The Silicon Hospital and a New Way to Make Medical Devices

Devcon | Bangkok | Nov 14 2024

Dr. Mary Lou Jepsen

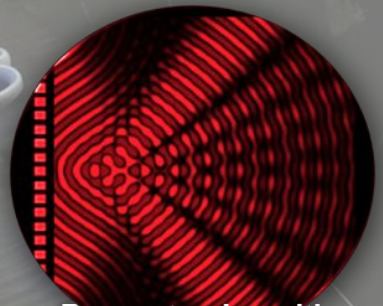
Founder, CEO & Chairman - Openwater.health

New Therapeutics: **Phase Wave Breakthrough**

Modulating the phase of light and sound which penetrate body and brain to deliver therapies and diagnoses

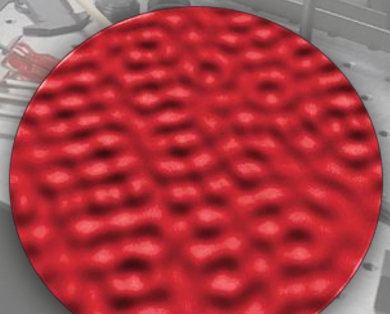
Moore's Law can enable phase modulation of light and sound with Consumer Electronics

A decade of work in labs like these
building up new modalities of physics and biology



Beam steering with phase

Breaking w/ sound harmonics

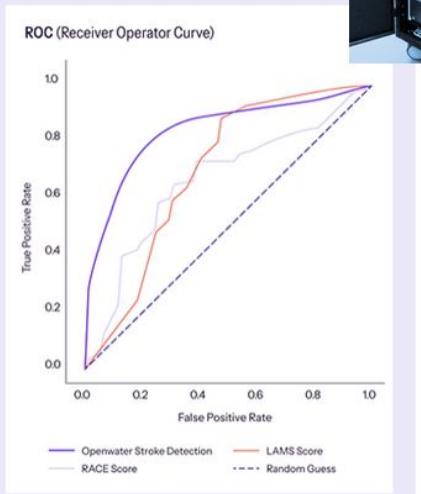


Decoding phase w/ interference

CLINICAL DATA

OPENWATER
www.openwater.health

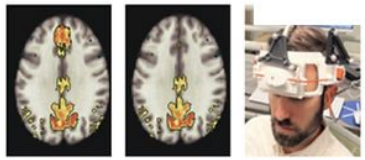
1
Stroke (LVO — Large Vessel Occlusion)

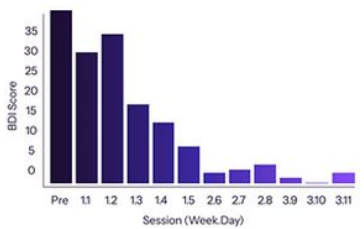


Record mobile device large vessel occlusion (LVO) stroke detection. 151 Stroke patients measured at comprehensive stroke centers: 68 LVO, 36 Ischemic non-LVO, 15 Hemorrhagic, 39 mimics.

Equipment: Openwater Open-Motion Gen 2

2
Severe Depression

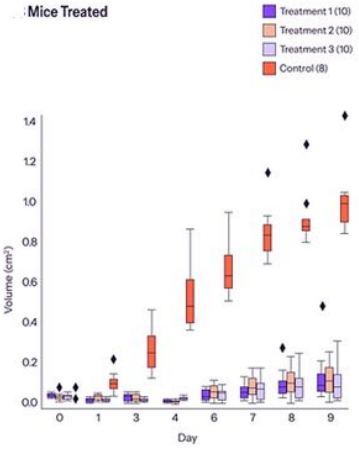




remission in a week with 10 minutes per day therapy via our headset. Week 2 and 3 treatment see further improvements. Over 1/3 of patients reached remission - publication eminent.

Equipment: Open-LIFU gen 1 unit

3
Glioblastoma



Stunning tumor shrinkage on study of 38 mice with glioblastoma shown above. One 2-minute treatment on day 0. All are Openwater treatments which can be delivered by our wearable non-invasive headset or body unit which was modified for physically smaller mice.

Equipment Open-LIFU gen 0.1

CLINICAL DATA

OPENWATER
www.openwater.health

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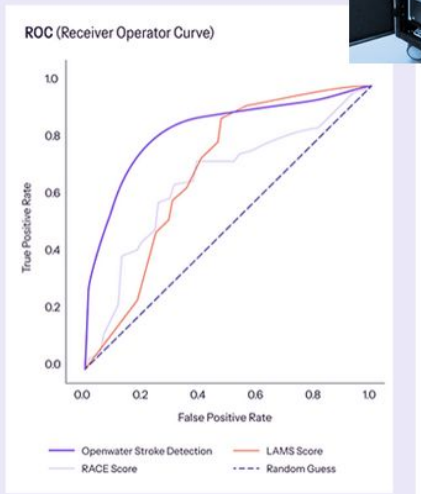

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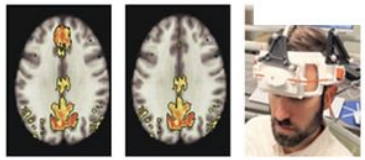

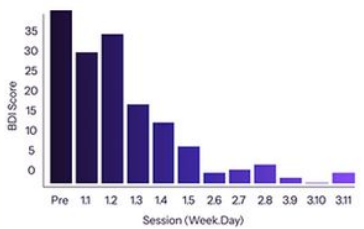

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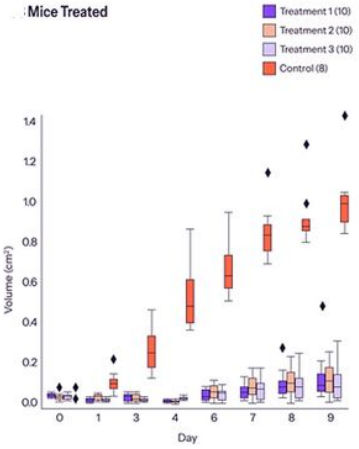

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Equipment Open-LIFU gen 0.1

Openwater Secures $100M to Tackle Diseases at the Cellular Level

by Fred Pennic 08/22/2024 — Leave a Comment

OPENWATER
www.openwater.health

Open-LIFU Specification

We have shrunk from carts to wearable & low-cost

We're pioneering the use of infrared and ultrasound to safely and effectively treat the world's most devastating diseases including lifesaving potential to treat cancers, mental diseases, neurodegenerative diseases and cardiovascular diseases

Cancer Treatments

Stroke

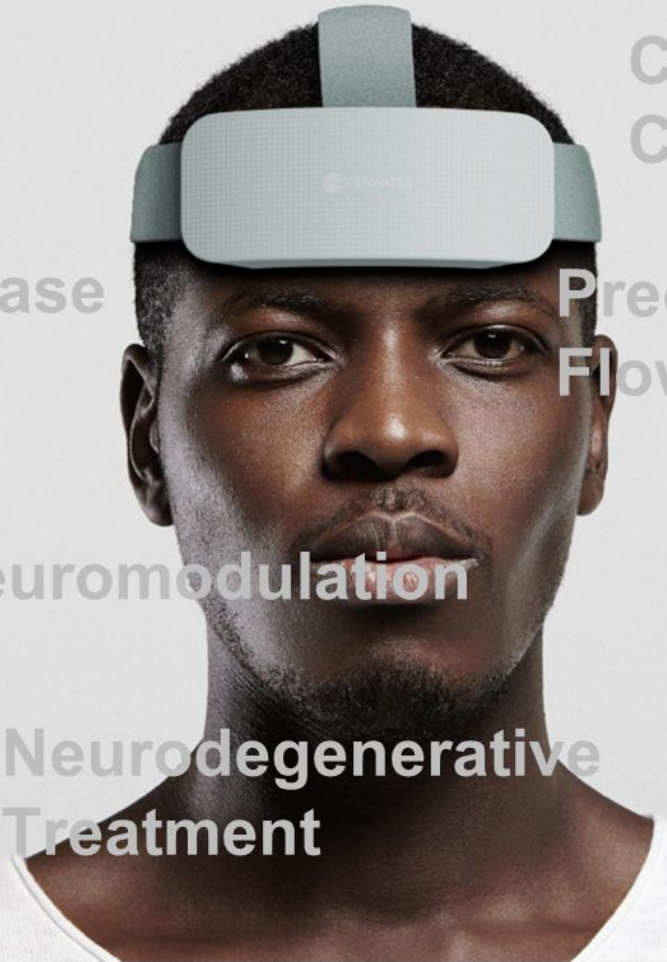
Mental Disease Treatment

COVID / Long Covid

Addiction Treatment

Stem Cell Stimulation

Precise Blood Flow Measurement



Neuromodulation

Neurodegenerative Treatment

https://www.openwater.health

Open-Motion specification

Pan-disease impact.

Picture an opera singer shattering a wine glass.

Our approach is similar: We manipulate the phase of infrared light, ultrasound, and electromagnetic waves to enable potential diagnosis and treatment of diseases through manipulation or destruction of cells and neurons individually without harming surrounding tissue

OPENWATER
www.openwater.health

Open Source

AGPL
Creative Commons - ShareAlike 4.0
Patent Pledge - 68 patents free to use for all

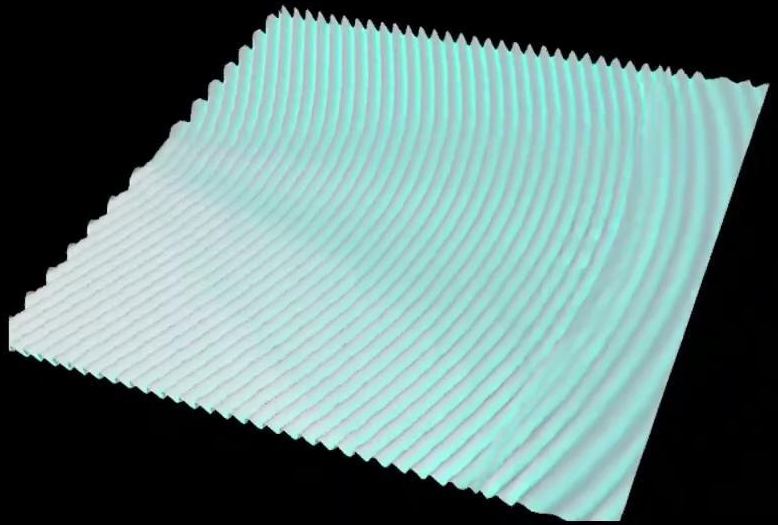
Fast & Low Cost Clinical Approvals in Reach and Scale

