

Dowing²

User manual

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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 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 fitting and elbow fitting	14
Adjust the balancing force	15
Disconnecting the human interface	16
Park position Dowing ²	17
Attach or detach Dowing ²	18
Controls	19
Accessories	20
Mounting instructions	21
Installing the table clamp	21
Installing the chair / stand mount	22
Adjusting the angle of the rotation head	22
Maintenance instructions	24
Maintenance hardware	24
Cleaning	24
Reuse	24
Decommissioning	24
Appendix 1 Technical specifications	25
Specifications Dowing ²	25
Dowing ² dimensions (human interface excluded)	26
Dimensions Table clamp and Chair / Stand mount	26
Dimensions loadarm Large (right handed version)	27
Dimensions loadarm X-Large (right handed version)	27
Dowing ² content of case	28

Appendix 2 Part numbers	29
Appendix 3 Used materials	31
Appendix 4 Quick Start Guide	33
Appendix 5 Declaration of conformity	47
Appendix 6 Conditions and Warranty	48
Conditions and Warranty: Dowing ² supplied through a representative of Focal Meditech	48
Conditions and Warranty: direct supply by Focal Meditech BV to consumers	48

Manual introduction






This is the user manual for Dowing², 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 Dowing², 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 Dowing², 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	<p>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.</p>
 Warning	<p>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.</p>
 Caution	<p>This symbol in combination with the word “Caution” is used to warn about possible unsafe practices. Extra attention is required.</p>
 	<p>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.</p>

Packaging

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

Certification Notices

	<p>This is a CE Class I medical device</p>
	<p>Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the bottom side of Dowing².</p>

Classification cf. Dutch Cliq 2013:

241827030309	Dynamic Arm Supports, compensation of diminished muscle function and change of range of motion, loadarm 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

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: Mechanical energy is stored for balancing the arm. During non-intended removal of the arm from the arm fitting of Dowing², this mechanical energy will be released resulting in a fast moving human interface 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

Dowing² is manufactured and sold by



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Intended use and operation of the device

Intended use

Dowing² is a dynamic arm support. It is designed for persons having a need for considerable compensation against gravity during movements of the human arm.

Intended users

The intended users of the dynamic arm support Dowing² 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 Dowing² is a system that consists of several axes which are interconnected via pivoting points. The axes are connected to a manually adjustable gravity compensation mechanism. At the distal end of the system an arm fitting, elbow fitting and optional a wrist support are attached. Dowing² is mounted on the 'solid' world (table or working chair). The lower arm of the user is placed in the arm fitting, and Dowing² can support the weight of the lower and partly the upper arm. The axes of Dowing² will support movements of the human lower arm and hand.

Dowing² 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 results in a smoothly running system. Therefore little energy is required to introduce the intended movements. The smooth running Dowing² combined with the accurate fit of the arm fitting results in little muscle forces required from the user. The kinematic chain of the axes results in a large range of motion. Gravity compensation characteristics of the device can depend on individual requirements easily be adjusted.

Dowing² can be used one- or two sided. Several properties of the user, being the personal limitations and possibilities combined with the needs of the user, determine if one or two Dowing²'s are required.

The user of Dowing² can use this device in various environments like home, workplace, school or institutional setting. A restricted tolerance of environmental humidity exists.

Dowing² can be mounted on a table or working chair. Due to safety and functional reasons, Dowing² should not be mounted on a (electric) wheelchair.

Dowing² is not designed to be used in combinations of large forces. Dowing² cannot be used as a support when standing up or getting seated or as an autonomous lifting device (without supporting the human arm).

Dowing² is not designed to withstand impacts that can be introduced during collisions with a wall or other objects. Also Dowing² is not constructed to withstand high external vertical forces that can be introduced for example by (abnormal use of) patient hoist systems.

Usage of the device

Dowing² 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, if well-adjusted 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. Dowing² 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 and easier task performance at the workplace. Dowing² returns the natural freedom of movement to the user.



Warning: If the user experiences problems using the Dowing², please contact Focal Meditech or a healthcare professional as soon as possible.

Risks and contra-indications

No essential user risks are known while using Dowing². Dowing² is an aid which should be used by the intended users. However there are no known contra-indications for Dowing². To be able to use Dowing² 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 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: Dowing² 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 Dowing² 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 the user may choose to select settings that initially protect joints that are at risk for overburden.

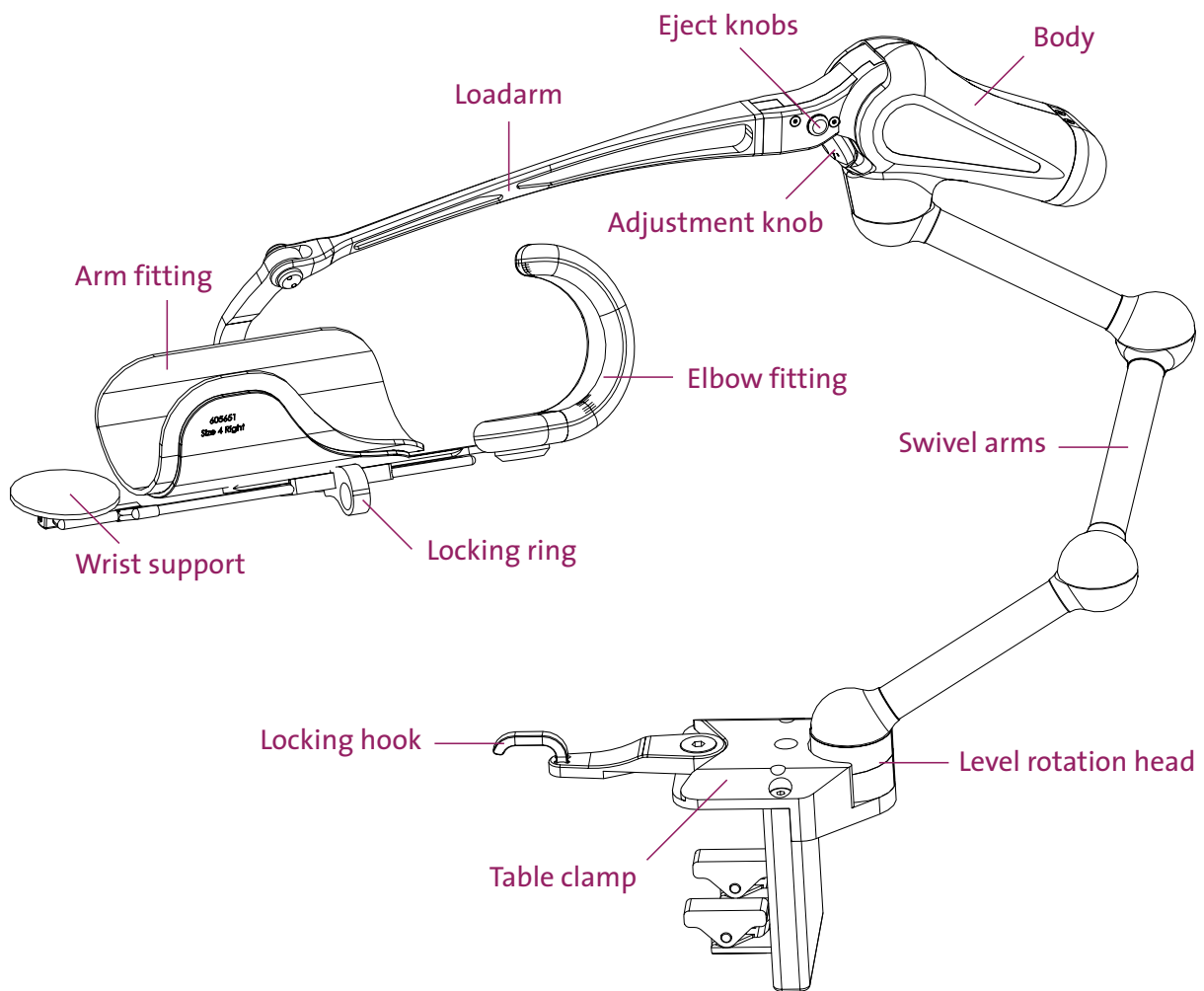


Warning: Dowing² does not have parts that can be modified or repaired by the user or other persons. Do not modify any part of this equipment without authorization of the manufacturer. Failure of this can lead to malfunctioning and void of warranty.



Warning: For safety reasons, Dowing² can only be removed from the locking position when the user's arm is correctly positioned in the arm fitting.

Technical information



Description

The following parts of Dowing² are described:

- From a user perspective the contact point with Dowing² is the arm fitting where the lower arm 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 Dowing². 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 loadarm is with moving base plate to which the arm fitting, elbow fitting and wrist support are attached.
- The loadarm is connecting the arm fitting, elbow fitting and wrist support to the body of Dowing².

