

vTone applicator provides electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women.

vTone TYPICAL TREATMENT PARAMETERS

Intensity Level	Treatment time [min]
To prepare the muscles for maximum stimulation, gradually increase intensity during first few minutes to reach notable muscle contractions. *	20-30

**Adjust parameters according to patient tolerance and muscle contraction level.*

PRE-TREATMENT

- Inspect all components of the handpiece for visible damage.
- Review patient intake, indications, contraindications, inform the patient about treatment schedule, typical treatment results and possible side effects and discomfort. Instruct the patient about the safety warnings.
- Hair should be shaved - not waxed or chemically removed - in the treatment area 2-4 days prior treatment.
- Remove any jewelry in the treatment area.
- The patient should empty the bladder prior to the procedure.
- The patient should be fully undressed from the waist down and be comfortable on the treatment table in a dorsal lithotomy position to provide clear exposure to the treatment area.
- Perform an exam of the treatment area immediately prior to the procedure to visualize the area that is going to be treated.
- Clean the treatment area with disinfecting solution. Ensure that the treatment area is clean and dry from all residue prior to beginning the procedure.

TREATMENT PROCEDURE

- Connect EMS adaptor to the device and hook it on the device cradle.
- Connect disposable single use applicator to the EMS adaptor.
- Apply thin layer of clear ultrasound gel (not oil) to the vTone Applicator electrodes. Applying additional gel manually into the vaginal canal may be helpful in cases of moderate to severe atrophy.
- Insert the Applicator into vaginal canal, until only the plastic rim at the base of the Applicator is visible.
- The metal parts conduct the electrical pulse and should be in contact with the tissue at all times.
- Avoid stimulating the introitus area as this zone is more sensitive.

- Align electrodes to the sides of the vaginal canal by positioning the handle of the Applicator vertically.
- The flange should not be inserted into the vaginal canal.
- Establish and confirm treatments parameters. Start with low energy levels and gradually increase according to patient's comfort and feeling of muscle contraction. Once intensity level is reached the patient can take legs down for more comfortable position during the treatment.
- The procedure should NOT feel intolerable to the patient. If the patient complains of discomfort, immediately pause the treatment and inspect the area. Reduce intensity if needed.
- Treatments can be paused by pressing the Pause button in the upper left corner of the screen.
- In case of extreme vaginal laxity, the applicator may be supported during the procedure to avoid self-extraction due to muscle contraction.
- When combined with FormaV Applicator, FormaV treatment should be done first to warm tissue. It improves treatment efficiency and comfort.
- When combined with Morpheus8V Applicator, vTone treatment should be done first.

POST-TREATMENT

- The patient should empty the bladder immediately post procedure.
- Patient should avoid mechanical contact with the treated area for at least 2 days.
- After each treatment session, the patient should be advised to contact the physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual or untoward symptoms.
- The applicator should be disposed of.

TREATMENT SCHEDULE

- The number of treatment sessions depends on the individual patient and is typically up to 6 sessions, every 1-3 weeks but can vary according to patient response.
- Longer treatment time may reduce number of sessions but depends on tissue response and patient tolerance .
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.