



Instructions for Use

INDICATIONS FOR USE

Noodle is intended to reduce injection-site pain of hypodermic injections into the upper extremities (arms), lower extremities (leg), buttocks, abdomen, and deltoid areas in patients 18 to 70 years of age.

The Noodle device may be used in the home by patients who self-administer injections or in a medical setting by professional healthcare providers. Body parts intended to be conditioned by the Noodle device are sites that are commonly the target of injections such as the upper and lower extremities (arms and legs), buttocks, abdomen, and deltoid.

The Noodle device is not intended to be used on smaller body parts such as the hands, feet, head (including ears, nose and around the eyes), neck, and the abdominal area in pregnant women.

CONTRAINDICATIONS

Do not use if you

- have a history of seizures
- have a cardiac pace-maker, or an implanted defibrillator.
- have a history of alteration of rhythm
- have a history of cerebrovascular problems including aneurysm, stroke or transient ischemic attack
- have a history of electrical accidents such as electric shock.

PRECAUTIONS

- Do not apply to skin near open wounds or dermatologic lesions.
- Pregnant women: the safety and effectiveness has not been established in pregnant women.
- Stimulation delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or across the chest because it may cause a cardiac arrhythmia.
- Do not place electrodes on the front of the throat as spasm of the laryngeal and pharyngeal muscle may occur. Stimulation over the neck region may close the airways, make breathing difficult, and may have adverse effects on the heart rhythm or blood pressure.

- Do not place electrodes on your head or any side that may cause the electrical current to flow transcerebrally (through the head).
- This device should not be used while driving, operating machinery, close to water, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Isolated cases of skin irritation may occur at the site of electrode placement. To avoid this problem, change the site of electrode placement. If the problem reoccurs, discontinue use and consult your physician.
- This device has no AP/APG protection. Do not use it in the presence of explosive atmosphere and flammable mixture.

WARNINGS

Electronic monitoring equipment, such as electrocardiogram (ECG) monitors and ECG alarms, may not operate properly when this device is in use.

Use caution in applying Noodle to patients suspected of having heart disease.

Electrodes should not be placed over the eyes, in the mouth, or internally.

Noodle is not cleared by FDA for individuals under 18 years old.

Do not store Sponge Sticks above 180 degrees F.

The long-term effects of chronic electrical stimulation are unknown.

Make sure to place the needle at the location indicated by the triangle in order to avoid local or systemic infection.

If your clothing prevents you from seeing your belly, choose a more visible location for injection, or ask someone for help to place the needle at the area indicated by the blue arrow.

Users that suffer from tremor of the hand should ask someone else to give them the injection.

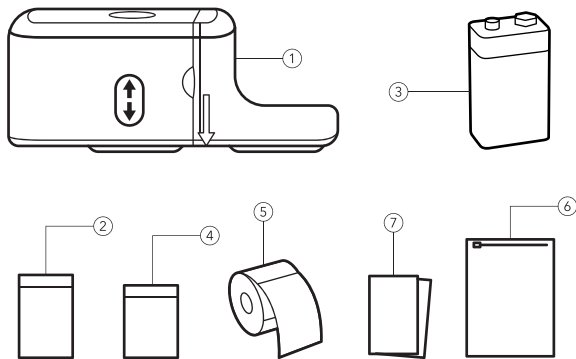
KEEP OUT OF REACH OF CHILDREN

ADVERSE REACTIONS

Skin irritation and Electrode burns are potential adverse reactions. If skin irritation occurs, lower the intensity of electrical pulses and change where you place the electrodes. If the tingling sensation of Noodle is too high to tolerate, use the down button to lower the tingling sensation or remove Noodle from the skin.

CONTENTS

Each package of Noodle comes complete with standard accessories and the standard labels as in the following.



1. A unit of Noodle.
2. A 6-pack of 1.34" x 1.34 electrode gels.
3. 9 volt battery.
4. A pack of 30 sponge sticks for single use.
5. A pack of Stickers.
6. A Carry-On bag for Noodle.
7. Instruction manual.

