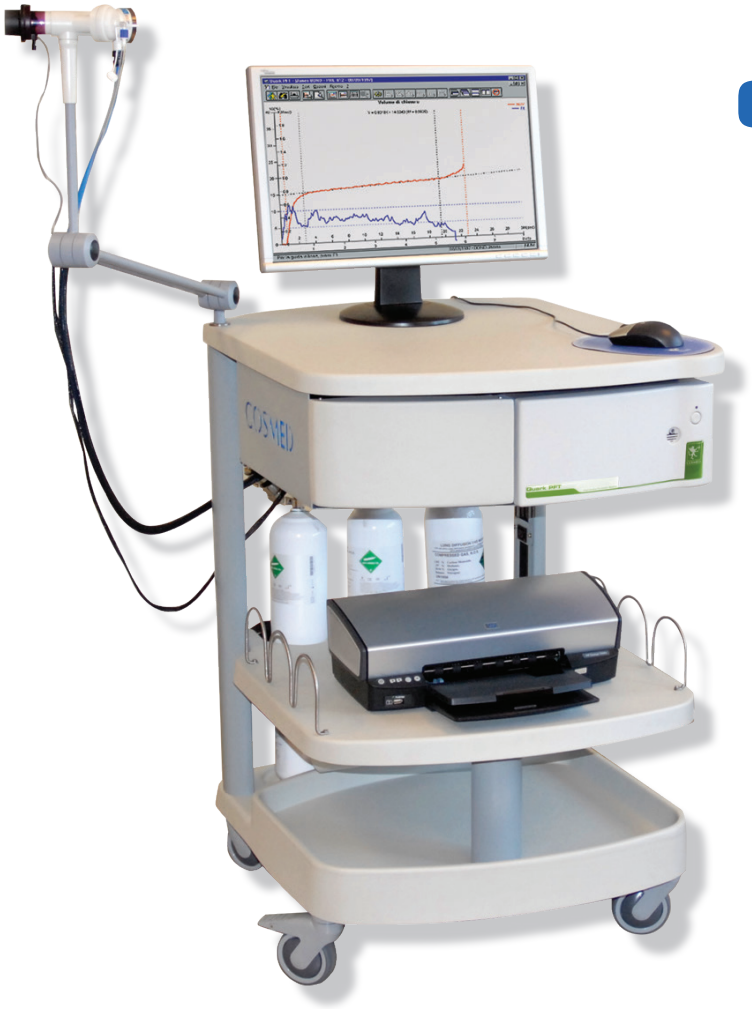
Quark PFT
Quark CPET
Quark SPIRO



Manuale Utente

User Manual

Manuel d'utilisation

Benutzerhandbuch

Manual del Usuario

COSMED
The Metabolic Company

Quark User manual, XIII Edition

01/2018

COSMED Srl - Italy

http://www.cosmed.com

Part N. C03262-02-91

Table of Contents

Getting Started

Important Notices

Intended Use

The COSMED Quark Series is a modular system with multiple configurations which can perform the following tests: Spirometry, Lung Function, Cardiopulmonary Exercise, and Resting Metabolic Testing.

The system and its accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic parameters. The main measurements which are displayed by this product line are Oxygen Uptake, Carbon Dioxide Production, Air Flow, Ventilation, Heart Rate and Energy Expenditure. It is intended to assist a clinician in the diagnosis of cardiac and pulmonary diseases.

Caution: Federal law restricts the sale of this device by or on the order of a licensed healthcare practitioner ~~to be sold to the order of a physician~~.

The Quark Series devices must not be used as monitoring device, nor as a sole means for determining a patient's diagnosis, but for the purpose of assisting the clinician in the cardiac and pulmonary ~~cardio-pulmonary~~ diseases.

This equipment is intended to be used for the following applications:

- Understanding and Formulating lung pathology diagnosis
- Assisting with human physiology studies
- Contributing to sports medicine applications

COSMED Srl is not responsible for incidents which occur due to improper use of this device. Examples include:

- Operation of the device by unqualified individuals
- Use of the device not indicated by this manual
- Not complying with the precautions and instructions described in this manual

Specific Indications for Use

Model	Indication for Use	Major Clinical Applications	Measured Parameters
Quark SPIRO	Pulmonary Function testing (Age 6 to adult)	Spontaneously breathing patients, healthy or individuals affected by respiratory disease (asthma or COPD, etc.)	FVC, FEV_1, $FEF_{25-75\%}$, PEF, MVV, SpO_2
Quark PFT	Pulmonary Function testing (Age 6 to adult) Cardiopulmonary Exercise Testing (Age 6 to adult)	Spontaneously breathing patients, healthy or individuals affected by respiratory disease (asthma or COPD, etc.)	FVC, FEV_1, $FEF_{25-75\%}$, PEF, MVV, FRC, DLCO, MIP/MEP, P0.1, SpO_2, Ve, RF, HR, VO_2, VCO_2, TGV
Quark CPET	Pulmonary Function testing (Age 6 to adult) Cardiopulmonary Exercise testing (Age 6 to adult)	Spontaneously breathing patients, healthy or individuals affected by diseases which limit exercise tolerance	FVC, FEV_1, $FEF_{25-75\%}$, PEF, MVV, VO_2, VCO_2, Ve, RF, HR, SpO_2

Quark SPIRO and Quark PFT can also measure Airways Resistance Test using the interrupter technique (R_{OCC} test) for pediatric patients (3 to 6 years old). R_{OCC} technique was specifically developed for pediatric population and uncooperative children unable to perform spirometric maneuvers (FVC, SVC, etc.). The interrupter technique is possible to perform with preschool children, with repeatable results that correlate well with "gold standard" techniques.

Measured Parameter Table

Parameter	Description	Parameter	Description
FVC	Forced Expiratory Vital Capacity	**P0.1**	Respiratory Drive
FEV_1	Forced Expiratory Volume in 1 sec	**V_E**	Ventilation
$FEF_{25-75\%}$	Mid-expiratory flow between 25-75% of the FVC	**RF**	Respiratory frequency
PEF	Peak Expiratory Flow	**HR**	Heart Rate
MVV	Maximum Voluntary Ventilation	**VO_2**	Oxygen uptake
FRC	Functional Residual Capacity	**VCO_2**	Carbon Dioxide production
DLCO	CO Diffusion Capacity	**SpO_2**	Hemoglobin saturation
MIP	Maximum inspiratory pressure	**TGV**	Thoracic Gas Volume
MEP	Maximum expiratory pressure		

Warnings

The device, program algorithms and presentation of the measured data has been developed in accordance with the specifications outlined by the ATS (American Thoracic Society) and ERS (European Respiratory Society). Additional international references have also been applied where applicable. There is a bibliography of all references in the AppendixThis User Manual has been developed in accordance with the Class IIa European Medical Device Directive requirements

> ***Warning:*** *To avoid risk of electric shocks, this device must be connected to sockets with protective earth*

Read and understand these precautions before operating the device to ensure the safety of user and subject

1. This User Manual should always be available as a reference while testing
2. The following standards should be applied to ensure the accuracy of individual test results:
   - Accessories should only be used as they are described in this manual. The manufacturer does not warranty the use of any unauthorized accessories. The manufacturer may offer suggestions while using third-party accessories and the complications which may occur
   - Device Service and Repair should ONLY be performed by COSMED authorized and trained personnel
   - Environmental and electrical conditions in which the device operates must comply with this manual. Note that the reliability of the device ground and leakage current suppression is only assured when the three-wire power cord is connected to a grounding point (yellow-green return connected to earth ground). Any attempt to avoid the proper groung connection is dangerous for both the user and equipment
   - Equipment maintenance, inspections, disinfection and cleaning should be as described in this manual.
3. Prior to powering on the system, the power cords and plugs should be fully inspected. Any damaged electrical part(s) must be replaced immediately by COSMED authorized personnel.
4. Gas cylinders:
   a. Large gas cylinders provided by the manufacturer or purchased by the customer must be secured with cylinder safety chains or safety stands as required by local law
   b. After removing the cylinder's protective cap, the valve should be inspected for damaged threads, dirt, oil and/or grease. Any dust or dirt should be removed; however, the cylinder should not be used if oil, grease, or damaged threads are present
   c. Ensure that the pressure regulator is compatible with the intended gas cylinder (chemically and physically) prior to installation
   d. The regulator must be properly connected and working pressure adjusted and displayed on the regulator
   e. Close cylinder before disconnecting the cylinder from the
5. Residue and other contaminants in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminants can be potentially life-threatening. Each component in contact with the subject's breath should be cleaned and disinfected prior to each test
6. The cleaning procedures and inspections in the System Cleaning & Maintenance section should be performed prior to each test
7. This device should not be used in the presence of flammable anaesthetics. This is not an AP or APG device (according to the EN 60 601-1 definitions)
8. The device should not come near any heat or flame sources, flammable or inflammable liquids or gases and explosive properties
9. The device should not be used in conjunction with any other medical device unless that device is recommended by the manufacturer

10. The device should be used with a computer with electromagnetic compatibility, CE marking and low radiation emission displays
11. The PC connected to the device must be compliant with EN 60601-1 by means of an isolation transformer
12. Precautions regarding EMC should be taken prior to installation and can be noted in the section EMC
13. Portable and mobile RF communication equipment may interfere with the performance of the device
14. Only the cables and accessories supplied with the equipment should be used with the device. The use of any other accessories and/or cables may result in increased emissions or decreased immunity of the equipment
15. The device should not be placed adjacent to or stacked either on top or under other equipment. If this is absolutely necessary, the device operation must be verified to ensure normal operation The graphical symbols used with the device are described below:


Applied part type B (EN60601-1)


Applied part type BF (EN60601-1)


OFF

ON


Protective earth ground

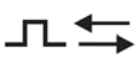

Alternating current


Refer to the instructions for use


Potential equalization node


PC connection


Connector for the RH/TA sensor


TTL auxiliary input/output


USB connector


HR probe connector

Contraindications

Performing forced expiratory maneuvers in spirometry testing may be contraindicated as outlined below.

Contraindications for the Spirometry

Absolute Contraindications

FVC, VC and MVV tests:

- Post-operative thoracic surgery patients

FVC tests:

- Severe instability of the airways (patients with severe Emphysema)
- Bronchial non-specific marked hypersensitivity
- Severe gas exchange impairment (total or partial respiratory insufficiency)

Relative Contraindications

FVC tests:

- Spontaneous post-pneumothorax
- Arterial-venous aneurysm
- Severe arterial hypertension
- Pregnant with complications in the 3rd month (12 weeks)

MVV tests:

- Hyperventilation syndrome

Contraindications for Bronchial Provocation Testing

Bronchial Provocation testing must be executed under the direction of a physician. Testing is considered safe when executed properly in a clinical setting, however the following contraindications should be acknowledged prior to testing:

Absolute Contraindications

- Severe bronchial obstruction (decreased FEV_1 in adults)
- Recent myocardium infarction
- Recent cerebral vascular accident
- Known arterial aneurysm
- Inability to understand the provocation testing procedures implications

Relative Contraindications

- Bronchial obstruction caused by performing respiratory maneuvers
- Moderate or serious bronchial obstruction ($FEV_1 < 1.51$ in men and $FEV_1 < 1.21$ in women)
- Recent respiratory infection
- Recent Asthma exacerbation
- Hypertension
- Pregnancy
- Epilepsy

Contraindications for Exercise Testing

Absolute Contraindications

- Acute MI (within the past 2 days)
- High-risk/unstable angina
- Uncontrolled cardiac dysrhythmias causing symptoms of hemodynamic compromise
- Active endocarditis
- Symptomatic severe aortic stenosis
- Decompensated symptomatic heart failure
- Acute pulmonary embolus or pulmonary infarction
- Acute non-cardiac disorder that may affect exercise performance or be aggravated by exercise (e.g., infection, renal failure, thyrotoxicosis)
- Acute myocarditis or pericarditis
- Physical disability that would preclude safe and adequate test performance
- Inability to obtain consent

Relative Contraindications

- Left main coronary stenosis or its equivalent
- Moderate stenotic valvular heart disease
- Electrolyte abnormalities
- Tachyarrhythmias or bradyarrhythmias
- Atrial fibrillation with uncontrolled ventricular rate
- Hypertrophic cardiomyopathy
- Mental impairment leading to inability to cooperate
- High-degree AV block

> ***Note:*** *Relative contraindications can be superseded if benefits outweigh risks of exercise.*

Review the section, *Prepare the Quark Unit and Subject for Exercise Testing*

Environmental Conditions for Operation

1. COSMED devices should not be operated near explosive substances
2. COSMED devices should not be installed near electrical or magnetic devices such as x-ray equipment, transformers or power lines. These devices could create electrical interference when performing testing procedures.
3. COSMED devices are not AP or APG units (according to EN 60601-1) and should never be operated in the presence of flammable anaesthetic mixtures
4. COSMED devices should be operated under normal environmental temperatures and conditions [IEC 60601-1/EN 60601-1]:
   - **Temperature**: 10°C (50°F) and 40°C (104°F)
   - **Relative humidity**: 30% to 90% (not condensing)
   - **Atmospheric Pressure**: 600 mBar (450 mmHg) to 1060 mBar (795 mmHg)
   - Avoid operating equipment in the presence of noxious fumes or in a dusty environment
   - Do not place units near heating sources
   - Cardiopulmonary resuscitation equipment should be accessible in the case of an emergency
   - Adequate floor space and easy access to the subject during exercise testing is necessary
   - Adequate ventilation should be maintained in the room the testing is to be performed
   - No other testing should be performed in the room simultaneously

Overview

This manual is organized in the following chapters:

1. ***Getting Started*** –Describes the intended use of the device, how to properly use it and features of the unit and accessories
2. ***Installation*** – Lists the steps required to properly install the device
3. ***System Cleaning & Maintenance*** –Describes system cleaning, disinfection and routine maintenance procedures
4. ***Appendix*** – Contains information regarding the warranty, treatment of personal data, reference standards, technical features, predicted values and bibliographic references

Software and test execution are described in the Software Manual. We recommend reading both manuals before using this device.

Introduction

The Quark is the designed for evaluation of the cardiorespiratory system

The system can perform spirometry, lung volumes, diffusion or exercise testing

The Quark can be configured with the following modules according to the specific application:

	Quark Spiro	Quark PFT	Quark CPET
Spirometry	☑	☑	○
Lung Volumes	-	○	-
Diffusing Capacity (DLCO)	-	○	-
Respiratory Mechanics	-	○	-
CPET	-	○	☑
Dosimeter	○	○	-
Oximeter	○	○	○
Airway Resistance	○	○	-
Mixing Chamber	-	○	○

☑ Standard

○ Optional

The Quark Spiro and Quark PFT **must** be configured with either the turbine flowmeter or X-9 PNT

Each module will allow the following tests to be performed:

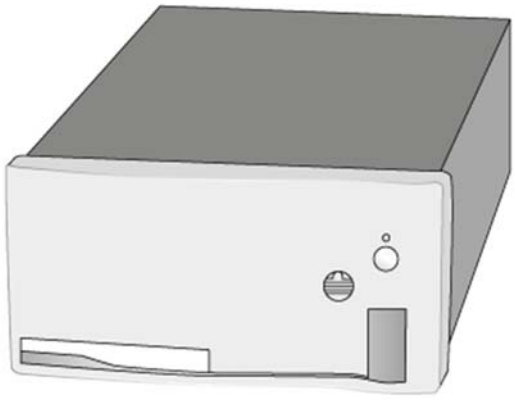
Module	Tests Available
Spirometry	FVC, VC, MVV
Lung Volumes	FRC (via Nitorgen Wash-out), Closing Volume
Diffusing Capacity (DLCO)	Diffusing Capacity (with or without apnea, or intra-breath method)
Respiratory Mechanics	MIP/MEP, P0.1
CPET	Breath-by-breath exercise testing
Dosimeter	Allows measurements to be obtained after the delivery of broncho-provocators according to standardized protocols
Oximeter	Oximetry Tests
Airway Resistance	Airways Resistance using the interrupter technique (Rocc)
Mixing Chamber	Exercise testing using the mixing chamber technique (ideal for sports medicine)

System Overview

The Quark Series consists of the following main parts:

- Quark unit
- Flowmeter
- Breathing valve (if required)
- Additional external sensors and devices (temperature-humidity, HR, oximeter)

Quark Unit



The Quark unit contains the following elements:

- Power switch (located on the front panel)
- Connectors and ports (located on the rear panel)

Powering on the device

When the unit is plugged in, press the power switch on the front panel. The green led above the switch will turn on, indicating that the Quark is on

Powering off the device

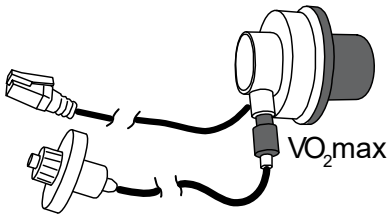
Press the power switch on the front panel. The green led above the switch will turn off, indicating that the Quark is no longer powered on

Flowmeter(s)

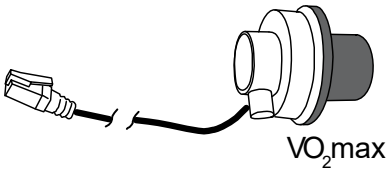
Turbine Flowmeter

The turbine flowmeter assembly consists of a bidirectional turbine and an optoelectronic reader. The reader measures infrared light interruptions caused by the spinning blade inside the turbine. The device may be used to measure a wide flow range and is not affected by ambient conditions (pressure, humidity, room temperature, exhaled gas concentration). Daily calibration of the turbine is not necessary, however calibrations should be performed regularly to ensure accurate measurements.

