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   Conditions and Warranty: Balancer supplied through a representative of Focal Meditech 28
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This is the user manual for Balancer 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 Balancer, 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 Balancer, 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**

<table>
<thead>
<tr>
<th>CE mark</th>
<th>This is a CE Class I medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="CE mark" /></td>
<td>Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the bottom side of Balancer</td>
</tr>
<tr>
<td><img src="image2" alt="CE mark" /></td>
<td>Do not remove this label. If the label is removed, the warranty will be void. This label is positioned at the bottom side of Balancer Heavy duty</td>
</tr>
</tbody>
</table>

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

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

Balancer can be mounted on a wheel/working chair or stand.

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

Balancer is not designed to withstand impacts that can be introduced during collisions with a wall or other objects. Also Balancer 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
Balancer 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. Balancer 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. Balancer 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 Balancer, please contact Focal Meditech or a healthcare professional as soon as possible.

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

---

**Intended use and operation of the device**

### Intended use
Balancer 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 Balancer 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 system Balancer is a system that consists of several beams which are interconnected via pivoting points. The beams are connected to a manually adjustable gravity compensation mechanism. At the distal end of the system an arm fitting and elbow fitting attached. Balancer is mounted on the ‘solid’ world (wheel or working chair or stand). The lower arm of the user is placed in the arm fitting, and Balancer can support the weight of the under and partly the upper arm. The rotatable beam will support movements of the human underarm and hand.

Balancer 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 Balancer combined with the accurate fit of the arm fitting results in little muscle forces required of the user. The setup of the rotation axis and use of rope to transmit the balancing force results in a large range of motion. Gravity compensation characteristics of the device can depend on individual requirements easily be adjusted

Balancer can be used one- or two sided. Several properties of the user being the personal limitations, possibilities combined with the needs of the user determine if one or two Balancers are required.
**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:** Balancer 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 Balancer 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:** Balancer 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 Balancer 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 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 balancing mechanism to the Human Interface.
- The horizontal tube brings the arm fitting into the user’s working area.
- Link rotation can be used to level the horizontal tube or to fold the Balancer. It also provides a pivoting point in the horizontal plane.
- The vertical tube brings the horizontal tube above the user.
- Both link rotation and link vertical can be used to fold the Balancer.
- The balancing mechanism contains the spring system which generates the balancing force. In addition, the balancing force can be set using the knob balancing force.
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 hook is well closed.

Adjusting the tilting point
Although the Balancer can be used with only a wrist strap, Balancer 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.

⚠️ Warning: The settings of the tilting point are of great importance for the functioning of Balancer. Changing these positions can result in a severe decrease of the performance or even malfunction of Balancer. Therefore, only trained persons are allowed to change the settings of the tilting point.

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 Human Interface 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.


**Connect and disconnect the Human Interface**

When the user wants to fold Balancer, 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 Balancer.

- **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:** Make sure that the balance force is set to the minimum.

**STEP 2:** Hold with one hand the rope just above the mounting loop and with the other hand the slide bar.

**STEP 3:** Pull the rope with mounting loop to a comfortable height.

**STEP 4:** Clip and hold open the snap hook.

**STEP 5:** Lift the Human Interface in an 45° angle out of the mounting loop.

**STEP 6:** Let the rope slowly retract into the Balancer.

To connect the Human Interface, follow the steps.

**STEP 1:** Make sure that the balance force is set to the minimum.

**STEP 2:** Hold with one hand the rope just above the mounting loop and with the other hand the slide bar.

**STEP 3:** Pull the rope with mounting loop to a comfortable height.

**STEP 4:** Clip and hold open the snap hook.

**STEP 5:** Lower the Human Interface in an 45° angle in the opening of the mounting loop.

**STEP 6:** Let the rope slowly retract into the Balancer.

---

**Folding and unfolding the Balancer**

The Balancer can be folded when it is not used. This provides a safe setting for the user and the device. There are two options to fold the Balancer, only the horizontal tube for a quick folding option or both the horizontal and vertical tubes for a more compact setting.

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

- **Warning:** After folding back, the Balancer make sure that the levers are tighten firmly however do not overtighten the levers or replace them with a nut.

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

**Folding horizontal bar:**

**STEP 1:** Loosen the lever of the rotation link.

**STEP 2:** Hold with one hand the vertical tube and with the other hand the horizontal tube.

**STEP 3:** Move the horizontal tube 90° down.

**STEP 4:** Tighten the lever of the rotation link.

**Folding vertical bar:**

**STEP 1:** Loosen the lever of the Vertical link.

**STEP 2:** Hold with one hand the combination of the vertical with horizontal tube and with the other hand the mounting tube.

**STEP 3:** Move the combination 180° backwards.

**STEP 4:** Tighten the lever of the vertical link.
To fold back Balancer, follow the steps.

Fold back vertical bar:
STEP 1: Loosen the lever of the Vertical link.
STEP 2: Hold with one hand the combination of the vertical with horizontal tube and with the other hand the mounting tube.
STEP 3: Move the combination 180° forwards.
STEP 4: Tighten the lever of the vertical link.

Fold back horizontal bar:
STEP 1: Loosen the lever of the rotation link.
STEP 2: Hold with one hand the vertical tube and with the other hand the horizontal tube.
STEP 3: Move the horizontal tube 90° up.
STEP 4: Tighten the lever of the rotation link.

Adjust the balancing force
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 and can be used to adjust the system using little force. Rotating the knob clockwise will give more balancing force, counter clock wise will give less 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.

