system to measure $VO_2$ and $VCO_2$ in a field setting.

Such a portable apparatus may also be useful to determine the energy cost of many sport and real life activities.

K4 $b^2$ is an electrical medical device designed to perform pulmonary function tests. It is to be used by physicians or by trained personnel on a physician responsibility.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

This equipment has been conceived with the aim of providing an auxiliary instrument allowing:

- the formulation of lung pathology diagnosis;
- important studies concerning human physiology;
- the collection of important information in sport medicine.

No responsibility attaches COSMED Srl for any accident happened after a wrong use of the device, such as:

- use by non qualified people;
- non respect of the device intended use;
- non respect of the hereunder reported precautions and instructions.

## Warnings

The device, the programme algorithms and the presentation of measured data have been developed according to the specifications of ATS (American Thoracic Society) and ERS (European Respiratory Society). Other international references have been followed when these were not available. All bibliography references are reported in Appendix.

The present handbook has been developed with respect of the European Medical Device Directive requirements which sort K4 $b^2$ within Class II a.

It is recommended to read carefully the following precautions before putting the device into operation.

The precautions reported below are of fundamental importance to assure the safety of all COSMED equipment users.

1. This user manual is to be considered as a part of the medical device and should always be kept on hand.
2. Safety, measure accuracy and precision can be assured only:

   - using the accessories described in the manual or given with the device. Actually non recommended accessories can affect safety unfavourable. Before using non recommended accessories it is necessary to get in touch with the manufacturer;
   - ordinary equipment maintenance, inspections, disinfection and cleaning are performed in the way and with the frequency described;
   - any modification or fixing is carried out by qualified personnel;
   - the environmental conditions and the electrical plants where the device operates are in compliance with the specifications of the manual and the present regulations concerning electrical plants. In particular grounding reliability and leakage current suppression can only be assured when the device three – wire receptacle is connected to a yellow - green return connected to earth ground. Attempting to defeat the proper connection of the ground wire is dangerous for users and equipment.

3. Before powering the system, check the power cables and the plugs. Damaged electrical parts must be replaced immediately by authorised personnel.
4. Large gas cylinders, which may be given by the manufacturer or purchased by the customer, should be secured with cylinder safety chains or safety stands.
5. When removing the protective cap, inspect the cylinder valve for damaged threads, dirt, oil or grease. Remove any dust or dirt with a clean cloth. If oil or grease is present on the valve of a cylinder which contains oxygen, do not attempt to use. Such combustible substances in contact with oxygen are explosive.
6. Be certain that the materials of the pressure regulators are chemically compatible with the intended gas service before installation. Inspect the regulator for the proper connection and note the ranges of the pressure gauges. Also examine the physical condition of the regulator including threads and fittings. Remove any dust or dirt from the regulator or cylinder valve with a clean cloth. Do not install a regulator on a cylinder valve containing oxygen if grease or oil is present on either. Such substances in contact with oxygen are explosive.
7. Cleaning residue, particulates, and other contaminates (including pieces of torn or broken components) in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminates can potentially be life-threatening. Use disposable anti-bacterial filters or disinfect each part in contact with the patient before each test.
8. You must follow all the cleaning procedures in System Maintenance, and you must thoroughly inspect the components after cleaning and before each patient test.
9. This device is not suitable for use in presence of flammable anaesthetics. It is not an AP nor an APG device (according to the EN 60 601-1 definitions).
10. Keep the device away from heat and flame source, flammable or inflammable liquids or gases and explosive atmospheres.
11. In accordance with their intended use K4 $b^2$ is not to be handled together with other medical devices unless it is clearly declared by the manufacturer itself.
12. It is recommended to use a computer with electromagnetic compatibility CE marking and with low radiation emission displays.
13. It is necessary to make the PC, connected to the K4 $b^2$, compliant with EN 60601-1 by means of an isolation transformer.
14. Graphical symbols used in accordance to present specifications are described here below:

Equipment type B (EN60601-1)

Equipment type BF (EN60601-1)

Danger: high temperature

OFF


ON

Protective earth ground

Alternating current

# Contraindication

The physical strain to execute the respiratory manoeuvre is contraindicated in case of some symptoms or pathology. The following list is not complete and must be considered as a piece of mere information.

## Contraindications for the Spirometer tests

### Absolute contraindications

For FVC, VC and MVV tests:

- Post-operating state from thoracic surgery

For FVC tests:

- Severe instability of the airways (such as a destructive bronchial emphysema)
- Bronchial non-specific marked hypersensitivity
- Serious problems for the gas exchange (total or partial respiratory insufficiency)

### Relative contraindications

For FVC tests:

- spontaneous post-pneumothorax state
- arterial-venous aneurysm
- strong arterial hypertension
- pregnancy with complications at the 3rd month.

For MVV test:

- hyperventilation syndrome

## Contraindications for Bronchial provocation tests

The bronchial provocation tests must be executed according to the doctor's discretion. There are not data that reveal specific contraindication for the bronchial provocation test through inhalation.

The modern standard processes have been revealing secure in several clinical studies. However it is recommendable to respect the following contraindications:

### Absolute contraindications

- Serious bronchial obstruction (FEV1 in adults)
- Recent myocardium infarct
- Recent vascular-cerebral accident
- Known arterial aneurysm
- Incapacity for understanding the provocation test procedures and its implications.

### Relative contraindications

- Bronchial obstruction caused by the respiratory manoeuvre.
- Moderate or serious bronchial obstruction. For ex. FEV1 < 1.51 in men and FEV1 in women < than 1.21.
- Recent infection in the superior air tracts
- During the asthmatic re-acuting
- Hypertension
- Pregnancy
- A pharmacology treatment epilepsy

## Contraindications for Exercise testing

Read carefully the exercise testing chapter.

## Environmental condition of use

COSMED units have been conceived for operating in medically utilised rooms without potential explosion hazards.

The units should not be installed in vicinity of x-ray equipment, motors or transformers with high installed power rating since electric or magnetic interferences may falsify the result of measurements or make them impossible. Due to this the vicinity of power lines is to be avoided as well.

Cosmed equipment are not AP not APG devices (according to EN 60601-1): they are not suitable for use in presence of flammable anaesthetic mixtures with air, oxygen or nitrogen protoxide.

If not otherwise stated in the shipping documents, Cosmed equipment have been conceived for operating under normal environmental temperatures and conditions [IEC 601-1(1988)/EN 60 601-1 (1990)].

- Temperature range 10°C (50°F) and 40°C (104°F).
- Relative humidity range 20% to 80%
- Atmospheric Pressure range 700 to 1060 mBar
- Avoid to use it in presence of noxious fumes or dusty environment and near heat sources.
- Do not place near heat sources.
- Cardiopulmonary resuscitation emergency equipment accessible.
- Adequate floor space to assure access to the patient during exercise testing.
- Adequate ventilation in the room.

# Safety and conformity

### Safety

IEC 601-1 (1988) /EN 60 601-1 (1990);

Find reported below the complete classification of the device:

- Class I type B device
- Protection against water penetration: IP00, ordinary equipment unprotected against water penetration
- Non sterile device
- Device not suitable in the presence of flammable anaesthetics;
- Continuous functioning equipment;

### EMC

The system meets the EMC Directive 89/336

EN 60601-1-2

EN 55011 Class B (emission), IEC 1000-4-2, IEC 1000-4-3, IEC 1000-4-4

### Telemetry

I-ETS 300 220, CEPT T/R 01-04

pr ETS RES 0908 (CE type conformity)

Transmission frequency and output power can be changed upon request according to the destination country requirements.

### Quality Assurance

UNI EN ISO 9001:2000 (Registration n° 387-A Cermet)

### Medical Device Directive (CE mark)

MDD 93/42/EEC (Notified Body 0476).

Class IIa

### FCC (only USA version)

FCC ID: SN7-K4B2T-USA (transmitter)

FCC ID: SN7-K4B2R-USA (receiver)

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

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

# Keynotes

Here are the keynotes used to make the manual easier to read.

## Typographic keynotes

These are the typographic keynotes used in the manual.

| Style | Description |
|---|---|
| **Bold** | indicates a control or a key to be pressed. |
| "*Italic*" | indicates a messages shown by the firmware. |

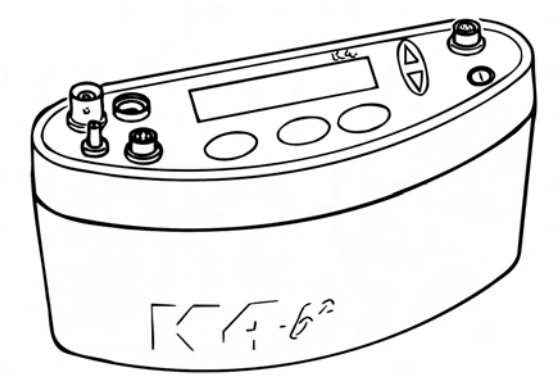
## Graphic keynotes

These are the graphic keynotes used in the manual.

| Illustration | Description |
|---|---|
| | shows the button to click in the software to activate the related feature. |

# System overview

## Portable Unit (PU)



It is fixed to the patient during the test by an anatomic harness. The PU contains the $O_2$ and $CO_2$ analyzers, sampling pump, UHF transmitter, barometric sensors and electronics. It is powered by the rechargeable battery fixed to the back side of the harness.

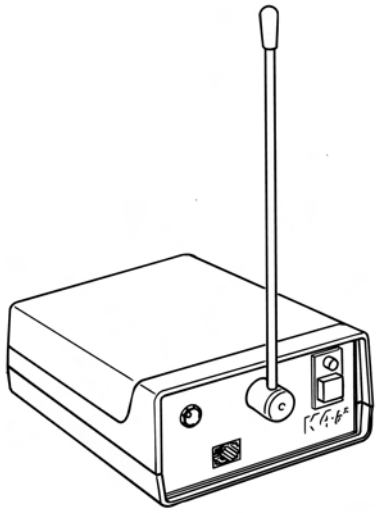
K4 b² is also provided with a small display, the PU shows in real time the following parameters: VT, VE, $VO_2$, $VCO_2$, R, HR, Rf Marker, battery charge level, temperature and barometric pressure.

USA and Japan versions have the antenna not detachable from the portable unit.

Besides data processing and presentation, the Portable Unit has the following functions:

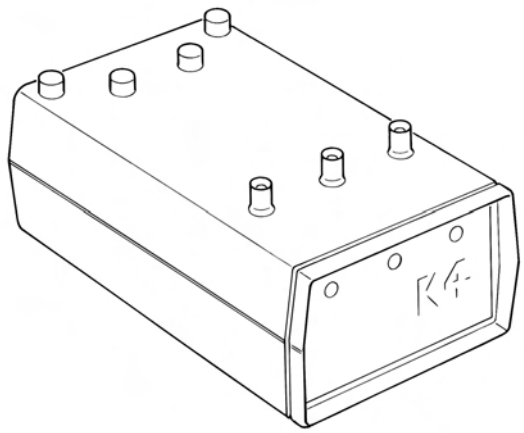
- Patient data input
- Environment data input (humidity)
- Gas and turbine calibration (automatic)
- Memory functions
- Tests data management
- Data loading to a PC (via RS232)

## Telemetry Data Transmission, Receiver Unit (RU)



The RU consists of a small unit connected to a PC through the RS 232 serial port. The transmission is achieved by a miniaturized transmitter module located inside the Portable Unit.

## Battery Charger Unit (CU)



The CU allows the simultaneously charge of the 3 Ni-Cd batteries and to supply the PU during the warm up time.

## Flowmeter

The system uses a bi-directional digital turbine. It opposes a very low resistance to flow (<0,7 $cmH_2O/l/s$ to 12 l/s). The air passing through the helical conveyors, takes a spiral motion which causes the rotation of the turbine rotor. The rolling blade interrupts the infrared light beamed by the three diodes of the optoelectronic reader. Every interruption represents 1/6 turn of the rotor, this allows to measure the number of turn in the time.

## Gas analysers

The $O_2$ and $CO_2$ analysers are temperature-controlled and the internal pressure and expired flow are monitored for an higher reliability if the measurements.

The K4 b² uses Nafion Permapure ® which is a semipermeable capillary tube capable of removing the humidity in excess without altering the gas concentrations..

The analysers calibration is automatic and shows both graphically and numerically the flow and concentration signals and the accuracy of the baseline/gain.

## PC Software

The PC software, running on Windows™, allows the user to manage data stored in the Portable Unit or transmitted to PC. Here following a list of the main features available:

- Test data management.
- Viewing data in table and graphic form
- Automatic and manual detection of anaerobic threshold (modified V-slope method).
- On-line data presentation during tests.
- Advanced data elaboration (filtering, smoothing, built in spread-sheet features).
- $O_2$ Kinetics ($O_2$ deficit, $O_2$ debt and time constant in both rising and falling edge of a constant load exercise test).
- Flow-Volume loops during the test and overlapped on the rest FVC.
- Real time display of the $O_2$ and $CO_2$ waveforms during the test.
- Control of any ergometer provided with a RS232 interface.
- Custom fittings (linear and exponential).
- Spirometry (FVC, VC, IVC, MVV).
- File exporting in three different formats (Lotus 123™, Excel™, ASCII).
- Automatic detection of the "Steady State".
- Adding parameters and predicted equations trough the "Formula Editor" tool-kit.
- DDE with Microsoft Excel.
- Customizing software environments (colours, printed parameters...).
- Help on line.

# Before starting

Before operating the K4 b$^2$ we strongly recommend to check the equipment and register you as a customer.

## Checking the packing contents

Make sure that the package contains the items listed below. In case of missing or damaged parts, please contact Cosmed technical assistance.

### K4 b$^2$ standard packaging

▲▲▲
***Note:***
*a: Non telemetric version*
*b: Internat. telemetric version*
*c: USA telemetric version*
*d: Japan telemetric version*

| Code (version) | Qty a | b | c | d | Description (see note by side) |
|---|---|---|---|---|---|
| C00950-01-04 | 1 | | | | K4 b$^2$ Portable Unit |
| C00952-01-04 | | 1 | | | K4 b$^2$ Portable Unit |
| C00952-02-04 | | | 1 | | K4 b$^2$ Portable Unit |
| C00949-01-04 | | | | 1 | K4 b$^2$ Portable Unit |
| C01599-01-04 | | 1 | | 1 | K4 b$^2$ Receiver Unit |
| C01599-02-04 | | | 1 | | K4 b$^2$ Receiver Unit |
| C00260-01-04 | 1 | 1 | 1 | 1 | K4 b$^2$ Battery Charger Unit |
| C01570-01-06 | | 1 | | | Antenna |
| C00342-01-12 | | 1 | | | Antenna cable |
| C02120-01-05 | 2 | 2 | 2 | 2 | Turbine Ø 28mm |
| C02200-01-11 | 1 | 1 | 1 | 1 | Kit optoelectronic reader K4 b$^2$ |
| A 800 900 001 | 2 | 2 | 2 | 2 | Head cap for the adult masks |
| C02210-01-08 | 1 | 1 | 1 | 1 | Permapure L73cm |
| C02125-01-10 | 1 | 1 | 1 | 1 | Mask mouth/nose breath adult S |
| C02135-01-10 | 1 | 1 | 1 | 1 | Mask mouth/nose breath adult M |
| C02145-01-10 | 1 | 1 | 1 | 1 | Mask mouth/nose breath adult L |
| A 661 200 001 | 1 | 1 | 1 | 1 | HR elastic belt |
| A 661 200 002 | 1 | 1 | 1 | 1 | HR polar transmitter |
| A 182 320 001 | 2 | 2 | 2 | 2 | Anti moisture filter |
| C01460-01-06 | 1 | 1 | 1 | 1 | RH/TA probe |
| A 362 060 001 | 1 | 1 | 1 | 1 | Power cord Schuko 2m |
| C01507-01-12 | 1 | 1 | 1 | 1 | RS232 cable K4 b$^2$ |
| C00659-01-12 | 1 | 1 | 1 | 1 | Cigar light adapter |
| A 410 110 002 | | 4 | 4 | 4 | Battery size AA 1,5V |
| C02100-01-06 | 3 | | 3 | 3 | Battery pack TX K4 b$^2$ |
| C02100-02-06 | | 3 | | | Battery pack TX K4 b$^2$ |
| C00341-01-12 | 2 | 2 | 1 | 1 | Cable power supply BNCxRF |
| C01577-01-12 | | 1 | 1 | 1 | Cable power supply RX unit |
| C01929-01-08 | 1 | 1 | 1 | 1 | Harness K4 b$^2$ adult |
| C01143-01-98 | 1 | 1 | 1 | 1 | Velcro strips (set 8 pieces) |
| C01800-01-05 | 1 | 1 | 1 | 1 | Kit gas calibration |
| C01509-01-30 | 1 | 1 | 1 | 1 | Carrying case |
| C01588-01-20 | 1 | 1 | 1 | 1 | Holder Portable Unit |
| A 680 023 500 | 2 | 2 | 2 | 2 | Time lag fuses 5x20 250V T500mA |
| A 680 044 500 | 1 | 1 | 1 | 1 | Fuses 6,3x32 250V F5A |
| C01790-01-36 | 1 | 1 | 1 | 1 | PC software |
| C01999-02-DC | 1 | 1 | 1 | 1 | Conformity declaration |
| C00067-02-94 | 1 | 1 | 1 | 1 | Registration card |
| C01508-02-91 | 1 | 1 | 1 | 1 | K4 b$^2$ User Manual |

# Warranty registration

Before using the system, please take a moment to fill in the registration form and the warranty and return them to COSMED, by doing this you are eligible to the customers assistance service.

