



Clinical Evaluation Report

TensCare Itouch Sure

1. General details

Device: itouch Sure Pelvic Floor Exerciser Model: ITS
Manufacturer: TensCare Ltd.

Subcontractor: EasyMed Devices Ltd

GMDN Code and Term: 36784

Stimulator, electrical, neuromuscular, incontinence[36784]

Classification: IIa

2. Description of the device and its intended application

A non-implantable neuromuscular electrical stimulator designed to treat urinary and/or faecal incontinence that consists of a pair of electrodes on a plug or pessary that are connected to a battery powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor.

The itouch Sure is battery powered, microprocessor controlled, portable device, intended to be used by the patient in the home. It is connected by a 1.25m cable with safety connector to a vaginal (optional rectal electrode or self adhesive skin electrodes)

The product does not incorporate a medicinal substance (already on the market or new), tissues, or blood products.

The vaginal electrode is supplied non-sterile, for single patient use.

The vaginal electrode is intended to be used approximately 20 minutes a day in direct contact with vaginal mucosa.

3. Intended therapeutic and/or diagnostic indications and claims

Conditions:

- Stress, Urge, and Mixed Urinary incontinence in adults of both sexes.
- Faecal incontinence in adults of both sexes
- Post prostatectomy urinary incontinence in adult males

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

The itouch Sure was developed using existing technology, reproducing the specifications of existing competitive devices. The aim was to make a lower cost and simpler device available for widespread use in the community. The principle technical difference is the replacement of large inductance coils with inductance switching to charge capacitors. Previous devices have used both “constant current” and “constant voltage” control. The vaginal mucosa have very low impedance to muscle stimulation pulses (around 400 Ohm). However the electrical contact depends on the tension in muscles which are known to be weak, and can therefore be rapidly variable. True “constant current” control could give very large changes in

sensation as this contact changes. For patient comfort we therefore chose to use a combination of the two, with constant current at very low impedance, and constant voltage at higher impedance.

The history of continence stimulation is closely related to that of Empi 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), for which FDA have granted us 510K substantial equivalence.

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.

Although there is no specific standard for PFES, we judged that compliance with: **BS EN 60601-2-10:2001 Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators** would satisfy the risk requirements and that clinical trials were not required to establish safety.

TensCare undertook BioCompatibility Testing in accordance with ISO10993-5:2009 and ISO10993-10:2002.

5. Clinical Evidence

5.1 Search Strategy:

Because the technology is well established and the itouch Sure introduces no significant differences in technical design or clinical methodology, a search of existing published clinical data was judged to be sufficient.

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

Cochrane Reviews, NICE Guidelines, Insurance Coverage Policy Reviews, and professional guidelines.

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

5.2 Search Terms:

Continence, Stimulation, “urge incontinence”, urinary incontinence, urge, “detrusor instability”, “detrusor overactivity”, “humans”, English, “Electric Stimulation Therapy”, controlled clinical trial, Electrical stimulation, faecal incontinence, Prostatectomy, Randomized Controlled Trials.

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

5.3 Exclusions:

For Stress, only studies using vaginal or anal electrodes with electrical stimulation of a similar type to that of the itouch Sure 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.

6. Data analysis

6.1 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.

Using the theory of action in 6.2.1 and 6.2.2 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 the stimulation parameters used in the itouch Sure.

6.2.1 Overview of stimulation parameters for SI

It has been shown (Eccles et 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 μ s 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 (μ s) 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

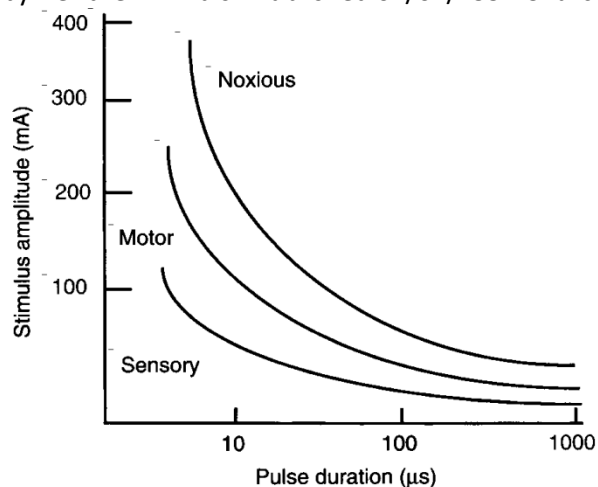


Figure 3.4 Strength-duration curves for sensory, motor and noxious responses. Any stimulus which has a combination of pulse amplitude and pulse duration which falls to the left of a specified curve is regarded as subthreshold and will not initiate an action potential. A stimulus which has a combination of pulse amplitude and pulse duration which falls to the right of a specified curve is regarded as suprathreshold and will initiate an action potential to produce the particular response specific to the type of nerve, i.e. motor, sensory.

