Clinical Evaluation Report
Continece Stimulation

1. Introduction

Because different types of nerves fibres have different electrical characteristics, comparatively small changes in parameters can make a very large difference in both subjective sensation and physiological effect. Simply trying to use the settings specified in different clinical trials will clearly and simply demonstrate the wide difference in therapies included under the umbrella of “Electrical Stimulation”

Existing reviews of RCTs have made no attempt to distinguish between the outcomes of trials using different stimulation parameters.

This review re-examines published reviews of RCTs and new results to try to see whether the most effective stimulation parameters can be identified, and whether the strength of evidence for use of these parameters is greater than that for ES as a whole.

2. Context of the evaluation and choice of clinical data types

The history of continence stimulation is closely related to that of Emipi which was established in 1977 to develop a device to cure female incontinence. In 1990 Empi entered into a joint venture with C.R. Bard to develop and sell an incontinence product. The device stimulated the bladder control muscles by means of electric pulses and thus aided in strengthening them. Empi received FDA approval in July 1991 for its female incontinence product. Clinical acceptance of the technology gradually spread and further competitors entered the market in 1998

Many of the published clinical trials were conducted with the Empi Innova device. The earliest published clinical reference to home stimulation for incontinence seems to have been in about 1985. (Plevnik S, Vodusek DB, Vrtacnik P, Janez J. (1985) Optimization of the pulse duration for vaginal or anal electric stimulation for urinary incontinence. Proceedings of the ICS meeting (London). 226–227.)

USA Medicare reviewed the available evidence in an extensive enquiry, and decided to give coverage for women who had failed trial of Pelvic Floor Muscle Training in October 2000.

Clinical trials were published using many different devices. However several used the EMPI Innova (see table).

There is no published RCT comparing the effect different PFES parameters or waveforms.

The conductive properties of vaginal mucosa are substantially different from pure resistance, and no comparisons of invivo current have been published.
The evidence regarding the most effective parameters and waveforms for general EMS is limited, with no published RCTs.

Hazard Analysis identified excessive Electric Current and Heat (C2,2&3) and BioCompatibility (C3,3)as potential hazards. Published RCTs were examined to identify additional hazards and side effects.

Although there is no specific standard for PFES, we judged that compliance with: BS EN 60601-2-10:2001Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators would identify general risks of electrical nerve stimulation.

3. Clinical Evidence

3.1 Search Strategy:
Because the technology is well established, a search of existing published clinical data was judged to be sufficient.

First search was for pre-existing reviews of RCT:—

Second search for RCTs published after the date of these reviews.

3.2 Search Terms:


Documentation also includes references to studies that were not RCTs, but contain reference to agreed principles of treatment and technical settings (References number X...)

3.3 Exclusions:

For Stress, only studies using vaginal or anal electrodes with conventional electrical stimulation were considered. Thus studies using Interferential stimulation, Percutaneous neuromodulation, Tibial nerve stimulation, Magnetic stimulation, or external skin electrodes were excluded.

For Urge and Mixed, studies using external skin electrodes were included because there is a widely agreed theoretical mechanism for the treatment.

English language only.
4. Data analysis

4.1 Performance
Electrical Stimulation is in widespread routine use in many countries for treatment of Urinary Incontinence. Reviews of recent RCTs conclude that evidence for or against PFES is weak, largely because trial numbers were either too small, or outcome measures were judged to be inadequate (This applies to RCTs on most forms of physical therapy). It is widely agreed that large scale, multi-centre clinical trials would be needed to give increased confidence levels. However the level of funding required means that this unlikely to happen.

Surprisingly few RCT papers give consideration to the mechanism of action of PFES, several report the parameters used in insufficient detail to establish the treatment delivered, and two cited RCTs, (Brubaker, 1997, Moore, 1999,), state erroneous parameters -which could not have been used in practice.

Because different types of nerves fibres have different electrical characteristics, comparatively small changes in parameters can make a very large difference in both subjective sensation and physiological effect.

Using the theory of action in 4.2.1 and 4.2.2 below as a guide, it is therefore intended to review the clinical evidence with regard to stimulation parameters, and to see whether the published RCTs support the use of particular stimulation parameters.

4.2.1 Overview of stimulation parameters for SI
It has been shown (Eccles at al, 1958) that the motor neurones innervating slow fibre discharge at a slow rate of 10-20Hz, and those that supply fast fibre do so at 30-60Hz. It has also been shown (Gilpin et al, 1989) that the pelvic floor has approximately 2/3 slow fibre and 1/3 fast fibre. Hence if the patient is to regain the use of non functional muscle, the correct frequency for the fibre to be targeted must be used. In the case of SI the patient is unable to perform a coordinated fast contraction of sufficient power and strength to withstand the extra pressure exerted during a cough, therefore the fast fibres need to be targeted.

A bi-phasic waveform will reduce the risk of any tissue damage, however the pulse width duration must be sufficient to overcome the excitation threshold of the nerve fibres to be stimulated. Pulse widths of too long a duration tend to stimulate nociceptive sensory fibres and are uncomfortable for the recipient. The range between 200-500 µs are those most frequently employed. The intensity must be adequate and uncontrolled studies seem to agree that high frequency (50-100Hz) and high amperage (>25mA) are required to obtain a 50% success rate in stress incontinence (SI) (Appell, 1998). It is also necessary to consider the duty cycle or ON/OFF time. There should always be care taken to ensure that the muscles are not unduly fatigued...Initially the rest phase may be 2-3 times the contraction phase ( Haslam 1998, Ref X9)

Parameters of treatment (CSP Clinical Guideline ( Review 9) recommendation:
The frequency of the pulses required to produce a tetanic contraction of mixed (fast-twitch and slow-twitch) skeletal muscles is between 35 and 50 Hz and less fatigue occurs with the lower frequency (Howe, 1996). In studies on cats, it was found that activation of the sphincter musculature was most effective at 50 Hz. However, care must be taken in the interpretation of animal studies (Ohlsson et al, 1986; Erlandson et al, 1977).
The pulse width and current amplitude determine the charge density, which will influence the response. Pulse widths less than 100 microseconds (μs) or 0.1 milliseconds (ms) are more suitable for sensory stimulation and the pulse width for activating muscles is generally between 0.1 and 0.3 ms, and current intensity up to 80 milliamps (mA). Work by Plevnik et al (1985), showed that the optimum pulse width for urethral closure was around 0.2 ms. Later studies (e.g. Bo and Maanum, 1996) demonstrated that electrical stimulation could significantly increase urethral closure pressure. The parameters used were a frequency of 50Hz, a pulse width of 0.75 ms and intensity range of 0-90mA.

To reduce fatigue, the duty cycle i.e. the "on - off" times, should be adjusted in such a way that the "off" time is at least double the "on" time, often commencing with the "off" time 4 or 5 times the "on" time, for weak muscles (Benton et al, 1981; Packman-Braun, 1988). Almost all the clinical trials quoted in this document have used different electrical parameters i.e. different frequencies, pulse widths, duty cycles, treatment times and number of treatments.

However, in view of the widely acknowledged work of Ohlsson et al (1986) and more recent studies (see Table 5), the GDG recommends regular stimulation, using a fixed frequency current of around 35 Hz, rectangular pulses with pulse width of 0.25 ms, and a non-fatiguing duty-cycle. Treatment times should start at 5 minutes once or twice each day, and progress as muscle strength increases and fatigue decreases, and the vaginal tissues become accustomed to the stimulation. The majority of recent clinical trials (Table 5) describe one or two daily sessions of electrical stimulation with a home unit, and no other treatment. Clinical experience and research evidence (Davila and Bernier, 1995), suggests that combination therapy i.e. electrical stimulation, pelvic floor muscle exercises and biofeedback, should be used if available and appropriate.

**The importance of correct Pulse Width**
- Diagram from textbook : TENS: Clinical Applications and Related Theory
  by Deirdre M. Walsh Published 01/02/1997 Churchill Livingstone ISBN9780443053238
4.2.2 Overview of stimulation parameters for Urge Incontinence

Salmons and Vrbova (1969) showed in rabbit and cat models that non-functional fast fibre was able to be transformed into functional slow fibre by stimulation at 10Hz. In the case of an unstable bladder the aim is to effect maximal pelvic floor tone and contraction ability in order to stimulate the perineo-detrusor reflex (Mahoney at a I, 1977). It can therefore be most appropriate to give stimulation at a frequency of 10Hz with a pulse width of 200-500 μs.”

Stimulation of afferent sacral nerves within the pelvis or lower extremities has been shown to increase the inhibitory stimulus to the efferent pelvic nerve and, therefore, bladder contractility. The sacral afferent nerves are poor conductors, as most are unmyelinated, and conduct current at a slow rate of <20Hz. The theory in patients with DI is that ES will result in reflex inhibition of the pelvic nerve to increase bladder capacity and that afferent pudendal stimulation will activate hypogastric efferents and inhibit pelvic efferents to stop or delay involuntary contractions. Researchers agree that low frequency (5-10Hz) and moderate amperage (<20 mA) are required to obtain results that vary widely, from 45-91% effectiveness.
4.3 PFES in STRESS incontinence

4.3.1 Review of RCTs for STRESS INCONTINENCE

**STRESS: PFES Vs Placebo**

Review 1 identified a number of studies which looked at the use of PFES versus sham with good outcome. These included:

- **Sand** (1995) (Ref 1.1) who used 50 Hz 300µs 5/10 stimulation. Twice daily 15 weeks. Patients included women with proven SI of which 35 had active PFES and 17 sham. There were 8 drop-outs. P=0.05. Diaries and pad test.

- Yamanishi 1997 (Ref 1.2) also showed improved outcome. This study included 31 individuals with SI, 4 with MI including 5 men. 50 Hz. 1000ms Twice daily for 4 weeks.

- **Brubaker**, 1997 (Ref 1.4) conducted a study including 60 women with SI, 33 with MI, 28 with UI. The trial involved 20 Hz 2/4 Twice daily 8 weeks. There was no significant difference between groups in SI patients, but significant improvement in patients with DI.

  (The Technological Assessment said that: "It has been proposed that the stimulation frequency in the Brubaker study was too low to effectively treat stress incontinence (Stuart and Elixhauser 1998")

  With reference to the principles above, we would not expect a 20 Hz stimulation to have a significant effect on SI. In addition, the Pulse Width is reported in the original paper as “pulse width of 0.1 µsecond” which must be an error, since typical nerve stimulation settings are 100-1000 µsecond. If the actual setting was 0.1ms = 100 µsecond, this is a little small for motor nerve recruitment (see diagram above). Laboratory testing has shown that pulse widths of > 200 uS are needed to give maximal muscle stimulation at normal current levels. This could be a further reason for the failure in SI patients in this study. Work rate of 2/4 is also different to that used in successful studies for SI.

- **Luber**, 1997 (Ref 1.3/2.270) used 50 Hz 2000 µs 2/4 stimulation. Twice daily 12 weeks. 67 women with SI who had failed PME. 26 active PFES, 28 sham. No significant difference between groups. 2000 µs is an extremely long pulse width, and is likely to have caused pain in patients using adequate current intensity. 6 patients in the treatment group dropped out – 26%. This was not remarked upon, since a similar number of controls also dropped out.

**Electrical stimulation versus sham stimulation (Rev 2)**


However the findings across these studies were inconsistent, with significant benefit with electrical stimulation versus sham stimulation reported for some but not all outcomes, and not across all studies. Not all studies reported between-group comparisons.

Three studies included women with stress UI:- 268 (Sand 1995) and 270 (Luber 1997) were considered previously above. 271 (Jeyaseeln 2000) showed no significant difference between groups, but used a new pattern of electrical stimulation which also failed to show good results in other muscle strengthening trials, and is not therefore to be included in consideration of conventional ES.
**STRESS: PFES Vs PME or other non-surgical alternatives**

Review 1 identified 5 RCTs of which three were considered too small for results to be statistically significant, including Smith 1996 (Ref 4.108). This left two trials to be considered:

**Olah et al 1990** considered PFES vs cones for women with SI, they used *interferential* current with externally applied electrodes (abdomen and thighs) – therefore they were *not included* in this review. (In addition, use of a 0-100 Hz sweep setting, suggests a lack of understanding of the principles of IF treatment for muscle strengthening.)

**Bo et al 1999** (Ref 4.80) looked at PFES vs. PME, cones, and no treatment for genuine stress urinary incontinence. Bo estimated that 30 patients per arm were required to detect a difference of one standard deviation. Parameters used were 50Hz, 200 µs, W/R varied during the treatment, max tolerable current. 7/25 patients using PFES were cured. This poor outcome contradicts the other RCTs. Bo also reported a high dropout rate of 7/32 in the PFES group: treatment was carried out at home and eight women reported motivation problems and difficulties in using the stimulator, suggesting that the device (specifications not available) was not easy to use. Although the main investigator was blinded, the PFES stimulation parameters were adjusted monthly according to the investigators evaluation of patients progress, so there was significant intervention by unblinded therapists.

**PFES + PME vs PME alone.**
Review 1 identified one RCT:

**Blowman 1991** (Ref 5.43)
Small trial – considered by the review to be too small for significance.
4 weeks at 10Hz 4/4 60 mins a day. 2 weeks at 35 Hz 15 mins a day. All PFES patients improved. The 35Hz is within the range expected to improve PF strength, however treatment time of 2 weeks is low – replacement of muscle fibre can take up to 12 weeks.

Blowman states : consideration of treatment protocol:
In our study two frequencies were used sequentially, the first being a very low frequency ie 10 Hz, for four weeks, which should improve the capillary bed of all structures stimulated and promote the changes which lead to an increase in slow oxidative motor units (Buller et al 1960). This was followed for two weeks by stimulations with 35 Hz to augment muscle strength (Numsat et al 1976)…It was hypothesised that NTS could have achieved these results by improving the capillary bed of the urethra or by improving the postural tone of the pelvic floor muscles and or their power.

Although the Technical Assessment performed for the2000 Review of Medicare Coverage (Review 1) showed a lack of robust evidence in favour of PFES was weak, position Statements from all but one of the relevant clinical bodies stated that they believed that PFES had a place in treatment, and the committee therefore voted to reimburse ES in certain conditions.

**STRESS -PFMT versus electrical stimulation**
Review 2 identified six RCTs comparing PFMT with electrical stimulation in women with stress UI. Four studies were of good quality.226,228,276,277 226 (Bo 1999) has been considered above.
228 (Henalla 1989) excluded as it used Interferential Therapy
276 Hahn 1991 Group size 10 patients, not controlled trial. Excluded.
277 Smith 1996 – Considered above.
NICE recommendations re STRESS Urinary Incontinence
The 2006 NICE Guideline CG40, which has not been superseded, recommends that women with poor pelvic floor muscle tone should be considered for PFES.

PFES for Mixed Urinary Incontinence (Rev2)

Review 2 identified two studies which included women with stress, mixed or urge UI: 272 & 273 (Brubaker et al 1997, Barroso et al 2004)
272 Brubaker, (1970) was considered above.

The study by Barroso (2004) looked at transvaginal electrical stimulation for the treatment of urinary incontinence. The patients had their treatment at home twice a day for 12 weeks. It involved: 20Hz for Mixed or 50 Hz for Stress, pulse width of 300 µs, with asymmetrical biphasic pulses, an adjustable current intensity (0–100 mA), a 1s rise time, sustained for 5 s and resting for 5 s. They were instructed that the intensity of stimulation should be the ‘most individually tolerable’. Sometimes the intensity is too low to activate reflexes or cause muscle contraction, but it can be compensated by the longer duration of treatment.

Studies of ES in patients with mixed urinary incontinence advocate initially treating the predominant symptoms, i.e. if the main complaint is voiding urgency and frequency, low-frequency electrical parameters are used. If the main complaint is stress-associated leakage, as long as the urodynamic evaluation does not show bladder instability, a 50-Hz frequency is used.

In the present study both the patients with mixed and urge urinary incontinence were treated at 20 Hz because the symptoms related to urge incontinence caused greater discomfort. There were too few patients to draw conclusions about the results obtained separately for each type of urinary incontinence.

RESULTS: The treatment group had a significant increase in maximum bladder capacity ($P < 0.02$), a significant reduction in the total number of voids (over 24 h; $P < 0.02$), in the number of episodes of voiding urgency ($P < 0.001$) and, importantly, in the number of episodes of urinary incontinence ($P < 0.001$). At the first evaluation, after ending the treatment, 88% of the patients had a significant reduction in symptoms or went into remission.

COMMENT: The Barroso, 2004 RCT confirms that the settings used in the itouch Sure for Stress and Mixed Incontinence (50 Hz and 20 Hz, 300 us, asymmetrical biphasic, 5/10) are effective.

Another newer study (Castro 2008) also confirmed that the Stress setting for the itouch Sure (50 Hz, 300 us, 5/10) can give positive results. This study involved a single blind RCT of PFMT, ES, vaginal cones and no treatment for women with stress incontinence.

TREATMENT: 50 Hz, 500 µs, W/R = 5/10, Bipolar square wave. 20 mins 3 times a week. Max tolerated. RESULTS: In the objective evaluation, a statistically significant reduction in the pad test ($p=0.003$) was observed, as well as in the number of stress urinary episodes ($p<0.001$), and a significant improvement in the quality of life ($p<0.001$) in subjects who used pelvic floor exercises, electrical stimulation, and vaginal cones compared to the control group. A significant improvement in all outcome measures was seen in all patients. The subjective rate of success of those physical therapies was approximately 56%, and the objective (pad test) rate was approximately 47%.

Treatment was very well tolerated, and no adverse events, such as vaginal bleeding, urinary infection, and vulvovaginitis, could be correlated with any of the active treatments.

This study did not reproduce the data generated by Bo et al. (1999), in which pelvic floor muscle training was more effective than electrical stimulation, vaginal cones, and no treatment control for women with stress urinary incontinence. This discrepancy in results may be due to differences in how the two studies carried out active treatment. In the present study, a physiotherapist supervised all sessions, coordinated the pelvic floor exercises, increased the intensity of electrical impulses, and encouraged the use of vaginal cones.

TREATMENT: Dualpex Uro 996. Frequency at 4 Hz, a 2- to 4-s work-rest cycle and a 0.1 µs pulse width. The bipolar square wave could be delivered over a range of 0–100 mA. Intensity was controlled according to patient discomfort level feedback. Three 20-min sessions per week over a 7-week period.

RESULTS: There was no statistically significant difference between the groups. COMMENT: The original paper specifically states a pulse width of 0.1 µs. This is unlikely to be correct, since virtually no nerve stimulation would result (since diagram above). No explanation is given for the choice of 4Hz, which is lower than that usually recommended, and is not used by the itouch Sure.

4.3.2 Conclusion PFES for STRESS INCONTINENCE

Overall the evidence suggests that compared with no/sham treatment Pelvic floor electrical stimulation may be more effective at increasing the proportion of men and women with improvement or cure of incontinence.

There is evidence that PFES at 35Hz or 50Hz, 300-1000 µseconds, maximum tolerance intensity, is of benefit in the treatment of Stress Urinary Incontinence.

There is no evidence that 4Hz is effective.
There is little evidence that 20Hz is effective.
50Hz, 2000 µseconds appears to be ineffective, probably because of the extreme discomfort of the pulse width.
4.4 PFES in URGE incontinence

4.4.1 Review of RCTs for URGE INCONTINENCE

**URGE Vs Sham**

Brubaker 1997 (Ref 1.4) conducted a study including women with Urge: 33 individuals had active treatment and 28 sham. UI decreased from 54% to 27% using 20 Hz. The outcome measures however did not include diaries and pad testing and were considered inadequate and evidence therefore was excluded by these reviewers. Urodynamic testing showed improvement with PFES: 54% reduced to 27%. Positive results agree with our model. We would expect 10-20 Hz stimulation to help UI, but not necessarily SI.

**URGE vs Other treatments**

Smith 1996 (4.108) Only included 19 patients per branch and there may have been inadequate power as had used EMPI stimulator at 12.5Hz. The results showed that 50% of those using PFES and 35% of those using medication had 50% improvement in diary. Clinical results in treating patients with DI seemed to appear much quicker, often in a matter of 2 weeks, resulted in a 72% improvement, which is consistent with previous reports (table 5). This compared with the 2 to 3 months that may be needed for improvement in patients with genuine stress urinary incontinence. Although this rate was not statistically significant compared with propantheline bromide, most of the patients whose condition responded requested to continue using the device. Many of these patients were on therapy for more than 18 months. In some instances patients used the device for 3 to 5 days to break a cycle of repeated episodes of urge incontinence.

**NOTE:** Smith noted that a number of patients with detrusor instability experimented by increasing the amplitude to greater than 25 mA. Believing that more energy must be better, they exceeded the 20 to 25 mA. range and lost the salutory effect. When the amplitude was reduced, the effect returned, which is an important concept, not unlike the dose response curve of pharmaceuticals. The higher dose is not necessarily better. How long the effect lasts is unknown at this time. Bladder inhibition and increased urethral tone have been demonstrated in the cat model at different frequencies, specifically, 5 to 10 Hz. resulted in a decrease in bladder instability and 20 to 50 Hz resulted in an increase in urethral sphincter tone. It is likely that these effects are mediated as a reflex through the pudendal system, although this is not entirely known. The higher frequencies appear to be conducted through the pudendal efferent motor fibers during intravaginal electrical stimulation, activating striated urethral and pelvic floor muscles. Finally, electrical stimulation may have a role in treating detrusor instability in patients who cannot or do not wish to take medication and possibly as a trial before bladder augmentation.

Franzen et al 2010 compared electrical stimulation with tolterodine for those with urgency/urge incontinence. TREATMENT: MS-310 Device, MIC Rehab AB, and delivered by a specialized nurse (Urotherapist) at the outpatient clinics. Over a time period of 5–7 weeks, altogether ten stimulation treatments were applied one to two times per week for 20 min with a frequency of 5–10 Hz. The maximum electrical stimulation was done with maximum tolerable intensity, which was adjusted up to the level of tolerable discomfort. According to the study protocol, additional electrical stimulation treatment was allowed during the study period, but no patients in the study requested this. RESULTS: There was a clearly significant difference for electrical stimulation, −2.8 (95% CI, −3.7 to −1.9), Severity of urinary symptoms reduced from 13 to 7 in 6 weeks

**COMMENT:** No information is provided on pulse width or waveform. Result might have been improved if stimulation had not been delivered with “maximum tolerable intensity”. Earlier evidence
suggests that excessive intensity may be counterproductive in UI, and there is no clear rationale for maximising stimulation.

