

Solo Bed Installation Guide and Technical Specifications







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1. Explanations of Symbols



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 Directives 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.



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.



Maximum permissible load.



Maximum patient weight.



Read instructions.

2. Installation and Commissioning

2.1 Contents

(A) Solo Bed x 1



(B) Headboard x 1



(C) Footboard x 1



(D) Footboard Bracket x 2



(E) Headboard Bracket x 2



(F) Head/Footboard Bolt x 8



(G) Head/Footboard Insert Nut X 8



(H) Mattress Retainer x 8



Before you begin you will also need:

- A size 4 and a size 5 Allen key
- Space with a wall and plugsocket nearby

^{*}Foot and headboards styles may vary



Read before you begin! We recommend that two people install and unpack this bed to avoid injury - Observe the general manual handling guidelines.

1

Place parts to one side

Unpack all parts and place to one side.

This includes the following:

- (D) Footboard bracket x 2
- (E) Headboard bracket x 2
- (F) Head/footboard bolt x 8
- (G) Head/footboard insert nuts x 8
- (H) Mattress Retainer x 6



2 Position the bed

Move the bed into the centre of the room. Lock all four castors by pressing down on the castor brakes.

Plug in the bed and raise the bed to a safe working height by using the bed platform height adjustment function (see page 20 on how to adjust the bed platform).



Ensure that there are no cables, limbs or objects in the movement paths of the

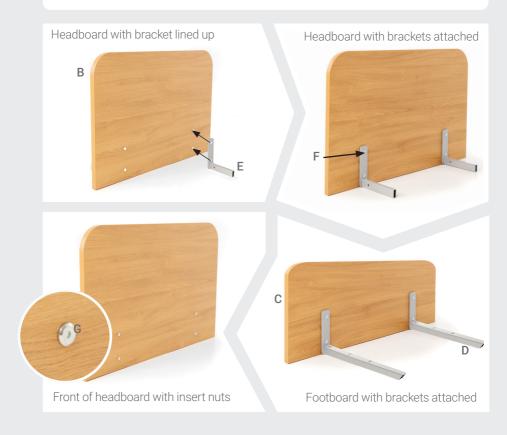


3 Attach the head and footboards

Align the two mounting holes of the headboard brackets (E) to the two pre-drilled holes in the headboard (B) on both ends.

Using an allen key, secure the headboard in place with the head/ footboard bolts (F). On the other side (the front) of the headboard push the insert nuts (G) into the mounting holes.

Repeat these steps for the footboard making sure that the correct brackets are used (D).

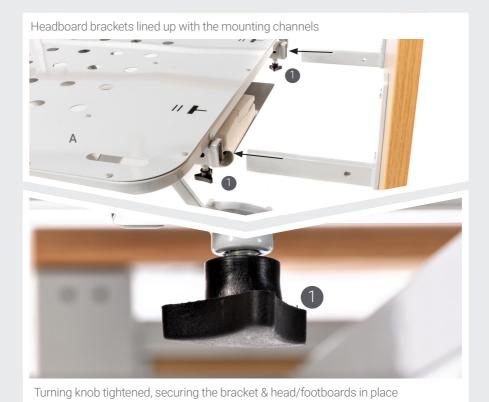


4 Insert the head and footboards

Loosen the head/footboard turning knobs (1) on the head/footboard mounting channels, these are under the head/foot ends of the bed platform, check that the channels are not obstructed. Lift the head/ footboard so that the two brackets either side of the head/footboard are in line with the two mounting slots of the mattress platform. Slide the brackets into the channels so that the head/footboard is aligned with the mattress platform. Tighten the head/footboard turning knobs to secure the brackets and head/footboards.



Do not overtighten the mounting hardware this will damage the mounting brackets.



5

Insert the mattress retainers

The mounting holes for the mattress retainers are pre-cast in the mattress platform. Align and insert the protruding T shape (that is under the plastic retainer) into the T shape mounting hole (H). Slide the retainer towards you and it will click into position 1 (see photos below). To move the retainer to position 2, lift the end of the retainer using the finger hole and slide towards you until position 2 is located. please note that it is recomended that position 2 is used for 90cm mattresses.

