EN-2011 Version 7

MotionPodTM System Users' Manual







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I. TERMINOLOGY

Code Name	Description
MPOD	MotionPod designates the wristwatch sized motion sensing case with a transparent casing. See figure 1 below.
CTRLER	MotionController or charger/data receiver of the MPOD device. Designates data receiving and/or recharging case which connects on the computer via USB port. See figure 2 below
CHARGER	Designates the recharging case which connects to the computer via USB port and is used only for charging the MPOD. It does not have data receiving capabilities.

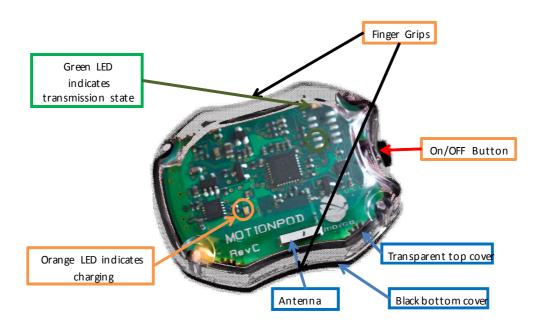
Please note that CTRLER/CHARGER initials are mentioned on the labels at the back of the devices

II. USED ICONS SIGNIFICANCE

Icon	Description
	« CAUTION » Symbol
	Environnemental friendly Recommandations
†	Part worn by the Patient



III. PRODUCT DIAGRAM



 $FIGURE\ 1:MOTIONPOD^{\mathsf{TM}}$



FIGURE 2 : MOTIONCONTROLLER™



IV. SAFETY RULES

Warning

Please read this user's guide very carefully before use.

Advise all recommendations to end-user and keep informed of all risks endured using the system.

CTRLER/CHARGER must be plugged using equipment in compliance with INTO standard 60950-1 via USB2 port with the provided cable. In order to fulfill safety requirements for electro-medical systems and equipments, power must be supplied by a transformer in compliance with the EN standard 60950.

MPOD is the part in contact with the patient, who is not to be in contact with the CTRLER or the computer during use. Patients are to be held at 1,20m to 1,60m away from this equipment.

MPOD is not meant to be used with inflammable gaz.

"The MPOD is not protected from defibrillation shocks. »



Do not open or replace the Li-ion battery of the MPOD. Do not use non rechargeable battery or any other battery that could damage the product and presents health risks or cause accidents.



DO NOT EXPOSE TO FIRE-Risk of explosion, DO NOT OPEN



CAUTION: For your own safety do not open the charging case, risk of electric shock.

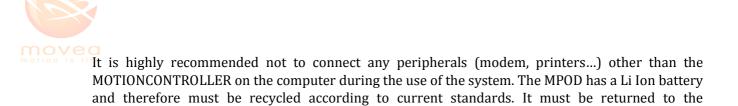


CAUTION: the USB cable serves as a disconnection device



Waste management process of electric and electronic products differs from that of municipal waste and requires special intervention from waste management services appointed by the government or the local community. The crossed trashcan shows that the European directive 2002/96/CE applies to this product.

Waste separation prevents from any negative consequences on the environment or public health. It is the most important condition for better handling and recycling electric and electronic components. For more information about handling of worn out equipments, contact your local waste management service or the nearest product distributor.



V. INTRODUCTION

Thank you for purchasing our motion sensing product **MPOD**.

This user manual was written to familiarize you with the use of this system. Read it carefully in order to rightfully use the device. Always have this guide near you when you use this product.

The MPOD is an electronic recording device with wireless transmission. It was conceived to provide "movement signature" of a body segment in real time and without cable connection.

Its main purpose is to record and/or compare a series of motion exercises: Series of rehabilitation exercises with prior exercises, movement amplitudes gestures protocols etc... carried out for limb rehabilitation (for example of joint movement).



manufacturer.

MPOD only gives information related to the orientation of a patient's part of body. Any other use must be avoided.

This product designed and manufactured by Movea, is well adapted for biomechanical applications, rehabilitation and joint assessment in physical therapy. For this reason, it must be used in a controlled environment, at a practice office, and by qualified personnel. The user of MPOD must have red and understood this notice.

The MPOD System is provided with software that must be the only software solution to be used with this product. For customers willing to manufacture a product based on the MPOD system, please make sure the person in charge of using the MotionPod system is fully trained.

