CLINICAL STUDY PROTOCOL

SAFETY AND FEASIBILITY OF THE EYECONTROL DEVICE (EYE-BASED COMMUNICATION DEVICE) FOR ALS PATIENTS

Sponsor: **Eyefree assistive communication Ltd.**

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Clinical Research Organization: **Israel**

Duet Medical
Consulting Ltd.

Protocol Number: CLN-001

Protocol Date: May 16th, 2016

Protocol Version 01

SPONSOR STATEMENT OF COMPLIANCE

The sponsor of this study, Eyefree assistive communication Ltd., manufacturer of the investigational device, legally represented by Or Retzkin, Chief Executive Officer, states the following:

- to assume responsibility related to the clinical investigation;
- that the treatments used to perform the clinical study are adequate for the device under investigation;
- that the clinical study, as for the responsibility of the manufacturer, will be conducted in conformity with:

Annex X of the Council Directive 93/42/EEC concerning medical devices, the Declaration of Helsinki, and the applicable parts of the ICH/GCP guidelines, the UNI EN ISO 14155:2011 standards, MEDDEV 2.7/3 and following revisions or other analogous internationally recognized standards, to be specified, and only after the approval, by the competent Ethics Committee, of the investigational protocol, the informed consent and the documentation required by the above mentioned standards;

Signature: _____ Date: _____

REVISION HISTORY

Title: Eyefree Clinical Study Protocol

Device name: EyeControl

Version number: 01, dated 16May2016

Previous version number: N/A

Summary of Changes

Rev.	Page/Section	Description of change	Reason for change
1	---	First issue	---

INVESTIGATOR AGREEMENT

Prior to participation in this study, a written approval must be obtained from the Ethics Committee, and copy should be provided to the Sponsor, Eyefree Ltd., or their authorized representatives, along with the Ethics Committee approved Informed Consent Form.

The Principal Investigator must also:

Conduct the study in accordance with the study protocol, the Investigator Agreement, Declaration of Helsinki, Good Clinical Practices, international harmonized standards for clinical investigation of medical devices (ISO 14155, Clinical investigation of medical devices for human subjects), the laws and regulations of the countries where the study will take place, indemnity/insurance requirements and any other applicable regulations.
Agree to participate in an appropriate training program as part of the study initiation.
Assure that informed consent is obtained from each subject prior to enrollment, using the Ethics Committee approved form.
Assure that the study is not commenced until Ethics Committee approval has been obtained.
Provide all required data and agree to source document verification of study data with subject's medical records.
Allow staff of the Sponsor and its authorized representatives, as well as representatives from regulatory agencies, to review, inspect and copy any documents pertaining to this clinical investigation.
Understand that this investigation, protocol, and trial results are confidential and agree not to disclose any such information to any person other than a representative of Study Sponsor or regulatory agency without the prior written consent of Study Sponsor.
The Principal Investigator (PI) may delegate one or more of the above functions to an associate or sub-investigator. However, the PI retains overall responsibility for proper conduct of the study, including obtaining and documenting subject informed consent, compliance with the study protocol, and the collection of all required data.

Principal Investigator Statement:

I the undersigned, have reviewed this protocol and agree to conduct this study in adherence to the study protocol, GCP compliance, Ethical principles set forth in the declaration of Helsinki and authority regulations for the protection of human subjects participating in clinical trials.

Print Name **Signature** **Date**

PROTOCOL SYNOPSIS

Sponsor:	Eyefree assistive communication Ltd, 31 Ma'ale ha-Tsofim St, Ramat Gan, Israel Tel: +972-526490093
Protocol title:	Safety and Feasibility of the EyeControl device (eye-based communication device) for ALS patients.
Protocol number:	CLN-001
Study Purpose/objective:	To demonstrate the safety and feasibility of the EyeControl device in healthy volunteers, and ALS patients in early stages.
Study phase:	First in Human – Proof of concept
The Device:	The EyeControl device is an eye movement-based communication device in the form of wearable glasses with connected infrared camera that tracks the pupil and translates blinks and movements into commands. The camera communicates with a small computer called "Odroid" via USB. The "Odroid" translates the user's eyes movements into commands and can transmit the commands to three outputs: an earphone, a speaker and a smartphone via Bluetooth. The smartphone runs an application which enables the patient to communicate. An algorithm is used to allow for a quick auto- calibration of the device, so that the patient does not need assistance in order to do so. The device is currently based on a 3-steps solution: 1. ***Alert sound*** **-** calling for assistance. 2. ***Predefined sentences*** **-** such as "I'm hot", "my hand hurts" etc. 3. ***Composing sentences*** - (similar to SMS).
Study Design:	The study will be conducted in 2 enrollment stages. Initially, up to 10 healthy volunteers will be recruited and go through a short training for the use of the device followed by actual controlled use of several hours. In the second stage, up to 5 early stage ALS patients will be recruited and go through the same steps of training and device use. Any feedback or safety concerns raised during the first stage of recruitment of healthy volunteers will be considered before moving forward to the second group of ALS patients.

	The overall duration of participation for each subject will be up to 3 weeks. The place: Rambam health care campus. Each subject will go through a series of 4 meetings (2 meetings per week), and up to 3 hours per meeting. Meetings will be accompanied by company representatives and/or trained study team. Procedure will consist of an introduction and demonstration of the device features followed by actual use of the device by each subject (including control of gestures, use of menus, activation of pre-defined modes and writing full sentences). User feedback/ questionnaire will be completed after the 2nd and 4th session. The user's ability to perform each of the pre-defined tasks, will be measured in each session. In addition, success rate and measured time for completion of pre-defined tasks, collected after the 4th session, will be compared to the success rate and times collected in previous sessions.
Patient Population:	The subject population is divided into two groups: 1. **Healthy volunteers-** up to 10 subjects 2. **Early stage ALS patients** – up to 5 early stage ALS patients that can still communicate orally.
No. of Subjects/Sites:	**1 site -** Rambam Health Care Campus
Study duration:	Screening: one day. Procedure: 4 sessions of about 2.5-3 hours for each participant, performed over 2 weeks' time. Follow up: none.
Endpoints	**Primary endpoint:** Assessment of the feasibility of the use of EyeControl device, measured by: • **Ability to perform device features**: o Controlling the EyeControl's Joystick [measured by successful correct performance of over 70% of the gestures]. o Controlling the Rest mode and Siren mode [measured by successful correct performance of over 70% of the gestures]. o Testing the logic of the pre-defined sentences; a. ability to say 10 pre-defined sentences [over 80% success rate];