Repeat this for all mattress retainers (2 mounting holes on the sides of the mattress platform and 2 at each end of the bed towards the Head board/footboards).



6 Extending the bed

To extend the bed, loosen both of the footboard retaining knobs located on the underside of the footrest platform (1). Taking hold of both sides of the footboard, extend to the desired length.

Next, loosen both platform extension knobs (2), taking hold of both sides of the mattress platform, pull the platform to extend it to either the 10cm or 20cm increments marked on the platform.

Tighten both platform extension knobs (2).

Push the footboard into the new extended position and tighten both footboard retaining knobs (1).

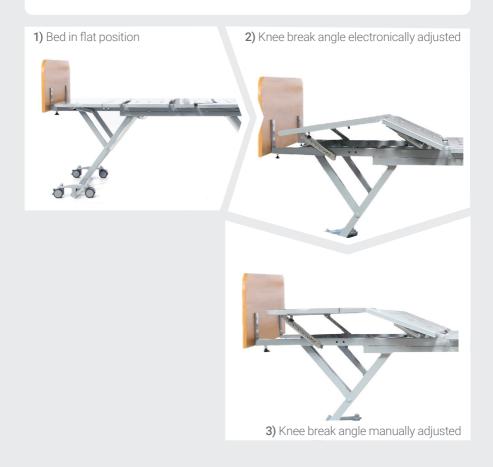


7 Manually adjusting the kneebreak angle

The foot rest section can be adjusted manually to elevate the lower legs and feet. Use the handset to adjust the knee break angle electronically (See diagram 2).

To further alter the knee break angle, manually lift the foot rest section up slowly. Audible clicks confirm when the platform is locked into a new position (See diagram 3).

To lower, lift the foot rest to its highest position and slowly lower it back down.



8 **Test functions**

To test that the controls on the bed are working correctly when the install is complete, perform the following steps:

- I. Test the height adjustment
- II. Test the backrest elevation
- III. Test the legrest elevation

Please refer to page 20 on how to use the handset to perform the above tests



Before lowering the bed check that the area underneath is clear, any obtructions could damage the bed.



Take extra care when lowering the bed fully, make sure that there are no limbs, persons, pets or objects under the bed that could become trapped and crushed. The lowering of the bed stops at 320mm from the floor to alllow the operator to check that the undercarriage is clear before fully lowering.

9 Position the bed

Once testing has been completed, unbrake the castors to move the bed into position and re-apply the brakes. Place the mattress onto the bed and make sure that it is securely held in place by the mattress retainers.



The bed should always be in the braked position when occupied, do not use the bed to transport occupants.

3. Bed Operation and Maintenance

3.1 Overview



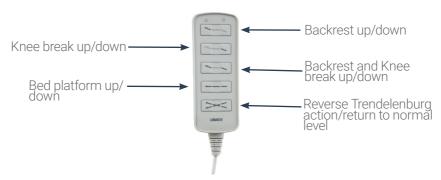


- 1. Control box
- 2. Electrically adjustable backrest
- 3. Electrically adjustable legrest
- 4. Mechanically adjustable knee break angle
- 5. Mechanically extendable platform
- 6. Chassis

- 7. Handset
- 8. Footboard
- 9. Headboard
- 10. Split side rail
- 11. Castors with mechanical brake
- 12. Chassis fixing bar holes

33 Handset

The motorised bed functions can be operated via the handset.





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

3.4 Using the Handset

Whilst operating the bed, the rear castors of the bed must be braked to ensure stability during bed adjustments. The Opera Solo Bed should only be moved to reposition the bed.

On the handset the up arrow on the controller indicates raising of the corresponding part of the bed. The down arrow indicates lowering of the corresponding part of thebed.

The bed is equipped with anti-entrapment features. If the bed platform is higher than 320mm from the floor, long press the bed platform down button to lower it to below 320mm. To continue lowering the bed, release and long press the button again. Ensure that there are no limbs, objects or obstacles within the beds moving range.

Where a connection fault is identified and rectified, the control system will require a reset in order to operate again. To reset the control system, press and hold down the back rest and knee break buttons (up and down) simultaneously for 6 seconds. If a back up battery is fitted it will beep intermittently during the system reset.

