SDI DIAGNOSTICS
Astra Pro
SPIROMETRY SOFTWARE

USER'S MANUAL

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1. SAFETY

1.1. SPECIAL PRECAUTIONS

The **SDI DIAGNOSTICS Astra Pro** spirometry software has been designed for use with the safety in mind. All operating instructions must be read before using it. Failure to do so could cause injury to the user or patient and damage to the equipment and/or accessories.

This spirometry software can be used in conjunction with several spirometers manufactured by SDI DIAGNOSTICS. It is very important to carefully read the User's Manual of the spirometer before using it with the software, especially the SAFETY section where all the safety considerations related to the spirometer are explained in detail.

1.2. INTENDED USE

The Astra Pro software when is used stand-alone can perform:

a) Numerical & Graphical representation of stored measurement tests (lung flows and volumes, blood oxygen saturation and respiratory pressures)
b) Diagnostic of lung flow and volume measurements
c) Test import and export from/to patient database

Furthermore, the Astra Pro Software when is used connected to the compatible ASTRA spirometers can perform and store in a patient database:

d) Signal acquisition and parametric calculus of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
e) Signal acquisition and parametric calculus of peripheral blood oxygen saturation and cardiac pulse for the respiratory diagnostic.

f) Signal acquisition and parametric calculus of inspiratory and expiratory maxima pressures for the respiratory diagnostic.

1.3. INTENDED PATIENT POPULATION

a) Age: more than 4 years until elderly

b) Weigth: > 15 Kg

c) Height: > 50 cm

d) Health status: physical and mental condition that allows the performance of the forced expiratory maneuver

1.4. USER PROFILE

The spirometry software is intended to be used by or under the direction of a medical professional. Specific training on the Spirometry technique is recommended.

Bronchoconstriction test must be supervised by a qualified technician in the art.

Before using the spirometry software on patients, you should be familiar with its operation. All information necessary for its operation is available in this Manual.

For additional training on the technique or on the product, contact SDI DIAGNOSTICS or your local dealer.

1.5. EFFECTS ON PATIENTS USING THE SPIROMETRY SOFTWARE

The spirometry tests require patient cooperation.

Complete forced expiration is required to obtain meaningful patient FVC values. The clinician administering the test must assess the patient's capacity to perform the spirometry test. Special attention must be paid to children, the elderly and the disabled.

An analysis of the results of spirometry tests is not enough to give a correct diagnosis of the patient's clinical condition. The patient's records and any tests that the clinician believes necessary must therefore also be considered. A doctor must interpret all data to determine the course of treatment required.

The patient's symptoms and capacity to perform a spirometry test must be taken into account by medical staff before any spirometric testing is undertaken. Acceptability of a test is the responsibility of the medical professionals.

The spirometry software should not be used when it is likely that the validity of the results could be compromised by external factors.

All accessories and spare parts must be originals and they must be requested from the manufacturer or authorized dealer in order to ensure the safety of the patient and the correct working order of the spirometer. Failure to do so may result in an increase of emissions or in a decrease of the immunity of the equipment.

2. INSTRUCTIONS FOR USE AND INSTALLATION

2.1 INTRODUCTION

The **SDI DIAGNOSTICS Astra Pro** is a software application for the transfer, analysis, storage and/or register of spirometric signals which works under 100/200/300soft Windows.

It is compatible with different ASTRA spirometers, among them, the **ASTRA TOUCH and A** and it can work in real time or deferred time, depending on the spirometer characteristics.

It allows:

- The management of different databases
- The performance of FVC, VC, MVV, Postbronchodilation and bronchoconstriction tests when connected to a compatible spirometer
- The graphic presentation in F/V and V/T modes
- The selection of different Reference Parameters
- The selection of different types of diagnosis
- The printing of different reports
- The presentation of graphics for motivated tests for children
- The performance of SpO2, MEP-MIP and Sniff pressure measurement tests when connected to a compatible spirometer supporting this functions

2.2 PREVIEW

This product is manufactured under strict quality controls. Nevertheless, accidents may happen in the transport or storage, so it is convenient to make a status check before installing it, as well as of its accessories.

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** consists of:

REF	Qty	Description
	1	Spirometry Software Astra Pro (CD media)
	1	Spirometry Software Astra Pro User Manual English Language (CD media)

The software has the possibility to enable the next software options:

REF	Description
	Bronchoconstriction Software option for Astra Pro
	MIP-MEP / Sniff Software option for Astra Pro
	Pulse oximetry Software option for Astra Pro
	HIS connectivity module compatible ECAP (ICS) for Astra Pro Spirometry software
	Standard HIS connectivity module for Astra Pro Spirometry software

Optional external software module:

	SibelHL7Link Module (HL7, CDA, XML)

Spare Parts and components:

REF	Description
	USB CableType A-B 2.0
	Serial connection RS-232 Cable for PC
	Bluetooth USB-PC adapter
	Galvanic isolator for USB
	Ethernet Cable

2.3 MANUFACTURER'S LIABILITY

SDI DIAGNOSTICS is only liable for the safety, reliability and working order of this product if:

- The computer, monitor and accessories where the software is used, meet the low voltage Directive (particularly EN60950 standard) and EMC Directive (particularly EN55022, EN61000-3-2, EN61000-3-3 and EN55024 standards)

- The repairs, checks or modifications, inside or outside the warranty period, are made by technical staff at SDI DIAGNOSTICS.

- The use of the software and the recommendations of use are made by qualified staff, according to the User's Manual.

- It is recommended to store the CD ROM at 25ºC, see Technical specifications

According to the different standards, it is advisable to verify and/or calibrate the medical products periodically, in order to warrant the liability of its functions and the security of the patient, user and environment.
It is advisable to make a general check of its safety systems, adjustments, functions, etc. with annual periodicity. Do not surpass eighteen months without doing it in any case. Make a check at any moment when a wrong functioning of the product is suspected.
These revisions must be done according to the Verifying and Adjustment Procedures of the manufacturer (SDI DIAGNOSTICS), by the manufacturer himself or the qualified staff authorised by SDI DIAGNOSTICS.

The software Astra Pro runs on PC, make sure you save the test before turning off the PC or disconnect the communications cable.

Verify that the hardware of your PC works properly.

Verify your operating system is properly installed and updated

Check if software updates are available Astra Pro

2.4 INSTALLATION AND SETUP

2.4.1 SPIROMETRY SOFTWARE INSTALLATION

The user must have administrator rights in order to install all the program's features. In case of any doubts, contact your System Administrator or check the help of the Operating System.

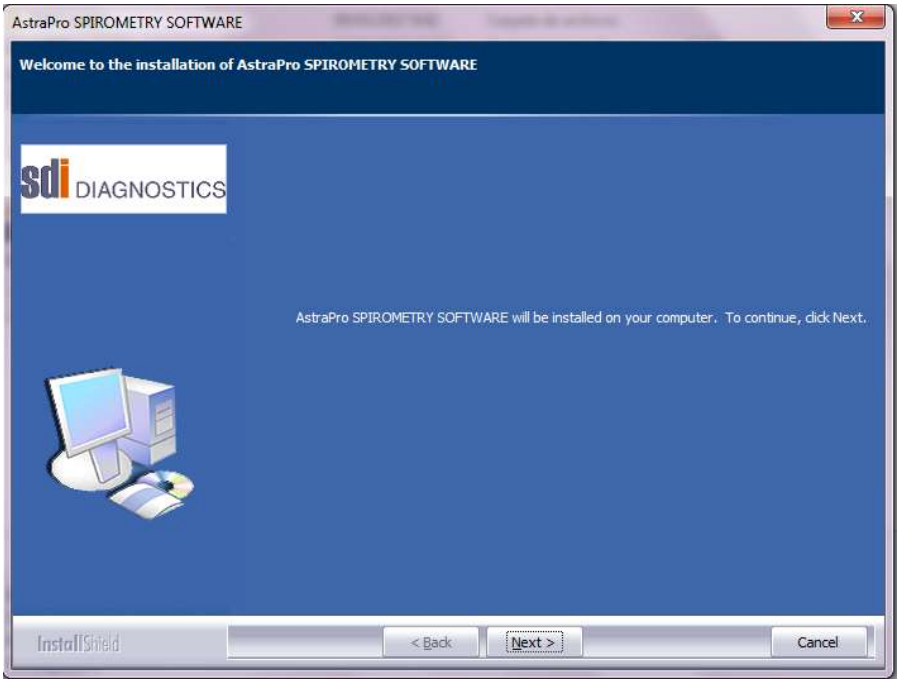
For the Software installation in PC hard disk media, you should proceed as follows:

1 Introduce the **CD_ROM** in the CD-ROM reading unit.

2 If the PC's CD_ROM unit has the auto run option enabled, it will run to the automatic installation, otherwise the program **Setup.exe** should be executed after acceding to the corresponding CD_ROM unit.

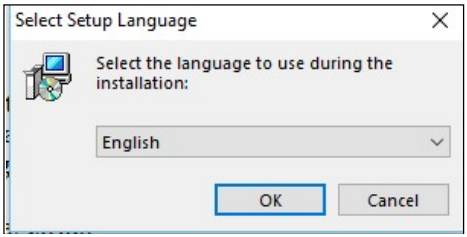
3 In the next window select the language for the setup process.

3 Please choose the directory where to install the program and the group of programs' name. The program's default installation directory is**: C:\SDI\Astra Pro**.

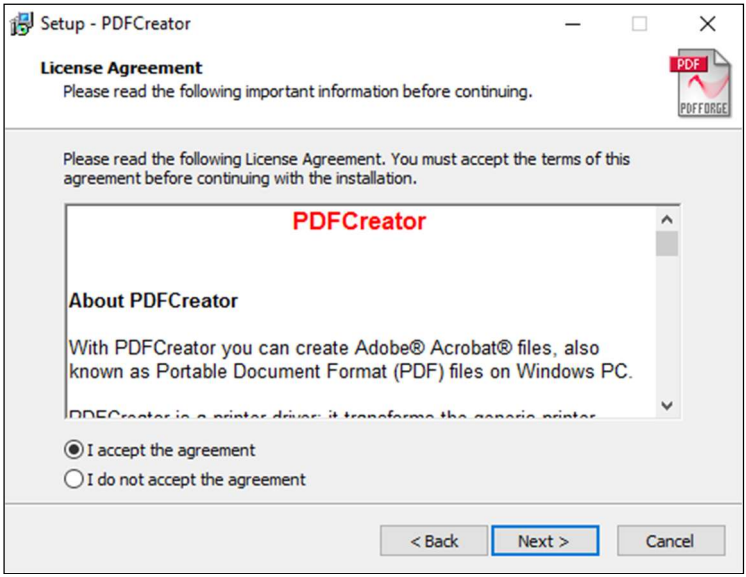


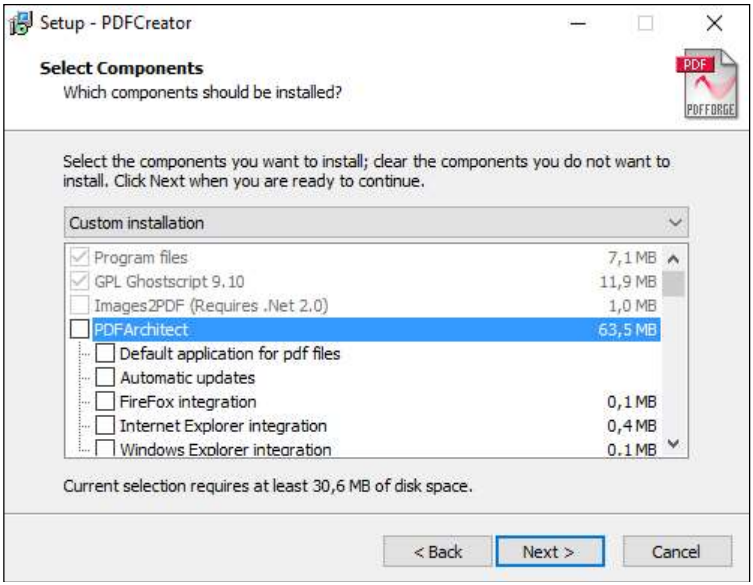
5 To print reports in PDF format, you must install the PDFCreator application, choosing the installation options that are displayed in the following screens. Please make sure you do not

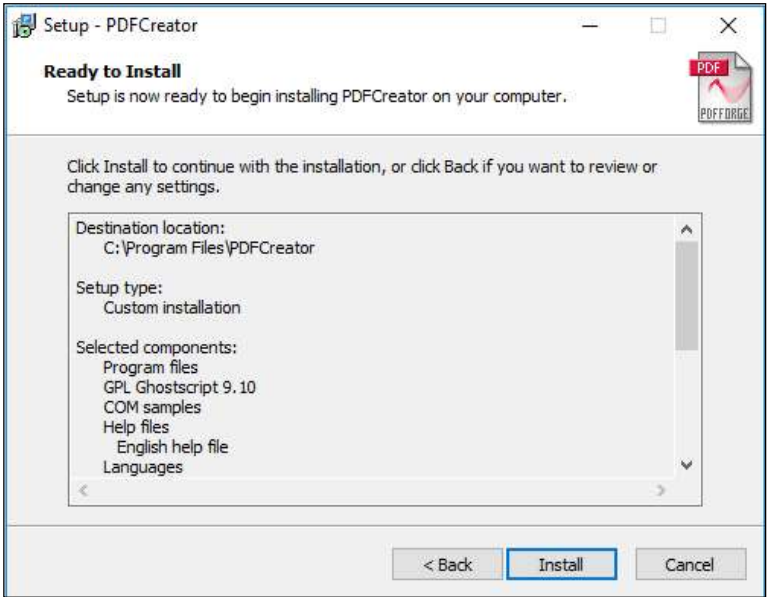
update the PDF Creator version as suggested by the setup program.
Note: The application Adobe Reader only allows viewing PDF files, not to print them.



In case the PDF Creator setup program asks to download a new versión simply select 'No'.


Setup - PDFCreator
License Agreement
Please read the following important information before continuing.
PDF
PDFFORGE
Please read the following License Agreement. You must accept the terms of this agreement before continuing with the installation.
PDFCreator
About PDFCreator
With PDFCreator you can create Adobe® Acrobat® files, also known as Portable Document Format (PDF) files on Windows PC.
I accept the agreement
I do not accept the agreement
< Back
Next >
Cancel


Setup - PDFCreator
Select Components
Which components should be installed?
Select the components you want to install; clear the components you do not want to install. Click Next when you are ready to continue.
Custom installation
Program files 7,1 MB
GPL Ghostscript 9.10 11,9 MB
Images2PDF (Requires .Net 2.0) 1,0 MB
PDFArchitect 63,5 MB
Default application for pdf files
Automatic updates
FireFox integration 0,1 MB
Internet Explorer integration 0,4 MB
Windows Explorer integration 0.1 MB
Current selection requires at least 30,6 MB of disk space.
< Back
Next >
Cancel


Setup - PDFCreator
Ready to Install
Setup is now ready to begin installing PDFCreator on your computer.
Click Install to continue with the installation, or click Back if you want to review or change any settings.
Destination location:
C:\Program Files\PDFCreator
Setup type:
Custom installation
Selected components:
Program files
GPL Ghostscript 9.10
COM samples
Help files
English help file
Languages
< Back
Install
Cancel

6 Once the installation is done, it will create the **SDI** group of programs' or the one chosen by the user and a shortcut will be created on the desktop.

2.4.2 OPTIONAL MODULES ACTIVATION

In case you have acquired one or more optional modules of the Astra Pro software (**Bronchoconstriction, SpO_2 or MIP-MEP**), you will have to enter the correct 15-digit key supplied, in order to activate them. (Main Menu **Setup > Utilities > Options Activation).**

In case you have acquired the options but do not have the key available, please consult our after sales department.

2.4.3 BLUETOOTH MODULE INSTALLATION

A Bluetooth module needs to be installed on the PC for Bluetooth compatible spirometers.

The Bluetooth interface allows data to transfer to the computer, both for performing real-time testing and for transferring tests saved in the internal spirometer database.

The Bluetooth chip installed in the spirometer uses the «Bluetooth Series Port» service or profile (known as SPP). This will be the profile that must be installed in the computer to allow communications with the equipment.

The installation of the Bluetooth device on the computer may vary according to the device brand and according to the operating system that it is installed on. Consult the INSTALLATION MANUAL FOR BLUETOOTH ADAPTER provided with the Bluetooth module of each SDI DIAGNOSTICS spirometer and the User's Manual of each Bluetooth adapter.

2.4.4 USB DRIVER INSTALLATION

For USB compatible spirometers, a driver needs to be installed on the computer.

This driver is installed automatically during the installation of the Astra Pro software. To perform this process, simply disconnect the USB cable from the computer, install Astra Pro software and plug in the USB cable with the spirometer switched on. From this moment, the driver is installed and you can start communications with the device.

Note: in Windows XP, it is necessary to select the automatic installation option when the found new hardware wizard screen appears.

In addition to the automatic procedure, it is possible to install the driver manually. To perform this, follow these steps:

1 Start up the spirometer (Consult the corresponding manual for use).

2 Insert the Astra Pro Installation CD into the computer.

Windows XP:

3 Connect the spirometer to the computer with the USB cable (consult the corresponding manual for use). Being the first time the equipment is connected to the computer, the Windows «Found New Hardware Wizard» screen will appear. Select «No, not this time» and click «Next».

4 In the next window select the option «Install from a list or specific location» and click «Next».

5 Select the options «Search for the best driver in these locations» and «Include this location in the search:». Click «Browse» to select the folder X:\SDI\AstraPro\Driver_espiro\WIN_XP_7_8.1\x86. Click «Next».

6 Windows will start installing the driver. Click «Next» and «Finish» to close the wizard.

7 Click on Next and Finish. The Driver will now install itself.

Windows 7, Windows 8.1, Windows 10:

3 Open the device manager via «Start > Control panel > Hardware and sound > Device manager». In the «Device manager» dialog, locate the entry that corresponds to your device and double click on it.

