

# opera<sup>®</sup>



## Bed Installation Guide and Technical Specifications for Opera<sup>®</sup> Signature Profiling Bed

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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 Directive (93/42 EEC).

**IPX4**

The electrical equipment is splash-proof.



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



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



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.



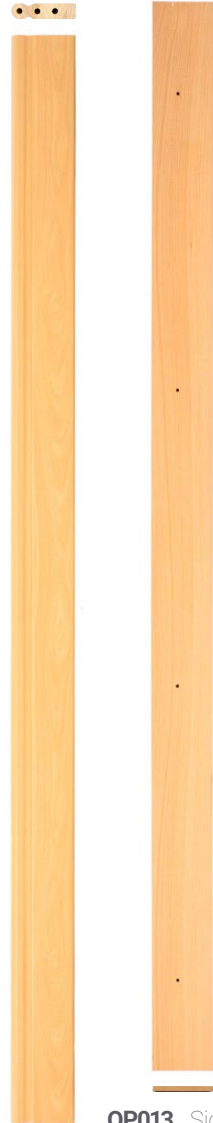
Read instructions

# What's in the box:

**OP011** Head/Footboard x 2



**OP012** Side Rail x 4



**OP041** Mattress Platform Securing Bolt\* x 16



**OP042** Side Skirt Fixing Bolt x 8



**OP043** Side Rail Channel Fixing Bolt\*\* x 4



**OP044** Chassis Securing Bolt x 4



\* Eight of these are already fitted to the Mattress Platform Backrest Section

\*\* These items are already fitted to the Head/Footboards

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

**OP013** Side Skirt x 2

## 2. Installation and Commissioning

**OP014** Mattress Platform Backrest Section  
N.B. Easily identifiable because it has both an actuator and the black control box.



**OP015** Mattress Platform Legrest Section  
N.B. Easily identifiable because it only has one actuator.



**OP022** Bed Chassis



**OP017** Mattress Holding Clip\*\*\* x 4



**OP018** Side Rail End Cap x 8



**OP019** Side Rail Runner x 4



**OP020** Handset



**OP021** Power Transformer



Before you begin, you will also need:

- Wall space with a plug socket nearby
- Tools: 4mm & 6mm Allen Key, Phillips Screw Driver ; Pair of scissors



**Before you begin!** We recommend that two people install this bed due to the weight of individual parts.

## Position the bed

Move the bed into the centre of the room. Place the side rail and side skirt boxes to one side.



1

## Place accessories to one side

Detach the following accessories:

- 1 OP018 - Side Rail End Caps
- 2 OP041 - Mattress Platform Securing Bolts
- 3 OP042 - Side Skirt Fixing Bolts
- 4 OP019 - Side Rail Runners
- 5 OP044 - Chassis Securing Bolts



OP018



OP041



OP042



OP019

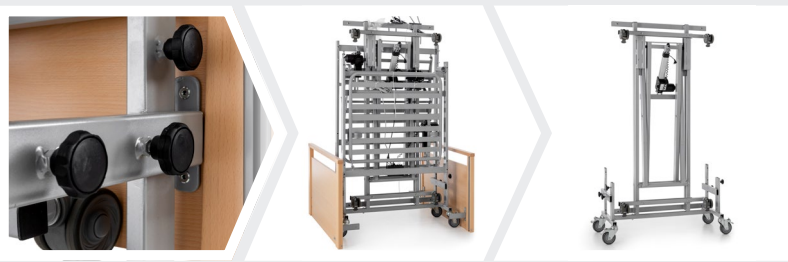


OP044

2

### 3 Remove bed components from transportation bracket

Loosen the thumb screws on each side of the transportation bracket and slide the head and foot boards out of the bracket. Then lift the mattress platform sections out of the transportation bracket. Place detached parts to one side.



### 4 Position bed chassis

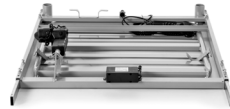
Lift the bed chassis off the transportation bracket and place on the floor. **CAUTION HEAVY!** Remove the transportation bracket. Once the chassis is positioned, put the brakes on all of the castors.



