

# *Astra*<sup>★</sup> **TOUCH™**

## **Spirometer** **USER'S MANUAL**

**29-5429**

Rev. 1.30.25



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The **AstraTouch Spirometer** has been designed with the collaboration of the Lung Function Laboratory of *Hospital de la Santa Creu i Sant Pau de Barcelona*, to comply with the standardization criteria of International Institutions: **ATS/ERS TASK FORCE 2005** (American Thoracic Society/ European Respiratory Society).

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**Approved**  
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## 1. SAFETY

### SPECIAL PRECAUTIONS

The **AstraTouch** spirometer has been designed for use with safety in mind. All operating instructions must be read before performing clinical tests with it. Failure to do so could cause injury to the user or patient and damage to the equipment and/or accessories.

### INTENDED USE

- a) Measurement of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
- b) Measurement of peripheral blood oxygen saturation and cardiac pulse for the respiratory diagnostic.
- c) Measurement of inspiratory and expiratory maximal pressures for respiratory diagnostics. Use in a health center or similar and indoor use (not for outdoor use). Not intended for home use or for use in moving transport vehicles.

### INDICATIONS for USE

The spirometer should not be used under high ambient noise levels to ensure that the patient can hear the acoustic signal of the device.

The equipment should be placed in a safe position to avoid falling that may result in equipment damage or harm to the patient and/or user. The spirometer is NOT designed for use under other conditions or using other power sources not indicated in this manual. Use only accessories specified in this manual.

This spirometer is intended to be used in the following patient population:

- a) Age 4 years to elderly
- b) Weight: >15Kg (35lb)
- c) Height: >50cm (20in)
- d) Health Status: Physical and mental condition that allows the performance of the forced maneuver.

## **USER PROFILE**

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

The Bronchoprovocation test must be supervised by a qualified technician familiar with this type of testing.

Before using the spirometer with patients, familiarize yourself with the operation of the instrument. All information necessary for its operation is available in this manual.

For additional training on spirometry testing or on the instrument, contact SDI Diagnostics at 1-800-678-5782 or your dealer.

## **EFFECTS ON PATIENTS USING THE SPIROMETER**

Spirometry testing requires patient cooperation.

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

## **LIMITATIONS FOR USE. CONTRAINDICATIONS**

An analysis of the spirometry test results is insufficient 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 spirometer should not be used when it is likely that the validity of the results could be compromised by external factors.

Take care **NOT** to place the equipment where it could be splashed by water or other liquids or cover it with objects that prevent air from circulating around it while it is running.

The device should **NOT** be used stacked or adjacent to other equipment.

All accessories and spare parts must be original 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.

The equipment must be stored and used within the temperature, pressure and humidity ranges specified in the section **6.1**.

## WATER ENTRY PROTECTION LEVEL

**IPX2. Vertically dripping water** shall have no harmful effect when the enclosure is tilted **at an angle up to 15° from its normal position**. In compliance with EN-ISO 99-19:2009 per substitute: ISO 80601-2-61:2011.

## ELECTRICAL RISKS

To avoid the risk of electric shock, this equipment must be connected to a power supply with protective grounding only.

**DO NOT** tamper with the integrity of the system's electric ground connection. Protection against electrical discharge is provided by the connection of the chassis to an electrical ground connection. The ground connection is only effective when the three-wire power cable supplied with the equipment is connected to a suitably grounded electrical socket.

**DO NOT** use a multiple socket strip, unless they comply with EN-60601.1. They can degrade electrical safety.

**DO NOT** disassemble the equipment or accessories case. The device must only be serviced and repaired by skilled personnel. The contact with voltage inside the device may cause serious injury.

**DO NOT** use damaged accessories. **DO NOT** use the equipment if the power cable is in poor condition or cracked.

**DO NOT** connect a line phone to the MIP-MEP connector.

## ELECTRICAL DISCHARGE

To ensure vital safety features under the EN 60601-1 standard, only equipment compliant with the electrical safety standards in force

may be connected to this device. To connect **AstraTouch** to a non-medical device with a ground conductor, you must install an additional ground conductor to the non medical device.

**NEVER** immerse any part of the equipment in liquid. **THIS COULD CAUSE AN ELECTRIC SHOCK.** Consult the section **7.1**.

## RISKS OF EXPLOSION

**NOT** suitable for use in the presence of volatile anesthetics, flammable gases or in oxygen-rich environments. **THIS MAY CAUSE AN EXPLOSION.**

## RISKS OF CONTAMINATION

To avoid the risk of contamination or cross infection, the **Turbine** transducers and some of the optional modules must be disinfected before use with a new patient or must be used with an adequate **protective barrier filter**, compatible with the equipment.

Reusable mouthpieces must also be disinfected. **Disposable** transducers and disposable mouthpieces must **NOT** be reused.

**DO NOT** use mouthpieces or other supplies from manufacturers that have not tested their biocompatibility, since it could endanger patient health. (See Section 7.1)

## RISKS OF INTERFERENCE

This is an electronic medical device; therefore requires special precautions regarding electromagnetic compatibility (EMC): it must be installed and put in service according to the information attached in **Annex 1. ELECTROMAGNETIC COMPATIBILITY.**

As this is an electronic product, high frequency emissions may interfere with its correct use. Thus, keep the spirometer away from products that may generate interference (radios, cell phones, etc).

All accessories, transducers, cables and spare parts must be original and must be requested from the manufacturer or dealer, to ensure patient safety and the proper operation of the spirometer. Failure to do so may increase the emissions or decrease the immunity of the equipment.



## DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE USA or EUROPEAN UNION



The product may **NOT** be disposed with domestic waste. Take it to a designated collection point for the recycling of electrical and electronic appliances. Contact the local authorities of your city or town, the domestic waste management service or the distributor who sold you the product for further information on its recycling.

### Devices commercialized before July 22, 2014:

*The device contains lead for the electric soldering. It uses a lithium battery and may use an optional NiMH battery. Proper disposal procedures should be followed according to local disposal codes.*

## 2. INSTRUCTIONS FOR USE AND INSTALLATION

### 2.1 INTRODUCTION

The **AstraTouch** spirometer is a compact device based on a **Digital Turbine** transducer, a wide high-resolution color touch-screen and an internal thermal printer. It has an internal database to store the performed tests and also allows connection to an external printer via USB or Bluetooth. In addition, it may incorporate a **Weather Station** to measure pressure and humidity (standard configuration includes a **temperature sensor**); a **MIP-MEP** module to measure Maximal Inspiratory and Expiratory Pressures, an electronic **Pulse Oximetry** module, exclusively for taking Oxygen Saturation and Pulse Rate samples (SpO<sub>2</sub>) and an **Ethernet** module.

Furthermore, the spirometer may be connected in real or deferred time to a **PC** via **USB, Bluetooth or Ethernet**, using the **AstraPro Spirometry software** to perform tests, download tests results from the device to permanent records, print hard copies of selected data or transfer test to telemedicine platforms or clinical information systems. Thus, it allows carrying out interactive real-time testing on your PC and transfer status device data.

## 2.2 MODELS AND OPERATING MODES

### 2.2.1. MODELS

This manual is intended for all models and options of the **AstraTOUCH** spirometer. Therefore, only specific options and functions of the model available will be applicable in each case.

### 2.2.2 OPERATING MODES

There are **2** operating modes available. Choose the settings that best fit your needs:

- **Diagnostic Mode (DG):** Oriented to **Lung Function Laboratories**. This is the most complete mode. Practically all the functions of the device, including Occupational Health workplace and disability testing are available and it allows you to use the mode that best serves your needs.
- **Primary Care Mode (PCP USA Mode):** Orientated to **Primary Care**. It includes quality alerts to assist you in producing high quality spirometry tests. Direct access to FVC, Bronchodilatation, VC and MVV tests.

#### FUNCTIONALITIES

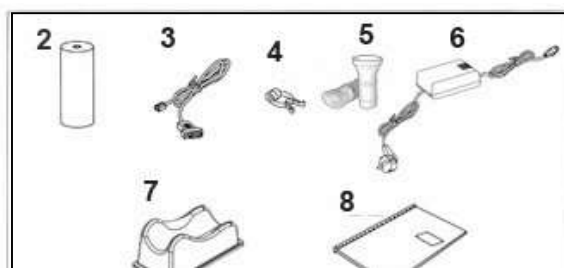
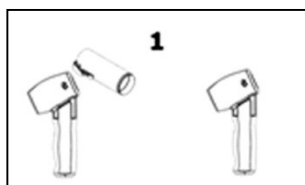
FVC  
VC  
MVV  
Bronchodilatation (Post)  
Bronchoconstriction  
Alternated V-T & F-V plots  
Simultaneous V-T & F-V plots  
Superimposed curves  
Acoustic signal for begin and end of maneuver  
Time-based progress bar (adult incentive)  
Volume-based progress bar (adult incentive)  
Parameter and plot selection (customization)  
Calibration program

Cal-check  
 Large graphs on reports  
 Print/save 3 maneuvers  
 Print 3 PRE maneuvers (data and graphs)  
 Time-audit module  
 Miller Interpretation  
 Snider, Kory & Lyons, NLHEP (Ferguson) Interpretation  
 ATS/ERS (McKay) Interpretation  
 Quality of the FVC test (NLHEP: QC prompts, QC grades)  
 Help screen in all menus (text)  
 Pediatric/adult incentives (in device)  
 Device auto-check program  
 Export data to Health Information Systems

A model can be upgraded at any time by adding the corresponding parts. To do so, please contact the **SDI Diagnostics Sales Department** or your dealer.