4 Choose the «Driver tab» and click on the button «Update driver».

5 Click «Search for driver software on your computer» and in the next window use the «Browse» option to locate the folder X:\SDI\AstraPro\Driver_espiro\WIN_XP_7_8.1\x86 (for Windows 7, 8.1)or X:\SDI\AstraPro\Driver_espiro\WIN_10\x86 (for Windows 10) if the operating system is 32bit. If the operating system is 64bitthen select the folder X:\ SDI\AstraPro\Driver_espiro\WIN_XP_7_8.1\x64 (for Windows7, 8.1) or X:\ SDI\AstraPro\Driver_espiro\WIN_10\x64(for Windows 10)".

6 Click on Next and Finish. The Driver will be installed.

2.4.5 SETUP

Start the PC and run the program:

Press once over the icon **Astra Pro** found inside the folder of the start menu **Programs/SDI**.

Press **OK** on the screen **ABOUT ...** to enter the **DATABASE WINDOW**.

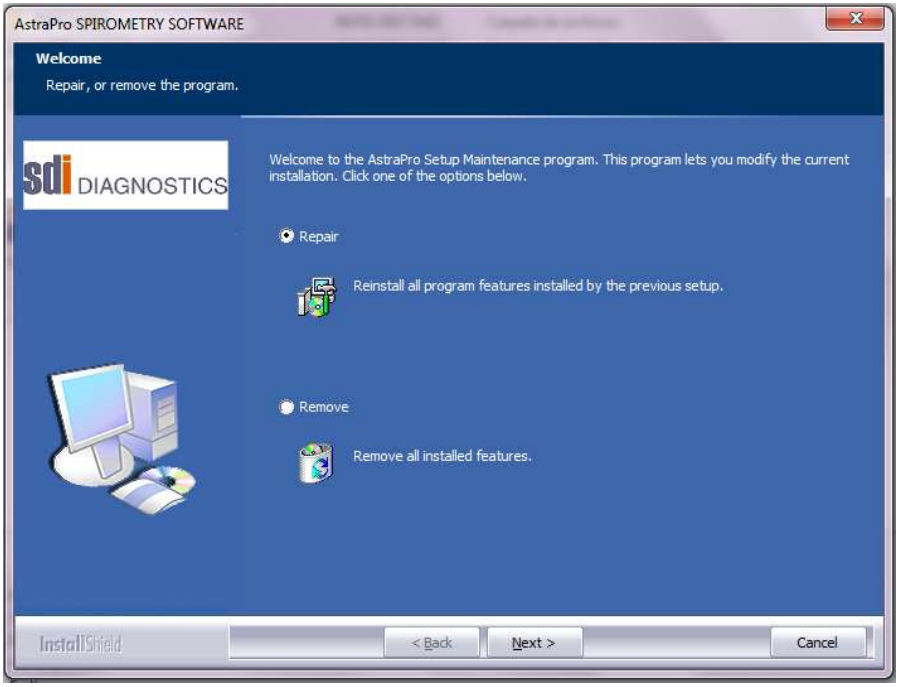
Connect the spirometer to the computer.

2.4.6 SPIROMETRY SOFTWARE UNINSTALLATION

1 Place the **CD_ROM** in the CD-ROM reading unit.

2 If the PC's CD_ROM drive unit has the auto run option active, it will run to the automatic installation, otherwise the program **Setup.exe** should be executed after acceding to the corresponding CD_ROM unit.

3 The next options can be chosen when the following window appears:



- **Repair**: It reinstalls the program. If there is a damaged or lost file, it will repair it.

- **Remove**: It uninstalls the software, but the database of the program is not deleted. It can be found in the folder where the software was installed.

2.5 ABOUT ON SCREEN HELP

The Spirometry Software **SDI DIAGNOSTICS Astra Pro** provides a link to the user manual to help the user to handle properly the different software options.

Generally, every screen has a Help menu that allows to open the user manual. This help is indicated in every screen with an icon, with text or both.

The user manual is in PDF format and is opened automatically with the software that Windows has registered as viewer of PDF files. If there is none, Windows will ask to select one.

2.6 DATABASE MENU

This screen presents the main options available in the **Spirometry Software SDI DIAGNOSTICS Astra Pro** with the corresponding sub options.

SETUP

- Spirometry
  - Graphs and incentive
  - Parameters and predicted
  - Transducer code
  - Bronchoconstriction
- Maximal pressure
- Units
- Printer selection
  - Report header
  - Printer selection
- Language
- Interoperability
- Links
  - Utilities (depending on the connected spirometer)
    - Activation code
    - Purchase the software
    - Update spirometer AT,BT
    - Download spirometer configuration
    - Spirometer Configuration (Astra BT)
    - Options activation
- Exit

DATABASE

- New patient
- Patient data
- Test data
- Trends
- Download spirometer data
- Mark all
- Unmark all
- Delete records
- Delete all records
- Sorting by
  - Record
  - Last name
  - ID code
- Maintenance
  - Select database
  - Change password
- Export tests CSV format
  - Disk
  - Mail
- Import tests CSV format

TESTS

- FVC
- Post-bronchodilation
- VC
- MVV
- Constriction
- Maximal pressure
- Pulse oximetry
- Preview report
- Complete report
  - **QUALITY CONTROL**

Calibration (Astra BT)
Quality control (Astra BT)
Calibration database (Astra BT)

QUALITY CONTROL

Calibration (ASTRA BT)

WINDOW

Cascade windows
Tile windows horizontally
Tile windows vertically

HELP

About the software

Some of these menu options may not be available, depending on the spirometer being used. By entering each of these options, the corresponding information is available.
Next, a description of each function available with the **SDI DIAGNOSTICS Astra Pro** is made.

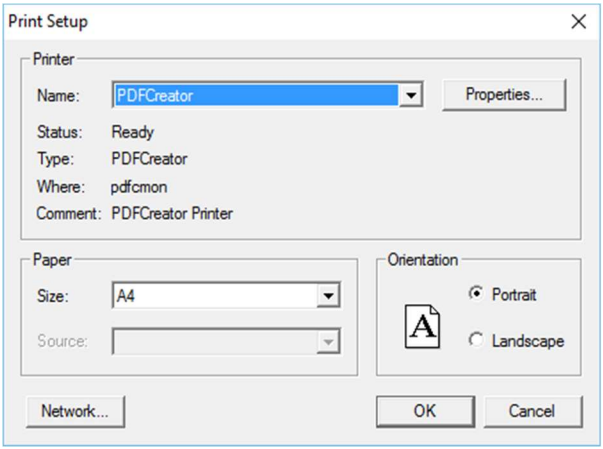
2.7. SOFTWARE CONFIGURATION

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** is a versatile program with multiple possibilities of functioning. Some of them could be of no use for certain users. So, once the Installation and Configuration process has finished, it is necessary to adapt it to the needs of each user. Thus, the system will be configured in each case and its handling and understanding of the functioning will be easier.

Next the different options that can be configured are detailed.

2.7.1. PRINTER SELECTION

Select the option **PRINT SETUP - PRINTER SELECTION** into the **SETUP**. The selection is made by placing the mouse cursor over the label SETUP and pressing the mouse left button. Next, do the same over the label PRINTER SELECTION.



The screen shows the printer selected by the operative system, as well as the available printers at that moment.

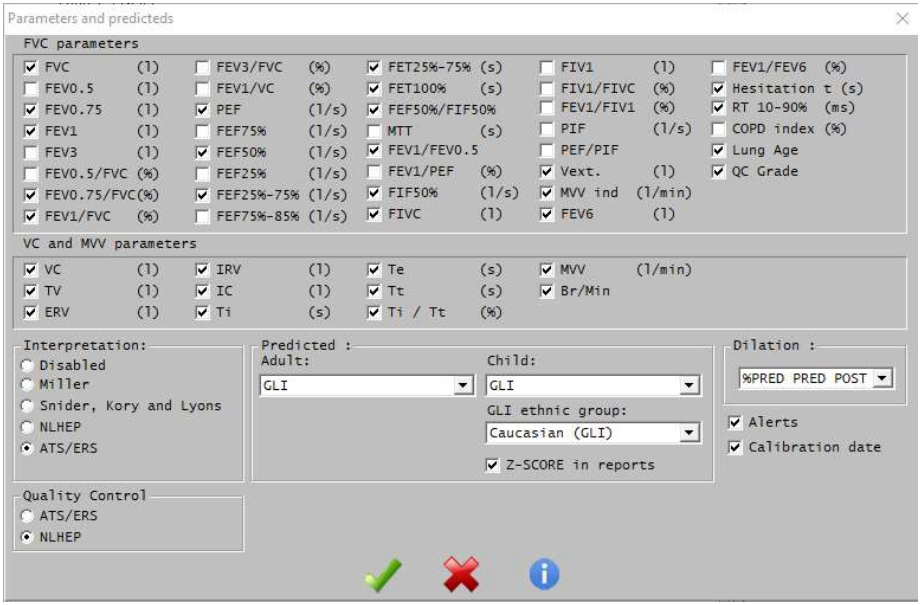
If the printer in use is not found in the relation, it is necessary to install it using the process defined by the system. Consult the computer Operative System Manual.

In the printed report includes a header with three customizable lines by the user. For example: name of the centre, doctor, address, etc. A logo in BMP may also be selected and will be printed in the top right corner of each report.

Change the report header from **PRINT SETUP – REPORT HEADER** in the **SETUP** menu."

2.7.2. PARAMETERS AND PREDICTED

Select the option **SPIROMETRY – PARAMETERS AND REFERENCES** in the **SETUP**.



This option allows the user to setup or select the following:

- **FVC Tests Parameters**
- **VC and MVV Parameters**
- **Interpretation algorithms (Diagnosis)**
  - Disabled
  - Miller chart
  - Snider, Kory & Lyons
  - Interpretation ATS/ERS.
  - Interpretation NLHEP.

See section **INTERPRETATION ALGORITHMS (DIAGNOSIS)** in the **TECHNICAL SPECIFICATIONS**

chapter for a detailed description.

- **Predicted sets available for Adults and Children**

  - SEPAR 2013
  - ERS
  - KNUDSON
  - CRAPO
  - ZAPLETAL
  - MORRIS
  - AUSTRIA
  - GUTIERREZ
  - CASTRO - PEREIRA 2002
  - POLGAR - WENG
  - HANKINSON - NHANES III
  - PEREZ - PADILLA
  - A.J. CRUZ
  - GOLSHAN
  - GARCIA RIO
  - CANDELA
  - PLATINO
  - THAI 2000
  - GLI
  - CASTRO - PEREIRA 2007

  See the section **PREDICTED SETS** in the **TECHNICAL SPECIFICATIONS** chapter for a detailed description.

- **Ethnic Factor**
  The ethnic factor modifies the Predicted values according to the selected percentage. **If no correction is to be included, the factor must be 100**.
- **Ethnic Group**
  The ethnic group can only be selected when using the GLI predicted values.

- **Comparing mode in the Bronchodilator Tests**
  % Average between PRE and POST {100x2(POST-PRE)/

	(POST+PRE)}
% between REF and POST	{100(POST)/REF}
% between PRE and POST	{100(POST-PRE)/PRE}
Difference between PRE and POST	{POST-PRE}

The second comparison mode (% between REF and POST) is fixed and is always shown, independently of the mode selected.

- **Alerts**

If this option is activated, the report will show some indications about the quality criteria according to ATS/ERS (ET, EX) or according to NLHEP (ET, EX, PEFT), as well as symptoms that have experienced the patient during the test (Cought, Weezing, Dyspnea, Sputum)"

- **Calibration F.**

When activated, shows the date of the last calibration in the report.

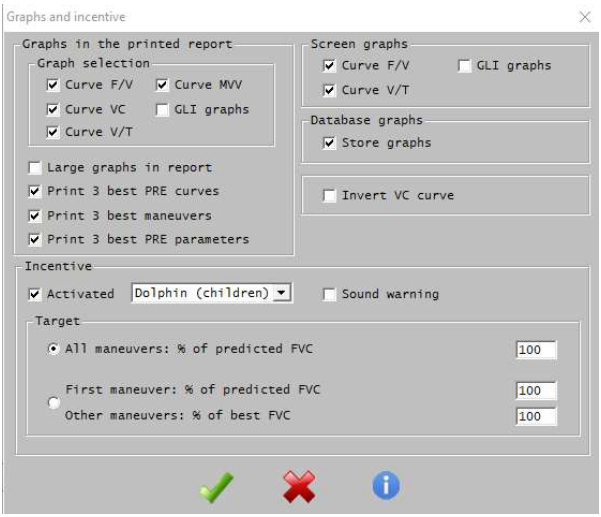
- **NLHEP Quality control**

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** incorporates an automatic quality control function, based on the recommendations of the **National Lung Health Education Program (NLHEP)**, with **prompts** and **grades** to assist the technician in providing the good instructions to the patient to produce high quality spirometry tests.

See the **QUALITY OF FVC TEST** section in the **TECHNICAL SPECIFICATIONS** chapter for a detailed explanation of QC prompts and QC grades.

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** always stores all the parameters of the different spirometric tests. Nevertheless, the selection made here affects only the screen presentation or in the printed reports.

2.7.3. SPIROMETRY – GRAPHS AND INCENTIVE



This option allows the user to select the following:

- **Graphs in the printed report**

  Curve F/V
  Curve V/T
  Curve VC
  Curve MVV
  Large graphs in report
  Print 3 Best PRE curves
  Print 3 Best maneuvers
  Print 3 Best PRE parameters
  GLI graphs

- **Graphs on the Screen**

  Curve F/V
  Curve V/T
  Curves F/V and V/T
  GLI graphs

- **Store graphs in the database**

  Store graphs

- **Motivation for pediatric tests**

  Several graphic incentives are available.

  The following parameters regarding the incentive can be configured:

  - First maneuver compared to a percentage of the predicted value.

  - Rest of maneuvers compared to a percentage of the patient´s best one.

  - Activation of a sound alarm if the goal is reached.

2.7.4. UNITS

Select the option UNITS and the units you want to use in the software.

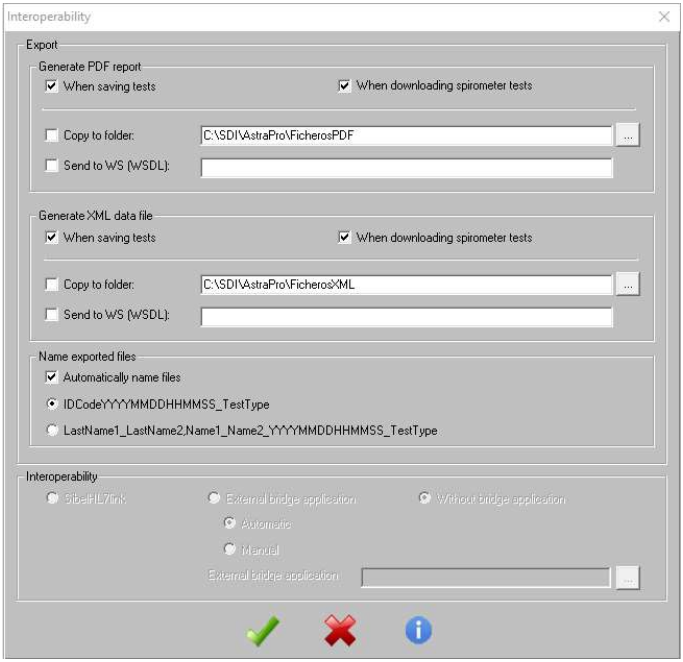
2.7.5. LANGUAGES

This dialog is used to select the language used in the messages and windows of the Astra Pro software. Go to SETUP- LANGUAGE to open this window.

2.7.6. INTEROPERABILITY CONFIGURATION

This menu allows you to configure the export of spirometry (FVC, VC, MVV and Dilation) tests to XML and PDF format when you save the test in progress in the database.

Select the **INTEROPERABILITY** option within the **SETUP** menu.



This option allows the user to select the following:

- **PDF Path** where the generated PDF file is saved.
- **XML Path** where the generated XML file is saved.
- **File name format**, both PDF as XML files.
- **Autosave PDF file**, to save it automatically without showing the corresponding dialog box.
- **SibelHL7link**

  This option allows you to convert the XML file to CDA format of spirometry which can be viewed through a browser, and use a work list with the scheduled patients.

This option is only available if the Astra ProLink option is purchased.

The **Local / Server** options allow you to configure if the SibelHL7link application is installed on the same computer where is installed the Astra Pro or on a remote computer.

- **External Bridge Application**

  This option allows linking the Astra Pro with a proprietary application of the client that generates the work list with the scheduled patients and export the generated PDF and XML files to external systems.

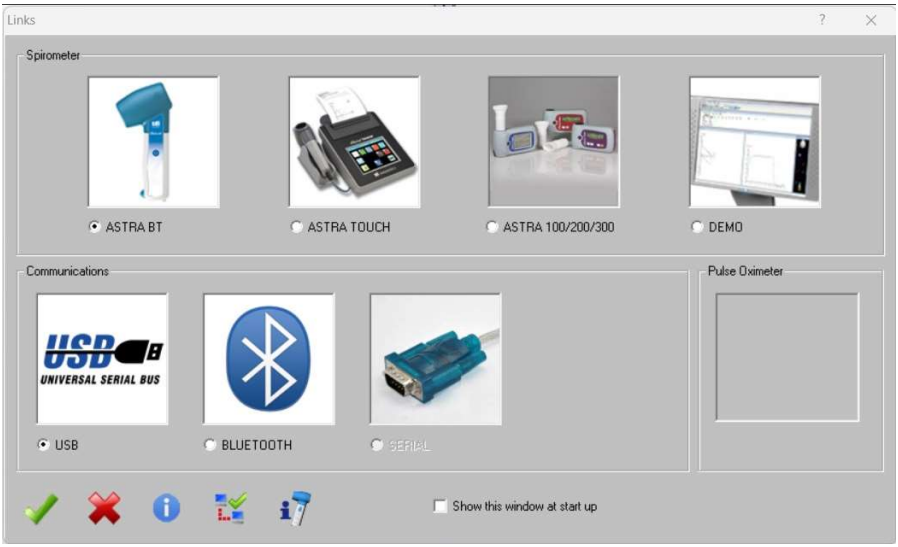
  This option is only available if the Astra ProLink option is purchased.

