

**Specificație tehnică completată**  
**Spirograf (260500)**  
**Model: Pony Fx; Producător: COSMED; Țara: Italia**

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofetantă
Spirograf Cod 260500 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer și a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forțată [SVI], fluxul de vîrf [PF], volumul expirator forțat într-o secundă [FEV1]). Parametrul Specificația Tip Spirometru portabil Gama de volum- 0-8 l Gama de flux- 0-16 l/s Memorarea automată a celor mai bune 3 rezultate de spirometrie da Parametri măsurați FVC FEV1 FEV1/FVC Raport PEF EVC IVC Ti Te IC IRV ERV TV Printer intern Memorie nu mai puțin de 300 teste grafice memorate Transfer date la PC teste pacient verificare aparat up-gradare software Dispozitivul de măsură bidirecțional Eroarea la volum ≤3% Eroarea la flux ≤3% Afișaj Alfanumeric Control taste alfanumerice Interfața PC da Alimentare Cu sursă internă de alimentare, acumulatori reîncărcabile Rețeaua electrică 220 V, 50 Hz Accesorii Să fie inclus toate consumabilele necesare pentru 200 investigații "filtre antibacteriale sau turbine de unică utilizare" Seringă de calibrare da, (doar în cazul dacă este necesară) Clește pentru nas tip adult 1 buc. Clește pentru nas tip pediatric 1 buc. Hîrtir 20 buc.	Spirograf <b>DA</b> Cod 260500 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer și a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forțată [SVI], fluxul de vîrf [PF], volumul expirator forțat într-o secundă [FEV1]). <b>DA</b> Parametrul Specificația Tip Spirometru portabil <b>DA</b> Gama de volum- 0-8 l <b>DA</b> Gama de flux- 0-16 l/s <b>DA</b> Memorarea automată a celor mai bune 3 rezultate de spirometrie <b>Da</b> Parametri măsurați FVC <b>DA</b> FEV1 <b>DA</b> FEV1/FVC <b>DA</b> Raport PEF <b>DA</b> EVC <b>DA</b> IVC <b>DA</b> Ti <b>DA</b> Te <b>DA</b> IC <b>DA</b> IRV <b>DA</b> ERV <b>DA</b> TV <b>DA</b> Printer intern <b>DA</b> Memorie nu mai puțin de <b>300 teste grafice memorate DA</b> Transfer date la PC teste pacient <b>DA</b> verificare aparat <b>DA</b> up-gradare software <b>DA</b> Dispozitivul de măsură bidirecțional <b>DA</b> Eroarea la volum ≤3% <b>DA</b> Eroarea la flux ≤2% <b>DA</b> Afișaj Alfanumeric <b>DA</b> Control taste alfanumerice <b>DA</b> Interfața PC <b>da</b> Alimentare Cu sursă internă de alimentare, acumulatori reîncărcabile <b>DA</b> Rețeaua electrică 220 V, 50 Hz <b>DA</b> Accesorii Să fie inclus toate consumabilele necesare pentru 200 investigații "filtre antibacteriale cu turbine de unică utilizare" <b>DA</b> Seringă de calibrare da, (doar în cazul dacă este necesară) <b>DA</b> Clește pentru nas tip adult si pediatric sint de o singura marimie. 200 buc. <b>DA</b> Hîrtir 20 buc. <b>DA</b>

# Antiviral/Antibacterial Filters

## The Most Effective, Safe and Affordable Solution to Prevent Viral and Bacterial Cross-Contamination



- ▶ High viral and bacterial filtration efficiency (99.999%)
- ▶ Low resistance to airflow
- ▶ Suitable for both lung function and exercise testing
- ▶ Minimal deadspace
- ▶ Available with both round and oval/ergonomic mouthpiece shape
- ▶ Individually packaged in 50 pieces box

Antiviral and antibacterial respiratory filters provide an easy way to ensure protection from cross-contamination which keeps both the patient and operator safe without compromising on system performance.

The use of filter during lung function and metabolic testing also reduce the amount of droplets aerosol dispersion in the air mitigating the contamination of the environment due to forced expirations and high ventilations required during testing. Preventing aerosol spreading is fundamental to minimize infection diseases transmission<sup>1,2</sup>.

The resistance of the combined system necessary to perform the tests is inferior to those suggested by the ATS/ERS (1.5cmH<sub>2</sub>O/L/s@14 L/s)<sup>3</sup> both during inhalation and exhalation.

Filters are tested by independent laboratories passing BFE and VFE test using Staphylococcus Aureus (\*ATCC #6538) and Bacteriophage PHI X174 (dimension about 0.025 µm). According to current knowledge Coronavirus species, including COVID-19 have a particle size of 0.06-0.2 µm, which is significantly larger than the bacteriophages used in the effectiveness tests. However, at this point in time we have not conducted any specific tests against COVID-19 as the challenge organism.

Filters comply with latest ERS guidelines recommending to use the filters with minimum proven efficiency for high expiratory flow of 600 to 700 L/min<sup>2</sup>.

Two mouthpiece types, oval and round, guarantee the maximum ergonomics and the compatibility with any equipment connector.