For further information, please refer to the enclosed registration and warranty form. If the form is not enclosed in the packaging, please contact directly COSMED.

### Register the product via software

Together with the PC software, a registration software is supplied. With this software it is possible to fill in an electronic form with the customer information.

1. To run the software, double click on the icon **Registration** or select **Registration…** from **?** menu.
2. Type the requested information and click **Send…** to send the form via e-mail to COSMED.

### How to contact COSMED

For any information you may need, please contact the manufacturer directly at the following address:

**COSMED S.r.l.**
Via dei Piani di Monte Savello, 37
P.O. Box n. 3
00040 - Pavona di Albano
Rome - ITALY

Voice: +39 (06) 931.5492
Fax: +39 (06) 931.4580
email: **customersupport@cosmed.it**
Internet: **http: //www.cosmed.it**

### Complain, feedback and suggestions

If you have any complain, feedback information or suggestion, please inform us at **complain@cosmed.it.**

# Options/Accessories

## Accessories

| Code | Quantity | Description |
|---|---|---|
| C02150-01-11 | 1 | Adapter Spirometry kit x opto-reader 2000 |
| C00600-01-11 | 1 | 3 liters syringe for flows and volume calibration |
| C02115-01-10 | 1 | Adult face mask with x Turbine 2000 |
| C01278-01-30 | 1 | Mask mouth/nose breath ID28 paediatric L |
| C01277-01-30 | 1 | Mask mouth/nose breath ID28 paediatric S |
| A 800 900 004 | 1 | Paediatric Headcap |

## Options

### Telemetry data transmission

The optional Telemetry data transmission allows the researcher to transmit data on line to a PC up to a distance of 800 meters. All signals are in real time transmitted via radio to the RU to be saved and displayed on-line to any PC.

### Spirometry Kit

Optional software and accessories designed for performing screening Spirometry such as Forced Vital Capacity, Slow Vital Capacity, Maximum Voluntary Ventilation and broncho-challenge tests.

## PC configuration required

- Pentium II 350 MHz.
- Windows 98, XP.
- 64 Mb RAM .
- CD drive.
- VGA, SVGA monitor.
- Serial Port RS 232 available (2 serial ports in case of Ergometer control). An USB port can replace one RS232 serial port, if using the USB-RS232 adaptor (Cosmed code A 388 410 001).
- Any Mouse and Printer compatible with the MS Windows™ operative system.
- PC conform to European Directive 89/336 EMC

# Technical features

### Portable Unit

| | |
|---|---|
| Memory | 16,000 breaths |
| Display LCD | 2 lines x 16 characters |
| Keyboard: | waterproof, 6 keys |
| Serial Port | RS 232C |
| Power supply: | Ni-MH rechargeable batteries 3 hours endurance |
| Thermometer: | 0-50°C |
| Barometer: | 53-106 Kpa |
| Dimensions PU : | 170x55x100 mm, |
| Dimensions battery: | 120x20x80 mm |
| Weight: | 400g |

### Receiver Unit

| | |
|---|---|
| Transmission range: | 800 meters |
| Battery: | 4 x 1.5 V AA |
| Dimension: | 170 x 48 x 90 mm |
| Weight: | 550 g |
| PC interface: | RS 232 |

### Battery charger Unit

| | |
|---|---|
| Power supply | 120V - 240 V |
| Power consumption | 25 W |

### Flowmeter

| | |
|---|---|
| Type: | Bidirectional digital turbine Ø 28 mm |
| Flow Range: | 0,03-20 L/sec |
| Accuracy: | ± 2% |
| Resistance: | <0.7 $cmH_2O$ s/L @ 12 L/s |
| Ventilation Range: | 0-300 litres x min |

### Oxygen Sensor ($O_2$)

| | |
|---|---|
| Response time: | <150 ms |
| Range: | 7-24% $O_2$ |
| Accuracy: | ±0.02% $O_2$ |

### Carbon Dioxide Sensor ($CO_2$)

| | |
|---|---|
| Response time: | <150 ms |
| Range: | 0-8% |
| Accuracy: | ±0.01% |

### Humidity absorber

Capillary of Nafion (Permapure ®)

### Power Supply

| | |
|---|---|
| Voltage: | 100V-240V ±10%; 50/60Hz |
| Power consumption | 60W |

### Environmental Sensors

| | |
|---|---|
| Temperature: | 0-50°C |
| Barometer: | 400-800 mmHg |
| Humidity: | 0-100% |

# Measurements

# Pulmonary function tests and measured parameters

## Breath by Breath exercise testing

| Symbol | UM | Parameter |
|---|---|---|
| VO2 | ml/min | Oxygen Uptake |
| VCO2 | ml/min | Carbon Dioxide production |
| Vt | l | Tidal Volume |
| FetO2 | % | End Tidal O2 |
| FetCO2 | % | End Tidal CO2 |
| R | --- | Respiratory Quotient |
| VE | l/min | Ventilation |
| HR | 1/min | Heart Rate |
| Qt | l | Cardiac output |
| AT | --- | Anaerobic Threshold |
| VE | l/min | Ventilation |
| SV | l/min | Stroke volume |
| RF | 1/min | Respiratory Frequency |
| FeO2, FeCO2 | % | Averaged expiratory concentration of O2 e CO |
| VE/VO2 | --- | ventilatory equivalent for O2 |
| VE/VCO2 | --- | ventilatory equivalent for CO2 |
| VO2/HR | ml/beat | Oxygen pulse |
| VO2/Kg | ml/min/Kg | VO2 per Kg |
| Ti, Te, Ti/Ttot | sec | time breaths |
| Vd/Vt | --- | Vd/Vt ratio |
| PaCO2 | mmHg | arterial PCO2 (estimated) |
| P(a-et)CO2 | mmHg | Delta PaCO2 – PetCO2 |

## Indirect Calorimetry

| Symbol | UM | Parameter |
|---|---|---|
| EE | Kcal/day | Energy Expenditure |
| EE/BSA | Kcal/day/$m^2$ | Energy Expenditure/Body surface area |
| EE/Kg | Kcal/day/Kg | Energy Expenditure pro Kg |
| FAT | Kcal/day | Fats |
| CHO | Kcal/day | Carbohydrate |
| PRO | Kcal/day | Protein |
| FAT% | % | % Fat |
| CHO% | % | % Carbohydrate |
| PRO% | % | % Protein |
| npRQ | —- | Respiratory quotient not protein |

## Lactate Threshold (V-Slope)

| Symbol | UM | Description |
|---|---|---|
| $VO_2$ @ LT | l/m | Lactate (Anaerobic) Threshold STPD |
| R @ LT | -- | Respiratory Quotient @ LT |
| Time @ LT | hh:mm:ss | Time @ LT |
| $VCO_2$ | ml/min | CO2 output @ LT STPD |
| VE | l/min | Ventilation @ LT BTPS |

| | | |
|---|---|---|
| HR | bpm | Heart Rate @ LT |

## O2 Kinetics

| Parameter | UM | Calculation |
|---|---|---|
| $O_2$ deficit | l/m | VO2@work*tau |
| $O_2$ debt | l/m | VO2'@work*tau |

## Spirometry Tests (option)

### FVC - Forced Vital Capacity

| Symbol | UM | Parameter |
|---|---|---|
| FVC | l | Forced Expiratory Vital Capacity |
| FEV1 | l | Forced Expiratory Volume in 1 sec |
| FEV1/FVC% | % | FEV1 as a percentage of FVC |
| PEF | l/sec | Peak Expiratory Flow |
| FEV0.5 | l | Forced Expiratory Volume in 0.5 sec |
| FEV6 | l | Forced Expiratory Volume in 6 sec |
| FEV1/FEV6 | % | FEV1 as a percentage of FEV6 |
| FEV6/FVC% | % | FEV6 as a percentage of FVC |
| Best FVC | l | Best Forced Expiratory Vital Capacity |
| Best FEV1 | l | Best Forced Expiratory Volume in 1 sec |
| Best PEF | l/sec | Best Peak Expiratory Flow |
| Vmax25% | l/sec | Expiratory Flow when 75% of the FVC remains to be exhaled |
| Vmax50% | l/sec | Expiratory Flow when 50% of the FVC remains to be exhaled |
| Vmax75% | l/sec | Expiratory Flow when 25% of the FVC remains to be exhaled |
| FEF25-75% | l/sec | Mid-exp flow between 25-75%FVC |
| FET100% | sec | Forced expiratory time |
| FEV2 | l | Forced Expiratory Volume in 2 sec |
| FEV3 | l | Forced Expiratory Volume in 3 sec |
| FEV2/FVC% | % | FEV2 as a percentage of FVC |
| FEV3/FVC% | % | FEV3 as a percentage of FVC |
| FEV1/VC% | % | Tiffenau index |
| FEF50-75% | l/sec | Mid-exp flow between 50-75%FVC |
| FEF75-85% | l/sec | Mid-exp flow between 75-85%FVC |
| FEF0.2-1.2% | l/sec | Mid-exp flow between 0.2 l - 1.2 l |
| FiVC | L | Inspiratory Forced Vital Capacity |
| FiF25-75% | l/sec | Forced mid-inspiratory flow |
| FiV1 | l/sec | Forced Inspiratory Volume in 1 sec |
| PIF | l/sec | Peak Inspiratory Flow |
| VEXT | ml | Extrapolated Volume (back extrapolation) |
| PEFT | msec | Time to PEF (10% - 90%) |

### VC/IVC - Slow Vital Capacity and Ventilatory pattern

| Symbol | UM | Parameter |
|---|---|---|
| EVC | l | Expiratory Vital Capacity |
| IVC | l | Inspiratory Vital Capacity |
| ERV | l | Expiratory Reserve Volume |
| IRV | l | Inspiratory Reserve Volume |
| IC | l | Inspiratory Capacity |

| | | |
|---|---|---|
| VE | l/min | Expiratory Minute Ventilation |
| Vt | l | Tidal Volume |
| Rf | 1/min | Respiratory Frequency |
| Ti | sec | Duration of Inspiration |
| Te | sec | Duration of Expiration |
| Ttot | sec | Duration of Total breathing cycle |
| Ti/Ttot | —- | Ti/Ttot ratio |
| Vt/ti | l/sec | Vt/ti ratio |

### MVV - Maximum Voluntary Ventilation

| Symbol | UM | Parameter |
|---|---|---|
| MVV | l/min | Maximum Voluntary Ventilation |
| MVt | l | Tidal Volume (during MVV) |
| MRf | 1/min | Maximum Respiratory frequency |
| MVVt | sec | MVV duration time |

### Bronchoprovocation Response

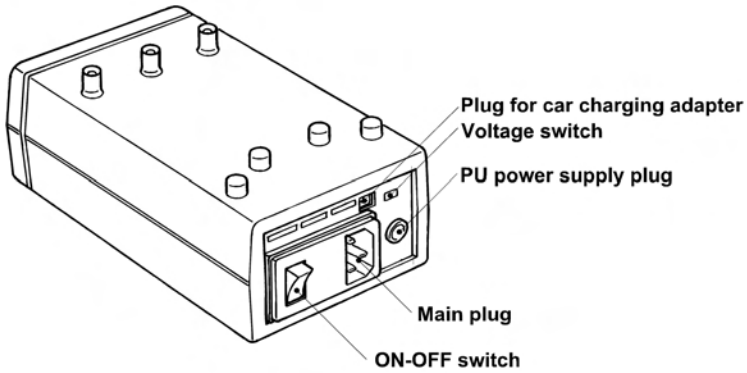
| Symbol | UM | Parameter |
|---|---|---|
| FallFEV1 | % | Fall in FEV1 from baseline or post diluent |
| FallVmax50% | % | Fall in Vmax50% from baseline or post diluent |
| P10 | —- | Provocative dose causing FEV1 to fall 10% from baseline |
| P15 | —- | Provocative dose causing FEV1 to fall 15% from baseline |
| P20 | —- | Provocative dose causing FEV1 to fall 20% from baseline |

# Installation

# Installation sequence

Before starting operating with the system make sure to meet the environmental and operational conditions reported in Chapter 1.

## Battery Charger Unit




The Battery Charger Unit allows the following functions:

- Charge 3 rechargeable batteries simultaneously.
- Charge batteries by means of the car lighter plug.
- Supply the K4 b$^2$ Portable Unit directly by the main power.

▲▲▲
***Warning**: Before turning the Battery Charger Unit on, check the voltage switch selected meets your main voltage.*

### Check voltage

The Battery Charger Unit is provided with a switch that allows to change the voltage according to the following values:

- 115V 50-60 Hz (100V-120V)
- 220V 50-60 Hz (200V-240V)

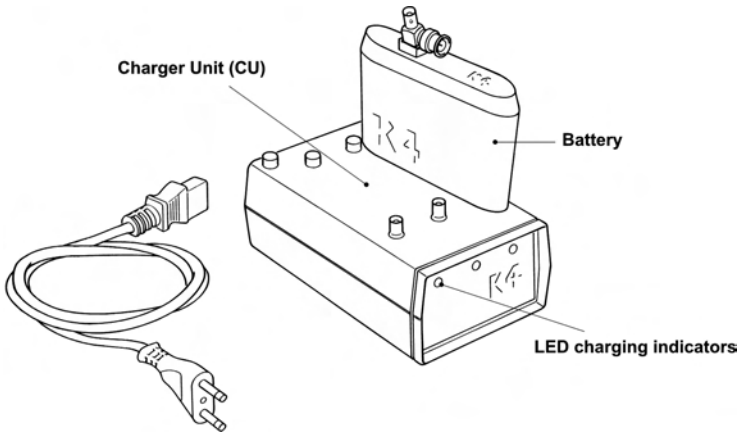
To change setting, move the switch on the new voltage by using a small screwdriver or a pen.