**Electrical Stimulation in Overactive Bladder**

Yamanishi et al (2000) conducted a study to evaluate the usefulness of electrical stimulation for UI linked to detrusor overactivity. The treatment involved: 10Hz square waves. 1000µs pulse width, 15 mins twice daily. Max tolerable intensity. RESULTS: 81% improved ADVERSE EFFECTS: Adverse effects were noted in 2 (5.4%) of 37 patients of the active group (vaginal pain in 1 and faecal incontinence in 1), and in 2 (6.5%) of 31 patients of the sham group (disagreeable feeling).COMMENT: Positive results agree with our model. We would expect 10-20 Hz stimulation to help UI, but not necessarily SI.

Berghmans, 2002, (Ref 2.275) compared electrical stimulation with 'lower urinary tract exercises', PFMT and bladder training, and with both interventions combined, in women with DO (n = 68). Intention-to-treat analysis in the group of 68 patients showed a statistically significant decrease of DAI scores in the FES group. TREATMENT: Frequency modulation of 0.1s trains of rectangular biphasic 200us pulses varying between 4 and 10Hz. Innocept ProSeco device. Max tolerable intensity. 9weeks. Daily treatment time not specified. RESULTS: Combined centre and home-based FES seems to be an effective treatment modality for the treatment of women with proven bladder instability.COMMENT: A low frequency stimulation at medium/low pulse width improves UI.

Wang (2004) conducted a trial to evaluate optimum treatment for women with overactive bladder. Of the 103 women who completed this study, 34 were in the PFMT group, 34 in the BAPFMT group, and 35 in the ES group. The changes in the three parameters of King's Health Questionnaire revealed statistically significant differences, except for the total score, between ES and BAPFMT (domain 7, P = 0.003; domain 9, P = 0.029; and total score, P = 0.952). These same parameters were significantly different between ES and PFMT (domain 7, P = 0.007; domain 9, P = 0.001; and total score P = 0.004). The change in total score was significantly different between BAPFMT and PFMT (P = 0.003). The subjective improvement/cure rate of OAB was 51.4% for ES, 50.0% for BAPFMT, and 38.2% for PFMT (P = 0.567).CONCLUSIONS: ES had the greatest subjective reduction rate of OAB and was the most effective of the three treatments. BAPFMT was more effective than PFMT.

**Electrical Stimulation in Mixed Incontinence**

Liu et al 2009 conducted a study to evaluate the efficacy of PFES for idiopathic overactive bladder and stress incontinence. TREATMENT: Neurotrac. Sequential cycle not specified. RESULTS: In total, fifty women (71%) finally completed treatment for twelve weeks, and urinary incontinence disappeared in 8 (16%), detrusor overactivity disappeared in 10 (20%), and leakage was no found in 6 (12%) in leakage point pressure measurement COMMENT: Insufficient information to comment.

**URGE -PFMT versus electrical stimulation**

Review 2 identified one RCT with mixed or urge UI.

This study, Spruijt 2003 (Ref 4.114), looked at the use of vaginal electrical stimulation of the pelvic floor in a group of elderly women with incontinence. TREATMENT: Urogyn 8900 biphasic current. Pulse width 1000µs. SI 50 Hz, UI 20Hz (A stimulation frequency of 20 Hz instead of 10 Hz was used because of the expected high percentage of mixed incontinence in our study group). W/R =2/4
Intensity tolerable discomfort 30 min three times a week for 8 weeks
Elderly (>65 years old) women. 24 treated. Of which 18 had DI before and 14 after.
RESULTS: 29.2% showed improvement in pad test. 17 out of 24 women treated with ES (70.8%) improved pelvic muscle strength.
The authors commented: “Treating elderly women with vaginal ES of the pelvic floor has a high physical and emotional cost for the individual”. Fourteen women out of 37 felt they were unable to cope with the treatment regimen or treatment itself if vaginal ES was to be performed. Pelvic muscle strength has a tendency to increase in most women treated with ES, but without resulting in a comparable decrease of urinary leakage (PAD test). Mixed incontinence (and not genuine stress incontinence) is the most common cause of urinary incontinence in elderly women, and may explain this observation.

COMMENT:
The reference to “high physical and emotional cost” is not explained. However the use of 1000µs Pulse Width is more likely to recruit Nociceptive nerve fibres (see diagram above), and increase discomfort. 75% of the patients had DI. In treatment of DI, muscle contraction is actively discouraged, and this high pulse width could have been counterproductive. Smith, 1996 noted that excessive current reduced the success in treatment of DI, and the protocol in this study required “maximum tolerable to discomfort level.”

**Electrical stimulation in combination with PFMT**
Review 2 identified four RCTs - three studies were of poor quality, and one of good quality. [EL = 1+]
This study by Lo SK et al (2003) was excluded from this review as it used Interferential Therapy: Additive effect of interferential therapy over pelvic floor exercise alone in the treatment of female urinary stress and urge incontinence: a randomized controlled trial. Hong Kong Physiotherapy Journal 2003;21:37–42.

The 2007 AHCPR Clinical Practice Guideline (Rev3) recommended that “PFES should be performed in conjunction with Kegel exercises.”

**PFMT plus ES vs no treatment**
TREATMENT: Biphasic 20Hz, pulse width 1 millisecond, W/R 1:1
Intensity maximum level she could tolerate comfortably, 15 minutes every other day.
RESULTS: Home PF exercising with weekly biofeedback and PFES gave no better results than without PFES.
COMMENT: 65% of the patients had mixed or UI. It could be expected that intensive PFMT with biofeedback would increase pelvic muscle strength. Addition of PFES would therefore not be expected to give significant benefits for SI patients.
It appears that 20Hz is not an effective treatment for UI, particularly when combined with a high pulse width, and high intensity designed for muscle strengthening rather than UI.

### 4.4.2 Conclusion PFES for URGEE INCONTINENCE
Overall the evidence suggests that compared with no/sham treatment Pelvic floor electrical stimulation may be more effective at increasing the proportion of men and women with improvement or cure of incontinence.

There is therefore evidence for the benefit of PFES in the treatment of Urge Urinary Incontinence. Parameters of 4-12.5Hz, 200-1000 µseconds are effective. 20 Hz may be effective. However, maximum tolerance intensity is ineffective.
4.5.1 Electrical Stimulation and Faecal Incontinence

Cochrane Review Electrical stimulation for faecal incontinence in adults (2007) concluded that: “The review does not provide sufficient evidence on which to judge the effectiveness of electrical stimulation in the management of people with faecal incontinence. In particular there is not enough evidence on which to select patients suitable for this type of treatment, nor to know which modality of electrical stimulation is optimal.”

NICE guideline (CG49 Faecal Incontinence) concluded that: “The evidence was inconclusive in this area (PFES)”, but retained ES as a method for specialist use.

4.5.2 Review of RCTs - Electrical Stimulation and Faecal Incontinence

**Electrical stimulation versus any other treatment**
Cochrane review found one trial: *(Osterberg 2004 Ref 6.3).*

**TREATMENT:** MS210TM (Medicon, Trondheim,Norway. 25 Hz, W/R 1.5/3 s. Intensity just below the sensation of burning or pain was given for maximum effect. Each treatment lasted for 20 min, and a total of 12 sessions were administered over 4–5 weeks.
**RESULTS:** Incontinence scores were significantly reduced during the entire observation period in both groups *(P < 0.001)* as was the use of pads *(P = 0.003 to P < 0.001).* Incontinence score reduced from 12 to 7.5.
**COMMENT:** Pulse width not specified. 25Hz is a little low for muscle strengthening – should be >35Hz.

**Electrical stimulation as an adjunct versus any other treatment**
Cochrane Review found one trial:

**Fynes 1999 (Ref 6.1)**

**TREATMENT:** Electrical stimulation using low-frequency 20-Hz and high frequency 50-Hz settings to target static (slow twitch) and dynamic (fast twitch) fiber activity with a 20 percent ramp modulation time. Ten minutes at 20 Hz 5/8, then 50 Hz 8/30. Daily for 12 weeks.
**RESULTS:** Continence scores improved in both treatment groups, but the results were better for those who received augmented biofeedback.
**COMMENT:** Pulse width and waveform not specified.
Frequencies are those used in itouch programmes Stress and Mixed.

**One modality of electrical stimulation versus any other modalities of electrical stimulation**
Cochrane Review found one trial:

**Norton 2006a (Ref 6.2)**

**TREATMENT:** Elpha 4 Conti. 35Hz, 300us, 5/5 20 mins daily. Intnesity to muscle contraction. Control 1Hz.
**RESULTS:** On an intention to treat analysis, there were no statistically significant differences in patients’ rating of outcome, patients’ rating of change in symptoms, frequency of incontinent episodes, manometric resting or squeeze pressures, comfort, satisfaction with treatment, impact on quality of life or patients’ rating of bowel control after 8 weeks of stimulation
**COMMENT:** No comment
4.5.3 Conclusion - Electrical Stimulation for Faecal Incontinence

Fynes 1999 demonstrated in a group of 20 women with obstetric trauma that higher frequencies could improve recovery over biofeedback alone.

Other trials, using lower frequencies were not successful.

There is weak evidence for the benefit of PFES at 50Hz in the treatment of Faecal Incontinence is the women with obstetric trauma.

4.6 Electrical Stimulation for Postprostatectomy Stress Incontinence

4.6.1 Review of RCTs for Postprostatectomy Stress Incontinence

The Cochrane Conservative management for urinary incontinence 2009 (Updated 2007) found only one valid RCT which found that ES + PME was no better that PME alone.

Moore, 1999 (Ref 8.3) Trial of standard PME, intense PME, intense PME +PFES.
TREATMENT: 50 Hz Biphasic. 1 sec burst, 1 sec pulse width, 1 sec train. 30 min twice a week. 12 weeks. Intensity sufficient for visible lifting of muscle.
RESULTS: This study showed no significant differences between groups, but improved in all three groups.
COMMENT: Treatment once a week was reported at 50 Hz 1s bursts, 1s pulse width and 1 s pulse trains?? It is not possible to know what this means (1s pulse width is not possible), so an evaluation of the technique is not possible. Active treatment was only once a week, which is much less than other successful SI treatment protocols

Yamanishi (2010) compared placebo versus PFES with PFMT. TREATMENT: 50 Hz square waves of 300 µs pulse duration and a 5 seconds on, 5 seconds off duty cycle were applied for 15 minutes twice daily with an anal electrode. Highest tolerable intensity. Active group 26 males.
RESULTS: Electrical stimulation resulted in earlier recovery of continence in patients with urinary incontinence after radical prostatectomy. P= 0.0006 The continence rate was significantly higher in the active ES group than in the sham group after 1, 3 and 6 months of treatment”
COMMENT : Itouch Sure STRES programme 50Hz, 300 µs, 5/10 is very close to a treatment protocol that gave good success with SI following radical prostatectomy over 6 months.

