ULTRASOUND SOP

SOP Code	SOP ContAct003-02
Effective Date	02-APR-2025

A. PURPOSE AND BACKGROUND

Applying or ordering the application of a form of energy is considered a controlled act. This SOP describes the procedures for researchers to conduct a study with participants using an ultrasound device.

B. DATA/IMAGE COLLECTION

1. **Types of images collected in accordance with this SOP:**
   - Images and videos of ultrasound scans
   - Doppler velocity signals

2. **Types of images NOT collected in accordance with this SOP (require a separate SOP:**
   - Invasive scans such as transrectal, transesophageal, and transvaginal
   - Obstetric or fetal scans
   - Ophthalmic or eye scans
   - Gas contrast/microbubbles

C. PROCEDURES/STUDY PROTOCOL

1. The researcher washes hands thoroughly with soap and warm water or uses an alcohol-based sanitizer. Hands are to be properly cleaned before the gloves are put on and after the gloves are removed. Hand hygiene is also needed before and after the replacement of gloves during a procedure or in between tasks. The use of gloves does not replace the need for hand hygiene.

2. The participant is invited to take a comfortable seat or lie down on the bed, depending on the study protocol.

3. The researcher applies ultrasound gel to a probe, makes contact between the probe and the skin, and optimizes the image or signal by adjusting the settings on the device and/or adjusting the position of the probe.

4. When the ultrasound measurement(s) is/are completed, the researcher lifts the probe off the skin and provides the participant with disposable cleaning tissue to clean the gel off.

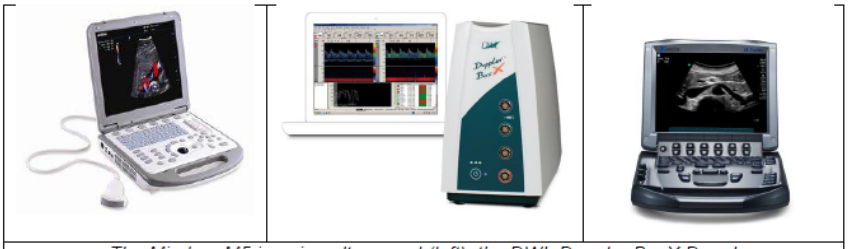
5. Upon completion of the ultrasound measurement(s), probes are cleaned by wiping them with disinfectant.

C. EQUIPMENT

Only commercial off-the-shelf (COTS) ultrasound devices with Health Canada and/or CE approval will be used. Non-COTS ultrasound devices and devices that are not Health Canada/CE approved are not the topic of this SOP and will require separate research ethics approval (and possibly additional processes). Contact the research ethics office.

At time of writing this SOP, there is a large commercial ultrasound market which includes dozens of brands such as GE, DWL, Philips, Toshiba, Samsung, etc. To achieve Health Canada and/or CE safety certifications, individual companies must have demonstrated to the industry regulatory bodies that the devices they sell meet the strict safety standards set out by the Health Canada and/or CE.

The devices used may look similar to these below:



The Mindray M5 imaging ultrasound (left), the DWL Doppler BoxX Doppler ultrasound device (centre), and the SonoSite M-Turbo (right) are shown above.

Supplies used during ultrasound scans include (but are not limited to):

- Ultrasound gel
- Disinfectant wipes

- Paper towels/tissue
- Nitrile/vinyl gloves

Disposable, single use materials or equipment are to be used whenever possible and any reusable materials or equipment must be cleaned and disinfected following standard infection prevention and control procedures before use with another participant.

D. DESCRIPTION TO STUDY PARTCIPANTS

1. The information-consent letter must include the following:
    - An overview of the training and experience of the person performing the ultrasound. If an individual has been delegated this task, a description that a physician has authorized the trained and qualified person to carry out the ultrasound procedure, ensuring it is done safely and within legal guidelines.
    - Specific clothing participants may be asked to wear for the ultrasound session.
    - The part(s) of the body to be scanned will be exposed.
    - The risks and safeguards.
    - Participants can ask questions or ask to stop the procedure at any time.

