
Cosmed does not assume the liability for interpretation mistakes of this documentation or for casual or consequential damages in connection with the provision, representation or use of this documentation.
No parts of this manual may be reproduced or transmitted in any form without the express permission of COSMED Srl.

COSMED Software can be installed only in one device.

Excel is a registered trademark of Microsoft Corporation.

DBIII is a registered trademark of Bordland International Inc.

Lotus 123 is a registered trademark of Lotus Development Corporation .

K4 b² User manual, XII Edition
01/2005

Copyright © 1998 COSMED

Copyright © 2003 COSMED

COSMED Srl - Italy

<http://www.cosmed.it>

Part N. C01508-02-91

Table of contents

Getting started	13
Important notices	14
Intended use	14
Warnings	14
Contraindication	16
Contraindications for the Spirometer tests	16
Absolute contraindications	16
Relative contraindications	16
Contraindications for Bronchial provocation tests	16
Absolute contraindications	16
Relative contraindications	16
Contraindications for Exercise testing	16
Environmental condition of use	17
Safety and conformity	18
Safety	18
EMC	18
Telemetry	18
Quality Assurance	18
Medical Device Directive (CE mark)	18
FCC (only USA version)	18
Keynotes	19
Typographic keynotes	19
Graphic keynotes	19
System overview	20
Portable Unit (PU)	20
Telemetry Data Transmission, Receiver Unit (RU)	20
Battery Charger Unit (CU)	20
Flowmeter	21
Gas analysers	21
PC Software	21
Before starting	22
Checking the packing contents	22
K4 b ² standard packaging	22
Warranty registration	23
Register the product via software	23
How to contact COSMED	23
Complain, feedback and suggestions	23
Options/Accessories	24
Accessories	24
Options	24
Telemetry data transmission	24
Spirometry Kit	24

PC configuration required.....	25
Technical features	26
Portable Unit	26
Receiver Unit	26
Battery charger Unit.....	26
Flowmeter	26
Oxygen Sensor (O ₂)	26
Carbon Dioxide Sensor (CO ₂)	26
Humidity absorber.....	26
Power Supply	26
Environmental Sensors.....	26
Measurements	27
Pulmonary function tests and measured parameters	28
Breath by Breath exercise testing	28
Indirect Calorimetry	28
Lactate Threshold (V-Slope)	28
O ₂ Kinetics.....	29
Spirometry Tests (option).....	29
FVC - Forced Vital Capacity	29
VC/IVC - Slow Vital Capacity and Ventilatory pattern.....	29
MVV - Maximum Voluntary Ventilation	30
Bronchoprovocation Response.....	30
Installation	31
Installation sequence	32
Battery Charger Unit	32
Check voltage.....	32
Turn the Unit on	32
Charge the batteries.....	32
Battery low	33
Portable Unit.....	33
Warm up.....	34
Warming-up the unit by main power	34
Turning on/off the portable unit.....	34
Connect the rechargeable battery	34
Receiver Unit.....	35
Turning on/off the receiver unit	35
Receiver unit power supply.....	35
Calibration Gas Cylinder.....	35
Connecting the K4 b² to the patient.....	36
Assemble the mask and the flowmeter	36
Using the "Ultimate Seal".....	36
Apply the seal to the mask	37
To remove seal on mask.....	37
Assembling the flowmeter for spirometry tests.....	37

Fixing the K4 b ² to the patient.....	38
Connecting the K4 b² to the PC.....	39
Connect the Portable Unit to the PC.....	39
Connect the Receiver Unit to the PC.....	39
Software installation	40
Installing the software.....	40
Run the software	40
PC port configuration	40
Software main features	41
Display.....	41
Tool bar.....	41
Show/hide the toolbar.....	41
Dialog windows.....	41
Use of the keyboard.....	41
Use of the mouse	41
Scroll bars	41
On line help	41
Software version.....	41

Calibration	43
Gas calibration procedures	44
Running the Calibration program	44
Log file	44
Setting reference values.....	44
Set the reference values using the PC software.....	44
Set the reference values using the Portable Unit	45
Room air calibration	45
Room air calibration using the PC software.....	45
Room air calibration using the Portable Unit	45
Reference gas calibration.....	45
The calibration unit	46
Reference gas calibration using the PC software	46
Reference gas calibration using the Portable Unit.....	46
Gas delay calibration	47
Delay calibration using the PC software	47
Delay calibration using the Portable Unit	47
Print the calibration report.....	48
Edit the calibration factors.....	48
Turbine calibration	49
Assembling the flowmeter for calibration.....	49
Calibrating the turbine	49
Turbine calibration using the PC software	49
Turbine calibration using the Portable Unit	50
Checking the system signals	51
The control panel.....	51
Using the control panel.....	51

