microQuark

PC-based Spirometer

Manuale Utente

User Manual

Manuel d'utilisation

Benutzerhandbuch

Manual del Usuario

COSMED
The Metabolic Company

microQuark User manual, XVII Edition

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COSMED Srl - Italy

http://www.cosmed.com

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Getting started

Important notices

Intended use

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

Caution: Federal law restricts this device to be sold by the order of a physician.

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

- Formulating of a 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.

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. All bibliography references are reported in the Appendix.

This User Manual has been developed in accordance with the Class IIa European Medical Device Directive requirements.

The precautions listed below should be noted before operating the device to ensure the safety of the user.

1. This User Manual should always be available as a reference when testing.
2. The following standards should be applied to ensure the accuracy of individual test results:
   - Accessories should only be used as described in this manual. The manufacturer does not warranty any non-authorized accessories used by the end user. The manufacturer may offer suggestions while using such accessories and the complications they could cause;
   - Repairs or modifications of the device should ONLY be carried out by qualified and trained personnel;
   - Environmental and electrical conditions in which the device operates should be in compliance with the specifications of this manual. In particular grounding reliability and leakage current suppression can only be assured when the device three-wire receptacle is connected to a yellow-green return connected to earth ground. Attempting to defeat the proper connection of the ground wire is dangerous for users and equipment.
   - Equipment maintenance, inspections, disinfection and cleaning should be as described in this manual.
3. Before powering on the system, the power cords and plugs should be inspected. Damaged electrical parts must be replaced immediately by authorized personnel.
4. 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. If the recommended disposable anti-bacterial filters are not used, you must disinfect each part coming into contact with the patient and patient's breath prior to each test.
5. The cleaning procedures and inspections in the System Maintenance section should be performed prior to each test.
6. 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).
7. The device should not come near any heat or flame sources, flammable or inflammable liquids or gases and explosive properties.
8. The device should not be used in conjunction with any other medical device unless that device is recommended by the manufacturer.
9. The device should be used with a computer with electromagnetic compatibility, CE marking and low radiation emission displays.
10. The PC connected to the device must be compliant with EN 60601-1 by means of an isolation transformer.
11. Precautions regarding EMC should be taken prior to installation and can be noted in the section *EMC*.
12. Portable and mobile RF communication equipment may interfere with the performance of the device.

13. Only the cable and accessories supplied with the equipment should be used with the device. The use of accessories and/or cables other than those supplied may result in increased emissions or decreased immunity of the equipment.
14. The device should not be used adjacent to or stacked with other equipment. If this is necessary, you must verify that the device continues to operate normally in the configuration in which it will be used.
15. 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

Contraindications

Performing forced expiratory manoeuvres involved in spirometry testing may be contraindicated in certain conditions.

Contraindications for the spirometry testing

Absolute contraindications

For FVC, VC and MVV tests:

- Post-operative thoracic surgery patients.

For 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

For FVC tests:

- Spontaneous post-pneumothorax.
- Arterial-venous aneurysm.
- Severe arterial hypertension.
- Pregnant with complications in the 3rd month.

For 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, but the following contraindications should be acknowledged prior to testing:

Absolute contraindications

- Severe bronchial obstruction (decreased FEV_1 in adults).
- Recent myocardium infarct.
- Recent cerebral vascular accident.
- Known arterial aneurysm.
- Incapacity for understanding the provocation test procedures and its implications.

Relative contraindications

- Bronchial obstruction caused by performing respiratory manoeuvres.
- 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

Environmental condition of use

COSMED units should not be operated near explosive substances.

Equipment should not be installed near electrical or magnetic devices such as x-ray equipment, transformers or power lines. These devices could create electrical interferences when performing testing procedures. 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.

COSMED equipment should be operated under normal environmental temperatures and conditions which are defined as follows [IEC 60601-1/EN 60601-1]:

- Temperatures range: 10°C (50°F) and 40°C (104°F).
- Relative humidity range: 30% to 90% (not condensing).
- Atmospheric Pressure range: 600 mBar to 1060 mBar.
- Avoid operating equipment in the presence of noxious fumes or in dusty environments.
- Do not place units near heat sources.
- Cardiopulmonary resuscitation equipment should be accessible in the case of an emergency.
- Adequate floor space and easy access to the patient during exercise testing is necessary.
- Adequate ventilation should be maintained in the room the testing is performed.