- At the top of Dowing² there are two eject knobs. Pressing these two towards each other makes it possible to remove the human interface, containing the loadarm, arm fitting, elbow fitting and wrist support.
- Body of Dowing². The body of Dowing² contains: the balancing system including the possibility to adjust the balancing force.
- Balancing force adjustment knob.
- Swivel arms
- Level rotation head
- Locking hook
- Table clamp

Adjusting the 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 it is important that:

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

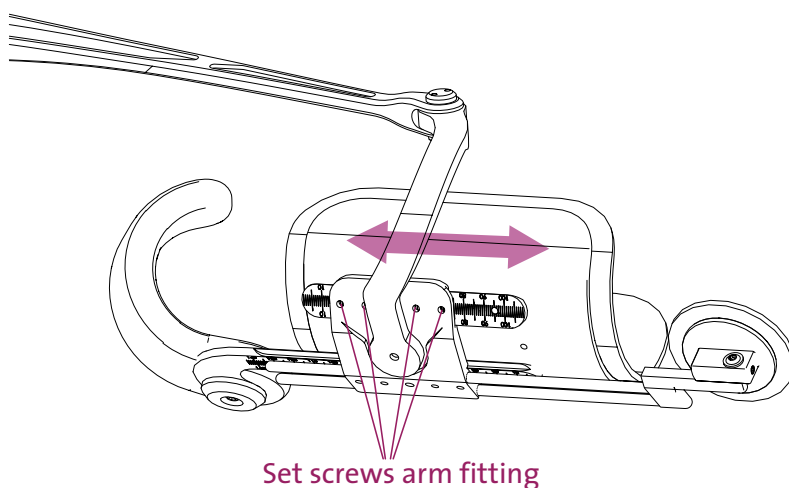
If you notice that the arm is not stable and tends to slip out, reposition the arm in the proper way.



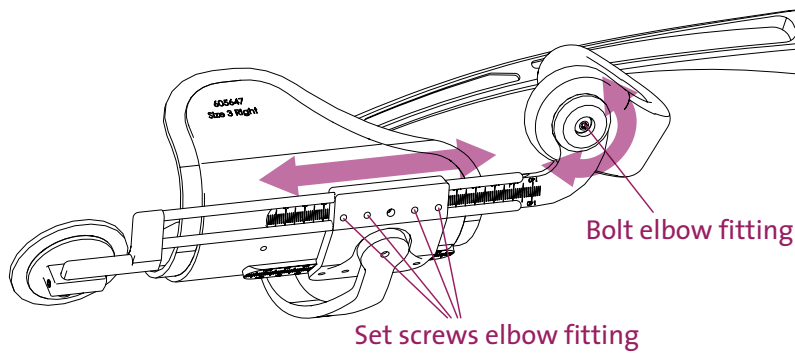
Warning: The positions of arm fitting and elbow fitting are crucial for the performance of Dowing². Changing these positions can result in a severe decrease of the performance or even malfunction of Dowing². Therefore only trained persons are allowed to change the settings of the arm fitting and elbow fitting.



Warning: Adjusting the arm fitting can result in malfunction of Dowing².



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 red arrow. Fasten all set screws of the arm fitting.



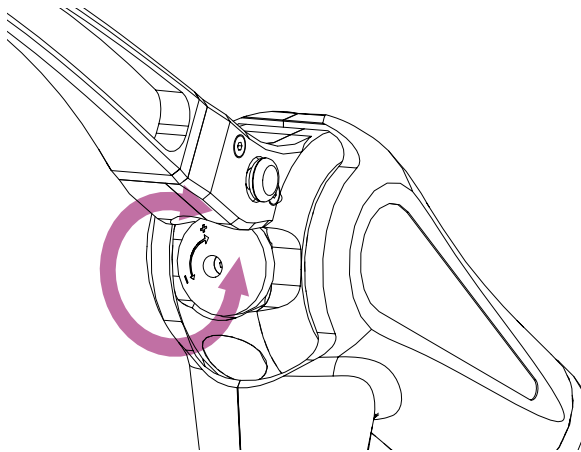
The elbow fitting can be adjusted in two directions:

- 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 of the elbow fitting. Adjust the elbow fitting by shifting this fitting in the direction of the arrow. Fasten all set screws of the elbow fitting.

Adjust the balancing force



Warning: Adjusting the balancing force can result in forces that are higher than the mass of the arm, resulting in an upwards movement of the arm.

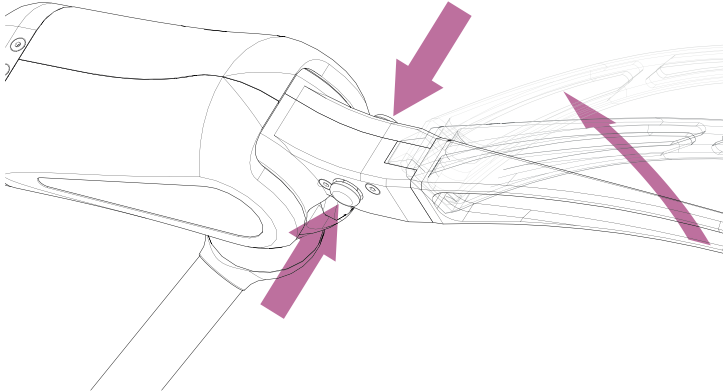


The upwards balancing force can be adjusted by turning the adjustment knob. The force required to rotate the adjustment knob can change depending on the position of the human interface. This is normal behaviour. Because of this, the system can be adjusted using little force. Rotating the knob clockwise will give more balancing force, counter clock wise will give less force.

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.

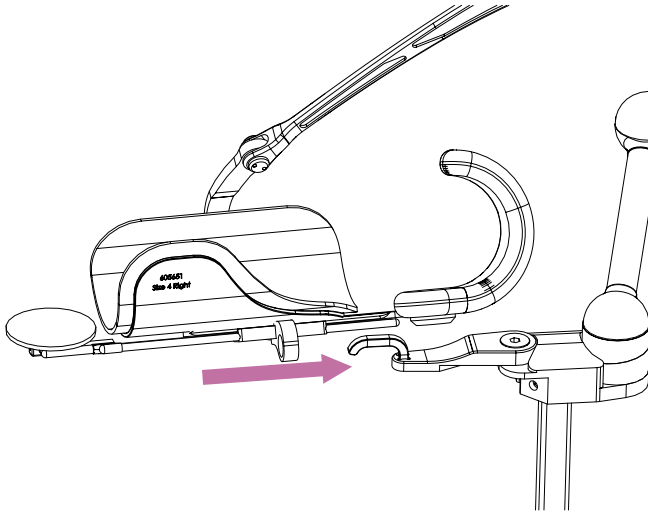


The human interface including the loadarm, arm fitting, elbow fitting and wrist support can be removed easily. To disconnect the human interface, press both red buttons at the top of Dowing², and move the Human interface away from the body in the upwards direction.

Replacing the human interface can be done by pushing the human interface into the body of Dowing². The buttons do not have to be pushed. When the lever is in position, it cannot be removed without pressing the buttons.

Park position Dowling²

If Dowling² is not used for a short time it is recommended to place the Dowling² in his intended parking bracket. This will provide a safe situation for both Dowling² and its surrounding. This is the same procedure for the table clamp and the chair / stand clamp.

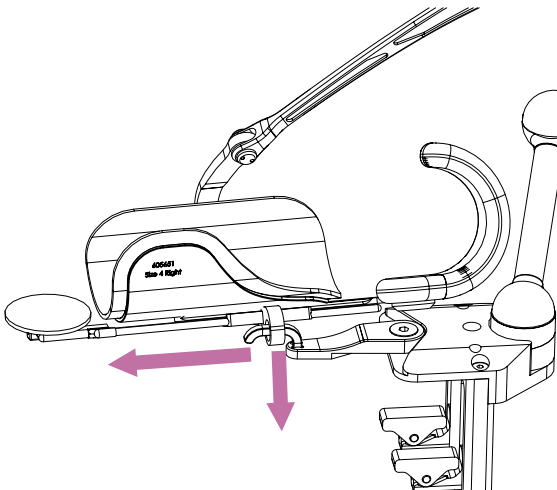


Park Dowling²

STEP 1: Move human interface with the locking ring backwards over the locking hook.

STEP 2: Move the arm with human interface up until the balance becomes less.

STEP 3: Remove the user's arm.



