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A prospective efficacy study comparing FREquency of use and Efficacy of a personalized surgery-free wearable and personalized bladder modulation system with objective confirmation of nerve activation for use in the home by subjects with OverActive Bladder syndrome

FREEOAB Study

Protocol Number	AMHOAB2001
Version Number	V 2, February 15, 2021

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Protocol Signature Page

Study Title: A prospective efficacy study comparing frequency of use of a surgery-free wearable and personalized bladder modulation system with objective confirmation of nerve activation for use in the home by subjects with overactive bladder syndrome.

Protocol Number: AMHOAB2001

Version: V 2.0, February 15, 2021

Investigator's Statement

I agree to conduct this clinical investigation in accordance with the design and specific provisions of this protocol; modifications to the study are acceptable only with a mutually agreed upon protocol amendment as approved by the Sponsor and ethics review board. I agree to await ethics review board approval of the protocol and informed consent before initiating the study, to obtain consent from participants prior to their enrollment in the study, to collect and record data as required by the protocol and case report forms, and to maintain study documents for the period of time required.

Confidential

This document contains confidential information belonging to Avation Medical except as may be otherwise agreed to in writing, by accepting or reviewing these materials, I agree to hold such information in confidence and not to disclose it to others (except where required by applicable law), nor use it for unauthorized purposes.

Investigator's Signature	**Date of Signature**

Table of Contents

1. Abbreviations and Definitions

Term	Definition
BOTOX	Botulinum toxin
CRF	Case Report Form
DCF	Data Clarification Form
EMG	Electromyography
IIQ-7	Incontinence Impact Questionnaire – Short Form
I-QOL	Incontinence Quality of Life
ISF	Investigator Site File
OAB	Overactive Bladder
OAB-q	Overactive Bladder questionnaire
OHQ	Oxford Happiness Questionnaire
PGIC	Patient's Global Impression of Change
PTNS	Percutaneous Tibial Nerve Stimulation
SAE	Serious Adverse Event
SNS	Sacral Nerve Stimulation
UUI	Urge Urinary Incontinence
WiFi	Wireless Fidelity

2. Protocol Summary

Title	A prospective efficacy study comparing frequency of use and efficacy of a surgery-free wearable personalized bladder modulation system with objective confirmation of nerve activation for use in the home by subjects with Overactive Bladder syndrome.
Test Article	Avation Medical's surgery-free wearable and personalized bladder modulation system that provides objective confirmation of nerve activation, can be used in a home environment, and is controlled with a tablet-based application
Protocol Number	AMHOAB2001
Objectives	• To compare the effectiveness of 1 treatment session per week to 3 treatment sessions per week on OAB symptoms using the Test Article. • To evaluate the overall effectiveness. • To evaluate any side effects of the Test Article. • To evaluate the tolerability, usability, and satisfaction of the Test Article. • To evaluate the compliance of subjects using the Test Article.
Subject Population	Subjects diagnosed with OAB.
Population Size	80 completed subjects
Number of Centers	Up to 12 sites
Structure	Prospective open label study, 12-week treatment duration with an optional additional 21-month long-term follow-up period, for a total participation time of 24 months.
Method of Assignment	All subjects who meet the inclusion/exclusion criteria and sign the informed consent will be enrolled. Subjects will be randomized to once a week or three times a week of stimulation for a twelve-week period. Eligible subjects that elect to enroll in the long-term follow up study will sign a new informed consent and then be instructed to slowly taper down their treatment frequency stepwise from three treatment sessions per week, to two per week, to one per week, and finally one session every other week. The subjects that were assigned to one treatment session per week in the lead-in portion of the study will move directly to twice monthly treatment sessions. Subjects will then be instructed to perform treatments as needed or a minimum of twice per month.

Randomization	1:1, 1 treatment session per week: 3 treatment sessions per week
Selection Criteria	**Inclusion Criteria**: To be eligible for study entry, subjects must satisfy all of the following inclusion criteria: 1. Male or female and 18 years of age or older at the time of enrollment 2. Willing and capable of giving informed consent 3. Willing and able to comply with study-related requirements and procedures 4. Are an appropriate candidate for the study Test Article based on the clinical judgment of the Investigator. 5. Have been diagnosed or have symptoms of OAB for at least 3 months prior to enrollment 6. Have an average of 10 or more frequency events per day in a 3-Day Bladder Diary 7. Able to provide clear, thoughtful responses to questions and questionnaires 8. Able to toilet self and have and maintain personal hygiene 9. Able to don and doff the bladder modulation garment on their ankle area, replace Gel Pads and use the controller 10. Have ankle and foot anatomy that allows the garment to fit properly, including having the hook and loop closures close and without excessive gapping and allowing the electrodes to fit firmly on the skin. 11. Able to sense and tolerate stimulation for the entire 30-minute therapy session 12. Has detectable EMG signal in response to modulation system stimulation during an investigator supervised screening session 13. If currently on medications that may affect their OAB symptoms, is on a stable dose (no new, discontinued, or change in dose) of all prescribed medication for at least 4 weeks prior to enrollment 14. Female subjects of child-bearing potential must have a negative urine dip stick pregnancy test at baseline 15. Have access to Wi-Fi at least weekly 16. Are capable of using the tablet-based controlling app

	Exclusion Criteria: Subjects will be excluded from the study if 1 or more of the following exclusion criteria are applicable: 1. Have evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance of intervention and/or ability to evaluate treatment outcomes, in the opinion of the investigator. 2. Allergic, or have shown hypersensitivity, to any materials of the system which come into contact with the body 3. Have a pacemaker or implanted defibrillator 4. Have a documented current or reoccurring Urinary Tract Infection (3 or more in the 12months prior to enrollment) 5. Current use of a marketed device for treatment of their OAB or incontinence (including but not limited to Interstim®) 6. Have had Botox treatment for their OAB in the previous 8 months 7. Current use of TENS in pelvic region, back or legs 8. Had PTNS treatment within 6 months prior to enrollment 9. Use of investigational drug/device therapy within past 12 weeks 10. Current participation in another clinical study 11. Had within 6 months of enrollment a significant untreated substance abuse disorder or polysubstance abuse disorder stemming from dependency producing medications, alcohol, and/or illicit drugs 12. Pregnant or planning to become pregnant within the next 12 weeks 13. Has scar tissue, metal, or other implant in the target ankle that would interfere with stimulation 14. Has a neurological disorder that causes abnormal sensations in the lower leg (loss of sensation or allodynia) 15. Has a neurological disorder that affects the bladder or a diagnosis of interstitial cystitis, radiation cystitis, or fistulas. 16. Has a skin condition in the area of the ankle stimulation location that would preclude them from using surface stimulation 17. Has been diagnosed with incontinence due to neurogenic bladder 18. Have failed a third line treatment for their OAB because of lack of effectiveness in the last 2 years (PTNS, Botox, or SNS) 19. Urge incontinence due to stress predominant mixed urinary incontinence (greater that 60% of the time) 20. Have polyuria (>2500 cc urine output per day) 21. Has urinary retention or incomplete bladder emptying 22. Has symptoms of benign prostatic hyperplasia (weak stream, straining, hesitancy, or intermittency)

Study design	Subjects that have signed the Informed Consent Form and meet all applicable eligibility criteria will be randomized 1:1 to 30-minute stimulation treatments either once a week or three times a week over a treatment period of 12 weeks. Subjects will return to the clinic at 1-, 4-, 8-, and 12-weeks post-baseline for visit assessments listed in the Schedule of Activities. Investigative sites may elect to have some visits completed remotely via use of ePRO for visit questionnaires. On weeks where a subject does not have an in-clinic visit, they will be contacted by phone and queried for health and medication changes and any device issues. At the end of the first 12 weeks of stimulation, subjects will return to the clinic for final assessments, then will either enroll in the long-term follow up phase, if eligible, or exit from the study.
Statistical Methods	Analyses will be performed within both the intent-to-treat (ITT) population of all enrolled patients and among the subset of patients who complete the study. Patients may be missing endpoint data at one or more, or possibly all, post-screening time points, at which endpoint data will be provided by carrying forward the most recent observation. Enrollment will continue until 80 patients complete the study. Expecting 15% dropout, the anticipated total enrollment will be approximately 94 patients.

3. Introduction

Overactive bladder is a stressful and disruptive chronic disorder that affects more than 16% of the adult population [1], an estimated 42 million adults in the just the United States alone. The symptoms of OAB cause millions of individuals to suffer with a decrease in their quality of life and put them at increased risk of falls, bone fractures due to falls and higher rates of anxiety and depression

OAB is characterized by four symptoms; urgency, frequency, nocturia, and urge incontinence[2]. Urgency is the complaint of a sudden, irresistible desire to pass urine which often is difficult to resist. Frequency is the number of voids per day. In OAB, there are usually 8 or more voiding episodes during waking hours. Nocturia is the number of voids per night. In OAB, the complaint of sleep interruption due to the need to void is 1+ times, per night. Urge incontinence is the involuntary leakage of urine, associated with sudden compelling desire to void. In order to be diagnosed, these symptoms or a combination of them, must be present without a pathologic or metabolic component causing them[3].

