A Short Description of the SCN4ALL System

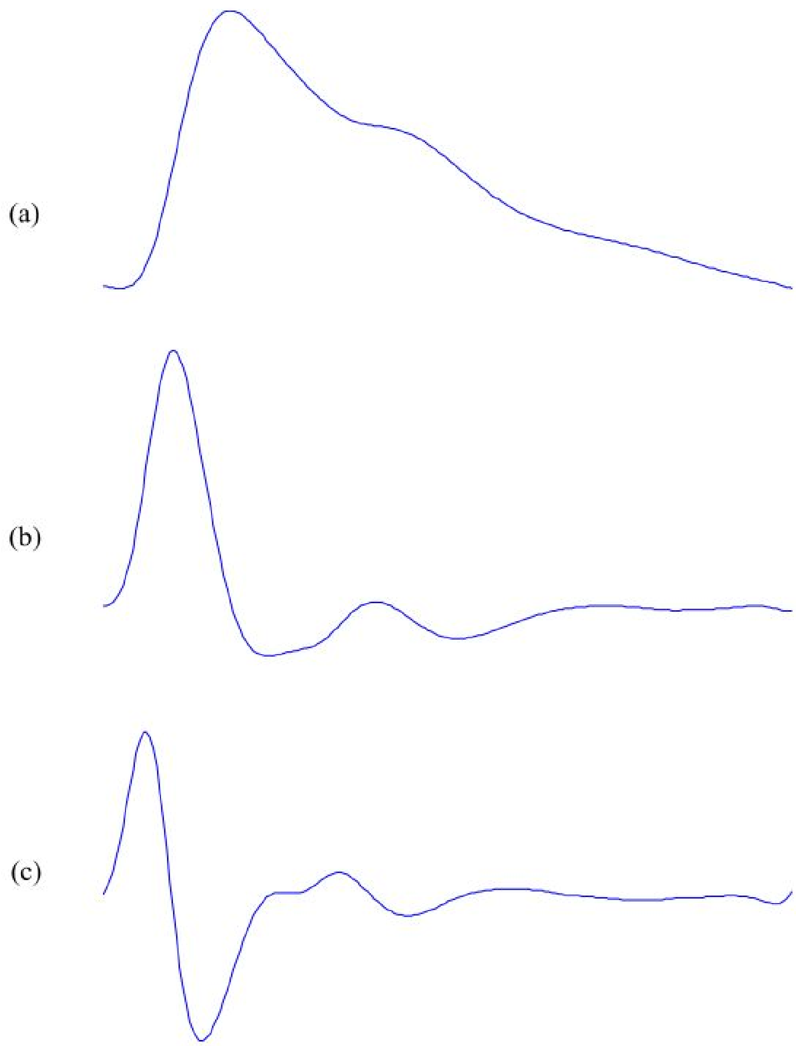
The purpose of this document is to introduce the doctor colleagues a telemonitoring system that can be used in an everyday practice, and helps the work of clinicians and researchers by providing them with relevant and objective data. This system can be used both for monitoring cardiovascular patients and for home-based therapy in a wider range, as well as for risk assessment.

Our system is based on the analysis of the signal recorded by the collection of finger photoplethysmography data (PPG curve), which is recorded by a special pulse oximeter. The PPG curve is automatically analyzed by the system, providing relevant clinical data about the current condition of the patient, as well as the cardiovascular risk, and can be used to follow up cardiological and other therapies. The development relies on data from medical literature and our own research. Numerous articles [1–5] and the technology present on the market (Meridian DPA, Smart Pulse, Arteriograph, etc.) proves that a cardiologically relevant signal reflecting central processes can be recorded on the periphery in a non-invasive way.

Our system, with the 21st century possibilities, can be used for patient monitoring at home. This way, it can even meet the increasing needs of on-site monitoring in clinical studies.

