Foreword

Important notices

Intended use

Pony graphic 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.

This equipment has been conceived to be used as an auxiliary instrument in order to:

- formulate lung pathology diagnosis;
- perform studies concerning human physiology;
- get information in sport medicine.

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

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

Warnings

The device, the programme 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 manual Appendix.

The present handbook has been developed following the 93/42 CEE requirements, according to which Pony graphic is to be considered Class IIa device.

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 if:

- are used the accessories described in the manual or given with the device. Actually non recommended accessories can affect safety unfavourable. Before using non recommended accessories 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.

3. This device is not suitable for use in presence of flammable anesthetics. It is not an AP nor an APG device (according to the EN 60 601-1 definitions).
4. Keep the device away from heat and flame source, flammable or inflammable liquids or gases and explosive atmospheres.
5. We recommend to use only the provided battery charger (P/N C00766-0X-30). Any other charger could damage the device.
6. According to the intended use of this device, Pony graphic is not to be used together with other medical devices unless it is clearly declared by the manufacturer itself.
7. In case the device is to be used with a PC, is recommended to use a computer with electromagnetic compatibility CE marking and with low radiation emission displays.
8. It is necessary to make the PC, connected to the Pony graphic, compliants with EEN 60601-1 by mean of an isolation trasformer.

9. Graphical symbols used in accordance to present specifications are described here below:


Equipment type B (EN60601-1)


Danger: high temperature


OFF

ON


Protective Earth Ground


Alternating Current

Contraindication

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 no-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 3 mouth.

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. Predicted value FEV1 less than 1.51 in men and predicted value FEV1 in women less than 1.21.
- Recent infection in the superior air tracts
- During the asthmatic re- acuting
- Hypertension
- Pregnancy
- A pharmacology treatment epilepsy

Checking the packing contents

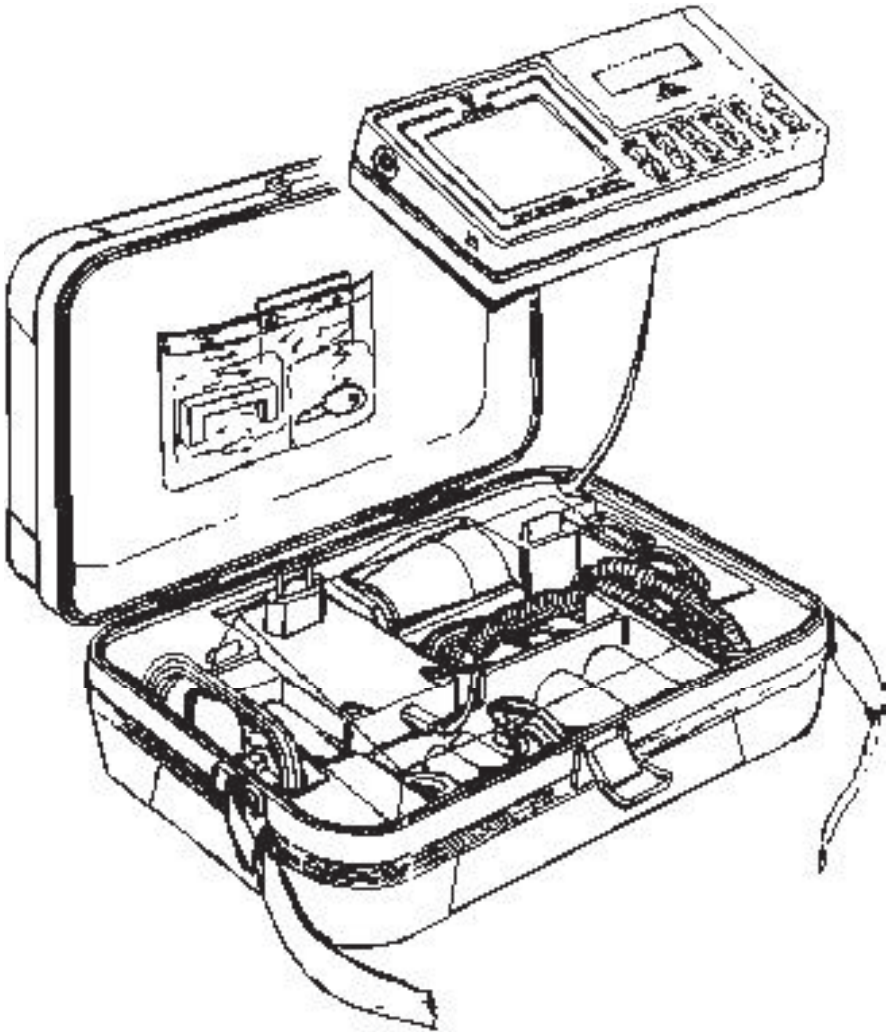
The Pony graphic is composed by a Main unit and by some other accessories.

Make sure that the packing box contains the instruments listed below. In case of missing or damaged parts, please contact your nearest COSMED technical assistance.

Pony Graphic standard equipment

The Pony graphic contains the following instruments:

Description	Part number	Quantity
Turbine L89	C00292-01-05	1
Optoelectronic reader	C00095-01-05	1
Mouthpiece adapter for children	C00214-01-20	1
Carrying case	C00109-01-30	1
Paper mouthpiece for adults	C00136-01-20	50
Paper mouthpiece for children	C00137-01-20	50
Nose clips	A662100001	2
Roll of paper	C00643-01-98	2
Printer ribbon	A 666 905 001	2
Power supply 220V 12V 1A	C00766-01-30	1
Batteries charger adapter in car	C00297-01-12	1
Serial cable RS232	C00150-01-12	1
SW_PC Win Pony Graphic	C01335-02-35	1
User manual	C00296-02-91	1
Registration card	C00067-02-94	1
Turbine attention paper	C00169-01-92	



Warranty registration

Before operating the system, please fill in the registration form and send it to COSMED.

To be registered means being entitled to customer's assistance.

For further information concerning the benefits, please refer to the registration form.

Contacting COSMED

For further information you may contact the manufacturer directly 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: +39-06-93.15.492

fax: +39-06-93.14.580

E-mail: info@cosmed.it

Internet: www.cosmed.it/support

Safety and conformity

Safety

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

Below is reported the complete classification of the device:

- Class II B device if used with specified power supply or internally powered equipment class B device if used stand alone.
- Protection against water penetration: IP00, ordinary equipment unprotected against water penetration
- Non sterile device
- Device not suitable in the presence of flammable anesthetics;
- Continuos functioning equipment;

EMC

The system meets the EMC Directive 89/336

EN 60601-1-2

EN 55011 Class B (emission)
IEC 1000-4-2 (1991, immunity ESD): 4KV CD, 8 KV AD
IEC 1000-4-3 (1984, immunity fields EM): 3 V/m
IEC 1000-4-4 (1988, immunity Burst): 1 KV

Quality Assurance

UNI ISO EN 9001 (Registration n° 387 Cermet)

Medical Device Directive (CE mark)

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

Environmental condition of utilization

COSMED units have been conceived for operating in medically utilized 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.

Notice: *if accidentally droppings, exposure to heat source and excessive humidity may compromise the validity of the system, we recommend you a calibration check or ask for a technical assistance.*

Conventions

Here are the conventions used for its draft.

Typographic conventions

The following typographic conventions are used in this manual:

Type	Represents
Bold	It indicates an item to be selected or a key to be pressed, in this last opportunity the beginner letter is always a capital letter.
"italic"	It indicates, if it is in inverted commas", the message showed on the Pony display.

Graphic conventions

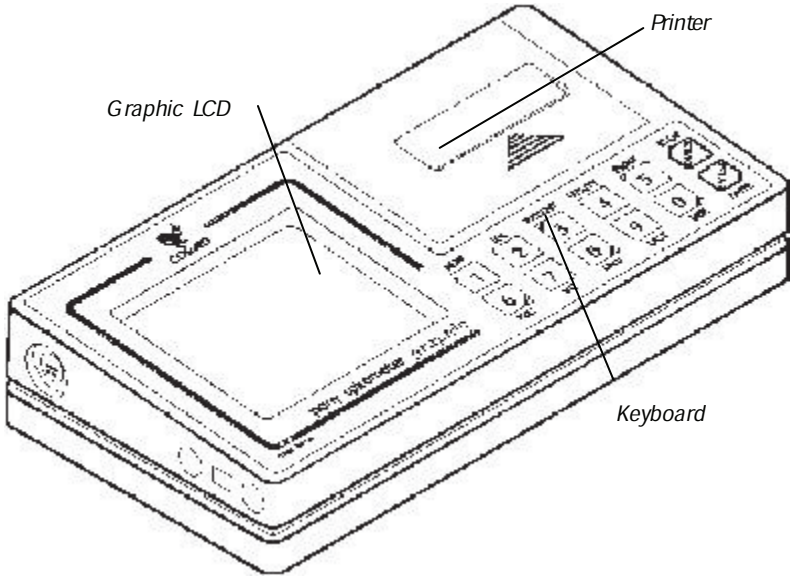
The following Graphic conventions are used in this manual:

Symbol	Description
Key	It represents the key to be pressed to execute the predicted function.
Display	It represents prompts and messages on the Pony display during the execution of corresponding functions.

Features

Pony graphic, which is represented in the figure below, is a spirometric system to evaluate static and dynamic lung functionality.

Pony graphic allows to download data to a PC through a serial RS232 connection.



New features

Graphic display

The wide display allows to show in real time the flow/volume loop during the Forced Vital Capacity manoeuvre and the volume/time loop during Slow Vital Capacity and Maximum Voluntary Ventilation manoeuvre. The back-lighting gives a better visibility even in conditions of poor lighting.

Turbine

Due to new helicoidal conveyers, it offers very low resistance to the flow (< 0.7 cmH2O/l/s at 12 l/s of flow).

Printer

The new High speed Epson printer (2.5 lin/s). Pony graphic provides a complete print out report in few seconds. Pony graphic enables to print a wide print out meeting the ATS 1987 requirements through an external printer. This feature is compatible with printers having HP PCL3 printer language and with a serial port.

Test management

It is possible to display and print out tests stored in the archive even afterwards.

Bronchial provocation response

With the Pony graphic it is possible to display and print out the fall of FEV1 at the end of each Post test choosing **Fall Fev1** command at the end of every FVC post.

Predicted values

By means of the Predicted command of the Configuration menu it is possible to select the following predicted values:

Adults	Paediatric
ERS 93	Zapletal
ITS	ITS
Knudson 83	Knudson83
MC Barcelona	MC Barcelona
LAM	LAM

Calibration

The calibration process is completely managed by the keyboard.

Automatic diagnosis

The automatic diagnosis can now be enabled or disabled by user.

Supply

The new Ni-Cd batteries (without memory effect) and rapid batteries charger allow to use the Pony graphic even during the batteries charging.

Accessories

Here following the list of the main accessories consumables for Pony graphic.

Accessories/consumables

Description	Part Number
Calibration syringe (3 litres)	C00600-01-11
Paper mouthpiece for children (500pcs)	C01814-01-98
Paper mouthpiece for adults (500pcs)	C01805-01-98
Roll of paper (10pcs)	C00643-01-98
Printer ribbon (5 pcs)	A666 905 001
Nose clips (5 pcs)	C00441-01-98

Technical Features

Features	Value
Flow meter	Digital bidirectional turbine
Flow range	0.03 - 20 l/s
Volume range	10 l
Accuracy F/V	± 3% or ± 50 ml
Dynamic res at 12 l/s	< 0.7 cm H2O/l/s
Mouthpieces	Ø 31 and 22 mm
Graphic display	Back lighting LCD 70x80 mm
Printer	Graphic, 24 char/lin, 2,5 lines/s
Keyboard	12 multifunction keys
Serial cable	RS 232 bidirectional 4800 baud.
Power supply	Batteries Ni-Cd 5V, 1,2 Ah
Battery autonomy	200 tests including prints out
Battery charge	12V dc - 1,2 A
Dimensions	237x127x46 mm
Weight	1,2 kg

PC configuration required

- Pentium 133 MMz.
- Windows 95, 98, NT.
- 16 Mb RAM .

- 3.5 drive.
- VGA, SVGA monitor.
- Serial Port RS 232 available (two serial ports available in case of Ergometer control).
- Any Mouse and Printer compatible with the MS Windows™ operative system.
- PC conform to European Directive 89/336 EMC

List of parameters calculated

FVC - Forced Vital Capacity

Symbols	um	Parameter
FVC	l	Forced Vital Capacity
Best FVC	l	Best Forced Vital Capacity
FEV1	l	Volume exhaled after 1s of the FVC
PEF	l/s	Peak Expiratory Flow
PIF	l/s	Peak Inspiratory Flow
Vmax 25%	l/s	Expiratory flow at 25% of FVC
Vmax 50%	l/s	Expiratory flow at 50% of FVC
Vmax 75%	l/s	Expiratory flow at 75% of FVC
FEF25-75%	l/s	Average expiratory flow between 25% and 75% of FVC
FEV1/FVC%	%	FEV1/FVC x 100
FET 100 %	s	Forced expiration time (100% FV)
VEXT	ml	Extrapolated Volume (back extrapolation)

VC- IVC Slow Vital Capacity and Ventilatory pattern

Symbols	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/m	Expiratory Minute ventilation
Vt	l	Tidal Volume
Rf	resp/min	Respiratory frequency
Te	s	Duration of expiratory
Ti	s	Duration of inspiratory

Ttot	sec	Duration of Total breathing cycle
Vt/ti	l/s	Vt/ti ratio
Ti/Ttot	l	Ti/Ttot

MVV- Maximum Voluntary Ventilation

Symbols	um	Parameter
MVV	l/m	Maximum Voluntary Ventilation

Bronchoprovocation Response

Symbol	UM	Parameter
FallFEV1	%	Fall in FEV1 from baseline or post diluent
Fall Vmax50%	%	Fall in Vmax from baseline or post diluent
P10	%	Provocative dose (or concentrat.) causing FEV1 to fall 10% baseline
P15	%	Provocative dose (or concentrat.) causing FEV1 to fall 15% baseline
P20	%	Provocative dose (or concentrat.) causing FEV1 to fall 20% baseline

Pony graphic archive

The pony graphic archive can store data from tests conducted on over 200 patients. Its actual capacity depends on the width (volume axis) of the flow volume loops stored: the flatter the loops, the greater the number of tests that can be stored.

