Tactiq
&
Applied Neurodiagnostics Ltd (ANL)

PLR60 Glaucoma Screening Ophthalmology Device Product Development

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1 Introduction

The International Glaucoma Association (IGA) says that in the UK, glaucoma can be found in around two per cent of the population over the age of 40. It also affects children and young adults, but is not so prevalent. Glaucoma is a disease affecting the optic nerve that has been called the 'sneak thief of sight' because it leads to the loss of sight over a prolonged period. Current tests for the disease are infrequent and can take up to an hour to perform and rely on the patient's subjective reaction to stimuli. ANL in conjunction with leading researchers, have developed a technique to stimulate the eye and objectively measure the pupils reaction. Each test takes two minutes to complete and enables an optician to determine the presence or absence of damage to the retina to assess the patient's risk of glaucoma. They have now developed this into a product called the Pupilmetrix ™ PLR60.

Tactiq played a major role in developing the electronics, software and user interface for the PLR60 and continues to support ANL.

Puplimetrix ™ PLR60

2 Tactiq Role in PLR60 Development

ANL, supported by it's sister company Applied Science Laboratories in Boston USA, have experience with eye tracking technology and had selected some existing bespoke electronics as part of the product platform. Part of Tactiq's role as a development partner was to take responsibility for developing the system electronics using a mix of bespoke and off-the-shelf technology to meet the time and budget constraints whilst ensuring the level of performance required. Tactiq was also responsible for developing the user interface software and the

operating software to tie together all of the sub-systems. Finally Tactiq's role encompassed support for the technical file, user manual and for EMC and Electrical Safety conformance to support ANL's successful application for the CE marking.

3 Development Process

3.1 Requirements

Firstly Tactiq led the clear documentation of the requirements which were captured in the requirements documents and agreed by all the stakeholders.

3.2 Risk Assessment

An early risk assessment was conducted to identify key product and project risks in order to plan to address and mitigate them. An initial validation and verification plan was developed.

3.3 Top Level Design

Next Tactiq produced the top level design to capture the overall system architecture and ensure all of the sub-systems were accounted for and integrated. This top level design was closely matched with the requirements and modifications made to both documents to ensure all the requirements could be met by the proposed design. An initial, costed, bill of materials was created and sources identified or all of the key components and sub-systems.

3.4 Implementation

Tactiq then developed the system electronics using a mix of existing bespoke electronics, an off-the-shelf processing platform and some new bespoke electronics.

ANL's industrial design team produced the user interface framework design and Tactiq then implemented this in software and advised on recommended changes. Tactiq then wrote additional application software to tie together all of the sub-systems and give the required functionality and performance.

A bench system was designed, built and tested to ensure the core functionality and the performance of the system could be achieved and modifications made where required.

Working closely with the industrial design team, the packaging layout was developed and frozen with consideration for performance, cooling, EMC and Electrical safety. The cabling was designed and prototypes built and debugged.

3.5 Validation

The validation and verification plan was updated, implemented and tracked against the requirements. This included performance testing, EMC, Electrical safety and environmental testing. Support was given for series production process development. ANL were then in the position to launch PLR60 device on the first global glaucoma day on 6th March 2008.

All of this was achieved from start to finish in less than 12 months.