Guidance and manufacturer's declaration - electromagnetic emissions		
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.		
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 B	The device is suitable for use in all establishments, including 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 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**
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 at least 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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 separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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.

Overview of the manual

This manual is organized in the following chapters:

Getting started. Describes the intended use of the device, how to properly use it and features of the unit and accessories.

Installation. Lists the steps required to properly install the device.

System maintenance. Describes system maintenance procedures.

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 to read both manuals before using this device.

Introduction

MicroQuark is an instrument designed for lung function screening; the core of the system is the “intelligent” flowmeter that, connected to a Personal Computer (laptop or desktop), turns it in a complete spirometric lab.

The system is composed by the turbine flowmeter, the measurement and data elaboration device (lightweight and ergonomic), the communication cable and by the Software pack.

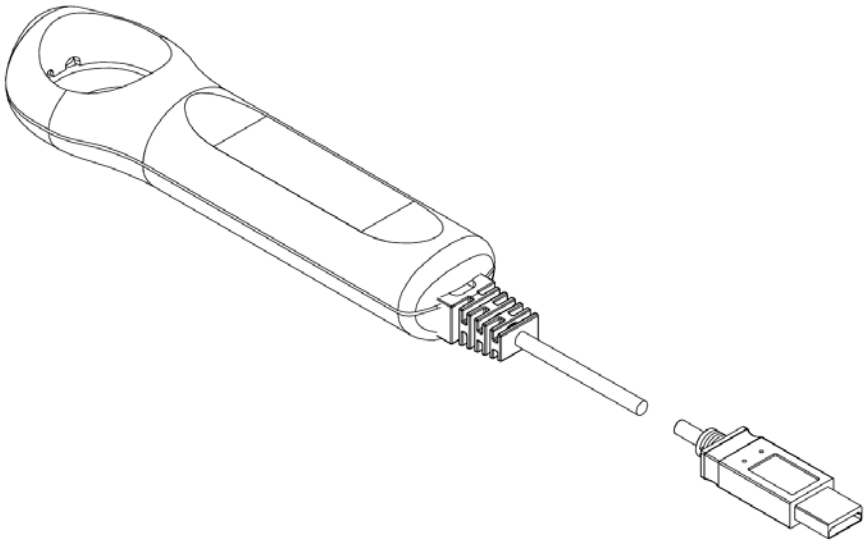
MicroQuark overview

MicroQuark is mainly made of:

- MicroQuark unit
- Flowmeter
- Other accessories

Let us see an overview of the parts and their assembly.

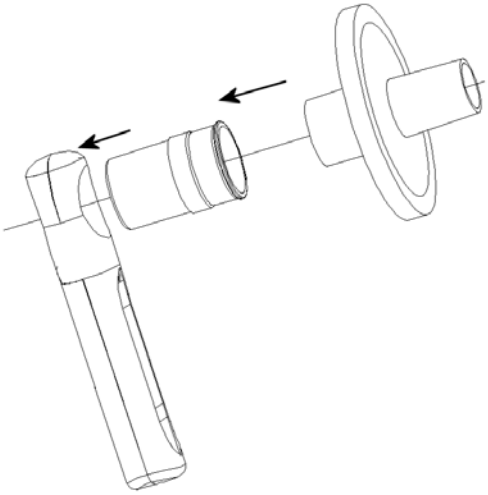
MicroQuark unit



The unit is the core of the device, with the electronics and cables for its working.

The flowmeter

The turbine flowmeter is made of a handle (the reader) with a hole, in which it is placed the turbine.

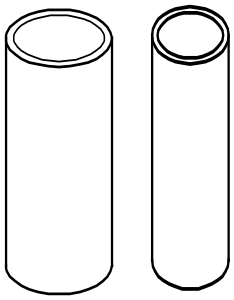


The air passing through the helical conveyors, takes a spiral motion which causes the rotation of the turbine rotor. The rolling blade interrupts the infrared light beamed by the two diodes of the reader. Every interruption represents 1/4 turn of the rotor, this allows to measure the number of turn in the time.

For hygienic reasons, we strongly recommend the use of a bacterial filter, to be connected as in the picture by side.

