

Runtime Verification of Pacemaker Functionality Using Hierarchical Fuzzy Colored Petri-nets

Negar Majma^{1,2} · Seyed Morteza Babamir³ · Amirhassan Monadjemi⁴

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Abstract Today, implanted medical devices are increasingly used for many patients and in case of diverse health problems. However, several runtime problems and errors are reported by the relevant organizations, even resulting in patient death. One of those devices is the pacemaker. The pacemaker is a device helping the patient to regulate the heartbeat by connecting to the cardiac vessels. This device is directed by its software, so any failure in this software causes a serious malfunction. Therefore, this study aims to a better way to monitor the device's software behavior to decrease the failure risk. Accordingly, we supervise the runtime function and status of the software. The software verification means examining limitations and needs of the system users by the system running software. In this paper, a method to verify the pacemaker software, based on the fuzzy function of the device, is presented. So, the function limitations of the device are identified and presented as fuzzy rules and then the device is verified based on the hierarchical Fuzzy Colored Petri-net (FCPN), which is

formed considering the software limits. Regarding the experiences of using: 1) Fuzzy Petri-nets (FPN) to verify insulin pumps, 2) Colored Petri-nets (CPN) to verify the pacemaker and 3) To verify the pacemaker by a software agent with Petri-network based knowledge, which we gained during the previous studies, the runtime behavior of the pacemaker software is examined by HFCPN, in this paper. This is considered a developing step compared to the earlier work. HFCPN in this paper, compared to the FPN and CPN used in our previous studies reduces the complexity. By presenting the Petri-net (PN) in a hierarchical form, the verification runtime, decreased as 90.61% compared to the verification runtime in the earlier work. Since we need an inference engine in the runtime verification, we used the HFCPN to enhance the performance of the inference engine.

Keywords Pacemaker · Hierarchical fuzzy colored Petri-net · Runtime verification · Petri-net

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✉ Seyed Morteza Babamir
Babamir@kashanu.ac.ir

Negar Majma
Majma@grad.kashanu.ac.ir

Amirhassan Monadjemi
monadjemi@eng.ui.ac.ir

¹ Department of Computer, University of Kashan, Kashan, Iran

² Naghshejahan Higher Education Institute, Isfahan, Iran

³ Department of Computer, University of Kashan, Kashan, Iran

⁴ Department of Artificial Intelligence, Faculty of Computer Engineering University of Isfahan, Isfahan 81746, Iran

Introduction

Nowadays, the implantable medical devices are increasingly used. According to the U. S Food and Drug Administration (FDA), the medical devices sale has increased 56% between 2004 and 2009, while the drug sale has increased only 38% [1, 2]. The medical devices, whose main purpose is medical care, are used to cure and prevent abnormal physical conditions without manual intervention in human body. Medical devices are categorized into three classes: the first class is at minimal risk for patients including simple equipment such as tongue depressors and handheld surgical instruments. The higher risk devices like wheelchairs, surgical needles and insulin pumps are placed in class II. The class III devices have higher risks and it is important to guarantee their normal accurate function

in every situation. Examples of these devices include cardiac pacemakers and neurostimulators, and replacement heart valves. These devices can monitor the health conditions of the patient everywhere, even in remotely, thanks to the connection to the patient body. These devices have some software applications controlling their behavior and activities. Regarding the dispersion of the hospitals and their wide unavailability for the patients, the proper and accurate function of these devices should be guaranteed. Between 2006 and 2011, 2294 fault cases and 1,154,451 side effects cases were reported by FDA due to the medical devices malfunction. 92,600 cases of these reports include injuries, and 4590 cases are fatal. 1210 (22.9%) of these faults were blamed on the medical device software applications [1]. Among these, there were 234 device operation failures in class II devices and 23 cases in class III. Again there were 311 calculation or output errors in class II devices and 20 cases in class III [1]. One of the ways to decrease such malfunction is using software verification methods as a tester beside a medical device.

As mentioned before, a pacemaker is a device helping regulation of the heart beat by connecting to the cardiac vessels. The pacemaker is implanted under skin by an expert and is used to cure arrhythmia. Irregularity in the normal heart rate is called arrhythmia. Formerly, a pacemaker was a simple device stimulated the heart muscles in order to produce pulses in a regular rhythm [3]. Figure 1a and b show the older and current pacemaker respectively [4].

Figure 1b shows that, logic and control parts have been added to the modern pacemaker which can make decisions about the device functioning while receives information directly from the attached sensors. Modern pacemaker devices include one or more sensors that can identify the patient body changes made by exercise or increasing metabolism. The information received from the sensors help the pacemaker to plan the heart rate for an individual and personalize the device [4]. As this device is set once at the beginning and then it has to keep working accurately in the body for 5 to 10 years without any regular physical availability, assurance of its functioning accuracy is essential.

The above mentioned problems of a medical device can be dealt with by either: (1) examining description and structure of its software (static verification) or, (2) Examining the runtime function of the software (runtime verification). In the first method, the correctness of limitations and needs of the users are addressed. Despite the correctness of the software description, due to the possibility of error, in its implementation and impossibility of its perfect prediction in the software environment, the software may have an error while running. Proving the correctness of the software is complicated and not simply possible due to the large number of the running states of the software.

In the second method, the device runtime function is examined. The runtime verification studies, develops and implements the verification approaches which allow examination of the user's needs, goals, and limitations. Based on the previous experiences of the authors, the insulin pump and pacemaker software is verified, which will be described later.

Regarding the above mentioned items, runtime verification can be a solution to verify pacemaker behavior that will be described in "The proposed method" section. In this paper, runtime verification is performed by a software monitor, which momentarily controls accuracy of the target software running, regarding the software inputs status in order to prevent any error and unsafe mode, if any, or report it. This runtime monitor includes the knowledge which is the accurate process of the software running. Therefore, in this paper, knowledge representation techniques are used in the runtime monitoring.

In recent years, different knowledge representation methods have been introduced, some of which are as follows: Weighted Fuzzy Production Rules(WFPRs); Disjunctive Logic Programming; Semantic Networks; Extended Hierarchical Censored Production Rules; FPNs; Ontology and the Entity Relation Propagation Diagram Tree [5, 6]. One of the knowledge representation techniques is PN. Regarding the advantages of PN in software modeling based on the software descriptions and limitations, also considering the requirement of fuzzy inference, FPN is used instead of PN for verification in this study.

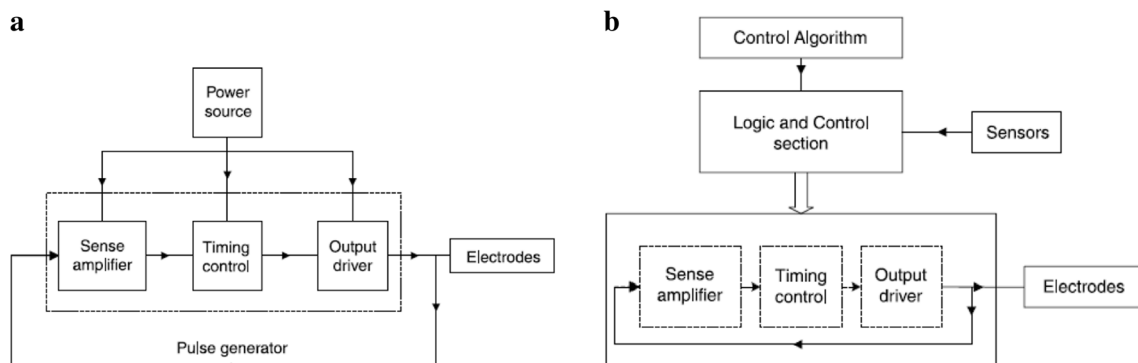


Fig. 1 a The old pacemaker device [4]. b. The modern pacemaker device [4]

FPN was used in our previous research to verify the insulin pump [7]. The insulin pump is a device used in the body of the patients with diabetes, helping to regulate their blood sugar. Applying measurement sensors, this device momentarily measures the blood sugar and other factors influencing the blood sugar measurement such as the insulin produced by the human's body and four other parameters and also calculate the insulin which needs to be injected. Regarding the uncertain behavior of the insulin pump, FPN was used to examine the correctness of runtime function, resulting in the exact verification of the insulin pump's behavior. There will be a large network with 26 places and 277 transitions by using FPN for pacemaker and then the speed of the verification will be slowed. In this paper, FPN and CPN will be combined, then the scale of the network will be reduced to 6 places and 277 transitions, also, by using hierarchical FCPN, the scale of the network will be reducing to 6 places and 26 transitions. The pacemaker verification by contribution of a software agent with PN-based knowledge is also presented by the authors previously in [8] that only three parameters of the parameters influencing the heartbeat calculation are used. In the current paper, these parameters will be increased to five, and the structure will be changed to HFPCN.

The pacemaker verification has been done in [9] using the CPN, in which the previous method has been improved and the verification has got a more accurate structure than the previous experience. By using the CPN for the pacemaker, the scale of the network has been reduced to 6 places and 277 transitions. Examining the potentiality of transition for firing is very time-consuming. Then we will change the structure of the network to hierarchical to reduce the scale of it to 6 places and 26 transitions. In the current paper, the past approaches will be developed to HFPCN instead of nonhierarchical FCPN and the number of parameters influencing the measurement of the heartbeat control will be increased to five cases, then the runtime verification will be improved to 90.61% which is elaborated in "The proposed method" section.

