Specificație Completată
Spirograf
Model: Pony Fx; Producător: COSMED; Țara: Italia.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea contractantă
Spirograf Cod 260500 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer şi a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forţată [SVI], fluxul de vîrf [PF], volumul expirator forţat 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 Diapazonul de volum ≥ 0- 5 l Diapazonul de flux ≥ 0- 10 l/s Eroarea la volum ≤3% Eroarea la flux ≤3% Afișaj Alfanumeric Control taste alfanumerice Interfața PC da Alimentare Cu sursă internă de alimentare, acumulatoare 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	Spirograf **DA** Cod 260500 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer şi a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forţată [SVI], fluxul de vîrf [PF], volumul expirator forţat într-o secundă [FEV1]). **DA** Parametrul Specificația Tip Spirometru portabil **DA inclusa si geanta pentru transportare.** Gama de volum- 0-8 l **DA** Gama de flux- 0-16 l/s **DA** Memorarea automată a celor mai bune 3 rezultate de spirometrie **DA** Parametri măsurați FVC **DA** FEV1 **DA** FEV1/FVC **DA** Raport PEF **DA** EVC **DA** IVC **DA** Ti **DA** Te **DA** IC **DA** IRV **DA** ERV **DA** TV **DA** Printer intern **DA** Memorie nu mai puțin de **600 teste grafice memorate DA** Transfer date la PC teste pacient **DA** verificare aparat **DA** up-gradare software **DA** Dispozitivul de măsură bidirecțional **DA** Diapazonul de volum ≥ 0- 5 l **DA** Diapazonul de flux ≥ 0- 10 l/s **DA** Eroarea la volum ≤3% **DA** Eroarea la flux ≤2% **DA** Afișaj Alfanumeric **DA** Control taste alfanumerice **DA** Interfața PC **DA** Alimentare Cu sursă internă de alimentare, acumulatoare reîncărcabile **DA** Rețeaua electrică 220 V, 50 Hz **DA** Accesorii Să fie inclus toate consumabilele necesare pentru 200 investigații "filtre antibacteriale cu turbine

necesară) Clește pentru nas tip adult 1 buc. Clește pentru nas tip pediatric 1 buc. Hîrtir 20 buc.	integrata unică utilizare" **DA** Seringă de calibrare da, (doar în cazul dacă este necesară) **DA inclusă** Clește pentru nas tip adult si pediatric sint de o singura marimie. 200 buc. Hîrtir 20 buc. **DA**

Specificație Completată
Spirograf pentru conexiune la PC
Model: microQuark; Producător: COSMED; Țara: Italia.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea contractantă
Spirograf pentru conexiune la PC Cod 260510 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer şi a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forţată [SVI], fluxul de vîrf [PF], volumul expirator forţat într-o secundă [FEV1]). Afișarea se face pe PC. Parametrul Specificația Tip Pentru conexiune la PC 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 Memorie nu mai puțin de 300 teste grafice memorate Transfer date la PC teste pacient verificare aparat up-gradare software Dispozitivul de măsură bidirecțional Diapazonul de volum ≥ 0- 5 l Diapazonul de flux ≥ 0- 10 l/s Eroarea la volum ≤ 3% Eroarea la flux ≤ 3% Interfața PC da Alimentare Cu sursă internă de alimentare, acumulatoare reîncărcabile Rețeaua electrică 220 V, 50 Hz Accesorii "Soft specializat pentru PC penture afișarea rezultatelor " da	Spirograf pentru conexiune la PC **DA** Cod 260510 Descriere Spirometru de diagnosticare utilizat pentru a măsura debitul de aer şi a volumelor rezultate din manevrele de spirometrie de bază (de exemplu, capacitatea vitală forţată [SVI], fluxul de vîrf [PF], volumul expirator forţat într-o secundă [FEV1]).**DA** Afișarea se face pe PC. **DA** Parametrul Specificația Tip Pentru conexiune la PC **interfața USB DA** Gama de volum 0-8 l **DA** Gama de flux 0-16 l/s **DA** Memorarea automată a celor mai bune 3 rezultate de spirometrie **DA** Parametri măsurați FVC **DA** FEV1 **DA** FEV1/FVC **DA** Raport PEF **DA** EVC **DA** IVC **DA** Ti **DA** Te **DA** IC **DA** IRV **DA** ERV **DA** TV **DA** Memorie nu mai puțin de 300 teste grafice memorate **in PC** Transfer date la PC teste pacient **DA** verificare aparat **DA** up-gradare software **DA** Dispozitivul de măsură bidirecțional **DA** Diapazonul de volum ≥ 0- 5 l **DA** Diapazonul de flux ≥ 0- 10 l/s **DA** Eroarea la volum ≤ 3% **DA** Eroarea la flux ≤ 3% **DA** Interfața PC **DA USB** Alimentare Cu sursă internă de alimentare, acumulatoare reîncărcabile **NU necesită conectarea la PC obligatoriu.** Rețeaua electrică 220 V, 50 Hz **NU alimentare direct de la PC** Accesorii "Soft specializat pentru PC penture afișarea rezultatelor " **DA PC nu este inclus in set.**