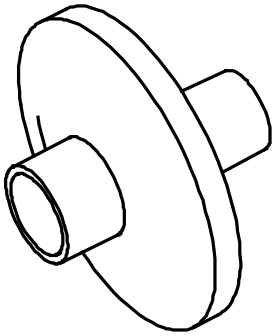
> ***Note:*** *While inserting the turbine, be sure to push the turbine up to touch the end of the reader.*

Paper mouthpieces



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

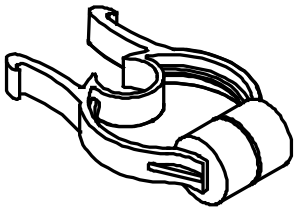
Antibacterial filters



The use of antibacterial filters is recommended for infection control. However, regular cleaning and decontamination of lung function equipment should always be performed.

> ***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 manoeuvres.

Installation

Before starting

Before operating the MicroQuark you should inspect the equipment and complete the product registration.

Checking the packing contents

When opening your product you should assure that the package contains the items listed in the packing list enclosed with the device. If there are any missing or damaged parts you should contact Cosmed's technical assistance.

Options/Accessories

The following options are available with the microQuark system:

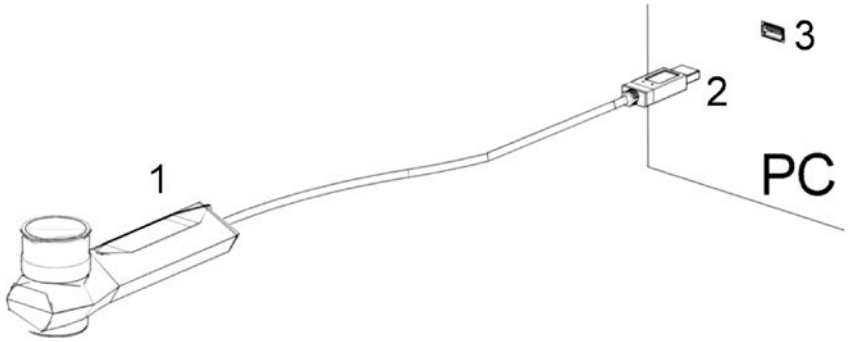
Code	Quantity	Description
C00600-01-11	1	3 litres calibration syringe

Preparing MicroQuark

Power supply is provided by PC through the USB plug. The unit is turned on/off automatically by the PC.

Insert the turbine and be sure to push the turbine up to touch the end of the holder.

MicroQuark connects to the PC as shown in the following picture.



1. microQuark
2. USB connector
3. USB port

How to contact COSMED

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

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

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

Complaints, feedback and suggestions

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

System maintenance

System maintenance

All service operations which are not specified in this user manual should be performed by qualified personnel in accordance with the service handbook (to be required to the manufacturer).

All materials used in the construction of the MicroQuark are non toxic and pose no safety risk to the patient or operator.

Prior to the device cleaning, disinfection and inspection it is necessary to switch off the device and to disconnect adapters from the supply mains.

In order to guarantee the highest accuracy of measurements we recommend you to disinfect the turbine periodically.

Use disposable anti-bacterial filters or disinfect each part in contact with the patient before each test.

Cleaning and disinfecting

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:

1. The responsibility for handling, cleaning and decontaminating reusable medical devices should be assigned to trained, qualified individuals.
2. Appropriate protective clothing (gloves, masks, eye protection, gowns) will minimize the potential for personal exposure to blood borne and other disease-producing organisms.
3. 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.
4. A disinfectant solution is only effective if it can contact all surfaces of the items to be disinfected or sterilized.

5. 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)*

Introduction

Decontamination is a multi-step process that includes preparation at point of use, thorough cleaning and rinsing and a microbicidal process. Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing it might not be possible to achieve high level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil, to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material, lubricants, or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.

The second step in decontamination is the microbicidal process which is defined as a process to provide a particular level of microbial lethality (kill). COSMED components are classified as "semi-critical" items which are devices that come into contact with intact mucous membranes. Semi-critical devices at a minimum require a high-level disinfection procedure. Sterilization is not absolutely essential.

COSMED components require complete or partial disassembly for cleaning and disinfection. It is the responsibility of the user (health care personnel) for ensuring that: the cleaning methods recommended can be duplicated in their environment, that appropriate tools, and replacement parts are available and that instructions are followed correctly.

Cleaning

> ***Note:*** *Please refer to additional, specific cleaning instructions for the turbine assembly below.*

Cleaning Agents/supplies

Mild detergents with a neutral pH (7) are recommended for cleaning. Use warm water (22°-43°c) with the mild detergent. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agents manufacturer's directions.

