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CONCEPT OF PERSONALISED BIOMEDICAL INSTRUMENTATION; CASE STUDY - BLOOD PRESSURE

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Abstract – In this paper we are introducing the concept of personal instrumentation. Personal instrumentation stands for a measuring device, which includes also calculative algorithms and measuring methods and techniques, which along measuring of physiological parameters enable also collecting other types of data for a certain patient in a certain condition at a certain time. Therefore such devices would be a useful tool for the physician to better diagnostically evaluate the state the patient is in, and that in a holistic manner. The evaluation of the concept of personalised instrumentation is discussed in the field of non-invasive blood pressure measurements.

The majority of nowadays home-use, GP and clinical practice non-invasive blood pressure (NIBP) measurement devices use the oscillometric principle of measurement. In this paper we are discussing and describing an oscillometric device including also other forms of collecting data. Its aim is to produce correction factors, which would enable calculative corrections of the measured systolic and diastolic blood pressure levels to better suit the patient current status.

Keywords: blood pressure, soft metrology, data mining, personal instrumentation

1. INTRODUCTION

The advancements in biomedical science and technology are leading to novel types of medical measuring instrumentation. One of the types is instrumentation whose measuring function is adapted and/or adjusted not only to specific physiological parameters of the patient, but also to various subjective, psychophysical state of the patient. In this paper a novel holistic instrument for non-invasive blood pressure measurement is discussed. During the measurement process the instrument takes into account also other parameters, which are not necessarily of physiological origin but in any case relevant for the blood pressure level, such as emotional stress of the patient, anxiety, white-coat hypertension effect, activities prior the measurements, etc.

Measuring blood pressure non-invasively was first described already in the late 1800s. Different method for blood pressure determination were used and described, i.e. oscillometry was first described already in 1860 by Marey. A couple of decades later today's classical Riva-Rocci and Korotkov auscultation method was described. Nowadays, these methods are the main blood pressure measuring methods used in both clinical and home-care environment. In 1980s the oscillometric method has re-emerged in clinical use. Today it is used with increasing regularity mainly in the scope of semi- or full automatic NIBP devices.

The main idea of the oscillometric method is measurement of pressure pulses, which occur in the bladder of a non-invasive cuff wrapped over an artery around the patient's limb. Arterial pulse waves are transmitted via the cuff and measured in form of pressure pulses by a pressure sensor in the NIBP device. The amplitude and shape of pressure pulses vary as the static pressure in the bladder is reduced from above systolic to below diastolic blood pressure. Using different (proprietary) calculative algorithms, systolic and diastolic blood pressures are determined from the pressure pulses' envelope.

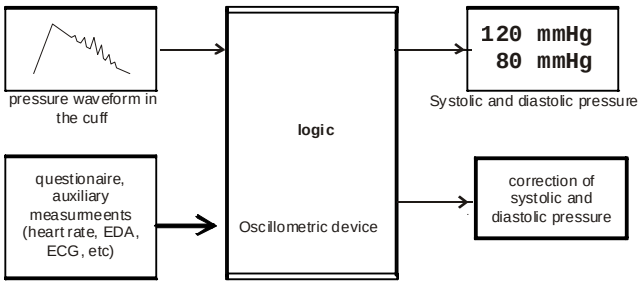

Fig. 1. Principle of personalised oscillometric blood pressure device. By measuring changes in cuff pressure systolic and diastolic blood pressure are determined. Determination is performed by empirical calculative algorithms of the device's logic. Correction factors are determined by other type of input data (heart rate, skin conductivity, ECG signal, level of relaxation, physical activities, current health condition, etc).

Oscillometry is an attractive measuring method for the simplicity of cuff application and device operation. On the other hand, it suffers from the empirical nature of existing algorithmic methods, the disagreements over methodology, the proprietarily of commercial algorithms, and the resulting problems with accuracy. Commonly, the oscillometric devices are quite accurate compared to classic mercury-in-glass sphygmomanometers and auscultatory measuring method when measuring a normo-tension patient. But they tend to develop measuring errors when not well maintained, regularly calibrated and/or measuring severe hypertension patients, or patients with certain physiological properties (arteriosclerosis, heart arrhythmia, and various heart conditions). Oscillometry is known to be also quite sensitive to moving artefacts [1, 2, 3, 4].

