DIAGNOSTICS

The Spirometry Source

Astra 300™

User's Manual

1-800-678-5782 1-508-238-7033
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sdi
DIAGNOSTICS
The Spirometry Source

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CAUTION: Federal law restricts this device to sale by or on the order of a physician!

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SAFETY

SPECIAL PRECAUTIONS

The **ASTRA 300** spirometer has been designed for use with safety in mind. All operating instructions must be read before using the **ASTRA 300**. Failure to do so may lead to injuries to the user or the patient and damage to equipment and/or accessories.

INTENDED USE

The spirometer measures and calculates a series of parameters related to human respiratory function. It is intended to be used by or under the direction of a medical professional

The spirometer is not designed for use outdoors or under other conditions or using other power sources not indicated in this manual.

EFFECTS ON PATIENTS USING THE SPIROMETER

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.

LIMITATIONS OF USE. CONTRAINDICATIONS

An analysis of the results of spirometry tests is not enough in of itself 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.

ELECTRICAL RISKS

Dot NOT disassemble the equipment casing. 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 submerge the parts of the device in any liquid.

Consult the equipment cleaning method in Chapter 8, Section 8.1. UPKEEP, PREVENTIVE AND CORRECTIVE MAINTENANCE.

To ensure vital safety features under the EN 60601-1-1 standard, only equipment compliant with the electrical safety standards in force may be connected to this device. To connect ASTRA 300 to a non-medical device with a ground conductor, you must install an additional ground conductor to the non medical device.

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

RISKS OF EXPLOSION

Do NOT use the equipment in the presence of volatile anesthetics or inflammable gases.

RISKS OF CONTAMINATION

Turbine transducer: To avoid the risk of contamination or cross infection, the turbine must be cleaned before use or used with a protective barrier filter as indicated in this manual.

Disposable mouthpieces must not be reused.

Pulse oximeter finger clip: The pulse oximeter finger clip should be washed after each patient use using either soapy water or using a medical equipment disinfectant of choice.

1. INSTRUCTIONS FOR USE AND INSTALLATION

1.1 INTRODUCTION

The **Astra 300** spirometer is a compact device with a high-resolution graphic touch screen. It functions using accurate and precise turbine transducers and may be be connected to an external printer via USB.

The entire system is controlled by a microprocessor for the acquisition, calculation and presentation of alphanumeric and graphical data.

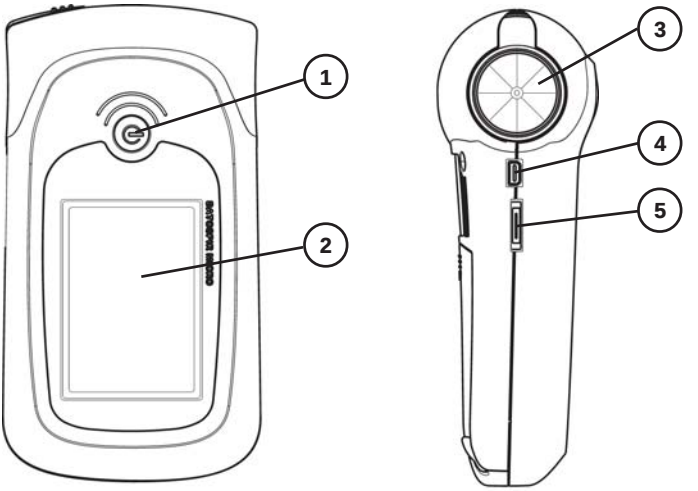
PCP PROGRAM

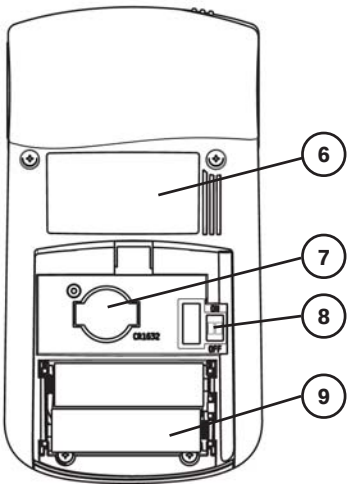
Your Astra 300 comes to you preconfigured with a preset program based on the recommendations of the National Lung Health Education Program (NLHEP). It is configured as the PCP mode. It meets all the recommended guidelines of NLHEP for spirometry testing, including the NHANES III predicted set and quality alerts to assist you in producing high quality spirometry tests. The PCP mode can be cancelled in the Spirometry Customization menu. Cancelling the PCP mode will automatically set the Astra 300 in the full Customization mode to allow you to configure the device based on your needs.

ASTRA 300 LIST OF CONTENTS

Part No.	Qty.	Description
29-5300	1	**SDI Astra 300**
29-5002	1	Stylus, Astra Series Spirometers
29-7990	10	AstraGuard Bacteria/Viral Filters
29-7966	10	The Klip Noseclips
29-5021	1	Cable Mini USB B 5 Pins USB 1
29-5023	2	AA 1.5 V Alkaline Battery
29-5003	1	Turbine Transducer
29-5022	1	Cable Mini USB(External Printer Option)
29-5310	1	Quick Reference Card, Astra 300

1.2 LAYOUT OF CONTROLS, PILOT LIGHTS AND CONNECTORS





1- On/off button
2- Graphic LCD display
3- Turbine transducer
4- USB connection
5- RS·232 series connection
6- Specifications plate
7- Lithium battery (CR1632)
8- Firmware loading switch
9- Main batteries (2xAA 1.5V)

1.3 INSTALLATION AND START-UP

Astra 300 INSTALLATION

The **ASTRA 300** spirometer is **CLASS IIa** according to the criteria of the **93/42/EEC European Medical Device Directive** and, in line with the type of protection against electric shocks established by the **EN60601.1** standard, the equipment is rated as **CLASS IP type B**.

Batteries
The **Astra 300** spirometer typically operates with two AA 1.5 V alkaline batteries or optionally with two rechargeable NiMh batteries (AA 1.2 V type).

WARNING:
Never try to recharge alkaline batteries. This would cause damage to both the batteries and the charger.

In both cases, the battery charge will depend on the quality of the batteries used. 1.5 V alkaline batteries or 2400 mAh rechargeable batteries will last for approximately 40 hours. The charge may drop by 50% when working via Bluetooth. USB Connection to the PC will not use any battery power, given that the equipment is powered through the PC's USB port.
The charging time for rechargeable NiMh batteries will depend on the charger used.

To conserve power, the equipment includes an auto switch off system that turns the equipment off when the screen is not accessed for **5 minutes**, except in main spirometry and pulse oximetry screens. In this case, you will be prompted to save the data before powering off.
NOTE:
When inserting the batteries for the first time or when replacing them, the equipment may switch on automatically. This is normal and does not indicate malfunction.

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Atmospheric conditions
The atmospheric working conditions are:

- Ambient temperature between 10 and 40 ºC (50 and 104 ºF)
(The American Thoracic Society recommends 17 to 40 ºC)

- Relative humidity below 75% (without condensation)

- Atmospheric pressure from 430 to 800 mmHg

EQUIPMENT PROTECTION

To insure the security of patient data, the **ASTRA 300** has an equipment protection option accessed by PIN.This option can be customized, enabled or disabled as required. Where enabled, a screen will appear requesting the PIN (user-configured) when the equipment is turned on.
If an erroneous PIN is entered three times, the equipment will lock and will switch off. On restarting it, a screen will appear requesting the unlock code. Call SDI's technical service department for the unlock code at 1-800-678-5782.

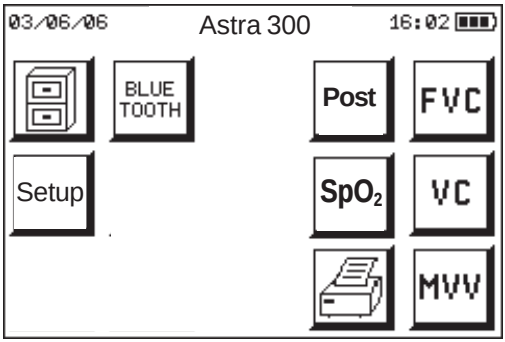
START-UP

To start the **ASTRA 300** spirometer,

press the key  for 2 seconds .

The equipment will then make a beeping sound and will check itself. The <**SDI**> logo, the name of the equipment, the program version and the address of SDI Diagnostics will appear on screen for two seconds.

If equipment protection is enabled, the PIN entry screen will appear. If equipment protection is not enabled or if the correct PIN has been entered, the **MAIN MENU** will then be displayed, which varies according to the model.



NOTE:
The first time the equipment is started, the protection is disabled and the PIN is set to 0000. See Section 2.2 / 3.2 EQUIPMENT CUSTOMIZATION to enable it and configure the PIN.

HANDLING THE EQUIPMENT

The spirometer has been designed to be simple to operate. Although it allows a number of functions, its unique navigation properties will quickly demonstrate that it is truly intuitive for any clinician

All functions are accessed using the icons on the screen using the supplied stylus.

The spirometer may be connected to an external printer when this has been previously selected in the Customization option and the appropriate printer is selected

1.4 OPERATING MODES

- **Spirometry**
  . Patient Details (Reference, Age, Weight, Height, Sex, Smoker Index)
  . Atmospheric Conditions (Temperature, Pressure, Humidity)
  . Tests (FVC, VC, MVV , Bronchodilation)
  . Report

- **Customization** (selectable options)
  . Spirometry (Predicteds/Parameters/Graphs/ Interpretation/Bronchodilation Modes/Warnings)
  . Printers
  . Standard curves (Retrieve standard / Modify standard)
  . Battery
  . Language
  . Set clock (Time / Date)
  . Pulse oximetry

- **Calibration**

- Internal **Database** to save tests with alphanumeric and graphical data (depending on model).

- **Maintenance**
  . Warnings
  . LCD contrast
  . Equipment check
  . Equipment configuration
  . ATS curves

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2. ASTRA 300 FUNCTIONAL OPERATION

2.1 FUNCTION TREE

The **ASTRA300** spirometer function tree (following) is displayed to allow the user a better understanding of its structure.

To move around the different equipment menus, ASTRA300 utilizes a stylus to select the functions appearing on screen.

The character (number or letter) must also be selected for insertion in the numeric or alphanumeric fields using the stylus.

WARNING
It is recommended to use only the stylus included with your ASTRA300 spirometer. SDI Diagnostics is not responsible for any damage caused where other styli are used.
Pointed objects must not be used under any circumstances.

The following can be accessed from the Main Menu, depending on the options included:

SPIROMETRY
CALIBRATION
DATABASE
CUSTOMIZATION
MAINTENANCE
OPERATING MODE
PULSE OXIMETRY
DILATION REPORT
BLUETOOTH

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SPIROMETRY

- Forced Vital Capacity «FVC» Test
  - Test data
    - Patient
      - Code
      - Full name
      - Age, height, weight and sex
      - Smoker index
      - Ethnic factor
      - Barometric Pressure
      - Temperature
    - Start of the spirometric maneuver
    - Graph presentation
      - Flow/Volume Loop or Curve (only in FVC)
      - Volume/Time Curve
    - Maneuver selection
    - Select the best maneuver
    - Maneuver data selected
      - Memory for five maneuvers
      - Deleting a maneuver
      - Interpretation
      - Saving test for Post-Bronchodilation
      - Saving test in the Database
    - Test printout
- Slow Vital Capacity «VC» Test
  - Similar ro the FVC criteria above
- Maximum Voluntary Ventilation «MVV» Test
  - Similar to the FVC criteria above

CALIBRATION

- Calibration using a syringe
- Report on the latest calibrations

DATABASE

- Search by patient code or register number
- Summarized display of the tests saved
- Printing and displaying a test

- Deleting a test
- Summarized printing of the tests saved

CUSTOMIZATION

- Standard Configuration
  - Retrieving the configuration
  - Saving the configuration
- Database customization
  - Number of registers
- Common customization
  - Setting the clock
  - Patient code and others
    - Numeric
    - Alphanumeric
  - Battery type
  - Operating language
  - Entering a heading in the report
  - Selecting the printer type
- Spirometry customization
  - Parameters of reference and ethnic factor
  - Observed parameters (FVC, VC, MVV)
  - Graph selection
    - Saving graphs on the database
    - Printing FVC Flow/Volume graph
    - Printing FVC Flow/Time graph
    - Printing VC Flow/Time graph
    - Printing MVV Flow/Time graph
  - Interpretation selection
  - Comparison mode in POST bronchodilation
    - Weighted % between PRE and POST
    - % between REF and POST
    - % between PRE and POST
    - Difference between PRE and POST
  - Display of alerts for maneuvers not in compliance with ATS/ERS or NLHEPcriteria
- SpO_2 Pulse oximetry customization

- Equipment protection customization
  - Modifying the PIN

MAINTENANCE

- Alerts selection
  - Period between calibrations
  - Period between maintenance work
- Adjusting the LCD contrast
- Checking hardware
- Checking with standard curves (FVC, VC, MVV)
- Others
  - Notifies ProgramUpdate key and allows System initialization.

