

A large, abstract graphic on the left side of the page, composed of several overlapping red geometric shapes (squares, rectangles, and triangles) and diagonal lines, creating a dynamic, layered effect.

ALPHA Motion Tracker User Manual

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Revision History

Date of creation	Date of release for review	Author
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Revision History

Revision #	Revision Date	Description of change	Author
1	29/06/2018	Addition of disclaimer according with FCC regulations.	Sara Francisco
2	01/02/2019	Change of Regulatory Requirements	Sara Francisco
3	11/09/2019	Change of Regulatory Requirements	Sara Francisco

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This manual applies to ALPHA Motion Tracker.



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TABLE OF CONTENTS

1. ABOUT THIS MANUAL	6
1.1. EXPLANATION OF THE PICTOGRAMS.....	6
2. INTRODUCTION AND INTENDED USE	7
3. GETTING TO KNOW ALPHA MOTION TRACKER.....	8
3.1. OPERATING CONDITIONS.....	9
3.2. POWER MODES.....	10
4. SERVICE AND INSPECTIONS	12
4.1. CLEANING	12
4.2. MAINTENANCE	12
4.3. TECHNICAL SPECIFICATIONS	Erro! Marcador não definido.
5. REGULATORY STATEMENTS.....	13

1. ABOUT THIS MANUAL

This manual provides detailed technical and operational information on the ALPHA Motion Trackers.



Caution – Do not use ALPHA Motion Tracker without reading this manual.

1.1. Explanation of the pictograms

Pictogram	Description
	General warning sign according to IEC 60601-1 (2005)
	Manufacturer symbol sign according to NP EN 980 (2008)

2. INTRODUCTION AND INTENDED USE

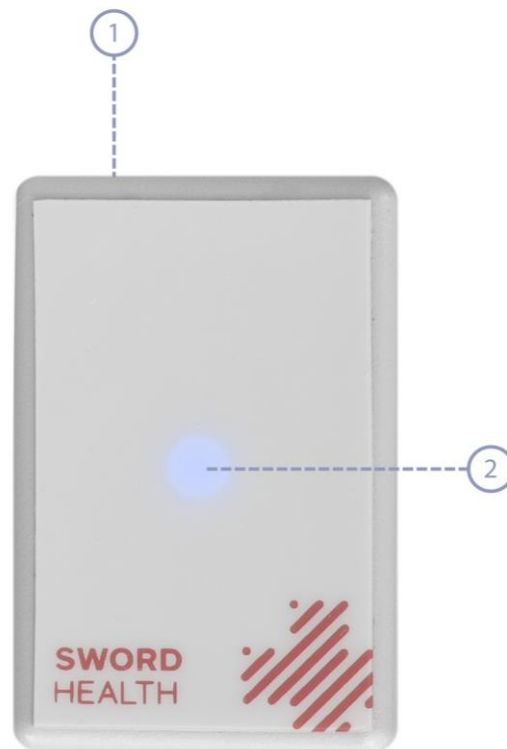
At **SWORD Health**, we focus on finding technological solutions for some of the most important problems in healthcare systems. By identifying common needs across different problems, we are maximizing our impact on people's lives. This is why we have focused on physical rehabilitation.

Current rehabilitation models are based on a one-to-one interaction between therapist and patient. However, high economic costs and heavy logistics represent major impediments in a day-to-day setting. Moreover, tools for communication within and between clinical teams are inefficient and process accountability is low.

We believe that the solution for this problem is a wise combination of novel science-driven therapeutic methods with effective technologies that facilitate dissemination of care, communication and the use of all the knowledge produced in the rehabilitation process of each patient.

Pursuing this vision, we have developed SWORD Phoenix, and alongside ALPHA Motion Tracker. This is a motion tracker easy to use for full body human motion capture; it was developed to be used as part of SWORD Phoenix system, however, being possible to be used independently for joints angles measurement and communicating via Bluetooth.

3. GETTING TO KNOW ALPHA MOTION TRACKER



1- Micro USB port

2- LED

Lightweight, high precision motion trackers that acquire and digitize patient motion and communicate wirelessly with the Phoenix App.

They are available in four different colors (red, yellow, blue and green) with the following scheme.

The motion trackers provide 3D angular velocity (by using gyroscopes), 3D acceleration (by using accelerometers) and 3D earth magnetic field (by using magnetometers). These are integrated using sensor fusion algorithms to provide 3D special orientation of limb segments.

These motion trackers were specifically designed to be used in a clinical or ambulatory setting with a minimum need of calibration procedures.

The equipment may be supplied without a connector. Use a USB 2.0 Micro-B (5pins) connector to plug into Micro USB port.

3.1. Operating conditions

The recommended operating temperature of the motion trackers is between -10°C and +50°C. If operated outside this temperature range performance may decrease or the motion trackers might be damaged. Fast transient temperature fluctuations may cause significant temperature gradients across the device.

The motion trackers contain the absolute possible minimum amount of ferromagnetic materials. Nonetheless, some minor components can be magnetized permanently by exposure to strong magnetic fields. This will render the calibration of the magnetometers useless. Therefore, it is necessary to prevent exposure of the motion trackers to strong magnetic fields, such as close proximity of permanent magnets, speakers, electro motors, among others. It is also advisable to ensure that measurements, in particular calibration steps, are conducted in an area free of or with minimal magnetic distortions.

The motion trackers should be protected from electro static discharges or sources of radiation, as exposure to such sources will damage the internal electronics. The motion trackers should be protected from violent handling such as drops on hard surfaces. Excessive shocks or violent handling may damage the motion trackers.

The motion trackers, cables and must be kept dry at all times. Condensation and water may damage the internal electronics.

