Research on Quality Control of Medical Device Production Process

Weihong Sun, Jingwen Ma, and Man Liang

***Abstract*—Firstly, the information of the workpiece is collected into the MES (Manufacturing Execution System) system, the control charts are drawn according to the process quality data, and the network model based on the abnormal pattern recognition of the control charts is established. The PSO algorithm is improved by referring to the linear mutation operator to optimize the parameters of the BP algorithm. The output error is minimized. Then, the improved PSO-BP algorithm is used to identify the abnormal pattern and find the problems in production and stop processing. Finally, the experimental results show that compared with the BP algorithm and the PSO-BP algorithm, the improved PSO-BP algorithm has improved both accuracy and speed, and provides a viable solution for quality control of medical device manufacturing processes.**

***Index Terms*—Medical device, process, SPC, improved pso-bp algorithm, quality control.**

I. Introduction

As a part of the health business, medical equipment has received more and more attention to its product quality [1]. Medical devices are special products that play an important role in the treatment and prevention of people's diseases, and are also a vital component of the medical profession [2]. Medical device products are characterized by high risks and are therefore important for the management of their quality. In the past, the production management methods of medical device products could not meet the high requirements of enterprises and customers for product quality, and could not monitor the production process in real time. Therefore, how to effectively control the quality of medical device processing processes is of great significance.

The US FDA (Food and Drug Administration) has certain standards for the quality of medical devices, and products that meet the standards can enter the market [3]. Literature [4] mentioned that South Korea mainly uses the analytic hierarchy process in the management of medical device production, but the evaluation in the analytic hierarchy process is done manually, and is susceptible to subjective factors and not rigorous. In the development of existing medical device enterprises, the combination of information technology and traditional quality tools have contributed to the management of medical device quality. SPC technology is based on statistics and is widely used in quality monitoring techniques in production processes [5], [6], which is used to improve the monitoring of production processes. However, the traditional SPC technology can only judge whether the production process is abnormal, and it is impossible to determine which part of the problem occurs and it is not real-time. In the literature [7], [8], the combination of BP neural network and SPC technology is applied respectively, and the method based on key process quality control is proposed. However, the traditional BP neural network is easy to fall into local optimum, resulting in high diagnostic error and convergence. The speed is slower.

This article starts from the processing of CNC pneumatic tourniquets made by medical device companies. Through the real-time acquisition of process quality data, the control charts are drawn, and the improved PSO-BP algorithm is used to identify the abnormal mode and adjust the key processes to achieve the purpose of improving quality. It provides a new program for rapid quality control of medical equipment manufacturers.

II. Overall Research program

With the development of information technology, MES, ERP (Enterprise Resources Planning), etc. are widely used in manufacturing enterprises. MES is used to collect a large amount of real-time data generated during the entire production process [9]. After processing by the production model, it maintains two-way communication capabilities with ERP and DCS (Distributed Control System) to obtain corresponding data. The medical device production workshop issues a plan order, and the materials enter the workshop to start processing. When the workpiece enters the key process, the staff records the quality data of the workpiece according to the process card requirements and inputs it into the MES system [10]. After preprocessing the data, the system generates the mean-extreme control map of the quality data of the workpiece, and uses the improved PSO-BP algorithm to identify the abnormal pattern of the control graph and analyze the cause, and then adjust the production process to re-enter Process. The overall scheme of MES quality control based on improved PSO-BP algorithm is shown in Fig. 1.

The main steps of the program are as follows: SQL Server 2012 is used as the background support database, the control charts are drawn by Minitab17 software according to the quality data, and the PSO-BP algorithm is used to improve

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Weihong Sun, Jingwen Ma, and Man Liang are with the College of Mechanical and Electrical Engineering, China Jiliang University, No.258, Xueyuan Street, Xiasha Advanced Education Park, 310018 Hangzhou, China (Corresponding Author: Weihong Sun; e-mail: whsun@126.com, 15382357130@163.com, 18A0104152@cjlu.edu.cn).

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the abnormal mode after MATLAB programming operation, and the problem process is adjusted in time to improve the process quality.

