

Clinical Evaluation Report

Dr Ho's Muscle Therapy Unit (Modulated TENS device)

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Summary

The use of modulated TENS, and in particular the use of Dr Ho's MTU appears to be an effective pain relief therapy. Thus, the clinical evidence demonstrates conformity with relevant Essential Principles. No known reports of adverse effects or other safety concerns emerged in the process of generating this document. Thus, the performance and safety of the device as claimed have been established. Finally given no evidence of risk other than the possibility of skin irritation, the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

1.0 General overview

This evaluation report was organized according to the suggestions outlined in the GHTF document entitled "Clinical Evaluation". The authors are Professor Stuart McGill, and Jordan Cannon, both in the department of Kinesiology at the University of Waterloo, Canada. Professor McGill has performed several investigative studies on Dr Ho's Muscle Therapy Unit (referred to as the MTU for the remainder of this document) which is the subject of this evaluation. He has published approximately 200 peer reviewed articles on back pain and back function, injury mechanisms and performance enhancement. His edited CV is contained in Appendix A. Jordan Cannon is a research assistant and conducted the literature search.

1.1 General details

The proprietary name of the device is 'DR-HO'S™ Muscle Therapy' but during development and throughout clinical studies can also be found to be referred to as: DR-HO'S™ Muscle Massage Therapy; DR-HO'S™ Massage Therapy; DR-HO'S™ Dual Muscle Therapy; DR-HO'S™ Pain Therapy.

The manufacturer of the device is VGH Solutions Inc. of Markham, Ontario, Canada. The device is listed in SGS report number CN/CAN 12171.

2.0 Description of the device and its intended application

2.1 Overview

The device is categorized as a modulated TENS (Transcutaneous Electrical Nerve Stimulation) unit. In simple terms it is a signal generator that applies the waveforms to the skin overlaying muscle and nerve via conductive electrode pads. Traditional TENS outputs a signal that is constant in waveform shape, voltage and frequency. Modulated TENS is different in that the signal voltage and frequency continually changes over a treatment session.

A brief description of the muscle contraction process is necessary. Muscles are comprised of subunits (motor units) that are triggered by nerve impulses to contract and create force. As a muscle receives more stimulating nerve pulses, more of the motor units are recruited to contract. There is a specific order to this recruitment as the trigger level to contract depends on the characteristics of a particular motor unit. The theory is that traditional TENS will preferentially stimulate those motor units whose trigger level most closely matches the constant signal frequency and magnitude. On the other hand, modulated TENS sends a signal with a variety of frequencies and magnitudes thus stimulating a greater portion of the muscle motor units, if not the entire muscle. The therapeutic effects are discussed later in this document.

Stimulation of nerve via TENS is thought to provide an analgesic effect. More detail of this process is provided later.

2.2 Actual Device

The enclosure and main body of the device is white plastic, secured by one screw and nine plastic snap-on clips (see figure 1). There are no openings except to the battery compartment. The overall dimensions of the device are 77x110x20mm (WxHxD), and its weight is approximately 85g. The device is internally powered by two AAA, 1.5Vdc alkaline batteries with an available power of less than 15W. In our experience the batteries last years even with daily personal use. It is a handheld device with which either two or four detachable conductive electrode pads are placed on the skin at strategic locations. The smaller pads are 45x45mm and the larger ones are 120x80mm. The device contains no medicinal substances, bodily substances, liquids, drugs or chemicals of any kind. The working waveform is a multiple therapeutic pulse wave. The frequency range is 1.0 – 250 Hz variable. Output voltage is (+) (-) 130 V DC. It consumes approximately 200mw. All conductors and connectors are mounted and secured to the printed circuit board (PCB); the PCB is flame rated UL 94 V-0, min 105°C. The main unit has an intensity/on/off dial, and two

buttons to select treatment mode and duration. The “Mode” button has three options defining the waveform shape, Mode A: variable intensity cycling mode, B: a low frequency mode (approximately 1 pulse per second), C: a pulse mode of 4 seconds of sustained pulses followed by 1 second off. These different patterns are what distinguish modulated TENS from traditional TENS which only outputs a single frequency and voltage waveform over a treatment session. The “Time” button selects the desired treatment length, 10, 20, or 40 minutes. The treatment time determines the length of time the signal is sent to the electrode pads. Thus the only contact with the body is via the electrodes on the skin and therefore a non-invasive therapy. With proper care and use, the pads can be used 70 to 100 times before needing to be replaced. With the exception of the conductive electrode pads; the circuits and live parts are enclosed and not intended to be removed, they can only be accessed with the aid of a tool. The device was shown to present no breakdowns, hazards or safety concerns when tested for leakage currents, electrical strength and mechanical strength by independent engineers (see appendix B). Anecdotally, the primary author of this report has been experimenting with these units for over 10 years and the original units from 10 years ago are still providing service – we have never had a unit failure.



Figure 1. The device with 4 gel electrodes

2.3 Description of the signal and theoretical mechanism of action

The unique quality this device that distinguishes it from other electrical therapies is that it can incorporate three signals (TENS, EMS <write this out> and pulse massaging therapies) in one unit. It does so by multiple modulations with varying pulse patterns, intensities and frequencies. As described above there are three modes (a medium, strong and gentle technique) in which the device can be set with each one attempting to replicate a different form of massage.

The TENS pulse is a characteristic biphasic waveform where the signal is produced by building various sequences of pulse trains. While the typical pulse characteristics of TENS are incorporated into the DR-HO'STM 4 Pad TENS signal patterns, we have concluded that the sequenced patterns incorporated into the DR-HO'STM 4 Pad TENS device form the next generation in evolution of TENS devices.

The signals generated by TENS devices vary by unit and manufacturer. Common characteristics include high frequency stimulation patterns of individual biphasic pulses where the positive phase of each pulse is typically a square-wave while the negative phase is a sawtooth-ramp waveform. The positive/negative phases may be asymmetric about zero voltage (to minimize DC effects to the skin and subcutaneous metabolites). The duration of the individual pulses typically range from 30 to 250 microseconds. Pulse rate typically varies from 3 to 1000 Hz. TENS units generally fall into one of three categories; traditional TENS, burst TENS, or modulated TENS. Burst TENS units output bursts of pulses – for example a repeating pattern of 8 pulses per burst with 12 bursts per second. Modulated TENS outputs variable burst patterns, and of variable intensity. In summary, there is no single burst pattern considered to be TENS exclusively, rather the pulse itself seems to characterize TENS.

The pulse signal generated by the DR-HO'STM 4 Pad TENS device matches the typical type of pulse signal generated by other TENS units with the difference being in the variety of signal pulse sequencing – specifically it outputs a unique type of modulated burst pattern (see figure 2). For example traditional TENS units typically output a singular pattern that does not change although the stimulating strength is adjusted for a patient by altering the peak to peak voltage, or the current intensity. In contrast, the DR-HO'STM 4 Pad TENS device outputs a pre-programmed sequence of stimulating pulse patterns that appears to be quite effective for the therapeutic claims made.

The signal begins by generating stimulating pulse sequences that slowly increase in peak to peak voltage over several seconds which then decrease in a ramp-like fashion providing a wave-like stimulation-contraction perceived by the patient. Other patterns follow that incorporate short duration but more intense bursts of TENS pulses to provide a perception of “chopping” such as what a masseuse would deliver to a patients back. The sequences typically conclude with the slower ramp increase/decrease of pulse trains as they diminish in signal intensity. This modulated pattern also addresses the issue of “adaptation”. If a similar stimulation pattern is maintained for a prolonged period, the patient/subject will notice a gradual diminution in response to the stimulus.

