QME
Qualified Medical Engineer

Aankondiging **Pleuni Kirch**

Openbare eindpresentatie

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Link to online presentation

Focus on user-centered design
of the Lumante Imaging System (LIS) for clinical application in bladder cancer diagnoses –

Towards the development of a new feature in LIS that incorporates the attenuation coefficient alongside OCT images

Ontwerpproject uitgevoerd bij: **Scinvivo**
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Scinvivo developed the Lumante Imaging System (LIS) to enable real-time differentiation of bladder wall structures during white light cystoscopy. Using optical coherence tomography (OCT) technology, LIS generates high-resolution, cross-sectional images of the bladder wall, which also contain optical property data. Research suggests the attenuation coefficient may help distinguish healthy- from tumorous tissue. Displaying this coefficient alongside OCT images could enhance diagnosis, but real-time in-vivo implementation has not been achieved. This QME project had two primary goals: integrating LIS into the clinical setting by focusing on a user-centered design and developing a new attenuation coefficient feature.

The first goal focused on user-centered LIS implementation during TURBT procedures by prioritizing patient and staff safety, data quality, ease of use, and clinical compatibility. Continuous user feedback led to iterative improvements in the base station, software, catheter, and clinical workflow. Bladder tissue from cystectomy patients revealed issues like unsafe data management, poor usability due to a missing pilot light, and fragile components during the ex-vivo clinical trial with the LIS – Alpha Design. The revealed issues were used as input to improve the LIS-Beta design. During the realization of the LIS – Beta Design, user observation from field studies, and user input led to understanding of the real-world environment of the clinical application of the LIS. The in-vivo clinical study protocol ignited adjustments to the LIS to improve the base station setup in the OR, the TURBT-procedure, and the data capturing process. At the end of the beta phase, the first in-vivo clinical trial was initiated, involving 15 patients undergoing TURBT. Optimizing procedural efficiency and user experience enabled the successful use of the LIS during a TURBT-procedure for the first two patients, marking a critical step toward Scinvivo's business goals, including CE/FDA certification, LIS adoption in urology, and high-quality OCT data for future development.

The second goal of this QME project was to develop towards a new feature that incorporates the attenuation coefficient in the LIS, alongside OCT-captures. The attenuation coefficient was required to be calculated accurately enough to support urologist in their decision making. Moreover, the feature required to present insightful information during a TURBT-procedure, in real-time. Consequently, two development steps were implied for the attenuation coefficient feature in the LIS. First, correction tables are required for each catheter and each base station of the PSF, roll-off, and dispersion. Second, the software of the LIS should be adapted to allow real-time correction of the OCT-data while it is being captured in the clinical setting. In this QME project correction tables were estimated for 54 catheters and one base station, which will be used for post-processing purposes of the first bladder tissue OCT-data the in-vivo clinical trial. Even though software adjustments for real-time OCT-data correction were found to be unfeasible in the LIS – Beta Design, the results of this QME project form a starting point for future development of the attenuation coefficient feature.

In conclusion, the recent inclusion of the first two patients in the first in-vivo clinical trial is a remarkable milestone in the user-centered design and implementation of the LIS. Moreover, further development of the attenuation coefficient feature is aimed to enhance the quality, ease of use, safety, and compatibility of the LIS during a TURBT-procedure. Based on the results of this QME-project, it is recommended that Scinvivo prioritizes the user's needs during progression of the LIS design and the companies' strategies. Because the implementation of the LIS in the intended clinical setting will be optimized, and the adoption of the LIS during bladder cancer diagnosis by urologists will be more likely to be successful. Consequently, Scinvivo will prove to be a valuable supplier to the urology industry.