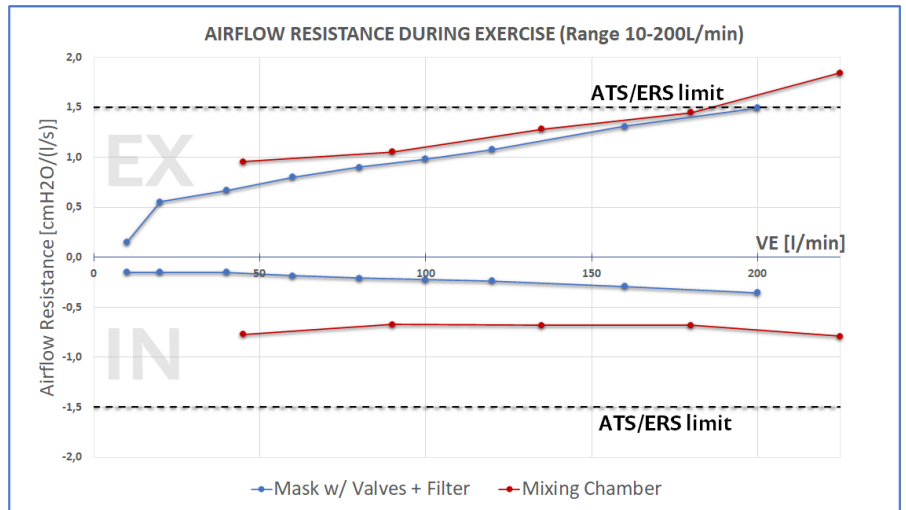
Filters have been tested to be used during Cardio Pulmonary Exercise Testing.

The following chart provides results of resistance to air flow at different ventilation rates up to 200 L/min that represent ventilation rates reached by high-level athletes.

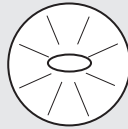
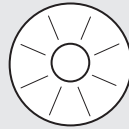
The validation protocol compares the results against a conventional mixing chamber metabolic cart and ATS/ERS maximal acceptable resistance for lung function testing equipment.

The new setups show good results for both expiratory and inspiratory resistance when using masks with or without inspiratory valves.

The additional dead space introduced by the new setups, does not affect  $VO_2$  or  $VCO_2$  calculation.



### Technical Specifications

Mouthpiece Shape		
Product	Patient filter - Oval mouthpiece	Patient filter - Round mouthpiece
Part number	A 182 300 005	A 182 300 004
Dimensions	Machine side: OD 30.7mm, ID 26mm Patient side: Integrated mouthpiece Length: 86mm Width: 97mm	Machine side: OD 30.7mm, ID 26mm Patient side: OD 24.9mm, ID 20.9mm Length: 77mm Width: 97mm
Material	Housing: Polypropylene Filter Media: 200g electrostatic blended synthetic fibre	
Packaging	Box of 50 filters individually packed in single plastic bags	
Pathogenous agents	Bacteria and virus	
Bacterial filtration efficiency*	99.999% (Staphylococcus aureus @ 30L/min)	
Viral filtration efficiency*	99.999% (Bacteriophage @ 30L/min)	
Resistance (EN ISO 9360-1)	0.27cmH <sub>2</sub> O @ 30L/min 0.59cmH <sub>2</sub> O @ 60L/min 0.97cmH <sub>2</sub> O @ 90L/min	0.39cmH <sub>2</sub> O @ 30L/min 0.74cmH <sub>2</sub> O @ 60L/min 1.1cmH <sub>2</sub> O @ 90L/min
Dead space	75ml	
Applications	Pulmonary function test Spirometry	Cardio pulmonary exercise test (with adapter C05085-01-20) Indirect calorimetry



\* The significance of % filtration efficiency is explained by the number of organisms passing through the filter. If the number of organisms challenging the filter are 1 000 000, when the efficiency is 99.999% only 10 organisms pass through (or only 1 if the efficiency is 99.9999%). A 99.9999% filter is therefore 10 times more efficient than 99.999% filter.

#### References:

- (1) ERS COVID-19 resource centre (<https://www.ersnet.org/the-society/news/novel-coronavirus-outbreak--update-and-information-for-healthcare-professionals>); Novel Coronavirus (COVID-19): The ATS Response (<https://www.thoracic.org/professionals/clinical-resources/disease-related-resources/novel-coronavirus.php>)
- (2) Recommendation from ERS Group 9.1 (Respiratory function technologists/Scientists) Lung function testing during COVID-19 pandemic and beyond (<https://ers.app.box.com/s/zs1uu88wy51monr0ewd990itoz4tsn2h>)
- (3) "STANDARDISATION OF LUNG FUNCTION TESTING" Edited by V. Brusasco, R.Crapo and G. Viegi: Standardisation of spirometry, Eur Respir J 2005; 26: 319–338








