

ORTHOPUS

SUPPORTER

USER MANUAL



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SYMBOL EXPLANATION

	This symbol, associated with the word "Danger," is used when there is important information that can help you avoid the risk of equipment failure and/or serious or fatal injuries.
	This symbol, associated with the word "Caution," is used when there is important information to avoid certain actions that may lead to equipment failure or potentially hazardous practices.
	This symbol is used to indicate contraindications for the use of the device.
	This symbol is used to communicate usage recommendations.
	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.
	Read the user manual before use.
	Keep dry.
	Applied parts of type BF (Arm brace / remote control).
	Serial number.



	Product reference.
	Medical device.
	Unique device identifier.
	Date of manufacture.
	Manufacturer information.
	Humidity limits.
	Pressure limits.
	Temperature limits.
	Direct current.
	CE marking for Class I medical device.
IP 22	An IP22-rated product is protected against the penetration of solid foreign objects with a diameter of 12.5 millimeters or more. It is also protected against vertically falling water drops when tilted up to 15° from its normal position.



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 Lovett 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

WARNING



DANGER: Do not apply excessive force to the device. For example, do not lean on it. The ORTHOPUS Supporter is designed solely to support the arm.



DANGER: The user may experience joint pain due to the new arm movement freedoms gained with the device. To prevent this, it is recommended to **use the device gradually** and to be monitored by a qualified healthcare professional.



DANGER: If defects occur due to a fall of more than 20 cm or damage to the casings, cables, connectors, powered components, or battery connections, **do not use the device. Contact your medical distributor for any maintenance issues.**



DANGER: If there is any doubt about the safety of electronic devices, the product **should no longer be used and must be removed from the wheelchair.** Failure to comply with this instruction may result in the loss of warranty. **Contact your medical distributor for any maintenance issues.**





DANGER: If damage is found on the **remote control**, **dispose of it and contact your medical distributor.**



DANGER: The ORTHOPUS Supporter contains no user-serviceable or modifiable parts. Do not modify any part of this equipment without the manufacturer's authorization. **Failure to comply with this instruction may result in malfunction and loss of warranty.**



DANGER: During assembly, screws must be sufficiently tightened, and adjustments must be properly made. **Only a trained person** is authorized to install the ORTHOPUS Supporter.



DANGER: This equipment has **potential pinch points**. Ensure that people, **especially children**, do not touch the device while it is in use.



DANGER: Use the device in a **suitable environment**:

- Do not place the device in direct sunlight or near a heat source for prolonged periods.
- The device is resistant to water splashes but is **not waterproof**. Do not expose it to heavy rain, high humidity, or snowfall.



DANGER: **Only connect the XLR 3 cable to the battery of a compatible electric wheelchair.** For more information on the list of compatible wheelchairs, contact your medical distributor.



DANGER: Do not use accessories, spare parts, or equipment not described in the user manual.



DANGER: Do not connect the device to other equipment not described in the user manual.



DANGER: Do not immerse the ORTHOPUS Supporter in water or snow, either fully or partially, or expose it to corrosive environments.



DANGER: Do not hit the device too forcefully against a door frame or any



other hard surface. Impact may damage internal components or break the device structure.

USAGE RECOMMENDATIONS



CAUTION: The ORTHOPUS Supporter must be powered on without an arm installed in the orthosis and without touching the remote control.



CAUTION: The ORTHOPUS Supporter is intended for adults and children **over 7 years old**.



CAUTION: Before using the ORTHOPUS Supporter, ensure that it is correctly installed.



CAUTION: Do not exceed a usage load of 4 kg (including the weight of the arm).



CAUTION: Before removing the user's arm from the device, always check that the ORTHOPUS Supporter is in **FIXED** or **STANDBY mode**.



CAUTION: Be aware of nearby transmitters such as radio and television stations and try to avoid them.



CAUTION: Adding accessories or components near the ORTHOPUS Supporter may increase its sensitivity to electromagnetic interference (EMI).



CONTRAINDICATIONS



For conditions causing joint pain related to arm movement, usage must be assessed and validated by a healthcare professional.



Individuals with cognitive or behavioral disorders that could compromise adherence to usage instructions.



History of upper limb fractures within six months prior to using the device.



Any injuries or conditions that may interfere with the use of the device.