  Automatic / Manual options allow you to configure if the external bridge application is executed automatically (for example, applications that run in the background) or must run from the Astra Pro. In the second case, you must indicate its path and name in the **External Bridge Application** field and must be run using the icon in the main menu.

- **Without Bridge Application**

  This option allows you to use the Astra Pro without the work list of scheduled patients. However, it continues generating the PDF file and the XML file.

2.7.7. SOFTWARE LINKS



This dialog is used to select the spirometer used to make the tests and the communications link used to transfer data to the PC.

Select your device model under Spirometer. The option labeled as Demo lets the user select the ATS standard curves included with the software. These can be used for learning purposes, not being necessary to blow air in the transducer, or for the verification of the software operation.

Communications links include USB, Bluetooth and serial port. Select the option suitable for your spirometer. In case of Bluetooth or serial communications the COM port must also be selected. Verify how many serial ports are available in the

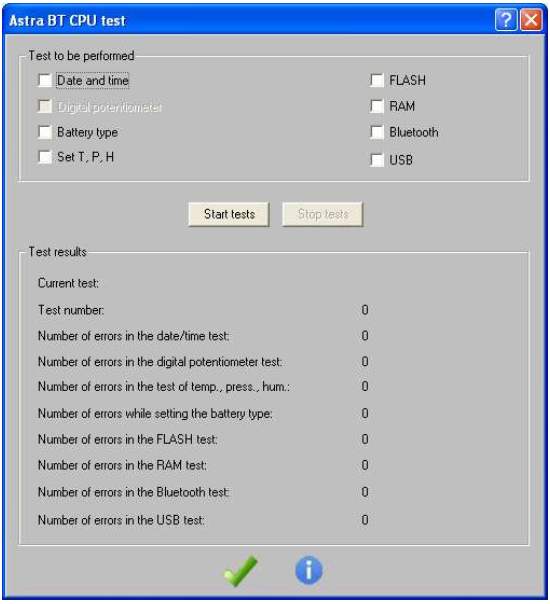
computer. For a Bluetooth connection you have to select the serial port assigned by the Bluetooth driver (check the software included with the Bluetooth Adapter). For a USB connection this option is not used.

The button Communications test should be used to check the functioning of the communications between the spirometer and the PC. For this purpose, it is necessary to connect the spirometer to the computer and click the button.

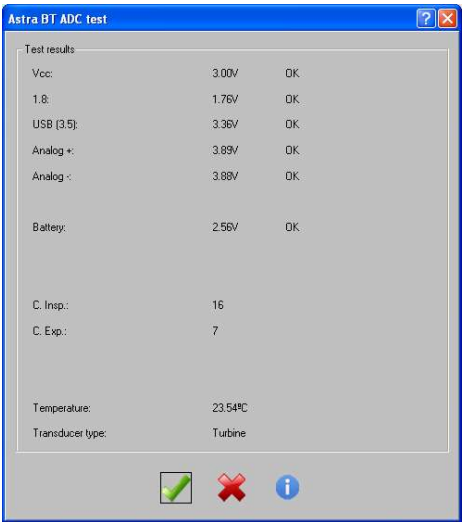
Next, verify that the information is transferred, so no error window should appear.

Astra BT information
This option displays a window with information related to the connected ASTRA BT, whenever such spirometer is connected to the PC, including the model, serial number, firmware version, type and level of battery charge, connection type, date of last calibration, date of last servicing, total number of maneuvers performed with the spirometer, maneuvers since the last maintenance, number of pulses for the turbine, temperature measured by the spirometer, humidity and pressure.

CPU test: checks the proper functioning of the spirometers's electronics.



A/D test: gets the voltage values of the spirometer and transducer, as well as the temperature.



2.7.8. UTILITIES

The Utilities menu will appear in the Links menu with the next options:

ASTRA BT

- Update spirometer
- Spirometer configuration
- Options activation

ASTRA TOUCH

- Update spirometer
- Download spirometer configuration
- Options activation

ASTRA 100/200/300 spirometer

- BIOS update
- Flash update
- Download spirometer configuration

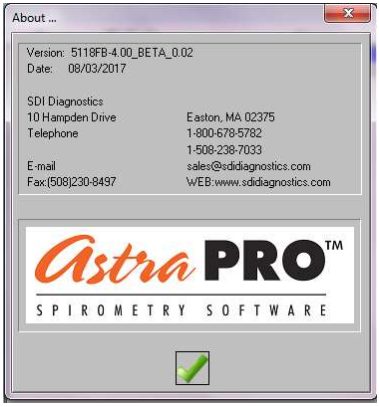
- Options activation

    - These options are explained in detail in sections **FIRMWARE UPDATE**, **DATA DOWNLOAD FROM THE DEVICE**, **CONFIGURATION OF ASTRA BT** respectively, at the end of this chapter.”.

2.7.9. ABOUT

This option shows an information window with the program's data:

- Version
- Date
- Manufacturer's Data

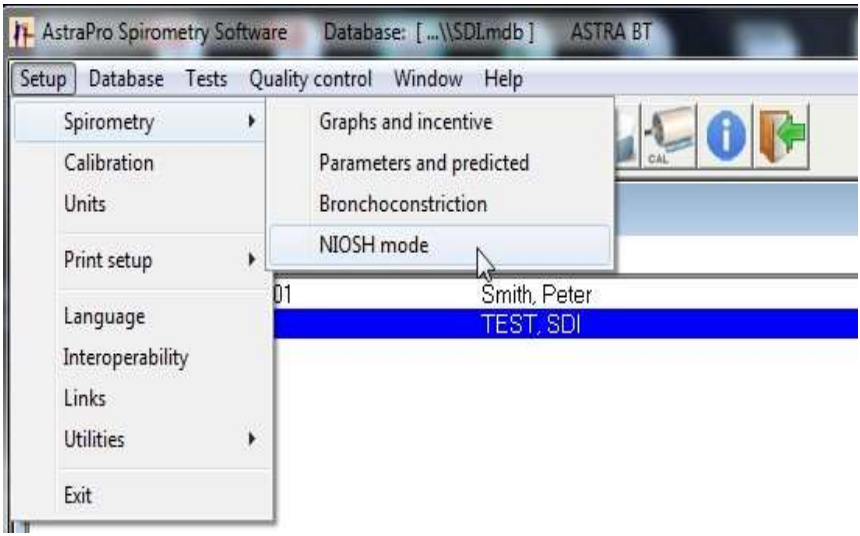


2.7.10 NIOSH MODE

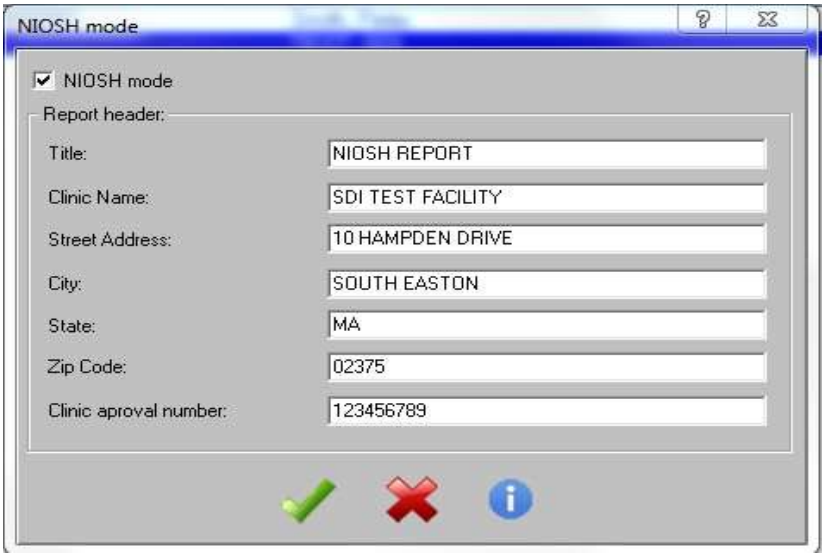
Astra BT Only

NIOSH mode allows you so select a report that is compatible with NIOSH reporting guidelines with the ASTRA BT Spiromter.

To activate NIOSH mode from the main menu, select Setup, Spirometery, Niosh mode



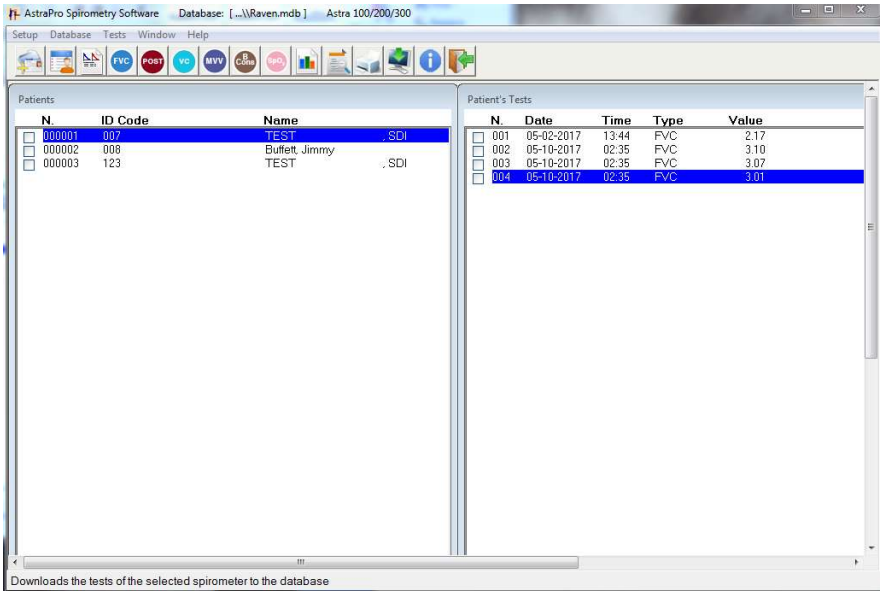
Check the box for NIOSH mode and fill out the the information section and select the green check. Once completed you reports will now be printed in the NIOSH format.



2.8. DATABASE

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** can work with different databases. All the information related to spirometric tests is stored in the database.

2.8.1. EXPLORING THE DATABASE

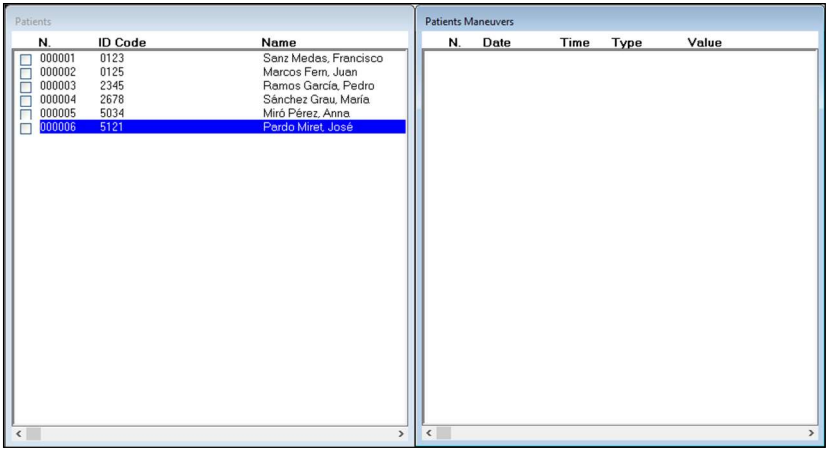


This window shows the database patient's list and their corresponding tests.
Double-click on a **patient** to view the patient's data or a test to open the test.
FVC, VC and MVV tests can be continued if the time elapsed between the first maneuver is less than six hours.
The window «Patient Maneuvers» (on the right in the above image) is complementary to the window «Patients». Only the tests of the selected patient will appear in the window «Patient Maneuvers».

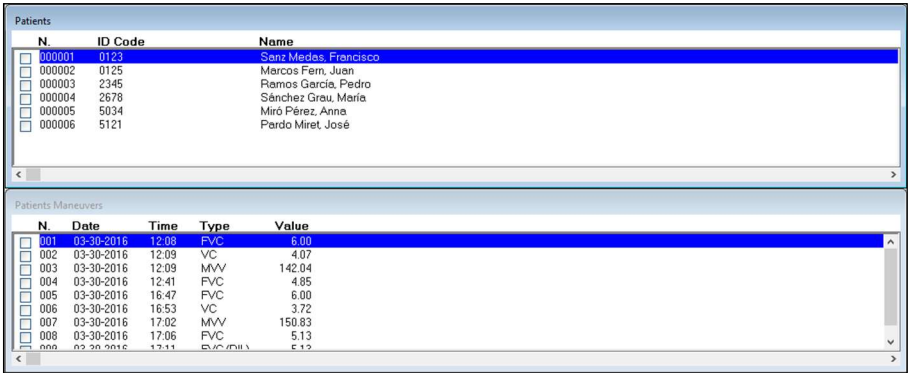
2.8.2. WINDOW ARRANGEMENT

Windows may be arranged by pulling any edge with the cursor or selecting the options available in the menu «Patients», like in the following pictures:

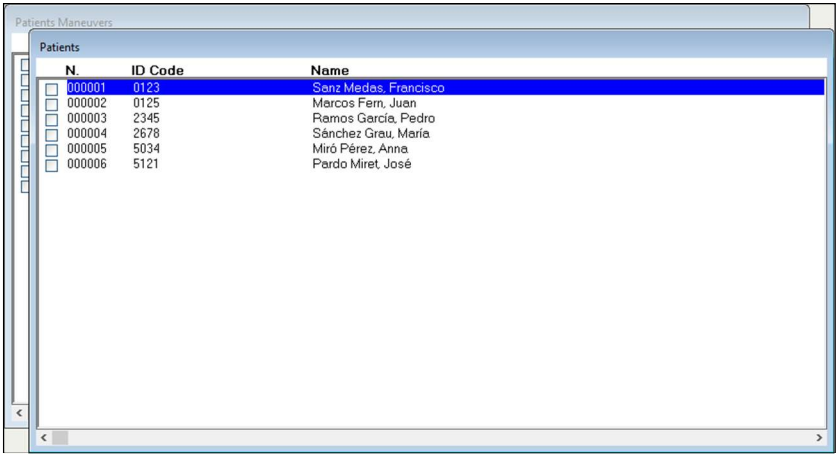
Tile windows vertically:



Tile windows horizontally:

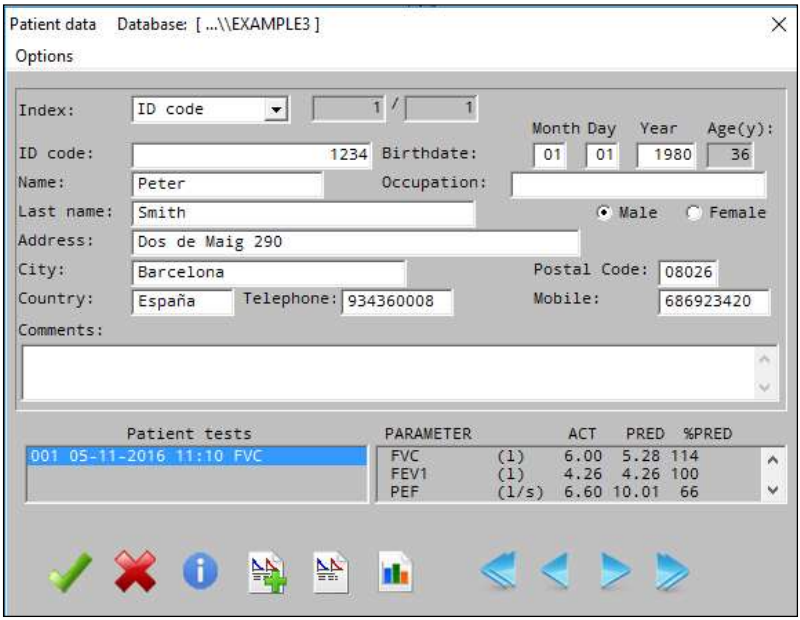


Cascade windows:



2.8.3. PATIENT DATA

Select **DATABASE – PATIENT DATA**
This screen allows to:



A – Open the window menu by selecting Options to:

- **NEW:** Enter a new patient
- **DELETE:** Delete a patient and all his corresponding tests
- **CONSULT:** Search a patient record.
- **TRENDS:** Shows a report of all selected tests of the patient.
- **EXPORT:** Opens the exporting module, to select tests of this patient, configure the export destination and export the tests with the format implied by the quotation marks.

The fields containing the patient's information are:

Field	Type	Nr. Characters

Reference	A/N	10
Date of Birth	N	8 (dd/mm/yyyy)
Name	A/N	20
Surname	A/N	38
Profession	A/N	20
Sex		
Address	A/N	50
City	A/N	30
Postal Code	A/N	5
Country	A/N	11
Telephone	A/N	10
Mobile	A/N	10
Comments (5 lines)	A/N	74 x 5

A/N = Alphanumeric Field
N = Numeric Field
Date format: dd= 01, 02 ..... 09, 10 ...
mm= 01,02 ..... 09, 10, 11, 12.
yyyy= 1998

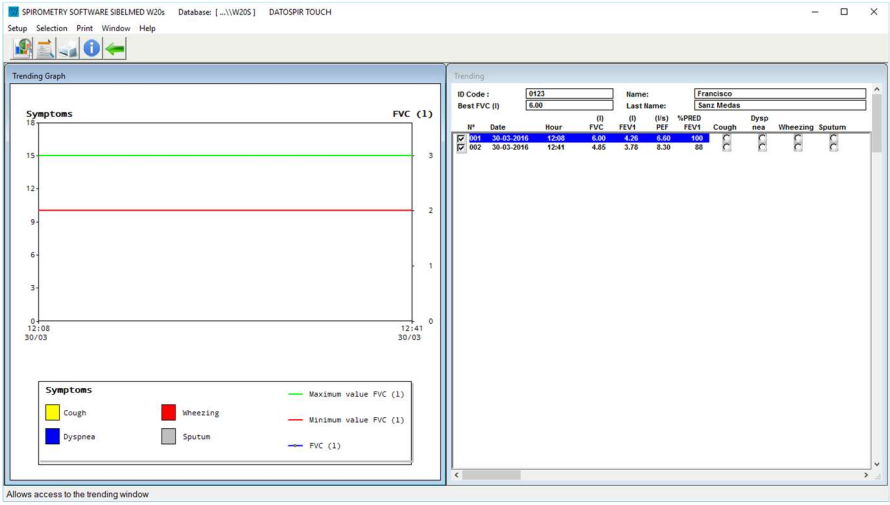
B - Display in **Tests** the different tests of a patient with the most important parameters. In order to display all the **Test Data**, there are two ways: one is to choose the test **(selecting it in the list of tests of the patient card)** and double click on it. The other way consists of choosing the test and clicking the button **Tests** in the Patient Record dialog.

