Periodic Reporting for period 2 - Eyecontrol (EyeControl: A Communication Solution for Ventilated ICU Patients and Locked-in Individuals)

Reporting period: 2021-08-01 to 2022-07-31

Summary of the context and overall objectives of the project

Annually, millions of patients in EU and US intensive care units (ICUs) are unable to communicate, resulting in multibillion euro loss. Lack of communication leads to disorientation and higher rates of...
Delirium, a serious mental disturbance resulting in confused thinking and reduced awareness. Delirium affects 60-80% of intubated ICU patients; it is estimated to cost the US healthcare system $6B-20B annually.

COVID-19 patients requiring respiratory support are unable to communicate through conventional methods; and, medical staff in close proximity have an increased likelihood of contagion. A remote communication solution is needed to safeguard hospital workforces.

EyeFree Assisting Communication Ltd. is a pioneer of medical technology, specializing in innovative communication solutions that address unmet healthcare needs. We implement disruptive AI-technologies that connect people and bridge information barriers, facilitating better medical care and decision-making.

Our eye-tracking wearable and smart platforms empower communication between patients who cannot speak, their families, and medical teams.

EyeFree’s cutting-edge medical innovations are the first of their kind for acute and home care settings:

1. EyeControl-Med is a communication solution for healthcare facilities, enabling remote connectivity between the patient’s headset, nurse work station, and loved ones from afar. It aims to drive improved clinical outcomes via real-time analytics, and revolutionize the industry standard for medical communication.
2. EyeControl–Home is a comprehensive communication solution for patients transitioning from medical facilities to remote home care and other Locked-in patients, who cannot speak. It improves quality of life by providing round-the-clock connectivity and freedom of expression.

This project is focused on robust technological developments that will expedite EyeFree’s entry to the medical facilities market (EyeControl-Med). Short-term demand in this segment is growing; the unmet need for ICU communication already existed, and has been further exasperated by an influx of ventilation caused by the Coronavirus. There are no comprehensive solutions on the market; and, that places EyeControl-Med at the forefront, as an immediate and effective technology, facilitating easy and safe communication between patients, medical staff, caregivers, and families, and leading to higher quality care. Once this niche market has been consolidated, we will boost the market entry and be known as the global communication platform for both ventilated and Locked-in patients.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

The past two years were riddled with the ever-present ebb and flow of the COVID-19 pandemic; regardless, our company continued to thrive, adjusting to dynamic uncertainty and benefiting from heightened awareness of the need for our medical facility communication solution.

This was a period of intense R&D; our highly committed team worked tirelessly to build EyeControl-Med for bi-directional communication in medical facilities, which is listed for commercial use by the
FDA and CE, and includes enhanced nurse dashboard capabilities. Product uptake was swift and demand was high as clinical trials commenced in the US, European, and Israeli hospitals. The device continues to evolve as we learn more about market needs and investigate its efficacy in reducing Delirium.

The Beilinson Hospital clinical trial, successfully concluded its first phase with 15 patients, who were perceived to be more orientated and cooperative when using EyeControl-Med. This resulted in a TV report with testimonials by medical staff and patients; additionally, a joint peer-reviewed research article was written by the department head. Beilinson’s phase two trial commenced in February 2022, and includes a comparison group.

This activity spurred receipt of Clalit Health Fund codes (MAKAT), which are facilitating commercial purchase of our solution by institutions affiliated with Israel’s largest HMO. We also achieved the Israeli regulatory AMAR.

To further hone product development and formulate our go-to-market, we initiated in-depth research targeting stakeholders, who shared crucial information about the need for improved communication with ventilated patients and better detection and management of ICU Delirium.

The company received international recognition:

* Winners of the Genesis Prize – Start-up Nation Central’s COVID-19 solutions competition
* Published in a Harvard Business School case study
* Featured in Forbes Israel ‘Small Giants’
* EyeControl’s CEO winning Peres Heritage Initiative, being selected as Israel’s only European Innovation Council Ambassador, and joining the 8400 Healthcare Network
* Company winning top design in two European Product Design Awards categories

The company continues to plan and execute international medical facility trials and pilots. These have resulted in encouraging testimonials from medical staff, patients, and their families:

“Due to COVID-19, there are no family visits to the ward. One patient told me that not having his wife with him is the most difficult part of his rehabilitation. EyeControl-Med facilitates family involvement in the care plan; when this patient heard recorded messages from his wife, he was motivated and showed tremendous functional progress.”

Additional regulatory milestones include achieving ISO 27001 and 27799 and HIPAA/GDPR compliance.

**Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)**

EyeFree presented at the 2021 and 2022 American Delirium Society conferences, which resulted in increased product awareness and multiple follow-ups with physicians and industry KOLs. This, along
with extensive stakeholder analysis, indicates high market demand for an ICU communication solution with Delirium management tools.

The project’s impact is most clearly demonstrated through its use cases; our communication solution enhances patient engagement and emotional wellbeing, and improves treatment accuracy. Remote connectivity also ensures safety:

M was admitted to an ICU COVID-19 ward and used EyeControl-Med while ventilated and isolated:

M: “The most amazing thing about EyeControl-Med is that when you awake from anaesthesia, YOU CAN CONTROL SOMETHING. Not everyone does whatever they want to you. It gave me hope and motivation to get better.”
Wife: “Enabling family and friends to record messages allowed them to feel involved in a safe way and assisted M a lot. He was very excited and emotional to hear their voices after not seeing them for almost two months.”

Y is sedated and isolated as he recovers from extensive burns. His loved ones are using EyeControl-Med to maintain contact and keep him oriented. They initiated a joint public relations initiative to share their gratitude for the device, and are providing user testimonials.

D has been living with ALS for 20 years, and was recently hospitalized:
“I wish the EyeControl device was with me when I was hospitalized. That way I could communicate with the medical staff and environment as easily as I do at home with family and caregivers.”

E used the device for 30 hours; he successfully indicated pain and shared other needs with his medical team.