## 2.2.3 ACCESSORIES

1. Turbine transducer
2. Thermal paper 110x50
3. USB and printer cable connection
4. Noseclip
5. AstraGuard filter
6. External power supply
7. Transducer holder
8. User's manual

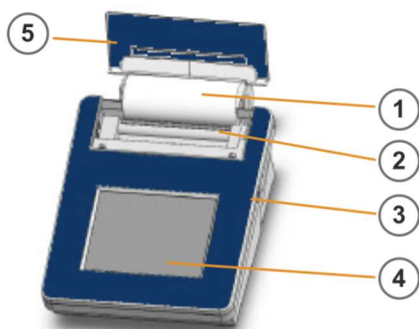


## 2.2.4 SPARE PARTS AND COMPONENTS

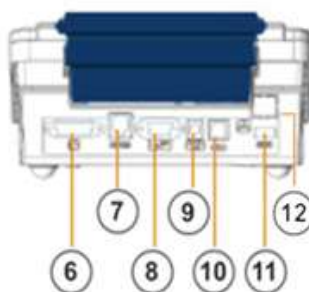
1. Weather station module
2. Bluetooth module
3. Ethernet module
4. Thermal paper 110x50 (5 u)
5. Rechargeable battery
6. Carrying bag
7. Bluetooth adapter for PC
8. USB 2.0 and printer cable connection
9. Ethernet cable
10. Shutter probe MIP-MEP
11. Sniff probe (for MIP-MEP module)
12. Adult MIP-MEP mouthpieces

## 2.3 LAYOUT OF CONTROLS AND CONNECTORS

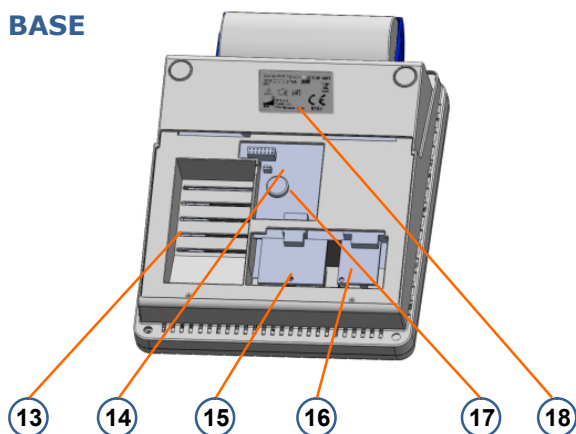
### FRONT PANNEL



### REAR PANNEL



## BASE



- |  |   |
|--|---|
| 1- Internal printer (thermal paper roll).        | 10- USB connector for PC                        |
| 2- Lever to lock/unlock the paper roll.          | 11- USB connector for external printer          |
| 3- ON/OFF button                                 | 12- Ethernet Connection                         |
| 4- Color graphic touch screen (640 x480 pixels). | 13- Rechargeable battery location               |
| 5- Printer casing                                | 14- Pulse oximetry board connection             |
| 6-Transducer Connection                          | 15- Electronic Weather Station board connection |
| 7- MIP-MEP Connection                            | 16- Bluetooth board connection                  |
| 8- Pulse oximetry sensor connection              | 17- Lithium battery CR1815                      |
| 9- Power supply connection                       | 18- Specifications plate                        |


## 2.4 INSTALLATION AND START-UP

This spirometer has been manufactured using solid-state professional components under strict quality controls. However, accidents may occur during the transportation or storage of the equipment and it is therefore wise to initially check its condition and that of its accessories before installing them.

If you detect any damage to the packaging, contact the shipping agency and distributor immediately before starting the installation. Packaging must not be disposed of until the correct working order of the device has been fully verified.




2.4.1 START-UP









- 1 Connect the **external power supply** to socket no.9, located on the rear of the device, and to the main AC power outlet.
- 2 Insert the plug of the **transducer** cord into the socket no.6
- 3 Connect the other **optional modules** that you have acquired. Consult the specific user's manuals.
- 4 Press the **ON/OFF button** (no.3).

 The first time the equipment is started, the protection is disabled and the PIN is set to 0000.

- 5 The **MAIN MENU** will then be displayed, which varies according to the model:



	Access to the FVC test
	Access to the Post Bronchodilation test
	Access to the VC test

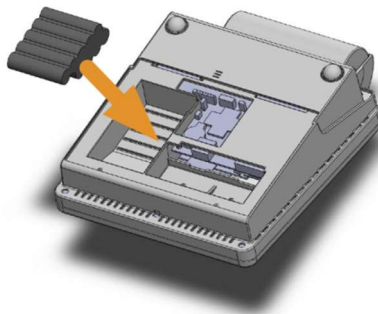
	Access to the MVV test
	Access to the Bronchoprovocation test
	Access to the Pulse oximetry test
	Access to the MIP-MEP test
	Quality control procedure: Calibration check
	Access to the Internal database/ Database customization
	Printing a report
	Access to the Setup options: Calibration, Customization and Maintenance.

## 2.4.2 RECHARGEABLE BATTERY: INSTALLATION AND LOAD

The **AstraTOUCH** spirometer has available an optional **rechargeable Ni-Mh battery** (10.8V 2500mAh) with a charge life of **1.5 hours** approx.

To **install** the battery, remove the base cover and insert it where indicated in the figure.

The battery is recharged by connecting the spirometer to the power supply, even though the device is turned off. The charging time is about **20 hours**.





**DO NOT** charge other type of batteries, they could EXPLODE. Remove old batteries to avoid leakage of corrosive chemicals.

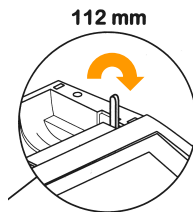
### 2.4.3 POWER SAVING

To save power when working with the battery, the device includes an auto switch-off system that turns the equipment off when the screen is not accessed for **one minute**, except in tests screens. In this case, you will be prompted to save the data before powering down.

When the spirometer is connected to the power supply, the backlight turns off after not accessing the screen for **two minutes**. The device will “sleep” until one key is pressed, recovering the information previously displayed.

### 2.4.4 PLACEMENT OF THE PAPER INTO THE INTERNAL PRINTER

Open the printer cover, lift the lever that unlocks the pull cylinder and insert the paper roll. Pull a small amount of paper out, put down the header lever, pass the paper through the slot of the cover and close it. A screen will appear to pull the paper in/out. Cut the paper pulling it forward against the gate.



### 2.4.5 CONNECTION TO AN EXTERNAL PRINTER

Select the **external printer** option in the **COMMON CUSTOMIZATION** menu. Connect the USB cable into the socket n.11 (PRINT) and the other end to the printer.




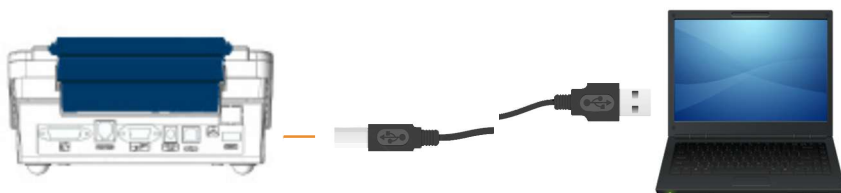


Contact the manufacturer or dealer for a list of compatible printers.

## 2.4.6 USB CONNECTION TO PC

To connect the device to a PC, install the **USB driver** and the **AstraPro Spirometry Software** in the PC. Consult the **AstraPro Spirometry Software User's Manual**.

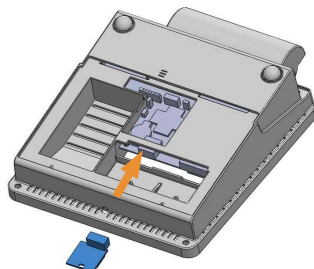
Then, connect the correct end of the USB cable to the socket n.10 , and the other end to the computer.



## 2.4.7 BLUETOOTH CONNECTION TO PC

If you have purchased this module with the spirometer, it will be already installed. Otherwise, you must remove the cover from the base of the spirometer and insert the **bluetooth board** where is shown in Figure.

In either case (USB or Bluetooth), connect the **Bluetooth adapter** to the PC and simply install the software included. To do so, consult the **Bluetooth adapter user's manual**.

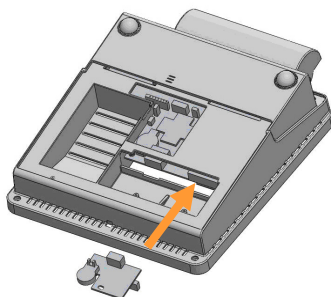


Install the **AstraPro Spirometry Software** to the PC and choose the Bluetooth link option, consult the **AstraPro Spirometry Software User's Manual**, included in the CD.

The Bluetooth is enabled (and disabled) by accessing the Bluetooth option on the **COMMON CUSTOMIZATION** screen of the spirometer. (See section 3.2.3). Once the Bluetooth adapter has been configured in the PC, a connection will be established every time the equipment and the PC are started. The PC is then ready to receive the data transmitted by the equipment.

## 2.4.8 INSTALLATION OF THE WEATHER STATION


As in the previous case, if you have purchased the weather station module with the spirometer, it will be ready to use. Otherwise, remove the bottom case of the spirometer and insert the



**weather station's board**, as shown in the figure.

## 3. SPIROMETER CONFIGURATION

### 3.1 SETUP

Press  and access the options of the **SETUP MENU**:

**1. CALIBRATION**



**2. CUSTOMIZATION**



**3. INTERNAL DATABASE**



**4. MAINTENANCE**



### 3.2 QUALITY CONTROL: CALIBRATION CHECK

The **2005 ATS/ERS TASK FORCE** recommends that all spirometers be checked daily for calibration before testing begins.

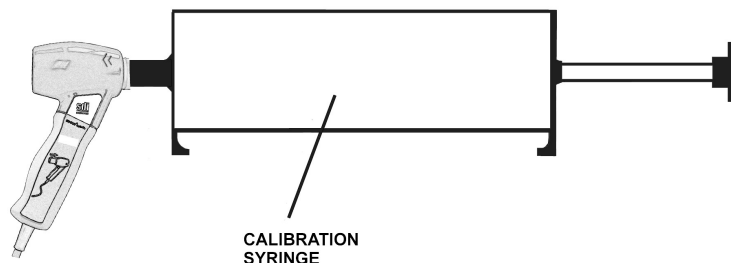
The possible aging or the accumulated dirt of transducers may measure inaccurately.


