Final Project Presentation

EMF Wearable
A Solution for Children with Neuroblastoma

By Khanh Nguyen, Manish Sharma, & Zachary Kunz

Outline

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III. EMF Wearable

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- C. Device Simulation with COMSOL Multiphysics & Sim4Life
- D. Safety issues

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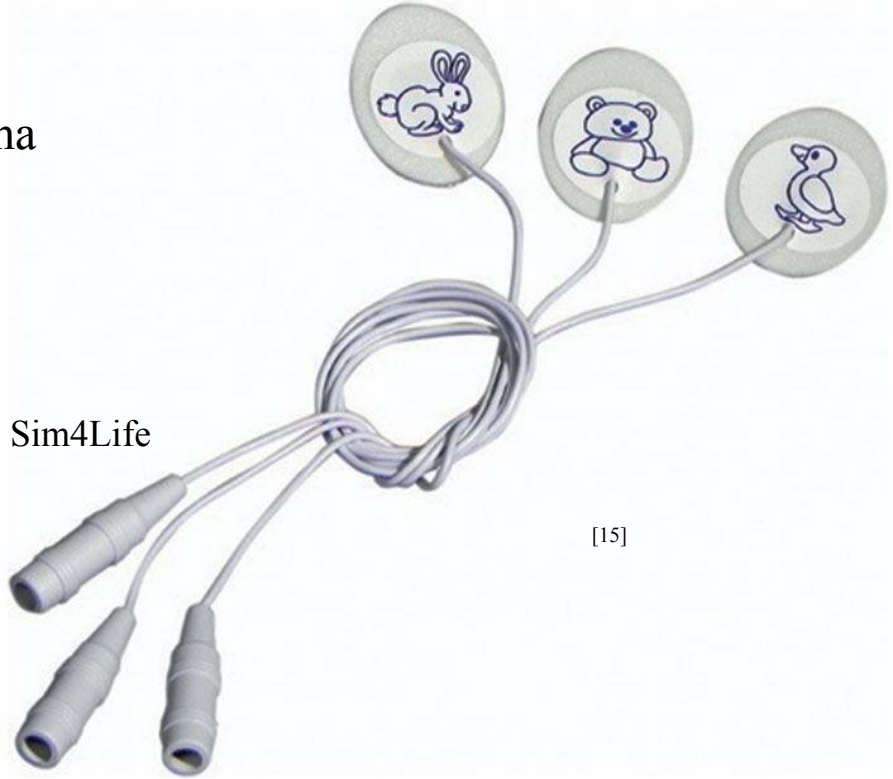
V. Future Development



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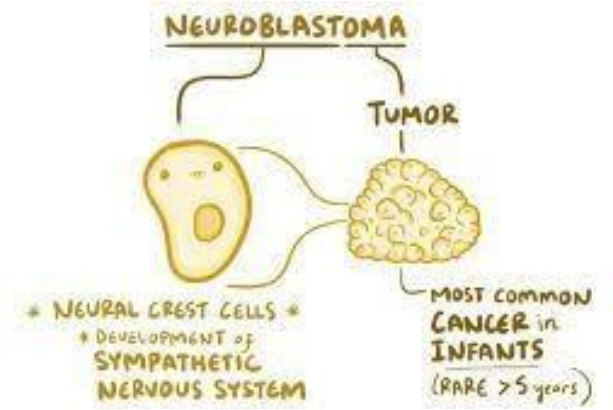
I. Project Background

- ***NEED STATEMENT: A diagnosis and treatment tool for neuroblastoma to reduce average hospitalization stay time and cost.***
- Neuroblastomas are one of the most prevalent types of pediatric cancer
- Typically latches around the adrenal medulla or paraspinal sites
- Current treatment options include
  - Chemotherapy - in more advanced cases
    - High-dose myeloablative chemotherapy
  - Surgery
    - Autologous hematopoietic stem cell transplantation
  - Medical devices



