User manual

Operating table RiEye Mk2S

- **Model R5 100-00105-05**
- **Model R6 100-00105-06**
- **Model R7 100-00105-07**

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rini

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1. Introduction - operating table RiEye Mk2S

Thank you for choosing Rini's Operating table for microsurgery.

RiEye Mk2S with modern attractive design is developed functionally and ergonomically in close collaboration with several leading Swedish and international clinics. The table has a wide area of applications in both "stationary mode" procedures or in "mobile roll-in roll-out" procedures.

Great care has been put into the design of the table and its accessories to improve the freedom of movement for both the surgeon and assisting personnel in the vicinity of the patient's head. The headrest is easy to adjust and has a unique ergonomic design that makes it comfortable for the patient while at the same time provides for high accessibility.

Thanks to smooth surfaces and smart seams as well as cushions that are easy to remove, the table is easy to keep clean and hygienic.

RiEye Mk2S is battery-powered, and the settings are easily adjustably with both the hand and optional foot control. Customized positions can also be pre-programmed. The table is raised and lowered by two electrically driven telescopic columns.

The table is also equipped with an electric "Trendelenburg" feature that is activated by a button on the hand control.

The minimum height is 500mm, allowing for easy boarding and exit for the patient, and the maximum height ensures good ergonomic working positions for the surgeon and assisting personnel.

Accessory rails are fitted on each side of the back cushion enabling mounting of various optional accessories from Rini or a third-party supplier.

The four large wheels, that are equipped with heavy duty ball bearings, are all steerable for easy manoeuvring and, the table can be placed to reach the correct working position even when there is limited space.

The chassis is painted with durable powder coating and important parts are covered with protective caps that makes the table easy to clean. The table has a new type of wheel suspension and will stand steady, including on uneven floors due to the unique adaptive chassis.

An ergonomically placed central break can lock all four wheels simultaneously in operating mode. If moved it can also move sideways thanks to wheels that easily rotate.

The hand control has an intuitive layout where back- leg- and seat cushion as well as height can be set individually. Special quick buttons are available for "Trendelenburg" and zero level positions as well as the possibility to pre-program user settings.

RiEye Mk2S is based on a base platform and is available in three models that can be equipped with most of the available accessories making it possible to customize the table for different mobile and stationary procedures.

Model R5 Width 580mm/23in and leg rest 400mm/16in. Suitable when physical space in the clinic is limited or the requirement is that the table should be possible to fold the table as a chair. Accessories shown: Holder hand control and width extension.

Model R6 Width 580mm/23in and leg rest 500mm/20in. This model offers a good compromise between mobility and patient comfort. Accessories shown: Holder hand control, width extension, bracket for oxygen tank, collapsible siderail, driving handles back and foot control.

Model R7 Width 580mm/ 23in and Leg rest 700mm/28in. For longer treatments and anesthesia surgery this model is best suited. Accessories shown: Holder hand control, width extension, driving handles, foot control, collapsible side rails, drape support and electrical headrest.

2. Unpacking

To ensure patient safety and the life span 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.

Before you unpack check the packaging. Report any damage immediately to the transport company and your local Rini representative. Remove the top of the pallet and take out any non-installed accessories that are packed separately

Do not use sharp tools when removing the packaging material. This can cause damage.

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

Be careful when lifting the table off the pallet. The table is heavy and may cause injury.

Before using the product, please check the following:

- All cables are connected as described in this manual

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

3. Important – Before use

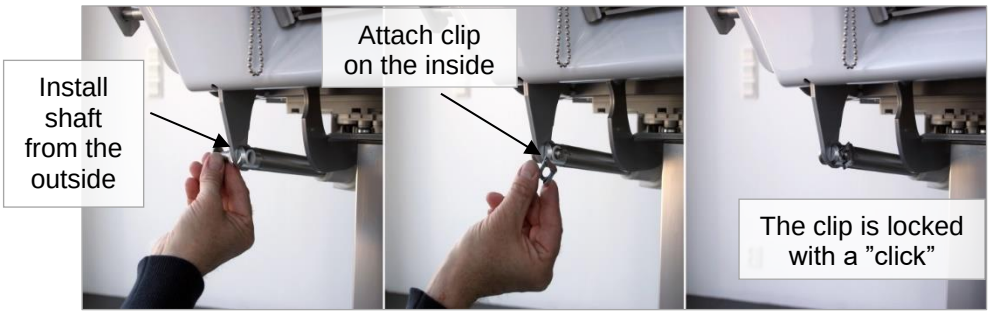
To reduce packing size and cost of shipping the only part that may need to be configured is the back rest and mounting of cushions.

If accessories are separately included in the package they must be assembled as described in this manual or as directed by Rini or your local Rini representative.

All electrical connections are pre-wired and ready to use. Check that the battery is charged and connected and also make sure that the emergency stop is deactivated.

Mounting of backrest actuator

Fold the backrest in a position so that it is possible to mount the bolt with the included locking mechanism.



Mounting of cushions

The cushions have a quick locking mechanism that allows easy mounting and removal. Make sure when mounting that the material between the cushions is placed as shown in the pictures so it does not get stuck.

Before use for maximum safety of persons and product:

Read through this manual or make sure you have received the required training to handle this product.

Understand where the emergency stop is located and how to use it. Understand how the "Trendelenburg" position is activated.

4. 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.

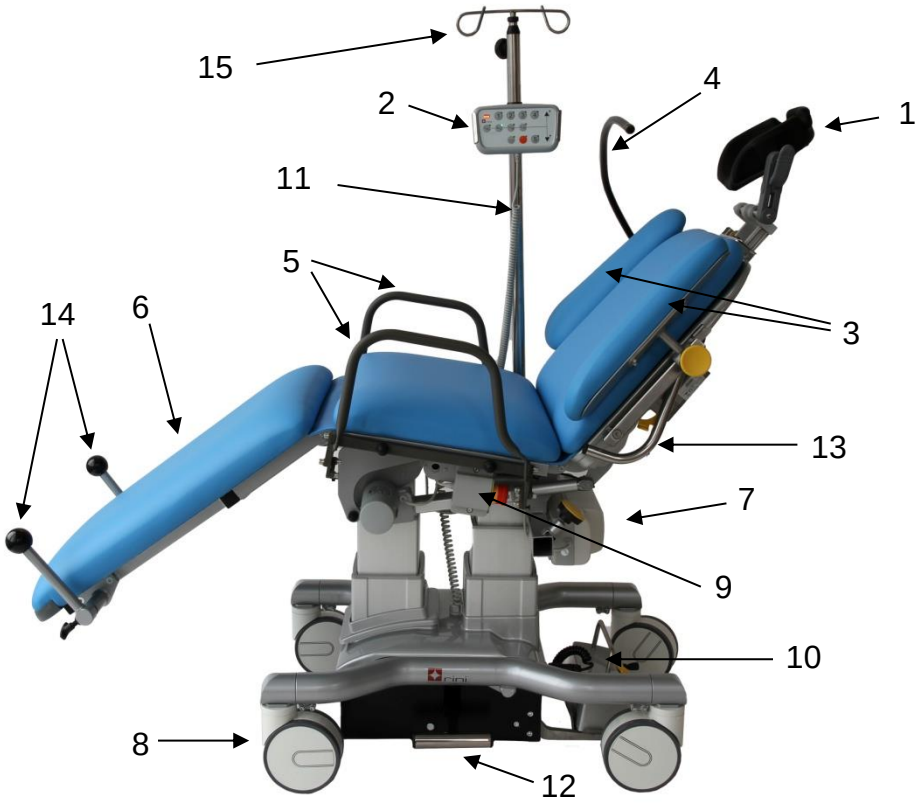
Technical specification can be found in a separate chapter in this manual. Information about the manufacturer and where and when the product was manufactured appears on the type plate below. For questions about this product, specify the UDI and SN for identification.

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.

5. Getting started

5.1 Picture and location of components



Main components of RiEye Mk2S (Model R7)

1 Headrest (standard model)
2 Hand control
3 Backrest width extension (option)
4 Drape support with air connection (option)
5 Side rails (option)
6 Leg rest (show in picture is model R6)
7 Detachable battery module
8 Front wheels left with directional lock capability
9 Emergency stop
10 Foot control (option)
11 Hand control holder (3 different options are available)
12 Central break on all four wheels (downward position) and control of directional lock on left wheel for transport (upward position) Electrical brake is available as option to the mechanical one.
13 Foldable driving handles backrest (option)
14 Foldable driving handles leg rest (option)
15 IV pole (option)

5.2 Areas of use

The RiEye Mk2S operating table is designed for microsurgery and can be used either as a stationary unit in the operating room or used as a mobile unit according to the "roll-in roll-out" method.

The table ensures a high freedom of movement for surgeons and assistants around the patient's head. Its intended areas of use include:

- Eye surgery
- Ear, nose and throat surgery
- Esthetic facial surgery
- Dental surgery

If full anesthesia is used the table should be equipped with the optional extended leg rest and anesthesia armrest.
The table is only intended for indoor use and transport of patients on normal floor conditions.

The table may only be equipped with accessories and components that have been approved by Rini. Repairs or any other technical modifications of the table may only be performed by authorized personnel from Rini.

The table should not be used by patients weighing more than 300kg. The wheels must be secure and locked with the central brake during operation.