6.2.2 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 et al, 1977). It can therefore be most appropriate to give stimulation at a frequency of 10Hz with a pulse width of 200-500 μ s.”

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.

6.3 PFES in STRESS incontinence

6.3.1 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. Another study by 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 0.1msecond = 100 µsecond, this is a little small for motor nerve recruitment (see diagram above). Laboratory testing has shown that pulse widths of > 200 µs 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)

Review 2 considered that studies 268–273 [EL = 1+] (Sand et al 1995, Yamanishi et al 2000, Luber & Wolde-Tsadik 1999, Jeyaseeln et al 2000, Brubaker et al 1997, Barroso et al 2004) were of good quality.

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.

STRESS: PFES Vs PME or other non-surgical alternatives

Review 1 identified 5 RCT of which three were considered too small for results to be statistically significant, including Smith 1996 (Ref 4.108).

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 μ s, 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 .

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.

4weeks 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 the 2000 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 300µs, 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 (50Hz and 20Hz, 300us, asymmetrical biphasic, 5/10) are effective.

Another newer study (Castro 2008) also confirmed that the Stress setting for the itouch Sure (50 Hz, 300us, 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, 500µs, 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

Amaro et al (2005) looked at the effect of intravaginal electrical stimulation on pelvic floor muscle strength. TREATMENT: Dualpex Uro 996. Frequency at 4 Hz, a 2- to 4-s work-rest cycle and a 0.1 μ s 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 μ s. 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.

Onwude (2008) BMJ Clinical Evidence 2008 reviewed non surgical treatments for UI looking specifically at PFES. CONCLUSION:*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).*

6.3.2 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 μ seconds, maximum tolerance intensity, is of benefit in the treatment of Stress Urinary Incontinence.

4Hz and 20Hz appear to be ineffective.

50Hz, 2000 μ seconds appears to be ineffective.

6.4 PFES in URGE incontinence

6.4.1 Review of RCTs for STRESS 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 salutary 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 200µs 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. 281 [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

Review 3 identified one additional English language RCT: Ref 3.123 Goode (2003)

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.

6.4.2 Conclusion PFES for URGE 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. Maximum tolerance intensity is ineffective.

6.5.1 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.

6.5.2 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. Intensity 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

6.5.3 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 in the women with obstetric trauma.

6.6 Electrical Stimulation for Postprostatectomy Stress Incontinence

6.6.1 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 than PME alone.

Moore, 1999 (Ref 8.3) Trial of standard PME, intense PME, intense PME +PFES.

TREATMENT: 50 Hz Biphasic.1sec 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 μ s 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 μ s, 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.

6.6.2 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.

6.7 ADVERSE EVENTS:

6.7.1 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

Osterberg 2004. One woman who underwent pelvic floor stimulation experienced a burning sensation in the vagina 2 weeks after treatment.

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

6.7.2 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.

6.8.1 Program Parameter Comparison

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

6.8.2 Program Parameter Comparison

The EMPI Innova was used in several successful trials.
Programme settings compare as follows:

Itouch Sure					EMPI Innova				
Prog	Hz	µS	Work sec	Rest Sec	Prog	Hz	µS	Work	Rest
1	50	300	5	10		50	300	5	5
2	10	200	5	10		50	300	5	10
3	20	250	5	10		12.5	300	5	5
4	35	250	3	6		12.5	300	5	10

6.8.2 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. The itouch Sure uses this duty cycle since it is less likely to cause discomfort due to fatigued muscles and it complies with 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.

There is no grounds for believing that the new device introduces additional risk or compromises effectiveness

Frequency

The itouch Sure Stress setting 50Hz is the same as that the majority of the successful RCTs and complies with UK professional guidelines

The itouch Sure Urge setting of 10Hz is very similar to the EMPI and is close to that used in two successful RCTs (1.2, 4.108)

The itouch Sure Mixed setting of 20Hz is uses a frequency which has been used n successful RCTs (R5, 1.4, 2.273)

The itouch Tone setting 35Hz uses a frequency which has been used in one successful RCT (5.43)

There are no grounds for believing that the new device introduces additional risk or compromises effectiveness

Pulse Width

The itouch Sure Stress setting of 300µs is the same as that of the Empi Innova and complies with UK professional guidelines.

There are no grounds for believing that the new device introduces additional risk or compromises effectiveness

Output current intensity

Generally speaking, the impedance load of vaginal mucosa is very complicated, it depends on the moisture, force applied to the probe, etc. Different people may be of quite different impedance. In considering the design of a continence stimulator, we should allow for a large range of load impedance. Therefore it would be a good solution that with a low load the device is of constant current output to prevent production of a high current which may lead to local skin irritation; with high load the device is switched to constant voltage output to prevent production of high voltage which may lead to electrical shock. This solution is much better than those devices with only constant current or only constant voltage.