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.	Să fie inclus toate consumabilele necesare pentru 200 investigații "filtre antibacteriale sau turbine de unică utilizare" **DA** Seringă de calibrare da, (doar în cazul dacă este necesară) **DA** Clește pentru nas tip adult si adult 200 buc. **DA**

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[1,2].

The resistance of the combined system necessary to perform the tests is inferior to those suggested by the ATS/ERS (1.5cmH2O/L/s@14 L/s)[3] 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[2].

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

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The Metabolic Company

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.

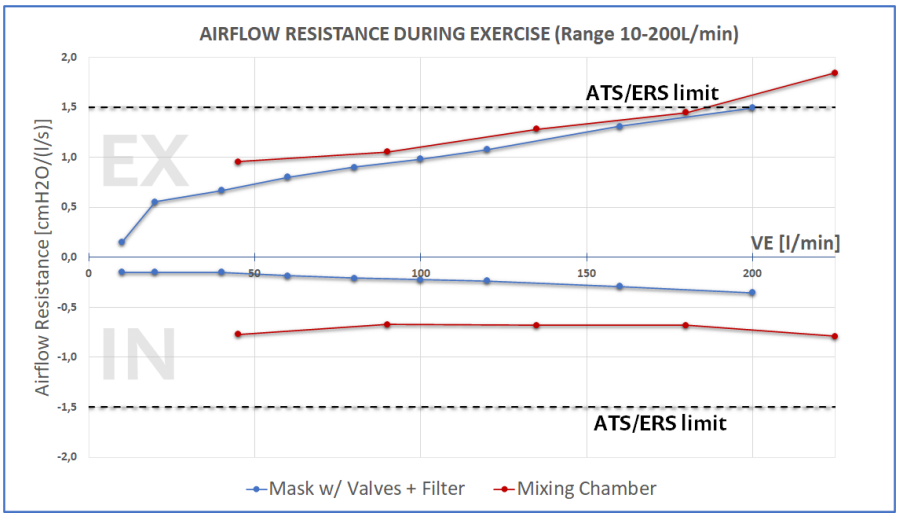
The validation protocol compares the results against a conventional mixing chamber metabolic cart and ATS/ERS maximal acceptable resistance for lung function testing equipment.

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

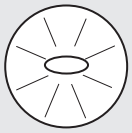
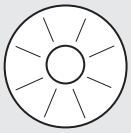
The additional dead space introduced by the new setups, does not affect VO_2 or VCO_2 calculation.