PULSE OXIMETRY

- Test data
  - Patient
    - Code
    - Full name
    - Age, height, weight and sex
- Configuration
  - Average in the SpO_2
- Saving Trends
- Displaying Trends
  - Configuration
  - Signal forwards and backwards
  - Test Parameters
    - Parameter printout
    - Saving parameters in the database

BRONCHODILATION

- Carrying out Post bronchodilation test

REPORT

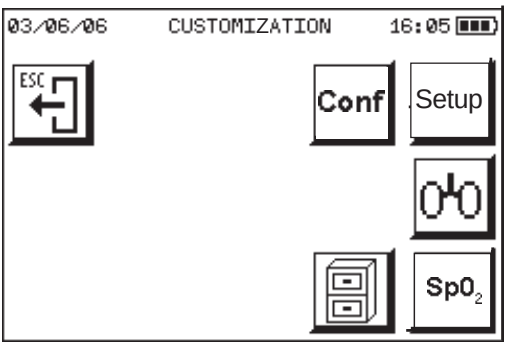
- Printing a report

2.2 EQUIPMENT CUSTOMIZATION

Because of the wide variety of options available, users should customize their **ASTRA300** spirometer based on their requirements.

The different options included in the Customization Menu are explained in detail in the previous section.

To access this option, press Setup in the main menu, then Setup again from the Setup Utilities menu.
The following screen will appear:



Exits this screen and goes back to the previous one

Standard Configuration


Database customization

Common customization


Spirometry customization

Pulse oximetry customization

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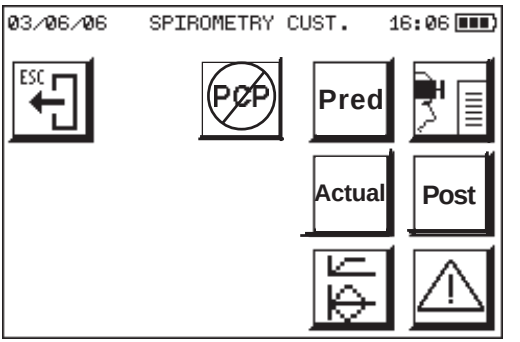
SPIROMETRY CUSTOMIZATION

This option customizes any suboptions specific to the spirometric tests



Predicted Values
Allows selecting among several authors for children and adults
Prioritizes the age range selected for adults if a different table is chosen for children.
Extrapolates the values for the ages outside the selected table range.

Observed Parameters
Allows for the observed parameters or measured parameters you want to use to be selected. 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.

Selecting the graph type

Interpretation Selection according to:Miller, Snider/Kory/Lyons, NLHEP or ATS/ERS

Post

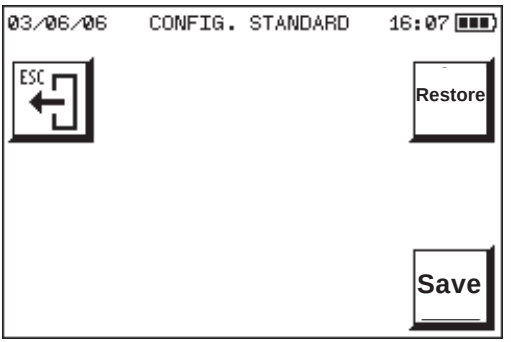
Mode of comparison between PRE bronchodilator and POST bronchodilator
W Average weighted % between PRE and POST
% between PRED and POST
% Percentage between PRE and POST
Dif. Difference between PRE and POST

Alerts
Select Alerts displayed for maneuvers not compliant with ATS/ERS or NLHEP criteria
Date of latest calibration

STANDARD CONFIGURATION

Conf

This option memorizes a user-defined customization program status to retrieve it at any time globally and automatically. This option restores the original customization if it has been modified either voluntarily or inadvertently. In general, this configuration will correspond to that most often used.



Restore — Restores the standard configuration

Save — Saves the standard configuration

Follow the instructions below to save the Standard configuration:

1 You can customize each of the following options:
Database customization
Common customization
Spirometry customization
Pulse oximetry customization
Protection customization

as described in this section.

2 Go back to the Standard Configuration option and press the Save key

3 Your Standard Configuration has now been saved.

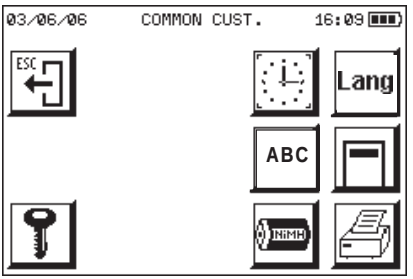
Should you need to modify a customization option during a test, it can be accessed manually and modified.

The Standard Configuration can be restored at any time. To do so, press the key Restore .

COMMON CUSTOMIZATION

Setup

This option customizes certain suboptions that are common to any test made using the **ASTRA300**.



Sets the internal equipment clock (time and date)

ABC or 123 Mode (alphanumeric or numeric)

ALK or NiMH Battery type (alkaline or NiMh)
This selection only affects how the battery voltage level is calculated

Lang Select language (Spanish or English)

Enter a heading in the report
This allows inserting two heading lines with a maximum of 33 characters/line. This can include the name of the hospital, the doctor, etc. and will appear in each report.

Printer type

Protection customization (PIN)

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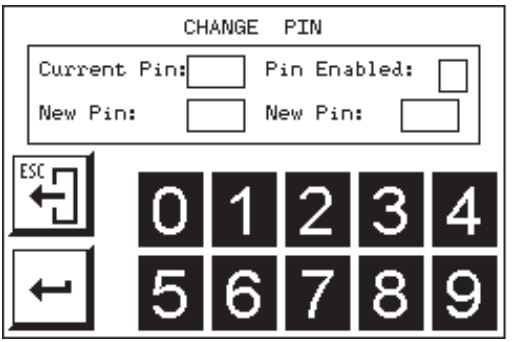
EQUIPMENT PROTECTION CUSTOMIZATION

This allows you to change the PIN required to start the equipment (if the protection option is enabled) and to enable or disable equipment protection.
The following screen appears on accessing this option



To enable the protection, tick 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. If an erroneous PIN is entered three times, the equipment will lock and switch off.

The PIN can be re-enabled by entering the current PIN and unticking the PIN-enabled checkbox.

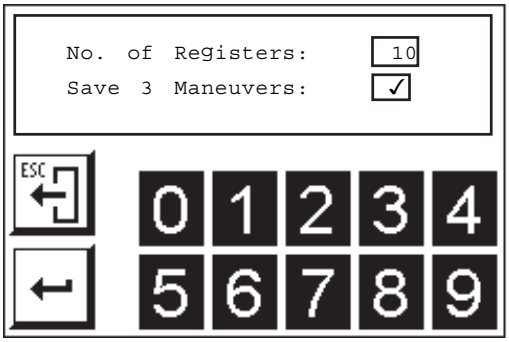
*As with any data entry, in order to save the changes be sure to touch the enter key before exiting the screen .

PULSE OXIMETRY CUSTOMIZATION

The SpO_2 module is an option available for the **ASTRA300** spirometer. Each user should customize it to suit their needs.

DATABASE CUSTOMIZATION

This option allows you to choose the number of registers to be advanced if performing a fast advance using the database search engine. Also allows for saving three maneuvers at once with the Occupational Health Module (see p. 59 for more information).



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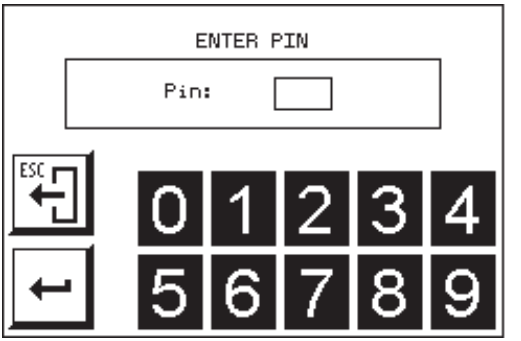
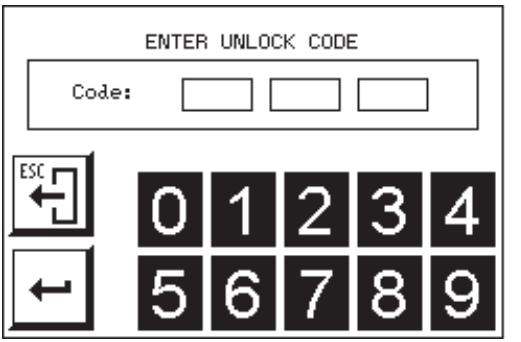
2.3 EQUIPMENT PROTECTION

If equipment protection has been enabled, the following screen will appear when it is started:



Enter the PIN and press ↵.

If the PIN configured in Equipment Protection Customization is entered, access will be given to the **ASTRA300** and the main screen will appear.
If an erroneous PIN is entered three times, the equipment will lock and switch off. The following screen will appear when it is restarted:



Enter the pin unlock code (PUK) supplied upon purchasing the equipment and press ↵.

If the correct code is entered, the **ASTRA300** 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 incorrect code is entered, the equipment will remain locked. This prevents unauthorized access to the equipment and, more specifically, to the patient data it contains.

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2.4 PERFORMING SPIROMETRY

Before testing patients, it is important to keep in mind that spirometry is an effort-dependent test requiring the complete cooperation of the patient. In order to achieve this, you as the coach play a critical role.

- Be sure the patient is comfortable. Make note as to whether the patient is seated or standing, because subsequent testing of that patient should be performed from that same position. If the patient is standing, have a chair behind him in the event that he becomes lightheaded after the blow. It is generally a good idea to have the elderly seated for spirometry testing. If the patient is wearing a shirt or blouse with a tight-fitting collar, have him unbutton the top button and if wearing a tie, it should be loosened. If wearing dentures that are loose, it may be necessary to have the patient remove them.

- Explain clearly and in simple terms that they will be performing a “breathing evaluation”. Try to avoid the word “test” since this has connotations of passing or failing and may make the patients apprehensive. Point out that they will be taking a slow maximal inhalation followed by a maximal exhalation, but that the exhalation will be “blasting out” the breath as fast as they can and as hard as they can. Key them that you will be coaching them to continue to blow out for a minimum of six seconds. Assure them that it is quite normal to blow out for that period of time. The American Thoracic Society in their 1994 Standardization of Spirometry Update highly recommends that a six second blow be the goal for all spirometry testing.[1]

- To ensure that the patients take an adequate deep breath, it is valuable to emulate exactly what you expect. A good way to do this is through one of the filters. Prior to your demonstrating the maneuver, tell your patient to be especially aware of the latter portion of the blow when you are “squeezing out” the last bit of air. If the patient has a visual cue as to what a “big deep breath” is and can actually

see *and* hear a forced expiration, they are more apt to perform well. Body language is the key to good performance. Instruct the patient to put the AstraGuard filter between his/her teeth and make a good, tight seal with his lips. After the patient slowly makes a maximal inspiration, the first phase of the test, loudly exhort the patient to BLAST out. This element of surprise will help the patient to realize the maximum peak flow, which is the second phase of the test.

- The third phase of the test, which involves diminished flow, is important to achieve the highest possible volume of patient FVC. Traditionally, technicians have loudly instructed the patient to *"blow, blow, blow…keep going, keep going!"* to achieve the maximal forced volume, when the opposite approach may actually be more effective.

- Evidence suggests that using the "soft sell" may be better for achieving the best performance during the third phase. "Draw [the patient's] attention to the …audio tone of the flow-sensing spirometers, which shows that he or she is continuing to get out some air." "Patients should be quietly told to 'keep going; I can see you're still getting more air out.'"[2] This is a critical part of the test, since an obstructed patient may actually still be expelling a volume of air, but it may not seem apparent, and many times the test is stopped too soon. This results in a lower FVC than normal and when interpreted, may suggest that the patient is restricted. Your SDI spirometer is designed to give you an audible "beep" when flow has reached a specific diminished threshold. The spirometer will also alert you with an error message when it sees an abrupt cessation of flow. Another key indicator might be to note the FET (Forced Expiratory Time) that is sometimes displayed as part of the data. If the time was appreciably shorter than six seconds, this would suggest that the patient ended the test too quickly.

[1] European Respiratory Journal. *Standardisation of Spirometry*. Eur Resp J 2005; 26:319-338.

[2] Enright, Paul L., MD. How to Make Sure Your Spirometry Tests Are of Good Quality. *Respiratory Care* August 2003; 48:774.

2.5 FORCED VITAL CAPACITY «FVC» TEST PROCEDURE

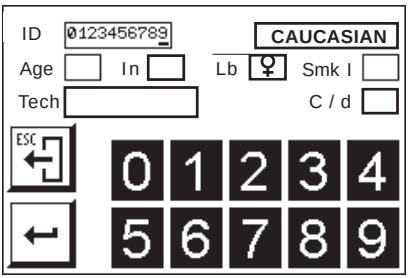
The procedures to be completed to carry out the **Forced Vital Capacity «FVC», slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.

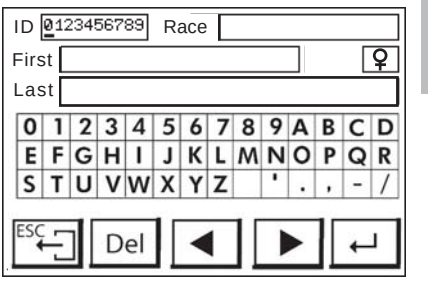
ENTERING PATIENT PARAMETERS

Turn on **ASTRA300 spirometer** using the key,

wait for the Main Screen to appear and press FVC

One of the following screens will appear, depending on the mode selected (numeric or alphanumeric):





The meaning of each field is as follows:

ID: A 10-character numeric or alphanumeric patient identifier, depending on the customized option chosen.

Tech: (Technician): 10-character numeric field corresponding to the ID code of the technician carrying out the test.

Yrs (Age): Number corresponding to the age, between 4 and 100.

in (Height): Height in inches between 20 and 90.

lb (Weight): Weight in lb between 33 and 440.

♂ / ♀ (Sex): Male or Female

C/d (Cigarettes/day):Between 0 and 100 cigarettes.

SmkI (Smoker index): Between 0 and 200 packs a day multiplied by the number of years.

The Smoker Index is the same as the number of cigarettes smoked a day divided by 20 and multiplied by the number of years smoking (cigarettes day x years smoking / 20).

EtF (Ethnic Factor, not shown): Between 80 and 120% The Ethnic Factor is used in areas without their own reference parameters , and the data needs to be corrected to a specific percentage.
This factor **MUST BE SET TO 100 IF NOT USED** and can only be modified through the Customization Program.

If the **NHANESIII** predicted set has been chosen in the Customization section or if your Astra 300 is being operated in the **PCP** Mode, the default race chosen will be displayed and **Race** will appear next to the window

First (First name): 20-character alphanumeric field corresponding to the patient's name. This can be omitted if you wish.

Last (Surnames): 25-character alphanumeric field corresponding to the patient's last name. This can be omitted if you wish.

In alphanumeric fields (Name, Code, etc.), a **double click** on the field can fully **delete it**.

Enter the patient's details and press the ↵ key to go to the test screen.

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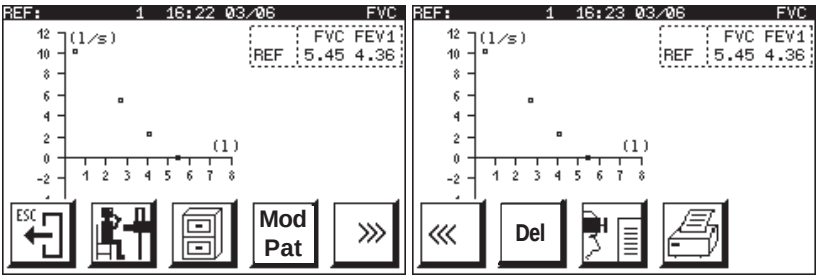
ENTERING FORCED VITAL CAPACITY «FVC» TESTS



Go back to the previous screen


Start the maneuver


Save the maneuver to the database

Modify the patient's details


Next (view the second group of buttons)


Back (view the first group of buttons)

Delete the maneuver


Display the maneuver interpretation


Print the maneuver report

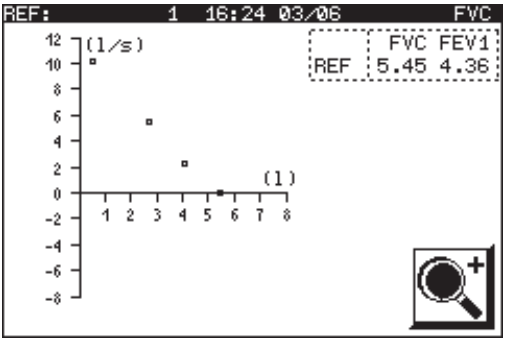
There are other areas of the screen that also have certain functions:

• Pressing on the **axes** changes the type of graph (Flow/Volume or Volume/Time).

• Pressing on the **parameters** displays the screen containing the data on the selected maneuver.

• Pressing on a **maneuver** selects it. This allows you to see its graph, consult its parameters or print a report.

• Pressing on the **graph** area makes the buttons disappear and makes it larger or smaller.



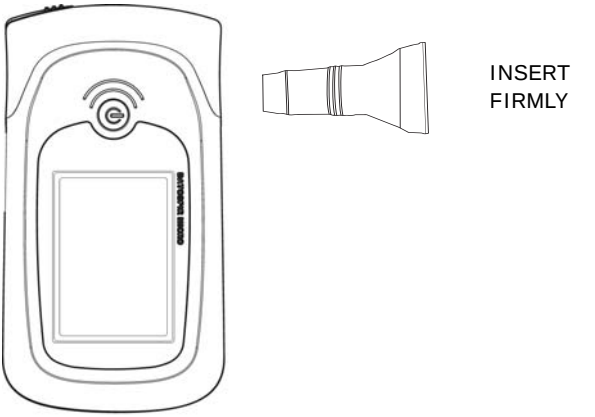
 or  Makes the graph larger or smaller

• Pressing on the **REF:** area (top left border of the screen) accesses the patient's details.

The technician who is going to carry out the forced or relaxed spirometry tests should be trained to carry out the normal testing protocols and procedures required so that the patient can be coached properly. Otherwise, it is recommended to review documentation on proper spirometry testing technique.

When testing a patient, consider the following:

1 It is highly recommended that a disposable filter or mouthpiece be used for patient testing. Check that the flter or disposable mouthpiece is correctly inserted into the spirometer, as in the figure



2 Instruct the patient as to how the test should be performed, as his cooperation is vital for the test to provide meaningful data.

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

- In the first method, the patient breathes normally through the turbine, 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.

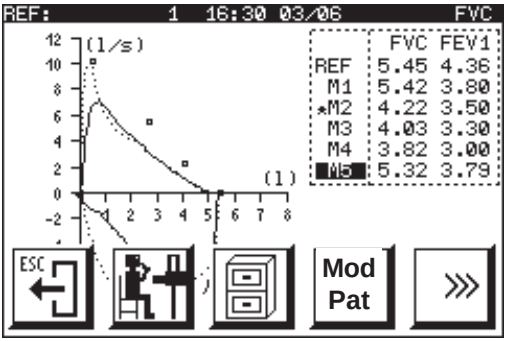
- An alternate method consists of starting the maneuver with **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if desired.

3 Inform the patient of how to hold the equipment when using the spirometer, taking care not to press any key.

4 Press the  key and wait until a **flashing arrow** appears on the screen. Then start the spirometry maneuver.

The maneuver underway can be ended at any time by pressing the  key.

The equipment is held so that the technician can see the screen while the patient is carrying out the tests.



REF indicates the patient's Predicted value
* : indicates the current maneuver
■M5■ : indicates the selected maneuver
(the best is selected by default - M1)

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At the end of the maneuver, one or more of the QC Warnings (if enabled in the Customization Program) may appear, alerting the technician as to whether the maneuver is in compliance with ATS or NLHEP Quality Control criteria.

Depending on the indication, if the maneuver has not been carried out according to one of the following ATS criteria:

ET - Indicates that the blow has not completed satisfactorily, as the variation on volume in the last second of the maneuver was more than 25 ml, or the maneuver has lasted less than 6 seconds (in patients over 10 years of age) or less than 3 seconds (in patients 10 years of age or less).

EX - Indicates that the start of expiration was not satisfactory, as the extrapolated volume is above 5% of the FVC or 0.15 liters. The ATS/ERS recommends that the extrapolated volume be less than 5% of the FVC or 0.15 liters, whichever is highest.

The technician doing the testing may, where considered appropriate, disable these warnings in the Customization Program. 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.

ATTENTION: Check in the Customization Program that the Predicteds  **and the ETHNIC FACTOR are suitably selected. The ethnic factor modifies the value of the References according to the percentage selected. 100% is equivalent to the unmodified standard value of the References.**

• The new curve is superimposed to compare it with the best (M1/ dotted line) of those saved.

• As many maneuvers as required can be carried out. The **ASTRA300** will always save the five best FVC and VC values and the three best values for MVV, according to **ATS/ERS criteria**

• Different regulations recommend at least three satisfactory maneuvers in which the repeatability criterion is satisfied, but no more than eight efforts performed.

• The last maneuver entered remains flashing and corresponds to the continual line graph. When more than five maneuvers have been entered and none are flashing, this indicates that the last maneuver entered is worse than the five saved and will be deleted.

• If three or more maneuvers have been completed and the **FVC and/or FEV1** signs are flashing, this indicates that the **repeatability criteria** for one or both parameters has been met, according to the ATS/ERS. This criterion indicates that the best two observed values of FVC and the best two of FEV1 differ by no more than 150 ml if the FVC is greater than 1 liter or no more than 100 ml if the FVC is below or equal to one liter.

NOTE: Remember that by using the back key 

it is possible to go backward in the menu without losing the information available to date, unless you enter a new patient by entering a new code or at another time.

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

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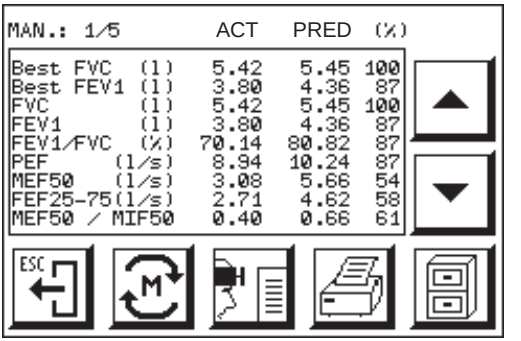
DISPLAYING RESULTS

Press the parameter area. The data on the selected maneuver (M) will be displayed (M1 by default).



Go back to the previous screen

Select and view different maneuver


Display the interpretation of the selected maneuver


Print the report on the selected maneuver


Save the selected maneuver in the database


or

Display the remaining parameters, if selected

• The screen displays the Predicted (Reference)values, the Actual values and the % between both parameters selected in the Customization Program. If an * appears after the REF test, this means that the Predicted values have been extrapolated.

• It also displays:

- The best FVC and FEV1 values that may correspond to different maneuvers.

- Ethnic factor (if not used, this must be 100)

- Warnings of non-compliance with ATS/ERS criteria for each maneuver.

WARNING:
As indicated, the BEST maneuver is set at M1. Therefore, use M1 to display the interpretation, to print the report or to save the maneuver for the POST bronchodilation test or for the Internal Database. The technician has the option to override this selection.

TYPE OF INTERPRETATION

Pred

The **ASTRA300** spirometer has, as part of the firmware a selection of interpretation criteria that can be selected in the Spirometry Customization Program. Choose the Interpretation from the screen selection.

NOTE:
If you do not agree with the interpretation criteria, do not use them as a reference or diagnosis

The interpretation and the results of the test must always be validated by the specialist.

