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INFO SHEET

MODELS: FED AND MFED

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INFORMATION SHEET

COMPANY SUMMARY

DESCRIPTION

"Aston Medical Technology Ltd." (AMT Ltd.) is focused on medical technology and health monitoring through wearables and medical devices. Our mission is to design, develop, and market new, patented technologies in the non-invasive device field, filling a current need in everyday life, personalised medicine, and performance health status monitoring.

Much of our efforts have so far concentrated on the development of our flagship product: a wearable watch style bio-monitoring device featuring technology currently only available in bulky and immobile form factors for research or clinical application. This product monitors several unique and highly informative biomarkers, combined analysis of which can provide extensive information about the wearer's condition.

CURRENT TECHNOLOGY

FLAGSHIP PRODUCT

Currently, the FED-1 (figure 1) is the flagship prototype featuring an LDF monitor, thermometer, and accelerometer to produce effective real time blood flow monitoring while allowing for freedom of movement. These prototypes employ VCSEL lasers and are equivalent to conventional tabletop systems.

Figure 1: AMT Ltd. wearable LDF sensor from the back and front

In addition to the flagship FED-1, we also develop a line of prototype devices incorporating an autofluorescence channel. With all the previous features, this line adds the ability to record the relative metabolic rate through measurement of metabolic cofactors NADH and FAD. These variants are broken into two types: original version of these devices is the MFED-1, and the modernised MFED-2 version. The latter boasts a form factor similar to the FED-1 (figure 2).

Figure 2: FED-1 and MFED-2

UNDERLYING SCIENCE

LASER DOPPLER FLOWMETRY

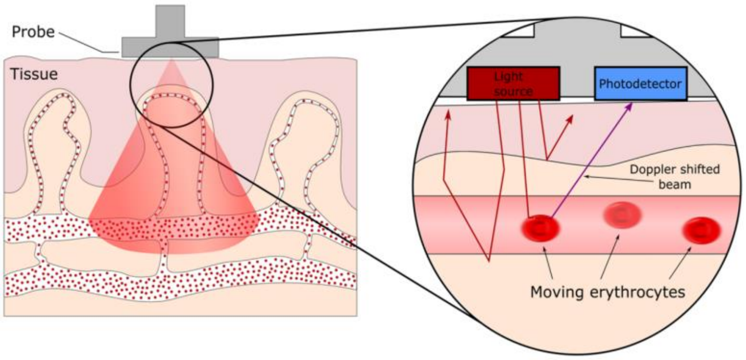

Figure 3: Basic principle of point LDF

Since its first commercialisation in the 1980's, Laser Doppler Flowmetry (LDF) became an object of wide interest in both research and industrial fields. This has been steadily expanded upon by various European laboratories and companies, constantly expanding the technology developed in this field. Such work has meant that at present, LDF based products come in a variety of options allowing for *in-vivo* measurements. Specifically, these come in two forms: the LDF imagers (including laser speckle imagers) and LDF monitors. While the former systems allow for visualisation of blood flow in the microcapillaries of the skin and living tissues at a depth of 1-2 mm, the latter systems feature single point measurements in living tissue (figure 3).

Such advancement of the LDF technique has led to it presenting itself as highly informative across a range of medical conditions as well as offering a method for general physiological health monitoring. To date, studies have investigated early indicators of vascular changes during diabetes [1], including very early microangiopathy stages [2], and detection of endothelial dysfunction in end-stage renal disease and risk

1 Zherebtsov, E. A., et al (2019) 'Novel wearable VCSEL-based sensors for multipoint measurements of blood perfusion', in Tuchin, V. V., Leahy, M. J., and Wang, R. K. (eds) Dynamics and Fluctuations in Biomedical Photonics XVI. SPIE, p. 6. doi: 10.1117/12.2509578.

2 Skrha J, Prázný M, Haas T, Kvasnicka J, Kalvodová B. Comparison of laser-Doppler flowmetry with biochemical indicators of endothelial dysfunction related to early microangiopathy in Type 1 diabetic patients. J Diabetes Complications. (2001);15(5):234-40.

of cardiovascular disease [3]. Furthermore, signal processing based on 1-D wavelet transform has shown that sensors can detect heartbeat rate as well as all other microcirculatory rhythmic oscillations by analysis of the small vessels' blood flow rhythms in the frequency domain [4] [5] (figure 4a).

Despite the evident potentials of various LDF techniques, they suffer from several limitations. The imager systems feature large physical dimensions and high-power consumption, preventing their potential applications from being rapid and easy to use. Additionally, many of these systems also require the use of fibre optics. The signal suffers a heavy impact caused by optical fibre movement leading to considerable noise [6].

