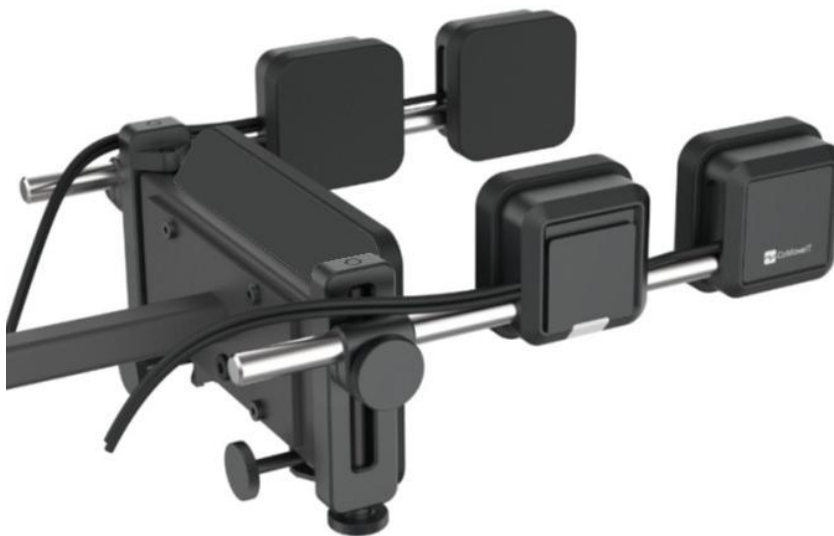




CoMoveIT

CoMoveIT Drive

Specialty Input Head Control Device for Powered Wheelchairs



Instructions for Use

How to contact CoMoveIT?

	CoMoveIT NV, Baron Ruzettelaan 5/1.1, 8310, Assebroek (Bruges), Belgium www.comoveit.com info@comoveit.com +32 477 880 175
CH REP	SKS Rehab AG, Im Wyden 3, CH-8762, Schwanden, Switzerland
UK Responsible Person	UK REP MED Limited, Unit D Crondall Place, Coxbridge Business Park, Alton Road, Farnham, GU10 5EH, United Kingdom

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Important information about these Instructions for Use

Congratulations with your CoMoveIT product!

Before using this product, it is important to read these Instructions for Use and in particular the Safety Instructions. They also contain important safety and maintenance information, as well as describe how to use the product in the best way.

Make sure to store these Instructions for Use for future reference.

We sincerely apologize for any inconvenience caused, as the instructions for use are currently not accessible to visually impaired individuals.

All information, pictures, illustrations, and specifications are based upon the product information that was available at the time that these Instructions for Use were printed. Pictures and illustrations that are found in these Instructions for Use are representative examples and are not intended to be exact depictions of the various parts of the product. CoMoveIT reserves the right to make changes to the product without prior notice.

Ordering of documentation

If you need another copy of this Instruction for Use document, it can be ordered from CoMoveIT via info@comoveit.com, by asking for item CM0120-IFU-EN.

You can find the latest version of this document on www.comoveit.com. To obtain a paper version, contact CoMoveIT.

Serious incidents

SERIOUS INCIDENTS

In case of adverse or serious incidents causing human injury, this should be reported as soon as possible to CoMoveIT (vigilance@comoveit.com) or your local distributor, and to the competent authority of the Member State in which the user is established.

Support, scrapping and spare parts

Technical support

In the event of technical problems, contact your local distributor or CoMoveIT at +32 477 88 01 75 or via info@comoveit.com.

Always state the Reference and Serial Number of the product to ensure that the correct information is provided.

Scrapping

Contact your local distributor or CoMoveIT for information about scrapping agreements in force.



CAUTION

Follow the local waste legislation for scrapping. Dispose of obsolete electronic parts responsibly in accordance with local recycling regulations.

Spare parts and accessories

Contact your local distributor for information about and to order spare parts consumables or accessories.

Warranty

CoMoveIT warrants CoMoveIT Drive to be free from defects in material and workmanship for a period of two years under proper use, care and service.

