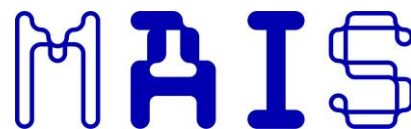


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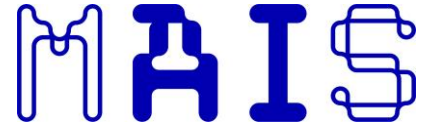


**Model:  
SMAIRTHERO 2.0**

**Medical Device**



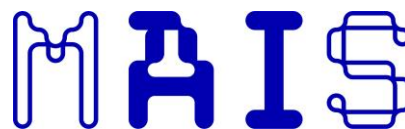
**Use and Maintenance Manual**



## SUMMARY

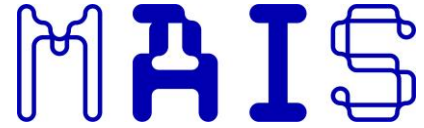
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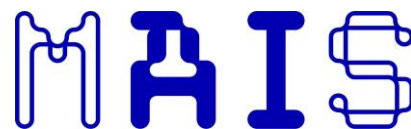


## 1 GENERAL WARNINGS

- **The device is powered by a rechargeable lithium-polymer battery (Li-Po).**
- **Before using the device read this manual and use it carefully!!**
- **Never tamper the device!!**
- **If an accident occur to the device, report the incident as soon as possible to the manufacturer and to the authority ( by filling in the MIR Form present on the website <https://ec.europa.eu/docsroom/documents/41681> )**

**2 SIMBOLS**

<p><b>Mark of Conformity to Directive 93/42 / EEC</b></p>	
<p><b>Attention!! Refer to the User Manual</b></p>	
<p><b>Storage temperature:</b></p>	
<p><b>% of Relative humidity</b></p>	
<p><b>Keep in a cool and dry place.</b></p>	
<p><b>Type B device</b></p>	
<p><b>Fuse</b></p>	
<p><b>AC</b></p>	
<p><b>Dispose in accordance with the regulations in force</b></p>	
<p><b>Consult the instructions for use</b></p>	
<p><b>Manufacturer</b></p>	



**Manufacturing date**





### 3 HOW TO USE THE INSTRUCTIONS FOR USE

Thank you for purchasing SMAIRTHERO 2.0.

These instructions for use contain all the necessary and sufficient information to inform the user about the product, its operating characteristics, the warranty conditions and the maintenance procedures.

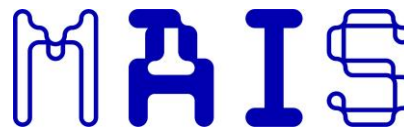
This document, approved in its final version, by all interested parties, describes in an unequivocal way the correct use of the device, it is therefore recommended to read carefully.

The Instruction Manual for Use is considered an integral part of the equipment and must be kept for any consultations or clarifications.

#### 3.1 Revision Description

##### Rev. 0: First issue of the document.

Editor: Technical Department Date: 10/03/2021	Control: Technical Department Date: 10/03/2021	Check: Technical Department Date: 10/03/2021
-----------------------------------------------------	------------------------------------------------------	----------------------------------------------------



## 4 GENERAL INFORMATION

### 4.1 Manufacturer

**The manufacturer of the medical device is:**

Machine Artificial Intelligence System  
Società a responsabilità limitata  
In short also MAIS SRL

VAT Number: IT01324800323

Chamber of Commerce of Venezia Giulia Registration Number (R.E.A.): TS-204478

**Registered Office:**

VIA GIUSEPPE MAZZINI 20  
34121 - TRIESTE (TS)

### 4.2 Responsibilities of the manufacturer

The MAIS SRL is responsible for the safety, the reliability and performance of the equipment to the extent that:

- The use of the wearable device complies with the provisions of this manual together with the SmairtHero app necessary for its operation

### 4.3 Responsibility of the user

The user is fully responsible for any damage caused to himself and to third parties by improper or incorrect use of the appliance, by incorrect maintenance, by negligence or by repairs carried out by personnel not authorized by MAIS SRL.



