

OPERA® CLASSIC & CLASSIC
LOW PROFILING 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.



Symbol for direct current.



Symbol for alternating current.



Maximum permissible load.



Maximum patient weight.



Read instructions.

2. Installation and Commissioning

(A) Head/Foot Board x 2



(B) Side Rail x 4



(C) Black Thumb Screws** x 4



* These items are already fitted to the Head/Foot Board

** These items are already fitted to the Mattress Platform Sections

Please note that styles may vary depending upon purchase.

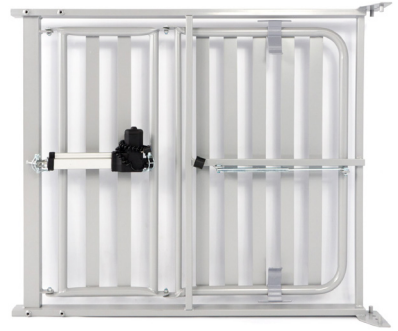
(D) Mattress Backrest Platform x 1

N.B. Easily identifiable because it has both an actuator and the black control box.



(E) Mattress Legrest Platform x 1

N.B. Easily identifiable because it only has one actuator.



(F) Transportation Bracket x 2



(G) Mattress Retainers ** x 4



(H) Side Rail End Cap x 8



(I) Side Rail Runner* x 4



(J) Handset x 1



(K) Power Transformer x 1



Before you begin, you will also need:

- Wall space with a plug socket nearby.
- Tools: 4mm & 6mm Allen Key, A cross head screw driver, Pair of scissors.



Read before you begin!

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

1. Position the Bed

Move the bed into the centre of the room and remove the packaging from the bed.

Place the side rail box to one side.



2. Place Accessories to One Side

Detach the following accessories and place to one side.

(H) Side Rail End Caps x 8



X 8

3. Remove the Mattress Platforms

With two people, carefully hold the backrest mattress platform (D) at both ends and pull it up and out of the transport bracket. Carefully place to one side with the actuator on top (1). Repeat these steps to remove the leg rest mattress platform (E) from the transport bracket.

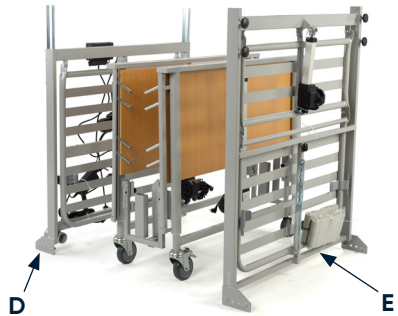


Attention: The mattress platforms are heavy, please observe the general rules of manual handling to prevent strain and injury.

1 | Mattress platform lifted out of the transport bracket.



2 | Mattress platforms removed from transport bracket.



3 | Mattress backrest platform facing up.



4. Position the Head/Footboards

Move the head/footboards over towards a wall. Position so that one of the head/footboards is placed against the wall (this will become the headboard). Apply the brakes on the two castors of the headboard. Push down on the brake pedal to brake/lock the castors.

Castor Unlocked/Unbraked

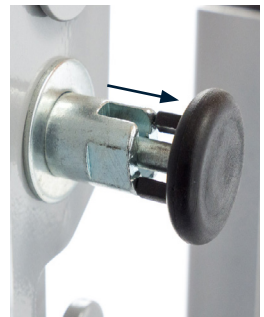


Castor Locked/Braked



5. Detach the Transport Bracket

Release the two securing bolts (2) on the transport bracket by pulling out the bolt (as per the photos below). The securing bolts are on the inside frame of the head/footboards, with one at each side.



6. Detach the Head and Footboards

With two hands at either side of the board (the one that is not against the wall) carefully lift it up and out of the transport bracket. Place this to one side, this will become the footboard of the bed.

Repeat the steps above to remove the headboard, place the headboard against the wall and place the detached transport bracket to one side.

