

Instructions for use MiS® Activ

UULKER

### Help

### **Hyperlinks**

Hyperlinks are cross-references in the text. They are marked with the symbol. The entries in the Table of contents also have hyperlink functionality.

- Clicking 

   takes you to the relevant page.
- Clicking on in the Acrobat navigation bar takes you back to the start page.

#### Full-text search for a term

Clicking opens the "Search" window.

You can search for any term in this Acrobat document or optionally search all of the Acrobat files stored on your computer or those that are accessible.

#### Other interactive functions

The Adobe Reader and all Adobe Acrobat program versions offer the experienced user a whole range of highly useful functions for interactive working with documents. For more information, see the relevant user manuals or online help.

Display table of contents

Jump to Help page (this page)

Help

Contents

2 of 88

V1.1 (13.04.2012)

# Version, Imprint, Type label

Instructions for use G121 Version 1.1 (13.04.2012) for Völker MiS® Activ from year of construction January 2011

© by Völker GmbH 2011-2012

Völker GmbH Wullener Feld 79 58454 Witten

#### **GERMANY**

Tel.: +49 2302 96096-0 Fax: +49 2302 96096-16 E-mail: info@voelker.de Internet: www.voelker.de

All rights reserved. Reproduction - even

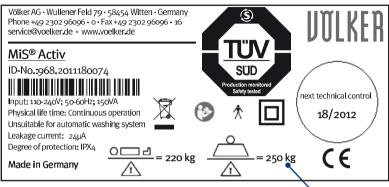
in part - is not permitted.

We reserve the right to make changes to reflect technical advances.

The contents of this document are subject to change without prior notification.

Customers are advised to contact the responsible area sales manager before placing an order.

### Type label



The type label is located on the lowest support profile of the seat section of the MiS® Activ.

For further information on the type label, see Appendix @ 69.



### **Table of Contents 1/2**

Help  2 Version, imprint, type label  3 Table of contents  4 Foreword  6	Activation 26 Preparation 27 Mechanical activation 27 Plug-in connections 30 Plug-in connections Vis-a-Vis bed	Cleaning and disinfection  51 Cleaning 52 Wipe and spray disinfection 52 Spray lances and automatic washing systems 53
Notes 🕮 7	<b>32</b>	Cleaning the mattress 🕮 53
General information   8	Hand control, power supply unit,	
Designated purpose 🚨 9	power supply unit holder 🕮 33	Maintenance 🚨 54
General regulations, training/	Electrical activation 🕮 34	Staff training 🚨 55
instruction of users, further	Functional check 🕮 35	Safety notes 🚨 55
requirements 🕮 11	Removal 🚨 36	Maintenance schedule 🕮 56
General safety notes 🕮 12		
-	Operation 🕮 37	Technical inspection @ 57
<b>Indications/Contraindications</b> 15	Switching ON/OFF, key lock 🕮 38	Documentation 🕮 58
Indications 🕮 16	Function keys 🕮 39	Lying surface 🕮 58
Contraindications 🕮 17	Option keys 40	Mains connection cable, plug 🕮 58
	Menu 🕮 41	Strain relief, kink protection 🕮 58
Functional description 🕮 18	Control keys 🕮 41	Fit of the plug-in contacts 🕮 58
Overview 🕮 19	Main menu 🚨 42	Power supply unit housing 🕮 58
Hand control @ 20	Day program 🕮 43	Hand control 🕮 58
Basic programs vs. day programs	Logbook 🕮 46	Wear and tear 🕮 59
<u>22</u>	Settings 🕮 47	Functional check of the drives   59
Basic programs 🕮 23	Service 🕮 49	Measurement in accordance with
Accessories 🚇 24	-	DIN EN 62353 🚇 59
Versions and options   25		Further accessories  59
TOTOTO GITA OPTIONO E EO		1 414101 40000001100 🕮 00

Contents 4 of 88 Help

### Table of contents 2/2

Table of faults 🕮 61

Service points 🕮 64

### **Appendix** 465

Technical data 🕮 67

Classification @ 68

Type label 🕮 69

Service life/disposal 🕮 71

Manufacturer's declarations, forms,

electronic instructions for use 🕮 72

### **Foreword**

According to the study "Nursing Problems in Germany" of the Institute of Health, Sciences Education and Nursing Science of Charité, over 60% of the residents in nursing homes and over 40% of the patients in hospitals are at risk of decubitus ulcers (Braden value ≤ 20 points). The rate of those actually affected among immobile persons in nursing homes is 11.7%, and in hospitals 27.7% (decubitus degree 1-4). Decubitus entails unending pain for the patients, psychological distress among patients and care providers as well as enormous nursing expense and unnecessary costs.

Since May 2003, the beds of Völker GmbH have been fitted with a microstimulation lying surface (MiS®) as standard. This provides a nursing aid directly integrated in the bed, which technically implements the theoretical principles of basal stimulation, the Bobath concept and kinaesthesia, based on insights from neuroscience. The MiS® Activ described here is the upgrade of the Völker MiS® standard spring support.

The MiS® Activ uses specially developed drives to provide compensatory feedback for physical perception among increasingly immobile individuals in need of care, this being necessary for independent movement and prophylactic nursing measures.

The combination of continuous pressure distribution and movement stimulation ensures better circulation and heightened physical perception.

Flexibly suspended struts reinforced by fibre glass with winged springs ensure mechanical feedback in respect to the patient's movement. The very good cushioning performance of the lying system minimises the risk of pressure peaks. When the fibre glass struts are activated by the electric motor, 14 activators independent of one another are raised and lowered by 14 mm in a defined rhythm. Minimal raising and lowering provides somatic, vestibular and vibratory impulses.

In combination with a 12 cm mattress coordinated to the system, this is the ideal way to bring together support in physical perception, movement stimulation and a continuous pressure distribution, thereby ensuring better blood circulation.

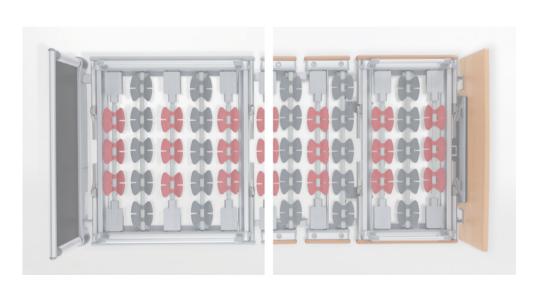
Besides an effective decubitus prophylaxis and assisting a corresponding therapy, this also brings about higher vigilance and a reduction in chronic (non-malignant) pain.

Thanks to greater lying comfort and mobility, the MiS® Activ makes patients more sensitive for a stimulating therapy, thus enabling therapy to be realised on a lasting basis.

Yours Völker GmbH

### **Notes**

The **Notes** section contains information on the designated purpose of the product, as well as general safety notes.



#### **CONTENTS**

General information 🕮 8

Designated purpose 🕮 9

General regulations, training/instruction of users, further requirements 🚨 11

General safety notes 🕮 12

## **Notes | General information**

#### **General notes**

With the MiS® Activ you have purchased a product from Völker GmbH. MiS® Activ has been built in accordance with the applicable national and international standards and the regulations reflecting the current state of technology.

The MiS® Activ satisfies requirements in terms of safety and functionality. It has been tested in accordance with international standards and bears the CE mark, which documents the compliance with essential requirements for medical products.

Please read the general safety notes

12. Please also note (with particular attention to any warranty claims) the further notes on the following pages.

### Copyright protection

These instructions for use may only be transferred to third parties with the written consent of Völker GmbH. All documents are protected under copyright.

#### Warranty and liability

Völker GmbH is liable for any faults or failures, not including further claims arising in the context of the warranty obligations detailed in the main agreement. Claims for compensation, for whatever legal reason such claims may be raised, will not be entertained.

We reserve the right to make technical modifications without notice as part of the further development of the lying system which forms the subject of these instructions for use. All specifications are non binding. Printing errors excepted.

We accept no liability for damage and operational faults caused as a result of misuse and/or non-observance of these instructions for use.

The portrayal of the accessories does not necessarily match the actual product.

## Notes | Designated purpose 1/2

#### Correct use

As a lying system, the MiS® Activ represents a medical product in conjunction with a Völker bed and a suitable mattress, which is intended for the bedding and care of residents/patients in nursing homes, clinics and in suitable rooms in residential houses.

The lying system is intended for use by people over the age of 12 or who are taller than 146 cm.

The lying system's safe working load is 250 kg. The maximum permissible weight of the individual is derived by deducting the weight of the mattress and other accessories from this. These values apply for the MiS® Activ system and presuppose that the beds used support this load bearing capacity. If beds with a lower load bearing capacity are used, the maximum working and patient load will apply.

Any use of the lying system other than for the purpose intended excludes the company from any possible liability.

#### Inappropriate use

Inappropriate use can be dangerous. This includes, but is not limited to:

- Incorrect actuation of electrical functions and uncontrolled positioning;
- Operation of the lying system by the occupant/patient without having received prior instruction in how to do so;
- Use of other electrical equipment on the lying system;
- Pulling on cables to move the lying system;
- Removing electrical plug connections by pulling on the cable;
- Use of a bed with the MiS® Activ on a slope of more than ten degrees of inclination (the bed's brakes are designed for an angle of inclination of no more than ten degrees);
- Any attempt to move a bed with the MiS® Activ while it is in braked position;

- Use of a bed with the MiS® Activ for transport with a vehicle;
- Overloading of the lying system beyond the specified safe working load.