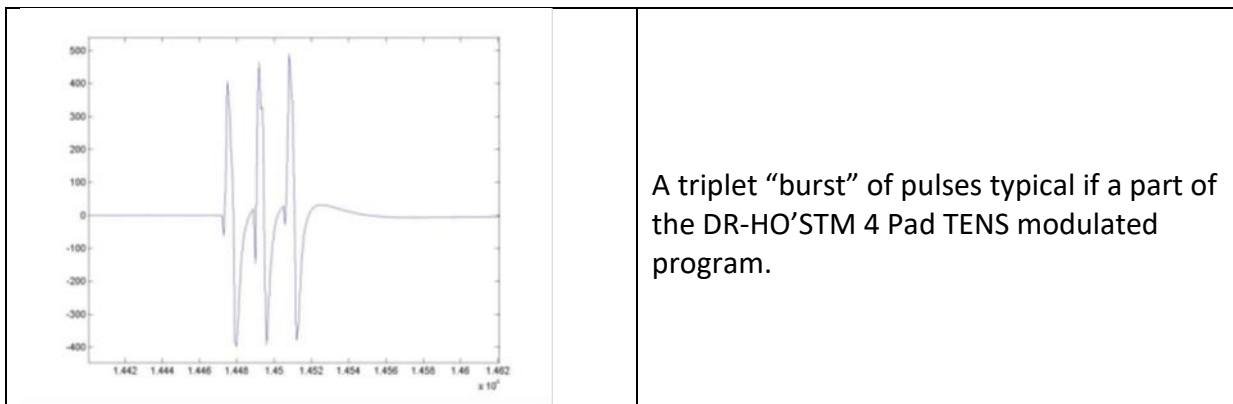
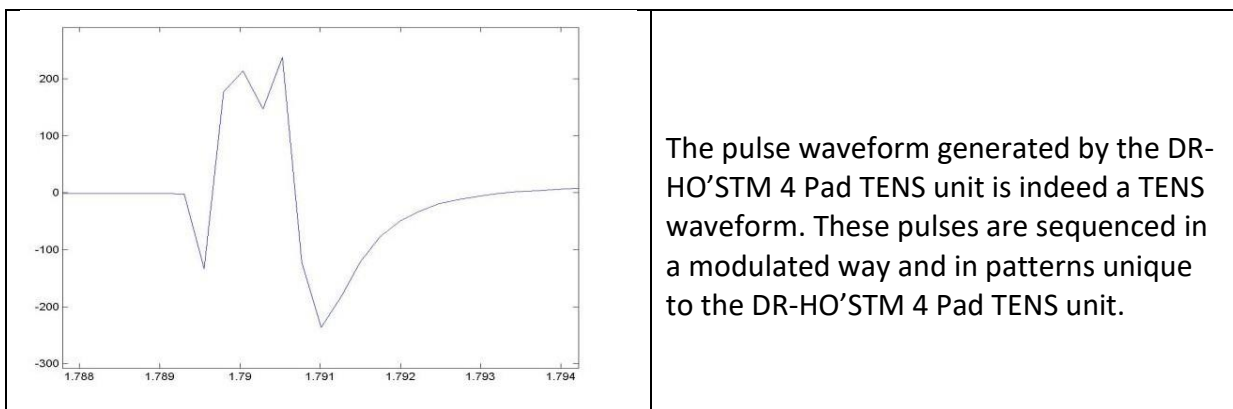
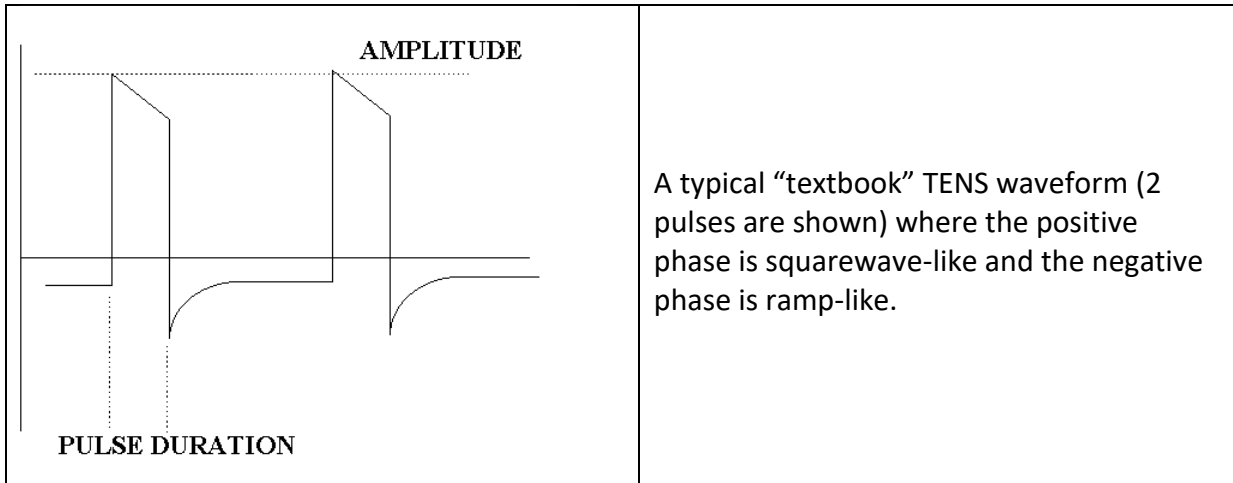
It is well known that there is an adaptation to the TENS signal. This can be reduced by interrupting or varying the signal amplitude and pulse frequency (e.g. Snyder-Mackler and

Robinson, 1989, *Clinical Electrophysiology: Electrotherapy and Electrophysiologic Testing*. Williams and Wilkins, Baltimore). In summary the major difference in the DR-HO'STM 4 Pad TENS signal and a typical modulated TENS pattern is in the way the program builds a stimulation treatment where the greatest intensity is contained in the middle of the program. Thus, one more layer of program sophistication is built-in.

Debate continues as to the mechanism of action of TENS which has focused on nerve physiology. Conventional TENS units have an intensity so low that only cutaneous sensory nerve fibers are stimulated. High intensity TENS produces high pulse amplitudes that activate skeletal muscle fibers. Current hypotheses are dominated by the notion that traditional TENS decreases the sensitivity of pain-sensing nerve fibers. This remains a low intensity-based hypothesis. As will be shown, our work shows that the sophisticated modulated patterns of the high intensity DR-HO'STM 4 Pad TENS stimulation device reduces muscle spasm and increases oxygenation suggesting that the pain-spasm cycle is reduced.

Further, the 'Gate Control Theory' is critical in how TENS manages to relieve pain perception. There are several proposed mechanisms as to how the aforementioned therapies achieve their intended purpose; these include but are not limited to the segmental, extrasegmental and peripheral mechanisms. The segmental mechanism is supported by evidence that shows TENS reduces ongoing nociceptive cell activity and sensitization in the CNS when applied to somatic receptive fields (essentially impeding the pain signal). This can cause depression of central nociceptive cell activity for up to 2 hours. The extrasegmental mechanism is based on the idea that TENS leads to activation of cell activity in certain areas of the midbrain and medulla and thus inhibiting descending pain facilitatory pathways. In this mechanism larger effects have been reported when muscle rather than skin afferents are used. The peripheral mechanism involves nerve impulses generated by TENS colliding and extinguishing noxiously induced pain signals from peripheral structures. This barrier of nociceptive impulses is seen mostly in high frequency and high intensity TENS.

Figure 2. Waveforms of traditional TENS and Dr Ho's modulated TENS



3.0 Intended therapeutic and/or diagnostic indications and claims

It is made clear in the owner's manual and instructions for use that the device is not designed to diagnose, treat or cure any disease. What it does claim is its ability to treat certain medical conditions. It states it can relieve acute, chronic and musculoskeletal pain. It claims to reduce muscle tension, as well as treat muscle cramps and pulls. The device is also said to be effective in treating headaches and sports related sprains and also in increasing range of motion (of the neck and back) and strength (of upper body and lower back). The device claims to be able to treat poor circulation and help with trouble relaxing and sleeping; it has also been shown to increase muscle oxygenation. The target treatment group is simply those who experience any of the medical conditions that Dr-Ho's system could help treat, manage or improve. The manufacturer claims the device is a safe, effective, easy to use treatment that is economical as it is self-administered and cost effective. The long-term effects of electrical stimulation are unknown, however as will be shown in the literature review, none have been reported.