The aim of our research is to build a NIBP device, based on oscillometry, but instead of a common empirical calculative algorithm employing regression models gained from data-mining methods. As such it would potentially estimate blood pressure more reliably and accurately also for commonly problematic type of oscillometric measurements (severely hypertensive patients, arteriosclerosis, heart arrhythmia, excessive moving, incorrect body position, measurements in not relaxed state, etc). In this paper we are describing and evaluating the idea of replacing the empirical calculative algorithms of oscillometric NIBP devices by data-mining methods in order to increase device's accuracy and reliability.

2. PERSONALISED INSTRUMENT FOR NON-INVASIVE BLOOD PRESSURE MEASUREMENT

The necessary data for teaching phase of building the regression model was acquired by an upgraded virtual instrument for blood pressure measurement designed in LabVIEW environment for a previous study [5]. The instrument consisted of a data-acquisition module and a data-processing module. In the data- acquisition module the oscillometric envelopes were sampled by means of a cuff and a calibrated pressure transducer. Oscillometric envelopes represented the input data for the data-processing module. The inputs for the teaching phase of the data-processing module were systolic and diastolic values of blood pressure. Values were determined by measuring 20 healthy volunteers using a verified clinically validated commercial NIBP device. Prior to the measurement the volunteers filled-in a questionnaire about their psycho-emotional status, e.g. 5 grade level of relaxation, description of physical activities prior the measurements, current health condition (healthy, acute, chronic illness), heart rate before the measurement, skin conductivity, ECG signal, etc. In the data-processing module the calculation of both systolic (SYS) and diastolic (DIA) blood pressure levels took place. Basic inputs for the regression model, built with data mining tool for the determination of blood pressure levels were pairs of an oscillometric envelope of the pressure pulses and resulting systolic and diastolic blood pressure values, determined within the same measurement.

In the future, calculative corrections of SYS and DIA will be implemented taking into account some general correlations between blood pressure level and psycho-physical state of the patient. E.g. a patient climbing up the stairs to reach the physicians office has elevated blood pressure level or patient sitting in incorrect position would have the blood pressure levels altered. At the moment the teaching group is far too small to draw any conclusions about these correlations. With a larger teaching group the values of the correlation coefficients would be more significantly determined. Resulting in a more reliably SYS and DIA corrections.

2.1. Acquiring of the oscillometric envelopes

A set-up for acquiring the oscillometric envelopes and blood pressure determination was built. System was built by means of a suitable pressure transducer and a measurement system with high enough sampling frequency. Pressure transducer XFPM 050KPG-P1 (by Fujikura) was used. By means of an A/D card SCB-100TT (by National Instruments) it was connected to a personal computer. In LabVIEW environment a programme for acquiring of the pressure transducer's output, pre-processing and processing of acquired data was written. Output of the programme was a time series of pressure pulses amplitudes versus the cuff pressure, i.e. the oscillometric envelope with sampling frequency 300 Hz.

Raw data was processed in LabVIEW environment. It was preconditioned (removing the outliers, preparation for the processing). The oscillations were filtered from the acquired raw signal by using a simple subtractive method. The deflating cuff pressure was fitted by a polynomial function and subtracted from the acquired raw signal, resulting in a time dependant function of the oscillations' amplitudes. Filtering using the fitted ramp is not equivalent to subtracting the base cuff pressure, i.e. the cuff pressure as it would be without oscillations, from the acquired signal. It involved a certain averaging, resulting in waveform shown in Fig. 2. In-time conditioning was included, enabling manual improvement of the envelope shape to exclude errors due to incorrect sampling process, motion artefacts, tremor or cardiovascular abnormalities during the measuring period, etc.