Goode, (2011) compared behavioural therapy with/without biofeedback and PFES for incontinence following prostatectomy
TREATMENT: daily home pelvic floor electrical stimulation at 20 Hz, current up to 100 mA (behavior plus);
RESULTS: The addition of biofeedback and pelvic floor electrical stimulation did not result in greater effectiveness.
COMMENT: As other studies have shown, 20Hz with maximal intensity appears not to enhance muscle strength.

4.6.2 Conclusion - Electrical Stimulation for Postprostatectomy Stress Incontinence

There is therefore weak evidence for the benefit of Anal ES using 50 Hz in the treatment of severe incontinence following radical prostatectomy.
4.7 ADVERSE EVENTS:

4.7.1 Reviews of RCTs reported few Adverse Effects:

Sand 1995 2 withdrew because of persistent vaginal irritation after 6 and 7 weeks of device use.

Yamanishi 2000 Adverse effects were noted in 2 (5.4%) of 37 patients of the active group (vaginal pain in 1 and fecal incontinence in 1), and in 2 (6.5%) of 31 patients of the sham group (disagreeable feeling).

Bø 1999 10/32 31 0/32 0 Smarting (tenderness, bleeding, discomfort), motivation problem, difficulty in using the stimulator

Rev2 Five studies considered adverse effects. None were reported in one study. Across the others, adverse effects or complications noted were: vaginal irritation (12–22%), pain (6–9%) and cases of faecal incontinence, discomfort, and tenderness and bleeding. One study reported difficulty in maintaining motivation in 32% of the ES group.

Luber 1997 No complications related to device use were observed, i.e., no vaginal bleeding, vaginal erosions, urinary tract infections, worsening of urinary incontinence, electrical accidents, or discomfort that persisted after device removal

Bo 1999. Seven .. dropped out (two because of pain, one because of bleeding, and four through lack of motivation)

Smith 1996 Complications from use of the device were minor. Two patients complained of vaginal irritation, which subsided after changing the lubricant. Two women had urinary tract infections while participating in the study. One patient complained of an ill-defined tingling in the thigh of unknown cause.

Spruijt 2003. 1. Treating elderly women with vaginal ES of the pelvic floor results in high levels of physical and emotional stress.

Yamanishi 2010 Regarding adverse events 6 patients (2 in the active ES group and 4 in the sham group) discontinued the study due to discomfort or anal pain, but there were no serious side effects or adverse events as a result of ES. Thus, ES seems to be safe if patients do not feel discomfort during insertion of the electrode.

BMJ Review: Pelvic floor ES is associated with tenderness and vaginal bleeding.

FAECAL

Review 7 Management of Fecal Incontinence in Adults: Of all studies that considered the effectiveness of electrical stimulation, five considered adverse effects. None were reported in one study. Across the others, adverse effects or complications noted were: vaginal irritation (12–22%), pain (6–9%), and cases of faecal incontinence, discomfort, and tenderness and bleeding. One study reported difficulty in maintaining motivation in 32% of the electrical stimulation group
4.7.2 Conclusion

There are no significant adverse effects associated with electrical stimulation for incontinence. There are no grounds for believing that the technical features of the itouch Sure would increase the risk of adverse effects.
### 4.8.1 Program Parameter Comparison

<table>
<thead>
<tr>
<th>Reference</th>
<th>Type</th>
<th>Make</th>
<th>Hz</th>
<th>μS</th>
<th>W/R</th>
<th>Time</th>
<th>Frequency</th>
<th>Strength</th>
<th>Wave</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Stress</td>
<td>EMPI</td>
<td>50</td>
<td>300</td>
<td>5/10</td>
<td>15m</td>
<td>Twice Daily 12 weeks</td>
<td>Highest tolerable</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>1.2</td>
<td>Stress</td>
<td>50</td>
<td>1000</td>
<td>?</td>
<td>15</td>
<td>4 weeks</td>
<td>?</td>
<td>square</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>R1</td>
<td>Stress</td>
<td>50</td>
<td>500</td>
<td>5/10</td>
<td>20m</td>
<td>3 times a week</td>
<td>Up to 100mA</td>
<td>Bipolar square</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>Urge</td>
<td>Neurotrac Programmed sequence</td>
<td>4/4</td>
<td>60m</td>
<td>3 times a week</td>
<td>Muscle lift</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R3</td>
<td>Urge</td>
<td>?</td>
<td></td>
<td></td>
<td></td>
<td>Ten over 5–7 weeks</td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2.269</td>
<td>Urge</td>
<td>10</td>
<td>1000</td>
<td>15</td>
<td>4 weeks</td>
<td>Max tolerable</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R4</td>
<td>Post Prostatectomy</td>
<td>50</td>
<td>300</td>
<td>5/5</td>
<td>15m</td>
<td>Twice daily 6 months</td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>R5</td>
<td>PP</td>
<td>20</td>
<td></td>
<td>daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2.270</td>
<td>Stress</td>
<td>Hollister</td>
<td>50</td>
<td>2000</td>
<td>2/4</td>
<td>15</td>
<td>Twice daily 12 weeks</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2.271</td>
<td>Stress</td>
<td>Experimental Hour</td>
<td>Daily</td>
<td>8 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Stress + Urge</td>
<td>Incare</td>
<td>20</td>
<td>100</td>
<td>2/4</td>
<td>20</td>
<td>Twice daily 8 weeks</td>
<td>Max tolerable</td>
<td>Bipolar square</td>
<td>No effect on Stress – Urge - 50%</td>
</tr>
<tr>
<td>2.273</td>
<td>Stress</td>
<td>50</td>
<td>300</td>
<td>5/5</td>
<td>20</td>
<td>Twice daily 12 weeks</td>
<td>Asymmetric biphasic</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2.273</td>
<td>Mixed/Urge</td>
<td>20</td>
<td>300</td>
<td>5/5</td>
<td>20</td>
<td>Twice daily 12 weeks</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.274</td>
<td>Urge</td>
<td>4</td>
<td>1000</td>
<td>2/4</td>
<td>3 times a week</td>
<td>Patient discomfort</td>
<td>Bipolar symmetric</td>
<td>Marginal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.43</td>
<td>Stress</td>
<td>Neurotech</td>
<td>10</td>
<td>35</td>
<td>80</td>
<td>4/4</td>
<td>60</td>
<td>15</td>
<td>28 days 14 days</td>
<td>No contraction</td>
</tr>
<tr>
<td>4.80</td>
<td>Stress</td>
<td>Vitacon</td>
<td>50</td>
<td>200</td>
<td>Variable</td>
<td>30</td>
<td>daily</td>
<td>Max tolerable</td>
<td></td>
<td>Small</td>
</tr>
<tr>
<td>4.108</td>
<td>Stress</td>
<td>EMPI</td>
<td>50</td>
<td>300</td>
<td>5/10</td>
<td>15-60</td>
<td>Twice daily 4 months</td>
<td>Max tolerable</td>
<td>Asymmetric biphasic</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Urge</td>
<td>12.5</td>
<td>300</td>
<td>5/10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>6.3</td>
<td>Faecal</td>
<td>Medicon</td>
<td>25</td>
<td>?</td>
<td>1.5/3</td>
<td>20</td>
<td>12 over 4-5 weeks</td>
<td>Max tolerable</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>8.1</td>
<td>PP</td>
<td>50</td>
<td>?</td>
<td>1/1</td>
<td>30</td>
<td>Once a week</td>
<td>Muscle lift</td>
<td>Biphasic</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
4.8.2 Discussion of Programme Parameter Settings

Duty Cycle
Several of the published clinical trials (1.1,  have been conducted with the EMPI Innova using the 5/10 duty cycle. UK professional guidelines (See Rev 9 Section 18.1 “To reduce fatigue, the duty cycle i.e. the "on - off" times, should be adjusted in such a way that the "off" time is at least double the "on" time”)

There is no published clinical evidence comparing the effectiveness of 5/5 and 5/10 duty cycles.

Frequency
The majority of the successful RCTs for Stress used 50Hz and this complies with UK professional guidelines

The Urge setting of 10-12.5Hz was used in two successful RCTs (1.2, 4.108)

The Mixed setting of 20Hz has been used n successful RCTs (R5, 1.4, 2.273), but has also achieved negative results in other RCTs.

The setting of 35Hz has been used in one successful RCT (5.43)

Pulse Width
The setting of 300µs is the used by the Empi Innova and complies with UK professional guidelines.

Output current intensity
There is no evidence that effectiveness is affected by the choice of constant current/constant voltage control. Both methods have been used successfully in published clinical trials. (EMPI/Neurotrac are CC, others are CV)

Because the actual motor nerve stimulation current is affected by a combination of the total output current, and the electrode position and contact points, the patient cannot set a fixed “correct” current, but needs to adjust the output to achieve maximal muscle contraction. Therefore the difference between constant current and constant voltage control is not significant.
Output Waveform
Comparison of output waveforms used in clinical trials.
The description of waveform is often brief or non-existent.
Many different waveforms have been used with good results.

Sure

Neurotrac (R2)

Neurotech (5.43)

EMPI Innova (1.1, 4.108)

Treatment Time

4.9 Safety

Continence stimulators have been in use for 40 years without any report of significant hazards to patients. See 4.7 above

Over 10,000 itouch Sure devices have been sold. One adverse report was received from a woman who had severe abdominal cramps lasting several days after exceeding the advised treatment time by 400%. User manual was re-written to emphasise the importance of slow increase in treatment parameters.
5. Conclusions

There is evidence that the programmes used in the itouch Sure, Elise, and Embagyn are effective and safe.

Andrew Brown
Regulatory Affairs Manager
10/10/2011
### 5. Summary of the clinical data

#### REVIEW PAPERS - Urinary Incontinence

<table>
<thead>
<tr>
<th>Ref</th>
<th>Review Paper</th>
<th>Author</th>
<th>Date</th>
<th>Type</th>
<th>Parameters</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medicare Coverage Policy Decision: Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (#CAG-00021)</td>
<td></td>
<td>Oct 2000</td>
<td>Insurance coverage enquiry</td>
<td><strong>Summary</strong> Urinary incontinence remains a significant medical problem for a large number of beneficiaries. After reviewing the entire body of scientific and clinical literature, the position statement by specialty societies, discussion at the MCAC, and numerous letters from individual patients and physicians, we can conclude that PFES is effective for those patients with stress and/or urge incontinence. Such patients must undergo a trial of pelvic muscle exercise training prior to use of the device.(^1) Patients with post-prostatectomy incontinence may receive this therapy as long as they have undergone and failed a trial of PME, and have their condition diagnosed as stress/urge. We encourage additional clinical trials to determine the exact role of this therapy, especially in relation to other incontinence treatments. The assessment made the following conclusions: 1. Evidence is not adequate to determine the efficacy of PFES for stress incontinence. 2. Evidence does not suggest that PFES is superior to alternatives for stress incontinence. 3. Evidence for PFES in urge incontinence, and post-prostatectomy incontinence is sparse. The methods of PFES vary in location (vaginal, rectal), stimulus frequency, stimulus and intensity, pulse duration, treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings.(^2) For urge incontinence, the objective is to reinforce the inhibitory system; these inhibitory neurons operate at low frequencies, so stimulation is generally administered at 5-20 Hz. For stress incontinence, the objective is to activate the motor neurons, so stimulation is generally administered at 20-50 Hz. For mixed incontinence, the treatment sessions generally alternate between those for urge and stress incontinence. A total of 25 studies were evaluated; 13 were randomized control trials, 12 were case series. Over 80% of the studies evaluated the effectiveness of PFES in stress incontinence. Of the 13 randomized studies, 5 showed benefit of PFES that was</td>
<td></td>
</tr>
</tbody>
</table>
statistically significant. The others either showed no difference (or difference was not statistically significant), or greater benefit of PME over PFES. Of the 12 case series, 9 showed some benefit. The majority of other studies had no comparison group, so it is difficult to determine if these patients would have improved without the use of PFES. The majority of patients experienced a reduction of a few leak episodes per day. Although the majority of patients remained incontinent, a reduction in a few episodes per day can have enormous functional relevance. There is also reasonable data on urge incontinence. Both Yaminishi and Brubaker were well-designed studies that showed effectiveness. Combined with the Smith study and several studies from the exclusion tables, one can conclude that PFES works for urge incontinence as well.

