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

Trademarks and Design
Focal Meditech is a registered trademark of Focal Meditech BV.
Manual introduction

This is the user manual for Sling, 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 Sling, 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 Sling, information about safety issues and contact information.

Please read this information carefully: increase of knowledge will result in an increase of effectiveness. You should also tell people close to you about the main features, for example, the person who looks after the wheelchair or those who help you with transfers.
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.

Certification Notices

This is a CE Class I medical device

Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the bottom of the vertical tube of the Sling.

Packaging

Fragile
This way up

Keep away from water
Do not stack

Non-sterile product
Do not use if package is damaged
**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:** In accordance with the Code VVR, the device must be disconnected from the wheelchair when the user is transported in the wheelchair by means of transport that is accessible for wheelchairs. Failure of this can lead to malfunctioning of device or bodily harm.

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

**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**

Sling is manufactured and sold by Focal Meditech BV

**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 and operation of the device

#### Intended use
Sling 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 Sling are users in need of a function device requiring limited learning efforts:

1. Persons challenged by considerable muscular weakness causing the inability to perform essential Activities of Daily Living (ADL) activities including eating, drinking, facial care, computer use, wheelchair control. No problem solving through application of simple arm supports possible.
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 Sling is a set of axes equipped with a string. The string connects an arm-fitting (Human Interface) with a counterweight. The Sling will always be attached to the ‘fixed’ world (chair, wheelchair or frame). The forearm rests in the Human Interface, the Sling can now largely bear the weight of the arm and relieve the pectoral girdle. The counterweight will allow every movement of the arm and hand against gravity. Dynamic arm supports are mainly used by people with limited strength in the pectoral girdle or arm due to neurological or orthopaedic state of these areas. By using their own residual capabilities, these people can move their hands to where it is useful. Reaching, grasping, moving things and all kinds of everyday activities are now possible. The Sling works in both the horizontal and the vertical way and requires no electrical power. A typical feature of the Sling is that the whole suspension approaches the user’s arm from above. In this way, unlike other types of arm support, there are no parts under the arm that may occupy space. Arm support systems of this type are very suitable in case the device could come into conflict with objects such as the working table, joystick, armrest or keyboard. As a result, the Sling is used by people with their own capabilities and desires.

---

### Usage of the device
Sling 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. Sling 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. Sling returns the natural freedom of movement to the user.

---

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

**Warning:** If the user experience problems using Sling, please contact Focal Meditech or a healthcare professional as soon as possible.
Risks and contra-indications

No essential user risks are known while using Sling. Sling is an aid which should be used by the intended users. However, there are no known contra-indications for Sling. To be able to use Sling the following warnings must be considered.

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

**Warning:** Sling 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.

Description

The following parts of Sling are described

- From a user perspective, the contact point with Balancer is the Human Interface (wrist strap or wrist with elbow strap) in which the lower arm of the user’s is located. Therefore, the Human Interface is a component that is individually determined for the user. During use, the user’s arm must continue to maintain in the Human Interface.
- The cord is used to transfer the forces of the counter weight in the vertical tube to the Human Interface.
- The linear translation combined with the carrier brings the arm fitting into the user’s working area.
- The Slider can be used to unblock the fold axis, it will be hold in place by two thumbscrews.
- Rotation head provides a pivoting point in the horizontal plane it can be locked out by lockout knob.
Adjusting the tilting point

Although the Sling can be used with only a wrist strap, Sling is most likely equipped with a wrist strap and elbow strap on a slide bar together also called the Human Interface. This gives the ability to balance the forearm. To move the arm freely the weight of the arm is balanced.

The desired tilting point of the forearm can be adjusted by shifting the rod to the front or back. Find such a balance that the forearm in the arm fitting can easily be tilted forwards and backwards.

The shifting of the rod can be done after loosening the bolt (in the circle) on the bottom of the bracket. Shift the rod into the desired position, and tighten the bolt.

The more the rod is slid backwards (towards the elbow), the easier arm and hand are tilted upwards. If the rod is slid more forward (towards the wrist), then the arm and hand are more easily tilted down.

---

**Warning:** The settings of the arm fitting are of great importance for the functioning of Sling. Changing these positions can result in a severe decrease of the performance or even malfunction of Sling. Therefore, only trained persons are allowed to change the settings of the Human Interface.

---

The vertical tube brings the linear translation above the user and provides room and guidance for the counter weight.

The lock knob can be used to easily take of Sling.

Level unit can be used to level the vertical tube perpendicular to the gravity plane.

Connect and disconnect the wrist strap and or the elbow strap

To make it easier to position the users arm in the Human Interface it is recommended to disconnect the wrist strap and the elbow strap.

