Using the profile capability indices as health measures: A simulation study on human blood pressure

[*]Arash Nemati[1], Shirin Mehrdoost[2]

[1]r.nemati@nit.ac.ir; +9891111451079

[2]Shirinmehrdoost@nit.ac.ir

[1,2]Department of Industrial Engineering, Babol Noshirvani University of Technology, Babol city, Mazandaran province, Iran, Postal code:47148-71167

Abstract

In the multivariate statistical process control literature, the profile is a function or curve representing the relation between two or more variables. Several types of complicated curves are conventionally applied to analyze the health of humans, such as Systolic and Diastolic blood pressure profiles. This paper proposes a new approach to interpreting the process capability indices of complex health profiles in the human body performance assessment. Using the popular multivariate statistical techniques of profile monitoring for complex health profiles is too complicated or impossible. Hence, the proposed method transforms the health profile into a univariate specification using dissimilarity indices. The applicability of the new approach is verified via a simulation study on an example of human blood pressure profiles. This application also represented the simplicity of the proposed method to conventional techniques and how the profile capability indices could be applied in health evaluation. In addition, it provides valuable

information to evaluate the Heart's performance in terms of blood pressure and make a judgment on the blood circulation system.

Keywords: Statistical Process Control, Process capability indices, Profile monitoring, Medical curves, Curves dissimilarity indices, Blood pressure assessment

1 Introduction

Statistical process control (SPC) involves techniques to detect the out-of-control state of the process caused by at least one assignable cause. Shewhart control charts are commonly applied to monitor the variability of the process(Oakland and Oakland [1], Berger and Hart [2]). When engineering characteristics are correlated, multivariate SPC techniques such as Hotelling T^2, Principal component analysis(PCA), and Mean coding strategy are used Ge and Song [3].

In recent decades, some curvature-type quality specifications have been mentioned, named profiles. The first step in Profile analysis is fitting a regression model, and then, a multivariate SPC method was applied to monitor the process regarding the coefficients and error variance of the fitted regression models [4, 5].

Process capability indices (PCIs) were defined to describe the ability of a process in the conforming-items production[6-9]. Kane [10] introduced univariate PCIs, such as C_{pk}, and Dharmasena and Zeephongsekul [11] applied principal component analysis (PCA) to evaluate the multivariate PCIs. Hadian and Rahimifard [12] introduced some practical multivariate PCIs to assess the capability of a project to satisfy the requirements. Yang et al. [13] evaluated the capability of the manufacturing processes based on the truncated data from supplier products. Wang et al. [14] applied the robust approach to assessing the PCIs of a production process using a model selection method. They aimed at two examples to illustrate the improvement strategy in

the manufacturing process of products. In addition, PCIs could be applied to assessing the processes, producing profiles as engineering characteristics. Some techniques, such as non-conforming percentage-based methods, functional indices, PCA-based approaches, and Hausdorff distance-based methods, have been developed for profile capability evaluation [15-18].

In the clinical assessment, some curves might be helpful to analyze the state of patients. For example, Systolic and Diastolic blood pressure curves are two commonly used profiles in human blood pressure evaluation. In this paper, we propose a new approach to applying the PCIs of health profiles as diagnosis indices for health assessment. The pattern of health profiles is commonly too complicated to fit a regression model. Hence, the distance between an observed profile and the Target profile is considered a value of an engineering characteristic, resulting in no need for regression model fitting, tolerance setting for coefficients, or using complex multivariate statistical methods. In other words, the main novelty aspect of this paper is using CDIs to summarize the complicated health profiles into a univariate engineering characteristic. Furthermore, interpreting the PCIs of profiles as health indicators and applying the new approach in the human blood pressure profile assessment presents the first application of profile monitoring and capability assessment in the healthcare sector.

The remained sections of the paper are as follows. Section 2 reviews the literature on PCIs of profiles and CDIs. The related concepts and methods are reviewed in section 3, and a simulation study on the blood pressure profiles is proposed in section 4. Finally, section 5 provides conclusions and future work remarks.

2 Literature review

Most literature on PCIs of profiles has concentrated on SLP and has employed complicated multivariate statistical techniques in their proposed methods. In this section, the literature on the PCIs of profile assessment is reviewed to show the high degree of popularity of multivariate statistical approaches, particularly in PCIs assessment of SLP. In addition, a literature review on the most significant CDIs is provided.

2.1 Literature of PCIs of profiles

Hosseinifard and Abbasi [19] suggested a non-conforming proportion-based PCI of the dependent variable as PCI of simple linear profile(SLP). They also investigated the differences between the five methods to assess the PCI of SLPs under non-normality conditions [20]. Ebadi and Amiri [21] proposed three approaches, including a non-conforming percentage-based technique, the multivariate capability vector, and the PCA-based method, to assess the capability of multivariate SLPs. Ebadi and Shahriari [22] calculated the process capability indices for SLP using the non-conforming percentage method and multivariate capability vector. Wang and Guo [23] presented the estimated S_{pkA} to measure the process performance of simple nonlinear profiles with measurement errors. Nemati Keshteli et al. [15] proposed a functional PCI for the roundness profile, defining the PCI as a function of the explanatory variable. They also developed functional process capability indices for simple linear profiles [24]. Wang [25] proposed the estimated S_{pkA} for simple linear profiles. In the same year, Wang [26] applied the non-conforming percentage method to develop two measures for the capability of SLP when there is only one side of specification limits. Wang and Tamirat [27, 28] proposed a new approach to assess the PCI of linear profiles using S_{pkA}, which considers the autocorrelation between profiles and within each profile. Guevara and Vargas [29] investigated the use of two methods based on the functional depth concept using Clement's indices and showed the

applicability of these new methods via a numerical example [30]. Amiri and Rezaye Abbasi Charkhi [31] , and also Rezaye Abbasi Charkhi et al. [32] presented a PCI for processes characterized by a logistic regression profile using the percentage of non-conforming items and the average of the process output. Karimi Ghartemani et al. [33] developed a process capability vector to estimate the process capability using functional specification limits [34]. Guevara and Vargas [35] applied a method based on PCA for multivariate functional data to measure the capability of multivariate nonlinear profiles. Wang [36] extended the S_{pkA} for nonlinear profiles capability assessment in the presentence of the gauge. Wang [37] evaluated the process capability using TS_{pkA} of process yield in multivariate linear profiles by constructing a confidence interval. He measured the exact process yield instead of providing a point estimate. This procedure is close to the target when the sample size with smaller standard deviation increases. Guevara et al. [16] applied the Hausdorff distance to assess the capability of nonlinear profiles. They used the functional PCIs of Clements, which quantiles functions obtained using Hausdorff distance. Wang and Tamirat [38] proposed two indices to assess the process capability of multivariate linear profiles when specification limits are one-sided. Chiang et al. [39] used two capability indices based on non-conforming items for SLP with within-profile autocorrelation. Wang et al. [40] applied a non-conforming percentage method to assess the capability of SLP with one-sided specifications in a wind turbine case study. Aslam et al. [41] used the capability index of linear profiles to develop a novel multiple-dependent state repetitive sampling plan, and Alevizakos et al. [18] investigated the capability of Poisson regression profiles using the S_{pmk} index. Abbasi Ganji and Sadeghpour Gildeh [42] developed two fuzzy capability indices for SLPs. Alevizakos and Koukouvinos [43] calculated the capability of gamma regression profiles using the S_{pmk} index. Pakzad et al. [44] developed loss-based indices for the capability of SLPs

using a functional approach. Mehri et al. [45] used the *M*-estimator and the Fast-τ-estimator to propose robust PCIs for multiple linear profiles. Couto et al. [17] reviewed the literature on the process capability indices for the linear, nonlinear, generalized linear model(GLM), and circular profiles. They concluded that most process capability indices had been developed for SLP, and future studies may investigate more complex profiles. Guevara and Lopez(2022) proposed a three-component vector to assess the process capability of multivariate nonlinear simple profiles [46].