REPLACEABLE PARTS

The following are replaceable parts and accessories of Noodle.

- > Commercial 9V Battery,
- > Electrode gels, and
- > Sponge sticks.
- > Stickers

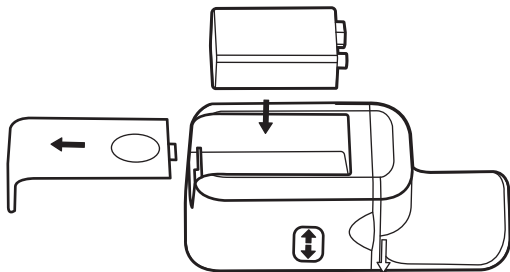
**PLEASE ORDER REPLACEMENT ELECTRODES AND SPONGE STICKS BY VISITING
PAINLESS.WORLD OR CALLING 201-200-0100.**

Congratulations for purchasing Noodle. You are now on your path to reduced injection site pain.

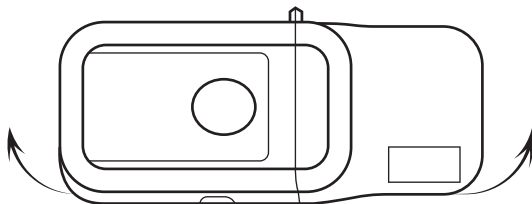
PRE-INJECTION INSTRUCTIONS

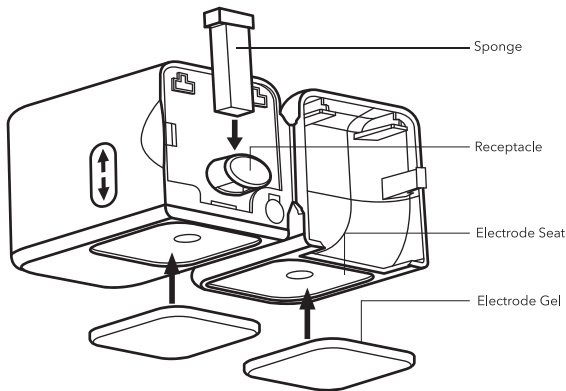
Open the battery door. Remove the plastic seal on the 9 volt battery. Insert the provided 9V battery into the battery compartment and fasten it to the battery clip. Close the battery door. Replace battery as needed.

Wipe Noodle with a wiping cloth impregnated with isopropyl or ethyl alcohol 60-80%.



Open the compartment as in the diagram.



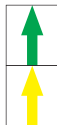


- Remove a sponge stick from the green sponge bag included without touching the other sponges. Insert the sponge stick into the slot of the receptacle provided in the Noodle device as shown in the diagram above. It doesn't matter what the orientation of the receptacle is.
- Close the compartment.
- Remove two electrode gels included in the package. One side of the electrode has a black surface, one side a brown surface. Peel the cover from the brown surface and adhere the brown surface to an electrode seat as shown in the diagram. Repeat to adhere another electrode gel to the other electrode seat. **DO NOT** remove the protective cover from the black surface yet.
- Electrode pads and sponge sticks should be replaced with each use of the device.

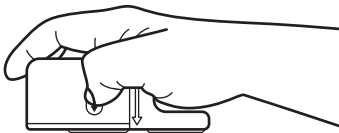
You are now ready to operate Noodle.

Instruction For Injection Site Use

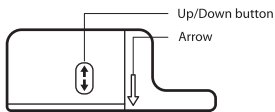
- Peel the adhesive cover off one sticker and have it available for easy access with the adhesive side facing up.
- Locate an injection site where both electrodes on Noodle can touch the skin - referencing the warnings and precautions listed earlier in this user manual.



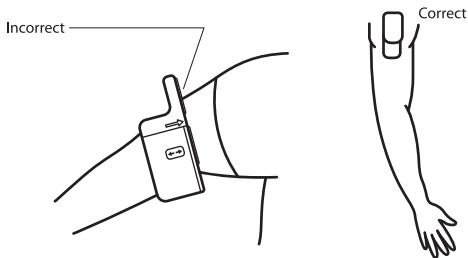
- If the injection site is visibly soiled, wash it with soap and dry it; and prep injection site with antiseptic wipes (e.g., isopropyl or ethyl alcohol 60-80%).
- Hold Noodle with your right hand as in the diagram.