3.1 Evidence of mechanism of action

A number of years ago, the principle author of this report conducted a study to investigate possible mechanisms of action. For background, we have investigated other devices together with therapeutic protocols such as Chiropractic manipulation and Osteopathic manual treatments. We found Dr Ho's muscle therapy (modulated TENS unit) to be about the most effective in pain relief and in breaking up and reducing local muscle spasm. We found that muscle spasm was reduced and that this was linked to increased muscle oxygenation in the muscle. This could have been due to the relaxation of the muscle reducing occlusion of the capillary bed increasing capillary blood flow and/or reduction of oxygen consumption from continually activated muscle. While the full report is reviewed later in this report, the abstract is as follows:

Published Research Report Abstract: Kavcic, N., Lehman, G., and McGill, S.M. (2005) Effect of Modulated TENS on muscle oxygenation, muscle spasm and pain: Searching for a physiological mechanism. J.M.S. Pain, 13(2): 19-30.

Objective: To assess claims of pain reduction from a novel TENS stimulation device using myoelectric and muscular oxygenation signals.

Design: Three cascading studies. One group, control trial, pretest-posttest.

Patients and Setting: Measures of muscle activity and self-perceived pain from 41 male and female subjects from an outpatient clinic. Measures of muscle oxygenation and pain levels from 12 different subjects.

Interventions: All subjects self-administered the novel muscle TENS stimulator.

Main Outcome Measures: Electromyography (EMG) measured muscle activity and Near-Infrared Spectroscopy (NIRS) measured muscle oxygenation. Pain reduction was assessed using a visual analogue scale of pain intensity (VAS).

Results: Myoelectric activation level (indicating spasm level) and pain scores of painful muscles were reduced after treatment ($p < 0.001$), but no change in activation or pain in the control muscles. The relative change in muscle oxygenation showed a significant difference between the control and treatment trials ($p = 0.013$), as did VAS pain scores ($p < .05$).

Conclusions: A treatment consisting of muscle stimulation with a novel device while relaxing in a lying posture reduces pain, which may be due to the observed reduction in spasm and increase in muscle oxygenation

4.0 Context of the evaluation and choice of clinical data types

4.1 Developmental context for the device

The technology incorporated into the Dr Ho's MTU is not new. The waveform is not new however the patterning of the pulses is unique. Marked on the front of the device is: 'T.E.N.S + E.M.S. + Pulse Massager' suggesting that it attempts to combine these existing technologies into one unit. Since the device is essentially a TENS waveform generator, related literature on the safety of TENS is the most justifiable to review. As will be shown in the summary of the existing literature, the safety of TENS and lack of serious adverse events has been well established over the years. There is no reason for the modulating pulse sequencing pattern of Dr-Ho's device to pose any new safety concerns. As noted above (ref), the textbook description of modulated TENS units have noted the advantage of varying pulse sequencing so that the pained area is not susceptible to the diminishing effects of adaptation. A concern of traditional TENS in reaching and maintaining maximal benefits for users is they adapt to the stimuli during treatment and/or over time.

4.2 Essential principles relevant to safety concerns

The major safety concern with any electrical device is the potential for tissue damage. Dr Ho's MTU has been approved by various safety associations (see appendix A) for mitigating this risk. Still, reasonable precautionary measures are recommended for special populations with potential unknown effects. For example, contraindications for use include heart pacemaker wearers, epileptics, and pregnant women. Areas of the body that the electrodes should not be

placed include: the front and side of the neck, the anterior and posterior chest, across the head, over cancerous lesions, broken or damaged skin of any kind, areas of abnormal sensation, areas of internal bleeding, over a menstruating uterus and some surgical lesions. The device should not be used while driving, operating machinery or ever be immersed in water. Note that there was no evidence found of any of the adverse events actually occurring.

A more minor safety concern relates to skin sensitivity of the conductive gel used to conduct the signals to the skin. A report assessing this risk follows in the literature review.

4.3 Description of the literature search process

The literature search was conducted to find any and all appropriate studies relating to the performance and efficacy of the Dr Ho's MTU device, its ability to reduce pain, as well as investigate the safety of the device and investigate any reports of adverse events. While several studies have been conducted specifically on the Dr Ho's MTU, a broader search was conducted on TENS in general. Specifically, the search was conducted over several days in September of 2012. The period covered by the search was over the past 12 years, specifically from 01/01/2000 to the present.

The literature search engine used to identify related reports was PubMed. This database was exclusively used as it includes over 22 million citations extracted from a wide array of journal libraries, online books and numerous other databases contents (including MEDLINE). PubMed is recognised as the leading resource for researchers in the health field to find peer reviewed academic medical journals.

A total of six searches were undertaken in order to maximise efforts to find articles relating specifically to the scope of this clinical evaluation report. The exact words and phrases entered into the search bar are listed below (note that the letter case does not effect the search results).

- a) modulated TENS
- b) TENS adverse event
- c) TENS injury
- d) TENS safety
- e) TENS pain reduction
- f) TENS efficacy

The filters activated throughout the search were simply customized for the date range of 01/01/2012 to 31/12/2012, the requirement of subjects to be humans and that the article be available in English.

In order to incorporate a broad spectrum of articles involving TENS or modulated TENS in the report, specific inclusion criteria was not directly outlined so as not to constrict the search. Rather articles that did not fall under the scope were excluded (see figure 3).

The reports identified in initial results of each search were evaluated and excluded for reasons including but not limited to irrelevancy, non pertinence and studies failing to involve TENS therapy. The remaining articles were then read and further examined for eligibility; at this stage articles were culled for unacceptable research design. Note that no report was excluded that contained any reports of adverse safety events.

In addition to reports identified in the search process documented above, articles provided by the manufacturer together with some that we were familiar with given our extensive involvement in this area were also included. This was thought to be sufficient to capture all reports on the efficacy and safety of the MTU. Specifically, those additional papers included were:

Kavcic, N., Lehman, G, McGill, S. (2005). Effect of Modulated TENS on Muscle Activation, Oxygenation, and Pain: Searching for a Physiological Mechanism. *Journal of Musculoskeletal Pain*. 13(2): 19-30.

Chauhan, A., Mullins, PA., Thuraisingham, SI., Taylor, G., Petch, MC., Schofield, PM. (1994). Effect of transcutaneous electrical nerve stimulation on coronary blood flow. *Circulation*. 89: 694-702.

Johnson, M., Martinson, M. (2007). The efficacy of Electrical Nerve Stimulation for Chronic Musculoskeletal Pain: A meta-analysis of Randomised Control Trials. *Pain*. 130: 157 – 165.

Chen, L., Tang, J., White, P., Sloninsky, A., Wender, R., Naruse, R., Kariger, R. (1998). The Effect of Location of Transcutaneous Electrical Nerve Stimulation on Postoperative Opioid Analgesic Requirement: Acupoint Versus Nonacupoint Stimulation. *Anesthesia & Analgesia* 87 (5): 1129-34.

Mazak, R. Vetere, P., Finch, L. (1983). Transcutaneous Electrical Nerve Stimulation for Low Back Pain and Range of Motion. *Journal of the American Physical Therapy Association*. 63(4): 489-493.

Ng, S., Hui-Chan, C. (2009). Does the use of TENS increase the effectiveness of exercise for improving walking after stroke? A randomized controlled clinical trial. *Clinical Rehabilitation* 2009; 23: 1093-1103.

Severhof, L., Zdawczyk, A., & Lubelski, C. (2012). Cytotoxicity Study Using the ISO Agarose Overlay Method. *NAMSA Report*.

Stevenson, C., Carter, A. (2011). ISO Skin Irritation Study in Rabbits. *NAMSA Report*.

Stevenson, C. (2011) ISO Closed Patch Sensitization Study in Guinea Pigs. *NAMSA Report*.

Jones, Iain., & Johnson, Mark I. (2009). Transcutaneous Electrical Nerve Stimulation. *The British Journal of Anaesthesia. Continuing Education in Anaesthesia, Critical Pain & Pain*. 9(4): 130-135.

