



ORBITA INTERACTIVE EXERCISE BALL

**The smartest tool to guide
patients during physical therapy
and training.**

USER MANUAL



 **REAL-TIME
VISUAL FEEDBACK**

 **REACTS TO
PRESSURE**

 **CUSTOM TRAINING
PLANS**


M A D E I N I T A L Y

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INTRODUCTION

1 Introduction

1.1 Purpose of the Instruction Manual

This **instruction manual** refers to the **medical device ORBITA - Smart Motility Ball**. It is intended to provide users with all the information required for correct, safe use of the device and it contains all the information needed to ensure that the product is used correctly and in compliance with safety regulations for the entire lifetime of the product and/or its components.



Before performing any operation, the user manual must be read in full in order to avoid possible damage to the device, people and property.

1.2 Supply and Storage

The manual is supplied in both hard copy and electronic format.



MANDATORY!

This manual is also considered an integral part of the device for safety purposes and must be kept close to the device so that it can be easily consulted by the user until the device is disposed of (even if it is moved, sold, rented, etc.). If it is lost or damaged, a copy should be requested immediately.

Ledragomma Srl specifies that the manual reflects the state of the art at the time the device was marketed and cannot be regarded as inadequate merely because it was subsequently updated based on new knowledge.

Ledragomma Srl reserves the right to update previous products and manuals, except in exceptional cases concerning the health and safety of persons and property.

However, the customer may contact **Ledragomma Srl**, to request the latest revision of the manual listing any updates or additions, which is also considered an integral part of the device.

Requests for additional manuals should be addressed to:

LEDRAGOMMA S.r.l.

Via Giovanni De Simon - 33010 Osoppo (UD) Italy

Tel: +39 0432 986049 Fax +39 0432/986255

Email: info@ledragomma.com - info@ledragommapec.com

1.3 Symbols Used in the Manual

The symbols used in the manual to emphasise important information are listed below:

Symbol	Type	Description
	MANDATORY	Symbol used to indicate that specific parts of the instruction manual must be consulted.
	MANDATORY	Symbol used to identify particularly important information in the manual. The information also concerns user safety during use of the device.
	WARNING	Symbol used to identify important warnings for user safety and to avoid damage to property or the device.
	FORBIDDEN	Symbol used to identify operations that should NOT be performed or behaviour that should NOT be adopted as it could cause personal injury or damage to the device.

1.4 Glossary of Terms

To improve understanding of this manual, the terms used in it are specified below:

Term	Description
USER	Any professional operator or user of the device.
MOBILE DEVICE	In this instruction manual, this term refers to the electronic device that can be fully utilised as the user is moving, commonly referred to as a 'smart-phone'.
MOBILE APPLICATION	Software application for mobile devices such as smartphones and tablets.
MAINTENANCE	Set of predefined, periodic operations designed to maintain the functionality and cleanliness of the device.
DANGER	Source of possible injury or damage to health.
RESIDUAL RISK	This risk remains even after design and construction safety measures have been implemented, pertaining especially to maintenance, loading and cleaning.
SOURCES OF ENERGY	Any form of energy administered and necessary to operate the device (electricity).
MEDICAL DEVICE	A medical device is a product based on medical technology, used in medicine for diagnostic and/or therapeutic purposes.
WASHING	Cleaning and sanitising method envisaged for the device exterior.
SAFETY DISTANCE	The minimum distance the device should be held in specific situations.

1.5 Technical Assistance

For any requests for technical assistance, the customer may contact **Ledragomma Srl** directly using the contact details indicated on the back cover of this manual.

1.6 Warranty

Ledragomma Srl guarantees the product to be free of defects in material or workmanship.

The warranty is valid for two years on all mechanical, electrical and electronic parts.

The warranty period runs from the date of purchase, which is confirmed via a delivery document issued by the parent company or retailer.

The warranty covers the free replacement or repair of the device and its components acknowledged to be defective due to manufacturing defects, excluding any parts found to be defective due to negligence, carelessness, improper use, a failure to perform ordinary maintenance, unauthorised use, improper assembly, incorrect installation or maintenance carried out by personnel not authorised by **Ledragomma Srl**.

Ledragomma Srl disclaims all liability for any damage to property, people or animals as a result of failure to observe all the prescriptions set out in the designated manual regarding maintenance and use of the device.

1.6.1 Warranty Exclusions

The warranty does not apply if problems are caused by the following:

- inadequate or incorrect maintenance by the operator;
- unintended and unauthorised modifications, adjustments or adaptations;
- misuse;
- use for purposes other than those for which the device was designed;
- use in unsuitable conditions.



WARNING!

It should be noted that by their nature, rechargeable batteries have a limited lifetime and gradually lose power over time. Natural performance degradation and progressive loss of battery power are not covered by any warranty.



SPECIFICATIONS

2 Specifications

2.1 Classifications

2.1.1 Classification according to Regulation (EU) 2017/745 (MDR)

CLASS I medical device.

2.1.2 Classifications according to the IEC 60601-1 standard

BALL	Applied Part Type BF and EM device powered by internal electrical source.
CHARGING BASE	Class II EM equipment.
DEGREE OF PROTECTION AGAINST WATER PENETRATION	IPX0.
 WARNING! Device not intended to be sterilised or used in oxygen-rich environments or in the presence of flammable anaesthetics.	

2.2 Electromagnetic compatibility (ref. IEC EN 60601-1-2)

TABLE I: Manufacturer's declarations - Electromagnetic emissions.



WARNING!

ORBITA is designed to operate in electromagnetic environments with the characteristics listed below. The ORBITA customer and/or user must ensure that the device is used in such environments.

Emissions tests	Compliance	Electromagnetic environment guidelines
<i>RF emission CISPR 11</i>	<i>Group 1 Class B</i>	When in operation, ORBITA emits electromagnetic energy that could affect the operation of nearby electronic devices
<i>Harmonic emissions IEC 61000-3-2</i>		Not applicable
<i>Voltage fluctuations/ flicker emissions IEC 61000-3-3</i>		Not applicable

TABLE II: Manufacturer's declarations - Electromagnetic immunity.

Phenomenon	Basic EMC standards or testing method	Immunity test levels required for environments in professional healthcare facilities	Compliance testing levels
<i>Electrostatic discharge</i>	<i>IEC 61000-4-2</i>	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
<i>Radiated RF electromagnetic fields</i>	<i>IEC 61000-4-3</i>	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz
<i>Proximity fields from RF wireless communications equipment</i>	<i>IEC 61000-4-3</i>	See TABLE III	See TABLE III
<i>Rated power frequency magnetic fields</i>	<i>IEC 61000-4-8</i>	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

TABLE III: Test specifications for enclosure port immunity to RF wireless communications equipment.

Test frequency	Band	Service	Modulation	Maximum power	Distance	Immunity test level
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900;	Pulse modulation 217 Hz	2	0.3	28
1845						
1970		GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS				
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

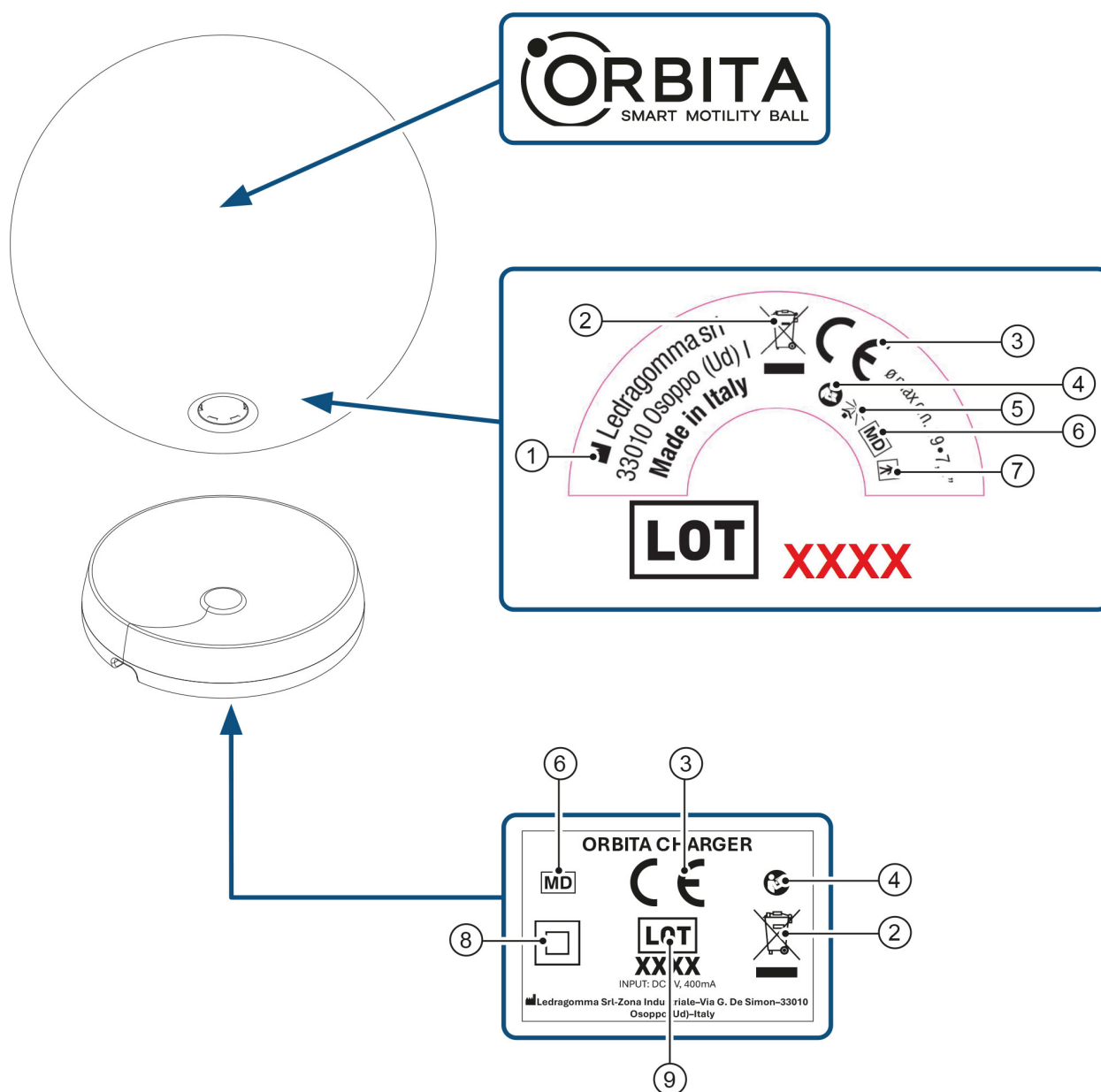
2.3 Labelling

For any enquiries or orders, always refer to the nameplates attached to the device, which contain all the main data and features.



MANDATORY!

It is absolutely forbidden to remove labels or replace them with others. If the labels are accidentally damaged or removed, inform Ledragomma Srl.



Pos.	Symbol	Description
1		Manufacturer.
2		Waste from electrical and electronic equipment.
3		Compliance with European Community standards.
4		Refer to the user manual.
5		Keep away from sources of light and heat.
6		Medical device.
7		Applied part type BF.
8		Class II EM equipment.
9		Lot number.