---

**Warning:** After connecting the straps make sure that the snap hooks are well closed.
**Connect and disconnect the Human Interface**
When the user wants to fold Sling, it is recommended that the human Interface is disconnected from the system.

---

**Warning:** Before disconnecting the Human Interface make sure that the user’s arm is removed from the system.

**Warning:** After connecting the Human Interface make sure that the snap hook is well closed.

---

To disconnect the Human Interface, make sure that the user’s arm is removed out of the interface and follow the steps.

**STEP 1:** Hold with one hand the rope just above the mounting loop and with the other hand the slide bar.
**STEP 2:** Pull the rope with mounting loop to a comfortable height.
**STEP 3:** Clip and hold open the snap hook.
**STEP 4:** Lift the Human Interface in an 45° angle out of the mounting loop.
**STEP 5:** Let the rope slowly retract into the balancer.

To connect the Human Interface, follow the steps.

**STEP 1:** Hold with one hand the rope just above the mounting loop and with the other hand the slide bar.
**STEP 2:** Pull the rope with mounting loop to a comfortable height.
**STEP 3:** Clip and hold open the snap hook.
**STEP 4:** Lower the Human Interface in an 45° angle in the opening of the mounting loop.
**STEP 5:** Let the rope slowly retract into the balancer.

---

**Folding and unfolding Sling**
The Sling can be folded when it is not used. This provides a safe setting for the user and the device.

---

**Warning:** Before folding the Sling make sure that the Human Interface is removed from the system.

**Warning:** After folding back, the Sling make sure that the thumbscrews are tighten firmly however do not overtighten the screws or replace them with a bolt.

---

To fold Sling, make sure that Human Interface is removed from the system and follow the steps.

Folding linear translation:
**STEP 1:** Loosen the two thumbscrews.
**STEP 2:** Hold with one hand the linear translation and slide with the other hand the slider away from the rotation head.
**STEP 3:** Move the linear translation 90° down.
**STEP 4:** Tighten the thumbscrews to prevent losing them.

Folding back linear translation:
**STEP 1:** Loosen the two thumbscrews.
**STEP 2:** Move the linear translation 90° up.
**STEP 3:** Hold with one hand the linear translation and slide with the other hand the slider towards the rotation head.
**STEP 4:** Tighten the thumbscrews to lock the slider.
**Adjust the balancing force**
The balancing force in Sling consists of a counter weight which is placed in the vertical tube. However, the possibility to change the counter weight is limited.

**Warning:** Adjusting the counter weight can result in forces that are higher than the mass of the arm, resulting in an upwards movement of the arm

The balancing force can be adjusted by removing or adding addable weights. To change the counterweight, it is necessary to fold the Sling first.

To add weight, couple the weight by tighten the setscrew above the relevant weight. And loosen the setscrew below the weight.

**Rotation**
The Sling has a rotation of 45° to the left and 45° to the right which provide the user to be able to make the needed horizontal movement.

**Warning:** Do not change the rotation limitation by yourself please contact Focal Meditech or a by Focal authorized healthcare professional.

**Warning:** Please note that if the rotation exceeds the footprint of the wheelchair, there is a risk of collisions against, for example, a door post

Although the rotation of the system can be changed, this should be done Focal Meditech or a by Focal authorised professional. Always keep in mind that the linear translation does not exceeds the footprint of the wheelchair.
Removing and placing
The Sling can be removed if it is not used for a longer time. This provides a safe setting for the user and the device.

- **Warning:** Before removing Sling make sure that the Human Interface is removed from the system and Sling is folded.
- **Warning:** After replacing Sling make sure that the bolts are tighten firmly however do not overtighten the them.

---

Adjusting the Level unit
The optimal performance of Sling will be reached when the linear translation is perpendicular to the gravity plane. However, it is in some cases needed or desirable to use an off-level setup.

- **Warning:** The settings of the level unit are of great importance for the functioning of Sling. Changing these settings can result in a severe decrease of the performance or even malfunction of Sling. Therefore, only trained persons are allowed to change the settings of the level unit.
- **Warning:** After adjusting the level unit make sure that the centre bolt is tighten firmly however do not overtighten the bolt.

---

The required angle of the level unit depends on a number of factors. For example, a correction must be made for the angular error that arises during mounting. But even when the user cannot move in at well, it is an option to set the angle so that the linear translation falls slightly inward.

Before the level unit can be adjusted, the Sling must be removed from it. There is a bolt in the middle of the level unit. The three level bolts on the outside can be turned after the bolt in the middle has been loosened. Turning in the level bolts (viewed clockwise from above) shifts the center of gravity in the direction of the respective level bolt. By loosening a level bolt (counter clockwise seen from above) the centre of gravity shifts in the direction opposite to the respective level bolt. Any angle can be set with the three level bolts together.

After adjusting the level unit make sure that the centre bolt is tighten firmly however do not overtighten the bolt.

