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(12) **United States Design Patent** (10) **Patent No.:** **US D837,394 S**
Cryan et al. (45) **Date of Patent:** **** Jan. 1, 2019**

(54) **TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICE**

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(**) Term: **15 Years**

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(52) **U.S. Cl.**
USPC **D24/200**

(58) **Field of Classification Search**
USPC D24/171, 185, 186, 187, 188, 200, 201, D24/206, 207, 209, 215; D29/101.3, D29/101.5; D3/205, 299; D21/683; 128/95.1, 96.1, 99.1, 845, 846, 112.1; 602/2, 5, 6, 41; 607/1, 48
CPC ... A61N 1/04; A61N 1/06; A61N 1/18; A61N 1/26; A61N 1/36; A61N 1/0424; A61N 1/0484; A61N 1/0456; A61N 1/0452; A61N

(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,327,874 A 8/1943 Jong
D243,417 S 2/1977 Allen et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CN 1919139 A 2/2007
CN 101626804 1/2010

(Continued)

OTHER PUBLICATIONS

Ancoli-Israel, S. et al., The Role of Actigraphy in the Study of Sleep and Circadian Rhythms, Sleep, 2003, 26(3), p. 342-392.

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Primary Examiner — Wan Laymon
Assistant Examiner — Clint A Samuel

(57) **CLAIM**

The ornamental design for a transcutaneous electrical nerve stimulation (TENS) device, as shown and described.

DESCRIPTION

FIG. 1 is a perspective view of the transcutaneous electrical nerve stimulation (TENS) device;

FIG. 2 is a front view of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 1;

FIG. 3 is a rear view of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 1;

FIG. 4 is a side view, in elevation, of one side of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 2;

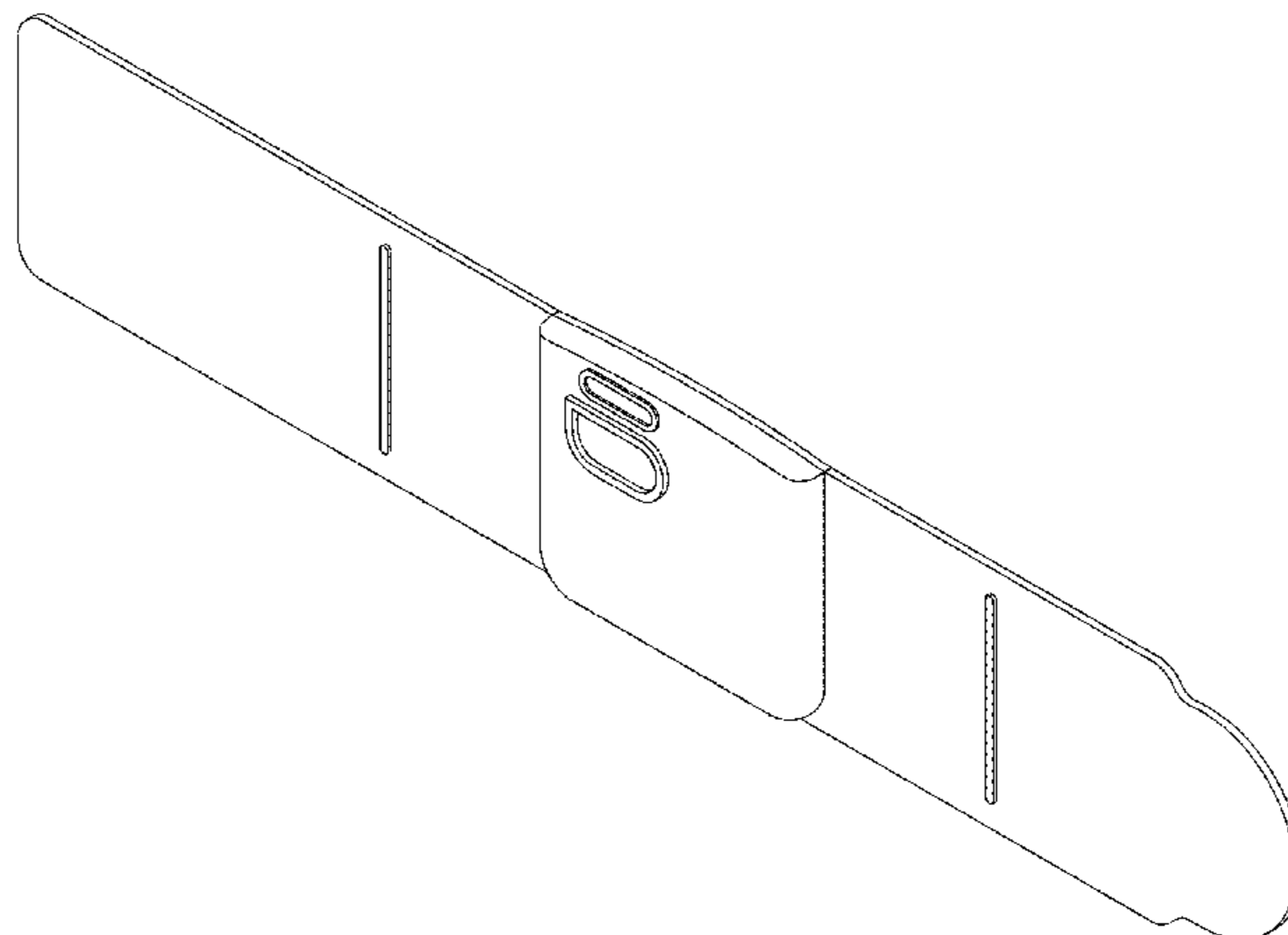
FIG. 5 is a side view, in elevation, of the other side of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 2;