4. Troubleshooting

Fault	Possible cause	Remedy
Bed idlle when controller buttons are pressed.	Power not connected or damaged. Hand controller or acuator connector loose.	Ensure power cable is properly connected to the elctrical socket and the bed. Contact Opera if the cable is damaged. Ensure tight connection of all connectors to control box.
	Back up battery (where used) is not connected properly to the control box.	Ensure tight connection of all connectors to control box.
	The connecting terminals are damaged.	Disconnect and reconnect the backup battery to the control box.
	Actuator in need of service or load is too high.	Contact Opera for more information.
	Handset system has not been reset after faults were fixed.	Refer to page 13 on how to reset the handset.
Castors/brakes noisy or stiff.	Debris in the bearings (Hair, dust, lint).	Clean or replace the castors, see page 25.
Noisy or dry sound from the pivots.	Requires lubrication.	Lubricate pivots.
Unusual noise from actuator.	Actuator is worn or damaged or the spindle may be bent.	Replace the actuator. Contact Opera.
Bed will not lower close to the ground when down button is pressed.	Entrapment safety measure is in place.	Refer to page 13 on the handset functions.
Head or footboard is unstable.	Head or footboard frame not tightly secured.	Refer to pages 6 & 7 on securing the head and footboards.

5. Safety Instructions

5.1 General Safety Instructions



During the briefing, specific attention must be drawn to any potential dangers for the first time, the instruction manual must be read conscientiously and in detail by the user / care personnel.

Any incidents or issues must be reported to Opera ,at: support@opera-care. co.uk



When operating the adjusting functions, there must be no objects or limbs in the movement paths of the bed due to the risk of entrapment and crushing.



The Opera Solo bed is designed to stop when lowered to 320mm from the floor, always check that there are no objects or limbs under the bed before lowering further. Non-compliance with this warning may result in entrapment and crushing.

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



Ensure that children cannot operate the control system and check if pets or children are under the bed before operating any of the functions. Never store anything under the bed.

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



Disconnect the mains plug from the socket before moving the bed, 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 up in anything, as it gets carried along when the bed height is adjusted and the mains plug may be pulled out of its socket and electric leads exposed as a result.



Do not use a mattress that is not compatible with the bed, refer to the specifications in this instructoin manual. Incompatible mattresses can result in creating entrapment risks and hazards resulting in injury.

5. Safety Instructions

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 the sockets causing a fire hazard and a possible electric shock.



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 motor unit, must remain plugged in. This is necessary to prevent water ingress into the control box.



When the care 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 in and out of the 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 brake on all four castors must be released and the mattress platform 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 Technical Data).

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

The care bed must only be taken apart if there is no patient or occupant in it.

Do not modify any equipment, this will void the Terms Conditions and Warranty and may compromise the safety of the bed and accessories.



Do not exceed the maximum weight limitation of the bed. The maximum safe working load is (SWL) 200kg for the Opera Solo Bed 105, and 250kg for the Opera Solo Bed 90 and 120.



The side rails have been designed in accordance with IEC 60601-2-52 to reduce entrapment risks and falls. When the side rails are used, the following instructions must be adhered to ensure compliance with IEC 60601-2-52:

- Do not allow children to use the side rails, this may result in entrapment, injury or asphyxiation.
- Do not operate the side rails if they are damaged.

- The side rails are designed to be used to help prevent falls from the care bed, they are not designed to be leaned or climbed on, doing this may result in injury.
- Do carry out regular checks to ensure that the side rails are being used safely and are securely fixed to the bed.
- Only suitably instructed personnel can operate the side rails safely.
- Lower the side rails slowly and take care not to let them drop down.
- Do not lower or lift the side rails from inside of the bed
- The side rail height from the top of the mattress in an uncompressed condition must be at least 220mm, not conforming to this may result in entrapement and injury.
- The side rails only provide protection against rolling out of the care bed if the backrest and lower leg adjustments are in the horizontal position.
- Excercise caution when using the side rails with a disabled occupant, always conduct a risk assessment to ensure that the side rails are suitable for use.



5.2 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.