A-182-300-005

A-182-300-004



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)	*0.27cmH2O @ 30L/min* *0.59cmH2O @60L/min* *0.97cmH2O @ 90L/min*	*0.39cmH2O @ 30L/min* *0.74cmH2O @60L/min* *1.1cmH2O @ 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 99.999% filter is therefore 10 times more efficient than 99.99% 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

COSMED

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COSMED Spirometers

Choose the product according to required features and purpose of use.
Call +39 (06) 931-5492 (International) or +1 (773) 645-8113 (US only) for more info

Product Comparison Matrix





	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 Pneumotach (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), Multicèntrico 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_2, HR) w/ Nonin ipod		○	○	●	

● Standard ○ Upgrade

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CERTIFICATE

Reg. Numero / *Reg. Number*	MED 9811A	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2018-04-23	Valido da / *Valid from*	2018-04-23
Scadenza / *Valid until*	2023-04-24	Ultima modifica / *Last change date*	2018-04-23

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*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 9811A	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2018-04-23	Valido da / *Valid from*	2018-04-23
Scadenza / *Valid until*	2023-04-24	Ultima modifica / *Last change date*	2018-04-23

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.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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

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 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*

Kiwa Cermet Italia S.p.A.
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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

CERTIFICATE

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Scadenza / *Valid until*	2023-04-24	Ultima modifica / *Last change date*	2018-04-23

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
Giampiero Belcredi

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CERMET

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

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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:*
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.
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Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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www.kiwacermet.it

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

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

CERTIFICATE

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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SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

microQuark

PC-based Spirometer

- Full spirometry testing (FVC, SVC, MVV, Pre-Post BD, Bronchial challenge).
- Plug-and-play technology.
- Independently validated turbine flowmeter by LDS Hospital using the ATS 24 standard volume-time waveforms.
- User-friendly, beautiful software interface providing comprehensive graphical and text interpretation.
- Full Networking and multi-language environment.
- Compatible with Win 8 PRO (32/64), Win 7 (32/64), Win Vista (32/64).
- Meet latest ATS/ERS standards.

Directly connected to a USB port turns any PC into a spirometer

microQuark is the new PC-based spirometer from COSMED that, thanks to its compact and lightweight size (77gr), represents the perfect solution for performing screening spirometry everywhere and in any conditions.

microQuark can be used with any PC, either desktop or laptop, by simply installing the application software and connecting the USB cable to the USB socket of the computer.

microQuark incorporates the well proven COSMED bidirectional digital turbine technology, which is extremely accurate and reliable in any conditions.

Performing spirometry tests is extremely easy and intuitive with microQuark and OMNIA, the new generation software developed by COSMED, which is included in the standard package.

OMNIA is user-friendly thanks to its modern interface and includes innovative and pediatric incentivation for spirometry tests with selectable effort grade (%PEF, %FVC).

OMNIA allows easy navigation and quick access to all features and tests without need of training. Compatibility with Windows 10 and touch-screen ready interface make OMNIA the most modern software in the industry.

A comprehensive interpretation tool with a powerful algorithm automatically elaborates results and provides interpretation text strings including numerical results.

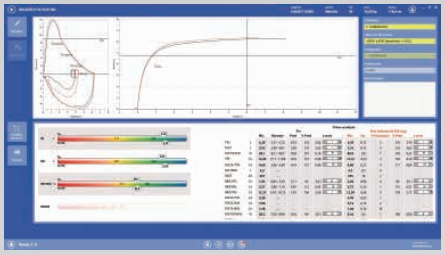
OMNIA encompasses all the latest industry standards for spirometry tests, including the 2005 ATS/ERS Consensus Statement on the "Standardization of the measurement of spirometry" and the 2012 Global Lung Initiative (GLI) predicted sets.