It is not recommended in any situation that prevents the safe and autonomous use of electric wheelchair driving controls.

USAGE GUIDELINES



The ORTHOPUS Supporter must be fixed to an electric wheelchair, a table, or any other similar **stable and rigid** support with a thickness between 2 cm and 5 cm.

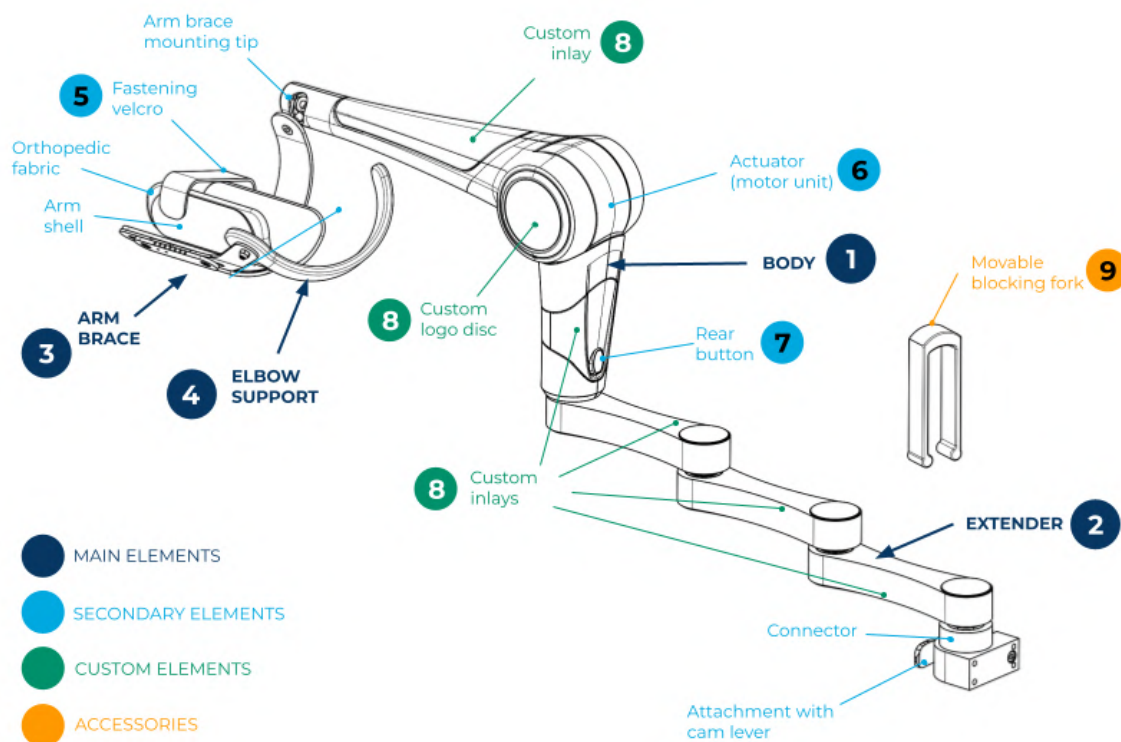


If the ORTHOPUS Supporter is not mounted on a table support or wheelchair, it should **always be stored in its packaging box** to avoid falls or other impacts that could damage the system. It should be stored **according to the instructions in this document**. The box must be kept in case the device needs to be returned.



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 shell possible (Left/Right)



DESCRIPTION

- The arm brace (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 shell are adaptable to each user. The fastening velcro (5) provides further stability of the arm in the arm shell.
- 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.
- The movable blocking fork (9) allows to block the extender when the ORTHOPUS Supporter isn't used

USAGE

This device features two (2) operating modes. The user has the choice between **assisted movements (FREE mode)**, mobilizing the residual force, and a **FIXED mode** that **accompanies the arm at all times (FIXED 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 shell is available for each side. This allows both arms to be equipped alternately.