## Secure actuator motor

5

Stand the legrest section of the mattress platform (OP015) on its end with the actuator motor at the top. On the actuator securing bracket, remove the safety pin to allow the actuator to be positioned in line with the mounting bracket, then reapply the safety pin to secure the actuator in place. Repeat for backrest.





## 6 Place the backrest mattress platform on the bed chassis

Lift the backrest section of the mattress platform onto the head end of the bed chassis. **Ensure the backrest section is NOT placed above the height adjustment actuator/motor on the chassis!** Position so that the securing bar pictured in the first image below is aligned with the u-bracket which is on the underside of the backrest mattress platform section.



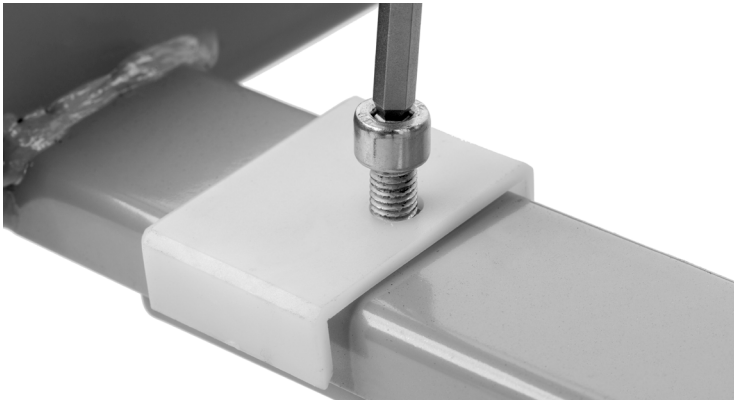
**ATTENTION:**

Do NOT place the mattress platform backrest section over the actuator/motor on the bed chassis.

## Fix backrest mattress platform

7

Now that the backrest section has been placed on the bed chassis, line up the mattress platform so the two screw holes either end align. Manually lift the backrest profiling section (not whole platform) to access the screw holes. Then place the chassis securing bolts (OP044) into the holes and and tighten with a 6mm Allen key. Repeat on the other side.



## 8 Plug in actuators to raise bed

Plug the height adjustment actuator, backrest actuator and handset control into the correct color-coded sections of the control box as shown below.



## 9 Raise the bed

Plug the bed into a mains power supply and raise the bed to a suitable working height to attach the legrest mattress platform section to the chassis.



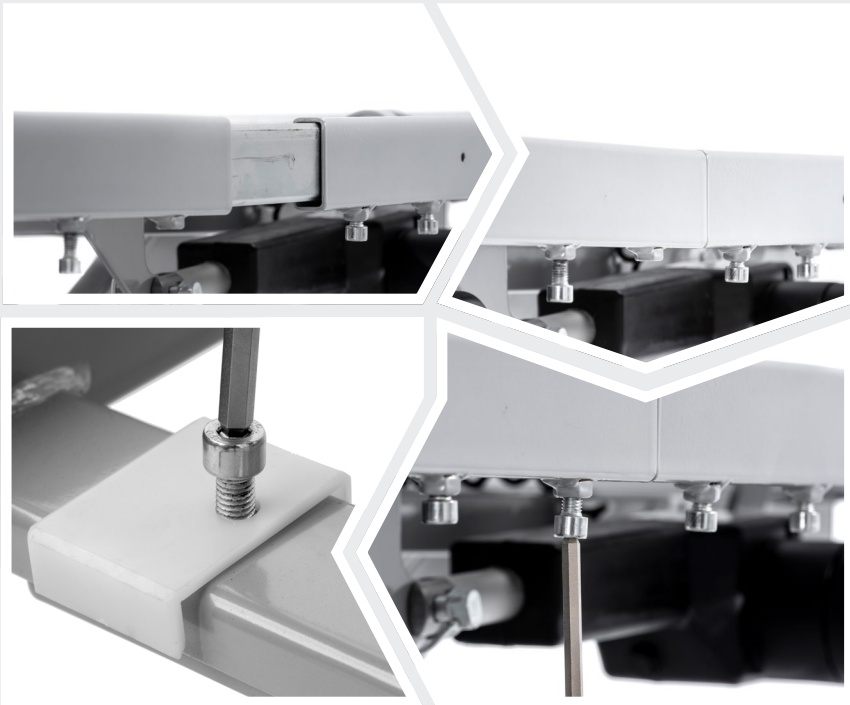
**ATTENTION:**

Ensure there are no trailing wires caught in the scissor-action mechanism.

