

DATOSPIR TOUCH

SPIROMETER

Bronchoconstriction test

USER'S MANUAL

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Sales Director

1. INSTRUCTIONS FOR USE AND INSTALLATION

1.1. INTRODUCTION AND SAFETY

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

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

We suggest consulting some bibliography 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 qualified on this technique or under his/her supervision.

1.1.1. PACKING LIST

07060	The Bronchoconstriction module includes:
07067	User's manual
03028	Bronchoconstriction option for W20s software
07209	Activation code card

1.1.2 MODULE ACTIVATION

To activate the option in the spirometer, consult section **5.3 ADDING MODULE, OPTIONS AND/OR TRANSDUCER** of the device user's manual.

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, specially the FEV₁ fall. It must be taken into account that each test has several forced spirometric maneuvers and the device selects the best one to include it in the summary report according to the criteria in the different standards.

The **DATOSPIR TOUCH** spirometer has the possibility 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 applying to the patient a certain number of inhalations of an allergen at a certain concentration.

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 and in the second case, inhalations are applied to make it faster.

The general test procedure is as follows:

1 BASAL (BAS)

Perform a basal spirometry maneuver

2 DILUENT (DIL)

Apply a diluent with PH neutral to the patient, if convenient, and perform a spirometry maneuver and compare it to the basal.

3 CONSTRIC. (BC1)

Apply the patient an initial dose of allergen and after the stipulated time, perform the spirometry. It is compared to the DILUENT (DIL), or to the BASAL (BAS), if the diluent has not been made. Then,

subsequent Bronchoconstriction tests may be done, allowing the patient to rest between them.

4 CONSTRIC. (BC2)

Apply the patient the second drug-dose.

5 CONSTRIC. (BC3)

Apply the patient the third drug-dose.

The process can be repeated until it is convenient. The system allows applying a maximum of 10 drug-doses (BC10).

6 When the lung function parameters show a significant response, after a new confirmation, or according to the criteria of the operator who makes the test, the bronchoconstriction test can be finished. The system analyses and shows the value of PDx graphical and numerically.

7 CONST + DILAT

Finally, once the test is finished, the bronchodilator drug has to be applied to revert the resultant Bronchoconstriction.

1.3. BRONCHOCONSTRICTION TEST CUSTOMIZATION

It is recommended that each user customize the option of Bronchoconstriction according to their needs.

From the main screen, enter to the CONFIGURATION MENU by

pressing , then press  to access to the CUSTOMIZATION

MENU. Then, press  to access to 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 to use dissolution or not
- 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 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. BROCHOCONSTRICTION TEST PROCEDURE



To avoid the risk a patient breathing difficult due to a bronchoconstrictor overdose, check the spirometer is correctly calibrated or perform a new calibration before the test. In the case of using disposable transducer check the calibration code (lot depending) is correctly inserted before performing the test.



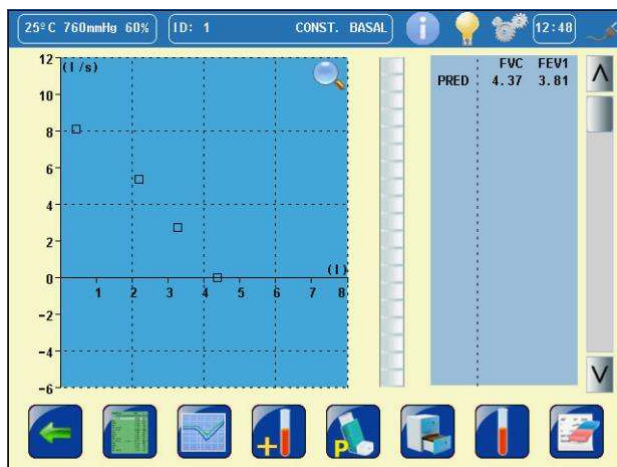
The physician should supervise the patient's breathing during the test.