C - Search a patient already existent in the database. For this purpose, order the base through the **INDEX** by:
- Reference
- Surname
- Nr. of Record

Next, use the **CONSULT** option in the menu and enter the information corresponding to the patient being searched. It is also possible to navigate through the patient records with the buttons **slow advance** (record by record) and **fast**

advance (by 10 records). The dialog shows the total number of patients in the base and the number of the selected one.

When clicking the button **TRENDS,** the next screen appears:



In this window all the patient tests **FVC** are displayed, in order to make a report of the trend for parameters **FVC, FEV1, PEF and its variability**.

The following options are presented:

Setup: this option is used to **setup the printer type**, and the display parameters.

Selection: use this option to select a test to include it in the trends report. It is possible to mark all the tests or one by one.

In order to select a group in a quick way, follow these steps: Mark the first test of the group and then with the **Shift** key pressed, choose the last test of the group with the mouse

(by doing this, the group will be selected).

It is also possible to add tests, for this purpose press the **Control** key and select one by one with the mouse.

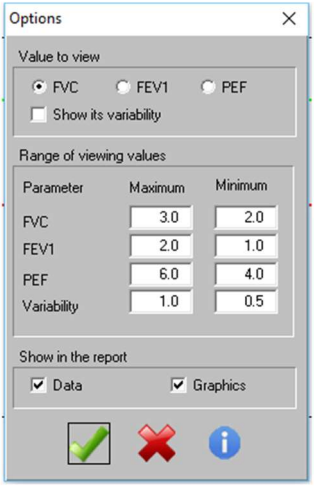
Print: prints a report in the printer.
Window: allows organizing the windows automatically.
Help: show the help file.

In the **Trending Graph** symptoms of each test may be displayed as overlapped areas and the numeric values of the selected parameter in the X and Y axis.

The warnings are represented with a color code indicating its severity. These codes are the following:

White	Nothing (No symptom)
Green	Low
Yellow	Medium
Red	High

When clicking on **Viewing Parameters** in the **Setup** menu, the next dialog appears:



In this window it is possible to set up the maximum and minimum values for each parameter appearing in the trends report. These parameters are the following: **FVC, FEV1, PEF** and the Variability of each.

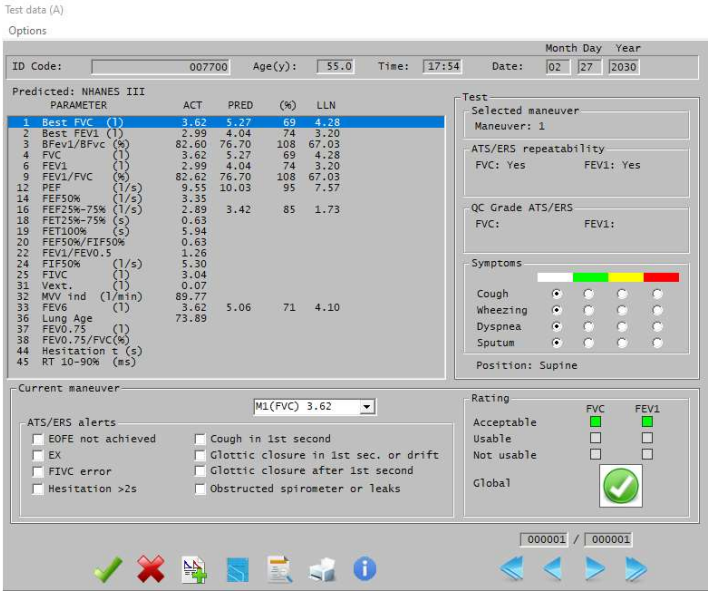
For each parameter a range of values is defined (maximum and minimum). These values are represented in the graph with green and red lines in order to identify clearly when these limits are surpassed. The variability graph is represented through variation percentage for the selected parameter between A.M. and P.M. The calculation of the variability value is defined in this way: **100 * (A.M. Value - P.M. Value) / A.M. Value.**

The tests being made from 0h until 12:00h are considered to be performed during the A.M. and the ones being made from 12:00h up to 0h are considered to be performed during the P.M.

Use the option **Show in the report** to select whether numeric data, graphs or both will be displayed simultaneously in the report.

2.8.4. TEST DATA

This screen presents the Test Data performed to the patient in the date and time indicated in the same window.



The following options are allowed in the window's menu and the different buttons:

Delete: deletes all the information related to this test.

Test Data: presents the information related to the test.

Graphic: displays the graphic corresponding to the test.

Print: creates the report of the test.

Export: exports the test in the files PRUEBAS.CSV and GRAF001.CSV, by default in the folder C:\ESPWIN\TMP.

Preliminary View: shows a preliminary view of the report.

The screen also presents the following information:

- The Observed and Predicted values of the different parameters, as well as the %.

- The Quality Control alerts according to ATS/ERS or NLHEP criteria regarding the following:

  ET - End of Test (ATS/ERS and NLHEP).

  EX - Start of test (ATS/ERS and NLHEP).

  PEFT - Time to reach PEF (only NLHEP).

  If the test was performed with the NLHEP quality control criteria, the QC Grades will be displayed when 2 or more maneuvers were performed during the test session. In case of a Bronchodilation test, the PRE and POST QC Grades will be displayed (the QC Grades are not shown when using the ATS/ERS criteria).

- Shows whether the patient had cough, weezing, dyspnea or sputum during the test. Each of these symptoms can have the following values:

White	No symptom
Green	Mild symptom
Yellow	Moderate symptom
Red	Severe symptom

- Tests made to the same patient can be browsed by using the buttons **Next / Previous** (test by tests) or **Next 10 / Previous 10** (shift 10 tests).

2.8.5. SELECTING PATIENTS AND TESTS

Use the checkboxes located in the left side of each patient and test to select them one by one. Select patients and tests in order to delete or export them, as explained in the following sections.

You can also use the following options in the menu DATABASE to select patients and tests:

Mark All

If the Patient window is active, all the patients and their tests are selected.
If the Tests window is active, all the tests of the selected patient are selected.

Unmark All

If the patient window is active, all patients and tests are unmarked.
If the Tests window is active, all the tests of the selected patient are unmarked.

2.8.6. DELETING PATIENTS AND TESTS

Clicking with the mouse's right button on a patient or test will pop-up a menu with the option **Delete** which deletes the selected patient/s and/or test/s from the database.

2.8.7. EXPORT TESTS IN CSV FORMAT

Use this option to export the selected tests and patients to a CSV file, suitable for data interchange with other software programs. Data is delimited by inverted comas.

In the main menu click Database / Export tests CSV format.

The information of the generated files are fields between

inverted comas, separated by a semicolon:

(…);"17/02/1999";"08:21";"24";"56";"165";"0 Woman"; "1 SEPAR"; (…)

The file structure is a table with the same number of columns for each line. Each line represents a maneuver within a test. FVC, VC and MVV tests always store 8 maneuvers for every test. Bronchodilation tests store 16 maneuvers (8 pre-bronchodilator maneuvers and 8 post-bronchodilator maneuvers). Maximal pressure tests store 2 maneuvers for every test. Bronchoconstriction tests store 14 maneuvers for every test.

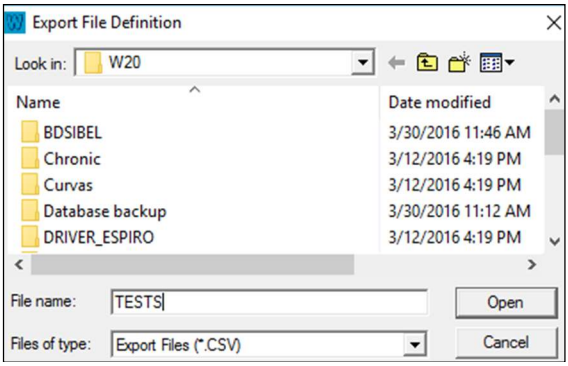
The first record is reserved for the name of the fields.

There are two fields in the PRUEBAS.CSV file, «Graph file» and «Graph Column», which enable to associate the dots of the graphic pressure-time to the test. For example, if File Graphic=1 and Graphic Column=23, the dots for the graphic for this record are located in the GRAF001.CSV, column 23.

To start the export process:

1 Mark the tests to be exported as explained previously.

2 Select the menu option Database / Export tests CSV format / Disk. The destination folder used by default by the program is TMP, which is to be located in the folder where the program was installed. Data concerning the tests are stored in the file PRUEBAS.CSV, data related to patients are stored in the file PATIENT.CSV and the pressure graphs are stored in the files GRAF001.CSV, GRAF002.CSV, … If these files are already in the folder, they will be deleted and replaced by the new ones, including the exported tests.



3 Click Open to start the process. A dialog will appear showing the progress of the export process.

2.8.8. EXPORT TESTS TO E-MAIL

Use this module to export tests to files with .CSV extension and text format delimited by quotation marks, and send them via email for use with other software programs.

In the main menu go to **Database / Export tests CSV format / Email**.

To perform the export:

1 Mark the tests to be sent.

2 Next, the email assistant installed in the computer will pop up, cerating a new message with the attached documents PRUEBAS, PATIENT and GRAFxxx, which contain the selected tests.

3 Introduce the address email and the desired information.

4 Press Send to transmit de mail.

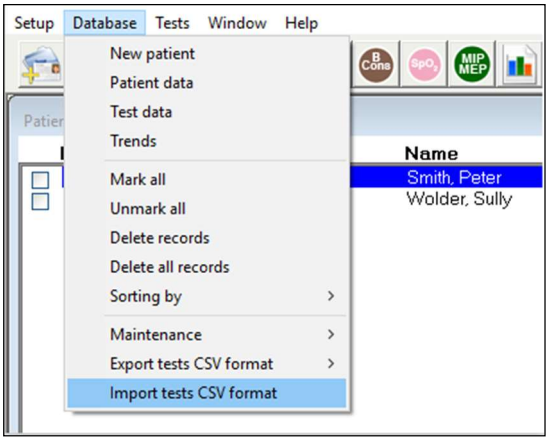
2.8.9. TESTS IMPORT FROM A REMOTE HEALTHCARE CENTER

The export module in combination with the import module enables the browsing in the local examination room of the tests performed in a remote healthcare center. Both healthcare centers must have the spirometry software **SDI DIAGNOSTICS Astra Pro** available.
For that, after having made all the spirometric tests of maximal pressures, and / or pulse oximetry, the following steps must be performed:

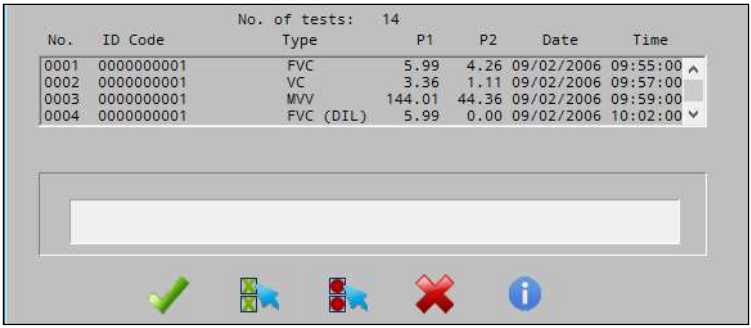
EXPORT -> TRANSPORT -> IMPORT

A. EXPORT: Use the option **Export tests CSV format** in the remote PC to store the tests to be explored in the local PC, as indicated in the previous paragraphs. The tests will be stored in the selected directory, in the files PRUEBAS.CSV, PATIENT.CSV and GRAFxxx.CSV (usually GRAF001.CSV).
B. TRANSPORT: These files will be sent via e-mail or transferred through an interchangeable USB memory drive or portable hard disk to the other healthcare center.
C. IMPORT: Execute the CSV import process, as indicated below: Enter the option **Database /Import tests CSV format** in the main menu.

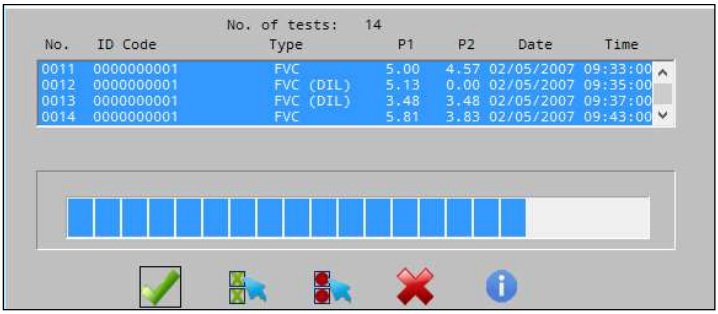
The following window appears:



Choose the directory and the .csv file you want to import.
The following window appears:



Click with the mouse over the tests to be imported to the database of the spirometry software SDI DIAGNOSTICS Astra Pro, or click over the button **Select all** in order to select all the tests.
Click **OK**. The program will show the progression of the import process



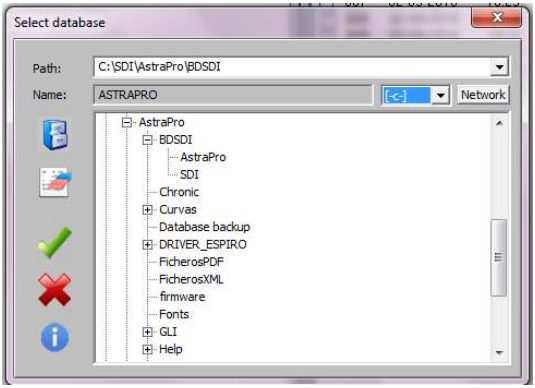
2.8.10. ORDERING THE PATIENTS

Select the menu option «Database / Sort by» to order patients list by the selected criteria (register, surname, reference).

2.8.11. DATABASE MAINTENANCE

The **Maintenance** option included here is oriented only to the database and not to the device hardware. The information regarding the spirometer's database must be consulted in the corresponding chapter of the spirometer **User Manual.**

Select database
Use this option to create a new database or select an existing one.
The selected database may also be deleted by clicking the «Erase» button.



Change password

To modify the password of a database, the working password must be introduced before pressing ENTER. Then, the system asks for the new password and its confirmation.
It is very important to introduce an easy-to-remember password. If the password gets forgotten, please contact with the SDI DIAGNOSTICS Technical Service and they will explain the recovering process.

2.9. FORCED VITAL CAPACITY «FVC» TEST PROCEDURE

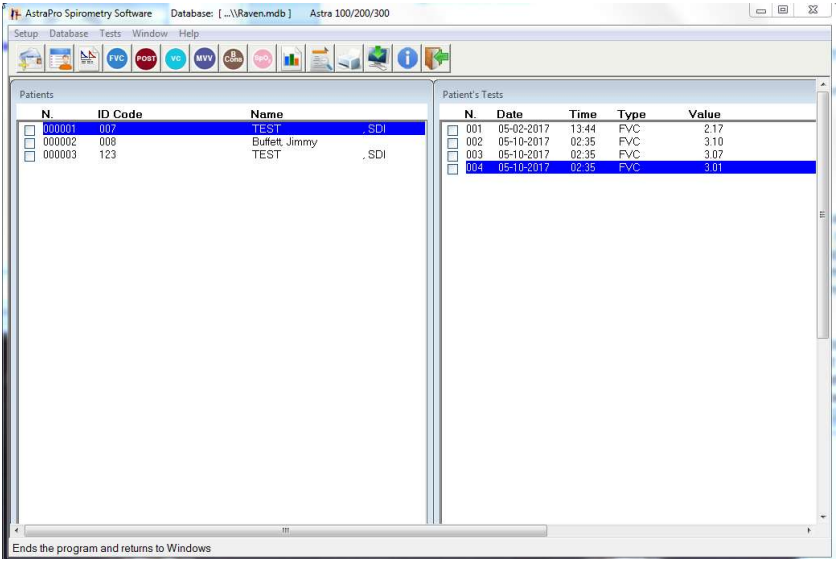
The procedures to be used for the spirometric test of **Forced Vital Capacity "FVC"**, **Slow Vital Capacity "VC" and** the **Maximum Voluntary Ventilation "MVV"**, as well as the **Postbronchodilation "POST"** mode are very similar. Only a detailed explanation of this procedure will be

made in this section.

The use of bacterial filters is recommended for performing spirometric tests.

2.9.1. ENTERING PATIENT AND ENVIRONMENTAL DATA

The connected spirometer must have the menu Spirometry selected.



If the patient is not already in the database or if you want to search him by Reference or Surname then select the menu option DATABASE - NEW PATIENT or directly click the icon in the toolbar. Next, enter the number of Patient Reference to add a new patient to the database and the Reference or Surname if patient already exits.

In the first case, after pressing OK, the Patient Card appears which must be completed with the convenient data. At least the fields Reference, Date of Birth (the age is automatically calculated) and Sex must be filled, since they are needed for the calculation of the Spirometric Predicted Set.

Once the card is filled in, press OK.

Next, select the patient in the database and click the icon «FVC» in the toolbar or select the menu option TESTS - FVC. A new window with the test data will be shown.

When performing a spirometric test it is necessary to enter certain data related to the patient, to the environment or others that vary from one test to another.