In [10, 33], PN is used to control the system behavior of the insulin pumps. Using PN, the accurate behavior of the insulin pump is modeled and its inaccurate behavior is identified if the system safety is not assured. In [7], to examine the accurate behavior of the insulin pump software, the FPNs are used. Every time the insulin pump software is run, its behavior is compared to the PN, so that when a runtime error occurs and in the case of unsafe behavior of the software, its inaccurate running can be prevented. [11] Presents a method to examine the medical equipment behavior using PN. In this reference, PN is used to track system operational and security needs. To show how to do this, injection pump is used as a medical device. [12] Modeled real time systems including cardiac pacemaker, using the timed automata and then automatically launched model checking process to produce a code. Then consider preserving security properties transformed from a

model to code in order to guarantee the security properties of the code and a strategy to identify the errors in the insulin pump system using the blood sugar continuous control is proposed. [13, 14] have used the combination of the fuzzy inference and PN to identify the certainty failure and analysis. In [13], the hardware implementation corresponding to the PN is presented which provide a fast implementation of the PN. In [15], PNs are applied as Rule-based expert systems for the distributed systems inference. In [16] designs a rule-based system to make decision about Arteriovenous Shunt Stenosis diagnosis. [15] used CPN as an inference engine on the semi-parallel knowledgebase to find the appropriate switching function for the services of the parallel distributed systems. In [17], the identification and control systems in nuclear power plants are automatically monitored by an FCPN. Fault identification modeling using an FCPN is applied in [14]. In [18], a reliable multi-level routing algorithm is presented which uses an FPN for cluster head selection and choosing one route among the cluster heads next.

This paper presents a new method for runtime verification of the pacemaker function. The runtime verification is carried out by a software monitor, which momentarily controls accuracy of the target software running, regarding the software inputs situation in order to prevent any error and unsafe mode, if any, or report it. Instead of directly changing the code into a high level design, we made a design mechanism for running stage as an applicable model of software description which can be implemented as an abstract inference engine and can refine medical devices rules. This abstract inference engine is a HFPCN.

In "Backgrounds" section, an overview of the backgrounds is presented. In "Justification of using the Petri-nets" section, benefits of PN over knowledge-based system are discussed. Next, the proposed method is explained in "The proposed methods" section and some scenarios are presented in "Experiments results" section. Finally in "Discussion" section, discussion and future works are presented.

Backgrounds

Fuzzy expert system

Fuzzy logic is a relatively new concept introduced in 1965 by Zadeh. The difference between crisp and fuzzy sets is established by introducing a graded membership function. The membership functions of the five input parameters used in this paper and their areas are described in "The proposed method" section.

In Fig. 2, a typical expert system is shown. One of the major parts of an expert system is its inference engine. The inference engine can make decisions and determine the output value based on its accompanying knowledgebase. Fuzzy expert system (Fig. 2) usually has four major components:

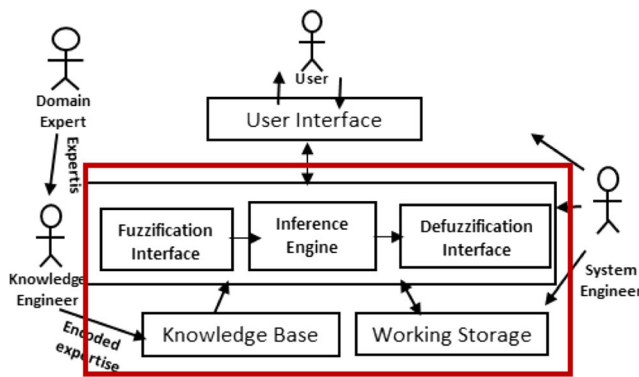


Fig. 2 Fuzzy Expert System

- (1) Fuzzification interface; this component is used to define the fuzzy sets used to represent linguistic values in the fuzzy rules and translate crisp (definite) values into linguistic values. A fuzzy set is characterized by a membership function associating each variable with a membership degree value. In real world, the variables of the Pacemaker are fuzzy. The set membership functions of input and output parameters are shown in “Fuzzification of the inputs and output of the pacemaker” section and “Obtaining pacemaker constraints” section.
- (2) Fuzzy knowledge base; this component consists of fuzzy rules in form of IF-THEN rules.
- (3) Fuzzy inference engine; this component is used for reasoning fuzzy rules and input values.
- (4) Defuzzification interface, which translates fuzzy set output values into crisp values. For defuzzification of output, all fuzzy outputs of the system are aggregated with a union operator. In fact, aggregation is unification of all rule outputs.

An example of this process is shown in Fig. 3. This figure indicates that the aggregation of three types of fuzzy rules where output of rules C1, C2 and C3 are 0.1, 0.2 and 0.5, respectively and the aggregated rule has been specified by the Σ notation. The input to the expert system and the values produced temporarily are stored in the working storage and then used in the next decision makings.

Among other defuzzification techniques, we use the centroid defuzzification known as center of gravity or center of area defuzzification. This is the most commonly used

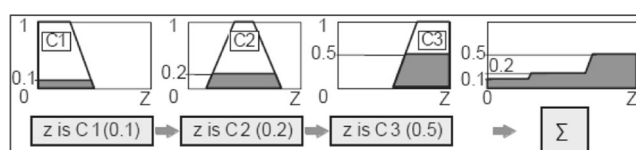


Fig. 3 Aggregation of three rules

and accurate defuzzification technique, which is expressed as (1) [19]:

$$x^* = \frac{\int \mu_i(x) x dx}{\int \mu_i(x) dx} \tag{1}$$

Where x^* is the defuzzified output, $\int \mu_i(x)$ is the aggregated membership function and x is the output variable. It must be noted that the difficulty of computation for complex membership functions is the main problem of this method. The pacemaker is in fact a fuzzy expert system as it makes decisions based on the input values and regarding the knowledge existing in its knowledgebase and acts accordingly.

Fuzzy Petri-net

PN theory provides a graphical language (model) for describing software needs and limitations. PN has the capacity to provide a simple strategy for control, correctness, consistency, and completeness of the software [5]. PN as a runtime simulator has an intuitive capability in visual representation of the logic. These capabilities are applicable in the software using the logic and rules. By graphically satisfying the needs and limitations of the software which is working based on the logic, the complication of decision making in a PN is reduced to one route [20]. PN approach can be easily combined with other techniques and theories such as programming, fuzzy theory, neural networks, and so on. These modified PNs are widely used in computer; manufacturing; robotic; knowledge based system; process control; as well as other engineering applications. For example, FPN is used for modeling, analyzing, and inference in knowledge-based systems (KBSs) [21].

Colored Petri-nets

CPN is a tool by which validation of discrete-event systems can be studied and modeled. CPNs are used to analyze and obtain significant and useful information from the structure and dynamic performance of the modeled system. CPN mainly focus on synchronization, and concurrency of asynchronous events [22]. The graphic features of CPNs specify the applicability and visualization of the modeled system. Furthermore, synchronous and asynchronous events present their prioritized relations and structural adaptive effects. PN characteristics are:

- 1) More activeness for its graphical presentation,
- 2) Not allotting to specific systems,
- 3) Being proper in modeling all systems,
- 4) Less planning but efficient elements which caused the simple use of this tool. FCPN is a special kind of FPN. In FCPN, tokens, places, and transitions can be colored [17].

FCPN is a combination of two CPN and FPN networks in which the tokens, places, and transitions are colored, while they have fuzzy and CPN characteristics, too.

In this paper, FCPN is used for presentation of the pacemaker knowledge. PN is used in a fuzzy form because of uncertain quantities measured by input sensors and therefore the uncertain rules of decision making. CPN decreases the number of input places and makes decision making simple, compared to the non-colored state. In this paper, a combination of CPN and FPN is used to represent the runtime verification knowledge of the pacemaker, which will be shown in “[The Proposed Method](#)”, and a comparison of the application results and advantages of CPN and FPN combination are presented in “[Experiments Results](#)” in a simple and hierarchical form. The hierarchical or high-level PNs are hierarchical presentation of a PN structure whose advantages include hiding details in an inference, dividing the network into the accessible and comprehensible parts, making single reusable subnets, supporting bottom-up and top-down system design, and high graphical expression. Regarding the above mentioned advantages, HFCPN, whose application in FCPN network is discussed in “[Experiments Results](#)”, is used.

HFCPN as an expert system substitute three categories of inference engine, knowledge base, and working storage. These parts are shown within the red box in Fig. 2. The expert system’s knowledge base in the HFCPN is identified using the rules on each transition. The tokens located at each place in a running PN indicate the facts in the working storage. Therefore, we can simply substitute an inference engine of the expert system with a HFCPN. As said before, these phases are elaborately described in “[The Proposed Method](#)”.

Justification of using the Petri-nets

Using PNs in knowledge-based systems has got some advantages. Below some of these advantages are listed:

- PN’s graphical nature simulates the firing mechanism very well by token movement (replacement) along the network and makes PN a suitable development tool for rule-based systems.
- PN has well-established formal mechanisms for modeling and checking features of the parallel and concurrent structures which are used to obtain parallel AND/OR in rule-based systems.
- PN mathematical base represents a dynamic behavior and system formation in an algebraic formation.
- When a rule changes to a PN, the indefinite inference problem can turn into a linear equation which is solvable in a parallel form [23].
- Inference route in a complicated expert system reduces by FPN to a simple sprouting tree [5, 24].

- FPN allows checking the features of the modeled systems using main features of the PNs such as correctness, consistency, and reachability [5].
- FPNs are also used to represent fuzzy knowledge and inference; many results have shown that FPN is appropriate to represent and reason in misty logic implication relations [25].
- Different studies proved that FPN is the best choice for representing and inferring logical relations in expert systems [26].
- The main advantage of using PNs in a rule-based system is providing a structured knowledge representation; where relationships between the rules are easily understood and a systemic inference capability can also be provided.
- Using a FPN to model fuzzy rule based reasoning provides a couple of advantages such as: [27]

The visual representation of a FPN can help experts to construct and modify fuzzy rule bases.

