# PERFORM Operating Document

# Use and Cleaning Procedures for
# Cosmed K4 b$^2$ Portable Metabolic System

# PC-POD-CP-009-v01

Revision History

| Version | Reason for Revision | Date |
|---------|--------------------|------|
| 01 | New POD | October 27, 2015 |

## Summary

The content of this PERFORM Operating Document (POD) provides for the safe use and cleaning of the Cosmed K4 b$^2$ portable metabolic system as identified as equipment inventory at the PERFORM Centre, Concordia University.

# Table of contents

# 1. Definition of Terms

| | |
|---|---|
| PERFORM operating document (POD) | Operating documents that are specific to an instrument or technique that require approval by area managers. |
| Standard Operating Procedure (SOP) | SOP's at PERFORM are any operating document that require a full review process and approval by the SD. |
| Supervisor | Knowledgeable person regarding all or an aspect of a project or program and is familiar with PERFORM's best practices, that is responsible for ensuring that users conduct their activities in a safe manner and within scope of the project. |
| User | Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training. |

# 2. Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:

- PC-SOP-GA-007 "General Access to PERFORM Centre".
- PC-SOP-GA-009 "Emergency Response Procedures at the PERFORM Centre".
- PC-SOP-GA-011 "Guidelines for Management of Incidental Findings at PERFORM".
- PC-SOP-GA-005 "Professional Supervision of Physical Activity and Exercise Testing at the PERFORM Centre".
- PC-POD-GA-001 "PERFORM Centre Booking System for Facilities and Equipment".
- PC-POD-CF-001 "Clearance for Physical Activity at PERFORM".
- PC-POD-CP-002 "Use and Cleaning Procedures for Manual and Automatic Aneroid Sphygmomanometers".

# 3. Introduction

### 3.1 Background

The Cosmed K4 b$^2$ is a portable electrical medical device designed to perform pulmonary function tests and record breath-by-breath data for the purpose of exercise testing, which can be performed underwater. The data one may acquire from this reliable and valid portable system is oxygen consumption ($VO_2$), carbon dioxide excretion ($VCO_2$), energy expenditure, among others.

### 3.2 Purpose

The objectives of the current POD are to 1) outline the procedure of using the Cosmed K4 b$^2$ portable metabolic system; 2) provide a set of standard practices for the safe operation of the Cosmed K4 b$^2$; and 3) outline the procedure of cleaning/disinfecting at the PERFORM Centre, Concordia University.

### 3.3 Scope

This POD applies to all users and supervisors using the Cosmed K4 b$^2$ portable metabolic system at the PERFORM Centre, Concordia University. Any other document other than this POD is out of scope for this operating procedure.

### 3.4 Responsibility

It is the responsibility of all users and supervisors to ensure that this POD is followed.

# 4. Main Components

**4.1  K4 b$^2$ Portable Unit** - contains the $O_2$ and $CO_2$ analyzers, sampling pump, UHF transmitter, barometric sensors and electronics. The portable unit shows in real time the following parameters: tidal volume ($V_T$), minute ventilation ($V_E$), $VO_2$, $VCO_2$, respiratory quotient (R), heart rate (HR), respiratory frequency (RF), battery charge level, temperature, and barometric pressure.

**4.2 K4 b$^2$ Receiver Unit** - consists of a small unit connected to a PC through the RS 232 serial port. It houses a miniaturized transmitter module, which is responsible for the transmission.
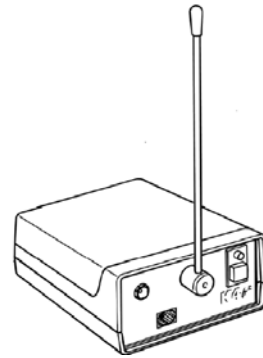


**4.3 Battery Charger** - allows the simultaneously charge of the 3 Ni-Cd batteries and to supply the portable unit during the warm up time.
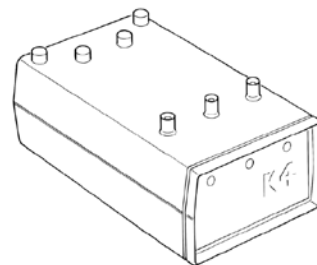
**4.4 Battery –** The battery powers the portable unit for approximately 3 hours.
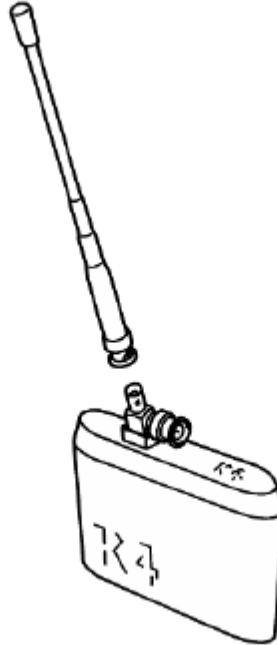


**4.5 The HR Probe** – The HR probe consists of two parts: the HR transmitter (belt) and receiver. Both parts should be assembled as close as possible to one another to acquire the most effective communication signal.
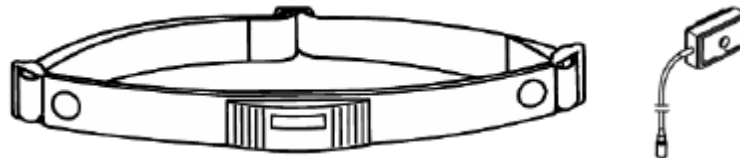


**4.6 Harness –** The harness, worn by the participant, is a holder for the portable unit and other accessories during the test.
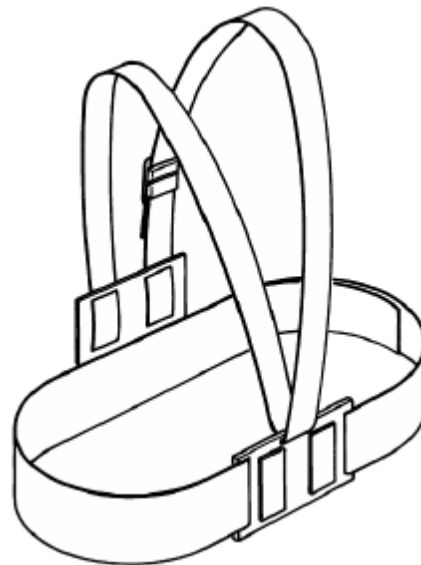
**4.7 ID28 Flowmeter (a.k.a. turbine)** – consists of a bidirectional turbine and an optoelectronic reader. The reader measures a wide flow range of infrared light interruptions caused by the spinning blade inside the turbine. The ID28 can be used for all tests except for RMR testing.
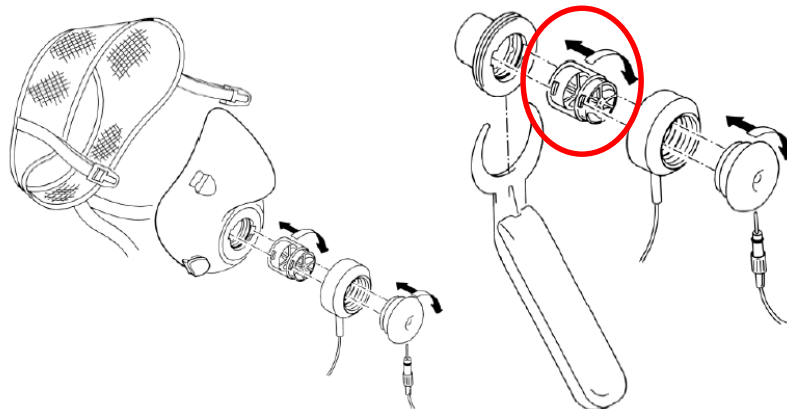


NOTE: The ID18 flowmeter is used for RMR testing and is provided with the canopy option only, which is not included with the system at the PERFORM Centre, Concordia University.

**4.8 Gas Cylinder** – The gas cylinder is composed of 16% $O_2$, 5% $CO_2$, and remaining balance of $N_2$ and is used to calibrate the system.





Secondary leak valve
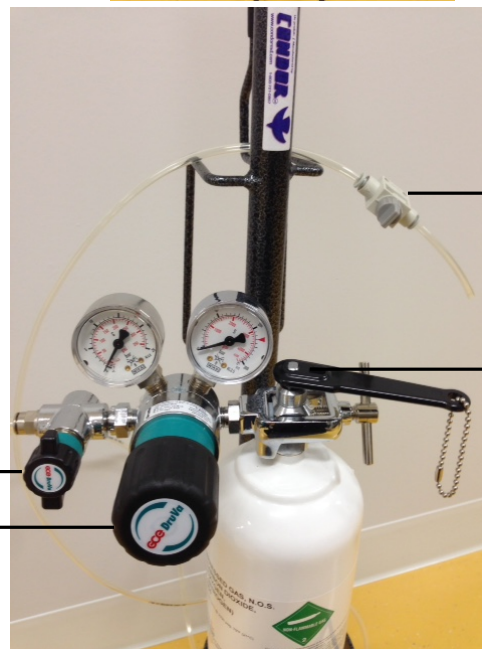
Main valve

Primary leak valve

Knob to adjust kpa

*4.9* **Calibration Unit** – The calibration unit, connected between the gas cylinder and the unit, is the tool for its calibration, according to the procedure shown below.
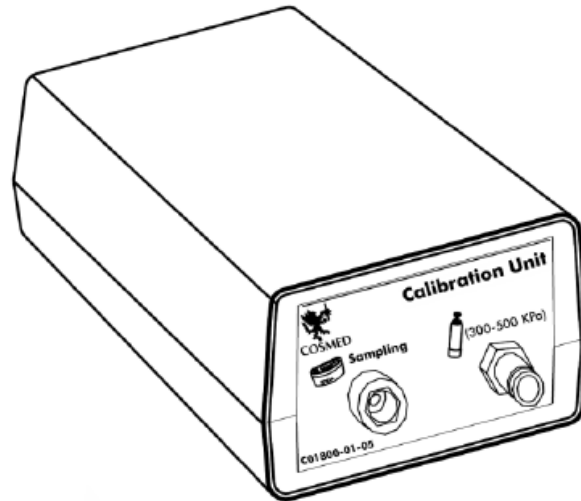


*4.10* **GPS** – The GPS unit detects the participant's path, stores it and allows its graphing after the test.
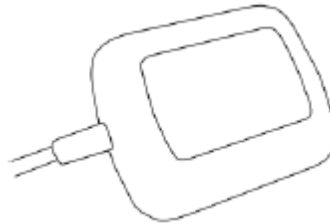


*4.11* **K4 b$^2$ Software** - software used to capture exercise-testing data.

### 4.12 Smaller Components
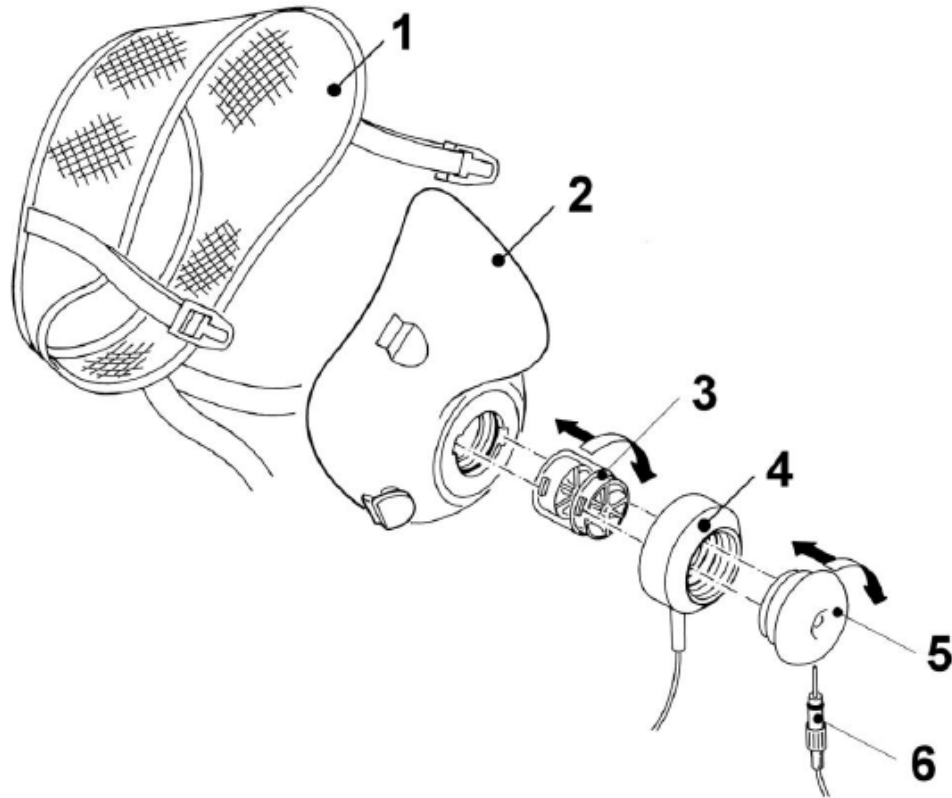


1. Head cap
2. Mask
3. Flowmeter/Turbine
4. Optoelectronic reader
5. Wind cover
6. Sampling line

### 4.13 ECG Option – 12-lead ECG used to capture electrical activity of the heart.

**4.14** **Aquatrainer (underwater feature) Option** – provides similar breath-by-breath data, only underwater.

    *4.14.1* **Snorkel and Tube** – For the convenience of the participant, this is one of the last pieces of equipment to be set up.



