DATOSPIR TOUCH

SPIROMETER

Pulse Oximetry option Module

USER'S MANUAL

CE 0197

511-BE0-MU2 • REV. 1.05 • 2017-04

Sibelmed

SIBEL S.A.U., Rosellón 500 bajos 08026 BARCELONA (Spain)
National Sales: Tel. 93 436 00 08 e-mail: comercial@sibelmed.com
International Sales: Tel. +34 93 436 00 07 e-mail: export@sibelmed.com
Technical service: Tel. +34 93 433 54 50 e-mail: sat@sibelmed.com
Fax: +34 93 436 16 11, Website: **www.sibelmed.com**

TABLE OF CONTENTS

CE 0197 **COMPLIANT PRODUCT**
93/42/EEC Medical Device Directive. Class IIa

Revised
Date: 2017-04
Technical Director

Approved
Date: 2017-04
Sales Director

1. SAFETY

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

INTENDED USE

See the general manual DATOSPIR TOUCH spirometer

INDICATIONS FOR USE

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

⚠ **The validated probes for the pulse oximeter are the clip probes of the M50 series of CHOICEMMED, for example: M-50B (pediatric) and M-50E (adult). Follow strictly the safety instructions of these probes.**

The adult finger clip sensor is for people older than 12 years. The pediatric sensor is for children between 3 and 12 years old, although **DATOSPIR TOUCH** is intended for ages greater than 4 years.

⚠ **The point of placement of the sensor must be reviewed frequently (at least every 4 hours) to determine the correct position and alignment of the sensor, and the correct blood circulation, skin sensitivity and integrity of the patient.**

For long term measurements, we recommend to use the soft sensor manufactured by Choicemmed.

Reaction to the sensors by patients may be different depending on their health state and skin condition. No adhesive material should be used if the patient shows an allergic reaction to it. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin.

This device must be used in conjunction with clinical signs and symptoms. It is only intended to be an adjunct in patient assessment.

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 (such electrosurgery) or patient movement could affect the device accuracy.

An excessive ambient light may affect the measurements of the device. Cover the sensor if it's necessary.

Do NOT perform measurements with polished fingernails, false fingernails or pigmented skin. They may affect the accuracy of the SpO2 values.

Any condition that restricts blood flow (such as use of blood pressure cuff) may cause an inability to determine accurate pulse rate and SpO2 readings.

The pulse oximetry sensor is CE marked and cannot reach temperatures >41 °C.
A functional tester can not be used to evaluate the device accuracy.

RISK OF CONTAMINATION

Although unlikely, the organisms can be transmitted by pulse oximetry. Therefore, the pulse oximeter finger clip should be cleaned or disinfected according to the instructions for use of the manufacturer.
The device and sensor do not contain phthalates or other contaminants that could lead to an additional risk for preguant, children or sanitary personal.

RISK OF INTERFERENCES

Operation of this device may be adversely affected in the presence of computed tomography equipment or magnetic resonance imaging (MRI). MRI devices may induce currents that can cause patient injury.

Dyes or intravascular contrast introduced in the blood stream may adversely affect the SpO2 readings.

Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methahemoglobin, will affect the accuracy of the device.

Optical cross talk may occur when two or more sensors are placed closely. It can be eliminated by covering the sensors with opaque materials. Optical cross talk may affect the accuracy of the device.

Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are not obstructions and the sensor is clean.

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 **DATOSPIR TOUCH** 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 **DATOSPIR TOUCH**, 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 (**SpO_2**) and **pulse rate** (**BPM**) 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 **SpO_2** and **BPM** 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 **940 nm (infrared).** The optical power is about **3.8 mW.**

