Service manual

Operating table RiEye Mk2S

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





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1. Introduction



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.

Tests for basic safety and essential performance have been done according to standard EN/IEC 60601-1 and EN/IEC 60601-2-46.

The original version of this manual was written in English.

This service manual contains the 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 operating table, 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 RiEye Mk2S user's guide.

This Service Manual covers the RiEye Mk2S operating table of:

Mechanical release from serial number 0001-01

Software release from v1.0

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 operating table should only be used as it is intended to as described 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.





Foot control (optional)

Main unit

\triangle	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 RiEye Mk2S operating table 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 Ergoteknik AB 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 RiEye Mk2S operation table or its accessories than authorized by Rini Ergoteknik AB can lead to partial or full cancellation of the warranty.



For service, troubleshooting, repair operations as well as cleaning, the RiEye Mk2S operation table must be in a parking position with and the emergency stop button pressed.



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 RiEye Mk2S operation table.



Be careful when lifting the RiEye Mk2S operation table as is heavy and may cause injury. If the table 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 table 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

Please see Rini document 2011-087 Protocol for service of RiEye Mk2S

5.2 Periodic maintenance and check

Monthly		
Head rest Loosen the latch and lubricate the two joints with a drop of		
Anesthesia armrest **	Lubricate the joints with a drop of oil *	
Collapsible side rails** Lubricate the joints with a drop of oil *		
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.		

^{*} Most types of non-corrosive lubricating oils can be used

5.3 Spare parts and repairs

The following list is a set of typical spare parts for the RiEye Mk2S operating table. 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 RiEye Mk2S and with limited technical skill SPK2 – User with multiple RiEye Mk2S and with good technical skill

Code	Description	Kit
010-01058-00	Control unit with cable lock	SPK2
010-00867-00	Main lifting column (front and back identical)	SPK2
010-00976-00	Actuator backrest or leg support	SPK2
010-00872-00	Mini-actuator electrical headrest or brake	
010-01060-00	Battery bracket	SPK2
010-01059-00	Emergency stop unit	SPK2

^{**} Optional accessories



010-01062-00	Dottom, charger station	SPK1	
010-01062-00	Battery charger station	SPKI	
010-01063-00	Charger EU		
010-01069-00	Charger UK	SPK1/2	
010-01069-01	Charger US		
140-00237-02	Battery	SPK1/2	
	E cini		
140-00319-00	Hand control standard	SPK1/2	
140-00319-01	Hand control - electric headrest	SPK2	
140-00319-02	Hand control - electric headrest and brake	SPK2	
140-00319-03	Hand control - electric brake	SPK2	
010-01056-00	Y-Cable hand control	SPK2	
010-00691-00	Wheel without guide barrier (3 pcs/RiEye)	SPK2	
010-00692-00	Wheel with guide barrier front left (1 pc/RiEye)	SPK2	
000-05228-01	Wheel adaptor RiEye Mk2S	SPK2	
010-00331-00	Headrest lock double link	SPK1/2	
010-00332-00	Tightening plates, 2 pc	SPK1/2	
010-00334-00	Lock plates, 2pc	SPK1/2	
010-00333-00	Tightening tool headrest	SPK1/2	
000-05269-00	Headrest standard	SPK1/2	
Standard	Contact Rini for spares for special models XL		
Cushions	(100mm wider), other colours etc		
010-00674-00	Snap lock for seat		
010-00673-00	Snap lock for chassis		
000-05285-60	Cushion back RiEye blue Illusion		



000-05285-61	Cushion back RiEye black Illusion
000-05286-60	Cushion seat RiEye blue Illusion
000-05286-61	Cushion seat RiEye black Illusion
000-05127-60	Cushion leg RiEye R5 blue Illusion
000-05127-61	Cushion leg RiEye R5 black Illusion
000-05290-60	Cushion leg RiEye R6 blue Illusion
000-05290-61	Cushion leg RiEye R6 black Illusion
000-05287-60	Cushion leg RiEye R7 blue Illusion
000-05287-61	Cushion leg RiEye R7 black Ilusion

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

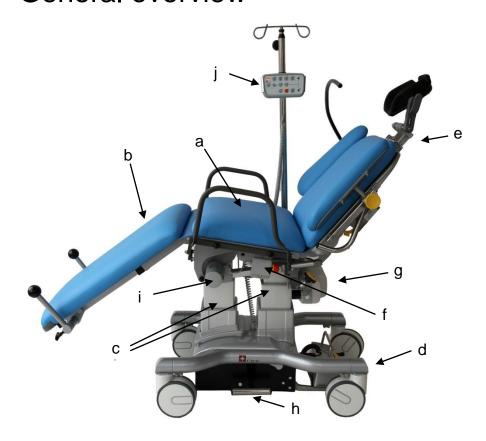


The product should only be repaired by Rini or by Rini authorized service center/engineer. Items under warranty must be sent to a by Rini authorized service center.

