Anexa 125 la Formularul Specificație Tehnică

Spirograf Cod 260500

Model Pony FX (Desktop Spirometer) (COSMED Srl., Italia)

Specificatia tehnica solicitata	Specificatia tehnica ofertata model Pony FX (Desktop Spirometer)
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 întro secundă [FEV1]). Parametrul Specificația Tip Spirometru portabil 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 232200up-gradare software Dispozitivul de măsură bidirecțional Diapazonul de volum ≥ 0-8 l Diapazonul de flux ≥ 0-16 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 necesară) Clește pentru nas tip adult 1 buc. Clește pentru nas tip pediatric 1 buc. Hîrtie 20 buc.	Spirograf 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 forţată [SVI], fluxul de vîrf [PF], volumul expirator forţat întro secundă [FEV1]). **DA** **Parametrul Specificația** Tip Spirometru portabil **DA pag 2 a broșurii** 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 300 teste grafice memorate **DA** Transfer date la PC teste pacient **DA** verificare aparat upgradare software **DA** Dispozitivul de măsură bidirectional **DA** Diapazonul de volum ≥ 0-8 l **DA** Diapazonul de flux ≥ 0-16 l/s **DA** Eroarea la volum ≤3% **DA** Eroarea la flux ≤3% **DA** Afișaj Alfanumeric **DA** Control taste alfanumerice **DA** Interfața PC **DA** Alimentare Cu sursă internă de alimentare, **DA** acumulatoare reîncărcabile **DA** Rețeaua electrică 220 V, 50 Hz **DA** Accesorii **DA** 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 1 buc. **DA** Clește pentru nas tip pediatric 1 buc. **DA** Hîrtie 20 buc. **DA**

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)
- Respiratory Mechanics assesment (MIP/MEP)
- Airway resistance by Occlusion Technique (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 module 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 and light weight
- 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
- Easy interface with PC and other devices through the ports: USB-A, USB-B, RS 232

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

Respiratory Mechanics (MIP/MEP)

- Measurement of respiratory muscle strength
- Easy to perform, quick, non-invasive
- Either for healthy subjects or patients with pulmonary/neuromuscular diseases
- Special mouth pressuremeter
- Complies with ATS/ERS Guidelines

Data Management & Software

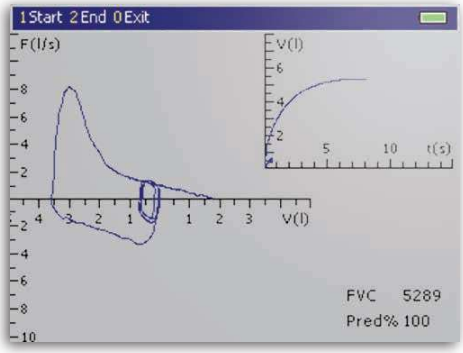
Spirometry tests can be also performed real-time with Pony FX connected to a PC through the powerful software OMNIA.

- Innovative user interface, touch screen, easy and self-explanatory
- Graphical data presentation both at screen and on printouts with gauges (pictograms)
- Powerful algorithm automatically elaborates results and provides comprehensive interpretation text strings including numerical results
- Full customizable time-based trends of main measured parameters
- Access and security compliant to international regulations
- Multi-device management (single license for multiple products)
- Advanced network capabilities (Optional). Running on SQL database.

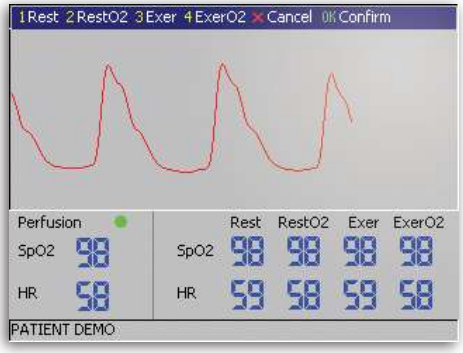
(1) Crapo R. O. (LDS Hospital) 2004 “Validation of COSMED turbine vs ATS 24 standard volume-time waveforms“

Options & Accessories

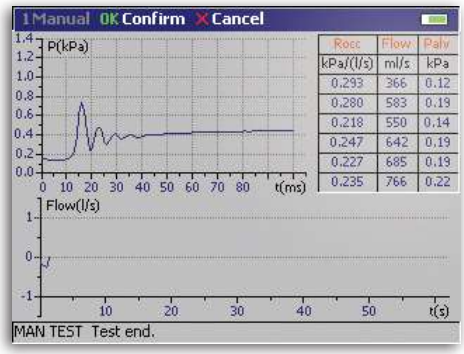
- **Respiratory resistance by interrupter technique (Rint, Rocc)**. Ideal solution for testing children (requires low patient collaboration) and good alternative to body plethysmography for airway resistance. Test is performed during tidal breathing through, a dedicated low flow PNT mouthpiece while 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 and intelligent pulse-by-pulse filtering.



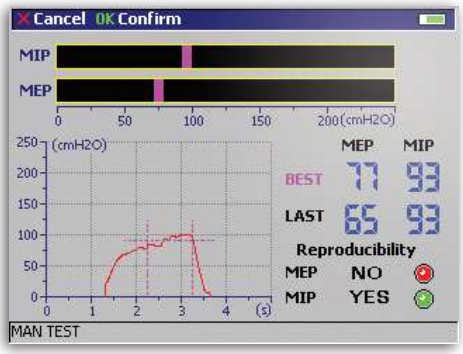
Pony FX screenshot: real-time FVC



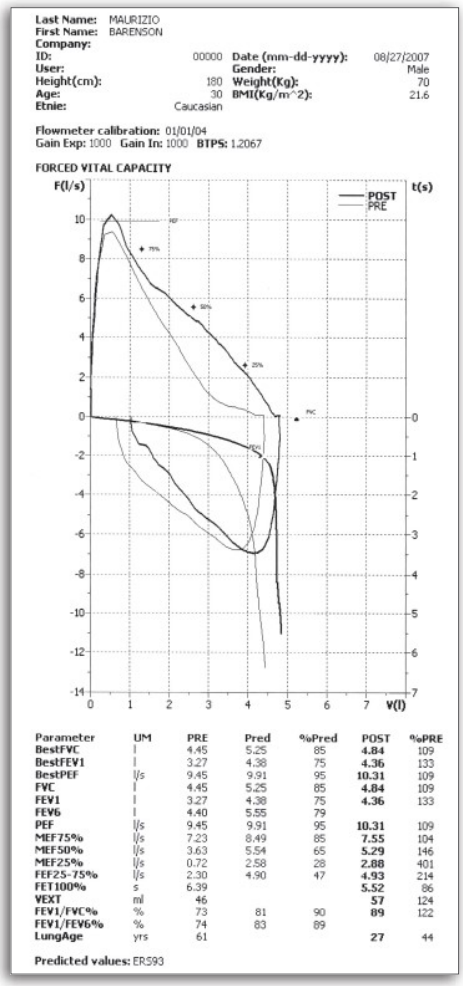
Pony FX screenshot: real-time SpO_2



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

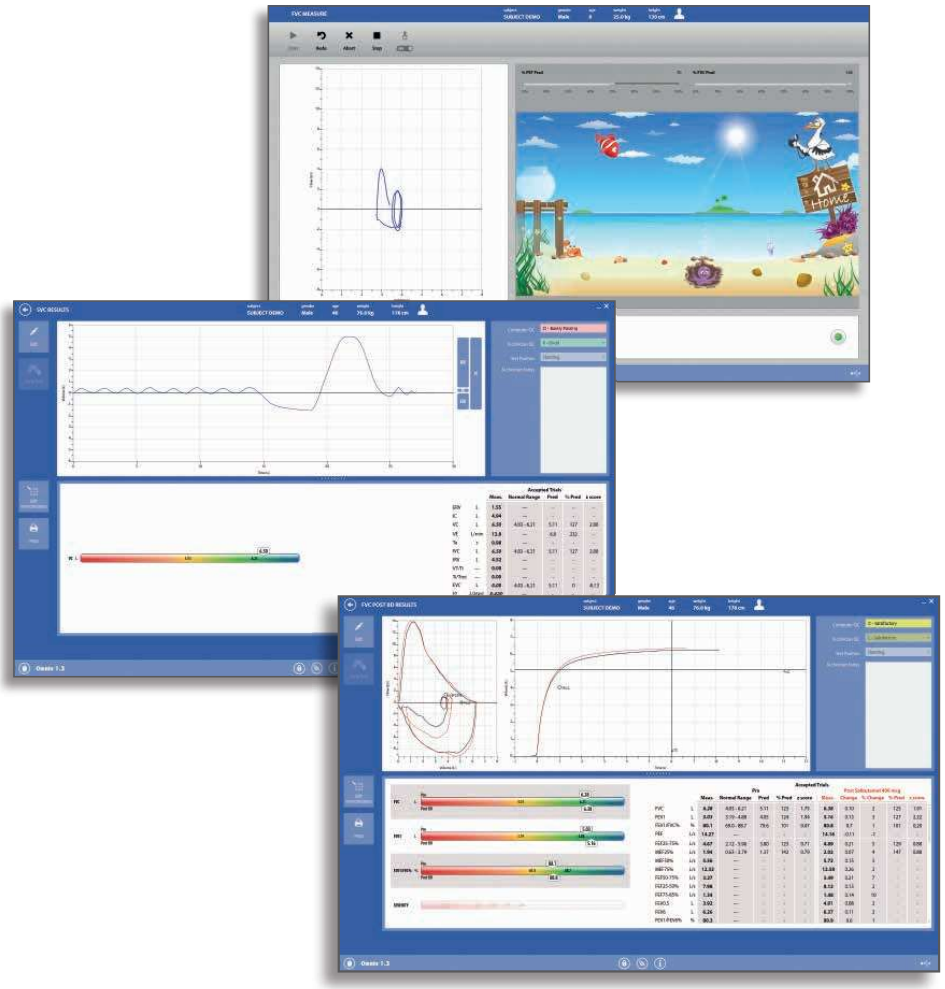
Flowmeter calibration: 01/01/04
Gain Exp: 1000 Gain In: 1000 BTPS: 1.2067

FORCED VITAL CAPACITY

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: ERS93

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



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

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To know more

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03/2005

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Part N. C02361-02-91

Table of contents

Getting started

Important notices

Intended use

Pony FX 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 sale by or on the order of a physician.

This equipment has been conceived with the aim of providing an auxiliary instrument allowing:

- the formulation of lung pathology diagnosis;
- important studies concerning human physiology;
- the collection of important information in sport medicine.

No responsibility attaches COSMED Srl for any accident happened after a wrong use of the device, such as:

- use by non qualified people;
- non respect of the device intended use;
- non respect of the hereunder reported precautions and instructions.

Warnings

The device, the program algorithms and the presentation of measured data have been developed according to the specifications of ATS (American Thoracic Society) and ERS (European Respiratory Society). Other international references have been followed when these were not available. All bibliography references are reported in Appendix.

The present handbook has been developed with respect of the European Medical Device Directive requirements which sort Pony FX within Class II a.

It is recommended to read carefully the following precautions before putting the device into operation.

The precautions reported below are of fundamental importance to assure the safety of all COSMED equipment users.

1. This user manual is to be considered as a part of the medical device and should always be kept on hand.
2. Safety, measure accuracy and precision can be assured only:

- using the accessories described in the manual or given with the device. Actually non recommended accessories can affect safety unfavourable. Before using non recommended accessories it is necessary to get in touch with the manufacturer;
- ordinary equipment maintenance, inspections, disinfection and cleaning are performed in the way and with the frequency described;
- any modification or fixing is carried out by qualified personnel;
- the environmental conditions and the electrical plants where the device operates are in compliance with the specifications of the manual and the present regulations concerning electrical plants. 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.

3. Before powering the system, check the power cables and the plugs. Damaged electrical parts must be replaced immediately by authorised personnel.
4. Cleaning residue, particulates, and other contaminates (including pieces of torn or broken components) in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminates can potentially be life-threatening. Use disposable anti-bacterial filters or disinfect each part in contact with the patient before each test.
5. You must follow all the cleaning procedures in System Maintenance, and you must thoroughly inspect the components after cleaning and before each patient test.
6. This device is not suitable for use in presence of flammable anaesthetics. It is not an AP nor an APG device (according to the EN 60 601-1 definitions).
7. Keep the device away from heat and flame source, flammable or inflammable liquids or gases and explosive atmospheres.
8. In accordance with their intended use Pony FX is not to be handled together with other medical devices unless it is clearly declared by the manufacturer itself.

9. It is recommended to use a computer with electromagnetic compatibility CE marking and with low radiation emission displays.
10. It is necessary to make the PC, connected to the Pony FX, compliant with EN 60601-1 by means of an isolation transformer.
11. The Pony FX needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the section *EMC*.
12. Portable and mobile RF communications equipment can affect the Pony FX.
13. Use only the cable and accessories supplied with the equipment. The use of accessories and/or cables other than those supplied may result in increased emissions or decreased immunity of the equipment.
14. The Pony FX should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pony FX should be observed to verify normal operation in the configuration in which it will be used.
15. Graphical symbols used in accordance to present specifications are described here below:

Equipment type B (EN60601-1)

Equipment type BF (EN60601-1)

Danger: high temperature

OFF

ON

Protective earth ground

Alternating current

Contraindications

The physical strain to execute the respiratory manoeuvre is contraindicated in case of some symptoms or pathology. The following list is not complete and must be considered as a piece of mere information.

Contraindications for the Spirometer tests

Absolute contraindications

For FVC, VC and MVV tests:

- Post-operating state from thoracic surgery

For FVC tests:

- Severe instability of the airways (such as a destructive bronchial emphysema)
- Bronchial non-specific marked hypersensitivity
- Serious problems for the gas exchange (total or partial respiratory insufficiency)

Relative contraindications

For FVC tests:

- spontaneous post-pneumothorax state
- arterial-venous aneurysm
- strong arterial hypertension
- pregnancy with complications at the 3rd month.

For MVV test:

- hyperventilation syndrome

Contraindications for Bronchial provocation tests

The bronchial provocation tests must be executed according to the doctor's discretion. There are not data that reveal specific contraindication for the bronchial provocation test through inhalation.

The modern standard processes have been revealing secure in several clinical studies. However it is recommendable to respect the following contraindications:

Absolute contraindications

- Serious bronchial obstruction (FEV1 in adults)
- Recent myocardium infarct
- Recent vascular-cerebral accident
- Known arterial aneurysm
- Incapacity for understanding the provocation test procedures and its implications.

Relative contraindications

- Bronchial obstruction caused by the respiratory manoeuvre.
- Moderate or serious bronchial obstruction. For ex. FEV1 < 1.51 in men and FEV1 in women < than 1.21.
- Recent infection in the superior air tracts
- During the asthmatic re-acuting
- Hypertension
- Pregnancy
- A pharmacology treatment epilepsy

Environmental condition of use

COSMED units have been conceived for operating in medically utilised rooms without potential explosion hazards.

The units should not be installed in vicinity of x-ray equipment, motors or transformers with high installed power rating since electric or magnetic interferences may falsify the result of measurements or make them impossible. Due to this the vicinity of power lines is to be avoided as well.

Cosmed equipment are not AP not APG devices (according to EN 60601-1): they are not suitable for use in presence of flammable anaesthetic mixtures with air, oxygen or nitrogen protoxide.

If not otherwise stated in the shipping documents, Cosmed equipment have been conceived for operating under normal environmental temperatures and conditions [IEC 601-1(1988)/EN 60 601-1 (1990)].

- Temperature range 10°C (50°F) and 40°C (104°F).
- Relative humidity range 20% to 80%
- Atmospheric Pressure range 700 to 1060 mBar
- Avoid to use it in presence of noxious fumes or dusty environment and near heat sources.
- Do not place near heat sources.
- Cardiopulmonary resuscitation emergency equipment accessible.
- Adequate floor space to assure access to the patient during exercise testing.
- Adequate ventilation in the room.

EMC

Guidance and manufacturer's declaration - electromagnetic emissions		
The Pony FX is intended for use in the electromagnetic environment specified below. The customer or the user of the Pony FX should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Pony FX 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 Pony FX 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 Pony FX is intended for use in the electromagnetic environment specified below. The customer or the user of the Pony FX should assure that it is used in such an environment.			
Immunity test	**Test level**	**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 Pony FX requires continued operation during power mains interruptions, it is recommended that the Pony FX 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.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Pony FX is intended for use in the electromagnetic environment specified below. The customer or the user of the Pony FX should assure that it is used in such an environment.			
Immunity test	**Test level**	**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 Pony FX, 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 Pony FX is used exceeds the applicable RF compliance level above, the Pony FX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pony FX. 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 Pony FX			
The Pony FX is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Pony FX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pony FX 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.			

Safety and conformity

Safety

IEC 601-1 (1988) /EN 60 601-1 (1990);

Find reported below the complete classification of the device:

- Internally powered equipment type BF device (used stand alone), class II type BF device (used connected to mains)
- Protection against water penetration: IP41
- Non sterile device
- Device not suitable in the presence of flammable anaesthetics;
- Continuous functioning equipment;

EMC

The system meets the EMC Directive 89/336

EN 60601-1-2

EN 55011 Class B (emission), IEC 1000-4-2, IEC 1000-4-3, IEC 1000-4-4

Quality Assurance

UNI EN ISO 9001:2000 (Registration n° 387-A Cermet)

Medical Device Directive (CE mark)

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

Class IIa

Keynotes

Here are the keynotes used to make the manual easier to read.

Typographic keynotes

These are the typographic keynotes used in the manual.

Style	Description
Bold	indicates a control or a key to be pressed.
"*Italic*"	indicates a messages shown by the firmware.

Graphic keynotes

These are the graphic keynotes used in the manual.

Illustration	Description
	shows the button to click in the software to activate the related feature.

Systems Overview

Pony FX is a device designed for lung function screening; the core of the system is the “intelligent” flowmeter, connected to the main unit, with graphical colour display. It can be considered a complete portable spirometric laboratory.

Pony FX can be connected to a PC in order to transfer and store the performed tests, to view the tests and, if it is used the medical grade battery charger, to perform the tests and display them on the PC monitor.

The system is composed by the turbine flowmeter, the measurement and data elaboration device, the communication cable, the battery charger and by the Software pack.

Before starting

Before operating the Pony FX system we strongly recommend to check the equipment and register you as a customer.

Checking the packing contents

Make sure that the package contains the items listed below. In case of missing or damaged parts, please contact Cosmed technical assistance.

