SKANLAB NG PRO

User Manual

ver.15 - 2023 – English for Skanlab NG Pro

Made in Norway

CE 2460

Skanlab AS
Box 226
N-1601 Fredrikstad
Norway

Org.nr. 976079027MVA

Phone: +47 69 35 20 80
email: info@skanlab.no
www.skanlab.no

Table of content

CHAPTER 1. GENERAL INFORMATION

Congratulations on your new Skanlab NG Pro!

This is an electromedical device for use in treating patients with various types of acute or chronic ailments.

Take the time to read through this user manual to get to know your new device.

In order to satisfy the high quality and safety requirements of manufacturer, each device that leaves production has undergone a quality test.

In the delivery you will find a separate **test-certificate** that only applies to this specific device. Please do an extra quality check by checking that the serial number on the certificate corresponds to the serial number of the embossed sign on the back of the device. Take care of this certificate. It is a good reference for us if you have any questions regarding the product in the future

The device should only be used after reading this "Instructions for Use"

1.1 Unpacking

In the received box you will find the following:

- 1 Skanlab NG Pro
- 1 cable for power supply connection
- 1 patient circuit return-electrode steel rod with Ø4mm connector
- 1 cable with connection ring to the device at one end, and to the patient circuit return electrode at the other end
- 1 treatment probe connected to cable
- 1 treatment electrode
    - Ø 30 mm (connected to treatment probe)
- Silicone pad for use for storage of the electrodes between treatments
- 1 document that is the test certificate (please archive this)
- 1 Instructions for Use (This document)
- 1 Information Booklet on paper

Optional extras that can be purchased on order:

- Treatment electrode (Ø23mm) for treatment of smaller areas
- Electrode Cream, 1 l or 5 l
- See technical specifications for ordering replacement parts

CHAPTER 2 - INTRODUCTION

2.1 General Information

Skanlab NG Pro is a medical-technical device intended for the treatment of musculoskeletal problems. The device and treatment method were developed in Norway and was first introduced as Skanlab 25 Bodywave® in 1988. The Skanlab NG Pro is a system intended to perform Long-Wave Deep Heat Therapy (LWDHT) as a diathermy device. Specific applications include:

- Acceleration of soft tissue and muscle healing following injury.
- Control of pain, including joint pain.
- Acceleration of joint healing and arthritis.
- Improving muscle and soft tissue extensibility.

Skanlab NG Pro bases its operation on capacitive current. A capacitance is a physical-electrical property of 2 adjacent, isolated conductors (electrodes). Between these lies a dielectric (the capacitor). The energy is generated in an electric field that occurs between these two conductors. An electrode is used to transfer the energy of the signal into the human. Two capacitive electrodes are used to transfer the signal into the patient's body. One acts as the active electrode which passes the signal from the circuit into the human body while the other is the return electrode which collects the signal from the human body and passes it back to the circuit. The generated signal can be modulated in terms of amplitude, frequency or phase.

The body consists of several types of tissue that conduct the energy differently, and at different depths. Skanlab has documentation that the heat enters the tissue up to 4 cm, and the increased local temperature is maintained up to 40 min [1), 2), 3)]. Hence the term: **Deep heat treatment (Skanlab Deep Heat Therapy)**. The patient feels comfortable warmth during treatment.

The device produces an electrostatic alternating current field (capacitor current) of 500 kHz with a wavelength of 600m. Hence the name "Long Wave Treatment", as opposed to previously known "short wave treatment".

In the treatment, the patient is exposed to an electrostatic high frequency alternating current field. A capacitor's capacity is determined by:

- The size of the plate (here; the square area of the treatment electrode)
- The insulation material (here; the nature of the fabric, the electrode surface and the electrode cream).

Only Electrode Cream should be used!
After treatment, wash of the cream with mild soap and water!

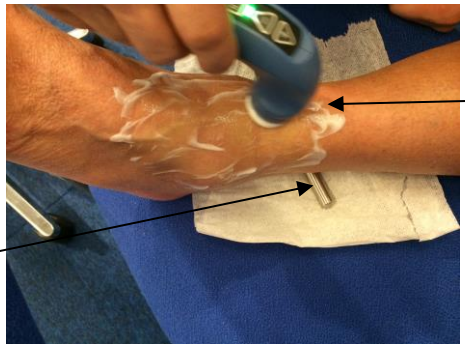
Apply cream to the site for the patient's return electrode and always secure that the patient circuit return electrode is placed first. You should ensure that a well vascularized muscle mass is chosen, and that you avoid areas of vascular insufficiency in irregular body contours and bony prominences. Secure that the patient's return electrode has continuous good contact with the skin during the whole treatment.
The treatment electrode shall easily and continuously be moved in circles (3-5 times diameter of electrode – before moving to new area), due to the concentrated energy transfer.
NB! Always communicate with patient during treatment.

Electrode selection is made depending on the scope of the treatment area and the size of the electrodes, which determines the heat output at the treatment site.

The patient should only feel nice comfortable warmth under the treatment electrode (handle).

You should choose Skanlab NG Pro when you want:

- To treat deep-seated areas and tissues
- To treat poorly-conductive areas, such as joints and deep-seated structures that you wish to be passively heated
- To reduce pain that may be crucial for further training



Skanlab NG Pro is for professional use and should only be used by healthcare professionals who have been trained in the use of the device.

Please contact our local representatives (or distributors) who will arrange product demonstration, education and practical training using **Skanlab NG Pro.**

References:

1) *Prof.dr.med.Kaare Rodahl, S. Mæhlum, H. Frøseth og O. Søvde* - Virkningen av behandling med Skanlab 25 Bodywave på den dype underhudstemperaturen
2) *Prof.dr.med. K.Rodahl, fysioterapeut og spesialist i manuell terapi H. Frøseth, prof.dr.med. S.Mæhlum, J.Meyer og R.Bjørklund* - Virkning av behandling av tennisalbu med Skanlab 25 Bodywave
3) H.*Frøseth, T.Eklund, L.D.Klilwer, T.Guthe, R.Bjørklund og K.Rodahl* - Måling av behandlingseffekt hos pasienter med epicondylitis radialis ("tennisalbu"),behandlet etter kondensator-metoden med Skanlab 25 Bodywave

CHAPTER 3 – CONTRAINDICATIONS

3.1 General information on contraindications

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

Skanlab NG Pro should not be used for:

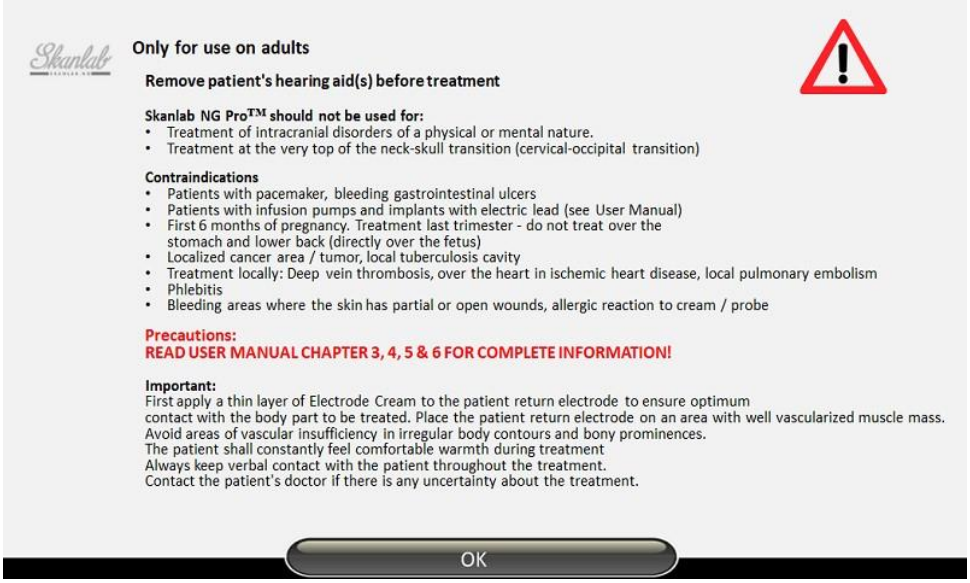
- Treatment of intracranial disorders of a physical or mental nature.
- Treatment at the very top of the neck-skull transition (cervical-occipital transition)

3.2 Contraindications

- Patients with pacemaker
- Patients with bleeding gastrointestinal ulcers
- Patients with an infusion pump and implants with electric lead
- 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

3.3 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 Skanlab NG Pro after startup

CHAPTER 4 - SAFETY

4.1 General introduction

It is important to read the instructions carefully before using Skanlab NG Pro. Please make sure the instructions are available to all users.

1. The Skanlab NG Pro should only be connected to an approved electrical installation, with a earth-grounded plug.

2. 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 patient circuit return electrode (metal steel rod) fully into the connector on the right side of the device.

3. Make sure the patient's return electrode cable is fully seated inside the return electrode itself (metal steel rod).

4. If you need to remove the cable from the return electrode, or from the treatment probe: First turn off the power to the device and then unplug the plug from the wall.

5. 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 and pulling gently.

6. 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 Skanlab NG Pro.

7. Other electrotherapy / electrical devices should NOT be used simultaneously on the patient when treated with Skanlab NG Pro. It can cause electrical interference and result in electrode burns.

8. To prevent electromagnetic interference, we strongly recommend the use of separate main power connection lines for Skanlab NG Pro and other therapeutic devices

9. The device must not be used in so-called hydrotherapy rooms (wet rooms)

10. Wireless phones should not be used near the machine.

11. Always first apply a little cream to the patient's return electrode, and place this, but be more generous in the treatment area. Use only **Electrode Cream**, as this has been developed for this device. Other type of cream may cause lack of effect / cause harm to the patient.

12. 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.

13. Avoid touching the patient during treatment. The patient can then feel for a moment a slightly stinging local feeling. If you need to touch the patient, hold a firm contact with your hand.

14. After treatment, wash off the cream with mild soap and water!

15. Skanlab Therapy Cream: avoid direct contact with eyes, if so – immediately rinse with water

CHAPTER 5 - INSTALLATION OF SKANLAB NG PRO

5.1 Location of Skanlab NG Pro.

- Place the device on a firm, flat and stable surface
- Do not use the device near a heat source, e.g., 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 Manufacturer or distributer immediately.

5.2 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 must be used.

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

Only the manufacturer's approved parts defined as the patient return electrode and the treatment electrode must be used

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

5.3 Startup / Self-test

All of the device's functions are automatically checked by a built-in microprocessor when the device is turned on using the on / off switch on the back of the device. Then the device runs a self-test. All the time the device is in use, the actual current at the output is automatically measured and compared to the specified requirement. If a fault in the current is detected, the power is switched off automatically.

- Use the ON / OFF switch on the back of the unit
- Immediately after the device is switched on, it automatically performs a self-test

5.4 Turn Off

- Use the main power switch on the back of the device to turn off the device
- Unplug the power cord

5.5 Calibration of touchscreen/display

All devices are individually calibrated several times during production and final testing. Due to transport of the device, the resistive display can be affected and the touch-screen might be difficult to pin-point the exact wished point on screen. End-user (therapist) can easily calibrate the display to standard. Please follow the description below if needed. This is seldom necessary.

<u>Alternative 1 – Please try this first</u>

Procedure for calibration of the Skanlab NG Pro display from the Touch screen:

The calibration of the display is done by the touch point calibration. This can be needed once in a while if the user experiences that pressing a certain point in one of the displays does not give wished response in display. This Alternative 1 can be used when the accuracy or differences in touch screen are small. If it is almost impossible to calibrate directly on touch screen display – please go to Alternative 2 – calibration by Remote handle.

1.Turn on the device and wait until it enters the main menu

2. Press «i» at the bottom of the menu screen

3. Press the picture of the wrench at the bottom of the display screen

3. You now see the numbers display for entering code.

4. Enter the code 928 and press «OK»

5. You are now in the calibration menu.

6. Three points have appeared. The top left has a ring around it. Put your finger in the middle of the circle and press carefully until the circle moves to the next point. Then repeat the procedure until the circle has disappeared.