	b. Time - perform each sentence in less than 2 minutes – [over 80% success rate for all sentences]. ○ Controlling the application and Free text features –words per minute, using the application Alphabet • Required Training time/ learning curve of; ○ pre-defined device features [selected results after the 4the meeting compared with results results of previous meetings] ○ free speech [selected results after the 4th meeting compared with results after the 3rd meeting] • Usability feedback (user experience) questionnaire completed by each user. **Secondary endpoints:** Clinical Safety assessment, measured by number of device related adverse events.
Inclusion criteria	1. Subjects 18 to 65 years old 2. Subject with understandable speaking communication 3. Subject fluent in Hebrew (speech and writing skills) Additional inclusion criteria for Stage 2 of the study: 4. Subjects with early stage ALS diagnosis – whose speech capability is unaffected
Exclusion criteria	1. Subjects with glasses or contact lenses 2. Subjects with eye conditions such as Ptosis, Strabismus And Crossed Eyes 3. Medical history of epilepsy 4. Subjects who according to investigator's judgement, are unable to comply with the requirements of this protocol 5. Pregnant or lactating women

Table of Content

1 INTRODUCTION

1.1 BACKGROUND-ALS

Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gehrig's disease) is an adult-onset, fatal neurodegenerative disease. The disease is characterized by degeneration of motor neurons in the primary motor cortex, brainstem and spinal cord, leading to progressive weakness and atrophy of voluntary skeletal muscles. It is recognized as a multi-system disorder. In about a quarter of ALS patients, the disease is associated with subtle cognitive deficits.

The majority of patients die within 3-5 years from disease onset, usually from respiratory failure. Only about 10% of the patients survive for more than a decade.

ALS exhibits phenotypic heterogeneity. Most ALS cases are sporadic, with unknown etiology, whereas 10-15% are familial with clear genetic background – both types are clinically indistinguishable and share several pathogenetic pathways. The incidence of sporadic ALS is 1-2 per 100,000 person-years with an estimated lifetime risk of 1 in 400. The mean age at onset for sporadic ALS is 58-63.

There is no cure for ALS. Riluzole is the only FDA approved drug – which appears to prolong ALS survival by 3 months on average.

Almost all people with amyotrophic lateral sclerosis (ALS) experience a motor speech disorder, such as dysarthria, as the disease progresses. At some point, 80 to 95% of people with ALS are unable to meet their daily communication needs using natural speech[1].

1.2 OTHER "LOCKED IN"

Neurodegenerative and cerebrovascular diseases often lead to deterioration of motor function in patients. These diseases impair traffic capacity, but in some cases they do not harm the mind and cognitive function

These diseases lead to involuntary loss of ability to exercise the muscles of the limbs and the ability to speak, preserving eye movement function. Since in most cases the patient's cognitive function is not impaired, but given their lack of ability to exercise the muscles, they lose their ability to interact with their environment. These patients are defined as "Locked In" as they are imprisoned in their own bodies.

Among these diseases and injuries are stroke of the posterior circulation, MJD (Machado-Joseph disease) and other degenerative diseases such as MG, MS, some of the muscular dystrophies and Parkinson's disease in some cases. Events such as traffic accidents and other accidents also bring patients to such situation, making them arget population for our proposed solution. Each segment of the target population, as a standalone, is relatively small, and therefore there are no available appropriate

[1] **Communication Support for People with ALS**- David Beukelman, Susan Fager, and Amy Nordness

solutions. However, looking at all patients within the different categories above as a whole, there is a large common denominator and significant demand which our generic systems can address.

1.3 THE SOLUTION

Today, the major leading company that controls the communication devices market is the Swedish company "Tobii"."Tobii" offers a "high-end" technology to the clients, with a variety of products for the fields of gaming and assistive technology.

Tobii's Assistive technology - Tobii products are designed to allow control over the computer via Eye tracker.

The company offers several products: The EyeMobile and the PCEye GO, allowing controlling the computer using the eyes, but they restrict movement - every movement requires re-calibration by another (healthy) person (an assistant) and the device must be connected to the computer and to the power supply. This is an expensive technology that requires learning, training and maintenance, as well as third-party assistance per session.

Two other devices that Tobii offers are the I12 and I5. These devices enable communication via tablets, with a 24-hour battery. These two products enable mobility on the one hand but on the other hand all other faults such as the need for re-calibration, high price and the limitation of "environmental restrictions"(Inside the shower, at bed, etc.).These devices costs even more and can sum up to 14,000$ per unit. The "low cost" mobile solution that Tobii offers is a tablet based on Microsoft hardware with the Tobii software installed on it. This product costs about $4,000 and still has the same problems such as the need of calibration by third party and the dependent in the screen.

Today, Tobii as a huge company in the field of Eye Tracking offers low cost devices for Eye Tracking in the field of gaming although when coming to the field of assistive communication devices field they use "high end" hardware and a screen as hardware and hours of developing to reach Tobii specific software which is estimated around $2,000-3,000 per unit (including Tobii's eyetracking camera). This situation takes out automatically many clients who can't afford buying those products (most of the clients) and also doesn’t solve the necessary to communicate anywhere, anytime

The EyeControl solution is a set of glasses which are connected to an infrared camera detecting the movement of the pupil and blinks.

The camera connects to a small computer, "Odroid", which is connected to a speaker. The computer translates the pupil's movements and gives an audible sound environment. In addition, by broadcasting through Bluetooth, the patient can use various applications on their smart phone to communicate with others. An outstanding benefit is the fact that the calibration of the pupils is automatic process based on an algorithm without the need for outside aid.

The Product is based on an innovative technology that enables the eye to function as a joystick. The product is innovative (being **portable**), significantly cheaper than other products on the market, comfortable (automatic calibration and independence), Mobile (glasses and a tiny small computer), and allows the patient to communicate with the environment anywhere and anytime. **This is a revolution for patients and their surroundings – the possibility to return to social activity regaining independence and the ability to communicate with the environment.**

The solution developed consists of 3 levels: a call for help, choosing from pre-defined phrases (English and Hebrew) and composing sentences using a virtual board with the alphabet encoding. All these can be played over the loudspeaker while the user is able to hear with headset every letter/word/sentence before he chooses\ it, so that the user doesn't need the screen in front of him.

