

Intramuscular Heating Rates of a Chattanooga Intelect XT Therapeutic Ultrasound with a 3 MHz frequency and 1.0 W/cm<sup>2</sup> Intensity at Three Depths up to 2.5 cm.

1-22-19

## Methods and Procedures Attachment

Individual subjects will report to the Bentson Bunker Fieldhouse, Room 14. They will be instructed to wear appropriate shorts or pants that can be rolled up to expose the gastrocnemius (calf) muscle. Upon their arrival to room 14, they will be given a copy of the consent form to read and sign. The subject will be given the opportunity to ask questions to the researchers regarding the consent form at this time. The subjects will lie prone on a treatment table for insertion of the thermocouple and for the ultrasound treatment. A towel will be placed under the subjects' knee as needed for comfort. The 21-gauge flexible, implantable thermocouples (very small temperature probes) will be calibrated before the study begins and then will be sterilized in MetriCide for at least 12 hours before use. The thermocouples will be inserted into the medial side of the gastrocnemius muscle horizontally and parallel to the ultrasound treatment surface at depths of 1.0cm, 1.75cm, and 2.5cm. Horizontal insertion of the thermocouples allows the ultrasound to be applied without interfering with the thermocouple lead wires.

The subject will lay prone on the treatment table with the foot and lower leg off of the treatment table in a relaxed, comfortable position. The following procedures will be completed using universal precautions:

1. The investigator will prep the treatment area by having the subject flex the calf to determine the proper location for the ultrasound treatment in the middle of the medial gastrocnemius muscle belly at its largest girth.
  - a. A carpenter's square with markings along the vertical arm at the three experimental depths (1.0, 1.75, 2.5 cm) will be used.

- b. The horizontal arm of the carpenter's square will be covered in tape. The carpenter's square is then placed just proximal to the treatment mark while the level on the horizontal arm is used to maintain a level measure.
- c. Marks will be made on the muscle belly parallel to the marks on the vertical axis at 1.0, 1.75 and 2.5 cm depths.
- d. A mark is also made on the horizontal arm tape in line with the treatment mark on the medial gastrocnemius.



- 2. The Terason uSmart 3300 diagnostic ultrasound unit will be used to measure the adipose thickness over the treatment area and look for abnormalities in the treatment and thermocouple insertion areas. Aquasonic® 100 ultrasound gel will be placed on the 15L4 transducer. The transducer with gel will be placed over the mark of the treatment area. Once the transducer is in place, the screen will be frozen and the skin and adipose thickness will be measured using the caliper tool.
  - a. If adipose thickness is greater than 1.0 cm or any tissue abnormalities exist that could contraindicate thermocouple insertion, the subject will be excluded.

3. The thermocouples will be removed from the MetriCide after sterilizing for a minimum of 12 hours prior to insertion.
  - a. The distal aspect of the thermocouple will be wiped dry with sterile gauze.
  - b. A mark with a sharpie will be made on each thermocouple just past the length marked on the horizontal arm of the carpenter's square. This allows the tip of each thermocouple to be directly below the treatment site. A second mark will be made at 5 cm to make sure the thermocouple does not go too deep into the tissue.



- c. The distal end of the thermocouple will be wiped clean again using a 70% isopropyl alcohol wipe up to the marks and then the thermocouple will be wrapped in sterile gauze until it is inserted.



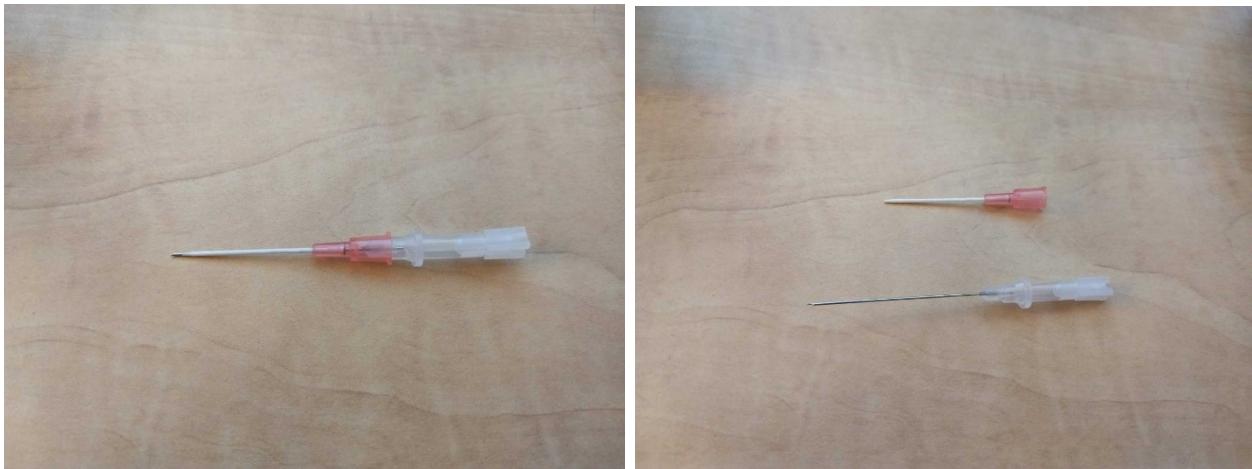
4. The insertion areas will be shaved to remove any body hair (if necessary) and cleaned using Betadine.

a. Once the Betadine dries, 70% isopropyl alcohol will be wiped over the insertion area and given time to dry.



5. The subject will be instructed to take two deep breaths, while the researcher lightly grasps the gastrocnemius to confirm muscle relaxation.

a. During the second exhalation, the 1.16 in needle catheter will be placed into the subject's calf at the 1.0 cm depth insertion mark using the level to guide the needle in. The needle will be removed leaving the catheter in the tissue.



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- b. The thermocouple will be threaded through the catheter to the appropriate depth marked on the thermocouple and the catheter will be removed.



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- c. The thermocouple will be secured using medical tape to keep it from moving.
- d. This procedure will be performed 3 times, with one thermocouple placed at each respective depth: 1.0 cm, 1.75 cm, and 2.5 cm.
6. Each thermocouple will be attached to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH), which will measure and record intramuscular temperatures from the tips of the thermocouples.
7. An ultrasound treatment template will be applied at the treatment site and secured with tape to maintain consistent treatment size.
  - a. This template will be twice the size of the transducer's Effective Radiating Area (ERA).



8. A metronome will be utilized to consistently move the transducer at a rate of 4 cm/s .
9. The ultrasound treatment will begin once the intramuscular temperature has remained the same for a minute.
10. Each subject will receive one ultrasound treatment at the following parameters: 3 MHz frequency, 1.0 W/cm<sup>2</sup> intensity, and 100% duty cycle using the Chattanooga Intelect<sup>®</sup> Legend XT.
  - a. Termination of treatment will result when any of the following occur:
    - i. A 15-minute treatment time is obtained.
    - ii. A 4°C temperature increase occurs at all three depths as this has been shown as the necessary temperature change to increase tissue extensibility.
    - iii. A 45°C temperature is reached at any depth, due to concern of tissue damage at high temperatures.
    - iv. The subject experiences any pain or discomfort during the treatment.
11. Following the treatment, the ultrasound gel will be wiped from the leg, the template and thermocouples will be removed, and the insertion sites will be cleaned with 70% isopropyl alcohol wipes and covered with a band aid.
12. The subject will then be instructed on the possibility of minor soreness for the next day or two and instructed on an icing schedule to decrease discomfort.