DANGER: 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.**



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

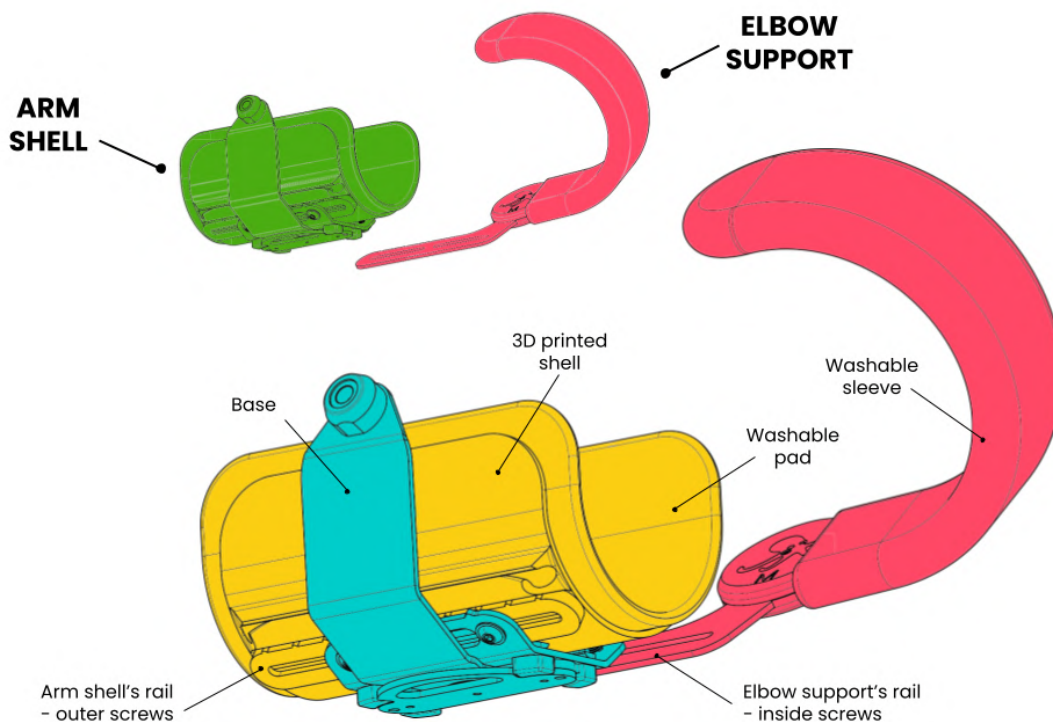
INSTALLATION AND UNINSTALLATION

Arm brace adjustments

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

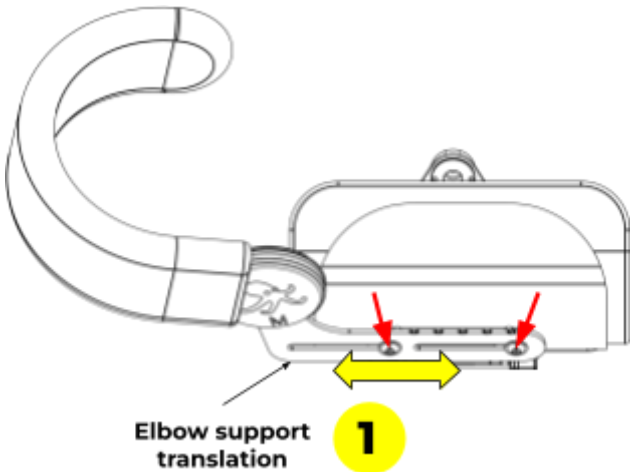
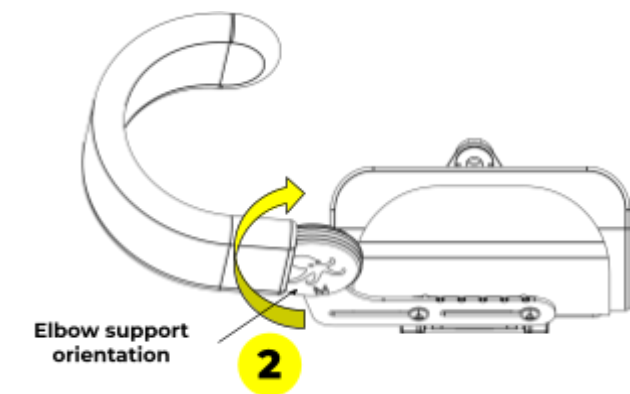
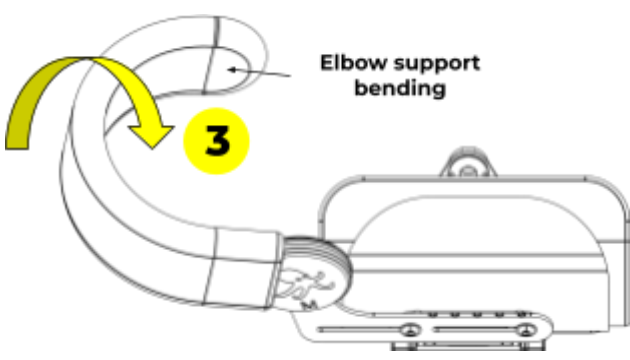
The user's arm must always:

- stay in contact with the elbow support
- be horizontal in neutral position (above the arm rest), that means not lean forwards or backwards

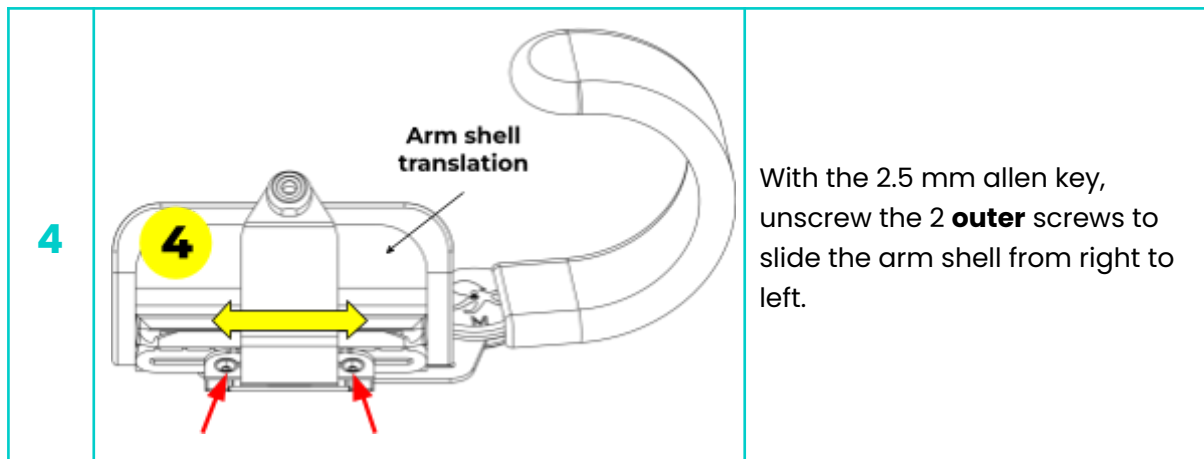


These settings can be adjusted separately during the fitting process. The purpose always being the users' comfort.

We encourage you to control and adjust some settings over time.

1	 Elbow support translation	With the 2.5 mm allen key, unscrew the 2 inside screws to slide the elbow from right to left.
2	 Elbow support orientation	WITHOUT UNSCREWING THE SCREW, direct the elbow support by rotating it around its axis.
3	 Elbow support bending	Adjust the elbow support's form by applying pressure and bending it with your hands. It can be formed as you wish, in every way possible.





CAUTION: The position of both the arm shell 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 shell and elbow support.



To ensure optimum assembly and settings of the arm brace, please refer to the "Arm brace operating manual" document on orthopus.com/en/documentation.

Mounting and dismounting the arm brace



Fit the arm brace on the ORTHOPUS Supporter with balls spindle.

The ORTHOPUS Supporter may be mounted to the right and/or left side.



Wheelchair installation



Pictures below are an example with an electric Permobil wheelchair.



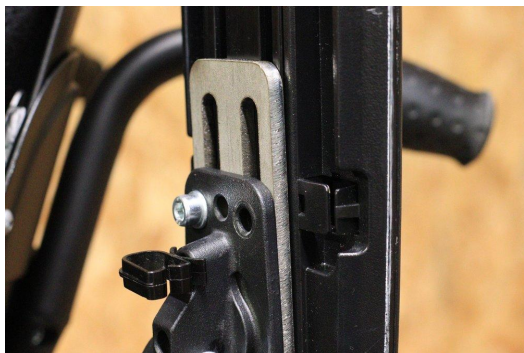
1. Take the regular user' position on the armrest in picture : please write the inclination down and mark the arm pad on the armrest in order to replace it at the exact same place when reassembling.