• ATS Interpretation
This presents the following information: **NORMAL, RESTRICTIVE,** or **OBSTRUCTIVE**, according to the criteria of the following table:

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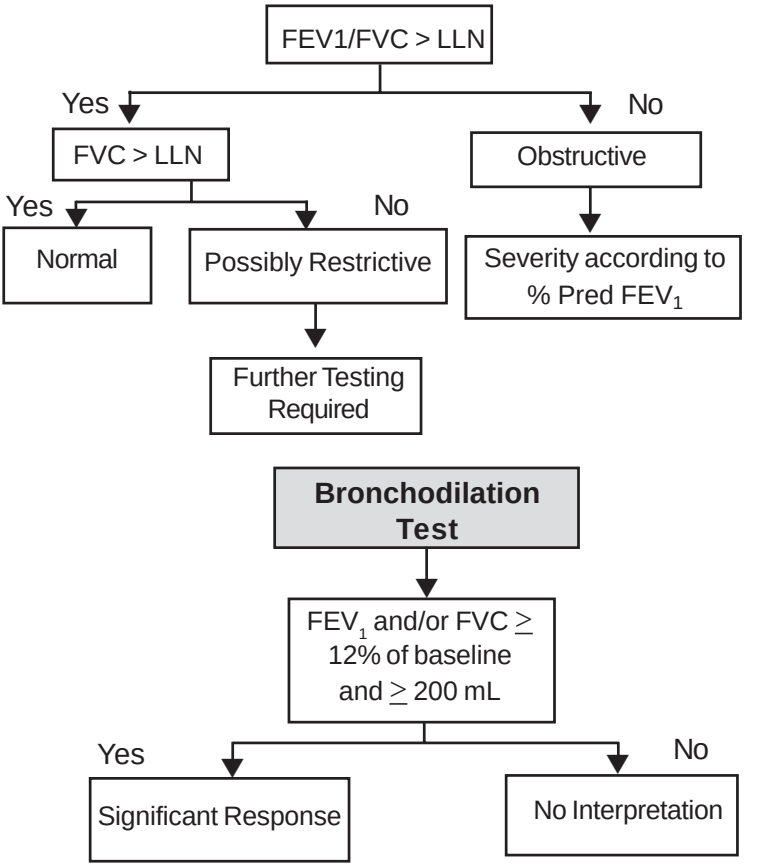
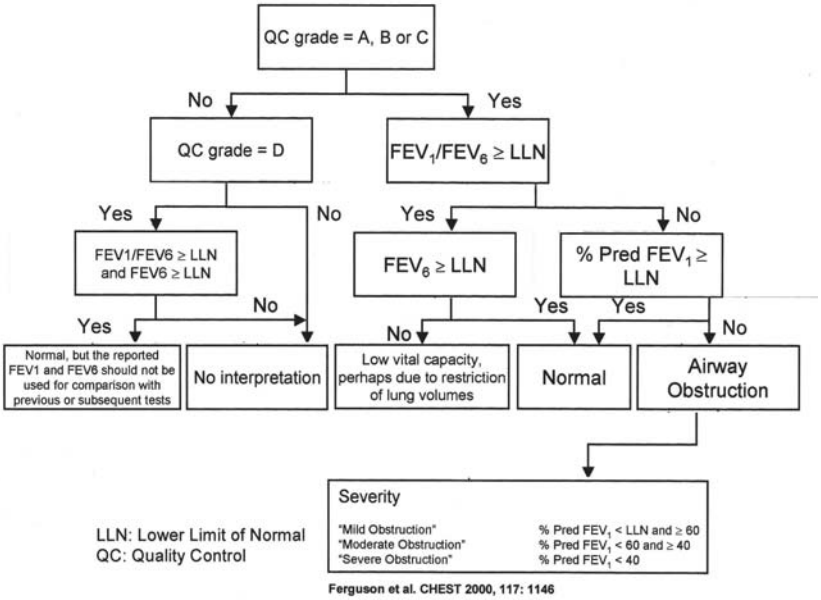


"Mild"	% Pred FEV_1 ≥70
"Moderate"	% Pred FEV_1 < 70 and ≥ 60
"Moderately Severe"	% Pred FEV_1 < 60 and ≥ 50
"Severe"	% Pred FEV_1 < 50 and ≥ 34
"Very Severe"	% Pred FEV_1 < 34

LLN: Lower Limit of Normal



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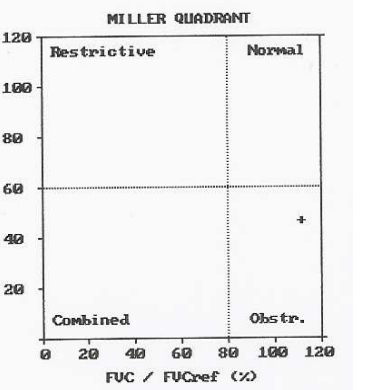
• Miller Diagnosis

This presents the following information: NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED, according to the criteria of the following chart



• Snider, Kory & Lyons Diagnosis

This is based on the following criteria:

If FVC > 80% of the FVC Reference
and FEV1 > 80% of the FEV1 Reference
Values in the range of reference. Normal Diagnosis

If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 < 80% of the FEV1 Reference
Obstructive ventilatory disturbance
FEV1 < 80% Slight
FEV1 < 65% Moderate
FEV1 < 50% Intense
FEV1 < 35% Very Intense

If FEV1/FVC% < FEV1/FVC% Reference
and FVC < 80% of the FVC Reference
Non-obstructive ventilatory disturbance
FVC < 80% Slight
FVC < 65% Moderate
FVC < 50% Intense

FVC < 35% Very Intense

If FEV1/FVC% < FEV1/FVC% Reference
and FVC > 80% of the FVC Reference
Mixed ventilatory disturbance is suspected

If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 > 80% of the FEV1 Reference
Mixed ventilatory disturbance is suspected

If the POST bronchodilation test is carried out and the FEV1 POST degree of reversibility exceeds the base FEV1 or PRE by 15%, **this is considered a positive response to the bronchodilator**

QC GRADES

Quality Control grades will be assigned according to the following guideline

A = At least 2 acceptable maneuvers with the largest two FEV1 values matching within 100 mL and the largest 2 FEV6 values matching better than 100 mL

B = At least 2 acceptable maneuvers with FEV1 values matching matching between 101 and 150 mL

C = At least 2 acceptable maneuvers with FEV1 values matching between 151 and 200 mL

D = Only one acceptable maneuver, or more than one, but the FEV1 values match >200mL (no interpretation)

F= No acceptable maneuvers (no interpretation)

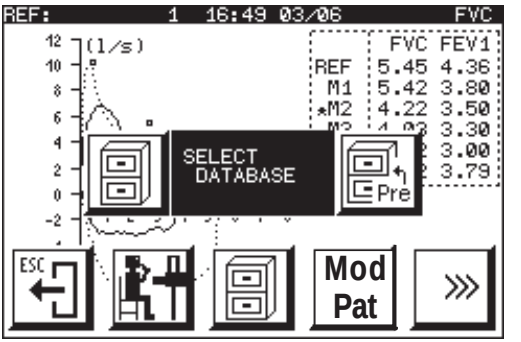
SAVING FVC TESTS

Saving a test in the Internal Database

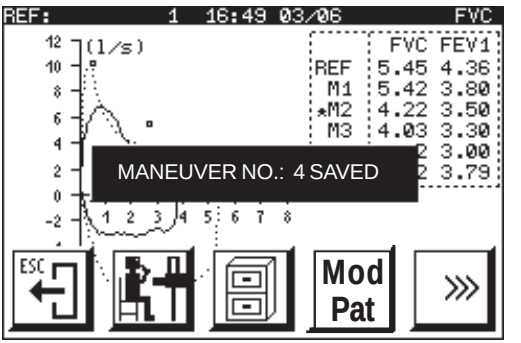
The **ASTRA300** spirometer has an **Internal Database** that can save different tests which can subsequently be transferred to a PC Database.

The maneuver selected by default is the best (M1). If you want to save another, it must first be selected. Once the maneuver to be saved on the database has been selected, on the test screen press the key.

The following screen will appear:



Press the key. The following message will appear, indicating that the maneuver has been saved:



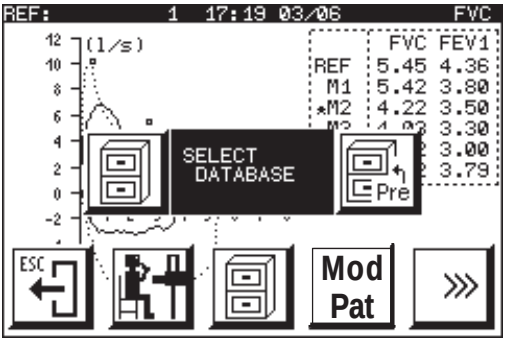
Saving a test to compare in POST bronchodilator mode

This option allows a test to be saved in PRE bronchodilator mode to then compare with a test in POST bronchodilator mode.

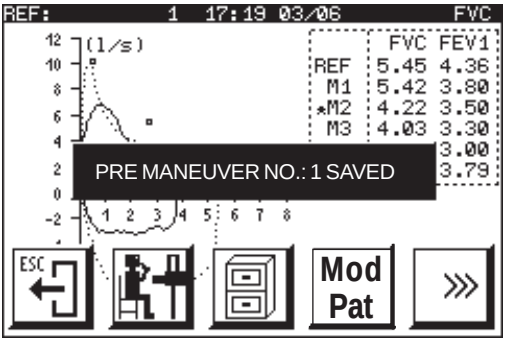
The process is similar to that described above:

Once the maneuver to be saved on the database has been selected, press the key on the test screen.

The following screen will appear:



Press the key . The following message will appear, indicating that the maneuver has been saved to the Pre-Drug database



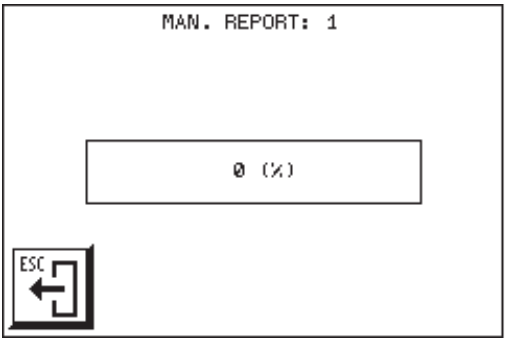
PRINTING THE FVC

The **ASTRA300** spirometer can print any maneuver on an external HP PCL 6 compatible printer.

The maneuver selected by default is the best (M1). If you want to produce a report on another, it must first be selected.

Check that the printer is ready and connected. Select the maneuver to be printed (flashing) from the test screen and press  . **The best (M1) is recommended.**

The following screen will then indicate printing in progress.



The printer will present a report similar to the one shown on the next page. This will include the parameters and graphs corresponding to the selected curve.
If you do not want graphs, certain parameters, the diagnosis and/or ATS/ERS warnings to appear, disable them as described in section 3.2.

If you want a global printout of the report, including the FVC, VC and MVV tests made on a patient, follow the steps described in the General Report Printout section.

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ASTRA SPIROMETER SDI DIAGNOSTICS
10 HAMPDEN DRIVE EASTON MA 02375

PULMONARY FUNCTION TEST **ASTRA 300**

Code:	5493			**Date:** 08/16/2007	**Time:** 11:03
Name:	JONES			CARL	
Sex:	Male	**Age(y):**	52	**Height(in):** 73	**Wt.(lb):** 209
Temp(°F):	79	**BP(mmHg):**	760	**Humidity(%):** 60	**Smok. I.:** 0
Predicted :	NHANES III			**Race:** CAUCASIAN	
Technician:	FENTON			**Transducer:** Turbine	
Prog Ver.:	511A5S-1.13				

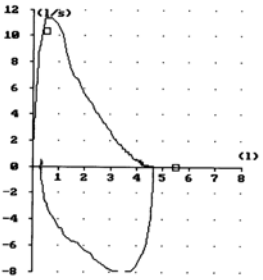
FVC REPORT **MANEUVER No.: 1/3**

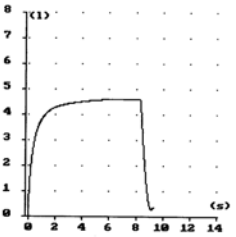
PARAMETER		**BEST**	**PRED**	**(%)**
Best FVC	(l)	**4.63**	**5.49**	**84**
Best FEV1	(l)	**3.79**	**4.24**	**89**
FVC	(l)	4.63	5.49	84
FEV1	(l)	3.79	4.24	89
FEV1/FVC	(%)	81.85	77.32	106
PEF	(l/s)	11.04	10.38	106
FEV6	(l)	4.60	5.29	87
FEV1/FEV6	(%)	82.34	80.15	103
QC Grade		B		

REPEATABILITY: FVC:Yes, FEV1:Yes

ATS INTERPRETATION
Normal

Comments: .....
.....





