

## THE PERICALM CONTINENCE STIMULATION UNIT: OPERATING INSTRUCTIONS

1. To operate the unit, insert the battery supplied.
2. Attach the electrode to the Channel A or B on the top of the unit, using one of the wires supplied with the Pericalm.
3. Use the ON button on the top of the unit (has icon showing circle with line in it) to switch on the Pericalm.
4. Use the PRG button to move through the available programs. For a list of program options, see page 9 of booklet. Programs 1-6 are already pre-set in the Unit and cover the needs of most users. Your health practitioner may create a program specifically for you in PRG 7 8 or 9. Instructions on how to do this appear on Page 8 of the booklet, but are only relevant to a practitioner who wants to design a specific program that isn't already in the unit.
5. Once you've chosen your program, use the + and - buttons under the channel the electrode is plugged into (can be either A or B – doesn't matter) to control intensity. The program you've selected will determine the timing, duration and cycle of the stimulation, leaving you to control only the intensity through the + or - buttons.

To check that the Pericalm is working correctly before you use the electrode vaginally, follow steps 1-4 above, then wrap your hand firmly around vaginal sensor and increase intensity using the + button under the channel the electrode is plugged into, until you can feel the tingle from the electrode in your hand. Observe the increasing reading of the mA indicator immediately above the + button you are pressing.

**Please note that if the Pericalm unit detects an "open" electrode, it will automatically reset the mA level to zero as soon as it reaches 5mA. If this happens, ensure that the electrode connections are correctly in place, and that the metal plates of the electrode are fully in contact with the hand. If you open your hand as the intensity increases, contact will be broken and the unit will reset.**

**If you experience this cut-out when using a vaginal electrode, it means that the electrode plates are not maintaining contact with vaginal tissue. You may be able to overcome this problem by adjusting your position (eg sitting, rather than lying down), but you may need to seek advice from a health professional regarding the best position for your own needs.**

Once you have practised setting up the Pericalm following the steps above, and are satisfied with how the Pericalm works, the electrode can be used vaginally. Your health practitioner can assist you with the correct internal positioning of the electrode to suit your needs, and with guidance on the correct program and intensity level.

## THE PERICALM CONTINENCE STIMULATION UNIT: INFORMATION FOR HEALTH PRACTITIONERS

*The Pericalm Continence Stimulation Unit is designed for use with the guidance of a physiotherapist, doctor or continence adviser. Some patients in Australia may not have access to a practitioner who has specific experience in using NMES (neuromuscular electrical stimulation) to strengthen the pelvic floor, and they may seek guidance from more generalist practitioners.*

*This information sheet is intended to provide a starting point for health professionals who are not familiar with this area of practice. The points below should be read in conjunction with the Pericalm Operator's Manual.*

The Pericalm is a dual channel unit, which means that two separate electrodes can be connected to it at one time.

However pelvic floor muscle stimulation requires a single internal electrode (selected from our available range) which is used on its own. Therefore only one channel on the Pericalm is used at a time when it is used for internal electrical stimulation. It does not matter whether the internal electrode is connected to the Channel A or Channel B socket on the top of the Pericalm. Whichever channel is used, the corresponding control buttons underneath that channel are used to control the output from the Pericalm.

The Pericalm electrical muscle stimulator comes complete with six pre-set programs most relevant to the pelvic floor muscles (Operator's Manual, p 9). Three customizable programs are also available for practitioners who wish to design specific programs for their patients.

The six pre-set programs incorporate appropriate frequencies (Hz), stimulation and resting times, and a maximum total run-time. The user can control intensity within all programs to suit their own comfort level, using the +/- buttons on the side of the unit to which the internal electrode is connected.

The internal electrode must always be positioned correctly within the vagina or anus to ensure that the transmitting surfaces are in contact with the area to be treated. Note that the unit will reset intensity to zero if contact is not maintained (see boxed text in Operating Instructions section above).