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

Enter the patient's data. The procedure is the same as the one described in the section **4.1.1 ENTERING PATIENT DATA** of the **DATOSPIR TOUCH** 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 of the performed steps



Deletes the selected maneuver



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



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



Presents the graphic dose/response graph of the performed steps



Viewing or changing the drug dose

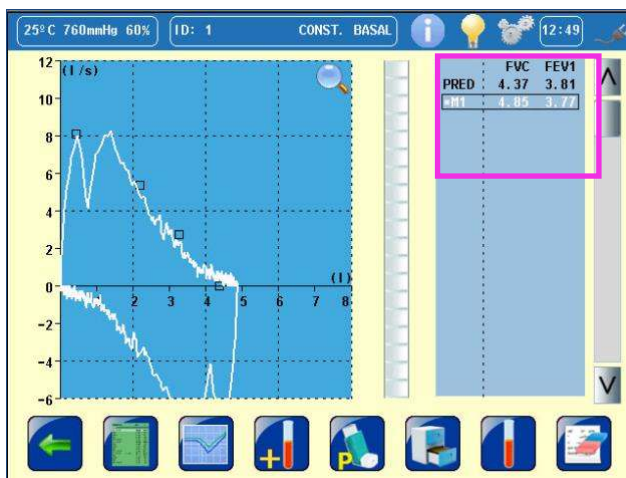


Stores the test summary in the internal database

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.

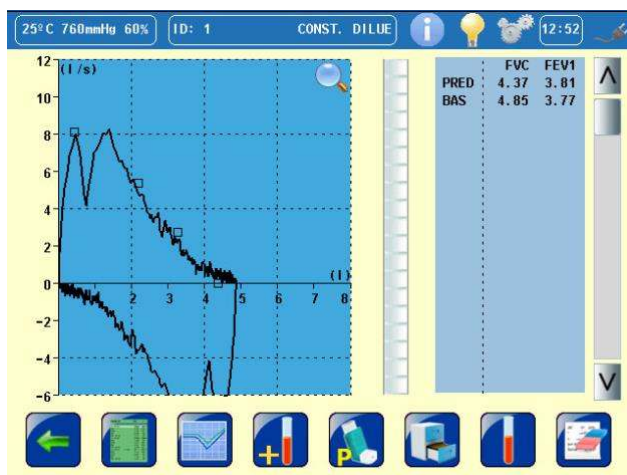
Press the **Parameters** area and the data of all maneuvers performed will be displayed:



The maneuvers are compared with 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)

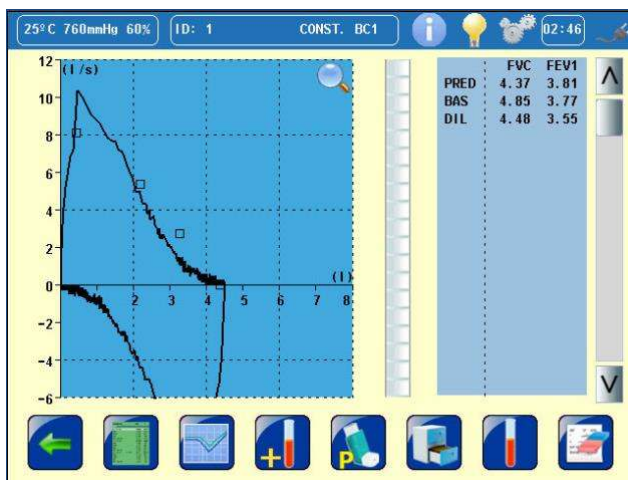
Apply the diluent with neutral PH to the patient, if you have selected this option. Start a new set of forced maneuvers, once the normalized time has passed.

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:

The screenshot shows the Sibelmed software interface in normal mode for dose entry. The top status bar displays environmental conditions (25°C, 760mmHg, 60%), the next dose status (NEXT DOSE), and the time (12:50). The main area is divided into two sections. The top section, with a yellow background, contains input fields for 'Dose (mg/ml)' (0.50) and 'BC. drug' (METHACOLINE). The bottom section, with a blue background, features a numeric keypad with buttons for digits 0-9, a decimal point, and navigation keys (ESC, BACK, ENT, left arrow, right arrow).