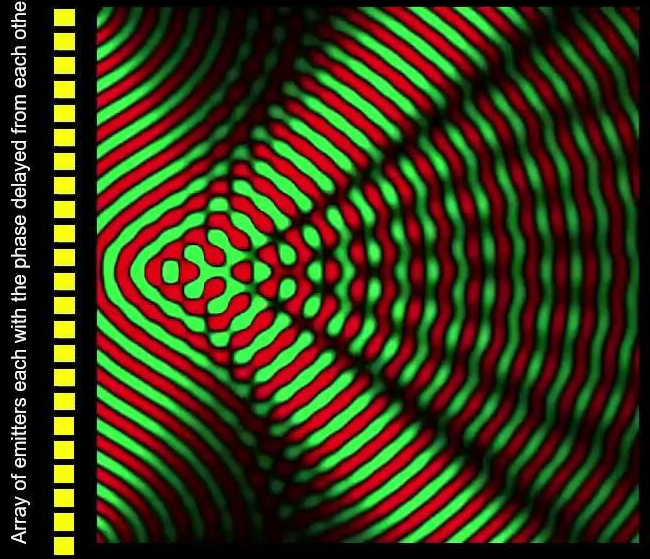
$658M Avg. capitalized cost to FDA approval of a novel therapeutic medical device is $658M and more than 13 years
DOI: 10.1001/jamanetworkopen.2022.31609

85% of cost is in device development, additional savings in pan-disease trials

$5M Estimated FDA in-all De Novo approval costs w/ our Open-source Safety-data-shared devices in 2.5 years. (*see logic on this hypothesis here*)

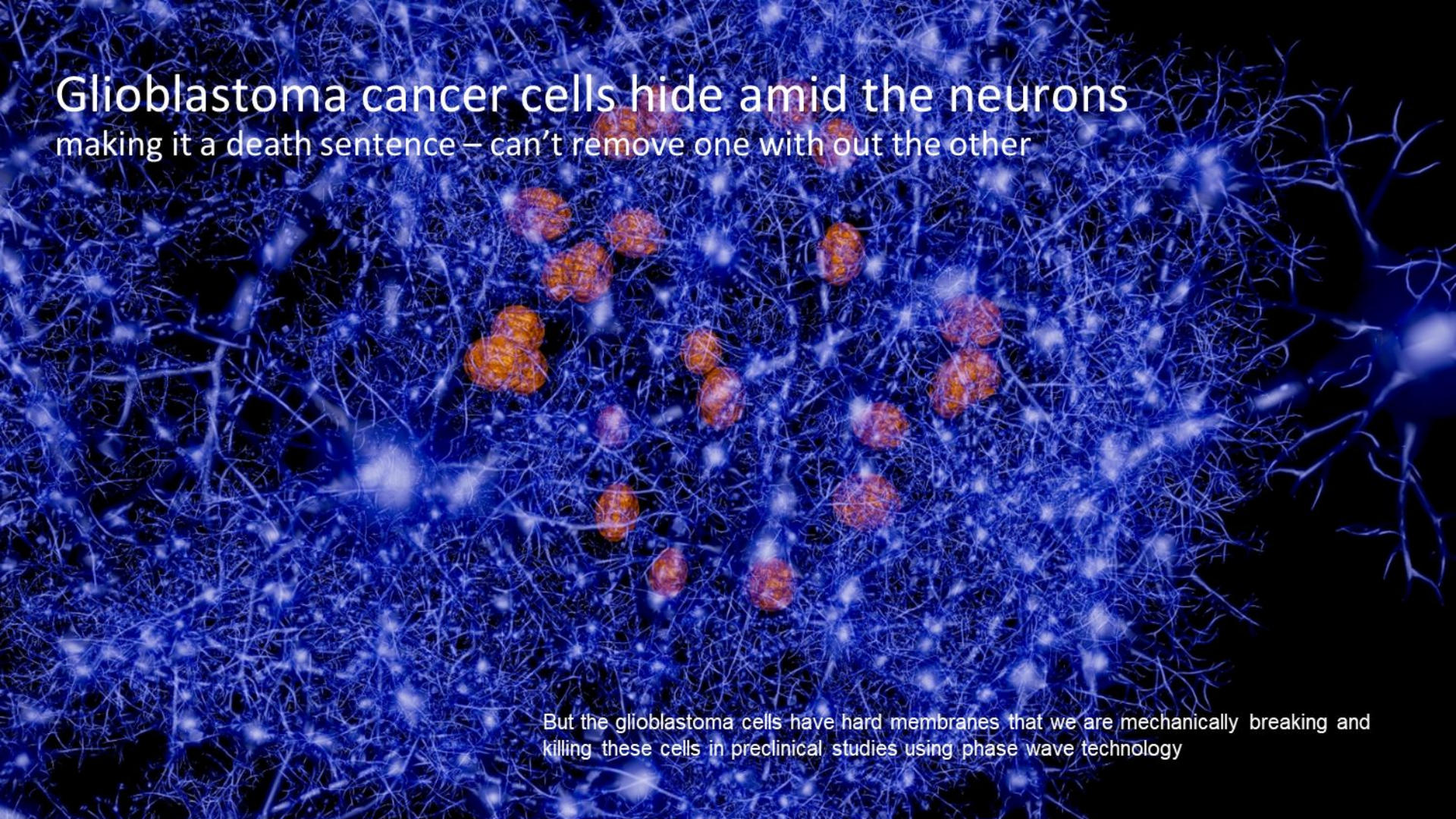
Phase Wave: Phase Delays enable Beam Focus and Steering



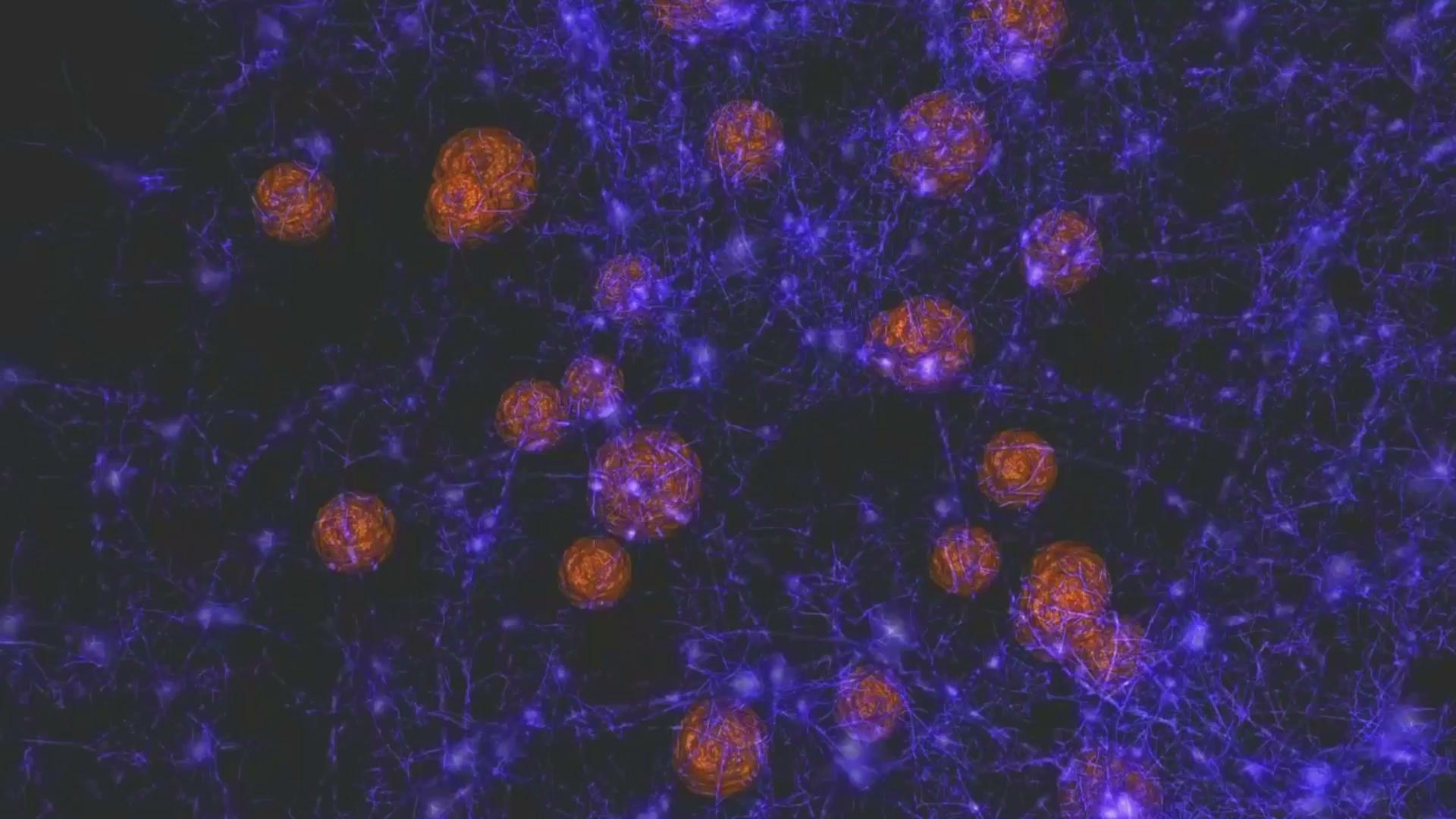


Glioblastoma cancer cells hide amid the neurons

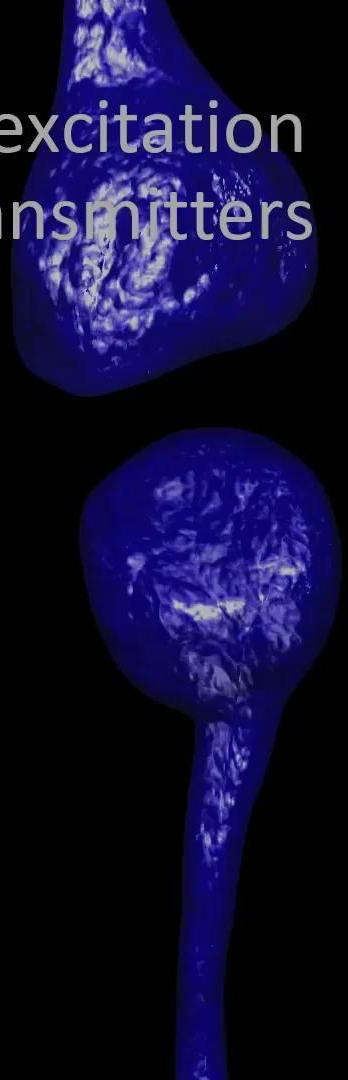
making it a death sentence – can't remove one with out the other