**CAUTION** If, in an emergency situation, it is impossible to avoid putting children under the age of 12 or people who are less than 146 cm tall in the lying system, protective covers must be placed on the side rails. This also applies to the use of the lying system by weak or confused patients. A use for children under 8 years of

A use for children under 8 years of age is not permitted.

# Notes | Designated purpose 2/2



**WARNING** The lying system may not be placed right next to or stacked up with other equipment. If operation near to or stacked up with other equipment is necessary, it must be ensured that the operation of the lying system is observed and correct use in this arrangement is checked.

Contents 10 of 88 Help

### Notes | General regulations, user training / instruction, further requirements

### **General regulations**

The MiS® Activ must only be operated and used in accordance with its designated purpose, in line with the conditions of the law on medical products (MPG) and approved legislation pursuant to this, the generally-acknowledged rules of technology and the stipulations of occupational safety and accident protection guidelines. The MiS® Activ must **not** be operated in a faulty state that could endanger its occupant/patient, care personnel or third parties.

#### **User training**

The MiS® Activ may only be operated by individuals whose training or understanding and experience offer surety for correct handling (MPG).

#### **User instruction**

The thorough induction of care personnel in the operation of the MiS® Activ can be provided by Völker or its representatives at the customer's request.

Attendance of such training can be certified and confirmed by Völker using the form provided for this purpose, specifying the name, date and signature.

#### Other requirements

Whoever is in charge of the activation, operation or preparation of the MiS® Activ must have been given a copy of these instructions for use (in printed or electronic form) and have read them.

To avoid operating errors and to safeguard the smooth operation of the MiS® Activ, care personnel must always have access to the safety notes below.

Contents 11 of 88 Help

# Notes | General safety notes 1/3



Warning symbols Information marked with this symbol must always be read and strictly observed!



**DANGER** represents an immediate threat of danger that can cause serious physical injury or death.



**WARNING** represents potentially dangerous situations that can lead to serious physical injury or death.



**CAUTION** represents potentially dangerous situations that can cause slight physical injuries.

**NOTE** warns of potential damage to objects or property.

#### Before first activation

Before the MiS® Activ is put into action for the first time, care personnel must read these instructions for use in full and with care.

The instructions for use of the relevant bed must be followed parallel to these instructions for use.

Before the MiS® Activ is activated for the first time, care personnel must be instructed in the handling of the MiS® Activ using the instructions for use. The potential dangers that can arise despite correct operation of the MiS® Activ must also be pointed out in full.

### Before and during use

Before each use of the MiS® Activ, the user must be sure that the MiS® Activ is in a good, safe condition and that safe use is ensured (Functional check \$\to\$ 35).



WARNING If other equipment which has cables, air pipes or the like is to be operated on the bed, it must be ensured that these cables are routed so that they cannot become trapped in the movable parts of the bed or the MiS® Activ, and thus be damaged.

#### Cleaning and disinfection

In order to maintain consistent functioning of the MiS® Activ, the MiS® Activ should be cleaned, disinfected and tested as soon as possible following each use, so that it can be reused immediately without risk.

## Notes | General safety notes 2/3

# Electromagnetic and electrostatic disturbances

MiS® Activ satisfy the EMC requirements in accordance with the law on medical products (MPG). The basis for testing is standard EN 60601-1-2.

#### Maintenance and repair

Anyone responsible for carrying out maintenance and repair work must at least have received service training from Völker, have read the safety notes and be qualified in accordance with MPBetreibV section 4.

After maintenance work or repairs have been carried out, a technical inspection \$\omega\$ 57 must be carried out on the affected parts and/or functions. During this check, it must be determined that the MiS® Activ can be used in accordance with the specifications without risk to occupants/patients, users or third parties.

The technical inspection must be carried out at least once a year.

Any discernible damage, such as signs of wear and tear, loose screws or breaks/fractures must be eliminated immediately.

### **Transport**



**CAUTION** When moving the bed with MiS® Activ it must always be ensured that the mains connection cables do not touch the ground and the lying surface is in a horizontal position as low as possible.

#### **Accessories**



WARNING "Risk of injury"

Only original Völker accessories should be used! Third-party accessories must undergo testing

### Compatibility

before use

The MiS® Activ is compatible with all Völker beds with removable MiS® lying surfaces which were constructed after August 2005.

Adaptation to Völker beds that were constructed between May 2003 and August 2005 on request.

# Notes | General safety notes 3/3

#### Occupant/Patient weight

The safe working load of the MiS® Activ is 250 kg. A lifting movement of the MiS® Activ is carried out within 4-16 seconds dependent on the relevant movement and the selected speed.

There is no need to set the occupant/patient weight.

After switching off the MiS® Activ, the non-moving lying surface can be used as a normal lying surface.

# Continuation of therapeutic measures

It is essential to note that use of the MiS® Activ cannot on any account replace the normal movement, bedding and transfer techniques, or the implementation of prophylactic measures by the nursing staff!

# Use of the MiS® Activ in beds with side rails

When using the MiS® Activ, observe the instructions for use of the relevant bed and the instructions on using the side rails continued therein.

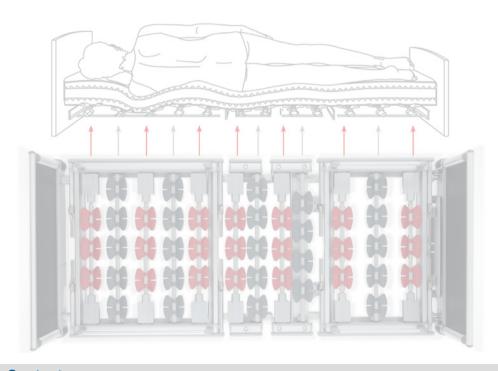
The specified minimum distance of 22 cm between the upper edge of the mattress and the installed side rail must be complied with when using the MiS<sup>®</sup> Activ, if a mattress specified by us with a height of 12 cm is used.

### Reusability

If the relevant user no longer requires the MiS® Activ, the system can be reused by a new occupant/patient at any time after a thorough treatment. Please observe the current information in the VAH list of 01.01.2008 (Verbund für angewandte Hygiene e.V.) in regard to this.

## **Indications/Contraindications**

The indications/contraindications of the MiS® Activ are described in the section **Indications/Contraindications**.



### **CONTENTS**

Indications 🕮 16

Contraindications 17

Contents 15 of 88 Help

# **Indications/Contraindications | Indications**

The MiS® Activ serves for treating patients, compensating disability (inability or restricted opportunity to change position) and the prevention of a disability.

The MiS® Activ stimulates and activates physical perception, independent movement and vigilance.

Somatic, vestibular and also vibratory stimulation enables support for

- · decubitus prophylaxis,
- · decubitus therapy,
- · pain therapy,
- contracture, pneumonia and thrombosis prophylaxis as well as
- therapy for gentle and antispasmodic bedding of the torso and the extremities

to be achieved.

Use in the case of clinical pictures or disabilities with functional disorders of the torso and/or the extremities, which restrict independent changes in position when lying, e.g. in cases of

- · immobility,
- decubitus risk (Braden scale ≤ 20 points),
- dementia, general listlessness, age-induced loss of sensitivity of the skin,
- neurological and muscular disabilities and paralyses, insofar as an independent bedding is still possible, e.g. state after stroke (hemiplegia), Parkinson's disease,
- · chronic, non-malignant pain,
- painful clinical pictures which hence limit own movement, e.g. state after trauma, inflammatory or wearing joint diseases or deformities of the support apparatus,

- neurological and geriatric psychiatric diseases,
- too high or too low muscle tone,
- body image disorders,
- restricted vigilance,
- motor nerve and psychological unrest,
- sleep disorders,
- perception of negative side effects, which are due to other bedding systems.

# **Indications/Contraindications | Contraindications**

No contraindications are known.

In the following situation, the MiS® Activ may only be used after consultation with the treating doctor:

In the case of diseases which prevent movement of the patient/occupant and even minimal movements are unsuitable.

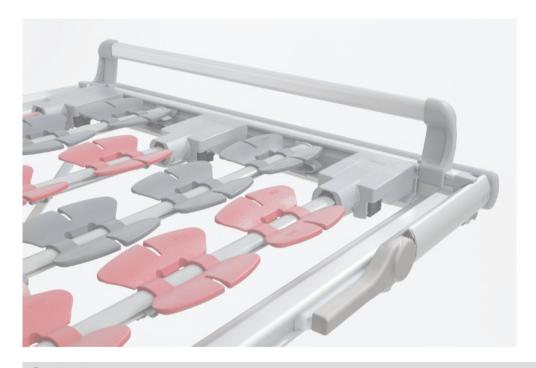
Therapy with the MiS® Activ should be terminated if

- a visible refusal or
- a defensive behaviour by the patient/occupant or
- a deterioration in the state of health

is observed and it cannot be ruled out that therapy with the MiS® Activ is the cause of this.