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



General overview

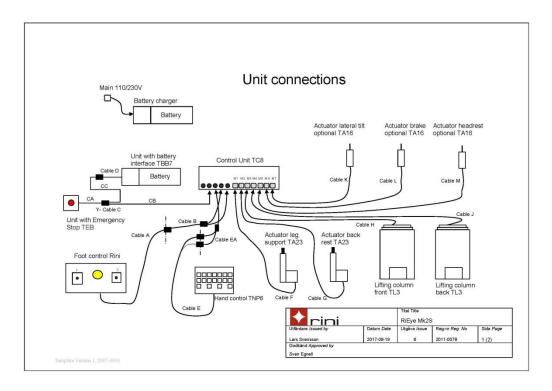


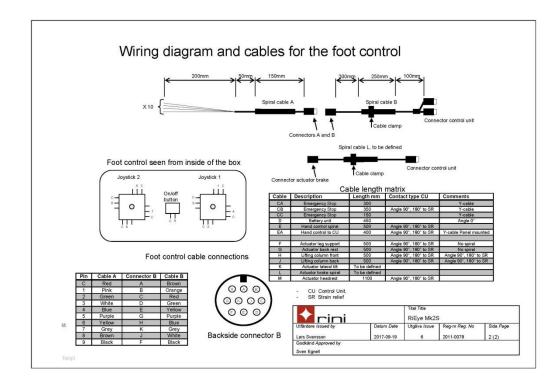
Location of main components of RiEye Mk2S (R7)

- **a.** Control unit item 010-01058-00 is located under the seat. Lift cushion and unscrew 4 snap locks M10. Remove plastic cover and cables.
- **b.** Leg rest powered by one actuator item 010-00976-00
- c. Lifting column back and front item 010-00867-00
- d. Shelf with foot control (option). Can be re-fitted in the field on tables
- e. Head rest manual or electrical by one mini-actuator item 010-00872-00
- **f.** Emergency stop item 010-01059-00
- g. Battery module Detachable battery item 140-00237-02 and battery bracket item 010-01060-00
- h. Central break manual or electrical control by mini-actuator item 010-00872-00
- i. Back rest powered by one actuator item 010-00976-00
- **j.** Hand control module with appropriate label (mechanical brake, electric brake, electric headrest and electrical headrest/brake).



7. Electrical architecture







Trouble shooting and solutions

This section is divided in practical guides to deal with possible service actions needed.

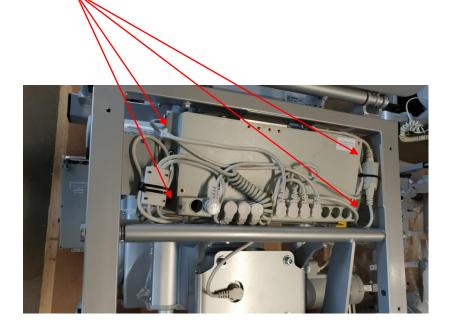
8.1 Software update – by control unit replacement See chapter Control unit – replacement below.

8.2 Control unit - replacement

The control unit holds the complete software program from version 1.1 upwards.

A "software update" can be performed by replacing the complete control unit, the software version should be marked on the side of the control unit. Take a picture and move as little as possible of the cables during the procedure.

- a. Press emergency stop and remove the battery. During work with the control box and cabling the battery must be removed.
- Remove the table seat cushion and use number 10 socket wrench to remove the four cushion lock knobs. Remove the plastic cover.
- c. Use standard Alan key number 5 and 13 socket wrench to remove the four screws holding the control, see picture below.





- d. Mark the connectors so they can be put back in the same order and then unplug them.
- e. Put back the contacts in the same order. Check that all cables are wired correctly and not squashed.
- f. Insert the battery and check that the emergency stop is released, press the "On" button at the battery bracket. The green light at the control unit shall light up, see picture below.



