ORTHOPUS SUPPORTER USER MANUAL

SYMBOL EXPLANATION

	In combination with the word, "Warning", this symbol is used to relay vital information on how to prevent certain actions that may lead to equipment failure or dangerous practices.
	In combination with the word, "Hazard", this symbol is used to relay vital information that may help you avoid a risk of equipment failure, serious injury and/or death.
	This symbol indicates that the product is not to be disposed of with your household waste, in accordance with the EEEW (Electrical and Electronic Equipment Waste) Directive (2002/96/CE) and your country's legislation. Improper handling of this type of waste may have a negative impact on the environment and human health due to potentially-hazardous substances generally associated with EEE. For more information on where you can recycle your used equipment, please contact your City Hall, Waste authority, approved EEEW program or Household Waste Disposal Department.

INTRODUCTION

This document is the User Manual for the ORTHOPUS Supporter, a dynamic arm support system manufactured by ORTHOPUS. This manual contains information for installation and use of this medical device, its safety and contact details. ***Prior to using it, please ensure that you read through this document carefully and keep it in a convenient location where you may refer back to it as needed.***

BACKGROUND

The ORTHOPUS Supporter alleviates the weight of the arm so as to facilitate mobility for those individuals with a reduced range of arm movement. This support system is directly mounted to an electric wheelchair, as well as to a table or workstation. Non-invasive, this device is indicated in the case of upper extremity muscle weakness.

The ORTHOPUS Supporter arm support system is a CE-certified, Class I medical device in accordance with Rule 13 of Appendix VIII of European Regulation 2017/745 on medical devices.

This device is to be installed by an individual trained specifically for that purpose. We recommend that users be monitored by a healthcare professional to ensure proper use of the ORTHOPUS Supporter.

WHO ARE THE INTENDED USERS OF THIS DEVICE?

The ORTHOPUS Supporter has been developed for individuals with:

Residual mobility in the elbow and shoulder

Mobility in the horizontal plane (moving the arm from left to right)

Everyday hand function

Examples of which may be found below:

- Individuals suffering from muscle weakness, resulting in the inability to carry out basic day-to-day activities (eating, drinking, using a computer, etc.) and for which mechanical arm support systems lack sufficient compensation;

- Individuals suffering from arm, neck and/or shoulder pain due to difficult work conditions (repetitive tasks, heavy loads, static posture, etc.).

The Brooke Upper Extremity Rating Scale ***(diagram in the appendix of this document)*** may serve, for information purposes, as a frame of reference: The ORTHOPUS Supporter is intended primarily for individuals at levels 2-4.

USE OF DEVICE

INTENDED USE OF DEVICE AND RECOMMENDATIONS

The ORTHOPUS Supporter is to be mounted to an electric wheelchair, table or any other similar surface that is both **sturdy and of rigid frame** with a thickness ranging between 1 cm and 5.5 cm.

If the ORTHOPUS Supporter cannot be mounted to a table or wheelchair, **it must remain in its packaging and box at all times** to avoid falls or other impacts that may damage the support system. The box is to be kept should the device need to be returned.

Prior to removing the user's arm from the support, please always ensure that the ORTHOPUS Supporter is **in STATIONARY or SLEEP mode**. The ORTHOPUS Supporter is **designed exclusively to support the arm**: it is not to be used as an aid when standing up or sitting down, or for any other purpose.

The user may experience joint pain given the newly-acquired ranges of arm movement from use of the device. To avoid this, it is recommended that the user **become acclimated to the device gradually** and be monitored by a qualified healthcare professional.

In the event of faulty or damaged casings, cables, connectors, power-operated parts or battery connection, **please refrain from using the device**. Should you have doubts regarding the safety of the electronic devices, the product is no longer to be used, and must be removed from the wheelchair. Failure to do so may result in loss of warranty. **Please contact your ORTHOPUS Supporter Country Representative for any maintenance issues.**

The ORTHOPUS Supporter does not have parts that may be modified or repaired by the user or other individuals, except for the custom inlay components and images on the logo disc. Please do not modify any part of this equipment without permission from the manufacturer. **Failure to do so may result in a malfunction and the loss of warranty.**

When mounting the device, the screws are to be sufficiently tightened and the appropriate adjustments made. To ensure this, only **an individual**

trained specifically for this purpose is authorized to install the ORTHOPUS Supporter.

This equipment has potential pinch point areas. Please ensure that those individuals present, **children namely**, keep their fingers away from the motor unit when the device is in use.

Please use the device in **an appropriate setting**:
- Do not place the device in direct sunlight or directly near a source of heat for an extended period of time.
- The device is water-resistant, but **not waterproof**. Do not expose it to heavy rainfall or significant ambient air humidity.

CONTRAINDICATIONS

For those conditions generating joint pain from arm movement, device use is to be verified and validated by a healthcare professional.