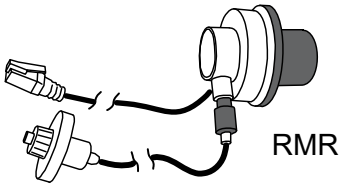
There are three turbine flowmeters: ID28, ID28 Spiro and ID18.



The ID28 flowmeter can be used for all tests except for RMR testing and is provided with the Quark PFT and Quark CPET units and CPET module

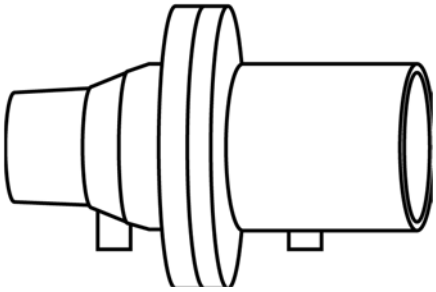


The ID28 Spiro flowmeter is identical to the ID28 with the absence of a sampling line. This flowmeter should only be used for spirometry testing when exhaled gas analysis is not necessary. This flowmeter is provided with the Quark Spiro unit.



The ID18 flowmeter is used for RMR testing and it is provided with the Nutritional assessment module

Pneumotach X9 (PNT)



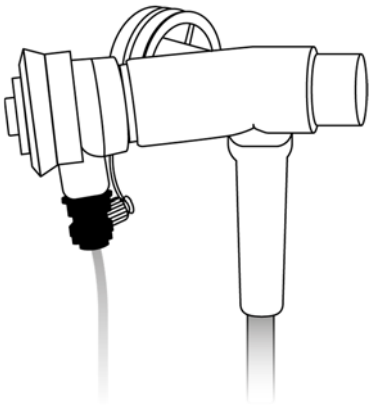
The X9 calculates the flow by measuring differential pressure between the two sides of a polyester mesh net.

The X9 can be reused, after proper disinfection and must be calibrated using the same procedure asthe turbine flowmeter, however it is required to calibrate prior to each test. It can be used for all spirometry tests

Each X9 is shipped with an individualized linearization table. It is necessary to load the table from the paired USB drive (same serial number) into OMNIA, see the *Calibration* chapter for more information.

> ***NOTE:*** *The PNT X9 can ONLY be used with the COSMED antibacterial filter*

The Breathing Valve



This breathing valve allows the breathing circuit to automatically switch between the demand valve (connected to the gas cylinder) and ambient air. This valve closes during DLCO testing to block the air going to the patient during the required apnea time. The body of the valve is made of ABS plastic with a silicone membrane used to open and close the breathing circuit. The valve is easily connected to the flowmeter and easily disassembled for disinfection. Either the patient should hold the valve, or an articulated arm should can be used to support it

> *There are 2 versions of the breathing valve depending on which flowmeter is used (PNT X9 or Turbine)*

Hans Rudolph V2 Exercise Testing Mask

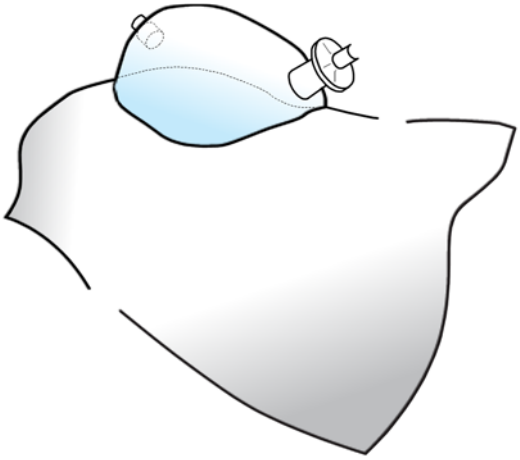
The exercise test masks are made of silicone and may be reused after proper disinfection (see the chapter System Cleaning & Maintenance). These blue masks are available in different sizes and should be assembled the included head cap as shown in the chapter *Exercise testing*.

Mask without Inspiratory Valves
(Required for Exercise Flow Volume Loops)

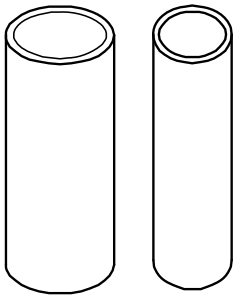
Mask with Inspiratory Valves

Turbine Assembly with Mask

The canopy hood

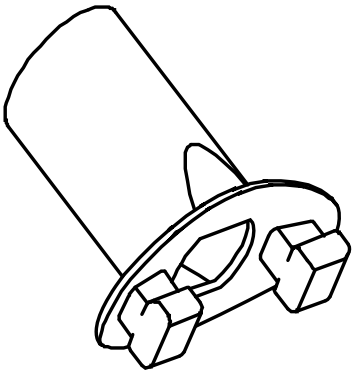


The canopy hood allows mixes the exhaled air from the subject with ambient air. This mixture is then drawn by a pump with a known flow and the subject's Oxygen Consumption, CO_2 production and Energy Expenditure can be calculated.Paper mouthpieces



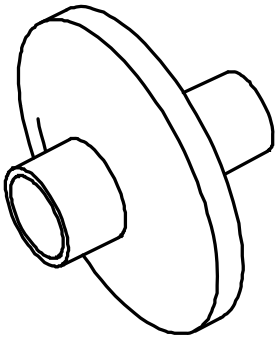
Paper mouthpieces are available for simple spirometry tests (FVC, VC, and MVV). The mouthpieces should not be used for any other testing.

Soft PTE Mouthpieces



The soft PTE mouthpieces are available for all lung function tests other than spirometry.

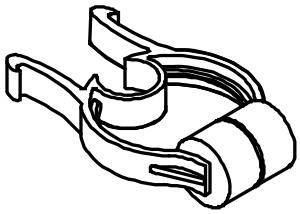
Antibacterial filters



Antibacterial filters are recommended for infection control, however, this does not eliminate the need for regular cleaning and decontamination of lung function equipment

> ***Note:*** *The use of antibacterial filters is recommended even when using disposable mouthpieces to prevent cross-contamination*

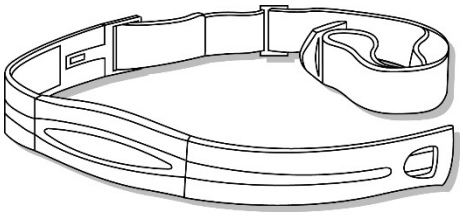
Nose Clips



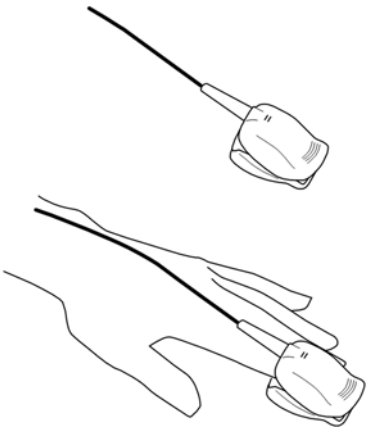
Nose clips should be used during spirometry testing to prevent respiration through the nasal passage while performing testing maneuver

HR Monitor

The HR Monitor consists of three parts: the elastic belt containing the transmitter and the USB receiver. The parts should be near one another for the most effective communication signal

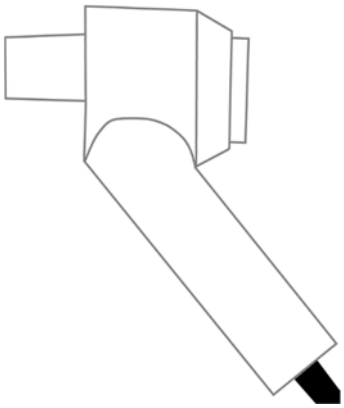


Oximeter



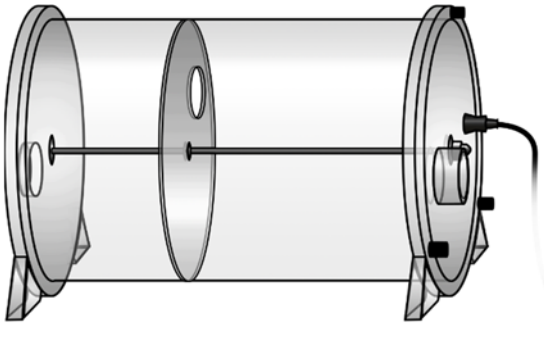
The oximeter probe should be placed on the patient's finger to measure oxygen saturation both at rest and during exercise. The probe should be oriented with the image of the finger on the top and the cable running down the hand as shown in the image above

R_{OCC} PNT



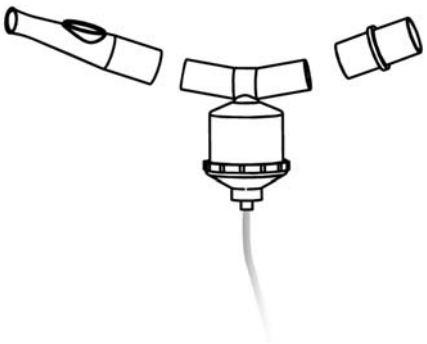
The R_{occ} PNT measures airway resistance by interrupter technique

Mixing Chamber



The mixing chamber is a 8.7-liter plexiglass cylinder for resting or exercise or resting dtudies utilizing the mixing chamber modality instead of breath-by-breath

Dosimeter



The dosimeter is comprised of a nebulizer and accessories used to deliver the bronchoprovocator to the subject during bronchoprovocation tests. The package includes nebulizer, tube to connect to quar, mouthpiece and multiple adapters, detailed information on operation can be found in the *Dosimeter* chapter

System Warm-Up

Each Quark unit must be warmed up prior to use for the required amount of time. The warm-up time depends on which test is being performed. Below is a table displaying minimum warm-up times based on each test:

Test	Warm-up Time (mins)
FVC, VC, MVV	-
FRC	5
CV	5
DLCO	15
MIP/MEP	-
P0.1	-
Oximetry	-
R_{occ}	-
CPET	5
RMR	5

During the warm-up, the device must be powered on, however the software does not need to be open.

Calibration and/or testing procedures should not be performed until the warm-up period has been completed.

Installation

Before Starting

Before operating any model in the Quark Series, the equipment must be inspected and the COSMED Installation-Training Report completed

Checking the Packing contents

- Check the items shipped against the Packing Slilp / Invoice to ensure all items have arrived. If any piece is missing, note it on the Installation-Training Report And contact COSMED Education for assistance (education@cosmed.com)

Optional Modules

The unit is made of a main unit which may or may not have one or more optional modules installed (listed below)

The table below contains the REF (part number) and description for each module and associated Quark model which they can be configured for If you wish to purchase an optional module after the initial purchase, please contact COSEMD sales department or your local distributor.

REF	Description	Available for
C03248-01-11	Turbine (ID28) module	PFT, CPET
C03248-02-11	Turbine SPIRO (ID28) module	SPIRO
C03246-01-11	PNT X9 module	SPIRO, PFT
C03255-01-11	Lung Volumes Module	PFT
C03256-02-11	Lung Volumes Module (with CPET pre-installed)	PFT
C03240-01-11	DLCO Module	PFT
C03257-01-11	Respiratory Mechanics Module	PFT
C03254-02-11	CPET Module	PFT
C03254-01-11	CPET Module (with Lung Volumes pre-installed)	PFT
C02390-01-05	Oximeter Module (with finger probe)	SPIRO, PFT, CPET
C02700-01-11	Airways Resistance Module	SPIRO, PFT
C03261-01-11	Mixing Chamber Module	PFT, CPET
C03250-01-11	Dosimeter Module	SPIRO, PFT
C03251-01-11	Q-Box Module	PFT

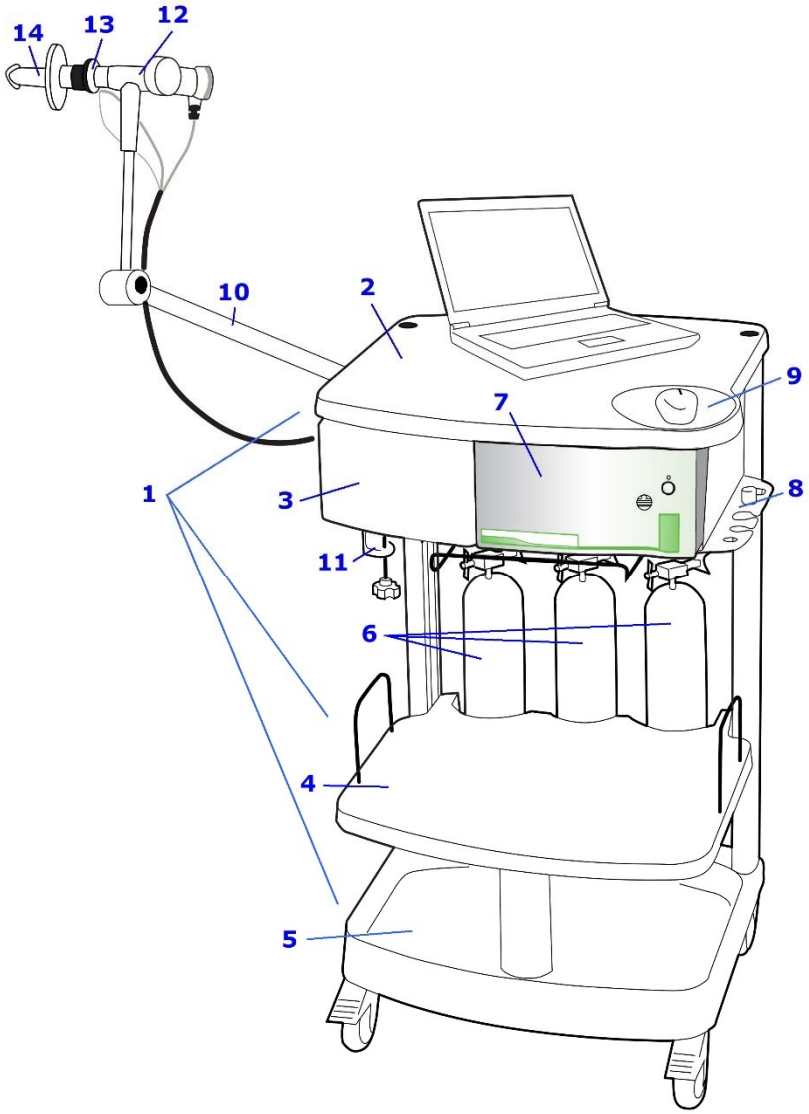
Options / Accessories

The following Options / Accessories are available with the Quark system:

REF	Quantity	Description
A 860 000 004	1	Calibration cylinder (5% CO_2, 16% O_2, balance N_2)
A 860 000 005	1	DLCO cylinder (0.3% CO, 0.3% CH_4, 21% O_2, bal. N_2)
A 860 000 006	1	DLCO cylinder Steady State (0.1% CO, 0.1% CH_4, 21% O_2, bal.N_2)
A 860 000 007	1	Oxygen cylinder
C02900-01-04	1	Trolley (without Arm)
C02870-01-04	1	Arm for Trolley
A 870 150 005	1	Pressure Regulator for Calibration cylinder
A 870 150 006	1	Pressure regulator for O_2 cylinder
A 870 150 011	1	Pressure regulator for DLCO cylinder
C03611-01-10	1	Mask VO_2max Small
C03612-01-10	1	Mask VO_2max Medium
C03613-01-10	1	Mask VO_2max Large
C03616-01-10	1	Mask VO_2max X-Small (paediatric)
C03620-01-10	1	Mask VO_2max Petite (paediatric)
C03614-01-10	1	Mask RMR X-Ssmall (paediatric)
C03615-01-10	1	Mask RMR Petite (paediatric)
C03617-01-10	1	Mask RMR Small
C03618-01-10	1	Mask RMR Medium
C03619-01-10	1	Mask RMR Large
A-800-900-022	1	Head cap for the adult masks (L)
C02600-01-05	1	Xpod Oximeter (w/o probe)
A-661-900-030	1	Xpod finger probe adult
A-661-900-031	1	Xpod finger probe pediatric
A-661-900-033	1	Xpod reflectance probe
A-661-900-032	1	Xpod ear probe

System Description

The Quark system consists of the main unit, modules and accessories. The following picture displays the correct assembly.