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.



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

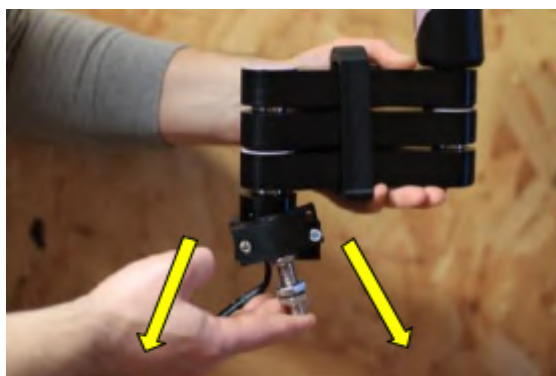


CAUTION: If need be, once the ORTHOPUS Supporter has been mounted, lower the height of the armrest by a few centimeters so as to keep the shoulder from shifting upwards when using the device.



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

Adjusting the Inclination with the Adjustable Clamping Nut



If, during installation, you notice that the ORTHOPUS Supporter is not horizontal, you can loosen the two screws of the adjustable clamping nut to adjust the inclination of the device.

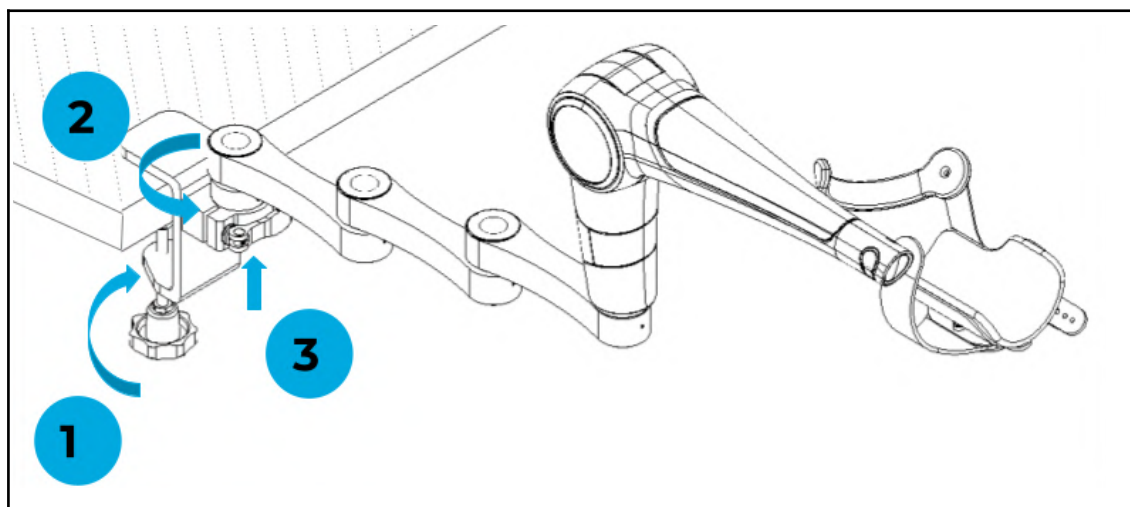
We recommend performing this operation after removing the ORTHOPUS Supporter from its mounting.



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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 2 cm and 5 cm.

