



# Balancer

## User manual

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## Introduction

This is the user manual for the Balancer dynamic arm support. Balancer is produced and can also be supplied by Focal Meditech BV. This manual provides you with information about the product, its use and the consequences of its use.

The aim of this information is to enable the user to get the best and safest use out of the dynamic arm support over the long term. The information will tell you what you should and should not expect from the dynamic arm support, how the device can be adjusted, and what you should bear in mind when using it. You will also find all the supplier contact details.

Read this information carefully: a better understanding of the product will enable you to get the most out of it and lead to better results.

Always keep this manual on hand so that you can consult it easily.

## Explanation of symbols

Symbols used in this manual	
 <p>Warning!</p>	<p>This symbol is used to indicate important information that may help you avoid serious personal injury, which may ultimately result in death.</p>
 <p>Waste</p>	<p>This symbol is used to indicate that this product may not be disposed of with your household waste, in accordance with the WEEE directive (2002/96/EC) and national legislation. When you buy a new, similar such product, this product must be taken to a designated collection point, or to an authorised recycling centre for electrical and electronic equipment (EEE). Improper processing of this type of waste can have a negative impact on the environment and on public health resulting from potentially hazardous substances which are commonly associated with EEA. By helping to dispose of this product in the proper manner, you will also be contributing to the effective use of natural resources. For more information about where used products can be handed in for recycling, please contact your local council offices, waste collection point, authorised EEA body or household waste disposal service.</p>
<i>Packaging</i>	
 <p>Fragile</p>	 <p>This side up</p>
 <p>Protect against moisture</p>	 <p>Do not stack</p>

## Certification notes

	This is a CE class 1 medical device
	This label must not be removed. Removal of this label will result in termination of the warranty.
	
<b>Dutch Cliq classification:</b>	
241827030309	Forearm supports, compensation of reduced muscle function and change in range of movement, support arm construction
241827060309	Forearm supports, control of excessive muscle function, support arm construction
241827090309	Forearm supports, redistribution of pressure/force, support arm construction
241827990306	Forearm pad

## Safety notes

	<b>Danger:</b>	Avoid direct contact with water or other fluids. Failure to do so may lead to incorrect functioning of the equipment or to personal injury.
	<b>Danger:</b>	Avoid exposure to extreme temperatures (see environmental conditions). Failure to do so may lead to incorrect functioning of the equipment or to personal injury.
	<b>Warning:</b>	Balancing of the arm is achieved with the aid of mechanical energy. If the arm slips out of the arm pad, mechanical energy will be released resulting in a fast-moving arm-fitting. This may result in physical injury (for more information, see page 9)
	<b>Warning:</b>	Do not make changes to any part of this equipment without the permission of the manufacturer. Failure to do so may lead to incorrect functioning of the equipment or to personal injury.
	<b>Warning:</b>	If the equipment is not functioning correctly, you should contact Focal immediately. Do not try to repair it yourself. Failure to observe this warning may lead to the termination of the warranty.
	<b>Warning:</b>	In case of doubt about safety, please contact Focal.

## Contact details

Balancer is produced and sold by:

Focal Meditech BV  
 Droogdokkeneiland 19  
 5026 SP Tilburg  
 The Netherlands  
 Tel.: +31 (0)88 119 31 3  
 Tel.: +31 (0)88 119 50 4  
 E-mail: [info@focalmeditech.nl](mailto:info@focalmeditech.nl)  
 Internet: [www.focalmeditech.nl](http://www.focalmeditech.nl)

## Intended user and use of the device

### Application of the device

Balancer is a dynamic, suspension-type arm support: the weight of the arm is compensated for from above. A cord attached to the arm of the user fed through a system of tubes to a pre-tensioned spring mechanism which enables the user to move the forearm freely.

Balancer is an aid to persons with a reduced arm function. It enables them to move their arms and hands more easily. Balancer eliminates gravity by lifting the weight of the arm. The device helps persons extend their reach, to grip and to manipulate, and to carry out everyday activities, such as eating, drinking, using the computer, communication and games.