Pony graphic assigns a progressive number to each new chart (i.e. paper archive), in which all the data and test results relative to the new patient are stored. The Pony graphic also assigns an ID Code number for each patient.

For each patient's ID code, the best FVC, VC, IVC, MVV and Post FVC tests can be stored.

The criteria to choose the best tests are:

FVC the greatest summation value FVC + FEV1

VC the greatest VC value

IVC the greatest IVC value

MVV the greatest MVV value.

The parameters calculated during the entire test session are grouped in two categories:

LAST data and loop of the last test executed

BEST data and loop of the best test executed.

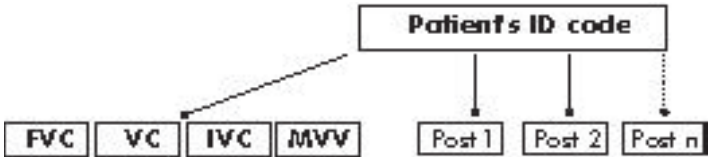
These data are stored until you enter data on a new patient with **New** command.

For each patient, only the group of parameters calculated based on the best tests, is transferred to the archive memory by means of the key **Enter** as soon as the execution test is completed.

Notice: *all the stored data are saved even when the Pony graphic is turned off (power switch off) so long as the Ni-Cd batteries are sufficiently charged.*

Archive structure

Patient's ID Code



List of commands

Pony graphic is provided with a multifuction keyboard, whose keys have different meanings in relation to the kind of executing function.

Function Keys

The main function/keys list is the following.

Key	Function
New	inserts anthropometric data and ID Code of a new patient.
Sex	modification of the sex value in the anthropometric data.
Patient	displays and modifies the last inserted patient's data.
Utility	accesses the utility menu.
Print	prints out patient's data or test.
FVC	carries out the Forced Vital Capacity test.
VC	carries out the Slow Vital Capacity test.
MVV	carries out the Maximum Voluntary Ventilation test.
Last	displays the last test.
Best	displays the best test.
Paper	advancing roll of printer paper.

Confirm and cancel commands

The following commands are active during every Pony graphic functions:

Key	Function
Cancel	cancels the last operation
Enter	confirms the operation in progress

Utility menu

Some commands, like the utility and configuration commands, allow to access other functions.

Pressing the utility key , the keyboard is structured as follows:

Key	Function
Post test	selects a reference Pre test for the execution of the post tests.
Test list	printouts or displays the patients' contents of the archive.
Test search	searches for an archived test to display or print out of the test data or loops.
Transmit Data	allows the data transferring to a PC or modem.
Erase Archive	allows to erase all data of the archive.
Configure	displays the utility menu.

Configure Menu

Pressing the configuration key, the key board is structured as follows:

Key	Function
Calibrate F/V	allows the turbine calibration .
Predicted values	allows the predicted value selection.
Diagnosis	allows to disable or enable the automatic diagnosis.
Units	allows the selection of the unity of measurement.
BTPS	allows to calculate the BTPS factor

Setting up the Pony graphic

Preparing the unit

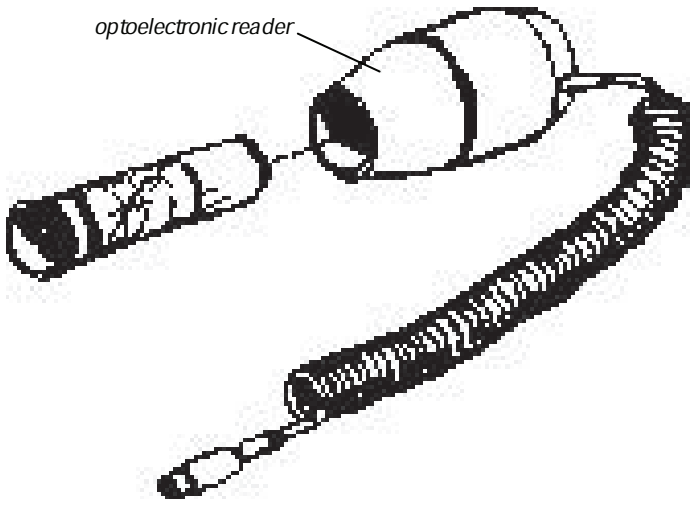
Before using the Pony graphic it's necessary:

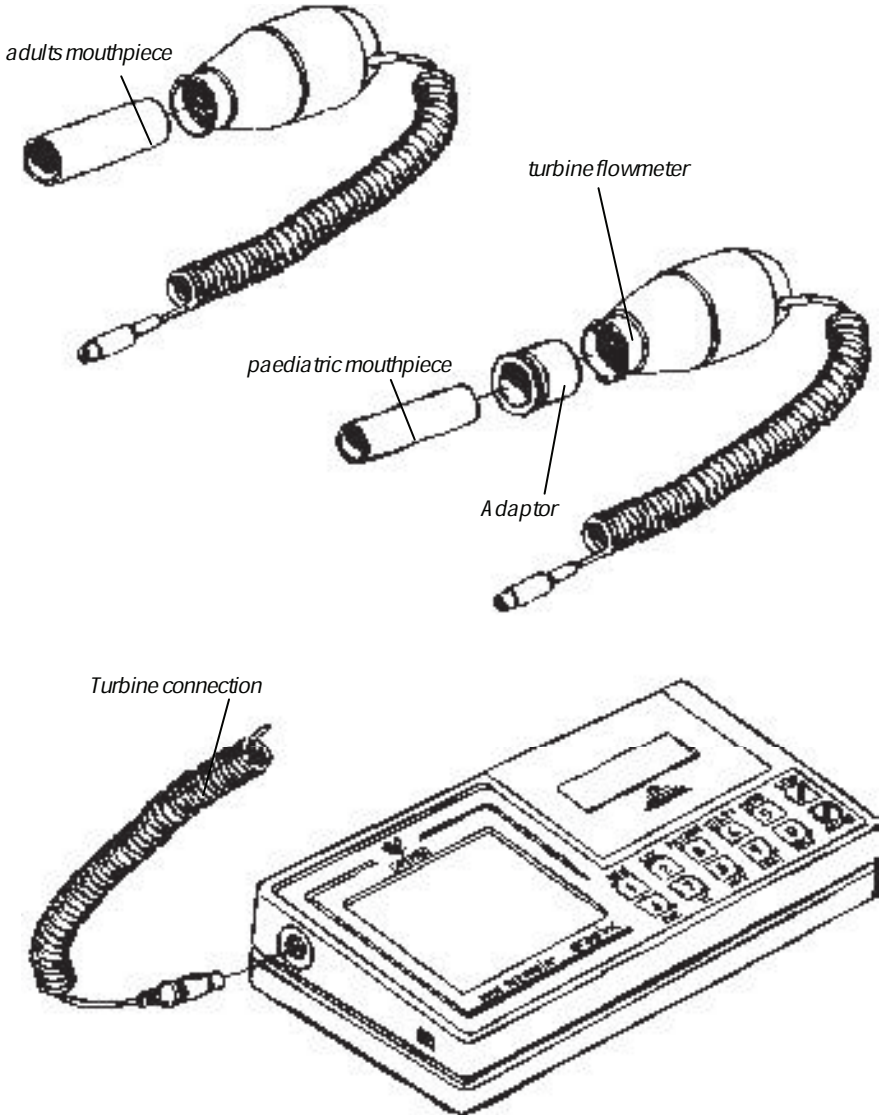
- set up the turbine Flow Meter
- check the paper in the printer
- check the ribbon in the printer
- make sure the batteries are charged

Turbine

To install the turbine:

1. Connect the turbine flow meter to the Main Unit, by inserting the 4-pin turbine Flow Meter plug in the slotted jack.
2. Insert the disposable mouthpiece on the turbine flow. Use the proper mouthpiece adapter for children.




adults mouthpiece
turbine flowmeter
paediatric mouthpiece
Adaptor
Turbine connection

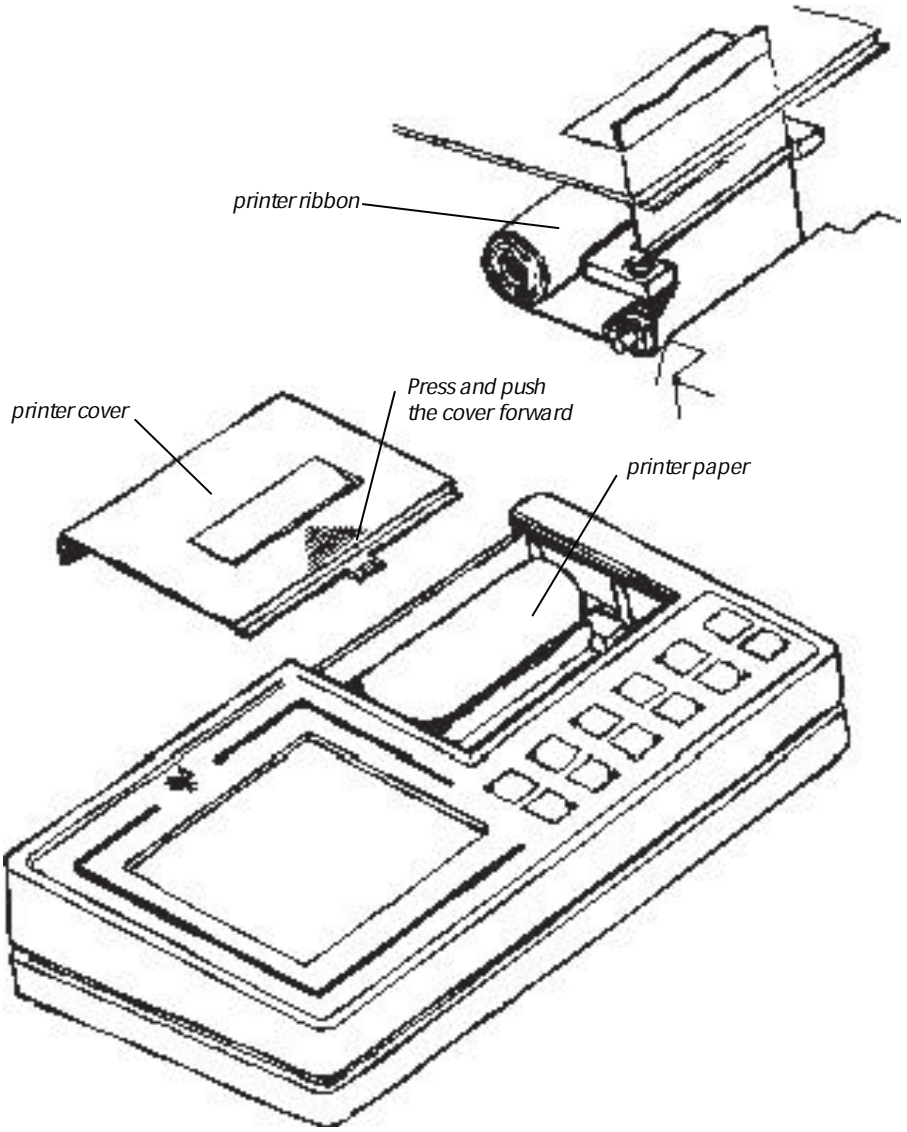
Internal Printer

To replace the printer ribbon

1. Remove the printer cover.
2. Press the ribbon cartridge down where it says Push.
3. Insert the new ribbon cartridge.
4. Replace the printer cover introducing the paper roll in the opening on the printer front.

To replace the printer paper

1. Remove the printer cover.
2. Remove the empty roll.
3. Turn on the system until *the message "select a function"* appears on the screen.
4. Insert the roll of paper through the opening towards the rear of the printer.
5. Press the paper key to advance the roll of paper.
6. Replace the printer cover.

