Clinical Evaluation Report

Product name: TENS device-EmeTerm
Issued Date: July. 17, 2017
Report No.: EmeTerm-20170717

1 The purpose and means of clinical assessment

1.1 Clinical evaluation purposes

TENS device-EmeTerm is to be implemented clinical assessment, and meet the basic requirements of the MDD 93/42/EEC Appendix I. Also benefit is much larger than the risk of the product, we may place the medical device into market based on sufficient safety and effectiveness.

1.2 Means of clinical assessment

TENS device-EmeTerm produced by our company are based on existing, mature technology and used for intended purpose of mature （ based on existing, well established technologies ad intended for an established use）. In addition, the product's intended use and works on the planet has been widely recognized. Therefore, in order to effectively demonstrate that the TENS device-EmeTerm produced is safety and efficacy for placing into market. Clinical assessment method used to document ways via clinical and risk analysis.

2 Product Overview

2.1 **Product name**: TENS device-EmeTerm

2.2 Product Contraindication

(1) Patients who suffer from acute inflammation, hemorrhagic tendency, arrhythmia and epilepsy;

(2) People who have metal piece or cardiac pacemaker within their bodies;

(3) Please consult your physician if you have any other contraindications.

2.3 Product Profile

2.3.1 Product Components

Main unit, rubber wristband and IFU..

2.3.2 Working principle

By releasing the low-frequency pulse with a particular frequency and reaching the advanced nerve center of cerebral cortex via the median nerve on wrists, they can adjust all signals causing nervous vomiting which come from the biological and physical channels. Meanwhile, they can also adjust the vagus nerve signals traveling to or from the stomach, so as to prevent or postpone the transmission of vomiting signals from brain to stomach and slow down the frequency of abnormal gastric peristalsis.

2.3.3 Performance parameters

2.3.3.1 Productappearance

The surface should be bright, clean and smooth, without obvious dent, scratch, crack, etc. The metal electrode and metal watch strap buckle should be non-corroding and unscathed, and the operation key should be flexible and in good condition.

This item belongs to product testing.
2.3.3.2 Pulse repetition frequency
When the load resistance is 1,000 Ω, the standard pulse repetition frequency is 33Hz (±1Hz) on the oscilloscope.
When the load resistance fluctuation is within ±10%, the pulse repetition frequency deviation is not greater than ±30%.
When the power supply voltage fluctuation is within ±10%, the pulse repetition frequency deviation is not more than ±10%.
This item belongs to product testing.
2.3.3.3 Pulse width
When the load resistance is 1,000 Ω, the standard pulse width is 90us (±15us) on the oscilloscope.
When the load resistance fluctuation is within ±10%, the pulse width deviation is not more than ±30%.
When the power supply voltage fluctuation is within ±10%, the pulse width deviation is not more than ±10%.
This item belongs to product testing.
2.3.3.4 Impulse amplitude value
Five-range gear (without series resistance between electrodes), and the pulse amplitude value is 110V (±1 0 V) on the oscilloscope.
Five-range gear, connect a 1,000Ω resistance between two electrodes in series, and the pulse amplitude value is 36V (±3V).
This item belongs to product testing.
2.3.3.5 Pulse energy
Five-range gear, full battery power: connect a 1,000Ω resistance between two electrodes in series, and the pulse energy is 80 uJ (±10%) measured by pulse energy tester.
This item belongs to type testing.
2.3.3.6 Gear adjustment
The device for preventing and treating medicine-induced nausea and vomiting has five gears, and it is default 1st gear after start-up, and the gear is adjustable.
This item belongs to product testing.
2.3.3.7 Continuous working hours
1,000 Ω load resistance, charging once can ensure 7 hours or more accumulative using time.
This item belongs to type testing.
2.3.3.8 Electrode
The length and width is 24.4 mm (±0.5mm) and 9.2 mm (±0.5mm), and there are eight bumps on the surface, which is shiny and smooth.
This item belongs to product testing.
2.3.3.9 Low battery warning
When the battery voltage is lower than 3.7 V, after the gear light and button light glisten for 5 seconds continuously, the product will shut down automatically.

This item belongs to type testing.

2.3.3.10 Resistance to dropping

After drop test, the product performance should comply with the requirements of Section 2.3.3.3、2.3.3.4、2.3.3.5、2.3.3.6、2.3.3.7、2.3.3.8、2.3.3.10.