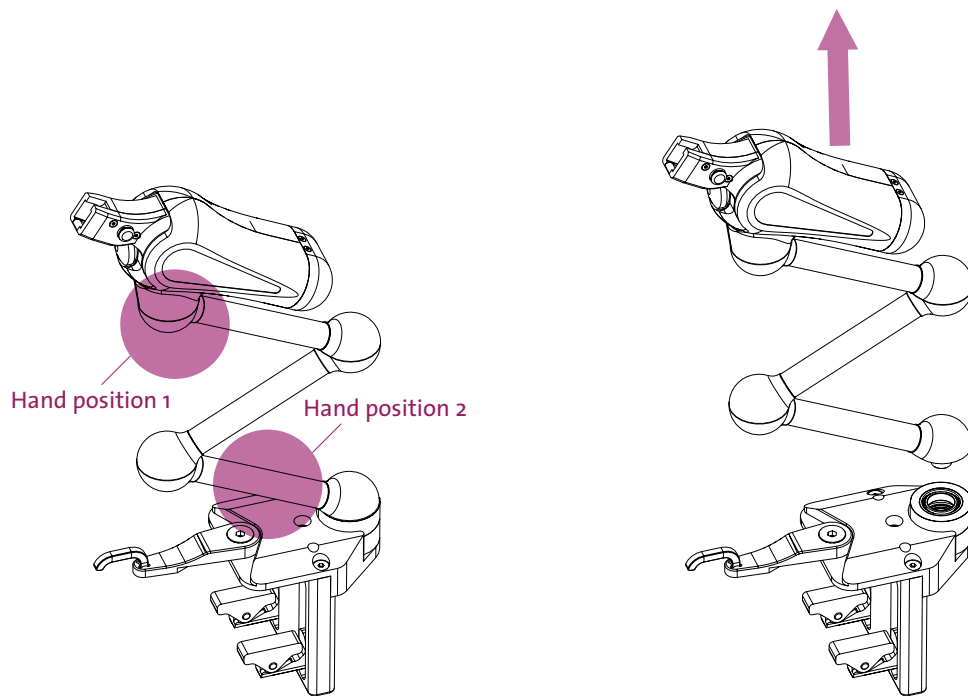
Start using Dowling²

STEP 1: Position the user's arm in the arm fitting.

STEP 2: Apply a small force downwards and slide the locking ring forwards over the hook.

Attach or detach Dowing²

If Dowing² is not used for a long time it is recommended to detach the Dowing² from its bracket. This will provide a safe situation for both Dowing² and its surrounding.



Detach Dowing²

STEP 1: Lock Dowing² in the parking position (see park position Dowing²).

STEP 2: Remove the user's arm.

STEP 3: Remove Dowing² from the parking position. Warning: the arm fitting will move upwards due to the energy stored in the spring.

STEP 4: Remove the human interface (See disconnecting the human interface).

STEP 5: Hold with one hand the body of Dowing²; with the other hand, lift up in a straight line the lower swivel arm from the clamp.

STEP 6: Store Dowing² in its case.

Attach Dowing²

STEP 1: Position Dowing² above the clamp.

STEP 2: Insert the lower swivel arm into the rotation head.

STEP 3: Attach the human interface.

STEP 4: Lock Dowing² in the parking position.

Controls

There are no electrical / software controls available for Dowling².

Accessories

There are no accessories available for Dowling².

Mounting instructions

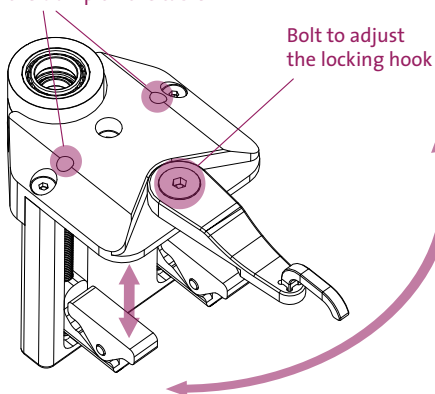
In order to make stable and safe use of Dowing², there are two options available to mount Dowing². The way to attach those mounting options is explained in this chapter.



Warning: Due to safety and functional reasons, Dowing² should not be mounted on a (electric) wheelchair.

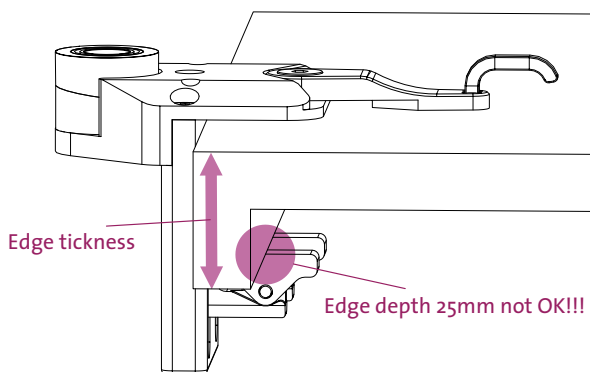
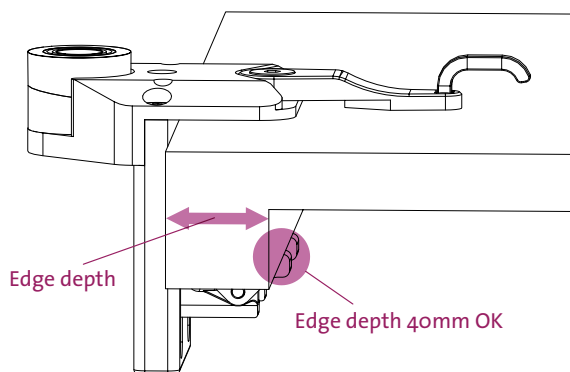
Installing the table clamp

Bolts to fixate the clamp on the table



When a Dowing² have to be mounted on a table top the table clamp should be used.

The table clamp can be mounted on a large variety of tables with a thickness between the 17 mm and 75 mm. Also the orientation angle of the locking hook can be adjusted from 0° to 66° to the left or right, this can be useful when it is hard for the user to make a straight line. To change the angle loosen the bolt first before adjust the locking hook. If the locking hook is set to the desired angle tighten the bolt with 6 Nm.

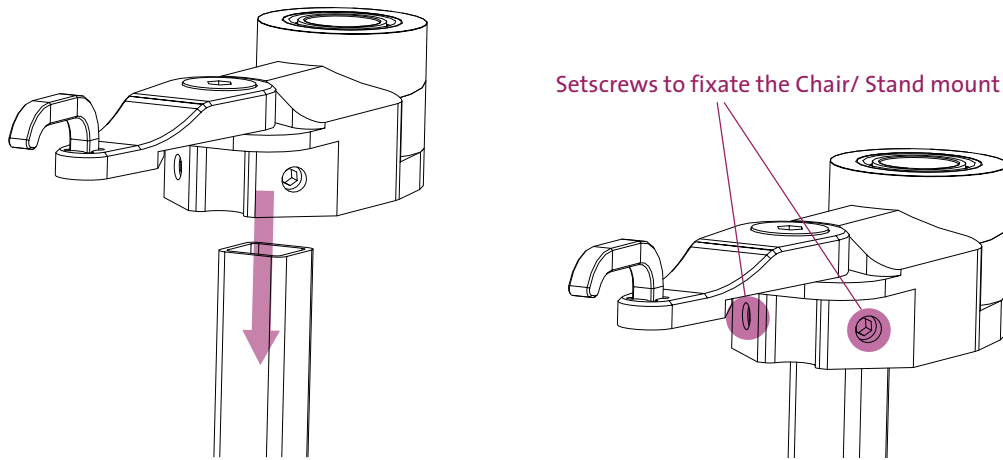


Please check the thickness, edge depth and type material off your table top before installing the table clamp. Edge thickness should be between 17 mm and 75 mm, the edge depth should be at least 40mm see picture above. It is not allowed to install the Table clamp to a table top made of glass.

To install the clamp to the table, make sure that the gap of the clamp is bigger than the edge thickness of the table. Slide the clamp completely over the edge of the table top and tighten the bolts. Turn them clockwise to fixate the clamp, be aware that if the bolts are tightened too strong the table top might deform.