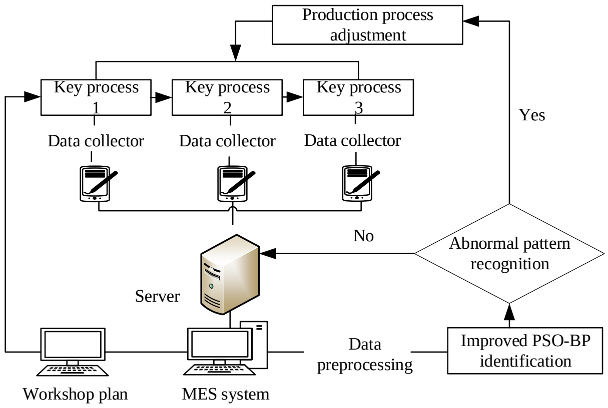


Fig. 1. Overall scheme of MES quality control based on improved PSO-BP algorithm.

III. SPC Technology Application Process

The process in statistical process control contains more content. In the process, the process that has a key impact on product service characteristics and quality is the key process [11]. After confirming the key process, the information process is used to process the key process on site. Quality data is collected. Control charts are commonly used data analysis tools in SPC technology. Each type of control charts has its corresponding physical meaning for easy identification. In general, there are eight exception modes in the control charts. The corresponding mode of the target output is shown in Table I. The control charts are drawn according to the quality data collected during the production process, and the abnormal mode is judged according to the control charts.

TABLE I: Control Exception Mode Coding Table

Number	Mode	Code
1	Normal mode	1 0 0 0 0 0 0 0
2	Periodic mode	0 1 0 0 0 0 0 0
3	Gradually rising	0 0 1 0 0 0 0 0
4	Decreasing gradually	0 0 0 1 0 0 0 0
5	Up step	0 0 0 0 1 0 0 0
6	Down step	0 0 0 0 0 1 0 0
7	Layered mode	0 0 0 0 0 0 1 0
8	System mode	0 0 0 0 0 0 0 1

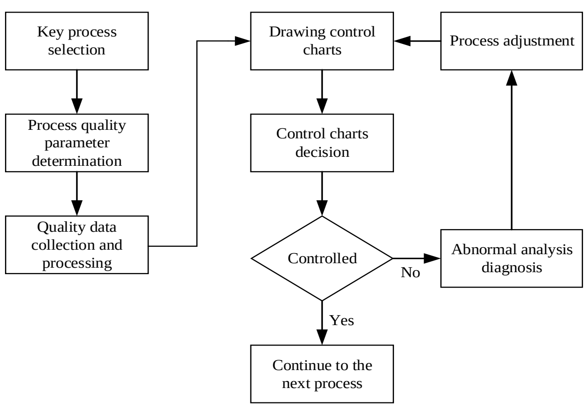


Fig. 2. SPC technology application process.

SPC technology can be used to comprehensively analyze the factors that affect the process quality of medical devices in the production process, including "human, machine, method, material, measurement and ring". In case of abnormalities, problems can be found in time and procedures can be adjusted. The SPC technical process is shown in Fig. 2.

IV. Research on Abnormal Pattern Recognition Algorithm of Control Charts

A. BP Neural Network Algorithm

BP (backpropagation) neural network is a typical multi-layer feedforward neural network, and it is also an algorithm with strong classification and prediction ability. At present, BP neural network has been successfully applied in the field of pattern recognition, which also includes the identification of SPC control charts. The structure of the neural network model is shown in Fig. 3.

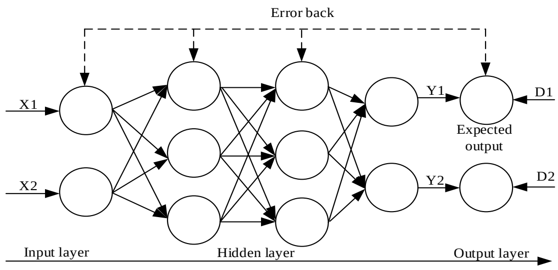


Fig. 3. BP neural network model.