This item belongs to type testing.

2.3.3.11 Electrical safety performance

The products shall comply with the requirements of EN 60601-1:2012, EN 60601-1-11:2015, IEC 60601-2-10:2012.

This item belongs to type testing.

2.3.3.12 Electromagnetic compatibility

The products should be in line with the requirements of EN 60601-1-2:2015 & CISPR 11: 2010

This item belongs to type testing.

3 Intended Use

TENS device-EmeTerm is a wearable device for the treatment of nausea and vomiting induced by：

- medicine. e.g. chemotherapy, general anesthesia and morphine.
- motion sickness. e.g. seasickness, carsickness, airsickness, altitude stress and VR dizziness
- morning sickness. e.g. pregnancy.

4 Environmental requirements

4.1Transportation

In addition to requirements stipulated in the contract, it is required to prevent from shock, severe vibration and humidity during transportation.

4.2Storage:

The product should be stored in accordance with the following requirements:

Environment temperature: --20℃—+55℃

Relative humidity: ≤80%

Atmospheric pressure: (50-106) kPa

Indoor, dry and well-ventilated, free from corrosive substances

Great pressure is not allowed to be put on the product.

5 Cautions and warnings

1. Please use the device by the instruction manual in order to ensure a safe use.
2. Please do not use the device if you suffer from skin ulceration, allergy, bleeding, infection and so on.
3. The patient is not allowed to use the product together with a high-frequency device. It is forbidden to put this device and a high-frequency device in the same treatment room.
4. It is not suitable for patients to adjust the device at a high gear in their first use of the

device because they have not got prepared psychologically. After 2 to 3 times of treatment, patients can have gear up gradually.

5. It is not allowed to put the electrode on the unspecified part for use.

6. The normal operating temperature of the device ranges from -10℃to+40℃.

7. Patients who have medical electronic products in their bodies such as cardiac pacemakers, metal implants and so on are forbidden to use the device.

8. Patients who have metal foreign bodies in them are forbidden to use the device.

9. The electroconductibility of the device varies with individual physique and surrounding environment, thus affecting the using effect. It is general to intensify the electroconductibility by gearing up the device, tightening the wrist strap, or applying conductive paste or appropriate amount of water on the wrist.

10. It is normal that a slight tingling will develop on the wrist while wearing the device. For users who have pruritus and tingling, they may wear the device on the other wrist. Generally, the pruritus and tingling will disappear in 24 hours.

6Clinical documents

6.1 Scope

This clinical evaluation is based on a comprehensive analysis or available pre and post market clinical data relevant to the intended use of the device in question, with special regard to clinical performance data and safety data. This includes data specific to the device in question as well as any data relating to devices claimed as equivalent by the manufacturer. The literature search focused on TENS device-EmeTerm.

6.2 Literature search protocol

6.2.1 Date of search:2016-11-3

6.2.2 Search by: Richard Taylor

Period covered by search: 1995.1.1~2016.10.31

6.2.3 Literature sources used to identify data.

For this clinical evaluation a systematic literature search was performed by the sponsor in the international databases MEDLINE(PubMed).

PubMed is a free database accessing primarily the MEDLINEdatabase of citations and abstracts on life sciences and biomedical topics. The United States National Library of Medicine (NLM) at the National Institutes of Health (NIH) maintains PubMed as part of the Entrezinformation retrieval system.

In addition to MEDLINE, PubMed also provides access to: OLDMEDLINE, In-process citations, publisher-supplied citations and some life science journals that submit full text to the PubMed Centraldigital library and may not have been recommended for inclusion in MEDLINE.

