



NG Shield™

User Manual

Cat.# NGUM001 Ver.01

Table of Contents

General Information	3
General Description.....	3
Definitions	3
Clinical Information	5
Intended Use.....	5
Patient Eligibility.....	5
Contraindications	5
Pre-Use Preparations	6
General instructions:	6
Instructions for the Patient	6
Using the NG Shield	7
Applying the NG Shield.....	7
NG Shield Description	10
Magnetic field	11
Environment requirements	11
Safety Information.....	14
Charging Requirements.....	14
Product Classification	14
Compliance with Standards.....	14
Storage and Maintenance	16
Storage before Use / Expiration Dates	16
Cleaning the units.....	16
Frequently Asked Questions	17
Addresses	18

General Information

General Description

The NanoVibronix NG Shield is designed as an add-on device, aimed to decrease pain and discomfort associated with NG tube insertion and usage. A miniature clip-on device is attached to the extracorporeal part of the NG tube which generates surface micro vibrations along the tube. These vibrations reduce the friction between the tube and the internal tissues thus minimizing the damage caused to the nasal, pharyngeal and esophagus mucosa. The actuator is secured to the tube from its distal end. The actuator is driven by high frequency electrical signals from a proprietary generator powered by rechargeable batteries

Definitions

- NG tube** – Naso Gastric tube introduced through the nose into the stomach
- Vibrations** – Acoustic (mechanical) waves
- Driver** – Electronic unit that provides the electronic signal to the Actuator
- Actuator** – The element which creates vibrations on the surface of NG tube. The actuator converts the electronic signal provided by the driver into vibrations

WARNING! Identifies situations or actions that may affect patient's or user's safety.

CAUTION! Points out special procedures or precautions that must be followed to avoid equipment damage

ATTENTION! Stresses that the following note should be clearly understood by the user or patient before using the device

Important Notices

- WARNING!*** NG Shield should only be used in the manner described in this User Manual.
- WARNING!*** The unit is classified as internally powered, intermittently operated; ordinary equipment with disposable type BF applied part. The device is not intended for use in the presence of flammable mixtures.
- CAUTION!*** Applies for the Lithium ion rechargeable batteries only. Do not disassemble heat above 100 ° C, incinerate or expose contents to water.
- CAUTION!*** NG tube should be inserted by skilled medical professional as per facility standard of care.
- CAUTION!*** The driver should not be connected and used during charging mode.
- WARNING!*** The NG Shield driver and actuator are not waterproof and therefore should not be immersed in water or other liquid.

Clinical Information

Intended Use

NG Shield is intended to decrease friction between the NG tube and body tissues that it is coming in contact with, thus it decreases pain and discomfort associated with NG tube during insertion and indwelling term.

NG Shield is indicated as an active accessory to an indwelling NG tube.

Patient Eligibility

Any patient requiring insertion of NG tube.

Contraindications

NG tube size over 18 Fr.

NG tube size under 8 Fr.

Patients with pace-maker or electrical implanted devices.

Pre-Use Preparations

General instructions:

1. The actuator is designed for one-time use only.
2. The hospital staff should check the LED indicators on the driver during each shift to ensure proper device function.
3. After use, the actuator must be disposed of along with the NG tube, according to facility standards for the disposal of used medical devices.
4. Should the actuator become soiled; it should be cleaned with a slightly damp sponge and be allowed to air dry.
5. A fully charged NG Shield driver has an operation life of - 24 h and should be replaced by fully recharged driver. The drained driver should be only charged using the supplied charger.
6. Driver UD-13A should be used only after it was fully charged. Do not use the driver directly from packaging. Charge it for six hours before first use.

Instructions for the Patient

1. Instruct the patient not to pull or open the NG Shield actuator at any time.
2. Instruct the patient not to disconnect the cord that connects the actuator to the driver.
3. Instruct the patient not to press the ON/OFF button on the driver unit.
4. Instruct the patient to inform the nursing staff if any alarms are heard, or if the green light has stopped blinking.

Using the NG Shield

Applying the NG Shield

1. Remove actuator from its package and place it at the distal end of the NG tube (see Figure 1).

Do not remove the adhesive tape strips at this stage.