## Connect mattress platforms and secure legrest section

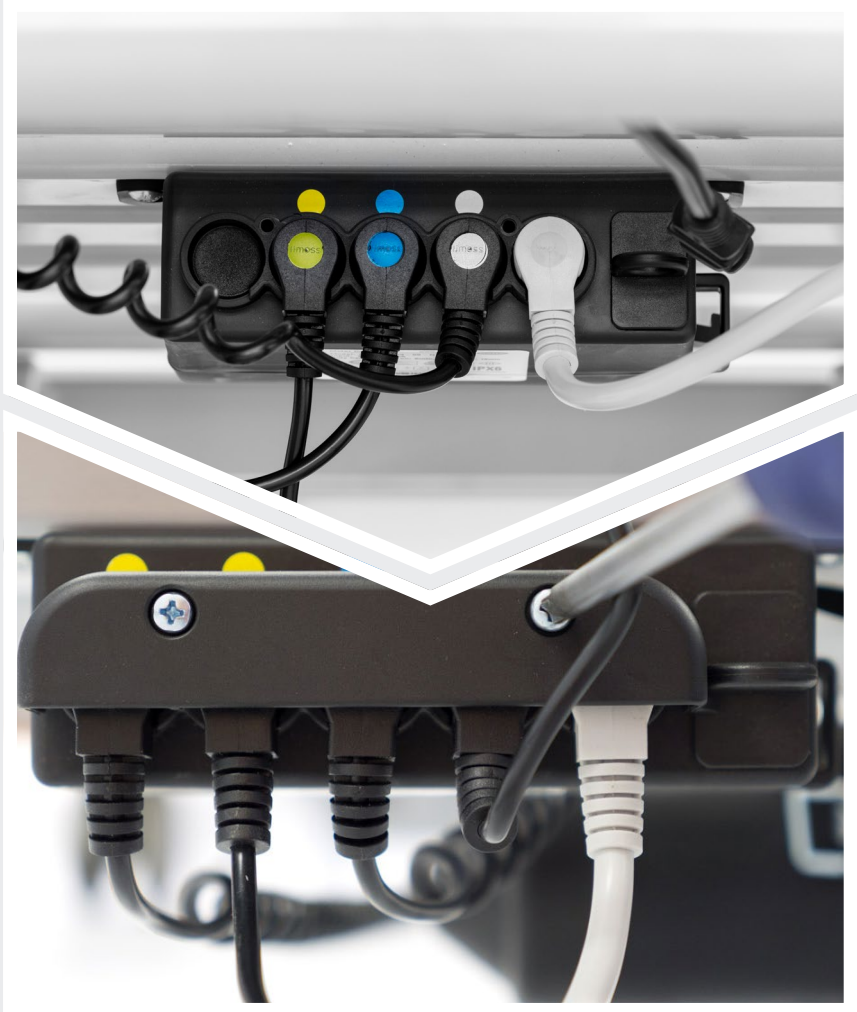
10

Lift the legrest mattress platform onto the chassis and align the metal prongs in the backrest section with the holes in the legrest section. Feed the metal prongs into the holes until the mattress platforms are joined. Once joined and the legrest mattress platform is onto the securing bar, tighten the Mattress Platform Securing Bolts (OP041) to secure the mattress platforms together. After this, repeat the process in step 7 to secure the legrest mattress platform to the chassis.



## 11 Connect remaining actuators

Plug in the legrest actuator into the control box. Once completed, attach the control box cover using a standard Phillips screw driver.



## Attach head and foot boards

12

Lift the head/foot board so the two metal prongs either side are in line with the two holes at the end of the mattress platform. Slide into place so that the head/foot board is flush with the mattress platform. Once in place, secure using the Mattress Platform Securing Bolts and a 6mm Allen key.



