

**SKANLAB NG PRO
Information Booklet
English**



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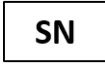
CE 2460


INTENDED USE AND INTENDED USER

The Skanolab NG Pro is a system intended to perform Long-Wave Deep Heat Therapy (LWDHT).

The Skanolab NG Pro is intended to be used, and shall ONLY be used, by or under the supervision of professional users in the field of physical medicine and rehabilitation.

- ❗ It is important to read the following instructions carefully before using your Skanolab NG Pro properly and safely. The manufacturer cannot be held responsible for the results of using this device for any purposes other than described in these operating instructions.
- ❗ If the use of this device may have caused or contributed to an undesirable event such as death or serious injury to the user, the manufacturer AND the Competent Authority of the Member State MUST be notified immediately!
- ❗ In case of damage from transport is noticed, contact your local distributor. DO NOT USE the device!

Symbol used	Description
	Follow the instructions in the Instructions for Use. It is important that you read, understand and observe the precautionary and operating instructions
	General Prohibition Sign. Prohibition is used to mean "You MUST NOT..."
	Warning or Caution: Indicates a hazardous situation which, if not avoided, could result in: <ul style="list-style-type: none"> a. Death or serious injury to the patient (or) b. Minor to moderate injury to the patient (or) c. Damage to the equipment
	General mandatory action sign. Mandatory action is used to mean, "You must..."
	Type BF Applied part Indicates devices that have conductive contact with the patient, or having medium or long-term contact with the patient.
	Temperature Range Indicates acceptable temperature range
	Humidity Limits Indicates acceptable relative humidity
	Atmospheric Pressure Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Waste electrical items that can be recycled
	Keep the device dry
	Manufacturer name and address
	Reference Number or Part Number
	Indicates the serial number so that a specific medical device can be identified.

Symbol used	Description
	CE Mark along with number indicates conformity with European Council of directive concerning Medical Devices and this device is under the direct supervision of the Notified Body.

General information on contraindications

- ! Only for use on adults
- ! Remove patient's hearing aid(s) before treatment.

Skanolab NG Pro should not be used for:

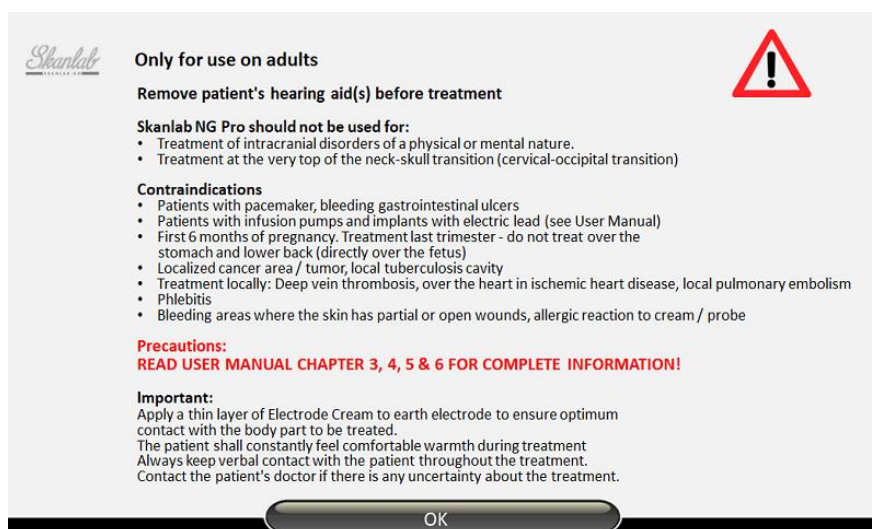
- ⊘ Treatment of intracranial disorders of a physical or mental nature.
- ⊘ Treatment at the very top of the neck-skull transition (cervical-occipital transition)

Contraindications

- ⊘ Patients with pacemaker
- ⊘ Patients with bleeding gastrointestinal ulcers
- ⊘ Patients with an infusion pump with electric lead (see user manual)
- ⊘ First 6 months of pregnancy. Treatment last trimester - do not treat over the stomach and lower back (directly over the fetus)
- ⊘ Treatment over localized cancer area / tumor
- ⊘ Treatment over local tuberculosis cavity
- ⊘ Allergic reaction to cream / probe
- ⊘ Treatment of deep vein thrombosis
- ⊘ Treatment over the heart in patients with ischemic heart disease
- ⊘ Phlebitis
- ⊘ Bleeding areas where the skin has partial or open wounds