Pulse wave analysis

We record the pulse wave for 120 seconds, and evaluate them with our self-developed algorithm running under Matlab. The evaluation runs automatically, no medical annotation is required. The figure below shows a PPG wave recorded on a finger, as well as its first and second derivatives in time.



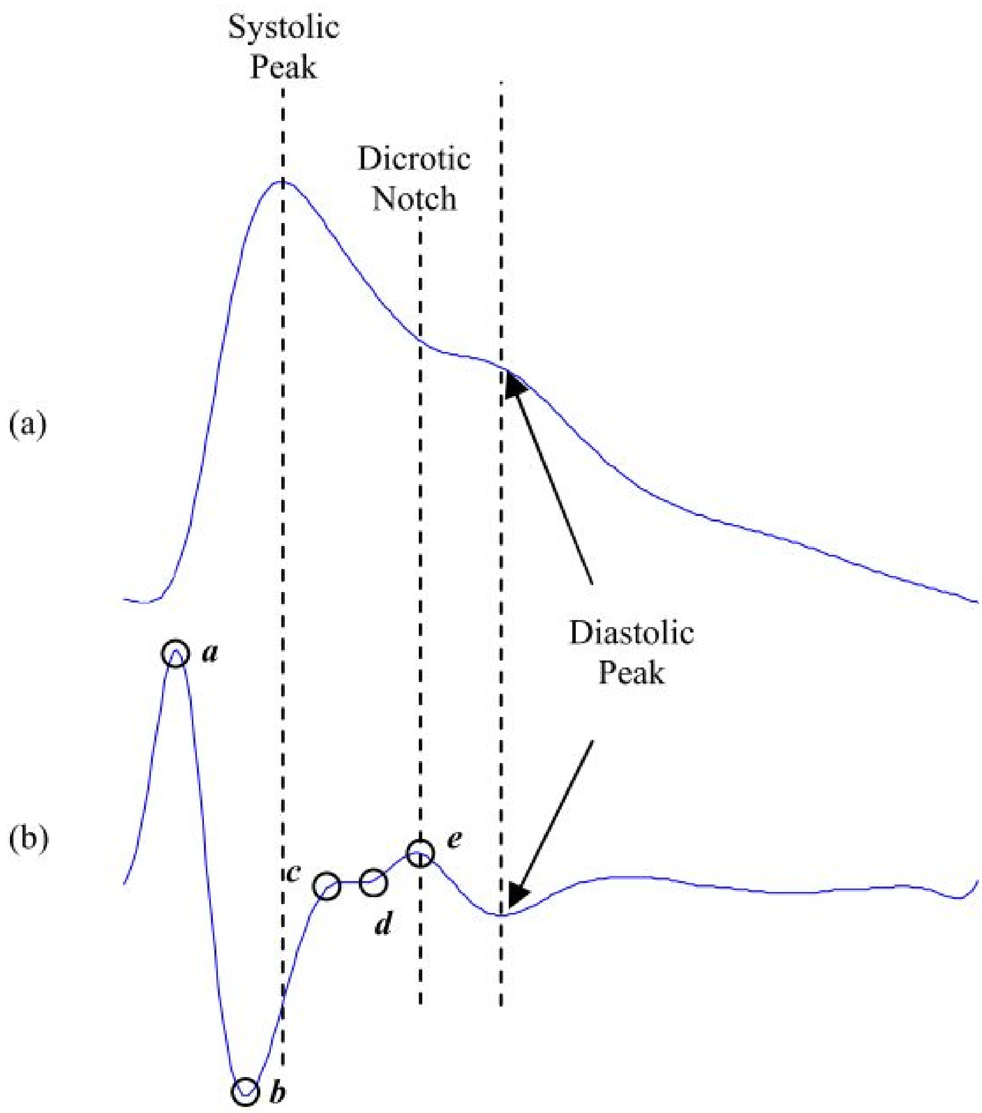
The morphology of the waves is influenced by a number of factors.

