Service 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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rini

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1. Introduction

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

Tested according to EN/IEC 60601-1

Tests for basic safety and essential performance have been done according to standard EN/IEC 60601-1

The original version of this manual was written in English.

This service manual contains information necessary for the most common types of repairs, service and update of software. In addition preventive service actions are also described.

The manual provides the qualified and trained staff, who are the only persons granted to service the surgeon chair, with helpful guidance and descriptions necessary for maintenance and troubleshooting.

Before any inspection or repair operation this manual must be read carefully as well as the related functional operation that might be affected as describes in the Carl Mk2 user's guide.

This Service Manual covers the Carl Mk2 Carl 4-wheel (Heel/Foot) surgeon chairs of:

Carl Mk2 product release from serial number 0000-01
Software release from v1.0

Carl Mk2 product release from serial number 0000-02
Software release from v1.0

Carl 4-wheel product release from serial number 0000-09
Software release from v1.0

Carl 4-wheel product release from serial number 0000-10
Software release from v2.1

In you have any questions or suggestions, please contact Rini direct at e-mail: support@rini.se or your local Rini distributor.

2. Warning and lables

The surgeon chair should only be used as it is intended to as describe in the user guide. Improper use and departure from the safety instructions can cause injury to personal or product.

No other accessory than those mentioned in this guide may be used.

Please note warning signs on the product and in the manual

Warning signs are used when there is a risk for person or product.

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.

	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. Safety

Service operation carried out on the Carl surgeon chair can lead to a hazardous situation if the following safety measures are not respected. As these measures are intended to worker safety and injury prevention, it is required to respect them.

Therefore, it is essential to read and understand these warnings before going further into the manual.

Service must be carried out only by a qualified technician, who has received the appropriate training by Rini or an authorized Rini distributor. A non-qualified technician may be exposed mechanical risks and risk of electric shock, which could lead to severe injury or death.

Any other technical intervention on the product or its accessories than authorized by Rini can lead to partial or full cancellation of the warranty.

For service, troubleshooting, repair operations as well as cleaning, the product must be in a parking position.

Never spray any kind of liquid on the electrical modules. No liquid or cleaning agent must get into the system. This would lead to dangerous issues and could damage the product.

Be careful when lifting the product as is heavy and may cause injury. If the product must be put on the side during service actions make sure sufficient padding is used for protection.

5. Preventive service and maintenance

Annual service of the chair is recommended to maintain optimum performance of operational features and maximize personal security.

This involves:

- Safety check and replacement/adjustment of moving mechanical parts and accessories if required.
- Check of cushions quality and damages to avoid bacteria traps.
- Check of electrical equipment, battery status and battery charger.

In the case of service being carried out by a Rini distributor or by technical staff at the end user it is important that a service record with serial number is filled in and sent to the factory.

5.1 Checklist for annual service

a. Inspect the brake function, locking the back double wheels. Adjust or replace if necessary.

b. Lock the wheels, use the up/down controls, and run the chair between its end positions, listen so it is no unusual sounds, in the actuators, column or bearings. If there are strange sounds, identify the source, adjust, or propose package of measures.

c. Run the chair to each of the end positions, inspect the mechanical stop at each end position, adjust if necessary.

d. Run the chair and stop just before each of the end positions, find looseness bearings, replace, or propose action. Inspect the actuators fix to the chassis.

e. Inspect the armrests (R5 "Easy", R6 "Rilis" R6, R7 "OneGrip" armrest or R8 "FlexiDoc" armrest) and adjust them if necessary.

f. Inspect electrical wires with its connections, inspection also include the wires under the hatch. Take care of broken cables or propose replacements.

g. Verify the battery charger function. Find damages like cracks or holes in the battery or charger.

h. Find damages at the cushions like holes or cracks. Also inspect the cushion corner covers, propose replacement if anything is broken.

