

Category

Best Startup

Product/Solution Name

EyeControl

Date of Approval

2018-07-04

Indications

Adult, critically ill patients hospitalized in an intensive care unit who require mechanical ventilation and/or are unable to verbally communicate

Therapeutic Categories

Communication, Cognitive protection

Background information and need for solution/product

The original motivation behind the development of the EyeControl was to provide ALS, and other patients who are paralyzed, have lost their ability to speak and can only communicate with eye movements, the ability to independently communicate. The goal was to enable these individuals to communicate 24/7 without the need to be calibrated to an external computer screen. Existing solutions required a screen for typing and/or communicating, limiting basic communication abilities under many daily conditions.

Three Co-founders, Or Retzkin(CEO), Itai Kornberg (CTO), and Shay Rishoni (1966-2018 | CEO of Israeli NGO, Prize4Life), all with personal connections to ALS and other Locked-in conditions, came together to form EyeControl and to develop the first wearable, assistive communication device enabling communication 24/7, the EyeControl-Home. Under the activity of Prize4Life, the solution evolved, and at 2016, it was decided to establish the company and provide shares to the NGO, which became the biggest asset of the NGO.

The EyeControl-Home solution provides wearable, screenless, assistive communication without the need for calibration. Users control audio menus with pupil movements tracked by a head-mounted camera. Communication selections are converted to speech via the output speaker and/or attached Bluetooth device.

The wearable enables three main advantages:

- 24/7 communication availability – the first standalone communication solution that can be used while going to sleep, immediately upon waking, and even in the car.
- Screenless – There is no bulky screen to block the line of sight between the patient and the caregiver. The audio feedback to the patient via the bone conduction earphone provides privacy of communication without the need to display all communication on the screen.
- User experience – No calibration required, the product is customized and adapts to the patients current level of abilities, and it has a very short learning curve.

The EyeControl-Home is FDA listed, CE marked, and fully reimbursable through Israel's national health basket, and through CMS codes for reimbursement in the US.

During the COVID-19 pandemic, the company became aware of the even greater need for patient communication solutions within ICUs. In the US alone, over 6 million people are admitted to ICU departments every year, and approximately 40% of all ICU patients are unable to communicate with the medical staff and their loved ones due to mechanical ventilation, heavy sedation, and other medical conditions. This loss in communication is a major contributing factor to one of the largest problems facing the ICU today, a condition known as ICU delirium.

ICU delirium is an acute and fluctuating disturbance of consciousness and cognition, often presenting as a severe state of confusion. Delirium can occur in various hospital settings and is considered to be equivalent pathophysiologic states across these settings (1). However, delirium rates are higher in the intensive care unit (ICU) compared to other inpatient settings, with 22.9% prevalence in acute and rehabilitation hospital wards versus up to 89% incidence in the intensive care setting (2).

Delirium days is the most significant predictor of time on mechanical ventilation and increased ICU length of stay (increasing the LOS up to 5-10 days in the unit), and one day of delirium is associated with a 70% higher risk of death (3). In addition to mortality, ICU delirium is associated with significantly worse functional neurological outcomes. At hospital discharge, ICU patients who experienced any delirium are 9 times more likely to have cognitive impairment than patients who did not experience delirium (adjusted hazards ratio 9.1; 95% CI 2.3, 35.2; $p=0.002$) (4).

Delirium incidences also increase nursing time per patient, and higher per-day hospital costs, at an estimated \$2,500 per patient/ per hospitalization, totaling nearly \$7B in medicare expenditures (5). The one year costs following an episode of delirium is conservatively estimated at \$60,000 per year/per patient, totaling a direct 1-year healthcare cost attributable to delirium in a range from \$38B up to \$152B in the US (5).

There are currently no pharmacological solutions to mitigate delirium, furthermore, it was found that some sedatives, especially Benzodiazepines, are known to cause delirium or further prolong it (6).

Multiple nonpharmacological interventions are associated with significant and clinically meaningful improvements in patient outcomes including reduced mortality, mechanical ventilation use, coma, delirium, restraint-free care, ICU readmissions, and post-ICU discharge disposition (7, 8, 9, 10). The Society for Critical Care Medicine published a bundle of these recommended interventions as a practice guideline for ICU departments to follow (11). In reality, implementing these practices has many hurdles and the compliance is very low worldwide - both for each of the bundles and for each of the strategies independently (12,13). Various factors have been identified as impediments to the effective implementation of delirium screening and reduction programs. These factors include the burden that the programs place on nursing staff, excessive turnover of ICU leadership, staff morale issues, lack of respect among disciplines within the hospital, knowledge deficits, and excessive use of registry staff (14,15).

Attached is a short video explaining how it works and providing testimonials. <https://www.youtube.com/watch?v=MZS740LFZe4>

Attached Files:

- EyeControl Testimonials.mp4

History of the development of the solution/product

The EyeControl-Home product for ALS patients evolved into our most recent product development, the EyeControl-Med. The EyeControl-Med includes the convenience of the EyeControl-Home wearable, with the additional benefit of WiFi connectivity between the patient's headset and our nurse station platform, enabling bi-directional communication between the patient and the medical staff, operating according to the patient's eye status and current level of awareness.

The EyeControl-Med platform fully automates the methods that have been shown to protect the patient's brain from falling into a state of ICU delirium, including enabling patient communication abilities, providing continuous orientation, familiar voices, and interaction with loved ones, listening to music, and administering assessments of cognitive brain function. The EyeControl-Med empowers loved ones to be included in the patient's care via a secure web portal where they can record special messages, which are played directly to the headset of the patient throughout the day, providing familiar voices in what is often a very unfamiliar and confusing environment.

