



Völker MiS® Activ.

The active Micro-Stimulation-System for bedsore prophylaxis, mobilisation, pain reduction and the promotion of perception.

VÖLKER





Völker MiS® Activ

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Preface

Experts call bedsores a national tragedy. The risk of developing bedsores in hospitals is estimated at 30 %, in old people's nursing homes at at least 50 %, the incidence rate fluctuates between 4 % and 27 %. These are 4 % to 27 % too many. After all, bedsores mean enormous expenditure, unnecessary costs, unspeakable suffering by patients and they burden nursing staff in an emotional way, too.

According to experts, the prevalence of this problem – despite an experts' standard and a whole bunch of nursing measures plus positioning aids of all kinds and, finally, high-tech mattress systems – can be put down to a lack of information, difficult handling and incorrect application. In addition, there is the basic problem of patients' insufficient mobility.

For a bedsore therapy of immobile patients in bedsore stages III and IV, there is now the Völker bed MiS® Activ, which supports the suspension elements in the areas of risk through automatic, minimal movements of the bracket profiles and frame rails.

Here, Völker MiS® Activ is a real and, in many cases, better and much cheaper alternative - at the same rate of successful treatments.

A handwritten signature in black ink, appearing to read "Heinrich Völker".

Heinrich Völker
CEO Völker AG

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Notes and Precautions | General Information

General Information

Thank you for purchasing a Völker product. This product is manufactured according to national and international norms and standards, and incorporates state-of-the-art technology.

Völker products meet the demands of both safety and functionality. They have been tested against international norms and are designated with the CE seal, confirming that the basic requirements for medical products are met.

Please read the basic safety regulations. We also ask you to familiarize yourself with the additional notes given on the following pages, especially with regard to potential warranty claims.

Copyright protection

Providing these instructions to a third party for their use is permissible only upon prior written approval by the Völker AG.

All of these documents are protected by copyright laws.

Warranty and liability

Within the limits of the warranty obligations specified by the main contract, Völker AG is liable only for potential defects or omissions, to the exclusion of further claims. Compensation claims are excluded, notwithstanding any legal argument upon which they might be based.

We reserve the right to make technical changes in this manual without notice, in the course of the continuing development of these product.

We do not accept responsibility for damages and operational breakdowns that are caused by operating errors and non-compliance with these service instructions.

The indicated accessories will not necessarily correspond to the graphic illustrations.



Notes and Precautions | Intended Use and Misuse

Intended Use

The MiS® Activ-System is to use for bedsore prophylaxis and - therapy in Völker healthcare and hospital beds.

Misuse

Misuse of the healthcare bed can lead to potential dangerous situations. Such misuse includes, for example:

- improper operation of electric functions and failure to check the positioning,
- operation of the system by patients without proper instruction,
- use of electrical appliances in the bed that are incompatible with its safe operation (this is the responsibility of the operator),
- moving the bed or system by pulling on the electrical cords,
- unplugging electric cords by pulling on the cable,
- trying to move the bed when the locking mechanism has been engaged,
- overloading the system beyond the specified safe load-bearing capacity.



Notes and Precautions | Regulations, User Qualification and Training

Regulations

MiS® Activ must only be set up, operated and used according to its intended use to be in compliance with the legal regulations for medical products and any relevant issued statutory orders, and to comply with recognized engineering guidelines as well as industry regulations for safety and the prevention of accidents.

MiS® Activ must not be operated if it is defective or might put patients, nursing staff or any third party at risk.

User qualification

MiS® Activ should only be operated by trained professionals who have the skill and experience to guarantee proper handling.

User training

Völker or its representatives will provide basic instruction in the operation of this bed to the nursing staff as required by the customer.

Participation by the nursing staff in such training can be certified by Völker using a form specifically designed for this purpose that includes the participant's name, date and signature.

The nursing staff should familiarize the patients with the use of the hand control prior to unlocking it.