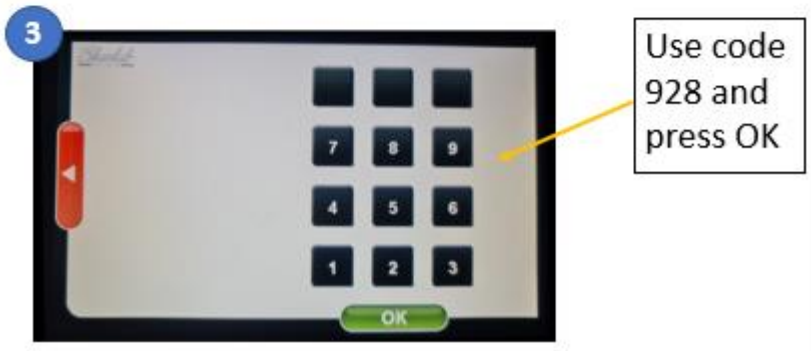
7. Exit the menu by pressing the arrow on the left of the display.
The display is now calibrated, but the accuracy depends on the accuracy of the calibration procedure.

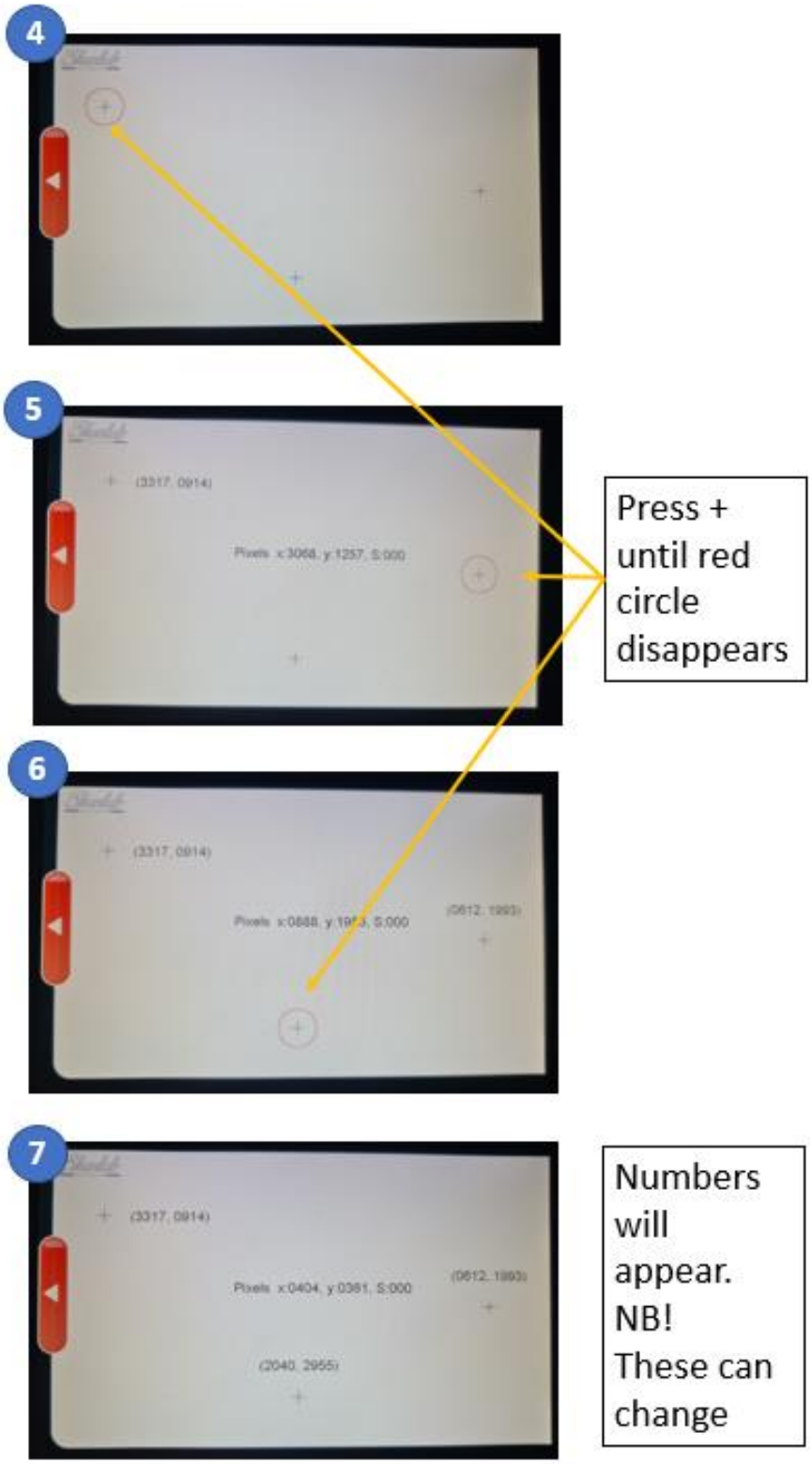
See pictures below.

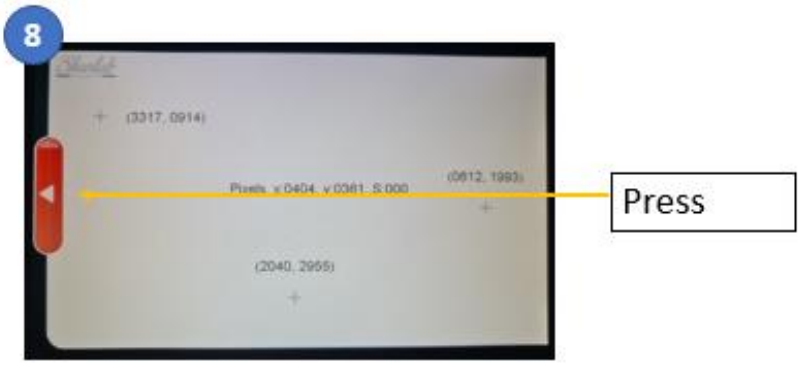
In some cases, it may be better to use the patient return electrode (steel bar) instead of the finger. It might be easier to touch in the middle of the circle.

HOW TO ADJUST TOUCH SCREEN

Skanlab NG Pro




4
5
(3317, 0914)
Pixels x:3068, y:1257, S:000
Press + until red circle disappears
6
(3317, 0914)
(0612, 1993)
7
(3317, 0914)
Pixels x:0404, y:0361, S:000
(0612, 1993)
(2040, 2955)
Numbers will appear. NB! These can change



<u>Alternative 2 – If not able to calibrate via display</u>

Procedure for calibration of the Skanlab NG Pro display from the remote handle:

This alternative is used if the accuracy of the touch points in the display are impossible to calibrate. Here you start out by using the remote handle to start up the calibration.