5.3 Wheels and brakes

The table has four large rotatable wheels where the left front wheel has a directional lock capability. When space is limited or fine positioning side-ways of the table is required it is achievable thanks to the rotating wheels.

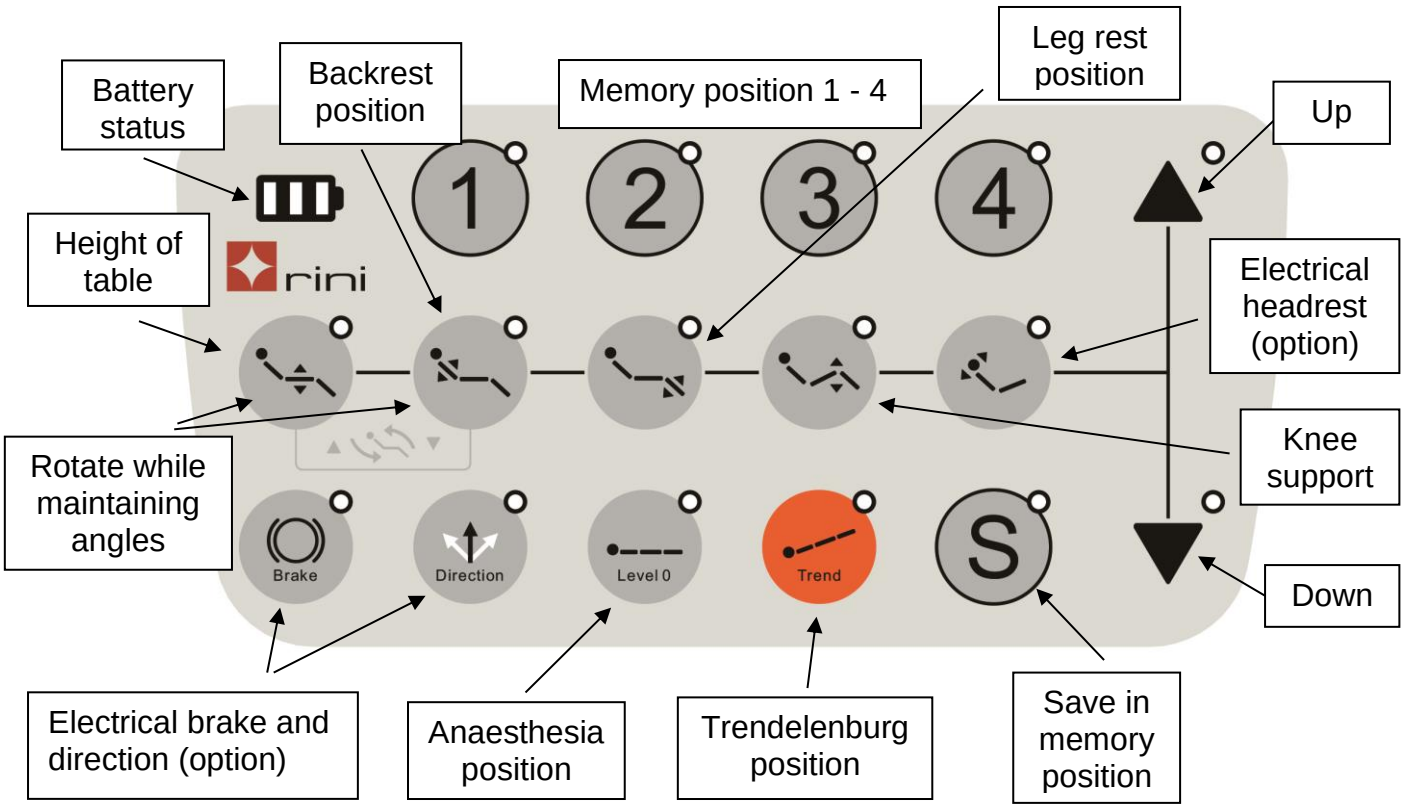
To facilitate transport over longer distances the directional lock makes the table easy to steer straight, during transport in corridors. All wheels have brakes which are centrally controlled by two identical foot pedals on each side of the table that also control the directional lock.

To brake and lock the position of the table the foot pedal is pressed down. The brake is released by lifting the pedal until the middle position has been reached. To set the directional lock, first align the front left wheel straight and then pull the foot pedal fully upwards. To release the directional lock function, move the pedal in the downwards one step until the middle position has been reached.

There is an option to have electrical brake and directional control on the RiEye Mk2S and then no brake pedal is fitted. Braking and directional control is maneuverer with the hand control.

Warning! It is important that the wheels are kept locked during surgery. Improper use may cause personal injury.

