Levator Elite LE9011

Nu-Tek® Levator Elite

Single Channel EMG, EMS & ETS

- EMG Triggered Stimulation (Passive +Active), Muscle Stimulation and EMG Modes
- One channel EMG and One channel EMS stimulation
- One channel ETS with stimulation on one channel
- Nu-Tek scale scoring for Pelvic Floor Muscle and used as an assessment tool
- Programs for Incontinence treatment, Pelvic floor muscle development and neuromuscular Rehabilitation
- User programs for EMG/ETS (1 phase) and STIM (up to 5 stimulation phases) mode

Application:

- Promote continence
- Improve Pelvic floor Exercise
- Re-educate the Pelvic muscles

Specifications:

Power Supply:	1.5V AA batteries, 6V
Low Voltage Warning:	≤4V±0.2V
Dimensions:	139mm×68mm×33mm (L*W*H)
Weight:	156g (without batteries)
EMG: One Channel:	
EMG Range:	0.2 to 2000μV
Sensitivity:	0.1μV
Accuracy:	4% of μ V reading, +/- 0.3μV at 200 Hz
Work/Rest Periods:	2-99 seconds
STIM: One Channel:	
Stimulation Intensity:	90V±10V (V max), Adjustable from 0 to 90mA (on 1000Ω)
Pulse Width:	50-450μS (2% accuracy)
Pulse Rate:	2-100Hz (2% accuracy)
Work/Rest periods:	1-99 seconds
Ramp Time (up and down):	0.1-9.9 seconds
Treatment Time:	1-99 minutes
Programs	Pre-set: 11 Customs:3

Standard Accessories:

NULEADPATRD	Nu-Tek Patient Lead- Red
NULEADEARTH	Nu-Tek Earth Lead - Black
ACPROBEV	Incontinence Probe - Vaginal
ACF35050	AllCare Electrodes - 5cm x 5cm - Square- Self Adhesive

Optional Accessories:

NUSOFTWARE	Nu-Tek Biofeedback Software
ACPROBEA	Incontinence Probe - Anal
ACF35090	AllCare Electrodes - 5cm x 9cm - Rectangle - Self Adhesive
ACF350R	AllCare Electrodes - 5cm - Round - Self Adhesive

Code:	**Description:**
NULEVATOR	Nu-Tek® Levator Elite

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Nu-Tek Levator Elite

User Manual

www.nutekmedical.com

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Issue Date: 06/05/2016 *Document Number:* LE9011-Rev. V1.1

Warnings

- ※ This device must be used with the guidance of a Physiotherapist or Doctor.
- ※ Type BF equipment, Continuous Operation.
- ※ Do not immerse device into water or any other substance.
- ※ Do not use the device in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
- ※ This device uses 4 x AA Batteries. If using rechargeable Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect it directly to a battery charger or to any other mains powered equipment.
- ※ To avoid the effects of electromagnetic interference, never use the device in the EMG mode, within 4 metres of a mobile telephone or near any other powerful radio interference producing equipment that causes electrical sparks etc. In the EMG mode, the device may be susceptible to strong interfering radio type emissions that may lead to temporally increased EMG microvolt readings. The reading will immediately return to the correct value when the interference ceases. (Remember that a relaxed muscle should read below 4μV).
- ※ Patient electrodes including all skin surface electrodes, vaginal and rectal probe are for single patient use only!
- ※ Do not use stimulation on your facial area unless you are under strict guidance from a qualified clinician.
- ※ Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- ※ Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- ※ Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- ※ No modification of this equipment is allowed!
- ※ Keep the device out of reach of children
- ※ Skin irritation from the electrode gel and electrode burns are potential adverse reactions. If skin irritation occurs, discontinue use and consult your physician.
- ※ Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- ※ Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

Device name: Nu-Tek Levator Elite Model number: LE9011

Introduction

The Nu-Tek Levator Elite combined EMG [electromyography] and Neuromuscular Stimulation is a simple to use advanced product for reducing incontinence in females with urinary incontinence. The device has been developed to enhance and support the Clinician, to assist the end user at home to learn more about their Pelvic muscle and above all to improve their Pelvic Muscle strength and their incontinence therapy.
The Nu-Tek Levator Elite: EMG Biofeedback measures the Pelvic contraction, and assists users to maximise Pelvic floor exercises, after periodic training, it also helps to assess the pelvic floor muscle condition, quantify the need for further treatment and evaluate report on the patient's progress. Muscular Stimulation improves blood circulation, capillary bed density and strengthens the Pelvic floor muscles. EMG triggered stimulation facilitate those with flaccid muscles; ETS helps reduce the symptoms in Genuine Stress incontinence in some patient's and is being used more frequently by clinicians for this condition

For the end user, in **patient mode**, a simple and easy to understand EMG Biofeedback bar graph displays the Nu-Tek pelvic muscle strength grading on a scale of 1 to 6, and assists the user to meet their pre-set targets. In the **therapy mode**, the EMG graph can be changed to a waveform format, as viewed on the LCD screen of the device or using the Nu-Tek software link on a desk top or laptop computer . The waveform can be used to help analyse the patient's condition. Periodically the doctor or therapist will be able to download newly developed programs for Muscle Stimulation, EMG Biofeedback and EMG- TRIGGERED STIMULATION. This helps this unique product to keep abreast of any clinical trials where the conclusion is that a specific program or program set may assist in enhancing the treatment of continence. The Nu-Tek Levator Elite has 3 clinical modes: EMG, ETS, and STIM. Each of these modes has custom programs. The device also includes pre-set EMG and STIM programs: there are 20 pre-set Pelvic muscle stimulation programs: Genuine Stress, Urge, Frequency, weekly maintenance. Lack of sensation, rectal stimulation and several other Patient conditions. One pre-set EMG program for assessment. The custom program has a diverse range of parameters that can be programmed by the patient or therapist to meet individual user conditions. Any one of the pre-set or custom programs can also be selected freely by the user. The essential performance of the device are free from the production of unwanted or excessive stimulation output and free from the display of incorrect numerical values associated with measure to be performed.

Customer Care

We welcome constructive comments regarding our equipment particularly those that might help us to improve existing features, add new ones and / or develop new products for the future.

Contra-Indications and Precautions

STIM: Neuromuscular Stimulation (NMS)

Before using this device you must first seek the advice of your doctor or therapist.

