SONAR: Breast Lesion Localization Solution

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Our Mission: *Develop an advanced breast localization solution that offers surgeons precise and reliable tumor identification, ultimately improving patient outcomes by reducing the need for repeat procedures and lowering the financial burden on patients.*

Clinical Need

Breast lesion localization is used in surgeries to pinpoint non-palpable breast tumors for removal. Current wire-guided methods have drawbacks, including patient discomfort, logistical issues, and safety concerns.

Figure 1. Wired versus non-wired localization methods [1].

Design Input

Customer Needs: Accuracy, comfort, safety, efficiency, and usability
Metrics: frequency of additional surgeries, localization rate, procedure length, and ease of use.
Primary Users: Becton-Dickinson (Manufacturer) and clinicians
Economics: 2023 market valued at $1.13-$1.12B USD, CAGR 7.8% - 11.7% from 2024-2033

Product Concept

Solution: handheld probe, similar to a metal detector that will pick up on the signal of magnetic seeds implanted on lesions, allowing clinicians to directly locate magnetic markers.
Advancements in the technology:

- Adjustable field strength for flexibility at various depths
- Non-invasive and patient friendly
- Compatible with minimally invasive surgical practices

Product Architecture

1. Solenoid for a Magnetic Field

$$B_{solenoid} = \mu_0 \frac{NI}{l}$$

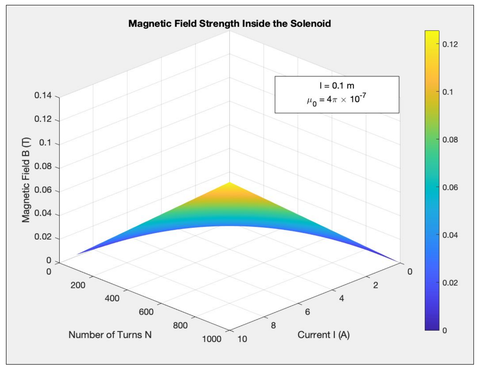

Figure 2. Magnetic strength inside a solenoid as a function of the number of turns (N), and current (I), with fixed solenoid length, 0.1m.

2. Force between Magnetic Seed and Handheld Detector

$$F = \frac{\mu_0 \bullet m_1 \bullet m_2}{4\pi r^2}$$

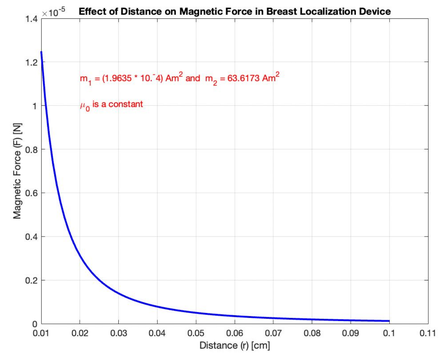

Figure 3. Effect of distance (r) on magnetic force between a magnetic seed and a handheld detector, showing an inverse square relationship.

Design for Manufacturing

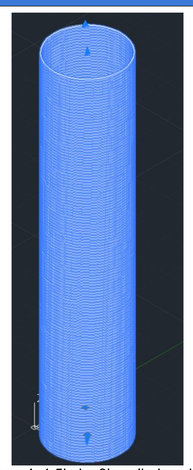

Figure 4. 1.5in by 3in cylinder with a helix to represent solenoid seed with 500 turns demonstrated using AutoCAD.

Materials	Cost
3cm x 1.5cm cylindrical plate for probe tip	$51.99 [2][7]
5mm x 1mm solenoid for seed	$14.95 [3]
Universal Qi Wireless Receiver Module	$14.95 [4]
DigiKey Breadboard	$4.95 [5]
Arduino board	$26.30 [6]

Product Specifications

Specifications	Target Value
Seed radius	0.5 mm
Seed length	5 mm
Number of turns	500
Probe tip radius	1.5 cm
Probe tip height	3 cm

Project Planning

Phase 1: **Initial Development** - Allocate resources and initiate risk assessment to identify and mitigate early challenges.
Phase 2: **Stakeholder Engagement -** Regular check-ins with advisors and mentors for feedback on design process and feasibility.
Phase 3: **Iterative Prototyping -** Develop and refine prototypes in iterative cycles based on risk assessments and feedback.
Phase 4: **Pre-Launch Preparation -** Finalize regulatory requirements, quality control measures, and manufacturing readiness for market entry.

Future Directions

Prototype Development → **Testing and Design Validation** → **Design Iteration with FDA Compliance**

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References

[1] Garzotto, F., Comoretto, R. I., Michieletto, S., Franzoso, G., Lo Mele, M., Gregori, D., Bonavina, M. G., Bozza, F., Caumo, F., & Saibene, T. (2021). Preoperative non-palpable breast lesion localization, innovative techniques and clinical outcomes in surgical practice: A systematic review and meta-analysis. *The Breast*, *58*, 93–105. https://doi.org/10.1016/j.breast.2021.04.007
[2] *304 Stainless Steel Plate, Thicknesses 1.5mm, width 300mm and length 300mm*. (2024). Walmart.com. https://www.walmart.com/ip/304-Stainless-Steel-Plate-Thicknesses-1-5mm-width-300mm-and-length-300mm/5616023911?wmlspartner=wlpa&selectedSellerId=101591995
[3] Industries, A. (n.d.). *Large push-pull solenoid*. Www.adafruit.com. https://www.adafruit.com/product/413
[4] Adafruit Industries. (2014). *Universal Qi Wireless Receiver Module*. Adafruit.com. https://www.adafruit.com/product/1903?gad_source=1&gclid=CjwKCAiAuqG5BhAREiwAWMISj45k4LIAJmreEgCQIPyNXV71oo6xetGoTQMb40qQvINAaJ5krNZ4xoC_wgQAvD_BwE
[5] (n.d.). *64 Adafruit Industries LLC* [Review of *64 Adafruit Industries LLC*]. DigiKey. https://www.digikey.com/en/products/detail/adafruit-industries-llc/64/7241427?utm_adgroup=General&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Shopping_Product_Zombie%20SKUs&utm_term=&utm_content=General&utm_id=go_cmp-17815035045_adg-_ad-__dev-c_ext-_prd-7241427_sig-CjwKCAiAuqG5BhAREiwAWMISjGfyGlkWmuhG-JgxqeI0LR_3IBIxcPzvYYxahBKTUFvvkSGmEHzoMORoCqZMQAvD_BwE&gad_source=1&gclid=CjwKCAiAuqG5BhAREiwAWMISjGfyGlkWmuhG-JgxqeI0LR_3IBIxcPzvYYxahBKTUFvvkSGmEHzoMORoCqZMQAvD_BwE
[6] *Arduino Uno Rev3 SMD*. (2021). Arduino Online Shop. https://store-usa.arduino.cc/products/arduino-uno-rev3-smd?gad_source=1&gclid=CjwKCAiAuqG5BhAREiwAWMISjAjMH22UlhEtSYMKy1KrzMc1yGr8R52yZLiowkdB1hb9LPz0QVURUgRoC7YwQAvD_BwE
[7] Amazon. (n.d.). Stainless steel disc plate, 3 cm diameter. Amazon.com. https://www.amazon.com/Stainless-Steel-Disc-Plate-Diameter/dp/B08JQHJDF4/G?source=ps-sl-shoppingads-lpcontext&ref_=fplfs&smid=AR88GRBHPCMHU&th=1

Gantt Chart

Youtube Video

Place Holder