White Paper:

Transforming a Smartphone into an Electroretinogram (ERG) Medical Device with Wearable Biosensor Integration

Introduction

The intersection of smartphone technology, biosensors, and medical diagnostics holds tremendous potential for revolutionizing healthcare. This white paper focuses on leveraging smartphones as ERG devices and integrating them with wearable biosensors for cloud-based data analysis. The smartphone ERG makes this fundamental electrophysiology test accessible to those that need it. Furthermore, it explores the applications of ERG in Visual Evoked Potential (VEP) assessment for neurotrauma and neurodegenerative diseases, highlighting the benefits of this integrated approach.

From Smartphone to ERG Medical Device

To convert a smartphone into an ERG medical device, the following modifications and additions are essential:

- **Light Stimulation and Detection**: The smartphone's display and camera flash system are optimized for delivering controlled light stimuli and capturing retinal responses. This is done by adding two critical features to make the smartphone flash and flicker at proper intensities with pan-retinal illumination. The ERG Ganzfeld Generator (EGG) turns the single LED flash into a pan-retinal illuminator, for maximal retina response. Secondly, neutral density filters allow the camera flash to become a calibrated photo-stimulator. A key requirement for accurately recording ERG is knowing exactly when the flash occurs: zero time. This is done with a novel beacon system that transmits the flash to the biosensor. Thus, the biosensor can precisely timestamp the data acquired from the evoked response to the flash.

- **Electrode Interface**: Low impedance skin electrodes are easier to use than traditional contact lens electrodes to capture retinal signals and are more comfortable on the patient. The signal quality of the skin electrode is monitored throughout the examination process to confirm good contact for high quality data output, not some false result.

- **ERG Software in an App**: Custom software for Android® has been developed to enter patient data, run standardized protocols, analyze waveforms, and generate diagnostic reports through the smartphone. The software platform also restricts access to only essential applications because a smartphone ERG needs to work reliably without disruption, just like all critical medical devices.

- **Operational Environment Ready**: Conducting ERG tests should be easy in a variety of environments from the pediatric ICU to the annual eye exam. The smartphone can be configured to work in the most austere environments, using robust technology to make it a reliable portable medical device.

- **Phone-Tester**: Not all smartphones are created equal! A testing software process to determine if various phones make the grade of an ERG medical device is required. The Phone-Tester application can be used to test any phone's capability. The results of each phone's capability to generate accurate flashes and flickers including its operating system characteristics are stored in the cloud for future performance analysis.

Figure 1: SmartERG Android Software Application and Evoq Cloud Data Platform Connectivity Puts Data Securely in a Global AWS Database for Powerful Analysis.

- **Score**: ERG and VEP waveforms are repeatable and uniform. Algorithms are useful in assessing expected waveform attributes. And depending on the quality of all waveform attributes, a composite score with underlying attribute details allows the smartphone ERG to present the examiner a score of good, suspect, or bad on a real time basis. The smartphone ERG is "smart" enough to tell the user if they captured an acceptable result or not.

Integration with Wearable Biosensor Technology

In addition to smartphone-based ERG capabilities, integration with wearable biosensor technology enhances the system by:

- **Precision Data Collection Tool**: The single channel wearable biosensor uses an active, reference, and ground acquisition of bio-electrical data. Electrophysiological data standards are adhered to for comparability with other legacy ERG devices to capture vital signs relevant to retinal and neurological health.

- **Untethered Body to Phone Connectivity**: Biosensors send data wirelessly to the smartphone, leveraging Bluetooth technology and proprietary protocols for seamless integration. The wearability makes movement and comfort greater for the patient.

- **Universal Compatibility with Other ERGs**: The photosensor is capable of detecting any flash or flicker from another device and record the results. This offers an opportunity to include products from different manufacturers on a shared, standardized cloud data collection platform.

- **Cloud-Based Data Analysis**: Data collected from the smartphone and biosensors is securely transmitted to the cloud for storage and real-time analysis.

- **Real-time Environmental Monitoring**: Biosensor is also an envirosensor; monitoring light, sound, electrical, pressure, movement, and smell are all possible stimuli the wearable biosensor can detect.
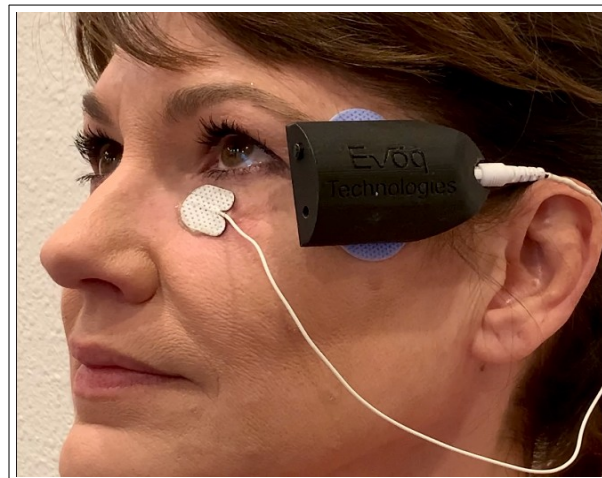

Figure 2: Single-channel wearable biosensor with ground/reference skin electrode and separate active eyelid electrode provides "sight of stimulus" data collection for accuracy and greater patient comfort.