FIG. 6 is an end view, in elevation, of one end of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 2; and,

FIG. 7 is an end view, in elevation, of the other end of the transcutaneous electrical nerve stimulation (TENS) device, taken from the frame of reference of FIG. 2.

The broken lines are included for the purpose of illustrating unclaimed portions of the transcutaneous electrical nerve stimulation (TENS) device and form no part of the claimed design.

1 Claim, 6 Drawing Sheets



(58) **Field of Classification Search**
 CPC 1/0476; A61N 1/36014; A61B 5/00; A61B
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 See application file for complete search history.

(56) **References Cited**
 U.S. PATENT DOCUMENTS

4,033,356 A 7/1977 Hara
 4,121,573 A 10/1978 Crovella et al.
 D255,938 S 7/1980 Hawke et al.
 4,419,998 A 12/1983 Heath
 4,503,863 A 3/1985 Katims
 4,605,010 A 8/1986 McEwen
 4,630,483 A 10/1986 Engdahl
 4,738,250 A 4/1988 Fulkerson et al.
 D299,746 S 2/1989 Guldalian, Jr.
 5,010,896 A 4/1991 Westbrook
 5,063,929 A 11/1991 Bartelt et al.
 5,125,100 A 6/1992 Katznelson
 5,169,384 A 12/1992 Bosniak et al.
 5,327,902 A 7/1994 Lemmen
 5,350,414 A 9/1994 Kolen
 5,487,759 A 1/1996 Bastyr et al.
 5,562,718 A 10/1996 Palermo
 5,755,750 A 5/1998 Petruska et al.
 5,797,902 A 8/1998 Netherly
 5,806,522 A 9/1998 Katims
 5,851,191 A 12/1998 Gozani
 D407,822 S 4/1999 Davis et al.
 5,948,000 A 9/1999 Larsen et al.
 5,991,355 A 11/1999 Dhalke
 6,132,386 A 10/2000 Gozani et al.
 6,141,587 A 10/2000 Mower
 6,146,335 A 11/2000 Gozani
 6,161,044 A 12/2000 Silverstone
 6,266,558 B1 7/2001 Gozani et al.
 6,298,255 B1 10/2001 Cordero et al.
 6,312,392 B1 11/2001 Herzon
 6,430,450 B1 8/2002 Bach-y-Rita et al.
 6,456,884 B1 9/2002 Kenney
 D475,138 S 5/2003 Baura et al.
 6,662,051 B1 12/2003 Eraker et al.
 D484,984 S * 1/2004 Takizawa D24/189
 D534,871 S * 1/2007 Larsen D13/162
 7,459,984 B2 12/2008 Wang et al.
 D584,414 S * 1/2009 Lash D24/187
 D598,114 S 8/2009 Cryan
 D600,352 S 9/2009 Cryan
 D609,353 S 2/2010 Cryan
 7,668,598 B2 2/2010 Horregraven et al.
 7,720,548 B2 5/2010 King
 7,725,193 B1 5/2010 Chu
 7,760,428 B2 7/2010 Sieckmann
 D625,016 S * 10/2010 Potts D24/155
 7,844,325 B2 11/2010 Takehara
 7,917,201 B2 3/2011 Gozani et al.
 D638,131 S 5/2011 Buckels et al.
 8,108,049 B2 1/2012 King
 8,121,702 B2 2/2012 King
 8,131,374 B2 3/2012 Moore et al.
 D669,186 S 10/2012 Gozani
 D669,187 S 10/2012 Gozani
 8,320,988 B2 11/2012 Axelgaard
 8,421,642 B1 4/2013 Mcintosh et al.
 D704,848 S * 5/2014 Thomas D24/200
 D712,052 S * 8/2014 Thomas D24/200
 D713,049 S * 9/2014 Shah D24/200
 8,825,175 B2 9/2014 King
 8,862,238 B2 10/2014 Rahimi et al.
 8,948,876 B2 2/2015 Gozani et al.
 9,168,375 B2 10/2015 Ratlimi et al.
 9,173,581 B2 11/2015 Boettcher et al.
 D745,975 S * 12/2015 Igaue D24/206
 9,220,431 B2 12/2015 Holzhacker