Neuromuscular Stimulation should not be used by:

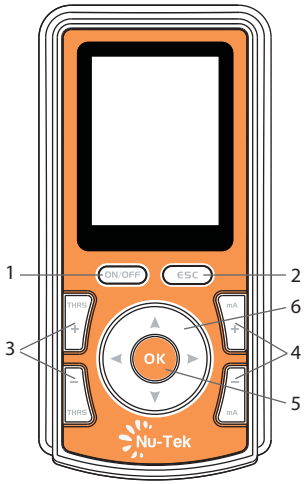
※ Patients fitted with demand style cardiac pacemakers
※ During pregnancy (unless medically advised)
※ Patients with undiagnosed pain conditions
※ Do not place electrodes:
- Over carotid sinus nerves
- Over larynx or trachea
- Inside mouth
- On anaesthetised or desensitised skin
- Do not drive a vehicle while the device is stimulating and attached to your body
※ Skin irritation from the treatment of NMS or EMG itself does not generally occur. However, rubber electrodes may irritate some skin types, therefore; in this case we recommend using hypoallergenic self adhesive electrodes.
※ The patient should only use the device for what it was prescribed for
※ Do not immerse the device in water or any other liquid substance
※ Do not use stimulation on your facial area unless you are under strict guidance from a qualified clinician

EMG

There are no precautions when using EMG unless used for pelvic floor exercising or assessment. In this case EMG should not be used:

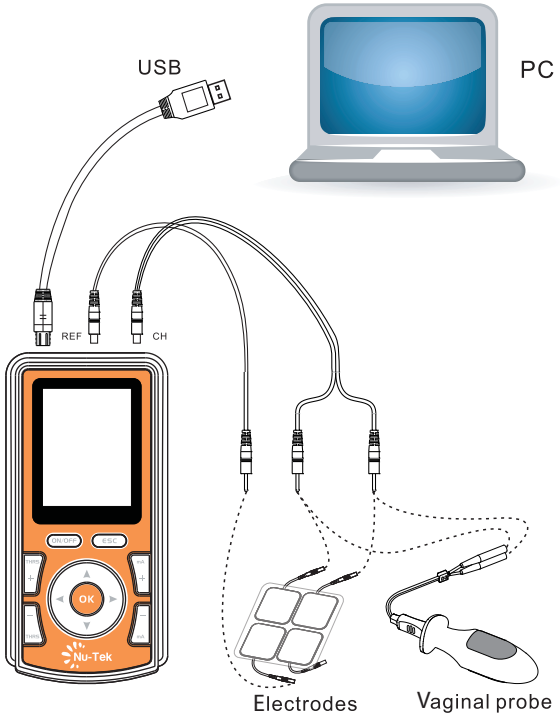
※ During menstrual period
※ Inflammation or infection in the vaginal area or urinary tract.
※ With patients who have diminished mental capacity or physical competence who cannot handle the device properly.
※ The absence of sensation due to denervation of the pelvic floor.
※ In children - when using internal probe.

Keypad Layout



1. **ON/OFF:** press to power on or switch off the device.
2. **ESC:** press to finish the session (program) or the settings, or return to previous menu.
3. **THRS+** and **THRS-:** adjust the EMG threshold level (ETS target) and adjust the other parameters and settings.
4. **mA+** and **mA -:** start the STIM or ETS phase, increase or decrease the stimulation intensity.
5. **OK:** press to complete selection
6. **▲,▼,◄,► :** select mode in main menu, or switch parameter and settings.

Lead / Electrode Connection Assembly



USB cable: Connection to the PC
REF: Reference wire (REF) for precise EMG measurement
CH: dual conductor lead wire for STIM or EMG

Note: The REF EMG lead / electrode is only required for EMG and ETS and NOT for Neuromuscular stimulation.
The lead wires, electrodes, vaginal probe and REF wires are supplied as part of the kit.

Quick Start Instructions

1. **Insert four AA batteries**
   Remove battery cover. Insert batteries as labelled inside the battery compartment and then replace the back cover.
2. **Insert lead wire**
   Insert the lead wire/s into the sockets of the device. The round black EMG reference lead wire connects to the round black socket in the top of the unit; the red stimulation lead wire connects to the red socket.
   IMPORTANT! If you don't use the round EMG reference wire (REF), your EMG and ETS results will be inaccurate.
3. **Skin electrodes/probe placement**
   When using the EMG or ETS phase, connect the EMG reference lead wire to a surface skin electrode and place it appropriately on the body, making sure the skin is free from grease and dirt; repeat the above procedure with the other two skin electrodes. If using a probe, place the single surface skin electrode on the thigh area and then insert the probe.
4. **Turn on** Levator Elite by pressing the **ON/OFF** button once for 3 seconds.
   Note: This product has a **Patient Mode** which we suggest the general public use and a **Therapy Mode** which is more practical for the Clinician. Selecting the **Therapy Mode** requires a password. When selected the **Patient Mode**, the product would be locked. The details setting method refer to "Change using mode" of page 27. In **Patient Mode**, you can not select the therapy program and set the parameters of the custom program.
5. The EMG, the **Patient Mode** uses the Nu Tek bar graph; the **Therapy Mode** uses a line graph.
6. There are pre-set (ready to use) programs and custom programs (which can be adjusted by the patient or therapist in **Therapy Mode**). The parameters of pre-set programs can not be changed.
   Note: Individual custom programs set for the patient should ideally be under the guidance of a doctor or therapist in **Therapy Mode**.

Using the circular button black arrow keys navigate to select **EMG** and press the **OK** button. The screen displays **Training Program** and **Assessment Program**. In Assessment Program, there is only one preset program: Threshold = 30µV, WIDE Filter, ABOVE Biofeedback sound, Work time = 5s, Rest time = 5s, and 5 Trials, AUTO threshold is advised to be used to see the treatment progress during periodic training. In the **Training program**, there are two custom programs, you can select all the EMG Biofeedback parameters by using the up and down black arrow keys, and change settings by using the **THRS+** and **THRS-** buttons. In **Patient Mode**, the program, work time, rest time,trial and A/M threshold can not be adjust.

When you have completed your settings, press the **OK** button which will take you into the vertical Bar graph **Patient Mode** or the EMG line graph **Therapy Mode**, then press the **OK** button to begin the session.

Working with EMG

※ Always use the Reference wire (REF) for more accurate EMG measurement! Place the reference electrode anywhere on your skin. When using the device with a vaginal probe, place the reference electrode on your thigh.

※ Place the device on the desk, in its stand or hold the device.

※ Relax so that the microvolt reading is as low as you can manage; below 6μV is acceptable while below 4μV is ideal.

ETS (EMG TRIGGERED STIMULATION) Patient / Therapy MODE

Using the circular button select **ETS**, press the **OK** button to enter the ETS parameter settings interface. Using the circular button scroll and using the **THRS+** and **THRS-** buttons to change the EMG Biofeedback and Stimulation settings. In **Patient Mode**, the program, work time, rest time,trial, A/M threshold and stimulation parameters can not be adjust. When you have completed your settings, press the **OK** button this will then take you into the standby mode. Press the **mA+** button to increase the electrical current (mA) and to start the treatment. As soon as the patient reaches the target level (threshold) in the work period stimulation takes place for several seconds which helps to contract the pelvic muscles. Ideally contract your pelvic muscle along with the electrical stimulation.

STIM (STIMULATION) MODE

Using the circular button select **STIM**, press the **OK** button which brings up the pre-set and custom programs, in **Therapy Mode** press the **THRS+** or **THRS-** buttons to select the required program. Press the **OK** button, and then press the **mA+** button to increase the electrical current (mA) and to start the treatment. The parameters of pre-set programs can not be changed; those of custom programs can be adjusted by the therapist in **Therapy Mode**. Using the **THRS+** and **THRS-** the phase parameters of the program can be viewed. At the end of the session the screen will display the Date and Time, Average Current used (mA), Program, and the Frequency (Hz) used. Only the mA (current) will be saved.