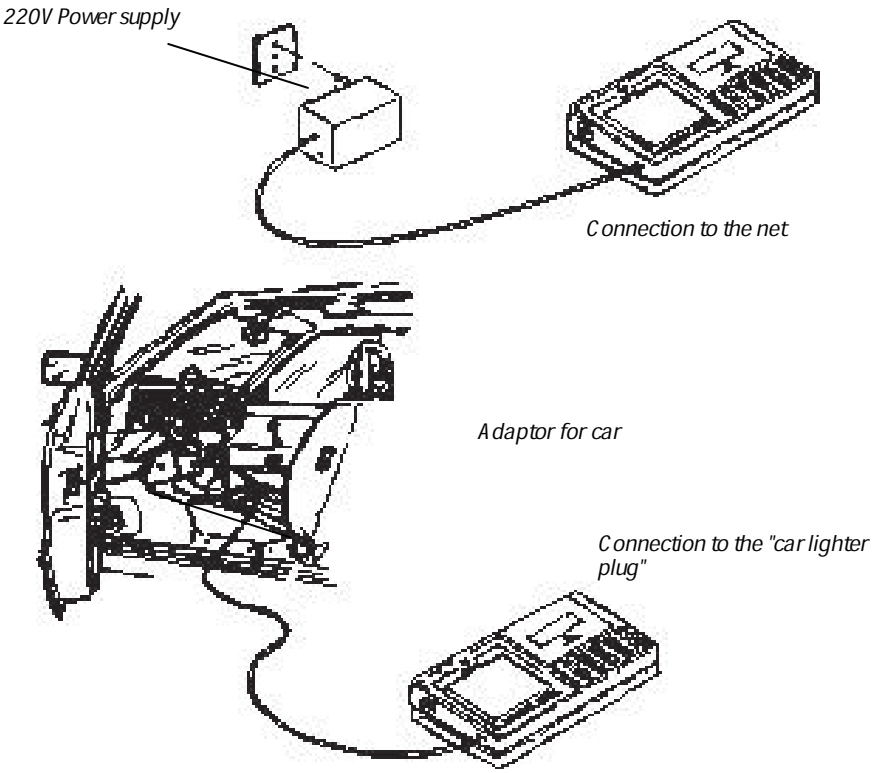

printer ribbon
printer cover
Press and push
the cover forward
printer paper

Power Supply

The Pony graphic can be supplied by the following ways:

- NI- Cd recharging batteries.
- Connection to 110-220v plug by the proper batteries charger-power supply.
- Connection to the “car lighter ”plug.

If the Pony graphic is used when it is connected to the main the recharging time will be longer.



Once the batteries are fully charged, they allow the execution of about 200 tests.

When the batteries reaches a lower level, the Pony graphic shows it with the "Battery" sign on the screen. In this case you can still use the unit but it's suggested to recharge the batteries.

Notice: *In case of complete battery discharge, the Pony graphic will lose all data*

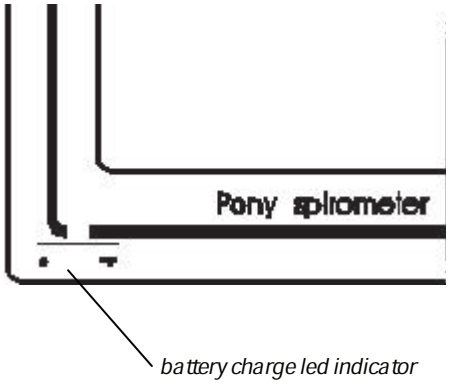
To charge the batteries

1. Connect the batteries charger or the lighter adapter to a power supply connector.
2. Connect the batteries charger to a socket, as it is specified on the batteries charge itself and check that the “charge “ indicator is on.

Maximum recharging time is 1 hour and 30 minutes and if the batteries are not fully discharged the time is shorter. Leaving the batteries charger connected longer than the maximum charging time not damage will occur.

Notice: *It's suggested not to use the pony graphic during the first minutes of charging.*

When the green led indicator of the charger batteries is flashing, the batteries are charged.

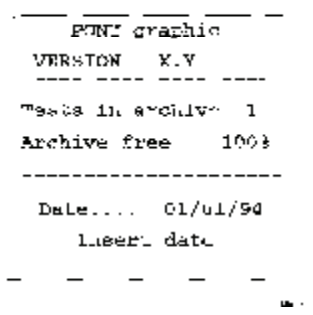


Using the Pony graphic

Turning the Pony graphic on

After having connected the turbine Flow Meter, checked if there is any paper and ribbon in the printer, turn the Pony graphic on:

1. Set the power switch on “I” and the display should show information about the tests in archive, the free memory and the message *“insert date”*.
2. Confirm or modify the date on the display pressing the keys corresponding to the number to type. For example if you want to insert the date “ 12.- 07- 1994 “ it is necessary to type sequential the keys 1, 2, 0, 7, 9 ,4 and press **Enter** to confirm.
3. Once the date is confirmed with **Enter**, the main pattern appears on the display.



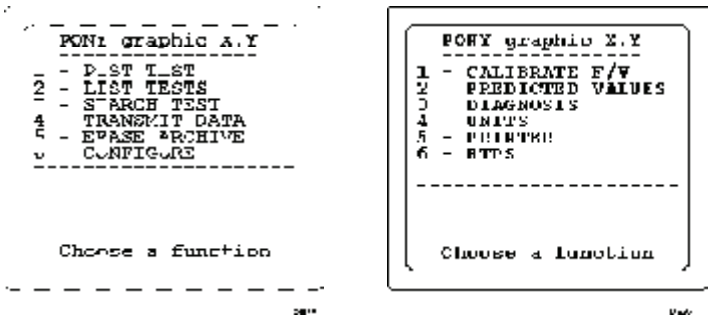
Configuring the Pony graphic

The Pony graphic allows the user to configure the following features:

- Predicted values.
- Automatic diagnosis.
- Unit of measurement.

Accessing to the Configuration Menu

1. Turn the system on, confirm or modify the date and press **Enter**.
2. Press the **Utility** key.
3. Select **Configure** by pressing the key **6.**



Predicted values

It is possible to select 6 predicted values, they are:

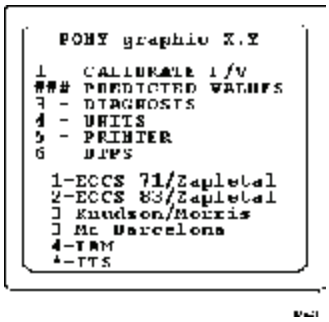
1. ERS 93
2. ITS White
3. ITS Black
4. Knudson 83
5. Multicèntrico Barcelona
6. LAM

To select the predicted values

1. On the **Configure** menu press the key **2**

2. Press the key corresponding to the selected predicted value.

***Notice**: Before modifying the configuration of the predicted values, check if the software is able to read the predicted values. Otherwise the patient's predicted values in the Pony graphic's archive won't correspond with the ones on the PC.*



Units of measurement

It is possible to select two units of measurement .

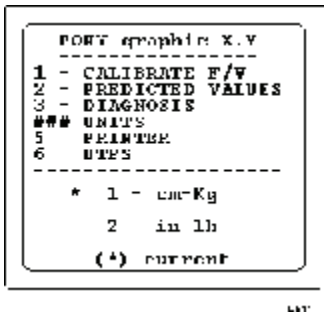
Unit	decimal metric	English
Weight	kg	Pound
Height	cm	inches

Selecting the unit of measurement

1.On the Configure menu press the **4** key

2. Press the key corresponding to the selected unit of measurement.

***Notice:** Modifying the unit of measurement the data in the archive will be erased.*



Printer

Pony graphic besides to print on its own printer allows to print a wide printout report with loops and data to an external printer. The external printout is compatible only with printers with HP PCL3 printer language equipped with a serial input RS232.

Print out report characteristics

The report is printed on a single sheet of 297x210 mm (A4 standard size).

The flow/volume and volume/time loops are printed according to ATS 1987 Hand-Measurement standards.

To connect Pony graphic to the external printer

1. Turn the Pony graphic on.
2. Connect the serial adapter 9-25 pin to the serial cable.
3. Connect the 9 pin connector in the Pony graphic plug and the 25 pin connector in the printer serial plug.

To select the printing mode

1. On the Configure menu press key **5.**
2. Press the key corresponding to the printer chose.

Notice :The program maintains the configuration even after turning the unit off.

To print with the external printer

1. Set the unit for external printing and press **Print** key.
2. Press **Enter** to confirm or **DEL** to cancel the task.

Notice: *The external printer setting enables the printing of a complete report, all the other printouts, tests list, cannot be transferred and will continue to be printed with the internal printer.*

Calculating the BTPS factor

Ambient conditions values are used to calculate the BTPS factor to which all the measured volumes and flows are corrected.

BTPS Body Temperature Saturated Ambient Pressure

ATPS Ambient Temperature Saturated Ambient Pressure

PB Barometric Pressure (mmHg)

PH20 Partial Pressure of water vapour (mmHg)

T Temperature at the flowmeter (C°)

TA Ambient Temperature (C°)

The BTPS factor is calculated as follows:

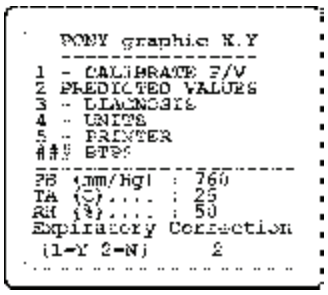
V(BTPS)=V(ATPS)*[(273+37)/(273+T)]*[(PB-PH20)/(PB-47)];

LOG(PH20)=8.10765-1750.286/(235+TA).

PH20(KPa)=1.63---0.07*T+0.0053*T^2 (ERS 1993)

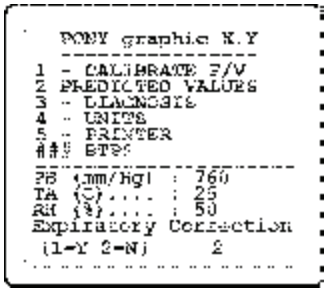
BTPS inspiratory correction

1. Turn the system on and press the **Utility** Key.
2. Select **Configure** by pressing the key **6**.
3. Press **6** corresponding to the BTPS choice.
4. Type on the data pattern the PB, TA, RH values and press **Enter** key twice.



BTPS expiratory correction

1. Turn the system on and press the **Utility** Key.
2. Select **Configure** by pressing the key **6**.
3. Press **6** corresponding to the BTPS choice.
4. Press **Enter** key three times and choose **1** for enable and **2** for disable the expiratory correction.



Entering data

Before executing tests the Pony graphic must have certain information on the patient to be tested, which will be inserted in the relative chart.

The table below shows admissible values for the above parameters.

Parameter	min	max	um	keyboard operation
Id Code	1000	9999	--	type the keys corresponding to the number
sex	F	M	--	press the key sex to modify the sex
Age	3	100	years	type the keys corresponding to the age
Height	50	230	cm	type the keys corresponding to the height
Weight	5	200	kg	type the keys corresponding to the weight
Eth.corr.	50	150	%	type the key corresponding to the %

The Ethnic correction value allows to increase or decrease predicted values according to the patient characteristics.

Typing for example the value “105”, it indicates an increase of 5%. The value “95” indicates a decrease of 5% of the predicted values.

In case of loss of patient’s data , it won’t be possible to carry out tests and the Pony graphic will display the message: *Insert patient’s data.*

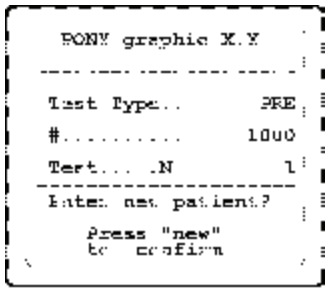
New Patient

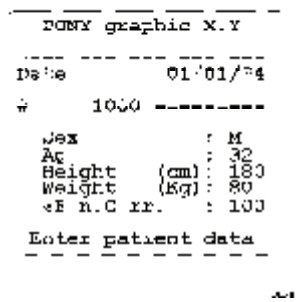
Before executing tests, except for the Post FVC test, it is necessary to insert the patient’s data.

To insert patient’s data

1. Turn the pony graphic on and confirm or modify the date.

2. The message "*Select a function*" appears on the display, press the **New** key twice (the second time to confirm the selection).
3. Type the new ID code or confirm the automatic ID code and input the patient's data.





In case the code has been already used, the message *" already in use"* will appear on the display, press any key and start inputting the patient's data again.

Press the **Enter** key to confirm each value.

To switch between Male and Female press **Sex**.

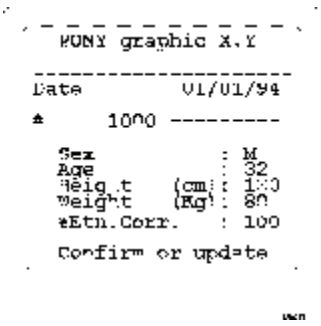
At any time it is possible to cancel the value inserted, if it has not been confirmed. To do this press **Cancel** and type the new value.

To modify patient's data

The unit allows to edit the patient's data, only before having confirmed any test executed by the patient.

1. Press **Patient**, the patient's data window will appear.
2. Press the **Enter** key until you reach the value to be edited.
3. Type the new value and confirm by pressing **Enter.**
4. Confirm or modify all the other values to save the changes.

Notice: *When you choose the Post FVC test it is not possible to modify the patient's data; pressing the Patient key you will obtain the display of the data themselves.*



Test storing

The pony graphic stores the best test of every test.

If a patient executes more FVC; MVC; VC; or IVC tests during the same examination, the Pony graphic will always store the best test for any kind of test.

When the bronchial provocation test is executed, the stored data will be:

- The best pre FVC (Loop and parameter).
- Every post FVC test (loop and parameter).

Performing spirometric Tests

Once inserted patient's data, the selection of tests to be executed starts.

The pony graphic allows the execution of the following exams:

Key	Exam
FVC	Forced Vital capacity.
VC	Slow capacity (Expiratory or inspiratory) and respiratory pattern.
MVV	Maximum voluntary ventilation.