B. PSO Algorithm

Although BP has been widely used in statistical process control technology, it also has some shortcomings. For example, traditional BP algorithm has problems such as easy to fall into local minimum value and slow convergence speed during training. Combining the particle swarm optimization algorithm and the neural network, the particle swarm optimization algorithm is used to optimize the parameters of the error back propagation neural network, and reduce the time of the iteration, so that the possibility of falling into the local optimal solution is reduced. Each particle in the particle swarm algorithm represents a potential solution to a problem. Each particle corresponds to a fitness value determined by a fitness function. The velocity of the particle determines the direction of the particle's movement and the speed of the distance with its own and other particles. Dynamic adjustments are made to achieve individual optimization of the solution space [12].

The standard particle swarm optimization algorithm seeks the optimal solution process as follows: Assume that in a $D-\dim ensional$ search space, there are populations $X=\left(X_1,X_2,......,X_n\right)$ composed of n particles, where the $i-th$ particle is represented as a $D-\dim ensional$ vector $X=\left(X_{i1},X_{i2},......,X_{iD}\right)^T$, representing the $i-th$ particle The location in the $D-\dim ensional$ search space also represents a potential solution to the problem. According to the objective function, the fitness value corresponding to the X position of each particle can be calculated.

In each iteration, the particles update their speed and position through individual extremum and global extremum. The formulas are updated as follows:

$$V_{id}^{k+1} = \omega V_{id}^{k} + c_1 r_1 \left(P_{\mathrm{id}}^{k} - X_{\mathrm{id}}^{k}\right) + c_2 r_2 \left(P_{\mathrm{id}}^{k} - X_{\mathrm{id}}^{k}\right) \quad (1)$$

$$X_{id}^{k+1} = X_{id}^{k} + V_{id}^{k+1} \quad (2)$$

$d = 1,2,3,......,D$

In the formulas (1) and (2), V_{id} represents the velocity of the $i-th$ particle($\mathrm{i} = 1,2,3,......,n$); X_{id} represents the position of the $i-th$ particle; P_{id} represents the individual extremum; P_{gd} represents the population extremum; k represents the current iteration number; c_1, c_2 represent the acceleration factors which are non-negative constants; r_1, r_2 are two numbers between [0, 1].

In the formula, ω represents the inertia weight, which is also the key adjustable parameter in the particle swarm algorithm. It can be known from formula (1) that the parameters of ω are adjusted appropriately to improve the convergence speed and search ability. Refer to the nonlinear weight calculation formula in [13]. To determine ω, the formula is as follows:

$$\omega = \omega_{\max} - \left(\omega_{\max} - \omega_{\min}\right) \tan\left(\frac{t}{t_{\max}} \times \frac{\pi}{4}\right) \quad (3)$$

In formula (3), when the algorithm is initially, the time t is small, ω changes linearly; as t increases, ω nonlinearly decrements, using this method to calculate ω, which not only ensures the global search ability, but also guarantees the local Search ability.

C. Improved PSO Algorithm

Although the original particle swarm algorithm has strong convergence, the efficiency of post-iteration will decrease. Therefore, this paper introduces a mutation operation for the PSO algorithm, and re-initializes some particles in the population with a certain probability. This operation can expand the search space in the iterative process, so that the particles can jump out preferentially and improve the possibility of finding the optimal solution.

In view of the shortcomings of the traditional PSO algorithm, this paper introduces a linear mutation operator with the following formula:

$$P(n) = P_{\min} + \frac{n}{N}\left(P_{\max} - P_{\min}\right) \quad (4)$$

In formula (4), $P(\mathrm{n})$ represents the current mutation probability; n represents the current number of iterations; N represents the maximum number of iterations; $P_{\min}$ represents the minimum mutation probability; $P_{\max}$ represents the maximum mutation probability.

According to the formula, after the mutation operator is introduced, when the population first iterates, the mutation is performed with a small probability. As the number of iterations increases, the mutation probability increases, and the particles can jump out of the current region preferentially. Large space to find the optimal solution.

D. Improved PSO-BP Algorithm

Using the improved PSO-BP algorithm, the convergence speed is improved under the premise of ensuring accuracy, so that the time for judging abnormality is reduced.