2.1.1.PACKING LIST

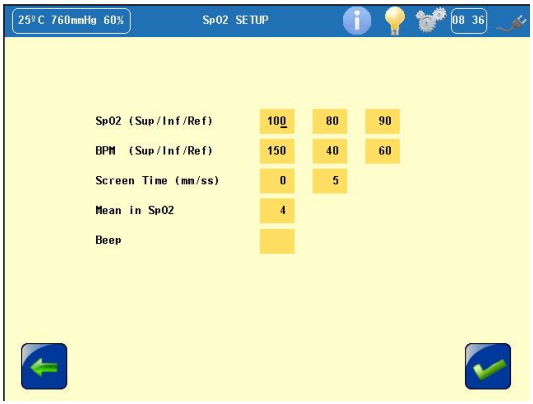
07272	**The Pulsioximetry (SpO_2) module includes:**
06390	SpO_2 board
06391	Clip sensor adult (M-50E, choicemmed)
07050	User's manual
03031	SpO_2 option for W20s software
07209	Activation code card
07288	Protective cover
Optional	
07725	SpO_2 soft sensor children (M-50B)

2.1.2. 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.

2.2. PULSE OXIMETRY SETUP

Start up 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 **SpO_2** (between 4 and 16 samples).
  The lower the value selected for the average SPO_2, the faster the response will be; but also the more susceptible to variations. However, if the average value chosen is higher, the measure 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 is better a low value.

- The Average **BPM** 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 SpO_2 and BPM trends.
- Reference (Ref) line level for both channels.
- On-screen display time (between 5s and 29m 59s).

Exits this screen or goes back to the previous one.

Validates the entered data and goes to the next screen.

2.3. PULSE OXIMETRY TEST PROCEDURE

2.3.1. START UP

1 If you have purchased the **DATOSPIR TOUCH** with the pulse oximetry module, it will be ready to use.
If you have acquired the module later, you have to install the module in the device.

The following steps (a to e) must only be carried out by technical personeel used to dealing with electronic devices.

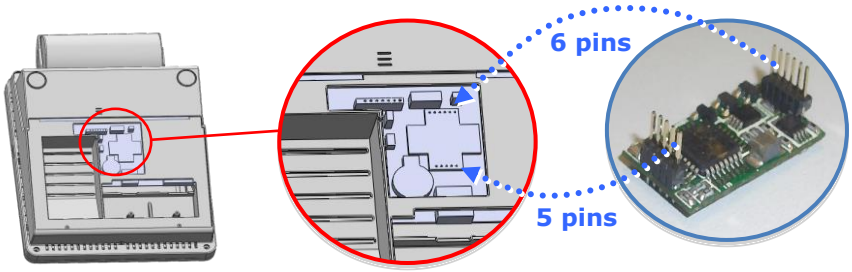
a Disconnect the power supply.

b Remove the bottom case from the spirometer with the use of a screwdriver.

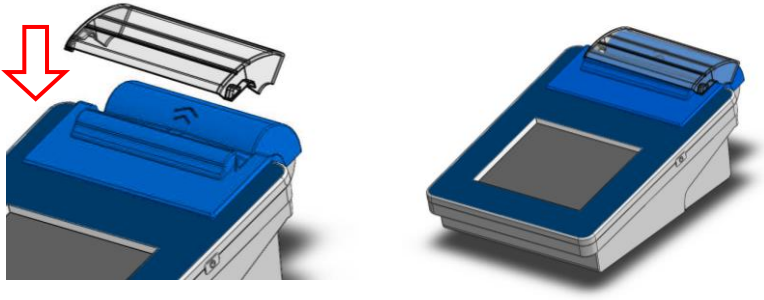
c In case of using battery, disconnect it first.

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.

e Place again the bottom case to the spirometer.



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 EN ISO 80601-2-61:2011.

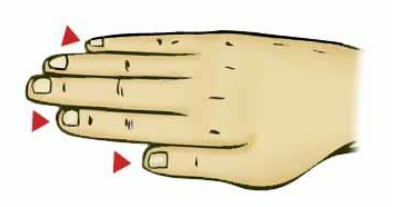


Remember to place the protective cover against splashes of water whenever you perform pulse oximetry tests.

3 Plug the pulse oximetry sensor supplied into the no.8 jack on the rear of the device (see section 2.3 of the **DATOSPIR TOUCH** GENERAL manual).

Use only the oximetry sensor supplied for the DATOSPIR TOUCH spirometer manufacturer. If you use non-validated sensors with this equipment, that may cause significant measurement errors.

4 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.