5.2 Periodic maintenance and check

Monthly	
Armrests	Control function and Rilis push button shafts lubricate with lubrication spray
Battery	Batteries should be recharged at least once a month for continued capacity. Batteries over 5 years old from manufacturing date need to be replaced for full function.

5.3 Spare parts and repairs

The following list is a set of typical spare parts for the Carl Surgeon chair. In the last column it is noted if this spare part is included in one or Rini's spare part kits.

SPK1 – User with single Carl Mk2 and with limited technical skill
SPK2 – User with multiple Carl Mk2 and with good technical skill

Code	Description	Kit
010-00868-00	Control unit with cable lock (Product release -01) 	SPK2
140-00330-00	Control unit (Product release -02) 	SPK2
010-00867-00	Lifting column 	SPK2
010-00872-00	Brake actuator 	SPK2
010-00870-00	Battery charger with power cable for different regions (Product release -01). **Shall not be used, can cause battery damage** 	SPK1
	Battery charger, different type for different regions. 010-01063-00 EU 010-01069-00 UK 010-01069-01 US (Product release -02) 	SPK1
010-00869-00	Battery module (Product release -01) 	SPK1/2
140-00329-00	Battery module (Product release -02) 	SPK1/2
010-00890-00	Back wheel (2 pc/Carl Mk2) 	SPK2
010-00873-00	Front wheel (1 pc/Carl Mk2) 	SPK2
010-00157-00	Snap lock cushion back	
010-00164-00	Cushion back blue	
010-00626-00	Cushion back black	
010-00621-00	Cushion back black soft	
010-00165-00	Cushion seat blue	
010-00627-00	Cushion seat black	

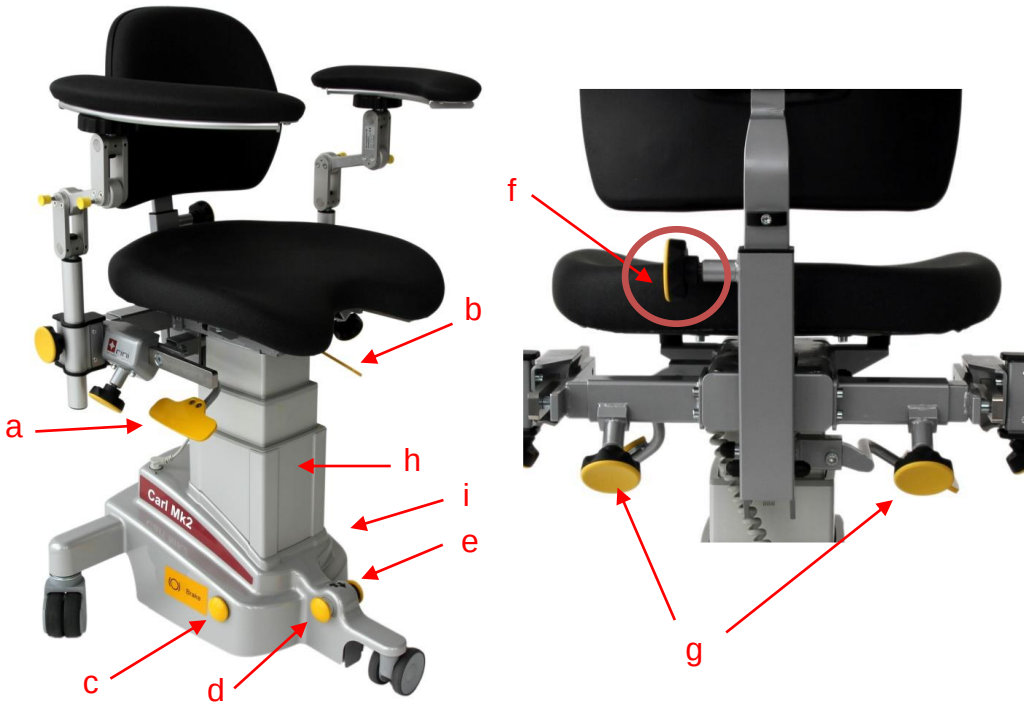
010-00621-00	Cushion seat black soft	
000-00121-00	Armrest pillow blue	
000-00121-02	Armrest pillow black	
000-00121-01	Armrest pillow black soft	

The above list is not complete. Please contact Rini or your local Rini distributor for more detailed information regarding spare parts for your product.

