



NerveCube



PMST

Pulsed
Magnetic
Therapy



HILT

High
Intensity
Laser



LLLT

Low Level
Laser



IFC

Electrotherapy

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

Content

Nerve Cube (MAGNETO + HILT + LLLT) — 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	3
Pulsed magnetic field (PMST / Magneto)	4
Laser safety (HILT and LLLT)	4
Electrotherapy and ultrasound (Control Unit)	4
Electrical, installation, and environmental safety	5
Setup and operation	5
Safety during treatment and patient monitoring	6
Emergency procedures	6
Maintenance and service safety	6
Laser maintenance (HILT / LLLT)	6
General user-maintenance scope	7
Residual risk	8

CAUTIONS & WARNINGS

Nerve Cube (MAGNETO + HILT + LLLT) — 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 (MAGNETO + HILT + LLLT) — the product configuration delivering pulsed magnetic field (PMST / Magneto), high-intensity laser (HILT), and low-level laser (LLLT) therapy, plus the Control Unit's electrotherapy (IFC / TENS) functions. Not every device is configured with every modality; apply the sections relevant to your configuration. For full operating instructions, refer to the Nerve Cube (MAGNETO + HILT + LLLT) 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 devices and applicators 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.
(laser hazard)	IEC 60825-1	Laser radiation — avoid eye and skin exposure.
(strong magnetic field / no pacemaker)	ISO 7010	Strong magnetic field — keep persons with active implants clear.
(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 (MAGNETO + HILT + LLLT) is a combination physiotherapy system delivering high-intensity pulsed magnetic field (PMST / Magneto), high-intensity laser (HILT), and low-level laser (LLLT) therapy 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 the aiming/indicator systems before starting treatment.
- Inspect the applicator, handpiece, fibre, and cables for damage; 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	Applies to
Active implanted electronic devices (pacemaker, ICD, neurostimulator, cochlear implant, infusion pump)	Magnetic / electrotherapy
Pregnancy, or treatment over the gravid uterus	All modalities
Active or suspected malignancy in the treatment area	All modalities
Active haemorrhage, or anticoagulant-related bleeding risk in the area	All modalities
Direct treatment over the eyes, or laser exposure to the eye	Laser (HILT/LLLT)
Treatment over an active infection, open wound, or recent thrombosis	All modalities
Photosensitivity, or use of photosensitizing medication	Laser

Precautions (treat only with additional care / physician guidance)

Precaution	Reason
Impaired skin sensation or inability to report discomfort	Patient cannot signal overheating/pain
Ferromagnetic or metallic implants in the treatment area	Heating / movement in magnetic field
Epilepsy, cardiac disease, or fever	Systemic reaction risk
Tattoos or heavily pigmented skin in the laser field	Excess heat absorption / burn risk
Paediatric patients, or treatment over growth plates	Developing tissue

Modality-specific safety

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



PMST



HILT



LLLT



IFC

CAUTIONS & WARNINGS

Pulsed magnetic field (PMST / Magneto)

WARNING!

WARNING — Strong pulsed magnetic field. The magnetic applicator generates a strong field that can interfere with active implants and accelerate or heat ferromagnetic objects.

- Keep persons with pacemakers or other active/electronic implants at least **1 metre** from the applicator, including operators and bystanders.
- Before treatment, ensure all metallic objects (rings, chains, watches, glasses, keys, belts, phones, hearing aids) are removed from the patient and the treatment field.
- Keep magnetic-sensitive items (credit/ID cards, mechanical watches, storage media) away from the applicator.
- Do not treat over metallic or ferromagnetic implants.

Laser safety (HILT and LLLT)

WARNING!

DANGER — Laser radiation. Avoid eye and skin exposure to the beam. The Nerve Cube emits high-power (HILT) and low-level (LLLT) laser radiation, including invisible wavelengths. Class 4 laser radiation can cause instant, permanent eye injury and skin burns, and can ignite flammable materials.