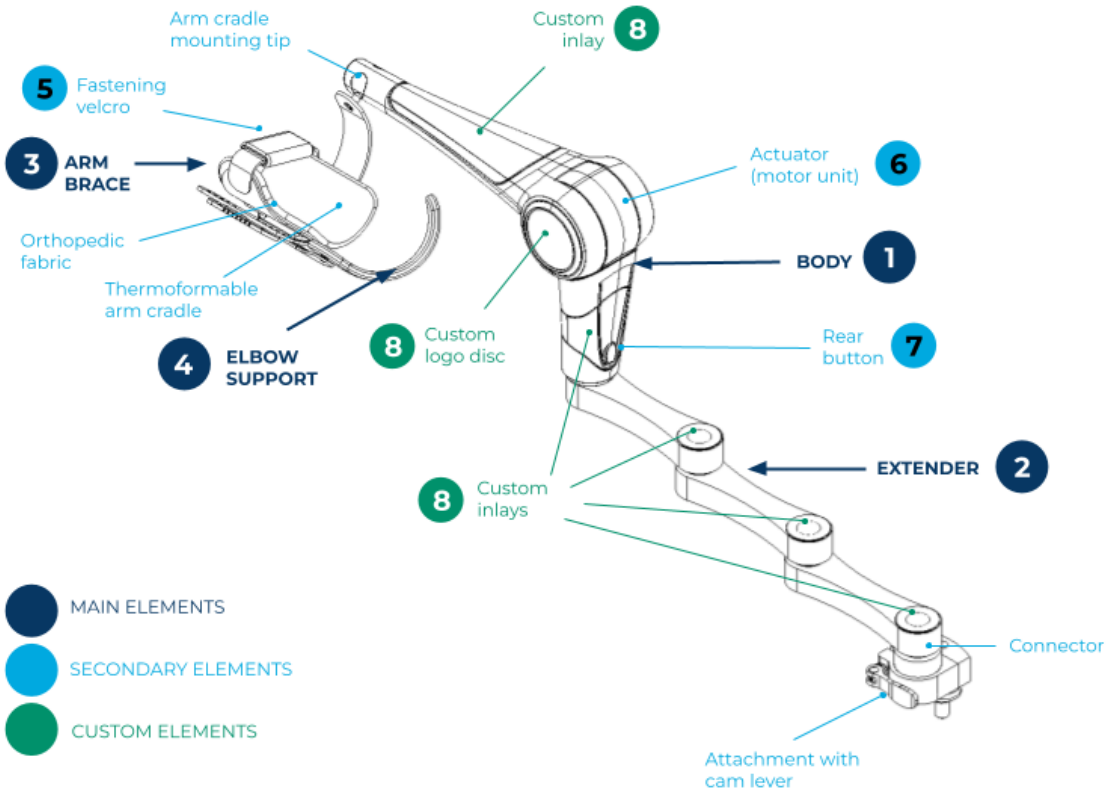
Individuals whose cognitive or behavioral disorders are likely to compromise proper follow-through of recommendations.

History of dominant upper extremity fractures in the three (3) months prior to fitting.

Any impairment or injury that may interfere with use of the device.

TECHNICAL ELEMENTS

TECHNICAL INFORMATION



ORTHOPUS SUPPORTER SETTINGS	
Dimensions	Max. length: 765 mm – Min. length: 530 mm Width: 200 mm Height at 90°: 320 mm
Load weight	4 kg (includes weight of arm and object held)
Movement speed	0 to 100 mm/s
Average power consumption	4 W for basic usage
Maximum power consumption	15 W during peak demand
Range of motion	Two (2) symmetrical ranges of motion on arm cradle possible (Left/Right)

DESCRIPTION

- The arm cradle (**3**) is the main part of the ORTHOPUS Supporter in contact with the user. The user's arm is positioned in this component lined with an orthopedic fabric to ensure comfort. The shape and size of the arm cradle are adaptable to each user. The fastening velcro (**5**) provides further stability of the arm in the arm cradle.

- The elbow support (**4**) enables the upper part of the user's arm to be held in place when using the device. It helps to keep the arm from slipping out when the user bends his/her elbow or lifts his/her arm.

- The extender (**2**) enables the user to move about freely in the horizontal plane.

- The body (**1**) of the ORTHOPUS Supporter is made up of:
    - The actuator (motor unit) (**6**), enabling movements to be made; and
    - The On/Off (Rear) button (**7**), enabling the user to switch from one mode to the other, set the position swing limits, and activate the sleep mode on the device.

- The inlay components and logo disc (**8**) are the elements that may be customized based on the user's preferences.

USAGE

This device features two (2) operating modes. The user has the choice between **assisted movements (FREE mode)**, mobilizing the residual force, and a **STATIONARY mode** that **accompanies the arm at all times (STATIONARY mode)**, enabling movements that require no effort on behalf of the user.

The ORTHOPUS Supporter may be mounted to the right and/or the left side: an appropriate arm cradle is available for each side. This allows both arms to be equipped alternately.

⚠ To fully leverage ORTHOPUS Supporter functionality, **it is vital to not only choose the right size of arm cradle and elbow support, but also adjust them accordingly. *See section below.***

⚠ Should the user encounter any issues when using the ORTHOPUS Supporter, please contact your ORTHOPUS Supporter Country Representative or a healthcare professional as soon as possible.