The product should only be repaired by Rini or by Rini authorized service center/engineer. Items under warranty must be sent to a by Rini authorized service center. Unauthorized repairs and modifications may result in loss of function and void warranty.

6. General overview

All models of the Carl Mk2 operation chair have the same chassis and electrical components. The only part that differs are the type of armrests and type of cushion.



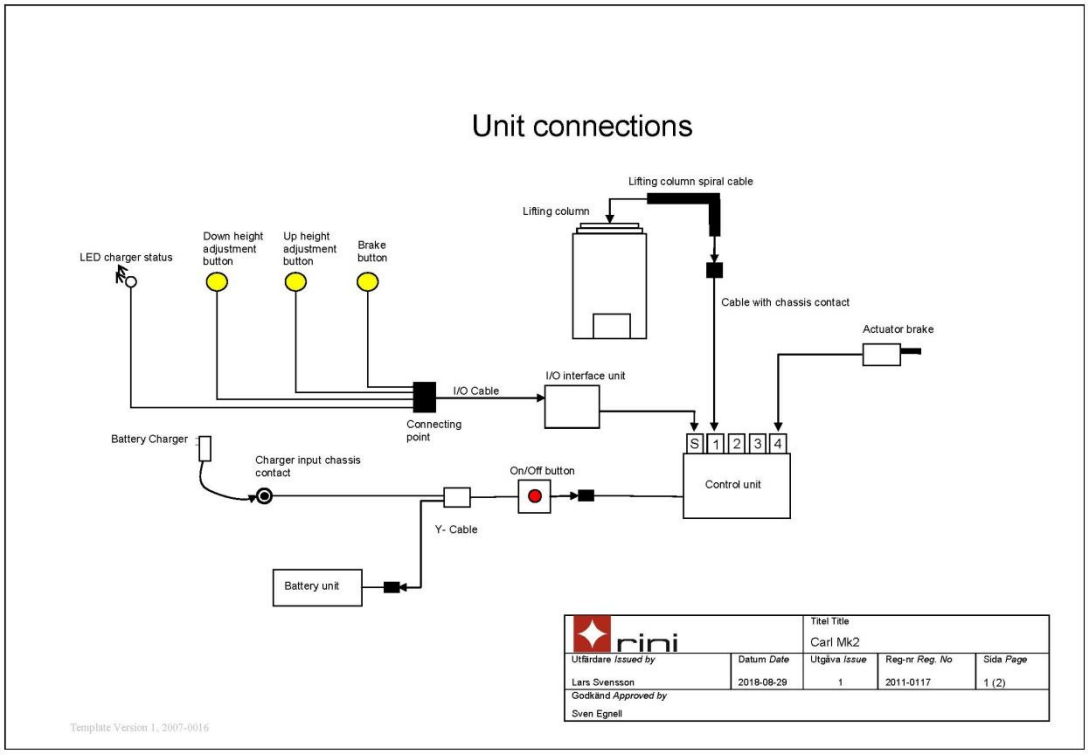
Location of main components of Carl Mk2 (R6)

a) Seat adjusting lever
b) Back rest adjusting lever
c) Brake actuator button
d) Lift actuator button - up
e) Lift actuator button - down
f) Back rest adjustment knob - forward and backwards
g) Width adjustment - inwards and outwards
h) Lifting column - item 010-00867-00

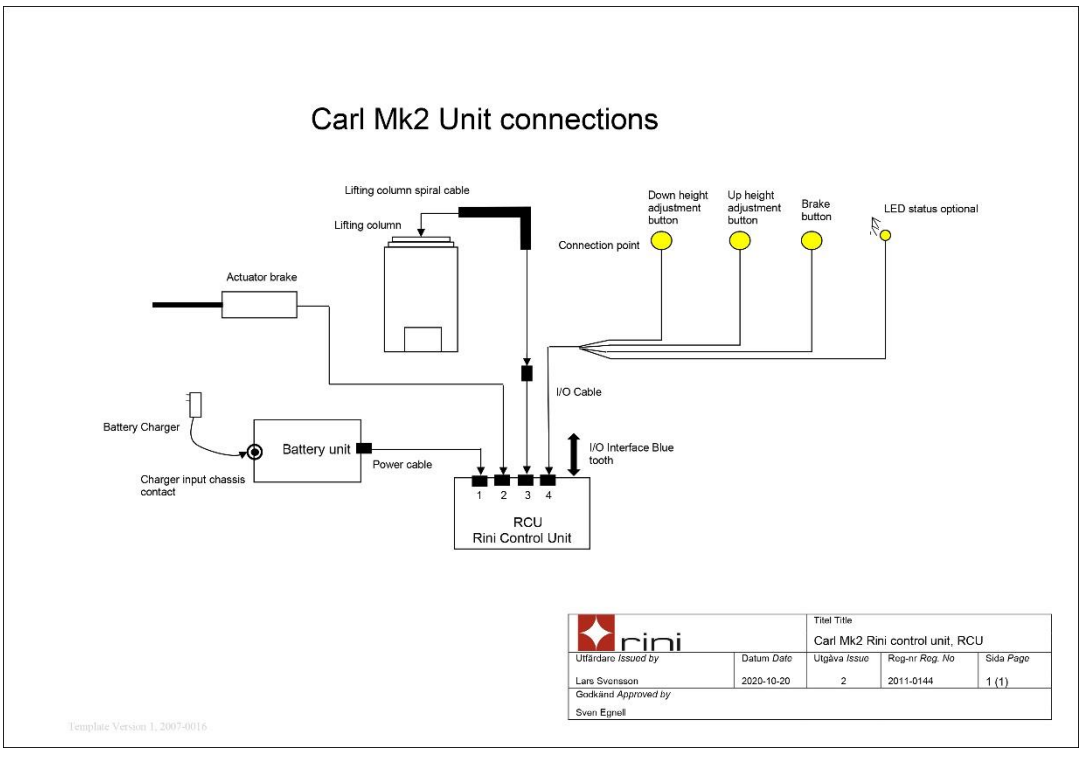
i) Brake actuator under cover - item 010-00872-00