Operating modes	53
K4 b² Operating modes	54
Holter Data Recorder.....	54
Telemetry Data Transmission (option).....	54
Serial (Laboratory) Station	54
Portable Unit User Interface diagram	55
Holter Data Recorder Mode	56
Operating sequence	56
Warming-up the system	56
Enter new patient.....	56
Calibrate and start the test	56
Stop the test	57
Transferring test to PC	57
Telemetry Data Transmission Mode	58
Operating sequence	58
Warming-up the system	58
Connect the receiver unit to the PC.....	58
Enable transmission	58
Enter new patient.....	58
Enable reception on PC	59
Calibrate and start the test	59
Stop the test	60
Transferring test to PC	60
Serial Mode	61
Operating sequence	61
Warming-up the system	61
Connect the Portable unit to the PC	61
Calibrate the system	61
Enter patient data.....	61
Start the test.....	62
Stop the test	62
Database Management	63
Exercise testing patient's database	64
Enter a new patient	64
Find a patient	64
Edit patient data.....	64
Delete a patient	64
Uploading tests from the Portable Unit	65
Archive maintenance	66
Reorganise the archive	66
Delete the archive	66
Delete a test	66
Backup and restore	66
Backup.....	66
Restore.....	66

Spirometry patient's database	67
Patient Card	67
Visit Card	67
Test Card	68
Import/export a Tests card	68
Diagnosis Database.....	68
Spirometry program settings	69
Graphs	69
Serial port	69
Units of measurements	69
Using extra fields.....	69
Customise the fields	69

Exercise testing	71
Recommendations for the exercise testing	72
The evaluation of the cardiorespiratory function.....	72
Precautions.....	72
Laboratory	72
Ending the test	72
Preparing the patient	72
Before testing	72
Patient assent	73
Ending the test	73
Real time test	74
Start a test	74
Abort the test without saving data	74
End the test saving data	74
View data in real-time	74
View graphs in real-time	74
Parameters to view.....	74
Manual protocol.....	75
Enter Load and Phase	75
Set the markers	75
Automatic protocol	75
Modify the load during the test	75
Set the BPM alarm.....	75
Enter the BPM	75
Data management	76
Viewing data	76
View data in table form	76
Creating graphs.....	76
View data in graph form.....	76
Customise the graphs.....	77
Switch from graph to data and vice versa	77
Viewing predicted values	78
View predicted values	78

Anaerobic (Lactate) Threshold detection	78
View the Lactate Threshold	78
Detect the Lactate Threshold.....	78
Customise graphs for the LT viewing.....	78
Fittings.....	79
Fit a graph with a linear regression	79
Fit a graph with a Mono-exponential regression.....	79
Calculate the "Mean Value"	80
Oxygen Kinetic.....	80
Run the O2 Kinetic function	80
Information about the Test	81
View the Information	81
Modify the information	81
Summary.....	81
View the summary	81
Print the data.....	81
Print the current window	82
Print the report.....	82
View the report.....	82
Data Editing	83
Editing values and input numerical values.....	83
Data filtering	83
Using the User fields.....	84
Deleting steps	84
Advanced Editing.....	84
Restore the original test.....	85
Overwrite the original test.....	85
Customise the desktop.....	85
Customise the display colours.....	85
Smart edit.....	85
Apply the graphical noise suppression.....	85
Apply the threshold noise suppression.....	85
Customise the parameters.....	86
Create a new parameter	86
Create a new predicted parameter	86
Exporting data	87
Export a test.....	87
DDE with Excel	87
Creating Test Protocols	88
Create a new protocol.....	88
Software configuration	89
Data viewing.....	89
Select the parameters to view.....	89
Select the parameters to view during the test.....	89
Sort the parameters.....	89
Steady State	89

Customise the Steady State detection criteria	89
Printout reports	90
Set up the printout	90
Select parameters to be printed.....	90
Customise the printout header	90
Electronic reports (*.pdf)	91
Print the current window	91
Print the customised report	91
Events management during exercise testing	92
Flow Volume loops.....	92
Flow Volume loop during the test	92
O2, CO2 vs Time.....	92
O2, CO2 vs Time during the test.....	92
O2 Saturation (optional)	93
O2 Saturation during the test.....	93
Spirogram	93
Spirogram during the test	93
View the events after the test.....	93
Raw data	93
Save Raw data	94

Resting Metabolic Rate Test	95
Metabolism	96
Total Metabolic Rate	96
Resting Metabolic Rate (RMR).....	96
Importance to measure RMR.....	96
Measure of the rest metabolic rate with indirect calorimetry ...	96
How to perform a RMR test	96
Recommendations	97
Resting metabolic rate test using the face mask	97
Resting metabolic rate test using the canopy option.....	97
Performing a test using the face mask	98
Calibrations.....	98
How to prepare a patient.....	98
Start the test	98
Viewing the test	99
How to modify the average interval	100
Print	100
Performing a test using the canopy option.....	102
Calibrations.....	102
How to prepare the canopy and the patient.....	102
Replacement of the power plug.....	102
Connecting the Canopy	102
How to prepare the patient	103
Performing the test.....	103
Viewing the test	104

How to modify the average interval	104
Print	104
Sub-maximal Exercise Testing	105
Introduction.....	106
Pre-test screening.....	106
Sub-maximal exercise testing	107
Considerations with sub-maximal exercise testing.....	107
Staffing	108
Test termination.....	108
Considerations for accuracy.....	109
Performing the test	110
An example of testing protocol	110
Spirometry	111
Setting spirometry options.....	112
Spirometry	112
Automatic Interpretation	112
Quality control	112
Parameters manager.....	113
Predicted values manager	113
Predicteds set.....	113
Set the current predicted.....	114
Formula definition.....	114
Page set-up.....	115
Spirometry tests	116
Forced Vital Capacity (pre).....	117
Recommendations	117
Perform a FVC (pre) test	117
Test encouragement.....	117
Perform the FVC test with the encouragement	118
Slow Vital Capacity.....	119
Perform a SVC test	119
Maximum Voluntary Ventilation.....	120
Perform a MVV test	120
Bronchial Provocation Test	121
Bronchodilator test	121
Methacholine and Histamine Bronchial provocation Tests....	121
Perform the test.....	122
Bronchial Provocation protocols Database.....	122
Enter a new Bronchial provocation protocol in the archive	122
Viewing results.....	123
Tests of the current patient.....	123
Delete a test	123
Printing results.....	124
Printing Reports.....	124