    *4.14.2* **Harness and Rod –** Worn by the operator, harness and rod allow Aquatrainer case to be suspended in the air while participant swims.
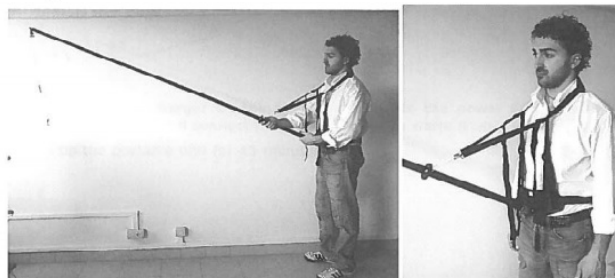
4.14.3 **Polar Heart Rate Transmitter** – Transmits heart rate signal to computer.



4.14.4 **Noseclip** – Crucial to ensure that participant is breathing through the mouthpiece.

4.14.5 **Aquatrainer Case** – Attaches onto rod and contains portable unit and battery.



# 5. Installation

## 5.1 Installation of battery charger
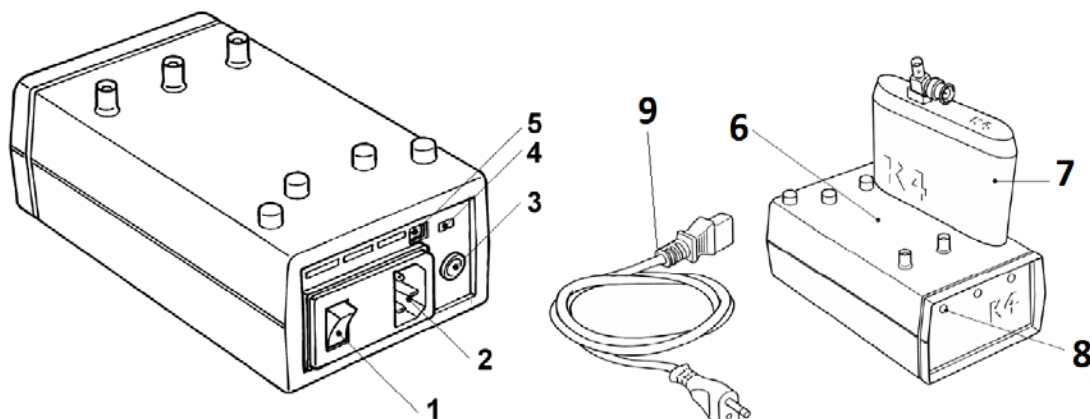
**Legend**
1. On-Off switch
2. Main plug
3. Portable unit power supply plug
4. Voltage switch
5. Plug for car charging adapter
6. Charger unit
7. Battery
8. Led charging indicator
9. Black charging cable

5.1.1   Plug the black charging cable (9) into the main plug (2) and turn on the battery charger unit by pressing the green On-Off switch (1) to ON.

5.1.2   Place the batteries (7) on the top of the charger unit (6) as shown above. When the green LED lights at the front (8) turn on, this means that the batteries are charging.

5.1.3   When the LED lights at the front (8) begin to flash, this indicates that the batteries have been fully charged.

NOTE: It is recommended to charge batteries before each test. When the batteries are low, the Portable Unit will deliver two beeps as a warning for a half charged battery and three beeps for a completely empty battery. One must then change said batteries immediately. The system allows changing the battery during testing as well.

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

### 5.2 Installation of portable unit
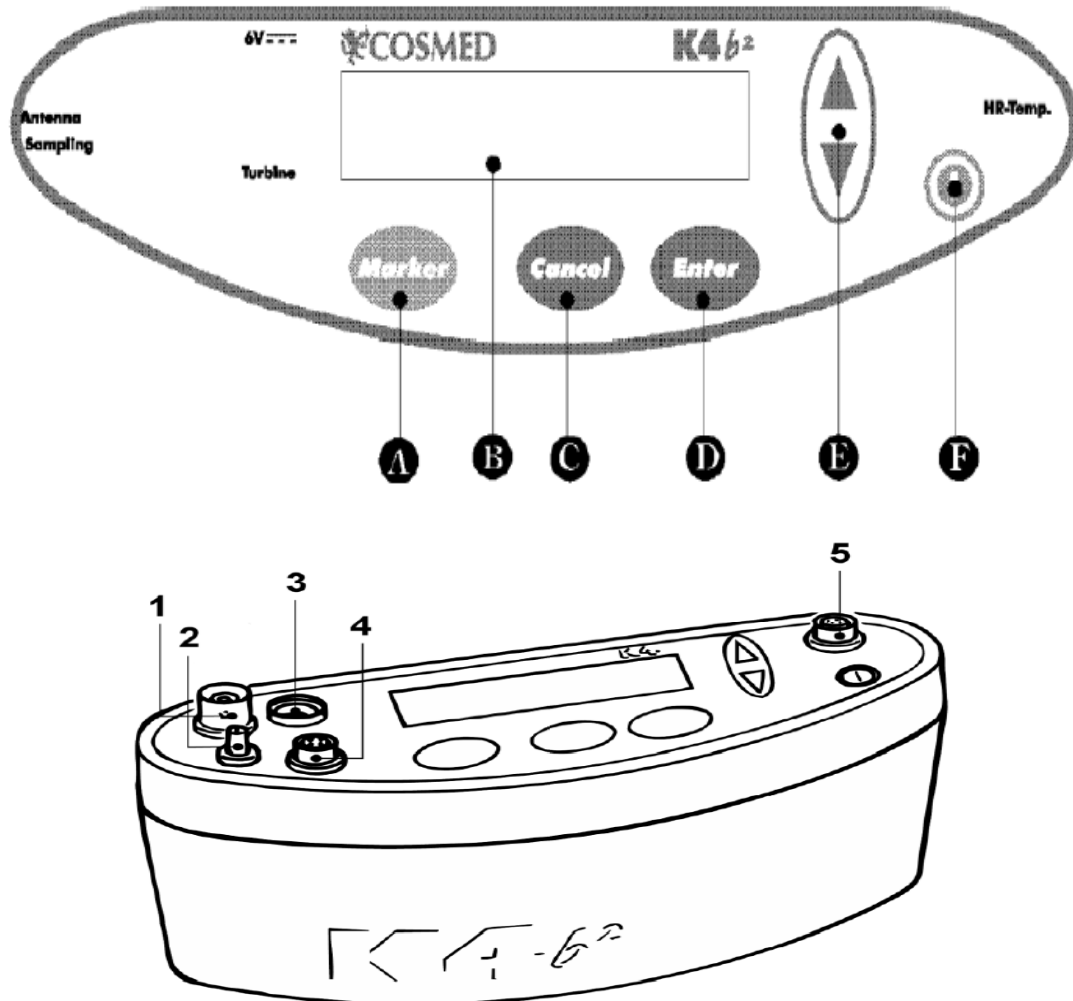


**Legend**
A.  Marker key
B.  Display
C.  Cancel key
D.  Enter key
E.  Scroll up/down key
F.  On/Off key
1.  Antenna
2.  Sampling
3.  6V power cable
4.  Turbine
5.  Temperature and HR probe

5.2.1    Connect the 6V power-supply cable to the Charger Unit and K4 b$^2$ and turn on charger unit.
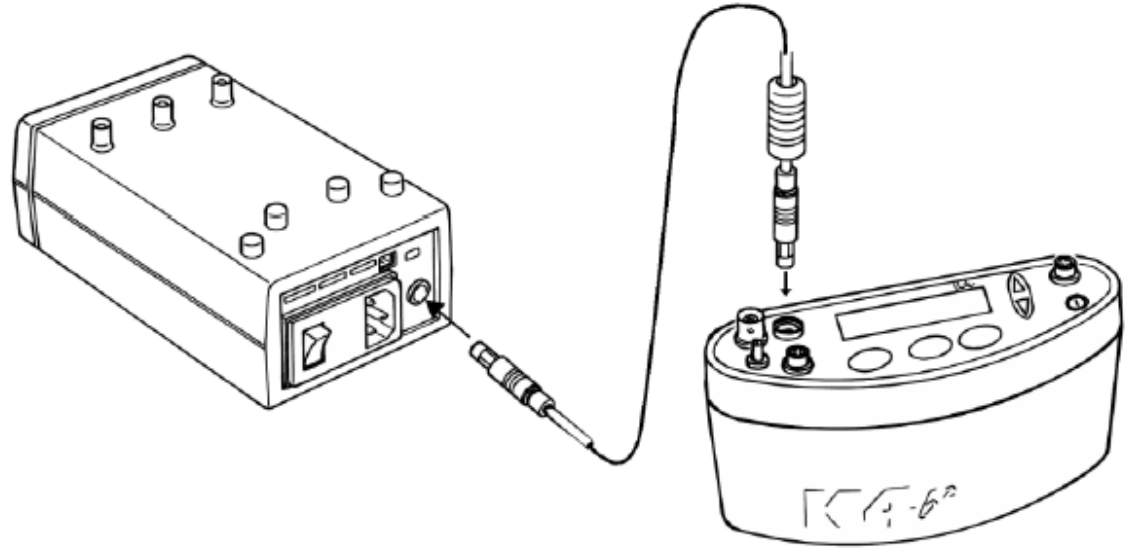


5.2.2    Turn the K4 b$^2$ on by pressing the on/off key (F).

**5.3**  Warming-Up Cosmed K4 b$^2$

5.3.1    System warm-up needs to be completed before calibrating the system and before any tests are performed. The following table displays the warm-up time required for each test:

| Test | Warm-up time (mins) |
|---|---|
| CPET (exercise test) | 45 |
| RMR | 45 |
| FVC, VC, MVV | 0 |
| Oximetry | 0 |

**NOTE**: During the warm-up period, the device must be powered on, but the software does not need to be open.

# 6. Calibration

**NOTE:** Calibration should not be performed until the system has completed the required warm-up period.

**NOTE**: Prior to calibrating, cellular phones should be turned off to eliminate potential electrical interferences.

### 6.1 Setting Reference Values

6.1.1    OPTION 1: Set reference values using the PC software.
**NOTE:** It is only necessary to configure these values the first time the device is used or if the reference values were to change (when cylinders are replaced). The system will store the most recently entered reference values for future calibrations.

6.1.1.1  Connect the Portable Unit to the PC by the serial port.
6.1.1.2  Open computer.
6.1.1.3  Open K4 b$^2$ software.

6.1.1.4  Click "Test" → "Calibration" OR press [icon].

**NOTE**: A log file is automatically created. It logs a history of past calibrations conducted by the user. To access the log file, select "File" → "Report File…" from the calibration program.
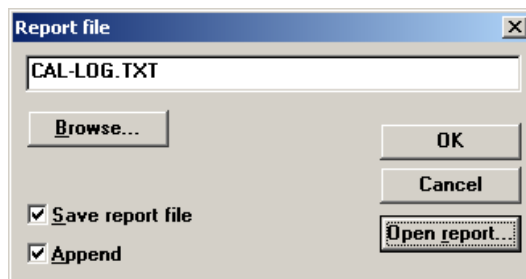


6.1.1.5  Click on "Calibration" → "Reference Values…"
6.1.1.6  In the reference values box, type the correct values as follows, unless concentration of calibration gas changes:

*6.1.1.7* Click "OK".

*6.1.2* OPTION 2: Set reference values using the Portable Unit

*6.1.2.1* Using up/down arrows, select "Calibration" → "Enter".