7. Electrical architecture

Product release -01



Product release -02



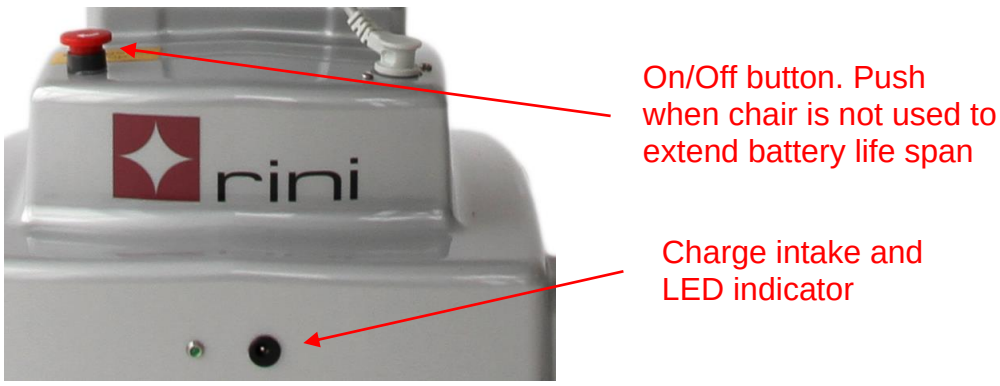
8. Trouble shooting and solutions

8.1 Trouble shooting, Product release -02

Symtoms	Cause	Action
Up/down and brake buttons is not working	User have by mistake activated the transport protection	Carl Mk2 chairs delivered with S/N suffix nnnn-02 or earlier. Activate/deactivate the transport protection by pressing the brake button continuously until a beep sound is heard. Carl chairs S/N with suffix nnnn-03 and later you keep the down button pressed continuously until a beep sound is heard. The button must be released before the beep sound ends.
Pressing up or down button carl moves 1-2 seconds and then stops by a beep sound	Battery needs to be charged. Charger lamp goes from yellow to green after some seconds.	Connect charger and charger lamp shall light yellow 30minutes or longer. The battery is probably broken and need to be replaced.
Pushing up button nothing happens, and a beep sound is heard. Pushing down button Carl moves down	The lifting column motor has lost position tracking.	Press down button until Carl is in its bottom end position, keep press the down button for 2 seconds. Push up button again and check Carl moves up

8.2 Battery status&replacement, Product release -01

Batteries have a limited lifespan and battery module must during normal working conditions be replaced after about four years. A new battery module can be ordered from your local distributor or Rini.



The On/Off button must be “On” during charging and the LED-indicator shows the following status:

Battery status	Green LED-indicator
Battery charging	Lit constantly
Battery OK	Unlit
Battery < 20%	During operation - blinking twice/sec and buzzer sound

The battery module itself also has an indicator showing:

Status	LED indication - color & mode	
Charging State	Green	Continuously short flashing- On (1 sec) / Off (1 sec)
Fully Charged State	Green	Continuously On
High Capacity State	Green	Continuously long flashing- On (0.5 sec) / Off (4 sec)
Low Capacity State	Orange	Continuously long flashing- On (0.5 sec) / Off (4 sec)
Under protection	LED is continuously off	

The chair shall not be used during charging. Only the dedicated charger must be used for the chair.

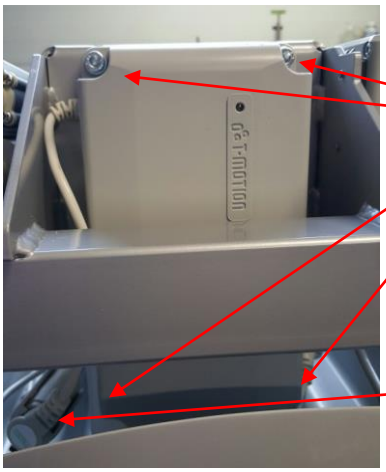
Battery replacement

1. Raise the lifting column approx. 100mm from its lowest position and then press the On/Off button

Remove screw holding cover

2. Tilt the seat so its lean forward.

3. Remove the armrests and backrest.
4. Lift the chair and place it upside down on a table.
5. Remove the screw holding the plastic wheel frame cover, see picture above, slide frame cover down gently.



Two screws holding the battery unit.

Earlier models with suffix -00 in serial number have four screws and the holes in the battery may have to be widen.

Cable lock

6. Open the battery unit cable lock and remove cable.
7. Remove the screws holding the battery unit.
8. Mount the new battery and mount cover.

8.3 Battery status&replacement, Product release -02

The Carl Mk2 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 Mk2 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.

Charging socket located on the battery module

Battery charger with status indicator

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 Mk2 chair must be used.

