PhysioNova
Health Care Systems

OPERATING INSTRUCTIONS
ROTOFLEX BASIC &
Basic Low

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

Issue date: 17 Dec 2024

Key to the symbols:

Warning against personal injury. Dangerous electrical voltage.
There is danger to life.

General risk.
There is danger to life and health.

Useful Tip. Facilitates the operation of the nursing bed or helps to obtain a better understanding.

ROTOFLEX©

Contents

Preamble

Thank you, for having opted for the **RotoFlex®** Nursing and mobilization bed.
You have a functional and high-quality product that has been developed and produced in Germany and is drawn on over 20 years of experience and knowledge in the manufacture of such special beds.
Please read the operating instructions manual carefully before using it for the first time. Keep these operating instructions, so that you always have them to hand for reference. You will be able to use this product safely only if you have read and understood these instructions completely. It is also important that you have read all the listed safety instructions and follow them. This also applies to anyone who uses this bed, such as carers or relatives.
The **RotoFlex®** will then be your reliable support for many years.

EXPLANATION FOR THE DESIGNATED GROUPS OF PERSONS

The following groups of persons have been named in these instructions for use:

Operator

Operator (for example: medical supply stores, specialist dealers, health insurance companies) is any natural or legal person who uses the **RotoFlex®** nursing bed or on whose behalf it is used. The operator is responsible for providing proper instructions to the user.

User

Users are persons who on account of their education, experience or training are entitled to operate or carry out work on the **RotoFlex®** nursing bed or are trained in handling the nursing bed. The user can also recognize and avoid possible hazards and asses the clinical condition of the patient.

Patient

The patient in these instructions for use refers to the person lying on this bed who is frail, disabled or in need of care.

Specalist staff

Specialist staff are employees of the operator, who on account of their training or instruction are entitled to deliver, assemble, disassemble and transport the nursing bed. They are also trained in the requirements for cleaning and disinfection.

Purpose

The **RotoFlex®** is a tool used to bring the patient from the lying position in the bed to a seated position on the edge of the bed. It is used to maintain or restore the independence of the patients with regard to sitting up or getting up and aids their mobility; it also helps to give physical relief to the carer.

The **RotoFlex®** is a hospital nursing bed with an additional therapeutic, nursing mobilization function with stand-up support and use as an armchair. The patient can control all the functions himself and can stand up independently with the help of the bed as long as the clinical picture allows it.

The **RotoFlex®** can be operated by patients, who are fully in control of their mental faculties. If this is not the case, then the bed must be operated by a healthcare assistant and the manual operation of the bed must be blocked or made inaccessible to the patient.
This applies particularly to the use of bed barriers.

Delivery and assembly

The installation and assembly should only be performed by an authorized specialist dealer or by a qualified specialist person authorized for instruction. The patient and the user must be instructed by an authorized person.

During the installation, it is important to ensure that an adequate distance from the wall is secured and complied with, to allow the **RotoFlex®** to rotate freely. This distance is min. 25 cm for a backrest angle of 30°, and 11 cm for a backrest angle of 45°.

Connect the bed directly to a power socket. Extension cable and/or multiple sockets should not be used.

Caution: The power cable connecting the bed to the power socket must be free of tension. It should not run through the bed in any manner.
It is important to ensure that the cable does not get pinched anywhere.

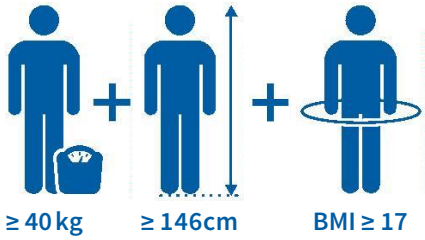
The same holds true for all other electrical devices in proximity to the bed. We advise that no other electrical devices (such as electric blankets) be operated in the bed.

Contraindication

Caution is advised for people with severely impaired balance, severe muscle or joint weaknesses, who are unable to sit or stand independently even with the support of the bed, as well as for people with diagnoses such as epilepsy or sudden seizures, as the movement mechanism of the bed could pose a risk of injury in such cases. Mental limitations (e.g. advanced dementia) may pose a risk, if the person does not understand the function of the bed and this could lead to incorrect operation of the bed or confusion of the patient. In any case it is important that the use of such a bed is always individually coordinated with doctors and therapists to ensure that is supports the patient's mobility and safety, rather than endangering the patient.

Minimum patient dimensions / weight:

Body Size: 146 cm,
Weight: 40 kg,
Body Mass Index “BMI”: 17



When using side rails, there is an increased risk of patients with smaller sizes / weights getting jammed between the clearances of the side rails owing to their smaller limbs.

Clean and disinfect the bed before first use.

In conformance with § 2 of the Medical Products Operator Ordinance, the user must ensure prior to use that the nursing bed is functional and in proper condition and must observe the instructions for use. The same applies to accessories.

In conformance with the Medical Products Operator Ordinance (MPBetreibV), please therefore note that as the operator it is your obligation to ensure a consistently safe operation of this medical product without posing any danger to patients, users and third parties.

This manual contains safety information that needs to be heeded. All persons working on and with the nursing bed must know the contents of this instructions manual and follow the safety instructions. Ensure that that any substitute staff are also trained in the operation of the bed.