All warranties will cover parts only and do not extend beyond the initial purchaser from an authorized CoMoveIT dealer. Normal wear and tear and consumables are always excluded from the warranty.

Commencement of Warranty Period

The warranty of CoMoveIT Drive begins on the date that the product is first delivered to the customer, or forty (40) days from the date that the product is shipped to the authorized distributor by CoMoveIT, whichever comes first.

Repair or Replacement

For warranty service, customers should contact the authorized distributor from whom the product was purchased. In the event of a defect in material or workmanship, the distributor must obtain a return authorization number from CoMoveIT, and the product must be shipped to a service center designated by CoMoveIT. CoMoveIT will repair or replace any product covered by the warranty. This warranty does not include any labor charges or shipping charges incurred in replacement for installation or repair.

Amendments

No person is authorized to change, extend, or waive the warranties of CoMoveIT. Warranty shall only be extended as necessary to comply with state laws and requirements.

Voiding of Warranties

The above-mentioned warranties are depended to proper use, maintenance, and care of the product. The warranty will be void if the product has been used improperly or if it has been repaired or any part replaced by persons other than CoMoveIT or an authorized CoMoveIT distributor.

The addition of equipment, peripherals or features that are not manufactured or recommended by CoMoveIT could affect the intended function of CoMoveIT Drive product.

The use or installation of equipment not issued or accepted by CoMoveIT invalidates the warranty.

Safety Rules

General

Read the Instructions for Use carefully, paying particular attention to the safety instructions and the warning texts.

Follow the recommendations in the Operation section carefully in order to prevent the risk of accidents from use.

All alterations to and interventions the product must be performed by a qualified service engineer. In case of doubt, always contact CoMoveIT or a qualified local distributor.

All information and specifications included applied at the time of delivery of this product. CoMoveIT reserves the right to make changes without prior notification. These Instructions for Use are related to Installation Instructions CM0120-INST--XX.

Warning labels

These Instructions for Use utilize the following warning labels, which are intended to draw attention to situations that could lead to unwanted problems, personal injury, or damage to the wheelchair, etc.

	CAUTION
Please use caution where this symbol appears. A situation could result in minor or moderate injury.	

	WARNING!
Please use extreme caution where this warning symbol appears. Failure to observe warnings can lead to serious injury or death.	

General Warnings and Cautions

	WARNING!
Do not attempt to operate a powered wheelchair with the CoMoveIT Drive without the assistance, training and permission from a qualified healthcare professional.	

	WARNING!
The wheelchair must be fitted with an emergency stop function that is within the reach of the attendant. Users who are unable to operate an emergency stop button should have an accompanying person with them at all times.	

	WARNING!
Stop using the device immediately if it is behaving abnormally or erratically.	



WARNING!

The device may inadvertently activate when exposed to rain, causing the wheelchair to drive in an unintended manner, creating a dangerous situation.



WARNING!

Electromagnetic Compatibility (EMC)

This product complies with the limit values for Electromagnetic Compatibility (EMC) with respect to powered wheelchairs, as set out in ISO 7176-21.

This device can disturb the operation of devices in its environment that emit electromagnetic fields (e.g. alarm systems, automatic doors, etc.).

The driving performance of this device can be influenced by electromagnetic fields (e.g. those emitted by electricity generators or high-power sources).



WARNING!

Do not bump against other objects, do not compress or squeeze any parts of your device.



WARNING!

In case of critical fault, the device may come to a sudden stop at any time during operation.



CAUTION

CoMoveIT accepts no liability for personal injury or property damage that may arise from the failure of the users to follow the indications, recommendations, warnings, cautions, and instructions given in this Instructions for Use document.



CAUTION

Do not press the head pads using sharp objects. This will affect the operation.



CAUTION

Obsolete parts of CoMoveIT Drive should be responsibly disposed according to local recycling regulations.



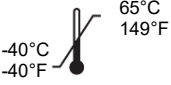
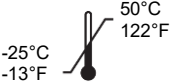
CAUTION

The maximal forces applied on the head array in any direction are specified to be up to 170 newtons.