COMMUNICATE

Connect the device to the PC via a USB cable, then using the circular black arrow keys select **COMMUNICATE**, press the **OK** button, the data can be transferred between PC and the device. (This function is an optional extra

and the user will need to purchase the Nu-Tek System, the USB connection cable to the PC).

DATA MANAGE

Using the circular button to select **DATA MANAGE**, press the **OK** button, then using or select **Data query , Delete data** or **Send data to pc**, then press the **OK** button. The information is stored and displayed on the two linear graphs on the LCD screen. The two vertical graphs are combined by up to 90 records respectively, and the history of the user's sessions can be viewed. For training data, the device saves the data on a daily basis to form statistics. In the Assessment data, the device stores the weekly statistics by carrying out an assessment of the programs once or twice per week. The device can store more than one patient's statistics, but it can not distinguish between different patients. Only when the device connected via the Nu- Tek PC software, can the recorded data in PC be distinguished between different patients. The user can delete the treatment data when selected **Delete Data** and press **OK** button.

SYSTEM SETTING

Using the circular button select **SYSTEM SETTING**, press the **OK** button which will bring up the various options, including **Date and Time, Backlight Setting, Sound Setting, Set Language (English, German, French, Italian, Spanish)**, **Change Using Mode, Factory Data Reset.** Using the circular button scroll down to the settings you want to change, press the **OK** button, then using the **THRS+** and **THRS-** buttons to set the various options. Use or to select **Save** or **Cancel**, press the **OK** button. If you select **Factory Data Reset**, all the values are restored to the original factory setting. (*Note: If the factory setting is restored all the patient's statistics will be lost*)

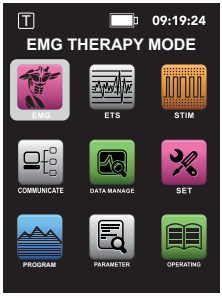
PROGRAM MANAGE

Using the circular button select **PROGRAM MANAGE**, press the **OK** button. Then using ▲ or ▼ select **Downloaded Programs** (There are three modes: EMG, ETS, and STIM. For either mode, there are up to a maximum of 3 programs) or **To Download Programs**, then press the **OK** button. For example, select **Downloaded Programs**, to view the downloaded program, press the **OK** button, to use the program. Only the last selected downloaded program in **Therapy Mode** is available for display and for use in the **Patient Mode**. Select to download Programs by connecting the device to the PC via the USB cable. If three programs have been downloaded the fourth program will not be possible, at this point the screen displays a prompt for the user to choose which one program to select to make up the three programs.

PARAMETER MANAGE
Using the circular button select **PARAMETER MANAGE**, press the **OK** button to bring up the details.

OPERATING MANAGE
Using the circular button select **OPERATING MANAGE**, press **OK** button to bring up the details.

7. After completing the settings, Press the **ESC** button to exit.
8. When you have finished, press and hold the **ON/OFF** button for 3 seconds to turn off the device. Remove and replace the skin electrodes onto the clear plastic film, reseal them in the plastic zip bag and store them in a cool place. If using a vaginal or rectal probe thoroughly clean the probe and seal it in plastic zip bag.



Clinical Mode - Program - Phase

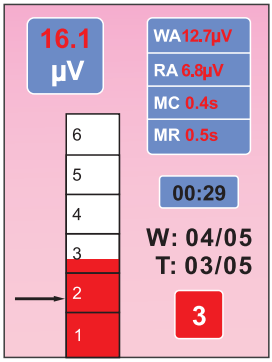
The Nu-Tek Levator Elite enables the patient or therapist to select a pre-set program or a custom program to make the appropriate treatment. **Clinical Mode:** Using the circular button select either **EMG, STIM** or **ETS** and press the **OK** button to enter the mode. In EMG mode, there are two functions: assessment and training. For assessment, only one pre-set program is used, the user can view the treatment progress.

The device has two custom EMG/ETS programs. You can set up one EMG/ ETS phase with your chosen parameters.

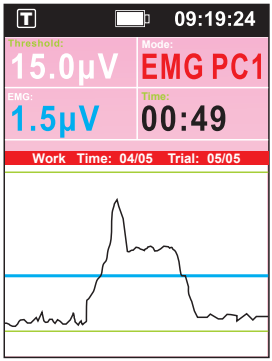
In **STIM** mode, Levator Elite has 20 pre-set Pelvic floor muscle stimulation programs covering Genuine Stress, Urge, Frequency, weekly maintenance, Lack of sensation, Rectal stimulation and several other patient conditions. There are 3 custom programs that can be programmed to meet individual user conditions and have a diverse range of parameters to meet any current stimulation requirements. The programs can be divided into a maximum of 5 sequential phases. Phase Time is the time remaining for the Current Phase. The overall time is a combined time of all the program phases. Overall time always indicates the remaining time of the program session.

EMG mode operation

1. Using the circular button black arrow keys navigate to the **EMG** and press the **OK** button, the screen will then display two modes: **Assessment Program** or **Training Program**. Select mode and press the **OK** button to enter the parameter mode.
2. After completing the settings, press the **OK** button to enter standby mode of the vertical Bar graph **(Patient Mode)** or the EMG line graph **(Therapy Mode).**
3. Press the **OK** button again to begin the session.
4. At the end of the session the screen will display the work/rest microvolt, onset/relax time
5. There are two EMG custom programs for training purposes, all the parameters can be adjusted by the patient or therapist in **Therapy Mode**.
6. If **Assessment Program** is selected, there is only one pre-set program used, the user can view their progress on the LCD screen



Patient mode



Therapy mode

Examples of EMG treatment

EMG Work/Rest

The W/R phase consists of Work and Rest periods and repeated Trial times (repetitions). During the Work period, the patient is prompted to contract their muscle. During the Rest period, the patient is prompted to relax their muscles. At the end of the work/rest sessions the EMG values display the information on the LCD screen of the device. The device can also be linked to a PC or laptop computer.

Relaxation test:

The ideal resting value when conducting work/rest sessions for improving the Pelvic Floor Muscle is 4 µV (microvolt). The relaxing value is just as important as the pelvic floor muscle contracting value. The resting time for the pelvic floor muscle exercises should be at least 5 seconds and longer, if the user is unable to contract their pelvic floor muscle above muscle strength scale 1.

Rapid contractions:

The patient should perform 5 rapid contractions, note how quickly the bar graph rises and falls. If the contractions and release times are slow, the user will need to improve their fast twitch muscle fibres by conducting quality Pelvic floor muscle exercises at least once per day or more. If after a few weeks there is no marked improvement, consider electrical stimulation using a setting of 35Hz, 220µS Pulse Duration, for 20 -25 minutes per day.

Contract and hold:(Endurance Training)

The patient should contract the pelvic floor muscle for as long as possible, 5 seconds is reasonable, 10 seconds would indicate a strong muscle, any longer would be excellent.

Work/rest session:

Two basic purposes for Work/Rest session:

1. Enhances Pelvic Floor Muscle exercises for both strengthening and relaxing the muscles, and to ascertain if other forms of treatment are required.
2. Periodically perform Work/Rest session and note the results, especially the data of the assessment program. This allows the patient or therapist to see or analyse muscle improvements, which can be organised or used as a valuable clinical report.