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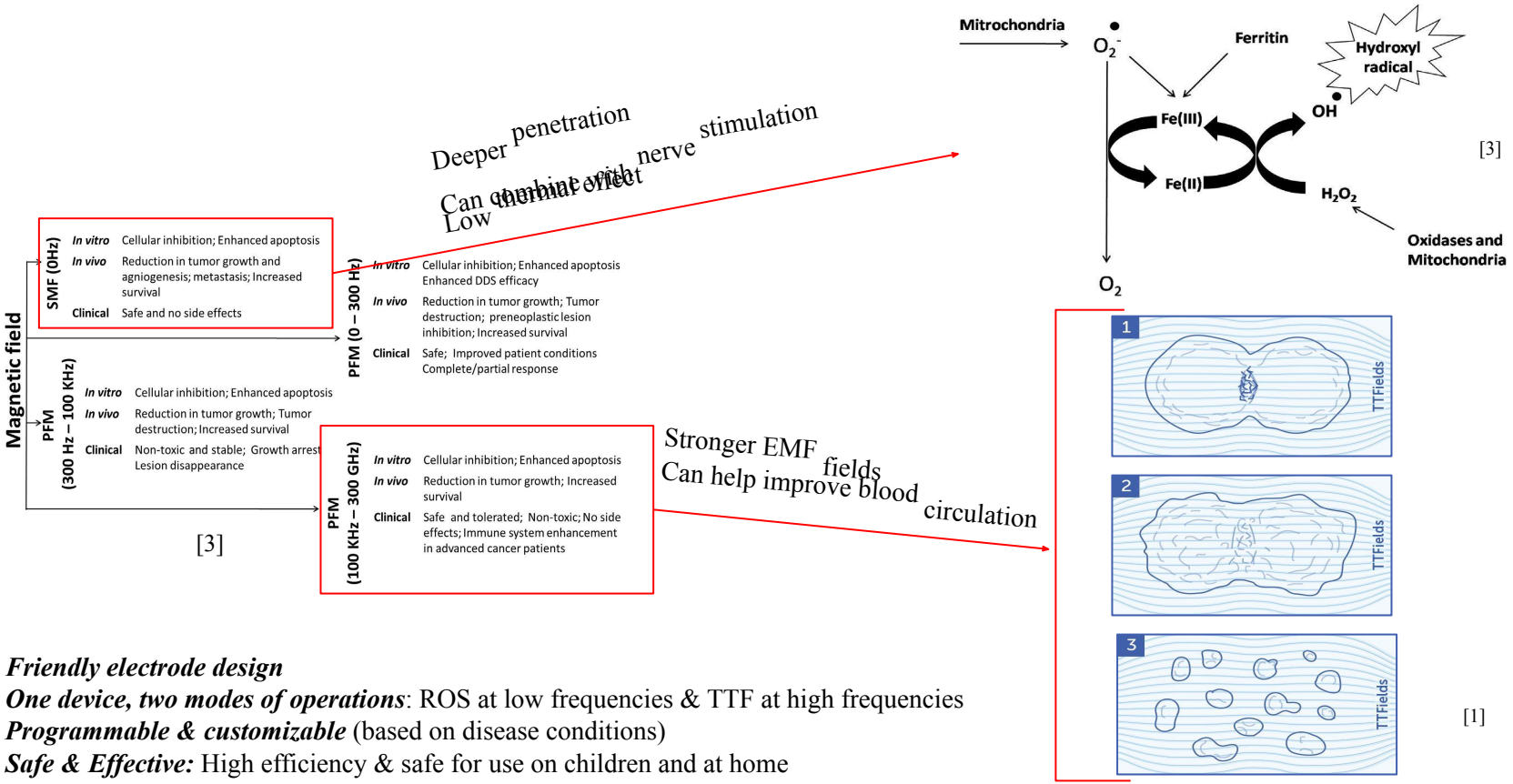
I. Project Background

- Average total cost incurred by families suffering from Neuroblastoma over the course of treatment was **$205,747**
- Since the year 2019 the incidence of neuroblastoma occurring has increased dramatically
  - Drug market size will grow by 190.82 million US
- Emotional and Financial burden from pediatric cancer
  - Pushes around 15% of families experiencing this under the poverty line
  - Loss of jobs due to extensive traveling and caregiving times

II. EMF Wearable for Neuroblastoma



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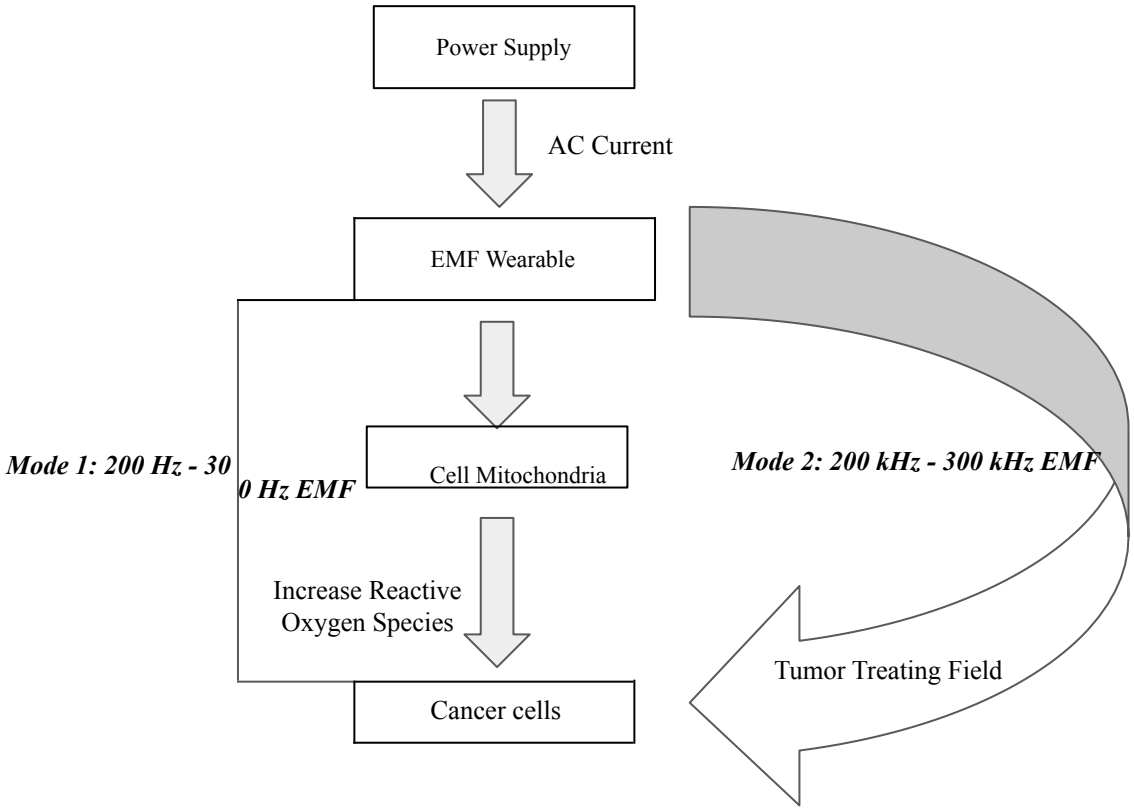
Friendly electrode design
One device, two modes of operations: ROS at low frequencies & TTF at high frequencies
Programmable & customizable (based on disease conditions)
Safe & Effective: High efficiency & safe for use on children and at home