The motion tracker is intended to be used on clothes.



- Do not expose the motion trackers to strong magnetic fields or electrostatic discharges
- Do not expose the motion trackers, charger or power supply to water or liquids.
- Do not open the charger or power supply case; there are no user serviceable parts inside.
- Do not cover the fan exhaust or obstruct the airflow, this will cause overheating.
- Use only the manufacturer's power supply and observe terminal polarity.
- Place the charger in a cool spot, away from external heat sources
- Caution - during charging the charger may become warm.

3.2. Power modes

The motion trackers support four power modes:

a) Standby

The motion tracker wakes up on detecting motion. In normal use, the tracker will be in standby mode and the user just needs to pick it up to wake the device. If this doesn't work, pressing the power button will wake the tracker from deep sleep.

b) Active

When in active mode, the motion tracker actively advertises its presence by slow blinking – 0,62 Hz. When connected to the tablet, the motion tracker actively advertises its presence by fast blinking – 2,5 Hz. When advertising, if movement stops and no connection is initiated by a host within 3 minutes, the tracker will return to standby; if the battery is between 20% and 5%, the standby mode is activated within 1 minute.

c) Deep sleep

The motion tracker may be in deep sleep for transportation and development purposes. This mode may be activated via Bluetooth by the manufacturer.

d) Charging

In order to charge the tracker, the user must insert a micro USB cable into the micro-USB slot on motion tracker. When connected to USB power, the tracker will charge its internal battery. The LED changes its color to green to indicate the charge state. When the tracker is fully charged, the LED will stay lit.

Instructions

- 1** - Plug the micro-USB cable end-point into micro USB port of each motion tracker.
- 2** - Plug USB cable into the charger.
- 3** - Plug the charger into the power supply.

4. SERVICE AND INSPECTIONS

4.1. Cleaning

Follow these general rules when cleaning the outside of ALPHA Motion Tracker:

- Make sure the motion tracker is unplugged from the power supply before cleaning.
- Do not use alcohol (methyl, ethyl or isopropyl) or any strong dissolvent. Do not use thinner or benzene, abrasive cleaners or compressed air.
- To clean the trackers, use a cloth lightly dampened with a mild detergent.
- Avoid getting liquids inside. If liquid does get inside, have a qualified service technician to check it before you power it on again.

4.2. Maintenance

ALPHA Motion Tracker has an expected service life of 3 years. In order to guarantee a perfect and effective functioning of the equipment, it is recommended an annual inspection by a service technician authorized by the manufacturer.



Only authorized specialists can perform technical support and maintenance of ALPHA Motion Trackers. Do not open the equipment. Opening the equipment by unauthorized personnel will result in loss of warranty. In case of malfunction, contact the manufacturer.

5. REGULATORY STATEMENTS

OWNERSHIP

"ALPHA Motion Tracker" including all the components and documents that are included in the kits, are the sole property of SWORD Health, S.A..

INTENDED USE

"ALPHA Motion Tracker" is a motion tracker that intends to be used with "SWORD Phoenix", a rehabilitation interface, to quantify movement.

SIDEEFFECTS AND CONTRAINDICATIONS

The device is contra-indicated for hemodynamic instability or other serious medical condition limiting physical rehabilitation; hyper-acute stroke patients; pain or deformity limiting the movement of target joints; respiratory and/or cardiovascular disease contraindicating mild to moderate exercise; skin lesions or any continuity solution in the area where the motion trackers would need to be placed. SWORD Health has exercised great diligence in selecting the materials for SWORD Phoenix. Nevertheless, there is always a small chance that some materials may lead to allergic reactions in individuals under exceptional circumstances.

LIABILITY

In no event will SWORD Health be liable to the misuse or lack of the "ALPHA Motion Tracker", including negligence or any other use not described in this document. Whilst being a motor rehabilitation tool, the use of the SWORD Phoenix does not automatically guarantee patient improvement.

INTELLECTUAL PROPERTY RIGHTS

The "intellectual property" rights are the exclusive property of SWORD Health, S.A.. These include all the intellectual property and/or industrial property rights/and or rights about software or hardware owned by SWORD Health, S.A. and/or related with the activity of SWORD Health, inter alia, relating to SWORD Phoenix or any other product, technological solution, technical documentation, software, databases, feedbacks, documents and manuals, know-how, as well as all the studies and conclusions of any nature, including the ones connected with technics, business, process and commercialization, already existing and/or which are subsequently created and/or developed by SWORD Health, S.A. and/or by others.

TERMINATION EFFECTS

Upon the termination of the contract, all system components must be returned to SWORD Health, S.A., including hardware, accessories and support documents.

USER MANUAL

The User Manual describes the system components, features, setup, and operability. The User Manual

is not intended to replace and does not replace the need for appropriate training regarding the use of SWORD Phoenix.

FCC and RF EXPOSURE STATEMENTS

This equipment complies with FCC radiation exposure limits set forth for an controlled environment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. (Example - use only shielded interface cables when connecting to computer or peripheral devices).

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

ISED and RF EXPOSURE STATEMENTS

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC radio frequency (RF) Exposure rules.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

- this device may not cause interference and
- this device must accept any interference, including interference that may cause undesired operation of the device

Cet équipement est conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques.

(RF CNR-102 de l'ISED)

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes :

- l'appareil ne doit pas produire de brouillage, et
- l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

ADVERSE EVENT AND SYSTEM MALFUNCTION REPORTING

In case of detection of an adverse event or system malfunction, contact "SWORD Health, S.A. immediately via e-mail (support@swordhealth.com) or by phone (+351 223 248 286).