**The UK Chartered Society of Physiotherapists make the following recommendations regarding the use of vaginal NMES for the management of stress incontinence, using electrical parameters similar to Stress 1 and Stress 2 pre-set programs on the Pericalm:**

- Treatment daily/twice daily
- Treatment time: 5 minutes initially, gradually increasing to 20 minutes.
- Patients should "join in" with the electrically induced contraction.
- NMES stimulation is a treatment for women who demonstrate a grade 0, 1 (or possibly grade 2) on the modified Oxford scale and would otherwise be unable to re-educate their pelvic floor muscles. Once a grade 3 voluntary contraction is achieved, electrical stimulation may be discontinued and therapy continued with pelvic floor exercises.

**Precautions**

- Altered vaginal sensation.
- Selection of appropriate stimulation parameters to avoid muscle damage.
- Patients with epilepsy should only be treated following consultation with an appropriate medical practitioner.

**Contraindications to the use of NMES**

- Patients who do not comprehend instructions and are unable to co-operate.
- Implanted pacemaker (especially demand type).
- Application of electrodes over active or suspected malignant tumours.
- Severe allergic reaction to electrode or electrode gel.
- Inflammation and/or infection of the vulva and vagina.
- Recurrent or current haemorrhage/haematoma.
- Open wounds and/or abrasions in the area of stimulation.
- Compromised circulation.
- Atrophic vaginitis.
- Pregnancy.
- Presence of abnormal or malignant cells in the pelvic or abdominal area.
- Patients on anticoagulant therapy, history of pulmonary embolus or deep vein thrombosis.
- Use of suction electrodes for patients who bruise easily.

*Chartered Society of Physiotherapists, Clinical guidelines for the physiotherapy management of females aged 16–65 years with stress urinary incontinence, Revised edition 2004*

**RESEARCH SUMMARY: The following studies have explored the use of NMES for various types of incontinence, using a range of protocols.**

Treatment group	Study Design	Treatment protocols	Results	References
SUI Women	DB RCT	Weeks 1-4 = 15 mins x 2 pd Weeks 5- = 30 mins x 2pd	50% improvement in 62% of women using real device	Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: A multicenter, placebo-controlled trial. PK Sand & others. Am J of Obstetrics &Gynecology. 173(1):72-9
SUI Women	Non-RCT	15 mins x 2 pd x 20 weeks	Significant objective & subjective improvement between weeks 10-14. Findings suggest at least 14 week program is necessary.	Pelvic floor electrical stimulation for genuine stress incontinence: Who will benefit and when? K Miller & others. Int Urogynecology Jnl. 9(5):256-270
SUI, UI and Mixed women	DB RCT	20 mins x 2pd x 12 weeks	88% of active group experienced significant reduction in symptoms or remission.	Transvaginal electrical stimulation in the treatment of urinary incontinence. JCV Barroso & others. BJU Intl 93(3):319-323
UI and Mixed Women	Non-RCT	15 mins x 2 pd and 15 mins x 2 every other day	69% cured or improved by at least 50%. No differences between daily and every other day users.	Pelvic floor electrical stimulation for the treatment of urge and mixed urinary incontinence in women. SW Siegel & others. Urology 50(6):934-940
UI Women & men	DB RCT	15 min x 2 pd x 4 weeks	Bladder capacity significantly increased in active group and members assessed as cured or improved; 76% remained so 8 months later.	Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity. T Yamanishia & others. Urology 55(3):353-357
UI women	DBV RCT	20 mins x 2 pd x 8 weeks	49% of users cured. No change in sham group	Transvaginal electrical stimulation for female urinary incontinence. L Brubaker & others. Am J of Obstetrics and Gynecology. 177(3):536-540
UI Women	SB RCT	20 min x 2 pw	51.4% of ES group experienced subjective improvement (higher than other groups)	Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. AC Wang & others. Urology 63(1):61-66

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