Pony FX standard packaging

Code	Qty	Description
C00962-01-04	1	Pony FX Unit
C02235-01-05	1	Turbine
C02364-01-05	1	Reader
A 362 100 001	1	Turbine cable
A 662 100 001	2	Nose clips
C01788-02-36	1	PC Software
C00137-01-20	20	Paediatric paper mouthpieces
C00136-01-20	20	Adult paper mouthpieces
C00063-01-20	1	Conic mouthpiece
C00214-01-20	1	Paediatric mouthpiece adapter
A 362 315 001	1	USB cable
A 182 300 004	5	Bacterial filter
C02383-01-05	1	Pony FX battery charger
A 196 056 001	2	Thermic paper
C00067-02-94	1	Registration card
C01999-02-DC	1	Conformity declaration
C02361-04-91	1	User Manual

Warranty registration

Before using the system, please take a moment to fill in the registration form and the warranty and return them to COSMED, by doing this you are eligible to the customers assistance service.

For further information, please refer to the enclosed registration and warranty form. If the form is not enclosed in the packaging, please contact directly COSMED.

Register the product via software

Together with the PC software, a registration software is supplied. With this software it is possible to fill in an electronic form with the customer information.

1. To run the software, double click on the icon **Registration** or select **Registration…** from **?** menu.
2. Type the requested information and click **Send…** to send the form via e-mail to COSMED.

How to contact COSMED

For any information you may need, please contact the manufacturer directly at the following address:

COSMED S.r.l.
Via dei Piani di Monte Savello, 37
P.O. Box n. 3
00040 - Pavona di Albano
Rome - ITALY

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

Complain, feedback and suggestions

If you have any complain, feedback information or suggestion, please inform us at **complain@cosmed.it.**

PC configuration required

- Pentium II 350 MHz.
- Windows 98, XP.
- 64 Mb RAM .
- CD drive.
- VGA, SVGA monitor.
- USB or RS232 port.
- Any Mouse and Printer compatible with the MS Windows™ operative system.
- PC conform to European Directive 89/336 EMC

If you use an external printer, it must support the PCL language and have an USB port for data transmission.

The USB connection works properly only with Windows XP. Otherwise, use the serial RS232 connection.

Technical features

Flowmeter	Bidirectional digital turbine (standard), disposable pneumotachograph (option)
Flow Range:	0.03 - 20 l/s
Volume Range:	12 l
Accuracy:	± 3% or 50 ml
Resistance @12 l/s:	< 0.7 cmH2O/l/sec
Mouthpieces:	Ø 31 and Ø22 mm
Internal temperature sensor:	0-50°C (32-122°F)
Dimensions:	198 x 238 x 76 mm
Weight:	1.2 kg
Supply:	4 Ni-Mh rechargeable batteries 1.3V, 2300 mAh, no memory effect
Power supply AC/DC	220/110 VAC in, 12 VDC 1A out (class II according to EN 60 601-1 standard)
Interface	RS232, USB-A, USB-B (for the external printer)
LCD	320x240 STN colour backlighted
In-built printer	Thermo sensitive, 832 pixel per line
Printer paper	112 cm, standard sensibility, good stability , image duration 15 years

Measurements

Measured parameters

FVC - Forced Vital Capacity

▲▲▲
***Note**: Some parameters are computed only by the PC software.*

Symbol	UM	Parameter
FVC	l	Forced Expiratory Vital Capacity
FEV1	l	Forced Expiratory Volume in 1 sec
FEV1/FVC%	%	FEV1 as a percentage of FVC
PEF	l/sec	Peak Expiratory Flow
FEV0.5	l	Forced Expiratory Volume in 0.5 sec
FEV6	l	Forced Expiratory Volume in 6 sec
FEV1/FEV6	%	FEV1 as a percentage of FEV6
FEV6/FVC%	%	FEV6 as a percentage of FVC
Best FVC	l	Best Forced Expiratory Vital Capacity
Best FEV1	l	Best Forced Expiratory Volume in 1 sec
Best PEF	l/sec	Best Peak Expiratory Flow
Vmax25%	l/sec	Expiratory Flow @25% of the FVC
Vmax50%	l/sec	Expiratory Flow @50% of the FVC
Vmax75%	l/sec	Expiratory Flow @75% of the FVC
FEF25-75%	l/sec	Mid-exp flow between 25-75%FVC
FET100%	sec	Forced expiratory time
FEV2	l	Forced Expiratory Volume in 2 sec
FEV3	l	Forced Expiratory Volume in 3 sec
FEV2/FVC%	%	FEV2 as a percentage of FVC
FEV3/FVC%	%	FEV3 as a percentage of FVC
FEV1/VC%	%	Tiffenau index
FEF50-75%	l/sec	Mid-exp flow between 50-75%FVC
FEF75-85%	l/sec	Mid-exp flow between 75-85%FVC
FEF0.2-1.2%	l/sec	Mid-exp flow between 0.2 l - 1.2 l
FiVC	L	Inspiratory Forced Vital Capacity
FiF25-75%	l/sec	Forced mid-inspiratory flow
FiV1	l/sec	Forced Inspiratory Volume in 1 sec
PIF	l/sec	Peak Inspiratory Flow
VEXT	ml	Extrapolated Volume (back extrapolation)
PEFT	msec	Time to PEF (10% - 90%)

VC/IVC - Slow Vital Capacity and Ventilatory pattern

Symbol	UM	Parameter
EVC	l	Expiratory Vital Capacity
IVC	l	Inspiratory Vital Capacity
ERV	l	Expiratory Reserve Volume
IRV	l	Inspiratory Reserve Volume
IC	l	Inspiratory Capacity
VE	l/min	Expiratory Minute Ventilation
Vt	l	Tidal Volume
Rf	1/min	Respiratory Frequency
Ti	sec	Duration of Inspiration
Te	sec	Duration of Expiration
Ttot	sec	Duration of Total breathing cycle
Ti/Ttot	—-	Ti/Ttot ratio
Vt/ti	l/sec	Vt/ti ratio

MVV - Maximum Voluntary Ventilation

Symbol	UM	Parameter
MVV	l/min	Maximum Voluntary Ventilation
MVt	l	Tidal Volume (during MVV)
MRf	1/min	Maximum Respiratory frequency
MVVt	sec	MVV duration time

Bronchoprovocation Response

Symbol	UM	Parameter
FallFEV1	%	Fall in FEV1 from baseline or post diluent
FallVmax50%	%	Fall in Vmax50% from ref.
P10	—-	Provocative dose causing FEV1 to fall 10%
P15	—-	Provocative dose causing FEV1 to fall 15%
P20	—-	Provocative dose causing FEV1 to fall 20%

Installation

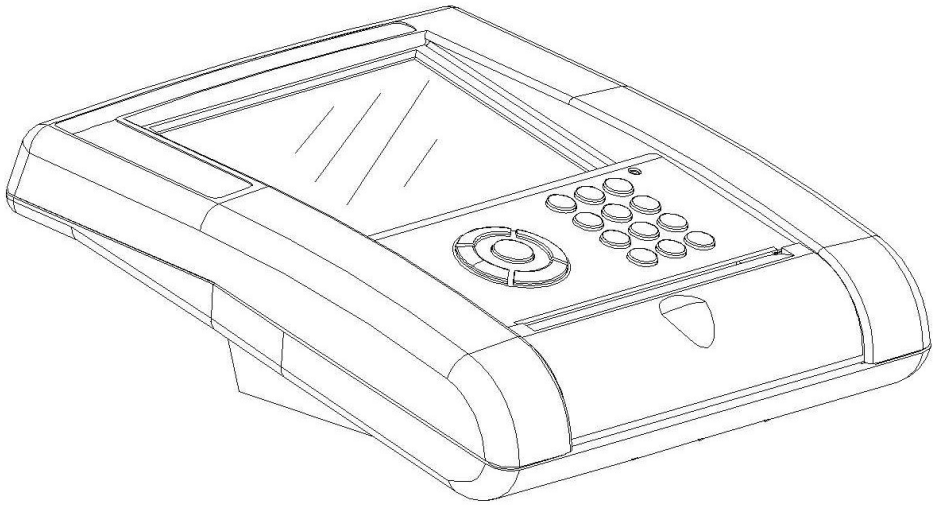
Preparing Pony FX

Pony FX is mainly made of:

- Pony FX unit
- Battery charger
- Flowmeter (pneumotachograph or turbine, depending on the version)

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

Pony FX unit



The main elements a user can detect in the Pony FX unit are the following:

- A colour display
- A keyboard
- An internal printer
- Some connectors on the bottom side of the device.

The display

The colour display interfaces the device with the user, allowing the user to access to the functions of the device and to display the performed tests.

The keyboard

Pony FX has a keyboard (see the next picture), which allows the user to interact with the device.

The keyboard is divided into two groups. In the left one there are the on/off-menu key (at the centre) and four direction keys.

In the right group there are 10 alphanumeric keys, the confirm and the delete keys.

A more detailed description of the keys functions, of the keyboard logics and of the menus, see the chapter *Using Pony FX*.

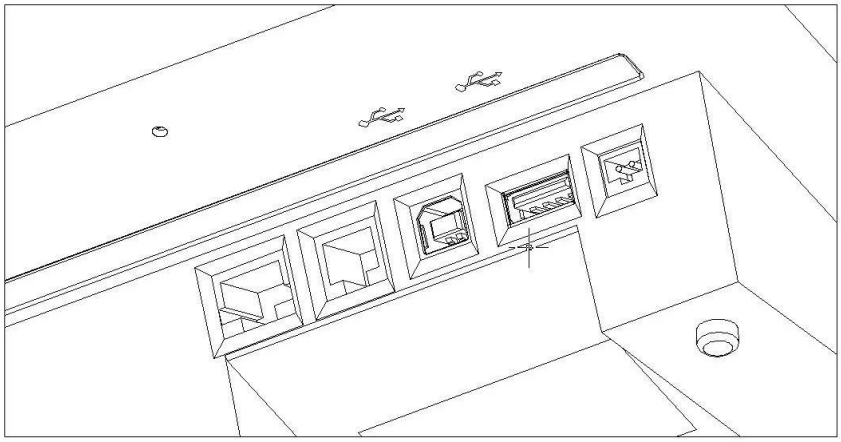
The printer

It is a thermal printer, which allows the printing of the test performed.

For more information about the use of the internal (or an external) printer, see the chapter *Using Pony FX*.

The connectors

On the bottom side of the device there are 7 connectors, as shown in the following picture.



A label details the connection type:

From the left to the right, in order:

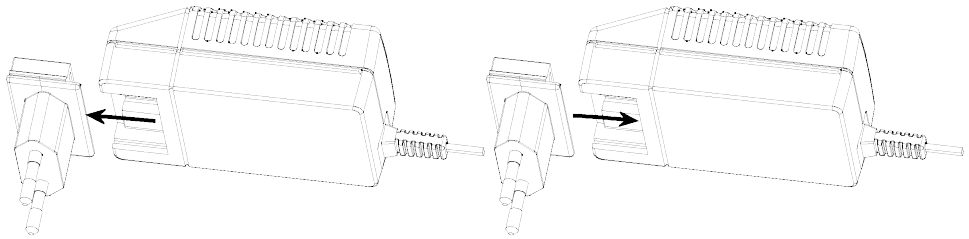
- 2 pneumatic connectors for pneumotachograph, if you do not use the turbine flowmeter.
- Connector for the RS232 cable, if the PC doesn't have an USB port, or for the oxymeter (option).
- Connector for the turbine flowmeter or for the airway resistance measurement module (option).
- USB connector for the PC.
- USB connector for an external printer.
- Battery charger connector.

Replacement of the power plug

If the power plug does not fit into the mains socket, replace it with the one in the packaging.

In order to replace the plug:

1. Extract the plug from the battery charger
2. Insert the proper plug in the battery charger.



Battery charger

Pony FX is powered by a battery pack, rechargeable by means of a battery charger.

⎓ Connect the battery charger to the Pony FX unit through the connector with the symbol by side.

Near the keyboard, a led indicates the battery status:

Green led	In charge
Orange led	Full charged
Red led	Error.

The red led can be due to:

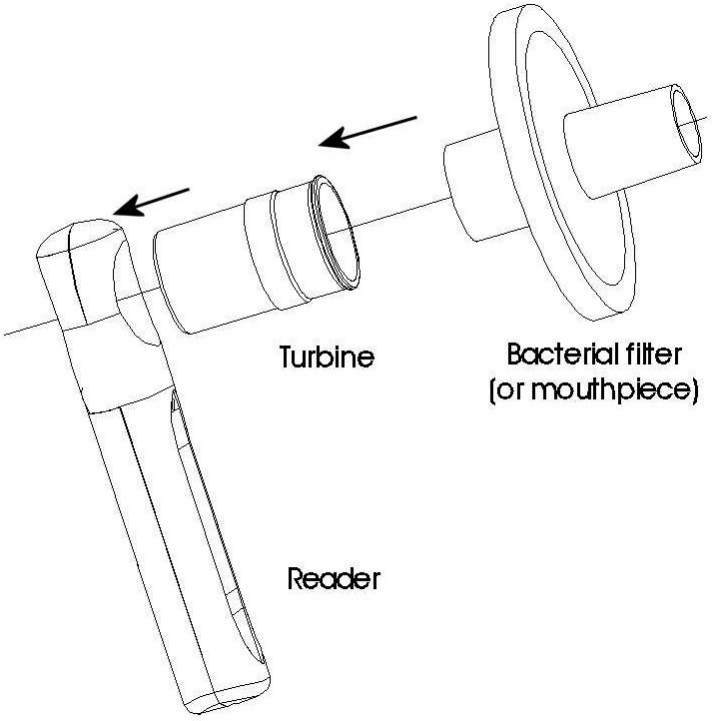
- Battery temperature <5°C. The red led should switch off when the temperature falls again in the range 5-45°C.
- Battery temperature >45°C. The red led should switch off when the temperature falls again in the range 5-45°C.

- Very low battery, because of the unit has been not used for a long time. The led switches to green after some time of charging. Please fully charge the unit.
- Failed battery. Please contact the technical support.

Note: *The first time you use the device, charge the battery for at least 12 hours, even if the led indicates the completion of the charge before the time elapsed.*

Note: *The batteries must be replaced when they do not maintain their charge for enough time. Please contact the technical support.*

Connect the flowmeter to the Pony FX



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

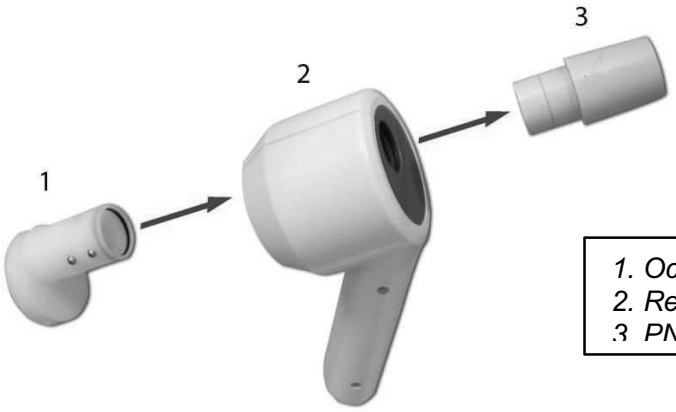
The air passing through the helical conveyors, takes a spiral motion which causes the rotation of the turbine rotor. The rolling blade interrupts the infrared light beamed by the two diodes of the reader. Every interruption represents 1/4 turn of the rotor, this allows to measure the number of turn in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

It is connected to the unit through the *Turb./Raw* connector.

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.*

Connect the R_{OCC} module (option) to the Pony FX



1. Occlusion valve
2. Reader
3. PNT

1. Connect the three parts of the R_{OCC} module as in the picture by side.
2. Connect the module to the Pony FX unit through the *Turb./Raw* connector.

Connect the oxymeter (option) to the Pony FX

It is connected to the unit through the RS232/SpO_2 connector.

Connect the Pony FX to the PC

The Pony FX can be connected to the PC in order to transfer and store the performed tests, to back-up the data on a different unit (HD, floppy, CD ROM), to analyse the tests or to perform the tests sending the controls directly from the PC.

If the PC connected to the Pony FX is placed within the patient area (according to the IEC 60601-1-1 norm), the PC has to be made compliant with the IEC 60601-1-1 norm by means of an isolation transformer.

The PC is connected to the Pony FX unit, through an USB connection, to the USB port with the symbol by side.

If the PC does not have an USB port, it is possible to use a RS232 serial connection.

Select the communication port both on the PC (selecting the menu item **Options/Configure**) and on the unit (selecting the menu item **2.Options/1.Settings**).

The first time you connect the Pony FX to the PC through an USB connection, you will be requested for the drivers. Install them from the installation CD.

Connect the Pony FX to an external printer

The Pony FX can be directly connected to an external printer in order to print the performed tests on a different paper.

If the printer connected to the Pony FX is placed within the patient area (according to the IEC 60601-1-1 norm), it has to be made compliant with the IEC 60601-1-1 norm by means of an isolation transformer.

The printer is connected to the Pony FX unit, through an USB connection, to the USB port with the symbol by side.

Software installation

Installing the software

1. Select **Run...** from Windows **Start** menu.
2. Insert the disk in the proper drive.
3. In the Command line, type **<name of the drive>:\install**.
4. Click on **OK** (or press **ENTER** key).
5. The program will load up a dialog box and ask for a directory where to be installed.
6. When the installation is over, the program will advise you with a message indicating that the installation has been successfully completed, click on **End.**

***Notice**: The software is copy-protected. Install the software from the original disk.*

Run the software

1. In the Windows **Start** menu, open the Program Group in which the software was installed.
2. Click the **PFT Suite** icon.

PC port configuration

The first time the software is used, it is necessary to configure the communication port with the PC (USB, COM1, COM2,…).

For further details, see the chapter *Database management*.

Software main features

Display

The program may contain several windows. The active window is highlighted with a different colour of the caption. Some functions of the program are "active window" sensitive (Print, right key of the mouse).

Tool bar

Many of the functions that may be selected from the menu can be activated more rapidly by clicking with the mouse on the corresponding icon in the tool bar.

Positioning the mouse cursor on one of the buttons of the toolbar (if the option Hints is enabled), the description of the corresponding function is shown in a label.

Show/hide the toolbar

Select **Toolbar** from **Options** menu in order to show or hide the toolbar.

Dialog windows

The typical operating environment of Microsoft Windows is the Dialog box. This window is provided with a series of fields in which input the information.

Use of the keyboard

- To move the cursor among fields, press the **Tab** key until you reach the desired field.
- Press the **Enter** key to confirm the information input on the dialog box or press the **Esc** key to cancel changes.

Use of the mouse

- To move the cursor among fields, move the mouse on the desired field and left-click.
- Click on the **OK** button with the Left button of the mouse to confirm the information input on the dialog box or click on **Cancel** button to cancel changes.

Scroll bars

Some windows are provided with scroll bars that help to see data exceeding the window space available.

- To move the scroll bar row by row click the scroll arrows at the end of the scroll bars
- To move the scroll bar page by page click on the grey area at both sides of the scroll fields

On-line help

COSMED Help is a complete on-line reference tool that you can use at any time. Help is especially useful when you need information quickly or when the user manual is not available. Help contains a description of each command and dialog box, and explains many procedures for accomplishing common tasks.

To get the Help on line, press the **F1** key.