They include:

- Dynamics of heart contractions
- Condition of the vascular system
- Modifying factors of the autonomic nervous system

The shape of the waves is indirectly influenced by, among other things, age, gender, and various cardiovascular diseases, in particular, atherosclerosis and heart failure, as well as pathological conditions associated with changes in the condition of the vessel walls.[6]

There are numerous distinguished points and derivative parameters for describing the morphology of the waves.[1] Some of these are shown in the figure below:



<u>Parameters calculated from the PPG curve:</u>

Large artery stiffness index: provides information about the stiffness of the arteries [7]

Reflection index: marker of the resultant of the vascular tone and the aorta elasticity [3]

Dicrotic Notch Index

It describes the relationship between the diastolic (second) peak and the valley before it (morphological signal induced by the aortic valve closure). A parameter defined by our research group. For the time being there are only empirical data regarding its meaning. Generally speaking, this value decreases with ageing, but it may also change dynamically in a short-term period to some effects (e.g. the value increases to the effect of a sauna or a hot bath).

Systolic slope inclination (alpha): Specifies the maximum slope of the ascending wave. It correlates with the ejaculation dynamics of the left ventricle (~dP/dt echocardiography). (the stronger the left ventricle contracts, the more steeply the pressure builds in the vascular system).

b/a

The ratio of the first two inflection points of the second derivative of the pulse wave. It correlates with the elasticity of the large arteries and the contractility of the left ventricle. Cardiovascular risk factors impair (increase) this value. The value increases with ageing. [2]

d/a

The ratio of the first and fourth inflection points of the second derivative of the pulse wave. Inoue et al. have found this parameter to be an independent cardiovascular risk factor. [6] The tone of the small blood vessels affects this value. [2] The value decreases with ageing.

Ageing index

The value derived from the second derivative of the PPG wave, its absolute value decreases with ageing. [2]

c-d point detection rate

Specifies the ratio of the detection of points c and d on the second derivative to all periods in the 2 minute register.

Systolic/diastolic time ratio – The length of the cardiac cycles related to each other. It's important to know for the assessment of the coronary filling.

Left ventricular ejection time index: in systolic dysfunction decreased values have been described, while in diastolic dysfunction increased values; deviation in both ways increased mortality [8]

Ejection time @ 60

Ejection time corrected to 60/min pulse. The time elapsed between the beginning of the period and the aortic valve closure (dicrotic notch).

Crest time @ 60

The time elapsed between the beginning of the period and the maximum systolic amplitude corrected to 60/min pulse.

ELVET1 @ 60

ELVET2 @ 60

The two time component of the "crest time". During ELVET1 the heart does not have to cope with the retroactivity of the afterload, while in the case of ELVET2 the afterload can affect the length of this time period significantly.

In addition to the parameters mentioned above, as a result of the measurement we are provided with the results of the average heart rate (**mean HR**) and the arterial oxygen saturation (**SpO2**) during the measurement as well.

Heart Rate Variability (HRV)

The 120 second PPG register allows us to analyze the HRV (heart rate variability). The HRV parameters also provide valuable information on the general condition of the patient, and the regulation of the heart by the autonomic nervous system.

For example in the case of diabetics, where the activity of the vagus is impaired, a typical pattern of the HRV parameters can be observed, which is different from the healthy pattern. (Cardiac autonomic neuropathy (CAN))[9]

We use the recommendations of HRV analysis as described and accepted by international cardiology organizations in 1996. [10] We analyze time-, frequency-domain and non-linear parameters according to specific mathematical rules. HRV analysis was also used in a number of articles for the risk assessment of post-infarction patients. [10,11]

From numerous HRV parameters these are the most widely-known [10]:

SDNN

Its value is influenced by all cyclic components affecting heart rate variability. A quasi summative vegetative nervous system index. In the case of young people and athletes the value is higher, while in case of individuals with stressful, unhealthy lifestyles it's lower.

rMSSD

The activity of the parasympathetic function of the vegetative nervous system directly affects its value.

