3270 Clifton Place
Montrose, CA 91020
Phone: (213) 493-4400
E-Mail: info@syntouchINC.com
Web: www.syntouchINC.com

Dear Potential Volunteer,

You are invited to participate in our research to evaluate how a novel prosthetic hand, equipped with contact detecting sensors, compares to existing prosthetic technology, especially during fragile grasping tasks. The results of this study will be used to influence next-generation prosthetic hand technology and the technology used has the potential to be directly beneficial to you.

Please review the attached document carefully. It outlines both the benefits to society and risks to you if you choose to participate in this research. Please know that if you agree to participate, or do not agree to participate it will not alter or affect your relationship with SynTouch, INC or Berke Prosthetics. Also please know if you agree to participate, you may change your mind or withdraw from the study at any point prior to or during the research without penalty. Additionally, there is a video and audio recording component of this study used for data analysis. Information gathered from the recordings may be used in printed research such as articles and confidentiality will be preserved.

If after reviewing the description of the research study you have any questions, please contact the researchers directly using the contact information provided below.

Thank you for your consideration of this request for participation.

Sincerely,

Jeremy A. Fishel
Principal Investigator
SynTouch, LLC
office: (213) 493-4400
email: Jeremy.Fishel@SynTouchINC.com

Gary Berke
Clinical Investigator
Berke Prosthetics
office: (650) 570-5861
email: GBerke@BerkeProsthetics.com

3270 Clifton Place
Montrose, CA 91020
Phone: (213) 493-4400
E-Mail: info@syntouchINC.com
Web: www.syntouchINC.com

PROSTHETIC HAND USE STUDY

INFORMATION AND CONSENT FORM

Introduction:
You are invited to participate in our research to evaluate how a novel prosthetic hand, equipped with contact detecting sensors, compares to existing prosthetic technology, especially during fragile grasping tasks. The results of this study will be used to influence next-generation prosthetic hand technology. This DOD funded study is being conducted by Jeremy Fishel of SynTouch, INC and Gary Berke at Berke Prosthetics in San Mateo, CA. You have been selected as a possible participant in this research because you are a healthy unilateral amputee and myoelectric prosthesis user. Please read this form and ask questions before you agree to participate in the study, which can be directed to either Jeremy Fishel or Gary Berke (contact information below).

Background Information:
The purpose of this study is to compare your speed and accuracy performance using various prosthetic hands when grasping fragile objects with and without a visual or cognitive distraction. There is also a take-home portion to understand your daily prosthesis use patterns as well as an in-office observation of prosthesis hand technique patterns during a common task of your choosing. Ten people are expected to participate in this research study.

Procedures:
If you decide to participate, you will be asked to participate in four 2-3 hour office sessions and three take-home sessions when you will use a provided prosthetic hand for 1 month of normal use. Each office visit will consist of different combinations of some of the following tasks:

1) You will complete a questionnaire asking you to indicate what media sources you are familiar with and able to describe (movies, TV shows, books, etc.) or write down alternative titles from such sources (5 minutes).
2) You will complete a questionnaire asking you to reflect upon your 1 month hand use take-home session, if applicable (5 minutes).
3) You will be informed of the testing procedures of the tasks and allowed to practice these tasks. You will be asked if you consent to the test being video and audio recorded (5 minutes).
4) ACMC (Assessment of Capacity for Myoelectric Control): You will be asked to perform an untimed, daily bimanual task (folding laundry, assembling sandwich, etc) while your use patterns and hand technique are observed by a researcher (30 minutes).
5) Bimanual Passing Procedure: Each task will be completed and timed before moving on to the next task. You will cycle through the 3 tasks several times. You will be allowed to rest in between each trial if desired (25-60 minutes total). You will use your personal prosthesis or a prosthetic hand provided by the researcher, depending on the office visit.
    a. Task 1: While standing, the researcher will present trays of fragile objects for you to grasp with one, pass to your other hand, and drop in a predetermined location. The total amount of unbroken objects passed in 30 seconds will be recorded.
    b. Task 2: The same as Task 1, but without the ability to see your hands.
    c. Task 3: The same as Task 1, but while summarizing a form of media (movie, book, etc.).
6) You will fill out an exit questionnaire about your experience.
7) A provided experimental hand may be configured for your at-home use.