2.2 Literature of CDIs

Assessing the dissimilarity/ similarity of curves is a fundamental problem in many applications, including computer vision, graphics, and geographic information systems. The dissimilarity between two objects is a numerical measure of how different two things are. In other words, similarities are higher for pairs of shapes that are more alike. Each of the various similarity/dissimilarity indices has its strengths and weaknesses. Goshtasby [47] explained similarity/dissimilarity measures, including Manhattan distance, Euclidean distance, Rank distance, and the median of absolute differences. Seyed Shirkhorshidi et al. [48] reviewed standard similarity measures such as Mahalanobis, Mean Character Difference, Manhattan, Euclidean Distance, and Chord. Bernardi et al. [49] presented a method to determine the distance between models and experimental data naming curve matching. Jekel et al. [50] proposed a similarity index to calculate the bounded area between curves and reviewed four approaches, including partial curve mapping value, discrete Frechet distance, dynamic time warping, and curve length approach. Lv et al. [51] introduced a similarity measure to compare noses. Meng et al. [52] proposed a multi-feature fusion (MFF) to solve the mismatch between driver and car during the operation using curves comparison. Li and Li [53] designed the rough similarity index

based on Hausdorff distance and the fine similarity index based on dynamic time-bending. Ontañón [54] reviewed the distance/similarity functions, including Cosine similarity, Tversky, Minkowski distances (Manhattan distance, Euclidean distance, Chebyshev distance), and Wasserstein metric.

According to the literature mentioned above, almost all research on the PCIs of profiles is limited to one type of profile, commonly SLP. That is because the complicated multivariate statistical methods face restrictions in a bit more complex profiles such as health profiles. Hence, this paper proposes an approach to summarize complex health profiles into a univariate quality specification and interpret the corresponding PCIs as health indices. This approach is not dependent on the type of the profile and needs no regression model fitting. None of these advantages have not been considered in the previous research yet. Furthermore, the literature review on CDIs showed that Euclidean distance, Manhattan distance, and Hausdorff distance are the most popular distances in the curves dissimilarity studies.

3 Background

This section reviews concepts about univariate control charts, PCIs, CDIs, and human blood pressure curves.

3.1 Univariate control charts of variable characteristics

In the SPC, $\bar{X}-R$ and $\bar{X}-S$ are conventional control charts to monitor the output of a process. Using *m* random samples of size *n* from the outputs, $X \sim N(\mu,\sigma^2)$, the control limits of these univariate control charts are as equations 1 and 2, respectively.

$$UCL = \bar{\bar{X}} + 3\frac{\bar{R}}{d_2 n}$$
$$CL = \bar{\bar{X}}$$
$$LCL = \bar{\bar{X}} - 3\frac{\bar{R}}{d_2 n} \quad (1)$$

$$UCL = \bar{\bar{X}} + 3\frac{\bar{S}}{c_4 n}$$
$$CL = \bar{\bar{X}} \quad (2)$$
$$LCL = \bar{\bar{X}} - 3\frac{\bar{S}}{c_4 n}$$

Where, $\bar{\bar{X}}$, $\bar{R}$, $\bar{S}$, and n are the estimated mean of process, the mean of sample ranges, the mean of sample standard deviations, and the sample size, respectively, and d_2 and c_4 are coefficients, depending on n. In some exceptional cases, the sample size is equal to one, and there is only one observation in each sample. These control charts are named individual control charts, shown in equation 3.

$$UCL = \bar{X} + 3\frac{\bar{M}}{d_2}$$
$$CL = \bar{X} \quad (3)$$
$$LCL = \bar{X} - 3\frac{\bar{M}}{d_2}$$

Where, $\bar{X}$ and $\bar{M}$ are the mean of individual observations and moving ranges, respectively. Table 1 summarizes the statistical estimators of parameters in the mentioned above control charts [2].

<< Insert Table 1 >>

3.2 Process capability indices

PCIs are indices to evaluate the performance of a process to produce conforming items. There are several types of PCI, such as C_p, C_{pm}, C_{pk}, C_{pmk}, P_{pk}, and S_{pmk}, in the univariate SPC [9]. Equation 4 represents the formula of C_{pk}, the most conventional PCI.

$$C_{pk} = \min\left\{\frac{USL-\mu}{UNTL-\mu}, \frac{\mu-LSL}{\mu-LNTL}\right\} = \min\left\{\frac{USL-\mu}{3\sigma}, \frac{\mu-LSL}{3\sigma}\right\} \quad (4)$$

Where σ, *LSL*, *USL*, $LNTL = \mu - 3\sigma$, and $UNTL = \mu + 3\sigma$ are the process standard deviation, lower specification limit(LSL), upper specification limit(USL), lower natural tolerance limit(LNSL), and upper natural tolerance limit(UNTL), respectively. When C_{pk} is greater than one, the process can produce more than 99.73% of products as conforming items. Equation 5 represents the relation between C_{pk} and the process non-conforming proportion denoted by p [55].

$$p = 2 - 2\Phi(3C_{pk}) \quad (5)$$

3.3 Curves dissimilarity indices

In this section, some standard distances are reviewed. Suppose two sets of points from curves T and S are presented in equations 6 and 7, respectively.

$$\left\{(x_1^T, y_1^T), (x_2^T, y_2^T), \quad \dots \quad , (x_{n-1}^T, y_{n-1}^T), (x_n^T, y_n^T)\right\} \quad (6)$$

$$\left\{(x_1^S, y_1^S), (x_2^S, y_2^S), \quad \dots \quad , (x_{n-1}^S, y_{n-1}^S), (x_n^S, y_n^S)\right\} \quad (7)$$

The most popular distances, including Euclidean distance, Manhattan distance, and Hausdorff distance, are reviewed in the following sub-sections.

3.3.1 Euclidean distance

Euclidean distance is the most well-known distance to assess the similarity of two points in multi-dimensional space. Equation 8 defines the Euclidean distance between two points (x_i^T, y_i^T) and (x_i^S, y_i^S).

$$d_E^i = d_E(x_i^T, y_i^T), (x_i^S, y_i^S)) = \sqrt{(x_i^T - x_i^S)^2 + (y_i^T - y_i^S)^2} \quad (8)$$

3.3.2 Manhattan distance

Equation 9 represents the Manhattan distance between two points (x_i^T, y_i^T) and (x_i^S, y_i^S).

$$d_{Man}^i = d_{Man}((x_i^T, y_i^T), (x_i^S, y_i^S)) = \left|x_i^T - x_i^S\right| + \left|y_i^T - y_i^S\right| \quad (9)$$

3.3.3 Hausdorff distance

Hausdorff distance is the degree of direct mismatch between two groups of points. Hausdorff distance from *S* to *T* is represented by *h(S,T)* and defined as follows.

$$h(S,T) = \max_{(x_i^S, y_i^S) \in S} \left\{ \min_{(x_i^T, y_i^T) \in T} \left\{ \left\| (x_i^S, y_i^S) - (x_i^T, y_i^T) \right\| \right\} \right\} \quad (10)$$

Where $\left\| (x_i^S, y_i^S) - (x_i^T, y_i^T) \right\|$ represents the distance between points of two curves *S*, and *T* [53]. Hausdorff distance from *T* to *S*, *h(T,S)*, could be defined by substituting $(x_i^T, y_i^T) \in T$ with $(x_i^S, y_i^S) \in S$ in equation (10). The minimum distance between a couple of points is their Euclidian distance. Therefore, the Hausdorf distance between two curves S and T is represented in equation (11).

$$d_{Hos(S,T) = h(S,T) = h(T,S)} = \max(\sqrt{(x_i^T - x_i^S)^2 + (y_i^T - y_i^S)^2}; i = 1, 2, ..., n) \quad (11)$$

3.4 Human blood pressure profiles

Blood pressure patterns are applied to assess the performance of the human heart in blood pumping. Conventionally, two types of blood pressure, including Systolic blood pressure(mmHg) and Diastolic blood pressure(mmHg) are assessed to investigate the health of the blood circulation system of an individual. Systolic pressure indicates the blood pressure when the heart has a beat, and Diastolic pressure represents the blood pressure between two sequential beats [56]. Figure 1 illustrates the pattern of Systolic and Diastolic pressure in an individual.

<< Insert Figure 1 >>

In figure 1, it is evident that it is impossible to fit only one regression line to the Systolic or Diastolic blood pressure, and there might be a need to use many separate SLPs.

Normal blood pressure provides oxygen and nutrients for the human body. When blood pressure becomes high or gets too low, the health of human fall in danger. Blood Pressure is continuously varying throughout time. Conveniently, blood pressure falls to its lowest level during the first few hours of sleep, about ten percent lower than during waking hours. According to O'Brien and Dolan [57], a satisfactory recording should have at least seventy percent of the expected measurements. Variations in blood pressure might result from changes in physical activity and environmental conditions. Currently, some wearing devices can measure blood pressure continuously [58]. If the blood pressure is in control, it reduces the risk of Stroke**,** Heart attack**,** Kidney dialysis, and death. High blood pressure, cigarette smoking, sedentary lifestyle, diabetes mellitus, lipid abnormalities, and overweight or obesity are the significant risk factors caused to cardiovascular disease (CVD). High blood pressure could be considered an alarm for human health, and it is crucial to control hypertension for several reasons, such as improving heart health, decreasing the chance of a Stroke, and protecting the Kidneys [59]. Figure 2 shows

the various ranges of blood pressure for adults according to National Health Service(NHS) recommendations.

