

# *Astra* **TOUCH** Spirometer

## Bronchial Challenge Testing

### USER'S MANUAL

PN: 29-5474

Rev. 4.29.14





**SDI Diagnostics, Inc.**

10 Hampden Drive, Easton, MA 02375

Tel: 800-678-5782

e-mail: [sales@sdidiagnostics.com](mailto:sales@sdidiagnostics.com)

Fax: 508-230-2752, Website: [www.sdidiagnostics.com](http://www.sdidiagnostics.com)

**TABLE OF CONTENTS**

<b>1. INSTRUCTIONS FOR USE AND INSTALLATION ....</b>	<b>4</b>
<b>1.1. INTRODUCTION AND SAFETY</b>	
<b>1.2. DESCRIPTION OF THE TEST</b>	
<b>1.3. BRONCHOCONSTRICTION TEST CUSTOMIZATION</b>	
<b>1.4. BRONCHOCONSTRICTION TEST PROCEDURE</b>	
<b>2. TECHNICAL SPECIFICATIONS .....</b>	<b>22</b>

**Revised**  
**Date: 4/29/2014**

**Approved**  
**Date: 4/29/2014**

## 1. INSTRUCTIONS FOR USE AND INSTALLATION

### 1.1. INTRODUCTION AND SAFETY

The **Bronchoconstriction test module** is an option of the **AstraTOUCH** spirometer.

This manual is an addendum to the manual of the **AstraTOUCH** Spirometer, dedicated exclusively to the operation of this module, and it is designed for use alongside the general manual.

We suggest consulting reference data on the usual procedure required to perform correctly bronchoconstriction tests. See the European Respiratory Journal (Volume 6, Supplement 16, March 1993), among others.



The bronchoconstriction test must be performed by a physician or qualified clinician under his/her supervision.

### 1.2 TEST DESCRIPTION

The bronchoconstriction tests consist of performing a forced spirometric test, after the application of different pharmacological stimulus to the patient to evaluate the changes produced in the spirometric parameters, specifically the FEV<sub>1</sub> fall. It must be taken into account that each test has several forced spirometric maneuvers and the device selects the best one to include in the summary report according to the criteria in the different standards.

The **AstraTOUCH** spirometer has the capacity to perform the test according to two different methods:

- **Normal or continuous method:** Consists of administering to the patient a certain concentration of an allergen for a specified time.
- **Abbreviated/short method:** Consists of administering to the patient a certain number of inhalations of an allergen at specific concentrations.

The procedure in both cases is the same; what varies is how the drug is applied. In the first case, the patient is breathing a specific concentration of drug during a specific time via a nebulizer dosimeter and in the second case, inhalations are given to make the testing quicker to perform. The general test procedure is as follows:

### **1 BASAL (BAS)**

Perform a basal spirometry maneuver

### **2 DILUENT (DIL)**

Administer a pH neutral diluents to the patient, if convenient, and perform a spirometry maneuver and compare it to the basal.

### **3 CONSTRIC. (BC1)**

Administer an initial dose of allergen to the patient and after the stipulated time, perform a spirometry test. It is compared to the DILUENT (DIL), or to the BASAL (BAS) if the diluent dose has not been administered. Subsequent Bronchoconstriction tests may be done, allowing the patient to rest between each.

### **4 CONSTRIC. (BC2)**

Administer the second drug dose to the patient.

### **5 CONSTRIC. (BC3)**

Addminister the third drug dose to the patient.

The process can be repeated as needed. The system allows applying a maximum of 10 drug-doses (BC10).





**6** When the lung function parameters show a significant response, according to the criteria of the operator who oversees the test, the bronchoconstriction test can be terminated. The system analyzes and shows the value of PDx graphical and numerically.

## **7 CONST + DILAT**

Once the test is completed, a bronchodilator drug should be administered to reverse the Bronchoconstriction.

### **1.3. BRONCHOCONSTRICTION TEST CUSTOMIZATION**

It is recommended that clinicians customize the Bronchoconstriction module based on their needs.

From the main screen, enter to the CONFIGURATION MENU by pressing , then press  to access the CUSTOMIZATION MENU. Then, press  to access the Spirometry customization menu and choose Bronchoconstriction option by pressing  and the following screen will appear:

25°C 760mmHg 60% BRONCHO-CONSTRICTION SELECT. 12:47

Normal Mode	
Short Mode	✓
Use Diluent	✓



Time between Const. (min) 3 P.D. (%) 20

Time between Dilat. (min) 15 BC. drug METHACOLINE


Initial Dose (mg/ml) 0.50 BD. drug SALBUTAMOL


← →


- Select the method or operating mode
  - Normal
  - Short
- Select whether or not to use a diluent.
- Set the time between Bronchoconstriction drug application and the start of the maneuvers.
- Set the time between drug application and initiation of bronchodilator maneuvers.
- Enter the initial dose of bronchoconstrictor drug in mg/ml.
- Enter the bronchoconstrictor drug
- Enter the bronchodilator drug
- Select the Select the lower limit of the dose
- PDx

At the end, press  key to validate the data or  to go back or exit the test screen

## 1.4. BRONCHOCONSTRICTION TEST PROCEDURE

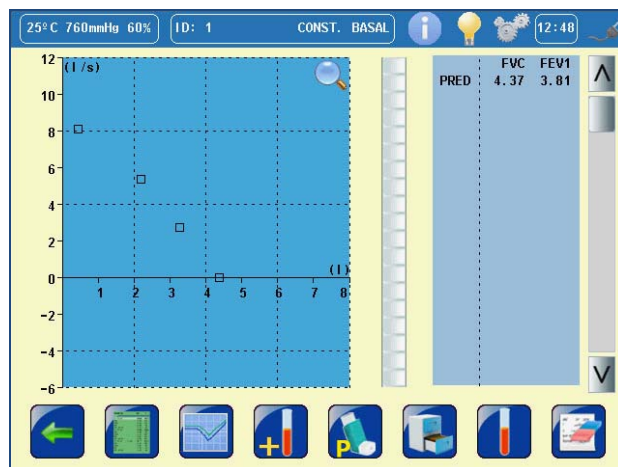
 To avoid risking patient breathing difficulty due to a bronchoconstrictor overdose, ensure that the spirometer is correctly calibrated or perform a new calibration before the test.

 The physician should supervise the patient's breathing during the test

Press  from the main menu, to enter into the **Bronchoconstriction** test mode.

Enter the patient's data. The procedure is the same as the one described in the section **5.2 ENTER PATIENT DATA** of the **AstraTOUCH** general user's manual.

The **Bronchoconstriction** customization screen will appear. See section **1.3. BRONCHOCONSTRICTION TEST CUSTOMIZATION**. Then, the following screen will appear:







Goes back or exits the test screen



Presents a summary with the data from the performed steps



Deletes the selected maneuver



Saves the best maneuver and sequences to the next step (**NORMAL** mode)



Saves the best maneuver and sequences to the next step (**SHORT** mode)



Presents the graphic dose/response graph of the performed steps



Viewing or changing the drug dose

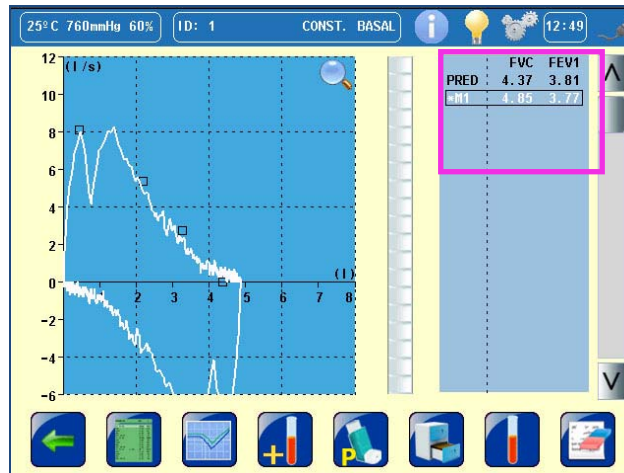


Stores the test summary in the internal database

The test procedure is as follows:

## 1 BASAL (BAS)

Start the process of forced maneuvers as described in section **FORCED VITAL CAPACITY "FVC" TEST** of the general user's manual.




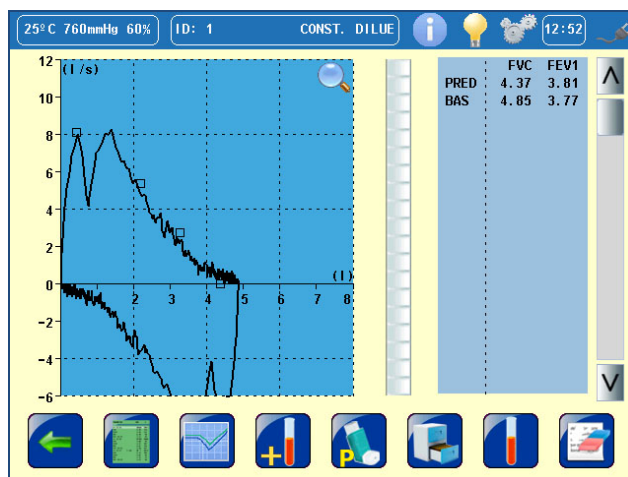
Maneuvers are ordered best to worst according to **ATS/ERS criteria**, M1 being the best.