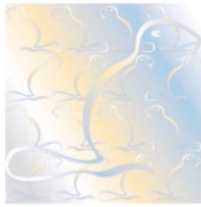
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<b>Product Comparison Matrix</b>						
		microQuark	Pony FX	Pony FX Mip/Mep	Spiropalm 6MWT	Quark Spiro
Technology						
Spirometer Type		PC based	Desktop	Desktop	Desktop	Stationary
Flowmeter						
Characteristics		Digital Bidirectional Turbine	Digital Bidirectional Turbine	Digital Bidirectional Turbine	Digital Bidirectional Turbine	Multi-use Pneumatich (Lilly)
Accuracy		±2% or 20 ml/s	±2% or 20 ml/s	±2% or 20 ml/s	±2% or 20 ml/s	±2% or 20 ml/s
Flow Range		0-16 l/s	0-16 l/s	0-16 l/s	0-16 l/s	0-14 l/sec
Ventilation Range (MVV - Exercise)		0-300 l/min	0-300 l/min	0-300 l/min	0-300 l/min	
Resolution		12 ml	12 ml	12 ml	12 ml	1 ml
Resistance		<0.6 cmH2O/l/s @14l/s	<0.6 cmH2O/l/s @14l/s	<0.6 cmH2O/l/s @14l/s	<0.6 cmH2O/l/s @14l/s	<1.0 cmH2O/l/s @ 14 l/s
Calibration		w/ 3L Syringe	w/ 3L Syringe	w/ 3L Syringe	w/ 3L Syringe	w/ 3L Syringe
Printing						
Built-in high-speed thermal printer (110mm)			•	•		
Direct USB connection w/ external printer (HP PCL-3 compatible)			•	•	•	
PC printer (through software)		•	•	•	•	
Hardware						
Display		PC monitor	Colour LCD 320x240 pixel	Colour LCD 320x240 pixel	LCD B/W 320x240 pixel	PC monitor
Interfaces		USB	USB/RS232	USB/RS232	USB	USB/RS-232
Memory capacity		PC limited	400-600 tests	400-600 tests	600-1000 tests	PC limited
Batteries Autonomy (operating mode)			5 hours	5 hours	6 hours	
Electrical Requirements		USB (5V)	AC/DC 100-240V	AC/DC 100-240V	AC/DC 100-240V	AC/DC 100-240V
Dimensions (cm)		15x4.5x5.3	19.8x23.8x7.6	19.8x23.8x7.6	18.5x8.6x3.1	33x41x16
Weight (gr)		77	1,200	1,200	600	6,000
Software						
PC Software (OMNIA)		•	•	•	•	•
Available languages		Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional & Simplified), Korean, Romanian, Polish, Czech, Norwegian, Hebrew				
PC Configuration		i3 or higher processor speed. Compatible with Windows 7, 8, 8.1, 10 (32 or 64 bit). RAM 4GB (8GB recommended). HD with 10GB of free space				
Predicted Values (partial listing)		2012 Global Lung initiative (GLI), ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicentrico Barcelona, Thai 2000, Austria (Forche), Crapo 1981 user defined predicted calculations.				
Automatic Interpretation		ATS/ERS 2005 (Spirometry), GOLD COPD, ATS/ERS 2005 (Obstruction Reversibility based on FVC Post BD), ATS/ERS 2007 (Obstruction Reversibility based on Rocc)				
Tests						
Spirometry						
Forced/Slow Vital Capacity (SVC-FVC)		•	•	•	•	•
Maximum Voluntary Ventilation (MVV)		•	•	•	•	•
Bronchial Challenge Test (Pre-Post)		•	•	•	•	•
Bronchial Challenge Test with integrated dosimeter						○
Airway Resistance (Rocc/Rint)			○	○		○
Respiratory Mechanics (MIP/MEP)			○	•		
6 Minute Walk Test (6MWT)					•	
Oxygen Saturation (SpO <sub>2</sub> , HR) w/ Nonin ipod			○	○	•	



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## Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

### **COSMED S.r.l.**

:  
Via dei Piani di Monte Savello, 37  
00041 Albano Laziale, RM - Italia  
**Sede Legale / Registered Headquarter**  
Viale Bruno Buozzi, 77  
00197 Roma, RM - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Accessori monouso / *Disposable accessories*  
Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*

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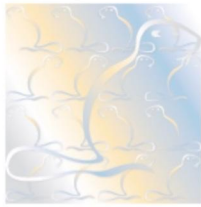
Rif. rapporto di audit/ *Ref. audit report:* 31/01/2018, 01-02/02/2018, 26/03/2018, 22/04/2018

Chief Operating Officer  
Giampiero Belcredi



Organismo Notificato n. 0476  
Notified Body nr. 0476





Reg. Numero /  
Reg. Number MED 9811A

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First issue date 2018-04-23

Scadenza /  
Valid until 2023-04-24

Revisione /  
Revision 0

Valido da /  
Valid from 2018-04-23

Ultima modifica /  
Last change date 2018-04-23

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CERTIFICATE

## Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

**Tipologia / Medical Devices:**  
Accessori monouso / Disposable accessories

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
COSMED

**Modello / Model:**  
Filtri antibatterici / Bacterial filters

**Tipologia / Medical Devices:**  
Dispositivi monouso per diagnostica polmonare / Disposable devices for pulmonary test

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
COSMED

**Modello / Model:**  
Boccagli / Mouthpieces

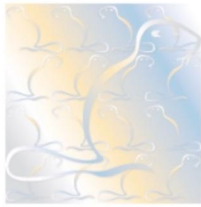
La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.  
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Reg. Numero / <i>Reg. Number</i>	MED 9811	Revisione / <i>Revision</i>	15
Primo rilascio / <i>First issue date</i>	1998-06-11	Valido da / <i>Valid from</i>	2018-04-23
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Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