1.Turn on the device and wait until it enters the main menu

2. Press "+ and -" on the remote control at the same time and wait until there appears some numbers at the top of the display/screen. then release + and -, then press the start / pause button

3. You are now in the calibration menu.

4. Three points have appeared. The top left has a ring around it. Put your finger in the middle of the circle and press carefully until the circle moves to the next point. Then repeat the procedure until the circle has disappeared.

5. Exit the menu by pressing the arrow on the left of the display.
The display is now calibrated, but the accuracy depends on the accuracy of the calibration procedure. See pictures above.

In some cases, it may be better to use the patient return electrode (steel rod) instead of the finger. It might be easier to touch in the middle of the circle.

CHAPTER 6. 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 in section 3.0.

⚠ 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 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. If you want to have physical contact, keep a firm contact with your hand over a longer period.

⚠ Do not use Skanlab 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.

⚠ Do not use in hydrotherapy rooms. Avoid contact with the electrodes and control unit with water during use.

⚠ Skanlab 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 patient circuit. Examples are bed, bench or chairs that have metal frames, where the metal can come into direct contact with the patient's skin.

⚠ Ensure that the insulation on the outside of the treatment probe and return electrode cables are undamaged. Do not use damaged cables or probes.

⚠ Always place the patient circuit return (the steel rod) first, together with cream, in contact with a well vascularized muscle mass, and avoid areas of vascular insufficiency in irregular body contours and bony prominences. Secure that the patient's return electrode has continuous good contact with the skin during the whole treatment. In many situations – it is convenient to let the patient hold the metal rod in a firm continuous grip in the hand. Remember Therapy crem.

⚠ 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.

⚠ Other equipment related to the patient must be removed before starting treatment, i.e. hearing aids, infusion pump, and likewise.

⚠ 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.

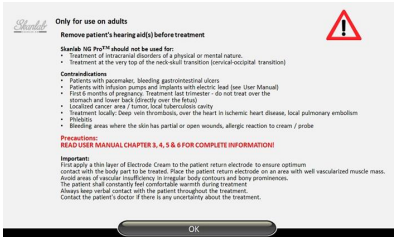
⚠ If the use of this device may have caused or contributed to an undesirable event such as death or serious injury to the user and/or the patient, the manufacturer AND the competent authority of the Member State MUST be notified immediately!

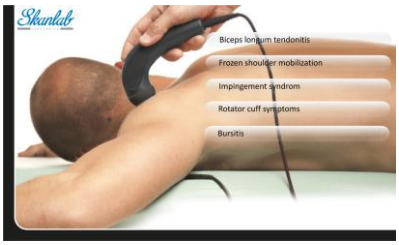
⚠ After treatment, wash of the cream with mild soap and water!

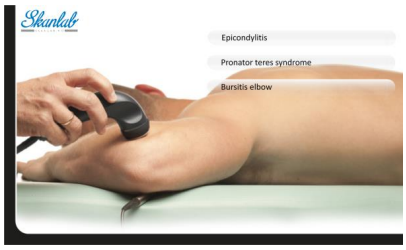
⚠ Skanlab Therapy Cream: avoid direct contact with eyes, if so – immediately rinse with water

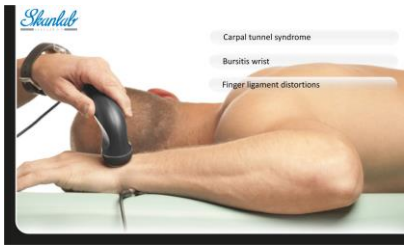
CHAPTER 7. SKANLAB NG PRO – OVERVIEW IMAGES

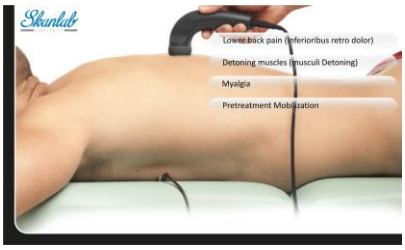
1. Picture 1: Start-up screen (during device self-test)
2. Picture 2: Select the language.
3. Picture 3: The most important contraindications and important information (read the User Manual for additional information)
4. Picture 4: Touch the red dots to select the area of the patient's body you want to treat
5. Figure 5-14: Select the condition you want to treat

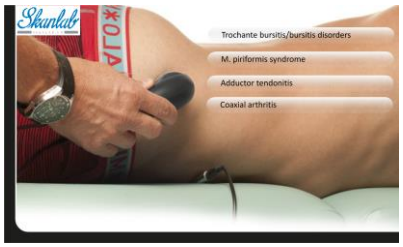


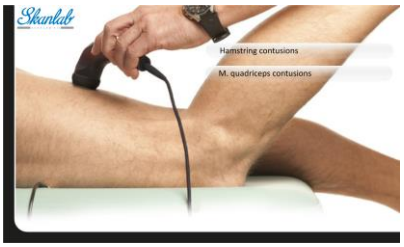


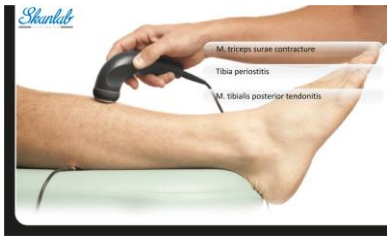




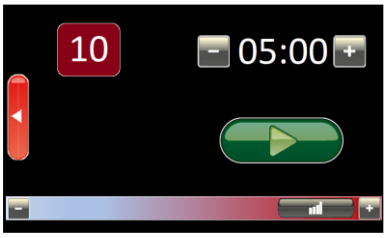


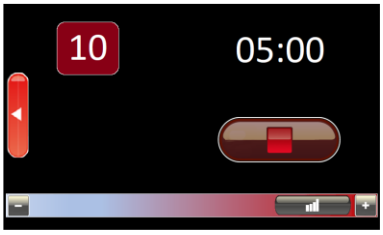




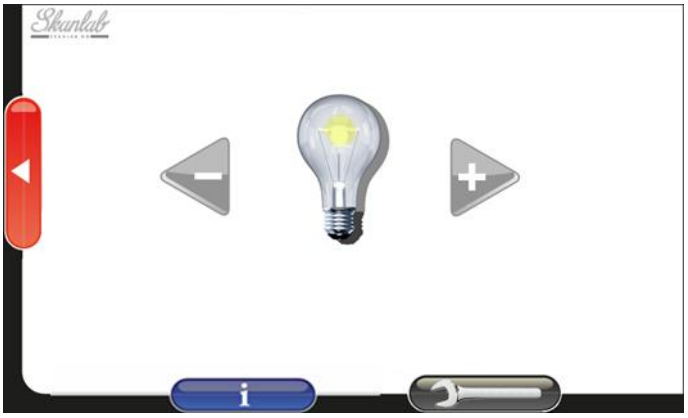


6. Once you have selected the condition you want to treat, you will be taken to the first image below. Skanlab NG Pro is ready to start treatment. You can now start the treatment by pressing the button on the treatment probe. You will see that timer is counting down. You can press the pause button / stop button at the treatment handle at any time. Likewise, you can adjust the strength up or down from the handle at any time.