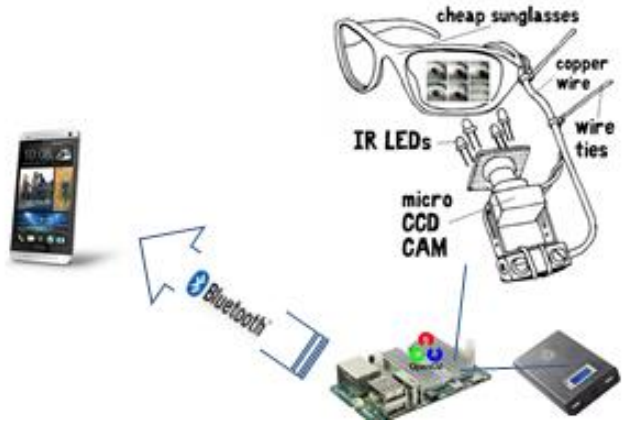

Chart 1: The product

1.4 STUDY RATIONALE

As discussed above, validity of this concept of eye tracking devices used for “locked-in” patients, such as ALS patients, have been proved and is vastly used on the market today. The EyeControl device is indicated for the same group of patients, but due to its size and ease of mobility will allow patients the possibility to return to social activity regaining independence and the ability to communicate with the environment.

1.5 STUDY JUSTIFICATION

The justification for the experiment is based on the fact that the group of people tested are cognitive in the same status of the ALS patients that will be the final user of the product. Moreover, the product is being tested on an early stage ALS patients.

In order to minimize possible risks prior to clinical application, Eyefree Ltd. designed and performed verification and validation tests for the EyeControl device. The testing

included aspects of the device's clinical safety, production and software and quality assurance.

1.6 STUDY OBJECTIVES

To demonstrate the safety and feasibility of the EyeControl device in healthy volunteers, and ALS patients in early stages.

1.7 STUDY ENDPOINTS

Primary endpoint:

Assessment of the feasibility of the use of EyeControl device, measured by:

- **Ability to perform device features**:
  - Controlling the EyeControl's Joystick [measured by successful correct performance of over 70% of the gestures].
  - Controlling the Rest mode and Siren mode [measured by successful correct performance of over 70% of the gestures].
  - Testing the logic of the pre-defined sentences;

    a. ability to say 10 pre-defined sentences [over 80% success rate];

    b. Time - perform each sentence in less than 2 minutes – [over 80% success rate for all sentences].

  - Controlling the application and Free text features –words per minute, using the application Alphabet
- **Required Training time/ learning curve of;**
  - pre-defined device features [selected results after the 4the meeting compared with results results of previous meetings]
  - free speech [selected results after the 4th meeting compared with results after the 3rd meeting]
- **Usability** feedback (user experience) questionnaire completed by each user.

Secondary endpoints:

Clinical Safety assessment, measured by number of device related adverse events.

2 STUDY DESIGN

This will be a single center, single arm, open label, prospective study.

The study will be conducted in 2 enrollment stages. Initially, up to 10 healthy volunteers will be recruited and go through a short training for the use of the device followed by actual controlled use of several hours. In the second stage, up to 5 early stage ALS patients will be recruited and go through the same steps of training and device use.

Any feedback or safety concerns raised during the first stage of recruitment of healthy volunteers will be considered before moving forward to the second group of ALS patients.

The overall duration of participation for each subject will be up to 3 weeks.

The place: Rambam health care campus.

Each subject will go through a series of 4 meetings (2 meetings per week), and up to 3 hours per meeting. Meeting will be accompanied by company representatives and/or trained study team for support and guidance in each session..

Procedure will consist of an introduction and demonstration of the device features followed by actual use of the device by each subject (including control of gestures, use of menus, activation of pre- defined modes and writing full sentences). User feedback/ questionnaire will be completed after the 2nd and 4th session.

The user's ability to perform each of the pre-defined tasks will be measured in each session. In addition, success rate and measured time for completion of pre-defined tasks, collected after the 4th session, will be compared to the success rate and times collected in previous sessions.

For detailed study procedures refer to section 4, as well as appendix A.

3 STUDY POPULATION

The patient population is divided into two groups:

1. **Healthy volunteers-** up to 10 subjects.
2. **Early stage ALS patients** – up to 5 early stage ALS patients that can still communicate orally.

3.1 INCLUSION CRITERIA

1. Subjects 18 to 65 years old
2. Subject with understandable speaking communication
3. Subject fluent in Hebrew (speech and writing skills)

Additional inclusion criteria for Stage 2 of the study:

4. Subjects with early stage ALS diagnosis – whose speech capability is unaffected.

3.2 EXCLUSION CRITERIA

1. Subjects with glasses or contact lenses
2. Subjects with eye conditions such as Ptosis, Strabismus And Crossed Eyes
3. Medical history of epilepsy
4. Subjects who according to investigator's judgement, are unable to comply with the requirements of this protocol
5. Pregnant or lactating women.

3.3 SUBJECT IDENTIFICATION

A unique identification number will be assigned when an individual subject is qualified for study enrollment (based on inclusion/exclusion criteria). All enrolled subjects will be identified by the 2 digit identification number as well as their initials.

3.4 ENROLLMENT POINT

A subject will be considered enrolled once the use of the EyeControl is initiated according to the Instructions for Use.

Subjects withdrawn prior to this point of enrollment will be considered screen failure, and the reason will be documented in the study logs.

3.5 REMOVAL, REPLACEMENT, OR EARLY WITHDRAWAL OF SUBJECTS FROM TREATMENT OR ASSESSMENTS

Subjects are free to discontinue their participation in the study at any time and without prejudice to further treatment. The investigator must withdraw any subject from the study if that subject requests to be withdrawn.

The subject's participation in this study may be discontinued due to the following reasons:

- Request of regulatory agency, or sponsor or primary care physician or investigator
- Subject withdrew consent
- AE
- Investigator decides that withdrawal from the study is in the best interest of the subject.

3.6 HANDLING OF WITHDRAWALS

If a subject is withdrawn from the study either at his or her request or at the investigator's discretion, every effort should be made to determine the reason.

The reason for study exit (including screen failure) will be documented on the applicable CRF from.

3.7 STUDY TERMINATION

Eyefree assistive communication Ltd., reserves the right to discontinue the study for administrative reasons at any time, such as, but not limited to a decision to discontinue further clinical investigation with the device, improper conduct of the study by the investigator, inability to obtain the number of subjects required by the protocol, etc. Reimbursements for reasonable expenses will be made if such an action is necessary.

A principal investigator, EC, or regulatory authority may suspend or prematurely terminate participation in a clinical investigation at the investigation sites for which they are responsible.

If suspicion of an unacceptable risk to subjects arises during the clinical investigation, or when so instructed by the EC or regulatory authorities, the sponsor shall suspend the clinical investigation while the risk is assessed. The sponsor shall terminate the clinical investigation if an unacceptable risk is confirmed.