II. EMF Wearable for Neuroblastoma



Mode 1: 200-300Hz EMF

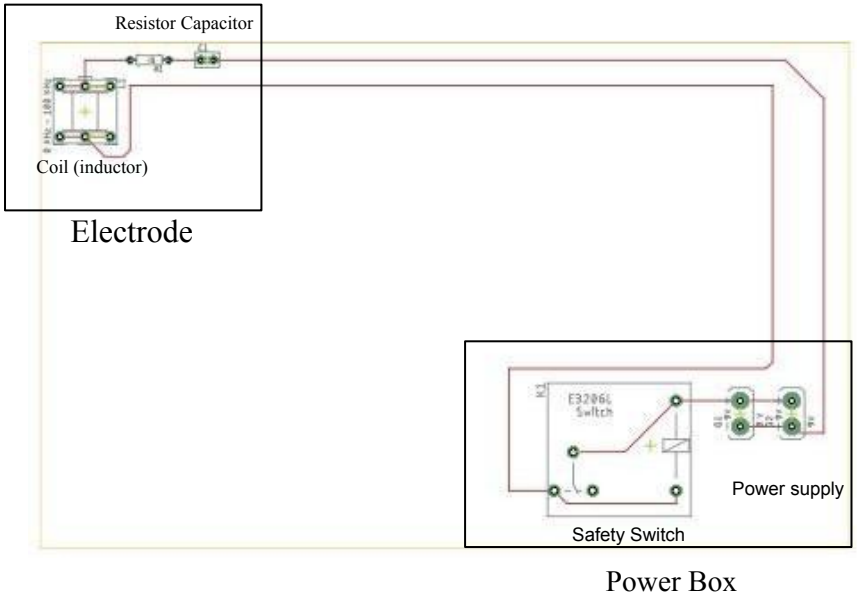
Tumor deep inside the body

Mode 2: 200kHz-300kHz EMF

Tumor near the skin or in sensitive tiss

Combination of mode 1 & 2 is also possible

III. EMF Wearable - Circuit Design with EAGLE

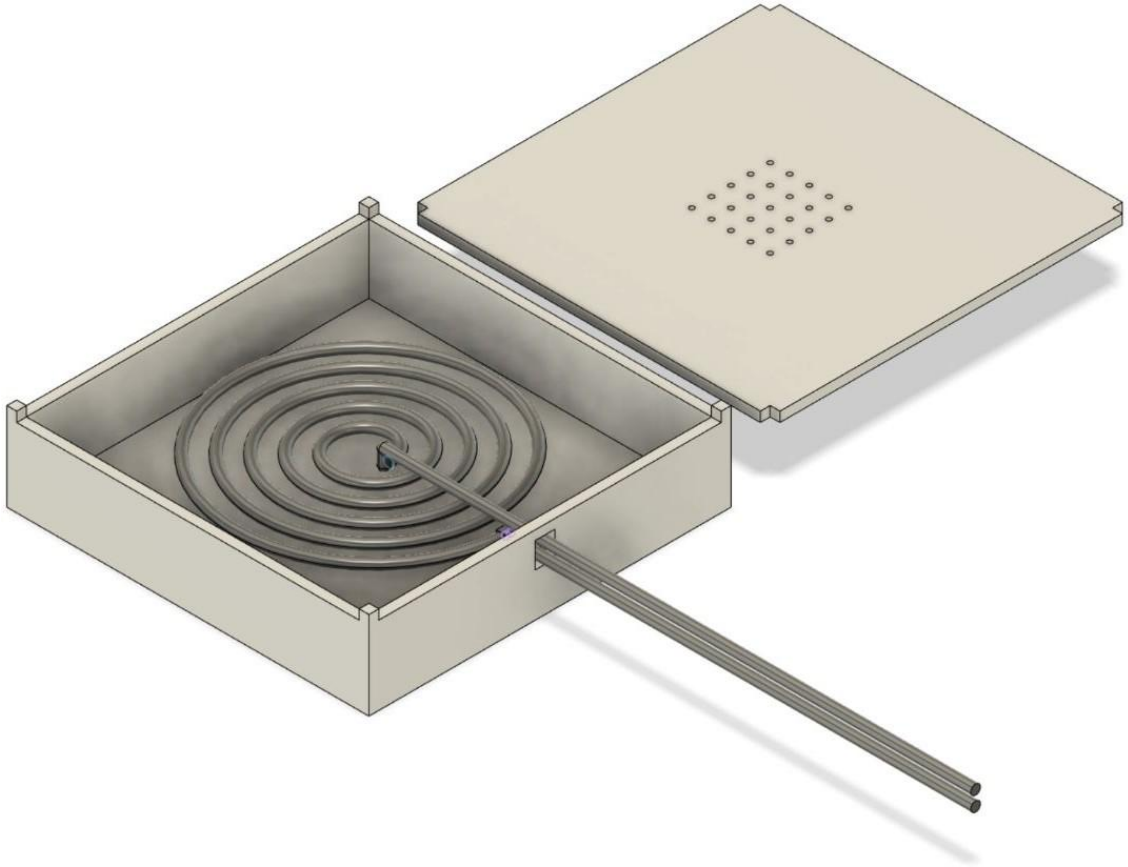


The circuit consists of:

- Coil
- Resistor
- Capacitor
- AC Power Supply

III. EMF Wearable - Device Design with Fusion 360

- ➔ Coil Dimensions
  - 5 revolution coil
  - Outer radius of 30 mm
  - Inner radius is 4 mm
  - Wire radius 1 mm
- ➔ Box Dimensions
  - 70 mm x 70 mm x 18 mm
  - 25 holes with 0.5 mm radii