7. There is a separate image for adjusting the brightness of the display on the device itself.



8. You can also make all adjustments during treatment by tapping the arrows on the display itself during processing.

9. If you want to use other than the predefined settings, you can choose manual settings yourself. However, this is only recommended when you are familiar with treatment with Skanlab NG Pro, and requires a close dialogue with the patient.

Remote treatment probe For adjusting the levels of effect (energy) + / - and ON/OFF w/indicator diode which lights up when active.

Patient circuit return electrode w/black cable

Main power switch ON/OFF marked with which fuse to be used.

Main power cable

Treatment electrode

Remote treatment handle with cable for adjusting level of energy +/-

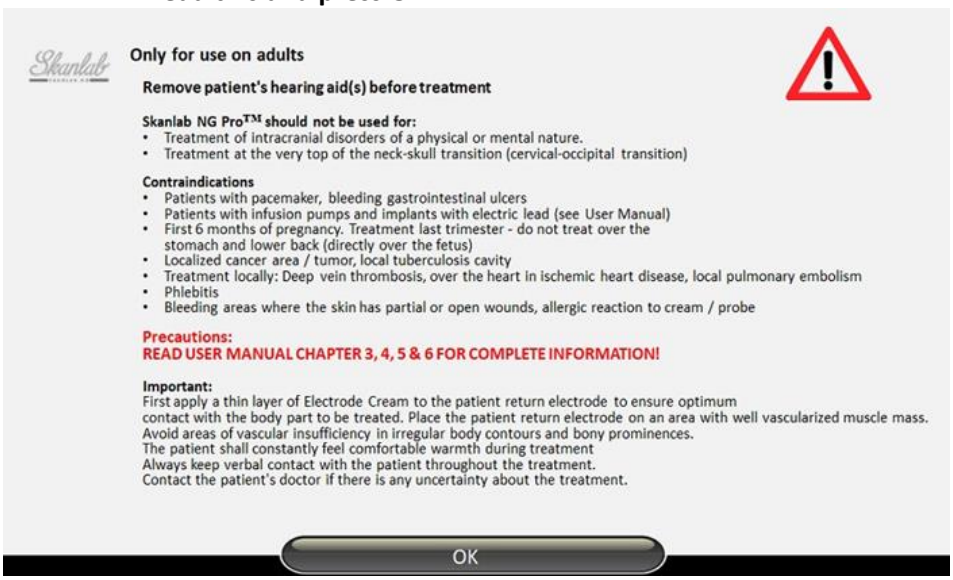
CHAPTER 8. STARTING UP OF TREATMENT

All information is clearly displayed on the display. Follow the instructions that appear

Remember:

- **Check the condition of the treatment probe surface for damage**
- **Keep verbal contact with the patient throughout the treatment.**
- **Avoid touching the patient's skin when treatment is started (See chapter 6)**
- **The patient should always only feel comfortable warmth (see also contraindications when it comes to, among other things, reduced skin sensitivity)**

Read this and press OK



NB! This picture does not show a complete list – see contraindications and precautions in this user manual!

The following overview appears in the display and you get 2 options:

A. **Predefined settings:** Predefined conditions with predefined strength and duration (can be adjusted manually during treatment)
B. **Manual Settings:** You as a therapist determine the strength and duration of the treatment itself.

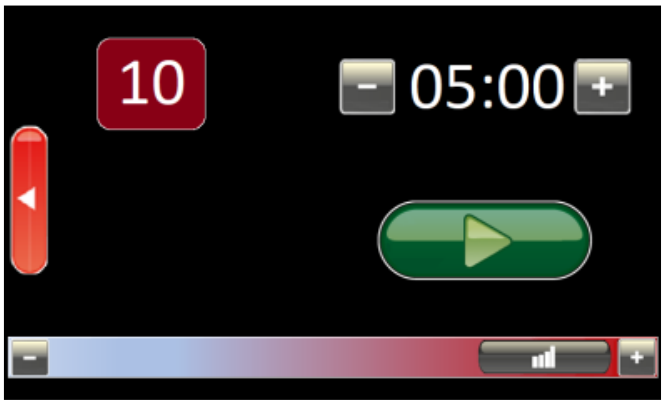
8.1 Predefined settings:

Press body part to treat i.e., knee. Then you come to the suggested conditions you can choose from. Select the condition you want to treat. Start treatment with the treatment probe. Remember to apply Electrode Cream to both electrodes.

8.2 Manual Settings:

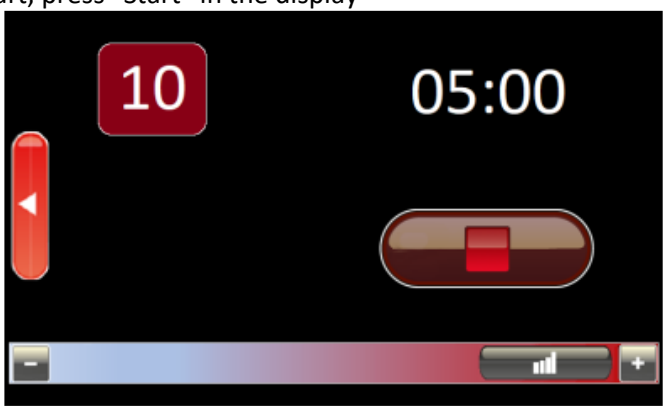
Press 

at the bottom of the patient image and you will go directly to the manual option. Choose time and strength and then start treatment from the treatment probe