Additional requirements

Everyone who is involved in starting up, operating or servicing MiS® Activ must have read these instructions for use thoroughly, in either the print or digital version.

In order to avoid operating errors and to ensure smooth operation of the bed, the nursing staff must always have access to these safety guidelines.

Notes and Precautions | General safety Notes



Information marked by this symbol must be read and adhered to!

Before initial start-up

Before putting MiS® Activ into operation the first time, these instructions for use must have been read thoroughly and understood by the persons responsible for the nursing service.

A performance check must have been carried out prior to the initial use of this system.

The nursing staff must have attended detailed training in the handling of MiS® Activ before they operate it with patients. In addition, they must be made aware of potential hazards that might occur even when the system is operated properly.

Prior to and during each use

Prior to and during each use, the operator must ensure that the system is in proper condition and that the system is safe to use

Cleaning and disinfection

In order to maintain a consistent functional capability, the system should be cleaned, disinfected and tested at the soonest possible time following each use, so that it can be reused immediately without risk.

Dangers might arise from improper cleaning or disinfection of the system

Electromagnetic and electrostatic interference

MiS® Activ demands the EMV – protection requirements corresponding to German Law about medical products (MPG). Control basis is standard EN 60601-1-2.

Service and Maintenance

Anyone who is responsible for carrying out maintenance or service on the system must at least have read the Safety Regulations and the Service Manual and be qualified according to the legal requirements.

If any damage is detected, such as signs of wear and tear, loose bolts and breaks, the damaged portion must be repaired or replaced immediately.

Transport

During moving the bed or system the electric supply cables must not touch the ground and the mattress frame must be in the lowest possible horizontal position.

Mattresses

To minimize the risk of injury, do not use this bed with mattresses of any size other than those described below. If you decide not to use a Völker mattress, contact a reputable dealer of your choice.

We expressly suggest the use of MiS® Activ in combination with the „Metzeler Rubex Finess“ – mattress (tested with PU-cover).

Size of mattress	Size of mattress frame	Recommended volume weight
88 x 200 x 12 cm	90 x 200 cm	50 kg/m ³
88 x 210 x 12 cm	90 x 210 cm	50 kg/m ³
88 x 220 x 12 cm	90 x 220 cm	50 kg/m ³
98 x 200 x 12 cm	100 x 200 cm	50 kg/m ³
98 x 210 x 12 cm	100 x 210 cm	50 kg/m ³
98 x 220 x 12 cm	100 x 220 cm	50 kg/m ³



The use of mattresses that do not correspond to these specifications will carry a risk of injury!

Compatibility

Völker MiS® Activ is compatible with all Völker beds with removable mattress frame, which were build past August 2005.

Adaption on Völker beds which were build between May 2003 and August 2005 on request.

Patient weight

The safe working load of MiS® Activ is 210 kg. The stroke movement is executed within 8 – 10 seconds whereas an automatic adaption on the patient weight takes place.

An adjustment of the patient weight is not necessary.

After shutting down the system, the non-moved mattress frame can used as a normal bed.

