

User Manual

Surgeon chair Carl Mk2 and Carl 4 Foot/Heel

- Model R5 – Easy
- Model R6 – Rilis
- Model R7 – OneGrip
- Model R8 – FlexiDoc (Carl Mk2)



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1. Surgeon chair Carl

Thank you for choosing the Rini Surgeon chair Carl.

- Carl Mk2 with extra accessibility for feet and pedals through uniquely designed chassis with three wheels or Carl 4 Foot/Heel with four wheels
- Ergonomic comfort for the surgeon through an intuitive setup and with either "Easy" armrest (R5), the patented safety armrest "Rilis" (R6), "OneGrip" armrest (R7) or "FlexiDoc" armrest (R8 only available for Carl Mk2)
- Convenient to move thanks to easy-rolling wheels and a stable parking position by an electric or mechanical brake
- Easy to clean with smooth surfaces and encapsulated details

Carl Mk2 and Carl 4 Foot/Heel is the second generation of Rini's popular electrically adjustable surgeon chairs where lots of user feedback and new technologies have been combined. The goal has been to provide a quality chair with a small footprint, maximizing the area around the feet often where pedals and other product are placed.

At the same time for the surgeon, Carl chairs and armrests offers maximum ergonomic comfort by extensive configuration options achieved using intuitive hand grips. The model R5 is supplied armrest "Easy" where the armrest plate can be angled 360°. The model R6 is supplied with Rini's patented safety armrest "Rilis" that can be adjusted with high precision to the desired position. The model R7 is equipped with "OneGrip" armrest, popular when small adjustments are required. The model R8 is equipped with "FlexiDoc" armrest for the most demanding procedures.

The Carl surgeon's chair is easy to raise and lower electrically with pushbuttons and has a stable parking position through an electric or mechanical brake on the rear wheels. A cover is supplied to protect the wheels frame. Overall, Carl chairs gives the surgeon a tailor-made work environment of the highest quality.

Rini is constantly improving existing products and developing new ones. Consequently, we value the professional user's point of view; so, don't hesitate to let us know your opinion about any of our product lines.

2. Important – Before Use



To ensure patient safety and the lifespan of the product, it is important to observe the following instructions before use. Please read this manual carefully and understand how to use the product before you start.

2.1 Unpacking

Before the product is unpacked make sure that the packaging has not been damaged during transport. If so, document these with a picture and report this immediately to the transport company and your local Rini representative.

In the packages the chair is normally in the following parts:

- Complete chair with wheels and seat mounted
- Backrest and two armrests
- Battery charger and user manual



Be careful when lifting the chair off the pallet. The chair is heavy and may cause injury. Do not use sharp tools when removing the packaging material. This may cause damage.

Make sure that the delivery includes all ordered parts. Contact your Rini sales representative if you find any discrepancies.

2.2 Installation

When you get the surgeon chair delivered, it is not ready to be used. It must be mounted accordingly to this manual.

Place the chair on a firm surface and mount the backrest and armrests. The transport lock for the lifting column is normally activated and is removed by holding down the "Down" button (different placement of buttons depending on the model) for about 5 seconds and releasing it before the "beep" ceases.





For safety reasons including both person and product it is necessary to have sufficient training in using the product. Before use, please check the following:

- That the product has not been damaged in transport.
- That adjustment of back, seat, height and armrest can be done according to this manual
- That the brake is working
- That the battery is fully charged

Please contact your local Rini representative if you have any questions or concerns.

2.3 Intended areas of use

The surgeon chair Carl is developed for different types of microsurgeries where the surgeon needs a stable seated work position with flexible relief for the arms.

The design of Carl chair gives great freedom of movement to the surgeon while the chair provides space for other product at the feet.

Intended uses include:

- Neurosurgery
- Eye Surgery
- Ear, nose and throat surgery
- Facial Plastic Surgery
- Robotic Surgery
- Dental Surgery



The chair is intended for indoor use and on floors with hard floor standard. The chair may not be equipped with other accessories or components than those authorized by Rini Ergoteknik AB. Repairs and other technical measures should only be performed by personnel authorized by Rini Ergoteknik AB. The chair may only be used for the purposes specified in this manual. Any other use may pose a risk to the user.