E. RISKS

Participants:

- Physical and/or psychological discomfort.
- Irritation/rash from the ultrasound gel.
- Thermal risks involve heating of soft tissue, bone and potential skin burn.
- Non-thermal risks from the pressure of the ultrasound waves, such as cavitation (the development, growth, vibration and possible collapse of air bubbles in the tissues).
- Exposure to infectious diseases.

Researchers

- Risk of injury to researchers if equipment is not used correctly as per the manual.

F. SAFEGUARDS/SAFETY PROCEDURES

1. Researcher is to have completed:
   - First Aid/CPR training
   - Any required safety training from the UWaterloo Safety Office
   - Training in the safe operation of the ultrasound equipment

2. Routine practices are to be applied at all times. Refer to the Canadian Centre for Occupational Health and Safety guidelines: CCOHS: Routine Practices. https://www.ccohs.ca/oshanswers/prevention/universa.html#workers

3. The researcher is to follow the guidelines for safe use of diagnostic ultrasound and ALARA (As Low As Reasonably Achievable) principle for ultrasound power output. See https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/radiation/guidelines-safe-use-diagnostic-ultrasound.html

4. The researcher must follow UWaterloo Safety Office guidelines on use of personal protective equipment and specifically use of gloves. See Personal Protective Equipment (PPE) | Safety Office (uwaterloo.ca)

5. A new pair of disposable nitrile/vinyl gloves are used with each participant. Gloves are for single procedure use only. Gloves should always be removed using a glove-to-glove/skin-to-skin technique to prevent contaminating the hands. Gloves are to be disposed in an appropriate container.

6. To minimize physical and/or psychological discomfort, a familiarization period is used to explain the ultrasound procedure to the participant including the equipment used during the ultrasound. Participant is given time to ask questions prior to participating.

7. Irritation from the ultrasound gel can occur. The participant is asked prior to participating whether they are sensitive or have had an allergic reaction to ultrasound gel. If they indicate they are sensitive/have an allergy, the researcher may check for alternatives.

8. If a participant experiences a rash from the ultrasound gel, they are asked to keep the area clean and dry. The rash should subside in 2-4 days. If symptoms worsen, the participant should seek medical attention.

9. The participant is asked to indicate to the researcher if the ultrasound probe feels too warm.

10. If a skin burn should occur, a cold compress and a sterile covering is applied.

G. EQUIPMENT MAINTENANCE

- Maintenance testing will be conducted as per the ultrasound device manual.
- Visual inspections will be conducted by turning the device on/off, inspecting all cables/electrodes for visible damage, and verifying that the device is complete.

F. REFERENCES

1. Public Health Ontario (2013). *Best Practices for Cleaning Disinfection and Sterilization of Medical Equipment/Devices in all Health Care Settings, 3rd edition.* Retrieved on March 26, 2025, from bp-cleaning-disinfection-sterilization-hcs.pdf (publichealthontario.ca)

2. Public Health Ontario (2015). *Infection Prevention and Control for Clinical Office Practice.* Retrieved on March 27, 2025, from bp-clinical-office-practice.pdf (publichealthontario.ca)

3. Health Canada (2001). *Guidelines on Safe Use of Diagnostic Ultrasound*. Retrieved on March 27, 2025, from https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/radiation/guidelines-safe-use-diagnostic-ultrasound.html

4. University of Waterloo Office of Research Ethics (2013). *Human Participant Research Guidelines: Controlled Acts and the Delegation of Controlled Acts.* Retrieved on March 27, 2025, from Controlled acts and medical directives | Research (uwaterloo.ca)

SOP Code	Effective Date	Summary of Changes
SOP ContAct-003-01	11-May-2017	Original
SOP ContAct-003-02	02-APR-2025	Updates to procedures, description to participants, risk, and safeguards. Updates to links for researchers. Updates to references.