In compliance with the Standard DIN EN 60601-1-52, the **RotoFlex®** is suitable for the areas of application: Application Environment 3. (201.3.203), in the long-term care. These include care centers, rehabilitation centers and the like.

Application Environment 4. (201.3.204) in homes or domestic care, to compensate for an injury, disability or illness.

Application Environment 5. (201.3.205) for outpatient treatment in a hospital or any other medical environment in which the equipment for the treatment, diagnosis or monitoring of people with a disability or illness is necessary. The **RotoFlex®** is designed for use in hospitals only for areas falling under application group 0.

This bed has no specific connection option for a potential compensation. Note this before integrating with additional mains-powered (medical) devices.

This product is not approved for the North American market, in particular the United States of America (USA). The dissemination and use of the nursing bed in these markets, including through third parties, is prohibited by the manufacturer.

Operation of the RotoFlex®

Device description

The **RotoFlex®** consists of a lifting unit, a rotating frame and a 4-section electrically adjustable slatted frame.
All settings of the bed are controlled using a cabled remote control via a program circuit.
To support the action of getting up, the lying surface is converted into a trough-like position, rotated horizontally to the side through 90° and then turned into an armchair position. From this position, the patient can either be brought into the standing position, made to sit at the table in the “armchair” or be mobilized as applicable.

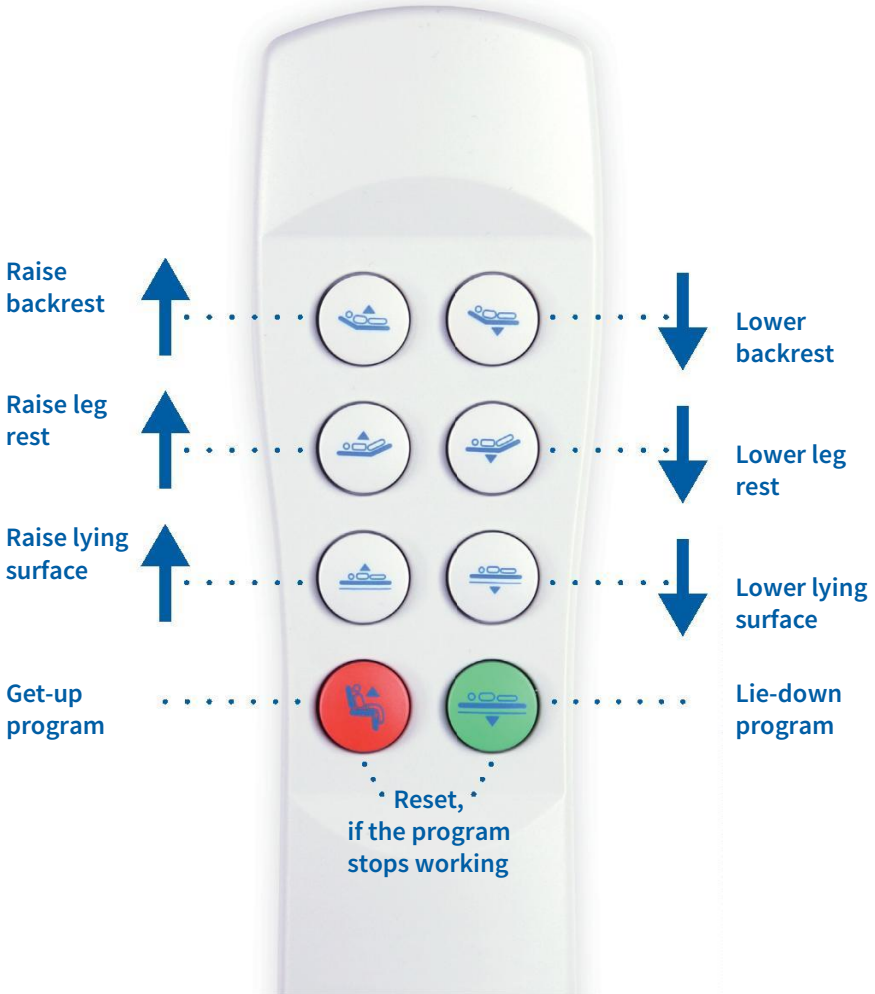
Manual control panel

The entire control of the **RotoFlex®** is via the cabled manual operating unit.

The top three rows of switches are designed for manual control of the **RotoFlex®**, while the lower is for program control. You can switch between manual mode and program mode at any time.

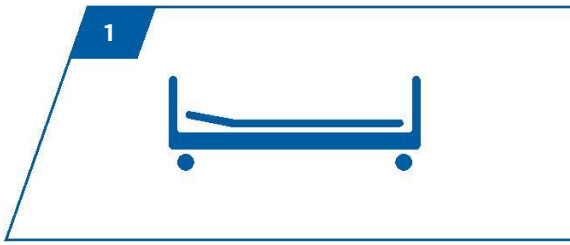
The manual mode is deactivated during the rotational movement. In this mode the program control is to be continued until the position reactivates the manual control either before or after the rotational movement.
For safety reasons only one function can be controlled at a time.