D746,987 S 1/2016 Okuda et al.
 D754,355 S 4/2016 Ganapathy et al.
 D760,395 S 6/2016 Barbaric et al.
 9,452,287 B2 9/2016 Rosenbluth et al.
 9,474,898 B2 10/2016 Gozani et al.
 D775,361 S * 12/2016 Vosch D24/187
 9,656,070 B2 5/2017 Gozani et al.
 9,675,801 B2 6/2017 Kong et al.
 9,730,606 B2 8/2017 Bianchi
 9,731,126 B2 8/2017 Ferree et al.
 D798,170 S * 9/2017 Toth D10/65
 9,827,420 B2 11/2017 Ferree et al.
 D810,311 S * 2/2018 Chen D24/200
 D810,952 S * 2/2018 Hsu D24/200
 2002/0010497 A1 1/2002 Merfeld et al.
 2002/0173828 A1 11/2002 Gozani et al.
 2003/0023192 A1 1/2003 Foxlin
 2003/0035506 A1 2/2003 Tybinkowski et al.
 2003/0074037 A1 4/2003 Moore et al.
 2003/0093006 A1 5/2003 Wells et al.
 2003/0114892 A1 6/2003 Nathan et al.
 2003/0208246 A1 11/2003 Kotlik et al.
 2004/0017895 A1 1/2004 Suzuki et al.
 2004/0231772 A1 11/2004 Leonard et al.
 2005/0059903 A1 3/2005 Izumi
 2005/0080463 A1 4/2005 Stahmann et al.
 2005/0083527 A1 4/2005 Flaherty et al.
 2005/0234525 A1 10/2005 Phillips
 2006/0020291 A1 1/2006 Gozani et al.
 2006/0052788 A1 3/2006 Thelon et al.
 2006/0085049 A1 4/2006 Cory et al.
 2006/0095088 A1 5/2006 De Ridder
 2006/0173507 A1 8/2006 Mrva et al.
 2006/0190057 A1 8/2006 Reese
 2007/0041507 A1 2/2007 Kendall et al.
 2007/0060922 A1 3/2007 Dreyfuss
 2007/0129771 A1 6/2007 Kurtz et al.
 2007/0149892 A1 6/2007 Guldalian
 2007/0185409 A1 8/2007 Wu et al.
 2007/0219441 A1 9/2007 Carlin et al.
 2007/0276449 A1 11/2007 Gunter et al.
 2008/0077192 A1 3/2008 Harry et al.
 2008/0146980 A1 6/2008 Rouso et al.
 2008/0147146 A1 6/2008 Wahlgren et al.
 2008/0288026 A1 11/2008 Cross et al.
 2008/0306400 A1 12/2008 Takehara
 2008/0312551 A1 12/2008 Fadern
 2008/0312709 A1 12/2008 Volpe et al.
 2009/0030476 A1 1/2009 Hargrove
 2009/0105795 A1 4/2009 Minogue et al.
 2009/0112214 A1 4/2009 Philippon et al.
 2009/0131993 A1 5/2009 Rouso et al.
 2009/0209840 A1 8/2009 Axelgaard
 2009/0240303 A1 9/2009 Wahlstrand et al.
 2009/0264789 A1 10/2009 Molnar et al.
 2009/0270947 A1 10/2009 Stone et al.
 2009/0326604 A1 12/2009 Tyler et al.
 2010/0004715 A1 1/2010 Fahey
 2010/0042180 A1 2/2010 Mueller et al.
 2010/0057149 A1 3/2010 Fahey
 2010/0087903 A1 4/2010 Van Herk et al.
 2010/0094103 A1 4/2010 Kaplan et al.
 2010/0114257 A1 5/2010 Torgerson
 2010/0128851 A1 5/2010 Bailey et al.
 2010/0131028 A1 5/2010 Hsu et al.
 2010/0198124 A1 8/2010 Bhugra
 2010/0217349 A1 8/2010 Fahey
 2010/0241464 A1 9/2010 Amigo et al.
 2011/0066209 A1 3/2011 Bodlaender et al.
 2011/0106214 A1 5/2011 Carbanaru et al.
 2011/0224665 A1 9/2011 Crosby et al.
 2011/0257468 A1 10/2011 Oser et al.
 2011/0264171 A1 10/2011 Torgerson
 2011/0276107 A1 11/2011 Simon et al.
 2011/0282164 A1 11/2011 Yang et al.
 2012/0010680 A1 1/2012 Wei et al.
 2012/0016259 A1 1/2012 Odderson
 2012/0108998 A1 5/2012 Molnar et al.
 2012/0226186 A1 9/2012 Baars et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2013/0096641	A1	4/2013	Strother et al.	
2013/0158627	A1	6/2013	Gozani et al.	
2013/0197341	A1*	8/2013	Grob	A61N 1/0472 600/391
2013/0317333	A1*	11/2013	Yang	A61B 5/00 600/372
2014/0039450	A1	2/2014	Green et al.	
2014/0107729	A1	4/2014	Sumners et al.	
2014/0163444	A1	6/2014	Ingvarsson et al.	
2014/0206976	A1*	7/2014	Thompson	A61B 5/0006 600/391
2014/0276549	A1	9/2014	Osorio	
2014/0296934	A1	10/2014	Gozani et al.	
2014/0296935	A1	10/2014	Ferree et al.	
2014/0309709	A1	10/2014	Gozani et al.	
2014/0336730	A1	11/2014	Simon et al.	
2014/0379045	A1	12/2014	Rahimi et al.	
2015/0038873	A1	2/2015	Boettcher et al.	
2015/0045853	A1	2/2015	Alataris et al.	
2015/0148865	A1	5/2015	Gozani et al.	
2015/0174402	A1	6/2015	Thomas et al.	
2015/0238094	A1*	8/2015	Lai	A61B 5/0002 600/301
2015/0306387	A1	10/2015	Kong et al.	
2015/0321000	A1	11/2015	Rosenbluth et al.	
2015/0328467	A1	11/2015	Demers et al.	
2015/0335288	A1	11/2015	Toth et al.	
2016/0120425	A1	5/2016	Boettcher et al.	
2016/0271413	A1	9/2016	Vallejo et al.	
2017/0036015	A1	2/2017	Gozani et al.	
2017/0056643	A1	3/2017	Herb et al.	
2017/0188872	A1*	7/2017	Hughes	A61B 5/04087
2017/0209693	A1*	7/2017	An	A61N 1/36014
2017/0224990	A1*	8/2017	Goldwasser	A61N 1/36025
2017/0312515	A1	11/2017	Ferree et al.	
2017/0368345	A1*	12/2017	Kong	A61N 1/0456
2018/0015285	A1	1/2018	Gozani et al.	
2018/0028808	A1	2/2018	Ferree et al.	

FOREIGN PATENT DOCUMENTS

CN	102355847	2/2012
CN	102740919	2/2012
DE	102010052710	5/2012
JP	60-41851	3/1985
JP	S60-194933	10/1985
JP	61-171943	10/1986
JP	4-347140	12/1992
JP	9-117453	5/1997
JP	2000-167067	6/2000
JP	2005-34402	2/2005
JP	2005-81068	3/2005
JP	2006-68300	3/2006
JP	4185846	9/2008
WO	WO 97/42999	11/1997
WO	WO 99/64105	12/1999
WO	WO 00/09999	2/2000
WO	WO 2003/051453	6/2003
WO	WO 2004/078132	9/2004
WO	WO 2007/061746	5/2007
WO	WO 2008/079757	7/2008
WO	WO 2008/088985	7/2008
WO	WO 2011/075179	6/2011
WO	WO 2011/137193	11/2011
WO	WO 2012/037527	3/2012
WO	WO 2012/116407	9/2012
WO	WO 2013/074809	5/2013
WO	WO 2014/161000	10/2014
WO	WO 2014/172381	10/2014
WO	WO 2016/111863	7/2016

OTHER PUBLICATIONS

Barbarisi, Manlio et al., Pregabalin and Transcutaneous Electrical Nerve Stimulation for Postherpetic Neuralgia Treatment, *The Clinical Journal of Pain*, Sep. 2010;26(7):567-572.

Bjordal JM et al., Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain, *European Journal of Pain*, 2003, vol. 7(2): 181-188.

Bloodworth DM et al., Comparison of stochastic vs. conventional transcutaneous electrical stimulation for pain modulation in patients with electromyographically documented radiculopathy. *American Journal of Physical Medicine & Rehabilitation*, 2004, vol. 83(8): 584-591.

Chandran P et al., Development of opioid tolerance with repeated transcutaneous electrical nerve stimulation administration, *Pain*, 2003, vol. 102: 195-201.

Chen CC et al, A comparison of transcutaneous electrical nerve stimulation (TENS) at 3 and 80 pulses per second on cold-pressor pain in healthy human participants, *Clinical Physiology and Functioning Imaging*, 2010, vol. 30(4): 260-268.

