

Astra **TOUCH** Spirometer

Pulse Oximetry Module

USER'S MANUAL

Rev. 4.29.14





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1. SAFETY

INTENDED USE

The pulse oximeter is an AstraTOUCH accessory and as such must meet the requirements set forth in the SAFETY section of the spirometer (see the general manual AstraTOUCH spirometer).

The system allows measurement of pulse and functional oxygen saturation. A functional meter cannot be used to evaluate the accuracy of a pulse oximetry probe or of a pulse oximeter monitor.

The pulse oximetry sensor must be used under close supervision of medical personnel.

The validated probes for the pulse oximeter are the M50 series of SDI Diagnostics. Follow strictly the safety instructions of these probes. These probes have been validated with this pulse oximeter module .

The adult finger clip sensor is for people older than 12 years. The pediatric sensor is for children between 3 and 12 years old.

The maximum recommended time of application of an oximeter probe in the same location is 8 hours. The point of placement must be reviewed frequently to determine the position, blood circulation and skin sensitivity of the patient. Reaction to the sensors by patients may vary depending on their state-of-health and skin condition. No adhesive material should be used if the patient shows an allergic reaction to it.

For extended measurement times, we recommend using the soft sensor.

LIMITATIONS FOR USE. CONTRAINDICATIONS

The pulse oximeter is calibrated to display the functional oxygen saturation and it does **NOT** require calibration

The pulse oximeter does **NOT** have physiological-type alarms.

The pulse oximetry probes do **NOT** allow temporary immersion.

The pulse oximetry waveform is not normalized.

Electromagnetic disturbances, patient movement or an excessive illumination could affect the device accuracy.

The pulse oximetry module is CE marked and cannot be exposed to temperatures >108° F (>42 °C).

The pulse and SpO₂ measurement must be done only using the sensors manufactured by SDI Diagnostics or significant measurement errors may appear.

RISK OF CONTAMINATION

Although unlikely, organisms can be transmitted by pulse oximetry. Therefore, the pulse oximeter finger clip should be washed after each patient use using either soapy water or using a medical equipment disinfectant specified by the manufacturer. See instructions for the sensor to evaluate the toxicity of SpO₂ sensor.

RISK OF INTERFERENCES

Avoid interference such as electromagnetic disturbances, stroke, abnormal hemoglobin, intravascular contrast, states of low perfusion and skin pigmentation can affect the operation of the oximeter. Dark fingernail polish may interfere with the sensor reading.

RISK OF EXPLOSION

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

WASTE DISPOSAL



The product must be recycled under the WEEE directive.

2. INSTRUCTIONS FOR USE AND INSTALLATION

2.1. INTRODUCTION

The **AstraTOUCH** can incorporate a dedicated electronic board to take samples of oxygen saturation and heart rate. This board is fed to the main board and communicates with it through a specific serial port.

This manual is an addendum to the manual of the Spirometer **AstraTOUCH**, dedicated exclusively to the **Pulse Oximetry Module**, and it is designed for use alongside the general manual.

This option allows you to take pulse oximetry measurements individually or while performing a spirometry test. In addition, you can carry out specific measures of **functional** oxygen saturation (**SpO₂**) and **pulse rate (PR)** or during long-term studies (8 hours approx.), for patient control or sleep monitoring.




In long-term studies, you can display the **Trends** (evolution of **SpO₂** and **PR** signal versus time) to calculate the parameters associated to the trends, print them or/and save them in the internal database.

The measurement principle of pulse oximetry is based on the different absorption of certain wavelengths of light (red and infrared) through the arteries, depending on the amount of hemoglobin carrying red blood cells.

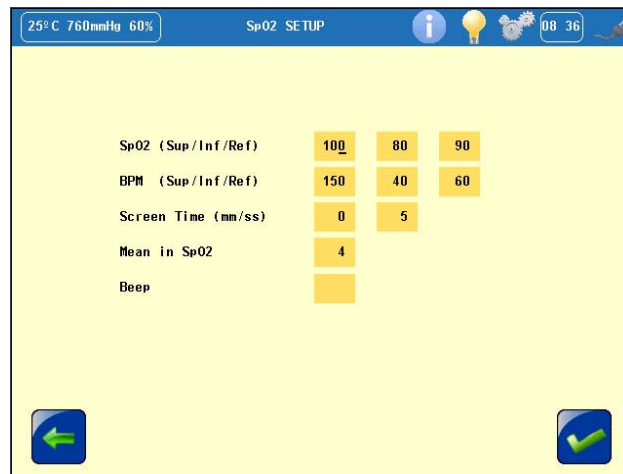
The wavelengths used are **660 nm (red)** and **910 nm (infrared)**. The optical power is about **9.6 mW**.