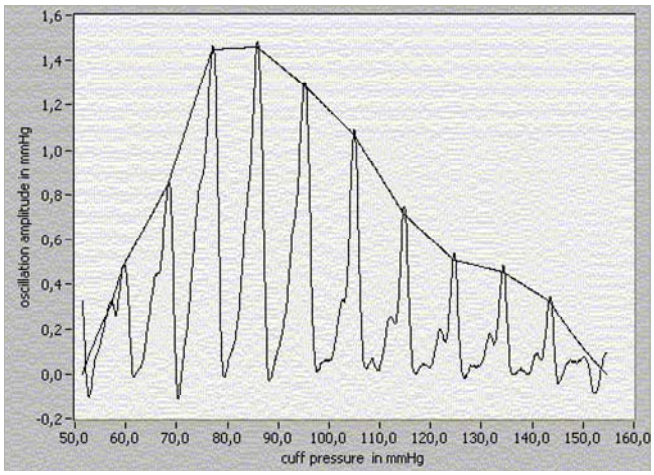

Fig. 2. Oscillometric envelope formed using baseline-to-peak oscillation amplitude.

Commonly, there are three main possibilities of conditioning the oscillation amplitudes to form the oscillometric envelope; peak-to-peak oscillation amplitude, function of partial or full time-integral of the oscillometric pulses and baseline-to-peak oscillation amplitude [6]. Due to simplicity we decided on the latter.

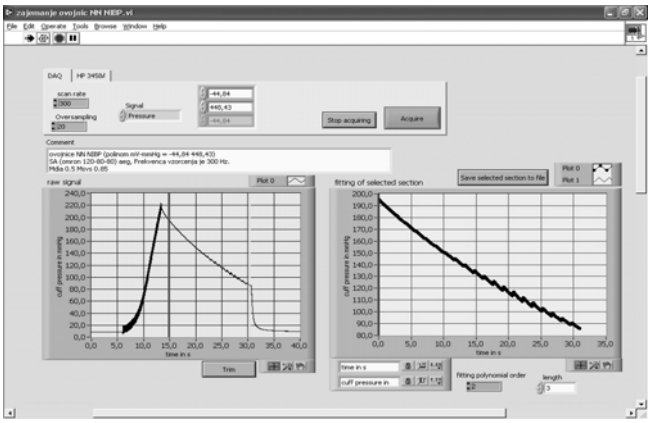

Fig. 3. LabVIEW front panel of the cuff pressure pulses acquiring. The graph on the left shows the acquired raw pressure signal in the cuff while inflating and deflating. The graph on the right shows the selected part of the deflation, with oscillometric pressure pulses noticeable.

2.2 Acquiring the blood pressure levels

For the purpose of this research two blood pressure signals were used for generation of oscillometric envelopes. Ninety real physiological blood pressure signals from 23 healthy volunteers were acquired. Blood pressure levels were determined by means of a commercial clinically validated NIBP device M6 (HEM-7001-E by Omron Healthcare) [7]. The acquiring of the raw pressure signal was followed by removing the moving artefacts, outliers and other errors in measurements by the pre-processing module. Using the LabVIEW programme the optimal envelope shape could be adjusted and optimised (Fig. 3.).

2.3 Building of the model

A transfer function has been built by means of regression model, built with data mining tool, which was further used for estimation of blood pressure.

For systolic and diastolic pressure modelling we used open-source machine learning software WEKA, which is in the universities' environment a well-known tool for data mining [9]. Regression models were built on the dataset, which consisted of 125 physiological envelopes of healthy volunteers (fig. 6). Inputs of regression models were built in form of vectors from the envelopes using sampling. We varied the length of the input vector from 10 to 1000. Sampling with different time delays was additionally performed. Outputs of the models are either systolic or diastolic pressure (fig. 4). The following model types were used: simple linear regression, feed-forward neural network (multilayer perceptron) and a model based on support vector regression.

