



PhysioNova
Health Care Systems



ROTOFLEX[®]

Into and Out of Bed at the Touch of a Button.

ROTOFLEX[®] Turning Bed System User Manual



Introduction and General information

Thank you for buying a RotoFlex Electrically Adjustable Turning Bed System which is produced from PhysioNova GmbH. The bed is a high quality product and properly used and looked after, it should give you years of good reliable service.

In order that you get the best from your bed, please ensure that you and anyone else who is involved with the use of the bed read these instructions carefully.

Please make sure that everyone concerned in using and operating the bed, cleaning it, and cleaning around it, is aware of the section on health and safety. This is particularly important if there are ever children in the area in which the bed is situated.

We would also like to draw your attention to the section on warranty, and particularly the things you can do which will invalidate that warranty. The warranty certificate supplied with the bed will show the details of the warranty arrangements applicable to your purchase.

Please contact us if your requirements change after you have bought the bed. We have a number of accessories, which can assist users in making the most of their bed.

Thank you again for buying PhysioNova's RotoFlex.

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Intended Use

The intended use of a RotoFlex Electrically Adjustable Turning Bed System is to:

- Provide the user with an aid to help them in and out bed.
- Provide the user with a comfortable chair which will provide assistance with standing.
- Provide the user with independence allowing them to get into and out of the chair and into and out of the bed.
- Accommodate only the number of users which the bed has been designed.
- Be used by a person or persons whose weight at the time of use, is within the load capacity of the bed.
- Be used in a clean, dry environment at a temperature to suit human habitation.

Limitations of Use

The bed should not be used:

- To lift or store any object other than a user for which the bed is suitable.
- To accommodate a child under 12 or an adult of similar size.
- To support a user whose weight is in excess of the weight capacity of the bed.
- To support more than one person.
- By a person who does not have the ability to be able to understand and operate the hand control.
- By a person without sufficient mobility to use the bed effectively and avoid accidents

Product Description

The RotoFlex bed consists of a mattress platform constructed from 4 profiling sections which through electrically powered actuators assists users to get in and out of the bed.

Access to the bed is provided from a sitting position in a chair which is created by the movement of the bed sections to form the chair



When the correct button on the handset is pushed the leg sections of the bed will lift the users legs and the back will slightly recline. At the point where the leg sections are clear of the side strips of the bed, the complete bed will rotate until the mattress platform is in line with the main frame of the bed.



The inclination of the head and foot sections of the mattress platform can be adjusted to suit the users requirement

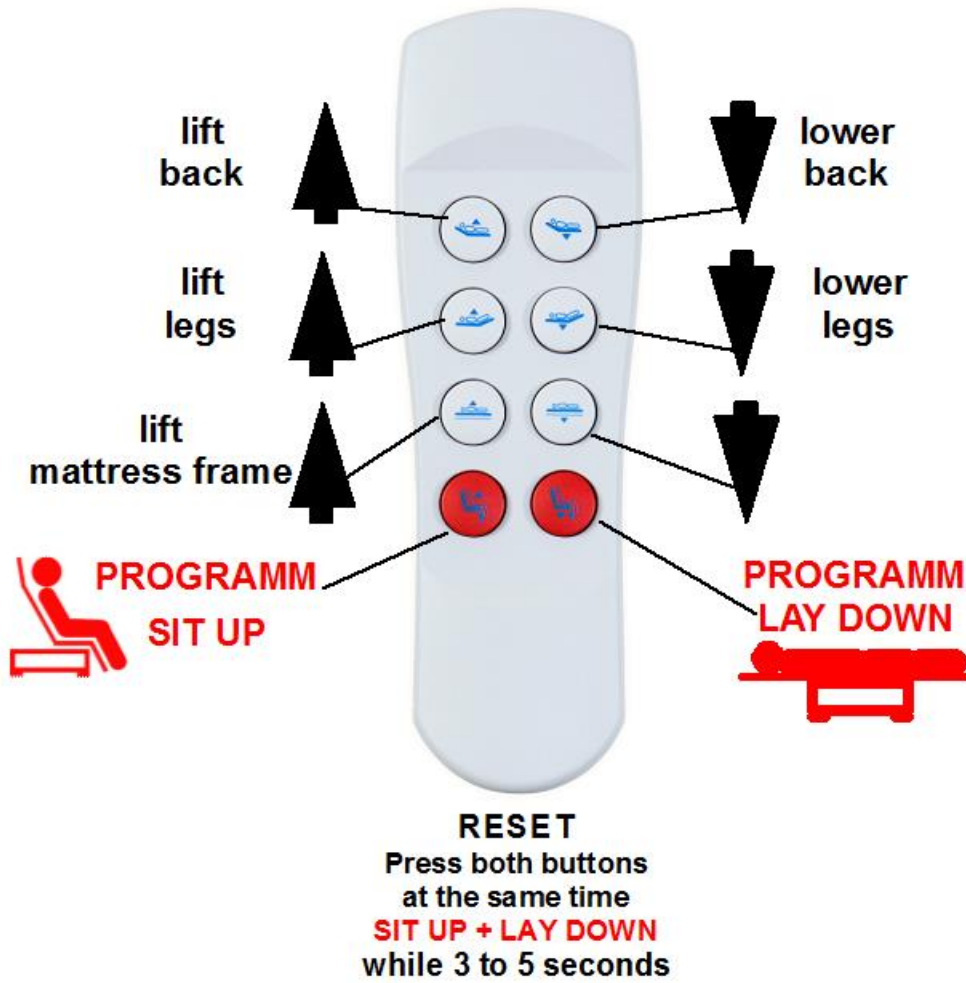
The bed has a variable height platform to assist Carers and bed transfers. This feature can also be used to assist the user to stand when the mattress platform is in the chair position.

