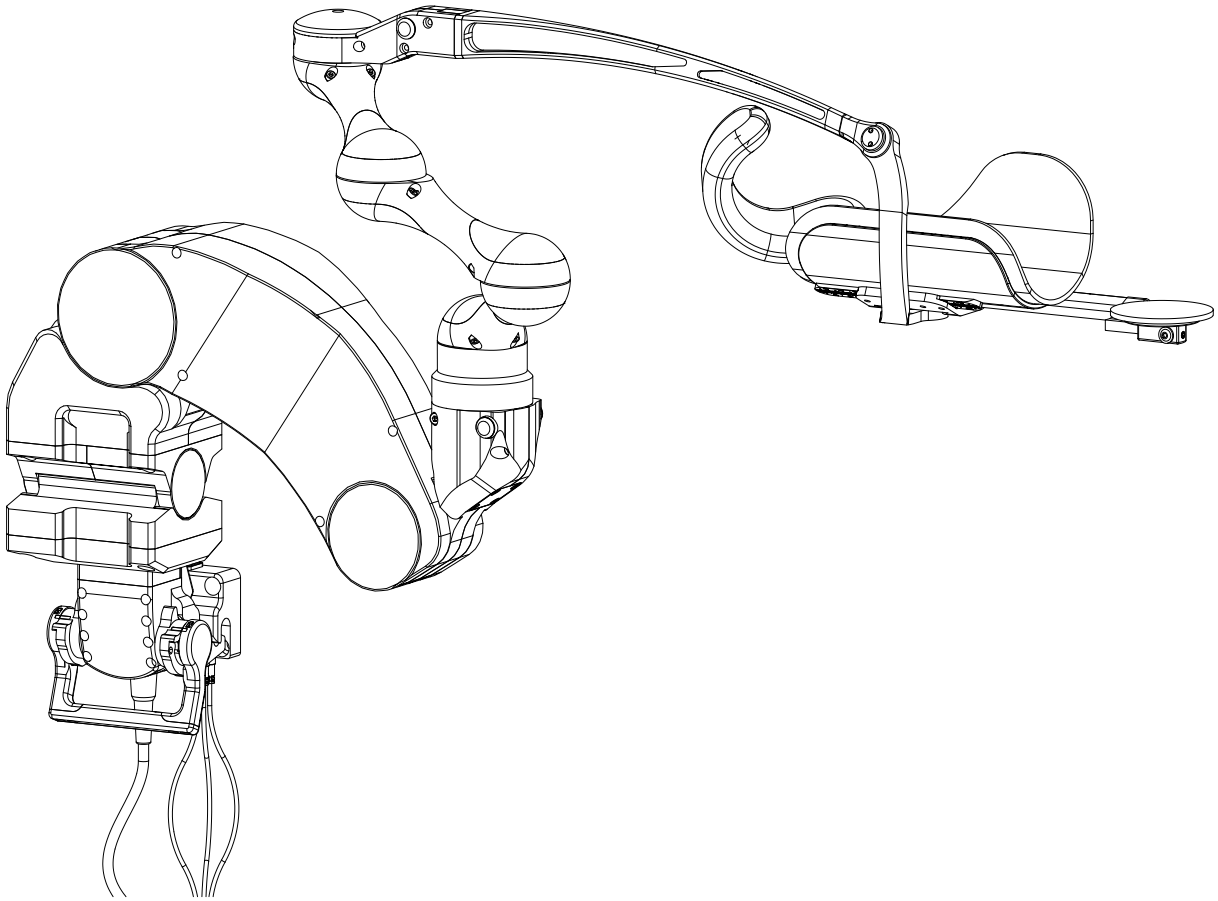


Flowing+

User manual

ID manual: 607640
Revision: 1.0.0
Date: 23-09-2022

FOCAL meditech

Disclaimer

The content of this manual is for informational use only and is subject to change without notice. Focal Meditech assumes no responsibility or liability for any errors or inaccuracies that may appear in this document.
Periodically, changes may be made to the information in this manual; these changes will be incorporated into new editions of this publication. Focal Meditech may make improvements and/or changes in the products and/or software programs described in this publication at any time.

Copyright Notice

Address comments about this publication to: info@focalmeditech.nl

Trademarks

Focal Meditech is a registered trademark of Focal Meditech BV.
Flowing⁺ is a registered trademark of Focal Meditech BV.

Content

Manual introduction

This is the user manual for the Flowing+. This product is developed, manufactured and distributed by Focal Meditech or one of its authorized representatives.

This manual contains important information regarding Flowing , its intended use and possible consequences of usage. The aim of this information is to ensure successful, safe and effective use of the device. This manual contains essential information for using Flowing , information about safety issues and contact information.

Please read this information carefully: increase of knowledge will allow Flowing to be used to its full potential. You should also inform people close to you about the main features, for example the person who looks after the wheelchair or those who help you with transfers, to prevent damage by accidental misuse.

Symbol explanation

Symbols used in this manual

Danger	This symbol in combination with the word “Danger” is used when there is important information which can help you avoid the risk of an equipment failure and serious personal injury or death.
Warning	This symbol in combination with the word “Warning” is used when there is important information to avoid certain actions that can lead to an equipment failure.
Caution	This symbol in combination with the word “Caution” is used to warn about possible unsafe practices. Extra attention is required.
	This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2002/96/EC) and your national law. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or your household waste disposal service.

Packaging

	Fragile		This way up
	Keep away from water		Do not stack
	Non-sterile product		Do not use if package is damaged

Certification Notices

CE	This is a CE Class I medical device
REF 605540 IN: 20V ⎓ 1A peak LOT TESTB SN Uxxxxx Gowing+ FOCAL Droogdokkeneiland 19 5026 SP Tilburg www.focalmeditech.nl	Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the rear side of Flowing+.
REF 605547 IN: 20V ⎓ 1A peak LOT TESTB SN Uxxxxx Eneaswitch+ FOCAL Droogdokkeneiland 19 5026 SP Tilburg www.focalmeditech.nl	Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the rear side of the Power module ext sw
REF 607762 LOT LED display FOCAL Droogdokkeneiland 19 5026 SP Tilburg www.focalmeditech.nl	Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the rear side of the LED display
REF 607761 LOT Triple action switch FOCAL Droogdokkeneiland 19 5026 SP Tilburg www.focalmeditech.nl	Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the rear side of the triple action switch
REF 607500 LOT Dual action switch FOCAL Droogdokkeneiland 19 5026 SP Tilburg www.focalmeditech.nl	Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the rear side of the Dual action switch

Safety notices

Danger: Prevent direct contact with water or any other liquid. Failure to prevent this can lead to malfunctioning of device or bodily harm.

Danger: Prevent exposure to extreme temperature (see environment conditions). Failure to prevent this can lead to malfunctioning of the device or bodily harm.

Danger: It is not recommended to use Flowing under heavy rain or snow. This can lead to malfunctioning of the device or bodily harm.

Danger: Wait until Flowing⁺ has reached room temperature before switching on Flowing⁺. Failure to do this can lead to malfunctioning of device or bodily harm.

Danger: Stop using Flowing⁺ if problems persist after readjusting the settings.

Danger: Stop using if, despite adjustments, the irritation continues and contact Focal Meditech, your dealer of therapist.

Danger: During installation ensure there is a fuse of 7.5A between power supply and Flowing⁺. Failure to do this can lead to malfunctioning of the device and bodily harm.

Danger: Do not handle very sharp or any dangerous tools or objects (e.g. cutting) with Flowing⁺. This can lead to bodily harm.

Danger: Do not immerse any part of Flowing⁺ under water or snow. This can lead to malfunctioning of the device or bodily harm.

Warning: Do not modify any part of this device without authorization of Focal Meditech. This can lead to malfunctioning and will void the warranty.

Warning: In case of a faulty device contact Focal Meditech or your dealer. Do not try to fix it yourself. Failure to do this will void the warranty.