To run the assessment Work/Rest session:

1. The assessment program ideally should follow the settings: Work Time=5s, Rest Time=5s, =5s, Threshold=30µV, ABOVE feedback sound, WIDE filter,

AUTO threshold and 5 Trials. Use the **WIDE** filter band for continence as the measurement will be more accurate. When using the electrodes near heart the proximity of the upper arms, back, etc., use the NARROW filter band (filters out the unwanted heart beat frequencies).

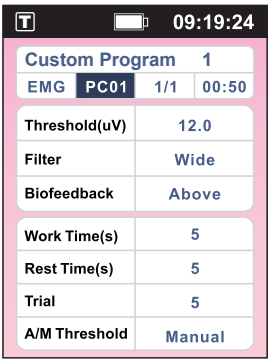
2. Press the **OK** button, the initial REST prompt will appear, followed by 5 repetitions (trials) of 5 sec of Work followed by 5 sec of Rest. At the end of the sessions the user can view the session statistics on screen at the end of the last Rest period. During the Work period, the patient should contract the muscle as hard and firmly as possible, ideally during Rest period the patient should relax as quickly as possible, below 4µV or lower. Suggest to patient to run the assessment program each week or at another suitable time.
3. When the device is connected to the PC, the PC Software records the statistics and stores the information on to the database.

EMG Parameters

EMG	Parameter
Program time	Max:99mins
Threshold（μV）	0.6-2000μV, During work period the patient is prompted to contract above the Threshold. In the rest phase the patient is prompted to relax their muscle.
Filter	Wide/Narrow
Biofeedback	Above/Below/Continue/OFF: Above the threshold, Below the threshold, Continue-sound, OFF-no bar graph sound
Work/Rest time(S)	2-99 sec
Threshold setting	Auto/Manual
Trial	Number of work/rest repetitions, 2-99

Note:

1. In **Therapy Mode**, you can change all the EMG Biofeedback settings.
2. Electrodes placed on the lower abdominals, legs, arms and back, face, buttock or pelvic area use **WIDE** lter band setting.
   All other areas i.e.upper abdominals, chest, shoulder, upper arms and back use **NARROW** lter band setting.
   NARROW setting is used due to the interference from the heart beat frequency, this interference has to be eliminated.



EMG and ETS Threshold

What is EMG THRESHOLD?
Threshold is an EMG value measured in µV (microvolt). For strong muscles which perform higher EMG biofeedback muscle contractions the threshold level will be higher than for weak or flaccid muscles. In ETS mode (EMG Triggered Stimulation) the patient needs to contract the muscle above the target threshold to trigger the stimulation.

Auto threshold:
To select **Auto** threshold of the EMG or ETS parameter setting mode use the **THRS+** or **THRS-** buttons. Automatic threshold is designed to adjust the EMG muscle strength scale (and the point of ETS triggering) to the actual level of the patient's EMG biofeedback muscle contraction

Auto threshold during EMG session:
Select the **EMG** mode and press **OK** to begin the EMG session. Work/Rest prompts will appear. During each Work period the device measures Work Average EMG, at the beginning of the next Work period, the threshold is set at 80% of the previous Work Average. (This functionality is available only for Auto threshold)

Auto threshold during ETS session:
Select the **ETS** mode, press **mA+** button to start the session. If the target threshold is reached (EMG will trigger the stimulation) in seconds, the device will increase the target threshold for the next trial. For example , the work period is 20 seconds, If the patient reaches the threshold very quickly in Sector A (1-5s), the next threshold will be calculated as previous threshold plus 12.5%; if reached the threshold in Sector B(6-10s), as previous threshold plus 5%, if reached in Sector C(11-15s), as same as the previous threshold. If the Patient had difficulties with triggering from EMG to stimulation in Sector D(16-20s), or didn't trigger the stimulation during the Work period, the next threshold will be reduced by 5%.

MANUAL threshold
At any time when the EMG or ETS is displayed, the threshold can be adjusted manually by pressing the **THRS+** or **THRS-** buttons.

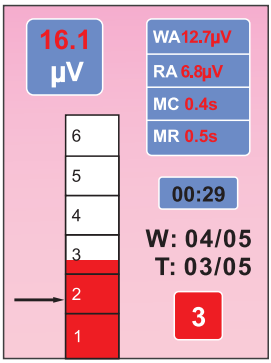
NOTE! For better control of **ETS Score** statistics we recommend to use **Manual** threshold for ETS session.

EMG in Patient Mode

In the **Patient Mode**, a simple and easy to understand EMG Biofeedback bar graph displays the pelvic floor muscle strength and assists the user to meet their pre-set targets. The bar graph scale on the device is divided between 1- 5, plus 6 as an extra for those people who can contract above the standard scoring of 5.

Muscle Strength Grading Scale (Nu Tek Scale) Measured in EMG Microvolt's µV	
Scale 1	Virtually no muscle contraction and very little microvolt readings
Scale 2	Slight muscle contraction with little movement, increase microvolt reading and a short muscle contraction holding time
Scale 3	Moderate muscle contraction with increased movement and microvolt reading and a longer muscle contraction holding time
Scale 4	Firm contraction and improved muscle holding time
Scale 5	Strong contraction with much longer muscle holding time
Scale 6	Robust contraction with greatly improved muscle holding time

Note:
The normal resting muscle tone is 4 Microvolt's (µV) or lower. Between work/rest trials it can be for some users a challenge to relax the pelvic floor muscle as low as 4µV, under 6µV in such circumstances is satisfactory



EMG measurement

1. If the Patient measures EMG near the heart we suggest using the NARROW filter band to filter out the heart beat. **For measurement of the pelvic muscle always use the WIDE BAND FILTER**
2. The filter makes sure the 50Hz [Europe] and 60 Hz [USA] (mains) frequencies do not interfere with the muscle biofeedback measured in microvolt. Specific filtering as well as other adjustments and improvements allows the device to measure the EMG down to as low as 0.2µV.
3. REMEMBER WHEN USING EMG! **Please always be sure to use the reference electrode otherwise the EMG signal will be incorrect**, distorted or too high. (see the picture on page 7 for how to connect the reference lead wire).
4. To avoid the effects of electromagnetic interference, never use the Nu-Tek Levator Elite in the **EMG** Mode, within 3-4 metres of a mobile telephone or near any other powerful radio interference producing equipment that causes electrical sparks etc. In the **EMG** Mode, the device may be susceptible to strong interfering radio type emissions that may lead to temporary increased EMG microvolt readings. The reading will immediately return to the correct value when the interference ceases. (Remember that a relaxed muscle should read below 4µV).

Conditions respond to EMG

Available Nu-Tek software Protocol for EMG Training

※ The Nu -Tek® Software provides additional benefits for EMG training:
- It displays the EMG graph on the computer screen.
- It creates Templates.
- It features a patient database with the history of the sessions.
- It produces comprehensive progress reports based on assessment statistics.
- It downloads newly developed programs; this helps the unique product to keep abreast of any clinical trials.
- Many other additional functions useful for clinicians and patients.