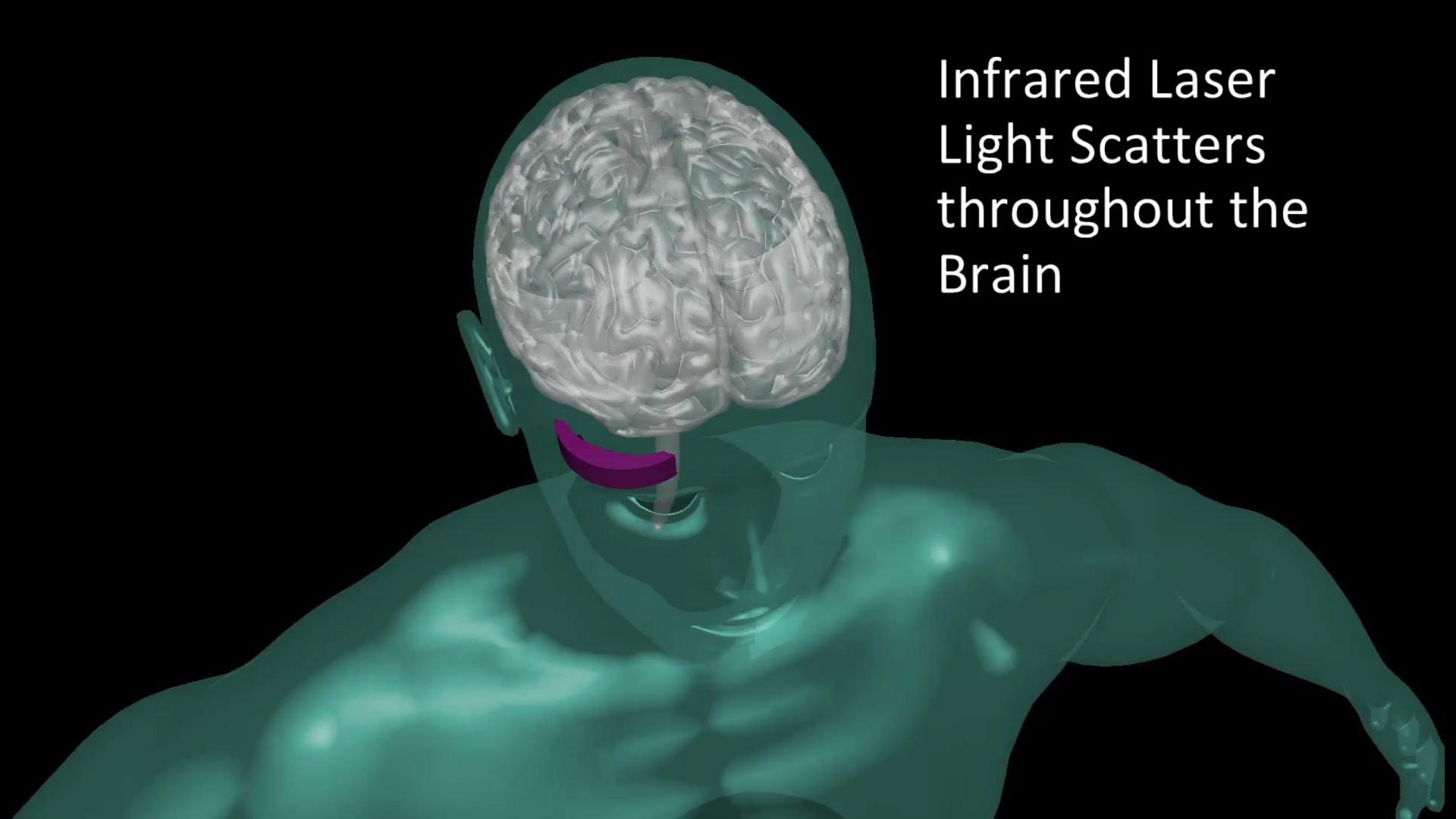
But the glioblastoma cells have hard membranes that we are mechanically breaking and killing these cells in preclinical studies using phase wave technology



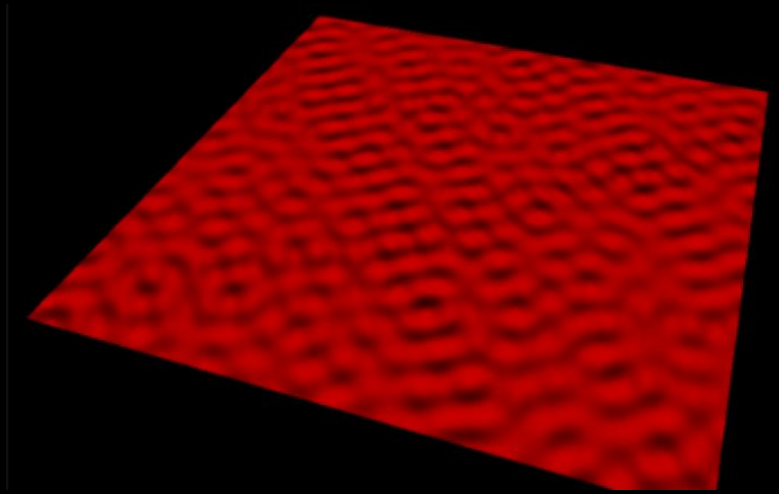
Neurons under harmonic excitation inhibit or release neurotransmitters

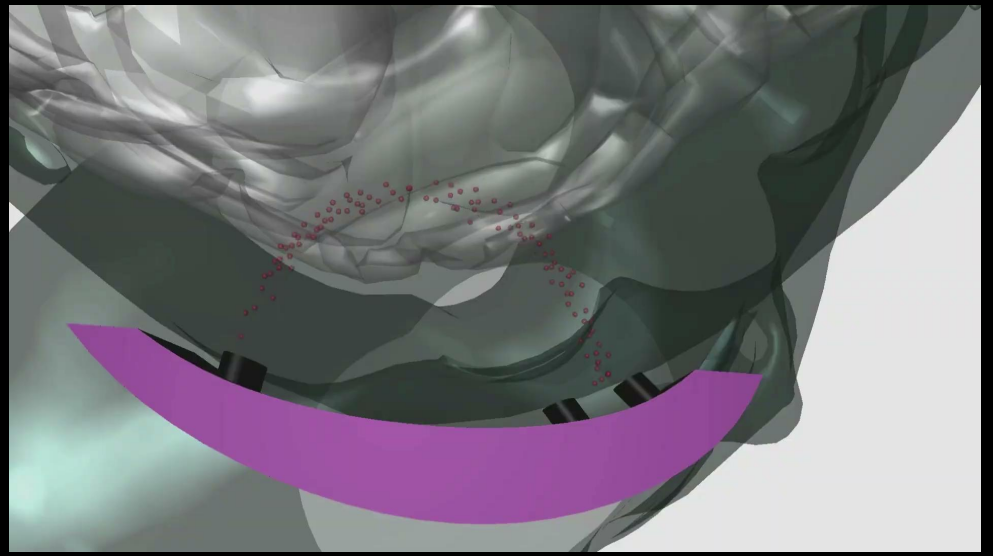


- Key for depression and other mental disease
- At high intensity, ultrasound can ablate tissue. At low-intensity, it can cause gentler, transient biological effects, such as altering neuron and nerve cell electrical activity. Stimulating stem cells, selectively killing cancer cells etc.


Infrared Laser
Light Scatters
throughout the
Brain

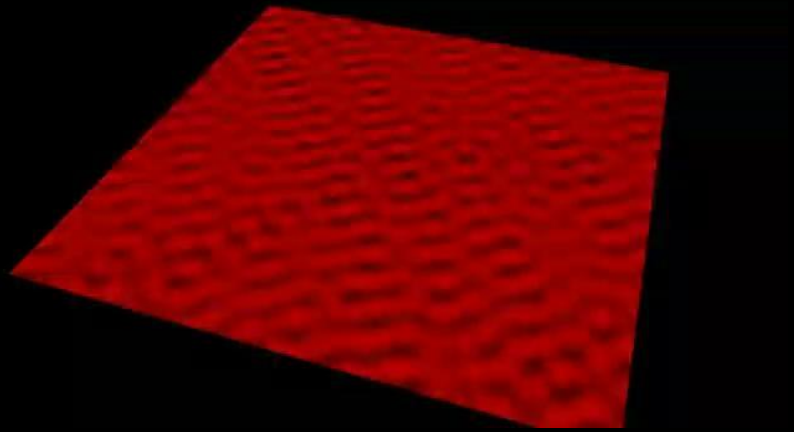
Our camera chip “sees” only light on this banana path
It records a phase wave hologram of the interference.

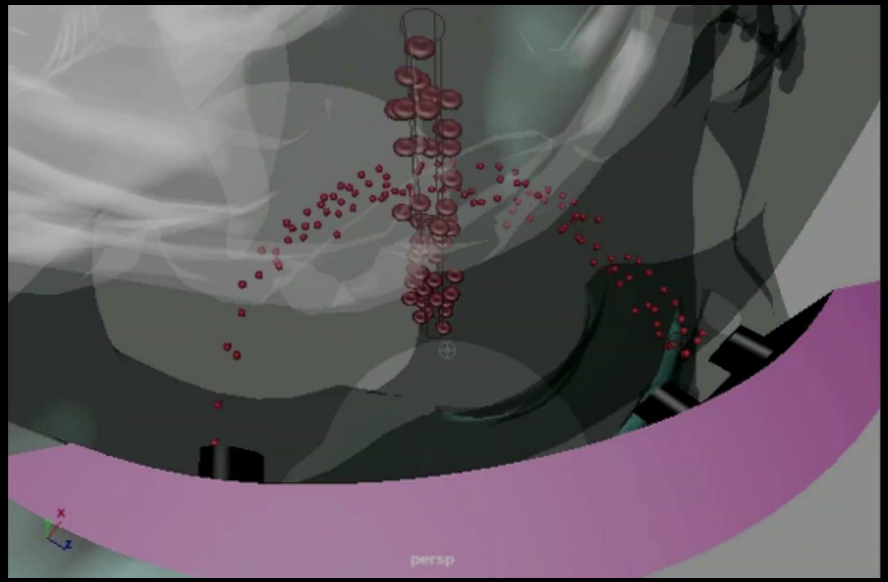




The camera sees changes in the bloodflow

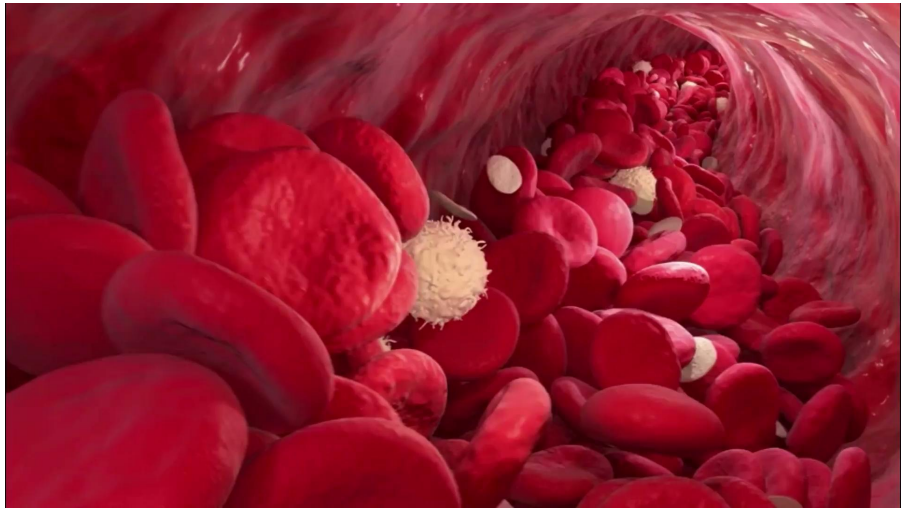
changes in the interference patterns, frequencies and contrast – we decode to see bloodflow