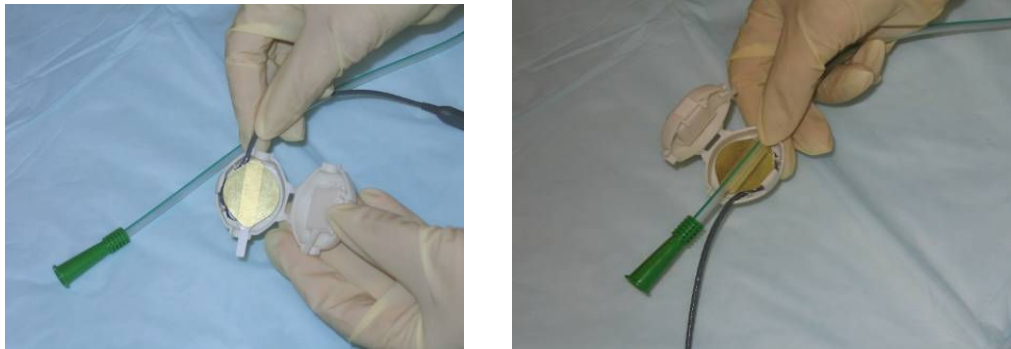


Figure 1: Actuator placement

2. Clip the actuator and close it on the NG tube and then connect the actuator's cable with the driver's cable (see Figure 2).

The NG Shield system is ready to use. Turn it on according to "Activation of the NG Shield" instructions (please see below).



Figure 2: Actuator attachment and system activation

3. Insert the NG tube through patient nose while the NG Shield system is active (Tube vibrations can be felt) (see Figure 3).



Figure 3: NG Tube insertion

4. Slide the actuator on the tube in proximal direction to the optimal position (determined by the physician according to patient's comfort level) (see Figure 4).

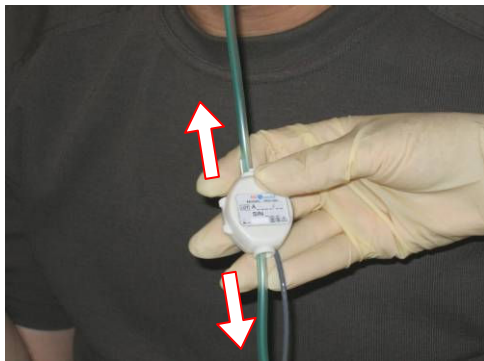


Figure 4: Actuator optimal position

5. Apply a fixation NG strip as commonly used to NG tubes.
6. Open the actuator's case, remove the adhesive tapes (both sides 1, 2) and fix the actuator at the designated position (see Figure 5).

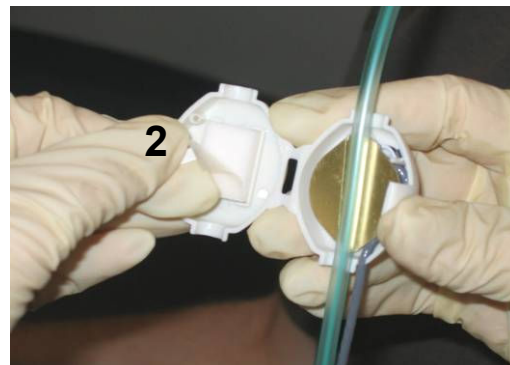
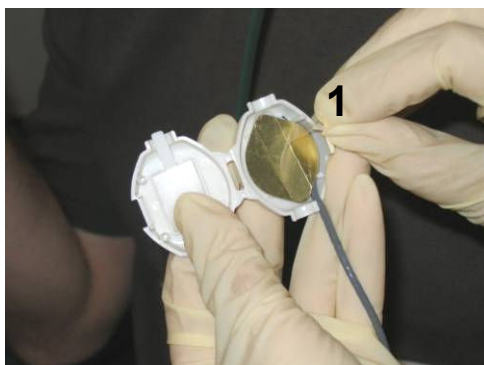


Figure 5: Actuator fixation

Activation of the NG Shield

1. Press ON/OFF button on driver's front panel to activate the device. Note that a blinking green light indicates that the system is working (see Figure 6).

