harvesthealthcare®
a prismhealthcare company

General User/ Safety Guide

WOBURN 6 AND WOBURN LOW 4 PROFILING BEDS

PROFILING BEDS

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WARNINGS

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CAUTIONS & WARNINGS

READ THIS INSTRUCTION MANUAL AND OBSERVE SAFETY INSTRUCTIONS.

⚠ CAUTION

Please read and observe this instruction manual before each use. In the event the care bed changes owners, please supply this instruction manual to the new owner.

When the bed is moved on the transport frame take care not to allow it to overbalance. The narrow, tall design saves storage space but may tip over if handled carelessly.

Please check all fixings on your bed at least once a month. Pay special attention to sleeping platform connections.

Before cleaning and disinfection, the mains plug must be disconnected and hung up safely. Plugs for the handset and the motors which are inserted into the mattress base control box and the motor unit must remain plugged in. This is necessary to prevent water ingress to the control box.

Do not sit on the leg section of the bed when operating the raise function.

Ensure the recommended service and maintenance schedule in this manual is completed.

Failure to do so could invalidate warranty claims.

⚠ WARNING

The side rail guards are designed to prevent a person falling out of bed; under no circumstances should they be climbed or leaned upon.

When lowering the rails, take care not to drop them - they should be lowered carefully.

GENERAL INFORMATION

1 GENERAL INFORMATION

BEFORE USING THIS BED FOR THE FIRST TIME:

- **Read through this instruction manual conscientiously**
- **Please note in particular that the various safety instructions must be observed**
- **Clean and disinfect the care bed before first use**

Harvest Healthcare care beds bear the CE mark and meet all safety and functionality requirements. These care beds were tested according to the international standards which contain the safety requirements for medical products. These safety requirements can only be met however if the user satisfies himself of the proper state of the care bed (including accessories) before using the bed.

Please observe the legislation in your country.

1.1 EXPLANATION OF THE SYMBOLS USED

Read information with this symbol carefully and urgently follow instructions. This information is safety-relevant.

This symbol indicates hazards due to electrical voltage. There is mortal danger!

This symbol indicates general hazards. There is danger to life and health.

Conformity mark in accordance with the Medical Device Directive (93/42 EEC).

IPX4 The electrical equipment is splash-proof.

Symbol for Protection Class II device, double shock-proof.

Symbol for type B device according to DIN EN 60601-1.

MD Medical Device

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GENERAL INFORMATION

This care bed may only be used indoors

This product must be disposed of in a separate refuse collection in the European Union. Do not dispose of as normal domestic waste.

Symbol for direct current.

Symbol for alternating current.

Maximum permissible load.

Maximum patient weight.

1.2 DEFINITION OF THE GROUPS INVOLVED

OPERATOR
An operator is any person who uses the care bed or on whose instruction it is used (e.g. nursing homes, specialised retailers, health insurance companies, medical suppliers).

USERS
Users are persons who, as a result of their vocational training, experience or briefing are authorised to operate the care bed or to carry out work on it, or are instructed in handling the bed. Furthermore the user can recognise and avoid potential dangers and assess the clinical condition of the patient.

PATIENT / OCCUPANT
Persons in need of care, handicapped or infirm and occupying a care bed.

QUALIFIED PERSONNEL
Qualified personnel are employees of the operator who as a result of their vocational training or briefing are entitled to deliver, assemble, disassemble and transport the care bed. In addition, these persons are instructed in the cleaning and disinfection regulations for the care bed.

If any serious incident occurs in connection with the Woburn bed range, you must report it to Manufacturer TekVor Care GmbH and or the responsible Health Authority as well as Harvest Healthcare Ltd.

GENERAL INFORMATION

2 INTENDED PURPOSE

2.1 USES FOR THE PURPOSE INTENDED (APPLICATION ENVIRONMENT)

This care bed is intended for accommodating patients or occupants (with body mass ≥150cm to max. 185kg for Woburn and Woburn Low) in residential homes, nursing homes and in care in the home (application environments 3 and 4) and may only be used under the conditions for use described in this Instruction Manual.

Any other use shall be regarded as non-compliant with the regulations and is excluded from any liability.

ATTENTION: The care bed is not designed for use in hospitals.

The care bed is not suitable for medical electrical applications which involve intravascular or intercardiac processes with the patient. The care bed is not designed for the transport of patients.

Under certain conditions the care bed can be used for other medical purposes with medical appliances such as antidecubitus mattresses, aerators, alimentation systems etc. In this case all bed functions must be locked out with the nurse key on the handset for safety. The medical appliance providers are liable for the compliance of the device with the directives of IEC 60601-1-1.

If other electrical devices are used in the bed and to prevent the risk of an electrical shock, protective measures and precautions must be established to prevent power cords from being trapped and squeezed in movable parts of the bed.

2.2 NON-COMPLIANT USE

All uses deviating from the intended purpose, which may be hazardous as a result.
This includes for example:

- Loading the care bed beyond the safe admissible working load (see section **13.1** and identity label on bed frame).
- Operation of the care bed by patients or occupants who have not been instructed in its use.
- Use of the care bed for children.
- Attempting to move the care bed when castors are braked.
- Use of the care bed on a non-horizontal surface (max. incline 5°).

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GENERAL INFORMATION

3 GENERAL REGULATIONS FOR USERS

The care bed must only be used for the purpose intended. When setting up, operating and using the care bed, respect the regulations in your country and the general recognised rules of technology and the occupational health and safety and accident prevention regulations.
If the care bed is in a faulty state, in which the patient/occupant, care personnel or third persons could be endangered, do not operate.

3.1 QUALIFICATION OF USERS

The care bed must only be operated by persons who have the corresponding training or experience to enable them to handle the care bed correctly.

4 SAFETY INSTRUCTIONS

4.1 GENERAL SAFETY INSTRUCTIONS

Never store anything under the bed.
Ensure that children cannot operate the control system and check if pets are under the bed before operating any of the function.
Do not sit on the leg section of the bed when operating the raise function.

During the briefing, specific attention must be drawn to any potential dangers which can occur despite correct operation. Before putting the care bed into service for the first time, the Instruction Manual must be read in detail by the user / care personnel.

When operating the adjusting functions, there must be no objects or people's limbs in the plane of movement of the care bed. **Risk of crushing**.

If the physical or mental state of the patient requires, the handset should be locked on the reverse side of the handset when not in use (nurses' key). See detailed description of the locking operation at section **7.2**. (it may be advisable to keep the handset out of reach of such a patient to avoid the risk of strangulation with the handset cord).

Adjustments to the bed must only be carried out by suitably instructed persons or in the presence of an instructed person.

GENERAL INFORMATION

Unplug the mains plug from the socket before moving the care bed and take care to avoid dragging the mains plug across the floor when moving the bed.

