FOCAL meditech

listening
creating
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Dowing

User manual

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Dowing is a registered trademark of Focal Meditech BV.
Dowing Model Design is registered by Focal Meditech BV.

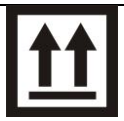
Content

Manual introduction

This is the user manual for Dowing, a dynamic arm support system. This product is developed, manufactured and possibly distributed by Focal Meditech B.V. This manual contains the information regarding Dowing, the intended use and the consequences of usage. The aim of this information is to ensure successful, safe and effective use of the device. This manual contains the essential information for using Dowing, safety issues and contact information.

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

Symbol explanation

Symbols used in user manual	
 Warning!	This symbol is used when there is important information which can help you avoid the risk of serious personal injury or death.
 Disposal	This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2002/96/EC) and your national law. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or your household waste disposal service.
Packaging	
 Fragile	 This way up
 Keep away from water	 Do not stack

Certifications Notices

CE	This is a CE Class I medical device
Classification cf. Dutch Cliq 2013:	
241827030309	Dynamic Arm Supports, compensation of diminished muscle function and change of range of motion, load arm construction, hybrid actuation
241827060309	Dynamic Arm Supports, managing excessive muscle functioning, hybrid actuation
241827090309	Dynamic Arm Supports, redistribution of pressure/forces, hybrid actuation
241827990306	Forearm support
241827990900	Axis locking

Safety notices

	**Danger:**	Prevent direct contact with water or any other liquid. Failure of this can lead to malfunctioning of device or bodily harm
	**Danger:**	Prevent extreme temperature (see environment conditions). Failure of this can lead to malfunctioning of the device or bodily harm
	**Danger:**	During installation ensure there is at least a fuse of 5A between power supply and Dowing. Failure of this can lead to malfunctioning of the device and bodily harm
	**Warning:**	Do not modify any part of this equipment without authorization of the manufacturer. Failure of this can lead to malfunctioning and loss of warranty
	**Warning:**	In case of faulty device contact Focal. Do not try to fix it yourself. Failure of this can lead to loss of warranty
	**Warning**:	In case of doubt about safety of the device contact Focal

Contact information

Dowing is manufactured and sold by

Focal Meditech BV
Droogdokkeneiland 19
5026SP Tilburg
Netherlands
Tel.: +31 (0)13-533 31 03
Fax: +31 (0)13-533 50 04
E-mail: info@focalmeditech.nl
Internet: www.focalmeditech.nl

Intended use and operation of the device

Operation of the device

The dynamic arm support system Dowing 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. Dowing is mounted on the 'solid' world (table or working chair). The under arm of the user is placed in the arm fitting, and Dowing can support the weight of the under and partly the upper arm. The axes of Dowing will support movements of the human underarm and hand.

Dowing 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 Dowing combined with the accurate fit of the arm fitting results in little muscle forces required of the user. The kinematic chain of the axes results in a large range of motion. Gravity compensation characteristics of the device can depending on individual requirements easily be adjusted

The intended users of the dynamic arm support Dowing are:

1. Persons challenged by muscular weakness causing the inability to perform essential Activities of Daily Living (ADL) activities including eating, drinking, facial care, computer use. Dowing's users are not requiring frequent or dynamic adjustments.
2. Persons challenged by excessive muscle functioning – ditto.
3. Persons in the need of redistribution of pressure/forces - ditto.
4. Combinations of these.
5. Persons who do not suffer from one or more of the above mentioned medical conditions but who are at risk for such conditions e.g. due to repetitive movements, work above shoulder height or precision work. Being at risks may include the consequences of Complaints of Arm Neck and-or Shoulder (CANS) and similar work related disorders.

In the need of a functional device requiring limited learning efforts.

Intended use of the device

Dowing is a medical device. It is primarily designed for persons having a need for compensation of muscle force. Depending upon personal (dis)abilities Dowing may also diminish the effects of excessive muscle functioning (guide spastic movements). Further, Dowing will redistribute pressures and forces of the arm and shoulder concerned and can possibly diminish pain in the shoulder girdle .

Dowing 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 Dowings are required.

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

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

The intended use of Dowing also includes the application as an ergonomic aid for 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.