6.2.4 Database search details:

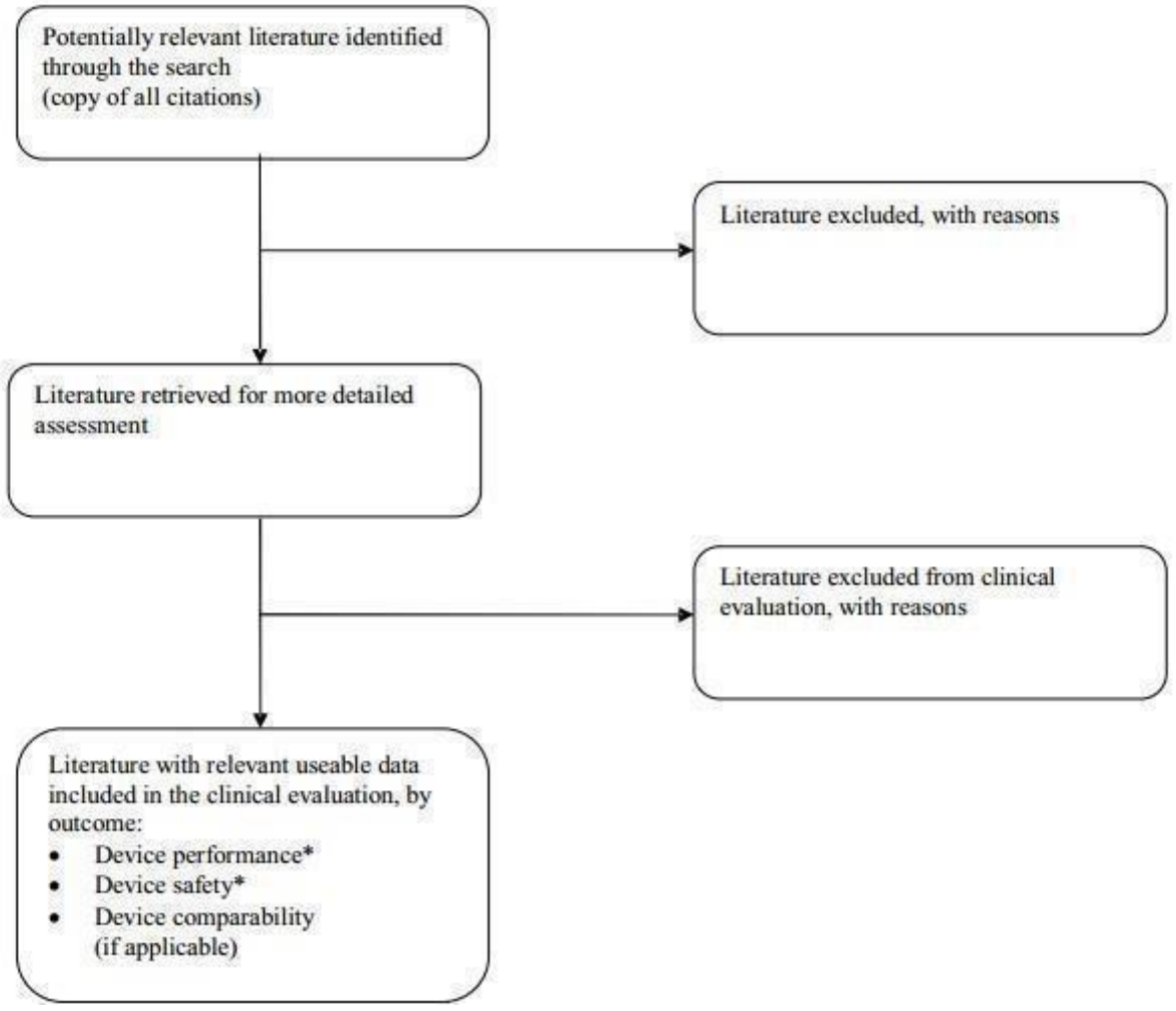
Keywords:

1. electrical stimulation, neuromuscular, nausea andvomiting

2. standard antiemetic, emetogenic chemotherapy, retching, vomiting, nausea
3. transcutaneous electrical nerve stimulation, motion sickness
4. electrical acustimulation, symptoms of motion sickness
5. acustimulation, antiemetic prophylaxis, ondansetron, surgery, study
6. transcutaneous electrical stimulation, nausea scores, vomiting episodes
7. Nausea, vomiting, pregnancy, hyperemesis, motion sickness, vestibular

- Search media used: Network.
- The logical combination of search terms: and / and, or / or, not /non
- Reason for the logical allocation of the search path, the search term, and the search word: the most common use, logicality
- Output of search results: Directory, including keywords, title, abstract, author, author unit

The following flowchart shows the methodology we used for documenting the screening and selection of literature.