<table>
<thead>
<tr>
<th>Study</th>
<th>PFES</th>
<th>Sham PFES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sand 1995</td>
<td>42%*</td>
<td>26%</td>
</tr>
<tr>
<td>Luber 1997</td>
<td>14%</td>
<td>11%</td>
</tr>
<tr>
<td>Laycock 1993</td>
<td>No difference</td>
<td>No difference</td>
</tr>
<tr>
<td>Brubaker 1997</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Yamanishi 1997</td>
<td>33%*</td>
<td>0%</td>
</tr>
</tbody>
</table>

*statistically significant
Summary. There is lack of consistency in the electrical stimulation protocols employed in available studies. There is limited evidence for the benefit of electrical stimulation versus sham electrical stimulation in the treatment of urge UI. There is no evidence of additional benefit of electrical stimulation in combination with PFMT compared with PFMT alone.

Recommendation. Electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy.

Research into the optimal electrical stimulation parameters is required to inform future clinical practice. Studies investigating the role of electrical stimulation in women who cannot contract the pelvic floor muscle are required.

Various types of current were used, with various intensities. The setting (home or clinic), duration (15-30 minutes) and frequency (2-3 times per week) or individual treatments also varied.

**ES versus Sham**

Eight RCTs compared ES with sham. Treatment duration ranged from 4-15 weeks, with the number of women in each study ranging from 24 to 121. (248,268-274). Four studies included women with stress UI (248, 268,270,271) two included women with stress, urge, or mixed UI (272,273) and two included women or men and women (57% women) with urge UI. (269,274). One study was of poor quality (248), and the others were of good quality.

The findings across these studies were inconsistent, with significant benefit with ES versus sham reported in some but not all outcomes. A further RCT compared ES with PTMT and bladder training and with both combined in women with DO. At 9-11 weeks no significant differences were found.

**ES versus PFMT**

Eight RCTs compared PFMT with ES in women (six with Stress, one of which included mixed or Urge), and one with OAB with Urge.

The RCTs with Stress UI recruited between 18 and 51 patients. Duration of treatment ranged from 6 weeks to 12 months. The PFMT group also used vaginal cones in one study. The quality of two studies was poor (248,278), while four were of good quality (226,228,276,277)
None of the studies reported significant differences between groups. Subjective cure rates ranged from 10% to 56% with PFMT and from 4% to 12% with ES, and objective cure rates from 10% to 54% versus 4% to 40%. The RCT involving women with stress, urge, or mixed UI found no significant differences between PFMT and ES after 8 weeks treatment. (n=35) (279)

The RCT in women with overactive bladder and Urge UI reported significantly greater improvements in PFM parameters, but no significant differences in self-reported cure after 12 weeks treatment. (n=103) (265)

**Adverse Effects**

Five studies considered adverse effects. None were reported in one study. Across the others, adverse effects or complications noted were: vaginal irritation (12-22%), pain (6-9%) and cases of faecal incontinence, discomfort, and tenderness and bleeding. One study reported difficulty in maintaining motivation in 32% of the ES group.

| 3 | Urinary Incontinence in Adults: Clinical Practice Guideline Update | Agency for Health Care Policy and Research (AHCPR) | 2007 | Treatment Recommendations
| Pelvic Muscle Rehabilitation—to improve pelvic muscle tone and prevent leakage.
  * Pelvic floor electrical stimulation. Mild electrical pulses stimulate muscle contractions. Should be performed in conjunction with Kegel exercises. |
<table>
<thead>
<tr>
<th>4</th>
<th>Systematic Review: Randomized, Controlled Trials of Nonsurgical Treatments for Urinary Incontinence in Women.</th>
<th>Tatyana Shamilyan</th>
<th>Annals of Internal Medicine Vol 148, Number 6, 459</th>
<th>March 2008</th>
<th>Review of RCTs</th>
</tr>
</thead>
</table>

**Conclusion:** Moderate levels of evidence suggest that pelvic floor muscle training and bladder training resolved urinary incontinence in women. Anticholinergic drugs resolved urinary incontinence, with similar effects from oxybutynin or tolterodine. Duloxetine improved but did not resolve urinary incontinence. The effects of electrostimulation, medical devices, injectable bulking agents, and local estrogen therapy were inconsistent.

Continence rates were not greater after active compared with sham stimulation. Rates of resolved Urge UI were higher in 1 RCT (risk difference, 0.4[CI,0.22-0.58]) of 52 women after 2 months of treatment. Improvement in mixed UI was greater after active compared with sham stimulation (risk difference, 0.19[CI, .03-0.34]) in 148 women after 2 months of treatment. Active stimulation was not better than pelvic floor muscle training.

Electrical stimulation resulted in continence in about 20% of women (84, 108). However, 2 RCTs that assessed continence at 6 months or more of follow-up failed to show statistically significant benefit from electrical stimulation compared with continence services or medications (80, 108). Other RCTs also did not demonstrate significant relative benefit of electrical simulation compared with Kegel exercises (108), biofeedback-assisted training (79), or placebo (109 –112).

The effectiveness of stimulation to improve urinary incontinence depended on the type of urinary incontinence and administering therapy. The improvement after magnetic stimulation varied from 23% in women with urge UI (113) to 74% in those with stress UI (110). The greatest improvement in urge UI (85%) was observed after intravaginal electrical stimulation in women with predominantly urge UI (88). The design of the studies may alter the interpretations of the results; most of the studies had short-term follow-up, and only a few justified the sample size (80,84,88,109,114). Trials were designed to show a decrease in the frequency or severity of UI rather than long-term continence after stimulation therapy.
<table>
<thead>
<tr>
<th>Ref</th>
<th>Review Paper</th>
<th>Author</th>
<th>Date</th>
<th>Type</th>
<th>Parameters</th>
<th>Summary</th>
</tr>
</thead>
</table>
| 5   | BMJ Clinical Evidence Women’s health Stress incontinence Non-surgical treatments Pelvic floor electrical stimulation | Joseph L Onwude | June 2008 | Review of RCTs | Incontinence frequency  
Compared with no/sham treatment Pelvic floor electrical stimulation is more effective at reducing the frequency of incontinence episodes in women with incontinence ([moderate-quality evidence]).  
Compared with vaginal cones Pelvic floor electrical stimulation and vaginal cones seem equally effective at preventing episodes of incontinence in women (moderate-quality evidence).  
Improvement of incontinence  
Compared with no/sham treatment Pelvic floor electrical stimulation may be more effective at increasing the proportion of men and women with improvement or cure of incontinence ([very low-quality evidence]).  
Compared with vaginal cones  
Pelvic floor electrical stimulation and vaginal cones are equally effective at increasing cure or improvement rates in women with stress incontinence ([high-quality evidence]).  
Compared with oestrogen supplements  
Pelvic floor electrical stimulation and oestrogen supplements seem equally effective at increasing cure or improvement rates in women with stress incontinence (moderate-quality evidence).  
Adverse effects  
Pelvic floor electrical stimulation is associated with tenderness and vaginal bleeding. |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Review Paper</th>
<th>Author</th>
<th>Date</th>
<th>Type</th>
<th>Parameters</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>Single blind RCT of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence.</td>
<td>Rodrigo Castro. <em>Clinics 2008:63:46 5-72</em></td>
<td>2008</td>
<td>RCT</td>
<td>Double ring electrode. 50Hz, 5/10s cycle, 500uS. Up to 100mA. 20 mins.</td>
<td>Based on this study, pelvic floor exercises, electrical stimulation and vaginal cones are equally effective treatments and are far superior to no treatment in women with urodynamic stress urinary incontinence. Bipolar square 20 mins. 3 times a week. Supervised</td>
</tr>
<tr>
<td>Ref</td>
<td>Review Paper</td>
<td>Author</td>
<td>Date</td>
<td>Type</td>
<td>Parameters</td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>-------------------------------------------------------</td>
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<td>--------------------------------</td>
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</tr>
</tbody>
</table>

Results. In total, fifty women (71%) finally completed treatment for twelve weeks, and urinary incontinence disappeared in 8 (16%), detrusor overactivity disappeared in 10 (20%), and leakage was not found in 6 (12%) in leakage point pressure measurement. Moreover, the total time of voiding (72 h), total time of leakage (72 h), total scores of ICI-Q-SF, max detrusor uninhibited contraction pressure and detrusor uninhibited contraction duration were significantly lower than those before treatment; max voided volume, normal desired cystometric capacity, maximum cystometric capacity, Valsalva leak point pressure and max urethral closure pressure were significantly higher than those before treatment ($P < 0.05$). The effective rate following up three months was 60%, not significantly lower than that after treatment ($P > 0.05$).

Conclusions: PFES using surface electrode combined with PFT under intensive supervision is a useful therapy to treat women with IDO and USI (NeuroTracTM ETS, produced by VML Denmark’s company). The patients were asked to lie down, then the skin surface electrode was selected and placed in the perineal area that was besides the line of the vagina and anus. The sequential stimulation programmes were the same as those in previous research[8]. The stimulating cycle was 4S stimulation and 4S rest afterwards. The current strength of stimulus increased by 1% to 5% each time from 0 mA, until the patients had the feelings, while on computer screen electromyologram of perineum and muscle of perineum and anus contraction was observed, but without any significant discomfort. The treatment course was 3 times a week, each time 60 minutes, for 12 weeks.
<table>
<thead>
<tr>
<th>R3</th>
<th>Electrical stimulation compared with tolterodine for treatment of urge/urge incontinence amongst women—a randomized controlled trial, Karin Franzén, International Urogynecology Journal Volume 21, Number 12, Dec 2010</th>
<th>RCT</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sixty-one women completed the study. There was no significant difference between the two treatment groups in micturition rate from baseline to 6 months, mean difference, −0.40 (95% confidence interval (CI), −1.61 to 0.82), but a clearly significant difference within each group for electrical stimulation, −2.8 (95% CI, −3.7 to −1.9), and for tolterodine, −3.2 (95% CI, −4.1 to −2.4).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Conclusions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Both treatments reduced the number of micturitions, but electrical stimulation was not found to be superior to tolterodine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protocol: Ten electrical stimulation treatments vaginally and transanally over a period of 5–7 weeks</td>
</tr>
<tr>
<td>Ref</td>
<td>Review Paper</td>
<td>Author</td>
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<tr>
<td>Rev 10</td>
<td>The management of faecal incontinence in adults. NICE Guideline CG49</td>
<td>2007</td>
<td>Anal probe. Frequencies capable of producing a tetanic muscle contraction, with appropriate duty cycle. Treatment time 5-30 mins. No generally agreed protocols</td>
</tr>
<tr>
<td>6</td>
<td>Cochrane Review. Electrical stimulation for faecal incontinence in adults</td>
<td>2009 (Updated May 2007)</td>
<td>Four eligible trials with 260 participants were identified. Findings from one trial suggest that electrical stimulation with anal biofeedback and exercises provides more short-term benefits than vaginal biofeedback and exercises for women with obstetric-related faecal incontinence. Another study found contradictory results, with no added benefit from electrical stimulation over biofeedback and exercises alone. Although all trials report that patient’s symptoms are generally improved, it is not clear that this is the effect of electrical stimulation. No further conclusions could be drawn from the data available.</td>
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</table>
| 7 | Management of Fecal Incontinence in Adults | C. Norton,1* W.E. Whitehead, 2 D.Z. Bliss,3 D. Harari,4 and J. Lang | Neurourology and Urodynamics Volume 29, Issue 1, 2010 | EXTERNAL ELECTRICAL STIMULATION FOR FI  
Six controlled studies of ES in FI were found. Results are contradictory and inconsistent. There is at present no experimental evidence upon which to select optimum electrical stimulation parameters for different symptoms and clinical conditions. A Cochrane review of trials of electrical stimulation for FI has concluded that “At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of FI. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain. Larger, more generalizable trials are needed.”30 Based on currently available evidence it is not possible to recommended electrical stimulation for FI.  
<table>
<thead>
<tr>
<th>Ref</th>
<th>Review Paper</th>
<th>Author</th>
<th>Date</th>
<th>Type</th>
<th>Parameters</th>
<th>Ref</th>
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<tr>
<td>8</td>
<td>Cochrane Review: Conservative management for postprostatectomy urinary incontinence</td>
<td>2009</td>
<td></td>
<td></td>
<td>Authors conclusions. Implications for practice. In keeping with conclusions from earlier versions of this review, at this point there remains no clear support that conservative management of any type for post-prostatectomy UI is either helpful or harmful, whether delivered as treatment to men who are incontinent or as prevention to all men undergoing surgery.</td>
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<td>2. Post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment (Comparison 02)</td>
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<td>Only a single trial with data was identified for this comparison (Moore 1999). This trial reported using PFMT with anal electrical stimulation. This was the second intervention group in the Moore trial.</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Author</td>
<td>Year</td>
<td>Study Type</td>
<td>ES Parameters</td>
<td>Conclusion</td>
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<td><strong>R4</strong></td>
<td>Randomized, Placebo Controlled Study of Electrical Stimulation With Pelvic Floor Muscle Training for Severe Urinary Incontinence After Radical Prostatectomy.</td>
<td>Yamanishi.</td>
<td>2010</td>
<td>RCT</td>
<td>50 Hz square wave 15 mins Twice daily Anal electrode</td>
<td>The continence rate was significantly higher in the active ES group than in the sham group after 1, 3 and 6 months of treatment. However, there was no difference between the groups at 12 months and the effect of ES after more than 6 months of treatment was slight. Accordingly we recommend a combination of ES and PFMT for at least 3 to 6 months in patients with severe incontinence after RRP. Electrical stimulation with PFMT led to earlier restoration of continence in patients with urinary incontinence after RRP. <strong>Results:</strong> In the active group, 8 (36%), 14 (63%), 18 (81%) and 19 (86%) patients were continent (22) vs 1 (4%), 4 (16%), 11 (44%) and 17 (86%) in the sham group (25) (leakage less than 8 gm daily) after 1, 3, 6 and 12 months, respectively. There was a significant difference in the number of continent patients between the groups at 1, 3 and 6 months (p _ 0.0161, p _ 0.0021 and p _ 0.0156, respectively). The time to achieve continence was significantly shorter in the active group (2.71 _ 2.6 months) than in the sham group (6.82 _ 3.9 months, p _ 0.0006). Changes in the amount of leakage, the International Consultation on Incontinence Questionnaire-Short Form score and the King’s Health Questionnaire score were significantly larger in the active group at 1 month but there was no difference at 12 months. Electrical stimulation resulted in earlier recovery of continence in patients with urinary incontinence after radical prostatectomy. Electrical stimulation was performed for 15 minutes twice daily with an anal electrode. Improving the contractility of the pelvic floor muscle was thought to be most beneficial for the treatment of UI after RRP. Therefore, 50 Hz square waves with a 300 _s pulse duration and a maximum output of 70 mA (5 seconds on, 5 seconds off duty cycle) were used for active stimulation.</td>
</tr>
<tr>
<td>R5</td>
<td>Behavioral Therapy With or Without Biofeedback and Pelvic Floor Electrical Stimulation for Persistent Postprostatectomy Incontinence A Randomized Controlled Trial</td>
<td>Goode JAMA. 2011;305(2):151-159.</td>
<td>2011</td>
<td>RCT</td>
<td>Daily home pelvic floor electrical stimulation at 20 Hz, current up to 100 mA (behavior plus)</td>
<td>Among patients with postprostatectomy incontinence for at least 1 year, 8 weeks of behavioral therapy, compared with a delayed-treatment control, resulted in fewer incontinence episodes. The addition of biofeedback and pelvic floor electrical stimulation did not result in greater effectiveness.</td>
</tr>
<tr>
<td>R6</td>
<td>Pelvic floor muscle training for stress urinary incontinence: A randomized, controlled trial comparing different conservative therapies</td>
<td>Markus Huebner, Katja Riegel, et al Physiotherapy Research International September 2011 Volume 16, Issue 3 Pages 125–186</td>
<td>2010</td>
<td>RCT</td>
<td>Method. Three-arm RCT comparing 1) EMG biofeedback-assisted PFMT and conventional ES; 2) EMG biofeedback-assisted PFMT and dynamic ES; and 3) EMG biofeedback-assisted PFMT. Primary outcome measures were quality of life (King's Health Questionnaire) and degree of suffering (rated on a visual analogue scale from 1 to 10). Secondary outcome measures were number of pads used, pad weight test, contractility of the pelvic floor measured by digital palpation and intra-vaginal EMG. Results. The quality of life significantly increased over the 12-week training. The number of pads used was reduced, the pad weight test and the contractility of the pelvic floor significantly improved. There were no significant differences between the three groups. Conclusion. This RCT shows significant improvement in patients' quality of life for conservative therapy of SUI. Differences between the three therapeutic options analyzed could not be found. Additional ES showed no benefit for patients with SUI, capable of voluntary pelvic floor contraction.</td>
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<td>ADVERSE EFFECTS</td>
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<td><strong>NICE CG40</strong></td>
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<td>Management of Urinary Incontinence in Women Para 4.2.4</td>
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<td>Adverse effects</td>
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<td>Of all studies that considered the effectiveness of electrical stimulation, five considered adverse effects. None were reported in one study. Across the others, adverse effects or complications noted were: vaginal irritation (12-22%), pain (6-9%), and cases of faecal incontinence, discomfort, and tenderness and bleeding. One study reported difficulty in maintaining motivation in 32% of the electrical stimulation group.</td>
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<td>In one of the RCTs [27] identified by the review, [25] adverse effects included tenderness and vaginal bleeding (1/25 [4%]) and discomfort (1/25 [4%]) in the PFES group</td>
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<td><strong>Continence UK June 2009 Vol 3 Issue 2 Clinical continence Supervision Group</strong></td>
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<td>Risks of harm.</td>
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<td>So what harm can unsupervised use of neuromuscular stimulation do? There are many contraindications listed by the manufacturers of which professionals have to be aware. Professionals will exclude women who are known to have contraindications from treatment. The most frequent reported adverse affects with transrectal stimulation are abdominal cramps, diarrhoea, pan and canal bleeding and vaginal irritation, and with vaginal stimulation, pain and bleeding.</td>
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<td>Clinical Guidelines</td>
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| Re v9 Clinical guidelines for the physiotherapy management of females aged 16–65 years with stress urinary incontinence | CSP May 2003 | CSP Guidelines 3.6.3 Recommendations:  
• The selection of safe and suitable electrical parameters is important. The GDG recommends the following, although different parameters have also produced effective pelvic floor muscle training:  
  Frequency: 35Hz  
  Pulse width: 250μs (0.25ms)  
  Current type: bi-phasic rectangular  
  Intensity: maximum tolerated  
  Duty-cycle: 5s on/10s off. Very weak muscles: 5s on/15s off  
  Treatment daily/twice daily (home treatment)  
  Treatment time: 5 minutes initially, gradually increasing to 20 minutes. |

METHODS:
The interventions for the 12-week treatment period, conducted by the physiotherapist who was unaware of the progress and outcome, included (a) a PFMT program tailored to the subject's PERFECT (power, endurance, repetitions, and fast [1-second] contractions, with every contraction timed) scheme, used for training at home; (b) an electromyography BAPFMT program and home program tailored to the subject's PERFECT scheme; and (c) an ES program using biphasic symmetric probe current with 10-Hz frequency, 400-microsecond pulse width, 10/5 duty cycle, and varying intensity. Identical preintervention and postintervention assessment included King's Health Questionnaire, as well as outcomes of urge incontinence and other urinary symptoms.

RESULTS:
Of the 103 women who completed this study, 34 were in the PFMT group, 34 in the BAPFMT group, and 35 in the ES group. The changes in the three parameters of King's Health Questionnaire revealed statistically significant differences, except for the total score, between ES and BAPFMT (domain 7, P = 0.003; domain 9, P = 0.029; and total score, P = 0.952). These same parameters were significantly different between ES and PFMT (domain 7, P = 0.007; domain 9, P = 0.001; and total score P = 0.004). The change in total score was significantly different between BAPFMT and PFMT (P = 0.003). The subjective improvement/cure rate of OAB was 51.4% for ES, 50.0% for BAPFMT, and 38.2% for PFMT (P = 0.567).

CONCLUSIONS:
ES had the greatest subjective reduction rate of OAB and was
the most effective of the three treatments. BAPFMT was more effective than PFMT.

RESULTS: Significant improvements from baseline were found in patients using active devices but not in controls. Comparisons of changes from baseline between active-device and control patients showed that active-device patients had significantly greater improvement in weekly (p = 0.009) and daily (p = 0.04) leakage episodes, pad testing (p = 0.005), and vaginal muscle strength (p = 0.02) when compared with control subjects. Significantly greater improvement was also found for both visual analog scores of urinary incontinence (p = 0.007) and stress incontinence (p = 0.02), as well as for subjective reporting of frequency of urine loss (p = 0.002), and urine loss with sneezing, coughing, or laughing (p = 0.02), when compared with controls. Pad testing showed that stress incontinence was improved by at least 50% in 62% of patients using an active device compared with only 19% of patients using sham devices (p = 0.01). Voiding diaries showed at least 50% improvement in 48% of active-device patients compared with 13% of women using the sham device (p = 0.02). No irreversible adverse effects were noted in either group.