### Turn the Unit on

1. Connect the Charger Unit to the main plug.
2. Turn on the Unit by pressing the orange power switch.

### Charge the batteries

1. Insert the batteries into the places on the top of the unit as shown in the illustration below.
2. The small green LED placed on the front panel warns the charge in progress. The battery is charged when the light signal placed on the front panel of the Charger Unit starts blinking.




***Note:** USA and Japan versions have not the antenna connector on the battery.*

### Battery low

It is recommended to charge batteries before each test. When the batteries are low the warning message is prompted on the PU by two beeps for an half charged battery and three beeps for a complete discharged battery.

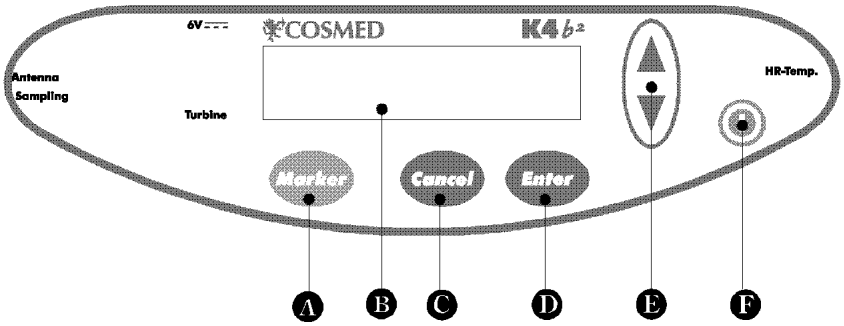
As soon as the message appears, you must change batteries immediately since the system has only few minutes of endurance still available. The system allows to change the battery during testing as well.

During the test, it is possible to monitor the battery status in real time by selecting **Information** from **View** menu.

## Portable Unit

The PU can be supplied either by the Charger Unit or by rechargeable batteries. It is recommended during Warm-up to supply it exclusively by the Charger Unit time in order to save the battery used normally during the test.

The control panel of the Portable Unit is mainly composed by a keyboard, and 4 plugs for power supply, turbine, antenna, heart frequency and sampling tube connections. The following illustrations show in detail the control panel.




A Marker key

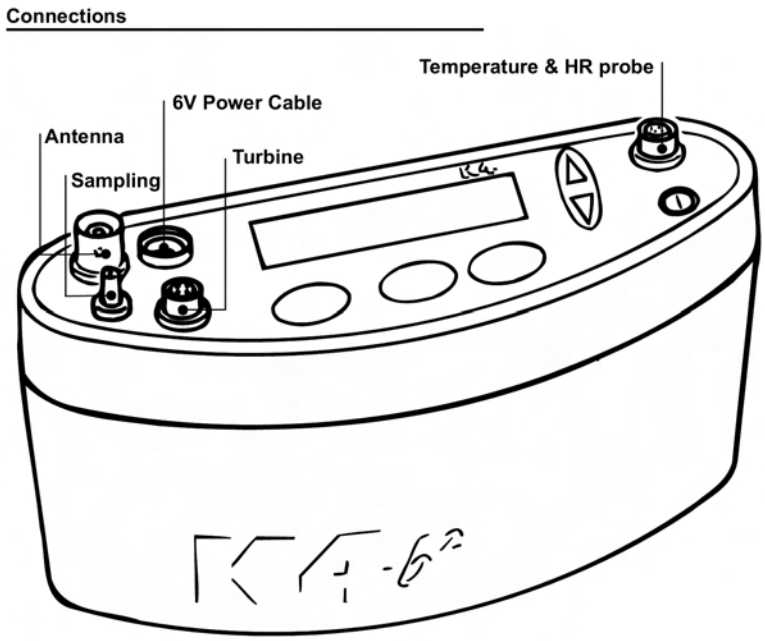
B Display

C Cancel key

D Enter key

E Scroll up/down key

F On/Off switch




***Note:*** *USA and Japan versions have the antenna not detachable from the portable unit.*

▲▲▲
***Important**: In order to ensure accurate gas measurements, you must wait for a warming-up time before operating the K4 b². During this period the PU must be turned on for at least 45 minutes.*

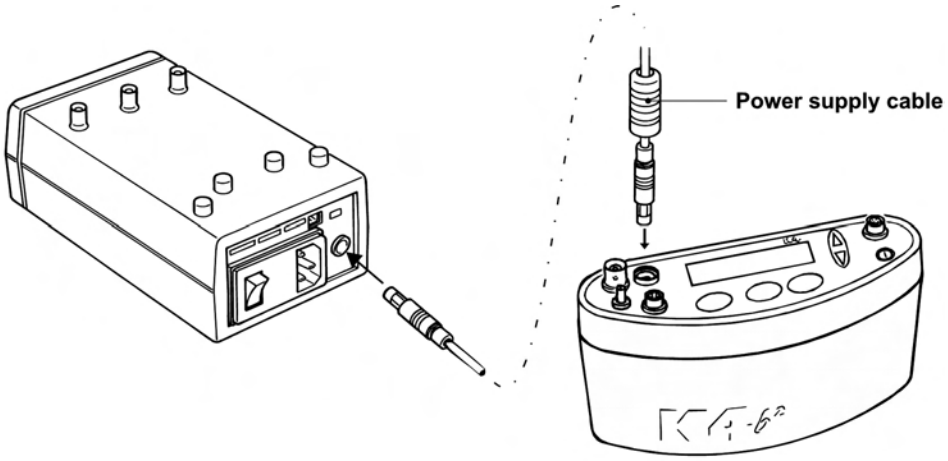
▲▲▲
***Warning**: Supply K4 b² with Charger Unit for warming up only.*

### Warm up

The K4 $b^2$ uses $O_2$ and $CO_2$ heated sensors. We strongly recommend at least 45 minutes warm-up time at an ambient temperature of 20°C. More time is necessary if the environmental temperature is lower. Calibration or testing before warm-up time is completed, can cause wrong results.

### Warming-up the unit by main power

1. Connect the Charger Unit to the main power by the AC power cable.
2. Connect the power-supply cable both in the Charger Unit and K4 $b^2$ as shown below and turn both the units on.

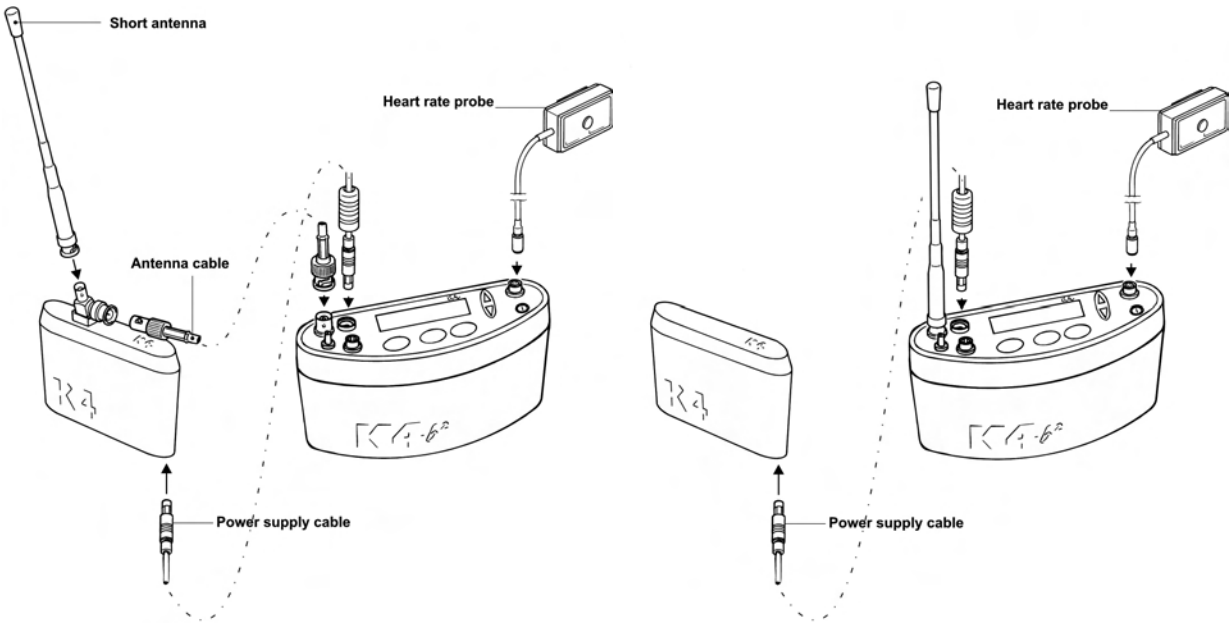



### Turning on/off the portable unit

To turn the K4 $b^2$ on or off press the **on/off** key.

### Connect the rechargeable battery

Plug the power supply cable into the battery socket as shown in the following illustration.



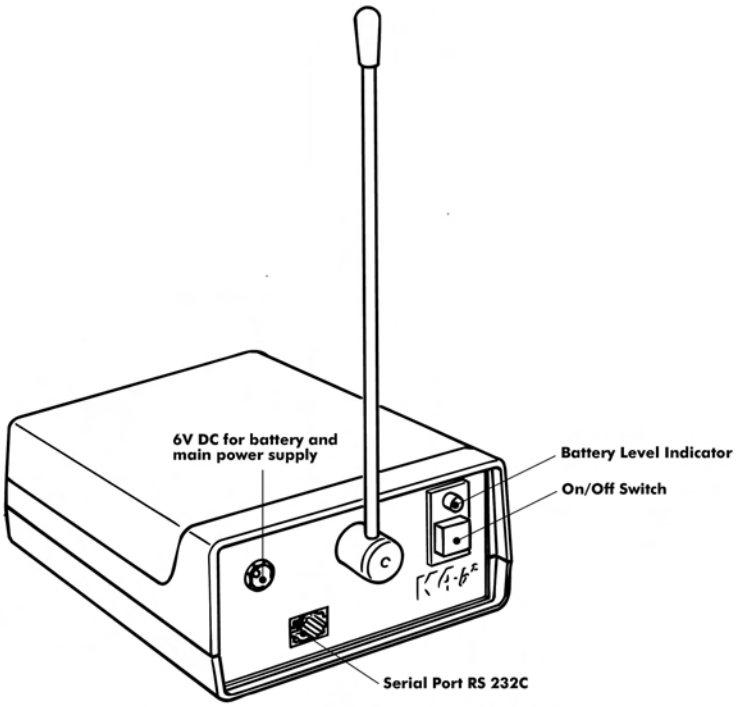

*International telemetric version* *USA and Japan Telemetric version*

Sometimes you might need to change the battery during the test. To do this you must change the battery in the shorter time possible. The Portable Unit does not transmit data while it is not powered.

***Warning**: During testing make sure to change the battery as fast as possible, since a long time could compromise the reliability of measurements.*

## Receiver Unit

Optionally the K4 $b^2$ is provided with a transmitter board (located inside the K4 $b^2$ unit) and a Receiver Unit to monitor "on-line" exercise tests performed either in the field or in the lab. All data measured by the K4 $b^2$ are transmitted "breath by breath" to the Receiver Unit in real time. The RU (illustrated below) must be connected to a Personal Computer with any RS 232 serial port to display data "on-line" in the management software. The transmission range is 800 meters in open field. However during transmission the test is stored in the memory of the K4 $b^2$ Unit so that, in case of transmission interference no data is lost.




### Turning on/off the receiver unit

To turn the receiver unit on or off use the switch on the front side of the unit.

### Receiver unit power supply

The K4 $b^2$ Receiver Unit is provided with four 1.5 V AA batteries. Before turning the unit on be sure that batteries are charged. If the status battery indicator blinks red you must replace the 4 batteries. The unit can be also supplied by 6V DC power through the cable provided in the equipment.

The receiver unit can be supplied by two different sources:

- by the Battery Charger Unit: connect the units by the 6V DC cable.
- by 4 AA 1,5V batteries.

## Calibration Gas Cylinder

In order to calibrate the sensors you need to have available calibration cylinder with the following gas concentration:

| Cylinder | Recommended Gas mixture |
|---|---|
| Calibration | $O_2$ 16%, $CO_2$ 5%, $N_2$ Balance |

For the calibration procedure, see the Calibration chapter.

# Connecting the K4 b² to the patient

K4 b² is a portable system with a total weight lower than 1 kg. Cosmed has developed a special harness to fix the unit to any subject. The harness consists of a belt that can be adjusted to fit different sizes and positions. I.e. if you need to test cyclist or rower athletes we recommend to locate both units (K4 b² and battery) on the back of the subject to increase comfort and to avoid any obstacles during movements. For this reasons plates are provided with the harness and they can be easily removed and placed in different positions.

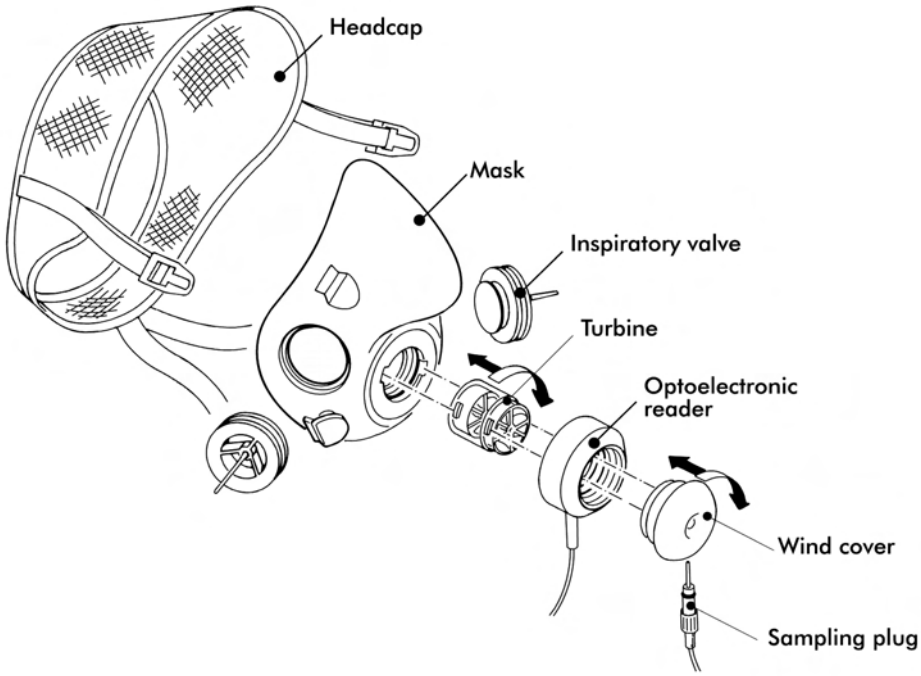
## Assemble the mask and the flowmeter

K4 b² is provided with a turbine flowmeter that can be easily disassembled for allowing cleaning and disinfection.

1. Plug the turbine in the mask adapter by pushing and rotating it clock-wise till you feel a stop.
2. Insert the optoelectronic reader over the turbine and press it till the mask.
3. Plug the wind cover as described in point 1.
4. Plug the sampling tube in the little hole located in the optoelectronic-electronic reader.
5. Plug the turbine cable in the Turbine plug control panel of the K4 b².