### **Functional description**

The features of the MiS® Activ and its function are set out in the section **Functional description.** 



### **CONTENTS**

Overview 🕮 19

Hand control 20

Basic programs vs. day programs

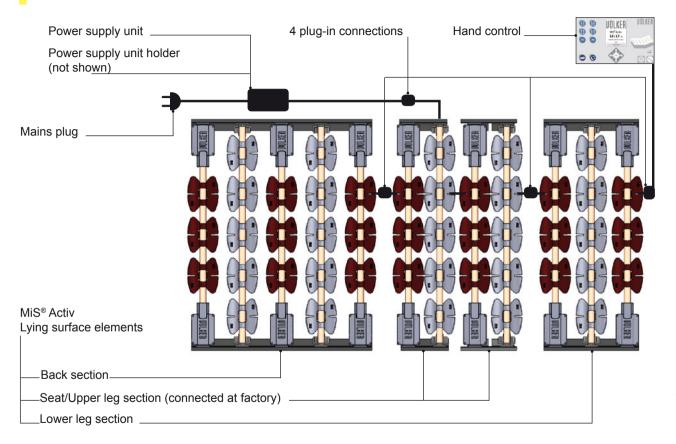
**22** 

Basic programs 🕮 23

Accessories 🕮 24

Versions and options (2) 25

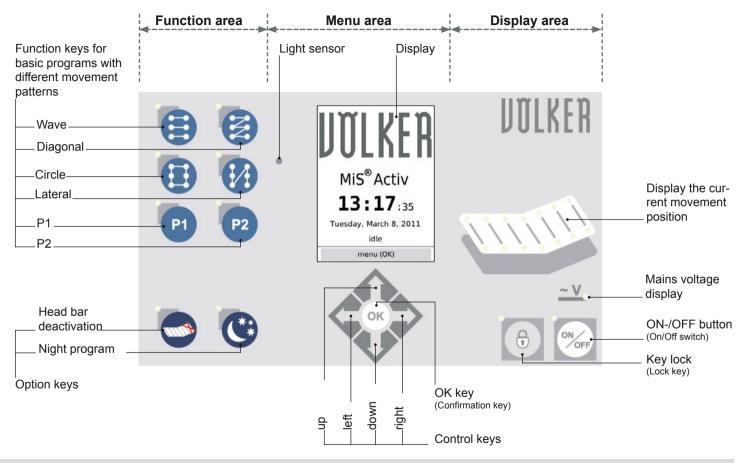
# Functional description | Overview



Adapter cable for Vis-a-Vis bed (not shown)

Contents 19 of 88 Help

# Functional description | Hand control 1/2



Contents 20 of 88 Help

## Functional description | Hand control 2/2

The hand control is divided into three logical areas:

- Function area
- Menu area
- Display area

#### **Function area**

The function area primarily serves for end users. All actions are available at the press of a button here. This applies both to the function keys, which can be used to call up movement patterns, as well as to the option keys, which enable a modification to the movement patterns.

P1 and P2 are placeholders both for future basic programs and for adapted test programs.

#### Menu area

The menu area is primarily used by qualified nursing staff to compile test programs or adjust properties of the control unit. Amongst other things, the speed of a movement pattern can be changed, while the volume of the "peep" or the time interval for the key lock can also be set.

The area also serves for reading usage and diagnostic data.

### Display area

The display area primarily serves for displaying the current situation. It displays whether the mains power has been connected and which drive is currently active.

The ON/OFF button and the key lock are also mounted in this area.

**NOTE** LEDs lit up green on the hand control symbolise that the relevant function is active.

**NOTE** If the LED of the lock key is lit up red, the key lock is activated. The hand control can only be operated after deactivating the key lock 38.

### **Light sensor**

The hand control has an integrated light sensor 20.

The light sensor is used to adjust brightness of the Hand control display to the prevailing light conditions. During darkness the display and the LEDs are automatically dimmed.

# Display the current movement posi-

The green LED on the display of the current movement position 20 indicates the relevant active motor(s) during the course of the selected movement pattern.

# Functional description | Hand control | Basic programs vs. day programs

#### **Basic programs**

Basic programs have a medical background. They are compiled on the basis of medical studies and experience. Basic programs are only compiled by qualified Völker staff from the MiS® Activ team based on acquired medical insights.

The following basic programs 23 are provided as standard:

- Wave
- Diagonal
- Circle
- Lateral.

Any number of extra basic programs can be defined in the event of new insights, which can then be assigned to the function keys P1 and/or P2.

#### Day programs

Day programs are based on basic programs which can be put into a time sequence.

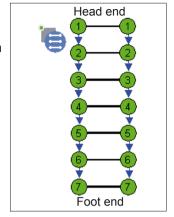
It is therefore possible to individualise a patient treatment and/or automatically save the day programs adapted to the daily routine of running the hospital.

Basic programs start automatically at defined times without any member of staff having to do this.

# Functional description | Hand control | Basic programs

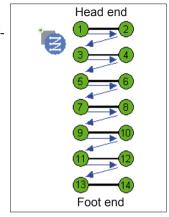
#### Wave

The drive units are activated right and left in parallel. The stimulation pattern is similar to a wave that ripples through the bed.



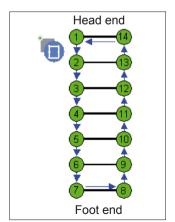
### Diagonal

The drive units are activated alternately right and left, beginning at the head section.



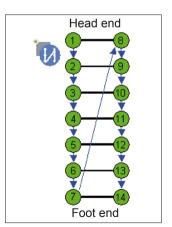
#### Circle

The drive units of one side are activated beginning with the head, then change at the foot end to the other side and return to the head.



#### Lateral

The drive units of one side are activated starting from the head and then change to the other side.



Contents 23 of 88 Help

# **Functional description | Accessories**

#### **Mattresses**

#### Mattress size

ze Mattress frame size

88 x 200/210/220 x 12 cm 98 x 200/210/220 x 12 cm 90 x 200/210/220 cm 100 x 200/210/220 cm

To minimise the risk of injury, only use Völker mattresses with the dimensions and properties detailed above.



**DANGER** The height of the raised side rail above the mattress must always be greater than or equal to 220 mm; otherwise the occupant/patient may accidentally fall out of bed. Please note that the height of the mattress has a direct influence on this.



**DANGER** If mattresses are used that do not match these specifications, there is a risk of suffocation!

#### Restraints

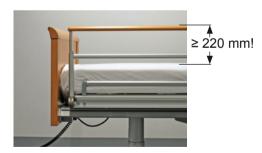


**CAUTION** If you use the MiS Activ® with a restrained occupant/ patient, this must be carefully observed by the nursing staff.

#### **Accessories**



**WARNING** Only original Völker accessories should be used!



# Functional description | Versions and options

Besides the standard design, the MiS® Activ can be supplied with various versions and options.

Versions/ Options	Description
MiS® Activ (Standard)	90 x 200 cm
MiS® Activ (Variants)	90 x 210 cm 90 x 220 cm 100 x 200 cm 100 x 210 cm 100 x 220 cm

Versions/ Description Options

Transport case aluminium (Option)

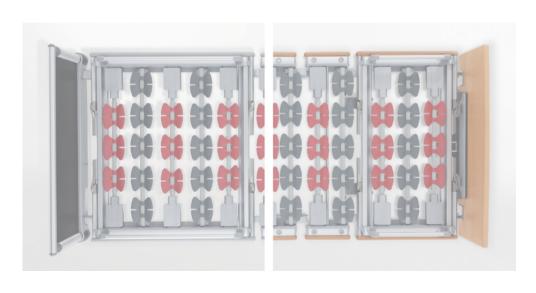


MiS® Activ Sincluding Völker mattress (variants)

Sizes identical to above sizes

### **Activation**

The section entitled **Activation** describes the preparation of the Mis<sup>®</sup> Activ for use, including the functional check.



### **CONTENTS**

Preparation 

27

Mechanical activation  $\ \square$  27

Plug-in connections ☐ 30 Plug-in connections Vis-a-Vis bed

<u>32</u>

Hand control, power supply unit, power supply unit holder \( \mathref{Q} \) 33

Electrical activation 🕮 34

Functional check 35

Removal 🕮 36

# **Activation | Preparation, mechanical activation 1/3**

#### Conditions for set-up

Mechanical activation

The MiS® Activ is only approved for use in dry rooms (technical data sheet). A mains power supply is required for operation of the MiS® Activ in any suitable room.

Mains plug

If using the MiS® Activ in a Vis-a-Vis bed, please observe the diagram 2 32 with the additional plug-in connection.

> MiS® Activ Lying surface elements

> > Back section \_\_\_\_\_

Seat/Upper leg section (connected at factory)—

Hand control Power 4 plug-in connections supply unit Lower leg section \_\_\_\_\_

### **Activation | Mechanical activation 2/3**

- Bring the bed into a horizontal position.
- 2. Remove the existing MiS® lying surface from the frame.
- 3. Place the back section of the MiS<sup>®</sup> Activ lying surface in the frame 27.
- Place the seat and upper leg section of the MiS® Activ lying surface in the frame 
   □ 27. Note that the two elements are connected to one another by cable at the factory.
- Place the lower leg section of the MiS<sup>®</sup> Activ lying surface in the frame
   27.
- 6. Fasten the hand control at the foot section of the bed 33.
- 8. Connect the plug and socket between the MiS® Activ upper leg section and the lower leg section 31.

