



Service manual Rev. 1.5

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1. INTRODUCTION

1.1. INTRODUCTORY REMARKS

1.1.1. General Aspects

The spirometers from the product group **MIR040** are marketed under the label **spirodoc**.

This manual has been written for technicians involved in the service of the **spirodoc**. Service can be carried out by the service organization of the manufacturer or by any other technician authorized by MIR srl.

The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

1.1.2. Safety Aspects

Safe execution of the procedures in this manual requires technical experience and general knowledge of safety precautions.

 **Before you start any operation on the unit, you must have first read both the User and this Service Manual.**

Warnings, Cautions and Notes are used throughout this manual to bring special matters to the immediate attention of the reader.

-  **Warning** The **Warning** concerns danger to the safety of the technician or user.
-  **Caution** The **Caution** draws attention to an action which may damage the equipment.
- Note** The **Note** points out a statement deserving more emphasis than the general text, but which does not deserve a Warning or Caution.

 **Warning**

In order to prevent unforeseen incidents, keep away from sensitive electronical devices. Inside the spirodoc there are low voltages and very low currents, so these represent no danger for persons with experience and with a general knowledge of safety precautions.

The sequence of steps in a procedure may also be important from the point of view of personal safety and prevention of damage, therefore never change the sequence of steps or alter any procedure.

 **Warning**

Batteries may explode if defective or damaged or disposed of in fire. Do not short-circuit the batteries!

1.1.3. Legal Aspects

This manual and the information herein are property of MIR srl (Rome, Italy).

Copying this manual in whole or in part is strictly forbidden.

MIR srl disclaims any responsibility for personal injury and/or damage to equipment caused by:

- negligence or disregard of a Warning or Caution
- deviation from any of the prescribed procedures
- execution of activities which are not prescribed
- ignorance of the general safety precautions for handling tools and the use of electricity
- incorrect or unreasonable use

1.1.4. Environmental Aspects

Please dispose properly of any items replaced, following all the local regulations.

All components (housing, PCBs, batteries, electronic and disposable parts, etc.) must be disposed of according to the relevant local regulations.

1.2. DATA REGISTRATION

1.2.1. Equipment and customer registration / Service file

From the point of view of safety and product liability the following data must be registered for each unit:

Equipment data	Model, REF code and serial number
Customer data	date of purchase
	name and full address of the customer
Service data	log of all service activities
Configuration data	the actual configuration of the equipment (hardware and software versions)

The distributor (through their dealer and/or service organization, if any) is responsible for maintaining these records and they must be able to provide these data when requested.

1.2.2. Configuration register

A configuration file gives the serial numbers and/or batch numbers of main sub-assemblies and/or important parts of each unit. The parts listed in a configuration file are defined as registered parts. For example parts as mainboards, display, batteries and internal software.

Note

MIR srl has the original configuration file of each unit sold. Any possible changes in the original configuration of the supplied units must be filed and the distributor must be able to provide this data.

1.2.3. Product documentation

The documentation set for the **spirodoc** includes a User Manual. The User Manual is a recommended item for all service engineers. The user manual is available in the following languages:

- English
- Spanish
- German
- French
- Italian
- Polish

1.2.4. Technical modifications

This publication could include technical inaccuracies or typographical errors. Changes are periodically made to the information herein; these changes will be published as Service Info in appendix B of this Service Manual.

Note

Some functions described in this manual may not be activated in the present software or hardware version. For detailed information, please refer to the User Manual.

1.2.5. Product evaluation

In order continuously to improve the quality of our products, MIR srl requests that the service organizations should report any device issue which may be discovered. When the same issue regularly occurs or when a safety issue occurs, MIR srl would like you to send us a product complaint report. The report must contain the name, the type of product, a detailed

description of the problem, the frequency of the same problems, the quantity of sold equipment and your solution to the problem (if any).

1.2.6. Additional Information

Please do not hesitate to contact MIR if you require additional information.

Manufacturer's address:

MIR srl
Medical International Research
Via del Maggiolino, 125
00155 Rome
Italy
Tel.: +39/06/2275 4777
Fax.: +39/06/2275 4785
Email: mir@spirometry.com

1.2.7. Installation



Warning:

Before using spirodoc check internal battery pack charge level.

- turn on the **SPIRODOC** by pressing and release the power key placed in the middle on the side of the device
- Check battery level on the upper right of the display as shown in the image.



1.3. GENERAL

spirodoc is an “open circuit system” for the measurement of inspiratory and expiratory lung function parameters and oximetry values, such as pulse rate and SpO2. It is suitable for basic lung function analysis of the mechanical respiratory tract parameters. Three different respiratory tests can be performed:

- the forced vital capacity test (FVC),
- the slow Vital Capacity test (VC/IVC)
- the Maximum Voluntary Ventilation test (MVV)

spirodoc has been designed and manufactured to ensure the highest level of safety and the unit fully complies with the stringent international EN 60601-1 and EN 60601-1-2 standards.

1.3.1. Technical Data

1.3.1.1. spirodoc unit

Max. current inside the unit	90 mA (with LCD at the maximum lightness)
Internal batteries	Rechargeable Battery pack Li-ion 3.7 V 1100mAh
Approval	CE 0476 EC mark for Medical Devices FDA
Dimensions	101x48x16 mm; turbine housing 46x47x24 mm

Weight	Central unit 99g (including batteries) Turbine housing 17g
Volume range	10 L
Flow range	± 16 L/s
Volume accuracy	$\pm 3\%$ or 100 mL
Flow accuracy	$\pm 5\%$ or 250 mL/s
Dynamic resistance at 12 L/s	$< 0,5$ cmH ₂ O/L/s
Type of electrical protection	Class II device
Level of protection against direct or indirect contact	Category BF apparatus
Level of water ingress protection	IPX1 device, protected against water drops
Level of assurance of use in the presence of an anaesthetic mix flammable with air or oxygen or protoxide of nitrogen	Apparatus not suitable
Conditions of use	Apparatus for repeated use
Storage conditions	Temperature: MIN -20 °C, MAX +60 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN +10 °C, MAX +40 °C Humidity: MIN 10% RH; MAX 95%RH

1.3.1.2. Battery charger

Battery charger supply: Voltage = 5VDC, Current = 1300 mA
 Permissible mains voltage var.: 100 V-240 V
 Mains frequency: 50 – 60 Hz
 Max. current: 1300 mA at 5 VDC

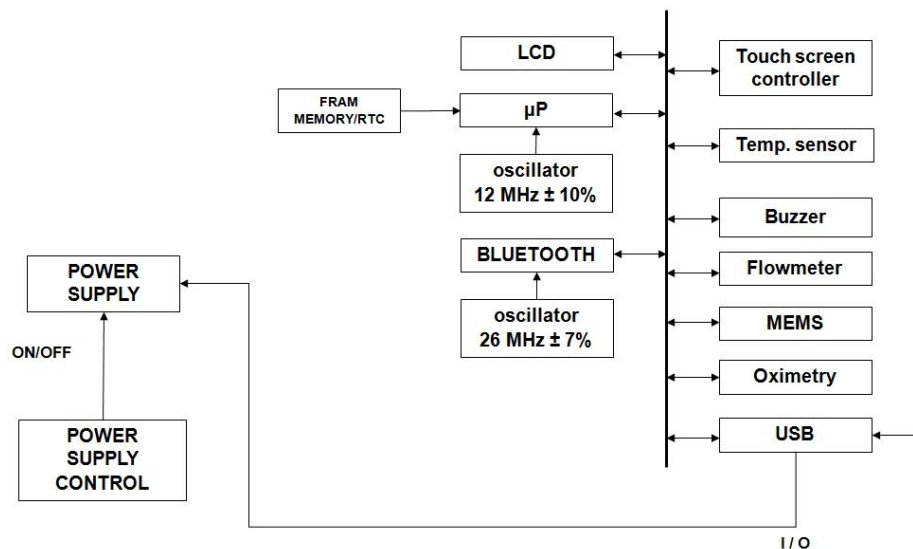
1.4. STANDARDS APPLIED

- According to rule 10 of the European directive 93/42/CEE the device is classified as Class IIa
- EN 60601-1 Electronic medical apparatus. Part 1: General safety standards
- EN 60601-1-1 Electronic Medical apparatus. Part 1: General safety standards 1. Collateral standard: Safety requirements for medical electronic systems
- EN 60601-1-2 Electronic medical apparatus. Part 1: General safety standards 2. Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 60601-1-4 Electronic medical apparatus. Part 1: General safety standards 4. Collateral standards: Programmable medical electronic systems
- UNI CEI EN ISO 14971 Medical devices: application of risk management to medical devices
- ATS/ERS TASK FORCE: Standardisation of lung function testing (volume 26/numbers 1-5/2005)
- Health Canada Medical Device Regulation: P.C. 1998-783 del 7 /5/1998
- SANS 451:2008 Spirometry — Generation of acceptable and repeatable spirometrys FDA Regulations
- Japanese MHLW Ministerial Ordinance 169: 2004

2. HARDWARE DESCRIPTION

Because of the modular design of the **spirodoc**, the description is on a block diagram level.

BLOCK DIAGRAM



2.1. MAINBOARD MODULE

The mainboard module translates the input signal from the turbine flowmeter into spirometry values and compares them with the predicted values calculated with the parameters age, sex, height, weight and ethnic group. Test results are displayed on a LCD and can be printed on paper with an external printer. Spirometry test data are stored into memory and are available for later use.

The mainboard module also makes a calculation using the oximetry input signal; from this signal collected at a 16 msec/frequency the percentage value of oxygen saturation in the blood and the heart beat values are obtained, which are oximetry parameters.

The mainboard module includes:

- Main Microcontroller
- FLASH memory with device configuration and spirometry data
- FRAM IC with non volatile memory and real time clock
- Measuring controller for flow, volume and ambient temperature
- Ambient temperature sensor (to enable conversion from ATP to BTPS conditions).
- USB port
- Oximetry port
- Bluetooth module

2.1.1. Charging controller for battery pack (IC7 LTC 4067)

The charging controlling circuit used in the **Spirodoc** ensures a charge and optimum condition of the battery pack providing that the battery temperature and voltage are within the preset limits. Temperature, voltage and time are all monitored throughout the charge process.