Chen CC et al., 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*, 2009, vol. 10(10): 1029-1037.

Chen CC et al., Differential frequency effects of strong nonpainful transcutaneous electrical nerve stimulation on experimentally induced ischemic pain in healthy human participants, *The Clinical Journal of Pain*, 2011, vol. 27(5): 434-441.

Chen CC et al., Does the pulse frequency of transcutaneous electrical nerve stimulation (TENS) influence hypoalgesia? A systematic review of studies using experimental pain and healthy human participants, *Physiotherapy*, 2008, vol. 94: 11-20.

Claydon LS et al., Dose-specific effects of transcutaneous electrical nerve stimulation on experimental pain, *Clinical Journal of Pain*, 2011, vol. 27(7): 635-647.

Cole, R.J. et al., Automatic Sleep/Wake Identification From Wrist Activity, *Sleep*, 1992, 15(5), p. 461-469.

Cruccu G. et al., EFNS guidelines on neurostimulation therapy for neuropathic pain, *European Journal of Neurology*, 2007, vol. 14: 952-970.

Davies Hto et al., Diminishing returns or appropriate treatment strategy?—an analysis of short-term outcomes after pain clinic treatment, *Pain*, 1997, vol. 70: 203-208.

Desantana JM et al., Effectiveness of transcutaneous electrical nerve stimulation for treatment of hyperalgesia and pain, *Curr Rheumatol Rep*. 2008, vol. 10(6): 492-499.

Dubinsky RM et al, Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review): Report of the therapeutics and technology assessment subcommittee of the american academy of neurology, *Neurology*, 2010, vol. 74: 173-176.

Fary RE et al., Monophasic electrical stimulation produces high rates of adverse skin reactions in healthy subjects, *Physiotherapy Theory and Practice*, 2011, vol. 27(3): 246-251.

Fishbain, David A. et al. Does Pain Mediate the Pain Interference with Sleep Problem in Chronic Pain? Findings from Studies for Management of Diabetic Peripheral Neuropathic Pain with Duloxetine, *Journal of Pain Symptom Management*, Dec. 2008;36(6):639-647.

Fishbain, David A. et al., Transcutaneous Electrical Nerve Stimulation (TENS) Treatment Outcome in Long-Term Users, *The Clinical Journal of Pain*, Sep. 1996;12(3):201-214.

Food and Drug Administration, Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief, Apr. 5, 2010.

Garrison DW et al., Decreased activity of spontaneous and noxiously evoked dorsal horn cells during transcutaneous electrical nerve stimulation (TENS), *Pain*, 1994, vol. 58: 309-315.

Gilron, I. et al., Chronobiological Characteristics of Neuropathic Pain: Clinical Predictors of Diurnal Pain Rhythmicity, *The Clinical Journal of Pain*, 2013.

Hori, T. et al., Skin Potential Activities and Their Regional Differences During Normal Sleep in Humans, *The Japanese Journal of Physiology*, 1970, vol. 20, p. 657-671.

(56)

References Cited

OTHER PUBLICATIONS

- Jelinek HF et al., Electric pulse frequency and magnitude of perceived sensation during electrocutaneous forearm stimulation, *Arch Phys Med Rehabil*, 2010, vol. 91; 1372-1382.
- Jin DM et al., Effect of transcutaneous electrical nerve stimulation on symptomatic diabetic peripheral neuropathy: a meta-analysis of randomized controlled trials, *Diabetes Research and Clinical Practice*, 2010, vol. 89: 10-15.
- Johnson MI et al., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, *Pain*, 1989, vol. 39: 231-236.
- Johnson MI et al., Transcutaneous Electrical Nerve Stimulation (TENS) and TENS-like devices: do they provide pain relief?, *Pain Reviews*, 2001, vol. 8: 7-44.
- Johnson MI et al., Transcutaneous electrical nerve stimulation for the management of painful conditions; focus on neuropathic pain, *Expert Review of Neurotherapeutics*, 2011, vol. 11(5): 735-753.
- Johnson, M.I. et al., An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS. *Pain*. Mar. 1991;44(3):221-229.
- Kaczmarek, Kurt A. et al., Electrotactile and Vibrotactile Displays for Sensory Substitution Systems. *IEEE Trans. Biomed. Eng.* Jan. 1991;38 (1):1-16.
- Kantor G et al., The effects of selected stimulus waveforms on pulse and phase characteristics at sensory and motor thresholds, *Physical Therapy*, 1994, vol. 74(10): 951-962.
- Keller, Thierry et al., Electrodes for transcutaneous (surface) electrical stimulation. *J. Automatic Control*; University of Belgrade. 2008;18(2):35-45.
- Koumans, A. J. R. et al., Electrodermal Levels and Fluctuations During Normal Sleep, *Psychophysiology*, 1968, 5(3), p. 300-306.
- Kripke, D.F. et al., Wrist Actigraphic Scoring for Sleep Laboratory Patients: Algorithm Development, *Journal of Sleep Research*, 2010, 19(4), p. 612-619.
- Law PPW et al., Optimal stimulation frequency of transcutaneous electrical nerve stimulation on people with knee osteoarthritis, *J Rehabil Med*, 2004, vol. 36: 220-225.
- Leonard G et al., Deciphering the role of endogenous opioids in high-frequency TENS using low and high doses of naloxone, *Pain*, 2010, vol. 151: 215-219.
- Levy et al., A comparison of two methods for measuring thermal thresholds in diabetic neuropathy, *Journal of Neurology, Neurosurgery, and Psychiatry*, 1989, vol. 52: 1072-1077.
- Lykken, D.T., Properties of Electrodes Used in Electrodermal Measurement, *J. Comp. Physiol. Psychol.* Oct. 1959;52:629-634.
- Lykken, D.T., Square-Wave Analysis of Skin Impedance. *Psychophysiology*. Sep. 1970;7(2):262-275.
- Melzack R et al., Pain mechanisms: A New Theory, *Science*, 1965, vol. 150(3699): 971-979.
- Moran F et al., Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity, *The Journal of Pain*, 2011, vol. 12(8): 929-935.
- Oosterhof, Jan et al., Outcome of transcutaneous electrical nerve stimulation in chronic pain: short-term results of a double-blind, randomised, placebo-controlled trial. *J. Headache Pain*. Sep. 2006;7 (4):196-205.
- Oosterhof, Jan et al., The long-term outcome of transcutaneous electrical nerve stimulation in the treatment for patients with chronic pain: a randomized, placebo-controlled trial. *Pain Pract.* Sep. 2012;12(7):513-522.
- Pantaleao MA et al., Adjusting pulse amplitude during transcutaneous electrical nerve stimulation (TENS) application produces greater hypoalgesia, *The Journal of Pain*, 2011, vol. 12(5): 581-590.