Information about continuation of therapeutic actions

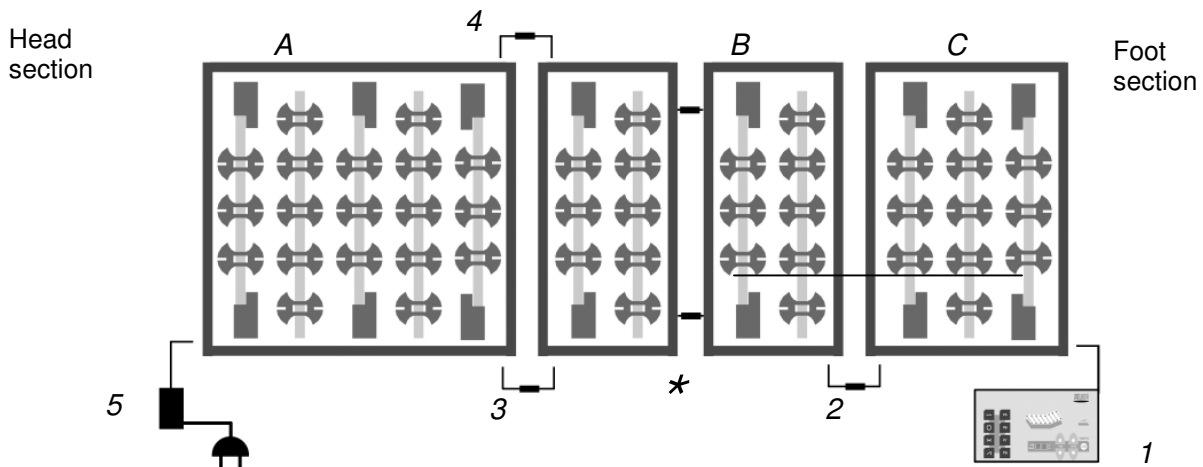
Please notice that the use of the MIS-Active-system can not substitute the usual motion -, bedding and transfer techniques as well as the execution of prophylactical actions by the nursing staff.

Informations about the use von MiS® Activ of in beds with side rails

When using MIS® in a bed with side rails please pay attention to the instructions for use of the respective bed and the therein contained instructions to use the side rails.

The height of the side rail about the mattress frame is about 34 cm. When a standard mattress with a height of 12 cm is used, the prescribed distance of 22 cm between mattress and top edge of the side rail is observed when using MIS® Activ.

Installation and launch of MiS® Activ



* Cabling between seating part and upper leg section is pre-connected on delivery.



To ease the installation the cables to be connected are marked with equal numbers. Please follow the instructions below.

- bring the bed into maximum height and the lying surface into a flat, horizontal position
- remove the existing lying surface elements

A Put the back section element of MiS® Activ into the bed frame. The cabling has to be placed underneath.

B Put seating part and upper leg section of MiS® Activ into the bed frame. The cabling between these parts is pre-connected on delivery. Cable 3+4 provide the connection between seating part and back section / power supply, and cable 2 connects upper- and lower leg section.

C Put lower leg section of MiS® Activ in the bed frame.

1 Connect the control board of MiS® Activ (fig. 6 to 9, fig. 3).

2 Connect upper- and lower leg section (fig. 1, 4 & 5, page 2).

3-4 Connect back section and seating part (fig. 1 to 3, page 2).

5 Connect the power supply unit with the corresponding cable at the upper leg section and an electrical outlet (fig. 10 to 14 – page 3).

- Press the „On“-button (button 13 – page 4) to start MiS® Activ and select a program within five minutes by pressing a program button (see page 4).

**Depiction of plug connections
Connections between elements**

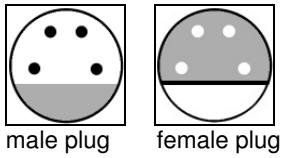


fig. 1



The connectors are encoded as shown on the left. Please handle the cabling carefully to avoid any damages.