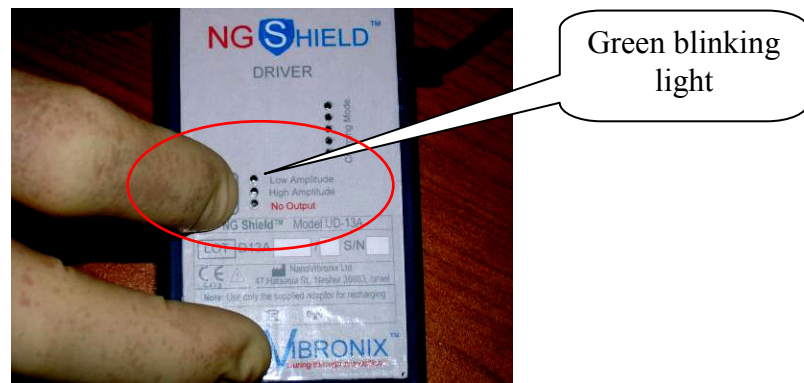


Figure 6: Driver activation

Deactivation of the NG Shield

1. Press the ON/OFF button till you hear a beeping sound. Once the driver is off, LEDs should not be blinking (see Figure 7).

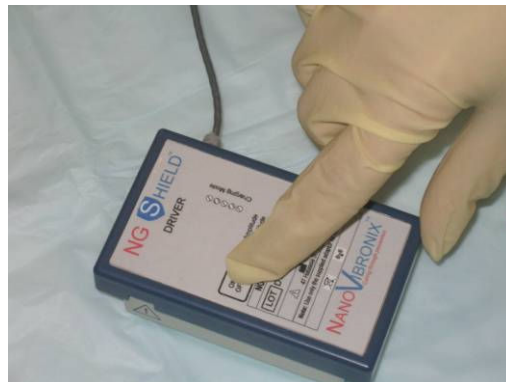




Figure 7: Driver deactivation

NG Shield Description

The NG Shield System is comprised of two main components:

1. **The Disposable NG Shield Actuator** – a disposable, small, lightweight clip-on actuator, which is attached to the NG tube prior to its insertion into the patient’s nose. The actuator does not have direct contact with patient’s skin. The actuator receives the energy and electrical signals from the NG Shield Driver.
2. **The NG Shield Driver** – a driver unit, which supplies electrical signals to the NG Shield Actuator. The driver unit is battery operated and controls the functionality of the actuator unit. The driver is small, lightweight and can be placed on the patient bed, or worn on a belt if the patient is ambulatory.

<p><u>NG Shield Actuator</u></p> <p>Length: 42mm</p> <p>Width: 34mm</p> <p>Height: 15mm</p> <p>Weight: 17 grams</p> <p>Housing: Polypropylene</p>	
<p><u>NG Shield Driver</u></p> <p>External dimensions: 90 mm x 53 mm x 35 mm</p> <p>Weight: less than 250 gr.</p> <p>Housing: ABS box</p> <p>Batteries: Lithium-Ion rechargeable batteries</p>	