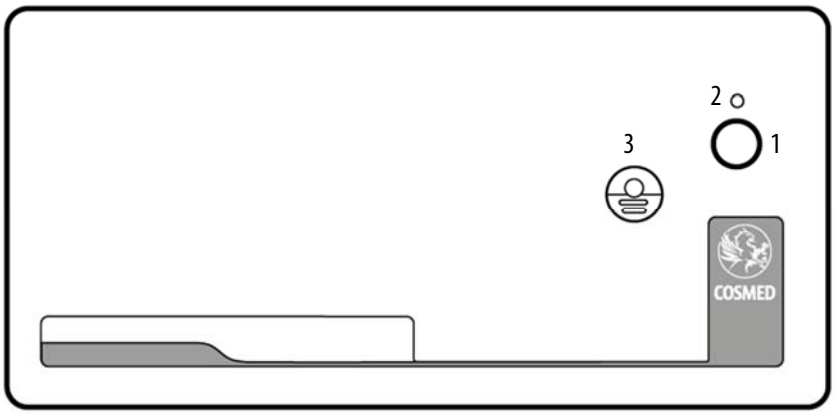


1. Trolley
2. Trolley Top
3. Supply Drawer
4. Printer shelf
5. Accessory shelf
6. Gas Cylinders
7. Quark unit
8. Holder for breathing valve, turbine, etc.
9. Mouse pad area
10. Support Arm
11. Vice for fixing the arm
12. Breathing valve
13. Turbine flowmeter
14. Antibacterial filter

Quark Installation

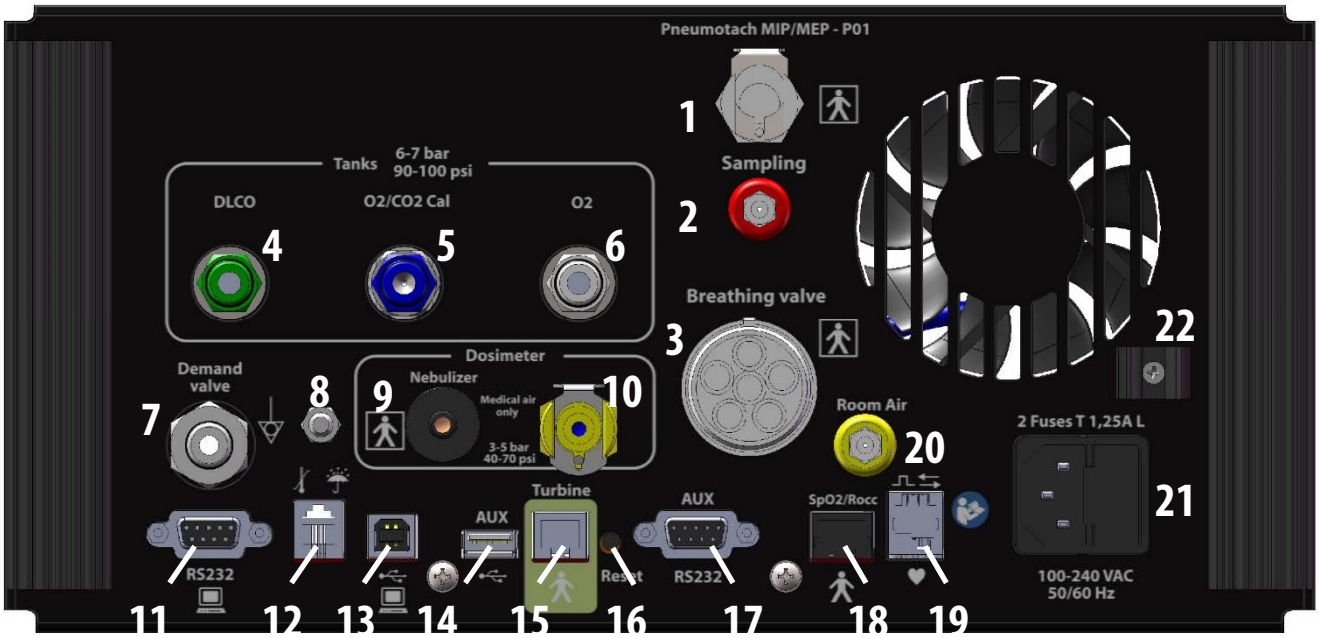
Before operating the Quark Unit, the required environmental conditions should be verified to be within the acceptable range, for more information, refer to the Environmental Conditions for Operation seciton

Quark front panel



1. Power switch
2. LED power indicator on/off
3. Sampling line Calibration port

Quark Unit Rear Panel



Connection	Description	Quark Model
1. PNT/MIP-MEP/P0.1 port	Pneumatic connection for X9 PNT and MIP-MEP/P0.1	PFT, SPIRO
2. Permapure sampling line port	Connection for the sample line, luer lock, rotate clockwise to tighten	PFT, CPET
3. Breathing alve connector	Large connector for Breathing Valve Assembly	PFT
4. DLCO cylinder connector	Push connector with quick release for DLCO gas cylinder	PFT
5. O_2/CO_2 calibration cylinder connector	Push connector with quick release for O_2/CO_2 calibration gas cylinder	PFT, CPET
6. Oxygen cylinder connector	Push connector with quick release for O_2 gas cylinder	PFT
7. Demand valve pneumatic connection	Connection for demand valve for gas delivery from S/N 2014041001	PFT (newer)
8. Supplemental ground (earthing)	Connection to ground the unit	PFT, SPIRO, CPET
9. Dosimeter Port	Connections for controlling delivery of medications to subject	PFT, SPIRO
10. Medical air connector	Push connector with quick release for medical air to control dosimeter	
11. RS232 port for PC	Serial connection to computer (COM Port)	PFT, SPIRO, CPET
12. Temperature / Relative Humidity Port	Connection for Temperature and Humidity Probe (external)	PFT, SPIRO, CPET
13. USB-A port to PC	USB connection to computer (printer style cable)	PFT, SPIRO, CPET
14. Auxiliary USB port for HR Monitor	USB connection (USB Drive connection) for Heart Rate Monitor Dongle	PFT, CPET
15. Turbine flowmeter port	Phone style connection for connection of Turbine Flowmeter(s)	PFT, SPIRO, CPET
16. Reset button	Button to reset system, power button is preferred method	PFT, SPIRO, CPET
17. Auxiliary RS232 port – Ergometers	Communication with Ergometers / accessories via RS232	PFT, CPET
18. Oximeter/PNT ROCC connector (for PNT ROCC, an adapter is required)	Connection for Oximeter(s) and the PNT Rocc	PFT, CPET
19. Auxiliary TTL input/output port	Auxiliary connection for input / output of TTL signals (ECG / Polar HRM)	PFT, CPET
20. Port for the soda lime CO_2 absorber output (pre-installed)	Luer lock connection for soda lime absorber, rotate clockwise to tighten	PFT, CPET
21. Power cable plug	Plug to insert appropriate power cord into	PFT, SPIRO, CPET
22. Soda Lime CO_2 Absorber slot (pre-installed)	Carbon Dioxide absorber holder	PFT, CPET

1.

Gas Cylinders (Calibration and Testing)

Sensor calibration requires specific gas mixtures, table below outlines gases required:

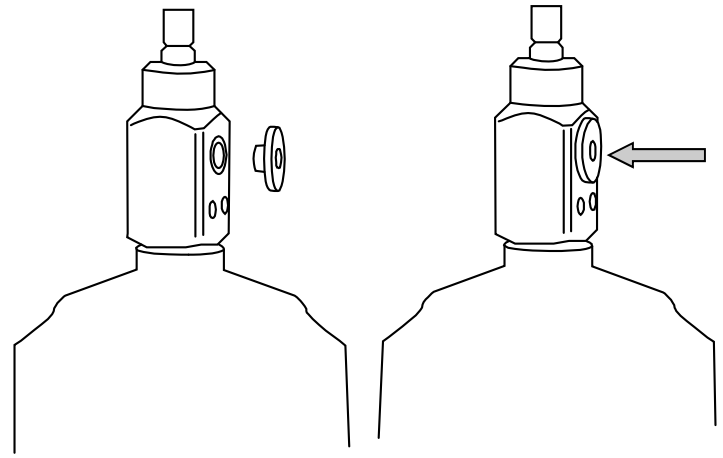
Cylinder	Recommended Gas Mixture	Test
Calibration	O_2 16.0%, CO_2 5.0%, Balance N_2	FRC, CV, CPET, RMR
DLCO	CO 0.3%, CH_4 0.3%, O_2 21.0%, Balance N_2	DLCO
Oxygen	O_2 100 %	FRC, CV

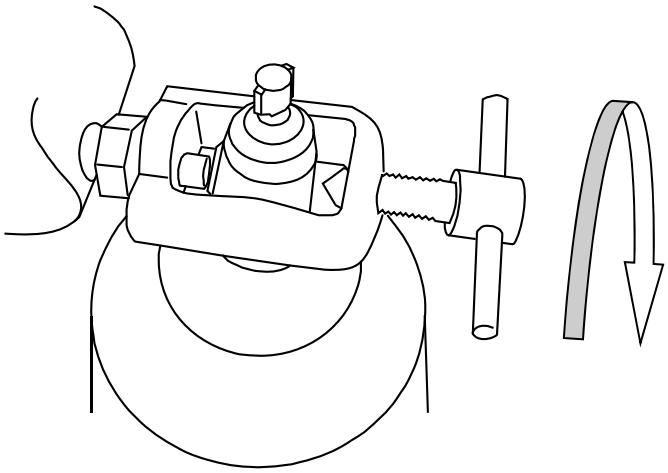
Each of the gas cylinders can be secured on the rear of the trolley (option).

> ***Note:*** *The cylinders must contain a calibration certificate which indicates actual gas concentrations*

Install the gas regulators on the cylinder

Secure the gas regulator on the cylinder as shown in the next following picture. A new white washer should be placed between the cylinder and the gas regulator.



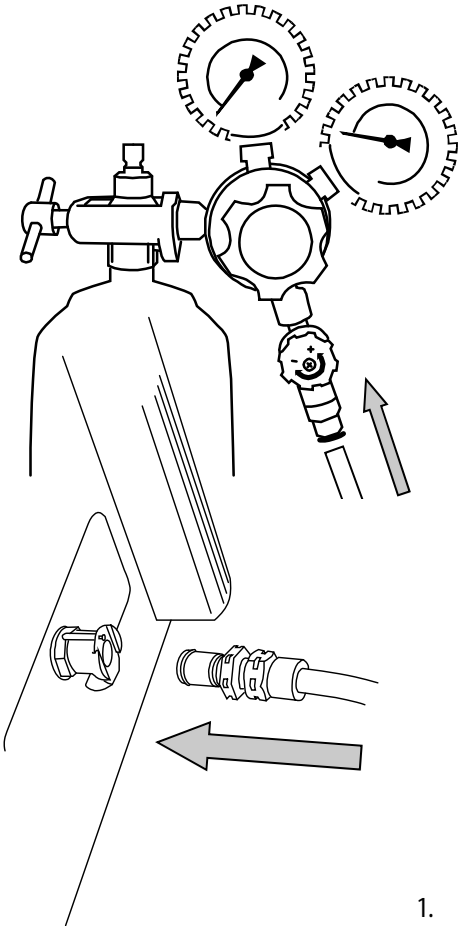


> ***Warning:*** *The regulator should be tightly connected to avoid leaks (clockwise rotation)*

> ***Note:*** *Gas regulators have different connections depending on the composition of gas. Ensure the proper regulator has been chosen for the gas mixture*

Each regulator has an adjustable second stage which must be configuredwhen used for the first time, this is necessary to protect the internal demand valve from the high pressure created as the cylinder is opened.

Connect the hoses to the regulators



The following table outlines the appropriate coloured connector for each cylinder in use

Connect the hoses to the Quark

> ***Warning:*** *The gas tank must be off prior to connecting the cylinders to the Quark (turn counter clockwise to ensure "off")*

1. Match the colored connector push hose and connector into port on Quark
2. Enssure that the pressure adjustment knob is closed (turning it counter clockwise).
3. Open the gas cylinder
   a) Turn the tank valve (top of the cylinder) counter clockwise
   b) Turn the needle valve (tap) at the end of the regulator counter clockwise

> ***Note:*** *To ensure a long cylinder life, do not force the valve to its maximum opening or open and close repeatedly. Close the cylinder for a short period of time by rotating the needle valve (tap) at the end of the regulator clockwise*

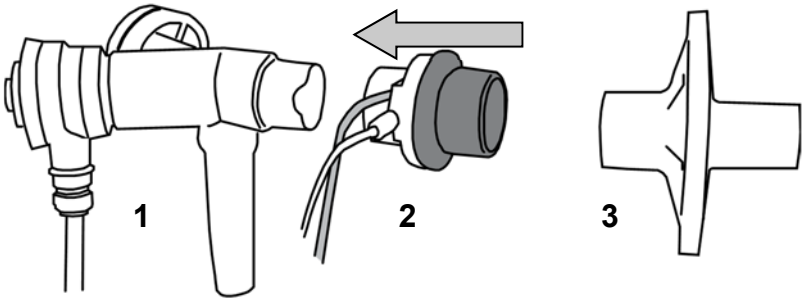
5. Rotate the pressure adjustment knob (large knob under two gauges) clockwise slowly and adjust the pressure between 5 and 6 bar (70-90 psi). This is the only time you SHOULD need to adjust this.Cylinders should be replaced when the internal pressure falls below 10 bar (150 psi)

> ***Caution:*** *You should always close the cylinder and the gas regulator before disconnecting the hoses from the Quark*

Assemble the Breathing Valve and flowmeter

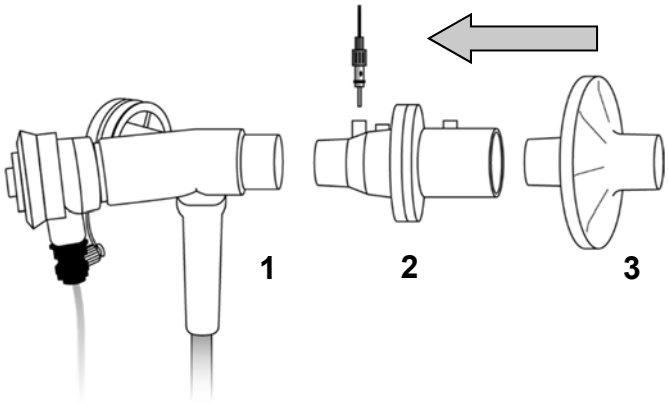
> ***Note****: Align the sampling line of the turbine with the notch on the smart valve*
>
> ***There are two Breathing Valves for the Quark:***
>
> - ***Turbine*** *– REF C04250-03-05*
> - ***PNT X9*** *– REF C02380-02-06*

Turbine



1. Breathing valve
2. Turbine
3. Antibacterial filter

PNT X9

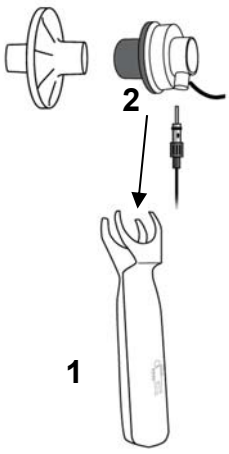


1. Breathing valve
2. PNT X9
3. Antibacterial filter

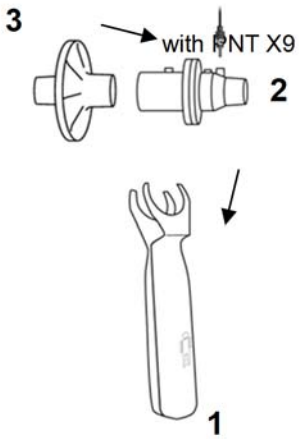
Note: *in order to obtain reliable measurements, the PNT X9 must be always used with the antibacterial filter.*

