Targets and Metrics

Team 314: Abbott Reusable RF Probes

Targets

Targets are derived from functions necessary for our device. A *target* is a tool that shows a function criterion has been met. Usually, this is signified through a quantitative value. Since our sponsor has not worked out the details for setting up an NDA for our team, we have no access to any details of specifications of the current probe. The targets and metrics in this document were developed utilizing the current medical industry data we were able to obtain. The additional targets/metrics correspond to our most important customer needs: reusable for up to 100 times and have a unit cost of less than $200.

Critical Targets

Functions	Targets
Transmit RF Signal	Signals from 2Hz to 460kHz can be transmitted
Transmit Voltage	Voltage ranges between 1.845 V and 7.2 V
Converts RF Signal into Thermal Energy	Thermal energy between 50 - 110 degrees C
Read Temperature	Range of temperature between 50 degrees C and 110 degrees C

Table 1. Critical targets function table

Transmit RF Signal

The RF signal is transmitted from the RF generator through the electrode and into the probe. The current design of the Abbott probe uses Stainless Steel 304 for their probe, which is capable of transmitting RF signals from 2Hz to 460kHz. Our team's probe will continue to use Abbott's current Stainless Steel (304) shaft due to its durability and capacity to propagate the necessary signals for RF ablation.

Transmit Voltage

The voltage being generated by the RF generator is transmitted through the shaft to the point of ablation. The material used in the probe will be a conductor that has the capability to transmit voltage between 1.845 V and 7.2 V. These voltage values

correspond to the output from a thermocouple used to measure the temperature at the tip of the probe.

Converts RF Signal into Thermal Energy

The RF signal is converted into thermal energy in order to treat the patient for nerve pain. This heat is used to heat a patient's pain-transmitting nerve and create a heat lesion.

During the RF ablation procedure, the energy absorbed by the human tissue from the RF signal (referred to as specific absorption rate or SAR) can be calculated using the following equation:

$$SAR = \frac{\sigma}{\rho}|E|^2 = \frac{1}{\sigma\rho}|J|^2 \ (W/kg)$$

$$\sigma = 0.5(S/m) : human\ tissue\ electrical\ conductivity$$

$$\rho = 1.030(g/cm^3) : human\ tissue\ mass\ density$$

$$E^*(V/m) : electric\ field\ strength$$

$$J^*(A/m^2) : electric\ current\ density$$

**We do not have access to the specifications for Abbotts RF generator, thus we do not know the electric field strength, or the electric current density.*

From the medical papers referenced, the average temperature used in RF ablation for nerve pain ranges between 50°C and 110°C. Using the equation above, we should get the SAR, and subsequently, we can calculate the temperature.

Read Temperature

A thermocouple sensor is used to measure tissue heating in voltage values that correspond to temperatures.

Additional Targets

In addition to the critical targets for our system design, we identified the following targets that fulfill our customer needs.

Functions	Targets
Durability of Materials	Reusable for at least 100 times (procedure and sterilization)
Affordable Cost	The production cost for one probe should stay below $200
Compatible with Medical Sterilization	The device will undergo medical sterilization

Techniques	techniques successfully (eg. autoclave)

Table 2. Additional targets function table

Durability of Materials

The product should be able to withstand at least 100 uses for both procedure and sterilization purposes. For the product to achieve greater than 100 uses would be advantageous, but we must also consider other limiting factors.

Affordable Cost

The product should be below $200 for an estimated 100 uses. The price target can be adjusted depending on how much improvement can be made compared to the current Abbott probes.

Compatible with Medical Sterilization Techniques

The product should be capable of withstanding the sterilization process 100 times or more. The product should retain its usability and function and should not have it diminished by repeated cleanings up until the targeted interval .

Metrics

Metrics are a standard of measurement on which we base our targets on. We will be testing concepts based on these metrics, which we derived based on the governing equations for the RF ablation process.

Critical Metrics

Functions	Metrics
Transmit RF Signal	Signal is successfully transmitted from the RF generator to the tissue
Transmit Voltage	Voltage is successfully transmitted from the RF generator to the tissue
Converts RF Signal Into Thermal Energy	RF signal is converted into thermal energy when the tissue heats up
Read Temperature	Reads in the tissue temperature

Table 3. Critical metrics function table

Transmit RF Signal

To ensure the proper RF signal is being transmitted from the generator to the tip, we will measure both locations using an EMF meter and compare the results.

Transmit Voltage

To ensure that the proper range of voltage is being transmitted from the generator to the tip, we will measure both locations using a Multimeter and compare the results. Multimeters are abundantly available in the ECE department and would be the most effective method to measure the voltage transmitted.

Converts RF Signal Into Thermal Energy

To measure and observe the RF signals conversion into thermal energy we will use a temperature-sensing device, such as a thermal camera, to observe the differences in heating at the ablation site due to the nature of how RF signals travel.

Read Temperature

For reading the temperature, we will use a Multimeter to measure the voltage given by the thermocouple. The observed voltage values correspond to temperature values that will allow us to see the temperature at the ablation site.

Additional Metrics

Functions	Metrics
Durability of Materials	Device will successfully work for at least 100 uses
Affordable Cost	The quote for the prototype (materials and development) will not exceed $200 per unit
Compatible with Medical Sterilization Techniques	The device will be able to withstand the sterilization procedure successfully

Table 4. Additional metrics function table

Durability of Materials

We define “use” as a successful transmission of RF signal into the tissue and a successful sterilization process of the device. Our device should be able to withstand 100 uses. We will test the device either in person or via simulations (depending on what our sponsor is able to give us) and record how many uses it can handle.

Affordable Cost

The production of the product should stay below $200, but that number can be scaled up based on the efficacy of the product. The sponsor will provide us with a more accurate method of measuring the efficacy vs cost of production.

Compatible with Medical Sterilization Techniques

The device will be sterilized using a standard medical procedure (the current technique used is autoclave sterilization, but it can change based on future information given by our sponsor).

Appendix: Targets and Metrics

Functions	Targets	Metrics
Transmit RF signal	Signals from 2Hz to 460kHz can be transmitted	Signal is successfully transmitted from the RF generator to the tissue
Transmit Voltage	Voltage ranges between 1.845 V and 7.2 V	Voltage is successfully transmitted from the RF generator to the tissue
Converts RF Signal into Thermal Energy Measured by SAR	Specific absorption rate between x W/kg to y W/kg	RF signal is absorbed by the tissue and measured by the SAR value
Read Temperature	Range of temperature between 50 degrees C and 110 degrees C	Reads in the tissue temperature
Durability of Materials	Reusable for at least 100 times (procedure and sterilization)	Device will successfully work for at least 100 uses
Affordable Cost	The production cost for one probe should stay below $200	The quote for the prototype (materials and development) will not exceed $200 per unit
Compatible with Medical Sterilization Techniques	The device will undergo medical sterilization techniques successfully (eg. autoclave)	The device will be able to withstand the sterilization procedure successfully

* Highlighted text: Critical Targets and Metrics