Transport Bracket with Footboard Removed



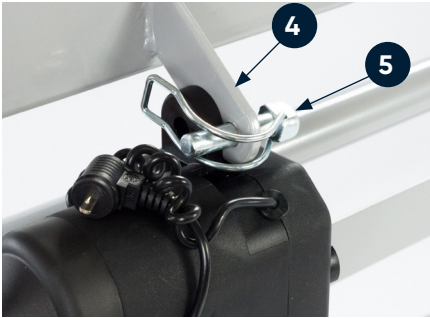
7. Secure the Actuator Motors

Lay down the mattress leg rest platform (E) with the actuator motor facing upwards (3).

On the actuator securing bracket (4) pull back the metal guard and remove the pin (5). Align the holes in the actuator to the bracket (this is where the pin was). Insert the pin through the holes and pull the metal guard back over the pin to secure the actuator in place. Repeat for the mattress backrest platform.



1 | Actuator not aligned.



2 | Pin removed and holes aligned.



3 | Pin inserted.



4 | Pin inserted with guard in place.

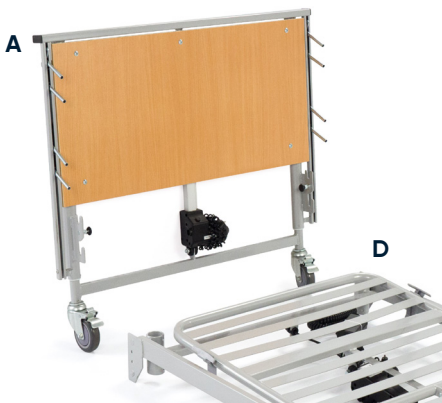


8. Attach the Headboard to the Backrest

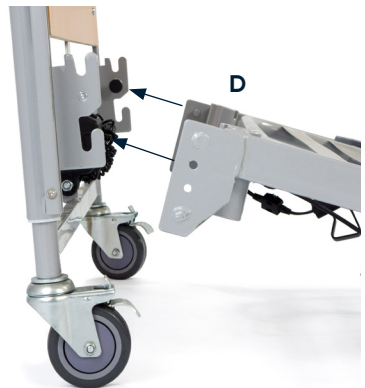
Place the mattress backrest platform (D) down in front of that headrest (A). Slide the metal prongs (with the two holes in) on the mattress platform side channels of the mattress backrest platform (D) into the metal plates on the headboard (as per the photos below).

Secure the headboard to the mattress backrest platform with the securing bolts. Push the securing bolts back through the headboards metal prongs and into the mattress backrest platform prongs.

1 | Mattress backrest platform lined up to headboard.



2 | Mattress backrest platform side channels lined up to the headboard.



3 | Mattress backrest platform and headboard secured by securing bolt.



4 | Securing bolt securing the mattress backrest platform to the headboard.



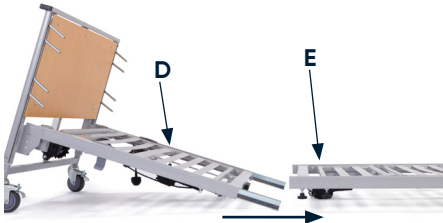
9. Connect the Mattress Platforms

Feed the metal prongs on the mattress backrest platform (D) into the mattress platform side channels of the mattress legrest platform (E) until the platforms are joined.

Make sure that the actuator on the mattress legrest platform is at the centre of the bed, located near the control box (circled).

Secure the platforms together by tightening the black thumb screws (C) on the mattress legrest platform (see photos below).

1 | Backrest platform lined up with the mattress legrest platform.



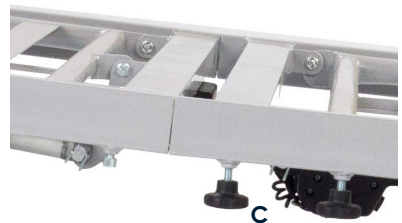
2 | Backrest platform inserted into the mattress legrest platform.