5.4 Hand control panel picture and description



On/Off and battery status

”On” is activated by pressing any button for 2 seconds and the battery indicator and latest chosen function will light up. If no other button is activated in 30 seconds the system returns automatically to the “Off” position. If the LED bar flashes and makes a "beeping" sound the battery need to be re-charged.

Buttons for primary adjustment of the table

These buttons control the operating table functions. The respective LED light turns on when the selected function is chosen. Only one

function can be selected at a time. The function keys are used in conjunction with Up and Down buttons.

Seat - Raises and lowers the height of the table

Back - Changes the angle of the backrest

Leg - Changes the angle of the leg rest

Knee - Raises or lowers the knee support

Up - Controls the upward direction after the selection function

Down - Controls the downward direction after the selection function

Rotate - The table can be rotated while keeping the angle between the back rest, seat, and leg rest by pressing the buttons for **Seat and Back** rest simultaneously. Both will light up. Then rotate the chair by pressing the Up or Down button.

5.5 Programmable user setting

The buttons 1 - 4 handle memory settings of the table. Users can easily design own chosen positions of the table for example “Preparation” “Transport” “Surgery” “Recovery” and store them.

How to store a desired position

Press and hold the ”S” button for 3 seconds until a beeping sound is heard and LED lights turn on. Then, within 2 seconds, press one of the buttons 1 - 4 to store the desired position and a successful programming is confirmed by a beeping sound and LED light turn on.

If the selected button 1 - 4 already had a pre-programmed position stored, this will delete it and replace it with the new one.

How to load a desired position

If you want to load one of your stored positions simply press the button 1 - 4.The automatic movement will stop if another button is pressed.

5.6 Level 0 - Anaesthesia position

Anaesthesia position is a pre-programmed function that puts the table in horizontal position.

5.7 Trendelenburg position

In an acute patient situation, the table can be put in Trendelenburg position so that the patients head is lower than the rest of the body.

To quickly activate this function there is a dedicated button “Trend”. If this button is pressed the whole table is made flat with an angle of minus 15 degrees with the head in the lowest position.

Be careful handling this function so it is not activated by mistake. It can cause personal injury.

5.8 Foot control (optional)

The foot control gives additional control of some key adjustments normally to be used by the surgeon for fine tuning during operation.

These adjustments include raising and lowering the table as well as changing the angle of the back support.

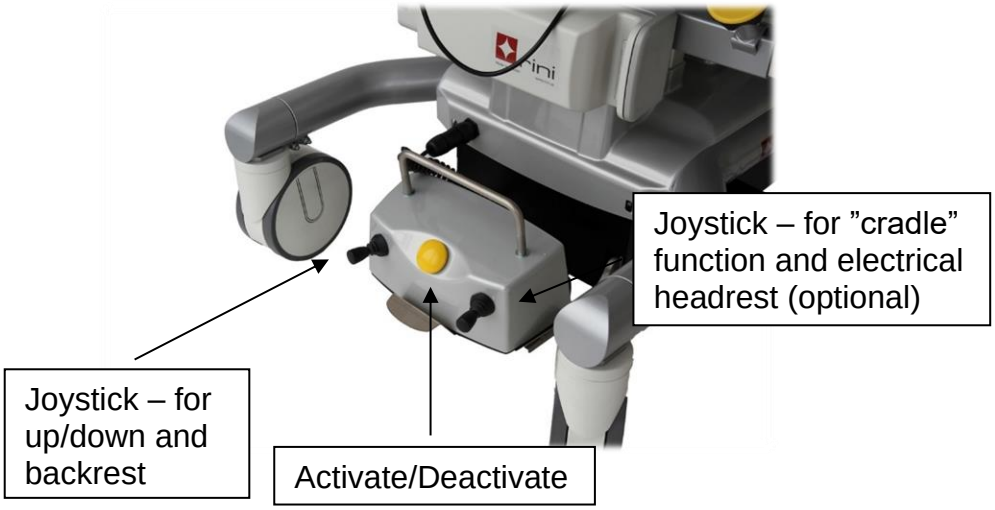
To use the foot control, first push the yellow On/Off button to activate the function and for safety reasons the button needs to be pressed down for at least 0,5 seconds.

The yellow button activation function can be deactivated, please contact Rini or your local Rini distributor. If the Yellow button activation function is deactivated the joysticks will have direct control and the joysticks are always active.

The active state is confirmed with a "beeping" sound and the LEDs for the “Table height” and “Back rest” light up on the hand control.

If no joy-stick movement is done for 10 seconds the system automatically returns to the “Off” mode. If the yellow button is pressed when the system is in the “On” mode, then the “Off” mode is activated immediately.

The foot control function should be tested before every new operation: Activate, Up, Down, Right, Left and Deactivate.