According to the American Urological Association, the first line of treatment is behavioral therapy. These therapies include the use of exercises, timed voiding, and fluid monitoring. This approach may be effective for some, but many patients are not compliant, and they do not see consistent relief of symptoms [2]. The next line of treatment is medications. Medication can be effective in around 70% of patients but they can produce significant side effects and are cost prohibitive[4] . Further, more than 70% of patients quit drug therapy within 6 months making longer term compliance an issue [5]. Third line therapies include Botulinum toxin (BT), PTNS, and SNS. BT can also be effective in up to 70% of cases; however, 39.8% of all who discontinued therapy, did so because of the side effects, including the risk or urinary retention [2]. The full effect of BT treatment is temporary and requires additional procedures every 4 to 9 months. PTNS is found to be around 55-70% effective, minimally invasive, and has very little side effects, but is temporary and requires frequent visit to the clinic (once a week) which may be difficult for patients who work full time or those who must travel a long distance to reach a provider [6] [7]. SNS is typically regarded as the most effective treatment at 85%, but it is also the most invasive[8]. SNS requires a surgical implant which may cause a series of adverse events. Further, the currently available neuromodulation options are open-loop and do not provide objective confirmation that the target nerve is being reached.

In summary, while there are many treatment options available to manage symptoms associated with OAB, each carry with it considerable drawbacks for patients. Patients drop out of the treatment pathway for OAB in great numbers. Further, of the 42 million adults in the United States estimated to have OAB, fewer than 500,000 have opted for neuromodulation treatment due to the need for surgery or temporary insertion as well as inconvenience, despite demonstrated clinical evidence.

There is a compelling clinical need for better treatment options that are not only effective and safe but also convenient, accessible, and have a minimal side effect profile. There is a need for a surgery-free and drug-free easy-to-use wearable system that allows patients to treat their chronic OAB symptoms when and where it is convenient for them and one that offers an objective confirmation that the neuromodulation target has been reached and one that automatically adjusts based on the patient's anatomy and movement during treatment sessions.

This study will evaluate the clinical efficacy, subject compliance, side-effects, and subject satisfaction of a surgery-free wearable and personalized bladder modulation system that provides personalized treatment through objective confirmation of nerve recruitment and can used in the home by subjects suffering from the symptoms of OAB.

4. Objectives

- To compare the effectiveness of 1 treatment session per week to 3 treatment sessions per week on OAB symptoms using the Test Article.
- To evaluate the overall effectiveness
- To evaluate any side effects of the Test Article.
- To evaluate the tolerability, usability, and satisfaction of the Test Article.
- To evaluate the compliance by subjects using the Test Article.

5. Study Design

This is a prospective, multicenter study comparing the effectiveness of 1 treatment session per week to 3 treatment sessions per week using the Test Article on subjects diagnosed with OAB in a home environment.

After subjects have signed informed consent, they will undergo two screening evaluations. The first evaluation will involve examining the data collected during a 3-day bladder diary. The second evaluation will involve evaluation of the EMG signal produced while using the Test Article. Once the subject has met all eligibility and screening criteria, they will be enrolled in the study. Subjects will be randomized to once a week or three times a week of therapy. Demographic and baseline measurements will be taken including quality of life questionnaires and OAB questionnaires. All subjects will be given the Test Article and instructed on its use. All stimulation parameters will be personalized for the subject and within the commercially approved levels.

Subjects will be asked to use the Test Article either once (1) or three (3) times a week for thirty (30) minutes each time over a 12-week period. Subjects will either return to the clinic or have a remote visit (via phone/video conferencing) after one (1) week ± 2 days, four (4) weeks ± 4 days, eight (8) weeks ± 4 days, and twelve (12) weeks ± 4 days for evaluations. Subjects will be called by the site on the weeks they do not have a study visit and queried for any changes to health and medications, as well as address any questions or issues. If a subject needs additional training on use of any Test Article components, they will be asked to either return to the clinic or undergo troubleshooting

instructions over the phone. At the end of the twelve (12) weeks ± 4 days of stimulation treatments, eligible subjects will be offered the opportunity to participate in the long-term follow up portion of the study. Ineligible subjects and those that decline participation in the long-term portion will exit from the study and the Test Article will be collected by the site. Subjects electing to enroll in the follow up study will sign a new informed consent and then be instructed to taper down their treatment frequency stepwise from three treatment sessions per week, to two per week, to one per week, and finally one session every other week. The subjects that were assigned to one treatment session per week in the lead-in portion of the study will move directly to twice monthly treatment sessions. Subjects will then be instructed to perform treatments as needed or a minimum of twice per month.

5.1. Purpose

The purpose of this study is to compare the efficacy, usability, safety, and comfort of 1 treatment session per week to 3 treatment sessions per week using the Test Article on subjects with OAB. This study will also help to evaluate the dose response of two different dose levels to aid in the development of a larger scale study to evaluate the safety and effectiveness of the Test Article.

5.2. Study Rationale

Electrical stimulation has been used to treat chronic pain for several decades. This includes placing electrodes over the spinal cord, in deep brain structures, and over nerves in the periphery. Stimulation has also been used to treat disorders that are not pain related such as Parkinson's disease, epilepsy, and depression. Recently, SNS and PTNS have been used to modulate bladder function and treat subjects with OAB and provided some relief of OAB symptoms. However, currently commercial options for bladder modulation are invasive and have significant drawbacks that have limited their appeal to patients. SNS requires a major surgery, is costly and results in a permanent foreign body implant and, frequently, additional surgeries to replace batteries or address other issues PTNS requires a skin puncture and requires the Subject to travel to a physician's office weekly for therapy. Of the estimated 42 million adults in the United States with OAB, fewer than 500,000 are estimated to have been treated with commercially available neuromodulation options despite evidence of clinical efficacy.

The Test Article can be used in the home and offers personalized treatment through objective confirmation of nerve activation. It is noninvasive, eliminating the risk of surgery, and minimizes the inconvenience of frequent visits to the physician's office. This study will evaluate the tolerability, usability and satisfaction of the Test Article on subjects with OAB. Further, the study will also evaluate the use of evoked EMG signals to help control the Test Article and customize the stimulation experience for each subject.

6. Subject Selection

Selection Criteria	**Inclusion Criteria**: To be eligible for study entry, subjects must satisfy all of the following inclusion criteria: 1. Male or female and 18 years of age or older at the time of enrollment 2. Willing and capable of giving informed consent 3. Willing and able to comply with study-related requirements and procedures 4. Are an appropriate candidate for the system required in this study based on the clinical judgment of the Investigator. 5. Have been diagnosed or have symptoms of OAB for at least 3 months prior to enrollment 6. Have an average of 10 or more frequency events per day in a 3-Day Bladder Diary 7. Able to provide clear, thoughtful responses to questions and questionnaires 8. Able to toilet self and have and maintain personal hygiene 9. Able to don and doff the bladder modulation garment on their ankle area, replace Gel Pads and use the controller 10. Have ankle and foot anatomy that allows the garment to fit properly, including having the hook and loop closures close and without excessive gapping and allowing the electrodes to fit firmly on the skin. 11. Able to sense and tolerate stimulation for the entire 30-minute therapy session 12. Has detectable EMG signal in response to modulation system stimulation during an investigator supervised screening session 13. If currently on medications that may affect their OAB symptoms, is on a stable dose (no new, discontinued, or change in dose) of all prescribed medication for at least 4 weeks prior to enrollment 14. Female subjects of child-bearing potential must have a negative urine dip stick pregnancy test at baseline 15. Have access to Wi-Fi at least weekly 16. Are capable of using the tablet-based controlling app

	Exclusion Criteria: Subjects will be excluded from the study if 1 or more of the following exclusion criteria are applicable: 1. Have evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance of intervention and/or ability to evaluate treatment outcomes, in the opinion of the investigator. 2. Allergic, or have shown hypersensitivity, to any materials of the system which come into contact with the body. 3. Have a pacemaker or implanted defibrillator. 4. Have a documented current or reoccurring Urinary Tract Infection (3 or more in the 12 months prior to enrollment). 5. Current use of a marketed device for treatment of their OAB or incontinence (including but not limited to Interstim®). 6. Have had botulinum toxin treatment for their OAB in the previous 8 months. 7. Current use of TENS in pelvic region, back or legs. 8. Had PTNS treatment within 6 months prior to enrollment. 9. Use of investigational drug/device therapy within past 12 weeks. 10. Current participation in another clinical study. 11. Had within 6 months of enrollment a significant untreated substance abuse disorder or polysubstance abuse disorder stemming from dependency-producing medications, alcohol, and/or illicit drugs. 12. Pregnant or planning to become pregnant within the next 12 weeks. 13. Has scar tissue, metal, or other implant in the target ankle that would interfere with stimulation. 14. Has a neurological disorder that causes abnormal sensations in the lower leg (loss of sensation or allodynia). 15. Has a neurological disorder that affects the bladder or a diagnosis of interstitial cystitis, radiation cystitis, or fistulas. 16. Has a skin condition in the area of the ankle stimulation location that would preclude them from using surface stimulation. 17. Has been diagnosed with incontinence due to neurogenic bladder. 18. Have failed a third line treatment for their OAB because of lack of effectiveness in the last 2 years (PTNS, botulinum toxin, or SNS). 19. Urge incontinence due to stress-predominant mixed urinary incontinence (greater that 60% of the time) 20. Have polyuria (>2500 cc urine output per day) 21. Has urinary retention or incomplete bladder emptying 22. Has symptoms of benign prostatic hyperplasia (BPH) - weak stream, straining, hesitancy or intermittency.