Application of Visual Evoked Potential (VEP)

A smartphone ERG can by its basic design conduct Visual Evoked Potential (VEP) for detecting, monitoring, and assessing neurotrauma and neurodegenerative diseases. From the retina to the back of the brain, a smartphone ERG/VEP will be used for:

- **Detection of Optic Nerve Dysfunction**: VEP identify abnormalities in evoked responses indicative of optic nerve damage or dysfunction.

- **Monitoring Disease Progression**: Changes in VEP waveforms over time can track the progression of conditions like multiple sclerosis, Alzheimer's disease, or diseases affecting visual pathway like Glaucoma.

- **Assessment of Treatment Efficacy**: VEP can be used to evaluate the effectiveness of therapies targeting neurotrauma or neurodegenerative diseases, providing objective measures of visual function recovery.

Benefits and Impact

The integration of smartphone ERG with wearable biosensors and cloud-based analysis offers numerous benefits:

- **The Perfect Artificial Intelligence Platform**: With high signal-to-noise quality data, standardized structures, and protocols, building a solid ground truth for detection of diseases will be the source of future breakthroughs in retinal and systemic disease detection.

- **Enhanced Accessibility**: Enables convenient and affordable retinal and neurological health monitoring outside traditional clinical settings.

- **Early Detection and Intervention**: Facilitates early detection of neurotrauma and neurodegenerative diseases, enabling timely interventions to preserve visual and neurological function.

- **Personalized Healthcare**: Provides personalized insights based on real-time data, guiding tailored treatment plans, and optimizing patient outcomes.

- **Lowest Cost of Healthcare Delivery**: Smartphones are powerful and inexpensive communication devices, made in the millions. By utilizing this technology, the smartphone ERG/VEP can be scaled, connected, and distributed around the world; faster than any other diagnostic device.
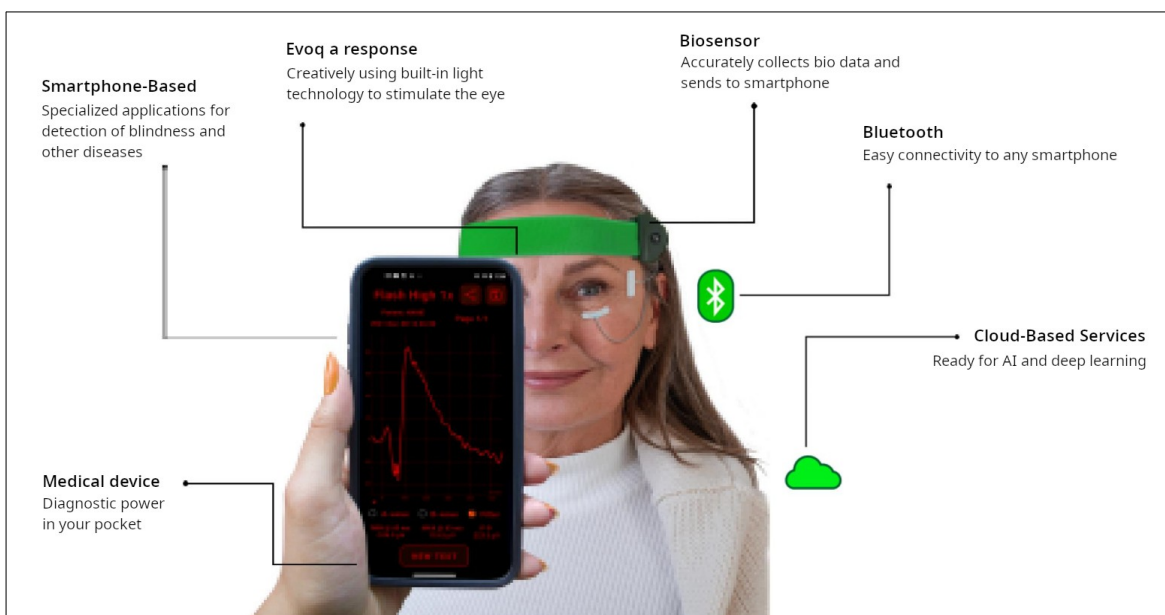

Figure 3: A smartphone ERG harnesses the power of a low cost, scalable operating device to feed power data analytics capable of deep learning and artificial intelligence.

Conclusion

In conclusion, transforming a smartphone into an ERG medical device integrated with wearable biosensors represents a significant advancement in healthcare technology. This integrated system not only facilitates comprehensive retinal and neurological health monitoring but also enables early detection and personalized management of neurotrauma and neurodegenerative diseases. By harnessing the power of smartphone technology and cloud-based analytics, we can usher in a new era of accessible, proactive, and personalized healthcare.

For further information or inquiries regarding this integrated approach,
please contact **EVOQ Technologies** at **founder@retinatesting.com**