Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PARTICIPANT NAME:	**DATE:**
PRINCIPAL INVESTIGATOR:	Hasan Dosluoglu, MD
TITLE OF RESEARCH STUDY:	Assessment of Quality of Life Changes on Lower Extremity Lymphedema Patients using an Advanced Pneumatic Compression Device at Home. (Protocol # 5010)

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by Tactile Medical about the effect of pneumatic compression in improving symptoms and quality of life in patients with lymphedema if the leg(s). This summary is intended to give you key information to help you decide whether to participate. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

With this research we hope to learn the effect of pneumatic compression in improving symptoms and quality of life in patients with lymphedema of the leg(s). Over a 12-month period, this study will look at the effect that the Flexitouch® system has on your lymphedema.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The possible benefit of this study is improved lymphedema management.

For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There are minimal side effects expected from the treatment you will receive in this study (which is the same treatment you would receive as standard of care). This study does not present risks above and beyond those normally associated with the use of the prescribed product.

Some of the standard of care treatments for lower extremity lymphedema include manual lymphatic drainage, compression wrapping, bandaging, exercise and skin care.

For a complete description of alternate treatment/procedures, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

It is important to tell the study team if you are taking part in another research study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Hasan Dosluoglu MD of the VA Western New York Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: hasan.dosluoglu@va.gov or (716) 862-8937.

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DETAILED CONSENT

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn the effect of pneumatic compression in improving symptoms and quality of life in patients with lymphedema of the leg(s). Over a 12-month period, this study will look at the effect that the Flexitouch® system has on your lymphedema.

You are being asked to participate in this study because your physician has diagnosed you with primary or secondary lymphedema of the leg(s) and have been prescribed the Flexitouch system by your physician. There is no cure for lymphedema, and the available treatment options consist of manual lymphatic drainage, compression therapy, and in very bad cases, surgery.The Flexitouch system is a segmental, fabric, compression sleeve that wraps around the leg and is connected by hoses to a programmable air pump. The Flexitouch system has been cleared for prescription use by the FDA.

The study is being run at multiple VA facilities in the area. Approximately 300 subjects with diagnosed lymphedema affecting one or both legs will be enrolled into the study. This study is sponsored by the manufacturer of the Flexitouch system, Tactile Medical®, based in Minneapolis, Minnesota.

HOW LONG WILL I BE IN THE STUDY?

Your participation in this research study is expected to take 12 months. The study will include 6 in-person study visits: the baseline visit, clinic visits occurring every 4 weeks (week 4, 8 and 12), then a visit at 6 months (week 24) and 1 year (week 52) after device training.

There will also be a follow-up phone call taking place one week after you receive your Flexitouch training and again at 18 weeks, 32 weeks, and 40 weeks.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 25 people will participate in this research study at the VA Western New York Healthcare System.

Additionally, about 275 people will participate at other sites across the United States, for a total enrollment of 300 people at all sites.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Screening/ Baseline Visit:

Members of the research staff will clearly explain the consent form and consent process to you. You will be given as much time as you need to read, ask questions, and consult with your family

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members before agreeing to participate.

- Feel free to ask questions at any time throughout the study.
- Participation in this study is completely voluntary and you are free to withdraw from the study at any time for any reason.

If you agree to participate and sign this consent form, the Screening/ Baseline Visit will happen next.

- A member of the research staff will conduct an examination of your affected leg(s).
- Limb circumference of each leg will be measured using a tape measure.
- Photos of your legs will be taken.
- You will be asked to complete quality of life questionnaires.
- You will be instructed on how to complete the study diary and to bring it back at each study visit.
- The visit should take about an hour and a half to complete.

Following the Screening/ Baseline visit, if you are found to be eligible for the study, you will receive your device and have your device training session.

Phone Call Follow-up:

A member of the research staff will call you 1 week after you receive device training and again at 18 weeks, 32 weeks and 40 weeks after you start the study.

- During the call the staff member will ask about your lymphedema treatment, healthcare visits, and medications. They will also address any questions you may have about:
  - How to put on the device
  - When and how often you should use the device
  - Upcoming visits
  - Discuss whether you have had any clinic, urgent care, hospital or ER visits for your lymphedema or other vascular problems since your last visit or call
- The call should take about ten minutes to complete

Weeks 4, 8, 12, 24, and 52 Clinic Visits:

You will return to the clinic for the 4, 8, 12, 24 and 52-week visits. During these visits, the study staff will:

- Examine your affected leg(s)
- Complete limb circumference measurements on both legs using a tape measure
- Take photographs of limbs
- Review your study diary(ies)

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- Discuss whether you have had any clinic, urgent care, hospital or ER visits for your lymphedema or other vascular problems since your last visit or call
- You will be asked to complete quality of life questionnaires at the 12, 24, and 52-week visits
- All visits should take about an hour to complete

Research will be carried out within the VA Healthcare System with research staff members under the direction of Dr. Dosluoglu. Visits will occur as scheduled with a research staff member every four weeks for three visits, then two additional visits occurring at twenty-four and fifty-two weeks after the initial study visit for a total of six visits in the one year you will participate in this study.

- It is very important that you keep your study appointments. If it is necessary to miss an appointment, please contact the investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- It is very important that you keep your diary as complete and accurate as possible as instructed by the research staff member.
- Tell the investigator or research study staff if you believe you might be pregnant.
- Remember to tell the investigator or research staff if you change your mind about staying in the study at any time.
- If you are participating in another clinical study you will not be eligible to participate in this study. While participating in this research study, do not take part in any other research studies without approval from the investigators.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There are minimal side effects expected from the treatment you will receive in this study (which is the same treatment you would receive as standard of care). This study does not present risks above and beyond those normally associated with the use of the prescribed product.