COSMED

The Metabolic Company

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*



Technical Specifications

Product	Description	REF
microQuark	USB PC-based Spirometer	C09061-01-99
Standard packaging	Main Unit, T2 flowmeter, carrying case, conical adapter, PC software (OMNIA) and user manual.	
Standard Tests (Spirometry)		
Tests	Forced Vital Capacity (FVC) Pre/Post, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV), Bronchial challenge - Bronchial Dilator/Constrictor test	
Measured Parameters (partial listing)	FVC • IVC • VC • MVV • VT • FEV1 • FEV6 • FEV1/FEV6 • FEV6/FVC • PEF • PIF • FEV1/FVC • FEF 25-75 • 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)	2012 Global Lung initiative (GLI), ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicèntrico Barcelona, Thai 2000, Austria (Forche), Crapo 1981 user defined predicted calculations.	
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	150 x 45 x 53 mm / 77 gr	
Interfaces	USB	
Power supply	via USB	
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	<0.8 cmH_2O /l/s @ 14l/s	
Software	**OMNIA**	
Available languages	Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional & Simplified), Korean, Romanian, Czech, Norwegian	
Required 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 4GB of free space (plus tools)	
Options & Accessories	**Description**	**REF**
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(box contains 50 pcs) Single-use filters with oval mouthpiece(box contains 50 pcs)	A-182-300-004 A-182-300-005
Nose clips	Clips for performing spirometry tests (box contains 100 pcs)	C04451-01-98
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		

CE 0476

COSMED

COSMED Srl

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info@cosmed.com | cosmed.com

To know more:

Pony FX

Desktop Spirometer

Advanced desktop spirometer with spirometry, airway resistance and respiratory mechanics

COSMED

The Metabolic Company

“The COSMED Pony FX meets ATS recommendations for accuracy and precision in measuring FVC, FEV_1, $FEF_{25-75\%}$ and peak expiratory flow under ambient and BTPS conditions[(1)]”

- **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_2 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) predicteds (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

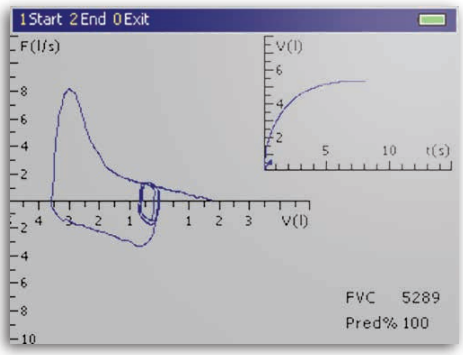
Spirometry tests can be also performed real-time with Pony FX connected to a PC through the powerful software OMNIA (included in the standard package).

- 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)

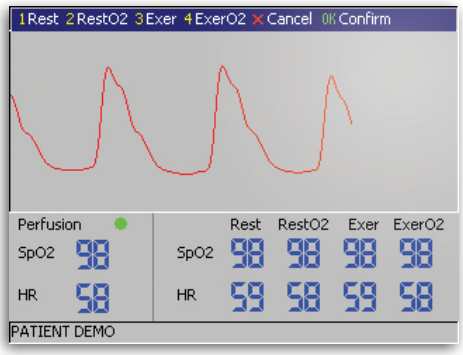
(1) Crapo R. O. (LDS Hospital) 2004 “Validation of COSMED turbine vs ATS 24 standard volume-time waveforms”

Options & Accessories

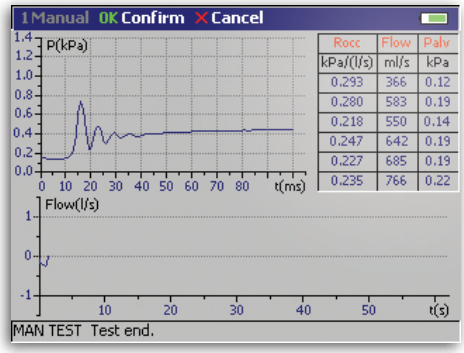
- **Measurement of respiratory muscle strength (MIP/MEP)**. Easy to perform, quick, non-invasive. Mouth pressures recorded during these repeated maneuvers are assumed to reflect respiratory muscle strength and can be followed in real-time directly on the LCD screen.
- **Respiratory resistance by interrupter 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_2)**. Oxygen desaturation and heart rate measurement with high quality integrated monitor (Nonin© technology). Low power draw (60 mW) and intelligent pulse-by-pulse filtering.



