

Rosi

Instructions for use

Product Name: Rosi

Document Code: BIC-KTR-2412



【Marketing Authorization Holder】

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Before Use

Thank you for purchasing a product from BIC Group.

To ensure safe and correct usage, please read this manual before using the device. If the device does not function correctly or you suspect it needs servicing, stop using it and contact our customer service.

1. Safety Precautions

If you experience rash, redness, or itching during use, stop using the device immediately.

Contraindications / Prohibited Use:

- Patients with cardiac pacemakers or other active implanted electrical devices
- Patients with epilepsy or suspected epilepsy
- Patients with skin cancer or undiagnosed pain syndromes
- Pregnant or postpartum individuals
- Individuals with open wounds or skin eruptions
- Individuals lacking normal skin sensation
- Children or individuals unable to express themselves

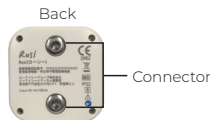
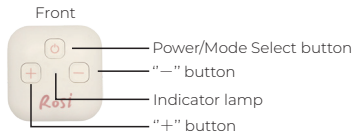
Warnings:

- Do not use on the head, eyes, or mouth
- Do not apply to the front of the neck (especially the carotid sinus)
- Do not modify the device
- Do not place electrode pads across the chest
- Do not use near implants like cochlear implants, pacemakers, electric or skeletal anchors, or other active devices
- Do not use on the brain or entire head

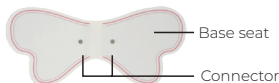
2. Product Description

1) Components

- Main unit (1x)



- Adhesive electrode pads (1x)



Electrode surface



Protective seat



- USB Type-C charging cable (1x)



- Storage pouch (1x)



- Thank You card (1x)



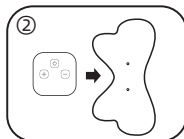
- Quick guide (1x)



- Warranty card (1x)

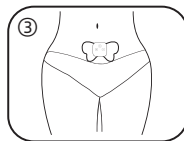
2) Main Specifications

Output waveform	Symmetrical biphasic square pulse
Pulse width	240µs
Frequency	1 - 60Hz
Modes: 3 modes	<ul style="list-style-type: none"> o Mode 1: 30 min o Mode 2: 60 min o Mode 3: 60 min
Output intensity levels	30 levels
Dimensions	50W×50H×14.75D(mm)
Main unit weight	28.3g
Pad size	160×70mm
Power	Lithium-ion battery, 3.7V, 200mAh
EMC	Conforms to IEC standards
Protection rating	IP22
Classification	Internal power source, BF-type applied part, continuous operation



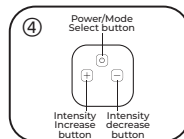
(2) Setup

- Connect the main unit to the pad via connectors until a click sound is heard



(3) Attaching Butterfly Pad

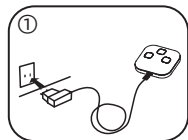
- Peel off the protective sheet and attach the pad to the desired area (e.g., abdomen)
- Keep the protective sheet for reuse after use



(4) Operating the Device

- Press the ON/OFF button to start; indicator lights up and beeps
- Long press to power off
- Use '+' and '-' to adjust output intensity (0 to 30 levels)

3. How to Use









(1) Charging





- Charge before use or periodically
- Connect USB cable to the USB port of the device and an AC adapter
- When the indicator blinks, battery is low
- Fully charged use: 6+ hours

(5) Selecting Mode & Auto Shutdown

- Short press ON/OFF button during operation to switch among 3 modes
- Mode 1: 30 minutes; Mode 2/3: 60 minutes
- Auto shut-off after treatment duration
- If no intensity is set within 60 seconds after startup, device will shut off automatically

4. Setting Modes and Intensity Levels

Setting Modes ()					
Step	Mode	Operation	Indicator	Sound (Short Beep)	Operation Time
①	On	Press 	Steady green light	Once	30min
②	Mode 1				
③	Mode 2	Press  again	Blinks twice, then steady green	Once	60min
④	Mode 3	Press  again	Blinks three times, then steady green	Once	60min
⑤	Mode 1	Press  again	Blinks once, then steady green	Once	30min
<ul style="list-style-type: none"> • The device starts in Mode 1 upon powering on. • Pressing the  button cycles through Modes 1 to 3 sequentially. • Each mode stops automatically after the preset time ends. 					

Output Level Adjustment ( )			
Action	Button	Sound	Range
To increase intensity		Short beep	Up to 30
To decrease intensity		No sound	Down to 30
Important Notes: <ul style="list-style-type: none"> • Select the mode before adjusting intensity. • Each time the power is turned on, the output level resets to "0". • If powered on without being worn, the device will shut off automatically after 60 seconds. • Turn on the power after wearing the device. • If the + button is not pressed within 60 seconds of powering on, the device will shut off automatically. 			