The mains plug must always remain accessible to enable immediate cut-off by unplugging the mains plug from the wall socket in case of emergency. The mains cable must be free and not caught in anything, as it gets carried along when the bed height is adjusted. Otherwise, the mains cable may be torn out and damaged. In addition, the mains plug may be pulled out of its socket and electric leads exposed as a result. If the mains cable or the mains plug are damaged, the relevant part must be replaced. This work should only be carried out by the manufacturer or authorised professionals.

When connecting the mains plug do not use multiple sockets since liquids may penetrate into these (fire hazard and electric shock).

Before cleaning and disinfection the mains plug must be unplugged and hung up safely. Plugs for the handset and the motors which are inserted into the mattress base control box and motor unit must remain plugged in. This is necessary to prevent water ingress into the control box.

When the bed is stationary the castors must always be in the braked position. If the castors are not braked, the bed can move when the occupant gets into and out of bed, since the occupant uses the bed for support. Injury can result if the care bed rolls away.

In order to move the care bed, the brakes on all four castors must be released and the mattress base be adjusted to the lowest horizontal position.

The maximum duty cycle and the safe working load must not be exceeded otherwise safe operation cannot be guaranteed (please refer to the Technical Data in section 14).

The bed must not be used in rooms where there is a risk of explosion.

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GENERAL INFORMATION

4.2 SAFETY INFORMATION FOR THE OPERATOR

With the help of this Instruction Manual, instruct each user in the safe operation of this care bed before it is put into service for the first time.

Advise the user of any hazards which may occur if not handled correctly.

Only persons who have been properly instructed may operate this care bed. This also applies for persons who only operate the care bed on a temporary basis.

According to the Medical Products Act (German abbreviation: MPG, Medizinproduktgesetz), care beds are Class I active medical products.

Please observe your obligations as the operator in accordance with the Operators of Medical Products Ordinance (Medizinprodukte-Betreiberverordnung, German abbreviation: MPBetreibV), in order to ensure the permanently safe operation of this medical product with no risk of danger to patients, users or third parties. If the care bed is used on a long-term basis, checks for proper functioning and for any visible damage must be performed and documented at least once a year. There is section **10.2** for this purpose.

4.3 SAFETY INFORMATION FOR THE USER

Ensure that the operator instructs you in the safe operation of this bed.

In addition, pay particular attention to the general safety information as described in **4.1**. Adjustments of the bed must only be carried out by suitably instructed persons or in the presence of an instructed person.

Make sure that the mattress base has travelled to its lowest position before leaving the patient unattended. This will minimise the risk of injury to the patient when getting in or out of bed.

If there is a suspected fault or damage, unplug the mains plug from the socket. Clearly mark the care bed as “Out of Order” and take it immediately out of service. Please inform the person in charge without delay.

GENERAL INFORMATION

4.4 CLEANING & DISINFECTION

Before cleaning and disinfection the mains plug must be unplugged and hung up safely. Plugs for the handset and the motors which are plugged into the control box must remain in their sockets. This is necessary to prevent water from getting into the control system.

Do not immerse electrical components in water but wipe clean with a damp cloth. The electrical components must not be cleaned with a high pressure cleaner or a water jet! Only disinfection by wiping is allowed.

Always wear waterproof gloves when cleaning and disinfecting to avoid skin irritation.

Attention: In the event of disinfection by spraying on a large scale with products containing alcohol there is a danger of explosion and fire.

4.5 SERVICING & MAINTENANCE

Servicing work must only be carried out by persons who have at least read the safety regulations and are qualified according to the MPBetreibV (Operators of Medical Products Ordinance) § 4 and 6.

A technical check and/or safety inspection must be conducted at least once a year and after a lengthy break in use and before each further use. See section 10..
Any defects, damage or signs of wear must be rectified without delay. Only original spare parts from Harvest Healthcare Ltd may be used, otherwise all guarantees or warranties will be excluded.

The 9V block battery is the energy store for electrical emergency lowering in the event of a power failure. The energy store is sufficient for one emergency lowering at the most and must then be replaced. If the expiry date of the battery has elapsed, replace immediately. Since batteries are subject to self-discharging, it is recommended the battery is replaced every two years if not used. Ensure it is a type 6LR61 alkaline manganese battery and not any other type. Used batteries must be disposed of in an environmentally compatible way.

Please check all fixings on your bed at least once a month. Pay special attention to sleeping platform connections.

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GENERAL INFORMATION

4.6 ACCESSORIES

The optional accessories available include a patient lifting pole of which the safe working load of 80 kg **must not be exceeded**. The lifting pole may only be used within its admissible adjusting range which is defined by the sleeve on the bed. Otherwise the bed may tip up and result in serious injury.

4.7 ELECTROMAGNETIC COMPATIBILITY

Regarding their emitted interference and interference resistance the electric motor units comply with the requirements of EN 60601-1-2:2007 (see section **14.7**). But it is possible that electrical devices interfere with each other. In this case switch off the care bed for a short time or remove the interference source. We refer to the paper of the BfArm reference n° 9/0508 (Bundesinstitutfür Arzneimittel und Medizinprodukte).

4.8 TRANSPORT & STORAGE

The care bed can be easily transported on the transport rack. It can be maneuvered in very small spaces on the bed's castors.

If the bed is stored for a lengthy period, the 9V block battery should be removed, as otherwise it would discharge.

State as delivered (in cover)

Care bed on the transport device

When the bed is moved on the transport frame take care not to allow it to overbalance. The narrow, tall design saves storage space but may tip over if handled carelessly.

4.9 SERVICE LIFE & DISPOSAL

The normal service life for care beds in domestic use is approximately 5 years. The care bed must not be disposed of as normal domestic waste after its service life has expired. To ensure that it is disposed of in an environmentally compatible way please contact Harvest Healthcare Ltd.

INSTALLATION

5 PRE-INSTALLATION CHECK

After unpacking check the following parts are present:

- **A** Backrest section with mounted actuator & control box
- **B** Legrest section with mounted kneebreak actuator
- **C** 2x height adjustable bed ends with mounted actuators & castors
- **D** Power supply with cord and plug
- **E** Handset with locking device
- **F** 4 piece wooden sideguards with 8 plastic cap ends

⚠ **On delivery and before installation check that the packaging is undamaged. Report any visible damage to the transport company immediately.**

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INSTALLATION

6 INSTALLATION & COMMISSIONING

Harvest Healthcare Ltd recommends that a risk assessment is completed by the Operator before this bed is assembled.

6.1 REMOVAL FROM THE TRANSPORT DEVICE

Lift the cover from the bed unit and transporting device.

Please do not dispose of the cover. It can be used again as a dust cover in the event that the care bed is later stored in the transport rack.

Bed as delivered

Care bed on transport device

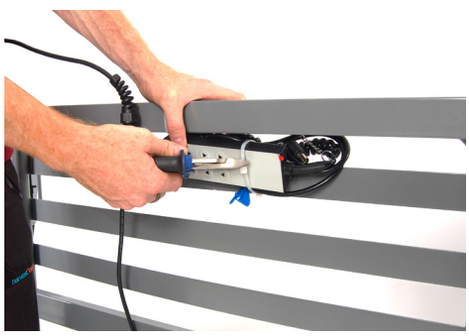
Do not remove the cardboard protection from the top of the headboard /footboard sections at this time as it will protect the bed during assembly.