In case of the FVC test, other two tests can be executed by the patient: the Pre and Post bronchial stimulation.

When the test is over, it is possible to print out the Best test (**Best** key) and the last executed test (**Last** key).

The Pony graphic assigns a maximum time for the execution of the test, after which the test is interrupted, even if has not finished yet.

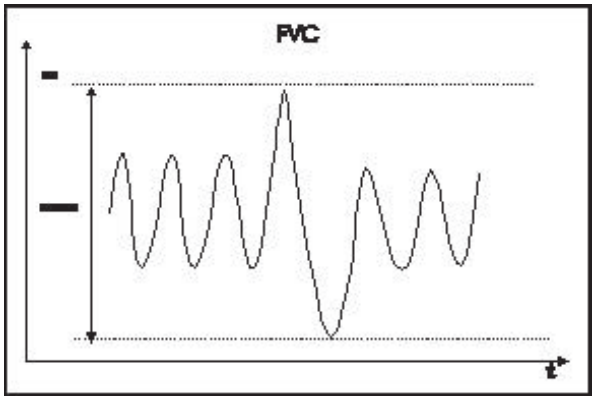
If you want to interrupt the test in advance, press the **Stop** key.

Forced Vital Capacity

This test provides important information about the resistance of the airways.

FVC test manoeuvre

1. Breathe normally several times (optional).
2. Execute a maximum inspiration.
3. Execute a maximum forced expiration.
4. Execute a maximum forced inspiration 8 (optional).
5. Breath normally.



Parameters calculated

During the FVC test the following parameters are calculated :

Parameter	um	Parameter name
FVC	l	Forced vital capacity
FEV1	l	Volume exhaled after 1 m''
PEF	l/s	Peak Expiratory flow
PIF	l/s	Peak Inspiratory flow
Vmax 25%	l/s	Expiratory flow at 25 % of FVC
Vmax 50%	l/s	Expiratory flow at 50% of FVC
Vmax 70%	l/s	Expiratory flow at 75 % of FVC
FEF 25- 75%	l/s	Average Expiratory Flow between 25% and 75% of FVC
FEV1/FVC%	%	100x FEV1/ FVC
FEV/VC%	%	100x FEV1/VC
FET100%	s	Forced Expiration Time

To carry out the FVC test

1. Connect the patient to the turbine flow meter.
2. Apply the nose clamp to the patient and check if the mouth-piece is properly set.
3. When the message *" select a function "* appears press **FVC** key and start the test.

Notice: *The respiration must start only after having pressed the FVC test and do not wait longer than 5 seconds, otherwise the program will return to the Main Menu.*

To Interrupt the test

The examination is interrupted when:

1. Pressing the Stop key.
2. In case of the flow absence, after 5 seconds confirming and erasing the test.

Confirming or cancelling the test

At the end, the test will be confirmed pressing the **Enter** key or erased pressing the **1** key.

Results

The Pony graphic stores the best executed test. However it is possible to display data and loops of the last executed test (**Last** key) and of the best test (**Best** key) by means of the corresponding keys.

The **Last** and **Best** functions are active until the new patient's data are inserted.

It is possible to display and print out the results of the tests in the following ways:

Option	Operation
Displaying the parameters	press several times the Enter key to read the obtained results.
Printing out	press the **Print** key.

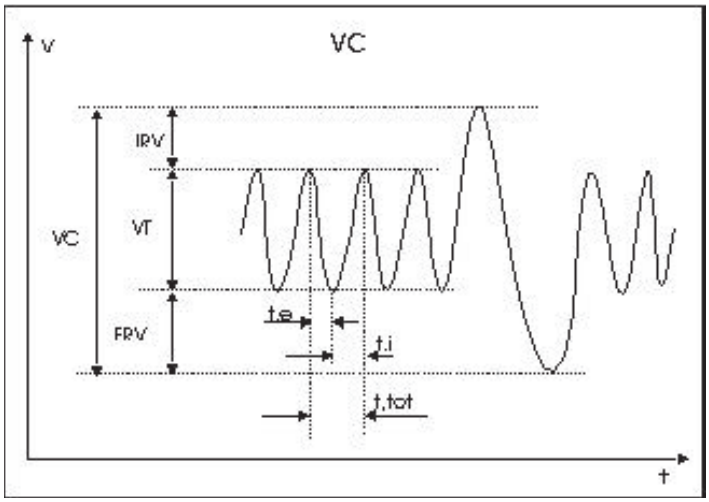
Slow Vital Capacity

The Slow Vital Capacity (VC) is the maximum amount of air that can be expirated after a maximum inspiration condition.

The Slow Inspiratory Vital Capacity is the maximum amount of air that can be inspired after a maximum expiration condition. The Pony graphic recognises automatically during the execution of the test whether it is a VC or a IVC.

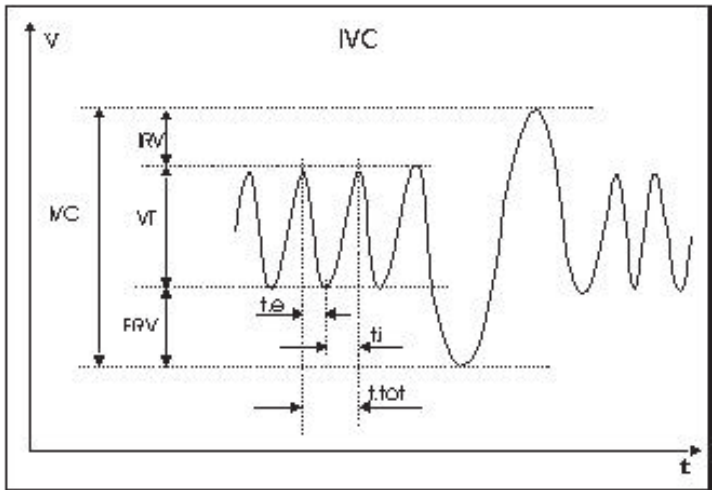
VC test manoeuvre

1. Breath normally for several times (optional).
2. Execute a maximum inspiration.
3. Execute a slow maximum expiration.
4. Breathe normally (optional).



IVC test manoeuvre

1. Breathe normally several times (optional).
2. Execute a maximum expiration.
3. Execute a slow maximum inspiration.
4. Breath normally (optional).



Parameters calculated

Parameter	um	parameter names
VC	l	Slow Expiratory Vital Capacity
IVC	l	Slow Inspiratory Vital Capacity
ERV	l	Expiratory Reserve Volume
VE	l/m	Minute Ventilation
Rf	resp/ m	Respiratory Frequency
t, E	s	Average expiratory time during rest respiration
t, I	s	Average inspiratory time during rest respiration
VT	l	Tidal Volume
VT/t,1	l/s	Tidal volume /average inspiratory time
t,I/tot	l	Average inspiratory time (average inspiratory time + average expiratory time)

To carry out the VC test

1. Connect the patient to the turbine flow meter.
2. Apply the nose clamps and check if the mouth piece is properly set.
3. At the request *" Select a function "* and press the **VC** key and start the test.

Notice: *The respiration must start, after having pressed the VC key and do not wait longer than 5 seconds, otherwise the program will return to the Main Menu.*

To calculate the parameters of the Respiratory Pattern, make the patient breathe for 3 sufficiently regular consecutive respiration acts.

To interrupt the test

The examination is interrupted when:

1. Pressing the **Stop** key.
2. In case of flow absence, after 5 seconds.
3. In any case after 45 seconds after the beginning of the test.

Confirming and erasing the test

At the end of the test, the test will be confirmed pressing the **Enter** key or erased pressing the **Cancel** key.

Results

The Pony graphic always stores the best test executed during the tests. However it is possible to display or print out the data and the loops of the last test (**Last** key) and of the best test (**Best** key) by means of the corresponding keys.

The Last and Best functions are active until the new patient's data are inserted. After having confirmed the test with **Enter**, on the display the results are shown.

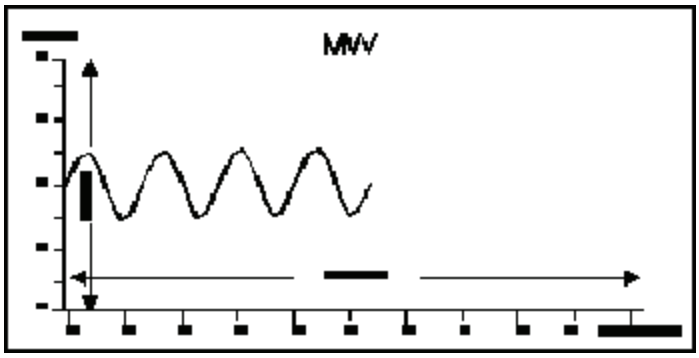
To print out the test press the **Print** key.

Maximum Voluntary Ventilation

The maximum voluntary respiration is the maximum volume that can be breathed in 1 minute. The measure is executed in 12 seconds (ATS) and extrapolated at once.

MVV Test manoeuvre

Have the patient breathe deeply at a rate of 30 breaths/m'.



Parameters calculated

Parameter	um	parameter name
MVV	l/m'	Maximum Voluntary Ventilation

To carry out the MVV test

1. Connect the patient to the turbine flow meter.
2. Apply the nose clamps and check if the mouth piece is properly set.
3. At the request *"Select a function "* press the **MVV** key and start the test.

Notice: *The Respiration must start after having pressed the MVV key and do not wait longer than 5 seconds, otherwise the program return to the Main menu.*

To interrupt the test

To end the test before 12 seconds, press the **Stop** key or interrupt the test and wait 5 seconds.

Confirming or erasing the test

At the end of the test, the test will be confirmed pressing the key **Enter** or erased pressing the **Cancel** key.

Results

The Pony graphic always stores the best test executed during the tests.

However it is possible to display or to print out the data and the loops of the last test (**Last** key) and of the best (**Best** key) by means of the corresponding keys.

The Last and Best function are active until the new patient's data are inserted. At the end of the test, on the display results are shown.

To print out the test press the **Print** key.

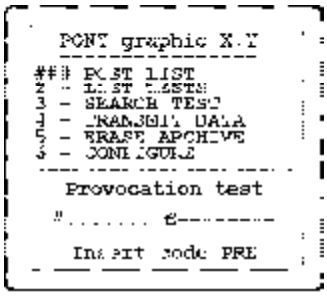
Bronchial Provocation Test

The Pony graphic allows the execution of the FVC Test before and after (PRE and POST) bronchial stimulation.

The values of the POST FVC tests are compared with the corresponding PRE values.

To carry out the Post FVC test

1. At the request *"select a function"*, press the **Utility** key.
2. Select "Post test" pressing the **1** key.
3. At the request *"Insert a code"* type the ID Code of the patient
4. Confirm with **Enter** and check that the message *" Kind of test Post"* and the ID code appear on the display .
5. Press the **FVC** key.
6. At the request *"Insert the quantity of bronchial drug"*, type the amount of the drug administration and confirm with **Enter**.
7. Execute the FVC test.



At the end the test will be confirmed pressing the **Enter** key or erased pressing the **1** key.

To execute several Post FVC tests and to store the best one, after each administration, press FVC and confirm without typing the amount of the bronchial drug. Every time the quantity of bronchial drug is administered, the Pony starts the next "step " and the best test is stored.

The PRE and POST flow -volume loops are shown superimposed on one another for a better comparison.

Notice: *The quantity of drug must be a whole 5 digit number between 0 and 65535.*

To carry out a bronchial provocation test and analyse how the airways react to the drug in several steps:

1. Once the first administration test has been confirmed, at the request *" Select a function "* press the **FVC** key.
2. At the request *"Insert the quantity of bronchial drug "* type the value of the addition of the data of the first administration and the second one.
3. Execute the FVC test.
4. Repeat the above operations for the number of the Post tests executed.

Notice: *The dose administered during the POST FVC execution must be a cumulative dose (The last dose + The addition of the previous doses); since the Pony doesn't add up the value typed in the previous phases.*

Response to the drug

To analyse the response of the airways to the administered drug and to calculate the fall of the FEV1, during the administration of the different doses:

1. At the end of the Post test, before executing the following one, select "*Response*" pressing the 2 key.

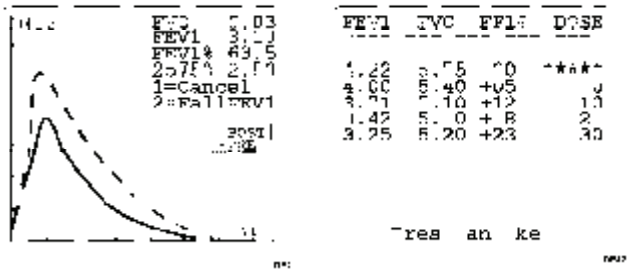
On the display the test and the Post tests list appear. The displayed fields are:

FEV1 FEV1 in absolute value.

FVC FVC in absolute value.

FF1% Percentage of the fall of the FEV1 in relation to the Pre value.

Dose Cumulative dose of the drug.



In this way it is possible to check the decrease of the FEV1 during the Post phases and to stop the test when the FEV1 reaches a significant value.

To interrupt the test

The test is interrupted:

1. Pressing the **Stop** key.
2. In case of flow absence, after 5 seconds.

Results

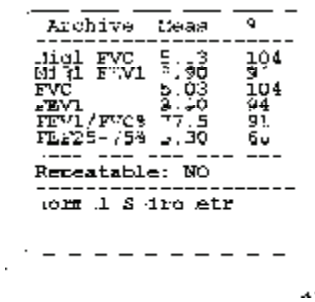
After having confirmed the test with **Enter**, the Pre and Post loops are displayed.