<< Insert Figure 2 >>

4 A new approach for using PCIs in health assessment

In this section, firstly, a CDI is nominated to determine the distance between the target profile and an observed profile. Then, a procedure would be proposed to apply the opted CDI to summarize the health profile in the similarity variable and use the corresponding PCI as a health index.

4.1 A proper curves dissimilarity index for profiles summarization

Consider a target profile and some points of an observed profile, as illustrated in figure 3. Suppose that $x_1, x_2, \ldots, x_n$ are n predefined designed values of the independent variable. Also, $\left\{(x_1, y_1^T), (x_2, y_2^T), \ldots, (x_{n-1}, y_{n-1}^T), (x_n, y_n^T)\right\}$, and $\left\{(x_1, y_1^S), (x_2, y_2^S), \ldots, (x_{n-1}, y_{n-1}^S), (x_n, y_n^S)\right\}$ are points from the Target profile and observed profile, respectively.

<< Insert Figure 3 >>

The Euclidean distance, Manhattan distance, and Hausdorff distance between points (x_i, y_i^T) and (x_i, y_i^S) could be defined as follows.

$$d_E((x_i, y_i^T), (x_i, y_i^S)) = \sqrt{(x_i - x_i)^2 + (y_i^T - y_i^S)^2} = \left|y_i^T - y_i^S\right| \tag{12}$$

$$d_{Man}((x_i, y_i^T), (x_i, y_i^S)) = \left|x_i - x_i\right| + \left|y_i^T - y_i^S\right| = \left|y_i^T - y_i^S\right| \tag{13}$$

$$d_{Hos} = \max(\sqrt{(x_i - x_i)^2 + (y_i^T - y_i^S)^2}; i = 1, 2, \ldots, n) = \max(\left|y_i^T - y_i^S\right|; i = 1, 2, \ldots, n) \tag{14}$$

Euclidean distance and Manhattan distance provide *n* distance values for the distance between the target profile and the observed profile from figure 3, and adversely, Hausdorff distance proposes only one distance value as the degree of dissimilarity between these curves. Consequently, as shown in equation 15, a Hausdorff distance, the maximum value of Euclidean distances, or the most significant value among Manhattan distances are the same, which could be considered an index for dissimilarity assessment.

$$D_{\max} = \max\left\{d_E^i; i = 1, 2, ..., n\right\} = \max\left\{d_{Man}^i; i = 1, 2, ..., n\right\} \\ = d_{Hos} = \max(\left|y_i^T - y_i^S\right|; i = 1, 2, ..., n) \quad (15)$$

Where D_{max} represents the degree of dissimilarity of the observed profile to the Target profile. The first consequence resulting from the use of D_{max} would be the lack of need to fit a statistical model to each of the observed profiles and simplifies the process monitoring procedure due to replacing the multivariate profile monitoring methods with a univariate SPC.

4.2 The new approach for health assessment using PCI of health profiles

Each health profile represents the values of at least one human health factor as a dependent variable. For example, the Systolic profile shows the blood pressure when a heartbeat occurs. Hence, blood pressure could be considered a dependent variable in Systolic profiles. Some health factors, such as blood pressure, should be assessed over time. Therefore, the independent variable in such a health profile is time. For instance, the blood pressure is determined every fifteen minutes or half an hour daily. At first, the target curve, specification limits of D_{max}, predefined design points, and the sample size of health profiles should be provided as input information. Then, the values of the dependent variable in the design points of each observed profile would be measured. In this step, the information gathering for each observed profile might last one day or even more. For example, the information corresponding to one Diastolic

blood pressure profile is collected within 24 hours. After gathering all the essential points of the observed profile, it is time to measure the value of D_{max} for each observed profile. Now, there is a sample of D_{max}, considered an engineering characteristic. To do phase I of SPC for mentioned health profile, it is sufficient to do Phase I of SPC on D_{max}. As a result, a large-scale multivariate profile monitoring is replaced with a univariate SPC. To be more specific, for example, each of the Systolic and Diastolic profiles in figure 1 contains more than thirty separate simple linear profiles. Hence, it is necessary to monitor a huge number of parameters, including intercepts, slopes, and error variances of all these SLPs, using a unique Hotelling T^2, containing about 90 variables. On the other hand, using D_{max} mitigates the issues related to defining specification limits for many coefficients of SLPs when we determine the PCIs.

The following steps apply traditional phase I of SPC on D_{max}. If the result of the test of normality test about the distribution of D_{max} is positive, univariate control charts, such as *I-MR* control charts, are applied to monitor the health. After passing phase I, it is possible to determine the value of PCIs to assess the body's capability to perform typically. But, when the normality test shows a negative result, it is necessary to modify the sample size of the observed profiles to satisfy the central limit theorem conditions. Figure 4 illustrates a schematic representation of the proposed approach.

<< Insert Figure 4 >>

4.3 Simulation study on the blood pressure assessment

In this sub-section, the new approach is applied to assess the health of an individual's blood pressure. To analyze the human blood pressure, both Systolic and Diastolic profiles should pass

the mentioned above steps of the new approach, and an aggregate PCI should be calculated as the overall health of the body in terms of blood pressure as follows.

Step 1: The pattern of human blood pressure is different per person, and there is no target curve in this regard. Hence, only a standard curve could be proposed for each person under approximately constant physical and environmental conditions. However, according to figure 2, it is only possible to define target values for Systolic and Diastolic blood pressures. Table 2 gives the formulas of the partitions of a standard curve of Systolic and Diastolic profiles belonging to one person to some extent, similar to Figure 1.

<< Insert Table 2 >>

In table 2, Systolic and Diastolic profiles contain eighteen and seventeen linear segments, respectively. Considerably, in the traditional profile monitoring approach, a lot of quantities, including 35 slopes, 35 intercepts, and 35 error variances, must be monitored simultaneously. Figures 5 and 6 show the curves of the aforementioned Systolic and Diastolic profiles, respectively.

<< Insert Figure 5 >>

<< Insert Figure 6 >>

According to table 2, it is supposed that the intervals [90-140] and [60-90] are acceptable ranges of Systolic and Diastolic blood pressure, and observations out of these ranges imply that the person has low or high blood pressure. As a result, in this study, the midpoint of these intervals - 115(mmHg) and 75(mmHg)- are considered target values of Systolic and Diastolic blood pressure.

Step 2: In the human blood pressure study, the independent variable of Systolic and Diastolic profiles is time. A thirty-minute gap between two blood pressure measurements is a conventional policy in medicine. Therefore, in this simulation study, forty-eight design points are considered, and blood pressures are measured per half an hour between today at 9:30 AM and tomorrow at 9:00 AM. In figures 5-8, these points are coded from 0.5 to 24.

Step 3: When 115(mmHg) and 75(mmHg) are assumed target values of Systolic and Diastolic blood pressure, 25 and 15 could be supposed as the USL of D_{max} in Systolic and Diastolic profiles, respectively. This is clear that the LSL of D_{max} is zero.

Step 4: The sample size of observed profiles is supposed to be 25 in each Systolic and Diastolic blood pressure.

Step 5: A code is developed in the *MATLAB R2021a* to generate eighteen points of twenty-five Systolic observed profiles using the formulas from table 2 under the assumption that the variance of normally distributed error terms is 2.5 in the Systolic profile. Moreover, this simulation study supposes $\varepsilon \sim N(0, 0.9)$ to generate twenty-five Diastolic profiles. The generated Systolic and Diastolic profiles are shown in figures 7 and 8, respectively.

<< Insert Figure 7 >>

<< Insert Figure 8 >>

Figures 7 and 8 show the lowest blood pressure between 14 and 21, corresponding to the sleep time of the understudy person between 23:00 and 06:00.

Step 6: The values of D_{max} are presented in table 3.

<< Insert Table 3 >>

Step 7: Figures 9 and 10 show the probability plot of D_{max}, confirming its normality for both Systolic and Diastolic profiles, respectively, since the corresponding *p*-values are more significant than 0.05.

<< Insert Figure 9 >>

<< Insert Figure 10 >>

Step 8: The I-MR control charts of D_{max} of Systolic and Diastolic profiles are presented in figures 11 and 12, respectively. These control charts are analyzed using MINITAB 20.2.0.0 software.

<< Insert Figure 11 >>

<< Insert Figure 12 >>

The in-control state of control charts in figures 11 and 12 mean that phase I of SPC is passed successfully.