2.2. PULSE OXIMETRY SETUP

Turn on the spirometer, access the pulse oximetry setup menu, by

pressing ,  and finally .

Then, the following screen will appear:



Customize the pulse oximetry parameters according to your needs

- The average **SpO₂** (between 4 and 16 samples).
The lower the value selected for the average SPO₂, the faster the response time will be; but also the more susceptible to variations. However, if the average value chosen is higher, the measurement will be more stable, and will have a slower response.

For specific measures, it is preferable to use a high average value. But, for desaturations studies, it is recommended to choose a low value.

- The Average **PR** is fixed (10 samples).
- Enable the beeping sound (signal coinciding with each heart beat)

2.2.1. TRENDS CUSTOMIZATION

- Top (Top) and bottom (Bot) levels for displaying SpO₂ and PR trends.
- Reference (Ref) line level for both channels.
- On-screen display time (between 5s and 29m 59s).



Exits this screen or returns to the previous screen.

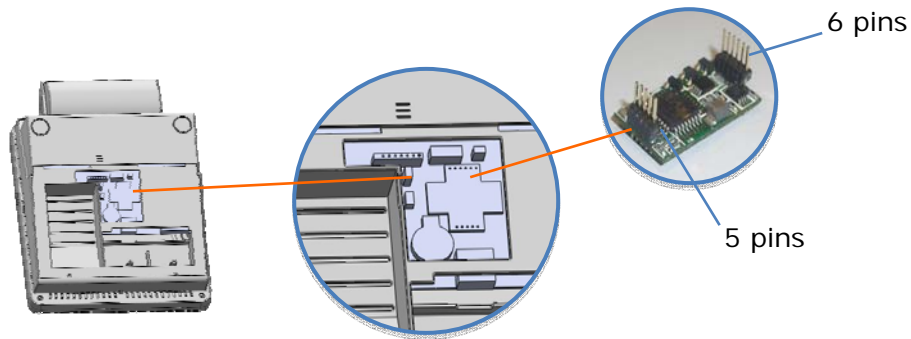


Validates the entered data and proceeds to the next screen.

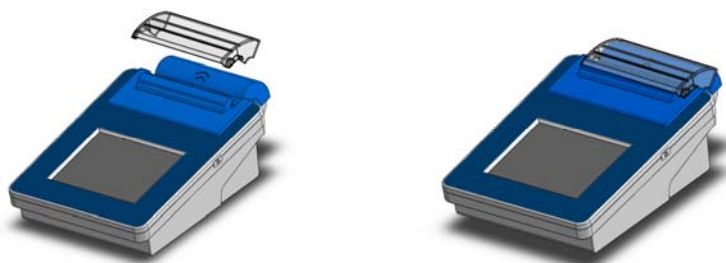
2.3. PULSE OXIMETRY TEST PROCEDURE

2.3.1. START UP

- 1 If you have purchased the **AstraTOUCH** with the pulse oximetry module, it will be ready to use.
If you have acquired the module later,
 - a Disconnect the power supply.
 - b Remove the bottom case from the spirometer.
 - c In case of using battery, disconnect it first.
 - d Insert the printed circuit board (included in the pulse oximetry module) in the equipment. Take special care to place it as shown in the figure below.



- 2 Place the **protective cover** over the printer. Thus, the spirometer will be protected against splashing water (IPX2) during the pulse oximetry test, as described in standard ISO 80601-2-61:2011.



Remember to place the protective cover against splashes of water whenever you perform pulse oximetry tests.

- 3** Plug the pulse oximetry sensor supplied into the no.8 jack on the rear of the device.



Use only the oximetry sensor supplied by the AstraTOUCH spirometer manufacturer. If you use non-validated sensors with this equipment, it may cause significant measurement errors.

- 3** Select a suitable site for the sensor. The first finger (index) is the preferred location. Alternative sites recommended are the thumb, little finger or the large toe.

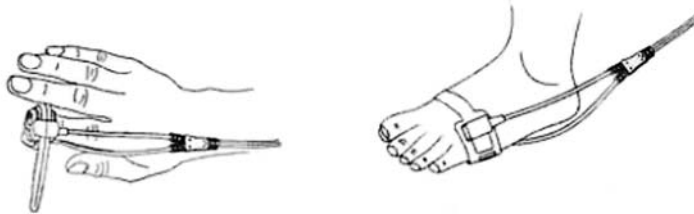


Insert the finger right to the end of the sensor to get the most accurate measurements.