List of Symbols

All symbols used in the labeling of CoMoveIT Drive are in accordance with ISO 15223-1:2021 Medical devices

Symbol	Description	Symbol	Description
	Consult instructions for use or consult electronic instructions for use		Keep away from rain
	Medical device		Protect from heat and radioactive sources

Symbol	Description	Symbol	Description
	Manufacturer		Handle careful to avoid damage
	Country and date of manufacture		Don't used if the package is damaged or opened and consult instructions for use.
REF	Product reference number	CH REP	Authorized representative e.g. for Switzerland
LOT	Batch number		Local distributor
SN	Serial number		Don't discard as unsorted waste, send to separate collection facilities for recovery and recycling
	Storage temperature range	CE	Conformity with European health, safety, and environmental protection standards.
	Operating temperature range	IP41	Protection against solid foreign objects ≥ 1 mm and against vertically falling water drops (IEC 60529).
UDI	Unique device identifier		
UDI  (01) (11) (21)	(01) Global Trade Item Number (10) Batch number: 6-digits: YYMM and 2-digit number (11) Date of Manufacture: 6-digit indicating year, month and date in the following format: YYMMDD. (21) Serial Number: 9-digit number		

Intended Use

CoMoveIT Drive is intended to be used as a specialty input control device for powered wheelchairs. CoMoveIT Drive allows users to control their powered wheelchair with their head.

CoMoveIT Drive captures pressure applied by the user on the head array and translates them into driving commands for the powered wheelchairs. CoMoveIT Drive offers multiple degrees of freedom for the adjustment of the head array and function and sensitivity per sensors are configurable by the supplier at installation.

Intended User Group

CoMoveIT Drive is intended to be used in adult and pediatric power wheelchairs for people who lack the ability to control the powered wheelchair via conventional means such as joysticks, chin controls, etc.

CoMoveIT Drive is intended to be used by people diagnosed with Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS), Tetraplegia, Spinal Cord Injuries (SCI), Cerebral Palsy (CP) and other complex movement disorders.

Contraindications

CoMoveIT Drive must not be used by individuals who have a severe mental disability, and are not able to follow and understand basic instructions, are diagnosed with severe visual

impairment, or suffer from severe epilepsy. The user must be able to estimate and correct the results of actions when operating the wheelchair.

Environmental Conditions

Operation

- Operating temperature range: -25°C to 50°C // -13°F to 122°F
- Relative humidity: 10% and 90%.



WARNING!

Do not use the device under rain. To assure the water ingress level of the CoMoveIT Drive, always leave the connection protection in place.

Storage

- Recommended storage temperature range: room temperature
- Maximum temperature range: -40°C to 65°C // -40°F to 149°F
- Keep dry
- Keep away from sunlight and sharp objects.

Always conduct a functional check before using your device after a long-term storage.

Device Description

General

CoMoveIT Drive consists of a head array with five sensor pads. The sensors detect user-applied pressure and translate it into driving and other control commands for a powered wheelchair.

Identification of parts

Item picture	UDI (part number / GTIN), Product name, description
	UDI : 05430002911144 CoMoveIT Drive: Head array with 5 head pads with pressure sensors with one connection cable DB9 for input to the wheelchair controller

Mounting parts

One or more of the following parts have to be ordered with the CoMoveIT Drive.

Item picture	Part number, Product name, description
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	UDI : 05430002911151 CoMoveIT Drive rod set • Vertical rod for head array mounting to wheelchair • Horizontal bar for head array adjustment (to be purchase separately from CoMoveIT Drive)
	UDI: 05430002911069 Head array Mounting Clamp: Mounting clamp for fixation and height adjustment – Fit for CoMoveIT Drive rod set on a.o. Permobil powered chairs. (to be purchase separately from CoMoveIT Drive)
	UDI: 05430002911090 Head array Mounting Clamp S: Mounting clamp for fixation and height adjustment – Fit for CoMoveIT Drive rod set on a.o. Sunrise Medical powered chairs. (to be purchase separately from CoMoveIT Drive)
	UDI: 05430002911168 Ball joint plate Drive: plate covering the back of CoMoveIT Drive for use with e.g. Bodilink ball joint (to be purchase separately from CoMoveIT Drive). Bodilink products are not sold by CoMoveIT.