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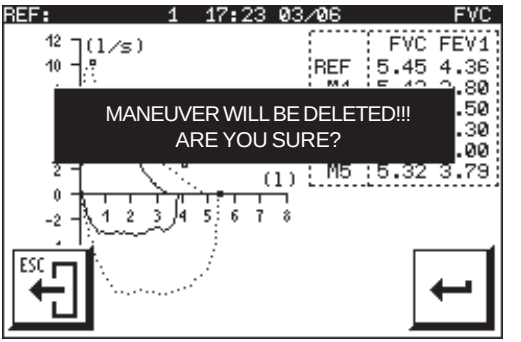
DELETING AN EXISTING MANEUVER

With the **ASTRA 300** spirometer, you may delete any maneuver, whether it is because you question the data value due to questionable patient effort or for any other reason.

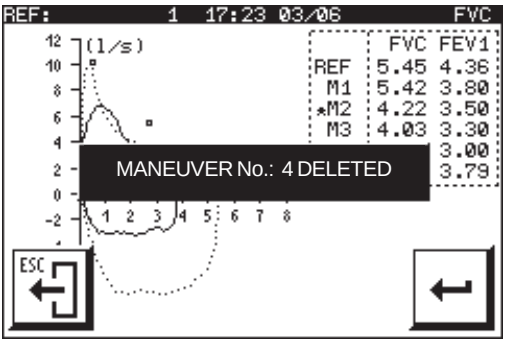
The maneuver selected by default is the best (M1). If you want to delete another, it must first be selected.

Select the maneuver to be deleted (flashing) from the test screen and press Del. The following message will appear:



Press the ↵ key to delete the maneuver. Then

the following message will appear to indicate that the maneuver has been deleted.



OTHER TESTS ON THE SAME PATIENT

You can do the following after carrying out the FVC test on a patient:

- A **VC** test on the same patient
- An **MVV** test on the same patient
- A **Post bronchodilator** test on the same patient
- Print the **general report** of all tests on the same patient
- Enter data for **a new patient**.

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

CHANGE PATIENT DATA/ENTER NEW PATIENT

This option is used to change some details of an existing patient or to enter a new patient.

Press the Mod Pat key on the test screen to access the patient's details screen.

Follow the procedure described in the **ENTERING PATIENT PARAMETERS** procedure to enter the details of a new patient or to modify the details of an existing patient.

NOTE:
When details of an existing patient have been modified (age, height,sex), the patient's parameters will be recalculated accordingly.

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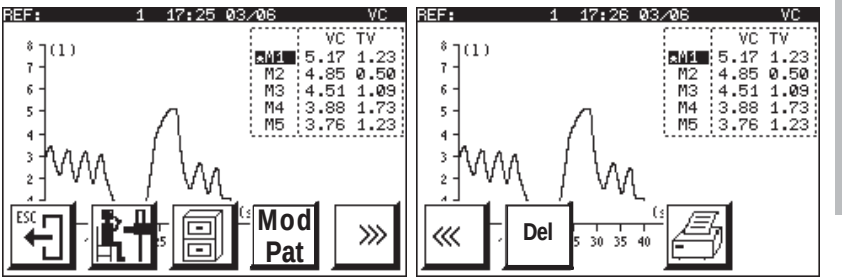
2.6 SLOW VITAL CAPACITY «VC» TEST PROCEDURE

The procedure to carry out the Slow Vital Capacity «VC» test is similar to that described in section 3.4 FORCED VITAL CAPACITY «FVC» PROCEDURE with the following variations:

1 Access the «VC» test by pressing the key VC from the main screen and perform a maneuver.



2 The axes are always displayed in VOLUME/TIME mode.

3 Instruct the patient as to how to perform the test, as the cooperation is vital to provide meaningful data.

4 The maximum time allowed for the maneuver is **45 seconds**. The spirometer saves a maximum of five maneuvers, ordered according to the VC value, where M1 is the best VC and M5 the worst.

5 To measure the ERV and TV parameters correctly, each maneuver must have at least four tidal breaths.

6 The reporting of parameters and graphs is as shown below:

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ASTRA SPIROMETER SDI DIAGNOSTICS
10 HAMPDEN DRIVE EASTON MA 02375

PULMONARY FUNCTION TEST **ASTRA 300**

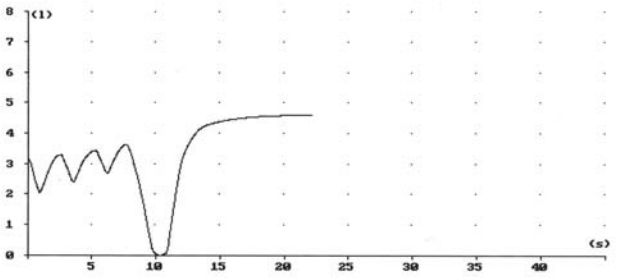
Code:	5493		Date: 00/00/2000	Time:	00:00
Name:	JONES		CARL		
Sex:	Fem.	Age(y): 52	Height(in): 73	Wt.(lb):	209
Temp(°F):	77	BP(mmHg): 760	Humidity(%): 60	Smok. I.:	0
Predicted :	NHANES III		Race: CAUCASIAN		
Technician:	FENTON		Transducer: Turbine		
Prog Ver.:	511A5S-1.13				

VC REPORT **MANEUVER No.: 1/1**

PARAMETER		BEST	PRED	(%)
VC	(1)	4.60		
TV	(1)	1.07		
ERV	(1)	1.13		
IC	(1)	3.47		

Comments: .....

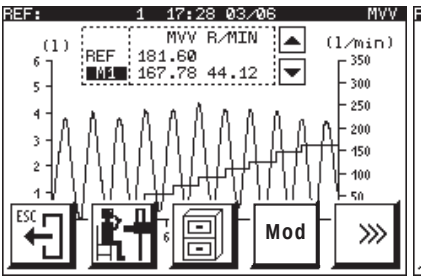
.....

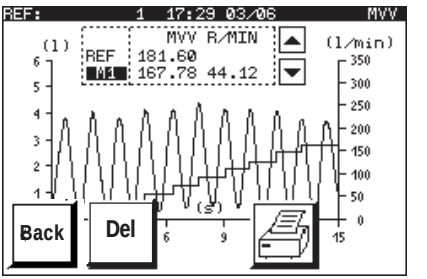


2.7 MAXIMUM VOLUNTARY VENTILATION «MVV TEST PROCEDURE

The procedure to carry out the Maximum Voluntary Ventilation «MVV» test is similar to that described in section 3.4 FORCED VITAL CAPACITY «FVC» PROCEDURE with the following variations:

1 Access the «MVV» test by pressing the key MVV from the main screen and perform a maneuver.





2 The axes are displayed in VOLUME/TIME mode.

3 Instruct the patient as to how to perform the test, as patient cooperation is vital for it to be completed correctly and provide meaningful results..

4 The maximum time allowed for the maneuver is **15 seconds**. The equipment saves a maximum of three maneuvers, ordered according to the MVV value, where M1 is the best MVV and M3 the worst.

sdi

ASTRA SPIROMETER SDI DIAGNOSTICS
10 HAMPDEN DRIVE EASTON MA 02375

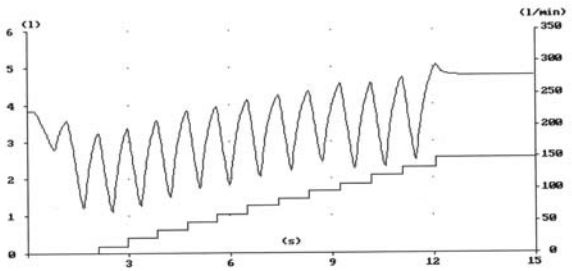
PULMONARY FUNCTION TEST **ASTRA 300**

Code:	5493			Date: 00/00/2000	Time: 00:00
Name:	JONES			CARL	
Sex:	Fem.	Age(y):	52	Height(in): 73	Wt.(lb): 209
Temp(°F):	77	BP(mmHg):	760	Humidity(%): 60	Smok. I.: 0
Predicted :	NHANES III			Race: CAUCASIAN	
Technician:	FENTON			Transducer: Turbine	
Prog Ver.:	511A5S-1.13				

MVV REPORT **MANEUVER No.: 1/1**

PARAMETER	BEST	PRED	(%)
MVV (l/min)	136.59		
Br / min	66.06		

Comments: .....
.....



2.8 POST BRONCHODILATOR SPIROMETRY PROCEDURE

The **ASTRA 300** spirometer allows for spirometry tests to be performed after the administration of a bronchodilator drug. These tests may be done in in FVC, VC or MVV modes provided a test has previously been completed in PRE bronchodilator mode and saved to the PRE database.

The procedure to carry out POST-Bronchodilator spirometry is as follows:

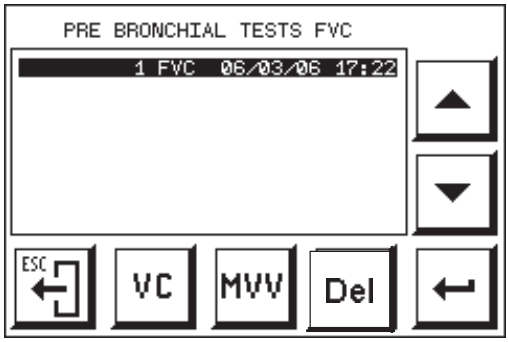
1 Complete an FVC, VC or MVV test with the patient as described in the previous sections before administration of the bronchodilating drug.

2 Save the PRE test in the database for comparison to the POST-Drug test, as explained in SAVING FVC TESTS in section 3.4.

3 Administer the dose of the bronchodilator drug prescribed and wait for the standardized period.

4 On the main screen, press the key 

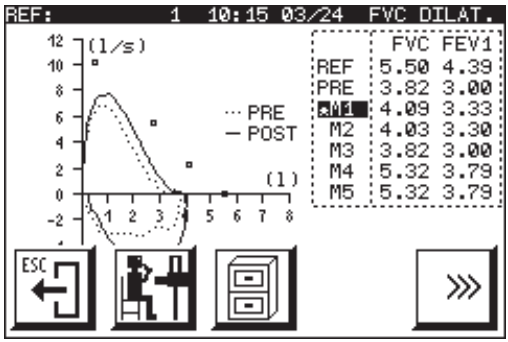
A screen similar to the following will appear, which displays the tests saved in PRE mode.



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

5 Select the PRE test with which it is to be compared and press ↵

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



POST

6 Then continue as described in section 3.4 FVC TEST PROCEDURE.

- The curve in POST bronchodilator mode is compared with the curve saved in PRE bronchodilator mode.

- 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 customization. See section 2.2 EQUIPMENT CUSTOMIZATION.

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

- The most common method of comparison is the **Weighted %**, which corresponds to **%WEIGHT = 100x2(POST-PRE)/(POST+PRE)**.

(See J.E. Cotes: Lung Function Assessment and Aplication in Medicine. Blackwell Sci. 4th Edition 1979, p52-53)

The registering of parameters and graphs is as shown following:

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10 HAMPDEN DRIVE EASTON MA 02375

PULMONARY FUNCTION TEST **ASTRA 300**

Code:	5493		**Date:** 08/16/2007	**Time:**	11:03
Name:	JONES		CARL		
Sex:	Male	**Age(y):** 52	**Height(in):** 73	**Wt.(lb):**	209
Temp(°F):	79	**BP(mmHg):** 760	**Humidity(%):** 60	**Smok. I.:**	0
Predicted :	NHANES III		**Race:** CAUCASIAN		
Technician:	FENTON		**Transducer:** Turbine		
Prog Ver.:	511A5S-1.13				

FVC REPORT **MANEUVER No.: 1/1**

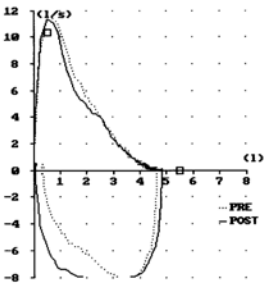
PARAMETER		**PRE**	**PRED**	**(%)**	**POST**	**%Ch**
Best FVC	(l)	4.63	5.49	84	4.83	4
Best FEV1	(l)	3.79	4.24	89	3.72	-2
FVC	(l)	4.63	5.49	84	4.83	4
FEV1	(l)	3.79	4.24	89	3.72	-2
FEV1/FVC	(%)	81.85	77.32	106	77.11	-6
PEF	(l/s)	11.04	10.38	106	10.84	-2
FEV6	(l)	4.60	5.29	87	4.73	3
FEV1/FEV6	(%)	82.34	80.15	103	78.83	-4
QC Grade		B				

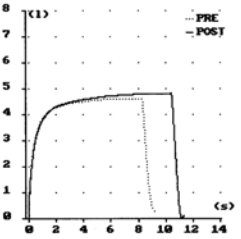
REPEATABILITY: FVC: No, FEV1: No

ATS INTERPRETATION
Normal
Post-BD: Not significant response

Comments: .....

