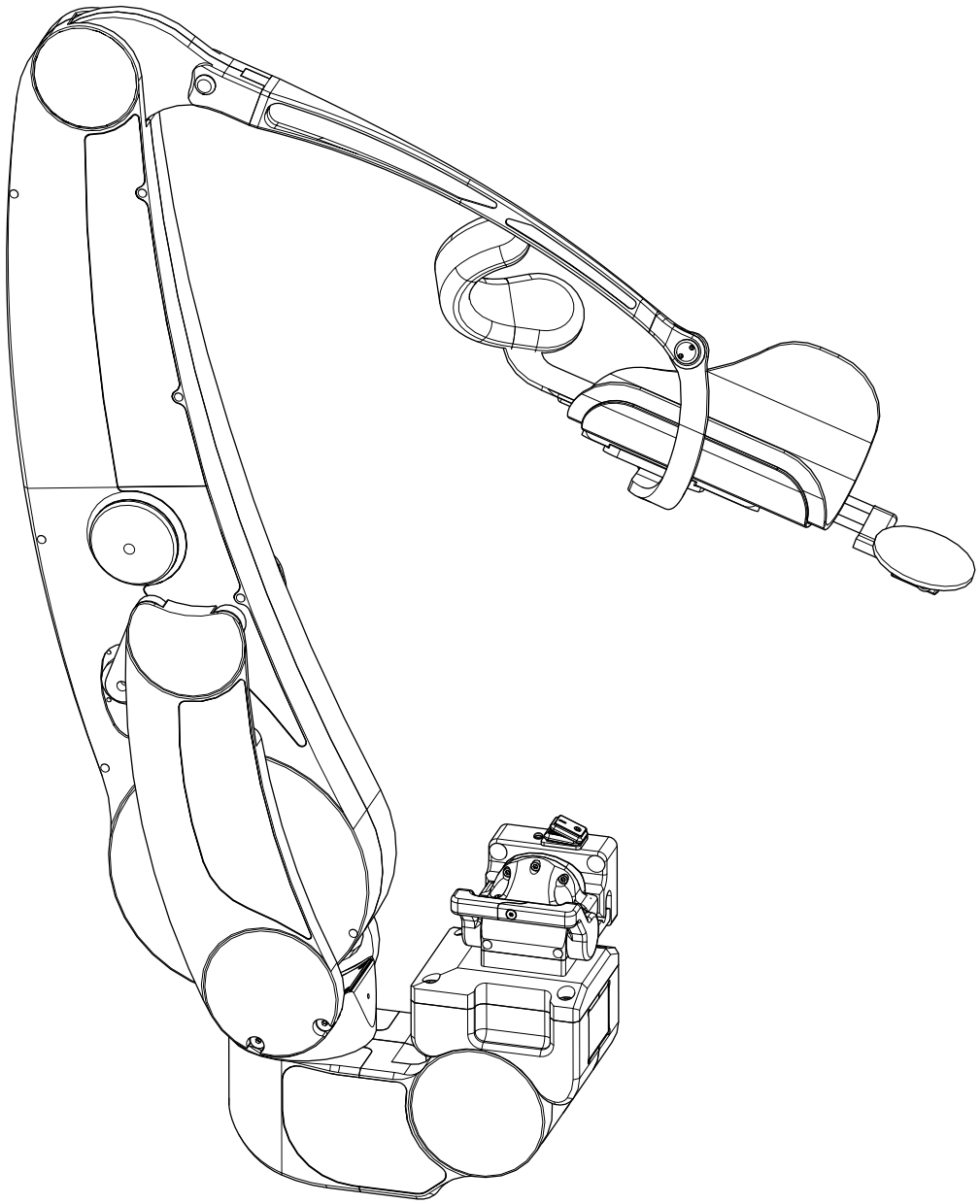

Gowing^2

User manual

ID manual: 605689
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Date: 01-02-2020

FOCAL meditech

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Content

Disclaimer 2
Copyright Notice 2
Trademarks 2
Content 3
Manual introduction 5
Symbol explanation 6
Certification Notices 7
Safety notices 8
Contact information 9
Intended use, intended users and operation of the device 10
- Intended use 10
- Intended users 10
- Operation of the device 10
- Usage of the device 11
- Risks and contra-indications 11

Technical information 13
- Description 13
- Adjusting the arm swing, arm fitting and elbow fitting 14
- Disconnecting the human interface 16
- Removing / mounting the Gowing² 17
- Removing the cables 18

Controls 20
- Eneaswitch² 20
- Adjustment of balancing force / blocking function 20
- Adjustment of the tilt function 21
- Adjustment of the lift function 21
- Optional inputs on the Eneaswitch². 22
- Single switch control Eneaswitch². 23

Accessories 24
- Battery pack and charger 24
- Power adapter 24

Installation instructions 25
- Installing the Gowing² 25
- Installing the Eneaswitch² 25
- Installing the Power Module 26

Maintenance instructions 27
- Hardware maintenance 27
- Cleaning 27
- Reuse 27
- Decommissioning 27

Appendix 1 Technical specifications 28
Gowing² specifications 28
Power Module specifications (part of Gowing²) 30
Eneaswitch² specifications (part of Gowing²) 31
Gowing² dimensions 32
Dimensions (human interface excluded) 32
Dimensions armrest Large (right handed version) 33
Dimensions armrest X-Large (right handed version) 33
Content of case Gowing² 34
Appendix 2 Part numbers 35
Appendix 3 Used materials 37
Appendix 4 Quick Start Guide 41
Appendix 5 Troubleshooting guide 59
Entering the troubleshoot mode 59
Appendix 6 Declaration of conformity 60
Appendix 7 Conditions and Warranty 61
Conditions and Warranty: Gowing² supplied through a representative of Focal Meditech 61
Conditions and Warranty: direct supply by Focal Meditech BV to end users 61

Manual introduction

This is the user manual for Gowing², a dynamic arm support system. This product is developed, manufactured and distributed by Focal Meditech B.V. or one of its authorized representatives.

This manual contains important information regarding Gowing², 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 Gowing², information about safety issues and contact information.

Please read this information carefully: increase of knowledge of the arm support will result in an increase of effectiveness. Important: always keep this user manual in a convenient location for easy reference.

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.
	Disposal 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 LOT TESTB IN: 20V 1A peak SN Uxxxxx Gowing² 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 Gowing².
REF 605547 LOT TESTB IN: 20V 1A peak SN Uxxxxx Eneaswitch² 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 bottom side of the Eneaswitch².
REF 604782 LOT TESTB IN: 24V 1.5A peak SN Uxxxxx OUT: 20V 1.5A peak 7.5A Power module 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.

Classification cf. Dutch Cliq 2013:

241827030309	Dynamic Arm Supports, compensation of impaired arm muscle function and change of range of motion, load arm construction, hybrid actuation
241827060309	Dynamic Arm Supports, managing excessive muscle functioning, hybrid actuation
241827090309	Dynamic Arm Supports, redistribution of pressure/forces, hybrid actuation
241827990306	Forearm support
241827990900	Axis locking

Safety notices

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

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

Danger: During installation ensure there is a fuse of 7.5A between power supply and Gowing². Failure of this can lead to malfunctioning of the device and bodily harm.

Danger: Mechanical energy is stored for balancing the arm. During non-intended removal of the arm from the arm fitting of Gowing², this mechanical energy will be released resulting in a fast moving lever and arm fitting which can result in bodily harm.

Warning: Do not modify any part of this equipment without authorization of the manufacturer. Failure of this can lead to malfunctioning and will void the warranty.

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

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

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

Contact information

Gowing² is manufactured and sold by

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg
Netherlands

Tel.: +31 13 533 31 03
Fax: +31 13 533 50 04
E-mail: info@focalmeditech.nl
Internet: www.focalmeditech.nl

Intended use, intended users and operation of the device

Intended use

Gowing² 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 dynamic arm support Gowing² 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, computer use and wheelchair control. 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 Gowing² 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. Gowing² can be mounted on a chair, wheelchair or movable frame. The forearm of the user is placed in the arm fitting, and Gowing² can support the weight of the forearm and partly the upper arm. The axes of Gowing² will support movements of the human forearm and hand.

Gowing² has a robust design combined with low friction and low play. This is realised 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 Gowing² 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.

Gowing² can be used one- or two sided. The selection for one or two Gowings depends on several properties of the user, like the needs of the user combined with the personal limitations and possibilities.

The user of Gowing² can use this device in various environments like home, the workplace, school, institutional settings or outdoors. Gowing² can be used within a restricted range of environmental humidity.

Gowing² is not designed to able to cope with large forces. Gowing² cannot be used as a support when standing up, sitting down or as an autonomous lifting device (without supporting the human arm).
Gowing² is not designed to withstand impacts that can be introduced during collisions with a wall or other objects. Also Gowing² 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

Gowing² 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) no more force is added than strictly is needed. The principle at work here is called 'Assist as needed'. Application of this principle is both beneficial from a health perspective and for one's self esteem. Furthermore it is also cost effective. Gowing² operates on the basis of compensation of the weight of the arm. This is called 'balancing the arm'. The large horizontal movements hardly require any effort anymore. The construction enables easy and quick reach of the mouth and face. Gowing² returns the natural freedom of movement to the user. Gowing² does not make the wheelchair any wider – not even when the arm of the user is rotated inwards. Gowing² allows the user to choose for assisted movements (assist as needed) to move freely or to let the device lift the arm in order to stabilise the arm.