Warning: In case of doubt about safety of the device contact Focal Meditech or your dealer.

Warning: In case of a serious incident when using the device, contact Focal Meditech, or your dealer, and the national authority of your country.

Warning: Check for each use that the hinges are properly fixed.

Warning: Flowing⁺ is not intended to be used nearby flammable substances. Flowing⁺ is not AP or APG certified e.g. Flowing⁺ is not intended to be used nearby anaesthetic gasses.

Warning: Anyone using the Flowing⁺, the user and the carer/therapist, needs to be instructed about how it can be adjusted

Contact information

Flowing⁺ is manufactured and sold by

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg
Netherlands

Tel.: +31 (0)13 533 31 03
E-mail: info@focalmeditech.nl
Internet: www.focalmeditech.nl

Intended use, intended users and operation of the device

Intended use

Flowing⁺ is a dynamic arm support system. It is designed for users requiring considerable compensation against gravity during movements of the human arm.

Intended users

The intended users of the Flowing⁺ are users in the need of a function device requiring limited learning efforts:

1. Persons challenged by considerable muscular weakness resulting in the inability to perform essential Activities of Daily Living (ADL) activities including eating, drinking, facial care and computer use. Simple arm supports do not compensate sufficiently;
2. Persons challenged by excessive muscle functioning;
3. Persons in the need of redistribution of pressure/forces;
4. Persons who are at risk for Complaints of Arm Neck and-or Shoulder (CANS), overload or strong fatigue due to challenging working conditions, which may be due to continuous or frequent task performance above shoulder level or performance of many static manual activities;
5. Combinations of these.

Operation of the device

The dynamic arm support system Flowing⁺ is a system that consists of several axes which are interconnected via pivoting points. At the end of the system an arm fitting, elbow fitting and optional a wrist support are attached.
Flowing⁺ can be mounted on a chair, wheelchair or movable frame. The forearm of the user is placed in the arm fitting, and Flowing⁺ can support the weight of the forearm and partly the upper arm. The axes of Flowing⁺ will support movements of the human forearm and hand. Flowing⁺ has a robust design combined with low friction and low play. This is realized by using high quality bearing systems combined with high accuracy mechanical parts which result in a smoothly running system. Therefore little energy is required to introduce the intended movements. The smooth running Flowing⁺ combined with the accurate fit of the arm fitting means the user needs only very little muscle power to move his or her arm. The kinematic chain of the axes results in a large range of motion. If required, personal adaptations are possible. Flowing⁺ can be used one- or two sided. The selection for one or two Flowings depends on several properties of the user, like the needs of the user combined with the personal limitations and possibilities. The user of Flowing⁺ can use this device in various environments like home, the workplace, school, institutional settings or outdoors. Flowing⁺ can be used within a restricted range of environmental humidity. Flowing⁺ is not designed to able to cope with large forces. Flowing⁺ cannot be used as a support when standing up, sitting down or as an autonomous lifting device (without supporting the human arm). Flowing⁺ is not designed to withstand impacts that can be introduced during collisions with a wall or other objects. Also Flowing is not constructed to withstand high external vertical forces that can be introduced for example by (abnormal use of) patient hoist systems for the transport of disabled persons.

Usage of the device

Flowing+ supports the execution of numerous daily activities like eating, drinking, tooth brushing, typing or scratching one's nose. Independence in lifting and manipulating objects and in personal care is possible again. In general it is desirable for users to use their remaining capacities as much as possible. The device adds force to the user's arm when lifting objects in the vertical plane, but (if not in the lifting mode). Application of this principle is both beneficial from a health perspective and for one's self esteem. Furthermore it is also cost effective. Flowing+ operates on the principle of an stepless height adjustment support. This is called 'lifting the arm'. The large horizontal movements hardly require any effort anymore. The construction enables easy and quick reach of the mouth and face. Flowing+ returns the natural freedom of movement to the user. Flowing+ does not make the wheelchair any wider – not even when the arm of the user is rotated inwards. Flowing+ allows the user to choose for assisted movements by changing the gravity plane to move more easily to the front/ rear or moving the users arm in locked position towards the mouth, the device lifts the arm this way in a stabilized manner.

Danger: In accordance with the Code VVR, the device must be disconnected from the wheelchair when the user is transported in the wheelchair by means of transport that is accessible for wheelchairs. Failure of this can lead to malfunctioning of device or bodily harm.

Warning: If the user experiences problems using Flowing+, please contact Focal Meditech, your dealer or a healthcare professional as soon as possible.

Risks and contra-indications

No essential user risks are known while using Flowing+. Flowing+ is an aid which should be used by the intended users. There are no known contra-indications for Flowing+. To be able to use Flowing+ the following warnings must be taken into account.

Danger: Do not overload the Flowing+. If there is any doubt about the stability, try the setup first in an safe area (away from the user) to see if there is no tendency to tilt.

Danger: When Flowing+ is used for eating or drinking, check whether the user suffers from swallowing disorders. If so they should use the Flowing+ only under expert supervision. If in doubt, consult a speech therapist.

Warning: In case of doubt about the safety of the device, the product should not be used anymore and should be removed from the (wheel)chair. Do not try to fix it yourself but contact Focal Meditech or your dealer. Failure to do this will void the warranty.

Warning: Flowing+ does not have parts that can be modified or repaired by the user or other persons. Do not modify any part without the authorization of Focal Meditech. Failure of this can lead to malfunctioning and void the warranty.

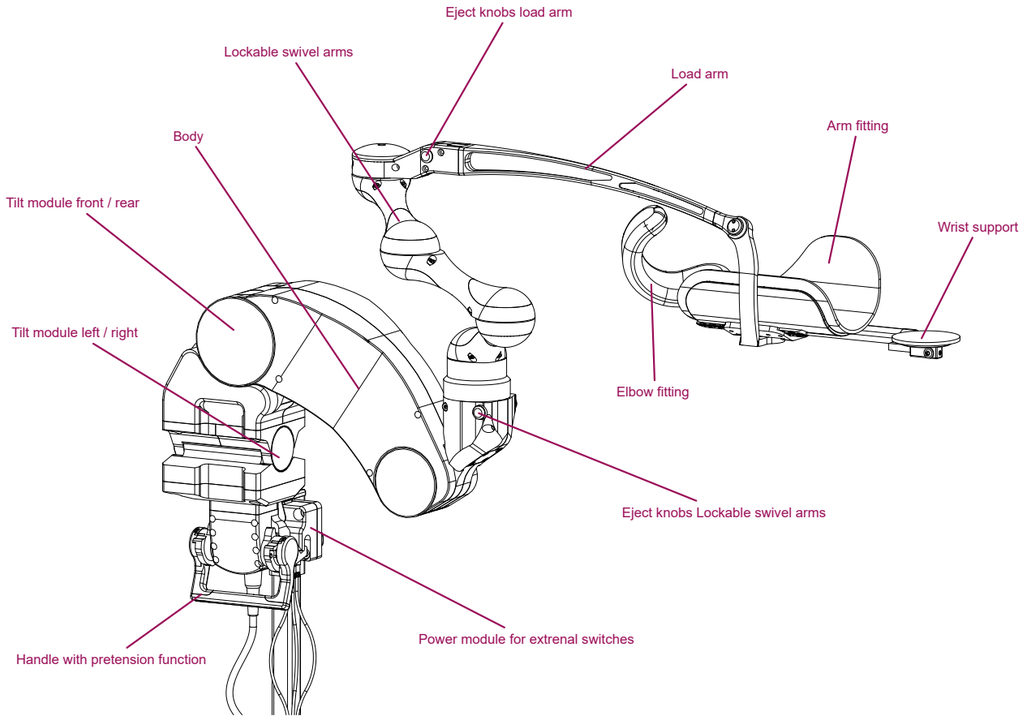
Warning: The arm support system cannot be used by the user as a support when standing up and sitting down. During the evaluation attention is required to determine if the user is able to sit in a stable position and if one can stand-up without using a support.