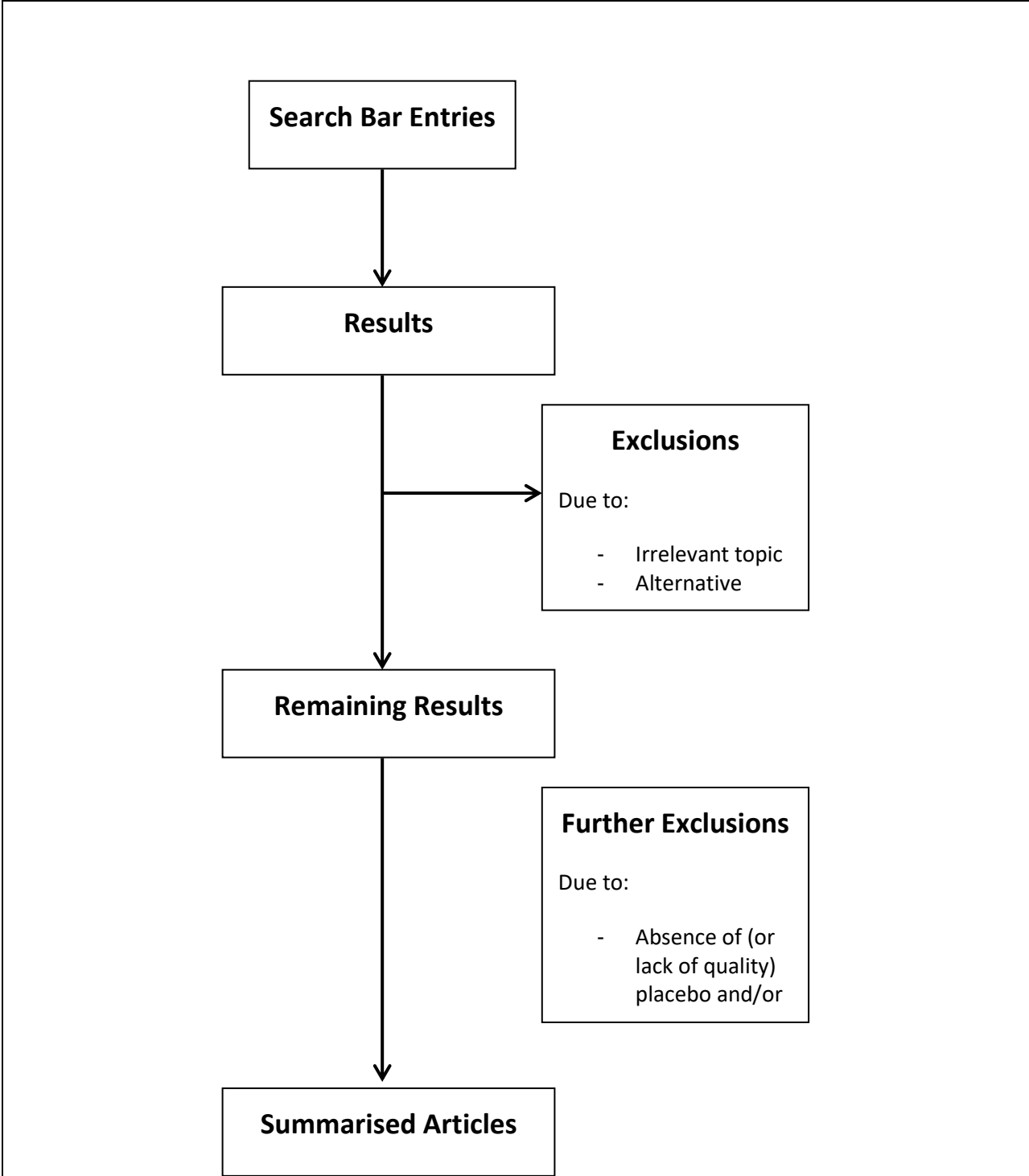


Figure 3. Literature search approach.

5.0 Summary of the clinical data and appraisal

The following reports were organised to document:

1. Reports specifically evaluating the Dr Ho's MTU for efficacy and possible mechanisms of action;
2. Reports on mechanism of action of TENS units in general;
3. Reports on the efficacy to reduce pain of TENS in general;
4. Reports on changes in function using TENS units;
5. Reports addressing safety aspects specifically with Dr Ho's MTU;
6. Unpublished evidence related to Dr Ho's MTU
7. Summary where the literature converges and diverges together with highlighting what remains unknown.

5.1 Document reports specifically evaluating the Dr Ho's MTU for efficacy and possible mechanisms of action

Three studies have reported possible mechanisms of action for Dr Ho's MTU. Two are reasonably rigorous while the third lacks rigour in study design. Collectively they suggest that pain is reduced, muscle spasm is reduced, muscle oxygenation is increased and joint range of motion is increased.

1. McGill, Stuart M., Lehman, Greg. 1999. Report on the ability of "Dr. Ho's Muscle Massage Therapy" Device to Reduce Muscle Spasm and Pain. Delivered to Dr Ho. Available from these authors upon request.

This clinical study by McGill and Lehman, used electromyography (EMG) to quantify levels of muscle activation (in this case spasm) in unilateral painful muscles of the neck and shoulder region, and/or the back. 41 people attending a pain clinic were randomly selected and asked to participate in the study, designed to be representative of the populations seen in everyday pain clinic practice. A sliding template Visual Analogue Scale (VAS) was used to obtain patients' level of pain; the patients were blinded to the corresponding numbers indicating their score. The treatment intervention was the use of "Dr. Ho's MTU". A test group of 31 patients had pre and post treatment measures recorded, of the 70 painful muscles observed (non-painful contralateral muscles served as a control) mean muscle activation level before the TENS treatment was 10.3 %(SD 9.9) and after the treatment was significantly reduced to 8.0% (SD 7.7). The VAS scores from the same 31 patients were significantly reduced from 5.21 (SD 2.4) to 2.22 (SD 3.7) following the treatment. The remaining 10 patients were used as a control group,

to consider the effects of the relaxed treatment posture on muscle activation levels. There was a significant decrease in muscle activation between the initial measurement of 20.3% (SD 12.7) and after the control session (pre-treatment) to 14.7% (SD 6.3) but a further significant decrease was seen post-treatment when mean muscle activation levels were 11.9% (SD 5.5). The implication of this study was that the manufacturer claims that the device can relieve muscle tension and stiffness was substantiated by the significant decrease in muscle spasm, indicated by the decreased levels of muscle activation and a correspondingly lower level of perceived pain by the patient. No adverse events were reported.

2. Kavcic, N., Lehman, G., McGill, S. (2005). Effect of Modulated TENS on Muscle Activation, Oxygenation, and Pain: Searching for a Physiological Mechanism. *Journal of Musculoskeletal Pain*. 13(2): 19-30.

Given the results reported in the previous study, a follow up study was designed and conducted to probe any possible underlying mechanism by which the device reduces pain. Near Infrared Spectroscopy (NIRS) was used to measure levels of oxygen saturation in muscle tissue. NIRS was used, as it is a non-invasive option that could detect changes in blood flow and oxygen volume, perfusion and utilisation in response to spasm. Similarly to the first study, a sliding template (with the numbers blinded to the subject) VAS score was obtained. Of the 12 subjects three were excluded; two could not tolerate lying in the same position for the required 40 minutes, and the third did not have the device on high enough to induce muscle contractions. The remaining 9 subjects showed a significant increase in muscle oxygenation over the course of the treatment compared to the control trials. Initially the average VAS scores were 3.12 (SD 1.62), following the control period it had decreased to 2.83 (SD 1.57) but not significantly. However after the treatment the average VAS score was reduced to 1.41 (SD 0.86), which was significantly lower than both the initial measurement and the pre-treatment/post control average. The reduction in perceived pain by the patients was interpreted to be associated with the reduced

muscle spasm and increased muscle oxygenation. Further, it was also noted that “Blood flow is essential to remove metabolites known to cause pain.” There were only nine subjects from whom data could be considered, however, statistically significant results were obtained. The devices pads were in less than optimal placement due to the need for the NIRS pad to be exactly over the muscle; however it was hypothesized that optimal placement of the devices pads would only serve to further increase muscle oxygenation levels and the accompanying analgesic effects. No adverse events were reported.