*6.1.2.2* Using up/down arrows, select "Set. Cal. Predicted Values" → "Enter"

*6.1.2.3* Type the values using the arrow keys: Cylinders (%x100): $O_2$ = 1600, $CO_2$ = 500, $O_2$ 100% = 100; Environment (%x100): $O_2$ = 2093, $CO_2$ = 3 → Syringe (ml) = 3000 → "Enter" to confirm changes → "Cancel" to go back to main menu.
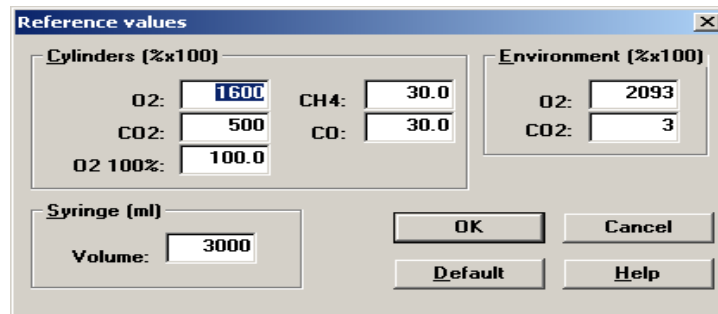
## 6.2 Calibrating Flow and Volume

*6.2.1* Connect 3 Liter syringe to smaller components as shown below:
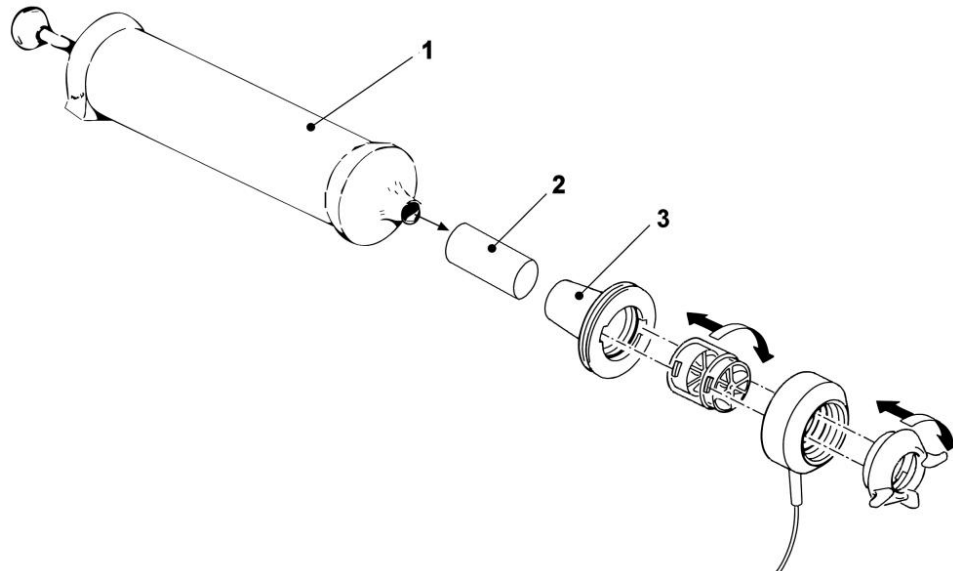


**Legend**:

1. Calibration syringe
2. Silicone tube
3. Calibration syringe adapter

NOTE: If a bacterial filter is used for testing you should also include one during the turbine calibration.

6.2.2 OPTION 1: Select appropriate turbine type using the PC software

    6.2.2.1 Click "Calibration" → "Turbine results…" → In "Turbine calibration results window under "Type (mm)" enter "28".



    6.2.2.2 Click "Ok".

6.2.3 OPTION 2: Select appropriate turbine type using the Portable Unit.

    6.2.3.1 Using up/down arrow keys, select "Settings" → "Enter".

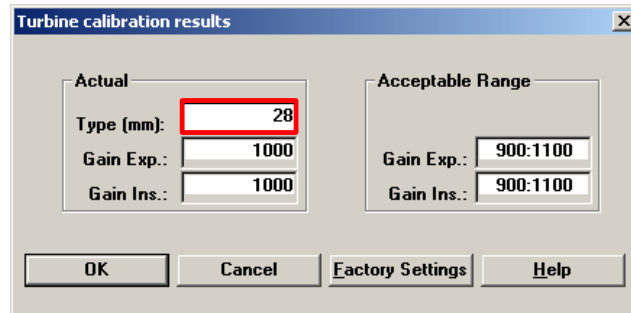    6.2.3.2 Using up/down arrow keys, select "Turbine 18/28" → Press "Enter".

    6.2.3.3 Using up/down arrow keys, select "28" → "Enter" → "Cancel" to go back to main menu.
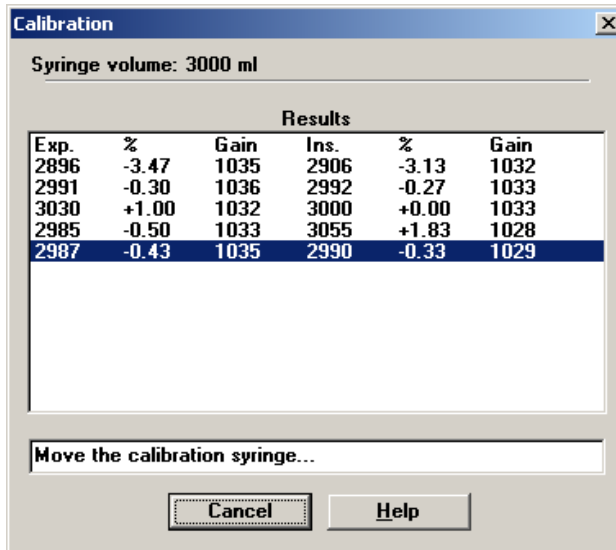
6.2.4 OPTION 1: ID28 turbine calibration using PC software

    6.2.4.1 Select "Calibration" then "Turbine".

    6.2.4.2 Make sure that calibration piston on 3 Liter syringe is pushed all the way in and sample line is connected to optoelectronic reader.

    6.2.4.3 In "Turbine Calibration" window, instructions to follow appear. Click "Ok".

    6.2.4.4 When "Calibration" dialogue box appears, move piston out and in for 10 strokes.
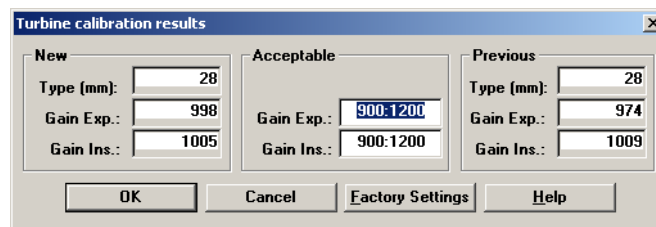
6.2.4.5 In the "Turbine calibration results" window, the new calibration factors and the acceptability ranges will be displayed.



6.2.4.6 Click "OK".

6.2.5 OPTION 2: ID28 turbine calibration using the Portable Unit

6.2.5.1 Connect sampling line to portable unit in inlet called "Sampling" and optoelectronic reader.

6.2.5.2 Connect optoelectronic wire (black) to portable unit in inlet called "Turbine".

6.2.5.3 Using up/down arrows, select "Calibration" → "Enter".

6.2.5.4 Select "Turbine Calibration" → "Enter".

6.2.5.5 Move the syringe until message "Operate syringe" disappears. Display will show expired (E) and inspired (I) readings for each stroke.

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

6.2.5.6 When display reads "Calibration Done" the new calibration factor has been stored.

6.2.5.7 Press "Cancel" twice to return to main menu.

6.2.5.8 Remove optoelectronic reader and syringe adapter from 3L syringe and separate both pieces.

### 6.3 Room Air Calibration – Before Every Test

6.3.1    OPTION 1: Room air calibration using PC software

6.3.1.1  Remove optoelectronic reader from 3L syringe and syringe adapter.
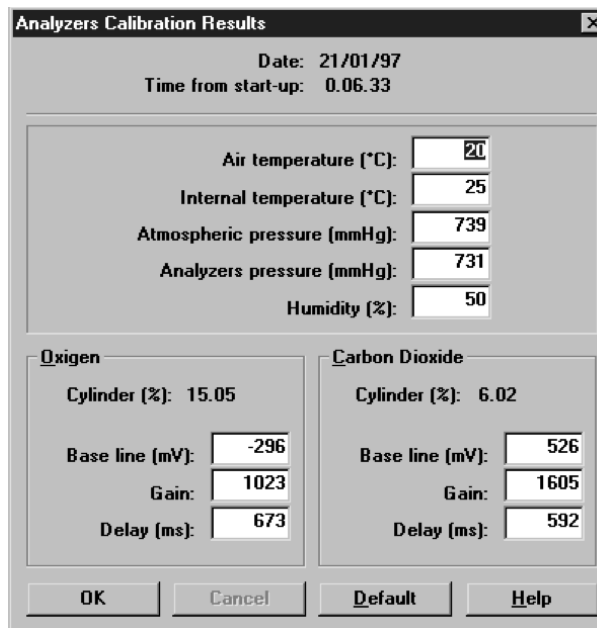
6.3.1.2  Remove sampling line from optoelectronic reader leaving sampling line attached to portable unit.

6.3.1.3  From "Calibration" menu, select "Room Air".

6.3.1.4  The message "Room air calibration in progress…" will appear and a graph will show in real time $O_2$ and $CO_2$ calibration. At end of calibration, message "Calibration done" will appear.

6.3.1.5  The "Analyzers Calibration Results" window will appear.

**Analyzers Calibration Results**

Date: 21/01/97
Time from start-up: 0.06.33

| | |
|---|---|
| Air temperature (°C): | 20 |
| Internal temperature (°C): | 25 |
| Atmospheric pressure (mmHg): | 739 |
| Analyzers pressure (mmHg): | 731 |
| Humidity (%): | 50 |

**Oxigen**

Cylinder (%): 15.05

| | |
|---|---|
| Base line (mV): | -296 |
| Gain: | 1023 |
| Delay (ms): | 673 |

**Carbon Dioxide**

Cylinder (%): 6.02

| | |
|---|---|
| Base line (mV): | 526 |
| Gain: | 1605 |
| Delay (ms): | 592 |

OK    Cancel    Default    Help

6.3.1.6  Click "OK".

6.3.2    OPTION 2: Room Air Calibration using Portable Unit.

NOTE: Room air calibration performed is small rooms (high concentration of $CO_2$) affects the calibration results and the accuracy of the following tests.

NOTE: Be sure to put the sampling line far away from expired gas otherwise calibration could be affected.

6.3.2.1  Using up/down arrows, select "Calibration" → "Enter" → "Room Air Calibration" → "Enter". Screen will display the following:

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

*6.3.2.2* Procedure is automatically performed until message "Calibration done" appears. $O_2$ and $CO_2$ values will be displayed on screen as such:

```
Calibration done
O2:20.9 CO2:0.0
```
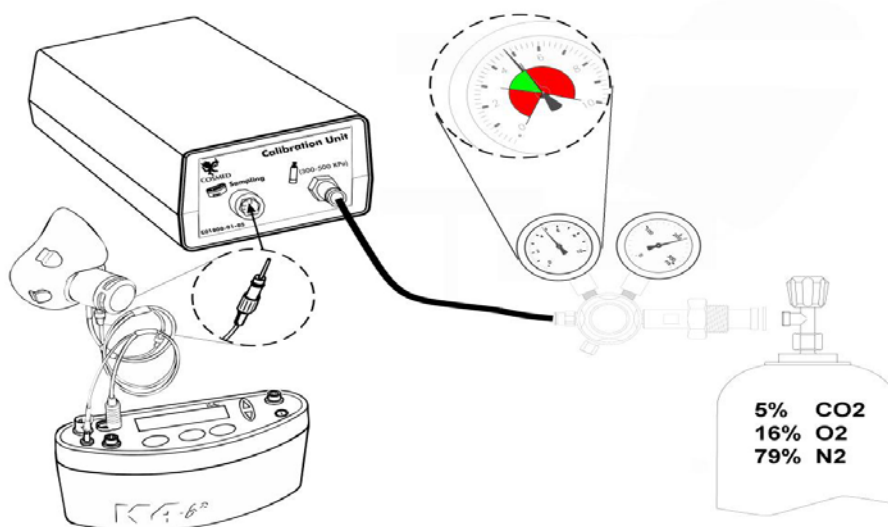
*6.3.2.3* Press "Cancel" to exit calibration menu.

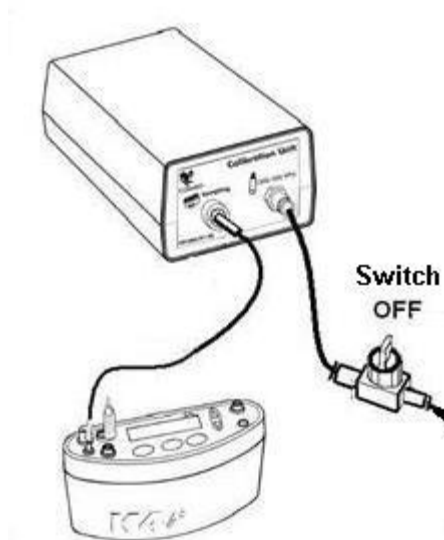## 6.4 Reference Gas Calibration

*6.4.1* OPTION 1: Reference gas calibration using PC software.