The care bed outlined in this manual is a Class I Medical Device as defined by the Medical Device Directives 93/42 EEC and a Class 1 Medical Device as defined by the Medical Device Regulation 2017/745.

Please observe your obligations as the operator.



5.3 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 laid out in section 5.1.

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 bed 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. The mattress platform should be kept in a flat position if a patients condition could lead to entrapment.



If there is a suspected fault or damage, disconnect the mains plug from the socket. Clearly mark the care bed as "Out of Order" and take it immediately out of service. Then inform the person responsible for the bed immediately.

5. Electrical and Earthing

Do not, under any circumstances, cut or remove the earthing prong from any plugs. If you must use an extension cable, use only a three-wired extension cable with the same or a higher electrrical rating as the connected device.



Do not use if the power cable is cut, frayed or loosely connected to the device.

5.4 Cleaning and Disinfection



Before cleaning and disinfection, the mains plug must be disconnected and hung up safely. Plugs for the handset and the motors that 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 them with a damp cloth.

The bed and castors may be cleaned with a cloth dampened with water and mild detergent, or a non-abrasive cleaner.

The electrical components must not be cleaned with a high pressure cleaner or a water jet. Only disinfection by wiping is permitted.



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

5.5 Servicing and 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 every 6 months and after a lengthy brake in use and before each further use. Refer to section 7 for further detail. Any defects, damage or signs of wear must be rectified without delay. Only original spare parts from Opera may be used, otherwise all guarantees or warranties will be excluded.

Please check all fixings on your bed at least once a month. Regular cleaning and maintenance will reveal any loose or worn parts.

5 6 Accessories

Use only mattresses compatible with the side rails (BOA82) and bed. The dimension between the mattress upper surface in an uncompressed condition and the top edge of the upper side rail must be 220mm minimum. If this dimension is less than 220mm, an extension side rail kit should be fitted.

5.7 Electromagnetic Compatibility

Regarding the emitted interference and interference resistance, the electric motor units comply with the requirements of EN 60601-1-2:2007. However it is possible that electrical devices can interfere with each other. In this case, switch off the care bed for a short time or remove the interference source.

5.8 Storage and Handling

The bed should be stored between -10°C and 60°C, in a room with a relative humidity between 30% and 75%, keep the bed dry and out of direct sunlight.

6. General Information

61 **Definitions of Users**

Operator

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

Users

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

Patient/Occupant

Persons in need of care; handicapped or infirm; and occupying a care bed.

Oualified 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 cleaning and disinfection regulations for the bed.

6.2 General Notice

Clean and disinfect the care bed before using it for the first time. Please note that the various safety instructions must be observed. Refer to section 5.4 on how to clean and care for the bed.

Opera Beds bear the CE mark and meet all general safety and performance requirements. The beds have been tested in accordance with national standards.

The safety and performance requirements can only be met if the user uses the care bed as outlined in this manual.

6.3 Intended Use

The Opera Solo Bed is intended for accomodating patients/occupants with a maximum body mass of 165kg for the Opera Solo Bed 90 and 215kg for the 105 and 120. The bed is designed to be used in residential homes, nursing homes and the domestic environment as a care bed for adults. The bed can only be used with accessories that are provided by Opera Care, such as the Opera Solo Telescopic Side Rails (BOA82) and the Opera pressure care mattress range. Using the bed under different conditions will be regarded as non-intended use, invalidating the terms conditions and warranty, excluding Opera from any liability.

6.4 Non-intended Use

A non-intended use is a use that deviates from the intended purpose and is not outlined in the instruction manual.

Non-intended uses include, but are not limited to the following:

- Loading the bed beyond the safe admissibe working load (refer to technical specifications).
- Operation of the care bed by occupants who have not been instructed on its use.
- Use of the bed for children
- Attempting to move the bed in its braked position.
- Using the bed for transporting occupants.
- Use of the bed on a non-horizontal surface (max incline of 5 degrees).
- Use as a hospital bed or in hospitals.
- Use with electrical applications which involve intravascular or intercardiac processes with the occupant.
- Use with any devices that will compromise the general safety and performance requirements of the care beds.

6.5 General Regulations

The beds must only be used for the purpose intended. When setting up, operating and using the care bed, respect the health and safety regulations of your country and servicing regulations.