To give flexibility and allow for good ergonomic work positions the foot control can either be placed on the designated shelf on the chassis or placed on the floor.

For safety reason the On/Off button needs to be pressed down for 0,5 seconds switched off automatically after 30 seconds.

Never insert hand or other body parts in the table when it is in motion. It can cause personal injury.

It is important that the foot control is always placed on the shelf when the table is not used or in transport mode.

5.9 Automotion by the Foot control (optional)

All RiEye with serial number suffix XXXX-04 or over the automotion can be controlled by the foot control, please contact Rini or your local Rini distributor.

When automotion is activated by the foot control, the yellow button safety activation function will be deactivated, joysticks are always active and cause RiEye motions when touched.

When double tapping on the yellow button the RiEye will move automatically to the button 1 stored position, if the RiEye has the automation accessory.

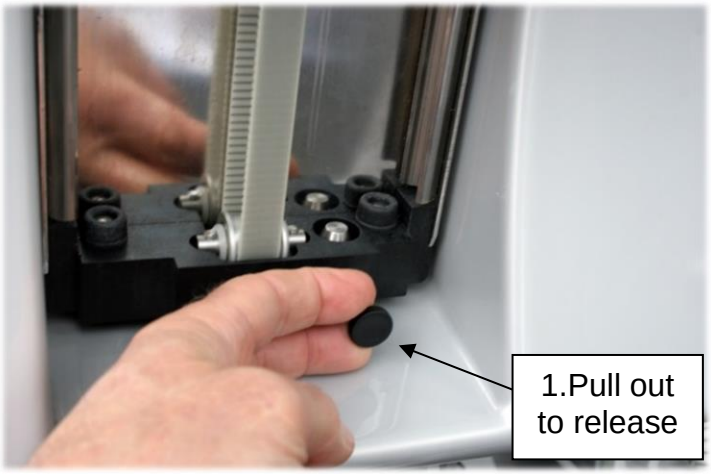
5.10 Headrest (weightless)

A patented design has been developed to minimize the number of manual adjustments needed for medical staff during an operation cycle. At the same time the patient will experience greater comfort compared to a conventional operating table.

There are several headrest models, adapted for different treatment areas, available and please view full range at www.rinicompany.com

The headrest is adjustable in length, height, and angle at the same time as the headrest is perceived as weightless. It automatically adapts to the operating table's different angular settings while the patient's head remains firmly fixed.

For easy cleaning or if different types of headrests are used there is a quick release “1” function to detach the complete headrest mechanism. Make in such case sure that the locking screw “A” is tightened before mechanism is removed out of the backrest.



Before the patient sits on the operating table check that the headrest can move freely in the longitudinal direction and that screw “A” is un-locked. Normally the screw “A” is un-locked and locked only if there are special needs where the length needs to be fixed.

Lock “A” must be open when the backrest of the table is adjusted otherwise the patient may be harmed.

5.11 Headrest Doublelink

Adjust a base angle and height of the headrest bowl with the locking mechanism “B”. The headrest should normally have a slightly raised angle by the neck for maximum patient comfort.

A basic setting of the headrest should be made while the patient is in a sitting position (backrest in upraised position) according to the pictures below.

Patient height lower than 180cm

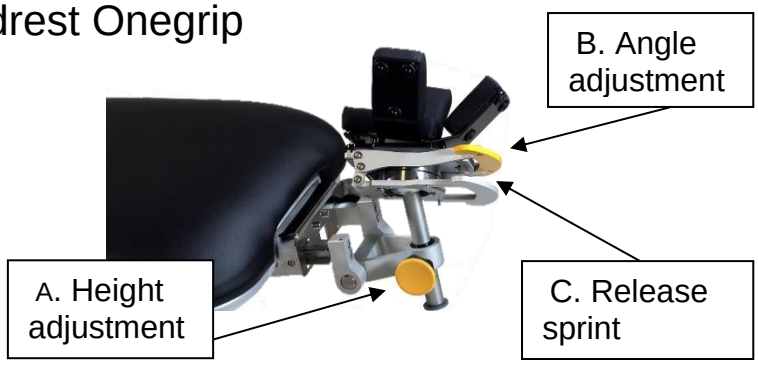
Patient height over 180cm

This default setting covers over 90% of all patient cases. In some cases, additional adjustment may be necessary.

It is also important that the headrest is extracted to a minimum of 60mm/2in to account for the movement that is generally associated with the table backrest adjustment.

Never loosen the headrest mechanism “B” without supporting the patient's head with one hand under the headrest.

5.12 Headrest Onegrip



Adjust the height of the headrest by loosening the screw “A”, set the headrest in the desired height and tighten the screw “A”.