Attach the flowmeter to the handle

with turbine



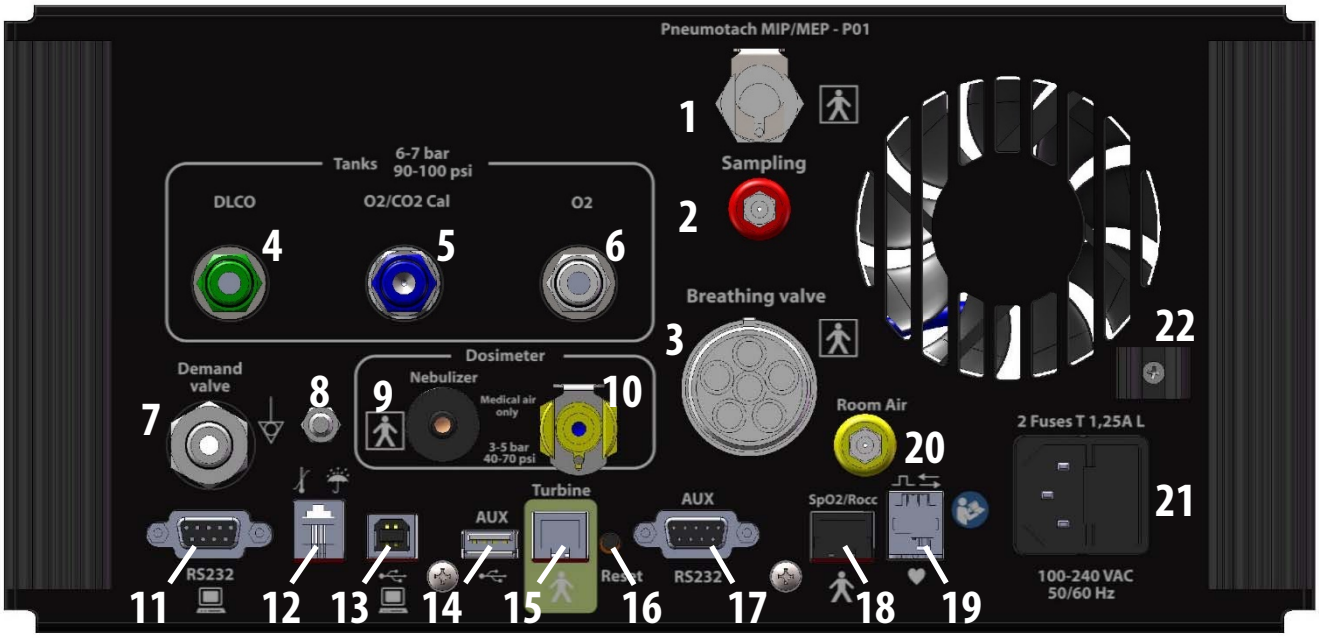
1. Handle
2. Turbine



1. Handle
2. X9 PNT
3. Anti-bacterial Filter

Note: *To obtain reliable measurements, the PNT X9 always must be used with the antibacterial filter*

Connect the breathing valve and/or the flowmeter to the Quark

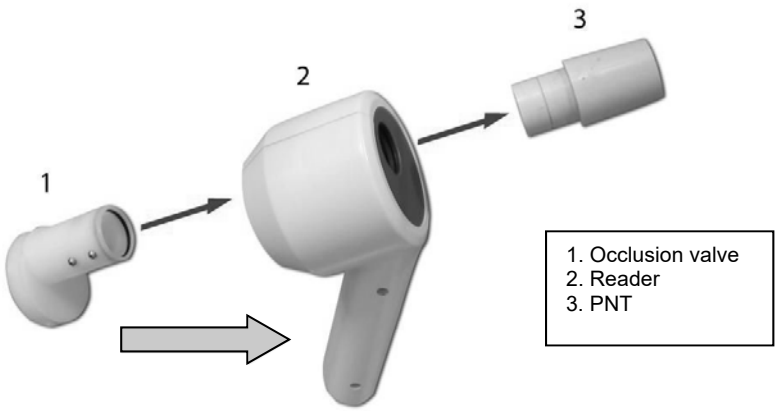


Connecting the breathing valve (if present) and the flowmeter to the Quark rear panel:

5. Breathing Valve - The two tubes coming from the breathing valve must be connected to connectors #3 and 7 on the rear panel of the Quark (Breathing valve and Demand valve). Demand valve pneumatic connection is from S/N 2014041001
6. Sampling Line - Must be connected to connector #2 of the rear panel of the Quark (Sampling)
7. PNT X9 - Pneumatic tubes from the flowmeter must be connected to connector #1 of the rear panel of the Quark (Pneumotach MIP/MEP - P01)
8. Turbine - The cable from the turbine must be connected to connector #15 of the rear panel of the Quark (Turbine)

Assemble the VO_2max mask and the turbine flowmeter

Assemble the R_{OCC} PNT



Connect the Quark to the computer (PC)

Connect the Quark unit to the PC using the USB or RS232 ports with the appropriate cable (USB or RS232) to the proper (USB or COM) Quark and PC ports

Power the Quark Unit when installed on the Optional Trolley

1. Place the Quark Unit inside the Trolley in the appropriate location
2. Using the power cables included with the trolley, use a short cable and insert the power cable in the Quark rear panel
3. Connect the opposite end to the Trolley power strip located behind the drawer or on the vertical support
4. Repeat the above steps for the PC, monitor(s) and printer using additional included cables and the power socket closest to the location of the device
5. Insert main power cord into the trolley and connect to the wall
6. Trolley has a power switch independent from the Quark Unit, make sure it is togged to the On position as shown in the Important Notices Section

> ***Warning:*** *Always power off the trolley and the Quark when not in use*

Prepare the Quark Unit and Subject for Exercise Testing

Note: *If the exercise test must include flow/volume loop events, it is mandatory to use masks without valves (REF C04490-01-10 extra small, C04490-02-10 small, C04490-03-10 medium)*

Prepare the Quark

Connect the head cap, the VO_2max mask and the ID28 turbine as shown in the following picture:

- Head cap is secured with the red side towards the head, wider portion at the dop and narrower at the bottom. Head cap is connected to mask with black clips.
- HR Monitor should be connected to rear panel of the Quark (if No ECG)
- Connect the Turbine to the rear panel of the Quark
- Controlling Ergometer – connect the ergometer RS232 cable to the Auxiliary RS232 port on the rear panel of the Quark or directly to the computer via COM port or USB-to-Serial adapter. Ergometer must be selected prior to starting the test

Note: *Cellular phones should be turned off to eliminate potential electrical interference*

Subject Preparation

Select the correct mask size for the subject

Selecting the appropriate mask size is crucial for accurate data and subject comfort. A mask which is too large can introduce leaks and a mask which is too small may make the subject feel claustrophobic limiting performance on the exercise test.

The seal inside the mask should fit from the top of the nose of the subject (between the eyes) to just below the bottom lip with the base of the mask going underneath the chin.

General Guide

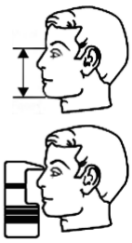
Average Adult Males – Small Mask

Average Adult Females – Extra Small Mask

- Align top of gauge with bridge of nose and measure to bottom of chin
- Mouth closed

Between sizes → Choose smaller size

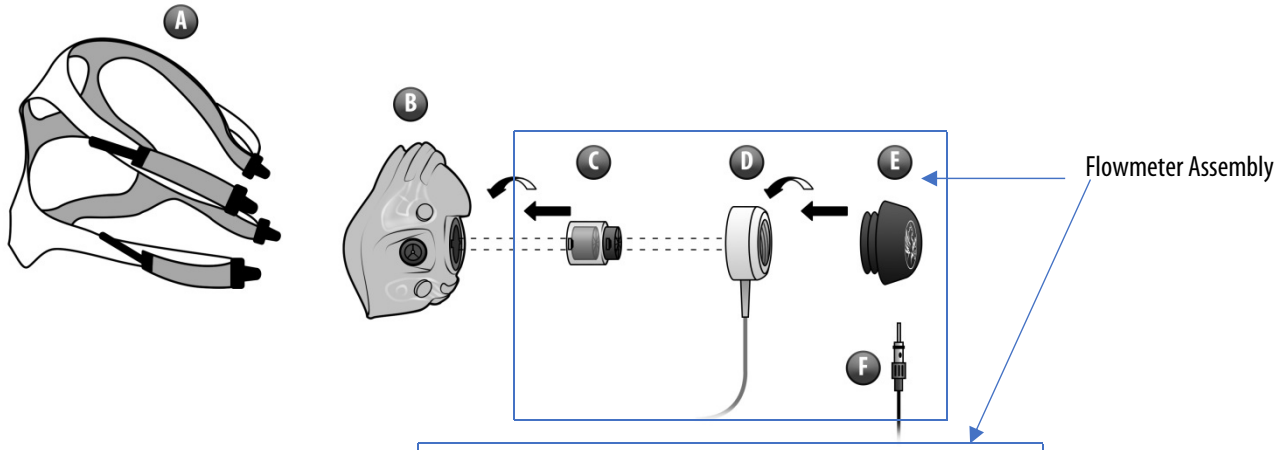
Head cap sizes match mask sizes

Measurement	Mask Size	Distance (in)	Distance (mm)
	Too small	3.60″	91
	Petite (P)	4.00″″	102
	Extra Small (XS)	4.40″	112
	Small (S)	4.90″	125
	Medium (M)	5.40″	137
	Large (L)	5.90″	150

Assemble the Flowmeter and Mask

1. Construct Flowmeter Assembly
   a) Insert the turbine in mask adapter and lock in place by rotating 1/8 turn clockwise, there will be small resistance, DO NOT FORCE the rotation as this can damage parts
   b) Slide the optoelectronic reader over the turbine, the tapered end will correspond to the smaller connector of the turbine, cable should be oriented down
   c) Attach the wind shield to the turbine and rotate 1/8 turn so that the sampling line port aligns with the cable from the optoelectronic reader
   d) Insert sampling line into the port in the wind shield
2. Plug the turbine cable in the *Flow* port of the K5

***Note**: Any component which has an O-ring should be greased periodically with silicone grease for long-term use*



A. Headgear
B. Mask
C. Turbine
D. Optoelectronic reader
E. Wind shield
F. Sampling line

***Note:** If the exercise test must include flow/volume loop events, it is mandatory to use masks without valves (REF C03704-01-10 extra small, C03701-01-10 small, C03702-01-10 medium, C03703-01-10 large)*

Secure the mask

Pictures below demonstrate proper mask placement

After securing mask, adjust head cap and secure Velcro to form a tight seal and perform a leak test, described below

Mask Leak Test

After the mask is secured to the subject, the best practice is to perform a leak test according to the following steps:

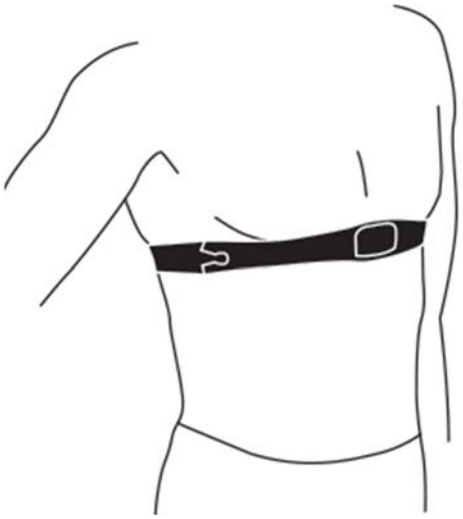
1. Place palm of hand (operator or subject) over turbine connector of mask
2. Perform check:
   a. Masks with inspiratory valve: Have subject exhale – Mask should remain in place and no air should be felt around the eyes
   b. Masks without inspiratory valves: Have subject inhale, the lines around the mask should compress, and no air movement should be felt around the eyes
3. Tighten mask to secure and repeat

	Turbine Attached	Turbine Not Attached
No Inspiratory Valves "Inspire"		
Inspiratory Valves "Expire"		
Instructions	Wind shield not attached Hand over open end, occlude and have subject breathe as shown	Hand over open end, occlude and have subject breathe as shown

The HR Monitor

Assemble the HR Monitor Belt:

1. Snap the transmitter onto the elastic strap
2. Wet the electrode surfaces on the inside of the belt on either side of the transmitter with water, contact lens solution, electrode gel to improve conductivity
3. Adjust the strap to fit tightly and comfortably around the subject's thorax without restricting breathing
4. Secure the strap tightly around the chest (below the nipple line) and lock the buckle



5.

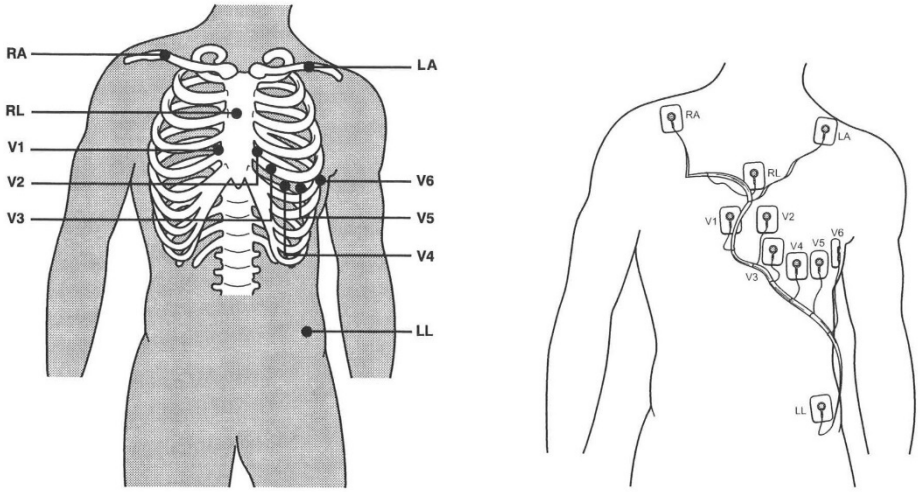
The HR Monitor must be worn against bare skin to ensure successful operation. Best Practice – To acquire the most accurate HR signal, the HR transmitter and receiver should be in close proximity

ECG Electrodes

Proper electrode placement is important for acquiring a clean ECG signal. Subject preparations which can improve signal quality include removal of oil, lotions and hair from the skin:

1. Shave the areas where the electrodes will be placed
2. Using ECG abrasive material, abrade the skin (in an 'X' pattern) where the electrodes will be located
3. Rub the area with gauze that has been saturated with alcohol, ether or acetone
4. Remove any residual oil with dry gauze
5. Connect the patient cable to the electrodes and place them as shown in the pictures below

> ***Note:*** *The patient cable and the transmitter are not water-proof. It is necessary to prevent any liquids from penetrating the area and avoid submerging the electrodes in liquid*



The electrodes should be placed as follows:

V1 4th intercostal space, to the right of the sternum

V2 4th intercostal space, to the left of the sternum

V3 Between V2 and V4 electrodes

V4 5th intercostal space, at the midclavicular line

V5 5th intercostal space, at the anterior axillary line

V6 5th intercostal space, at the left midaxillary line

Limb electrodes for the arms should be placed in the subclavicular areas near each arm

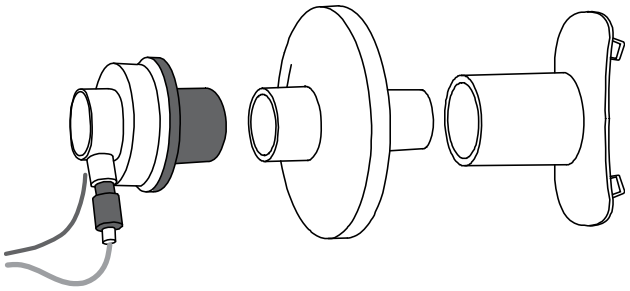
Limb electrodes for the legs should be placed on the trunk at the level of the bottom rib on either side of the torso

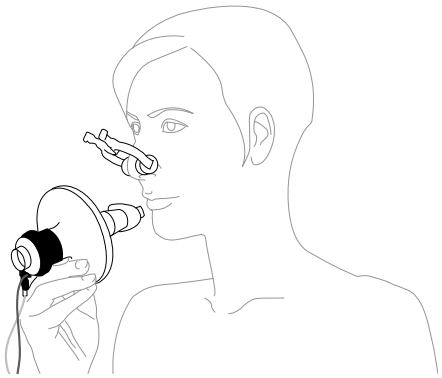
> ***Warning:*** *QRS morphology may be slightly different from the standard ECG due to the different positioning of lower limb electrodes. To reduce these differences attempt to position the LL electrode as low as possible.*

Testing with a Mouthpiece

Sub-maximal tests (with ventilation values maintained at less than 100 L/min), it is possible to use a rubber mouthpiece, anti-bacterial filter and nose clip in place of the mask

Assemble the mouthpiece, filter and reader as illustrated in the picture below. Ensure that no leaks are present between the patient and the mouthpiece.