*6.4.1.1* Connect high-pressure tube on gas tank to the "300-500 Kpa" inlet on calibration unit.



*6.4.1.2* Make sure that the secondary leak valve on the high-pressure tube is off (i.e. perpendicular to line).

6.4.1.3 Open gas tank by turning main valve counter-clockwise. Open primary leak valve. Set the pressure value within the range of 300-500 Kpa (3-5 bars or 44-73 psi).

6.4.1.4 Connect Portable Unit to PC by serial port. Remove sampling line from the optoelectronic reader.
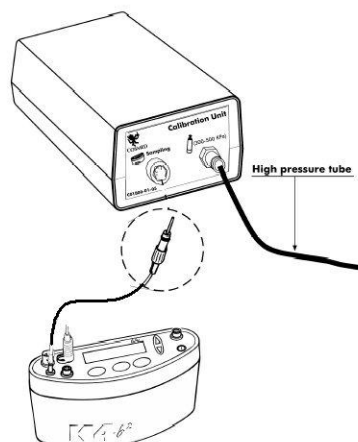


6.4.1.5 Change the secondary leak valve on high-pressure tube to on (i.e. parallel to line).

6.4.1.6 Run calibration program. Click on "Calibration" → "Gas".

6.4.1.7 In "Gas Calibration" window, instructions to follow appear. Click "Ok".

6.4.1.8 The message "Reference Gas calibration in progress…" will appear. When "Sample reference gas…" appears, plug in sampling line into "Sampling" inlet on calibration unit.



6.4.1.9 The message "Calibration done" will appear.

6.4.1.10 Click "Ok".

6.4.1.11 Change the secondary leak valve on high-pressure tube to off (i.e. perpendicular to line).

6.4.1.12 Remove sampling line and close gas tank by turning valve clockwise.
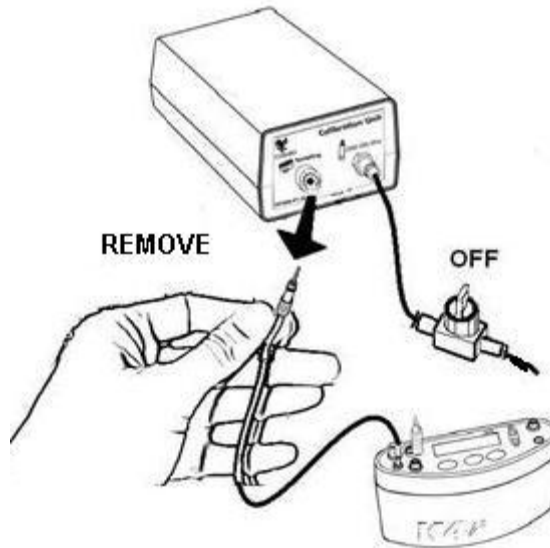
6.4.2    OPTION 2: Reference gas calibration using Portable Unit.

    6.4.2.1   Connect high-pressure tube on gas tank to the "300-500 Kpa" inlet on the calibration unit.
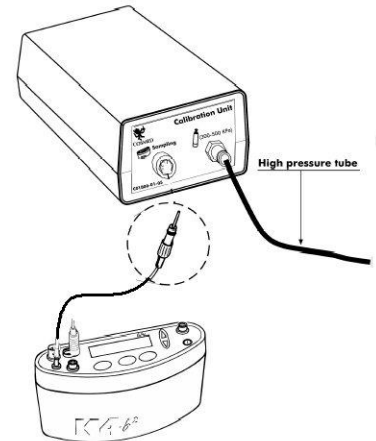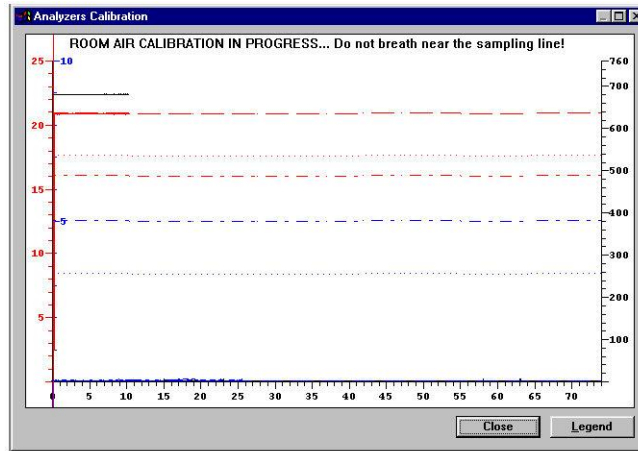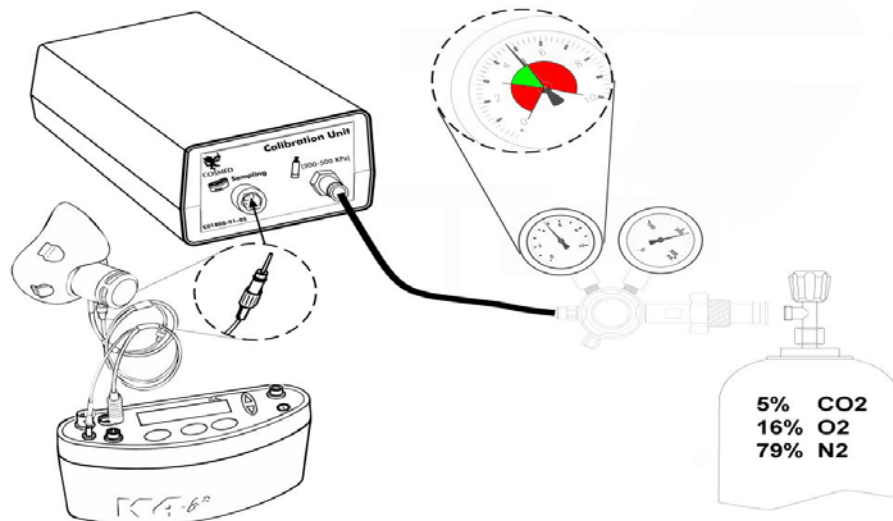


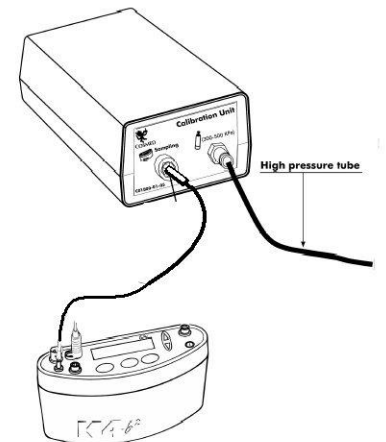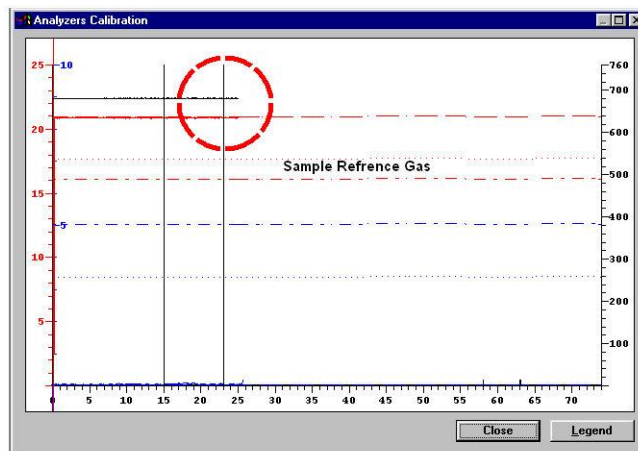    6.4.2.2   Make sure that the secondary leak valve on the high-pressure tube is off (i.e. perpendicular to line).
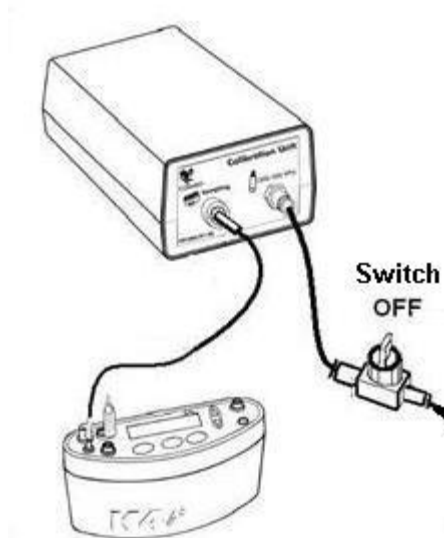
6.4.2.3  Open gas tank by turning main valve counter-clockwise. Open primary leak valve. Set the pressure value within the range of 300-500 Kpa (3-5 bars or 44-73 psi).

6.4.2.4  Make sure sampling line is not connected to "Sampling" inlet on calibration unit.
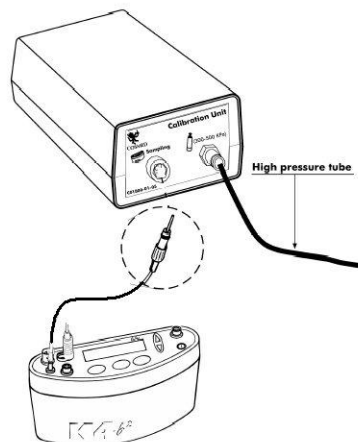


6.4.2.5  Open secondary leak valve on high-pressure tube.

6.4.2.6  Click "Calibration" → "Enter" → "Reference gas calibration" → "Enter".

6.4.2.7  When message "Sample reference gas…" appears connect sampling line to "Sampling" inlet on calibration unit.

```
Do not breath..
O2:20.7 CO2: 0.4
```
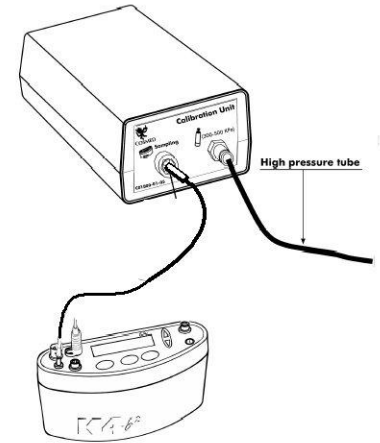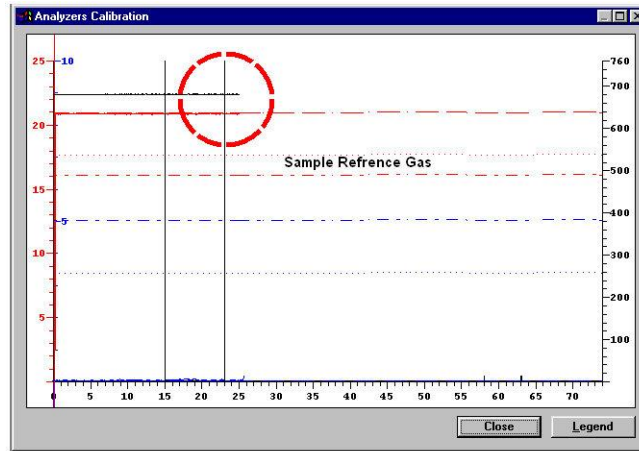
*6.4.2.8* The message "Calibration done" will appear.

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

*6.4.2.9* Press "Enter" or "Cancel".

*6.4.2.10* Change the secondary leak valve on high-pressure tube to off (i.e. perpendicular to line).
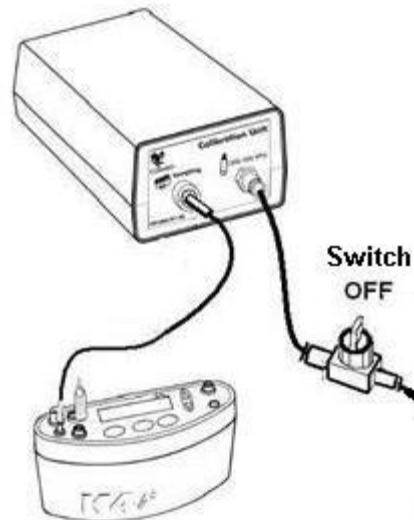


*6.4.2.11* Remove sampling line and close gas tank by turning valve clockwise.