- 9. Connect the plug and socket between the MiS® Activ back section and the seat section 

  31.
- 10. Connect the plug and socket between MiS® Activ power supply unit and the seat section 

  31.
- 11. Fasten the MiS® Activ power supply unit holder at the head end on the accessories rail of the bed, and insert the power supply unit in the power supply unit holder 🚨 33.

**NOTE** When doing so, choose a position for the power supply unit at which the brake arm remains freely accessible (if present). Especially in the case of a Vis-a-Vis bed, the movement of the entire bed in the direction of the foot end and back must be ensured. The cable must not become tensioned or clamped on the movement path of 25 cm.

**NOTE** For simple positioning of the MiS® Activ elements, each element contains a printed wing on which the installation direction of the element is marked.

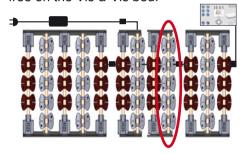


Additional information on mechanical activation of the MiS® Activ in a Vis-a-Vis bed can be found on the following page.

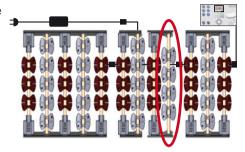
## **Activation | Mechanical activation 3/3**

# Mechanical activation of the MiS<sup>®</sup> Activ in a Vis-a-Vis bed

If you use the Mis® Activ in a Vis-a-Vis bed, please note that you have to remove a wing of the external support profile on the MiS® Activ upper leg section in order to keep the area of the mattress holder free on the Vis-a-Vis bed.



Then move the remaining wing at the same distance to the middle of the support profile.



The mechanical activation of the MiS® Activ 28 in a Vis-a-Vis bed is carried out in the same way as every other Völker bed.

Only point 8 described on  $\square$  28 does not apply and is replaced by the following point:

8.a Use the MiS® Activ adapter cable to make a connection between the upper leg section and the lower leg section 

32.

# Activation | Mechanical activation | Plug-in connections 1/2

The plug-in connections have a reverse polarity protection.

The design prevents damage to the plug-in contacts when plugging in.





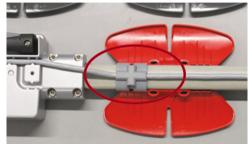


**CAUTION** Make sure that no cable can become trapped by moving parts of the bed.

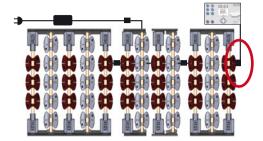




**CAUTION** Make sure that all cables are fastened on the support profiles using cable clips.



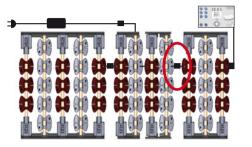
Plug-in connection Lower leg section - hand control



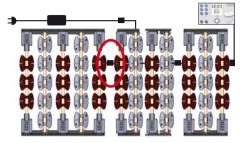


# Activation | Mechanical activation | Plug-in connections 2/2

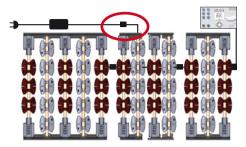
Plug-in connection Upper leg section - lower leg section



Plug-in connection
Back section - seat section



Plug-in connection Power supply unit - seat section



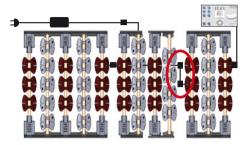


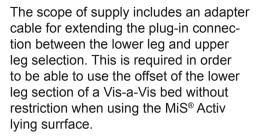




# Activation | Mechanical activation | Plug-in connections Vis-a-Vis bed

Plug-in connection Vis-a-Vis bed Lower leg section - upper leg section





**NOTE** If the lower leg section is moved without using the cable extension, this can cause damage to the cables and plug-in connections.



To remove the MiS® Activ from a bed, first carry out the described steps for electrical activation 34 and then those of the mechanical activation 27 in the reverse order.

# Activation | Mechanical activation | hand control, power supply unit, power supply unit holder

### **Hand control**



Power supply unit, power supply unit holder



## **Activation | Electrical activation**

Connect the mains plug to a mains socket with a protective conductor for the electrical activation.



WARNING Without a protective conductor connection, the EMC values and the permitted leakage current will not be complied with. Although this product is a protection-insulated device, operating it without a protective conductor or functional earthing is not permitted! If no mains socket with a protective conductor is available, please contact your responsible area sales manager.



WARNING Make sure that the mains plug is accessible at all times so that the power supply unit can immediately be disconnected from the mains in the event of a fault.

If the MiS® Activ is properly connected to the mains, the mains voltage display 
20 will light up green.

If the MiS® Activ is disconnected from the mains, the display will go out.



**WARNING** Ensure that the plug-in connections are located correctly!



**WARNING** Check the mains cable for damage. If the cable is damaged, the MiS® Activ must not be used and must be taken out of service immediately!



**WARNING** Make sure that only the power supply unit supplied (article no. E2340) is used.

## **Activation | Functional check**

#### Visual inspection

Before each new occupancy of the bed, the following checks must be carried out:

- Ensure the MiS® Activ exhibits no visible signs of damage.
- Ensure that the insulation of the electrical cables is intact.
- Ensure that the next testing date has not been missed (see testing label).



WARNING Only an undamaged MiS® Activ that is still within its testing interval periods may be used!

#### **Functional check**

A functional check must be carried out before each new occupancy:

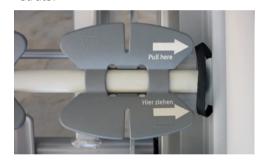
- 1. The MiS® Activ lying surfaces must be engaged in the frame profile.
- 3. The basic program Wave must be performed twice for the test.

Once a fault-free functional check has been carried out, the MiS® Activ is ready for use.

# **Activation | Removal**

To remove the MiS® Activ from a bed, first carry out the described steps for electrical activation 34 and then those of the mechanical activation 37 in the reverse order.

**NOTE** The MiS® Activ lying surface elements can be removed from the frame by pulling on the black removal straps. The position of the removal straps is marked by the inscription "Hier ziehen / Pull here" on the wings. For the subsequent removal, hold the lying surface elements on the side frame or on the non-motor-powered struts.



# **Operation**

The **Operation** section provides you with all the information required to operate the Völker bed.



### **CONTENTS**

Switching ON/OFF, key lock 🕮 38

Function keys 🕮 39

Option keys 🕮 40

Menu 🕮 41

Control keys 🕮 41

Main menu 🕮 42

Day program 🕮 43

Logbook 🕮 44

Settings 🕮 47

Service 49

# Operation | Switching ON/OFF, key lock

### Switching on

To switch on the MiS® Activ, keep the ON/OFF button

20 pressed until "Start..." appears on the display.



MiS® Activ is ready for operation when the following information appears on the display.



#### **Key lock**

If the pilot light of the key lock 20 lights up red, the hand control is locked.

The factory setting envisages that the hand control is automatically locked if no key is pressed for 120 seconds.

The time interval for the key lock can be changed or completely deactivated in the menu 47.

To unlock the key lock, keep the Lock key pressed for at least 2 seconds until the red pilot light goes out.

### **Switching off**

Keep the ON/OFF button

☐ 20 pressed until the "O" symbol appears on the display.

MiS® Activ switches off afterwards. The display and pilot light of the ON/OFF button go out.

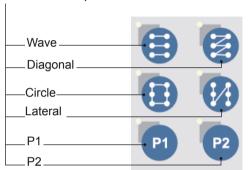


Contents 38 of 88 Help

# Operation | Function keys

The hand control contains 6 function keys 20 for basic programs with different movement patterns.

Function keys for basic programs with different movement patterns



Using the basic programs is the simplest way of operating the MiS® Activ.

Basic programs have a medical background. They are compiled on the basis of medical studies and experience. Basic programs are only compiled by qualified Völker staff from the MiS® Activ team based on acquired medical insights.

The following basic programs  $\square$  23 are provided as standard:

- Wave
- Diagonal
- Circle
- Lateral.

Any number of extra basic programs can be defined in the event of new insights, which can then be assigned to the function keys P1 and/or P2.

The activity of a function key is marked by the green LED next to the relevant key.

#### Starting a basic program

Press the relevant function key to start a basic program.

The pilot light next to the function key now lights up green, and the selected program starts at average speed in continuous operation (factory setting).

The execution time and speed of basic programs can be changed via the menu.

#### Changing the basic program

You can change the basic program while it is operating by pressing one of the other function keys.

### **Ending a basic program**

Press the function key that is currently active to end a basic program. The green pilot light next to the function key now goes out.

Alternatively, you can end the program by selecting stop with the control keys in the menu 41.

# **Operation | Option keys**

The hand control contains two option keys  $\square$  20.

Option keys

Head bar
deactivation
Night program

These serve for the simple operation of important options.

The keys are used in combination with basic programs.

#### **Head bar deactivation**

The key for deactivating the head bar deactivates the sequence of the selected basic program in the head area of the MiS® Activ.

### Night program

Activating the night program 20 extends the individual pauses in the movement patterns of a basic program by 3 seconds.

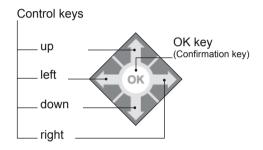
These functions are activated and deactivated by pressing the corresponding option key. The key must be pressed for around 2 seconds for this.

The activity of an option key is marked by the green pilot light next to the relevant key.