Step 9: The corresponding C_{pk} and the proportion of non-conforming profiles are determined by using equations 4 and 5, respectively, which are presented in table 4.

<< Insert Table 4 >>

In table 4, the C_{pk} of the Systolic profile is less than one, which means the Systolic blood pressure of the under-study person is capable of following its corresponding standard pattern less than 99.73 percent of the time. In other words, his heart performance would be abnormal 0.36 percent of the time. Compared to Systolic profile capability indices, the situation is a bit better in Diastolic blood pressure. Because the C_{pk} of the Diastolic profile is more significant than one, the percent of the times that the body of this person has abnormal performance in terms of Diastolic blood pressure is less than 0.01. Furthermore, the aggregate capability indices are

p=0.004532825 and C_{pk} =0.946162. Overall, this person falls in the abnormal range of blood pressure about 0.45 percent of the time. Medicines could make some thresholds for p and C_{pk} of the Systolic blood pressure, Diastolic blood pressure, and the overall blood pressure of each patient to provide the best curing or care policy.

5 Conclusion

The monitoring of health-related profiles and their capability assessment was considered in this paper. The conventional multivariate profile monitoring methods are not applicable for these profiles due to their complicated pattern. A new approach was proposed to replace the conventional multivariate techniques with a univariate SPC using dissimilarity indices. Additionally, the capability indices of profiles were interpreted as an index of health. The new approach was applied in a simulation study of human blood pressure assessment. The results showed that the heart of the under-study person has a better performance in terms of Diastolic blood pressure than Systolic blood pressure. Moreover, the blood pressure of this person is abnormal about 0.5 percent of the time.

The most significant limitation of the proposed method is allocating the specification limits to D_{max}. In addition, autocorrelation and correlation studies on the Systolic and Diastolic profiles could be recommended in future studies. Developing a new approach in other types of health profiles such as the Electrocardiogram (ECG), Electroencephalography(ECC), Heart rate monitoring, Lung diseases, Alzheimer's, and Parkinson's is an attractive topic for future works. Finally, the health capability analysis could be applied to providing related Internet of things (IoT) tools or expert systems.

Funding statement: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration of Conflicting Interests: The authors report no competing interests to declare.

Data and code availability statement: The Authors would submit the related data set and codes whenever a request is received.

Ethical statement: The Authors declare that no real clinical data is applied in this paper, and the required information is generated via simulation.

References

1. Oakland, J. and Oakland, R. "Statistical process control", *Routledge* (2018).
2. Berger, R.W. and Hart, T. "Statistical process control: A guide for implementation", *CRC Press* (2020).
3. Ge, Z. and Song, Z. "Multivariate statistical process control: Process monitoring methods and applications", *Springer Science & Business Media* (2012).
4. Noorossana, R., Saghaei, A., and Amiri, A. "Statistical analysis of profile monitoring", *John Wiley & Sons* (2011).
5. Maleki, M.R., Amiri, A., and Castagliola, P. "An overview on recent profile monitoring papers (2008–2018) based on conceptual classification scheme", *Computers & Industrial Engineering*, **126**, pp. 705-728 (2018).
6. Kotz, S. and Johnson, N.L. "Process capability indices—a review, 1992–2000", *Journal of quality technology*, **34**(1), pp. 2-19 (2002).
7. Pearn, W.l. and Kotz, S. "Encyclopedia and handbook of process capability indices: a comprehensive exposition of quality control measures", *World Scientific* (2006).
8. de-Felipe, D. and Benedito, E. "A review of univariate and multivariate process capability indices", "The International Journal of Advanced Manufacturing Technology", **92**(5), pp. 1687-1705 (2017).
9. Chakraborty, A.K. and Chatterjee, M. "Handbook of Multivariate Process Capability Indices", *CRC Press* (2021).
10. Kane, V.E. "Process capability indices", *Journal of quality technology*, **18**(1), pp. 41-52 (1986).

11. Dharmasena, L. and Zeephongsekul, P. "A new process capability index for multiple quality characteristics based on principal components", *International Journal of Production Research*, **54**(15), pp. 4617-4633 (2016).
12. Hadian, H. and Rahimifard, A. "Multivariate statistical control chart and process capability indices for simultaneous monitoring of project duration and cost", *Computers & Industrial Engineering*, **130**, pp. 788-797 (2019).
13. Yang, J., Meng, F., Huang, S., et al. "Process capability analysis for manufacturing processes based on the truncated data from supplier products", *International Journal of Production Research*, **58**(20), pp. 6235-6251 (2020).
14. Wang, S., Chiang, J.Y., Tsai, T.R. et al. "Robust process capability indices and statistical inference based on model selection", *Computers & Industrial Engineering*, **156**, pp. 107265 (2021).
15. Nemati Keshteli, R., Baradaran Kazemzadeh, R., Amiri, A. et al. "Functional process capability indices for circular profile", *Quality and Reliability Engineering International*, **30**(5), pp. 633-644 (2014).
16. Guevara, R.D., Vargas, J.A. and Castagliola, P. "Evaluation of process capability in non-linear profiles using Hausdorff distance", *Quality Technology & Quantitative Management*, **13**(1), pp. 1-15 (2016).
17. Couto, G.E., Oprime, P.C. and Ganga, G.M.D. "Process capability indices for profiles: a systematic literature review", *Revista Gestão da Produção Operações e Sistemas*, **16**(1), (2021).
18. Alevizakos, V., Koukouvinos, C. and Castagliola, P. "Process capability index for Poisson regression profile based on the S pmk index", *Quality Engineering*, **31**(3), pp. 430-438, (2019).
19. Hosseinifard, S.Z. and Abbasi, B. "Evaluation of process capability indices of linear profiles", *International Journal of Quality & Reliability Management*, 29(2), pp.162-176 (2012).
20. Hosseinifard, S.Z. and Abbasi, B. "Process capability analysis in non normal linear regression profiles", *Communications in Statistics-Simulation and Computation*, **41**(10), pp. 1761-1784 (2012).
21. Ebadi, M. and Amiri, A. "Evaluation of process capability in multivariate simple linear profiles", *Scientia Iranica*, **19**(6), pp. 1960-1968, (2012).
22. Ebadi, M. and Shahriari, H. "A process capability index for simple linear profile", *The International Journal of Advanced Manufacturing Technology*, **64**(5-8), pp. 857-865, (2013).
23. Wang, F.K. and Guo, Y.C. "Measuring process yield for nonlinear profiles", *Quality and Reliability Engineering International*, **30**(8), pp. 1333-1339 (2014).
24. Nemati Keshteli, R., Baradaran Kazemzadeh, R., Amiri, A. et al. "Developing functional process capability índices for simple linear profile", *Scientia Iranica- Transaction E, Industrial Engineering*, **21**(3), pp. 1096-1104 (2014).
25. Wang, F.K. "A process yield for simple linear profiles", *Quality Engineering*, **26**(3), pp. 311-318 (2014).
26. Wang, F.K. "Measuring the process yield for simple linear profiles with one-sided specification", *Quality and Reliability Engineering International*, **30**(8), pp. 1145-1151 (2014).