Dowing is not designed to be used in combinations of large forces. Dowing cannot be used as a support when standing up or getting seated or as an autonomous lifting device (without supporting the human arm).
Dowing is not designed to withstand impacts that can be introduced during collisions with a wall or other objects. Also Dowing 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

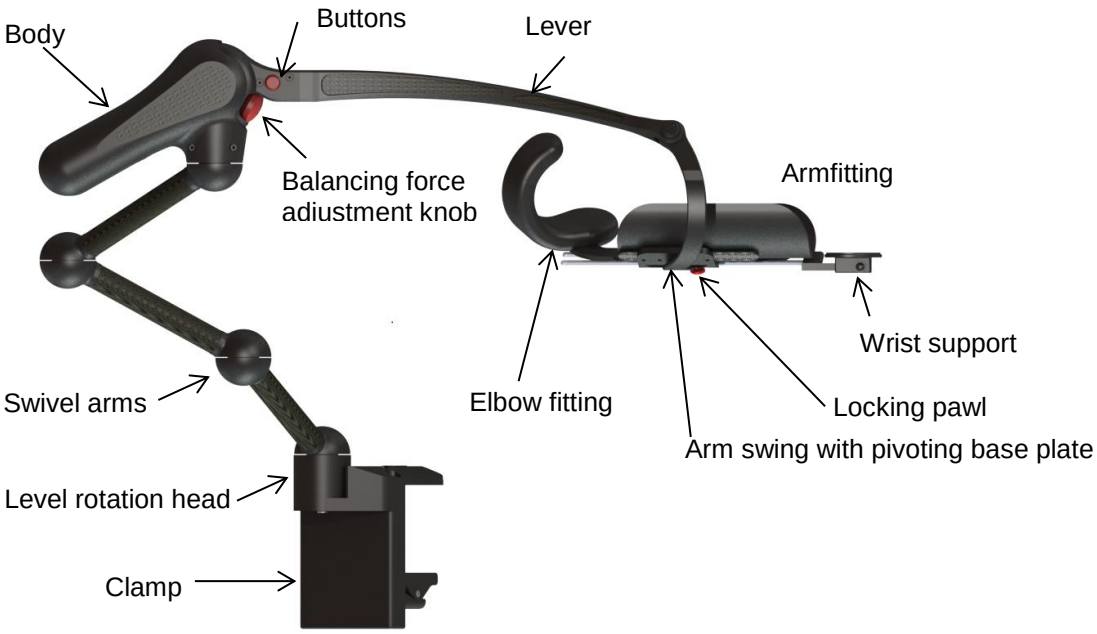
Dowing supports the execution of numerous daily activities like eating, drinking, tooth brushing, typing or scratching one's nose. Independence in lifting and manipulating objects and in personal care is possible again. In general it is desirable for users to use their remaining capacities as much as 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. Dowing 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. Dowing returns the natural freedom of movement to the user.

Risks and contra-indications

No essential user risks are known while using Dowing. Dowing is an aid which should be used by the intended users. However there are no known contra-indications for Dowing. To be able to use Dowing 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:**	Dowing 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 Dowing 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:**	Dowing 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 loss of warranty
	Warning:	For safety reasons, Dowing can only be removed from the locking position when the user's arm is correctly positioned in the arm fitting.

Technical information



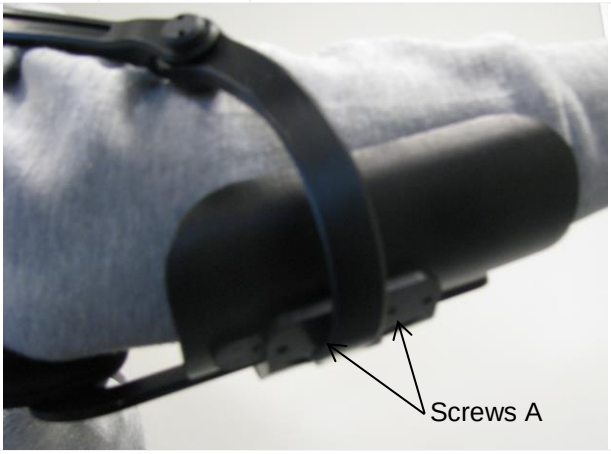
Description

The following parts of Dowing are described

- From a user perspective the contact point with Dowing is the arm fitting where the under arm of the user is positioned in..
- The elbow fitting. The upper arm of the user should be in contact with this part during the use of Dowing.
- The optional 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 arm swing with pivoting base plate which holds the arm fitting, elbow fitting and the wrist support.
- Locking pawl.
- The lever is connecting the arm, elbow fittings and the wrist support to the body of Dowing.
- At the top of Dowing there are two red buttons. Pressing these two buttons towards each other makes it possible to remove the lever, arm swing containing the arm fitting, elbow fitting and the optional wrist support.
- Body of Dowing. The body of Dowing contains: -the balancing system including the possibility to adjust the balancing force.
- Balancing force adjustment knob.
- Swivel arms
- Level rotation head
- Clamp

Adjusting the arm swing, arm fitting and elbow fitting

Warning: The positions of arm fitting and elbow fitting are crucial for the performance of Dowing. Changing these positions can result in a severe decrease of the performance or even malfunction of Dowing. 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 Dowing.