3 | Thumb screw tightened.



4 | Loose thumb screws on the mattress legrest platform.



10. Attach the Footboard

Follow step 7 to attach the footboard to the end of the mattress legrest platform.



11. Remove the Cable Ties

Using a pair of scissors, carefully remove the cable ties from the actuator motors, handset and the mattress platform. Be careful, ensure that no wires are cut or damaged.

12. Plug in the Actuators

Lift the backrest profiling section fully up, this should remain upright without support, giving you access to the control box.

Remove the control box cover with a cross head screwdriver.

Plug in all four actuator cables into the correct colour coded sockets (as per the photo below), plug the handset control in and replace the control box cover.

1 | Backrest platform lifted up.



2 | Control box under the bed platform.



3 | Control box with cover attached.



4 | Control box with actuators plugged in.



13. Fit the Side Rail End Caps

Unpack the side rails (B) from their box. Lay all four side rails on the floor.

Fit the plastic end caps (H) to both ends of the individual side rails. To do this use the bottom of the side rail as a leading edge and push on the cap (see photo below).

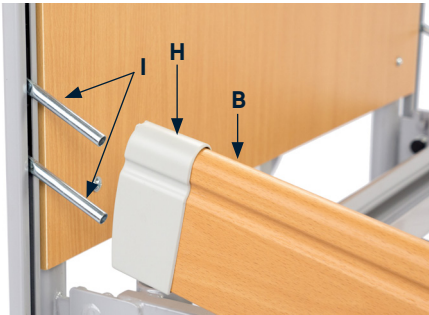


14. Fit the Side Rails to the Headboard

At the head of the bed, press down on the triangular latch in the side rail runner channel to release the side rail runner (circled in photo 3).

Fit the wooden side rails onto the side rail runner by sliding the rail runners (I) all the way into the side rail end caps (H) and into the wood of the side rails (B). The side rail runners go into the top and bottom holes of the side rail end caps.

1 | Side rail runners lined up with side rail.



2 | Side rail runners inserted into side rail.



3 | Side rail attached to headboard.



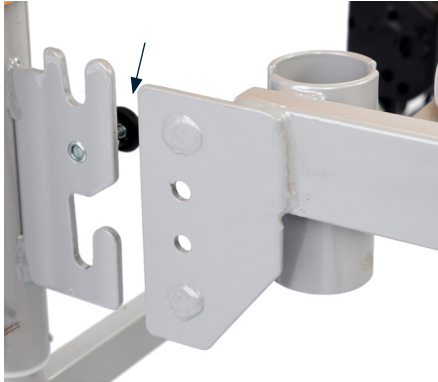
15. Fit the Side Rails to the Footboard

Release the black securing bolts that secure the footboard to the mattress legrest platform and pull the footboard slightly away (as per the photos below).

Repeat step 14 to fit the side rails to the footboard.

Slide the footboard back into the mattress platform mounting channels and secure with the black securing bolts.

1 | Securing bolt released and footboard pulled away.



2 | Side rail runners inserted into side rail.



3 | Footboard secured to mattress legrest platform.



4 | Side rails attached.



16. Secure the Side Rail Channels

Tighten the side rail channel fixing bolts (circled) with a cross head screwdriver. The fixing bolts go through the bottom of the side rail channels at both sides of the head and footboards, securing the side rail runners in place.

To detach the side rails remove the side rail channel fixing bolt, as you remove the bolt make sure to hold the side rails to prevent them dropping out onto the floor.

To replace the side rails, slide the runners back into the side rail channels. The footboard may need to be removed as per step 15 to fit the side rails back on to the footboard. After replacing the side rails, secure the side rails with the side rail channel fixing bolts.

Side rail channel fixing bolts circled



17. Clip on the Mattress Retainers

Clip in place the mattress retainers (J), 2 slats down from the top of the backrest, and 2 slats up from the bottom of the leg rest. Repeat for the other side of the bed.