Contact COSMED

You may contact COSMED, the manufacturer, directly at the following address for information:

COSMED S.r.l.
Via dei Piani di Monte Savello, 37
00041 - Pavona di Albano
Rome - ITALY

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

Comments, Feedback and Suggestions

If you have any comments, feedback or suggestions you may inform us at **complain@cosmed.com**

System Cleaning & Maintenance

System Maintenance

Any service operations not specified in this manual should only be only performed by authorized personnel in accordance with the service manual.

Rubber mouthpieces, face masks, breathing valves and the other parts are not shipped sterile, therefore these items should be disinfected prior to first useAll materials used in the construction of the Quark and its accessories are nontoxic and pose no safety risks to the patient or operator.

The device should be powered off with the power supply disconnected prior to cleaning, disinfecting and/or inspecting the device.

The turbine should be disinfected regularly to ensure the accuracy of measurements.

If the recommended disposable anti-bacterial filters are not used, each part which comes into contact with the patient should be disinfected prior to each test.

Cleaning & Disinfection

Introduction

The goal of infection control is to prevent the transmission of infection to patients/subjects and staff during pulmonary function testing.

Cleaning and disinfecting instructions should be strictly followed to control infections and assure the safety of the patient. Aspiration of residue, particles and/or contaminated agents could be life threatening.

The recommendations in the following section are retrieved from Miller MR, Crapo R, Hankinson J, et al.: General considerations for lung function testing. Eur Respir J 2005; 26:153–162.

Prevention of infection transmission

Transmission to technicians

Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing and use of barrier devices, such as suitable gloves. To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if the technician has any open cuts or sores on his/her hands. Hands should always be washed between patients.

Cross-contamination

To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves and manifolds should be disinfected regularly. Mouthpieces, nose clips and any other equipment that comes into direct contact with mucosal surfaces should be disinfected, or, if disposable, discarded after each use.

Only the portion of the circuit through which rebreathing occurs must be decontaminated between patients, or, if disposable, discarded after each use. Disposable sensors, when appropriately used, avoid the need for decontamination of sensors and mouthpieces.

Tuberculosis

In settings where tubercolosis or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

Haemoptysis and oral lesions

Special precautions should be taken when testing patients with haemoptysis, open sores on the oral mucosa or bleeding gums. Tubing and breathing valves should be decontaminated before reuse, and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.

Other known transmissible infectious diseases

Extra precautions should be taken for patients with known transmissible infectious diseases. Possible precautions include the following: 1) reserving equipment for the sole purpose of testing infected patients; 2) testing such patients at the end of the day to allow time for spirometer disassembly and disinfection; and 3) testing patients in their own rooms with adequate ventilation and appropriate protection for the technician.

Disposable in-line filters

These may be an effective and less expensive method of preventing equipment contamination.

The use of in-line filters does not eliminate the need for regular cleaning and decontamination of lung function equipment.

Other precautions and warnings

Please take the following precautions during the cleaning and disinfection activities:

4. The responsibility for handling, cleaning and decontaminating reusable medical devices should be assigned to trained, qualified individuals.
5. Appropriate protective clothing (gloves, masks, eye protection, gowns) will minimize the potential for personal exposure to blood borne and other disease-producing organisms.
6. Immediately separate and contain soiled reusable devices at the point of use and transport to the decontamination area so as to minimize risk of personal contact with contaminants.
7. A disinfectant solution is only effective if it can contact all surfaces of the items to be disinfected or sterilized.

8. Adequate ventilation is required in the disinfection area to evacuate the chemical vapors from glutaraldehyde (if used). Use lidded containers for the disinfectant solution when appropriate. The inhalation of fumes from disinfectant solutions or skin contact with liquid disinfectants can be hazardous to personnel.

> ***Warning:*** *Particular precautions should be taken when testing patients with high risk communicable diseases (i.e. Tuberculosis, Multidrug Resistant Staphylococcus infections, etc.). When such conditions are present the clinical need for performing the test should justify the risks.*

When performing the disinfection:

- Do not use alcohol or other liquids containing Gluteraldehyde on the exterior surface of the equipment.
- Do not use abrasive powders or glass cleaners containing alcohol or ammonia on the plexiglas component (mixing chamber or canopy) of the equipment.
- Do not steam autoclave any component other then rubber reusable masks (plastic adapter and clips should be removed).

> ***Warning:*** *Do not immerse any parts in liquid unless indicated (see following sections)*

During testing , parts which directly come in contact with the skin and mucosa of subjects, or their respiratory gases can become contaminated by microorganisms which can be transmitted to the next test subject. Even small droplets of condensation or aerosols are considered possible contaminants. To avoid cross-contamination, all contaminated parts must be thoroughly disinfected or disposed of.

COSMED components which come into (direct or indirect) contact with mucosa or broken skin are classified as “semi-critical” devices and require high-level disinfection according to applicable regulatory bodies. All other components are classified as non-critical.

The cleaning and disinfection procedure has been validated by an independent test laboratory

Applicable parts, when maintained properly and reprocessed in accordance with these instructions, should function within specifications for a minimum of 50 cycles. Verify proper functioning of applicable parts after the cleaning and disinfection process by performing both Flowmeter and Gas Calibration ensuring that calibration factors are within acceptable range.

The following chemicals were used for the validation, and are recommended for use:

Detergent: Cidezyme®/Enzol® (Johnson & Johnson)

Disinfectants: CIDEX® OPA Solution (Johnson & Johnson), Clinell Sporicidal Wipes (Gama Healthcare)

It is the responsibility of the users to:

- Follow instructions carefully
- Replicate recommended cleaning conditions and methods in their environment
- Observe legal provisions of their country and hygiene requirements of their organization, in addition to the instructions provided by this manual
- Assign trained and qualified individuals to be responsible for the handling, cleaning and decontamination of the devices

To avoid contamination and ensure optimal performance:

- Equipment and applied parts MUST BE cleaned and disinfected prior to their first use
- Single-use items MUST BE disposed of after every test
- Parts which show defects on the material surfaces (cracks, brittleness) are disposed of
- Standard precautionary measures (hand hygiene, gloves, gown, mask, face shields) are taken as necessary
- Devices are disinfected immediately after use

Chemicals for disinfection must be:

- Applied thoroughly to all surfaces of the items to be disinfected
- Used according to instructions and expiration deadlines of the manufacturer are observed to ensure effective application
- Always stored and prepared in clearly marked containers to prevent accidental use

Decontamination

Decontamination is a multi-step process which includes the following:

1. Preparation at point of use
2. Thorough cleaning
3. Rinsing
4. A microbicidal process

Pretreatment

The purpose of pretreatment (thorough cleaning) is to:

1. Remove protein residue which can inhibit effective disinfection
2. Reduce the number of microorganisms and other pathogenic substances attached to the part.
3. Rinsing is also important as it can remove any residual organic material, lubricants, and/or cleaning agents which can inactivate chemical disinfectants and inhibit their anti-bactericidal properties.

The pretreatment should be performed immediately after use

Water

A sterile water rinse is recommended, when available, although tap potable water is also acceptable for use in cleaning COSMED components

Maintenance

The applied parts which have been disassembled, must be reassembled following Cleaning & Disinfection according to the installation section of this manual. Some components, which contain O-rings, must be lubricated with medical grade biocompatible Vaseline before storage.

Procedure For Third-Party Products

Instructions to clean and disinfect third party products is not part of these instructions, therefore, those products are not listed in the following tables. The original manufacturer is responsible for these third-party products, for this reason, COSMED does not list its own cleaning and disinfection directives for those products. Refer to manufacturers included instructions or website for more information on cleaning and disinfection procedures.

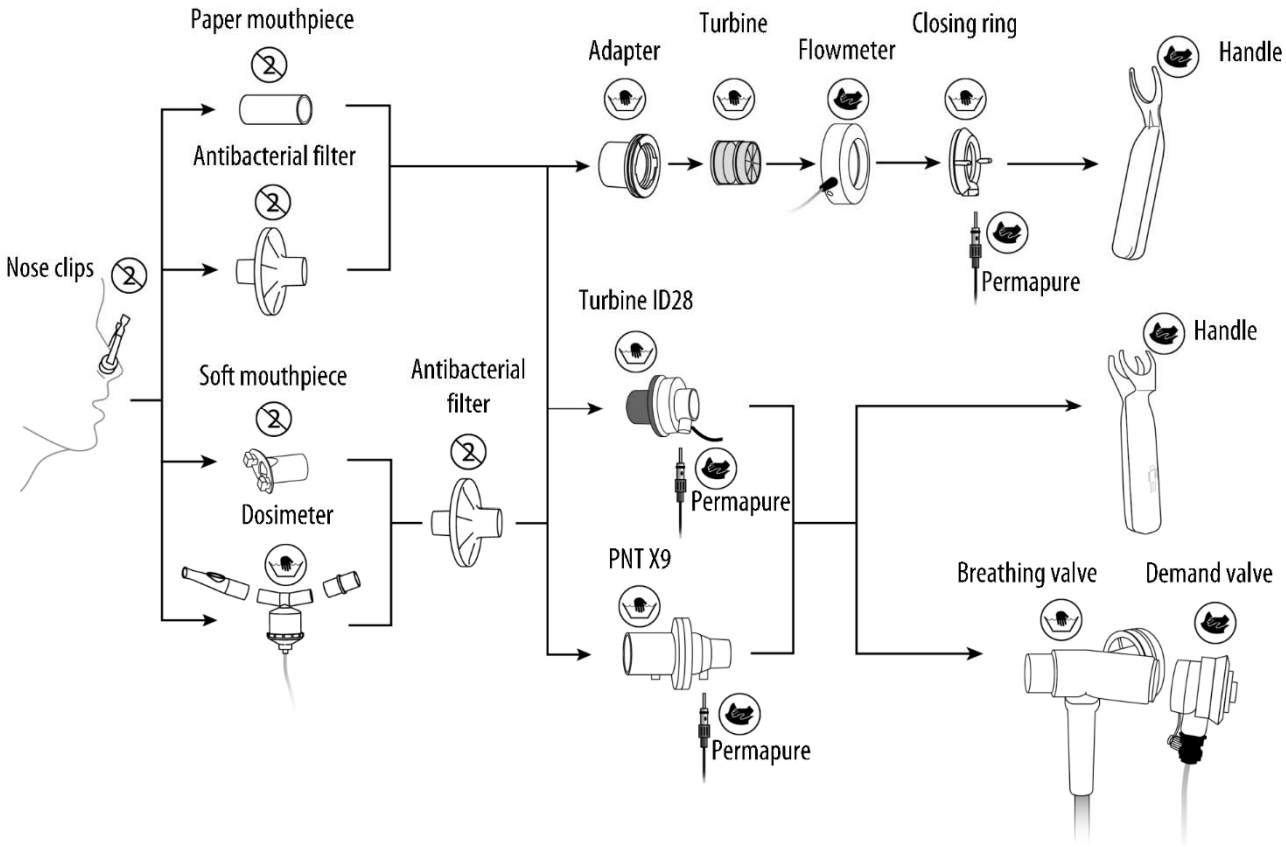
Symbols


Manual Cleaning


Wiping

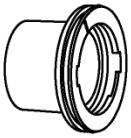

Single-use Item

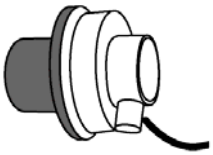
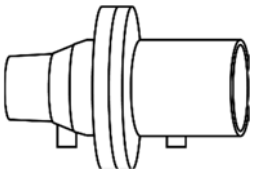
Spirometry Tests



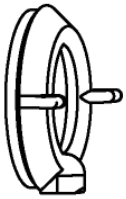
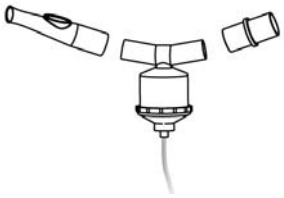
Cleaning and Disinfection Methods

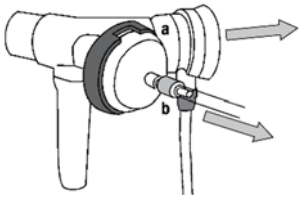
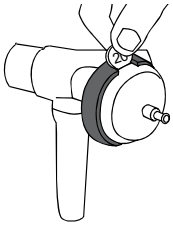
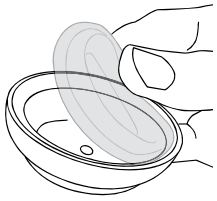
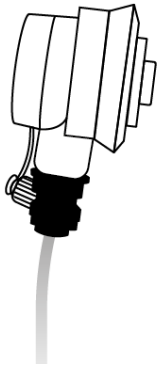
Always follow the instructions on the cleaning agent for solution mixing and personal protective equipment (PPE)

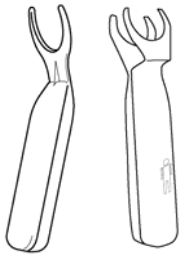
Item	Turbine	Adapter
		
When?	Before first use and immediately after use	Before first use and immediately after use
Notes	DO NOT use running water to rinse the item DO NOT brush the inside of the turbine	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning/Rinsing	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes

Item	Turbine	PNT X9
		
When?	Before first use and immediately after use	Daily
Notes	1. Do not place the turbine under running water or move the turbine while submerged 2. Do not use a brush for the internal part of the turbine, doing so will damages to the turbine blade 3. For cleaning and rinsing, do not wet the sampling line. 4. After cleaning the turbine, always calibrate prior to subsequent testing. 	1. Use distilled water for preparing the disinfectant solution, otherwise calcium deposits could damage the flowmeter mesh 2. Do not dry the PNT X9 with hot air which may damage the flowmeter net (<40°C) 3. This item is protected by the antibacterial filter
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning/Rinsing	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes (only scrub outside only) 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	2-3 hours

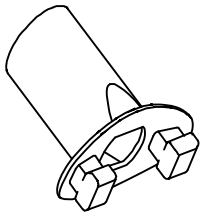
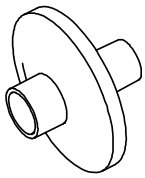
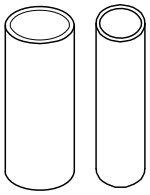
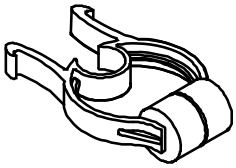
Item	Flowmeter	Sampling line tip
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	Do not clean and disinfect the internal surface of the reader	Lubricate the O-ring of the sampling line plug after cleaning with biocompatible lubricant
Pretreatment	Wipe soil with a moist sponge or lint-free towel	Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe with a damp soft cloth	Wipe with a damp soft cloth
Disinfection	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry
Cleaning Time	1 minutes	1 minutes
Drying Time	10-15 minutes	10-15 minutes

Item	Closing Ring	Dosimeter
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note		To verify the proper functioning of the device after the reprocessing please refer to ATS document "Guidelines for Methacholine and Exercise Challenge Testing-1999"
Pretreatment	Rinse the component in tap water at 22-40°C	Please refer to the manufacturer's cleaning and disinfection instructions provided
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	
Cleaning Time	30 minutes	
Drying Time	2-3 hours	