- **Protective eyewear is mandatory** for the operator, the patient, and everyone in the treatment room, whenever the laser is armed. Eyewear must match the device wavelengths and provide the required optical density.
- Operate the laser only inside a designated **laser controlled area**. Post the required laser-warning sign at every entrance and restrict access while the laser is armed.
- Remove or cover reflective surfaces, mirrors, jewellery, and polished instruments in the beam path. Use matte/anodized instruments where possible.
- **Fire hazard:** never aim at, or operate near, flammable materials, gauze, alcohol-based skin preps, or oxygen-enriched atmospheres. Allow prep solutions to dry fully before use.
- Never look into the beam or the aiming beam, and never point the handpiece at anyone except at the intended treatment site. Keep the device in **standby** whenever the beam is not being delivered.
- Inspect the fibre, handpiece, and optical lens before each use; a damaged or contaminated lens can cause hazardous backscatter (see **Maintenance**).
- Use the key control / interlock to prevent unauthorized emission.

Electrotherapy and ultrasound (Control Unit)

When the Control Unit's electrotherapy (TENS / IFC) or therapeutic ultrasound functions are used:



PMST



HILT



LLLT



IFC

CAUTIONS & WARNINGS

- Do not place electrodes transthoracically (across the chest), over the carotid sinus, over the eyes, or over broken/irritated skin.
- Do not use electrical stimulation on patients with active implanted stimulators without physician approval.
- Do not apply ultrasound over the eyes, reproductive organs, the gravid uterus, growth plates, or ischaemic tissue.

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 the applicator or the 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.

Setup and operation

The applicator must not rest on the Nerve Cube during operation.

- Maintain a safety distance of at least **30 cm** between the Nerve Cube and the applicator; otherwise the device could be damaged.
- When treatment is not taking place, place the applicator in the holder on the housing or in the cradle on the holding arm.
- Keep the ventilation slits uncovered, and **never cover the device when in use.**
- Check that the device is in perfect working order before each use.
- Position the device so the mains plug and **emergency stop remain accessible** at all times.



CAUTIONS & WARNINGS

Safety during treatment and patient monitoring

Pulses 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.

- The operator is responsible for correctly positioning the applicator and selecting the correct treatment zone.
- Brief the patient before treatment on normal sensations and on how to signal discomfort; keep communication open throughout.
- Stop treatment immediately if the patient reports pain, excessive heat, or any adverse reaction, or if a device fault is signalled.

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.
5. 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.

Laser maintenance (HILT / LLLT)



CAUTIONS & WARNINGS

Operational prohibitions

Item	Description	Notes
Unauthorized disassembly	✗ Do not disassemble or modify the device	May void warranty and cause safety hazards
Fiber-optic cable handling	✗ Do not bend, compress, step on, or pull the fiber	Minimum bending radius 5 cm (2 inches)
Hand-piece connection	✗ Do not insert or remove while powered on	Always turn power OFF before connecting or removing the hand piece

Optical-lens maintenance

Step	Action	Guidelines
Pre-treatment inspection	✓ Visually check for dust, smudges, or cracks	Ensure the lens is clean and clear before each use
Cleaning procedure	✓ Gently wipe with a soft, lint-free cloth	Do not press hard; clean only if contamination is visible
Strict prohibitions	✗ No bare-hand contact; ✗ no abrasive materials (paper towels, clothing); ✗ no unauthorized alcohol use	Follow only approved cleaning protocols

A dirty or damaged lens creates heat points that can crack the lens, can cause **hazardous backscatter** (dangerous energy reflection), and weakens or scatters the beam, compromising results.

TIP:

Inspect the lens monthly for micro-fractures or surface damage. Power off the device before cleaning.

General user-maintenance scope

Task	User responsibility	Remarks
Daily cleaning	✓ Wipe exterior, hand piece, and touchscreen	Use a soft cloth or alcohol-free disinfectant wipes
Basic checks	✓ Inspect cables, connectors, and plugs	Before each use
Troubleshooting	✓ Follow guided steps from support engineers	For basic errors only
Internal repairs	✗ Not allowed	To be handled by certified technicians only



CAUTIONS & WARNINGS

Residual risk

Even when the device is used as intended and all instructions are followed, residual risks remain — for example thermal effects from laser or magnetic therapy, 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.