



NerveCube



RSWT

Radial
Shockwave
Therapy



FSWT

Focus
Shockwave



VIBE

Vibration
Therapy



ULTRA

Ultrasound
Therapy

C A U T I O N S & W A R N I N G S

Content

Nerve Cube (FSWT + RSWT + Vibration + Ultrasound) — Cautions & Warnings	1
Safety alert conventions	1
Safety symbols and labels	1
Intended use, users, and operating environment	2
Contraindications, warnings, and precautions	3
Modality-specific safety	4
Focused and radial shockwave (FSWT / RSWT)	4
Mechanical vibration	4
Therapeutic ultrasound	5
Electrical, installation, and environmental safety	5
Setup and operation	6
Safety during treatment and patient monitoring	6
Emergency procedures	6
Maintenance and service safety	7
Handpiece cleaning (shockwave / vibration)	7
General maintenance	7
Residual risk	8

CAUTIONS & WARNINGS

Nerve Cube (FSWT + RSWT + Vibration + Ultrasound) — Cautions & Warnings

Read this packet before installing, operating, cleaning, or servicing the Nerve Cube. Keep it with the device and available to all users at all times.

This packet consolidates the essential safety information for the Nerve Cube (FSWT + RSWT + Vibration + Ultrasound) — the product configuration delivering focused (FSWT) and radial (RSWT) extracorporeal shockwave, mechanical vibration, and therapeutic ultrasound therapy. Not every device is configured with every modality; apply the sections relevant to your configuration. For full operating instructions, refer to the Nerve Cube (FSWT + RSWT + Vibration + Ultrasound) user manual.

Safety alert conventions

Safety messages use standardized signal words. Understand them before operating the device:

Signal word	Meaning
DANGER	Imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
NOTICE	Practice not related to personal injury, but which could result in equipment damage or loss of data.
NOTE	Additional information to help operate the device effectively.

WARNING!

WARNING — Incorrect handling of the device. Risk of injury to the patient and the operating personnel.

- Read this packet, and the complete user manual, before using the Nerve Cube.
- Read the separate operating manuals for all applicators and devices used with the Nerve Cube.
- Use the device only for its intended purpose and only as described in the manual.

Safety symbols and labels

Symbols appear on the device rating plate, on the applicators, and throughout the manuals. Become familiar with them before use.



CAUTIONS & WARNINGS

Symbol	Reference	Meaning
	ISO 7010 / 15223-1	Consult the instructions for use before operating.
(type BF applied part)	IEC 60601-1	Degree of protection of the applied part.
(manufacturer)	ISO 15223-1	Manufacturer name and address.
(CE / UDI / type rating)	MDR / IEC 60601-1	Conformity mark, unique device identifier, and electrical type rating.

Intended use, users, and operating environment

Intended use. In general terms, the Nerve Cube (FSWT + RSWT + Vibration + Ultrasound) is a combination physiotherapy system delivering focused (FSWT) and radial (RSWT) extracorporeal shockwave therapy, mechanical vibration therapy, and therapeutic ultrasound for the treatment of musculoskeletal pain and the support of tissue repair.

Intended users. The device is for use **only by trained, qualified healthcare professionals** who have read the manual and are competent in the applied therapies. It is not for lay or unsupervised use.

Operating environment. The device is intended for use in a professional healthcare facility. It is not intended for home use, and not for use in the patient environment of life-support equipment.

To ensure the device is used in accordance with its intended use, the operator must have the necessary technical proficiency and knowledge of the manual. All status and fault messages signalled during treatment must be attended to without delay.

Checks and inspections prior to treatment

Always confirm the device is functioning safely before each use:

- Check device functions and indicators before starting treatment.
- Inspect each applicator, handpiece, and cable for damage: check whether any cable is loose, whether cable insulation is cracked, whether a handle shell is cracked, and whether the display functions normally. Do not use damaged components.
- Have the maintenance procedures recommended by the manufacturer carried out only by suitably authorized personnel.



CAUTIONS & WARNINGS

Contraindications, warnings, and precautions

WARNING!

WARNING — Do not begin treatment if any contraindication applies. Screen every patient before treatment. Treating a contraindicated patient can cause serious harm. When in doubt, do not treat, and consult the responsible physician.