Total Power

It specifies the area under the frequency-domain analysis curve. It carries similar information like SDNN, and the factors influencing its value are the same.

LF/HF

A number describing the ratio between the different frequency bands resulting from HRV frequency domain analysis. The LF (low frequency-0,04Hz-0,15 Hz) component is increased by both sympathetic and parasympathetic effects, while the HF (high frequency-0,15Hz-0,4Hz) component is only affected by parasympathetic activity. It follows that the ratio of the two roughly describes whether the sympathetic or parasympathetic effects of the vegetative nervous system are stronger at the moment of measurement.

DFA Alpha 1

One of the so-called non-linear parameters of the HRV analysis. It provides information on the regulation of the heart rate. In case of lower values (<0.7) there is no regularity at the heart rate (e.g. atrial fibrillation), while in the case of higher values (> 1.4) the regulation is too rigid (e.g. stress, cardiac autonomic neuropathy).

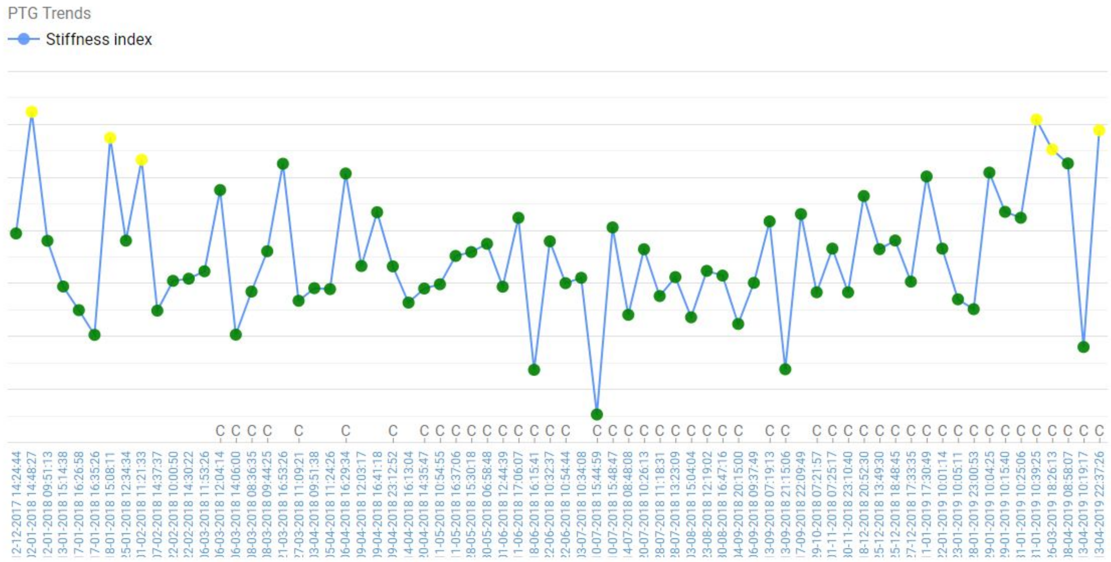
<u>Display</u>

Our self developed software displays the registered PPG curves, their first and second derivatives, and the highlighted points marked above, calculates and displays parameters derived from the pulse wave.

Fig.1. -the original pulse wave, then the first and second derivative of the curve below each other

Fig.2. – *Visualization of the HRV results*

Fig.3. – *PTG parameters and the visualization of the pulse wave*



Parameter	Own Range	Average	SD	Normal Range	Unit
SpO2		-	-	95 - 100	%
Mean HR		-	-	60 - 90	1/min
Stiffness index	✔	7.1	0.8	5.6 - 8.6	m/s
Reflection index	✔	61.6	8.3	45.1 - 78.1	%

Fig.4. – Trend view of the Stiffness Index of a patient - even if there are some outlier measurements, the beaseline of the patient can be determined. Trend view is absolutely important to monitor the effect of a newly administered drug or lifestyle change.

References

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