▲▲▲

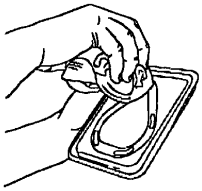
***Notice**: In order to preserve items composing the mask, it's recommended to grease periodically O-rings in the optoelectronic reader with Silicone compound grease.*

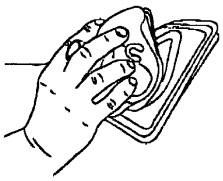


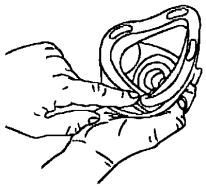

## Using the "Ultimate Seal"

The "ultimate seal" is a moulded of Elasto-Gel, a glycerine based hydrogel. This product is a unique polymer gel that forms an intimate seal between the face and the mask. It has to be used for mask applications on hard to seal faces and where leaks are not tolerated.

- Will not irritate the skin
- Contains no adhesives.
- Has no odour
- Will not dry out
- Single patient use







▲▲▲
***Notice:*** *Avoid the exposure to the sun. Do not put the seal into the water.*

### Apply the seal to the mask

Apply seal to clean, residue-free mask only and follow the instructions below:

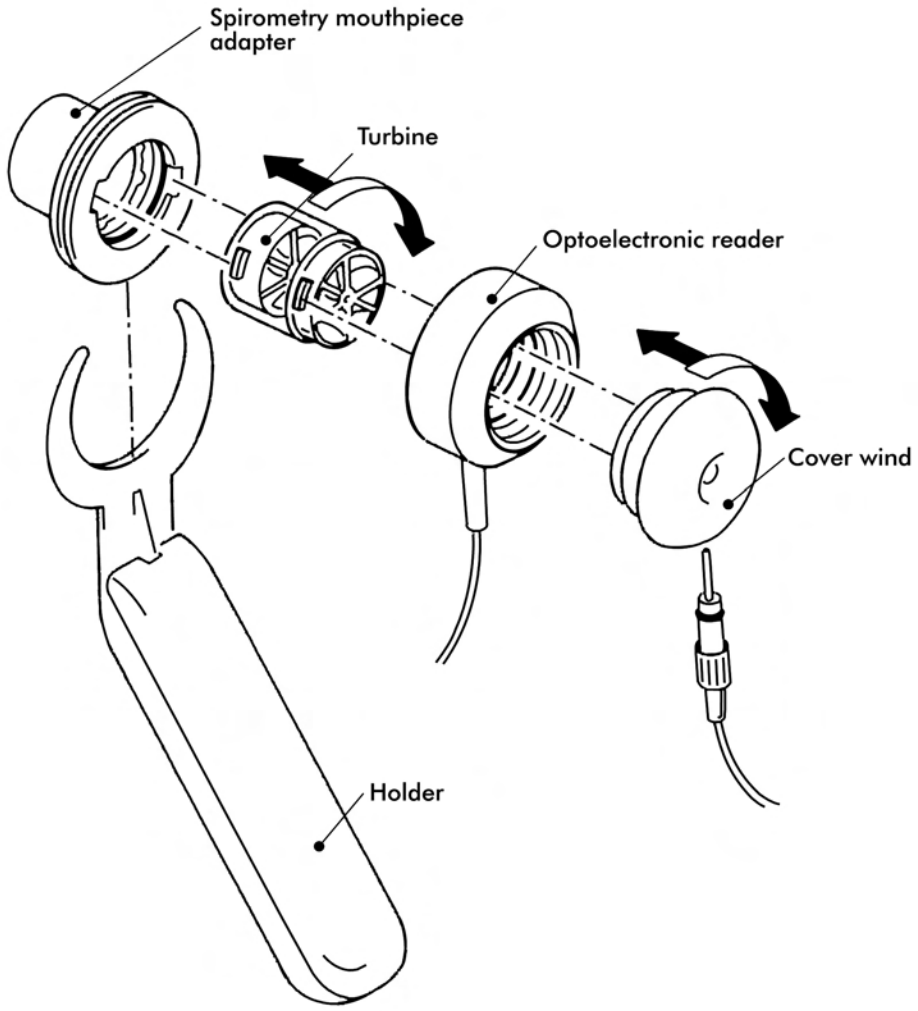
1. Remove the plastic tray from the bag. Peel off clear film and retain for later use.
2. While holding tray align the nose area of mask to nose area of Ultimate Seal™ gel. Press together and roll mask down over the surface of the gel seal attaching it to the mask and releasing it from the tray.
3. If needed, adjust the position of the seal, aligning it with the outer perimeter of the mask sealing surface.
4. The mask is now ready to be placed on the subject's face.

### To remove seal on mask

- The Ultimate Seal™ have been conceived for a single patient use only, it can not be cleaned or sterilised.
- If mask requires cleaning for a new patient application then pull off and dispose of the Ultimate Seal™.
- To keep the seal clean between use, keep it attached to the mask and place the clear film against the Ultimate Seal™ gel on the mask. When the seal becomes discoloured or opaque (approximately two weeks) dispose of the current seal and replace it with a new one.

## Assembling the flowmeter for spirometry tests

In case the spirometry kit option is purchased assemble the turbine as shown in the illustration below.

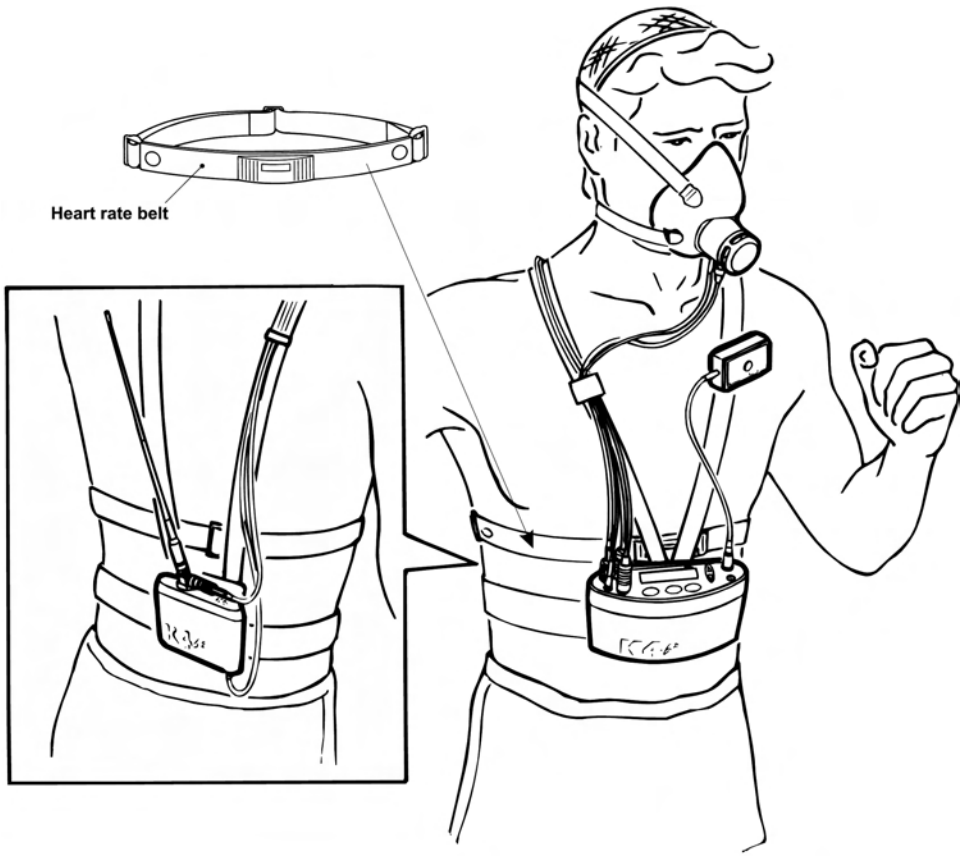


## Fixing the K4 b² to the patient

1. Fix the heart belt to the patient's box thorax.
2. Fix the K4 b² unit to the front of the harness. Do the same operation with the battery on the back .
3. Connect the battery cable to the 6V plug of the K4 b² control panel. Be sure that the red plug, that repairs the plug from water or sweat drops, is on the Portable Unit side.
4. Connect the antenna cable to the Antenna plug of Portable Unit control panel.
5. Insert the heart frequency receiver and temperature probe cable in the HR-Temp plug placed on the control panel.
6. Insert the male connector of the turbine in the Turbine plug on the control panel.
7. Fix the power supply cables, antenna and turbine on the right side of the jacket with the velcro stripes provided in the equipment. Fix the heart frequency probe on the left side.

▲▲▲
***Notice:*** *Be sure to fix the Heart rate probe on the left side, while the other cables have to be fixed on the right side. This must be done for avoiding interferences between cables.*

▲▲▲
***Notice:*** *Fix all cables with the velcro strips provided with the equipment.*



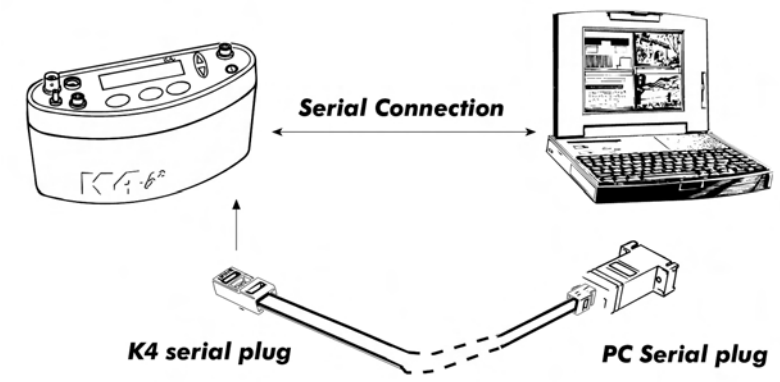

***Note:*** *USA and Japan versions differ from the picture because of the antenna placement.*

# Connecting the K4 b$^2$ to the PC

K4 b$^2$ can be connected to any PC provided with serial port in order to monitor "on-line" physiological data during any kind of activity.

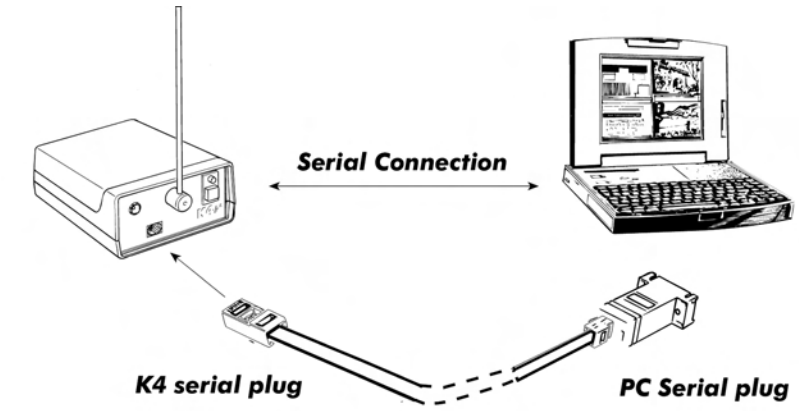
## Connect the Portable Unit to the PC

Connect the K4 b$^2$ Portable Unit to a serial port available in the PC. Be sure to set the K4 b$^2$ software to the proper serial port for the transmission.




## Connect the Receiver Unit to the PC

Connect the telemetry module to a serial port available in the PC. Be sure to set the K4 b$^2$ software to the proper serial port for the transmission.



# Software installation

The software is made of two programs: one for the ergometry and the other one for the spirometry (option). The two programs share the same archive and use the same program for the system calibration, even if they are used for performing completely different tests.

## Installing the software

▲▲▲
***Notice**: The software is copy-protected. Install the software from the original disk.*

1. Select **Run...** from Windows **Start** menu.
2. Insert the disk in the proper drive.
3. In the Command line, type **<name of the drive>:\install**.
4. Click on **OK** (or press **ENTER** key).
5. The program will load up a dialog box and ask for a directory where to be installed.
6. When the installation is over, the program will advise you with a message indicating that the installation has been successfully completed, click on **End.**

***Note:** the directory for the Spiro software must be the same of the K4 b$^2$ (ergo).*

## Run the software

1. In the Windows **Start** menu, open the Program Group in which the software was installed.
2. Click the **K4 b$^2$** icon.

## PC port configuration

The first time the software is used, it is necessary to configure the communication port with the PC (USB, COM1, COM2,…).

For further details, see the chapter *Database management*.

# Software main features

## Display

The program may contain several windows. The active window is highlighted with a different colour of the caption. Some functions of the program are "active window" sensitive (Print, right key of the mouse).

## Tool bar

Many of the functions that may be selected from the menu can be activated more rapidly by clicking with the mouse on the corresponding icon in the tool bar.

Positioning the mouse cursor on one of the buttons of the toolbar (if the option Hints is enabled), the description of the corresponding function is shown in a label.

### Show/hide the toolbar

Select **Toolbar** from **Options** menu in order to show or hide the toolbar.

## Dialog windows

The typical operating environment of Microsoft Windows is the Dialog box. This window is provided with a series of fields in which input the information.

### Use of the keyboard

- To move the cursor among fields, press the **Tab** key until you reach the desired field.
- Press the **Enter** key to confirm the information input on the dialog box or press the **Esc** key to cancel changes.

### Use of the mouse

- To move the cursor among fields, move the mouse on the desired field and left-click.
- Click on the **OK** button with the Left button of the mouse to confirm the information input on the dialog box or click on **Cancel** button to cancel changes.

## Scroll bars

Some windows are provided with scroll bars that help to see data exceeding the window space available.

- To move the scroll bar row by row click the scroll arrows at the end of the scroll bars
- To move the scroll bar page by page click on the grey area at both sides of the scroll fields

## On line help

COSMED K4 $b^2$ Help is a complete on-line reference tool that you can use at any time. Help is especially useful when you need information quickly or when the user manual is not available. Help contains a description of each command and dialog box, and explains many procedures for accomplishing common tasks.

To get the Help on line, press the **F1** key.

## Software version

To know the software version and the serial number of the software, select **About…** from **?** menu.

# Calibration

# Gas calibration procedures

The system can be calibrated according to the following procedures:

1. Room air calibration
2. Reference gas calibration
3. Delay calibration
4. Turbine calibration

The Room air calibration, forced by the system before every test, consists of a sampling room air. It updates the baseline of the $CO_2$ analyzer and the gain of the $O_2$ analyzer, in order to match the readings with the predicted athmospheric values (20.93% for $O_2$ and 0.03% for $CO_2$).

The Reference gas calibration, recommended to be carried out daily, consists of sampling a gas with a known composition (i.e. 16.00% for $O_2$ and 5.00% for $CO_2$) from a calibration cylinder, and updating the baseline and the gain (span) of the analyzers in order to match the readings with the predicted values (i.e. 16.00% for $O_2$ and 5.00% for $CO_2$).

The Delay calibration, recommended to be carried out ones a week or whenever the sampling line is replaced, is necessary to measure accurately the time necessary for the gas sample to pass through the sampling line before being analyzed.

The Turbine calibration, recommended to be carried out quarterly, consists in measuring the volume of a 3 litres calibration syringe and in updating the gain of the flowmeter in order to match the predicted value.

## Running the Calibration program

Start the program and choose **Calibration** from the **Test** Menu. The software runs the Calibration software and the main menu changes accordingly.

## Log file

The program creates and updates as default the calibration log file, containing the conditions and the results of all the calibrations performed by the user.

To access the file select **File/Report File...** from the calibration program.

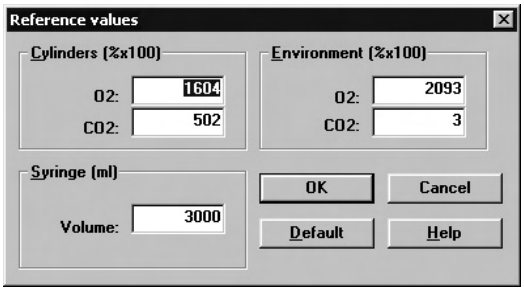
## Setting reference values

Before starting calibrating  make sure that the system has been configured correctly by setting the right values of gas concentration of: room air (i.e. 20.95% $O_2$ and 0.03% $CO_2$), of gas mixture contained in the cylinders and the volume of the calibration syringe (i.e. 3 litres).