27. Wang, F.K. and Tamirat, Y. "Process yield analysis for autocorrelation between linear profiles", *Computers & Industrial Engineering*, **71**, pp. 50-56 (2014).
28. Wang, F.K. and Tamirat, Y. "Process Yield Analysis for Linear Within-Profile Autocorrelation", *Quality and Reliability Engineering International*, **31**(6), pp. 1053-1061 (2015).
29. Clements, J.A. "Process capability calculations, for non-normal distributions", *Quality progress*, **22**, pp. 95-100 (1989).
30. Guevara, R.D. and Vargas, J.A. "Process capability analysis for nonlinear profiles using depth functions", *Quality and Reliability Engineering International*, **31**(3), pp. 465-487, (2015).
31. Rezaye Abbasi Charkhi, M., Aminnayeri, M. and Amiri, A. "Process capability indices for logistic regression profile", *Quality and Reliability Engineering International*, **32**(5), pp. 1655-1661 (2016).
32. Amiri, A. and Rezaye Abbasi Charkhi, M. "Process capability index for logistic regression profile based on Spmk Index", *International Journal of Engineering*, **28**(8), pp. 1186-1192 (2015).
33. Niavarani, M.R., Noorossana, R. and Abbasi, B. "Three new multivariate process capability indices", *Communications in Statistics-Theory and Methods*, **41**(2), pp. 341-356 (2012).
34. Karimi Ghartemani, M., Noorossana, R. and Niaki, S.T.A. "A new approach in capability analysis of processes monitored by a simple linear regression profile", *Quality and Reliability Engineering International*, **32**(1), pp. 209-221 (2016).
35. Guevara, R.D. and Vargas, J.A. "Evaluation of process capability in multivariate nonlinear profiles", *Journal of Statistical Computation and Simulation*, **86**(12), pp. 2411-2428 (2016).
36. Wang, F.K. "Process yield analysis for nonlinear profiles in the presence of gauge measurement errors", *Quality and Reliability Engineering International*, **32**(7), pp. 2435-2442 (2016).
37. Wang, F. K. "Process yield analysis for multivariate linear profiles", *Quality Technology and Quantitative Management*, **13**(2), pp. 124-138 (2016).
38. Wang, F.K. and Tamirat, Y. "Process Yield for Multivariate Linear Profiles with One-sided Specification Limits", *Quality and Reliability Engineering International*, **32**(4), pp. 1281-1293 (2016).
39. Chiang, J.Y., Lio, Y. and Tsai, T.R. "MEWMA control chart and process capability indices for simple linear profiles with within-profile autocorrelation", *Quality and Reliability Engineering International*, **33**(5), pp. 1083-1094 (2017).
40. Wang, F.K., Huang, C.Y. and Tamirat, Y. "Implementing EWMA Yield Index for Simple Linear Profiles with One-sided Specifications in Product Acceptance Determination", *Quality and Reliability Engineering International*, **33**(2), pp. 401-412 (2017).
41. Aslam, M., Wang, F.K., Khan, N. et al. "A multiple dependent state repetitive sampling plan for linear profiles", *Journal of the operational research society*, **69**(3), pp. 467-473 (2018).
42. Abbasi Ganji, Z. and Sadeghpour Gildeh, B. "Fuzzy process capability indices for simple linear profile", *Journal of Applied Statistics*, **47**(12), pp. 2136-2158 (2020).

43. Alevizakos, V. and Koukouvinos, C. "Evaluation of process capability in gamma regression profiles", *Communications in Statistics-Simulation and Computation*, **51**(9), pp. 5174-5189 (2022).
44. Pakzad, A., Razavi, H. and Sadeghpour Gildeh, B. "Developing loss-based functional process capability indices for simple linear profile", *Journal of Statistical Computation and Simulation*, **92**(1), pp. 115-144 (2022).
45. Mehri, S., Ahmadi, M.M., Shahriari, H. et al. "Robust process capability indices for multiple linear profiles", *Quality and Reliability Engineering International*, **37**(8): pp. 3568-3579 (2021).
46. Guevara G, R.D. and Alejandra López, T. "Process capability vector for multivariate nonlinear profiles", *Journal of Statistical Computation and Simulation*, **92**(6), pp. 1292-1321 (2022).
47. Goshtasby, A.A. "Image registration: Principles, tools and methods", *Springer Science and Business Media* (2012).
48. Shirkhorshidi, A.S., Aghabozorgi, S. and Wah, T.Y. "A comparison study on similarity and dissimilarity measures in clustering continuous data", *PloS one*, **10**(12), p.e0144059 (2015).
49. Bernardi, M. S., Pelucchi, M. A. T. T. E. O., Stagni, A. L. E. S. S. A. N. D. R. O., et al. "Curve matching, a generalized framework for models/experiments comparison: An application to n-heptane combustion kinetic mechanisms", *Combustion and Flame*, **168**, pp. 186-203 (2016).
50. Jekel, C. F., Venter, G., Venter, M. P., et al. "Similarity measures for identifying material parameters from hysteresis loops using inverse analysis", *International Journal of Material Forming*, **12**(3), pp. 355-378 (2019).
51. Lv, C., Wu, Z., Wang, X., et al. "Nasal similarity measure of 3D faces based on curve shape space", *Pattern Recognition*, **88**, pp. 458-469 (2019).
52. Meng, X., Fu, H., Liu, G., et al. "Multi-Feature Fusion: A Driver-Car Matching Model Based on Curve Comparison", *IEEE Access*, **7**, pp. 83526-83535 (2019).
53. Li, W. and Li, G. "Railway's Turnout Fault Diagnosis Based on Power Curve Similarity. in 2019 International Conference on Communications", *Information System and Computer Engineering (CISCE)-IEEE*, pp. 112-115 (2019).
54. Ontañón, S. "An overview of distance and similarity functions for structured data", *Artificial Intelligence Review*, **53**(7), pp. 5309-5351 (2020).
55. Wang, C. C., Chen, K. S., Wang, C. H., et al. "Application of 6-sigma design system to developing an improvement model for multi-process multi-characteristic product quality", *Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture*, **225**(7), pp. 1205-1216 (2011).
56. Ezzati, M., Lopez, A. D., Rodgers, A. A., et al. "Comparative quantification of health risks. Global and regional burden of disease attributable to selected major risk factors", *Geneva: World Health Organization*, pp. 1987-1997 (2004).
57. O'Brien, E. and Dolan, E. "Ambulatory blood pressure monitoring for the effective management of antihypertensive drug treatment", *Clinical therapeutics*, **38**(10), pp. 2142-2151 (2016).
58. Asayama, K., Satoh, M. and Kikuya, M. "Diurnal blood pressure changes", *Hypertension Research*, **41**(9), pp. 669-678 (2018).

59. Fuchs, F.D. and Whelton, P.K. "High blood pressure and cardiovascular disease", *Hypertension*, **75**(2), pp. 285-292 (2020).

Biographical note:

Arash Nemati is an assistant professor of Industrial Engineering at the Babol Noshirvani University of Technology. His research interest is the application of Statistical Quality Control and Supply Chain Planning in the Healthcare sector. He has published several papers on the Process capability indices of profiles. And currently, he is working on the Additive manufacturing process quality assurance using Computer vision.

Shirin Mehrdoost is a Master's degree student in Industrial Engineering at the Babol Noshirvani University of Technology. Her research has focused on Profile Monitoring, Process Capability Indices, Simulation, and Healthcare Engineering.

List of Tables' caption:

Table 1. The estimator of parameters in univariate control charts

Table 2. An example of mathematical formulas of blood pressure profiles on an individual

Table 3. The values of D_{max} in Systolic and Diastolic profiles

Table 4. The results of Systolic and Diastolic profiles capability analysis

List of Figures' caption:

Figure 1. Systolic, the upper diagram, and Diastolic patterns of human blood pressure for an individual (O'Brien and Dolan (2016))

Figure 2. Standard ranges of blood pressure

Figure 3. Distance between the target profile and an observed profile

Figure 4. Schematic representation of the proposed approach

Figure 5. The standard curve of the Systolic profile of the under-study person

Figure 6. The standard curve of the Diastolic profile of the under-study person

Figure 7. The pattern of generated Systolic profiles

Figure 8. The pattern of generated Diastolic profiles

Figure 9. The probability plot of D_{max} for Systolic profile

Figure 10. The probability plot of D_{max} for the Diastolic profile

Figure 11. I-MR control charts of D_{max} of the Systolic profile

Figure 12. I-MR control charts of D_{max} of the Diastolic profile

Tables:

Table 1. The estimator of parameters in univariate control charts

Control Chart	μ	σ
$\overline{X}-S$	$\overline{\overline{X}}$	$\frac{\overline{S}}{C_4}$
$\overline{X}-R$	$\overline{\overline{X}}$	$\frac{\overline{R}}{d_2}$
$I-MR$	$\overline{X}$	$\frac{\overline{M}}{d_2}$

Table 2. An example of mathematical formulas of blood pressure profiles on an individual

Line	Systolic	Diastolic

1	$-8x+121$	$-7x+79.5$
2	$-3x+116$	$2.66x+65$
3	$6x+98$	$-0.857x+75.57$
4	$-12x+152$	$2.66x+52.662$
5	$3.5x+97.75$	$-1.5x+86$
6	$-18x+216$	$0.5x+66$
7	$2.33x+94$	$-6x+144$
8	$-3.2x+143.8$	$6x-6$
9	$2.8x+74.8$	$-5.5x+149.25$
10	$-18x+366$	$6x-29$
11	$10x-54$	$-2x+99$
12	$-12x+298$	$8x-76$
13	$6.66x-10$	$-8x+212$
14	$-5.5x+209$	$5.33x-41.33$
15	$26x-421$	$-3.33x+136.33$
16	$-12x+358$	$12x-201$
17	$10.66x-129.33$	$-3x+144$
18	$-3x+185$	