### **COSMED S.r.l.**

**Sede Operativa / Operational Headquarter:**

Via dei Piani di Monte Savello, 37  
00041 Albano Laziale, RM - Italia

**Sede Legale / Registered Headquarter**

Viale Bruno Buozzi, 77  
00197 Roma, RM - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

**Accessori monouso / Disposable accessories**

Dispositivi per la valutazione della funzione respiratoria, cardiaca e metabolica / *Devices for evaluation of the respiratory, cardiac and metabolic function*

Elettrocardiografi / *Electrocardiographs*

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Rif. rapporto di audit/ *Ref. audit report:* 31/01/2018, 01-02/02/2018, 26/03/2018, 22/04/2018

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## **Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate***

### **Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:***

**Tipologia / *Medical Devices:***  
*Accessori monouso / Disposable accessories*

**Classe di rischio / *Risk class:***

II a

**Codice NANDO / *NANDO codes:***

MD 1301

**Marca / *Brandname:***

COSMED

**Modello / *Model:***

Flow Ree

**Tipologia / *Medical Devices:***

*Dispositivi per la valutazione della funzione respiratoria, cardiaca e metabolica / Devices for evaluation of the respiratory, cardiac and metabolic function*

**Classe di rischio / *Risk class:***

II a

**Codice NANDO / *NANDO codes:***

MD 1301

**Marca / *Brandname:***

COSMED

**Modello / *Model:***

Fitmate Pro

**Modello / *Model:***

Fitmate

**Modello / *Model:***

Fitmate GS

**Modello / *Model:***

Quark RMR

**Modello / *Model:***

microQuark

**Modello / *Model:***

Pony FX

Chief Operating Officer  
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# CERTIFICATE

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**CERMET**





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#### Tipologia / *Medical Devices:*

Dispositivi per la valutazione della funzione respiratoria, cardiaca e metabolica / *Devices for evaluation of the respiratory, cardiac and metabolic function*

#### Marca / *Brandname:*

COSMED

#### Modello / *Model:*

Pony FX Flowsafe

#### Modello / *Model:*

Pony FX MIP/MEP

#### Modello / *Model:*

Q-Box

#### Modello / *Model:*

Quark i2m

#### Modello / *Model:*

Quark NObreath

#### Modello / *Model:*

Quark PFT1

#### Modello / *Model:*

Quark PFT2

#### Modello / *Model:*

Quark PFT3

#### Modello / *Model:*

Quark PFT4

#### Modello / *Model:*

Quark Spiro

#### Modello / *Model:*

Spiropalm

#### Modello / *Model:*

Spiropalm 6MWT

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#### **Tipologia / *Medical Devices:***

Dispositivi per la valutazione della funzione respiratoria, cardiaca e metabolica / *Devices for evaluation of the respiratory, cardiac and metabolic function*

#### **Marca / *Brandname:***

COSMED

#### **Modello / *Model:***

Spiropalm Plus

#### **Modello / *Model:***

Fitmate Med

#### **Modello / *Model:***

K5

#### **Modello / *Model:***

Quark CPET

#### **Modello / *Model:***

Quark PFT

#### **Modello / *Model:***

Quark PFT ergo

#### **Modello / *Model:***

Quark PFT2ergo

#### **Modello / *Model:***

Quark PFT4ergo

# CERTIFICATE

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*Notified Body nr. 0476*

**CERMET**



Reg. Numero / Reg. Number	MED 9811	Revisione / Revision	15
Primo rilascio / First issue date	1998-06-11	Valido da / Valid from	2018-04-23
Scadenza / Valid until	2023-04-24	Ultima modifica / Last change date	2018-04-23

Pagina / Page 5 di / of 5

## Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

**Tipologia / Medical Devices:**  
Elettrocardiografi / *Electrocardiographs*

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 1301

**Marca / Brandname:**  
COSMED

**Modello / Model:**  
Quark C12x

**Modello / Model:**  
Quark T12x

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
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di Kiwa Italia Holding S.r.l.  
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Chief Operating Officer  
Giampiero Belcredi



Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. Number	387 - A	Valid From	2018-04-24
First issue date	1997-12-10	Last change date	2018-04-24
Valid Until	2021-04-24	IAF Sector	EA: 19

## Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

### **COSMED S.r.l.**

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing and marketing of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism

Chief Operating Officer  
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

**Kiwa Cermet Italia S.p.A.**  
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### **COSMED S.r.l.**

#### **Registered Headquarters**

- Viale Bruno Buozzi, 77 00197 Roma Italia

#### **Certified sites**

- Via dei Piani di Monte Savello, 37 00041 Albano Laziale ( RM ) Italia



Reg. Number	387 - M	Valid From	2018-04-24
First issue date	2006-10-13	Last change date	2018-04-24
Valid until	2021-04-24		

## Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

### **COSMED S.r.l.**

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design, manufacturing and marketing of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism

Chief Operating Officer  
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

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SGQ N° 007A  
SGA N° 010D  
PRD N° 069B  
FSM N° 0041  
PRS N° 089C



**Pony FX**  
Desktop Spirometer

Advanced desktop spirometer with spirometry,  
airway resistance and respiratory mechanics

“Effective, simple  
lung screening in  
any environment”



**COSMED**  
The Metabolic Company

“ The COSMED Pony FX meets ATS recommendations for accuracy and precision in measuring FVC, FEV<sub>1</sub>, FEF<sub>25-75%</sub> and peak expiratory flow under ambient and BTPS conditions<sup>(1)</sup> ”