### Set the reference values using the PC software

This operation must be performed only the first time. The next times, the system keeps stored the reference values entered in this step.

1. Select **Reference Values** from the **Calibration** menu.
2. Type the correct values for the $O_2$ and $CO_2$ room air concentration (i.e. 2093 for 20.93%), and do the same for the gas concentration of the calibration cylinder.




3. Type the volume of the calibration syringe (i.e. 3000 for a 3 litres calibration syringe).
4. Press **OK** button to confirm changes.

### Set the reference values using the Portable Unit

To set reference values from the K4 b² Portable Unit go to the main menu, choose **Calibration** and scroll tasks up to choose **Set Cal. Predicted Values**, type the values using the arrow keys and press **Enter** to confirm changes.

## Room air calibration

▲▲▲
***Note**: After turning on the unit, wait 45 minutes warm up time before starting the calibration procedure.*

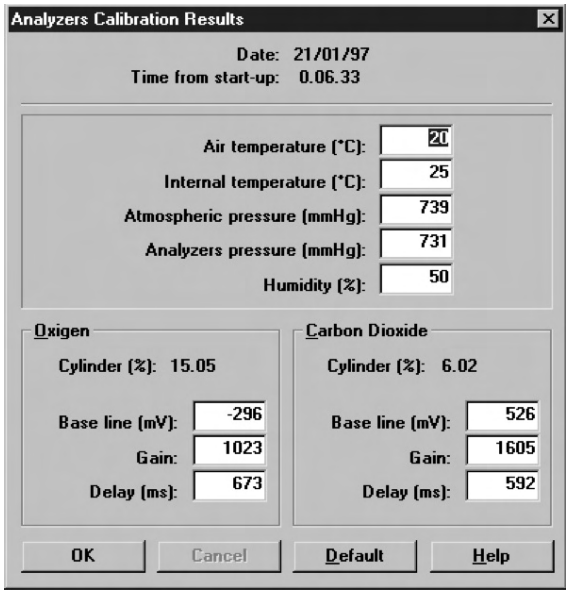
Room Air calibration is forced to be performed before each test. With this procedure the system calibrates both gas analyzers according to the Room Air Concentrations (20.95% $O_2$ and 0.03% for $CO_2$). You can run this procedure either with the software or directly with the Portable Unit.

### Room air calibration using the PC software

▲▲▲
***Important**: During calibration always remove the sampling tube from the optoelectronic reader. Do not remove the sampling tube from the Portable Unit otherwise calibration could be affected.*

1. Connect the Portable Unit to the PC by the serial port. Remove the sampling plug from the flowmeter.
2. Run the calibration program and choose **Room air** from the **Calibration** menu.
3. The message "*Room air calibration in progress...*" will appear and a graph will show in real time the $O_2$ and $CO_2$ calibration. At the end of the manoeuvre the message "*Calibration done*" will be visualized.
4. The following dialogue box will appear showing the calibration results, press **OK** to confirm the calibration.

▲▲▲
***Caution**: During Room Air calibration be sure to put the sampling line far from the expired gas otherwise calibration could be affected.*




▲▲▲
***Caution**: Room Air calibration performed in small ambients (high concentration of $CO_2$) affects the calibration results and the accuracy of the following test.*

### Room air calibration using the Portable Unit

1. Remove the sampling plug from the flowmeter.
2. In the main menu choose **Calibration** menu, choose **Room Air Calibration** and confirm by pressing **Enter**.

```
Do not breath..
O2:20.7 CO2: 0.4
```

3. The procedure is automatically performed until the message "*Calibration done*" appears, the $O_2$ and $CO_2$ values will be visualized on the display.

```
Calibration done
O2:20.9 CO2:0.0
```

## Reference gas calibration

▲▲▲
***Notice**: Do not use mixtures with a $O_2$ concentration above 24% since it is out of the oxygen sensor range*

The software allows to automatically calibrate zero, gain and alignments of the gases sensors. Even if the program doesn't force you to carry out the calibration, the system should be calibrated before each test. To perform the sensor calibration is necessary to

have available a cylinder filled of a concentration known of mixed gas. It is suggested to use $CO_2$ 5,00% , $O_2$ 16% concentrations and $N_2$ for balance.

### The calibration unit

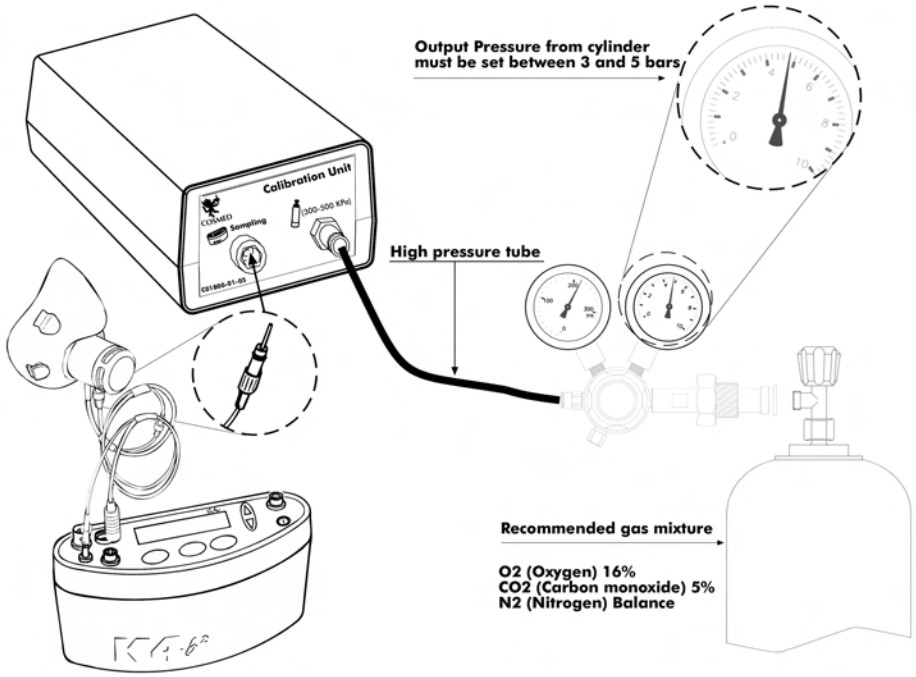
▲▲▲
***Notice**: Before calibrating be sure the "Reference values" of room air and reference gas are properly entered.*

▲▲▲
***Caution**: Be sure that the cylinder pressure out is regulated to 3 and 5 bar.*

▲▲▲
***Notice**: If the pressure regulator is set at a different pressure from what specified, room air could be mixed together with reference gas and the calibration could be affected.*

The gas regulator has an adjustable second stage that must be open every time the cylinder is used for the calibration. This is necessary to avoid a small leakage in the connections can discharge the bottle in few time.

1. Make sure you wait for warm-up time before starting calibrating. Be sure the high-pressure tube supplied together with the system is connected to the "Cylinder" plug.
2. Open the cylinder valve by turning the valve counter-clockwise, the pressure value must be set within a range of 300-500 Kpa (3-5 bars or 44-73 Psi).




After these operation, please operate as follows.

### Reference gas calibration using the PC software

▲▲▲
***Notice**: Before calibrating be sure the "Reference values" of room air and reference gas are properly entered.*

1. Connect the K4 $b^2$ unit to the PC by the serial port. Remove the sampling plug from the optoelectronic reader.
2. Run the calibration program and choose **Gas** from the **Calibration** menu.
3. The message *"Gas calibration in progress..."* will appear and a graph will show in real time the $O_2$ and $CO_2$ calibration. The software runs first the Room Air calibration, so do not connect the sample plug to cylinder output until the message *"Sample reference gas..."* will be displayed. At the end of the procedure the message *"Calibration done"* will be visualized.
4. The dialogue box showing the calibration results will appear, press **OK** to confirm the calibration.

### Reference gas calibration using the Portable Unit

1. Remove the sampling plug from the flowmeter.
2. In the main menu choose **Calibration** menu, choose **Refernce gas calibration** and confirm by pressing **Enter**.

```
Do not breath..
O2:20.7 CO2: 0.4
```

3. The K4 $b^2$ runs first the Room Air calibration, so do not connect the sample plug to cylinder output until the message *" Sample reference gas..."* will be displayed. At the end of the procedure the message *"Calibration done"* will be visualized.

```
Calibration done
O2:16.0 CO2:5.0
```

## Gas delay calibration

The delay calibration procedure is a calibration included in the software due the time alignment between flow and gas concentration measurements is one of the potential problems to consider to assure accurate readings during test. The gas delay calibration is the measurement of time required by the gas to reach the gas analyzer.

For "breath by breath" analysis it is essential that the instantaneous flow rate must be multiplied by the proper time-matched expired gas concentration. Although flow can be instantaneously measured, gas concentration measurements can be calculated with a delay related both to the time necessary for the gas to be transported to the sensor and to intrinsic characteristics of the analyzer principle.

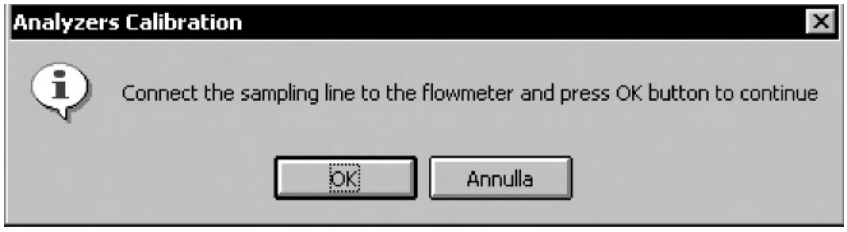
Two factors contribute to the time alignments delay. K4 $b^2$ uses a capillary sampling tube with a pump to draw a continuous gas sample into the analyzers. The gas transport time depends on the dimensions of the tube and on the pump flow rate. Additionally the gas sensors have a response time that must be added to the above delay for calculating the total delay.

The software of the K4 $b^2$ by carrying out the Gas Delay procedure calculates this delay and introduces a correction to realign both flow and gas measurements.

This procedure must be carried out each time some changes occur in the sampling system, i.e. when the sampling tube is changed. However it is recommended to carry out this calibration each week in order to prevent wrongs measurements.

### Delay calibration using the PC software

1. Connect the K4 $b^2$ unit to the PC by the serial port. Remove the sampling plug from the optoelectronic reader.
2. Run the calibration program and choose **Delay** from the **Calibration** menu.
3. The message *"Gas calibration in progress..."* will appear and a graph will show in real time the $O_2$ and $CO_2$ calibration. The software first runs the Room Air calibration. At the end of the Room Air calibration the following message appears.




4. Connect the sampling tube to the optoelectronic reader and press **OK** button to start breathing at a constant rate.
5. The software helps to maintain a constant rate by means of a beep sound. It is not important to maintain the same rate suggested by the system but it is very important to breath constantly.
6. Continue breathing some cycles until the message "Calibration done" appears. The software open a dialogue box with the new calibration factors and the new delay value. Press **OK** to confirm the calibration.

### Delay calibration using the Portable Unit

1. On the main menu scroll the commands, choose **Calibration** and press **Enter** to confirm the choice.
2. Choose **$O_2$/$CO_2$ delay calibration** and press **Enter** to confirm.
3. The following message appears, and the software automatically run the Room air Calibration.

```
Do not breath..
O2:20.7 CO2: 0.4
```

4. When the message "*Connect the sampling line and press Enter*" appears press **Enter** and start breathing at a constant rate. The software helps to maintain a constant rate by means of a beep sound. It is not important to maintain the same rate suggested by the system but it is most important to breath constantly.
5. After some cycles a message will appear confirming the delay calibration and the new values will be shown on the display. Press **Cancel** to return to the previous menu.

## Print the calibration report

In the Calibration program choose **Print** from the **File** menu.

## Edit the calibration factors

The last sensors calibration factors can be either edited or viewed. To do this choose **Gas Results…** from the **File** menu.

To view or edit the last Turbine calibration factor choose **Turbine results…** from the **File** menu.

***Note:*** *To restore factory setting press* ***Default*** *button in the dialog box. Once you press the default button you must run a new calibration before testing.*

# Turbine calibration

The system uses a turbine flowmeter. It opposes a very low resistance to flow. The air passing through the helical conveyors, takes a spiral motion which causes the rotation of the turbine rotor. The rolling blade interrupts the infrared light beamed by the three diodes of the optoelectronic reader. Every interruption represents 1/6 turn of the rotor, this allows to measure the number of turn in the time. There is a constant ratio between air passing through the turbine and number of turns. This allows an accurate measure of flows and volume. The turbine flowmeter doesn't need daily calibrations as it is not affected by pressure, humidity and temperature.

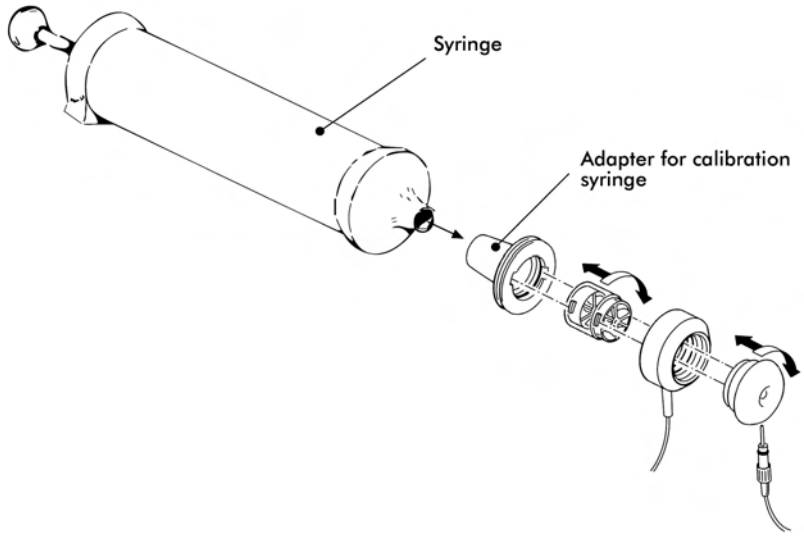
To work properly, the turbine only requires the rotor to rotate freely without any friction that might be caused by dust that can be easily avoided with an ordinary cleaning procedure (see Maintenance).

However in order to ensure accuracy it's recommended to run periodically the calibration procedure. Calibration has to be carried out with a calibration syringe of 3 litres volume, the calibration procedure is totally managed by software.

A measurement system should be calibrated daily in order to ensure maximum accuracy and reliable test results. If a correct maintenance is provided it’s possible to check the calibration of the turbine flowmeter even at relatively long intervals (i.e. 1 month). The calibration procedure assures valid and verifiable results within a ±3% accuracy.

#### Assembling the flowmeter for calibration

1. Connect the Opto-reader to the calibration syringe through the adapter.
2. Connect the flowmeter to the syringe with the rubber cylinder supplied in the standard packaging.