If a device fails its **calibration check**, then new calibration procedure or equipment maintenance is required to ensure the proper use of the Spirometer.

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

### Test procedure:

- 1 Connect the spirometer to the 3 or 6L-syringe, as in the following figure, you may insert a tube one meter long to avoid the influence of the turbulence caused by the abrupt departure of the air:

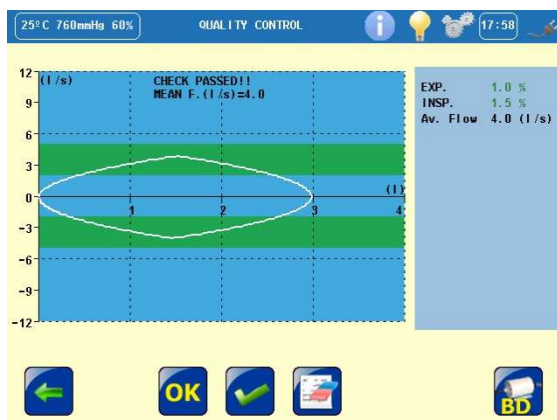


- 1 Power up the **AstraTOUCH** and press  from the main menu.
- 2 Press ENT to accept the defaults.
- 3 Discharge the syringe **once** at any range of the following flows varying between 0-12L/s, then refill the syringe at the same flow rate:



**Low flow level: 0 - 1 L/s**


**Mid-flow level: 2 - 5 L/s**

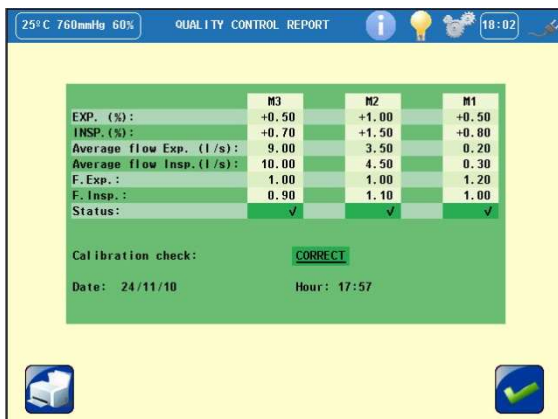
## High flow level: 6 - 12 L/s



To simplify the procedure, the spirometer allows you to carry out a single maneuver at Mid-flow level: **2 - 5 l / s**.

**4** Press  to cancel the maneuver or  to accept it and go to the next range of flow.

**5** At the end of the operation, press  to see the results of the maneuvers performed: the percentages of variation and calibration factors calculated as the average of all the maneuvers performed on a range flow.




	M3	M2	M1
EXP. (%) :	+0.50	+1.00	+0.50
INSP. (%) :	+0.70	+1.50	+0.80
Average flow Exp. (l/s) :	9.00	3.50	0.20
Average flow Insp. (l/s) :	10.00	4.50	0.30
F. Exp. :	1.00	1.00	1.20
F. Insp. :	0.90	1.10	1.00
Status :	✓	✓	✓

Calibration check: **CORRECT**

Date: 24/11/10      Hour: 17:57

- 6** If the session is correct, the results will be automatically saved to the **calibration record**.



Press  to see the data of the record (See section [3.7](#)).

- 7** Once calibration check performed satisfactorily, access the Spirometry program to begin the tests.

- 8** If the calibration check is not correct, do a full calibration of the instrument. To do so, see **3.6 CALIBRATION PROCEDURE**.





The error at each flow should be less than **±3.5%**. The **expiratory and inspiratory factors remain unchanged** in this routine.



You can program the spirometer, in the **COMMON CUSTOMIZATION** menu, to **require a daily calibration check** before allowing access to any test. By default, this option is disabled.

### 3.3 CALIBRATION PROCEDURE

This procedure should be followed if the calibration check is not correct. The Calibration procedure is similar to the Calibration check, but in this case the **calibration factors** (expiratory and inspiratory) will be recalculated as the average of all maneuvers performed and applied on the spirometer. It will be necessary to deliver **3** maneuvers at the range flow of 0-12L/s.

To carry out the calibration procedure, press  and then . Enter the necessary data described below and follow the instructions detailed in the section **3.6**.

- **Volume of the syringe:** 1-6L.
- **Humidity (%):** set to 0.
- **No. of Pulses** of the **Turbine transducer**. Each turbine is factory calibrated individually and is associated to a factor (3-digits) equivalent to the pulses/liter detected and printed on it.

If several sessions have been performed, only the correct last one will be saved. Then, you can print a report with the calibration record. If calibration is performed to more than one level of flow, the results on screen and on the report will be sorted from lowest to highest flow.

### 3.4 CALIBRATION RECORD





The spirometer has a record containing the information of the last **30 calibrations check and calibrations performed**, indicating: date, time, volume accuracy percentage and average flow for inspiratory and expiratory factors. This is extremely useful for

centers requiring a quality control of the processes they use and also to help define day-to-day laboratory variability.

From the results screen:



DATE	HOUR	Type	VCal	ExpF	InseF	SExp	SInseF
01/10/10	09:14	Cal	3.00	0.96	0.97		
02/10/10	09:15	Chk	3.00			-0.1	-0.2
03/10/10	09:20	Chk	3.00			-0.3	-0.5
04/10/10	09:08	Cal	3.00	1.01	1.03		
05/10/10	09:10	Chk	3.00			-0.8	-0.9
06/10/10	09:12	Chk	3.00			-1.6	-3.6
07/10/10	09:00	Cal	3.00	0.97	0.97		
08/10/10	09:02	Chk	3.00			-0.2	-0.1
09/10/10	09:05	Chk	3.00			-0.2	-0.3
10/10/10	09:04	Cal	3.00	1.02	1.01		
11/10/10	09:15	Chk	3.00			-0.6	-0.8
12/10/10	09:13	Chk	3.00			-1.4	-1.8
13/10/10	09:05	Cal	3.00	0.95	0.94		
14/10/10	09:10	Chk	3.00			-0.2	-0.1

Press  to delete a record and  to delete the entire database. Press  to print the calibration report. Use the scroll bar  to select the record desired.



## 3.5 CUSTOMIZATION

### 3.5.1 TOOLBAR CUSTOMIZATION




This label displays the values of atmospheric parameters: **Temperature**, **Pressure** and **Humidity**. The temperature is automatically obtained from an internal sensor incorporated to the spirometer and its value will always appear in the tools bar. If you acquire the **Weather Station** module, the real values of pressure and humidity will be shown in addition to temperature. Tick the label to enter them manually.



Touch on this label to choose the operating mode among Diagnostic or PCP USA mode.



The spirometer has been developed to make it user-friendly. Ease of use is assured through **context sensitive help screens** that explain every **AstraTouch** feature, by touching this icon .



Touch this icon to adjust **brightness**.



**Clock - calendar:** Touch the displayed time to adjust time and date.



**Battery status:** Displays the levels of battery charge by the segmented battery icon. When this icon turns red the battery



is nearly discharged and it must be recharged. See the battery's charging procedure in section **2.4.2**.






Touch this icon to enter directly to the **SETUP MENU**.














### 3.5.2 COMMON CUSTOMIZATION

If you wish to change any logging parameter, do so under this menu.

Access this option by pressing  from the main screen, and then .

The options included in the **CUSTOMIZATION MENU** are:

	<p><b>Standard Configuration:</b> This option saves a user-defined customization program status</p> <p> Load config: restores the original customization.</p> <p> Save config: Allows you to modify and save the configuration most often used.</p>
	<p><b>Internal Database customization</b></p> <ul style="list-style-type: none"> <li>• Number of registers to be advanced if performing a fast advance using the database search engine</li> <li>• Save 3 maneuvers from the FVC test</li> <li>• Sort database</li> <li>• Auto save</li> </ul>
	<p><b>Common customization</b></p> <p> Language</p>

	Enter a report header
	Select the printer type: internal or external
	Set clock-calendar: time and date
	Set units: cm/Kg or in/lb
	Main menu icons (enable/disable)
	Equipment Protection code (PIN)
	Bluetooth: (enable/disable)
	Ethernet: (enable/disable)
	<b>Spirometry customization</b>
	Operating mode: Select PC or DG. (Only available in Diagnosis mode (DG))
	Incentive for children and adults
	Time audit: (enable/disable) show the time when the spirometry maneuver was performed
	Predicted sets : <ul style="list-style-type: none"> <li>- Choose predicted set among several authors for children and adults</li> <li>- Prioritizes the age range selected for adults if a different table is chosen for children.</li> <li>- Extrapolates the values for the ages outside the selected table range.</li> </ul>

- Ethnic factor



Parameters: (This is only at display level or for the report. All the parameters are saved on the database and can be enabled at any time).



Graphs and report customization:

- Save graphs on the database
- F/V- FVC Report
- V/T- FVC Report
- VC Report
- MVV Report
- D/R Report
- Print large curves
- Print 3 curves PRE
- Print Data of 3 best maneuvers PRE



Interpretation: Select diagnosis according to ATS/ERS, Miller, Snider/Kory/Lyons or NLHEP. Printing the interpretation.



Quality control alerts:

- Display of quality alerts to assure compliance with ATS/ERS (EX, ET) or NLHEP criteria (QC Prompts)
- Date of latest calibration



Calibration check alerts:

- Require a daily Calibration check
- Enable the use of the Spirometer without Calibration check.