⚠ Ensure that long fingernails do not interfere with the proper positioning of the finger or with sensor function. Remove nail polish or artificial nails before placing the SpO₂ sensor, as they could cause incorrect readings.

The fingernail must be kept pointing toward the upper part of the sensor and the cable must be positioned along the top of the hand (or foot)

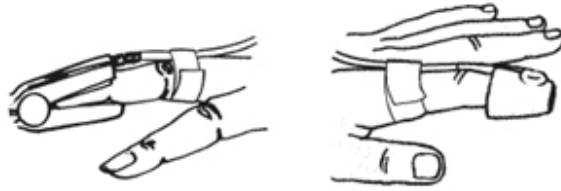


⚠ Do not twist the cable unnecessarily or use excessive force when using, connecting, disconnecting or storing the finger sensor.




Incorrect use or inappropriate handling of the sensors can cause damage to the sensor or cable. This could result in incorrect measurements and readings.

- 4** To obtain the best results, especially during long-term studies (8 hours approx.), fasten the cable separately from the sensor, using surgical tape; preferably around the base of the finger (see the figure above). Make sure that the tape fastening the cable does not restrict blood circulation.



For long term monitoring, is recommended to use flexible or disposable sensors.

- 5** To carry out a pulse oximetry test, press  from the main screen.

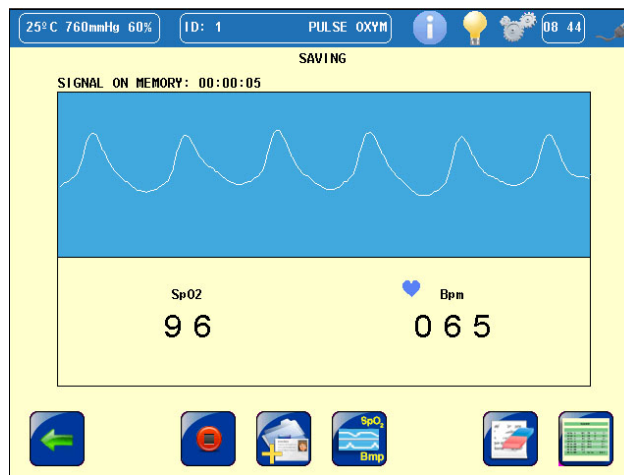
2.3.2. ENTERING TEST DATA


After accessing the Pulse Oximetry program, the first thing to do is to enter patient data. Consult the section **ENTERING TEST DATA** of the general user's manual.


If there is a saved test in memory, the program will jump directly to the next screen (see section **2.3.3** of this manual).


2.3.3. PERFORMING PULSE OXIMETRY TESTS


On accessing this screen, the pulse oximeter automatically begins to acquire samples. The Oxygen Saturation (**SpO₂**) and Pulse Rate (**PR**) values are displayed as is the corresponding **peripheral pulse wave**. The wave's registration lasts **5 seconds** on the screen.



 When the signal quality is low or finger is not present, SpO₂ values are set to zero to avoid showing incorrect values. Additionally, the device will inform you of this via a message on the screen.

 SpO₂ data is updated every second and the SpO₂ and pulse rate values are directly provided by the module.

 The device does not lose patient data if it is turned off.

 During a long term study, keep the pulse oximeter probe connected to the device.



If the mains power is interrupted, for a period longer than 30 seconds, patient data is not lost. Then, you may enter into the **PULSE OXIMETRY MENU** and start the test again.

If the beeping sound is enabled, you will also hear an audible warning.

The top of the screen indicates the **signal time (trends)** saved in the memory to date.



Exits this screen and goes back to the previous one



Calculates and displays the value of the parameters



Starts or stops saving a study



Accesses directly to the Trends customization screen (See section 2.3.4 of this manual)



Deletes the study from the memory



Accesses the patient details screen

A) SPECIFIC TESTS


In specific pulse oximetry studies, the screen will indicate the **SpO₂** and **PR** values according to the average configured. In order to print the results, you must first save the signal (by pressing



) during the period required and then follow the instructions given in sections 2.3.5 and 2.3.6.

B) LONG-TERM TESTS





In long-term tests, press  to begin saving. A flashing message ("SAVING") will appear in the centre of the screen to indicate that the study is being saved).

If the spirometer is saving the signal for more than **5 minutes** and no key is pressed, the light of the display will turn off automatically. This is to avoid discomfort to the patient in a long-term study. If you touch the screen, the light will turn on again.