VI. GET FAMILIAR WITH MOTIONPOD™

Please take a moment to familiarize with the different components of your measuring system. For the following section it is advised to refer to the material scheme II.

1. MOTIONPOD™

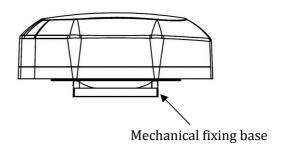
MPOD is standard wristwatch-sized sensor with a transparent casing that embodies the Motion sensing component on the upper side (Figure 3). It is intended to be worn on the moving part of the body where we want to perform motion measurement. It must be fixed mechanically by means of straps or bracelets (not provided) via the transparent mechanical interface.



Photo of MotionPod™







 $FIGURE\ 3:MOTIONPOD^{\mathsf{TM}}$

On the top of MPOD you can see the electronic components with an imprinted name and logo of the manufacturer (Movea,), the brand name of the product (MotionPod). The sensor button indicates the exact orientation of the MPOD when positioning it properly on the body. Please pay attention to these elements as they are useful to establish the MPOD correctly in the application that is provided with your system.

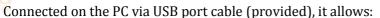
From a side view (see Figure 3, on the right), you can see a Black bottom cover of the MPOD. This part allows fixing the MPOD on any kind of supporting facet designed to accommodate it. It can be the charging box (see below) or the mechanical interface for bracelet or strap. Figure 1 summarizes the first visual elements on the MPOD.



FIGURE 4: MPOD MECHNICAL INTERFACE FOR BRACELET OR STRAP

2. MOTIONCONTROLLER™

The CTRLER is a white case with a surface identical to that of a credit card and approximately 2cm thick (see Figure 5). On the upper facet you can see an imprinted logo of Movea, and light indicator inscriptions (see below for their significance). At the back of the Motion controller a sticker imprinted ControllerTM distinguishes it from the Charger who has the same casing.



- Data reception transmitted from the MPOD by radio frequency (2.45 GHz Bluetooth Band)
- Charging of the MPOD



FIGURE 5 : MOTIONCONTROLLER™

The CTRLER features a wireless link between the MPOD and the computer where you run your applications. The data goes to the computer via USB cable.

3. MPOD CHARGER



FIGURE 6: MPOD CHARGER

The CHARGER and the CTRLER have the same casing. Since the CTRLER has the same functionality, the CHARGER is therefore optional. It's only needed when several MPODs need to be charged regularly. On the upper facet you can see an imprinted logo of Movea, and light indicator inscriptions (see below for their significance). At the back of the Motion controller a sticker imprinted Controller $^{\text{TM}}$ distinguishes it from the Charger who has the same casing.

Connected on the PC via USB port cable (provided), it allows:

• Charging of the MPOD



VII. USAGE

1. RECHARGING YOUR MOTIONPOD™



The CTRLER must be connected to a computer in compliance with IEC/EN 60950-1 standard. In order to fulfill safety, power must be supplied by a transformer in compliance with EN standard 60950. Only the MPOD is in contact with the patient environment.

First connect the CTRLER to the USB port of your computer using the provided cable.

Once the CTRLER is connected, the light indicator "pwr" goes on and gives a green continuous light (see Figure 2). The two other light indicators are blue diodes which light up along with the first one once connected to the USB port. They switch off immediately then blink twice to finally go off completely.

Put the CTRLER horizontally on a table, facet where the logo is imprinted upwards. You can see the cavity where you can clip the MPOD in. Insert the MPOD by its Black bottom cover directly in the cavity. The button of the MPOD must be pointing to the Logo. The MPOD must completely fit in the cavity.

A clockwise rotation of approximately 30° mechanically locks the MPOD in the cavity and therefore electrically connects it to the CTRLER for recharge. A "click" sound indicates that the system is suitably locked and started charging (if charging is needed). The whole unit must look like the photograph on Figure 5.



MPOD encloses a battery. The performance gradually decreases over an extended period of time (see the number of possible charging cycles).



In case of extended period of no use, it is advised to check the battery condition by charging it. If the battery does not charge any more, it is necessary to return the product to the manufacturer for maintenance (battery exchange). This operation cannot be carried out by the user. Opening of MPOD (or CTRLER) will void the manufacturer's warranty.