Adjust the angle of the headrest by pinching the handle “B”, set in the desired angle and release the handle “B”. The headrest should normally have a slightly raised angle by the neck for maximum patient comfort.

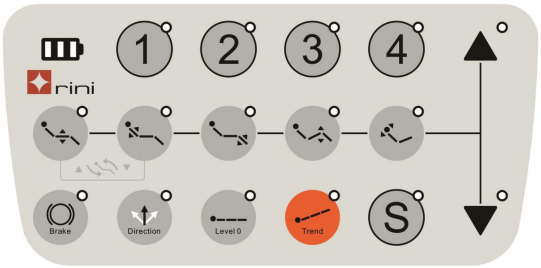
To change between different headrest types, pull the sprint “C” to release the headrest, a new headrest slides into position and are fixed by pushing down to the headrest base.

Never loosen the headrest height adjustment “A” without supporting the patient's head with one hand under the headrest.

5.13 Electrical adjustment for doublelink (optional)

Fine adjusting the angle of the weightless headrest can be made electrically by the hand control with the right joystick on the foot control.

The electrical adjustment can be useful when the angle between the patient's head and the microscope needs to be fine-tuned and the headrest as such is covered and sterile.



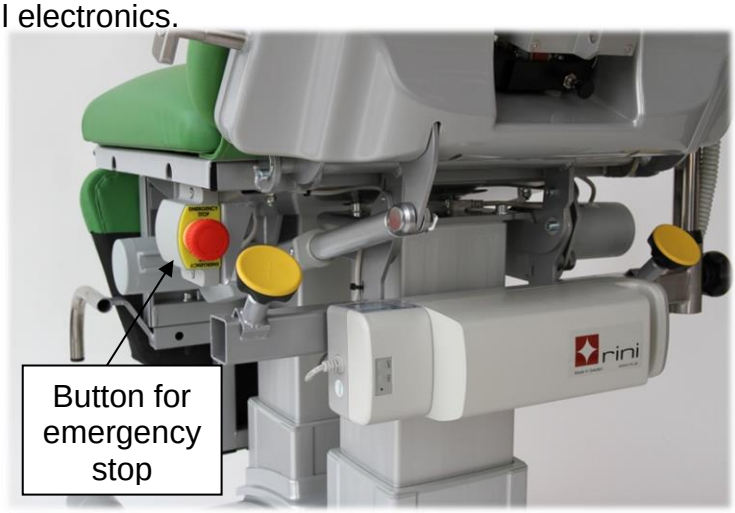
Hand control layout for headrest

Right joystick controls headrest

Set headrest in the middle position and get maximum adjustment range – press the headrest button on the hand control until the motor stops.

5.14 Emergency stop

The table has an emergency stop button which cuts the power supply to all electronics.



To activate the emergency stop, push the red button. To deactivate the emergency stop, turn the button until it pops out.

5.15 Charging and handling of batteries

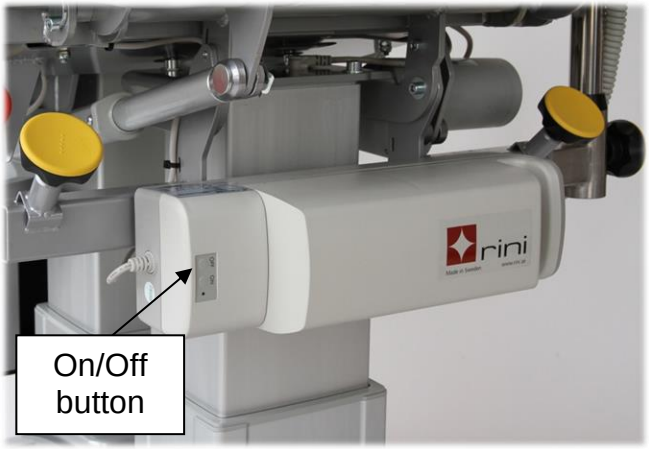
The external charger delivered with the table connects to a standard 110 - 240V main outlet. Batteries should be charged at least once a month to maintain capacity.

Make sure that the new battery is fully charged before use. Make a habit of charging the battery at the end of the working day with lead batteries. If the battery stays in the table when not in use, press the "Off" button on the batterybracket, to avoid self-discharge. For backup, order an extra battery that is always charged and on "stand-by".

Lead batteries older than 4 years should be replaced. New batteries must be ordered from Rini or a Rini approved distributor.

Lithium iron batteries can do twice the number of operating cycles and weighs half of the lead batteries and have a longer lifespan.

During charging there is a yellow indication light that turns green when the charging is complete. When the battery is mounted back on the operating table the "on" button must be pressed.



