Machine Learning Techniques for Performance Prediction of Medical Devices: Infant Incubators

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Abstract

This paper presents development of Expert System for prediction of performance of infant incubators based on real-time measured data. Temperature error, preventive maintenance intervals, number of additional parts and utilization coefficient were used as input information for the development of this system. Expert system is based on Artificial Neural Network (ANN) and Fuzzy logic (FL) classifier. Feed forward back-propagation artificial neural network with 12 neurons in hidden layer and sigmoid transfer function, using Bayesian regulation algorithm has shown best properties for prediction of the functionality of incubators based on performance output error. Fuzzy logic using Mamdani implication logic was developed as an extension of ANN and finally used for prediction of device performance. The developed expert system presented in this paper presents the first step in researching possibilities of usage such systems for upgrading medical device management strategies in healthcare institutions to answer challenges of increased sophistication of devices, but patient safety demands as well.

Keywords

Infant incubators • Artificial neural network • Fuzzy logic • Expert system • Medical devices • Inspection • Performance

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1 Introduction

Since 1891 and the invention of the first neonatal incubator, incubators are used worldwide present in the neonatal intensive care units (NICUs) of all hospitals [1]. In 1897, due to the increased death rate of pre-mature babies, the utilization of infant incubators became prominent worldwide [2]. Main applications of infant incubators include oxygenation of the baby and protection from harmful agents. During incubator use temperature, respiration, cardiac function (ECG) and brain activity (EEG), relative humidity, sound and skin temperature are monitored [3].

Every medical device has its benefits and risks, therefore patient safety can only be ensured when these risks and benefits are openly disclosed [4]. Ongoing sophistication of medical equipment occurs, with medical staff relying on their results for patient treatment and care. In spite of this, malfunctioning may still occur at any time. Therefore maintenance, safety and performance evaluation are critical for preventing malfunctions in all medical devices, including infant incubators [5].

One of the major priorities pertaining to maintenance of medical devices are their compliance to defined international standards. These standards establish a universal testing procedure for biomedical service [6]. In the case of infant incubators sensors for all parameters such as temperature, humidity, airflow and sound should be measured and tested [7]. Furthermore, certain test equipment for testing of wire resistance and chassis leakage exist [8]. An additional method for the inspections of medical devices is the implementation of legal metrology framework, implemented with the goal of compliance to EU Directives of new approach (New Approach Standardization) [9]. The legal metrology framework implemented in Bosnia and Herzegovina is presented in the work of Badnjevic et al. and others [9–14].

In the past researches have set their goal on developing software programs for the maintenance of medical device

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systems. Previous research of Nichols and Linberg [15] and Linberg [16] presents successful disclosure of automated software updates to programmers. Advantages of such software is that they are based on newer methods, while older methods are limited to Excel spreadsheets and physical documentation [17–19]. With the beginning of the development of software programs and collecting big data from medical devices, machine learning algorithms in big data analytics became a prominent subject [20]. The effectiveness of this approach has resulted in developing clinically validated diagnostic techniques using artificial intelligence with the algorithms and techniques improving at a constant rate [21, 22].

Therefore, scientists in the past have conducted research deducing techniques for fast and accurate prediction of optimal usage of neonatal incubators. Amongst them Hagar et al. [23] focused on implementing different algorithms for intelligent incubator Length of Stay (LOS) prediction using data mining which proved to be an efficient technique. In the study of Sezdi [24] two distinct strategies were employed, preventive maintenance for older technology devices and predictive maintenance for newer high-tech devices. The results of the study had hidden medical equipment failures as a result of noncompliance with international standards. Furthermore, Chaudhary and Kaul [25] tested 30 medical diagnostic devices with the goal to determine their utilization coefficient (UC). Up to 23% of the devices were proven to be inadequately used.