Among them, we point out:

- **Date** and **time** of test performance

- **Smoker Ind.** (Smoker Index) Between 0 and 200
It is equal to the number of cigarettes smoked in one day divided by 20 and multiplied by the number of years as a

smoker

(Cigarettes day x years as a smoker/20)

- **Cigar/d:** Cigarettes per day (to calculate the Lung's Age)

- **Age** in **years**, it is automatically calculated from the birth date of the patient.

- **Height** in **Inch** / **cm** between 20 and 90 Inch / 50 and 230 cm.

Patient data affect the predicted values and diagnosis, so make sure data are correct.

- **Weight** in **Pound** / **Kg** between 22 and 440 Pound / 10 and 200 Kg.

- **Temperature** in the room in Cº

- **Pressure** in hPa / mmHg

- **Humidity** in the environment, in % (these 3 last values are automatically obtained if the equipment has an integrated meteorological station).

Environmental conditions affect the BTPS factor and the calculation of the volume, make sure data are correct.

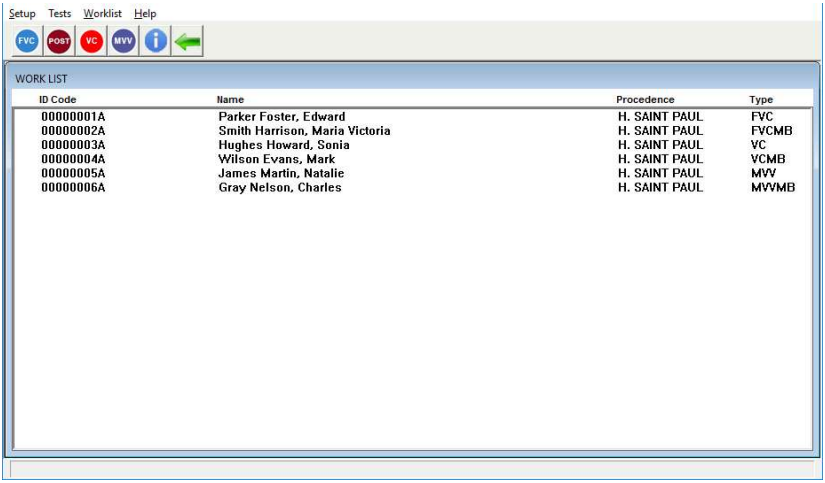
There are other fields like:

- **Motive** or cause for performing this test
- **Precedence** or centre, department, doctor, etc. where the patient comes from
- **Technician** who makes the test
- **Ethnic Factor** and **Theoretic Values** used in the test
- **Comments** on the test

2.9.1.1 ENTERING THE PATIENT AND ENVIRONMENTAL PARAMETERS THROUGH WORK LIST

If the Astra ProLink option has been purchased and **SibelHL7link** or **External Bridge Application** is selected in the **Interoperability** menu, it is not necessary to enter patient data to initiate spirometry tests, since they are included in the work list that is imported from the external Information System (HIS).

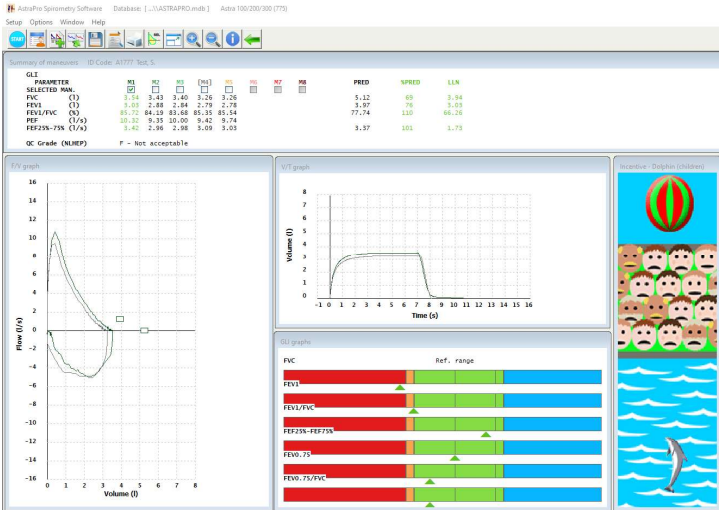
Click the «Work list» icon in the toolbar and the work list screen will be displayed:



This list shows the data of scheduled patients to perform spirometry tests (ID Code, Name, Origin, Type of Test and Hour of the test). To select a patient you must simply double click on it. Then, the test data tab is displayed, enabling the modification of any parameter. After clicking the OK button the test is automatically started.

Every demanded test in the work list must be generated from the external Information System (HIS). Then, **SibelHL7link** or the **External Bridge Application** are responsible for transferring the work list to the Astra Pro.

2.9.2. ENTERING FORCED VITAL CAPACITY TESTS



This screen is the essential core where the spirometric maneuvers are performed. In this case, the axes for the Flow/Volume Graphics and Volume/Time, as well as the incentive plot are showed**.** The user can select another configuration in **SETUP – PARAMETERS AND OTHERS - GRAPHS AND INCENTIVE**.

If the graph windows are not adjusted to the size of the general window or if they are not organized, click on WINDOW - MOSAIC to the let the program automatically resize them.

In this screen the following parts or windows can be pointed out:

MENUS AND TOOLBAR ICONS

The **SETUP** menu allows to:

Spirometry

Graphs and incentive (Check SETUP / GRAPHS AND

INCENTIVE)

Parameters and references (Check SETUP / PARAMETERS AND REFERENCES)

Show NLHEP analysis

Units

Report header

Printer Selection (Check SETUP / PRINTER SELECTION)

Return

The **OPTIONS** menu allows to:

Maneuver start/finish
When activating this option, the device is ready to start the spirometric maneuver.

Patient Data
Opens the Patient Data dialog window.

Test data
Opens the Test Data window with some patient data, environmental data or other data related to the test being performed.

Maneuver data
Allows to:

- Display the available information of the performed maneuvers
- Save the maneuvers to the database
- Delete a maneuver
- Create a report based on the maneuver data
- Present the diagnosis

Save test
Saves the test to the database.

Report preview
Opens the report preview window.

Report
Creates a report corresponding to the selected maneuver in the **Maneuver Data** window.

Graphic selection
This option opens a window to select the visibility of the graphs of the performed maneuvers. The asterisks indicate the position taken by the last maneuver.

Auto scale
When activating this option, axes of the graphs adjust their dimensions, without losing the relation 2 l/s, they are equal to 1 l in the F/V graph and 1 l is equal to 2 s in the V/T graph and only in FVC mode.

Zoom + and -
Enlarges or reduces the graphs while maintaining the relations previously indicated.

The **WINDOW** menu allows to:

Mosaic
This option allows the user to organize the different windows and fill the whole main window. The user can adjust the sizes manually by using the mouse and moving any side or edge of a window.

The **HELP** menu has the following options:

About the software
Visit SDI DIAGNOSTICS web site
About

MANEUVERS SUMMARY WINDOW

Forced Vital Capacity Mode
While performing the FVC test the following parameters are

shown in this window: the predicted set being used, FVC, FEV1, FEV1/FVC PEF and FEF25%-75% of the eight best performed maneuvers (M1-M8), the best values according to ATS criteria (green color), the predicted value, the percentage difference of the best values according to the predicted value and the low limit of normal value. In POST bronchodilation mode the predicted values are changed by the ones obtained in PRE bronchodilation mode.

The maneuvers are ordered from best M1 to worst M8, according to the ATS criteria of the maximum addition of FVC+FEV1 and according to the detected errors in each maneuver.

The labels M1-M8 indicate the color for the associated graphic. The square brackets (e.g. [M3]) indicate the position taken by the last performed maneuver. The curve corresponding to the last performed maneuver is drawn in grey in the graph.

Click the left mouse button on the parameters of any of the maneuvers to show / hide the graph of the maneuver on the charts. Click the right mouse button to directly open the window "Maneuvers data" for the maneuver on which the click was made.

Finally, the best maneuver (by default always labeled as M1) is that with the check mark in row " SELECTED MAN." activated. If you want to select any other maneuver as the best one then check the box corresponding to the desired maneuver.

Slow Vital Capacity Mode
The following parameters are displayed in VC tests: VC, VT and ERV.

Maximum Voluntary Ventilation Mode
The following parameters are displayed in MVV tests: MVV and Br/min.

If working with the ASTRA BT spirometer, an indication of the battery level is shown in the top left corner of the Summary window:

High level

Medium level

Low level

Not available

GRAPHS

Presents the graphic windows selected in the menu **SETUP – SPIROMETRY - GRAPHS AND INCENTIVE**.

The squares shown in the **F/V** graph are equal to the patient predicted values for the parameters **FVC, FEF75%, FEF50%, FEF25%** and **PEF**. These indications only appear if the predicted values exist. The **PEF** is placed at 10% of the FVC reference volume.

INCENTIVES

The incentive is a graphic possibility useful for motivating children during the performance of **FVC** spirometric maneuvers. This option can be activated or deactivated by entering **SETUP – ESPIROMETRY - GRAPHS AND INCENTIVE,** as well as selecting among different incentive pictures and a sound warning.

TEST EXECUTION

It is desirable that the technician performing the forced

spirometry tests knows the usual procedure required for the patient to properly perform them. If not, he/she should review any related documentation.

In the performance of the spirometry, the following steps must be taken into account:

1 Verify that the spirometer is connected to the computer and setup correctly.

2 Train the patient about the performance of the test, since his cooperation is essential for proper execution.

The patient can perform the maneuver in two different ways:

- The first consists of starting the maneuver over the transducer with the FORCED ESPIRATION followed by the FORCED INSPIRATION, if needed.

- The second consists of the patient breathing normally through the transducer and when the technician indicates it, fill the lungs completely, and then start the FORCED ESPIRATION followed by the FORCED INSPIRATION, if needed.

3 Indicate the patient the most convenient way of taking the transducer without obstructing the air passing through when making the spirometric maneuver and put him the nasal tweezers.

4 Press the **"START"** icon and from that moment the patient has 30 seconds to start the forced maneuver.

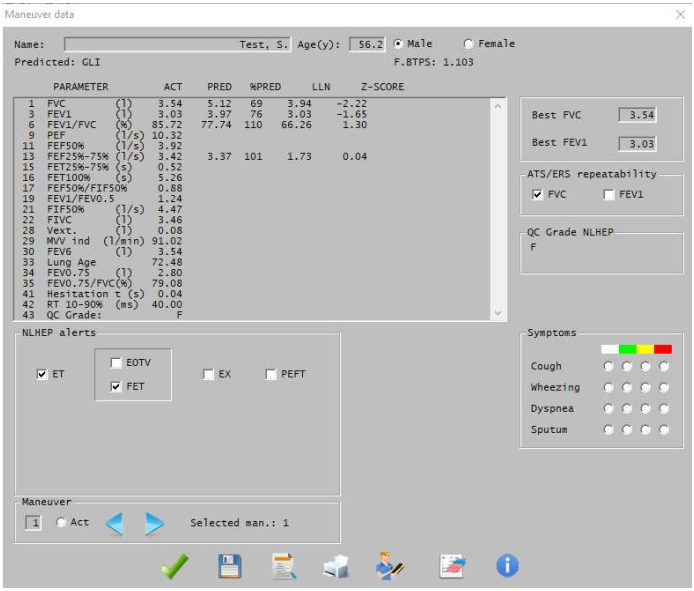
If the device model is a ASTRA Touch then the spirometer automatically detects the beginning of the maneuver, so you do not have to press the START icon.

5 After the first spirometric maneuver, the patient can perform the maneuvers indicated by the technician.

2.9.3. MANEUVER DATA

After having performed, at least, one spirometric maneuver, the resulting data can be consulted in the Maneuver Data window through **OPTIONS - MANEUVER DATA** (MANEUVER DATA Icon).
This window presents all the information related to each performed maneuver. A * is added to REF when the predicted values have been extrapolated and in the report appears the text: «Warning: Reference values extrapolated!». In a similar way if the low limit of normal value is not available in the selected predicted set the message «Warning: LLN = 80%» is also shown, indicating that the LLN value will be calculated as the 80% of the predicted value.

The following data are available in this window:



PARAMETERS

The list presents all the parameters selected in on Setup / Parameters and Others / Spirometry with the observed values and the reference value, as well as the % between the OBS value (Observed) and the REF (Reference) of the best or the best 3 maneuvers performed (depending on the option selected on Setup / Parameters and Others / Graphs and Others). In the case of Postbronchodilation, the following columns appear:

PRE. Prebronchodilation value.
PRED Reference (predicted normal) value .
% % between PRE/PRED.
LLN Lower limit of normal of the predicted value.
POST Postbronchodilation value.
%P % between the POST/PRE or other according to setup
(%R) % between REF and POST. This column appears depending on the configuration of the previous parameter.

WARNINGS

SYMPTOMS

Allows noting down events like cough, weezing, dyspnea or sputum that the patient may experience during the test. Each of these symptoms can have the following values:

White No symptom
Green Mild symptom
Yellow Moderate symptom
Red Severe symptom

BEST

Shows the highest FVC and FEV1 values from those maneuvers with an acceptable start (without EX alert).

MANEUVER

Shows the number of the maneuver being displayed on screen. Any of the available maneuvers can be displayed up to a maximum of eight. The order of the maneuvers is

presented according to the **ATS/ERS** criteria or the **NLHEP** criteria (depending on what is selected in the **menu Setup / Spirometry / Parameters and references**) and is based on the errors of each maneuver and on the **highest value of FVC+FEV1,** being number 1 (best maneuver) the maneuver with less errors and/or highest addition, and number 8 (worst maneuver), the one with more errors and/or lowest addition.

«Last» option will be automatically checked if the one being displayed is the last performed maneuver. «Selected man.» shows the maneuver selected by the technician as the best one (M1 by default if the technician has not selected any one).

ATS/ERS ALERTS

For each maneuver, the ATS/ERS criteria that **are not fulfilled** are indicated:

ET – End of Test; based on the EOTV and FET criteria (the user can change the status of the FET criterion if he/she considers that the patient has tried to exhale for a longer period than the criterion)

EX – Start of test based on back extrapolation.

For a complete description of these alerts, consult section QUALITY OF FVC TEST in the TECHNICAL SPECIFICATIONS chapter.

NLHEP ALERTS

For each maneuver, the NLHEP criteria that **are not fulfilled** are indicated:

ET – End of Test; based on the EOTV and FET criteria (the user can change the status of the FET criterion if he/she considers that the patient has tried to exhale for a longer period than the criterion)

PEFT – Time to reach the PEF.

EX – Start of test based on back extrapolation.

For a complete description of these alerts, consult section QUALITY OF FVC TEST in the TECHNICAL SPECIFICATIONS chapter.

REPEATABILITY ATS/ERS

If three or more **acceptable** maneuvers (without EX or ET alerts) have been performed, the repeatability criteria for FVC or FEV1 parameters is indicated if the **two largest values of FVC or FEV1** (from maneuvers with an acceptable start, without EX alert) **are within 150 ml** of each other, respectively (if FVC ≤ 1.0L the criterion is 100 ml). If there are no maneuvers without and acceptable start, the ATS/ERS repeatability criteria are not fulfilled.

Besides the previously said, the following can be made from this screen:

SAVE

Saves the test in the database and marks as selected maneuver by the technician, the maneuver that is being displayed in this window.

PREVIEW REPORT

Shows the preview report of the maneuver displayed in this window.

DIAGNOSIS

Presents the diagnosis of the selected maneuver. The type of diagnosis can be selected in **SETUP - PARAMETERS AND OTHERS - SPIROMETRY**.

DELETE

Deletes the selected maneuver.

2.9.4. PRINTING THE REPORT

It is possible to make a report of any maneuver performed. This option is found in the Maneuver Data window, in the MANEUVER DATA section.

It is also possible to print a general, grouped report with the different spirometric tests made to a patient in a certain session. This option is accessible through the Printer Icon.