The quality of regression models, which we also call predictors, was estimated by means of the following performance measures: root mean squared error (*RMSE*), correlation coefficient (*CC*), and Mean Absolute Error (*MAE*).

$$RMSE(\Theta) = \sqrt{MSE(\Theta)}$$

$$MSE(\Theta) = \frac{1}{N}\sum_{t=1}^{N}(y(t) - \hat{y}(t;\Theta))^2$$

$$MAE(\Theta) = \frac{1}{N}\sum_{t=1}^{N}\left|y(t) - \hat{y}(t;\Theta)\right| \quad (1)$$

RMSE (1) estimates the standard deviation of the mean value of the estimation (SIS/DIA pressure), which was subject of our modelling. *CC* measures the correlation between real and estimated values $CC \in [0,1]$. Of good quality are those who's *CC* is near value of 1. *MAE* measures the mean value of the absolute discrepancies (deviation). Because our dataset was of limited size, with an aim of avoiding the overfitting, we used a mechanism called n-fold cross validation in order to estimate the error of prediction (regression) [11]. The data set was divided into *N* subsets, and the holdout method was repeated *N* times. Each time, one of the *N* subsets was used as the test set and the other *N-1* subsets were put together to form a training set. Afterwards the average error across all *N* trials was computed. The advantage of this method was that it mattered much less how the data got divided. The variance of the resulting estimate was reduced as *N* was increased. The disadvantage of this method was that the training algorithm had to be rerun from scratch *N* times, which meant it took *N* times as much computation to make an evaluation. We build the final model on the whole dataset.

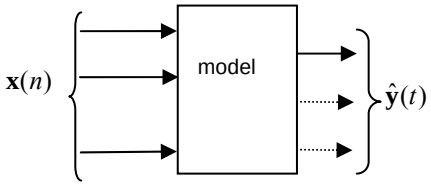

Fig. 4. Regression model for estimation of pressure. The length of input vector x(n) was varied from 10 to 1000. The length of output vector is 1 and represents SYS and DIA pressure.

2.3.1 Data mining models

Linear regression is a simple statistical method that models the relationship between a dependent variable $\hat{y}(t)$, independent variables $x_i(t), i = 1..p$ and a random term ε. The model can be written as:

$$\hat{y}(t) = \beta_0 + \beta_1 x_1(t) + ...\beta_p x_p(t) + \varepsilon \quad (2)$$

where β_0 is the intercept ("constant" term), the β_i are the respective parameters (weights) of independent variables, and p is the number of parameters to be estimated in the linear regression. The main idea of linear regression is to find the set of β_i which minimizes:

$$\sum_{n=1}^{N}\left(x(n) - \sum_{j=1}^{p}\beta_j x_j(n)\right)^2 \quad (3)$$

For the estimation of weights β_i in the (3), could be used different methods.

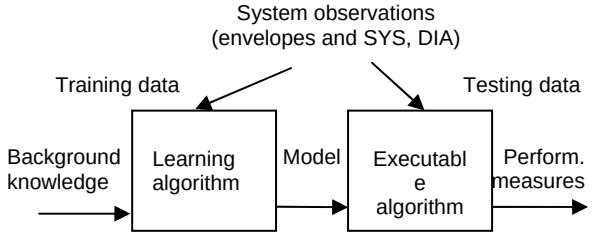

Fig. 5 Estimation of the performance of models for pressure prediction.

Apart linear regression also neural network (NN) was used, because it represented an emerging technology with some important characteristics, such as universal approximation (input-output mapping) and ability to learn from and adapt to their environment. Multilayer perceptron is feed-forward network. As learning algorithm we used generalized δ-rule or back-propagation (BP). The user interface provides regulation of the following parameters: number of layers, number of neurons in each layer, learning rate η and momentum term α. Parameters η and α could be changed during the training. Neurons in input layer act as buffers for distributing the input signals **x(n)** to neurons in the hidden layer [11]. MP is usually used as pattern recognition tool, but from a systems theoretic point of view it can be also used for approximation of non-linear maps [11]. MP as a feed-forward network by its computational power could be compared to the fuzzy-logic systems.