Contraindications (do not treat)

Contraindication	Reason
Pregnancy	Potential unknown effects on fetal development
Malignant tumors / cancer	Risk of stimulating tumor growth or metastasis
Active infection or open wound	May worsen infection or delay healing
Blood clotting disorders / anticoagulant use	Increased risk of internal bleeding or hematoma
Use over growth plates (children)	May affect bone development in growing individuals
Treatment over lungs or brain	Risk of tissue damage or complications
Presence of pacemaker or defibrillator	Risk of device interference or malfunction
Severe peripheral neuropathy or numbness	Patient may not perceive pain/discomfort (higher risk)
Acute inflammation (uncontrolled)	May aggravate inflammatory response

Precautions (treat only with additional care / physician guidance)

Precaution	Recommendation
Bony prominences or thin soft-tissue areas	Use lower energy settings to avoid bruising or pain
Metal implants near the treatment site	Avoid direct application over implants unless medically necessary
Low pain tolerance or anxiety	Start with low energy, monitor closely, explain the sensation beforehand
Treating near critical structures (nerves, vessels)	Ensure precise targeting and proper energy settings
Over tattoos or scar tissue	May cause discomfort — test with lower energy first
Recent corticosteroid injection	Delay treatment to avoid tissue fragility or delayed healing
Previous adverse reaction to shock wave therapy	Reassess risk–benefit and consider alternative modalities

Post-treatment. Mild soreness or redness of the treated area is common and usually resolves within **24–48 hours**; advise the patient accordingly.

CAUTIONS & WARNINGS

Modality-specific safety

Apply the subsections below that correspond to the modalities in your device configuration.

Focused and radial shockwave (FSWT / RSWT)

WARNING!

WARNING — High-energy acoustic pulses. Focused and radial shockwaves deliver concentrated mechanical energy into tissue and can cause bruising, petechiae, hematoma, and transient pain.

- Do not apply shockwaves over the **lungs, gas-filled organs (gut), the brain or skull, the spine over the spinal cord, large blood vessels, or major nerve trunks.**
- Do not treat over **growth plates** in children/adolescents, over **malignancy, active infection, open wounds, or recent thrombosis**, or in patients with **coagulation disorders or on anticoagulants.**
- Set energy to a level the patient tolerates; do not exceed the conventional treatment time and impact intensity.

Applicator handling (device-specific). The machine uses changeable applicators. Before starting the machine, the applicator **MUST BE** attached to the device firmly. **If no applicator is attached and the machine is started, the energy has no way to release and will burn the circuit board.** This misuse-caused failure **WILL NOT** be covered by the warranty.

- When the machine is powered on, do **not** install the shockwave applicator and do **not** remove handles from their outlets.
- Never insert metal into the output port.
- A **gel medium must be used** during treatment so energy penetrates stably and deeply into the treatment area. Without gel, output power is reduced by ~30%.



Consult your sales representative for video guidance on installing and changing applicators.

Mechanical vibration

WARNING!

WARNING — Mechanical vibration. Apply the vibration handpiece only to soft tissue at a comfortable intensity.

- Avoid bony prominences and thin soft-tissue areas.
- Some patients (e.g. those with paralysis or impaired sensation) may not be able to judge the degree of stimulation themselves; take care to prevent excessive stimulation.



CAUTIONS & WARNINGS

Therapeutic ultrasound

WARNING!

WARNING — Therapeutic ultrasound. Ultrasound deposits heat in tissue and can cause burns if misapplied.

- Do not apply ultrasound over the **eyes, the gravid uterus, growth plates, ischaemic tissue, the heart, or over malignancy.**
- Keep the ultrasound applicator **moving** during treatment to avoid localized hot spots, and use an appropriate coupling gel.

Electrical, installation, and environmental safety

WARNING!

WARNING — Electrical hazard. Improper connection or damaged cabling can cause electric shock or fire.

- Connect only to a correctly earthed (protective-earth) mains supply matching the device rating.
- Do not use the device with a damaged power cord, plug, or applicator cable.
- Do not open the housing. There are no user-serviceable parts inside.

Protection against electrical hazards

Disconnect the Nerve Cube from the mains before any cleaning or maintenance.

- Do not reconnect it until it has been completely reassembled.
- Ensure there is no damage to any applicator or applicator cable.