Lift the foot end mattress base section out of the transporting device. To prevent fingers getting trapped please hold the bed section on the inside of the platform section and not on the outer frame (see images).

Lay the platform section face down, on the floor.

INSTALLATION

Remove the cable tie from the mains adapter and handset.



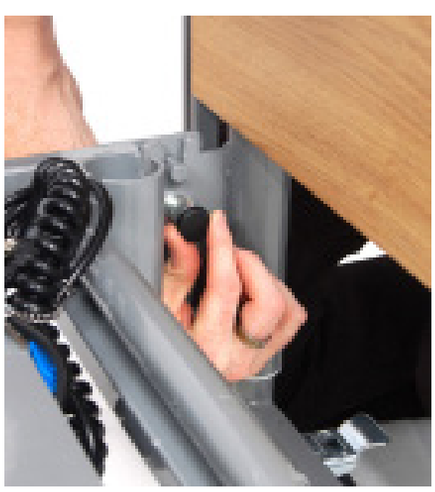
Handset

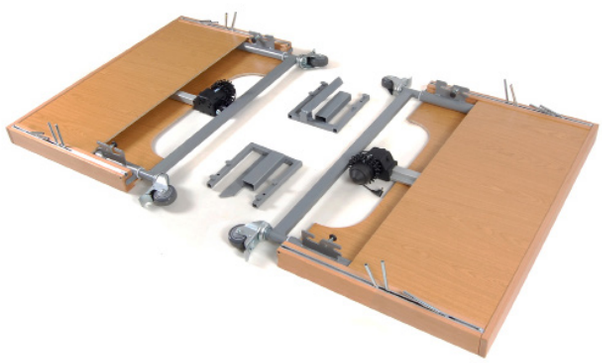
Mains cable

Caution! Do not damage the cable

Remove the height-adjustable head and foot end panels from the transporting device. To do
this, release the spring-loaded catches that are later used to fix the height-adjustable head
and foot end panels to the mattress base.

Pull out catch and turn through 90°





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INSTALLATION

6.2 ASSEMBLY OF THE CARE BED

Connecting the two halves of the mattress base

Lay one platform section face down on the floor adjacent to the other half. Then slide the connecting bars together. Secure using the star knobs.

Lay the mattress base on the floor and attach the first of the bed ends to the mattress base. To do this, apply the brakes on the bed castors by pressing the brake pedal and then release the spring-loaded catches (see 6.2) at the height-adjustable head and foot end panels so the mattress base can be slotted onto the mounting lugs.

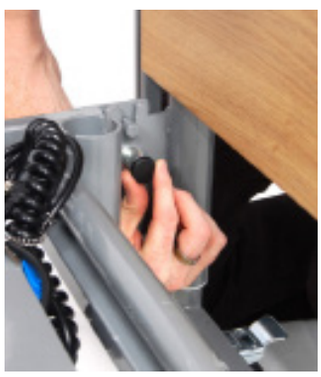
Lock the foot peddle

Connect mattress base

Ensure the power cable runs underneath the actuator

INSTALLATION

When securing the spring-loaded catches, ensure the bolt locks into place in the hole provided for it.



The bolt of the spring-loaded catch must be securely latched into the hole

Now slot the mattress base into place on the second height-adjustable bed-end panel at the other end of the bed.

Fix both the spring-loaded catches securely in place. Now slide the (four) side guards onto the location bolts of the side guard guides, resting the other ends of the side guards on the mattress base at the other end of the bed.

At the end of the bed where the side guards have not yet been pushed onto the location bolts, lift one corner of the mattress base off the mounting lug and pull the mattress base back far enough to allow you to push the side guards onto the location bolts.

Slide both side guards onto the location bolts

Lift one corner of the mattress base slightly. Pull back the bed end panel with mounting lug

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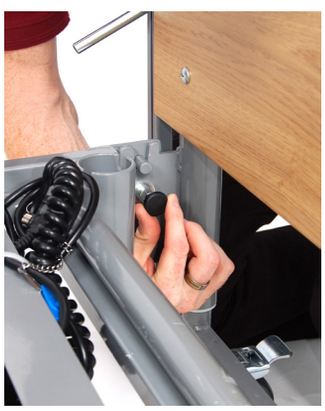
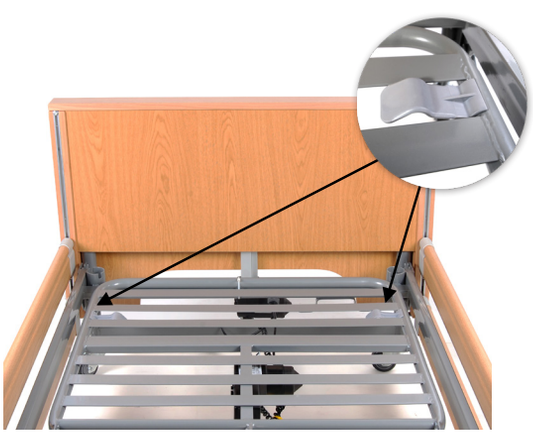
INSTALLATION

Push the end panel back towards the mattress base and place the base onto the mounting lug. Fix both the spring-loaded catches securely in place.

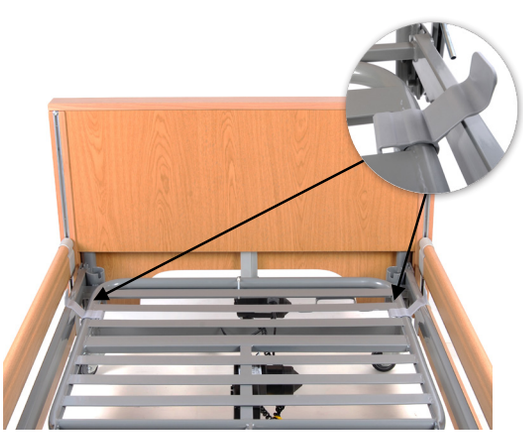


With the side guards slotted into place, the end panel can be pushed back up to the mattress base and secured with the mounting lug. Repeat this procedure on the other side of the bed with the remaining two side guards and fix the two spring-loaded catches securely to the mattress base.

The bed has folding mattress guides. It is important that the mattress guides are moved from the “transport position” into the “in use position” before the bed is put in use.