6.1. Subject Assignment to Treatment and Masking

Each subject complying with the inclusion/exclusion criteria who is willing to participate in the study, and signs the informed consent, will be enrolled. At baseline subjects will be randomized to use the system for 30 minutes either one (1) time per week or three (3) times per week for a total of 12 weeks. All subjects will independently complete stimulation treatment sessions; no blinding will occur

7. Methods and Procedures

7.1. Informed Consent

Written Informed Consent will be obtained from each subject prior to any study procedures being performed. All potential subjects will be properly informed as to the purpose of the study and the potential risks and benefits known or that can be reasonably predicted or expected. The Investigator will retain the original copy of the Informed Consent Form signed by the subject; a duplicate will be provided to the subject. Only the consent form approved by the ethics committee will be used.

7.2. Visit Schedule

	Study Visit	Tele-visit
Screening 1	Visit 0	
Screening 2/ Baseline	Visit 1	
Week 1	Visit 2	optional
Week 2		X (Weekly Phone Call)
Week 3		X (Weekly Phone Call)
Week 4	Visit 3	optional
Week 5		X (Weekly Phone Call)
Week 6		X (Weekly Phone Call)
Week 7		X (Weekly Phone Call)
Week 8	Visit 4	optional
Week 9		X (Weekly Phone Call)
Week 10		X (Weekly Phone Call)
Week 11		X (Weekly Phone Call)
Week 12	Visit 5	

7.3. Pre-Screening

Potential study candidates will be initially pre-screened by the investigator prior to screening and enrollment according to the Inclusion and Exclusion criteria.

7.4. Visit 0 - Screening 1 (Informed Consent and Diary Distribution)

This visit involves the review and signing of the Informed Consent, eligibility criteria review, and distribution of a 3-day Bladder Diary.

Step	Action
1.	Subjects will be informed of the study and review the informed consent.
2.	Subjects will be given a 3-day Bladder Diary to take home and complete within 3 days leading up to their scheduled Visit 1.
Note	Only subject that sign the informed consent will be given the 3-day Bladder Diary.

7.5. Visit 1 - Screening 2 (EMG evaluation)

This procedure will evaluate if EMG signals can be recorded during stimulation of the tibial nerve with the wearable bladder modulation system.

Step	Action
1.	Screening evaluations will be collected including (using a 3-day Bladder Diary): 1. Number of daytime voids 2. Number of urge events 3. Number of nighttime voids 4. Number of urge incontinence events
Note	Only subjects that meet the inclusion/exclusion criteria with regard to the Bladder Diary will proceed to EMG testing.
2.	Only delegated, qualified, site personnel will instruct the subject on how to place the Test Article on the foot and ankle area.
3.	Once the Test Article is placed, site personnel will use the Test Article to stimulate the tibial nerve, evaluate EMG signals and instruct the subject how to use the Test Article.
4.	The subject will be asked to rate various sensations experienced during the stimulation therapy.
5.	Subject will be enrolled in the study and given a subject ID.
Note	Only subjects that have a detectable EMG and find the stimulation sensation tolerable will be eligible for enrollment.

7.6. Visit 1- Baseline Evaluations

These evaluation procedures outline the baseline evaluation that will take place before a subject begins stimulation therapy. These procedures can also be done during the Screening 2 / Baseline visit.

Step	Action
1.	The inclusion and exclusion criteria will be confirmed as being met
2.	Demographic information will be collected.
3.	OAB questionnaires will be completed including: 1. OAB-q 2. IIQ-7 (only for those with incontinence) 3. I-QoL 4. and OHQ
4.	Subjects will be randomized 1:1 to perform 30-minute stimulation sessions once per week or three times per week for the 12-week treatment period.

7.7. Visit 1- System fitting and training

This procedure outlines the training that will take place before the subject begins stimulation.

Step	Action
1.	The subject will be fitted for the Test Article.
2.	The subject be given instruction by site personnel as to how to use the Test Article.
3.	Once the Test Article is placed, the subject will use the controller to start the stimulator to activate the tibial nerve (trial session should not exceed 15 minutes).
4.	The subject will be asked questions regarding the feeling of Test Article during use and the ease of use of the Test Article.
5.	Subjects will be given a new 3-day Bladder Diary to complete in the days leading up to the next scheduled study visit.

7.8. Visit 2 - Week 1 ± 2 days

This visit will be scheduled after 1 week of therapy for evaluations. This visit may be performed remotely via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 1 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed.
4.	The subject will be asked questions regarding the feeling of the therapy and ease of use of the Test Article.
6.	Subjects will be given a new 3-day Bladder Diary to complete in the days leading up to the next scheduled study visit.

7.9. Visit 3 - Week 4 ± 4 days

This visit will be scheduled after 4 weeks of therapy for evaluations. This visit may be performed remotely via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 2 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed: 1. OAB-q 2. IIQ-7 3. I-QoL 4. PGIC
4.	The subject will be asked questions regarding the feeling of the therapy and ease of use of the Test Article.
5.	Subjects will be given a new 3-day Bladder Diary to complete in the days leading up to the next scheduled study visit.

7.10. Visit 4 - Week 8 ± 4 days

This visit will be scheduled after 8 weeks of therapy for evaluations. This visit may be performed remotely via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 3 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed
4.	Subjects will be given a new 3-day Bladder Diary to complete in the days leading up to the next scheduled study visit.

7.11. Visit 5 – Week 12 ± 4 days

This visit will be scheduled after 12 weeks of stimulation for final evaluations.

Step	Action
1.	Subjects will be queried for AE/SAE or changes to concomitant medications.
2.	The 3-day Bladder Diary dispensed at Visit 4 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed, including the Study Exit Form.
4.	The subject will be asked questions regarding the feeling of the therapy and ease of use of the Test Article.
5.	Subjects will either exit from the study or be given the option to enroll in the long-term follow-up study, if eligible.

7.12. Visit Schedule for Lead-in Phase

	Visit 0	Visit 1	Visit 2	Week 2 Week 3		Visit 3	Week 5 Week 6 Week 7			Visit 4	Week 9 Week 10 Week 11			Visit 5
Informed Consent	X													
3-day Bladder Diary (a,b)	X	X	X			X				X				X
EMG Detection Trial		X (c)												
Inclusion/Exclusion Check		X												
Medical History		X												
Test Article Assessment Form		X												
Device Training		X												
OAB-q		X				X								X
IIQ-7		X				X								X
I-QoL		X				X								X
PGIC			X			X				X				X
OHQ		X												X
Study Visit Form			X			X				X				X
Exit Form														X
Weekly Phone Call				X	X		X	X	X		X	X	X	
a - 3-Day Bladder Diary to be dispensed at Visit 0, Visit 1, Visit 2, Visit 3, and Visit 4.														
b - 3-Day Bladder Diary to be collected at Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5.														
c - EMG Detection trial to be performed after review of Bladder Diary from Visit 0, and before any other visit procedures														

8. Long-Term Follow-Up Phase

8.1. Subject Selection

Selection Criteria	**Inclusion Criteria**: To be eligible for entry into the long-term follow-up portion of the study, subjects must satisfy all the following inclusion criteria: 1. Successful completion of the lead-in portion of the FREEOAB study 2. A rating of 5 or greater on the PGIC questionnaire at Visit 5 3. A minimum compliance of 90% with diary and questionnaire completion 4. A minimum compliance of 80% with stimulation sessions during the lead-in portion of the FREEOAB study. **Exclusion Criteria**: Subjects will be excluded from participation if the following exclusion criteria are met: 1. Any change in health status that might affect the subject's ability to comply with the visit schedule, assessments, and/or stimulation session completion.

8.2. Informed Consent

Written Informed Consent will be obtained from each subject before recruitment into the long-term follow-up portion of the FREEOAB trial. All potential subjects will be properly informed as to the purpose and the potential risks and benefits known or that can be reasonably predicted or expected. The Investigator will retain the original copy of the Informed Consent Form signed by the subject; a duplicate will be provided to the subject. Only the consent form approved by the ethics committee will be used.

8.3. Visit Schedule

	Study Visit (in-clinic)	Remote/Tele-visit
Enrollment	Visit 6	
Month 6		Visit 7
Month 9		Visit 8
Month 12	Visit 9	Optional
Month 18		Visit 10
Month 24	Visit 11	

8.4. Visit 6 - Enrollment

This procedure will occur at the completion of Visit 5/Week 12 of the lead-in portion of the FREEOAB study. Eligible subjects will sign a new Informed Consent Form. (Visit 5 and 6 may occur on the same day)

Step	Action
1.	Eligible subjects that elect to enroll in the long-term follow up study will sign a new informed consent form.
2.	Subjects will be given detailed instructions to begin an augmented treatment schedule, based on original treatment group assignment in the lead-in portion of the study. • Subjects will be instructed to slowly taper down their treatment frequency stepwise from three treatment sessions per week, to two per week, to one per week, and finally one session every other week. • Subjects that were assigned to one treatment session per week in the lead-in portion will move directly to twice monthly treatment sessions.
3.	Subjects will be given a new 3-day Bladder Diary to complete within 3 days leading up to their next scheduled visit.