- g. To make a simple test and verify that the back rest connection is ok. Push any button at the hand control to activate the system. Push the back rest button (below button 1), lamp just above should light up, move the back rest down by one of the down arrow buttons. If the back rest moves down its correct connected.
- h. To make a simple test and verify that the leg rest connection is ok. Activate the system as above. Push the leg rest button (below button 2), lamp above should light up, move up by one of the up arrow buttons. If the leg rest is moves up its correctly connected.
- i. The system must now be synchronized. See chapter "System synchronisation" below, read and follow the instruction carefully.
- j. Before putting back the plastic top, make sure the cables are not stressed by moving the table in its extreme positions and at the same time checking from underneath. **Important**, cable from the battery bracket should not be too tight when seat is tilted max backwards. Assemble the rest of the removed parts



8.3 System synchronisation

"System synchronisation" is used to reset the positions of all actuators so the system starts from a defined initial state and dynamic motion of operation.

The system synchronisation involves all columns and actuators. The below system synchronisation is always made in the factory before delivery.



- a. Insert the battery and check that the emergency stop is released, Press any button and the light shall turn on.
- b. Push simultaneously Arrows buttons, after 5 sec auto initiation will follows. Keep pressing, and all motors runs to its end positions, no sound or peeping, all just driving to the end pos. The following motor positions are target by the automatically synchronization process, Leg support highest, Back support lowest, Main columns lowest, electrical headrest actuator bottom end, Electrical brake direction control position (bottom end).
- c. Normally after synchronisation shall all earlier stored factory positions still will be accurate. **Important**, if the control is replaced all factory settings below and user positions button 1-4 must be completed.

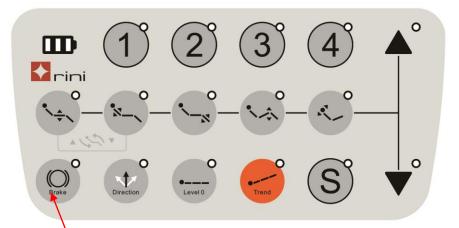
8.4 Electrical brake and free wheel swivel adjustemet

Dependent on mechanical tolerances in the chassis the actuator handling the brake and wheel swivel function may need to be programmed in middle (Free swivel) and top end position (brake).



The position reference is the "direction control" position. That is when the brake actuator is in its inner end position. The brake actuator moves automatically between its stored positions, the motion stops if the Direction or Brake button is pressed before arriving to stored positions.

a. First run the table motors synchronization process as described in pervious section. Before pressing the brake button at the hand control, check that the direction control wheel locks and the three other wheels are free swiveling. If not please don't continue to work after this instruction, call Rini technical support.

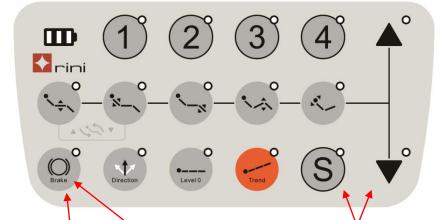


To set the actuator brake lever position, start position for this setting instruction is the wheel in direction control after the synchronization process above is made.

- b. Press any button and the light shall turn on.
- c. First identify the brake lever under the wheel frame. Press the brake button 0,5 second and press it once more when the lever is approximately 5 mm from the wheel frame.
- d. In the following picture the actuator pushes too far out and is too close to the wheel frame, so you must try once more.







- e. When the brake lever position is found (5 mm stop from the wheel frame), check that all four wheels are locked. Then press simultaneously the Brake button and the S-button, keep them pressed, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to a constant pep, approximately after 5 seconds. Now the new brake lever position is stored. Test if its works by pressing the Brake button a couple of times. It should now stop 5 mm from the wheel frame if the new stored position is correct.
- f. To clear an earlier stored brake position and make a new storage. Push simultaneously the down arrow in the right corner and the Brake button and keep them pressed, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to a constant pep, approximately after 5 seconds. Now the old position is cleared.
- g. To adjust the actuator in middle free swivel position. Start to move the plastic wheel frame cover so the brake actuator is visible.
- h. If a rattling noise from one of the wheels, the wheel can be out of the 90° angle against the floor (see end of chapter Replacing a wheel) or the actuator middle free swivel position must be adjusted. The target is to find a free swivel position and save it.
- i. Start from actuator top end position or inner position. If top end press Brake button once and the actuator moves to current middle position. Press the brake button so the actuator just starts to move and press brake button again to stop the actuator, should just move 3-4 mm. Still rattling noise from some wheel, press Direction button or Brake button to go back to current middle position. Press the Direction button so the actuator just starts to move and press Directions button again to stop the actuator, should just move 3-4 mm. Repite until a new middle position without rattling noise from wheels is found.



j. Save a new middle position by pressing S and Direction control button simultaneously keep buttons pressed until the pep is changed to a constant pep, approximately after 5 seconds. Now the New middle position is cleared.

8.5 Set and change factory stored positions

When the positions are stored as described below, let the system stay for one and half minute without unplug the control unit contacts, or remove the battery and not pressing the emergency stop button or the hand control. To allows the system to power down and store the memory positions.