A FPN can model the dynamic behavior of fuzzy rule-based reasoning. The token evaluation is used to simulate the dynamic behavior of the system. The conclusion part of each rule is expressed through the movements of tokens in the FPN.

A FPN eliminates the necessity of all the rules scanning. Fuzzy rule based reasoning is improved efficiently by connecting fuzzy rule as a net-based structure.

A FPN can check properties of a modeled system to gain deeper insights into the system.

Therefore a HFCPN for pacemaker monitoring is employed in this study.

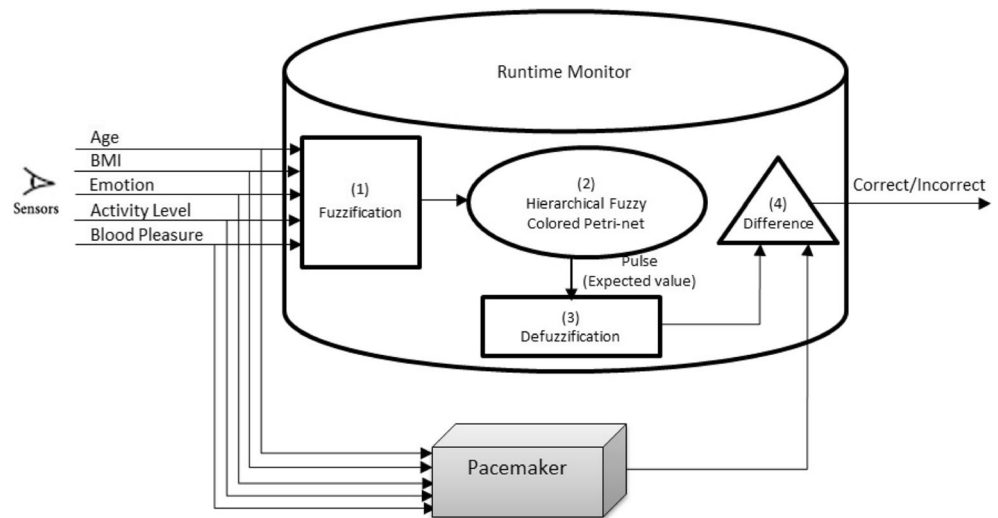
The proposed method

In Fig. 4, the diagram determines the proposed method.

As can be seen, the sensor inputs enter the pacemaker and runtime monitor at the same time. The runtime verification steps are shown by numbers in Fig. 4.

- (1) This monitor changes the sensor inputs into their corresponding fuzzy values. The approach used in this operation is described in “[A- Age](#)” to “[F- Pacemaker output](#)” sections.
- (2) By entering these values into the HFCPN, an acceptable output, which is the expected heart rate, is given. The approach of making HFCPN is described in “[Obtaining pacemaker constraints](#)” section and its inference is explained in “[Knowledge representation and reasoning by FCPN](#)” section and a corresponding HFCPN for the pacemaker is elaborated in “[Fuzzy colored Petri-net for pacemaker](#)” section.

Fig. 4 Structure of Proposed Method



(3) The output of HFCON is fuzzy; therefore, it is necessary to transform it to a crisp value before comparison with the pacemaker output. This is carried out by defuzzification (see “The proposed methods and Experimental results” sections). Then this value is compared with the pacemaker output and rightly or faulty modes are identified. The rightly mode represents the validity and acceptability of the pacemaker output and the faulty mode shows unacceptability of the device output. The details are shown in Fig. 5.

Fuzzification of the inputs and output of the pacemaker

The pacemaker carries out a complicated function, which can be studied in [28]. Firstly, it determines the device’s limitations. To consider those limitations five criteria are considered as the main criteria in this paper. Each of them is divided into a few diverse subsets for more accurate estimation in fuzzy systems. In Table 1, the proposed categorization of these criteria can be seen.

Below we detail the criteria.

A- Age

Age is categorized into five ranges, each transforms to a membership function set. The allowable age range is from 0 to 100 as shown in Table 2. The older people have lower heart rate. The heart rate in newborn babies is 150 BPM, while this rate reduces to 60–80 BPM in the adults. Each membership function set includes support, core, and boundary zone. Table 2 indicates the ranges of values and their intersection with each zone. For example, in young zone, the support range is between 17 and 30; core zone is between 18 and 28; the left boundary zone is between 17 and 18; and the right boundary zone is between 28 and 30. Chosen age membership function can be seen in Fig. 6, where in the example of the age 29, 0.4 is a member of young zone and 0.6 is a member of the middle-aged zone.

B- Body mass index (BMI)

The second parameter that determines the human heart rate is the body mass index. This index is obtained using height and weight. This index is divided into 4 levels according to [29] changing from 0 to 35. (1) Light-weight (below), (2) Normal-weight (Normal), (3) Over-weight, and (4) Obese. The membership functions of other parameters are not shown because of limitation of the paper.

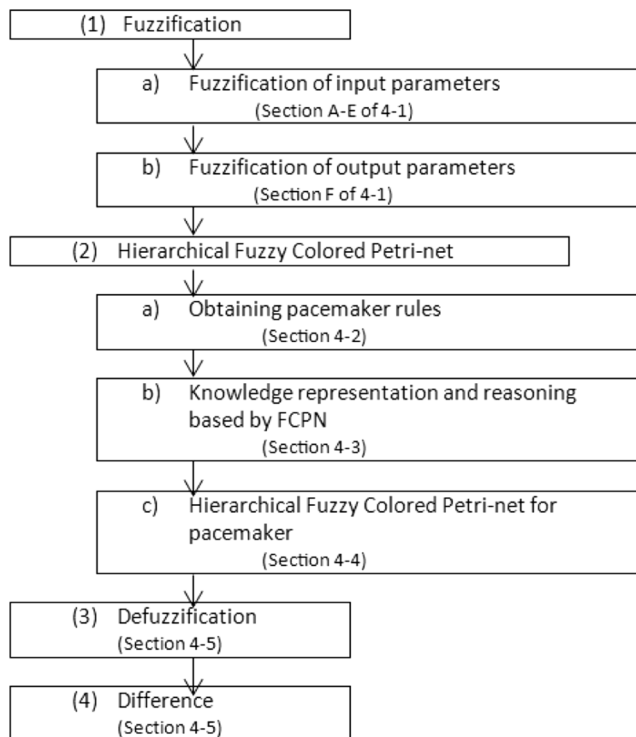


Fig. 5 Structure of the paper

Table 1 The proposed categorization of five criteria for pacemaker

Criteria	Age	BMI	Emotion
Range	0–100	0–35	1–100
Categorization	Title	Range	Title
	Child	0–10	Blow
	Teenager	8–18	Normal
	Young	17–30	Over
	Middle-age	28–60	Obese
Criteria	Activity level	Blood pressure	
Range	1–100	8–16	
Categorization	Title	Range	Title
	Level 0 (Normal zone)	0–15	Low
	Level 1 (weight management zone)	10–25	Normal
	Level 2 (Healthy hearth zone)	23–50	High
	Level 3 (Aerobic zone)	45–75	
	Level 4 (Anaerobic Zone)	70–95	
	Level 5 (Red zone)	90–100	

C- Activity level

Activity level shows the patient activity level. This index is between 0 and 100. The best way to identify the activity level of a body is using an activity sensor referred to as Accelerometer [30]. This Accelerometer can change the human activity level into signals based on the patient body movements. The emotional state of the patient can be measured based on his or her breath. This can be done by a minute ventilation sensor or a blended sensor.

D- Emotion

Emotions are considered as effective factors in human heart rate. In this paper, Emotions are categorized into four parts as shown in Table 1. For example, in Anxious set, the support zone is between 50 and 85, within which the range of 58–80 is related to the core zone, the 50–58 range is in Left boundary zone and the 80–85 range is in right boundary subset.

E- Blood pressure

Blood pressure is one of the most effective factors in the heart rate. The blood pressure range is divided into three parts as shown in Table 1. For example, the high zone supports the pressure between 12.5 and 16 from which the 13.5–16 range is in the core zone and 12.5–13.5 range is in left boundary zone.

F- Pacemaker output

Heart rate is the pacemaker output whose categorization can be seen in Table 1. The heart rate is divided into four groups. For example, the normal heart rate supports the range of 55–100 pulses per second from which the heart rate range of 60–95 is in the core subset and the range of 55–60 is in the left support subset and the 95–100 range is in the right support subset.