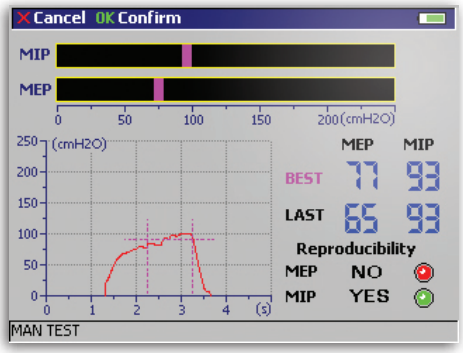
Pony FX screenshot: real-time FVC



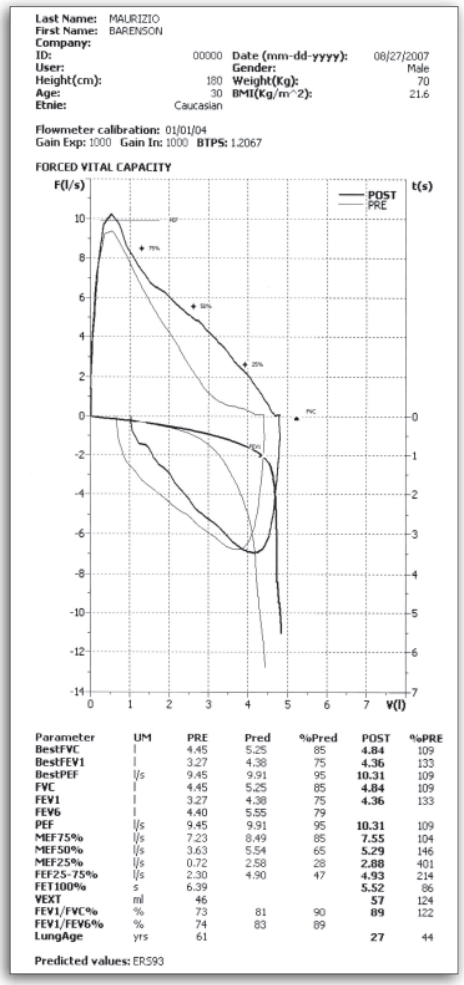
Pony FX screenshot: real-time SpO_2



Pony FX screenshot: real-time Rocc



Pony FX screenshot: real-time MIP/MEP



Last Name: MAURIZIO
First Name: BARENSON
Company:
ID: 00000 Date (mm-dd-yyyy): 08/27/2007
User: Gender: Male
Height(cm): 180 Weight(Kg): 70
Age: 30 BMI(Kg/m^2): 21.6
Etnie: Caucasian