The basic steps of the improved PSO-BP algorithm are as follows: Firstly, the input and output parameters of the topology of the neural network are determined according to the problem to be solved; then the BP neural network threshold and weight sequence are mapped to the individual length of the particle group, and the particles are updated by iteration. The speed and position achieve the purpose of parameter optimization; finally, the PSO algorithm assigns the optimal individual found to the neural network, so that the neural network obtains the optimal weight and offset as the initial value of the training. After the network is trained, Predictive output, improved PSO-BP algorithm flow chart shown in Fig. 4.

The improved PSO-BP algorithm combined with SPC technology is applied in the production process of medical device products. By judging the abnormal pattern of the control charts, the problem links in the above six links are found, and the accuracy is improved while the time efficiency is improved.

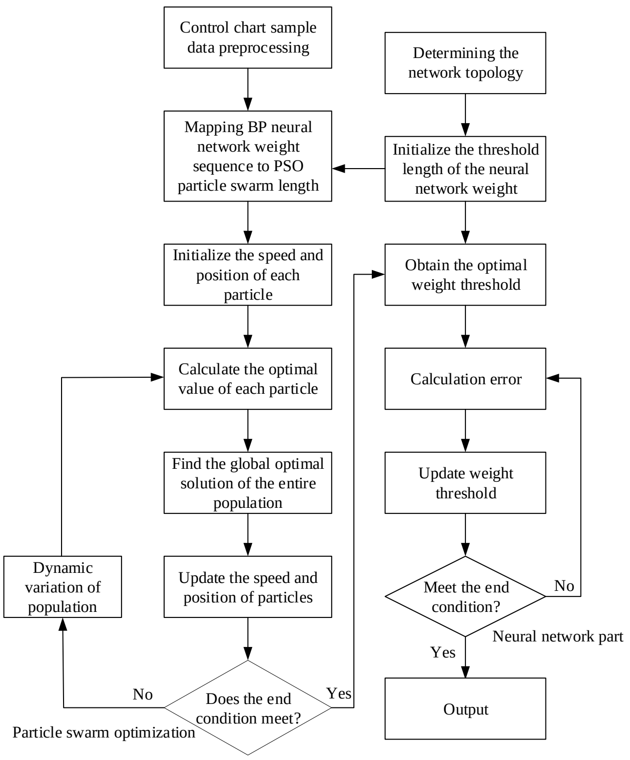


Fig. 4. Flow chart of improved PSO-BP algorithm.

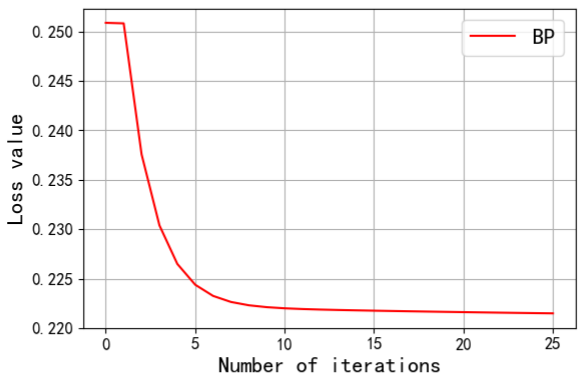
After network training, the sum of the absolute values of the error between the predicted output and the expected output is calculated as the fitness function, and its calculation formula is:

$$F = k\left(\sum_{i=1}^{n} abs\left(y_i - o_i\right)\right) \quad (5)$$

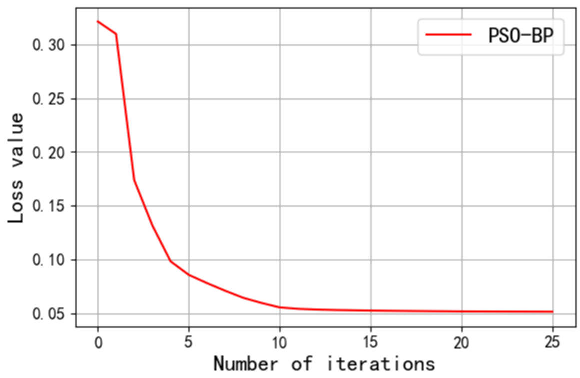
In formula (5), y_i represents the network prediction output after training; o_i represents the network expected output after training; n represents the total number of test samples; k represents a constant coefficient.