Table 2 Age membership function values

Zone name	Support	Core	Left boundary	Right boundary
Child	0–10	0–8	-	8–10
Teenager	8–18	10–17	8–10	17–18
Young	17–30	18–28	17–18	28–30
Middle-age	28–60	30–58	28–30	58–60
Aged	58–100	60–100	58–60	-

Support: the crisp set containing nonzero membership degrees for all elements.
 Core: the crisp set containing membership degree in A for all x elements.
 Boundary: the crisp containing membership degree $0 < \mu_A(x) < 1$ in A for all x elements

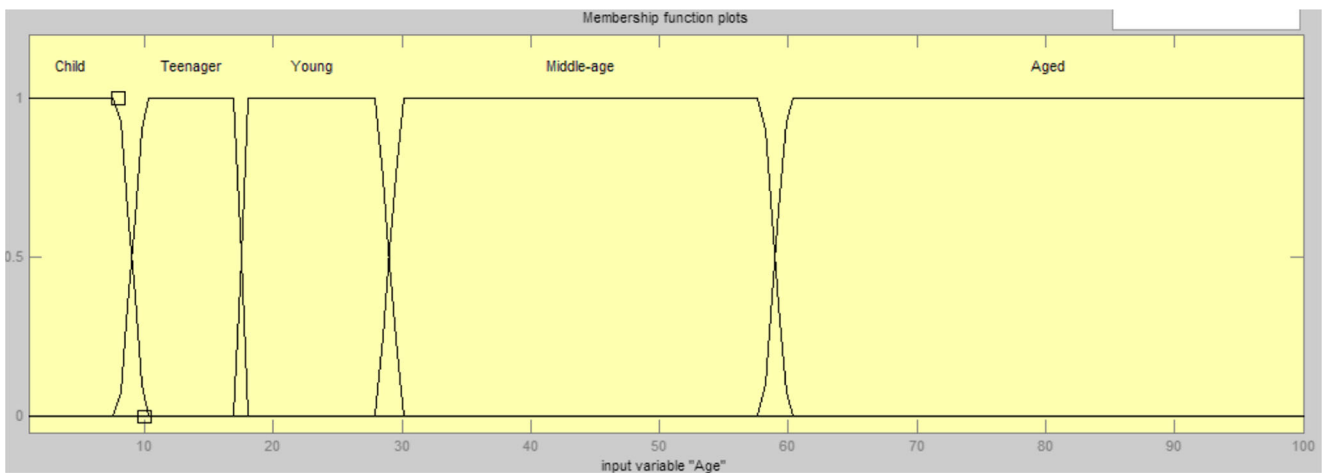


Fig. 6 Membership functions of Age

Obtaining pacemaker constraints

Regarding the different zone of each fuzzy variable and pacemaker’s experts view, 1440 rules have to be defined. However, considering the fact that some fuzzy variables are unimportant in some rules, this number has been reduced to 277. These rules were verifiably to the experts too. Figure 7 shows a part of these rules. We used these rules through the inference in Matlab format. All of the rules can be seen in appendix.

Some rules have same left side hypothesis. We can gather these rules together in a hierarchical FCPN. As can be seen in Fig. 7, each rule has at least 1 term and at most 5 terms in its hypothesis part. Some rules have the same terms in their left side hypothesis parts. Thanks to the same terms, it is possible to categorize the rules and FCPN structure can be depicted hierarchically. Therefore, status of the Age parameter is examined first and then the input parameters including BMI, Activity level, Emotion, and finally Blood Pressure are examined. Some transitions are divided into other transitions, which will be explained in “Fuzzy colored Petri-net for pacemaker” section. The number of the places will be reduced by using hierarchical FCPN too. In “Experiments results” section, a comparison between hierarchical FCPN and nonhierarchical FCPN will be made.

Knowledge representation and reasoning by FCPN

In this section, knowledge representation and FCPN-based inference are discussed. Using the items mentioned above, an FCPN can be used to build up the knowledge-based of fuzzy production rules; a typical rule is R_l where C_1 and C_2 in the rule hypothesis consist of fuzzy variables such as *high* and *low*.

$$R_l) \text{ IF } X \text{ is } C_1 (\alpha_1) \text{ THEN } Y \text{ is } C_2 (\alpha_2). (CF = \beta_1)$$

Hypotheses of a rule consist of a probability between 0 and 1 (Table 3) indicated by α_1 and α_2 in R_l . For each rule a certainty factor, indicated by β_1 in R_l , is determined showing degree of the belief in the rule.

(1) Places X and Y as input and output places respectively are shown as Set P , (2) Transition R_l is done as Set T , (3) colored tokens in the input place X are done as Set D_{PX} , expressed like (C_1, α_1) and (4) colored token in output place Y are done as Set D_{PY} , expressed like (C_2, α_2) . Probability of firing of R_l is β_1 . Figure 8 shows the FCPN for the rule R_l regarding to Table 4.

For instance, corresponding FCPN for the Rule1 is shown as:

Fig. 7 Part of pacemaker rules

- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level0) and (Emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level1) and (Emotion is Relax) then (Pulse is Normal) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level1) and (Emotion is Ex-Sad-Happy) then (Pulse is Normal) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level1) and (emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level1) and (emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level2) and (emotion is Relax) then (Pulse is Normal) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level2) and (emotion is Ex-Sad-Happy) then (Pulse is Normal) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level2) and (emotion is Anxious) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level2) and (emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level3) and (emotion is Relax) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level3) and (emotion is Ex-Sad-Happy) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level3) and (emotion is Anxious) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level3) and (emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level4) and (emotion is Relax) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level4) and (emotion is Ex-Sad-Happy) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level4) and (emotion is Anxious) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level4) and (emotion is Stress) then (Pulse is High) (1)
- If (Age is Young) and (BMI is Blow) and (Activity-Level is Level5) then (Pulse is High) (1)

Table 3 Validity scale and numerical interval corresponding to each [31]

Degree of accuracy	Numerical distance
Always true	[1.00,1.00]
Extremely true	[0.95,0.99]
Very true	[0.80,0.94]
Considerately true	[0.650,0.79]
Moderately true	[0.45,0.64]
More or less true	[0.30,0.44]
Minor true	[0.10,0.29]
Minimally true	[0.01,0.09]
Not true	[0.00,0.00]

Rule1: IF Age is Teenager (0.9) AND BMI is Below (0.8) AND Activity_level is Level1(0.3) THEN Pulse is normal (CF = 0.8)

FPN = (P, T, D, I, O, f, α , β)

$P = \{Age, BMI, ActivityLevel, Puls\}$, $T = \{Rule1\}$, $D = \{age\ is\ teenager\ AND\ BMI\ is\ blow\ AND\ activity_level\ is\ level1\ THEN\ pulse\ is\ normal\}$,

$I(Rule1) = \{Age, BMI, ActivityLevel\}$, $O(Rule1) = \{Pulse\}$, $f(rule1) = 0.8$,

$\alpha(Age) = 0.9$, $\alpha(BMI) = 0.8$, $\alpha(ActivityLevel) = 0.3$,

$\beta(Age) = is\ teenager$, $\beta(BMI) = is\ blow$, $\beta(ActivityLevel) = is\ level1$, $\beta(Pulse) = is\ normal$

Figure 9a shows Rule1 before firing consisting of colored tokens: (1) *Teenager with certainty of 0.9*, (2) *Below with certainty of 0.8* and (3) *Level1 with certainty of 0.3* in places Age, BMI, and ActivityLevel respectively as the hypothesis of Rule1. Each colored token consists of 2 elements, a fuzzy variable and a correctness level. By firing *Rule1*, the *Pulse2* place will contain a token with *Normal* value and certainty of 0.24 (Fig. 9b). The certainty is calculated by minimum of the input certainty factors multiplied by 0.8 (CF rule).

Figure 9 shows a token in *Age* place with *Teenager* value, and there is a token in *BMI* place with *Below* value, and also a token in *Activity level* place with *level 10* value. With these setting, rule 1 can be fired. CF of this rule is 0.8 as written below. By firing this rule, the token with normal value and certainty factor of 0.24 are in output pulse place (Fig. 9b). This value is obtained from minimum input multiple of 0.8.

Fuzzy colored Petri-net for pacemaker

According to the extracted fuzzy rules in “**Obtaining pacemaker constraints**” section, based on which the pacemaker works; the corresponding FCPN is built up and

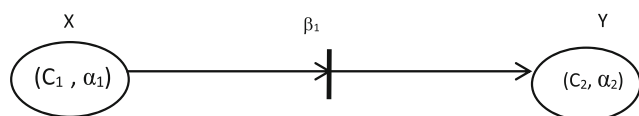


Fig. 8 Rule R1 in FCPN

Table 4 The conversion of R1 to FCPN

Rule R ₁	FCPN (Fig. 8)
X, Y	Places
$D_{PX} = (C_1, \alpha_1)$	Token in place X
$D_{PY} = (C_2, \alpha_2)$	Token in Place Y
Firing the rule	Transition
β_1	Possibility of firing the rule

illustrated in CPN tool environment. For a better representation of a PN, the hierarchical representation of the subnet in PN is used here. In Fig. 10, the highest level of the network with two places and one transition is shown.

The transition in Fig. 10 (RulesAge) will be activated when one of its internal subnet is fired. This transition consists of five subnets, depicted in Figs. 11, 12, 13, 14, and 15. Figure 11 shows the first sublevel of the network.

As Fig. 11 shows, in the first sublevel of the PN, the age status is evaluated based on the five states of the *Age*, which can be active and fired based on the input values received from the related input. Having implemented the network based on the first input, the second sublevel-the level related to BMI-will be applied. This level is shown in Fig. 12.

Figure 12 shows four examined BMI running states (according to Table 1). Having implemented the network based on the BMI input, the third sublevel, the level related to the activity level, will be applied (Fig. 13).

As Fig. 13 shows, the network status are examined based on six activity-level inputs (Table 1). The routes are departed in the second part of the network (right side of Fig. 13) due to the difference of the outputs of three first rules and those of the three second rules. That is, for the first three rules, the output has to be calculated accurately and the heart rate has to be *Normal*, while in the three second rules, this output is *High*. Therefore, in the second part of the network, these two routes are departed. Having implemented this level, the fourth sublevel in the network, the emotion input, which is shown in Fig. 14, will be applied.

The fourth sublevel is applied by examining input emotions (Table 1). The route in the right side of Fig. 14 is departed for the same reason as the route in the third sublevel is departed. Having implemented this sublevel, the fifth sublevel will be applied (Fig. 15).