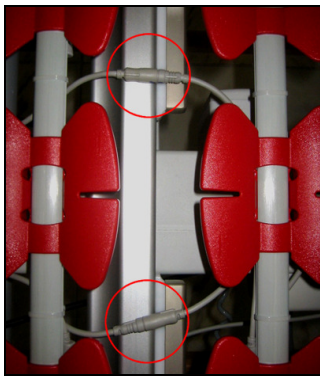


fig. 2 back section – seating part

Head section

Foot section

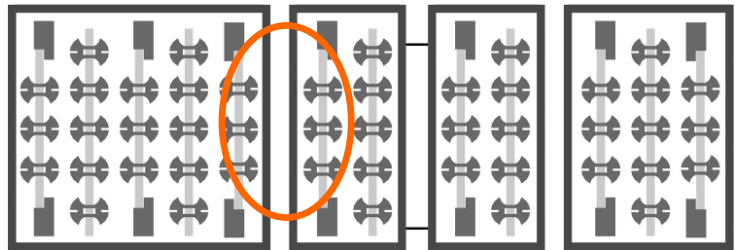


fig. 3 position of connection back section – seating part

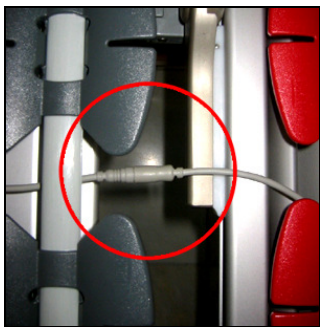


fig. 4 upper leg section – lower leg section

Head section

Foot section

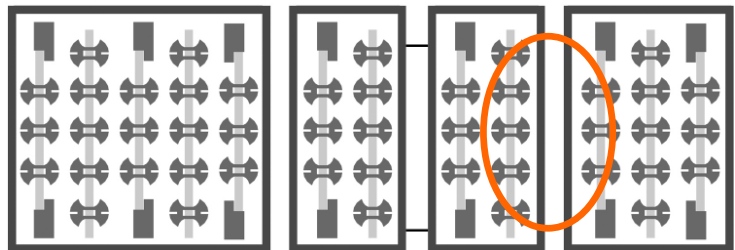


fig. 5 position of connection upper leg section – lower leg section



Connect the cables carefully and mind the anti-twist-protection.

Connection to control board

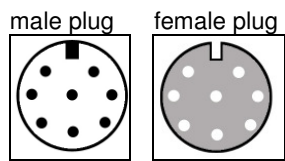


fig. 6 connection to control board



fig. 7 connection to control board



fig. 8 position control board plug

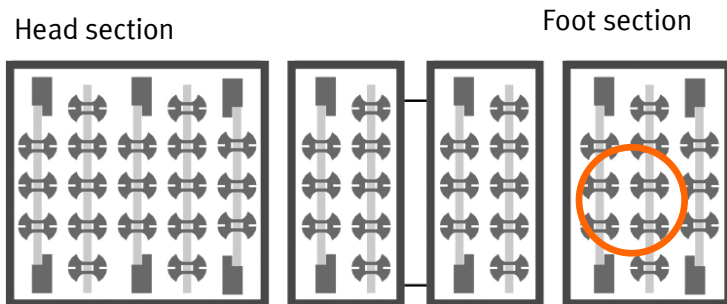


fig. 9 position control board plug



Connect the cables carefully and mind the guideway. Don't screw the plugs together before properly connected!