NG Shield System Applied

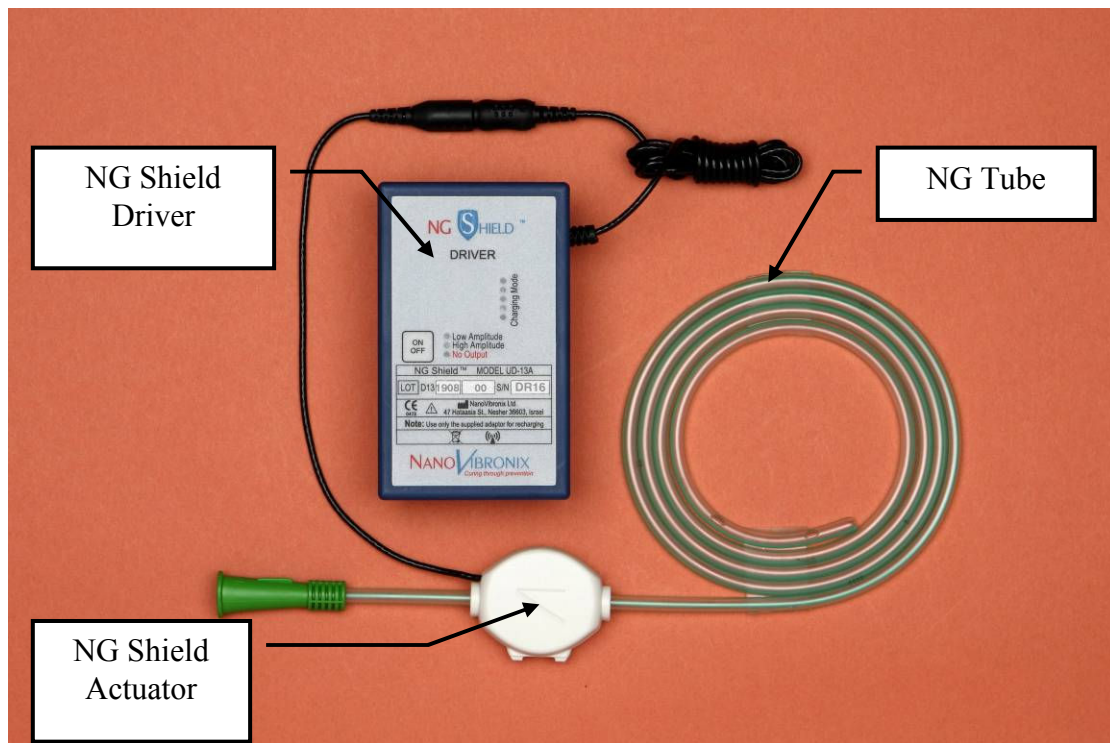


Figure 8: NG Shield System

NG Shield operating modes:

- **Working mode** – an actuator is connected and power is applied to electrical circuitry. If no load occurs, the system generates audible and visual alarms.
- **Off Mode** – no power output to the actuator.
- **Charging mode** – external power supply is connected to recharge battery. The system should be in Off Mode (no signal to Actuator).

Magnetic field

The system emits low energy onto the inner and outer surfaces of the NG tube. It is designed to comply with the requirements of the recognized standards IEC-60601-1 and EN60601-1-2.

Environment requirements

- Temp: 0°-40°C.
- Humidity: 20-85%.

Labels

The following labels are attached to the system:

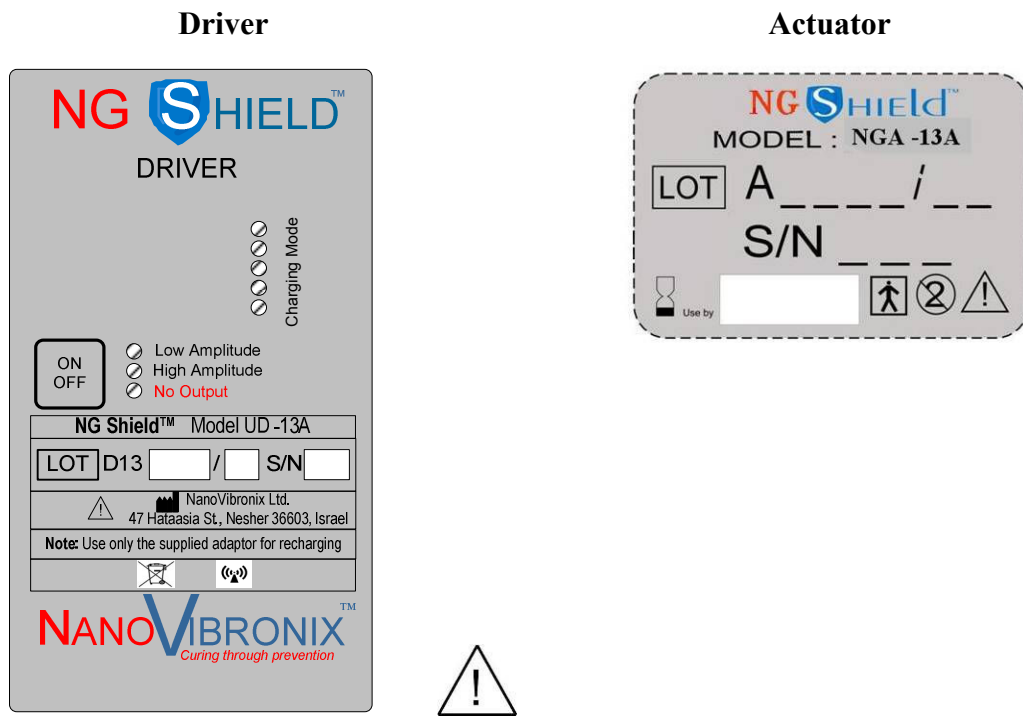


Figure 9: NG Shield Labels

Symbols



Class BF applied part



Do not reuse



Caution, consult accompanying documents



Manufacturer



Authorized representative in the European Community



Use by YYYY-MM

Used by YYYY-MM

S/N

Serial number



LOT number



Separate collection for electrical and electronic equipment



Rated frequency or rated frequency range(s) (Hz)