.....





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2.9 OCCUPATIONAL HEALTH (OHM) MODULE (if equipped)

The Astra 300 Occupational Health settings will afford the user compliance with the standards for spirometry testing of National Institute for Occupational Safety and Health as outlined in the U.S Department of Labor Standard 1910.1043 (Pulmonary Function Standards for the Cotton Dust Standard) and follow the guidelines of the Social Security Administration Disability Testing (SSA Pub No. 64-055) requirements.

To configure the Astra 300 for OHM operation:

1. Turn on the spirometer

2. From the Main Menu. press [Setup]. this will bring you the SETUP UTILITIES menu. Press [Setup] again to bring you to the CUSTOMIZATION menu.

3. Press [DB] and ensure that “Save 3 Maneuvers” is checked. If not, tap on the small box to initiate the save function. Press the [Enter] button to save the action and return you the CUSTOMIZATION screen.

4. Press [lungs] to bring you to the SPIROMETRY CUSTOMIZATION menu. In this menu, press the [graphs] button to bring you to the GRAPH STATUS menu. Be sure that the following are checked:

   - F/V Report
   - V/T Report
   - Print large curves
   - Print curves 3 PRE
   - Print Data 3 PRE

If not, use the [Up] or [Down] keys to highlight the selection, then press [Check] . After ensuring that the proper items have been checked off, press [Enter] to save the action and return to the previous menus.

CALIBRATION CHECK

1 Set up the spirometer and the syringe as in the Calibration instructions

2 Power up the **Astra 300** using the (On) button and at the Startup menu, press (Setup) to bring you to the SETUP UTILITIES menu: Press the (CAL) button

3 As in the Calibration routine, if the syringe volume is correct (3 Liters is the default) and the number of pulses is the same as that engraved on the side of the turbine, press (Enter). In the Calibration measuring screen, press (CAL CHECK) .

4 Push to empty the syringe then pull out the plunger fully. do this maneuver two more cycles If the Astra 300 is in precise calibration, you will get the message:

CAL PASSED!
MEAN F.(l/s) = XX

If an error message appears because the flow is either too high or too low, press (CAL CHECK) again and make a correction in flow by either pushing the plunger slower or faster.

In rare cases, the spirometer will alert you to do a full calibration of the instrument. To do a full calibration, see page 61.

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2.10 CALIBRATION PROCEDURE

GENERAL OBSERVATIONS

Since turbine flowmeters are mechanical devices typically not affected by temperature, pressure or humidity,the standards in force regarding spirometry recommend that all spirometers be periodically checked for calibration. This is due to alterations which may modify the characteristics of the electronic circuits and mechanical elements over time and cause a change in the spirometer calibration factors. Hence, a calibration system has been incorporated based on a reference volume signal (e.g. a syringe).

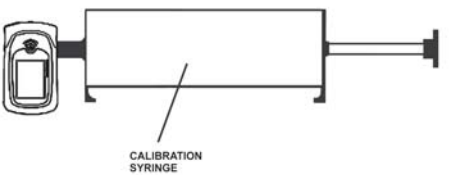
The **Astra 300** includes a Calibration Program for fast (less than one minute) and easy checking and auto-correcting of deviations in the measurements taken based on a standard or reference volume for the quality control of the different spirometric tests.

The regularity of calibration checks depend on the user, although the standards recommend it be done on a daily or weekly basis.

CALIBRATION PROCESS

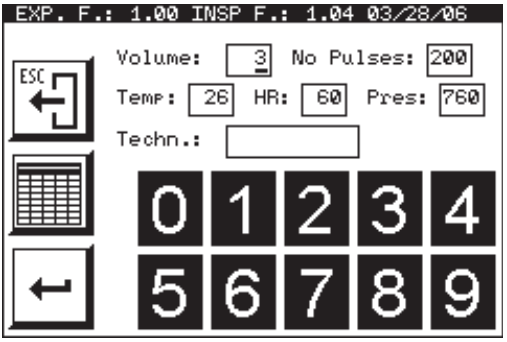
The calibration process is as follows:

1 Connect the spirometer to the syringe as in the following figure



2 Press Setup to access the Setup Utilities screen

2 From the Setup Utilities screen press the CAL key
The following screen will appear:



If there are previous calibrations, the details of the last one will appear in the title.

Enter the necessary data:

Volume: between 0 and 6 liters, depending on the syringe volume.
If a 0 is entered, the default factors are used (Fct = 1 and NPulses = 200) and the calibration process is completed.

No. of Pulses: this number, engraved on the turbine corresponds to the number of pulses/rotation. If the number of pulses associated to its turbine is as appears on screen, continue without modifying it.

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If it is different, enter the number of turbine pulses. In this case, the factors will be recalculated and the calibration process completed.

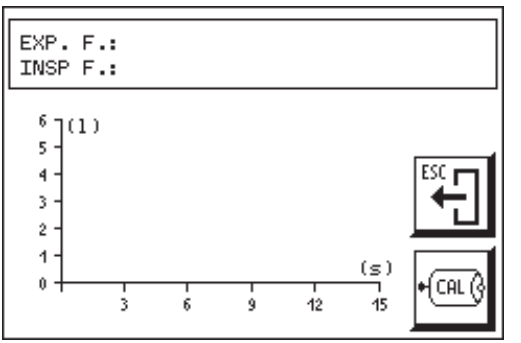
NOTE:
Each turbine is factory calibrated individually and is associated with a factor equivalent to the pulses/ liter detected which is engraved on the turbine body. Although variability between turbines is within ±3%, it is worth entering this factor in the spirometer if the turbine is changed to obtain the maximum measurement precision.

Temp (ambient temperature in ºF): detected by a sensor inside the equipment. This can be modified if required.

HR (relative humidity in %): entered in the last calibration. This can be modified if required.

Pres (atmospheric pressure in mmHg):entered in the last calibration. This can be modified if required.

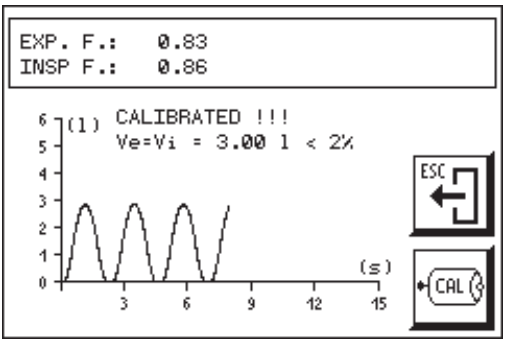
3Press ↵. If a Volume other than 0 has been entered and the No. of Pulses has not been modified, the following screen will appear:



4 Press  and start the calibration process.

Empty the syringe for two or more consecutive cycles (one cycle is equal to emptying and refilling the syringe). When emptying and filling, the syringe plunger must move all the volume used as a reference. If this is not done correctly, the equipment will detect it as «incorrect maneuvers». Furthermore, this process should be completed in a regular and uniform manner, without causing flow rates that are too high or too low. Where this is not the case, you will be told to repeat the maneuver. The time for each cycle must be no less than three seconds and no more than six.

5 The screen shows the expiratory and inspiratory factors taken by the equipment and, if they are within 2%, will consider the system calibrated. Where this is not the case, point **4** is repeated.



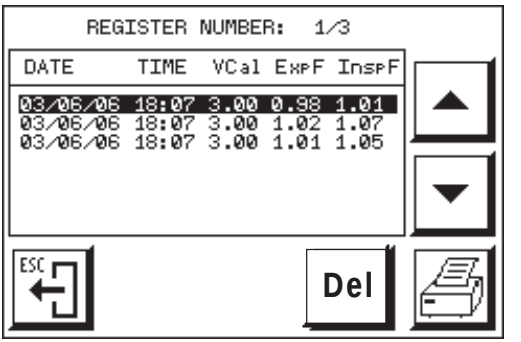
6 Once calibrated, exit the Calibration Program and access the Spirometry program to begin the tests.

Note:
If, upon entering the calibration parameters in point 2, "Calibration Volume (l): 0" is allocated, the system takes the calibration factors "EXP F. and INS F.:1.00", corresponding to original factory calibration. This calibration should only be used as a guideline and in the event of a syringe not being available.

CALIBRATION REGISTERING

The spirometer has a register containing the expiratory and inspiratory factors of the last ten calibrations performed. This is extremely useful for centers requiring a quality control of the processes they use.

To do so, press  on the first calibration process screen. The following screen will appear:



 Deletes a register

 Prints existing registers

 and  Moves the different calibrations

The information shown is:

- Number of registers available
- Date of calibration
- Time of calibration
- Volume of calibration
- Expiratory factor
- Inspiratory factor

2.11 INTERNAL DATABASE

The **Astra 300** has an Internal Database as standard that saves the different tests made using the equipment and subsequently displays them, prints them and/or transfers them to a PC or other computerized system for storage or management.

The base information remains, even when the equipment is unplugged.

The tests that can be saved (using a six-second FVC as reference) are:

Database «H» >1100

The saving of the tests has already been described in the sections corresponding to each test.

The database always saves all the spirometric parameters of each of the different test modalities, FVC, VC, MVV or Bronchodilation, despite their not being selected in the Customization program.

Different functions are possible from the spirometer:

1 Search the database

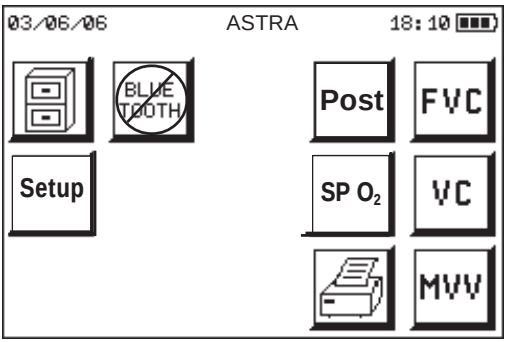
2 Search for a patient

3 Search for a register

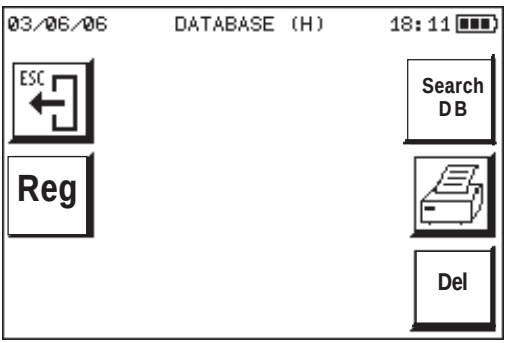
4 Print a summarized report

5 Delete the database

To do so, turn on the **ASTRA 300** using the key and wait for the following screen to appear:



Press to access the screen with the options to be chosen with the database.



Go back to the main screen

Search for register

Search the database.

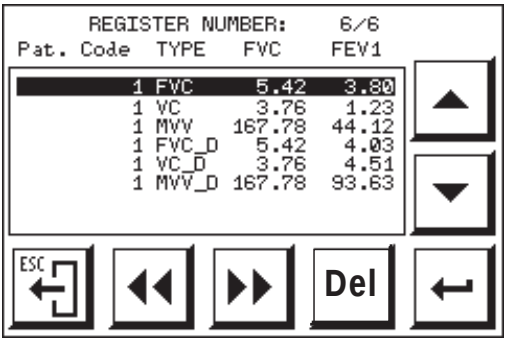

Summarized report

Delete the database.

DATABASE SEARCH

Select 

option to display the tests saved on the database



Go back to the previous screen

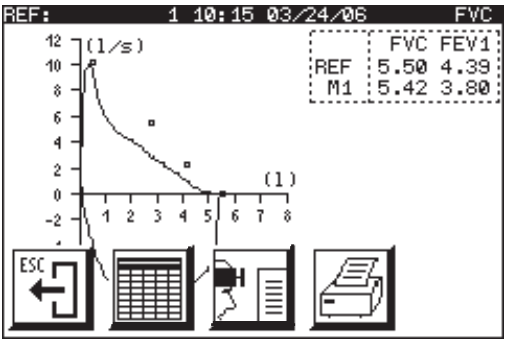
 and  Fast back/forwards through the registers. The movement value is configured in the Customization menu.

 Deletes the test selected

 Displays the test selected

 and  Moves around the different tests

Select a test and press  . The following screen is accessed:



 Go back to the previous screen

 Display test data

 Display the test interpretation

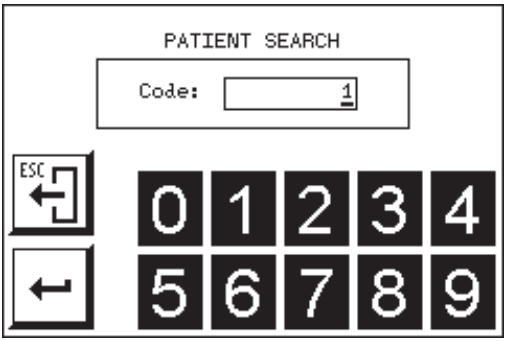
 Print the test

• Pressing the axes changes the type of graph (Flow/Volume or Volume/Time).

• Pressing the graph area makes the buttons disappear and makes the graph larger or smaller.

PATIENT SEARCH

Select the option Reg to search for a patient in the database. The following screen will appear:



Enter the patient code and press ↵ .

If the patient exists, the database search screen will appear. Where this is not the case, the following warning message will appear:
«PATIENT CODE NOT FOUND».

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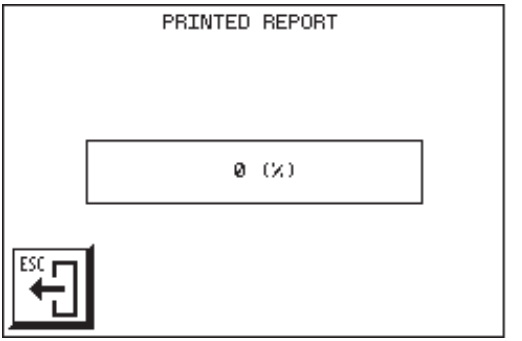
SUMMARIZED REPORT

Select the option  to print a report with the list of tests saved on the database.

The following screen will appear, indicating printing in progress:



DELETE DATABASE

Select the option Del to delete the database.

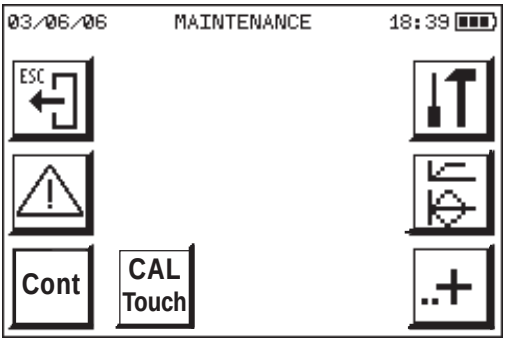
The following message will appear:

Press ↵ to accept and delete the database or press ESC to go back to the previous screen without deleting it.

2.12 MAINTENANCE PROGRAM

The equipment has a maintenance program. The Astra 300 is designed to provide a new level of sophistication in spirometry testing, giving you a wealth of choices in how to configure your spirometer to meet your needs. Choose the comprehensive pre-set program or custom design your own program from a number of selections for testing, interpreting or reporting .
To adjust and/or check the working order of certain options.

From the **Main Menu** screen, press, Setup then 



 Enables the calibration and/or maintenance warnings

 Adjusts the screen contrast

 Recalibrate Screen

 Check equipment

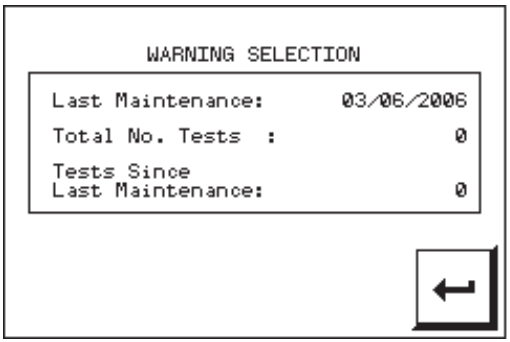
 Checks with pre-saved standard curves

 Equipment configuration

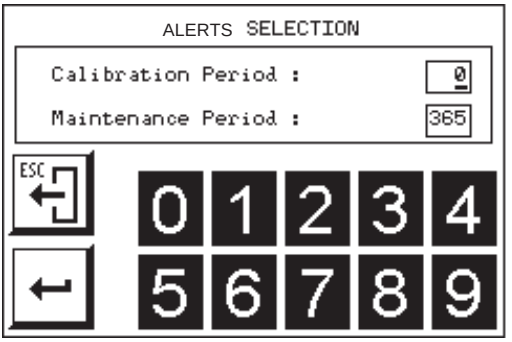
WARNINGS

Select the option  .

The following screen will appear with the information on the latest maintenance work, the tests performed and the tests performed since the last maintenance work.



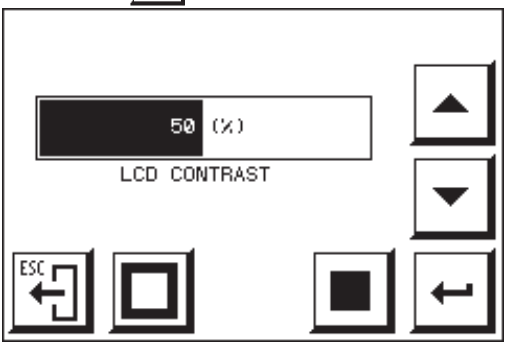
Press  .



This screen defines the periods in days between calibrations or between preventive maintenance work on the equipment.
If the days specified without calibration or maintenance 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.

LCD CONTRAST

Select the option Cont to configure the screen contrast.



Go back to the previous screen

Black background/white content

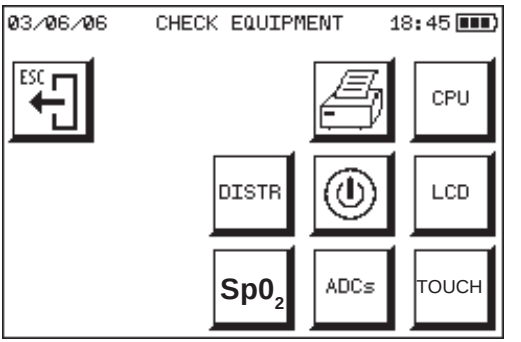
White background/black content

Validate choice

and Increase/decrease contrast

EQUIPMENT CHECK

Select the option to check different parts of the equipment.



Go back to the previous screen

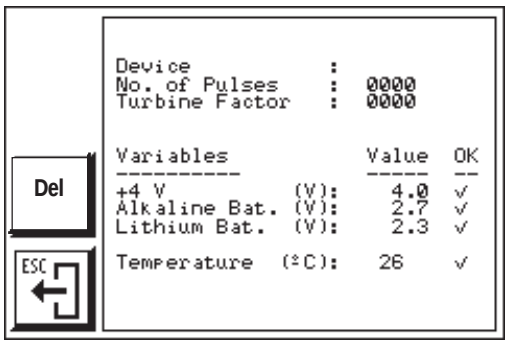
Distributor details

Pulse oximetry module

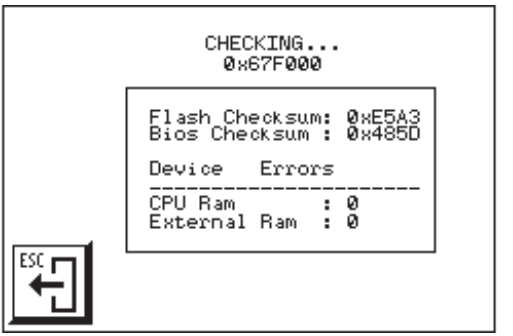
Check the external printer selected. The SDI logo, heading lines and 10 lines of characters will be printed.

Check that the automatic on and off work properly. Upon selecting this option, the equipment switches off and on automatically after 5 seconds.

Display the values of different variables (No. pulses, Turbine Fct, Alk. B., Li. B., etc.). This indicates whether the read value is correct.



CPU check. This calculates the Flash program checksum and the Bios program checksum. It also indicates whether there are errors in the RAM memory of the CPU and in the external RAM.

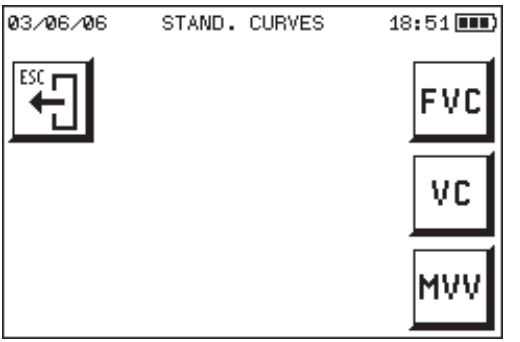


LCD — Performs a test on the LCD. Follow the instructions given on the screen.

Touch — Touch Screen

STANDARD CURVES

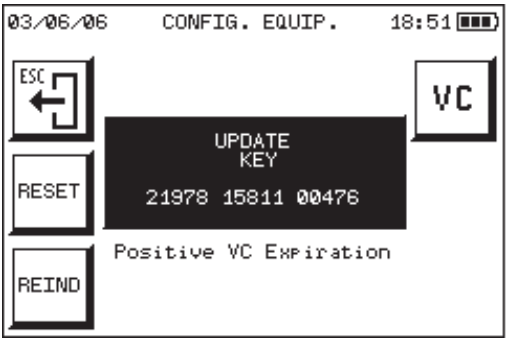
Select the option to check the working order of the equipment through certain pre-saved curves.



Select the curve type and follow the instructions on the screen, which are similar to the FVC, VC and MVV procedures. With these curves you can operate the equipment as if they were real patient curves, with slight exceptions.

EQUIPMENT CONFIGURATION

Select the option ..+ to configure different options for the equipment.



ESC — Go back to the previous screen

RESET — Reset all equipment variables.

REIND — Reindex the database.

VC — Change from positive VC to negative VC and vice versa

• An **updating key** is also displayed, which is necessary for updating the firmware.

WARNING
This option should be carried out by a qualified technician!

3. COMMUNICATIONS SYSTEM

One of the strengths of the ASTRA300 spirometer is its Communications System, which allows the user to:

Transfer patient tests to a PC
Export patient tests to other Management Systems

Communications can be made using three different inputs when using the corresponding software:

- RS232C Series (standard)
- USB (standard)
- Bluetooth (optional)

3.1 PATIENT TEST MANAGEMENT IN 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 on p. 81.

3 Load the Database data from the PC using the W-20 Software **BATCH** option.

4 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 Configuration option.

5 From then on, you can select, view or print any of the tests imported or transferred to the PC.

3.2 EXPORTING TESTS TO OTHER SYSTEMS

The **Astra 300** 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:

TESTS.TXT Contains the database tests
GRAPHICS.TXT 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 must be taken into account:

The flow signal with the turbine-type transducer is sampled at 50Hz.

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 **SDI Technical Support**, who will provide any further information you may require.

3.3 INSTALLING ASTRAPRO™ SPIROMETRY SOFTWARE FOR PC

For USB compatible spirometers, a driver must be installed on the computer. These instructions are for use with PC and software only. Not needed for direct print.

To install the Software and Driver, follow these steps:

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

2 Insert installation CD and Run D:\Setup.exe (or appropriate cd drive) and follow prompts for cd installation.

3 Open software and connect spirometer to PC with the USB cable. As it is the first time that the equipment is connected to the computer, the Windows **<<New Hardware Detected>>** screen will appear, with the name of the equipment that you have connected. Select **<<Next>>**

4 A screen will appear that allows you to select between two options:

First: Find best controller for your device
Second: Show a list of all controllers in a location

Select the **Second** and click on **<<Next>>**

5 Now a screen will appear which allows you to select between Show All Hardware or Show Compatible Hardware. Select **<<Show All Hardware>>** and click the **<<Use Disk>>** button.

6 If your operating system is Windows 98, select the file D13TEST in the directory D:\W98 of the spirometry CD. For other operating systems such as Windows 2000, Windows XP (software is not compatible with Vista), select the file "sibelusb" of the directory D:\W2k_WXP. Press **<<OK>>** (Windows XP may find this file automatically).

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

8 Under **Setup** from the main menu, Select **<<Links>>**

Transducer: Spirometer
Equipment: DMicro\Astra
Channel: Serial Channel
Serial Port: COM1
Then click √

Your spirometer is now ready to use.

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4. TECHNICAL SPECIFICATIONS

The specifications given below are applicable in each case, depending on the model available, as indicated in detail in Section **1.3 SPIROMETER MODELS**.