REMOVE    OFF
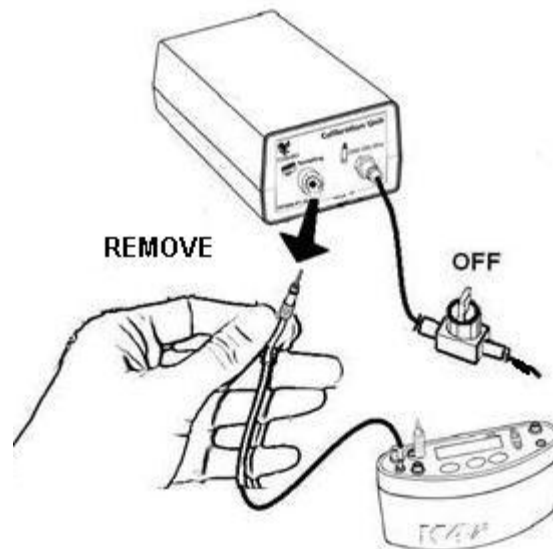
### 6.5 Gas Delay Calibration - Performed each week or when change occurs to sampling system (i.e. when sampling line is changed)

6.5.1    OPTION 1: Gas delay calibration using PC software

6.5.1.1    Connect Portable Unit to PC by serial port. Remove sampling plug from the optoelectronic reader.

6.5.1.2    Click "Calibration" → "Delay"

6.5.1.3    In "Delay Calibration" window, instructions to follow appear. Click "Ok".

6.5.1.4    The message "Gas calibration in progress..." will appear. At the end of the Room Air calibration the following message appears:
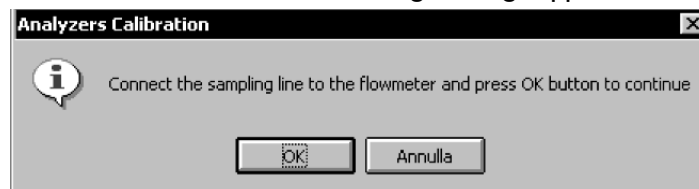


6.5.1.5    Click "Ok" to start breathing at a constant rate.

6.5.1.6    Synchronise the breath (inspiration and expiration) with acoustic signal.

6.5.1.7    Continue breathing until message "Calibration Done…" appears.

6.5.1.8    When dialogue box opens, illustrating new calibration factors click "Ok".

6.5.2    OPTION 2: Gas delay calibration using portable unit

6.5.2.1    On main menu, select "Calibration" → "Enter"→ "$O_2/CO_2$ delay calibration" → "Enter".

6.5.2.2    A room air calibration will be performed with the following message appearing:

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

6.5.2.3  When message "Connect the sampling line and press enter" appears, press "Enter" and start breathing at a constant rate. Synchronize the breath (inspiration and expiration) with the acoustic signal.

6.5.2.4  When dialogue box illustrates new calibration factors click "Cancel".

## 6.6 Previewing Calibration Report

6.6.1  Click "File" → "Preview".
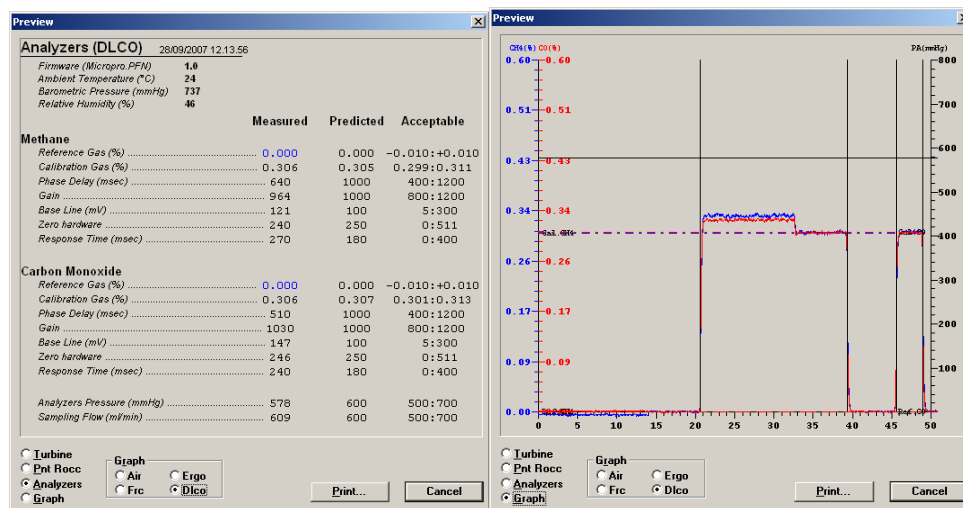


6.6.2  Choose desired report visualization (numerical values or graphs) by selecting the relative option in the lower part of the dialogue box. Values in blue indicate that the values are equal to their predicted value. Values in red represent a result that occurred outside of the acceptable range.

6.6.3  Click "File" → "Print".

# 7. Installation of K4 b$^2$ on Participant

## 7.1 Installation of HR transmitter

7.1.1  Wet sensors of HR transmitter.

7.1.2  Place HR transmitter on thorax of participant under breast line directly on the skin. Strap should be tight and comfortable. Adjust strap if necessary.
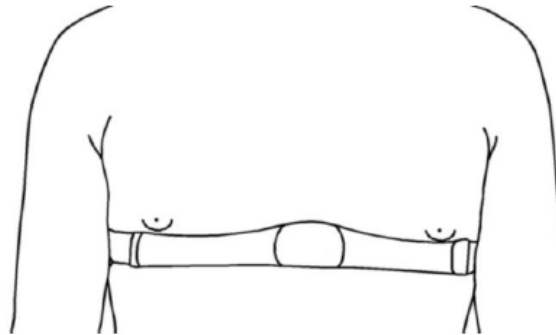
### 7.2 ECG Preparation and Placement (if required)

7.2.1    Ask participant to remove jewelry (i.e. necklace) and watch, if any.

7.2.2    Wearing gloves, shave hair from electrode sites, if necessary.

NOTE: For females, place the precordial electrodes on top of the breast (not over the breast tissue).

7.2.3    Cleanse area with alcohol swab.

7.2.4    Using abrasive ECG prep tape, lightly scratch an "X" pattern into the skin, taking care to avoid excess abrading.

7.2.5    Dry the skin vigorously with a gauze pad.

7.2.6    Attach the electrodes to the lead wires before attaching them to participant.

7.2.7    Place electrodes as instructed by the manufacturer. Press the contour of electrode. Avoid pressing the center of the gel area.

### 7.3 Installation of Harness

7.3.1      Place harness on participant.

7.3.2      Place K4 $b^2$ Unit on the front of the harness and a battery pack on the back.

7.3.3      Connect the battery cable to the 6V plug of the K4 $b^2$ control panel. Be sure that the red plug, that protects the plug from water or sweat drops, is on the Portable Unit side.

7.3.4      Connect the antenna plug to the "Antenna" plug of the Portable Unit control panel and to the side of the antenna on the battery.

7.3.5      Connect the antenna to the top of the battery.

7.3.6      Insert the heart receiver and temperature probe cable in the "HR-Temp" plug placed on the control panel.

7.3.7      Insert the male connector of the turbine in the Turbine plug on the control panel.

7.3.8      Fix the power supply cables, antenna and turbine on the right side of the harness with the Velcro straps. Fix the heart frequency probe on the left side.

NOTE: Be sure to position the HR probe on the left side, while the other cables have to be fixed on the right side. This must be done to avoid interferences between cables.
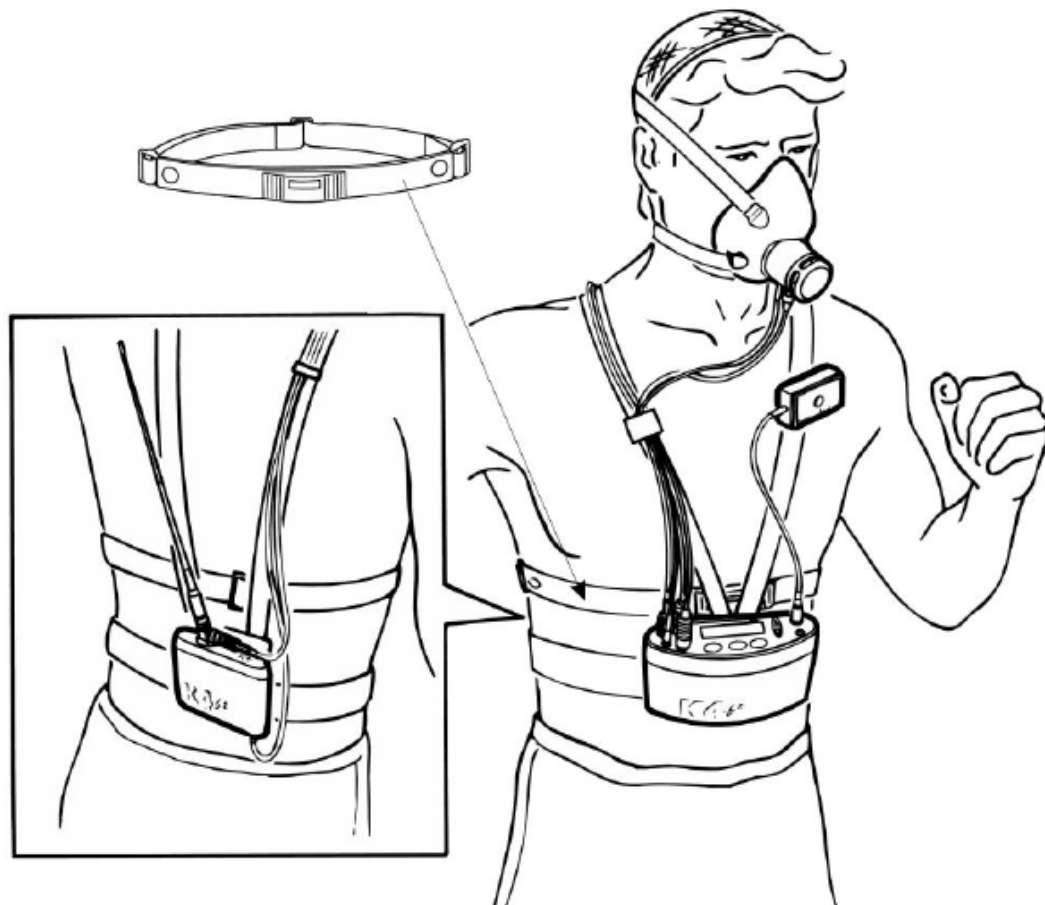
### 7.4 Installation of Mask

7.4.1   Fix the mask as illustrated in the picture below. Adjust the elastic bands on the head cap as necessary to eliminate possible leaks and create a tight seal around the subject's face.
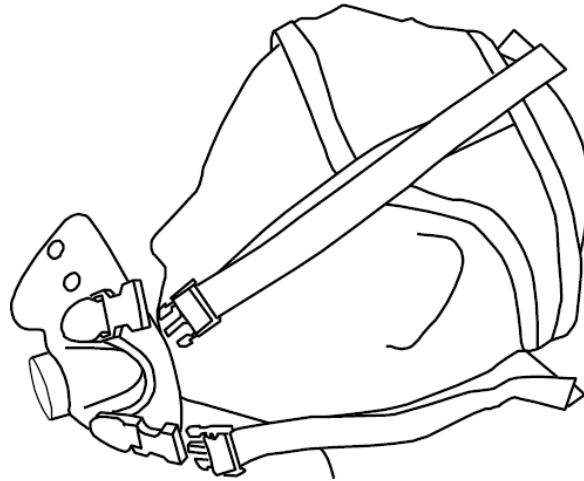
7.4.2     Ask participant to lightly seal hole with palm of hand to check for any mask leaks. If pressed too hard, mask will deform thereby creating leaks.

# 8. Spirometry

## 8.1 Patient Preparation

8.1.1     Disconnect the sampling line from the flowmeter.

8.1.2     Calibrate the turbine as indicated in the *Calibration* portion of this POD.

8.1.3     Attach flowmeter to the handle.

8.1.4     Put on antibacterial filter.

8.1.5     Explain the manoeuvre to the participant: "Breathe normally, then perform a maximum inspiration followed by a maximum forced exhalation". Make sure that participant is sitting with both feet on the floor, back on the chair.

8.1.6     Instruct participant to apply nose clip.

## 8.2 Performing a Forced Vital Capacity (FVC) Test

8.2.1     In the menu, select "Test" → "Start" → "Forced Vital Capacity" or press "Test" icon → "Forced Vital Capacity pre" and wait until the green LED appears on the right side of the screen.