## 5 DEVICE DESCRIPTION

### 5.1 GENERAL INFORMATIONS

SmairtHero is a safety and protection service that gives the possibility to be monitored through the smartphone.

SmairtHero system collects data from the sensors of the smartphone and from those of the SMAIRTHERO 2.0 device, transmitting to our servers: the heart beat frequency, the GPS position, movements, acceleration, skin temperature.

In the event of imminent danger, recognized by the artificial intelligence, an audible alarm is provided on the smartphone and the activation of the intervention of the Operations Centre.

### 5.2 CONTENT OF THE PACKAGING

Your SMAIRTHERO 2.0 package include:



SMAIRTHERO 2.0



CHARGING CABLE



QUICK START MANUAL

SMAIRTHERO 2.0's removable rubber wristband are available in a variety of colours, sold separately.

### 5.3 DEVICE OVERVIEW



In the lower part there are sensors for:

- heartbeat with beat-to-beat detection
- surface temperature of the skin
- blood oxygen saturation (SpO2)
- proximity
- accident and fall detection

In the upper part there is a button and three LEDs used for various signals (ref. Par. "Light signals").

In the short side there is the USB Type-C port for recharging the device.

SMAIRTHERO 2.0 also emits variable acoustic signals depending on the status reported by the SmairtHero app or in which the device is located (ref. Par. "Acoustic signals").



## 5.4 THE SENSORS

SMAIRTHERO 2.0, when worn, will continuously monitor heart rate, skin surface temperature and movement. Worn 24 hours a day, it guarantees total monitoring coverage.

For correct operation it is necessary to wait a couple of minutes for the recorded values to be the actual ones.

The measured values, although not all shown on the dashboard of SmairtHero's app, are used by the Artificial Intelligence to understand your status and decide independently if you need help.

### Heartbeat

The photoplethysmographic sensor (PPG) measures the absorption of a green light beam through the skin by detecting the blood flowing, the different absorption of light between one beat and the other allows to calculate the heart rate.

SMAIRTHERO 2.0 reads the values of the beat-to-beat split times, ie the time between two heart beats; these values are read up to 240 times per minute.

The green led of SMAIRTHERO 2.0 pulses periodically, if the pulsations are constant, it is a confirmation of the fact that every heartbeat is detected.

### Skin temperature

With the temperature sensor, SMAIRTHERO 2.0 measures the external temperature of the skin.

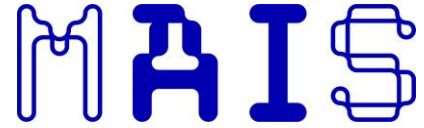
### Accelerometer

With the accelerometer, SMAIRTHERO 2.0 reads the G-force to which the wrist and the body are exposed. The accelerometer is read 3 times per second.

### SpO<sub>2</sub> pulse oximeter

Blood oxygen saturation is the percentage of haemoglobin linked to oxygen in the blood or, more simply, the amount of oxygen in the blood, and is therefore an indicator of the condition of your respiratory system.

## What to do to get the best results



To get the best out of your biometric data, SMAIRTHERO 2.0 must be worn correctly. Everybody and every skin is different, so you have to find the point where the signal is best picked up.

The position in which it is worn on the wrist is very important: SMAIRTHERO 2.0 must be positioned above the bones of the wrist, snug but comfortable.

There are also other factors that can affect the performance of SMAIRTHERO 2.0:

- Water: it can block the Bluetooth signal, thus not allowing the dialogue with the smartphone, and it can inhibit the reading of the heart rate.
- Movement: introduces noise in the detection of the sensor signal; for this reason, some measurements, such as skin oxygenation, can only and exclusively be carried out while stationary.
- Skin: imperfections and alterations of the skin, such as tattoos, abrasions scars or injuries, can affect correct reading, preventing the photoplethysmograph from reading correctly. Also, skin pigmentation, which varies from person to person, can affect heart rate reading.