If the bed is faulty, operation must not be started. Any issues or incidents must be reported to Opera Care. Please refer to the back cover for contact details.

6.7 Qualification of Users

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

7. Servicing

Operators of care beds are obliged according to the regulations in your country.

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

- Visual checks
- Functional tests
- Overall evaluation

IMPORTANT: If you have any doubts about the safety or functioningg of the care bed or a component as a result of the checks performed below, the bed should under no circumstances be placed into service again. Contact Opera when there is any uncertainty.

7.1 Technical Safety Checks according to EN 62353

Care bed:
Serial No:
Location:
Person responsible:
Inspected by:

Item	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.	Are the side guard beams free of any fractures, cracks or other damage?			
12.	Do the side guard beams sit securely in their anchorage?			
13.	Has the load test been carried out successfully according to the regulations?			
14.	Are the patient's lifting pole and pole sleeve undamaged without any signs of wear?			
15.	Do the side rails lock safely into place?			
16.	Max. distance between the side rails 120mm?			

7. Servicing

Item	Instruction for testing	Comment	Yes	No
17.	Height of side rails above the mattress at least 220mm?			
18.	Height of side guards above the mattress at least 220 mm?			
19.	Have castors including locking brake been tested for safe functioningg?			
20.	Mains cable, connecting cables and plugs without damage?			
21.	Fixture available for safe transportation of mains plug?			
22.	Strain relief of the mains cable and handset securely attached?			
23.	Are all plug-in connections securely attached? (Washers without damage?)			
24.	Are cables laid correctly and safely? (No damage)			
25.	Motor housing and SMPS housing, mains plug housing without damage?			
26.	Are the thrust pipes of the height adjustment motors undamaged?			
27.	Functional test of the handset: can the buttons be operated properly?			
28.	Functional test of handset locking device: On/Off working correctly?			
29.	Testing of initial fault safety by means of integrated blocking box in handset			
30.	9V block battery OK / expiry date sufficient until next test?			
31.	Is the safe working load adhered to?			

Comments:
Place / Date:
Inspected by:
Next inspection:
Signature:

8. Technical Specifcations

8.1 Technical Data

Safe working load (Max admissible load): 200kg / 250kg

Individual loads of the safe working load (advisory):

Max. Weight of patient: 165kg/215kg

Mattress: 20kg Accessories: 15kg

	Measurement		
Specification	Opera Solo Bed 90	Opera Solo Bed 105	Opera Solo Bed 120
Safe Working Load (SFW)	200kg/31st 5lb	250kg	/39st 4lb
Max. weight of occupant	165kg/26st	215kg,	/33st 8lb
Height Range (floor to top of mattress platform)	11	0mm-735mm/4.3"	-29.9"
External Length	2120mm/83.5" (can be increased b	y a max' of 200mm)
External Width	918/36.1"	1068/42.0"	1218/47.9"
Internal Length		2000mm/78.7"	
External Height (In lowest position, from floor to bed platform)	110mm/4.3"		
Internal Width	900mm/35.4"	1050mm/41.3"	1200mm/47.2"
Backrest angle adjustment (electronically)	0° - 70°		
Thighrest angle adjustment (electronically)	0°-39°		
Footrest Angle Adjustments (Mechanically raised)	128° - 148°		
Reverse Trendelenburg	12° +/- 2°		
Mattress Base Surface (Material)	Steel		
Castors	4 with brakes, 4 without		
Max. Castor Loading Capacity	90kg/14st 17lb		
Operating Noise	< 50db		

8. Technical Specifications

Specification cont.	Opera Solo Bed 90	Opera Solo Bed 105	Opera Solo Bed 120
Maximum Mattress Depth	203mm/8"		
Recommended Mattress Length	2000mm/78.7"		
Recommended Mattress Width	900mm/35.4"	1050mm/41.3"	1200mm/47.2"
Backrest Length	880mm/34.5"		
Thighrest Length	330mm/12.8"		
Legrest Length	530mm/20.9" (can be increased by a max' of 200mm)		
Bed platform weight	92kg/14st 4lb	105kg/16st 5lb	113kg/17st 8lb