8.5. Visit 7 - (Month 6 ± 14 days of stimulation)

Visit 7 will occur after 6 months of treatment (including lead-in portion of the FREEOAB study). This visit may be conducted remotely, via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 6 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed
4.	Subjects will be given a new 3-day Bladder Diary to complete within 3 days leading up to their next scheduled visit.

8.6. Visit 8 – (Month 9 ± 14 days of stimulation)

Visit 8 will occur after 9 months of treatment (including lead-in portion of the FREEOAB study) . This visit may be conducted remotely, via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 7 will be collected and reviewed
3.	Applicable visit forms and questionnaires will be completed

4.	Subjects will be given a new 3-day Bladder Diary to complete within 3 days leading up to their next scheduled visit.

8.7. Visit 9 – (Month 12 ± 14 days of stimulation)

Visit 9 will occur after 12 months of treatment (including lead-in portion of the FREEOAB study).This visit may be conducted remotely via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 8 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed.
4.	Subjects will be given a new 3-day Bladder Diary to complete within 3 days leading up to their next scheduled visit.

8.8. Visit 10 – (Month 18 ± 14 days of stimulation)

Visit 10 will occur after 18 months of stimulation (including lead-in portion of the FREEOAB study). This visit may be conducted remotely via ePRO.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 9 will be collected and reviewed.
3.	Applicable visit forms and questionnaires will be completed
4.	Subjects will be given a new 3-day Bladder Diary to complete within 3 days leading up to their next scheduled visit.

8.9. Visit 11 – (Month 24 ± 14 days of stimulation) – End of Study

Visit 11 will occur after 24 months of stimulation.

Step	Action
1.	Subjects will be queried for AE/SAE or concomitant medication changes.
2.	The 3-day Bladder Diary dispensed at Visit 8 will be collected and reviewed
3.	Applicable visit forms and questionnaires will be completed
4.	Subjects will return their study equipment and supplies to the site staff and exit the from the study.

8.10. Unscheduled Visits

Unscheduled visits are permitted to occur as needed, for the purposes of resolving issues, AE/SAE follow up, and may be performed remotely or in-clinic, depending on the reason for the visit.

8.11. Visit Schedule for Long-Term Follow-Up Phase

	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
Study Phase	**enrollment**	**Month 6**	**Month 9**	**Month 12**	**Month 18**	**Month 24**
Informed Consent	X					
3-day Bladder Diary (a,b)	X	X	X	X	X	X
Inclusion/Exclusion Check	X					
OAB-q				X		X
IIQ-7				X		X
I-QoL				X		X
PGIC		X	X	X	X	X
OHQ				X		X
Study Visit Form	X	X	X	X	X	X
Exit Form						X
a - 3-Day Bladder Diary to be dispensed at Visit 6, Visit 7, Visit 8, Visit 9, and Visit 10.						
b - 3-Day Bladder Diary to be collected at Visit 7, Visit 8, Visit 9, Visit 10, and Visit 11.						

9. Outcome Variables

All outcome variables will be collected by the investigator.

9.1. Demographics

Basic subject demographics will be collected such as height, weight, race, and ethnicity.

9.2. Study Visit Form

This form asks questions regarding comfort, tolerability, and satisfaction of the Test Article as well as comfort and tolerability of the therapy.

9.3. Test Article Assessment Form

The subject will be asked several questions regarding the Test Article, specifically ease of use and comfort.

9.4. IIQ-7

The IIQ-7 questionnaire asks subjects about areas of their life that may have been influenced or changed by incontinence. It looks at its effect on activities, relationships, and feelings.

9.5. I-QOL

The incontinence quality of life questionnaire is used to assess the quality of life in subjects with urinary incontinence due to neurogenic detrusor overactivity [5].

9.6. OAB-q

This questionnaire asks about how much you have been bothered by selected bladder symptoms during the past 4 weeks.

9.7. PGIC

The Subject global impression of change evaluates all aspects of Subjects' health and assesses if there has been an improvement or decline in clinical status.

9.8. OHQ

This questionnaire assesses the level of happiness experienced by the Subject by asking them to rate a series of statements based on their level of agreement.

10. Test Article

The Test Article consists of a garment, a stimulator, gel pads, a controller, and charging system.

10.1. Garment , Stimulator, Charger, and Gel Pads

The Garment is worn on the foot and ankle area to provide a comfortable and convenient method of holding the electrodes in the desired location and a place to hold the stimulator. The stimulator unit can be easily removed to allow recharging. Replaceable gel pads are located inside the Garment to improve skin contact. Gel Pads can be replaced. The stimulator will have and on/off button and LED's to indicate Bluetooth connection status and battery level.

Figure 1 Wearable tibial nerve stimulation garment with built-in stimulating and sensing electrodes, fits left & right ankles

10.2. Material

Article	Material
Garment	Neoprene
Stimulator and Charger	3D Printed Plastic (ABS-Like)
Gel Pads	Hydrogel

10.3. Stimulation Specifications

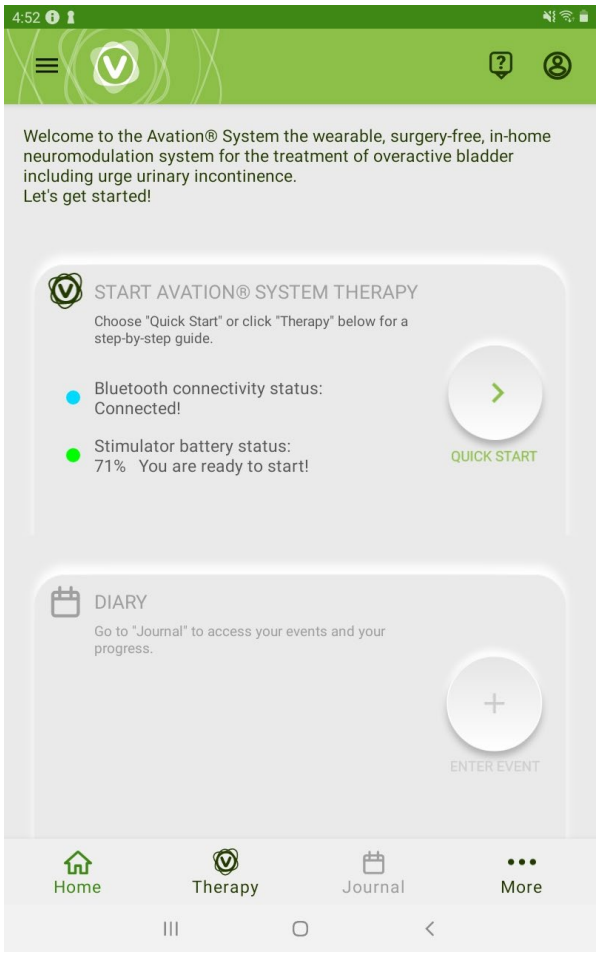
Parameters	Technical Description
Pulse Type	Charged balanced biphasic
Output	Current-controlled
Number of stimulation electrodes	2 (one cathode, one anode)

Number of recording electrodes	3 (two differential inputs, one reference input)
Maximum current amplitude	40 mA
Maximum output voltage	200 V
Maximum pulse width per phase	800 us
Maximum pulse frequency	20 Hz
Worst-case current density per phase	7.8 mA/ cm^2
Worst-case charge density per phase	3.1 uC/cm^2
Power Source	Lithium-ion battery
Connection to mains power	None

10.4. Controller

The Stimulator will be controlled using an application on a tablet. This tablet will be supplied by the Sponsor and will only be enabled as a controller for the stimulator.

The controller application will have screens which will allow both the physician and subject to easily interact with the stimulator. Data collected by the stimulator will be transmitted to a HIPAA-compliant cloud to allow the investigators and Sponsor to easily review the subject's usage of the system while completing their treatment sessions at home. This will also allow troubleshooting to take place without a visit to the office.



11. Regulatory Status

The Test Article is not approved for sale in any country.

12. Safety and adverse events

12.1. Definitions

Adverse Events (AE)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device.
Serious Adverse Events (SAE)	A current adverse event that worsened or the occurrence of a new adverse event that: a) led to death b) led to serious deterioration in the health of the subject, that either resulted in: 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function, or 3) in-patient or prolonged hospitalization, or 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function c) led to fetal distress, fetal death or a congenital abnormality or birth defect
Unanticipated Adverse Device Effect (UADE)	Adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

12.2. AE Recording

All AEs or UADEs volunteered by the subjects or elicited by the Investigator must be recorded on the appropriate AE CRF. In accordance with the medical device incident reporting and investigation scheme (IRIS) (in the US follow 21 CFR 812.150(a)(l)), an Investigator shall submit to the Sponsor and IRB a report of any UADE occurring during the investigation as soon as possible, but no later than 10 days after the Investigator first learns of the event. Unanticipated Serious Adverse Device Effect (USADEs) will be reported to the regulatory authorities as required. This report must be confirmed by using the AE source documentation and eCRF data.