Note: Only specified products shall be used with the device.

Features

Head control with 5 sensors: The system can be configured based on the abilities of the user. The function of each sensor is assigned by the supplier using a configuration program at installation.

Sensor positioning: The position of sensors on the head array can be adjusted in a high number of ways to optimize operation and comfort of the user.

Driving and non-driving functions: besides driving commands forward, reverse, left and right, the user can select “User Switch” to open the controller menu (e.g. to adjust seating position). Also “Relax” to change from driving mode to sleep mode can be selected.

Sensitivity adjustment for each sensor. The sensitivity range can be set individually, defining the minimum required and maximum permitted force to activate the assigned function.

Selectable switched or proportional control: Switched operates at a defined speed. Proportional control transfers increasing pressure into increasing driving speed.

Installation

	CAUTION
The Installation of CoMoveIT Drive has to be done by qualified personnel and according to the Installation manual which can be downloaded from www.comoveit.com	

	CAUTION
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Installation should only be done by individuals familiar with the process as there may be multiple mounting and fastening tools used to secure the product.



CAUTION

Don't use the product or the wheelchair and contact your local distributor in case the installation has not been completed or in case of problems after installation.



CAUTION

All elements of the system should be fitted in a stable and proper way, avoiding damage of any part, cables or sensors. The head array needs to be solid for use. Contact your local distributor in case of doubt.

In short, installation steps:

- Mechanical installation
- Wheelchair controller programming
- CoMoveIT Drive set up by the supplier as described in the installation manual.

Compatibility

CoMoveIT Drive works with PG Drives Technology R-net OMNI2 (including related like Permobil Power Platform), Q-Logic 3 EX Enhanced Display, Curtis Instruments AG Display Module and Dynamic Controls LiNX IN 500.

If only 3 driving commands forward, left and right are used, the wheelchair controller shall be configured in 3-axis proportional driving. If also reverse is used as separate command, the wheelchair controller shall be configured in proportional driving.



CAUTION

The powered wheelchair must always be programmed for proportional driving. Selection between proportional and switched driving is at installation by the supplier.



CAUTION

Programming of compatible wheelchair control systems should only be done by qualified personnel and in accordance with the specifications, requirements and safety rules defined in the installation manuals of the control system.

Removal



CAUTION

It is recommended that the removal of the product is done by qualified personnel and according to the Installation manual which can be downloaded from www.comoveit.com

In short, removal steps:

- Switch off the wheelchair.
- Remove tie wraps and disconnect the cable.
- Remove the head array.

Operation and Set up for Use



WARNING!

Do not use the device under rain.



WARNING!

Do not attempt to operate a powered wheelchair with the CoMoveIT Drive without the assistance, training and permission from a qualified healthcare professional.



WARNING!

The wheelchair must be fitted with an emergency stop function that is within the reach of the attendant.



WARNING!

The attendant or healthcare professional is expected to interpret the abilities of the user in terms of speed, any of the functionalities, cognitive and mental ability to use a powered wheelchair, in particular the safety mechanisms such as on/off button or an emergency button.



WARNING!

CoMoveIT Drive is not appropriate to use during car transportation of the powered wheelchair.



WARNING!

Do not cover the head array



CAUTION

CoMoveIT Drive is designed for both indoors and outdoors use. For use indoors, normal care should be observed. Outdoors you must remember to move very slowly on steep inclined terrain and be extremely careful when moving over uneven surfaces. Consult the wheelchair's instruction manual for more information on the wheelchair's driving rules.

Using the CoMoveIT

Before using CoMoveIT Drive for the first time, it is advised that the provider assists and explains the different possibilities and options to the user and/or the attendant. If you are unsure how to use your CoMoveIT Drive to control your powered wheelchair, it is advisable to consult your healthcare provider or local authorized distributor.

It is important that the user and the attendant are fully aware of how to use the system and the possible adjustments to optimize the use experience.

It is recommended, prior to using your CoMoveIT Drive in public places, crowded places, or in tight driving situations, that you try it out several times in an open space area that is familiar to you, so that you become comfortable with how your CoMoveIT Drive operates.