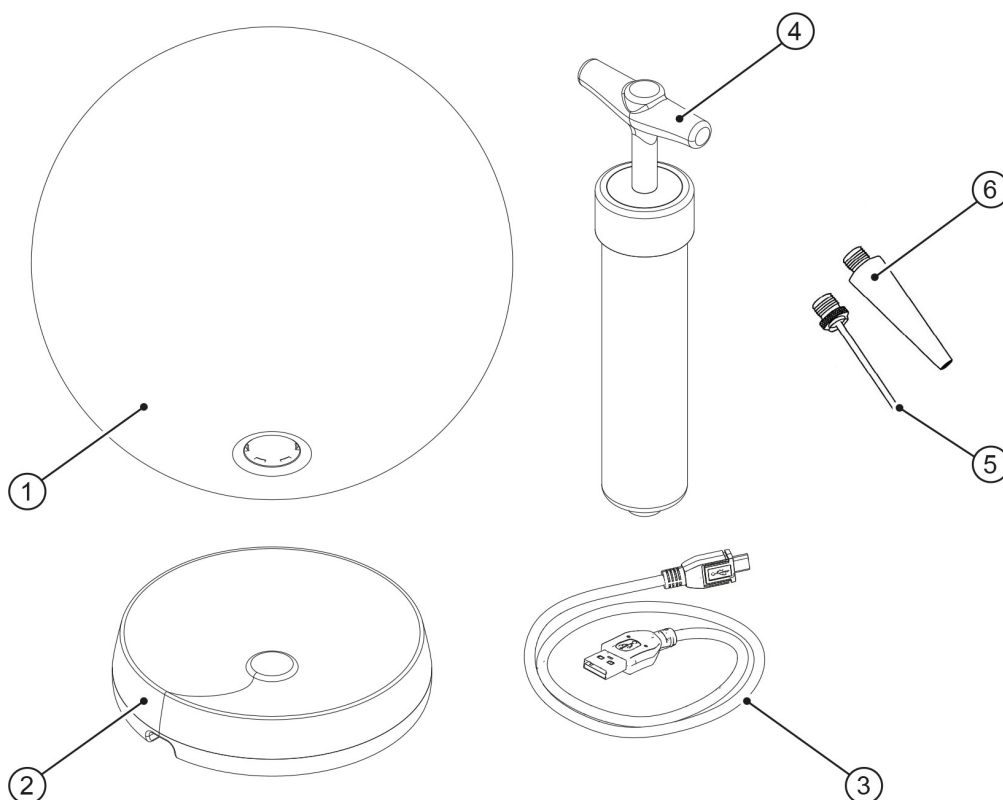
DESCRIPTION AND TECHNICAL FEATURES

3 Description and technical features

3.1 Packaging contents

The main components inside the box are listed below:

Pos.	Element
1	ORBITA ball.
2	Charging base.
3	Micro USB cable.
4	Inflation pump.
5	Needle (used to inflate ORBITA).
6	Tapered inflation adapter (NOT suitable for ORBITA).
-	Instruction Manual.



3.2 Description of the ORBITA Medical Device

ORBITA is a medical device designed for use in association with a mobile application (see Section '5.5 Installing the Mobile Application "Orbita App" on a Smartphone').

3.3 Intended Use

The ORBITA device is intended for use exclusively for:

- **rehabilitation and physiotherapy;**
- **athletic preparation;**
- **education.**

The device can be used by any individual, independently or with the support of a professional (e.g. physiotherapist or athletic trainer).

The ultimate goal of the playful exercises described in the appropriate section of the mobile application (see Section '6.2.2 Exercise Database') is to develop the user's motor skills.



WARNING!

- **The device must be used in accordance with the instructions and limits of use given in this manual.**
- **Uses other than those indicated or with materials that do not comply with the device can be a source of danger for operators and the device itself.**



MANDATORY!

The ORBITA device must be used by no more than one person at a time.

3.4 Misuse, Unintended Uses and Contraindications



FORBIDDEN!

The following is a list of reasonably foreseeable improper uses, which are strictly **FORBIDDEN**:

- **DO NOT** use the ORBITA device as a toy, but only for its intended use as stated in Section '3.3 Intended Use'.
- **DO NOT** expose the ORBITA device to direct sunlight.
- ORBITA should **NOT** be bounced or thrown against a wall.
- The ORBITA device should **NOT** be used by more than one person at a time.
- **DO NOT** use the device as a foothold or walking surface.
- **DO NOT** use the device other than as provided for in Section '3.3 Intended Use'.
- **DO NOT** allow children under 36 months of age to use the device.
- **DO NOT** use in places exposed to moisture or where the device may be splashed with water. The device itself may be damaged.
- **DO NOT** use the device in moving vehicles (car, plane, etc.).
- **DO NOT** use the device in environments other than those described in Section '3.5 Environmental Operating Conditions' to avoid damaging it.
- **DO NOT** connect the power cable to the electrical outlet if the voltage is different from what is indicated in Section '3.6 Technical Data'.



WARNING!

- Any use of the device other than those intended is considered 'improper use' and LEDRAGOMMA Srl therefore declines any liability for damage caused to people or property, and any warranty on the device is therefore void.
- The device is not designed to operate with hazardous materials such as explosive, toxic, flammable or harmful materials or in explosive atmospheres.

3.5 Environmental Operating Conditions

The ORBITA device is designed and built to operate safely under the following environmental conditions:

Environmental conditions of use	
Operating temperature	+18–23°C
Humidity	0–75% (without condensation)
Altitude	up to 1000 metres above sea level For higher altitudes, contact the Ledragomma Srl service department

The environment where the device is used should be indoors, sheltered from atmospheric agents such as rain, hail, snow, fog, suspended dust, combustible dust and aggressive agents such as corrosive vapours or excessive sources of heat, and it must not be a classified environment.



WARNING!

- For particularly cold temperatures, inflate the ball only after allowing it to reach room temperature.
- If the device is used in an open environment, observe everything in this manual to avoid damaging the ORBITA device.



FORBIDDEN!

The device may not be used under conditions other than those specified in Section '3.5 Environmental Operating Conditions'.

3.6 Technical Data

3.6.1 Mobile devices that can be associated with ORBITA

The ORBITA mobile application is available for both iOS (60.0 MB) and Android (100 MB) devices.

3.6.2 Features of the power supply connected to the cable provided

The cable supplied with the ORBITA device should only be connected to a **5 V power supply**.



SAFETY

4 Safety

4.1 General Safety Warnings

The purpose of this chapter is to inform users of any particularly significant risks or dangers and general and specific precautions to eliminate or neutralise them.

This chapter contains information and instructions on:

- hazardous situations that may occur during use and maintenance of the device;
- safety provisions to adopt;
- residual risks and behaviour (general and specific precautions to eliminate or limit them).

These instructions are summarised later in the manual where the respective situations arise.



WARNING!

Before using the device, users must fully understand:

- the device features;
- this user manual.



FORBIDDEN!

- Do not work on electrical and electronic parts.
- Some illustrations may depict parts of the device with or without disassembled parts. This is done for the sake of clarity. It is forbidden to operate the device without the covers and guards.
Ignoring this may result in serious accidents and/or damage to the device itself.



MANDATORY!

Replacement parts to order from Ledragomma Srl

If the customer does not use original spare parts or spare parts authorised by Ledragomma Srl in writing, Ledragomma Srl shall be held free of any liability for the operation of the device and safety of the operators.



WARNING - REPORTING SERIOUS ACCIDENTS!

ANY SERIOUS ACCIDENT IN CONNECTION WITH THE DEVICE MUST BE REPORTED TO THE MANUFACTURER (by email: info@ledragomma.com) AND THE RELEVANT AUTHORITY OF THE MEMBER STATE WHERE THE USER IS LOCATED.

4.2 Requirements



MANDATORY!

- The requirements listed below must be read carefully and become an essential part of the use of ORBITA to prevent any sort of injury to people and/or damage to property.
- Read the important information regarding electromagnetic compatibility (EMC) in Section '2.2 Electromagnetic Compatibility (ref. IEC EN 60601-1-2)'.



MANDATORY!

The user MUST:

- Keep the floor and/or platform where the device is used clean and free of clutter and water.
- Pay close attention to all precaution, warning or danger signs placed on the ORBITA device. Do not remove any labels from the device. Disconnect all devices when you have finished charging the ball.
- Adult supervision is strictly required if the device is used by children under the age of 14.
- **CONSULT YOUR DOCTOR BEFORE USING ORBITA DURING PREGNANCY (INCLUDING CASES OF PRE-ECLAMPSIA) OR IN THE PRESENCE OF MAJOR FUNCTIONAL LIMITATIONS OF THE MUSCULOSKELETAL SYSTEM.**

4.3 Attention



WARNING!

- Use only the components supplied or described in this manual. The use of components other than those specified may damage the product. Ledragomma Srl assumes no liability for damage caused by a failure to comply with this warning.
- During charging, the ORBITA cap can reach temperatures exceeding 41°C.
- The use of accessories, transducers and cables other than those specified or intended by the manufacturer of this device may result in increased electromagnetic emissions or decreased electromagnetic immunity of this device, leading to improper operation.
- The use of this device adjacent to or stacked with other devices should be avoided, as it may lead to improper operation.
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance of more than 30 cm (12 in) from any ORBITA component, including cables specified by the manufacturer. A failure to do so could degrade the performance of this equipment.
- IT IS NOT A TOY and not suitable for children under 36 months of age: it contains small parts which may cause a choking hazard.
- Plug the power cable connector into a suitable voltage socket to avoid damaging the device.

4.4 Prohibitions



FORBIDDEN!

- **DO NOT** subject the device or the charging station to mechanical shocks. Avoid loading them with the weight of other objects.
- **DO NOT** use the device if there are obvious defects in the packaging or the device itself.
- **DO NOT** inflate by mouth.
- **NEVER** use the product in the presence of sharp or pointed objects or near sources of heat.
- **DO NOT** perform exercises with barbells, dumbbells or any sort of weight on the product. **DO NOT** use the device if any anomalies are found during use. **DO NOT** use the device until its operation is clearly understood. If any doubts arise despite having read this manual carefully and completely, promptly contact the Ledragomma Srl service department. **DO NOT** use the device with parts of it disassembled.
- **DO NOT** carry out maintenance until you are certain that power to the charging base has been cut and that it cannot possibly be switched on again accidentally or without the user's knowledge.
- **DO NOT** use the device when physically overworked or if you are under the influence of medication, sedatives, alcohol, etc.
- **DO NOT** attempt to modify the ORBITA device.
- **DO NOT** tamper with or remove parts of the ORBITA device. Ledragomma Srl disclaims any liability for the safety of the device in the event of failure to comply with this prohibition.
- **DO NOT** use ORBITA while other electromedical devices are in use.
- **DO NOT** use the device in areas where high-frequency surgical equipment, MRI or CT scanners are present, or in oxygen-rich environments.
- **DO NOT** leave the device unattended as the power cord can lead to strangulation for infants or children.
- **DO NOT** leave the inflation needle unattended as it can cause choking if inadvertently swallowed by infants or children.
- **DO NOT** use the power cable if it appears to be damaged.
- **DO NOT** use multiple sockets.
- **DO NOT** connect or disconnect the power supply cable with wet hands.
- **DO NOT** use any cable to power the device other than the one supplied.
- **DO NOT** disassemble any parts of the ORBITA device.
- **DO NOT** allow children under 36 months of age to use the device.