Option	Operation
Displaying the parameters	press the **Enter** key several times to read the obtained results.
Printing out	press the **Print** key.

ATS reproducibility

The ATS recommendations (see the Appendix chapter) show that the test is in agreement with the ATS reproducibility criteria (1987) if 2 tests out of at least 3 executed by the same patient differ in the FVC and FEV1 values of a quantity smaller than the 5% or 100 ml (if the 5% was larger than 100 ml).

If this criteria is met, the system displays: "*ATS reproducibility*" message, followed by the relative parameters (FVC, FEV1 or both).



Other Functions

The Pony graphic provides other functions to make the management of the archive easier, whether for the search of the data or for their transmission to a PC.

Utility Menu

The Utility Command pools many functions to increase the Pony graphic potential.

These functions are:

Key	Function
Post Test	allows the execution of a bronchial-provocation test.
List	allows to display and print out the list of the tests in archive.
Search test	allows the search of a test in archive to display and print out the loops and data .
Transmit	allows the transmission of the archived data on the Pony to a PC.
Erase Archive	allows to erase the data in archive
Configure	accesses to the Configuration Menu of the System.

Accessing to the Utility Menu

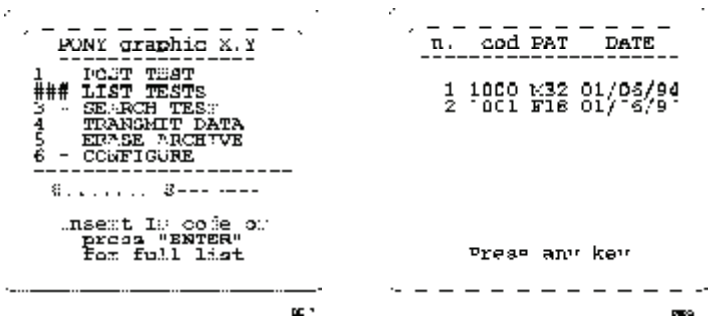
- After having confirmed the date at the request *" Select a function"*, press the **Utility** key.

Tests list

The system allows to display or print out information about the tests stored in the memory. To choose which test retrieve from the memory it is suggested first to get a complete list of the contents of the archive.

To display the list in the archive

1. After having turned the Pony graphic on and confirmed the date, press the **Utility** key
2. Press key **2**.
3. Press the **Enter** key to obtain the complete list in the archive, otherwise type the code to get the list of tests that belong to it.



The parameters in the list are:

- Progressive number of the test.
- Number of the patient's ID code.
- Patient's sex.
- Patient's age.
- Date of test execution.

The list is displayed on 10 lines pages; to display the following lists press the **Enter** key.

If in the archive no test is present, on the display the following message will appear: *"Empty Archive"*.

Printing the list

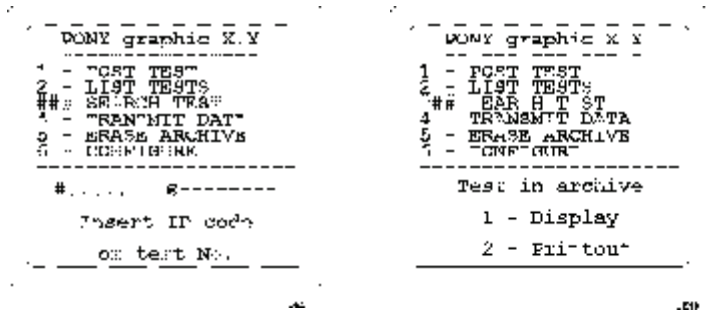
- To obtain the complete list or a partial one press the **Print** key.

Search Test

The Pony graphic provides a new function to search a test stored in the archive. In this way it is possible to consult an examination whether on the display or on printout without downloading data on a PC

To search a test in the archive

1. Turn the Pony graphic on, confirm the date and press the **Utility** key.
2. Select **"Search test"**.
3. Insert the ID code or the test number you want to examine and confirm pressing **Enter**.
4. Press **1** to display the test or **2** to print it out.



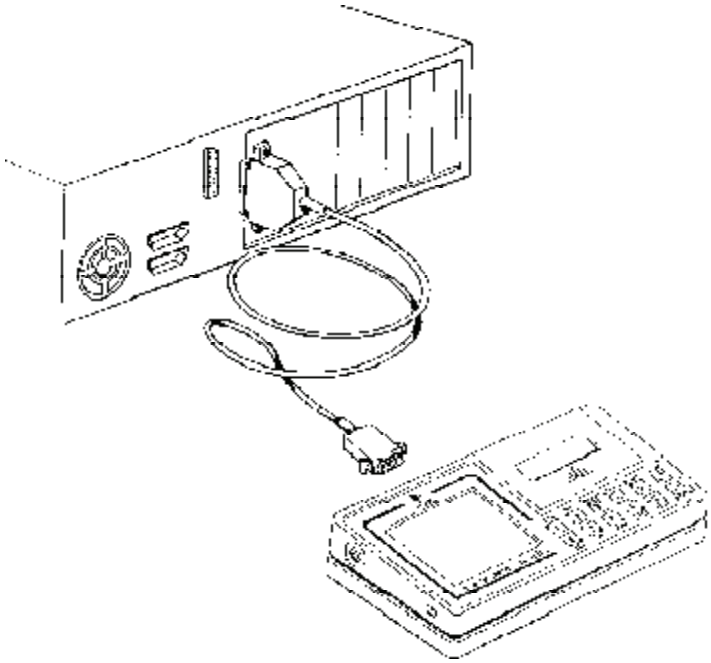
Data transmission

The pony graphic allows to transmit the data archived on the PC hard disk by means of a serial cable " RS 232 "

For this operation, follows instructions described in the chapter concerning software.

Link to the PC

- Connect the RS232 supplied cable as it is described in the following figure.



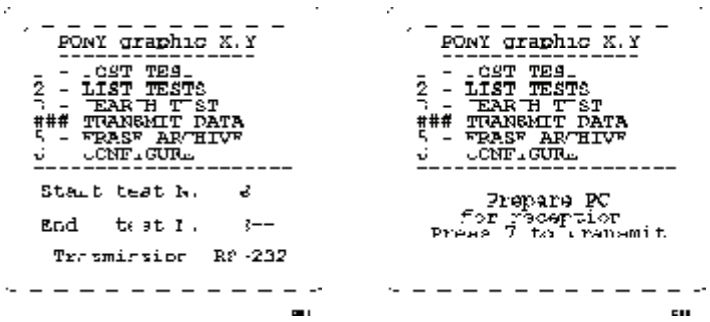
To prepare the Pony graphic to transmit data to PC

1. Turn the Pony on.
2. On the **Utility** menu select Download by pressing key **4**.
3. Press twice **Enter** to transmit all the test in the archive otherwise select tests by typing the appropriate test numbers.

Notice: *The selection is relative to the numbers of the tests. Before executing the selection it is advisable to print out the list of the tests in the archive.*

To prepare the PC for reception

1. Choose **Receive** from the **Test** menu.
2. Into the "Receiving Test" dialogue window press the **Receive** button to prepare the software.



To start the transmission

1. To start the transmission press **7**.
2. The software shows a bar indicating the transmission in progress.

Notice: *For further operation on PC, consult the chapter 4.*

Erasing data

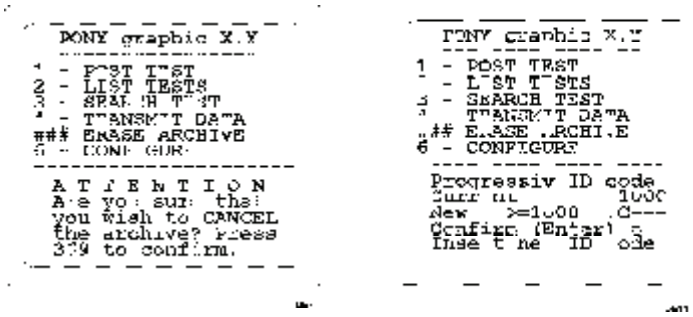
The Pony graphic memory has a capacity of 100 tests circa. When the message "Memory Full appears it is suggested to download all data to PC and than erase all tests stored to leave the memory for new tests.

Notice: *By choosing " Erase archive ", all data stored in the Pony graphic archive, will be erased.*

If you want to save the tests into a permanent memory, before erasing them, you can transfer them to a PC as it has just described in the previous paragraph.

To erase file

1. Turn the Pony graphic on and press the **Utility** key.
2. Select the function **Erase archive** pressing the **5** key.
3. Confirm the command typing sequentially the keys '**369**".
4. Check if the message *"archive erased"* is shown and the message *"Request new ID code"* appears on the display.
5. Confirm the ID code (code: 1000) or insert a new start code pressing **Enter**.



Data management

Setting up the Pony graphic

Preparing Pony graphic

Before using the Pony graphic it is necessary:

- Set up the turbine flowmeter.
- Insert the batteries placing them as indicated on the back of the instrument.
- Link the instrument to your PC throw the serial port available (COM1 or COM2).

Installation of the PC software

From the **Windows Program Manager** menu bar:

1. Use the mouse or keyboard to select **File**.
2. Select **Run** from the File menu.
3. In the **Command line** box, type **a:\install** (assuming the disk is in drive A:)
4. Click on **OK** (or press **ENTER** key).

The program will load up a dialog box and ask for a directory to be installed in. We recommend **Ponywin** for the exported files and the program. After the program has finished installing, it will present a message indicating that the installation was successful; click on **end.**

To actually use the program, you need only to open the **Program Group (Ponywin)** and double-click on the **Ponywin** icon.

Configuring the program

Test option

Before using the software it is suggested to set the options in the **Configure** dialog window from the **Option** menu.

Serial port

You must select the serial port that will be used to connect the Pony graphic with the PC.

To select the serial port:

1. Select **RS-232**
2. Click on **COM 1** or **COM 2** button (the selected port must be different from the mouse one).

Units of measurements

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

To select the units of measurements:

- Click on **cm/Kg** or **in/lb** according to the desired format.

User free fields

The Patient's database is mainly made of 3 cards (Patient card, Visit Card and Test card.) where it is possible to store the information about the patient and the visits .

Even though the information that can be typed as a standard is a lot, it is however possible to customize some fields (user free fields) labelling them with the desired name (insurance #, social security #...).

The customizable 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)

To customize the fields:

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

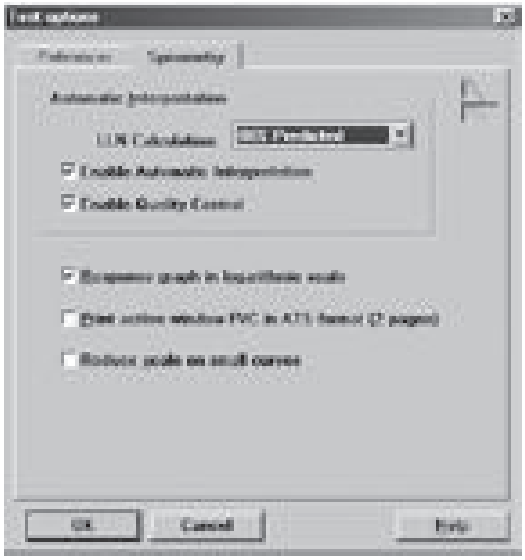
Graphs

All the graphs visualized and/or printed can customized in colors and appearance.

To customize the graphs:

1. Select the group **Graphs**
2. Select the desired colors of the curves (5 curves max can be overlapped on the same graph).
3. Enable or disable the **Grid** option.

The Automatic Diagnosis



Pony graphic has a function to calculate the automatic diagnosis. The algorithm has been carried out referring to international scientific literature mentioned in the bibliography paragraph of the appendix chapter.

The automatic diagnosis is calculated at the end of the FVC Test if:

- The automatic diagnosis option is enabled.
- The patient's anthropometric data allow the calculation of the LNN (Lower Limit of Normal range).
- At least one FVC test has been carried out.

To enable/disable the Automatic Diagnosis

- Click on the **Enable** button of the group **Spirometry** to enable the calculation and the visualization of the automatic interpretation.

Quality control

Pony graphic allows a quality test control. The calculation has been carried out referring to international scientific literature mentioned in the bibliography paragraph of the appendix chapter. The messages concerning the quality control are shown at the end of the test execution.

- Enable/disable the quality control.

Ambient conditions

Ambient conditions value are used to calculate the BTPS factor to which all the measured volumes and flows are corrected.

BTPS	Body Temperature Saturated Ambient Pressure
ATPS	Ambient Temperature Saturated Ambient Pressure
PB	Barometric Pressure (mmHg)
PH20	Partial Pressure of water vapor (mmHg)
T	Temperature at the flowmeter (C°)
TA	Ambient Temperature (C°)

V(BTPS)=V(ATPS)*[(273+37)/(273+T)]*[(PB-PH20)/(PB-47)];

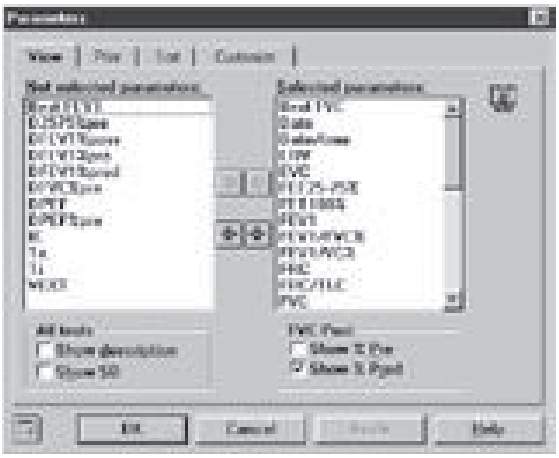
LOG(PH20)=8.10765-1750.286/(235+TA).

PH20(KPa)=1.63---0.07*T+0.0053*T^2 (ERS 1993)

To insert the ambient conditions values

1. Select **Ambient conditions** from the **Option** menu and type the values in the corresponding fields.

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 order the only desired parameters.

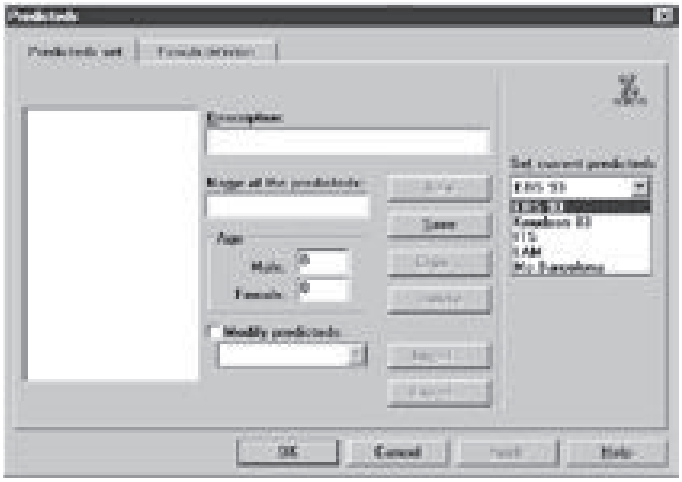
1. Select the menu **Options/Parameters manager**
   View: Move the parameters to view in the Parameters selected list.
   Print: Move the parameters to print in the Parameters selected list.
   Order: Drag the parameter up or down through the mouse.
   Customize: Insert, modify and delete the custom parameters.

Predicteds manager

The program contains a preset of predicteds, but the user is allowed to customize its own predicted sets.

1. Select **Options /Predicteds manager**.

The Predicteds manager 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:	Identify the set and cannot be duplicated;
Description:	free field;
Age:	the adult predicteds start since this age.

- To insert 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 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.

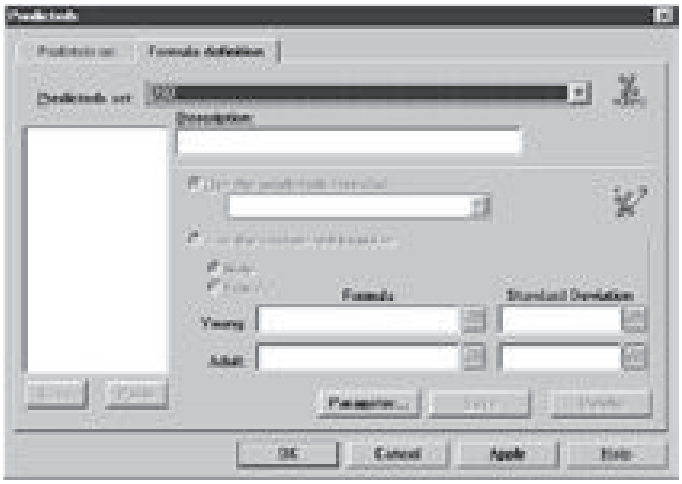
Set the current predicted

Pony graphic allows to calculate the predicted values according to 4 configurable sets:

ERS 93	Zapletal
Knudson83	Knudson83
ITS white	ITS white
ITS black	ITS black
LAM	LAM
MC Barcellona	MC Barcellona

- Select the desired choice in the group **Predicted**.

Formula definition



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

1. Select the set of predicteds to manager from the list Predicteds set.
2. To insert a new parameter click on the New... button.
3. The parameter formulae can be:
   • calculated according to the predicteds in the list Use the predicteds formulae;
   • or customized by the user with the option ...or the customized formulae.
4. The button Copy stores the selected parameter in memory.
5. The button Paste 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.

Archive path

This program allows to work with different archive path; you can for instance use a path as **C:\PONYGRAPHICW20\1995** to manage tests performed during 1995 and **C:\PONYGRAPHICW20\1996** during 1996.

To select a different directory

1. Select **Archive Path** from the **Option** menu
2. Select the desired directory.
3. Enable the **LAN** (Local Area Network) support if you want to share the archive with other user or you are accessing to other shared archives, indicating your User Name.

Uploading data from the spirometer

Before starting any analysis you must upload the data from the spirometer via the serial port.

1. Link up the spirometer to the PC with the **RS232** cable supplied.

2. Select **Receive** from the **Test** menu or press the button by side.
3. Prepare the spirometer to transmit the data.
4. Click the **Receive** button on PC.
5. Start data transmission from the spirometer.

Linking tests to a Patient in the archive

The data received from the spirometer are held in temporary memory. These tests must then be stored within the patient database by linking each test to the corresponding patient.

To link a test to a patient

1.Selct **Link** from the **Test** menu or press the button by side.

2.Select the test you want to link in the top area of the window.

3. Select the correspondent Patient in the bottom area of the window.

Buttons description relative to the test link area:

 Move to the first test to link

 Move to the previous test to link

 Move to the next test to link

 Move to the last test to link

 Delete current test

 Compare the paper report of the spirometer

Buttons description relative to the patient card area:

 Find a patient in the archive by the Archive Navigator

 Find a patient in the archive with the same ID Code of the current test to link.

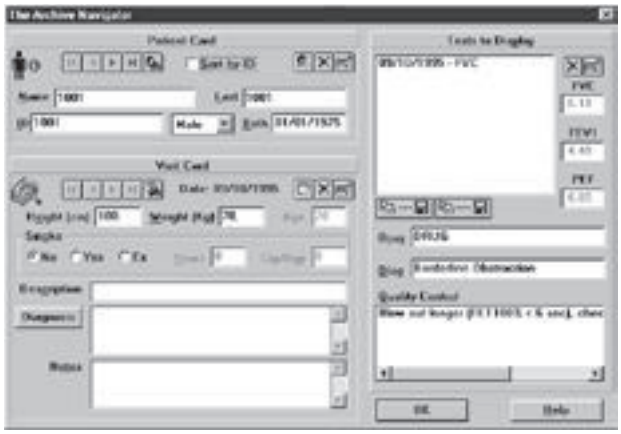
 Visualize the spirometer print report

 Link the current test to the current patient.

Link automatically all the tests creating, if necessary, a new patient card with the same ID Code of the test.

Managing the Patient's database

The Patients database is mainly composed by : the Patient Card, the Visit Card and the Test card.



Patient Card

Contains all the information relative to the Patient that remain the same during the different visits (first name, last name, date of birth...); it is created the first time that the Patient come to be tested and it is recalled during the following visits. Each Patient is related to only one Patient Card.

Buttons description:

 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

 Delete current patient from the archive

 Edit current patient card

Visit Card

Contains all the information relative to the visit (diagnosis, visit description...) and those one related to the patient that can change between different visits (height, weight, smoke...). Each Patient can be related to several Visit Cards but it is not possible to create two different Visit Cards during the same day. Before carrying out any spirometric test it is necessary to create a new Visit Card or to open the today's Visit Card.

Buttons description:

 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

 Delete current visit from the archive

 Edit current visit card

---

***NOTE**: several features of the program are enabled only if there is an "Active Patient"; the name of the active patient is shown on the status bar.*

Test card

Contains all the information about the test.

 Delete current test from the archive.

 Edit current test

To import/export a Tets card

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

1. Select the patient and press the key by side.
2. Choose the test and press **OK .** All data will be imported/ exported in the XPO file format.

Viewing results

All the visualization functions refer to the test carried out by the active patient, whose name is indicated on the left-side of the status bar.

To view the results of a test proceed as follows:

1. Select the **Archive Navigator** 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

 view Volume Time graph

 view data of the test

 view bronchial provocation response

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

Deleting a test from the archive

1. Select **Archive navigator** 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 active patient and press the button by side.

Managing the optional databases

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 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 **Database Diagnosis...** from the **File** menu.

Printing results

You can print out in two different ways:

- printing the Report
- printing the Active Window

Printing the report

The standard Report is composed by 2 or 3 pages depending if you wish to printout the bronchoprovocation response.

The 1st page contains the F/V and V/t curves of the best Forced Vital Capacity, the patient data, the notes and the diagnosis.

The 2nd page contains the numerical results of the all test FVC, VC/IVC and MVV carried out in the current visit.

The third page is the bronchoprovocation response.

1. Select **Print Report** from the **File** menu.
2. Select the desired option among:

FVC graph: print the F/V and V/T curves of the best FVC test

Response: print the bronchoprovocation response

FVC post Tests: print curves and data of the FVC post test.

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

1. Ensure that the active window is one of the preceding objects.
2. Select **Print Active window** from **File** menu.

Data exporting

With this function you can export the test in 3 formats:

- Lotus 1,2,3

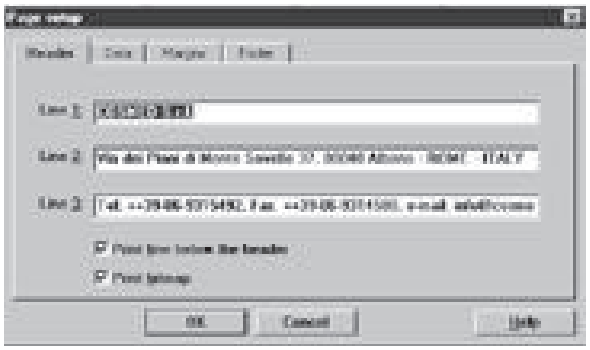
- Excel
- ASCII (Text File)
- XPO (Cosmed file format)

To export data

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**.

Nota: 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.

Page setup



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

Header

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

Data

Patient and visit informations are printed below the header. These data are reported on 3 columns and 5 rows, and is possible to configure the disposition of the voices or avoid to print those that don't interest.

Margin

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

Footer

Insert the physician name.

Other features of the program

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

Archive

Initialising the database

It deletes all file stored by the software:

Select **Initialize.**

Reorganizing the archive

In order to free space on the hard disk and/or to correct possible errors present within the database:

Select **Reorganize.**

Backup

It is strongly recommended to backup files periodically.

On the **Backup** dialog box set the different options, selecting the destination path with the Browse key or pressing New to create a new directory.

Press **OK** to confirm.

Restore

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

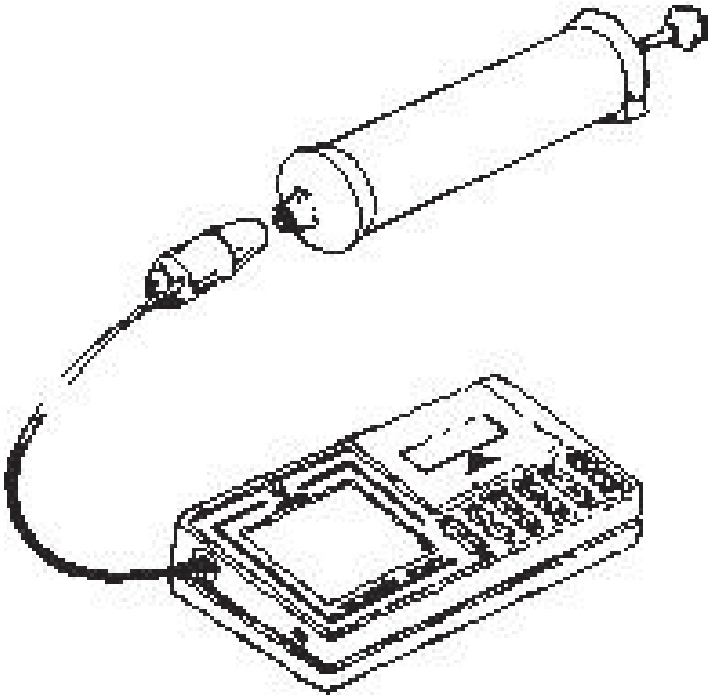
Appendix

Calibration

The system is precisely calibrated by Cosmed and will remain so as long as it is used properly. If a proper maintenance is executed it is possible to check the calibration of the Flow meter turbine even after long periods.

You may check the calibration by measuring a known volume (syringe) using the FVC and VC tests and comparing the results measured with the predicted one (the syringe one). If the discrepancy is more than 3% the system should be re calibrated.

This standard calibrated syringe (3 Litres) is supplied by COSMED:
Calibration syringe: P/N 00600-01-11



Calibrating flows and volume

1. Turn the Pony graphic on and confirm or change the date.
2. Disable the expiratory correction following the instruction written in the "Calculating the BTPS factor" paragraph.
3. At the request *"Select a function"* execute a FVC or a VC test, using the calibrated syringe in order to obtain a comparison between the volume of the Turbine Flow meter and the syringe one. If the volume is the same you should not calibrate the system, vice versa execute as it is described below.
4. Access to the Utility menu pressing the **Utility** menu.
5. Press the **6** key to open the **Configure** menu.
6. Press the **1** key and insert:
   • The value measured in cl
   • The predicted value in cl (300 if you are checking the system with a 3- litres syringe)
7. Press the **Enter** key obtaining the Flow/Volume correction.
8. To store the new correction type **369** and press **Enter** to confirm.
9. Enable the expiratory correction following the instruction written in the"Calculating the BTPS factor" paragraph.