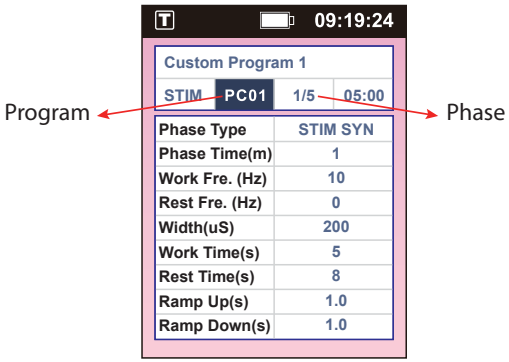
※ Use the Nu-Tek Software manual to learn more about the optional Nu-Tek Software.

Conditions known to respond to EMG:

※ Incontinence
※ Neuro feedback
※ Pelvic floor pain

STIM mode operation

1. Using the circular button select the **STIM** mode, press the **OK** button and enter parameters setting.
2. using ◄ and ►select **PR** or **PC**, then press the **THRS+** or **THRS-** buttons to select the required program. The parameters in the pre-set programs can not be changed. Setting up custom programs should be under the guidance and set by the therapist or doctor in **Therapy Mode**. Use the circular button to select the parameters, then using the **THRS+** or **THRS-** buttons set the parameter settings – Frequency {Hz}, Pulse duration {µS}, work and rest times, ramp up and ramp down times.
3. Press the **OK** button, then press the **mA +** button to increase the electrical current (mA) until you reach a comfortable level of stimulation. **After each phase of a program session, the user may need to press the mA+ button to continue stimulation**
4. To stop stimulation press and hold the **ON/OFF** for 3 seconds, or the **ESC**, **OK** , ▲, ▼, ◄, ► buttons to stop the treatment.
5. At the end of the session, the screen will display the statistics: average current intensity (mA). In some patients the mA level (current) can have a bearing on the sensory nerve damage.



STIM Parameters

STIM	Parameters
Program time	1- 99mins
Phase type	W/R, CON
Phase time(m)	1~99min
Frequency (Hz)	2-100 Hz
Pulse Width(μS)	50 - 450 μS
Ramp down /up time (s)	0.1-9.9sec
Work/Rest time (s)	1-99 sec

Note:
In **Therapy Mode**, all the parameters of the custom programs are available.
In **Patient Mode** (Locked Mode), the parameters can not be changed.

Conditions known to respond to NMS (Stimulation):

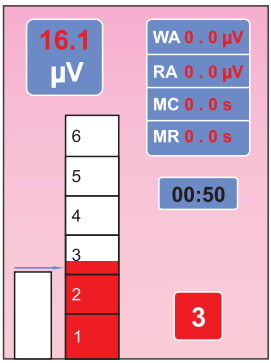
※ Strengthening of the Pelvic Muscles
※ Urge
※ Genuine Stress
※ Neuro degeneration of sensory nerves
※ Overactive Bladder
※ Prolapse
※ Frequency

ETS mode operation

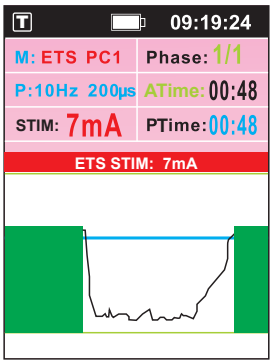
ETS treatment is especially useful for Pelvic Floor Muscle improvement. ETS begins with EMG Work/Rest training. The Patient can adjust the desired Target (EMG Threshold) level by pressing the **THRS+** or **THRS-** buttons. If the patient reaches the Target during the Work period of EMG, the EMG triggers the Stimulation which helps the patient keep their pelvic floor muscle contracted. **ETS** mode also enables the patient to stimulate weak muscles by setting a low level threshold target and adjusting the work and rest periods to meet individual patient requirements.

Example: Assuming patient has weak pelvic floor muscle, set threshold level at 5 microvolt, ETS and EMG Work at 5 sec, ETS and EMG Rest at 10 sec and Stimulation time at 5 sec, when the patient reaches the threshold level in the EMG working period, the EMG triggers the stimulation and each trial has a constant stimulation time of 5 sec.

Work time, Rest time and the Stimulation time must be taken into consideration in order to adjust the basic ETS treatment parameters.



Patient mode



Therapy mode

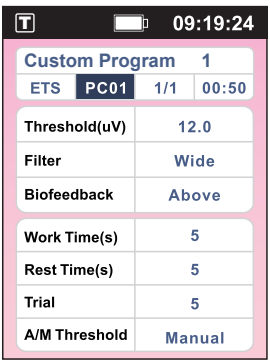
Conditions known to respond to ETS

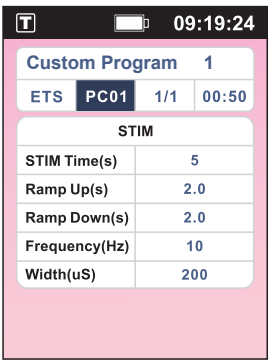
※ Pelvic floor conditions - Genuine Stress and Flaccid muscle

ETS Parameters

ETS	Parameters
Program time	Max:99mins
Threshold(μV)	0.6-2000μV, During work period the patient is prompted to contract above the Threshold. In the rest phase the patient is prompted to relax their pelvic muscle.
Filter	Wide/Narrow
Biofeedback	Above/Below/Continue/OFF : Above the threshold, Below the threshold, Continue-sound, OFF-no bar graph sound
Work/Rest time (s)	2-99 sec
Threshold setting	Auto/Manual
Trial	Number of work/rest repetitions, 2-99
Threshold setting	Auto/Manual
STIM time(s)	1-99sec
Frequency(Hz)	2-100Hz
Pulse width(μS)	50-450 μS
Ramp up/down time(s)	0.1-9.9sec

Note:
For custom program: in **Therapy Mode** therapist can change all the EMG Biofeedback and stimulation settings.





Data Report for progress

The Nu-Tek Levator Elite has a built-in ability to store and send Patient's day -by-day home compliance and periodic assessment data to the PC. (The Nu-Tek Software can be purchased at an additional cost, for details contact Shenzhen Dongdixin Technology Co., Ltd.

Step by step with the Data Report

Step 1. Check or Set the Date/Time
View the next page on how to change Date and Time settings. The statistics will be saved on a daily or periodic basis. It is very important to make sure the date is correct.

Step 2. Select the program to train or assess
After completing the training session or assessment, the record is stored automatically. The device can store every 90 records of 90 days or 90 weeks.

Note: Only in Patient Mode, the training record can be stored automatically.

Step 3. Instruct the patient when, how often and how to use the device.
The patient follows the clinician's instructions on how to use the program, and how to handle statistics recorded for training or assessment.

Step 4.Connect the Device to the PC and download the statistics to PC.
After long term training (days or months) and periodic assessment (after weeks or months) is completed, connect the device to the PC via the USB cable, switch on device and select **COMMUNICATE**. Then press **ESC** button to main menu. Select **DATA MANAGE**, press the **OK** button to select **Send data to PC**, then press the **OK** button to download the statistics to the PC.