Safety Information

- This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained in this manual.
- There are no user serviceable parts in this system. If your product does not operate as expected, please contact your local representative.
- The NG Shield Driver and Actuator are not MRI compatible. Before entering the MRI suite, the Driver and Actuator should be turned off and then disconnected from the patient to insure that it is not in the area of the MRI magnetic field
- Before using this device, the operator must be familiar with the operator instructions and safety precautions listed here and throughout the manual.
- If the product does not operate properly or if it fails to respond to the controls as described in this manual, the operator should contact the local representative.

Charging Requirements

Use only the provided power supply to recharge the Driver.

Product Classification

Low risk device classification:

CE mark – Class II a

Compliance with Standards

IEC 60601-1, IEC-60601-2.

ISO 10993.

Switch and Indications

Audio visual indication of proper operation or malfunction (see fig.10):

<i>Indication / Switch</i>	<i>Meaning</i>
“Low Amplitude” LED is blinking (Green)	The system is ON.
“High Amplitude” LED is continuously lit	The vibration generator is ON.
“Charging Mode” LED bar is full	Battery is fully charged.
ON / OFF button	Momentary switch for activation / deactivation of the driver.
The lower LED at the “Charging Mode” LED bar is blinking and an audible alert is heard	Low Battery. The driver requires charging.
“No Output” - LED is on (Red) and an audible alert is heard	Actuator disconnected (no load)

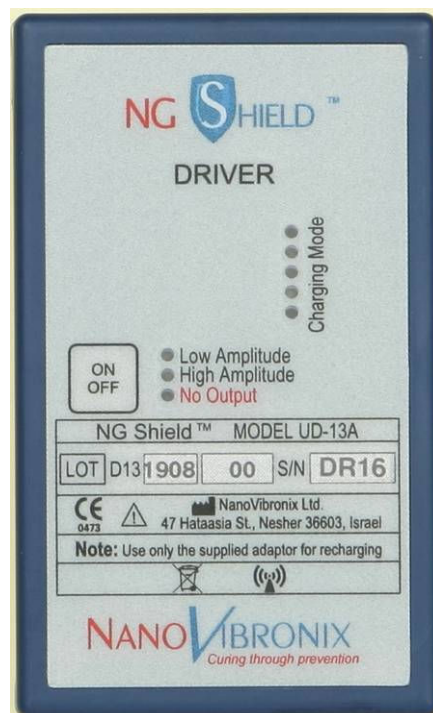


Figure 10: NG Shield Indicators

Storage and Maintenance

Storage before Use / Expiration Dates

The system should not be exposed to extreme environmental conditions; therefore, the NG Shield system and accessories must be stored in its shipment box under standard conditions:

Temp: 10° - 30° C

Humidity: 20 - 55 %

Disposable actuator is warranted up to 2 year in original packaging.

Operational period

NG tubes are to be replaced according to the local facility clinical guidelines. Replacing the tube requires a new actuator to be clipped on and then reattached to driver.

The driver is intended to work without recharging for 24 hours *.

The actuator is intended to work for 24 hours *.

The driver is under manufacturer's warranty for 1 year.

* *Only with standard parameters and conditions.*

Cleaning the units

- The components are supplied clean. No sterilization or disinfection is required.
- If needed, clean the actuator and the driver with 70% alcohol pads.

Frequently Asked Questions

Question

Answer

Can the NG Shield be used with all types of NG tube? No, it can only be used with 8 -18 Fr. tubes

Is it OK to reuse the Actuator if I disinfect it? No, the actuator is for-one time use only.

Addresses

Company address – plant (manufacturer)

NanoVibronix Ltd.,

47 Hataasia st.,

P.O.Box 515, Nesher 36603,

Israel.

Tel: +972 - 4- 8200581

Fax: +972-4-8202794

Company address

NanoVibronix Inc.,

P.O.Box 507,

Cedarhurst, NY 11516,

USA.

Tel: 516-5696872

Representative in Europe

MEDNET GmbH

BORKSTRASSE 10,
48163 MUNSTER,
GERMANY.

PHONE: 49-251-32266-0

Fax: 49-251-32266-22

E-MAIL ADDRESS: INFO@MEDNETEUROPE.COM