Bronchodilation test customization



Bronchoconstriction test customization (See the Bronchoconstriction user's manual)



**Pulse oximetry customization** (See the Pulse oximetry User's Manual)



**MIP-MEP customization** (Consult the MIP-MEP User's Manual)



Press on to save new settings.

### 3.5.3 EQUIPMENT PROTECTION



In compliance with the **Data Protection Act, Directive 95/46/EC**, the **AstraTouch** has a protection option accessed by a **PIN** of 4 digits to prevent access to the equipment and, more specifically, to the private data it contains by unauthorized people.

Enable this option in the **CUSTOMIZATION MENU** (consult section **3.2.3**), by ticking the "PIN Enabled" checkbox and enter the PIN in the "New PIN" boxes. To change the PIN, you must enter the current one in the "Current Pin" box and then the new one in the "New Pin" boxes. The PIN can be disabled again by entering the current PIN and unticking the "PIN-enabled" checkbox.

If enabled, a screen will appear requesting the PIN, when the equipment is turned on:

**ENTER PIN**  
**Pin: 0000**

Enter the PIN and you may access the main menu screen. If an incorrect PIN is entered three times, the equipment will lock and

switch off. On restarting it, a screen will appear requesting the **unlock code** or **PUK** (supplied upon purchasing the equipment).

**UNLOCK CODE (PUK)**  
**0000000000000000**

If the correct code is entered, the device will unlock and the main screen will appear. From then on, the equipment will return to its initial status (Protection disabled and PIN 0000). If an erroneous code is entered, the equipment will remain locked.

### 3.5.4 INTERNAL DATABASE



The **DATOSPIR TOUCH** has an internal database to store the tests performed for later review, print and/or transfer to a computer (using the **AstraPro Spirometry Software**) or other computerized systems.

There are two storage capacities:

**Database «L» (1000 tests)**  
**Database «H» (3000 tests)**








It is possible to save spirometric, bronchoconstriction, MIP-MEP or pulse oximetry test.



The database always saves all the spirometric parameters, despite them not being selected in the **CUSTOMIZATION MENU** (Section **3.2.3**).





The base information remains, even when the equipment is turned off or the rechargeable battery is removed.





	<p>Search patient: by <b>ID code</b> or <b>last name</b>. In addition, you may:</p> <ul style="list-style-type: none"> <li>• Display tests</li> <li>• Print tests</li> <li>• Delete tests</li> </ul>
	Search record: Summarized display of the tests saved
	Delete database
	Print summarized Report of the test saved
	<p>Database customization:</p> <ul style="list-style-type: none"> <li>• Sort by ID or name</li> <li>• Number of records</li> <li>• Save 1 or 3 maneuvers in tests, etc.</li> <li>• Auto Save on/off</li> </ul>












### 3.6 MAINTENANCE PROGRAM

The equipment has an internal diagnostic program to perform system checks and several adjustments.

It is not necessary to open the instrument to carry out the maintenance program. Doing so may void the warranty

From the main screen, press  and then . The **MAINTENANCE MENU** options are:

	Equipment's hardware Check: CPU, ADCs, touch screen, printer, reindex the database, reset all variables	
		CPU
		ADCs
		touch screen


	printer
	reindex the database
	reset all variables
	Demo mode: checkup of the product with pre-saved standard curves FVC, VC, MVV
	Calibration and/or maintenance alerts
	Adjust of screen brightness and Internal printer contrast
	Dealer's data
	Equipment configuration: change from positive VC to negative VC or vice versa-
	Adding a new transducer. Enter the new pre-calibration code to load the new calibration factors.
	Adding a new option. Enter the Activation code
	Display the activation code


## 4. SPIROMETRIC TESTS PROCEDURES

The procedures to be completed to carry out the **Forced Vital Capacity «FVC»**, **slow Vital Capacity «VC»** and **Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.



## 4.1 FORCED VITAL CAPACITY «FVC» TEST

- 1 Ensure that the transducer is plugged in the correct socket. Insert the antibacterial filter and/or the **disposable mouthpiece** into the transducer, as in the figures:
- 2 Turn on the spirometer and press  on the Main Screen.

 The first time you carry out a spirometric test for the day, the spirometer may advise you to **check the calibration**, as ATS-ERS recommends. Enable this option on the **SETUP MENU**.

To avoid the risk of contamination or cross infection, the **Turbine** transducers and some of the optional modules must be disinfected before use in a new patient or must be used with an adequate **protective barrier filter** compatible with the equipment (see section 7.1)

### 4.1.1 ENTERING PATIENT DATA

Then, the following screens will appear:




The screenshot shows the 'PATIENT DETAIL' screen with the following fields and controls:


- Top status bar: 25°C 768ml/min 60% | PATIENT DETAIL | Information, Lightbulb, and User icons | 08:33
- ID: [Text input field]
- First Name: [Text input field]
- Last Name: [Text input field]
- Age: [Text input field] in [Text input field] Lb [Text input field]
- Ethnic F: [Text input field] Sex: [Text input field]
- Smoke yrs: [Text input field] Cig./day: [Text input field]
- Technician: [Text input field]
- Bottom navigation bar: Back, Home, Add, and Confirm icons

<b>ID:</b>	Patient identifier, 10-character alphanumeric.
<b>Name:</b>	20-character alphanumeric field
<b>Surname:</b>	25-character alphanumeric field
<b>Age:</b>	Number of years, between 4 and 100.
<b>Weight:</b>	Between 33 and 440 Lb /Between 15 and 200 kg
<b>Height:</b>	Between 20 and 90 In /Between 50 and 230 cm
<b>Sex:</b>	Male or female
<b>Race:</b>	Ethnic Factor, between 80 and 120%. It is used in areas without prescribed local predicted equations, so data needs to be corrected to a specific percentage. 100% is equivalent to the unmodified standard value of the predicted.  If the NHANESIII predicted set has been chosen, in the Customization menu, the RACE can be changed from the following groups: Caucasian, Afro-American and Hispanic.
<b>Smoke yrs:</b>	Number of years the patient has been smoking
<b>C/d:</b>	Cigarettes smoked per day. Between 0 and 100. This helps to calculate the COPD index parameter.
<b>Technician</b>	10-character alphanumeric technician's code or name.

- 3 Enter the patient's details by pressing on each field. An alphanumeric or numeric keyboard that will appear, depending on the field data type required. Enter patient's data and press



If patient already exists in the database, press  to retrieve the patient's details from memory. Once patient is selected, the patient's ID will appear at the top of the screen. When finished

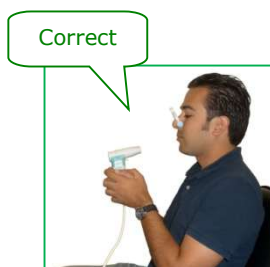
press  to go to the test screen.

- 3 Instruct the patient on the test performance, his cooperation is essential for acquiring meaningful test data.



The test must be carried out by medical staff. Review data on spirometry technique or request information about spirometry courses.

- 4 When the patient is ready and has assumed a correct posture, fit the nose clip. The subject must hold the transducer without moving it, and wait until a blinking arrow appears on the screen. **The transducer must remain in the same position until the end of the maneuver.**



- 5 Patients can carry out the spirometry maneuvers in either of two different ways:

- Starting the maneuver with **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if desired.
- The patient breathes normally and when indicated by the technician, takes a deep breath completely filling his lungs, and then performs a **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if desired.



- 6 The device will detect the **end of maneuver** as ATS/ERS criteria and then will display the resulting graph and the parameters.

The maneuver performance can be ended at any time by pressing, which will appear on the bottom left-hand of the screen.



At the end of the maneuver, one or more of the **QC Alerts** (if the option is enabled in the **Customization menu**) may appear, alerting the technician as to whether the maneuver is in compliance with **ATS/ERS** or **NLHEP Quality Control criteria**. Consult section **4.2**.



**ATS/ERS Criteria:** The maneuver with the least warnings is considered the best (ET, EX). With the same number of ATS/ERS warnings (ET, EX), the maneuver with the highest sum of FVC+FEV1 is considered the best.

**7** Perform your maneuvers, but no more than **8**, as this would tire the patient.

If 3 or more maneuvers have been performed and the FVC and/or FEV<sub>1</sub> parameters blink on and off, this indicates that the **repeatability criteria** has been achieved for one or both parameters, according to the **ATS/ERS criteria**. This criteria indicates that the two best **FVC** or **FEV<sub>1</sub>** values do not differ by **more than 150 ml** if **FVC** is **more than 1 liter** or **more than 100 ml** if **FVC** is **less than or equal to one liter**.

### 4.1.3 DISPLAYING RESULTS AND OPTIONS



At the end of the test:


- The current, predicted and best maneuver graphs are shown.
- On the summary frame, the **FVC** and **FEV<sub>1</sub>** values of all the maneuvers performed will appear:

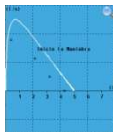
**PRED:** indicates the patient's Predicted value


**\***: indicates the current maneuver


**Mx**: indicates the selected maneuver

Maneuvers are sorted from best (M1) to worst (M8) according to **ATS/ERS criteria** and are shown in different colors: green for those that are acceptable and repetitive and from yellow to red for the lower-quality maneuvers. The current maneuver is in white.

- Press  to enlarge or reduce the graph.

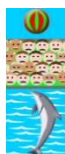


- Press on the plot  to switch from one graphic type to the other: Flow/Volume, Volume/Time, both or incentive and a small Flow/Volume graph.

- **Selection of the desired maneuver** : the scroll bar allows you to move over the maneuvers performed and select the desired one to **see the graph, view the parameters, consult the interpretation, delete or save a maneuver or print out a report.** (Consult sections 4.1.4 to 4.1.9)




**By default, the maneuver selected is the best, M1.**

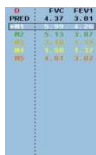


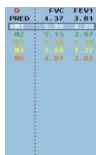
**a Temporal bar:** Progress bar in function of time, in three colors: red indicating less than 4 seconds, orange between 4 and 6 seconds and green for more than 6 seconds.