**FORBIDDEN!**

- **DO NOT** use in places exposed to moisture or where the device may be splashed with water. The device itself may be damaged.
- **DO NOT** SUBJECT THE DEVICE TO strong impacts, falls or excessive vibration.
- **DO NOT** use the device in any environment other than the one described in Section '3.5 Environmental Operating Conditions'.

4.5 Residual Risks

Following a careful hazard analysis in the design stage, all possible measures were taken to eliminate or minimise hazards for users of the ORBITA device.

However, users must be protected from remaining risks, which are described in the following sections.

4.5.1 Risk of Electrical Shock or Fire

To reduce the risk of electrical shock or fire, observe the following guidelines:

- Do not expose the ORBITA device to rain or water.
- Do not place objects containing liquids, such as vases, near the device.
- In the event of liquids being spilled on or into the device, immediately disconnect the power.
- Do not place the device near burning candles, open flames or other sources of heat, including direct sunlight.
- Do not insert objects into the slots on the device.
- Do not place heavy objects on the power cable.
- Avoid exerting excessive pressure on the power plugs. Improperly inserted power plugs can cause electric arcs or fires. The power cable must not be stretched.
- To disconnect the device from the power supply, always pull by grasping the connector and not the cable. Ensure that the connectors, power cable and power socket, if any, are always accessible.
- Protect the device from electrical surges (e.g. atmospheric discharges).

4.5.2 Risk of Personal Injury or Damage to the ORBITA Device

To reduce the risk of personal injury or damage to the device, observe the following guidelines:

- Place the ORBITA device on a flat, smooth surface that can support the weight of the ball and charging base;
- Before connecting the device to the electrical outlet, make sure that the voltage corresponds to the value stated in Section '3.6 Technical Data' and on the label on the bottom of the charging base. Never plug the device into an electrical outlet if the voltage is different.

4.5.3 Risk of the Device Bursting.

Never exceed the maximum prescribed diameter.

4.5.4 Risk of Injury to Children

Take the following precautions to prevent possible injury to children:

- Do not place the device on a surface covered with a cloth or other material that could be pulled or removed.

4.5.5 Risk of Swallowing Small Parts of the Device

The needle for inflating the ORBITA ball and cap on the inflation pump where the needle is placed can easily be swallowed by children.

Take the following precautions to prevent possible ingestion of these device parts by children:

- Keep the needle and cap on the inflation pump out of the reach of children.

4.5.6 Risk of Overheating

To prevent the charging base of the ORBITA device from overheating, observe the following instructions:

- Leave a space of at least 10 cm around the device to allow for ventilation while it is being charged.

4.5.7 Risk of Condensation on Electrical Parts

On rare occasions, depending on humidity and temperature, a small amount of condensation may form in the charging base. To avoid this, observe the following guidelines:

- DO NOT expose the device to direct sunlight, heat or high humidity.



WARNING!

Any condensation will disappear spontaneously after a few hours by moving the device to a cool, dry place. With these actions, condensation will not cause any damage to the ORBITA device or its malfunction.

4.6 Protective Devices

These are guards that prevent users from coming into contact with electronic parts that ensure proper functioning of the medical device.

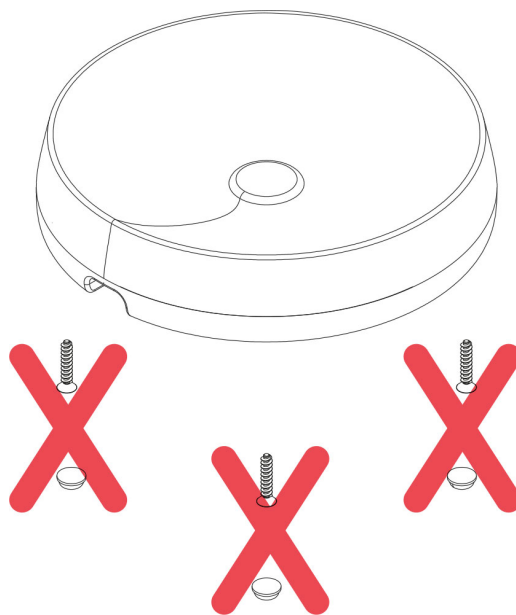
These guards can be removed to enable checks of the electrical and electronic parts contained inside.

To prevent tampering or accidental opening, the cover under the charging base is secured with screws.



WARNING!

DO NOT unscrew or open the charging base under any circumstances. Maintenance or repair work on electrical and electronic parts is reserved exclusively for Ledragomma Srl technicians or other technicians indicated and authorised by the manufacturer.



4.7 Safety Pictograms

The ORBITA device is fitted with two labels bearing a series of pictograms, some of which are intended to warn users of the presence of residual risks (see Section '2.3 Labelling').



FORBIDDEN!

It is absolutely forbidden to remove the labels on the device. Ledragomma Srl disclaims any liability for the safety of the device in the event of failure to comply with this prohibition.



PREPARATION FOR USE

5 Preparation for Use

5.1 Introduction



MANDATORY!

- Check that the supply corresponds to the order specifications. If any damage or missing parts are found, immediately inform the forwarding agent and Le-dragomma Srl of the details.
- It is recommended to keep the packaging as a container for the device when it is not being used.
- The packaging materials are recyclable. Dispose of them in an environmentally friendly manner by taking them to a collection point or following current regulations in the area where you will dispose of the product.

5.2 Device Storage

If the ORBITA device will not be used in the short term, the environmental storage conditions must be as follows:

Environmental storage conditions	
Temperature	+10–40°C
Humidity	0–75% (without condensation)
Atmospheric pressure	70–106 kPa

5.3 Inflation Information and Directions

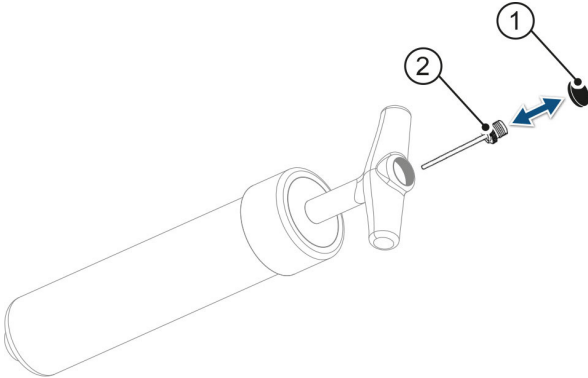
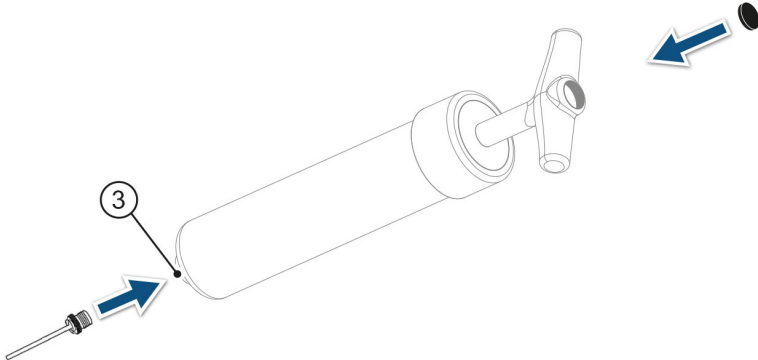


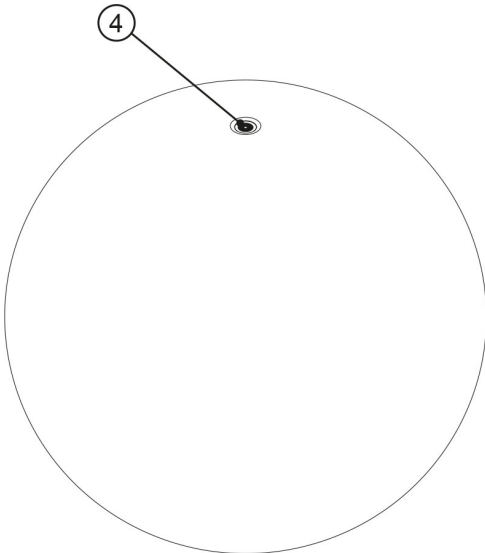
FORBIDDEN!

- Check the surface of the ball before each use. Avoid using the ball if it shows cuts, abrasions, punctures or damage of any kind. If it does, the safety of the product is compromised as the ball could tear instantly, injuring the user.
- **DO NOT** inflate by mouth.

To inflate ORBITA, use the supplied pump or any other bicycle pump or small compressor, as long as it is equipped with the appropriate needle.

5.3.1 Inflation Procedure

Step	Action
1	Remove the cap (pos. 1) on the pump plunger and remove the needle (pos. 2) stored inside. 
2	Screw the needle onto the threaded part of the pump (pos. 3). Replace the cap (pos. 1) in its original position to prevent it from being lost or being swallowed by children. 

Step	Action
3	Insert the needle into the hole on the ball (pos. 4) and inflate the ball until it reaches a diameter of 19 cm. 


WARNING!

- When inflated, the maximum diameter of ORBITA should be 19 cm.
- Never exceed the maximum prescribed diameter. Risk of the Device Bursting.
- Proper inflation allows the ball to properly adhere to the charging base.

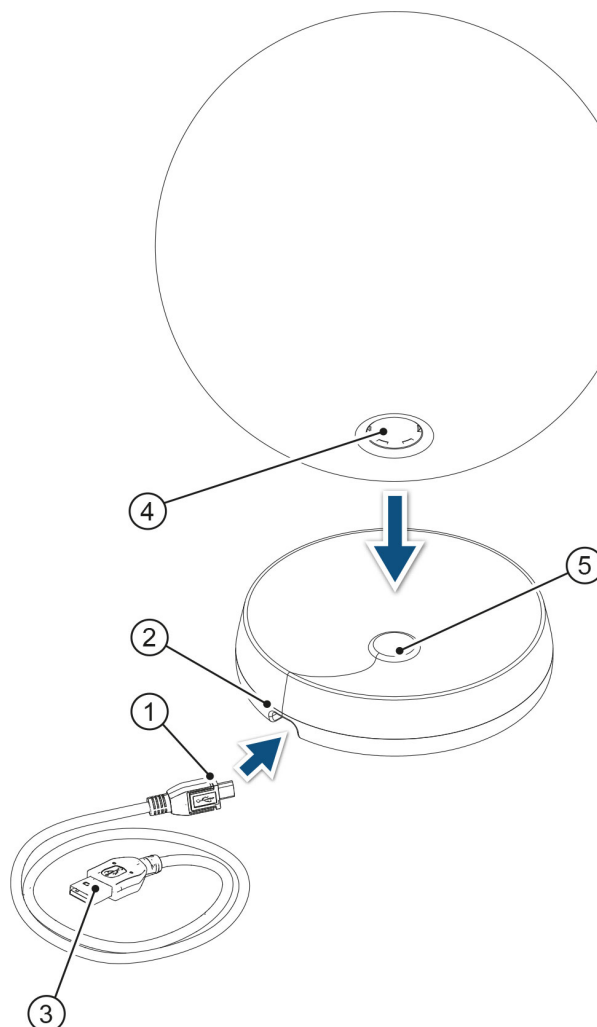
5.4 Electrical Connection and Charging the Device



WARNING!

Ensure the correct mains voltage and frequency (see Section '3.6 Technical Data').

When using the device for the first time and each time it needs to be recharged, proceed as follows:



Step	Action
1	Connect the micro USB connector (pos. 1) on the cable supplied to the base of ORBITA (pos. 2).
2	Connect the connector on the opposite end of the cable (pos. 3) to the USB port on a PC (switched on and connected to the mains) or a charger with USB input port (also connected to the mains).