## 5.5 COMPATIBILITY OF THE DEVICE

SMAIRTHERO 2.0 can only be used with the app SmairtHero Version 3.001 or later available for iPhone and Android smartphone (Android™ 5 or later certified by Google with the Google Mobile Services GMS preinstalled, and Apple iPhone iOS 12 or later) equipped with Bluetooth Low Energy (Bluetooth 4+).

The Android smartphones need to be equipped with at least 1.5 GB of RAM, and the Google Mobile Services preinstalled. To find out if your device is equipped with Google Mobile Services, make sure you have preinstalled apps such as the Google Play Store and others from the Google universe (YouTube, Gmail, Maps etc...) on your device. The SmairtHero's App might not be downloadable from the store on smartphones that are not certified by the operating system vendor. Operation is not guaranteed on devices not certified by Google.

In case of updating the operating system to a later version, check in the SUPPORT section of our website on the Internet or in the change log of SMAIRTHERO'S APP from the App Store or Play Store that full compatibility is indicated.

## 5.6 LIGHT SIGNALS

The upper circular ring of LEDs will indicate different mode of the device, in some cases also accompanied by an acoustic signal.

Light Signals of SMAIRTHERO 2.0	
Colour	Meaning
Green and blue flashing	Not connected to the smartphone
Green flashing	Connected to the smartphone
Red and blue flashing	Battery charge below 20%, not connected to smartphone
Red and green flashing	Battery charge less than 20%, connected to the

	smartphone
Red, green and blue flashing	Alarm in progress, with the possibility of stopping it in the SmairHero app, when connected to the smartphone
Solid Red	Charging in progress, the device is connected to the power cable
Solid Green	Fully charged, the device is connected to power cable

### 5.7 ACOUSTIC SIGNALS

SMAIRTHERO 2.0 is equipped with a buzzer to emit sound signals to the user. In some cases the acoustic signals (“beeps”) are accompanied by a specific luminous signal.

Acoustic Signals SMAIRTHERO 2.0	
Nr. Of Bip	Meaning
1	Single press of the button to search for the phone, when connected to the smartphone
1	Long press (> 5s) of the button to put the device in airplane mode, when not connected to the smartphone
3	Heart values out of range (see the SmairHero app user manual), when connected to the smartphone
2	Heart values close to the threshold (see the SmairHero app user manual), when connected to the smartphone
3	Bluetooth disconnection, issued after 60 seconds
2	Long press (3s) of the button to activate the anti-panic function, when connected to the smartphone

### 5.8 DEVICE BATTERY CHARGE

#### ▲ ATTENTION

The device is powered by a rechargeable lithium polymer (Li-Po) battery.

SMAIRTHERO 2.0 is provided with a port USB Type-C used exclusive mind for charging the same.

To recharge:

1. Remove the internal electronics core from the rubber wristband.
2. Insert the USB Type-C connector into the port on the device.
3. Insert the USB Standard connector on the other end of the cable into a USB powerbank or power adapter plugged into the power socket.



When recharging, the steady red LED will light up; once the battery is at 100% it will change colour to green. It will therefore be possible to wear SMAIRTHERO 2.0 and use the service through the SmairtHero app.

You can use any USB type charger, which shows in the specifications "5V output" and which can deliver a minimum current of 2.0A. Verify that the USB power adapter is approved for safety (indicated with "LPS", "Limited Power Supply", "UL listed" or "CE").

It is good practice to recharge the battery at room temperature to keep it efficient and long-lasting.

In case of problems with the battery life or the time and capacity of its recharge it is recommended to try using a different charger and / or a different cable.

#### NOTICE

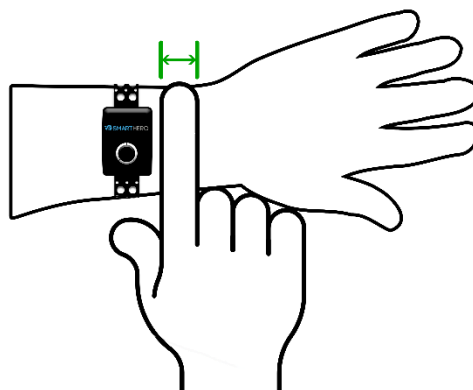
Do not charge the battery in temperatures below  $-10^{\circ}\text{C}$  or above  $+50^{\circ}\text{C}$ .  
Do not charge the battery with the device wet or damp.