- Full spirometry testing (FVC, SVC, MVV, Pre/Post BD)
- Airway resistance by Occlusion Technique (option)
- Respiratory mechanics MIP/MEP (option)
- Oxygen saturimetry with integrated SpO<sub>2</sub> monitor (option)
- Colour LCD display with real time graphs and embedded high speed thermal printer
- Validated turbine flowmeter
- Provided with OMNIA software for data management, real time testing and interpretation on PC



Pressure Transducer with AB filter for MIP/MEP testing



Turbine flowmeter with AB filter for Spirometry testing



Pony FX is the new generation family of portable spirometers from COSMED, representing the ideal solution for flexible lung function screening in many fields of application. Pony FX design allows easy spirometry testing without sacrificing anything to functionality.

Two different Pony FX models are currently available:

**Pony FX:** desktop spirometer with COSMED validated digital bidirectional turbine flowmeter.

**Pony FX MIP/MEP:** desktop spirometer with digital turbine and included kit for respiratory mechanics measurements (MIP/MEP).

## Design

High quality color LCD display for real time testing

Integrated 120 mm high speed thermal printer for high quality reports in few seconds

Compact size (20x23x6cm) and light weight (1.2 kg)

Alphanumeric keyboard and navigator tool to allow user access to all functions

Internal memory of up to 600 tests/patients

New Li-Ion battery with autonomy of up to 6 hours (charging time 2h10)

Easy interface with PC and other devices through the ports: USB-A, USB-B, RS 232  
Possibility to print reports without using a computer by connecting directly the Pony FX via USB with a PCL5 compatible printer

## Spirometry

Full spirometry (FVC, SVC, MVV, Pre/post BD)

New Trial Selection and Quality Control functions (in compliance with ATS/ERS guidelines)

Innovative pediatric incentivation with selectable effort grade

Full compliance with "2005 ATS/ERS consensus" (Interpretation, QC, etc.)

GOLD COPD interpretation on FVC PostBD

Includes latest Global Lung Initiative (GLI) predicted (including Z-score)

ATS, Metacholine-dose, Mannitol and user defined bronchochallenge protocols

Possibility to download Six Minute Walk Test data from any Spiropalm 6MWT

## Data Management & Software

Spirometry tests can be also performed real-time with Pony FX connected to a PC through the powerful software OMNIA (included in the standard package).

Innovative user interface, touch screen, easy and self-explanatory

Compatible with Windows 10

Graphical data presentation both at screen and on printouts with gauges (pictograms)

Powerful algorithm automatically elaborating results and providing comprehensive interpretation text strings including numerical results

Full customizable time-based trends of main measured parameters

GDT data interface protocol included

Access and security compliant (according to US HipAA, ISO 27799:2008, EU 95/46/CE and 2002/58/CE)

Multi-device management (single license for multiple products)

Advanced network capabilities (Optional). Running on SQL database (both Express or Enterprise)

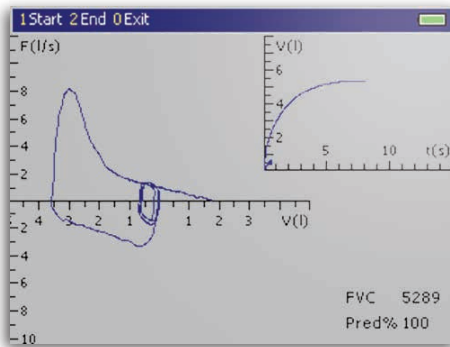
(1) Crapo R. O. (LDS Hospital) 2004 "Validation of COSMED turbine vs ATS 24 standard volume-time waveforms"

## Options & Accessories

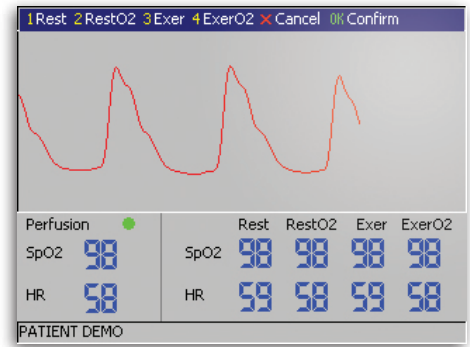
**Measurement of respiratory muscle strength (MIP/MEP).** Easy to perform, quick, non-invasive. Mouth pressures recorded during these repeated maneuvers are assumed to reflect respiratory muscle strength and can be followed in real-time directly on the LCD screen.

**Respiratory resistance by interrupter technique (Rint, Rocc).** Ideal solution for testing children (requires low patient collaboration) and good alternative to body plethysmography for airway resistance. Test is performed during tidal breathing through a dedicated low flow PNT mouthpiece while an occlusion valve interrupts the airflow for 100 msec

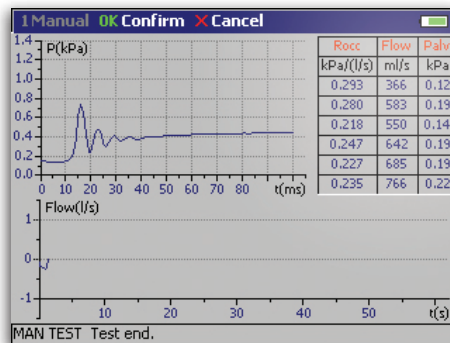
**Pulse oximetry (SpO<sub>2</sub>).** Oxygen desaturation and heart rate measurement with high quality integrated monitor (Nonin® technology). Low power draw (60 mW) and intelligent pulse-by-pulse filtering.