Battery replacement

1. Raise the lifting column to approx. 100mm from its lowest position and release the cover back and front.

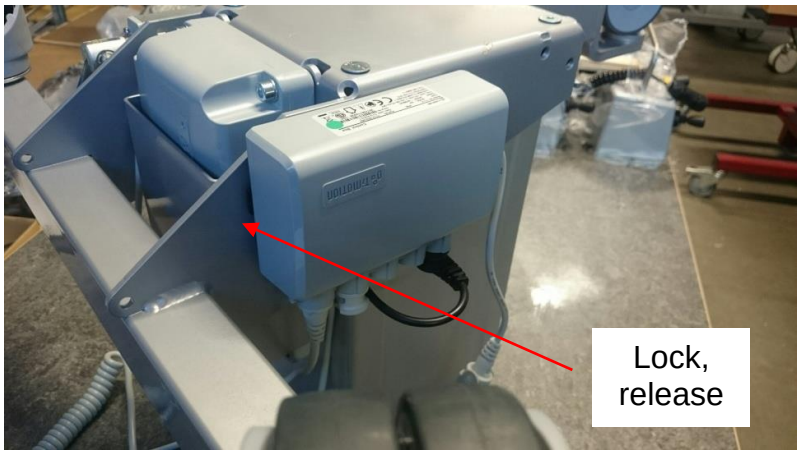
2. Lift the cover from the wheel frame and un-plug the battery module.

3. Replace the battery module with the new one and re-assemble.

8.4 Control unit replacement, Product release -01

The control unit holds the complete software program. A “software update” is performed by replacing the control unit and the software version should be marked on the side of the control unit.

Follow instruction step in previous chapter to remove cover.



1. Remove cable lock and disconnect all cables.
2. Open cable lock on power supply cable and take it apart.

3. Push locker on the attachment plate towards frame and slide control box forward.
4. Slide new control box on attachment plate noting a distinct “click” when at final position.
5. Reconnect all cables and safety lock.
6. Mount cover.

8.5 Control unit replacement, Product release -02

The control unit holds the complete software program. A “software update” is performed by replacing the control unit and the software version should be marked on the side of the control unit.

Follow instruction step in previous chapter to remove cover.

1. Disconnect all cables.
2. Unscrew the control unit
3. Push locker on the attachment plate towards frame and slide control box forward.
4. Mount new control and re-connect all cables
5. Mount cover

8.6 Control unit DIP switch, Product release -02

The red DIP switch impacts some functions for the Carl Mk2 chair.

Software version 2.1 and newer:

DIP 6: Off = Brake button activating peep sound off

On = Brake button activating peep sound On

Software version 2.2 and newer:

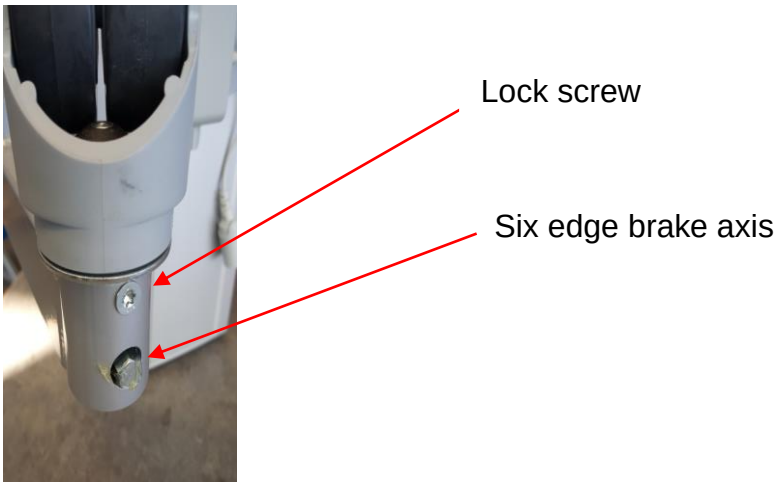
DIP 4: Off = No brake button activation delay

On = Brake button activation delay 2sec

8.6 Wheels replacement

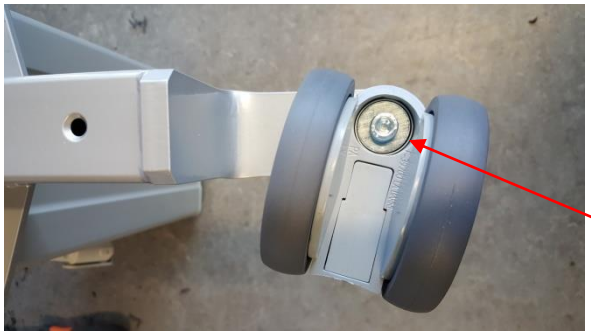
Follow instruction step in previous chapter to remove cover either for Product release -01 or -02.