### 5.9 HOW TO WEAR THE DEVICE

#### NOTICE

The device should be snug but comfortable, meaning it shouldn't cause blood circulation difficulties or pain. Once worn, for more accurate heart rate readings, the device should not move.

Wear the device slightly behind the wrist, approximately one centimetre.





The wristband must be fastened so that SMAIRTHERO 2.0 adheres comfortably to the wrist.

Once worn, after a few seconds, the device will turn on (green and blue leds flashing) and the SMAIR THERO 2.0 will be detectable by the smartphone.

**NB** The rubber wristband and the device are made with top quality, hypoallergenic and certified materials. MAIS SRL assumes no responsibility for improper or incorrect use of its devices and accessories. Excessive pressure of the sensor on the skin can cause problems with blood circulation and be ineffective for the correct reading of the data.

## 5.10 BUTTON FUNCTIONS

The button on the top of SMAIRTHERO 2.0 has several functions:

### **Manual start**

It allows you to turn on the device manually with a single pression of the button.

### **Panic (\*)**

It is activated by pressing the button on the device for 3 seconds.

You will be notified with an audio signal and a visual message on your smartphone.

For further information on the functionality, refer to the user manual of the SmairtHero app.

### **Flight mode**

With the device disconnected from the SmairtHero app, a long press (5 seconds) will turn off the device. For more information on this feature, see the "Flight mode" chapter.

### **Phone search (\*)**

With one short pressure of the button on SMAIRTHERO 2.0, you activate the function of phone search.

For further information on the functionality, refer to the user manual of the app.

*(\*) functions available with SMAIRTHERO 2.0 connected to the SmairtHero app with the service active.*

## 5.11 HOW TO RESET THE DEVICE

In case of anomalies (incorrect data reading, impossibility of pairing with the smartphone, etc.) it is possible to proceed with a reset of SMAIRTHERO 2.0.

To do this you have to connect it, via the charging socket, to a power source, and wait a couple of seconds after which the device will emit acoustic and luminous signals (flashing of the three LEDs) and finally the red LED will light up.

Once the procedure is complete, you can reconnect it to the SmairtHero app.



## 5.12 TRANSFER OF THE DEVICE TO ANOTHER PERSON

SMAIRTHERO 2.0, once a reset has been performed, performs a self-calibration to adapt its operation to the biometric characteristics of the person wearing it.

In the event that you have to lend or sell your SMAIRTHERO 2.0 to another person, reset it (see "How to reset the device"), to allow it to calibrate itself correctly.

Failure to perform this procedure could lead to abnormal behaviour of the device.

## 5.13 SWITCHING OFF THE DEVICE

SMAIRTHERO 2.0 turns off automatically after 10 minutes after it has been disconnected from the SmairtHero app and removed from the body, or by performing the reset procedure.

In addition, with the device disconnected from the SmairtHero app, a long press on the button (5 seconds) will turn off the device. For more information on this feature, refer to the "Airplane mode" chapter.

## 5.14 AIRPLANE MODE (FLIGHT MODE)

Before boarding a plane (or entering all those places where it is forbidden to have Bluetooth devices turned on), follow these steps:

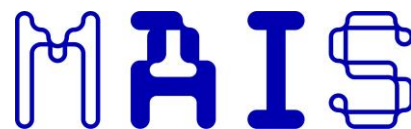
1. Stop the SmairtHero service (if active).
2. With the green and blue LEDs flashing, press the button on the device for 5 seconds until you hear a long beep and the LEDs turn off.

Upon arrival, before reactivating the service, briefly press the button to turn it on (once placed in airplane mode, automatic ignition is disabled).

## 6 FIRMWARE UPDATE

You will be notified via the SmairtHero app if there is a device firmware update.

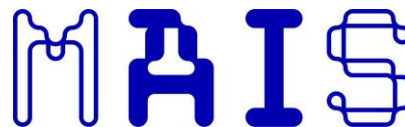
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Refer to the SmairtHero app user manual for the update procedure.