OPERATION

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



Control pad



Rear button



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



STARTING



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

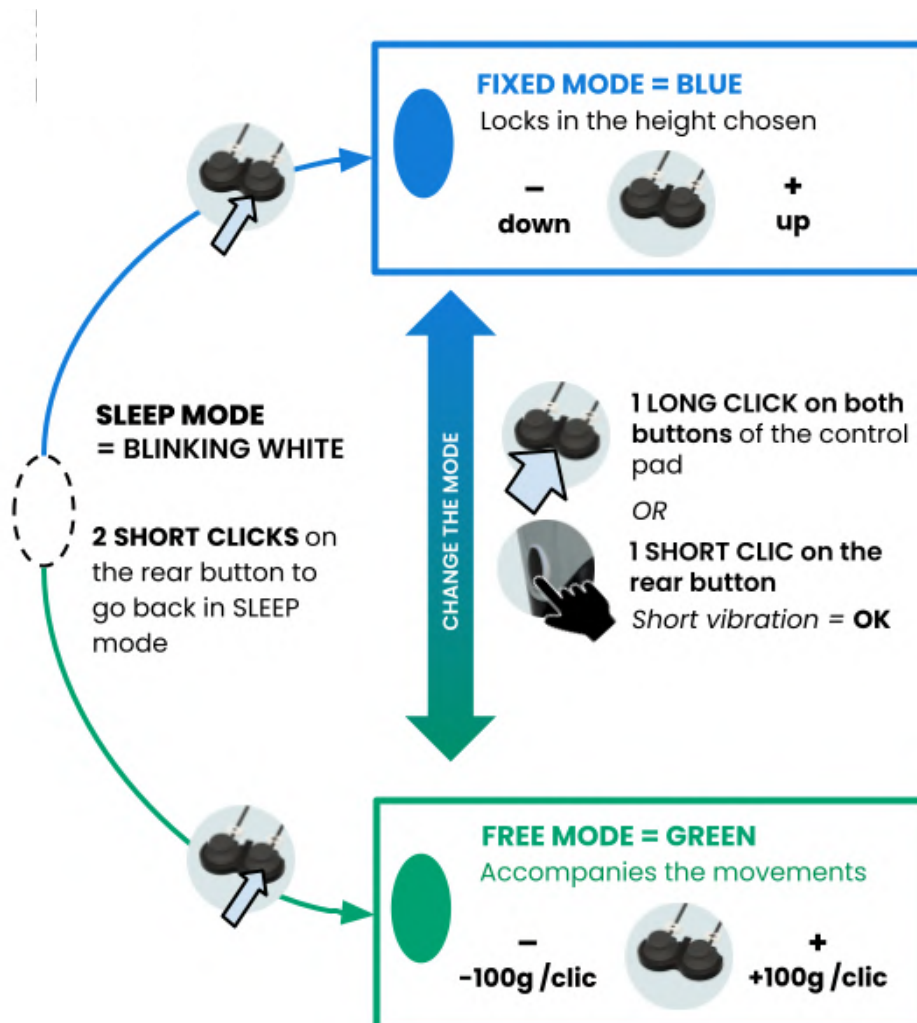
As soon as the device is plugged, it's automatically in SLEEP mode



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.



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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 FIXED MODE

	1. Switch to FIXED MODE .
	2. 1 LONG CLICK on the Rear button to enter in configuration process
	3. Rear button blinking ORANGE = 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 <i>Long vibration</i> = 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 <i>Long vibration = OK</i> To skip WITHOUT setting, 1 SHORT CLICK
	9. Back in FIXED 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 shell 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 **FIXED** 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* 

WAITING 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**

ERROR MODE

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.



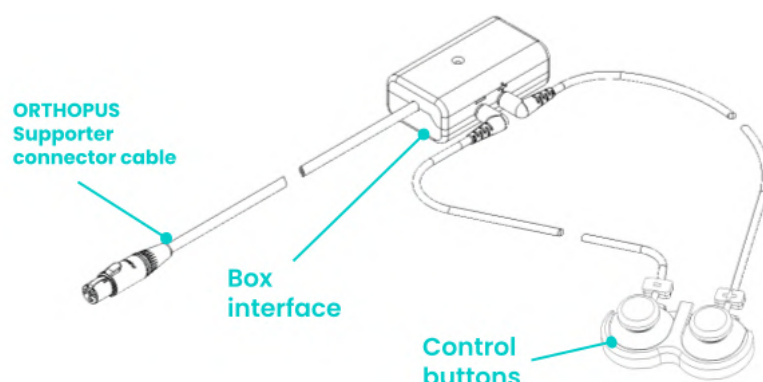
Solid **red**
rear button



CAUTION: 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 **FIXED MODE** or **INCREASE the COMPENSATION FORCE** in **FREE MODE**.
- The **-** enables the user to **MOVE DOWN** in **FIXED MODE** or **DECREASE the COMPENSATION FORCE** in **FREE MODE**.