Warning: If the user experiences problems using the Gowing², please contact Focal Meditech or a healthcare professional as soon as possible.

Risks and contra-indications

No essential user risks are known while using Gowing². Gowing² is an aid which should be used by the intended users. There are no known contra-indications for Gowing². To be able to use Gowing² the following warnings must be taken into account.

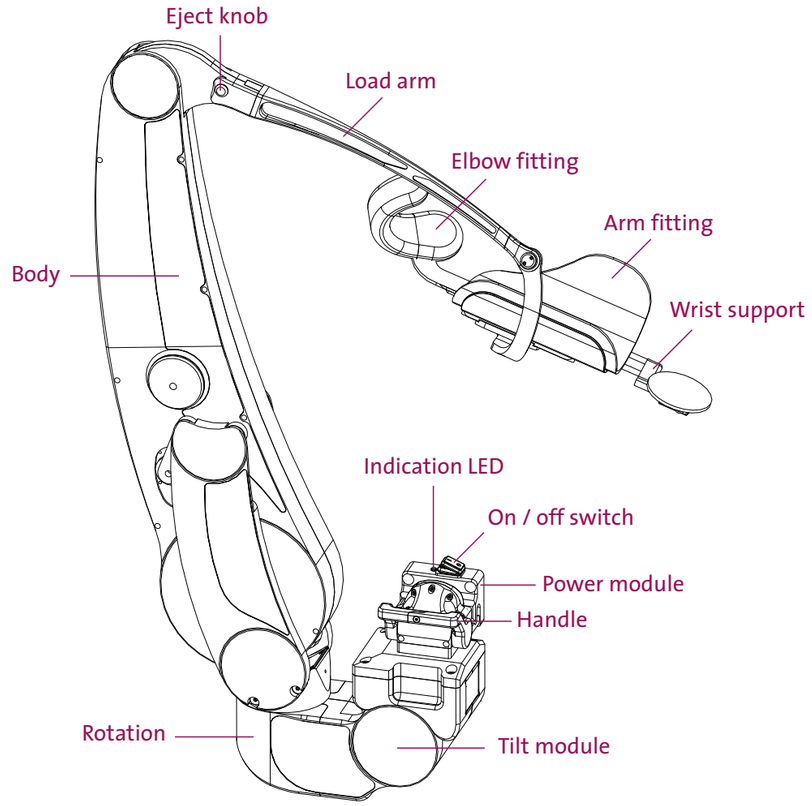
Warning: The arm support system cannot be used by the user as a support when standing up and sitting down. During the evaluationof Gowing² attention is required to determine if the user is able to sit in a stable position and if one can stand-up without using a support.

Warning: In case of defective electrical wiring, electrical powered parts or the connection to the batteries, contact Focal Meditech. In case of doubt about the safety of the electronic 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 its authorized representative. Failure to do this will void the warranty.

Warning: Gowing² does not have parts that can be modified or repaired by the user or other persons. Do not modify any part of this equipment without the manufacturer's authorization. Failure of this can lead to malfunctioning and void the warranty.

Warning: For safety reasons, Gowing² can only be switched on when the user's arm is correctly positioned in the arm fitting. For the same safety reasons, it is only allowed to switch off Gowing² before the user's arm is removed from the arm fitting.

Technical information



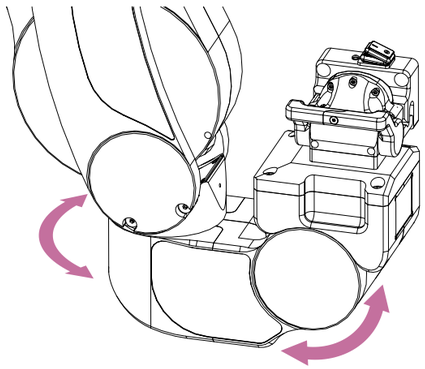
Description

The following parts of Gowing² are described below:

- From a user perspective the contact point with Gowing² 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 Gowing². 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 Gowing².
- At the top of Gowing² 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.

- Body of Gowing². The body of Gowing² contains: the actuator for the lift function, the actuator to adjust the balance force and an actuator to operate the blocking mechanism for any up/down and forward/backward movement.
- The tilt module contains the sensor and actuator for the tilt function, the blocking mechanism system for the rotation and the control electronics. Finally a red handle is attached to this module. This handle can be used to remove Gowing².



The tilt module can be used to adjust the rotation axis of Gowing² with respect to the horizontal plane. With the help of the tilt module the direction of the rigth arrow can be adjusted or set to perpendicular to the gravity plane. (The right arrow shows the movement of the tilt module).

The Power module contains the On/Off switch of Gowing². Under the module two connectors are available, one for the power supply and one for the Focal bus. These connectors do not have to be disconnected if Gowing² is removed using the red handle.

Next to the switch is a indication LED, if the Gowing² is switched on the LED should be light up.

- Green: properly connected, working fine.
- Red: Gowing² is not properly connected, see remove/ placing Gowing².
- Green with Orange blinking: there is an error, for more information see trouble shooting guide.

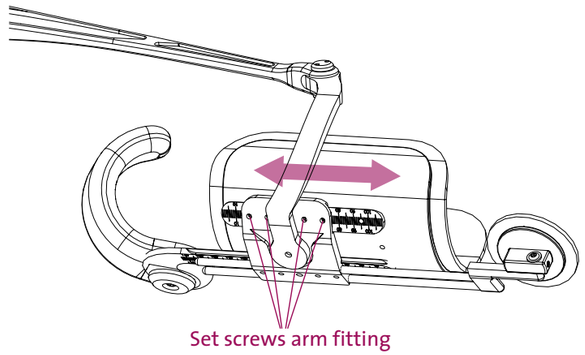
Adjusting the arm swing, arm fitting and elbow fitting

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.

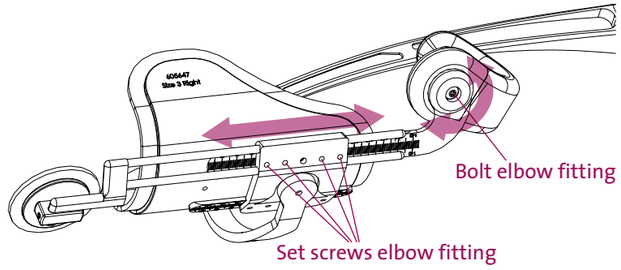
If you notice that the arm is not stable and tends to slip out, reposition the arm in the proper way.

Warning: Adjusting the arm fitting can result in a malfunction of Gowing².



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 Gowing².



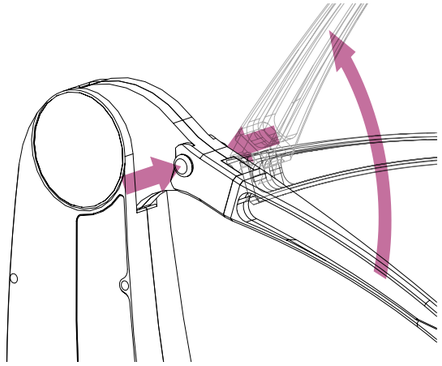
The elbow fitting can be adjusted in two directions:

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 Gowing². Changing these positions can result in a severe decrease of the performance or even malfunction of Gowing². 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.