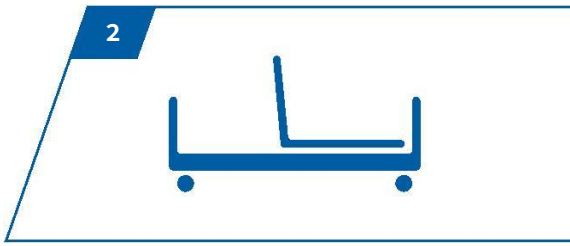
If the control stops working, it is reset by pressing the program buttons simultaneously for about 5 seconds.



Backrest adjustment

You can adjust the tilt of the backrest using the up / down buttons for backrest adjustment according to the clinical condition of the patient or as the patient desires. It is possible to raise the upper part of the body up to an angle of 87°.





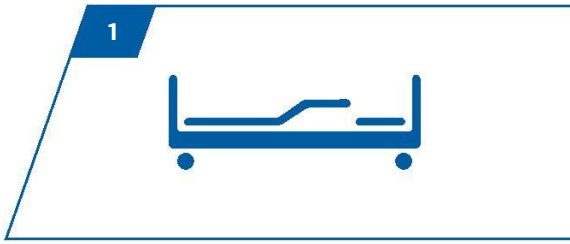
Activation:

- Press and hold down the raise backrest button to raise the backrest. 1
- Release the button when the desired height is achieved. 2
- Likewise, use the down button to lower the backrest.

Caution: Backrest and leg rest should not be moved simultaneously into the max. position as it may be restrictive for the patient. This is not possible when using the program control. (The function of the vertical position of the back is necessary to support the action of getting up in the seated position)

Leg rest adjustment

Like the backrest, the angle of inclination of the leg rest can also be adjusted individually within a range of 0-35°. The leg rest bends slightly at the knee so that the calf area is raised only slightly from the horizontal position.

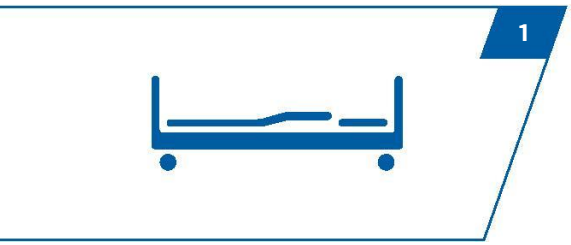


Activation:

- Hold down the raise leg rest button until the desired height is achieved. 1
- Likewise, use the down button to lower the leg rest.

Caution: There must be no fixation on the patient's ankles if you use this function, or this could otherwise cause injury to the patient. The permissible places for securing fixing straps to the bed can be seen in the figure on page 14.

Caution: Make sure that there are no devices or similar gadgets on the leg rest during its adjustment, as this can damage them.



Heel relief

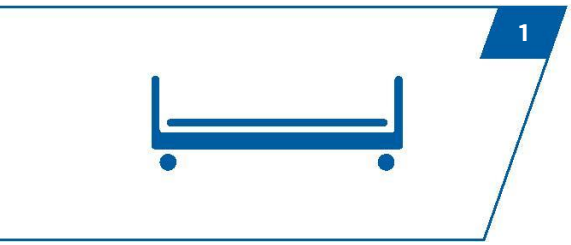
Using the leg rest adjustment it is possible to relieve the heels of pressure as a decubitus prophylaxis.
Raise the leg rest using the “raise leg rest” button until the heels no longer rest on the footrest. 1

Shock position

If required, you can quickly and easily create a shock position by lowering the backrest all the way down. Then hold down the “raise leg rest” button and allow the leg rest to go upwards to its limit. The leg rest automatically stops at an angle of 35°.

Vertical adjustment of the lying surface

The height of the lying surface can be adjusted using the up / down buttons for the overall vertical adjustment.
A low position is recommended for patient safety.
A high position is useful for the examination of the patient or is gentle on the back when nursing measures are being carried out.

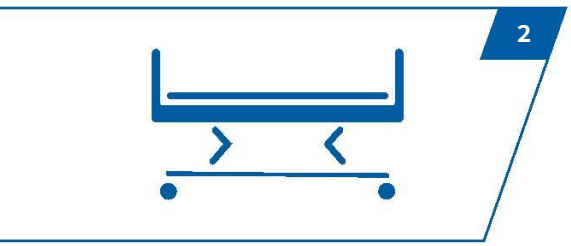


Activation:

Hold down the up button to raise the lying surface, or the down button to lower the lying surface. 1

Release the button when the desired height is achieved. 2

CAUTION: If left unattended, leave the bed in its lowest position to reduce the risk of injury caused by falling out.
If necessary, a crash mat may be placed next to the bed as an additional protection for the patient.

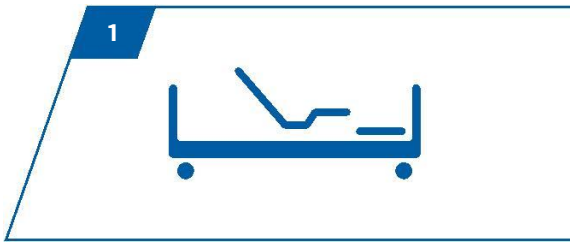


CAUTION: Make sure that the tubes from any drainage vessels etc. kept on the floor are long enough and are not exposed to tension or become pulled out when the lying surface is raised.