The charging process itself is automatically initiated in two situations:

1. After connecting the battery charger to the unit.
2. When the unit is switched on, the battery charger is connected and the voltage level of the battery is below a preset limit. In this situation the LCD indicates the low battery status with one line in the battery indicator.

The fast charging process is terminated by any of the following:

- Battery voltage out of range (Maximum/Minimum)
- Battery temperature out of range (Maximum/Minimum)
- Maximum charging time (timeout = 2h after the voltage arrives at the maximum value, 4.2 V)

Charging phases:

1. If everything is in order (battery temperature, temperature rising, battery voltage etc.) then the charging process starts and the display shows the following image in the upper right



2. At the end of the regular charging process, the display shows the following message:

Battery full

3. If after completing the charging process the battery charger is still connected, a so-called Pulse-Trickle-Function is activated that gives a very low charge to compensate the self-discharging of the battery while it is idle connected to the charger.

2.1.2. Room temperature sensor

(IC6) DALLAS DS 18B20 to measure the ambient (room) temperature to enable the calculation of the BTPS conversion factor.

2.1.3. USB communication port

Version 2.0.

2.1.4. Oximetry port

The connector beside the USB ports is used to connect the oximetry sensor, where this function is enabled on the device. Many sensors can be used on **spirodoc** based on the type of test to be performed and on the patient characteristics. The manufacturer provides the most frequently used sensor with the device, which has the following features:

mechanical part	finger
electrical part	two light emitting diodes (LEDs), one emits in the visible spectre and one infrared

Both lights then pass through the finger and are “read” by the receiver. As these lights pass through the finger, a proportion of the light is absorbed by the blood and by the soft tissue, in function of the concentration of heamoglobin. The quantity of light absorbed, at each frequency, depends on the degree of oxygenation of the haemoglobin inside the soft tissue.

2.2. DISPLAY MODULE

The display module shows patient data, user set parameters and test results. The display has the touch screen function. It is connected with:

- 20-pin flat-cable for digital connection (CON 12)
- 4 spring contacts for the display lamp (CON 7 and CON 8)
- 4 pin flat cable for touch controller (CON 2)

The touch controller (IC17) MAX 11800

The lamp controller (IC12) MAX 8822

2.3. TURBINE FLOWMETER

The sensor for measuring flow and volume is similar to the model already used in other spirometers produced by MIR (Series MIR 020 rev 5 Mod. **Spirobank II**, MIR024_REV2 Mod. **Spirobank G USB**).

The turbine flowmeter consists of one mechanical and two electrical parts:

Mechanical parts:

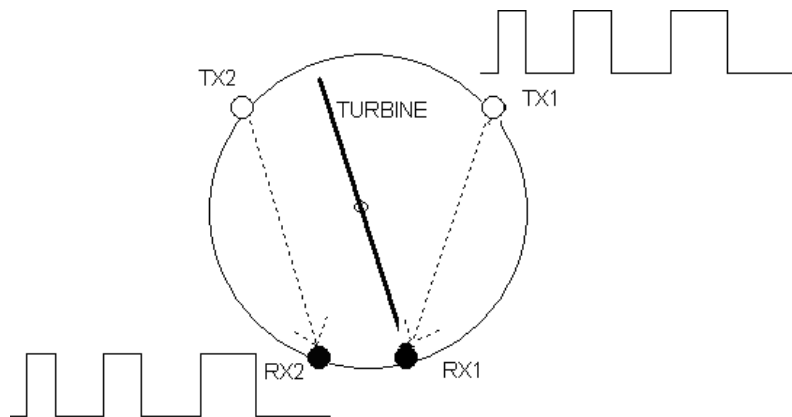
- turbine

Electrical parts:

- Two pairs of infrared transmitters/receivers positioned as shown below.
- A signal conditioning circuit to rectify the output signal from the two infrared light receivers.

The rotation of the rotor causes the interruption of the infrared beam, thus creating a pulse signal which has a frequency directly proportional to the flow.

The measurement of the air flow which passes through the tube is therefore proportional to the number of interruptions of the infrared beam.

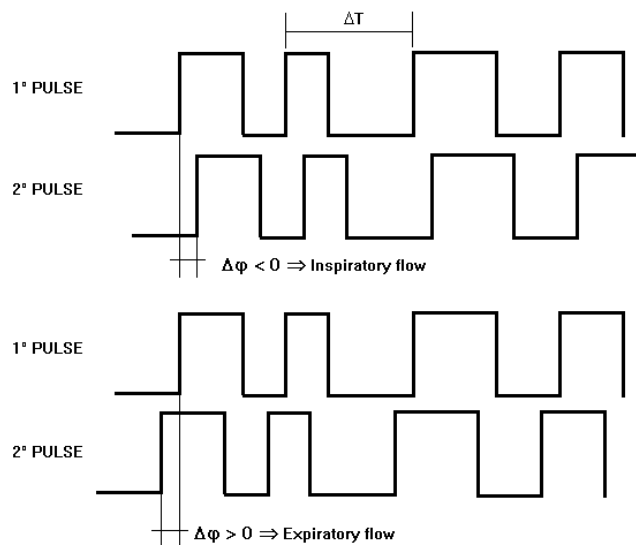


The phase difference $\Delta\phi$ (positive or negative) between the signals from each of the two infrared receivers (RX1 and RX2) depends upon the direction of rotation of the moving rotor and therefore supply the information of the direction of the air flow (expiration or inspiration).

In detail, $\Delta\phi > 0$ for expiratory flow, $\Delta\phi < 0$ for inspiratory flow.

The two pulse trains are squared by a Schmitt trigger (LMV932MM on MiniFlowmeter) and then sent to two input ports of the microprocessor (IC17 CP3BT26, pins 38 and 36).

The main microprocessor has the possibility to switch all the peripheral ports on or off, including the turbine.



$$\text{FLOW} = \frac{K}{\Delta T}$$

3. MAINTENANCE

3.1. GENERAL

We recommend checking the **spirodoc** on an annual basis.

For cleaning of the **spirodoc** and the accessories please see the User Manual.

3.2. TEST EQUIPMENT

For the repair and maintenance procedures of the **spirodoc** the following test equipment and accessories are required:

- Complete set of precision engineering tools (including 2.5 mm allen key and cross-screwdriver)
- Calibration syringe (3L is recommended)
- Case opener

- Digital multimeter, at least 3½ digits, accuracy better than 1%.
- Oscilloscope
- Digital Thermometer
- PC
- winspiroPRO Software Installation CD
- USB port connection cable
- Oximeter sensor (MIR code 919024_INV)
- Hot Glue Gun
- 3 mm double-sided adhesive tape
- Welder
- Signal cable (MIR code ZC017).

If a problem cannot be solved with the present equipment and suitable instruments are not available, please send the **spirodoc** to the manufacturer to carry out the service.

3.3. CHECKLIST

The following procedures must be carried out during an inspection and/or after every repair:

- Modifications, if any, must be noted on the “Service Info” sheets. See Appendix B of this manual for further information.
- Visual inspection. Check the electrical connection for safety and check that all components are properly fastened.
- Check that all accessories do not present any visible damage.
- Functional test (see Paragraph 3.3.1)
- File a copy of all service activities.

3.3.1. Functional test

3.3.1.1. Self test

Switch on the equipment. **spirodoc** will carry out the so-called self-test for approx 3 seconds. It is assumed that when the self-test is passed all functions of **spirodoc** are okay.

Any severe malfunction (if any) will be reported on the display.

Switch off **spirodoc**.

3.3.1.2. Software version

To check the software version installed on the device, switch on **spirodoc** pressing and releasing the power key placed in the middle on the side of the device, wait for the first screen to appear; the software version is found as indicated in the image alongside.



4. REPLACEMENT PROCEDURES

4.1. General

When handling sensitive static devices such as the mainboard of the **spirodoc** the following precautions should be observed:

- Persons should be earthed by means of a wrist strap.
- Ground all electrical equipment, workbench etc.

Also make sure that you have not left any tools inside and all screws including their washers are again fixed in the original place.

Note

Where not otherwise indicated, the reinstallation of a part is in reverse order of the removal procedure.

After every repair a functional test must be performed.



Caution

If any soldering (especially on SMD-parts) is to be made, make sure that your tools are suitable for such precision work.

4.2. Cover

The **spirodoc** case consists of several parts as illustrated in the image beside.

The display is housed inside its casing which is made up of two parts held together with three screws.

4.2.1. Opening the device

To open **spirodoc**:

1. Switch off the device and make sure that the turbine housing is removed from the main body of the device
2. Place the device on a flat surface with bottom part face-up
3. Remove the battery compartment cover using the case opener all around the perimeter to drop the clips and then remove the label  **SpO2**. Pay attention to not damage the plastic material.
4. Remove the battery pack by dropping the connector using a screwdriver or a tweezers
5. Completely remove the three screws using a screwdriver



3



4



5

6. Remove the lower case using the same method for the battery compartment cover; insert the case opener in the space between the white and the orange part and drop the clips. Pay attention to not damage the plastic material.
7. Remove the upper case with the same method described above; the upper case is attached with the reinforcement sheet.

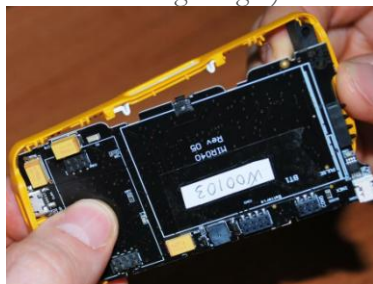


Caution

Pay attention to the display flat cables connected to the main PCB and passing through the reinforcement sheet.

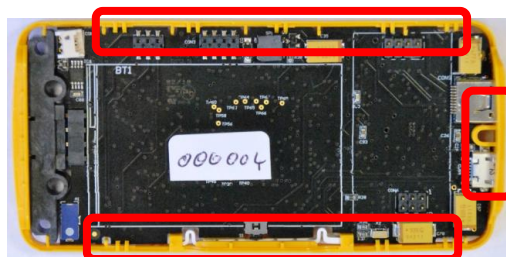
Disconnect the two cables from the PCB.

8. The PCB now is only inserted in the middle case (orange). To remove the PCB take the PCB with both hands and operate a horizontal movement to separate the case and the PCB (see the following images).

