COVER PAGE

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Official Title: Assessment of Penile Vibratory Stimulation Using the Viberect in Men with Mild-Moderate ED

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Principal Investigator: Arthur L. Burnett

Participating Site: Johns Hopkins University, Baltimore, MD, USA

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MEDICINE
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Date: July 2, 2018
Principal Investigator: Arthur L. Burnett, II, MD MBA
Application No.: IRB00130002

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Clinical Assessment of Penile Vibratory Stimulation Viberect Device in Men with Mild to Moderate Erectile Dysfunction.**

Application No.: **IRB00130002**

Principal Investigator: **Arthur L. Burnett, II, MD MBA**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research study is being done to explore the effect on sexual satisfaction in patients with mild to moderate erectile dysfunction using the Viberect penile vibratory device. Device safety, participant and, if applicable, partner sexual satisfaction, and ease of use of the Viberect device will be evaluated.

Erectile Dysfunction (ED) is the inability to achieve and maintain an erection adequate for sexual satisfaction. Advancement in medical management, noninvasive strategies, and invasive therapies, have improved sexual outcomes for men suffering from ED. Even with recent improvements, there has been a gradual decrease in treatment efficacy over time.

Using the Viberect penile vibratory stimulation system for 7-10 minutes a day may help erectile function by stimulating the nerves of the penis. The Viberect Device is an FDA-cleared medical device approved for sale in the United States. The Viberect is a medical device intended to provoke erection in men who experience erectile dysfunction and to provoke ejaculation in spinal cord injured men. Viberect is a hand held medical device intended for use by the person on-demand, to stimulate the nerves of the penis and improve erection rigidity. The Viberect mimics rapid and repetitive manual/vaginal stimulation of the penis. The device has two vibrating motors powered by rechargeable batteries. These motors stimulate both sides of the penis at the same time causing an increased sexual response. The device is easily held by one hand, and the penis is placed between the vibrating pads. As the device is squeezed, pressure is applied and the device is automatically activated. The person has complete control of the device.

The goal of this study is to test the safety and participant reported effects of this device. And determine if it can become a main stream treatment for erectile dysfunction. This may become an alternative option for patients who find medical treatments ineffective and expensive, or for those whom are not interested in more invasive therapies.

Men with ED ages 30 to 70 years old may join.

How many people will be in this study?

About 20 men are expected to take part at Johns Hopkins Medical Institutions.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screening/Baseline Visit:

This will be your regularly scheduled clinic appointment in the Urology outpatient center. At this visit we will review the study in its entirety and obtain your signed, informed consent. In order to ensure you are able to participate, you will:

- Receive a full physical examination by a physician. This will include a genital examination to check for genital ulcers or skin lesions.
- Be asked about your medical history and sexual function.
- Complete 4 short, validated questionnaires on sexual function. These include the: International Index of Erectile Function (IIEF-5), Treatment Satisfactions Scale (TSS), Erection Hardness Scale (EHS), and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS).

Depending on the results of the evaluations you may or may not be eligible for the study. If you are not eligible to participate in the study, the study doctor will tell you why. If you are eligible for the study you will then do the following:

- You will be enrolled in the study group. All eligible participants will receive the Viberect device.

- You will be given a Viberect device and the instruction manual
- You must be able to understand and demonstrate device use instructions before being allowed to take the device home.
- You will begin using the Viberect device at least 3 days per week (or daily with 24 hours apart) for 7-10 minutes in a relaxed setting with sexual thoughts or foreplay. The Viberect is not to be used more than once in 24 hours. Viberect method can be performed by your sexual partner if you wish.
- You will also be given a User's manual. You will be given a diary to record device use, erection hardness scale, and sexual satisfaction
- If you choose to use a PDE-5 inhibitor, such as Viagra, Levitra, or Cialis during the study, you will be asked to record the frequency of use, time, drug type, dosage of the drug used, and a comment about sexual response in your diary. If you choose to use these drugs they will not be provided by the study. You will be responsible for purchasing them.