Auto-contour

The auto-contour function prevents the patient from slipping in the direction of the foot-end by raising the footrest in parallel with the backrest.

Activation:

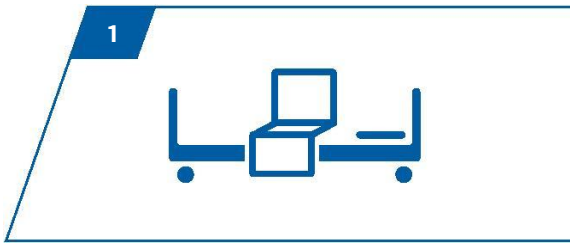


- Press and hold the “Get up” program button.
- The leg rest rises up to an angle of 35°.
- Now the backrest rises up to an angle of 30°.
- If you have achieved the desired setting, release the button.
- You can now proceed with individually adjusting the position with the help of the manual control.
- Likewise release the button once the backrest or the leg rest comes to a halt in the upper position. Otherwise the bed will now continue with the “Get up” program and begin the rotational movement.
- If the bed has already commenced the rotational movement or if the button for manual control is disabled, press the “Lie-down” button until the backrest / leg rest begin to go down again. The manual control is now reactivated, and you can adjust the settings as desired.

Armchair position

The armchair position allows the patient to position himself upright in the bed, just as he would sit in an armchair. In this way the patient can be moved easily and gently into a sitting position, which is desirable for mobilization purposes or for eating.

Activation:



- Hold down the “Get up” program button until the lying surface is rotated through 90° and is in an armchair-like position. 1
- You can now adjust the position with the help of the buttons on the manual control unit to suit your requirements.

Caution: You should make sure that the patient in the armchair position-on has his feet in contact with the floor. Using the buttons for vertical adjustment of the lying surface, adjust the distance to the floor.

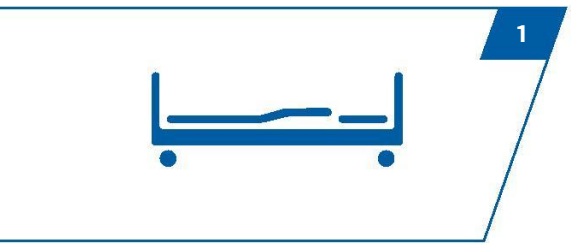
Caution: Especially in the case of frail patients it may be necessary to stabilize them in the sitting position with the help of the side rail and some cushions.

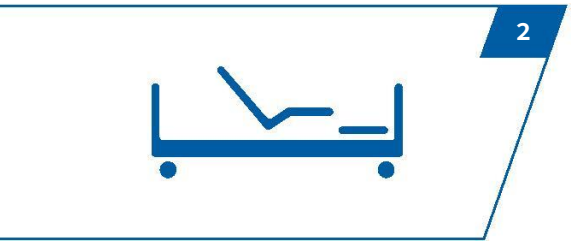
Caution: Do not let patients sit in the armchair position for longer than approximately 1.5 hours, as sitting for longer periods could be too tiring.

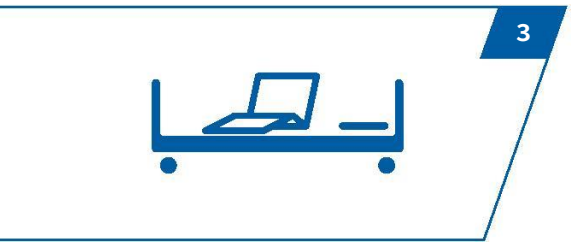
Caution: The bed with the patient in the armchair position should not be moved, as this could cause personal injury and material damage.

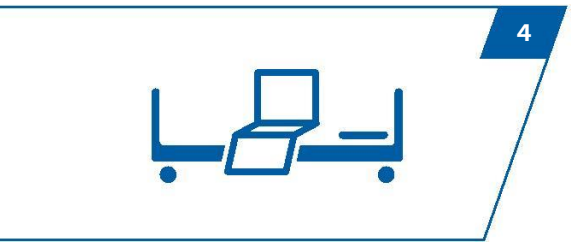
Get-up / Lie-down program

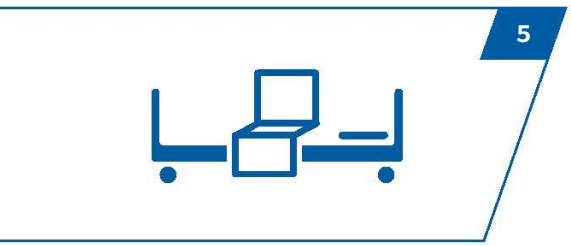
The **RotoFlex®** makes it easy for the patient to get up from the bed and easier for the nursing staff by allowing them to bring the patient gently to a standing position. The transfer from the bed is then simple for the patient and easy on nursing staff's backs. This function also makes it easier for the patient to lie down.











Activating the getting up procedure:

Press and hold the "Get up" program button.

The leg rest first rises to the top position and then the backrest to 30°. 1 2

The **RotoFlex®** now rotates to the side through 90°.