Intended users of the Balancer dynamic arm support are:

1. Persons who are disabled as a result of a significant muscle weakness, resulting in an inability to carry out essential activities of daily living (ADL), including eating, drinking, facial care, use of the computer and wheelchair controls.
2. Persons who are disabled as a result of hypertonic muscle tone – likewise resulting in the above.
3. Persons who need to redistribute pressure and forces - likewise resulting in the above.
4. Combinations of these.

Where relevant, with a need for an aid requiring a limited amount of learning to use.

### Intended use of the device

Balancer is a medical device. Balancer can be used on one or both sides. The device can be mounted on a wheelchair, a chair or on a mobile base, as required. Due to its well-thought-out design and use of high-quality materials, it offers easy, unimpeded use.

Balancer can be actively used in all sorts of settings: at home, at school or in the workplace, in an institution or outdoors.

Because of the risk of physical strain, in the first instance, use of the device by persons with a limited arm and hand movement needs to be carried out gradually and under expert supervision.

### Risks and contra-indications

There are no known major risks associated in using Balancer. Balancer is a device that an intended user must be able to use. Nevertheless, there are no known contra-indications with respect to the use of Balancer. In order to use Balancer effectively, the user must take note of the following warnings.

	<b>Warning:</b>	The arm support cannot be used by users as a support for raising themselves. During the evaluation phase, ensure that the user has a sufficiently stable sitting position, and, if required, the user is able to raise himself/herself adequately.
	<b>Warning:</b>	Balancer does not have any parts which can be repaired or replaced by the user or persons in their surroundings. Opening up the device or making modifications to it can lead to damage or defects in its proper working and to the warranty being terminated.

## Technical information



### Description

The following components of Balancer are described below:

- From the user's perspective, the point of contact with Balancer is via the wrist/arm-fitting into which the user's wrist/arm is inserted. As such, the arm-fitting is a component which is specific to the individual user. The arm-fitting is connected to an attachment. When in use, the user's arm must remain in contact with this arm-fitting at all times.
- The cord is used to transfer the force from the spring mechanism to the arm-fitting.
- The horizontal arm brings the arm-fitting into the working reach of the user.
- Hinge 1 can be used to rotate the horizontal arm so that the system can be folded.
- The vertical arm brings the horizontal arm above the user.
- Hinge 2 can be used to enable Balancer to be folded.
- The spring mechanism contains the spring with which the balancing force is achieved. Additionally, the balancing force can be adjusted using the knob.

## Adapting the arm balance

Balancer can be designed with both a wrist- and an arm-fitting. This enables the forearm to be balanced.



### Warning:

The functioning of Balancer is to a large part determined by the settings on the wrist- and arm-fitting. Altering these settings can result in a significant deterioration in performance or the Balancer not functioning at all. For that reason only qualified persons are permitted to adjust the settings on the wrist- and arm-fittings.

- **Wrist support**

The desired balance for the forearm can be adjusted by shifting the forearm in relation to the wrist-fitting. For that reason, try to seek a balance whereby the forearm can be tilted easily back and forth in the support unit.

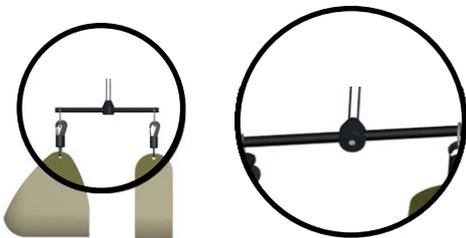


The more the wrist-fitting is moved backwards (i.e. towards the elbow), the easier the arm and hand can be tilted downwards.

If the wrist-fitting is moved forwards, the arm and the hand can be tilted upwards more easily.

- **Arm-fitting**

The desired balance for the forearm can be set by shifting the spindle in relation to the rod. For that reason, try to seek a balance whereby the forearm can be tilted easily back and forth in the support units.



The spindle can be moved by loosening the socket-head screw underneath. Slide the rod into the spindles and re-tighten the screw.



The more the spindle is moved backwards (i.e. towards the elbow), the easier the arm and hand can be tilted downwards.



If the spindle is moved forwards, the arm and the hand can be tilted upwards more easily.

In both cases, the settings should be such that the forearm is able to rest on the lowest position of the armrest or, if required, in the user's lap.

## Adapting the balancing force

To enable the arm to move freely, the weight of the arm is compensated for using a balancing system. Considerable forces are required to compensate for the weight of the arm. In order to use the system safely, it is essential for the arm to be in a stable position in the arm-fitting

The balancing force can be modified by turning the knob on the spring mechanism. Turn the knob in an anti-clockwise direction to increase the balancing force. For less balancing force, the knob first must first be retracted and turned in a clockwise direction whilst retracted.



### Warning:

If you feel that the arm is not stable and may slip out of the arm pad, it will be necessary to position the arm back in the system.

## Folding and unfolding the Balancer

### 1 Unfolding the Balancer

From its storage position, the vertical rod is unfolded by placing it in a vertical position. The shaft on the vertical rod is then fixed in position by *firmly turning the black lever to the right*. Do not pull the lever outwards. Repeat the same procedure for the shaft on the horizontal rod. The lever should only be pulled outwards to fix this in its optimum position after unfolding.

### 2 Folding the Balancer

Start by loosening the shaft on the vertical rod. This will avoid the user's head coming into contact with it when Balancer is being unfolded. This is loosened by turning the black lever anti-clockwise through 90 degrees. Do not turn this any further.



### Warning:

If you turn this through more than 90 degrees, this may result in the small locking pin under the black disc on the rear of the shaft (not visible during normal use) no longer holding this disc in position.

Should the locking pin no longer function as a result of turning the lever too far and the rear disc starts to rotate freely, the following needs to be done:

- Push the shaft back so that the rear disc fits onto the shaft mechanism.
- Rotate this disc using the hand until the locking pin clicks back into position in its hole.

## Assembly instructions

The horizontal arm of Balancer should be positioned slightly above the user's head. The position of the housing with the spring mechanism depends on the available space. It's important that you do not select a setting that brings about an unfavourable horizontal arc (the range of the rotating arm). The technician can adjust this range.



**Warning:**

When installing Balancer, you should take note of the horizontal (sideways) range of the horizontal arm. At all times this needs to stay within the dimensions of the wheelchair. This is because the horizontal arm might otherwise get jammed in a doorway or narrow opening and cause irreparable damage.

## Maintenance instructions

### Maintenance of physical components

All housings and the cord must be inspected on a regular basis. If these parts are visibly damaged, the device should not be used. It is not permitted to make any alterations to Balancer. There are no components in Balancer which can be maintained by parties other than Focal. Please contact Focal if you have any questions about maintenance. When Balancer is not mounted on its mounting unit, the device should always be stored in its box. This is so that the effects of falling or other mishaps can be avoided that might damage the system.

### Cleaning

Balancer requires limited maintenance. Balancer can be cleaned using a damp cloth and a non-aggressive cleaning agent.

### Recycling

Balancer needs to be taken apart by a professional. Balancer then needs to be cleaned and inspected intensively. The arm-fitting must be replaced.



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## DECLARATION OF CONFORMITY

**WE:**

**MANUFACTURER:** Focal Meditech BV

**ADDRESS:** Droogdokkeneiland 19  
5026 SP Tilburg  
Netherlands

**TEL.:** +31 13 533 3103

**FAX:** +31 13 533 5004

**WEBSITE:** www.focalmeditech.nl

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

<b>DEVICE (MODEL):</b>	<b>DESCRIPTION</b>
872FOCSABLC**ABC091	Balancer complete
872FOCSABLC**ABD291	Balancer complete (Heavy duty)

(\*\*) means each number between 00 and 99 (for internal use Focal)

**have been classified as Class I, according to Annex IX, rule number 1,**

**and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC**

**and are subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.**

**SIGNED AT:** Tilburg, The Netherlands

**DATE:** 28-8-2017

**SIGNATURE:**

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P.C.M. Groenland  
CEO

## Appendix 2 Conditions and warranty

### **Conditions and warranty: by an authorised representative of Focal Meditech BV**

The conditions and warranty in the event of issue by authorised representative of Focal Meditech BV are in accordance with the conditions of the national or local authorised representative. This being in accordance with national legislation.

### **Conditions and warranty: direct delivery by Focal Meditech BV to consumers**

In the event of delivery by Focal Meditech BV to purchasers who are consumers, the General terms & conditions for consumers of the Koninklijke Metaalunie apply. This being in accordance with national legislation.