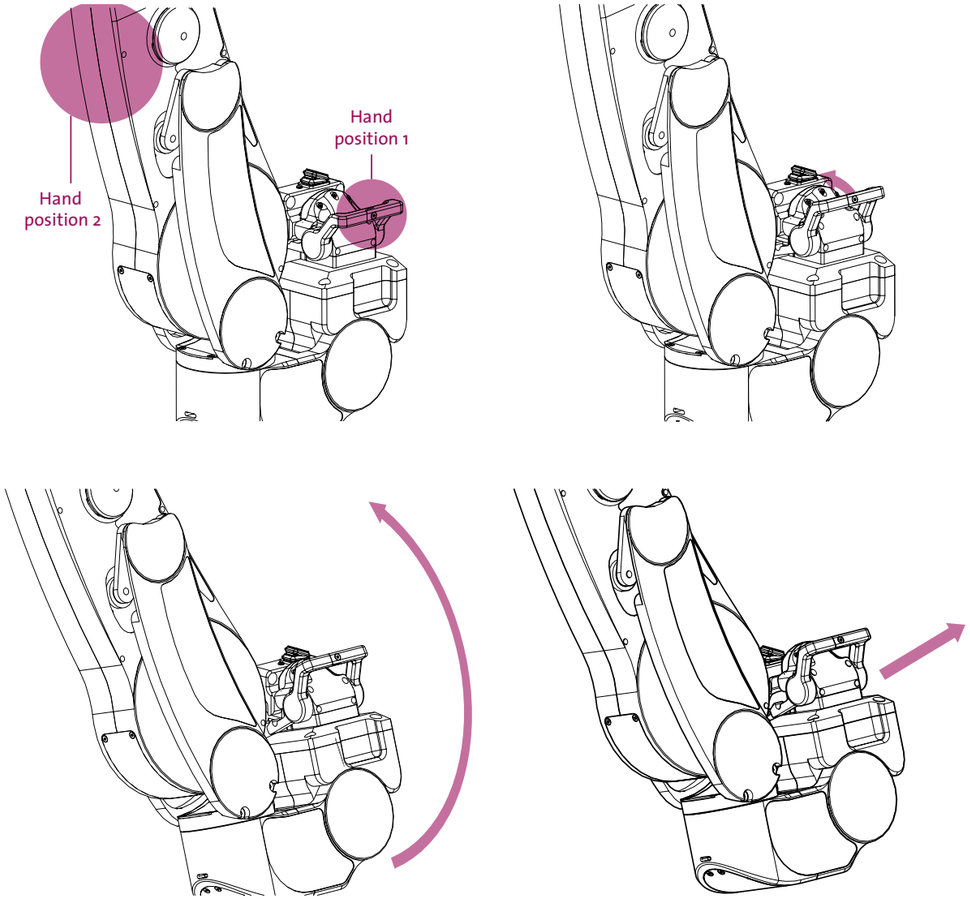
The human interface containing the loadarm, arm fitting, elbow fitting and wrist support can be removed easily. To disconnect the lever, press both red knobs at the top of Gowing², and move the lever away from the body in the upwards direction.

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.

Removing / mounting the Gowing²

Gowing² can easily be removed from the Power module.



Removing Gowing² from the power module (right handed version)

STEP 1: Set all settings to default.
STEP 2: Remove the user's arm from the arm fitting.
STEP 3: Switch off Gowing².
STEP 4: Disconnect the human interface and store it in the case.
STEP 5: Place your right hand on position 1 and your left hand on position 2.
STEP 6: Rotate the red handle upwards in the direction of the arrow.
STEP 7: Tilt the Gowing² approximately 15° in the direction of the arrow.
STEP 8: Move the Gowing² up in a slanted line until it is free from the Power module.
STEP 9: Store Gowing² always in its case to prevent the Gowing² being damaged.

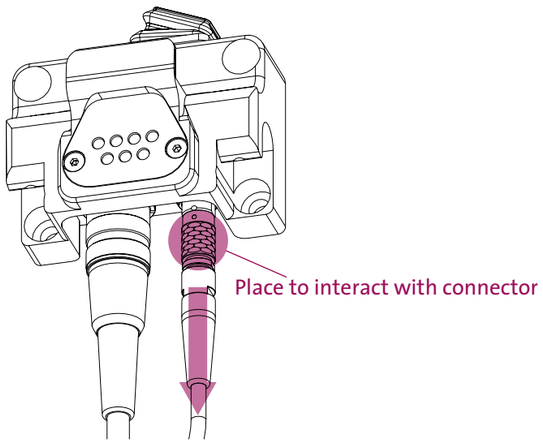
Placing Gowing² to the power module (right handed version)

STEP 1: Hold the Gowing² with your right hand on position 1 and your left hand on position 2.
STEP 2: Hold the Gowing² above and in a tilted position approximately 15° towards the Power module.
STEP 3: Move the Gowing² down in a slanted line until it catches the hook of the power module.
STEP 4: Tilt the Gowing² down until the body of Gowing² is vertical.
STEP 5: Push the red handle down.
STEP 6: Attach the human interface to Gowing².
STEP 7: Position the user's arm in the arm fitting.
STEP 8: Switch on Gowing².

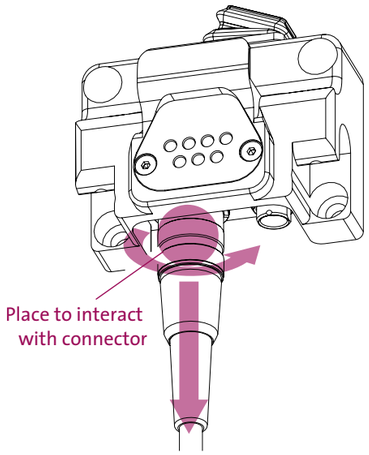
Left handed version of the Gowing²
The removing and placing procedure of the left handed version of Gowing² are similar. The only difference is that your left hand is on position 1 and your right on position 2.

Removing the cables

In case the Power module of Gowing² has to be removed, the two cables must be disconnected first.



To remove the Focal bus connector: hold the connector as close as possible inside the mounting base and pull and disconnect the connector. The connector should slide easily out of the chassis part.



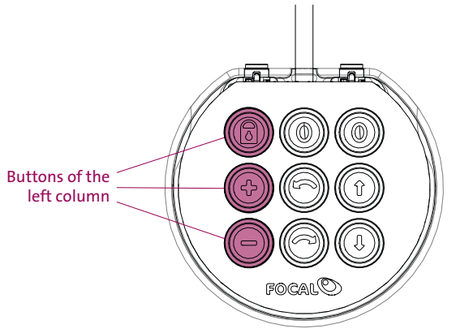
To remove the power connector: hold the connector as close as possible inside the mounting base and turn counter clockwise the outer ring until it moves completely free. Then pull the connector out of the chassis part.

Controls

Eneaswitch²

Gowing² has a 9-button interface called Eneaswitch² with LED indicators and a buzzer for user feedback. The functions are divided in three columns (see drawing below). The Eneaswitch² is easy to operate. The level of protection (Ingress Protection) is IP22. Even though the IP rating is at this level, care must be taken to not operate the silicone keypad with sharp objects. This can damage the silicone keypad and makes it vulnerable to moisture.

Adjustment of balancing force / blocking function

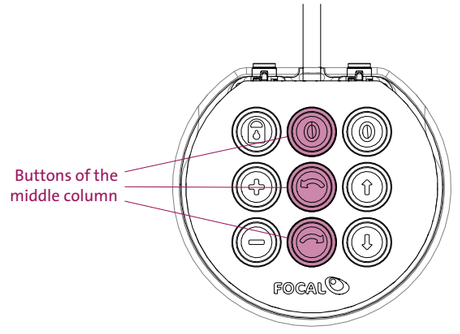


The left column contains the blocking function and the adjustment of the balancing force. Gowing² has blocking mechanisms for its up/down movement, forward/backward movement and rotation (in the horizontal plane). The human interface containing the arm fitting, elbow fitting and the optional wrist support does not have a blocking mechanism. This results in the behaviour that the arm of the user can still swing and rotate in the arm fitting.
The push button has a toggle function. This means that the blocking mechanism will be activated when it is deactivated and vice versa. Incidentally it may appear that not all axes are blocked although the blocking mechanisms are activated. Should this occur minimal arm movement will block all axes immediately.

When the blocking mechanism is deactivated, it can be the case that one or more axes remain blocked. To deactivate the blocking mechanism a little movement is required that will result in a decrease of the force on the blocking mechanism. The design of the blocking mechanism results in the behaviour that the state transition of Gowing², from blocked to unblocked, will never occur directly when a force is on this mechanism. While the blocking mechanism is activated it is not possible to adjust the balance force or the lift position.

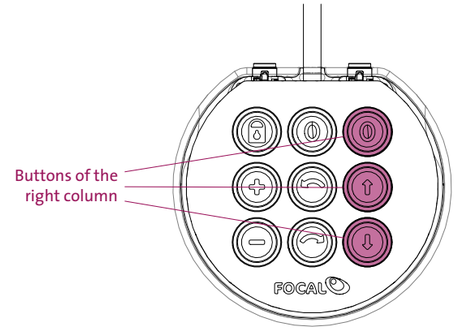
Two buttons are assigned to adjust the balance force in the vertical plane. Pushing the plus ⊕ button will result in increasing the balance force. Pushing the minus ⊖ button will result in decreasing the balance force. The speed of adjustment of the balance force depends on the time the button is pressed. The longer the button is pressed, the faster the adjustment will be. If the adjustment has reached his end the ring-LED will blink red and a beep will sound. If the plus ⊕ or minus ⊖ button is pressed when the system is locked the ring-LED will blink red and a double beep will sound

Adjustment of the tilt function



The buttons in middle column are used for the tilt function. Gowing² is able to adjust its position with respect to the gravity in the horizontal plane. The button marked with ⊙ will adjust the tilt module to the position where the rotating axis is set perpendicular to the gravity plane. After pressing this button the LEDs around this button will start blinking green and the tilt module will level to 0°. After reaching this position the controller will switch off if there is no movement for the duration of 10 seconds. For most users the 0° position will be the best setting. The buttons ↶ and ↷ can be used to adjust the tilt of Gowing². This option can be used to help the arm of the user to have a preferred movement in the forward or backward direction. ↶ Means tilt forward and ↷ means tilt backwards. If the tiltfunction has reached his end the ring-LED will blink red and a beep will sound.