18. Test Functions

To test that the controls* on the bed are working correctly, perform the following steps:

- I. Test the height adjustment
- II. Test the backrest elevation
- III. Test the legrest elevation
- IV. Test the tilt feature
- V. Test the tilt feature in the opposite direction
- VI. Test that the bed lowers into its lowest position

*Please refer to page 21 on how to use the handset to perform the above tests.



Attention: Ensure that there are no cables caught when adjusting the bed height.

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

19. Position the Bed

Move the bed into the desired position and plug into a mains socket (unbrake the castors before moving). Position the bed and apply the brakes to the castors.

Place the mattress onto the bed, make sure that the mattress is secure and all mattress holders are in place.

20. Confirm Compliance

Mattresses used with the Opera Classic Profiling Beds must meet the following requirements:

- The side rail height from the top of the mattress in an uncompressed condition and top edge of the upper side rail must be a minimum of 220mm.
- The mattress must meet the requirements outlined in the technical specifications.

3. Bed Operation and Maintenance

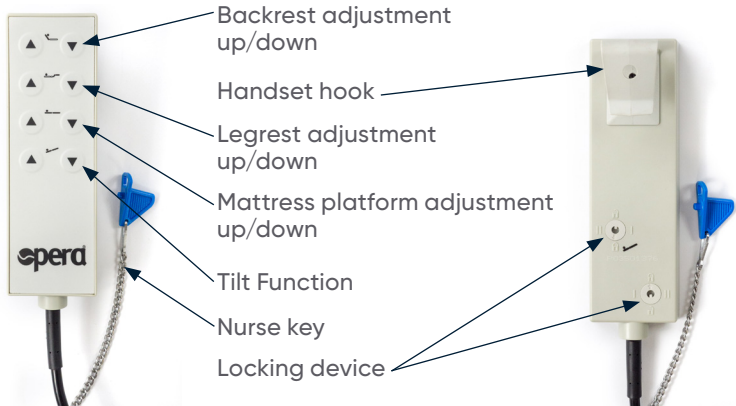
3.1 Overview



- | | |
|--|--|
| 1. Headboard with integrated height adjustment | 10. Height adjustment actuator for headboard |
| 2. Footboard with integrated height adjustment | 11. Height adjustment actuator for footboard |
| 3. Electrically adjustable backrest | 12. Mains power coiled cable with SMPS power supply box and plug |
| 4. Electrically adjustable legrest | 13. Mattress holder |
| 5. Mechanically adjustable legrest | 14. Side rails |
| 6. Handset with locking key | 15. Side rail channel and runner |
| 7. Backrest actuator | 16. Brakeable castors |
| 8. Legrest actuator | |
| 9. Control box | |

3.2 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 (e.g. on the mattress base or side rail) when not in use.



Attention: Press only one button at a time, pressing multiple buttons at one time, may overload and damage the system.

3.3 Tilt Function



Caution: Risk of Fatal Injury

Using the tilt feature can have fatal effects on the user if they are sensitive to increased blood pressure in the upper part of their body.

The following points are guidance for the tilt function:

- Only medically trained persons must operate the tilt function.
- A medical evaluation must be performed prior to tilting the bed with the users upper body positioned below their heart.

3.4 Locking Function



Locking device



Unlocked Handset



Locked Handset

All electric adjustment functions can be locked by using the nurses' key (the blue key).

To lock the adjusting functions, insert the nurses' key into the locking device and turn the key so that the locked padlock setting is selected (see photos above).

The switching positions I and II are testing settings, used to check the safety of the bed during annual inspections, after repair work or each time the bed is put into storage. Please refer to page 36 for further information.

3.5 Operation of the Side Rails

To use the side rails, lift the upper side rail until it locks into place in its highest position.

To lower the side rails, lift the upper side rail and at the same time push the triangular release catch in the side rail runner (circled) and lower the side rails down carefully.