Warning: Flowing+ is before all intended to be used by persons challenged by limited muscle force in their arms and shoulder girdle. Due to diminished use of their musculoskeletal functions prior to the supply of Flowing+ and also due to the limited ability to stabilise and control joints, the risk of initial overburden is present. The user is at risk of possible overburden of the arm and shoulder, but the possible risk exists for the whole kinetic chain. The risk of overburden is considered to be the largest shortly after supply of the device when the user experiences new freedom of movement of arm and hand. It is advised to gradually build up deployment of the device in cooperation with a skilled healthcare professional. In collaboration with Focal Meditech the user may choose to select settings that initially protect joints that are at risk for overburden.

Warning: For safety reasons, Flowing+ can only be removed from the locking position when the user's arm is correctly positioned in the arm fitting.

Warning: Make sure the knobs are always tightened firmly.

Technical information

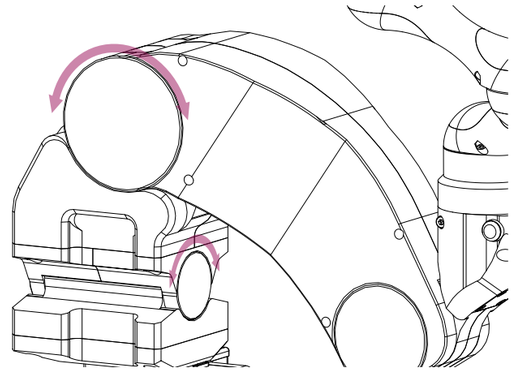


Description

The following parts of Flowing⁺ are described below:

- From a user perspective the contact point with Flowing⁺ is the arm fitting where the forearm of the user is positioned in. This arm fitting is mostly a part that is individually adapted to the user.
- The elbow fitting. The upper arm of the user should be in contact with this part during the use of Flowing⁺. It will prevent that the user will slip out of the arm fitting when the user bends his elbow.
- The wrist support. This part can be used to support the wrist and hand. This wrist support can be shifted and can be removed. The support itself can rotate.
- The Load arm with moving base plate to which the arm fitting, elbow fitting and wrist support are attached.
- The Load arm is connecting the arm fitting, elbow fitting and the wrist support to the body of Flowing⁺.

- At the top of Flowing⁺ there are two eject knobs. Pressing these two knobs towards each other makes it possible to remove the Human Interface, containing the loadarm, arm fitting, elbow fitting and wrist support.
- The lockable swivel arms provide a smooth movement in the horizontal plane the complete unit can be disconnected from the body by pressing the two knobs at the base of the unit towards each other.
- The Body of Flowing⁺ where the actuator for the lift function is located.
- The tilt module contains the sensor and actuator for the tilt function.
- Finally a red handle is attached to this module. This handle can be used to connect Flowing⁺ and to remove any play in the connection between Flowing⁺ and the power module.



The tilt module(s) can be used to adjust the rotation axis of the Lockable swivel arms with respect to the horizontal plane. With the help of the tilt module the direction of the arrow(s) can be adjusted or set perpendicular to the gravity plane. The top arrow shows the movement of the front / rear tilting action the bottommost arrow shows the left / right tilting action.

The Power module contains the On/Off switch of Flowing⁺. Under the module two connectors are available, one for the power supply and one for the Focal bus there are also three stereo jack plugs inputs. All of these connectors do not have to be disconnected if Flowing⁺ is removed using the red handle.

Next to the switch is an indication LED, if the Flowing⁺ is switched on the LED should light up.

- Green: properly connected, working fine.
- Blue blinking: properly connected, there is an communication error.
- Red: Flowing⁺ is not properly connected, see remove/ placing Flowing⁺.

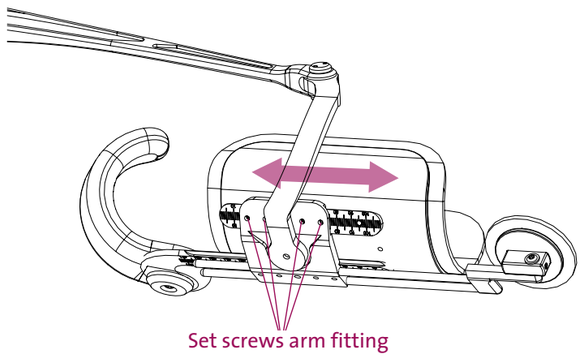
Adjusting the arm swing, arm fitting and elbow fitting

To move the arm freely the weight of the arm is balanced. To balance the arm in the vertical direction, considerable forces are required. For safe use the following is important:

- the arm is positioned in a stable way in the arm fitting
- the arm is always in contact with the elbow rest.

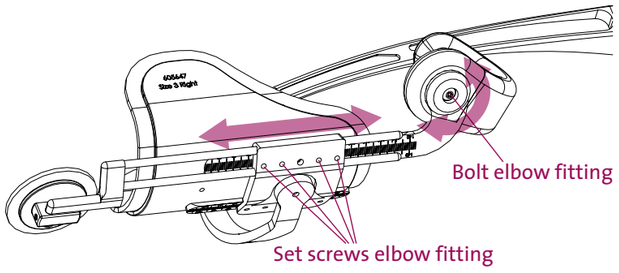
If you notice that the arm is not stable and tends to slip out, reposition the arm in the proper way.

Warning: Adjusting the arm fitting can result in a malfunction of Flowing⁺.



The arm fitting can be adjusted in one axis. Adjusting the position of the arm fitting is done in the following way: Loosen one or multiple set screws of the arm fitting. Adjust the arm fitting by shifting this fitting in the direction of the arrow. Fasten all adjustment screws of the arm fitting.

Caution: Adjusting the elbow fitting can result in a malfunction of Flowing⁺.



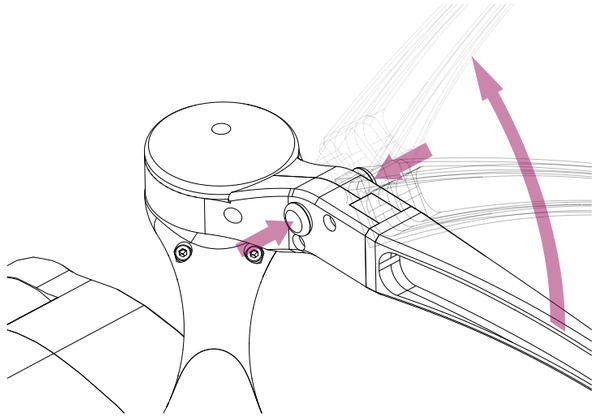
The elbow fitting can be adjusted in two directions:

1. Adjusting the rotation of the elbow fitting: loosen the “bolt elbow fitting” until the fitting can be rotated. Adjust the fitting in the desired position and fasten the “bolt elbow fitting”.
2. Adjusting the position of the elbow fitting: loosen one or multiple “set screws elbow fitting”. Adjust the elbow fitting by shifting this fitting in the direction of the arrow. Fasten all “set screws elbow fitting”.

Caution: The positions of the arm fitting and elbow fitting are crucial for the performance of Flowing⁺. Changing these positions can result in a severe decrease of the performance or even malfunction of Flowing⁺. Therefore only trained persons are allowed to change the settings of the arm fitting and elbow fitting.

Disconnecting the human interface

Danger: Please carefully disconnect/remove the different parts and take notice of the steps described in this manual to avoid possible injuries.



The human interface containing the loadarm, arm fitting, elbow fitting and wrist support can be removed easily. Before disconnecting the human interface it is advisable to lock the swivel arms first. This provide a stable situation which makes the operation much easier and ensures that the arms do not accidentally touch something or someone.

To disconnect the lever, press both red knobs at the top of Flowing⁺, and move the lever away from the body in the upwards direction.