As Fig. 15 shows, blood pressure input conditions are examined in this level (Table 1). Finally, by having this sublevel implemented the output transfers to the output place.

Experiments results

To evaluate our pro-posed method, and to show its effectiveness, five scenarios are presented. We implemented the proposed method in C# and CPN-tools. Each scenario enters to the implemented program as shows in Fig. 16a and b.

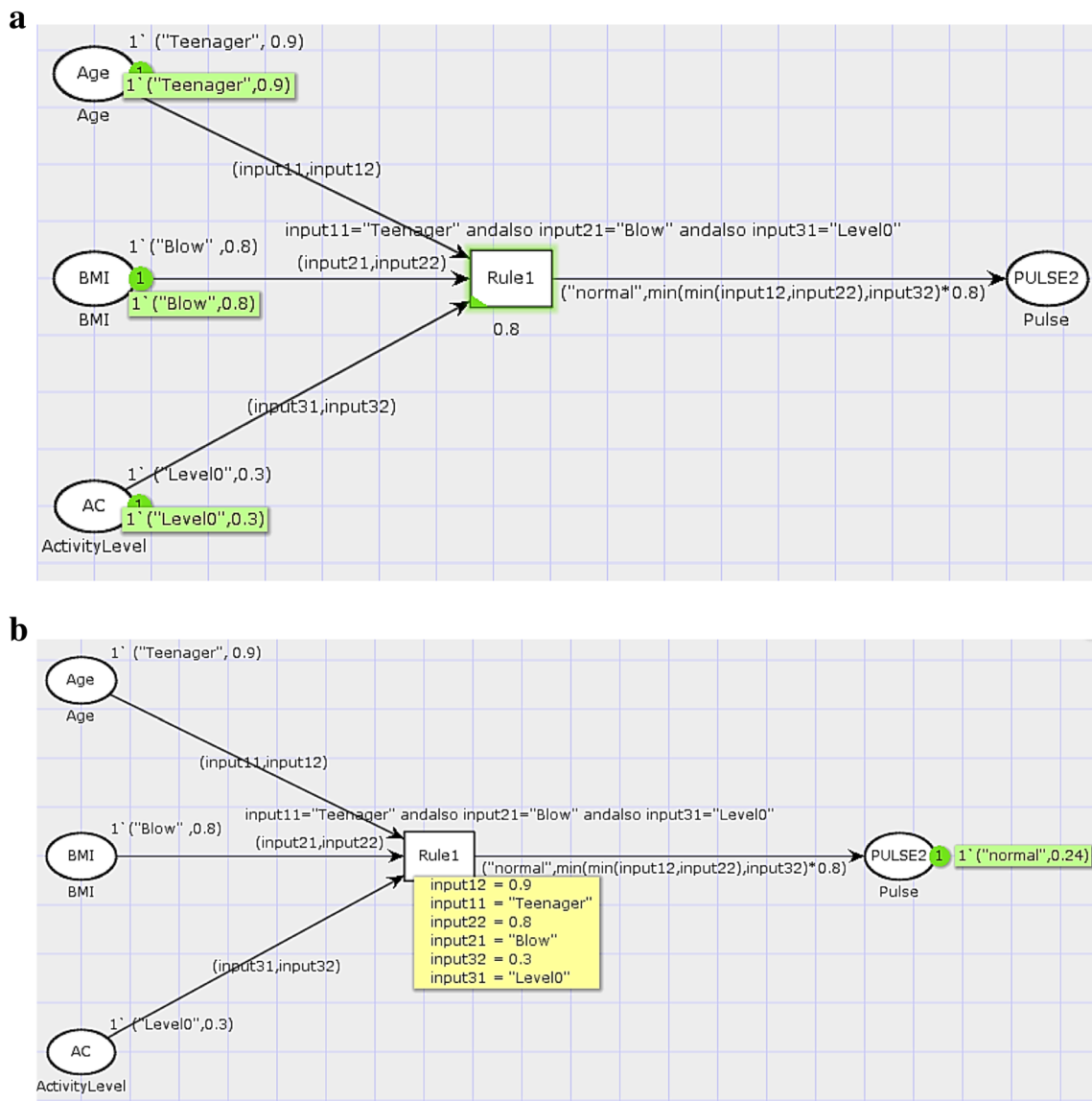


Fig. 9 Showing the rule in FCPN. a Before firing. b After Firing

Scenario 1: a thirty-year-old patient with the mass body index of nineteen is sitting calmly and his/ her blood pressure is low. Figure 16a and b show inputs and outputs for scenario 1, respectively.

Figure 16b shows that the heart rate is 30–55 BPM. However, if the pacemaker software determines the output between 30 and 55, it will threaten the patient health. Therefore, by making a comparison between this value and the monitor output, this contradiction becomes revealed.