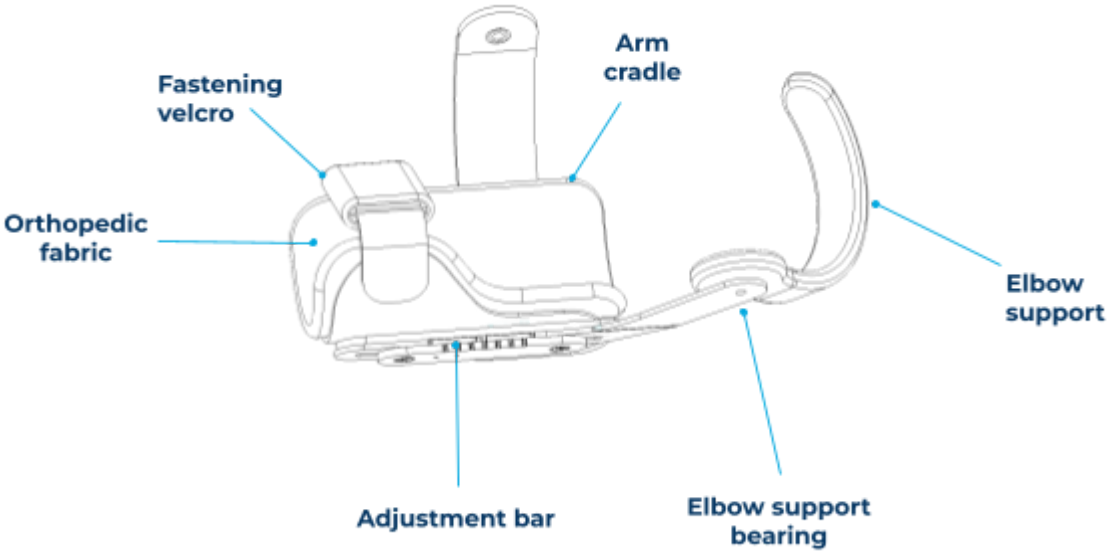
INSTALLATION AND UNINSTALLATION

Arm cradle adjustments

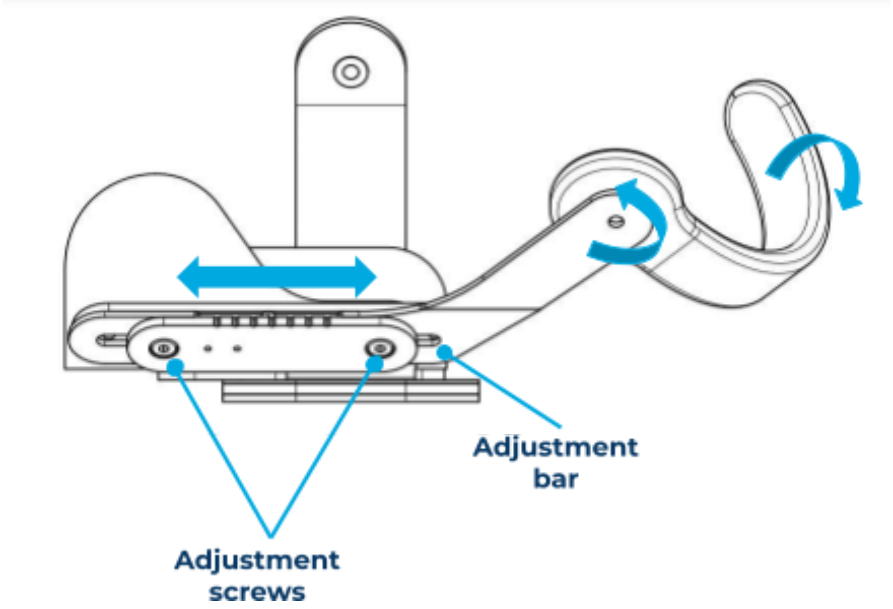
To take full advantage of all that the ORTHOPUS Supporter has to offer, proper adjustments of the arm support are of utmost importance.

Please ensure that:

- ➔ The arm is stabilized in the arm cradle; and
- ➔ The arm is always in contact witch the elbow support. Should you notice that the arm is not securely in place, or tends to slip out, reposition it accordingly.



To adjust the position of the arm cradle, loosen the adjusting screws, slide the adjustment bar until the position desired, and then tighten the screws again.



The elbow support may be adjusted in two (2) directions:

1. Rotation of elbow support: Loosen the elbow support bearing until the elbow support can be rotated. Adjust the elbow support.

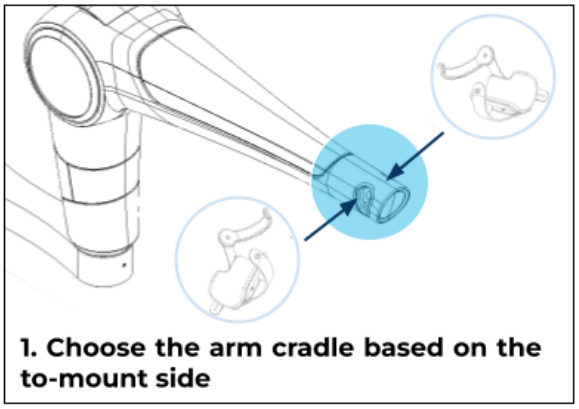
2. Position of elbow support: Loosen one or several screw(s) on the adjustment bar. Adjust the elbow support by sliding it in the direction of the arrow. Once the desired distance between the arm cradle and elbow support has been reached, tighten the adjustment screws again.

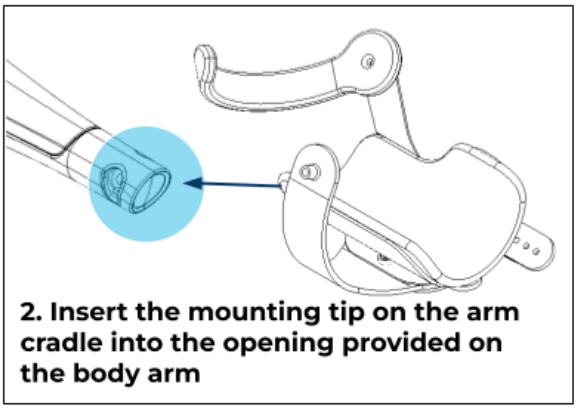
⚠ The position of both the arm cradle and elbow support is vital to ensuring optimal user-device interaction and performance. Poor adjustments to these positions may result in a significant decrease in the performance or even a malfunction of the ORTHOPUS Supporter. Therefore, only individuals trained specifically for this purpose are authorized to modify the settings on the arm cradle and elbow support.

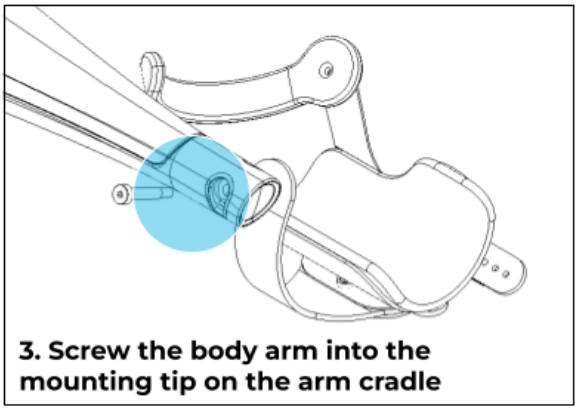
📘 ***To ensure optimal arm cradle adjustments, please refer to the "Choosing and Installing the Arm Brace" document on orthopus.com/en/documentation.***

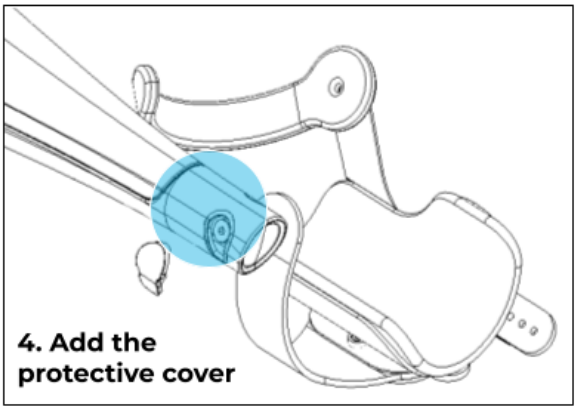
Mounting and dismounting the arm cradle

Please follow the steps below on how to mount the arm cradle, as well as dismount it by undoing all of the mounting actions.