8.2 Technical Data (Electrical)

Power supply unit	Mains	
Voltage rating	110V - 240V	
Frequency rating	50Hz - 60Hz	
Type of current	AC	
Nominal consumption during operation	363W	
Nominal consumption in idle state	0.5W	
Nominal operating time/idle time	2 Minutes/ 18 Minutes	
Primary safety fuse	Yes	
Motor unit protection class	IPX6	

8.3 Classification

Medical Device (in accordance to MDD 93/42 EEC)	Class I	
Degree of protectoin to DIN EN 60601-2	Type B	
Housing degree of protection to EN 60529	IP X4	
Max. switching cycles/mins	Interruption 10%, Max. 2 min/18min	
Safety inspections	Annually	

8.4 Technical Data (Environmental)

Temperature range during operation	5°C - 40°C
Temperature range for storage/	-10°C - 50°C
transport	
Humidity of the air for storage/transport	20% - 90% at 30°C
Air pressure for storage/transport	700 - 1060 hPa

8.6 Information about Electromagnetic Emissions

Guidance and Manufacturer's Decleration - 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.

Emitted interference	Compliance	Electromagentic Environment - Guidelines
RF emissions according to CISPR11	Group 1	The care bed uses RF energy only for its internal functioning. Therefore the 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 ans those determined to be directly connected to a public supply netwrok that supplies buildings used for residential purposes.
Emissions of harmonics according to CISPR11	Class A	
Emissions of voltage fluctuations/Flicker according to IEC 61000-3-3	Complies	

8.7 Information about Electromagnetic Interference **Immunity**

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 Immunity Certification	IEC 60601 Test Level	Compliance Level	Electromagentic Environment - Guidelines	
Electrostatic Discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air	± 6 kV Contact discharge ± 8 kV Air	Floors should be wood, concrete or ceramic tile floors.	
	discharge	discharge	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	± 2 kV For power lines	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.	
	± 1 kV for input and output lines	± 1 kV For input and output lines		
Surges according to IEC 61000-4-5	± 1 Kv Voltage phase-phase conductor	± 1 Kv Voltage phase-phase conductor	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.	
	1 Kv Voltage phase-ground conductor	1 Kv Voltage phase-ground conductor		
RF emissions according to CISPR11	Class B		The care bed is designed for use in all establishments including domestic establishments ans those determined to be directly connected to a public supply	

8.8 Information about Non Life Support Devices **Electromagnetic Interference Immunity**

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 Immunity Certification	IEC 60601 Test Level	Compliance Level	Electromagentic Environment - Guidelines
Conducted RF interferences according to IEC 61000-4-6	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.
Emitted RF interferences according to IEC 61000-4-3			Where P is the Power of the transmitter in Watts (W) according to specifications of the transmitter manufacturer and D is the recommended working clearance in meters.
			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 vincinity of equipment, bearing the following symbol, interference .

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.

a) Field strengths from fixed transmitters, such as base stations of mobile telephones and land mobile radios, amateur radio, AM,FM radio and TV broadcast can not be predicted 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

8. Technical Specifications

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

8.9 Working Clearances

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

The care bed is intended for use in the 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 communications equipment (transmitters) and the care bed as recommended below, according to the maximum output power of the communication device

Output Power of Transmitter in Watts (W)	Working clearance according to transmission frequency (In meters - M)				
	150 kHz to 80 MHz at 3 V/m	80 MHz to 800 MHz at 3 V/m	800 MHz to 2.5 GHz at 3 V/m		
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 communications 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.

9. Service Life and Disposal



The service life of the care bed is approximately 5 years. This is dependent upon the manner of use. The care bed is suitable to be put into service again if all measures of section 5.4 and 7 are completed. Frequent transportation, setting up and adjustment reduce the service life, as does improper treatment, irregular servicing and exceeding the safe working load or the admissible load cycle of the electric motors. The bed must not be disposed of as normal household waste after the end of its service life. Contact your local waste recycling facility for furtherinstructions.

10 **Guarantee**

As stated in the Standard Terms and Conditions, below, Opera provides a manufacturers warranty of 3 years from the date of purchase for the Opera Solo Bed.