Connection to power supply unit

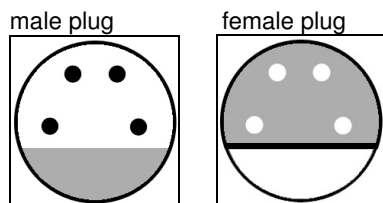


fig. 10 connection to power supply unit



fig. 11 plug connection



fig. 12 power supply unit

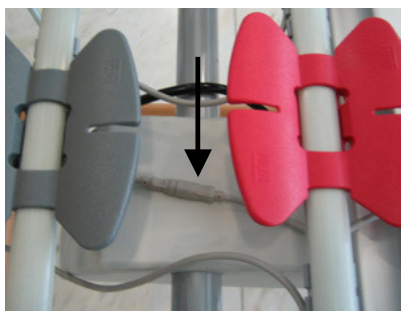


fig. 13 power supply unit connection

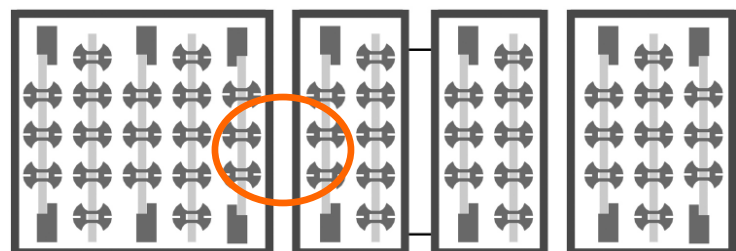
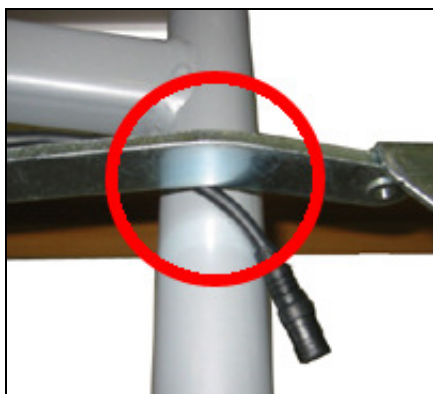


fig. 14 position power supply unit connection



Connect the cables carefully and mind the anti-twist-protection.



Take care that no cable can be jammed by movable parts of the bed.



Take care that all cables are fixed by clamp-connexions with the cross-beams.

If the bed is properly connected to the main supply corresponding LED (as shown below) will glow. If the bed is separated from the the main supply an audible signal will resound and the LED will not glow any more.

On:



Off:



Only use the provided power supply unit (Article-No.: E2132) !



Indication / Contraindication

Indication

In the following situations an usage of the Völker MiS® Activ-System is medically sensible:

- Assistance of bedsore prophylaxis, - therapy and pain therapy.
- Basal Stimulation.

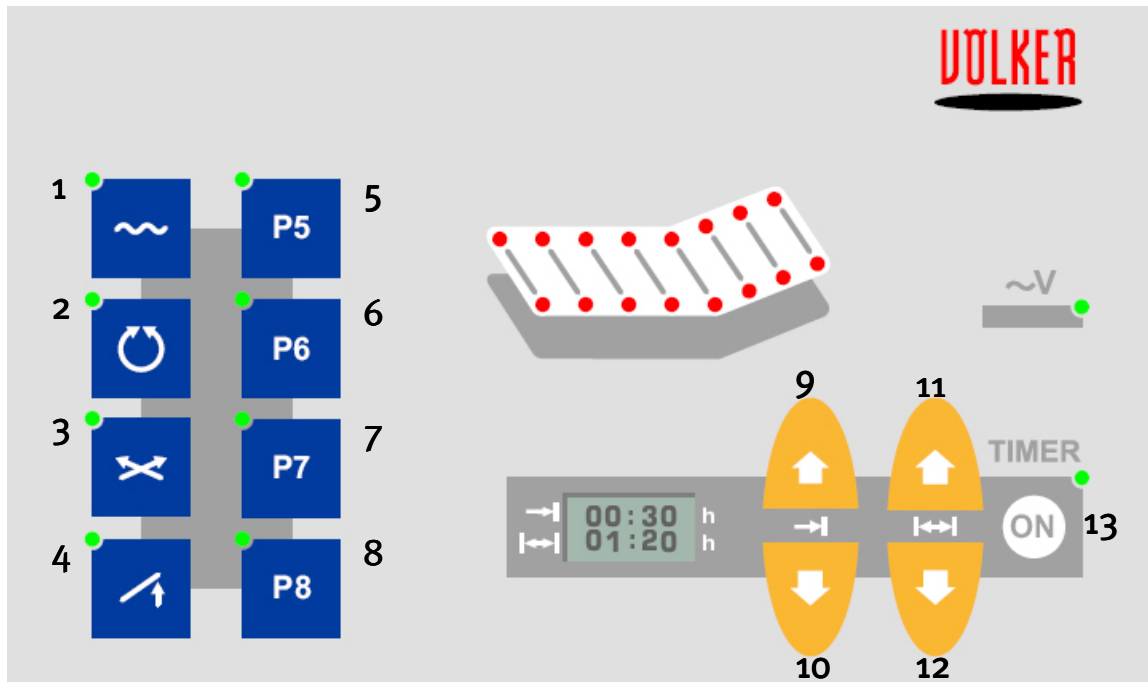
Contraindication

In the following situations the Völker MiS® Activ-system must not be used:

- Newly operated paraplegia.