Software version

To know the software version and the serial number of the software, select **About…** from **Help** menu.

Calibration

The calibration program

Running the Calibration program

Start the program and choose **Calibration** from the **Test** Menu. The software runs the Calibration software and the main menu changes accordingly.

Log file

The program creates and updates as default the calibration log file, containing the conditions and the results of all the calibrations performed by the user.

To access the file select **File/Report File...** from the calibration program.

Turbine calibration

Pony FX is calibrated by COSMED. ATS recommends a daily calibration of the turbine. However if it is correctly maintained, turbine retains its precision for longer periods. We advice to calibrate the turbine daily to detect malfunctioning.

***Note**: if you are using a slow PC, we recommend to set an higher refresh time.*

Calibrating the turbine without a PC

In order to calibrate the turbine by means of the Pony FX unit:

1. Connect the turbine flowmeter to the calibration syringe.
2. Select the menu item **3.Utilities/1.Calibration**.
3. Move the piston in and out for 10 strokes (IN and EX).

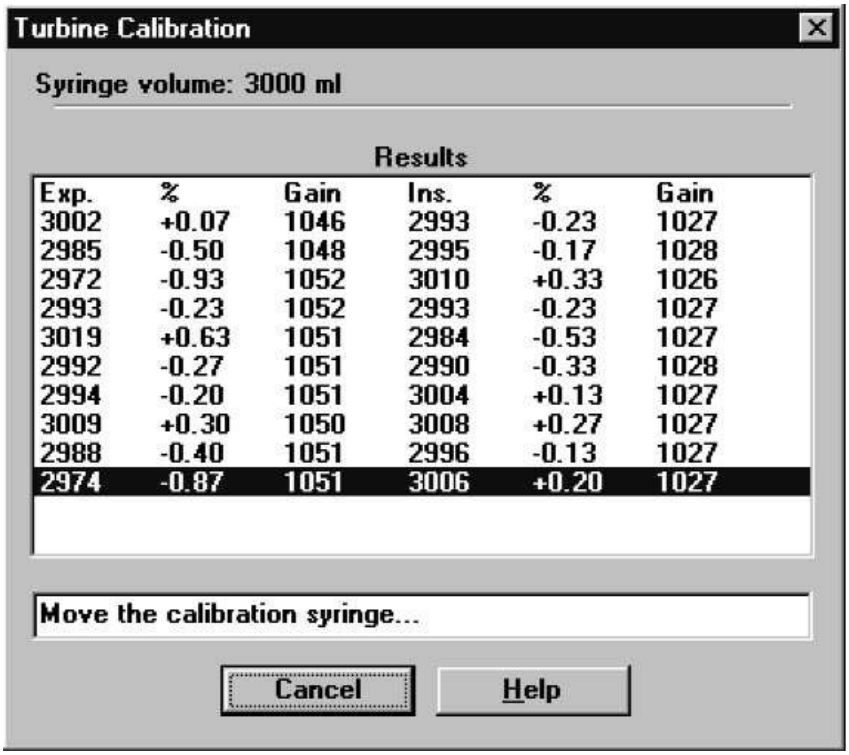
The 3 litres calibration syringe can be purchased directly from COSMED (P/N: C00600-01-11).

***Note:** If a bacterial filter is used for the tests, do use it also during the turbine calibration.*

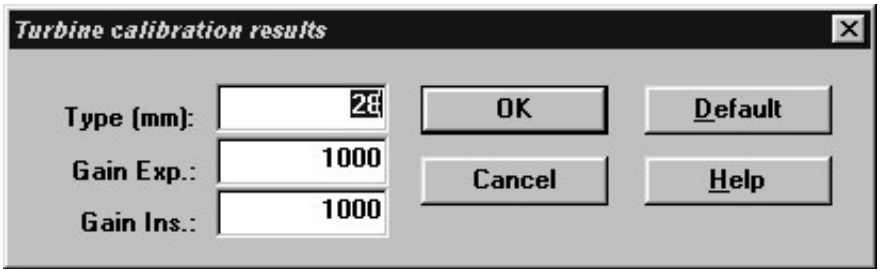
Calibrating the turbine by means of a PC

In order to calibrate the turbine by means of the PC software:

1. Connect the turbine flowmeter to the calibration syringe.
2. Select **Calibration** from **Test** menu.
3. Select **Reference values** from the **Calibration** menu and enter the syringe volume, if different to the displayed one.
4. Select **Turbine** from the **Calibration** menu.
5. When the **Calibration Turbine** dialog box appears with the syringe piston initially pushed all the way in, move the piston in and out for 5 inspiratory strokes and 5 expiratory strokes in order to get the first values appearing on the screen. Then move the syringe piston for other 10 strokes (IN and EX).
6. At each of the 10 steps the software displays the results of the manoeuvre and the percentage error in the reading.



7. At the end of this operation, the software displays the new calibration factors. Press **OK** to store the new value.



The 3 litres calibration syringe can be purchased directly from COSMED (P/N: C00600-01-11).

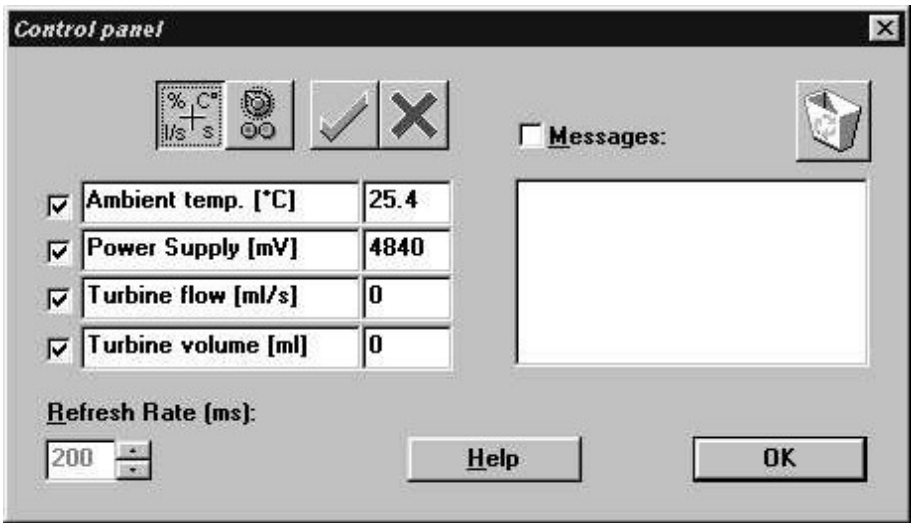
Note: *If a bacterial filter is used for the tests, do use it also during the turbine calibration.*

Checking the system signals

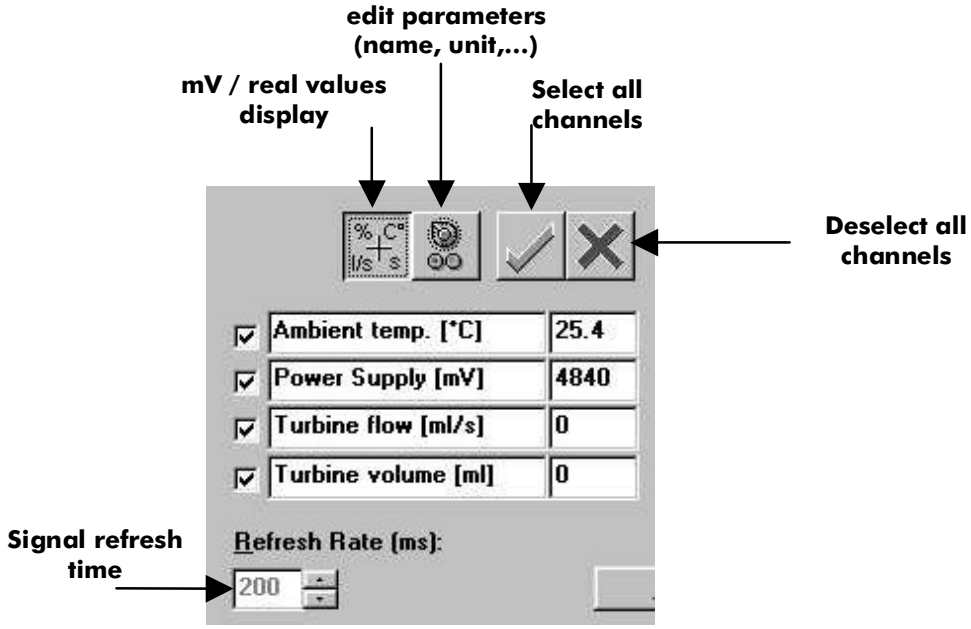
The control panel

The **Control Panel**, which can be activated from the **Calibration/Control panel…** menu item, is a useful tool to check the main hardware functions of Pony FX.

By using the controls on Control Panel you are able to read the signals acquired by the system both as voltages and processed data.



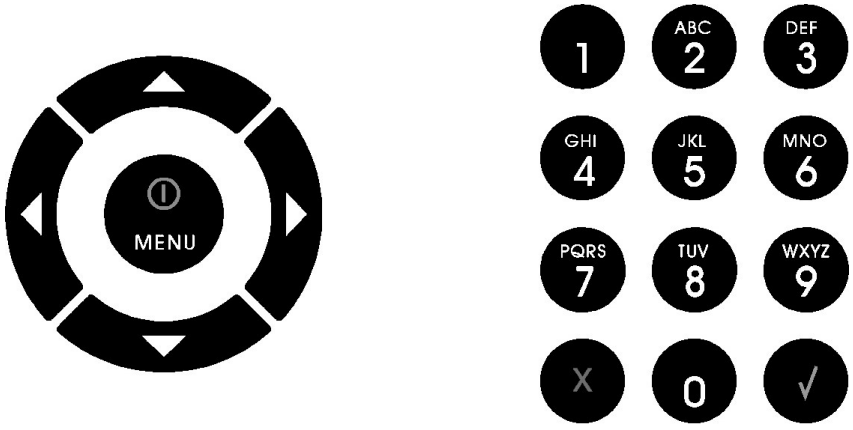
Using the control panel



Using Pony FX

Main functions of the Pony FX

All the Pony's functions are controlled by means of the keyboard (see the following picture).



Turning on/off the Pony FX

In order to turn on or off the device, hold the MENU key pressed for few seconds.

Pony FX has two automatic turning-off functions:

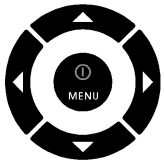
- of the display. If you don't use the unit for at least the time set in configuration (see later, *Options*), the display turns off automatically. In order to avoid this, press any key.
- of the device. If you don't use the unit for at least 5 minutes, the unit turns off automatically. In order to turn on the device, press the MENU key.

Using the menu

The menu bar is displayed in the upper part of the screen, and it appears different, depending on the context.

In the lower part of the display, a status bar indicates useful information and short Help messages.

Accessing the menu



You can access the menu in two ways:

- Press shortly the MENU key, and then change menu by means of the direction keys. Confirm the selected item by means of the key 

.

- Press the key on the alphanumeric keyboard corresponding to the selected menu item, until the desired function is highlighted.

The two methods (direction keys and alphanumeric keyboard) are fully interchangeable.

To exit the menu, press the MENU key.

Using the keyboard

Please find in the following a brief description of the functions of the keys, and then a description of the keyboard logic.

Key	Description
	Turns on/off the Pony FX, accesses the menus.
	Goes to the upper menu item or (in input data mode) to the previous field.
	Goes to the lower menu item or (in input data mode) to the next field.
	Goes to the menu item on the right. In input data mode, adds a blank space to the right or (in multi-options fields) scrolls forwards the available options.
	Goes to the menu item on the left. In input data mode, deletes the last character entered or (in multi-options fields) scrolls backwards the available options.
	Enters the digit 1 or a character . , ; : # @ - = ! ? $ & / ( )
	Enters the digit 2 or a character A B C
 as the  key	
	Enters the digit 0
	Cancels the operation.
	Confirms the operation or the selected menu item.

Logic of the keyboard

The logic of the keyboard follows these rules:

- If the current input field (the one with the cursor) allows an alphanumeric input (for example, name, company,…), you have to follow these instructions in order to enter the characters:

  ⇒ A repeated pressure of a key scrolls the available characters for that key until another key is pressed or it elapses 1 second.

  ⇒ If you wait more than 1 second or if you press another key, you confirm the input and the cursor moves 1 place towards right.

  For example, in order to enter the string "BB4" you have to press the following keys:

  The keys will enter the character first (letter or signs), and then the digit.

- Pressing the *Left* key, the cursor moves towards left, deleting the characters.

  For some fields, you have to select an option from a predefined list. In these cases, this key allows scrolling backwards the list.

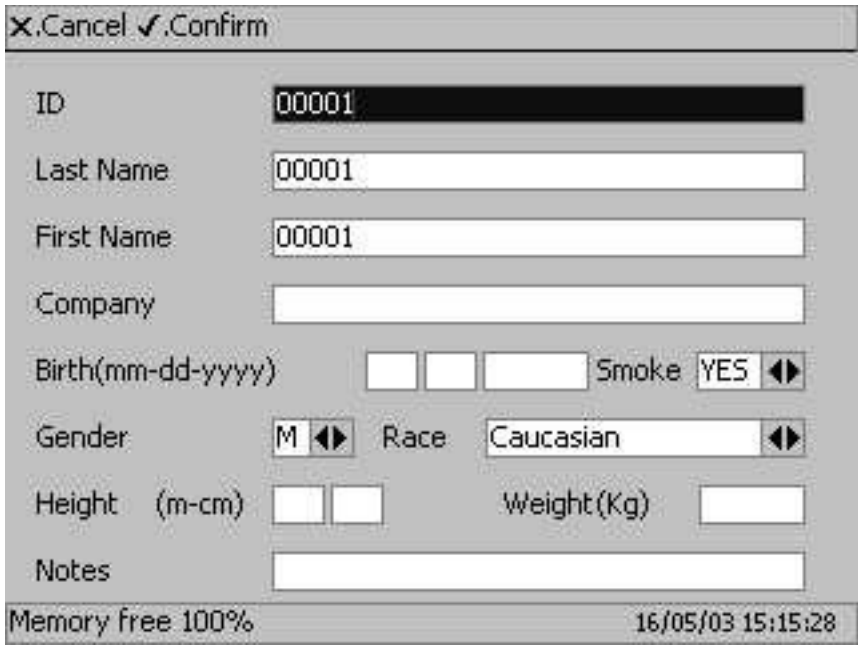
- Pressing the *Right* key, the cursor moves towards right, adding blank spaces.

  For some fields, you have to select an option from a predefined list. In these cases, this key allows scrolling forwards the list.

Patient database management

Create a new patient

In order to create a new patient, select the menu item **1.Patients/1.New** and enter the required data.

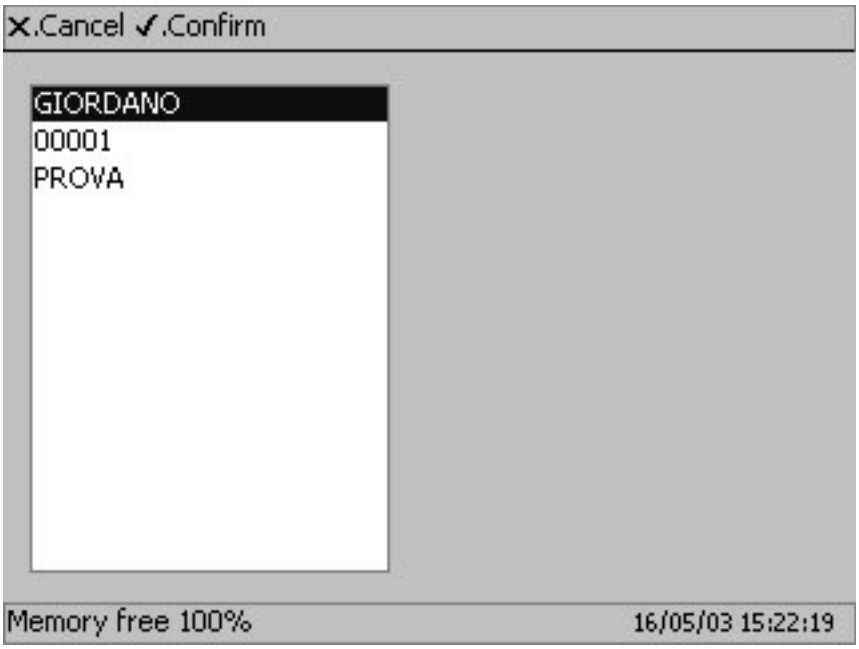


In the following you will find some useful notes for proper data entry.

- ID is an alphanumeric sequence, which identifies the patient. It is assigned automatically by the unit, but can be modified as you want. The maximum length is 16 chars.
- The birth date must be entered as month-day-year. The year must be four-digit format.
- The height has to be entered in the two fields: the first one for metres, the second one for centimetres.

Search a patient in archive

In order to search a patient stored in the archive, select the menu item **1.Patients/2.View/Search**. It will open a window with the patient list.



√ Scroll the list by means of the arrows and confirm the selected patient with the key by side.

x If necessary, cancel the operation with the key by side.

Performing the spirometric tests

▲▲▲
***Note**: Read carefully the contraindications in Chapter 1.*

Once completed the phase of the introduction of the patient's data (or selection of an already archived patient), it is possible to carry out the spirometric tests.

For a complete description of the tests and of the measured parameters, see the chapter *Spirometry*.

Recommendations for spirometry tests

- The patient should wear the nose clip
- The turbine has been recently calibrated (ATS recommends a daily calibration)
- If you are using the pneumotachograph, do not breathe into the flowmeter, until the proper message appears.
- The paper mouthpiece or the antibacterial filter is properly connected to the flowmeter through the corresponding adapter

For hygienic reasons, we strongly recommend the use of a bacterial filter.

If a kid must perform the test it is recommended to enable the encouragement function which shows exactly the manoeuvre of the FVC test.

Forced Vital Capacity (pre)

1. Explain the manoeuvre to the patient (breathe at rest for some time, perform a maximal inspiration and then a maximal forced exhalation).
2. Select the menu item **1.Test/1.FVC Pre**.
3. Wait until the program is ready for the test.
4. After having performed the test, press **2.Stop** or wait for the automatic end (5 seconds without flow), so that the device displays the F/V graph, the main parameters, and the predicteds values.
5. Press **0.Abort** in order to abort the test and discard the results. Press **1.Redo** in order to restart the test.
6. Repeat the test until it is correctly performed (ATS recommends 3 times) , by pressing **1.Redo**.
7. The three best tests will be displayed superimposed each to the other, identified by different colours. On the right side of

the display, the three best tests, their colours and the measured parameters are reported, ordered from the best to the worst. The best and the last test performed are highlighted.

8. Press **2.Save & Exit** in order to exit saving a test. You will be ask to select the test to store: press the digit corresponding to the test to be stored.
9. Otherwise, press **0.Exit without saving** in order to exit the test mode without saving the tests.