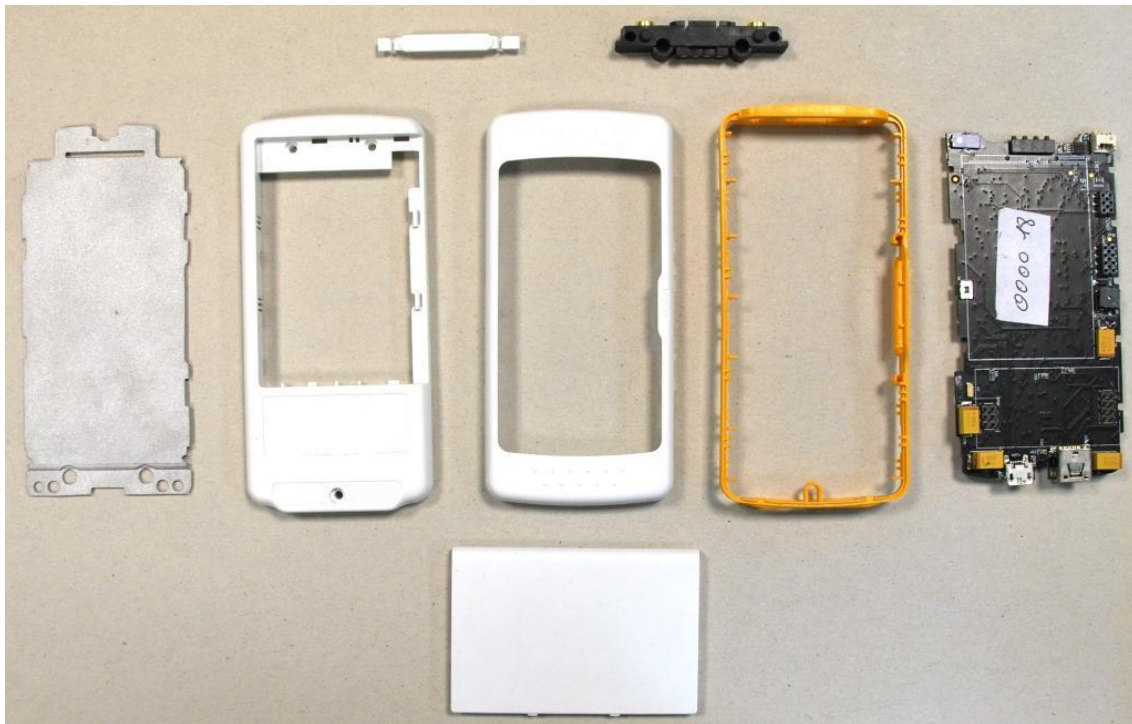


Caution

During this phase do not break the elements shown below



At the end we have the following parts disassembled of the device:



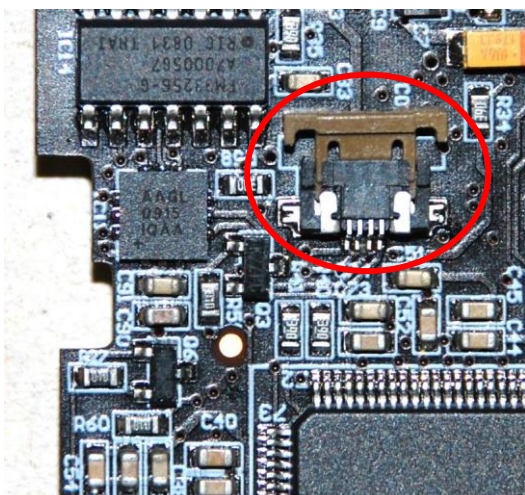
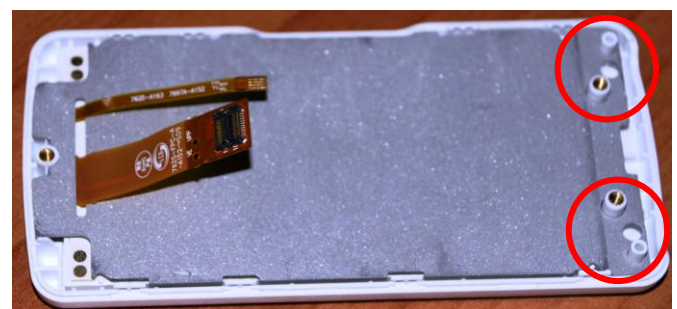
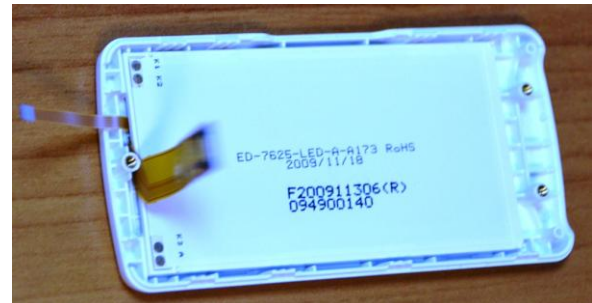
4.3. PCBs and components

4.3.1. Removing and replacing the display

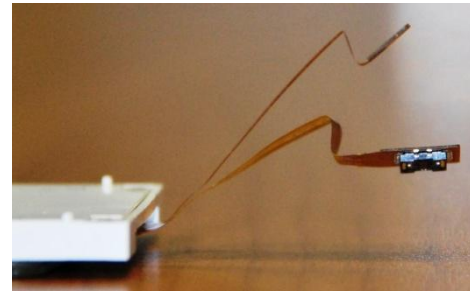
Open **spirodoc** as described in Paragraph 4.2.1; once the PCB is separated from the upper casing, remove the reinforcement sheet and the damaged display from the upper casing.

Then apply a new display in the correct position on the upper casing; apply again the reinforcement sheet. The position of this element is mandatory so check the correct housing as indicated in the image alongside.

Connect the two flat cables of the display to the PCB. First apply the square connector to CON 12: apply pressure with one finger until a click is heard; then apply the other connector to CON 2. After the connector is inserted then close the brown wings to block the connector.



Do not apply an excessive bend to the flats of the display near to the connector, as this could cause breakage or malfunction. The picture below shows an excessive bending:



At this time it is possible to close the device following the instruction described in point 4.2.1 in reverse order.

From may 2014 it is available a new spirodoc display with more high resolution. The new one shows the traffic light on the right side.

It is possible to replace the new one to the older, but it is mandatory to update the internal firmware for the correct working.

The new display has the following id code: 660580_HR

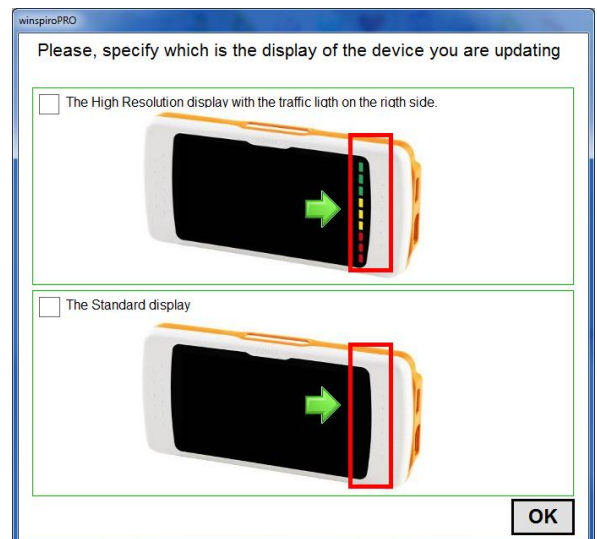
The new firmware version to update should be greater than or equal to ver. 3.0.

The winspiroPRO software version should be greater than or equal to ver. 5.7.4.

After replacing the new display on the device and closed it as described in point 4.2.1, than connect it to a PC where it is available a correct winspiroPRO version. Update the internal firmware as described in point 4.3.5. During this procedure choose a firmware to install with version greater than or equal to ver.3.0.

The software will recognize the display change on the device and will show a warning message as follow:

Choose what type of display is now on the device: the first one is the new high resolution display, and the second one is the old display. Check one of the square in the upper left corner and click on "OK". If the selection is right, then will start the upload procedure, else winspiroPRO will show a warning message for the incompatibility of hardware and firmware version.



4.3.2. Touch screen calibration

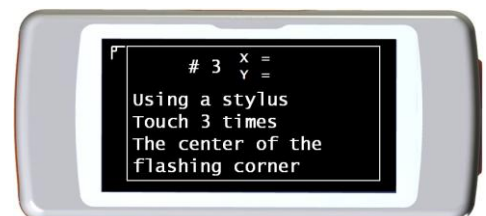
This function is used to check the proper response of the touch screen; the device initially request a confirmation, touching OK icon the calibration begin

There are four phases as follows:

- Touch three times the top left-hand point of the display
- Touch three times the top right-hand point
- Touch three times the bottom right hand point
- Touch three times the bottom right hand point

The reference area is the one inside the flashing outline.

This procedure will then be set up in function of the dimensions of the display.



This procedure must be carried out using the tip of a touch-screen "pointer" held vertically at 90 degrees to the display. if the calibration is made correctly then the device shows:

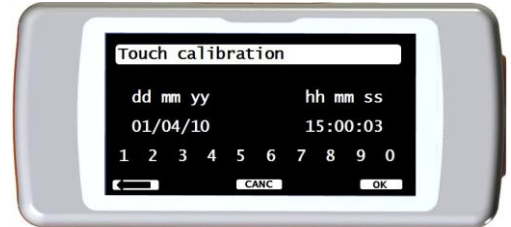
Calibration is OK

Otherwise, the user is requested to repeat the calibration procedure.

The procedure cannot be cancelled once started, so the user must carry perform the procedure correctly to return to the service menu.

In event the touch screen doesn't work correctly, it is possible to follow the following procedure to reset this function:

- Switch off the device pressing the ON/OFF key until the device is switched off.
- Now, open the device as described in point 4.2.1 in order to remove the battery pack.
- Press the ON/OFF key 3 or 4 times to discharge capacitors.
- Re-connect the battery pack.
- Close and switch on the device.
- The first display will appear as the screen on the right.
- Touch for at least 4 times the icon "touch calibration" at the top of the display and follow the directions; the procedure is the same described above. This procedure allows to enter in the touch calibration even if the display is not calibrated or broken.