Printing the active window	124
To print the active window	124
Printing a series of reports	124
Electronic reports (*.pdf)	124
Export data	125
Export a test	125

External devices	127
GPS	128
GPS initialisation	128
Initialize the GPS	128
Fixing the antenna to the subject	128
Operating sequence	129
Run a test with GPS	129
Monitoring GPS parameters in real time	130
Pulse Oximeter (option)	131
Operating Sequence	131

System maintenance	133
System maintenance	134
Cleaning and disinfection	134
Preparing the disinfecting solution	134
Cleaning the turbine flowmeter	135
Precautions during the cleaning of the turbine	135
Suggested disinfection solutions	135
Masks cleaning and disinfection	135
Disassembling the different parts of the mask	135
Cleaning the mask	135
Disinfecting the mask	136
Permapure maintenance	136
Inspections	136
Replace the fuses	136

Appendix	139
Service - Warranty	140
Warranty and limitation of liability	140
Return goods policy for warranty or non warranty repair	140
Repair Service Policy	141
Privacy Information	142
Personal data treatment and purposes	142
How your personal data are treated	142
The consent is optional, but	142
Holder of the treatment	142
Customer rights	142
Converting factors configuration	143
Calculations references	144

VO ₂ and VCO ₂	144
Anaerobic threshold (modified V-Slope)	144
O ₂ kinetics	144
ATS 94 recommendations	145
ATS recommendations	145
Predicted values.....	146
Automatic diagnosis (algorithm)	147
Quality Control Messages	147
References.....	149
Gas Exchange References	149
Indirect calorimetry	149
Spirometry	149
Sub-maximal testing.....	149

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 b² 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 b² 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 contaminants (including pieces of torn or broken components) in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminants 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 b² 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 b², 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-acuteing
- 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.
<i>“Italic”</i>	indicates a messages shown by the firmware.

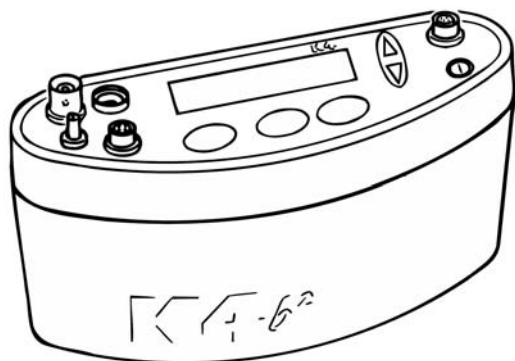
Graphic keynotes

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 O₂ and CO₂ analyzers, sampling pump, UHF transmitter, barometric sensors and electronics. It is powered by the rechargeable battery fixed to the back side of the harness.

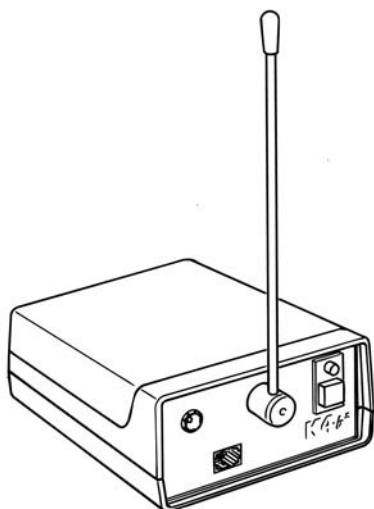
K4 b² is also provided with a small display, the PU shows in real time the following parameters: VT, VE, VO₂, VCO₂, R, HR, Rf Marker, battery charge level, temperature and barometric pressure.

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:

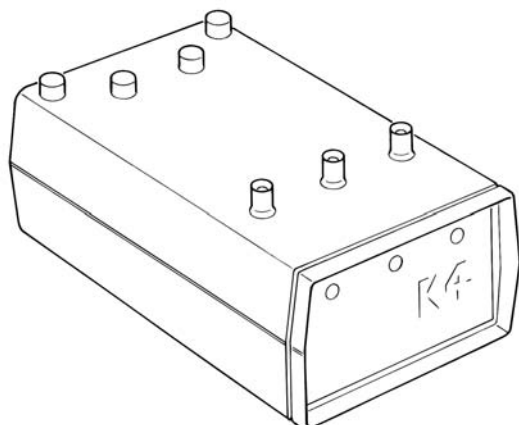
- Patient data input
- Environment data input (humidity)
- Gas and turbine calibration (automatic)
- Memory functions
- Tests data management
- Data loading to a PC (via RS232)

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 ($<0,7 \text{ cmH}_2\text{O/l/s}$ 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 b² 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 b² standard packaging



Note:

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

Code (version)	Qty				Description (see note by side)
	a	b	c	d	
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 ₂ O s/L @ 12 L/s
Ventilation Range:	0-300 litres x min

Oxygen Sensor (O₂)

Response time:	<150 ms
Range:	7-24% O ₂
Accuracy:	±0.02% O ₂

Carbon Dioxide Sensor (CO₂)

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%

--

Pulmonary function tests and measured parameters

Breath by Breath exercise testing

Symbol	UM	Parameter
VO ₂	ml/min	Oxygen Uptake
VCO ₂	ml/min	Carbon Dioxide production
V _t	l	Tidal Volume
FetO ₂	%	End Tidal O ₂
FetCO ₂	%	End Tidal CO ₂
R	---	Respiratory Quotient
VE	l/min	Ventilation
HR	1/min	Heart Rate
Q _t	l	Cardiac output
AT	---	Anaerobic Threshold
VE	l/min	Ventilation
SV	l/min	Stroke volume
RF	1/min	Respiratory Frequency
FeO ₂ , FeCO ₂	%	Averaged expiratory concentration of O ₂ e CO
VE/VO ₂	---	ventilatory equivalent for O ₂
VE/VCO ₂	---	ventilatory equivalent for CO ₂
VO ₂ /HR	ml/beat	Oxygen pulse
VO ₂ /Kg	ml/min/Kg	VO ₂ per Kg
Ti, Te, Ti/Ttot	sec	time breaths
Vd/Vt	---	Vd/Vt ratio
PaCO ₂	mmHg	arterial PCO ₂ (estimated)
P(a-et)CO ₂	mmHg	Delta PaCO ₂ – PetCO ₂

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	CO ₂ output @ LT STPD
VE	l/min	Ventilation @ LT BTPS

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

O₂ Kinetics

Parameter	UM	Calculation
O ₂ deficit	l/m	VO ₂ @work*tau
O ₂ debt	l/m	VO ₂ '@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

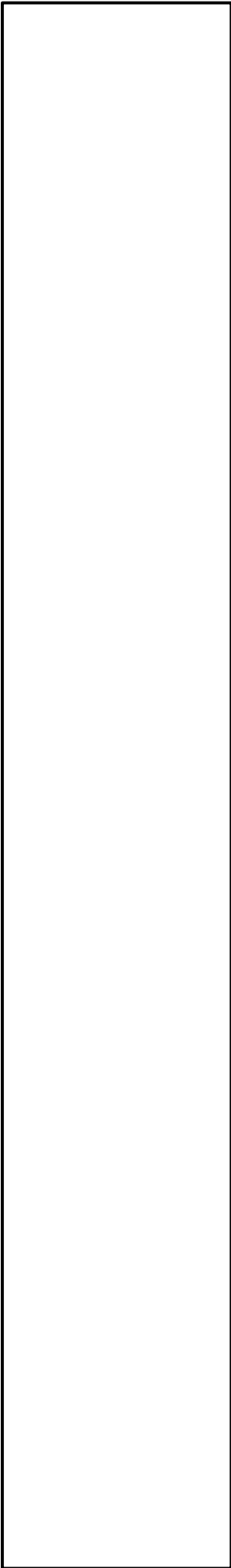
MVV - Maximum Voluntary Ventilation

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

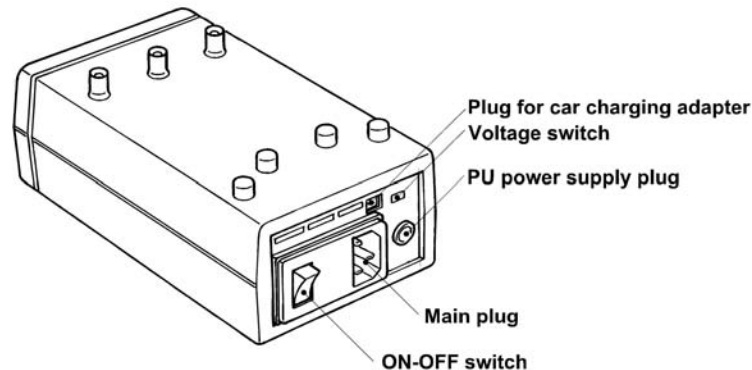
Installation



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 b² 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)

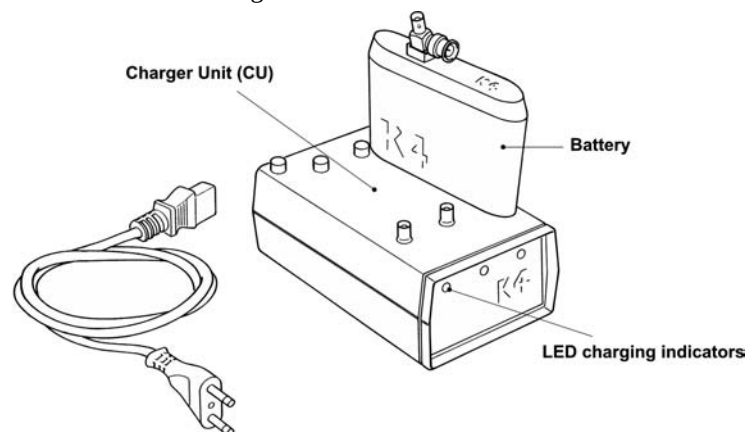
To change setting, move the switch on the new voltage by using a small screwdriver or a pen.