**b Volume bar:** Progress bar in terms of the expired volume. Red indicates 75% below the predicted value, the orange between 75% and 100% and green 100% above the predicted value.

**c Incentives for children:** Choice of two cartoon graphics

- **Time audit:** shows the exact time the test has been carried out in the reports for further review.
- Press on *ID area*  to access the patient's data screen.



- Press the  to display all parameters data of maneuvers performed.

25°C 70mmHg REF TEST DATA

M1 M2 M3 M4 M5 M6 M7 M8

MAN : 1/5 M1 M2 M3 REF (%)









Best FVC (L)	5.99			4.37	137
Best FEV1 (L)	4.24			3.81	112
FEV1/FVC (%)	71.08				
QC Grade	0				
Time	00:37	00:36	00:36		
FVC (L)	5.99	5.12	3.48	4.37	137
FEV1 (L)	4.24	3.87	1.19	3.81	112
FEV1/FVC (%)	71.08	75.27	34.15	87.28	81
MAX PEF (L/s)	6.60	7.70	1.50		
PEF (L/s)	0.08	0.08	0.11		
FEF50% (L/s)	3.77	4.93	0.70	5.38	70
FEF25%-75% (L/s)	3.41	3.21	0.67	4.95	68

Navigation icons: back, home, print, and a device icon.









- Observed values** of the parameters selected in the **CUSTOMIZATION MENU**
- Predicted values** <REF> (If patient's data has been filled in)
- %** between both parameters. If an \* appears after the REF test, this means that the predicted values have been extrapolated
- The **best FVC** and **FEV1 values** (not necessary from the same maneuver).
- QC grade**
- ATS/ERS alerts**
- Time audit.**



The screen only displays the results of 3 maneuvers and the predicted values. By default, the data shown is of the 3 best

maneuvers: ,  and . To view the data of the other maneuvers performed, press on its button , , ,  or .



The **BEST maneuver** is set at M1. This represents the test with the highest FVC+FEV1. Therefore, this will be used to display the interpretation, to print the report or to save the maneuver. The technician has the option to override this selection by pressing , , , , , ,  or .

#### 4.1.4 DELETING AN EXISTING MANEUVER




Select the maneuver that you want to delete and press

#### 4.1.5 SAVING A TEST TO THE INTERNAL DATABASE


- 1 Select the maneuver you wish to save. The maneuver selected by default is the best (M1).



- 2 Press  to save **the best maneuver** or **the 3 best maneuvers** on the database, according to the option selected in **SETUP MENU** (Option not available in PLP USA mode).

#### 4.1.6 VIEWING THE INTERPRETATION




Press  to view the interpretation according to the diagnosis available on your device's operating mode or depending on the customized option selected on the **CONFIGURATION MENU**: **Miller - ATS/ERS - Snider, Kory & Lyons** or **NLHEP**.



#### 4.1.7 PRINTING A MANEUVER

Print the test report via the **internal** or **external printer**. Select the desired printer on the **CUSTOMIZATION menu**.

Then, select the maneuver to be printed and press  to print

the report of the maneuver selected and  to print the report of the 3 best maneuvers, if the "Save 3 Maneuvers" option is activated.

The report will include the parameters and graphs corresponding to the selected maneuver or 3 maneuvers. If you do not want graphs, certain parameters, the diagnosis and/or ATS/ERS warnings to appear, disable them on the **CUSTOMIZATION MENU**.



By pressing  in the Main menu you may print:



The last test performed



All the tests carried out during the day



Whatever test you want of the database

#### 4.1.8 OTHER TESTS ON THE SAME PATIENT

After carrying out the FVC test on a patient, you may do the following:

- A **VC** test on the same patient
- An **MVV** test on the same patient

- A **Post-Drug Bronchodilator** test on the same patient
- Enter data for **a new patient**.
- Print the **general report** of all tests on the same patient



The spirometer saves the best maneuver of each FVC, VC, MVV and/or bronchodilator test to print a general report.

#### 4.1.9 CHANGING PATIENT DATA/ ENTER A NEW PATIENT:



This option allows you to enter a new patient data or to modify existing patient data. (Follow the procedure described in the section **ENTERING PATIENT PARAMETERS**).

You may access to this menu by pressing on the ID area in the center of the tool bar in any test.



If you have modified existing patient data (age, height, sex, etc.) the predicted parameters will be calculated again.

#### 4.2 QUALITY OF FVC TEST



The **AstraTOUCH** spirometer includes quality alerts to assist you in producing high quality spirometry tests. These alerts may be enabled or disabled in the **CUSTOMIZATION MENU**.

##### I. ATS/ERS ALERTS

To ensure good spirometry tests, the technician should pay particular attention that the patient has made the maximum effort, that the start had been satisfactory and that no coughing or Valsava maneuver due to glottis closure has occurred. Special

attention must be made to preventing a premature expiratory effort.

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

**ET** - This indicates that **expiration did not end satisfactorily** because the quantity of accumulated volume during the last second of the maneuver was more than 25 ml, or that the maneuver lasted for less than 6 seconds (in individuals 10 or older) or less than 3 seconds (in children under 10).

**EX** - This indicates that the **expiratory effort did not start satisfactorily** because the extrapolated volume was greater than 5% of the FVC or 0.15 liters. According to the ATS/ERS recommendations, this volume should be lower than 5% of the FVC or 0.15 liters, whichever is greater.



The technician performing the spirometry may disable these alerts in the **CUSTOMIZATION 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 classifying the order of the maneuvers.

## II. NLHEP ALERTS: QC PROMPTS

In order to assess the pulmonary function of the patient, it is necessary to obtain acceptable test quality. The test quality is dependent on the technician's instructions and the cooperation of the patient.

Accordingly, **AstraTOUCH** incorporates an automatic quality control function, based on the recommendations of the **National Lung Health Education Program (NLHEP)**, with prompts to assist the technician in providing performance guidance to the patient to produce high quality spirometry tests.

At the end of a maneuver, a message on the screen will inform you as to whether the maneuver was acceptable or not. If not, a prompt will guide you on how to coach the patient to improve the effort. (See the rows in white of the following table).

As soon as the message **"Good Test Session"** appears, do not carry out further maneuvers. If, even after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, you should pause the testing to allow the patient to rest, (depending on how the patient feels) or stop 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?
<b>Don't Hesitate</b>	EX error	The patient must start exhaling harder.
<b>Blast Out Faster</b>	Time to PEF higher than 120ms	The patient must exhale as hard, firm and fast as possible.
<b>Blow Out Longer</b>	ET error	The patient has abruptly interrupted exhalation. The patient must exhale even more and expel as much air as possible from his/her lungs.
<b>Correct Maneuver</b>		Good Maneuver.
<b>Blast Out Harder</b>	If there are not 3 acceptable maneuvers, with at least the largest 2 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.

<b>Deeper Breath</b>	If there are not 3 acceptable maneuvers, with at least the largest 2 FVC values matching within 150mL and 1L/s for PEF.	The maneuver differs significantly from the previous ones. The patient must inhale more deeply and exhale even more air.
<b>Good Test Session</b>	After 3 acceptable maneuvers with at least the best 2 maneuvers match.	TEST COMPLETE. Adequate number of good maneuvers.



Referring to the quality of the last maneuver performed

Referring to the reproducibility of the maneuvers performed

### 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
<b>A</b>	VERY GOOD	At least 3 acceptable maneuvers with the largest two FEV <sub>1</sub> and FVC values matching within 100 mL.
<b>B</b>	GOOD	At least 3 acceptable maneuvers with at least two FEV <sub>1</sub> values matching between 101 and 150 mL
<b>C</b>	ACCEPTABLE	At least 3 acceptable maneuvers with at least two FEV <sub>1</sub> values matching between 151 and 200 mL
<b>D</b>	POOR	Only one acceptable maneuver, or more than one, but the FEV <sub>1</sub> values match > 200 mL
<b>F</b>	NOT ACCEPTABLE	No acceptable maneuvers


### 4.3 POST-DRUG BRONCHODILATION TEST



The **AstraTOUCH** spirometer allows spirometry tests: FVC, VC or MVV after the administration of a bronchodilator drug. For this, the patient tests should have previously been completed in PRE bronchodilator mode and saved to the PRE (Pre-Drug) database.

The procedure to carry out POST-Bronchodilator spirometry is:

- 1 Complete an FVC, VC or MVV test with the patient (as described in [4.1](#)) before administration of the bronchodilator drug.
- 2 Save the **PRE test** in the database  for comparison to the **POST**-Drug test.
- 3 Administer the dose of the bronchodilator drug prescribed and wait for the recommended period.
- 4 On the main screen, press . A screen similar to the following will appear which displays the tests saved in PRE mode.

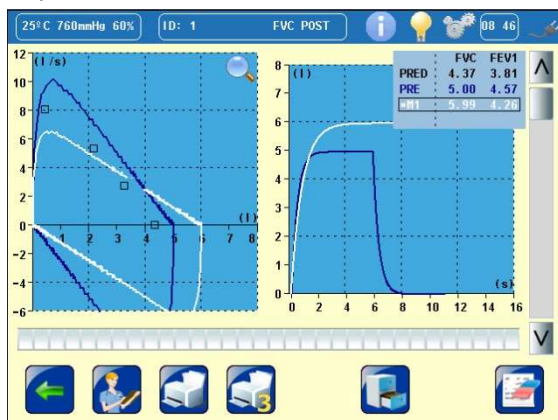


5 Select the PRE test that will be compared and press . (FVC selected by default)

6 Using keys  and , the VC and MVV tests can be seen and saved in PRE mode.

7 Perform selected test.

The screen then shows the two graphs (PRE and POST) for comparison purposes:




The data screen shows the observed values in PRE and POST mode and the method of comparison between them, depending on the option selected in the **CUSTOMIZATION MENU**.