Step	Action
3	Once inflated (see Section '5.3.1 Inflation Procedure'), place the ORBITA ball on the charging base so that the ball cap (pos. 4) is perfectly aligned and in contact with the slot in the centre of the base (pos. 5).
4	The different flashing colour of the ball indicates the following: - flashing RED: the ball is charging; - flashing GREEN: battery charging is complete.


WARNING!

- **There is no on/off button for the device.**
- **Proper inflation allows the ball to properly adhere to the charging base.**

If the battery is sufficiently charged, ORBITA will be constantly visible from any device with active Blue-tooth and equipped with the dedicated mobile application.



Once the device has been paired with the application, the battery level can be checked at any time on the screen that lists the modes of use (see Section '6.2 Main Page') or by accessing the settings (see Section '6.4 Settings').

NOTE: When the battery dies, simply place ORBITA on the base as described above to start charging.

5.5 Installing the Orbita Mobile Application on a Smartphone

To use the ORBITA medical device, it must be paired with a mobile application (see Section '5.6 Pairing the ORBITA Device with the Smartphone') installed on your mobile device (smartphone) as follows:

- Check that the smartphone is connected to the Internet, possibly also via Wi-Fi;
- Using the search function in the Google Play Store or App Store on your device, type in 'Orbita app':

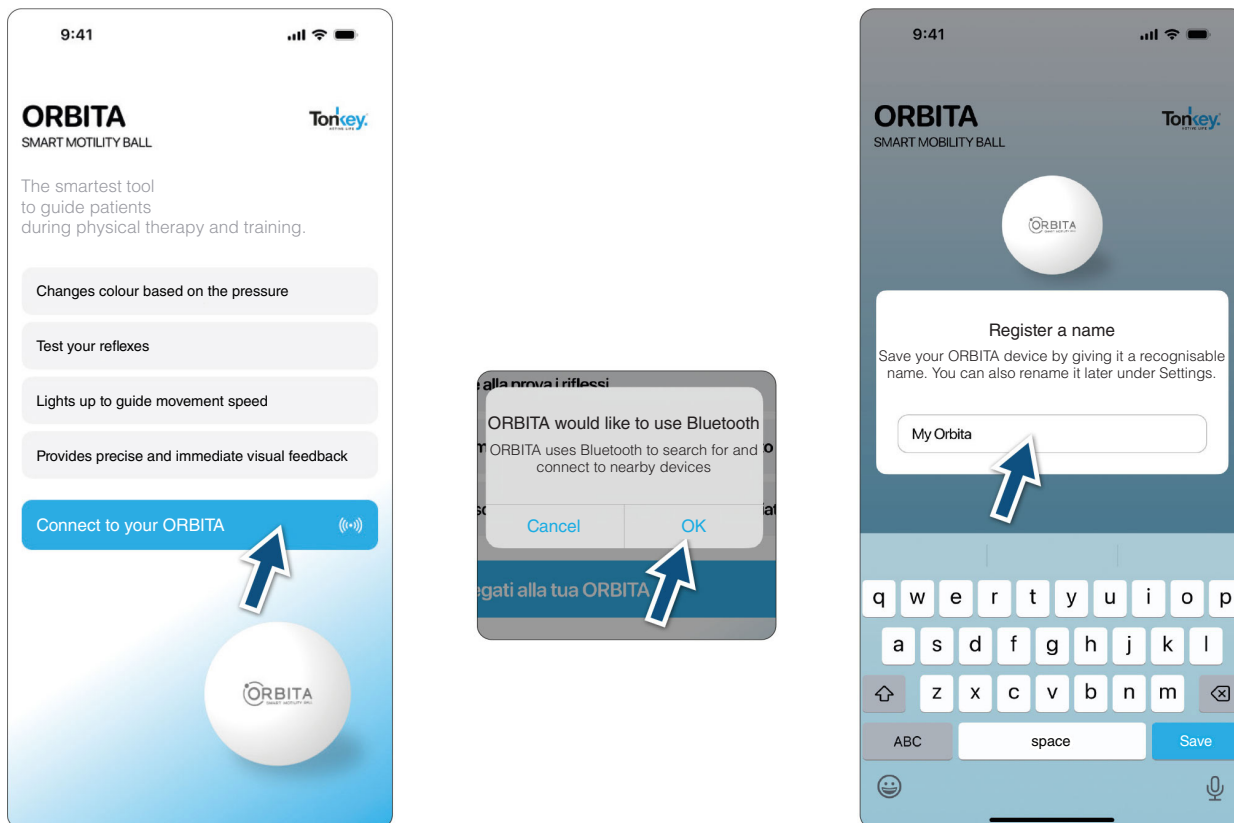


- Download and install the mobile application to your smartphone;
- The application icon will appear on the mobile device when installation is complete.

5.6 Pairing the ORBITA Device with a Smartphone

After downloading the Orbita app to your smartphone, make sure you have activated BLUETOOTH before opening the app.

When it is first opened, you will be asked to pair the ORBITA device and, if desired, to rename it.



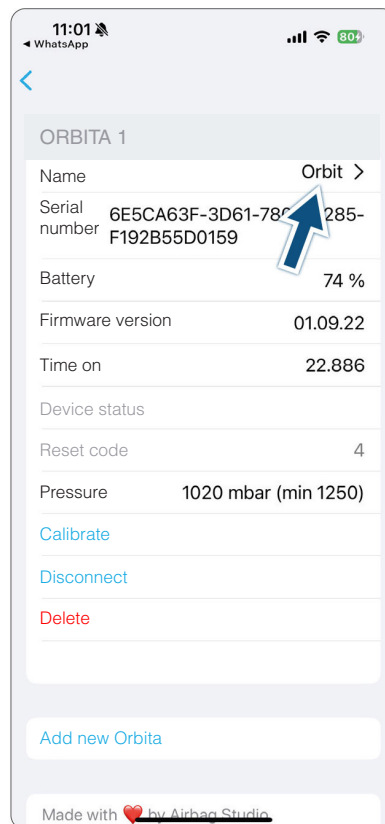
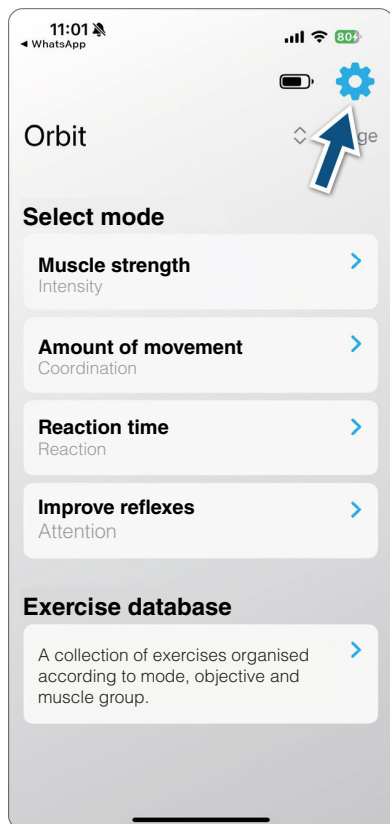
Once you have paired the ORBITA device, its functions can be used.



WARNING!

To pair the two devices, the ORBITA ball must be charged and placed near the mobile device.

You can rename the ORBITA device at any time by accessing the Settings page:





USE OF THE ORBITA MEDICAL DEVICE

6 Use of the ORBITA Medical Device

6.1 Introduction

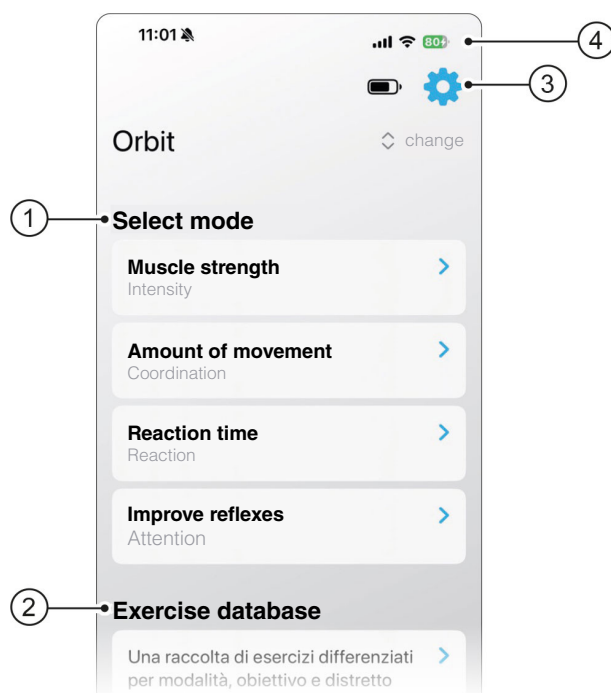


FORBIDDEN!

The product should be used on soft surfaces. Never use the product in the presence of sharp or pointed objects or near sources of heat.

6.2 Main Page

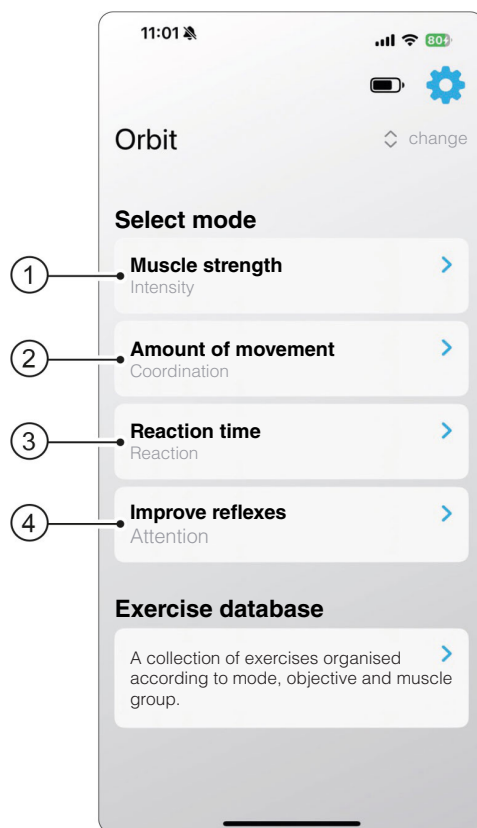
After the ORBITA device has been paired with the smartphone, as indicated in Chapter '5 Preparation for Use', the first screen with two sections is displayed. Here, buttons can be used to access the different operating modes (**pos. 1**) or the exercise database (**pos. 2**):



Pos.	Description
1	Select mode: press the buttons in this section to access different functions of the device.
2	Press the button in this section to access a list of exercises organised by purpose, accompanied by a demonstration video and description (see Section '6.2.1 Select Mode').
3	Press this icon to access the Settings page (see Section '6.4 Settings')
4	The icon (pos. 4) visually indicates the battery level of the ORBITA device.