Installing the chair / stand mount

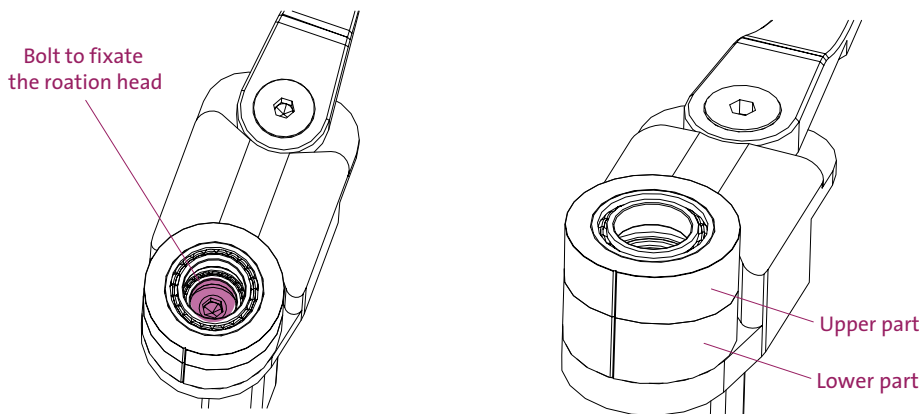
When a Dowing² needs to be mounted on a working chair or stand the Dowing² should be mounted on the chair/stand mount.



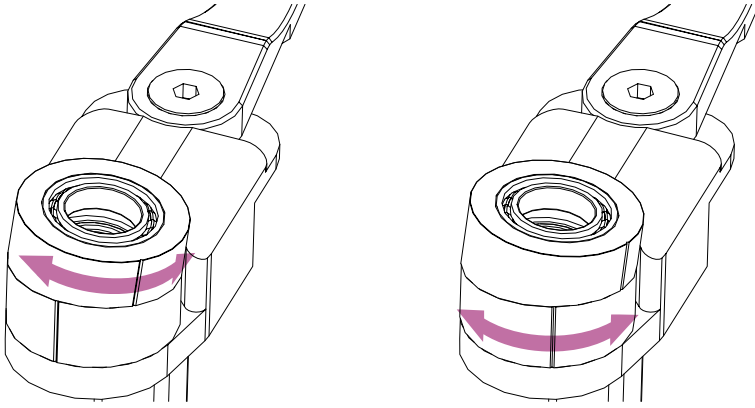
The chair/stand mount is designed to fit on a square tube 20 x 20 x 1.5 mm. To install the chair/stand mount slide it over the tube and tighten the screws. For a proper installation, the tube should slide at least 25 mm into the bracket. Tighten both screws with 6 Nm.

Adjusting the angle of the rotation head

Dowing² will perform the best when the rotation head is leveled. By default the rotation head is parallel with the table- and chair/ stand mount (i.e. the stripes on the two rings are in line). In some cases it is desired to adjust the angle of the rotation head. For example when a table is tilted, or according to user needs.



To change the angle of the rotation head, first the bolt which fixates it has to be loosened. Second, only the upper half of the rotation head should be turned to the desired angle.



For setting the orientation of this angle the complete rotation head upper and lower half should be turned together to the desired orientation. If the setting is done fixate the rotation head by tighten the bolt with 6 Nm.

Maintenance instructions

Maintenance hardware

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 must be regularly inspected. If any housing is visibly damaged, do not use the device. It is prohibited to physical modify Dowing². There are no serviceable parts inside Dowing². Contact Focal Meditech for any maintenance issues.

In case Dowing² is not mounted on the mounting base it should always be stored in the case to prevent falling or other impacts that can damage the system.

Cleaning

Maintenance of Dowing² is limited. Dowing² can be cleaned using a moist cloth and a non-aggressive cleaning agent.

Reuse

To reuse Dowing², it must be disassembled and reviewed by Focal Meditech or an authorized professional that is approved by Focal Meditech. Dowing² must intensively be cleaned and inspected. The plastic parts of the buttons can be removed and replaced by new button parts. The arm fitting, elbow fitting and wrist support have to be replaced.

Focal Meditech will refurbish and repackage the reused Dowing² in such a way that it will meet the safety and performance requirements according to applicable regulations.

Decommissioning



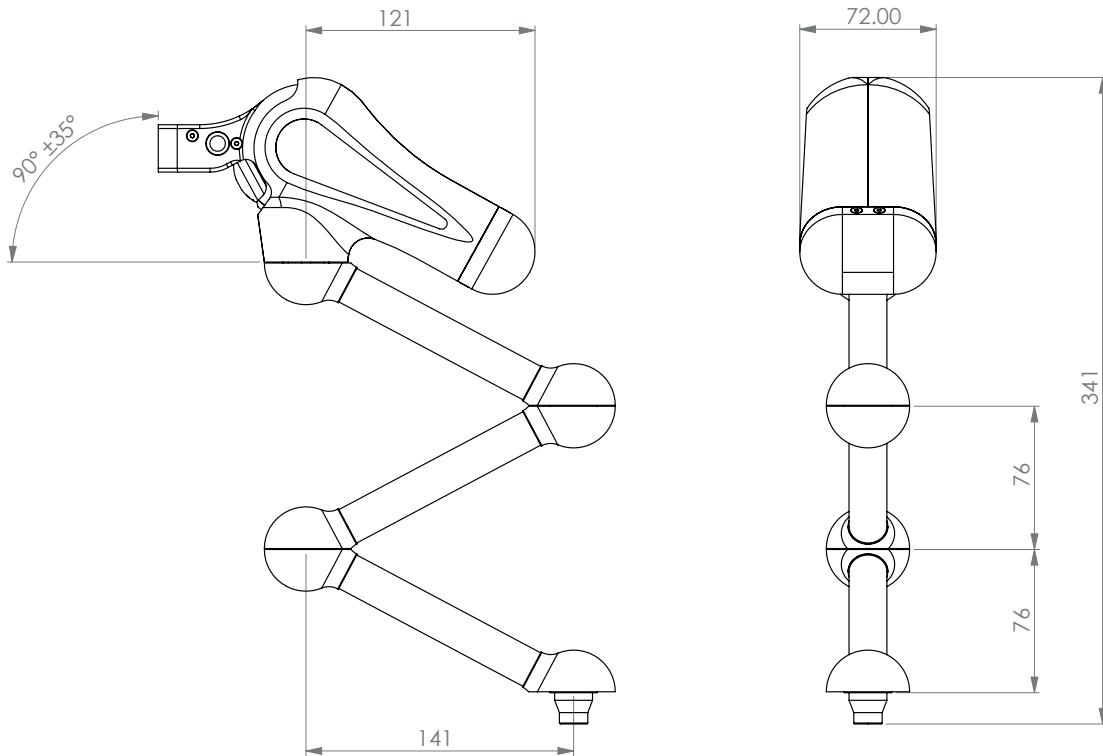
Appendix 1 Technical specifications

Specifications Dowing²

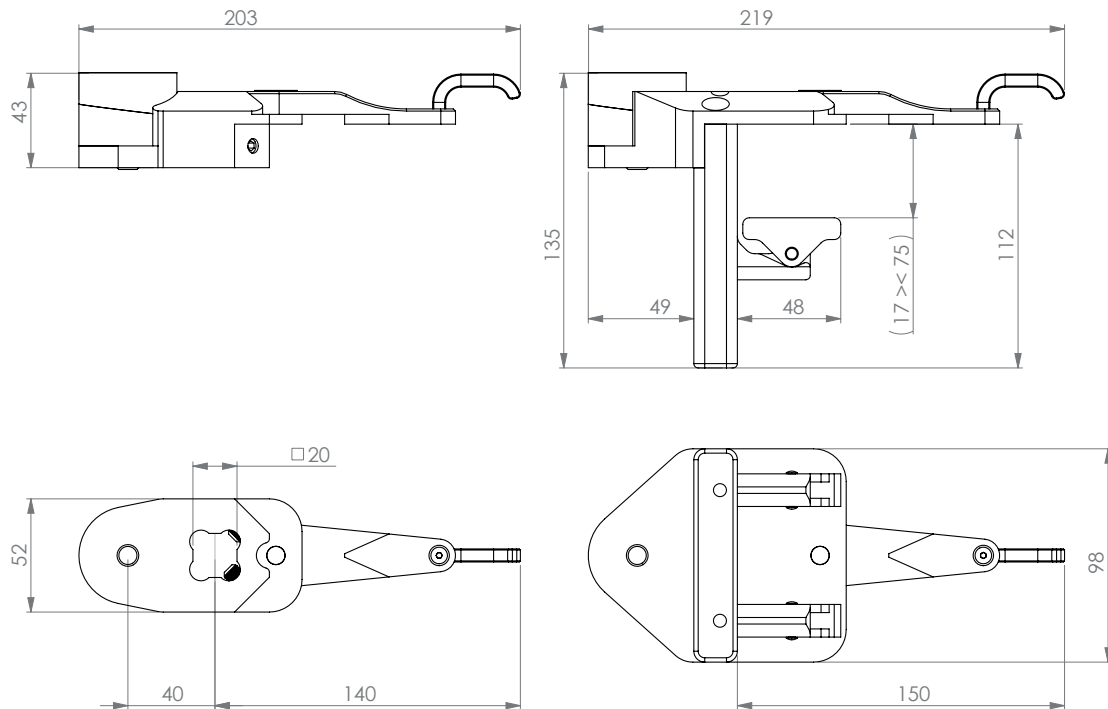
Mass		
• Mass Dowing ² (body)	0.680	[kg]
Dimensions (in default position)		
• Height	341	[mm]
• Width	72	[mm]
• Depth	241	[mm]
Rotation tilt function		
• Angle	-20...20	[°]
Range of motion		
• Up/Down	415	[mm] @ end of lever
• Forward backward stroke	420	[mm] @ end of loadarm
• Horizontal rotation	unlimited	[°]
Balance mass		
• Up/Down		
• Mass	.25...4.5	[kg] @ end of loadarm
• Mechanic adjustable	0...100	[%]
Mounting position		
• Maximum allowed mounting angle	-20...20	(°)
Storage conditions		
• Temperature	-40...85	[°C]
• Humidity	35...85	[%] non condensing
Operation conditions		
• Temperature	-10...+50	[°C]
• Humidity	35...85	[%] non condensing
Degree of protection		
• IP-class	IP40	(IEC60529)
Safety features		
• IFDS		