Step 5. PATIENT statistics
The device stores and records one patient's training and assessment data at a time for up to 90 recordings. This data can be downloaded onto the Nu-Tek PC software. To record new patient's data the Device must first clear the saved data.

System setting

Setting the Date/Time
To check if the date or time is correct (it is important for daily statistics!). Using the circular button select **SET**, press the **OK** button. Using the circular button scroll down to settings **Date and Time**, press the **OK** button, the calendar date is displayed on the LCD screen. Using the circular button select Year, Month, Day, Hours (24 hour format only), Minutes, Seconds, then press the **THRS+** or **THRS-** buttons to set the time and date.
When you have completed the settings, select **Save** on the LCD screen, then press the **OK** button. Press the **ESC** button to exit.

Note: The real time clock ensures that an accurate record of EMG Biofeedback is measured by the hour, day and month.

Setting Backlight/Sound
Using the circular button select **SET**, press the **OK** button. Using the circular button scroll down to settings "**Backlight Setting**" or "**Sound Setting**", press the **OK** button, then press the **THRS+** or **THRS-** buttons to set the "brightness" and "Backlight time" or "Sound Volume" and "Key sound". When you have completed the settings, select **Save** on the LCD screen, then press the **OK** button. Press the **ESC** button to exit.

Setting the Language
Using the circular button select **SET**, press the **OK** button. Using the circular button scroll down to settings "**Set Language**", press the **OK** button, then press the **THRS+** or **THRS**- buttons to select either English, German, French, Spanish or Italian. Once the desired language is displayed, select **Save** and press the **OK** button to exit from the language menu. The word or abbreviations on the device LCD screen will appear in the selected language.

Change Using Mode
Using the circular button select **SET**, press the **OK** button. Using the circular button scroll down to settings "**Change using mode**", press the **OK** button, there are two case as following:

1. If there are **therapy mode** in current, the product enter parameters setting mode, Using the circular button scroll down to settings "**EMG MODE**", "**ETS MODE**" or "**STIM MODE**", press the **OK** button to enter the parameters setting mode. (the details setting methods for each mode refer to page 14, 22 or 24.) Press the **OK** button again to set the "**Therapy**" or "**Patient**" by press the **THRS+** or **THRS-** buttons .
   When you have completed the settings, select **Save** on the LCD screen, then press the **OK** button. Press the **ESC** button to exit.

2. If there are **Patient Mode** in current, the product enter "Therapy mode" or "patient mode" setting mode by press the **THRS+** or **THRS-** buttons . select **Save** and press the **OK** button to be prompted to enter the password which is ▲,▼,◄, ►. The product back to previous menu if the password is correct.

Note:
There are "Ⓣ" symbol display on LCD when the product in **therapy mode**, "Ⓟ" and "🔒" symbols display on LCD when the product in **patient mode**.

Statistics

Statistics on the Device LCD

To check the statistics, the patient **must complete the session** . After each session, the device displays the last session statistics. In addition, for training of EMG, ETS or STIM, the device stores the first statistics and records on a daily basis data per one calendar day. For assessment of EMG, the device stores the weekly statistics by carrying out an assessment program every one or two weeks, Select the mode and program; press the **OK** (EMG mode)or **mA+** (ETS and STIM mode) button and follow the instructions on the LCD screen, until all phases of the program are completed. Then the statistics of the last used program will be displayed on the LCD.

1. WORK AVG This is the work average for the session measured in (µV) microvolt. The average readings will vary from one patient to another.

2. REST AVG This is the work average for the session measured in (µV) microvolt. The average readings will vary from one patient to another.

3. ONSET TIME This is the average onset of muscle contraction measured in seconds; readings below 1 sec are considered normal for most muscles.

4. RELAX TIME This is the average muscle relaxed measured in seconds; readings below 1 sec are considered normal for most muscles.

5. W/R PEAK This is the average peak value measured in µV. The value will vary from one patient to another.

6. WORK DEV This is the average muscle deviation when contracting the muscle. Deviation percentages vary according to the muscle type.

7. REST DEV This is the average muscle deviation; when the muscle is relaxing.

8. STIM TIME This is total electrical stimulation time during ETS.

9. ETS AVG This is the average Stimulation level measured in mA; the value indicates the average mA level used by the patient during stimulation treatment.

10. THRS AVG This is the average Target/Threshold level measured in µV; the value indicates the average Target reached by the patient during the ETS treatment. (Auto or Manual)

11.ETS SCORE This is the percentage of the patient's score during the ETS Treatment. If the patient reached the Target very fast, the

score will be higher. Example: 10%: it means that the Patient's average in reaching the Target had a long delay, at the end of the ETS Work cycles. 90%: the patient is reaching the Target almost immediately. The Patient's muscle condition is good.

12.STIM AVG This is the average Stimulation level measured in mA; the value indicates the average mA level used by the patient During STIM treatment.

More about EMG Statistics

1. WORK AVG Work Average: The average value in microvolt of all the Work segments excluding the first second of each segment.

2. REST AVG Rest Average: The average value of the Rest segments excluding the first second.

3. ONSET TIME Average Onset: The average time taken after each respective "Work" prompt to reach 75% of the average value of the previous work period. If the onset of trial(s) is longer than 2 seconds, it (or they) will be rejected. The display will indicate the average of only those trials which were 2 seconds or less.

4. RELAX TIME Average Release: The average time taken, after the REST prompt to reach 37.5% of the average EMG from the previous work period. If any Release of the trials is longer than 2 seconds then it (or they) will be rejected. The display will indicate the average of only those trials which were 2 seconds or less.

5. W/R PEAK Work/Rest Peak: It is the peak value during the whole cycle of all the trials.

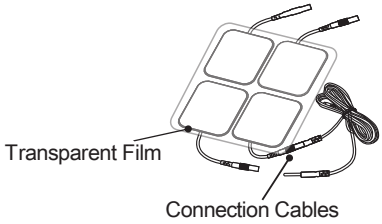
6. WORK DEV Average Deviation (per second) of Work. It is the average deviation of one second samples from the average value in the second in which they occur (excluding the first second of each Work segment).

7. REST DEV Average Deviation (per second) of Rest. The average deviation of one second samples from the average value in the second in which they occur (excluding the first second of each Rest segment).

Electrodes Types and Tips

※ Self-Adhesive Hypoallergenic electrodes have a typical life span (if looked after) of 4/6 weeks. We recommend cleaning the skin before placing the electrodes. After use place the electrodes back onto the plastic film and in the zip-tag plastic pouch. Store in a cool environment.

Skin Electrode Types Available: 50 x 50mm, square (recommended for general use) other electrode sizes are available, typically 50 x 100mm, 40 x 40mm and 30mm dia.



A Few Good Tips [Self- Adhesive Electrodes]

※ If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.

※ Clip away hair on the skin using scissors; don't use a razor to remove the hairs!

※ The electrodes conductive material is water-based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out (replace on plastic film in the morning). At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will increase the electrode life by few more days.

※ Place the tacky surface to the prescribed skin area by pressing the electrode firmly against the skin.

Care, Maintenance,Accessories and Disposal

WARNING! Only medically approved accessories should be used!