## 13 Fit side skirts

Unpack the 2 Side Skirts (OP013) from their box. Using the Side Skirt Fixing Bolts (OP042) and the 4mm Allen key to attach the Side Skirts to the mattress platform side channels using the holes provided. Insert all the bolts before tightening fully.



## Fit side rail end caps

14

Unpack the side rails (OP012) from their box. Lay all four side rails on the floor. Fit the plastic end caps (OP018) to both ends of the rails. The easiest way to put the end caps on is to use the bottom of the side rail as a leading edge (as pictured).





## 15 Insert side rail runners into head board

Unscrew the Side Rail Channel Fixing Bolt (OP043) on the head board and slide the side rail runners up the channel. Once in place fix the runners by replacing the bolts.



## Fit side rails to headboard

16

Fit the wooden side rails onto the side rail runner by sliding the fingers all the way into the wood of the side rails. The side rail runner fingers go into the top and bottom holes of the side rail.



## 17 Complete side rail fitting

Remove the Side Rail Channel Fixing Bolt (OP043) from the footboard. Attach the side rail runner to the foot end of the side rails as shown in step 16. Now slide the side rail runner into the channel and bring it up until it clicks into place at the top of the channel. Lift the rails up to their highest position and screw the channel bolts back into place. Go back to step 15 and repeat the process for the other side of the bed.



## Mattress holders

18

Clip in place the mattress holders (OP017), 2 slats down from the top of the backrest, and 2 slats up from the bottom of the legrest. Repeat for the other side of the bed.



## Test functions

19

Test the controls on the bed are working correctly, by performing the following steps:

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

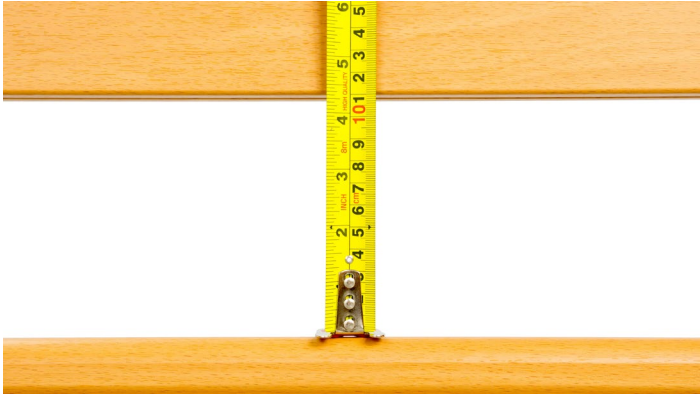


**ATTENTION:**

Ensure there are no trailing wires caught in the scissor-action mechanism.

## 20 Confirm compliance

Measure the distance between the side rails when in the up position. This distance should be around 110mm, which is less than the maximum 120mm stipulated in the bed rail regulations.



## 21 Position the bed

Once the testing has been completed satisfactorily, you are ready to move the bed into the desired position. Position the bed and apply the brakes to the castors. You are now ready to place the mattress onto the bed.



# Installation Complete!

22

Remove all packaging and the transportation brackets from the room, and you have successfully completed the installation!



## 2. Installation and Commissioning

## Construct the Patient Pole

1

Assemble the patient pole by first fitting together the two poles by inserting the smaller end of the crooked pole into the opening in the straight pole. Secure by tightening the black thumb screw, ensuring it threads through both the hole in the straight pole and the hole in the crooked pole.



## Secure Patient Pole to the Bed

2

Insert the patient pole into the holding sleeve in the corner of the mattress platform. Slot the pole in fully, ensuring the cylinder pins are in the notches at the top of the sleeve.





