Ambient Gamma Wave Frequency Light and Sound Source Prospectus

Highlights

Produces auditory and visual stimuli at 40 Hz

Screws into standard light socket

Simple, compact design

Programming versatility

Extraordinary profit margin potential

I. Primary Material

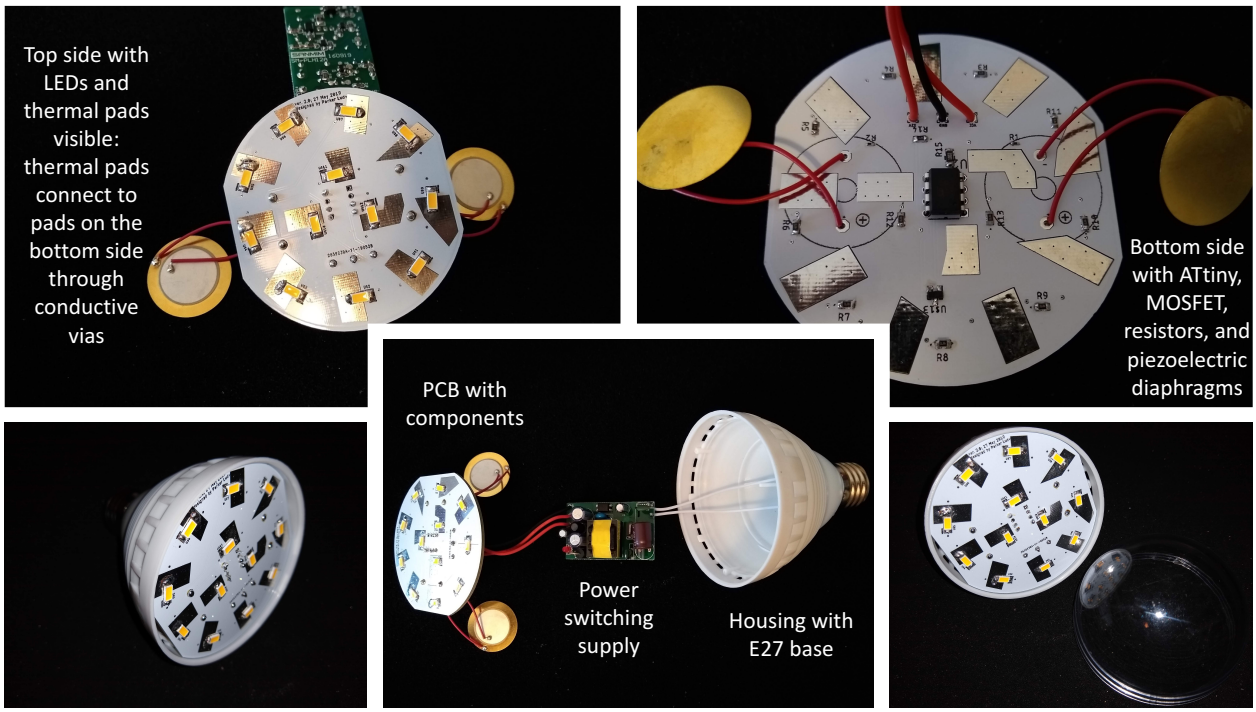
Device

An electric device, comprising:

(a) an E26 or E27 lamp base for electrical connection to a 110-220 V alternating current power supply
(b) power switching supplies for switching and stepping-down the power supply to 12 V direct current, and either 5 V or 3.3 V direct current
(c) a heat-spreader and/or thermally-conductive vias and thermal pads in the PCB for dissipating heat
(d) a housing appropriate for heat dissipation
(e) a MOSFET (metal-oxide-semiconductor field-effect transistor) switching circuit for managing the 12 V load

(f) an AVR 8-pin 20 MHz 8K ATtiny85-20PU microcontroller running C++ code for controlling outputs including
   (1) a series-parallel circuit comprised of 4 parallel sets of components, each being comprised of three 5730 3000K SMD light emitting diodes (LEDs) and three 4.7 Ohm resistors in series, connected to the 12 V MOSFET-gated supply producing electromagnetic radiation within the human visible light spectrum being switched on and off at a rate of 40 Hz, and
   (2) two piezoelectric ceramic elements or diaphragms each in series with a 100 Ohm resistor supplied with electricity from individual pins in the lower-voltage circuit to produce sound with a periodic rate of 40 Hz
(g) a lens and/or diffusor for the even distribution of outgoing light

whereby said outputs alter the ambient light and audio environment of a room for the purpose of treating or providing prophylaxis against amyloid-β protein deposition in the brain, a pathophysiologic contributor to the development of Alzheimer's disease.