Cleaning supplies are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton or foam tipped applicators, soft brushes, and soft cloths. Cleaning supplies should be cleaned and disinfected or sterilized daily.

Water Quality: tap water is acceptable for use in cleaning COSMED components.

COSMED components should be soaked and rinsed in tap water at 22°-43°C to prevent the coagulation of solid substances onto the device and thus facilitate the removal of debris.

Enzymatic detergents with a neutral pH (7) are recommended when processing difficult-to-clean items with dried-on matter. Soaking mask and valve components in an enzymatic detergent solution can effectively remove visible debris except for lubricants thus providing an acceptable alternative to manual cleaning. Rinsing is necessary to remove all traces of detergent and extraneous debris.

Standard cleaning procedure

These steps are common to all the cleaning procedures

Step 1 Preparation at Point of Use. The cleaning of reusable items begins soon after use. At the point of use, personnel wearing gloves and other protective attire separate disposable items or components from reusable items and discard them in appropriate receptacles. Soil is wiped from device surfaces with a moist sponge or towel. The soiled/contaminated items are then contained in a manner that will reduce the risk of personal exposure to pathogens. Items are usually placed in a basket, tray or rigid container for transportation to the processing area, usually transported in or on a cart, as hand carrying of soiled items is discouraged.

Step 2 Inspection. Inspect the items for damage at all stages of handling. If damage is detected on any of the components it should be identified and documented. Complete the disinfection/sterilization process and contact technical service for replacement.

Step 3 Presoak. Protective attire is required of personnel handling contaminated items. At the processing area soak or rinse the items in tap water 22°-43° C. Please note that rinse with flowing water is not possible on the turbine. If an enzyme product is required, soak for one to two minutes. Remove and examine, extend the soak time for components with dried-on matter, prolonged soaking of components may be detrimental, causing damage to the component surfaces. Refer to the detergent instructions for its usage and soak time.

Step 4 Disassembly. Disassemble the item (if necessary) according to the instructions reported in the corresponding section.

Step 5 Cleaning. Protective attire is required for personnel handling contaminated items. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

1. Manual cleaning of the items should be done under 22°-43°C water. Use a neutral pH (7) mild detergent. Water hardness, temperature and the type of soil affect the effectiveness of the detergents; the detergent manufacturer's instructions should be consulted. Use a small soft brush to scrub all parts. Abrasive cleaning compounds and implements can damage the items and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.
2. Items must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components. Use a flowing triple rinse cycle at a minimum with tap water. Please note that rinse with flowing water is not possible on the turbine.
3. Dry all components thoroughly using soft clean clothes or disposable paper towels.

Disinfection

The recommendations in this sections have been retrieved from:

William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC): Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

(http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf)

High-level disinfection is the recommended decontamination procedure for semi-critical devices.

Devices are classified semi-critical when they touches mucous membranes or broken skin. Examples of semi-critical devices are flexible endoscopes, laryngoscopes, endotracheal tubes, respiratory therapy and anesthesia equipment, diaphragm fitting rings, and other similar devices.

Preparing the disinfecting solution

The recommended disinfection solutions are as follows:

- Sodium hypochlorite 0.5% (5000 ppm) prepared fresh for use within 24 hours.
- Sodium hypochlorite 1% (10000 ppm) prepared fresh for use within 30 days.

The first solution can be prepared by adding 1 part household bleach (sodium hypochlorite 5.25%) to 9 parts water. The second solution can be prepared by adding 1 part household bleach to 4 parts water.

. The turbine flowmeter

Guidelines recommend that the turbine should be cleaned and disinfected prior to every test to ensure accurate measurements and to comply with recommended sanitation measures as follow.

Cleaning the turbine

Follow the standard cleaning procedure reported above, paying attention to the following:

1. For rinsing, do not use flowing water, which may damage the turbine. Rinse the turbine in a vessel, filled of clean water, shaking gently to remove the disinfectant. Do not place the turbine under running water or move the turbine while submerged.
2. For cleaning and rinsing, do not wet the sampling line.
3. Use the brush (point 1 step 5) only for the external parts of the turbine, in order to avoid damages to the turbine blade.

Disinfecting the turbine

1. Take out the turbine.
2. Dip it in a disinfectant solution (non alcoholic based) for about 20 minutes.
3. Rinse the turbine in a vessel, filled of clean water, shaking gently to remove the disinfectant (do not clean the turbine by putting it under running water!).