Test encouragement

During FVC manoeuvre you might experience some lack of collaboration with kids or with other patients. In this case you may find a good help in using the encouragement tool.

1. Select the menu item **1.Test/6.Encouragement**.
2. Perform the test as described in the previous paragraph.

Slow Vital Capacity

1. Explain the manoeuvre to the patient (breathe at rest for some time, perform a maximal inspiration, then a slow forced exhalation, and finally a deep inspiration).
2. Select the menu item **1.Test/4.SVC**.
3. Wait until the program is ready for the test.
4. After having performed the test, press **2.Stop** or wait for the automatic end (5 seconds without flow), so that the device displays the V/T graph, the main parameters, and the predicteds values.
5. Press **0.Abort** in order to abort the test and discard the results. Press **1.Redo** in order to restart the test.
6. Repeat the test until it is correctly performed (ATS recommends 3 times), by pressing **1.Redo**.
7. The three best tests will be displayed superimposed each to the other, identified by different colours. On the right side of the display, the three best tests, their colours and the measured parameters are reported, ordered from the best to the worst. The best and the last test performed are highlighted.
8. Press **2.Save & Exit** in order to exit saving a test. You will be ask to select the test to store: press the digit corresponding to the test to be stored.

9. Otherwise, press **0.Exit without saving** in order to exit the test mode without saving the tests.

Maximum Voluntary Ventilation

1. Explain the manoeuvre to the patient (breathe as deep and fast as possible for about 12 seconds).
2. Select the menu item **1.Test/5.MVV**.
3. Wait the program is ready for the test.
4. After having performed the test, the device displays the V/T graph, the main parameters, and the predicteds values.
5. Press **0.Abort** in order to abort the test and discard the results. Press **1.Redo** in order to restart the test.
6. Repeat the test until it is correctly performed (ATS recommends 3 times), by pressing **1.Redo**.
7. The three best tests will be displayed superimposed each to the other, identified by different colours. On the right side of the display, the three best tests, their colours and the measured parameters are reported, ordered from the best to the worst. The best and the last test performed are highlighted.
8. Press **2.Save & Exit** in order to exit saving a test. You will be ask to select the test to store: press the digit corresponding to the test to be stored.
9. Otherwise, press **0.Exit without saving** in order to exit the test mode without saving the tests.

Bronchial Provocation Test

The program refers to the **FVC pre** which is selected (highlighted) at the test start.

The name of the drug, the quantity and unit of measurement, and, only for bronchoconstrictor tests, the delivery protocol, can be customised from the **Utility** menu (see later in this document).

Bronchodilators test

The manoeuvre is identical to the FVC test.

1. Select the menu item **1.Test/2.FVC Post BD**.
2. Wait until the program is ready for the test.
3. After having performed the test, press **2.Stop** or wait for the automatic end (5 seconds without flow), so that the device

displays the V/T graph, the main parameters, and the predicteds values.

4. Press **0.Abort** in order to abort the test and discard the results. Press **1.Redo** in order to restart the test.
5. Repeat the test until it is correctly performed (ATS recommends 3 times), by pressing **1.Redo**.
6. The three best tests will be displayed superimposed each to the other, identified by different colours. On the right side of the display, the three best tests, their colours and the measured parameters are reported, ordered from the best to the worst. The best and the last test performed are highlighted.
7. Press **2.Save & Exit** in order to exit saving a test. You will be ask to select the test to store: press the digit corresponding to the test to be stored.
8. Otherwise, press **0.Exit without saving** in order to exit the test mode without saving the tests.

Bronchoconstrictor test

The manoeuvre is identical to the FVC test.

1. Select the menu item **1.Test/3.FVC Post BC**.
2. A window with bronchoconstrictor name, quantity and measurement unit, as set in **2.Options/3.FVC Post**, will be displayed.
3. If you accept the protocol, confirm, otherwise modify the values and confirm.
4. Wait until the program is ready for the test.
5. After having performed the test, press **2.Stop** or wait for the automatic end (5 seconds without flow), so that the device displays the V/T graph, the main parameters, and the predicteds values.
6. Press **0.Abort** in order to abort the test and discard the results. Press **1.Redo** in order to restart the test.
7. Repeat the test until it is correctly performed (ATS recommends 3 times), by pressing **1.Redo**.
8. The three best tests will be displayed superimposed each to the other, identified by different colours. On the right side of the display, the three best tests, their colours and the measured parameters are reported, ordered from the best to

the worst. The best and the last test performed are highlighted.

9. Press **2.Save & Exit** in order to exit saving a test. You will be asked to select the test to store: press the digit corresponding to the test to be stored.
10. Otherwise, press **0.Exit without saving** in order to exit the test mode without saving the tests.
11. Repeat all the FVC Post until the FEV1 falls down by more than 20% of the FVC Pre value.

Performing the oximetry test (option)

The oximetry test measures the haemoglobin saturation, i.e. the percentage of the blood haemoglobin bearing oxygen. The test can be performed at rest or during/after a light exercise phase (cycling, jogging).

The test is completely automatic.

The measured parameters are:

SpO_2 Haemoglobin saturation

HR Heart rate

Recommendations for oximetry tests

- Be sure that the sensor has been properly disinfected.
- Use only the original COSMED sensor.
- Operation and accuracy of the measurement may be affected by the following:

– high ambient light

– fingernail polish or artificial fingernail

– excessive motion

Performing the test

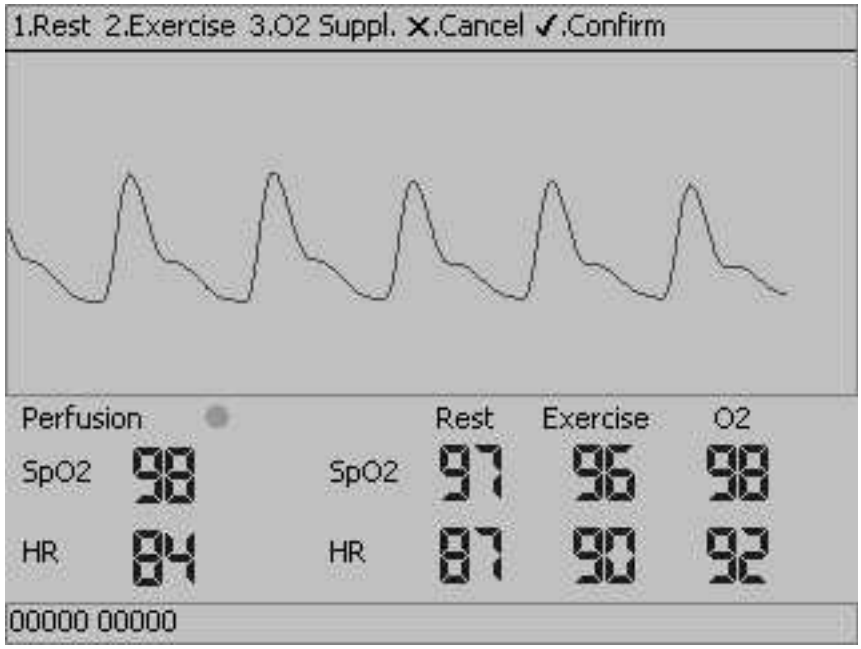
1. Connect the sensor to the Pony FX unit through the RS232/SpO_2 port.
2. Connect the probe to patient's index finger and affix with adhesive tape if necessary.
3. Select the menu item **1.Test/7.SpO2**.
4. In the first part of the test the HR and SpO_2 values, together with a plethysmographic graph, are displayed. The graph monitors the quality of the signal.
5. Wait for an acceptable quality of the real-time trace and verify that the *Perfusion* indicator is green. Press:

– **1.Rest** to store the rest value.

– **2.Exercise** to store the exercise value.

– **3.O2 Suppl.** to store the value with inspired oxygen supplement.

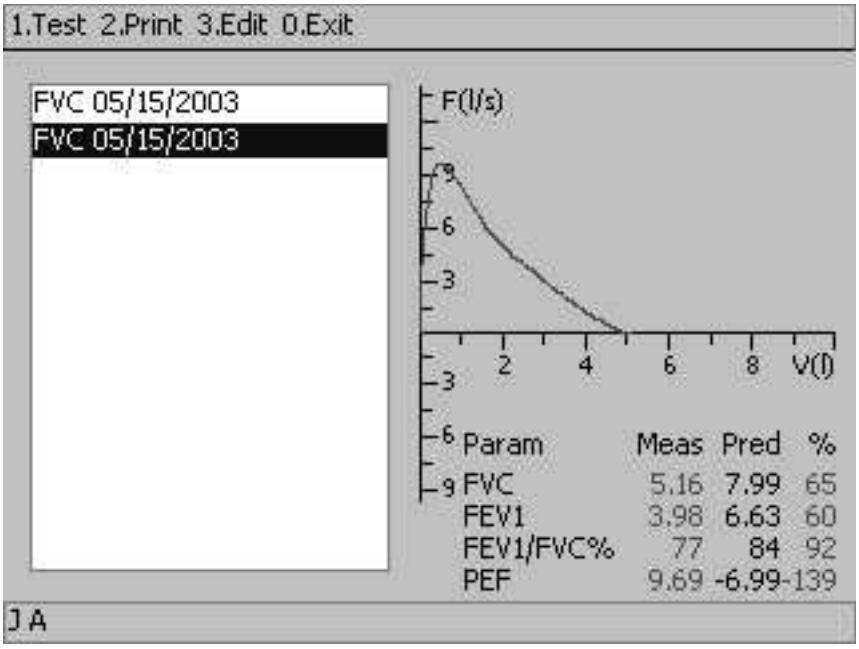
It is not necessary to store all the three values during a single test.


1.Rest 2.Exercise 3.O2 Suppl. ✕.Cancel ✓.Confirm
Perfusion
SpO2 98
HR 84
Rest
Exercise
O2
SpO2 97 96 98
HR 87 90 92
00000 00000

Viewing results

View a test in archive

After having selected a patient, highlight the desired test by means of the arrow keys. The graph of the selected test will appear on the right side of the display.



Printing results

Replace the printer paper

You need thermic paper (P/N A 196 056 001, 10 pcs.).

1. Open the azure paper cover.
2. Lift up the green lever.
3. Insert the paper into the slot with the two light grey stripes under the green lever.
4. Lift down the green lever.
5. Select the menu item **3.Utility/4.Paper Feed** and wait the paper exit above the green lever. If the paper does not exit, check that the paper is properly inserted.
6. Close the paper cover.

Printing tests by means of the internal printer

1. View the desired test.
2. Select the menu item **2.Print/1.Selected Test** in order to print this test. Select the menu item **2.Print/2.Report** in order to print a report for the selected patient.

Printing tests by means of an external printer

When an external printer is connected through an USB connection to the Pony FX unit, the test will be printed on the external printer.

Note: *If the printer connected to the Pony FX is placed within the patient area (according to the IEC 60601-1-1 norm), it has to be made compliant with the IEC 60601-1-1 norm by means of an isolation transformer.*

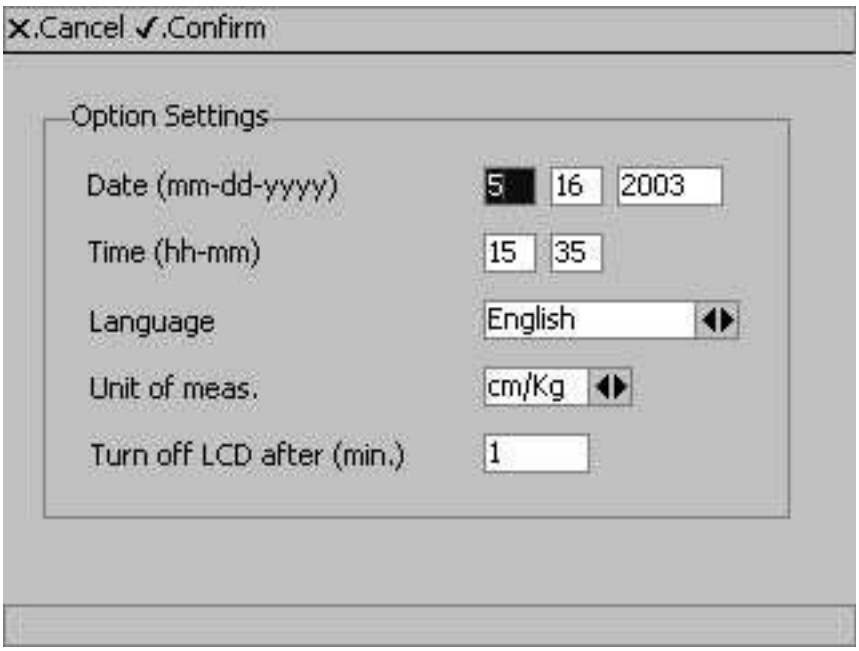
Note: *The printer must support the PCL language and have an USB port for data transmission.*

Options

The Pony FX unit allows the configuration of some options, by means of the **2.Options** menu.

General settings

Select the menu item **2.Options/1.Settings**.



You can set:

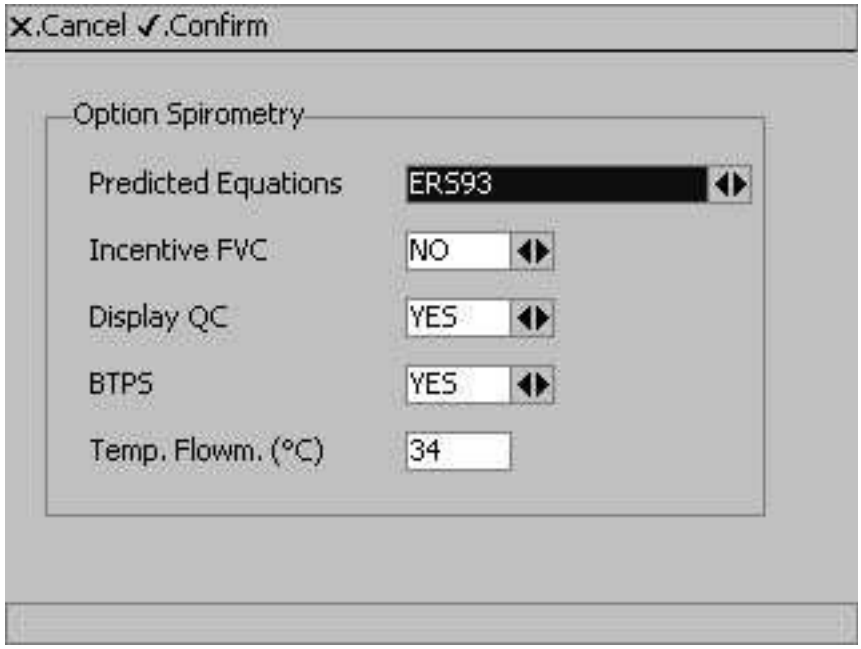
- Date and time. The date must be entered as month-day-year. The year must be expressed in 4-digit format.
- Language.
- Measurement unit (cm/kg or in/lb)
- Amount of time after which the display turns off automatically, if the unit was not used.

Spirometry options

Select the menu item **2.Options/2.Spirometry**.

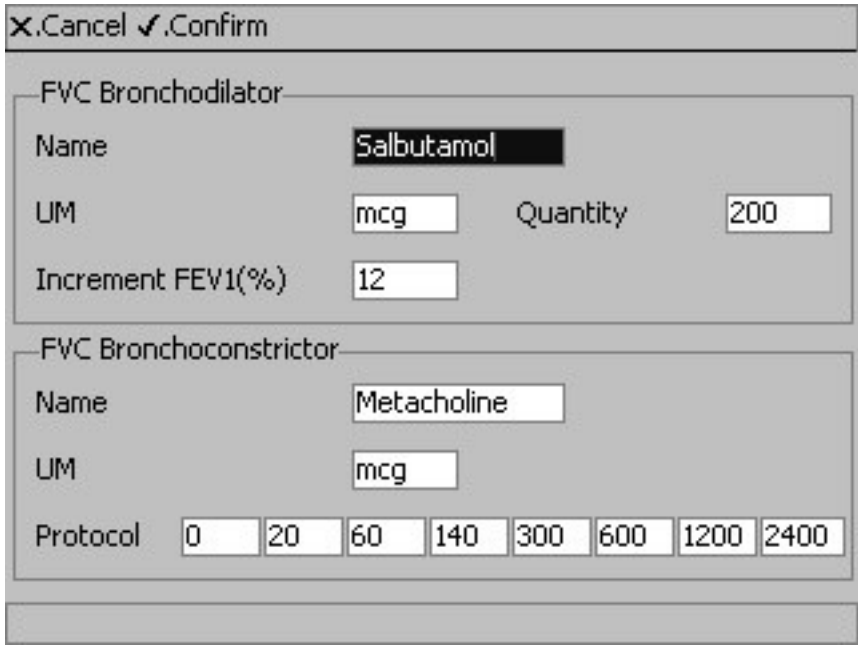
You can set:

- The equation set used for the predicteds values calculation.
- If the test quality control visualisation is enabled.
- If the BTPS correction is applied.
- The flowmeter temperature.



FVC Post options

Select the menu item **2.Options/3.FVC Post**.

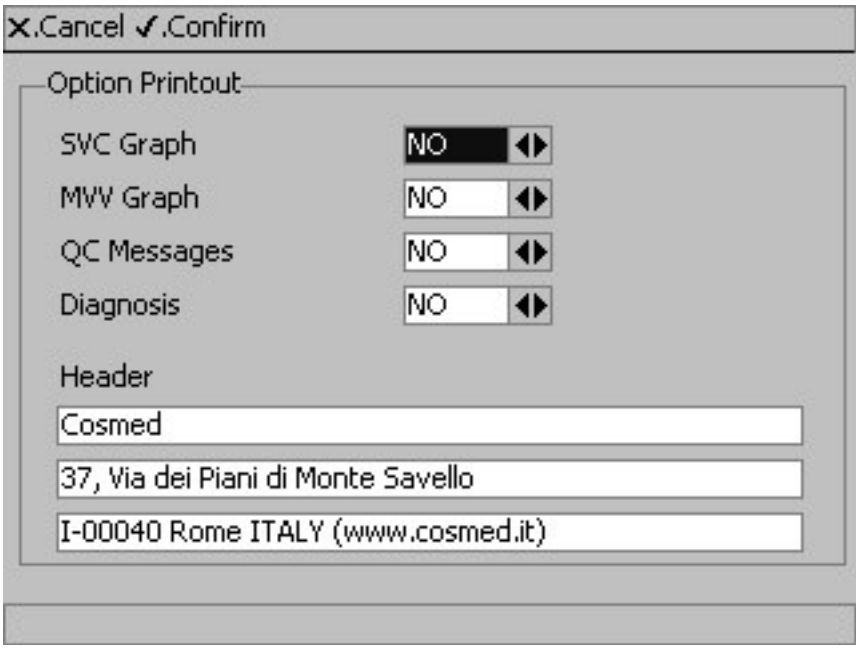


You can set:

- Name, measurement unit and quantity of the bronchodilator.
- Reversibility threshold for the airways obstruction (as % increment of the FEV1).
- Name and measurement unit of the bronchoconstrictor.
- Protocol for the use of the bronchoconstrictor (quantity to be delivered to the patient in the steps of the FVC Post test).