***Note:*** *If a bacterial filter is used for the tests, do use it also during the turbine calibration.*

## Calibrating the turbine

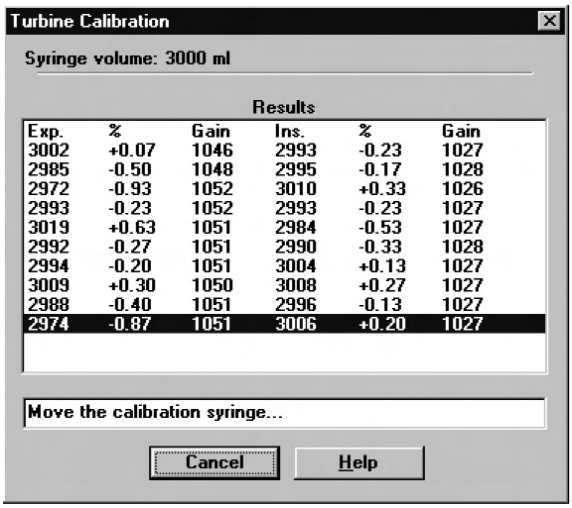
▲▲▲
***Note****: If you are using a slow PC, we recommend to set an higher refresh time.*

#### Turbine calibration using the PC software

After having run the calibration program:

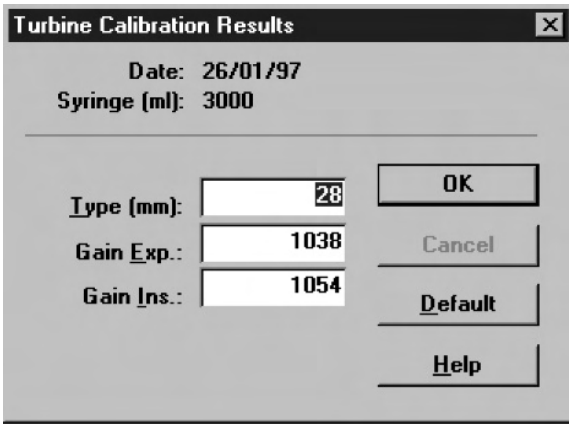
1. Select **Reference Values** from the **File** menu. If your syringe has a different value from the default one (3 litres), please enter the correct value.
2. Select **Calibration/Turbine….**
3. When the **Calibration Turbine** dialog box appears with the syringe piston initially pushed all the way in, move the piston in and out for 5 inspiratory strokes and 5

expiratory strokes in order to get the first values appearing on the display. Then move the syringe piston for other 10 strokes (IN and EX).




| Exp. | % | Gain | Ins. | % | Gain |
|---|---|---|---|---|---|
| 3002 | +0.07 | 1046 | 2993 | -0.23 | 1027 |
| 2985 | -0.50 | 1048 | 2995 | -0.17 | 1028 |
| 2972 | -0.93 | 1052 | 3010 | +0.33 | 1026 |
| 2993 | -0.23 | 1052 | 2993 | -0.23 | 1027 |
| 3019 | +0.63 | 1051 | 2984 | -0.53 | 1027 |
| 2992 | -0.27 | 1051 | 2990 | -0.33 | 1028 |
| 2994 | -0.20 | 1051 | 3004 | +0.13 | 1027 |
| 3009 | +0.30 | 1050 | 3008 | +0.27 | 1027 |
| 2988 | -0.40 | 1051 | 2996 | -0.13 | 1027 |
| 2974 | -0.87 | 1051 | 3006 | +0.20 | 1027 |

4. At each of the 10 steps the software displays the results of the manoeuvre and the percentage error in the reading.
5. At the end of this operation, the software displays the new calibration factors. Press **OK** to store the new value.




### Turbine calibration using the Portable Unit

1. Screw up the adapter for the calibration syringe to the optoelectronic reader.
2. Connect the optoelectronic reader to the calibration syringe. Before starting the calibration be sure to have inserted the right reference value for the syringe. To check it, select **Volume Syringe** from the **Set predicted value** menu.

```
Syringe volume
vol:3000 ml
```

3. Then choose **Calibration** from the main menu and press **Enter**.
4. Scroll the menu, choose **Turbine Calibration** and press **Enter.**
5. Start moving the syringe till the message *"Operate syringe"* will disappear on the display. The display will show expired (E) and inspired (I) readings for each stroke.

```
Operate syringe
#x/8E:2926I:2936
```

6. When the display visualizes the message *"Calibration done"* the Turbine has been calibrated, press **Cancel** to return to the main menu, the new calibration factor will be automatically stored.

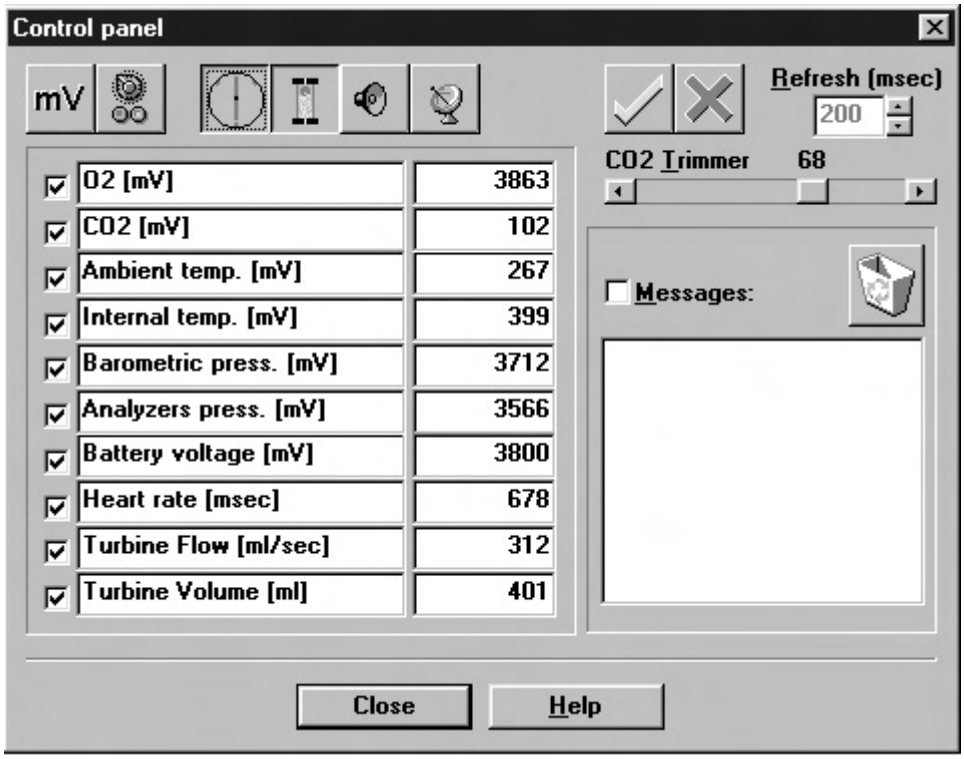
# Checking the system signals

## The control panel

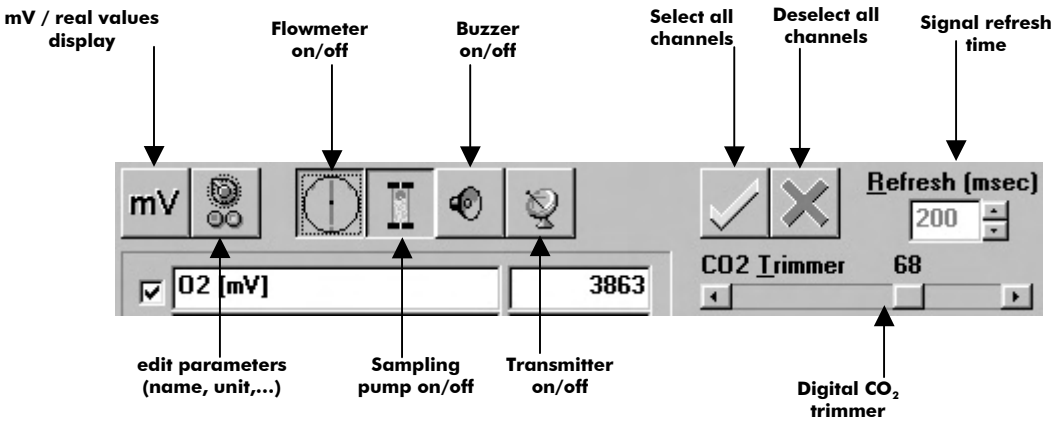
The **Control Panel**, which can be activated from the **Calibration/Control panel…** menu item, is a useful tool to check the main hardware functions of K4 $b^2$.

By using the controls on Control Panel you are able to do the following:

1. Reading the signals acquired by the system both as voltages and processed data;
2. Activating/Disactivating the valves, the sampling pump and other installed components (for example, oxymeter).




### Using the control panel



# Operating modes

# K4 b² Operating modes

K4 b² is a versatile system. You can use it in the field or in the lab without any kind of limitation. Test can be carried out in the following three different configuration:

- Holter Data Recorder
- Telemetry Data Transmission
- Laboratory Station

## Holter Data Recorder

Using the system in the field without the Receiver unit you can store data "breath by breath" in high capacity memory (1 MB). The memory allows to store up to 16 thousands breaths, when the test is completed, the results can be downloaded to the PC via the RS 232 port provided with the equipment.

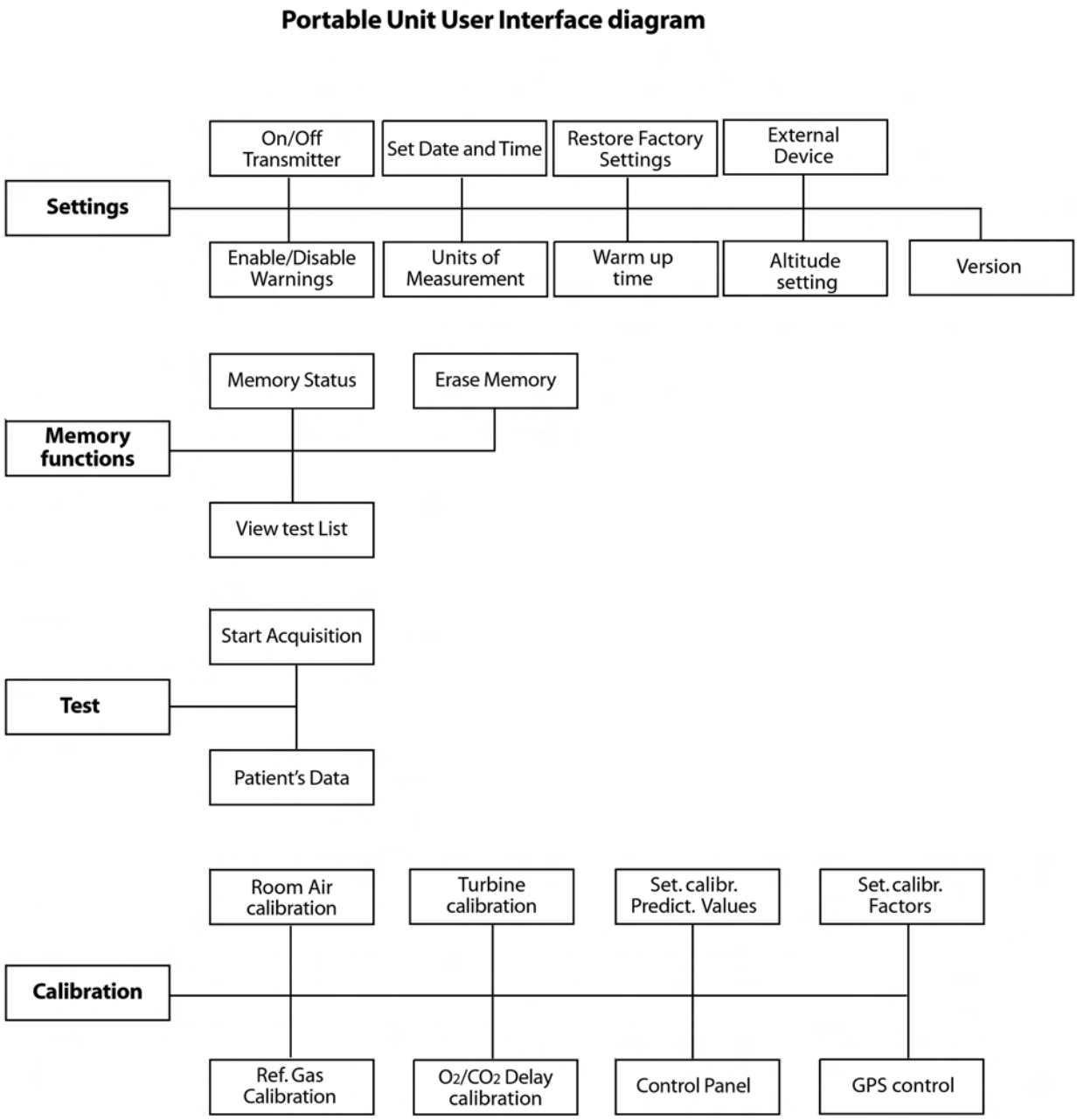
## Telemetry Data Transmission (option)

In case the telemetry Data Transmission module is available, the K4 b² portable unit provided with a small transmitter that allows to send data by telemetry up to a distance of 800 meters. All data are transmitted "breath by breath" to the receiver unit. The Receiver Unit must be connected to a PC by serial port, it allows the resercher to monitor data on line both in table and graphic format. Anyway tests are stored in the memory of the portable unit, thus in case of transmission interferences no data are lost. By using the system with a PC the software K4 b² can also control and synchronise ergometers by using user defined exercise protocol.

## Serial (Laboratory) Station

Although K4 b² has been designed for tests in the field, it can also be used as a conventional laboratory station as it offers the same features of the best stand alone devices. Under this operating mode the K4 b² Portable Unit is simply connected to the PC through the RS232 serial port and all tasks, exactly like any conventional laboratory device. Anyway tests are stored on the memory of the portable unit as well.

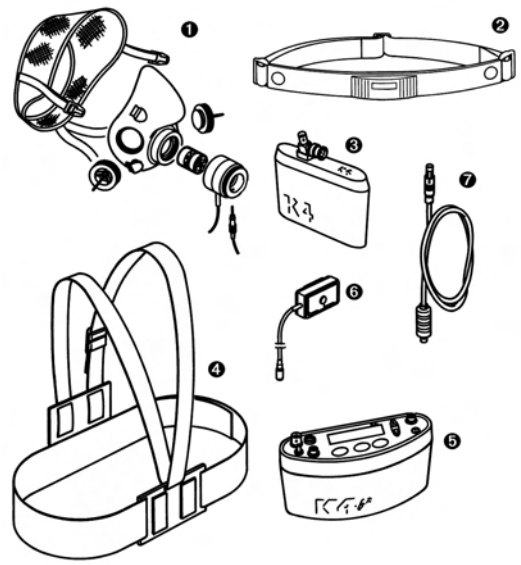
# Portable Unit User Interface diagram



# Holter Data Recorder Mode

It is ideal operating modes if you need to test a patient difficult to monitor by Telemetry (i.e. climbing, long distances races, etc). The memory capacity of the K4 $b^2$ is able to store data up to 16 thousands breaths. The system saves data for each breath, hence time storing capacity depends on the respiratory frequency.

▲▲▲
***Note:*** *USA and Japan versions have the items 3 and 5 slightly different because of the antenna placement.*



1. Mask + flowmeter
2. Heart rate belt
3. Rechargeable battery
4. Harness
5. K4 $b^2$ Unit
6. HR probe
7. Power cable

## Operating sequence

### Warming-up the system

Warm-up the K4 $b^2$ for 45 minutes before testing or calibrating.

### Enter new patient

1. Connect K4 $b^2$ to the subject.
2. Go to the K4 $b^2$ control panel and choose **Patient's data** from **Test** menu.

```
1.Patient's
  data
```

3. Move the cursor among fields with the **Enter** key and use the **Up** and **Down** keys to modify values.

```
#:xxx A:xx H:xxx
W:xxx S:M HR:xxx
```

   The fields are shown in the following order:
   #: patient ID
   A: age in years
   H: height (cm or inch)
   W: weight (kg or Lbs)
   S: sex (M or F)
   HR: HR max
4. The HR Max is automatically calculated by the formula 220-age, however it can be also changed according to physician experience and patient medical history. By confirming the HR rate value all the patient data are automatically saved.