Table 3. The values of D_{max} in Systolic and Diastolic profiles

Generated profiles	D_{max} of the Systolic profile	D_{max} of the Diastolic profile	Generated profiles	D_{max} of the Systolic profile	D_{max} of the Diastolic profile
1	17.0473	11.7204	14	16.8429	11.5203
2	20.9575	12.1474	15	18.2551	12.4613
3	20.9936	12.2501	16	18.3082	12.6730
4	20.7002	12.8064	17	18.7449	12.3032
5	19.0091	13.0134	18	24.3298	11.2402
6	18.2920	10.8982	19	18.8387	12.1013
7	18.6474	13.7902	20	21.6882	12.7924
8	23.6527	11.6414	21	19.2333	11.4111
9	21.6072	13.1249	22	18.8730	13.7797
10	17.7449	12.6239	23	18.7283	11.2252
11	16.4043	12.6649	24	22.0732	11.5247
12	19.8625	11.9071	25	19.6733	11.5445
13	19.1312	12.1583			

Table 4. The results of Systolic and Diastolic profiles capability analysis

Chart	p	C_{pk}
Systolic	0.003565	0.9714231

Diastolic	0.000971	1.0995928

Figures:

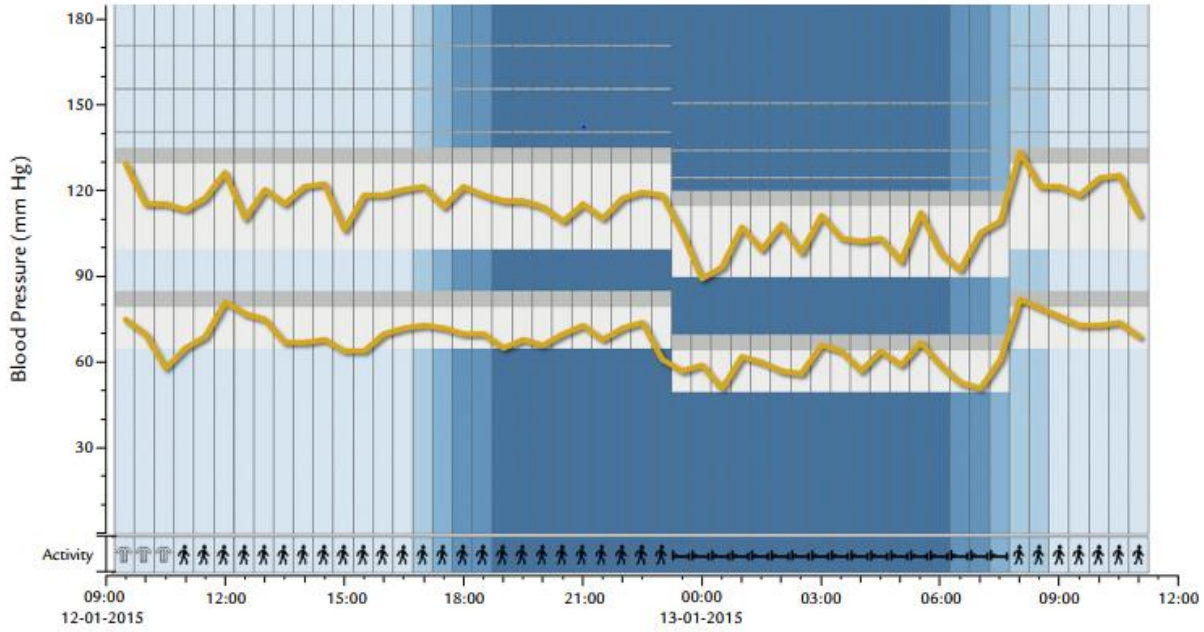

Figure 1. Systolic, the upper diagram, and Diastolic patterns of human blood pressure for an individual (O'Brien and Dolan (2016))