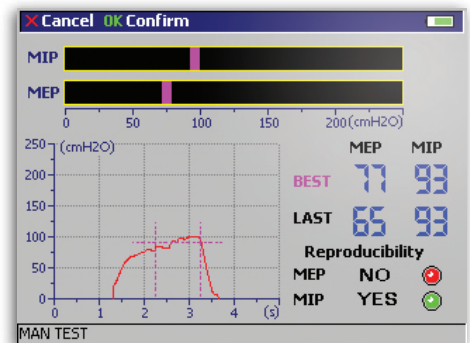
Pony FX screenshot: real-time FVC



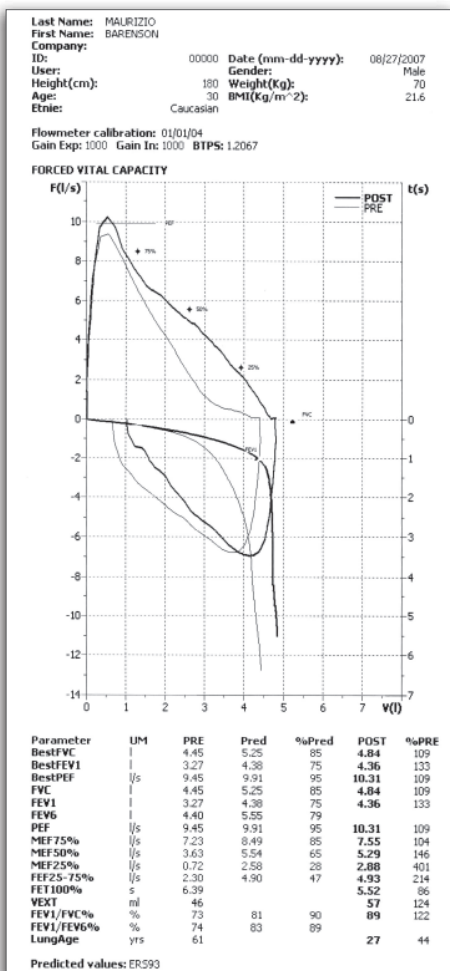
Pony FX screenshot: real-time SpO<sub>2</sub>



Pony FX screenshot: real-time Rocc



Pony FX screenshot: real-time MIP/MEP



Thermal printout sample (original size 110mm wide): Forced Vital Capacity (FVC)



Advanced software for data management, real time testing and interpretation directly on PC



## Validation articles

- Crapo R. O. (LDS Hospital) 2004 "Validation of COSMED turbine vs ATS 24 standard volume-time waveforms"
- More scientific studies on [www.cosmed.com/bibliography](http://www.cosmed.com/bibliography)



## Technical Specifications

Product	Description	REF
Pony FX	Desktop Spirometer with turbine flowmeter	C09062-01-99
Pony FX MIP/MEP	Desktop Spirometer with turbine flowmeter and respiratory mechanics module	C09062-05-99
Standard Tests (Spirometry)		
Tests	Forced Vital Capacity (FVC) Pre/Post, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV), Bronchochallenge - Bronchial Dilator/Constrictor test	
Measured Parameters (partial listing)	FVC • IVC • VC • MVV • VT • FEV1 • FEV6 • FEV1/FEV6 • FEV6/FVC • PEF • PIF • FEV1/FVC • FEV1/VC% • %FEV1 • MEF25% • MEF50% • MEF75% • FET 100% • Lung Age • ERV • IRV • VE • Rf • ti • te • ti/t.tot • VT/ti • Best FVC • Best FEV1 • IC	
Predicted Values (partial listing)	GLI, ERS 93, NHANES III, Knudson 83, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicentrico Barcelona, Thai 2000, Austria (Forche), Crapo 1981	
Automatic Interpretation	Automatic and comprehensive, with statements based on: ATS/ERS 2005 (Spirometry), GOLD COPD, ATS/ERS 2005 (Obstruction Reversibility based on FVC Post BD), ATS/ERS 2007 (Obstruction Reversibility based on Rocc)	
Hardware		
Dimensions & Weight	19.8x23.8x7.6 cm / 1.2 Kg	
Interfaces	USB-A, USB-B, RS 232	
Display	Color LCD 320 x 240 pixel	
Printer	High speed thermal printer 110 mm	
Batteries	Rechargeable Li-ion batteries (2600 mAh)	
Power Supply	100-240V ± 10% 50/60 Hz	
Flowmeter		
	Turbine Ø-28mm	
Type	Bidirectional Digital Turbine	
Resolution	12 ml	
Ventilation Range	0-300 l/min	
Flow Range	0-16 l/s	
Accuracy	± 2% or 20 ml/s	
Resistance	<0.6 cmH <sub>2</sub> O /l/s @ 14l/s	
Software		
	OMNIA	
Available languages	Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional & Simplified), Korean, Romanian, Polish, Czech, Norwegian, Hebrew (Interpretation only)	
Required PC configuration	I3 or higher processor speed. Compatible with Windows 7, 8, 10 (32 or 64 bit). RAM 4GB (8GB recommended). HD with 4GB of free space (plus tools)	
Options & Accessories		
	Description	REF
Rocc	Airway Resistance kit (Rocc)	C02650-01-11
Pulse Oximetry	Oximeter Xpod (broad range of probes available)	C02600-01-05
Calibration syringe	3L syringe for accuracy check of flow volume measurements	C00600-01-11
Consumables		
	Description	REF
Antibacterial filters	Single-use filters with round mouthpiece (50 pcs)	A-182-300-004
	Single-use filters with oval mouthpiece (50 pcs)	A-182-300-005
Nose clips	Clips for performing spirometry tests (100 pcs)	C04451-01-98
Thermal paper, Pony FX	Rolls for Pony FX thermal printer (10 pcs)	A-196-056-001
Safety & Quality Standards		
MDD (93/42 EEC); FDA 510(k); EN 60601-1 (safety) / EN 60601-1-2 (EMC) Complies with ATS/ERS 2005 guidelines		