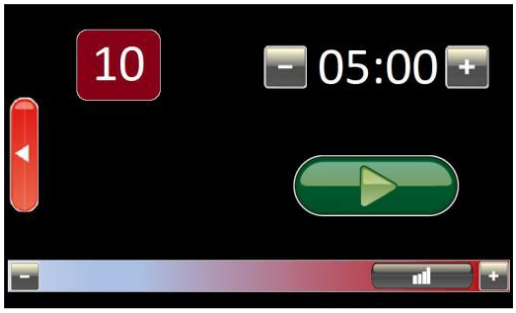


8.3 Pause

- Press STOP
- To restart, press “Start” in the display

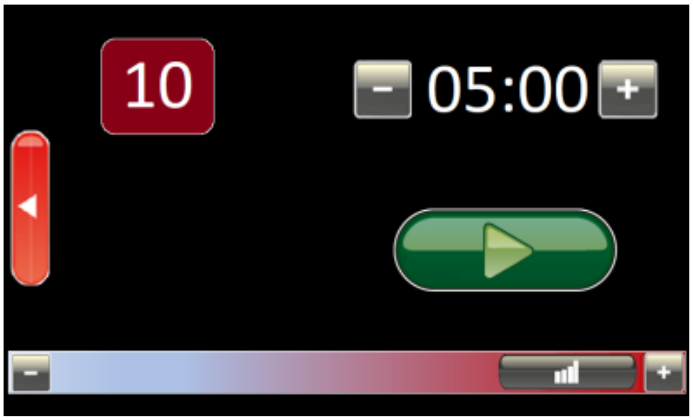


8.4 Adjusting strength level during treatment



a. Press + or - on the small buttons at each end of the scale at the bottom of the screen. The change happens in one step at a time. See change in display
b. Drag the slide icon itself toward + or - to change strength. See change in display
c. Adjust + or - on the treatment handle

8.5 Adjusting duration time of treatment

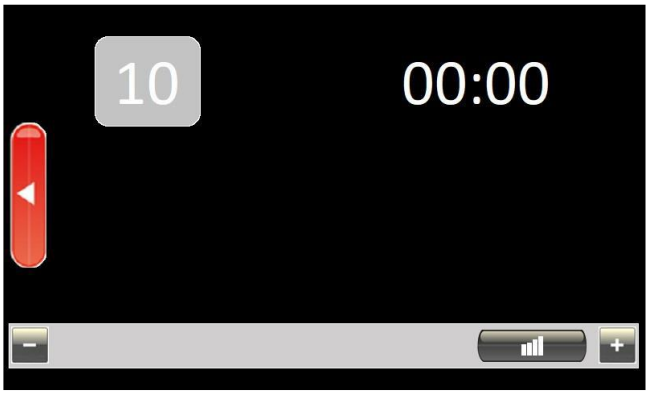


Press + or - next to mm: ss (here: 05:00)

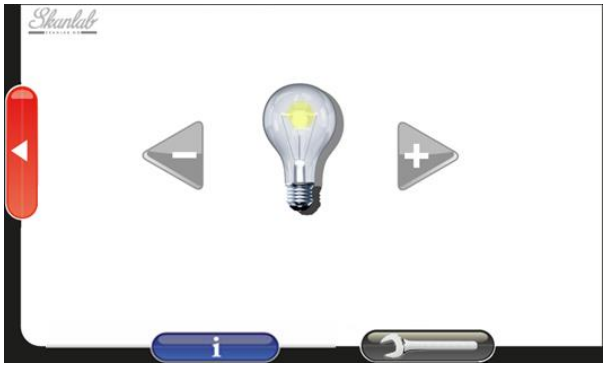
a. In manual mode, set the time before the treatment starts
b. For programs directly from the body part, the recommended time is used
c. Recommended time can be manually changed

8.6 Treatment time ended

The time is automatically counted down and you hear a signal when the treatment is over. The device can be prepared for the next patient.



8.7 Brightness Adjustment



Press “I” and you go to the next picture where you use + or - to adjust the "brightness"

CHAPTER 9. PRACTICAL INFORMATION ON ELECTRODES AND ELECTRODE CREAM

- Make an accurate palpation to get an impression of the extent of the injury
- Always place the patient circuit return (the steel rod) first, together with cream, in contact with a well vascularized muscle mass, and avoid areas of vascular insufficiency in irregular body contours and bony prominences. Secure that the patient's return electrode has continuous good contact with the skin during the whole treatment. If convenient, the patient can hold the steel rod in a firm grip in the hand. NB! Remember therapy cream
- Apply **Electrode Cream** to the treatment area

9.1 Treatment time

- The treatment time varies with the size of the injury area and the condition of the damage.
- It is rare to exceed 10 minutes, but sometimes there are large areas to be treated and then the time can be increased by treating 2 different areas with 8-10 minutes.
- The main principle is not less than 4 minutes.

9.2 Level of treatment

The strength varies from 1-10, with 10 being the highest level.
It may differ somewhat how therapists treat patients. The extent of the injury area and the thickness of the tissue, determines the energy level and treatment time. Sometimes you move the electrode faster in circular motion, which gives less energy per square centimeter per second and at other times you work slower, giving more energy per square centimeter per second. This means that the level of energy will vary.
We recommend working fairly slow, and then reducing the strength based on the patient's subjective heat feeling. However, if the patient experiences the treated area too hot, even at a low energy level, try increasing the speed to maintain the same strength as described in the condition chart below.

9.3 Electrodes

A. Use of patient's circuit return electrode (blank steel rod):

The patient's return electrode can be placed under body part when the patient is lying or sitting. If convenient, and the treatment character allows it, the patient can hold the return electrode in a firm grip in his/her hand. Important to inform that it must be held firmly during the whole treatment. Otherwise place the patient circuit return (the steel rod) together with cream, in contact with a well vascularized muscle mass, and avoid areas of vascular insufficiency in irregular body contours and bony prominences. Secure that the patient's return electrode has continuous good contact with the skin during the whole treatment.