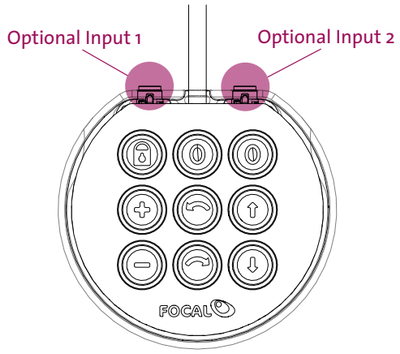
Adjustment of the lift function



The buttons in the right column are used for the lift function of Gowing². Gowing² is able to lift the lever and hereby the arm of the user. This means that no force of the user is required to bring the arm to a certain position. When pushing the button ⊙, the lever will go to the lowest position. The user is now able to move the arm freely again. The buttons ↑ and ↓ can be used to adjust the lift position. The speed of adjustment of the balance force depends on the duration the button is pushed.

The longer the button is pushed, the faster the adjustment will be. The button ⓘ Means lift the lever up and ⓙ means lower the lever.
If the lift has reached its end the ring-LED will blink red and a beep will sound. If the ⓘ or ⓙ button is pressed when the system is locked the ring-LED will blink red and a double beep will sound

Optional inputs on the Eneaswitch².



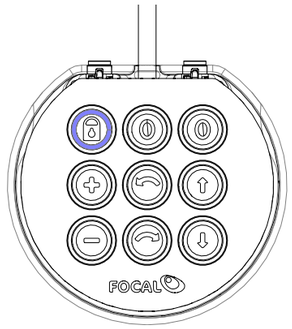
The Eneaswitch² has two optional input ports (mini-jack 3,5mm stereo). Via the stereo to mono splitter two switches can be connected to a single input port. In total there can be a maximum of four switches connected to the Eneaswitch². Be sure that the device is turned off before connecting external switches. It is also possible to plug a switch directly into the input port.
The functionality for each external switch can be set via software.
The type of external switch is free to choose but the length of the cable, or total length of the cables when extended with an extension cable, should not be longer than 3 meters.

Functions that can be set are:

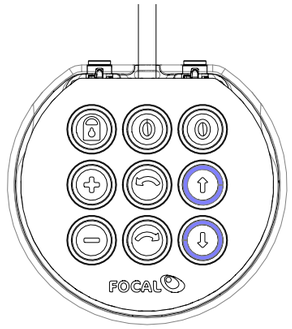
- Tilt
- Balance
- Block
- Lift
- Default
- Single switch

Single switch control Eneaswitch².

The single switch mode of Gowing² allows the user to control the Gowing² with only one switch. To control the Gowing² in single switch mode there must be one external switch be configured as “Single switch”. The configuration can only be done by authorised people.



The single switch control starts scanning after pressing the external button. The function that is indicated by the blue LED will be activated when the external switch is being pressed. For example in the figure above the “lock” function will be activated by pressing the external switch. If the user does not give an input within 1 second the scanning resumes.



If a function is indicated by two blue LEDs, the corresponding function will also be activated when the external switch is being pressed. The output of the function will toggle between the two indicated blue LEDs. For example, in the figure above the “lift” function will be activated by pressing the external switch. If the user does not give an input within 1 second the scanning resumes.

Accessories

Battery pack and charger

The battery pack can be used if there is no or not enough power to operate Gowing², for example on a working chair or 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.

Power adapter

Usually when the Gowing² 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 Gowing² with the necessary power. For more information see the user manual of the power adapter.

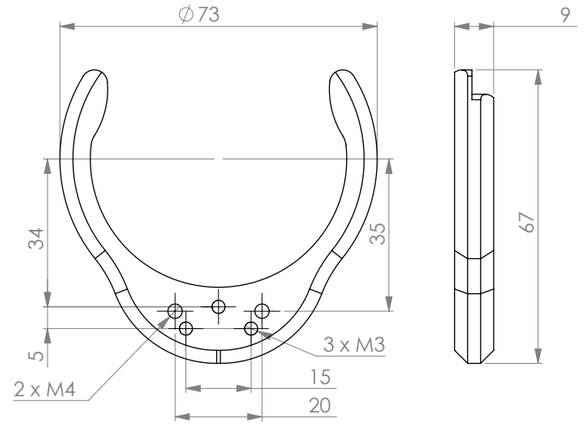
Installation instructions

Installing the Gowing²

If the Gowing² needs to be installed on other equipment (for example an electric wheel chair), the operation of other equipment will not be impacted by the installation of the Gowing². See page 10 of this manual.
Installation of the Gowing² needs to be executed by Focal or a certified professional that is approved by Focal Meditech or one of its authorized professional, to ensure a safe integration of the Gowing² and the other equipment.

Installing the Eneaswitch²

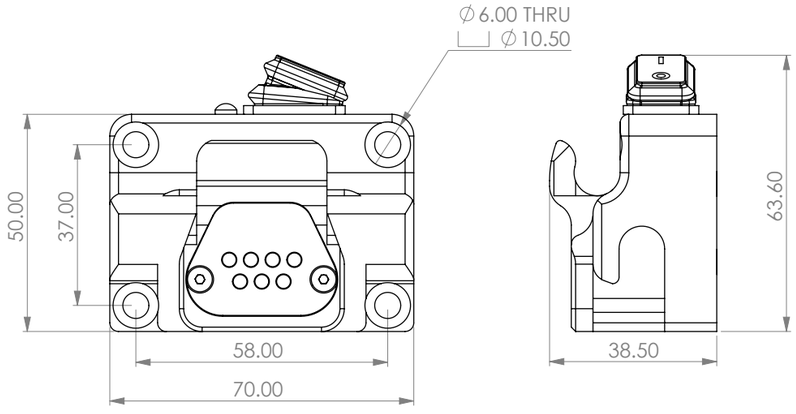
To provide a secure mounting of the Eneaswitch² it will be delivered with mounting bracket. The Eneaswitch² should be always be mounted using this clip. The clip can be mounted on or in the worktop of a wheelchair. This can be done using the treated holes (M4) in the clip. If the Eneaswitch² should be mounted in a worktop a hole (Ø 65mm) must be drilled in the worktop.



Warning: Take extra care how to position the Gowing² control switch if the user controls Gowing² with the hand of the Gowing² 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 of Gowing² 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 Gowing² 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. 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 housing or cable is visibly damaged, do not use the device. It is prohibited to physically modify Gowing². There are no serviceable parts inside Gowing². Contact Focal Meditech for any maintenance issues.

In case Gowing² 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 Gowing² is limited. Gowing² can be cleaned using a moist cloth and a non-aggressive cleaning agent.

Reuse

To reuse Gowing², it must be disassembled and reviewed by a professional from Focal or a certified professional that is approved by Focal Meditech or one of its authorized professionals. Gowing² 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 will refurbish and repackage the reused Gowing² in such a way that it will meet the safety and performance requirements according to applicable regulations.

Decommissioning

Appendix 1 Technical specifications

Gowing² specifications

Mass		
• Mass Gowing²	7.1	[kg]
Dimensions (in default position)		
• Height	706	[mm]
• Width	84	[mm]
• Depth	299	[mm]
Mounting position(angle)		
• Maximum allowed	–10...10	[°]
Range of motion		
• Up/Down	550	[mm] @ end of lever
• Forward backward stroke	400	[mm] @ end of load arm
• Horizontal rotation	–69...+69	[°]
Balance mass		
• Up/Down		
◦ Mass	0.25...5	[kg] @ end of load arm
◦ Electronic adjustable	0...100	[mm] @ end of load arm
Lift capacity		
• Up/Down		
◦ Mass	0...7	[kg] @ end of load arm
◦ Electronic adjustable	0...100	[%]
Blocking mechanism		
• Up/Down movement		
◦ Blocking force	100	[N] @ end of load arm
◦ Index (default position)	15	[mm] @ end of load arm
• Forward/Backward movement		
◦ Blocking force	100	[N] @ end of load arm
◦ Index (default position)	23	[mm] @ end of load arm
• Horizontal rotation		
◦ Blocking force	100	[N] @ end of load arm
◦ Index (default position)	15	[mm] @ end of load arm

Tilt function (Intergraded tilt module)		
• Angle	–16...120	[°]
• Accuracy	1.5	[°]
• Speed	2.7	[°/s]
Operation voltage		
• Nominal voltage	20	[V]
Operation current (incl. Power module and Eneaswitch²)		
• Standby	40	[mA]
• During adjustments typical	0.4	[A]
• During adjustments maximum	1.0	[A]
Power consumption (incl. Power module and Eneaswitch²)		
• 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 Gowing²)

Mass		
• Mass Power module	0.135	[kg]
Dimensions		
• Height	62	[mm]
• Width	70	[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	10	[mA]
Output current		
• Maximum continues @ 25°	0.9	[A]
• Maximum continues @ 50°	0.6	[A]
Power consumption		
• Standby	0.24	[W]
• Maximum continues @ 25°	21.6	[W]
• Maximum continues @ 50°	15	[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)