Rotation of the bed can be programmed to provide a clockwise or anti clockwise rotation.

Two removable side rails are supplied with each bed.

The RotoFlex bed can be supplied as part of a double combination.

MANUAL REMOTE CONTROL



Product Specification

Mattress Platform Length Standard 210cm Extended 230cm Width Standard 90cm
Extended 120cm

Mattress Platform Heights (without mattress and with standard castors)

Minimum - 41.5 cm Maximum - 80.5 m

Mattress Thickness 15cm

Maximum User Capacity 135

Rotation Clockwise or Counter Clockwise.

Castor Dimensions 12.5, 7.5 (Standard), or 5 cm diameter.

Electricity Supply 220Volts 50 Hz 0.6Amp

Operating Voltage 24 Volts

Electrical System Protection IPX4

Class II

Health and Safety

- 1) The operating instructions for use must be read before using the bed and must be observed at all times.
- 2) The bed must not be used if faults or defects occur which could result in risks to people.
- 3) Before putting the bed into service it should be checked to ensure that it is functionally safe and in good working order.
- 4) Regularly check the main electrical supply cable for damage. If this is evident switch off the main supply and seek professional advice.
- 5) Electrically adjustable beds use extremely powerful motors. The beds are safe if properly used, but care must be taken when using the bed to ensure that damage is not caused when operating these motors.
- 6) The electrics meet all relevant standards for this sort of use. BUT the motors are not fully watertight AND are not suitable for use in an oxygen-rich environment. (An oxygen mask or nasal bleed may be used)
- 7) Select a suitable location for the bed:
 - Around 10 cm from adjacent walls and furniture, taking into account the rotation of the mattress platform.
 - With an electrical socket adjacent, so that there is no trip risk from the wire
 - If a lifting pole is fitted please ensure that there is sufficient ceiling height available with the bed in the raised position. (Approx 210cm, but it can vary slightly depending on the model of the bed)
- 8) Whenever the bed is being adjusted, all objects and all people (especially children and animals) must be kept clear of the beds moving parts.
- 9) The height of the bed should only be raised when it is necessary to do so. It should normally be in the lowest position.
- 10) No parts of the users body must extend beyond the edge of the bed platform.
- 11) Ensure that bedding does not become entrapped within moving parts of the bed as it is adjusted.

- 12) The main connector cable must be free of the rotation and height adjustment mechanism, and be free to move when adjustment is taking place.
- 13) Ensure that the hand control is always accessible, and correctly stored. Ensure that it is not jammed between any sections of the bed which may cause the buttons to be accidentally operated.
- 14) The wheels on the bed must be braked unless it is actually being moved. This is required to ensure that the user does not fall when getting into or out of the bed.
- 15) Ensure the waterproof mattress cover is in use if there is may risk of the user being incontinent.