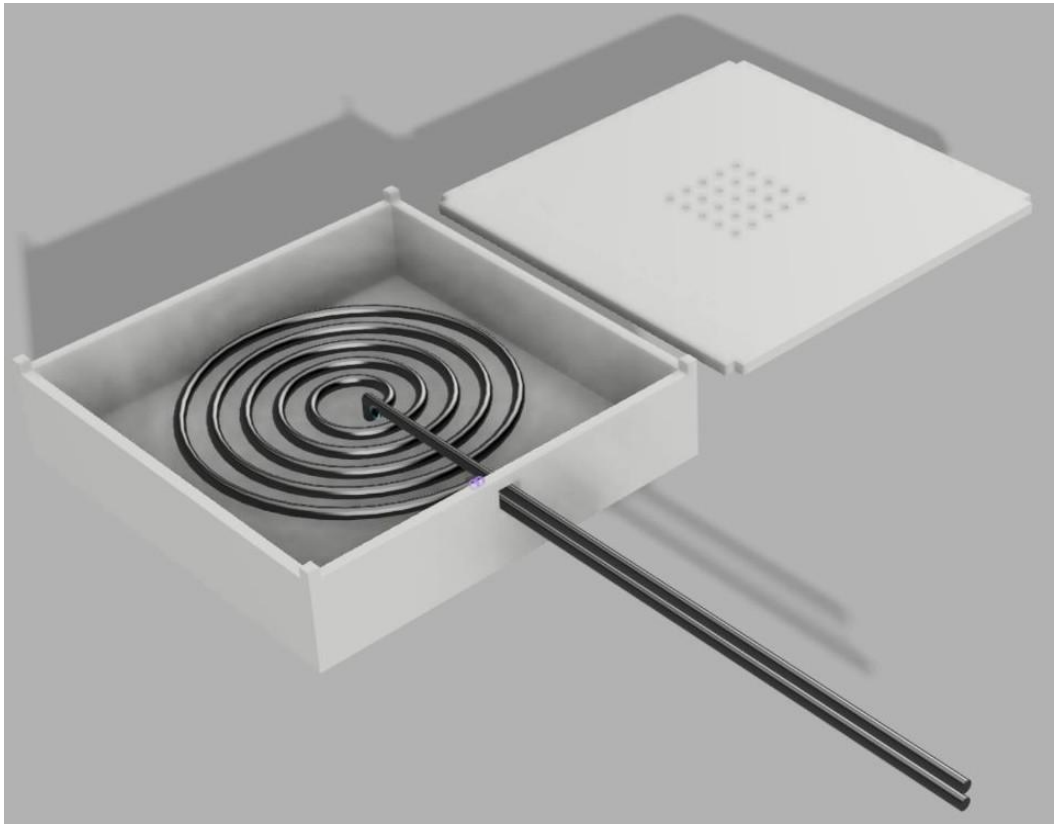
III. EMF Wearable - Device Design with Fusion 360

Materials

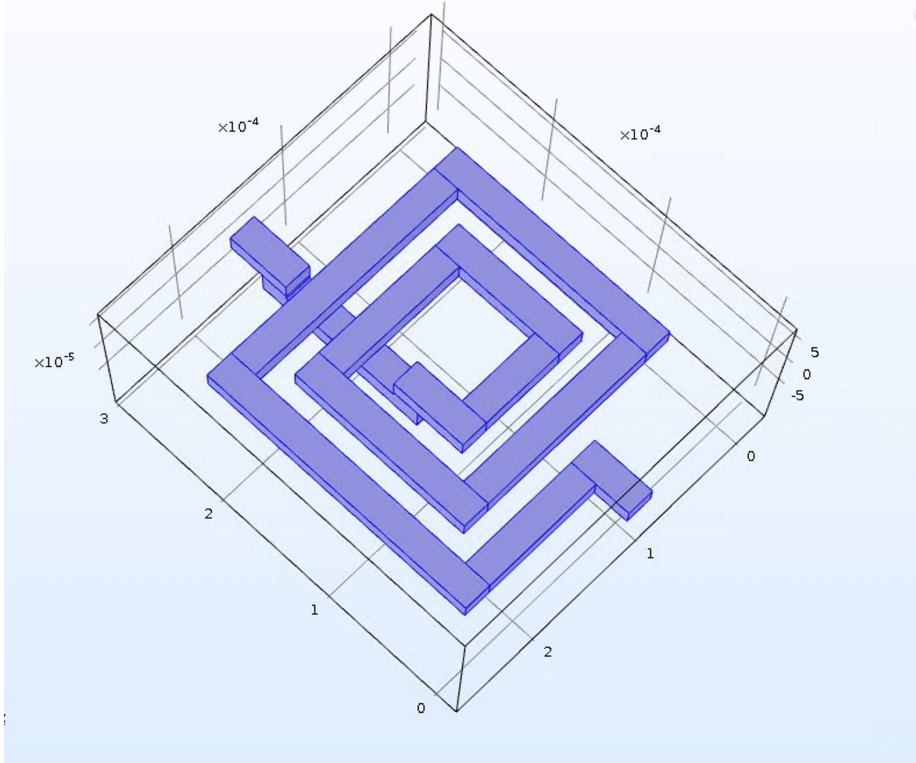
- Enclosure - Soft polymer
- Coil - Copper
- Wires - Plastic coated insulated wires

Layout

- 5 mm on all sides away from coil to prevent burns
- 25 holes to allow the heat to escape
- 4 prongs on top of box to keep lid in place