The side rails are designed to only prevent the occupant from falling out of the bed. Leaning or climbing on the side rail may result in injury.



When the side rails are in their highest position, ensure that they are securely locked into place, failing to do this may result in injury.

3.6 Operation of the Castors

All castors on the bed can be braked, to brake the castors push down on the brake peddle. The castors must always be in the braked position during normal operation.



Brake Off



Brake On



The brakes must only be released to move the bed into a new position. The bed is not intended to be used to transport occupants, doing so may result in injury.

3.7 Electric Emergency Lowering

The power supply unit fitted on the bed frame is equipped with a 9V block battery. This makes it possible to make a CPR emergency lowering in accordance with EN 60601-2-52 in the event of a power failure.

Please note that CPR emergency lowering is limited to one time per 9V battery and should be replaced after an emergency lowering. If the battery is not used in a two year period, it should be replaced. Replace the battery with a 9V type 6LR61 alkaline battery.

3.8 9V Battery Change



To replace, check or remove the 9V battery, open the battery compartment on the power supply unit, this is attached to the headrest motor.

Follow the below instructions to carry out a battery change:

- Turn off the power supply and unplug the mains plug, **failure to do this may result in electric shock and injury.**
- Take off the control box cover by removing the two screws with a cross head screw driver.
- Carefully pull out the battery holder and replace the 9V battery with a new one. Connect the new battery and slide the battery holder back into the control box.
- Replace the cover and secure.



3.9 Adjusting the Knee Break Angle

To adjust the knee break angle manually, follow the below steps:

- Use the handset to adjust the knee break angle electronically (see the handset controls on page 21).
- To further alter the knee break angle, lift the footrest section up. Audible clicks confirm when the platform is locked into a new position.
- To lower the footrest section manually, lift it to its highest position and then slowly lower it back down.

To allow the occupant of the care bed to electronically adjust the knee break angle further, carry out the following steps:

- Manually lift the footrest section up by three clicks. Using the handset, lower the kneebreak angle back down to its flat position. Use the handset to raise the knee break angle back up. This will allow the occupant to further adjust the knee break angle with the handset.

4. Troubleshooting

Fault	Possible cause	Remedy
No response	Mains plug not plugged in	Insert the mains plug into a mains socket
	Locking function on the handset has been activated	Unlock the handset (see page 34 on how to do this)
	Handset not plugged in	Insert the handset plug into the correct control box* socket
	Actuator motor/s not plugged in	Plug actuator motor/s into the correct control box* socket/s*
Handset functions do not perform the correct actions	Actuator motor cables in the wrong sockets on the control box*	Ensure the colour coded plugs match the correct colour on the socket*
No function after power failure	9V block battery is discharged	Replace the 9V block battery (See page 21 on how to do this)
Bed 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 (See page 19 on how to do this)

* The control box is located underneath the mattress platform

5. Safety Instructions

5.1 General Safety Instructions



During the briefing, specific attention must be drawn to any potential dangers. Prior to the first use, 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@operabeds.com.



When operating the adjusting functions, there must not be any objects or limbs in the movement paths of the bed due to the risk of 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 are under the bed before operating any of the functions. Never store anything under the bed.



If the physical or mental state of the patient requires, the handset can be locked on the reverse side of the handset when not in use (nurse's key). See detailed description of the locking operation in section 3.3 (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.



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, to ensure compliance with IEC 60601-2-52:

- Use only approved side rails supplied as an option by Opera.
- Only suitably instructed personnel are allowed to operate the side rails.

- Lower the side rails slowly and take care not to let them drop down.
- When operating the adjusting functions, the patient's limbs must not protrude beyond the mattress base or touch the side rails.
- **The side rails are only designed to prevent a person falling out of the bed; under no circumstances should they be climbed or leaned on.**
- 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.
- The side rail height from the top of the mattress in uncompressed condition must be at least 220mm. If the height is less than 220mm, increase the side rail height with an extension side rail kit.
- During use, ensure that the side rails are level.
- Do not allow children to use the side rails, this may result in entrapment, injury and/or asphyxiation.
- Exercise 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.