Specific safety information where children and others unable to be responsible are in, or likely to be in, proximity to the bed.

PhysioNova wishes to draw users attention to the potential dangers of children playing in and around the bed. Children are naturally inquisitive, and enjoy playing with moving items. They find beds with moving parts, fascinating .

However, because of the powerful motors, the bed is not a suitable plaything. Incorrectly used, the bed has entrapment dangers to the children, and to the supply wiring. For the above and other reasons:

- DO NOT allow children to play with the bed at any time.
- DO warn visitors of the potential dangers of the bed.
- DO warn those with responsibility for children of the potential dangers of the bed.
- DO ensure that children within the proximity of the bed are well supervised and never left alone.
- DO always ensure that the control hand set is stored out of the way of inquisitive eyes and hands.
- DO disconnect the power supply, (when applicable)

Safety Features

- 24 Volt operating system
- Movement stops immediately a button is released .
- Wheels supplied with locking castors.
- Buttons on the hand control are clearly marked to avoid unintentional operation of a function .

Warranty Information

- 1) A PhysioNova bed is a quality product, which should give years of trouble free use.
- 2) If purchased new, then it has a warranty period as stated on the warranty certificate.
- 3) This warranty covers parts and labour for faults in the product during that period, unless otherwise stated on the sales agreement.
- 4) The warranty covers faults, which are as the result of design fault or part failure, but only of course whilst the bed is being used in accordance with these instructions.
- 5) Incorrect use of the bed, misuse and accidental damage is not covered under the warranty and there will be a charge for the repair. A minor breach of warranty will not affect the continuation of the warranty . In certain circumstances, however, actions, which do fundamental damage to the bed, will lead to the invalidation of the remainder of the warranty period.
- 6) Common incidents, which are not covered by warranty, include:-
 - Accidental damage to the hand control, whether for example crushing under a wheelchair, or dropping it in liquid.
 - Liquid spoiling the mattress, or penetrating and degrading the mechanism or electrics, or frame of the bed.
 - Damage caused to leads by running them over or catching them in moving parts of the bed.
 - Damage to the mechanism or electrics under the bed by incorrect use of lifting or hoisting equipment.
 - Damage to the upholstery of the bed, however caused.
 - Damage caused to a wall, or adjacent furniture, by the operation of the bed is the user's responsibility.
 - Damage to the electrical plug howsoever caused
- 7) The bed is designed to carry a specific weight. This maximum figure is shown on page 4 of this manual which should not be exceeded.

The above are examples only and the list is not intended to be exhaustive.

Instructions when using the bed for the first time

- 1) Position the bed and lock the wheels of the bed. (see section 6 of the Health and Safety notes)
- 2) Plug the electrical supply plug into the Battery Back Up Unit supplied.
- 3) Plug the supply to the Battery Back Up Unit into a supply socket having ensured that the socket is operating satisfactorily.
- 4) Check the operation of the Hand Control and that the user is familiar with the operation of it.
- 5) Check that there is room for the bed to rotate when it is required to do so.
- 6) Ensure that the footrest is clear of the floor when the bed is in the chair position.

1) Getting into the bed

- a) Start with the bed in the seat position. Hold the hand control in the most convenient hand. If necessary, adjust the height of the seat to make it easy to sit into it. This height adjustment is achieved by operating the vertical height adjustment using one of the two buttons at the hand control. Sit on the seat, sitting as far back into the seat as possible. This is important for comfort and for the successful operation of the bed to avoid putting excessive stresses on the foot motors.



- b) When the bed is required to be rotated, push the lower button of the two red buttons at the bottom of the hand control and keep it held. If it is required to stop the movement at any stage release the button. Initially the Lower Leg Section will lift, and this will be followed by the Upper Leg Section which will be in conjunction with the back section reclining.



- c) Continuing to hold the bottom red button will cause the sleeping platform to rotate taking it in line with the bed. At this stage there are two options. One option is to keep the lower red button pressed which will automatically allow the back section to lower, followed by the upper leg and lower leg sections which will result in a flat bed. The lower red button can then be released. The other option is to release the lower red button at the stage when the sleeping platform is in line with the bed and adjust the head and foot sections using the appropriate grey buttons"



Maintenance

RotoFlex beds do not need a great deal of maintenance, but keeping the area around the bed clean and keeping liquids away from the hand control, motors and other electrical parts will minimize any potential problems.