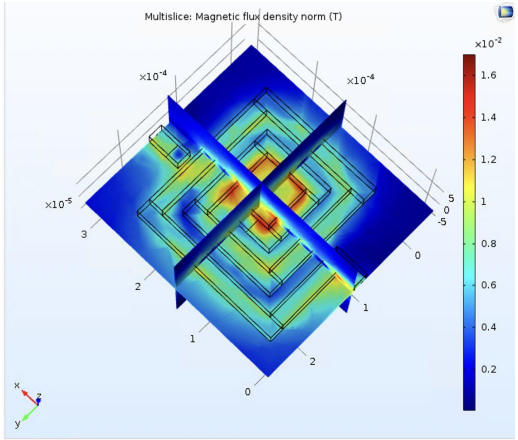


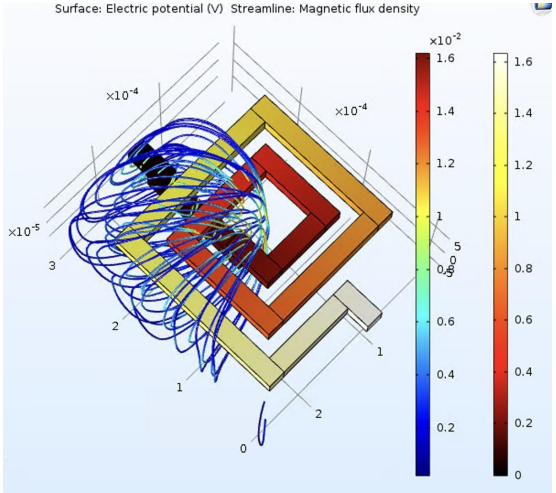
III. EMF Wearable - Simulation with COMSOL Multiphysics



- Interested Results
  - Magnetic Field Strength & Flux Density
  - Electric Field Strength
  - Thermal Distribution
- Model Parameters
  - Coil shape and size
  - Enclosure materials
  - Flowing current & applied power
  - Applied frequency

III. EMF Wearable - Simulation with COMSOL Multiphysics





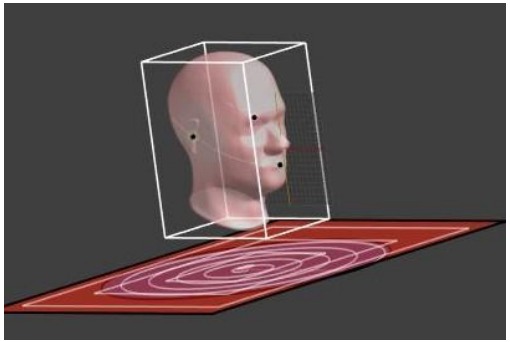
- EMF components vary with
  - Coil shape and size
  - Enclosure materials
  - Flowing current & applied power
  - Applied frequency

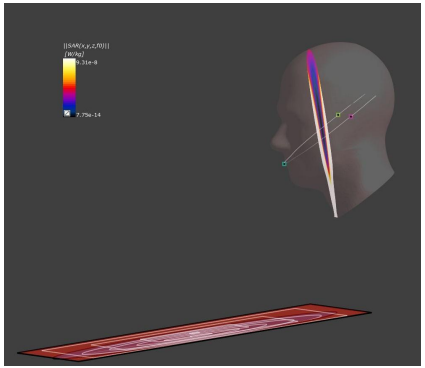
- COMSOL Multiphysics (Ver 5.2) Limitations
  - Unavailability of RF module

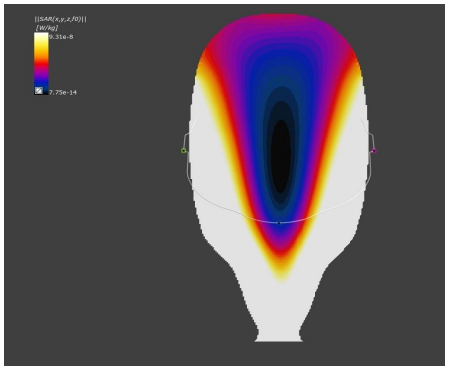
=> Can’t simulate at different frequencies