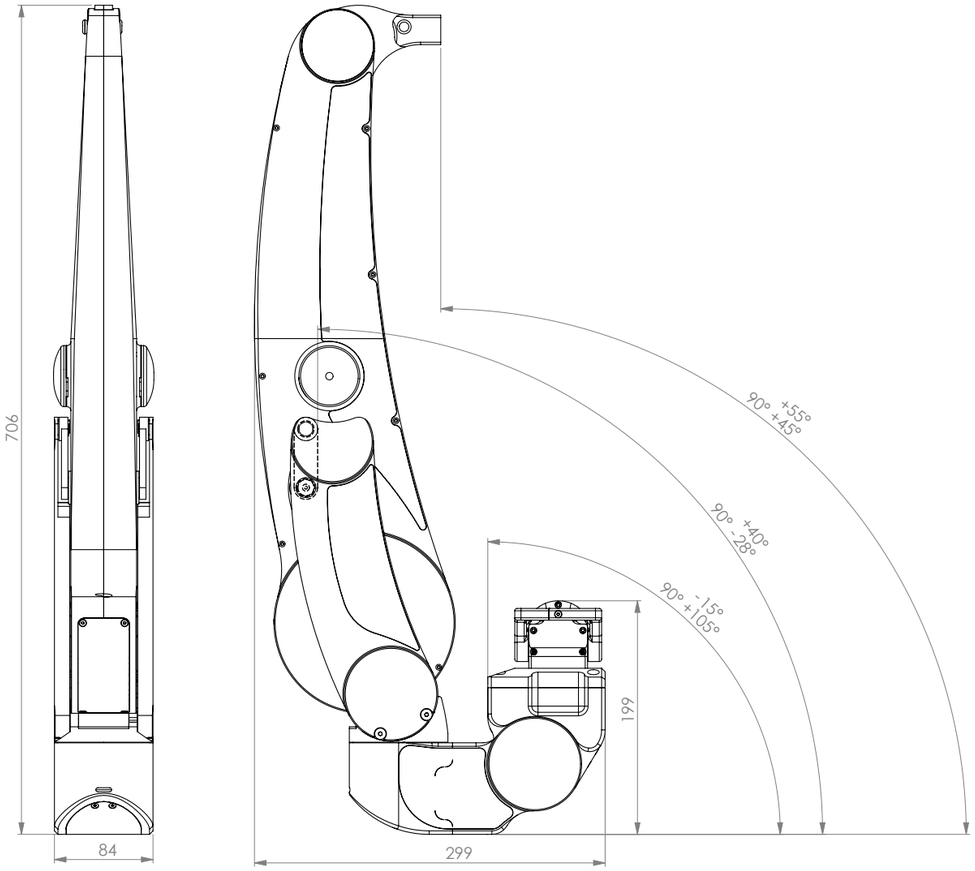
Eneaswitch² specifications (part of Gowing²)

Mass		
• Mass Eneaswitch²	0.122	[kg]
Dimensions (with mounting clip)		
• Height	15	[mm]
• Width	75	[mm]
• Depth	77	[mm]
Cable length		
• Length	2445±20	[mm]
Input voltage		
• Nominal input voltage	20	[V]
Operation current		
• Standby	10	[mA]
• Maximum continues	0.17	[A]
Power consumption		
• Standby	0.2	[W]
• Maximum	3.4	[W]
Storage conditions		
• Temperature	–40...+85	[°C]
• Humidity	35...85	[%] non condensing
Operation conditions		
• Temperature	0...+50	[°C]
• Humidity	35...85	[%] non condensing
Degree of protection		
• IP-class	IP22	(IEC60529)

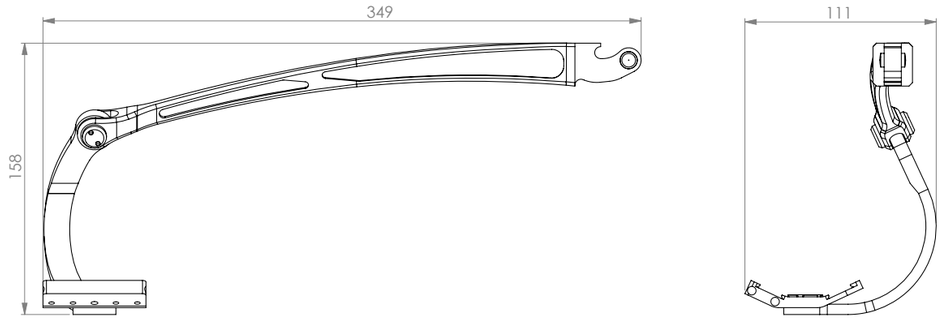
Gowing² dimensions

Dimensions of Gowing² 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.

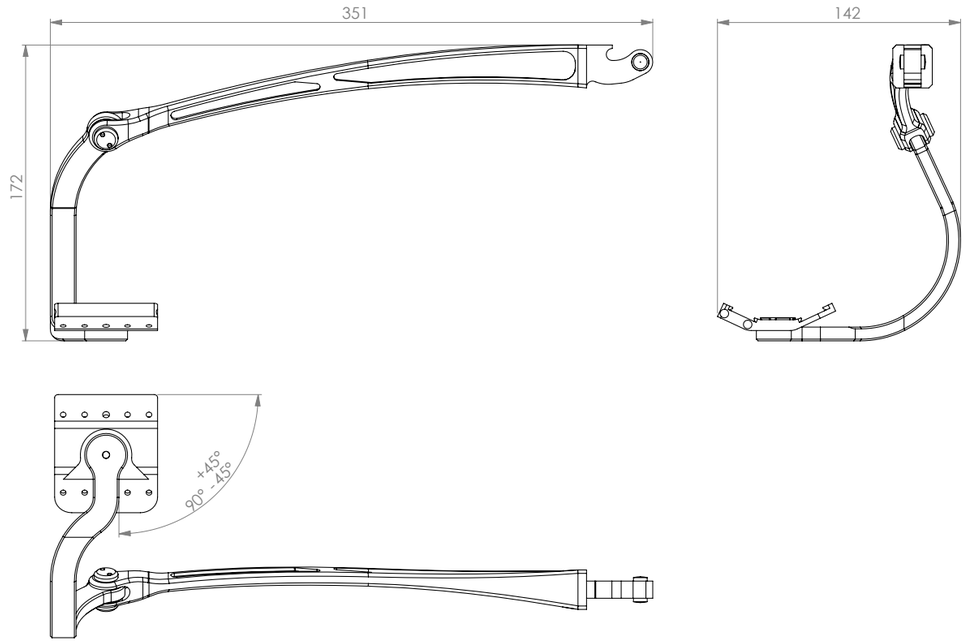
Dimensions (human interface excluded)



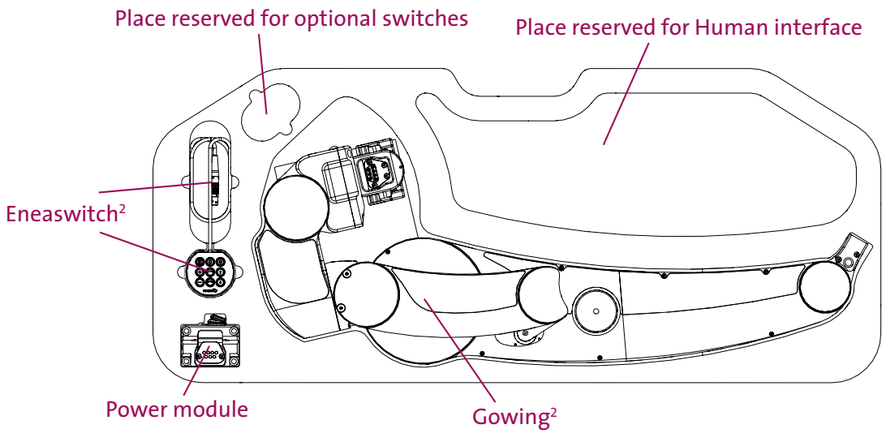
Dimensions armrest Large (right handed version)



Dimensions armrest X-Large (right handed version)



Content of case Gowing²



The case of Gowing² contains the following parts:

- Gowing²
- Power module
- Eneaswitch²
- 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
- Switches
- Extension cable for switches
- Splitters

Appendix 2 Part numbers

Focal number	Description
605540	Subassembly Gowing²
604782	Power module
605694	Case with inlay Gowing²
605547	Eneaswitch²
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

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

604190	Fixation strap complete Large
604191	Fixation strap complete Small
605926	Elbow bracket L shape short left
605927	Elbow bracket L shape short right
605683	Mobile stand

Appendix 3 Used materials

Focal number	Description	Material(s)
605540	Subassembly Gowing[2]	Aluminium 6082T6 + stainless steel (AISI 304)
604782	Power module	Aluminium 6082T6
605694	Case with inlay Gowing[2]	
605547	Eneaswitch[2]	
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	

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)	