4. In order to let it dry, please shake it in air and/or connect it to the calibration syringe through the antibacterial filter and perform some strokes.
5. After cleaning the turbine, check if the turbine propeller rotates freely even with a low speed air flow.
6. Connect the turbine to the reader.

Precautions to take when cleaning, disinfecting and drying the turbine

- Do not expose the turbine to high heat or to a direct flow of water.
- Do not expose the sampling tube or the connector on the end of the cable to any liquids.
- Do not use alcoholic solutions to clean the turbine.

Inspections

The equipment requires easy inspections to be carried out in order to assure a proper electrical and mechanical safety level in the years.

These inspections are highly recommended after a rough use of the equipment or after a period of storage in unfavourable environmental conditions.

Referring to the electrical safety, it is important to check the conditions of insulation materials of cables, plugs and any other visible part by means of simple inspection, when the equipment is switched off and adapters (or electrical feeders) are disconnected from the supply mains.

Extract the turbine from the unit and verify, by inspection, that the turbine axis fits correctly its seats and the blade is strongly fastened on the axis itself (it can be useful to shake slightly the turbine in order to note any anomalous movement).

Check if there are any torn or broken components in the breathing circuits: remember that they can create safety risk to patients during tests.

Appendix

Declaration of conformity

Manufacturer: COSMED S.r.l.
Address: Via dei Piani di Monte Savello 37
00041 Albano Laziale (RM)
ITALY
phone: +39-06-9315492
fax: +39-06-9314580

manufacturer of the following equipment:

microQuark

declares under his sole responsibility that:

- the above listed equipment comply 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 CERMET (certificates nr. 387-A and 387-M);
- are CE marked according to the Medical Device Directive 93/42/EEC and certified by CERMET (certificate nr. MED 9811).

The equipment conform with the following specifications:

Safety: IEC 60601-1

EMC: IEC 60601-1-2

CE
0476

Service - Warranty

Warranty and limitation 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 a 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 warranties provided by the third-party manufacturer will be the only ones available for 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 a void of the warranty.

The limited warranty shall not be enlarged, 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 **Service Return Number (SRN)** 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.
   - Damages 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
00041 Albano Laziale - 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: usa.sales@cosmed.it

To ensure that you receive efficient technical service, please specify the nature of the problem as indicated on the assistance information form.

You should save the original packaging in case the need to ship the unit to a technical assistance centre should arise.

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 purposes

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.

Holder of the personal data

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 2002/96/EEC. 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 type B
- 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.

Quality Assurance

UNI EN ISO 9001:2008 (Registration n° 387-A Cermet)

UNI EN ISO 13485:2003 (Registration n° 387-M Cermet)

Medical Device Directive (CE mark)

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

Class IIa

Technical features

Flowmeter	Bidirectional digital turbine
Flow Range:	0 - 16 l/s
Volume Range:	12 l
Accuracy:	± 2% or 20 ml/s
Resistance:	< 0.6 cmH2O/l/s @14 l/s
Mouthpieces:	Ø 31 and Ø22 mm
Dimensions:	150 x 45 x 53 mm
Weight:	77g

Predicted values

ERS93

Standardized Lung Function Testing: Official Statement of the European Respiratory Society, The European Respiratory Journal Volume 6, Supplement 16, March 1993.

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

Knudson, Morris and Bass

The maximal Expiratory Flow-Volume curve: Knudson et al. ARRD Vol. 123, p. 659-664, 1981

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

Pereira (Brazil)

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.

Mallozi MC. Valores de referência para espirometria em crianças e adolescentes, calculados a partir de uma amostra da cidade de São Paulo. Valores finais publicados em : Pereira CAC; Lemle A; Algranti E; Jansen JM; Valença LM; Nery LE; Mallozi M; Gerbasi M; Dias RM; Zim W. I Consenso Brasileiro sobre Espirometria. Jornal de Pneumologia 1996; 22:105-164.

Scalambrini Costa F, Scueiri CEB, Silva Jr WC, Pereira CAC, Nakatani J. Valores de referência para espirometria em uma amostra da população brasileira adulta da raça negra. J Pneumologia 1996;22: 165-170.

Neder JA; Andreoni S; Castelo-Filho A; Nery LE. Reference values for lung function tests. I. Static Volumes. Brazilian Journal Medical and Biological Research 1999; 32:703-17.

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

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

Rint

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

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.

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

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

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General

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ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Interpretative strategies for lung function test, Eur Respir J 2005; 26: 720-735.

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