=>Sim4Life is used for this purpose instead

III. EMF Wearable - Simulation with Sim4Life

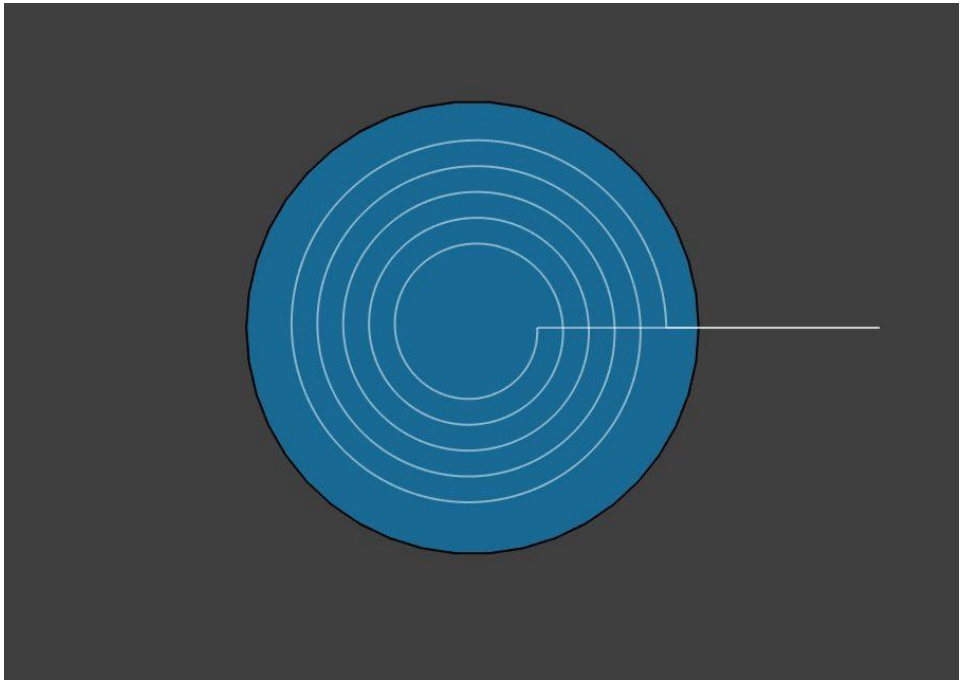






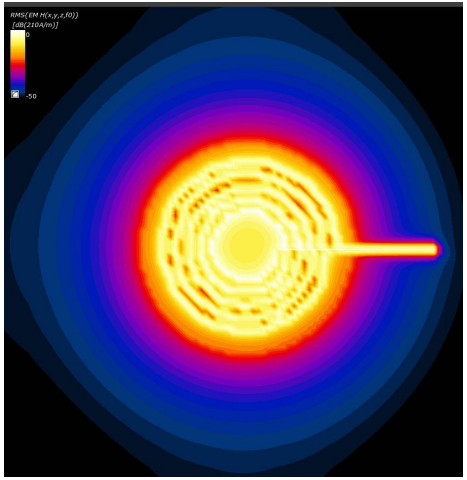
- Sim4Life is a software that specializes in physics simulations with biological models
- Sim4Life is especially useful with simulation of low frequencies (under 1GHz)
- Since the RF module is NOT available in COMSOL Multiphysics ver 5.2, Sim4Life is an alternative. However, some of the main disadvantages for this option is
    - Can not simulate model with high frequencies
    - The student version (Sim4Life Light) does not support 3D view of the analysis
    - Limiting computation capacity compared to COMSOL Multiphysics

III. EMF Wearable - Simulation with Sim4Life

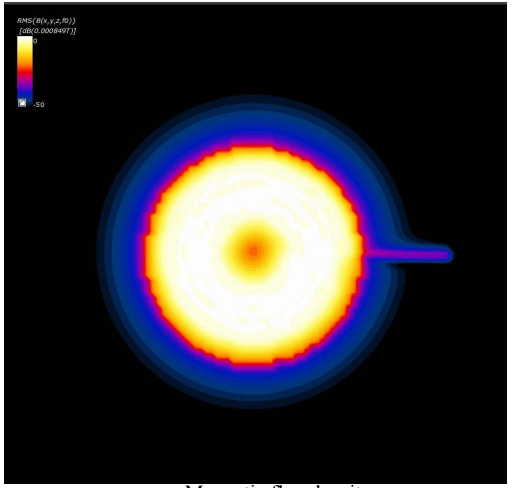


- Model Parameters
  - Coil shape and size
    - Shape: Circular, spiral
    - Inner radius: 10mm
    - Outer Radius: 30mm
    - Turns: 5
  - Enclosure materials: Soft polymer
  - Applied Current: 0.5A
  - Applied frequency: 200kHz

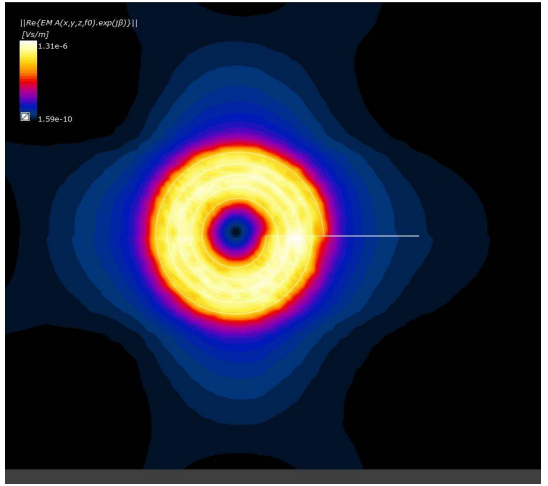
III. EMF Wearable - Simulation with Sim4Life