# Operation | Menu | Control keys

Operation of the MiS® Activ via the menu should only carried out by medical experts.

The functions in the menu are selected and activated using the control keys and the OK key.



Press the OK key to reach the Main menu.

You can use the control keys (up, down, left, right) to navigate through the Main menu and the menu items (Home) and back

A menu item that has been selected has a grey background on the display and is activated by pressing "OK".

**NOTE** The following basic principles apply for the menu control: First use the control keys to navigate to the required menu item so that this is shown with a grey background on the display then confirm this with "OK".

# Operation | Menu | Main menu

The Main menu is divided into the following menu items:



The Main menu items Logbook (2) 46 and Service (2) 49 serve for information and can be viewed directly including their submenu items.

The Main menu items Day Programs  $\square$  43 and Settings  $\square$  47 can be used to compile day programs and change factory settings.

The creation of day programs and changes to the settings is reserved for medical experts only. These menu items are therefore additionally locked against unintentional activation.

To reach these menu items, you need to keep the "OK" and the Lock keys pressed down simultaneously for 3 seconds. If you do not select one of the locked menu items within 6 seconds, the menu items will automatically become locked again.

# Operation | Menu | Main menu | Day Program 1/3

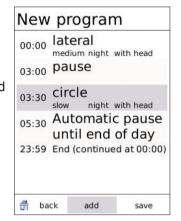


The day Program allows you to create, manage and start day programs.

A day program is a program comprising any sequence of basic programs.

You can then either add a further program step or the newly created program can be saved with save.

An automatic pause until the end of the day is assigned to any remaining rest time when compiling the program.



### Creating a new day program

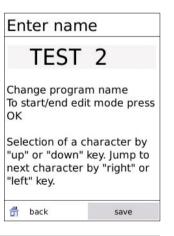
Create new day programs by stringing together various basic programs and pauses.

In doing so, you can define the program (basic program), start and end time, speed, day/night and the activity of the head bar.

save the newly created program step.



When saving, you can give any name to the program corresponding to the description on the display. Confirm this with

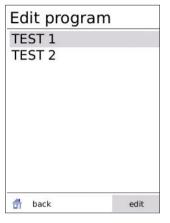


Contents 43 of 88 Help

# Operation | Menu | Main menu | Day Program 2/3

#### Changing a day program

Select the program you wish to change and confirm the selection with edit.

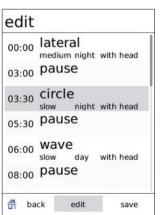


Make the desired changes to the program item as described above at "Creating a day program" 42 and then confirm with save.

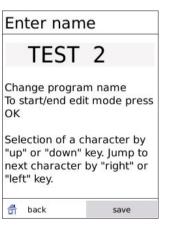
Alternatively, you can also delete program step here.



Now select the program step you wish to change.



When saving, you can give any name to the program corresponding to the description on the display or retain the old name and thus overwrite the old program. Confirm the name with save .

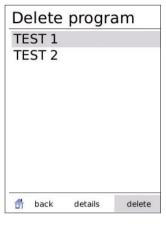


# Operation | Menu | Main menu | Day Program 3/3

### Deleting a day program

Select the program you wish to delete and confirm with delete.

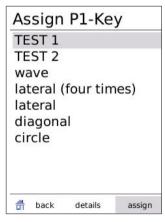
Before deleting, you can view the program via details .



# Assigning a day program to the P1 key or P2 key

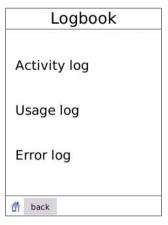
Select the program you wish to assign to the P1 or P2 key, and confirm with assign.

Before assigning, you can view the program via details .



Contents 45 of 88 Help

# Operation | Menu | Main menu | Logbook



Activities, operations and errors of the MiS® Activ are recorded in the Logbook and can be viewed there.

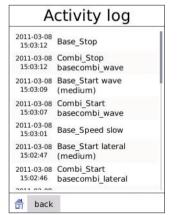
#### **Usage log**

The Usage log records all operations of the MiS® Activ and allows them to be viewed.



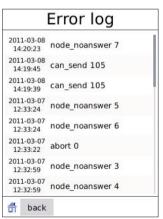
### **Activity log**

The Activity log records all activities of the MiS<sup>®</sup> Activ and allows them to be viewed.



#### **Error log**

The Error log records all error messages of the MiS® Activ and allows them to be viewed.



# Operation | Menu | Main menu | Settings 1/2



Changes can be made to the date and time, keyboard display and language settings in the Settings menu item.

### Keyboard

You can deactivate the keyboard beep and individually adjust its volume.

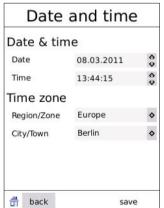
In addition, you can deactivate the automatic key lock and adjust the time period until the key lock is triggered. The factory setting is 120 seconds.



#### **Date and Time**

You can set the date and time as well as your relevant time zone and save.

The changeover from summer to winter time occurs automatically.

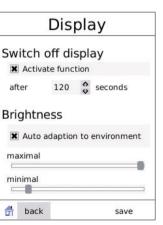


### **Display**

You can individually set whether and after what time period the display automatically switches off.

Pressing "OK" switches the display on again.

Furthermore, you can activate or deactivate the automatic adjustment to the ambient brightness and individually set the brightness.



# Operation | Menu | Main menu | Settings 2/2

You can change the language of the menus in your MiS<sup>®</sup> Activ hand control and save this.



Contents 48 of 88 Help

# Operation | Menu | Main menu | Service 1/2



The menu item Service allows you to view information on Hand control and Drives, Statistics, Technical inspection and Licenses.

#### **Info Drives**

Here you can find information on the software and hardware of the individual MiS® Activ drives.

A numerical assignment of the drives is shown in the graphic below.

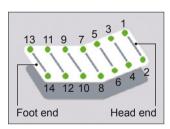


Info Hand control

Here you can find information on the software and hardware of the MiS® Activ hand control.



Assignment of the individual drives of the MiS® Activ:



Contents 49 of 88 Help

# Operation | Menu | Main menu | Service 2/2

#### **Statistics**

This section contains statistical data in respect to the operating duration and movements made by the individual drives.

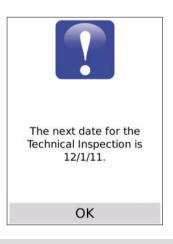


back Hand control

Drive 2

### **Technical inspection**

The Technical inspection menu item allows you to see when the next technical inspection has to be carried out on your MiS® Activ.



#### Licenses

The Licenses menu item contains information on the licences of individual module parts of the software.

#### Licenses

This product contains modules published under several licenses:

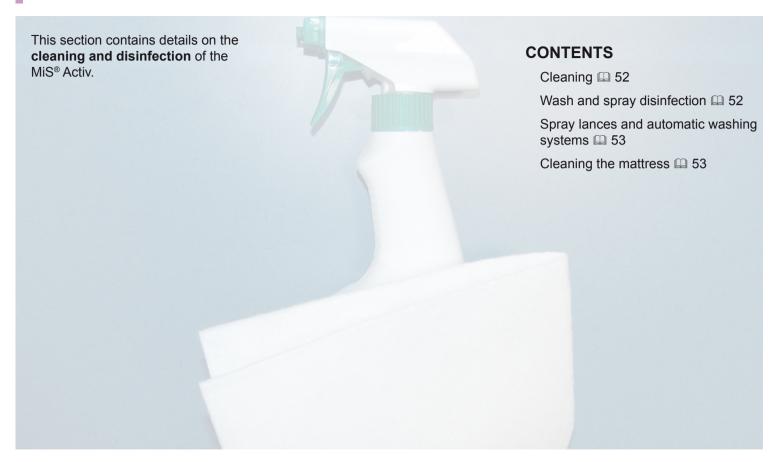
GNU GENERAL PUBLIC LICENSE (GPL)

For more information about the GPL, see: http://www.gnu.org/ licenses/ gpl.html

- · linux (http://www.kernel.org)
- ahavi (http://avahi.org/)
- busybox
- (http://busybox.net/
- hacorl

dack

# **Cleaning and disinfection**



Contents 51 of 88 Help

# Cleaning and disinfection 1/2

In order to maintain consistent functioning of the MiS® Activ, the MiS® Activ should be cleaned, disinfected and tested as soon as possible following each use, so that it can be reused immediately without risk. Incorrect cleaning/ disinfection of the MiS® Activ can cause hazards.

### Cleaning

Depending on the degree of soiling, we recommend cleaning the MiS<sup>®</sup> Activ with a damp cloth or similar.

#### Wipe and spray disinfection

For wipe and spray disinfection, the disinfecting agents featured in the VAH (Verbund für angewandte Hygiene e.V.) list dated 01.01.2008 can be used in their specified concentrations in Germany. They must be applied at the dilution ratio specified by the relevant manufacturer's instructions for use. The list can be obtained under ISBN Number 978-3-88681-089-5.

**NOTE** Solvents are not permitted. Grinding agents, scouring pads or other dulling substances must not be used.

Organic solvents such as halogenated / aromatic hydrocarbons and ketones must not be used.

The following instructions must be noted when using cleaning and disinfecting agents:

- The working solutions should be freshly prepared.
- 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 circumstances should someone using a disinfectant follow their own judgement to add a detergent such as a soap or detergent substance (leads to soap becoming ineffective).
- There is a risk of fire or explosion from alcoholic spray disinfectants when these are used over large areas.