CONCLUSIONS: Transvaginal pelvic floor electrical stimulation was found to be a safe and effective therapy for genuine stress incontinence.

Treatment Protocol:
EMPI Innova 50Hz and 12.5 Hz. 300uS. Highest tolerable. 5/10 for 15 mins progressing to 30 mins.
Objectives. To evaluate the usefulness of electrical stimulation for urinary incontinence due to detrusor overactivity in a randomized, double-blind manner.

Methods. Sixty-eight patients (29 men, 39 women, 70.0 ± 11.2 years) were studied. Detrusor overactivity was urodynamically defined as involuntary detrusor contractions of more than 15 cm H2O during the filling phase. The efficacy was evaluated on the basis of a frequency/volume chart and urodynamic study before and after treatment. Ten-hertz square waves of 1-ms pulse duration were used. A vaginal electrode was used in the women and an anal or surface electrode in the men. The stimulation was given for 15 minutes twice daily for 4 weeks. maximum output current of 60 mA were used for active electrical stimulation. Stimulation up to the maximum tolerable level was given.

Results. Thirty-two patients in the active group and 28 in the sham group completed the study. The patient impressions were very good or good in 59% and 39% of the active and the sham group, respectively (P = 0.0354). On the cystometrogram, the bladder capacity at the first desire to void and the maximum desire to void increased significantly (P = 0.0104 and P = 0.0046, respectively) in the active group, but not in the sham group. Seven patients in the active group and 1 patient in the sham group were cured (P = 0.0324); 26 patients (81.3%) in the active group and 9 (32.1%) in the sham group improved (P = 0.0001). Of 17 patients in the active group, 13 remained cured or improved for an average of 8.4 months after completion of the 4-week treatment; in the sham group, 3 of 6 patients were cured or improved for an average of 4.7 months after completion of the 4-week treatment.

Conclusions. Electrical stimulation was useful in treating urinary incontinence due to detrusor overactivity.
Yamanishi T, Yasuda et al

Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigational study and a placebo controlled double-blind study

J Urol 1997 Dec;158(6):2127-31

 MATERIALS AND METHODS:
We studied 44 patients with stress incontinence (six men and 38 women, age 63 +/- 13), including 9 patients in the investigational study and 35 in the double-blind study. We used 50 Hz. square waves of 1 ms. pulse duration for stimulation. A vaginal electrode was used in women and an anal electrode in men. Urethral pressure profile before, during and after 15-minute stimulation was measured in the investigational study. In the double-blind trial an active device and a dummy device were used, and efficacy was judged from patient impressions, records in frequency/volume chart, results of 1-hour pad test and urodynamic parameters after 4-week treatment.

RESULTS:
In the investigational study maximum urethral closure pressure (mean plus or minus standard deviation) before, during and after stimulation was 44.4 +/- 17.5, 64.5 +/- 28.8 and 46.8 +/- 25.6 cm. water, respectively. This parameter significantly increased (p = 0.0275) during stimulation. In the double-blind trial patient impressions were good in 60% of the active device group and 8% of the dummy device group (p = 0.0051). For the pad test significant improvement was noted in the active device group (p = 0.0100). Cure rate was 45% in the active device group and 7.7% in the dummy device group. There were significantly more cured or improved patients for frequency of leakage (p = 0.0196) and pad test (p = 0.0100).

CONCLUSIONS:
Electrical stimulation is effective for the treatment of stress incontinence.

Luber KM and Wolde-Tsadik G.

Efficacy of functional electrical stimulation in treating genuine stress incontinence: a randomized clinical trial.

Neurology and Urodynamics 1997;16(6):543-51

In this patient population, functional electrical stimulation was no more effective at improving or eliminating the symptoms of genuine stress incontinence than was the daily retention of the control probe.

Jeyaseeln SM, Haslam EJ, Winstanley J et al.

An evaluation of a new pattern of electrical stimulation as a treatment for urinary stress incontinence: a randomized, double


The stimulation protocol consisted of a background low frequency (to target slow twitch fibres) and intermediate frequency with an initial doublet (to target fast twitch fibres). A low number of impulses within the high-frequency component and adequate rest periods between stimulus trains were used to reduce premature fatigue. The electrostimulation technique...
blind, controlled trial.

|---|---|---|---|---|---|

The transvaginal electric stimulation group (stimulation group) used the InCare Microgyn II. The selected electric parameters included a frequency of 20 Hz, a 2-second-4-second work-rest cycle, and a pulse width of 0.1 t*second. The bipolar square wave could be delivered over a range of 0 to 100 mA. Stimulation subjects were instructed to stimulate to the maximum tolerable motor response. The treatment began with use of the assigned device for 20 minutes twice daily.

Table V. Additional outcome variables

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Sham stimulation</th>
<th>Significance (sham vs electric stimulation)</th>
<th>Mann-Whitney test</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 wk 24 hr frequency (average)</td>
<td>9.5 ± 2.8</td>
<td>9.3 ± 6.8</td>
<td>0.049</td>
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<tr>
<td>6 wk No. of accidents/24 hr (average)</td>
<td>2.2 ± 2.7</td>
<td>2.4 ± 3.1</td>
<td>0.75</td>
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<tr>
<td>Adequate subjective improvement</td>
<td>17%</td>
<td>35%</td>
<td>0.027</td>
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<tr>
<td>8 wk compliance (%)</td>
<td>83.7 ± 14.7</td>
<td>78.8 ± 20.5</td>
<td>0.25</td>
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<tr>
<td>Final urodynamic diagnosis of detrusor overactivity</td>
<td>41%</td>
<td>27%</td>
<td>0.22</td>
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<td>The patients had their treatment at home twice a day (20-min sessions) for 12 weeks. 20 or 50 Hz, a pulse width of 300ms, with asymmetrical biphasic pulses, an adjustable current intensity (0–100 mA), a 1 s rise time, sustained for 5 s and resting for 5 s. Patients exposed to TES increased the intensity slowly and significantly (P &lt; 0.001). The mean electrical current used during the first 30 days of treatment was 48.13 (13.24) mA and after 90 days it increased to 96.97 (20.68) mA. In situations in which a urodynamic evaluation is not available, the type of electrical stimulation can be adapted to the clinical situation, i.e. for genuine urinary incontinence 50 Hz, and in urge or mixed urinary incontinence, lower frequencies (10–20 Hz). <strong>RESULTS</strong> Patients using TES, despite more severe disease than in the control group, after treatment had a significantly greater reduction in loss of urine (P &lt; 0.001). There was also a significant increase in the cystometric capacity, evaluated by urodynamic study, in patients who used TES (P &lt; 0.02). At the end of the treatment(120 days), 88% of the patients were cured or improved. At 6 month follow up 33% needed another therapeutic approach. TES is a practical alternative with few side effects, and is effective for treating the main forms of female urinary incontinence. Women, 50 Hz, 300uS, 0-100mA 5s on, 5s off. 20 mins twice a day. 20Hz for Urge and Mixed – insufficient patients.</td>
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<td>Authors</td>
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<tr>
<td>274</td>
<td>Amaro JL, Gameiro MO, Padovani CR.</td>
<td>Effect of intravaginal electrical stimulation on pelvic floor muscle strength</td>
<td>International Urogynecology Journal 2005;16(5):35-8</td>
</tr>
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</table>
TREATMENT: Frequency modulation of 0.1s trains of rectangular biphasic 200us pulses varying between 4 and 10Hz. Innocept ProSeco device. Max tolerable intensity. 9weeks. Daily treatment time not specified.  
RESULTS: Combined centre and home-based FES seems to be an effective treatment modality for the treatment of women with proven bladder instability. |
| 123  | Goode PS, Burgio KL, Locher JL, Roth DL, Umlauf MG, Richter HE, et al. | Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial | JAMA 2003;290(3):345–52. | Interventions Patients were randomly assigned to 8 weeks (4 visits) of behavioural training (with biofeedback), 8 weeks (4 visits) of the behavioral training plus home PFES, or 8 weeks of self-administered behavioral treatment using a self-help booklet (control condition). |
Pelvic Floor Electrical Stimulation. 

biphasic pulses (frequency of 20 Hz), pulse width of 1 milliseconds, and pulse train to rest period of 1:1 (to keep the exercise and relaxation phases the same among treatment groups). Frequency settings between 20 and 50 Hz have been reported as optimal for sphincter closure and pelvic floor muscle contraction, and 5 to 20 Hz for reflex detrusor inhibition. Therefore, 20 Hz was selected since many of the patients were expected to have mixed stress and urge incontinence. The current intensity was adjusted by the patient to the maximum level she could tolerate comfortably, up to 100 mA. 15 minutes every other day.

Conclusions Treatment with PFES did not increase effectiveness of a comprehensive behavioral program for women with stress incontinence. A self-help booklet reduced incontinence and improved quality of life but not as much as the clinic-based programs.
genuine stress incontinence.

perceptible – no contraction.
Then 14 days at 35 Hz 15 mins per day.
Side Effects: On direct questioning none of the patients reported any discomfort or side-effects from the NTS

**Results**
Patient assessment of results:

<table>
<thead>
<tr>
<th>Active n=7</th>
<th>Inactive n=6</th>
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<tbody>
<tr>
<td>No change since end of study</td>
<td>0</td>
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<tr>
<td>Deteriorated</td>
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<td>No reply</td>
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An MS 106 Twin (Vitacon AS, Trondheim, Norway) was used according the manufacturer’s recommended protocol for 30 minutes of intermittent vaginal electrical stimulation per day. Selected parameters included biphasic intermittent current, frequency 50 Hz, pulse width 0.2 milliseconds, and current intensity between 0-120 mA with individually adapted on-off (duty) cycles on the basis of each woman’s ability to hold a voluntary contraction. On time ranged from 0.5 seconds to 10 seconds, and off time from 0 seconds to 30 seconds. If ability to hold the contraction improved the duty cycle was progressed each month. All patients were encouraged to tolerate as high an intensity as possible to get a contraction.
Amplitude 0-120 mA biphasic
PW 200us square pulse
Urge 10Hz Mix 20Hz Stress 50Hz
On adjustable ro 0.5 to 10 s OFF 0 to 30s
Time adjustable from 5 to 120 min.

**Results** Improvement in muscle strength was significantly greater ($P = 0.03$) after pelvic floor exercises (11.0 cm H2O (95% confidence interval 7.7 to 14.3) before v 19.2 cm H2O (15.3 to 23.1) after) than either electrical stimulation (14.8 cm H2O (10.9 to 18.7) v 18.6 cm H2O (13.3 to 23.9)) or vaginal cones (11.8 cm H2O (8.5 to 15.1) v 15.4 cm H2O (11.1 to 19.7)). Reduction in leakage on pad test was greater in the exercise group (-30.2 g; -43.3 to 16.9) than in the electrical stimulation group (-7.4 g; -20.9 to 6.1) and the vaginal cones group (-14.7 g; -27.6 to -1.8). On completion of the trial three in the electrical stimulation group no longer considered themselves as having a problem.