IMPORTANT (Switzerland): Part 4.10 of the SR 814.013 norm is applicable to batteries





FIGURE 7: THE MPODFIXED ON THE CTRLER, READY FOR RECHARGE

While charging, an orange light indicator located at the back of the MPOD switches on. It switches off as soon as the recharging process is complete. Theoretically, charging duration is 3 hours.

When the MPOD is recharged after a very long period of no use, it is possible that the orange light indicator takes a few minutes before switching on.

If the battery reaches its critical point due to a long period of storage, the only solution is to return the MPOD to your supplier for battery replacement (at own expense).



It is dangerous and strictly prohibited to use any other charging equipment than the CTRLER/CHARGER of Movea. Using other charger can damage the MPOD and will void your manufacturer's warranty.



The MPOD should not be opened. Battery replacement should only be carried out by your supplier.

2. HOW TO SWITCH THE MOTIONPOD™ ON/OFF

The MOTIONCONTROLLER $^{\text{m}}$ must be connected to the PC. The MPOD must formerly be recharged. Take the MPOD off the CTRLER.

Slightly push the button on the MPOD to switch it on. At this stage, the green light indicator blinks with a 4 second interval. The MPOD is not transmitting any data to the CTRLER at this point, it is simply on IDLE state. You can switch the MPOD off by a pressing on the button for 4 seconds. The green light indicator blinks twice before switching off for 3 seconds. It then switches on for 1 second. As soon as the indicator emits a continuous light, you can release the button.

The provided software will guide you through an effective data transmission between the MPOD and the CTRLER.

3. HOW TO WEAR THE MOTIONPOD™



To fix MPOD on the body patient, use solutions provided by the product supplier. Be sure not to tighten up excessively. The MPOD is provided with a mechanical interface to attach bracelets, belts or straps. This is the only interface that the user must use to adapt non-magnetic bracelets provided by the manufacturer. The MPOD should not be in contact with any other material that can cause measurement distortion.

MPOD must however remain attached on the body. A biocompatible Clothing interface will be placed between the skin and the MPOD to guarantee hygiene and to avoid direct contact.

Do not use any other mechanical interface than the one provided by the supplier and specially made for this purpose.

VIII. PRECAUTIONS

1. USING ENVIRONMENTS

The MPOD is a measurement technology based on accelerometers, magnetometers and gyroscopes. Its main purpose is to provide the user with 3D orientation of the body segment wearing the sensor. The MPOD is well-adapted to estimate posture of a joint segment. Measurements must be carried out within the limitations of the sensor:

- 8G acceleration
- Maximum Angular velocity: 1600°/s

The use of MPOD does not have any long term effect. Movements of the patient must however be carried-out under the supervision of a health professional. Indications given by the MPOD are provided as an indication.

The MPOD encloses sensors that to measure orientation parameters in space. These measurements should not be used for diagnosis. They are only informative and meant to support the physical therapists decision. They are not certified, so the information they give must be subject to discussion.



Like any other electronic device, there is a risk of modification of the system's essential performances in case of electromagnetic disturbances. This risk is increased by the presence of magnetometers in the system.

- Note 1: A magnetic object is disturbing. Similarly, a ferrous object (attractable by a magnet) is also very likely to disturb magnetometers of the MPOD™.
- → Note 2: A mobile phone often has a loudspeaker which contains magnets itself.

For best performances of your system, you must respect conditions of use and rightfully choose the site where you carry out your measurements:

- You must carry out sessions of measures at a usual chosen place, where magnetic disturbances are minimal.
- When various postures or positions are carried out by the subject, it is necessary to avoid translations higher than 1m of amplitude. The static magnetic field must be constant and uniform inside the area of work.
- Keep any ferrous objects far from the measurement site (approximately at a distance twice the largest dimension of the ferrous object); for example:
 - o Scissors: 30 cm
 - o Laptop battery: 50 cm



- o Keys: 15 cm
- While using the MPOD for measurement or calibration (see further below), see to it that there isn't any object likely to disturb measurements (ferrous objects, watches, mobile phone...)
- o MPOD should be used far from motorized chairs or beds.
- Only small magnets are accepted in the same room (i.e. whiteboard magnet), but must be kept far from the MPOD (>50 cm), as they might cause a serious decrease in the systems accuracy.
- o do not to put the mpod in contact with a magnet as it will make it permanantly useless.
- o The presence of strong magnetic field generating machines (like MRI) is not adapted to the use of MPOD[™].