- Always apply a thin layer of Electrode Cream to the patient return electrode

B. Use of treatment electrode:

- Choose treatment electrode that fits the treatment area / site.
- The treatment is done by working with a light pressure on the electrode. The treatment electrode is placed in the center of the treatment site and circulated several times for 3-5 times the diameter of the electrode selected, before moving to another nearby area.
- When the set processing time is over, the device automatically turns off the electrode current and the device is ready for the next treatment.
- Clean the electrodes after use (see section 10.3)

CHAPTER 10. MAINTENANCE AND CLEANING

10.1 Technical maintenance

Always check the surface of the treatment electrode, before use, for damage, wounds or scratches. If there is damage or cracks in the enamel paint, or black dots that cannot be removed, the treatment electrode must be replaced.

There is no requirement for frequent service intervals from the manufacturer, but we recommend that the device is checked annually. This can be done by the manufacturer, your dealer or by other authorized professionals approved by the manufacturer. It is recommended that you keep an overview of the services that are performed on the device for later maintenance. In some countries, this is mandatory.

Maintenance and all repairs must only be carried out by authorized service personnel. The manufacturer cannot be held responsible for the results of maintenance performed by unauthorized persons. It is not allowed for anyone other than the dealer, or his authorized professionals to open the device. Contact your local supplier or manufacturer directly

10.2 Cleaning the device

Turn off the device and remove the main electric socket from the wall before carrying out any cleaning. The appliance can be cleaned with a damp cloth. Use lukewarm water and mild soap (without scrubbing particles and without any alcohol solution)

10.3 Cleaning accessories

The treatment electrode
The treatment electrode is cleaned with soap and lukewarm water. The treatment surface itself on the treatment probe can withstand alcoholic fluid if needed for disinfection. Avoid alcohol on the plastic handle.
After cleaning, place the electrodes in the electrode magazine.

Patient circuit return electrode (blank steel rod)
The patient's return electrode can be cleaned with a damp cloth. Use soap and lukewarm water or alcohol solution.

Electrode cables
The cables can be cleaned with a damp cloth. Use lukewarm water and mild soap. Check the cable at regular intervals for damage to the insulation. Avoid pulling hard on the cables as this can cause damage to the connector itself. We also recommend that you have an extra cable in stock.

10.4 Environment Information - Disposal

Skanlab NG Pro contains both materials that can be recycled and materials that are harmful to the environment. It is advisable to separate them from each other (when not to be used any more) and to sort out the harmful parts and parts that can be recycled. By doing so, you contribute to a better environment.

Follow the local regulations regarding disposal of electrical equipment and accessories.

CHAPTER 11. TROUBLESHOOTING

11.1 Power failure - no light in the display - no light in standby diode (blue)

Check if the device is connected to main electricity supply line

If still no light in the display - no light standby diode (blue)

- Remove the power cable
- Remove fuse box and check fuses (2xT 2.5A H 250V)
- Turn on the machine and check if the display lights up
- If there is still no power (light in the display), contact your dealer

11.2 Blank patient's return electrode provides minor electroshock – "sting"

- There is only partly skin contact in part of the rod while the electrode current is on.
- Place the patient return electrode so that there is maximum skin contact along the entire rod, (see over) – place in a well vascularized area. Avoid bony prominences.
- The patient or therapist comes into contact with energy-absorbing objects, i.e., metal on treatment bench, chair or the like
- Avoid static electricity
- Always apply a thin layer of Electrode Cream to the entire rod before placing the patient's return electrode.

11.3 Gray treatment electrode gives shock / "sting"

- Do not touch the patient's skin during treatment.
- Do not drop the electrodes on a hard surface, strike against the metal edge, etc. Then there may be cracks in the coating on the treatment head itself. Therefore, check the electrode surface regularly. You will be able to see the cracks as a black field/spots that cannot be wiped away.
- Only use Electrode Cream. Other cream may cause shocks.

11.4 No heat, but light in the display

- Cable break (treatment electrode or patient circuit return cable). Replace cable immediately!
- Poor contact between electrode and electrode holder. Check that the contacts are "in-place"

11.5 Not possible to use display/touch-screen and pin-point alternatives

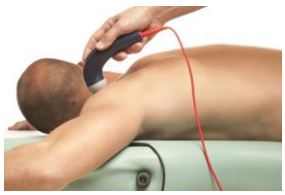
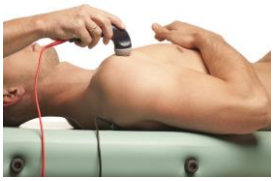
- See Chapter 5.5 – Calibration of touch-screen / display

CHAPTER 12. TREATMENT IMAGES AND PRE-PROGRAMMED CONDITIONS WHERE SKANLAB NG PRO TREATMENT HAS SHOWN GOOD EFFECT

Neck

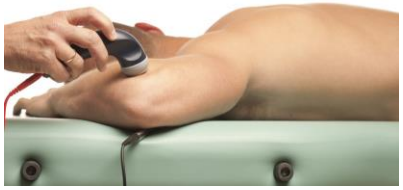
- Whiplash syndrome
- Myalgia
- Torticollis
- Pretreatment mobilization

Shoulder

- Biceps longum tendonitis
- Frozen shoulder mobilization
- Impingement syndrome
- Rotator cuff symptoms
- Bursitis

Elbow

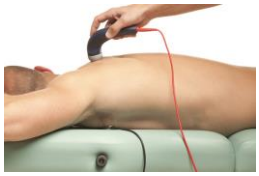


- Epicondylitis
- Pronator teres syndrome
- Bursitis elbow

Wrist - fingers

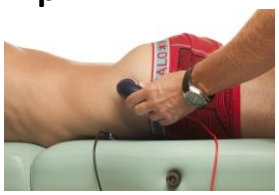
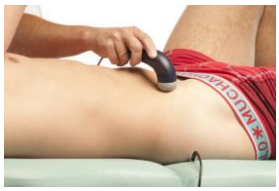

- Carpal tunnel syndrome
- Bursitis wrist
- Finger ligament distortions

Back

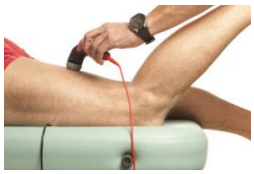
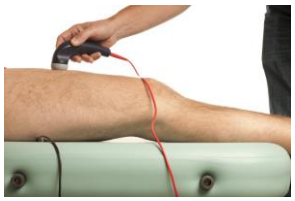
- Lower Back Pain (Inferioribus retro dolor)
- Detoning muscles (musculi detoning)
- Myalgia
- Pretreatment mobilization