- **Weighted % between PRE and POST**
- **% between REF (Predicted) and POST**
- **% between PRE and POST**
- **Difference between PRE and POST**

This will provide a single **report** of spirometric results before (PRE) and after (POST) application of a bronchodilator drug.

## 4.4 SLOW VITAL CAPACITY «VC» TEST


1 Access the test by pressing , from the main screen.

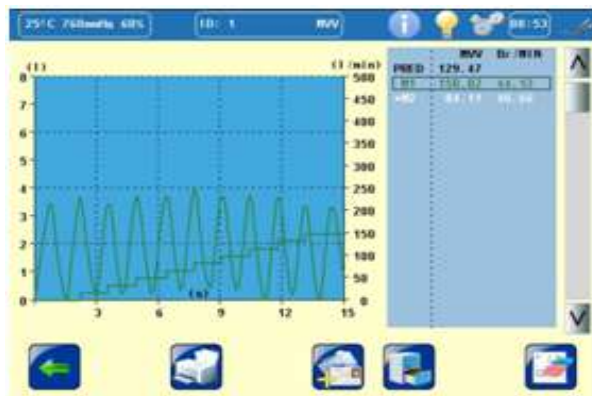


- The **axes** are always displayed in **VOLUME/TIME mode**.
- The equipment saves a maximum of **8** maneuvers ordered according to the VC value, where M1 is the best VC and M8 the worst.
- The **maximum time** allowed for the maneuver is **45 seconds**.
- To measure the **ERV** and **TV** parameters correctly, each maneuver must have **at least four respiratory cycles**.



## 4.5 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST

- 1 Press , from the main screen.
- 2 Inhale and exhale completely without interruption for at least 12 seconds.
  - The **axes** are displayed in VOLUME/TIME mode.
  - The **maximum time** allowed for the maneuver is **15 seconds**.
  - The equipment saves a maximum of 8 maneuvers, ordered according to the MVV value, where M1 is the best MVV and M8 the worst.



## 5 COMMUNICATIONS SYSTEM

One of the strengths of the **AstraTOUCH** spirometer is its Communications System, which allows the user to:


1. Transfer patient tests to a PC
2. Transfer Equipment Checking Data
3. Update Internal Software
4. Export patient tests to other Management Systems (EMR)

Communications can be made via USB (standard), Bluetooth (optional) or Ethernet (optional).

### 5.1 TRANSFERRING TESTS TO THE PC

If you want to view, print, manage and/or save the tests to the PC, you must have **AstraPRO Spirometry Software**.

The process to follow is:

- 1 Save the tests required in the equipment's internal Database
- 2 Install the **AstraPRO Spirometry Software**, as detailed in its **User's manual**.
- 3 Load the data to the PC, by pressing  in the AstraPRO Software. The screen shows a list of the tests transferred and you can select those to be imported to the **PC Database** selected in the AstraPro Software SETUP option. For USB compatible spirometers, a driver must be installed on the PC.
- 4 There you can select, view or print any of the tests imported or transferred to the PC.

## 5.2 TRANSFERRING EQUIPMENT CHECK DATA

The **AstraTOUCH** includes a program that auto-checks the working order of certain parts of the equipment, displaying the information on the screen and saving it in an internal file.

- Hardware checkup
- Firmware checkup
- Equipment customization
- Calibration Record
- FVC test with standard curves

- 1 Turn on the spirometer, press  from the main menu and select **MAINTENANCE**. Access the **Tool Menu** and run CPU and ADC options.
- 2 Connect the equipment and the PC via USB or Bluetooth.
- 3 Run the previously installed **AstraPRO Spirometry Software**, making sure that "AstraTOUCH" is selected in **Setup - Links** and access the **Setup - Utilities - Download Data** option.

The transferred information is saved in the **DATA** directory of the application, in the files:

<b>STATUS.CSV</b>	Contains the errors detected
<b>CALIBRA.CSV</b>	Contains the calibration data
<b>CONFIG.CSV</b>	Contains the equipment customization
<b>PRUEBAS.CSV</b>	Contains the database tests
<b>GRAFXxx.CSV</b>	Contains the graphs in Flow/Time mode

The files from the previous transfer are renamed with the extension **.OLD**

- 4** If you want to view the information of any of the files, load them using MICROSOFT EXCEL.
- 5** If a problem is detected that the user is unable to solve, send the auto-check information by e-mail or fax to **SDI Diagnostics After-sales Service** or to **your distributor**, who will analyze it and assess the cause of the problem, providing or proposing a suitable solution.

### 5.3 EXPORTING TESTS TO OTHER SYSTEMS

The **AstraTOUCH** spirometer can export the tests saved previously in the **Internal Database** to other management systems at other locations.

The equipment shows the information in **comma-delimited mode**, making it compatible with many different systems.

The information is available in the following files:

<b>PRUEBAS. CSV</b>	Contains the database tests
<b>PATIENTS.CSV</b>	Contains the database patients
<b>GRAFxx. CSV</b>	Contains the graphs in Flow/Time mode

The graph file, as indicated, contains the graphs for each test in **Flow/Time** mode. If you want to display the graphs in **Volume/Time** or **Flow/Volume** mode in the new management system, the following aspects must be taken into account:

- The Flow signal is sampled at 100Hz.
- The ratio of the axes in the Volume/Time graph must be adjusted to 1 liter = 2 seconds.
- The ratio of the axes in the Flow/Volume graph must be adjusted to 2 l/s = 1 l.

In the event of doubt or queries, contact the **SDI Diagnostics Technical Support** or your distributor, who will provide any further information you may require.

## 6. TECHNICAL SPECIFICATIONS

### 6.1 GENERAL SPECIFICATIONS

<b>Power supply</b>	Input 100 to 240V, 50 to 60Hz Output 12V 2.5 A (Electrical Protection: Class I)
<b>Compatible external power supplies</b>	<ul style="list-style-type: none"> <li>• MEANWELL MES30A 3P1J</li> <li>• EMERSON DP4012N3M</li> <li>• DANUBE FRM030</li> </ul>
<b>Medical device classification</b>	Class II
<b>Protection level</b>	IPX2: Device (not power supply) is protected against vertically dripping water when the enclosure is tilted up to 15 degrees.
<b>Dimensions and Weight</b>	195 x 270 x 100mm 1,7 kg (with battery) approx.
<b>Storage capacity (Database)</b>	<ul style="list-style-type: none"> <li>• 2 types of database according to their storage capacity: Small: &gt;1000 tests including F/V loops and V/T curves. Large: &gt;3000 tests including F/V loops and V/T curves.</li> <li>• Storage of spirometry, pulse oximetry and MIP-MEP tests.</li> </ul>
<b>Communications</b>	<ul style="list-style-type: none"> <li>• PC: USB 2.0, Bluetooth 2.0 (op.), Ethernet (op.)</li> <li>• Printer: USB 2.0 Bluetooth 2.0 (op.)</li> </ul>
<b>Printer protocol</b>	PCL 3 HPA, PCL 5e
<b>Display</b>	High resolution touch screen LCD, VGA of 640x480
<b>Battery pack</b>	NiMH Rechargeable, 9.6V 2.5Ah
<b>Operating Conditions</b>	Temperature: 5 to 40 °C (ATS recommends 17 to 40 °C) Humidity < 85% (without condensation) Pressure: 525 to 800 mmHg. (3000 to -400m approx.)
<b>Transport and storage</b>	Temperature: -20 to 70 °C Humidity < 85% (without condensation)
<b>Internal temperature sensor</b>	5 to 40 °C ± 1 °C
<b>Max. N° of maneuvers per subject</b>	8 FVC maneuvers, 8 VC maneuvers, 8 MVV maneuvers
<b>Device Lifetime</b>	7 years (See Section 6.6 for each transducer and the User's Manual for each of the products)
<b>Weather station</b>	Pressure: 500 to 1040 hPa, accuracy: ± 6.67 hPa (375 to 780mmHg, accuracy: ± 5 mmHg) Humidity: 0 to 100% (accuracy: ± 5%)
<b>Applicable standards</b>	<ul style="list-style-type: none"> <li>• European directive concerning medical devices 93/42/EEC (RD 1591:2009)</li> <li>• Quality (EN ISO 13485:2012/AC:2012, EN ISO 9001:2008 and EN ISO 14971:2009)</li> <li>• Compliance with data protection Act. Directive 95/46/EC</li> <li>• Safety Medical devices (EN 60601-1:2006/AC2010)</li> <li>• Electro-magnetic Compatibility (EN 60601-1:2007)</li> <li>• Biocompatibility: Biological evaluation of medical devices. (EN ISO 13485:2012/AC:2012)</li> <li>• Usability (EN 60601-1-6:2007)</li> <li>• Aptitude of use (EN 62366:2008)</li> <li>• Spirometers for forced respiratory volumes measurement</li> </ul>

	<p>(EN ISO 26782:2009/AC:2009)</p> <ul style="list-style-type: none"> <li>• Spirometers for peak respiratory flow (EN ISO 23747:2007)</li> <li>• Pulse oximetry (EN ISO 9919:2009 per ISO 80601-2-61:2011)</li> <li>• Vibration and temperature: (Series EN 60721:1995 and Series EN 60068:1999)</li> <li>• Documentation and information (EN 1041:2008, EN 980:2008) EN ISO 15223-1:2012</li> <li>• Waste disposal according to WEEE Directive 2002/96/CE.</li> <li>• Software of medical devices (EN 62304:2006)Electronic Device:2011/65/EU Rohs Directive (starting on July 22, 2014)</li> </ul>
<b>Spirometry standards in force</b>	<ul style="list-style-type: none"> <li>• ATS/ ERS Standards: <ul style="list-style-type: none"> <li>No. 1. Miller MR, Crapo R, Hankinson J, et al. General considerations for lung function testing. Eur Respir J 2005; 26:153–161.</li> <li>No. 2. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J 2005; 26: 319–338.</li> <li>No. 3. V. Brusasco, R. Crapo and G. Viegi. Standardisation of the measurement of lung volumen Eur Respir J 2005; 26: 511-522</li> </ul> </li> <li>• SEPAR: Sanchis et al Normativa para la espirometría forzada. Recomendaciones SEPAR núm. 1. Arch Bronconeumol 1989; 25: 132-142.</li> <li>• NLHEP: Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117:1146-1161.</li> </ul>