4.1 TYPES OF TEST, FUNCTIONS AND PARAMETERS

FORCED VITAL CAPACITY FVC

Parameters:

• FVC	(l)	Forced Vital Capacity
• FEV.5	(l)	Forced Expiratory Volume in .5 seconds
• 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

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- MIF50% (l/s) Maximum Inspiratory flow with 50% of FVC inspired
- FIVC (l) Forced Inspiratory Vital Capacity
- FIV1 (l) Forced Inspirometry 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 rate Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. Indicates the risk of EPOC.
- Lung Age Parameter that depends on the height and FEV1. Indicates the equivalent age of the lung.

Interpretation based on:

- ATS

Percentage deviation in relation to values of reference

Standardized values of predicteds that can be selected from several standards

Patient's ID details

Atmospheric data on temperature, pressure and relative humidity

Graphs in FLOW / VOLUME and VOLUME / TIME

Quality alerts to assure compliance with ATS / ERS criteria

Saving of five maneuvers from the same study

Acoustic and graphic indication of the start and end of each maneuver

SLOW VITAL CAPACITY

Parameters:

•	VC	(l)	Slow vital capacity
•	TV	(l)	Tidal volume
•	ERV	(l)	Expiratory Residual Volume
•	IRV	(l)	Inspiratory Residual Volume
•	IC	(l)	Inspiratory Capacity
•	Ti	(s)	Inspiratory time
•	Te	(s)	Expiratory time
•	Tt	(s)	Total time
•	Ti/Tt	(-)	Ratio

Percentage deviation in relation to reference values

Standardized predicted values that can be selected from several authors

Patient's ID details

Temperature, pressure and relative humidity details

Graphs in VOLUME / TIME mode

Saving of five maneuvers from the same study

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MAXIMUM VOLUNTARY VENTILATION

Parameters:

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

Percentage deviation relative to predicted values

Standardized predicted values that can be selected from several authors

Patient's ID details

Temperature, pressure and relative humidity details

Graphs in VOLUME/TIME mode

Saving of five maneuvers from the same study

POST 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

CALIBRATION

Calibration program for dynamic tests with syringe of 1 to 6 liters in volume.

Registry of the latest calibrations

Where required, calibration warning

Customization of the language, printer and report heading, etc.

Spirometry customization
Parameters of reference
Observed parameters
Graph selection
Interpretation selection
Report customization

INTERNAL DATABASE

Saving of spirometric and pulse oximetry tests.

Two types of databases based on storage capacity

CLOCK-CALENDAR

Hour-Minute-Second

Month-Day-Year

4.2 MEASURING SYSTEM

TYPE OF TRANSDUCER

Turbine-type transducer with axial-type two-way volumetrics, with opto-electronic rotary sensor that is detachable for cleaning and sterilization. Rotation is made on sapphire bearings for high reproducibility and duration.

RANGES AND MEASUREMENTS

Turbine

- Measurement Scale (BTPS)
  - Flow (l/s) 0 to ± 16
  - Volume (l) 0 to 10
- Dynamic flow resistance
  - kPa/l/s < 0.122 to 14 l/s
- Precision of measurements (BTPS)
  - Volume (the highest) 3% or 50 ml
  - Flow (the highest) 5% or 150 ml/s
  - Time-related precision 0.5%
- Resolution in volume (ml) < 6
- Sampling frequency (Hz) 25
- Turbine lifetime 600 disinfections or 3 years

SpO_2 and Pulse

	SpO_2 (%)	Pulse (BPM)
Measurement Range	0-100	0-250
Resolution	1	1
Precision 70 to 100	+/- 2	+/- 1 or 3% (the highest)
< 70		Not specified

4.3 MICRO CONTROLLER

System micro controller:

- Hitachi H8S2144

Volume accumulation time:

- Five FVC curves with a maximum of 25 seconds each
- Five VC curves with a maximum of 45 seconds each
- Five MVV curves with a maximum of 15 seconds each

Start FVC expiration:

- Using the back extrapolation method

End FVC expiration:

- When the volume accumulated in the last second is below 0.025 litres

FVC test selection:

- Based highest value of FVC or on operator decision

Parameter selection:

- FVC and FEV1, the two with the highest value of the tests saved. Remaining parameters of the selected test, with the highest sum being recommended.

Keypad:

- All instructions, data, etc. transmitted by the operator to the microprocessor involve a touch screen.

Communications channel:

- RS 232C
- USB 2.0
- Bluetooth 2.0
- Compatible with HP-PCL black and white or color printers.

4.4 PRESENTATION OF DATA

High resolution touch screen LCD (Liquid Crystal Display) with 240 x 160 pixel array

By external printer

By PC with the corresponding software

4.5 TEMPERATURE SENSOR

Internal temperature sensor from 23 to 50 ºC ± 1%

Relative humidity:

- Less than 75% (without condensation)

Barometric pressure:

- Between 430 and 800 mmHg (approx. 4500 to -400 meters altitude)

Temperature:
- Storage, between 32 and 94 °F
- Working, between 42 and 72 °F

Applicable standards:
- Spirometry (ATS/ERS, SEPAR)
- Safety (EN 60601.1, EN 60601.1.1)
- Electro-magnetic Compatibility (EN 60601.1.2). See Appendix 1
- Quality (EN 13485, ISO 9001:2000)
- Spirometers for peak expiratory flow (UNE EN 13826:2004)
- Bluetooth Module
  - Compliance with Standard 2.0
  - Class II
  - CE and FCC Certificate.

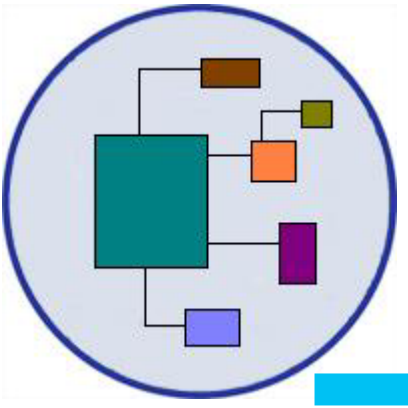
Power supply:
- 1.2 NiMh battery

Power:
- Below 400 mW

Size:
- 153.5 x 80 x 52 mm

Weight:
- 250 g

Equipment lifetime:
- 10 years



5. OPERATING PRINCIPLES

The **Astra 300** spirometer is an instrument that acquires mechanical signals and processes the information provided by the signal related to the pulmonary function. For processing purposes, mechanical must be changed to electrical. The devices responsible for this change are called transducers. The **ASTRA 300** has a Turbine-type transducer.

The turbine transducer performs transduction in two stages: The volume to be measured crosses the turbine vane and records its rotation that is proportional to that volume. This rotation is detected by the interrupting of a beam of infrared light, the sensor of which converts the light received into a digital-type electrical signal.

5.1 TURBINE

The turbine is axial with two stators in the form of a propeller and a rotor made up of a flat, rectangular blade. The shape of the stators means that the air flow passing turns, which makes the blade turn. The turbine operates based on the Fluid Mechanics theory and, more specifically, the Machine Turbo theory. Applied to this case, the angle at which the rotor turns is directly proportional to the fluid volume crossing the turbine and the proportionality constant depends on its shape.

5.2 TURBINE ROTATION SENSOR

The turbine rotation sensor consists of three pairs of emitting diodes and an infrared (invisible) photo-transistor that detect the rotation and direction of the blade. The number of times the beam is interrupted is equivalent to an accumulated angle of rotations and, therefore, the volume of air to have crossed the turbine. The photo-transistor provides a digital electrical signal that represents the times the beam of light is interrupted and is directly acquired by the microprocessor.

5.3 MICROPROCESSOR

PHYSICAL DESCRIPTION

The microprocessor section is made up of a series of electronic devices that save, manage, receive and send data. In general terms, it is divided into:

- Basic hardware control program (BIOS) residing in the internal Flash memory of the Micro controller (128 KBytes).

- Spirometry and equipment management program and test database residing in the 2 MByte FLASH memory.

- Non-volatile 512 KByte RAM to save the equipment configuration, status variables and calibration database.

- Central Processing Unit (CPU).

- Communications controller (RS232, USB and Bluetooth) with external sources.

- Clock - Calendar - Alarm.

PROGRAM

The control program has been developed in assembly code and top level C language to ensure very fast time control and a structured program. It is divided into two parts: the BIOS in internal Flash memory and the application in external Flash memory.

MEMORY

The storage capacity for temporary data, for the customized equipment configuration and for the calibration database is 512 KB in non-volatile RAM. The test database has a maximum capacity of 1 MByte.

CPU

This device manages and runs the process that is coded into the data that forms the program. The Renesas H8S2144 micro controller is used as a CPU.

CONTROLLERS

These are responsible for transferring data between the CPU and the other devices, i.e. the keypad, the screen and the printer. They form part of the integrated microcontroller circuit, except for the RS-232 series communications channel interface and the screen controller.

QUALITATIVE DESCRIPTION

The control program is responsible for ensuring the spirometry signals are handled in line with the applicable standards, particularly the calculation of:

- Identification of the start of expiration
The start of the test is determined by the filling of a maximum level of flow of approximately 100ml/s, although the immediately inferior values are not rejected.

- Retrograde extrapolation = Back extrapolation
The start of the FVC maneuver is established through back extrapolation according to A.T.S. criteria

- Identification of the end of inspiration
The end of the FVC maneuver is established according to A.T.S. criteria, i.e. when the volume accumulated in the last second is below 25ml.

- Calibration program

Any aging of or accumulated dirt in the turbine transducer may lead to imprecise measurements. To ensure the turbine measures correctly, the system includes a simple checking procedure based on measuring the known volume of a calibration syringe.

6. UPKEEP, PREVENTIVE AND CORRECTIVE MAINTENANCE

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Like any equipment, particularly if for medical applications, the **ASTRA 300** spirometer requires upkeep and maintenance to ensure the safety of patients, operators and the environment, and at ensuring the reliability and precision of the functions for which it has been developed. All this leads to a series of routines that must be completed.

6.1 UPKEEP

Upkeep is aimed at ensuring the correct working order of the equipment. The person undertaking it requires no special technical skills except knowledge of the functions and handling of the equipment. The equipment user normally performs this. The operations to be completed are as follows:

CLEANING THE TURBINE TRANSDUCER

ATTENTION: to avoid the risk of cross-contamination when using turbine with plain cardboard mouthpiece, the turbine must be cleaned after every use. Clean the turbine daily if using a one-way valve mouthpiece, and weekly cleaning is recommended if using a bacterial/viral filter. To do so, proceed as follows:

1 The turbine is removed from the equipment housing by pressing slightly so that is comes away from its fixtures.

2 Wash the turbine by soaking in a warm soap and water solution, avoiding solvents or abrasive substances that may damage the components. Given that its reliability depends on the condition of the turbine, examine it for external damage.

3 Rinse by soaking the turbine in clean water. **Do not rinse the turbine by holding itunder running water.**

4 You can then leave it to dry at room temperature.

5 Reassemble the turbine in the housing.

Top level disinfection:
If you suspect contamination, use one of the more complex antiseptic solutions. For example, replace Step **2** by submerging it in a glutaraldehyde solution (or similar) for 10 minutes (follow the manufacturer's instructions).

PRECAUTION
DO NOT EXPOSE THE TURBINE TO TEMPERATURES OF OVER 60°C OR BELOW 0°C. DO NOT USE SOLVENTS OR OTHER SIMILAR SUBSTANCES FOR CLEANING AS THEY MAY DAMAGE IT.

SPIROMETER

The spirometer is cleaned gently with a dry cloth or a cloth dampened slightly with soapy water. Pay special attention to ensure no liquid enters the inside or connectors and connections.
Do not use abrasive substances or solvents.

WARNING

6.2 PREVENTIVE MAINTENANCE

Preventive maintenance consists of any actions aimed at keeping the equipment in a good state of repair.

Four types of preventive maintenance are established:

1 Each time the spirometer is turned on, the equipment will check certain parts and/or functions.

2 A second procedure, which can be performed by the user, consists of the 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.

In the event of detecting any problem that the user cannot solve, contact the **SDI Diagnostics Repair Department or your distributor**.

3 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.

4 A fourth type consists of a general technical check of the safety systems, adjustments and functions, etc. forming the equipment.

THIS TECHNICAL CHECK SHOULD BE PERFORMED EVERY YEAR following **the ASTRA 300** Verification and Adjustment Procedure available from the manufacturer. This type of operation must be carried out by skilled technical staff from the hospital's maintenance department or from the distributor's or manufacturer's technical service.

SDI Diagnostics, Inc., 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.

7.0 LIMITED WARRANTY CONDITIONS

This SDI product together with its standard accessories is guaranteed for a period of ONE YEAR 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.

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
- High risk medication

See Inside Back Cover for CPT and ICD-9 Codes for Spirometry

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