Patients who can not tolerate Micro-Stimulation.

Control Board



- | | | | |
|---|-----------------------------------|----|----------------------|
| 1 | Movement pattern „Wave“ *1 | 9 | Start time „up“ *3 |
| 2 | Movement pattern „Rotation“ *1 | 10 | Start time „down“ *3 |
| 3 | Movement pattern „Criss-Cross“ *1 | 11 | Timer „up“ *4 |
| 4 | Movement pattern „Inclination“ *1 | 12 | Timer „down“ *4 |
| 5 | Movement pattern „Wave“ *2 | 13 | „On“ – button *5 |
| 6 | Movement pattern „Rotation“ *2 | | |
| 7 | Movement pattern „Criss-Cross“ *2 | | |
| 8 | Movement pattern „Inclination“ *2 | | |

*1 Activates the pre-programmed movement pattern.

*2 Activates the pre-programmed movement pattern, except top cross bar at the head section.

*3 A countdown function for starting the system can be operated by „start time up“ and „start time down“ buttons (15-minute steps).

*4 The duration of the movement can be adjusted by „timer up“ and „timer down“ button.

*5 Please select a movement within 5 minutes after pressing the „ON“-button. Otherwise the system will be switched off automatically.



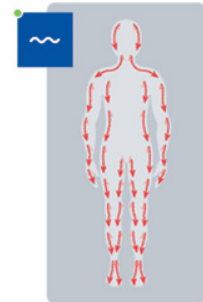
Please notice that the MIS-Active system is no full substitution of the regular medical measurements against pressure sore by the nursing staff!

Explanation of movement patterns

To consider the needs of each single patient, several different movement patterns (based on the basal stimulation) can be selected.

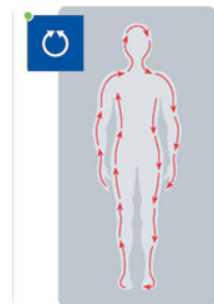
„Wave“

The Activators on the left and on the right side are accessed parallel. The pattern resembles a wave which runs through the bed and stimulates the body of the patient from head to foot.



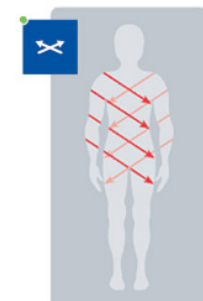
„Rotation“

The Activators on the left and on the right side are accessed out of phase. So counterrotating peaks are created which corresponds a rotation. After three passes the rotating direction is changed.



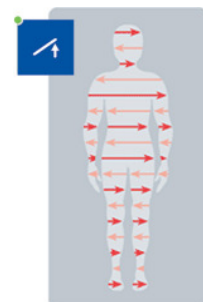
„Criss-Cross“

The Activators are accessed alternately on the left and on the right side. The pattern starts at the head section.



„Bevelled layer“

The activators on one side are all accessed at the same time. So the “bevelled layer” is created. After the selection of three given time intervals the tilting angle switches to the other side.



Cleaning and Disinfection

Wipe and spray disinfection

The wipe and spray disinfectants listed in the DGHM List dated Feb. 4, 2002 (Deutsche Gesellschaft für Hygiene und Mikrobiologie = “German Society for Hygiene and Microbiology”) can be used at the concentrations recommended in the corresponding manufacturer’s instructions. The instructions below should be followed when using cleaning agents and/or disinfectants.



- The use of solvents is **not** permitted.
- Do **not** use abrasive cleaners, scouring pads or similar cleaning aids.
- Do **not** use organic solvents such as halogenated/aromatic hydrocarbons or ketones.