(Max voltage at $2k\Omega$ is 58V compared with 128V for the Empi Innova)

Bench and invivo testing have illustrated the good performance of itouch Sure over this range.

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.

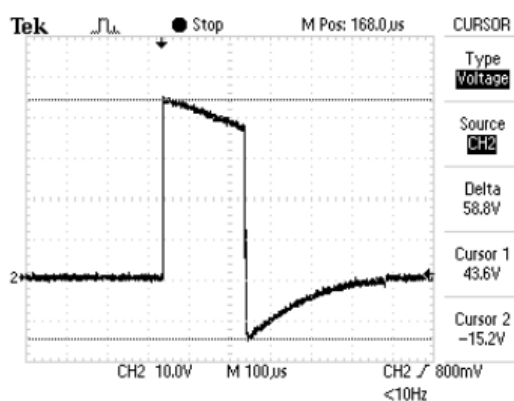
There are no grounds for believing that the new device introduces additional risk or compromises effectiveness

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.

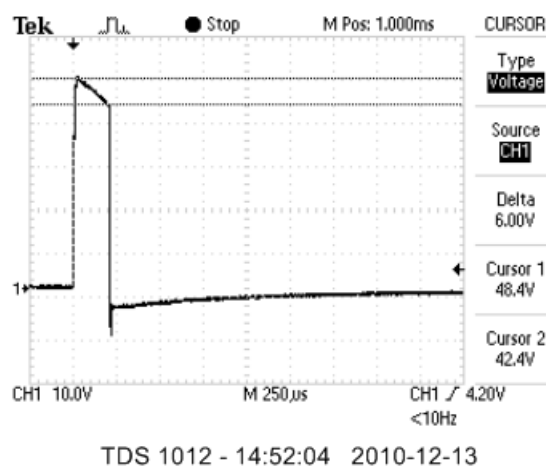
One trial used Neurotrac, which has a very similar waveform and current control to the Sure.
Several used EMPI, which also has a similar waveform.

Others used symmetrical square waveform.

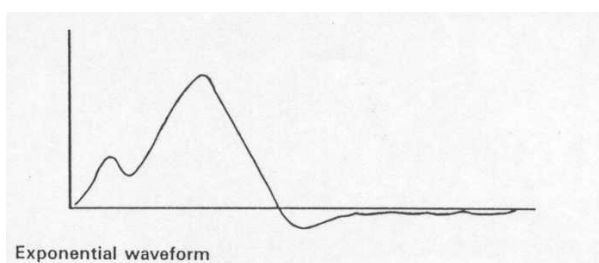


Sure

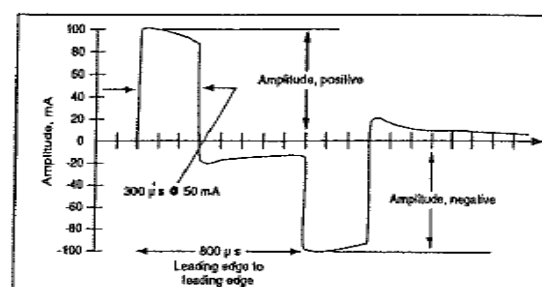
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Neurotrac (R2)



Neurotech (5.43)



EMPI Innova (1.1, 4.108)

The itouch Sure waveform is similar to that used in successful RCTs.
There are no grounds for believing that the new device introduces additional risk or compromises effectiveness

6.9 Safety

Continence stimulators have been in use for 40 years without any report of significant hazards to patients. See 6.7 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.

7. Conclusions

The risks identified in the risk management documentation were addressed by reference to existing standards. The clinical data has revealed no additional risks.

The relevant Essential Requirements are as follows:

	GENERAL REQUIREMENTS	Comply?
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: <ul style="list-style-type: none"> • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted. 	Yes
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Yes
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Yes
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.	Yes
12.6	<i>Protection against electrical risks</i> Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.	Yes
12.7 12.7.1	<i>Protection against mechanical and thermal risks</i> Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	Yes

The prime objective of this review is to answer Item 6 : Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.

The Clinical Data has revealed no information to suggest that the itouch Sure presents any additional risk, or any less performance than those products already on the market.