CONTROL DEVICE

※ Wipe the surface once a week with a damp cloth or antiseptic wipe
※ Do not use cleaning sprays or alcohol based cleaning solutions
※ Control device disposal: please return to Shenzhen Dongdixin Technology Co., LTD or to the appointed distributor.

ACCESSORIES

Battery:

※ This device uses 4 x AA Batteries. Never connect the Nu -Tek® Levator Elite directly to a battery charger or to any other mains powered equipment.
※ To replace the batteries, open the battery door on the rear of the device. To open, press down on the raised rib of the battery door near the middle of the device. Pull the four batteries out and replace them with the new batteries. When inserting the batteries, follow the polarity information on the bottom of the device's battery compartment. This simple procedure can be performed by the end user and does not require specialist expertise.
※ Remove battery completely from device if not in use for any extended period of time (typically one week).
※ Low battery indicator is shown on LCD display. When flashing, replace batteries. (Replace with quality batteries)
※ Batteries may be fatal if swallowed. Therefore, keep the batteries and the product out of the range of children, if a battery was swallowed, consult a physician immediately.

Lead Wires:

※ the lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
※ Examine lead wires before each treatment for loose connections or damage.
※ Avoid stretching and twisting the lead wires.
※ Store the lead wires carefully after each use.
※ Lead wires Disposal: please return to the supplier from whom you've purchased them.

Self-Adhesive Electrodes:

※ Check that the short connectors are well connected to the electrodes
※ Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to the conductive gel making the electrodes ineffective

Electrode life can be considerably reduced by:

※ The type and condition of the skin
※ Deep seated moisturizers or make-up
※ Storing electrodes in hot conditions

Vaginal / Rectal Probes:

※ Check if the connectors have not become separated from the probe
※ We advise you to use Shenzhen Dongdixin Technology Co., Ltd. Probes.
※ Cleaning: Remember! The Vaginal or Rectal probe is for use with one Patient only! Carefully clean the Probe after use. Wash the probe gently in mild soapy water, rinse and make sure the probe is completely dry before returning to storage in the plastic bag. Read carefully the probe instruction of use, originally attached to the probe package.

NOTE:

Only Shenzhen Dongdixin Technology Co., Ltd. or appointed distributors /importers are approved to undertake servicing.
Please contact us about our Vaginal /Rectal Probe

Disposal

If you need to dispose of the device and/or accessories, do so in accordance with the statutory regulations, Contact your local administration or a disposal company.

Specifications

1. EMG

1.1 Single channel EMG
1.2 EMG Range: 0.2 to 2000 µV RMS (continuous)
1.3 Sensitivity: 0.1 µV RMS
1.4 Accuracy: 4% of µV reading +/-0.3 µV at 200 Hz
1.5 Selectable Band pass filter - 3db Bandwidth,
a. Wide: 18 Hz +/- 4 Hz to 370 Hz +/- 10%
b. Narrow: 100 Hz +/- 5% to 370 Hz +/- 10%
1.6 Notch filter: 50 Hz (Canada 60Hz) - 33 dbs (0.1% accuracy)
1.7 Common Mode Rejection Ratio: 130 dbs Minimum @ 50 Hz
1.8 Battery: 1.5V, AA battery
1.9 Work / Rest periods: 2-99 seconds
1.10 Number of Trials: 2-99

2. STIM (Neuromuscular Stimulation)

2.1 Single channel Stimulator
2.2 Amplitude: 0-90 mA into1000 Ohm load - actual mA will tend to be less than indicated due to Electrode impedance
2.3 Type: Constant current, maximum output voltage 90 Volts +10/-10 Volts
2.4 Waveform: Symmetrical, rectangular, bi-phasic with net zero DC current
2.5 Pulse width selection: 50 - 450 µS (2% accuracy)
2.6 Pulse rate selection: 2-100 Hz (2% accuracy)
2.7 Work / Rest periods: 1-99 seconds
2.8 Time: 1 - 99 minutes
2.9 Ramp up time: 0.1 - 9.9 seconds
2.10 Preset and user programmable treatment Programs
2.11 Automatic output shut off with detection of open electrode above 1mA

Battery: Low battery indication at 4V +/- 0.2 volts, automatic shut off when voltage drops below the low indication. Replace the batteries immediately! When changing batteries it is recommended to have done it within ten minutes so that the internal clock is not lost. If the internal clock is lost, the setting of the internal clock can be done from the system setting menu.

The device switches off automatically when not in use (energy saving): For example when in some interfaces and no key pressed over 3 minutes.

Service life of the device: 3 years

Service life of the batteries: With new super heavy duty batteries, approximately 30 days when used for 25 minutes a day in program 01 at 45 level intensity.

Environmental Conditions for use:

5°C~40°C, 15%-93% Humidity.

Environmental conditions for storage & transport:
-10ºC~50ºC, 0-93% Humidity.
Atmospheric pressure:70.0 kPa ~106.0 kPa
Dimensions: Length 139mm, Width 68 mm, Depth 33 mm.
Weight: 156g (without batteries).

Information regarding Electromagnetic compatibility and interference (EMC)

Nu-Tek products are designed to produce very low levels of radio frequency (RF) emissions (interference), to reduce the effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2. For more information please refer to the tables 1, 2, 3 and 4.

The Nu-Tek Levator Elite may be subjected to Electromagnetic Interference.

Additionally, the power supplies of some notebook computers can give off substantial amounts of interference which the device is susceptible. This can happen when the power supply "block" has only a two pin connector connecting it to the mains with no earth.

As a precaution, make sure that the power cable from the notebook is placed as far away as possible from the connection wires of the device.

Try to keep the Nu-Tek Levator Elite close to the patient's body (in the "field" of the patient) either on their lap, in their pocket or clipped to their belt. Keep the electrode wires as close as possible to the patients' body and not dangling freely.

A relaxed muscle ideally should read below 4 microvolt (µV). If even when the patient's muscle is soft and relaxed to the touch, the reading is still high, try turning off the notebooks external main power supply. (The notebook will continue to run on its own internal battery). If the µV reading(s) suddenly reduce(s) and then go back up after turning on the notebook power supply, it means that and interference has occurred.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The Nu-Tek Levator Elite is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in all establishments , including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable- Battery Operated Device	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable- Battery Operated Device	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The Nu-Tek Levator Elite is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not Applicable - Battery	Mains power quality should be that of a typical commercial or

		Operated Device	hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Not Applicable - Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is needed that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency Magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
The Nu-Tek Levator Elite is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60501 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d=1.2√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d=1.2√P , 80MHz to 800MHz
			d=1.2√P , 800MHz to 2,5GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) Should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz ends 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Nu-Tek Levator Elite.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Nu-Tek Levator Elite			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by Maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nu-Tek Levator Elite as recommended below, according to the Maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of t ransmitter m**		
	150 kHz to 80 MHz d=1.2√P	**80 MHz to 800 MHz d=1.2√P**	**800 MHz to 2,5 GHz d=2.3√P**
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Trouble Shooting

If you are experiencing trouble with the device, please follow the steps below:

1. Check the lead wires for splits or breaks in the wire or at the end where the connectors are attached to the wire.
2. Check the lead wires of surface and or internal electrodes. Poor quality electrodes will cause incorrect readings. We always recommend the use of good quality electrodes. we also recommend you keep a spare pack of electrodes.
3. If you are using Vaginal or Rectal probes, we suggest the usage of conductive gel as recommended by the physiotherapist or doctor.
4. Some patients' vaginal aperture may be too large for some internal probes causing intermittent contact with the walls of the pelvic floor muscle. In such cases try larger probe. We provide different size vaginal probes.
5. If connected to a laptop or desk top computer, Check the USB cable for any visible damage as this may obstruct the signal from the device to the computer.
6. If none of the above-mentioned problems help, try to restore factory setting. In system setting, using ▲ ,▼ select **Factory Data Reset**, select **Save.**

If this problem causes ongoing difficulties, please contact Shenzhen Dongdixin Technology Co., Ltd. for assistance.