Depending on the level of contamination, we advise that the bed should be cleaned with a damp cloth or the like.

The following guidelines should be observed regarding cleaning and disinfecting agents:

- The working solutions should be freshly prepared as a general rule.
- The concentrations used should be neither higher nor lower than those given in the list. The so-called "shot method" should not be used under any circumstances. Under no circumstance should someone using a disinfectant follow their own judgement to add a detergent such as a soap or detergent substance (leads to soap failure).
- There is a risk of fire or explosion from alcoholic spray disinfectants when these are used over large areas.
- They may not contain any corrosive or caustic substances.
- They may not contain substances that alter the characteristics of surface or the properties of plastic or synthetic materials.
- They may not affect the properties of lubricants.
- The water pH may not fall outside the range of 6-8.
- Water hardness may not exceed 0.9 mmol/L (to 5° d).

Fully desalinated water may not be used.

Chloride	< 100 ppm
Silicate as SiO ₂	< 15 ppm
Iron	< 0.05 ppm
Manganese	< 0.01 ppm
Copper	< 0.05 ppm

This information is based on the booklet "The DGHM List of Disinfectants" dated Feb. 4, 2002 (mhp Verlag GmbH ISBN 3-88681-053-4).

It does not relieve product users from the responsibility of carrying out their own tests and trials, since conditions such as water hardness can differ by location. No legally binding guarantee of any kind is granted or can be assumed.

Völker AG accepts no liability for possible damage to surfaces arising from the use of unsuitable cleaning agents or disinfectants, from the use of incorrect concentrations or from the unsatisfactory care of the bed.



Electric shock / fire hazards and functional deficiency

Generally, the system must be disconnected from the bed when it is being cleaned and disinfected.



Spray lances and automatic washing systems

Cleaning and disinfecting the bed using a spray lance from a high-pressure cleaning apparatus, or the use of an automatic washing system, are **not** permitted.

Appendix

Explanation of symbols



Information marked by this symbol must be read and adhered to!



Direct Current (DC)



Alternating Current (AC)



Safe Category II, protected against electric shock



Type B device according to DIN EN 60601-1



This device fulfills the basic requirements of Attachment 1 of the European Directive 93/42/EC.



The device must be disposed according to the European Directive 2002/96/EC regarding old electrical and electronic products.



Scope of delivery


Included in the delivery of MiS® Activ are the following components:

- Four elements of the mattress frame
- Keyboard
- Power supply
- Cabling

Technical Data

Save working load:	210 kg (weight spreading according to DIN EN ISO 60601-2-38)
Max. load per drive:	25 kg
Lift of single units:	14mm
Number of drives:	14 (Igarashi)
Max. acceptable loudness:	30 dB (A) +2db(A)
Max. power-on time	15%
Supply Voltage:	Max. 16 V
Load current:	3,5 A
Power supply:	16 V power supply
Temperatur range, in operation:	+ 10 °C to +50 °C
Temperature range, storage:	- 20 °C to +60 °C
Temperature range, cleaning:	+10 °C to +50 °C
Humidity:	30% to 85% rel.
Weight (ready-made-use)	18 kg
Allowable weight of Patient	0 – 180 kg

Classification

Type of protection:	IPX 4
Protection against electric shock:	low voltage device
Degree of protection of parts handled by users against electric shock:	Typ B 
MPG category:	Klasse I
Operational mode:	Continuous operation, up to 24 hours

Product Lifetime / Disposal

The average product lifetime of the healthcare bed is approx. 10 years. To guarantee environmentally friendly disposal after the bed is put out of service, please contact your authorized sales representative.