**Adverse effects and treatment tolerance**
In the electrical stimulation group two participants reported smarting (one tenderness and bleeding, one discomfort), and eight women reported motivation problems and difficulties in using the stimulator.

**Results**: Of patients using electrical stimulation in the stress urinary incontinence group 66% improved and 72% of the patients with detrusor instability treated with electrical stimulation improved. These rates were not statistically significant when compared to traditional therapy.

**Conclusions**: Electrical stimulation is safe and at least as effective as properly performed Kegel and anticholinergic therapy in the treatment of stress urinary incontinence and detrusor instability.
The device uses 2 programs simultaneously at 12.5 Hz. and 50 Hz. (EMPI). The technical characteristics of the device are shown in Appendix 2.

Compliance was monitored by a built-in digital readout of the number of hours of use, of which patients were not aware. The patients with genuine stress urinary incontinence started with a 5-second contraction time (range 3 to 15), a duty cycle of 1 to 2 (range 1 to 1 to 1 to 2), and an increasing treatment time from 15, 30, 45 and 60 minutes twice a day for 4 months. Amplitude started at 5 to 10 mA. and was increased each month to a maximum of 80 mA. (range 1 to 100). The patients with detrusor instability started with a 5-second impulse time, a duty cycle of 1 to 2, and an increasing monthly treatment time from 15, 30, 45 and 60 minutes. The amplitude started at 5 mA. and did not exceed 25 mA.

Complications from use of the device were minor. Two patients complained of vaginal irritation, which subsided after changing the lubricant. Two women had urinary tract infections while participating in the study. One patient complained of an ill-defined tingling in the thigh of unknown cause.

**APPENDIX 2: ELECTRICAL STIMULATION PARAMETERS**

Waveform current
- Asymmetric balanced biphasic pulsed

Amplitude
- 1 to 100 mA.

Pulse rate
- Channel 1: 50 Hz.; channel 2: 12.5 Hz.

Phase duration
- 300 w.

Cycle on time
- 5 seconds

Cycle off time
- 5 or 10 seconds

Ramp up
- 2 seconds

Ramp down
- 1 second
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<th>Page</th>
<th>Reference</th>
<th>Details</th>
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<tbody>
<tr>
<td>279</td>
<td>Spruijt J, Vierhout M, Verstraeten R, Janssens J, Burger C.</td>
<td>Vaginal electrical stimulation of the pelvic floor: a randomized feasibility study in urinary incontinent elderly women.</td>
</tr>
<tr>
<td>1</td>
<td>Mahony RT, Malone PA, Nalty J, Behan M, O’Connell PR, O’Herlihy C</td>
<td>Randomized clinical trial of intra-anal electromyographic biofeedback</td>
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**Methods**

Ninety patients (9 males, 81 females), with median age of 55 (range, 30–77) years were randomized, 47 to active anal stimulation at 35 Hz and 43 to “sham” stimulation at 1 Hz. Outcome measures included a one-week bowel diary, symptom questionnaire, manometry, and patients' evaluation of outcome.

**Results**

Seventy patients completed the study. On an intention-to-treat analysis, there was no difference between the two groups on any of the outcome measures after eight weeks. Of those who completed stimulation, 44 (63 percent) felt the stimulation had improved their continence. Those with intact anal sphincters were not likely to rate their change more positively than those with sphincter disruption ($P = 0.71$). Median patient rating of bowel control increased from 3 of 10 before stimulation to 5 of 10 after stimulation ($P = 0.001$).
**Conclusions**

Eight weeks of anal electric stimulation was rated by patients as having improved their bowel control to a modest extent. There was no statistically significant difference detected between the groups, suggesting that 1 Hz was as effective as 35 Hz. This raises the possibility that the main effect is not sphincter contraction but sensitization of the patient to the anal area, or simply the effect of intervening *per se*. Home electric stimulation is a relatively cheap and generally well-tolerated therapy in the conservative treatment of fecal incontinence.

The “active” stimulation involved the use of a home electric stimulation unit (Elpha 4 Conti, Danmeter A/S, Denmark) with an “Anuform” anal plug electrode (Neen Healthcare, Dereham, United Kingdom) for eight weeks. Patients were given a printed instruction sheet. For the first three weeks the stimulator was to be used for 20 minutes per day; then for weeks 4 to 8 it was to be used for 40 minutes per day. “Active” stimulation was at 35 Hz with a 0.5-second ramped pulse, 5 seconds on, 0.5-second ramp down, and 5-second off-duty cycle. Pulse width was 300 ms. Intensity at 35Hz which should cause tonic contraction of the striated muscle external anal sphincter, and control stimulation at 1 Hz, which should cause a sensation only.

| 3 | Osterberg A, Edebol Eeg-Olofsson K, Hallden M, Graf W. | Randomized clinical trial comparing conservative and surgical treatment of neurogenic faecal incontinence. | **Background:**
The treatment of choice in idiopathic (neurogenic) faecal incontinence is controversial. In a randomized study levatorplasty was compared with anal plug electrostimulation of the pelvic floor with respect to functional outcome and physiological variables. | **Methods:** |
Thirty-one patients underwent levatorplasty and 28 anal plug electrostimulation of the pelvic floor over 3 years. The results were evaluated at 3, 12 and 24 months after completion of treatment by means of a validated questionnaire and anorectal manometry and manovolumetry.

Results:

Incontinence scores were significantly reduced during the entire observation period in both groups \( (P < 0.001) \) as was the use of pads \( (P = 0.003 \) to \( P < 0.001) \). The proportion of patients reporting improvement in physical and social handicap was greater in the levatorplasty group after 3, 12 and 24 months \( (P = 0.036 \) to \( P < 0.001) \). No significant changes in physiological variables were observed in either group. Conclusion:

Better results were obtained with levatorplasty than with anal plug electrostimulation of the pelvic floor in patients with idiopathic (neurogenic) faecal incontinence. Levatorplasty should be therefore be considered the treatment of choice for this condition. Anal plug electrostimulation of the pelvic floor should be reserved for those with mild symptoms, or elderly and frail patients.

The pelvic floor stimulator MS210TM (Medicon, Trondheim, Norway) consists of a pulse generator with an anal (in women also a vaginal) plastic plug with attached electrodes. The pulse generator is supplied with two controls, by which the energy delivered and the frequency of stimulation can be varied. The stimulation frequency was 25 Hz and the duration 1・5 s, with a pulse-train interval of 3 s. The electrodes were lubricated with an electrically conductive cream and introduced into the anal canal and vagina. A varying current just below the sensation of burning or pain was given for maximum effect. Each treatment lasted for 20 min, and a total of 12 sessions were administered over 4–5 weeks. All patients were treated by the same therapist. One woman who underwent
pelvic floor stimulation experienced a burning sensation in the 
vagina 2 weeks after treatment.

| 7 | 8.1 | Moore KN, Griffiths DJ, Hughton A. | Urinary incontinence after post radical prostatectomy: A 

**Conclusions.** Incontinence improved rapidly in all three groups. Surface anal electrode. Twice a week 30 mins. 50 Hz biphasic burst of 1 sec, each second, 1s pulse width. Intensity to give visible lifting of the muscle.

ES+PME no different to PME alone.
### Other references – Clinical reports and reviews of technology

|   | Transcutaneous Electrical Nerve Stimulation and temporary S3 neuromodulation in idiopathic detrusor instability | Hasan, S Tahaseen | The Journal of Urology Vol155, 2005-2011, June 1996 | 1996 | Not RCT | In patients with severe detrusor instability refractory to conservative treatments the use of TENS and S3 neuromodulation produced significant changes in presenting symptoms.

TENS 50Hz 200uS
Skin electrodes over S2-S3 dermatomes.
Less than 2 hours. |
|---|---|---|---|---|---|---|
Cure rate was 45% in the active device group and 7.7% in the dummy device group
A vaginal electrode was used in women and an anal electrode in men. |
| X3 | Pelvic floor electrical stimulation for genuine stress incontinence: who will benefit and when? | Miller J, Richardson | Int Urogynecol J Pelvic Floor Dysfunct. 1998;9(5):265-70 | Not RCT | 50Hz 14 weeks required. EMPI INNOVA | A significant objective improvement was seen by 14 weeks in those who responded to therapy.
68% showed a 50% decrease in the total number of leakage episodes in voiding diaries. |
| X4 | Maximal electrostimulation of the pelvic floor in urge incontinence | Eriksen | Neurourology and Urodynamics 8:219-230 | 1989 | Not controlled or randomised | Monophasic square 5-10Hz 1000us. 
Initially cures were obtained in about 50% of patients. In addition a significant improvement was observed in 33%.
At 1 year follow up persisting positive effect was found in 77% |
| X5 | Electrical Stimulation for the Treatment of Urinary Incontinence | Appell, Rodney A | Cleveland Clinic Urology 51 (suppl 2A):24-26, 1998 | 1998 | Review of theory not RCT. | Low frequencies <10Hz are used for DI and high frequencies > 50Hz For SUI. | Detrusor Instability: Researchers agree that low frequency (5-10 Hz) and moderate amperage (<20mA) are required to obtain results from 45 to 91% effectiveness |
| X6 | Pelvic Floor Electrical Stimulation for the treatment of urge and mixed urinary incontinence in women. | Siegal S W, Richardson D A, Miller K L, | Urology 50:934-940 1997 | 1997 | Not controlled or randomised. | Device current range was limited to 60mA | 3-10% of women 15-64 yrs are affected. Significant decrease in urge leakage. Significant improvement in every subjective measure. Urge incontinence was treated with 12.5Hz 5sec work/10 sec rest. |
| X7 | Critical evaluation of electrostimulation for management of female urinary incontinence | K Yasuda & T Yamanashi | Opin Obstet Gynecol 11:503-507 1999 | 1999 | Review of parameters | 20-50Hz Stress, 5-10 Hz Urge | Drugs are sometimes associated with adverse events such as dry mouth, dyspepsia, nausea and constipation. Cure and improvement rates have been reported as 20-45% and 55-91% respectively |
| X8 | Intravaginal Maximal Stimulation in the treatment of urinary incontinence | Caputo | J of Reproductive Medecine Vol 38 no9 1993 | Not RCT | 20Hz 2s work, 4 sec rest 15 min + 15 min Kegel 6 Weekly sessions. | Objective improvement 89% GSUI 73% DI 70% MI Experimentally, the optimal frequency of electrical stimulation for increased urethral tone and bladder inhibition is 20-50 and 5-10 Hz respectively. |
Reviews:

Review 1  Decision Memorandum for Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence. Health Care Financing Administration. Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (#CAG-00021) Date:October 5, 2000

Review 1 Appendix #CAG-00021N Technology Assessment


Review 10  NICE Guideline CG49 The management of faecal incontinence in adults. 2007
References:


Goode PS, Burgio KL et al. (2011) Behavioral Therapy With or Without Biofeedback and Pelvic Floor Electrical Stimulation for Persistent Postprostatectomy Incontinence A Randomized Controlled Trial. JAMA. 2011;305(2):151-159.