We also used Support Vector Machine (SVM) for Regression. The basic idea of SVM is to map the input space into a high dimensional feature space via non-linear mapping and to do linear regression in this space. The linear regression in a high dimensional feature space corresponds to nonlinear regression in the low dimensional input space. Vapnik showed that the functions that minimize the risk depends on the finite number of parameters and can be described by kernel functions. Empirical risk minimization is used to estimate the parameters of feature space, which realization is a quadratic programming problem and which outputs are support vectors [9, 10, 12]. The capacity of predictor is controlled by VC dimension [12]. In the paper we used ε-SVR variant of the algorithm with Platt's optimization algorithm, called Sequential Minimal Optimization (SMO) [9].

4. RESULTS

The input parameters for the modelling consisted of two groups. The first group was a series of pairs of real physiological oscillometric envelope (Fig. 6) and resulting blood pressure levels, measured by a clinically validated commercial NIBP device Omron M6 (Table 1). The repeatability of Omron M6 device was proven by a series of 90 measurements. When measuring artificial signals measuring errors of less than 1 mmHg were recorded for various blood pressure levels and heart rates.

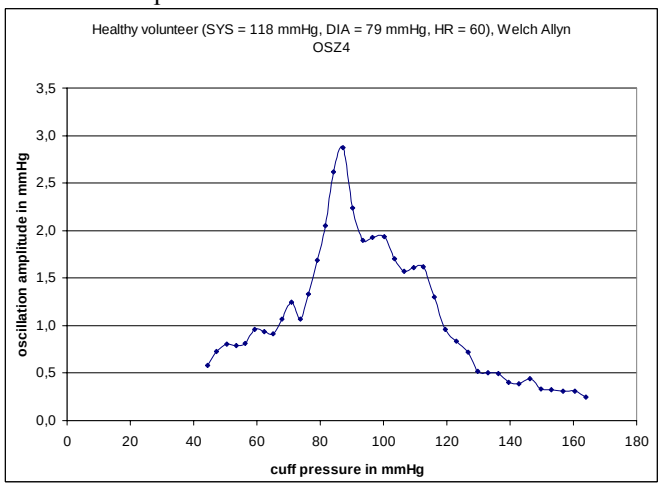

Fig. 6. Oscillometric envelope, acquired by a blood pressure measurement of a volunteer SYS/DIA/HR = 118/79/60.

Regression accuracy or the quality of predictor, which is prediction of SYS and DIA value, was estimated by means of the explained performance measures: correlation coefficient (CC), Mean Absolute Error (MAE) and root mean squared error (RMSE).

Table 2 is giving the results of comparison of different types of models. RMSE is calculated by 10-fold cross validation. In bold-faced type are give the best results for each model (for example, for linear regression we achieved the best results for input length of 600, CC ≈ 1, MAE ≈ 2 and RMSE=2.5. The best results of pressure modelling were achieved by a neural network, multilayer perceptron. Fig. 7 is illustrating the RMSE dependence of the length of input vector |x(n)| in the modelling with neural networks. RMSE was estimated by means of 10-fold cross validation. The best result of SYS modelling was achieved for input length 20, while the best result for DIA modelling was achieved for input length 45 (figure 7).

Table 1: Statistics of 90 blood pressures measured by commercial NIBP device as one of the input parameters for data mining models (physiological signals were measured on 23 healthy volunteers totalling 90 measurements, SYS – systolic, DIA – diastolic blood pressure, HR - heart rate, AVG and STD of SYS, DIA and HR – average and standard deviation of 23 volunteers).

	gender	age (years)	height (cm)	weight (cm)	upper-arm circumference (cm)	SYS (mmHg)	DIA (mmHg)	HR (/min)
AVG	52 % male 48 % female	32,0	173,6	70,2	26,8	113,5	73,8	69,2
STD		14,7	9,6	14,2	2,9	9,6	8,3	9,3