4.3.3. Removing and replacing the internal battery pack

Open **spirodoc** as described in Paragraph 4.2.1 up to point 3.

Remove the battery pack, only after the device is switched off, by dropping the connector using a screwdriver or a tweezers.



Replace the battery with a new one.



Caution

Insert the connector in the correct position all the way to the stop. Do not force the connector. Place the cable of the battery bended as shown in the image above; the cable must be blocked between the battery and the upper casing.



Warning

Handle battery pack with care. Contact between battery poles with the circuit board can cause permanent damage to the circuit board itself.

Close the device as described in point 4.2.1.



Caution

Inserting the battery cover do not crush the battery cable.

Note

Batteries must be disposed of properly, according to the local regulations.

For proper use of the battery pack please read carefully the warning below.



WARNING

Use only battery packs supplied by MIR

Improper use of the battery pack may cause acid leakage, overheating, smoke, breakage, an explosion and/or fire. Consequently the battery pack may be damaged or suffer a drop in overall performance. The internal battery pack safety sensor could also be damaged as well by any of the above events. Furthermore the user of the device could be harmed and other nearby appliances could be damaged as well.

Please read the following instructions carefully.

DANGER

Do not disassemble or modify the battery pack. The battery pack comes with an internal safety sensor; which if tampered with may cause acid leakage, overheating, smoke, breakage, an explosion and/or fire.

Do not short-circuit the positive(+) and negative (-) poles with any metal objects.

Do not carry the battery pack in your pocket or in a bag with other metallic objects like necklaces, hairpins, coins or screws.

Do not store the battery pack near any such objects.

Do not warm-up or throw the battery pack in a fire.

Do not use or store the battery pack near a fire or in a vehicle where the temperature may reach 60°C or higher

Do not immerge the battery pack in water or salt-water, and do not leave it wet.

Such events may damage the internal battery safety sensor, thus causing the battery to be charged at a higher voltage, triggering abnormal chemical reactions leading to acid leakage, overheating, smoke, an explosion and/or fire

Do not charge the battery pack near a fire or in an extremely hot environment. High temperature may activate the internal battery safety sensor thus inhibiting the charge. The high temperature may also damage the internal battery safety sensor causing extremely high current surge; and consequently causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage, an explosion and/or fire.

Use only the battery charger supplied by MIR to recharge the battery pack. Recharging with an unsuitable charger in unconfirming conditions may cause the battery pack to overcharge or the charging current to be extremely high thus causing abnormal chemical reactions in the battery pack triggering acid leakage, overheating, smoke breakage an explosion and/or fire.

Do not puncture the battery pack with sharp objects such as a nail.

Do not hammer, step-on, throw or cause a forceful impact to the battery-pack.

A damaged or deformed battery pack may cause internal short-circuits thus creating the possibility for acid leakage, overheating, smoke, breakage and/or fire.

Do not use a heavily scratched or deformed battery back as this may be cause for acid leakage, overheating, smoke, breakage and/or fire.

Do not solder directly on the battery pack.

Do not mount the battery pack inside the device with the + and – poles inverted.

If the battery leads do not connect easily to the battery charger or to the device do not apply excessive force. Check to see that the leads are properly aligned. If the leads are inverted, an inverse polarity connection may provoke acid leakage, overheating, smoke, breakage and/or fire.

Do not connect the battery pack leads to a wall socket or to the car lighter. Under high voltage the battery may leak acid, overheat, emit smoke, explode and/or catch fire.

Do not use the battery pack for any other purpose other than those specified otherwise its features may be compromised, and its useful life reduced

If the battery acid inadvertently enters the eyes do not rub the eyes, instead wash the eyes with clean running water and call a doctor immediately.

WARNING

Do not leave the battery pack charging longer than the average charging length of time specified.

Do not place the battery in a micro-wave oven or in a pressurized container. Rapid overheating or loss of proofing may cause acid leakage, overheating, smoke, breakage and/or fire.

If the battery pack gives off a bad smell, if it generates heat, if it fades/deforms or if anything abnormal happens during storage, usage and recharging immediately remove the battery pack from the device or the battery charger and do not use it any longer, as any of these events may cause acid leakage, overheating, smoke, breakage and/or fire.

NOTE

The battery pack includes an internal safety protector. Do not use the battery pack where static electricity is present (higher than what is declared by the manufacturer).

If acid from the battery pack comes into contact with skin or clothing immediately wash with running water to avoid skin inflammation

Store the battery pack away from children's reach to avoid any accidental swallowing.

If a child uses the battery pack an adult must explain the proper use to the child.

Before using the battery pack read the manual carefully paying attention to all the recommendations for proper handling.

Please read the manual carefully to insert and remove of the battery pack in the device properly.

Before charging the battery pack read the manual carefully.

The battery pack life cycle is definite-. If you notice a much shorter time usage between charges please substitute the battery pack with a new one.

Remove the battery pack if its cycle life has expired.

When the battery pack has been removed from the device, ensure that the (+) and (-) leads have been isolated with electrical tape; to properly dispose of the battery pack please follow the local regulations or hand over the battery pack to a battery recycling centre.

Prior to storage or for long periods of disuse of the device remove the battery pack and store in a place where the temperature and humidity fall within specified ranges.

If the battery pack leads are dirty clean with a dry cloth prior to usage.

The battery pack can be charged within a temperature range between 0°C and approximately 40°C

The battery pack may be used within a temperature range between -20°C and approximately 60°C.

The battery pack may be stored within a temperature range between -20°C and approximately 60°C.

4.3.4. Turbine

There are two types of flow and volume measurement sensors used on **spirodoc**, single-patient disposable and reusable.

Note

The spirodoc turbine measurement system is calibrated in the factory and does not require any adjustments or calibrations.



Warning



Disposable Turbine



Reusable Turbine

If you are going to perform the spirometry test with a “single-patient” disposable turbine it is important to use a new turbine for every new patient. The characteristics, accuracy and the hygiene of the disposable turbine can only be guaranteed if it has been conserved beforehand in its original sealed packaging.

The disposable turbine is made of plastic and its disposal after use should adhere to the local authority guidelines / norms.

The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. If the turbine has not been cleaned sufficiently this could cause cross contamination from one patient to another. Periodic cleaning should only be done when the instrument is for personal use and will only be used by one patient. The cleaning of the turbine should be done following the guidelines in the User’s Manual.

The following information applies to both turbine models.

Do not expose the turbine to a direct jet of water or air, and avoid contact with high temperature liquids.

Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities (such as hair, sputum, threads etc.) within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

The turbines ensure high precision in measurements and have the great advantage of requiring no periodic calibration. In order to maintain the characteristics of the turbine a simple cleaning is required prior to each use (**only for the reusable turbine**). This operation will also guarantee perfect hygiene and the highest possible safety conditions for the patients.

Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

4.3.4.1. Cleaning the reusable turbine

Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

Turbine operation check:

- Turn on **SPIRODOC** and setup the device to perform a spirometry test (for example **FVC**).
- Hold the **SPIRODOC** with one hand and move it slowly sideways, having the air pass through the turbine.
- If the rotor spins properly the device will emit a series of acoustic signals “beeps”. The beeping frequency is a function of the air flow passing through the turbine.
- If no beeps are heard while moving the device, proceed to clean the turbine



CAUTION

Periodically check the inside of the turbine to ensure that there are no impurities, corpuscles, or any foreign matter like hairs which could inadvertently block or even slow down the mobile equipment in the turbine and as a consequence compromise spirometry measurement accuracy.

To clean the **reusable** turbine, first remove it by pulling it gently from the **spirodoc** turning it anti-clockwise and pressing lightly. It can be helpful to push it gently from underneath with one finger from the bottom of the turbine to lift it out of its housing.

Immerse the turbine in a cold liquid solution and move it within the liquid to remove any impurities which may be deposited inside. Leave the turbine immersed for the time specified in the instruction of the solution.

Rinse the turbine by immersing it in clean water (**not hot**).

Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

To ensure that the turbine is functioning correctly before replacing it inside the instrument, it is good practice to make a visual check of the rotation blade. Placing the turbine tube horizontally and moving it gently from left to right and vice versa, the rotation blade (rotor) must rotate freely. Otherwise, accurate measurement is no longer guaranteed and the turbine must be replaced.

Once the turbine has been cleaned insert the turbine tube in its place following the instructions indicated by the closed lock symbol printed on the plastic casing of the **spirodoc**.

To insert the turbine correctly push it and then turn it clockwise until it reaches the stop, which ensures that the tube has been blocked inside the casing.

4.3.4.2. Calibration of the reusable turbine

Only reusable turbines can be calibrated.

See instructions in the Calibration section of the User Manual of the device.

The turbines used on **spirodoc** do not require periodic calibration as they are already calibrated.

4.3.5. Internal software upgrade procedure

In order to upgrade the software winspiroPRO must already be installed and the PC must have an internet connection for downloading the upgrades and firmware of the **spirodoc** from www.spirometry.com.

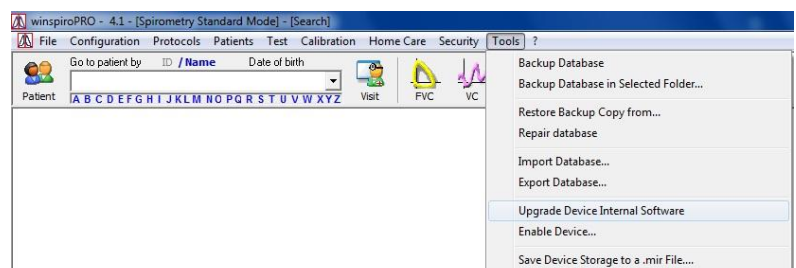
Launch winspiroPRO on the PC and connect **spirodoc** to the PC using the USB cable.

winspiroPRO can check the correct functioning of the USB port from the "options" menu; before downloading any newer releases make sure that the device is correctly connected to the PC software, the software will automatically recognize the device if it has already been connected to the PC and then carry out the following instructions.