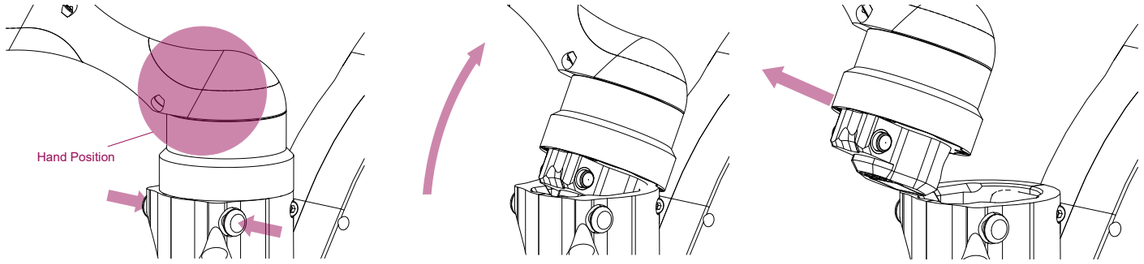
Replacing the human interface can be done by pushing the lever into the body. The buttons do not have to be pushed. When the human interface is in position, it cannot be removed without pressing the buttons.

Optionally for storage purposes a holder for the human interface can be mounted at the back of the wheelchair

Disconnecting the lockable swivel arms

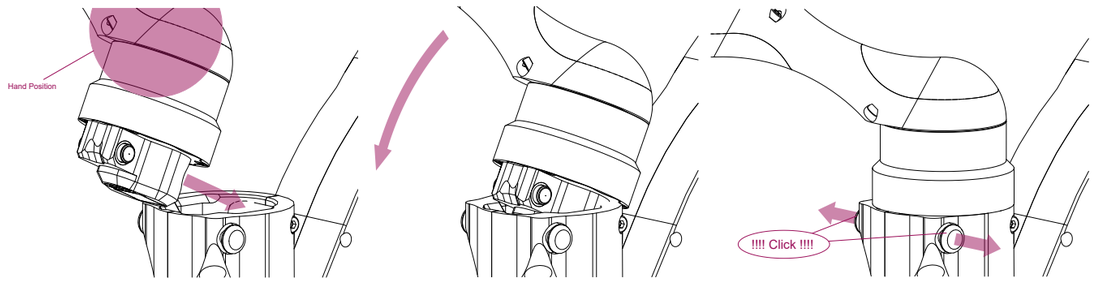
Caution: Please carefully disconnect/remove the different parts and take notice of the steps described in this manual to avoid possible injuries.

The lockable swivel arms can be removed easily. Before disconnecting the lockable swivel arms it is advisable to remove the human interface see previous chapter, and in addition, it is convenient to lock them first. This provide a stable situation which makes the operation much easier and ensures that the arms do not accidentally touch something or someone.



Removing blockable swivel arms from Flowing⁺

STEP 1: Place one hand on the position of the circle (first arm after the base).
STEP 2: Press with the other hand both red knobs at the base of the swivel arms towards each other.
STEP 3: Rotate the unit towards the body in the direction of the arrow for approximately 25°.
STEP 4: Move the lockable swivel arms up in a slanted line until it is free from the body.
STEP 5: Store the lockable swivel arms always in its case to prevent the them being damaged.



Placing blockable swivel arms to Flowing⁺

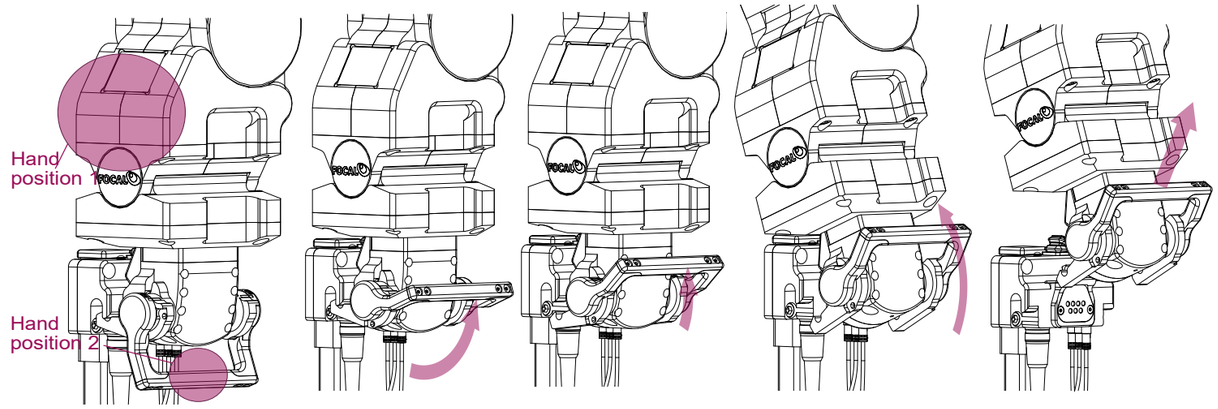
STEP 1: Take the blockable swivel arms from its case.
STEP 2: Place one hand on the position of the circle (first arm after the base).
STEP 3: Move the blockable swivel arms down in a slanted line until the lip catches the round bar.
STEP 4: Rotate the unit towards the body in the direction of the arrow.
STEP 5: Press with the other hand

Removing / mounting Flowing⁺

Caution: Please carefully disconnect/remove the different parts and take notice of the steps described in this manual to avoid possible injuries.

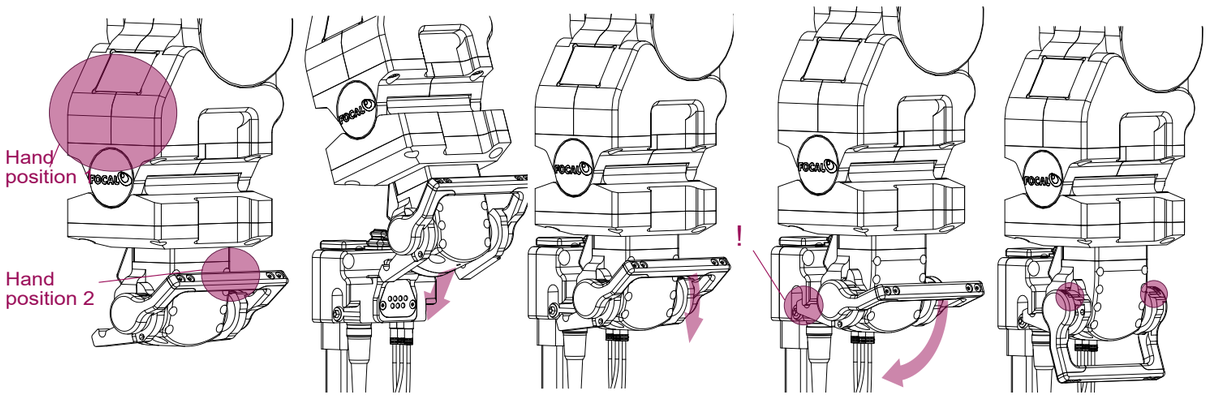
However Flowing⁺ can be removed easily there are some points that require some attention. Before disconnecting Flowing⁺ the human interface and the lockable swivel arms should be removed according to the in the previous two chapters. This provide a stable situation which makes the operation much easier.

Removing Flowing+ from the power module (right handed version)



STEP 1: Set all settings to default and switch off Flowing (not sown in pictures above).
STEP 2: Push the tension handle to the right to release the preloaded tension.
STEP 3: Place your left hand on position 1 and your right hand on position 2.
STEP 4: Rotate the red handle upwards in the direction of the arrow.
STEP 5: Tilt the Flowing approximately 20° in the direction of the arrow.
STEP 6: Move the Flowing up in a slanted line until it is free from the Power module.
STEP 7: Store Flowing always in its case to prevent it being damaged (not sown in pictures above).