Precautions

- ⚠ Patients with impaired skin / neuropathy sensitivity. Avoid treatment in patients with reduced skin sensibility in the area to be treated, unless the treatment is specifically recommended by the patient's physician. If the treatment is to be used, test on the corresponding fresh body part. This is to avoid tissue overheating.
- ⚠ Patients with a bacteriological inflammation (can treat around the area)
- ⚠ Diabetes mellitus: Patients with diabetes can often have neuropathy (see above)
- ⚠ Other conditions with reduced skin sensation:
 - Patients coming in from the cold
 - Post-operative patients



Screenshot on Skanolab NG Pro after startup

- ❗ The Skanlab Pro NG Pro should only be connected to an approved electrical installation, with a grounded plug.
- ❗ Make sure the electrode cables are firmly seated in the connectors on the device itself. Screw the mounting ring of the connector of the treatment probe cable into the connector on the right side of the device. Plug ground electrode (metal rod) fully into the connector on the right side of the device.
- ❗ Make sure the ground electrode cable is fully seated inside the ground electrode itself (metal rod).
- ❗ If you need to remove the cable from the ground electrode, or from the treatment probe: First turn off the power to the device and then unplug the plug from the wall.
- ❗ Never pull directly the cables themselves to pull them out of the electrodes or device. Then you can damage the electrical inner wire and the device might not work. Always pull out wires by grasping the contacts themselves and pulling gently.
- ⚠ The device must not be used in so-called hydrotherapy rooms (wet rooms)
- ❗ Always apply a little cream to the earth electrode, but be more generous in the treatment area. Use only **Skanlab Therapy Cream**, as this has been developed for this device. Other type of cream may cause lack of effect / cause harm to the patient.
- ❗ Communicate with the patient during treatment, and encourage the patient to notify if the heat becomes uncomfortable. Then the strength is reduced 1-2 steps.
- ⚠ Avoid touching the patient during treatment. The patient can then feel for a moment a slightly stinging local feeling.

Location of Skanlab NG Pro

- ❗ Place the device on a firm, flat and stable surface
- ⚠ Do not use the device near a heat source, eg. heat radiator.
- ⚠ Avoid direct sunlight, rain, dust accumulation, moisture, mechanical vibration and hard mechanical shock.
- ⚠ Make sure that water and moisture do not enter the device (if necessary, cover the equipment with a waterproof plastic). Should water still come into the device itself, unplug the device (if connected) and contact Skanlab AS immediately.

Connection

- ❗ Main electric power supply must comply with national requirements for approved electrical installations.
- ❗ Place the Skanlab NG Pro so that it is easy to reach the ON / OFF switch on the back of the unit
- ❗ Before connecting this device to the power supply, check that the voltage and frequency specified on the rating plate on the back of the device match the intended power supply.

IMPORTANT INFORMATION

Only the manufacturer's approved power cable (power cable) must be used.

Only the manufacturer's approved electrode cables must be used.

Only the manufacturer's approved parts defined as the floating earth electrode and the treatment electrode must be used

NB! Connection of optional equipment not specified by Skanlab AS can endanger the patient and cause the device to malfunction.