The calibration is indicated by a message and the print out of new correction Flow /Volume result.

Notice: *We advice you to maintain the print out of the new correction F/V result, since, in case the Pony could lose the data for a batteries discharge, such value will be requested. If such value had been lost execute the system calibration again .*

The calibration F/V= 100 value correspond to no correction.

The sistem maintenance

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

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

Cleaning and disinfection instructions are of fundamental importance to control infections and assure patient safety. In fact aspiration of residue, particulates and contaminates are life – threatening.

In this handbook is recommended 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 and adapted for COSMED products in the following part:

- Accessible internal as well as external surfaces of equipment exposed to expirates should be washed and disinfected prior to testing of subsequent patients.
- Disinfection should ideally be performed by heat sterilization, but gas or liquid sterilization 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. tubercolosis, multidrug – resistant staphylococcus). In these cases, the clinical need for such testing should justify the risks.

During 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 unealthy 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.

The mouthpieces are single use not sterilized accessories. It is highly recommended to follow the suggestions given in the handbook concerning the *general rules for infection control in lung tests*.

In order to ensure maximum precision in measurements, we advise you to disinfect the system periodically.

As disinfecting solution it is suggested Sodium hypoclhorite 5% (bleach).

To disinfect the turbine, pour one litres of water and add the disinfecting solution. The disinfection procedure is easy and can be effected every time it will be necessary, keeping attention to some precautions.

To dean the turbine

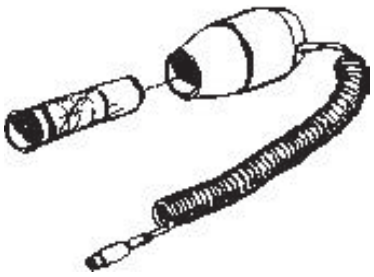
The following is the disinfection procedure you should follow:

1. Disassemble the Turbine Flow meter as described in the figure below.
2. Dip it in a disinfecting solution for about 2 hours.
3. Rinse it in a container filled with clean water and shaking gently until it is clean (do not clean the Turbine by putting it under running water!)
4. Let it dry to the air

Notice: *Do not expose the Turbine or any part of the system to high heat and do not put it under running water!*

After having cleaned the Turbine, check if the Turbine propeller rotates freely even with a low speed air flow.

At the end reassemble the Turbine as it is described in the figure below.



Inspections

The equipment needs 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, is important to control the conditions of insulation materials of cables, plugs and of 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.

Mechanical parts to be checked are essentially the turbine flowmeter and the breathing circuits. Follow these instructions:

- extract the turbine flowmeter form the optoelectronic reader;
- verify, by inspection, that the turbine axis fits correctly in 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).

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

Troubleshooting

It is possible to solve some problems of the system directly, without contacting your nearest technical assistance. If you need a further help consult the information of the following paragraph.

The printer is locked

- Check the paper is not jammed.
- Check the batteries charge.

The Pony points out a memory lost

If the batteries are discharged, the Pony graphic loses some or all the stored data. Therefore insert the predicted data to re configure the system (ID code, F/V factor, predicted values, automatic diagnosis , unit of measurement).

During the execution the loop doesn't appear

- Check the Turbine connector is connected properly
- Check the Turbine is deeply inserted in the optoelectronic reader
- Blowing in the Turbine, check it rotates freely, otherwise clean it as it is described in the previous paragraph.

Batteries are not being charged

- Check if the green led down on the left is on
- Check if there is current in the power plug
- Check that the batteries charger connector is inserted properly
- Before connecting the battery charger, make sure you are using the proper voltage and frequency

The Pony does not transmit the data to the PC

- Make sure the serial port RS 232 selected for the transmission is configured properly with the Software.
- Check the serial cable connectors are inserted properly.

The external printer doesn't print

- Check the cable is the RS232 provided by Cosmed and make sure it is correctly connected.

- Check the printer uses the HP PCL3 or following printing language.
- Check on the manual printer that its communication protocol is the following:

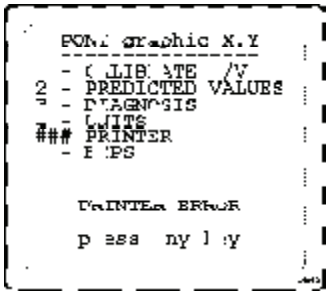
Bit number	8
Parity	None
Speed	9600 Baud
Bit Stop	2

Error messages

The Pony graphic points out if the system is not working properly, by means of the following displayed message:

Two can be the likely problems:

Problem	Solution
Printer failure	Remove the printer cover and make sure the paper is inserted properly.
Batteries discharged	Charge the Pony graphic batteries.
Printer error	Check if the external printer has been set up properly.



Assistance, Warranty

If you can not solve the problems independently, contact Cosmed or your nearest technical assistance centre.

Returning the system for service

In case you should send the system for repair, send it directly to 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. +39-06-93.25.492
fax +39-06-93.14.580

email: customersupport@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 packing box. You may need it if it is necessary to ship it to a technical assistance centre.

Warranty

The system is provided with a 12 months warranty, starting from the purchasing date . It covers failures happened during normal use of the system, due to provable faults of the components or to manufacture.

Exclusions

The following components are excluded from warranty:

- Parts subject to consume
- Fragile parts of glass or plastic
- The batteries, the rechargeable batteries
- Damages of the paintings
- Damages due to a not proper use of the system or failure to observe the manual instructions.

In case the warranty is expired, send besides the system, the copy of a document (such a bill of lading or invoice), which prove the purchase date.

The transport must be executed in free port and it will be re-shipped charges collect. In case of transport damages this costs will be charged to the buyer.

Information form for assistance

Fill a photocopy of the form and send it with the system.

If not, the repair can not be effected.

Information form for assistance

Client ..... Date.....

Address.....

City..... zip .....

tel..... fax .....

Vat number.....

System

Model .....S/N.....

Purchase date.....(enclose the bill of lading or invoice)

Maintenance contract n°:..... (if there is one)

Before sending the system, make sure you have executed the procedures of the paragraph " Problem solving "properly. Do not send superfluous accessories for assistance (manuals, consumables etc.).

List of the sent parts

.....

.....

.....

Trouble description

.....

.....

.....

.....

Is the failure intermittent? yes ❒ not ❒

When the system is delivered, enclose any evident printout.

Delivering instructions

.....

.....

.....

ATS 94 recommendations

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

ATS recommendations

Range Volume:	8l (BTPS)
Range Flow:	±14 l/sec
Accuracy Volume:	± 3% or < 50 ml
Accuracy Flow:	± 5% or < 200 ml/s
Flow resistance:	< 1.5 cmH_2O at 14 l/s

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 manoeuvres 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.

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. Features F/V e V/t.

Predicted values

Here are the formula to calculate the predicted values.

Generality

In the following formula are respected these conventions:

Ht Height in cm

Wt Weight in kg

BSA Body Surface Area cm^2

Age Age in year

SD Standard Deviation

The formula of the Body Surface Area :

$BSA(m^2)(71.84^* \times Wt^{0.425^*} \times Ht^{0.725})/1000$

The software allows the calculation of the Predicted values according to the following forms:

ERS 93

Reference Adult:

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

Reference Paediatric:

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.

Males (> 18 years)

Symbol	Formula	SD
IVC	0.061*H-0.028*A-4.65	0.56
FVC	0.0576*H-0.026*A-4.34	0.61
TLC	0.0799*H-7.08	0.7

RV	0.0131*H+0.022*A-1.23	0.41
FRC	0.0234*H+0.009*A-1.09	0.6
RV/TLC	0.39*A+13.96	5.46
FRC/TLC	0.21*A+43.8	6.74
FEV1	0.043*H-0.029*A-2.49	0.51
FEV1/FVC	-0.18*A+87.21	7.17
FEV1/VC	-0.18*A+87.21	7.17
FEF25%-75%	0.0194*H-0.043*A+2.7	1.04
Vmax25%	0.0546*H-0.029*A-0.47	1.71
Vmax50%	0.0379*H-0.031*A-0.35	1.32
Vmax75%	0.0261*H-0.026*A-1.34	0.78
PEF	0.0614*H-0.043*A+0.15	1.21
MVV	1.19*H-0.816*A-37.95	
ERV	Pred FRC-PredRV	
VC	Pred IVC	0.56

Females (> 18 years)

Symbol	Formula	SD
IVC	0.0466*H-0.026*A-3.28	0.42
FVC	0.0443*H-0.026*A-2.89	0.43
TLC	0.066*H-5.79	0.6
RV	0.0181*H+0.016*A-2	0.35
FRC	0.0224*H+0.001*A-1	0.5
RV/TLC	0.34*A+18.96	5.83
FRC/TLC	0.16*A+45.1	5.93
FEV1	0.0395*H-0.025*A-2.6	0.38
FEV1/FVC	-0.19*A+89.1	6.51
FEV1/VC	-0.19*A+89.1	6.51
FEF25%-75%	0.0125*H-0.034*A+2.92	0.85
Vmax25%	0.0322*H-0.025*A+1.6	1.35
Vmax50%	0.0245*H-0.025*A+1.16	1.1
Vmax75%	0.0105*H-0.025*A+1.11	0.69
PEF	0.055*H-0.03*A-1.11	0.9
MVV	0.842*H-0.685*A-4.87	
ERV	PredFRC-PredRV	
VC	Pred IVC	0.42

Males (< 18 years)

Symbol	Formula	SD
IVC	7.9942-0.12509*H+0.000605*H^2	0.393
FVC	PredIVC0.393	
TLC	15.1397-0.22713*H+0.001002*H^2	
RV	-1.052+0.012*H	
FRC	9.372-0.1415*H+0.000602*H^2	0.35
RV/TLC	34.7-0.0647*H	3.91
FRC/TLC	38.73+0.0615*H	4
FEV1	6.6314-0.10261*H+0.000499*H^2 0.523	
FEV1/FVC	84.47	4.55
FEV1/VC	84.47	4.55
Vmax25%	-6.822+0.07811*H	
Vmax50%	-4.5848+0.0543*H	
Vmax75%	-2.3069+0.02817*H	
PEF	-6.9865+0.0806*H	
VC	PredFVC	

Females (< 18 years)

Symbol	Formula		SD
IVC	PredFVC	0.263	
FVC	0.169-0.01217*H+0.000189*H^2		0.263
TLC	1.7592-0.03394*H+0.0003*H^2		
RV	-0.805+0.0109*H		
FRC	0.02556*H-2.1778	0.26	
RV/TLC	34.7-0.0647*H		3.91
FRC/TLC	38.73+0.0615*H		4
FEV1	0.0364*H-3.0378		0.42
FEV1/FVC 84.47		4.55	
FEV1/VC	84.47		4.55
Vmax25%	0.06367*H-5.1934		
Vmax50%	0.04477*H-3.3655		
Vmax75%	0.02483*H-1.8576		
PEF	0.06594*H-5.3794		
VC	PredFVC	0.263	

KNUDSON 83

Reference Adult/Paediatric

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

Note: SD@FEV1/FVC and FEV1/VC from ERS93

Males (> 25 years)

Symbol	Formula	SD
IVC	PredFVC	1.183
FVC	-8.7818+0.0844*H-0.0298*A	1.183
FEV1	-6.5147+0.0665*H-0.0292*A	1.017
FEV1/FVC	PredFEV1/PredFVC*100	6.51
FEV1/VC	PredFEV1/PredVC*100	6.51
FEF25%-75%	-4.5175+0.0579*H-0.0363*A	1.422
Vmax50%	-5.5409+0.0684*H-0.0366*A	1.624
Vmax75%	-2.4827+0.031*H-0.023*A	0.884
MVV	PredFEV1*40	
VC	PredFVC	1.183

Females (> 20 years)

Symbol	Formula	SD
IVC	PredFVC	0.721
FVC	-2.9001+0.0427*H-0.0174*A	0.721
FEV1	-1.405+0.0309*H-0.0201*A	0.65
FEV1/FVC	PredFEV1/PredFVC*100	6.51
FEV1/VC	PredFEV1/PredVC*100	6.51
FEF25%-75%	1.1277+0.0209*H-0.0344*A	1.131
Vmax50%	0.6088+0.0268*H-0.0289*A	1.178
Vmax75%	1.1177+0.0096*H-0.0259*A	0.848
MVV	PredFEV1*40	
VC	PredFVC	0.721

Males (< 25 years)

Symbol	Formula		SD
IVC	PredFVC	1.048	
FVC	-6.8865+0.059*H+0.0739*A		1.048
FEV1	-6.1181+0.0519*H+0.0636*A		0.932
FEV1/FVC	PredFEV1/PredFVC*100	4.55	
FEV1/VC	PredFEV1/PredVC*100		4.55
FEF25%-75%	-6.199+0.0539*H+0.0749*A		1.315
Vmax50%	-6.3851+0.0543*H+0.115*A	1.504	
Vmax75%	-4.2421+0.0397*H	0.89	
MVV	PredFEV1*40		
VC	PredFVC	1.048	

Females (< 20 years)