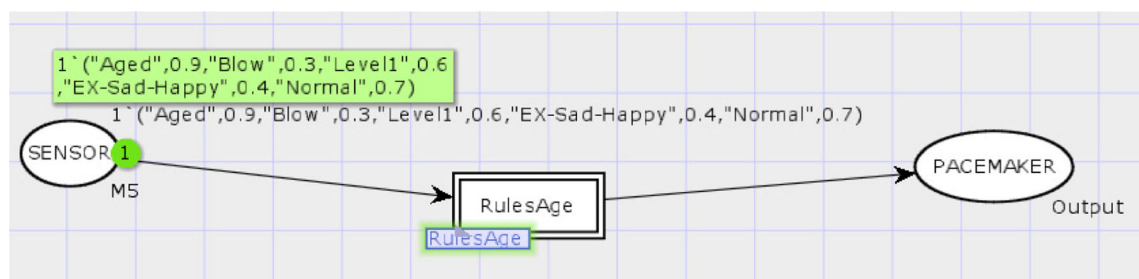


Fig. 10 FCPN of pacemaker

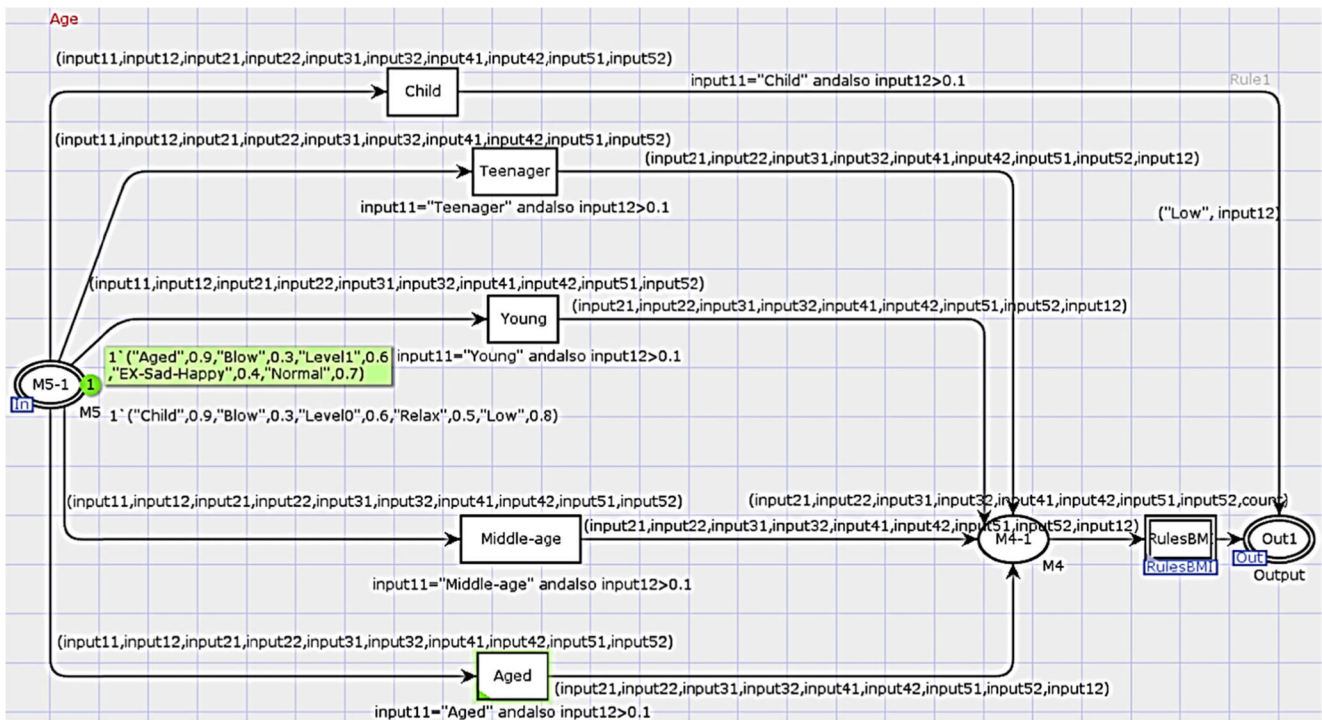


Fig. 11 First sublevel of FCPN of pacemaker

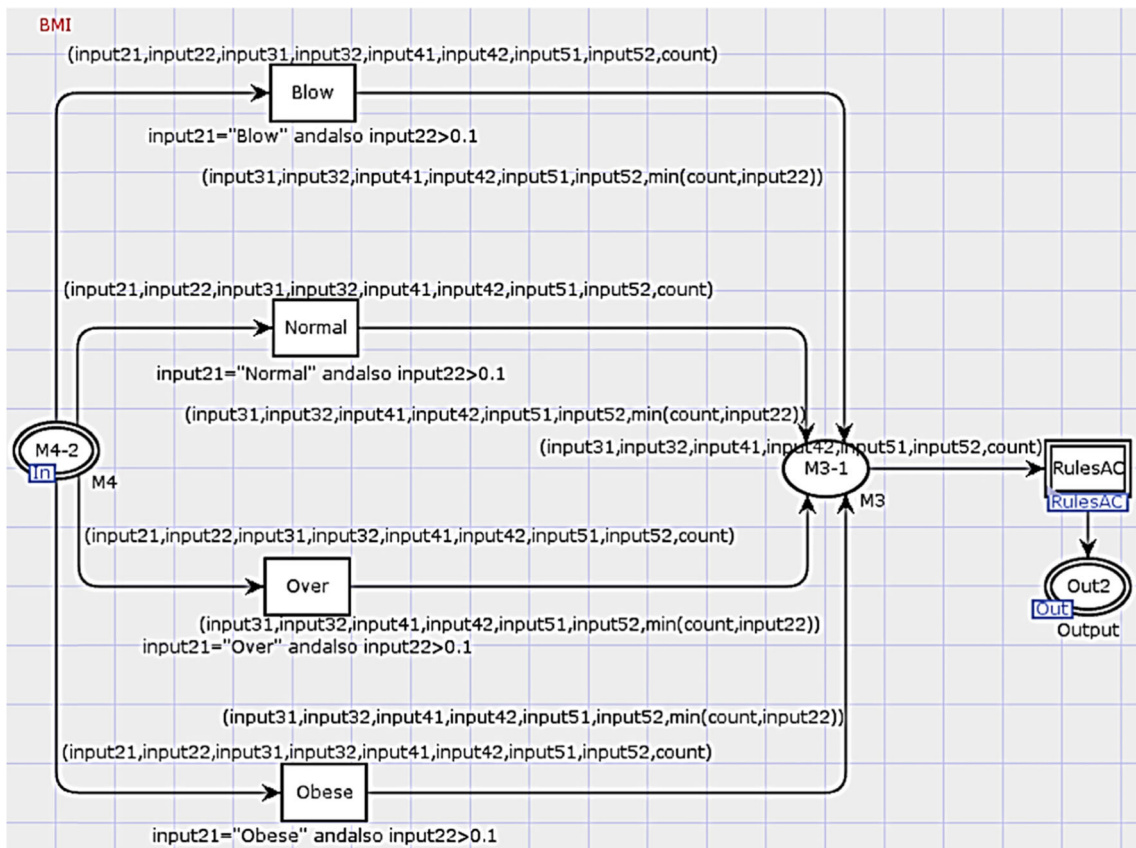


Fig. 12 Second sublevel of FCPN of pacemaker

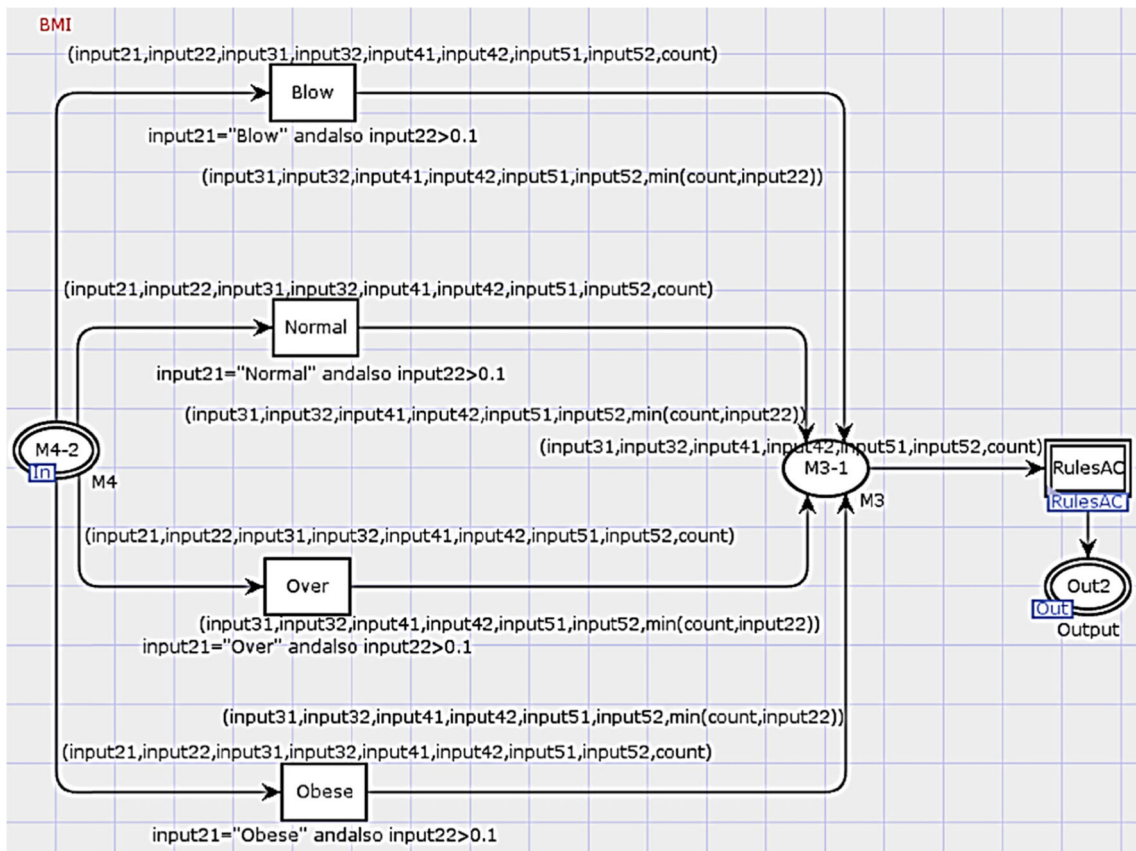


Fig. 13 Third sublevel of FCPN of pacemaker

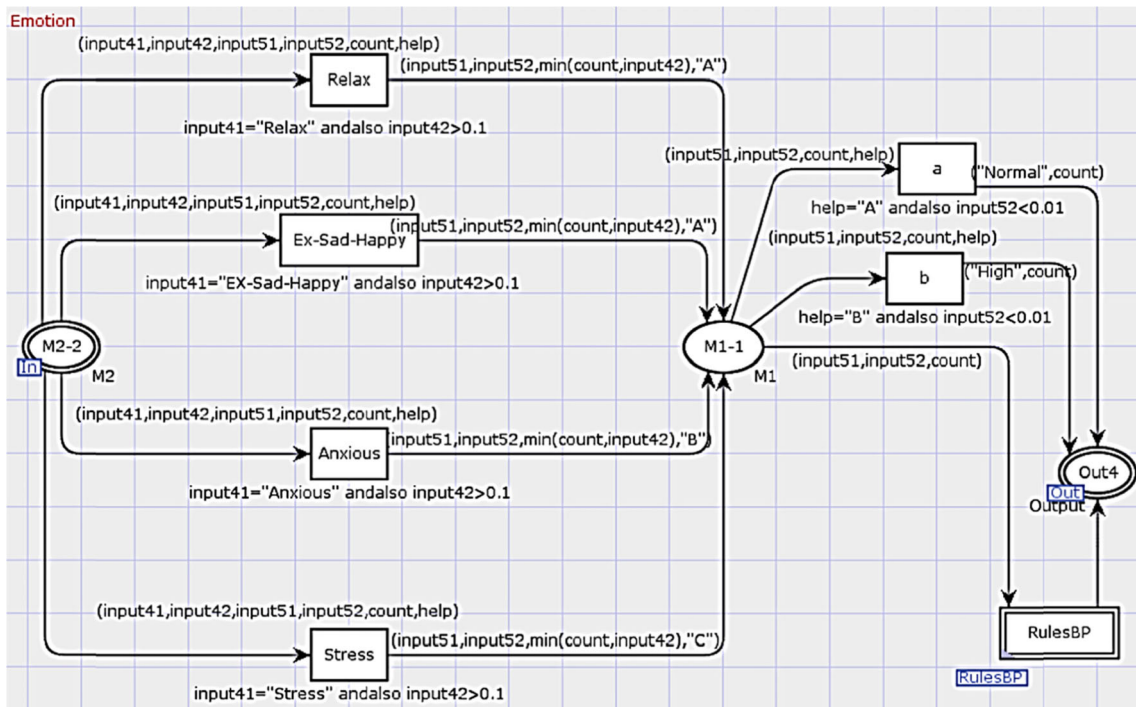
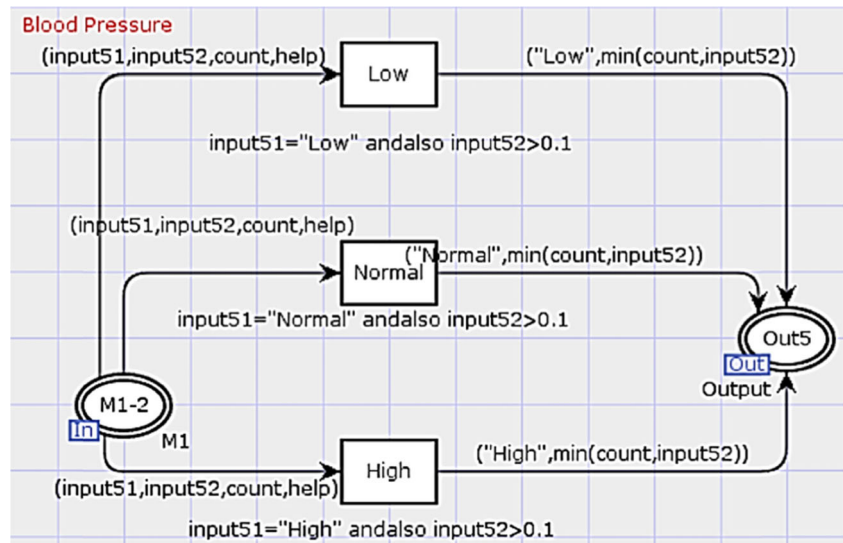