6.2.5. Document screening process:

6.2.5.1 General Screening principle

- Eliminate repetitive literature;
- Browse keywords, title, abstract, author, author unit (after screening) to remove irrelevant literature
- After browsing the full text to removeirrelevant literature

6.2.5.2 Screening criteria:

1. The literature should be related to antiemetictherapy research.
2. The literature should be related to transcutaneous electrical nerve stimulation therapy research.
3. The literature should be related to medicine induced nausea and vomiting, motion sickness and pregnant nausea &vomiting.
4. The conclusion of literature should illustrate the difference and relationship between transcutaneous electrical nerve stimulation therapy and chemotherapy when they are used in motion sickness therapeutic process, pregnant nausea and vomiting therapeutic process and medicine induced nausea and vomiting therapeutic process.

6.2.5.3 The reasons for the selection of the literature screening criteria: Most commonly used, more in line with conventional logic

6.2.5.4. Output of Document Selection Results: Full Text

6.2.6 Document output

6. 3Literature output

Literature 1

Title: Monitoring of neuromuscular blockade at the P6 acupuncture point reduces the incidence of
postoperative nausea and vomiting.

Author: r, M.D.,* Karin Stadelmann, M.D.,† Petra Alischer, M.D.,‡ Regina Ponert, M.D.,‡ Andrea Melber, M.D.,§ Robert Greif, M.D., M.M.E. Unibe)||

Summary: Electrical stimulation of the P6 acupuncture point reduces the incidence of postoperative nausea and vomiting (PONV). Neuromuscular blockade during general anesthesia can be monitored with electrical peripheral nerve stimulation at the wrist. The authors tested the effect of neuromuscular monitoring over the P6 acupuncture point on the reduction of PONV. In this prospective, double-blinded, randomized control trial, the authors investigated, with institutional review board approval and informed consent, 220 women undergoing elective laparoscopic surgery anesthetized with fentanyl, sevoflurane, and rocuronium. During anesthesia, neuromuscular blockade was monitored by a conventional nerve stimulator at a frequency of 1 Hz over the ulnar nerve (n = 110, control group) or over the median nerve (n = 110, P6 group) stimulating at the P6 acupuncture point at the same time. The authors evaluated the incidence of nausea and vomiting during the first 24 h. No differences in demographic and morphometric data were found between both groups. The 24-h incidence of PONV was 45% in the P6 acupuncture group versus 61% in the control group (P = 0.022). Nausea decreased from 56% in the control group to 40% in the P6 group (P = 0.022), but emesis decreased only from 28% to 23% (P = 0.439). Nausea decreased substantially during the first 6 h of the observation period (P = 0.009). Fewer subjects in the acupuncture group

required ondansetron as rescue therapy (27% vs. 39%; P = 0.086). Intraoperative P6 acupuncture point stimulation with a conventional nerve stimulator during surgery significantly reduced the incidence of PONV over 24 h. The efficacy of P6 stimulation is similar to that of commonly used antiemetic drugs in the prevention of PONV.

Literature 2

Title: Randomized double-blind study of the Reliefband as an adjunct to standard antiemetics in patients receiving moderately-high to highly emetogenic chemotherapy.

Author: Imad Treish、Stacy Shord、John Valgus、Donald Harvey、Jessica Nagy、Jennifer Stegal、 Celeste Lindley

Summary: Our goal was to evaluate the efficacy and tolerability of the Reliefband as an adjunct to standard antiemetics in patients receiving moderately-high to highly emetogenic chemotherapy. Forty-nine adult cancer patients receiving moderately-high or highly emetogenic chemotherapy were randomized to receive either the active Reliefband (n=26) or an inactive device (n=23). Patients continued to receive all scheduled and as needed antiemetic agents as prescribed. The device was worn the day of chemotherapy administration for 5 days (days 1-5). Patients maintained a daily dairy of nausea severity, vomiting and retching episodes, and antiemetic medications taken. Each patient completed a Functional Living Index Emesis (FLIE) and a tolerability survey at the conclusion of the study. A Wilcoxon rank sum test was used to compare the number of vomiting episodes, severity of nausea and FLIE scores between the two groups. Patients wearing the active Relifband experienced less vomiting (Reliefband 1.9 versus inactive device 4.6 mean episodes; p=0.05), retching (1.4 versus 3.6 mean episodes; p=0.05), and nausea severity (0.91 versus 1.65 mean cm/day; p=0.01) over the 5-day period compared to patients wearing the inactive device. Vomiting was statistically significantly reduced during the delayed period (0.42 versus 1; p=0.032), whereas nausea was significantly reduced during the acute (0.71 versus 2.3; p=0.028) and delayed (1.8 versus 3.3; p=0.020) periods. FLIE scores did not differ between the two treatment groups (91 versus 80; p=0.088). This study suggests that patients receiving moderately-high to highly emetogenic chemotherapy who experience nausea and vomiting despite scheduled antiemetics may benefit from the use of the Reliefband as an adjunct to antiemetics. Limitations of this study include differences in risk factors for emesis, chemotherapy, and antiemetic regimens. A larger, better, controlled randomized study is needed to better define optimal use of thisdevice.