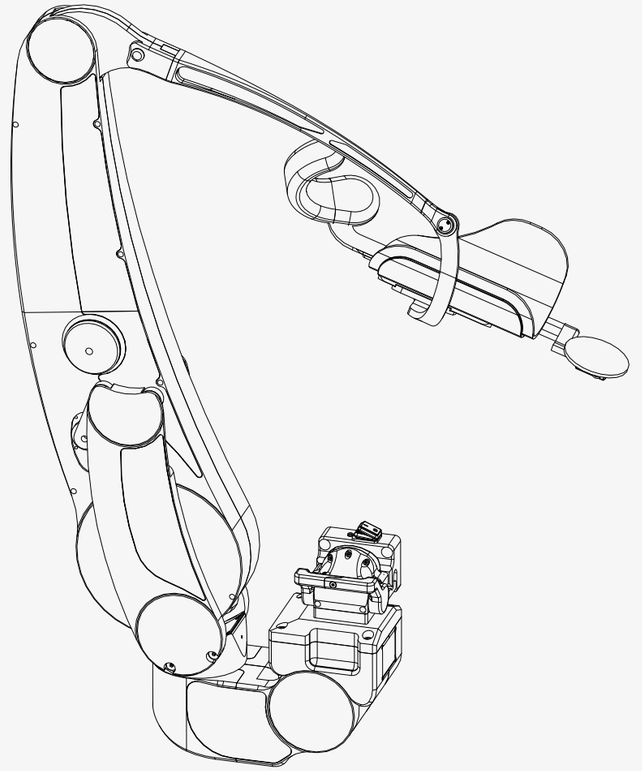
605639	Assembly Armfitting size 1 right	Aluminium 6082T6 + Vikureen (PS)
605659	Assembly Armfitting size 1 left	
605643	Assembly Armfitting size 2 right	
605663	Assembly Armfitting size 2 left	
605647	Assembly Armfitting size 3 right	
605667	Assembly Armfitting size 3 left	
605651	Assembly Armfitting 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	POM + stainless steel (AISI 304)

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	

Appendix 4 Quick Start Guide



Gowing²

Quick Start Guide / Snelstartgids

ID manual: 606103
Revision / Revisie: 1.0.0
Date / Datum: 01-02-2020

FOCAL meditech

Introduction / Voorwoord

This is the Quick start guide for Gowing², a dynamic arm support system. This product is developed, manufactured and possibly distributed by Focal Meditech B.V. This quick start guide contains the basic information regarding Gowing². The aim of this information is to ensure successful, safe and effective use of the device. This quick start guide will give you a quick look on the features and important safety warnings of Gowing² Please take note of the safety warnings before using Gowing².

Dit is de snelstartkaart voor Gowing², een dynamische armondersteuning. Dit product wordt ontwikkeld, geproduceerd en eventueel gedistribueerd door Focal Meditech B.V. Deze snelstartkaart bevat de basisinformatie over Gowing². Het doel van deze informatie is te zorgen voor een succesvol, veilig en effectief gebruik van het apparaat. Deze snelstartkaart geeft u een snelle blik op de functies en belangrijke veiligheidswaarschuwingen van Gowing². Houd rekening met de veiligheidswaarschuwingen voordat u Gowing² gebruikt.

Overview / Overzicht

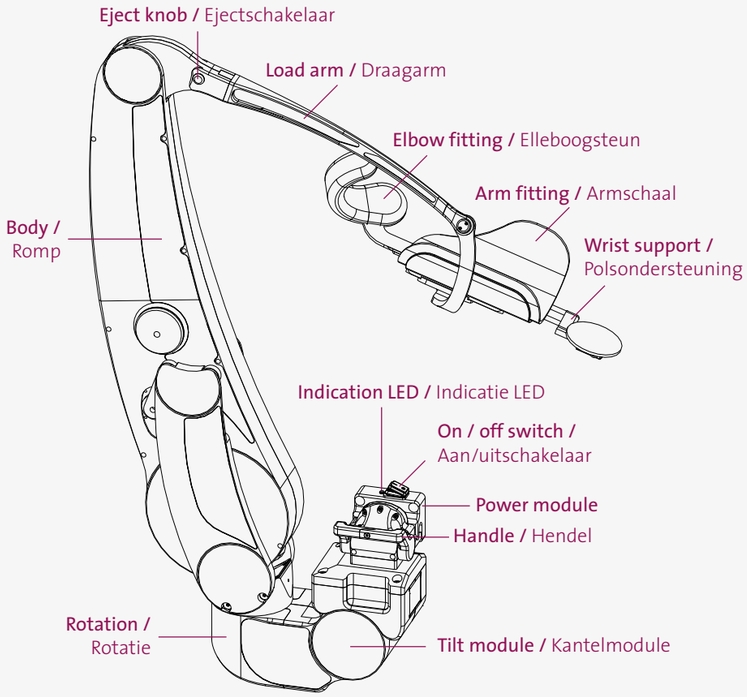


Figure 1: Overview Gowing² with terms of specific parts
Figuur 1: Overzicht Gowing² met benaming specifieke onderdelen

Safety notices / Veiligheidsnotities

Danger: Prevent direct contact with water or any other liquid. Failure of this can lead to malfunctioning of device or bodily harm.
Gevaar: Voorkom direct contact met water of enige andere vloeistof. Het niet voorkomen hiervan kan leiden tot onjuist functioneren van het apparaat of tot lichamelijke schade.

Danger: Prevent extreme temperature (see environment conditions). Failure of this can lead to malfunctioning of the device or bodily harm.
Gevaar: Voorkom blootstelling aan extreme temperaturen. Het niet voorkomen hiervan kan leiden tot onjuist functioneren van het apparaat of tot lichamelijke schade.

Danger: During installation ensure there is a fuse of 7.5A between power supply and Gowing². Failure of this can lead to malfunctioning of the device and bodily harm.
Gevaar: Let er tijdens de installatie op dat er zich tenminste een zekering van 7,5A bevindt tussen de energiebron en Gowing². Indien dit niet gedaan wordt kan dit leiden tot onjuist functioneren van het apparaat of tot lichamelijke schade.

Danger: Mechanical energy is stored for balancing the arm. During non-intended removal of the arm from the arm fitting of Gowing², this mechanical energy will be released resulting in a fast moving lever and arm fitting which can result in bodily harm.
Gevaar: Mechanische energie wordt opgeslagen om de arm te balanceren. Tijdens niet-bedoelde verwijdering van de arm uit de armschaal van Gowing² zal deze mechanische energie vrijkomen wat resulteert in een snel bewegende hendel en armschaal wat lichamelijk letsel tot gevolg zou kunnen hebben.

Warning: Do not modify any part of this equipment without authorization of the manufacturer. Failure of this can lead to malfunctioning and will void the warranty.
Waarschuwing: Wijzig geen enkel onderdeel van dit apparaat zonder toestemming van de fabrikant. Indien dit toch gedaan wordt, kan dit leiden tot onjuist functioneren van het apparaat en het verlies van garantie.

Warning: In case of a faulty device contact Focal. Do not try to fix it yourself. Failure of this will void the warranty.
Waarschuwing: Neem indien het apparaat onjuist functioneert direct contact op met Focal. Probeer het niet zelf te repareren. Het niet opvolgen van deze waarschuwing kan leiden tot het verlies van garantie.

Warning: In case of doubt about the safety of the device contact Focal Meditech.
Waarschuwing: Neem in geval van twijfel over de veiligheid van het apparaat contact op met Focal Meditech.

Warning: In case of a serious incident when using the device, contact Focal Meditech and the national authority of your country.
Waarschuwing: Bij een ernstig voorval met betrekking tot dit apparaat dient contact te worden opgenomen met Focal Meditech en de bevoegde autoriteit van de lidstaat.

Switch on Gowing² / Aanzetten Gowing²

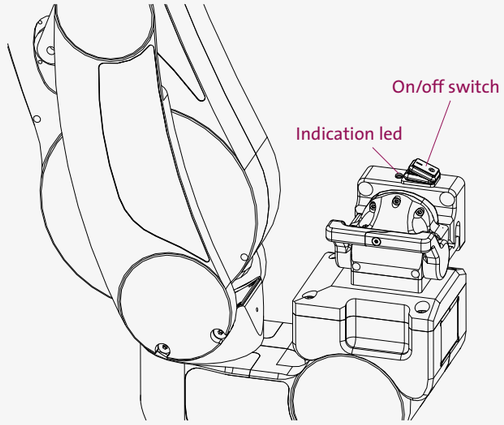


Figure 2: Picture of on/off switch with indication LED
Figuur 2: Afbeelding van de aan/uit schakelaar met indicatie LED

Before switching on Gowing², the Gowing² has to be attached to the Power Module (See “Attach / Detach Gowing²”). Gowing² can be switched on by turning the on/off switch to (I). The indication LED will light up green. If the LED lights up red Gowing² might not be properly attached to the Power Module.