Disconnect the mains plug from the socket before moving the 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 up in anything, as it gets carried along when the bed height is adjusted, 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 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 bed is stationary, the castors must always be in the braked position. If the castors are not in the braked position, 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 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 Technical Data).

Do not exceed the maximum weight limitation of the care bed. The maximum safe working load (SWL) is 220kg/34st 6lb for the Opera Classic Profiling Bed and Opera Classic Low Profiling Bed.

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

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

5.2 Safety Information for the Operator

With the help of this Instruction Manual, instruct each user in the safe operation of the 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 the bed. This also applies for persons who only operate the care bed on a temporary basis.

The bed outlined in this manual is a Class I Medical Device as defined by the Medical Device Directive 93/42/EEC.

Please observe your obligations as the operator, see section 7.1.

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 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, 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.

5.4 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 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 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, after a lengthy break in use and before each further use. Refer to section 7.1.

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. Pay special attention to side rail components and mattress platform connections.

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 and must then be replaced. If the expiry date of the battery has passed it must be replaced. Since batteries are subject to self-discharging, it is recommended to use a 6LR61 alkaline manganese battery and to replace it every two years. Used batteries must be disposed of in an environmentally compatible way, contact your local waste recycling facility for further details.

5.6 Accessories

The optional accessories available include a patients lifting pole (product code: BOA011) of which the safe working load is 80kg and must not be exceeded. The patients 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, resulting in serious injury.

Only the supplied side rails (BOA003) can be used with the Opera Classic Profiling Beds, please see the specifications for further details on the side rails.

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

5.7 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 8.8). However it is possible that electrical devices can interfere with each other. In this case, switch off the bed for a short time or remove the interference source.

5.8 Storage

If the care bed is stored for a lengthy period, the 9V block battery should be removed as it will be subject to a higher rate of self-discharge. The bed should be stored between -10°C to 60°C in a room with a relative humidity between 30% to 75%. Keep the bed dry and out of direct sunlight.

5.9 Service Life and Disposal

The normal service life for care beds in domestic use is approximately 5 years. Please refer to chapter 9 for further instructions.

6. General Information

6.1 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 medical product 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 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.

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 Chapter 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 international 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 Classic Profiling Beds (enclosed and unenclosed variants) and the Classic Low Beds (enclosed and unenclosed variants) are intended for accommodating occupants in residential homes, nursing homes and the domestic environment. The care beds may only be used under the conditions for use described in this Instruction Manual.

The Opera Classic Profiling Beds and Classic Low Beds are designed to accommodate adults weighing up to 185kg/29st 1lb.

The beds are intended to be used for occupants who have a condition where care from the bed is required, this may be to alleviate or compensate for handicaps and/or disabilities and to facilitate the working conditions of the carer. Any other use shall be regarded as non-compliant with the intended uses. This will void the warranty terms and conditions.

Under certain conditions the care beds may be used with other medical devices, such as antidecubitus/pressure relieving mattresses, aerators and alimentation systems. Always conduct a risk assessment when using the bed with accessories, equipment and other medical devices.

The mattress must meet the technical specifications and requirements outlined in Sections 5 and 8.

If electrical devices are used in the care bed and/or near the care bed, a risk assessment must be conducted and measures taken to ensure that any cables do not interfere with the bed.

6.4 Non-Intended Use

A non-intended use is a use that deviates from the intended purpose.

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

- Loading the care bed beyond the safe admissible working load (refer to specifications in Section 8).
- Operation of the care bed by occupants who have not been instructed on its use.

