**Spring Biomed Vision – Scope of Work**

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| **Revised by** | **Date** |
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**Introduction**

Retinal imaging analysis is routinely used for diagnosis and monitoring of most ocular and blinding diseases, including Glaucoma, AMD and Diabetes Retinopathy (DR) as well as most systemic cardiovascular diseases. However, Fluorescein Angiography (FA), the current means of detection and monitoring of various early-stage and other ocular conditions, requiring a higher-resolution imaging of the retinal capillaries, necessitates intravenous administration of the contrast agent fluorescein. Spring Vision is currently developing an innovative method of retinal photography using multi- spectral imaging technology (SPRING FAIR(, embedded in a proprietary

device, the RetinoSpect, that detects subtle, micron-scale changes in small (capillary) blood vessels, the level where all the body’s vascular diseases start. This technology allows ophthalmologists to better differentiate between healthy and diseased retinal blood vessels without the expensive, invasive, logistically complex and toxic side-effects of the fluorescein injection. Utilizing the information generated by the device, medical practitioners will be able to use the device for screening, identifying and monitoring ocular diseases at an earlier stage, significantly increasing the likelihood of successful treatment. In addition, the potential for using retinal imaging to diagnose brain and cardio-vascular systemic diseases has already been shown by many research groups in the world. Consequently, SPRING technology is well-suited for the early-stage diagnosis and screening even pre-symptomatic stages of a growing number of systemic diseases, currently detected only in later stages, and represents a major opportunity for the company. Thus, the technology will enable earlier treatment of the conditions even and provide prognosis estimates. Spring Vision, in collaboration with the renowned Sheba Medical

Center, collaborates with Tel Aviv University’s Eye Research Institute for the development of retinal-imaging-based advanced techniques for automated diagnostics for ocular and systemic diseases, and expects to leverage its technology and this relationship into becoming the global leader in this area.

Our vision is to introduce a solution that enables a fully automated capturing and analyzing device that enables hereinabove stated.

In this Scope of Work (SOW) we will describe **all** project aspects, from research to production and development of all the system capabilities, including clinical trials on animals and human groups.

**General Project Description**

1. System – HW
   1. Optic – in the optic section we include all system optics from optic axis analysis to lenses design, focus engines and controllers, and illumination path. Including materials, and production aspects.
      1. Optic research – subcontractor (Israel) under the following constrains:
         1. Acquiring 45 degrees from 3mm pupil diameter.
         2. Minimal distortion at the FOV edges.
         3. Wavelengths (illumination) from 365 to 940 clear path and supported materials.
         4. High transmittance materials
      2. Optic design – subcontractor (Israel)
         1. Lenses type and layout
         2. Physical focal mechanism and layout.
         3. Lenses mounting design – the design should consider mass production by non-expert workers (non-expert in optics).
         4. Camera mounting design – the design should consider mass production by non-expert workers (non-expert in optics).
         5. Optic tube – non reflectance, etc.
         6. Illumination axis design – see specifications at illumination section (next HW section).
      3. Optic prototyping – subcontractor (Israel)
         1. Open layout – in dark room on optic table – including acquiring test images of physical targets, fixing hidden assumptions and rejects upon failures within open layout.
            1. By the end of this stage the optic system is fixed in the manner of lenses type, working distances, materials, etc.
         2. Order parts.
         3. Prototype assembly
         4. Prototype testing – we may return to open layout in case of major failure.
      4. Focus HW control –
         1. HW controller –
            1. Stage 1 – of the shelf RT controller – GPIO usage is optional.
            2. Stage 2 – dedicated RT controller including control board design.
         2. Physical communication layer – UART – on-board GPIO optional.
      5. Optic production – subcontractor
         1. Production file – subcontractor (ISR) – the one that handled 1.1.1-1.1.4
         2. Optics system production – subcontractor (India)
            1. Will produce with full comply to the production file.
            2. Will manage internal QC while Spring will independently test the production quality.
            3. 30 Units production – TODO time periods
      6. Quality Control (QC) – TODO
   2. Illumination
      1. Illumination research –
         1. PoC animal blood vessels test
         2. PoC animal\human eyes
      2. Illumination design –
         1. Osram LEDs –
         2. Optics design – see 1.1.2 above
      3. Illumination prototyping -
         1. Osram prototyping –
         2. Optics prototyping –
            1. Open layout –
            2. Prototype assembly -
      4. Illumination production – TODO
      5. Illumination HW control –
         1. Stage 1: of the shelf controller – GPIO combination with PWM dedicated controller is optional.
         2. Stage 2: dedicated RT controller including control board design.
      6. QC – TODO.
   3. Fundus camera
      1. Design –
      2. Prototyping –
      3. Fundus camera assembly –
      4. Fundus camera production –
      5. Fundus camera QC –
   4. Automated acquiring system
      1. Research –
      2. Prototyping –
      3. Design –
      4. Assembly –
      5. Production –
      6. HW control –
      7. QC –
   5. Computing and Backup Units –
      1. Fundus camera computing unit –
      2. Automated acquiring system computing unit –
      3. Display computing unit and display –
      4. AI & deep learning platform – (local\remote)
      5. Data storage –
2. Algorithms –
   1. Blood vessels extraction –
   2. Blood leaks extraction –
   3. Oximetry measuring –
   4. Choroid texture extraction -
   5. Artery-vessel crossing detection and measuring –
   6. Indexes extraction – auto diseases detection
   7. Automated positioning –
   8. Auto focus & illumination –
3. System SW – Generally speaking we already have the SRD in build, here we’ll describe main SW activities depend of HW and personnel
   1. Fundus camera –
      1. Focus control –
         1. HW control – controller programming
         2. Auto Focus algorithm implementation
         3. Focal setting relative to illumination mode.
         4. QA
      2. Illumination control –
         1. HW control – controller programing
         2. Illumination auto-modes setting
         3. Auto calibration implementation
         4. QA
      3. Acquisition control –
         1. Auto image acquisition –
            1. All 5 acquisition modes separately
            2. All 5 acquisition modes continuously
            3. Auto acquisition image quality testing
         2. Manual image acquisition –
            1. Manual parameters settings – general setting see SRD
            2. Single image acquisition manually.
      4. Communication –
      5. Algorithms implementation-
         1. CUDA optimization
      6. GUI – GUI implementation.
         1. Consider advanced setting UI at tablet.
   2. Display Tablet –
      1. Communication –
         1. Communication to clinical systems
         2. Communication to acquiring unit
         3. Communication to storing server\cloud platform
         4. Communication to clinic\hospital DB configuration
         5. Clinical data transfer protocols implementation (security\privacy)
      2. Card reader\external input devices interface.
      3. GUI – see SRD definitions
      4. Image registration algorithm implementation at tablet platform.
   3. Storage server –
   4. Cloud server –
4. Trials & Clinical Trials –
5. Israel innovation authority –
6. Patents & IP –
7. Gant -