*Annex 2*

**Description of the Object**

**SUMMARY OF THE INVENTION:**

Auction object: consists of know-how obtained from ERDF project no. 1.1.1.1/16/A/065 within, together with the initial version of the prototype measuring device for patient examinations, and the prototype of the patient measuring device developed in the project KC-PI-2020/50. Knowhow includes a method for visualization of oxygen saturation in the skin using multispectral diffuses reflectance images obtained under the illumination of narrowband spectra of visible light.

The description of knowhow includes the mathematical model of light transport in the skin, devices application software description and code in Matlab environment, laboratory validations protocol, physiological model experiment protocol, patient examination protocol, patient enrollment and therapy management guidelines, and prototype drawings.

More detailed information about the invention can be provided by the project manager: Andris Grabovskis (andris.grabovskis@lu.lv) and the initial commercialization strategy can be commented by project commercialization expert Didzis Rūtītis (didzisr@gmail.com).

• Price range: according to the applicant's offer.

• Keywords: multispectral imaging, multispectral imaging, skins diagnostics, skin oxygen saturation.

• The research was carried out by: Department of Atomic Physics and Spectroscopy of the University of Latvia institute. Patient examinations were carried out at the Toxicology and Sepsis Clinic of Riga East Clinical University Hospital.

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**SUMMARY:**

In recent years, more and more evidence has been obtained that human skin the microcirculation may reflect various aspects of neuroimmune-endocrine functions and can serve as an early marker for various pathological conditions, such as diabetes, systemic rheumatic diseases, neuropathy and sepsis. Blood supply disorders cause skin oxygen saturation disorders, which is one of for the most important vital parameters in the assessment of tissue health. As a result of blood supply disturbances, blood accumulates in the tissues, causing skin spots, characterized by a purple or reddish color covering the periphery of the body the skin. The classification and quantification of mottling today is subjective, based on visual inspection by a clinical expert.

The proposed method for non-invasive assessment of skin circulation is based on the four visible image analysis of narrowband spectral bands (540, 560, 580 and 680nm) using diffuse reflection model, resulting in a spatial skin oxygen saturation distribution map. In addition, infrared thermal imaging is also used analysis for evaluating skin temperature distribution that reflects the skin mirocirculation heterogeneity, which is an important clinical parameter of septic shock for diagnostics and dynamic monitoring of the patient's condition. The technology has been implemented portable device in prototype, with which it is possible to perform real-time patient examinations in the intensive care unit at the patient's bedside.

**PRODUCT OF THE INVENTION:** technology and methodology for non-invasive diagnosis of early skin blood circulation lesions.

1. Operating principle of the patient examination measuring device prototype.

The portable device is designed for a quick and non-invasive application of the patient's skin for calculation of oxygen saturation and temperature distribution in real time using analysis of narrow-band and infrared heat radiation images of the visible spectrum.

Device consists of the following main components: 1) Circular LED skin lighting module with polarizer; 2) Spectral image registration module – 4 camera cluster with optical filters and light polarizers; 3) Numerical calculation module (mini-computer, touch screen); 4) Power supply system (batteries and UPS power unit); thermal imaging camera.

A wide range of green spectrum (567nm) is used to illuminate the skin LED light source. Registration of multispectral skin images is performed using 4 video cameras (Ximea 2.3 Mpix, CMOS monochrome) placed side by side close by. For obtaining spectral images, camera lenses have narrowband optical filters (540, 560, 580 and 680nm). The LEDs are perpendicular to the light source and the cameras placed polarizers to prevent glare from direct reflected light. Thermal radiation camera (FLIR Boson, 640x512 px.) serves for heat radiation distribution for registration, calculation module (mini-computer, touch screen); 4) Power supply system (batteries and UPS power unit); thermal imaging camera.

Image processing is performed using a mini-computer with Microsoft Windows 10 system, in which the Matlab computer program interface is implemented. All functions of patient data input and visualization of skin parameters are provided with a touch screen help. Stable operation of light source, video cameras and mini-computer is provided by UPS power system connected to 8 LI-ion batteries (provides approx. 45 min active work).

2. Algorithm for obtaining skin parameters.

The following algorithmic sequence is used to obtain parametric images of the skin: Since the 4 cameras are at a slight angle to each other, all images are slightly distorted. First, the spectral images are compensated using geometric transformations algorithm. The 540 nm, 560 nm, and 580 nm images are then normalized by dividing by 680 nm image. To obtain uniform illumination, spectral images are divided by white for standard images. Next, the data is reduced using k-means segmentation algorithm. Finally, in each cluster of multispectral images, calculated skin hemoglobin and oxyhemoglobin concentration using modified Beer-Lambert model, as well as skin oxygen saturation and distribution. Skin diagnostic parameter calculations are performed using lights diffuse reflection (modified Lambert-Beer) model.

Skin parametric images are calculated as spatial distribution maps. 1) Blood the concentration in the skin is calculated as follows: Mblood = Chb02 + Chb ; 2) The skin is saturated with oxygen

calculated as: MSaO = Chb02/(Chb02 + Chb).

3. Computer program interface.

Data processing is performed using a specially developed Matlab image. It consists of three main modules: 1) patient data input, 2) multispectral image preview/recording and 3) visualization of parametric maps. When you turn on the device, after a few minutes the Matlab environment starts and the main window of the computer program (Main windows). Next, there is an option to create a new series of measurements for the patient for whom first personal data (patient card) must be entered. A series of measurements is assigned identification number and date. LED turns on in video preview mode illuminator, and the device should be placed in contact with the examined skin area. There is an opportunity to perform measurement in multispectral or thermography mode. Multiple measurements can be taken within the specific measurement series. Once the measurements have been taken, they can be viewed as a measurement in the list. For each measurement, you can view: 1) a black and white image of the skin; 2) skin oxygenation saturation SaO2 distribution map, its minimum, maximum and average weighted value, and standard deviation; 3) skin blood perfusion; 4) thermal image. By touching for a touch-sensitive screen, it is possible to read the numerical value of a parameter for a particular skin in the zone.

**INDUSTRY:** The invention relates primarily to technology and devices for visualization of early microcirculation damage and tissue oxygen utilization and for quantitative parameterization. The invention is intended for intensive use for early diagnosis and condition monitoring of therapy patients.

**OBJECT AND ESSENTIAL OF THE INVENTION:** The object of the invention is to substantially improve diagnosis of septic shock, speeding up the initiation of therapy and providing critical

management of patient therapy in vasopressor and fluid infusion therapy.

Disadvantages of other equivalent devices:

a) invasive application (PiCCO - Göttinge)

Common features with other methods and devices:

(a) Spectral imaging (Hypermed)

**INTELLECTUAL PROPERTY PROTECTION:** Knowhow includes a detailed description of spectral image processing algorithms and processes, including software code.

**ADDITIONAL INFORMATION:** N/A

**INTELLECTUAL PROPERTY DOCUMENTATION** includes technical documentation, schemes, drawings, program codes, methods of use guidelines and protocols.