Short Mode:

The screenshot shows the Sibelmed Bronchoconstriction test user interface. At the top, a status bar displays environmental conditions: 25°C, 760mmHg, 60%. The main header area shows 'NEXT DOSE' and a timer at 12:48. The data entry section is highlighted in yellow and contains the following fields:

Inhalat. Num.	1
Dose / Inhalation (mg/ml)	0.50
BC. drug	METHACOLINE

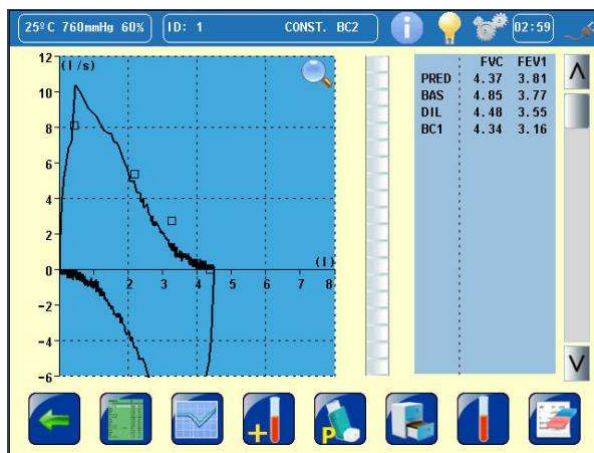
Below the data entry section is a numeric keypad with the following buttons:

7	8	9	ESC
4	5	6	BACK
1	2	3	ENT
←	0	.	→

Modify the data if necessary and press **ENT**. Apply the first dose of bronchoconstrictor drug and start another series of maneuvers again, when the timer **02:59** reaches 00:00 and an audible alarm sounds.



Press **+** to save the best maneuver carried out, and goes to the next stage.



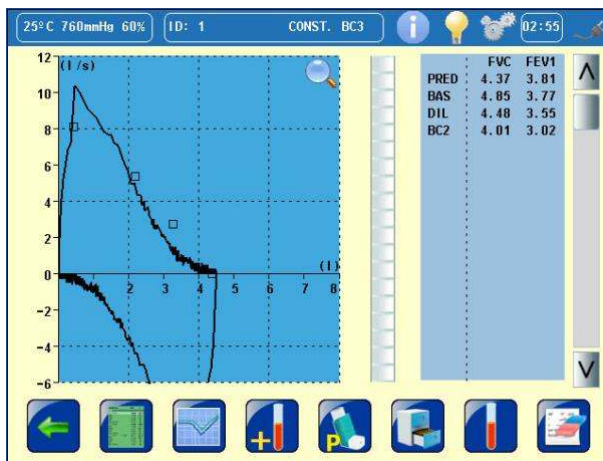
Presents the dose/response graph of the performed steps.



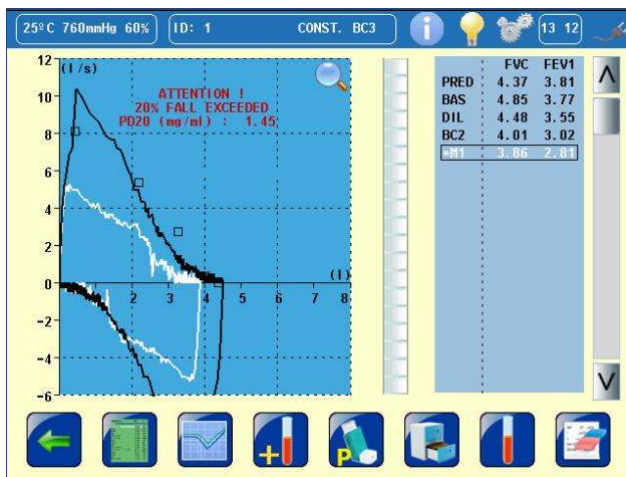
Allows you to view or change the dose of drug.