Summary of the market

The population of the United States is approximately 325,720,000. About 13% of the population, or 42,343,600 are age 50-59. Another 11% or 35,829,200 people are 60-69, 7% or 22,800,400 people are 70-79, and 4% or 13,028,800 people are 80 or older for a total of approximately 114 million people age 50 or older in the United States alone [1]. The market of this device could be scaled globally for a dramatic expansion.

Preliminary market analysis indicates that 83.5% of individuals age 50 and older would purchase this device (if proven effective in humans) at 30 USD, 76.7% reported they would purchase at 40 USD, 72.8% at 50 USD, and 55.3% would purchase the device for 100 USD. Additionally, 32.0% of respondents indicated that they would purchase the device if a benefit had been shown in animals, but it had not yet been tested in humans.[1]

Based on these responses, if the device were sold for 50 USD at a manufacturing cost of 3 USD, factoring in 40% for shipping, handling, and retailer markup, the device would generate an estimated 2.34 billion USD net revenue annually in the United States alone assuming the longevity of the device to be approximately 1 year. This would be scalable globally for exponentially greater profits.

There are two primary channels of distribution that could be pursued with such a device: it could be distributed as a general commercial product through online and brick-and-mortar retailers, or through a medical device distributor in coordination with healthcare providers. There are advantages and disadvantages to both channels. With the former, the product could be marketed and sold directly to consumers which would simplify the distribution, and increase the number of units sold by limiting external factors. The latter approach would have a much higher barrier to entry involving medical device distributors and healthcare providers; however, higher prices could be charged if insurance were to be billed for the use of the device. When asked how they would like to purchase the device, 44.7% of respondents age 50 and older reported a preference for the medical device distributor channel in coordination with their physicians, 16.5% would like to purchase through a physical retail location, and the other 35.0% preferred to purchase online.

Respondents indicated that a brochure in the doctor's office would be the most effective form of advertisement (66.0%), followed by social media ads (47.6%), then television (36.9%) and magazine (26.2%) ads, with mailed promotional materials (16.5%) and radio advertisements (11.7%) ranking in as least effective.

[1] Survey results cited are current as of 11/14/19; n=103.

Competition

Meditation systems, headsets, and audio files:

Gamma Meditation System 2.0

- Audio album available for $9.97 on Amazon.
- Limitations: audio stimulus only, requires streaming device or CD or MP3 player, targets small share of the market interested in meditation and related products, no direct effect on Alzheimer's disease demonstrated.

MUSE: The Brain Sensing Headband

- Headset retailing for $178.00 on Amazon.
- Limitations: relatively expensive, targets small share of the market interested in meditation and related products, no direct effect on Alzheimer's disease demonstrated.

NeuroSky MindWave Mobile 2

- Headset retailing for $99.99 on Amazon.
- Limitations: reportedly uncomfortable causing headaches in many users, much of its functionality is geared toward entertainment, no direct effect on Alzheimer's disease demonstrated.

Versus Headset

- On pre-order for $1,299.00 with monthly subscriptions at $29.95/month on iOS app.
- Limitations: very expensive, subscription service required, reportedly uncomfortable sensors, targets share of the market interested in brain training, no direct effect on Alzheimer's disease demonstrated.

Device(s) presumably being developed by ***Cognito Therapeutics***

- Gamma stimulation therapy-based devices and services.

II. Support Material

Provisional patent cover sheet

Doc Code: **TR.PROV**
Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (11-08)
Approved for use through 05/31/2015. OMB 0651-0032
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Provisional Application for Patent Cover Sheet
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1 — Remove

Given Name	Middle Name	Family Name	City	State	Country i
Parker		Ludwig	Omaha	NE	

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

Title of Invention	Ambient Gamma Wave Frequency Light and Sound Source
Attorney Docket Number (if applicable)	

Correspondence Address

Direct all correspondence to (select one):

◯ The address corresponding to Customer Number	◉ Firm or Individual Name
Firm or Individual Name 1	Parker Ludwig
Firm or Individual Name 2	

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Phone	801-635-5374		

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

◉ No.

◯ Yes, the invention was made by an agency of the United States Government. The U.S. Government agency name is:

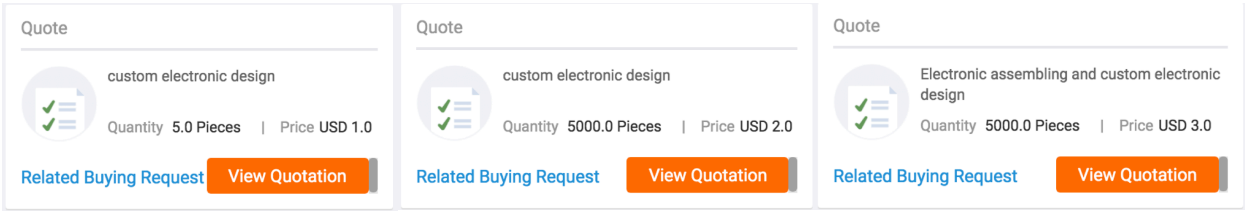
◯ Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:

EFS - Web 1.0.1

Example advertisement
(Product name would be added)

Manufacturer price quotes

Preliminary quotes range from 1 to 3 USD per unit when ordered in quantity of 5000 (from Shenzhen, China):



Relevant publications

Gamma frequency entrainment attenuates amyloid load and modifies microglia

Hannah F. Iaccarino[1,3]*, Annabelle C. Singer[2,3,4]*, Anthony J. Martorell[1,3], Andrii Rudenko[1,3], Fan Gao[1,3], Tyler Z. Gillingham[1,3], Hansruedi Mathys[1,3], Jinsoo Seo[1,3], Oleg Kritskiy[1,3], Fatema Abdurrob[1,3], Chinnakkaruppan Adaikkan[1,3], Rebecca G. Canter[1,3], Richard Rueda[1,3], Emery N. Brown[1,3,5,6], Edward S. Boyden[2,3,4] & Li-Huei Tsai[1,3,7]

Changes in gamma oscillations (20–50 Hz) have been observed in several neurological disorders. However, the relationship between gamma oscillations and cellular pathologies is unclear. Here we show reduced, behaviourally driven gamma oscillations before the onset of plaque formation or cognitive decline in a mouse model of Alzheimer's disease. Optogenetically driving fast-spiking parvalbumin-positive (FS-PV)-interneurons at gamma (40 Hz), but not other frequencies, reduces levels of amyloid-β ($A\beta_{1-40}$ and $A\beta_{1-42}$ isoforms. Gene expression profiling revealed induction of genes associated with morphological transformation of microglia, and histological analysis confirmed increased microglia co-localization with Aβ. Subsequently, we designed a non-invasive 40 Hz light-flickering regime that reduced $A\beta_{1-40}$ and $A\beta_{1-42}$ levels in the visual cortex of pre-depositing mice and mitigated plaque load in aged, depositing mice. Our findings uncover a previously unappreciated function of gamma rhythms in recruiting both neuronal and glial responses to attenuate Alzheimer's-disease-associated pathology.

Multi-sensory Gamma Stimulation Ameliorates Alzheimer's-Associated Pathology and Improves Cognition

Anthony J. Martorell,[1,2,13] Abigail L. Paulson,[3,13] Ho-Jun Suk,[4,5,6,12] Fatema Abdurrob,[1,2,12] Gabrielle T. Drummond,[1,2] Webster Guan,[7] Jennie Z. Young,[1,2] David Nam-Woo Kim,[1,2] Oleg Kritskiy,[1,2] Scarlett J. Barker,[1,2] Vamsi Mangena,[6] Stephanie M. Prince,[3] Emery N. Brown,[1,2,8,10,11] Kwanghun Chung,[1,2,7,8,9] Edward S. Boyden,[2,4,5] Annabelle C. Singer,[3] and Li-Huei Tsai[1,2,9,14,*]

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https://doi.org/10.1016/j.cell.2019.02.014

SUMMARY

We previously reported that inducing gamma oscillations with a non-invasive light flicker (gamma entrainment using sensory stimulus or GENUS) impacted pathology in the visual cortex of Alzheimer's disease mouse models. Here, we designed auditory tone stimulation that drove gamma frequency neural activity in auditory cortex (AC) and hippocampal CA1. Seven days of auditory GENUS improved spatial and recognition memory and reduced amyloid in AC and hippocampus of 5XFAD mice. Changes in activation responses were evident in microglia, astrocytes, and vasculature. Auditory GENUS also reduced phosphorylated tau in the P301S tauopathy model. Furthermore, combined auditory and visual GENUS, but not either alone, produced microglial-clustering responses, and decreased amyloid in medial prefrontal cortex. Whole brain analysis using SHIELD revealed widespread reduction of amyloid plaques throughout neocortex after multi-sensory GENUS. Thus, GENUS can be achieved through multiple sensory modalities with wide-ranging effects across multiple brain areas to improve cognitive function.

Neurodegenerative disorders

Neural synchronization in Alzheimer's disease

Liviu Aron & Bruce A. Yankner

Nature **540**, 207–208 (08 December 2016) | Download Citation

Electrical oscillations generated by neural circuits are disrupted in Alzheimer's disease. Restoring these oscillations in mouse models activates immune cells to clear disease-associated amyloid-β protein from the brain. See Article p.230

Inventor bio

Parker Ludwig is a fourth-year medical student at Creighton University School of Medicine. After graduation, he plans to pursue residency training in radiology. He has a passion for innovation and medical device development. Previous inventions include a pressure-sensitive gastric calibration tube for use in bariatric surgery which is currently in cadaveric testing. Parker also enjoys playing the organ and carillon.

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