Andrew Brown
Regulatory Affairs Manager
10/10/2011

June Rogers

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5. Summary of the clinical data						
REVIEW PAPERS - Urinary Incontinence						
Ref	Review Paper	Author	Date	Type	Parameters	Summary
1	Medicare Coverage Policy Decision: Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (#CAG-00021)		Oct 2000	Insurance coverage enquiry		<p><i>Summary</i></p> <p>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.¹⁸ 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.</p> <p>The assessment made the following conclusions:</p> <ol style="list-style-type: none"> 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. <p>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.⁷ 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.</p> <p>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</p>

				<p>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.</p> <p>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</p> <table><tr><th><input type="checkbox"/>Study</th><th>PFES</th><th>Sham PFES</th></tr><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></table> <p>*statistically significant</p>	<input type="checkbox"/> Study	PFES	Sham PFES	Sand 1995	42%*	26%	Luber 1997	14%	11%	Laycock 1993	No difference	No difference	Brubaker 1997	NR	NR	Yamanishi 1997	33%*	0%
<input type="checkbox"/> Study	PFES	Sham PFES																				
Sand 1995	42%*	26%																				
Luber 1997	14%	11%																				
Laycock 1993	No difference	No difference																				
Brubaker 1997	NR	NR																				
Yamanishi 1997	33%*	0%																				

2	NICE CG40 Management of Urinary Incontinence in Women Para 4.2.4 + 4.2.7		Oct 2006	NICE Guideline	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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)</p>
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					<p>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)</p> <p>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)</p> <p>Adverse Effects</p> <p>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.</p>
3	Urinary Incontinence in Adults: Clinical Practice Guideline Update	Agency for Health Care Policy and Research (AHCPR)	2007		<p>Treatment Recommendations</p> <p>Pelvic Muscle Rehabilitation—to improve pelvic muscle tone and prevent leakage.</p> <ul style="list-style-type: none"> • Pelvic floor electrical stimulation. Mild electrical pulses stimulate muscle contractions. Should be performed in conjunction with Kegel exercises.

4	Systematic Review: Randomized, Controlled Trials of Nonsurgical Treatments for Urinary Incontinence in Women.	<p><i>Tatyana Shamilyan</i></p> <p><i>Annals of Internal Medicine</i> Vol 148, Number 6, 459</p>	March 2008	Review of RCTs	<p>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.</p> <p>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.</p> <p>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 stimulation compared with Kegel exercises (108), biofeedback-assisted training (79), or placebo (109 –112).</p> <p>The effectiveness of stimulation to improve urinary incontinence depended on the type of urinary incontinence and administered 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.</p>
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	Stress Incontinence					
Ref	Review Paper	Author	Date	Type	Parameters	Summary
5	<i>BMJ Clinical Evidence</i> <i>Women's health</i> Stress incontinence Non-surgical treatments Pelvic floor electrical stimulation	Joseph L Onwude	June 2008	Review of RCTs	<p>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).</p> <p>Compared with vaginal cones Pelvic floor electrical stimulation and vaginal cones seem equally effective at preventing episodes of incontinence in women (moderate-quality evidence).</p> <p>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).</p> <p>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).</p> <p>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).</p> <p>Adverse effects Pelvic floor electrical stimulation is associated with tenderness and vaginal bleeding.</p>	

New RCT s on Stress not included in June 2008 review papers						
<i>Ref</i>	<i>Review Paper</i>	<i>Author</i>	<i>Date</i>	<i>Type</i>	<i>Parameters</i>	<i>Result</i>
R1	Single blind RCT of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence.	Rodrigo Castro. <i>Clinics</i> 2008:63:46 5-72	2008	RCT	Double ring electrode. 50Hz, 5/10s cycle, 500uS. Up to 100mA. 20 mins.	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 <i>a</i> week. Supervised

New RCT s for Urge Incontinence not included in 2008 Review papers					
Ref	Review Paper	Author	Date	Type	Parameters
R2	Clinical Efficacy of pelvic floor stim for idiopathic detrusor instability.	Huifan Liu. Life Science Journal Vol6 No2, 2009	2009	Clinical study. Skin surface electrode s	<p>N=70</p> <p><i>Results.</i> 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. 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 ($P > 0.05$).</p> <p><i>Conclusions:</i> 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 electromyogram 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</p>