If battery is dropped or subjected to hard impact it must be checked. If the battery is replaced while a patient is on the table, verify that the emergency stop is activated.

6. Accessoaries to RiEye Mk2S

Some of the accessories ordered will come pre-mounted on the table but can also be mounted afterwards. These include Driving handle leg rest, Attachment rails on the seat and Collapsible side rails. Normally these should stay fixed on the table. Some additional accessories are available so the table can be tailored to fit the preferences of the surgeon and assisting personnel as well as the constitution of the patient or a particular treatment. These can be attached either permanently or temporarily and include the Anaesthesia armrest, Backrest extensions, Wrist support, Holder for hand control, IV pole and Drape support with or without air and more.

6.1 Driving handle leg rest (recumbent patient)

In addition to driving handles located at the backrest of the table there is also an option to fit driving handles near the leg rest. This is useful for transporting recumbent patients.

6.2 Driving handle backrest (foldable)

Foldable driving handles facilitates transport of the table with or without patient.

6.3 Attachment rails on seat

In addition to the standard rails located at the backrest of the table there is an option to have rails along the seat on the left/right side. This is useful to increase the flexibility when mounting other accessories.

6.4 Side rails

Collapsible and fixed side rails increase the safety of the patient and are practical for the patient to hold on to.

6.5 Anaesthesia armrest

The anaesthesia armrest is comfortable for the patient with its soft cushion for pressure relief and can easily be adjusted with a one-hand grip. It can be mounted on the left or right side of the backrest.

If backrest width extensions are used, first remove the one on the side where the anaesthesia armrest should be mounted and then lock the armrest with the clamp.

6.6 Backrest extension – width and length

Used for pressure relief and comfort typically for large or tall patients.

The width extension is attached to the rails on the backrest. The length extension can be used when the headrest is very extracted from the backrest, and it is mounted on top of the backrest to give comfort to the shoulders.

6.7 Holder for hand control

With the holder the hand control is always easily accessible for assisting personnel and reduces the risk of the hand control to be damaged or activated by mistake. There are three different models available.

- On the wheelbase - Formable and remains fixed in height when the table moves up/down and has a rotating top
- On the chassis - Follows table up/down and non rotational top
- On the IV pole - Follows table up/down and non rotational top

6.8 Wrist support

The wrist support is an accessory that grants pressure relief for the surgeon during operation. It is built around a foldable bow that can be adjusted in height, depth and sideways position.

6.9 Knee support

Knee support comes in two versions that are practical to have available and provide more comfort for the patient.

Knee support - round 150mm high and half round 200mm high

6.10 Special mattress for anaesthesia

Special mattresses with "slow recovery" materials can be placed on the operating table. These are available as a whole pad or divided into sections. These are useful during long operations and when the table is in a horizontal or nearly horizontal position.

6.11 Belts

Several types of belts are available if the patient needs to be in a fixed position.

Belts Waist, 700mm/28in and 2100mm/83in

6.12 IV pole

Easy to mount either on the left- or right-hand side of the table. Has twin hooks for infusion pumps and is easy to adjust in height.

6.13 Drape support with and without air connection

Both versions of the drape support are easy formable and keeps the drape over the patient's head. They can be attached on the standard rails, either on the left or right side.

6.14 Protective cover for leg cushion

The leg cushion can be equipped with an optional protective cover to facilitate cleaning and extend the life span of the cushion.

7. Maintenance

7.1 Cleaning and disinfection

Patient near surfaces need special attention regarding cleaning and disinfection. General cleaning of the table should be made once a week and exposed parts should be cleaned after each patient use.

Details	Detergent	Information
Cushions Headrest Chassis Wheel Plastic shell	PH neutral soap water	If stronger detergents are used, rinse afterwards with water to prevent drying and cracking
Electronic parts such as hand/foot control, control box, battery	Water	Use damp cloth Note! Do not flush with water under pressure
Battery charger	Water	Use damp cloth

Clean the table with disinfectant or germicidal agents according to the manufacturer's instructions and follow the hospital's or clinic's protocol for cleaning of body fluids off the table's surface.

Detail	Disinfectants	Information
Cushions	Soap water + ethanol 75% Soap water + hydrogen peroxide (6%) And other, in general always good to rinse with water	Contact Rini or your local sales representative for the full list of tested cleaning products Using cleaning agents can cause discoloration, but no deterioration of the coating layer
Hand control and other electronics	Noedischer Dekonta CCOTRADE RW (and most other disinfectants)	1-3 % concentration 0,5 % concentration Follow manufacturer's instructions Use damp cloth
Other parts	Same as above plus: M-alcohol, Periform or equivalent	Follow the manufacturer's instruction

7.2 Important continuous maintenance

After approximately 1.000 surgeries the "Maintenance Indicator" will be activated = The hand control "Up"/"Down" arrows LEDs blink continuously. Two actions are required:

Verification of motor positions

Activate the hand controller by pressing both "Up"/"Down" arrows buttons simultaneously. After 5 seconds a beep sound is heard indicating that the verification starts. Keep pressing until a continuous beep is heard and then stop pressing. The verification is now completed.