Press the **Parameters** area and the data of all maneuvers performed will be displayed:

MAN. : 1/1	M1	M2	M3	REF	(%)
Best FVC (l)	4.85			4.37	111
Best FEV1 (l)	3.77			3.81	99
BFV1/BFVC (%)	77.71				
FVC (l)	4.85			4.37	111
FEV1 (l)	3.77			3.81	99
FEV1/FVC (%)	77.71			87.28	89
MAX PEF (l/s)	8.30				
PEFT (s)	0.15				
FEF50% (l/s)	3.75			5.38	70
FEF25-75% (l/s)	3.36			4.95	68
FEF50% / FIF50%	1.00				
FEV1/FEV0.5	1.31				

The maneuvers are compared with the predicted values of the patient.

Once the adequate maneuvers are performed, press  to save the best maneuver as BASAL and go to the next step.



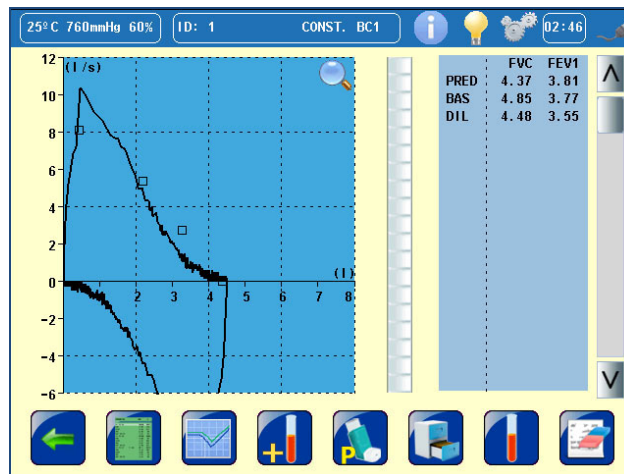
## 2 DILUENT (DIL)

Administer a neutral pH diluent to the patient, if you have selected this option. Start a new set of forced maneuvers, once the specified time has passed.

After carrying out the maneuvers, press the **Parameters** area to view the data of the maneuvers performed.

Press  to save the best maneuver performed and move to the next stage.

The performed maneuvers will be compared with the Basal.



Presents a summary with the data of the performed steps

### 3 CONSTRIC. (BC1)

Normal mode:

25°C 760mmHg 60% NEXT DOSE 12:50

Dose (mg/ml) 0.50

BC. drug METHACOLINE

7 8 9 ESC

4 5 6 BACK

1 2 3 ENT

← 0 . →

Short Mode:

25°C 760mmHg 60% NEXT DOSE 12:48

Inhalat. Num. 1

Dose / Inhalation (mg/ml) 0.50



BC. drug METHACOLINE

7 8 9 ESC

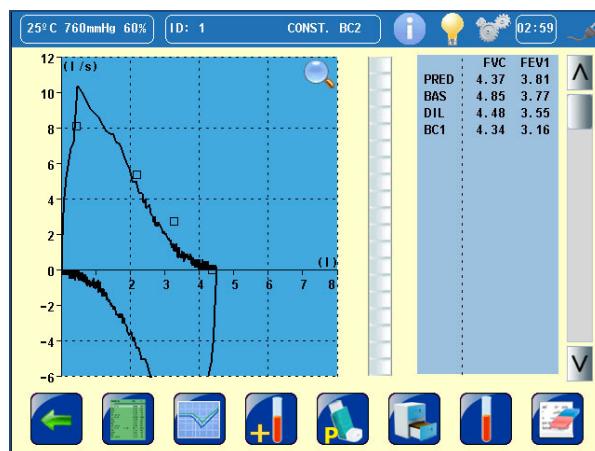
4 5 6 BACK

1 2 3 ENT

← 0 . →

Modify the data if necessary and press . Apply the first dose of bronchoconstrictor drug and start another series of maneuvers when the timer  reaches 00:00 and an audible alarm sounds.

Press  to save the best maneuver performed, and sequence to the next stage.