This transition of the company from the homecare market to the medical facilities market is featured as a Harvard Business School Case Study. During our company and product evolution we did not forget our roots, as we have dedicated a portion of our success to return to the ALS NGO as a shareholder in the company and our impact will continue to fund ALS research.

EyeControl's communication solution has been implemented within Clalit (Israel's largest HMO) medical facilities, supporting the growing need of patient communication solutions. Clalit medical staff were selected to present the EyeControl at the Society of Critical Care Medical Conference in San Francisco, USA in January 2023.

The company has been recognized for its progress and technology during the development of our communication solutions:

- The Genesis Prize – One of ten winners who demonstrated the most promising technologies to fight COVID-19, with our innovative remote communication solution for patients who were isolated from their loved ones (16).
- The Shimon Peres Heritage Award - commemorating young innovators developing technological innovation for social impact
- Horizon 2020 – Grant recipients for promising research and innovation projects
- SCCM Conference - Presentation of clinical trial results demonstrating the benefits of the solution
- BIRD Foundation – Grant funding for the multi-center trial was received after presenting the preliminary results of an ongoing RCT
- Harvard Business School case study is taught about the company's pivot from homecare to facilities.

In addition to the core founding team, the company has recruited experienced executives, including our Chairman of the Board, Avner Halperin, VP R&D, Moshe Hoori (over 15 years of R&D leadership), and VP Sales, Uzi Ron (over 15 years of Sales and Product experience). The team is also supported by a strong advisory board including members such as Lyn Ketelson (first Chief Patient Experience Officer of HCA), Karen Thompson (Asst. VP at HCA), Yaron Itzhari (ex-Country Director of Medtronic Israel), and

Dr. Ariel Modrykamien (Chief Medical Intensive Care Unit, Baylor University). Our board also includes experienced leading high-tech angels who have assisted to shape the company such as Benny Levin (founder of NICE), and Itsik Danziger (ex-President of Comverse).

Attached Files:

- EyeControl Deck Prix 16052.pdf

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

EyeControl implements disruptive AI technologies connecting people and bridging information barriers, facilitating better medical care and decision-making. Our eye-tracking wearable and innovative platform empower comprehensive, round-the-clock, bi-directional connectivity between patients with communication difficulties (primarily ventilated), their families, and medical teams. The company's value-based care approach of personalized communication is intended to mitigate the cognitive decline, diminish healthcare costs, and shorten the length of hospital stay. The EyeControl platform is set in place while the patient is sedated and supports the patient from the sedation stages to awareness while enabling the family members and staff to have a better way to interact with the patient 24/7.

THE EYECONTROL PLATFORM ENABLES BETTER COMMUNICATION FOR PATIENTS IN THE ICU

- Our communication platform uses eye-tracking technology to enable patients who are unable to speak or move their limbs to communicate with others.
- The Joint Commission set a goal to enable every patient to communicate, and the EyeControl platform can achieve this goal by enabling patients to communicate through eye movements (17).

THE EYECONTROL PLATFORM PROTECTS AGAINST COGNITIVE DECLINE IN THE ICU

- Prolonged stay in the ICU is associated with cognitive decline, and reducing sedation has been recommended as a way to mitigate this decline (18). Our platform can help reduce the need for sedation by providing an alternative way for patients to communicate, as well as providing regular scheduled interventions shown to provide calming and reassuring distractions, reducing the request for pain medications (1).
- EyeControl can help reduce the need for sedation by providing an alternative way for patients to communicate.
- By reducing the need for sedation and minimizing cognitive decline, EyeControl can improve the long-term outcomes for ICU patients (19).

GROWING MARKET FOR CRITICAL CARE IN ICU

- The number of patients in the ICU is increasing, driven in part by an aging population and advances in medical technology (20).
- Hospitals will become smaller as many patients will be treated at home but the part of the ICU will grow from 3%-5% beds at the hospital to 20%-30%. This trend is expected to continue in the coming years, with a projected increase in the number of ICU beds globally (21).

THE EYECONTROL PLATFORM IMPROVES INTERACTION BETWEEN PATIENTS AND FAMILY MEMBERS

- The COVID-19 pandemic highlighted the importance of communication between patients and their family members, particularly in the ICU (22).
- EyeControl enables more communication between patients and their loved ones, even when physical

visitation is restricted.¹

- Improved communication and interaction with family members can help reduce patient anxiety and improve their overall experience in the ICU (23).

THE EYECONTROL PLATFORM ASSISTS THE ICU STAFF TO PREVENT BURNOUT

- ICU staff are at risk of burnout due to the high-stress environment and long working hours (24).
- EyeControl can help provide more opportunities for staff to interact with patients, which can improve their job satisfaction and prevent burnout.

The company has ongoing trials in Israel with promising preliminary results and is beginning a randomized, controlled multi-center trial between BIDMC (Boston, USA), Beilinson (Israel), and Assuta (Israel). This multi-center trial is funded by a mutually awarded grant between EyeControl and BIDMC, and aims to demonstrate EyeControl as the first platform to support the reduction in ICU delirium and show the benefit of communication in protecting against cognitive decline

EyeControl's devices are FDA-listed and CE-marked as communication solutions; our outpatient product, EyeControl-Home, is government reimbursed in Israel, and the US. The EyeControl-Med, our healthcare facility product, is commercially active while in parallel undergoing clinical trials, validating its efficacy in preventing clinical deterioration decline via communication.

The company began as a volunteering activity alongside an ALS NGO, including one of our co-founders who had ALS, with a determination to provide the ability to communicate to every patient. With our new solution of the EyeControl-Med, we continue our mission to empower patients with communication tools that will improve the patient care experience, and lead to better patient outcomes.

Please provide appropriate references (ie Pubmed links)

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Attached Files:

- EYECONTROL_Prix reference list.pdf