Fig. 14 Fourth sublevel of FCPN of pacemaker

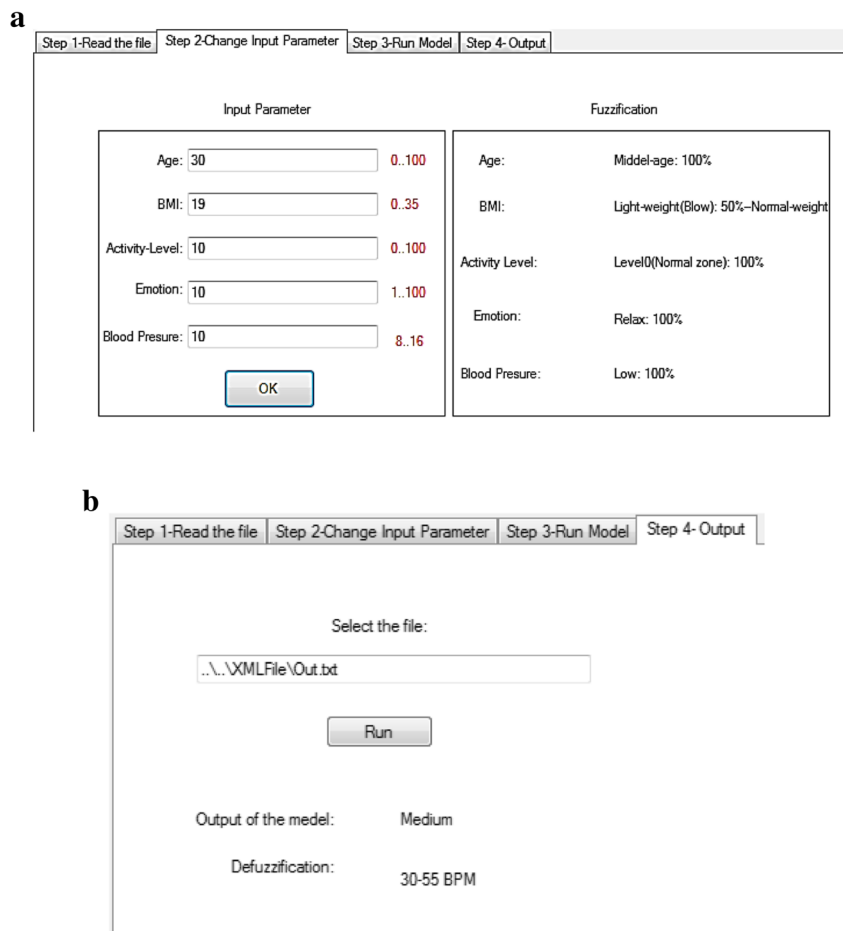
Fig. 15 Fifth sublevel of FCPN of pacemaker



Scenario 2: Consider a twenty years old patient with body mass index 32 whose activity level is between 4 and 5 (while running or swimming fast) and heart rate is between 95 and 150. If an ordinary inference engine is used instead of a PN, the output will be obtained by firing

rule 75; however, rule 76 meets the better conditions. Considering firing rules concurrently, rules 75 and 76 could be fired at the same time since the activity level 92 is a number between levels 4 and 5 (0.4 and 0.6 for levels 4 and 5 respectively, Fig. 17). Concurrent implementation is

Fig. 16 a The primary values in Scenario 1. **b** The output values of Scenario 1



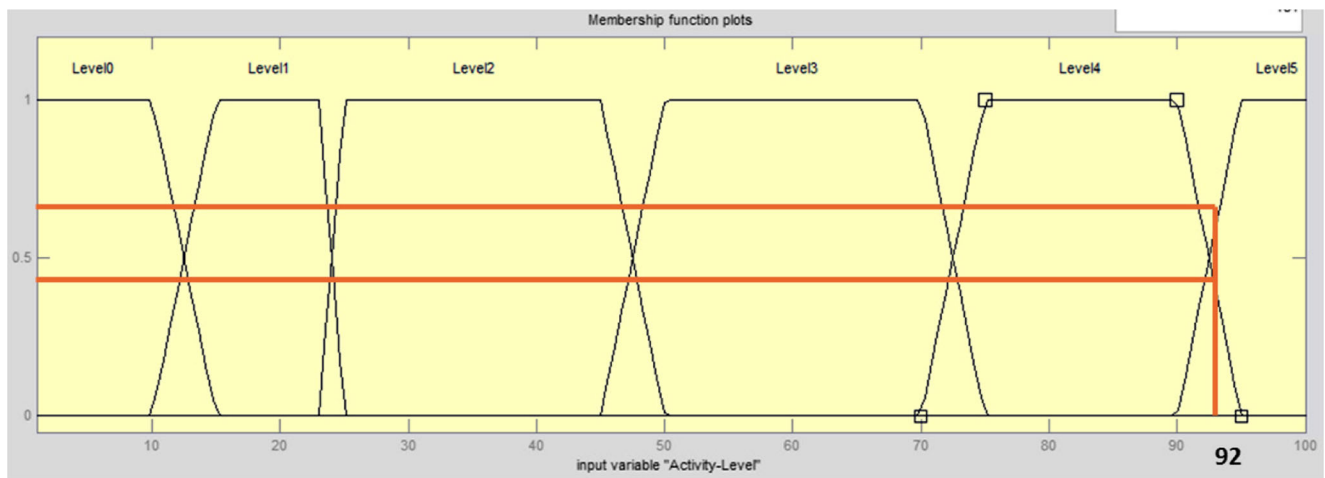


Fig. 17 Output for the rules 75 and 76 in scenario 2

one of the essential features of PN and the output can be followed by firing 2 transitions at the same time. In this case, we will have a more accurate and valid output.

Compared to the ordinal inference engines, HFCPN led to accuracy with 25% more by concurrently firing rules.

- 75. If (Age is Young) and (BMI is Obese) and (Activity_Level is Level4) then (Pulse is High) (1)
- 76. If (Age is Young) and (BMI is Obese) and (Activity_Level is Level5) then (Pulse is High) (1)

Scenario 3: One of the input sensors such as activity level stops working and does not produce an input. In this case, the device stops working and the breakdown will be reported by a warning. However, in the monitor PN, there is a token with the low priority in each place (the first token in Fig. 18) which makes a rule to be fired and produces an acceptable output value if any rule is not fired. So the device can have an output and the patient is not endangered until the problem is solved. As can be seen in Fig. 18, the second token in the *SENSOR* place has produced an empty (null) fuzzy value of 0.0, as the activity level sensor stopped working. However, due to the existence of the first token in this place, the network has produced an output.

Regarding lack of the input parameter by the activity level sensor, if a fuzzy inference engine is used, no rule can fire. This is resulted based on searching all rules which needs 277-time unit if each rule is examined in one-time unit. After this time, no rule can cover the conditions. Using HFCPN, searching will only include examining transitions of each level, i.e. (3 + 4 + 6 + 4 + 5 = 22), and if examining each transition needs only 1 s, the output will be obtained after 22-time unit, which is obtained 0.92% improvement in running time.

Scenario 4: One of the sensors produces two outputs successively. For example, the *Activity-level* sensor produces values of 43 and 51 consecutively. In an inference engine, the behavior is only based on the last value. In other words, the first value is ignored. In the PN, this situation put two tokens in the related place (Fig. 19a); however, the maximum value influences the rule firing and an output value is produced due to the inference functioning of the network (max-min), (see Fig. 19b).

Scenario 5: The age value is presumed as 9 and two tokens with (*Child*, 0.15) and (*Teenager*, 0.85) are located in the age place, according to the designed fuzzy membership functions. These two situations fire two different rules in the PN (Fig. 20a). The PN can be implemented

Fig. 18 Token with the low priority in each place

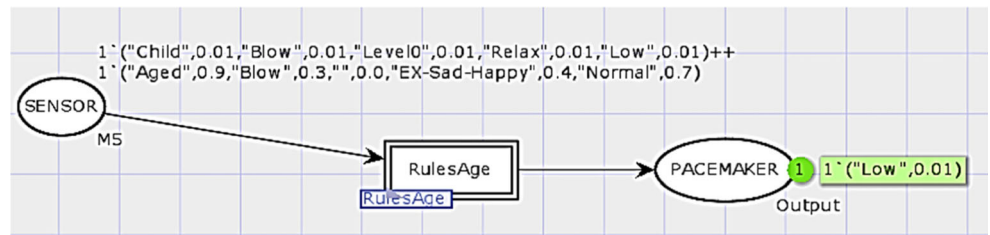
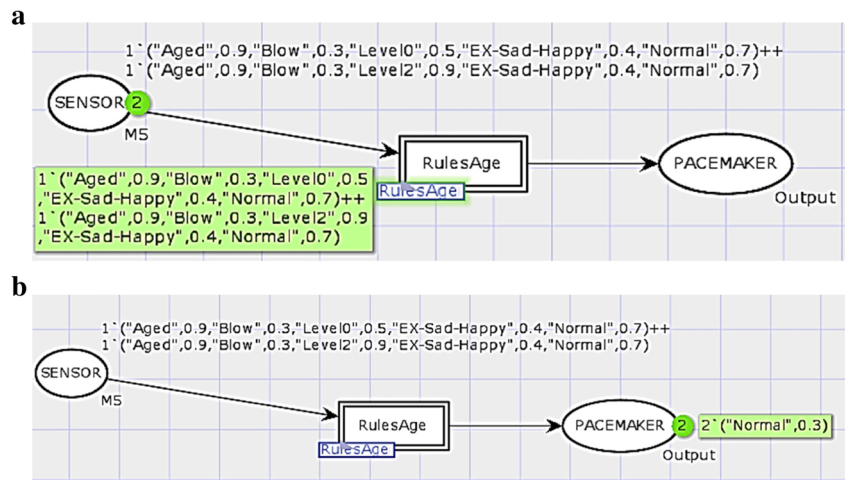


Fig. 19 a Scenario 4. b Output of Scenario 4



concurrently, therefore, by concurrent running of these two rules, two values are produced as the output that complement each other, ((Low, 0.15) and (Normal, 0.3)); it can be seen in Fig. 20b.