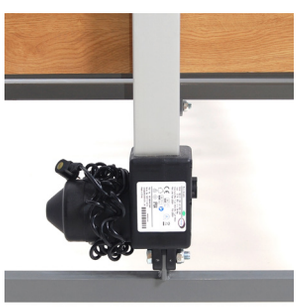
Mattress guides in transport position



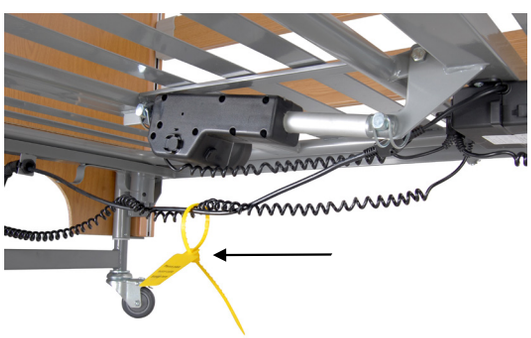
Mattress guides in the in use position

INSTALLATION

Connect the height adjustment motors and the thigh rest adjustment motor to the mains power supply. The power supply cables for the height adjustment motors are wound around its housing.

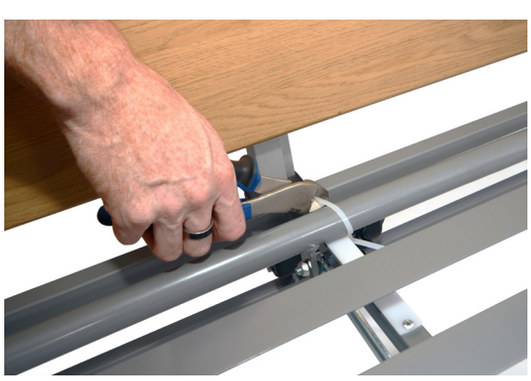


Unwind the cable of the electric motor.



The foot actuator cable MUST go through the yellow cable tie. Wrap the actuator cable round the power cable to reduce the amount of hanging wires under the bed.

First, remove the plug cover by unscrewing the two fixing screws. After you have inserted all the plugs, screw the plug cover back onto the power supply unit housing.



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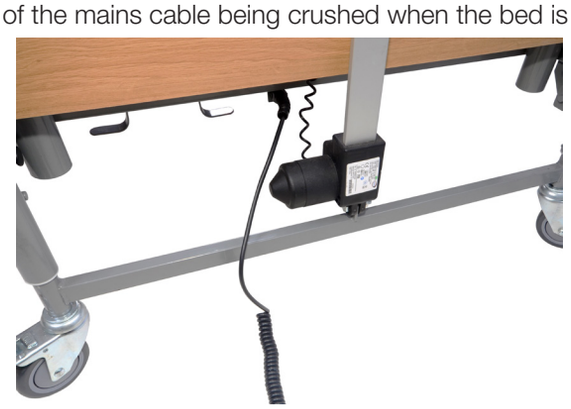
INSTALLATION

6.3 CONNECTING THE CARE BED TO THE MAINS SOCKET

Lay the coiled cable over the crossbeam from the head or foot end as shown in the picture. This reduces the risk of the mains cable being crushed when the bed is moved.



Always avoid rolling the bed over the mains cable.

Insert the mains plug into the socket.

The mains plug must always remain accessible to enable immediate removal from the wall socket in case of emergency.

The electrical adjustment motors are now ready for use.

6.4 PLACING INTO SERVICE

Make sure all assembly steps have been carried out according to **chapter 6, section 6.1 and 6.2.**

Carry out a safety check according to **chapter 10, section 10.2** after assembly.

Clean and disinfect the bed as described in chapter 8 before putting into service and before each further use.

6.5 DISASSEMBLY OF THE CARE BED

Remove the mains plug from the socket before disassembly.

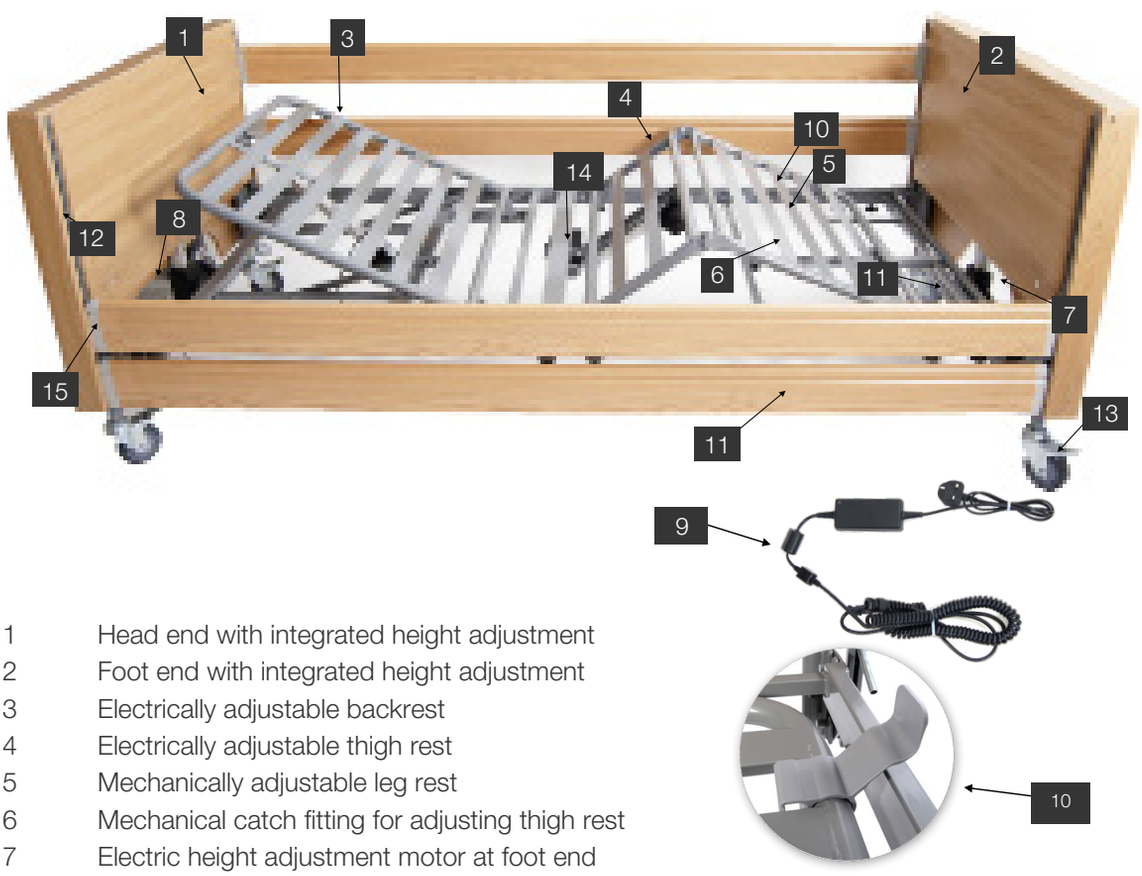
Disassembly of the care bed is carried out in reverse order of assembly.

When reassembling the care bed sections onto the transport brackets, please ensure you align the red dots on the headboard section with the red dots on the transport bracket.