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.

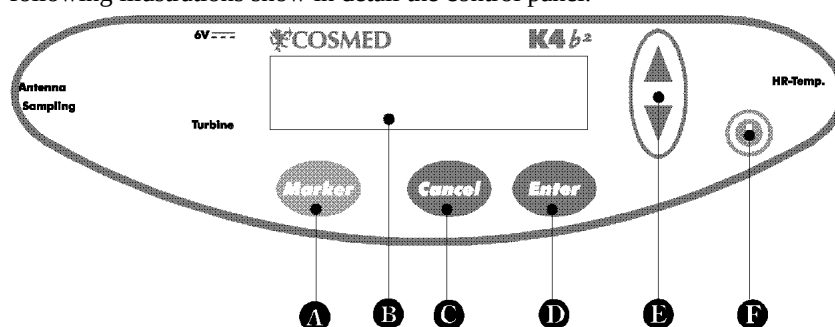
As soon as the message appears, you must change batteries immediately since the system has only few minutes of endurance still available. The system allows to change the battery during testing as well.

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

Portable Unit

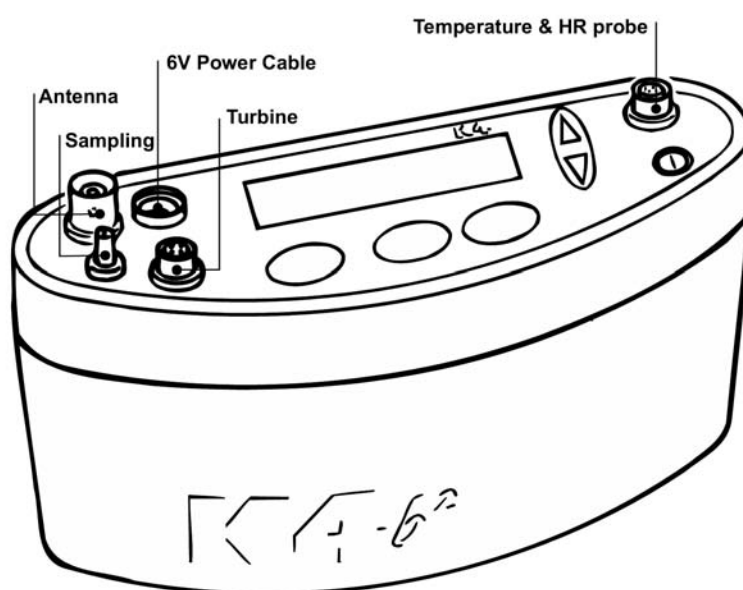
The PU can be supplied either by the Charger Unit or by rechargeable batteries. It is recommended during Warm-up to supply it exclusively by the Charger Unit time in order to save the battery used normally during the test.

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

Connections



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.



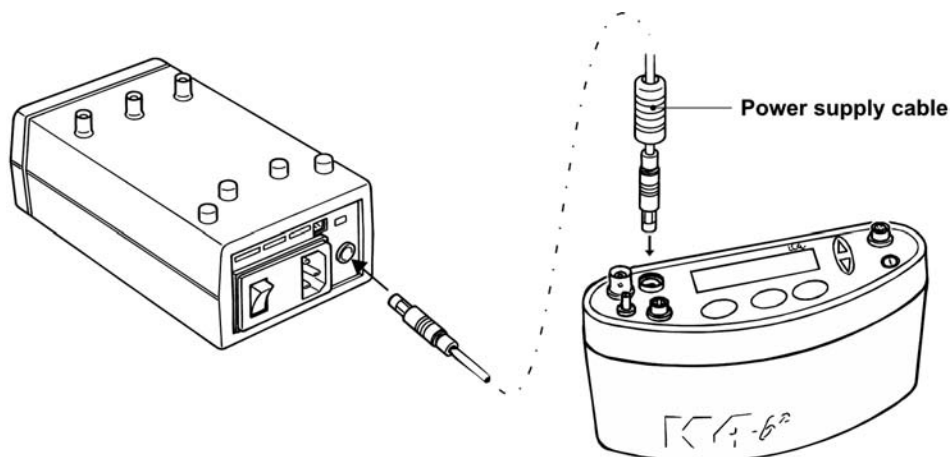
Warning: Supply K4 b² with Charger Unit for warming up only.

Warm up

The K4 b² uses O₂ and CO₂ 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 b² as shown below and turn both the units on.