To check the connection between the device and the PC, ensure that the led on the device is illuminated and check the correct functioning from the "options, communication" menu. On the display of **spirodoc** appears the following message:

External control

To download the new internal software version click on "Tools" menu, and then on "Upgrade Device Internal Software"



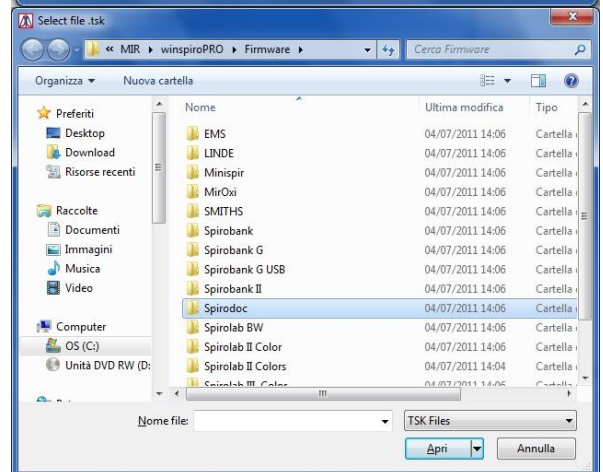
This wizard helps the user to select the method used to connect the device to the PC and then, with the “TEST” icon, the user can check the connection (see image).



Search for the .tsk file to be downloaded into the spirometer. Choose either auto-install or manual file search; browse system resources through list of folders, select .tsk file and then click on Next.



From the “Select file .tsk” search window select the firmware of your device; click on the **spirodoc** folder and then on the selected file to automatically launch the upgrading procedure of the internal software of the spirometer.



4.4. Oximeter module

To check the oximeter module used on the device, refer to Annex 4.

⚠ CAUTION

Make sure before operating on the oximetry module to switch off the device or disconnect the battery charger.

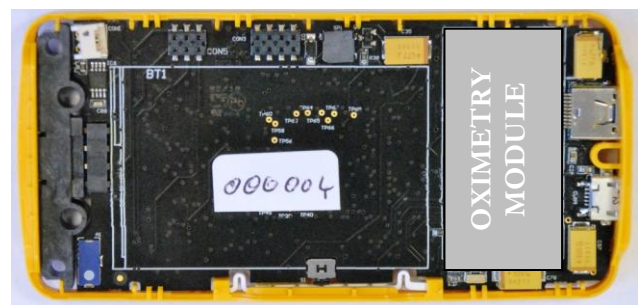
4.4.1. Replacing of the oximetry module

Open the device as described in point 4.2.1 up to point 6. The visible face of the PCB shows on the right the housing of the oximetry module.

Remove the oximetry module using the hand.

⚠ CAUTION

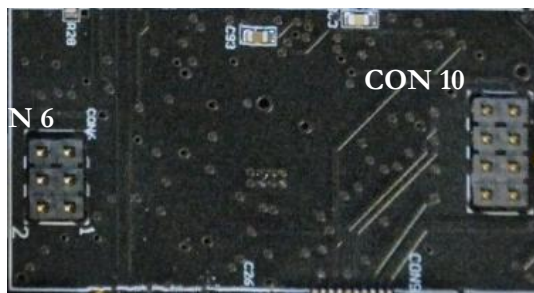
The module is fixed to the PCB so move gently until the module is completely removed.



Replace the oximetry module.

⚠ CAUTION

The two connectors on the PCB are different: CON10 has 8 pins, CON 6 has 6 pins. Pay attention to the correct position of the connector: all the pins must be inserted in the relative connector.



To attach the oximetry module to the PCB, it is recommended to apply an adhesive in the space between the PCB and the highest micro on the oximetry module (placed in the face not visible).
Close the device as in point 4.2.1 in reverse order.

4.5. Testing procedures

After making all repairs described in the previous paragraphs, correct functioning tests must be performed on both the Hardware and Software.

Devices with oximeter and devices without oximeter have their own specific testing procedures.

4.5.1. Testing procedures for devices with oximeter

The following checks must be carried out on each device:

Table 1

TESTS ON PCB MIR040 WITH OXIMETER

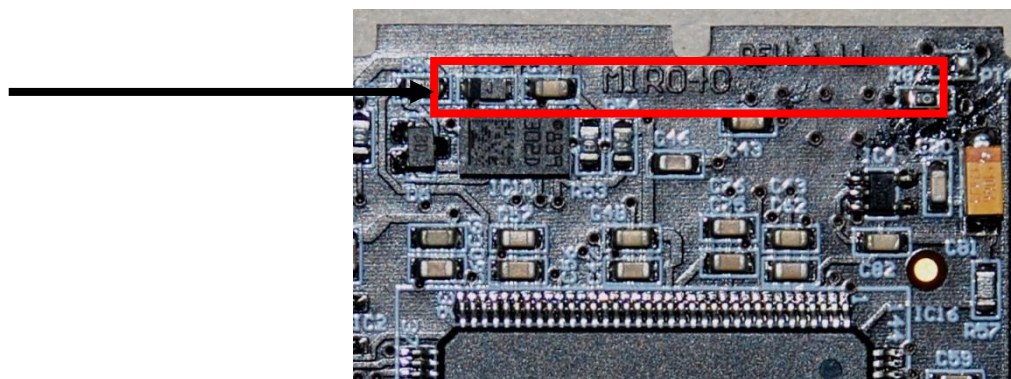
Test	Procedure	Test method	Instrument	Expected result
Blocking of oximetry module	Check that the oximetry module has been correctly applied	Visual	\	The doubled sided adhesives must be applied between the PCB and the greatest micro on the oximetry module
Battery pack connection to the PCB	Check correct procedure described in point 4.3.2	Visual	\	The battery pack must be completely connected and the cable must be bended as shown in image at point 4.3.2
Check display for scratches	Check the display	Visual	\	No scratches or creases must be present
Check display position	Check correct positioning of the display the upper casing	Visual	\	The display perimeter must be perfectly adjacent to the housing on the upper casing
Check the display flat cable	Check display flat cables and position of connectors on the PCB	Visual	\	The flat cables don't must be extremely bended and the connectors must be inserted in the corrected way
Check position of PCB MIR040 with the middle casing	Check that the PCB is placed correctly	Visual/ Quantitative	\	The teeth on the orange casing must be inserted in the special housings on the PCB
Check device is closed properly	Check the coupling of the three parts of casing	Visual/ Quantitative	\	Upper, middle and lower casing, after the closing of the device, must not have open points on the entire perimeter

CHECKS ON MAIN CASING OF THE ASSEMBLED DEVICE

Table 2

Test	Procedure	Test method	Instrument	Expected results
Temperature	Check that the temperature corresponds to the BTPS*	Instrument	Thermometer	Temperature equal to thermometer reading ± 1 °C
Date and time	Set time and date (see User Manual)	Visual/ Quantitative	\	The set parameters must remain as configured
Bluetooth	Carry out search for enabled devices	Visual	\	Device list is not empty
Auto-off	Set timer at 6 minutes and leave device on	Visual	\	After 6 minutes the device switches off
Display	Switch on the device and check screen shots	Visual	\	All pixels must work correctly

* The BTPS appears on the display during a spirometry test as shown below:



TESTS TO PERFORM AFTER POSITIVE RESULTS ARE OBTAINED FROM PREVIOUS TESTS

SPIROMETRY TEST

This test must be carried out as follows:

- Measure the ambient temperature using a digital thermometer and check that the BTPS value corresponds to the value in Table 3, the same temperature in the testing room.
- Fill in the FIVC nom (L) (min and max) fields of the SPIROMETRY TEST (Annex 1), min and max nominal values of current BTPS, from Table 3 below.
- Check that the stop of the 3 L calibration syringe is at “3.0”.
- Move the piston of the syringe so that the “0.0” of the calibrated shaft is positioned with the shaft exit.
- Connect the device with a mouthpiece to the calibration syringe.
- Make the FVC test.
- Push the piston at a constant rate until the “3.0” of the calibrated shaft is positioned with the shaft exit.
- Pull back the piston at the same rate as at letter (f) until the “0.0” of the calibrated shaft is positioned with the shaft exit.
- Push the piston until the “1.0” of the calibrated shaft is positioned with the shaft exit (0.5 L tolerance limit).
- Read the FVC, FIVC and 2575 measured values to enter the FVC, FIVC measured values in the proper field of the SPIROMETRY TEST (Annex 1 of this Manual).
- If the values given by the device are not within the set min and max volumes, analyze and resolve the problem, if there is no solution then the product must be identified as nonconforming.

At the end of the tests, the table contained in Annex 1 shall be completed.

The FVC (L) (min and max) nominal values contained in the SPIROMETRY TEST (Annex 1) are already inserted because the BTPS expiration factor is constant and equal to 1.026 (corresponding to 37°C, that is, the average body temperature).

At the end of the tests, where there are no negative results, the device is identified as conforming and can be returned to the user.

OXIMETRY TEST

This test must be performed using the following instruments:

- Device used to simulate oxygen saturation
- The device to be tested
- The device cable

The testing procedure is as follows:

- Connect the sensor cable to the MIR device using the proper connector.
- Connect the sensor to the oximetry simulator ensuring the correct positioning as shown in the following image.
- Set the oximetry value on the simulator at 85% and BPM at 40.
- Launch the oximetry test on the MIR device (see User Manual).
- Read the value given by the **spirodoc** (it must be between 83 and 87%).

TEMPERATURA AMBIENTE (C°)	BTPS	FIVC nominale	FIVC min	FIVC max
10	1,160	3,48	3,36	3,60
11	1,550	3,46	3,34	3,58
12	1,151	3,45	3,33	3,57
13	1,147	3,44	3,32	3,56
14	1,142	3,42	3,30	3,54
15	1,138	3,41	3,29	3,53
16	1,133	3,39	3,27	3,51
17	1,129	3,38	3,26	3,50
18	1,240	3,37	3,25	3,49
19	1,120	3,36	3,24	3,48
20	1,115	3,34	3,22	3,46
21	1,111	3,33	3,21	3,45
22	1,106	3,31	3,19	3,43
23	1,101	3,3	3,18	3,42
24	1,097	3,29	3,17	3,41
25	1,092	3,27	3,16	3,38
26	1,087	3,26	3,15	3,37
27	1,082	3,24	3,13	3,35
28	1,078	3,23	3,12	3,34
29	1,073	3,21	3,10	3,32
30	1,068	3,2	3,09	3,31
31	1,063	3,18	3,07	3,29
32	1,058	3,17	3,06	3,28
33	1,053	3,15	3,04	3,26
34	1,048	3,14	3,03	3,25
35	1,043	3,12	3,01	3,23
36	1,038	3,11	3,00	3,22
37	1,033	3,09	2,98	3,20
38	1,028	3,08	2,97	3,19
39	1,023	3,07	2,96	3,18
40	1,018	3,06	2,95	3,17

Table 3

FIVC min/max values, temperature or BTPS function

- f) Read the heart beat rate on the MIR device (it must be between 38 and 42).
- g) Enter the given values in the proper spaces on Annex 1 to this Manual.
- h) Repeat the same procedure for the saturation level set on the simulator at 95% and PBM at 80.
- i) Read the value given by the **spirodoc** (it must be between 93 and 97%).
- j) Read the heart beat rate on the **spirodoc** (it must be between 78 e 82).
- k) Enter the given values in the proper spaces on Annex 1 to this Manual.