**NOTE:** To utilize the patient encouragement function, select "View" → "Encouragement" prior to executing the test. The dotted bubble represents the predicted value, and the blue bubble represents the actual value.
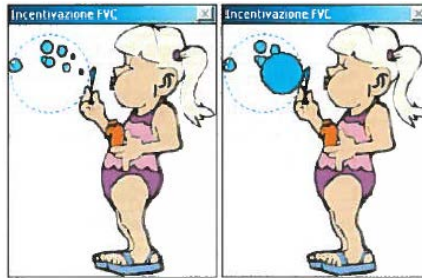
8.2.2    When ready press F2 or the "Start" icon to execute the test.

8.2.3    When completed press F3, the "Stop" icon, or wait for the automatic end (5 seconds without flow).

8.2.4    To abort the test press Alt+F3 or the "Abort" icon.

8.2.5    To restart the test, press the "Redo" icon.

8.2.6    To visualize the Flow-Volume graph, Volume-Time graph, or the main parameters click on one of the following:

 displays the Flow-Volume graph

 displays the Volume-Time graph

 displays all numeric data

8.2.7    Repeat the test until the desired number of manoeuvres has been obtained correctly.

8.2.8    Press  to visualize the test list carried out during the current session.

8.2.9    Select the test you wish to save (results are sorted from best to worst according to AATS criteria).

8.2.10  Press "OK".

**Choose the test to keep**

| FVC | | FEV1 | | FEV1/FVC% | | FEF25-75% | | |
|---|---|---|---|---|---|---|---|---|
| Meas | %Pred | Meas | %Pred | Meas | %Pred | Meas | %Pred | Test n. |
| 6.23 | 110.0 | 4.87 | 101.2 | 78.2 | 92.5 | 4.12 | 0.0 | 2 |
| 6.23 | 110.2 | 4.81 | 99.9 | 77.1 | 91.3 | 3.96 | 0.0 | 1 |
| 6.11 | 108.0 | 4.72 | 98.1 | 77.2 | 91.4 | 3.92 | 0.0 | 3 |

Tests are sorted from best to worst

| OK | Save all | Discard all | Cancel | Help |
|---|---|---|---|---|

### 8.3 Performing a Slow Vital Capacity (SVC) test

8.3.1    Select "Test" → "Start" → "Slow Vital Capacity" or press "Test" icon → "Slow Vital Capacity" and wait for the green LED to appear on the right side of the screen.

8.3.2    Explain the manoeuvre to the participant: "Breathe normally, then perform a maximal inspiration followed by a slow maximal exhalation". Make sure that participant is sitting with both feet on the floor, back on the chair.

8.3.3    Instruct participant to apply nose clip.

8.3.4    Press F2 or the "Start" icon to begin the test and follow the prompts on the monitor.

8.3.5    When completed press F3, or the "Stop" icon, or wait for the automatic end (5 seconds without flow).

8.3.6    To visualize the Flow-Volume graph, the Volume-Time graph, or the main parameters click on one of the following:

 displays the Flow-Volume graph

 displays the Volume-Time graph

 displays all numeric data

8.3.7    Repeat the test until the desired number of manoeuvres has been obtained correctly.

8.3.8    Press  to visualize the test list carried out during the current session.

8.3.9    Select the test you wish to save (results are sorted from best to worst according to American Thoracic Society (ATS) criteria).

8.3.10   Press "OK".

### 8.4 Performing a Maximal Voluntary Ventilation (MVV) Test

8.4.1    Select "Test" → "Start" → "Maximum Voluntary Ventilation", or press the "Test" icon → "Maximum Voluntary Ventilation" and wait until the green LED appears on the right side of the screen.

8.4.2    Explain the manoeuvre to the participant: "breathe as deep and fast as possible for 12 seconds". Make sure that participant is sitting with both feet on the floor, back on the chair.

8.4.3    Instruct participant to apply nose clip.

8.4.4    When the patient is ready instruct them to begin and press the F2 key or the "Start" icon.

8.4.5    When the effort is completed, press F3, or the "Stop" icon, or wait for the automatic end of the test (after 5 seconds without flow).

8.4.6    To abort the test, press Alt+F3 or the "abort" icon.

8.4.7    To restart the test, press the "Redo" icon.

8.4.8    To visualize the Flow-Volume graph, the Volume-Time graph, or the main
parameters click on one of the following:

displays the Flow-Volume graph

displays the Volume-Time graph

displays all numeric data

8.4.9    Repeat the test until the desired number of manoeuvres has been obtained
correctly.

8.4.10   Press ▮ to visualize the test list carried out during the current session.

8.4.11   Select the test you wish to save (results are sorted from best to worst
according to AATS criteria).

8.4.12   Press "OK".

## 8.5  Viewing Test Results

8.5.1    Press File → Patients or press the ▮ icon.

8.5.2    Select the patient whose test you would like to view.

8.5.3    Select up to 5 tests to view from the test list box (FVC, VC/IVC, or MVV).
Press "OK".

8.5.4    To switch between graph and/or data visualization use the following buttons:

shows the Flow-Volume graph (F5)

shows the Volume-Time graph (F6)

shows numeric data (F7)

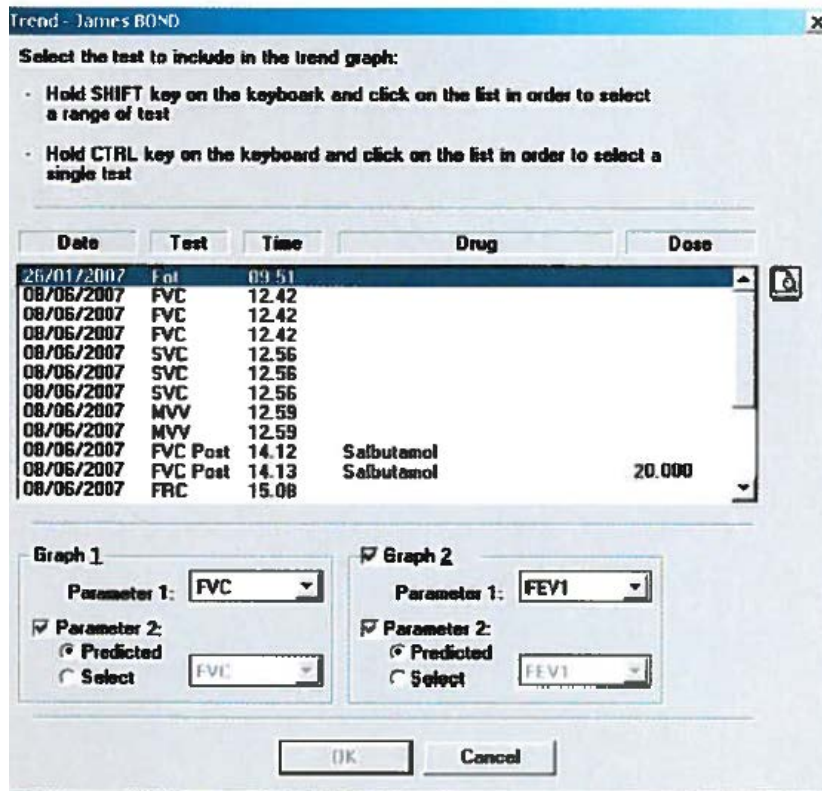shows the broncoprovocator response graph (F8).

8.5.5    To visualize more than one window at a time, select "Window" → "New
Window".

8.5.6    To display the list of tests of the current participant select "View" → "Test
current patient", or press the ▮ icon.

8.5.7    To display a trend of more than one test performed by the same patient select
"View" → "Trend".

*8.5.8*    Select the tests and graphing options you want to display.

*8.5.9*    Press "OK" to confirm.

## 9. Conducting an Exercise Test

***9.1    OPTION A - Holter Data Recorder Mode – used when a participant difficult to monitor by telemetry (i.e., climbing, long distance races, etc.).***

This option allows for the system to be used without the Receiver Unit. Up to 1 MB (16 thousand breaths) of breath-by-breath data is stored within the Portable Unit. Results can be downloaded to the PC via the RS 232 port.

*9.1.1*    Equipment required
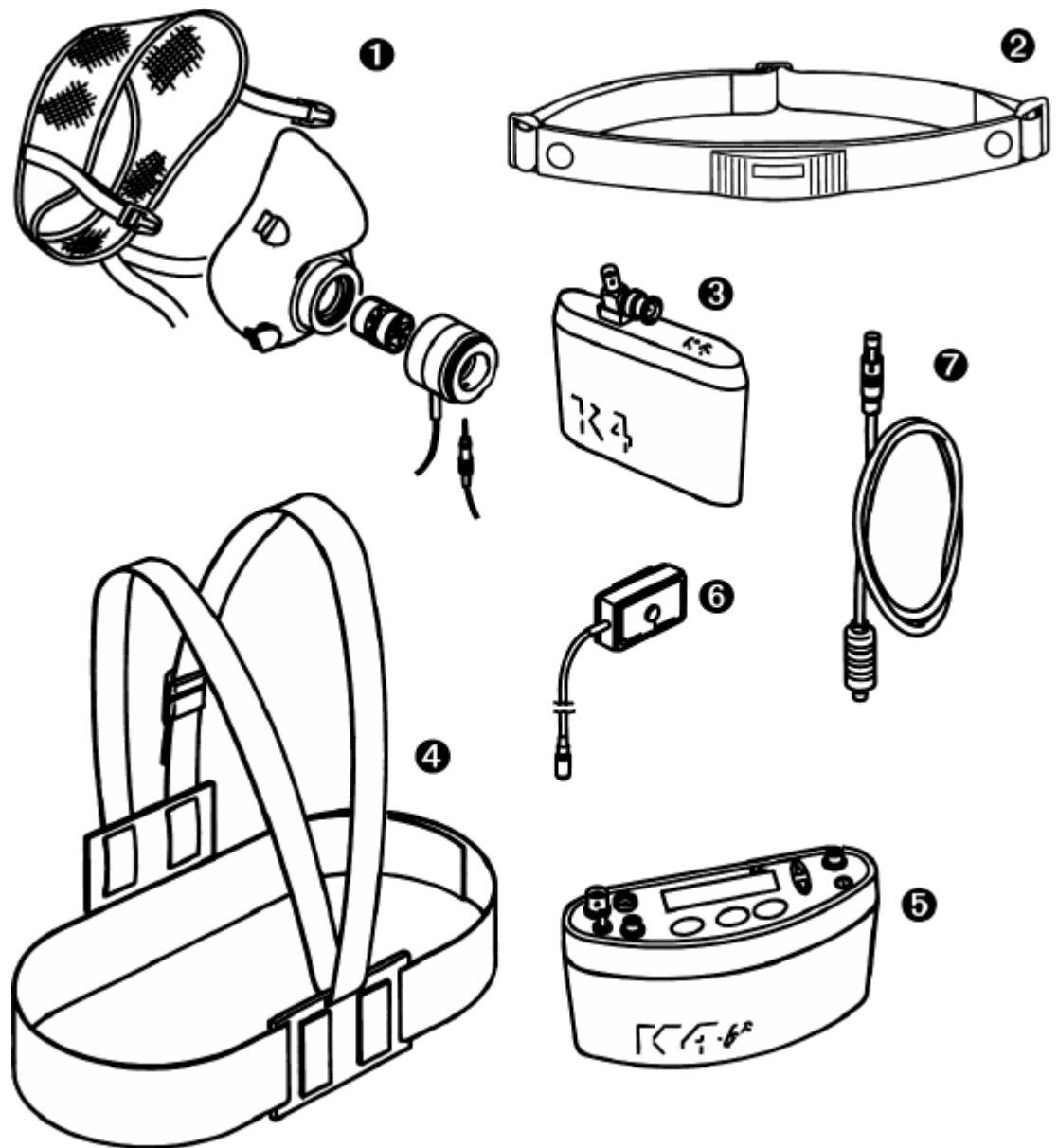
1. Mask, flowmeter, and optoelectronic meter
2. Heart rate transmitter
3. Rechargeable battery
4. Harness
5. Portable unit
6. HR probe
7. Power cable

*9.1.2* Set up K4 b$^2$ on participant

9.1.3   Enter new participant
    9.1.3.1   From "Test" menu, select "Patient's data".
    9.1.3.2   Move the cursor among fields with the Enter key and use Up and Down arrow keys to modify values.

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

# = patient ID
A = age in years
H = height (cm or inches)
W = weight (kg or lbs)
S = sex (M or F)
HR = HR max (automatically calculated using the formula 220-age)

9.1.4   Remove sampling line from the mask and do not breath close to it.

9.1.5   On "Patient Data" menu, scroll down and select "Start Test". Press "Enter" to confirm.

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

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

9.1.7   A Room Air Calibration will automatically start. The message "Do not breath near the sampling line" appears. Wait a few seconds until the message "Calibration done" will appear with a double beep sound.