- They must not contain any corrosive or irritant components.
- They must not contain any substances that change the surface structure or gripping properties of the materials.
- Lubricants must not be affected.
- The pH value of the solution must be no higher or lower than 6-8.
- Water should not exceed a total water hardness of 0.9 mmol/l (up to 5 °dH).

# Cleaning and disinfection 2/2

The specifications in the VAH list, as well as the specifications we have issued do not absolve the user of the obligation to carry out his or her own checks and investigations, since the ratios (e.g. water hardness) can vary depending on the geographical location. It is therefore impossible to offer legally binding assurance of certain properties.

If unsuitable cleaning and disinfecting agents are used, if the mixing ratio is incorrect or if there is inadequate care of the MiS® Activ, damage can occur to the surface coating for which Völker GmbH is not liable.



# WARNING "Risk of electric shock / fire and functional failure"

MiS® Activ must always be disconnected from the power supply during cleaning and disinfection.

Plugs and sockets are only protected against splash water when plugged in and engaged.

# Spray lances and automatic washing systems

Cleaning and disinfection using spray lances from high-pressure cleaning equipment and in automatic bed washing systems is **not** permissible.

### Cleaning the mattress

Please follow the cleaning and care notes supplied with the mattress when cleaning the mattress.

### **Maintenance**

The **Maintenance** section contains information on how to carry out maintenance work.

### **CONTENTS**

Staff training 55

Safety notes 🕮 55

Maintenance schedule 4 56



# Maintenance | Staff training, safety notes

#### Staff training

Every person involved with maintenance or servicing must at least

- have taken part in service training by Völker
- · have read the safety notes and
- be qualified in accordance with MPBetreibV § 4.

To avoid errors and ensure that the MiS® Activ works properly, these documents must always be accessible to service personnel.

Before commencing maintenance work, the instructions for use must be read in full by the person responsible for carrying out the servicing.

#### Safety notes

During maintenance and technical inspections, the following specifications must be strictly observed:

- The room's electrical installations must satisfy current technical requirements and the MiS® Activ must be used correctly.
- The MiS® Activ is not protected against explosion and must therefore only be serviced in an environment free from flammable substances and materials.



**WARNING** Always pull out the mains plug before carrying out repair work.



**WARNING** Maintenance and repair work should only be carried out after the MiS® Activ has been disinfected.



**WARNING** Maintenance and repair work should only be carried out on an unoccupied bed/ MiS<sup>®</sup> Activ. The occupant/patient may also have to be transferred to another bed before the work.



WARNING After maintenance (repair) work is complete, always check that the MiS® Activ is functioning correctly. It must be checked whether the MiS® Activ can be used correctly without risk to the occupant/patient or care personnel.

# **Maintenance | Maintenance schedule**

MiS® Activ requires little maintenance. It is recommended that MiS® Activ undergo a regular, or at least once a year, technical inspection 

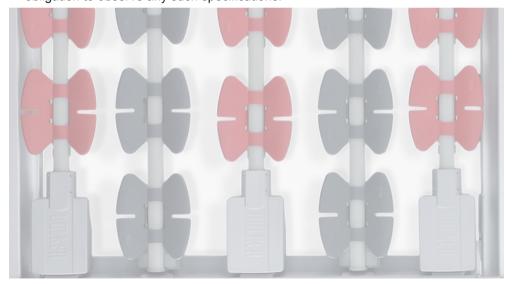
57 (including visual inspection and functional check) as described in the checklist 

81 and any damage uncovered as a result, such as signs of wear and tear, loose screws or breaks/fractures, be eliminated immediately.

Period	Work to be carried out
Annually	Technical inspection 🖺 57
As required	Replacement of wearing parts     Wings     Spring elements

# **Technical inspection**

The section entitled **Technical inspection** contains all the information needed to carry out the technical inspection in accordance with MPBetreibV, BGVA3, UVV on hospital and care beds and measurement as per DIN EN 62353. Other (e.g. country-specific) specifications have not been included here. This does not absolve the operator from the obligation to observe any such specifications.



#### **CONTENTS**

Documentation 58

Lying surface 58

Mains connection cable, plug 58

Strain relief, kink protection 58

Fit of the plug-in contacts 58

Power supply unit housing 58

Hand control 58

Wear and tear 59

Functional check of the drives  $\ \square \ 59$ 

Measurement in accordance with DIN EN 62353 
☐ 59

Further accessories 

59

### Technical inspection 1/2

#### 1. Documentation

Check whether all inscriptions on the MiS® Activ are clearly legible. The serial number is located on the type label on the lowest support profile of the seat section of the MiS® Activ.

Check whether the instructions for use of the MiS® Activ are available. At least one set of instructions for use must be available at each station.

#### 2. Lying surface

Check whether all parts of the lying surface are present (e.g. wing of the MiS® Activ). The spring elements must be firmly clamped in. The fibre glass support profiles must be checked for fracturing.

#### 3. Mains connection cable, plug

#### Check

- the mains connecting cable for signs of damage or cracks in the insulation
- the kink protection on the power supply unit (cable must be firm and must not be able to be pulled out)
- the mains connecting plug for damage and cracks.

#### 4. Strain relief, kink protection

Check all cables leading to the active components of the MiS® Activ. Pull the cable as a check. The plug must not become detached from the drive

#### 5. Fit of the plug-in contacts

Check all plug-in connections between the lying surface elements and also at the drives for a firm fit.

### 6. Power supply unit housing

Check the housing for damage (cracks or deformation through heat). All screws must be firmly tightened and seals must not exhibit any visible damage.

#### 7. Hand control

Check the hand control for cracks, deformations or keypad membrane that has swollen due to moisture. The labelling must be clearly legible.

### Technical inspection 2/2

#### 8. Wear and tear

Check all drives for damage to the paintwork.

#### 9. Functional check of the drives

Activate the basic programs and check the function of each individual drive. When doing so, pay attention to unusual noises, speed, smooth running, etc. Particularly ensure that the drive switches off automatically when it reaches the zero position.

# 10. Measurement in accordance with DIN EN 62353

The MiS® Activ must be checked electrically in accordance with DIN EN 62353. The leakage current must be measured. Patient leakage current and device leakage current are measured identically in the MiS® Activ. The measuring point is a screw on one of the drives. The max. measured value must be less than or equal to 100  $\mu$ A.

#### 11. Further accessories

Further accessories must always be checked in accordance with the manufacturer's instructions.

# **Troubleshooting**

The section entitled **Troubleshooting** contains a table of faults for users, together with information on the service points.

#### **CONTENTS**

Table of faults @ 61

Service points 🕮 64



# Troubleshooting | Table of faults 1/3

The table below contains information on possible problems that users can resolve themselves.

Anyone responsible for carrying out maintenance and repair work must at least have received service training from Völker, have read the safety notes and be qualified in accordance with MPBetreibV section 4.

**NOTE** Switch on the control unit before any troubleshooting and check that the MiS® Activ is connected to the power supply (the mains plug is in a live socket).



**WARNING** Before carrying out any repair work, ensure that the MiS® Activ has been disconnected from the power supply.

# **Troubleshooting | Table of faults 2/3**

Fault	Possible cause	Troubleshooting
MiS® Activ not functioning.	(1) The keypad lock is activated.	(1) Deactivate the key lock 🕮 38.
	(2) The mains plug is not plugged in or	(2) Connect the plug or check the socket.
	there is no power to the socket.	(3) Check connection between the individual
	(3) Connection between the individual MiS® Activ elements, power supply unit or hand control not correct.	MiS <sup>®</sup> Activ elements, power supply unit or hand control
		(4) Replace hand control.
	(4) Hand control defective.	(5) Replace power supply unit.
	(5) Power supply unit defective.	
The display is dark even though the pilot lights of the ON/OFF button and the mains voltage supply light up green.	(1) Display has switched off automatically corresponding to the settings 47.	(1) Press the "OK" key so that the display becomes active again.
Main menu items Day Pro-	(1) Menu items are locked.	(1) Cancel lock 🕮 42.
grams and Settings cannot be selected.		The menu items Day Programs and Settings should only be changed by medical experts.
Head bar not functioning.	(1) Option key "Deactivate Head Bar" is active.	(1) Activate head bar by pressing the option key "Deactivate Head Bar"
	This can be recognised from the illuminated LED of this option key.	noy bodonvato rioda bar 📾 20.

62 of 88	Help
	62 of 88

# **Troubleshooting | Table of faults 3/3**

Fault	Possible cause	Troubleshooting
Drives of the MiS® Activ have longer pause times than normal.	(1) Option key "Night Program" is active. The pauses are longer in the night program. This can be recognised from the illuminated LED of this option key.	(1) Deactivate night program by pressing the option key "Night Program"   □ 20.
The MiS® Activ has switched off automatically.	(1) A program has been selected, which has activity and pause times.	(1) Check set program and the program steps specified in this 🕮 43.

# **Troubleshooting | Service points**

If necessary, please seek assistance from the relevant contact at your nearest Völker sales organisation. You will receive all the information you need for comprehensive service promptly.

Contents 64 of 88 Help

# **Appendix**

The **Appendix** section contains the technical specifications and classifications, details on the service life and disposal of the equipment and links to the manufacturers' declarations and forms found in the appendix.