The chair should not be used for surgeons that weigh more than 150kg. The wheels must be locked with the electric brake during surgery. When transporting the chair, it should be empty and in its lowest position. The chair is not designed for person transports.



The Carl Mk2 chair with 3 wheels has an increased risk of tipping when leaning sideways in higher chair positions.

3. Product classification and key data

The product is designed for use in hospitals, specialist clinics or similar care environments by professional staff. The product's risk class in accordance with MDR 2017/745 Annex VIII is "Class 1". Previous generations and similar products are also within risk class "Class 1". The product's device class according to the US FDA is "Class 1" and exempt from premarket notification 510(k) requirements.



The product is traceable via serial number and Rini has a "Post-market surveillance" system integrated within its quality system that is certified according to ISO13485 for medical devices. Any incidents are reported to the relevant authorities in accordance with applicable laws.

The product has been tested against applicable standards in terms of "General safety and performance requirements", "Demonstration of conformity" and is covered by a "Risk Management" process in accordance with ISO14971.

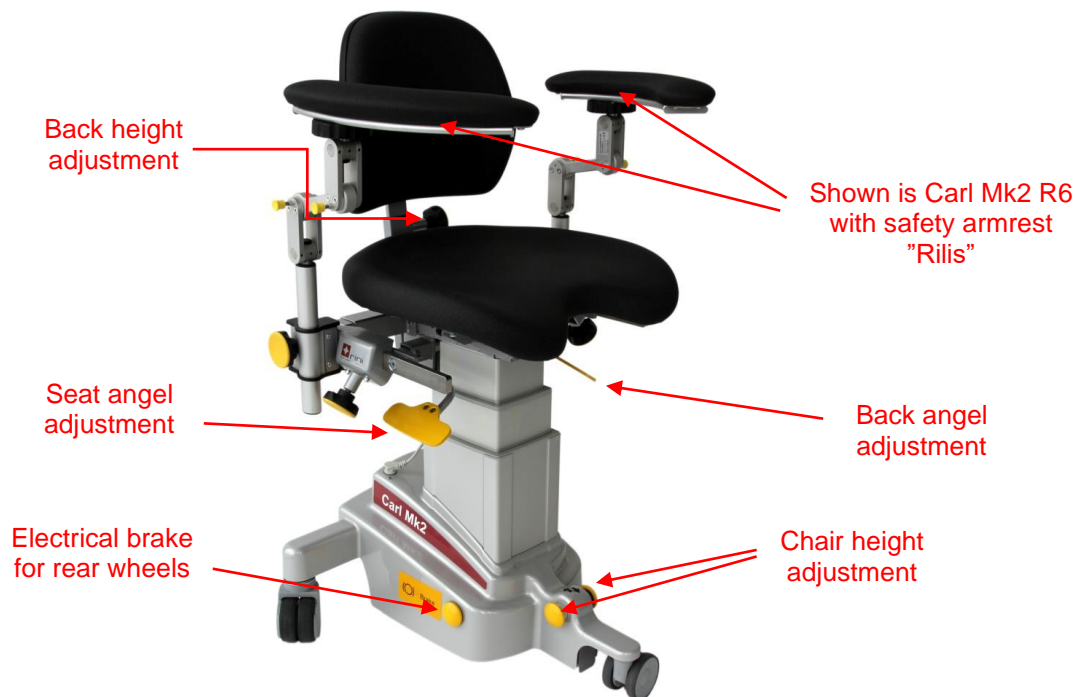
Technical specification can be found in a separate chapter in this manual. Information about the manufacturer and where and when the product was manufactured appears on the type plate below. For questions about this product, specify the UDI and SN for identification.



Label Description

	Warning. Risk is present. Read the applicable information in the user manual.
	Type B product with protection against electric shock.
SWL	Safe Work Load. The product must not be loaded with more than the specified weight.
IPX4	The product is protected from splash of water.
Duty cycle	Average ratio between operating time and idle time of the electrical lifting mechanism.