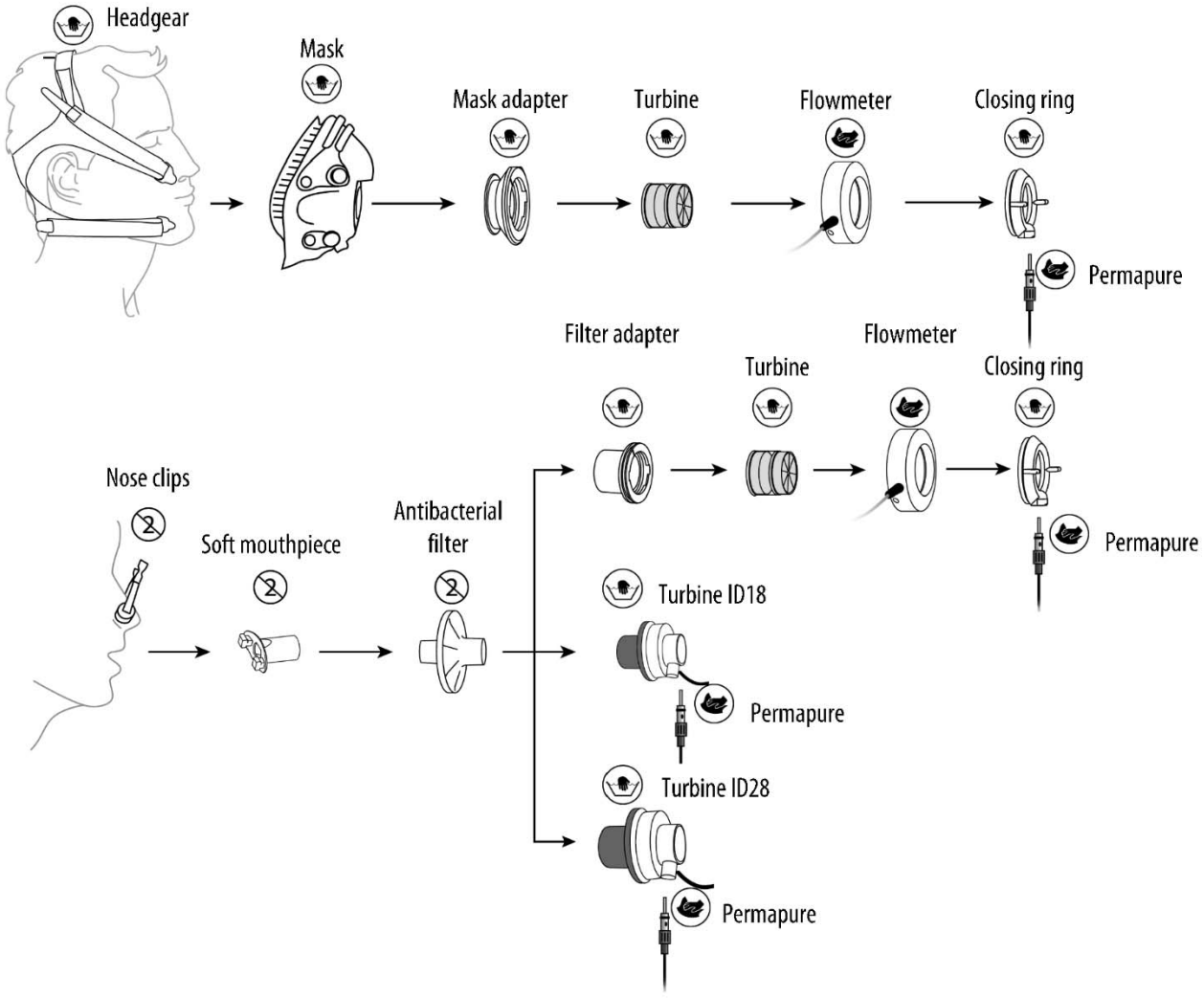
Item	Breathing Valve	Demand Valve
	 Remove the demand valve (a) from the breathing valve. Pay attention to the net behind it. Unscrew the tube (b)  Remove the cover on the rear of the breathing valve by means of a coin  Remove the membrane paying attention to its orientation (must not be replaced upside down)	
When?	Daily	Before first use and immediately after use
Note	Disinfection prior to every test is not necessary due to the presence of the anti-bacterial filter during test maneuvers	Disinfection prior to every test is not necessary due to the presence of the anti-bacterial filter during test maneuvers Do Not submerge the demand valve
Pretreatment	Rinse the component in tap water at 22-40°C	After disassembling the demand valve, wipe any soil with a moist sponge or lint-free towel
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	Wipe the component with a damp soft cloth
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	Not Applicable
Cleaning Time	30 minutes	
Drying Time	2-3 hours	

Item	Handle
	
	Before first use and immediately after use
When?	Do not clean and disinfect the internal surface of the reader
Pretreatment	Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe with a damp soft cloth
Disinfection	 Wear recommended PPE. Remove one Clinell Sporicidal wipe from the pack.  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water.  Wipe the surface, taking care not to go over the same area twice.  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry.
Cleaning Time	1 minutes
Drying Time	10-15 minutes

Disposable items

Description	Item	When?	Note
PTE soft mouthpieces		After each test	
Antibacterial filter		After each test	
Paper mouthpieces		After each test	
Nose clips		After each test	

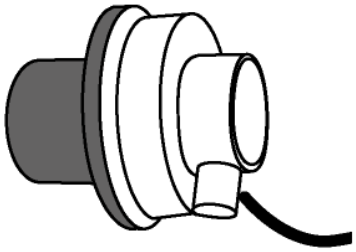
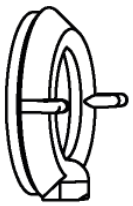
CPET & RMR Tests



Cleaning and Disinfection Mmethods

Item	Headgear	Mask
		
When?	Before first use and after every use	Before first use and immediately after use
Note	DO NOT iron	Disassemble all parts prior to cleaning
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the components in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Lay flat to Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry
Cleaning Time	30 minutes	30 minutes
Drying Time	3-4 hours	30 minutes

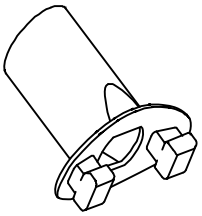
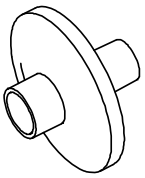
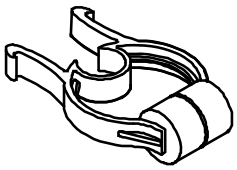
Item	Turbine	Windshield
		
When?	Before first use and immediately after use	Before first use and immediately after use
Notes	DO NOT use running water to rinse the item DO NOT brush the inside of the turbine	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning/Rinsing	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	0 minutes

Item	Turbine Flowmeter (ID18)	Closing ring
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	1. Do not place the turbine under running water or move the turbine while submerged 2. Do not use a brush for the internal part of the turbine, doing so will damages to the turbine blade 3. For cleaning and rinsing, do not wet the sampling line. 4. After cleaning the turbine, always calibrate prior to subsequent testing. 	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes (only scrub outside only) 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	0 minutes

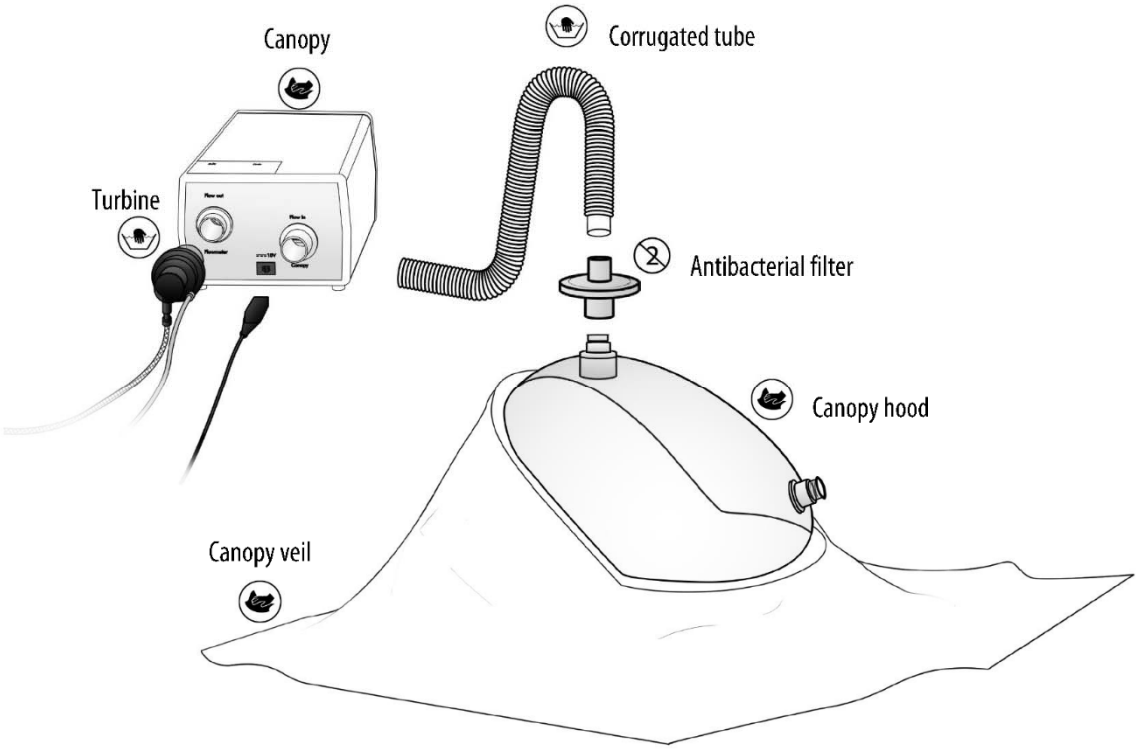
Item	Flowmeter	Sampling line tip
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	Do not clean and disinfect the internal surface of the reader	Lubricate the O-ring of the sampling line plug after cleaning with biocompatible lubricant
Pretreatment	Wipe soil with a moist sponge or lint-free towel	Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe with a damp soft cloth	Wipe with a damp soft cloth
Disinfection	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry
Cleaning Time	1 minutes	1 minutes
Drying Time	10-15 minutes	10-15 minutes

Item	Mask adapter
	
When?	Before first use and immediately after use
Pretreatment	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes
Drying Time	2-3 hours

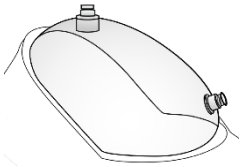
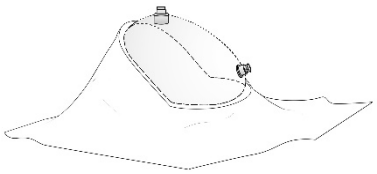
Disposable Items

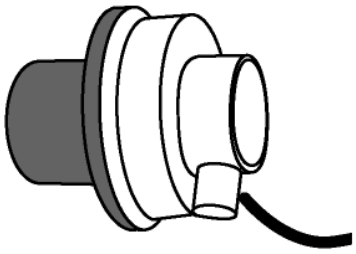
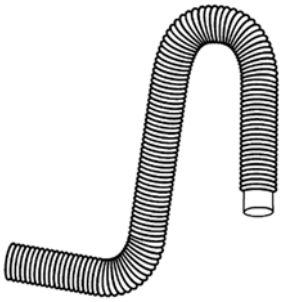
Description	Item	When?	Note
PTE soft mouthpieces		After each test	
Antibacterial filter		After each test	
Nose clips		After each test	

Canopy test


Canopy
Corrugated tube
Turbine
Antibacterial filter
Canopy hood
Canopy veil

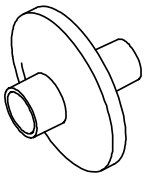
Cleaning and disinfecting methods

Item	Canopy hood	Canopy veil
		
When?	Immediately after use	Immediately after use
Pretreatment	Wipe soil with a moist sponge or towel.	Wipe soil with a moist sponge or towel.
Manual Cleaning	Wipe with a wet soft cloth.	Wipe with a wet soft cloth.
Disinfection	 Wear recommended PPE. Remove one Clinell Sporicidal wipe from the pack.  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water.  Wipe the surface, taking care not to go over the same area twice.  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry.	 Wear recommended PPE. Remove one Clinell Sporicidal wipe from the pack.  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water.  Wipe the surface, taking care not to go over the same area twice.  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry.
Cleaning Time		
Drying Time		

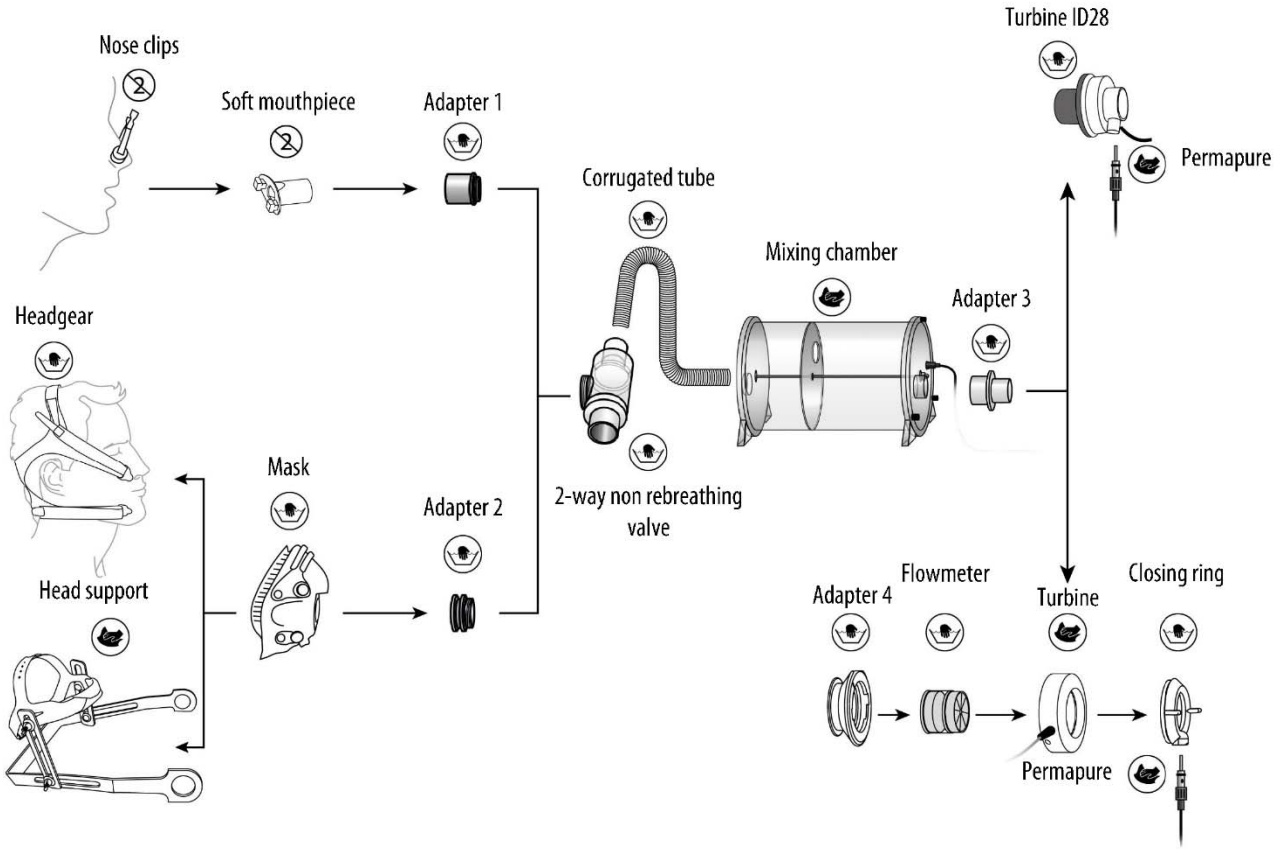
Item	Turbine Flowmeter	Corrugated tube
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	1. Do not place the turbine under running water or move the turbine while submerged 2. Do not use a brush for the internal part of the turbine, doing so will damages to the turbine blade 3. For cleaning and rinsing, do not wet the sampling line. 4. After cleaning the turbine, always calibrate prior to subsequent testing. 	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	4. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes (only scrub outside only) 5. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 6. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	7. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes (only scrub outside only) 8. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 9. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	10. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 11. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 12. Air dry	Soak the component in a disinfectant solution (e.g. Cidex OPA Solution) at room temperature for 12 minutes, then rinse in a large volume of water for at least 1 minute. Repeat this procedure two additional times, for a total of three rinses. Air dry.
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	2-3 hours

Item	Canopy device case
	
When?	Daily
Note	Cleaning only
Pretreatment	Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe the device with a wet soft cloth
Disinfection	Not applicable (not in contact with subject)
Cleaning Time	1 minute
Drying Time	1 minute

Disposable Items

Description	Item	When?	Note
Antibacterial filter		After each test	Protects canopy hose and device from possible cross contamination.