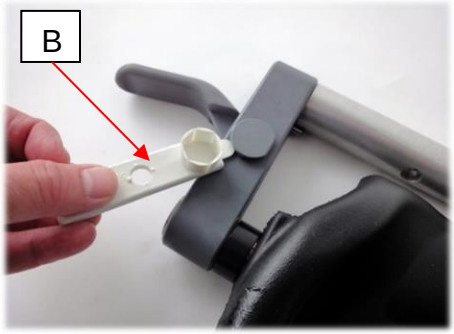
Adjusting the headrest Doublelink

The headrest is one part of the operating table that is always used and most patient critical. It is essential that the function is verified and adjusted when required. During normal wear and tear the mechanism needs tightening – typically every 3-6 months.

The headrest should be unable to move when locked even when using some force (10 kg). If the headrest tends to glide, the headrest needs to be tightened. This is to be checked for each use.

To adjust the headrest bracket, start by opening the handlebar "A" so that the headrest is free running and as loose as possible.

Then start by removing one of the two tightening plate (item 010-00332-00) located on the side with the backside of tightening tool "B" (item 010-00333-00). In some cases, both tightening plates need to be removed to get sufficient adjustment range.



Use the tightening tool again, now to tighten the lock mechanism. This is done with two nuts one with right and one with left thread. This should be done so that the friction starts almost when the handlebar is fully open

Put back a new tightening plate (they are of one time use and usually break when removed) to lock the new position and verify that the headrest is firm when locked.

7.3 Service and repairs

Annual service of the table is recommended to maintain optimum performance of operational performance and maximize personal security. Such services include:

- 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 products, batteries, and battery charger

Contact Rini or your local Rini distributor for information regarding spare parts for your product. The product should only be repaired by Rini or by a Rini authorized service centre/engineer. Items under warranty must be sent to a Rini authorized service centre.

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

8. 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.

8.1 CE Declaration of conformance

Operating table 100-00105-xx follows EU Medical Device Regulation 2017/745 for medical products.

Tested according to IEC 60601-1 and IEC 60601-2-46.

9. Technical data

Dimensions	Length x Width
Back support	500 x 580/680(XL)mm / 19 x 23/27(XL)in
Seat cushion	430 x 580/680(XL)mm / 17 x 23/27(XL)in
Leg support	400/500/700 x 580mm / 16/19/27in
Headrest	180 x 210mm / 7 x 8in (integral mould)
Maximum width	750mm /30in (footprint of chassis)
Maximum length	1940/2030/2200mm / 76/80/87in (with patient in horizontal position with head in headrest)
Height	500 - 900mm / 19 - 35in
Height with reverse Trendelenburg	550 - 950mm / 21 - 37in (optional)
Weight	95kg / 209lb (excluding accessories)
Safe working load	300kg / 660lb
Headrest	
Angle	-30º - +30º
Height	0 - 80mm / 0 - 3in
Length	0 - 450mm / 0 - 18in
Backrest angle	+90º vertical to -20º
Legrest angle	-90º/-45º/-35º (model R5, R6, R7)
Trendelenburg position	-18º (relative horizontal position of head)
Reverse Trendelenburg	+12 º (optional)
Material	
Stand and frame	Powder coated metal
Cushions	Med tech material available in different colours
Accessory rail	Stainless steel
Memory positions	4 users selectable
Battery	24V 5Ah Rechargeable lead acid (standard)
Charger	100-240V 500mA
Protection class	IPX4
Medical classification	Class 1 Type B
Standard	EN/IEC 60601
Working conditions	
Temperature	+10ºC to +40ºC / +50ºF to +104ºF
Relative humidity	20% to 90% at +30ºC / +86ºF
Atmosphere	700 to 1060hPa

Transportation and storage conditions

Transport condition	
Temperature	-10ºC to +50ºC / +14ºF to +122ºF
Relative humidity	20 % to 90 % at +30ºC / +86ºF
Atmospheric pressure	700 to 1060hPa
Storage condition	
Temperature	-10ºC to +50ºC / +14ºF to +122ºF
Relative humidity	20 % to 90 % at 30ºC / +86ºF
Atmospheric pressure	700 to 1060hPa

9.1 Disposal and recycling

The product is mainly made from environmentally recyclable materials such as steel, stainless steel, aluminium, and plastics. Rini recommends that the materials 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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rini