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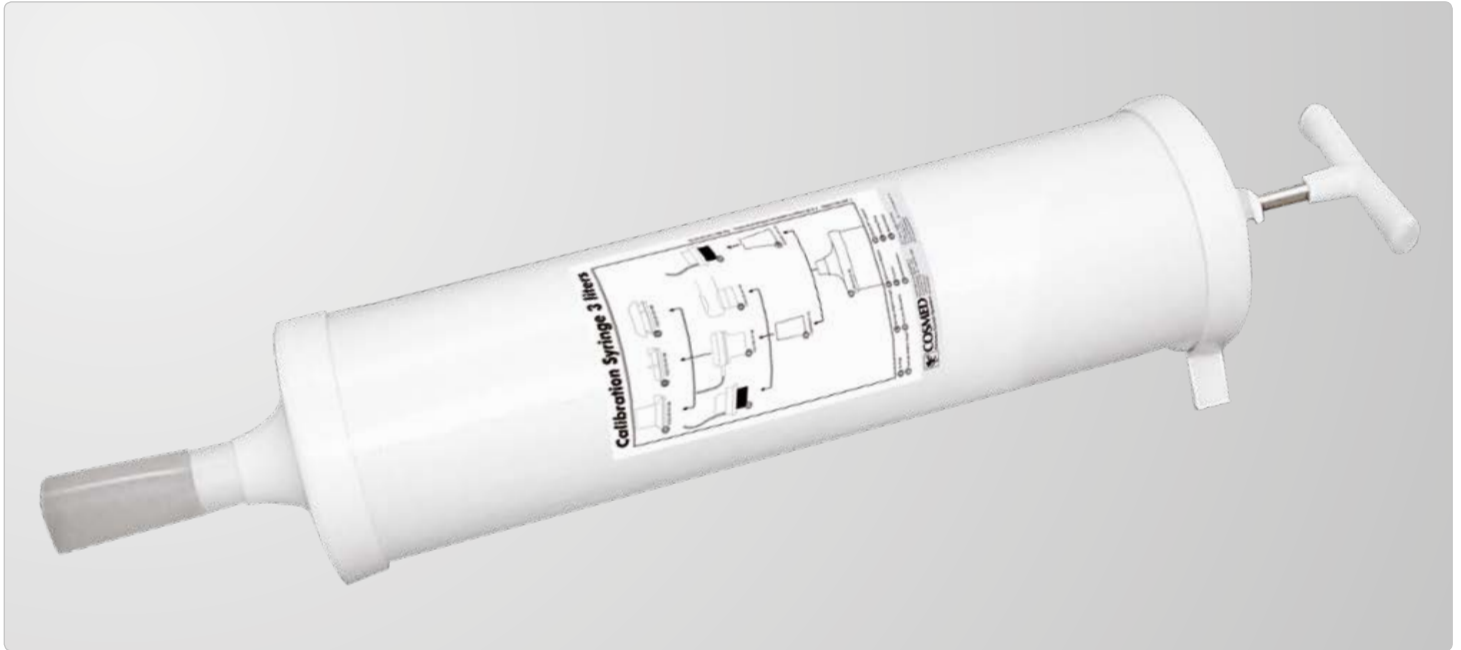


To know more:



# Calibration Syringe

The simplest and most reliable accuracy check of flow volume measurement



## Related Products

- ▶ Pony FX line
- ▶ microQuark
- ▶ Spiropalm line
- ▶ Quark line
- ▶ K4b2
- ▶ Fitmate line

## Reference

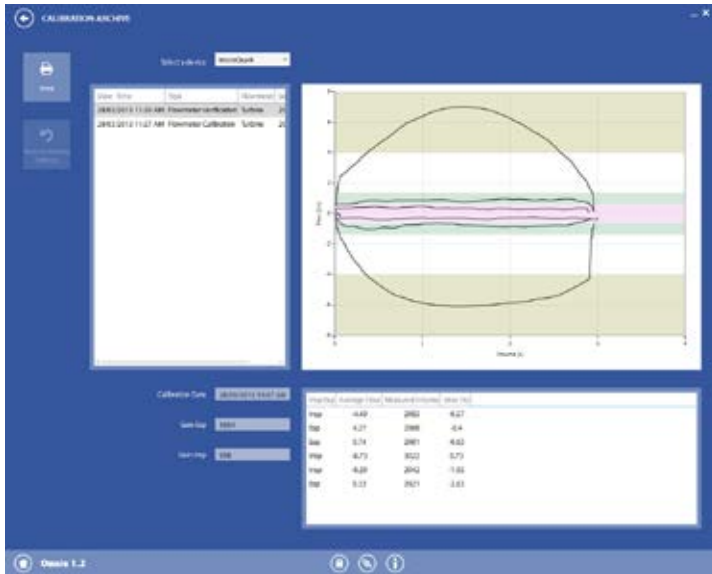
\*Miller MR et al; ATS/ERS Task Force. "Standardisation of spirometry." Eur Respir J. 2005 Aug;26(2):319-38.

- ▶ **Certified 3 liter aluminium calibration syringe**
- ▶ **Accuracy:  $\pm 1/2$  of 1% full scale**
- ▶ **Adjustable stops for additional smaller stroke volumes**
- ▶ **100% leak tested**
- ▶ **Calibration standard according to 2005 ATS/ERS Guidelines**

The COSMED 3L calibration syringe is a reliable precision tool for quick and easy verification and fine-tuning of COSMED flowmeters measurements (flow/volume). Having a known calibrated volume as a standard, the syringe provides an easy and reliable method of calibrating and measuring the accuracy of COSMED respiratory volume measuring equipment.

COSMED calibration syringe is fully compliant to the ATS/ERS Task Force standards\*, published Spring 2005, which require daily calibration checks of flow and volume spirometers using a 3-L calibration syringe with an accuracy of  $\pm 15$  mL or  $\pm 0.5\%$  of the full scale.



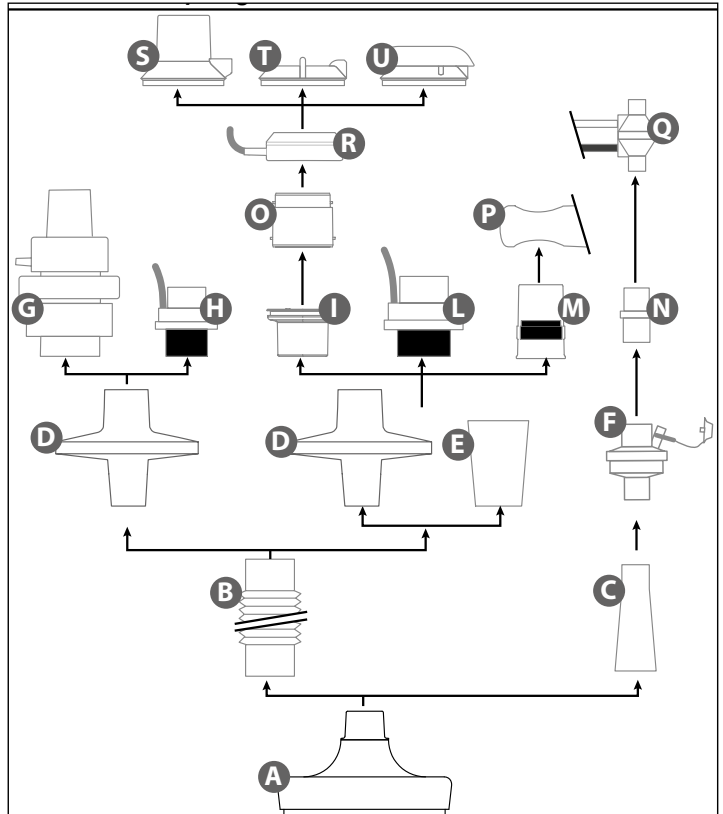


Simplified procedure and intuitive calibration using the 3L syringe with the new OMNIA software platform

## Technical Specification

### Hardware

Material	Anodized aluminum
Total volume	3L
Smallest graduation	100ml
Volume stroke	37.47 cm
Cylinder bore	10.16 cm
Weight	2268 gr



<b>A</b> Calibration Syringe 3 lt REF: C00600-01-11	<b>H</b> Flowmeter RMR ID18 REF: C02500-01-04	<b>L</b> Flow Ree part of REF: A-662-250-003
<b>B</b> Tubing REF: A-108-300-012	<b>I</b> Mouthpiece Adapter REF: C02106-01-08	<b>R</b> Opto-Reader 2000 REF: C02111-01-06
<b>C</b> ID18 turbine adapter REF: C03047-01-20	<b>L</b> Flowmeter V02 max ID28 REF: C02550-01-04	<b>S</b> PFT Adapter REF: C02229-01-08
<b>D</b> Antibacterial Filter REF: A-182-300-004	<b>M</b> Turbine T28 REF: C02235-01-05	<b>T</b> Closing Ring REF: C02155-01-08
<b>E</b> Conic Adapter REF: C00063-01-20	<b>N</b> Flow Ree adapter part of REF: A-662-250-003	<b>U</b> Wind Shield REF: C02107-01-08
<b>F</b> HME Filter REF: A-182-300-006	<b>O</b> Turbine 2000 REF: C02120-01-05	
<b>G</b> X9 PNT Pneumotach REF: C03600-01-05	<b>P</b> Digital Flowmeter for Turbine REF: T2 C02364-01-05	

Distributed by:



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