### Calibrate and start the test

1. Remove the sampling plug from the mask and put the tube far from expired gas concentrations.
2. On the **Patient's Data** menu scroll down the menu and select **Start Test** from the main menu and press **Enter** to confirm.

3. The message *"Insert relative humidity"* will be visualized, type the correct value and press **Enter**.

```
Insert relative
humidity HR:xx%
```

4. The K4 b² runs automatically the Room Air calibration. The message *"Do not breath near the sampling line"* appears. Wait for few seconds until the message *"Calibration done"* will appear together with a double beep sound.

```
Do not breath..
O2:20.7 CO2: 0.4
```

5. Connect the sampling plug to the optoelectronic reader. Some values (Heart Rate, R, $VO_2$, $VCO_2$,...) will be shown and updated each breath on the control panel display. The message *"Press Enter to start the test"* will be displayed each 10 secs. You can switch to different values by moving the **Up** and **Down** key.
6. After having pressed the **Enter** key the test starts but the K4b2 is not storing data. In this phase the PU is checking the main parameters and you can visualize it on the PU display by the time is blinking.

```
mmm:ss ♥─ᚠHR:xxx
VO2:xx.xR:x.xx
```

7. To start storing data press another time the **Enter** key. You can check the storing phase because the time parameter don't blink anymore.

```
Press Enter to..
VO2:x.xx R.x.xx
```

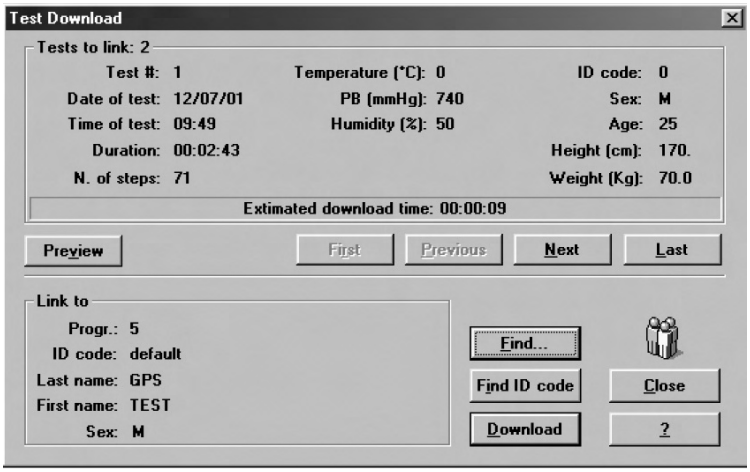
### Stop the test

To stop the test press **Cancel**. The message *"Press enter to stop test"* will appear, press **Enter** to stop the test.

### Transferring test to PC

Once the test is concluded you may download all data stored in the K4 b² to the management software.

1. Turn the K4 b² on.
2. Connect the K4 b² to the PC by the serial cable enclosed in the equipment.
3. Run the K4 b² software and choose **Receive Test** from the **Test** menu.



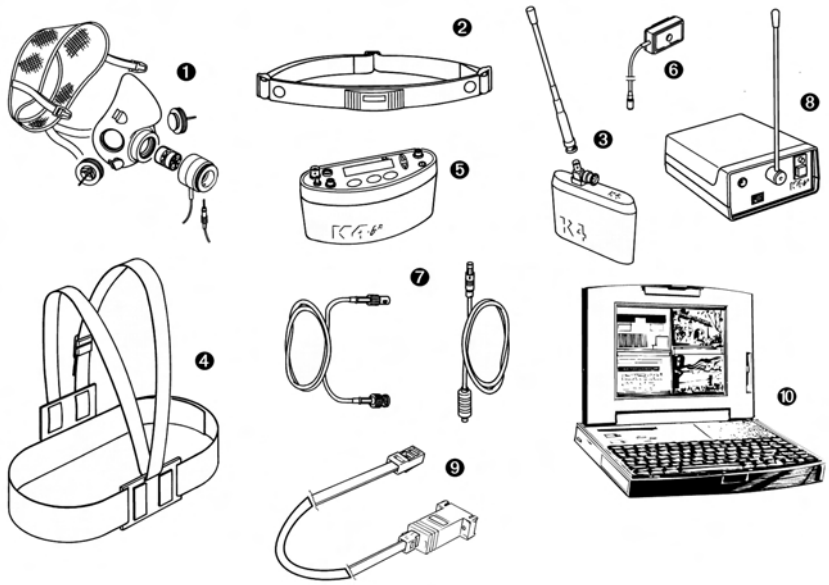

4. To download a test you must link it to an existing patient file. Choose **Find** and then **List** to select an existing patient. If the patient is new than select **Find** and then **New**, fill in the fields and press **OK** to confirm.
5. Select the test to link by using **First**, **Previous**, **Next** and **Last** buttons and press **Download** to confirm your choice and to store the test on the Hard Disk. You can use the **Preview** button to see some data and graph of the test in order to find out the proper one.

# Telemetry Data Transmission Mode

▲▲▲

***Note:*** *USA and Japan versions have the items 3 and 5 slightly different because of the antenna placement.*

In case you need to monitor in real time the test you can use the Telemetry Data Transmission module that is provided by COSMED as an option. The transmission range can reach 800 m allowing to monitor exercise testing in the field. To use this option you need a personal computer to connect the receiver unit.



1. Mask + flowmeter
2. Heart rate belt
3. Rechargeable battery + antenna
4. Harness
5. K4 $b^2$ Unit
6. HR probe
7. Power cable + antenna
8. Receiver unit
9. RS232 cable
10. Personal computer

## Operating sequence

### Warming-up the system

Warm-up the K4 $b^2$ for 45 minutes before testing or calibrating.

### Connect the receiver unit to the PC

Connect the receiver unit to PC with the serial cable provided in the standard packaging.

### Enable transmission

1. Go to the K4 $b^2$ control panel, verify that transmission is enabled by choosing **Settings /On/Off Transmitter** and press **Enter**.
2. Enable the transmission by moving the "*" sign on **Transmit. On** and press **Enter** to confirm settings.

### Enter new patient

1. Connect K4 $b^2$ to the subject.
2. Go to the K4 $b^2$ control panel and choose **Patient's data** from **Test** menu.

```
1.Patient's
  data
```

3. Move the cursor among fields with the **Enter** key and use the **Up** and **Down** keys to modify values.

```
#:xxx A:xx H:xxx
W:xxx S:M HR:xxx
```

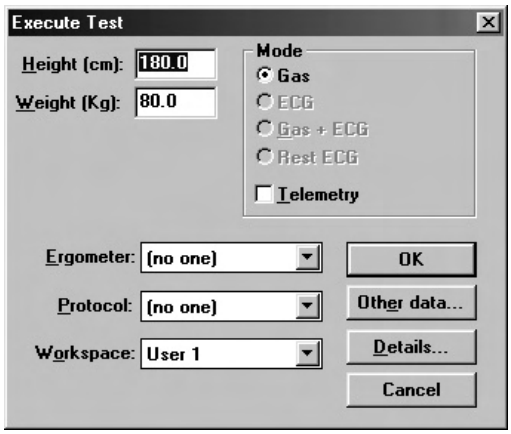
The fields are shown in the following order:

#: patient ID
A: age in years
H: height (cm or inch)
W: weight (kg or Lbs)
S: sex (M or F)
HR: HR max

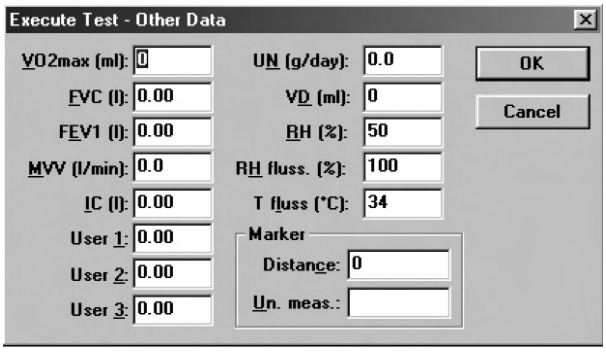
4. The HR Max is automatically calculated by the formula 220-age, however it can be also changed according to physician experience and patient medical history. By confirming the HR rate value all the patient data are automatically saved.

### Enable reception on PC

1. Run K4 $b^2$ software.
2. Open patient data dialog box, select or type a new name and press **OK** to confirm. The name of the selected patient will appear in the status bar of the software.
3. Choose **Execute test** from the **Test** menu.




4. Type the patient information, select a protocol from the list and an ergometer if you are going to carry out a test with an ergometer.
5. Chose **Other Data** if you want to insert other important informationon the the you are going to perform.




6. Select the workspace you would like to see during the test (it can be also changed during test), check the option box **Telemetry** to enable software receiving of data and press **OK** to confirm. The software will show blank windows waiting for the first breath.

### Calibrate and start the test

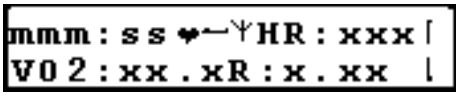
1. Remove the sampling plug from the mask and put the tube far from expired gas concentrations.
2. On the **Patient's Data** menu scroll down the menu and select **Start Test** from the main menu and press **Enter** to confirm..
3. The message *"Insert relative humidity"* will be visualized, type the correct value and press **Enter**.

```
Insert relative
humidity HR:xx%
```

4. The K4 $b^2$ runs automatically the Room Air calibration. The message *"Do not breath near the sampling line"* appears. Wait for few seconds until the message *"Calibration done"* will appear together with a double beep sound.

```
Do not breath..
O2:20.7 CO2: 0.4
```

5. Connect the sampling plug to the optoelectronic reader. Some values (Heart Rate, R, $VO_2$, $VCO_2$,...) will be shown and updated each breath on the control panel display. The message *"Press Enter to start the test"* will be displayed each 10 secs. You can switch to different values by moving the **Up** and **Down** key.
6. After having pressed the **Enter** key the test starts but the K4b2 is not storing data. In this phase the PU is checking the main parameters and you can visualize it on the PU display by the time is blinking.




7. To start storing data press another time the **Enter** key. You can check the storing phase because the time parameter don't blink anymore.

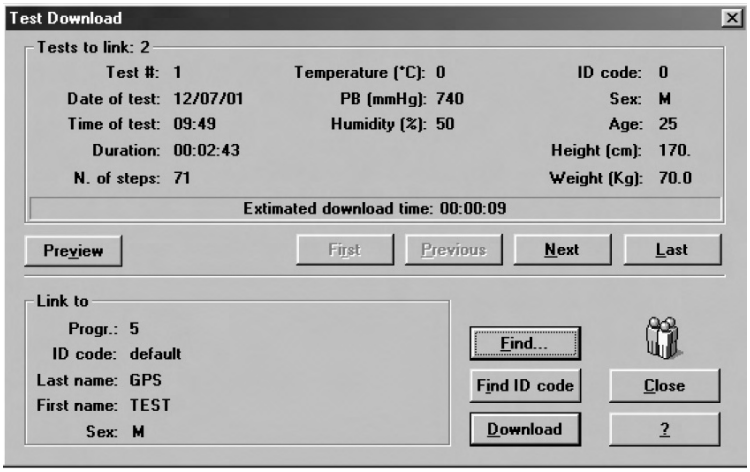
### Stop the test

To stop the test press **Cancel**. The message *"Press enter to stop test"* will appear, press **Enter** to stop the test.

### Transferring test to PC

If some interferences should occur during test execution by telemetry, some breaths could be lost. The software shows a message on the status bar warning that some steps missed . Since K4 $b^2$ stores every time the complete test in the memory, it is possible to download the test later to the management software to recover all lost data.

1. Turn the K4 $b^2$ on.
2. Connect the K4 $b^2$ to the PC by the serial cable enclosed in the equipment.
3. Run the K4 $b^2$ software and choose **Receive Test** from the **Test** menu.

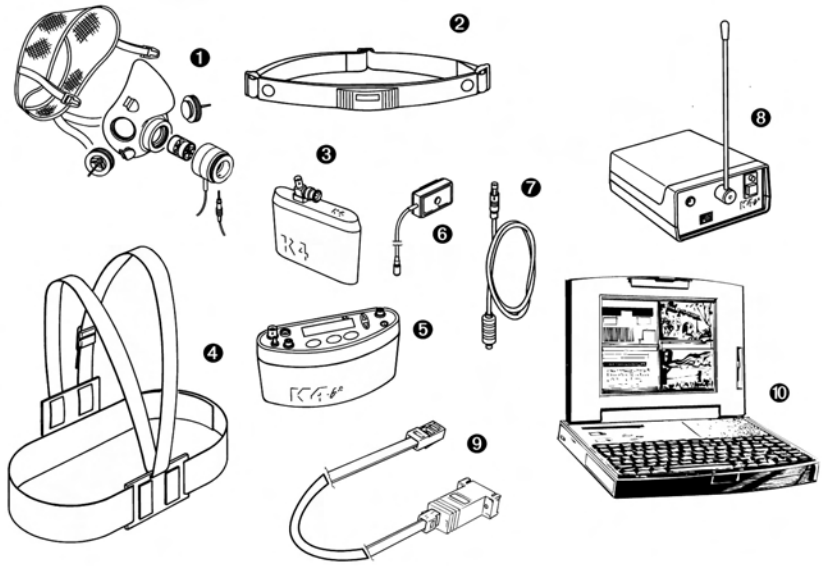



4. To download a test you must link it to an existing patient file. Choose **Find** and then **List** to select an existing patient. If the patient is new than select **Find** and then **New**, fill in the fields and press **OK** to confirm.
5. Select the test to link by using **First**, **Previous**, **Next** and **Last** buttons and press **Download** to confirm your choice and to store the test on the Hard Disk. You can use the **Preview** button to see some data and graph of the test in order to find out the proper one.

# Serial Mode

▲▲▲
***Note:*** *USA and Japan versions have the items 3 and 5 slightly different because of the antenna place*

When the K4 $b^2$ is used in the serial mode the system works exactly as any other conventional laboratory station. In this mode the software controls completely the K4 $b^2$ portable unit so that any command such as calibration can be run by the software. You can also drive an ergometer if a second serial port is available in the PC.



1. Mask + flowmeter
2. Heart rate belt
3. Rechargeable battery
4. Harness
5. K4 $b^2$ Unit
6. HR probe
7. Power cable
8. Receiver unit
9. RS232 cable
10. Personal computer

## Operating sequence

### Warming-up the system

Warm-up the K4 $b^2$ for 45 minutes before testing or calibrating.

### Connect the Portable unit to the PC

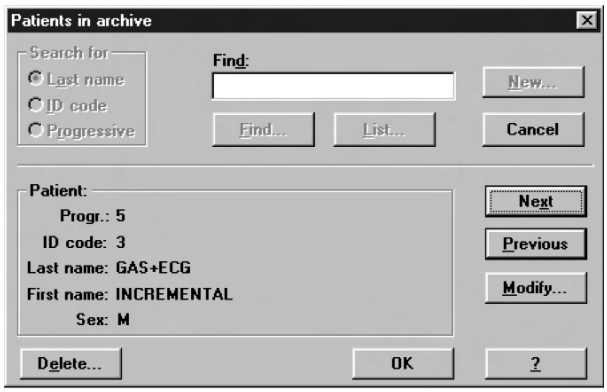
1. Connect K4 $b^2$ to the PC by the serial cable
2. Check that the Serial Port is properly selected by choosing **RS 232** from the **Option** menu.
3. Check the **Ergometer connected to PC** option box if you intend to use an ergometer for testing.