Literature 3

Title: Effects of transcutaneous electrical nerve stimulation on motion sickness induced by rotary chair: a crossover study.

Author: Hsin Chu, MD, PhD,1,2* Min-Hui Li, MD, PhD,1* Szu-Hsuan Juan, MS,1

and Wen-Yao Chiou, MD3

Summary: Motion sickness (MS) is evoked by the conflict among somatosensory, visual, and vestibular input. Some of the MS symptoms and signs are mediated by activation of the autonomic nervous system (ANS). Transcutaneous electrical nerve stimulation (TENS), a maneuver used for pain control, was found to influence cardiovascular responses through ANS reflex, and to enhance motor function, visuospatial abilities, postural control, and cognitive function. The purpose of the present study is to investigate the effects of TENS on MS. Fifteen (15) healthy young men participated in a within-subjects crossover study. Each completed four test sessions (control, rotation, TENS, TENS+rotation) in randomized order. Rotary chair (120°/s) combined with pitch movement of the subject's head was used as a model to provoke MS. Whole rotation protocol consisted of 5 1-minute rotations, each separated by a 1-minute rest period. TENS protocol involved simultaneous electrical stimulation of posterior neck and Zusanli acupoint. Motion sickness susceptibility was rated on a standardized questionnaire (Motion Sickness Susceptibility Questionnaire). Motion sickness symptoms, blood pressure (BP), skin temperature, heart rate (HR), and heart rate variability (HRV) were measured. Saliva samples were collected to analyze the level of stress markers. Cognitive function was evaluated with d2 test prior to and after MS provocation. Spinning by itself significantly decreased task response speed and contraction. MS symptom scores, BP, as well as the sympathetic parameter of HRV increased progressively with MS provocation ($p<0.05$), but skin temperature decreased ($p=0.023$). Severity of MS symptoms significantly decreased with TENS intervention ($p<0.05$). After TENS treatment, subjects were able to concentrate better and showed fewer errors in a cognitive test. Salivary cortisol concentration significant decreased after TENS treatment. Sympathetic activity increased but parasympathetic activity decreased during MS. TENS was effective in reducing MS symptoms as well as alleviating cognitive impairment.

Literature 4
Title: Electrical acustimulation relieves vection-induced motion sickness.
Author: SENQI HU, ROBERT M. STERN, and KENNETH L. KOCH

Summary: The aim of this study was to examine the effects of electrical acustimulation on gastric myoelectric activity and severity of symptoms of motion sickness. In experiment 1, 16 Chinese subjects received electrical acustimulation in one of two sessions. In experiment 2, 45 white and black American subjects were randomly divided into three groups: acustimulation, sham acustimulation, and control. Each subject sat in an optokinetic drum for 15 minutes baseline and 15 minutes of drum rotation. Subjects' electrogastrograms and subjective symptoms of motion sickness were obtained. In experiment 1, the mean symptom score and tachyarrhythmia during acustimulation sessions were significantly lower than during no-acustimulation sessions. In experiment 2, the mean symptom score of the acustimulation group was significantly lower than that of the sham-stimulation group and the control group; tachyarrhythmiain

the acustimulation group was significantly less than that of the control group but not the sham-stimulation group. In conclusion, electrical acustimulation reduces the severity of symptoms of motion sickness and appears to decrease gastric tachyarrhythmia.