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## 7 DEVICE IDENTIFICATION

The device is identified by means of a special identification placed on the plastic shell of the device and can be read by removing it from the silicone bracelet:

- The Serial Number or Serial Number or SN
- The CE marking

Alternatively, you can read some of this data from the device packaging:

- The manufacturer
- The Serial Number or Serial Number or SN
- Model
- The CE marking
- The class of the medical device

Any written or verbal communication must always mention the **model (Type)** and the **Serial Number** or **SN**.

## 8 REQUIREMENTS AND ENVIRONMENT

<b>Operating temperature range</b>	From -20 °C to 50 °C (from -4 °F to 122 °F)
<b>Charging temperature range</b>	From -10 °C to 50 °C (from -14 °F to 122 °F)

The symbol on the SMAIRTHERO 2.0 and on the packaging indicates that the product must be disposed of separately from household waste and in line with local regulations.

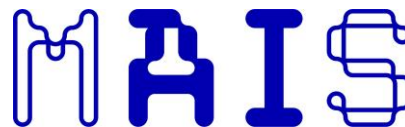


The package can be recycled following the local regulations in force.



The disposal of electronic devices in the designated collection points is the responsibility of the user.

Contact the competent authority to find out the nearest recycling points.

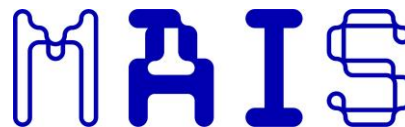


## 9 ELECTROMAGNETIC COMPATIBILITY

**The device was built in accordance with the EN 60601-1 standard**

From the outcome of the tests, no significant risks were found due to the use of the equipment with other equipment.

The equipment uses RF energy only for its internal functions; therefore, its emissions are very low and do not cause interference in the proximity of any electronic device.



## 10 CARE AND MAINTENANCE

When using SMAIRTHERO 2.0 in your daily life, it is a good idea to clean the device regularly.

The ideal is to always wear it on dry, clean skin in the absence of skin lesions.

Remove the inner part that contains the sensors from the rubber strap and rinse it with water or rub it with a cloth soaked in water and a little neutral liquid soap. Do not use other types of cleaners as they may damage the rubber and leave residues that could irritate the skin.

After washing the device dry it well.

In the event that there are stains or accumulations of dirt (skin grease, sun lotions, etc.) use a soft damp toothbrush and a little neutral liquid soap; do not rub excessively to avoid damaging the materials.

SMAIRTHERO 2.0 devices are resistant to dust or (fresh) water, but prolonged wearing in humid places is not recommended. In case you use it in the shower or after sweating it is good to dry the device.



## 11 DECOMMISSIONING AND SCRAPPING

The maximum expected technical life of the device is 10 years, if correct use, maintenance, periodic electrical safety checks and anything else contained in this Manual are guaranteed. **At the end of its useful life, the device must be taken out of service.**

The scrapping and disposal of the appliance must be done in compliance with the applicable laws.

The component parts of the appliance, divided into similar types of materials (rubber, plastic, metal, electric, etc.) must be disposed of according to local or national procedures in force for each specific type of material.

## 12 TECHNICAL DATA

<b>Battery Type</b>	Built-in, rechargeable lithium polymer battery
<b>Battery life</b>	Up to 24 hours with continuous data transmission to the smartphone
<b>Operating temperature range</b>	-20 ° C to 50 ° C (-4 ° F to 122 ° F)
<b>Charging temperature range</b>	-10 ° C to 50 ° C (-14 ° F to 122 ° F)
<b>Transmission protocols</b>	Bluetooth® 4.2 technology
<b>Water resistance classification</b>	IP68
<b>Dimensions (sensor only)</b>	3.6 x 2.3 x 1.3 cm
<b>Weight (sensor only)</b>	9 g
<b>Dimensions (including wristband)</b>	29.3 x 2.8 x 1.3 cm (maximum dimensions)
<b>Weight (including wristband)</b>	27 g

**ATTENTION!!! No modification of this equipment is allowed !!**

### 13 DEVICE CLASSIFICATION

The SMAIRTHERO 2.0 medical device is class IIa as defined by the classification criteria specified in Annex IX of Directive 93/42 / EEC, as it is a non-invasive active medical device with a long-term duration of use intended for the direct diagnosis of physiological processes in a potentially non-dangerous form (rule 10).