Placing Flowing+ to the power module (right handed version)



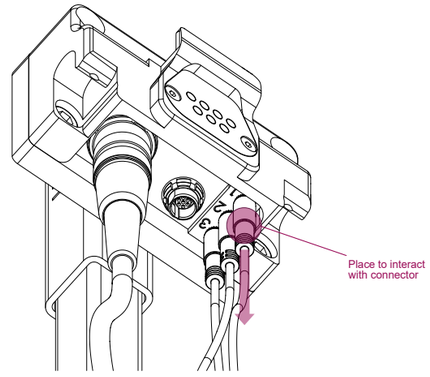
STEP 1: Hold Flowing+ with your left hand on position 1 and your right hand on position 2.
STEP 2: Hold the Flowing+ above and in a tilted position towards the Power module.
STEP 3: Move Flowing+ down in a slanted line until it catches the hook of the power module.
STEP 4: Tilt Flowing+ down until the body of Flowing+ is vertical.
STEP 5: Push the red handle down.
STEP 6: Push the tension handle to the left to add tension and reduce lateral clearance of the system.
STEP 7: Position the user's arm in the arm fitting.
STEP 8: Switch on Flowing+.

Left handed version of the Flowing+
The removing and placing procedure of the left handed version of Flowing+ are similar. The only difference is that your right hand is on position 1 and your left on position 2.

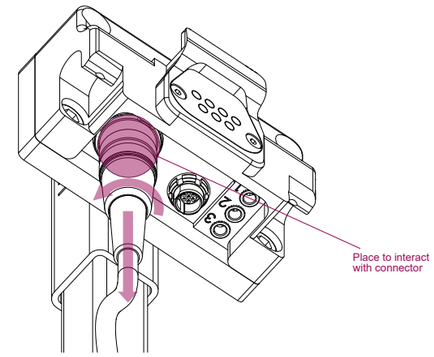
Removing the cables

In case the Power Module has to be removed, the cables must be disconnected first. In the section below is explained how to do this, it is possible that in your setup not all cables are used.

To remove the 3mm Jack cable(s): hold the connector as close as possible inside the Power module and pull to disconnect the connector. The connector should slide easily out of the chassis part.



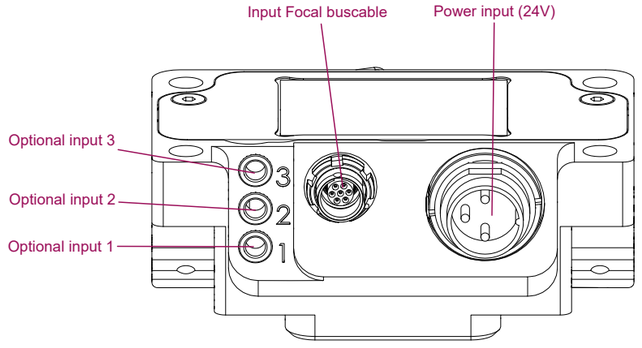
To remove the power connector: hold the connector as close as possible inside the mounting base and turn counter clockwise the outer ring until it moves completely free. Then pull the connector out of the chassis part



Controls

Inputs on Power module

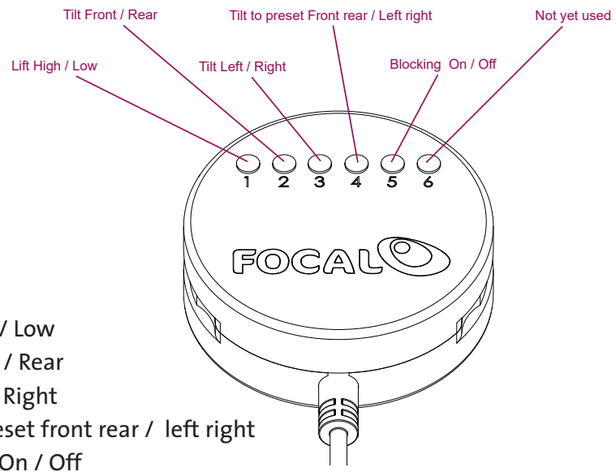
The functions of Flowing+ can be easily controlled by external switches which can be connected to the power module.



There are a few options to connect the external in and outputs to the power module.

LED display

The LED display can be used to visualize the function that can be controlled by the user. The LED display makes it possible to control all functions with only 2 inputs. To go to the next function press the switch that is set to for the scan command, a short press is forward scanning holding down is reverse scanning. The LED's of the display have always the same funtion those functions are:



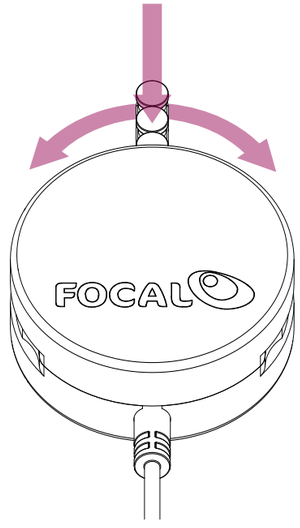
1. Lift High / Low
2. Tilt Front / Rear
3. Tilt Left / Right
4. Tilt to preset front rear / left right
5. Blocking On / Off
6. Not yet used

Depending on the user level it is possible that one or more functions are inactive. By pressing on the function switch it can be the LED jumps over the inactive functions.

Triple-action switch

The triple-action switch is a switch where three functions are combined in one switch. Seen from the top are the corresponding switching outputs:

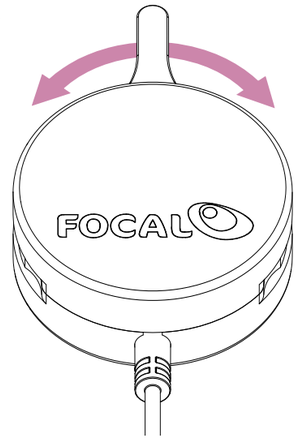
1. Swing lever clockwise
2. Swing lever counterclockwise
3. Pressing on lever



Dual-action switch

The dual-action switch is a switch where two functions are combined in one switch. Seen from the top are the corresponding switching outputs:

1. Swing lever clockwise
2. Swing lever counterclockwise



Single switch

There can be up to six "normal open" switches connected. To be able to do this, a splitter from a single stereo (male) to double mono (female) is required. If no split cables are used, a maximum of three switches can be connected. In this case only the mono input will be used.

Accessories

Battery pack and charger

The battery pack can be used if there is no or not enough power to operate Flowing⁺ for example on a trippelstoel (manual wheelchair). The battery pack comes with a charger and a power cable to connect the battery pack to the power module. For more information see the user manual of the battery pack.

- Charging time: 4hours (from empty to complete full)
- Standby the battery pack does not loose charge

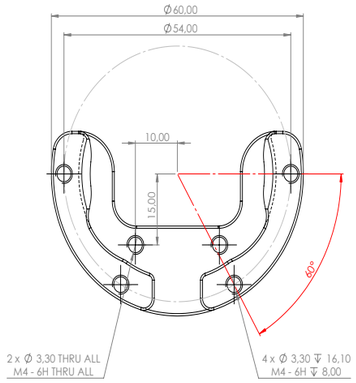
Power adapter

Usually when the Flowing⁺ is used on a stand in a fixed position the power adapter can be used. The power adapter will use the power from a wall socket to supply the Flowing⁺ with the necessary power. For more information see the user manual of the power adapter.