- After the end of the rotational movement the leg rest lowers and after the leg rest is in the horizontal position, the back rises until an upright sitting posture is attained. 3

The **RotoFlex®** now goes down to the lowest position, so that the patient's feet make contact with the floor.

The lower leg is drawn slightly behind the vertical, so that the patient can draw his legs back to some extent. 4

The patient should now tilt the upper part of his body forward over his feet, so that his center of gravity is over his feet, as in the usual way of getting up.

Now press the button "Raise bed height". The patient's thighs are now supported and he is raised into the standing position. 5

If the patient needs assistance, you should use your feet to block the patient's feet to the front and likewise support his knees with yours, guiding the patient's upper body with your hands.

- This way the patient can be brought into a standing position without you having to lift him in any way or the patient using his own strength to get up.

If additional support is needed for getting up, the patient can use the side grips.

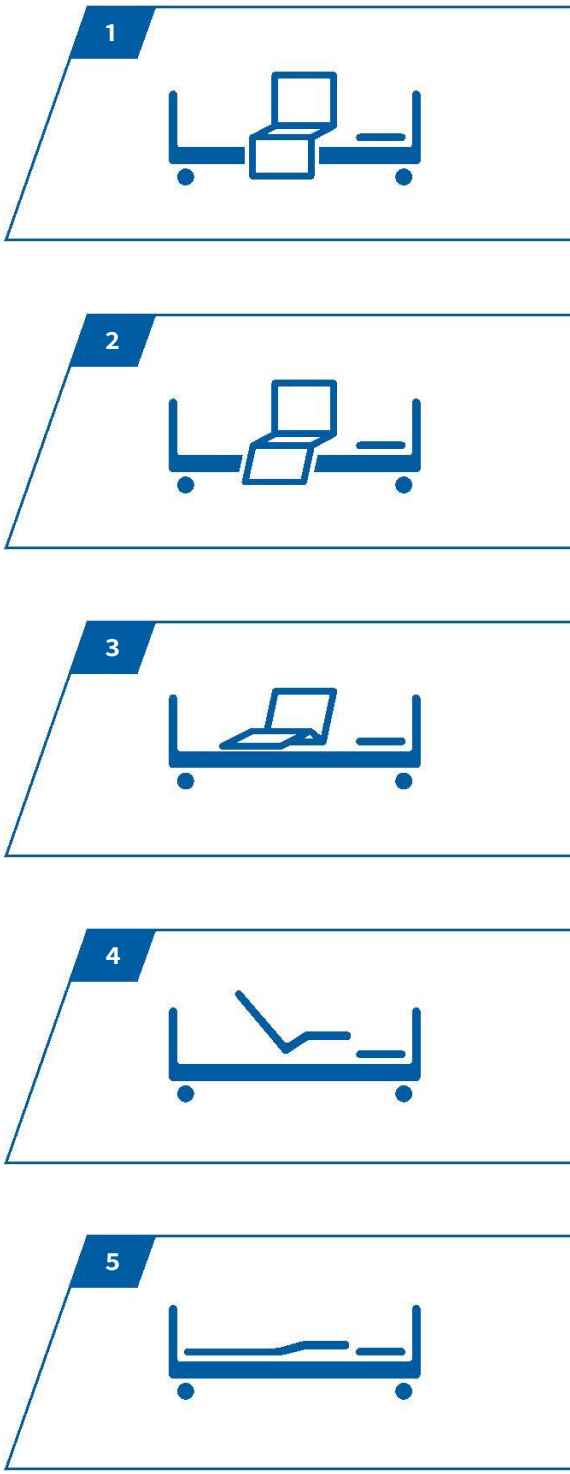
Info: During the rotational movement all other functions are blocked for security reasons. Using the manual control buttons, you can set any position before and after the rotational movement.

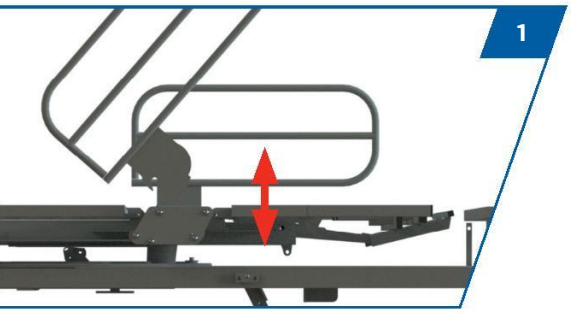
Activationg the lie-down:

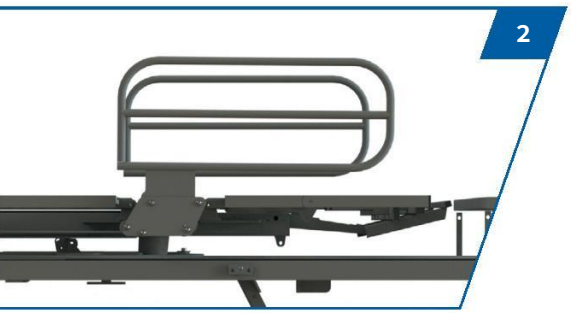
- In principle, the lying down process is just the opposite to that of the process of getting up.
- It has been shown that it is best to bring the bed to its lowest position in the seated position.
- The patient stands with his back to the bed, and his feet as close as possible to the mattress. (This is later crucial for achieving the correct lying position in the bed so that you do not need to “pull up” the patient again).
- The patient can now simply fall into the bed, so that he sits as close as possible to the backrest.
- Now press and hold the “Lie down” program button.
- The leg rest now rises and at the same time the backrest lowers to 30° until the patient lies securely in the trough-like position again. 1 2 3 (Leg rest at the max. height, backrest lowered to approximately 30°-35°)
- Now the lying surface rotates through 90°. 4
- Now you can set the lying surface and its height according to the requirements of the patient. Or you continue to press the lower red button until the program brings the patient in the lying position. 5

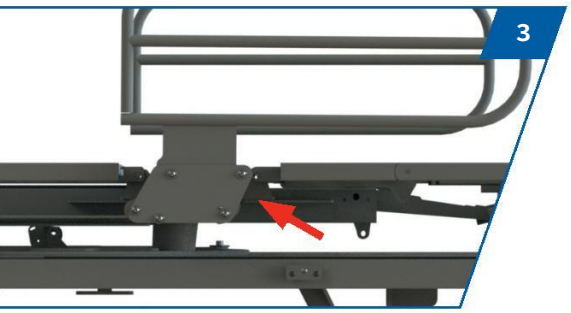
We recommend that for the safety of patients, the height be set to as low as possible when you are not working on the patient.

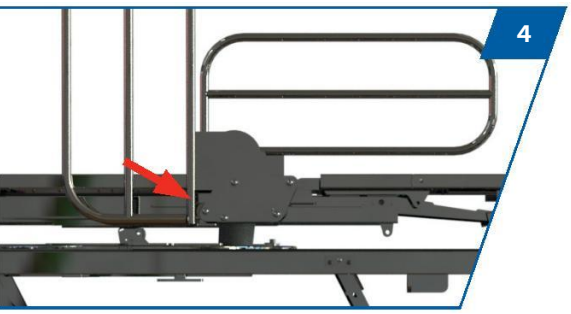
You will realise that neither you nor the patient need to find the strength to lie down or get up and lesser time and no additional staff are required for mobilisation.











Side guard

The additional side guards in the middle section are designed firstly for safety to prevent the patient from falling out, and secondly, they can also be used as handholds to assist in getting up.

Inserting the side guards:

- old the side guard upright and insert the bottom end at an angle of 45° in the bracket on the side of the bed until you feel a resistance. 1
- Now tilt the side guard towards the base until it snaps into place. Check if the side guard is snapped into place by gently pulling it upwards. 2
- The side guard is now firmly in place.

Removing the side guards:

- Hold the silver lever of the bracket on the side that is close to the foot end and press it inwards. 3
- Now tilt the side guard through 90° towards the head end.
- Now you can either leave the side guard this position or remove it completely. 4

Caution, risk of entrapment! 4

Brakes

By default, the **RotoFlex®** has totally adjustable rollers, all of which must be locked as soon as the bed is set down.

Locking the brakes:

Using your foot, press the brake lever at the roller downwards until it snaps into place. (Red arrow)

Releasing the brakes:

With the tip of your foot raise the brake lever at the roller until it snaps upwards. (Green arrow)

Caution:

Before any transport, make sure you disconnect the mains plug from the socket and fix the transformer unit / switch-mode power supply unit to the bed in such a way that the cables do not fall down or get dragged along the floor.

Always park the bed with the brakes applied. Likewise, the brakes of the bed must be applied when transferring the patient. Not doing so may cause personal injury and material damage.

Caution:

To prevent stumbling the wheels should always be positioned so that they do not protrude over the lower frame, i.e. they should point inwards.

Caution:

For your own as well as the patient's safety, always use suitable footwear whenever you move the bed or operate the brakes.

Accessories

- Mattress with anchor system,
- Clip-on handles,
- Incontinence mattress covers
- Fitted sheets
- Incontinence fitted sheet
- Trapeze bar

For information about accessories and adaptations of other resources, please contact your specialist dealer or get in touch with PhysioNova GmbH.

Use only those accessories that are approved by the manufacturer. If accessories other than those approved by the manufacturer are used, the manufacturer's liability may be invalidated.

Cleaning

The **RotoFlex®** is cleaned using commercially available disinfectants or household cleaning agents. Note the use instructions for use issued by the manufacturer! **RotoFlex®** may only be wiped clean with a damp but not dripping wet cloth (do not spray!).
Pull out the mains connector before cleaning.

Protect from moisture.
Do not clean in bed washing units.

Safety

The **RotoFlex®** was developed according to the very latest findings and is subject to constant quality control.

The maximum patient weight the **RotoFlex®** can be loaded with is **135 kg**.

The Safe working load of the **RotoFlex®** is **175 kg**.
This is composed of:

- Patient weight
- Mattress and further toppers if necessary
- Devices mounted on the bed
- The devices attached to the brackets on the bed

Warranty and product liability

The manufacturer issues a statutory warranty for the **RotoFlex®**. If a maintenance contract for the legally required annual safety check is taken, the warranty period can be extended up to 5 years; the warranty for the electrical drive unit is then 2 years.