3. Carmela Spano. Dr. Ho's Muscle Therapy: Range of Motion and Strength Testing.
Unpublished report.

In an experiment involving 8 subjects "Dr. Ho's MTU" was used as a treatment in a clinical setting to evaluate any influence on joint range of motion (ROM) and strength. Three tests were performed and results recorded for cervical rotation, forward flexion and low back strength. Dr. Ho's Tension Rating Scale (a simple standard 1 – 10 rating scale) was also utilized. Four subjects experiencing neck tension had their cervical rotation measured and tension rating recorded before and after being treated for 20 minutes with "Dr. Ho's Muscle Massage Therapy" device. All four subjects individually experienced a substantial increase in cervical rotation; on average left rotation increased 59% from 56 degrees to 92 degrees, right rotation went from an average of 53 degrees to 81 degrees showing a 35% increase. Lumbar/low back ROM was measured by having three subjects experiencing back pain perform forward trunk flexion. Before treatment with the device, an average of 66 degrees flexion was recorded and following treatment an 8% increase was recorded. Low back strength was measured using an ARCON machine which "provides a complete line of computerized strength, work capacity and range of motion evaluation hardware and software." An average of 61lbs was recorded pre-treatment and following treatment it had increased to 93lbs. This report is the only one of its kind however it is methodologically weak having no control, low subject numbers and no statistical analysis.

5.2 Mechanism of action of TENS units in general

Two studies were found contributing to the understanding of possible mechanisms of action of TENS. The first was a review performed by well-known scientists in the field, while the second was a trial investigating the influence on coronary heart vessel flow.

1. Jones, I, Johnson, M. (2009). Transcutaneous Electrical Nerve Stimulation. *The British Journal of Anaesthesia. Continuing Education in Anaesthesia, Critical Pain & Pain.* 9(4):130-135.

Jones and Johnson are well known scientists who wrote an informative paper on the potential mechanisms, clinical application, clinical effectiveness and known adverse events of TENS therapy. They stated that conventional TENS (low intensity, high frequency) relieves pain by way of a segmental mechanism "TENS reduces ongoing nociceptive cell activity and sensitization in the central nervous system when applied to somatic receptive fields. TENS induced A-d activity causes long-term depression of central nociceptive cell activity for up to 2 h." The extrasegmental mechanism works in a somewhat opposite way to that of segmental. Instead of depressing cell activity "TENS-induced activity in small diameter afferents (A-d) leads to activation of the midbrain periaqueductal grey and rostral ventromedial medulla (i.e.

descending inhibitory pathways) and inhibition of descending pain facilitatory pathways. Larger effects have been observed, when muscle rather than skin afferents are used.” The last mechanism described were the peripheral mechanisms that involve “TENS generating nerve impulses that will collide and extinguish noxiously induced orthodromic impulses arising from peripheral structures. Peripheral blockade of nociceptive impulses is more likely when TENS activates A-d fibres (i.e. intense TENS). TENS-induced activity in large diameter afferents (i.e. conventional TENS) will block afferent activity in large diameter fibres that may be contributing to pain.” Interestingly they reported that each mechanism has a unique optimal intensity and frequency to which it functions best. This would suggest that modulated TENS would be more effective. The authors make particular mention of the rarity of serious adverse events associated with the use of TENS therapy. However, it does make mention of some safety measures to be taken and patients to exclude, specifically; patients with pacemakers, epilepsy, bleeding disorders or who are pregnant should avoid the use of TENS unless a specialist administers the treatment. While the authors note a need for more high quality RCT’s, they also note that the high quality studies they did review suggest significant improvements with TENS for patients suffering from chronic musculoskeletal pain (especially knee osteoarthritis), postoperative patients’ reduced need for additional analgesics, and benefits for patients with dysmenorrhea. They also addressed the amount of weak evidence surrounding TENS therapy’s benefit in pain relief during labour, as most of the evidence is anecdotal as it is difficult to conduct a double blind, placebo controlled trial in this setting.

2. Chauhan, A., Mullins, PA., Thuraisingham, SI., Taylor, G., Petch, MC., Schofield, PM. (1994). Effect of transcutaneous electrical nerve stimulation on coronary blood flow. *Circulation*. 89: 694-702.

These authors report a study that investigated the ability of TENS to increase coronary blood flow and subsequently relieve angina pectoris and counteract ischemia in patients. The patients were split up into three groups depending on their symptoms. Group 1 (n=34) had typical symptoms of angina but normal coronary arteries. Group 2 (n=15) had significant coronary artery disease, defined as >50% reduction in intraluminal diameter of right coronary artery (left coronary artery was normal in all patients). For groups 1 and 2 the duration of symptoms was greater than 6 months and had stable symptoms of angina for the previous 2 months. None of the patients had hypertension, diabetes mellitus, lung disease or valvular heart disease. Group 3 (n=16) all had heart transplants, completely normal coronary arteries, no chest pain and were undergoing a routine follow up cardiac catheterization. Electrode placement for groups 1 and 2 were 10 to 30cm apart on the chest at the patients’ usual site of most intense pain, group 3 had their electrodes positioned 20 cm apart on the anterior chest wall over the precordium. TENS treatment was administered for 5 minutes, cardiac catheterization was performed before and after the treatment, as was the recording of resting

coronary blood flow velocity (CBFV), heart rate (HR), and mean systolic and arterial blood pressure. Quantitative measurements were taken for coronary artery diameter to indicate coronary flow changes. Blood samples were taken pre and post treatment to measure levels of epinephrine and norepinephrine. Group 1 saw a significant increase in resting CBFV from 6.8 ± 4.1 cm/s pre-treatment to 10.5 ± 5.7 cm/s post-treatment and also a significant decrease in arterial epinephrine concentration, there was no significant difference in norepinephrine levels. Group 2 experienced similar changes to group 1, their CBFV was initially 6.4 ± 2.5 cm/s but following treatment had increased to 11.3 ± 6.7 cm/s. Group 2 also saw a decrease in arterial epinephrine concentration, but no significant change in norepinephrine. Group 3 had no increase in CBFV, or any change in either epinephrine or norepinephrine concentrations. There were no significant systemic hemodynamic changes in any of the three groups, so HR, systolic BP, and mean arterial pressure never underwent any significant change. Thus there was no significant difference in the rate pressure product. There was no difference between men and women in resting CBFV or in response to TENS. Interestingly, TENS never caused a significant difference in arterial diameters (of left coronary system) either. The study was repeated in 10 patients from each group to test reproducibility, CBFV was allowed to return to normal after the initial TENS treatment before the test was reproduced. Again in groups 1 and 2 there was a significant increase in CBFV, but not in group 3; there was also no significant hemodynamic changes. The short duration (5 minutes) and high frequency (150 Hz) produced a varied response in patients from groups 1 and 2, independent of threshold stimulation and electrode placement; this further highlights the complex mechanisms by which TENS operates. The study did have several limitations; it was open and therefore exposed to bias, the study sited difficulty in designing a blind study involving TENS treatment as there is no placebo, however did use patients as their own control. All transplant patients were on immunosuppression therapy that could have affected pain threshold and coronary vasoreactivity, but there was no evidence to suggest this. This study produces strong evidence that not only does TENS treatment increase CBFV in patients with chest pain, but is reproducible and does not change the rate pressure product.

This study is also notable for what it did not report. Concern over the TENS signal affecting electric organs such as the heart has been expressed by groups responsible for patient safety such as ethics committees. In our own work, ethics committees who were not knowledgeable about TENS always expressed safety concern with electrodes in the chest/torso region. It would appear that there is no evidence to justify this concern.

5.3 Efficacy to reduce pain of TENS in general

Four studies have investigated the efficacy of TENS to reduce pain. The first is a meta-analysis that reviewed the available literature on electrically based therapies, including TENS, with some rigour for study quality to qualify for inclusion. The next study examined the influence of TENS to reduce the need for opioid analgesics. The third compared TENS to massage as an intervention to influence pain and joint range of motion given its application to conditions such as arthritis. The fourth study examines the ability of modulated TENS to influence pain sensitivity.

1. Johnson, M., Martinson, M. 2007. The efficacy of Electrical Nerve Stimulation for Chronic Musculoskeletal Pain: A meta-analysis of Randomized Control Trials. *Pain*. 130:157 – 165.