### Calibrate the system

1. Run the K4 $b^2$ software and choose **Calibration** from the **Test** menu.
2. In the Calibration software select **Analyzers -> Room Air** from the **Calibration** menu.

### Enter patient data

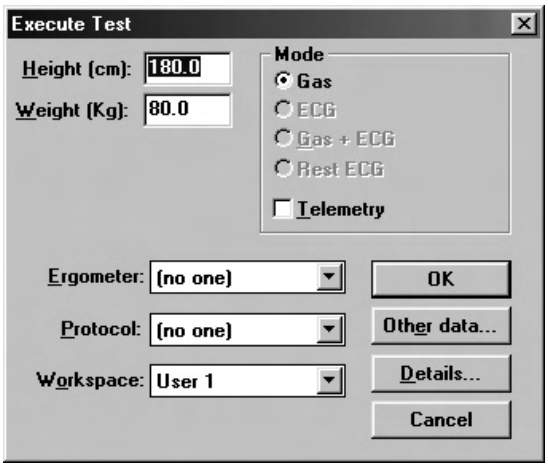
1. In the K4 $b^2$ software and choose **Patient** from the **File** menu.



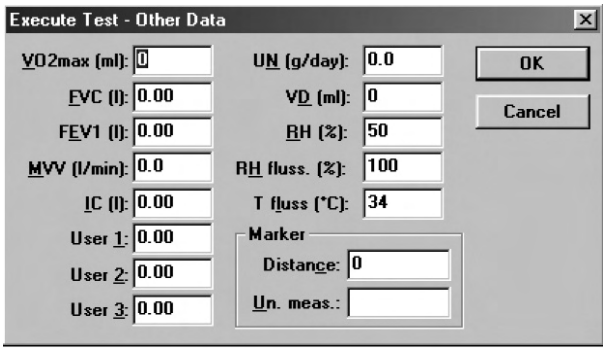

2. Select a patient from the list or press **New** to enter a new name and press **OK** to confirm.

### Start the test

1. Open patient data dialogue box, select or type a new name and press **OK** to confirm. The name of the selected patient will appear in the status bar of the software.
2. Choose **Execute test** from the **Test** menu.




3. Type the patient information, select a protocol from the list and an ergometer if you are going to carry out a test with an ergometer.
4. Chose **Other Data** if you want to insert other important informationon the the you are going to perform.




5. Select the workspace you would like to see during the test (it can be also changed during test) and be sure that option box **Telemetry** is disabled since the transmission will be done by serial cable. Press **OK** button to start acquisition.
6. The software displays the data according to the selected workspace. Check some breaths and press **F2** to start testing.

### Stop the test

To end the test press **F3**, press **OK** in the following dialogue box to confirm the end of the test. All data will be automatically saved on the Hard disk. Anyway test is stored on the memory of the portable unit as well.

# Database Management

# Exercise testing patient's database

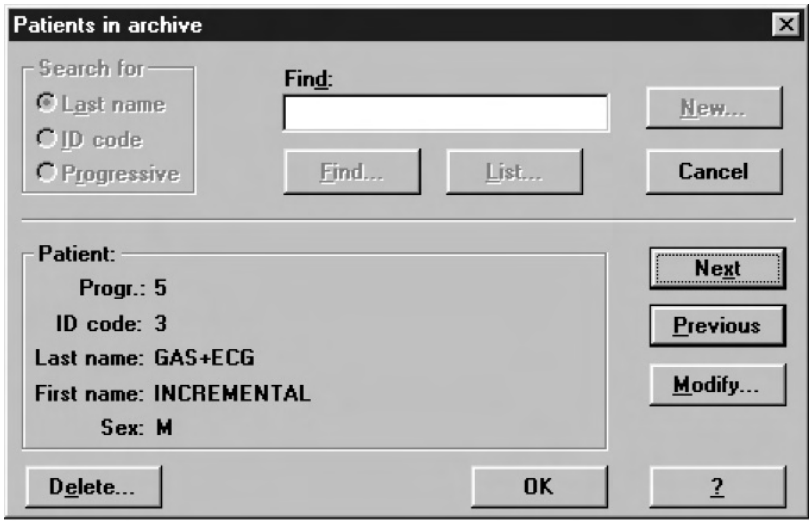
The exercise testing software uses a different interface for presenting patient information. The patient database allows to:

- Enter a new patient
- Find patient data
- Edit patient data
- Delete patient data.

Select **Patients** from the **File** menu.

## Enter a new patient

1. Press **New** to show the Patient dialog box.
2. Enter data of a new patient and press **OK** button to confirm.




## Find a patient

Enter a search string into the **Find** field and press **Find** to view the data concerning a subject already in the database. You can search for “Last name”, “ID code” or “Progressive”.

Or:

Press **List** to view the list of patients in the database. Press **Next** or **Previous** to view the data corresponding to the next or to the last patient. Press **OK** to confirm.

The **Next** and **Previous** buttons allow to move to the next or the previous patient in the database.

## Edit patient data

1. Select the patient.
2. Press **Modify…** in order to edit the patient’s data.
3. Edit the desired values and press **OK** to confirm.

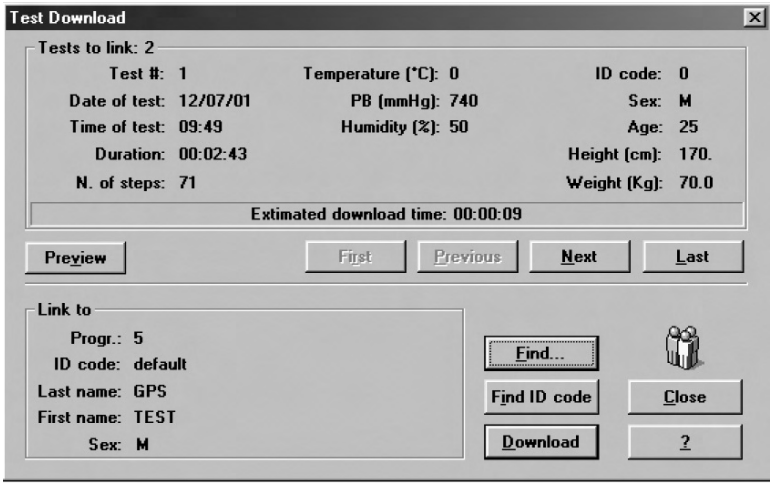
## Delete a patient

1. Select the patient to be deleted.
2. Press **Delete**.

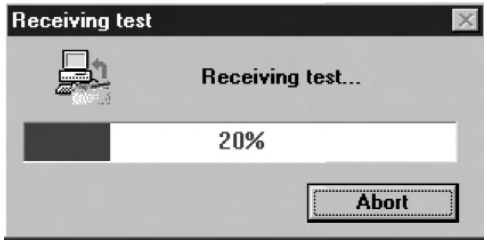
# Uploading tests from the Portable Unit

In telemetry and holter function you could need to upload data from the portable unit via serial port.

1. Link up the PU to the PC with the RS232 cable supplied.
2. Turn on the Portable Unit.
3. Choose **Receive Test** from **Test** menu or press **Alt F2**.




4. To be downloaded the test must be linked to a patient. If the current patient has already been inserted in the database, choose **Find** and then **List** select the patient and confirm. If the current patient doesn't belong to the archive he must be inserted, select **Find** and then **New**, fill in the fields and confirm. Now the download function is available and the test will be filed on the PC.
5. Choose the test to link with the **First**, **Previous**, **Next** and **Last** buttons and press **Download.**
6. A status bar will show the data acquisition in progress. At the end a message will indicate the end of data reception.



# Archive maintenance

The software allows to manage files selecting **Archive** from the **File** menu.

It is advisable to perform the archive reorganisation every month, in order to free space on the hard disk and/or to correct possible errors present within the database.

It is possible also that your have no more hard disk space. So, you have to delete all the data. In this case, it is useful to perform the initialising.

## Reorganise the archive

1. Select **Reorganize archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

## Delete the archive

1. Select **Initialize Archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

## Delete a test

To delete an ergometry test, select **Test/Delete test**.

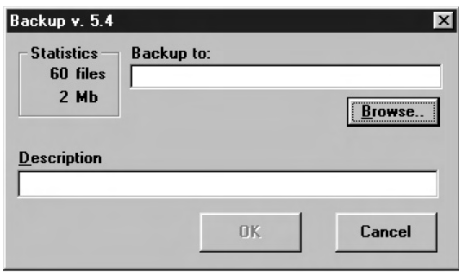
To delete a spirometry test, press the proper button in the Test Card.

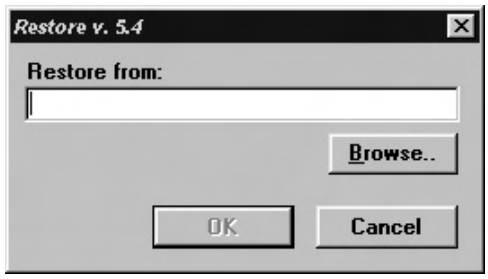
## Backup and restore

It is strongly recommended to backup files, a warning message will be displayed monthly. This function allows the user to restore the data if the PC or the HD will not work anymore.

### Backup

1. Select **Backup archive** from the **File** menu.
2. Selecting the destination path with the **Browse** key or press **New** to create a new directory. Press **OK** to confirm.
3. In the dialog box it will appear an estimate of the number of floppy disks you need in order to back up the archives. Press **OK**.



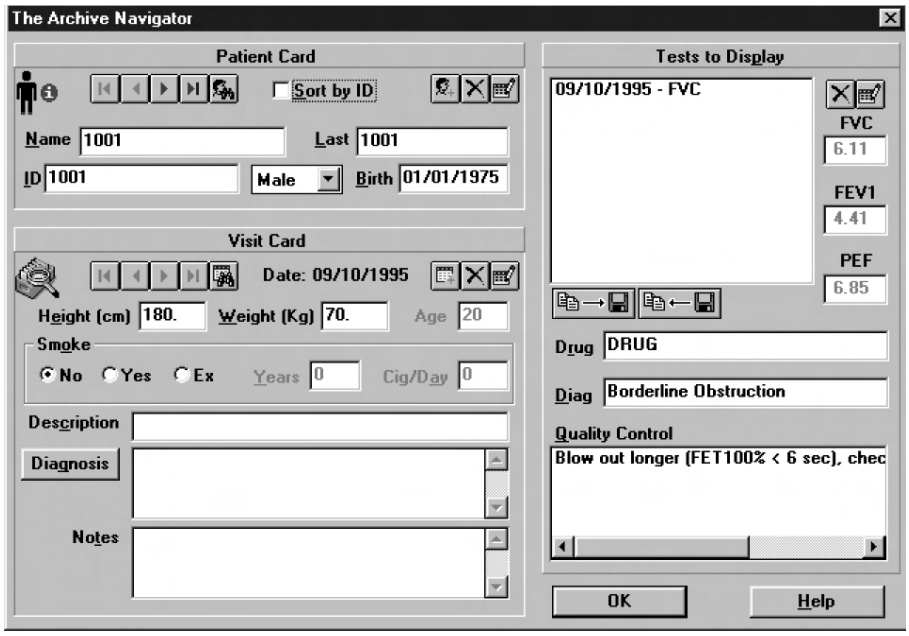

### Restore

1. Select **Restore archive** from the **File** menu.
2. On the **Restore** dialog box specify the drive source and press **OK**, a dialog box will appear indicating all data of the backup processed.

# Spirometry patient's database

The Patients database consists of a Patient Card, a Visit Card and a Test Card in which are listed all tests performed by the patient.

Select **Archive Navigator** from the **File** menu or press the button by side.




### Patient Card

It collects all the information of a patient (first name, last name, date of birth) which remain the same for each visit. For each patient there is only one Patient Card, which is created the first time the Patient performs a test.

To move within the database use the following buttons:

Move to the first patient in the archive

Move to the previous patient in the archive

Move to the next patient in the archive

Move to the last patient in the archive

Find a patient in the archive

Enter a new patient in the archive

Delete current patient from the archive

Edit the current patient card

▲▲▲

***Note**: after having deleted a record (patient, visit or test), it is recommended to reorganize the archive in order to free disk space.*

### Visit Card

It collects all information relative to the visit (diagnosis, visit description...) and to the patient information subject to change between one visit and another (height, weight, smoke). Each patient can be related to several Visit Cards provided they have been created in different days. Before carrying out any spirometric test it is necessary to create a new Visit Card or to open the today's Visit Card.

To move within the database use the following buttons:

Move to the first visit in the archive

Move to the previous visit in the archive

Move to the next visit in the archive

Move to the last visit in the archive

Find a visit in the archive

Enter a new visit card in the archive

Delete current visit card from the archive

Edit the current visit card

#### Test Card

It contains all the information about the test.

To move within the database use the following buttons:

Delete current test from the archive.

Edit the current test

## Import/export a Tests card

This function allows to import /export a test card with the respective visit and patient card.

1. Select the patient.
2. Choose the test and press the key by side. All data will be imported/exported in the XPO file format (Cosmed proprietary).

## Diagnosis Database

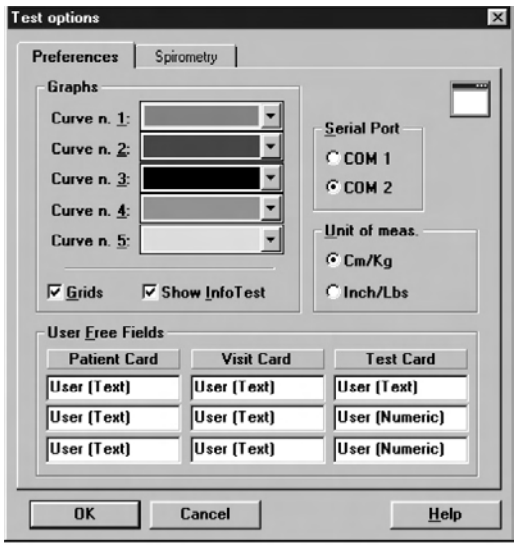
The program allows to manage a diagnosis database, whose records are composed by a diagnosis ID code and a string of text.

The report of the visits can be done either by typing the desired text in the field “Diagnosis” of the Visit Card or, more quickly, retrieving from the diagnosis database the desired one.

If you want to insert, modify or delete a diagnosis from the database select **Database Diagnosis...** from the **File** menu.

# Spirometry program settings

The software allows to configure some options selecting **Configure** from the **Option** menu.




### Graphs

All the graphs visualised and/or printed can be customised in colours and appearance.

1. Select the desired colours of the curves (5 curves max can be overlapped on the same graph).
2. Enable or disable the **Grid** option.
3. Enable or disable the **Show Info Test** option.

### Serial port

You must select the serial port RS 232 that will be used to connect the Quark $b^2$ with the PC.

To select the serial port, click on the proper **COM** button (the selected port must be different from the mouse one).

### Units of measurements

It is possible to configure the units of measurements, weight and height, for printing and viewing.

To select the units of measurement click on **cm/Kg** or **in/lb** according to the desired format.

### Using extra fields

The Patient's database is organised in 3 different cards (Patient card, Visit Card and Test card.) where it is possible to store the information about patients and visits .

Besides the standard information, it is possible to customise some fields (user free fields), entering and labelling measurements coming from other devices.

The customisable free fields are:

- 3 fields in the Patient Card (Patient's information)
- 3 fields in the Visit Card (information about the visits)
- 3 fields (2 numeric) in the Test card information about Test)

### Customise the fields

In the group **User free fields** type the desired text in the 9 fields available.