2. CHARACTERISTICS AND ENVIRONMENTAL CONDITIONS

Usage conditions	
Temperature	Stable between 0°C and 35°C
Maximum dynamic acceleration measured	-8g à 8g
When not using gyroscopes, orientation measures are	valid for static and quasi static
positions. When using gyroscopes body motion must be	limited to sensors limit.
The measured orientation parameter is valid in a uniform or quasi uniform magnetic field between	
gauss and +6 gauss ¹	
Maximum Shock resistance	4600 g for a time of 0,5 ms
	MPOD should not be thrown away violently.
	It is however resistant to shocks in normal
	conditions of use.
Magnetic field survivability	10 000 Gauss
Maximum rate of magnetic field tolerated before	miss- 20 Gauss
calibration	

Temperature	Between -20°C and 35°C (For 6 month maximum)
	45°C (For 1 month maximum)
Shock resistance	4600 g for a time of 0,5 ms
Magnetic field survivability	10 000 Gauss
$\label{eq:maximum} \textbf{Maximum rate of magnetic field tolerated before misscalibration}$	20 Gauss

¹ MotionDevTool v2.0.4 software automatically checks if this condition is verified during recording of the movement signature. An alarm is emitted in case of magnetic disturbance. If there is no alarm, the user is under desired conditions.



Temperature	Between -20°C à 35°C (For 6months
	maximum)
	45°C (For 1 month maximum)
Shock resistance	4600 g for a time of 0,5 ms
Magnetic field survivability	10 000 Gauss

Maximum rate of magnetic field tolerated before miss- 20 Gauss

calibration



MPOD transmits data to the CTRLER via radio signal. The transmitted signal is in the Bluetooth band. MPOD is tested in CEM. However, the presence of other radio transmitting devices can lead to interferences with MPOD $^{\text{TM}}$. Do not to use the MPOD when other radio operating devices are running and are priority for patients.



The device is mobile and portable. Its transporting conditions must respect the intended protection means. Internal transportation does not require particular precautions

IX. CALIBRATION

When to calibrate?

Your MPOD has been calibrated during the manufacturing process. Calibration consists in adjusting certain parameters for offset and sensitivity and to obtain standardized measurements. However, over a long period of time, or after a magnetic shock, the sensors are likely to drift. It is then necessary to calibrate.

In static mode, irregularities on accelerometer measures can be due to a very fast movement. The software will probably request re-recording with a slower gesture. If magnetometers are responsible for the anomaly, it's more likely because there are magnetic disturbances in the environment. In all other cases, it is necessary to calibrate.

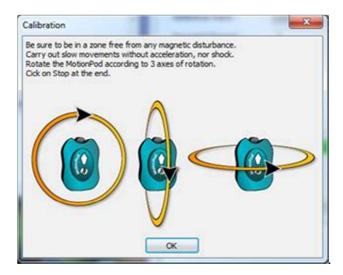
It is recommended to calibrate MPOD manually before any procedure. Calibration lasts 30 seconds and it is well guided by the provided MotionDevTool v2.0.4 Software. It mainly performs measurements, and has menus to calibrate the MPOD according to the procedure described below.

How to calibrate?

Here's the best way to calibrate the MPOD:

- Be sure that the zone where the calibration is carried-out is free from any magnetic disturbances (refer to section VII).
- Take the sensor only in hand. We recommend putting your elbows on a wooden table and maintaining the MPOD with your fingers
- It is advised to be oriented facing north.
- Rotate the MPOD with your fingers according to the 3 rotation axes (figure below):







Be sure to maintain the MPOD in the same position, in a sphere of 5cm of diameter. Carry out slow movements without acceleration, nor shock

X. CLEANING

1. CLEANING THE MOTIONCONTROLLER™

The CTRLER/CHARGER are made of ABS plastic. Frequent disinfection or cleaning is not needed because they're not in contact with the body.

Disconnect the CTRLER/CHARGER before cleaning. Use a soft and dry cloth.