Installation instructions

Installing LED display, Triple-action and Dual-action switch (controls)

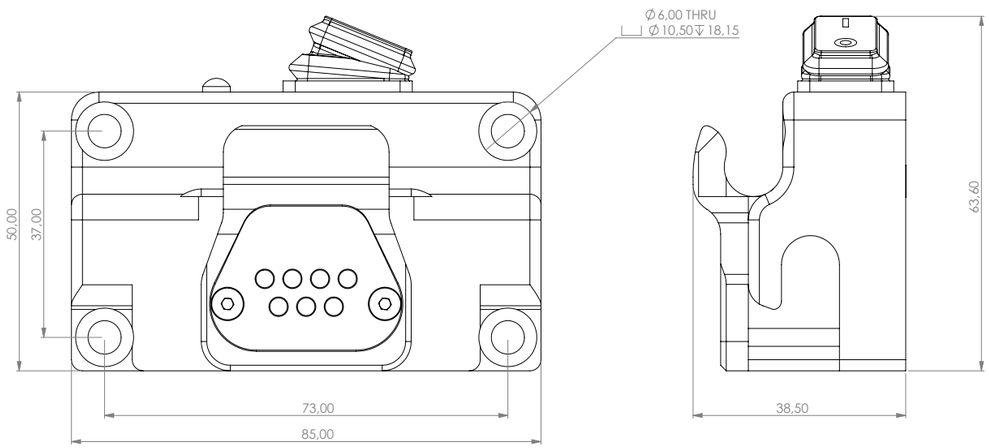
To provide a secure mounting of the controls for Flowing, they can be optional delivered with mounting bracket. If the controls are mounted on or under an worktop or armrest they should be always be mounted using this clip or using the magnetic connection inside the controls.
The clip can be mounted on, under or in the worktop of a wheelchair, or with a special folding / swing away mount under or next to the armrest. This can be done using the treated holes (M4) in the clip.



Warning: Take extra care how to position the Flowing⁺ control switch if the user controls Flowing⁺ with the hand of the Flowing⁺ supported arm (and vice versa). In these cases it is strongly recommended to place an extra switch in case the user is not able to reach the controls any more. The Eneaswitch² has a separate input for a switch that can be used as a “default” button. When this “default” button is pushed the blocking mechanism will be unblocked, the balance force will be minimised and the lift position will be lowered to the lowest position, giving the user the opportunity to control Flowing⁺ again. This switch can be placed somewhere close to the head, the other hand, legs or any other position where the user is able to control a switch..

Installing the Power Module

The power module should be always mounted with four M6 hexagon socket head cap screws (DIN 912) with a minimum class of 8.8 use a torque of 6Nm to tightening the bolts. The Power module should be mounted on a standard bracket. If the standard brackets do not fulfil the needs for the installation a custom made bracket can be made but this bracket should always need an approval by the R&D department of Focal Meditech.



Maintenance instructions

Hardware maintenance

Do not place the device in direct sunlight or in the direct vicinity of a heat source, otherwise this might result in discolouration or scorching of plastic parts. Direct sunlight may reduce the lifetime of system parts and interfere with operation.

All housings, cables and connectors must be regularly inspected. If any part is visibly damaged, do not use the device. It is prohibited to physically modify Flowing⁺. There are no serviceable parts inside Flowing⁺. Contact Focal Meditech or your dealer for any maintenance issues.

In case Flowing⁺ is not mounted on the mounting base it should always be stored in its case to prevent falling or other impacts that can damage the system.

Cleaning

Maintenance of Flowing⁺ is limited and can be cleaned using a moist cloth and a non-aggressive cleaning agent.

Reuse

To reuse Flowing⁺, it must be disassembled and reviewed by Focal Meditech or a certified professional that is approved by Focal Meditech. Flowing⁺ must intensively be cleaned and inspected. The keypad of the Eneaswitch² can be removed and replaced by a new one. The arm fitting, elbow fitting and wrist support have to be replaced. Focal Meditech will refurbish and repackage the reused Flowing⁺ in such a way that it will meet the safety and performance requirements according to applicable regulations.

Decommissioning

Appendix 1 Technical specifications

Specifications Flowing+

Mass		
• Mass Flowing+	4.1	[kg]
Dimensions		
• Height	450	[mm]
• Width	84	[mm]
• Depth	290	[mm]
Mounting position(angle)		
• Maximum allowed	–10...10	[°]
Range of motion		
• Up/Down	300	[mm]
Lift capacity		
• Up/Down		
• Mass	5	[kg] @ end of load arm
• Speed	50–200	[mm/s] @ end of load arm
Tilt function front rear (Intergrated tilt module)		
• Angle	–15 ... 15	[°]
• Accuracy	1.0	[°]
• Speed	2.7	[°/s]
Tilt function left right (Integrated tilt module)		
• Angle	–12...12	[°]
• Accuracy	1.0	[°]
• Speed	2.7	[°/s]
Operation voltage		
• Nominal voltage	20	[V]
Operation current (incl. Power module)		
• Standby	55	[mA]
• Sleep	5	[mA]
• During adjustments typical	0.6	[A]
• During adjustments maximum	1.6	[A]

Power consumption (incl. Power module)		
• Standby	1	[W]
• During adjustments typical	10	[W]
• During adjustments maximum	24	[W]
Storage conditions		
• Temperature	–40...85	[°C]
• Humidity	35...85	[%] non condensing
Operation conditions		
• Temperature	5...+40	[°C]
• Humidity	35...85	[%] non condensing
Degree of protection		
• IP-class	IP32	(IEC60529)

Power Module specifications (part of Flowing+)

Mass		
• Mass Power module	0.135	[kg]
Dimensions		
• Height	62	[mm]
• Width	85	[mm]
• Depth	39	[mm]
Mounting position(angle)		
• Maximum allowed	–10...10	[°]
Input voltage		
• Nominal input voltage	24	[V]
• Absolute input voltage range	23...40	[V]
Input current		
• Standby	5	[mA]
Output current		
• Maximum continues @ 25°	2	[A]
• Maximum continues @ 50°	1.2	[A]
Power consumption		
• Standby	0.12	[W]
• Maximum continues @ 25°	48	[W]
• Maximum continues @ 50°	28.8	[W]
Storage conditions		
• Temperature	-40...+85	[°C]
• Humidity	35...85	[%] non condensing
Operation conditions		
• Temperature	5...+50	[°C]
• Humidity	35...85	[%] non condensing
Degree of protection		
• IP-class	IP32	(IEC60529)

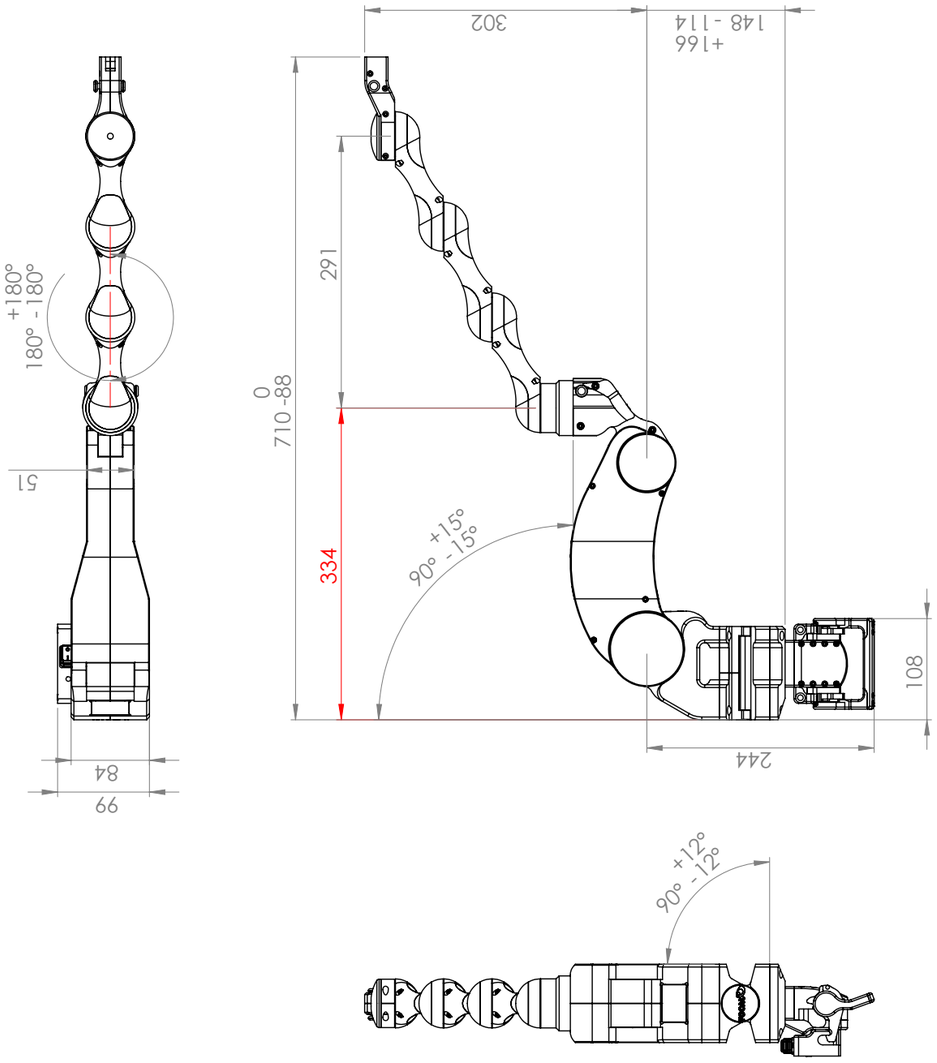
Specifications Blockable swivel arms (part of Flowing+)