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

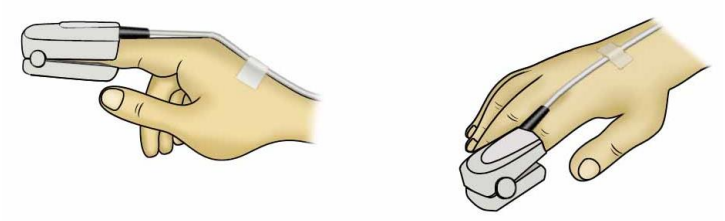
Ensure that long fingernails do not interfere with the proper positioning of the finger or with sensor function. Remove nail polish or artificial nails before placing the SpO_2 sensor, as they could cause incorrect readings.

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 unnecessary 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 would lead to incorrect measurements and readings.

6 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 check the sensor every 2 ó 3 hours (maximum 4 hours), and change the sensor to another finger if necessary.

7 To carry out a pulse oximetry test, press 

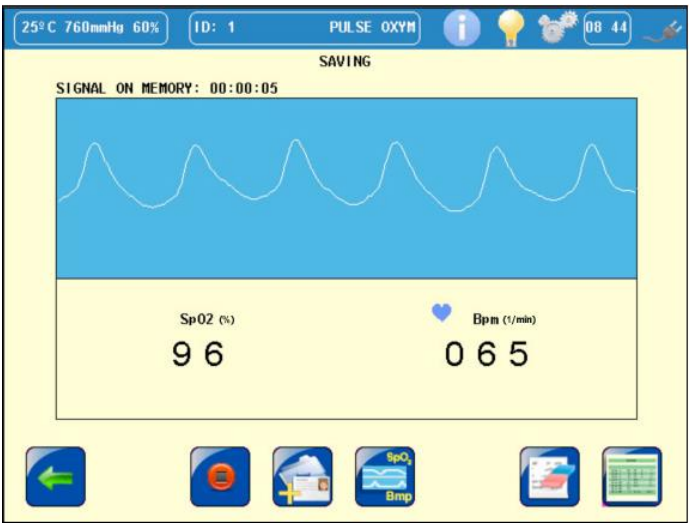
from the main screen.

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 **4.1.1 ENTERING PATIENT 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 (**SpO_2**), Pulse Rate (**BPM**) values are displayed and 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 or there is an error in the sensor, SpO2 values are set to zero to avoid showing incorrect values. Furthemore the following screen message will be displayed: "FINGER NOT PRESENT, SENSOR DISCONNECTED OR INCORRECT"

SpO_2 data is updated every second, the SpO_2 and pulse rate values are directly provided by the module.

The device does not lose patient data if it is turned off. It will show the message "TEST NOT SAVED. SAVE TO DATABASE?" if a test has not been saved.

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

If you try to initiate a different function with an SpO2 test not saved, the device will show "IF YOU CONTINUE YOU WILL LOOSE SpO2 TEST PERFORMED! ARE YOU SURE?

If the mains power is interrupted, for a period longer than 30 seconds, patient data is not lost. Then, you may enter to 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

If you press the Exit button with an unsaved test, the device will show the message "YOU WILL EXIT, ARE YOU SURE?".

Before deleting a test, the device will show the message "IF YOU CONTINUE YOU WILL LOSE SpO2 TEST !! ARE YOU SURE?"

A) SPECIFIC TESTS

In specific pulse oximetry studies, the screen will indicate the **SpO_2** and **BPM** 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 more than **5 minutes** saving signal without touching any key, the light of the screen 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 ).

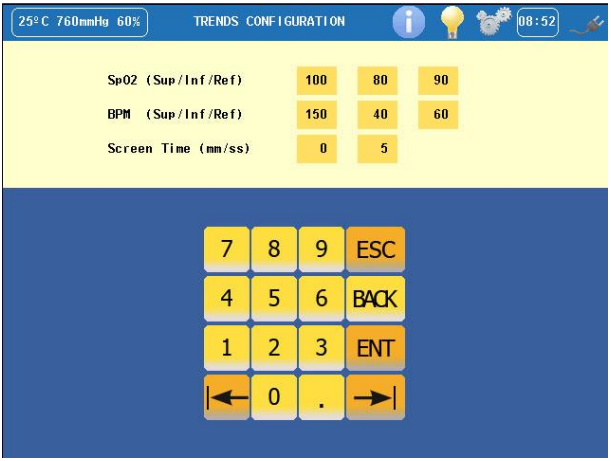
To display the signal saved, and calculate the parameters, access to the trends screen (by pressing 

).