If the values of both tests are within the preset range, the sensor passes the checks and can be given to the user together with the device, otherwise it is nonconforming and should be subject to further tests.



4.5.2. Testing procedures for devices without oximeter

The following checks must be carried out on each device:

Table 4

TESTS ON PCB MIR040 WITHOUT OXIMETER

Test	Procedure	Test method	Instrument	Expected result
Battery pack connection to the PCB	Check correct procedure described in point 4.3.2	Visual	\	The battery pack must be completely connected and the cable must be bended as shown in image at point 4.3.2
Check display for scratches	Check the display	Visual	\	No scratches or creases must be present
Check display position	Check correct positioning of the display the upper casing	Visual	\	The display perimeter must be perfectly adjacent to the housing on the upper casing
Check the display flat cable	Check display flat cables and position of connectors on the PCB	Visual	\	The flat cables don't must be extremely bended and the connectors must be inserted in the corrected way
Check position of PCB MIR040 with the middle casing	Check that the PCB is placed correctly	Visual/ Quantitative	\	The teeth on the orange casing must be inserted in the special housings on the PCB
Check device is closed properly	Check the coupling of the three parts of casing	Visual/ Quantitative	\	Upper, middle and lower casing, after the closing of the device, must not have open points i the entire perimeter

CHECKS ON MAIN CASING OF THE ASSEMBLED MACHINE

Repeat the same tests described in Table 2.

TESTS TO PERFORM AFTER POSITIVE RESULTS OBTAINED FROM PREVIOUS TESTS

SPIROMETRY TEST

Follow the instruction described at page 23. In this case to report the values obtained, use the form in annex 2.

At the end of the tests, where there are no negative results, the device is identified as conforming and can be returned to the user.

5. SPARE PARTS

This chapter deals with placing orders for spare parts (see appendix A) as well as the listing of actual spare parts (appendix A, spare parts list).

5.1. ORDERING

Spare parts can only be ordered if the following data is supplied:

- Part number
- Description
- Quantity
- Shipping details (Incoterms)

The required data is mentioned in Appendix A. For the current parts list please refer to the spare parts price list which is published every year.

MIR only supplies parts mentioned in Appendix A. Standard parts such as screws, nuts, cleaning agents and so on are not supplied by MIR, these parts must be purchased locally.

5.2. DELIVERY

5.2.1. Ordering PCB's

Printed circuit boards are only obtainable as spare part in their latest version. Consult the technical documentation for instructions of how to modify the latest version of the PCB for use in older versions of the equipment.

5.2.2. Warranty claims

Warranty claims must be provided with the MIR invoice number, the type of products and serial number of the equipment in question. The defective item must be returned back to MIR. The customer is responsible for the transportation and for all transport and customs charges for the delivery of the goods both to and from the service centre.

The customer must inform MIR about the substitution of a PCB. For the correct traceability the manufacturer must maintain the history of a single device during its life.

5.3. RETURN SHIPMENTS

Any instrument or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found.

If units are to be returned to MIR then a written or verbal permission (RAN - Return Authorization Number) must be received before any instrument is returned to MIR.

The unit must be returned in its original packaging.

MIR reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.

Note

Any instrument of accessory returned must be accompanied by a clear and detailed explanation of the defect or issue found.

6. TROUBLESHOOTING

Note

Where not indicated, voltages are measured versus the ground (i.e. the negative pole of the battery pack).

Where not indicated, voltages are measured while the unit is switched on.

Where not indicated, the values to be measured can vary by about 2%.



WARNING

Be careful not to short-circuit any contacts while measuring voltages.

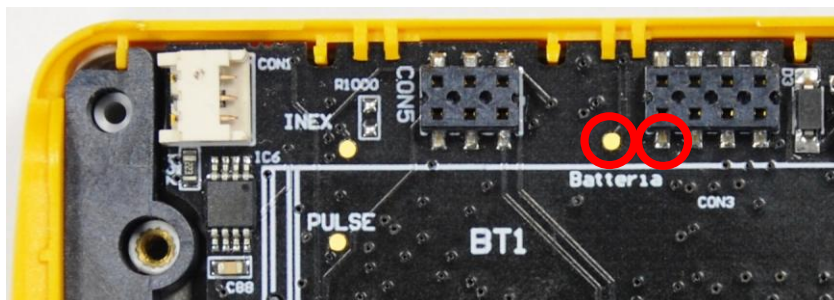
Batteries may explode if defective or damaged or disposed of in fire.

Do not short-circuit the batteries!

6.1. The device does not switch on

☒ Check the voltage of the internal battery pack.

- Open the **spirodoc** (see paragraph 4.2.1)
- Measure the voltage between the point shown in the following image near the battery pack connector:



The value must be between 2,7 V (battery low) and 4,2 V (battery full). If the Voltage is under 2,5 V the battery is compromised and must be replaced.

If the device is connected to the battery charger or via USB and the battery pack is disconnected or compromised, the display shows the message:

Battery failure

☒ If the battery charger is connected:

Check the battery charger:

- Make sure that the connector is fully inserted to the plug.
- Check the cable for visible damage.

☒ Recharge battery pack

- Connect power cable to the device using the micro USB connector
- Check that the device turns on
- Check that the battery indicator on the display shows the correct charging phase
- When the charging is completed the battery indicator on the display stops blinking

6.2. The LCD does not display

- ☑ Check that the two flat connectors of the display are integral:
 - Open the spirodoc (see Paragraph 4.2.1)
 - Check that the two connector are fully connected to the PCB
 - Check that the flats are integral and not excessively bent.

6.3. The battery pack is not working correctly

- ☑ Check the battery charger
 - Make sure that the main power supply's connector is correctly attached to the plug.
 - Check the cable for visible damage.
- ☑ Check the internal power supply
 - Open the **spirodoc** (see Paragraph 4.2.1).
 - Measure the voltage at the output of the battery pack. It must be approximately between 3 V and 4,2 V.

6.4. The Bluetooth printer does not print

- ☑ Ensure that the printer is switched on
- ☑ Check that the Bluetooth system is installed and enabled on the printer
- ☑ Check that the printer appears on the list of enabled printers
 - Switch on **spirodoc**
 - Enter the service menu, "Bluetooth settings"
 - Select "options printer" and check if the printer is inserted in the list as default, otherwise search for enabled printers and set it in the list of printers
- ☑ Check if the devices is provided with the Bluetooth function or not
 - Check the internal software version the correct version must be 1.8 or higher
 - If the version less than 1.8 , upgrade the software following the instruction on point 4.3.4 of this manual
 - Disconnect the device from the PC
 - Switch off the device
 - Switch on the device
 - Wait for the first screen

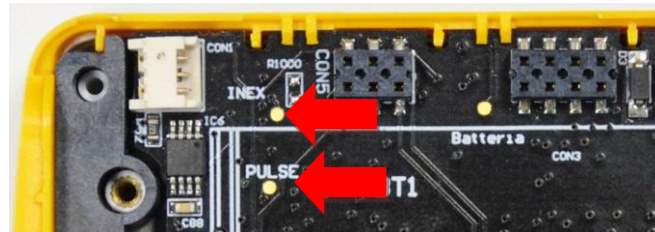


In the part pointed out in the above image it is possible to check if the device is provided with the Bluetooth function or not.

6.5. The device does not measure spirometry at all

- ☑ Check if any obstacle is blocking the free rotation of the turbine
- ☑ For information about maintenance cleaning please refer to paragraph 4.3.3 of this manual.
- ☑ The VC and MVV tests does not measure
 - Control if in service menu the standard is set up on NANHES III, in this case the VC and MVV tests does not work; thus set standard on ATS/ERS to make VC and MVV tests work

- Control if in service menu the spirometry parameters are set on “simplified”; in this setting is not possible to make VC and MVV tests
- Choose “Personal” or “Complete” to visualize all the parameters and then perform VC and MVV tests
- ☑ Check the signal using the test points shown below:



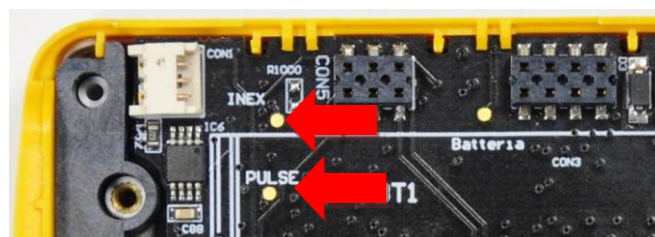
The signal measured with an oscilloscope must be a square wave with amplitude more than 2 V.

6.6. The device does not measure spirometry correctly

- ☑ Check if any obstacle is disturbing the free rotation of the turbine.
- ☑ For information about maintenance cleaning please refer to the paragraph 4.3.3 of this manual.
- ☑ Check the accuracy with the calibration syringe.
 - Make several tests FVC at different in/expiration speeds.
 - Check the measured volume. It may differ $\pm 3\%$ or 50 ml, depending on which value is bigger (i.e. using a 3000-ml-syringe, the measured valued must be between 2910 and 3090 ml, using a 1000-ml-syringe, between 950 and 1050 ml)

Check if a calibration has been made and if necessary recalibrate to original setting (see section Turbine Calibration in the User Manual).

- ☑ Check the signal using the test points showed below:



The signal measured with an oscilloscope must be a square wave with amplitude more than 2 V.