BED OVERVIEW

7 DESCRIPTION OF FUNCTION

7.1 BED OVERVIEW



1 Head end with integrated height adjustment
2 Foot end with integrated height adjustment
3 Electrically adjustable backrest
4 Electrically adjustable thigh rest
5 Mechanically adjustable leg rest
6 Mechanical catch fitting for adjusting thigh rest
7 Electric height adjustment motor at foot end
8 Electric height adjustment motor at head end
9 Coiled cable with SMPS (transformer) and main cable with power plug
10 Folding mattress guide
11 Wooden side rail (with end caps) (not supplied with the Woburn Low)
12 Side guard channel
13 Castor with mechanical brake
14 Control unit
15 Side Rail Release Catch

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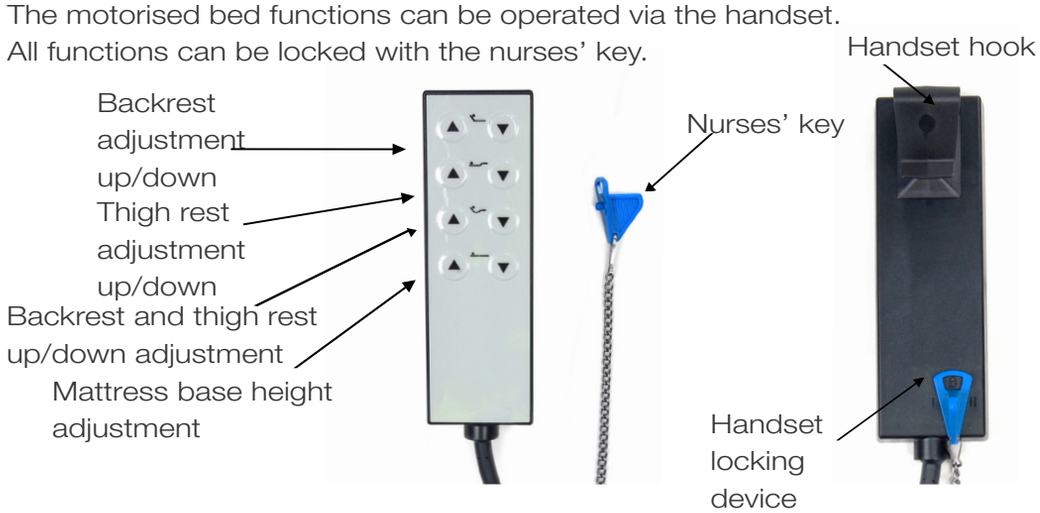
OPERATION

7.2 HANDSET WITH LOCKING FUNCTION

The motorised bed functions can be operated via the handset.
All functions can be locked with the nurses' key.



To avoid damage, the handset should always be hung up by the handset hook (e.g. on mattress base) when not in use.

Press only one button at a time, as the system could overload and become damaged.

7.3 LOCKING FUNCTION FOR THE HANDSET

On the back of the handset there is a locking device. All electric adjustment functions can be blocked at the same time using the nurses' key supplied.

All electric adjustment functions released

All electric adjustment functions locked

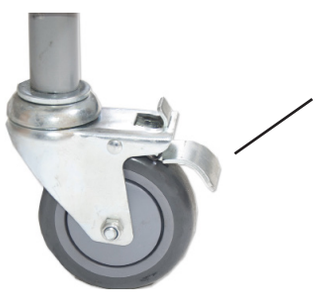
The switching positions I and II are testing settings, used to check the safety during the annual inspection or after repair work, or each time the bed is put into service again.

OPERATION

7.4 OPERATION OF CASTORS

All castors on the bed can be braked and must always be in the braked position during normal operation.

Foot pedal to apply brake



Foot pedal to release brake

The brakes must only be released when the beds needs to be moved. Please also refer to the Safety Information.

7.5 ELECTRIC EMERGENCY LOWERING VIA THE INTEGRATED 9V BATTERY

7.5.1 POSITION AND PRINCIPLE OF OPERATION

The power supply unit fitted (item 8, Overview) on the bed frame is equipped with a 9V block battery, which makes it possible to make a CPR emergency lowering according to EN 60601-2-52 in the event of a power failure. Please note, however, that this is only possible once per 9V battery, as the capacity of the 9V battery is limited.

After the emergency lowering has been used once, the 9V battery must be replaced (Type 6LR61 alkaline manganese battery). The 9V battery should however be replaced every 2 years even if it has not been used.

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MAINTENANCE

7.5.2 BATTERY CHANGE

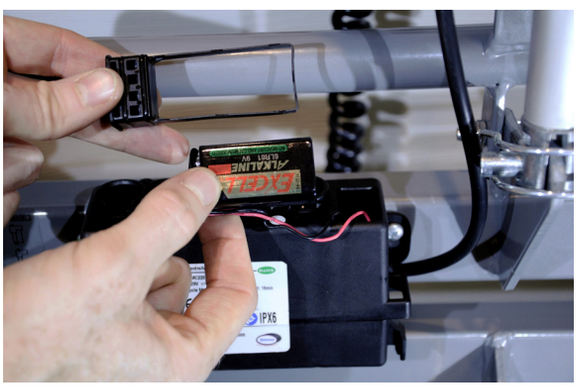
To replace, check or remove before lengthy storage of the 9V battery, open the battery compartment on the power supply unit attached to the backrest motor.

Proceed as follows:

UNPLUG MAINS PLUG

1 Unplug from the low voltage control unit at the plug of the connection cable from the SMPS transformer box.

2 Pull out the battery carrier (the black plastic ring protruding from the control box) and remove the 9V battery. If required, replace it with a new (type 6LR61 alkaline manganese) battery.



3 Reinstall the battery carrier. Be careful not to damage the wires or washer.

OPTIONAL EXTRA - IN-BUILT EXTENSION

8.1 IN-BUILT EXTENSION

To release the in-built extension, loosen the 4 hand screws at the foot end of the bed and carefully pull the extension piece until it is fully released. Please note - when the extension piece has fully released, it will not separate from the bed. Once fully extended, tighten all 4 hand screws.

If you have side rails fitted, these will need to be removed before extending the platform. It is important to regularly check all hand screws and snap pins for security.

In-Built Extension Retracted

In-Built Extension Extended

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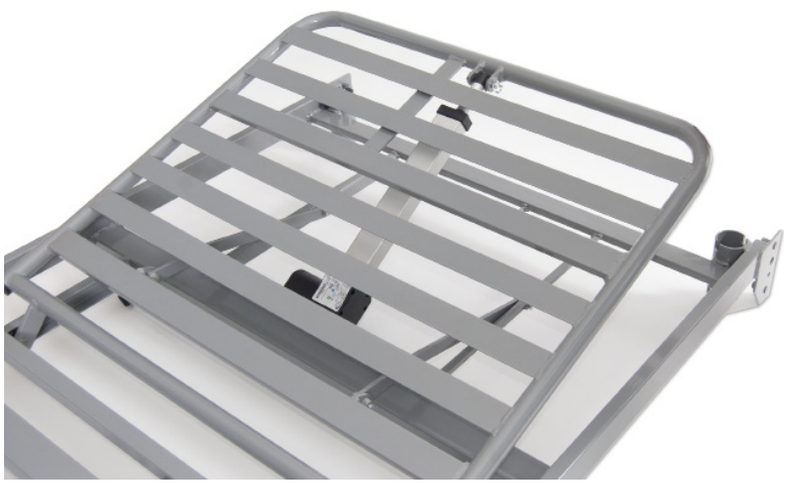
OPTIONAL EXTRA - AUTO-REGRESSION

8.2 AUTO-REGRESSION

The Auto-Regression back-rest



TROUBLESHOOTING

9 CARE, CLEANING & DISINFECTION

Clean and disinfect the bed before placing into service and before each re-use. To clean the care bed, wipe the bed by hand with a damp cloth. Use suitable cleaning and conditioning agents for wooden and synthetic furniture.