4. Basic adjustments of the chair



Carl Mk2 (upper picture) and Carl 4 Foot (lower picture) has intuitive controls and buttons to adjust the chair to an effective and ergonomic working indicated in yellow.

4.1 Chassis, wheels and brake

The chassis design with 3 wheels (Carl Mk2) combines stability with high availability of technical equipment such as pedals on the floor around the chair. The chair can also be equipped with a separate pedal stand as an accessory. Large high-quality ball bearing wheels facilitate movement and the rear wheels are lockable with an electric brake that is controlled by an alternating on / off button. When the brake is used, an audible signal sound.

The chassis design with 4 wheels (Carl 4) is extra stable and suits users who have less technical equipment on the floor near the chair. The Carl 4 chair is also equipped with large, high-quality ball bearing wheels to facilitate movement and has an easy mechanical brake as standard.



Always activate the brake during surgery to prevent accidental movement of the chair. When the seat is in a high position and used with high load, the chair can overbalance.

4.2 Chair height adjustment

The seat is raised and lowered electrically where the construction consists lifting column, control box and a battery pack. Seat height for Carl Mk2 is controlled by two buttons on the sides of the front wheel, Carl 4 Heel is controlled by pressing with heels on buttons between the front wheels and Carl 4 Foot by buttons on top of the front wheels.



The chair shall not be used by persons weighing over 150kg.

4.3 Seat angle adjustment

The chair is equipped with a lever on the right-hand side to adjust the seat angle between -15° and $+5^{\circ}$.



Adjust the seat to a comfortable position by lifting the lever which then locks in this position when it is dropped.

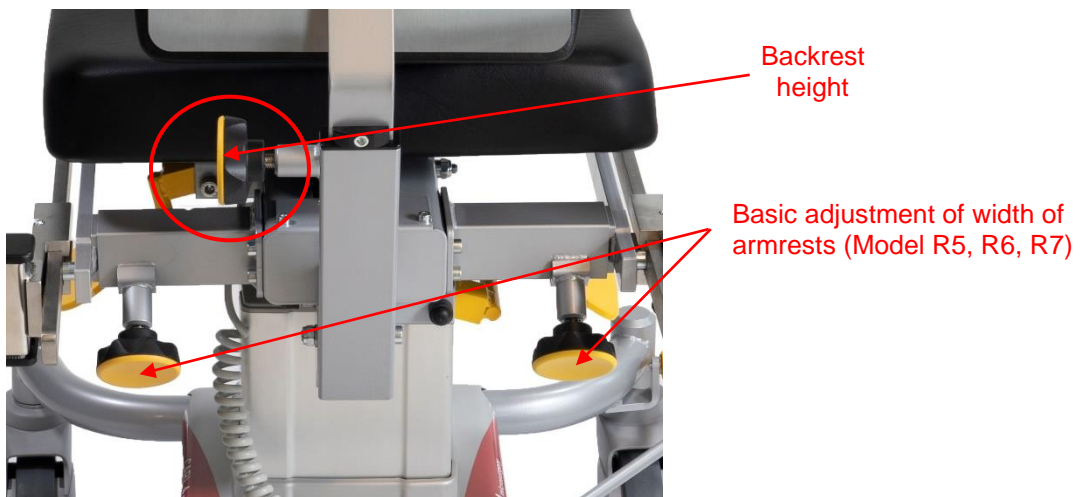
4.4 Backrest angle and height adjustment

The chair is equipped with a lever on the left side to adjust the backrest angle between -15° and $+20^{\circ}$.



Adjust the backrest to a comfortable position by lifting the lever which then locks in this position when it is dropped.