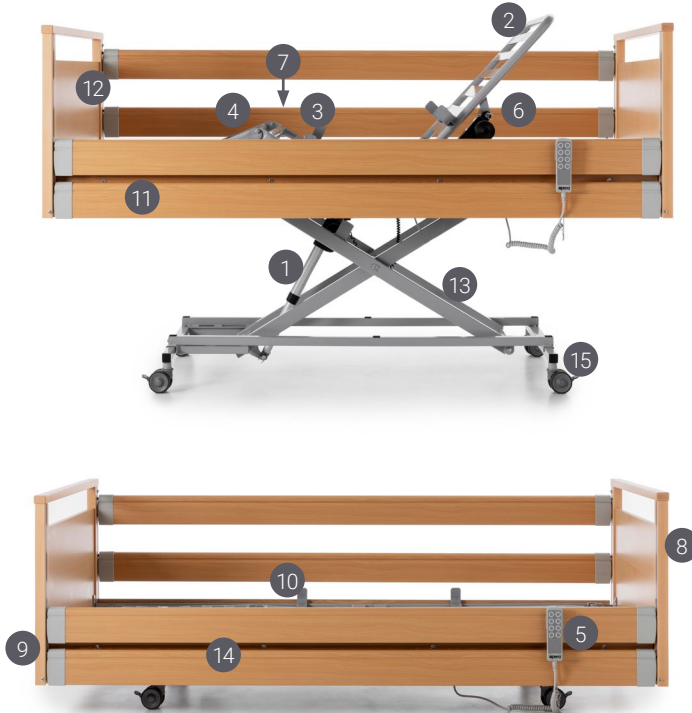
### 3 Attach the Handle

Place the loop of the webbing strap over the top of the pole and secure between the two pins. Test the triangular handle by pulling down tightly.



# 3 Bed Operation and Maintenance

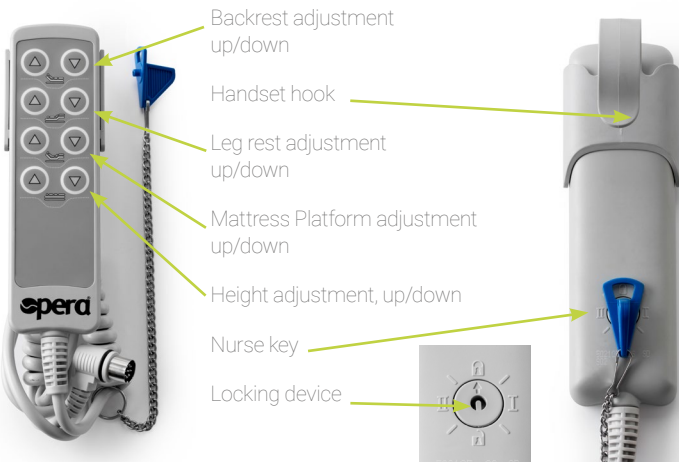
## 3.1 Overview



- |                                     |                                   |
|-------------------------------------|-----------------------------------|
| 1. Height adjustment actuator       | 9. Foot board                     |
| 2. Electrically adjustable backrest | 10. Mattress holders              |
| 3. Electrically adjustable legrest  | 11. Side rails                    |
| 4. Mechanically adjustable legrest  | 12. Side rail channel             |
| 5. Handset with locking key         | 13. Chassis                       |
| 6. Backrest actuator                | 14. Side skirt                    |
| 7. Legrest actuator                 | 15. Castors with mechanical brake |
| 8. Head board                       |                                   |

## 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, as the system could overload and become damaged.

## 3.3 Locking Function for Handset



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

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

### 3.4 Operation of the Side Rails

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

To lower the side rails, lift the upper side rail and at the same time push the triangular release catch and lower the side rails.

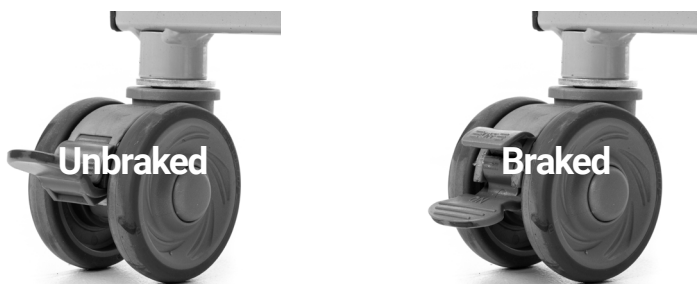
The side rails are designed only to prevent a person falling out of the bed, under no circumstances should they be climbed or leaned on!



If the side rail is in its high position, ensure that it is always safely locked into place!