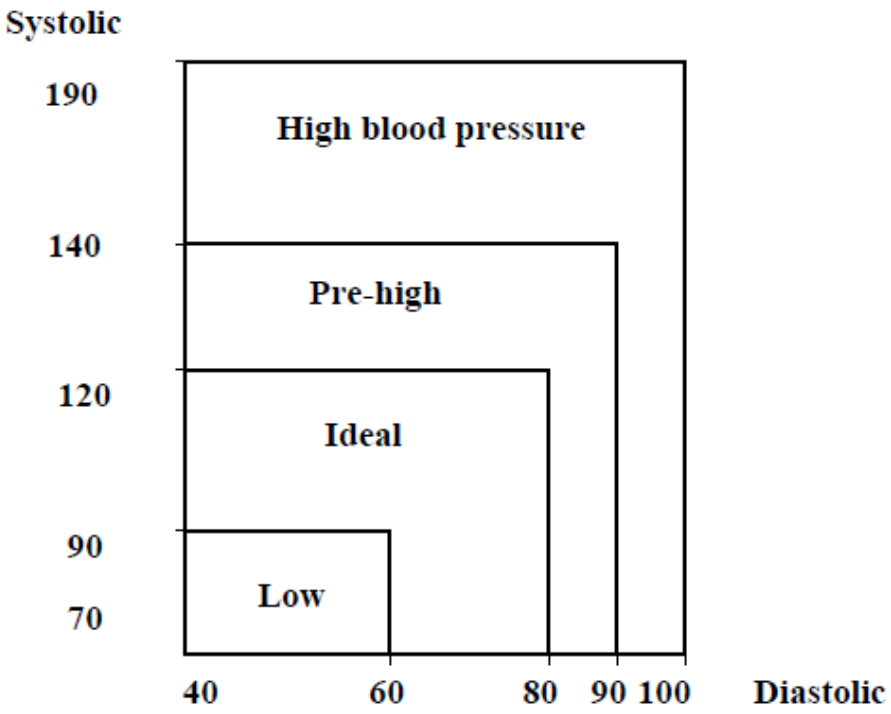

Figure 2. Standard ranges of blood pressure

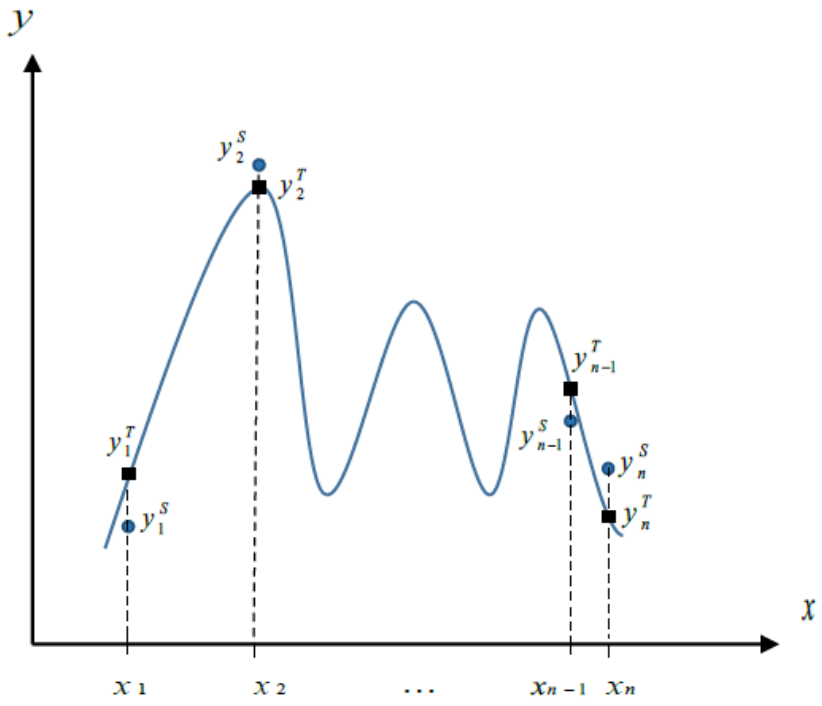

Figure 3. Distance between the target profile and an observed profile

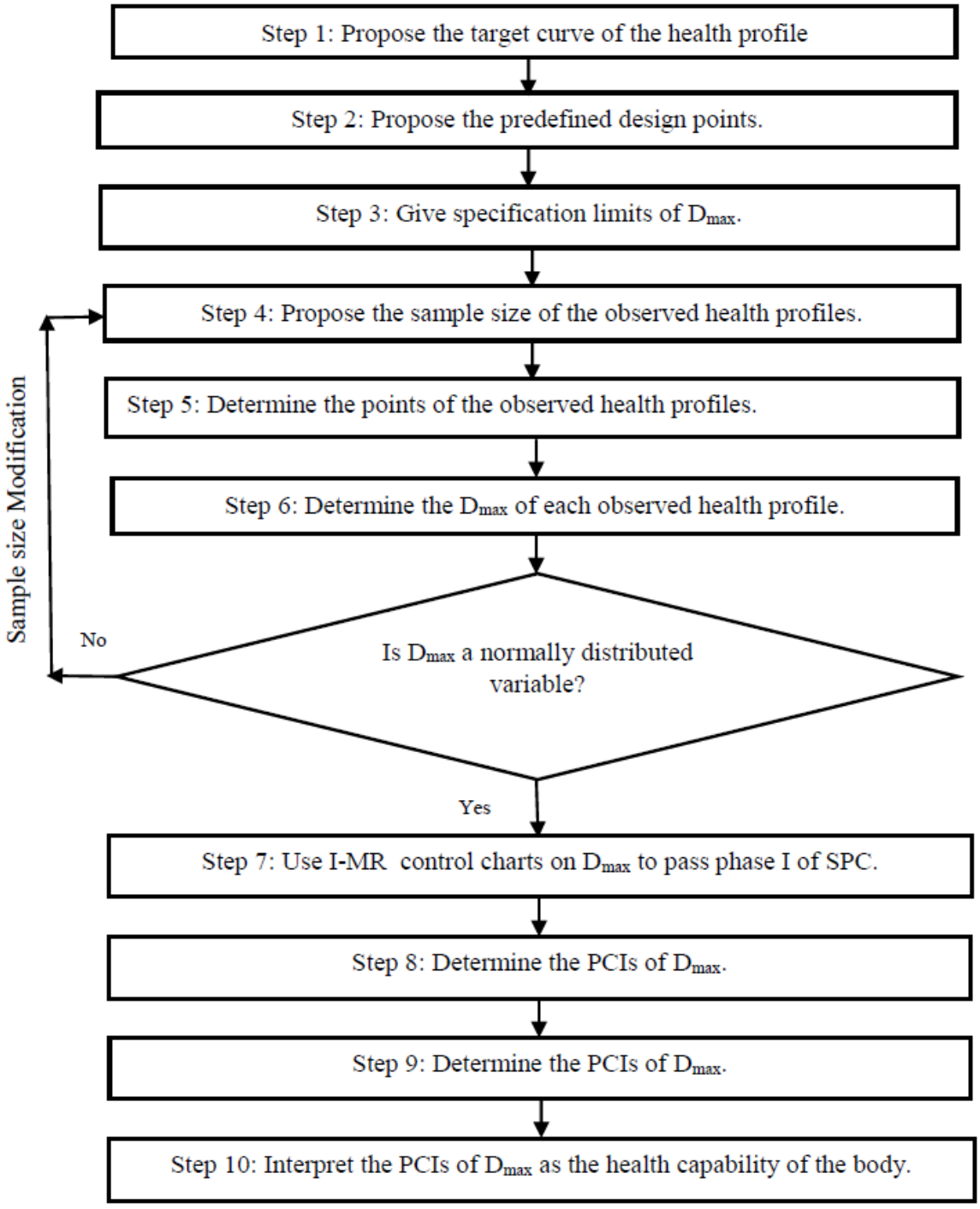

Figure 4. Schematic representation of the proposed approach

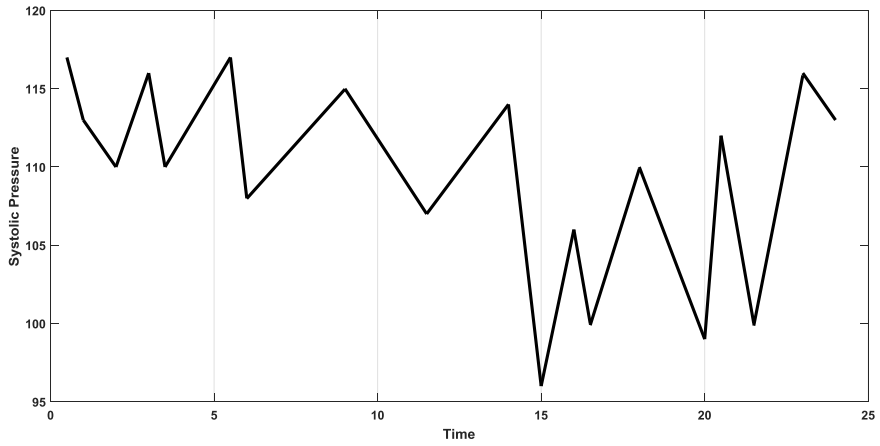

Figure 5. The standard curve of the Systolic profile of the under-study person

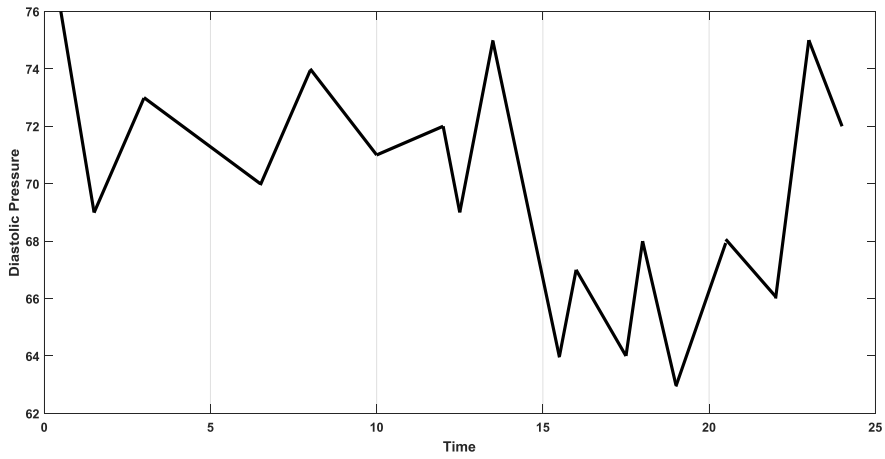

Figure 6. The standard curve of the Diastolic profile of the under-study person

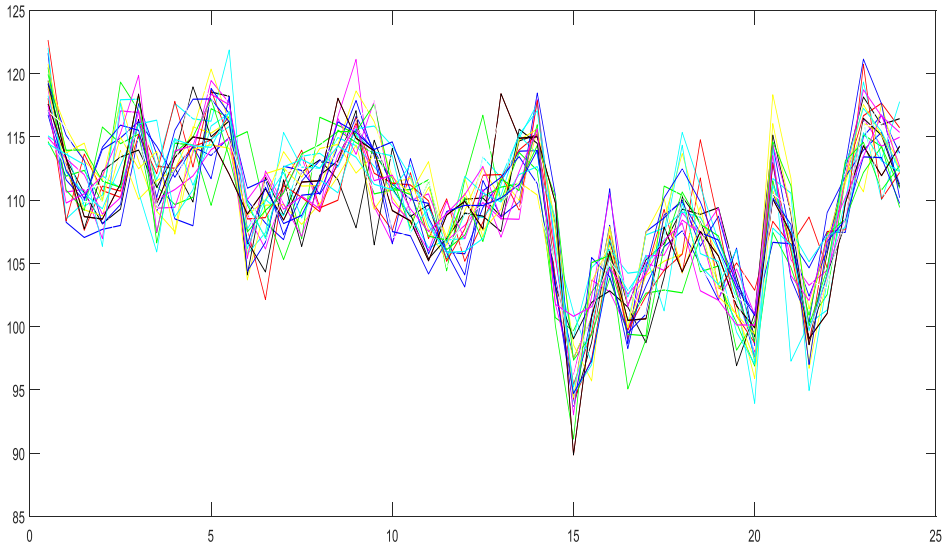