Subjects that were already included to the study must be followed according to the clinical procedures, and all information obtained for these subjects shall be reported to sponsor on the appropriate CRF.

4 STUDY PROCEDURES

Schedule of events for this study are shown in Appendix A. No protocol related procedures should be performed before written informed consent is signed as required by local regulations (i.e. subject, legal guardian, independent physician, etc). Study related events and activities including specific instructions, procedures, concomitant medications, dispensing of study device, and descriptions of AEs should be recorded in the appropriate source documents and CRF.

The study duration for each subject participating in the study will be identical.

The study duration for each subject will be approximately 2 weeks, as follows:

Screening period: one day (could be same day as procedure)

Surgery/Prodecure day: 4 meetings (up to 3 hours each) which will take place over 2 weeks time.

4.1 SCREENING VISIT (VISIT 0)

The purpose as well as the risks and benefits of the procedures of the study will be fully explained to participating subjects. Those wishing to enroll in the study will sign a written informed consent prior to initiating any study related evaluations or procedures.

The following procedures should be done at the screening visit:

- Review inclusion and exclusion criteria
- Obtain medical history and demographic data
- Record prior and concomitant medications

4.2 VISIT 1 (PROCEDURE DAY/ MEETING #1)

First meeting

Subjects will be asked to arrive to the clinic. Meeting duration is expected to be up to 3 hours. Activities for the meeting are detailed hereafter:

1. **Intro to EyeControl** - explanation about the device, the components, the logic of the device etc.- *~30 min*
2. **Demonstration of the EyeControl -** demonstration of the device - *~30 min*
3. **Controlling the EyeControl's Joystick -** *~ 1 hour***.**

The user will be asked to use the logic of the joystick- the user will be asked to perform the eye gestures of: left, right, up, down and blink -**10 times for each gesture** (**total:50** gestures). A computer with a visual software feedback will be attached to the user in order to assess and present the user results. The eye movement will be recorded in this stage. Subject's face will not be recorded.

4. **The Logic of the pre-defined sentences -** ~ *1 hour.*

   The user will go through the menus with the guiding team to explore the options of the device and to get a feel of the device capabilities. In addition the user will be guided about the Siren mode and rest mode, and will be asked to independently turn on these modes.

5. Any adverse events will be recorded.

4.3 VISIT 2 (PROCEDURE DAY/ MEETING #2)

Second meeting – will be performed at the clinic on the same week as the 1st meeting occurred (2-3 days post 1st meeting). (Each meeting will take about 2.5 hours):

1. **Refreshing about controlling the EyeControl's Joystick-** ~ *1 hour.*

   The user will be asked to use the logic of the joystick - the user will be asked to perform the eye gestures of: left, right, up, down and blink -**10 times for each gesture** (**total: 50** gestures). A computer with a visual software feedback will be attached to the user in order to assess and present the user results. The eye movement will be recorded in this stage, without recording the subject's face. The user will also be asked to turn on the Siren and rest modes.

2. **Testing the logic of the pre-defined sentences** - ~ *1 hour*.

   The first 20 min of the meeting will be dedicated for a short re-training on the logic of the device and the pre- defined sentences. Once completed, the user will be asked to perform specific gestures to complete **10 pre-defined sentences**.

   The participant will also be asked to complete a usability and feedback questionnaire at the end of meeting #2.

3. Any adverse events will be recorded.

4.4 VISIT 3 (PROCEDURE DAY / MEETING #3)

Third meeting - to be performed 1 week after the 1st meeting.

Activities for the meeting are detailed hereafter:

1. **Learning about the application:** Reviewing the manuals of the application, the different options, the logic etc. - *~30 min*.
2. **Using the application (with guidance of instructor):** Writing free sentences, using the features of the application, calling for help, going to rest mode etc. - *~1 hour*.
3. **Using the full logic of the EyeControl:** *~30 min*

   The user will be asked to go through the menus and turn on the application, and compose full sentences using the system. *(The tests in this session will focus on the*

application features. The test will include also the pre-defined sentences and the idea is to show the learning curve when compared to the Second meeting of the pre- defined sentences). **The test will include: 5 pre-defined sentences, Opening the application and writing 2-3 Words.**

Using the Alpha Bet feature / free text: writing the alphabet without the screen. **Writing 2-3 Words-same words as in the application** *~1 hour*.

4. Any adverse events will be recorded.

4.5 VISIT 4 (PROCEDURE DAY / MEETING #4)

Fourth meeting – to be performed on the same week as meeting #3 (2-3 days later).

1. **Using the full logic of the EyeControl -***~1.5 hours*

   The user will be asked to go through the menus and turn on the application, and compose full sentences using the device. The user will also be asked to use the application in order to write free text. Finally the user will be asked to write words in the application comparing to the Alpha Bet mode. (The tests will focus on the application features and different than the first test. Now the test will include writing free text in the application. The test will also consist the pre-defined sentences and the idea is showing the learning curve from the last test)- **The test will include: 5 pre-defined sentences, Opening the application and writing 5 Words in the application, writing 5 words in the Alpha Bet mode.**

2. Final Questionnaire – The users will be asked to complete a usability and feedback questionnaire at the end of meeting #4 - *~1 hour*.
3. Any adverse events will be recorded.
4. Complete study exit form.

4.6 DEVIATIONS FROM STUDY PROTOCOL

Any deviations from the study protocol should be notified to the sponsor and documented on study deviation forms.

5 MEDICAL DEVICE DESCRIPTION

5.1 DEVICE INTENDED USE

Paralyzed people cannot interact with their environment, despite the cognitive competence, due to motor limitations. Existing communication devices on the market are expensive and cumbersome, and unfortunately most of these devices are not portable. Even if a patient can afford to purchase one of these products financially, he cannot use the device without the screen of a portable computer, so that these patients are left without many appropriate means of communication when they are in bed, on the move in a wheelchair, car, at a hospital, etc. This fact is truly limiting and isolating for the patients and they might even find themselves in a life-threatening situation without the ability to express this to those surrounding them.

The EyeControl device is a speech generating device based on eye-movement detection, used by patients with ALS (Lou Gehrig's Disease), and other "locked in" conditions for communicating with their loved ones and caregivers.

5.2 DEVICE DESCRIPTION

The EyeControl device is an eye-based communication device in the form of wearable glasses with connected infrared camera that tracks the pupil and translates blinks and movements into commands. The camera communicates with a small computer that transmits the eye movement into speaking/writing. For further details please refer to device investigator's brochure.