Symbol	Formula	SD
IVC	PredFVC	0.716
FVC	-4.447+0.0416*H+0.0699*A	0.716
FEV1	-3.7622+0.0351*H+0.0694*A	0.622
FEV1/FVC	PredFEV1/PredFVC*100	4.55
FEV1/VC	PredFEV1/PredVC*100	4.55
FEF25%-75%	-2.8007+0.0279*H+0.1275*A	1.01
Vmax50%	-2.304+0.0288*H+0.1111*A	1.074
Vmax75%	0.024*H-4.4+0.2925*A-0.0075*A^2	0.763
MVV	PredFEV1*40	
VC	PredFVC	0.716

ITS White

Reference Adult/Paediatric

Intermountain Thoracic Society

Note: SD@FEV1/FVC and FEV1/VC from ERS93

Males (> 19years)

Symbol	Formula		SD
IVC	PredFVC	0.57	
FVC	-4.65+0.06*H-0.0214*A		0.57

FEV1	-2.19+0.0414*H-0.0244*A	0.43	
FEV1/FVC	110.49-0.13*H-0.152*A	4.23	
FEV1/VC	PredFEV1/FVC		4.23
FEF25%-75%	-2.133+0.038*H-0.0204*A	0.85	
Vmax25%	0.088*H-0.035*A-5.62		
Vmax50%	0.0684*H-0.0366*A-5.54		
Vmax75%	0.031*H-0.023*A-2.48		
PEF	0.094*H-0.035*A-5.99		
MVV	1.34*H-1.26*A-21.4		28.97
VC	PredFVC	0.57	
PIF	1.19*BSA-0.023*A+3.09		

Females (> 19 years)

Symbol	Formula		SD
IVC	PredFVC	0.35	
FVC	-3.59+0.0491*H-0.0216*A	0.35	
FEV1	-1.578+0.0342*H-0.0255*A	0.29	
FEV1/FVC	126.58-0.202*H-0.252*A	4.7	
FEV1/VC	PredFEV1/FVC		4.7
FEF25%-75%	2.683+0.0154*H-0.046*A		0.69
Vmax25%	0.043*H+0.025*A-0.13		
Vmax50%	0.0321*H-0.024*A-0.44		
Vmax75%	0.0174*H-0.025*A-0.18		
MVV	0.807*H-0.57*A-5.5		10.71
VC	PredFVC	0.35	
PIF	1.15*BSA-0.014*A+2.73		

Males (< 18 years)

Symbol	Formula		SD
IVC	PredFVC	1.048	
FVC	0.000358*H^3.18/1000		1.048
FEV1	0.000774*H^3/1000		0.932
FEV1/FVC	PredFEV1/PredFVC*100	4.55	
FEV1/VC	PredFEV1/PredVC*100		4.55
FEF25%-75%	0.000798*H^2.46/60		0.13

Vmax25%	0.07*H+0.147*A-7.05		
Vmax50%	0.0543*H+0.115*A-6.39		
Vmax75%	0.0397*H-0.0057*A-4.24		
PEF	0.078*H+0.166*A-8.06		
MVV	PredFEV1*40		
VC	PredFVC	1.048	
PIF	2.57*BSA+0.17*A-2.27		

Females (< 18 years)

Symbol	Formula		SD
IVC	PredFVC	0.716	
FVC	0.00257*H^2.76/1000		0.716
FEV1	0.00379*H^2.68/1000		0.622
FEV1/FVC	PredFEV1/PredFVC*100	4.55	
FEV1/VC	PredFEV1/PredVC*100		4.55
FEF25%-75%	0.00379*H^2.18/60		0.14
Vmax25%	0.044*H+0.144*A-3.37		
Vmax50%	0.0288*H+0.1111*A-2.3		
Vmax75%	0.0243*H+0.2923*A-0.0075*A^2-4.4		
PEF	0.049*H+0.157*A-3.92		
MVV	PredFEV1*40		
VC	PredFVC	0.716	
PIF	0.06*H-5.26		

ITS Black

Reference Adult/Pediatric

Intermountain Thoracic Society

Note: SD@FEV1/FVC and FEV1/VC from ERS93

Males (> 19 years)

Symbol	Formula		SD
IVC	PredFVC	0.57	
FVC	-4.65+0.06*H-0.0214*A		0.57
FEV1	-2.19+0.0414*H-0.0244*A	0.43	

FEV1/FVC	110.49-0.13*H-0.152*A	4.23	
FEV1/VC	PredFEV1/FVC		4.23
FEF25%-75%	-2.133+0.038*H-0.0204*A	0.85	
Vmax25%	0.088*H-0.035*A-5.62		
Vmax50%	0.0684*H-0.0366*A-5.54		
Vmax75%	0.031*H-0.023*A-2.48		
PEF	0.094*H-0.035*A-5.99		
MVV	1.34*H-1.26*A-21.4		28.97
VC	PredFVC	0.57	
PIF	1.19*BSA-0.023*A+3.09		

Females (> 19 years)

Symbol	Formula		SD
IVC	PredFVC	0.35	
FVC	-3.59+0.0491*H-0.0216*A	0.35	
FEV1	-1.578+0.0342*H-0.0255*A	0.29	
FEV1/FVC	126.58-0.202*H-0.252*A	4.7	
FEV1/VC	PredFEV1/FVC		4.7
FEF25%-75%	2.683+0.0154*H-0.046*A		0.69
Vmax25%	0.043*H+0.025*A-0.13		
Vmax50%	0.0321*H-0.024*A-0.44		
Vmax75%	0.0174*H-0.025*A-0.18		
MVV	0.807*H-0.57*A-5.5		10.71
VC	PredFVC	0.35	
PIF	1.15*BSA-0.014*A+2.73		

Males (< 18 years)

Symbol	Formula		SD
IVC	PredFVC	1.048	
FVC	0.00107*H^2.93/1000		1.048
FEV1	0.00103*H^2.92/1000		0.932
FEV1/FVC	PredFEV1/PredFVC*100	4.55	
FEV1/VC	PredFEV1/PredVC*100		4.55
FEF25%-75%	0.000361*H^2.6/60		0.18
Vmax25%	0.07*H+0.147*A-7.05		

Vmax50%	0.0543*H+0.115*A-6.39		
Vmax75%	0.0397*H-0.0057*A-4.24		
PEF	0.078*H+0.166*A-8.06		
MVV	PredFEV1*40		
VC	PredFVC	1.048	
PIF	2.57*BSA+0.17*A-2.27		

Females (< 18 years)

Symbol	Formula		SD
IVC	PredFVC	0.076	
FVC	0.000834*H^2.98/1000		0.076
FEV1	0.00114*H^2.89/1000		0.622
FEV1/FVC	PredFEV1/PredFVC*100	4.55	
FEV1/VC	PredFEV1/PredVC*100		4.55
FEF25%-75%	0.00145*H^2.34/60		
Vmax25%	0.044*H+0.144*A-3.37		
Vmax50%	0.0288*H+0.1111*A-2.3		
Vmax75%	0.0243*H+0.2923*A-0.0075*A^2-4.4		
PEF	0.049*H+0.157*A-3.92		
MVV	PredFEV1*40		
VC	PredFVC	0.076	
PIF	0.06*H-5.26		

Lam

Reference Adult/Pediatric

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.

Note: SD@FEV1/FVC and FEV1/VC from ERS93

Males (> 20 years)

Symbol	Formula	SD
IVC	PredFVC	(H/100)^2*0.22
FVC	(H/100)^2*(-0.013*A+1.912)	(H/100)^2*0.22
FEV1/FVC	PredFEV1/PredFVC*100	4.23

FEV1/VC	PredFEV1/PredVC*100	4.23
PEF	(0.86*A-0.00047*A^3+313.4)/60	0.84
MVV	PredFEV1*40	
VC	PredFVC	(H/100)^2*0.19
FEV1	(H/100)^2*(-0.016*A+1.823)	(H/100)^2*0.19

Females (> 20 years)

Symbol	Formula	SD
IVC	PredFVC	(H/100)^2*0.19
FVC	(H/100)^2*(-0.01*A+1.518)	(H/100)^2*0.19
FEV1	(H/100)^2*(-0.012*A+1.442)	(H/100)^2*0.17
FEV1/FVC	PredFEV1/PredFVC*100	4.7
FEV1/VC	PredFEV1/PredVC*100	4.7
PEF	(0.45*A-0.00032*A^3+259.7)/60	0.62
MVV	PredFEV1*40	
VC	PredFVC	(H/100)^2*0.19

Males (< 20 years)

Symbol	Formula	SD
IVC	PredFVC	(H/100)^2*0.17
FVC	(H/100)^2*(0.064*A+0.335)	(H/100)^2*0.17
FEV1	(H/100)^2*(0.059*A+0.322)	(H/100)^2*0.15
FEV1/FVC	PredFEV1/PredFVC*100	4.55
FEV1/VC	PredFEV1/PredVC*100	4.55
PEF	(15.08*A-0.0075*A^3+75.5)/60	0.54
MVV	PredFEV1*40	
VC	PredFVC	(H/100)^2*0.17

Females (< 20 years)

Symbol	Formula	SD
IVC	PredFVC	(H/100)^2*0.19
FVC	(H/100)^2*(0.041*A+0.507)	(H/100)^2*0.19
FEV1	(H/100)^2*(0.04*A+0.454)	(H/100)^2*0.17
FEV1/FVC	PredFEV1/PredFVC*100	4.55
FEV1/VC	PredFEV1/PredVC*100	4.55
PEF	(19.96*A-0.0209*A^3+33.8)/60	0.52
MVV	PredFEV1*40	
VC	PredFVC	(H/100)^2*0.19

Multicèntrico di Barcelona

Adult/Pediatric

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.

Males (> 20 years)

Symbol	Formula	SD
FVC	0.0678*Ht-0.0147*A-6.05	0.530
FEV1	0.0499*Ht-0.0211*A-3.84	0.444
FEV1/FVC%	85.58-0.1902*A	5.36
FEF25%-75%	0.0392*Ht-0.0430*A-1.16	1.000
PEF	0.0945*Ht-0.0209*A-5.77	1.470
Vmax75%	0.0190*Ht-0.0356*A-0.14	0.620
Vmax50%	0.0517*Ht-0.0397*A-2.40	

Females (> 20 years)

Symbol	Formula	SD
FVC	0.0454*Ht-0.0211*A-2.83	0.403
FEV1	0.0317*Ht-0.0250*A-1.23	0.307
FEV1/FVC%	-0.224*A-0.1126*W+94.88	5.31
FEF25%-75%	0.0230*Ht-0.0456*A+1.11	0.680
PEF	0.0448*Ht-0.0304*A+0.35	1.040
Vmax75%	0.02*Ht*0.031*A*0.0062*W*0.21	0.405
Vmax50%	0.0242*Ht*0.0418*A*1.62	0.925

Males (< 20 years)

Symbol	Formula	SD
FVC	0.02800*Ht+0.03451*W+0.05728*A-3.21	0.443
FEV1	0.02483*Ht+0.02266*W+0.07148*A-2.91	0.378
FEF25%-75%	0.038*Ht+0.140*A-4.33	0.796
PEF	0.075*Ht+0.275*A-9.08	1.073
Vmax75%	0.024*Ht+0.066*A-2.61	0.562
Vmax50%	0.017*Ht+0.157*A+0.029*W-2.17	0.811

Females (< 20 years)

Symbol	Formula	SD
FVC	0.03049*Ht+0.02220*W+0.03550*A-3.04	0.313
FEV1	0.02866*Ht+0.01713*W+0.02955*A-2.87	0.263
FEF25%-75%	0.046*Ht+0.051*A-4.30	0.651
PEF	0.073*Ht+0.134*A-7.57	0.831
Vmax75%	0.027*Ht+0.032*A-2.68	0.507
Vmax50%	0.046*Ht+0.067*A-4.17	0.669

Automatic diagnosis

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

LLN=Pred*0,8 (80% of the Pred.)

The AD is carried out at the end of the FVC manoeuvre if:

1. The automatic diagnosis is enable.
2. The patient’s data allows the calculation of the LLN.
3. It has been carried out a FVC PRE test.

Interpretation message	Criterion
Normal spirometry	FVC and FEV1/FVC >LLN
Obstructive abnormality	
Mild	% Pred FEV1<100 and 70
Moderate	% Pred FEV1<70 and 60
Moderately severe	% Pred FEV1<60 and 50
Severe	% Pred FEV1<50 and 34
Very severe	% Pred FEV1<34
Restrictive abnormality	
Mild	FVC<LLN e % Pred FVC70
Moderate	% Pred FVC<70 and 60
Moderately severe	% Pred FVC<60 and 50
Severe	% Pred FVC<50 and 34
Very severe	% Pred FVC<34

Quality Control Messages

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

QC Message	Criterion
Star faster	VEXT >5% della FVC e >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% best FEV1
That was a good test	No errors
FVC reproducible	At least 3 acceptable maneouvres. The 2 largest FVC within 0.2l of each other FVC
FEV1 reproducible	At least 3 acceptable maeouvres. The 2 largest FEV1 within 0.2l of each other.
PEF reproducible	The 2 largest PEF within 10 %
MVV time too short	MVV time less than 12 sec

Bibliography

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

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

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

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

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

This manual has been compiled by means of Adobe Page Maker 6.0 , Microsoft word and Cad programs.

Pony graphic user manual IV Revision.

May 2000 COSMED srl - Italy

Part n° C00296-02-91

Table of Contents