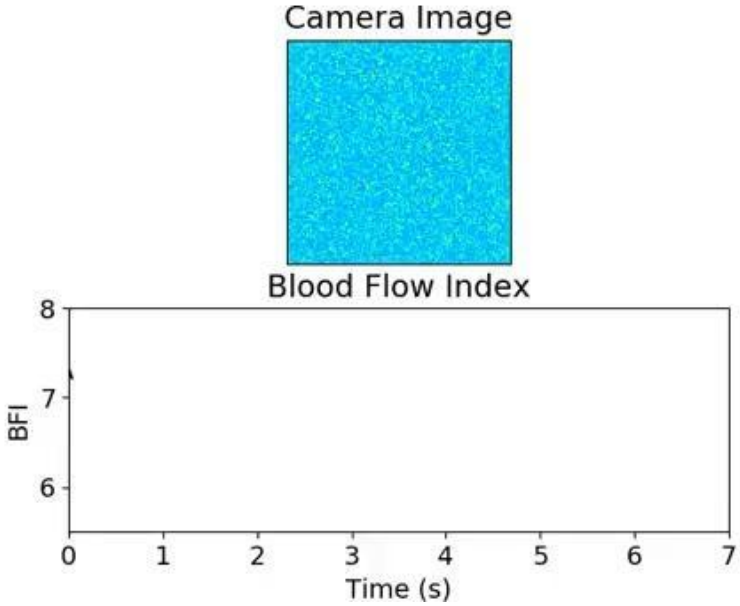




We extract the pulsing of the blood stream

we can see when the bloodflow stops too meaning it’s a stroke





Clinical & Research Partnerships Growing

Our Clinical Results in a snapshot

Cancer We are selectively killing aggressive cancers without harming healthy tissue in preclinical work at Terasaki Institute.

Mental Disease In the clinic with the same device we are treating severe depression in humans and moving majority of patients into remission at University of Arizona. Active new efforts with the National Insts of Health & Johns Hopkins.

Stroke Time to Diagnosis is the key to changing outcomes for the #2 killer in the world: Large Vessel Occlusion Stroke. We have record specificity and sensitivity data on detection of LVO stroke in a mobile device. Work at Brown University, University of Pennsylvania, Hartford Healthcare.

Suppressing Covid Cytokine Storms with Low Intensity Ultrasound

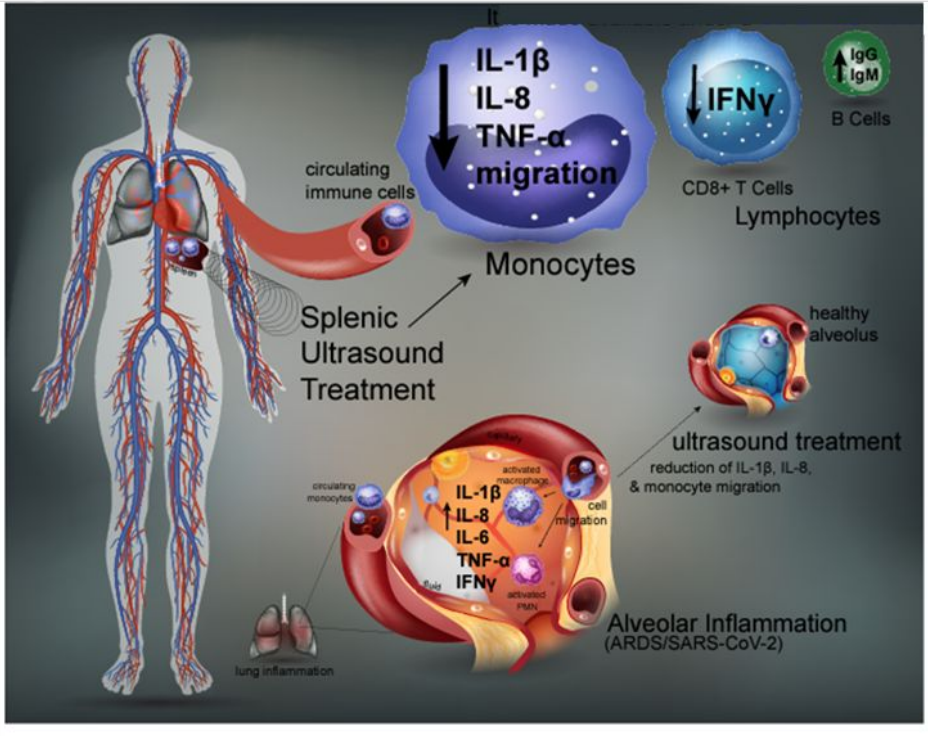
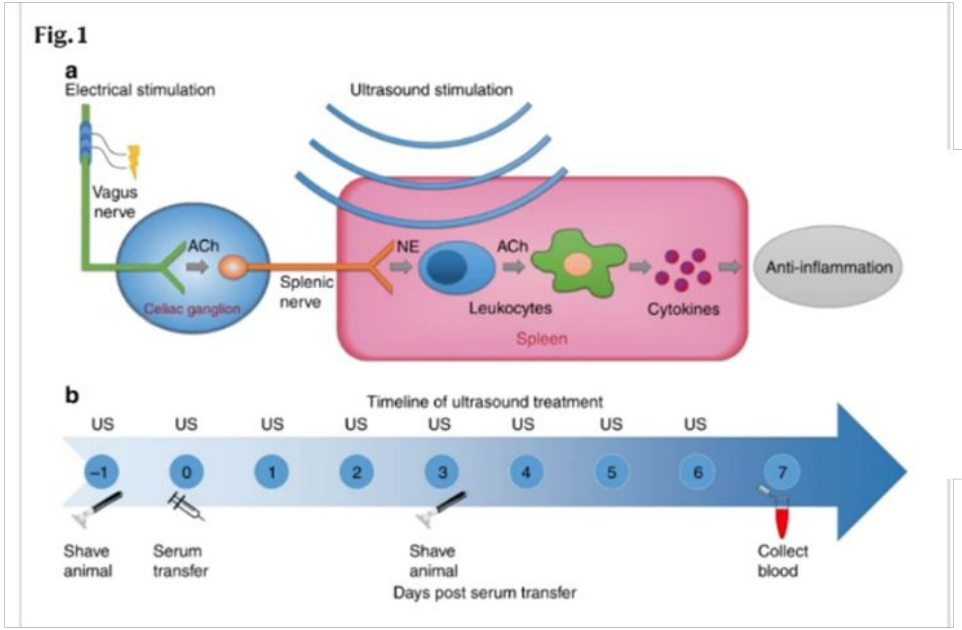
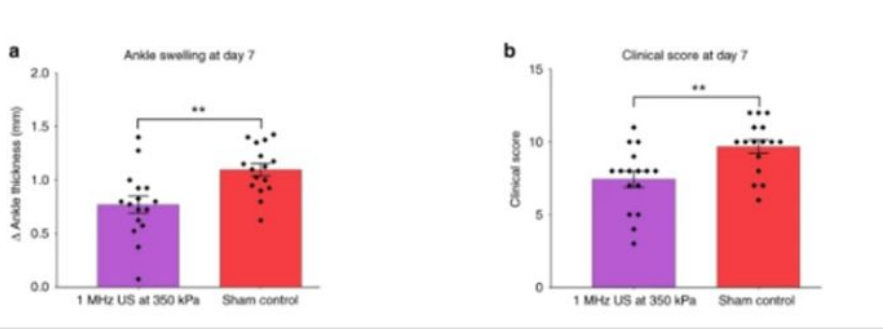


Figure S3. Non-invasive splenic ultrasound treatment for ameliorating immune hyperactivity for COVID-19. Schematic of the mechanism of splenic ultrasound treatment's effect on circulating immune cells. Splenic ultrasound reduces IL-1β, IL-8, TNF and genes involved in monocyte migration in monocytes, reduces IFNγ in CD8+ T cells, and increased IgG and IgM production in B cells (upper left, solid arrow). This treatment approach could help combat key elevated cytokines in alveoli and/or cellular migration to lungs in the context of COVID-19 (lower right, dashed

Graham, Rachel et. al. "*First-in-human demonstration of splenic ultrasound stimulation for non-invasively controlling inflammation*" medRxiv preprint Sept 11, 2020
DOI:10.1101/2020.07.14.20153528

Treating Inflammatory Arthritis

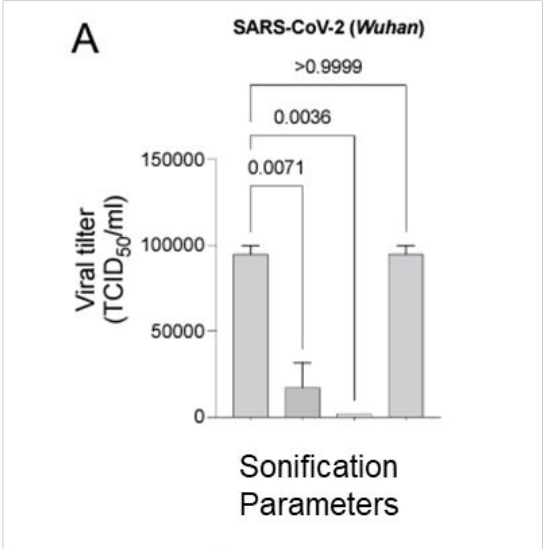


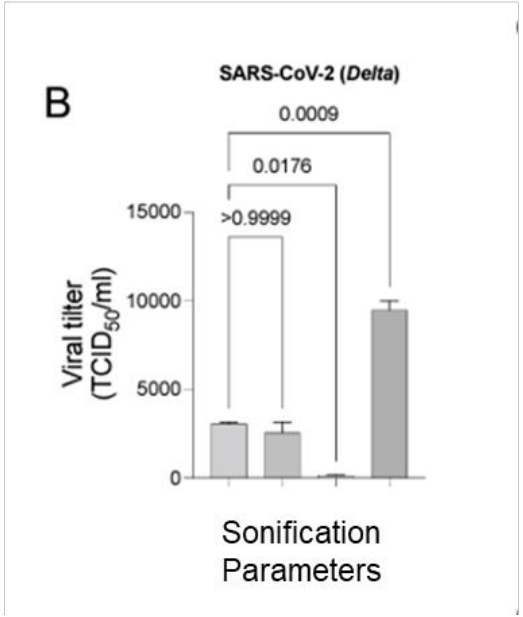


Zachs, Daniel, et. al "*Noninvasive ultrasound stimulation of the spleen to treat inflammatory arthritis*" Nature Communications 10: 951 (2019) DOI: 10.1038/s41467-019-08721-0