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

9.1.8   Connect the sampling line to the optoelectronic reader. Some values (HR, 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 every 10 seconds. You can switch to different values by moving the Up and Down arrow keys.

9.1.9   Press "Enter". At this time the Portable Unit is not storing data but checking the main parameters and you can visualize it on the Portable Unit display as "Time" will be blinking.

```
mmm:ss ♥⌐¥HR:xxx[
VO2:xx.xR:x.xx  |
```

9.1.10  Press "Enter" to start storing data.

```
Press Enter to..
VO2:x.xx  R.x.xx
```
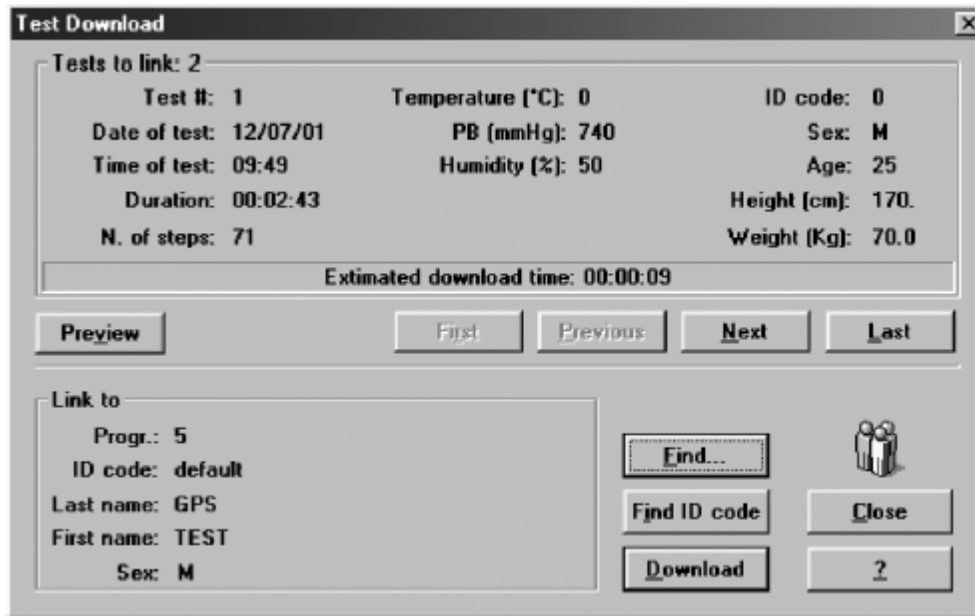
9.1.11  To stop the test, press "Cancel". The message "Press Enter to stop test" will
appear. Press "Enter" to stop test.

9.1.12  Transfer test to PC
    9.1.12.1    Turn Portable Unit on is not already.
    9.1.12.2    Connect Portable Unit to PC by the serial cable and open K4 b$^2$
         software.
    9.1.12.3    Click "Test" → "Receive Test".

**Test Download**

Tests to link: 2

| | | |
|---|---|---|
| Test #: 1 | Temperature (°C): 0 | ID code: 0 |
| Date of test: 12/07/01 | PB (mmHg): 740 | Sex: M |
| Time of test: 09:49 | Humidity (%): 50 | Age: 25 |
| Duration: 00:02:43 | | Height (cm): 170. |
| N. of steps: 71 | | Weight (Kg): 70.0 |

Extimated download time: 00:00:09

Preview    First    Previous    Next    Last

Link to
    Progr.: 5
    ID code: default        Find...
    Last name: GPS
    First name: TEST    Find ID code    Close
    Sex: M        Download    ?

    9.1.12.4    To download a test, click "Find" → "List" to select an existing
         participant. → "OK".
    9.1.12.5    Use "First", "Previous", "Next", and "Last" buttons to select a test on
         the Hard Disk → click "Download".

NOTE: The "Preview" button can be used to view data and graph a test in order to
verify whether it is the correct test.

### 9.2  OPTION B - Telemetry Data Transmission Mode – used to monitor test in real time from a distance.

This option allows for the system to be used with the Receiver Unit where breath-by-breath data is sent by telemetry to the Receiver Unit. The Receiver Unit must be connected to the PC by serial port. Tests are also stored in the memory of the Portable Unit, thus in case of transmission interferences no data will be lost. By using this option the individual can also control and synchronize ergometers by using user defined exercise protocols.

#### 9.2.1  Equipment required
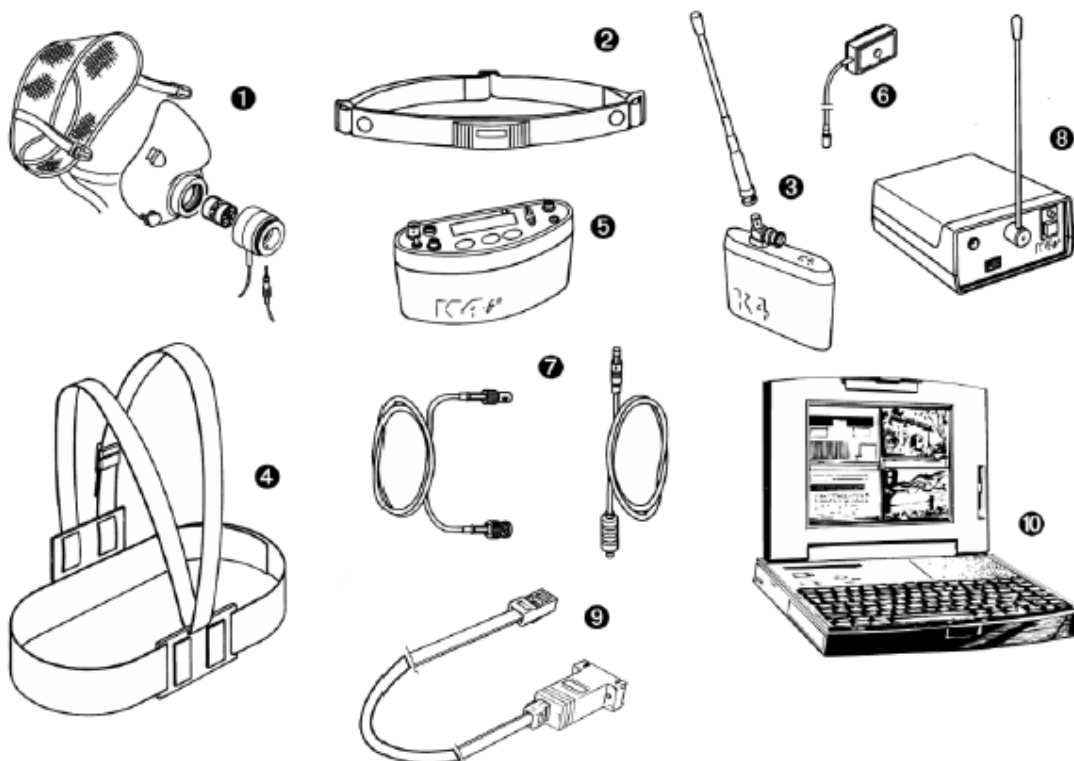


1.  Mask, flowmeter, and optoelectronic reader
2.  Heart rate transmitter
3.  Rechargeable battery and antenna
4.  Harness
5.  Portable Unit
6.  HR probe
7.  Power cable and antenna
8.  Receiver Unit
9.  RS232 cable

10. PC

*9.2.2*   Connect the receiver unit to the PC with serial cable.

*9.2.3*   Turn Receiver Unit on.

NOTE: The Receiver Unit must always be turned on before the Portable Unit.

*9.2.4*   On Portable Unit control panel, verify that transmission is enabled by choosing "Settings/On/Off Transmitter". Press "Enter". Move "*" sign on "Transmit On". Press "Enter".

*9.2.5*   Enter new participant

    *9.2.5.1*   From "Test" menu, select "Patient's data".

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

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

# = patient ID
A = age in years
H = height (cm or inches)
W = weight (kg or lbs)
S = sex (M or F)
HR = HR max (automatically calculated using the formula 220-age)

*9.2.6*   Enable reception on PC

    *9.2.6.1*   Run software

    *9.2.6.2*   Open participant dialogue box, select or type a new name and press "Ok".

*9.2.7*   Remove sampling line from the mask and do not breath close to it.

*9.2.8*   On "Patient Data" menu, scroll down and select "Start Test". Press "Enter" to confirm.

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

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

*9.2.10*  A Room Air Calibration will automatically start. The message "Do not breath near the sampling line" appears. Wait a few seconds until the message "Calibration done" will appear with a double beep sound.

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

9.2.11   Connect the sampling line to the optoelectronic reader. Some values (HR, 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 arrow keys.

9.2.12   Press "Enter". At this time the Portable Unit is not storing data but checking the main parameters and you can visualize it on the Portable Unit display as "Time" will be blinking.

```
mmm:ss ♥⌒Ⴤ HR:xxx
VO2:xx.xR:x.xx
```

9.2.13   Press "Enter" to start storing data.

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

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

9.2.15   Transferring test to PC

NOTE: If some interferences should occur during the test execution by telemetry, some breaths could be lost. The software shows a message on the status bar warning that some steps were missed. Since the Portable Unit stores the complete test in the memory, it is possible to download the test after completion to recover all lost data.

9.2.15.1   Turn Portable Unit on is not already.
9.2.15.2   Connect Portable Unit to PC by the serial cable and open K4 b[2] software.
9.2.15.3   Click "Test" → "Receive Test".
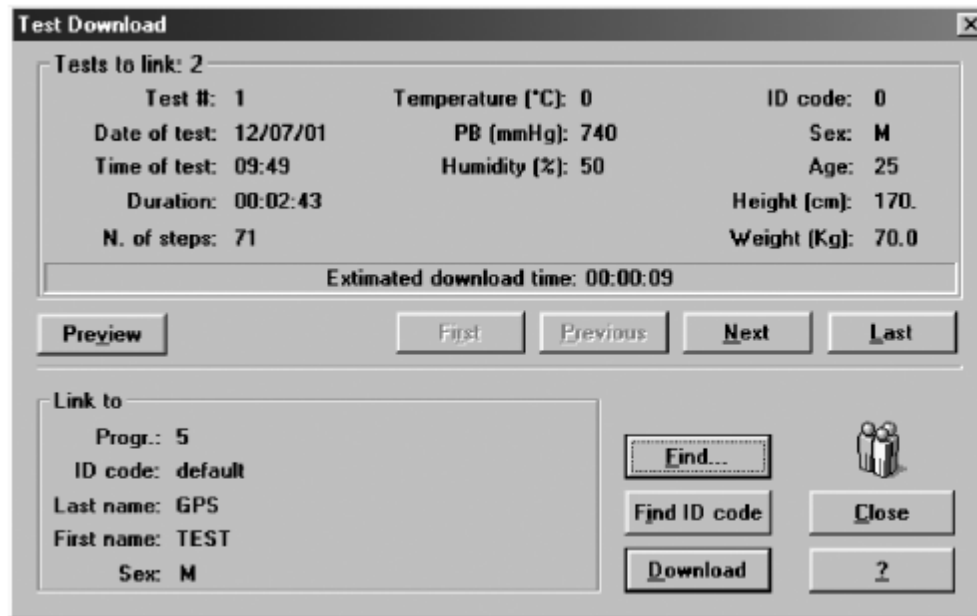
*9.2.15.4*    To download a test, click "Find" → "List" to select an existing
participant. → "OK".

*9.2.15.5*    Use "First", "Previous", "Next", and "Last" buttons to select a test on
the Hard Disk → click "Download".

NOTE: The "Preview" button can be used to view data and graph a test in order to
verify whether it is the correct test.

### 9.3   OPTION C - Serial Mode – used like a conventional laboratory station (i.e. software completely controls the unit).

Although the Cosmed K4 b$^2$ has been designed for field tests, it can also be used as a
conventional laboratory station as it offers the same features as standalone devices. For
this option, the Portable Unit needs to be connected to the PC through the RS232
serial port. Data is also stored on the memory of the portable unit.