Konformitätserklärung Anhang VII ELL-Richtlinie 93/42/EWG

Der Unterzeichnende Völker AG Wullener Feld 79 58454 Witten

mit einer Fertigungsstätte unter der Adresse Völker AG Ahornstraße 4

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:

OIN EN 60601-1:2007-07

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

The signatory Völker AG Wullener Feld 79 58454 Witten/Germany

with a manufacturing side a Völker AG Ahornstraße 4 09661 Hainichen/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 60601-1:2007-07, DIN EN 60601-1-2:2007-12 Déclaration de conformité annexe VII Directive EU 93/42/CEE

La soussignée Völker AG Wullener Feld 79 58454 Witten/Allemagne

avec un site de production à Völker AG Ahornstraße 4 09661 Hainichen/Allemagne

confirme que les produits spécifies cilessous sont conformes, dans le modèle nis en circulation, aux exigences condamentales de L'annexe L de la lirective européenne 93/42/CEE. Les standards suivants sont appliqués :

DIN EN 60601-1:2007-07

### **CONTENTS**

Symbols used  $\hfill \Box$  66

Technical data 🕮 67

Classification @ 68

Type label 🕮 69

Service life/disposal 🕮 71

Contents 65 of 88 Help

# Appendix | Symbols used



#### Warning symbols

Information marked with this symbol must always be read and strictly observed!



Direct current



Alternating current



Warning about the risk of crushing and entrapment!



Protection class II device, protection-insulated



Note the information in the instructions for use!



Functional earthing



Safe working load 250 kg.

This value applies for the MiS® Activ. Potentially lower load bearing capacities of beds must be taken into account.



Type B application part as per DIN EN 60601-1



The product satisfies the fundamental requirements of Appendix 1 of EU Directive 93/42/EEC.



Max. permissible weight of the occupant/patient 220 kg (approx. 30 kg for the mattress and accessories).

This value applies for the MiS® Activ. Potentially lower load bearing capacities of beds must be taken into account.



The product must be disposed of in accordance with EU Directive 2002/96 EC pertaining to old electrical and electronic equipment.

# Appendix | Technical data

External dimensions (W x L)	90 x 200 cm (Standard) 90 x 210 cm 90 x 220 cm 100 x 200 cm 100 x 210 cm 100 x 220 cm
Unladen weight (standard size)	approx. 19.8 kg
Safe working load MiS® Activ	As a result of the weight (approx. 30 kg) of the mattress and other accessories, the maximum permissible occupant/patient weight is 220 kg. If another mattress is used or other accessories, this value must be recalculated!
	These values apply for the MiS® Activ. Potentially lower load bearing capacities of beds must be taken into account.
Mains voltage Nominal power Nominal frequency	AC 110-240 V 150 VA 50-60 Hz

Primary fuse	T 3.15 A (non replaceable)
Operating temperature range	+ 10 °C to + 40 °C
Transport / storage temperature range	- 20 °C to + 60 °C
Air humidity	30 % to 75 % rel.
Air pressure	700 hPa to 1060 hPa
Operating volume	30 db(A)

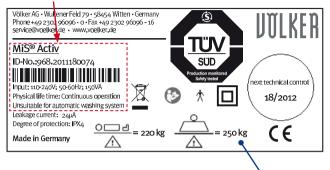
Contents 67 of 88 Help

# Appendix | Classification

Protection against electric shock	Protection class II
Protection type by housing as per EN 60529	IPX4 not suitable for clean- ing in automatic washing systems
Degree of protection of the applied part against electric shock as per DIN EN 60601-1	Type B
Degree of protection against explosive substances and mixtures	The MiS® Activ is not protected against explosion and should not be used in an environment in which flammable anaesthetics or flammable cleaning agents are present (see brochure from accident prevention organisation ZH 1/200)
Grouping/Classification as per 93/42/EEC Appendix IX	Class I
Mode of operation	Continuous operation
Technical inspection	1x yearly

# Appendix | Type label 1/2

### Type specifications

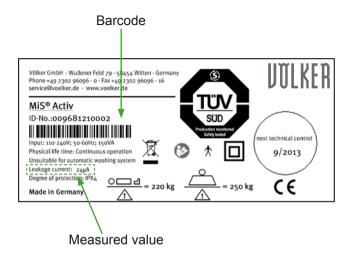


The type label is located on the lowest support profile of the seat section of the MiS® Activ.



Type specifications	Declaration
1st line	Model designation. In the example: MiS® Activ
2nd line	ID No. (made up as follows):  968 = Model  2011 = Year of construction  18 = Production week
3rd line	Input: mains voltage; mains frequency; power consumption
4th line	Physical life time: Continuous operation
5th line	Suitability for automatic washing systems. In the example: unsuitable for automatic washing systems

# Appendix | Type label 2/2



Measured value	Declaration
1st line	Leakage current in μA

The specified initial measured values were measured in accordance with DIN EN 62353.

The barcode (code 128) contains the numeric ID No. (10 digits).

# Appendix | Service life/disposal

The expected service life of the MiS<sup>®</sup> Activ is about 10 years. To ensure environmentally responsible disposal after decommissioning, please contact your responsible area sales manager.

Contents 71 of 88 Help

# Appendix | Manufacturer's declarations, forms, electronic instructions for use

#### Manufacturer's declarations

- Guidelines and manufacturer's declaration Electromagnetic emission

   for all ME devices and ME systems
   74
- Recommended protected distance between portable and mobile HF telecommunications equipment and the MiS® Activ – for devices and systems that are not life-sustaining \$\mathbb{Q}\$ 80

#### **Forms**

- Spare part order 

  82

#### **Electronic instructions for use**

Requirements for the use of the electronic instructions for use 

83

Contents 72 of 88 Help



# Konformitätserklärung / Declaration of Conformity / Déclaration de conformité

Déclaration de conformité Directive EU 93/42/CEE Annexe VII Declaration of conformity EU Directive 93/42/EEC Appendix VII Konformitätserklärung EU-Richtlinie 93/42/EWG Anhang VII

Wullener Feld 79 58454 Witten/Germany The signatory Völker GmbH mit einer Fertigungsstätte unter der Adresse: Völker GmbH Ahomstraße 4 09661 Hainichen Der Unterzeichnende Wullener Feld 79 58454 Witten /ölker GmbH

with a manufacturing side at: Völker GmbH Ahomstraße 4 09661 Hainichen/Germany

avec un site de production à: Ahornstraße 4 09661 Hainichen/Allemagne

Völker GmbH

Wullener Feld 79 58454 Witten/Allemagne

La soussignée Völker GmbH

confirme que les produits spécifies ci-dessous sont conformes, dans le modèle Les standards suivants sont appliqués mis en circulation, aux exigences fondamentales de L'annexe L de la directive européenne 93/42/CEE. ourselves meet the basic requirements of Appendix I of EU Directive 93/42/EEC. The following standards are applied: DIN EN 60601-1:1995, DIN EN 60601-1-2:2007-12, DIN EN 60601-1-4:1996+A1:1999, DIN EN 60601-2-52:2010-12. confirms that the products described below and in the form distributed by

DIN EN 60601-1:1995,
DIN EN 60601-1-2:2007-12,
DIN EN 60601-1-4:1996+A1:1999,
DIN EN 60601-2-52:2010-12.

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

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

produits, non autorisée par le fabrican nvaledée en cas de modification des Cette déclaration de conformité est

# Désignation du produit Modèle/Référence: WIS® Activ

Description of the product Type/Article No.: MIS® Activ

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

les produits médicaux (annexe I « Exigances fondamentales »). La conception du produit est conforme à la classe (Jannexe IX) Directive 93/42/CEE du 05.09.2007. Directives européennes : Directive 93/42/CEE du 14.06.1993 sur

bestäligt, dass die nachfolgend bezeichneten Produkte in der von uns in Verkehr gebrachten Ausführung die grundlegenden Anfordeungen des Anhangs I der EU. Richtlinie 93/42/EWG erfüllen. Es wurden die

DIN EN 60601-1:1995,
DIN EN 60601-1-2:2007-12,
DIN EN 60601-1-4:1996+A1:1999,
DIN EN 60601-2-52:2010-12.

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

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

# Bezeichnung des Produktes: MIS® Activ

Anforderungen\*).
Die Produkte sind Produkte der Klasse I
gemäß Anhang IX der Richtlinie 93/42/EWG
vom 05.09.2007. Richtlinie 93/42/EWG vom 14.06.1993 über Medizinprodukte (Anhang I "Grundlegende EG-Richtlinien:

concering medical products (Appendix I, assic requirements). The design and construction of this product conforms to Class I (Appendix IX) Directive 93/42/EEC of 05.09.2007.

Directive 93/42/EEC of 14.06.1993

EU Directives:

Witten, 20.02.2012

Geschäftsführer / Managing Director / Gérant Mitchel Tidman

Info

You can find a printable version of this document on the Internet at www.voelker.de.

**Contents** Help 73 of 88

# Guidelines and manufacturer's declaration – Electromagnetic emission – for all ME devices and ME systems

The MiS® Activ is intended for use in an electromagnetic environment as indicated below. The customer or user of the MiS® Activ should make sure that it is operated in such an environment.