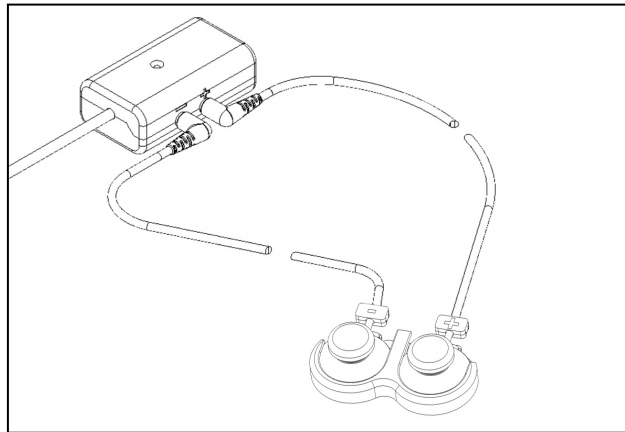
The buttons come assembled on the same pad. Should this configuration not be adapted as needed, it is possible to separate the buttons by unscrewing them from the pad so as



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.





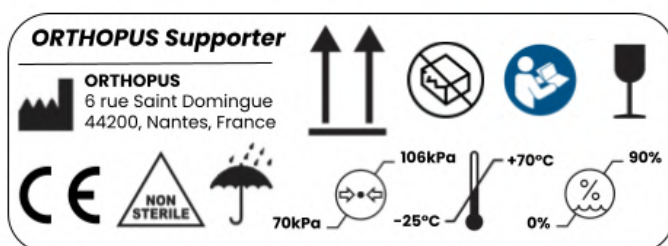
MAINTENANCE INSTRUCTIONS

CLEANING

The ORTHOPUS Supporter must be cleaned between each use using a cloth and a non-aggressive, non-abrasive disinfectant and detergent (such as Anios surface disinfectant). Do not put the ORTHOPUS Supporter in water. The orthosis fabric is machine washable at 30°C.

STORAGE AND TRANSPORT

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. The storage and transport conditions indicated on the packaging label below must be followed.



REUSE

For the purposes of reuse, the ORTHOPUS Supporter is to be disassembled and reviewed by an ORTHOPUS-trained professional or its distributor.



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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 shell, 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). The lifespan of the ORTHOPUS Supporter and all its accessories is three years.

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

LOVETT SCALE

To assess arm mobility, one of the scales that can be used is the Lovett scale. **As an indication, the ORTHOPUS Supporter is intended for individuals with a score between 2 and 4.**

MEASURING ARM MOBILITY WITH THE LOVETT SCALE

- 

0.
No muscle contraction
- 

1.
Visible or palpable muscle contraction under the fingers, but no movement possible
- 

2.
Movement possible on a horizontal plane **if the effect of gravity is eliminated**
- 

3.
Movement possible through its full range and **against gravity, but not against resistance**
- 

4.
Movement possible through its full range, **against gravity, and against moderate manual resistance**
- 

5.
Normal muscle strength

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
ISO 24971 : 2020	Medical devices — Guidance on the application of ISO 14971
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
EN ISO 10993-10:2020	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2020	Biological evaluation of medical devices — Part 23: Tests for irritation
62304: 2006	Medical device software
ISO 20417 : 2021	Medical devices — Information to be supplied by the manufacturer
IEC 61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Test and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4: Test and measurement techniques - Immunity tests to fast electrical burst transients
IEC 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Test and measurement techniques - Shock immunity test



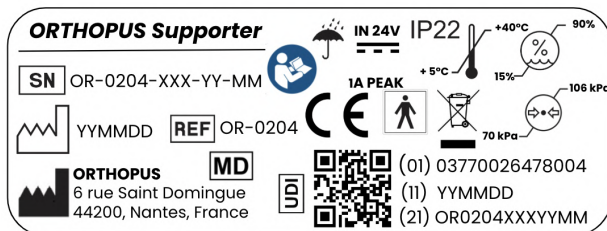
CE MARKING



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.