The ORTHOPUS Supporter may be mounted to the right and/or left side. An appropriate arm cradle is available for each side.

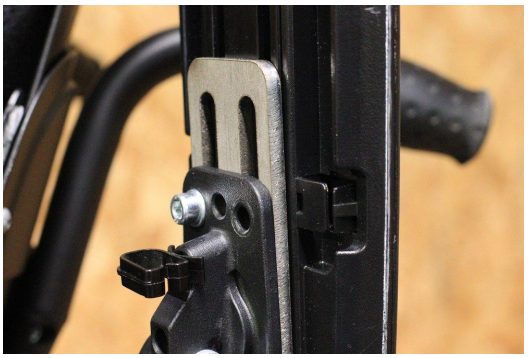
Wheelchair installation

⚠️ Pictures below are an example with a Permobil wheelchair. **To find the installation details on other wheelchair brands, *please refer to the "Wheelchair installation" document on orthopus.com/en/documentation***

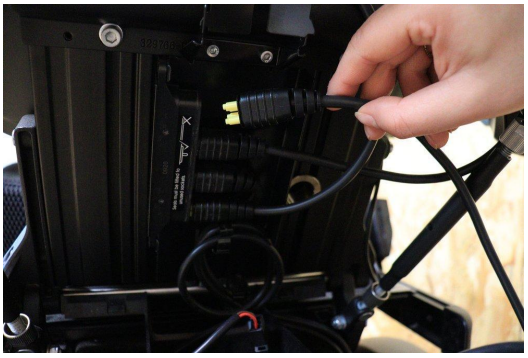
1. Take the regular user' position on the armrest in picture: please write the inclination down and mark the arm pad on the armrest in order to replace it at the exact same place when reassembling.

2. Dismount the armrest from the wheelchair (corresponding to the "to-mount" side or side chosen for device installation).

3. Place the wheelchair attachment with cam lever ("Wheel-Cam") on the slotted metal plate underneath the armrest using the screws already there.



4. Remount the armrest as per the instructions provided by the wheelchair manufacturer.



5. The connection to the wheelchair is done using a cable plugged directly into the Box interface. (Depending on the model of the electric wheelchair, connectors may differ. Please refer to the "Wheelchair Installation" document.)

6. Plug the cable into the socket along the white arrow.

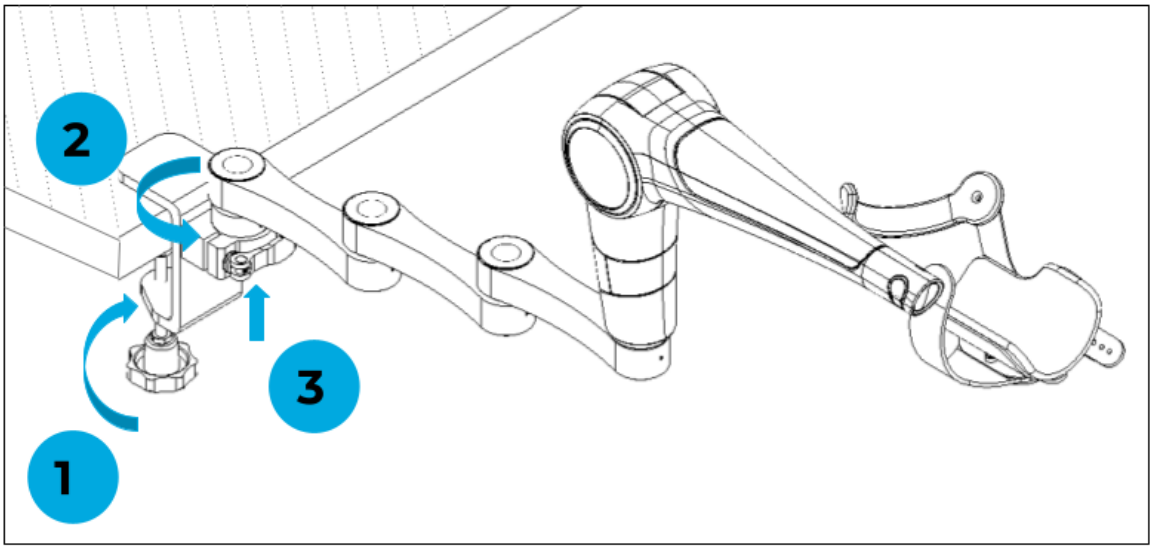
📘 ***For complete instructions on wheelchair installation and the list of compatible wheelchairs, please refer to the "Wheelchair Installation" document on orthopus.com/en/documentation.***

⚠️ If need be, once the ORTHOPUS Supporter has been mounted, lower the height of the armrest by a few centimeters so as to keep the shoulder from shifting upwards when using the device.

⚠️ Should the armrest be tilted upwards, raise the device to where it is attached, enabling it to move about freely without touching the armrest.

⚠️ The Box interface is to be stored on the back of the wheelchair to avoid contact with water.

Table installation



Install the table support by tightening the screw (1), and place the ORTHOPUS Supporter in it (2). Once the device is solidly in place and stabilized, plug in the cables (3).

⚠ The ORTHOPUS Supporter is to be mounted to a table or any other similar surface that is both **sturdy and of rigid frame** with a thickness ranging between 1 cm and 5.5 cm.

OPERATION

The ORTHOPUS Supporter is operated using the buttons on the control pad and Rear button.