Household cleaners without ammonium or scouring agents are allowed, but should be dermatologically tested.

Solvents and scouring agents are not permitted as they damage the various surfaces of the care bed.

To disinfect: In the homepage of the Robert Koch Institute < http://www.rki.de > you will find a list dated of 31.05.2007 of approved and generally accepted disinfection agents and treatments and their use.

Before cleaning and disinfection the mains plug must be unplugged and hung up safely. Plugs for the handset and the motors which are inserted in the control unit MUST remain plugged in. This is necessary to ensure water does not enter the control system.

The brakes must only be released to move the bed. Refer to the Safety Information

10 TROUBLESHOOTING

FAULT	POSSIBLE CAUSE	SOLUTION
No Response	Mains plug not plugged in	Insert mains plug into mains socket
	Locking function on handset activated	Unlock handset
	Handset not plugged in	Insert handset into mattress base motor
	Motor unit not plugged in	Plug motor unit into mattress base motor
Adjustment functions transposed	Connecting cables on the connectors transposed	Check plugs and connectors and change over plugging in locations
No function after power failure	9V block battery is discharged	Replace 9V block battery
Bed only moves very slowly	Bed only adjusted via the battery. Mains plug not plugged in	Plug in mains plug and replace the 9V block battery as a precaution

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SERVICING

11 SERVICING

111.1 PRINCIPLES

Operators of care beds are obliged according to MPBetreibV (Operators of Medical Products Ordinance) §4 to guarantee the safe condition of the medical product over their entire service life.

The test according to the regulation EN 62353 contains the following minimum requirements:

- Visual check
- Measurement of leakage resistance
- Measurement of leakage current
- Functional test
- Overall evaluation

The service life of the care bed depends essentially upon the handling and servicing.
To guarantee safe operation, a visual and functional test including an electrical test must be carried out at least once a year. For this purpose, proceed according to the technical safety checklist as per regulation EN 62353 in section 10.2

If you have any doubts about the safety or functionality of the bed or even a part of the bed as a result of the work performed below, the bed should under no circumstances be put into service again.

Contact the supplier or manufacturer in this case.

SERVICE RECORD

11.2 LIST OF TECHNICAL SAFETY CHECKS ACCORDING TO EN 62353

Care bed: **WOBURN BED** Person in charge: .....
Serial No.: ..... Location: .....

	INSTRUCTION FOR TESTING	COMMENT	YES	NO
1	Is the general condition OK?			
2	Are the type plates for the bed and the motors legible?			
3	Is the Instruction Manual available to staff?			
4	Is the use one for which it was intended and is it safe?			
5	No surface damage or corrosion?			
6	Mechanical components and welded joints without faults?			
7	Are all mechanical connecting elements securely fixed?			
8	Mattress base underside undamaged?			
9	Can all adjustment options for the bed be operated without hindrance on site?			
10	Is the mechanism for locking the thigh rest in place in working order?			
11	Has the load test been carried out successfully according to the regulations?			
12	Are the patient's lifting pole with the grab handle and the lifting pole sleeve undamaged and without any signs of wear?			
13	Have castors including locking brake been tested for safe functioning?			
14	Mains cable, connecting cables and plugs without damage?			
15	Fixture available for safe transportation of mains plug?			
16	Strain relief of the mains cable and handset securely attached?			
17	Are all plug-in connections securely attached? (Washers without damage?)			

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SERVICE RECORD

	INSTRUCTION FOR TESTING	COMMENT	YES	NO
18	Are cables laid correctly and safely? (No damage)			
19	Motor housing and SMPS housing, mains plug housing without damage?			
20	Are the thrust pipes of the height adjustment motors undamaged?			
21	Functional test of the handset: can the buttons be operated properly?			
22	Functional test of handset locking device: On/Off working correctly?			
23	Testing of initial fault safety by means of integrated blocking box in handset			
24	9V block battery OK / expiry date sufficient until next test?			
25	Is the safe working load adhered to?			
	Overall evaluation of the bed: Bed OK?			

Comments: ....
.....
.....
.....
.....
.....
.....

Place/date: ..... Next inspection: .....
Inspected by: ..... Signature: .....

⚠ **The care bed must be serviced every 12 months in order to take advantage of the 5 year warranty. Please contact Harvest Healthcare if you require another copy of this service record.**

SERVICING

11.3 CHECKING THE INITIAL FAULT SAFETY BY MEANS OF THE INTEGRATED CONTROL BOX IN THE HANDSET

To check the safety equipment, proceed as follows:

⚠ **The switching positions I and II are testing settings used only to check the safety during the annual inspection, or after repair work, or each time bed is put into service again.**

- Setting switch position 4 (padlock symbol open
  Move all bed adjustments to a slightly raised position.
- Setting switch position 3 (padlock symbol closed
  When operating the adjustment buttons, no motorised adjustments should be possible.
- Set switch on the back of the handset to testing position 1 (symbol I).)
  When operating the adjustment buttons, no motorised adjustments should be possible.
- Set switch on the back of the handset to testing position 2 (symbol II).)
  When operating the adjustment buttons, no motorised adjustments should be possible.

11.4 MEASUREMENT OF OVERALL ELECTRICAL SYSTEM

⚠ **The measurements described here must only be performed by a qualified electrician or by an electrotechnically trained person, (using suitable measuring and testing devices).**

The measurements shall include as a minimum the testing of the housing leakage current and the measurement of the isolation resistance.

The following measured values must be attained:

*Housing leakage current	<= 0.2mA
*Isolation resistance	<= 7MΩ

During testing the corresponding button on the handset must be constantly pressed.

The measurement is to be performed between:

- *The control unit and the bed frame
- *The control unit and the handset

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SERVICING

12 GUARANTEE

As stated in our Standard Terms and Conditions, we provide a manufacturer's warranty of 5 years from the date of purchase.

To take advantage of the 5 year warranty, the bed must be serviced (without exception) every 12 months by a Harvest Healthcare Ltd approved technician using only Harvest Healthcare Ltd original spare parts. A service record must be completed (an example can be found on **pages 28-29)**.