Rotation
The Balancer has a rotation of 30° to the left and 30° 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 inform always a Focal or a by Focal authorized representative.

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.

The rotation of the Balancer can be changed, however this is depending on couple of variables. For example the adapter that is used or the type of wheelchair. Detailed information and installation instructions (how to fixate the adapter) comes with the adapter.
Controls

There are no electrical / software controls available for Balancer.

Accessories

There are no accessories available for Balancer.

Mounting instructions

In order to make stable and safe use of Balancer, there are a couple of mounting brackets developed for Balancer. 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 Balancer. There are no serviceable parts inside Balancer. Contact Focal Meditech for any maintenance issues.

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

Reuse
To reuse Balancer, it must be disassembled and reviewed by Focal Meditech or an authorized professional that is approved by Focal Meditech. Balancer must intensively be cleaned and inspected. The plastic parts of the buttons can be removed and replaced by new button parts. The arm fitting and elbow fitting have to be replaced.
Focal Meditech will refurbish and repackage the reused Balancer in such a way that it will meet the safety and performance requirements according to applicable regulations.

Decommissioning

Appendix 1 Technical specifications

Specifications Balancer

<table>
<thead>
<tr>
<th>Mass</th>
<th>2.5</th>
<th>kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (in default position)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>778</td>
<td>mm</td>
</tr>
<tr>
<td>Width</td>
<td>120</td>
<td>mm</td>
</tr>
<tr>
<td>Depth</td>
<td>499</td>
<td>mm</td>
</tr>
<tr>
<td>Range of motion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up/Down</td>
<td>At least 800</td>
<td>mm</td>
</tr>
<tr>
<td>Forward backward stroke</td>
<td>it's a pendulum</td>
<td>mm</td>
</tr>
<tr>
<td>Horizontal rotation</td>
<td>± 30</td>
<td>°</td>
</tr>
<tr>
<td>Balance mass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up/Down</td>
<td>0...1.5</td>
<td>kg</td>
</tr>
<tr>
<td>Mass (heavy duty)</td>
<td>0...3</td>
<td>kg</td>
</tr>
<tr>
<td>Mechanic adjustable</td>
<td>0...100</td>
<td>%</td>
</tr>
<tr>
<td>Mounting position</td>
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<td></td>
</tr>
<tr>
<td>Maximum allowed mounting angle</td>
<td>-20...20</td>
<td>°</td>
</tr>
<tr>
<td>Storage conditions</td>
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<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>-40...85</td>
<td>°C</td>
</tr>
<tr>
<td>Humidity</td>
<td>35...85</td>
<td>% non-condensing</td>
</tr>
<tr>
<td>Operation conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>-10...+50</td>
<td>°C</td>
</tr>
<tr>
<td>Humidity</td>
<td>35...85</td>
<td>% non-condensing</td>
</tr>
<tr>
<td>Degree of protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IP-class</td>
<td>IP40</td>
<td></td>
</tr>
<tr>
<td>(IEC60529)</td>
<td></td>
<td></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.

Appendix 2 Part numbers

<table>
<thead>
<tr>
<th>Article number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>600236</td>
<td>Balancer</td>
</tr>
<tr>
<td>600235</td>
<td>Balancer heavy duty</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>Article number</th>
<th>Description</th>
<th>Materials used</th>
</tr>
</thead>
<tbody>
<tr>
<td>600236</td>
<td>Balancer</td>
<td>Aluminium 6082-T6 + RVS(AISI 304)</td>
</tr>
<tr>
<td>600235</td>
<td>Balancer heavy duty</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>603501</td>
<td>Wrist strap (Small)</td>
<td>Neoprene</td>
</tr>
<tr>
<td>603499</td>
<td>Wrist strap (Medium)</td>
<td></td>
</tr>
<tr>
<td>603497</td>
<td>Wrist strap (Large)</td>
<td></td>
</tr>
<tr>
<td>603503</td>
<td>Wrist 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</td>
<td>Neoprene</td>
</tr>
<tr>
<td>(Type 1 left)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>601200</td>
<td>Wrist strap with thumb cut-out</td>
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<tr>
<td>(Type 1 right)</td>
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<tr>
<td>601202</td>
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<tr>
<td>(Type 2 left)</td>
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<tr>
<td>601204</td>
<td>Wrist strap with thumb cut-out</td>
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</tr>
<tr>
<td>(Type 2 right)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>600616</td>
<td>Adapter clamp ring 20mm (Male)</td>
<td>Mild steel 1.0038 (S235JRC+C)</td>
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<td>600615</td>
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<td>604932</td>
<td>Adapter clamp ring 22mm (Male)</td>
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<tr>
<td>600618</td>
<td>Adapter clamp ring 22mm (Female)</td>
<td></td>
</tr>
<tr>
<td>604292</td>
<td>Mount bracket Sedeo</td>
<td>Mild steel 1.0038 (S235JRC+C)</td>
</tr>
</tbody>
</table>

### Appendix 4 Declaration of conformity

EC DECLARATION OF CONFORMITY

We, 
Focal Meditech 
Droogdokkenland 19 
5028 SP Tilburg 
The Netherlands

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

Balancer (type number 600236) 
Balancer Heavy Duty (type number 600235) 
and its accessories

having the intended purpose: Balancer 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 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 1094 - Information supplied by manufacturer of medical devices 
* EN 1099-1 - 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

Signature: 
Tilburg, The Netherlands

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

Focal Meditech BV 
Droogdokkenland 19 
5028 SP Tilburg
Appendix 5 Conditions and Warranty

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