Any repairs or modifications to the **RotoFlex®** or its components undertaken by unauthorized persons shall invalidate the warranty. In such cases, any product liability on the part of the manufacturer is excluded in advance.

For injuries to people or objects or animals, the manufacturer can assume no liability in the following cases:

- Misuse of the device.
- Use by unqualified persons.
- Improper fitting of parts or accessories.
- Change or interventions without prior approval of the manufacturer.
- Not using original spare parts or original accessories.
- Failure to comply with the provisions of this operating manual and the installation instructions.
- Unusual occurrences .
- The product liability sum is limited to € 200,000.00.

Spare parts

For functional safety and to obtain warranty claims, only original spare parts or spare parts approved by PhysioNova GmbH may be used!

For information about spare parts, please contact our customer support.
Tel: +49 (0) 911 / 977 248 – 0, Fax: +49 (0) 911 / 977 248 – 11, service@physionova.de

Malfunction

Depending on its type, the **RotoFlex®** is supplied with an internal or external switch-mode power supply unit. This power supply unit has 2 automatic internal fuses. In the event of faults in the control panel or in the cable remote-control unit, the device automatically stops.
A so-called reset is then required for restart. For this both the program buttons must be pressed simultaneously for approximately 5 seconds.

All motors are equipped with an overload cut-out and a separate limit switch. In the case of a continuous load of a motor for more than 2 minutes, the drive is automatically switched off. The control must then be restarted via the service.

Optionally, a battery-powered emergency supply to reset the lying position is available.

In the event of malfunctions, please contact your specialist dealer or PhysioNova GmbH.
Tel: +49 (0) 911 / 977 248 – 0, Fax: +49 (0) 911 / 977 248 – 11, service@physionova.de

Troubleshooting

Problem	Possible Cause	Solution
No response on pressing the manual pushbutton	Processor is faulty	Reset by pressing both the program buttons simultaneously for approx. 5 sec.
2 beeps after reset	Min. 1 motor is defective	Call Customer Service
3 beeps after reset	Min. 1 microswitch is defective	Call Customer Service
Continuous beeping sound for approx. 30 sec.	Power supply interrupted	Check mains plug or Call Customer Service
Continuous beeping sound	Continuous overload safety cut-out	Call Customer Service
1 drive without function or operation is functional only in one direction	Drive, manual switch, connector or cable is defective	Check connector, call Customer Service
No function on restart	Power connector not plugged in correctly Socket without voltage supply Switch-mode power supply unit defective	Connect the power plug Check the power socket or the fuse box Call Customer Service

Maintenance

Installation and maintenance may be undertaken only by an authorized specialist. In accordance with the requirements of the Medical Products Law and the BGV A3, the device must be inspected by an authorized specialist once a year and six months after the installation for your safety and to guarantee a long service life.

The **PhysioNova BEDS SERVICE** offers you a maintenance contract.

For information contact: **PhysioNova GmbH**
Tel: + 49 (0) 911 / 977 248 – 0,
Fax: + 49 (0) 911 / 977 248 – 11,
service@physionova.de

Warnings

- When the **ROTOFLEX®** is in operation, no persons, in particular children or pets may be under the bed and within the bed frame. Do not use the free space under the nursing bed as a “parking space” for any utensils.

- In the position that is rotated through 90° no person may sit on the lower leg rest or apply any additional weight when it is in the horizontal position.

- Children should not play with the appliance or be left unattended.

- Do not place multiple sockets under the bed. There is a fire hazard due to the infiltration of fluid.

- Damage to the mains supply or motor cables can lead to life-threatening situations for patients and carers.

- Regularly check the entire length of the cables for kinks, insulation damage (cuts, wear, visible inner conductors- blue, brown, black, green, yellow, metallic - colour changes of the insulation)

- Make sure that cables and wires of devices placed on the bed are routed in such a way that they do not get jammed, pinched or damaged due to moving parts of the bed.

- In the event of damage to the power cable and motor cable, pull out the mains connector and get the repairs done by an authorized specialist.

- Work on the electric components may be undertaken only by the customer service, the drive manufacturer or by qualified and authorized electricians, in compliance with the all relevant VDE regulations and safety rules!

- In the case of incontinent persons, use incontinence mattress covers.

- If unattended, leave the bed in its lowest position to reduce the risk of injury caused by falling (when getting into or off the bed, or when lying down).

CAUTION: Backrest and leg rest should not be moved simultaneously to the max. position as it may be restrictive for the patient. This is not possible when using the program control. (The function of the vertical position of the backrest is necessary to support the action of getting up in the seated position)

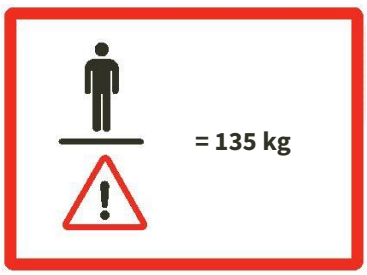
MATERIALS USED

The major part of the bed is made of steel profiles with a coating of polyester powder or a metallic coating of zinc or chromium. The headboards of the bed, the rails of the side guard as well as the spring-loaded bed frame are made of wood or wood composites, whose surfaces have been sealed. All surfaces are dermatologically safe.