---

Removing Sling:
- **STEP 1:** Loosen the wing screw.
- **STEP 2:** Lift the Sling in a vertical movement so that it is released from the level unit.
- **STEP 3:** Tighten the wing screw to prevent losing it.

Placing Sling:
- **STEP 1:** Loosen the wing screw.
- **STEP 2:** Lower the Sling in a vertical movement so that it slides into the level unit.
- **STEP 3:** Tighten the wing screw to lock the sling into place.
Controls

There are no electrical / software controls available for Sling.

Accessories

There are no accessories available for Sling.

Mounting instructions

In order to make stable and safe use of Sling, there are a couple of mounting brackets developed for Sling. The installation instructions (how to fixate the adapter) comes with the adapter. Most of those adapters will be mounted to the backrest of the wheelchair, the key point is to find an angle position of the backrests where the user sits comfortably and has the best possible moving range. The adapter will need to be installed to meet those needs.
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 Sling. There are no serviceable parts inside Sling. Contact Focal Meditech for any maintenance issues.

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

Reuse
To reuse Sling, it has to be disassembled by a professional. Sling must intensively be cleaned and inspected. The plastic parts of the buttons can be removed and replaced by new button parts. The Human Interface have to be replaced. Focal Meditech will refurbish and repackage the reused Sling in such a way that it will meet the safety and performance requirements according to applicable regulations.

Decommissioning

Appendix 1 Technical specifications

Specifications Sling

<table>
<thead>
<tr>
<th>Mass</th>
<th>2.5 [kg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (in default position)</td>
<td></td>
</tr>
<tr>
<td>• Height</td>
<td>712 [mm]</td>
</tr>
<tr>
<td>• Width</td>
<td>80 [mm]</td>
</tr>
<tr>
<td>• Depth</td>
<td>579 [mm]</td>
</tr>
<tr>
<td>Range of motion</td>
<td></td>
</tr>
<tr>
<td>• Up/Down</td>
<td>depends on counterweight</td>
</tr>
<tr>
<td>• Forward backward stroke</td>
<td>220 [mm]</td>
</tr>
<tr>
<td>• Horizontal rotation</td>
<td>± 45 [º]</td>
</tr>
<tr>
<td>Balance mass</td>
<td></td>
</tr>
<tr>
<td>• Up/Down</td>
<td></td>
</tr>
<tr>
<td>• Mass</td>
<td>0.20...3 [kg]</td>
</tr>
<tr>
<td>Mounting position</td>
<td></td>
</tr>
<tr>
<td>• Maximum allowed mounting angle</td>
<td>-20...20 [º]</td>
</tr>
<tr>
<td>Storage conditions</td>
<td></td>
</tr>
<tr>
<td>• Temperature</td>
<td>-40...85 [ºC]</td>
</tr>
<tr>
<td>• Humidity</td>
<td>35...85 [%] non-condensing</td>
</tr>
<tr>
<td>Operation conditions</td>
<td></td>
</tr>
<tr>
<td>• Temperature</td>
<td>-10...+50 [ºC]</td>
</tr>
<tr>
<td>• Humidity</td>
<td>35...85 [%] non-condensing</td>
</tr>
<tr>
<td>Degree of protection</td>
<td></td>
</tr>
<tr>
<td>• IP-class</td>
<td>IP40 (IEC60529)</td>
</tr>
</tbody>
</table>
**Dimensions**
Dimensions are variable. This is because it is a product with moving parts and it is a product with different configurations. All dimensions are given in [mm] millimetres.