SDI DIAGNOSTICS, INC
10 Hampden Drive, Easton, MA

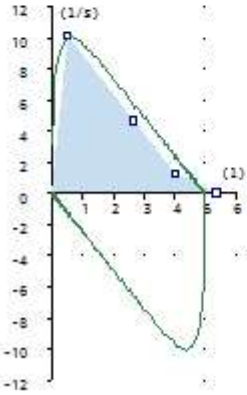
ID code:	0000000001	Date:	05-02-2016	Time:	09:33
Name:	Smith Peter				
Sex:	Male	Age(y):	61	Height(in):71	Wgt(lb):154
Temp.(°F)	77	Pres(mmHg)	760	Humidity(%)65	Smok.I.:
Technician:				Transducer:Disk	
Predicted:	SEPAR 2013-SPAIN			Ethnic f.: 100	BMI : 21.6
F.BTPS:	1.000				
Version:	S118FB-4.00_BETA_0.02				

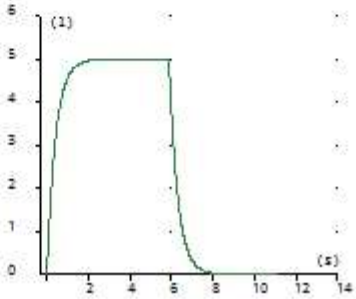
FVC REPORT Maneuver No.: 1

PARAMETER		ACT	(%)	PRED	LLN
Best FVC	(l)	5.00	95	5.25	4.38
Best FEV1	(l)	4.57	115	3.98	3.24
BFev1/BFvc	(%)	91.40	124	73.98	65.16
FVC	(l)	5.00	95	5.25	4.38
FEV1	(l)	4.57	115	3.98	3.24
FEV1/FVC	(%)	91.51	124	73.98	65.16
PEF	(l/s)	9.87	99	9.96	7.54
FEF50%	(l/s)	6.17	138	4.48	2.35
FEF25%-75%	(l/s)	5.68	173	3.28	1.63
FEF50%/FIF50%		1.00	152	0.66	0.53
FEV1/FEV0.5		1.30	90	1.45	1.16
FIF50%	(l/s)	6.17			
FIVC	(l)	5.00			
Vext.	(l)	0.07			
FEV6	(l)	5.00			
FEV0.75	(l)				
FEV0.75/FVC	(%)				

Repeatability ATS/ERS: FVC: No, FEV1: No

Interpretation ATS/ERS
NORMAL





SDI DIAGNOSTICS, INC
10 Hampden Drive, Easton, MA

SDI DIAGNOSTICS

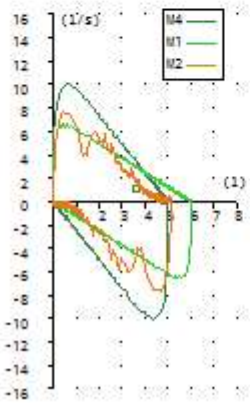
ID code: 0000000001 Date: 03-24-2017 Time: 14:01
Name: Smith Peter
Sex: Male Age(y): 62 Height(in):71 Wgt(lb):154
Temp.(°F) 77 Pres(mmHg)760 Humidity(%)65 Smok.I.:
Technician: Transducer:Disk
Predicted: GLI (Caucasian (GLI)) BMI : 21.6
F.BTPS: 1.086
Version: 5118FB-4.00_BETA_0.02

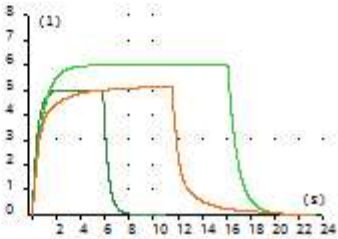
FVC REPORT AstraPro-SDI Diagnostics

PARAMETER		M4	%PRED	M1	%PRED	M2	%PRED	PRED	LLN
Best FVC	(l)	6.00	128	6.00	128	6.00	128	4.70	3.57
Best FEV1	(l)	4.58	127	4.58	127	4.58	127	3.61	2.70
BFev1/BFvc	(%)	76.32	99	76.32	99	76.32	99	77.03	0.65
FVC	(l)	5.00	106	6.00	128	5.13	109	4.70	3.57
FEV1	(l)	4.58	127	4.26	118	3.87	107	3.61	2.70
FEV1/FVC	(%)	91.54	119	71.11	92	75.41	98	77.03	0.65
PEF	(l/s)	10.10		6.60		7.70			
FEF50%	(l/s)	6.17		3.77		4.94			
FEF25%-75%	(l/s)	5.68	194	3.41	116	3.21	109	2.93	1.41
FEF50%/FIF50%		1.00		1.00		1.00			
FEV1/FEV0.5		1.30		1.55		1.39			
PIF50%	(l/s)	6.17		3.76		4.94			
PIVC	(l)	5.00		6.00		5.13			
Vext.	(l)	0.08		0.06		0.09			
FEV6	(l)	5.00		6.00		4.99			
FEV0.75	(l)	4.21		3.63		3.46			
FEV0.75/FVC	(%)	84.21		60.47		67.50			

Repeatability ATS/ERS: FVC: No, FEV1: No

Interpretation ATS/ERS
Possible restriction:
Mild





Report: It allows printing the report.

Forward / Backward: It allows advancing or moving back through the report to visualize each one of its sheets.

Help: It allows entering to the preliminary view help.

Return: It allows getting back to the previous screen.

2.10. SLOW VITAL CAPACITY «VC» TEST PROCEDURE

The procedure to perform the slow Vital Capacity test is similar to the one described in the **FORCED VITAL CAPACITY "FVC" TEST PROCEDURE** section but with the following variations:

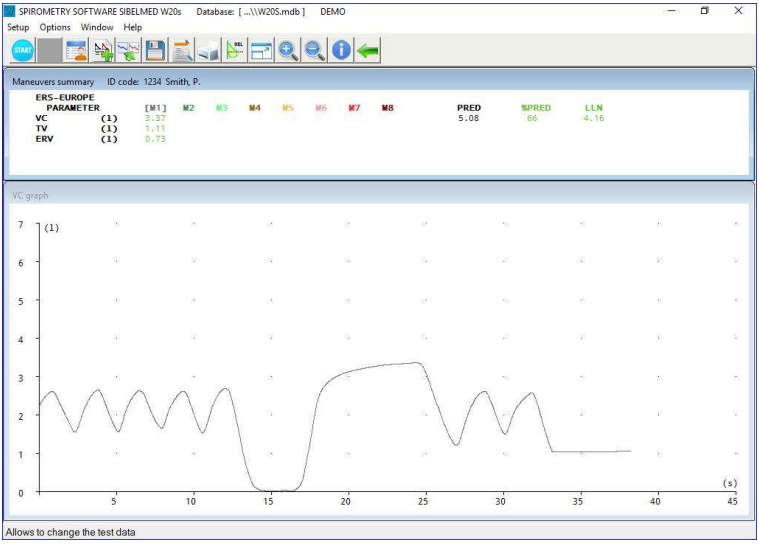
1 Select the patient in the database or create a new one as described previously, then click the button **VC**.

2 Train the patient about the performance of this kind of test, as his collaboration is essential for its correct execution.

3 The maximum time to make the maneuver is 60 seconds. The device stores a maximum of eight ordered maneuvers according to VC value and being M1 the one of highest VC and M8 the one of lowest.

4 In order to measure the parameters ERV and TV correctly, each maneuver must have, at least four respiratory cycles.

5 The graph is displayed in Volume/Time mode and the graphic incentive is not available.

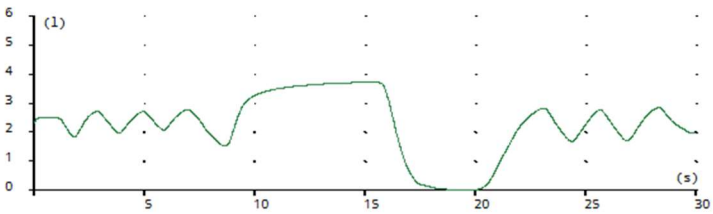


6 The report with the parameters and graphics is displayed next.

```
ID Code:        0123                    Date:     30-03-2016     Time:     16:53
Name:           Sanz Medas Francisco
Sex:            Male            Age(y):      40   Height(cm): 180  Wgt(Kg):  80
Temp(°C):       24              Pres(mmHg): 760   Humidity(%):60   Smok.I.:
Reason:                                                            BMI :     24.7
Procedence:
Technician:                                       Transducer: Disk
Predicted:      NHANES III Caucasian              Ethnic F.:  100
F.BTPS:         1.000
Version:        511-BLA-2.00

     VC REPORT          Maneuver No.:1

PARAMETER          ACT     (%)  PRED     LLN
VC          (l)    3.72
TV          (l)    0.78
ERV         (l)    0.98
IRV         (l)    1.96
IC          (l)    2.74
Ti          (s)    1.73
Te          (s)    2.31
Tt          (s)    4.04
Ti / Tt     (%)   42.81
```



2.11. MAXIMUM VOLUNTARY VENTILATION «MVV» TEST PROCEDURE

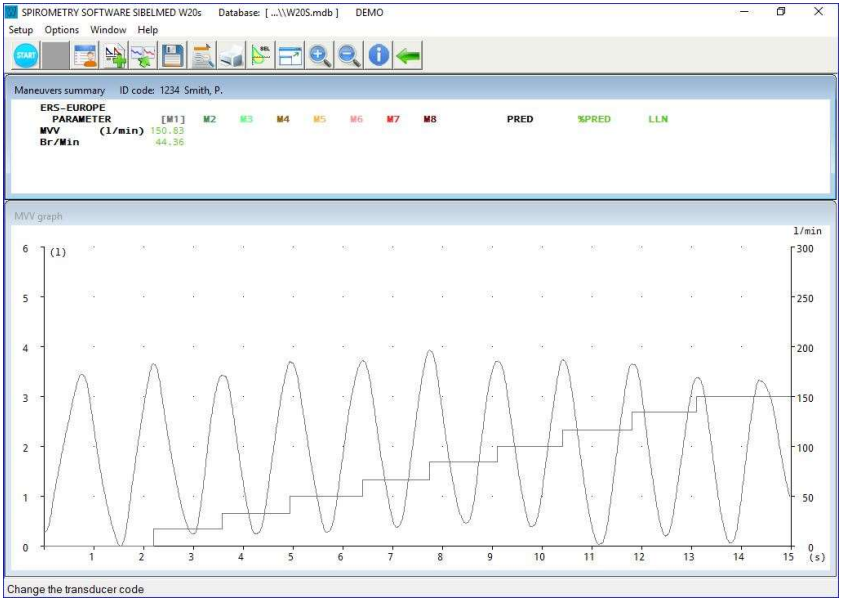
The procedure to make the test of Maximum Voluntary Ventilation "MVV" is similar to the one described in the **FORCED VITAL CAPACITY "FVC" TEST PROCEDURE** section but with the following variations:

1 Select the patient in the database or create a new one as described previously, then click the button **MVV**.

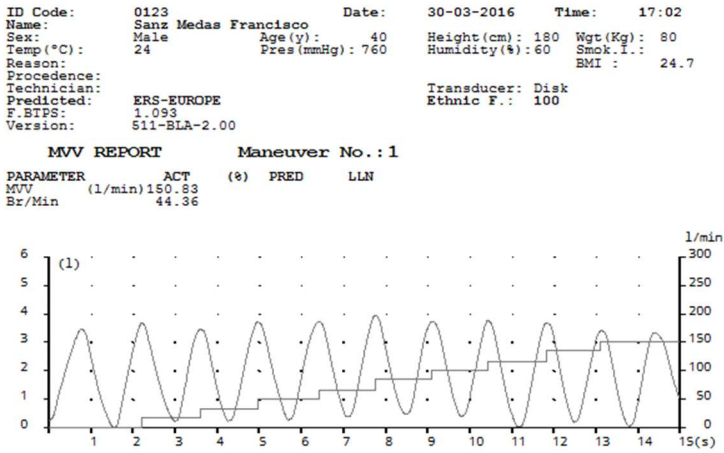
2 Train the patient about the performance of this kind of test, as his collaboration is essential for its correct execution.

3 The maximum time to perform the maneuver is 15 seconds. The device stores a maximum of eight maneuvers ordered according to the MVV value and being M1 the one of highest MVV and M8 the one of lowest.

4 The graph is represented in Volume/Time mode and no graphic incentive is available.



5 The report with the parameters and graphics is displayed next:



2.12. BRONCHODILATION TESTS

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** offers the possibility of making Postbronchodilation tests in Forced Vital Capacity «FVC» mode, Slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV».

The purpose of this operation mode is to have in the same report the spirometric results before (PRE) and after (POST) the application of a bronchodilator substance in order to compare them.

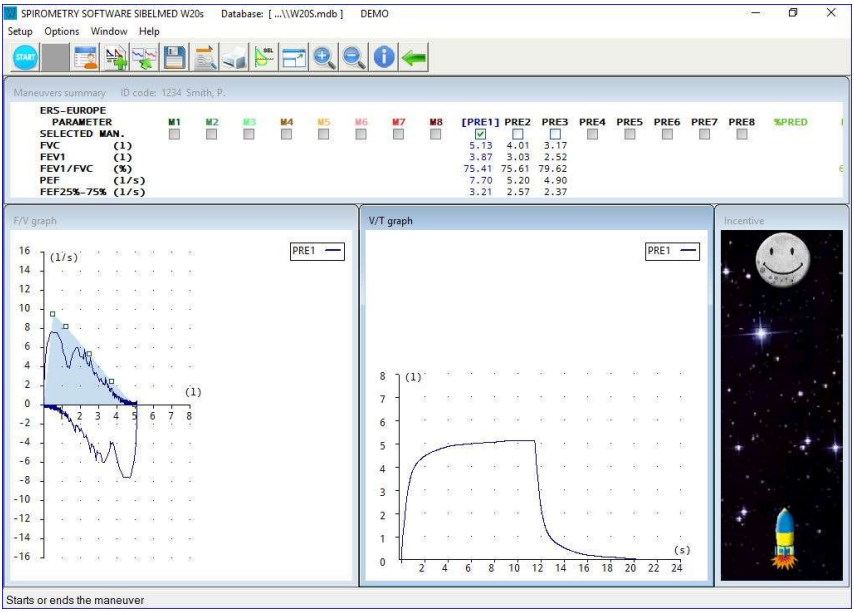
The procedure to make the Postbronchodilation Spirometry Test is the following:

1 Perform a «FVC», «VC» or «MVV» test, according to the previous sections.
Store the test as described in the section FVC PROCEDURE.

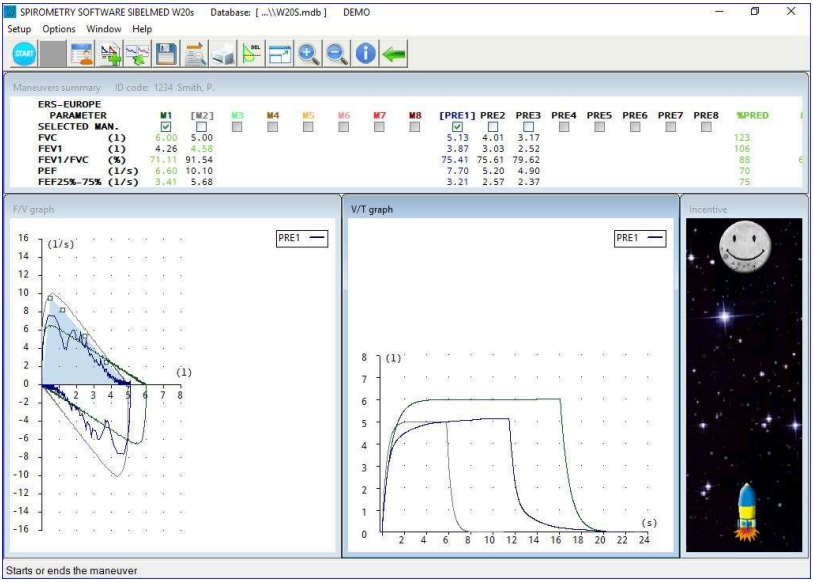
2 Apply to the patient the bronchodilator agent determined by the doctor. Tests made to other patients may be conducted while the bronchodilator effect takes place.

3 In the database select the test that will be used as Prebronchodilation and click the button **POST**."

4 Select the Prebronchodilation with which the POST data will be compared. Press **OK**.
When saving a PRE maneuver when using the disposable transducer, it also saves the Transducer Calibration Code and it is recovered in the POST maneuver.



5 Then, proceed as described in ENTERING FORCED VITAL CAPACITY TESTS subsection of the FVC PROCEDURE section.



6 If the printed report is required, data are represented in a similar way to this:

SDI DIAGNOSTICS, INC
10 Hampden Drive, Easton, MA

SDI DIAGNOSTICS

ID code:	0000000001	Date:	05-02-2016	Time:	09:37
Name:	Smith Peter				
Sex:	Male	Age(y):	61	Height(in): 71	Wgt(lb): 154
Temp.(°F)	77	Pres(mmHg)	760	Humidity(%) 65	Smok.I.:
Technician:				Transducer: Disk	
Predicted:	SEPAR 2013-SPAIN			Ethnic f.: 100	BMI : 21.6
F.BTPS:	1.086				
Version:	S118FB-4.00_BETA_0.02				

FVC REPORT — AstraPro-SDI Diagnostics

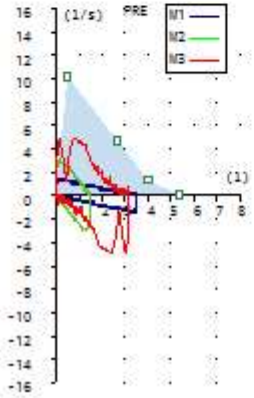
PARAMETER		PRE M1	PRE M2	PRE M3	%PRED	LLN	POST M1	(%)	POST M2
Best FVC	(l)	3.48	3.48	3.48	66	4.38	5.13	47	5.13
Best FEV1	(l)	1.19	1.19	1.19	30	3.24	3.87	225	3.87
BFev1/BFvc	(%)	34.20	34.20	34.20	46	65.16	75.44	121	75.44
FVC	(l)	3.48	1.50	3.17	66	4.38	5.13	47	2.73
FEV1	(l)	1.19	1.37	2.52	30	3.24	3.87	225	1.81
FEV1/FVC	(%)	34.15	91.51	79.50	46	65.16	75.37	121	66.23
PEF	(l/s)	1.38	2.95	4.75	14	7.54	7.53	446	3.71
FEF50%	(l/s)	0.71	1.90	2.77	16	2.35	4.94	596	1.54
FEF25%-75%	(l/s)	0.67	1.70	2.37	20	1.63	3.21	379	1.27
FEF50%/FIF50%		0.95	1.00	1.00	144	0.53	1.00	5	1.00
FEV1/FEV0.5		1.82	1.30	1.32	126	1.16	1.39	-24	1.53
FIF50%	(l/s)	0.74	1.90	2.77			4.94	568	1.54
FIVC	(l)	3.48	1.50	3.17			5.13	47	2.73
Vext.	(l)	0.01	0.02	0.35			0.09	800	0.02
FEV6	(l)	3.21	1.50	3.17			4.99	55	2.73
FEV0.75	(l)								
FEV0.75/FVC	(%)								

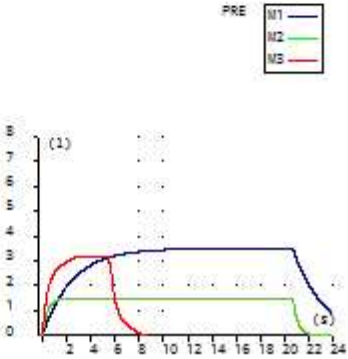
Repeatability ATS/ERS: FVC: No, FEV1: No

Symptoms : Cough

Alerts ATS/ERS : PRE M3: EX
POST M3: EX

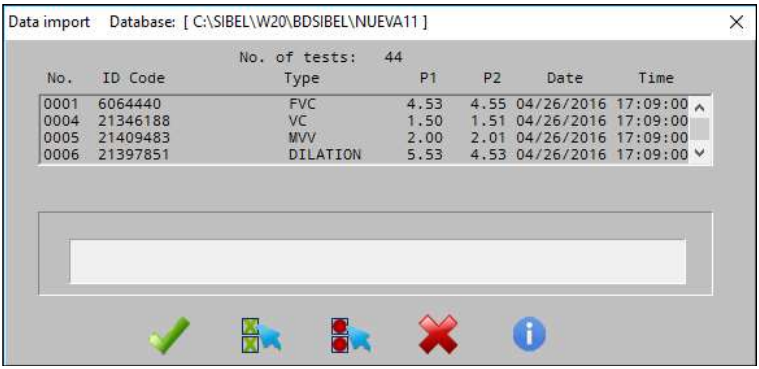
Interpretation ATS/ERS
NORMAL
Post-BD: Significant Response





2.13. IMPORTING TESTS FROM THE SPIROMETER

Click the button **Download spirometer data** or select the option in the menu **Database**



This option allows to transfer or import tests which are stored in the spirometer (**ASTRA TOUCH, ASTRA 100/200/300** or other compatible) to the computer database.