Mass		
• Mass Blockable swivel arms	4.1	[kg]
Dimensions		
• Height	245	[mm]
• Width	59	[mm]
• Depth	59	[mm]
Range of motion		
• Left right	290	[mm] @ end of lever
• Forward backward stroke	290	[mm] @ end of load arm
Blocking		
• Horizontal rotation		
◦ Blocking force	100	[N] @ end of load arm
◦ Index	<5	[mm] @ end of load arm
Storage conditions		
• Temperature	–40...+85	[°C]
• Humidity	35...85	[%] non condensing
Power consumption		
• Standby	0.2	[W]
• Maximum	3.4	[W]
Storage conditions		
• Temperature	–40...+85	[°C]
• Humidity	35...85	[%] non condensing
Operation conditions		
• Temperature	5...+50	[°C]
• Humidity	35...85	[%] non condensing
Degree of protection		
• IP-class	IP32	(IEC60529)

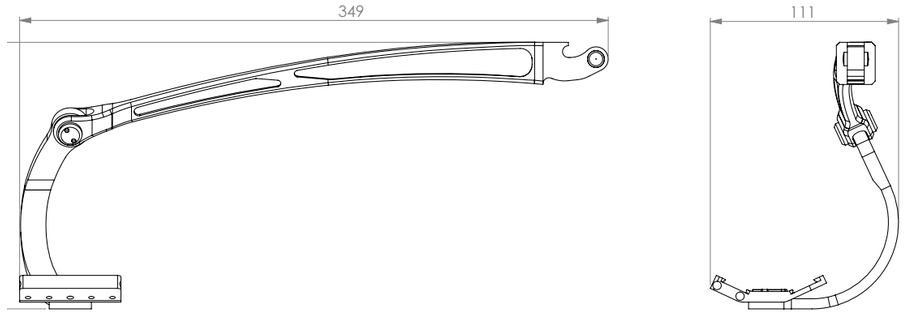
Dimensions

Dimensions are variable. This is because it is a product with moving parts and it is a product with different configurations. All dimensions are given in [mm] millimetres

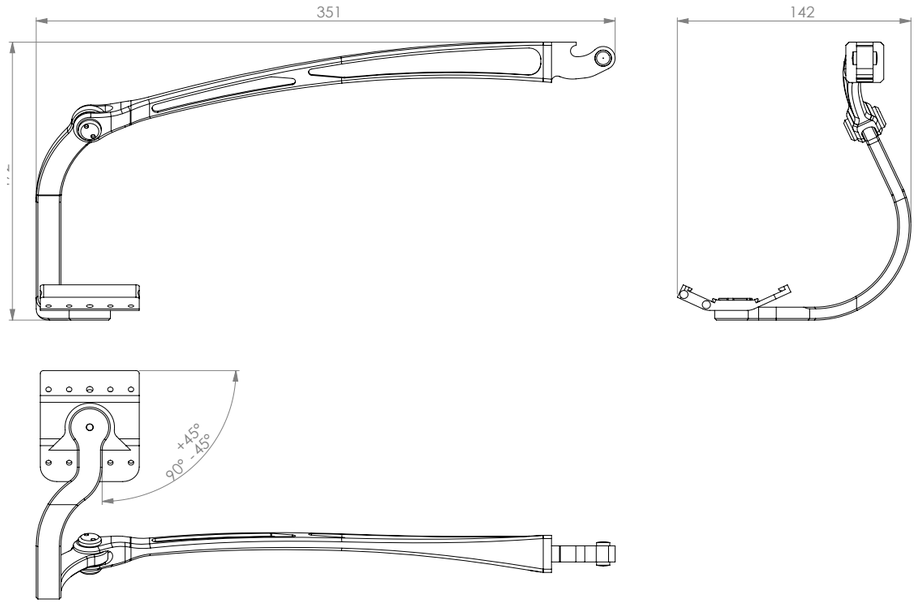
Dimensions (human interface excluded)



Dimensions armrest Large (right handed version)



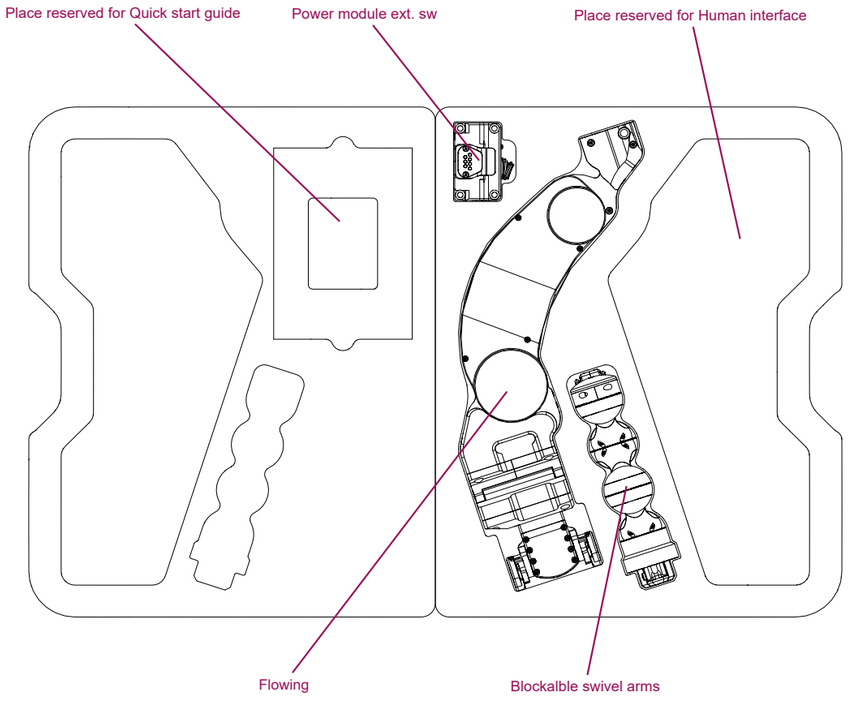
Dimensions armrest X-Large (right handed version)



Content of case

The case contains the following parts:

- Flowing+
- Blockable swivel arms
- Power module
- Battery power cable
- Quick Start Guide



Some parts are individual and are added on specifications but these depend on the user:

- Human interface
  - Load arm
  - Arm fitting
  - Elbow fitting
  - Wrist support
- Controls
  - LED display
  - Triple-action switch
  - Dual-action switch
- Extension cable for switches
- Splitters