R3	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 <u>12</u>	Dec 2010	RCT	<p>Results 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).</p> <p>Conclusions Both treatments reduced the number of micturitions, but electrical stimulation was not found to be superior to tolterodine</p> <p>Protocol: Ten electrical stimulation treatments vaginally and transanally over a period of 5–7 weeks</p>
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Faecal Incontinence					
<i>Ref</i>	<i>Review Paper</i>	<i>Author</i>	<i>Date</i>	<i>Type</i>	<i>Parameters</i>
Review 10	The management of faecal incontinence in adults. NICE Guideline CG49		2007	Anal probe. Frequencies capable of producing a tetanic muscle contraction, with appropriate duty cycle. Treatment time 5-30 mins. No generally agreed protocols	<p>The evidence was inconclusive in this area. People who continue to have episodes of faecal ..Incontinence after initial management should be considered for specialised management. This may involve referral to a specialist continence service, which may include ...electrical stimulation.</p> <p>We do not have specific evidence of the cost-effectiveness of these services. However, we know interventions, such as pelvic floor muscle training are safer and cheaper than surgery and therefore we believe they are likely to be cost-effective compared with immediate referral for surgery. On the other hand, they are likely to be more costly than initial management and therefore are only likely to be cost-effective in patients for whom initial management has not been fully effective.</p>
6	Cochrane Review. Electrical stimulation for faecal incontinence in adults		2009 (Updated May 2007)	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.	

7	Management of Fecal Incontinence in Adults	C. Norton,1* W.E. Whitehead, 2 D.Z. Bliss,3 D. Harari,4 and J. Lang	<u>Neuro</u> <u>urolog</u> <u>y and</u> <u>Urody</u> <u>namics</u> <u>Volum</u> <u>e 29,</u> <u>Issue</u> <u>1,</u> 2010	<p>EXTERNAL ELECTRICAL STIMULATION FOR FI</p> <p>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.</p> <p>30. Hosker G, Norton C, Brazzelli M. Electrical stimulation for faecal incontinence in adults Cochrane Database Syst Rev 2002;2. Superceded by Rev 6</p>
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PostProstatectomy Incontinence – REVIEW PAPERS						
Ref	Review Paper	Author	Date	Type	Parameters	Ref
8	Cochrane Review: Conservative management for postprostatectomy urinary incontinence		2009			<p>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.</p> <p>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)</p> <p>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.</p>

	PostProstatectomy Incontinence- New RCT s after 2009					
R4	Randomized, Placebo Controlled Study of Electrical Stimulation With Pelvic Floor Muscle Training for Severe Urinary Incontinence After Radical Prostatectomy.	Yamanishi. The Journal of Urology Volume 184, Issue 5, November 2010, Pages 2007-2012	2010	RCT	50 Hz square wave 15 mins Twice daily Anal electrode	<p>CONCLUSIONS</p> <p>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.</p> <p>Results: 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.</p> <p>Electrical stimulation resulted in earlier recovery of continence in patients with urinary incontinence after radical prostatectomy.</p> <p>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 μs pulse duration and a maximum output of 70 mA (5 seconds on, 5 seconds off duty cycle) were used for active stimulation.</p>

R5	Behavioral Therapy With or Without Biofeedback and Pelvic Floor Electrical Stimulation for Persistent Postprostatectomy Incontinence A Randomized Controlled Trial	Goode JAMA. 2011;305(2):151-159.	2011	RCT	Daily home pelvic floor electrical stimulation at 20 Hz , current up to 100 mA (behavior plus)	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.
R6	Pelvic floor muscle training for stress urinary incontinence: A randomized, controlled trial comparing different conservative therapies	Markus Huebner, Katja Riegel, et al Physiotherapy Research International September 2011 Volume 16, Issue 3 Pages 125–186	2010	RCT		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.

	ADVERSE EFFECTS			
Re v 2	NICE CG40 Management of Urinary Incontinence in Women Para 4.2.4			Adverse effects 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.
	BMJ CI			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
	Are women at risk if they purchase neuromuscular stimulation kits to treat urinary incontinence without professional assessment and advice?	Continence UK June 2009 Vol 3 Issue 2 Clinical continence Supervision Group		Risks of harm. 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 effects with transrectal stimulation are abdominal cramps, diarrhoea, pain and canal bleeding and vaginal irritation, and with vaginal stimulation, pain and bleeding.

Clinical Guidelines				
Re v9	Clinical guidelines for the physiotherapy management of females aged 16–65 years with stress urinary incontinence	CSP May 2003		<p>CSP Guidelines 3.6.3 Recommendations:</p> <ul style="list-style-type: none"> • 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: <p>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.</p>

REFERENCE PAPERS – USING REFERENCING CODES OF THE ORIGINAL REVIEW PAPERS

Rev 1	Rev 2	Rev 3	Rev 4	Rev 5	Rev 6				
	264					Wang AC, Wang YY, Chen MC.	Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder.	Urology. 2004 Jan;63(1):61-6.	<p>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-micros 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.</p> <p>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 ($P = 0.567$).</p> <p>CONCLUSIONS: ES had the greatest subjective reduction rate of OAB and was</p>

									the most effective of the three treatments. BAPFMT was more effective than PFMT.
1	268		84	58		Sand PK, Richardson DA. Staskin DR. et al.	Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: A multicentre, placebo-controlled trial.	<i>American Journal of Obstetrics and Gynecology</i> 1995;173(1):72-9	<p>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.</p> <p>CONCLUSIONS: Transvaginal pelvic floor electrical stimulation was found to be a safe and effective .therapy for genuine stress incontinence.</p> <p>Treatment Protocol: EMPI Innova 50Hz and 12.5 Hz. 300uS. Highest tolerable. 5/10 for 15 mins progressing to 30 mins.</p>