Control pad

Rear button

⚠ **Prior to removing the user's arm** from the support, please always ensure that the ORTHOPUS Supporter is **in STATIONARY or SLEEP mode**.

STARTING

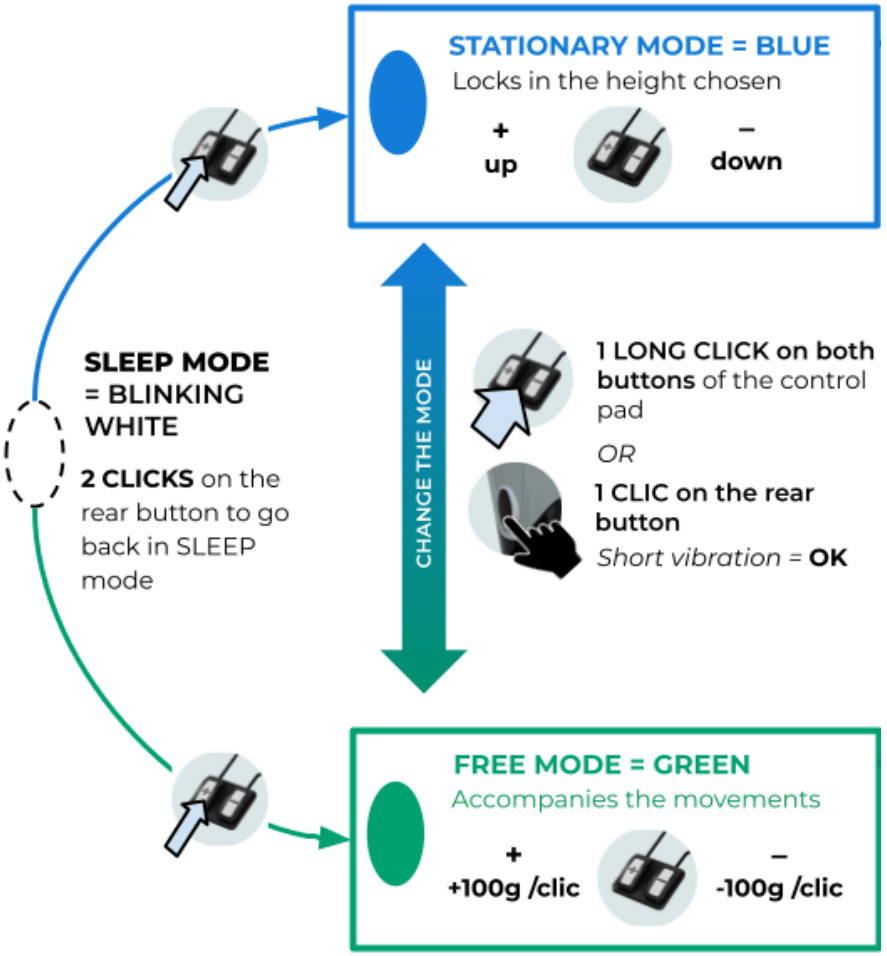
⚠ While starting the ORTHOPUS Supporter, don't touch the control pad and don't install an arm in the arm brace.

As soon as the device is plugged, it's automatically in SLEEP mode

Rear button
blinking **WHITE**

OPERATION

To switch from one mode to the other**: 1 LONG click on both buttons** of the control pad (user) **or 1 CLICK on the Rear button** (caregiver).
A short vibration indicates the switch of mode.



SETTING AN IDEAL COMPENSATION FORCE IN FREE MODE

	1. Switch to **FREE MODE.**
	2. **Determine the ideal compensation force** using the control pad (click to increase or decrease in increments of 100 g using the + and - signs).
	3. **1 LONG CLICK** on the Rear button to set the ideal force.
	4. The **short vibration** indicates that the force has been set.

Once the compensation force has been set, the user may move the arm without having to use the buttons.

- ➔ The set compensation force **remains in the memory** even when the user switches from one mode to the other, or when the device is off.
- ➔ To **modify** the force set, **repeat** the operation with the new force chosen.
- ➔ By default, the compensation force is set at **500g** at the first use

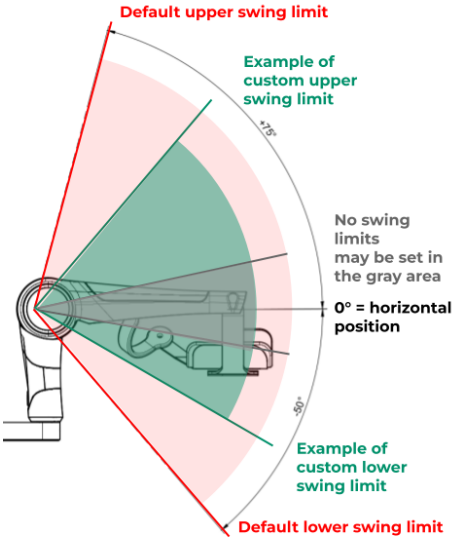
SETTING THE UPPER AND LOWER SWING LIMITS IN STATIONARY MODE

	1. Switch to **STATIONARY MODE.**

	2. **1 LONG CLICK** on the Rear button to enter in configuration process
	3. Rear button blinking **YELLOW** = set the **UPPER SWING LIMIT**
	4. **Position yourself** where you would like to set the upper swing limit
	5. To **SET, 1 LONG CLICK** on the Rear button *Long vibration* = OK **To skip WITHOUT setting, 1 SHORT CLICK**
	6. Rear button blinking **PURPLE** = set the **LOWER SWING LIMIT**.
	7. **Position yourself** where you would like to set the upper swing limit.
	8. To **SET, 1 LONG CLICK** on the Rear button *Long vibration* = OK **To skip WITHOUT setting, 1 SHORT CLICK**
	9. Back in **STATIONARY MODE**.

- We recommend setting **an upper swing limit inferior to the default upper swing limit** so as to keep the arm from slipping out of the arm cradle when raised very high (image below).

- **Warning:** The swing limits may not be set **at less than 10° from the horizontal position** of the ORTHOPUS Supporter: gray area on the diagram below.