Considering Artificial Neural Networks (ANNs) and fuzzy expert systems, the study of Virk et al. [26] provides a detailed analysis of developing expert systems for fault prediction of electronic components. Virk et al. [26] concluded that ANNs are highly efficient and used for prediction, along with fuzzy logic assisting in decision making and control purposes. Another successful fuzzy logic control system was conducted by Reddy et al. [27] in which fuzzy logic control which incorporates both incubator air temperature and infant's skin temperature to control the heating. The system resulted in a smooth fuzzy control with desired rise time. In addition, the study of Amer and Al-Aubidy [28] used ANN with back-propagation method to simulate the premature infant incubator control system. The sensor outputs of infant incubator were used as ANN inputs which identify the corresponding case and decide the suitable reaction upon previous training.

Expert systems and ANNs have the significant ability of changing and developing which makes them outstanding methodologies for creating systems which optimizes complex medical devices [29]. With the goal of determining the prediction of maintenance necessity of medical devices, experts work on fuzzy expert systems and ANNs which explicit advantages over manual testing procedures. One of them includes fuzzy expert systems being faster and more accurate, contrary to time consuming and potentially inaccurate manual testing [30].

This paper presents implementing machine learning techniques for the development of an Expert System with the ability to predict the maintenance necessity of infant incubators. An artificial Neural Network (ANN) was tested in conjunction with Fuzzy Expert System.

2 Methods

Expert system presented in this paper is made for prediction of performance of infant incubators. Parameters used for prediction and the output of system are graphically presented in Fig. 1, and the procedure is explained in detail in following chapters.

2.1 Dataset Used for the Development of Expert System

For the development of Expert System presented in this paper, measurement data acquired during three-year period from 137 infant incubators used in healthcare institutions in Bosnia and Herzegovina were used (Table 1 and Fig. 2) Each incubator was inspected once a year and measurements of air temperature and relative humidity were collected by staff from appointed laboratory for inspection of medical devices with measuring function. All measurements were performed according to ISO 17020 [31] and with calibrated etalons [32].

The error is calculated with respect to preset value and after calculation the error is compared to the limits stated in Table 2.

As it can be seen from Table 2, the devices were all classified as either functional (accurate) or non-functional (faulty). A medical device equipment verified as accurate is a medical device which successfully complies to safety and measurement requirements, while a faulty medical device equipment is a medical device that during testing has failed to comply with the same requirements [6]. According to Gurbeta et al. [6] for infant incubators the requirements are, in the case of air temperature, that the error must be smaller than 0.8 °C and the device can be classified as accurate. For humidity, if the deviation is smaller than 10 than the device is classified as accurate. In all other cases the devices are classified as faulty.

The output of the ANN is the inspection status of the medical device. This output information is used as one of the input parameters for the development of fuzzy classifier. Additionally, the number of additional parts (parts that are most susceptible to damage in incubators), utilization

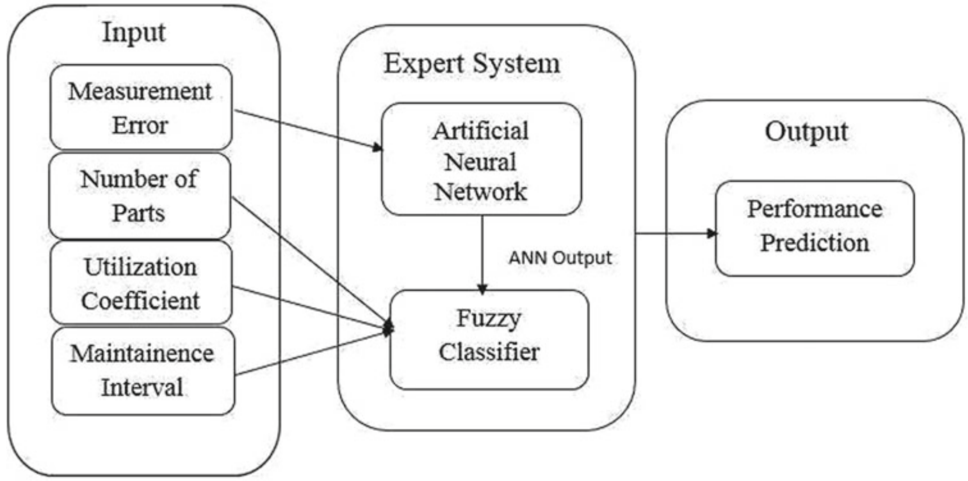

Fig. 1 Block diagram of the system

Table 1 Incubator inspection database

Period	Total number of devices	Accurate	Faulty
2015	22	14 (63.64%)	8 (36.36%)
2016	64	49 (76.56%)	15 (23.49%)
2017	54	38 (70.37%)	16 (29.63%)
Total	140	101 (72.14%)	39 (27.86%)