This large meta-analysis of randomized placebo-controlled trials was conducted to evaluate the efficacy of ENS therapy for chronic musculoskeletal pain; the study examined multiple types of ENS therapy including TENS. A total of 38 studies from 29 papers involving 1227 patients were examined, and of the 38 studies 24 showed a significant improvement in pain scores following some kind of ENS therapy. The remainder of the RCT's may have supported pain relief but lacked sufficient numbers to provide statistical significance. The studies ranged from those published between 1981 – 2005, and each one was weighted, *the assumption would be that they were weighted in terms of quality, power and sample size however specific criteria were not mentioned*. Overall ENS therapy provided a significant pain relief compared to placebo, and the average pain relief was reported to be nearly three times that of the placebo. This is the largest meta-analysis on the efficacy of ENS therapy to be conducted, the size of it allows for greater statistical power and validity of the results. The analysis did not restrict itself to any single anatomical origin of pain, and illustrates the range of chronic conditions for which it can be an effective therapy. The fact that studies involved dated back to 1981 would suggest that they may be outdated, however it demonstrates a history of previously established research supporting the efficacy of ENS therapy. What was specific to TENS was not always clear. The number or existence of adverse events is not reported.

2. Chen, L., Tang, J., White, P., Sloninsky, A., Wender, R., Naruse, R., Kariger, R. (1998). The Effect of Location of Transcutaneous Electrical Nerve Stimulation on Postoperative Opioid Analgesic Requirement: Acupoint Versus Nonacupoint Stimulation. *Anesthesia & Analgesia* 87 (5): 1129-34.

This randomized, single blind study was conducted to assess the belief that the site of TENS therapy can alter a patient's need for opioid analgesics following a surgical procedure. 100 women undergoing abdominal hysterectomy or myomectomy were split evenly into four groups. Group 1 formed the control group, as they received a sham TENS at the classical Chinese acupuncture point Zusanli. Group 2 received the TENS therapy at a non-acupoint, the

shoulders. Group 3 received TENS at the dermatome corresponding to the surgical incision. Group 4 received TENS at the Zusanli acupoint. Patient controlled analgesia (PCA) devices were also given to patients, in order to track the use of the opioid analgesic. If the TENS therapy is successful in managing pain then the use of PCA devices by postoperative patients could be reduced, and thus eliminating the known side effects and potential for serious complications associated with PCA. A standard 100mm visual analog scale (VAS) was used to indicate levels of sedation, fatigue, discomfort (whole body) and pain (related to incision). The VAS assessments were done pre-operative, then 24, 48 and 72 hours post-operative. The TENS treatment time was 30 minutes, the frequency alternated between 2 and 100 Hz every 3 seconds, and the intensity for groups 2,3 and 4 (actually receiving TENS) was set between 9 – 12 mA. The number of PCA demands in both the first 24 hours and throughout the duration of their stay at the postoperative anesthesia unit (PACU) was significantly less in groups 3 and 4 than 1 and 2. The duration of PCA use was also significantly shorter in groups 3 and 4 compared to groups 1 and 2, however there was no significant difference in length of stay at the PACU, duration of TENS use or length of hospitalization. There were significantly less amounts of hydromorphone received by patients in groups 3 and 4 than 1 and 2, however there were no significant differences between groups in their need for additional analgesics. With respect to the known side effects caused by PCA opioid analgesics; levels of nausea and dizziness in the first 24 hours and then between 24 and 72 hours was significantly reduced in groups 3 and 4 in the VAS assessments compared to groups 1 and 2. This evidence supports the use of TENS as a pain management tool, and the results indicate that there are specific sites of application to which one would receive optimal performance and enhanced benefits. The results derived from this study are of high quality considering their research design and methodology. They are also notable in that the instructional material accompanying Dr Ho's MTU suggest sites for electrode placement according to acupuncture meridians. These appear to have merit.

3. Mazak, R. Vetere, P., Finch, L. (1983). Transcutaneous Electrical Nerve Stimulation for Low Back Pain and Range of Motion. *Journal of the American Physical Therapy Association*. 63(4): 489-493.

It has been suggested that some types of TENS therapy can act as a substitute for massage therapy; this double blind study investigated a comparison between TENS and massage for influence on pain and joint range of motion. The massage feeling was created by an apparatus that involved four suction cups being held against the skin by mild negative pressure, the pressure varied in order to create a constant gentle massage. The TENS electrodes were placed over the site of pain on the back and on the lateral thigh; frequency was set at 4 to 8 Hz and the intensity was continuously raised throughout the treatment as accommodation increased but remained at a tolerable level. The McGill Pain Questionnaire (MPQ) was used to calculate percentage change in pain, the 2 indexes measured by the MPQ are the pain rating index (PRI)

and the present pain intensity (PPI). The authors noted that “the MPQ has been found to provide reliable and valid quantitative information about the subjective experience of pain.” *Two ROM tests were also performed before and after treatment, these being the straight leg raise and back flexion.* The 41 subjects were randomly assigned into either the TENS group (n=20) or the massage group (n=21). The treatments lasted 30 minutes, were twice a week and were stopped once one of the following four conditions was met: 1. Ten treatments were completed, 2. Patients pain ceased, no longer needed or wanted therapy, 3. Patient experienced no change in their pain and requested alternative therapy, 4. The therapist judged patients’ condition to be worse. After each treatment the patients were re-evaluated with the MPQ. TENS treatment produced significantly larger changes in the PRI and PPI than did the massage treatment. Percentage decrease was for TENS was 69.5% in PRI, and 80.8% in the PPI, compared to that of the massage treatments which were 37.2% and 40.9% respectively. According to the PRI the number of patients who experienced pain relief in excess of 50% was 38% in the massage group, and 85% in the TENS treatment group. This study is still relevant today due to the fact that it was able to design the research in such a way that it was double blind and involved patients already attending rehabilitative therapy.

4. Chen, C., Johnson, M. (2009). An Investigation Into the Effects of Frequency-Modulated Transcutaneous Electrical Nerve Stimulation (TENS) on Experimentally-Induced Pressure Pain in Healthy Human Participants. *The Journal of Pain, 10 (10), 1029-1037.*

This study compared the effects of constant frequency TENS, frequency modulated TENS and placebo TENS on blunt pressure pain. The placebo TENS output no current, the healthy volunteer participants had never received TENS before and were described as “TENS-naive” by the authors, they were simply told that some TENS devices produce a sensation and that others do not. The study design was a cross-over trial in which all participants received the three types of TENS in a randomised order for 20 minutes each and separated by a 40 minute ‘washout’ period aimed to return participants to baseline before moving on to the next type of TENS. Participants were measured at baseline before the treatment, then at 10 and 20 minutes during treatment, then again following the washout period before the procedure was repeated again for the next treatment. The principal investigator administering the pressure (induced pain) with the algometer probe was blinded to the TENS group and also throughout the data analysis. The constant frequency TENS was delivered at 80 pulses per second (pps) and the frequency modulated TENS started at 100 pps then decreased to 20 pps before increasing again to 100 pps over an 8 second period. There were no significant differences between the baseline measurements, indicating that the washout period was successful in returning participants to normal and that there were no remaining effects from the treatment administered before the washout. Compared to the placebo TENS and the baseline measurements the constant and frequency modulated TENS resulted in significantly increased pain thresholds (meaning higher

pain tolerance) at both the 10 and 20 minute intervals. “A statistically significant difference in pain threshold relative to baseline was detected at the 10 minute time point in favor of frequency-modulated TENS when compared with constant-frequency TENS ($P = .034$), although no statistically significant differences were detected at the 20-minute time point.” The authors suggested that the novelty of the frequency modulated TENS experienced at the 10 minute mark had disappeared by the 20 minute mark due to the nervous system becoming accustomed to the stimulus. “The comparison between constant-frequency TENS and frequency-modulated TENS produced an odds ratio of 1.54 in favor of constant-frequency TENS (95% CI, 0.29; 8.23, $P=1.0$, Fischer exact test).” In comparison to the placebo TENS the frequency modulated TENS was determined to have a number-needed-to-treat (NNT) of 1.44 (95% CI, 1.25; 1.85) compared to the constant frequency TENS NNT which was 1.38 (95% CI, 1.25; 1.85). However this difference was not considered statistically significant. The apparent effectiveness of the washout period, blinding of the principal investigator, and best attempts at limiting expectancy through participant selection produced results of relatively high quality. The statistical analysis was thorough and contributed to the validity of the results. None of the 36 volunteer participants originally made eligible were excluded from the study, discontinued the intervention or were lost to follow up. No adverse events were reported.

5.4 Changes in function using TENS units

Two studies have assessed changes in function due to TENS treatments. The first evaluated whether walking was improved in post-stroke patients, while the second assessed is TENS modulated spasticity in a group of spinal cord injured patients. These are real clinical issues in these special populations.