12.3. Reporting AEs

Qualified investigators and research staff will closely and carefully monitor study participants for all anticipated and any unanticipated adverse events. All serious and device related adverse events or device deficiency should be recorded on the appropriate case report form. All adverse events will be reported from the moment a consented participant is in contact with the study device, through to participant study exit. Investigational sites will be asked to report the final medical diagnosis as an AE, rather than reporting all signs and symptoms as separate events.

It is the responsibility of the investigator to decide when an adverse event has occurred. Adverse event information will be collected throughout the study. Adverse events will be recorded on the appropriate CRF by the investigator or study coordinator. Event, date of onset, severity, duration and relationship to the procedure or device will be recorded.

In case of a serious adverse event (whether or not related to the investigational device), or an unanticipated adverse device effect, the investigator should complete the applicable SAE CRF pages within 24 hours of being made aware of the event and begin the reporting process. If the case report form cannot be completed within 24 hours, the Investigator should advise the Sponsor by other means, within 24 hours.

The Sponsor will assist the site with reporting any SAEs to the reviewing ethics committee, according to their requirements and timelines.

All SAEs and UADEs must be reported to and reviewed by the Sponsor.

NOTE: As applicable, reports must only identify participants using the study's unique identifier to protect confidentiality.

Non-serious AEs should be reported at the next routine contact.

12.4. Anticipated Adverse Events and Complications

The anticipated AEs associated with using the Test Article include:

1. Pain at the stimulation site.
2. Allergic reaction.
3. Changes in skin color (reddening) under the electrode.

12.5. AE Classification

The Investigator will classify each AE according to the Adverse Event Form. If the AE is serious or the Investigator feels that the device contributed in any way to the AE, the Investigator must report the event to the Sponsor.

13. Data Analysis, Evaluation and Statistical Plan

13.1. Analysis Populations

Analyses will be performed within both the intent-to-treat (ITT) population of all enrolled patients and among the subset of patients who complete the study. Patients may be missing endpoint data at one or more, or possibly all, post-screening time points, at which endpoint data will be provided by carrying forward the most recent observation. Enrollment will continue until 80 subjects complete the study. Expecting 15% dropout, the anticipated total enrollment will be approximately 94 patients.

13.2. Analysis of Efficacy and Sample Size

Using data collected at each of Study Visits 2, 3, and 4, percent change from screening at each time point will be calculated for each patient with respect to frequency of OAB symptoms, including 3-day daily averages of daytime voids, urge events, nighttime voids, and urge incontinent events. The maximum percent improvement across the four symptoms will also be calculated at each time point as a composite endpoint. Percent improvement in daily average total voids relative to an upper normal limit of 8, will also be calculated, and will be bounded below at 0% for patients not achieving improvement and bounded above at 100% for patients achieving or surpassing the upper normal limit of 8. Longitudinal analyses will be performed using repeated measures models to assess and describe trends over time with respect to these endpoints. At individual time points, the one-sample T-test will be performed at significance level $\alpha=0.05$ within each treatment group and for the pooled study groups to assess the mean percent improvements, with 95% confidence intervals for mean percent improvements also calculated. The percent change endpoints are not likely to have approximately normal distributions, but the sample size is considered sufficient such that mean values will be approximately normally distributed, justifying the use of the T-tests. If there is concern with the distributions, then the Wilcoxon signed rank test will be used as an alternative to the one-sample T-test.

Sample size is evaluated by the performance of the 95% confidence interval for mean percent improvement percent improvement in daily average total voids relative to an upper normal limit of 8. Log ratios of daily average event frequencies at post-screening time points relative to the daily average event frequencies at baseline, which are mathematically related to the percent changes from baseline, are more likely than percent changes to have approximately normal distributions. If such log ratios are normally distributed so that in both treatment groups the median percent improvement (toward zero) in daily average total voids is 15% and so that 25% of patients will achieve a 50% improvement, then with a total evaluable sample size of 80 patients completing the study, there is an estimated 95.6% power to conclude that the mean percent improvement in daily average total voids relative to an upper normal limit of 8 is 25% or larger using the 95% confidence interval. Within each treatment group of size n=40, there is an estimated 90.8% power to conclude that the mean percent improvement in daily average total voids relative to an upper normal limit of 8 is 20% or larger using the 95% confidence interval.

Two-sample T-tests performed at a significance level $\alpha=0.05$ will be used to compare the treatment groups with respect to mean percent improvements in frequency of OAB symptoms, and with respect to results of OAB questionnaires. If there is concern with the non-normality of the distributions of these endpoints, then the Wilcoxon rank sum test will be used as an alternative to the two-sample T-test. Linear models will be constructed as extensions of the one-sample and two-sample T-tests to allow for assessments of mean percent improvements and group comparisons with covariate adjustments.

Frequencies of responders at individual time points and over all time points will also be calculated, where a responder for a given OAB symptom is defined as a subject achieving 50% improvement in frequency, and a responder for the composite collection of OAB symptoms is defined as a subject achieving 50% improvement in frequency for at least one symptom frequency. The treatment groups will be

compared with respect to response frequencies using chi-square of Fisher's exact tests, and exact 95% binomial confidence intervals will be calculated.

13.3. Analyses of Tolerability, Usability, and Satisfaction

Subject responses to questions regarding tolerability, usability, and satisfaction, will be tabulated.

13.4. Analyses of Safety

All adverse events will be collected as they occur and tabulated.

14. Withdrawal of Subjects from Study

Subjects may be discontinued from the study for non-treatment-related reasons only when no other option is possible. Reasons for discontinuation include, but are not necessarily limited to:

1. Voluntary withdrawal from the study by the subject.
2. Subject is unwilling or unable to cooperate with study requirements.
3. Subject has an adverse event such that they can no longer continue with stimulation.

The reason for discontinuation will be recorded on the appropriate subject Withdrawal form. Discontinued subjects may not be replaced in the study.

Prior to discontinuing a subject, every effort should be made to contact the subject in an effort either to get the subject back into compliance with the protocol, or to obtain as much follow-up data as possible.

15. Modification of Protocol

Any amendments to this protocol must be prepared by the Study Monitor and approved by Avation Medical, the Investigator, and the central or local authority (IRB/IEC) before implementation.

16. Discontinuation of Study

Avation Medical reserves the right to discontinue any study for administrative reasons at any time, such as but not limited to, a decision to discontinue further clinical investigations with the Test Article, improper conduct of the Study by the Investigator, inability to obtain the number of subjects required by the protocol, etc. Reimbursements for reasonable expenses will be made if such action is necessary.

17. Identified Risks

The Avation Medical Risk Management Procedure was used during the development of the protocol. This procedure complies with ISO 14971:2012 and ensures hazards are identified for which risks are assessed, designed out, mitigated, or labeled. Where residual risks remain high, risk/benefit analysis has been conducted.

All identified risks have been designed out, mitigated or disclosed with labeling.

17.1. Justification for study given risk/benefit outcomes

PTNS has been used to treat patients with OAB. It requires that a needle electrode be inserted through the patient's skin to provide stimulation to the tibial nerve near the inner ankle. PTNS therapy is performed in a doctor's office one time a week for a 30-minute session for 12 weeks in a doctor's office. Successful patients are then required to continuing therapy at least once a month to maintain success. There have been recent studies that have indicated that stimulating more often may be beneficial. PTNS protocols rely on a toe twitch to confirm the correct placement of the needle at the beginning of the session. Once the therapy session begins stimulation is typically reduced below toe twitch. Thus, in most cases there is no means of objectively confirming nerve recruitment during the therapy session. In those patients where stimulation cannot be increased to the level of a toe twitch, there is no objective confirmation of tibial nerve stimulation.

The current study involves testing a surgery-free and non-invasive wearable bladder modulation system in the home by subjects with OAB. In addition, the System, through sensors incorporated into the modulation garment, provide objective confirmation of tibial nerve activation at the beginning and through the modulation therapy which provides personalized treatment for each patient. The Test Article provides several benefits over PTNS. First, it is wearable eliminating any risks associated with a needle puncture. Second, it allows the patient to perform their therapy in their home, eliminating the need for weekly and monthly travel to a physician's office. Third, it will provide objective confirmation that the active tibial nerve stimulation is automatically adjusting the personalized stimulation level for each subject. The study will involve stimulating for 30 minutes transcutaneously over the tibial nerve, either 1 day or 3 days per week for a total of 12 weeks. The main risks to subjects participating in this study is the potential for skin irritation at the electrode site. We anticipate that the risk of pain in this study to be minimal. In the event of pain, the subject can stop the stimulation or continue at a reduced level. As a result of participating in this study, subjects may experience a temporary reduction in their OAB symptoms. Data collected from this study will help in the development of a new therapy to treat their OAB which may benefit them in the future

This study will compare two treatment frequencies, one session a week or three sessions a week for a 12-week treatment period, followed by an optional additional 21-month long-term follow-up phase. Pre-validation and pre-verification testing were done to ensure system functionality and safety for this study. There were no cadaver or animal model testing done with the Test Article. Voltage tests were done to ensure that the Stimulator would stay within the set voltage parameters. Testing was done to ensure the Test Article could run properly for the full 30-minute treatment duration.