## 6.2 SYMBOLS



SERIAL NUMBER



MANUFACTURER (Manufacturing date, manufacturer's name and address)



LOT NUMBER



EXPIRATION DATE



DO NOT REUSE



TEMPERATURE LIMITATION



CONSULT THE INSTRUCTIONS FOR USE



PRECAUTION



GROUND



START-UP (STANDBY)



BF APPLIED PART



NO PHYSIOLOGICAL PULSE OXIMETRY ALARM

**IPN.N<sub>2</sub>**

IPX2: PROTECTED AGAINST DRIPPING WATER WHEN TILTED UP TO 15°



WASTE DISPOSAL ACCORDING THE WEEE DIRECTIVE



SENSITIVE CONNECTOR TO ELECTROSTATIC DISCHARGES (See Annex 1)



ENTRANCE (EXTERNAL POWER SUPPLY)

## 6.3 TESTS, FUNCTIONS AND PARAMETERS

Available Information on tests:

- Percentage deviation in relation to predicted values
- Standardized values of predicted that can be selected from several standards
- Patient's ID details
- Atmospheric data on temperature, pressure and relative humidity.
- Availability of 8 maneuvers from the same study
- Graphs in FLOW/VOLUME and VOLUME/TIME for FVC, Bronchodilation and Bronchoconstriction tests.
- Graphs in FLOW/VOLUME for VC and MVV tests.

### FORCED VITAL CAPACITY FVC

- FVC (I) Forced Vital Capacity



- FEV0.5 (l) Forced Expiratory Volume in 0.5seconds
- FEV1 (l) Same in 1 second
- FEV3 (l) Same in 3 seconds
- FEV.5/FVC (%) Ratio
- FEV1/FVC (%) Ratio
- FEV3/FVC (%) Ratio
- FEV1/VC (%) Ratio
- PEF (l/s) Peak Expiratory Flow
- FEF25% (l/s) Forced Expiratory Flow 25% into the maneuver
- FEF50% (l/s) Same, 50% into the maneuver
- FEF75% (l/s) Same, 75% into the maneuver
- FEF25-75% (l/s) Mean expiratory flow between 25% and 75% of the FVC
- FEF75-85% (l/s) Mean flow between 75-85% of FVC
- FET25-75 (s) Forced expiratory time between 25-75% of FVC
- FET100 (s) Forced Expiratory Time
- MEF50/MIF50 (-) Ratio
- FEV1/FEV.5 (-) Ratio
- FEV1/PEF (-) Ratio
- MIF50%(l/s) Maximum Inspiratory Flow with 50% of FVC inspired
- FIVC (l) Forced Inspiratory Vital Capacity
- FIV1 (l) Forced Inspiratory Volume in 1 second
- FIV1/FIVC (%) Ratio
- FEV1/FIV1 (%) Ratio
- PIF (l/s) Inspiratory Flow Apex
- MTT (s) Mean Transit Time
- PEF/PIF (-) Ratio
- Vext (%) Extrapolated Volume
- MVVInd (l/min) Maximum Voluntary Ventilation (30 x FEV1)
- FEV6 (l) Forced Expiratory Volume in 6 seconds
- FEV1/FEV6 (%) Ratio
- EPOC Index – Parameter that depends on the number of cigarettes smoked per day, the age and the FEV1. Indicates the risk of EPOC
- Lung Age Parameter- Depends on the height and FEV1. This indicates the equivalent age of the lung.
- Quality alerts to assure compliance with ATS/ERS and NLHEP criteria

- Acoustic and graphic indication of the start and end of each maneuver
- Start FVC expiration: Using the retrograde extrapolation method
- End FVC expiration: When the volume accumulated in the last second is below 25ml.

## **BRONCHODILATION TEST**

- Same parameters and characteristics as in FVC
- Several methods of comparison among PRE, POST and REF values
- Superimposing of PRE and POST graphs

## **SLOW VITAL CAPACITY**

- 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 (-) Ratio

## **MAXIMUM VOLUNTARY VENTILATION**

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

## **6.4 PREDICTED SETS**

The spirometer includes several predicted tables that the user can select in the **CUSTOMIZATION MENU\ Spirometry**.

Predicted set	Country / Region	Age range (years)
SEPAR	SPAIN	6 to 70 <sup>(1)</sup>
ERS	EUROPE	18 to 70 <sup>(1)</sup>
KNUDSON	EEUU	6 to 84 <sup>(1)</sup>
CRAPO	EEUU	4 to 91 <sup>(1)</sup>
ZAPLETAL	EUROPE	4 to 17
MORRIS	EEUU	24 to 100
AUSTRIA	AUSTRIA	6 to 90 <sup>(1)</sup>
GUTIERREZ	XILE	5 to 100 <sup>(1)</sup>
CASTRO - PEREIRA	BRAZIL	6 to 76 <sup>(1)</sup>
POLGAR - WENG		4 to 100
HANKINSON - NHANES III	EEUU	4 to 100
PEREZ - PADILLA	MEXICO	7 to 100 <sup>(1)</sup>
A.J. CRUZ	MEXICO	17 to 64 <sup>(1)</sup>
GOLSHAN	IRAN	6 to 81 <sup>(1)</sup>
GARCIA RIO	EUROPE	65 to 85
CANDELA	SPAIN	2 to 7
PLATINO	LATIN AMERICA	-40 to 90
THAI 2000	THAILAND	>10

<sup>(1)</sup> If other ages are used, the predicted values are extrapolated

## 6.5 FVC INTERPRETATION (Diagnosis)

- **Miller chart**
- **Snider, Kory & Lyons**
- **Interpretation ATS/ERS.** Pellegrino et al. Task force: Standardisation of Lung Function Testing. Eur Respir J 2005; 26: 948–968
- **Interpretation NLHEP.** (Only valid for predicted values that calculates the LLN. For example: Hankinson, Ferguson et al.) Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117: 1146-1161.

## 6.6 TRANSDUCERS

### RANGES AND MEASUREMENTS (According to ATS/ERS2005)

	Fleisch	Turbine	Lilly Dispos.
<b>Measurement Scale (BTPS)</b> Flow Volume	0 to $\pm 16$ l/s 0 to 10 l		
<b>Dynamic flow resistance</b>	< 1.5 cmH <sub>2</sub> O / (l/s) at 14 l/s		
<b>Precision of measurements (BTPS)</b> Volume Flow PEF	(the highest value) 3% or 50 ml 5% or 200 ml/s 10% or 300 ml/s		
<b>Time related precision</b>	0,50%		
<b>Volume resolution</b>	<10ml	<10ml	<10ml
<b>Sampling frequency</b>	100Hz	100Hz	100Hz
<b>Transducer lifetime</b>	1400 disinfect. or 3 years	1400 disinfect. or 3 years	Only one use (Expir. 3 years)

## 6.7 MANUFACTURER'S LIABILITY

**SDI Diagnostics, Inc.** is liable for the safety, reliability and working order of this equipment only if:

- The location where the equipment is installed or used is compliant with the requirements related to the IEC electrical installation and other applicable regulations.
- All repairs, services and modifications inside and outside the guarantee period are carried out by SDI Diagnostics technical staff.
- The equipment is used by skilled staff according to the recommendations of this User's Manual.

## 7. CLEANING AND MAINTENANCE

Your **AstraTOUCH** spirometer requires cleaning and maintenance aimed at keeping the equipment functioning correctly and ensuring safety of patients and operators.

### 7.1 CLEANING / DISINFECTION

The person who carries this out does not require any special technical knowledge other than their own understanding of the functioning and handling of the equipment. It is usually done by the normal user of the equipment.



**For your safety, disconnect the equipment from electrical power or remove the battery before cleaning.**

#### 7.1.1 CLEANING THE SPIROMETER

The spirometer case can be cleaned with a wipe moistened with soapy (neutral) water or with 96% alcohol. Then it can be wiped dry. Take particular care to ensure that no liquid enters the interior of the device or the connectors and connections. **Do not use abrasive substances or solvents!**

The Turbine transducer must be disinfected prior to using it with a new patient, especially if you suspect microbial contamination. To do so, proceed as follows:



#### 7.1.2 HIGH LEVEL DISINFECTION OF THE TURBINE

- 1 Remove the turbine from its housing by pressing slightly its tab so that it comes away from the transducer housing.



- 2 Immerse the turbine in a Cidex **OPA** solution (follow the manufacturer's instructions). Rinse the turbine by immersion in distilled water. **Do not rinse the turbine by holding it under running water. Do not use abrasive cleaning agents.**
- 3 Given that the turbine reliability depends on it being in good condition, examine periodically for damage.
- 4 Leave it to dry at room temperature and re-assemble the turbine in the housing.
- 5 When performing intense use of this spirometer, it is recommended to have several spare transducers available to replace those that are being disinfected.  
If a bacteria filter is used in conjunction with the turbine transducer, the Cidex **OPA** solution indicated in Step2 can be replaced with soapy (neutral) water.

## D- HANDLE AND TRANSDUCER HOUSING

Clean the external parts of the transducer's housing and handle with a wipe moistened with soapy (neutral) water or with 96% alcohol. Wipe dry. **Do not use abrasive substances or solvents.**

## 7.2 PREVENTIVE MAINTENANCE

Preventive maintenance consists of any actions aimed at keeping the equipment in good working order.