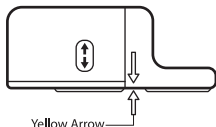
- Locate the arrow on Noodle. It is to the right of the Up/Down button.



- Place Noodle on the injection site. Make sure the arrow is visible to you when you place Noodle on the injection site, and the two black electrodes touch the skin at the same time. Avoid sharp curves on the body so that both electrodes can touch the skin at the same time. If the two black electrodes do not touch the skin, find a different location or position Noodle differently so they do



- Insert the green arrow of the sticker under Noodle with the adhesive side facing the skin. The yellow arrow should point to the arrow on Noodle. You'll have to lift Noodle slightly so that the sticker can fit between Noodle and the skin.



Press the sticker on the skin to secure it on the skin. You may need to remove Noodle from the skin to do that.

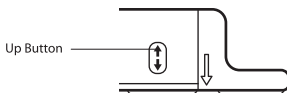
Peel off the covers from black surfaces of the electrodes.

Place Noodle back on the injection site.

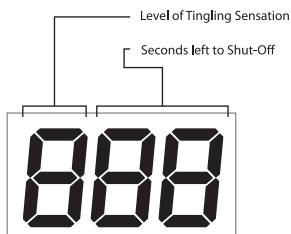
Line up the edge of Noodle with the black solid line on the sticker while the arrow on Noodle points to the yellow arrow on the sticker as you did before.

Make sure both electrodes touch the skin.

Press and hold the Up Button for a few seconds to turn on the device.



A 3-digit LED turns on to the left of the Up-Down Button. The left digit indicates the level of tingling (TENS) sensation you feel. The middle and right digit show the number of seconds remaining before shut off.

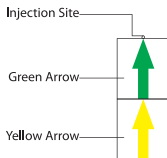


Noodle starts vibrating. If you don't feel the vibration, you are probably pressing Noodle too hard on the skin. Momentarily lighten the pressure to allow the sponge stick to start rotating.

Click the Up button a few times to increase the intensity of tingling sensation to maximum tolerable level.

When you are done adjusting the tingling level, the timer (the right and the middle digits) starts counting from 25 seconds to 0.

- While holding Noodle with one hand on the skin, hold the syringe with the other hand.
- Wait until Noodle beeps (25 seconds).
- Remove Noodle and place on a nearby surface.
- With the freed hand, uncap the syringe, and
- Inject as you normally do into the injection site which is pointed to by the green arrow on the sticker



- After the injection, remove the sticker; remove the electrode gel pads and sponge stick and discard.
- Store Noodle for future use.

Cleaning, Maintenance, Transportation, and Storage of the Device

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: do not smoke or work with open lights (for example candles) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Place the device in a ziplock bag provided before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment. Foot the device and the accessories in a ziplock bag, lock the ziplock bag, and keep it in a cool dry place.
6. Noodle should be stored and transported in the temperature range between -20° c to 60° c, relative humidity 20% to 95%, atmospheric pressure 500 hPa to 1060 hPa.

Conformity to Safety Standards

Noodle devices are compliant with the following Standards: IEC 60601-1, 60602-1-2, IEC 60601-2-10, and IEC 60601-1-11.

Important information regarding electromagnetic compatibility.

- This device passed the EMC testing method SRPS EN 60601-1-2:2016.
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm or 12 in to any part of the device. Otherwise, degradation of the performance of this equipment could result.
- When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the device may be affected as follows:
 - the device stops output;
 - the device turns off;
 - the device restarts.
- The above phenomenon does not affect the basic safety and essential performance of the device, and the user can use it according to the instructions. Please use the device according to the instructions in order to avoid the above phenomena.

Questions or Concerns

Please contact Painless World, 901 Bergen Ave., Jersey City, NJ 07306, phone: 201-200- 0100 for any questions or concerns you may have.