Dowing² dimensions (human interface excluded)

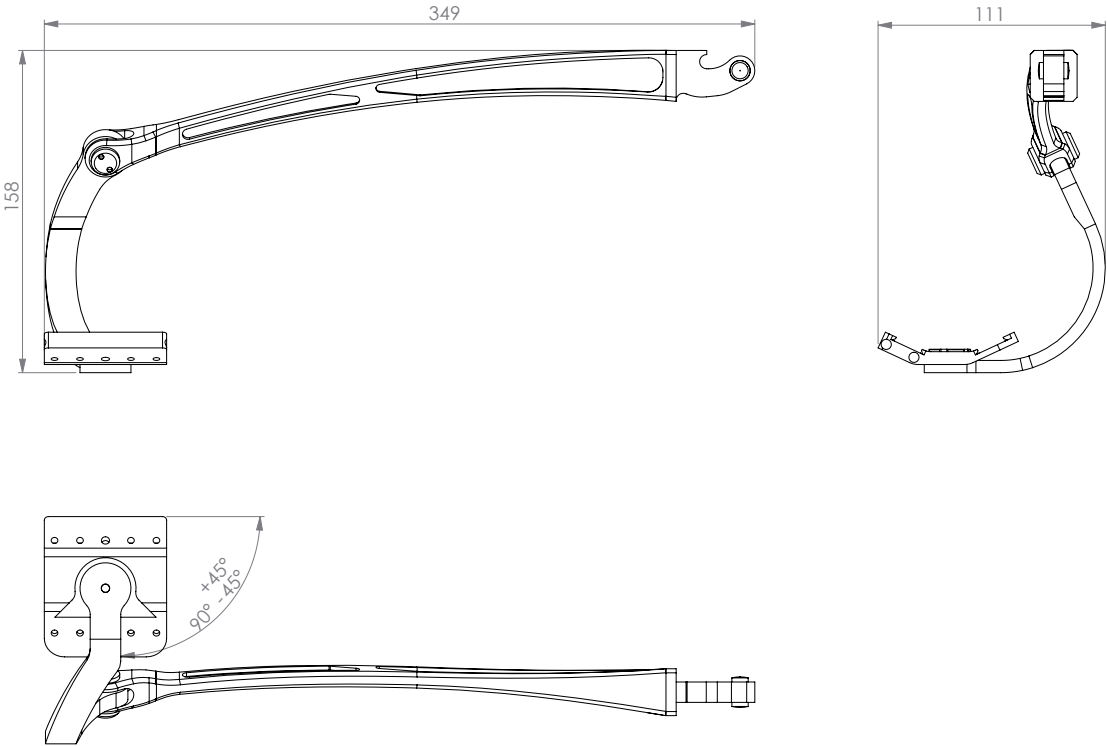
Dimensions of the Dowing² are variable. This is because it is a device with moving parts and different configurations. All dimensions are given in [mm] millimetres.



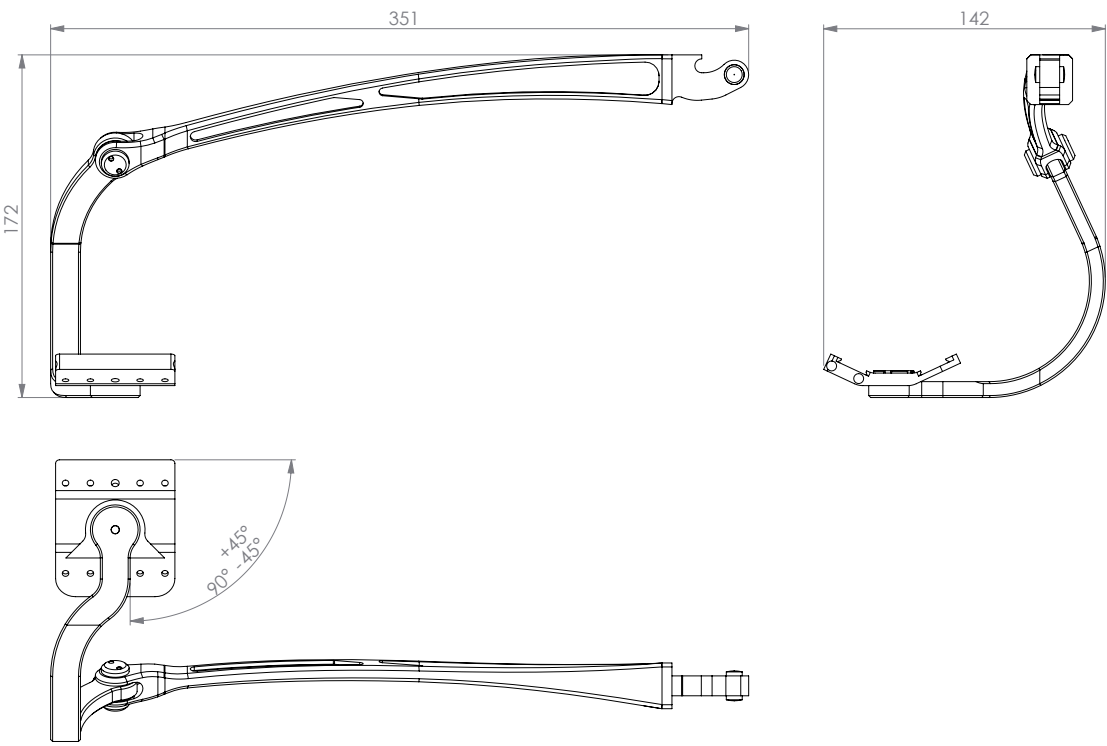
Dimensions Table clamp and Chair / Stand mount



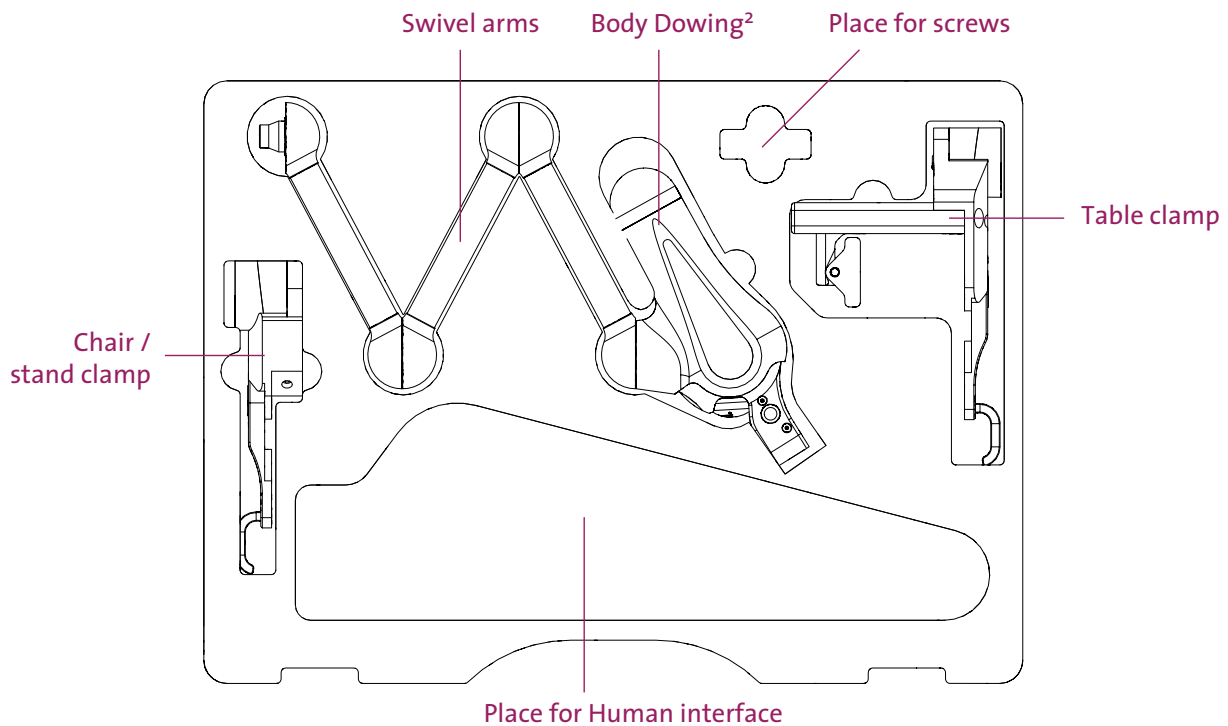
Dimensions loadarm Large (right handed version)