Printout options

Select the menu item **2.Options/4.Printouts**.

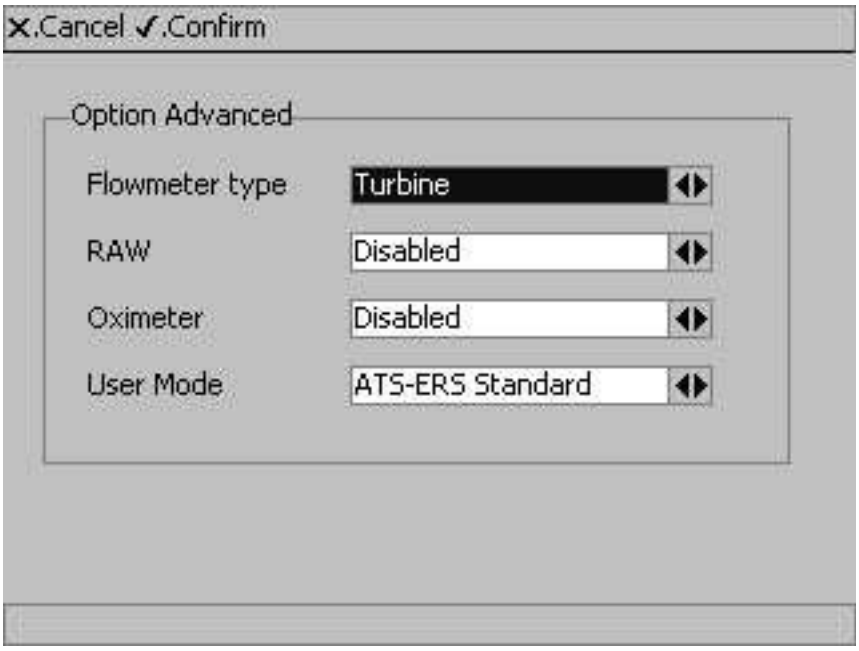


You can set:

- If the unit prints the SVC and MVV tests, the test quality controls and the automatic interpretation.
- A page header for the printout.

Advanced options

Select the menu item **2.Options/5.Advanced**.



You can set:

- The flowmeter type (turbine or pneumotachograph).
- The airway resistance option (enabled or not).
- The oximetry option (enabled or not).
- The mode of the spirometer (*ATS-ERS Standard* or *Office Spirometer*, a simplified and less detailed version).

Environmental data

Select the menu item **2.Options/6.Environment.**

You can set:

- Pressure
- Relative humidity

Restore of initial settings

Select the menu item **2.Options/7.Defaults**.

With this option you can reset the option and restore the original factory settings.

Other functions of Pony FX

There are other general functions, in order to operate at the best.

You can access to these functions by means of the **3.Utilities** menu.

Calibration

The calibration procedure allows exact measurements of flows, volumes and so on, correcting errors due to climatic changes, use of the device, wear, etc.

Select the menu item **3.Utilities/1.Calibration**.

For further details, see the chapter *Calibration*.

Control panel

The control panel allows to monitor the device status.

Select the menu item **3.Utilities/2.Control panel**. The display is divided into 3 zones.

Sensors

Temperature inside the unit and the flowmeter, and the battery charge in mV.

Controls

Pushing the key 1 the *Charger relais* activates. It simulates disconnection or connection between unit and battery charger cable.

Pushing the key 2, the *Printer relais* activates. It activates or deactivates the internal printer.

Embedded Printer

The *Heads* icon shows if the green lever is lifted or not.

The *Paper* icon shows if there is paper charged or not.

The *Termistor* value is the temperature of the printer.

LCD contrast

In order to modify the contrast of the Pony FX display:

1. Select the menu item **3.Utilities/3.LCD Contrast**.
2. Adjust the contrast by means of the right and left arrow keys.
3. Press the confirm key.

Paper feed

This function is useful mainly during the paper replacement.

Select the menu item **3.Utilities/4.Paper Feed**.

Memory deletion

It erases all the memory contents.

1. Select the menu item **3.Utilities/5.Erase Memory**.
2. Confirm by pressing the key by side.

Firmware version information

In order to get information about the installed firmware version, select the menu item **3.Utilities/6.Information**.

Reset

Reset of the unit

If the Pony FX does not run its firmware (the program of the unit, not the PC software), it can be rebooted by pressing, with a sharpened tool, a button inside a little hole on the rear side of the unit.

With this operation the data will not be lost.

Formatting the unit

If, for serious reasons, it is needed to erase all the archive and the memory of the Pony FX (also the firmware program), it is possible to format the unit.

Turn on the Pony FX keeping pressed the Cancel key. Release the Menu key, then the Cancel key.

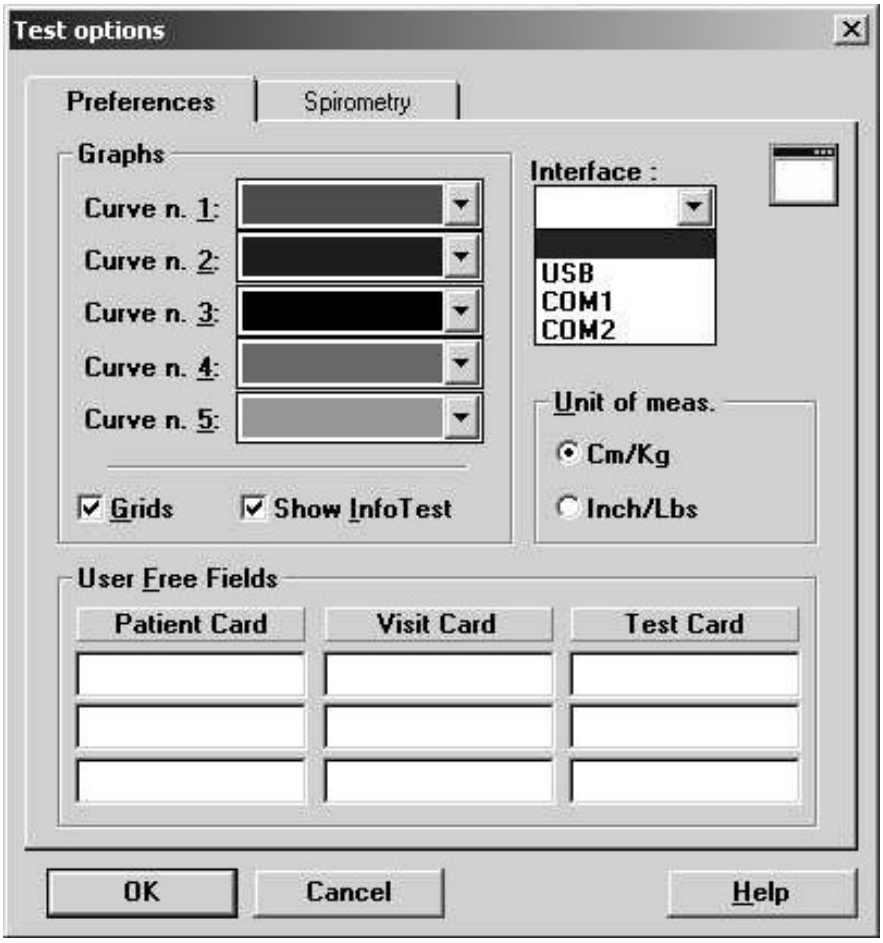
It will be necessary retransmit the firmware from the PC software (selecting, from the Calibration program, the menu item **Calibration/Transmit program…**).

Warning: *All the memory will be erased, and you'll are not able to retrieve any data or program.*

Database Management

Settings

The software allows to configure some options selecting **Configure** from the **Option** menu.



Graphs

All the graphs visualised and/or printed can be customised in colours and appearance.

1. Select the desired colours of the curves (5 curves max can be overlapped on the same graph).
2. Enable or disable the **Grid** option.
3. Enable or disable the **Show Info Test** option.

Interface

The port used for data transfer between Pony FX and the PC.

If the Pony FX is connected through USB, select USB from the list, otherwise select the serial port of the PC to which the unit is connected (COM1, COM2,…).

Units of measurements

It is possible to configure the units of measurements, weight and height, for printing and viewing.

To select the units of measurement click on **cm/Kg** or **in/lb** according to the desired format.

Using extra fields

The Patient's database is organised in 3 different cards (Patient card, Visit Card and Test card.) where it is possible to store the information about patients and visits .

Besides the standard information, it is possible to customise some fields (user free fields), entering and labelling measurements coming from other devices.

The customisable free fields are:

- 3 fields in the Patient Card (Patient's information)
- 3 fields in the Visit Card (information about the visits)
- 3 fields (2 numeric) in the Test card information about Test)

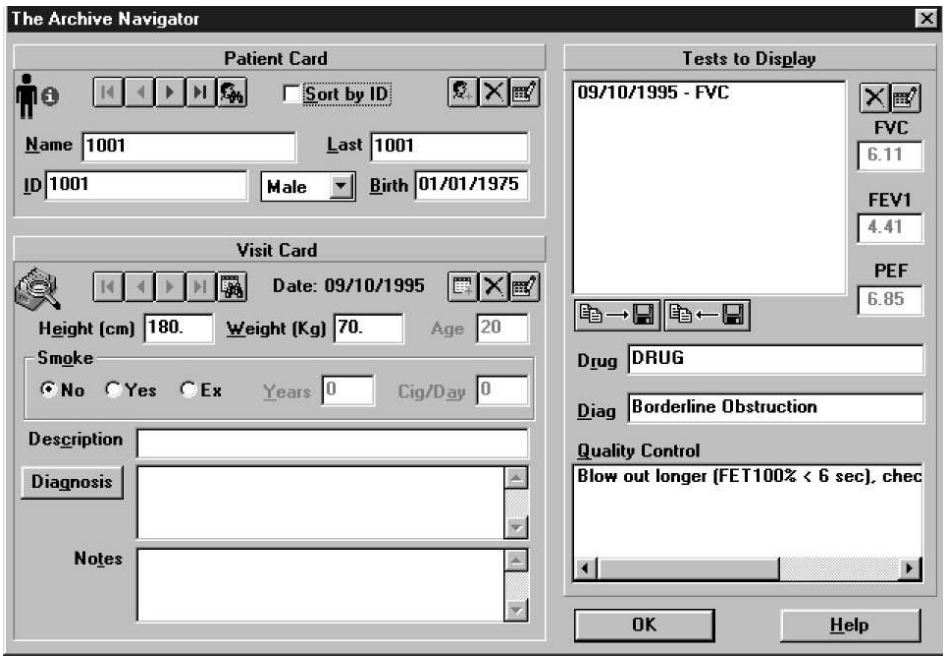
Customise the fields

In the group **User free fields** type the desired text in the 9 fields available.

Patient's database

The Patients database consists of a Patient Card, a Visit Card and a Test Card in which are listed all tests performed by the patient.

Select **Patients…** from the **File** menu or press the button by side.



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***Note**: after having deleted a record (patient, visit or test), it is recommended to reorganize the archive in order to free disk space.*

Patient Card

It collects all the information of a patient (first name, last name, date of birth) which remain the same for each visit. For each patient there is only one Patient Card, which is created the first time the Patient performs a test.

To move within the database use the following buttons:

 Move to the first patient in the archive

 Move to the previous patient in the archive

 Move to the next patient in the archive

 Move to the last patient in the archive

 Find a patient in the archive

 Enter a new patient in the archive

 Delete current patient from the archive

 Edit the current patient card

Visit Card

It collects all information relative to the visit (diagnosis, visit description...) and to the patient information subject to change between one visit and another (height, weight, smoke). Each patient can be related to several Visit Cards provided they have been created in different days. Before carrying out any spirometric test it is necessary to create a new Visit Card or to open the today's Visit Card.

To move within the database use the following buttons:

 Move to the first visit in the archive

 Move to the previous visit in the archive

 Move to the next visit in the archive

 Move to the last visit in the archive

 Find a visit in the archive

 Enter a new visit card in the archive

 Delete current visit card from the archive

 Edit the current visit card

Test Card

It contains all the information about the test.

To move within the database use the following buttons:

 Delete current test from the archive.

 Edit the current test

Import/export a Tests card

This function allows to import /export a test card with the respective visit and patient card.

1. Select the patient.

2. Choose the tests to be exported and press the key by side. All data will be imported/exported in the XPO file format (Cosmed proprietary).

Diagnosis Database

The program allows to manage a diagnosis database, whose records are composed by a diagnosis ID code and a string of text.

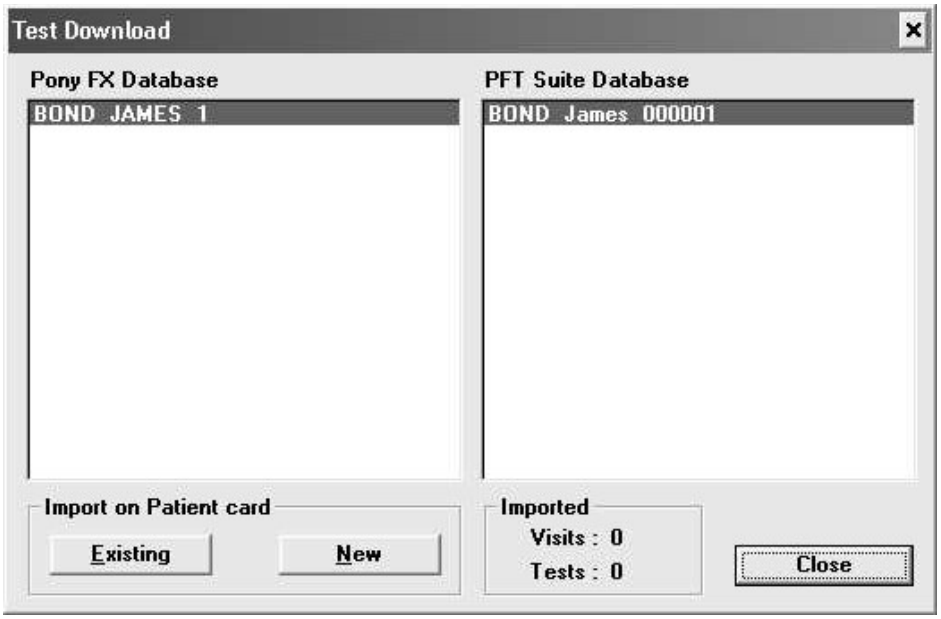
The report of the visits can be done either by typing the desired text in the field “Diagnosis” of the Visit Card or, more quickly, retrieving from the diagnosis database the desired one.

If you want to insert, modify or delete a diagnosis from the database select **Diagnosis Database...** from the **File** menu.

Receiving data from the unit

In order to download the tests performed and stored on the Pony FX unit, please do the following:

1. Connect the unit to the PC (through serial or USB connection, depending on the settings)
2. Select **Receive test…** from the **Test** menu.

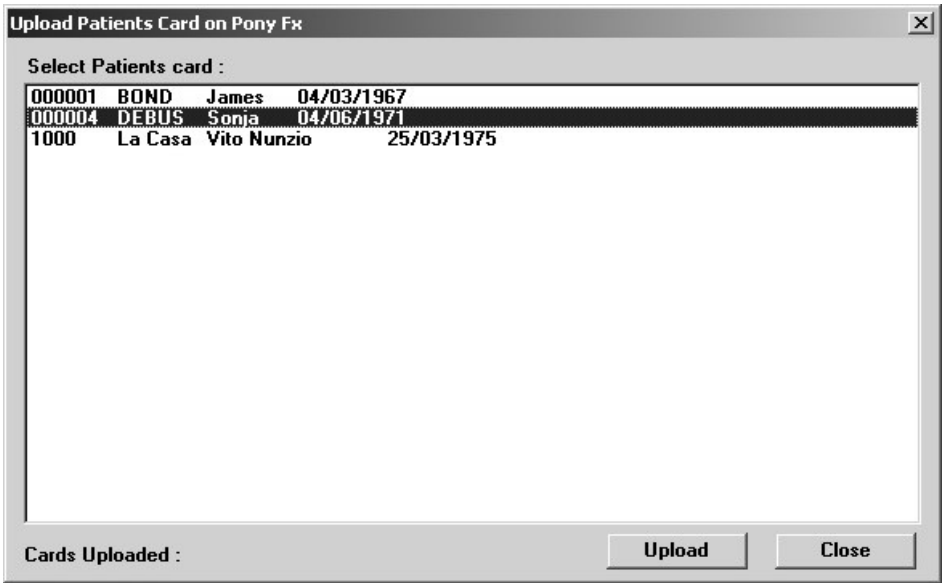


3. In the left side of the window, you have the patient list of the Pony FX archive, in the right side there is a list of the patients in the PC archive.
4. You can link the selected patient tests to a patient already present in the PC archive (**Existing**) or to a new patient (**New**). In this case, it will be created a new patient with the data stored in the Pony FX unit.
5. Press **Existing** or **New** to start the transmission.

Uploading patient cards to the unit

In order to upload patient cards from the PC to the Pony FX unit:

1. Connect the unit to the PC (through serial or USB connection, depending on the settings)
2. Select **Upload patients…** from the **Test** menu.



3. Select the desired patient cards to upload
4. Press **Upload** to start the transmission.

Archive maintenance

The software allows to manage files selecting **Archive** from the **File** menu.

It is advisable to perform the archive reorganisation every month, in order to free space on the hard disk and/or to correct possible errors present within the database.

It is possible also that your have no more hard disk space. So, you have to delete all the data. In this case, it is useful to perform the initialising.

Reorganise the archive

1. Select **Reorganize archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

Delete the archive

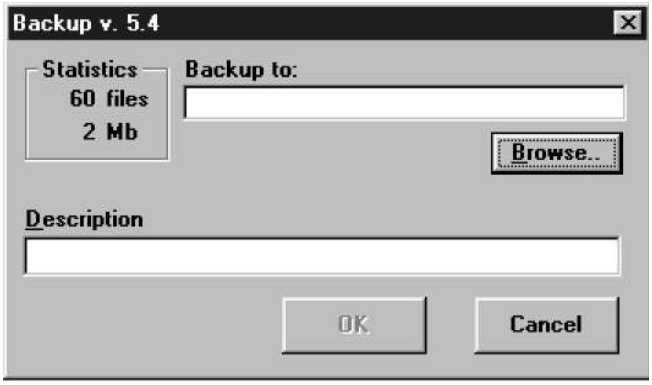
1. Select **Initialize Archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

Backup and restore

It is strongly recommended to backup files, a warning message will be displayed monthly. This function allows the user to restore the data if the PC or the HD will not work anymore.