1. Ng, S., Hui-Chan, C. (2009). Does the use of TENS increase the effectiveness of exercise for improving walking after stroke? A randomized controlled clinical trial. *Clinical Rehabilitation* 2009; 23: 1093-1103.

This single-blind, randomized, placebo controlled, clinical trial was conducted to assess the potential benefits of transcutaneous electrical nerve stimulation and exercise on stroke patients' walking capacities. A total of 109 patients were randomly assigned to one of four groups; including a control group, a TENS group, a placebo stimulation plus exercise group and a TENS plus exercise group. The average age of the group was 56.6 ± 7.9 years, inclusion criteria included being between 50 and 75 years of age, having experienced only one stroke, at least one year since the stroke, having moderate to severe spasticity in ankle plantar flexors and had at least 10° of passive ankle dorsiflexion. Patients were excluded if they had any other pre-existing neurological disorder, a medical comorbidity preventing them from full participation or

cognitive impairment. The three intervention groups were told that they may or may not feel the electrical stimulation. The TENS received treatment for 60 minutes on four selected acupuncture points of affected lower limb. TENS plus exercise received the same 60 minutes of treatment and then performed the outlined exercises for 60 minutes, the exercises were designed to increase muscle strength in affected limb and improve walking capacity. The placebo plus exercise received 60 minutes of placebo stimulation and then performed the same exercise routine for 60 minutes. Subjects in the intervention groups received treatment five days a week for four weeks, for a total of 20 sessions. Subjects had a baseline assessment done and were then re-assessed at week 2, week 4 and then a 4 week follow up was conducted. The TENS plus exercise group recorded an average of 47.9 ± 26.8 cm/s at baseline, and were the only group to see a significant improvement in gait velocity. Improvements were recorded from week 2 (a 37.1% increase from baseline) onwards and were still present at the four week follow up were a velocity of 70.2 ± 32.7 cm/s (an increase of 57.5 %) was recorded. In the 6 minute walk test the two groups involving exercise (showed significantly larger absolute and percentage increases in their average distance covered after four weeks of treatment, compared to the control group. However, from week 2 onwards the only group to show significantly more distance covered compared to the control and TENS group, was the TENS plus exercise group with an increase of 22.1% at week 2 and then increasing further to 34.7% at the 4 week follow up. The functional mobility test used was the Timed Up and Go (TUG), the TENS plus exercise group was the only group that saw significantly reduced times compared to the TENS and placebo plus exercise groups. At baseline the TENS plus exercise average TUG score was 25.5 ± 17.4 seconds and at the 4 week follow up had decreased 23.3% to 18.8 ± 11.2 seconds. Although the study involved a home based rehabilitation program subjects did attend 8 instructional sessions, were given an instructional package with pictures and text, kept a daily log and were regularly contacted by telephone to increase and maintain subject compliance. The results support the authors' hypotheses that a combined treatment of both TENS and exercise would yield greater improvements in various components of walking, compared to either one of the treatments individually. Given the study design, recruitment and randomization procedures, and best efforts to minimize the placebo effect as well as maintain subject compliance the finding were considered to be valid and of high quality.

2. Ping, B., Kam, B., (2010). Immediate effect of Transcutaneous electrical nerve stimulation on spasticity in patients with spinal cord injury. *Clinical Rehabilitation* 2010; 24(3): 202-210.

This randomized controlled trial investigated the effects of TENS on spasticity associated with spinal cord injury. There were three inclusion criteria: 1) spasticity over lower limbs caused by spinal cord injury; 2) between 18 and 80 years of age; 3) having the return of ankle jerk indicating recovery from spinal shock. Exclusion criteria included several known

contraindications of TENS and any previous experience with TENS. The high frequency TENS (0.25 ms, 100 Hz, 15 mA) and placebo TENS was administered over the common peroneal nerve that innervates the ankle dorsiflexors, the treatment lasted 60 minutes and then plantarflexors spasticity was immediately measured. The spasticity was measured using the 'Composite Spasticity Score' (CSS), which is comprised of three individual scores: Achilles tendon jerks, resistance to full range passive ankle dorsiflexion and ankle clonus. Some of the patients were on an anti-spasticity drug during the study, however their dosage remained the same throughout and thus would not effect the change seen in spasticity. At baseline the active TENS group (n=10) had an initial CSS of 10.5 ± 1.51 compared to the placebo group (n=8) which had a CSS of 11.63 ± 1.77 . These baseline measurements did not represent a statistically significant difference, suggesting that all participants were suffering from a similar degree of spasticity. Immediately following the treatment the active TENS group's CSS was significantly reduced to 7.40 ± 2.84 , a 29.5% reduction. The placebo group saw no such change, as their CSS after treatment was 11.50 ± 1.93 , a mere 1.1% drop. The authors recognised that their small sample size left them susceptible to type II error, however they noted their care in group blinding procedures, statistical analysis and in experiment execution. The study reported that three patients experienced a mild skin irritation and erythema, but no other substantial adverse events were reported.

5.5 Safety aspects specifically with Dr Ho's MTU

Given the history of Dr Ho's MTU seeking and receiving approval by several medical device groups around the world, studies were commissioned to assess the potential for skin irritation from the gel electrodes in contact with the skin. Three studies were commissioned: the first was a cytotoxicity analysis on cells in situ, the second and third studies used an animal model (rabbits and guinea pigs) to evaluate skin irritation and sensitivity.

1. Severhof, L., Zdawczyk, A., Lubelski, C. (2012). Cytotoxicity Study Using the ISO Agarose Overlay Method. *NAMSA Report*.

A cytotoxicity study was commissioned by the manufacturer of Dr. Ho's MTU device in compliance with ISO procedures, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro cytotoxicity. The test article itself was the electrode pad that is placed on the skin of the patient; this study investigated the potential of the pads to cause any cytotoxicity. A negative control article of high-density polyethylene (HDPE) and a positive control article of latex were used as comparators. The negative control article scored a grade of 0 meaning that there was no reactivity. The positive control article scored a grade of 3 meaning that there was moderate reactivity in a zone extending the specimen up to 1cm. The test article was given a grade of 2,

meaning there was mild reactivity limited to the zone under the specimen. *However the study made note that complete cell lysis was observed under the test article, suggesting that the cells in the zone that did experience lysis, fully disintegrated.* The test article met the requirements of the test, as it was grade 2 and only demonstrated mild reactivity. The results of this study are relevant to the safety of the device as the electrodes in contact with the skin were not deemed to cause any significant or alarming reactions to the contact or surrounding cells.

2. Stevenson, C., Carter, A., (2011). ISO Skin Irritation Study in Rabbits. *NAMSA Report.*

A skin irritation study was commissioned by the manufacturer of Dr. Ho's MTU device in compliance with ISO procedures, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization. The control article was essentially four-ply gauze cut into 25mm x 25mm sections, the test article was a 25mm x 25mm section of Dr. Ho's Replacement Electrode Pads. The three subjects in the study were female *Oryctolagus cuniculus* rabbits, these rabbits have been determined an appropriate animal for skin irritation studies. The conditions outlined in the "Guide for the Care and Use of Laboratory Animals" were followed throughout the study and approved by NAMSA Institutional Animal Care and Use Committees. The test article was applied to two sites on the subject, one cranially and one caudally, the control article was similarly applied to the opposite sides. The subjects were exposed to the test article and control article patches simultaneously for 24 hours, and then examined for erythema, edema and any other dermal changes at 1, 24, 48 and 72 hour intervals following the removal of the patches. One subject was reported to have no erythema and no edema for either article, at any of the locations and for all of the intervals times. A second subject scored "0" on everything (no edema or erythema) except at the one hour interval, the left test article was given a score of "1" for erythema. This score of 1 indicates there was a reaction, very slight erythema and barely perceptible; this falls into the slight category for irritation response. The last subject was also given a score of 1 on erythema for the test article on both sides at the 1 hour interval, everything else was "0". By the 24 hour interval only the right side was still at 1 (the left was at 0), but by the 48 hour interval there was no erythema. Time of onset to maximum irritation response was 1 hour. Overall the very slight erythema experienced by two of the subjects led to a Primary Irritation Index score of 0.1, placing it in the negligible response category. The study followed all regulations and procedures outlined by various international organizations; it was logical and thorough in its dermal observations implying high quality results were produced.