PARKING POSITION ON ELECTRIC WHEELCHAIR

In **STATIONARY** mode, pull down the ORTHOPUS Supporter on the armrest: the device stays blocked in place.

This position can be used for parking the ORTHOPUS Supporter when it isn't used or while driving the wheelchair. To go out of the Parking position, click on the **+** button of the control pad.

Rear button blinking **blue**
Parking position activated OK

SAFETY IN FREE MODE

If the device is switched in **FREE** mode without arm in the arm brace, the ORTHOPUS Supporter puts itself in safety: the Rear button blinking in green to mark the stop.

The safety is deactivated as soon as an arm is placed in the arm brace.

Rear button blinking **green**

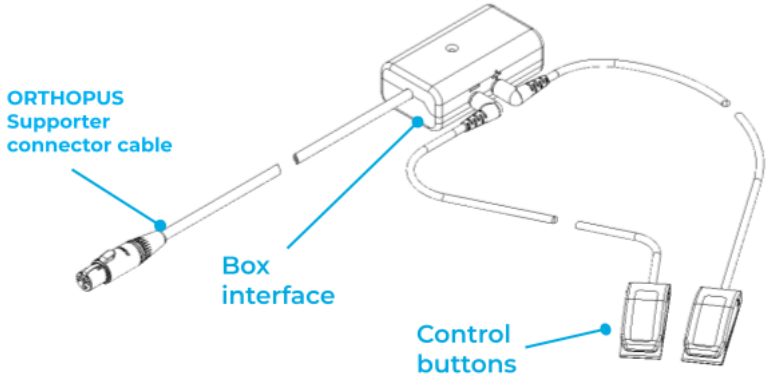
WARNING LIGHTS

Unplug the device and wait a few minutes before using it again.
If the Rear button stays red, please contact your ORTHOPUS Supporter Country Representative.

Rear button
Blinking red

⚠ If this error is repeated several times, please contact your ORTHOPUS Supporter Country Representative.

ACCESSORIES



BOX INTERFACE

The Box interface refers to the casing that links the various power supply and control elements to the ORTHOPUS Supporter.

Two (2) types of connections exist depending on how the device is used:

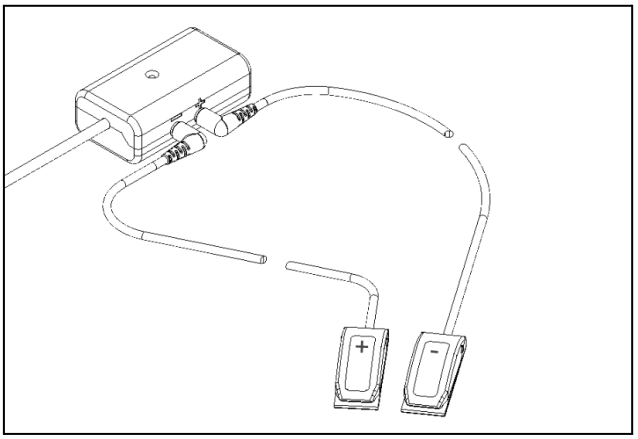
- Use on a table or any other stationary surface requiring a connection to a power outlet; or
- Use on an electric wheelchair requiring a direct connection to the wheelchair battery.

CONTROL BUTTONS

- The ➕ enables the user to **MOVE UP in STATIONARY MODE** or **INCREASE the COMPENSATION FORCE in FREE MODE**.
- The ➖ enables the user to **MOVE DOWN** in **STATIONARY MODE** or **DECREASE the COMPENSATION FORCE in FREE MODE**.

The buttons come assembled on the same pad. Should this configuration not be adapted as needed, it is possible to separate the buttons by unscrewing them from the pad so as to reconfigure them in a way that is best suited to the user.

⚠ Connection of the buttons to the Box interface must be done in accordance with the ➕ and ➖ symbols appearing on the image below.



Our device functions **with standard control buttons** found in stores. That said, please **contact your Country Representative to ensure compatibility**.

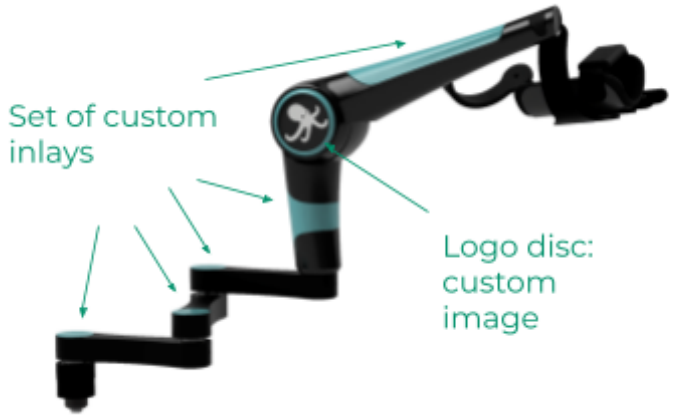
CUSTOM ELEMENTS

The device is made up of elements that may be chosen by the user:

- a set of interchangeable custom inlays (eight (8) colors possible); and
- the image, or logo disc, found on each side of the motor unit that may be changed as often as the user likes.

📘 ***Please find all the information related to changing the image on each logo disc (size, orientation, etc.) on orthopus.com/documentation.***

➔ Magnets may be found underneath the custom inlays and each logo disc, enabling easy removal of them. These elements do not allow access to the critical parts of the device (circuit board, motor unit, etc.), and may, therefore, be handled without any risk to the user.



MAINTENANCE INSTRUCTIONS

CLEANING

The ORTHOPUS Supporter may be cleaned using a damp towel and gentle, non-abrasive product. Do not put the ORTHOPUS Supporter in water.

STORAGE

The device is to be stored in a dry, dust-free location.
Whether for transport, storage or returns, the packaging and cut-to-size foam are to be used.