Dimensions loadarm X-Large (right handed version)



Dowing² content of case



Standard content of case

- Dowing²
- Allen Key (6 mm)
- Set screws for assembling the loadarm with the elbow fitting and arm fitting
- Receptacle locking mechanism with countersunk bolt for assembling
- Table clamp or chair/stand mount

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

- Loadarm
- Arm fitting
- Elbow fitting
- Wrist support

Appendix 2 Part numbers

Article number	Description
600817	Dowing ² Start kit
603194	Table clamp left/right
600600	Chair/stand mount left/right

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

603165	Wrist support left
603167	Wrist support right
606021	Wrist support cushion left
606020	Wrist support cushion right

603137	Elbow fitting left (Small)
603143	Elbow fitting right (Small)
603135	Elbow fitting left (Large)
603141	Elbow fitting right (Large)
603139	Elbow fitting left (X-Large)
603145	Elbow fitting right (X-Large)
603140	Elbow fitting left (XX-Large)
603146	Elbow fitting right (XX-Large)

603109	Arm fitting size 1 left
603111	Arm fitting size 1 right
603113	Arm fitting size 2 left
603115	Arm fitting size 2 right
603117	Arm fitting size 3 left
603119	Arm fitting size 3 right
603121	Arm fitting size 4 left

603123	Arm fitting size 4 right
603125	Arm fitting size 5 left
603126	Arm fitting size 5 right

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

603097	Assembly bracket human interface
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604191	Fixation strap complete (Small)
604190	Fixation strap complete (Large)

605926	Elbow bracket L shape short left
605927	Elbow bracket L shape short right

605683	Mobile stand
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Appendix 3 Used materials

Article number	Description	Material(s)
600817	Dowing ² Start kit	Aluminium 6082T6 + stainless steel (AISI 304) + steel
603194	Table clamp left/right	
600600	Chair/stand mount left/right	

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

603165	Wrist support left	Aluminium 6082T6 + stainless steel (AISI 304)+Neoprene
603167	Wrist support right	
606021	Wrist support cushion left	
606020	Wrist support cushion right	

603137	Elbow fitting left (Small)	Aluminium 6082T6 + stainless steel (AISI 304) +Neoprene
603143	Elbow fitting right (Small)	
603135	Elbow fitting left (Large)	
603141	Elbow fitting right (Large)	
603139	Elbow fitting left (X-Large)	
603145	Elbow fitting right (X-Large)	
603140	Elbow fitting left (XX-Large)	
603146	Elbow fitting right (XX-Large)	

603109	Arm fitting size 1 left	Aluminium 6082T6 + Vikureen (PS)+Velcro
603111	Arm fitting size 1 right	
603113	Arm fitting size 2 left	
603115	Arm fitting size 2 right	
603117	Arm fitting size 3 left	
603119	Arm fitting size 3 right	
603121	Arm fitting size 4 left	
603123	Arm fitting size 4 right	
603125	Arm fitting size 5 left	
603126	Arm fitting size 5 right	

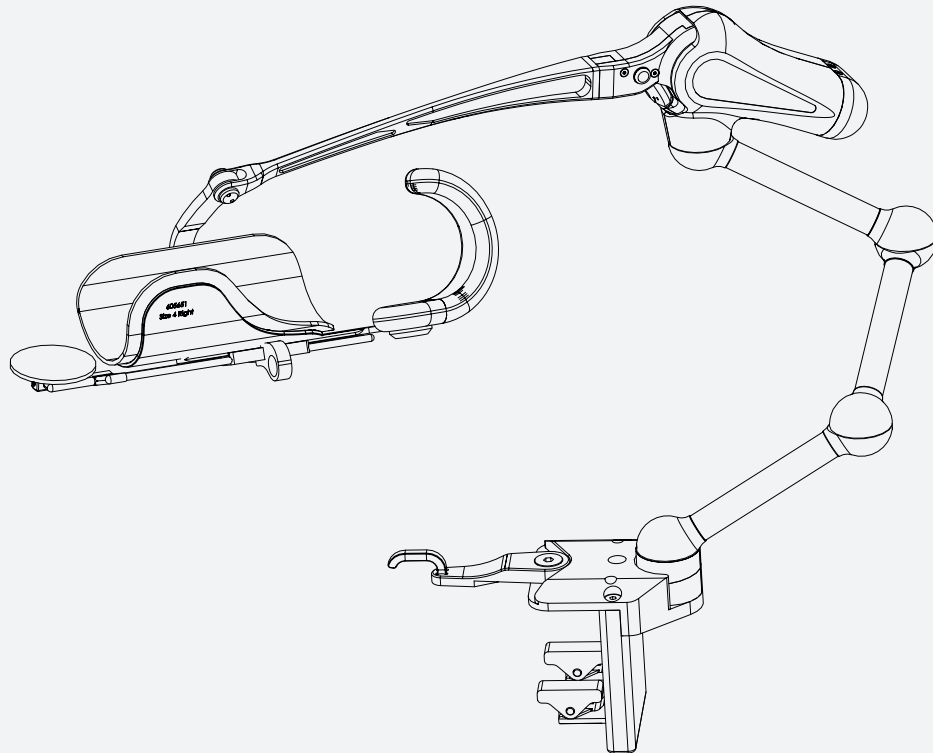
605658	Inlay arm fitting size 1 left	Neoprene
605638	Inlay arm fitting size 1 right	
605662	Inlay arm fitting size 2 left	
605642	Inlay arm fitting size 2 right	
605666	Inlay arm fitting size 3 left	
605646	Inlay arm fitting size 3 right	
605670	Inlay arm fitting size 4 left	
605650	Inlay arm fitting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

603097	Assembly bracket human interface	POM + stainless steel (AISI 304)
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604191	Fixation strap complete (Small)	Neoprene
604190	Fixation strap complete (Large)	

605926	Elbow bracket L shape short left	Aluminium 6082T6
605927	Elbow bracket L shape short right	

605683	Mobile stand	Steel S235
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Dowing²

Quick Start Guide / Snelstartgids

ID manual: 6o628o
Revision / Revisie: 1.0.0
Date / Datum: 01-05-2020



Introduction / Voorwoord

This is the Quick start guide for Dowing², a dynamic arm support system. This product is developed, manufactured and potentially distributed by Focal Meditech B.V. This quick start guide contains the basic information regarding Dowing². 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 Dowing². Please take note of the safety warnings before using Dowing².

Dit is de snelstartgids voor Dowing², een dynamische armondersteuning. Dit product wordt ontwikkeld, geproduceerd en eventueel gedistribueerd door Focal Meditech B.V. Deze snelstartgids bevat de basisinformatie over Dowing². Het doel van deze informatie is te zorgen voor een succesvol, veilig en effectief gebruik van het apparaat. Deze snelstartgids geeft u een snelle blik op de functies en belangrijke veiligheidswaarschuwingen van Dowing². Houd rekening met de veiligheidswaarschuwingen voordat u Dowing² gebruikt.