If removing cables or battery before the time has passed, all stored positions can be lost and the below procedures must be repeated.

8.6 Set and clear legrest inner position limitation (angle)

This is made to avoid the leg rest to hit the floor. The recommended distance between the floor and the leg rest is 25mm in its lowest position when the seat is in flat position (not tilted backwards).

- a. To clear an old leg rest limitation. Push any button to activate the system, lamps lights up. Then push simultaneously the down arrow in the right corner and S button and keep them pressed, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to a constant pep, approximately after 5 seconds. Now the old position is cleared.
- b. To set a new leg rest limitation. Push any bottom to activate the system, lamps should light up. Then push simultaneously the S button and the leg rest button (below button 2) and keep them pressed, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to a constant pep, approximately after 5 seconds. Now the new limitation position is set. Try it by move the leg rest up a bit and then down, it shall automatically stop at the new position.

8.7 Set Anaesthesia position, "level 0", button

- a. Push any button to activate the system, lamps should light up. Move seat, back rest and leg rest to flat positions and to the desired height, Factory standard is the top of the seat cushion should be approx 750mm from the floor
- b. Push the buttons S and Level-0 simultaneously, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to constant pep, aprox after 5 seconds. Now the new Level-0 position is stored.



8.8 Set Trendelenburg position

- a. Start from the "level 0" position described above
- b. Tilt backwards the backrest, seat and leg rest simultaneously by selecting the tilt function. Push simultaneously buttons (below battery status bar and below button 1) then move down with down arrow button. Praxis is that the RiEye tilts backward 15°.
- c. Push the buttons S and TREND simultaneously, a pep sound shall be heard. Keep both buttons pressed until the pep is changed to constant pep, approximately after 5seconds. Now the new Trendelenburg position is stored.

8.9 Set user positions buttons 1-4

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.

8.10 Aktivate/deactivate activation button on foot control

To deactivate the yellow button activation function, press arrow up and yellow button simultaneously for approx. 30 seconds, beeping confirms programming is in process, keep pressed until a continuous sound.



The foot control now has direct control, the RiEye Mk2s moves directly when you touch the joystick.

To activate the yellow button activation function, press arrow down and yellow button simultaneously for approx. 30 seconds, beeping confirms programming is in process, keep pressed until a continuous sound. The Yellow button is now active.

8.11 Set automotion by the foot control

To activate position 1 automotion on the foot control you press "1" on the hand control and the yellow button simultaneously for approx. 30 seconds, beeping confirms programming is in process, keep pressed until a continuous sound.



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.

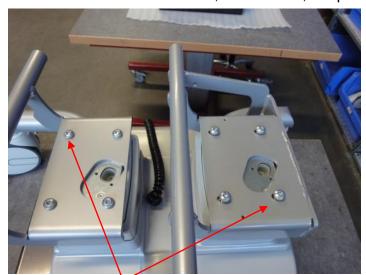
When this function is activated position 1 is chosen by double tapping the yellow button.



8.12 Replacement of front or back lifting column

Put the table on flat floor and in a location with sufficient space around that the table can be put in all its position (sitting, flat etc). Be careful and take preferably take pictures so the strapping of cables is identical after replacement. When the column is replaced a synchronisation of columns and actuators need also to be performed.

- a. Remove cushions and take away the plastic seat cover, 4 nobs
- b. Remove Control unit bracket, two screws, keep the seat frame on



- c. Remove the 4 screws at the column that shall be replaced and remove column cable.
- d. To make possible to lift upp the broken column: The column that works must run upwards by the hand control to make space.



Turn of the system off by remove the battery and connect the column cable to the CU backrest output (M2). Insert battery and turn the



system on and move the not broken column upp by the hand control with the backrest function.

- Tip the Mk2S on carefully on the side and remove the 4 screews from the broken column
- b. Remove the broken column and insert the new one and tight the 4 screws again, tip the Mk2S back on the wheels again.
- c. Run the old working column back to its bottom position, now shall both columns be close to end bottom positions, **note important don't tight the new column top 4 screws yet.**
- d. Connect all the cables to the control unit again and run the synchronisation procedure. Check that all motors works
- e. Now tight the broken columns top screws, **both columns must be in** the end bottom position when the 4 screws are tighten
- f. Mount back the control unit and cables. Test that all motors are synchronized by pressing the hand control 0-level button and the table shall move to flat position.

8.13 Adjusting the headrest

The headrest is one part of the operating table that is always used and also 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 has a tendency 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 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 plate 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 the friction starts almost when the handles bar 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.