5.3 DEVICE OPERATIONS

5.3.1 General

The EyeControl device enables the following list of actions:

1. Calling for help.
2. Choosing from a variety of predefined sentences.
3. Free text speech - using the Android app.

- The user will navigate through the options and execute them using blinking and 4 pupil movements: up, down, right, left.
- Fully supported in English and Hebrew.

5.3.2 Installation & Calibration

The device arrives ready for activation. The user/caregiver should plug it in to a battery or an electrical outlet and wait until the "All set" sound is spoken through the speaker. The calibration process begins several seconds afterwards.

The user will hear "Calibration" in earphone.

Then he will hear "1", "2", "3" which are corresponding to three stages of calibration.

We recommend the following:

- After the "Calibration" – the user should <u>blink few times</u> to allow the camera spot the area of interest – when he will hear "1" he can stop blink.
- After "1" he can <u>look straight at the camera</u> – to allow the camera to spot the pupil – when he will hear "2" he ca stop look at the camera.
- After "2" he user can <u>move his eye randomly to all sides</u> – to allow the camera to understand the range of movement of the pupil. When the user hear the word "3" he can stop do that, and the calibration is actually over.

The whole calibration stage should take 5-10 seconds.

After calibration stage the user immediately gets to the main menu which is described in the next section.

There is no visual display for the device, but it can be described schematically in the following way:

	words									
levels	directions	questions	hygiene	family	in hospital	in bed	clothing	general	actions	feelings
0-9	left, right,..., forward	why, who,..., where	tissue, toilet,...	father,..., grandson	nurse,..., doctor	light,..,tv	pants,...,shirt	yes, no,..., more, less	give, take,..., sleep	happy,...,frustrated

Chart 2: Navigation schema

To navigate between the words options, a user needs to look left or right.

To make a selection of a specific word, for example “father” the user need to look few times left or right (the menu is cyclic) until he hear “family” in the earphone, then he need to look down in order to hear “Father”. If he wants to say “Father” in the speaker he needs to blink to confirm.

Next to the words menu (look left or right) there are more menus which allow the user to connect to the application or to be in rest mode or to change settings.

application	rest mode	settings		
		toggle earphone language	toggle speaker language	toggle gender

Chart 3: The menus schema

- To choose any option that you hear- A blink.
- An "I need your help!" siren – 3 blinks (each blink should be about 0.25 seconds long). All three blinks should be executed in 4 seconds (default x = 4, can be configured in configuration file). If for example the user is making:
  - Blink1, Right, Blink2, Blink3 – that will count as two blinks (blink2 and blink3) If he will make another blink 4 seconds after blink2, a siren will be played.
- Going out of Rest Mode:
  - Looking Down- Center- Down- Center- Down- Center in 4 seconds.
- Getting in to Rest Mode: via menu or by making a sequence of
  - Blink-Up-Blink-Up in 4 seconds

5.3.3 Top Menu

- The **Settings** menu includes the following options
  - Toggle earphone language – select the language you will hear on earphone
    - English or Hebrew (other languages will be available in the future)
  - Toggle speaker language – select the language you and others will hear on speaker
    - English or Hebrew (other languages will be available in the future)
  - Toggle gender – select the gender of the voice heard on earphone and speaker
    - Male or Female

- **Rest mode**- A mode in which the application does not respond to the eyes' movements of the user. This mode allows the user to rest or look in different directions without activating the system, for example, in the middle of a treatment. In order to switch back from Rest Mode to regular Activation Mode, the user must look down quickly 3 times (Down- Center- Down- Center- Down) in a 4 seconds time frame. Outside of this sequence of gestures, there is another sequence that allows the user to express distress (3 quick blinks). These are the only two gestures sequences that are activated during Rest Mode. A partial execution of these commands will not be effective after 4 seconds since the beginning of the sequence.
- **Application** - Choosing the Application option results in trying to connect the device via Bluetooth, to a smartphone that went through Pairing in advance. In the case that the connection attempt is successful, the device goes from playing pre-recorded words/siren or settings menu mode to a mode in which eye gestures are sent to the app and there they're converted to letters and free speech. To return to the regular mode in which the user hears the pre-recorded words through a headphone/speaker, the companion will close the app on the smartphone.

5.3.4 WORDS MENU

The words menu includes more than 100 pre-recorded words in English or Hebrew (Based on the settings menu choice). The user can browse through the words in a group by looking left or right. The user can get out of a group by looking up or to get in the group by looking down.

The user first hears the words through the headphone only, and in order to play this word through the speaker the user has to blink.

5.3.5 SWITCHING FROM THE WORDS TO OTHER MENUS

To switch from words menu to the other options, the user must look up few times until he hears “words”, only then he will be able to navigate to other options such as “application” or “rest mode” by looking left or right.

CALLING FOR HELP

Blinking 4 times at any stage of the execution will issue a call for help.

5.3.6 SOLVING INITIAL PROBLEMS

- In case the user cannot hear words through the headphone, check the connection to the device.
- In case the user blinks and no sound is produced through the speaker, check the connection to the device. Also check that the speaker's battery is not empty (a light in the speaker is on).
- In case that one of the above issues was not resolve solved, check that the device is on (a blue light and a red light are on in the device's box).

- Check that the battery isn't empty. Recharge it if needed. If the battery is intact and the device still does not function properly, turn the device off and then turn it on.

  In case turning the device off and on does not resolve the issue, make sure that the blue light is on inside the camera itself. If the issue is not resolved, please refer to the technical support section.

5.4 Manufacturing, Supply and Support of Device

The EyeControl device is manufactured by Eyefree assistive communication Ltd. (Ramat Gan, Israel).

The device is supplied packed in a box that will be brought by the company.

5.5 Distribution and Shipment

The EyeControl device will be distributed to the investigational site following completion of regulatory clearance, including approval by the site's EC and training of the interventional staff.

Shipment of the study devices will be performed by Eyefree or their agents.

5.6 Training

Each Investigator participating in the clinical trial and the associated clinical study staff will receive training on the clinical protocol, as well as the investigational device. Investigators will be trained on device characteristics; storage requirements; device application; device use; and warnings, precautions, and contraindications.

5.7 Accountability and Compliance of Investigational Product

Complete traceability records will be kept of all devices during the study. The device will be provided by Eyefree Ltd., bearing required labeling. Device number will be documented in subject medical records, CRF and in center log.

Each clinical investigator will be responsible for the safe storage with restricted access of the investigational materials in their possession, thereby preventing use of any materials by any persons not participating in the study.

After completion of the study, all unused devices must be returned in their original package to Eyefree Ltd.