A Service and Inspection requirement are detailed on the Warranty Certificate supplied when the bed was purchased.

The Schedule of General Inspection and Service is as follows:

1. Electrical

- a) Check condition of all power cables for damage and security of all electrical connections.
- b) Check condition of mains plug
- c) Check operation of battery backup system (if fitted).
- d) Check operation and security of all limit switches.
- e) Check operation of hand Control and cable.

2. Mechanical

- a) Check all frame components for deformation, wear, damage or corrosion.
- b) Check head and foot sections operate quietly and for their full stroke
- c) Check that the lifting actuator operates quietly and for the full stroke.
- d) Check that the rotation actuator operates quietly and for the full stroke.
- e) Check all fixings (nuts, clips, retaining rings) are in place and tight.
- f) Check lifting pole (if fitted)
- g) Apply grease to all pivot points, and clean off excess grease.
- h) Check tension of rotation turret to be 10Kg

3. Wheels

- a) Check all wheels run freely and swivel satisfactorily
- b) Check brakes (when fitted) are effective
- c) Check wheels are secure to the bed

4. Rails

- a) Check Grab Handles for damage and ease of operation.

5. General

- a) Check condition and report on service sheet.

6. Mattress

- a) Check general condition and report on service sheet.

7. Massage

- a) Check function (if fitted)

Service Life

Bed frame is estimated to be 10 years and longer.

The life of the mattress core is expected to be about 3 years and the life of the mattress cover about 1 year. However, these are only indicative and will vary considerably according to the use, treatment and cleaning of the item.

Cleaning

The bed should be disinfected on a regular basis and ideally between each user.

Warnings

- a) Before cleaning, disconnect the bed from the mains power supply.
- b) Gloves and protective clothing should always be worn when carrying out cleaning procedures.
- c) Do not use hypochlorite or phenol based cleaning agents.
- d) Do not use abrasive compounds or pastes.
- e) Do not use washing machinery or any other method which uses sprayed water under pressure to clean the bed.

Metal Parts

All surfaces can be cleaned by wiping with a soft cloth moistened with hot water and a mild detergent. Avoid splashing any component associated with the electrical system such as the handset, motors or control box.

To disinfect the bed between patients where there is no visible staining, clean with Sodium Hypochlorite or similar (up to 1000ppm available chlorine). Use any proprietary cleaning agents according to the instructions of the manufacturer.

To decontaminate the bed to remove any potentially infectious material such as body fluids, or when used by a user with a known infection, clean afterwards with Sodium Hypochlorite or similar (up to 10,000ppm available chlorine). Use any proprietary cleaning agents according to the instructions of the manufacturer.

Rinse with a cloth moistened with clean water and dry. If this is not done thoroughly, the cleaning agent can cause damage to the bed. Make sure that parts are dry before replacing the mattress.

Wooden Parts

Use standard commercial furniture cleaning and care products for parts of the bed manufactured from wood.

The wood is a natural product and it undergoes a natural aging process, and over time environmental effects such as humidity, heat and UV radiation will result in changes to the colour of the wood surface. Given the nature of wood, as a natural product, PhysioNova cannot accept liability or provide any warranty for changes in the wood colours

EG – Declaration of Conformity

Accordance with Appendix VII of the guideline 93/42/EWG about medical devices

PhysioNova® GmbH
(Name of producer)

Im Wolfsgarten 9, D-91056 Erlangen
(Address)

We declare under our sole responsibility that the product/ the products:

Bedside, Nursingbed, Stand-up and mobilization help
(Article description)

RotoFlex® E , Typ Nr.: RO - 1002xxxxx

RotoFlex® P , Typ Nr.: RO - 1002xxxxx

RotoFlex® H , Typ Nr.: RO - 1002xxxxx
(type) xxxxx serial-number

The engineer standards:

DIN EN 60601-1 : 1995/03

DIN EN 1970 : 2000/12

DIN EN 60601-2-38 : 2001/07

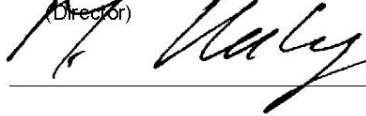
DIN EN 60601-1-2

DIN EN 60601-2-52

An thus meets the essential requirements of the guideline 93/42/EWG, Appendix I.

Erlangen, May 04 2011

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