REUSE

For the purposes of reuse, the ORTHOPUS Supporter is to be disassembled and reviewed by an ORTHOPUS-trained professional or its distributor.
The ORTHOPUS Supporter is to be cleaned and disinfected between users.
The plastic parts of the buttons may be removed and replaced with new ones. The orthopedic fabric lining the arm cradle, as well as the custom inlays, may be changed.
The ORTHOPUS Supporter will be refurbished and repackaged so as to comply with the essential safety and performance requirements in accordance with enforceable regulations.

WARRANTY

The ORTHOPUS Supporter is guaranteed **two (2) years** under **normal use and without modifications to the device**. The device is to be sent back in **its original packaging** with the label containing its unique identifier (stuck to the underside of the extender).

RECYCLING

This product and its components are to be disposed of in accordance with current environmental regulations.
Please contact the competent authorities in your country for further information on collection procedures and waste recycling.

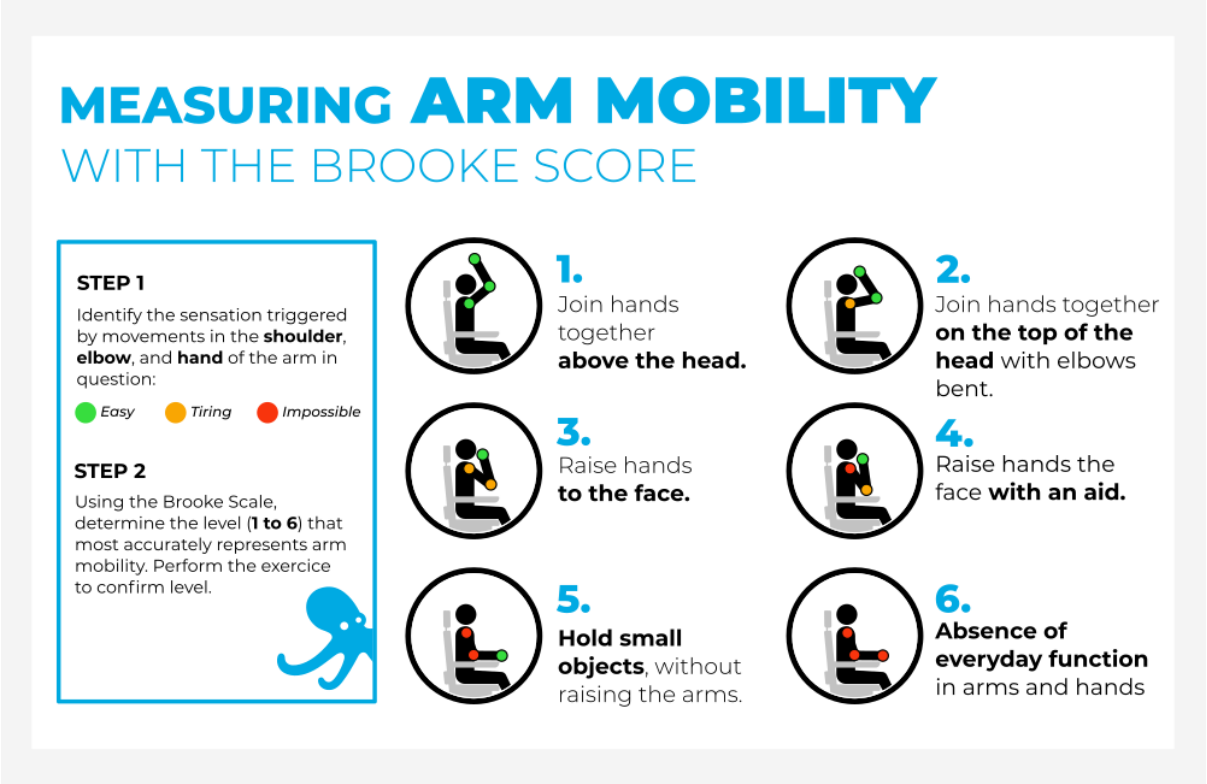
APPENDICES

BROOKE UPPER EXTREMITY RATING SCALE

To measure arm mobility, one tool available is the Brooke Upper Extremity Rating Scale.

Designed originally for muscular dystrophy, this scale is beneficial in a number of situations because it accounts for mobility: in the shoulder, elbow and hand, although other settings may also be assessed.

***For information purposes*, the ORTHOPUS Supporter is intended for individuals with a score of 2 or 4.**



APPLICABLE STANDARDS

REFERENCE	TITLE
13485: 2016 + A1: 2021	Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes
62366-1: 2015	Medical Devices — Part 1: Application of Usability Engineering to Medical Devices
15223-1: 2017	Medical Devices — Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied — Part 1: General Requirements

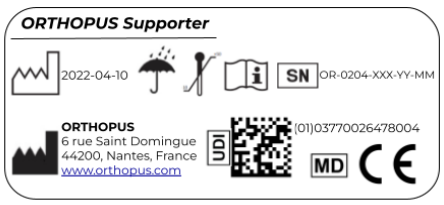
15223-2: 2010	Medical Devices — Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied — Part 2: Symbol Development, Selection and Validation
60601-1: 2006 + A1: 2021	Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance
60601-1-2: 2015 + A1: 2021	Medical Electrical Equipment — Parts 1-2: General Requirements for Basic Safety and Essential Performance — Collateral Standard: Electromagnetic Disturbances — Requirements and Tests
60601-1-6: 2010 + A1 + A2: 2021	Medical Electrical Equipment — Parts 1-6: General Requirements for Basic Safety and Essential Performance — Collateral Standard: Usability
62353	Medical Electrical Equipment — Recurrent Test and Test after Repair of Medical Electrical Equipment
14971: 2019	Medical Devices — Application of Risk Management to Medical Devices
14155: 2020	Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice
10993-1: 2020	Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process
62304: 2006	Medical device software