If the finger clip is disconnected, the periods in which the **SpO₂** and **BPM** 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:



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 forwards one page

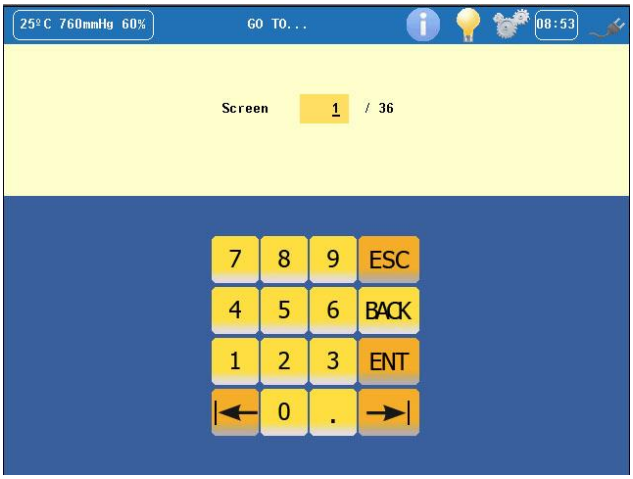
SEARCH mode:
Locates the next crossing point with the reference line

Calculates and displays the value of the parameters

The trends screen displays the fragment of the **SpO₂** and **BPM** 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 **SpO_2** 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:

 Exits this screen and goes back to the previous one

 Prints the study report

 Saves Parameters on the Database

Once a test has been saved on 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  .

If the device is still recording and you generate a report, the device will show "SAVING WILL STOP, DO YOU WANT TO CONTINUE?"

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 (BPM) 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 SpO_2 is below 80%
- **CT70** % of time in which SpO_2 is below 70%
- **IDH-4** Desaturation index (>= 4%) per hour
- **IDH-3** Desaturation index (>= 3%) per hour
- **IDH-2** Desaturation index (>= 2%) per hour
- **Maximum SpO_2** Maximum Saturation value
- **Average SpO_2** Average Saturation value
- **Minimum SpO_2** Minimum Saturation value
- **Std. SpO_2** Standard Saturation value
- **Maximum BPM** Maximum pulse rate value
- **Average BPM** Average pulse rate value
- **Minimum BPM** Minimum pulse rate value
- **Std. BPM** Standard pulse rate deviation
- **Test Time** Useful test time (when the finger clip is disconnected 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 -1/min)**
Measurement Range	0-100	30-235
Resolution	1	1
Accuracy:		
	±2 (81 to 100%) ±3 (70 to 80%) Undefined(<70%)	±2 bpm (30 to 100 /min) ±2% (101 to 235 /min)
Plethysmogram	0-100 Auto-gained for highest resolution	

Update rate: 1Hz
Signal quality indicator:
- Weak or wrong pulse
- There's no finger into the probe.

Recording time: up to 8 hours

3.3. APPLICABLE STANDARDS

- **PULSIOXIMETRY 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 EN ISO 80601-2-61:2011

4. CLEANING AND MAINTENANCE

4.1. CLEANING / DISINFECTION

Disconnect the SpO_2 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 an abnormality that the user himself can not solve, is made known **after-sales service SIBEL S.A.U.** 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 **DATOSPIR TOUCH's** Pulse oximetry module Verification and Adjustment Procedure, available from the manufacturer **SIBEL, S.A.U.** This type of operation must be carried out by skilled technical staff from the distributor's or manufacturer's **technical service.**

On all accounts, **SIBEL S.A.U.**, 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 belonging to **SIBEL S.A.U.**

4.3. CORRECTIVE MAINTENANCE

Where a fault is detected in the equipment which prevents it from being used normally, contact the **SIBEL S.A.U. 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.