Please inspect your device following the Maintenance section.



WARNING!

Turn off the wheelchair prior to entering or exiting the wheelchair.

Basic functionality for the driver:

Some of the below mentioned functions might not be possible for all wheelchair users. The feasible configuration is determined together with qualified personnel.

Driving the wheelchair	• Apply pressure on the sensors on the head array, which have been given driving functions, to drive forward and backward and to turn the wheelchair left and right. Combine forward/reverse with turning to veer. • Release any pressure from these sensors to stop wheelchair movement. • Operational forces can range between 50 gr and 15kg, depending on the sensitivity settings installed.  CAUTION When the wheelchair is programmed for latched driving, it may be necessary to activate a reset switch. Contact your provider for more details.
Speed control	• When the driving type is “Proportional”: press harder to drive faster • When the driving type is “Switched”, the wheelchair drives at a predefined speed.
Putting the wheelchair to sleep mode	• Press the <i>Relax</i> sensor. All sensors except this one will not respond until you exit the relax mode by pressing the <i>Relax</i> sensor
Use wheelchair operating modes like Seating adjustment	• Press the <i>User Switch</i> sensor to access the wheelchair controller modes. Navigate to e.g. seating with the <i>Forward</i> sensor and select with the <i>Right</i> sensor • Functions are typically Seating, Bluetooth device control, and infrared device control, as programmed by your provider.

Advanced functionality, configuration and set up

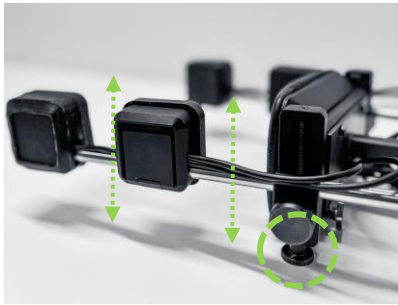
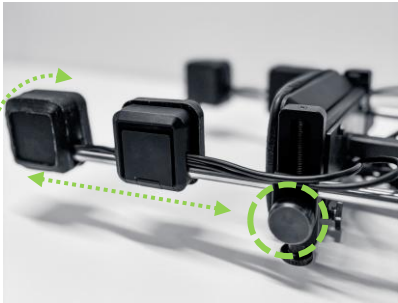
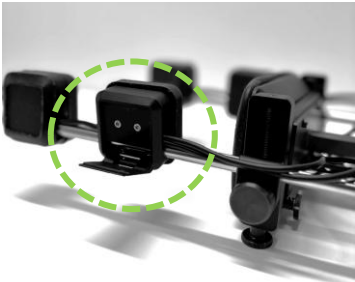
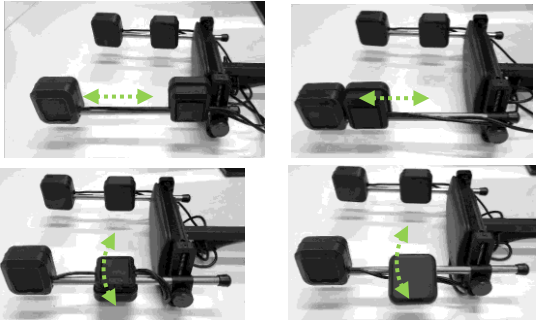
Qualified personnel can tailor the operation to the individual needs following the installation manual.

Connections

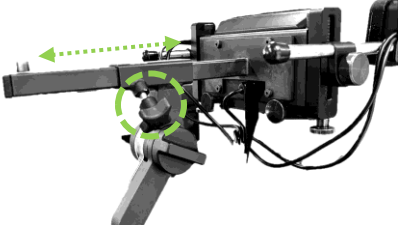
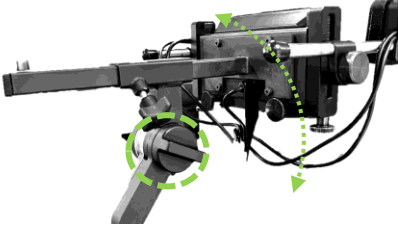
 CAUTION Handle the connectors and cables of the device elements with care.
 CAUTION Don't connect the output to non-compliant devices.