Overview / Overzicht

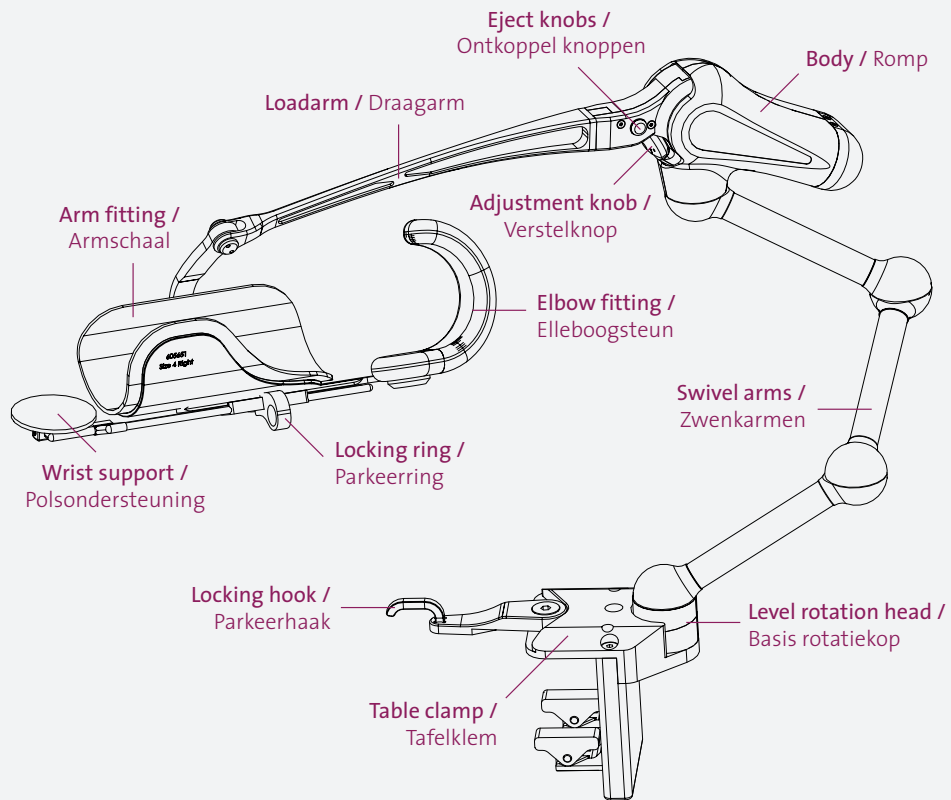


Figure 1: Overview Dowing² with terms of specific parts

Figuur 1: Overzicht Dowing² 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 in user manual). Failure of this can lead to malfunctioning of the device or bodily harm.

Gevaar: Voorkom extreme temperaturen (zie omgevingscondities). Het niet voorkomen kan slecht functioneren van het hulpmiddel of lichamelijk letsel tot gevolg hebben.



Danger: Mechanical energy is stored for balancing the arm. During non-intended removal of the arm from the arm fitting of Dowing², this mechanical energy will be released resulting in a fast moving Human Interface 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 Dowing² zal deze mechanische energie vrijkomen wat resulteert in een snel bewegende Human Interface 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 hulpmiddel zonder toestemming van Focal Meditech. Indien dit toch gedaan wordt, kan dit leiden tot onjuist functioneren en zal de garantie komen te vervallen.



Warning: In case of a faulty device contact Focal Meditech.

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 Meditech. 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.

Park or start using Dowing² / Parkeer of start gebruik Dowing²

If Dowing² is not used for a short time it is recommended to place the Dowing² in its intended parking bracket. This will provide a safe situation for both Dowing² and its surrounding. The same procedure is followed for the table clamp and the chair / stand clamp.

Wanneer Dowing² korte tijd niet wordt gebruikt, is het raadzaam om de Dowing² in zijn beoogde parkeerhaak te plaatsen. Dit zorgt voor een veilige situatie voor zowel Dowing² als voor de omgeving. Deze procedure is voor gebruik van de Dowing² in combinatie met een tafelklem of een stoel / standaardklem hetzelfde.

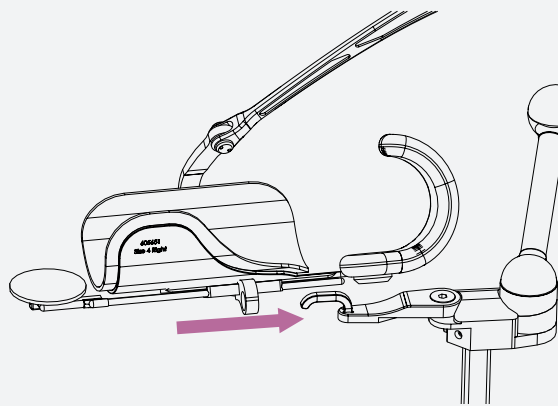


Figure 2: Park Dowing²
Figuur 2: Parkeer Dowing²

Park Dowing²

STEP 1: Move human interface with the locking ring backwards over the locking hook.

STEP 2: Move the arm with human interface up until the balance becomes less.

STEP 3: Remove the user's arm.

Parkeer Dowing²

STAP 1: Plaats de human interface met de borgring achterwaarts over de parkeerhaak.

STAP 2: Beweeg de human interface omhoog totdat de balans van de human interface minder wordt.

STAP 3: Verwijder de arm uit de armschaal.

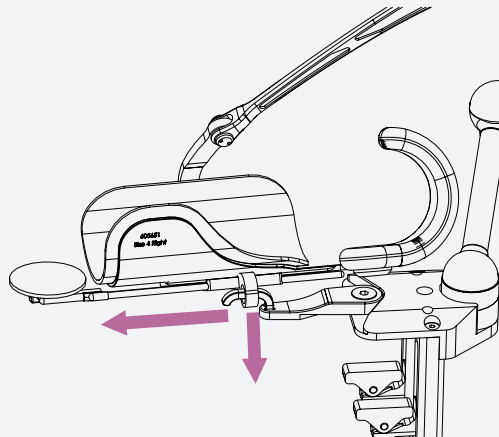


Figure 3: Start using Dowing²

Figure 3: Start using Dowing²

Start using Dowing²

STEP 1: Position the user's arm in the arm fitting.

STEP 2: Apply a small force downwards and slide the locking ring forwards over the hook.

Start gebruik Dowing²

STAP 1: Plaats de arm in de armschaal.

STAP 2: Oefen een beetje kracht uit naar beneden uit en schuif de armschaal naar voren zodat de parkeerring loskomt van de parkeerhaak.

Attach / detach the Human Interface / Koppelen / ontkoppelen van de Human Interface

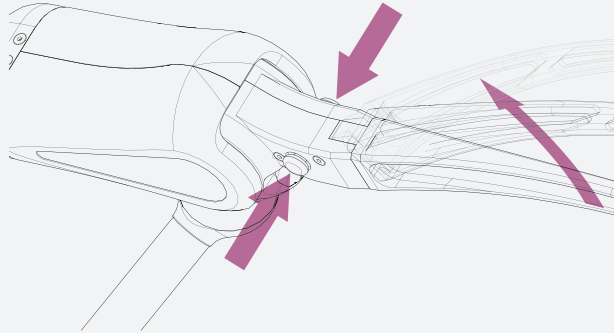


Figure 4: Attach / detach human interface

Figuur 4: Koppelen / ontkoppelen human interface

The human interface including the loadarm, arm fitting, elbow fitting and wrist support can be removed easily. To disconnect the Human Interface, press both red buttons at the top of Dowing², 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 Dowing² worden ingedrukt. Beweeg de human interface in bovenwaartse richting van de behuizing van Dowing² weg.

Replacing the human interface can be done by pushing the Human Interface into the body of Dowing². The buttons do not have to be pushed. When the lever 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.

Attach / detach Dowing² / Koppelen / ontkoppelen Dowing²

If Dowing² is not used for a long time it is recommended to detach the Dowing² from its bracket. This will provide a safe situation for both Dowing² and its surrounding.

Wanneer Dowing² voor langere tijd niet wordt gebruikt, wordt het aanbevolen om Dowing² te demonteren van de klem. Dit zorgt voor een veilige situatie voor zowel Dowing² als voor de omgeving.

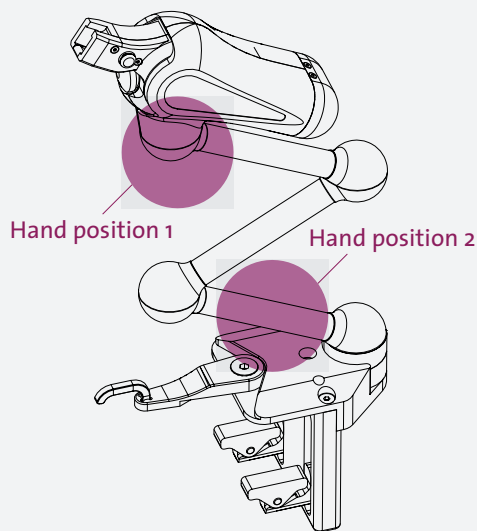


Figure 5: Indications of hand positions to detach Dowing²

Figuur 5: Aanduiding van handposities om Dowing² te ontkoppelen

Detach Dowing²

STEP 1: Lock Dowing² in the parking position (see park or start using Dowing²)

STEP 2: Remove the user's arm

STEP 3: Remove Dowing² from the parking position. Warning: the arm fitting will move upwards due to the energy stored in the spring.