V. Application Results and Case Studies

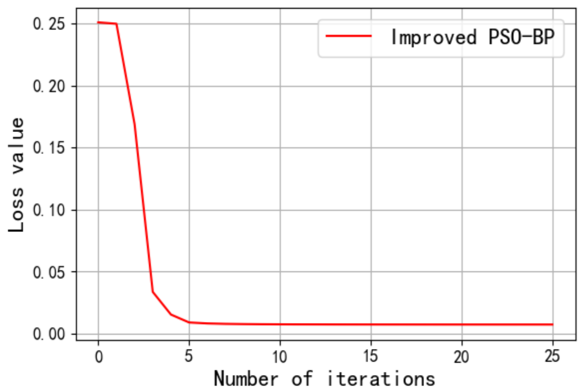
A. Parameter Settings



(a) BP algorithm



(b) PSO-BP algorithm



(c) Improved PSO-BP algorithm

Fig. 5. Network prediction output erro.

Based on the above analysis, the structure of the BP neural network is determined to be 24-30-8. There are 24 input layer neurons, which correspond to the quality characteristics of 24 consecutive points of the mean-extreme difference graph. The number of hidden layer neurons is 30, and the output layer neurons correspond to the 8 abnormal patterns of the control graph. The initial parameters of the optimized particle swarm optimization algorithm are: $\omega_{\max}, \omega_{\min}$ are 0.9 and 0.4 respectively, the particle swarm size m is 40, the number of iterations is 100, and the acceleration factors are set to 2.05. Because the population does not mutate at the beginning of the iteration, and the population diversity is ensured by a large mutation probability in the later stage. In order to ensure that the optimal individual of each generation is retained, the mutation probability cannot be too large, so $P_{\min}$ and $P_{\max}$ are respectively set to 0.01 and 0.36. For the BP neural network structure set in this case, 24-30-8, a total of 960 weights and 38 offsets can be calculated, so the particle swarm algorithm has a dimension of 998.

In order to enhance the data representation ability of BP neural network, the transfer function selects the Sigmoid activation function. Set the BP neural network parameters to be configured as follows: the number of iterations is 25 and the learning rate is 0.01.

Take 200 sets of historical quality data of a key processing procedure in the production workshop of the medical device enterprise and the control chart mode category of each group of data as the input and output of the network. 150 groups are randomly selected as training data, and the remaining 50 sets of data are used for testing. Using BP algorithm, PSO-BP algorithm, improved PSO-BP to test the remaining 50 sets of data. The predicted network error output is shown in Fig. 5, respectively.

According to the calculation in Fig. 5, the network error output of BP algorithm is 0.22066, the network error of PSO-BP algorithm is 0.05120, and the improved PSO-BP algorithm predicts network error is only 0.00542; thus, it can be obtained with traditional BP and Compared with the PSO-BP algorithm, the improved PSO-BP algorithm improves the accuracy of the predicted output and reduces the error. As shown in Table II.

TABLE II: Diagnostic Results of Different Algorithms

Diagnostic algorithm	Predictive error output
BP algorithm	0.22066
PSO-BP algorithm	0.05120
Improved PSO-BP algorithm	0.00542

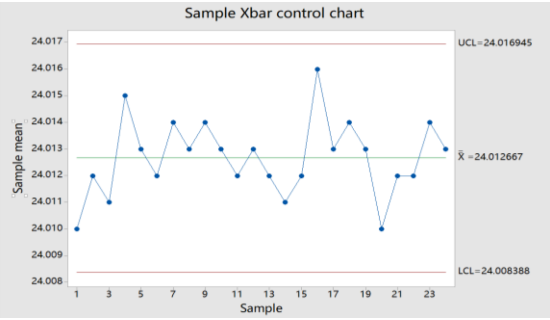
B. Abnormal Pattern Diagnosis

In the process of producing CNC pneumatic tourniquet, the manufacture of the tourniquet mouth is related to the use of patients in the later stage. Therefore, this article takes the manufacture of a tourniquet as an example. The standard diameter of the tourniquet mouth is 24 mm. Take the diameter measurement data for a certain period of time, collect 24 times, and record the data.