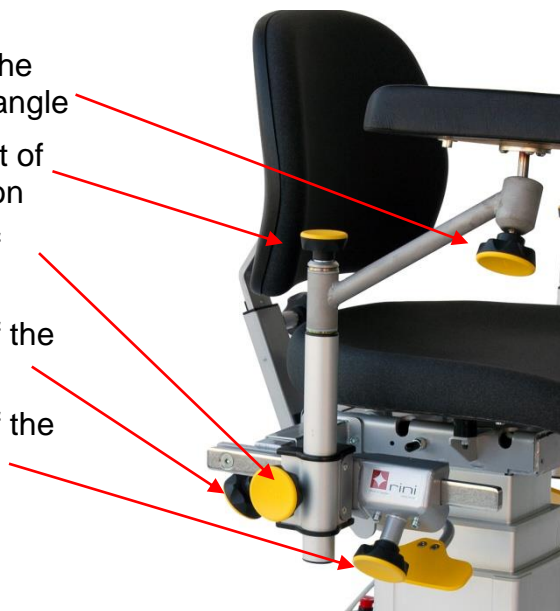
The backrest height adjustment device is placed on the back of the chair. Adjust the height by loosening the knob and lock a suitable position by tightening it again.



4.5 Model R5 - "Easy" armrest

Rinis "Easy" armrest have square cup shaped plates that are able to be set in all possible angles.

5. Knob for adjusting the armrest plate in 360° angle
4. Knob for adjustment of sideways position/friction
3. Basic adjustment of armrest height
2. Basic adjustment of the armrest width
1. Basic adjustment of the back/forward position



Setting 1 (Basic setting)

Move the position of the armrest by loosening the knob and sliding the armrests.

Setting 2 (Basic setting)

The width between the armrests can be adjusted by loosening the knob under the seat.

Setting 3 (Basic setting)

The height of the entire armrest can be adjusted so it is in the center of the work area for subsequent fine tuning. Use the knob to set the appropriate armrest height.

Setting 4

Turn knob to adjust the sideways position as well as the friction of the armrest.

Setting 5

Turn the knob to release and then set the armrest in the desired position and lock.



The armrest should not be loaded with more than 8 kg

4.6 Model R6 - "Rilis" safety armrest

Rinis patented safety armrest Rilis has the most extensive adjustment possibilities to offer an optimal ergonomic working position.

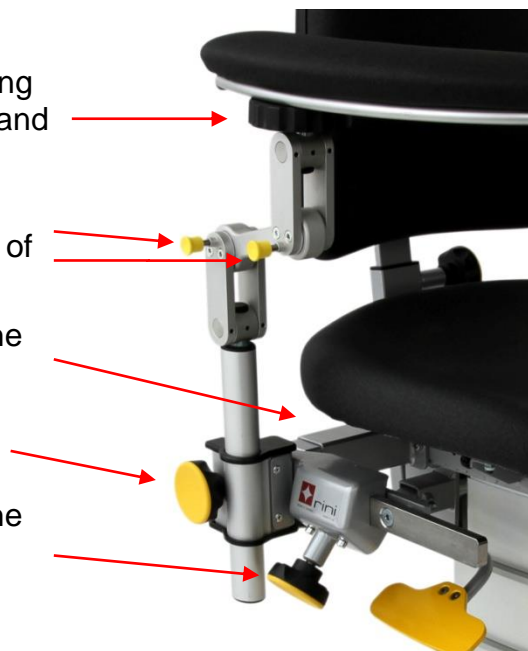
5. Lock wheel for adjusting the armrest longitudinal and lateral

4. Push buttons (without load) for fine adjustment of height and position

3. Basic adjustment of the armrest width

2. Basic adjustment of armrest height

1. Basic adjustment of the position



Setting 1 (Basic setting)

Move the position of the armrest by loosening the knob and sliding the armrests.

Setting 2 (Basic setting)

The height of the entire armrest can be adjusted so it is in the center of the work area for subsequent fine tuning. Use the knob to set the appropriate armrest height.

Setting 3 (Basic setting)

The width between the armrests can be adjusted by loosening the knob under the seat.

Setting 4

By pressing the buttons, the armrest can be adjusted for an optimal working position. To release the armrest, you need to use two hands for safety reasons. One hand to move the armrest pad up and down, while the other hand push the button. Set the armrest in the desired position and release the button to lock the position. **Note! that the adjustment of the armrest should be without load.**

Setting 5

The armrest plate is curved and loosen the black locking wheel to position the armrest. Tighten when the correct position is found. The armrest can also rotate around the black locking wheel, allowing maximum flexibility and ergonomic relief. It also helps the surgeon to be seated or get up from the chair and still be able to maintain sterile hands by using the elbows to rotate the armrests.