Product-specific symbols

Identifies the safe working load including:

- Patient weight
- Mattress and further toppers if necessary
- The devices mounted on the bed, or those attached to the brackets on the bed



Indicates the maximum permissible patient weight

Areas labelled this way should not be trodden on

Caution, risk of entrapment

CE We declare under sole responsibility that the product is in conformity with the applicable legislation.

Country of manufacturing

MD Medical Device

SN Serial Number

\# Model Number

UDI: 426055981ROTOFLEXBPEHWD

Disposal Instructions

This nursing bed – as far as it is electrically adjustable - is classified as a commercial electrical device (b2b) conforming to the WEEE Directive 2002/96/EC (Electronic Equipment Act).

Pursuant to the WEEE Directive, replaced electrical components (drives, control devices, manual switches, etc.) of these nursing beds must be treated like electronic waste and be disposed of correctly.

In the case of nursing beds that have been placed on the market after 13/08/2005 (see the information on the rating plate on the right-hand side of the intermediate frame), the operators are statutorily obliged not to deposit their electrical components in municipal collection points for disposal, but to send them directly to the manufacturer. PhysioNova and its service and sales partners take these parts back.

These returns are subject to our general terms and conditions.

Individual batteries that are no longer usable and have been removed must not be added to domestic waste but disposed of correctly in compliance with the Battery Directive.

For all components that are to be disposed of, the operator must ensure that these are not infectious / contaminated.

If the bed is to be scrapped, the plastic and metal components used must be disposed of separately and correctly.

Any existing pneumatic springs are under high pressure! They should be depressurized as per the manufacturer's instructions prior to disposal. This information is available on request from the manufacturers of pneumatic springs.

If you have any questions, contact your local municipalities, waste management companies or our service department.

Environmental Conditions

Noise during adjustment . . . . . max. 50 db (A)

The following environmental conditions must be complied with:

Storage temperature: . . . . . min. +5°C, max. +50°C
At relative humidity: . . . . . min. 50 %, max. 70 %

Operating temperature: . . . . . min. +10°C, max. 40°C
At relative humidity: . . . . . .min. 20 %, max. 90 % non condensing

EC DECLARATION OF CONFORMITY

according to Annex IV of the MDR Directive (2017/745) on medical devices
conformity assessment procedure Class I

PhysioNova GmbH
(Name of manufacturer)
Vacher Str. 43, D-90587 Obermichelbach
(Address)

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

Hospital and nursing bed, standing and mobilization aid
(article name)

RotoFlex, Basic No.: RO — 3001 xxxxx
RotoFlex, Low • RO - 1003xxxxx
RotoFlex, Type E • RO — 1003xxxxx E
RotoFlex, Type P No.: RO- 1003xxxxx P
RotoFlex, Type H RO - 1003xxxxx H
(Type) xxxxxx serial number

the standards

DIN EN 60601-1 DIN EN 60601-1-2
DIN EN 60601-2-52 and BfArM specifications
and thus meets the basic requirements of the MDR (2017/745), Annex IV.

Obermichelbach, September 24, 2024

Matthias Boeck (Dipl.- Kfm. Ing. Ing. Ing.)

PhysioNova GmbH
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D-90587 Obermichelbach
Telefon: +49(0)911 9772480
Fax: +49(0)911 97724811
Email: info@physionova.de

(Managing Director)

This declaration does not guarantee any properties.
The safety instructions in the corresponding product documentation must be observed.

If the product is used for purposes other than those intended and if changes are made to it that have not been agreed with the manufacturer, this declaration loses its validity.

Notes

Please note: A serious incident is defined as an even that could directly or indirectly lead to a serious deterioration in health, death or a serious hazard.

If such an incident occurs in connection with this product, please immediately report it to the manufacturer **PhysioNovaGmbH, Vacher Str. 43, 90587 Obermichelbach, Germany / Telephone: + 49 911 9772480 / Email: info@physionova.de** and the competent national authority, the BfArM using the following link:

htttps://www.brarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/Vorkommnis-melden/_node.html

This notification helps to identify potential risks for patients, users and third parties at an early stage and to initiate appropriate measures. Further information on the reporting obligation can be found in the applicable regulatory provisions of the MDR (Regulation (EU) 2017/745).

The **RotoFlex®** has been used in hospitals, nursing homes, rehabilitation centers and in households for more than 20 years. The exceptional functionality of the **RotoFlex®** sets new standards in the field of nursing beds, making nursing tasks less stressful for the staff and therefore helps to contribute to the required quality of care.

You have a question or wish to buy a product?

We can be contacted at the number **+49 (0) 911 / 977 248 – 0** from Monday to Friday between 8:00 and 17:00; our fax number is **+49 (0) 911 / 977 248 – 11**. Even outside the business hours you can find information on products, accessories and the background of PhysioNova GmbH by visiting our website at **www.physionova.de**. Alternatively you can get in touch with using the contact form of the website or send an e-mail to **info@physionova.de**.

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PhysioNova
Health Care Systems