Biocompatible materials were chosen for this system to reduce any allergic reactions.

The risks to subjects participating in this study are minimal. Although subjects may see some temporary improvement, there is minimal benefit in participating in this study. The data collected in this study will be used to support the 510K clearance of the Test Article.

17.2. Justification of study design

Electrical stimulation of peripheral nerves has been used to manage chronic pain, Parkinson's disease, epilepsy, and other neurological disorders. These treatments include placing electrodes over the spinal cord, in deep brain structures, and over nerves in the periphery, etc. Recently, PTNS has been used to treat subject with OAB. PTNS is thought to modify the signals from the bladder to achieve it effect, it usually takes 5-7 weeks for symptoms to change. However, patients respond at different rates. In a review of about 100 patients who responded to PTNS, onset of symptom relief began anywhere between 2-12 weeks after starting treatment. For about 20% of these patients, some symptoms didn't improve until after 8 weeks [1]. However, PTNS therapy is performed only in a doctor's office during weekly visits and requires that a needle-electrode is blindly inserted through the patient's skin near their inner ankle. A non-invasive transcutaneous system that can be used at home will make treatment more accessible and convenient for patients, will help to improve treatment compliance and subject satisfaction and may contribute to better outcomes.

Once subjects meet all eligibility and screening criteria, they will be enrolled in the study. Subjects will be randomized to therapy once a week or three times a week for 12 weeks. Unlike PTNS, the Test Article is fully non-invasive and can be done completely at home, eliminating the need for weekly visits to a medical office This study is designed to minimize patient and site contact to help reduce possible exposure to COVID 19. The only required in-person office visit would be to conduct EMG screening to confirm eligibility for enrollment and to set up the System for home use, and end of study assessments. To further minimize COVID19 exposure, this protocol enables sites to combine Screening Visit 2 and Visit 1/Baseline in a single office visit.

18. Administrative Requirements and Quality Assurance

18.1. Institutional Review Board (IRB) / Ethics Committee (EC)

Before study enrollment can begin, the Investigator must provide the Sponsor with a copy of the approval notice for the protocol and informed consent forms, signed by the committee Chairperson.

18.2. Informed Consent

Written Informed Consent must be obtained from all subjects or their legally authorized representative before recruitment into the study. All potential subjects must be properly informed as to the purpose of the study and the potential risks and benefits known or that can be reasonably predicted or expected.

The Investigator will retain the original copy of the Informed Consent form signed by the subject and a duplicate will be provided to the subject. Only the consent form approved by the IRB/EC must be used.

18.3. Clinical Supplies

All System components will be labeled as investigational and bear the following statement:

"For Investigational Use Only"

18.4. Data Management

All study data will be recorded on the eCRF EDC system or by using sponsor generated paper CRFs. When applicable, deidentified copies of all paper CRFs must be made available to the Sponsor so that the validity and completeness of the forms can be determined. Where possible all paper CRF and EDC data should originate from a verifiable medical record in source documentation for each subject.

Any corrections to paper CRFs should be made by scoring through the original value with a single line and writing the new value next to the original entry with the designated study staff initialing and dating the new entry. Only the designated study staff may amend or otherwise alter any data entered onto the paper CRF or site source documents. Once a change has been made on the paper CRF and the CRF has been submitted to the data department, no change may be made on the original CRF. All corrections must be made with a Data Clarification Form (DCF) for submission to Avation data management. Significant changes to eCRF EDC data entries are to be captured on a DCF and will require PI approval or approval by designated study personnel prior to submission to Avation.

If the reason for the correction is not obvious then, when appropriate, a brief explanation of the reason for the correction should be made. Correction fluids should never be used on any document. Before forwarding copies of completed paper CRFs to Avation Medical the Investigator or designated study staff should review their completeness, accuracy, and legibility. The Investigator/site must always retain a copy of all completed CRFs in his/her ISF.

Study centers will record all study information in an appropriate source document. The data will then be entered directly into an electronic data capture (EDC) system by completing the eCRF via a secure internet connection. Data entered into the eCRF must be verifiable against source documents at the study center. Any changes to the data entered in the EDC system will be recorded in the audit trail.

The Sponsor will be responsible for activities associated with the data management of this study.

18.5. Monitoring

The Investigator will permit the Study Monitor to visit the Investigational Site at regular intervals to review all the CRFs, study related adjunctive data, and study management. These reviews are for the purpose of verifying the adherence to the protocol and the completeness and exactness of the data being entered as per local requirements. The Study Monitor must be kept informed of all issues pertinent to the study. The Study Monitor will be available to discuss questions regarding adverse events, removal of subjects from the study, conduct of the study or any other questions that should arise. At the final monitoring visit the Study Monitor must resolve any outstanding data deficiencies and retrieve all used and unused Test Articles if applicable.

A detailed monitoring plan will be provided separately from the protocol.

18.6. On-site Audits

The various national regulatory authorities and the Sponsor in the person of a scientifically trained and properly authorized employee may request access to all study records, including source documents, for inspection and copying.

Study centers and study documents may be subject to Quality Assurance audits during the study by the sponsor or its representative. In addition, inspections may be conducted by regulatory authorities at their discretion.

18.7. Record Storage and Retention

Federal laws and GCP requires that a copy of all study records (e.g., Informed Consent documents, source documents, study records, etc.) which support CRFs of this study, must be retained in the ISF of the responsible Investigator for a minimum of two years in accordance with local regulations following notification by Avation Medical that all Investigations (not merely the Investigators portion) are completed, terminated, or discontinued, or that the Food and Drug Administration or the non-U.S regulatory authority has approved the submission.

If the Principal Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept responsibility. Avation Medical or its local sponsor must be notified in writing of the name and address of the new custodian.

18.8. Clinical Monitors

The name, title, address, phone, and fax number of the Study Monitor should be provided to the Investigator and Sponsor and kept in the respective Investigator and Regulatory Binders.

19. Publications

Investigator agrees, and will ensure that its Agents likewise agree, that neither shall, without Sponsor's prior written consent, independently publish, publicly disclose, present, or discuss any results of, or information pertaining to, Investigator's activities conducted under this protocol until such multi-center publication is released or twelve months after completion of the Study, whichever is the sooner.

After the events recited in the above paragraph of this protocol, the Investigator and/or its Agents shall then be free to publish or publicly present the results of the Study Subjects enrolled solely at Facilities, provided that the manuscript or abstract proposed to be published or presented shall be submitted to Sponsor at least ninety (90) days prior to submission for publication or presentation. Sponsor retains the right to direct removal of any Confidential Information provided by Sponsor and contained therein other than as required to communicate a scientifically appropriate description of the methods and results of the Study, to protect its rights to any patentable inventions set forth therein and to ensure the accuracy of the information contained in the publication or presentation. The Investigator agrees, and will ensure that its Agents likewise agree, to delete any Confidential Information provided by Sponsor that Sponsor directs should not be published pursuant to this paragraph.

Sponsor supports the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE). According to these guidelines, authorship credit is based only on substantial contributions to: (i) conception and design, or acquisition of data, or analysis and interpretation of data; (ii) drafting of the article or revising it critically for important intellectual content; and (iii) approving of the final version to be published. Neither Investigator nor its Agents qualify to be an author if its contribution consists solely of arranging funding, collecting data or supervising the research group. The Sponsor reserves the right to assign a co-author to any publication or public presentation.

20. References

[1] I. Milsom, P. Abrams, L. Cardozo, R. G. Roberts, J. Thüroff, and A. J. Wein, "How widespread are the symptoms of an overactive bladder and how are they managed? A population-based prevalence study," *BJU Int.*, vol. 87, no. 9, pp. 760–766, 2001.

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[3] C. R. Chapple *et al.*, "Total urgency and frequency score as a measure of urgency and frequency in overactive bladder and storage lower urinary tract symptoms: TUFS as measure of storage symptoms in LUTS and OAB," *BJU Int.*, vol. 113, no. 5, pp. 696–703, May 2014.

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[5] M. B. Chancellor, K. Migliaccio-Walle, T. J. Bramley, S. L. Chaudhari, C. Corbell, and D. Globe, "Long-Term Patterns of Use and Treatment Failure With Anticholinergic Agents for Overactive Bladder," *Clin. Ther.*, vol. 35, no. 11, pp. 1744–1751, Nov. 2013.

[6] K. M. Peters *et al.*, "Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Sham Efficacy in the Treatment of Overactive Bladder Syndrome: Results From the SUmiT Trial," *J. Urol.*, vol. 183, no. 4, pp. 1438–1443, Apr. 2010.

[7] Peters K.M. *et al.*, "Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Extended-Release Tolterodine: Results From the Overactive Bladder Innovative Therapy Trial," *J. Urol.*, vol. 182, no. 3, pp. 1055–1061, 2009.
[8] K. Noblett *et al.*, "Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder: 12 Month Outcomes of Sacral Neuromodulation for OAB," *Neurourol. Urodyn.*, vol. 35, no. 2, pp. 246–251, Feb. 2016.