1. To replace back wheels, Open the brake lever lock screw with an Alan key, Due to the small dimension of the lock screw it is important to get a firm grip and turn counterclockwise. The pictures show product release -01. In Product release -02, the lock screw is located more convenient from the back.



2. Remove the wheel lock screw, see above.

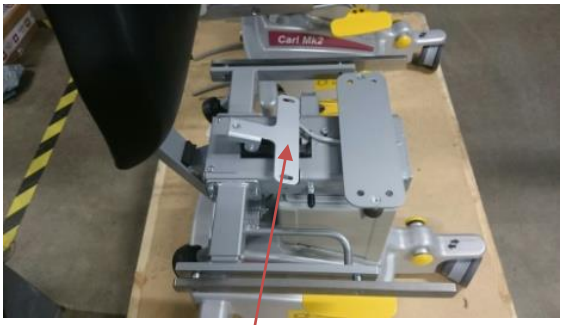
3. Press in and slide out the six edge brake axis, approximately 10cm seen from opposite side so the wheel is not blocked. Remove the broken wheel by pulling it out of the wheel frame.
4. Mount the new back wheel and assemble Carl Mk2 chair again.



Lock screw

1. Remove the front wheel lock screw, see picture above
2. Remove the broken wheel by pulling it out of the bracket
3. Mount the new front wheel and assemble Carl Mk2 chair again

8.8 Lifting column replacement



Adapter plate

Bolts holding top module

1. Tilt seat cushion slightly forward and remove it. Do not operate the seat/back rest adjusting levers until seat cushion is reinstalled.
2. Remove adapter plate (two countersunk screws).
3. Detach power cable at the top of column and at frame cover.
4. Unscrew four bolts holding the top module. Support the top module, as it now will become unstable.
5. Lift off top module carefully paying attention on the power cable and place it on a soft surface.

Bolts holding the lifting column

Place the wheel frame module upside down on a table and unscrew four bolts holding the bottom of lifting column.

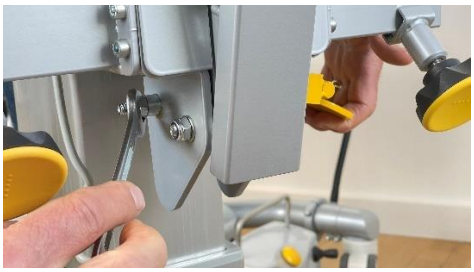
6. Gently lift the wheel frame up from the lifting column.

To reinstall lifting column reverse step 1 - 7.

8.9 Backrest and seat angle adjustment

If the backrest or seat is tilting without using the lever, you need to tighten the bolt on the opposite side of the lever, remove the plastic cover and use a 13 mm wrench to tighten it.

Backrest adjustment



Seat adjustment

8.10 Model R5 - "Easy" armrest service

Please contact a Rini or a Rini authorized service provider.

8.11 Model R6 - "Rilis" safety armrest service

Please contact a Rini or a Rini authorized service provider.

8.12 Model R7 - "OneGrip" armrest service

Please contact a Rini or a Rini authorized service provider.

8.13 Model R8 - "FlexiDoc" armrest service

Please contact a Rini or a Rini authorized service provider.