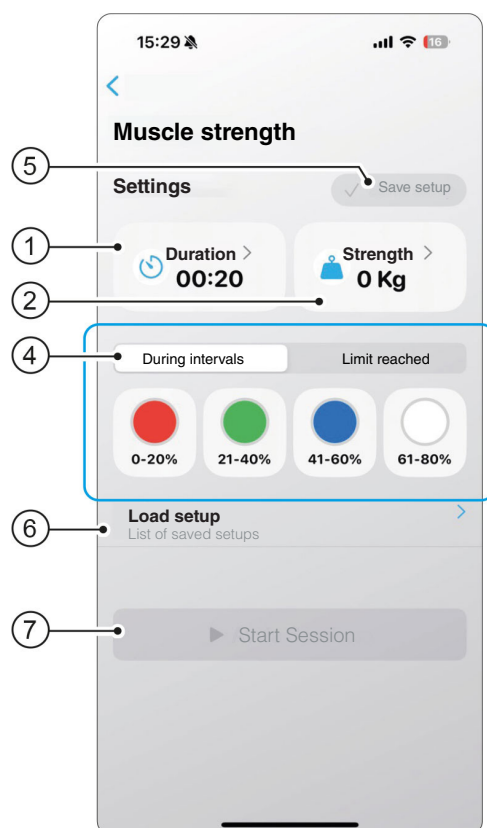
6.2.1 Select Mode

The available functions are specified below.

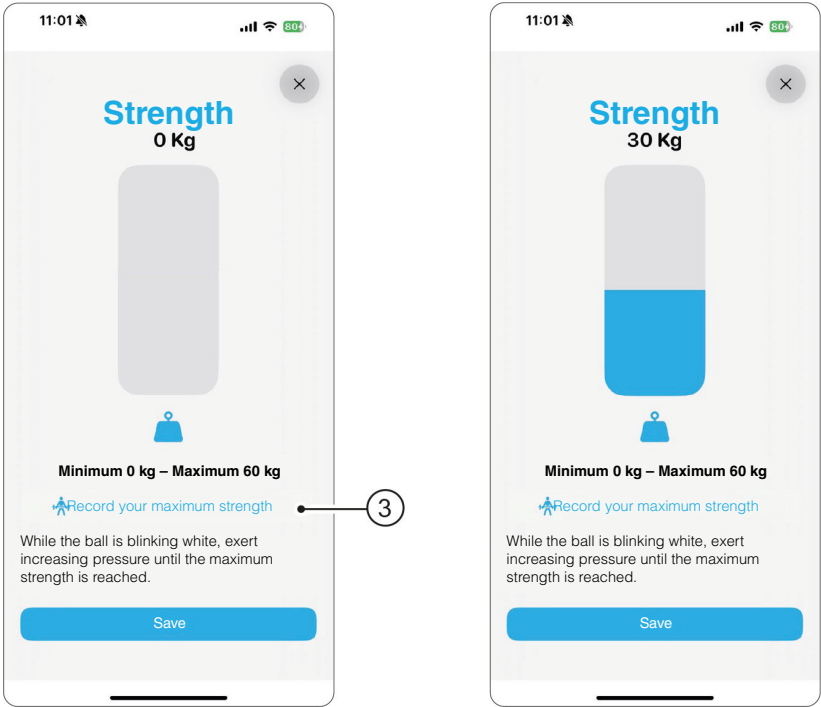


Pos.	Description
1	Muscle strength.
2	Amount of movement.
3	Reaction time.
4	Reflex improvement.

6.2.1.1 Muscle Strength



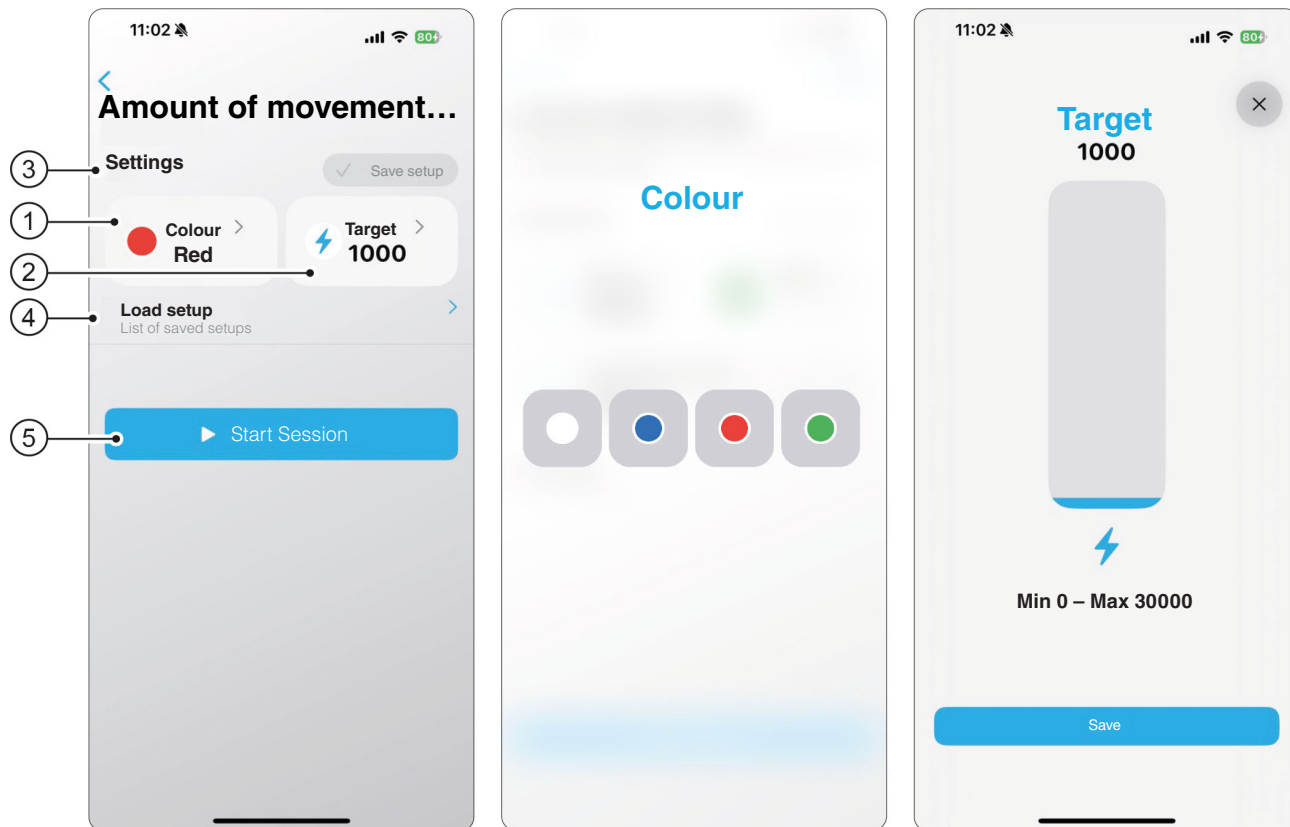
Pos.	Description
1	Duration: the value appearing on this button indicates the duration of the exercise. To change it, press the button and set the desired value.

Pos.	Description
2	Force: the value (in kg) appearing in this area indicates the reference used to calculate the % thresholds. To set a custom value: - Press 'Force' (pos. 2); - Press Record your maximum force (pos. 3): press this button and follow the instructions on the screen to set the limit for a test that requires the user to exert the maximum possible force on ORBITA. - Release and save the new set value using the 'SAVE' button. 

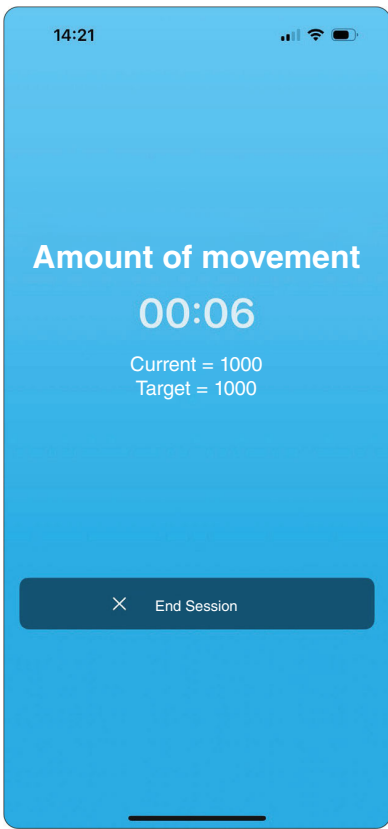
Pos.	Description
4	This section shows the colours ORBITA lights up as when the force applied during the session falls within the intervals represented by the % ('During intervals' function), or when the % is reached ('Limit reached' function). This function has two different variants: Ball lights up. The lighting modes can be selected using the buttons described below: During intervals ORBITA lights up and remains lit in the colour associated with the threshold when a force is exerted between the threshold value and lower value (0 in the first interval). Limit reached ORBITA lights up and remains lit in the colour associated with the threshold only when a constant pressure equal to the selected percentage is maintained. If threshold percentage should not be considered during the exercise, deactivate it by pressing the related eye symbol.
5	Settings ✓ Save setup New settings can be saved via 'Save Setups' (see Section '6.3 Creating Setup List').
6	Load setup: retrieve a previously saved setting.
7	Start session: once the session has started, a 3-second countdown anticipates the start of the actual duration of the exercise; the display shows the message 'Finished' at the end of the exercise.

6.2.1.2 Amount of Movement

Through this function, ORBITA measures the amount of ball movement.



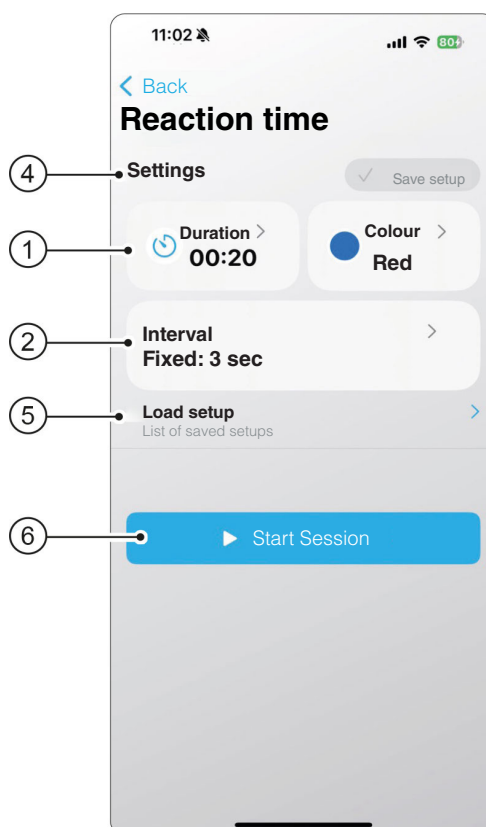
Pos.	Description
1	Colour: use this section to select the colour that ORBITA should light up as during the exercise.
2	Target: use to set the target value to reach in order to switch from flashing to steady light.
3	Settings ✓ Save setup New settings can be saved via 'Save Setups' (see Section '6.3 Creating Setup List').
4	Load setup: retrieve a previously saved setting.