IMPORTANT INFORMATION - TIPS AND WARNINGS BEFORE TREATMENT

- ⊘ *Always check the surface of the treatment electrode before treatment for damage, wounds or scratches. If there is damage or cracks in the special enamel paint, or black dots that cannot be removed, the treatment electrode must be replaced.*
- ❗ To avoid the risk of electric shock, this equipment must only be connected to the mains through an earthed socket.
- ❗ Prior to treatment, patients should be asked about their general state of health and screened against the list of contraindications.
- ⚠ Detected blood clots or disease history with the formation of thrombosis and / or embolization (blood clots) – only unaffected area should be treated. Blood clot can move due to local thermal effects. Confer with colleague or doctor
- ⚠ Bleeding disorders can be affected by increased heat and blood flow to treated areas. Extra attention in patients receiving anti-thrombotic medication such as warfarin and acetylsalicylic acid. Observe the treatment area. Confer with colleague or doctor
- ⚠ No matter what type of treatment, be sure to adopt a healthy and sensible approach. If you are uncertain, do not start without conferring a doctor, colleague, manufacturer or distributor with experience from the current injury.
- ⊘ Skanlab NG Pro is only for external treatment of muscles, tissues and connective tissues. It must not be used inside any body-openings.
- ⚠ Only touch the patient with the treatment probe during treatment. Do not touch the patient with your other hand as this may result in a change in electrical potential between the patient and the Skanlab NG Pro unit. This may result in a minor electrical shock to you and/or the patient.

- ⚠ Do not use in hydrotherapy rooms. Avoid contact with the electrodes and control unit with water during use.
- ⚠ Skanklab NG Pro treatment should be performed with direct contact between skin and electrode. Do not use on, or through, the patient's clothing.
- ⚠ The patient should not be in direct contact with materials that are grounded or materials that can act as a significant earth lead. It can cause undesirable paths to the high-frequency electric field. Examples are bed, bench or chairs that have metal frames, where the metal can come into direct contact with the patient's skin.
- ⚠ Avoid touching the cables themselves, either the treatment probe cable or ground cable, coming into direct contact with the patient, therapist, metal or other conductive / energy absorbing material.
- ⊘ Ensure that the insulation on the outside of the treatment probe and ground electrode cables are undamaged. Do not use damaged cables or probes.
- ⚠ During treatment, explain that the patient should feel comfortable warmth. Avoid excessive manual pressure with the treatment probe. That will feel uncomfortable.
- ⚠ Maintain verbal contact with the patient throughout the treatment. Do not leave the patient during treatment. Make sure you get feedback on how the patient feels throughout the treatment.
- ⚠ Local skin conditions may be irritated when using the probes, such as eczema or psoriasis. If this happens, do not treat the area directly.
- ⚠ Avoid treating a patient who has just come in from the cold. Wait until the patient has regained natural body temperature in the area to be treated.
- ⊘ When treating the upper back / neck, avoid the cervical occipital joint at the top of the columna. The head should not be treated.

EMC DETAILS:

- ⊘ Other equipment related to the patient must be removed before starting treatment, i.e. hearing aids, infusion pump, and likewise.
- ⊘ Do not use Skanklab NG Pro in a high-tech room with lots of advanced electrical equipment, eg. Intensive care unit in hospital. Electromagnetic radiation can affect critical care equipment.
- ⊘ The device must not be used in the vicinity (less than 2 m) of other electrotherapy devices in use. By using the device near (<2 meters) of short wave or microwave equipment, this can result in instability in the performance of Skanklab NG Pro.
- ⊘ Other electrotherapy / electrical devices should NOT be used simultaneously on the patient when treated with Skanklab NG Pro. It can cause electrical interference and result in electrode

burns.

- ⊘ To prevent electromagnetic interference, we strongly recommend the use of separate main power connection lines for Skanklab NG Pro and other therapeutic devices
- ⚠ Wireless phones should not be used near the machine.

PACKAGE CONTENTS

Below mentioned Standard Accessories will be contained in the main device packaging.

- 1 Skanklab NG Pro
- 1 cable for power supply connection
- 1 earth electrode (blank metal rod)
- 1 cable with connection ring to the device at one end, and to the ground electrode at the other end
- 1 treatment probe connected to cable
- 2 treatment electrodes
 - Ø 30 mm (connected to treatment probe)
 - Ø 23 mm
- 1 document that is the test certificate (please archive this)
- Silicone pad for use for storage between treatments of the electrodes
- 1 l Skanklab Therapy Cream
- Instructions for Use
- Information Booklet

Optional extras that can be purchased on order:

- Skanklab Therapy Cream, 1 l or 5 l
- See technical specifications in Instruction for Use for ordering replacement parts

ORDERING INFORMATION

The latest version (electronically or in print) of the User Manual / Treatment Manual can be downloaded free of charge from our website, <https://skanklab.no/>

or by calling:

Norway: +47 69 35 20 80

Sweden: 070- 0026434