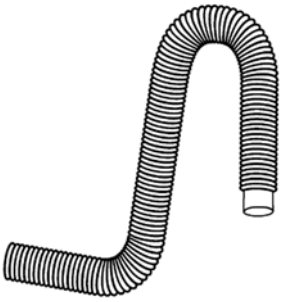
Mixing Chamber Test

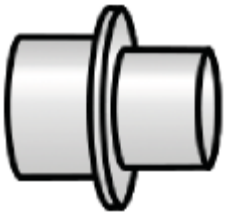


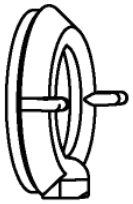
Cleaning and Disinfection Methods

Item	Headgear	Mask
		
When?	Before first use and after every use	Before first use and immediately after use
Note	DO NOT iron	Disassemble all parts prior to cleaning
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the components in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Lay flat to Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry
Cleaning Time	30 minutes	30 minutes
Drying Time	3-4 hours	30 minutes

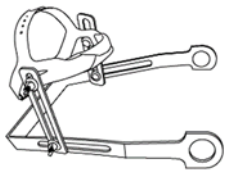
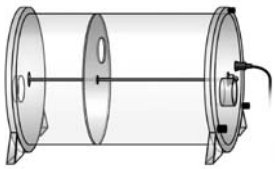
Item	Adapter 1	Adapter 2
		
When?	Before first use and immediately after use	Before first use and immediately after use
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	2-3 hours

Item	Two-way Non-Rebreathing Valve	Corrugated Tube
		
When?	Immediately after use	Immediately after use
Note	For additional information please refer to the indications reported in the sheet shipped together with the valve	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	2-3 hours

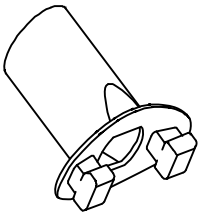
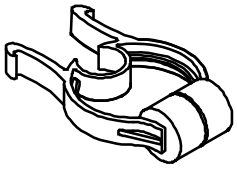
Item	Adapter	Adapter 3
		
When?	Before first use and immediately after use	Before first use and immediately after use
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	2-3 hours

Item	Turbine Flowmeter (ID28)	Closing ring
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	DO NOT use running water to rinse the item DO NOT brush the inside of the turbine	
Pretreatment	Rinse the component in tap water at 22-40°C	Rinse the component in tap water at 22-40°C
Manual Cleaning	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not
Disinfection	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel
Cleaning Time	30 minutes	30 minutes
Drying Time	2-3 hours	0 minutes

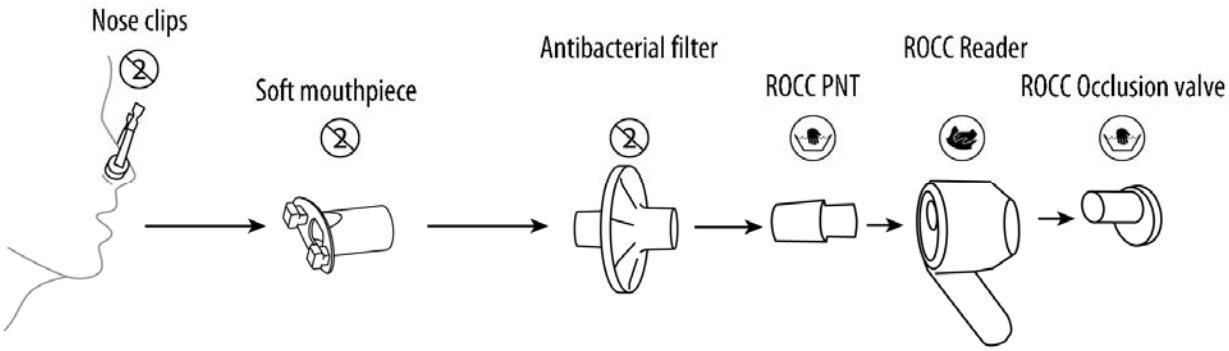
Item	Flowmeter	Sampling line tip
		
When?	Before first use and immediately after use	Before first use and immediately after use
Note	Do not clean and disinfect the internal surface of the reader	Lubricate the O-ring of the sampling line plug after cleaning with biocompatible lubricant
Pretreatment	Wipe soil with a moist sponge or lint-free towel	Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe with a damp soft cloth	Wipe with a damp soft cloth
Disinfection	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry
Cleaning Time	1 minutes	1 minutes
Drying Time	10-15 minutes	10-15 minutes

Item	Head support	Mixing chamber (rounded)
		
When?	Immediately after use	Daily
Note		1. After reprocessing, reassemble and carefully close the mixing chamber 2. Air passes through the chamber in a unidirectional way, from the patient to the device; thus, only a daily reprocessing is required.
Pretreatment	Wipe soil with a moist sponge or lint-free towel	1. Disassemble mixing chamber using the black screw 2. Wipe soil with a moist sponge or lint-free towel
Manual Cleaning	Wipe with a damp soft cloth	Wipe with a damp soft cloth
Disinfection	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry	 Wear recommended PPE according to the bottle. Remove one Clinell Sporicidal wipe from the pack  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water  Wipe the surface, taking care not to go over the same area twice  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry
Cleaning Time	1 minutes	1 minutes
Drying Time	10-15 minutes	10-15 minutes

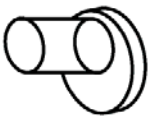
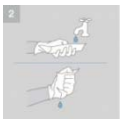
Disposable items

Description	Item	When?	Note
PTE soft mouthpieces		After each test	
Nose clips		After each test	

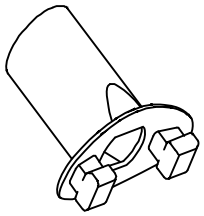
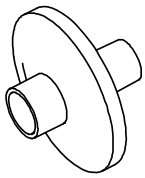
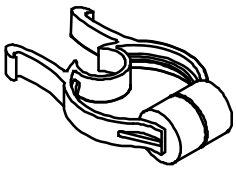
Rocc test


Nose clips
Soft mouthpiece
Antibacterial filter
ROCC PNT
ROCC Reader
ROCC Occlusion valve

Cleaning and Disinfection Methods

Item	Reader	Occlusion valve	PNT
			
When?	Immediately after use	Immediately after use	
Note	Do not place the component under running water.	These items are protected by the antibacterial filter	
Pretreatment	Wipe soil with a moist sponge or towel.	Rinse the component in tap water at 22-40°C	
Manual Cleaning	Wipe with a wet soft cloth.	1. Soak for 3 minutes in a mild detergent solution (Cidezyme) at room temperature (>22°C). Using a soft bristle brush, scrub the item submerged in the cleaning solution during the 3 minutes 2. Wipe while rinsing for 5 minutes in a large volume of water. Using a lint free towel or gauze, remove the water in excess from the item 3. Inspect all surfaces and item features to ensure that it is visibly clean, repeat Manual Cleaning if not	
Disinfection	 Wear recommended PPE. Remove one Clinell Sporicidal wipe from the pack.  To activate, wet the wipe with water under a tap or soak in a bucket. Squeeze out the wipe to remove excess water.  Wipe the surface, taking care not to go over the same area twice.  Change wipe if it becomes dry or soiled and discard in the clinical waste bin. Let the surface air dry.	1. Soak the component in disinfectant (Cidex OPA) at room temperature (>22°C) for 12 minutes 2. Rinse three (3) times in a large volume of water for at least 3-minutes for each rinsing cycle 3. Air dry / pat dry with towel	
Cleaning Time	1 minutes	30 minutes	
Drying Time	10-15 minutes	2-3 hours	

Disposable Items

Description	Item	When?	Note
PTE soft mouthpieces		After each test	
Antibacterial filter		After each test	
Nose clips		After each test	

Sampling line maintenance (Permapure)

- Do not bend, squash or deform the sampling line. Any "kink" in the sample line will reduce the internal lumen of the line and affect accuracy of measurement.
- Do not keep the sampling line open to the atmosphere, particularly in crowded or smoky environments. Keep the sampling line in sealed plastic bag in a dark cool and dry place.
- If saliva enters the tube it should be replaced immediately.
- Periodically grease the O-ring on the connector to ease fitting to optical flowmeter.
- Replace the sampling line every 100 exercise tests or 200 PFT test or every 6 months. In any case, sampling line will become discoloured (brown) with age and may cause calibration to fail.

> ***Note**: ALWAYS replace sample line as the first step in troubleshooting a failed gas calibration.*

Equipment Inspection

The equipment requires inspections to be carried out to assure proper electrical and mechanical safety levels.

The inspections are recommended after extensive use of the equipment or after a long period of storage in unfavourable environmental conditions.

The insulation materials of cables, plugs and any other visible parts should also be inspected. The equipment should be turned off and adapters should be disconnected from the power supply when inspecting the materials.

The turbine and breathing circuits also need to be inspected.

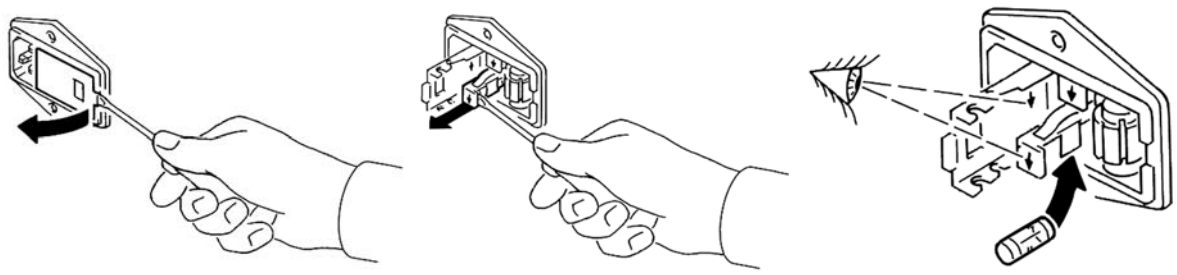
To inspect the turbine, perform the following procedure:

- Verify, by inspection, that the turbine axis fits correctly and the blade is fastened on the axis (you can lightly shake the turbine to note any anomalous movement).
- Assure that there are no torn or broken components in the breathing circuits.

The recommended interval between testing according to IEC 62353 is 24 months

Fuse Replacement

The fuses can be replaced by follow the following steps



1. Open the power supply cover using a screwdriver
2. Extract the fuse holder
3. Replace the damaged fuse(s)

> ***Note**: Ensure that the appropriate fuses are used when replacing previous fuses:*
> *A-680-024-125 (Time Lag Fuses 5x20 250V T1.25A)*

Appendix

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the environment below. User should not operate the system outside of this environment		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emission IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emission IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The device is intended for use in the environment below. User should not operate the system outside of this environment			
Immunity test	**Test level IEC 60601-1**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile If floors are covered with synthetic material, the relative humidity should be ≥ 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Power quality from the mains should be commercial or hospital quality
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Power quality from the mains should be commercial or hospital quality
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Power quality from the mains should be commercial or hospital quality. If device operation is required during power interruptions, it is recommended that the device be powered from an uninterruptible power supply or an external battery source
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	The apparatus doesn't contain devices susceptible to magnetic fields
Nota: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601-1**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance** $d=1.17\sqrt{P}$ $d=1.17\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: (1) At 80 MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Recommended Distances Between Portable RF Equipment and the Device			
The device is intended for use in an environment in which RF disturbances are controlled. The customer or user can prevent electromagnetic interference by maintaining a minimum distance between RF equipment (transmitters) and the device as recommended in the table below			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	**80 MHz to 800 MHz** $d=1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.38
100	11.70	11.70	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Declaration of Conformity

Manufacturer: COSMED S.r.l.

Address: Via dei Piani di Monte Savello 37
00041 Pavona di Albano Laziale (RM)
ITALY

phone: +39-06-9315492
fax: +39-06-9314580

Manufacturer of the following equipment:

Quark Spiro

Quark PFT

Quark CPET

Declares under his sole responsibility that:

- the above listed equipment complies with the essential requirements of the Annex I of the Medical Device Directive 93/42/EEC;
- are classified in Class IIa;
- their design, manufacturing and final checks are performed according the Cosmed's Quality System, conform to ISO 9001:2008 and ISO13485:2003 Norms, certified by KIWA CERMET (certificates nr. 387-A and 387-M);
- are CE marked according to the Medical Device Directive 93/42/EEC and subsequent amendments, and certified by KIWA CERMET (certificate nr. MED 9811).

The equipment conforms to the following specifications:

Safety: IEC 60601-1

EMC: IEC 60601-1-2

CE
0476

Service - Warranty

Warranty and limted of liability

COSMED provides a one-year limited warranty from the date of the original sale of the product. COSMED products are guaranteed to be free from defect upon shipment. Liability for products covered by this warranty is limited to the replacement, repair or issuance of a credit for the cost of the defective product at the discretion of COSMED.

The following conditions must exist for the warranty to apply:

1) COSMED is promptly notified in writing by the buyer upon the discovery of defect

2) The defective product is returned to COSMED with transportation charges prepaid by the buyer

3) The defective product is received by COSMED no later than four weeks after the last day of the one-year warranty period

4) COSMED's examination of the defective product verifies that the defect was not caused by misuse, neglect, improper installation or an unauthorized repair or alteration

If the product is manufactured by a third-party, the warranty provided by the third-party manufacturer will be the only one available to the buyer. COSMED hereby disclaims any warranties or liabilities arising from defects or damages to and/or caused by products manufactured by a third-party. The buyer must obtain written authorization from COSMED prior to the repair or alteration of any COSMED products. Failure to obtain a written authorization will result in voiding the warranty.

The limited warranty shall not be extended, diminished or modified by the renderings of technical service from COSMED's agents or employees when the product is ordered or following the use of the product(s).

Return goods policy for warranty or non-warranty repair

Products shipped to COSMED for repair are subject to the following conditions:

1. Products may only be returned upon receiving a receipt which includes the **Returned Materials Authorization Number (RMA)** from COSMED S.r.l
2. The SRN report and packing list should be placed on the outside of the package
3. Returned goods must be shipped with freight and insurance charges prepaid. **Collect shipments will not be accepted**
4. The following list of products is not eligible for return unless proven defective
   - Special order items
   - Expendable products
   - Products held over 30 days after the COSMED invoice date
   - Used products not in the original shipping containers
   - Goods which have been altered or abused in any way
5. The following parts are not covered by warranty:
   - Consumables
   - Fragile glass or plastic parts
   - Rechargeable batteries
   - Damage due to inappropriate use of the device

Repair Service Policy

Goods returned to seller for non-warranty repair will be subject to conditions 1, 2, 3, 4

Returned goods requiring customs documents (Pro-forma Invoice and Customs Paper) should comply with the Italian law

- The shipment must qualify as a temporary export
- Any goods returned to COSMED without customs papers will not be accepted

For European Community members:

The Pro-Forma invoice should include the following:

- Number
- Description of the product
- Quantity
- Serial Number
- Value in €
- Number of parcel
- Gross weight
- Net weight
- Reason for repair

If repairs are needed, you may contact COSMED at the one of the following addresses:

COSMED S.r.l.

Via dei Piani di Monte Savello 37
P.O. Box 3
00041 Pavona di Albano - Rome, Italy
tel. +39 (06) 9315492
fax +39 (06) 9314580
E-mail: customersupport@cosmed.it

USA contact:

COSMED USA Inc

2211 North Elston, Suite 305
Chicago IL 60614 USA
Phone: +1 (773) 645-8113
Fax: +1 (773) 645-8116
email: serviceusa@cosmed.com

COSMED USA Inc

1850 Bates Avenue

Concord CA 94520

Phone: +1 (800) 426-3763

+1 (925) 676-6002

email: serviceusa@cosmed.com

To ensure that you receive efficient technical service, please specify the nature of the problem as indicated on the assistance information form found on our website at http://www.cosmed.com/en/contact-us/support-enquiries

Original packaging should be retained in case the device is needed to be shipped for technical assistance.

Privacy Information

Dear Customer,

We would like to inform you that your personal data is gathered and will be used by COSMED Srl in conformity with the requirements of the Italian privacy law (Decreto Legislativo 196/2003). We believe it is important for you to acknowledge how your personal data is handled.

Personal data treatment and propose

We request and process your personal data for the following purposes:

a) To place an order, register a product, request a service, answer a survey, enter a contest, allow communication with us and to supply necessary authorities with the required information

b) To define your commercial profile

c) To use your commercial profile for marketing or advertising purposes

d) For necessary accounting procedures, such as emailing commercial invoices

e) To provide information to the selected business partners needed to supply your service

How your personal data is treated

Your personal data will be stored in an electronic format and protected against destruction, loss, unauthorized access or use not conforming to the purposes listed above

Consent

The consent to treat your personal data is optional, but if denied COSMED cannot supply the appropriate services

Responsible party

Personal data is held by Cosmed Srl, Via dei Piani di Monte Savello 37, Pavona di Albano Laziale (RM)

Customer rights

In accordance with Art.7, you may:

a) Obtain confirmation of the existence and sharing of your personal data

b) Obtain information on the:

- updating, correction or integration of your data;
- deletion or transformation of your personal data;

c) Deny your consent to treatment of your personal data;

These rights can be exercised by a request in writing to the holder responsible for your personal data.