6.7. The device does not measure oximetry at all

- ☑ Check if the devices is provided with the oximetry function or not
 - Check the internal software version the correct version must be 1.8 or higher
 - If the version less than 1.8 , upgrade the software following the instruction on point 4.3.4 of this manual
 - Disconnect the device from the PC
 - Switch off the device
 - Switch on the device
 - Wait for the first screen



In the part pointed out in the previous image it is possible to check if the device is provided with the oximetry function or not.

6.8. The device does not measure oximetry correctly

- ☒ Check the correct connection of the sensor
 - The connector must be fully inserted in the plug
 - Check if there is any damage on the cable connector
 - Check the correct position of the sensor on the patient, see section regarding the oximetry tests on the user manual

6.9. The data communication via USB does not function

- ☒ Check the cables, if there is any visible damage.
 - Replace the cable
 - If after changing the cable the problem persists, then send the device to the manufacturer
- ☒ Verify the correct installation of the winspiroPRO software
 - Check the winspiroPRO USB connection: from menu “Configuration”, “Options”, “Communication”
 - Check that the driver is installed in the following folder:

C:\MIR\winspiroPRO\Drivers\MIR USB drivers\WinVista-Win7

if the driver is not installed then it can be obtained from the manufacturer or downloaded from: www.spirometry.com. Then copy into the above-mentioned folder.

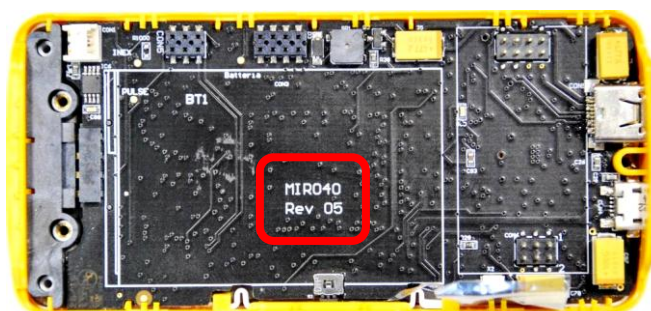
- If the problem persists contact the manufacturer.

6.10. Index of components

To simplify component identification they are marked in the attached drawing of the components layout of the Printed Circuit Board (PCB) MIR 040.

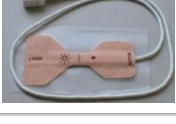
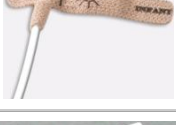
See Appendix C for more information on the component name and description.

The revision of the PCB is indicated where highlighted in red below:



APPENDIX A: SPARE PARTS LIST

Picture	Code Group Description	Pack q.ty
	970085 Battery Rechargeable battery pack	1
	920685 Battery Battery charger 100 V – 240 V/50 – 60 Hz	1
	890610 Board Mother board complete without Micro power Oximeter board (OXY Module)	1
	919002 Board Micro power oximeter board (OXY Module)	1
	919002_BO Board Micro power oximeter board (OXY Module)	1
	532367 Cable Micro USB cable for the PC connection	1
	301062 Case White case lower part	1
	301060 Case White case upper part	1
	301061 Case Orange plastic frame middle part	1
	301063 Case White door for battery compartment	1
	301064 Case ON/OFF switch	1
	910302 Consumable Disposable Bacterial/Viral filter, singularly packed	Box of 50

Picture	Code Group Description	Pack q.ty
	910300 Consumable Disposable paper adult mouthpiece, external diameter: 30 mm	Box of 100
	910310 Consumable Reusable plastic pediatric mouthpiece	Box of 15
	910320 Consumable Plastic noseclip	Bag of 10
	910700 Detergent solution PeraSafe detergent solution (162g) (makes up to 10 litres of solution) with dosimeter	Box of 5
	660580_HD Display Touch screen display with high resolution	1
	900604 Flowmeter Spiro detachable head without turbine flowmeter	1
	919013 Oximetry Sensor Pediatric disposable oximetry finger sensor, 10 pcs/box to be used with extension cable 919200_INV or 919210_INV	10 pcs
	919025 Oximetry sensor Pediatric reusable oximeter sensor finger probe	1
	919007 Oximetry Sensor Adult disposable oximetry finger sensor, to be used with extension cable 919200_INV or 919210_INV	10 pcs
	919006 Oximetry Sensor Neonate disposable oximetry finger sensor, to be used with extension cable 919200_INV or 919210_INV	10 pcs
	919003 Oximetry Sensor Infant disposable oximetry finger sensor, to be used with extension cable 919200_INV or 919210_INV	10 pcs
	919015 Oximetry Sensor Universal "Y" reusable oximetry Sensor to be used with extension cable 919200_INV or 919210_INV	1

Picture	Code Group Description	Pack q.ty
	919005 Oximetry sensor Neonatal wrap reusable oximeter sensor finger probe with extension cable	1
	919014 Oximetry sensor Neonatal wrap reusable oximeter sensor (without extension cable) to be used with extension cable 919200_INV or 919210_INV	1
	919011 Oximetry posey wrap (Original BCI-REF.3138) NEONATE-INFANT to be used with BCI reusable wrap sensors REF.3026/3025/3043	1
	919024_INV Oximetry sensor Adults reusable oximeter soft sensor finger probe	1
	919200_INV Oximetry sensor Extension cable to use with BCI standard fingers probe (150 cm)	1
	919210_INV Oximetry sensor Extension cable to use with BCI standard fingers probe (50 cm)	1
	919028 Ear oximetry sensor Reusable adult ear oximetry sensor	1
	919088 Belt for spirodoc Belt including device holder	1
	919000 Syringe Calibration syringe, 3 litres	1
	910004 Turbine Disposable Turbine with Cardboard Mouthpiece	4 boxes of 50
	910002 Reusable turbine NEW Reusable Turbine flow meter with mesh	1

APPENDIX B: SERVICE INFO'S (Product Change Notes)

General

The technical information in the service manuals of MIR srl is up to date at the date of issue.

Necessary additional information (of any kind) will be provided in the following way:

- as supplements to the manual, or
- as revised editions (chapters) of the manual, or
- as Service Info (product change notes).

When a supplement or a revision is made to the manual, a "document history file" is added to this chapter. This file will give information about the date of issue of supplements or revisions.

APPENDIX C

List of Components - spirodoc oxy

Code	Description	Identification on the PCB MIR040
340170	Antenna Bluetooth 431111500245	A1
560023	Buzzer SMD 5x5 3h mm SMT-G5030A Kepo	SP1
831746_0603	Capacitor CER SMD 0603 16V X7R 0,1u	C4, C20, C21, C22, C28, C29, C33, C34, C43, C48, C51, C55, C61, C63, C65, C67, C70, C72, C74, C79, C82, C84, C87, C88, C91, C98
831739_0603	Capacitor CER SMD 0603 16V X7R 10nF	C77, C80
832150_0603	Capacitor CER SMD 0603 16V X7R 1u	C6, C23, C25, C26, C83, C85, C93, C95, C96, C90
831708_0603	Capacitor CER SMD 0603 16V X7R 22p	C37, C42, Ct2
832150_0603_25	Capacitor CER SMD 0603 25V X5R 1u C0603C105K3PAC	C94
831728_0603	Capacitor CER SMD 0603 50V X7R 470p	C75
831715_0603	Capacitor CER SMD 0603 50V X7R 5 % 68p	Ct1
820770_0603	Capacitor CER SMD 0603 50V X7R 15p	C17, C18, C36, C41
832115_0603	Capacitor CER SMD 0603 50V X7R 2.7nF	C39, C44, C49, C56, C58
832135_0603	Capacitor CER SMD 0603 50V X7R 22nF	C9, C10, C11, C12, C13, C19
832137_0603	Capacitor CER SMD 0603 50V X7R 33nF	C38, C45, C47, C50, C54, C57, C59, C60, C62, C64, C66, C69, C71, C73
832145_0603	Capacitor CER SMD 0603 6V3 2u2 X5R	C27, C40, C52, C76
832146_0603	Capacitor CER SMD 0603 6V3 4u7 X5R	C24, C46, C53, C68
832145	Capacitor CER SMD 0805 16V 2u2 X7R	C8, C14
810074_0603	Capacitor TANT SMD 0603 6V3 20% 10uF	C7, C86
810037_CA	Capacitor TANT SMD A 6,3V 20% 47u 3.2x1.6 H1.6	C5
810074_CA_10	Capacitor TANT SMD CASE A 10 V 10% 10 uF	C3, C31, C81
810072_0603_10	Capacitor TANT SMD CASE L 10V 10% 4,7uF	C30
810068_0603_10	Capacitor TANT SMD CASE P 10V 20% 1uF Nichicon	C2, C32
810074_R	Capacitor TANT SMD CASE R 6,3V 20% 10u	C89
810095	Capacitor TANT SMD E 10V 470uF	C1
810090	Capacitor TANT SMD E 4V 1000uF LOW ESR	C78, C97
810096	Capacitor TANT SMD Y 6V3 470uF	C35
125002	Connettore 3pin MLX530480310 Molex	CON1
130006	Connettore 4 x 2 pin dual row passo 2.0mm	CON3
125001	Connettore 5 pin micro USB AB Molex 47589-001	CON4
130009	Connettore 6 pin dual row passo 2.0mm	CON6
130011	Connettore 8 pin dual row passo 2.0mm	CON10
111541	Connettore a molla SMT 2,54mm 2 pin PRECI-DIP 811-SS-002-30-008101	CON7, CON8
123706	Connettore FCI 4 pin ZIF-SMD SFV4R1STE1	CON2
124005	Connettore MINI HDMI-10PIN (F)	CON9
111547	Connettore MIR001_4_Mollette	CON11
123708	Connettore PANASONIC 20 pin SMD AXK8L20125B	CON12
130014	Connettore Samtec CLT-103-02-G-D-TR	CON5
602634	Diodo 1N4148W SMD package SOD 123	D3
600060	Diodo RB715 SMD 2/3 A UMD	D1, D6
602635	Diodo RB751 SMD DSM	D4, D5