Voordat de Gowing² ingeschakeld mag worden, moet Gowing² zijn bevestigd aan de Power Module (zie “koppelen / ontkoppelen Gowing²”). Gowing² kan worden ingeschakeld door de aan/uit naar (I) te schakelen. De indicatie-LED zal groen oplichten. Als de LED rood oplicht, is Gowing² mogelijk niet goed bevestigd aan de Power Module.

Attach / Detach Gowing² / Koppelen / ontkoppelen Gowing²

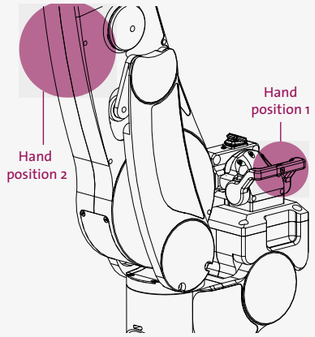


Figure 3: Indications of hand positions to detach Gowing²
Figuur 3: Aanduiding van handposities om Gowing² te ontkoppelen

Figure 4: Rotate the red handle upwards
Figuur 4: Trek de rode hendel omhoog

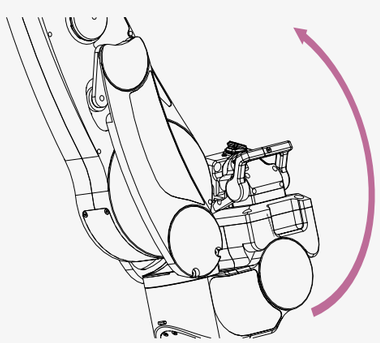


Figure 5: Tilt Gowing² 15°
Figuur 5: Kantel Gowing² 15°

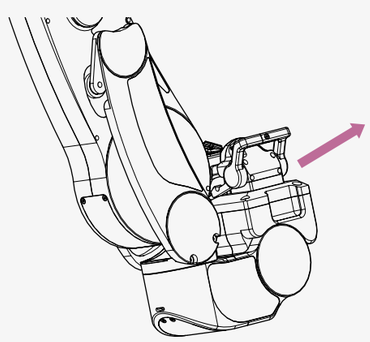


Figure 6: Take Gowing² apart from the Power Module
Figuur 6: Neem Gowing² los van de Power Module

Detach Gowing² from Power Module (right handed version):

STEP 1: Set all settings to default
STEP 2: Remove the user's arm
STEP 3: Switch off Gowing²
STEP 4: Disconnect the human interface and store it in the case
STEP 5: Place your right hand on position 1 and your left hand on position 2 (see Figure 3)
STEP 6: Rotate the red handle upwards in the direction of the arrow (see Figure 4)
STEP 7: Tilt the Gowing² approximately 15° in the direction of the arrow (see Figure 5)
STEP 8: Move the Gowing² up in a slanted line until it is free from the Power Module (see Figure 6)
STEP 9: Store Gowing² always in its case to prevent the Gowing² from breaking or being damaged.

Het ontkoppelen van Gowing² van de Power Module (rechtshandige versie):

STAP 1: Zet terug naar de standaardinstelling
STAP 2: Neem de arm van de gebruiker weg
STAP 3: Schakel Gowing² uit
STAP 4: Koppel de human interface los en bewaar deze in de opbergdoos
STAP 5: Plaats uw rechterhand op positie 1 en uw linkerhand op positie 2 (zie Figuur 3)
STAP 6: Trek de rode hendel omhoog in de richting van de pijl (zie Figuur 4)
STAP 7: Kantel de Gowing² ongeveer 15° in de richting van de pijl (zie Figuur 5)
STAP 8: Verplaats de Gowing² omhoog in een schuine lijn totdat deze vrij is van de Power Module (zie Figuur 6)
STAP 9: Bewaar Gowing² altijd in de opbergdoos om te voorkomen dat de Gowing² wordt beschadigd

Attach Gowing² to the Power Module (right handed version):

STEP 1: Grab Gowing² with your right and on position 1 and your left hand on position 2
STEP 2: Hold Gowing² above the Power Module in a tilted position of approximately 15°
STEP 3: Lower Gowing² in a slanted line until it catches the hook of the power module
STEP 4: Tilt Gowing² straight until the body of Gowing² is vertical
STEP 5: Push down the red handle
STEP 6: Attach the human interface to Gowing²
STEP 7: Position the user's arm in the arm fitting
STEP 8: Switch on Gowing²

Het plaatsen van de Gowing² van de Power Module (rechtshandige versie):

STAP 1: Pak Gowing² met uw rechterhand op positie 1 en uw linkerhand op positie 2
STAP 2: Houd Gowing² in een gekantelde positie van ongeveer 15° boven de Power Module
STAP 3: Laat Gowing² zakken totdat deze in de haak van de Power Module grijpt
STAP 4: Kantel Gowing² naar beneden totdat Gowing² rechtop staat
STAP 5: Druk de rode hendel naar beneden
STAP 6: Bevestig de human interface op Gowing²
STAP 7: Plaats de arm van de gebruiker in de armschaal
STAP 8: Schakel Gowing² in

The attach/detach procedure of the left handed version of Gowing² is similar. The only difference is that your left hand is on position 1 and your right hand on position 2.

De procedure voor het afnemen en plaatsen van de linkshandige versie van Gowing² is gelijk. Het enige verschil is dat de linkerhand geplaatst moet worden op positie 1 en de rechterhand op positie 2.

Attach / Detach the human interface / Koppelen / ontkoppelen van de human interface

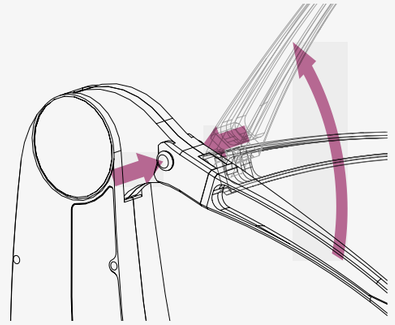


Figure 7: Attach / detach human interface
Figuur 7: Koppelen / ontkoppelen human interface

The human interface containing the load arm, arm fitting, elbow fitting and wrist support can be removed easily. To detach the human interface, press both red eject knobs at the top of Gowing², and move the human **interface away from the body in the upwards direction.**

De human interface inclusief draagarm, de armschaal, elleboogsteun en polssteun kunnen gemakkelijk worden afgenomen. Om de human interface te ontgrendelen moeten de beide rode ontkoppelknoppen bovenaan de Gowing² worden ingedrukt. Beweeg de human interface in bovenwaartse richting van de behuizing van Gowing² weg (zie Figuur 7).

Attaching 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.

De human interface kan worden teruggeplaatst door deze in het behuizingsdeel te drukken. De knoppen hoeven niet ingedrukt te worden. Eenmaal op zijn plek kan de human interface niet worden verwijderd zonder de rode knoppen in te drukken.

Eneaswitch² keypad control / Eneaswitch² toetsen bediening

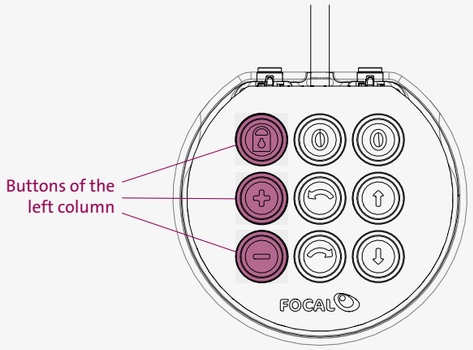


Figure 8: Blocking function / adjustment of balancing force
Figuur 8: Blokkeer functie / verstelling van balanceerkracht

The left column contains the blocking function and the adjustment of the balancing force. Gowing² has blocking mechanisms for its up/down movement, forward/backward movement and rotation (in the horizontal plane). Two buttons are assigned to adjust the balance force in the vertical plane. Pushing the plus ⊕ button will increase the balance force. Pushing the minus ⊖ button will decrease the balance force.

De linker kolom bevat de blokkeerfunctie en de aanpassing van de balanceerkracht. Gowing² heeft blokkeermechanismes voor hoog/laag en voor/achterwaarts bewegingen en de rotaties (in het horizontale vlak). Twee knoppen in de linker kolom dienen voor het aanpassen van de balanskracht in het verticale vlak. Het indrukken van de plus ⊕ knop resulteert in een toename van de balanskracht. Het indrukken van de minus ⊖ knop resulteert in afname van de balanskracht. De snelheid waarmee de balanskracht aangepast wordt is afhankelijk van de duur van het indrukken van de knop. De aanpassing zal sneller plaatsvinden als de knop langer wordt ingedrukt.

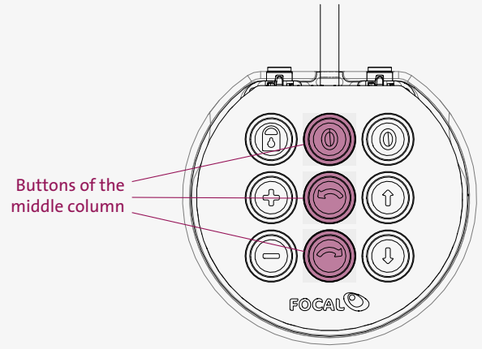


Figure 9: Adjust tilt angle of Gowing²
Figuur 9: Verstelling kantelhoek van Gowing²

The buttons in middle column are used for the tilt function. The button marked with ⓪ will adjust the tilt module to the position where the rotating axis is set perpendicular to the gravity plane. After pressing this button the LEDs around this button will start blinking green and the tilt module will level to 0°. For most users the 0° position will be the best setting. The buttons ↶ for forward and ↷ for backwards can be used to adjust the tilt of Gowing².