Figure 7. The pattern of generated Systolic profiles

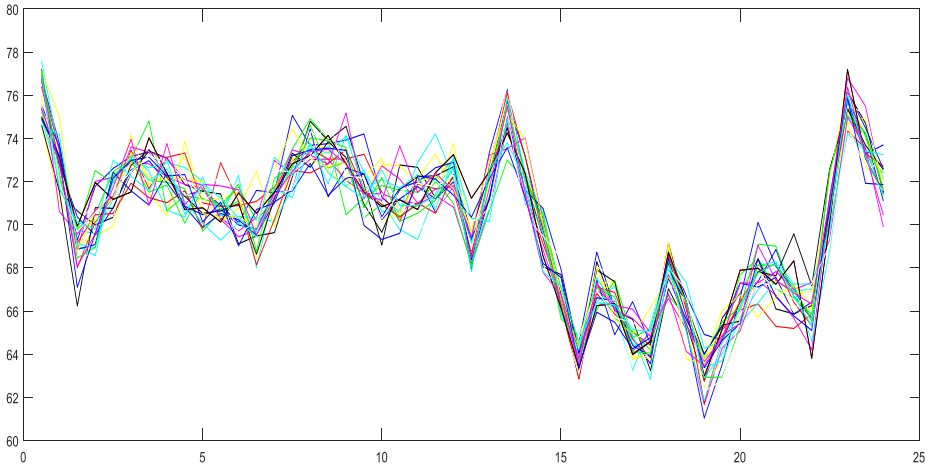

Figure 8. The pattern of generated Diastolic profiles

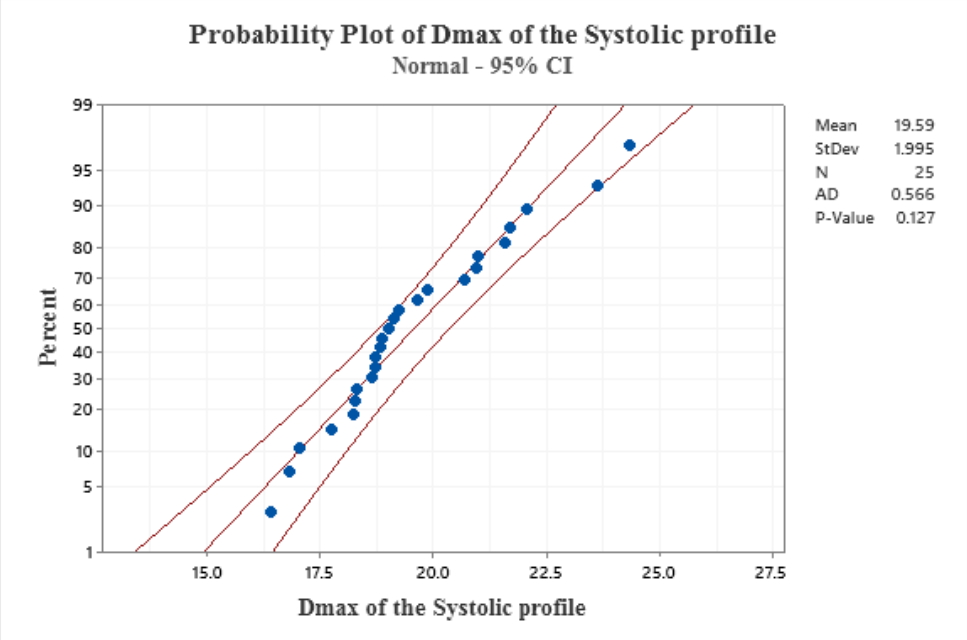

Figure 9. The probability plot of D_{max} for the Systolic profile

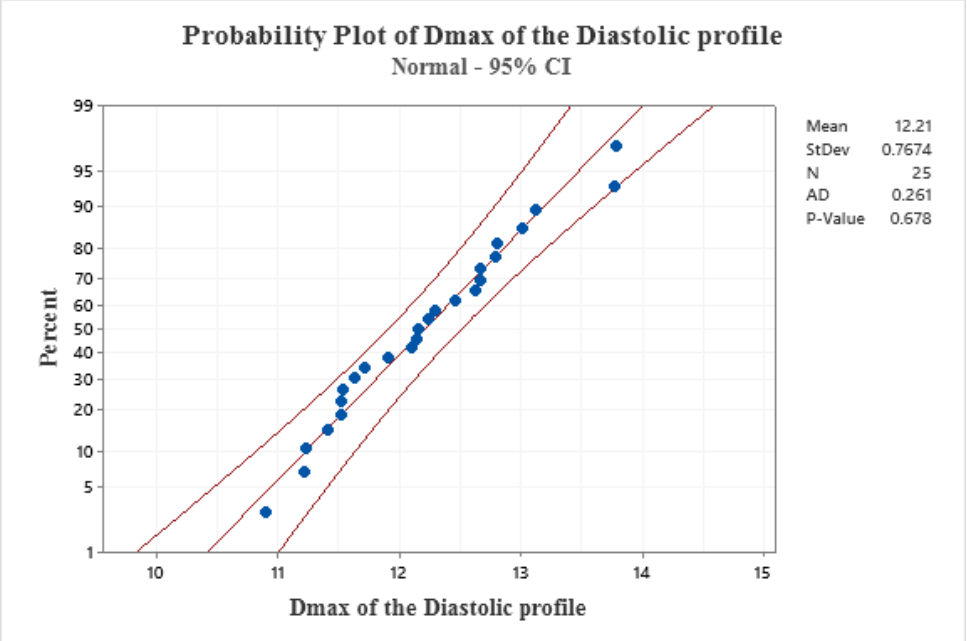

Figure 10. The probability plot of D_{max} for the Diastolic profile

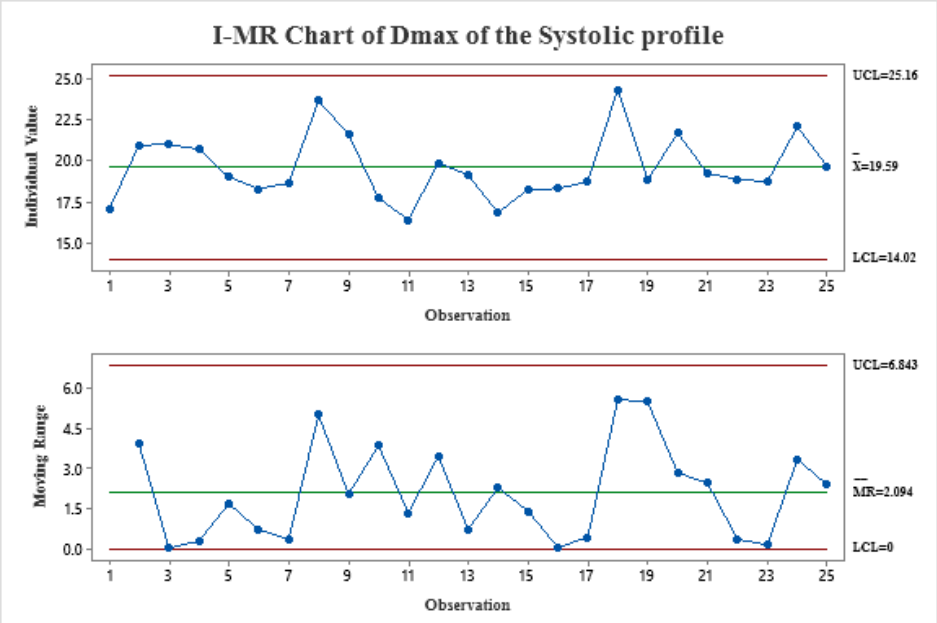

Figure 11. I-MR control charts of D_{max} of the Systolic profile

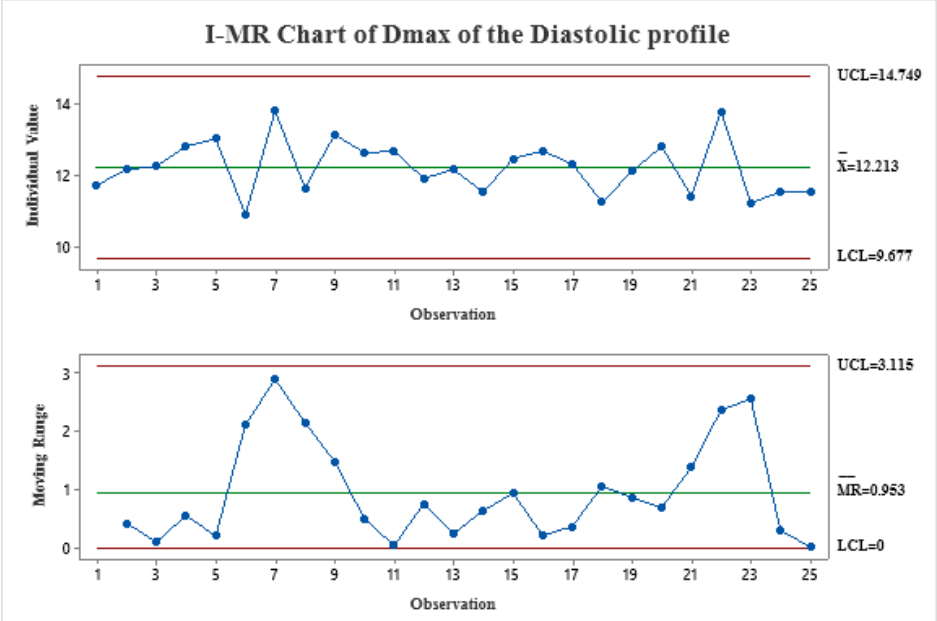

Figure 12. I-MR control charts of D_{max} of the Diastolic profile