Declaration of conformity

Konformitätserklärung Anhang VII EU-Richtlinie 93/42/EWG

Der Unterzeichnende
Völker AG
Wullener Feld 79
58454 Witten

bestätigt, dass die nachfolgend bezeichneten Produkte in der von uns in Verkehr gebrachten Ausführung die grundlegenden Anforderungen des Anhangs I der EU-Richtlinie 93/42/EWG erfüllen. Es wurden die folgenden Normen angewendet :

DIN EN 60601-1,
DIN EN 60601-1-2,
DIN EN 60601-1-4,
DIN EN 60601-2-38.

Damit sind die Anforderungen des Medizinproduktegesetzes zur Anbringung einer **CE Kennzeichnung** erfüllt.

Bei einer nicht mit dem Hersteller abgestimmten Änderung des Produktes verliert diese Konformitätserklärung ihre Gültigkeit.

Bezeichnung der Produkte :

MiS® Activ

EG-Richtlinien :
Richtlinie 93/42/EWG vom 14.06.1993 über Medizinprodukte (Anhang I „Grundlegende Anforderungen“). Die Produkte sind Produkte der Klasse I gemäß Anhang VII des Medizinproduktegesetzes MPG vom 02.08.1994

Witten 02.08.2006

Declaration of conformity Appendix VII EU Directive 93/42/EEC

The signatory
Völker AG
Wullener Feld 79
58454 Witten/Germany

confirms that the products described below and in the form distributed by ourselves meet the basic requirements of Appendix I of EU Directive 93/42/EEC.
The following standards are applied:

DIN EN 60601-1,
DIN EN 60601-1-2,
DIN EN 60601-1-4,
DIN EN 60601-2-38.

The requirements of the medical products law pertaining to the display of a **CE seal** of approval are thereby fulfilled.

This declaration of conformity becomes invalid if the products are altered without the agreement of the manufacturer.

Description of products Type/Article No.:

MiS® Activ

EU Directives :
Directive 93/42/EEC of 14.06.1993 concerning medical products (Appendix I, Basic requirements). The design and construction of this product conforms to Class I (Appendix VII) Medical products law (MPG) of 02.08.1994.

Déclaration de conformité Annexe VII Directive EU 93/42/CEE

La soussignée
Völker AG
Wullener Feld 79
58454 Witten/Allemagne

confirme que les produits spécifiés ci-dessous sont conformes, dans le modèle mis en circulation, aux exigences fondamentales de l'annexe L de la directive européenne 93/42/CEE.
Les standards suivants sont appliqués :

DIN EN 60601-1,
DIN EN 60601-1-2,
DIN EN 60601-1-4,
DIN EN 60601-2-38.

Les exigences de la loi sur les produits médicaux concernant le port de la **marque CE** sont ainsi satisfaites.

Cette déclaration de conformité est invalidée en cas de modification des produits, non autorisée par le fabricant.

Désignation des produits
Modèle/Référence :

MiS® Activ

Directives européennes :
Directive 93/42/CEE du 14.06.1993 sur les produits médicaux (annexe I « Exigences fondamentales »). La conception du produit est conforme à la classe I (annexe VII). Loi sur les produits médicaux (MPG) du 02.08.1994.




ppa. Heinrich Völker

Vorstandsvorsitzender / Executive board (chair) / Directoire (Président)

Table 204
Guidance and manufacturer's declaration – electromagnetic immunity
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (see 6.8.3.201 b))

MiS® Activ is intended for use in the electromagnetic environment specified below. The customer or the user of the MiS® Activ system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of MiS® Activ, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17\sqrt{P}$
Conducted RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,17\sqrt{P}$ 80 MHz to 800 MHz $d = 2,33\sqrt{P}$ 800 MHz to 2,5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MiS® Activ system is used exceeds the applicable RF compliance level above, MiS® Activ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating MiS® Activ.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



Table 206
Recommended separation distances between portable and mobile RF communications equipment and the equipment or systems - for equipment and systems that are not life-supporting (see 6.8.3.201 b))

MiS® Activ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MiS® Activ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MiS® Activ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,17\sqrt{P}$	80 MHz to 800 MHz $d = 1,17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.