Stimulation Mode

1. If the current mA reverts back to zero and you see displayed **Electrode falling off** on the LCD screen, it may be due to an open circuit (no connection) between the input lead wires connected to the unit and the lead wires connected to the surface electrodes. Remember! Our device will not produce the stimulation output without electrodes placed on your body! We suggest replacing the electrodes first and then check the lead wires connected to the unit, try a new set of electrodes, and or another set of lead wires.
2. If the stimulation current mA fails, please be sure that the battery is fully charged.

WE STRONGLY ADVISE YOU TO KEEP A SPARE SET OF DUAL AND SINGLE CONDUCTOR LEAD WIRES!

If you cannot find the answer from the above list of suggestions, please visit our website www.nutek-emg.com, select CONTACT US.

※ Contact your Distributor who may be able to guide you through any issues.
※ You will need to obtain notice from the Distributor from whom you purchased the device before returning it to them for replacement or repair (sometimes the returned products are not faulty and there is another reason for it not working, in this situation you might be charged for postage and/or product examination).

Symbols on the rear and top cabinet housing of Levator Elite explained:

Type BF applied part

Refer to instruction manual because of the higher levels of output

Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions

CE 0197

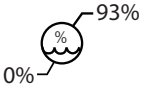
Complies with MDD 93/42/EEC and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)

The name and the address of the manufacturer

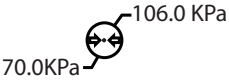
EC REP

The name and the address of the Authorized EC-representative in Europe

Transportation and storage temperature from -10℃ to 50℃



Transportation and storage humidity limits from 0% to 93%



Transportation and storage atmospheric pressure limits from 70.0 kPa to106.0 kPa

Keep dry

SN

Represent the manufacture date and Serial number.

Warranty

Shenzhen Dongdixin Technology Co., Ltd. provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 years from the date of purchase. If the distributor - from whom the product was purchased by the user – is satisfied that the product is defective, the user may return the device directly to this Distributor who will forward it to Shenzhen Dongdixin Technology Co., Ltd. All such returns from the Distributor to Shenzhen Dongdixin Technology Co., Ltd. must be authorised by Shenzhen Dongdixin Technology Co., Ltd. in advance. The liability of Shenzhen Dongdixin Technology Co., Ltd. under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the device in water or other liquid substance or tampering with the device or normal wear and tear. Any evidence of tampering will nullify this warranty.

Appendix: Program

STIM: Continence									
NO	Application	Phase	Mode	Phase time(min)	Frequency (Hz)	Pulse width (μS)	Work time (s)	Rest time (s)	Overall time (min)
P1	Female urge incontinence1	1	SYN	25	10	240	6	8	25
P2	Female genuine stress 1	1	SYN	20	35	250	6	10	20
P3	Female genuine stress 2	1	SYN	20	35	250	6	15	20
P4	Frequency	1	SYN	25	10	250	6	10	25
P5	External stress using surface Electrodes on the lower back	1-2	CONT or SYN	10-35	20-35	300	6	9	45
P6	OAB using surface Electrodes on the Tibial Nerves	1	CONT	25	10	220	/	/	25
P7	External Stress using surface electrodes on the buttock	1	SYN	30	35	450	7	9	30
P8	Mixed Stress/Urge/ Frequency	1-3	SYN	5-10	10-35	200-240	5	7-8	25
P9	Sensory nerve test	1	SYN	4	20	220	6	8	4
P10	Regenerate Sensory Nerves	1-5	SYN	5-10	4-40	200-300	5-6	8	35
P11	Female and Male Rectal stimulation	1	SYN	20	35	220	6	12	20
P12	Pelvic Floor Exercise Work Out	1-5	SYN	5-6	3-35	200-250	6-7	7-10	27
P13	Maximum Pelvic Floor Exercise Shoot Bursts	1-3	CONT or SYN	4-5	4-35	260-300	6	8	14
P14	Pelvic Floor Endurance	1-4	SYN	5-10	4-35	240-300	6-8	7	30
P15	Weekly Maintenance	1-5	SYN	4-5	4-35	200-240	5-6	8	24
P16	New Mums	1-5	SYN	4-10	4-35	200	5	10-12	28
P17	Hysterectomy	1-4	SYN	5-10	4-35	200-220	5-6	8-10	25
P18	Prolapse Cystocoele grade 1 only	1	SYN	25	10	220	5	8	25
P19	Sexual improvement	1-4	SYN	4-10	4-50	200-300	6-8	8	23
P20	Pain Relief	1-2	CONT	10-20	3-10	200	/	/	30
PC1 PC2 PC3	You can setup up to 5 stimulation phases, each phase can be Synchronous or Continuous, and Custom program used to set up individual requirements, maximum treat time is 99 mins.								

Note:

P3: This program allows for a longer resting time of 15 seconds for those who have a weak pelvic muscle.

P5: Place surface electrodes size 100 x50mm on lower back site S2-S3 50mm either side of spine.

P6: Place electrodes on lower leg above the ankle using surface electrodes size 100 x 50mm OAB {over active bladder}.

P7: Place four surface electrodes size 100x50mm, two on the rear and two on the side of the buttocks (You're recommended to order Electrodes from your distributor in case you need more).
P9: This program is to test the level of mA {milli amps} you reach at which you feel a muscle contraction. If your level of mA reading Is above 40 use P10 to improve Regeneration of Sensory Nerves.
P11: You're recommended to purchase rectal probe from your distributor before using this program.
P12: Use this program once or twice per week to maintain the Pelvic muscle condition.
P16: Use stimulation at least 6 weeks after birth or when advised by a doctor.
P17: Follow your gynaecologist's or physiotherapist's advice on the appropriate time to commence stimulation after hysterectomy.
P18: Use only for cystocele grade 1. Very important you seek guidance from your Therapist before using Electrical Stimulation.
P8, P10, P13, P14, P15, P19: Contract pelvic floor muscles during stimulation work periods.

EMG programs						
NO	Phase	Threshold	Work time (sec)	Rest time (sec)	Trials (repetitions)	Overall time (sec)
P1	1 EMG	Auto	5	5	5	50
PC1 PC2	You can setup1 EMG phases with your preferable parameters.					

ETS programs	
PC1 PC2	You can setup1 ETS phases with your preferable parameters.