All investigators will be responsible for using the products according to the instruction for use and protocol and maintaining product inventory and records.

5.8 Device failures, Malfunctions and Misuse

Investigators are instructed to report all possible device failures, malfunctions or misuse observed during the course of the trial (refer also to section 8, Device Deficiency). These incidents will be documented in the case report form provided and sent by fax or e-mail to the monitor within two working days.

5.9 Contra-indication

Only per exclusion criteria.

6 RISK BENEFIT ANALYSIS

The EyeControl device is designed according to international standards for medical devices. Compliance with these standards ensures that the device can be used safely in human beings. This study is intended to provide further data on the device safety and performance.

6.1 RISK MITIGATION MEASURES

Several mitigation measures were taken to minimize the possible risks;

6.1.1 Mechanical Tests

The device was tested in the SII in a radiation test in order the check that the Infra Red radiation of the device doesn't cause damage to the eye of the pupil.

The conclusions were that the device is safe in the "Infra Red" aspect. The Led light is classified as Exempt Group (For: Actinic UV, Near UV, Blue light, Blue light small source, Retinal thermal, Retinal thermal, weak visual stimulus, IR radiation, eye)

For detailed results refer to the device Investigator Brochure.

6.1.2 Software validation tests

A software validation was made by Med-Dev Design Ltd. The validation test included: ATP and ATR tests. The tests were successfully completed without any bugs or other unexpected results.

For detailed results refer to the device Investigator Brochure.

6.2 RISKS

1.**Infra-Red Radiation:** the cameras has 4 LEDs with 850 nm wave length- and the risk is that the waves transmitted will heat the eye and by that will cause damages to the user- **This risk was tested by the SII .**

2. **Electricity damages:** the hardware of the device is composed from a battery, Odroid U3 and a speaker which can all go through an electricity damage. All the products are off the shelf products, **bearing CE mark.**

3. **Parts falling apart:** The device is not a one product device yet- so pieces of the device can be split- this risk may cause damages in a very specific conditions. **– We are creating a custom made boxes (3D printer) for the battery and the additional hardware which shouldn't be exposed.**

4. **True Emergency situations –** In cases the user truly needs to call for help and the device doesn't work. **Our pilot involves only users who can communicate without any communication device.**

5. **Allergy to the device -** In case the user is has allergy to the device material (plastic, wires etc') in this case the patient will be switched.

Anticipated clinical risks to the participants, based on the above hazards may be (but not limited to); headache, nausea or dizziness caused by the multiple required eye-movements, local irritation due to allergy to device materials (glasses), burning sensation in the eyes.

6.3 BENEFITS

Based on compliance with standard requirements, the risk of occurrence of adverse events is not expected to be greater than the risk reported for other devices available in the market today. However, as the device is investigational, this study is intended to validate this. All adverse events reported will be recorded.

No direct benefit to the subject is expected in this study. Information gathered in this study will contribute to the development of the EyeControl solution which in the future may be more beneficial for the subjects with the same indication for treatment, when compared to the available solution on the market.

6.4 MINIMIZATION OF RISKS WITHIN THE STUDY

This study will be monitored to ensure (1) the identification, documentation and analysis of all AEs, and (2) compliance with the protocol, the terms of the participating IEC to protect the safety and rights of all subjects, and federal and local regulations. In addition, risks have been minimized through selection of investigators who are experienced in the surgical procedures included in this protocol.

7 SAFETY AND MEDICAL DEVICE VIGILANCE

All adverse events occurring during the study will be recorded on the appropriate case report form page by the investigator. The nature, severity and relation of the adverse event to the study device will be documented.

7.1 DEFINITIONS

7.1.1 Adverse Event (AE)

AE is defined as any untoward medical occurrence in a subject. This definition does not imply that there is a relationship between the adverse event and the device under investigation. An AE can therefore be any unintended sign, symptom, disease or injury or any untoward clinical signs (including an abnormal laboratory findings) in subjects, users or other persons whether or not related to the investigational medical device. The following should be reported as AE:

- Untoward medical conditions or signs or symptoms that were absent before starting study treatment.
- Untoward medical conditions or signs or symptoms present before starting study treatment and worsen (increase severity or frequency) after starting study treatment.
- Abnormal laboratory findings.

- Clinical signs or symptoms that require therapy.

7.1.2 Adverse Device Effect (ADE)

ADE is adverse event, related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device, the operation, or any malfunction of the investigational medical device, device failure or misuse, and any event that is a result of a user error.

7.1.3 Serious Adverse Events (SAE)

A SAE is an adverse event that:

- Led to a death,
- Led to a serious deterioration in the health of the subject that:
    - Resulted in a life-threatening illness or injury
    - Resulted in a permanent impairment of a body structure or a body function
    - Required in-patient hospitalization or prolongation of existing hospitalization
    - Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.
- Led to fetal distress, fetal death or a congenital abnormality or birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be **serious** when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Inpatient hospitalization or prolongation of existing hospitalization means that hospital inpatient admission and/or prolongation of hospital stay were required for treatment of AE, or that they occurred as a consequence of the event. Hospitalization for elective treatment of a pre-study condition that did not worsen while on study and hospitalizations for treatment of non-adverse events (e.g. cosmetic surgery or diagnostic procedure) are not considered serious adverse events.

Any new SAE that occurs after the study period and is considered to be related (possibly/probably) to the investigational product or study participation should be recorded and reported immediately.

7.1.4 Serious Adverse Device Effect (SADE)

A Serious Adverse Device Effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

7.1.5 Unanticipated Serious Adverse Device Effect (USADE)

USADE is defined as serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report or other study related documents.

Note: Anticipated adverse events expected (with relation to the device and/or procedure) are detailed in section 6.2.

7.2 ADVERSE EVENTS CLASSIFICATION

AEs reported by the subject or observed by the investigator will be individually listed on an adverse event form in the CRF as follows: the specific event or condition, whether the event was present pre-study, the dates and times of occurrence, duration, severity, relationship to study device, specific countermeasures, and outcome.

Note: Event which was present pre-study is not considered as an adverse event unless it has worsened since the enrollment to the study.

All AEs will be characterized by the following criteria:

- Intensity or Severity
- Relatedness
- Outcome
- Treatment or Action Taken

7.2.1 Intensity/Severity Definition

The intensity or severity of the AE will be characterized as follows:

Mild: Transient or mild discomfort; no limitation in activity; no medical intervention/therapy required.

Moderate: Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required.

Severe: Marked limitation in activity, some assistance usually required; medical intervention/therapy required, hospitalization possible.

