

Urgent[®] PC

NEUROMODULATION SYSTEM

Treatment Steps



Step 1: Check Battery

Prior to beginning treatment, check battery level. To turn on the stimulator, hold down the Power button for two seconds. Change battery when there is only one line remaining in the Battery icon. Turn off Stimulator.



Step 2: Locate Needle Insertion Site

On the inner leg, use the width of 3 fingers to measure approximately 2 inches from the center of the ankle bone (2A). Move the top finger back $\frac{3}{4}$ - 1 inch (2B). Your finger should be positioned just behind the tibia.



Step 3: Place Needle Electrode at 60° Angle

Clean the insertion site with the provided alcohol pad. Before removing the clear guide tube or pink stop plug, place the Needle Electrode over the insertion location. The needle should be at a 60° angle from the ankle. Remove stop plug.



Step 4: Insert Needle Electrode

Gently tap the top of the Needle Electrode to pierce the skin. Remove the guide tube.



Step 5: Advance Needle Electrode

Using a rotating motion, advance the Needle Electrode until approximately 2 cm, or half of the bottom portion, is inserted into the leg.



Step 6: Connect Lead Wire to Stimulator



Step 7: Place Surface Electrode

Remove adhesive backing from the Surface Electrode. Place the Surface Electrode on the inside arch of the foot on the treatment leg.



Step 8: Attach Needle Electrode Clip

Attach Needle Electrode Clip by depressing the plunger and hooking it around the Needle Electrode, close to the skin.



Step 9: Begin Treatment

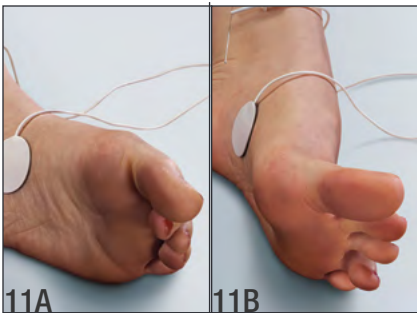
Before turning on the Stimulator, talk to your patient about how you will confirm that the stimulation is reaching the tibial nerve. Patient response may be either motor or sensory; for some patients it may be both. Ask your patient to let you know if they start to feel a sensation in their leg or foot.

After turning the Stimulator on, enter Test Mode by holding down the yellow Test button for 2 seconds.



Step 10: Identify Treatment Level

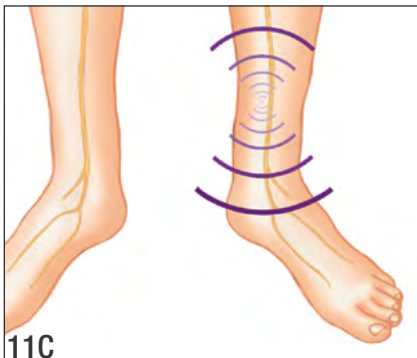
Using Current Adjustment button, slowly increase setting while observing patient's foot for a response and periodically asking the patient if they feel any sensation in their leg or foot.

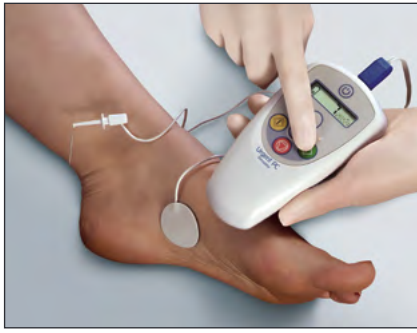


Step 11: Confirm Patient Response

Motor response is usually a toe flex (11A), toe fan (11B) or toe twitch. Sensory response (11C) is generally described as a mild pulsing sensation which travels away from the insertion site, towards the heel, arch, toes or up the leg.

- » If the patient is uncomfortable, reduce current setting, reposition needle electrode or try the other leg.
- » If the sensation is localized to the immediate area around the insertion site, the needle electrode may need to be inserted further. About half of the bottom portion of the electrode should be inserted in the leg.
- » If there is neither a motor or sensory response, adjust the needle electrode. If there is still no response, discard the needle electrode and try the other ankle.
- » Note that an individual patient's response may vary from treatment to treatment, based on the needle electrode depth and location.





Step 12: Therapy Mode

Reduce current setting by one increment and press the green Therapy button for 2 seconds. Therapy mode is automatically set for 30 minutes.



Step 13: Patient Receives Treatment with Urgent PC Neuromodulation System

The patient is seated comfortably during treatment.

Step 14: Complete Treatment Session

Therapy mode will automatically end after 30 minutes. At this point, the Stimulator will display the word "End" and emit a series of three beeps. Turn off Stimulator and remove the Needle Electrode and other components.

Urgent PC is indicated for the treatment of Overactive Bladder and associated symptoms of urinary urgency, urinary frequency and urge incontinence. **CONTRAINDICATIONS:** Treatment with Urgent PC is contraindicated for patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or patients who are pregnant or planning to become pregnant during the duration of the treatment. **PRECAUTIONS:** Exercise caution for patients with heart problems related to pacing. Most patients don't experience side-effects. If side-effects occur, they are typically temporary and include mild pain and skin inflammation at or near the stimulation site. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each Urgent PC product or online at www.cogentixmedical.com.

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