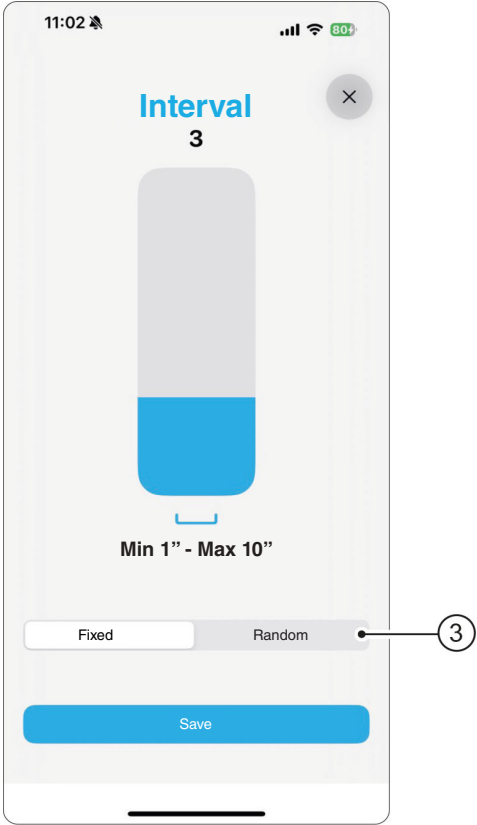
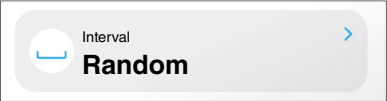
Pos.	Description
5	Start session: Once the session has started, a 3-second countdown anticipates the start of the exercise. At the start of the exercise, ORBITA will start flashing slowly. As it is moved closer to the target value, the frequency of the flashing will increase in proportion to the amount of movement recorded by the device, with the light remaining steady when the target is reached. The value of the parameter increases faster the more the ball is moved: slow movements equal small increments, fast movements equal larger increments. When the target value is reached, the timer stops and the session is finished: 

6.2.1.3 Reaction Time

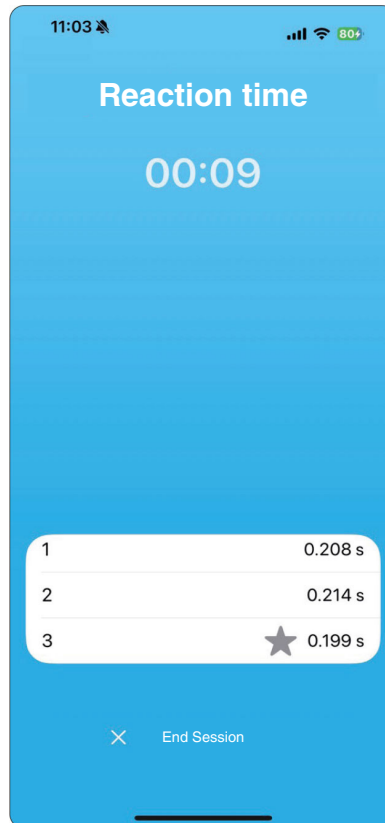
This function measures the user's ability to react to a visual stimulus.

In fact, the device is programmed to initiate series of light sequences (regular or random) of one colour, calculating the time that elapses between each ORBITA light signal and the reaction of the user, who exerts pressure to turn the light off.



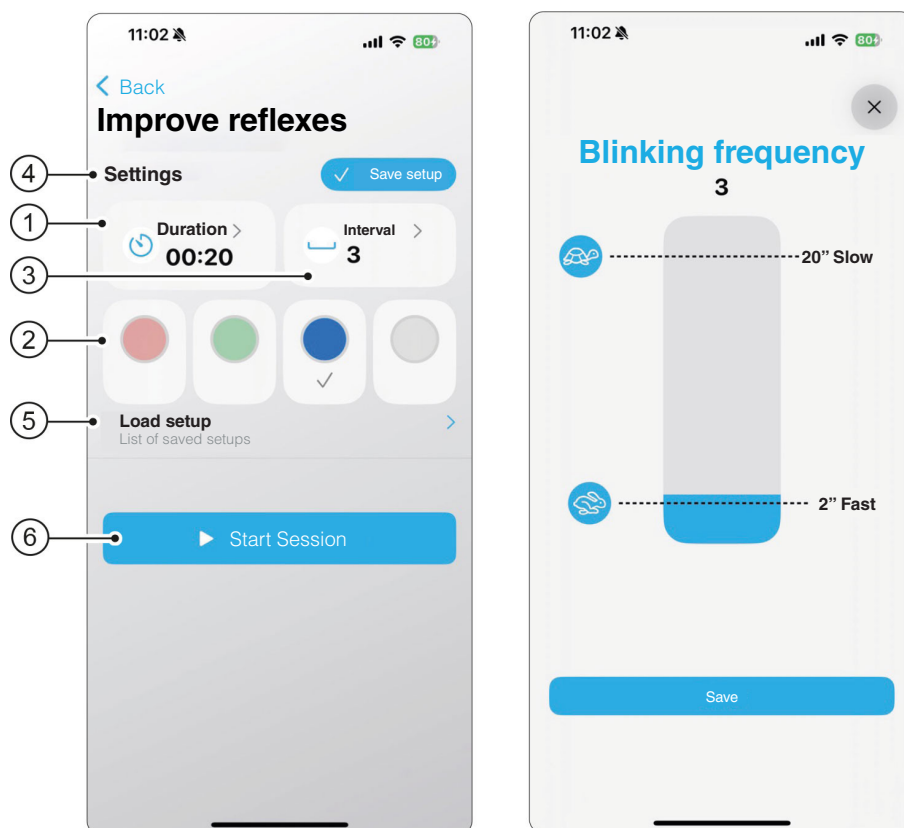
Pos.	Description
1	Duration: the value appearing on this button indicates the duration of the exercise. To change it, press the button and set the desired value.
2	Interval: the value shown on this button indicates the time (in seconds) that elapses between one light signal from the ball and the next. To change the value or make it random, press the button and set the new value.
3	By selecting the 'random' option, the interval between light signals is random.  'Random' will appear accordingly under 'Interval' on the main page of this function: 
4	Settings ✓ Save setup New settings can be saved via 'Save Setup' (see Section '6.3 Creating the Setup List').
5	Load setup: retrieve a previously saved setting.
6	Start session: Once the session has started, a 3-second countdown anticipates the duration of the exercise.

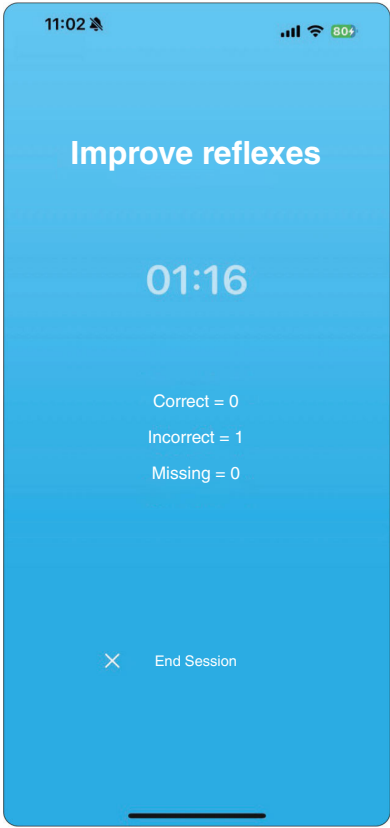
After starting the exercise, the screen will display the time elapsed between the light signal from the device and the user's reaction:



6.2.1.4 Improve Reflexes

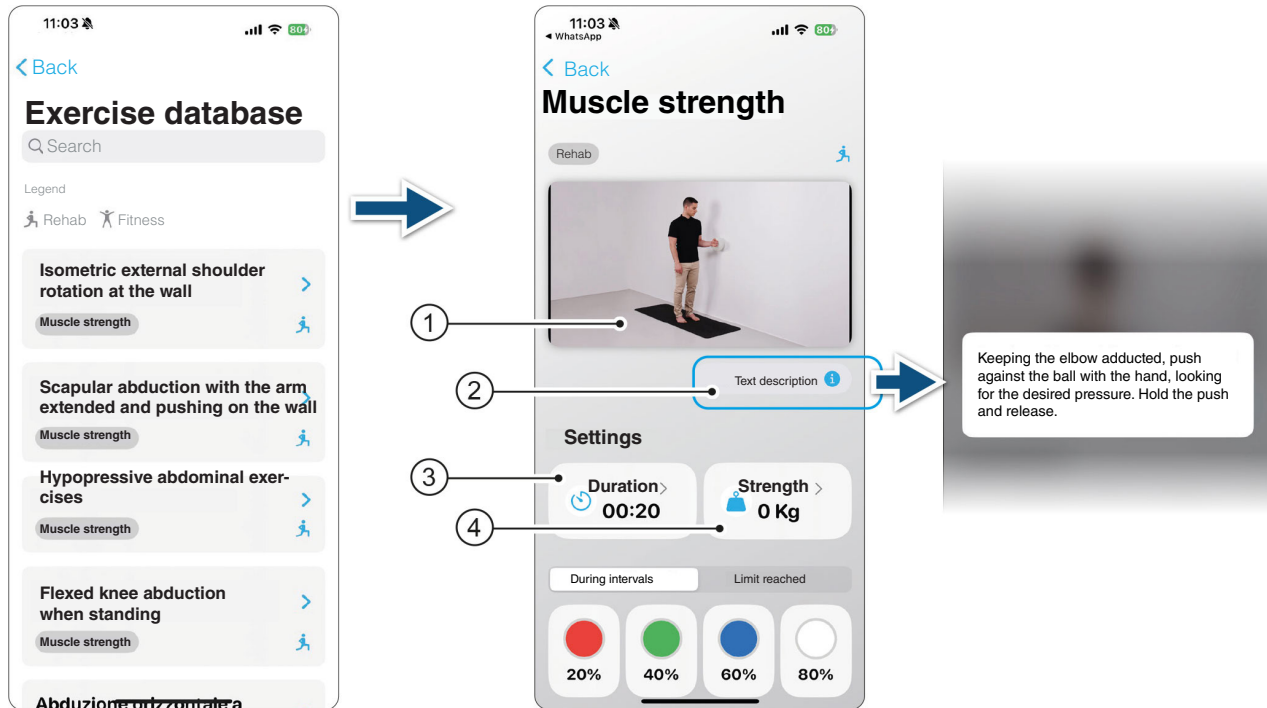
This function allows the user to improve his or her reaction skills.



Pos.	Description
1	Duration: the value appearing on this button indicates the duration of the exercise. To change it, press the button and set the desired value.
2	Colour: one or more colours can be selected from the four available. Once the session has started, the user must react by pressing ORBITA every time one or more of the selected colours appears.
3	Light signal frequency: use this button to adjust the speed at which the colours of the random lighting sequence change.
4	Settings ✓ Save setup New settings can be saved via 'Save Setup' (see Section '6.3 Creating the Setup List').
5	Load setup: retrieve a previously saved setting.
6	Start session: Once the session has started, a 3-second countdown anticipates the start of the duration of the exercise. The results of the exercise can be viewed on the screen during the session: 

6.2.2 Exercise Database

The section providing access to the exercise database appears on the home page of the mobile application below the list of functions. It contains a list of exercises organised by purpose and accompanied by a demonstration video and description.



Each exercise is associated with a corresponding function so that, with the help of the illustrative video and description, the exercise can be executed without leaving the screen.