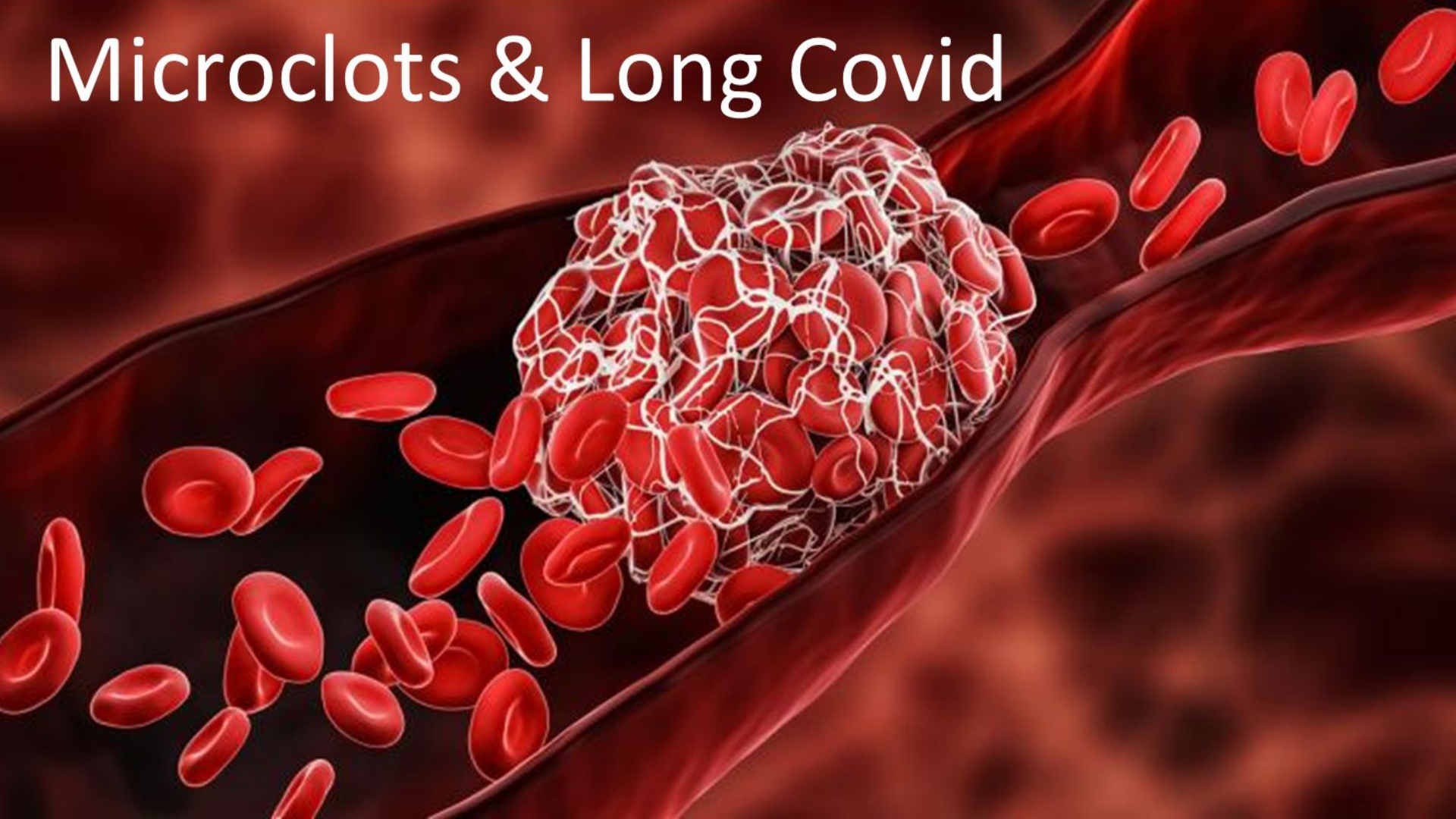
Even Deactivating Covid

Veras, Flavio et. al "*Ultrasound treatment inhibits SARS-CoV-2 in vitro infectivity*" bioRxiv preprint Nov 22, 2022 DOI: 10.1101/2022.11.21.517338



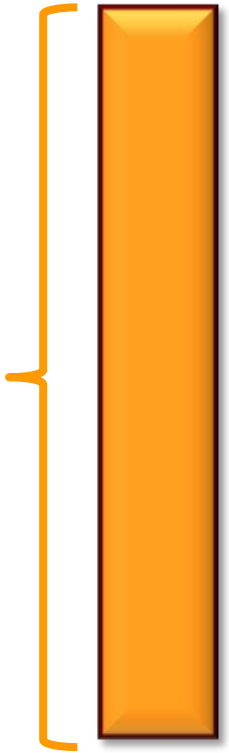


Microclots & Long Covid



Flipping Vertical Integration – A better outcome

$658M &
13 years
FDA approval for
a Single Disease



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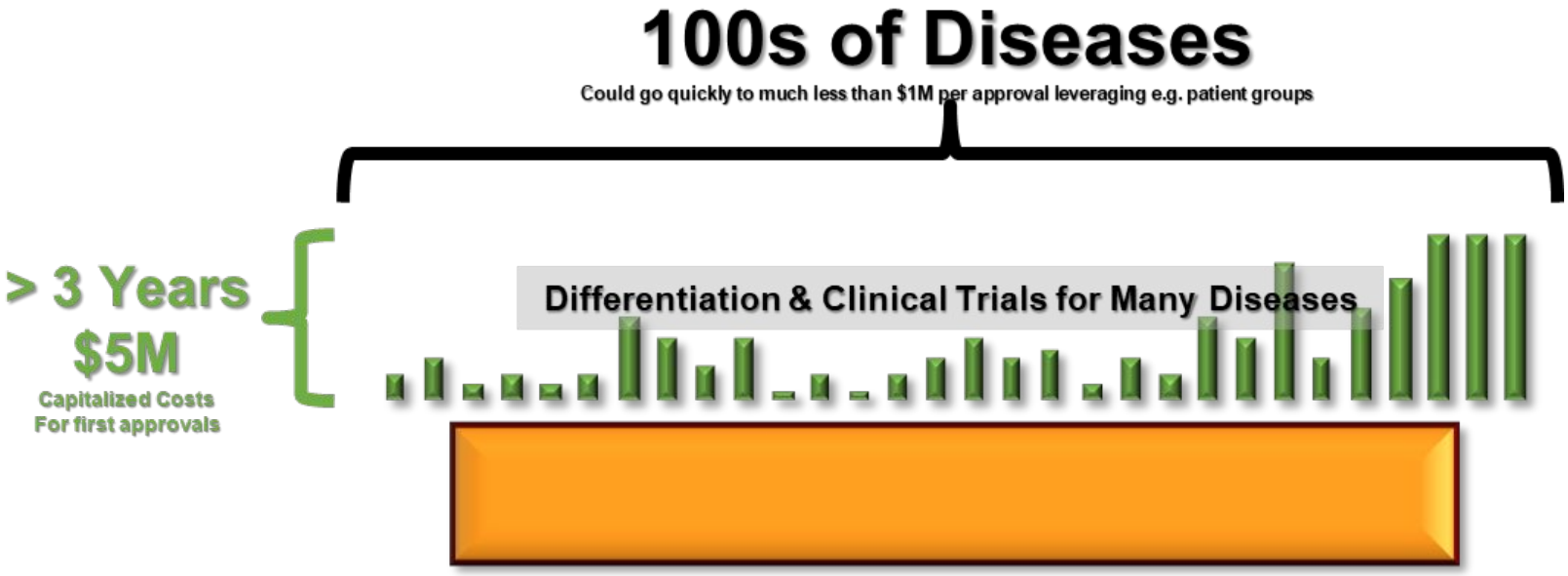

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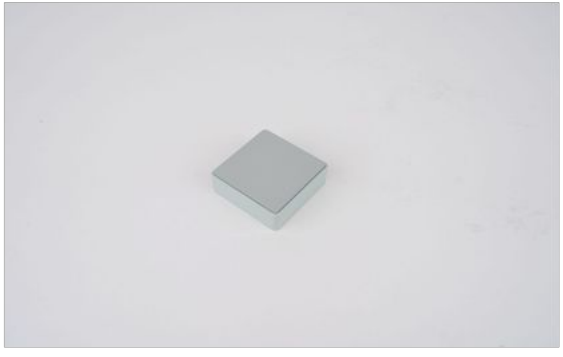
How do we make money in open source?

we make profit while saving many more lives.

Open-LIFU



Open-Motion

Open-Motion 3.0: the components are built

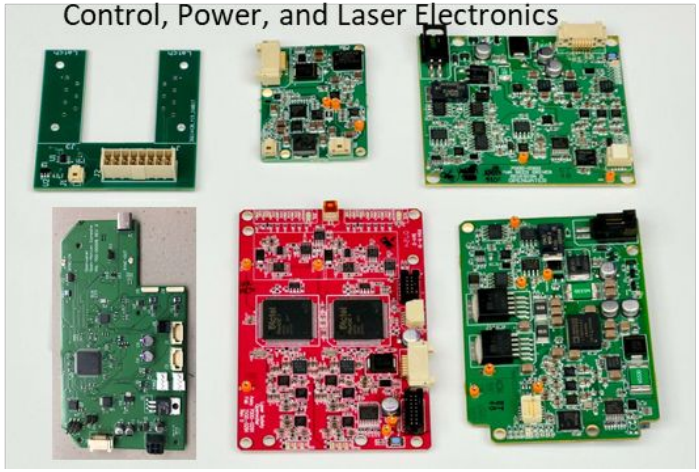
- This is a massive shrink from room size, to huge cart, to heavy toolbox size to this (over past 4 years)
- New modular design is expandable and enables many applications.

Detector Module

Camera w/
onboard FPGA

Console

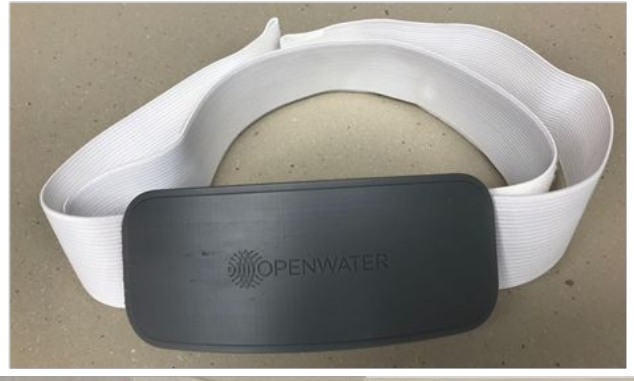
Control, Power, and Laser Electronics

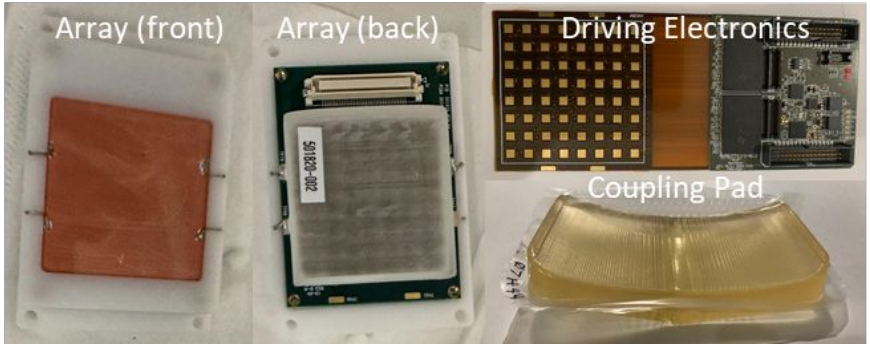


Open-LIFU 2.0 the components are built

- This is a massive shrink from the million dollar system we built and put into a clinical trial
- New modular design is expandable and enables many applications.