13 SERVICE LIFE & DISPOSAL

The service life of our care beds in domestic use is assumed to be approximately 5 years. This naturally depends upon the manner of use. The carebed is suitable for reuse if all measures of section 6.3 and 10 are taken. Frequent transportation, setting up and adjustment reduce the service life, as do improper treatment, irregular servicing and exceeding the safe working load or the admissible load cycle of the electric motors. The care bed must not be disposed of as normal household waste after the end of its service life. To ensure that it is disposed of in an environmentally compatible way please contact Harvest Healthcare Ltd.

TECHNICAL SPECIFICATION

14 TECHNICAL SPECIFICATION

14.1 TECHNICAL DATA (MECHANICAL)

Woburn 6 & Woburn Low 4

Safe working load (max. admissible load)	220 kg	
Individual loads of the safe working load	Max. weight of patient	185kg
	Mattress	20kg
	Accessories	15kg
	Total	220kg

Safe load, patient's lifting pole	80 kg	
Max. weight of patient	185kg	
Max. mattress height:	205mm	
Length	2130mm (2000mm long mattress)	
Width	1020mm (900mm wide mattress)	
Upper level of head section/foot section	Woburn 6:	86.5cm – 129cm
	Woburn Low 4:	79cm - 121.5cm
Height adjustment of mattress base continually adjustable electrically from:	Woburn 6:	365 - 795mm
	Woburn Low 4:	220 - 650mm
Backrest adjustment continually adjustable electrically up to	approx. 70°	
Thigh rest adjustment continually adjustable electrically up to	approx. 30°	
Leg rest in raised position	mechanically, -25° - 0° in 5 stages	
Mattress base surface	Steel slatted base	
Wooden side guards including plastic end caps	1973 x 115 x 28 mm	
Castors with individually lockable brake	Woburn 6 -	Ø75mm
	Woburn Low 4 -	Ø 50mm
Max. castor loading capacity	100 kg (static)	
Unloaded weight	106 kg	
Operating noise:	< 53 db(A) at a distance of 1m	

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TECHNICAL SPECIFICATION

14.2 TECHNICAL DATA (ELECTRONIC)

Power supply unit (LIMOSS)	control unit MC220 + SMPS MC125
Voltage rating	230/240V
Frequency rating	50/60 Hz
Type of current	AC
Nominal consumption during operation	70 Watt
Nominal consumption in idle state	0.5 Watt
Nominal operating time/ Nominal idle time	2 Min. / 18 Min (max. 5 switching cycles/min.)
Primary safety fuse	2.0 A
Battery for emergency lowering	9V block battery (alkaline manganese type 6LR61)
Mattress base motor unit (back)	MD100 (Fa. LIMOSS)
Mattress base motor unit (knee)	MD125 (Fa. LIMOSS)
Height adjustment motor unit	2x MD121 (Fa. LIMOSS)
Motor unit protection class	IPX4

14.3 TECHNICAL DATA (ENVIRONMENT)

Temperature range during operation	+10°C to + 40°C
Temperature range for storage/transport	-10°C to + 60°C
Humidity of the air	30% to 75% RH.
Air pressure	between 700 and 1060 hPa

14.4 CLASSIFICATION

Medical product	Class 1
Degree of protection to DIN EN 60601-1	Type B (protection against electric shock)
Housing degree of protection to EN60529	IPX 4 (not suitable for automated washing systems)
Max. duty rating	10%, ON 2 min / OFF 18 min
Max. switching cycles/min	5
Safety inspections	1x per year

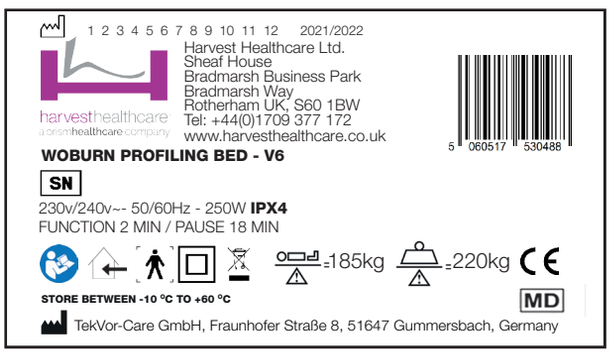
14.5 WEIGHTS OF INDIVIDUAL COMPONENTS

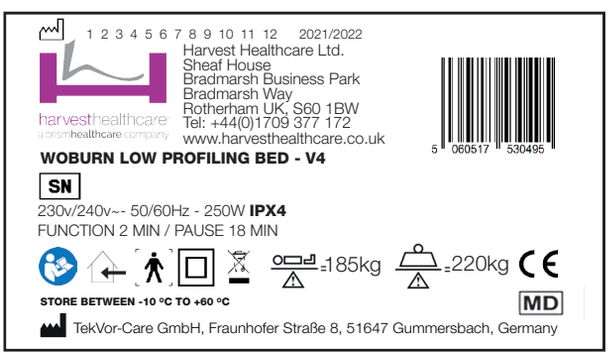
Mattress base / Head side	24.0	kg
Mattress base / Foot side	20.5	kg
Head end / Foot end	23.5	kg/each
Wooden side guards	12.0	kg
Patient’s lifting pole	4.2	kg
Transporting device	3.4	kg

TECHNICAL SPECIFICATION

14.6 TYPE PLATE

Attached to the outside surface of the mattress base frame. (See Overview)





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EMC STATEMENT

14.7 INFORMATION ABOUT ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration - electromagnetic emissions
The care bed is intended for use in the electromagnetic environment specified below. The customer or user of the care bed should ensure that it is used in such an environment.

EMISSION	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
RF emissions according to CISPR11	Group 1 -	The care bed uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
RF emissions according to CISPR11	Class B	The care bed is designed for use in all establishments including domestic establishments and those determined to be directly connected to a public supply network that supplies buildings used for residential purposes
Emissions of harmonics according to IEC61000-3-2	Class A	
Emissions of voltage fluctuations / Flicker according to IEC 61000-3-3		

EMC STATEMENT

Guidance and Manufacturer's Declarations - Electromagnetic Interference Immunity
The care bed is intended for use in the electromagnetic environment specified below. The customer or user of the care bed should ensure that it is used in such an environment.

INTERFERENCE	IEC 60601	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile floors. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input & output lines	± 2 kV for power lines ± 1 kV for input & output lines	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV Voltage phase-phase conductor ± 1 kV Voltage phase-ground conductor	± 1 kV Voltage phase-phase conductor ± 1 kV Voltage phase-ground conductor	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.
Voltage dips, short interruptions and supply voltage variations according to IEC 61000-4-11	< 5 % U_T for ½ cycle (> 95% dip) 40 % U_T for 5 cycles (60% dip) 70 % U_T for 25 cycles (30% dip) < 5 % U_T for 5s (> 95% dip)	< 5 % U_T for ½ cycle, 10 ms (> 95% dip) 40 % U_T for 5 cycles, 100 ms (60% dip) 70 % U_T for 25 cycles, 500 ms (30% dip) < 5 % U_T for 5s (> 95% dip)	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment If the user of care bed also requires continued operation during interruptions in energy supply demands, it is recommended to feed the care bed from an uninterruptible power supply or a battery.
Magnetic field of power frequency (50 / 60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m 0.3 A/m	Magnetic fields of power supply frequency should comply with the typical values, as can be found in a business and hospital environment.