- Make absolutely sure that no liquid can seep into the system housing or applicators.
- Operate and store the device only within the specified environmental limits.
- This device requires special EMC precautions; keep portable RF communications equipment away from it per the EMC tables.

Water system (focused-shockwave configurations)

Because the machine uses a water system for focused shockwave, distilled or purified water must be filled into the machine when the device is first received. For maintenance, change the water every month. Consult your sales representative for video guidance on adding and changing water.

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CAUTIONS & WARNINGS

Setup and operation

- Before starting, confirm the correct applicator is **firmly attached** (see *Warnings by Therapy* → *Focused and radial shockwave*) and that the water system is filled.
- For focused shockwave, adjust the water level in the water bag: press the water bag appropriately to balance water pressure, ensuring stable energy output and deep penetration. After treatment, lower the water level and confirm it is stable before turning off the machine.
- Ensure the focused/radial shockwave or mechanical-vibration handpiece makes contact with the patient's skin **before** initiating treatment, to avoid impacting without force and causing abrasion.
- Explain the whole treatment process to the patient, and instruct the patient to give feedback immediately if there is any discomfort.
- Confirm that all setting parameters meet the requirements before treatment starts.
- Keep the ventilation slits uncovered, and **never cover the device when in use**.
- Position the device so the mains plug and **emergency stop remain accessible** at all times.
- The interval between turning the power switch off and on again must be at least **3 seconds**.

Safety during treatment and patient monitoring

Treatment can give rise to undesirable reactions. The patient must be continuously observed during treatment, and the operator must respond to any reaction the patient experiences. **The patient must not be under anaesthetic** and must be able to perceive and report discomfort.

- Keep the output at an intensity level the patient finds comfortable.
- Some patients (e.g. with paralysis or impaired sensation) may not be able to judge the degree of stimulation; take care to prevent excessive stimulation.
- Do not exceed the conventional treatment time and impact intensity.
- Do **not** disconnect the control handle during treatment.
- Stop treatment immediately if the patient reports pain, excessive heat, or any adverse reaction, or if a device fault is signalled or any defect is suspected.

Emergency procedures

In an emergency (adverse patient reaction, smoke, abnormal noise, fluid ingress, or any device malfunction):

1. **Stop emission** — release the handpiece trigger and press the emergency stop / power off.
2. Disconnect the device from the mains if it is safe to do so.
3. Attend to the patient and provide care as clinically indicated.
4. Take the device out of service, label it, and contact authorized service.



RSWT



FSWT



VIBE



ULTRA

CAUTIONS & WARNINGS

- Report any serious incident to the manufacturer and the competent authority as required by local regulation.

Maintenance and service safety

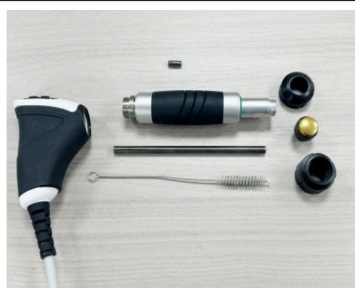
Proper maintenance is essential to ensure optimal performance, user safety, and extended equipment lifespan. Disconnect the device from the mains before any maintenance, and refer all internal repairs to certified technicians.

Handpiece cleaning (shockwave / vibration)

After treatment, clean the **radial shockwave handle or mechanical vibration handle** promptly to avoid residual gel corrosion and impact debris from clogging the handle and affecting its normal operation. Contact your sales representative for video guidance.



- | | |
|---|--|
| 1 | Cleaning work head — avoid gel corrosion leading to rust |
|---|--|



- | | |
|---|--|
| 1 | Clean the bullet |
| 2 | Use a cleaning brush to clean the inner tube |



General maintenance

- Change the water-system water every month (see *Electrical & Environmental* → *Water system*).
- After use, turn off the power and clean the equipment and treatment probes.
- Maintain at least a 3-second interval between turning the power switch off and on again.



CAUTIONS & WARNINGS

Residual risk

Even when the device is used as intended and all instructions are followed, residual risks remain — for example bruising, petechiae, or transient pain from shockwave therapy, thermal effects from ultrasound, or unexpected patient reactions. Use the device only when the clinical benefit outweighs these risks, keep the patient under observation, and report any serious incident to the manufacturer and the competent authority.