8.14 Replacing a wheel

Wheels are long life items that do not need to be replaces. If there has been a collision or any other physical damages to the table it may be necessary to replace one wheel and/or the wheel adaptor.





a. Secure the table and put a support underneath the centre pieces of the chassis so the wheel that needs to be exchanged is in the air with approximately 100mm margin. Set the brake level in the middle neutral position.



b. Unscrew and dismantle the wheel adaptor and wheel. It can be necessary to expand the locking mechanism to facilitate the extraction of the wheel adaptor.



c. Note the colour (green on left front wheel or red on all others) as well as the direction of the label on the dismantled wheel.







- d. Take the new wheel and verify that it is in the middle neutral position.
- e. <u>It should not be locked or in directional mode!</u> Use some appropriate tool for this. Then put on the wheel adaptor piece and carefully stick in the brake shaft.







f. Re-assemble and make sure the wheel adaptor is fully retracted. Tighten the screws but not fully as the final tuning must be done with the table standing on a 100% flat floor.



g. When the table is standing on a 100% flat floor move the wheel adaptor angel so that both wheel paths are firmly on the floor. Then tighten the screws fully and verify that the brake, free running and directional positions are correct.

8.15 Replacing backrest

A back rest is long life items that do not need to be replaced. An exception is if there has been a collision or any other physical damages to the table. When this service job is performed make sure to be 2 people.



a. First lock the headrest and length adjustment and the remove the complete headrest foundation from the backrest by pulling the knob as above.







b. Remove lock washers holding the 2pcs hinge bolts, use two screw drivers and press the lock washer out from the hinge bolt axis.





c. Remove the backrest actuator lock and bolt. One person holds the backrest and a second person carefully take out the hinge bolds by a screwdriver. When both hinge bolts are removed the back rest can be removed.





- d. Hold the new back rest in position and assemble the 2pcs hinge bolds and lock put back the lock washers by a screwdriver.
- e. But back the backrest actuator bolt and lock.
- f. Slide back the headrest foundation into the back rest, check so its locks ok.

9. Cleaning and disfection

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.

Patient near surfaces include among; Cushions, Headrest, Armrests and accessories; Cover bow, Soft headrest, Anesthesia armrest, IV pole, foot rests and side rail.

9.1 Periodic cleaning

General cleaning of the table should be made at least once a week and exposed parts should be cleaned after each patient use.

Detergents



Details	Detergent	Information	
Cushions			
Head rest			
Stand	Mild soap		
Wheel		If stronger detergents are used,	
Frame		rinse afterwards with water to prevent drying and cracking	
Metal			
Plastic shell			
Painted surfaces			
Electronic parts such		Use damp cloth	
as hand/foot control, joystick, control box and battery	Water	Note! Do not flush with water under pressure	
Battery charger	Water	Use damp cloth (if the charger is mounted vertically, wet brush can be used.)	
		Note! Do not flush with water under pressure	

9.2 Disinfection

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.

Recommended disinfection

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



10. Technical data

10.1 Specification

 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 550 - 950mm / 21 - 37in (optional)

Trendelenburg

Weight 95kg / 209lb (excluding accessories)

Safe working load 300kg / 660lb

Headrest

 Angle
 -30° - +30°

 Height
 0 - 80mm / 0 - 3in

 Length
 0 - 450mm / 0 - 18in

Backrest angle +90° vertical to -20°

Legrest angle -90°/-45°/-35° (model R5, R6, R7)

Trendelenburg position -18° (relative horizontal position of head)

Reverse Trendelenburg +12° (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 classificationClass 1 Type BStandardEN/IEC 60601

Working conditions

Temperature
Relative humidity
Atmosphere
+10°C to +40°C / +50°F to +104°F
20% to 90% at +30°C / +86°F

700 to 1060hPa

Transportation and storage conditions

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



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

RiEye Mk2S 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	RiEye Mk2S 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	RiEye Mk2S is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	supply network that supplies buildings used for domestic purposes.	

Guidance and manufacturer's declaration - electromagnetic immunity

RiEye Mk2S 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

Guidance and manufacturer's declaration – electromagnetic immunity continuing						
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance			
			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.

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 RiEye Mk2S

RiEye Mk2S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RiEye Mk2S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RiEye Mk2S as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance acc to frequency of transmitter (meters)				
output power of	150 kHz to 80 MHz 80 MHz to 800 MHz		800 MHz to 2.5 GHz		
transmitter W	$d = 1,2\sqrt{P}$	$d = 1, 2\sqrt{P}$	$d = 2,3\sqrt{P}$		
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.

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 RiEye Mk2S should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary.



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.