Turn Off			
Turn Off	 Press 2 sec	Green light off	No sound

5. Usage Warnings

- Keep out of reach of children
- Do not use during activities involving machine operation or driving
- Discontinue use if you experience rash, redness, or itchiness
- Do not share electrode pads with others
- Do not wear metal items during use (e.g., piercings, belt buckles)
- Do not use in water or humid environments (e.g., sauna)
- Do not use in high-oxygen environments (e.g., oxygen capsules)
- Do not use while sleeping
- Some individuals may experience skin irritation or sensitivity
- Do not allow foreign matter (dirt, water, metal) to enter the unit
- Do not use above 3,000 meters altitude
- Do not apply pads to injured or damaged skin
- Do not charge the device while wearing it
- Always turn off the device before removing electrodes
- Not a substitute for medication or professional pain treatment
- Do not use on inflamed, infected, or varicose skin

6. Storage and Expiry Conditions

Operating Conditions:

- Temperature: +5°C to +40°C
- Humidity: 0% to 80% RH

Storage Conditions:

- Temperature: 0°C to +55°C
- Humidity: 0% to 93% RH

7. Maintenance and Inspection

Daily Inspection (User Maintenance):

- Visually inspect the main unit, electrode wires, and adhesive pads before each use for damage or dirt.
- If dirty, wipe with a tightly wrung cloth dampened with water.

8. Troubleshooting











Symptom	Possible Cause	Recommended Action
Cannot power on	Battery depleted	Charge with USB cable
No stimulation felt	Output too low or electrodes not connected properly	Reconnect electrodes properly and increase intensity with '+' button
Device does not shut off after 30/60 min	Overheating	Power off manually and contact customer support
Pads do not stick to skin	Pads dirty, dry, or expired	Clean or replace pads
No sensation even though unit is operating	Pads not attached correctly	Attach pads correctly to skin

If the problem persists despite following the instructions above, contact customer support.










9. Product Disposal

Dispose of the product and all components (main unit, pads, etc.) in accordance with the waste disposal regulations of your local municipality.

10. Labels and Symbols

Symbols	Explanation
	Caution
	Serial number is indicated to the right of this symbol.
	Manufacturing date is indicated to the right of this symbol.
	Manufacturer's name and address are listed to the right of this symbol.
	Dispose of the device in accordance with local municipal regulations.
IP22	Protected against solid objects ≥ 12.5 mm and vertically falling water drops when tilted up to 15°.
	Remove the device before undergoing MRI scans.
	Refer to the instructions for use.
	Lot number is indicated.
	Type BF applied part.
	The name and address of the European Authorized Representative are listed adjacent to this symbol.

Additional Packaging & Transport Symbols

Symbols	Explanation
	Fragile – handle with care.
	This side up.
	Keep away from sunlight.
	Keep dry – protect against moisture.
	Temperature limits for transport and storage.
	Humidity limits for transport and storage.
	Atmospheric pressure limits for transport and storage.
	Direct current (DC).
	CE mark indicating conformity with EU health and safety requirements. "2862" identifies the notified body.

11. Electromagnetic Compatibility (EMC)

Rosi complies with IEC EMC standards for medical electrical equipment. To reduce interference:

- Maintain distance from RF sources such as mobile phones, radios, base stations, microwave devices, CT, MRI, X-ray machines, etc. - Do not stack or place near other devices without verifying performance
- Use only the supplied charging cable
- Keep RF devices at least 30 cm away from any part of the device

12. Radio Law Compliance

This product is for use in Japan only. Do not use abroad as it may violate local radio laws.

13. Biocompatibility

Materials used in Rosi comply with biocompatibility standards ISO 10993-5 (cytotoxicity) and ISO 10993-10 (irritation and sensitization).

14. Frequently Asked Questions (FAQ)

Q1: Is Rosi safe to use?

A: Yes. Rosi is approved in Japan, FDA-cleared, and compliant with MDR in the EU. It meets strict safety and quality standards.

Q2: Who can use Rosi?

A: Rosi is designed for those experiencing “pain on those days.” Suitable for most women. Consult a doctor if pregnant, undergoing fertility treatment, or with existing medical conditions.

Q3: Are there side effects?

A: Rosi and its Butterfly Pads are tested for skin safety. Discontinue if skin irritation occurs.

Q4: Are there usage restrictions?

A: Yes. Do not use if you have a pacemaker, cancerous skin lesions, or open/infected skin.

Q5: How do I set up Rosi?

A: Charge using the Type-C cable. Attach the pad to the lower abdomen or painful area. Turn on Rosi and select the desired intensity.

Q6: How long can I use it?

A: Use Rosi multiple times a day as needed. Each session can be 30 or 60 minutes.

Q7: How do I clean and store it?

A: Wipe the pad with a damp cloth. Store both device and pad in the provided pouch.

Q8: Can I use it while moving?

A: Yes. Rosi is portable and cordless, allowing freedom of movement.

Q9: Can I use it in public?

A: Yes. It's compact, lightweight, and discreet.

Q10: What if it won't turn on?

A: Ensure the device is charged. If not responding, press and hold the power button for 10 seconds to reset. Contact support if issue persists.

Q11: What if the pads won't stick?

A: Make sure skin and pads are clean and dry.
Replace pads if adhesion has weakened over time.

Q12: What if I don't feel relief?

A: Ensure correct pad placement and increase intensity level. If no improvement, contact customer support.

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