- Paquet, J. et al., Wake Detection Capacity of Actigraphy During Sleep, *Sleep*, 2007, 30(10), p. 1362-1369.
- Pieber K et al., Electrotherapy for the treatment of painful diabetic peripheral neuropathy: a review, *Journal of Rehabilitation Medicine*, 2010, vol. 42: 289-295.
- Raskin, J. et al., A Double-Blind, Randomized Multicenter Trial Comparing Duloxetine with Placebo in the Management of Diabetic Peripheral Neuropathic Pain, *Pain Medicine*, 2005, 6(5), p. 346-356.
- Sadeh, A., The Role and Validity of Actigraphy in Sleep Medicine: An Update, *Sleep Medicine Reviews*, 2011, vol. 15, p. 259-267.
- Sadosky, A. et al., Burden of Illness Associated with Painful Diabetic Peripheral Neuropathy Among Adults Seeking Treatment in the US: Results from a Retrospective Chart Review and Cross-Sectional Survey, *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, 2013, vol. 6, p. 79-92.
- Scherder, E. J. A. et al., Transcutaneous Electrical Nerve Stimulation (TENS) improves the Rest-Activity Rhythm in Midstage Alzheimer's Disease, *Behavioral Brain Research*, 1999. vol. 101, p. 105-107.
- Tryon, W. W., Issues of Validity in Actigraphic Sleep Assessment, *Sleep*, 2004, 27(1), p. 158-165.
- Tsai, Y. et al., Impact of Subjective Sleep Quality on Glycemic Control in Type 2 Diabetes Mellitus, *Family Practice*, 2012, vol. 29, p. 30-35.
- Van Boxtel, A., Skin resistance during square-wave electrical pulses of 1 to 10 mA. *Med. Biol. Eng. Comput*, Nov. 1977;15(6):679-687.
- Van Someren, E. J. W. et al., Gravitational Artefact in Frequency Spectra of Movement Acceleration: Implications for Actigraphy in Young and Elderly Subjects. *Journal of Neuroscience Methods*, 1996, vol. 65, p. 55-62.
- Webster, J. B. et al., An Activity-Based Sleep Monitor System for Ambulatory Use, *Sleep*, 1982, 5(4), p. 389-399.
- Zelman, D. C. et al., Sleep Impairment in Patients With Painful Diabetic Peripheral Neuropathy, *The Clinical Journal of Pain*, 2006, 22(8), p. 681-685.
- Aurora, R. et al., The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults an Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses, *Sleep*, 2012, vol. 35, No. 8, p. 1039-1062.
- Bonnet, M, et al., Recording and Scoring Leg Movements, *Sleep*, 1993, vol. 16, No. 8, p. 748-759.
- Boyle, J. et al., Randomized, Placebo-Controlled Comparison of Amitriptyline, Duloxetine, and Pregabalin in Patients With Chronic Diabetic Peripheral Neuropathic Pain, *Diabetes Care*, 2012, vol. 35, p. 2451-2458.
- Kovacevic-Ristanovic, R. et al., Nonpharmacologic Treatment of Periodic Leg Movements in Sleep, *Arch. Phys. Med. Rehabil.*, 1991, vol. 72, p. 385-389.
- Lopes, L. et al., Restless Legs Syndrome and Quality of Sleep in Type 2 Diabetes, *Diabetes Care*, 2005, vol. 28, No. 11, p. 2633-2636.
- Nightingale, S., The neuropathic pain market. *Nature Reviews*, 2012, vol. 11, p. 101-102.
- Zucconi, M. et al., The official World Association of Sleep Medicine (WASM) standards for recording and scoring periodic leg movements in sleep (PLMS) and wakefulness (PLMW) developed in collaboration with a task force from the International Restless Legs Syndrome Study Group (IRLSSG), *Sleep Medicine*, 2005, vol. 7, p. 175-183.
- Dailey D.L. et al., Transcutaneous Electrical Nerve Stimulation Reduces Pain, Fatigue and Hyperalgesia while Restoring Central Inhibition in Primary Fibromyalgia, *Pain*, Nov. 2013, vol. 154, No. 11, pp. 2554-2562.