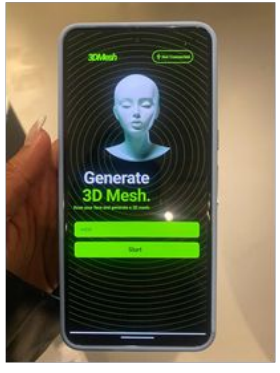
Transducer

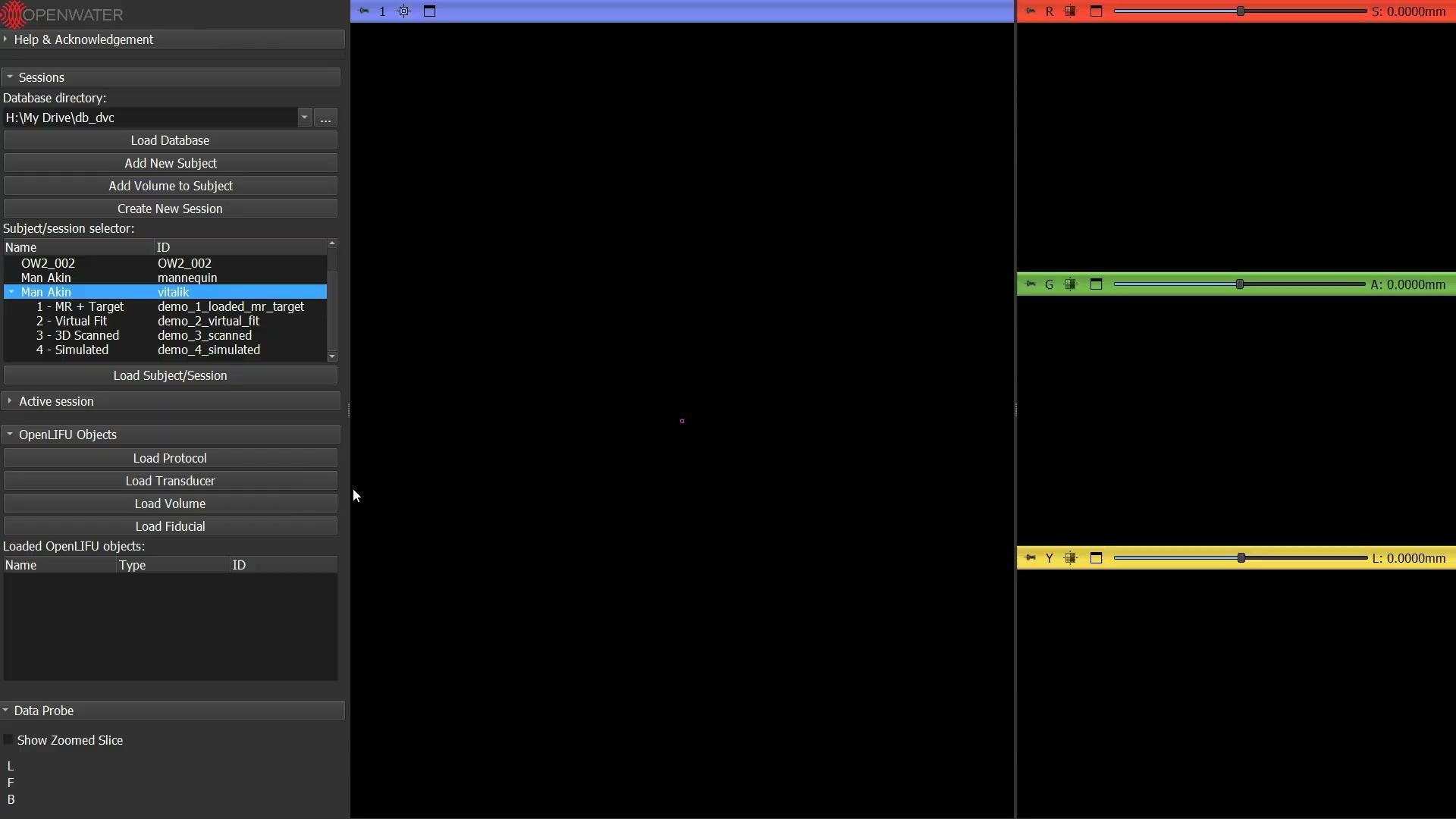


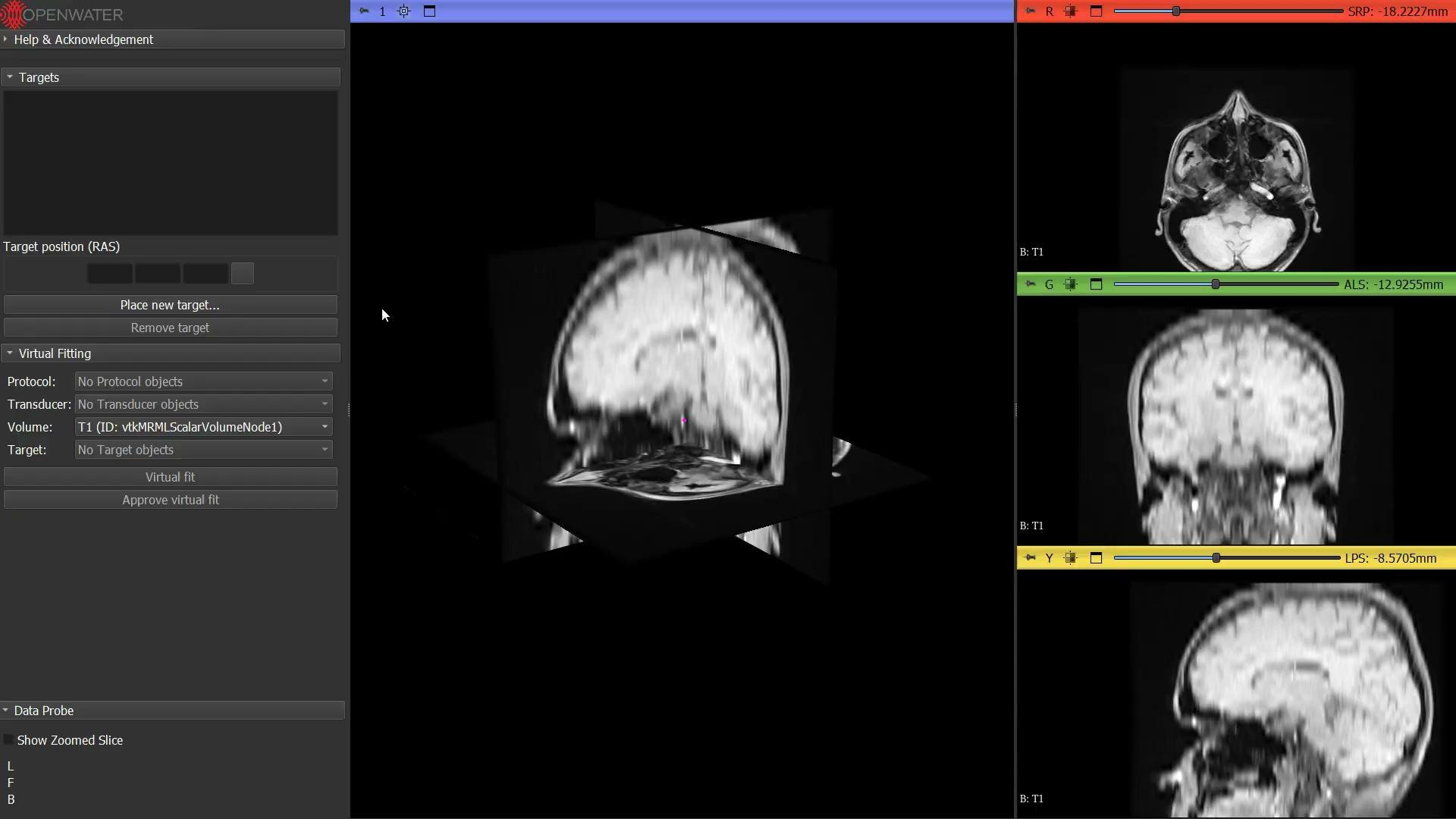


Console

Positioning App



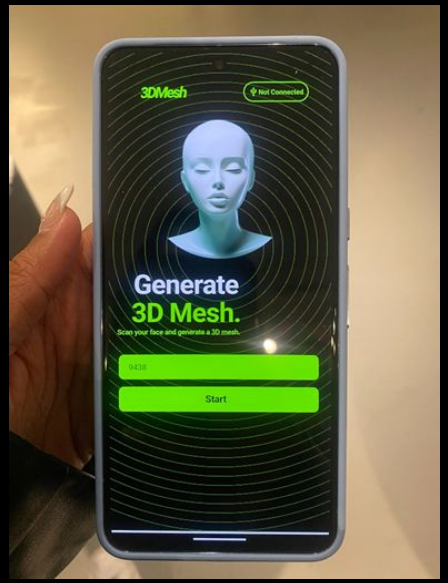

OPENWATER
Help & Acknowledgement
Sessions
Database directory:
H:\My Drive\db_dvc
...
Load Database
Add New Subject
Add Volume to Subject
Create New Session
Subject/session selector:
Name
ID
OW2_002
OW2_002
Man Akin
mannequin
Man Akin
vitalik
1 - MR + Target
demo_1_loaded_mr_target
2 - Virtual Fit
demo_2_virtual_fit
3 - 3D Scanned
demo_3_scanned
4 - Simulated
demo_4_simulated
Load Subject/Session
Active session
OpenLIFU Objects
Load Protocol
Load Transducer
Load Volume
Load Fiducial
Loaded OpenLIFU objects:
Name
Type
ID
Data Probe
Show Zoomed Slice
L
F
B
1
R
S: 0.0000mm
G
A: 0.0000mm
Y
L: 0.0000mm