Appendix 2 Part numbers

Focal number	Description
607404	Flowing
607482	Power module ext SW
605694	Case with inlay Flowing+
607380	Blockable swivel arms
605868	Battery pack
605893	Charger battery pack
605938	Battery power cable 2.9m
605937	Battery power cable 4.0m
605941	Battery adapter cable
605940	Battery pack power cable 0.5m
605939	Battery pack power cable 2.0m
605894	Power adapter
606062	Stereo to Mono Splitter 3,5mm
601577	Stereo extension cable 3,5mm jack 1m
607500	Dual action switch
607761	Triple action switch
607562	LED display

601826	Loadarm left (Large)
601830	Loadarm right (Large)
601828	Loadarm left (X-Large)
601832	Loadarm right (X-Large)

603167	Subassembly wrist support (right)
603166	Subassembly wrist support (left)
606020	Subassembly wrist support cushion (right)
606021	Subassembly wrist support cushion (left)

603137	Subassembly Elbow fitting left (Small)
603143	Subassembly Elbow fitting right (Small)
603135	Subassembly Elbow fitting left (Large)

603141	Subassembly Elbow fitting right (Large)
603139	Subassembly Elbow fitting left (X-Large)
603145	Subassembly Elbow fitting right (X-Large)
603140	Subassembly Elbow fitting left (XX-Large)
603146	Subassembly Elbow fitting right (XX-Large)

605639	Assembly Armfitting size 1 right
605659	Assembly Armfitting size 1 left
605643	Assembly Armfitting size 2 right
605663	Assembly Armfitting size 2 left
605647	Assembly Armfitting size 3 right
605667	Assembly Armfitting size 3 left
605651	Assembly Armfitting size 4 right
605671	Assembly Armfitting size 4 left
605655	Assembly Armfitting size 5 right
605675	Assembly Armfitting size 5 left

605638	Inlay Armfitting size 1 right
605658	Inlay Armfitting size 1 left
605642	Inlay Armfitting size 2 right
605662	Inlay Armfitting size 2 left
605646	Inlay Armfitting size 3 right
605666	Inlay Armfitting size 3 left
605650	Inlay Armfitting size 4 right
605670	Inlay Armfitting size 4 left
605654	Inlay Armfitting size 5 right
605674	Inlay Armfitting size 5 left

603097	Assembly Bracket human interface
605683	Mobile stand

604190	Fixation strap complete Large
604191	Fixation strap complete Small
605926	Elbow bracket L shape short left
605927	Elbow bracket L shape short right

Appendix 3 Used materials

Focal number	Description	Material(s)
607404	Flowing+	Aluminium 6082T6 + stainless steel (AISI 304)
607482	Power module ext SW	Aluminium 6082T6
605694	Case with inlay Flowing+	
607380	Blockable swivel arms	Aluminium 6082T6 + stainless steel (AISI 304)
605868	Battery pack	Aluminium 6082T6 + Li Ion battery
605893	Charger battery pack	Aluminium 6082T6
605938	Battery power cable 2.9m	
605937	Battery power cable 4.0m	
605941	Battery adapter cable	
605940	Battery pack power cable 0.5m	
605939	Battery pack power cable 2.0m	
605894	Power adapter	Aluminium 6082T6
606062	Stereo to Mono Splitter 3,5mm	
601577	Stereo extension cable 3,5mm jack 1m	
607500	Dual action switch	Aluminium 6082T6+ POM
607761	Triple action switch	Aluminium 6082T6+POM
607592	LED display	Aluminium 6082T6

601826	Loadarm left (Large)	Aluminium 6082T6 + stainless steel (AISI 304)
601830	Loadarm right (Large)	
601828	Loadarm left (X-Large)	
601832	Loadarm right (X-Large)	

603167	Subassembly wrist support (right)	Aluminium 6082T6 + stainless steel (AISI 304) + NEOPRENE
603166	Subassembly wrist support (left)	
606020	Subassembly wrist support cushion (right)	
606021	Subassembly wrist support cushion (left)	

603137	Subassembly Elbow fitting left (Small)	Aluminium 6082T6 + NEOPRENE
603143	Subassembly Elbow fitting right (Small)	
603135	Subassembly Elbow fitting left (Large)	
603141	Subassembly Elbow fitting right (Large)	
603139	Subassembly Elbow fitting left (X-Large)	
603145	Subassembly Elbow fitting right (X-Large)	
603140	Subassembly Elbow fitting left (XX-Large)	
603146	Subassembly Elbow fitting right (XX-Large)	

605639	Assembly Armfitting size 1 right	Aluminium 6082T6 + Vikureen (PS)
605659	Assembly Armfitting size 1 left	
605643	Assembly Armfitting size 2 right	
605663	Assembly Armfitting size 2 left	
605647	Assembly Armfitting size 3 right	
605667	Assembly Armfitting size 3 left	
605651	Assembly Armfitting size 4 right	
605671	Assembly Armfitting size 4 left	
605655	Assembly Armfitting size 5 right	
605675	Assembly Armfitting size 5 left	

605638	Inlay Armfitting size 1 right	NEOPRENE
605658	Inlay Armfitting size 1 left	
605642	Inlay Armfitting size 2 right	
605662	Inlay Armfitting size 2 left	
605646	Inlay Armfitting size 3 right	
605666	Inlay Armfitting size 3 left	
605650	Inlay Armfitting size 4 right	
605670	Inlay Armfitting size 4 left	
605654	Inlay Armfitting size 5 right	
605674	Inlay Armfitting size 5 left	

603097	Assembly Bracket human interface	Stainless steel (AISI 304) + POM

604190	Fixation strap complete Large	NEOPRENE
604191	Fixation strap complete Small	NEOPRENE
605926	Elbow bracket L shape short left	Aluminium 6082T6+
605927	Elbow bracket L shape short right	Aluminium 6082T6+
605683	Mobile stand	Construction steel (ASTM A36)

Appendix 4 Quick Start Guide

Appendix 5 Troubleshooting guide

Flowing⁺ saves errors for maintenance and service reasons and is able to show these errors in the troubleshoot mode. In the troubleshoot mode the LEDs of the Eneaswitch² will be used to show the error codes of Flowing⁺.

Entering the troubleshoot mode

Push the button ⓪ in the right column for 5 seconds and you will enter the configuration menu.

Appendix 6 Declaration of conformity

FOCAL meditech

EU DECLARATION OF CONFORMITY

We,

Focal Meditech
Droogdokkeneiland 19
5026 SP Tilburg
The Netherlands

registered in EUDAMED under the Single Registration Number NL-MF-000000536, hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

Flowing+ (type number 607404),
and its accessories

having the intended purpose: Flowing+ is a dynamic arm support system. It is designed for users requiring considerable compensation against gravity during movements of the human arm.

And have been registered under basic UDI-DI 87193276494FOCFW+PG, and classified as Class I, according to Annex VIII, Rule number 13,

and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards:

• EN 1041	Information supplied by manufacturer of medical devices
• EN-ISO 9999	Assistive products – Classification and terminology
• EN-ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
• EN-ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
• EN-ISO 14971	Medical devices – Application of risk management to medical devices
• ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
• EN-IEC 60529	Degrees of protection provided by enclosures (IP code)
• EN-IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
• EN-IEC 62304	Medical device software – Software life-cycle processes

and are in conformity with the requirements of directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Signature:

Tilburg, The Netherlands

Date: 20 November 2023
Name: Paul Groenland
Function: Managing Director

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg

Appendix 7 Conditions and Warranty

Conditions and Warranty: supplied through a representative of Focal Meditech

Conditions and Warranty in the case of supply through a representative of Focal Meditech are subject to conditions of the national or local representative and in accordance with national law.

Conditions and Warranty: direct supply by Focal Meditech BV to end users

In the case of direct supply by Focal Meditech to end users, Conditions and Warranty are subject to the Consumer General Terms and Conditions issued by Koninklijke Metaalunie and in accordance with Dutch law.