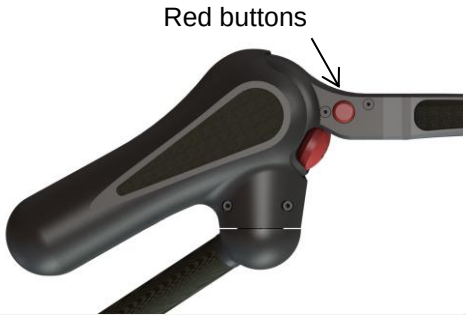
The arm fitting can be adjusted in one direction Adjusting the position of the arm fitting. Loose one or multiple screws (A). Adjust the arm fitting by shifting this fitting. Fasten all screws (A).

Warning: adjusting the elbow fitting can result in malfunction of Dowing for the user.

The elbow fitting can be adjusted in two directions:

1. Adjusting the rotation of the elbow fitting: loose screw (B) until the fitting can be rotated. Adjust the fitting and fasten the screw (B).
2. Adjusting the position of the elbow fitting: loose one or multiple screws (C). Adjust the elbow fitting by shifting this fitting. Fasten all screws (C).

Disconnect the lever



The lever including the arm swing, arm fitting, elbow fitting and wrist support can be removed easily. To disconnect the lever, press both red buttons at the top of Dowing, and move the lever away from the body in the upwards direction.

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

Remove Dowing

Dowing can easily be removed from the table or chair clamp.

Remove Dowing
Step 1: Lock Dowing in the parking position
Step 2: Remove the user's arm
Step 3: Remove Dowing from the parking position. Warning: the arm fitting will move upwards due to the spring
Step 4: Remove the lever
Step 5: Hold with one hand the body of Dowing; lift with the other hand the lower extension arm from the clamp
Step 6: Store Dowing in its case

Replace Dowing
Step 1: Position Dowing above the clamp
Step 2: Lower Dowing
Step 3: Attach the lever
Step 4: Position the user's arm in the arm fitting

Controls

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Accessories

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Mounting instructions

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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 Dowing. There are no serviceable parts inside Dowing. Contact Focal for any maintenance issues.

In case Dowing 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 Dowing is limited. Dowing can be cleaned using a moist cloth and a non-aggressive scour.

Reuse

To reuse Dowing, it has to be disassembled by a professional. Dowing 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.

Decommissioning

Appendix 1 Technical specifications

Specifications

Dowing		
Range of motion		
Up/Down	490	[mm] @ end of lever
Forward/Backward stroke	390	[mm] @ end of lever
Horizontal rotation	unlimited	
Balance mass		
Up/Down		
Mass	0.25 to 5	[kg] @ end of lever
Rotation block tilt function		
Angle	-20 .. 20	[°]
Mass		
Dowing body	6.8	[kg]
Storage		
Temperature	-40 .. 85	[°C]
Humidity	35 .. 85	[%] non condensing
Mounting position		
Maximum allowed mounting angle	-20..20	[°]
Operating		
Temperature	-10 .. 50	[°C]
Humidity	35 .. 85	[%] non condensing
Degree of protection (DIN 40050)	IP40	