**Appendix 2 Part numbers**

<table>
<thead>
<tr>
<th>Focal number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>603900 till 603908</td>
<td>Sling (mechanical)</td>
</tr>
<tr>
<td>603909 till 603917</td>
<td>Sling (electrical)</td>
</tr>
<tr>
<td>600923</td>
<td>Elbow strap (Small)</td>
</tr>
<tr>
<td>600920</td>
<td>Elbow strap (Medium)</td>
</tr>
<tr>
<td>600917</td>
<td>Elbow strap (Large)</td>
</tr>
<tr>
<td>600926</td>
<td>Elbow strap (X-Large)</td>
</tr>
<tr>
<td>603501</td>
<td>Wrist strap (Small)</td>
</tr>
<tr>
<td>603499</td>
<td>Wrist strap (medium)</td>
</tr>
<tr>
<td>603497</td>
<td>Wrist strap (Large)</td>
</tr>
<tr>
<td>603503</td>
<td>Wrist strap (X-Large)</td>
</tr>
<tr>
<td>600156</td>
<td>Mounting rod (Small)</td>
</tr>
<tr>
<td>600155</td>
<td>Mounting rod (Medium)</td>
</tr>
<tr>
<td>600154</td>
<td>Mounting rod (Large)</td>
</tr>
<tr>
<td>600157</td>
<td>Mounting rod (X-Large)</td>
</tr>
<tr>
<td>601198</td>
<td>Wrist strap with thumb cut-out (Type 1 left)</td>
</tr>
<tr>
<td>601200</td>
<td>Wrist strap with thumb cut-out (Type 1 right)</td>
</tr>
<tr>
<td>601202</td>
<td>Wrist strap with thumb cut-out (Type 2 left)</td>
</tr>
<tr>
<td>601204</td>
<td>Wrist strap with thumb cut-out (Type 2 right)</td>
</tr>
<tr>
<td>600616</td>
<td>Adapter clamp ring 20mm (Male)</td>
</tr>
<tr>
<td>600615</td>
<td>Adapter clamp ring 20mm (Female)</td>
</tr>
<tr>
<td>604932</td>
<td>Adapter clamp ring 22mm (Male)</td>
</tr>
<tr>
<td>600618</td>
<td>Adapter clamp ring 22mm (Female)</td>
</tr>
<tr>
<td>604292</td>
<td>Mount bracket Sedeo</td>
</tr>
</tbody>
</table>
## Appendix 3 Used materials

<table>
<thead>
<tr>
<th>Focal number</th>
<th>Description</th>
<th>Materials used</th>
</tr>
</thead>
<tbody>
<tr>
<td>603900 till</td>
<td>Sling (mechanical)</td>
<td>Aluminium 6082-T6 + RVS(AISI 304)</td>
</tr>
<tr>
<td>603908</td>
<td></td>
<td></td>
</tr>
<tr>
<td>603909 till</td>
<td>Sling (electrical)</td>
<td></td>
</tr>
<tr>
<td>603917</td>
<td></td>
<td></td>
</tr>
<tr>
<td>600923</td>
<td>Elbow strap (Small)</td>
<td>Neoprene</td>
</tr>
<tr>
<td>600920</td>
<td>Elbow strap (Medium)</td>
<td></td>
</tr>
<tr>
<td>600917</td>
<td>Elbow strap (Large)</td>
<td></td>
</tr>
<tr>
<td>600926</td>
<td>Elbow strap (X-Large)</td>
<td></td>
</tr>
<tr>
<td>600156</td>
<td>Mounting rod (Small)</td>
<td>Aluminium 6082-T6 + Mild steel 1.0038 (S235JRC+C)</td>
</tr>
<tr>
<td>600155</td>
<td>Mounting rod (Medium)</td>
<td></td>
</tr>
<tr>
<td>600154</td>
<td>Mounting rod (Large)</td>
<td></td>
</tr>
<tr>
<td>600157</td>
<td>Mounting rod (X-Large)</td>
<td></td>
</tr>
<tr>
<td>601198</td>
<td>Wrist strap with thumb cut-out (Type 1 left)</td>
<td>Neoprene</td>
</tr>
<tr>
<td>601200</td>
<td>Wrist strap with thumb cut-out (Type 1 right)</td>
<td></td>
</tr>
<tr>
<td>601202</td>
<td>Wrist strap with thumb cut-out (Type 2 left)</td>
<td></td>
</tr>
<tr>
<td>601204</td>
<td>Wrist strap with thumb cut-out (Type 2 right)</td>
<td></td>
</tr>
<tr>
<td>600616</td>
<td>Adapter clamp ring 20mm (Male)</td>
<td>Mild steel 1.0038 (S235JRC+C)</td>
</tr>
<tr>
<td>600615</td>
<td>Adapter clamp ring 20mm (Female)</td>
<td></td>
</tr>
<tr>
<td>604932</td>
<td>Adapter clamp ring 22mm (Male)</td>
<td></td>
</tr>
<tr>
<td>600618</td>
<td>Adapter clamp ring 22mm (Female)</td>
<td></td>
</tr>
<tr>
<td>604292</td>
<td>Mount bracket Sedio</td>
<td>Mild steel 1.0038 (S235JRC+C)</td>
</tr>
</tbody>
</table>

## Appendix 4 Declaration of conformity

![Declaration of conformity](image)

**EC DECLARATION OF CONFORMITY**

We,
Focal Meditech
Droogdokkenlaan 19
5026 SP Tilburg
The Netherlands

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,
Sling (type number 603900 till 603908) and its accessories

having the intended purpose: Sling 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 classified as Class I, according to Annex VIII, Rule number 1,
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
- EN 10993-1
- EN 13485
- EN 14971
- EN 15232-1
- EN 60601-1

Date: 1 April 2021
Name: Paul Groonder
Function: Managing Director

Tilburg, The Netherlands
Appendix 5 Conditions and Warranty

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

Conditions and Warranty: direct supply by Focal Meditech BV to 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.