The process to follow is this:

1 Connect the spirometer to the computer serial port.

2 Verify that the spirometer is turned on.

3 Select the tests to be transferred with the mouse if they are

4 Press the key **IMPORT** to transfer.

The screen presents the following information:

Nr Number of test order

Reference	Corresponding to the patient
Type	Corresponding to the type of test, being: **FVC** Forced Vital Capacity **VC** Slow Vital Capacity **MVV** Maximum Voluntary Ventilation **Dilat** Postbronchodilation Test in FVC mode
P1 and P2	Parameters corresponding to:

	P1	**P2**
FVC	FVC	FEV1
VC	VC	VT
MVV	MVV	Breath/min
Dilat	FVC-pre	FVC-post

Date and Time	Performance of the test

Each test transfers all the available parameters. The two previously mentioned are approximate for the user.

The information transferred is stored in the operative **Database** at that moment and in each corresponding patient card.

2.14. CALIBRATION PROCEDURE

The **Spirometry Software AstraPro** requires another product to be able to fulfill its functions. As a consequence, it does not include any calibration system, as this is performed from the linked spirometer, except while using with the **ASTRA BT**, as these device don't have an user interface and the calibration is done through this software.

COMMON REMARKS

As previously mentioned, the current standards for the spirometry recommend that all the spirometers must be calibrated periodically. This is due to the alterations that can modify the characteristics of the electronic circuits and mechanical elements, and produce a change in the spirometer calibration factors. For this reason, a

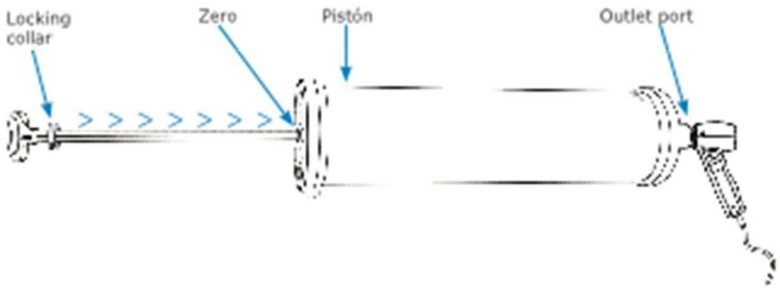
calibration system has been integrated using a signal of reference volume (for example, a syringe).
Besides this calibration factor, the changes in volume associated to the weather conditions (temperature, relative humidity and pressure) must be taken into account. The most influential factor is the temperature, followed by the humidity degree.
The **ASTRA BT** has a built-in Calibration Program, which in a quick and easy way (less than two minutes) verifies and self-corrects the deviations of the performed measurements. The periodicity of the calibration depends on the user criteria. SDI DIAGNOSTICS recommends, according to the different standards, a daily or weekly calibration.

TRANSDUCER TYPE

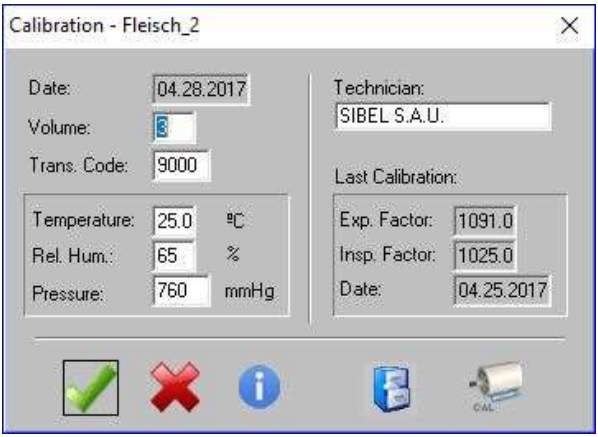
The turbine transducer type is a system of good reliability and reproducibility. Its duration is limited to the use and care applied to the transducer.

CALIBRATION PROCEDURE

1 Connect the transducer to the syringe, according to the illustration



2 In the database window click on or select the menu option **QUALITY CONTROL - CALIBRATION**.

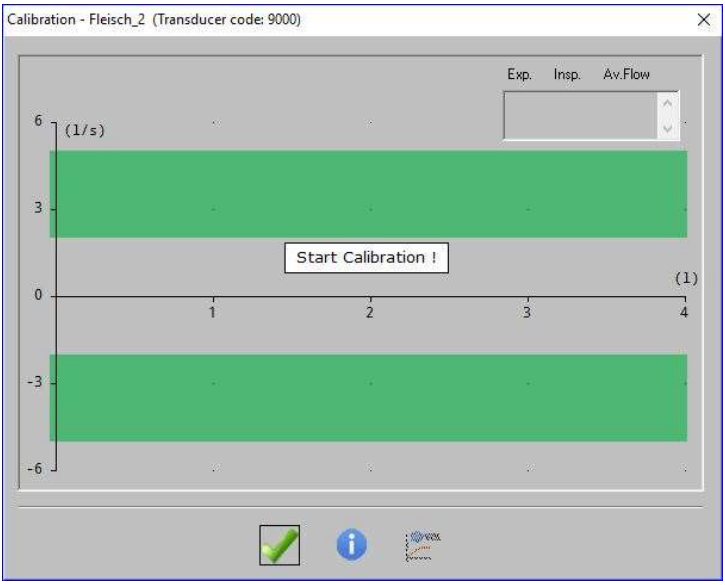


OK	Exits the calibration updating the values.
Cancel	Exits the calibration without updating.
Help	Shows the help file.
Calibrate	Starts the calibration process.
Base	Shows the database with the last calibrations made.

3 Fill in the data of the screen according to:

- Date: the date is filled automatically.
- Volume (l): volume of the syringe in liters, between 1 and 6 liters.
- N. pulses: number printed in the turbine corresponding to the number of pulses/turn.
- Temperature (ºC/ºF): value of temperature in ºC (ºF).
- Humidity (%): value of humidity in %.
- Pressure (mmHg): value of room pressure in mmHg.
- Technician: name or code of the person who performs the calibration (optional).

Data from last calibration (expiratory / inspiratory factors and date) are not modifiable. These are the factors applied by the device.
Click on the Calibrate button.



Calibration window in the ASTRA BT spirometer

4 It is advisable to perform the calibration process with three different flows, from 0 to 12 l/s: medium, high and slow. Start the calibration process by emptying the syringe for three consecutive cycles (one cycle consists of emptying and filling again the syringe). The syringe piston rod must displace the total volume of air taken as reference, both during the emptying and filling cycles. If this is not done properly, the computer will detect it as "incorrect maneuvers". Furthermore, this process should be performed in a regular and uniform way, not causing too high or low flows. The time of each cycle should not be less than three seconds and no more than six. Start the maneuver with the syringe piston rod completely out. During the maneuvers try to keep the curve within the green areas of the graph.

For simplicity, the calibration of the ASTRA BT may be achieved with at least **3 maneuvers in the medium flow level: 2 - 5 l/s**.

The screen presents the expiratory and inspiratory factors taken by the device. The button will be enabled to move to the next

flow level. After the three flow levels are calibrated click .

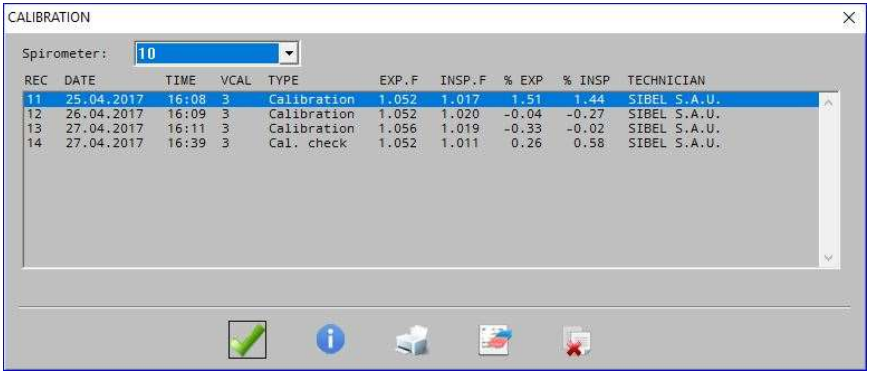
5 Once the device is calibrated, exit the Calibration process and start making the tests.

NOTE: If the Calibration Volume (l) is set to 0, the system sets the calibration factors to 1.00 (F. ESP. and F. INS). These are the original manufacturer's calibration factors. It is convenient to use these calibration factors only as an indication and only if a syringe is not available.

CALIBRATION DATABASE

The software has a database which stores the expiratory and inspiratory factors calculated in the **one hundred performed calibrations**. This is useful for those centers that require a quality control in the processes they use.

Click the Database button in the initial window of the calibration process or select the menu option **QUALITY CONTROL – CALIBRATION DATABASE**.



OK	Returns to the initial calibration window.
Help	Shows the help file.
Report	Prints all the records in the calibration database.
Delete	Deletes the selected record.
Delete all records	Deletes the whole calibration database.

The drop-down list in the upper left corner of the window allows to filter the calibration records with the selected serial number.
The information displayed in the report includes:

Serial number of the calibrated device

Number of record
Date of calibration
Time of calibration
Calibration volume
Type of maneuver (calibration / check)
Expiratory factor
Inspiratory factor
Expiratory volume error
Inspiratory volume error
Technician who performed the calibration

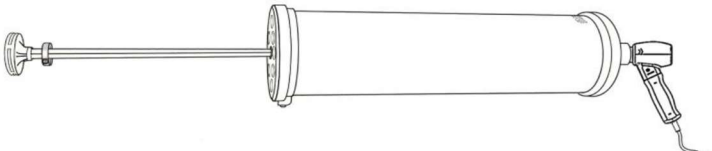
CALIBRATION CHECK

The ATS/ERS TASK FORCE 2005 recommends that all spirometers are daily checked for calibration, before further testing begins.
The possible aging or the accumulated dirt of transducers may lead to inaccurate measurements. In the Pneumotachometers, the relationship between the pressure drop and the airflow depends on the gas viscosity. This viscosity also depends on the atmospheric conditions (temperature, pressure and humidity). For this reason it is necessary to perform a daily calibration check in **order to validate that the equipment operates within calibration limits.**

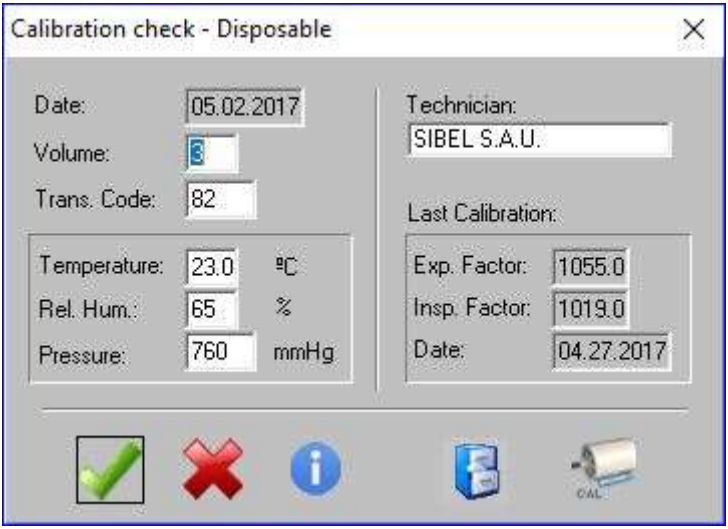
If the spirometer does not pass **the calibration check**, then it will be necessary to carry out the calibration procedure or maintenance of the device to ensure the proper use of the spirometer.

To verify that the transducer operates properly, the program includes a simple verification procedure based on measuring the known volume of a calibration syringe.

1 Couple the transducer to the syringe (between 3 and 6 L) according to figure.



2 Select the menu option **QUALITY CONTROL – QUALITY CONTROL**. Fill in the required fields and click on button .



3 Discharge the syringe **one time** at each of the following flow ranges between 0-12L/s:

Low flow level: 0,4 – 1,2 L/s
Medium flow level: 2 - 5 L/s
High flow level: 6 - 12 L/s

For simplicity, it is possible to carry out the calibration check with a single maneuver at the medium flow level: **2 - 5 L/s**.

4 Press to accept the maneuver and move to the next flow level.

5 Press to finish the calibration check procedure.

6 If calibration check has been correct, results will be saved automatically in the **calibration database**. Press to view the record data.

7 Once the calibration check is completed, start the desired spirometry test.

8 If the calibration check is not correct, proceed to calibrate the spirometer. See the previous section **CALIBRATION PROCEDURE**.

Note:
The error for each flow must be less than ± 3.5%. The inspiratory and expiratory factors are not modified in this procedure.

2.15. SOFTWARE UPDATE

Some of the software features, like the maximal pressure test or the pulse oximetry are optional modules and are disabled by default.

If you purchased these options please go to SETUP - UTILITIES – OPTIONS ACTIVATION or clic the icon in the toolbar. The next window will be shown. Enter the code supplied by SDI DIAGNOSTICS or your authorized distributor.

The new options will be available now in the Software Astra Pro.

2.16. FIRMWARE UPDATE

The **ASTRA** spirometers from **SDI DIAGNOSTICS** have the option of updating the internal software. To update the software version follow these instructions:

2.17. DATA DOWNLOAD FROM THE DEVICE

The spirometers **ASTRA 100/200/300** and **ASTRA TOUCH** have the option of transferring information to the computer. This information is saved in internal files and contains data about:

- Hardware verification
- Software verification
- Device customization
- Calibration register
- FVC Tests

If you detect any problem with the device that you cannot solve, send this information to the **SDI DIAGNOSTICS After Sales Department** or to your local **Dealer,** who will analyze and evaluate the origin of the problem and will try to offer you the most suitable solution.

To transfer this information follow the next steps:

1 Turn on the device and select the option **Auto-checking**. Execute all the sub options following the on-screen instructions.

2 Connect the device to the computer and select the link parameters in «**Setup/Links**».

3 Select the option «**Setup/Download spirometer configuration**».

4 Click on **OK** to transfer the information.

All downloaded data is stored in the application folder, in the following files:

STATUS.CSV contains the detected errors
CALIBRA.CSV contains the calibration data
CONFIG.CSV contains the device customization
PRUEBAS.CSV contains the tests of the database
GRAFICAS.CSV contains the graph in Flow/Time format

In case there are files from a previous download they will be renamed with the extension **.OLD**

5 If you want to visualize the information of any of the files, open them with MICROSOFT EXCEL

6 Attach the files in your e-mail program and send them to **SDI DIAGNOSTICS Technical Department** or to your local **Dealer**.

2.18 CONFIGURATION OF THE ASTRA BT SPIROMETER

Make sure your spirometer is running and connected to the PC. Check that the selected port is correct. Otherwise, proceed as discussed above in the "Settings / Links" menu option.

Select the "Setup / Utilities / Spirometer configuration" menu option. The following parameters can be set in the "Datospir Aira configuration" window:

Update temperature with the device value	When this option is enabled the program will use the temperature value measured by the spirometer. Uncheck this option to enter manually the temperature at the beginning of the spirometry test.
Transducer code	Numeric value that models the behavior of the transducer. Not modifiable by the user.
Interval between maintenance	Time elapsed for the program to advise on the desirability of a new preventive maintenance of the spirometer. Value between 0 and 999 days. If the value is 0, the message is never displayed.
Interval between calibrations	Time elapsed for the program to advise on whether to perform a calibration of the spirometer. Value between 0 and 999 days. If the value is 0, the message is never displayed.
Total number of tests	Total number of maneuvers performed with the spirometer. Not modifiable by the user.
Battery type	Indicate whether you are using NiMh (rechargeable) or alkaline batteries.
Model	Indicates the spirometer model. It also indicates whether the spirometer has Bluetooth connectivity, as well as USB connection.

3. TECHNICAL SPECIFICATIONS

3.1 SOFTWARE SPECIFICATIONS

3.1.1 COMPUTER INSTALLATION AND REQUIREMENTS

The computer installation will be carried out according to the User Manual. The computer must meet the following **minimum requirements**:

	Minimum	**Recommended**
RAM Memory:	1 GByte	2 GByte or more
Hard Disk:	20 MByte	200 GByte or more
Graphic Card:	1024x768	1280x1024 or more
Monitor:	15"	17"
Ports:	RS232, USB 1.1, USB 2.0	RS232, USB 2.0, USB 3.0, Ethernet

Backup Unit: Recommended

Printer: compatible with the operating system used.

3.1.2 OPERATING SYSTEM COMPATIBILITY

- Windows XP (SP1, SP2 or SP3)
- Windows 7 (32 or 64 bits; SP1)
- Windows 8.1 (32 or 64 bits)
- Windows 10 (32 or 64 bits)

3.1.3 SPIROMETER COMPATIBILITY

The software can be connected to the following ASTRA spirometers and its accessories:

- ASTRA BT
- ASTRA Touch model with or without:
    - ASTRA Touch MEP-MIP & Sniff modules
    - ASTRA Touch SpO2 module
- ASTRA 100/200/300 models

3.1.4 PC – SPIROMETER CONNECTIVITY

The software installed on a PC can be connected to spirometer via:

- RS-232 port
- USB port
- Bluetooth wireless port

Note: Not all the spirometers support all the connectivity.