### 3.5 Operation of the Castors

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



**ATTENTION:**

The brakes must only be released to move the bed! Please also refer to the Safety Information!

## 3.6 Electric Emergency Lowering

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

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

## 3.7 9V Battery Change

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

Carry out the battery change as follows:

### **ATTENTION:**

Unplug the mains plug!

- Take off the control box plug cover by removing the two crosshead screws
- Now pull out the battery holder and replace the 9V battery with the new one.



Connect the new battery and slide the holder back in again. Replace the control box cover and secure.

## 4. Troubleshooting

Fault	Possible cause	Remedy
No response	Mains plug not plugged in.	Insert mains plug into mains socket.
	Locking function on handset activated.	Unlock handset.
	Handset not plugged in.	Insert handset 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 9V block battery.
Bed moves but only 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.

\* 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 which can occur despite correct operation. Before putting the care bed into service for the first time, the Instruction Manual must be read conscientiously and in detail by the user / care personnel.

When operating the adjusting functions, there must not be any objects or people's limbs in the movement paths of the care bed. Risk of 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 at 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.

When the side rails are used, the following instructions must be adhered to:

- Use only approved side rails supplied as an option by Alpine HC. See suitable dimensions at section 7.1.
- Only suitably instructed personnel are allowed to operate the side rails.
- Side rails must only be adjusted to be either fully up and locked in place or fully down.
- Lower the side rails smoothly 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.**
- **When lowering the rails take care not to drop them, lower carefully.**
- 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.
- The gap between the two side rails or between the lower side rail and the top of the bed platform must be less than 120mm.
- During use, ensure that the side rails are level.



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 and 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 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 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).



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

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

## 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.

These homecare beds are Class I active medical products according to the MDD.

Please observe your obligations as the operator, see section 7.2.



## 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 according to the MPBetriebV (Operators of Medical Products Ordinance) § 4 and 6.



A technical check and/or safety inspection must be conducted at least once a year and after a lengthy break in use and before each further use. Refer to section 7.2.

Any defects, damage or signs of wear must be rectified without delay. Only original spare parts from Alpine HC 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 at the most and must then be replaced. If the expiry date of the battery has elapsed then it must be replaced immediately. Since batteries are subject to self-discharging, it is recommended that the battery is replaced every two years if not used. It must be ensured that the battery is a 6LR61 alkaline manganese battery and not any other type. Used batteries must be disposed of in an environmentally compatible way.

## 5.6 Accessories



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

Use only mattresses compatible with the supplied side rail system. The dimension between mattress upper surface in uncompressed condition and 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 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 interfere with each other. In this case, switch off the care 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.

## 5.9 Service Life and Disposal



The normal service life for care beds in domestic use is approx. 5 years. The care bed must not be disposed of as normal domestic waste after its service life has expired.

# 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, medical 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 the user can recognise and avoid potential dangers and assess the clinical condition of the patient.

### **Patient / Occupant**

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

### **Qualified Personnel**

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

## 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.

Alpine HC beds bear the CE mark and meet all safety and functionality requirements. These care beds were tested according to the international standards which contain the safety requirements for medical products.

These safety requirements can only be met however if the user satisfies themselves with the proper state of the care bed (including accessories) before using the bed.

Please observe the legislation in your country.

## 6.3 Intended Use

This care bed is intended for accommodating patients or occupants (with body mass  $\geq 150$  cm to max. 165 kg) in residential homes, nursing homes and the domestic environment. The bed may only be used under the conditions for use described in this Instruction Manual.

It is used to alleviate or compensate for handicaps or disabilities, and to facilitate the working conditions for the carer. Any other use shall be regarded as non-compliant with the regulations and is excluded from any liability.

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

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

The care bed is not designed for the transport of patients.

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

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

## 6.4 Non-Intended Use

All uses deviating from the intended purpose, which may also be hazardous as a result.

This includes for example:

- Loading the care bed beyond the safe admissible working load (see section 8.7 and identity label on bed frame)
- Operation of the care bed by patients or occupants who have not been instructed in its use
- Use of the care bed for children
- Attempting to move the care bed when it is in a braked position
- Use of the care bed on a non-horizontal surface (max. incline 5°)

## 6.5 General Regulations

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

If the care bed is in a faulty state causing the patient/occupant, care personnel or third persons to be endangered, operation must not be started.