- Use of the care bed for children.
- Attempting to move the care bed when in its braked position.
- Using the care bed for transporting occupants.
- Use of the care bed on a non-horizontal surface (max incline of 5°).
- Use as a hospital bed or in hospitals.
- Use with electrical applications which involve intravascular or intracardiac processes with the occupant.
- Use with any devices that will compromise the general safety and performance requirements of the care beds.

Using the care beds for any of the above uses or a use that is not outlined in this instruction manual will be regarded as a non-intended, this will void the warranty terms and conditions.

6.5 General Regulations

The care beds must only be used for the purpose intended. When setting up, operating and using the care bed, respect the regulations in your country, the general recognised rules of technology, the occupational health and safety, and accident prevention regulations.

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

6.6 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.

7. Servicing

Operators of care beds are obliged to conform to servicing regulations in your country.

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

- Visual checks
- Functional tests
- Overall evaluation

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.

Important: If you have any doubts about the safety or functioning 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?			

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 220mm?			
19.	Have castors including locking brake been tested for safe functioning?			
20.	Mains cable, connecting cables and handset securely attached?			
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:

7.2 Checking the Initial Fault Safety

To check the safety equipment, proceed as follows:

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

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

8. Technical Specifications

8.1 Technical Data

	Measurement	
Specification	Classic	Classic Low
Max. Weight of Occupants	185kg/29st 1lb	
Height Range (Floor to Top of Mattress Platform)	400 - 800mm/16" - 31"	220 - 620mm/8.25" - 23"
External Length	2180mm/86"	
External Width	1055mm/41.5"	
External Height (In Lowest Position)	890mm/35"	815mm/32"
External Height (In Highest Position)	1295mm/51"	1225mm/48.2"

Specification	Classic	Classic Low
Internal Length	2000mm/78.7"	
Internal Width	900mm/35.4"	
Upper Level of Head Section/Foot Section	70°, 30	
Height Adjustment of Mattress Base (range) from	400 - 800mm/16" - 31"	220 - 620mm/8.25" - 23"
Backrest Adjustment Adjustable Electronically up to	Approx. 70° (Electric, Stepless)	
Thigh Rest Adjustment Adjustable Electronically up to	Approx. 30° (Electric, Stepless)	
Foot Rest in Raised Position (Raised Mechanically) to	-25° to 0° Degrees in Five Stages	
Mattress Base Surface	Powder-Coated Steel	
Wooden Side Guards (with plastic ends)	1973 X 115 X 28mm (77.8" X 4.5" X 1.1")	
Castors with Individual Lockable Brake	4 of 4	
Max. Castor Loading Capacity	100kg pcs/15st 7lb	
Operating Noise	< 53 db(A) at a distance of 1m	
Maximum Mattress Depth	120mm - 200mm/4.7" - 7.9"	
Recommended Mattress Length	2000mm/78.7"	
Recommended Mattress Width	870mm to 900mm/35.4"	
Backrest Length	745mm/29.25"	
Thighrest Length	350mm/13.75"	
Legrest Length	540mm/21.25"	
Maximum Backrest Angle	Approx. 70°	
Maximum Legrest Angle	Approx. 30°	

Specification	Classic	Classic Low
Safe Working Load - SWL (Max Weight of Patient + Mattress + Accessories)	Max. Weight of Patient: 185kg/29st 11lb Advisory Weight of Mattress: 20kg/3st 11lb Advisory Weight of Accessories: 15kg/2st 4lb SWL: 220kg/34st 6lb	
	Split Side Rails	
Length	1973mm/77.7"	
Height in Lowest and Highest Position	84mm - 425mm/3.3" - 16.7"	
Weight	11kg for 4 pieces	
Safe Working Load (SWL)	220kg/34st 6lb	