De knoppen in de middelste kolom worden gebruikt voor de kantelfunctie. De knop ⓪ past de kantelmodule aan naar de positie waar de roterende as loodrecht op het zwaartekrachtsvlak staat. Bij het indrukken van de 0-knop beginnen de LED's rond deze knop groen te knipperen en de kantelmodule wordt op 0° ingesteld. Voor de meeste gebruikers is de 0°-positie de beste instelling. De knoppen ↶ en ↷ kunnen worden gebruikt om de kanteling van de Gowing² aan te passen.

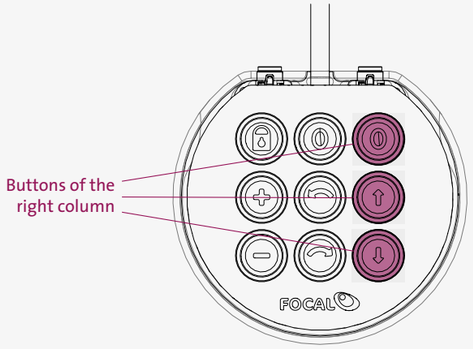


Figure 10: Adjust tilt angle of Gowing²
Figuur 10: Verstelling liftfunctie van Gowing²

The buttons in the right column are used for the lift function of Gowing². When pushing the button ⓪, the human interface will go to the lowest position. The user is now able to move the arm freely again. The buttons ⬆ and ⬇ can be used to adjust the lift position.

De knoppen in de rechterkolom worden gebruikt voor de liftfunctie van Gowing². Wanneer de knop ⓪ wordt ingedrukt, gaat de human interface naar de laagste positie. De gebruiker kan nu de arm weer vrij bewegen. De knoppen ⬆ en ⬇ kunnen worden gebruikt om de liftpositie aan te passen.

Eneaswitch² Single switch control / Eneaswitch² een-knops bediening

The single switch mode of Gowing² allows the user to control the Gowing² with only one switch. To control Gowing² in single switch mode there must one external switch be configured as “Single switch”. This can be only be done by authorised people.

De single switch-modus van Gowing² stelt de gebruiker in staat om de Gowing² met slechts één schakelaar te bedienen. Om de Gowing² in een-knops bediening te gebruiken, moet er één externe schakelaar worden geconfigureerd als “Single switch”. Dit kan alleen worden gedaan door geautoriseerde personen.

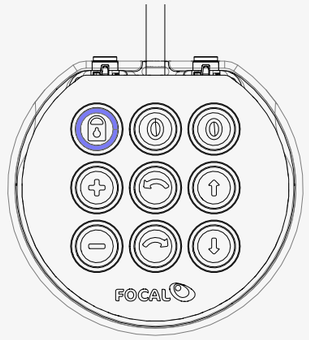


Figure 11: Lock function selected
Figuur 11: Blokkeer functie geselecteerd

The single switch control starts scanning after pressing the external switch. The function that is indicated by the blue LED will be activated when the external switch is being pressed. For example, In Figure 11 the “lock” function will be activated when the external switch is being pressed. If the user does not give an input within 1 second the scanning resumes.

De bediening met één schakelaar begint te scannen na het indrukken van de externe knop. De functie die door de blauwe LED wordt aangegeven, wordt geactiveerd wanneer de externe schakelaar wordt ingedrukt. Bijvoorbeeld in Figuur 11 zal de blokkeer functie worden geactiveerd wanneer op de externe schakelaar wordt gedrukt. Als de gebruiker gedurende 1 seconde geen input geeft, wordt het scannen hervat.

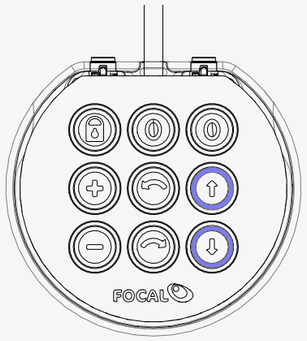


Figure 12: Lift function selected
Figuur 12: Lift functie geselecteerd

If a function is indicated by two blue LEDs, the corresponding function will also be activated when the external switch is being pressed. Subsequently the activated function will toggle between the two indicated blue LEDS. See Figure 12 where the lift function will be activated when the external switch is being pressed. If the user does not give an input for 1 second the scanning resumes.

Als een functie wordt aangegeven door twee blauwe LEDs, wordt de bijbehorende functie ook geactiveerd wanneer de externe schakelaar wordt ingedrukt. Vervolgens wisselt de geactiveerde functie tussen de twee aangegeven blauwe LEDs'. Zie Figuur 12 waar de lift functie zal worden geactiveerd wanneer de externe schakelaar wordt ingedrukt. Als de gebruiker gedurende 1 seconde geen input geeft, wordt het scannen hervat.

Contact information / Contact informatie

Gowing² is manufactured and sold by:
Gowing² wordt gefabriceerd en verkocht door:

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg
Netherlands

Tel.: +31 13 533 31 03
Fax: +31 13 533 50 04
E-mail: info@focalmeditech.nl
Internet: www.focalmeditech.nl

The complete user manual is available on our website and can be downloaded (https://www.focalmeditech.nl/nl/documentatie). In case you want to receive a printed user manual in your own language, please contact us at +31 (0)13 533 31 03 and we will send you without any costs a hard copy.

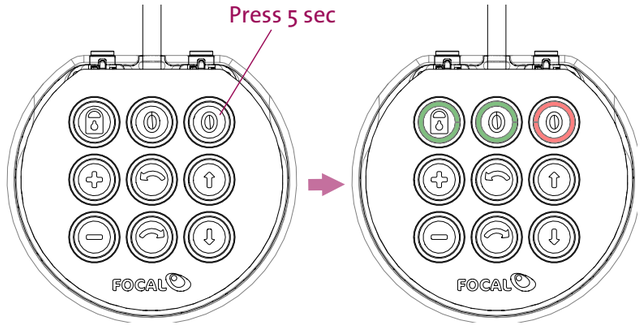
De complete gebruikershandleiding is beschikbaar op onze website en gedownload worden op (https://www.focalmeditech.nl/nl/documentatie). In het geval dat u een geprinte gebruikershandleiding wil, neem contact op via +31 (0)13 533 31 03 en we zenden u een geprint exemplaar toe.

Appendix 5 Troubleshooting guide

Gowing² 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 Gowing².

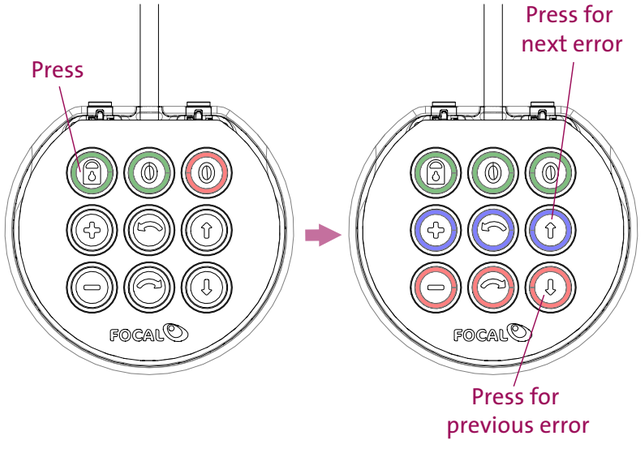
Entering the troubleshoot mode

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



By pressing the “lock” icon you will enter the list of errors that have occurred, by pressing the ⓣ and ⓓ arrows you can step through the errors. ⓣ Means previous error message and ⓓ means next error message. If an error occurs, please contact Focal Meditech for assistance and provide the error message.

To exit the error messages menu press the “lock” icon. To exit the configurations menu press the button ⓪ of the right column. When there is no user input for 20 seconds the Eneaswitch² will turn back to operational mode.



In the figure above (right side) you see an illustration of a possible error.

Appendix 6 Declaration of conformity

FOCAL meditech

EC DECLARATION OF CONFORMITY

We,

Focal Meditech
Droogdokkeneiland 19
5026 SP Tilburg
The Netherlands

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

Gowing² (type number 605540)
and its accessories

having the intended purpose: Gowing² is a dynamic arm support. It is designed for persons having a need for considerable compensation against gravity during movements of the human arm.
and have been 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 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
• EN 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
• EN 14971	Medical devices – Application of risk management to medical devices
• EN 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
• EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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: 1 February 2020
Name: Paul Groenland
Function: Managing Director

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg

Appendix 7 Conditions and Warranty

Conditions and Warranty: Gowing² 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 BV 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.