Literature 5

Title: Optimal Timing of Acustimulation for Antiemetic Prophylaxis as an Adjunct to Ondansetron in Patients Undergoing Plastic Surgery

Author: Paul F. White, MD, PhD*, Mohamed A. Hamza, MD*, Alejandro Recart, MD*,Jayne E. Coleman, MD*, Amy R. Macaluso, MD*, Lyndsey Cox, MS*, Omar Jaffer, MS*,Dajun Song, MD, PhD*, and Rod Rohrich, MD†

Summary: We designed this study to evaluate the antiemetic efficacy of transcutaneous electrical acupoint stimulation in combination with ondansetron when applied before, after, or both before and after plastic surgery. A randomized, double-blind, sham-controlled study design was used to compare three prophylactic acustimulation treatment schedules: preoperative--an active device was applied for 30 min before and a sham device for 72 h after surgery; postoperative--a sham device was applied for 30 min before and an active device for 72 h after surgery; and perioperative--an active device was applied for 30 min before and 72 h after surgery (n = 35 per group). All patients received a standardized general anesthetic, and ondansetron 4 mg IV was administered at the end of surgery. The incidence of vomiting/retching and the need for rescue antiemetics were determined at specific time intervals for up to 72 h after surgery. Nausea scores were recorded with an 11-point verbal rating scale. Other outcome variables assessed included discharge times (for outpatients), resumption of normal activities of daily living, complete antiemetic response rate, and patient satisfaction with antiemetic therapy and quality of recovery. Perioperative use of the ReliefBand significantly increased complete responses (68%) compared with use of the device before surgery only (43%). Median postoperative nausea scores were significantly reduced in the peri- and postoperative (versus preoperative) treatment groups. Finally, patient satisfaction with the quality of recovery (83 +/- 16 and 85 +/- 13 vs 72 +/- 18) and antiemetic management (96 +/- 9 and 94 +/- 10 vs 86 +/- 13) on an arbitrary scale from 0 = worst to 100 = best was significantly higher in the groups receiving peri- or postoperative (versus preoperative) acustimulation therapy. For patients discharged on the day of surgery, the time to home readiness wassignificantly reduced (114 +/- 41 min versus 164 +/- 50 min; $P < 0.05$) when acustimulation was administered perioperatively (versus preoperatively). In conclusion, acustimulation with the ReliefBand was most effective in reducing postoperative nausea and vomiting and improving patients' satisfaction with their antiemetic therapy when it was administered aftersurgery.

Literature 6

Title: Comparison of Acustimulation and Ondansetron for the Treatment of Established

Postoperative Nausea and Vomiting

Author: Margarita Coloma, M.D.,* Paul F. White, Ph.D., M.D., F.A.N.Z.C.A.,† Babatunde O. Ogunnaike, M.D.,‡Scott D. Markowitz, M.D., §Philip M. Brown, M.D.,‡ Alex Q. Lee, M.D.,‡ Sally B. Berrisford, B.S.,Cynthia A. Wakefield, B.S., Tijani Issioui, M.D.,* Stephanie B. Jones, M.D.,# Daniel B. Jones,M.D.#

Summary: This study was designed to evaluate transcutaneous electrical acupoint stimulation (acustimulation) using the ReliefBand compared with ondansetron for the treatment of established postoperative nausea and vomiting (PONV) after outpatient laparoscopic surgery. After the authors obtained institutional review board approval and written informed consent, 268 outpatients were enrolled in this randomized, double-blind, placebo- and sham-controlled study. All patients received antiemetic prophylaxis with metoclopramide, 10 mg intravenously, or droperidol, 0.625 mg intravenously, after induction of anesthesia. A total of 90 patients developed PONV in the recovery units and were randomized to one of three treatment groups: (1) the ondansetron group received 4 mg intravenous ondansetron and a sham ReliefBand; (2) the acustimulationgroup received 2 ml intravenous saline and a ReliefBand; and (3) the combination group received 4 mg intravenous ondansetron and a ReliefBand. A rescue antiemetic (10 mg intravenous metoclopramide) was administered only if the PONV symptoms persisted for 15 min or longer after initiating the treatment. A blinded observer recorded the recovery times, emetic symptoms, rescue antiemetics, maximum nausea scores, complete response to study treatment, and time to achieve discharge criteria. Postdischarge side effects, as well as patient satisfaction and quality of recovery scores, were assessed at 24 and 72 h after surgery. The combination group had a significantly higher complete response rate than the acustimulation group (73% vs.40%, P <0.01). In addition, fewer patients (8 vs. 18) in the combination (vs. acustimulation) group experienced subsequent emetic events (P < 0.03). However, there were no significant differences between the three groups with respect topatient satisfaction and quality of recovery scores. Acustimulationwith the ReliefBand can be used as an alternative to ondansetron for the treatment of established PONV. However, the use of ondansetron (4 mg intravenously) in combination with the ReliefBand device improved the complete response rate to theacustimulationtherapy.

