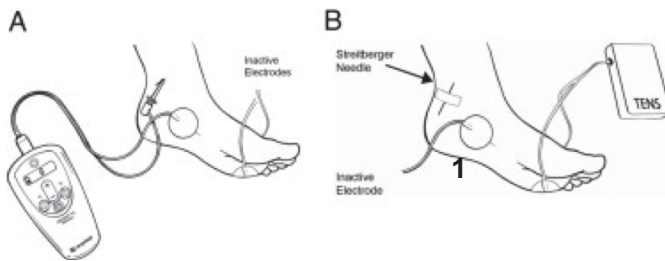


CONTROL of Faecal Incontinence using Distal Neuromodulation (CONFIDeNT)

Standardised PTNS and Sham

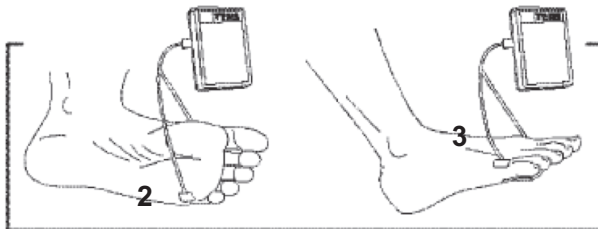
EQUIPMENT SET UP

Figure 1



1. Just distal to calcaneus on sole of foot in midline (active for PTNS)
2. Bottom of foot just proximal to smallest toe
3. Top of foot just above smallest toe

Figure 2



Sham

PTNS: Urgent® PC neuromodulation system (Uroplasty Ltd., Manchester, UK).

- Needle: Lower inner aspect of the RIGHT leg - three finger breaths (5 cm) cephalad to the medial malleolus and approximately one fingerbreadth (2 cm) posterior to the tibia. 60-degree angle between electrode and ankle.
- Electrode: Ipsilateral calcaneus.

TENS: Biostim M7 TENS unit, Biomedical Life Systems, Vista, California

- Electrodes: Right foot, one under the little toe and one on top of the foot.

FOR PTNS:

- Set up both machines.
- Place tape over wire connected to PTNS needle (so appearance is identical to sham).
- Only turn on PTNS machine - fixed-pulse frequency of 20Hz and a pulse width of 200 microseconds
- Continue treatment as usual – increasing amplitude until a sensory or motor response – reduce.
- DO NOT ALLOW PARTICIPANT TO ALTER SETTINGS THEMSELVES

FOR SHAM:

- Set up both machines. With PTNS, DO NOT CONNECT LEAD TO PTNS NEEDLE.
- Instead, tape lead near needle so it is not possible to tell at a glance if connected or not.
- Pick up both the TENS and PTNS machines
- Check TENS settings **pulse frequency 10Hz and pulse width 200 microseconds**.
- Press buttons simultaneously on PTNS and TENS machines to increase Amplitude (participant will only feel TENS as PTNS machine is not properly connected). THE PARTICIPANT WILL THEN HEAR THE BEEPS FROM THE PTNS MACHINE AS IN THE PTNS ARM.
- When a significant sensory or motor response is observed, turn down one setting.
- **Press timer button twice – 30 mins will count down on TENS display**
- Leave the participant as usual for the 30 minute treatment.
- DO NOT ALLOW PARTICIPANT TO ALTER SETTINGS THEMSELVES

VERBAL EXPLANATION TO PARTICIPANT

“I am now going to start the nerve stimulation treatment. I will be inserting a small electrode needle, like an acupuncture needle, into your leg and putting sticky electrodes onto your foot. When I turn the machine on you will be asked when you can first feel an electrical sensation in your ankle or foot. I will carry on increasing the intensity of this until it is slightly uncomfortable, then I will turn it down a little if necessary. Occasionally you may also feel numbness or slight movement of your toes. This is normal. I will set the machine up and leave it running for 30 minutes. You may or may not continue to feel the stimulation during this time – this is normal also. After 30 minutes have elapsed I will remove the needle and sticky electrodes (the machine automatically turns off at this time). If the treatment becomes uncomfortable at any point please let me know and I will turn it down or stop the machine.”