Code	Description	Identification on the PCB MIR040
351302	Filtro LC x RF 2450 MHz SOSHIN - MDR741F taping	L4
330024	Induttanza 10 uH +/-20% 4x4mm	L2, L3
648030	Integrato 74HC74PW SMD D flip flop TSSOP	IC1
648183	Integrato BC57G687C-INN-E4 CSR BC5	IC13
648392	Integrato FLASH NUMONYX NUMM28W320FCB70N6E 32MX16 TSOP-1 48	IC15
640835	Integrato Linear LTC3531ES6-3.3 R.T.3.3V S6 Package	IC8, IC9
649340	Integrato LMV932MM 8 pin MSOP oper.ampl.	IC5
647555	Integrato LTC4067EDE battery charger SMD 4x3mm DFN	IC7
644935	Integrato MAX 4715EXK-T/S	IC3, IC4
647235	Integrato MAX 8822ETE+ 16 THIN QFN-EP*	IC12
647218	Integrato MAX11800ETC+	IC17
645424	Integrato MAX9119 SMD SC70 5 pin operativo	IC11
648395	Integrato memoria FM33256 SO14 3V Memory	IC14
648179	Integrato microprocessore AT32UC3A0512 ATMEL	IC16
640825	Integrato S812C25AMCCFT2 regolatore 2.5V Seiko	IC2
450130	PCB MIR040 rev5	Mir040_rev5
680519	Quarzo 7M12000137 12,00000MHz 3,2x2,5	Y1
680216	Quarzo CX3225SB (CX-101F) 26 MHz 3.2x2.5mm 7ppm 19pF CL KYOCERA	X1
680400	Quarzo SMD 32,768KHz Q13FC1353276800 Epson	X2, X3
712642_1_0603	Resistenza SMD 00603 0,1W 1% 220	R45
712600_1_0603	Resistenza SMD 0603 0,1W 1% 0	R8, R20, R21
712708_1_0603	Resistenza SMD 0603 0,1W 1% 100K	R12, R14, R15, R22, R23, R27, R28, R47, R50, R59, R60, R63
712710_1_0603	Resistenza SMD 0603 0,1W 1% 120K	R42, R43, R56
712686_1_0603	Resistenza SMD 0603 0,1W 1% 12K	R1
712604_1_0603	Resistenza SMD 0603 0,1W 1% 2,2R	R18, R19
712716_1_0603	Resistenza SMD 0603 0,1W 1% 220K	R44, R49
712692_1_0603	Resistenza SMD 0603 0,1W 1% 22K	R51, R52
712717_1_0603	Resistenza SMD 0603 0,1W 1% 249K	R24, R26, R34, R35, R57, R62, R10, R11, R58
712669_1_0603	Resistenza SMD 0603 0,1W 1% 2K94	R9
712783_1_0603	Resistenza SMD 0603 0,1W 1% 2M	R29
712620_1_0603	Resistenza SMD 0603 0,1W 1% 39R	R40, R41
712684_0603	Resistenza SMD 0603 0,1W 5% 10K	R7, R39, R53, R54
712784_0603	Resistenza SMD 0603 0,1W 5% 10M	R30
712660_0603	Resistenza SMD 0603 0,1W 5% 1K	R38
712668_0603	Resistenza SMD 0603 0,1W 5% 2K2	R5
712676_0603	Resistenza SMD 0603 0,1W 5% 4K7	R2, R3, R4, R6, R13, R16, R17, R31, R32, R46, R48, R55
641530	Sensore DS18B20U sensore di temperatura	IC6
641535	Sensore SMD LIS302DLTR accelerometro triaxial	IC10
210856	Switch PTCF-V-T/R DIPTRONICS	S1
612080	Transistor MMST2222A SMD SOT 23 (SC59)	Q5
612081	Transistor SI1305DL-T1 Vishay CMOS	Q1
612082	Transistor SI2302CDS-T1-GE3 Vishay MOSFET	Q2, Q3, Q4, Q6, Q7

List of Components - spirodoc without oxy

Code	Description	Identification on the PCB MIR040
560023	Buzzer SMD 5x5 3h mm SMT-G5030A Kepo	SP1
831746_0603	Capacitor CER SMD 0603 16V X7R 0,1u	C4, C20, C21, C22, C28, C29, C33, C34, C43, C48, C51, C55, C61, C63, C65, C67, C70, C72, C74, C82, C84, C87, C88, C91
831739_0603	Capacitor CER SMD 0603 16V X7R 10nF	C80
832150_0603	Capacitor CER SMD 0603 16V X7R 1u	C6, C23, C25, C26, C83, C85, C93, C95, C96, C90
831708_0603	Capacitor CER SMD 0603 16V X7R 22p	C37, C42
832150_0603_25	Capacitor CER SMD 0603 25V X5R 1u C0603C105K3PAC	C94
831728_0603	Capacitor CER SMD 0603 50V X7R 470p	C75
820770_0603	Capacitor CER SMD 0603 50V X7R 15p	C36, C41
832115_0603	Capacitor CER SMD 0603 50V X7R 2.7nF	C39, C44, C49, C56, C58
832137_0603	Capacitor CER SMD 0603 50V X7R 33nF	C38, C45, C47, C50, C54, C57, C59, C60, C62, C64, C66, C69, C71, C73
832145_0603	Capacitor CER SMD 0603 6V3 2u2 X5R	C27, C40, C52, C76
832146_0603	Capacitor CER SMD 0603 6V3 4u7 X5R	C24, C46, C53, C68
810074_0603	Capacitor TANT SMD 0603 6V3 20% 10uF	C7, C86
810074_CA_10	Capacitor TANT SMD CASE A 10 V 10% 10 uF	C3, C31, C81
810072_0603_10	Capacitor TANT SMD CASE L 10V 10% 4,7uF	C30
810068_0603_10	Capacitor TANT SMD CASE P 10V 20% 1uF Nichicon	C2, C32
810095	Capacitor TANT SMD E 10V 470uF	C1
810096	Capacitor TANT SMD Y 6V3 470uF	C35
125002	Connettore 3pin MLX530480310 Molex	CON1
130006	Connettore 4 x 2 pin dual row passo 2.0mm	CON3
125001	Connettore 5 pin micro USB AB Molex 47589-001	CON4
111541	Connettore a molla SMT 2,54mm 2 pin PRECI-DIP 811-SS-002-30-008101	CON7, CON8
123706	Connettore FCI 4 pin ZIF-SMD SFV4R1STE1	CON2
124005	Connettore MINI HDMI-10PIN (F)	CON9
111547	Connettore MIR001_4_Mollette	CON11
123708	Connettore PANASONIC 20 pin SMD AXK8L20125B	CON12
602634	Diodo 1N4148W SMD package SOD 123	D3
600060	Diodo RB715 SMD 2/3 A UMD	D1, D6
602635	Diodo RB751 SMD DSM	D4, D5
330024	Induttanza 10 uH +/-20% 4x4mm	L3
648030	Integrato 74HC74PW SMD D flip flop TSSOP	IC1
648392	Integrato FLASH NUMONYX NUMM28W320FCB70N6E 32MX16 TSOP-1 48	IC15
640835	Integrato Linear LTC3531ES6-3.3 R.T.3.3V S6 Package	IC9
649340	Integrato LMV932MM 8 pin MSOP oper.ampl.	IC5
647555	Integrato LTC4067EDE battery charger SMD 4x3mm DFN	IC7
644935	Integrato MAX 4715EXK-T/S	IC4
647235	Integrato MAX 8822ETE+ 16 THIN QFN-EP*	IC12
647218	Integrato MAX11800ETC+	IC17
645424	Integrato MAX9119 SMD SC70 5 pin operativo	IC11
648395	Integrato memoria FM33256 SO14 3V Memory	IC14

Code	Description	Identification on the PCB MIR040
648179	Integrato microprocessore AT32UC3A0512 ATMEL	IC16
640825	Integrato S812C25AMCCFT2 regolatore 2.5V Seiko	IC2
450130	PCB MIR040 rev5	Mir040_rev5
680519	Quarzo 7M12000137 12,00000MHz 3,2x2,5	Y1
680400	Quarzo SMD 32,768KHz Q13FC1353276800 Epson	X2, X3
712642_1_0603	Resistenza SMD 00603 0,1W 1% 220	R45
712600_1_0603	Resistenza SMD 0603 0,1W 1% 0	R8
712708_1_0603	Resistenza SMD 0603 0,1W 1% 100K	R12, R14, R15, R22, R23, R27, R28, R47, R50, R59, R60, R63
712710_1_0603	Resistenza SMD 0603 0,1W 1% 120K	R42, R43, R56
712686_1_0603	Resistenza SMD 0603 0,1W 1% 12K	R1
712716_1_0603	Resistenza SMD 0603 0,1W 1% 220K	R44, R49
712692_1_0603	Resistenza SMD 0603 0,1W 1% 22K	R51, R52
712717_1_0603	Resistenza SMD 0603 0,1W 1% 249K	R24, R26, R34, R35, R57, R62, R10, R11, R58
712669_1_0603	Resistenza SMD 0603 0,1W 1% 2K94	R9
712783_1_0603	Resistenza SMD 0603 0,1W 1% 2M	R29
712620_1_0603	Resistenza SMD 0603 0,1W 1% 39R	R40, R41
712684_0603	Resistenza SMD 0603 0,1W 5% 10K	R7, R39, R53, R54
712784_0603	Resistenza SMD 0603 0,1W 5% 10M	R30
712660_0603	Resistenza SMD 0603 0,1W 5% 1K	R38
712668_0603	Resistenza SMD 0603 0,1W 5% 2K2	R5
712676_0603	Resistenza SMD 0603 0,1W 5% 4K7	R2, R3, R4, R6, R13, R16, R17, R32, R46, R48, R55
641530	Sensore DS18B20U sensore di temperatura	IC6
641535	Sensore SMD LIS302DLTR accelerometro triaxial	IC10
210856	Switch PTCF-V-T/R DIPTRONICS	S1
612080	Transistor MMST2222A SMD SOT 23 (SC59)	Q5
612081	Transistor SI1305DL-T1 Vishay CMOS	Q1
612082	Transistor SI2302CDS-T1-GE3 Vishay MOSFET	Q2, Q3, Q4, Q6, Q7

ANNEX

- 1 Test report form after device repair with oximetry module
- 2 Test report form after device repair without oximetry module
- 3 Electrical layout of device
- 4 Micro Power Oximeter Board Technical Specifications