It is important to note that the signal is related to the patient code entered. **If the study is started or stopped without changing the patient code or deleting the study, fragments of signal will be saved one after the other until the 8 hours are completed.** The equipment will interpret that all the fragments correspond to the same patient and the parameters will be calculated on the total memory.

If you want to perform the test on another patient, you must


delete the test (by pressing ) and change the patient's details (by pressing )

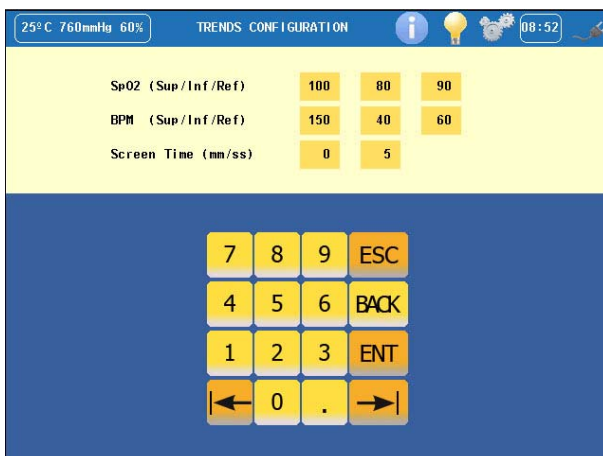
To display the signal saved, and calculate the parameters, access

to the trends screen (by pressing )

If the finger clip is disconnected, the periods in which the **SpO₂** and **PR** value is 0 will not be taken into account when calculating the parameters and the length of the test.

2.3.4. TRENDS CUSTOMIZATION



During the acquisition of oximetry and pulse wave signals, you may access to the trends customization menu. Press on  to modify any of the data displayed on the following screen:



Parameter	Sup	Inf	Ref
SpO ₂ (Sup/Inf/Ref)	100	80	90
BPM (Sup/Inf/Ref)	150	40	60
Screen Time (mm/ss)	0	5	

Consult the section [2.2.1](#) for more details.

2.3.5. DISPLAYING TRENDS

Only if the study has been previously recorded () , trends can be shown by pressing 



Exits this screen and goes back to the previous one



Goes to a specific page (signal fragment)



NORMAL mode:



Goes back or forward one page



SEARCH mode:

Locates the next crossing point with the reference line

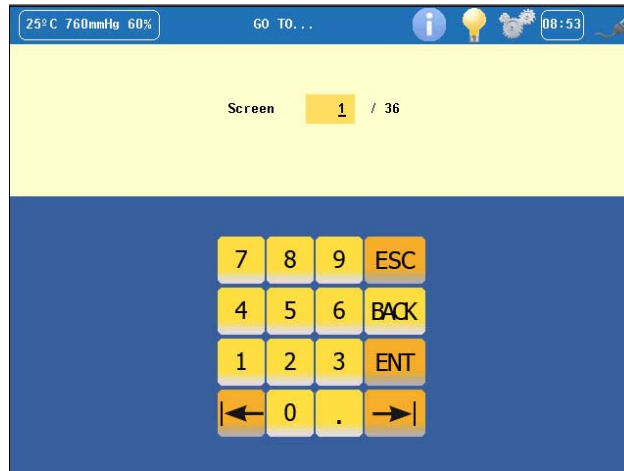





Calculates and displays the value of the parameters

The Trends screen displays the fragment of the **SpO₂** and **PR** signal according to the screen time selected.

The top left shows the relative time at the start of the study (**hh:mm:ss**).


Each channel allows for a dotted line of references to be displayed that can be selected by the user during configuration. This line may be extremely useful when checking whether the samples exceed a certain value.



Pressing , you will enter in the SEARCH mode. By pressing  or  in this mode, the program will locate the next (or previous) point where the **SpO₂** signal exceeds the reference value.


2.3.6. PRINTING AND/OR SAVING THE DATABASE


The parameters are calculated upon accessing this screen. This option may take a few seconds, depending on the length of the study.


Press the key  to access the parameters screen:

25°C 760mmHg 60%


PULSE OXIMETER DATA









08:55




PULSE OXIMETER

SpO2 Max (%)	97.0	CT90 (%)	25.6
SpO2 Med (%)	93.3	CT80 (%)	13.4
SpO2 Min (%)	81.0	CT70 (%)	8.0
SpO2 Std (%)	3.2	IDH-4%	10.3
BPM Max (BPM)	125.0	IDH-3%	18.3
BPM Med (BPM)	75.6	IDH-2%	24.3
BPM Min (BPM)	65.0		
BPM Std (BPM)	12.8	Test Time	: 02:01:12










Exits this screen and goes back to the previous one




Prints the study report



Saves Parameters to the Database

Once a test has been saved to the Database (by pressing ), it can be retrieved in the same manner as any spirometric test. To

obtain a report on the study performed, press .