Backup

1. Select **Backup archive** from the **File** menu.

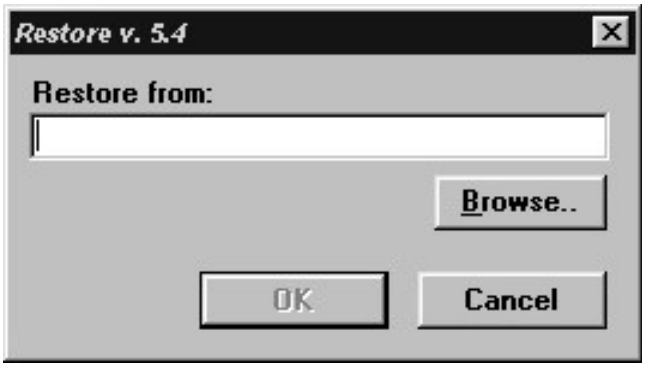


2. Selecting the destination path with the **Browse** key or press **New** to create a new directory. Press **OK** to confirm.

3. In the dialog box it will appear an estimate of the number of floppy you need in order to back up the archives. Press **OK**.

Restore

1. Select **Restore archive** from the **File** menu.



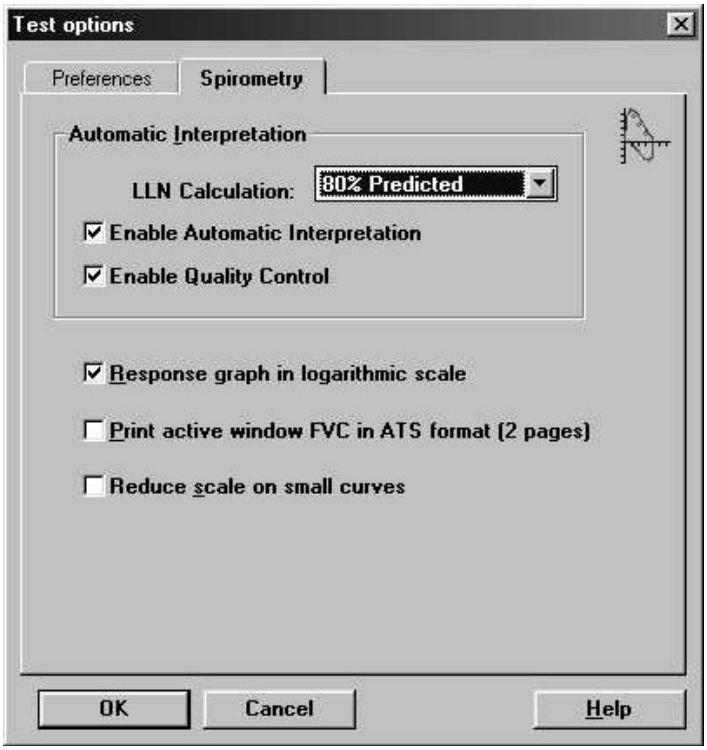
2. On the **Restore** dialog box specify the drive source and press **OK**, a dialog box will appear indicating all data of the backup processed.

Spirometry

Setting spirometry options

The software allows to configure some options selecting **Configure** from the **Option** menu.

Spirometry



Automatic Interpretation

Pony FX has the function of interpreting each test performed by a patient visualising an automatic interpretation. The algorithm has been calculated basing on "Lung Function Testing: selection of reference values and interpretative strategies, A.R.R.D. 144/ 1991:1202-1218". The automatic interpretation is calculated at the end of the FVC if:

- the automatic interpretation option is enabled.
- the patient's anthropometric data allow the calculation of the LLN (Lower Limit of Normal range).
- at least one FVC test has been performed.

To enable/disable the automatic interpretation:

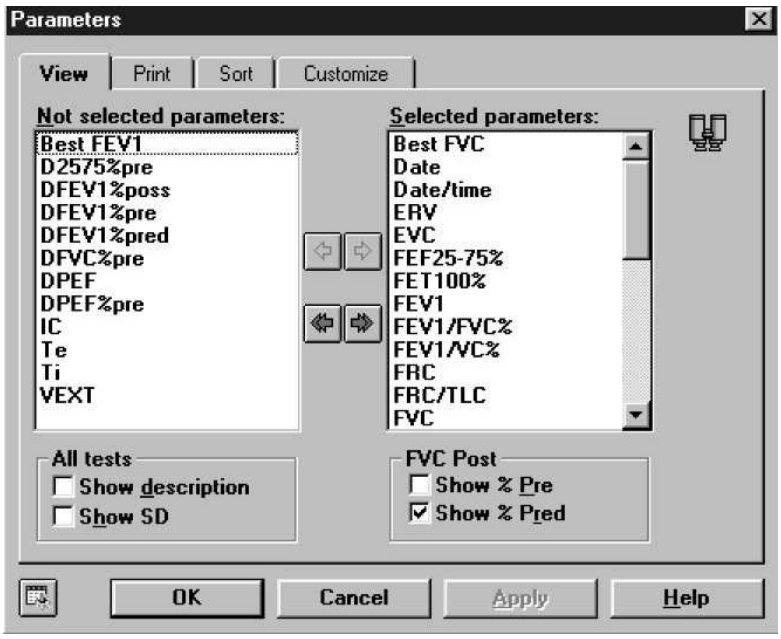
1. Click on **Enable Automatic Interpretation**.
2. Select the LLN (Lower Limit of Normal Range) criteria among the ATS (LLN=Pred-0.674*SD), ERS (LLN=Pred-1.647*SD) or 80%Pred (LLN=Pred*0.8) specifications.

Quality control

Pony FX allows a quality test control. The calculation has been carried out referring to "Spirometry in the Lung Health Study: Methods and Quality Control, A.R.R.D. 1991; 143:1215-1223". The messages concerning the quality control are shown at the end of the test.

To enable/disable the quality control, click on **Enable Quality Control** checkbox.

Parameters manager



The program allows to calculate a huge number of parameters; it is advisable, in order to simplify the analysis of the results, to view, to print and to sort the desired parameters only. Select the menu item **Options/Parameters...**

View

Move the parameters to view into the *Selected parameters* list.

Print

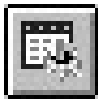
Move the parameters to print into the *Selected parameters* list.

Sort

Drag the parameter up or down with the mouse.

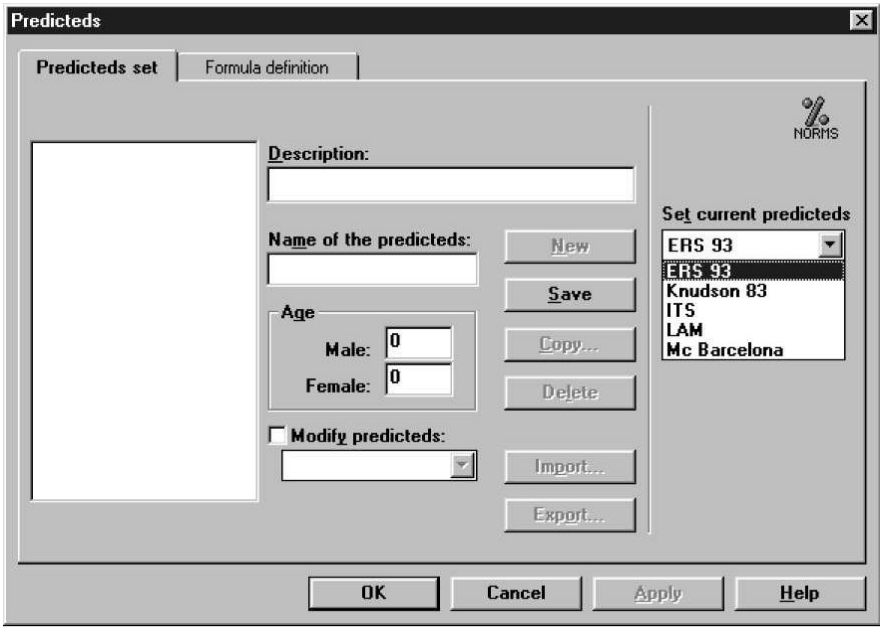
Customise

Add, modify and delete custom parameters.



If it is necessary to restore the default parameters press the button in the left corner of the window to initialise the parameters database.

Predicted values manager



The program contains a preset of predicted equations, but the user is allowed to customise its own predicted sets. Select **Predicteds.**.. from **Options menu.**

The window is divided into two forms: **Predicteds set** and **Formula definition**.

Predicteds set

This form allows the user to manage the set of predicteds. The following information define a set:

Name: identifies the set and cannot be duplicated;

Description: free field;

Age: the adult predicteds start since this age.

To enter a new set of predicteds click on the **New** button. The field **Name** must be filled and must be unique. To stop without saving click on the **Cancel** button. To save the set, click on the **Save** button.

To delete a set of predicteds click on the **Delete** button. If a set is deleted, also the associated formulae are deleted.

It is possible to generate a new set of predicteds with the same attributes and the same formulae of the selected one. To do this click on the **Copy**... button and specify a new Name.

To import a set of predicteds click on the **Import**... button and select a file of Predicteds files type.

To export a set of predicteds click on the **Export**... button.

In the list **Set current predicteds** choose the current predicteds for printing and viewing.

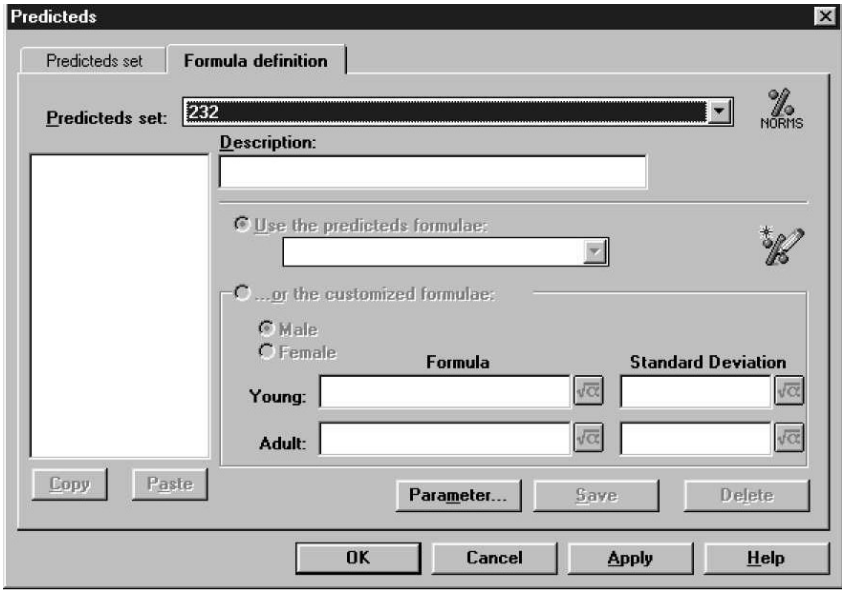
Set the current predicted

Pony FX allows to calculate the predicted values according to the following configurable sets:

Adults	Paediatrics
ERS 93	Zapletal
Knudson83	Knudson83
ITS white	ITS white
ITS black	ITS black
LAM	LAM
MC Barcelona	MC Barcelona
Nhanes III	Nhanes III

Select the desired choice in the group **Predicteds**.

Formula definition



This form allows the user to manage the formulae associated to a set of predicteds.

Select the set of predicteds from the list **Predicteds** set.

To insert a new parameter click on the **New**... button.

The parameter formulae can be:

- calculated according to the predicteds in the list **Use the predicteds formulae**;

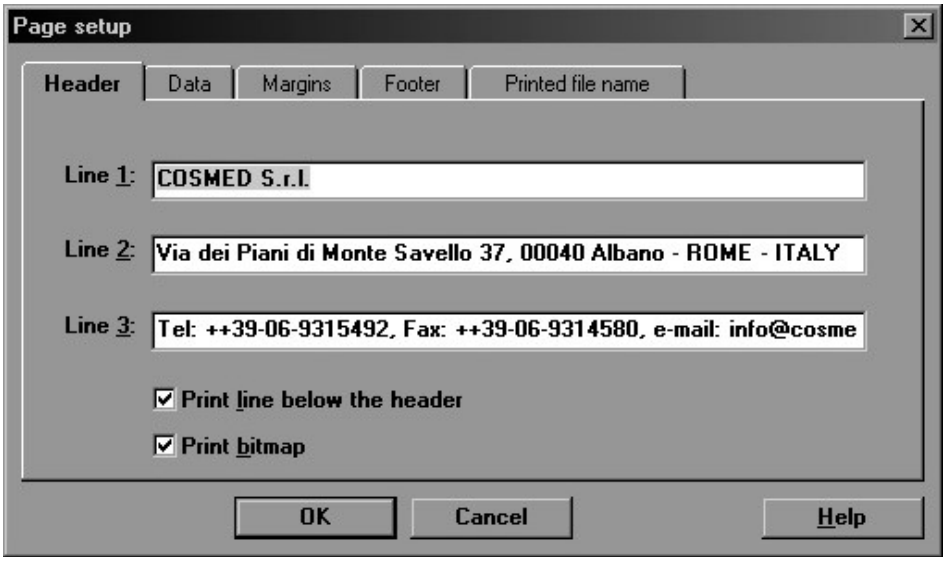
- customised by the user with the option **...or the customised formulae**.

The **Delete** button deletes the selected parameter.

The **Copy** button stores the selected parameter in memory.

The **Paste** button inserts a new parameter from the one copied. If the name is not unique, the user is asked whether to specify a new name or to replace the existing parameter.

Page set-up



Select **Page Setup**... from the **File** menu.

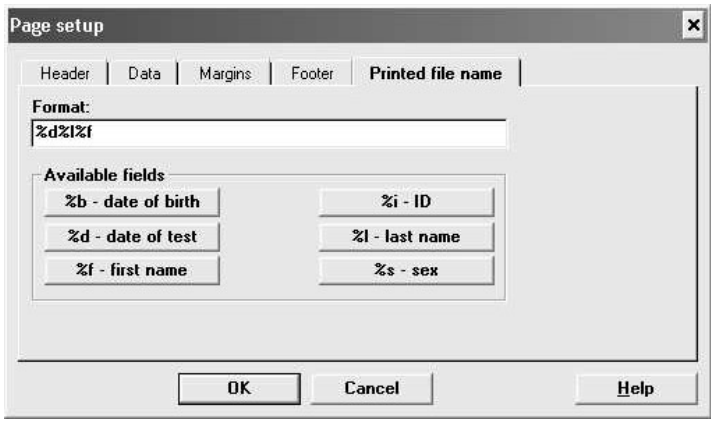
Header — All the printouts carried out by the program are preceded by 3 rows of customisable header (usually they contain the name and the address of the Hospital using the spirometer).

Data — Patient and visit information are printed below the header. These data are reported on 3 columns and 5 rows. the user may configure the disposition, change and eventually cancel the fields, as he prefers.

Margins — Configures the print margins from the borders of the paper. The unit of measure is decided in **Units of measurements**.

Footer — Configures information at the bottom of the page.

Printed file name Defines the automatic name to be asssigned to the pdf file, if the report will be printed in this format.



In the example it has been set to create a filename composed by <date of the test> followed by <last name> and <first name>.

Spirometry tests

Once completed the phases of the introduction of the patient's data and the visit data, it is possible to carry out the spirometric tests.

▲▲▲
***Note**: Read carefully the contraindications in Chapter 1.*

Pony FX allows to perform the following tests:

Key	Test
FVC pre	Forced Vital Capacity
FVC post	Forced Vital Capacity after bronchial stimulation
SVC	Slow Vital Capacity
MVV	Maximum Voluntary Ventilation

Before performing any test make sure that:

1. Pony FX is properly connected to your PC and the selected serial port (COM1, COM2) corresponds to the one effectively use.
2. The name shown on the status bar corresponds to the patient who is to carrying out the tests.
3. The today's visit card exists.

Recommendations for spirometry tests

- The patient should wear the nose clips
- The turbine has been recently calibrated (ATS recommends a daily calibration)
- If you are using the pneumotachograph, do not breathe into the flowmeter, until the proper message appears.
- The paper mouthpiece or the antibacterial filter is properly connected to the flowmeter through the corresponding adapter

For hygienic reasons, we strongly recommend the use of a bacterial filter.

If a kid must perform the test it is recommended to enable the encouragement function which shows exactly the manoeuvre of the FVC test.

Forced Vital Capacity (pre)

FVC is a reference test to verify obstructive (airflow limitations) and restrictive disorders (lung volume limitations). To achieve good test results it is fundamental a good manoeuvre (quality control messages, real time plots …)

The main parameters measured during FVC tests are:

FVC	Forced Vital Capacity
FEV1	Forced Expiratory Volume in 1 second
FEV1/FVC%	FEV1 as a percentage of FVC
PEF	Peak Expiratory Flow
FEF25-75%	Forced mid-Expiratory Flow

The two representative plots are the Flow/Volume and Volume/Time loops.

By comparing FVC, FEV1 and FEV1/FVC% values the software allows an automatic interpretation concerning the levels of obstructive and/or restrictive disorders.

Perform a FVC (pre) test

1. Select **Forced Vital Capacity pre** from the **Test** menu and wait for the green led is prompted on the right side of the screen.

2. Explain the manoeuvre to the patient and press the **F2** key.
3. Wait some seconds and perform the test.

4. After having performed the test, press **F3** or wait for the automatic end (5 seconds without flow), so that the software displays the F/V and V/t graphs, the main parameters, and the predicteds values.
5. In order to visualise the F/V and V/t graph and the main parameters press the following buttons:

view Flow Volume graph

view Volume Time graph

view data of the test

6. Press **Alt+F3** to stop the acquisition discarding the results.
7. Repeat the test until it is correctly performed (ATS recommends 3 times).

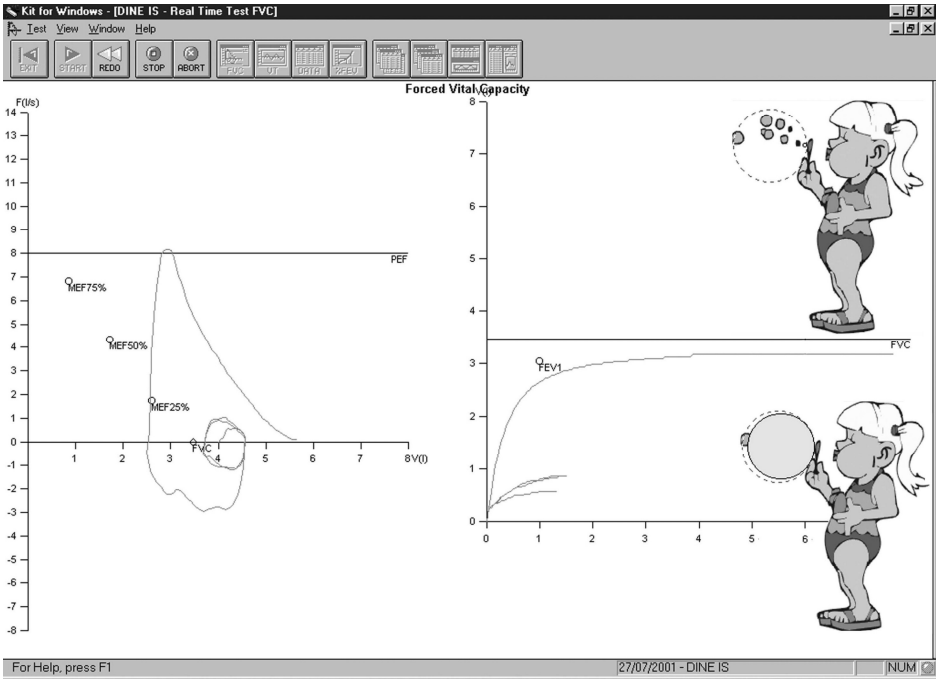
8. Press **Exit** to visualise the test list carried out during current session together with the results of the main parameters.
9. Select the test that you want to save (the Best Test according to the ATS criteria is highlighted as default) and press **OK.**

Test encouragement

During FVC manoeuvre you might experience some lack of collaboration with kids or with other patients. In this case you may find a good help in using the encouragement software tool.