Pneumatic compression is a minimal risk therapy with nominal complications or adverse events. Known reactions to sequential pneumatic compression therapy include:

Likely

- Local skin irritation
- Pain or discomfort
- Increased swelling

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Less Likely
- Cellulitis (infection of the skin which may include swelling, redness, and tenderness of the infected tissue)
- New or increased edema (swelling) in the trunk and/or genital region

Highly Unlikely
- Electric shock (if device is not stored or plugged in properly or if it is used by water)

The effects of the study devices on a developing fetus are unknown because of that reason you are not permitted to take part in this study if:
- You are pregnant
- Think that you may be pregnant
- Are trying to get pregnant.

You may be asked to take a pregnancy test and use birth control for the time you are in the study.

In addition, unforeseen adverse effects may occur. Any unforeseen adverse effects that occur will be closely monitored and treated accordingly. Some of the questions in the Quality of Life Surveys are of a personal nature and may be upsetting to some participants. The research staff will be available to discuss these questions should you have concerns. You do not have to answer any questions that you do not feel comfortable answering.

Study Information
There is a risk that study information (data) could be connected to your name. This is called "loss of confidentiality". Data collected from this study may be maintained on the VA server with access limited to the research team only. The methods and procedures used for data storage and security are consistent with those adopted by the VA.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit. The possible benefit of this study is improved lymphedema management. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other patients with lymphedema in

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the future. There is no guarantee that taking part in this research will result in any improvement in your condition.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, you will still be eligible for treatment with the Flexitouch device. There are other choices for treatment available and you should talk to your doctor about the advantages and disadvantages of each of them. Some of the standard of care treatments for lower extremity lymphedema include manual lymphatic drainage, compression wrapping, bandaging, exercise and skin care. You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your research records will be kept private. Your direct personal identifiers will be entered into the Tactile Medical electronic sales database (FileMaker) when the Flexitouch® system is ordered per standard ordering procedures. If you agree to participate in this study, your unique study code number will also be entered in the sales database. The Tactile field technicians who place device orders will only have access to the sales database and will not have access to the research database containing the study data. Only the Tactile research personnel will have access to both the sales and research databases and will be able to link personal identifiers with study data. Study participants will be identified in the sales database so that the date of device training and information concerning any device problems may be made available to Tactile research personnel.

Medical information produced by this study will become part of your medical record. Information that does not become part of your medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the VA Healthcare System in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, the investigator must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this trial.

Your medical and/ or research record, including sensitive information and/ or identifying information, may be inspected and/ or copied by the study sponsor (and/ or its agent), the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/ or its agents), or by any of these agencies, the VA Healthcare System will use reasonable efforts to protect your privacy and the confidentiality of your medical information. The information collected during this study will be shared with the study sponsor, Tactile

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Medical. Your study records including the links will be destroyed six years after study completion as required by the VA's policy for destruction of study records.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

Companies outside of the United States with access to information from the study, operate under the International Conference on Harmonization (ICH) guidelines and regulations. ICH established Guidelines for Good Clinical Practices (GCP), which defines standards for quality and ethics in international research.

Data Safety Monitoring: A periodic review may be completed by a designated member of the Scientific Advisory Board. The frequency of the review will be determined on many parameters. At the conclusion of the review, the reviewer may provide recommendations that pertain to study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

The Flexitouch system is covered by insurance for these indications and will be charged to your insurance company.

WILL I BE PAID FOR PARTICIPATING?

You will be reimbursed $35.00 for each completed in person study visits**.** You will receive a check by mail after each completed visit. If you drop out of the study before completing study visit you will be reimbursed for the visits you completed. If you complete all of the scheduled visits, you will have received a total of $175.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

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WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable safety measure will be used to protect your well being. If you are injured as a result of taking part in this study, the VA (not you or your insurance) will provide necessary medical treatment at no cost to you unless the injury is due to your not following the study procedures. If you usually pay co-payments for VA care and medications, these co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of the study. The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Financial compensation for research-related injuries is not available. However, by signing this form, you do not give up your legal rights to seek such compensation through the courts.

You will not be charged for procedures that are only performed as part of this research study. You or your insurance company will, however, be charged for any other portioon of your care that is considered standard care.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, please contact

DURING THE DAY:

Dr.Dosluoglu at (716) 862-8937

AFTER HOURS:

Dr. Dosluoglu at (716) 834-9200._____

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or you decide to leave the study early, you will not lose any VA benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you at the VA. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

At any time, you have the right to withdraw from this study. If you withdraw from this study, you will still receive usual care that is available to you at the VA. There are no consequences if you decide to withdraw from the study.

Any data collected prior to your withdrawal will continue to be reviewed by the investigator but no further information will be collected.

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RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your doctor may remove you from the study at any time if it's felt not to be in your best medical interest or you had a change that impacts your study eligibility.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

- In case there are medical problems, you are injured by the research, or you have questions or complaints about this research, you can contact Ann Galla by phone at (716) 834-9200 ext. 25088.
- If you have any questions, complaints, or concerns about your rights as a study participant, you should contact Jennifer Kress the Research Compliance officer at (716) 862-3218.
- If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the IRB support assistant Pat Bongiovanni at (716)834-9200 ext. 25836 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available about the Flexitouch that is being studied which might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Ms_____ _____has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

In the future, if I decide that I no longer wish to participate in this research study, I agree that my information, which were already collected, may continue to be used only for this research by

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removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Participant's DOB	_____ Participant's last 4 Social Security	

_____

Name of Person Obtaining Consent Date

_____

Signature of Person Obtaining Consent Date