Interference emission measurements	Conformity	Electromagnetic environment – guideline				
HF emission	Class B	The MiS® Activ is suitable for use in all equipment including that in				
CISPR 11		residential areas and that which is directly connected to the mains				
Emission of harmonics	Class A	<ul> <li>power supply, which also supplies buildings used for resident purposes.</li> </ul>				
IEC 61000-3-2						
Emission of voltage fluctuations and flicker	Conforms					
IEC 61000-3-3						

Contents 74 of 88 Help

# Guidelines and manufacturer's declaration – Electromagnetic immunity – for all ME devices and ME systems

The MiS® Activ is intended for use in an electromagnetic environment as indicated below. The customer or user of the MiS® Activ should make sure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guideline
Discharge of static electricity (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The ground should be made of wood or concrete and be laid with ceramic tiles. If the ground is covered with synthetic material, the relative air humidity must be at least 30%.  "Appropriate protection measures against electrostatc discharges, caused by the operating personnel must be ensured."
Rapid transient electrical disturbance / bursts IEC 61000-4-4	± 2 kV for power cables	± 2 kV for power cables	The quality of the supply voltage should be commensurate with a typical commercial or hospital environment.

© Continued on next page.

Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guideline
Surge voltages/ surges IEC 61000-4-5	± 1 kV voltage external conductor - ex- ternal conductor	± 1 kV voltage external conductor - exter- nal conductor	The quality of the supply voltage should be commensurate with a typical commercial or hospital environment.
	± 2 kV voltage external conductor - earth	± 2 kV voltage external conductor - earth	
Voltage dips, short-circuit interrup- tions and fluctuations in	$<5~\%~\mathrm{U_T}$ (>95 % dip in the $\mathrm{U_T}$ ) for 1/2 period	$< 5 \% \ U_{\rm T}$ (>95 % dip in the $\rm U_{\rm T}$ ) for 1/2 period	The quality of the supply voltage should be commensurate with a typical commercial or hospital environment.
the supply voltage IEC 61000-4-11	$40~\%~\mathrm{U_T}$ (60 % dip in the $\mathrm{U_T}$ ) for 5 periods	$40 \% U_{T}$ (60 % dip in the $U_{T}$ ) for 5 periods	If the user requires continued function of the MiS® Activ when interruptions in the power supply occur, it is recommended
	70 % UT (T tiefgestellt) (30 % dip in the UT) (T tiefgestellt) for 25 periods	70 % UT (T tiefgestellt) (30 % dip in the UT) (T tiefgestellt) for 25 periods	that the MiS® Activ be powered via an uninterruptible power supply or battery.
	$< 5 \% U_{\scriptscriptstyle T}$ (>95 % dip in the $U_{\scriptscriptstyle T}$ ) for 5 sec	$< 5 \% U_{T}$ (>95 % dip in the $U_{T}$ ) for 5 sec	
Magnetic field at supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should correspond to the typical values present in commercial and hospital environments.
NOTE 1: U <sub>T</sub> is the mains	alternating voltage before a	application of the test level	

Contents 76 of 88 Help

# Guidelines and manufacturer's declaration – Electromagnetic compatibility for all ME devices and ME systems that are <u>not</u> life-sustaining

The MiS® Activ is intended for use in the electromagnetic environment as described below. The customer or user of the MiS® Activ should make sure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment - guideline
Conducted HF disturbances IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V	Portable and mobile radio equipment should not be used any closer to the MiS® Activ or its cables than the recommended protected distance which is calculated based on the equation applicable for the transmission frequency.

© Continued on next page.

Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guideline
Radiated HF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended protected distance $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where $P$ is the rated output of the transmitter in Watts (W) as specified by the transmitter manu-
			facturer and <i>d</i> is the recommended protected distance in metres (m).  The field strength of stationary radio transmitters should be less than the conformity level <sup>b</sup> at all frequencies, as verified by an on-site test <sup>a</sup> .  Disturbance is possible in the environment of equipment that bears the following label.

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

NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is affected by the absorption and reflection of buildings, objects and people.

© Continued on next page.

<sup>a</sup> The field strength of stationary transmitters, such as base stations of cordless telephones and mobile land radio, amateur radio stations, AM and FM radio and TV stations cannot theoretically be accurately quantified in advance. To determine the electromagnetic environment in relation to a stationary transmitter, a study of the site should be considered. If the measured field strength at the site where the MiS® Activ is used exceeds the conformity levels stated above, the MiS® Activ should be observed to ensure that it functions correctly. If unusual performance characteristics are observed, additional measures may be necessary, such as changing the alignment or the location of the MiS® Activ.

<sup>b</sup> In the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

# Recommended protected distance between portable and mobile HF telecommunications equipment and the MiS® Activ – for devices and systems that are <u>not</u> life-sustaining

MiS® Activ is intended for operation in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the MiS® Activ can help to avoid electromagnetic disturbances by respecting the minimum distance between portable and mobile HF telecommunications equipment (transmitters) and the MiS® Activ. The recommended minimum distance d is dependent on the maximum power output of the communication device (see below).

	Protected distance, depending on the transmission frequency m				
Rated output of the transmitter  W	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √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 whose maximum rated output is not specified in the table above, the recommended protected distance *d* in metres (m) can be calculated using the equation in the column that features *P* as the maximum rated output of the transmitter in Watts (W) as defined by the transmitter manufacturer.

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

NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is affected by the absorption and reflection of buildings, objects and people.

Contents 80 of 88 Help

	62353	
TIOUS	IN EN	
reguis	per D	
sarety	ent as	
s and	suren	
ndard	ig mea	
an sta	cludin	
Serm	ctiv in	
e with	MiS® A	
ordanc	n the I	
n accc	NVV o	
ecnnical inspection in accordance with German standards and sarety regulations	APBetreibV, BGVA 3, UVV on the MiS® Activ including measurement as per DIN EN 62353	nber:
il Inspe	ibV, B(	roject, address, customer number:
cunica	Betre	ct, address, c
Φ	₩	roje

Project, address, customer number:	MIT BELIEIDY, DGVA 3, UVV OII LITE MIST ACLIV ITICIUALITY ITICIALITY IN BASALETTETT AS DEL DIN EN 62333	IIIeasureiii	elle da p		05222
Bed type, manufacturer,					
Location of the MiS® Activ: Identification of the MiS® Activ					
(e.g. corresponding to the in-house inventory and Völker ID no.):					
Date of the test:	Name of the inspector:	ector:			
Type of test	Component to be tested	Annu- ally	In order	Not in order	Not present
Visual inspection	Inscriptions on the MiS® Activ legible				
	Lying surface, wings and spring elements	B*S*			
	Mains connection cable, plug	å			
	Strain reliefs, kink protection	B*/S*			
	Connecting cable, plug-in contacts	B*/S*			
	Power supply unit housing	B*			
	Hand control (housing, cable)	å å			
Functional check of the drives	wear and tear Operate all motors - move to zero positions	x,W*X			
Remark					
Leakage current ≤ 100 µA		γn			
Measuring instrument used S/N					
Overall evaluation of the MIS® Activ:					
Signature of the inspector:	ian i	Next planned inspection:			
B <sup>+</sup> : Check for damage · F <sup>+</sup> : Check for de	B: Check for damage - F: Check for deformation - M*: Check function of the motors, switch off motors when reaching zero position - S*: Check correct seat - X*: General functional	china zero position · S	* Chack cornect s	eat · X*: General:	functional

### Info

You can find a printable version of this document on the Internet at www.voelker.de.

### Spare part order

Page	of	

Address:				Volker GmbH Service Wullener Feld 79 58454 Witten/Germai		LKER	
Name of the	ordering party:			Tel.: +49 2302 96096-62 Fax: +49 2302 96096-66			
Street addres	ss:			E-Mail: service@voelker.			
Zip code/city	/country:			Shipping address, if dit	ferent from the billing a	ddress	
Telephone n	umber:		Stamp	Address:			
Customer nu	ımber:						
Customer or	der number:	_		Attention of:			
Purchase or	der date:			Street address:			
	form use block letters)			Zip code/city/country:			
MODEL (Bed-type)	the information carefully and complete the form in SERIAL NO./ YEAR OF MANUFACTURE (Identification label inside of the bed-head)	its entirety, otherwise we may have problems in o	lelivering and processing this order.	ITEM NUN	IBER	QUANTITY	
						Info	
						You can	
						of this do on the In www.voe	ocument iternet at

Contents 82 of 88 Help

## Requirements for the use of the electronic instructions for use

In order to open the electronic version of these instructions for use (PDF file), you must have Adobe Reader 7.0.5 or later (or the corresponding Adobe Acrobat version) installed on your PC.

Adobe Reader is available for nearly all operating systems. The latest version can be downloaded free of charge from www.adobe.de/products/acrobat/readstep2.html .

The electronic version of these instructions for use can be found on the Internet at www.voelker.de.

### **Trademarks**

MiS® is a registered trademark of the company Thomashilfen.

Adobe, Acrobat and Reader are protected or registered trademarks of Adobe Systems Incorporated.

Windows is a registered trademark of the Microsoft Corporation.

### Notes

### Notes

### Notes

# **UULKER**

### Völker GmbH

Wullener Feld 79 · 58454 Witten/Germany Telephone +49 2302 960 96-0 Fax +49 2302 960 96-16 www.voelker.de · info@voelker.de