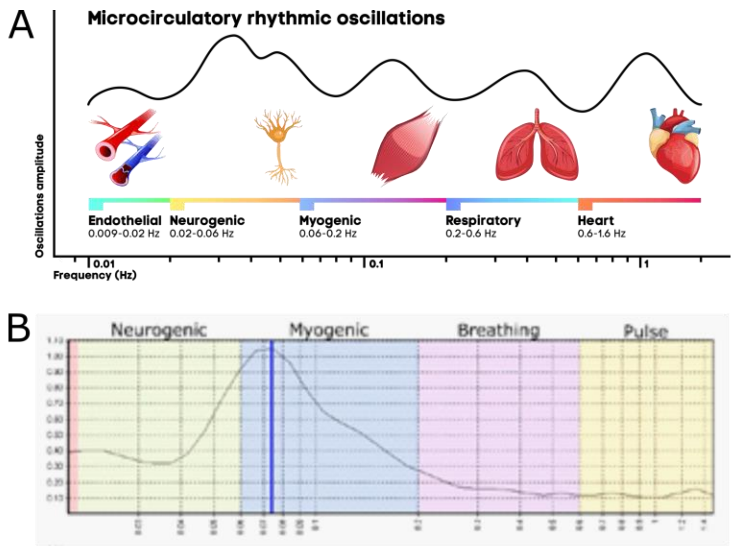

Figure 4: a) Example of microcirculatory rhythmic oscillations with indicated frequency ranges; b) Example of wavelet analysed microcirculatory rhythms from AMT software.

Regardless of the drawbacks, however, it is possible to remove the need for optical fibres in an LDF systems by using integrated diode lasers and detectors. Such systems have already been presented and have shown reduced effects of movement artefacts [7] [8]. This, of course, indicates that small-scale, wearable LDF sensors could remove the movement related drawbacks of LDF monitors, and compensate for the large and time-consuming nature of LDF imagers.

WORK USING AMT DEVICES

Through a series of volunteer-based assessments, AMT brand wearable LDF sensors have demonstrated a signal response comparable to that of conventional LDF monitors [9], with the software exhibiting capability of recording and analysing the microcirculatory rhythms even in wearable form (figure 4b).

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3 A. Kruger, J. Stewart, R. Sahityani, E. O'Riordan, C. Thompson, S. Adler, R. Garrick, P. Vallance, M.S. Goligorsky. Laser Doppler flowmetry detection of endothelial dysfunction in end-stage renal disease patients: Correlation with cardiovascular risk. Kidney International (2006);70,1,157–164

4 Skrha J, Prázný M, Haas T, Kvasnicka J, Kalvodová B. Comparison of laser-Doppler flowmetry with biochemical indicators of endothelial dysfunction related to early microangiopathy in Type 1 diabetic patients. J Diabetes Complications. (2001);15(5):234-40.

5 Zherebtsov, E., Sokolovski, S., Sidorov, V., Rafailov, I., Dunaev, A. and Rafailov, E. U. (2018) 'Novel wearable VCSEL-based blood perfusion sensor', Proceedings - International Conference Laser Optics 2018, ICLO 2018, 10063, p. 564. doi: 10.1109/LO.2018.8435409.

6 Newson T.P., Obeid A., Wolton R.S., Boggett D., Rolfe P. Laser Doppler velocimetry: The problem of fiber movement artefact. J. Biomed. Eng. 1987;9:169–172.

7 Iwasaki W., Nogami H., Higurashi E., Sawada R. Miniaturization of a laser Doppler blood flow sensor by system-inpackage technology: Fusion of an optical microelectromechanical system chip and integrated circuits. IEEJ Trans. Electr. Electron. Eng. (2010);5:137–142.

8 W. Iwasaki, H. Nogami, S. Takeuchi, M. Furue, E. Higurashi, and R. Sawada, "Detection of site-specific blood flow variation in humans during running by a wearable laser Doppler flowmeter," Sensors (Switzerland), vol. 15, no. 10, pp. 25507–25519, 2015.

9 Zherebtsov, E., Sokolovski, S., Sidorov, V., Rafailov, I., Dunaev, A. and Rafailov, E. U. (2018) 'Novel wearable VCSEL-based blood perfusion sensor', Proceedings - International Conference Laser Optics 2018, ICLO 2018, 10063, p. 564. doi: 10.1109/LO.2018.8435409.