7.2.2 Relationship

The investigator will document in his opinion the relationship of the AE to the investigational medical device using the criteria outlined in Table 1.

Table 1 Adverse Event Relationship Criteria

Relationship	Criteria
Unrelated	The subject was not treated by the investigational device. OR The temporal sequence of the AE onset relative to treatment by the investigational device is not reasonable. OR There is another obvious cause of the AE

Unlikely	The relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
Possible	The relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases were relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probable	The relationship with the use of the investigational device seems relevant and/or the event cannot reasonably explained by another cause, but additional information may be obtained.
Related	There is evidence of exposure to the investigational device. • The temporal sequence of the AE onset relative to use with the investigational device is reasonable. • The AE is more likely explained by the investigational device than by another cause. • The AE shows a pattern consistent with previous knowledge of the investigational device.

7.2.3 Outcome

The clinical outcome of the AE or SAE will be characterized as follows:

Death - The SAE CRF must be completed for this outcome

Recovered - The patient returned to baseline status

Ongoing - Patient did not recover and symptoms continue;

Recovered with sequelae - The patient has recovered but with clinical sequelae from the event

Unknown - The patient outcome is unknown

7.2.4 Treatment or Action taken

The treatment or action taken after the occurrence of an AE or SAE will be reported as:

Interventional Treatment - Surgical, percutaneous or other procedure

Medical Treatment - Medication dose reduction/interruption or discontinuation, or medication initiated for event

None - No action is taken

7.3 REPORTING REQUIREMENTS

7.3.1 Initial notification

If the investigator identifies a SAE, a SAE report form must be completed and sent by fax or email to Eyefree within 24 hours of the investigator's knowledge of the event. Also fax copies of hospital case reports (i.e., hospital progress notes, results of applicable diagnostic tests, lab results and biopsy results) should be sent as soon as they become available. Autopsy reports and other documents, as applicable, should be sent upon request.

Reports should be made to the following safety contact person:
Or Retzkin, CEO
Tel: +972-526490093
Email: orretzkin@gmail.com

The reporting should then be followed up by written notification within 5 days, using the Serious Adverse Event form in the study file.

Any fatal or life-threatening event should be reported immediately. These preliminary reports will be followed as soon as reasonably possible by detailed descriptions that will include a completed SAE form, copies of hospital case reports, autopsy reports, and other documents, when requested and applicable.

In accordance with European regulations, all investigators will be notified of the occurrence of serious unexpected AEs, if such AEs are associated with the use of the study device (i.e., if there is a reasonable possibility that the AE may have been caused by the device and are thus deemed significant new adverse effects or risks with respect to the investigational device).

If applicable, the investigator should also inform the representative of the appropriate local Ethics Committee, within 24 hours of investigator's awareness of the event. A copy of the report cover letter should be filed within the study file.

7.3.2 Follow- Up of SADE/USADEs

Follow-up of SADEs/ USADE that occur during the study will continue until their satisfactory resolution or stabilization.

If/ when supplementary information is available, a follow-up SAE Report Form must be completed by the site and faxed within 24 hours to Eyefree Ltd.

The contact information for follow up SAE reporting is the same as for initial SAE reports (see above section).

Once faxed, the SAE form and accompanying documentation should be placed in the SAE section of the investigator's file. If supplementary information on a SAE has to be sent, the SAE form has to be used marked as 'follow-up report'.

All other SAE/AEs will be followed for new information/resolution as possible, or may be defined as 'ongoing without further follow-up' by the Investigator and Sponsor's decision.

7.3.3 Notification to Authorities (CA/IECs)

Events will be reviewed to determine any reporting obligations to Competent Authorities as well as IECs. Reporting to Competent Authorities will occur within the timelines described as per local regulations.

In the event of a USADE, sponsor or designee will conduct and report the results of an evaluation to the Competent Authorities (as appropriate), reviewing IEC, and all participating investigators within 7 working days after sponsor first receives notice of the effect, unless the USADE indicates an imminent risk of death, serious injury, or serious illness and requires prompt remedial action, in which case reporting will occur within 2 days.

8 DEVICE DEFICIENCY

A Device deficiency is an inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling.

All investigational device deficiencies will be documented on the appropriate Device malfunction CRF and the device should be returned to the study sponsor for analysis, if possible. Instructions for returning the investigational device will be provided. Device deficiencies should also be documented in the subject's medical record.

Device deficiencies are not to be reported as AEs. However, if there is an AE that results from a device deficiency, that specific event would be recorded on the appropriate CRF.

9 STATISTICAL ANALYSIS PLAN

The planned sample size is considered adequate for this study. No formal sample size calculation was performed for this study, as the study was not expected to show statistical significance or statistical power.

10 ETHICS AND REGULATORY

10.1 INDEPENDENT ETHICS COMMITTEE (IEC) AND COMPETENT AUTHORITY (CA)

Prior to initiation of the study, the PI will submit the study protocol and amendments, sample Informed Consent Form (ICF), and any other documents that may be requested to the IEC for review and approval. The PI/Sponsor will request that the IEC and CA (if applicable) provide written approval of the study and will keep on file records of approval of all documents pertaining to this study. The PI will not begin the study until the protocol and ICF have been approved by the IEC and CA (if applicable). The PI must agree to make any required progress reports to the IEC and CA, as well as reports of SAEs, life-threatening conditions, or death.

10.2 ETHICAL CONDUCT OF THE STUDY

This study will be performed in accordance with the Declaration of Helsinki, the European Union's Medical Device Directive (93/42/EEC art.15) and local Member States transpositions. The study will be conducted in agreement with the guidelines for conducting a Clinical Investigation as outlined in the European Harmonized Standard, EN ISO 14155:2011(E), and in accordance with the principles of ICH GCP, and additional local guidelines.

The clinical investigation will not begin until all necessary approvals/favorable opinions are obtained from the appropriate IEC or regulatory authority, as appropriate. Should an IEC or regulatory authority impose any additional requirements, they will be followed.

Information regarding the study and study data will be made available via publication on clinicaltrials.gov.

10.3 SUBJECT INFORMATION AND CONSENT

Prior to screening for the study each subject will be informed in detail about the study device, and the nature of the clinical investigation with its risks and discomforts to be expected. The basic elements of informed consent as specified by ISO 14155:2011 and ICH-GCP will be followed. Written consent will be obtained from each subject to be involved in the clinical trial by using the IEC-approved Informed Consent Form (ICF) prior to the conduct of any study-related activity. Each subject will be given a copy of the written ICF. The subjects will also be instructed that they are free to withdraw their consent and discontinue their participation in the study at any time without prejudice. Each subject's chart will include the signed ICF for study participation. If new information becomes available that may affect a subject's decision to continue to take part in the study, this information will be discussed with the subject by the investigator and a new ICF version will be signed as needed. When the study treatment is completed and the CRF has been monitored, the ICF will be kept in the investigator's central study file for the required period of time. Regulatory authorities may check the existence of the signed ICF in this central study folder if not having done so during the study.