21. Protocol Amendment Summary of Changes

Summary of Changes for
Protocol Version 1 Dated: 06 JUL 2020 to Version 2 Dated: 07 DEC 2020

SECTION	DESCRIPTION OF CHANGE	RATIONALE
GLOBAL THROUGHOUT DOCUMENT	Formatting changes and other minor edits, including changes to references for consistency/correction, throughout the protocol, without change to meaning or substance.	Improve document consistency, accuracy, readability, and adherence to necessary style.
TITLE PAGE	Version / Date change.	To reflect the current version of the protocol
TABLE OF CONTENTS	Modified to include addition of Section 8 Long-Term Follow-Up.	To Provide necessary information relating to the long-term follow-up phase of the AMHOAB2001 trial.
SECTION 2 – Protocol Summary	Structure, Method of Assignment, and Study Design sections updated to include information related to the long-term follow-up phase of the AMHOAB2001 study.	To provide information regarding the long-term follow-up phase of the AMHOAB2001 study.
Section 5 – Study Design	Updated to include information related to the long-term follow-up phase of the AMHOAB2001 study.	To provide information regarding the long-term follow-up phase of the AMHOAB2001 study
Section 7 – Methods & Procedures	Updated to include information related to the long-term follow-up phase of the AMHOAB2001 study.	To provide information regarding the long-term follow-up phase of the AMHOAB2001 study
Section 8 – Long-Term Follow-Up Phase	Section added to provide information related to the long-term follow-up phase of the AMHOAB2001 study.	To provide information regarding the long-term follow-up phase of the AMHOAB2001 study
Section 10 – Test Article	Updated pictures for the Stimulator and controller app	To reflect latest design of Test Article
Section 21 – Protocol Amendment Summary of Changes	Section added to Protocol	To provide information regarding changes between Protocol Version 1.0 and Protocol Version 2.0.

21. Appendix A- Case Report Forms

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3-Day Bladder Diary Visit

Subject ID: _____ **Subject Initials:** _____

1. Choose **3 days** (entire 24 hours) to complete this record - they **do not** have to be in a row. Pick days during which it will be convenient to measure **every** void.
2. Begin recording when you wake up in the morning and continue for a full **24 hours**.
3. Make a separate entry each time you **void, leak** or have anything to **drink**.
4. Record each time you notice a leak - please indicate how much using a scale from 1-3 (1=drops/damp, 2=wet/soaked, 3=bladder emptied/voided). Record if you felt an "urge" with the leak (yes or no).

Time of Day	Fluid Intake (oz)	Leak Amount (1-3)	Activity with Leak	Urge with Leak (yes or no)	Comments
7:15 am					
7:45 am	2 oz				
9:00 am		2		Yes	
10:30 am	3 oz	1	Sneezing	No	

Version 2.0 dated February 15, 2021

3-Day Bladder Diary Visit

Subject ID: ____________ **Subject Initials:** ____________

Number of Pads for full 24 hours:

Time of Day	Fluid Intake (oz)	Leak Amount (1-3)	Activity with Leak	Urge with Leak (yes or no)	Comments

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete and accurate.

______________________________ | | | | | | | | | |

Authorized Signature Date

OAB-q (HQL) Form- Visit

Subject ID:_____ **Subject Initials:** _____

This questionnaire asks about how much you have been bothered by selected bladder symptoms during the past 4 weeks. Please mark the box that best describes the extent to which you were bother by each symptom during the past 4 weeks. There are no right or wrong answers. Please be sure to answer every question.						
During the past 4 weeks, how bothered were you by…	(1)	(2)	(3)	(4)	(5)	(6)
1. Frequent urination during day-time hours	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
2. An uncomfortable urge to urinate	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
3. A sudden urge to urinate with little or no warning	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
4. Accidental loss of small amounts of urine	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
5. Nighttime urination	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
6. Waking up at night because you had to urinate	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
7. An uncontrollable urge to urinate	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
8. Urine loss associated with a strong desire to urinate	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal

This questionnaire asks about how much you have been bothered by selected bladder symptoms during the past 4 weeks. Please circle what best describes the extent to which you were bothered by each symptom during the past 4 weeks. There are no right or wrong answers. Please be sure to answer every question.						
During the past 4 weeks, how often have your bladder symptoms…	(1)	(2)	(3)	(4)	(5)	(6)
9. Made you carefully plan your commute?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
10. Caused you to feel drowsy or sleepy during the day?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
11. Caused you to plan 'escape routes' to restrooms in public places?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time

OAB-q (HQL) Form- Visit

Subject ID:_____ **Subject Initials:** _____

12.Caused you distress?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
13.Frustrated you?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
14. Made you feel like there is something wrong with you?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
15. Interfered with your ability to get a good night's rest?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
16. Caused you to decrease your physical activities (exercising, sports, etc.) ?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
17. Prevented you from feeling rested upon walking in the morning?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
18.Frustrated your family or friends?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
19. Caused you anxiety or worry?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
20. Caused you to stay home more often than you would prefer?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
21.Caused you to adjust your travel plans so that you are always near a restroom?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
22 Made you avoid activities away from restrooms (i.e., walks, running, hiking)?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
23. Made you frustrated or annoyed about the amount of time you spend in the restroom?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
24. Awakened you during sleep?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
25. Made you worry about odor or hygiene?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time

OAB-q (HQL) Form- Visit

Subject ID:_____ **Subject Initials:** _____

26. Made you uncomfortable while traveling with others because of needing to stop for a restroom?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
27. Affected your relationships with family and friends?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
28. Caused you to decrease participating in social gatherings, such as parties or visits with family or friends?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
29. Caused you embarrassment?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
30. Interfered with getting the amount of sleep you needed?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
31.Caused you to have problems with your partner or spouse?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
32.Caused you to plan activities more carefully?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
33.Caused you to locate the closes restroom as soon as you arrive at a place you have never been?	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete and accurate.

_____ D D M M M Y Y Y Y

Authorized Signature **Date**

IIQ-7 SF Form- Visit

Subject ID:_____ **Subject Initials:** _____

Some people find that accidental urine loss may affect their activities, relationships, and feelings. The questions below refer to areas in your life that may have been influenced or changed by your problem. For each question, circle the response that best describes how much your activities, relationships, and feelings are being affected by urine leakage.

Has urine leakage affected your:	*Not at all*	*Slightly*	*Moderately*	*Greatly*	Subject Score
1. Ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3	__
2. Physical recreation such as walking, swimming, or other exercise?	0	1	2	3	__
3. Entertainment activities (movies, concerts, etc.)?	0	1	2	3	__
4. Ability to travel by car or bus more than 30 minutes from home?	0	1	2	3	__
5. Participation in social activities outside your home?	0	1	2	3	__
6. Emotional health (nervousness, depression, etc.)?	0	1	2	3	__
7. Feeling frustrated?	0	1	2	3	__
TOTAL					__

Reference. Uebersax, J.S., Wyman, J. F., Shumaker, S. A., McClish, D. K., Fantl, J. A., & the Continence Program for Women Research Group. (1995). Short forms to assess life quality and symptom distress for urinary incontinence in women: The incontinence impact questionnaire and the urogenital distress inventory. Neurourology and Urodynamics, 14, 131-139.

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete and accurate.

_____ D D M M M Y Y Y Y

Authorized Signature **Date**

PGIC – Visit

Subject ID: _____ **Subject Initials:** _____

Chief Complaint: _____	
Since beginning treatment how would you describe the change (if any) in ACTIVITY LIMITATIONS SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE, related to your condition? (tick ONE box)	
1. No change (or condition has got worse)	☐
2. Almost the same, hardly any change at all	☐
3. A little better, but no noticeable change	☐
4. Somewhat better but the change has not made any real difference	☐
5. Moderately better, and a slight but noticeable change	☐
6. Better, and a definite improvement that has made a real and worthwhile difference	☐
7. A great deal better and a considerable improvement that has made all the difference	☐

In a similar way, please circle the number below, that matches your degree of change since beginning care at this clinic:

0 1 2 3 4 5 6 7 8 9 10

Much Better	No Change	Much Worse

Reference: Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. J Manipulative Physiol Ther 2004;27:26-35.

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete and accurate.