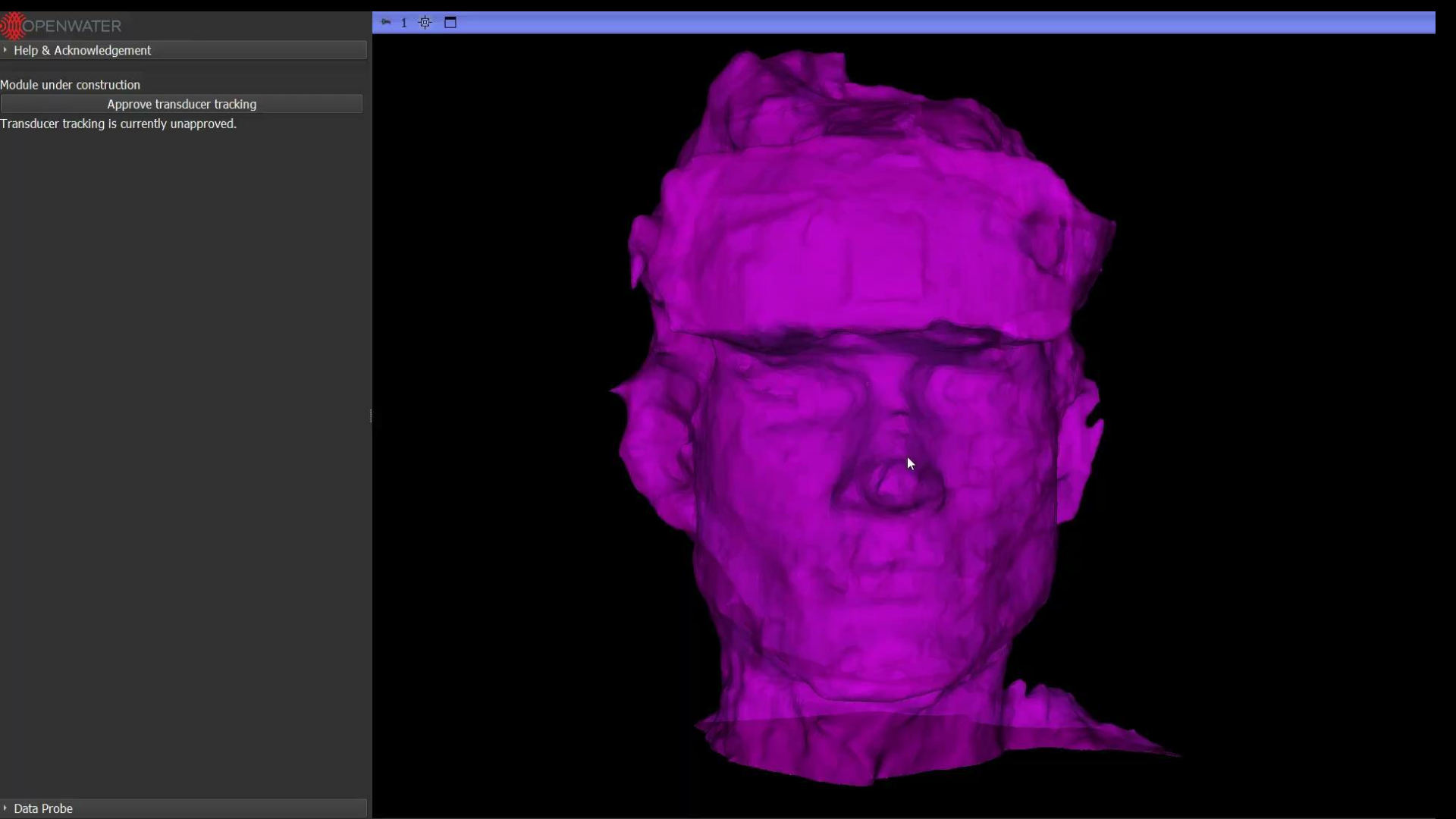

OPENWATER
Help & Acknowledgement
Targets
Target position (RAS)
Place new target...
Remove target
Virtual Fitting
Protocol:
No Protocol objects
Transducer:
No Transducer objects
Volume:
T1 (ID: vtkMRMLScalarVolumeNode1)
Target:
No Target objects
Virtual fit
Approve virtual fit
Data Probe
Show Zoomed Slice
L
F
B
1
R
SRP: -18.2227mm
B: T1
G
ALS: -12.9255mm
B: T1
Y
LPS: -8.5705mm
B: T1

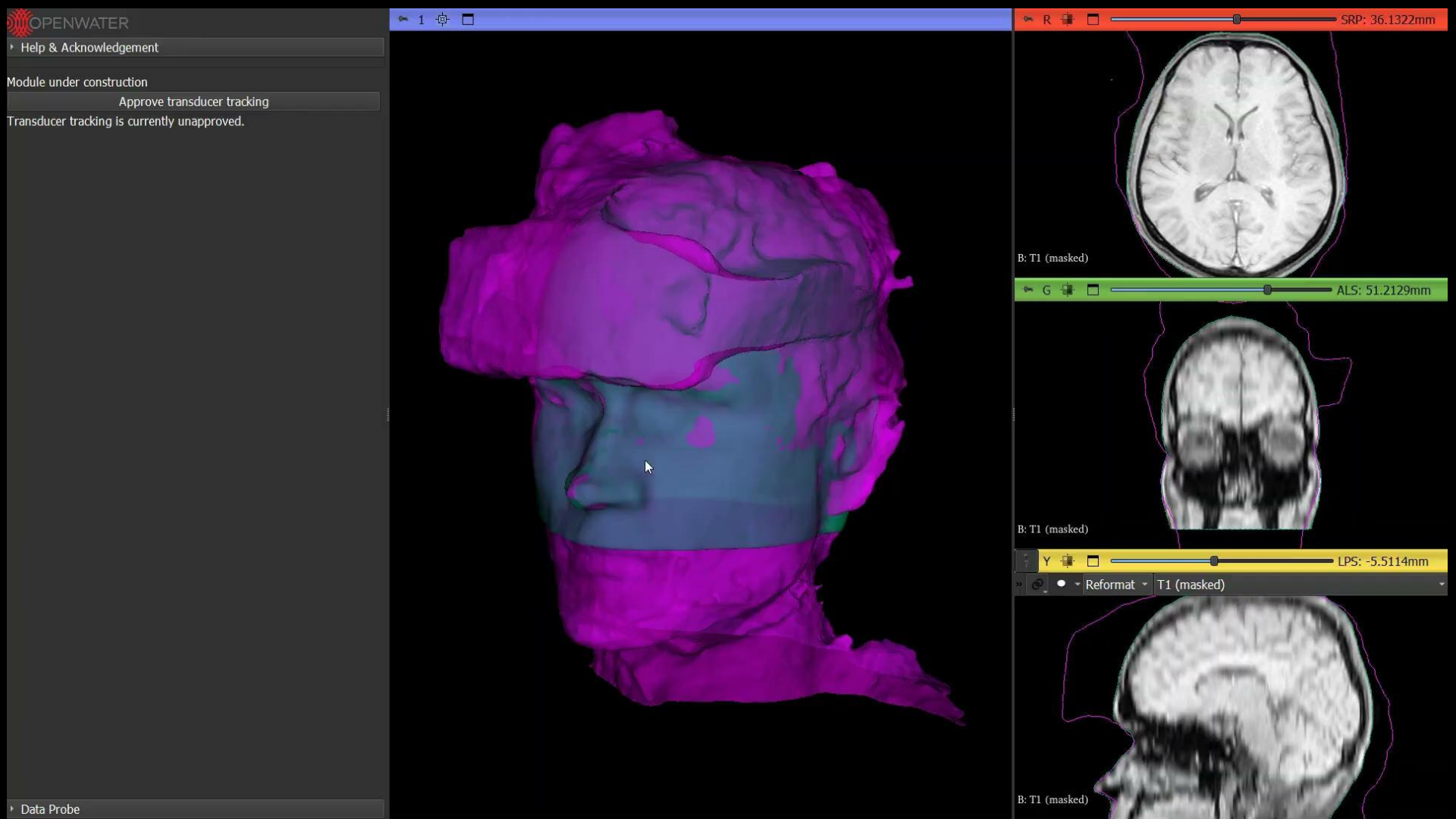
Scan Vitalik

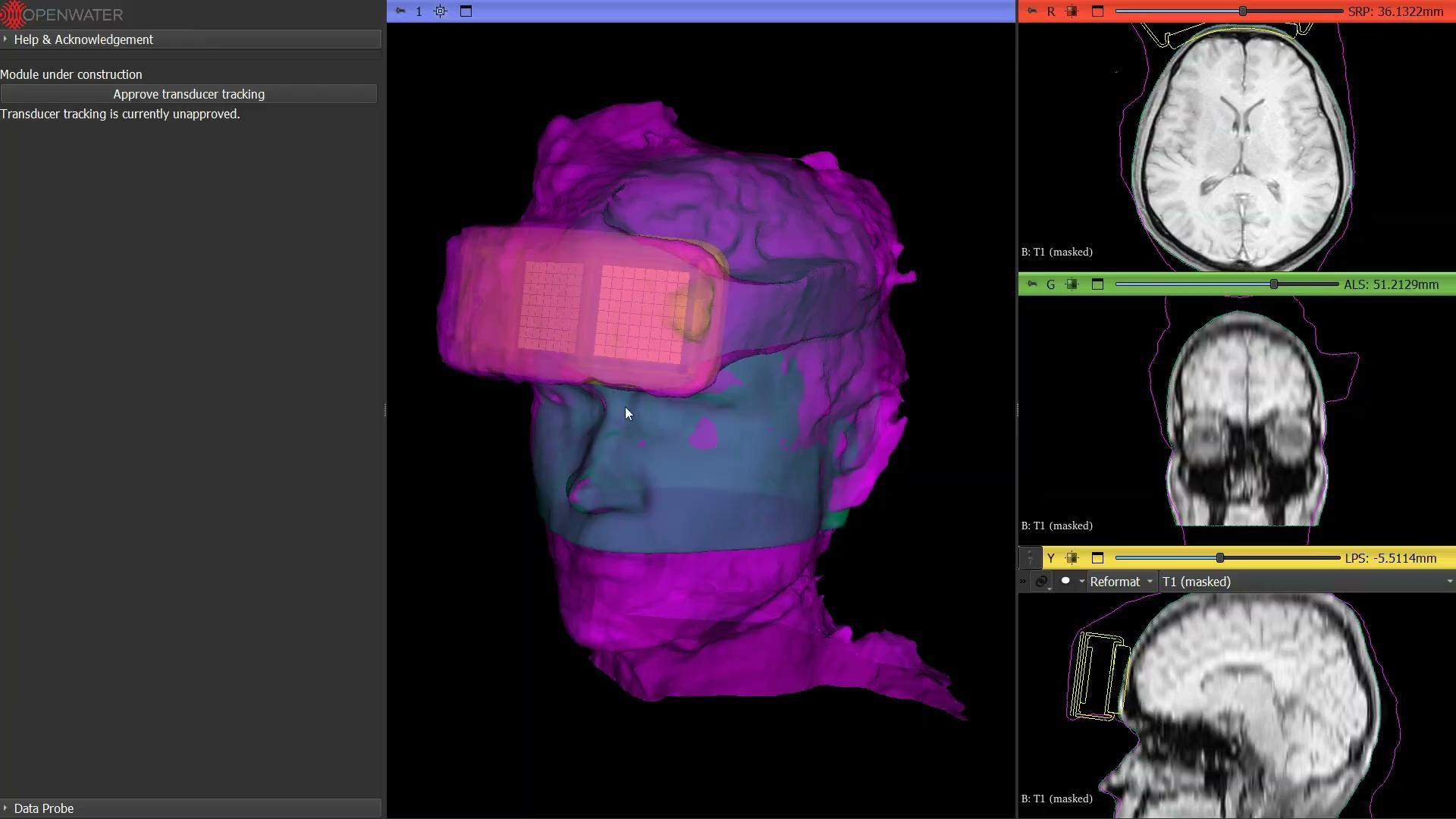
Scan Vitalik with Android Phone

App uses AR to automatically capture images as user orbits the subject to create a 3D construction of the head




