



THE UNIVERSITY OF BRITISH COLUMBIA

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SUBJECT INFORMATION AND CONSENT FORM

Touch your patient: Tactile display of physiological monitoring
Effect of a tactile belt display of a physiological monitoring system in the
simulated clinical environment

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BACKGROUND

Exponential growth in the number of monitored parameters, combined with the high probability of false alarms has proved counterintuitive for clinicians. Clinicians' visual and auditory senses are subject to overload. This cognitive burden will increase with the advance of monitoring technology unless a new means of linking the clinician to the information is found.

Our proposal aims to develop a tactile display to harness the skin to convey information from physiological monitors to attending clinicians. With advanced micro-sensor and wireless technologies, stimulation of the skin through a tactile display offers an innovative and very practical way to re-connect clinicians with their patients.

Tactile displays do not increase noise pollution in the operating room, and will function well despite background noise. Initial experiments indicate that tactile signals compete more successfully for attention than auditory ones and are virtually impossible to ignore.

Despite being highly suitable, tactile displays have not yet been used in the clinical monitoring environment. Additionally, a required aspect of an accepted new tactile display is usability – the device must be easy and pleasant to use. At this point it is not known how clinicians will react to a new tactile display.

WHAT IS THE PURPOSE OF THE STUDY?

To assess the technical performance (i.e. accuracy and response time of stimulus recognition) of the vibro-tactile belt under different conditions.

WHO CAN PARTICIPATE IN THE STUDY?

Anesthesiologists and final year resident anesthesiologists may participate in this study.

WHO CANNOT PARTICIPATE IN THIS STUDY?

Subjects that do not consent or who are unable to consent cannot participate in this study:

- ◆ Presence of any of the following conditions:
 - Neurological disorders including stroke and epilepsy
 - Cardiovascular disorders:
 - I. Ischemic heart disease (heart disease caused by narrowed heart arteries)
 - II. Raynaud's phenomenon (sudden and significant reduction of blood supply to fingers, toes, nose, ears and/or lips)
 - III. Resting blood pressure greater than 140/90
 - Mental disorders (including subjects on antidepressant medications)
 - Past history of drug or alcohol abuse
 - Simultaneous participation in another clinical trial
 - Pregnancy
 - Previous back surgery with sensory loss on abdomen/back
 - Back pain within last 6 months
 - Taken sedative medication within last 24 hours
- ◆ Inability/failure to obtain 75% or more in the post-training quiz on stimuli pattern identification in the Tactile Belt System and Think-Aloud Method Training and Testing Phase.

WHAT DOES THE STUDY INVOLVE?

As a subject in this study, you will be asked to wear a vibro-tactile display around the waist like a belt. You will feel vibrations at distinct locations around the belt.

The purpose of this phase is to evaluate the effectiveness of the vibro-tactile display and the alert stimulus scheme under different conditions.

During this phase of study, you will first be given a brief training to become familiar with the tactile belt prototype and the think-aloud method (i.e. speak aloud on what you are thinking). You will be given a post-training quiz before proceeding.

In the testing phase, you will be asked to identify the information communicated by the prototype in 2 situations: 1) undistracted, 2) distracted condition. Both situations require you to use the think-aloud method. The order of the tests will be randomized.

When the testing portion has been completed, you will be asked to fill out a short post-study questionnaire, for your feedback and comments on the tactile display prototype.

The entire study will be completed in 1 hour.

WHAT ARE YOUR RESPONSIBILITIES?

You are responsible for wearing the tactile display belt throughout the study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

It is unlikely that you will directly benefit from this study. The information gained during this study may help anesthesiologists in the future with the development of new physiological monitoring systems.

WHAT HAPPENS IF YOU DECIDE TO WITHDRAW CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without providing any reasons. If you decide to enter in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you choose to enter the study and then decide to withdraw at a later time, all data collected in the study will be retained for analysis. By law, this data cannot be destroyed.

WHAT HAPPENS IF SOMETHING GOES WRONG?

In the unlikely event that something goes wrong emergency medical services will be obtained promptly. The safety of the vibrotactile belt device will be ensured as it will run from a 9V portable power source. The devices do not invade the body, and are insulated from the skin surface. The devices will also undergo electrical safety testing before usage.

The belt will be worn over operating room scrubs so will not be in direct contact with skin to avoid direct irritation or allergenic reaction to skin.

By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

WHAT WILL THE STUDY COST?

There will be no cost to you for your participation in the study. You will be given \$5 as a token of appreciation for your time. This is not a reimbursement of your time.

WILL YOUR PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Board for the purpose of monitoring the research. However, records which identify you by name, initials or date of birth will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify you only by code number may be required by the regulatory agencies or viewed by other collaborators or industry partners in comparing different methods. However, you will not be identified by name, initials, or date of birth as part of this study data.

The fact of your participation in this study cannot be kept strictly confidential as you will be observed in the study during the scenario by the research assistant(s). However, we will not provide a list of participants or non-participants to anyone not involved in running this study. In particular, we will not provide such a list to anyone who has supervisory responsibilities. In reporting results from this study, we will not identify you.

WHO TO CONTACT IF YOU HAVE QUESTIONS ABOUT THE STUDY DURING YOUR PARTICIPATION?

If you have any questions or desire further information about this study before or during your participation, contact Dr. Guy Dumont at 604-822-2336.

WHO DO YOU CONTACT IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT YOUR RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights and/or experiences as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office Research Services, at 604-822-8598.

CONSENT TO PARTICIPATE

I have read all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my participation is entirely voluntary and that I may refuse to participate, or may withdraw from the study at any time.

I do not waive any of my legal rights by signing this consent form. I have been told that I will receive a dated and signed copy of this form.

Printed name of subject	Signature	Date
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Printed name of witness	Signature	Date
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Printed name of principal investigator/ designated representative	Signature	Date
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