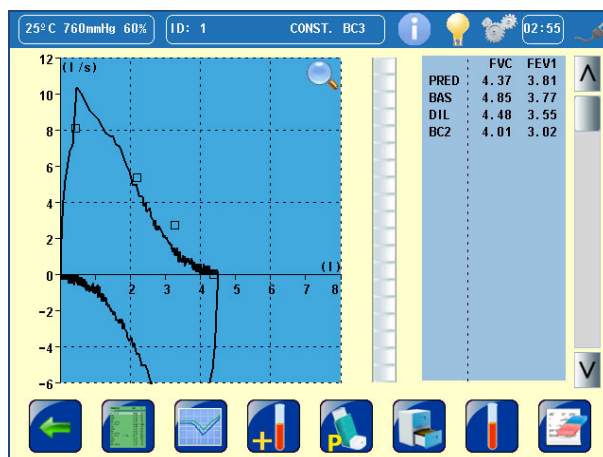
Presents the dose/response graph of the performed steps.



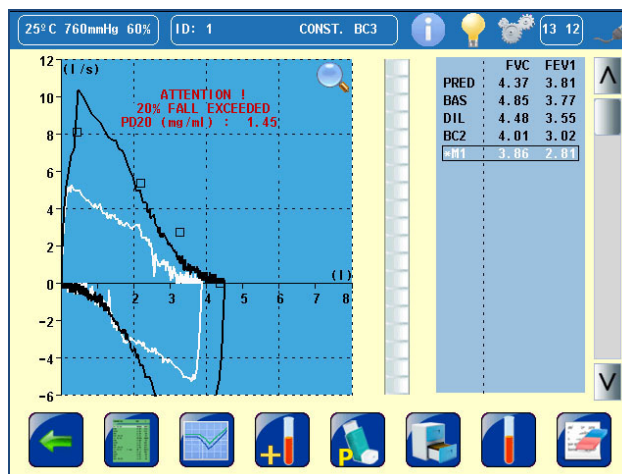
Allows you to view or change the dose of drug.

#### 4 CONSTRIC. (BC2, BC3, ... BC10)

Follow the same procedure as in the previous steps, for the subsequent drug-doses.



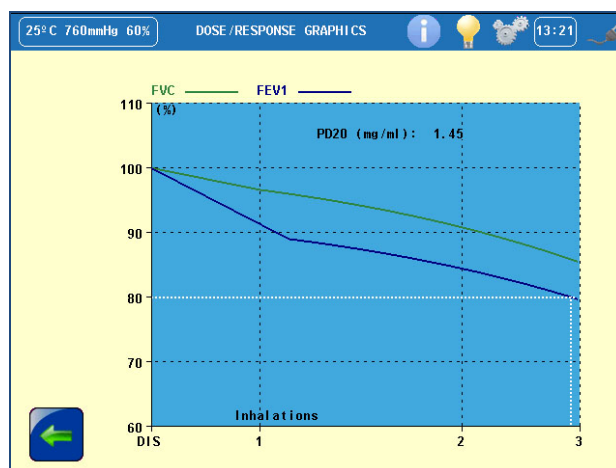
When the value of FEV1 falls below the user-configure limit (x %) compared to the diluent or the basal, the system alerts and the **PDx** value will appear on the **dose-response graph**.




The dose-response graph is presented mathematically adjusted through a process of logarithmic adjustment ( $y = C1 + C2 \log (x)$ )

if the coefficient of determination is better than (100-x) % and to calculate **PD<sub>x</sub>**, it is necessary to solve the equation.

If the coefficient of determination is lower than (100-x) %, the curve is linear and the calculation of **PD<sub>x</sub>** is done by linear interpolation.




## 5 CONSTRICTION + DILATION (BD<sub>x</sub>)

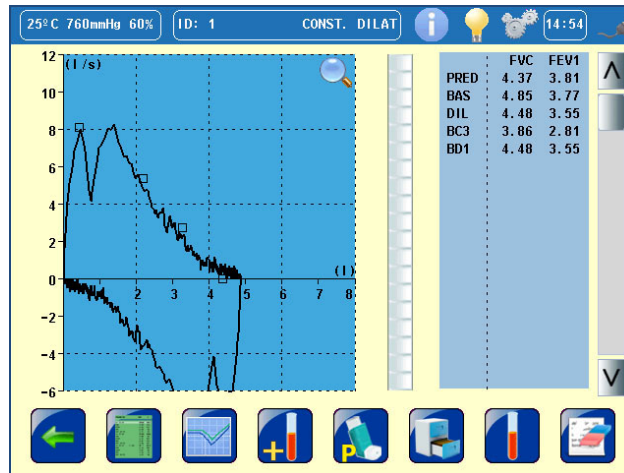
If you wish provide the patient a bronchodilator drug to reverse induced Bronchoconstriction, press  to save the last Bronchoconstriction carried out and sequence to the Bronchodilation stage.