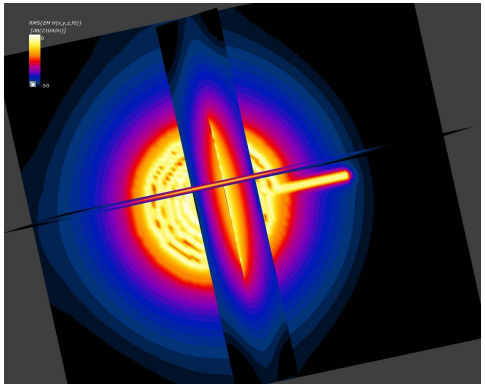
Magnetic field strength



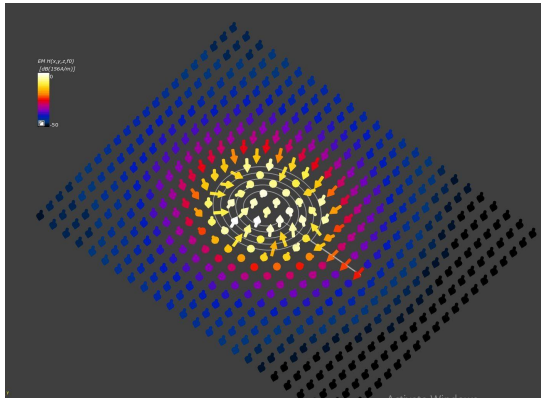
Magnetic flux density



Electric field strength



Magnetic field strength - Multislices

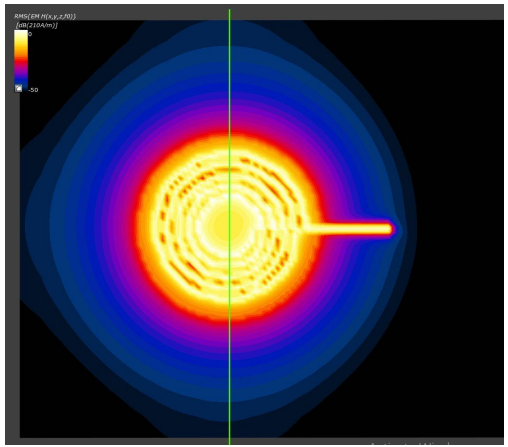


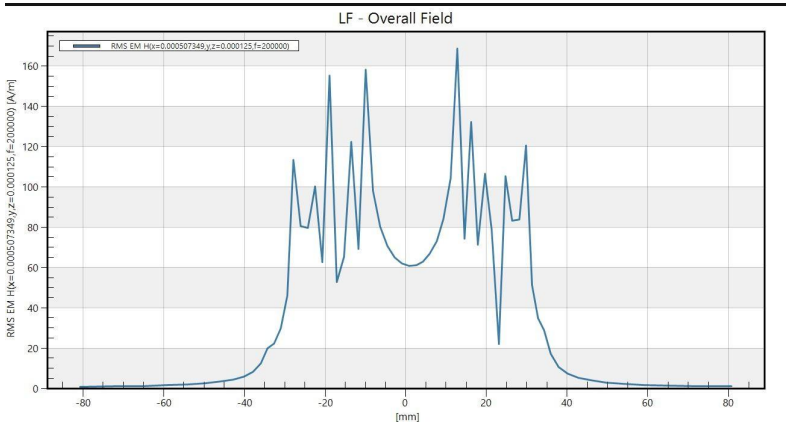
Magnetic field strength - Vector View

Every component of the EMF can be analyzed

Data is shown mostly in slice and surface views

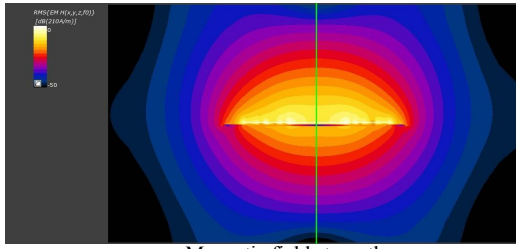
III. EMF Wearable - Simulation with Sim4Life



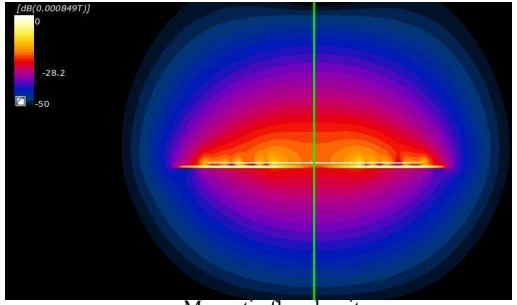


- Data can be extracted & plotted along a 2D line
- Detail information regarding the field strength and its location can be extracted from the plot (in .csv file)

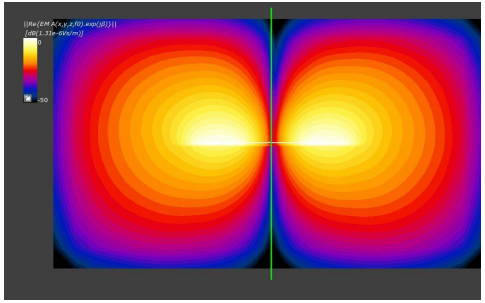
III. EMF Wearable - Simulation with Sim4Life



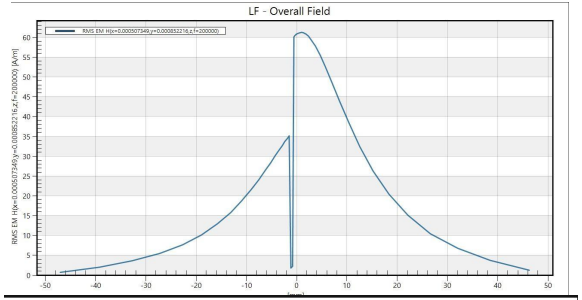
Magnetic field strength

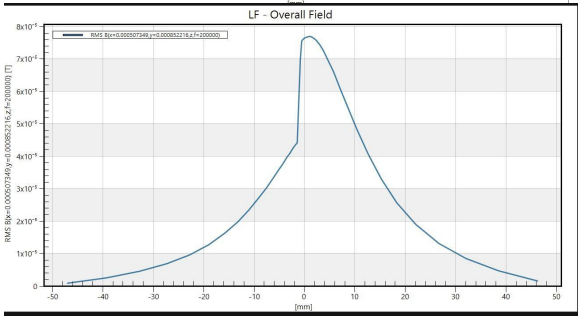


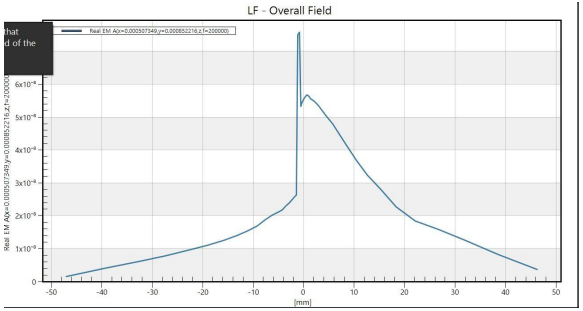
Magnetic flux density



Electric field strength







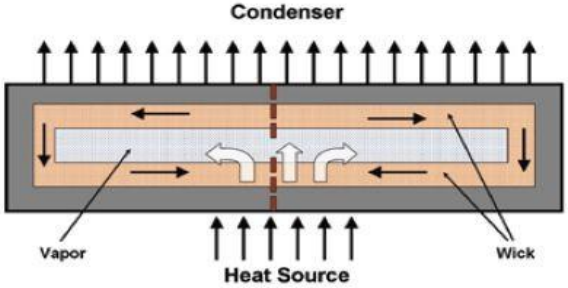
Data extracted

At 2.2cm above the center of the coil

- Magnetic field strength: 15.07A/m
- Magnetic flux density: 1.89x10^-5 T
- Electric field strength: 1.89x10^-8 V/m

