Official Title: Quantifying the Venous Congestion Curve of a Tissue Oximetry Device
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*Department of Plastic and Reconstructive Surgery*

# QUANTIFYING THE VENOUS CONGESTION CURVE OF A TISSUE OXIMETRY DEVICE

Informed Consent Form to Participate in Research
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Co-Investigator: Donald T. Browne, MD

## SUMMARY

You are invited to participate in a research study. The purpose of this research study is to gather data on your pulse oximetry and transcutaneous oximetry measurements using a device, ViOptix. You are invited to be in this study because you are 18-65 years old and meet our inclusion and exclusion criteria. Your participation in this research will involve 1 visit that will last about 1 hour.

Participation in this study will involve application of an upper extremity tourniquet and monitoring by the Vioptix device on both arms. All research studies involve some risks. The risk of harm or discomfort that may occur as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You are not expected to receive benefit from participating in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not participating in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

## INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you are 18-65 years old and meet our inclusion and exclusion criteria. Your participation is voluntary.

You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to measure rate of decline and pattern of tissue oxygenation using the device, ViOptix T.Ox. The data we collect will be used to formulate a mathematical model which will allow earlier detection and identification of venous congestion in tissue. Identifying these specific patterns will help to establish an evidence-based approach in recognizing specific problems and patterns associated with tissue compromise that can guide physicians to consider earlier flap salvage measures.

ViOptix T.Ox has been approved by the US Food and Drug Administration (FDA).

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At least 32 people at 1 research site will take part in this study. In order to identify the 32 subjects needed, we may need to screen as many as 100 patients because some people may not qualify to be included in the study.

## WHAT IS INVOLVED IN THE STUDY?

At your study visit you will enter an examination room in the Department of Plastic and Reconstructive Surgery clinic. After 10 minutes, you will have your baseline vitals measured and recorded, including heart rate, temperature, blood pressure, height, weight, and BMI. Your blood pressure will be taken once on each arm to determine the baseline blood pressure.

Next, two ViOptix probes will be secured to your arm and hand. The recording process on the ViOptix machine will begin and obtain baseline $StO_2$ levels for 5 minutes. After 5 minutes, a blood pressure cuff will be inflated on one arm. This blood pressure cuff will be left inflated for 10-20 minutes. Every 2 minutes a pulse check or doppler exam will be performed at your wrist. Last, the cuff will be deflated and the you will be free to leave the study room.

The variables to be measured and recorded will be pulse oximetry ($SpO_2$), transcutaneous oximetry ($StO_2$), demographic information, and past medical history.

If you take part in this study, you will have the following tests and procedures:

- Baseline vitals (heart rate, temperature, blood pressure, height, weight, and BMI)
- Blood pressure will be taken once on each arm
- Pulse oximetry ($SpO_2$) measurement
- Transcutaneous oximetry ($StO_2$) measurement

There will be no post-treatment follow-ups.

## HOW LONG WILL I BE IN THE STUDY?
You will be in the study for 1 day. There will be no follow-up.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

## WHAT ARE THE RISKS OF THE STUDY?
The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

## WHAT OTHER CHOICES ARE THERE?
You do not have to be in this study. This is not a treatment study. Your alternative is to not participate in this study.

## WHAT ARE THE COSTS?
All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published

in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction

## WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by ViOptix. The sponsor is providing equipment and other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes baseline vitals, heart rate, temperature, blood pressure, height, weight, and BMI, pulse oximetry ($SpO_2$) measurement, and transcutaneous oximetry ($StO_2$) measurement, however, no identifying patient information will be included in this study. Patient information will be recorded anonymously.

Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can contact Dr. Ramon Llull if you are concerned about the use of your Protected Health Information at any time by sending a letter to this address:

**Principal Investigator Name: Dr. Ramon Llull**
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your anonymous Protected Health Information for this study.

Test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site. Information about your participation in the study will be placed in the medical record, along with any medical test results that were obtained as part of this study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Ramon Llull at [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm