Document:
Needle Manufacturing and Testing Plan
Project:
Ultrasound Needle Guidance for Hydrogel Injection During Cervical Cancer Brachytherapy
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Materials Needed [Manufacture]:
- PZT Tube, Specs: PZT-5H, OD: 0.100”, Wall: 0.012”, Length: 0.070” ~ 0.1”
- Conductive Silver Epoxy
- Non-Conductive Insulating Epoxy
- Coaxial cable/wire
- Spinal Needle (for Hydrogel Injection)
- Clamp or other positioning mechanism
- Multimeter

Materials Needed [Testing]:
- Working Ultrasound System with Probe
- US-Key High Performance
- Acrylic Box
- Water
- Pelvic Phantom (Second Part of Project)

Procedure for Manufacturing the Needle:
1. Confirm the electrical conductivity of the needle.
2. Separate the live and ground wires of the coaxial cable, and wrap the ground wire around the needle.
3. Mix A and B parts of conductive silver epoxy in 1:1 ratio* evenly.
4. Apply conductive epoxy (wet solder) over the ground wires and an area slightly closer to the head of the needle. Place the piezo ceramic tube over the latter portion (as close to the tip as possible).
5. Using the multimeter, check for good electrical contact and shorting. Note: Electrical contact might not be established until the epoxy is dry.
6. Wait for the epoxy to dry.
7. After checking the contact again, mix insulating epoxy parts in 1:1 ratio* and apply insulating epoxy at the ends of the piezo tube and over the ground wire. Make sure to leave space for the other wire to wrap around the outer face of the piezo tube.
8. Repeat steps 3 to 7 for the live wire over the piezoelectric tube.
9. Carefully, wrap the element and wires with a heat shrink to provide maximal protection.

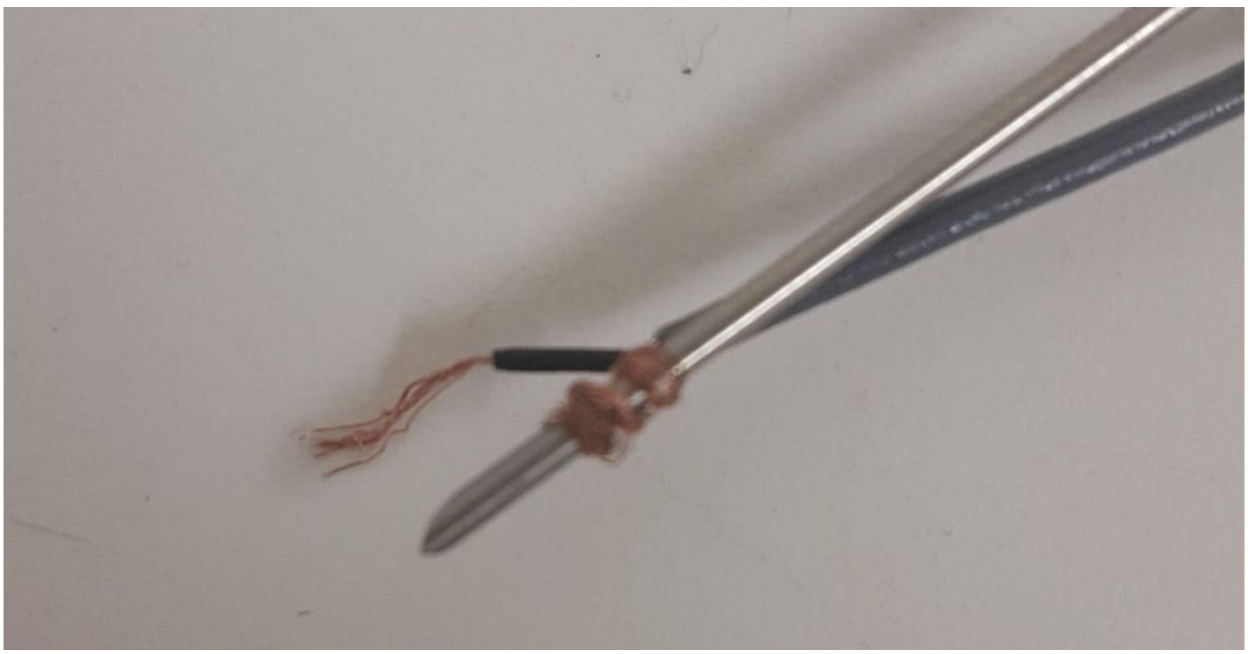
10. Check all connections.

*Respectively mix the ratios as specified by manufacturer.

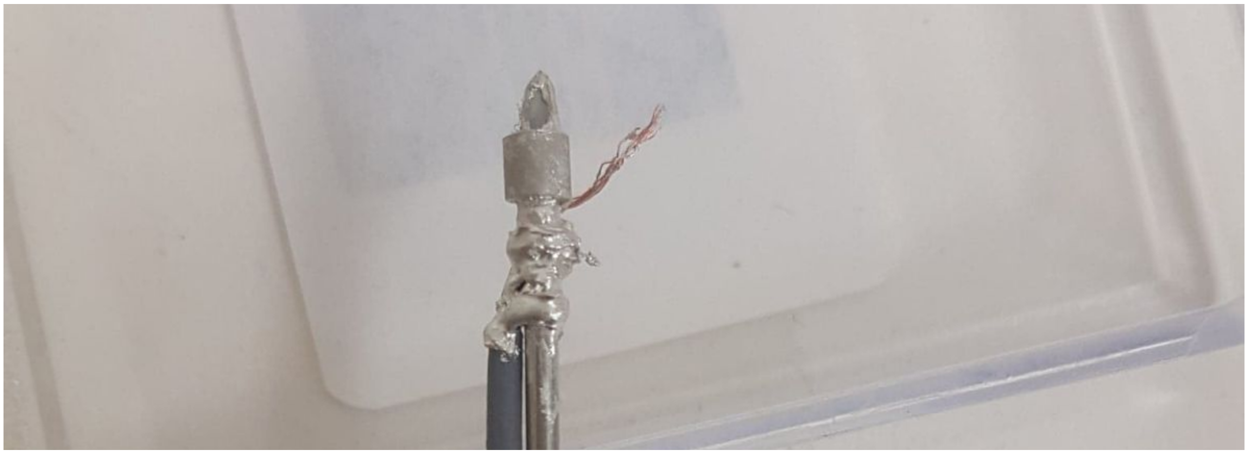
Caution:

- PZT tube is extremely fragile. USe care when handling during manufacture.
- Ensure there is no solder or electrical connection between the two electrode faces on the PZT tube while the solder is wet.
- Test the electrical connections prior to testing in water and with sensitive electronics.
- Cold solder and epoxy may take a few hours to dry.
- PZT tube is extremely sensitive to heat. Be careful when applying heat.

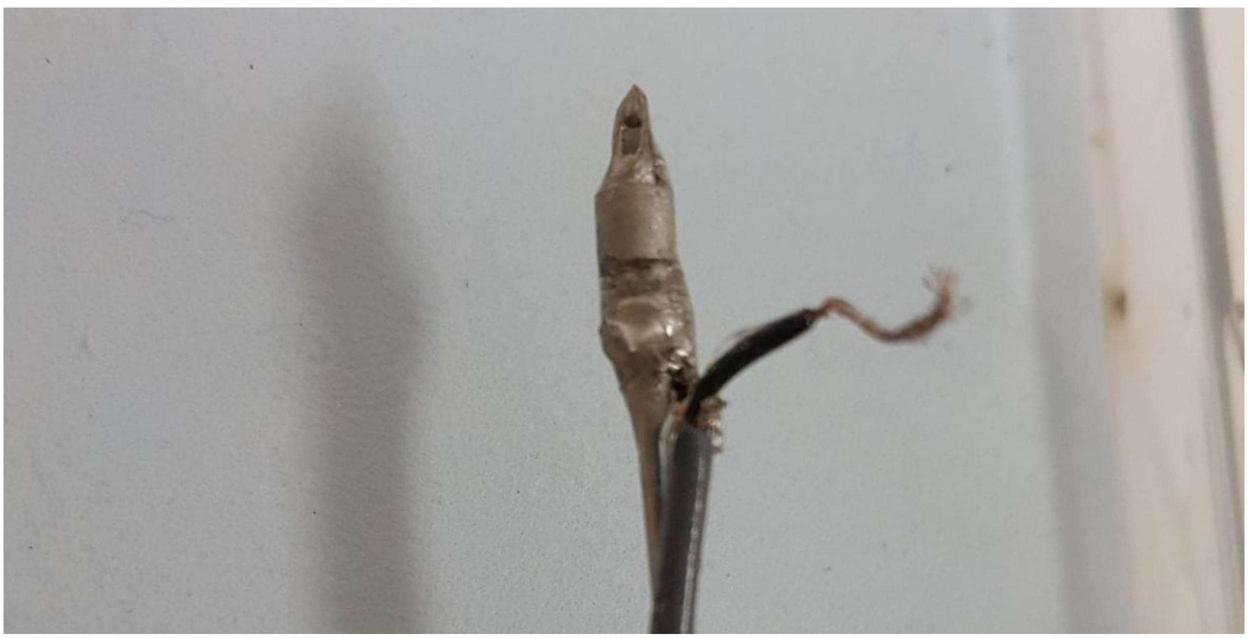
Example Figures:



Wrapping the ground wire around the needle at the tip.



Applying solder over the ground wire as well as on the underside of the PZT tube for electrical connection.



Coat with insulating epoxy to protect the elements and prevent the two electrodes from shorting. After doing the ground wire, you would repeat the application of cold solder and insulating epoxy for the live wire, wrapped around the PZT element on the top size. You would then heat shrink over the entire structure, to prevent possible shorting once the needle is placed in conductive media (e.g. water).

Caution: Handle the electronics with care and precision, as the PZT tube is extremely fragile and even scratches can affect the acoustic performance and influence the quality of the resulting ultrasound image . Use other tools for assistance as necessary.

Testing Plan:

1. **Connectivity Test:**

   Using a multimeter, you want to check that the parts that need to be connected are connected, and the parts that need to be insulated are insulated, in order to prevent any shorting. This step is crucial, as shorting can damage expensive and sensitive equipment in later tests, and also pose a danger to those use and testing this device.

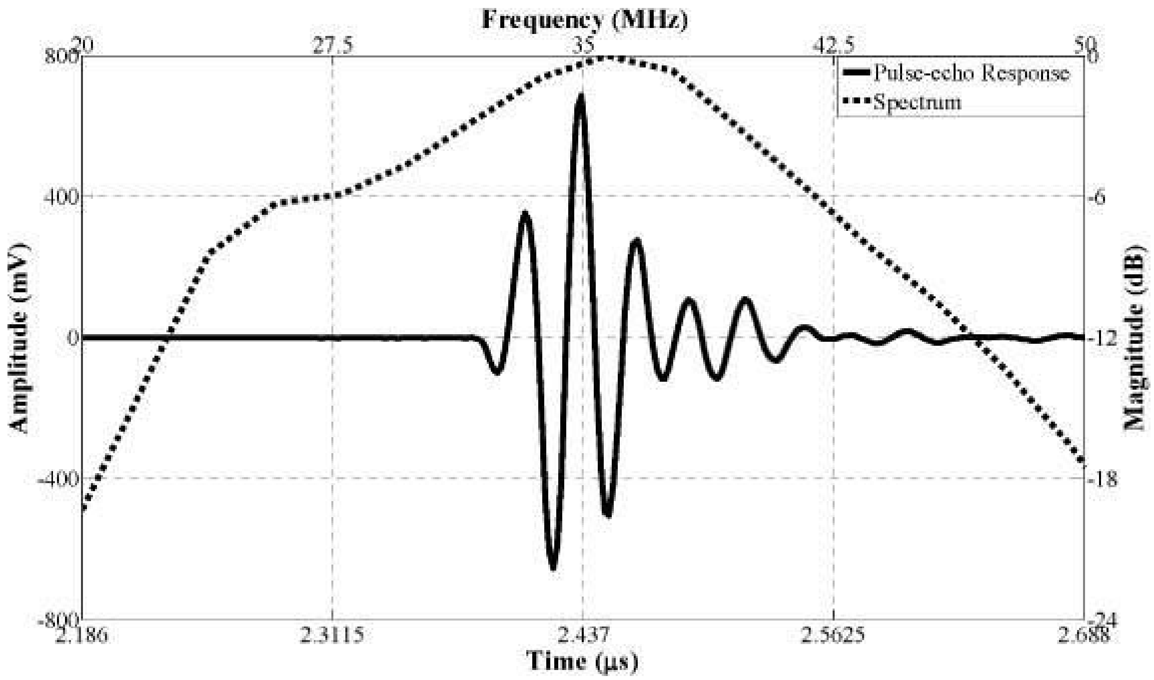
2. **Water Test:**

   In the water test, we will test the ultrasound transducing properties of our element on the needle. We will connect the active element with US-Key, a small, high-performing ultrasound device with a single channel to transmit and receive ultrasonic waves. The figure below shows a sample image of how the US-Key system can be used to test ultrasound imaging in a phantom. For this project, at this stage only a water phantom will be used as the media for ultrasound travel.

3. **Central Frequency Determination:**

   Next, you want to determine the central frequency, the resonant frequency of the piezo element, in order to try to match that frequency with the central frequency of the complementing ultrasound system (e.g. abdominal probe or transrectal probe). It is important to do this step because matching ensures maximal performance.

   It is expected that piezo tube will have a central frequency between 2 ~ 3 MHz. The central frequency can be estimated based on the geometry and characteristics of the material, but experimental determination of a match between our transducer and probe will be best. You want to generate data such as shown below, and you want the two systems to have a greater overlapping performance region.

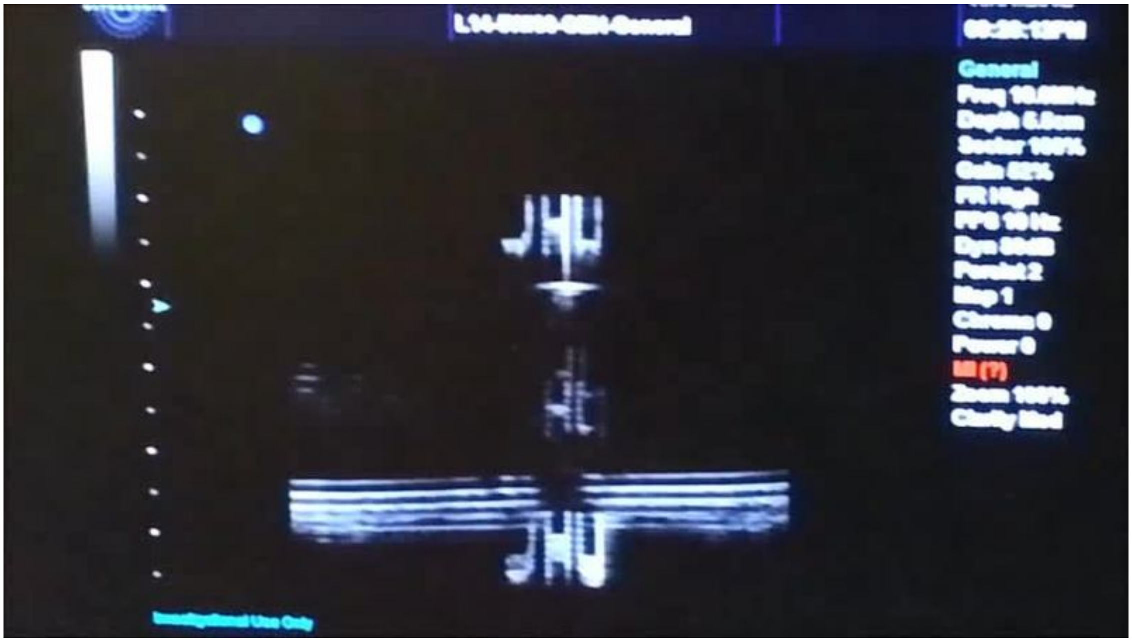


4. Phantom Test

In this stage, you test the probe and the needle on an actual phantom to best simulate realistic circumstances. You attempt to capture the ultrasound signal

Here is a link to a video of what the ultrasound should look like:
https://upload.wikimedia.org/wikipedia/commons/4/47/Active-Ultrasound-Pattern-Injection-System-%28AUSPIS%29-for-Interventional-Tool-Guidance-pone.0104262.s005.ogv

If you adjust the backprojection algorithm and pulsing pattern, you may be able to inject patterns such as this one. A custom message may be useful for the practitioner:


General
FR High
Map 1
JHU
JHU
Investigational Use Only