Appendix 2 Part numbers

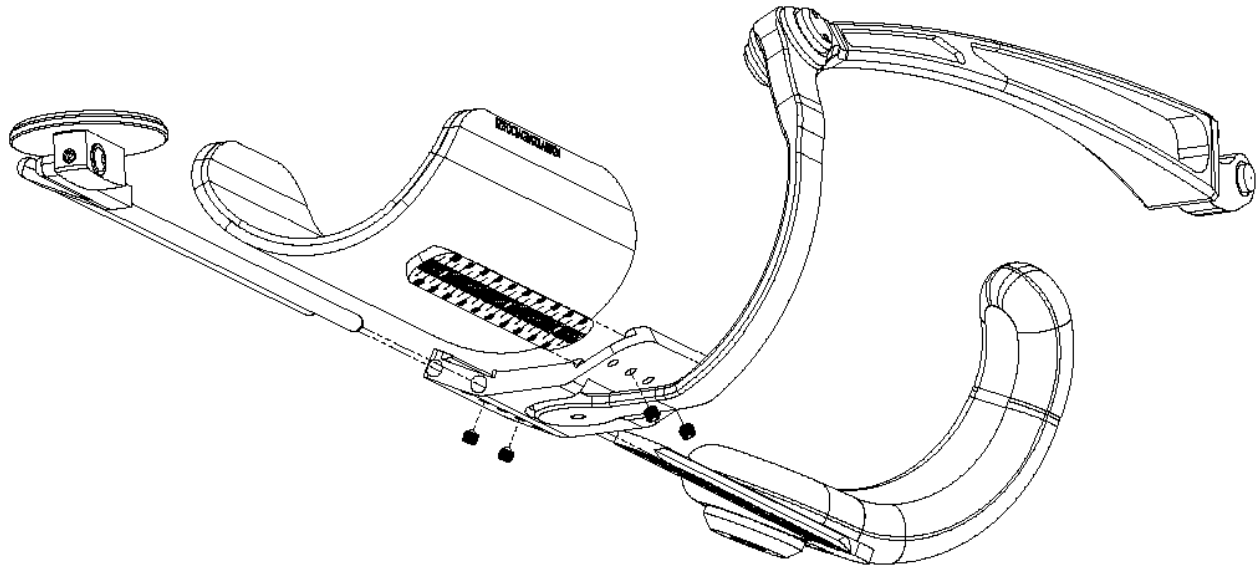
872FOCSADWG**ABB817	Dowing
872FOCSADWG**ABB819	Table mount
872FOCSADWG**ABB885	Chair mount
872FOCSAGWG**ABB122	Loadarm with arm swing right (Large)
872FOCSAGWG**ABB123	Loadarm with arm swing left (Large)
872FOCSAGWG**ABB212	Loadarm with arm swing left (X-Large)
872FOCSAGWG**ABB213	Loadarm with arm swing right (X-Large)
872FOCSAGWG**ABB144	Subassembly wrist support (Right)
872FOCSAGWG**ABB145	Subassembly wrist support (Left)
872FOCSAGWG**ABB140	Subassembly Elbow fitting Left (Large)
872FOCSAGWG**ABB141	Subassembly Elbow fitting Right (Large)
872FOCSAGWG**ABB214	Subassembly Elbow fitting Left (Small)
872FOCSAGWG**ABB215	Subassembly Elbow fitting Right (Small)
872FOCSAGWG**ABB130	Subassembly Armfitting size 1 Right
872FOCSAGWG**ABB131	Subassembly Armfitting size 1 Left
872FOCSAGWG**ABB132	Subassembly Armfitting size 2 Right
872FOCSAGWG**ABB159	Subassembly Armfitting size 2 Left
872FOCSAGWG**ABB133	Subassembly Armfitting size 3 Right
872FOCSAGWG**ABB134	Subassembly Armfitting size 3 Left
872FOCSAGWG**ABB135	Subassembly Armfitting size 4 Right
872FOCSAGWG**ABB136	Subassembly Armfitting size 4 Left
872FOCSAGWG**ABB631	Subassembly Armfitting size 5 Right
872FOCSAGWG**ABB630	Subassembly Armfitting size 5 Left

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

Appendix 3 Used materials

Part	Focal number	Material
872FOCSADWG**ABB878	Subassembly Dowing	Aluminium 6082T6+ RVS(AISA 304)
872FOCSADWG**ABB819	Subassembly Table clamp	Aluminium 6082T6+ RVS(AISA 304)
872FOCSADWG**ABB885	Subassembly Chair clamp	Aluminium 6082T6+ RVS(AISA 304)
872FOCSAGWG**ABB122	Load arm with arm swing	Aluminium 6082T6+Aisi + RVS(AISA 304)
872FOCSAGWG**ABB123		
872FOCSAGWG**ABB212		
872FOCSAGWG**ABB213		
872FOCSAGWG**ABB144	Subassemblies wrist support	Aluminium 6082T6+Aisi + RVS(AISA 304) + NEOPRENE+ Celrubber+ POM
872FOCSAGWG**ABB145		
872FOCSAGWG**ABB140	Subassemblies Elbow fitting	Aluminium 6082T6+Aisi + RVS(AISA 304) + NEOPRENE+ Celrubber+ POM
872FOCSAGWG**ABB141		
872FOCSAGWG**ABB214		
872FOCSAGWG**ABB215		
872FOCSAGWG**ABB130	Subassemblies Arm fitting	Aluminium 6082T6+Aisi + NEOPRENE+ POM
872FOCSAGWG**ABB131		
872FOCSAGWG**ABB132		
872FOCSAGWG**ABB159		
872FOCSAGWG**ABB133		
872FOCSAGWG**ABB134		
872FOCSAGWG**ABB135		
872FOCSAGWG**ABB136		
872FOCSAGWG**ABB630		
872FOCSAGWG**ABB631		