Hip

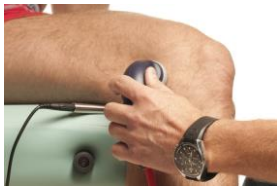
- Trochante bursistis/bursitis disorders
- M. piriformis syndrome
- Adductor tendonitis
- Coaxial arthritis

Thigh

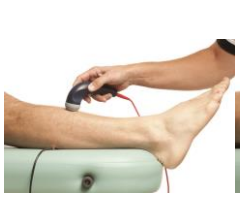
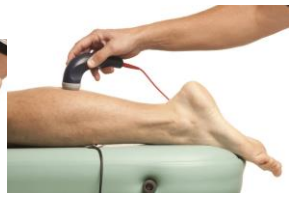
- Hamstring contusions
- M. quadriceps contusions

Knee

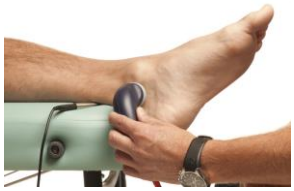
- Tractus iliotibialis tendinitis
- Patellar tendinopathy
- Gonarthritis
- Patello-femoral arthralgia
- Ligament injuries

Lower leg

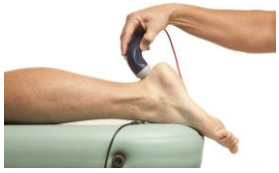
- M. triceps surae contracture
- Tibia periostitis
- M. tibialis posterior tendonitis

Ankle-joint

- Ankle distortion with oedema
- Sinus tarsi syndrome
- Talofibular anterior sprains

Achilles' heel

- Achilles tendonitis/paratendonitis

CHAPTER 13. TECHNICAL SPECIFICATIONS

13.1 Technical approvals

CE 2460

Skanlab NG Pro satisfies all orders and standards in accordance with the Medical Directive (93/42/EEC)

13.2 Standard equipment

Skanlab NG	Skanlab NG Pro	1
61-4	Treatment electrode, Ø30mm	1
11-4	Patient circuit return electrode rod	1
3444.583	Silicone block	1
70-3	Complete remote handle	1
21.3600-4	Electrode cable, black	1
21.3600-17	Power Supply cable	1

13.3 Additional Equipment

61-4	Treatment electrode, Ø30mm
62-4	Treatment electrode, Ø23mm
11-4	Patient return electrode rod
3444.583	Silicone block
70-3	Complete remote handle
21.3600-4	Electrode cable, black
21.3600-17	Power Supply cable
21.3600-6	Electrode Cream, bottle 1l
21.3600-13	Electrode Cream, canister of 5ltr
21.3600-11	Hand pump for 5l. canister

13.4 Technical specifications

Mains voltage	:	100-240Volt,
Frequency	:	60/ 50 Hz
AC Output current	:	0,6 –1,2 A
Maximum output power	:	25W
Output frequency	:	500 kHz
The Device:		
Medical device classification	:	IIa (according to MDD 93/42/EEC)
Safety class	:	I type BF, according to IEC 60601-1
Patient leakage current	:	better than IEC-req. (IEC≤ 100 μA)
Ditto, first wrong condition	:	better than IEC-req. (IEC≤ 500 μA)
Security Tests	:	CE-MDD
Dimensions	:	302x300x126,5mm (lxwxh)
Weight	:	4,3kg
Fuses	:	2xT 2.5A H 250Vu

13.5 Environment conditions

Environment conditions for transportation and storage

Environment temperature	:	- 10^0 C till + 40^0 C.
Relative humidity	:	10 till 90 % (no condensation)
Atmospheric pressure	:	500 till 1060 hPa

Environment conditions for normal use

Environment temperature	:	- 10^0 C till + 40^0 C.
Relative humidity	:	10 till 90 % (no condensation)
Atmospheric pressure	:	800 till 1060 hPa

13.6 Classification : CE 2460

Classification of Skanlab NG Pro

- Class IIa according to the Medical Devices Directive (MDD 93/42)

Software

- Class A Legacy according to EN ISO 62304, Software Safety Classification

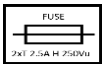
Implemented Safety Standards

- IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for safety
- IEC 60601-1-2: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Section 2: Collateral standard: Electromagnetic disturbances -- Requirements and tests
- IEC 60601-1-4: Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
- IEC 60601-1-6: Medical Electrical Equipment – Part 1: General requirements for safety – Section 6: Collateral standard: Usability
- IEC 60601-1-11: Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance – Section 11: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN ISO 62304: Medical device software – Software life-cycle processes
- EN ISO 14971: Medical devices – Application of risk management to medical devices
- EN ISO 10993: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

13.7 Manufacturing Standards

- EN ISO 13485 Medical devices – Quality management systems Requirements for regulatory purposes

CHAPTER 14. SYMBOLS

Symbols	Description
	Follow the instructions in the Instructions for Use. It is important that you read, understand, and observe the precautionary and operating instructions
	Warning or Caution: Indicates a hazardous situation which, if not avoided, could result in: a. Death or serious injury to the patient or operator (or) b. Minor to moderate injury to the patient or operator (or) c. Damage to the equipment
	
	Type BF applied part
	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.
	Electric waste can be reused. Indicates the electrical and electronic components of the device that can be recycled and must be disposed of separately.
	Keep the device dry
	Manufacturer name and address and production date
REF	Reference Number or Part Number
SN	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fuse
CE 2460	The Device Complies with Medical Device Directive 93/42/EEC

CHAPTER 15. LIMITATION OF LIABILITY

The manufacturer is not responsible for the use of the device for purposes other than those described in this manual.

Skanlab NG Pro is only for use within the treatment of soft and hard skeletal tissue such as joints, including the spine and skeletal muscle. The product is not intended for the treatment of other internal tissues or organs. See also contraindications and precautions in Chapter 3.

Under no circumstances will Manufacturer and their supplier and distributors be liable for indirect or direct damages arising from the use of the appliance. Either the user is qualified or not. This includes, without limitation, loss of relationships, work and productivity, computer errors, or other commercial losses, although the possibility of this is suggested and regardless of content in contracts and the like.

15.1 Product liability

A law on product liability has become applicable in many countries. The Product Liability Act states, among other things, that after a period of 10 years after the product was put into circulation, the manufacturer is no longer responsible for possible deficiencies in the product.[4)]

Reference:
4) Act on Product Liability