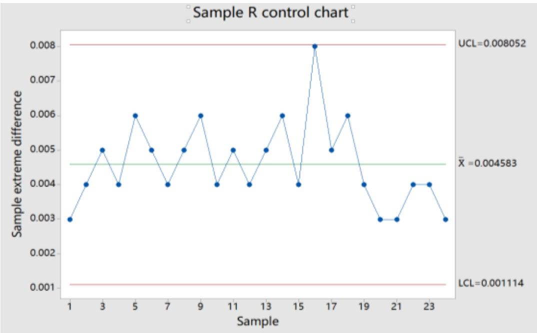
According to the above collected data, the mean-range control chart is drawn by using Minitab software, as shown in Fig. 6. The 24 quality feature samples of the mean control chart are: [24.010 24.012 24.011 24.015 24.013 24.012 24.014 24.013 24.014 24.013 24.012 24.013 24.012 24.011 24.012 24.016 24.013 24.014 24.013 24.010 24.012 24.012 24.014 24.013], the unit is mm; The 24 quality feature samples of the range control chart are: [0.003 0.004 0.005 0.004 0.006 0.005 0.004 0.005 0.006 0.004 0.005 0.004 0.005 0.006 0.004 0.008 0.005 0.006 0.004 0.003 0.003 0.004 0.004 0.003], unit is mm.

The formula is standardized as an input vector for improving the PSO-BP algorithm. After training, the output is: [0.0012 0.0164 0.0009 0.0021 0.9935 0.0014 0.0008 0.0003]. The result is compared with Table I, which is approximately equal to [0 0 0 0 1 0 0 0], and the abnormal mode is the upward step mode. It can be seen from Fig.6 that an abnormal phenomenon of an upward step does occur, which is consistent with the diagnosis result.

After determining that an abnormality has occurred, the workers stop the machine for inspection and find that the sewing diameter become larger due to the looseness of the machine screw. After the machine is replaced, the process is carried out to ensure the stability of the process.



(a) Mean control chart



(b) Range control chart

Fig. 6. Mean-range control chart.

VI. Conclusions

Based on the production characteristics of medical device products, this paper proposes a process quality control method that combines PSO-BP algorithm and SPC technology. Through the quality control of key processes to achieve the management of the entire production process, the quality of the entire production of medical devices is guaranteed. Compared with the traditional BP algorithm identification, the optimized algorithm overcomes the problem that it is easy to fall into the local optimum, and improves the accuracy and convergence speed of recognition. Compared with the PSO-BP algorithm, the improved PSO-BP algorithm improves the convergence speed and improves the calculation accuracy. At the same time, this method provides a feasible solution for the research of key process quality control in medical device enterprises.

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Weihong Sun was born in 1969. In July 1991, he graduated from the Mechanical Department of Nanchang University and got a bachelor's degree in engineering. He graduated from Huazhong University of Science and Technology Mechanical College in April 1998 and got a master degree in engineering. He graduated from Zhejiang University Department of Mechanics in December 2010 and got a doctor degree in engineering. He served as the dean of Academic Affairs Office, director of Higher Education Research Institute.

He is engaged in the teaching and research work of mechanical design and theory, CAD/CIMS and manufacturing enterprise information. He has completed nearly 40 scientific research projects, published nearly 40 academic papers, and he has applied nearly 50 intellectual property rights such as invention patents. Besides, he has guided 20 graduate students.

Jingwen Ma was born in Anhui, China. She received her bachelor degree from the School of Electrical Engineering of Anhui Polytechnic University in 2016. She is currently studying control engineering at the College of Mechanical and Electrical Engineering, China Jiliang University.

Man Liang was born in Anhui, China. She received her bachelor's degree from China Jiliang University in 2012. Her resesrch interests include mechanical design,manufacturing and optimization.