2. CLEANING THE MOTIONPOD™

MPOD and the mechanical interface are made of natural polycarbonate (for the transparent cover) and of "polycarbonate" (the Black bottom cover, and mechanical interface). The button on MPOD is in NBR. Use products listed below or other products compatible with these materials. Cleaning products must be compatible with Polycarbonate. Do not immerse the MPOD in these products.

- Use protection gloves (medical or latex)
- Use a wet cloth humidified with the below products example of well adapted cleaning products: HEXANIOS G+R from Anios laboratories

(http://www.anios.com)







Wet cleaning napkins



Liquid container

FIGURE 8: WELL ADAPTED DISINFECTION PRODUCTS HEXANIOS G+R



Before using the MPOD, it is recommended to avoid skin contact by applying biocompatible CE certified bandage (example: Urgoderm band, see figure 7)



FIGURE 9 BIOCOMPATIBLE BANDAGES TO PUT BETWEEN THE SKIN AND MPOD

XI. SIGNS AND LABELS

1. MOTIONPOD™

The MPOD is the part of the system in contact with the subject.

Label of the MPOD (on the bottom cover)



We can see

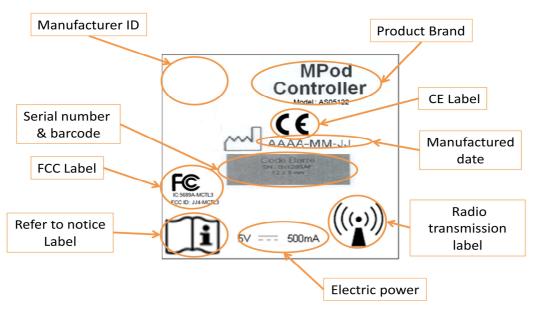
- The CE mark
- Radio frequency presence indicator
- Barcode with serial numbers
- "Refer to the user manual" symbol

15 mm of diameter



2. MOTIONCONTROLLER™

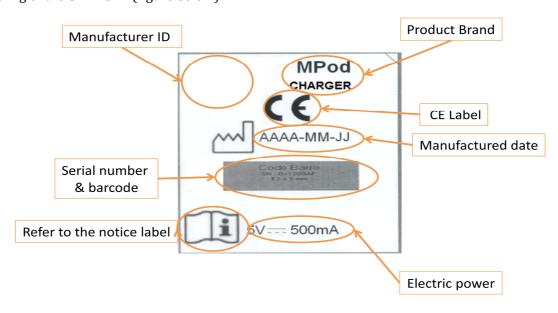
The label of the CTRLER figures at the bottom of the case



Dimension~ 30 x 33 mm

3. CHARGER

Labeling of the CHARGER (figure below)



Dimension~ 30 x 33 mm



XII. MAINTENANCE

The MPOD system does not require any particular maintenance other than cleaning after each use. Manufacturer calibration is carried out at the time of manufacture of the MPOD $^{\text{\tiny{M}}}$. Follow instructions on section VIII for re-calibration.



The MPOD should not be opened. Battery replacement operation should only be carried out by supplier's qualified personnel.

XIII. WHAT TO DO IN CASE OF SYSTEM BREAKDOWN

Symptoms	Possible solutions
The application doesn't recognize the CTRLER	 Make sure that the software has been installed properly Close the software, unplug, wait 5 seconds and replug the CTRLER, wait 5 seconds and rerun the software
	- If the problem persists contact your local distributor
The CTRLER doesn't work properly, the green light indicator doesn't go n when plugged on PC The MPOD green light indicator doesn't go on when pushing the	 Make sure that the PC is on and working Change the USB cable If problem persists, contact your local provider Make sure that the battery is not empty, for that place it on the CTRLER. The CTRLER must be
button	 plugged on a running PC. The orange light indicator goes on to show the start of recharging process. It can take up to 30 minutes if the battery is very low. If problem persists, contact your local provider.
There has been a power cut-off and the CTRLER lost connection with the PC, the software lost all contact with his reception peripheral. It could be an unfortunate disconnection of the CTRLER.	 Close the software, Unplug and re-plug the CTRLER and Rerun the software

The MPOD system doesn't need any particular maintenance (other than cleaning)



XIV. REGULATORY INFORMATION

3. NOTICE TO USERS:

This equipment has been tested and found to comply with the limits for 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.

FCC Statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Movea for compliance could void the user's authority to operate the equipment. The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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