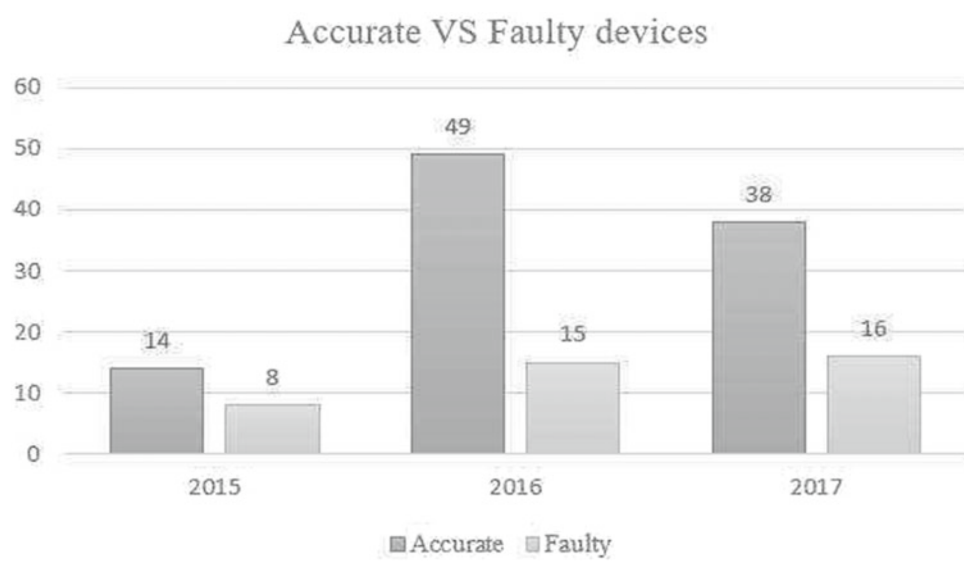

Fig. 2 Graphical representation of the ratio of accurate devices to faulty devices

Table 2 Parameters used for calculating the error

Parameters	Values verified	Allowed deviation	Criteria	
			Error deviation	Classification
Air temperature	31°–37 °C	±0.8 °C	<0.8	Accurate
			>0.8	Faulty
Humidity	40–90%	±10%	<10	Accurate
			>10	Faulty

coefficient and yearly maintenance frequency were utilized for the development of fuzzy classifier.

2.2 Expert System for Prediction of Medical Device Performance

2.2.1 Artificial Neural Network Development

Artificial Neural Network has 5 inputs and 1 output. Inputs are the following: measurement error on 31 °C, measurement error on 32 °C, measurement error on 33 °C, measurement error on 34 °C, and measurement error on 37 °C. The dataset for training of ANN was divided in an 80/20 ratio, as recommended by experts which was also confirmed by experimental work [33–35] (Table 3).

Before choosing the architecture to be used in convergence with Fuzzy logic, multiple combinations of neuron numbers, training algorithms and neural network architectures were tested. Performance and training set confusion matrix precision with combinations of different neuron numbers and different training algorithms, with Trainlm and Trainbr employed in feed forward network and Trainbfg employed in recurrent network, are presented in Table 4.

In addition to being convenient for ANN development from small number of samples datasets, Bayesian regulation has an extensive ability to prevent overfitting [36, 37]. Figure 3 presents the architecture of the developed ANN.

2.2.2 Fuzzy Classifier for Maintenance Necessity Prediction

The fuzzy classifier used in the development of this expert system consisted of 4 input parameters and one output parameter. The input parameters used are:

1. Inspection status drawn from ANN output,
2. Number of additional parts/parts that are most susceptible to damage in incubators ranging from 0 to 6 by averaging the information from user manuals for different incubators [38, 39],
3. Utilization coefficient calculated statistically for Bosnia and Herzegovina [40] and
4. Yearly maintenance frequency in range from 1 to 3 times per year because the advised preventive maintenance for infant incubators is every 4–6 months [11].

Fuzzy inputs were all presented as trapmf membership function with general equation:

$$f(x;a,b,c,d) = \begin{cases} 1, & x \le a \\ \frac{x-a}{b-a}, & a \le x \le b \\ 1, & b \le x \le c \\ \frac{d-x}{d-c}, & c \le x \le d \\ 0 & d \le x \end{cases}$$

The overall accuracy of ANN-fuzzy model is dependent upon the if-then-action of the rules in fuzzy inference. In

Table 3 Data division for testing and validation

Training dataset		Subsequent validation (testing) dataset	
Classification group	Number of samples	Classification group	Number of samples
Accurate	85	Accurate	16
Faulty	25	Faulty	11
$\sum$	110	$\sum$	27

Table 4 Training set confusion matrix and performance as a measure of success of ANN prediction

Training algorithm	Number of neurons	Data division	Training	Performance
Trainlm	20	70–15–15	96.4	0.0279
Trainlm	12	70–15–15	97.3	0.0182
Trainlm	10	70–15–15	100	0.0150
Trainlm	8	70–15–15	98.2	3.69E−5
Trainbr	20	70–15–15	98.2	0.0134
Trainbr	12	70–15–15	100	8.39E−8
Trainbr	10	70–15–15	99.1	0.0110
Trainbr	8	80–10–10	99.1	0.0091
Trainbfg	20	80–10–10	100	1.55E−9
Trainbfg	12	80–10–10	100	6.8E−10
Trainbfg	10	80–10–10	100	4.24E−10
Trainbfg	8	80–10–10	100	1.52E−7

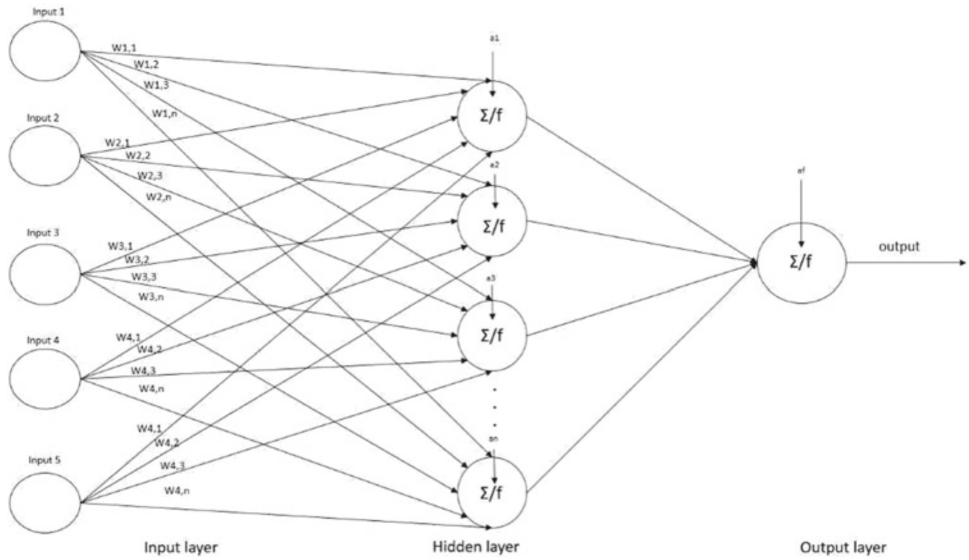

Fig. 3 Architecture of neural network

order to assure accurate prediction it is necessary to define precise combinations of input parameter membership functions. The membership functions are in minimum to maximum range with range adjustment for different parameters. Additional to the predicted ANN output, the fuzzy model enables control of final Expert System output on strictly defined rules so that fuzzy inference system will predict the correct maintenance necessity.

3 Results

A two-layer feed forward neural network in conjunction with Mamdani function fuzzy classifier was used for maintenance necessity prediction.

3.1 Testing Performance of Developed ANN

To evaluate the performance of developed ANN and the accuracy of prediction, mean square error was used as the measure of performance. Trial and error approach was employed in order to determine the final combination of number of neurons and training algorithm.

The performance of the neural network architecture was determined by the computation of the following parameters:

- Specificity: (number of correct classified samples functional)/(number of total samples of functional).
- Sensitivity: (number of correct classified samples of functional class)/(number of total samples of functional class).
- Accuracy was determined by (number of correctly classified samples)/(total number of samples).

The ANN performance was tested with 20 samples for each of the architectures presented above. The results are presented in Table 5.

3.2 Testing Performance of Fuzzy Classifier

After setting the rules for all possible combinations, accuracy of Fuzzy prediction based on those rules was tested. All

Table 5 Confusion matrix of subsequent validation of developed ANN

	ANN		
	Accurate	Faulty	
Accurate	9	0	9
Faulty	0	11	11
	Specificity 100%	Sensitivity 100%	Accuracy 100%

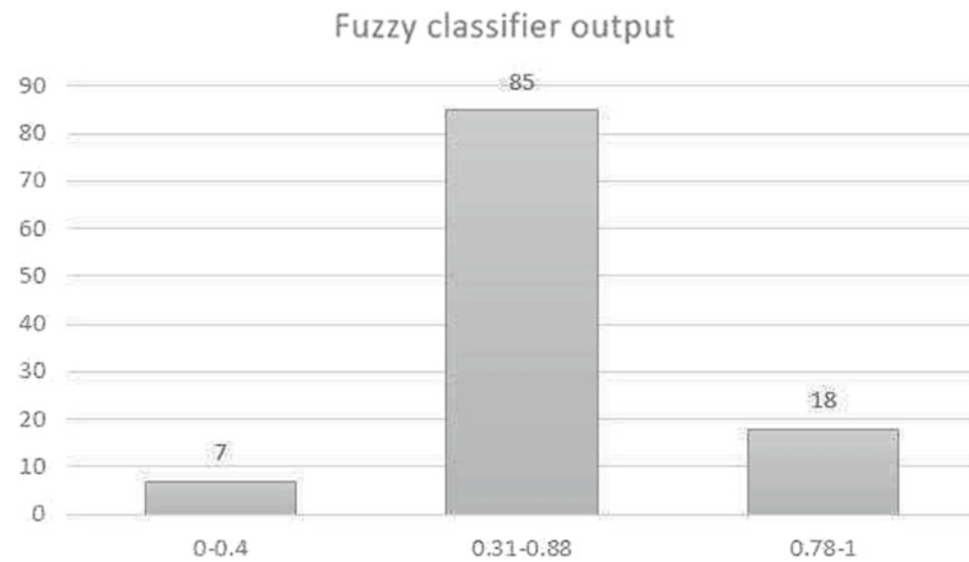

Fig. 4 Graphical display of number of devices classified into linguistic categories. Yes (0–0.4), Maybe (0.31–0.88), and No (0.78–1)

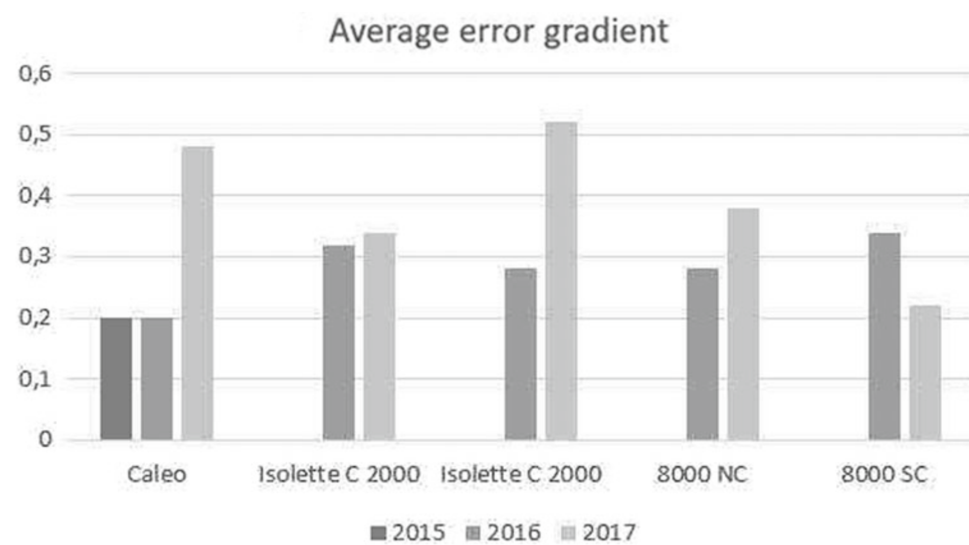

Fig. 5 Graphical display of average error gradient for 5 selected devices verified in consecutive years

Table 6 Evaluation of developed expert system

ANN input					Inspection status	Number of parts	Utilization coefficient	Preventive maintenance frequency	System output
0.8	0.1	0.3	0.2	0.3	1	3	0.9	2	0.97
0.6	0.3	0.7	0.4	0.6	1	3	0.7	3	0.23
0.3	0.2	0.3	0.1	0.2	1	4	0.9	2	0.97
0.2	0.3	0.4	0.3	0.2	1	4	0.6	1	0.53
0.4	0.5	0.7	0.3	0.5	1	6	0.4	2	0.75

of the samples were classified in correct linguistic categories. Results are presented in Fig. 4.

The final developed Expert System was tested using 5 samples (Fig. 5) with provisionally assigned numbers of parts, utilization coefficients and maintenance frequencies (Table 6).

As it can be seen from Table 6, the developed expert system provides the results which are consistent with the inference logic used for rule definition in Fuzzy classifier.

4 Conclusion

Inspection of infant incubators is done based on parameters of environment temperature, humidity and skin temperature if the sensor is present. Although a high number of babies are born in Bosnia and Herzegovina, the country has only 140 verified incubators, with 36 of them malfunctioning. Because infant incubators are used to maintain the life of babies it is very important to have a tool that is able to predict whether the devise needs maintenance and what is the exact level of that necessity.

Expert System developed in this paper was trained with 137 inspection samples from clinical centers and hospitals in Bosnia and Herzegovina. The samples are classified based on absolute error as accurate or faulty and then further including number of parts, utilization coefficient, and preventive maintenance frequency into three classes: incubators that need maintenance, incubators that maybe need maintenance (additional tests are needed), and incubators that do not need maintenance. Number of parts, utilization coefficient and preventive maintenance frequencies could not be punctually determined because that data is not presented in documentation. In order to have most accurate prediction, these data should be considered as relevant when doing inspection of medical devices.

Artificial Neural Network had 100% accuracy, meaning that inspection result was predicted correctly for all devices. Fuzzy classifier, correctly classified the samples in corresponding categories, based on syntax defined in rules. Concrete, reliable, realtime data would increase the reliability of the Expert System. However, this system has proven its efficiency in the field of maintenance prediction and can therefore be implemented in software solutions.

Expert System is a tool used in a lot of predictions including error and maintenance, but this paper presents a novel aspect of using Expert Systems in medical device performance evaluation. Overall system output is satisfying but further steps should be done in the field of data collection which would enable improvements.

Previous studies have shown that improved machine learning techniques are crucial in maintenance of medical devices today. The results obtained accurately prove the possibility of predicting maintenance necessity of the tested samples in both the ANN and Fuzzy Expert system. Similar results were obtained in one of the previous studies mentioned, in Sezdi [24], the system used detected 126 (22%) in 569 tested devices. The two systems created are, therefore, proven valuable in preventive maintenance. The expert system presented in this paper, along with the Expert System of Chaudhary and Kaul [25] had 100% accuracy of prediction of the devices used for testing. The studies and successful results provide useful insight in the many applications Expert Systems and machine learning have in the maintenance of medical devices.

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