Those results can be easily simulated in COMSOL Multiphysics using “derived values”

III. EMF Wearable - Safety Issues



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Thermal Dissipation

- Holes on the coil chamber to provide an inward flow of air and gives natural cooling
- *Vapor cooling*: Vapor cooling is employed when high power and heat fluxes are given to a small evaporator area. The heat input into the evaporator vaporizes liquid within the evaporator wick during operation. The vapor then circulates around the chamber forming an isothermal heat spreader. The vapor condenses on the condenser surfaces, where heat is removed by the convention of natural cooling.

Electrical Safety

- There is a switch with a thermal sensor (which can be calibrated), so the button will auto cut the power supply when the temperature rises above a specific limit.

III. EMF Wearable - Safety Issues

EMF Exposure Potential Harmful Effects

- Possible tissue damage due to overheating at high frequencies (>100kHz)
- Possible nerve stimulation & cell membrane permeability change at low frequencies (<100kHz)
- Carcinogenic? - Not enough evidence in humans
- Interference with electronic medical devices
- Safety guidelines have been setup to avoid potential harmful effects of EMF
  - ***ICNIRP 2010*** by the International Commission on Non-Ionizing Radiation Protection
  - ***IEEE C95.1*** by the International Committee on Electromagnetic Safety

General Public Exposure Limits[c]			
Exposure of	E-field strength *E (V / m)*	Magnetic field strength *H (A / m)*	Magnetic flux density *B (μT)*
head and torso		163	205
limbs		900	1130
whole body	614		
Controlled Environment Exposure Limits[d]			
Exposure of	E-field strength *E (V / m)*	Magnetic field strength *H (A / m)*	Magnetic flux density *B (μT)*
head and torso		490	615
limbs		900	1130
whole body	1842		

EMF Exposure Limit by IEEE C95.1 [14]

ICNIRP
INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

Basic restrictions

Parameter	Frequency range	ΔT	Spatial averaging	Temporal averaging	Health effect level	Reduction factor	Workers	Reduction factor	General public
Core ΔT	100 kHz-300 GHz	1°C	WBA*	30 min	4 W/kg	10	0.4 W/kg	50	0.08 W/kg
Local ΔT (Head & Torso)	100 kHz-6 GHz	2°C	10 g	6 min	20 W/kg	2	10 W/kg	10	2 W/kg
Local ΔT (Limbs)	100 kHz-6 GHz	5°C	10 g	6 min	40 W/kg	2	20 W/kg	10	4 W/kg
Local ΔT (Head & Torso, Limbs)	>6-300 GHz 30-300 GHz	5°C	4 cm^2 1 cm^2	6 min 6 min	200 W/m^2 400 W/m^2	2	100 W/m^2 200 W/m^2	10	20 W/m^2 40 W/m^2

* WBA: whole body average

SAR Limit by ICNIRP 2020 [13]

General Public Exposure Limits[a]			
Frequency range	E-field strength *E (V / m)*	Magnetic field strength *H (A / m)*	Magnetic flux density *B (μT)*
3 kHz – 10 MHz	83	21	27
Occupational Exposure Limits[b]			
Frequency range	E-field strength *E (V / m)*	Magnetic field strength *H (A / m)*	Magnetic flux density *B (μT)*
3 kHz – 10 MHz	170	80	100

EMF Exposure Limit by ICNIRP 2010 [14]

IV. IP Issues

- Utility Patent - A patent that covers the creation of a new or improved product and prohibits others from using or selling the product
    - Lasts 20 years
    - Claims - The usage of an electromagnetic field for targeted therapy of cancer cells by reactive oxygen species activation using frequencies 200-300Hz in combination with tumor treating field of 200-300kHz
- A similar device called Optune Wearable (NovoFFT-100A)
    - Has the classifications A61N1/32, A61K31/196, A61N1/36002, A61N1/40, and A61P43/00
- Freedom to operate: If we have the ability to have very different technology to optune than we will be able to patent but if our technology is similar we will not be able to patent.
    - Our idea has novelty as compared to Optunes design due to the fact that we have a different design and technical detail from them. This would allow for our company to have freedom to operate without paying royalties to Optune

IV. FDA Regulation

EMF Wearable is a class III device and will go through Pre-Market Approval

Clinical studies will be conducted with special cautions regarding use at home and on children

Clinical Study Design Details

- Disease: Pathological or histological evidence of Neuroblastoma
- Age range: children aged 1-5 years old
- Population: 1000 subject of diverse ethnic, racial, and geographical background
- Cancer stage: Stage I-IV
- Other disease diagnosis/treatment specifications:
    - Newly diagnosed or recurrent
    - Treated in conjunction with other therapies (if any)
- Life expectancy: At least 3 months from the beginning of the study
- Informed consent: Parents' consent is mandatory
- Access to the device: Having a parent or a caregiver being able to operate the device independently
- Testing environment: Uncontrolled environment (for at-home usage)
- Result: Cancer progress after treatment

V. Future Development

Device Design

Incorporate array design from single-coil to customize the EMF exposure (shape, size, and exposure level)

Improve thermal dissipation efficiency

Create a software that assist the users and report data to physicians

Device Testing

Complete simulation in COMSOL Multiphysics & Sim4Life

Evaluate the performance of the device in real-life setting

Evaluate the overall safety of the device considering general guidelines regarding EMF exposure


We
thank you!

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