3. Stevenson, Colleen M. (2011) ISO Closed Patch Sensitization Study in Guinea Pigs. *NAMSA Report.*

A skin sensitivity study was commissioned by the manufacturer of Dr. Ho's MTU device in compliance with ISO procedures, Biological Evaluation of Medical Devices – Part 10: Tests for

Irritation and Skin Sensitization. The test article was a 25mm x 25mm section of Dr. Ho's Replacement Electrode Pads, the control article a 25mm x 25mm section of four-ply gauze. The 15 subjects were all female Hartley albino guinea pigs, a commonly used animal for sensitization studies. In the induction period the test article was attached to 10 animals for 6 – 8 hours, three times a week for three weeks. The control article was attached to 5 animals, for the same time, duration and frequency as the test article. There was then a 2 week recovery period, before the challenge period began. The challenge period consisted of all 15 animals being patched with both the test and control articles, for 6 – 8 hours. Dermal observations were made at 24 and 48 hours after the patches were removed, no visible changes were observed. The test article was determined not to cause any delayed dermal contact sensitization in the guinea pig. There was one animal that suffered slight alopecia on several limbs for periods of times, however this condition occurred during the induction period and was one of the 5 animals in the control group. Therefore the animal hadn't been exposed to the test article yet, and thus not a reaction to it. The study was considered to be rigorous in its testing and produced strong evidence that the the gel pads do not cause any delayed dermal reactions.

5.6 Unpublished evidence related to Dr Ho's MTU

At the end of June 2000 a clinical trial using Dr Ho's MTU was conducted at a company that manufactures chrome automobile bumpers and wheel rims. This process involves heavy manual labour. As an aside, the principle author of this clinical report has also been involved in a large back pain trial at this same company and was well aware of the trial using the Dr Ho's MTU. In fact the company undertook the study upon the recommendation of the principle author. The following description is valid and bonafide. The company first undertook a 6-month study using the DR-HO'S MTUas an in-house treatment for muscle tension, stiffness or pain under the direction of the company nurse. The objectives of the study were to evaluate the ability of the device to:

1. Decrease employees painful conditions.
2. Decrease outside Physiotherapy referrals.
3. Improve employee recovery time.
4. Decrease overall company medical expenditures.

Over 50 employees were treated with the DR-HO'S MTU following directions supplied with the unit. Forty-three employees experienced an improvement in their condition. Of interest was the observation that at least 15 employees purchased one unit for themselves, with their own resources. Most employees with acute type problems were treated only 1 or 2 times for 20 minutes per treatment. Others with more chronic conditions were treated over a 2-3 week period at the nursing station during break time. Conditions included back, neck, and shoulder strains, headaches, carpal tunnel syndrome, fibromyalgia and muscle aches and pains. The

amount of time on modified work for these employees decreased and many did not require any modified work at all. A detailed cost benefit analysis was conducted:

Treatment Costs Year 1: Normal treatment involved sending employees to Physiotherapy as needed for work related injuries when they do not respond to in house treatments.

The cost of this includes: Taxi fare to and from treatment: Taxi costs \$12.50 x 2 = \$25.00 x 2 a week [one usually on day off] = \$50.00 x 7 = \$350.00 [Note: After discussion with corporate counsel it was decided that employees could drive their own vehicle if they chose, although most did not choose to do this].

Treatments: Treatment costs \$55.00 for assessment + \$35.00 per treatment x 3 a week = \$105.00 x 7 weeks = \$790.00 (which are usually 3 times per week, 6 – 8 weeks). This cost generally is over \$1000.00 per employee plus the time away from work, which they are paid. Time away from work: Approximately 2 hours - ½ hour to get there, 1 hour for treatment, ½ hour to get back @ approximately \$15.00 per hour x 2 = \$30.00 x 2 a week = \$60.00 x 7 weeks = \$420.00. Total costs \$ 1460.00 [this does not take into account the cost of the employee being on modified work.] Since the beginning of the study with Dr Ho's MTU the company reported a significant decreased in employees sent to Physiotherapy compared with records from previous years. From June, 2000 there were only 27 referrals to outside Physiotherapy. The direct cost savings was estimated at \$12,940.00. The company stated that the 4 objectives that were set at the beginning of the study, were met.

Treatment cost analysis for year 2: Following the perceived success of year 1 the company decided to extend the trial for another year. The following is a cost comparison of the treatments given to employees in the Health Services Department at XXX Inc. using the DR-HO'S MTU from January – September 2001--versus the cost of outside Physiotherapy/Chiropractic treatments. These data were obtained from company records. Costs for outside Physiotherapy/Chiropractic treatment: Time away from department – 2 hours = \$32.00 [average in wages paid]. Taxi fare to and from physiotherapy- \$25.00. Physiotherapy cost per treatment - \$35.00. Total cost for outside Physiotherapy treatment: \$92.00 per treatment.

Savings using DR-HO'STM Muscle Therapy System:

First Quarter: (Jan-March, 2001) – 161 in-house treatments savings x \$92.00 = \$14,812.00

NOTE: The company did not have a need to refer any employees to Physiotherapy and continued to experience excellent results (Their language).

Second Quarter: (April – June, 2001) – 201 in-house treatments savings x \$92.00 = \$18,492.00

Third Quarter: (July – September, 2001) – 141 in-house treatments savings x \$92.00 = \$12,972.00

Total Savings by XXX Inc. (3 quarters) = *\$46,276.00

*Amount of money XXX Inc. saved on outside medical costs in 3 business quarters in 2001.

5.7 Summary of where the literature converges and diverges together with highlighting what remains unknown.

First, there are relatively few good studies that have investigated the efficacy, safety and mechanisms of action. We feel that we have captured the important studies in this short review. The evidence supports the notions that modulated TENS is more effective than traditional TENS for pain reduction. More importantly, we were unable to find any documented side effects or contraindications for modulated TENS even though we scoured the literature. We did not uncover any substantial divergences of opinion in the literature, or any controversy between research groups.

Some areas of understanding remain unknown. Given the wide variety of pained conditions, only a few have been studied with TENS treatments. Nonetheless, common categories such as back pain and general occupational sprains and strains appear to be represented in this body of evidence. Confirmed mechanisms of action with penetrating understanding remain elusive.

6 Data analysis

6.1 Statement on Performance

The reviews above contained critical commentary on each article of evidence. The use of TENS and its effectiveness appears unequivocal and has not attracted any real substantiated challenge. This is an important observation given the great controversies that surround the use of other electrical therapies such as therapeutic ultrasound and laser therapy. All evidence regarding TENS reached the same general conclusions, whether the study was exceptionally well strong from a methodological perspective or not so strong.

Public perception of the device also is a source of insight. The device is sold on the internet through several large retailers. For example Costco sells the device and has a product review link where purchasers of the device may leave an anonymous review. Most reviews are extremely positive for supporting a beneficial treatment effect. Many reviews suggest that this was the most effective approach they have tried for their pains.

6.2 Statement on Safety

Throughout the entire review process, there was no evidence of adverse events associated with the use of modulated TENS. The greatest risk that was found in the review was the possibility of short-term skin redness from contact with the electrode gel pads.

6.3 Product Literature and Instructions for Use

The literature supplied by the manufacturer in product packaging and associated printed matter appears to be consistent with all evidence uncovered in this clinical review. There were no hazards or contraindications for use that were not listed in the product printed matter. Further, the list of these items appear to be extremely conservative given the absence of any reports of substantial harm.

7.0 Conclusions

In summary, the use of modulated TENS, and in particular the use of Dr Ho's MTU appears to be an effective pain relief therapy. Thus, the clinical evidence demonstrates conformity with relevant Essential Principles. No known reports of adverse effects or other safety concerns emerged in the process of generating this document. Thus, the performance and safety of the device as claimed have been established. Finally given no evidence of risk other than the possibility of skin irritation, the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

Appendices

Appendix A: CV Professor Stuart McGill

Appendix B: Professor McGill reports on the efficacy and mechanisms of Dr Ho's Muscle Therapy Unit

Appendix C: Product Test Service report for safety of medical electrical devices – Dr Ho's Therapy Unit