10.4 SUBJECT INSURANCE

The Sponsor has an insurance policy for the total duration of the study covering the subjects and investigators in respect of the risks involved in conducting this study according to this protocol. The insurance policy will be filed in the investigator's file or can be made available to the Investigator and to the IEC upon request.

10.5 PERSONAL DATA PROTECTION

The Sponsor complies with the principle of subject's right to protection against invasion of privacy. Throughout this trial, all data will be identified only by an identification number and subject initials. The data will be blinded in all data analyses. The subject must be informed and consent is required that authorized personnel of the Sponsor and/or designee (Study Monitor, Auditor, etc.) and relevant Health regulatory agency

will have direct access to personal medical data to assure a high quality standard of the study

10.6 Informing the General Practitioner

The Investigator will inform the subject's primary care physician of the subject's participation in the study, by sending a letter to the physician as required by the local regulations for the conduct of clinical trials.

11 QUALITY CONTROL AND QUALITY ASSURANCE

The study will be conducted according to GCP as outlined by ICH Topic E6 step 5 guidelines, and ISO 14155, Clinical investigation of medical devices for human subjects.

11.1 Data Monitoring

Monitoring of the study is the responsibility of the Sponsor and may be delegated to a CRO or a contract monitor. The study monitor will advise the Investigator regarding the practical conduct of the study and maintaining compliance with the protocol, GCP and all applicable regulatory requirements. Throughout the course of the study, the study monitor will oversee the conduct and the progress of the study by frequent contacts with the investigator, performed as defined within the study monitoring plan. This will include telephone calls and on-site visits. During the on-site visits, the CRF will be reviewed for completeness with corresponding source documents. As part of the data audit, source documents will be made available for review by the study monitor. The study monitor will also perform device accountability checks and may periodically request review of the investigator study file to ensure completeness of documentation in all respects of clinical study conduct.

Upon completion of the study, the study monitor will arrange for a final review of the study files after which the files should be secured for the appropriate time period. The investigator or appointed delegate will receive the study monitor during these on-site visits, cooperate in providing the documents for inspection, and respond to inquiries.

To ensure the rights, safety, and welfare of study subjects are being maintained, the monitor will maintain assurance that all study staff are trained on the study protocol and use of the study devices. If the monitor discovers that an investigator is not complying with the signed Investigator Agreement, the investigational plan, applicable laws, or any conditions of approval imposed by the reviewing IEC or Competent Authority, the monitor will report to the Sponsor and take such steps necessary to promptly secure compliance. If compliance cannot be secured, device shipments to the investigator may be discontinued and the investigator's participation in the investigation terminated. The monitor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

11.2 Study Documentation

Study documents will include the following:

- Signed ICFs
- Source documents (e.g., subject files, medical notes, study worksheets)
- Investigator copies of the CRFs and SAE reports
- Investigator site file + contents
- Investigator training materials, if applicable

Upon completion of the study, the study monitor will arrange for a final review of the study files after which the files should be secured for the appropriate time period.

12 STUDY ADMINISTRATION

12.1 PARTICIPATING CENTERS

Single site in Israel will participate in this study.

12.2 SELECTION OF CENTERS & INVESTIGATORS

The investigative site will meet the following selection criteria prior to inclusion in this study:

- Clinical research study experience and resources that demonstrate good compliance with study requirements and timely, complete documentation of subject follow-up.
- Sufficient subject volume to meet enrolment timeframe.
- Investigators who are certified surgeons experienced in the surgical procedures included in this protocol.

12.3 CLINICAL STUDY SUPPLIES

The Sponsor will be responsible for the supplying, administrating, inventory, and accountability of all clinical trial supplies, exercising accepted medical and pharmaceutical practices. An accurate and timely record of the disposition of all clinical supplies must be maintained. The supplies and inventory record must be made available for inspection upon request. Upon completion or termination of the study, the Investigator will keep the remaining clinical supplies along with a copy of the inventory record and a record of the clinical supplies returned. **Under no circumstances will the Investigator allow the study devices to be used other than as directed by this protocol.**

Clinical trial supplies include, however, not limited to: CRF, study worksheets, lab supplies and study device.

12.4 STUDY COMPLETION

This study is expected to end when all required subjects have been enrolled and the last subject has completed the study and the query resolution has been completed.

- Data and materials that are required before the study can be considered complete and/or terminated are:

- Laboratory findings, clinical data, and all special test results from screening through the end of the follow-up period
- CRF (including correction forms) properly completed by appropriate study personnel and electronically signed by the Investigator
- Completed Device Accountability Records
- Statement of outcome for each SAE reported
- Copies of protocol amendments and IRB/IEC as well as relevant health authority approval/notification (if applicable)

12.5 FINAL REPORT

A clinical study report will be developed by the Sponsor at completion of data analysis. This report will be a clinical and statistical integrated report, according to ISO 14155 guidelines.

12.6 RETENTION OF STUDY RECORDS

It is required that a copy of all records (e.g., informed consent documents, source documents, safety reports, study device dispensing record, etc.) which support case report forms for this study, be retained in the files of the responsible investigator for a period of time as defined per local regulations following notification by the sponsor that all investigations (not merely the investigator's portion) are completed, terminated and/or discontinued. If the principal investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. Eyefree Ltd. must be notified in writing of the name and address of the new custodian.

12.7 PUBLICATION POLICY

All information concerning this study that was not previously published is considered confidential information. This confidential information shall remain the sole property of Eyefree Ltd.; it shall not be disclosed to others without written consent of Eyefree Ltd. and shall not be used except in the performance of this study.

Any investigator involved with this study is obligated to provide the Sponsor with complete test results and all data derived from the study.

13 APPENDICES

Appendix A Study Activity Flow Chart

Visit / Procedures	Screening (Visit 0)	Procedure day #1	Procedure day #2	Procedure day #3	Procedure day #4
Informed Consent	+				
Eligibility Criteria	+				
Medical History	+				
General physical assessment	+				
Device use		+	+	+	+
User Questionnaire			+		+
Adverse Events		+	+	+	+

Each meeting will be conducted 3 days (±1 day) from the previous meeting.