Connect the DB9 output cable with the wheelchair controller. Make sure to fix the screws of the DB9 connector to avoid error messages.

Head array adjustments

	Use the rotary knobs at bottom side to change the height of the side pads.
	Use the rotary knobs at the back to change the opening angle of the side pad bar.
	Use the rotary knob at the side to rotate the bar around its axis or to slide it more to the front or to the back.  CAUTION Do not try to rotate the bar when the rotary knob is tightened. This might damage your device.
 	Open the lever to rotate the rearmost side pad or to slide it along the lateral bar.  CAUTION Do not force any adjustment of the rearmost side pad when the lever is locked. This might damage your device.

When using the CoMoveIT Drive rod set (part nr. 5430002911151) following adjustments are possible:

	Use the rotary knob or lever to move the head array more to the front or to the back
	Use the rotary knob to change inclination  CAUTION Do not overtighten the rotary knob to avoid damage.
	Use the lever to change the height of the head array.

 CAUTION
Forcing any of the adjustment mechanisms to move other than as described above might damage the locking mechanisms.

 CAUTION
Ensure that all adjustment mechanisms are locked before use.

Driving control type

If desired, request your supplier to set up the control type:

- **Proportional** control transfers increasing pressure to increasing driving speed.
- **Switched** control operates at a defined, fixed driving speed.

Sensitivity settings

Your supplier can set up the sensitivity per sensor. The supplier uses a configuration program supplied by CoMoveIT, connecting a computer with the CoMoveIT Drive through its USB-C connector at the back side.

How does it work?	• Applying a sensor pressure between the set low and high value will lead to activation of the function of that input. • In proportional driving type, the force applied just above “low” will lead to lowest speed, while a force applied just below “high” will lead to the highest speed. • Excessive pressure, for instance by hyperextension, on forward or reverse driving will stop the wheelchair.
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	• The low value is set allowing a rest position without unintended activation. The high value is set to define the maximum speed in case of proportional driving type. • The high value also defines the safety level at excessive pressure: any pressure to a certain extent higher than the set high value on the forward and reverse driving function will stop of the wheelchair movement. If this value is set too low, it could lead to overpressure too easily causing the wheelchair not to react. In this case, request the supplier to lower the max threshold value.
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Practical example

Programmed as 3-Axis Proportional driving

- Driving type in CoMoveIT Drive = Proportional
- Backpad used for command Forward: sensitivity low = 25
- Left rear side pad used for command Left : sensitivity low = 5
- Right rear side pad used for command Right : sensitivity low = 5
- Left frontal side pad used for command User Switch, sensitivity low = 25
- Right frontal side pad used for command Relax, sensitivity low = 25

In this example,

- The rest point of the back head is just below 25. In order not to activate the forward command too easily (allowing to rest the head), the value could be set higher (request the supplier).
- These values are indicative only and need to be determined per user.

Maintenance



WARNING!

In case excessive wear of any of the pads, it is mandatory to contact your local authorized dealer and have the worn parts replaced.

Maintenance is important for the safety and performance of your CoMoveIT Drive.

Perform a monthly inspection to ensure that:

- All rotary knobs are in place and in good shape.
- All bolts and screws are tightened.
- All cabling and connectors are undamaged and connections are tight.
- There is no excessive wear to any parts of the device, especially the pads of the head array.

Let your supplier perform a yearly check of the wheelchair and the subsystems.

Cleaning



WARNING!

Never spill water or use a water hose to clean CoMoveIT Drive parts to avoid damage.



WARNING!

Do not clean the device while in use by the patient.



CAUTION

Do not use aggressive cleaning agents or additional lubricants.

⚠ CAUTION
Water might affect the operation of sensors. Make sure that all parts and surfaces are completely dry before use.

⚠ CAUTION
Cleaning contributes to the overall hygienic condition of your device. Failure to clean on a regular basis, might cause excessive sweat and dirt build up on the cushions .