MAIS SRL  
SMAIRTHERO 2.0



2021

Declaration of conformity with EU directive 1999/5 / EC for medical use of Class IIa. MAIS SRL is authorized to apply the CE mark on the SMAIRTHERO 2.0 product, thus declaring compliance with the essential requirements and applicable provisions of Directive 1999/5 / EC.



SMAIRTHERO 2.0 complies with the RoHS Directive (2011/65 / EU).

**14 DECLARATION OF CONFORMITY**

**Declaration of Conformity **

**pursuant to Directive 93/42 / EEC and subsequent amendments  
(implemented by Legislative Decree 46/97 and subsequent  
amendments)**

Manufacturer: **Machine Artificial Intelligence System  
Società a responsabilità limitata (in short  
MAIS SRL)**

Address: **Via Giuseppe Mazzini 20  
34121 – Trieste (TS)**

VAT Number **IT 01324800323**

Model: **Ref. on product Packaging**

Serial Number: **Ref. on product Packaging**

The Manufacturer MAIS SRL ITALIA of MAIS SRL  
DECLARES, UNDER ITS OWN LIABILITY, THAT:

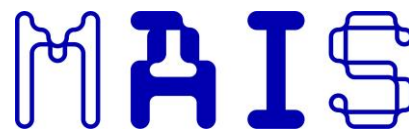
1. The aforementioned device meets all the essential requirements applicable from Annex I of Directive 93/42 / EEC and subsequent amendments (implemented by Legislative Decree 46/97 and subsequent amendments).
2. The design, construction and final checks are carried out as indicated by the Complete Quality Assurance System certified with n.ro ITXXXXXX approved by the notified body BUREAU VERITAS ITALIA SPA n.ro CE 1370 in accordance with the provisions of the annex II esc. Par. 4 of Directive 93/42 / EEC and subsequent amendments (implemented by Legislative Decree 46/97 and subsequent amendments) expiring dd / mm / yyyy.
3. The aforementioned device is to be considered as belonging to class IIa.
4. The device was designed and built applying the following standards:
  - EN 60601-1: 2006 "Medical electrical equipment - General requirements relating to basic safety and essential performance"
  - EN 60601-2: 2007 "Medical electrical equipment - General requirements relating to basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests"
  - EN 60601-1-6: 2010 "Medical electrical equipment - General requirements relating to basic safety and essential performance - Usability"
  - EN 62366: 2008 "Engineering for the Usability of Medical Devices"
  - EN 62304: 2006 "Software for Medical Devices"

This declaration is kept by the manufacturer and presented at the request of the Notified Body or the competent National Authority.

Trieste, 10/03/2021

The owner  
(MAIS SRL)





## 15 TECHNICAL ASSISTANCE

For technical assistance, refer to the SUPPORT page of the website <https://www.smairthero.com> or to what is reported inside the package.



## 16 WARRANTY

The equipment built by MAIS SRL is guaranteed for operation and the absence of material defects for a period of TWENTY-FOUR MONTHS from the date of delivery. The warranty is limited to the repair or replacement of parts recognized as defective, ex factory, excluding glass parts.

The Manufacturer: MAIS SRL

### GUARANTEES THE PRODUCT:

Model: Ref. Product packaging

Serial Number or Serial Number or SN: Ref. Product packaging

for a period of 24 months from the date of purchase.

MAIS SRL guarantees for 24 (twenty-four) months from the initial purchase date that this product is free from material, design and manufacturing defects.

The warranty also extends to the battery life.

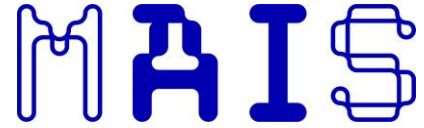
Any defects that may arise due to transport, improper use or inadequate storage or maintenance of the products are excluded from the guarantee.