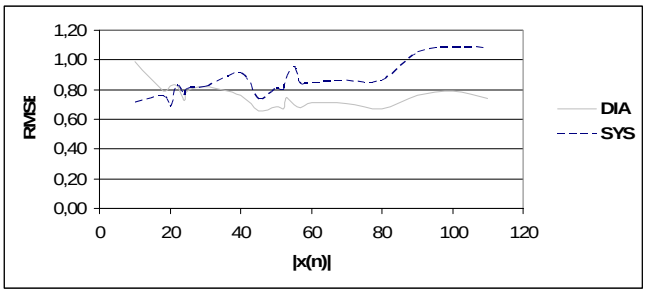

Fig. 7. RMSE dependence of the length of input vector |x(n)| in the modelling with neural networks. The best result for DIA (the smallest RMSE=0.65) is estimated |x(n)|=45. The best result for SYS (the smallest RMSE=0.68) is estimated |x(n)|=20.

Table 2. Modelling DIA pressure by means of data mining.

	Linear regression			Neural network			SVR		
Input length	CC	MAE	RMSE	CC	MAE	RMSE	CC	MAE	RMSE
10	0,71	3,92	6,01	0,99	0,70	0,99	0,87	2,19	4,20
100	0,90	2,36	4,31	**1,00**	**0,60**	**0,79**	**0,95**	**1,77**	**2,60**
200	0,94	1,97	2,98	0,99	0,67	0,95	0,95	1,77	2,67
300	0,90	2,39	3,67	0,99	0,71	1,08	0,95	1,79	2,70
400	0,95	1,84	2,67	0,99	0,68	0,91	0,94	1,95	2,78
500	0,95	1,79	2,67	0,99	0,93	1,34	0,95	1,83	2,76
600	**0,95**	**1,91**	**2,54**	0,99	0,85	1,31	0,94	1,86	2,79
800	0,66	4,04	6,35	0,99	0,94	1,44	0,87	2,37	4,21
1000	0,88	2,37	4,61	0,98	1,06	1,54	0,94	1,82	2,82

4. CONCLUSIONS

Nowadays, the oscillometric devices for blood pressure measurements are widely used in both clinical and home-care environment. Due to their reasonable price they are widely accessible. They are much more often used as automatic auscultation devices, although these are usually more accurate and reliable. The core of any oscillometric device are very simple calculative algorithms in their microprocessors, which determine the systolic and diastolic blood pressure levels from the measured amplitude of oscillometric pressure pulses. The oscillometric devices main advantages are simplicity and straightforwardness of use and high accuracy when measuring a normo-tension patient. On the other hand they tend to develop measuring error when measuring severe hypertension patients, or patients with certain physiological properties (arteriosclerosis, heart arrhythmia). Oscillometry is known to be also quite sensitive to moving artefacts.

In this paper we tried to investigate the possibility of substitution of the simple oscillometric algorithms with more complex ones, which would include also other important data describing the psychophysical state of the patient in order to enable a reliable functionality also in more demanding measuring conditions. Such an oscillometric device, which would estimate blood pressure by means of data mining modelling, should enable estimation of blood pressure for different levels and different amplitudes of oscillometric pulses with sufficient regression accuracy. The concept of personalised instrumentation includes extension of our modelling by adding attributes that describe the person involved in the measurement in more detail (physiological and psychophysical state of the person). Improvement of the regression accuracy is expected, if the modelling would consider certain attributes, which are confirmed by the research medicine as influence factors for hypertension (e.g. age group, arm circumference, emotional stress, white-coat hypertension, etc). We conclude that we have introduced the concept of personalised instrumentation and have proven the basic concepts in the case of non-invasive blood pressure measurements.

Currently there are many presumptions and simplifications included in our methodology, which enable possible future improvements. One of the main simplifications was that the measured level of the blood pressure, as one of the inputs for teaching process, was not measured invasively or by a classic manual methods i.e. auscultatory mercury-in-glass sphygmomanometer. Instead we were using a commercial device, which was simpler to use, more suitable for assessing the repeatability of measurements, well maintained and calibrated with a clear metrological history, containing no neuro-toxins and which passed the clinical validation.

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