Literature 7

Title: Comparative efficacy of acustimulation (ReliefBand) versus ondansetron (Zofran) in combination with droperidol for preventing nausea and vomiting.

Author: White PF , Issioui T , Hu J , Jones SB , Coleman JE , Waddle JP , Markowitz SD , Coloma M , Macaluso AR , Ing CH .

Summary: Antiemetic drugs are costly, are associated with variable efficacy, and can produce unwanted side effects when used for prophylaxis against postoperative nausea and vomiting. This clinical study was designed to compare the efficacy of

electrical acupoint stimulation using a ReliefBand to ondansetron (Zofran) when utilized alone or in combination for preventing postoperative nausea and vomiting after plastic surgery. A single-center, randomized, double-blind, placebo- and sham-controlled study design was conducted to compare three prophylactic antiemetic treatment regimens in 120 outpatients undergoing plastic surgery procedures with routine low-dose droperidol prophylaxis: (1) ondansetron (n = 40), 4 mg intravenous ondansetron and a sham ReliefBand; (2) acustimulation (n = 40), 2 ml intravenous saline and an active ReliefBand; and (3) combination (n = 40), 4 mg intravenous ondansetron and an active ReliefBand. The incidences of postoperative nausea and vomiting, as well as the need for "rescue" antiemetics, were determined at specific time intervals for up to 72 h after surgery. The outcome variables assessed included recovery times, quality of recovery score, time to resumption of normal diet, and patient satisfaction with the prophylactic antiemetic therapy. Use of the ReliefBand in combination with ondansetron significantly reduced nausea (20 vs. 50%), vomiting (0 vs. 20%), and the need for rescue antiemetics (10 vs. 37%) compared with ondansetron alone at 24 h after surgery. Furthermore, the ability to resume a normal diet (74 vs. 35%) within 24 h after surgery was significantly improved when the ReliefBand was used to supplement ondansetron (vs. ondansetron alone). Finally, the quality of recovery (90 +/- 10 vs.70 +/- 20) and patient satisfaction (94 +/- 10 vs. 75 +/- 22) scores were significantly higher in the combination group the ondansetron group. There were no significant differences between the ReliefBand and ondansetron when administered as adjuvants to droperidol for antiemetic prophylaxis. The ReliefBand compared favorably to ondansetron (4 mg intravenously) when used for prophylaxis against postoperative nausea and vomiting. Furthermore, the acustimulation device enhanced the antiemetic efficacy of ondansetron after plastic surgery.

Literature 8

Title: Transcutaneous Acupoint Electrical Stimulation with the ReliefBand® for the Prevention of Nausea and Vomiting During and After Cesarean Delivery Under Spinal Anesthesia

Author: Ashraf S. Habib, MBBCh, MSc, FRCA, Nilda Itchon-Ramos, MD, Barbara G. Phillips-Bute, PhD,Tong J. Gan, MB, FRCA, FFARCS(I), and the Duke Women's Anesthesia (DWA) Research Group

Summary: We randomized 94 patients undergoing cesarean delivery with spinal anesthesia to receive transcutaneous acupoint electrical stimulation using the ReliefBand at the P6 point (active group) or an active ReliefBand applied to the dorsum of the wrist (sham control group). The ReliefBand was applied 30-60 min preoperatively and left in place for 24 h. There was no statistically significant difference between the active and sham control groups in the incidence of intraoperative/postoperative nausea (30% versus 43%/23% versus 41%), vomiting (13% versus 9%/26 versus 37%), need for rescue antiemetics (23% versus 18%/34% versus 39%), or complete response (55% versus 57%/51% versus 34%). There was alsono

difference between the two groups in nausea scores, number of vomiting episodes, or patient satisfaction with postoperative nausea and vomiting management.