Discussion

In this paper, a method to verify the pacemaker software was presented. The pacemaker is one of the implanted devices which needs to keep working without external control and operates upon software. The patient life will be endangered if any error occurs in such software. There are many reports of implanted patient death due to software errors [2]. Therefore, the runtime verification has a vital role in such device. In this research, hierarchical FCPN is used for runtime verification. It

has many advantages compared to the typical inference engine. It can be used to represent software requirements and limitations description and provide a simple strategy to control correctness and consistency of the software needs. This Hierarchical FCPN as a runtime monitor is located beside the pacemaker and controls that the software never breaches the determined limitations. As rows 2 and 3 of Table 5 shows, the number of the places will be reduced from 277 to 6 using colored tokens reducing the network size significantly.

Compared to a simple inference engine, the HFCPN can cover the concurrent states by examining the validity and finding the inconformity in the system rules. This case is not achievable in one short running of the inference engine and the inference engine has to be run twice or acts in a parallel form in two processors for examining the concurrent states. In contrary,

Fig. 20 a Scenario 5. b Output of Scenario 5

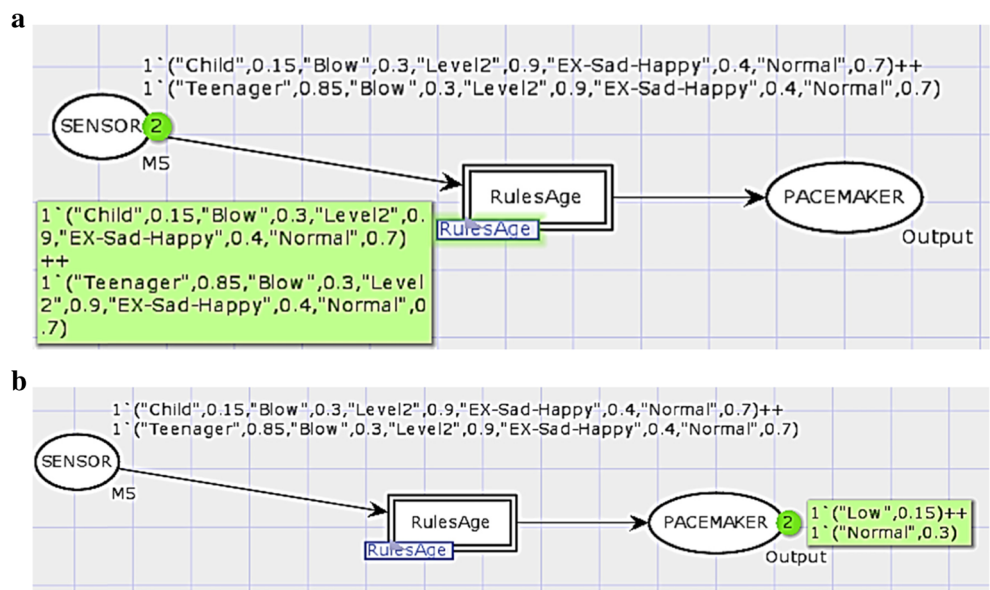


Table 5 Comparison between all kinds of PN

Method	The number of Places	The number of transition	Problem
Simple PN			It has no fuzzy computations and it is essential regarding the fuzzy calculations
FPN	277	22 Inputs- 4 Outputs	The number of places is high
Non Hierarchical FCPN	5 Inputs- 1 Outputs	277 transition that all of them must be examined for could be fire or not	The high number of the transitions that have to be activated
Hierarchical FCPN	5 Inputs- 1 Outputs and 4 middle place	22 and 4 middle transition	

HFCPN examining concurrent states are easily possible. If one of the sensors fails to work for any reason and cannot produce an output, an inference engine cannot make a decision, while by putting the primary tokens with lower priority in the HFCPN, we can be sure of output production of HFCPN even in a situation without receiving the primary value from the sensor. One of the other advantages of the HFCPN as a runtime monitor is that, the hardware implementation by fuzzy JK Flip-flop and fuzzy gate possible [32]. In Table 5, a comparison between all kinds of implementable methods is shown.

Regarding Table 5, using FPN, 26 places and 277 transitions exist. In case of network changes to a non-

hierarchical FCPN, number of places will reduce to six. If for examining each transition, just T seconds is spent, using FPN or nonhierarchical FCPN, 277 T seconds are spent to examine transitions. While by using a hierarchical FCPN, this time reduces to 26 T seconds (considering middle transitions) which shows a 90.61% decrease of runtime in the HFCPN compared to the non-hierarchical FCPN. It should be noted that in this research five effective criteria for the heart rate are considered; other criteria can be considered in the future works. As the implantable medical devices are increasingly used, happening faults becomes more critical. Our proposed method can help to reduce risk of the faults and increase the level of the device robustness.

Appendix

1. If (Age is Child) then (Pulse is High) (1)
2. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level0) then (Pulse is Normal) (1)
3. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level1) then (Pulse is Normal) (1)
4. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level2) then (Pulse is Normal) (1)
5. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level3) then (Pulse is High) (1)
6. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level4) then (Pulse is High) (1)
7. If (Age is Teenager) and (BMI is Blow) and (Activity-Level is Level5) then (Pulse is High) (1)
8. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level0) then (Pulse is Normal) (1)
9. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level1) then (Pulse is Normal) (1)
10. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level2) then (Pulse is Normal) (1)
11. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level3) then (Pulse is High) (1)
12. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level4) then (Pulse is High) (1)
13. If (Age is Teenager) and (BMI is Normal) and (Activity-Level is Level5) then (Pulse is High) (1)
14. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level0) then (Pulse is High) (1)
15. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level1) then (Pulse is High) (1)
16. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level2) then (Pulse is High) (1)
17. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level3) then (Pulse is High) (1)
18. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level4) then (Pulse is High) (1)
19. If (Age is Teenager) and (BMI is Over-Weight) and (Activity-Level is Level5) then (Pulse is High) (1)
20. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level0) then (Pulse is High) (1)
21. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level1) then (Pulse is High) (1)
22. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level2) then (Pulse is High) (1)
23. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level3) then (Pulse is High) (1)
24. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level4) then (Pulse is High) (1)
25. If (Age is Teenager) and (BMI is Obese) and (Activity-Level is Level5) then (Pulse is High) (1)
26. If (Age is Young) and (BMI is Blow) and (Activity-Level is Level0) and (Emotion is Relax) then (Pulse is Normal) (1)
27. If (Age is Young) and (BMI is Blow) and (Activity-Level is Level0) and (Emotion is Ex-Sad-Happy) then (Pulse is Normal) (1)
28. If (Age is Young) and (BMI is Blow) and (Activity-Level is Level0) and (Emotion is Anxious) then (Pulse is High) (1)
29. If (Age is Young) and (BMI is Blow) and (Activity-Level is Level0) and (Emotion is Stress) then (Pulse is High) (1)
30. If (Age is Young) and (BMI is Blow) and (Activity-Level is Level1) and (Emotion is Relax) then (Pulse is Normal) (1)

255. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level0) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is Low) then (Pulse is Normal) (1)
256. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level0) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is Normal) then (Pulse is Normal) (1)
257. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level0) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is High) then (Pulse is High) (1)
258. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level0) and (Emotion is Anxious) then (Pulse is High) (1)
259. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level0) and (Emotion is Stress) then (Pulse is High) (1)
260. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Relax) and (Blood-Pressure is Low) then (Pulse is Normal) (1)
261. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Relax) and (Blood-Pressure is Normal) then (Pulse is High) (1)
262. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Relax) and (Blood-Pressure is High) then (Pulse is High) (1)
263. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is Low) then (Pulse is Normal) (1)
264. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is Normal) then (Pulse is High) (1)
265. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Ex-Sad-Happy) and (Blood-Pressure is High) then (Pulse is High) (1)
266. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Anxious) then (Pulse is High) (1)
267. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level1) and (Emotion is Stress) then (Pulse is High) (1)
268. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level2) then (Pulse is High) (1)
269. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level3) then (Pulse is High) (1)
270. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level4) then (Pulse is High) (1)
271. If (Age is Aged) and (BMI is Over-Weight) and (Activity-Level is Level5) then (Pulse is High) (1)
272. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level0) then (Pulse is Normal) (1)
273. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level1) then (Pulse is Normal) (1)
274. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level2) then (Pulse is High) (1)
275. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level3) then (Pulse is High) (1)
276. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level4) then (Pulse is High) (1)
277. If (Age is Aged) and (BMI is Obese) and (Activity-Level is Level5) then (Pulse is High) (1)

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