The audio and video recording component of this study is done to aid in data analysis, which may be reported in print research.

Risks and Benefits of being in the study:
The study has minimal risks. First, you may experience fatigue, however, the likelihood of this risk is low if you do not experience this type of fatigue while using your hands for periods over 60 minutes. Second, while we will make every effort to ensure your participation in the study is kept confidential as required by protocol, there is always a risk that it may be accidentally disclosed unintentionally. Recordings will only be used by researchers and destroyed following the analysis of data. If you have any concerns with these risks it is advised that you discuss with the researchers before signing this consent form or participating in the study. If at any point during the study you appear to be in discomfort or unable to safely conduct the remainder of the study, the researchers will end the study.

There will be no direct benefits to you for participating in this research. Your participation is completely voluntary and if you decide not to participate, your relationships with Berke Prosthetics and SynTouch, INC will not change in any way.

Compensation:
If you participate in this study, we will compensate you for your time $200 for each office visit and reimbursed for travel. Depending on your location, you may be required to travel to San Mateo, CA, provided with airfare/train/bus in advance to travel to San Mateo, CA, or required to travel to a temporary office space within reasonable distance from you.

In the event that your participation in this research activity results in an injury, we will be unable to provide any compensation. Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please, inform the researchers as soon as possible so they can notify appropriate safety review boards.

Confidentiality:
Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your individual results will be kept confidential. In any media, written reports or publications, no one will be identified or identifiable and only group data will be presented.

The researchers will maintain all research results and records in locked file cabinets at offices of SynTouch and Berke Prosthetics. Only the researchers at these institutions will have access to the records while analyses of results are performed for this research project. The department of defense (DOD) or Federal representatives may access research records for the purpose of protecting human subjects.

Voluntary nature of the study:
Participation in this research study is voluntary. Your decision whether or not to participate will not affect your future relations with Berke Prosthetics or SynTouch, INC. If you decide to participate, you are free to stop at any time without affecting these relationships.

Contacts and questions:
If you have any questions, please feel free to contact the researchers:
Gary Berke, Berke Prosthetics – GBerke@BerkeProsthetics.com, phone: 650-570-5861.
Jeremy Fishel, SynTouch – email: Jeremy.Fishel@SynTouchINC.com, phone: 213-493-4400

You may ask questions now, or if you have any additional questions later, the researchers will be happy to answer them. If you are interested in participating, please notify the above researchers for additional information.

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Please, keep one copy of this letter and consent form for your records and return the other signed copy to the researcher/s.

Thank you,

Jeremy Fishel
213-493-4400

Gary Berke
650-570-5861

Statement of Consent

You are making a decision whether or not to participate.
Select whether you agree to participate or choose not to participate.
Your signature indicates that you have read this information and your questions have been answered.
Even after signing this form, please know that you may withdraw from the study at any time.

___ I consent to participate in the study.

___ I do NOT consent to participate in this study.

_____
Participant name (please, print)

_____
Signature of Participant Date

Video and Recording Consent

You are making a decision whether or not to give permission for the video and audio recording of this experiment.

Select whether you agree to be videoed and recorded in this experiment.
Even after signing this form, please know that you may withdraw from the study at any time.

___ I agree to have my session video and audio recorded and understand that I may withdraw my consent at any time without penalty.

___ I do NOT agree to have my session video or audio recorded

_____

Signature of Participant Date

Contact Information

If you consent to participation in this study and agree to be videoed and recorded as part of this study, please provide your contact information. Your contact information is for the purpose of scheduling office visits, verifying eligibility, and providing forms regarding the study that will be needed prior to your initial visit.

Name: _____

Date of birth:_____

Phone number: _____

Email address:_____

Address:_____

_____

English:

This project has been reviewed and approved by the Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB; Fax: (866) 300-0679; or by emailing director@heartlandirb.org.

Spanish:

Este proyecto ha sido revisado y aprobado por Heartland Institutional Review Board. Preguntas sobre sus derechos como participante en esta investigación pueden dirigirse al Directo Ejecutivo de Heartland IRB. Oficina: (866) 618-HIRB; Fax: (866) 300-0679; o por correo electrónico: director@heartlandirb.org.