Flowmeter calibration: 01/01/04
Gain Exp: 1000 Gain In: 1000 BTPS: 1.2067

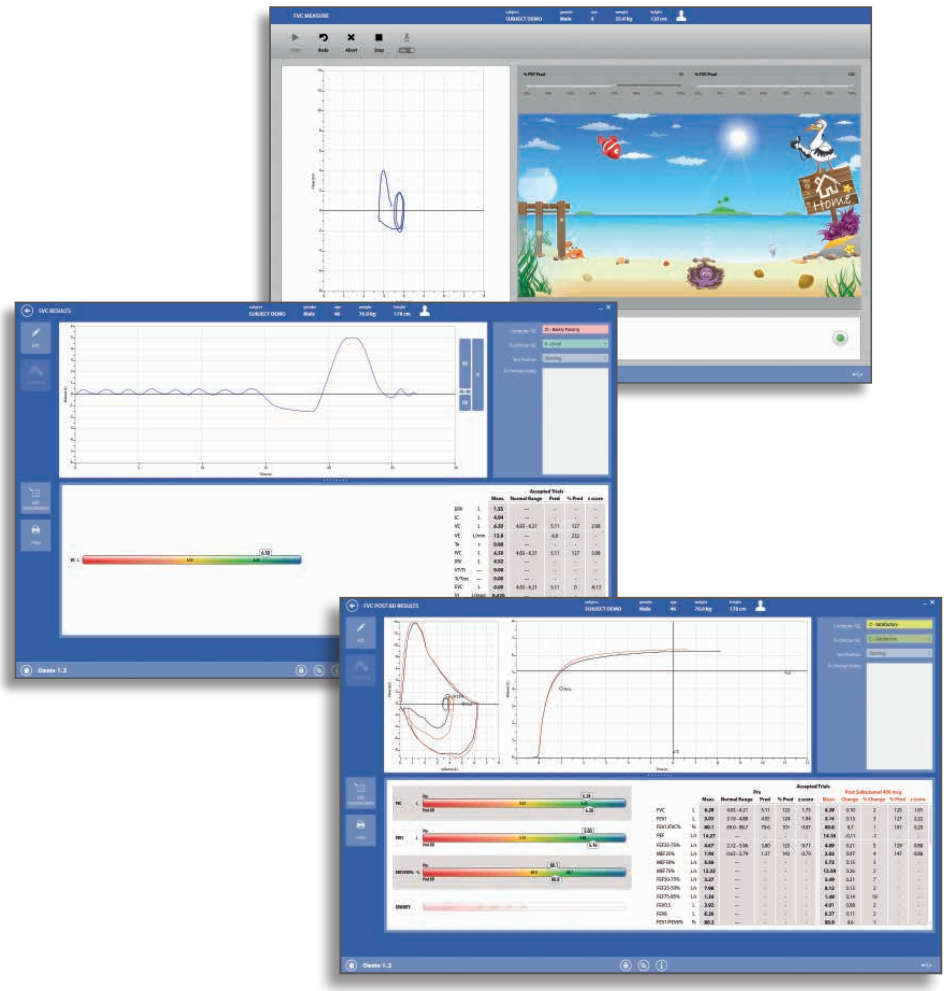
FORCED VITAL CAPACITY

F(l/s) t(s) POST PRE V(l)

Parameter	UM	PRE	Pred	%Pred	POST	%PRE
BestFVC	l	4.45	5.25	85	**4.84**	109
BestFEV1	l	3.27	4.38	75	**4.36**	133
BestPEF	l/s	9.45	9.91	95	**10.31**	109
FVC	l	4.45	5.25	85	**4.84**	109
FEV1	l	3.27	4.38	75	**4.36**	133
FEV6	l	4.40	5.55	79		
PEF	l/s	9.45	9.91	95	**10.31**	109
MEF75%	l/s	7.23	8.49	85	**7.55**	104
MEF50%	l/s	3.63	5.54	65	**5.29**	146
MEF25%	l/s	0.72	2.58	28	**2.88**	401
FEF25-75%	l/s	2.30	4.90	47	**4.93**	214
FET100%	s	6.39			**5.52**	86
VEXT	ml	46			**57**	124
FEV1/FVC%	%	73	81	90	**89**	122
FEV1/FEV6%	%	74	83	89		
LungAge	yrs	61			**27**	44

Predicted values: ER593

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

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 • FEF 25-75 • 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), Multicèntrico 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_2O /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) Single-use filters with oval mouthpiece (50 pcs)	A-182-300-004 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		

CE 0476

COSMED

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+39 (06) 931-5492 Phone
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info@cosmed.com | cosmed.com

To know more:

REF C09062-02-93

COSMED
The Metabolic Company

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

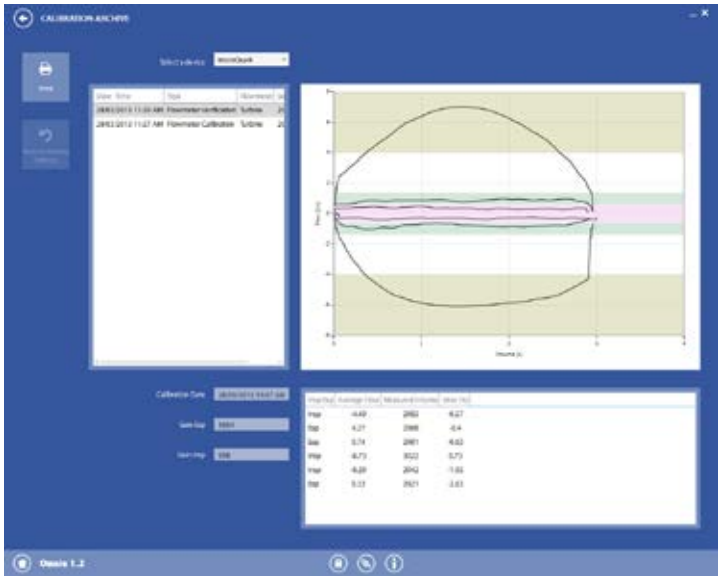
Reference

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

- Certified 3 liter alluminium calibration syringe
- Accuracy: ±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 verifification 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 sysringe 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 ±15 mL or ±0.5% of the full scale.

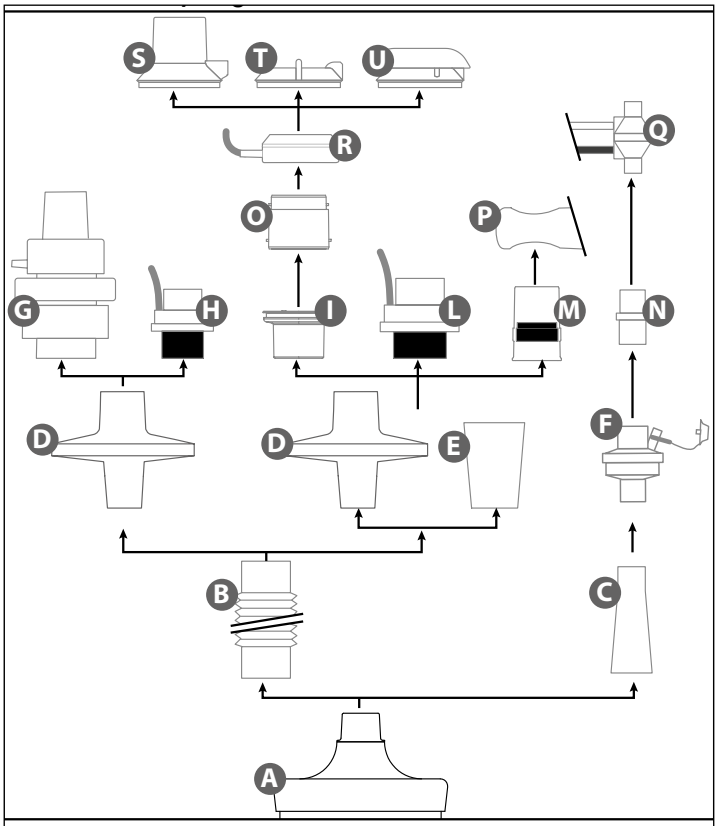


Simplified procedure and intuitive calibration using the 3L syringe with the new OMNIA software platform

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*



A Calibration Syringe 3 lt REF C00600-01-11	H Flowmeter RMR ID18 REF C02500-01-04	Q Flow Ree part of REF A-662-250-003
B Tubing REF A-108-300-012	I Mouthpiece Adapter REF C02106-01-08	R Opto-Reader 2000 REF C02111-01-06
C ID18 turbine adapter REF C03047-01-20	L Flowmeter VO2 max ID28 REF C02550-01-04	S PFT Adapter REF C02229-01-08
D Antibacterical Filter REF A-182-300-004	M Turbine T28 REF C02235-01-05	T Closing Ring REF C02155-01-08
E Conic Adapter REF C00063-01-20	N Flow Ree adapter part of REF A-662-250-003	U Wind Shield REF C02107-01-08
F HME Filter REF A-182-300-006	O Turbine 2000 REF C02120-01-05	
G X9 PNT Pneumotach REF C03600-01-05	P Digital Flowmeter for Turbine REF T2 C02364-01-05	

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