Perform the FVC test with the encouragement

1. Select **Encouragement** from **View** menu.
2. Perform the test as explained in the previous paragraph.



Slow Vital Capacity

Important test for assessing COPD (chronic obstructive pulmonary disease) patients affected by this disease might present a the Slow Vital Capacity could be higher than the Forced one (FVC).

The main parameters measured during SVC tests are:

EVC	Expiratory Slow Vital Capacity
IVC	Inspiratory Slow Vital Capacity
ERV	Expiratory Reserve Volume
IRV	Inspiratory Reserve Volume

If the inspiratory/expiratory maximal manoeuvre is preceded by a some breaths at tidal volume the software allows to measure the Respiratory Pattern, represented by the following parameters:

VE	Ventilation per minute
Vt	Tidal volume
Rf	Respiratory frequency
Ttot	Breath time
Ti/Ttot	Inspiratory time/Ttot
Vt/Ti	Vt/Ti

Perform a SVC test

1. Select **Slow Vital Capacity** from the **Test** menu and wait for the green led is prompted on the right side of the screen.

2. Press **F2** and instruct the Patient to breath normally until the message “carry out…” is prompted; then ask to perform a Slow Vital Capacity (deep inhalation, maximal slow expiration and deep inhalation again).

3. Press **F3** or wait for automatic interruption (5 seconds without flow) in order to visualise the V/t graph together with the main parameters compared to the predicted values

4. To visualise the V/t graph and the main parameters press the follow buttons:

view Volume Time graph

view data of the test

5. Press **Alt+F3** to stop the acquisition discarding the results.

6. Repeat the test until it is correctly performed (ATS recommends 3 times).
7. Press **Exit** to visualise the test list carried out during current session together with the results of the main parameters.
8. Select the test that you want to save (the Best Test according to the ATS criteria is highlighted by default) and press **OK.**

The reference for the ERV calculation is displayed on the V/T graph.

Maximum Voluntary Ventilation

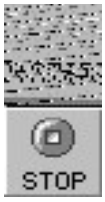
Test for assessing the maximum ventilatory capacity. In the past, it was commonly performed during routine PF tests, however its clinical use declined over the years. Today MVV test is most commonly performed as part of the exercise tolerance tests, where it is used as an index of maximum ventilatory capacity. Test consists in breathing in and out deeply and rapidly for 12, 15 seconds. The expired volume during this short period is then extrapolated

The most important measured parameter is the following:

MVV Maximum Voluntary Ventilation

Perform a MVV test

1. Select **Maximum Voluntary Ventilation** from the **test** menu and wait for the green led is prompted on the right side of the screen.



2. Press **F2** and make the Patient breath as much deeply and rapidly as possible for at least 12 seconds.
3. Press **F3** or wait for automatic interruption (5 seconds without flow) in order to visualise the V/t graph together with the main parameters compared to the predicted values
4. To visualise the V/t graph and the main parameters press the follow buttons:

view Volume Time graph

view data of the test

5. Press **Alt+F3** to stop the acquisition discarding the results.
6. Repeat the test until it is correctly performed (ATS recommends 3 times).

7. Press **Exit** to visualise the test list carried out during current session together with the results of the main parameters.
8. Select the test that you want to save (the Best Test according to the ATS criteria is highlighted as default) and press **OK.**

Bronchial Provocation Test

Bronchodilator test

▲▲▲
***Note**: Read carefully the contraindications in Chapter 1.*

Bronchodilators are administered routinely in the PFT laboratory to determine whether airflow obstruction is reversible. Bronchodilators increase airway calibre by relaxing airway smooth muscle.

The test consists of comparing results between the reference FVC (FVC PRE) and the FVC POST performed after the administration of the drug. Increasing value of 13-15% of FEV1, respect to the basal value (FVC Pre) is considered as a reversible condition.

Main parameters are the following:

DFEV1%pre Change of FEV1 as a percentage of test PRE

DFVC%pre Change of FVC as a percentage of test PRE

DPEF%pre Change of PEF as a percentage of test PRE

Some authors states that the above mentioned parameters are too dependent from the FVC Pre, hence latest reference (ERS93, [A comparison of six different ways of expressing the bronchodilating response in asthma and COPD; reproducibility and dependence of pre bronchodilator FEV1: E. Dompeling, C.P. van Schayck et Al; ERJ 1992, 5, 975-981]) recommend the following parameters:

DFEV1%pred Change of FVC as percentage of predicted value

DFEV1%poss Change of FEV1 as percentage of possible value

Methacholine and Histamine Bronchial provocation Tests

The most common indication for performing methacholine and histamine bronchial challenges is to diagnose hyperresponsive airways. Some patients demonstrate normal baseline pulmonary function despite complaints of “tightness” wheezing, cough, and a little or not response to bronchoconstrictor. Other patients demonstrate spirometric improvement after use of bronchoconstrictor have diurnal variation in peak flows. In this groups aerosolised bronchial challenges are used to confirm a diagnosis of Asthma.

We can summarise the use of the test as follows:

1. Diagnose asthma

2. Confirm a diagnosis of asthma
3. Document the severity of hyperresponsivness
4. Follow changes in hyperresponsivness

When patients with hyperresponsive airways inhale certain pharmacologic agents (i.e. Methacholine or histamine) the airways respond by constricting.

Test consists of executing repeated FVC following the pharmacologic agents inhalation according to an established protocol. The fall of the FEV1 parameter is used to calculate the bronchial hyperresponsivness. The most important parameter is the PD20 that is amount of drug (mg/ml) that causes a reduction of 20% of the FEV1 respect the basal value (without drug).

Main parameters are:

P10 Dose that causes a 10% fall of FEV1.

P15 Dose that causes a 15% fall of FEV1.

P20 Dose that causes a 20% fall of FEV1.

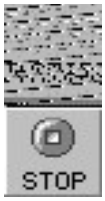
The representative plot is the *Dose/response curve*, showing the percentage variation of FEV1 versus the Drug dose in logarithmic scale.

The program assumes as the **baseline test** the best **FVC pre** carried out during the today's visit. You can change the reference pre test editing the **Post** test.

The name of the drug, its quantity and its unit of measurement, can be typed immediately before any **FVC post** manoeuvre (manual protocol) or can be stored in a database of bronchoprovocation (**File/Bronchial Provocation protocols Database…**).

Perform the test

(During 1st step only) select **Protocol...** from the **Test** menu and choose the name of the bronchoprovocation protocol that you are going to use (**manual protocol** if you want to type the information about the agent before any manoeuvre)



1. Select **FVC post** from the **Test** menu.
2. Select an existing protocol or click on "manual protocol", and wait the green leds turned on.
3. Press **F2**, or the button by side, to start the test.
4. Press **F3**, or the button by side, to achieve the test.

5. In order to visualise the V/t graph and the main parameters press the follow buttons:

view Flow Volume graph

view data of the test

view bronchial provocation response

6. Press **Alt+F3** to stop the acquisition discarding the results.
7. Repeat the test until it is correctly performed (ATS recommends 3 times).

8. Press **Exit** to visualise the test list carried out during current session together with the results of the main parameters.
9. Select the test that you want to save (the Best Test according to the ATS criteria is highlighted as default) and press **OK.**

Bronchial Provocation protocols Database

The response to a bronchoprovocator is usually assessed in terms of change in the FEV1, vital capacity or airways resistance on the basis of serial measurements (FVC manoeuvres) in which the results of the initial test constitute the reference values. The international literature proposes several standardised protocols in order to address the methodological issues of the various available techniques.

The possibility to store a bronchoprovocation protocol in a database is useful to simplify and automate the sequence of operations that the Physician need to execute during the bronchoprovocation tests.

The typical sequence of activities to carry out a bronchoprovocation test are:

1. Typing and storing a bronchoprovocation protocol in the database (usually only once).
2. Selection of protocol among the list of the ones already present in the database before carrying out the FVC post tests (the selection of “manual protocol” allows to execute the test fully manually).
3. Performing the Post tests.

Enter a new Bronchial provocation protocol in the archive

1. Select **Bronchoprov. protocols database** from the **File** menu.
2. Type the Protocol name**,** the Bronchoprovocator name and the unit of measurement in the proper input fields.
3. If the bronchoprovocator has a cumulative effect select the cumulative check button.
4. Enter the quantities for each step and press the button  .

Viewing results

All the visualisation functions refer to the test carried out by the Current Patient, whose name is indicated on the left-side of the status bar.

To view tests results:

1. Select the **Patients** from the **File** menu
2. Select the patient corresponding to the test you want to view.
3. Select in the list box of the tests up to 5 tests of the kind (FVC, VC/IVC, or MVV) and press **OK**.

To switch between graph and or data use the following buttons on the toolbar:

view Flow Volume graph (F5)

view Volume Time graph (F6)

view data of the test (F7)

view bronchial provocation response.

If you need more than one visualisation meantime use the **New Window** function from the **Window** menu.

If you need to display a list of visits:

- Select **Visits list...** from the **File** menu.
- Type the name of the Company and/or the time interval desired or simply confirm for the complete list.

Tests of the current patient

If a **current patient** has been selected you can quickly view his tests selecting **Test current patient...** from the **View** menu.

Delete a test

1. Select **Patients** from the **File** menu or press the button by side.
2. Select the test that you want to eliminate from the list of the tests referred to the Current Patient and press **Delete**.

Printing results

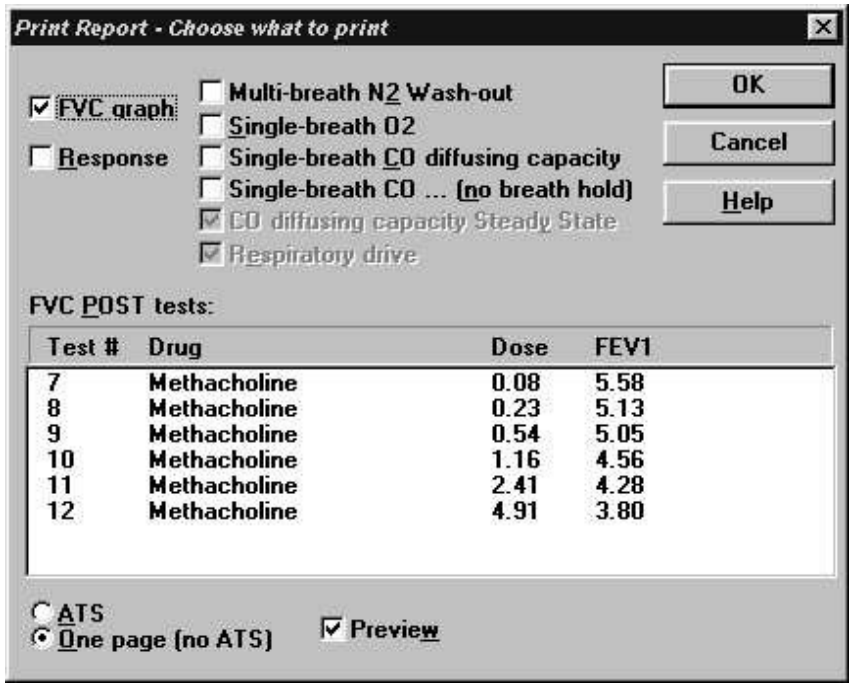
You can print out in three different ways:

- printing the Report
- printing the Active Window
- printing a series of reports

Printing Reports

To print a report of the current visit, select **Print report…** from **File** menu. The software will choose automatically the best performed test.

The standard Report is composed by 1, 2 or 3 pages depending if you wish to printout the FVC data and the graphs together on the first page or if you wish to printout the bronchoprovocation response.



- Selecting the option **One page (no ATS)** the report will contain, on one page, the F/V and V/t graphs of the best test, overlapped on the **FVC Post**, the patient data, the notes, the diagnosis and the test results.
- Otherwise the report will contain two pages, the first with the patient data, the graphs and the diagnosis, and the second one with the measured parameters, according to the ATS recommendations.
- The 3rd page will contain the bronchoprovocation response.

Select the desired options:

FVC graph	Prints the F/V and V/t curves for the best FVC test.
One page (no ATS)	Prints data and graphs on the first page.
Response	Prints the bronchoprovocator response.
FVC post	Prints data and graphs for the Post FVC test (the test can be selected among the test performed in the current visit).
Preview	Views a report preview on the screen.

Printing the active window

This printout function is only enabled when the active window (title bar highlighted) is one of the following objects:

- Any kind of Graph.
- Numeric data
- List of visit

To print the active window select **Print Active window** from **File** menu.

Printing a series of reports

Sometimes it is useful to printout automatically a series of reports (all tests carried out with the employees, all tests carried out in the today's session).

To print out proceed as follows:

1. Select **Visit List** from the **File** menu
2. Set the criteria of the visits to be added in the list (from, to,...)
3. Select **Print Report** from the **File** menu.

Electronic reports (*.pdf)

If an Adobe PDF writer “Printer Driver” is installed and set as the default printer, it is possible to store the printout report automatically in any location of the HD or eventually LAN paths according to a customizable filename format.

It is possible to define the created filename format selecting **File/Page Set up...** (see Page set-up).

Export data

With this function you can export the test data in 4 different formats:

- *.txt (ASCII)
- *.xls (Microsoft Excel)
- *.wk1 (Lotus 123)
- *.xpo (Cosmed)

Export a test

1. Select **Export tests** from the **File** menu**.**
2. Select the test to export from the list box and press **OK**.
3. Type the name and the format of the file in the dialog **Save as**. If the ASCII format is selected, the Text button in the dialog box Save as allows you to configure the separators for character based files.

   With the *.xpo Cosmed file format it is possible to import data from another Quark archive. Press **OK** to confirm.
4. Select the folder for the export and type the file name. Press **OK** to confirm. A status bar will show the file creation.

Airway resistance measurement (option)

The airway resistance measurement test

The measurement of the airway resistance is an important determinant for the assessment of the respiratory system. Traditional methods of measurement are based on body plethysmography which, although highly standardised, require a certain degree of patient's co-operation.

In many cases (critical illness, acute asthma, geriatric and unconscious patients, neonates, pre-school children) this is not possible and different measuring methods are required. Instruments based on the interrupter technique are good alternatives to body plethysmography.

The idea behind the interrupter technique is that alveolar pressure will rapidly equilibrate the pressure at the mouth during a transient airflow interruption. Thus if we provoke an airflow interruption and measure the pressure at the mouth immediately after the interruption, we are able to express the airway resistance as the ratio between the pressure at the mouth (identical to alveolar one) and the value of the flow before the interruption.

The Appendix reports bibliographic references, which demonstrate a high reproducibility and correlation between the values so measured and those measured by body plethysmography.

The measured parameters are the following:

R_{occ_ex} Expiratory resistance

G_{occ_ex} Expiratory conductance

R_{occ_in} Inspiratory resistance

G_{occ_in} Inspiratory conductance

Performing the test without the PC

After having connected the module to the unit (see *Installation* chapter):

1. Select **2.Option/8.Rocc**
2. Set the test options
   - Random (automatic) or manual occlusion
   - Occlusion activated on the inspiration or expiration
   - Value of the flow at which the occlusion is activated
   - Use of COSMED antibacterial filter

- Parameters for the back-extrapolation algorithm.

3. Select the patient
4. Select **1.Test/8.Rocc PRE** or **1.Test/9.Rocc POST**
5. Wait for the end of the calibration.
6. Let the patient to breathe inside the module.
7. If *manual occlusion* is selected, press **1.Manual** each time you desire to activate an occlusion.
8. After each occlusion, you are asked if accept or discard the result.

9. End the test by pressing the key by side.

10. Press the key by side to stop the acquisition discarding the results.

Performing the test with the PC

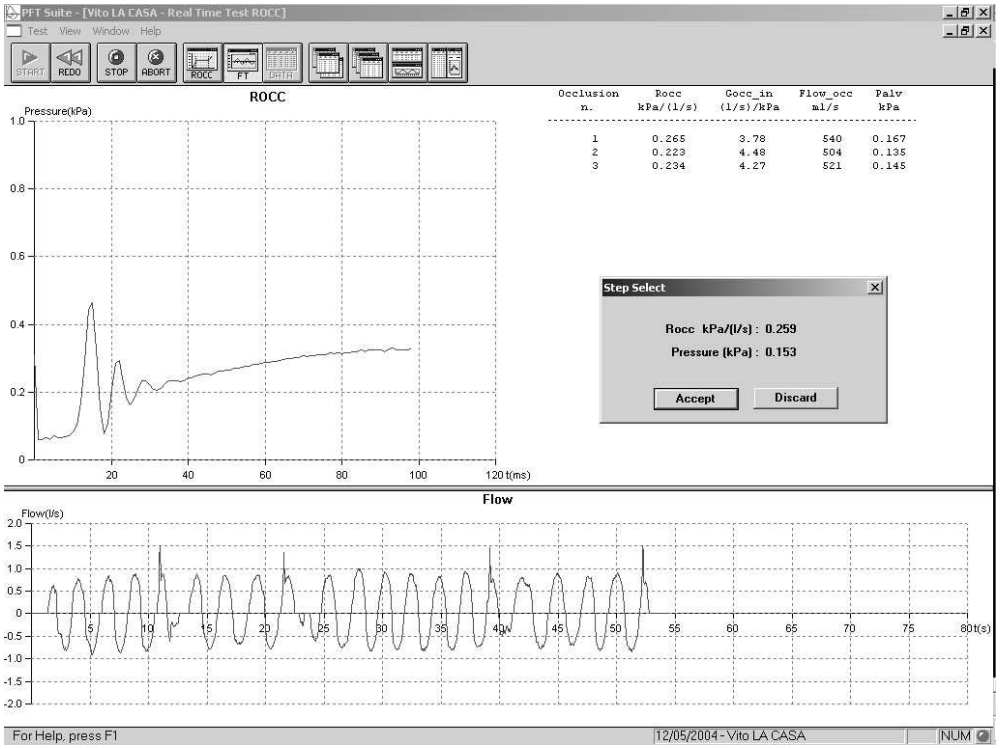
After having connected the module to the unit (see *Installation* chapter):

1. Select **Rocc** from the **Test** menu.
2. The *Test option* window will open

   By means of this window you can set the following options:

   - Random (automatic) or manual occlusion
   - Occlusion activated on the inspiration or expiration
   - Value of the flow at which the occlusion is activated
   - Use of COSMED antibacterial filter
   - Parameters for the back-extrapolation algorithm.