* cited by examiner

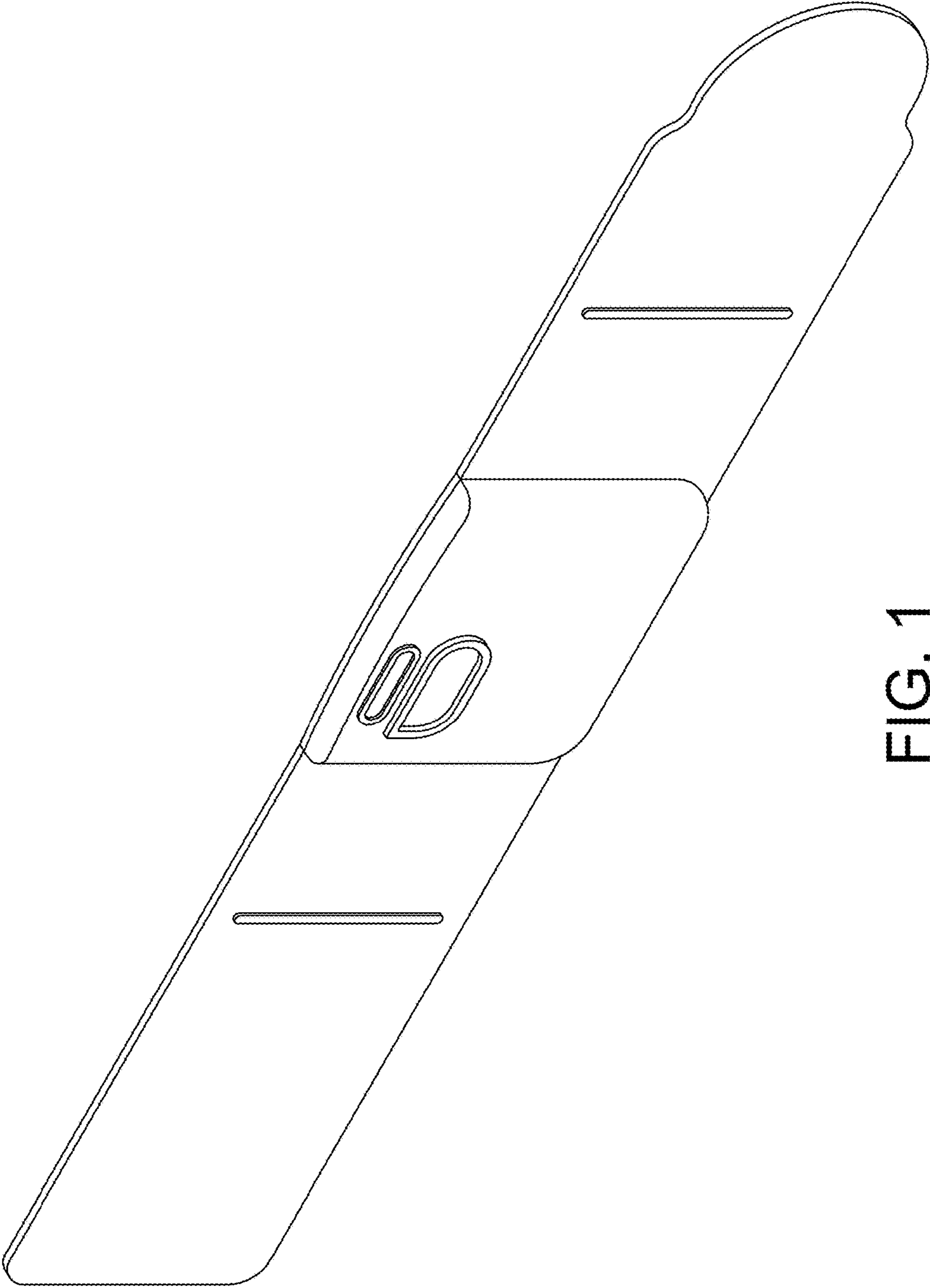


FIG. 1

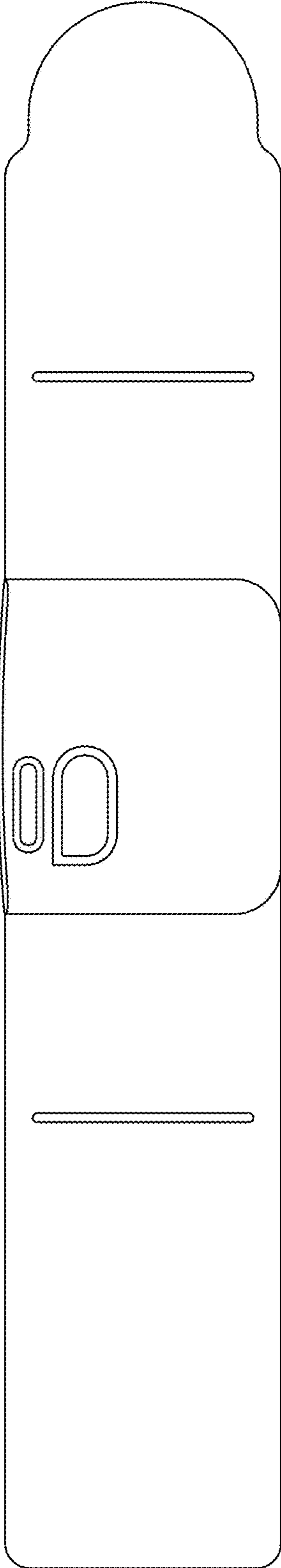


FIG. 2

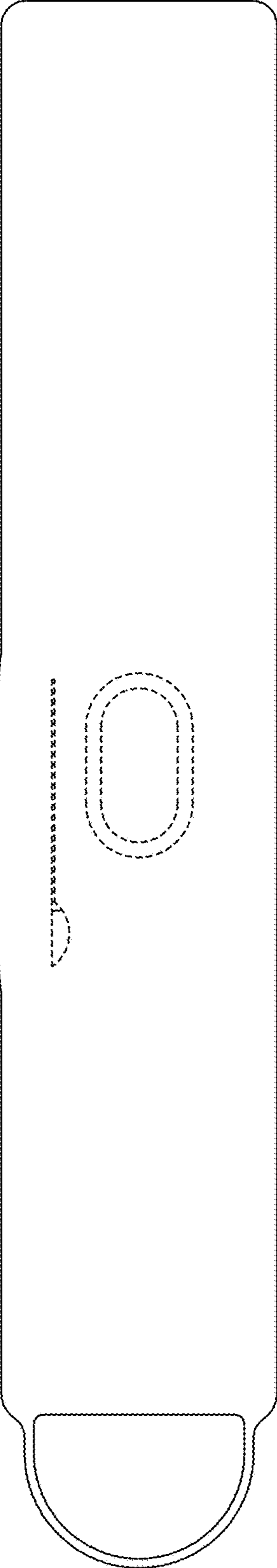


FIG. 3



FIG. 4



FIG. 5



FIG. 7

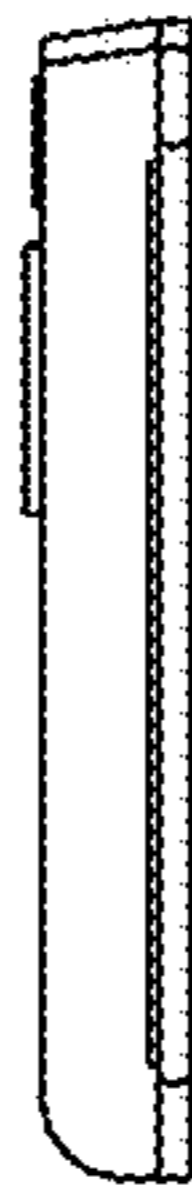


FIG. 6