STEP 4: Remove the human interface (See attach and detach the human interface)

STEP 5: Hold with one hand the body of Dowing²; with the other hand, lift up in a straight line the lower swivel arm from the clamp

STEP 6: Store Dowing² in its case.

Dowing² loskoppelen

STAP 1: Vergrendel Dowing² in de vergrendelingshaak (zie parkeer of start gebruik Dowing²).

STAP 2: Verwijder de arm uit de armschaal.

STAP 3: Haal de Dowing² uit de vergrendelingshaak. Waarschuwing: de armschaal zal door de opgeslagen energie naar boven bewegen wanneer deze uit de vergrendelingshaak is genomen.

STAP 4: Verwijder de human interface (Zie koppelen en ontkoppelen van de human interface).

STAP 5: Houdt met één hand het basislichaam van de Dowing² vast, til met de andere hand de onderste zwenkarm in een rechte lijn uit de bevestigingsklem.

STAP 6: Bewaar Dowing² in de opbergdoos.

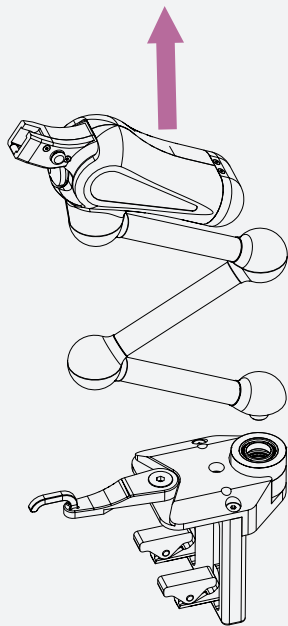


Figure 6: Take Dowing² apart from the table clamp or chair mount

Figuur 6: Neem Dowing² los van de tafel of stoel klem

Attach Dowing²

STEP 1: Position Dowing² above the clamp.

STEP 2: Insert the lower swivel arm into the rotation head.

STEP 3: Attach the human interface.

STEP 4: Lock Dowing² in the parking position.

Dowing² koppelen

STAP 1: Positioneer Dowing² boven de bevestigingsklem.

STAP 2: Steek de onderste zwenkarm in de rotatiekop.

STAP 3: Bevestig de human interface.

STAP 4: Vergrendel Dowing² in de vergrendelingshaak.

Adjust the balancing force / Aanpassen balanceerkracht

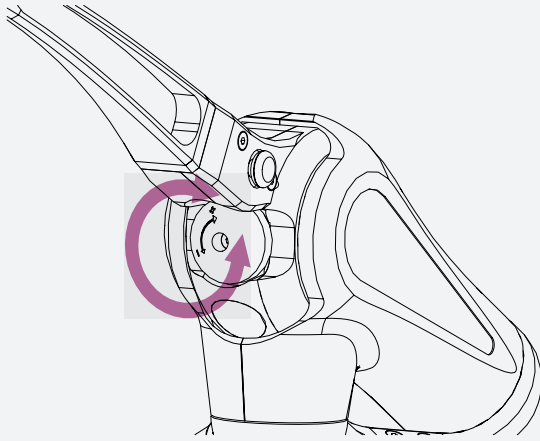


Figure 7: Adjust the balancing force
Figuur 7: Aanpassen balanceerkracht

The upwards balancing force can be adjusted by turning the adjustment knob. The force required to rotate the adjustment knob can change depending on the position of the human interface. This is normal behaviour. Because of this, the system can be adjusted using little force. Rotating the knob clockwise will give more balancing force, counter clockwise will give less force.

De opwaartse balanskracht kan worden aangepast door aan de instelknop te draaien. De kracht die nodig is om de instelknop te draaien, kan veranderen afhankelijk van de positie van de human interface, dit is normaal. Hierdoor is het systeem met weinig kracht te verstellen. Als de knop met de klok mee wordt gedraaid, wordt meer balanskracht verkregen. Als de knop tegen de klok in wordt gedraaid, wordt minder balanskracht verkregen.

Contact information / Contact informatie

Dowing² is manufactured and sold by:
Dowing² wordt gefabriceerd en verkocht door:



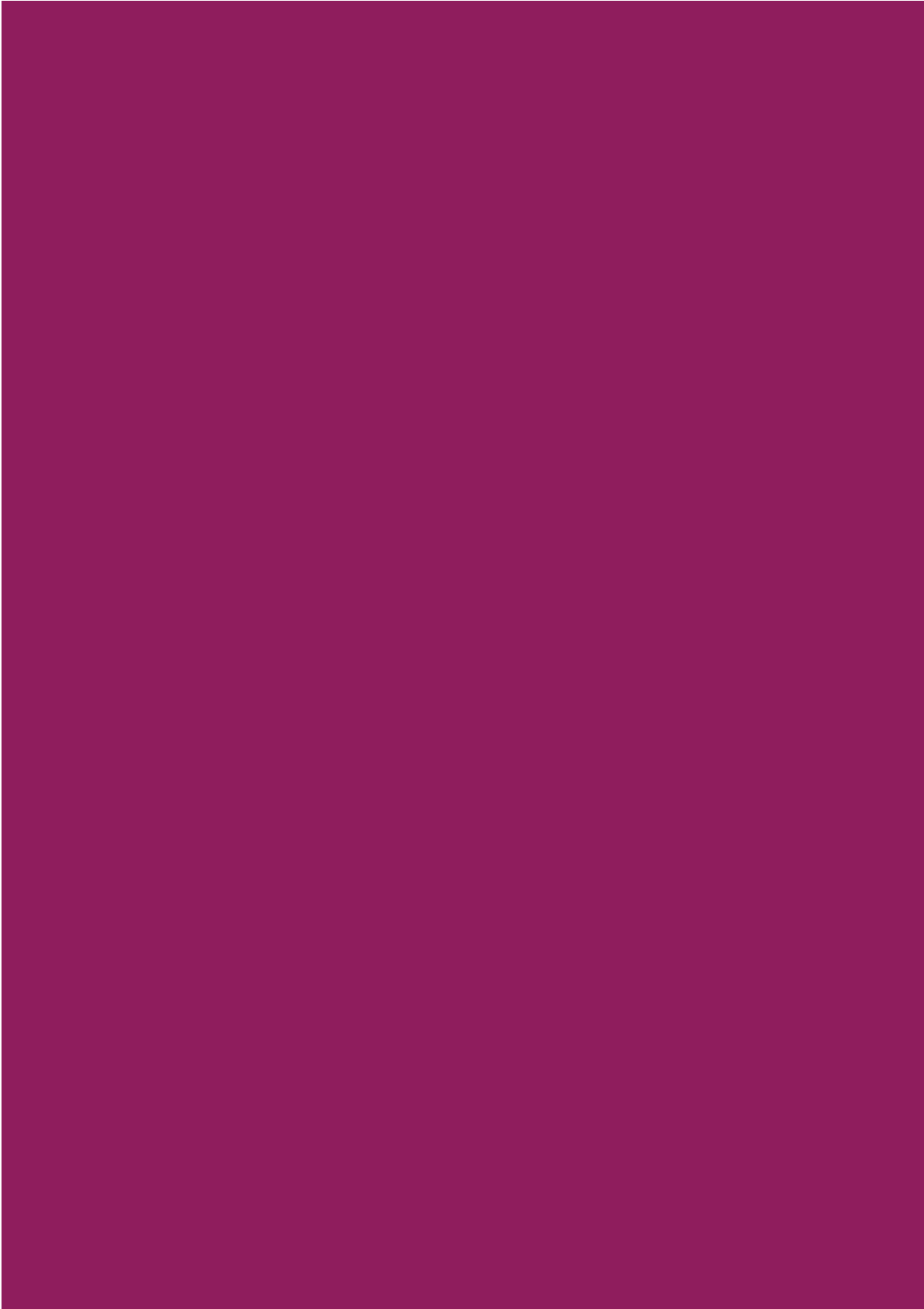
Focal Meditech BV

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 (<http://www.focalmeditech.nl/en/documentation>). 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 (<http://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 Declaration of conformity



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,

Dowing² (type number 600817)
and its accessories

having the intended purpose: Dowing² 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 IX, Rule number 1,

and are in conformity with the General Safety and Performance Requirements of the Council Directive 93/42/EEC of the European Parliament 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

and are in conformity with the requirements of directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 92/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

Signature:

A handwritten signature in blue ink, consisting of a series of loops and strokes, positioned above the printed name and function.

Tilburg, The Netherlands

Date: 1 May 2020
Name: Paul Groenland
Function: Managing Director



Appendix 6 Conditions and Warranty

Conditions and Warranty: Dowling² 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 consumers

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.