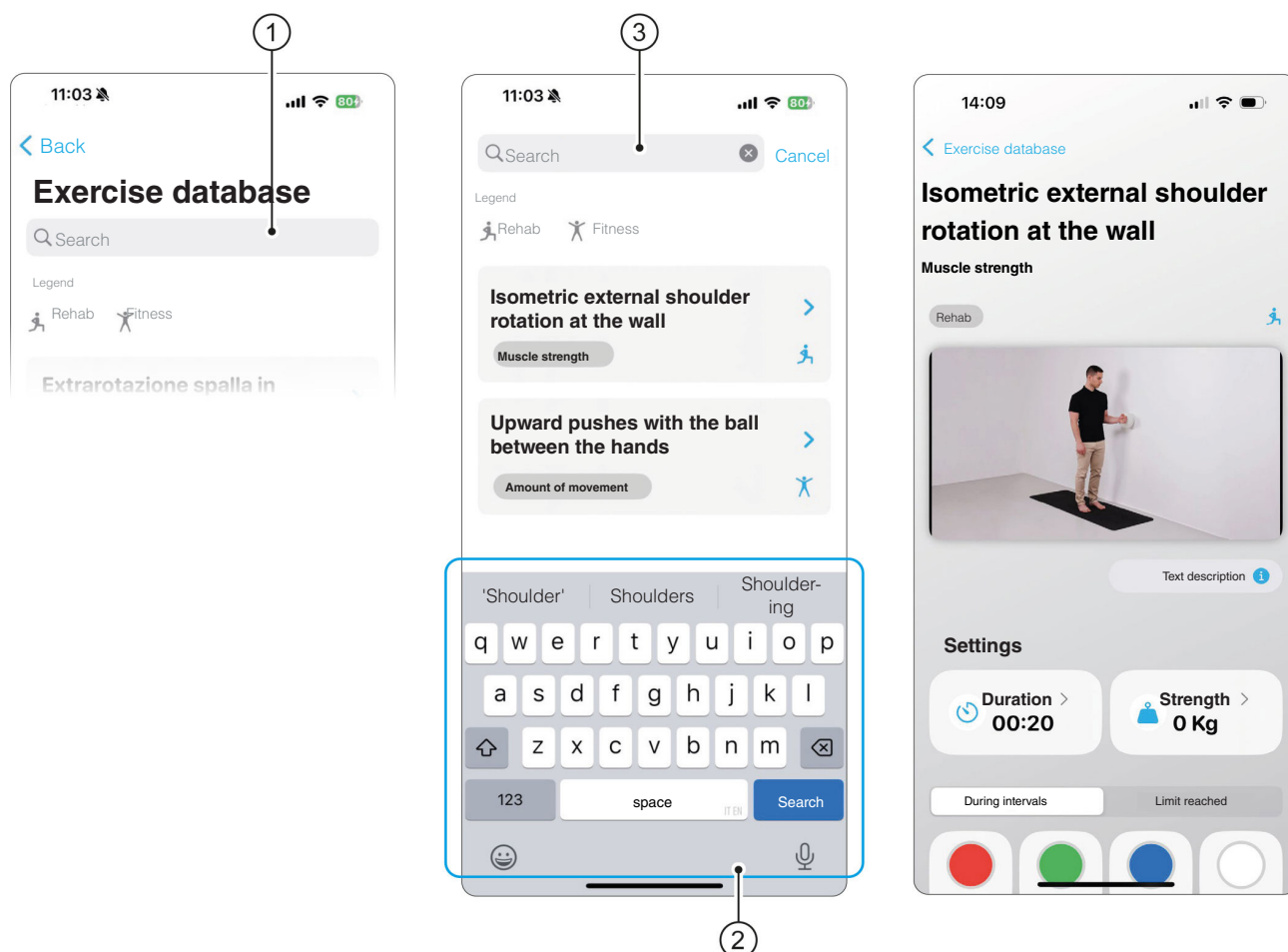
To proceed, perform the steps specified below:

Pos.	Action
1	Select the exercise from the list.
2	Watch the illustrative video (pos. 1) and/or access the text describing its execution by pressing 'Text description' (pos. 2).
3	The predefined exercises in the Orbita library in the application also allow you to set certain parameters such as duration, force, etc. (see pos. 3 and 4) to customise the exercise.

6.2.2.1 Search for and Filter by a Specific Exercise

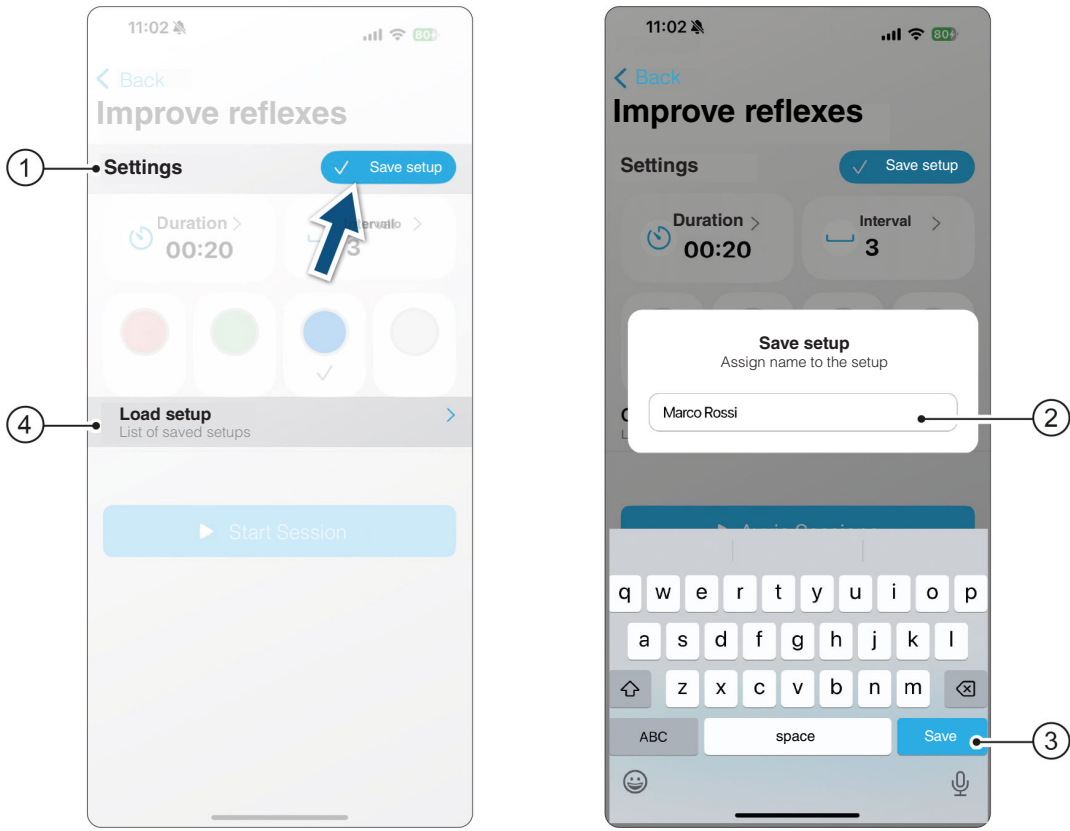
To search for and filter by a particular type of exercise in the library, click on the search bar (**pos. 1**) and type in the keyword (**pos. 3**) using the pop-up keyboard (**pos. 2**). Exercises containing the keyword will be listed automatically at the bottom of the screen.

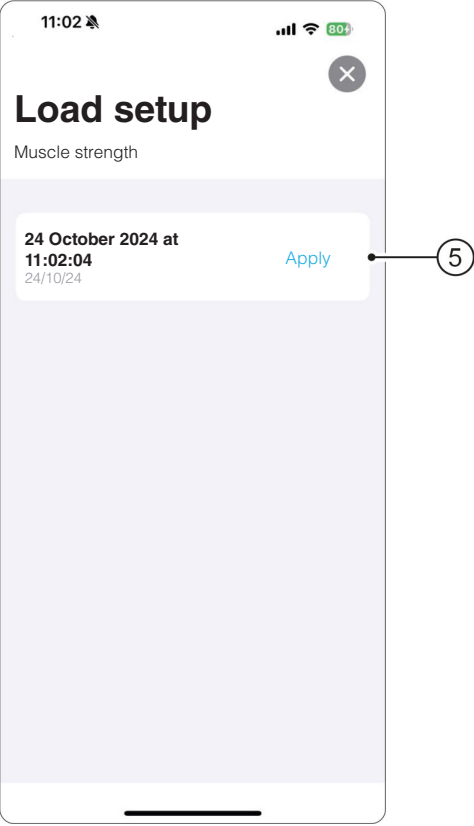
Press on the chosen exercise to perform it.



6.3 Creating the Setup List

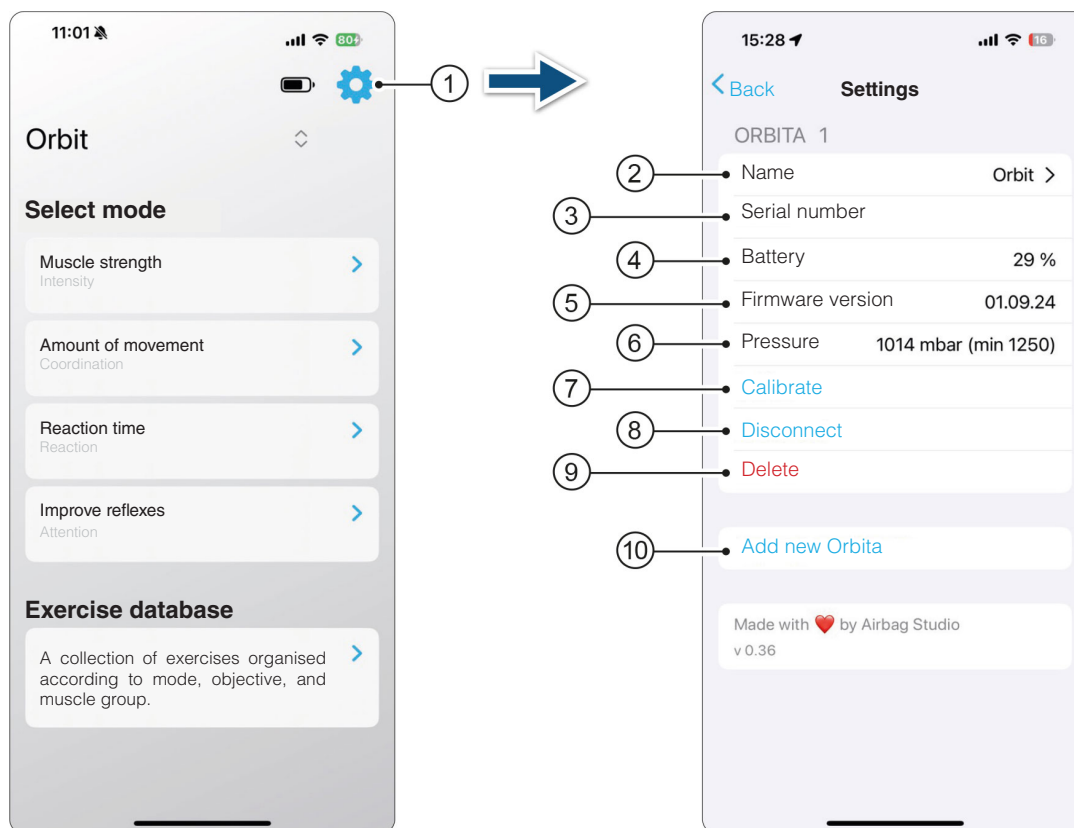
For each available function, the Orbita app allows certain parameters to be customised so that they can be saved and retrieved at a later date. To do so, proceed as follows:

Pos.	Action
1	Settings: once you have entered an ORBITA function and set the customised parameters, press the 'Save Setup' button (pos. 1) to open the page to rename the setup (pos. 2) and save(pos.3) the new setting. 