Appendix 4 Mounting instructions Dowing



Assembly of a left arm support.

Appendix 7 Declaration of conformity

WE:	
MANUFACTURER:	Focal Meditech B.V.
ADDRESS:	Droogdokkeneiland 19
	5026 SP Tilburg Netherlands
TEL:	+31 13 533 3103
FAX:	+31 13 533 5004
WEBSITE:	www.focalmeditech.nl

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HEREBY DECLARE THAT THE DEVICE:

DEVICE (MODEL):	**DESCRIPTION**
872FOCSADWG**ABB817	Subassembly Dowing
872FOCSADWG**ABB819	Subassembly Table clamp
872FOCSADWG**ABB885	Subassembly Chair clamp
872FOCSAGWG**ABB122	Loadarm with arm swing right (Large)
872FOCSAGWG**ABB123	Loadarm with arm swing left (Large)
872FOCSAGWG**ABB212	Loadarm with arm swing left (X-Large)
872FOCSAGWG**ABB213	Loadarm with arm swing right (X-Large)
872FOCSAGWG**ABB144	Subassembly wrist support Right
872FOCSAGWG**ABB145	Subassembly wrist support (Left)
872FOCSAGWG**ABB140	Subassembly Elbow fitting Left (Large)
872FOCSAGWG**ABB141	Subassembly Elbow fitting Right (Large)
872FOCSAGWG**ABB214	Subassembly Elbow fitting Left (Small)
872FOCSAGWG**ABB215	Subassembly Elbow fitting Right (Small)
872FOCSAGWG**ABB130	Subassembly Armfitting size 1 Right
872FOCSAGWG**ABB131	Subassembly Armfitting size 1 Left
872FOCSAGWG**ABB132	Subassembly Armfitting size 2 Right
872FOCSAGWG**ABB159	Subassembly Armfitting size 2 Left
872FOCSAGWG**ABB133	Subassembly Armfitting size 3 Right
872FOCSAGWG**ABB134	Subassembly Armfitting size 3 Left
872FOCSAGWG**ABB135	Subassembly Armfitting size 4 Right
872FOCSAGWG**ABB136	Subassembly Armfitting size 4 Left
872FOCSAGWG**ABB631	Subassembly Armfitting size 5 Right
872FOCSAGWG**ABB630	Subassembly Armfitting size 5 Left

COMPLY WITH THE FOLLOWING STANDARDS:

NUMBER	**TITLE**
EN ISO 14971	Medical devices - Application of risk management to medical
ISO 10993-1	Biological evaluation of medical devices - evaluation and testing
EN12182	Assistive products for persons with disability - General requirements and test methods
IEC 60601-1	Medical electrical equipment : General requirements for basic safety and essential performance
IEC 62079	Preparation of instructions

AND IF APPLICABLE, COMPLY WITH THE FOLLOWING DIRECTIVES:

NUMBER	**TITLE**
93/42/EEC	Medical Device Directive
89/336/EEC	Electromagnetic Compatibility Directive
73/23/EEC	Low Voltage Equipment Directive
93/68/EEC	CE Marking Directive

WITH LVFS 2001:6 TRANSPONDING THE EUROPEAN MEDICAL DEVICE DIRECTIVE 93/42/EEC.

SIGNED AT:	Tilburg, The Netherlands		P.C.M. Groenland
			Directeur
DATE:	1-10-2014	**SIGNATURE:**	

Appendix 8 Conditions and Warranty

Conditions and Warranty: supply 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 paying parties being consumers, Conditions and Warranty are subject to the Consumer General Terms and Conditions V. 2014 issued by Koninklijke Metaalunie and in accordance with national law.