The Rilis armrest should not be loaded with more than 15 kg.

4.7 Model R7 - "OneGrip" armrest

The OneGrip is suitable when an up/down adjustment range is needed, and it is required to be able to adjust the armrest while draped.

5. Lever for fine adjustment of the armrest up/down

4. Knob for adjustment of sideways position/friction

3. Basic adjustment of the armrest width

2. Basic adjustment of armrest height

1. Basic adjustment of the back/forward position



Setting 1 (Basic setting)

Move the position of the armrest by loosening the knob and sliding the armrests.

Setting 2 (Basic setting)

The height of the entire armrest can be adjusted so it is in the center of the work area for subsequent fine tuning. Use the knob to set the appropriate armrest height.

Setting 3 (Basic setting)

The width between the armrests can be adjusted by loosening the knob under the seat.

Setting 4

Turn knob to adjust the sideways position as well as the friction of the armrest.

Setting 5

By pulling the lever upwards, the armrest can be adjusted to an optimal working position. Set the armrest in the desired position and release the lever to lock the position.



The armrest should not be loaded with more than 10 kg.

4.8 Model R8 - "FlexiDoc" armrest (Carl Mk2)

The model R8 is equipped with the patented "FlexiDoc" armrest for the most demanding procedures where fine tuning of the armrest is continuously needed during surgical procedure.

2. Levers for fine adjustment of the armrest position

1. Basic adjustment of the back/forward position



Setting 1 (Basic setting)

Move the position of the armrest by loosening the knob and sliding the armrests.

Setting 2

The height and length of the entire armrest can be adjusted in a flexible way using the lever.



The armrest should not be loaded with more than 20 kg.

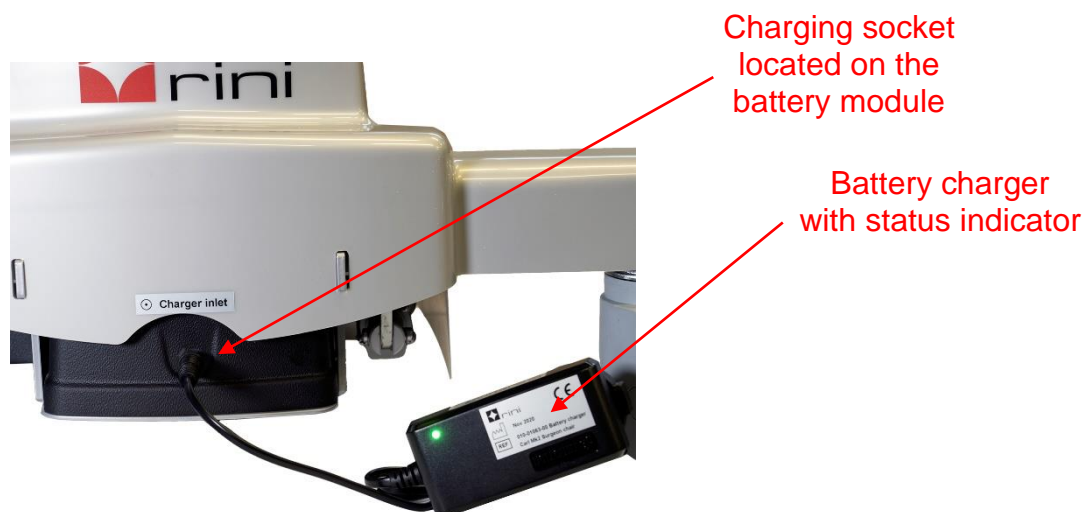
5. Battery operation and charging

The Carl chair is battery-powered and starts as soon as the "Up/Down button" or "Brake button" is activated. Under normal working conditions, a fully charged battery lasts up to 3 months. When the battery level is below 20%, it is indicated during operation with a beep sound.



The Carl chair has an associated battery charger that handles 100-240V mains voltage. The charging socket is located on the back of the chair and the status is indicated on the battery charger (see below).