11. Opera Warranty Terms and Conditions

11.1 Warranty Terms

11.1.1 Subject to the terms and conditions set out below, Opera agrees to repair or replace the product within the United Kingdom at its own cost, and any Opera accessory supplied with it, purchased by you from Opera. In circumstances where the product does not perform in accordance with Opera's specifications during the warranty period, commencing on the date of delivery (or deemed delivery) of the product.

11.1.2 This contractual product warranty does not operate to limit rights

11.2 Warranty Conditions

11.2.1 Proof of purchase (invoice) must be provided when requesting service under warranty.

under the statutory warranties referred to in clause 11.3.1 below.

11. Warranty Terms and Conditions

- **11.2.2** Opera requires any customer requesting service under the warranty to comply with directions from Opera staff in relation to troubleshooting any issue and facilitating any repair or replacment under these Warranty Terms and Conditions.
- **11.2.3** The customer is responsible for inspecting all goods recieved from Opera upon arrival. In instances where goods have been damaged in transit, the customer must report this to Opera within 3 working days of receipt of the product. Failure to report physical damage on arrival within three working days of receipt may result in denial of warranty for physical damage.
- **11.2.4** Opera reserves the right to replace the product or relevant part with the same or equivalent product or part, rather than repair it. Where a replacement is provided, Opera will determine, in its discretion, the closest product within the current range of products offered by Opera with which to replace the faulty or damaged product. The replacement product may differ with the replaced product in size and specifications, at the reasonable election of Opera. Opera may replace parts with refurbished parts. Replacement of the product or a part under the warranty does not extend or restart the warranty period.
- 11.2.5 If Opera is unable to repair or replace the product, the customer will be provided with credit for Opera products or may be refunded the price of the product (at Operas election). This credit or refund will be for the amount of the purchase price of the product, excluding the associated delivery cost.
- 11.2.6 In the event that a replacement, refund, or store credit is provided as per section 11.2.5, the faulty item will become the property of Opera.
- 11.2.7 Opera may seek reimbursement of any costs incurred by you where the product is found to be in good working order.

11.2.8 Opera reserves reasonable discretion to determine whether any product is or is not performing in accordance with Opera specifications, subject to applicable law.

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- 11.3.1 Legislation may imply warranties or conditions or imposes obligations on Opera, which cannot be excluded, restricted or modified in relation to consumer goods.
- 11.3.2 To the full extent permitted by law, but subject always to clause 11.3.1, the warranty will not apply in respect of a product:
- (a) If the product has not been installed, operated, maintained or used in accordance with the Opera instructions or specifications provided with the product;
- **(b)** If the factory-applied serial number has been altered or removed from the product;
- (c) To damage, malfunction or failure resulting from alteration, accident, misuse, abuse, fire, liquid spillage, mis-adjustment of customer controls, use on an incorrect voltage, power surges and dips, thunderstorm activity, force majeure, voltage supply problems, tampering or unauthorised repairs by an persons, use of defective or incompatible accessories, exposure to abnormally corrosive conditions or entry by any insect, vermin or foreign object in the product.
- (d) To damage arising during transportation, installation or while moving the product or to any transportation costs of the product or any parts thereof to and from the customer, unless otherwise specified in these warranty terms and conditions:
- (e) To any third-party software or hardware not contained in the product as originally configured by Opera.

11. Warranty Terms and Conditions

- (f) To any failure, to the extent that the failure is not a failure of the product to perform in accordance with its specifications.
- (g) To service of any product whilst it is outside the United Kingdom.
- 11.3.3 To the full extent permitted by law, but subject always to clause 11.3.1:
- (a) Opera will not be liable for any loss, damage or alterations to third party products, no matter how occurring; or for any loss or damage arising from loss of use, loss of profits or revenue, or for any resulting indirect or consequential loss of damage.
- **(b)** Opera's aggregate liability in respect of all claims under the warranty shall not exceed the original purchase price of the product or, at Opera's option, the replacement of the product with a like or similar product.
- (c) Opera excludes all other warranties, conditions, terms, representations and undertakings whether express or implied.

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Opera Care

Azure House, Connaught Road, Kingswood, Hull. HU7 3AP 0333 222 8584 support@opera-care.co.uk

opera-care.co.uk

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