Metal and plastic parts	Clean with a damp cloth. In case of excess dirt concentration, a soap water solution can be used. Always wipe dry after cleaning.
Head array pads	Clean weekly with a damp cloth using water or soap water. During hot weather conditions, clean them every day since sweat concentration might be increased. Gently, wipe dry after cleaning.
	⚠ WARNING!
	In case excessive wear of any of the head pads, it is mandatory to contact your local authorized dealer and have the worn parts replaced.

Troubleshooting

If your device does not react as expected, check the following:

- Make sure the wheelchair and the wheelchair controller are powered on.
- Make sure that the cable between CoMoveIT Drive and the controller (e.g. Omni module) is connected, tightened and connected to the right programmed port.

If one of the components no longer works, contact your local distributor.

Trouble	Remedy
No wheelchair movement when pressing a sensor	• Check if the wheelchair controller profile is set for usage with CoMoveIT Drive. • Make sure the used wheelchair controller port is correctly programmed in the wheelchair controller software. • Check for damage on cable, connector or sensor pad. • Request your supplier to decrease the 'low' sensitivity and increase the 'high' sensitivity
Functions get activated too easily	• Check for damage on sensor pad. • Request your supplier to increase both 'low' and 'high' sensitivity of the functions that are activated to easily.
Pushing to drive forward but driving backwards	• Request your supplier to check that the function for the sensor is set correctly. • Check the programming of the wheelchair controller (joystick axis, motor swap)
Pushing to the right turns left and/or vice versa	• Request your supplier to check that the function of the used sensor is set correctly • Check that the head array is mounted with the ID label on the bottom • Set the head array side bar in a higher position and tilt the side pads, or don't connect the rearmost side pads.

Glasses hinder to push the side pads	• Use the bottom rotary knob to position the side pads higher.
Side pads are loose on the bar	• Check that all adjustment clamps and rotary knobs are tightened. • If the pads remain loose, contact your local distributor for assistance.
Hearing beeps while pushing	• When you're in Relax (sleeping) mode, beeps will be heard when pushing sensors. • When you are not in Relax mode, contact your supplier to check the condition of product.
Error codes are shown on the wheelchair controller	• Ensure that any sensor is not pressed before or during the time you power on the wheelchair. Power cycle your wheelchair. • If the error persists, contact your local distributor for assistance.

Summary

This summary is not intended to replace complete user instructions. You must read the entire Instructions for Use before you operate your CoMoveIT Drive.

CoMoveIT Drive must not be used by individuals who have a severe mental disability, severe visual impairment, or suffer from severe epilepsy. The user must be able to estimate and correct the results of actions when operating the wheelchair.

Do not attempt to operate a powered wheelchair with the CoMoveIT Drive without the assistance and training from a healthcare professional qualified for these activities. Do not attempt to independently operate a powered wheelchair with the CoMoveIT Drive until a qualified healthcare professional gives you the permission to do so.

The wheelchair must be fitted with an emergency stop function that is within the reach of the attendant. You must stop using the device immediately if operating problems occur.

Do not use your device in rainy weather conditions. This may cause the wheelchair to drive in an unintended manner, creating a dangerous situation. Do not press the sensor pads of your device using sharp objects. This will affect the operation of the force sensors.

Programming of the controller (e.g. R-net) parameters of your wheelchair is important to be fine-tuned based on your needs and should only be conducted by skilled professionals with in-depth knowledge.

Before using your CoMoveIT Drive for the first time, you and your attendant must be fully aware of how to use the system and the possible adjustments to optimize the use experience.

To use your CoMoveIT Drive, power on your wheelchair and select the appropriate driving profile for your driving environment (e.g. indoors or outdoors). Apply pressure on the sensor pads to activate the assigned function.

Please inspect that there is no damage in the following parts of your device once a month: bolts and screws, cabling, connector, head cushions. Please clean the head array cushions, plastic and metal parts of your device with a damp cloth using water or a soap water solution once a week. Gently, wipe dry after cleaning and verify correct functioning before use.

Use this space to write potential user-specific instructions

Use this space to write phone numbers for help in case of emergency.

Your local distributor



CoMoveIT NV Baron Ruzettelaan 5/1.1, Assebroek (Bruges), 8310 Belgium

Email: info@comoveit.com

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