_____ D D M M M Y Y Y Y

Authorized Signature **Date**

Version 2.0 dated February 15, 2021

I-QoL – Visit

Subject ID: _____ **Subject Initials:** _____

ALB Domain					
1. I worry about not being able to get to the toilet on time	Extremely	Quite a bit	Moderately	A little	Not at all
2. I worry about coughing/sneezing because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
3. I have to be careful standing up from sitting	Extremely	Quite a bit	Moderately	A little	Not at all
4. I worry about where toilets are in new places	Extremely	Quite a bit	Moderately	A little	Not at all
5. It's important to me to make frequent trips to the toilet	Extremely	Quite a bit	Moderately	A little	Not at all
6. It's important to plan every detail in advance because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
7. I have difficulty getting a good night's sleep because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
8. I have to watch how much I drink because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
PSI Domain					
9. I feel depressed because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
10. I don't feel free to leave home for long periods of time because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
11. I feel frustrated because my incontinence prevents me doing what I want	Extremely	Quite a bit	Moderately	A little	Not at all
12. My incontinence is always on my mind	Extremely	Quite a bit	Moderately	A little	Not at all
13. My incontinence makes me feel unhealthy	Extremely	Quite a bit	Moderately	A little	Not at all
14. My incontinence makes me feel helpless	Extremely	Quite a bit	Moderately	A little	Not at all
15. I get less enjoyment out of life because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
16. My incontinence limits my choice of clothing	Extremely	Quite a bit	Moderately	A little	Not at all
17. I worry about having sex because of my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all

I-QoL – Visit

Subject ID: _____ **Subject Initials:** _____

SE Domain					
18. I worry about others smelling urine on me	Extremely	Quite a bit	Moderately	A little	Not at all
19. I worry about my incontinence getting worse as I get older	Extremely	Quite a bit	Moderately	A little	Not at all
20. I worry about being embarrassed or humiliated by my incontinence	Extremely	Quite a bit	Moderately	A little	Not at all
21. I worry about wetting myself	Extremely	Quite a bit	Moderately	A little	Not at all
22. I feel I have no control over my bladder	Extremely	Quite a bit	Moderately	A little	Not at all

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete and accurate.

_____ D D M M M Y Y Y Y

Authorized Signature **Date**

OHQ– Visit

Subject ID: _____ **Subject Initials:** _____

Instructions
Below are a number of statements about happiness. Please indicate how much you agree or disagree with each by entering a number in the blank after each statement, according to the following scale:

1 = strongly disagree
2 = moderately disagree
3 = slightly disagree
4 = slightly agree
5 = moderately agree
6 = strongly agree

	Response #
1. **I don't feel particularly pleased with the way I am.**	
2. **I am intensely interested in other people.**	
3. **I feel that life is very rewarding.**	
4. **I have very warm feelings towards almost everyone.**	
5. **I rarely wake up feeling rested.**	
6. **I am not particularly optimistic about the future.**	
7. **I find most things amusing.**	
8. **I am always committed and involved.**	
9. **Life is good.**	
10. **I do not think that the world is a good place.**	
11. **I laugh a lot.**	
12. **I am well satisfied about everything in my life.**	
13. **I don't think I look attractive.**	
14. **There is a gap between what I would like to do and what I have done.**	
15. **I am very happy.**	
16. **I find beauty in some things.**	
17. **I always have a cheerful effect on others.**	
18. **I can fit in (find time for) everything I want to do.**	
19. **I feel that I am not especially in control of my life**	
20. **I feel able to take anything on.**	
21. **I feel mentally alert.**	
22. **I often experience joy and elation.**	

Version 2.0 dated February 15, 2021

OHQ– Visit

Subject ID: _____ **Subject Initials:** _____

23. **I don't find it easy to make decisions.**	
24. **I don't have a particular sense of meaning and purpose in my life.**	
25. **I feel I have a great deal of energy.**	
26. **I usually have a good influence on events.**	
27. **I don't have fun with other people.**	
28. **I don't feel particularly healthy.**	
29. **I don't have particularly happy memories of my past.**	

SIGNATURE

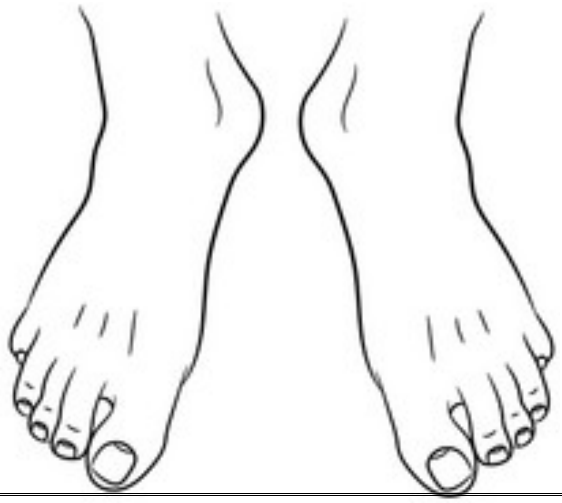
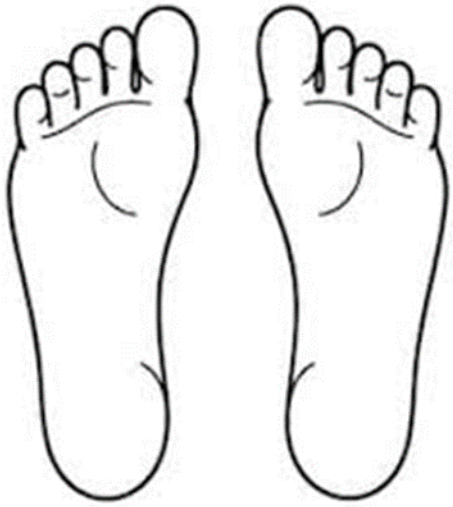
I have reviewed the recorded information for this visit and verified that it is complete and accurate.

_____ D D M M M Y Y Y Y

Authorized Signature **Date**

Paresthesia Map

Subject ID: _____ **Subject Initials:** _____

Paresthesia Map
Turn the stimulator to the maximum tolerable level. Mark on the figure below where the Subject feels stimulation.
R  L
R  L

Date | D | D | M | M | M | Y | Y | Y | Y |

Paresthesia Rating

Subject ID: _____ **Subject Initials:** _____

Ask the patient to rate each of the following words from 0 to 4 how well each describes the feeling of paresthesia. (0 does not at all describe the feeling --- 4 very much describes the feeling)

Warm	0 1 2 3 4	Fluttering	0 1 2 3 4
Tingling	0 1 2 3 4	Unpleasant	0 1 2 3 4
Aching	0 1 2 3 4	Tickling	0 1 2 3 4
Massaging	0 1 2 3 4	Jabbing	0 1 2 3 4
Prickly	0 1 2 3 4	Tapping	0 1 2 3 4
Aggravating	0 1 2 3 4	Vibrating	0 1 2 3 4
Gentle	0 1 2 3 4	Gentle Pressure	0 1 2 3 4
Cramping	0 1 2 3 4	Calming	0 1 2 3 4
Throbbing	0 1 2 3 4	Pulsing	0 1 2 3 4
Shocking	0 1 2 3 4	Sharp	0 1 2 3 4
Soothing	0 1 2 3 4	Pleasant	0 1 2 3 4
Buzzing	0 1 2 3 4	Numbing	0 1 2 3 4
Relaxing	0 1 2 3 4	Natural	0 1 2 3 4
Comfortable	0 1 2 3 4	Pins and Needles	0 1 2 3 4

SIGNATURE

I have reviewed the recorded information for this visit and verified that it is complete

_____ | | | | | | | | | |

Authorized Date

Version 2.0 dated February 15, 2021

Date | D | D | M | M | M | Y | Y | Y | Y |

Paresthesia Rating

Subject ID: _____ **Subject Initials:** _____

General Information					
1. How likely would you be willing to use a system like this for treating your OAB?	Not likely	A little likely	Moderately likely	Very likely	Extremely likely
Please comment on the willingness to use this System to treat OAB:					
2. How easy was it to use the overall System?	Not easy	A little easy	Moderately easy	Very easy	Extremely easy
Please comment on the ease of use of the System:					
3. How satisfied were you with the Avation System app?	Not satisfied	A little satisfied	Moderately satisfied	Very satisfied	Extremely satisfied
What in particular did you like about the App?					
What, if anything, can be improved about the App?					
4. How satisfied were you with the Garment?	Not satisfied	A little satisfied	Moderately satisfied	Very satisfied	Extremely satisfied
What in particular did you like about the Garment?					
What, if anything, can be improved about the Garment?					
5. How satisfied were you with the system overall?	Not satisfied	A little satisfied	Moderately satisfied	Very satisfied	Extremely satisfied
What in particular did you like about the system overall?					
What, if anything, can be improved about the overall system?					

Version 2.0 dated February 15, 2021

Date | D | D | M | M | M | Y | Y | Y | Y |

Paresthesia Rating

Subject ID: _____ **Subject Initials:** _____

General Information					
6. How easy was it to fit this stimulation therapy into your routine?	Not easy	A little easy	Moderately easy	Very easy	Extremely easy
Please comment on ease of fitting this modulation therapy into your routine.					
7. What type of activities were you doing when you used this system?	[ ] Reading [ ] Watching TV [ ] On the Computer [ ] Eating [ ] Other: _____				
8. What positions were you in while using the system?	[ ] Sitting [ ] Standing [ ] Lying [ ] Other: _____				
9. What positions were you in ***most often*** while using the system?	[ ] Sitting [ ] Standing [ ] Lying [ ] Other: _____				
10. What did you like about the stimulation sessions?					
11. What did you dislike about the stimulation sessions?					
12. How easy was it to change the Gel Pads?	Not easy	A little easy	Moderately easy	Very easy	Extremely easy
13. Did you use the subject manual?	[ ] Yes [ ] No				
If yes, why did you use the subject manual? Was the information clear and easy to locate?					