3.1.5 PROGRAM CONFIGURATION

Software setup by the user in the following aspects:

- Type of printer
- Parameters, diagnosis, references and others
- Graphs, pediatric incentive and language
- Databases
- Communication Links with the software

3.1.6 DATABASES

- Possibility to work with different databases
- Storing of spirometric tests in FVC, VC, Postbronchodilation or MVV
- Storing of tests and graphics
- Creation, deletion, modification in the patient cards
- Fast consulting in the database by:
  - Record
  - Reference

- Surname

- Printing Reports from the database

3.2 TESTS, FUNCTIONS AND PARAMETERS

3.2.1 FORCED VITAL CAPACITY

Parameters:

• FVC	(l)	Forced Vital Capacity
• FEV.5	(l)	Forced Expiratory Volume in 0.5 seconds
• FEV1	(l)	Idem in 1 second
• FEV3	(l)	Idem in 3 seconds
• FEV.5/FVC	(%)	Relation
• FEV.75/FVC	(%)	Relation
• FEV.75	(l)	Forced Expiratory Volume in 0.75 seconds
• FEV1/FVC	(%)	Relation
• FEV3/FVC	(%)	Relation
• FEV1/VC	(%)	Relation
• PEF	(l/s)	Peak Expiratory Flow
• FEF25%	(l/s)	Instantaneous forced expiratory flow when 25% has been expired.
• FEF50%	(l/s)	Idem, at 50%
• FEF75%	(l/s)	Idem, at 75%
• FEF25-75%	(l/s)	Forced Mesoexpiratory Flow
• FEF75-85%	(l/s)	Medium Flow between 75-85% of FVC
• FET25-75	(s)	Time passed between 25-75% of FVC
• FET100	(s)	Forced Expiratory Time
• FEF50/FIF50	(-)	Relation
• FEV1/FEV.5	(-)	Relation
• FEV1/PEF	(-)	Relation
• FIF50%	(l/s)	Maximum Inspiratory Flow when 50% of FVC has been inspired

• FIVC	(l)	Forced Inspiratory Vital Capacity
• FIV1	(l)	Forced Inspiratory Volume in 1 second
• FIV1/FIVC	(%)	Relation
• FEV1/FIV1	(%)	Relation
• PIF	(l/s)	Peak Inspiratory Flow
• MTT	(s)	Measured Transit Time
• PEF/PIF	(-)	Relation
• Vext	(l)	Extrapolated Volume related to FVC
• MVVInd	(l/min)	Maximum Voluntary Ventilation indirect (30 x FEV1)
• FEV6	(l)	Forced Expiratory Volume in 6 seconds
• FEV1/FEV6	(%)	Ratio
• COPD rate		Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. It indicates the risk of COPD.
• Lung Age		Parameter that depends on the height and FEV1. It indicates the equivalent age of the lung.
• QC grade		Quality Control Grade According to NLHEP criteria.

3.2.2 QUALITY OF FVC TEST

In order to assess the pulmonary function of the patient, it is necessary to obtain measurements of high quality. The quality of maneuvers (and of the complete test) depends on patient cooperation and this, in turn, depends on the instructions provided by the technician.

To ensure good quality spirometry tests, the technician has to pay particular attention to ensure that the patient has made the utmost effort, that the start has been good and that no coughing or Valsava's maneuver due to glottis closure

has occurred. Special attention must be paid for preventing an early termination of the expiration.

The **SDI DIAGNOSTICS Astra Pro Spirometry Software** includes quality alerts to assist you in producing high quality spirometry tests. These alerts are based on the recommendations of ATS/ERS o NLHEP (National Lung Health Education Program), which can be selected from the menu **SETUP - SPIROMETRY - PARAMETERS AND REFERENCES** menu.

I. ATS/ERS ALERTS

The ATS/ERS recommendations define the following acceptability criteria for the maneuvers, based on the start and end of test:

Once the maneuver is finished, **one** or **two warnings** may appear on the screen indicating that the maneuver has not been performed according to the **ATS/ERS criteria:**

ET - It indicates that **expiration did not end satisfactorily**. This alert is based on two criteria:
EOTV: It indicates that the variation of accumulated volume during the last 2 seconds of the maneuver was greater than 25 ml.
FET: It indicates that the maneuver lasted less than 6 second in individuals of 10 years or older, or less than 3 seconds in children under 10 years.
The ET alert is indicated when one or both of these criteria are met.

EX - It indicates that the **expiration did not start satisfactorily** because the extrapolated volume was greater than 5% of the FVC or 0.15 liters, whichever is greater.

These alerts may be disabled in the **SETUP - SPIROMETRY - PARAMETERS AND REFERENCES** menu. In this case, they will also be removed from the printed report. This disabling is only at display level. The warnings are still taken into account when ordering the maneuvers and will be displayed in the "Maneuver Data" window.

II. NLHEP ALERTS: QC PROMPTS

The **SDI DIAGNOSTICS Astra Pro** software includes an automatic quality control function, based on the recommendations of the **NLHEP** (National Lung Health Education Program), with **prompts** to assist the technician in providing instructions to the patient to produce high quality spirometry tests.

At the end of a maneuver, a message on the screen will inform you about the acceptability of the maneuver. If it is considered not acceptable, provide instructions to the patient for improving the maneuver based on the messages indicated in the following table (see the rows in white).

When the message **"Good test Session"** appears, it is not necessary to carry out further maneuvers. If after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, let the patient take a break or stop the measurement.

Only one of the following QC prompts is displayed after a performed maneuver (in the order of priority listed below).

QC Prompt	Criteria	How to improve the maneuver?
Don't Hesitate	EX error (see ATS/ERS alerts)	The patient must start exhaling harder.

Blast Out Faster	PEFT error (time to reach PEF higher than 120 ms)	The patient must exhale as hard, firm and fast as possible.
Blow Out Longer	ET error (FET < 6 seg and EOTV > 100 ml during the last 0.5 s of the maneuver)	The patient has abruptly interrupted exhalation. The patient must exhale even more and expel as much air as possible from his/her lungs.
Blast Out Harder	If there are not 2 acceptable maneuvers, with the two largest PEF values matching within 1 L/s	The maneuver differs significantly from the previous ones The patient can exhale even more vigorously and achieve a higher peak flow.
Deeper Breath	If there are not 2 acceptable maneuvers, with the two largest FEV6 values matching within 150 mL	The maneuver differs significantly from the previous ones. The patient must inhale more deeply and exhale even more air.
Good Test Session	After 2 acceptable maneuvers that match.	TEST COMPLETE. Adequate number of good maneuvers.

Refering to the **acceptability** of the last maneuver performed
Refering to the **repeatability** of the maneuvers

III. NLHEP QUALITY GRADING (QC GRADES)

At the end of the test (maneuvers session), a quality grading from A to F will be displayed to indicate the reliability of the results, according to NLHEP criteria.
A, B and C grades indicate a reliable result, but a grade D or F indicates a poor quality test (in this case, the results should be interpreted with caution).

GRADE	TEST	CRITERIA
A	VERY GOOD	At least 2 acceptable maneuvers with the largest 2 FEV_1 values matching within 100mL and the largest 2 FEV_6 values matching better than 100mL.
B	GOOD	At least 2 acceptable maneuvers with FEV_1 values matching between 101 and 150mL
C	ACCEPTABLE	At least 2 acceptable maneuvers with FEV_1 values matching between 151 and 200 mL
D	POOR	Only one acceptable maneuver, or more than one, but the FEV_1 values match > 200 ml (with no interpretation)
F	NOT ACCEPTABLE	No acceptable maneuvers (with no interpretation)

3.2.3 INTERPRETATION ALGORITHMS (DIAGNOSIS)

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** includes two types of diagnosis available through **SETUP – SPIROMETRY - PARAMETERS AND REFERENCES - SELECTION**.

Miller Diagnosis
It presents the following information NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED.

Snider, Kory & Lyons Diagnosis
It is based on the following criteria:

- If FVC > 80% of FVC Reference and FEV1 > 80% of

FEV1 Reference --> **Values in reference range. Normal Diagnosis**

● If FEV1/FVC% < FEV1/FVC% Reference and FEV1 < 80% of FEV1 Reference --> **Ventilatory alteration of Obstructive type**

FEV1 < 80%	**Light**
FEV1< 65%	**Moderate**
FEV1 < 50%	**Strong**
FEV1 < 35%	**Very Strong**

● If FEV1/FVC% > FEV1/FVC% Reference and FVC < 80% of FVC Reference --> **Ventilatory alteration of non Obstructive type**

FVC < 80%	**Light**
FVC < 65%	**Moderate**
FVC < 50%	**Strong**
FVC < 35%	**Very Strong**

● If FEV1/FVC% > FEV1/FVC% Reference and FVC > 80% of FVC Reference --> **Ventilatory alteration of Mixed type suspected**

● If FEV1/FVC% < FEV1/FVC% Reference and FEV1 > 80% of FEV1 Reference --> **Ventilatory alteration of Mixed type suspected**

● If a bronchodilation test is made and the FEV1 POST surpasses in 15% to the FEV1 basal or PRE --> **There is a positive reaction to the bronchodilater substance**

Interpretation ATS/ERS.
According to Pellegrino et al. Task force: Standardisation of Lung Function Testing. Eur Respir J 2005; 26: 948–968
Interpretation NLHEP.

Only valid for references that calculates the LLN. For example: Hankinson. According to Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117: 1146-1161.

3.2.4 PREDICTED SETS

Predicted set	Country / Region	Age range (years)
SEPAR 2013	SPAIN	6 to 85 (1)
ERS	EUROPE	18 to 70 (1)
KNUDSON	EEUU	6 to 84 (1)
CRAPO	EEUU	4 to 91 (1)
ZAPLETAL	EUROPE	4 to 17
MORRIS	EEUU	24 to 100
AUSTRIA	AUSTRIA	5 to 90 (1)
GUTIERREZ	CHILE	5 to 100 (1)
CASTRO- PEREIRA 2002	BRAZIL	6 to 25
POLGAR - WENG		4 to 100
HANKINSON - NHANES III	EEUU	4 to 100
PEREZ - PADILLA	MEXICO	7 to 100 (1)
A.J. CRUZ	MEXICO	17 to 65 (1)
GOLSHAN	IRAN	5 to 82 (1)
GARCIA RIO	EUROPE	65 to 85
CANDELA	SPAIN	2 to 7
PLATINO	LATIN-AMERICA (Mexic, Chile, Venezuela, Brazil, Uruguay)	40 to 90
THAI 2000	THAILAND	10 to 100
GLI	INTERNATIONAL	3 to 95
CASTRO-PEREIRA 2007	BRAZIL	26 to 86

(1) If other ages are used, the predicted values are extrapolated

It is possible to include other references. For this purpose, contact **SDI DIAGNOSTICS Technical staff.**

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in FLOW/VOLUME and VOLUME/TIME mode

Incentive graphics in pediatric tests
Concordance Maneuver Warnings with the ATS/ERS criteria

3.2.5 SLOW VITAL CAPACITY

Parameters:

- VC (l) Slow Vital Capacity
- TV (l) Tidal Volume
- ERV (l) Expiratory Reserve Volume
- IRV (l) Inspiratory Reserve Volume
- IC (l) Inspiratory Capacity
- Ti (s) Inspiratory Time
- Te (s) Expiratory Time
- Tt (s) Total Time
- Ti/Tt (-) Relation

Normalized Predicted Sets to be selected among different standards

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in VOLUME/TIME mode

3.2.6 MAXIMUM VOLUNTARY VENTILATION

Parameters:

- MVV (l/min) Maximum Voluntary Ventilation
- Br./min (Br/min) Breathing Frequency of MVV

Normalized Predicted sets to be selected among different standards

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in VOLUME/TIME mode

3.2.7 POSTBRONCHODILATION TEST

Same parameters as FVC tests

Comparing methods between PRE and POST

- % Average between PRE and POST
- % between REF and POST
- % between PRE and POST
- Difference between PRE and POST

Superposition of PRE and POST maneuvers graphs in the external printer

3.2.8 BRONCHOCONSTRICTION TEST

Parameters

- FVC (l) Forced Vital Capacity

- FEV1 (l) Idem in 1 second
- PEF (l/s) Peak Expiratory Flow
- FEF25-75% (l/s) Forced Mesoexpiratory Flow
- All the parameters of the FVC tests can be selected

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Continuous and short functioning modes

Deviation Percentage between Basal & Dissolution

Superimposition of graphics in FLOW/VOLUME or VOLUME/TIME mode

Stopwatch to control the steps

Type of drug and accumulated dose

Calculation of PD20 (FEV1) by mathematic adjustment or linear interpolation

Numeric and graphic (dose/response) data summary on screen

Link with bronchodilation test

3.2.9 MAXIMAL PRESSURES OPTION

PARAMETERS

The following paramaters are calculated for both expiratory and inspiratory tests:

- Maximum Pressure of the 5 maneuvers.
- Mean of the best 3.
- Standard Deviation of the best 3.

RANGES AND MEASUREMENTS

- Measurement Range ±295 hPa (±300 cmH_2O)
- Resolution 1 hPa (1 cmH_2O)
- Precision 3 %
- Sampling Frequency 100 Hz
- Maneuvers under 9,8 hPa (10 cmH_2O), are dismissed
- Start of Maneuver: When the threshold of 2.95 hPa (3 cmH2O) is exceeded
- End of Maneuver: Variation less than 1 hPa (1 cmH2O) in the last 2 sec.

CONTROL

- Number of maneuvers.
  A maximum of 5 maneuvers of each type can be performed (MEP and MIP)

- Maneuver Duration.
  The maximum duration is 8 seconds

- Maneuver Start.
  When it gets beyond the 2.95 hPa (3 cmH2O) threshold
- Maneuver Ending.
  Less than a 1 hPa (1 cmH2O) variation in the last 2 seconds

- Delay in the maximum pressure value calculation.
  1 second by default. Can be configured in the Setup

- Database
  The spirometer shares the database for all the different tests

3.2.10 PULSE OXIMETRY OPTION

TESTS AND PARAMETERS

- The various spirometers allow one-time or long-term measures, except for the ASTRA BT, which has no pulse oximetry option.".

For both, lone studies or long-duration studies, the next parameters can be calculated:

- **CT90** % of the time in which the **SpO_2** is under 90%
- **CT80** % of the time in which the **SpO_2** is under 80%
- **CT70** % of the time in which the **SpO_2** is under

70%

- **IDH-4** index of desaturations (>= 4%) per hour
- **IDH-3** index of desaturations (>= 3%) per hour
- **IDH-2** index of dessaturations (>= 2%) per hour
- **SpO2 Max** maximum value of the Saturation
- **SpO2 Medium** medium value of the Saturation
- **SpO2 Min** minimum value of the Saturation
- **SpO2 Std** standard deviation of the Saturation
- **PR Max** maximum value of the pulse rate
- **PR Medium** medium value of the pulse rate
- **PR Minimum** minimum value of the pulse rate
- **PR Std** standard deviation of the pulse rate
- **Test Time** time of use of the test (the finger probe unplugged time is not count)

RANGES AND MEASUREMENTS

ASTRA TOUCH			
Measurement Range		**SpO_2 (%)** 0 - 100	**Pulso (BPM)** 30-235
Resolution		1	1
Resolution	80 to 100 70 to 80	+/- 2 +/- 3	+/- 2 ó 2% (the greater of both)

CONTROL

- Start and ending of the maneuver suitable to the user.
- One only valid study until the change of patient.
- When initializing the data, the program allows starting a new study for the same patient.

3.3 GENERAL DATA

3.3.1 MEASUREMENT SYSTEM

- Transducer Turbine type.

- Measurement Scale:
  - Flow from -16 l/s to +16 l/s
  - Volume from 0 to 10 l

- Accumulative Volume Time
  - Eight curves FVC of maximum 60 seconds each
  - Eight curves VC of maximum 60 seconds each
  - Eight curves MVV of maximum 60 seconds each

3.3.2 ANALYSIS CRITERIA

- Start expiration FVC
  Calculated by the retrograde extrapolation method

- Final expiration FVC
  Calculated when the accumulated volume in the last second is lower than 0.025 liters

- Selection of tests FVC
  Performed according to the criteria of maximum addition of FVC+FEV1 or at the operator convenience

- Selection of parameters
  The displayed parameters are the corresponding to the selected maneuver (selected by the operator or by the best FVC + FEV1 default criteria) Also are displayed the best FVC and best FEV1 as the highest values recorded among the performed and stored maneuvers.

- Start of expiration in VC and MVV by signal level

- Selection of tests and parameters in VC and MVV
  . Highest value in VC or MVV

3.3.3 USEFUL LIFE

The useful life is 7 years

3.3.4 STORAGE

It is recommended to store a 25ºC, at this temperature manufacturers guarantee 1000.000h. At 70 ° C the life is reduced to 2000 h. See specifications of CD ROM for more information.

3.3.5 STANDARDS

The Astra Pro software fulfils ATS/ERS 2005 recommendations and the SEPAR recommendations.

3.4 SYMBOLS

MANUFACTURER (Manufacturer's name and address)

MANUFACTURING DATE

TEMPERATURE LIMITATION

LIMITATION OF MOISTURE

LIMITATION OF PRESSURE

ATTENTION IDENTIFIED RISK

4. MAINTENANCE

The **Spirometry Software SDI DIAGNOSTICS Astra Pro** does not require any specific maintenance, except that for any computer program handling information.

- Make a copy in a CD_ROM in case the original gets damaged.

- Make periodical backup copies of the databases used in order to be able to restore them if any loss of information occurs in the computer.

If any problem, doubt, suggestion arises before, during or after the use of the product, it is recommended to follow these steps:

1 Use the help windows available in the program

2 Use this User's Manual properly

3 Check that you are running the last version of the program

4 Contact with the Technical Service of SDI DIAGNOSTICS