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EMC STATEMENT

Guidance and Manufacturer's Declarations - Non-life-support devices
Electromagnetic Interference Immunity.

The care bed is intended for use in the electromagnetic environment specified below. The customer or user of the care bed should ensure that it is used in such an environment.

INTERFERENCE	IEC 60601	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted RF interferences according to IEC 61000-4-6 Emitted RF interferences according to IEC 61000-4-3	3 V eff 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	3 V eff 3 V/m	Portable and mobile radios, including cables, should not be used closer to the care bed than the recommended working clearance that is calculated by the equation for the appropriate frequency. Recommended working clearance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ for 80 MHz - 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ for 800 MHz – 2.5 GHz Where P is the power of transmitter in watts (W) according to specifications of the transmitter manufacturer and D is the recommended working clearance in meters (m) Field strengths from fixed RF transmitters should, at all frequencies, according to a site survey a - Note p. 5 be lower than the level of agreement be b - Note p. 5  In the vicinity of equipment, bearing the following symbol, interference is possible.

Note 1: At 80 and 800 MHz, the higher frequency range must be taken.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from structures, objects and persons.

EMC STATEMENT

a. Field strengths from fixed transmitters, such as base stations of mobile telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength at the location of the care bed exceeds the specified compliance level above, then the care bed should be monitored with respect to its normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the care bed.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended working clearances between portable and mobile RF communications equipment and the care bed.

The care bed is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the care bed can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF

OUTPUT POWER OF TRANSMITTER - W	**WORKING CLEARANCE ACCORDING TO TRANSMISSION FREQUENCY - M**		
	150 kHz to 80 MHz at 3 V/m $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz at 3 V/m $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz at 3 V/m $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters not rated in the list above, the working clearance can be determined using the equation, which belongs to the transmitter, where P is the nominal output of the transmitter in watts (W) according to specifications of the transmitter manufacturer.

NOTE 1: An additional factor of 10/3 is applied when calculating the recommended working clearance between transmitters in the 80 MHz to 2.5 GHz frequency range in order to reduce the probability that a mobile/portable communication device unintentionally brought into the patient area could lead to interference.

NOTE 2: These guidelines may not apply in all situations. Propagation of electromagnetic waves is affected by absorption and reflection from structures, objects and persons.

All parts and data continually undergo further development and may therefore deviate from the details given.

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DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

We, as company: Harvest Healthcare Ltd
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham, S60 IBW

Manufacturer (EU): TekVor-Care GmbH, Fraunhofer Straße 8, 51647 Gummersbach, Germany
SRN: **DE-MF-000007722**

Confirm on our own behalf that the medical product:

Woburn Profiling Bed **HLB791.03 - UDI: 5060517530488**
Woburn Low Profiling Bed **HLB797.03 - UDI: 5060517530495**
Risk Class: I

complies with all applicable requirements of the Regulation (EU) 2017/745. The associated documentation is kept on the manufacturer's premises.
EU legislation for this type of product covers all safety, health and environmental requirements.

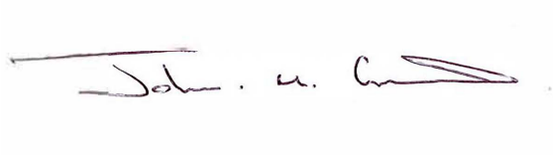
Classification according to Article 51 and Annex VIII: class I, rule 1 and 13

The applied conformity assessment procedure is in compliance with Article 52(7).

The product also meet the requirements of Directive 2011/65/EU.

Modifying this product without consultation with Harvest Healthcare Ltd will invalidate this declaration of conformity.

This declaration of conformity is issued under the sole responsibility of Harvest Healthcare.



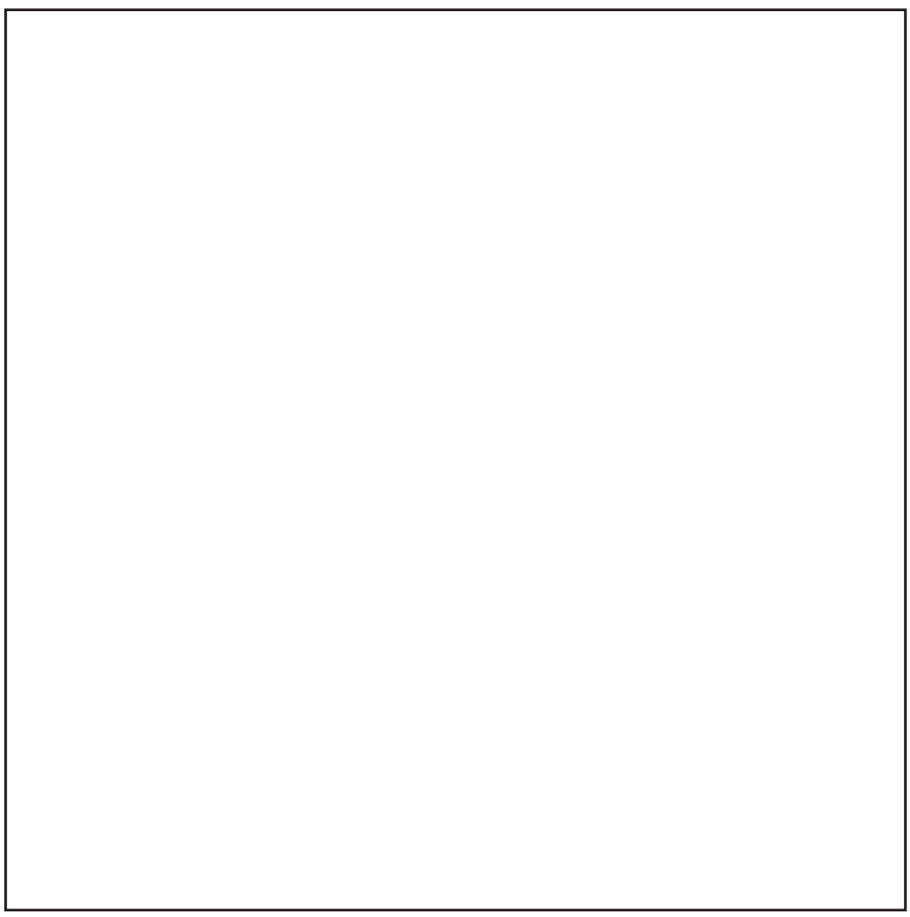
Product Development and Quality Manager

DATE OF PURCHASE

Date of purchase:.....

Distributor stamp:.....

You can fix your receipt here:



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Serial No:

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