### Actions which can be carried out by the same user:

- 1 Each time the spirometer is turned on, the equipment will check certain parts and/or functions. In addition, the user can access the **Maintenance Program** to adjust and/or check any parts of the equipment, as indicated in detail in the corresponding section.

- 2** A second procedure which can be performed by the user, consists of regular monitoring of the appearance of the different connections and other external parts of the equipment. Check that all connections are perfectly connected, that no cable and/or connector or any other element is broken or damaged.
- 3** Execute a calibration check with a 3-L syringe. Calibration checks must be undertaken daily.
- 4** Define the periods in days between calibrations or preventive maintenance work on the **CUSTOMIZATION MENU** of the equipment. If the days specified are exceeded, the equipment warns of such by displaying a sign every time it is started. If "0" days is entered, a warning is never given.

In the event of detecting any problem that the user cannot solve, contact **SDI Diagnostics Technical Service or your distributor** to review or repair it.

### **Actions carried out by skilled technical personnel:**

According to the different regulations, particularly the **93/42/EEC Medical Device Directive**, electromedical devices should be verified and/or calibrated regularly to ensure reliable functions and the safety of patients, users and the environment.

On all accounts, **SDI Diagnostics**, as **the manufacturer**, must provide written authorization, for at least the guarantee period, for the corresponding technical personnel to carry out said maintenance and will not be held liable under any circumstances for any damage, malfunction, etc. that may arise as a result of defective maintenance by people not employed by **SDI Diagnostics**.

### **7.3 CORRECTIVE MAINTENANCE**

Corrective maintenance consists of repairing the equipment that has stopped working, due to malfunctioning or misuse, leaving it in a good state.


On detecting any fault with equipment which interferes with its normal use, disconnect the equipment from the electrical circuit and contact **SDI Diagnostics Technical Service** at 800-678-5782. Specify the problem in as much detail as possible.



## **Annex 1. ELECTROMAGNETIC COMPATIBILITY**

### **1.1 ELECTROSTATIC DISCHARGE**

The AstraTouch uses the exception of electrostatic discharge test on the Ethernet connector as described in EN60601-1-2:2007.

For this reason, as stated in paragraph 5.1.2 of the standard, the symbol  must be placed next to the Ethernet connector.

This symbol does not imply any problem of safety to the technician or to the patient. Neither implies that the Ethernet module is damaged. It would only cause the Ethernet communication to stop running for a moment.


However, to avoid any problem, you should take the following precautions:

- Connect and disconnect the Ethernet cable when the device is turned off.
- During the functioning of the equipment, do not touch the connector with your fingers.
- Inform all staff involved of the meaning of the symbol and the precautions about discharge sensitivity.

## 1.2 GUIDANCE & MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
AstraTOUCH is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - Guidance
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	AstraTOUCH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Group 1 Class B	AstraTOUCH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Yes	

Guidance and manufacturer's declaration – electromagnetic immunity			
AstraTOUCH is intended for use in the electromagnetic environment specified below. The customer or the user of AstraTOUCH should assure that it is used in such an environment.			
Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines  ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.  To Ethernet cable.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	±1 kV differential ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut)for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	<5 % Ut (>95 % dip in Ut)for 0.5 cycle 40 % Ut (60 % dip in Ut)for 5 cycles 70 % Ut (30 % dip in Ut)for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AstraTOUCH requires continued operation during power mains interruptions, it is recommended that the AstraTOUCH be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital

EN-IEC 61000-4-8			environment.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			
<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
<b>AstraTOUCH</b> is intended for use in the electromagnetic environment specified below. The customer or the user of <b>AstraTOUCH</b> should assure that it is used in such an environment.			
Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF EN-IEC 61000-4-6	3 Vrms 150KHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of AstraTOUCH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{E} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[ \frac{3.5}{E} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = \left[ \frac{7}{E} \right] \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<b>Note 1.</b> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>Note 2.</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which AstraTOUCH is used exceeds the applicable RF compliance level above, AstraTOUCH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating AstraTOUCH.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m</p>			

**Recommended separation distances between portable and mobile RF communications equipment and AstraTOUCH**

**AstraTOUCH** is intended for use in an electronic environment in which radiated RF disturbances are controlled. The customer or the user of **AstraTOUCH** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **AstraTOUCH** as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter  W	Separation distance according to frequency of transmitter m		
	De 150 kHz a 80 MHz  $d = \left[ \frac{3.5}{3} \right] \sqrt{P}$	De 80 MHz a 800 MHz  $d = \left[ \frac{3.5}{3} \right] \sqrt{P}$	800 MHz to 2.5 GHz  $d = \left[ \frac{7}{3} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note 1** At 800 MHz, the separation distance for the higher frequency applies.

**Note 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Annex 2. COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC

### REQUIREMENTS AFFECTING THE USER OF THE EQUIPMENT

According to current legislation, the **user of this equipment is the only party responsible** for saving and processing the details of his patients according to the Law.

### CONFIGURATION OF AstraTOUCH PROTECTION

The **AstraTOUCH** spirometer has an equipment protection option that uses a PIN code, user-configurable that seeks to prevent access by unauthorized people to the equipment and, more specifically, to the private data it contains.

To comply with current legislation, users **must enable this option** and configure their PIN. They will be held responsible for providing this PIN to the authorized people. Thus, when the spirometer is started, the PIN will be requested and the equipment locked where this PIN is entered erroneously three times. On restarting the equipment, the unlock code (PUK), provided by the manufacturer upon purchasing the equipment, will be requested. If this code is not available, the equipment will remain locked.

- **PRINTING DOCUMENTS:** In the event of saving paper printouts containing patient details, these documents must be properly stored so that only duly authorized personnel have access to them.
- **DATA TRANSMISSION:** This spirometer can transmit files containing patient details via PC connection so that work can be subsequently carried out on them using the W20s Spirometry Software. This software is also compliant with the Data Protection Act, as explained in its User's Manual.

## **8.0 SPIROMETRY INDICATIONS**

Although the early detection of COPD is perhaps the most important indication for application of office spirometry, there are many others that have proven to be helped in the diagnosis of disease.

- Dyspnea (shortness of breath)
- Exercise-induced coughing
- Chest tightness
- Smokers over 45 years of age (NLHEP recommendation)
- Obesity
- Pre-operative testing
- Occupational exposure to dust and/or chemicals
- Ongoing assessment of patients receiving bronchodilator treatments
- Determination and/or documentation of pulmonary disability
- Asthma diagnosis
- Pre-existing pulmonary disease
- Frequent colds
- Assessment of congestive heart failure

## **8.1 AMA CPT CODES FOR SPIROMETRY**

Current Procedural Terminology (**CPT**) code numbers for office spirometry tests as specified by the American Medical Association (**AMA**) are useful when billing most third party insurers.

### **94010 FVC TEST**

Spirometry (Forced Vital Capacity maneuver) including calculation of the FVC, FEV<sub>1</sub>, and optionally flow rate measurements. A graphic record as well as an interpretation must be included.

### **94060 Bronchospasm Evaluation**

Spirometry as in 94010 above before and after administration of a bronchodilator or before and after exercise

### **95070 Inhalation Challenge**

Testing with histamine, methacholine or similar bronchoprovocation agent

### **94070 Functional Residual Capacity**

Multiple spirometric determinations after bronchodilator with spirometry as in 94010

### **94150 Vital Capacity**

Spirometry, Slow Vital Capacity

### **94200 Maximum Voluntary Ventilation**

Maximum breathing capacity, maximum volume ventilation

### **94375 Flow Volume Loop**

Respiratory flow volume loop

### **94664 Bronchodilator Administration**

Aerosol or vapor inhalation

## 8.2 INDICATIONS AND ICD-9 CODES FOR SPIROMETRY DIAGNOSIS

Diagnosis	ICD-9-CM Code(s)
Smokers over 40	491.0
Shortness of Breath	518.82
Chronic Cough	464.4, 493.9
Frequent Coughs	460 or 465, 465.0, 465.8, 465.9
Allergic Rhinitis	477, 477.0, 477.8, 477.9
Occupational Exposure to Dust or Chemicals	506, 506.0, 506.1, 506.2, 506.3, 506.4, 506.9
Scoliosis	737, 737.0, 737.1, 737.10, 12, 19 737.2, 737.20, 21, 22, 29, 737.3, 737.30, 31, 32, 33, 34, 39, 737.4, 737.40, 41, 42, 43, 737.8, 737.9
Pigeon Chest	738.3, 754.82
Barrel Chest	783.3
Diagnosis of Asthma	493, 493.0, 493.1, 493.2, 493.9
Diagnosis of Bronchitis	491, 491.0, 491.1, 491.2, 491.8, 491.9
Diagnosis of other COPD	496
Pre-Operative Evaluation	518.5
Wheezing	786.09
High Risk Medication	V58.69



## **9.0 LIMITED WARRANTY CONDITIONS**

This SDI product together with its standard accessories is guaranteed for a period of TWO YEARS from the date of purchase. In the case of any warranty claims the relevant sales invoice (or another proof of purchase document) must be submitted to SDI.

The instrument must be checked at the time of purchase and any claims must be made immediately in writing to SDI.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or defective parts.

All batteries and other consumable parts are specifically excluded from the terms of this guarantee.

The warranty is not valid in the following cases:

- Problems due to improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilized differently from the use described in the Users Manual.
- If any alteration, adjustment, modification or repair has been carried out by personnel not authorized by SDI.
- Problems caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the power source or by another product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The customer is responsible for the transportation and all transport and customs charges for delivery of the goods both to and from SDI.

Any instrument or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found. Written or verbal permission must be received before any instruments are returned to SDI.

SDI reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.