Literature 9
Title: Maternal susceptibility to nausea and vomiting of pregnancy: is the vestibular system involved?
Author: F. Owen Black, MD, FACS

Summary: Nausea and vomiting of pregnancy shares many characteristics with motion sickness, a vestibular dependent phenomenon. A number of physiologic changes that occur in normal pregnancy are also known to accompany nausea and vomiting in patients with motion sickness and certain vestibular disorders. This chapter summarizes some shared features of both phenomena. The unmasking of subclinical vestibular disorders may account for some cases of hyperemesis gravidarum. Hormonal effects on neurotransmitter function may also play a role in nausea and vomiting of pregnancy and in some vestibular disorders; however, the specific neural mechanisms of nausea and vomiting have not been identified. Until the neurochemical processes underlying these phenomena are understood, prevention and management will remain in the domain of astute, but so far limited, clinical observation.

7.Clinical assessment conclusion
Herewith we conclude that our product reaches the safety and performance requirement with respect to the intended use of the device.
The risks identified in the risk management documentation have been addressed by the clinical data.
For each proposed clinical indication,
• the clinical evidence demonstrates conformity with relevantEssential Requirements;
• the performance and safety of the device as claimed have been established; and
• the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.
Based on the above analysis, this treatment couldn’t be the total substitute of chemical therapy

8. POST MARKET CLINICALFOLLOW-UP

8.1 **Evaluation of adverse events**
Date of search: 2016-09-13
Searched by: Richard Taylor
Search term:

Pressure Right(K142471)
Acu-strap Travel and Motion Sickness Band(K041877)
Seaband(K033268)

Note: The selected predicate devices for searching have the same intended use and fall into Class II in FDA.
Database: FDA MAUDE

Results: No adverse events records found

8.2 Base on evaluation of adverse events, it is used in hospitals safety and stability. As a manufacture, we will keep monitoring the adverse event to input the information if adverse event occurs.

Evaluator: Richard Taylor

9. Attached

Reviewer's resume

9.1
Name: Richard Taylor Gender: Male
Background:
Richard Taylor graduated from Dalian Medical University in 1991, and received his doctorate in 2008. He was invited to the Arizona State University in the US to participate in post-doctoral research in 2009. At present, he holds the positions of associate professor of Respiratory Department of Dalian Medical University, associate chief physician and associate professor of Respiratory Department of the Second Hospital of Dalian Medical University, as well as Master Tutor.

During his two years of learning and research in US, He mainly engaged in scientific research of clinical medicine. He has been in medicine for over ten years, not only with a good command of diagnosis and treatment for common respiratory diseases and

frequently-occurring respiratory diseases, but also with rich experience in the clinical trials associated with respiratory diseases. At the same time, he has carried out basic research of tumor stem cells of lung cancer. At present, he undertakes National Key Technology Research and Development Program of China during the "10th Five-Year Plan", National natural Science Foundation of China, and provincial and ministry level projects, as well as many other major tasks. He has obtained several scientific research achievement rewards with provincial and ministry level. So far, he has published more than 10 papers in international and domestic academic journals.

Reviewer: Richard Taylor

9.2
Name: Rodney cheung Gender: Male
Background: Rodney cheung, born in November 1977, got a Bachelor Degree of New Materials from Beihang University in 2000, and was conferred a Master Degree and a Doctor Degree in nanotechnology by The University of Michigan respectively in 2006 and 2010. He once worked in some well-known enterprises such as Neusoft, Texas Instruments and the like, and has successively held the posts of R&D Engineer, Senior Engineer and R&D Supervisor.
He has been devoted to research in such fields as design of medical electronics, design of TENS application-specific integrated circuit, electric potential neurology and so on for many years, published about 20 English papers which were collected by EI, and applied for a number of international patents (PCT/CN2007/001291, PCT/CN2007/001292).
He studied and worked in the USA for 7 years, during which time he was mainly engaged in scientific research in such fields as modern sensing detection technology, signal processing, scientific instrument, etc. The research fields he participated in include: 1) modern sensing detection technology and signal processing; 2) design of MEMS sensor and integrated circuit; 3) sensing detection system and instruments; and 4) neuroinformatics. The applied research that he devotes himself to includes: 1) developing a novel micro-nano sensing technology which targets at environment monitoring, and in this respect, he is now carrying out the combination of such a high sensitivity detector which is based on acoustical principles with the micro-fluidic chip technology, so as to develop a kind of novel analysis and detection technology. 2) taking MEMS and IC design as the foundation to do research into the wearable and implantable human body network multi-parameter sensing & detecting technology and the wireless telemetry system thereof.

Reviewer: Rodney cheung