Disposing of electrical equipment

The device cannot be disposed as unsorted municipal waste. Electronic equipment must be collected separately according to the European Directive 2012/19/UE. Otherwise it can cause dangerous consequences for the environment and human health.

The crossed-out wheeled bin means that the product must be taken to a separate collection when you wish to dispose of it.

Safety and conformity

Safety

IEC 60601-1/EN 60601-1;

The complete classification of the device is as follows:

- Class I with applied parts type B and BF
- Protection against water penetration: IPX1
- Non sterile device
- Device not suitable in the presence of flammable anaesthetics
- Continuous functioning equipment

EMC

The system meets the Standard IEC 60601-1-2.

Paramagnetic O_2 analyzer

The paramagnetic oxygen analyzer meets the requirements of the Standard IEC 68-2 (Basic Environmental Testing Procedures)

IEC 68-2-27: Shock

Peak acceleration:	100g (980 m/s^2)
Duration:	6msecs
Pulse shape:	Half sine

IEC 68-2-6: Sinusoidal vibration

Frequency range:	10Hz - 500Hz
Acceleration amplitude:	1g (9.8 m/s^2)
Type and duration of endurance:	10 sweep cycles in each axis

IEC 68-2-34: Random Vibration, Wide Band

Frequency range:	20Hz - 500Hz
Acceleration spectral density:	0.02 g^2/Hz
Duration:	9 mins

Quality Assurance

_____ ISO 9001:2008 (Registration n° 387-A Kiwa Cermet)

_____ ISO 13485:2003 (Registration n° 387-M Kiwa Cermet)

Medical Device Directive (CE mark)

MDD 93/42/EEC and subsequent amendments (Notified Body 0476).

Class IIa

Technical Specifications

Flowmeter

	ID28 turbine	ID18 turbine	X9
Type:	Bidirectional	Bidirectional	PNT Lilly
Diameter (int.):	28mm	18mm	28mm
Flow range:	0-16 l/s	0-8 l/s	0-14 l/s
Volume range:	0-300 l/min	0-50 l/min	
Resolution:	12 ml	3 ml	1 ml
Accuracy:	± 2% or 20 ml/s	± 2% or 20 ml/s	± 2% or 20 ml/s
Resistance:	<0.6 $cmH_2O/l/s$ @ 14 l/s	<0.7 $cmH_2O/l/s$ @ 3 l/s	<1 $cmH_2O/l/s$ @ 14 l/s

O_2 analyzer

Type:	Paramagnetic
Response time:	120 ms
Range:	0-30% (0-100% FRC)
Accuracy:	±0.1%
Resolution:	0.01% (0.03% FRC)
Warm-up time:	5 min

CO_2 analyzer

Type:	Digital infrared
Response time:	100 ms
Range:	0-10%
Accuracy:	±0.1%
Resolution:	0.01%
Warm-up time:	10 min

CO analyzer

Type:	Infrared
Response time:	200 ms
Range:	0-0.35%
Accuracy:	±0.003%
Resolution:	0.001%
Warm-up time:	15 min

CH_4 analyser

Type:	Infrared
Response time:	200 ms
Range:	0-0.35%
Accuracy:	±0.003%
Resolution:	0.001%
Warm-up time:	15 min

Humidity absorber

Capillary of Nafion (Permapure ®)

Power Supply

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

Environmental Sensors

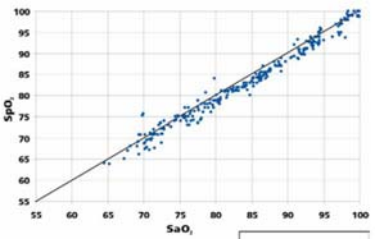
Temperature:	0-50°C
Barometer:	400-800 mmHg
Humidity:	0-100%

Dimension and Weight

Dimensions:	16x33x41 cm
Weight:	11 Kg (weight depends on the configuration)

Oximeter

A_{RMS} (70%-100%)	1.70
A_{RMS} (60%-70%)	2.16
A_{RMS} (70%-80%)	1.90
A_{RMS} (80%-90%)	1.80
A_{RMS} (90%-100%)	1.34



Accuracy specifications

FVC	±3.5% or 0.100L/s whichever is greater
FEV1	±3.5% or 0.100L/s whichever is greater
FEF25-75%	±5.5% or 0.250L/s whichever is greater
PEF	±7% or ±0.420 L/s whichever is greater
MVV	±10.5% or 20 L/min whichever is greater
FRC	±5%
DLCO	±5%
MIP/MEP	±3%
P0.1	±5% or 0.5 cmH_2O whichever is greater
SpO_2	±1%
Ve	±3%
RF	±3%
HR	±2 units
VO_2	±3%
VCO_2	±3%

Refernces - Calculations

VO_2 and VCO_2

"Energy Expenditure and Fuel Selection in Biological Systems: The Theory and Practice of Calculations Based on Indirect Calorimetry and Tracer Methods": M. Elia, G. Livesey, World Rev. Nutr. Diet. Basel, Karger, 1992, vol 70, pp 68-131.

"Nutritional Assessment in Critical Care, A Training Handbook": Donald C. Zavala

Anaerobic Threshold (modified V-Slope)

The intercept of the two slopes is defined as the VO_2 above which VCO_2 increases faster than VO_2 without hyperventilation and can be selected automatically or manually by the software.

During incremental exercise above the Lactate Threshold, a net increase in lactic acid production results in an accelerated rate in VCO_2 relative to VO_2. When plotting these variables a linear relationship is displayed. The slope of the lower component is slightly less than 1.0, whereas the upper component has a slope greater than 1.0. The intercept of these two slopes is the LT or AT point as measured by gas exchange.

The increase in VCO_2 more than that derived from aerobic metabolism must be generated from the buffering of lactic acid. This is seen in all subjects exercising at work levels above their LT.

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MVS, Modified V-Slope method: "Metabolic acidosis during exercise in patients with chronic obstructive pulmonary disease", Sue, Wasserman, CHEST 1988, 94:931-938.

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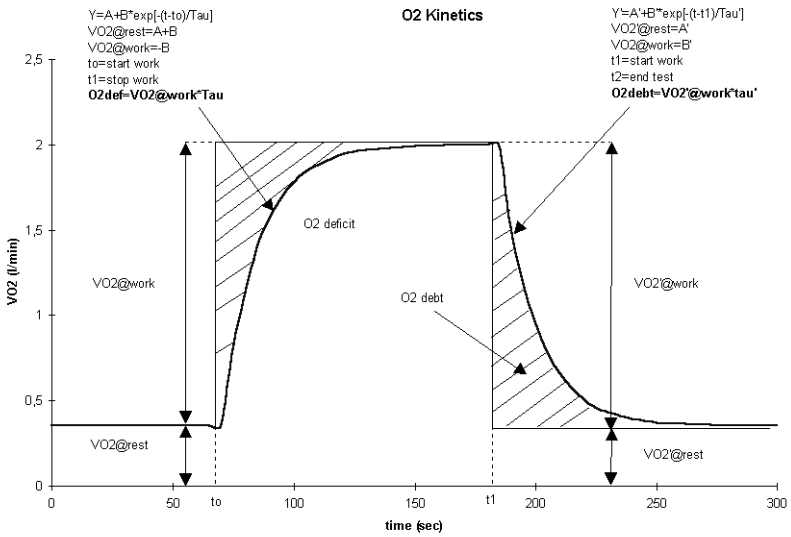
“Delayed Kinetics of VO_2 in the Transition from prior Exercise. Evidence for O2 Transport Limitation of VO2 Kinetics: A Review”; R.L. Hughson and M.A. Morrissey, Int. J. Sports Med. 4 (1983) 31-39

ISO 8996: Ergonomics – Determination of metabolic heat production, 1990

The following picture displays how O_2 debt and O_2 deficit values are calculated.



Predicted Sets

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Compilation of reference values for lung function measurements in children: Ph. H. Quanjer, J. Stocks, G.Polgar, M. Wise, J. Karlberg, G. Borsboom; ERJ 1989, 2, Supp.4,184s-261s.

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Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Anging: J. Knudson, D. Lebowitz, J. Holdberg, B. Burrows; ARRD 1983; 127:725-734

ITS

Intermountain Thoracic Society: Clinical Pulmonary Function Testing, second edition (1984) pp 101, 144

LAM

A survey of ventilatory capacity in Chinese subjects in Hong Kong: Lam Kwok-Kwong, Pang Shing et Al. Annals of Human Biology, 1982, vol. 9, No. 5, 459-472.

Multicéntrico de Barcelona

Spirometric reference values from a Mediterranean population: J. Roca, J. Sanchis, A. Agusti-Vidal, F. Segarra, D. Navajas. R. Rodriguez-Roisin, P. Casan, S. Sans. Bull. Eur. Physiopathol. Respir. 1986, 22, 217-224.

Nhanes III

Spirometric reference values from a sample of the general US population: John L. Hankinson, John. R. Odencrantz and Kathleen B. Fedan. Am J Respir Critr Care Med 1999, 159, 1798-187.

Pneumobil (Brazil)

Valores extraìdos do *Programa Pneumobil/Brasil* para a Tese de Doutoramento do Dr. Carlos Alberto de Castro Pereira. (Boehringer).

Gutierrez (Chile)

Gutierrez et Al. Reference values for Chile population

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Spirometric Standard for healthy non-smoking adults: ARRD Vol. 10-3, p. 57-67, 1971

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Pereira CAC; Barreto SP; Simões JG; Pereira FWL; Gerstler JG; Nakatani J. Valores de Referência para Espirometria em uma amostra da população brasileira adulta. Jornal de Pneumologia 1992; 18: 10-22.

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Neder JA, Andreoni S, Lerario MC, Nery LE. Reference values for lung function tests. II. Maximal respiratory pressures and voluntary ventilation. Braz J Med Biol Res 1999 ;32:719-27

Thai

Wanchai Dejsomritrutai; Khun Nanta Maranetra; Kittipong Maneechotesuwan; Nitipatana Chierakul; Jamsk Tscheikuna; Tasneeya Suthamsmai; Arth Nana; Benjamas Chuaychoo; Phunsup Wongsurakiat; Suchai Charoenratanakul; Wilawan Juengprasert; Chana Naruman: *Reference Spirometric Values for Healthy Lifetime Nonsmokers in Thailand,* J. Med. Assoc. May 2000 (83: 457-466)

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Reference Values for Residual Volume, Functional Residual Capacity and Total Lung Capacity - ATS workshop on Lung Volume measurements, official statement of the European Respiratory Society; J. Stocks, Ph. H. Quanjer: ERJ, 1995, 8, 492-506

Single Breath Oxygen Test

Buist SA, Ross BB: Quantitative Analysis of the Alveolar Plateau in the Diagnosis of Early Airway Obstruction. ARRD 108: 1081, 1973

Mansell A, Bryan C, Levison H: Airway Closure in Children. JAP 33: 711-714, 1972

Buist SA, Ross BB: Predicted Values for Closing Volumes Using a Modified Single Breath Test. ARRD 107: 744-751, 1973.

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Lombardi E, Sly PD, Concutelli G, et al. Reference values of interrupter respiratory resistance in healthy preschool white children. Thorax 2001; 56: 691-695.

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Leo F. Black, Robert E. Hyatt: Maximal Respiratory Pressures: Normal Values and Relationship to Age and Sex, American Review of Respiratory Disease, Volume 99, 1969

Vincken W, Ghezzo H & Cosio MG (1987). Maximal static respiratory pressures in adults: normal values and their relationship to determinants of respiratory function. Bull Eur Physiopathol Resp 23: 435-439.

Automatic Diagnosis (algorithm)

Reference: "Lung Function Testing: selection of reference values and interpretative strategies", A.R.R.D., 144/ 1991:1202-1218.

LLN=Pred-0.674*SD (ATS, 50° percentile)

LLN=Pred-1.647*SD (ERS, 95° percentile)

LLN=Pred*0.8 (80%Pred)

Message interpretation	Criterion
Normal spirometry	FVC and FEV1/FVC > LLN
Obstructive abnormality (may be physiological)	% Pred FEV1 >= 100
Obstructive abnormality: mild	% Pred FEV1 < 100 and >= 70
Obstructive abnormality: moderate	% Pred FEV1 < 70 and >= 60
Obstructive abnormality: moderately severe	% Pred FEV1 < 60 and >= 50
Obstructive abnormality: severe	% Pred FEV1 < 50 and >= 34
Obstructive abnormality: very severe	% Pred FEV1 < 34
Restrictive abnormality: mild	FVC < LLN and % Pred FVC >= 70
Restrictive abnormality: moderate	% Pred FVC < 70 and >= 60
Restrictive abnormality: moderately severe	% Pred FVC < 60 and >= 50
Restrictive abnormality: severe	% Pred FVC < 50 and >= 34
Restrictive abnormality: very severe	% Pred FVC < 34

Quality Control Messages

Reference: Spirometry in the Lung Health Study: Methods and Quality Control, ARRD 1991; 143:1215-1223.

Message	Criterion
Start faster	VEXT >5% of the FVC and >150ml
Blast out harder	PEFT >120 msec
Avoid coughing	50% drop in the flow in first second.
Blow out longer	FET100% <6 sec.
Blow out more air	Flow >0.2l/s within 20 ml of FVC
Blow out harder	dPEF<10%
Take a deeper breath	dFVC<200ml and 5% best FVC
Blow out faster	dFEV1<200ml and 5% FEV1
That was a good test	No errors
FVC reproducible	Diff. 2 max FVC within 0.2 l
FEV1 reproducible	Diff. 2 max FEV1 within 0.2 l
PEF reproducible	Diff. 2 max PEF within 10 %
MVV time too short	MVV time less than 12 sec

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Spirometry

ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Standardisation of spirometry, Eur Respir J 2005; 26: 319–338

Lung function", J.E. Cotes, Blackwell scientific publications

"Guidelines for Clinical Exercises Testing Laboratories", I.L. Pina, G.J. Balady, P. Hanson, A.J. Labovitz, D.W. Madonna, J. Myers. American Heart Association. 1995; 91, 912.

Dosimeter

Guidelines for Methacholine and Exercise Challenge Testing - 1999 Am. J. Respir. Crit. Care Med., Volume 161, Number 1, January 2000, 309-329 (Official Statement of the ATS adopted by the ATS Board of Directors, July 1999)

Lung Volumes

ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Standardisation of the measurement of lung volumes, Eur Respir J 2005; 26: 511-522

Single-Breath with Apnoea

ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Standardisation of the single breath determination of carbon monoxide uptake in the lung, Eur Respir J 2005; 26: 720-735

Single-Breath without Apnoea

Rest and Exercise Cardiac Output and Diffusing Capacity Assessed By a Single Slow Exhalation of Methane, Acetylene, and Carbon Monoxide; Ramage, Coleman and MacIntyre, CHEST 92, 1, July 1987

MIP/MEP

Leo F. Black, Robert E. Hyatt: Maximal Respiratory Pressures: Normal Values and Relationship to Age and Sex, American Review of Respiratory Disease, Volume 99, 1969

Vincken W, Ghezzo H & Cosio MG (1987). Maximal static respiratory pressures in adults: normal values and their relationship to determinants of respiratory function. Bull Eur Physiopathol Resp 23: 435-439.

P0.1

G.B.Drummond, J.Fischer, A.Zidulka, J.Milic-Emili: Pattern of Reduction of Ventilatory and Occlusion Pressure Response to Carbon Dioxide by Pentazocine in Man, Br. J. Anaesth. (1982), 54, 87-96

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G. Liistro, D. Stanescu, D. Rodenstein, C. Veriter: "Reassesment of interrupter, technique for measuring flow resistance in human", J. Appl. Physiol., 67(3), 933-937, 1989.

Gas Exchange

On line computer analysis and breath by breath graphical display of exercise function tests."; Beaver, Wasserman, Whipp, JAP , 34(1):128-132, 1973

Measurement and analysis of gas exchange during exercise using a programmable calculator"; Sue, Hansen, Blais, Wasserman, JAP, 49(3), 1980:456-461

Principles of exercise testing and interpretation, 2nd edition"; Wasserman et Al, 1994

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Cardiorespiratory Assessment of Apparently Healthy Populations", Timothy R. McConnell, in ACSM's Resource Manual for Guidelines for Exercise Testing and Prescription, 4th Edition, pp. 361-366

Franklin BA, ed. ACSM's Guidelines for Exercise Testing and Prescription, 6th Edition Philadelphia: Williams&Wilkins, 2000:22-29

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National Lung Health Education Program (NLHEP) - Guide to prescribing Home Oxygen. By Thomas L. Petty.

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