CE MARKING

CE

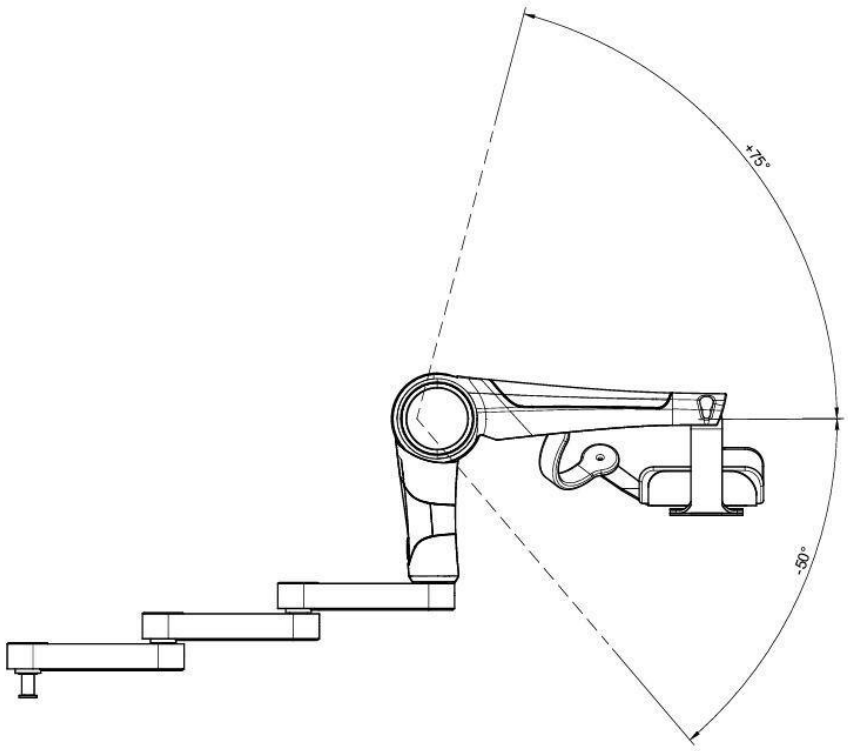
The ORTHOPUS Supporter is a Medical Device, CE certified since 02/09/2022, belonging to Class I according to rule 13 of the Annex VIII of the European Regulation 2017/745 on medical devices.
This product has an EU Declaration of Conformity attesting to the conformity of the product with the Medical Devices Regulation (EU) 2017/745, amending Directive 2001/83/EC, EC Regulation No. 178/2002 and EC Regulation No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and the French Public Health Code.

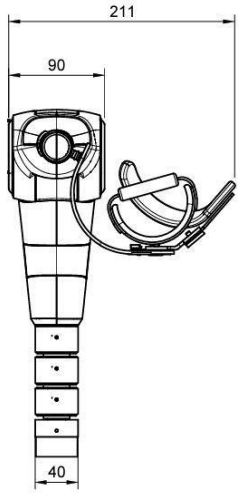
LABEL

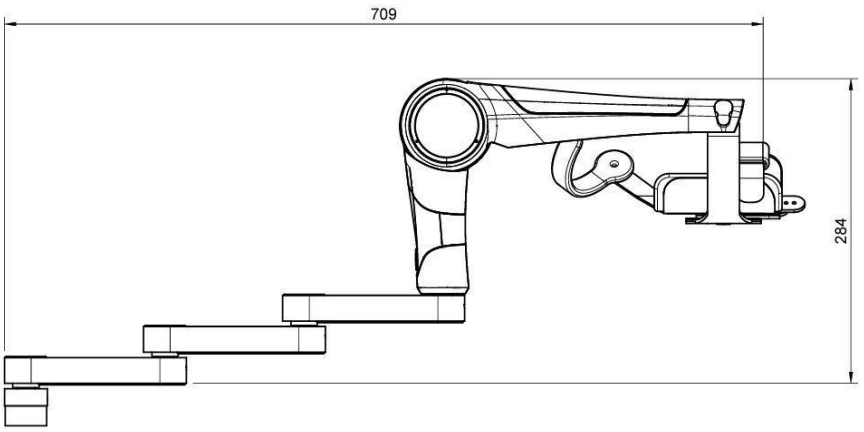


This label may be found on the ORTHOPUS Supporter and its packaging.
It features a Unique Device Identification (UDI) that enables its traceability. **This is, therefore, not to be removed from the product nor its packaging failing which use of the warranty may be jeopardized.**

TECHNICAL ELEMENTS







TECHNICAL SPECIFICATIONS	
Load weight	4 kg (includes weight of arm and object held)
Movement speed	0 to 100 mm/s
Swing space	Radius of the circle within which the plane mechanism can fluctuate = 400 mm

	Amplitude of motion = [-50°; 75°] in relation to horizontal position
Dimensions	Max. length: 765 mm – Min. length: 530 mm Width: 200 mm Height at 90°: 320 mm
Operating noise	< 60 dB
Average power consumption	4 W for basic usage
Maximum power consumption	15 W during peak demand
Storage temperature °C	[+10°C; +25°C]
Storage humidity	Max. 40% to 60%
Operating temperature °C	[-10°C; 50°C]. The temperature of the outer surfaces on the ORTHOPUS Supporter is not to exceed 60°C.
Operating humidity	Max. 40% to 60%
Degree of protection	IP 42
Range of motion	Two (2) symmetrical ranges of motion on arm cradle possible (Left/Right)
Wheelchair shutdown time	< 30 sec.
Materials	Aluminum, stainless steel, plastic (resin), orthopedic fabric

CONTENT OF THE PACKAGING BOX

Medical device elements:

- One (1) assembled ORTHOPUS Supporter (extender + arm brace + set of inlays in the color chosen by the user);
- One (1) Box interface (control casing);
- Two (2) Control buttons;
- One (1) Table support **OR** One (1) Wheelchair attachment with cam lever;
- One (1) Wheelchair connector cable **OR** One (1) 240-Watt power supply;
- One (1) Box interface > ORTHOPUS Supporter connector cable.

Documents:

- One (1) detailed User Manual;
- One (1) simplified User Manual;
- One (1) "Wheelchair Installation" Manual;
- One (1) "Choosing and Installing the Arm Brace" Manual.

CONTACT INFORMATION

The ORTHOPUS Supporter is manufactured by:

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