Follow-up visit (Week 4) :

- You will return to the office for a follow-up visit four weeks later
- A physical examination will be performed, including genital exam for any signs of penile irritation.
- You will be asked to complete the International Index of Erectile Function (IIEF-5), Treatment Satisfactions Scale (TSS), Erection Hardness Scale (EHS), and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaires.
- You will be asked about any problems you may have had with using the study device, and any problems which may have caused physical discomfort to you. You will also be asked about your satisfaction with using the study device.
- You will be asked about any physical problems you have had in general and any changes in the medications that you take.
- If you used PDE-5 inhibitors during the study, the information that you separately recorded will be collected.
- Your diary will be collected.
- Any remaining questions will be answered by the study physician

Once given the Viberect, the device will be yours to keep, unless you do not want it in which we will return the device to the manufacturing company. You are able to continue using the Viberect device for personal use after the study is complete.

How long will you be in this study?

The total duration of participation in this study is **4 weeks.** A total of 2 clinic visits will be included in this study. The first clinic visit will be the initial evaluation and explanation of the study, and then a follow-up visit about 4 weeks after initiation of study period.

4. What are the risks or discomforts of the study?

- Viberect Device Potential risks of the device may include local skin irritation, or temporary numbness as a result of vibration, pain, fatigue (tiredness), rash, or device malfunction. There could be pain or numbness of the hand holding the device.

- Serious adverse events would include device malfunction, the vibrating pad dislodgment, and the vibrating tip damaging the penis.

- The User's manual includes A WARNING that states: "Vibratory stimulation may cause a superficial trauma to the skin resulting in bruising, bleeding or superficial ulceration. If any such condition occurs, stop using the device and consult the study staff immediately."

- Unanticipated adverse device effects include overheating of the device and burns. The device will not be used while connected to the electric outlet, which minimizes the potential risk of burns or overheating.

- This device should not be used over swollen or inflamed areas or skin eruptions. The Viberect device must not be used more than 10 minutes a day with strict accordance to the User's manual. If the instructions are followed closely according to verbal instructions and the User's manual, and you use the device no more than once in 24 hours, the risk is minimal.

- If you develop an erection that lasts for more than four hours, you may have developed priapism (unwanted, prolonged erection of the penis), which is a medical/surgical emergency. Contact the study doctor immediately or go to the emergency room.

- **Interview and Questionnaires**

You may get tired or bored when we are asking you questions or when you are completing questionnaires. You do not have to answer any question you do not want to answer.

- **Unknown risks**

There may be risks and discomforts that are not yet known.

- **Risks of joining the study compared with standard of care**

The standard of care for men with mild to moderate erectile dysfunction seeking treatment are phosphodiesterase-5 inhibitor medications (Viagra, Levitra, Cialis). While you are on the study you may take these medications (but please record that), and therefore the standard of care is still an option for your treatment plan. Your treatment will not be affected by partaking in this study and using the Viberect device.

Confidentiality: There is the risk that information about you may become known to people outside this study. Paper consent forms, enrollment check sheets, and other source or study documentation will be kept in a study binder. This binder will be stored in a locked office available only to the study team. Electronic data will be housed in a secure password protected database maintained by the Johns Hopkins Biostatistics Center. Only the study team will have access to this secure database. To maintain your protected information, only the study Principal Investigator and primary coordinators will have the ability to export data containing identifying information from this master database. For the purposes of analysis, only de-identified data will be exported.

5. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

- If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments for erectile dysfunction include oral phosphodieterase type 5 (pde5) inhibitors such as Viagra, Cialis or Levitra; intraurethral suppositories such as MUSE; intracavernosal injection therapy drugs such as Alprostadil, bi-mix or tri-mix; Vacuum Erection Devices and penile prosthesis surgery. The Viberect study device is marketed over-the-counter and is available for purchase from commercial sources without a prescription.

- You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). You or your insurer will be financially responsible for the cost of the two office visits involved in this study.

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:
www.cancer.gov or 1.800-4-CANCER (1.800.422-6237)

8. Will you be paid if you join this study?

No. The study device is yours to keep at the end of your participation. You will be able to continue using the Viberect device for personal use after the study is complete.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- You will be asked to return the device if you leave the study early.

If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

The results of this research study may be published. You will not be identified in publications without your permission.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410.955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Arthur Burnett at 410.614-3986. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410.955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Arthur Burnett at 410.614-3986 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Arthur Burnett at 410.614-3986 during regular office hours and at 410.283-5030 after hours and on weekends. **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

We may use your information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.