8.2 Technical Data (Electrical)

Power Supply Unit	SMPS
Voltage Rating	Input Voltage: 100 - 240V AC and Voltage: 29V DC
Frequency Rating	50 - 60Hz
Type of Current	Input Voltage: AC and Output Voltage: DC
Nominal Consumption During Operation	Approx. 70W
Nominal Consumption in Idle State	Approx. 0.5W
Nominal Operating Time	Max. 2 minutes (Max. 5 Switch Cycles/ Minutes)
Nominal Idle Time	18 Minutes
Primary Safety Fuse	2A
Battery for Emergency Lowering	x1 6LR61
Mattress Base Motor Units (Back/Leg)	MD125 (Limoss)
Height Adjustment Motor Unit	MD121 (Limoss)
Motor Unit Protection Class	III

8.3 Classification

Medical Device Class (MDD 93/42 EEC)	Class 1
Degree of protection to DIN EN 60601-2	Group1, Class B (CISPR11)
Housing degree of protection to EN 60529	Power supply unit: IPX6 Motor units: IPX4 Control box: IPX6 Hand switch: IPX4
Max. duty rating	max. 2 minutes
Max. switching cycles/mins	max. 5 switch cycles/minutes
Safety inspections	Annually

8.4 Technical Data (Environmental)

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

8.5 Weights of the Individual Components

Mattress platform - head section	24kg
Mattress platform - leg section	20.5kg
Bed chassis - head section	27kg
Bed chassis - leg section	27kg
Wooden side rails	Approx 2.8kg each
Transportation bracket	5kg

8.6 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.		
Emitted Interference	Compliance	Electromagnetic Environment - Guidelines
RF emissions according to CISPR11	Class 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 and those determined to be directly connected to a public supply network that supplies buildings used for residential purposes.
Emissions of harmonics according to IEC 61000-3-2	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	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 and output lines	± 2 kV For power lines ± 1 kV For input and 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.
Magnetic field of power frequency (50/60Hz) according to IEC 61000-4-8	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.

<p>Voltage dips, short interruptions and supply voltage variations according to IEC 61000-4-11</p>	<p><5% UT for 1/2 cycle (>95% dip)</p> <p>40% UT for 5 cycles (60% dip)</p> <p>70% UT for 25 cycles (30% dip)</p> <p><5% UT for 5s (>95% dip)</p>	<p><5% UT for 1/2 cycle, 10ms (>95% dip)</p> <p>40% UT for 5 cycles 100ms (60% dip)</p> <p>70% UT for 25 cycles 500ms (30% dip)</p> <p><5% UT for 5s (>95% dip)</p>	<p>The quality of the supply voltage should be equivalent to that of a typical business or hospital environment. If the user of the 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.</p>
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8.8 Information about Non Life Support Devices

Guidance and Manufacturer's Declarations - Non-Life-Support-Devices Electromagnetic Interference Immunity.			
<p>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.</p>			
Interference Immunity Certification	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidelines
<p>Conducted RF interferences according to IEC 61000-4-6</p> <p>Emitted RF interferences according to IEC 61000-4-3</p>	<p>3 V eff</p> <p>150 kHz-80 MHz</p> <p>3 V/m</p> <p>80 MHz-2.5 GHz</p>	<p>3 V eff</p> <p>3 V/m</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>In the vicinity of equipment, bearing the following symbol, interference.</p>

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 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.

8.9 Working Clearances between Communications

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 Sections 2 and 7 are taken. Frequent transport, 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. When the service life has ended, do not dispose as normal domestic waste, please contact your local waste recycling facility for further instructions.

10. Guarantee

As stated in the Warranty Terms and Conditions, below, Opera provides a manufacturer's warranty of 3 years from the date of purchase.

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.

In circumstances where the product does not perform in accordance with Opera's specifications during the warranty period of 3 years, 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 under the statutory warranties referred to in clause 11.3.1 below.

11.2 Warranty Conditions

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

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 replacement under these Warranty Terms and Conditions.

11.2.3 The customer is responsible for inspecting all goods received from Opera upon arrival. In instances where goods have been damaged in transit, the customer must report this to Opera within three 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.

11.3 General

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 alterations, 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 any 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.

(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.

Notes



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