If during the warranty period the product exhibits defects relating to the materials used, design or manufacturing or in any case a malfunction that clearly limits the use of the monitoring service, in conditions of normal use and maintenance, it is necessary to forward to the seller, by registered letter with return receipt or by e-mail the relative complaint within two months from the discovery of the defect and then bring the product to the retailer or point of sale where it was purchased.

The points of sale or retailers authorized by MAIS SRL, will collect the defective product and ascertained that the complained defect falls within the guarantee provided (materials, manufacturing, operation), will replace the defective product with a new product.

### WARRANTY CONDITIONS

This warranty is valid on condition that proof of purchase (receipt, invoice) is presented. The buyer loses the rights provided for in Article 130, paragraph 2, of the Consumer Code if he does not report the lack of conformity to the seller within two months from the date on which he discovered the defect. The report is not necessary if the seller has recognized the existence of the defect or has concealed it. Unless proven otherwise, it is assumed that the lack of conformity that occurs within six months of delivery of the goods already existed on that date, unless this hypothesis is incompatible with the nature of the goods or with the nature of the lack of conformity. MAIS SRL reserves the right to refuse the service covered by the guarantee if the data listed above is deleted or altered after the initial purchase of the product from the retailer.



Under the warranty, MAIS SRL will be required to replace the defective product with another identical or functionally equivalent product.

The replacement of the product does not extend the warranty for another two years from the event and therefore the two-year warranty will always be calculated from the date of the first purchase.

This warranty does not extend to cases other than defects in material, workmanship and functionality.

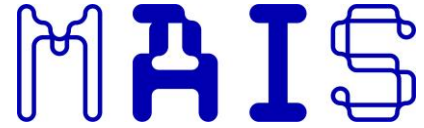
In particular, it does not cover the following:

- Decrease in the yield of consumables eg: battery, wristband, fixing clip (when supplied).
- Abuse or misuse of the product included, but not limited to the inability to use the product for the normal purposes attributed to it or in accordance with the instructions for use.
- Use of the product in combination with accessories or mobile phones that do not comply with the compatibility specified in the user manual.
- Product malfunction due to the use of third-party software suitable for altering, modifying, changing existing software approved by MAIS, which operate through it.
- Accidents, natural disasters or other calamities, beyond the control of MAIS, caused by lightning, water, fire, earthquakes, riots, terrorist acts.
- Unauthorized modifications made to the product to comply with local or national technical standards in force in countries not covered by MAIS.
- Damage to the battery caused by overloads or use in conflict with the specific instructions indicated in the user manual.
- Damage to the product due to repair attempts.
- If the model and serial number have been altered, deleted, removed or made illegible.
- The batteries have been recharged with a different battery charger from the one supplied with the product.
- Obvious signs of tampering.
- Exposure to extreme thermal or environmental conditions or sudden changes in such conditions.
- Spillage of liquids other than water or food on the product.
- Incidental or intentional breakage or breakage caused by an accident even if involuntary occurred to the Owner or other custodian.

This warranty does not modify or eliminate the rights of consumers established by the national laws of the countries in which the product was sold through an authorized reseller, nor those that the consumer may have towards resellers or points of sale by virtue of any sales contracts stipulated. with the retailers themselves. The warranty of the SMAIRTHERO 2.0 product is limited only to the services provided for in this warranty.

MAIS SRL will not be held liable for indirect damage or loss of profit.

Unless otherwise provided, the conditions of the Italian law regarding the guarantee against defects apply.



## **17 DISCLAIMER OF LIABILITY**

The hardware and software products described herein are subject to change without notice; this is due to the manufacturer's continuous development program.

MAIS SRL provides the above warranty exclusively to the product sold by it and contained in this manual (it does not make any representations or warranties regarding this manual and the products described within).

MAIS SRL will not be liable for damages, losses, costs or expenses, direct, indirect or accessory, caused or accidental, deriving from or attributable to the improper use of the product sold by the same and described in this manual (of this manual or of the products described inside).