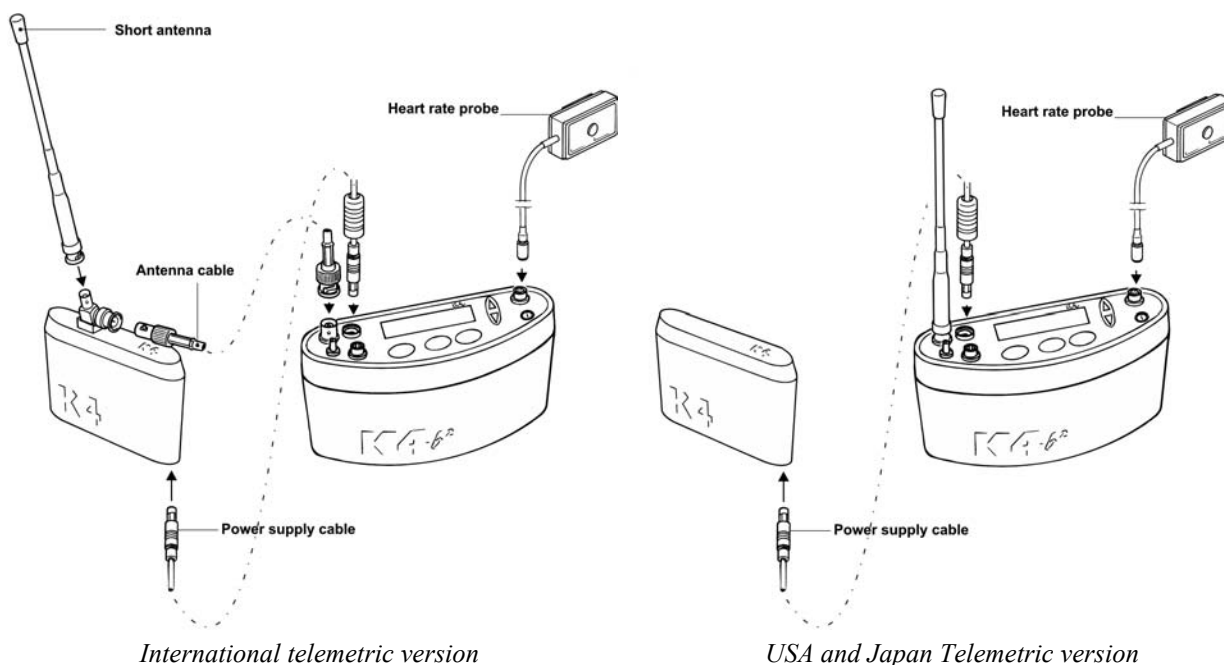


Turning on/off the portable unit

To turn the K4 b² 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.

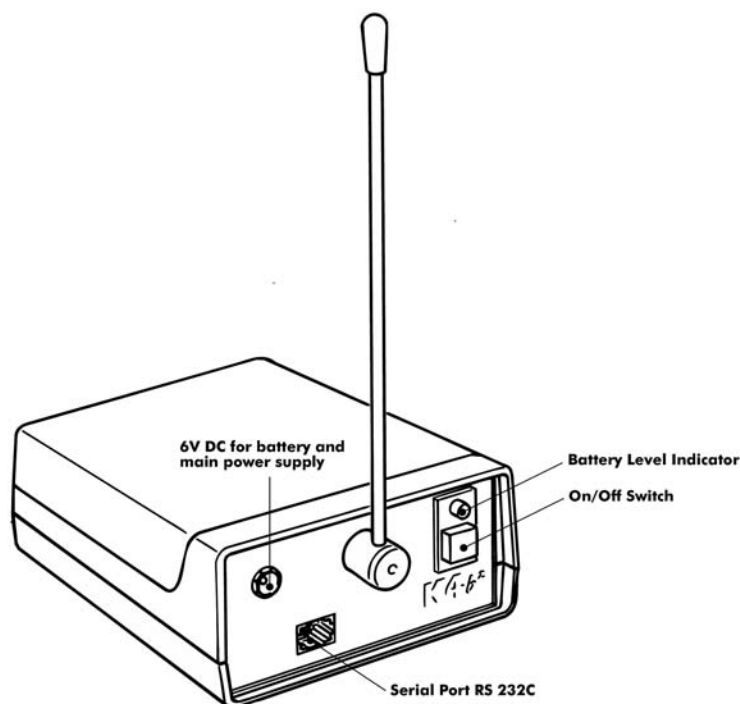


Sometimes you might need to change the battery during the test. To do this you must change the battery in the shorter time possible. The Portable Unit does not transmit data while it is not powered.

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 b² is provided with a transmitter board (located inside the K4 b² 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 b² 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 b² 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 b² 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.