3. Wait for the end of the calibration.
4. Let the patient to breathe inside the module.
5. If *manual occlusion* is selected, press **F2** each time you desire to activate an occlusion.
6. After each occlusion, you are asked if accept or discard the result.

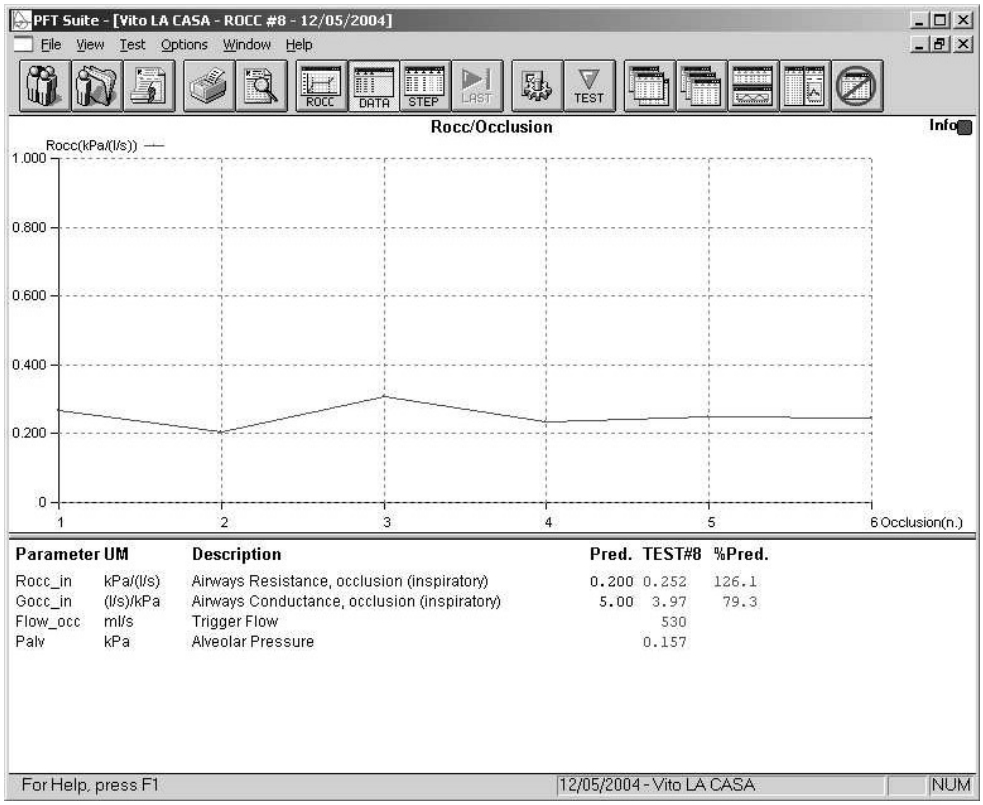


7. End the test by pressing **F3** or the button by side.
8. In order to view the graphs or the main parameters, press the following buttons:

view the R_{OCC} graph

view an average of the measured parameters

view all the performed steps



9. Press **Alt+F3** or the button by side to stop the acquisition discarding the results.

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 Pony FX 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 disinfection

Cleaning and disinfecting instructions are of fundamental importance to control infections and assure patient safety. In fact aspiration of residue, particles and contaminated agents are life – threatening.

In this handbook we strongly recommend you to follow the rules worked out by ATS and ERS (see: ”Lung Volume Equipment and Infection Control” – ERS/ATS WORKSHOP REPORT SERIES, European Respiratory Journal 1997; 10: 1928 – 1932), which are summarised as follows:

- Accessible internal as well as external surfaces of equipment exposed to expired gas should be washed and disinfected prior to testing of subsequent patients.
- Liquid disinfection can be used if the equipment is well cleaned first (no droplets of saliva/sputum remain).
- Disposable gloves should be worn when handling mouthpieces, when cleaning equipment exposed to saliva or sputum and especially when drawing blood.
- Laboratory staff should wash hands prior to testing of each patient.
- Adopt particular precautions when testing patients with recognised high - risk communicable diseases (e.g. tuberculosis, multidrug - resistant staphylococcus). In these cases, the clinical need for such testing should justify the risks.

During the disinfection:

- do not use alcohol or other liquids containing gluteraldehyde on the exterior surfaces of the equipment. Actually they can damage polycarbonates plastics and may produce unhealthy substances.
- do not use abrasive powders or glass cleaners containing alcohol or ammonia on the plexiglas components of the equipment
- do not steam autoclave any parts of the equipment unless it is clearly specified.
- do not immerse the optoelectronic reader.

Preparing the disinfecting solution

The following recommendations are retrieved from:

APIC (Association for Professionals in Infection Control and Epidemiology, Inc.): APIC Guidelines for Selection and Use of Disinfectants; William A. Rutala, PhD, MPH, CIC. American Journal of Infection Control, vol.24, N.4, pp. 313-342, August 1996 - http://www.apic.org/pdf/gddisinf.pdf

As disinfecting solution it is suggested:

- 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 easily prepared by adding 1 part household bleach (sodium hypochlorite 5.25%) to 9 parts water, the second one by adding 1 part household bleach to 4 parts water.

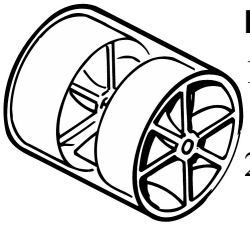
▲▲▲
Warning: *Do not use alcoholic solutions for the turbine, otherwise there can be damages to the plastic material.*

Cleaning the turbine flowmeter

It is necessary to disinfect periodically the turbine for sanitary measures or/and for the correct device function.

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. Let it dry to air.

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 during the cleaning of the turbine

1. Do not expose the turbine to high heat and do not put it under running water.
2. Do not ever dip the optoelectronic reader in any kind of solution, the liquid infiltration would damage the internal circuit.
3. Do not use alcoholic solutions to clean the turbine.

Suggested disinfection solutions

Helipur H Plus	Braun Melsungen AG
Gigasept FF	Schulke & Mayr GmbH
Dismozon pur	Bode Chemie GmbH
TETA-S	Fresenius AG
CIDEX	Johnson & Johnson

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

Service - Warranty

Warranty and limitation of liability

COSMED provides a one (1) year limited warranty from the date of the original sale of COSMED products. All COSMED products are guaranteed to be free from defect upon shipment. COSMED's liability for products covered by this warranty is limited exclusively to replacement, repair, or issuance of a credit for the cost of a defective product, at the sole discretion of COSMED. COSMED shall not be liable under the foregoing warranty unless (i) COSMED is promptly notified in writing by Buyer upon discovery of defect; (ii) the defective product is returned to COSMED, transportation charges prepaid by Buyer, (iii) the defective product is received by COSMED no later than four weeks after the last day of the one (1) year limited warranty period; and (iv) COSMED's examination of the defective product establishes, to COSMED's exclusive satisfaction, that such defect was not caused by misuse, neglect, improper installation, unauthorised repair or alteration, or accident. If the product is manufactured by a third-party, COSMED shall make available for the Buyer's benefit only those warranties which COSMED has received from the third-party manufacturer(s). COSMED hereby specifically disclaims any and all warranties and/or liabilities arising from defect(s) and/or damage(s) to and/or caused by products manufactured by third-party manufacturers. Buyer must obtain written authorisation from COSMED prior to the repair or alteration of COSMED products(s). Failure of Buyer to obtain such written authorisation shall void this warranty.

COSMED hereby specifically disclaims any and all other warranties of any kind, whether express or implied, in fact or by law, including, but without limitation, any and all warranties of merchantability and/or fitness for a particular purpose.

COSMED shall not be liable for special, indirect and/or consequential damages, nor for damages of any kind arising from the use of any COSMED's products, whether said products are used alone or in combination with other products or substances.

Determination of the suitability of any of COSMED's product(s) furnished hereunder for the use contemplated by Buyer is the sole risk and responsibility of Buyer, and COSMED has no responsibility in connection therewith. Buyer assumes all risks

and liabilities for loss, damage or injury to persons or property of Buyer or others arising out of the use or possession of COSMED's products.

The limited warranty as herein above set forth shall not be enlarged, diminished, modified or affected by, and no obligation or liability shall arise or grow out of, the renderings of technical advice or service by COSMED, its agents or employees in connection with Buyer's order or use of the product(s) furnished hereunder.

Return goods policy for warranty or non warranty repair

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

1. Goods may only be returned after your receipt of a **Service Return Number (SRN)** from COSMED S.r.l.
2. Place your SRN report and Packing List outside the package.
3. Goods returned must be shipped with freight and insurance charges prepaid. **Collect shipments will not be accepted**.
4. The following list of goods are not eligible for return unless proven defective.
   - Special order items
   - Expendable products
   - Goods held over 30 days from COSMED's invoice date.
   - Used goods not in 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 use of the device not conforming to the indication reported in this manual

Repair Service Policy

Goods returned to seller for Non-Warranty repair will be subject to conditions 1, 2, 3, 4.

The returned goods need to re-enter COSMED together with the customs documents (Pro-forma Invoice and Customs Paper) as requested by the Italian law.

- The shipment has to be qualified as a Temporary Export.

- All the goods returned to COSMED without the customs papers will not be accepted.

For European Community members:

Pro-Forma invoice complete with:

- Number
- Description of the goods
- Quantity
- Serial Number
- Value in €
- Number of parcel
- Gross weight
- Net weight
- Reason for resent (i.e. Resent for repair)

In case you should send the system for repair please contact the nearest service centre or contact COSMED at the following address:

COSMED S.r.l.

Via dei Piani di Monte Savello 37
P.O. Box 3
00040 Pavona di Albano - Rome, Italy
tel. +39 (06) 9315492
fax +39 (06) 9314580
E-mail: customersupport@cosmed.it

For USA customers only please contact:

COSMED USA Inc

2758 North Paulina
Chicago IL 60614 USA
Phone: +1 (773) 528-8113
Fax: +1 (773) 528-8116
email: usa.sales@cosmed.it

To ensure that you receive efficient technical assistance, please specify as precisely as possible the nature of the problem as it is specified on the assistance information form.

We advise you to save the original packaging. You may need it in case to ship the unit to a technical assistance centre.

Privacy Information

Dear Customer,

we inform you that your personal data are 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 know how we treat your personal data.

Personal data treatment and purposes

We request and process your personal data:

a. to place an order, register a product, request a service, answer a survey, enter a contest, correspond with us (all of the above, in the following: "service") and, if necessary, to supply the Competent Authorities with the required information;

b. in order to define your commercial profile;

c. in order to use your commercial profile for own marketing and advertising purposes;

d. for accounting purposes, including e-mailing of commercial invoices;

e. for providing your information to selected business partners (also abroad), in order to supply the service;

How your personal data are treated

Your personal data will be stored in electronic format, and protected at the best from destruction, loss (even accidental), not authorized accesses, not allowed treatment or use not in conformity with the purposes above listed.

The consent is optional, but...

If you deny the consent, we regret we cannot supply the service.

Holder of the treatment

The holder of the treatment is Cosmed Srl, Via dei Piani di Monte Savello 37, Pavona di Albano Laziale (RM). The responsible of the personal data treatment is indicated in the documentation stored by Cosmed Srl itself.

Customer rights

In accordance with art.7 of the Law, you can:

a. obtain confirmation of the existence of your personal data and their communication in intelligible form;

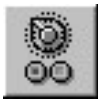
b. obtain:

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

c. deny your consent to the treatment of your personal data;

These rights can be exercised directly requesting in writing to the holder of the treatment.

Converting factors configuration



You can edit the parameters shown in Control Panel by selecting **Control Panel** from the **Calibration** menu in the calibration program, then pressing the button by side.

You might configure the following options:

Name: identify the parameter

Unit of meas..: unit of measurement

Base line and Gain: factors used to convert the acquired raw data (mV) into the final format according to **Y=(mV-BL)*Gain**. The value entered for gain must be multiplied by 1000 (for Gain=1, enter 1000).

Precision: the number of decimals shown as **0**

ATS 94 recommendations

Reference: “Standardization of Spirometry: 1994 Update” “American J. Respiratory Critical Care Medicine”, Vol. 152, 1107-1136; 1995.

ATS recommendations

Volume range:	8l (BTPS)
Flow range:	±14 l/sec
Volume accuracy:	±3% or < 50ml
Flow accuracy:	±5% or < 200ml/sec
Flowmeter resistance:	<1.5 cmH2O da 0 a 14 l/sec

Reproducibility: the 2 largest of 3 acceptable FEV1 and FVC values should be within 5% or 150 ml.

The end of test: no change in volume for 1 second with at least 6 seconds of collected volume.

Accumulation time: the maximum time allowed for volume accumulation during the VC manoeuvre should be at least 30 seconds and at least 15 seconds during the FVC.

The spirometer should be store at least 8 FVC maneuvres.

FEV1 should be calculated by using the “back extrapolation” method to detect the start of the test, extrapolated volume must not be higher then 5% FVC or 150ml.

The graphic resolution of the printed report must be as in the following:

Volume:	10 mm/l
Flow:	5 mm/l/sec
Time:	20 mm/sec
F/V ratio:	2:1

The total number of error (FVC e FEV1 >±3.5%, FEF25-75% >5.5%) during the measurement of the 24 standard waveforms must be lower than 4.

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.

KNUDSON 83

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

DLCO

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.

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

Single Breath Oxygen Test

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

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

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

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 interpretation (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)

Note: *This interpretation is only a suggestion that must be supported by clinical judgement.*

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

Restrictive abn.: severe	% Pred FVC < 50 and >= 34
Restrictive abn.: 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

References

ATS '94: "Standardization of Spirometry: 1994 Update", American J. Respiratory Critical Care Medicine, Vol. 152, 1107-1136; 1995

ERS '93: "Standardized Lung Function Testing: Official Statement of the European Respiratory Society", The European Respiratory Journal Volume 6, Supplement 16, March "

"Standardization of Spirometry: 1987 Update", American Review of Respiratory Disease, Vol. 136, 1285-1289; 1987

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

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

"Office spirometry", R.E. Hyatt - P.L. Enright, Lea & Febiger

CERTIFICATE

Reg. Number	387 - M	Valid From	2021-04-15
First issue date	2006-10-13	Last change date	2021-04-15
Valid until	2024-04-24		

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 with own brand of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism.
Marketing of equipment and accessories for the analysis and evaluation of the cardiorespiratory system, for the measurement of metabolism, body composition and rehabilitation

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.

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
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.kiwa.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

CERTIFICATE

Reg. Number	387 - A	Valid From	2021-04-15
First issue date	1997-12-10	Last change date	2021-04-15
Valid Until	2024-04-24	IAF Sector	19 , 29
Previous expiry date			

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 with own brand of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism.
Marketing of equipment and accessories for the analysis and evaluation of the cardiorespiratory system, for the measurement of metabolism, body composition and rehabilitation

Chief Operating Officer
Giampiero Belcredi

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

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 9811	Revisione / *Revision*	17
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*	2021-05-17

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

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:17/05/2021 11:42:22

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

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 1301

Marca / *Brandname:*
COSMED

Modello / Model:
Flow Ree

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1301, MDS 7010

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

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi e accessori per la valutazione della funzione respiratoria, cardiaca e metabolica / *Devices and accessories 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:
Q-i2m

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

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Chief Operating Officer
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Data:17/05/2021 11:43:02

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 9811	Revisione / *Revision*	17
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*	2021-05-17

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

Marca / *Brandname:*
COSMED

Modello / Model:
Spiropalm 6MWT

Modello / Model:
Spiropalm Plus

Modello / Model:
Fitmate Med

Modello / Model:
K5

Modello / Model:
Q-NRG; Q-NRG+

Modello / Model:
Quark CPET

Modello / Model:
Quark PFT

Modello / Model:
Quark PFT ergo

Modello / Model:
Quark PFT2ergo

Modello / Model:
Quark PFT4ergo

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:17/05/2021 11:43:24

Organismo Notificato n. 0476
Notified Body nr. 0476

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Reg. Numero / *Reg. Number*	MED 9811	Revisione / *Revision*	17
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Scadenza / *Valid until*	2023-04-24	Ultima modifica / *Last change date*	2021-05-17

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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.*

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Chief Operating Officer
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Data:17/05/2021 11:43:47

Organismo Notificato n. 0476
Notified Body nr. 0476

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

COSMED 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/sec@14 L/sec)[3] both during inhalation and exhalation.

COSMED 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.

COSMED 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.

COSMED©
The Metabolic Company

COSMED 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.

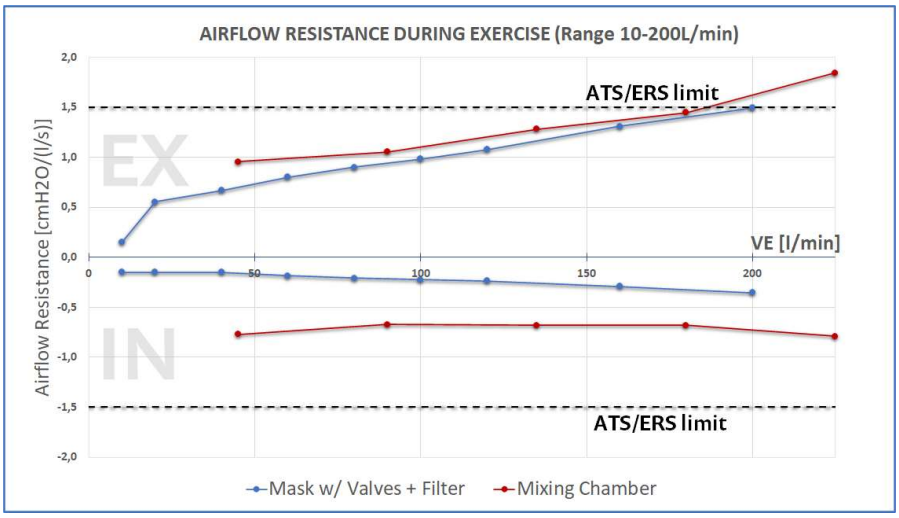
The validation protocol compares the results against a conventional mixing chamber metabolic cart and ATS/ERS maximal acceptable resistance for lung function testing equipment.

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

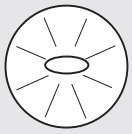
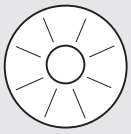
The additional dead space introduced by the new setups, does not affect VO_2 or VCO_2 calculation.

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

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