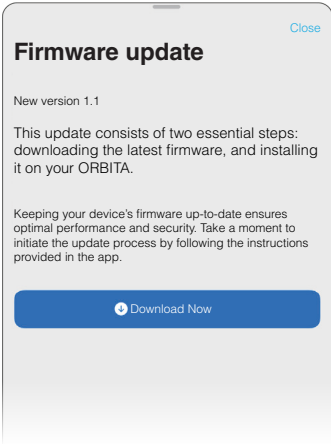
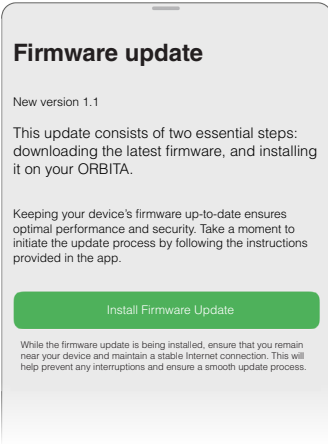
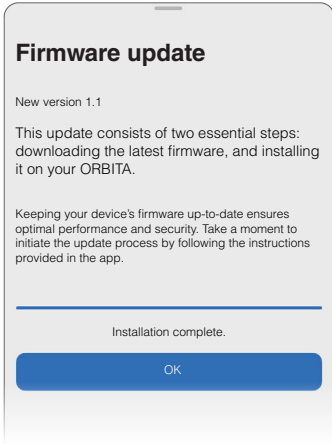
Pos.	Action
2	Load setup (pos. 4): retrieves a setting after it is chosen from the list of saved settings and pressing 'Apply' (pos. 5): 

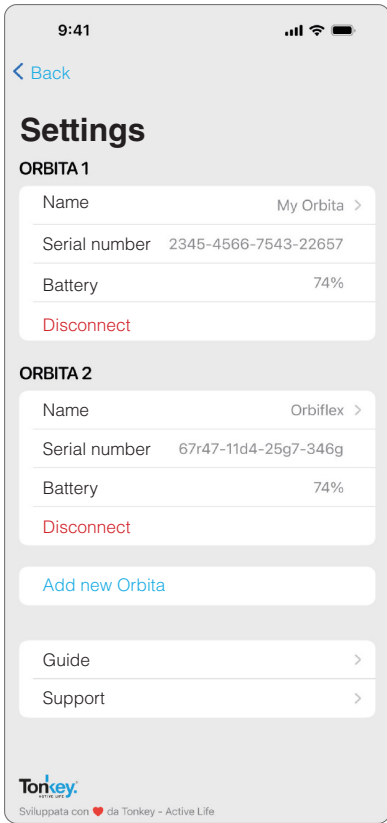
6.4 Settings

The settings section can be accessed from the main page.



Pos.	Description
1	Press this symbol to access the Settings page.  When a red notification dot appears on this symbol, it means that a firmware update is available for download.
2	Name: the name of the ORBITA device appears in this field; the device can be renamed at any time.
3	Serial number: the unique serial number of the paired device appears here.
4	Battery: the battery level of the connected ORBITA device appears here.

Pos.	Description
5	Firmware version: the version of the firmware (integrated software) installed on ORBITA appears here.  If a new firmware version has been released by the manufacturer, a blue dot and the words 'Update' will appear on the button. Press it to download the new version by following the steps indicated on the subsequent pages until you receive a notification that it has been installed:   
6	Pressure: indicates the pressure (in mbar) at a given time.
7	Calibrate: press this field to update the internal pressure of the ball; this is recommended at the beginning of each exercise.
8	Disconnect: press this button to disconnect the ORBITA device from your smartphone.
9	Delete: removes ORBITA from the list of other associated ORBITA devices.

Pos.	Description
10	Add new ORBITA: this button allows a second device to be paired. Once paired, this will also appear on the Settings page with its name and serial number. 



POSSIBLE PROBLEMS AND SOLUTIONS

7 Possible Problems and Solutions

This section lists some problems that may be encountered when operating the device and possible solutions. However, this does not necessarily imply that these problems will arise or that, if they do, they will be determined by the same causes.

Problem	Cause	Solution
The ball does not charge and/or light up.	One of the power cable connectors is not correctly inserted into the port.	Disconnect and firmly connect the connector to the corresponding port on the PC or USB charger. Check that the micro USB connector is firmly connected to the ORBITA charging base.
	The USB port that the power cable is connected to does not work.	Connect the power cable to another USB port.
	The ball is not fully inflated.	Inflate the ball to a diameter of 19 cm (see Section '5.3.1 Inflation Procedure').
	The ball is not correctly positioned on the charging base.	Make sure that the ball cap is perfectly aligned and in contact with the slot in the centre of the charging base (see Section '5.4 Electrical Connection and Charging the Device').
	Lack of electricity on the local network.	- Wait for the power to come back on. - Check the circuit breakers on the local network control panel and switch them to ON.
	Using a power cable other than the one supplied.	Use the power cord provided or one that meets the necessary requirements (see Section '5.4 Electrical Connection and Charging the Device').

Problem	Cause	Solution
The mobile device (smartphone) does not connect to ORBITA.	Bluetooth on the smartphone is switched off.	Activate Bluetooth on your smartphone.
	The ORBITA ball is discharged.	Charge the ball as described in Section '5.4 Electrical Connection and Device Charging'.
	The Orbita app is not up to date.	Search for and download the latest version of the mobile application as described in Section '6.4 Settings'.
The Orbita app does not open.	The Orbita app is not up to date.	- Search for and download the latest version of the mobile application as described in Section '6.4 Settings'. - Switch the smartphone off and on again.
The ball does not connect to the Orbita app.	Undetermined.	- Check that the ball is not connected to another phone. - Check that the ball is not discharged (put the ball back on the charging base). - Close and reopen the mobile application. - Delete the ball from the Settings page (as described in Section '6.4 Settings') and pair it with the smartphone again (see Section '5.6 Pairing the ORBITA Device with a Smartphone').
Other problems.	-	- Switch off and restart the smartphone. - Close and reopen the Orbita app. - Check if there are updates to the Orbita app available for download to the smartphone being paired (see Section '6.4 Settings').

**WARNING!**

If no solution to the problem can be found in the table in Chapter '7

Possible Problems and Solutions' or by consulting this user manual, contact the Ledragomma Srl service department to find the most appropriate solution:

Email: info@ledragomma.com - Tel. +39 0432/986049 - Fax +39 0432/986255

Alternatively, an information request form can be filled out in the contact section on the www.tonkey.it website.



MAINTENANCE

8 Maintenance

8.1 Device Repairs



WARNING!

LEDRAGOMMA SRL does not authorise users to make repairs or install replacements of any part of the ORBITA device.

In the event of malfunctions or failure, contact support to find the most appropriate solution:

Email: info@ledragomma.com - Tel. +39 0432/986049 - Fax +39 0432/986255

Alternatively, an information request form can be filled out in the contact section on the www.tonkey.it website.



FORBIDDEN!

DO NOT disassemble or attempt to repair the device or its components.

8.2 Cleaning

To clean the ORBITA device and charging base, follow the procedure described below.

Step.	Action
1	Disconnect the device from the power supply and charging cable.
2	Clean the ORBITA ball and charging base using only a soft cloth moistened with a solution of 10% alcohol in water.
3	Allow the parts of the device to dry completely before storing or using it.



FORBIDDEN!

- Do not use aggressive, abrasive or solvent cleaning products. They may damage the device.
- **DO NOT IMMERSE** the device or its parts!
- **DO NOT** use cleaning products other than those indicated.
- **DO NOT** disassemble or attempt to repair the device or its components.
- **DO NOT** allow the device to dry near sources of heat or exposed to sunlight.



DISPOSAL

9 Disposal

9.1 Disposal of Materials

Waste disposal must comply with current regulations in the area where the device is being disposed of, avoiding pollution of the soil, air and water.



WARNING!

- The ORBITA device is designed and assembled with materials and components that can be recycled and reused.
- The user's unauthorised disposal of the product will result in the application of sanctions provided for by current legislation.

9.1.1 Device Separation and Disposal Procedure

Step.	Action
1	Disconnect the device from all power sources.
2	Break the device down into its main parts.
3	Separate the parts replaced due to wear or breakage and the parts intended for demolition and take them to the sorted waste collection centres.

9.1.2 Waste from Electrical and Electronic Equipment (WEEE)

The symbol on the equipment indicates that the waste must be 'collected separately'.



Therefore, the user must deliver the waste or have it delivered to the waste collection centres established by the local authorities, or deliver it to the retailer against purchase of a new appliance of an equivalent type.

Sorted waste collection and subsequent treatment, recovery and disposal operations promote the production of equipment from recycled materials and limit the negative environmental and health effects that may be caused by improper waste management.

9.1.3 Disposal of Packaging

Recycle the packaging components. Always check local municipal regulations.





DECLARATION OF CONFORMITY

10 Declaration of Conformity

10.1 Declaration of Conformity (copy of the original)

 	FT06 ORBITA Declaration of Conformity	Annex 10 Rev. 00 Date 12/12/2024 Page 1 to 1
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DECLARATION OF CONFORMITY
Declaration of Conformity

Manufacturer: **Ledragomma S.r.l.**
(Manufacturer) Industrial area - Via G. De Simon 33010 Osoppo (UD), Italy

SRN (Single Registration number) **IT-MF-000018764**

Medical Device
(Medical Device) **Orbita - Smart Motility Ball**

Codes: **4101033D0019000P08** (UDI-DI: 08006531010459)
(Code)

Basic UDI-DI: **8006531FT06V7**
(BASIC UDI-DI)

Applicable Directives:
(Applicable Directives) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
 (REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC)

Directive 2011/65/EU (RoHS2), supplemented by Directive 2015/863/EU (RoHS3), on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
 Directive 2011/65/EU (RoHS2 Directive), supplemented by Directive 2015/863/EU (RoHS3), restriction of the use of certain hazardous substances, as amended by the following modifications and integrations

Classification (Annex VIII, Rule 13, MDR 2017/745): **Class I**
Classification (Annex VIII, Rule 13, MDR 2017/745): **Class I**

Under our sole responsibility, we state that the above-mentioned products meet all the applicable general and security requirements contained in Annex I of Regulation (EU) 2017/745 (Medical Devices Regulation) and all applicable standards.
 Under our sole responsibility, we state that the above-mentioned products meet all the applicable general and security requirements contained in Annex I of the Regulation (EU) 2017/745 (Medical Devices Regulation) and all applicable standards.

Applicable Harmonised European Standards

UNI EN ISO 10993-1
 EN IEC 60601-1
 EN IEC 60601-1-2
 UNI CEI EN ISO 14971
 UNI CEI EN ISO 13485
 For all other standards, refer to Annex 5 of the FT06 Orbit Technical Documentation.
 For all other standards, refer to Annex 5 of the FT06 Orbit Technical Documentation.

The manufacturer undertakes to keep and provide the relevant authorities with the technical documentation specified in Annex II of Regulation (EU) 2017/745 for a period of 10 years from the last product manufacture date.
 The manufacturer undertakes to keep and provide the relevant authorities with the technical documentation specified in Annex II of Regulation (EU) 2017/745 for a period of 10 years from the last product manufacture date.



Quality Manager

Signature

Riccardo Dondè



Issue place and date: Issue place and date:	Osoppo (UD) 12/12/2024 Rev. 00
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ORBITA is a branded device:



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Via G. De Simon
33010 Osoppo (UD) Italy

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info@ledragommapec.com

www.tonkey.it



Revision	Date	Description of the changes
00	12/12/2024	Issue

M A D E I N I T A L Y