269			21		Yamanishi T. Yasuda K. Sakakibara R, et al.	Randomized, double blind study of electrical stimulation for urinary incontinence due to detrusor overactivity.	Urology 2000;55(3):353-7	<p>Objectives. To evaluate the usefulness of electrical stimulation for urinary incontinence due to detrusor overactivity in a randomized, double-blind manner.</p> <p>Methods. Sixty-eight patients (29 men, 39 women, 70.0 \pm 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.</p> <p>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.</p> <p>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.</p> <p>Conclusions. Electrical stimulation was useful in treating urinary incontinence due to detrusor overactivity.</p>
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2						Yamanishi T, Yasuda et al	Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigational study and a placebo controlled double-blind	J Urol 1997 Dec;158(6):2127-31 <thai) <i="">Urol, 158:2127-2131.</thai)>	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.
3	270					Luber KM and Wolde-Tsadik G.	<i>Efficacy of functional electrical stimulation in treating genuine stress incrtinence: a reandomized clinical trial.</i>	<i>Neurology and Urodynamics 1997;16(6):543-51</i>	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.
	271					Jeyaseeln SM, Haslam EJ, Winstanley J et al.	<i>An evaluation of a new patterne of electrical stimulation as a treatment for urinary stress incontinence: a randomized, double</i>	<i>Clinical Rehabilitation 2000; 1 4(6):631-40</i>	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

							<i>blind, controlled trial.</i>		is as described by Oldham (International Patent Publication WO98/47357).21cepted 3rd August 2000. All patients were required to use the stimulator for an hour a day for eight weeks (except when menstruating). INTENSITY NOT DISCUSSED There was no significant difference between groups when quality of life was measured with the IIQ, however with the UDI a significant between-group difference was highlighted.																												
4	272			20		<i>Brubaker L . Benson JT, Bent A et al.</i>	<i>Transvaginal electrical stimulation for female urinary incontinence.</i>	<i>American Journal of Obstetrics and Gynecology 1997;177(3):536-40</i>	<p>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.</p> <p>Table V. Additional outcome variables</p> <table><tr><th><i>Outcome variable</i></th><th><i>Sham</i></th><th><i>stimulation</i></th><th><i>Significance (sham vs electric stimulation)</i></th></tr><tr><td></td><td></td><td></td><td><i>Mann-Whitney test</i></td></tr><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></tr><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></tr><tr><td>Adequate subjective improvement</td><td>17%</td><td>35%</td><td>0.027</td></tr><tr><td>8 wk compliance (%)</td><td>83.7 + 14.7</td><td>78.8 -+ 20.5</td><td>0.25,</td></tr><tr><td>Final urodynamic diagnosis of detrusor overactivity</td><td>41%</td><td>27%</td><td>0.22,</td></tr></table>	<i>Outcome variable</i>	<i>Sham</i>	<i>stimulation</i>	<i>Significance (sham vs electric stimulation)</i>				<i>Mann-Whitney test</i>	6 wk 24 hr frequency (average)	9.5 -+ 2.8	9.3 -+ 6.8	0.049	6 wk No. of accidents/24 hr (average)	2.2 + 2.7	2.4 _+ 3.1	0.75	Adequate subjective improvement	17%	35%	0.027	8 wk compliance (%)	83.7 + 14.7	78.8 -+ 20.5	0.25,	Final urodynamic diagnosis of detrusor overactivity	41%	27%	0.22,
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	273					<p><i>Barroso JC, Ramos JG, Martins-Costa S, et al.</i></p> <p><i>Transvaginal electrical stimulation in the treatment of urinary incontinence</i></p>	<p><i>BJU International</i> 2004;93(3):319-23</p>	<p>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 ($P < 0.001$). 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).</p> <p>RESULTS</p> <p>Patients using TES, despite more severe disease than in the control group, after treatment had a significantly greater reduction in loss of urine ($P < 0.001$). There was also a significant increase in the cystometric capacity, evaluated by urodynamic study, in patients who used TES ($P < 0.02$).</p> <p>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</p>
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	274				Amaro JL, Gameiro MO, Padovani CR.	Effect of intravaginal electrical stimulation on pelvic floor muscle strength	International Urogynecology Journal 2005;16(5):35-8	<p>Electric parameters were frequency at 4 Hz, a 2- to 4-s work-rest cycle and a 0.1-s 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 using a Dualpex Uro 996 at 4 Hz.bipolar symmetrical</p> <p>Urge incontinence, present in all patients before treatment, was reduced to 15% in G1 and 31.5% in G2 post-treatment. There was a significant improvement in PFM strength from both effective and sham electrostimulation, questioning the effectiveness of electrostimulation as a monotherapy in treating MUI.</p>
	275				Berghmans B, Van Waalwijk vD, Nieman F, et al.	Efficacy of physical therapeutic modalities in women with proven bladder overactivity.	European Urology 2002;41(6):581–7.	<p>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.</p> <p>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.</p> <p>RESULTS: Combined centre and home-based FES seems to be an effective treatment modality for the treatment of women with proven bladder instability.</p>
		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	JAMA 2003;290(3):345–52.	<p>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).</p>

						controlled trial.		<p>Pelvic Floor Electrical Stimulation.</p> <p>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.²⁵⁻²⁹ 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.</p> <p>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.</p>
				19	Berghmans LCM, Hendriks HJM, Bo K, et al.	Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials.	<i>Br J Urol</i> 1998;82:181– arch 191. Sedate 1998	<p>The trials by Sand et al. [58] and Blowman et al. [43] were of sufficient methodological quality, with a MQS of 7.5 and 6.5, respectively, and the remaining four trials were of low quality. Two of the trials [43,56] included PFM exercises with both active and sham stimulation groups, so these trials were considered to be a comparison of active and sham stimulation. Of the six trials, all but [56] and [65] report electrical stimulation to be more effective than sham stimulation. Combined results imply strong evidence for the efficacy of electrical stimulation vs sham electrical stimulation (level 1).</p>
6	282			43	Blowman C, Pickles C, Emery S et al.	Prospective double blind controlled trial of intensive physiotherapy with and without stimulation of the pelvic floor in treatment of	Physiotherapy 1991; 10: 661–4	<p>Neurotech NME Stimulator</p> <p>Asymmetrical bi-phasic waveform.</p> <p>Pulse width of 80 uS voltage 120V.</p> <p>Treatment protocol</p> <p>28 days at 10Hz 4/4 80uS 60 mins per day. Intensity just</p>

							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:		
										Active n=7	Inactive n=6
									<i>At end of study</i> Require further treatment of surgery	0	4
									<i>Six months after completion of study</i> No change since end of study		
									Deteriorated	4	
									No reply	2	3
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5			80			Bø K, Talseth T, Holme I.	Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women.	BMJ. 1999;318:487-93. [PMID: 10024253]	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		

								<p>Product specification 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.</p> <p>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 (11.1to 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.</p> <p>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.</p>
6	277		108			Smith JJ 3rd.	Intravaginal stimulation randomized trial.	<p>J Urol. 1996;155: 127-30. [PMID: 7490809]</p> <p>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.</p> <p>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.</p>

									<p>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.</p> <p>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.</p> <p>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.</p> <p>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 μs. Cycle on time-5 seconds Cycle off time-5 or 10 seconds Ramp u p 2 seconds Ramp down-1 second</p>
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	279		114			Spruijt J, Vierhout M, Verstraeten R, Janssens J, Burger C.	Vaginal electrical stimulation of the pelvic floor: a randomized feasibility study in urinary incontinent elderly women.	Acta Obstet Gynecol Scand. 2003;82:1043-8.[PMID: 14616279]	<p>Pelvic floor ES was accomplished by means of the Urogyn 8900 ES system (Incare Medical Products)</p> <p>The stimulator generated biphasic current pulses with a duration of 1ms and a frequency of 50 Hz in the case of (predominant) stress urinary incontinence or 20 Hz in the case of (predominant) urge urinary incontinence. (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). After the plug electrode was inserted into the vagina, the patients were treated with a 2-s contraction time and a duty cycle of 1–2 s, with stimulation intensity gradually increasing up to the level of tolerable discomfort (0–100 mA). Maximal ES was applied for 30 min (with a 5-min rest period after 15 min of treatment) three times a week (Monday, Wednesday, and Friday) for 8 weeks; a total of 24 sessions.</p> <p>Results. No significant improvement in objective outcome variables was observed in the population treated with ES compared with the population treated with KE (with 29.2% vs. 36.4% of the women showing objective improvement in measured urinary leakage). Neither was subjective improvement significant, with 29.2% vs. 27.3% of the women reporting improvement in the amount of urinary leakage.</p>
	285					Hasan ST, RobsonWA, Pridie AK, <i>et al.</i>	Transcutaneous electrical nerve stimulation and temporary S3 neuromodulation in idiopathic detrusor instability	<i>Journal of Urology</i> 1996;155(6):2005–11.	..
					1	Mahony RT, Malone PA, Nalty J, Behan M, O'Connell PR, O'Herlihy C	Randomized clinical trial of intra-anal electromyographic biofeedback	<i>American Journal of Obstetrics & Gynecology</i> 2004;191(3):885–	<p>Results</p> <p>Fifty-four women completed the treatment; 52 women (96%) had ultrasonic evidence of an external anal sphincter defect. After the treatment, both groups demonstrated significant</p>

						physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence.	90. [: 19215]	<p>improvement in continence score ($P < .001$) and in squeeze anal pressures ($P < .04$). Resting anal pressures did not alter significantly. Quality of life improved after the completion of physiotherapy, but there were no differences in outcome between intra-anal electromyographic biofeedback and electrical stimulation of the anal sphincter.</p> <p>Conclusion Intra-anal electromyographic biofeedback therapy was associated with improved continence and quality of life in women with altered fecal continence after delivery. The addition of electrical stimulation of the anal sphincter did not enhance symptomatic outcome. Key words: Intra-anal electromyographic biofeedback therapy; Fecal incontinence; Postpartum</p>
				2	Norton C, Gibbs A, Kamm MA	Randomized, controlled trial of anal electrical stimulation for fecal incontinence.	<i>Diseases of the Colon & Rectum</i> 2006; 49 (2):190–6. [: 21601]	<p>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.</p> <p>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 ($P = 0.001$).</p>

									<p>Conclusions</p> <p>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 <i>per se</i>. Home electric stimulation is a relatively cheap and generally well-tolerated therapy in the conservative treatment of fecal incontinence.</p> <p>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.</p>
					3	Osterberg A, Edebol Eeg-Olofsson K, Hallden M, Graf W.	Randomized clinical trial comparing conservative and surgical treatment of neurogenic faecal incontinence.	<i>British Journal of Surgery</i> 2004; 91 (9):1131–7. [: 19250]	<p>Background:</p> <p>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.</p> <p>Methods:</p>

									<p>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.</p> <p>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.</p> <p>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 weeks¹⁰. All patients were treated by the same therapist. One woman who underwent</p>
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									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 randomised controlled trial comparing pelvic muscle exercises with pelvic muscle exercises plus electrical stimulation.	<i>British Journal of Urology International</i> 1999; 83 :57–65.	<p>N=63</p> <p>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.</p> <p>ES+PME no different to PME alone.</p>

	Other references – Clinical reports and reviews of technology						
X1	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.		
X2	Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigational study and a placebo controlled double-blind trial.	Yamanishi T, Yasuda K, Sakakibara R, Hattori T, Ito H, Murakami	S. J Urol. 1997 Dec;158(6):2 127-31.	1997		50 Hz. square waves of 1 ms. pulse duration for stimulation .	Urethral pressure profile before, during and after 15-minute stimulation. 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 ,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 randomized	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 Stimulatation 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 randomized.	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 Medicine 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.
X9	Treating UI using biofeedback and neuromuscular stimulation	Haslam , Jeanette	Journal of Community Nursing Feb 1998 Volume 12:issue2	1998	Review and Discussion		

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 2** NICE Guideline CG40 The management of urinary incontinence in women October 2006.
- Review 3** **Imamura M, Abrams P, Bain C et al. (2010)** Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technology Assessment* 2010; Vol. 14: No. 40
- Review 4** **Shamliyan T A, Kane R L, Wyman J and Wilt T J. (2008).** Systematic Review: Randomized, Controlled Trials of Nonsurgical Treatments for Urinary Incontinence in Women. *Ann Intern Med.* 2008;148:459-473.
- Review 5** **Onwude J L. (2009).** Stress incontinence, Non-surgical treatments, Pelvic floor electrical stimulation. BMJ Clinical Evidence 14 Apr 2009 (based on June 2008 search)
- Review 6** **Hosker G, Cody J D, Norton C C.(2009)** Electrical stimulation for faecal incontinence in adults. Cochrane Collaboration. Review content assessed as up-to-date: 17 May 2007.
- Review 7** **Norton C, Whitehead W E, Bliss D Z,3 Harari D, and Lang J. (2010).** Management of Fecal Incontinence in Adults. . *Neurourology and Urodynamics* 29:199–206 (2010)
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- Review 9** **Laycock J, Standley A, Crothers E, Naylor D, Frank M, Garside S, Kiely E, Knight S, Pearson A. (2001).** *Clinical Guidelines for the Physiotherapy Management of Females aged 16–65 with Stress Urinary Incontinence.* Chartered Society of Physiotherapy, London. Review date: 2004
- Review 10** NICE Guideline CG49 The management of faecal incontinence in adults. 2007

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