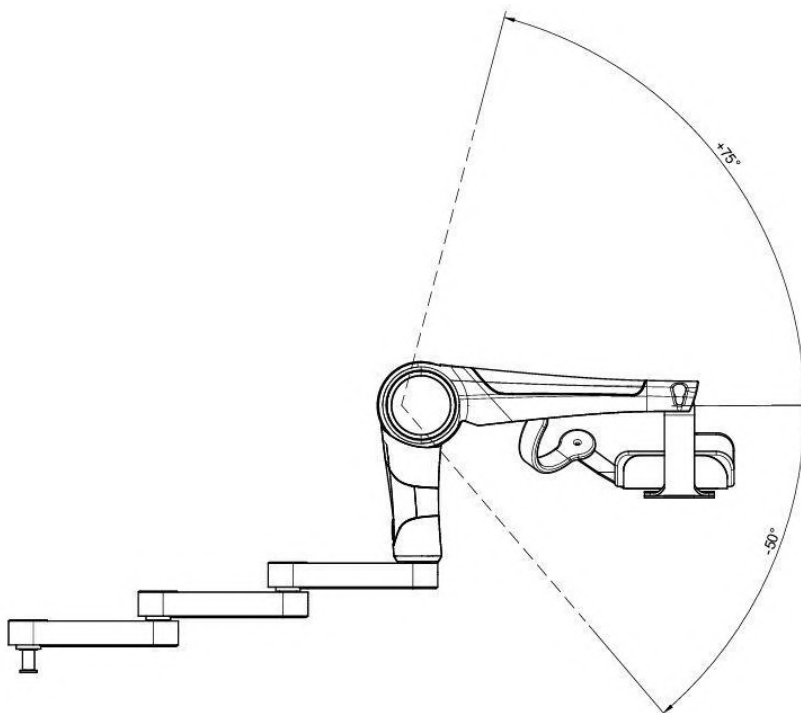
LABEL



This label may be found on the ORTHOPUS Supporter.

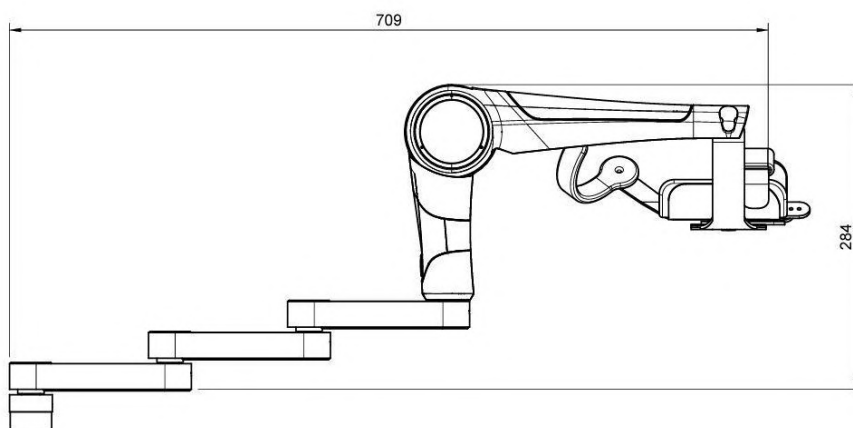
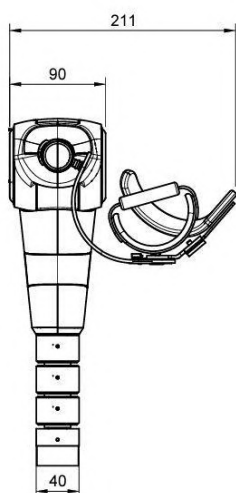
It features a Unique Device Identification (UDI) that enables its traceability. **This is, therefore, not to be removed from the product nor its packaging failing which use of the warranty may be jeopardized.**

TECHNICAL ELEMENTS



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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 = $[-50^{\circ}; 75^{\circ}]$ 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	$[-25^{\circ}\text{C}; +40^{\circ}\text{C}]$
Storage humidity	Max. 90%
Operating temperature °C	$[+5^{\circ}\text{C}; +40^{\circ}\text{C}]$. The temperature of the outer surfaces on the ORTHOPUS Supporter



	is not to exceed 40°C.
Operating humidity	Max. 90%
Operating pression	[700 hPa ; 1060 hPa]
Degree of protection	IP 22
Range of motion	Two (2) symmetrical ranges of motion on arm shell possible (Left/Right)
Wheelchair shutdown time	< 30 sec
Materials	Aluminum, stainless steel, plastic (PLA, ASA, PA), 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;



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- 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) Arm Brace User Manual;
- One (1) Welcome card.

CONTACT INFORMATION

The ORTHOPUS Supporter is manufactured by:



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