OPENWATER
Help & Acknowledgement
Module under construction
Approve transducer tracking
Transducer tracking is currently unapproved.
Data Probe


OPENWATER
Help & Acknowledgement
Module under construction
Approve transducer tracking
Transducer tracking is currently unapproved.
Data Probe
1
R
SRP: 36.1322mm
B: T1 (masked)
G
ALS: 51.2129mm
B: T1 (masked)
Y
LPS: -5.5114mm
Reformat
T1 (masked)
B: T1 (masked)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Data Probe
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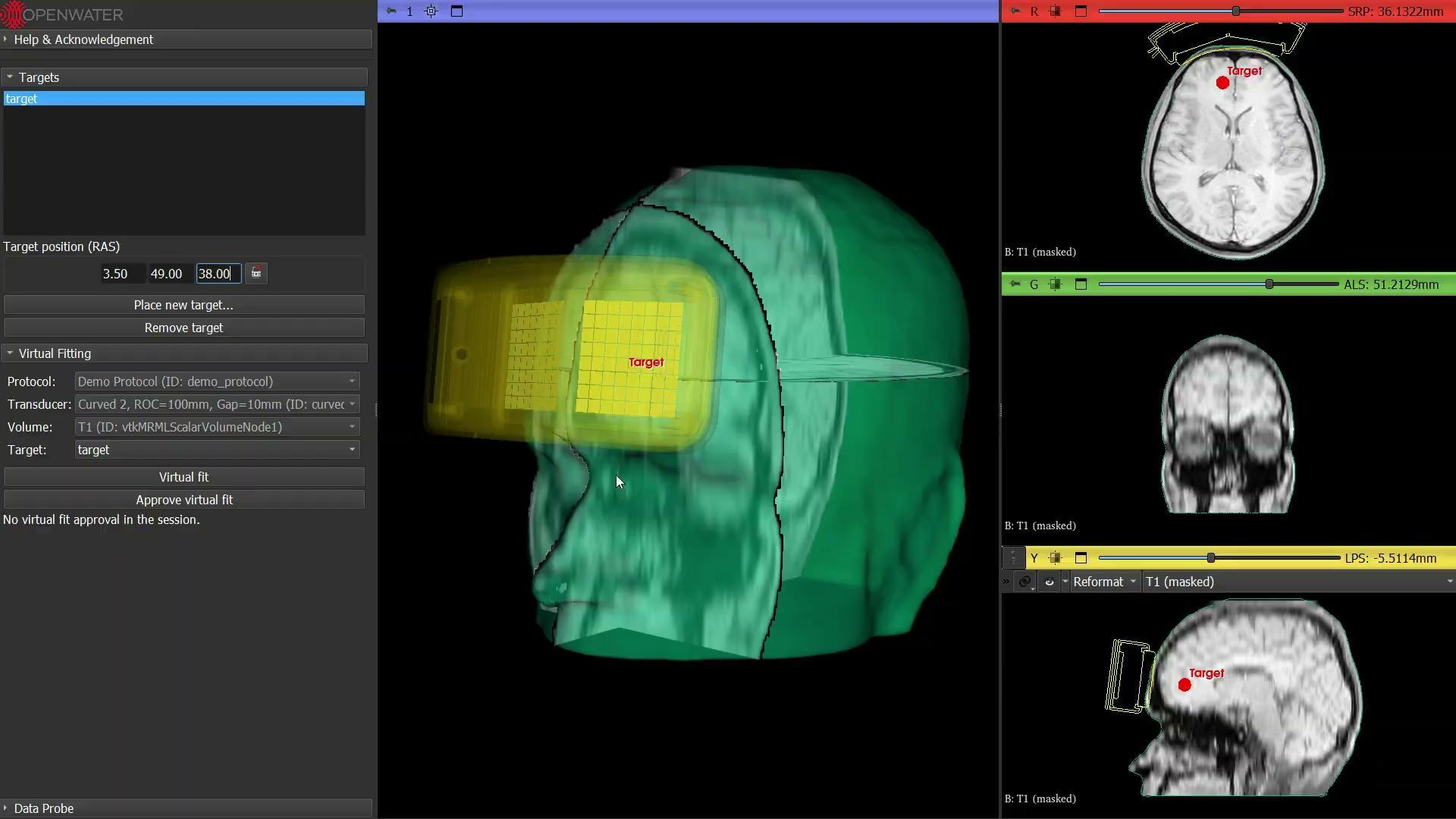
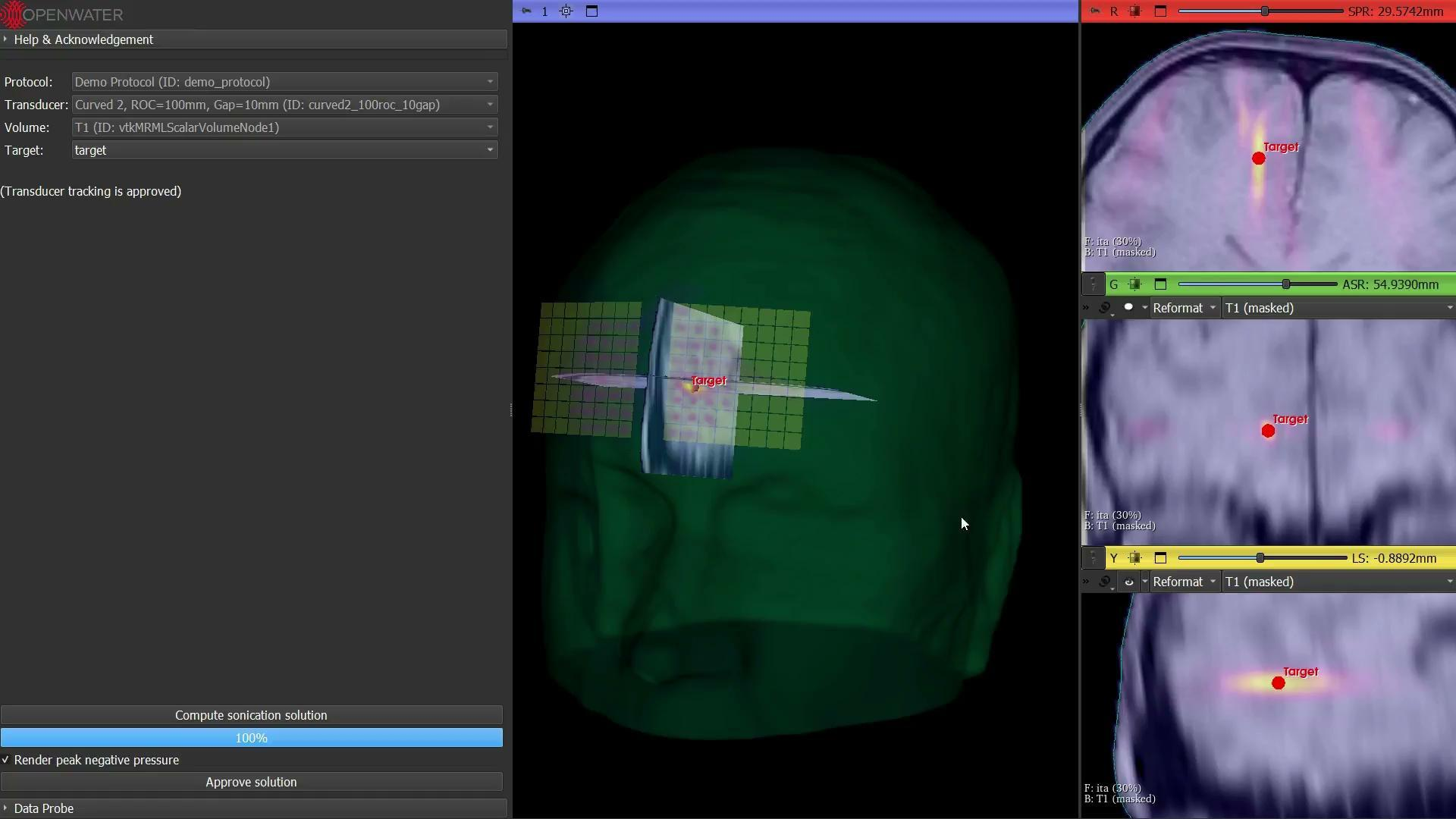
SRP: 36.1322mm
B: T1 (masked)
G
ALS: 51.2129mm
B: T1 (masked)
Y
LPS: -5.5114mm
Reformat
T1 (masked)
B: T1 (masked)


OPENWATER
Help & Acknowledgement
Targets
target
Target position (RAS)
3.50
49.00
38.00
Place new target...
Remove target
Virtual Fitting
Protocol:
Demo Protocol (ID: demo_protocol)
Transducer:
Curved 2, ROC=100mm, Gap=10mm (ID: curvec
Volume:
T1 (ID: vtkMRMLScalarVolumeNode1)
Target:
target
Virtual fit
Approve virtual fit
No virtual fit approval in the session.
Data Probe
1
Target
R
SRP: 36.1322mm
Target
B: T1 (masked)
G
ALS: 51.2129mm
B: T1 (masked)
Y
LPS: -5.5114mm
Reformat
T1 (masked)
Target
B: T1 (masked)


OPENWATER
Help & Acknowledgement
Protocol:
Demo Protocol (ID: demo_protocol)
Transducer:
Curved 2, ROC=100mm, Gap=10mm (ID: curved2_100roc_10gap)
Volume:
T1 (ID: vtkMRMLScalarVolumeNode1)
Target:
target
(Transducer tracking is approved)
Compute sonication solution
100%
Render peak negative pressure
Approve solution
Data Probe
1
Target
R
SPR: 29.5742mm
Target
F: ita (30%)
B: T1 (masked)
G
ASR: 54.9390mm
Reformat
T1 (masked)
Target
F: ita (30%)
B: T1 (masked)
Y
LS: -0.8892mm
Reformat
T1 (masked)
Target
F: ita (30%)
B: T1 (masked)

Can my **country, company, institute, patient or loved one** get some units or join a clinical trial in one of those diseases?

YES

Many trials are starting shortly - please talk to us!

Or get a system