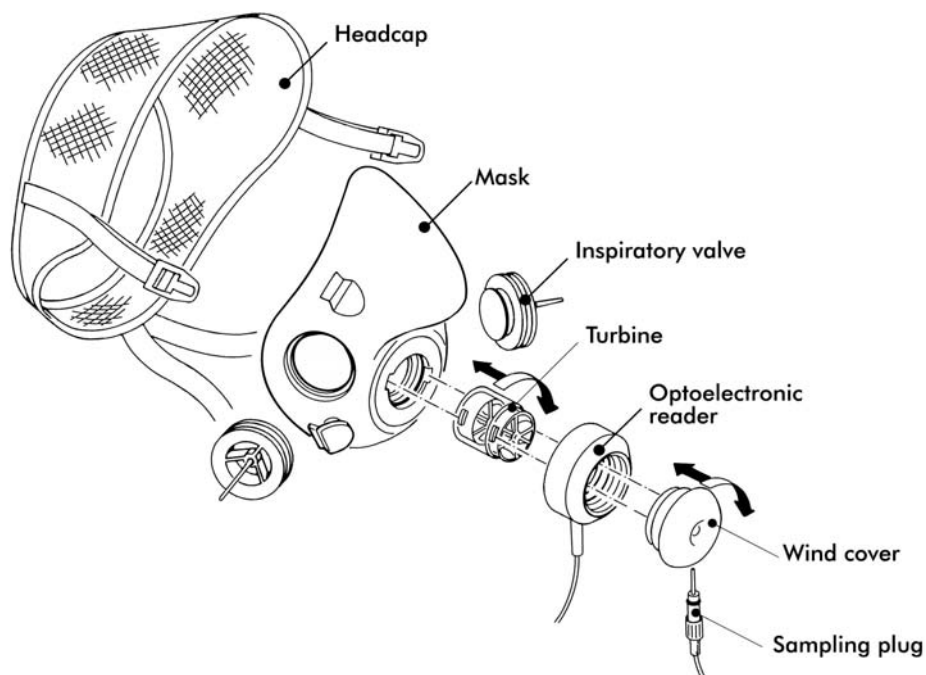
Assemble the mask and the flowmeter

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.



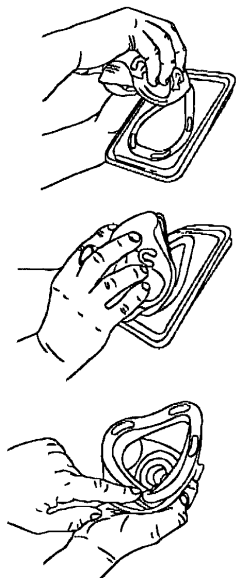
Notice: In order to preserve items composing the mask, it's recommended to grease periodically O-rings in the optoelectronic reader with Silicone compound grease.



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:

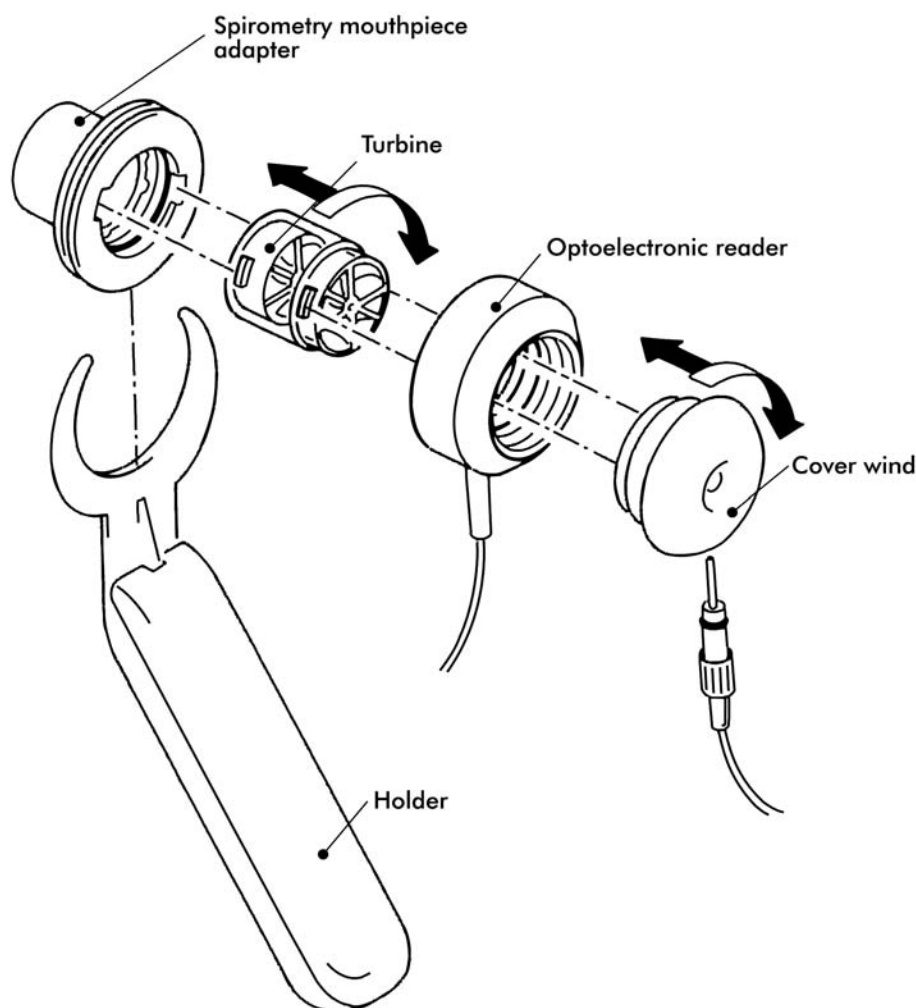
1. Remove the plastic tray from the bag. Peel off clear film and retain for later use.
2. While holding tray align the nose area of mask to nose area of Ultimate Seal™ gel. Press together and roll mask down over the surface of the gel seal attaching it to the mask and releasing it from the tray.
3. If 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.

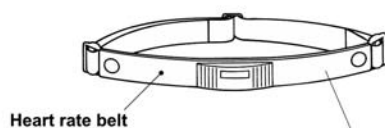


Fixing the K4 b² to the patient

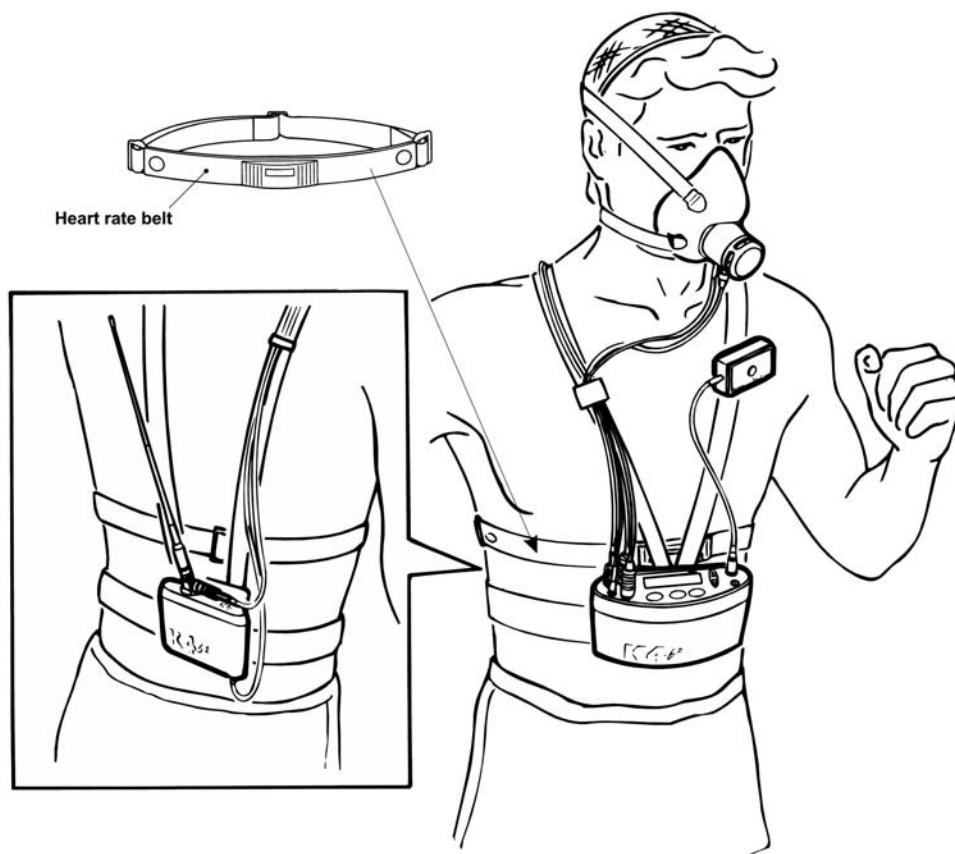
1. Fix the heart belt to the patient's box thorax.
2. Fix the K4 b² unit to the front of the harness. Do the same operation with the battery on the back.
3. Connect the battery cable to the 6V plug of the K4 b² control panel. Be sure that the red plug, that repairs the plug from water or sweat drops, 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.



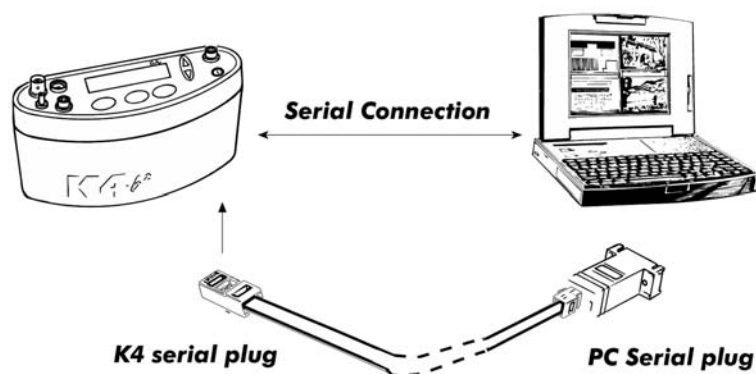
Note: USA and Japan versions differ from the picture because of the antenna placement.

Connecting the K4 b² to the PC

K4 b² can be connected to any PC provided with serial port in order to monitor "on-line" physiological data during any kind of activity.

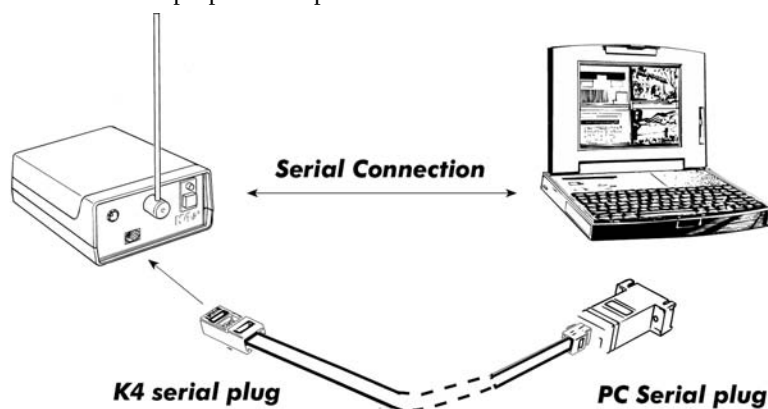
Connect the Portable Unit to the PC

Connect the K4 b² Portable Unit to a serial port available in the PC. Be sure to set the K4 b² 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 b² 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 b² (ergo).

Run the software

1. In the Windows **Start** menu, open the Program Group in which the software was installed.
2. Click the **K4 b²** 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 b² 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.