Using these sensors has been further demonstrated as an effective avenue for monitoring health status by combining multiple simultaneous measurements on various areas of interest on the body (figure 5). By using a combination of four sensors in different arrangements (figure 5a and 5c) and by trialling stress tests such as local occlusion (figure 5b), sensitive readings of the peripheral microcirculatory system can be recorded. Furthermore, these readings represent a marked advantage over alternative methods due to the low signal disruption stemming from movement and highly portable nature [10] [11].

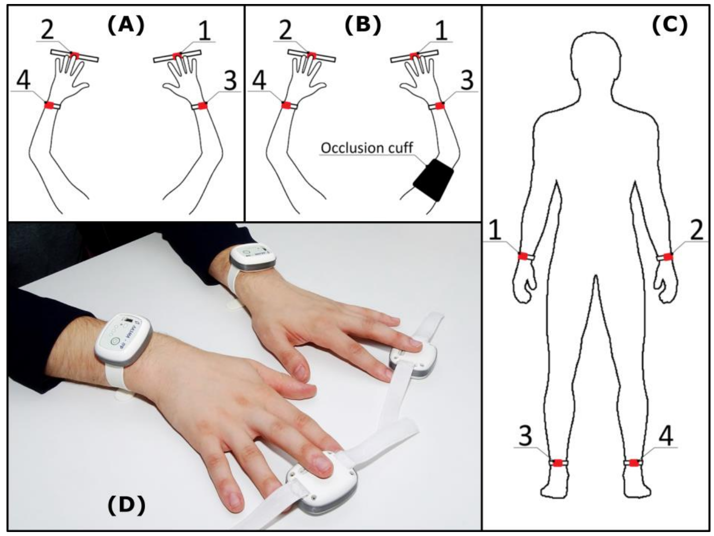

Figure 5: Multiple sensors arranged for simultaneous data acquisition. A) Experimental test setup 1 – on wrist and finger pad0s. B) Setup 1 with occlusion-based stress. C) Experimental test setup 2 – on wrists and ankles. D) Functioning setup 1.

The most recent publication featuring AMT technology was to conduct a pilot study into assessing the sensitivity of wearable LDF sensors in determining the effects of cigarette smoking on the blood microcirculation [12].

To progress our technology onto the next level, AMT has also sought to apply our devices to critically important areas of health research. Previous work into diabetes has demonstrated an increase in perfusion in patients with diabetes under basal conditions in connection with the effect of diabetic neuropathy on the blood flow. Thus, our investigation into type 2 diabetes has yielded some of our most promising data.

The current findings indicate that our devices are capable of picking up differences in the average perfusion between healthy volunteers of different age groups, healthy young volunteers and patients with Diabetes mellitus, and healthy volunteers of any age group and patients with Diabetes mellitus (figure 6).

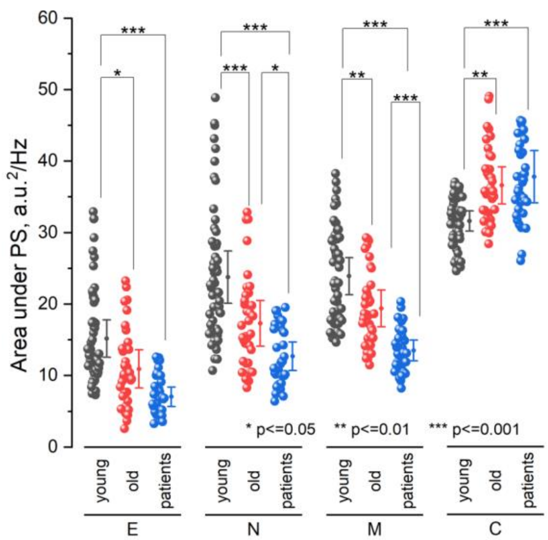

Figure 6: Analysis of blood flow oscillations measured in wrists of healthy controls (young and old) as well as patients with type 2 Diabetes.

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10 Skrha J, Prázný M, Haas T, Kvasnicka J, Kalvodová B. Comparison of laser-Doppler flowmetry with biochemical indicators of endothelial dysfunction related to early microangiopathy in Type 1 diabetic patients. J Diabetes Complications. (2001);15(5):234-40.

11 Loktionova, Y. I., et al. (2018) 'Pilot studies of age-related changes in blood perfusion in two different types of skin'. Proc. SPIE 11065, Saratov Fall Meeting 2018: Optical and Nano-Technologies for Biology and Medicine, 110650S; doi: 10.1117/12.2522968

12 Saha, M. et al. (2020) 'Wearable Laser Doppler Flowmetry Sensor: A Feasibility Study with Smoker and Non-Smoker Volunteers', Biosensors, 10(201), pp. 1–10. doi: 10.3390/bios10120201.