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

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

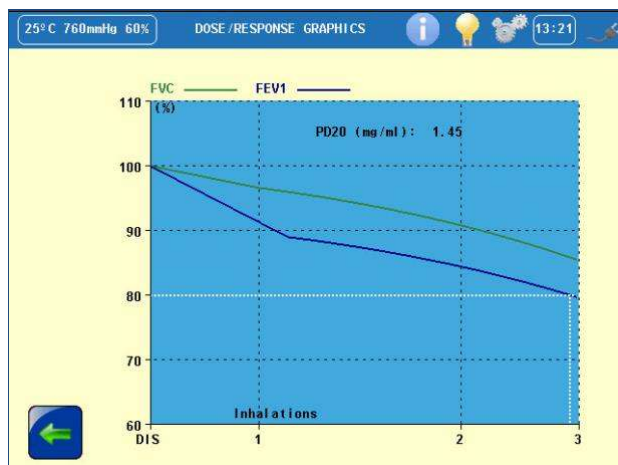


When the value of FEV1 falls below the user-configure limit (**x %**) compared to the diluent or the basal, the system warns it and the **PDx** value will appear on the **dose-response graph**.



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 **PDx**, 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 **PDx** is done by linear interpolation.



5 CONSTRICTION + DILATATION (BDx)

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

25°C 760mmHg 60% NEXT DOSE 13:23

Dose (mg/ml) 0.50

BD. drug SALBUTAMOL

7 8 9 ESC

4 5 6 BACK

1 2 3 ENT

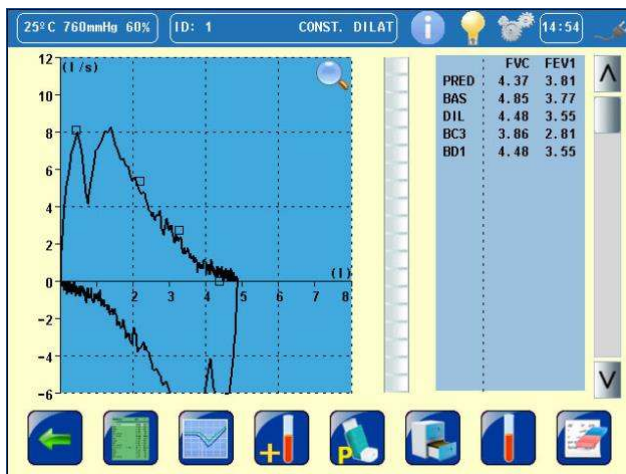
← 0 . →

Enter bronchodilator drug's data and press .

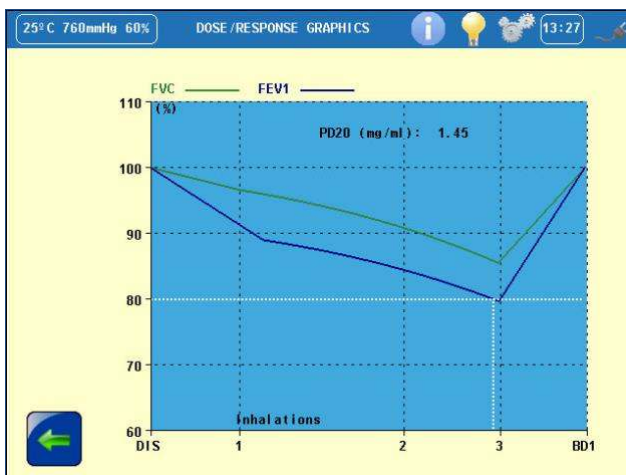
Apply the bronchodilator drug to the patient. After standardized time, perform a set of maneuvers. Save the best maneuver by



pressing **P** and, if necessary, repeat the process above.



Press **Graph** 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%		CONSTRUCTION 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 according 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
- Dilatation with the Basal.



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 STORAGING

Once a test has been saved on 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 the curve. (Consult section **5.1** of the general user's manual).

2. TECHNICAL SPECIFICATIONS

BRONCHOCONSTRICTION TEST

- Parameters
 - FVC (l) Forced Vital Capacity
 - FEV₁ (l) Idem in 1 second
 - PEF (l/s) Peak Expiratory Flow
 - FEF25-75% (l/s) forced mid-expiratory Flow
- Data of Patient identification
- Environmental data of temperature, pressure and relative humidity
- Continuous or shorter methods

- Deviation Percentage between Basal and dissolution
- Superposition of graphics in Flow/Volume or Volume/Time
- Timer for control of the steps
- Type of drug and accumulated dose
- Calculation of PD_x (FEV₁) by mathematics adjustment or linear interpolation
- Numeric and graphic (dose/response) data summary on screen
- Link with Bronchodilation test