## 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

## 7.1 Principles

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 check
- Functional test
- Overall evaluation

To guarantee safe operation, a visual and functional test including an electrical test must be carried out at least once a year. For this purpose, proceed according to the technical safety checklist as per regulation EN 62353

### **IMPORTANT**

If you have any doubts about the safety or functioning of the bed or even a part of the bed as a result of the work performed below, the bed should under no circumstances be placed into service again. Contact the supplier or manufacturer in this case.

## 7.2 List of Technical Safety Checks according to EN 62353

Care bed: Signature

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?			
17.	Height of side rails above the mattress at least 220mm?			

Item	Instruction for testing	Comment	Yes	No
18.	Height of side guards above the mattress at least 220 mm?			
19.	Have castors including locking brake been tested for safe functioning?			
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: .....

## 7.3 Checking the Initial Fault Safety

To check the safety equipment, proceed as follows:

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

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



# 8. Technical Specification

## 8.1 Technical Data (Mechanical)

Safe working load (max. admissible load): 220kg

Individual loads of the safe working load (advisory):


Max. Weight of patient	185kg
Mattress	20kg
Accessories	15kg
Total	220kg

Safe load, patient's lifting pole	80kg
Max. weight of patient	185kg
Max. mattress height:	180 – 350mm
Length	2150mm (in case of 2000mm long mattress base)
Width	1020mm (in case of 900mm wide mattress base)
Width	1120mm (in case of 1000mm wide mattress base)
Upper level of head section/foot section	865mm - approx. 1290mm
Height adjustment of mattress base adjustable height from:	190 - 715mm
Backrest adjustment continually adjustable electrically up to	approx. 70°
Thigh rest adjustment continually adjustable electrically up to	approx. 30°
Foot rest in raised position mechanically	-25°-0° in 5 stages
Mattress base surface	Steel slatted base
Wooden side guards including plastic end caps	1973 x 115 x 28mm
Castors with individually lockable brake	100mm
Max. castor loading capacity	100 kg (static)
Unloaded weight	153 kg
Operating noise:	< 53 db(A) at a distance of 1m

## 8.2 Technical Data (Electrical)

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

## 8.3 Classification

Medical product	Class 1
Degree of protection to DIN EN 60601-1	Type B 
Housing degree of protection to EN60529	IPX 4 (not suitable for automated washing systems)
Max. duty rating	10%, ON 2 min / OFF 18 min
Max. switching cycles/mins	5
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	30% to 75% rel.
Air pressure	795 – 1060 hPa

## 8.5 Weights of the Individual Components

Mattress platform - head section	24kg
Mattress platform – leg section	20.5kg
Bed chassis	45kg
Head and foot board (individual)	10kg
Wooden side rails	10.5kg
Patient's lifting pole (optional)	4.2kg
Transportation bracket	10kg

## 8.6 Type Plates

**1 2 3 4 5 6 7 8 9 10 11 12 2014/2015**





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**Signature**

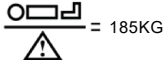
230/240V ~ - 50/60Hz – 250W **IPX4**  
FUNCTION 2 MIN / PAUSE 18 MIN

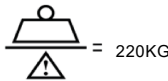
**S/N 14 0702400001**




















## 8.7 Information about Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The care bed is intended for use in the electromagnetic environment specified below. The customer or user of the care bed should ensure that it is used in such an environment.		
Emitted interference	Compliance	Electromagnetic Environment - Guidelines
RF emissions according to CISPR11	Group 1 -	The care bed uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
RF emissions according to CISPR11	Class B	The care bed is designed for use in all establishments including domestic establishments and those determined to be directly connected to a public supply network that supplies buildings used for residential purposes.
Emissions of harmonics according to IEC61000-3-2	Class A	
Emissions of voltage fluctuations / Flicker according to IEC 61000-3-3	Complies	

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.
Voltage dips, short interruptions and supply voltage variations according to IEC 61000-4-11	< 5 % UT for ½ cycle (> 95% dip) 40 % UT for 5 cycles (60% dip) 70 % UT for 25 cycles (30% dip) < 5 % UT for 5s (> 95% dip)	< 5 % UT for ½ cycle, 10 ms (> 95% dip) 40 % UT for 5 cycles 100 ms (60% dip) 70 % UT for 25 cycles 500 ms (30% dip) < 5 % UT for 5s (> 95% dip)	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment. If the user of 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.
Magnetic field of power frequency (50 / 60 Hz) 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.