Regular charging of the battery is recommended as full discharge reduces the life of the battery. Recharge the battery every month, but at least every three months to avoid damage to the battery that otherwise occurs through self-discharge.

A new or fully discharged battery must be charged for 24 hours. When the battery is fully charged, the charge automatically switches to maintenance charging to avoid overcharging.



The indicator on the battery charger shows the following

Status - when connected	Indicator
Battery is charging	
Battery is fully charged	

Batteries have a limited life span, and the battery module must be replaced under normal working conditions after about four years. Year of manufacture and month can be found on the battery's nameplate. If the operating time is greatly reduced despite 24 hours of charging, the battery module must be replaced. At low battery level it is possible to use the chair with the charger connected but it is not recommended. A new battery module is ordered from Rini and is easy to replace.



Only the dedicated charger for Carl chair must be used.

6. Disinfection, cleaning and repairs

No part of the product is normally in contact with the patient and the armrests are normally draped during surgery.

Disinfection

Part	Product	Other information
Upholstery and armrests	Virkon (including most disinfectants without alcohol).	1% concentration. (Disinfectants containing alcohol cannot be used due possible to dehydration)
Chassis and buttons	Noedischer Dekonta CCOTRADE RW	1-3% concentration 0,5% concentration

Cleaning

Part	Product	Other information
Upholstery and armrests	Water and soap	Use damp cloth
Chassis and buttons	Water and soap	Use damp cloth
Battery charger	Water	Use damp cloth

Repairs

The product should only be repaired by Rini or a Rini authorised service centre. Product to be repaired under warranty must be sent to Rini factory or an authorised Rini service centre.



Unauthorized repairs and modifications may result in loss of function and void warranty.

7. Safety

The product should only be used as intended otherwise it can cause injury to persons or product. Read this manual before the product is put into service. Necessary knowledge of the product is required before clinical use and this manual should always be available when using the product. No accessories other than those mentioned in this manual may be used. Please note the warning signs on the product.



Warning signs are used when there is a risk for patients, staff or product.

7.1 CE Declaration of conformance



Surgeon chair 120-001xx-xx follows EU Medical Device Regulation 2017/745 for medical products.

Tested according to EN/IEC 60601-1.

8. Technical data

General	
Weight base unit	Carl Mk2 43kg/95lb and Carl 4 45kg/99lb
Length (chassis)	Carl Mk2 560mm and Carl 4 530mm
Width (chassis)	Carl Mk2 550mm and Carl 4 520mm
Medical classification Standard	Class 1 Type B EN/IEC 60601
Protective class	IPX4
Battery	24V 2Ah rechargeable lead acid
Charger	100 - 240V
Cushions	Medical classified material - black colour (standard) or other colours as options
Operator data	
Lifting capacity	150kg / 331lbs (max weight surgeon)
Height adjustment	490 - 800mm - foot control by buttons on the side
Back support	
Type	Standard H 350mm x B 300mm - other types as options
Inclination and height	Angle -15° till +20° Height 200-300mm from seat
Seat	
Type	Standard L 420mm x B 460mm - other types available as options
Inclination	Angle +5° till -15°
Armrest	
Type	Model R5 - Easy Model R6 - Rilis safety armrest Model R7 - OneGrip Model R8 - FlexiDoc (Carl Mk2)
Brake	
Type	Carl Mk2 electric and Carl 4 mechanic on back wheels
Operational environment	
Temperature	+5°C to +40°C
Relative humidity	20% to 90% at 30°C
Atmospheric pressure	700 to 1060hPa
Transport and storage	
Temperature	-10°C to +50°C
Relative humidity	20% to 90% at 30°C
Atmospheric pressure	700 to 1060hPa

9. Disposal and recycling

The product is mainly made from environmentally recyclable materials as steel, stainless steel, aluminum and plastics. Rini recommends that the material be sorted and recycled in connection with the destruction of the product.



Electronic parts and cables shall be handled as electronic waste in accordance with local requirements. The battery contains lead and is disposed according to current environmental legislation.

10. Warranty

The warranty is valid one year from the date of purchase. Please contact Rini for further information.

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