9. Cleaning and Maintenance

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

Recommended disinfectants

Part	Product	Other information
Seating and other parts of art leather or nylon.	Virkon (including most disinfectants without alcohol).	1% concentration. (Disinfectants containing alcohol cannot be used due possible to dehydration of the leather.)
Foot control and other electronic parts.	Noedischer Dekonta CCOTRADE RW (Including most disinfectants).	1-3% concentration 0,5% concentration

Recommended cleaning agents

Part	Product	Other information
Padding, wheels and frame **Parts of metal and lacquered surfaces**	Water and soap	Use damp cloth
Electronic parts, hand control, control box and battery.	Water	Use damp cloth
Battery charger	Water	Use damp cloth

Periodic maintenance

Monthly	
Hinges and joints	Use non-corrosive, standard instrument spray.
Armrest locking system	Use non-corrosive, standard lubrication spray.

Accessories

Please contact your local distributor or Rini for information about accessories available for your equipment.

10. Technical data

10.1 Specification

General	
Weight base unit	40kg / 88lbs
Length (chassis)	560mm
Width (chassis)	560mm
Medical classification Standard Protective class Battery Charger	Class 1 Type B EN/IEC 60601 IPX4 24V 2Ah rechargeable lead acid 100 - 240V
Cushions	Medical classified material - black colour (standard) or other colours as options
Operator data	
Lifting capacity	150kg / 331lbs (max weight operator)
Height adjustment	490 - 800mm - foot control by buttons on the side
Back support	
Type	Standard H 250mm x B 280mm - other types as options
Inclination and height	Angle -15º till +20º Height 200-300mm from seat
Seat	
Type	Standard L 420mm x B 460mm - other types available as options
Inclination	Angle +5º till -15º
Armrest	
Type	Model R5 - Easy Model R6 - Rilis safety armrest Model R7 - OneGrip Model R8 - FlexiDoc
Brake	
Type	Electric with on-button control for back wheels
Operational environment	
Temperature	+5ºC to +40ºC
Relative humidity	20% to 90% at 30ºC
Atmospheric pressure	700 to 1060hPa

Transportation and storage conditions

Transport condition **Temperature** **Relative humidity** **Atmospheric pressure**	 -10ºC to +50ºC 20% to 90% at 30ºC 700 to 1060hPa
Storage condition **Temperature** **Relative humidity** **Atmospheric pressure**	 -10ºC to +50ºC 20% to 90% at 30ºC 700 to 1060hPa

10.2 Electromagnetic emission and immunity.

Medical electrical equipment is subject to special safety precautions regarding EMC requirements and must be installed and put into service in accordance to the following EMC information.

The aim is that the operating table not accidentally moves subjected to surrounding electromagnetic interference.

Guidance and manufacturer's declaration – electromagnetic emissions		
Carl Mk2 is intended to be used in the electromagnetic environment specified below. The customer or the user must assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Carl Mk2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Carl Mk2 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
Carl Mk2 is intended to be used in the electromagnetic environment specified below. The customer or the user must assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material then RH should be > 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV Line to Line	+/- 1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T)) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T)) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Equipment requires continued operation during power mains interruptions, it is recommended that the Equipment be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment
Note: U_T is the AC mains voltage prior to application of the test level			
			Portable and mobile RF communications equipment should be used no closer to any part including cables than the separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Separation distance $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [1)] should be less than the compliance level in each frequency range [2)].

Interference may occur in the vicinity of equipment marked with the following symbol.

These guidelines may not apply in all situations as electromagnetic propagation is affected by absorption and reflected from structures objects and people.

[1] Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location used exceeds the applicable RF compliance level above the Carl Mk2 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary.
[2] Over the frequency range 150 kHz to 80 MHz field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Carl Mk2

Carl Mk2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Carl Mk2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Carl Mk2 as recommended below, according to the maximum output power of the communications equipment.

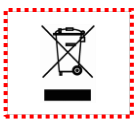
Rated maximum output power of transmitter W	**Separation distance acc to frequency of transmitter (meters)**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Transmitters rated at a maximum output power not listed above the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Portable and mobile RF equipment can effect Medical Electrical equipment.

11. 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.

12. Warranty

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

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