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	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 150 kHz - 80 MHz</p> <p>3 V/m 80 MHz - 2.5 GHz</p>	<p>3 V eff 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 transmitter in watts (W) according to specifications of the transmitter manufacturer and d is the recommended working clearance in meters (m)</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 is possible.</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 and FM radio and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength at the location of the care bed exceeds the specified compliance level above, then the care bed should be monitored with respect to its normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the care bed.

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

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

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

Output power of transmitter W	Working clearance according to transmission frequency 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 communication device unintentionally brought into the patient area could lead to interference.

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

## 9. Service Life and Disposal



The service life of our care beds in domestic use is assumed to be approximately 5 years. This naturally depends upon the manner of use. The care bed is suitable to be put into service again if all measures of section 2 and 7 are taken. 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 care bed must not be disposed of as normal household waste after the end of its service life.

## 10. Guarantee

As stated in our Standard Terms and Conditions we provide a manufacturer's warranty of 3 years from the date of purchase.

## 11. Opera Warranty Terms and Conditions

### 11.1 Warranty Terms

10.1.1 Subject to the terms and conditions set out below, Alpine HC Ltd 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 Alpine HC Ltd, in circumstances where the product does not perform in accordance with Alpine HC Ltd'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 Alpine HC Ltd requires any customer requesting service under the warranty to comply with directions from Alpine HC Ltd 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 to inspect all goods received from Alpine HC Ltd upon arrival. In instances where goods have been damaged in transit, the Customer must report this to Alpine HC Ltd 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 Alpine HC Ltd 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, Alpine HC Ltd will determine, in its discretion, the closest product within the then current range of products offered by Alpine HC Ltd 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 Alpine HC Ltd. Alpine HC Ltd 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 Alpine HC Ltd is unable to repair or replace the product, the customer will be provided with credit for Alpine HC Ltd product or may be refunded the price of the product (at Alpine HC Ltd's 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 Alpine HC Ltd.
11. 2.7 Alpine HC Ltd may seek reimbursement of any costs incurred by Us where the product is found to be in good working order.
- 11.2.8 Alpine HC Ltd reserves reasonable discretion to determine whether any product is or is not performing in accordance with Alpine HC Ltd specifications, subject to applicable law.

## 11.3 General

- 11.3.1 Legislation may imply warranties or conditions or imposes obligations on Alpine HC Ltd, 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 Alpine HC Ltd;

(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) Alpine HC Ltd 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 or damage.

(b) Alpine HC Ltd's aggregate liability in respect of all claims under the warranty shall not exceed the original purchase price of the product or, at Alpine HC Ltd's option, the replacement of the product with a like or similar product.

(c) Alpine HC Ltd excludes all other warranties, conditions, terms, representations and undertakings whether express or implied.

# 12. Declaration of Conformity

Product: Profiling Beds  
Date: 01/01/2018  
Revision: 0



## CE Declaration of Conformity



In accordance to annex VII of the 93/42 EEC for medical devices from September 2007

We:

Alpine HC Limited t/a Opera®  
Azure House, Connaught  
Road Kingswood  
Hull, HU7 3AP  
United Kingdom

declare on our own responsibility that the following group of products or products:

### **Opera® Signature**

which deals with this declaration, conform with the conformity assessment procedure set out in VII of the 93/42 EEC for medical devices from September 2007 and fulfil the basic requirements of annex I.

The products/groups are class I, rule 1, annex IX of the 93/42/EEC from September 2007.

Hull, HU7 3AP, 01/01/2018

Director



**opera**<sup>®</sup>

**alpine**<sup>®</sup>  
HC GROUP

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