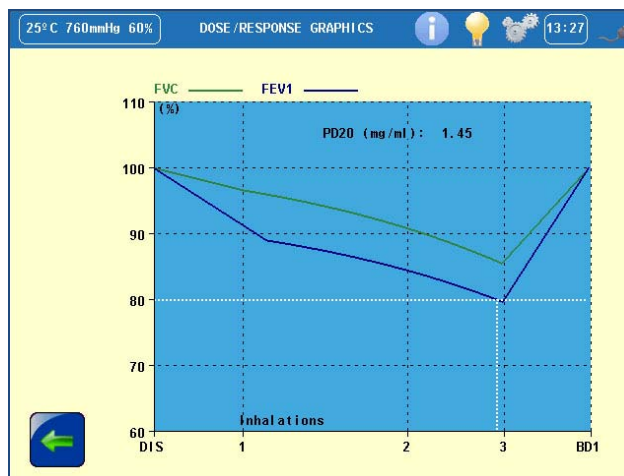
The screenshot shows the AstraTOUCH Bronchoprovocation Module User's Manual interface. At the top, there is a status bar with '25°C 760mmHg 60%' on the left, 'NEXT DOSE' in the center, and icons for information, a lightbulb, a gear, and a clock showing '13:23' on the right. Below this, the main display area is divided into two sections. The top section, with a yellow background, shows 'Dose (mg/ml)' with the value '0.50' and 'BD. drug' with the value 'SALBUTAMOL'. The bottom section, with a blue background, contains a numeric keypad with buttons for digits 0-9, a decimal point, and function keys: ESC, BACK, ENT, and left/right arrow keys.

Enter the bronchodilator drug data and press **ENT**.

Administer the bronchodilator to the patient. After the specified time, perform a set of maneuvers. Save the best maneuver by pressing  and, if necessary, repeat the process above.




Press  to view the dose/response graph of the Bronchodilation test:



### 1.4.1. TEST SUMMARY

The summary of the Bronchoconstriction test is presented in a graphic way (graphic dose/response shown before) or numerically (summary of the data shown next).

Press the key  to access the summary of the data screen:

25°C 760mmHg 60%		CONstriction SUMMARY		13:28	
PARAMETER		ACT	%		
** 13:10	2 inh	BC 2	%DIL		
FVC		4.01	90		
FEV1		3.02	85		
PEF		5.06	54		
FEF 25-75		2.57	76		
** 13:12	3 inh	BC 3	%DIL		
FVC		3.86	86		
FEV1		2.81	79		
PEF		5.05	54		
FEF 25-75		2.20	65		
** 13:25	0.50 mg/ml	BD 1	%BAS		
FVC		4.48	92		
FEV1		3.55	94		
PEF		9.40	121		
FEF 25-75		3.37	100		

Take into account that the observed values are compared to:

- Basal with the selected Reference of the patient
- Diluent, if made, with the Basal
- Constriction with the diluent, if made; otherwise, with the Basal
- Dilation with the Basal.F8 Stores the test summary in the internal database.



Prints the summary of the test



Stores the test summary in the internal database






Presents the graphic dose/response



Allows you to scroll through the data

### 1.4.2. PRINTING AND/OR DATABASE STORING

Once a test has been saved to the Database, by pressing  , it can be retrieved in the same manner as any spirometric test from the database menu  , print it and /or transfer it to a computer.

From the test screen, press  to obtain a report on the study performed through the internal or external printer.

### 1.4.3. TEST DATA TRANSFERRING TO PC

As with spirometric tests, the bronchoconstriction tests saved to the database can be transferred to a PC. Remember that only parameters are saved, not curves. (Consult section [6.1](#) of the general user's manual).

## **2. TECHNICAL SPECIFICATIONS**

### **BRONCHOCONSTRICTION TEST**

- Parameters
  - FVC (l) Forced Vital Capacity
  - FEV<sub>1</sub> (l) Forced Expiratory Volume in 1 second
  - PEF (l/s) Peak Expiratory Flow
  - FEF<sub>25-75%</sub> (l/s) forced mid-expiratory Flow
- Data of Patient identification
- Environmental data of temperature, pressure and relative humidity
- Continuous or shorter methods
- Deviation Percentage between Basal and Diluent
- Superposition of graphics in Flow/Volume or Volume/Time
- Timer for control of the steps
- Type of drug and accumulated dose
- Calculation of PD<sub>x</sub> (for FEV<sub>1</sub>) by mathematical adjustment or linear interpolation
- Numeric and graphic (dose/response) data summary on screen
- Link with Bronchodilation test