*9.3.1*    Equipment required
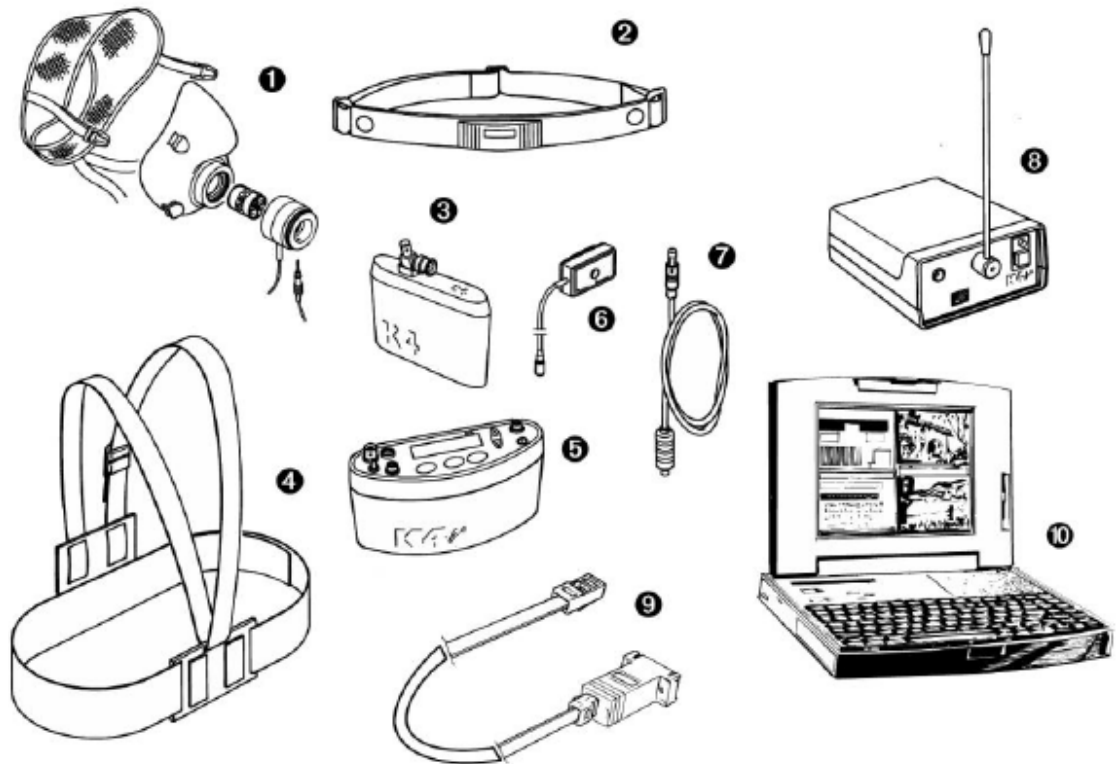
1. Mask, flowmeter, and optoelectronic reader
2. Heart rate transmitter
3. Rechargeable battery
4. Harness
5. Portable Unit
6. HR probe
7. Power cable
8. Receiver Unit
9. RS232 cable
10. PC

9.3.2    Connect the receiver unit to the PC with serial cable.

9.3.3    Click "Option" → select "RS232" to select serial port.

9.3.4    Check the box "Ergometer connected to PC" if you intend to use an ergometer for testing.

9.3.5    Enter participant data

   9.3.5.1    Run software

   9.3.5.2    Open participant dialogue box, select or type a new name and press "Ok".

9.3.6    Start test.

9.3.7    Select the participant.

9.3.8    Enter patient data

*9.3.9*     Start the test.

*9.3.10*    To stop test, click "F3" → "Ok"

NOTE: All data will be saved automatically on the Hard Disk and on Portable Unit.

# 10. GPS (Optional)

NOTE: The GPS can only be used in Holter Recorder Data Mode (OPTION A above) or Telemetry Data Transmission Mode (OPTION B above).

## 10.1 Initialize the GPS

*10.1.1*    If the receiver has not been used for a period of 6 months or more, the unit will search the sky in order to collect satellite orbital information. This process is fully automatic and, under normal circumstances, will take 3-4 minutes to achieve a navigation solution.

*10.1.2*    If the memory backup battery of the GPS fails, the receiver will search the sky as described above. Should the memory battery discharge, the unit needs to be powered on for several hours to ensure a sufficient recharge to maintain several months of clock operation and memory storage.

*10.1.3*    If the initial data is significantly inaccurate, the receiver will perform an operation known as AutoLocate™. This will occur automatically and, under normal circumstance, will require 1.5 minutes to calculate a navigation solution.

     NOTE: the AutoLocate™ function can be manually forced by selecting "Calibration" → "GPS AutoLocate".

*10.1.4*    During the acquisition process a message "acquiring satellites…" is prompted on the display of the Portable Unit.

## 10.2 Fixing the antenna to the participant

*10.2.1*    Position GPS as shown below. For cycling or rowing, it may be required to position the antenna differently.

10.2.2  Connect the receiver antenna to the Portable Unit and plug the phone jack into the RS232 port at the bottom of the Portable Unit.
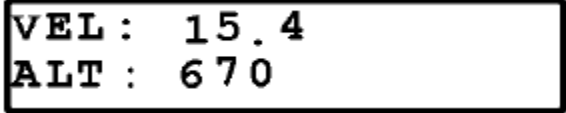


## 10.3  Run a test with the GPS

10.3.1  Select "Settings" → "External Device" → "Enter"

10.3.2  To enable GPS option, move "*" sign on GPS → "Enter"

10.3.3  Go outside and find a large open area that has a clear view of the sky. The GPS needs to receive at least three strong satellite signals to find your location.

10.3.4  To check GPS module functionality, click "Calibration" → "GPS Control" → "Enter"



```
LAT:  41°43.130
LONG: 12°36.701
```

10.3.5 Using Up and Down arrows verify that the displayed altitude value (Alt) is different from zero. If altitude value is zero, check to see if antenna receiver is well plugged in, the sky is visible and wait until the altitude value is shown.

```
VEL:  15.4
ALT :  670
```

10.3.6 To monitor GPS in real time, in PC software select "Options" → "Parameters to view/Test execution …" or " (real time) Parameters to view/Test visualization" (after download)

10.3.7 The following parameters can be viewed:
- Velocity – GPS Vel (m/sec)
- Distance – GPS Dist (meters, incremented during exercise phases only)
- Latitude – Lat (DD MM.MMM'N/S)
- Longitude – Long (DD MM.MMM'E/W)
- Altitude – Alt (meters)

NOTE: Distance is automatically calculated for the exercise phase only.

# 11. Cleaning and Disinfecting

## 11.1 ID28 Turbine

NOTE: The Turbine needs to be cleaned and disinfected after each test.

NOTE: Do not use alcoholic solutions to clean Turbine as it can damage the plastic material.

11.1.1 Take out the turbine.
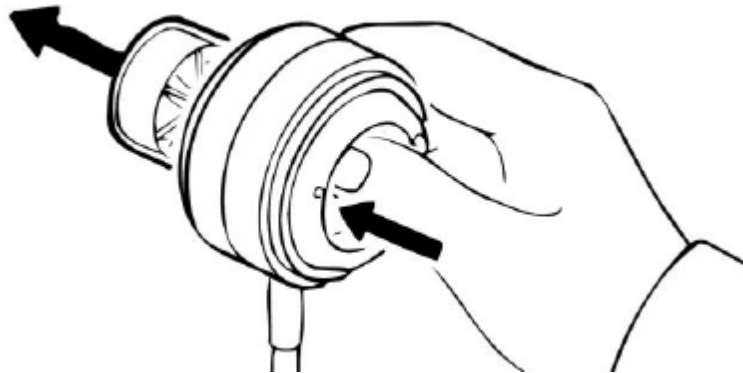
11.1.2   Prepare one of the following solutions:
- For use within 24 hours - 1 part household bleach (sodium hypochlorite 5.25%) to 9 parts water.
- For use within 30 days - 1 part household bleach (sodium hypochlorite 5.25%) to 4 parts water.

11.1.3   Soak Turbine in solution for 20 minutes.

11.1.4   Rinse the Turbine in a vessel filled with clean water, shaking gently to remove the disinfectant.

NOTE: DO NOT RINSE BY PUTTING UNDER RUNNING WATER!

11.1.5   Check if the turbine propeller rotates freely even with a low speed airflow.

11.1.6   Let air dry.

## 11.2   Facemasks

NOTE: Facemasks need to be cleaned and disinfected after each test.

11.2.1   Prepare a solution of hot water and mild detergent.

11.2.2   Place facemask(s) in solution.

11.2.3   Rub vigorously in soapy water.

11.2.4   Rinse facemask vigorously in warm water.

## 11.3  Sampling Line

11.3.1   No cleaning or disinfection required. Let air dry. Alternate use of sampling lines between participants.

## 11.4  Antibacterial Filters

11.4.1   No cleaning or disinfection required. Disposable after each use.


## 11.5  Tubing for Aquatrainer

11.5.1   Remove clear tubing from Aquatrainer by slowly sliding out of various loops and yellow plastic structures wrapped around tubing.

11.5.2   Prepare a solution with warm water and mild soap.

11.5.3   Place tubing in solution making sure that solution is found within the tubing. Shift tube up and down to allow water to displace.

11.5.4   Let air dry.

# APPENDIX I

# Portable Unit User Interface Diagram

# Portable Unit User Interface Diagram

**Settings**

- On/Off Transmitter
- Enable/Disable Warnings
- Set Date and Time
- Units of Measurement
- Restore Factory Settings
- Warm up time Setting
- External Device
- Turbine 18/28
- Altitude Setting
- Version

**Memory functions**

- Memory Status
- View Test list
- Erase Memory

**Test**

- Patient's Data
- Start Test

**Calibration**

- Room Air Calibration
- Reference Gas Calibration
- Turbine Calibration
- $O_2/CO_2$ Delay Calibration
- Set Calibr. Pred. Values
- Set Calibr. Factors
- Control Panel
- GPS Autolocate

# APPENDIX 2

# Toolbar Icons

## Toolbar icons of the PFT software

Opens the patients database

Opens a test of the current patient

Prints the report

Prints the current window

Preview print

Shows the F-V graph

Shows the Oximetry graph

Shows the Oximetry steps

Shows the Volume-Time graph

Shows the measured data

Shows the bronchoprovocator response

Shows the trend

Shows the last performed test

Starts the calibration program

Selects a test to be performed

Creates a new window

Places the windows in cascade

Tiles the windows horizontally

Tiles the windows vertically

Closes all open windows

## Toolbar icons in the PFT software (real time)

| Icon | Description |
|------|-------------|
| EXIT | Exits from the test mode |
| START | Starts the test |
| REDO | Restarts the test |
| STOP | Ends the test |
| ABORT | Aborts the test |
| FVC | Shows the F-V graph |
| SP02 | Shows the Oximetry graph |
| STEP | Shows the Oximetry steps |
| VT | Shows the Volume-Time graph |
| DATA | Shows the measured data |
| %FEV | Shows the bronchoprovocator response |
| | Shows the trend |
| | Creates a new window |
| | Places the windows in cascade |
| | Tiles the windows horizontally |
| | Tiles the windows vertically |

## Toolbar icons of the CPET software

Opens the patient's database

Prints the current window

Prints the report

Starts the calibration program

Starts the test

Shows the data from a test

Show the graph from a test

Calculates the Anaerobic Threshold

Shows the predicted values and the % predicteds of measured parameters

Opens an event of the selected test

Shows information from the selected test

Edits the test

Exports a test

Sends a test to Excel

Selects the parameters to be displayed

Selects, creates and/or edits the exercise protocol used to drive an ergometer during testing

Customizes parameters

Tiles the windows horizontally

Tiles the windows vertically

Closes all open windows

## Toolbar icons in the CPET software (real time)

| Icon | Description |
|------|-------------|
| START | Starts data acquisition during the test |
| STOP | Ends the test |
| EVENT | Performs an event during testing |
| VO2 VCO2 VE HR | Selects the parameters to be viewed during testing |
| GRAPH | Shows a graph of the current test |
| | Selects a test protocol |
| | Shows information of the current test |
| MARK | Enters a marker during testing |
| LOAD | Changes the load or phase during testing |
| BP | Enters a parameter (Systolic/Diastolic Blood Pressure, or a user defined parameter) |
| | Starts the exercise phase during testing |
| | Starts the recovery phase during testing |
| REC | Stores the ECG |
| QRS | Shows the QRS |
| LEADS | Shows the 12 leads |
| | Creates a snapshot of the ECG |
| | Tiles the windows horizontally |
| | Tiles the windows vertically |
| | Closes all open windows |

# APPENDIX 3

# POD Training Record Form

**Use and Cleaning Procedures for Cosmed K4 b$^2$ Portable Metabolic System**

**POD Code**

| Ownership | Document type | Area | POD Number | Version |
|-----------|---------------|------|------------|---------|
| PC | POD | CP | 009 | 01 |

**Training Record**

| Full Name | |
|-----------|---|
| Institution | |
| Contact (email or phone number) | |

**Signature**

_____          _____

Sign here (trainee)                                      Date


_____          _____

Sign here (Cardio-Pulmonary Coordinator)        Date