2.3.7. TEST TRANSFER

As the spirometric tests, the pulse oximetry tests saved to the database can be transferred to a PC. Only parameters are saved, not the curve. (Consult the section **TRANSFERRING TEST TO A PC** of general User's manual).

2.4. PULSE OXIMETRY AND SPIROMETRY MEASUREMENTS

It is possible to take pulse oximetry measurements while performing a spirometry test (only in FVC, VC and MVV tests).

To do so, the pulse oximetry finger clip must be connected when starting the spirometry.

While spirometry is being performed, the Saturation (SpO_2) and Pulse Rate (PR) value will appear on the screen with the curve and will be saved in the memory. The average of both values will be displayed on completion of the maneuver.

The pulse oximetry menu must be accessed to retrieve all the measured values from the memory. This will be dealt with like a Pulse Oximetry test saved in the memory.

3. TECHNICAL SPECIFICATIONS

3.1. TESTS, FUNCTIONS AND PARAMETERS

The parameters calculated to display, print or save on the Database are as follows:

- **CT90** % of time in which SpO_2 is below 90%

- **CT80** % of time in which SpO₂ is below 80%
- **CT70** % of time in which SpO₂ is below 70%
- **IDH-4** Desaturation index ($\geq 4\%$) per hour
- **IDH-3** Desaturation index ($\geq 3\%$) per hour
- **IDH-2** Desaturation index ($\geq 2\%$) per hour
- **Maximum SpO₂** Maximum Saturation value
- **Average SpO₂** Average Saturation value
- **Minimum SpO₂** Minimum Saturation value
- **Std. SpO₂** Standard Saturation value
- **Maximum PR** Maximum pulse rate value
- **Average PR** Average pulse rate value
- **Minimum PR** Minimum pulse rate value
- **Std. PR** Standard pulse rate deviation
- **Test Time** Useful test time (when the finger clip is disconnected, the time is not considered)

NOTE: Any time during which the finger clip is disconnected or the signal quality is low is not taken into account when calculating the parameters and Test Time.

3.2. MEASUREMENTS AND RANGES

	SpO ₂ (%)	Pulse (BPM)
Measurement Range	0-100	30-235
Resolution	1	1
Accuracy:		
• 80 to 100	±2	±2 bpm or ±2%
• 70 to 80	±3	
Plethysmogram	0-100	
	Auto-gained for highest resolution	
Update rate: 1Hz		
Signal quality indicator:		
- Weak or wrong pulse		
- No finger into the probe.		

3.3. APPLICABLE STANDARDS

• PULSE OXIMETRY STANDARD

In compliance with EN ISO 80601-2-61:2011 *Medical electrical equipment--particular requirements for the basic safety and essential performance of pulse oximeter equipment*.

WATER INGRESS PROTECTION LEVEL

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

4. CLEANING AND MAINTENANCE

4.1. CLEANING / DISINFECTION

Disconnect the SpO₂ sensor from the equipment before cleaning or disinfection.

Follow the pulse oximeter sensor manufacturer's instructions regarding sensor cleaning.



Sterilization must not be carried out using an autoclave or ETO (ethylene oxide) as a sterilizing agent, or by submerging the sensors in liquid.

4.2. PREVENTIVE MAINTENANCE

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

Actions which can be carried out by the user:

- 1 Carry out a regular inspection of the appearance of the external elements of the sensor: check the wire and/or connector and verify if they are broken or damaged.
- 2 Verify that the module measures correctly.
In the case of detecting a malfunction that the user himself cannot resolve, please contact SDI or **your distributor** to proceed with its review or repair.

Actions carried out by skilled technical personnel:

- 1 A second type consists of a general technical verification of security systems, settings, features, etc. that make up the Pulse Oximetry module.

This Technical check will be performed according to the **AstraTOUCH's** Pulse oximetry module Verification and Adjustment Procedure, available from the manufacturer **SDI Diagnostics**. This type of operation must be carried out by skilled technical staff from the distributor's or manufacturer's **technical service**.

SDI Diagnostics 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 authorized by **SDI Diagnostics..**

4.3. CORRECTIVE MAINTENANCE

Where a problem is detected in the equipment preventing it from being used normally, contact the **SDI Diagnostics After-Sales Service** and specify the problem in as much detail as possible.

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